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Virtual Three-Dimensional Analysis of Dimensional Accuracy of Dental Master Die Models Created by the iTeroTM Electronic Impression Device and Those Made From a Polyvinyl Siloxane Impression Material

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I. BACKGROUND

Introduction

It is very important to capture accurate impressions for fabrication of fixed dental prostheses. Accurately detailed, dimensionally stable impressions of prepared teeth and surrounding areas help in design of the prosthesis that fits; the fit of the definitive restoration relies on the impression material and the technique used. It has been suggested that the ideal impression material should exhibit ideal properties in adapting well to oral structures and resist tearing upon removal, but also in the lab where dimensional stability, accuracy on disinfection and other properties have to be considered.

Currently, elastomeric materials are some of the most reliable and stable materials in fixed prosthodontics, PVS (polyvinyl siloxane) impression material being one of the most widely used materials, known for its high dimensional accuracy and stability.[1-3] However, deficiencies in making the impression still exist pertaining to proper manipulation of the material. Manipulating impression material is very challenging overall, and impressions often result in indistinct margins, partially set streaks, cords or other debris impregnated into the impression material, the release of the impression material from the tray, and lack of representation of all of the necessary teeth for proper articulation of the cast.[4-6]

The iTero™ Intraoral Scanning Device for Digital Impressions

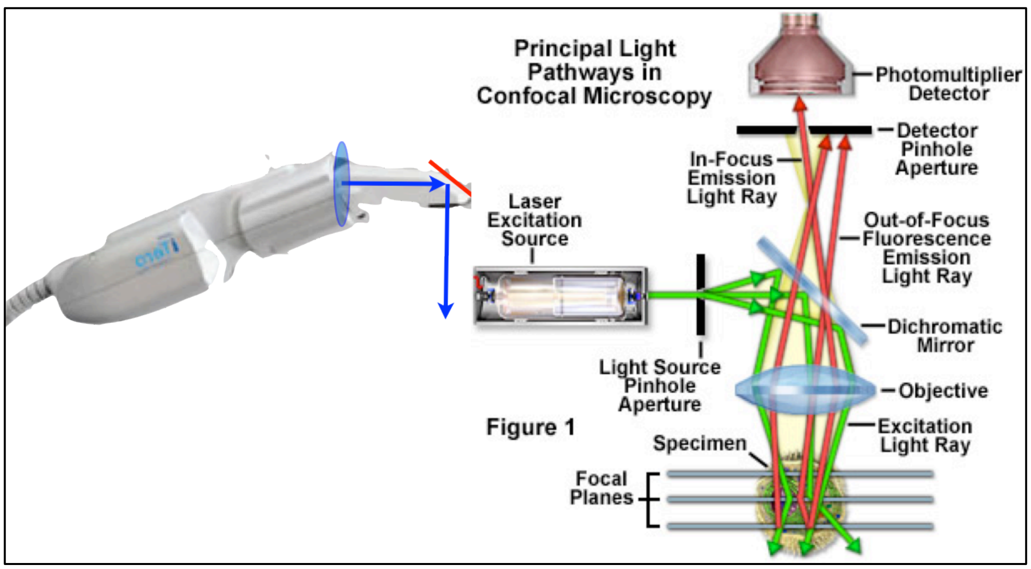
The evolution of dental technology with computer-aided design and computer-aided manufacturing (CAD/CAM) with the introduction of intra-oral scanning devices has a potential for eliminating the challenges stated above and allow for high quality fixed dental restorations. The new intraoral scanning device iTero™, manufactured by Cadent, is on the forefront of digital impression devices. Connected to a centralized milling center via the Internet, it allows for fabrication of CAD/CAM or traditionally made restorations fabricated by a dental lab (Figure 1).[7]

Figure 1. iTero™ digital impression unit

The scanning technology of iTero™ is based on a different concept from its competitors. It is called "parallel confocal" technique of focus finding found in microscopy. It was developed to improve the resolution of images produced from biological specimens. The device directs light through the optical system onto a target object and back. Only an object with proper focal length will reflect light

back through the filtering device and register, while points above and below the confocal plane direct light along a path that will not pass through a pinhole of a filtering device (Figure 2). With in-focus only and depth of field control, confocal technology of iTero™ offers excellent imaging, with capability of registering oral structures to within 15μm.[7] All structures and materials as well as preparation designs including margin design can be recorded, provided proper visibility for the scanning is provided. The expertise of the dentist in providing appropriate preparation with adequate incisal/occlusal reduction, total occlusal convergence, finish lines and tissue retraction are still critical for fabrication of a good prosthesis.[8]

Figure 2. Light Pathways in confocal microscopy as it relates to iTero™ scanning



The iTero™-milled model consists of an upper model, lower model, and dies (Figure 3). Each piece of the model is milled from a separate block made of polyurethane material using a computer numerical control (CNC) 5-axis milling machine at Cadent. The cutter of the milling machines rotates while the material

to be milled is moved in left-right, back-forth, and up-down directions, as well as spin for diagonal milling. The milling machines for Cadent are reported to be accurate within 2μm.[7] The models are articulated on a simple-hinge articulator. The dies are designed for easy removal from the model.

Figure 3. Polyurethane models articulated on simple-hinge iTero™ articulator

Accuracy of Polyvinyl Siloxane Impression Material (PVS)

PVS impression material sets by the reaction of hydrogen siloxane with vinyl-terminal siloxane in the presence of chloroplatinic acid, which serves as a catalyst to the reaction. Not only is it one of the most widely used impression materials in the dental field, but it also has many advantages when compared to other impression materials. It has excellent reproduction detail and dimensional accuracy.[1, 9] It is was shown that PVS has better dimensional stability than other materials as shown in the study by Clancy et al., where PVS changed very minimally over the course of 4 weeks.[3] PVS material has great elastic recovery to rebound from the undercuts.[1, 10] However, it exhibits a hydrophobic nature, and thus in the presence of a wet environment, it may not flow well into all areas, and the accuracy and detail reproduction of the impression would diminish.[9] Newer

PVS materials have been made with an addition of nonionic surfactants that has improved the "wettability" of the PVS. Nevertheless, the material is clinically acceptable in dry conditions.

The accuracy of impression materials has been assessed in two ways.[1] According to the American Dental Association specification #19, elastomeric impression materials used to fabricate precision castings must be able to reproduce fine detail of 25μm or less.[11] All currently available elastomeric impression materials meet this standard and PVS and polyether materials are excellent in this regard.[9, 12, 13] The greatest limiting factor in reproduction is the ability of gypsum die materials to replicate fine detail. The specification for reproduction of gypsum die material is 50μm.[14] The dimensional accuracy has been studied using stainless steel models and measuring preparation dimensions and tooth-to-tooth distances within the same quadrant and cross arch. PVS materials are very accurate when used with different types of trays and for complete arch impressions.[10, 15] Custom trays have been shown to produce dies that are more accurate in vertical dimensions than stock trays and are the tray of choice for PVS material.[10] PVS has demonstrated superior dimensional stability over time when compared to other elastomeric materials because it does not release any by-products.[1, 13, 16]

Rationale for the study

The iTero^{TM} digital impression technology has the capability to improve fixed prosthodontic impressions by removing many variables that contribute to poor impressions and eliminate the need for gypsum products. In addition, other steps can be eliminated that are associated with fabrication of the crowns, such as impression trays, shipping, disinfection, lab work that is involved in making the models, and finally actual fabrication of the dental prosthesis. The marginal fit and performance of restorations made by CAD/CAM systems have been evaluated in the study by Henkel (2007).[7] One hundred and seventeen patients had two sets of crowns made for one tooth – one from a digital impression (iTero^{TM} prototype), and the other from a PVS impression.[7] The crowns were evaluated for clinical parameters such as fit, retention, contact points, occlusion, and adjustment time. The article showed that for 68% of the cases, the crowns made from digital impressions were the crowns of choice. In addition, 85% of iTero^{TM} vs. 74% of conventionally made crowns were judged to be clinically acceptable. However, this study was sponsored by iTero^{TM}, and very limited data were available and no statistical analysis was shown.

The availability of independent research of the in-vivo and in-vitro accuracy of digital impressions is very limited. The purpose of this study is to compare the dimensional accuracy of models created by the iTero^{TM} electronic impression device and those made from a polyvinyl siloxane (PVS) impression material using a standard master model that scans properly with the iTero^{TM}

system. In the thesis research done by Dr. Adam Geach in 2009, the iTero™ impression device was compared to PVS impression material, and issues have been identified. The sample sizes of nine were too small to show significant differences. In addition, the material used for milling of the master model had problems with proper scanning by the iTero™. In this study the master model has been modified and instead of traveling microscopy as measurement device, a White Light optical scanner is used to create virtual models to compare PVS impression made models to iTero™ scanned made models. The basis for the use of a White Light scanner as measurement device comes from several articles evaluating and using similar devices in order to evaluate impression materials.

