Marginal gap comparison of empress crowns using three different CAD/CAM workflows to evaluate the effect of proprietary data conversion to an open format

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Thesis submitted to the Faculty of the
U.S. Army Advanced Education Program in Prosthodontics,
Uniformed Services University of the Health Sciences
In partial fulfillment of the requirements for the degree of
Masters of Science in Oral Biology.
June 2021

ACKNOWLEDGMENTS

Special thanks to COL Cynthia Aita-Holmes my faculty research mentor, and to Dr. James McPherson, my clinical investigations mentor, both of whose efforts helped tremendously in the completion of this manuscript. Additional thanks to Dr. Douglas Dickinson for his help with preparing the statistical analysis.

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29 June 2021

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ABSTRACT

Marginal gap comparison of empress crowns using three different CAD/CAM workflows to evaluate the effect of proprietary data conversion to an open format

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CLINICAL RELEVANCE STATEMENT

This study provides information on the effect of converting proprietary CEREC data to stl files on the marginal gap of CAD/CAM crowns.

ABSTRACT

INTRODUCTION: Many popular CAD/CAM based systems now allow the user to export data to other platforms for designing or manufacturing dental prostheses using open file types (i.e. stl). When the proprietary data is converted to stl, there is some inherent loss of data that occurs. Does the loss of data have any effect on the marginal gap?

OBJECTIVES: This project compared the mean marginal gap of crowns fabricated with Dentsply Sirona's proprietary chairside CEREC workflow to crowns manufactured from open workflows using stl files converted from the proprietary data.

METHODS: Ninety-six Empress crowns were manufactured with three different workflows (32 per group). The control group (Group A) was scanned with the Primescan, designed in CEREC 5.1 software, and milled using a Sirona MCXL milling machine. Group B was scanned with the Primescan and models were exported as stl files, designed with the Sirona inLab Software 18.0, and manufactured with a Sirona MCXL milling machine. Group C was scanned with the Primescan, designed in CEREC 5.1 software, exported to Sirona inLab Software 18.0, and converted to stl file, and manufactured with the Sirona MCXL milling machine. The marginal gap was measure at ten different locations with a 100x light microscope. The data was checked for normality by D'Agostino and Pearson and Shapiro-Wilks test and analyzed using a one-way ANOVA.

RESULTS: All ninety samples had marginal gaps well below the 120-micron threshold. The mean marginal gap calculated for each group were 34.21 um ± 3.99 (Group A), 35.34 um ± 3.15 (Group B), and 34.92 um ± 2.37 (Group C). A one-way ANOVA showed no statistically significant difference in mean marginal gap between groups ($p = 0.37$).

CONCLUSIONS: Within the limitations of this *in vitro* study, exporting CEREC data to an open file type had no effect on the observed marginal gap.

TABLE OF CONTENTS

CHAPTER 1: INTRODUCTION

STATEMENT OF THE PROBLEM

Computer-aided design/computer-aided manufacture (CAD/CAM) technology is frequently used today to fabricate dental restorations with the goal of restoring teeth to proper form and function and improve the esthetics of patients' smiles. Studies have shown that different CAD/CAM workflows can produce variations in the amount of marginal gap present in a crown. Alqahtani et al showed that the marginal gap of lithium disilicate crowns fabricated using Dentsply Sirona CEREC system were roughly double that of crowns fabricated using 3Shape CAD software paired with a Weiland Zenotec mill[1]. Ji et al showed that there was a statistically significant difference between the marginal gap of zirconia crowns fabricated using the Zirkonzahn Exocad system and the 3Shape/Weiland workflow[2]. These examples evaluated the workflows using solely proprietary files. Many intraoral scanners and CAD software suites offer users the ability to export the data as an open file commonly referred to as standard tessellation language (stl) allowing the user to export data from one manufacturer's system for import into another. It has been reported by some that conversion from proprietary file type to stl may affect the accuracy of the data. Erozan et al evaluated the fit of crowns designed with both proprietary and open workflows. They found that stl conversion workflows resulted in significantly poorer fit when compared to proprietary workflow[3].