One study used the digital scanner, Procera Forte touch probe scanner, to evaluate the impressions and their stone models.[17] Impression materials were scanned using a laser scanner, while stone replicas were digitized using this touch probe scanner. They reported that the differences between the master and the stone replicas or scanned impressions were within 40µm, with the exception of 2 molars. This study provided good support for potential use of digital impression systems. It also showed that digitized impressions and their digitized stone replicas had about the same mean discrepancy from the master model, which points to minimal potential gypsum dimensional error. However, this study still depended on PVS impressions as opposed to the iTero™ being completely "impression-free". In their previous study this group evaluated the repeatability and relative accuracy of the two scanners, and reported them repeatable within 10µm, with relative accuracy of +/- 6mm.[18] Our study used similar technique

using a touch probe scanner with known accuracy, as well as White Light optical scanner to evaluate the repeatability and accuracy of White Light scanner, and then use virtual digitization and computer aided analysis to compare iTero™ scanned models to the conventional PVS impression models through their discrepancy from the master model.

II. OBJECTIVES AND HYPOTHESIS

Objectives

1. Design and fabricate a Master model that can be properly scanned by iTero™ scanning system and have parameters that can be properly measured by virtual analysis. This is to involve two preparation cones in efforts to evaluate effect of dimensional accuracy for not only crown fabrication but also for fixed dental prosthesis fabrication (FDP).
2. Evaluate White Light optical Scanner (Steinblichler Vision Systems) accuracy and reproducibility through use of Coordinate Measuring Machine (Zeiss Contura Select 776).
3. Evaluate dimensional accuracy and perform qualitative analysis comparison of the models fabricated by iTero™ system and the models fabricated using PVS impressions as compared to their master model using virtual 3-dimensional analysis by White Light scanner.

Hypothesis

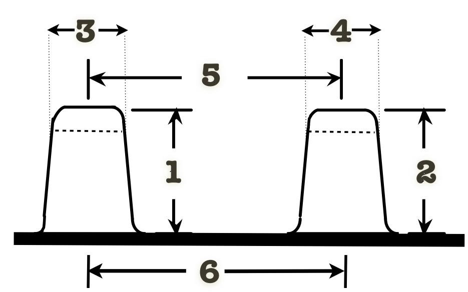
1. There is no significant difference in dimensional accuracy between master model and iTero™ models.
2. There is no significant difference in dimensional accuracy between master model and PVS models.
3. There is no significant difference in dimensional accuracy between iTero™ and PVS models.

III. MATERIALS AND METHODS

Master Model Design and Fabrication

The initial model was fabricated simulating the two abutment preparations for the three unit fixed partial denture by using the dimensions of preparations based on the design described by Johnson and Craig,[10, 16] and followed by Adam Geach (Figure 4). The modifications to the design were made as no engraved lines were needed, and in Geach's research it has been shown that detail reproduction of fine lines by iTero™ is not adequate. Access to the iTero™™ digital impression device was possible through a support of a local dental laboratory, Yankee Dental Arts, Wethersfield, CT.

Figure 4. Design of the master model, with the description of measurement parameters for the locations numbered.



Location Number	Description
1	Occlusal-gingival height of preparation 1 (Cone 1), ~8mm
2	Occlusal-gingival height of preparation 2 (Cone 2), ~8mm
3	Diameter of preparation 1, 1mm from the top, ~5mm
4	Diameter of preparation 2, 1mm from the top, ~5mm
5	Distance between preparations at the Top, ~14mm
6	Distance between preparations at the Bottom, ~14mm

A gypsum duplicate of the preparations was made from the stainless steel model and was set into a gypsum typodont model in order for the iTero™ scanning system to properly recognize the abutments (Figure 5). An opposing model required for the bite by the iTero™ system was then adjusted and articulated. The gypsum cast model was then scanned by the iTero™ system. The milled iTero™ polyurethane model copy of the gypsum model was then considered as a master model (Figure 6).

Figure 5. Preliminary model.

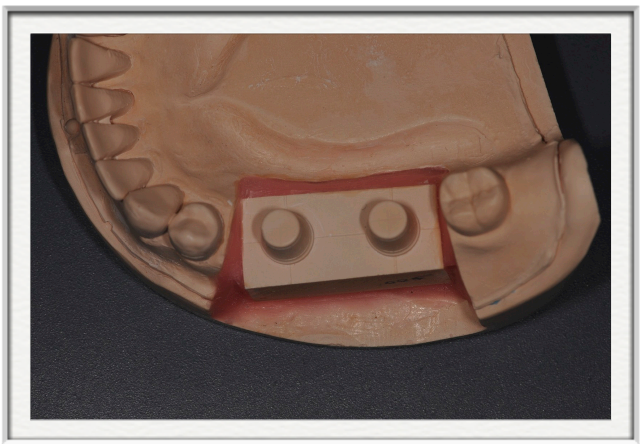


Figure 6. Polyurethane master model.

iTero™ scanning and PVS impression fabrication of sample models

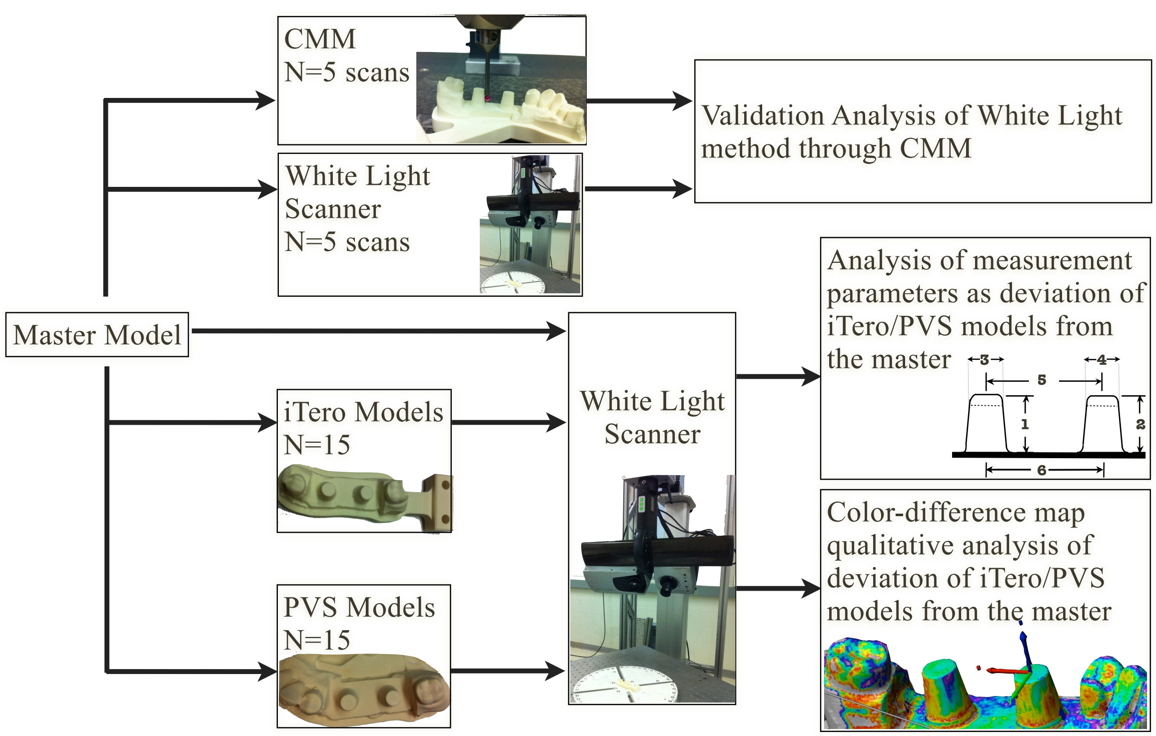
The master model was scanned 15 times by iTero™ scanner for milling of 15 polyurethane models without removable dies. For fabricating the 15 impression models, PVS impression material was used. Custom trays were constructed (Triad, Dentsply/Trubyte) on a duplicate model with uniform spacer of 2.5mm created with wax and rest stops created on the occlusal of typodont to facilitate the seating of the tray. Caulk Tray adhesive was applied and was let to dry for 10 min. PVS material was mixed according to manufacturer's instructions (Reprosil, Dentsply/Caulk); light-bodied PVS material was injected around abutments of the master model, while regular-bodied PVS material was loaded into the custom trays and the trays were seated onto the abutments. Impressions were allowed to set for 12 minutes. The setting time was double that of manufacturer's recommended setting time to accommodate room vs. mouth temperature differences for polymerization of the material, as documented in ADA Specification No.19, setting time specification.[11]

PVS impressions were rinsed with water for 45 seconds, dried with forced air, and allowed to sit for 10 minutes. The impressions were sprayed with surfactant (Almore International, Inc., debubblizer/surfactant) and cast in type IV gypsum product (Die Stone Peach, Heraeus Kulzer). The stone was mixed according to manufacturer's recommendations and the mixes were vibrated into the impressions and allowed to set for 1 hour before separation.

Digitization of Master, iTero™, and PVS models

The virtual analysis of the models was performed in the manner represented in Figure 7. The master, 15 iTero™ and 15 PVS models were scanned by the Comet White Light Scanner (Steinblichler Vision Systems) to be analyzed (Figure 8). The scanner is comprised of a table with a model holder and light projection and camera. It employs a topometric 3D measurement process through the mathematical concept of triangulation to measure coordinates of each point, which is then digitized through Polyworks software (InnovMetric Software, Quebec, Canada). The model is scanned and then rotated 30 degrees and scanned again until 360-degree digitization completed. The use of both CMM and White Light scanner was possible through cooperation with Bolton Works, East Hartford CT.

Figure 7 . Diagram of the Experimental Method.



To validate the use of White light as the measuring device, a Coordinate Measuring Machine (Zeiss Contura Select 776) (Figure 9) with a known linear accuracy of 2µm was used. The White Light has higher resolution than CMM in addition to a qualitative analysis capability. For that purpose, the master model

Figure 8. Coordinate Measuring Machine(CMM).

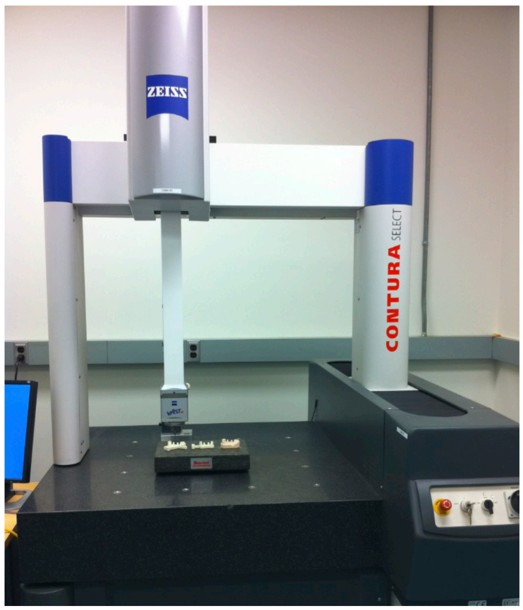
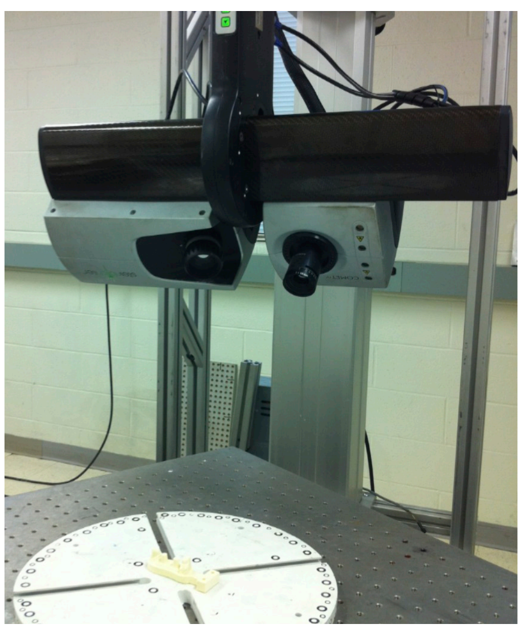


Figure 9. Comet White Light Scanner

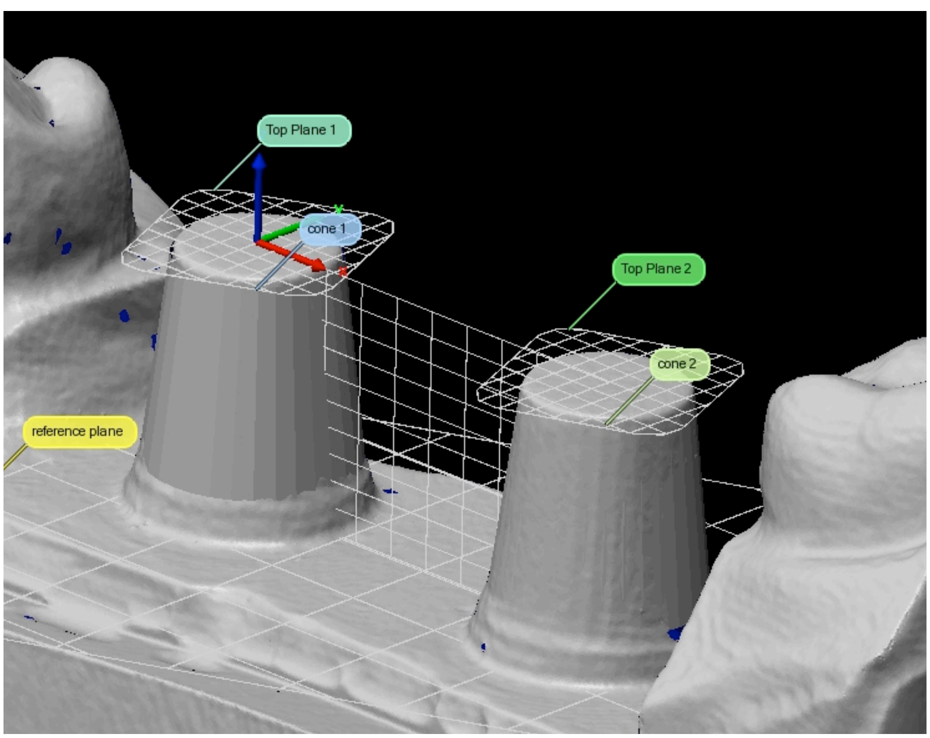


was scanned 5 times by CMM and 5 times by White Light Scanner. CMM's sapphire ball with radius of 1.5mm formed the tip of the scanner probe that contacts the surface of the preparations as it rotates around it. The touch probe was qualified before each use by a ceramic sphere of 0.1μm accuracy. Both machines were calibrated according to the manufacturer's instruction.

Analysis of CAD-Reference Models

For each model, whether it was from iTero™ scan or PVS impression, the resulting point-cloud from the scan was used as a virtual CAD-reference-model (CRM) by the Polyworks software. The measurements were done irrespective of alignment using the planes of the preparations and center points at both top and bottom planes (Figure 10). Four points were created using the intersections of cone centers and the planes (top and bottom). Those points were then used to measure the heights of the cones and distances between them. The diameters of the preparations were determined by taking the average of the cone diameter 1mm offset from the top plane of the preparation.

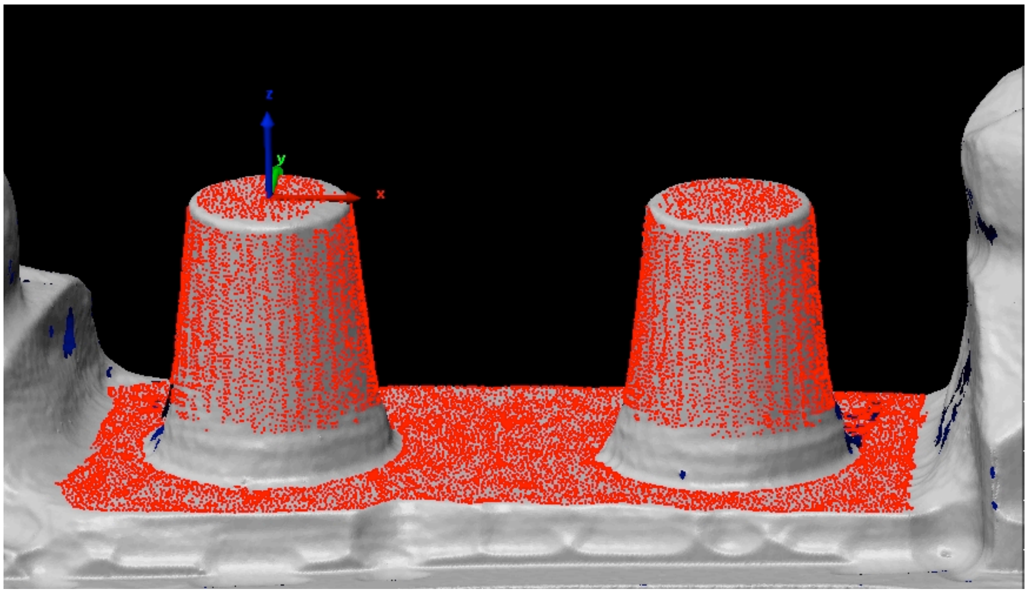
Figure 10. Reference planes used for measurements of the parameters and for the alignment.
The reference planes are shown as grid planes: 2 on top of the cones, 1 through the bottom of the cones, 1 through the center axes of the cones.