Currently the US Army utilizes three different workflows to digitally fabricate restorations. Most US Army dental clinics are equipped with a Dentsply Sirona scanner, CEREC software and mill (Dentsply Sirona, York, PA). The US Army Dental Laboratory (ADL) (Fort Gordon, Georgia) utilizes 3Shape CAD software to design restorations (3shape, Copenhagen, Denmark) and manufactures them on Weiland Zenotec (Wieland Dental GmbH, Pforzheim, Germany) and Ivoclar Vivadent mills (Ivoclar Vivodent, Schaan, Liechtenstein). Finally, the US Army Prosthodontic residency program predominately designs and manufactures CAD/CAM restorations with the Zirkonzahn system (Zirkonzahn GmbH; Gais, Italy). The release of CEREC software version 4.5 in 2017 introduced the option to export digital models in an open format (stl). Alternatively, a restoration can be designed in the Sirona inLab CAD software and exported as stl.

SIGNIFICANCE

Now that CEREC gives the user the option to export models and restorations as stl files, Army clinicians can choose to have the ADL manufacture their restorations via a digital workflow. They can either forward an stl file of the models or of the restoration, if they prefer to design the restoration locally. It is unknown whether the conversion of CEREC proprietary files (rst or dxd) to stl files lead to loss of data that could negatively affect marginal fit of the final restoration.

CHAPTER 2: REVIEW OF THE LITERATURE

CROWNS

According to the Glossary of Prosthodontic Terms, 9th Edition, "a crown is an artificial replacement that restores missing tooth structure by surrounding part or all of the remaining structure with a material such as cast metal alloy, metal-ceramics, ceramics, resin, or a combination of materials[4]." Crowns can be made from all metal, have a metal core with a ceramic exterior (metal ceramic), or they can be all ceramic[5]. All ceramic crowns (ACCs) are highly esthetic and depending on their composition are no longer only suitable for use in the esthetic zone[6]. Currently there are three classes of ceramics used to fabricate ACCs. They are predominately glass (most esthetic, lower strength), particle-filled glass, and polycrystalline (least esthetic, higher strength)[6]. Like metal ceramic crowns, ACCs can be fabricated with a core made of higher strength ceramic and veneered with more esthetic, predominately glass ceramic. The fabrication of ACCs may involve slip casting, hot pressing, or CAD/CAM technology[7].

ACCEPTABILITY AND ASSESSMENT OF CROWN MARGINS

The margin is defined as the outer edge of a crown, inlay, or onlay. The finish line is defined as the junction of the prepared and unprepared tooth structure[4]. J.R. Holmes is credited with coining the term marginal gap. Marginal gap has been defined by Holmes as "the perpendicular measurement from the internal surface of the casting to the axial wall of the preparation"[8]. No fixed indirect dental restorations are perfect and will always have some discrepancy between the margin and finish line. This can result in an open margin, overextended margin, or an under-extended margin[8]. The acceptability of the marginal gap is dependent on its size and location[9]. Christensen, McLean and von Fraunhofer suggested that a crown is clinically acceptable if the marginal gap is less than 120 micrometers[10]. Cemented restorations with marginal gaps in excess of 120 micrometers will lead to marginal leakage and dissolution of the cement[11]. Plaque can accumulate in the space once occupied by the cement which can lead to recurrent caries and periodontal problems[1]. The placement of the finish line can also have an effect on the gingival health. Subgingival finish lines have been shown to cause gingival inflammation while supra and equigingival finish lines have been shown to promote gingival health[12]. Margin fit and finish can also affect gingival health[13]. There are several techniques currently available to assess marginal gap. The easiest and most common clinical methods utilize visual examination and palpation with a sharp explorer[14]. It can be difficult to completely assess the margin intraorally because 360-degree visualization is frequently not possible. When utilizing an entirely digital workflow without the use of a cast, intraoral evaluation of the margins is the only available method of assessment. Other methods used for in vitro research involve making an impression of the cemented restoration, light microscopy, and CBCT analysis[15, 16].