Alignment of iTero^{TM} and PVS models to Master model

Each sample was aligned to the master CRM. The point-cloud was refined by setting tolerances of +/- 150µm in order not to use points that are farther from that when constructing the cone. In addition, any point-cloud that deviated more than 5 degrees from a plane was not used in the calculation of the plane/cone. Thus, the digitized data outside of our scope of analysis was not used (Figure 11).

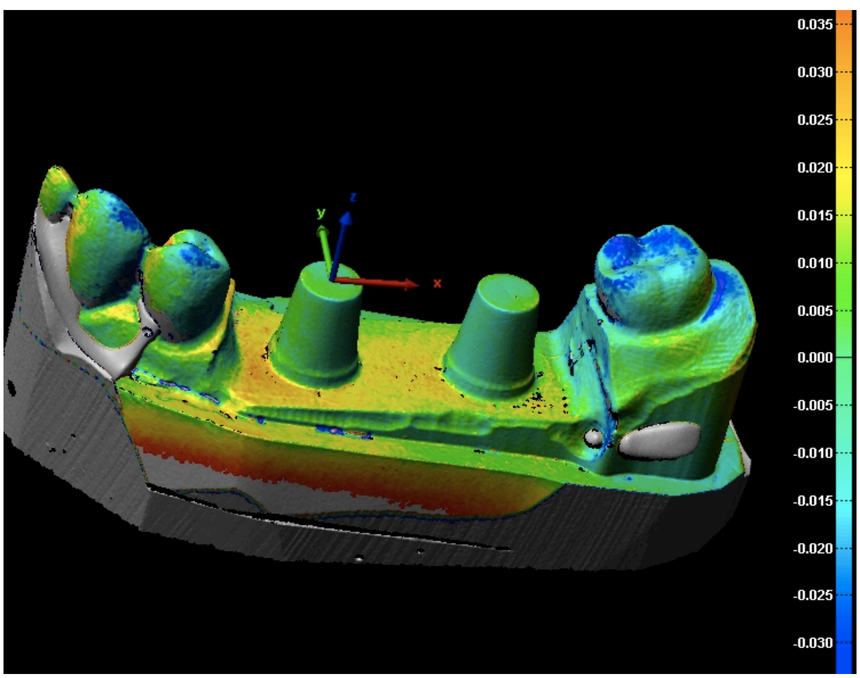
Figure 11. Point-cloud data used for measurements and alignments of iTero or PVS virtual models to the Master virtual model.



The cones/cylinders were used as axes of alignment. The master model CRM was used as a reference model CRM, and thereafter each experimental model CRM was selected as the alignment CRM as it was moved into position by moving and rotating it on x, y, and z axes to align with the master/reference CRM. This study required aligning the two preparations instead of one. Thus best-fit alignment was not adequate for proper distribution of priorities of alignment

procedure. To improve on the best-fit alignment done by Polyworks software, the center points of cone 1 and 2 were used as priority points to align the models. Using the four points already created for the measurement of experimental parameters, a plane was created based on best fit alignment from the top and bottom center cross-sections of both cones (Figure 10). The results of alignment were automatically presented with distribution of the discrepancies from the master presented in the color-difference-maps (Figure 12). The positive values in the color maps (yellow to red) illustrate that the experimental point-cloud is larger than reference/master point-cloud. The negative values (turquoise to blue) show that the point cloud is smaller than the reference/master one. Green areas indicate that there is no difference.

<u>Figure 12. Color map analysis of discrepancy of experimental from the reference model.</u>



Statistics

The measurements of respective parameters were done for each, and the F-test was performed to compare variance between two measuring methods to determine the repeatability of the White light. For validation of measuring methods, mean and standard deviations of measurements by White Light and reference CMM method were summarized and compared. A two-sample F-test was carried out to compare repeatability of the discrepancy between White Light and CMM. The 95% confidence interval (CI) of the difference between two methods was used to assess the relative accuracy of White Light method. When the 95% CI excludes zero, the measurement of White Light method was considered to be systematically higher (0 to the right) or lower (0 to the left) than CMM method. CI of 95% of discrepancy was also used to assess how close White Light approached the acceptable bounds for measuring accuracy of +/-5µm.

To evaluate the quality of casts made by iTero™ scanning and PVS impressions, the discrepancy between cast and master die with each method was visualized in boxplots. Mean and standard deviations of the discrepancy were summarized as well. For each method, the 95% confidence intervals of the discrepancy were used to assess the magnitude and direction of the discrepancy. When the 95% CI excludes zero, the cast was determined to be systematically higher (0 to the right) or lower (0 to the left) than master die. The 95% CI of the discrepancy was also used to assess how close it approached the clinically acceptable zone for discrepancy, +/-20µm. A two-sample F-test was carried out to compare variance of discrepancy between iTero™ and PVS method. A two-

sample t-test was performed to compare mean of discrepancy between these two methods. The P value less than 0.05 were considered statistically significant in analyses. All statistical analyses were performed using SAS V9.2.[19]

IV. RESULTS

Validation of Measurement Method (White Light Scanner) through CMM Method

The F-test variance comparison between two methods (White Light and CMM) for the heights of the preparation cones and the distances between them showed that for all measurement variables there is no evidence of statistically significant different variance (95% CI) that the repeatability of White Light method is different from CMM method (Table 1). Standard deviations for each of the measurement methods range from 0.31µm to 1.3µm.

Table 1. Variance Comparison between White light vs. CMM methods

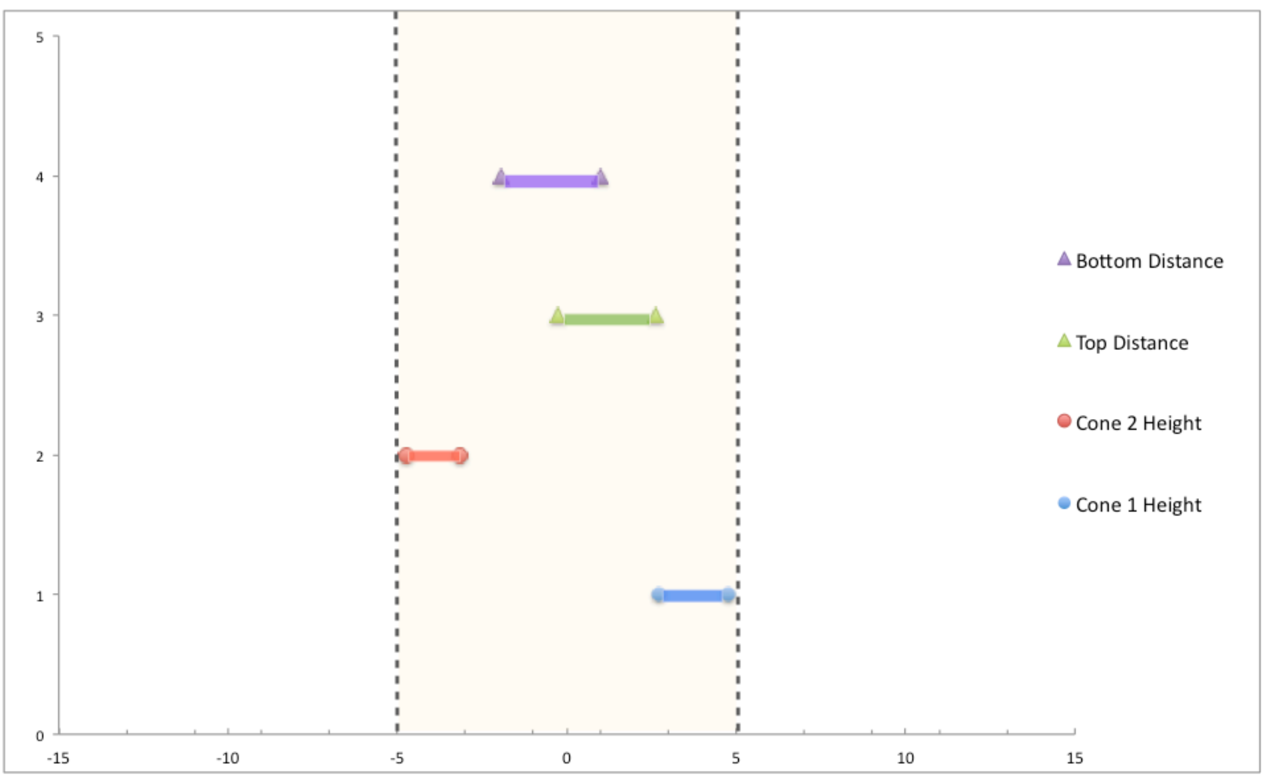
	CMM		White light		Test equality of variance
	Mean (µm)	Std. Dev (µm)	Mean (µm)	Std. Dev. (µm)	P value (F-test)
Cone 1 Height	8008.3	0.68	8012.0	0.71	0.9343
Cone 2 Height	8038.9	0.31	8035.0	0.71	0.1321
Top Distance	14064.8	0.98	14066.0	1.00	0.9717
Bottom Distance	13961.3	0.54	13960.8	1.30	0.1131

When evaluating the accuracy of White Light method in comparison to CMM, the mean discrepancy between two methods was: 3.74µm for Cone 1 Height, -3.94µm for Cone 2 Height, 1.16µm for Top Distance, 0.48µm for Bottom Distance (Table 2). White Light method statistically measured higher than CMM for Cone 1 Height measurement, while statistically measured lower for Cone 2 Height. Figure 13 shows 95% confidence interval ranges for all parameters measured in relation to acceptable accuracy measurement error range of +/-5µm.

Table 2. Mean Discrepancy comparison between White light and CMM methods. When the 95% CI excludes zero, the measurement of White Light methods is determined to be systematically higher (0 to the right) or lower (0 to the left) than CMM method. CI - Confidence interval; CI in bold font = Statistically significant difference.

	Discrepancy (White Light - CMM)		
	Mean discrepancy (µm)	**95% CI (µm)**	
Cone 1 Height	3.74	**2.73**	**4.75**
Cone 2 Height	-3.94	**-4.73**	**-3.15**
Top Distance	1.16	-0.285	2.60
Bottom Distance	-0.48	-1.93	0.97

Figure 13. Comparison of 95% CI ranges between White light and CMM methods for acceptable measurement error range +/- 5µm.
Bars represent 95% CI ranges for a given parameter.



µm

Comparison of iTero™/PVS to Master by White Light method

Table 3 shows mean discrepancies of iTero™ and PVS from the master model and 95% CI of the discrepancies. When comparing iTero™ to PVS models through the White Light method, PVS models gave statistically different measurements for Cone 2 Diameter and Height, Cone 1 Height, and Top and Bottom Distances. The iTero™ models were statistically different from the master in Cone 1 and Cone 2 Diameters and Heights. Box plot of iTero™ and PVS discrepancies from the master model is shown in Figure 14.

Table 3. Discrepancies of iTero™ scan models and PVS impression models from the Master model, by White Light Method.
Confidence intervals (CI) displayed in bold represent the method being statistically higher than the master (positive values) or lower than master (negative values) for that particular parameter.

	Discrepancy (PVS - Master) (µm)				**Discrepancy (iTero™ - Master) (µm)**			
	Mean	Std Dev	**95% CL**		Mean	Std Dev	**95% CI**	
Cone 1 Diameter	2.9333	15.5355	-5.6700	11.5366	33.4667	36.2765	**13.3774**	**53.5559**
Cone 2 Diameter	-30.4667	52.6781	**-59.6388**	**-1.2945**	-71.2670	64.4288	**-106.9000**	**-35.5872**
Cone 1 Height	-10.8667	9.7091	**-16.2434**	**-5.4899**	12.2667	11.9072	**5.6727**	**18.8606**
Cone 2 Height	-9.5333	12.0171	**-16.1882**	**-2.8785**	7.5333	9.6649	**2.1811**	**12.8856**
Top Distance	6.0000	3.7225	**3.9385**	**8.0615**	11.9333	21.8549	-0.1695	24.0362
Bottom Distance	12.2000	4.1266	**9.9148**	**14.4852**	3.6000	16.8472	-5.7297	12.9297

Figure 14. Discrepancies of iTero™ scan models and PVS impression models from the Master model, by White Light Method.

Plus: Mean; Middle line: Median; Box: Interquartile range; Whisker: Non-outlier range; dot: outliers

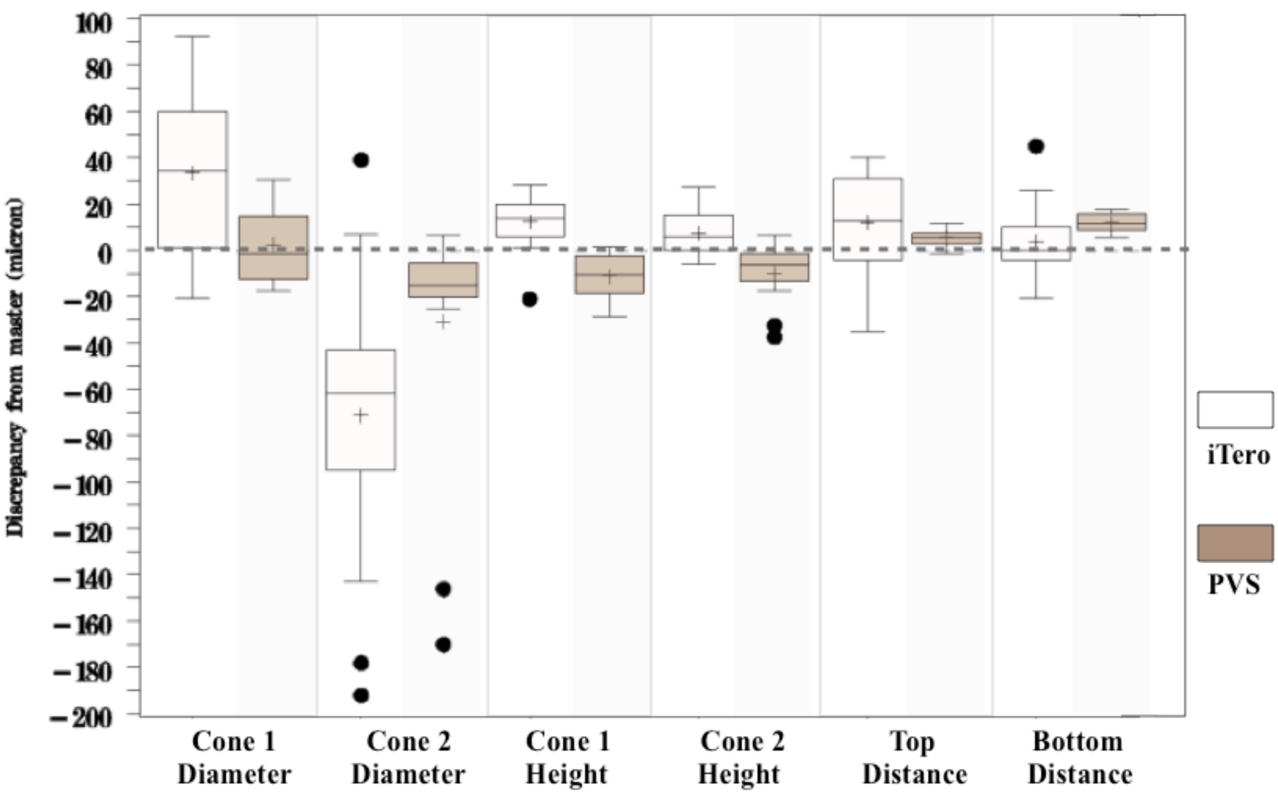
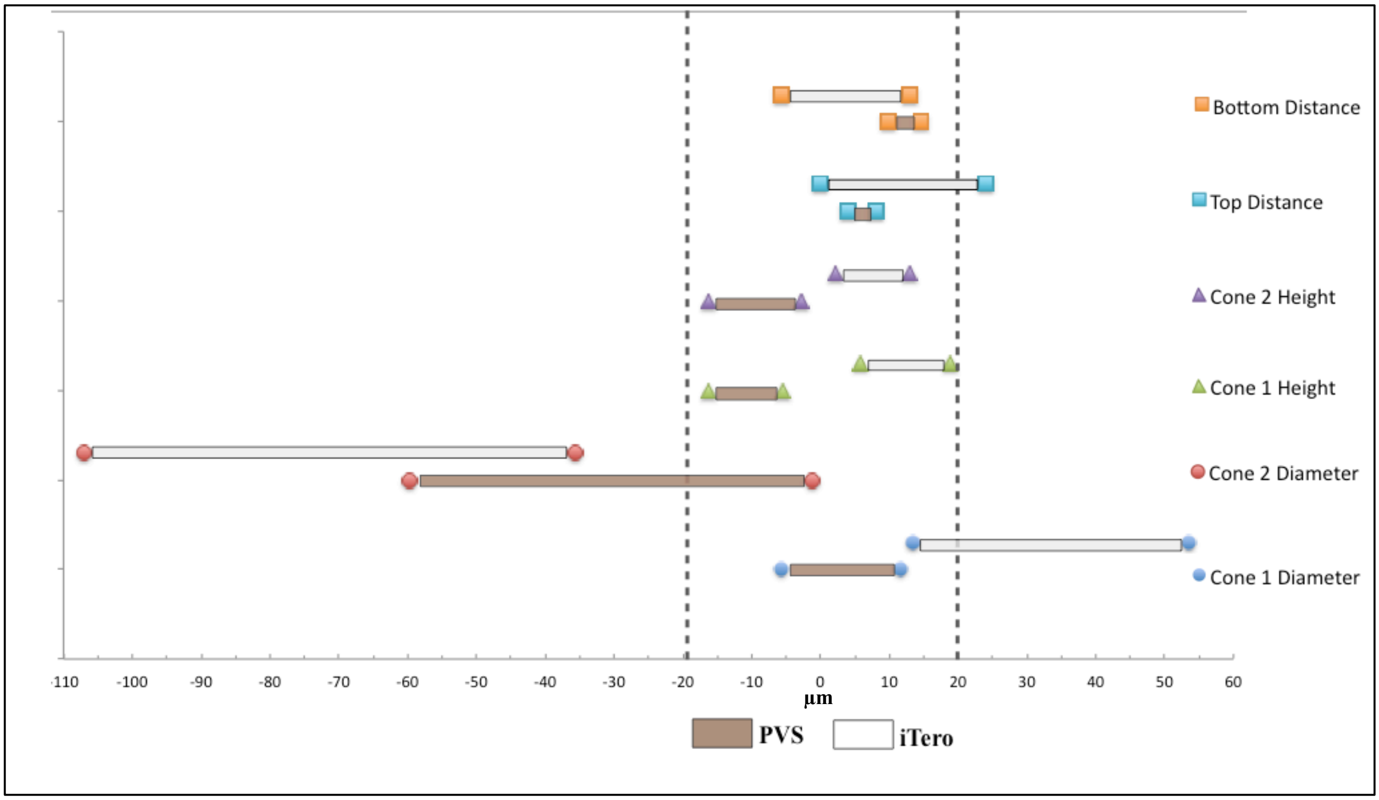