CAD/CAM TECHNOLOGY

The first application of CAD/CAM in dentistry was in 1987 with the advent of the CEREC 1 system[17]. The CAD/CAM process consists of three overarching steps. The first step involves scanning the preparation. This can be accomplished either intraorally or by scanning analog impressions or models extraorally. The second step is designing the restoration. The user utilizes sophisticated software that can copy an existing tooth or wax-up, mirror an opposing tooth, or design the prosthesis from a database of a variety of tooth form. The last step in the process is milling the prosthesis from a chosen material[18]. The minimum requirement of any dental prosthesis fabricated using a digital workflow is that it be at least equal in quality to its conventionally made counterpart. CAD/CAM has the advantage of eliminating multiple error prone steps needed for conventional fabrication techniques such as analog impressions, waxing and casting[19]. CAD/CAM based restorations have been shown to have clinically acceptable marginal gap measurements when compared to conventionally made prostheses. Alqahtani showed that lithium disilicate crowns fabricated from conventional means (hot pressed) had a mean marginal gap of 91.15 micrometers. In comparison, crowns fabricated using the CEREC system had a mean marginal gap of 111.07 micrometers, and crowns fabricated with the 3Shape system had a mean marginal gap of 60.17 micrometers[1]. With the advent of CAD/CAM, simple indirect restorations that would have previously required a second visit by the patient and a significant amount of laboratory time for fabrication can now be designed, milled and delivered to the patient in a single visit. CAD/CAM technology has drastically increased the number of restorations that can be fabricated in a given amount of time. There are several materials to choose from to fabricate crowns. Wax patterns for casting and pressing can also be fabricated using CAD/CAM. While CAD/CAM has several advantages over traditional fabrication techniques, the clinician needs to be aware of some differences. For example, the smallest detail that can be milled is dependent on the size and geometry of the burs in the milling unit. Therefore, clinicians must create preparation geometries that can actually be milled by the machine, to avoid over milling leading to an increase in the internal gap[20] and thin restorative material, or binding at the margin preventing seating of the restoration.

SUMMARY

The marginal gaps of crowns fabricated using CAD/CAM proprietary workflows have been previously investigated [1, 2]. However, the possibility of digital data deterioration potentially leading to clinically unacceptable marginal gaps when converting proprietary files to an open format (stl) has not been investigated.

PURPOSE

The purpose of this study is to evaluate and compare the marginal gap of leucite reinforced glass ceramic crowns manufactured using three different CADCAM workflows to determine whether converting proprietary files to an open file format results in loss of data that could have a negative impact on crown margin accuracy. Results will serve to determine whether the CAD/CAM workflow used by the Army Dental Laboratory to fabricate restorations from stl files is acceptable.

NULL HYPOTHESES

NULL HYPOTHESIS #1

The mean marginal gap of leucite reinforced glass ceramic crowns fabricated with the proprietary CEREC workflow will not be statistically significantly different than those fabricated by exporting a stl file at the working model.

NULL HYPOTHESIS #2

The mean marginal gap of leucite reinforced glass ceramic crowns fabricated with the proprietary CEREC workflow will not be statistically significantly different than those fabricated by exporting a dxd file at the designed restoration into CAM software.

SPECIFIC AIMS

The aim of this study was to determine if the conversion of CEREC proprietary data to an open file format (stl) resulted in an increase marginal gap measurement.

The hypotheses were tested in the following specific aims:

1. Manufactured leucite reinforced glass ceramic crown designed using CEREC's proprietary workflow and stl files generated at the model and restoration stages.

2. Measured marginal gap of fabricated restorations seated on master typodont tooth in the laboratory by light microscopy.
3. Calculated a mean marginal gap and standard error for the population.
4. Compared manufacturing methods according to mean marginal gap and estimated proportion of rejected samples.

CHAPTER 3: MATERIALS AND METHODS

Three different workflows were evaluated creating three testing groups. Each group involved an optical scan with the Primescan. From there, the workflows differed as follows:

- Group A: Primescan/CAD » MC XL.
- Group B: Primescan » models exported as stl » InLab CAD/CAM SW » MC XL.
- Group C: Primescan/CAD » restoration exported as dxd » InLab CAM SW » MC XL

Sample fabrication began with fabricating a master die by preparing tooth #3 on a typodont (A5A-200-INDIVIDUAL TEETH-Replacement Teeth with Straight Roots, Kilgore International Inc. Coldwater, MI) with 2.0 mm and 1.5 mm occlusal reduction at the cusps and central groove respectively, 1.5 mm axial reduction, and a 1.0 mm rounded shoulder finish line. The master die was prepared with course and fine diamond burs (Brasseler USA, Savannah, GA) and polished with enhance points (Dentsply Sirona, Charlotte, NC). Ten reference marks (three buccal, three palatal, two mesial and two distal) were place around the crown on the root surface of the master typodont tooth (Figure 3-1).