Figure 15 shows the 95% confidence intervals of discrepancies from the master for iTero™ and PVS, represented graphically and with consideration of clinically acceptable range of +/-20µm.

Figure 15. Comparison of 95% CI ranges for discrepancies from the master for iTero™ and PVS methods for clinical measurement error range +/-20µm.



Comparison of iTero™ scan models vs. PVS impression models by White Light Method

The variance between iTero™ and PVS models was compared and the results showed that for Cone 1 Diameter, Top and Bottom Distances the iTero™ method has higher variability, or less precision, than PVS method (Table 4).

Table 4. Variance of discrepancy from master of iTero™ vs. PVS models.

	Test equality of variance
	P value (F-test)
Cone 1 Diameter	**0.0031**
Cone 2 Diameter	0.4607
Cone 1 Height	0.4547
Cone 2 Height	0.4251
Top Distance	**<. 0001**
Bottom Distance	**<. 0001**

Table 5. Comparison of mean discrepancy from master (iTero™ vs. PVS). Confidence intervals (CI) displayed in bold represent the method being statistically higher than the PVS (positive values) or lower than PVS (negative values) for that particular parameter.

	iTero™ - PVS Discrepancy from the master (μm)			
	Mean	95% CL Mean		P value (α=0.05)
Cone 1 Diameter	30.5333	**9.2044**	**51.8622**	**0.0074**
Cone 2 Diameter	-40.8000	-84.8163	3.2163	0.0680
Cone 1 Height	23.1333	**15.0075**	**31.2592**	**<. 0001**
Cone 2 Height	17.0667	**8.9104**	**25.2230**	**0.0002**
Top Distance	5.9333	-6.2810	18.1477	0.3166
Bottom Distance	-8.6000	-18.1101	0.9101	0.0732

Two-sample t-test was performed to compare mean discrepancy from master between iTero™ and PVS (Table 5). For Cone 1 Diameter and Height, as well as Cone 2 Height the mean discrepancies from the master are significantly higher than PVS.

Qualitative Analysis of the iTero™ and PVS models

For the qualitative analysis of the iTero™ and PVS models aligned to the master, Figures 16 and 17 show color-difference-maps with +/-50µm range of deviations. Positive values (yellow to red)=that surface is larger/higher than master; negative values (turquoise to magenta)= smaller/lower than master model. Gray surfaces represent discrepancies beyond +/-50µm range. For example, when looking at iTero™ model #12 (Figure 16), the cones are displayed in yellow to red colors, indicating that the diameters of that iTero™ model are larger than the master model; conversely, for iTero™ model #11, blue and purple walls of the cones indicate that that model has diameters of the cones that are smaller than the master. When looking at the bottom plane of PVS model #11 in Figure 17, the bottom plane around Cone 2 is orange/red color, indicating that that plane for PVS model is higher than the master – thus the height of that Cone 2 is shorter than the master model.

For iTero™ models, the cone top edges of the models were often found to be smaller (more rounded) than the master. The diameters of the cones for iTero™ models vary in their form in the bucco-lingual direction, either being smaller or larger from the master. For the PVS models, some Cones are shorter than the master, thus changing the level of the bottom plane to be more red and sometimes skewing the alignment towards that cone.

Figure 16 . Qualitative Analysis of discrepancies between the master and iTero™ models through the color maps (+/- 50µm range). Positive values (yellow to red)=that surface is larger/higher than master; negative values (turquoise to magenta)=smaller/lower than master model. Gray surfaces represent discrepancies beyond +/-50µm range.

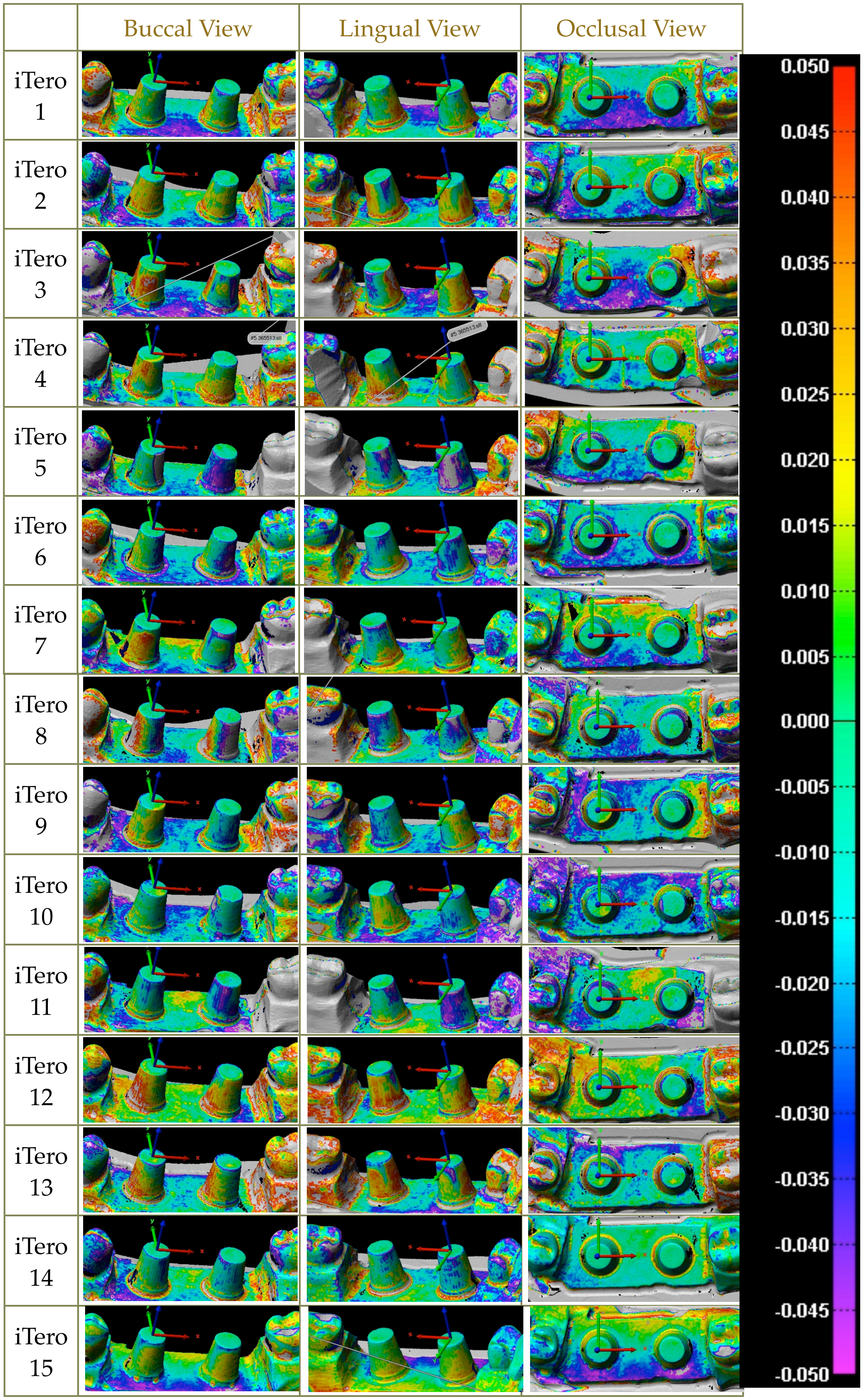
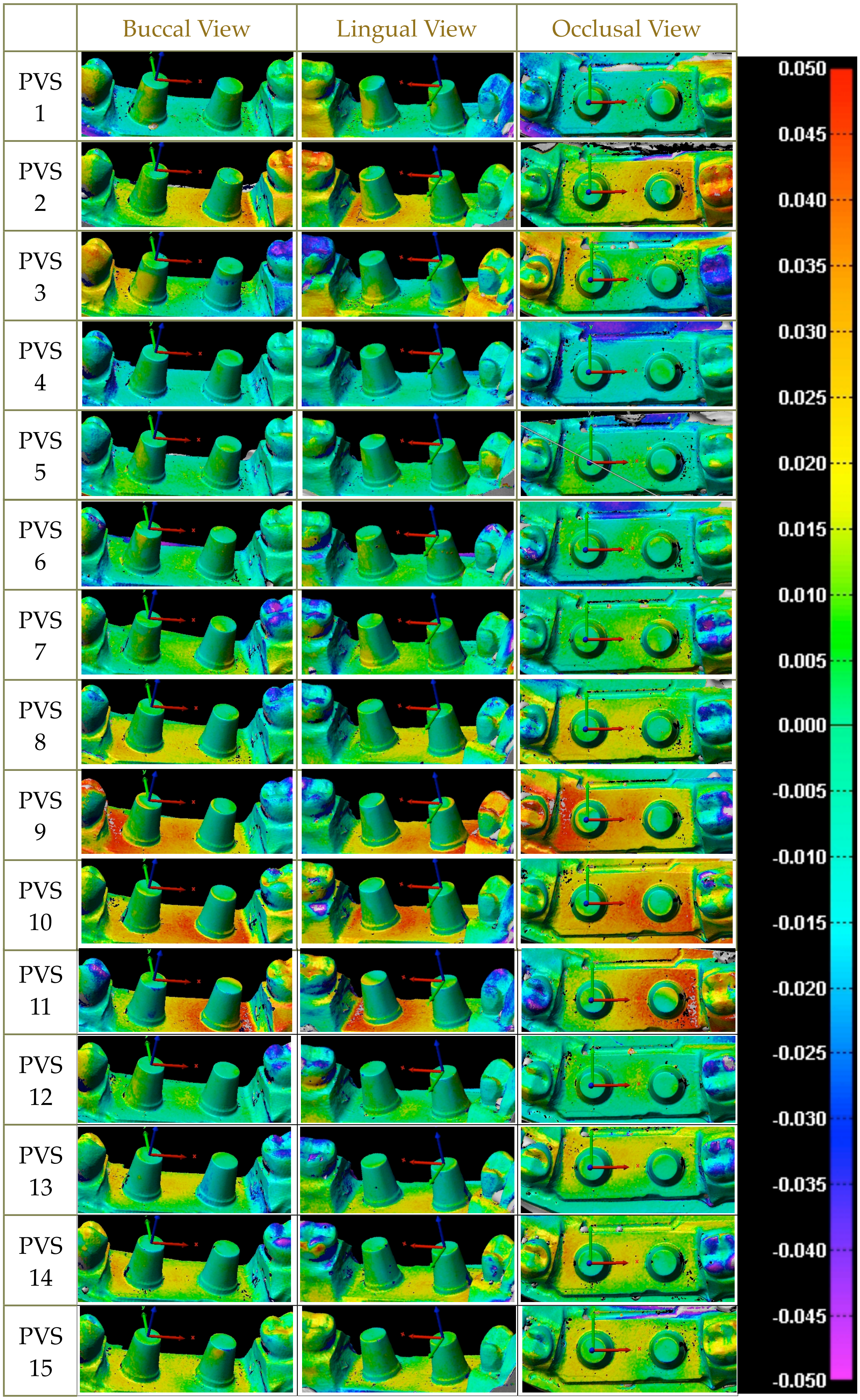


Figure 17. Qualitative Analysis of discrepancies between the master and PVS models through the color maps (+/- 50µm range). Positive values (yellow to red)=that surface is larger/higher than master model; negative values (turquoise to magenta)=smaller/lower than master model. Gray surfaces represent discrepancies beyond +/-50µm range.

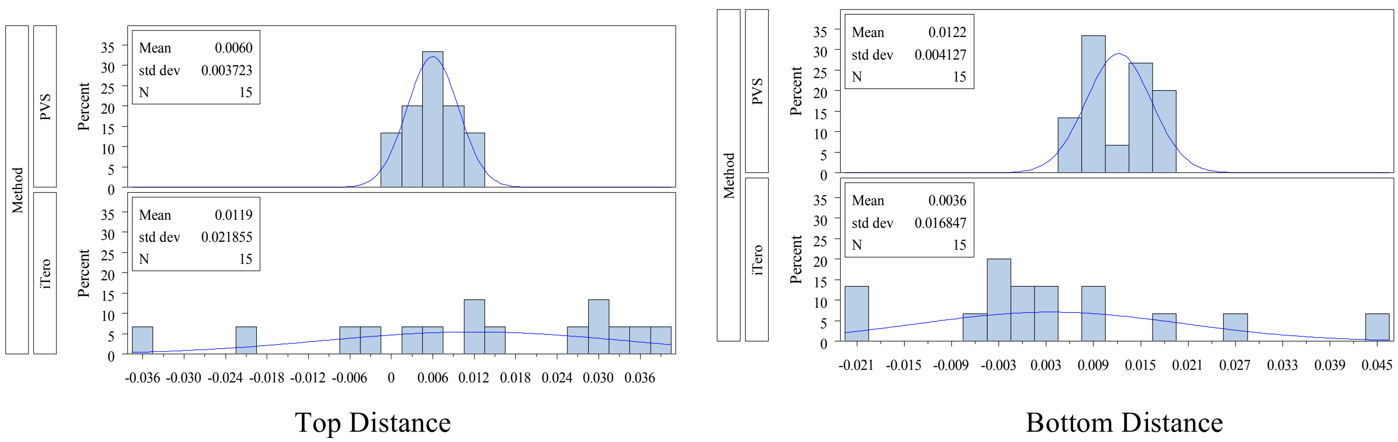


V. DISCUSION

The validation of White Light method has shown that the parameters to be measured did not vary statistically within our set 95% confidence interval. Even though the accuracy of White Light in relation to CMM methods was statistically different for Cone 1 and 2 Heights, the precision/repeatability of the White Light in relation to CMM was not statistically different within the 95% CI. CMM method did not allow for the measurement of the cone diameters, so we could not validate White Light method for those particular parameters. Within the acceptable range of accuracy measurement error, CMM method allowed to eliminate not only the human error of measurement that happens with traveling microscopy, but also the milling problems associated with fine lines engraved on the cones which are limited to the quality of milling resolution by iTero™ milling procedures, as described in the research done previously by Adam Geach.

The discrepancies from the master have shown that a standard procedure of PVS impression models was statistically significant for the majority of the parameters, just as iTero™ scan models were. However, the mean discrepancies varied more for iTero™ than PVS as seen in standard deviations and 95% CI's. Figure 15 shows that 95% CIs are smaller for PVS than iTero™, even though both are within the clinically acceptable range except for cone diameter measurements. Even though iTero™ scan models showed no statistical difference from the master for both of the distances, their standard deviations are 21.9μm and 16.8μm for Top and Bottom Distances, respectively, while for PVS they are 3.7μm and 4.1μm, respectively (Figure 18).

Figure 18. Mean discrepancy comparison of PVS and iTero^{TM} models



In statistical comparison of PVS to iTero^{TM} model fabrication methods, the iTero^{TM} is shown statistically significantly different in variance from PVS for Cone 1 Diameter and both Top and Bottom Distances. Since we consider PVS impression as a standard protocol for fabrication of a crown, we can see that for distances between two preparations that are usually needed to fabricate a Fixed Dental Prosthesis (FDP), the iTero^{TM} method varied significantly from PVS technique in its repeatability/precision. That means that sometimes the FDP made on iTero^{TM} model may seat accurately in the mouth, while other times it may not. Even though iTero^{TM} may vary in its measurements at longer distances, when evaluated in regards to the clinically acceptable range that we defined as -20µm to +20µm, it performed within that range for the Bottom Distance, while it went out of the range for Top Distance. For the Heights of the cones, iTero^{TM} was within the clinically acceptable range, but both cone Heights measured significantly

higher from the PVS impression technique (Table 5, Figure 15). Thus iTero™ estimated the Heights of the cones consistently higher than PVS. However, it does not seem to be a problem in the seating of the crowns in the error ranges shown. Moreover, the PVS results for the Heights were lower than the master which offsets the comparison.

Clinically acceptable range was defined based on a few parameters. PVS impression materials must be able to reproduce details ≤ 25µm.[11] The PVS impression technique is our gold standard, thus clinically acceptable error parameters should encompass that +/-25µm spectrum. In addition to that, since every preparation gets coated on its walls and top with spacer to accommodate for the cement thickness (40µm), +/-20µm of error would still allow crowns to seat and still have space for the cement thickness. Since all parameters would present different maximal clinically acceptable ranges, the lowest acceptable range used was +/-20µm.

The outlier values presented in Figure 14 were evaluated for potential explanation of measurement difference, however they were not excluded from the statistical evaluation. It was speculated that since the diameters were measured 1mm from the top plane of the cone, the diameter of the cone could be associated with the height discrepancy. However, in the evaluation of the outliers, the Heights and Diameters of the cones were not found to have any pattern of association. It is still advised for the future studies to evaluate cone diameters at not only 1mm from the top plane, but also 1mm from the bottom plane.

The study faced an issue with the cone diameter measurement, since both cones were not true circular cones. The software had to fit the best-fit circle through the point-cloud of the cross-section, which enters error into the calculation of diameters for a few reasons. If the cone preparation changed into oval form in one dimension vs. another, we would want to be able to differentiate that. Since the software draws a best-fit circle through the point-cloud, the diameter would be either smaller or larger than it actually is. This is where qualitative analysis helped us in evaluation of diameter. Another reason that created a possible error in diameter calculation is related to iTero™ in particular. When iTero™ scans the model, the pictures taken get stitched together by the software of iTero™, and later on changed or verified by the technician before the model is milled. However, in qualitative analysis it was shown often that the stitching of the buccal and lingual pictures was not always adequate. Sometimes the two halves of cones were overlapped excessively, resulting in oval and thinner diameter in the bucco-lingual direction, and other times not stitched completely, resulting in wider diameter in bucco-lingual direction. Because the diameter calculation is made by “best-fit circle”, the error by the iTero™ scan was under calculated. In the future studies, it is suggested that there should be a diameter evaluation in bucco-lingual, as well as mesio-distal directions.

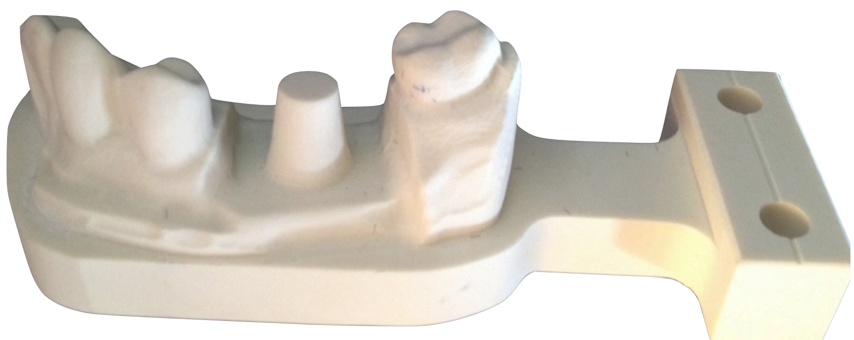
In the qualitative analysis of the samples, the color-difference maps have shown not only the issue with the diameter for the iTero™ models described above, but also it shows some other potential differences from the PVS technique. On the scale of +/-50µm range of the color maps, one can see that the diameters

are overbuilt or underbuilt in the bucco-lingual direction for the iTero™ samples. In addition, the top edges of the cone of iTero™ models were shown to be more rounded/smaller than the master at those edges, which would result in the crown not seating at that particular point, since the color maps at those edges were in the ranges above 30μm. This is an important qualitative observation, which points to possible error in either scanning or milling of the iTero™ models. It is possible that during manufacture of the iTero™ models the edges cannot be milled to the proper resolution, thus over milling of those edges is a possibility.

Another issue in relation to iTero™ observed during the performance of the study was the human error that is involved in manufacturing of the iTero™ models, similar to human error in the technique of taking PVS impressions. In a controlled setting for the PVS where the study was performed by one prosthodontist, all potential proper techniques were taken into account when fabricating PVS impression models. For the iTero™, however, this study was able to evaluate day-to-day errors that the dentist cannot control for. In this study the iTero™ scans were done by that same prosthodontist in a controlled setting and with the most attention to quality possible. Despite that, the study faced a few times problems with the software stitching the scans properly. In addition to that, even when the scans were stitched properly, the iTero™ technician's errors of re-stitching have shown a problem of incorrectly modifying the stitching. One iTero™ model was initially milled but could not be used in the study because the scan of it was re-stitched by the technician to include not two original cones as the scan showed, but only one (Figure 19). It was done by possibly the technician

overlapping the two cones into one. In the observation of Figure 14, there is a trend that the iTero™ models consistently under-stitched the Cone 1, creating consistently bigger diameter, while over-stitched the Cone 2, creating smaller diameter of the cone. This could be a potential unidentified problem with the path of scanning by the iTero™, where the tip of the wand will always face the most posterior portion of the mouth (corresponding to Cone 2), while the body of the wand would be towards anterior of the mouth.

Figure 19. iTero™ scan model re-stitched erroneously.
Model not used as a study sample in this study.



These types of errors would have to be measured on a vast amount of different models with different configurations and parameters. It would be interesting to see the human error involved relating to stitching of the scan pictures of iTero™. However, we understand that there are limitations to this and future studies in regards to evaluation of the scanning system itself, aside from milling and manufacturing, since iTero™ is a closed system and does not allow access to its scan files for the models, nor have we been able to get approved for such access for the purposes of this study.

VI. CONCLUSION

Within the limitations of this in vitro study, the following conclusions were made:

1. PVS impression models as well as iTero^{TM} scan models were significantly different from the master model in the dimensional accuracy for the majority of the parameters. However, within the clinically acceptable range of +/-20μm, both methods showed acceptable deviation from the master for the Height and Distance parameters.
2. Precision of iTero^{TM} scan models was inferior when compared to PVS models, and was significantly different in Distance parameters, and Cone 1 Diameter.
3. White Light optical scanner was found to be an acceptable repeatable method for evaluating dimensional accuracy of the models through virtual analysis and qualitative analysis.
4. There should be a standard protocol developed for the evaluation of the digital scan models, starting with the modification of current model design to evaluate better the pitfalls of the scanning system.

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