A maxillary and mandibular quadrant scan was made with the prepared typodont tooth #3 in the typodont (Nissin Dental Model, Kilgore International, Coldwater, MI) with a Primescan chairside scanner using CEREC 5.1 software (DENTSPLY Sirona, Charlotte, NC). The scan data was saved as two different file types. The first was as rst file to be used in the proprietary CEREC chairside workflow. The second as stl file that was used to export the models generated from the scans.

For the control group (Group A), a single crown was designed with the rst file generated in CEREC 5.1 software (DENTSPLY Sirona). The automatic margin detector was used to find the margin. No alterations were made to the proposed margin. Thirty-two repeat leucite reinforced glass ceramic (Empress shade A2 C-14 blocks, Ivoclar Vivadent, Somerset, NJ) crowns were milled using the CEREC MC XL Practice Lab mill (DENTSPLY Sirona). The designed restoration was also exported as a dxd file that was used in the third test group.

For Group B the sample were manufactured by importing the stl files of the maxillary and mandibular models into InLab 18 CAD software (DENTSPLY Sirona) and a single crown was designed. The automatic margin detector was used to find the margin. The proposed crown was used to mill thirty leucite reinforced glass ceramic crowns using the CEREC MC XL Practice Lab mill (DENTSPLY Sirona, Charlotte, NC) using Ivoclar Vivadent Empress C-14 shade A2 blocks (Ivoclar Vivadent).

In Group C, a dxd file generated from the designed restoration in groups A was imported into InLab 18 CAD software and the restoration was exported as a stl file. The stl was then imported into the InLab18 CAM software and thirty crowns were fabricated with the Sirona MCXL (DENTSPLY Sirona) using Ivoclar Vivodent Empress C-14 blocks shade A2 (Ivoclar Vivadent).

New Step bur 12S and cylinder pointed bur 12S were installed in the MCXL prior to milling the first sample from each group. Both burs were replaced after the sixteenth sample from each group was milled.

The sprue was removed from all samples using an aluminum oxide wheel (Dedeco International Inc,Long Eddy, NY). Each sample was placed in a manila coin envelope labeled with the appropriate group (A, B, or C) and sample number. All crowns were inspected for gross errors using 4.5x dental loupes (Oroscoptic, Madison, WI). The restorations were held onto the master die with a C-Style Clamp and without the use of a cement. The C-Clamp was torqued to 15 Ncm using a torque wrench with a flat end driver (Nobel Biocare, Yorba Linda, CA). The marginal gap measurements were recorded by a single individual using a 100x light microscope (Nikon, Melville, NY) equipped with digital x and y axis micrometers (Mitutoyo, Kawasaki, Kanagawa, Japan). One reading was made at each reference mark (three buccal, three palatal, two mesial, and two distal) for a total a ten readings per sample (Figure 3-1). A total of 960 linear measurements for all samples were recorded across the vertical gap between the crown and prepared typodont tooth.

The mean marginal gap was calculated for each sample from the ten measurements collected. The largest of the ten measurements for each sample was also recorded to identify the largest marginal gap per sample.

The reliability of the measured data collected by the first rater was evaluated. Twenty-one crowns (seven per group) were randomly selected for evaluation by a second rater. All readings were conducted as previously stated. Statistical analysis was preformed to examine rater reliability by intraclass correlation.

Graphpad Prism 6.0 software was used for most of the statistical analysis. Other calculations were performed in Excel. Intraclass correlation was performed using the Real Statistics extension of Excel.

CHAPTER 4: RESULTS

Based on power analysis, a sample size of 32 for each group proved to be sufficient to allow detection of a 20 μm difference in margin fit within each group (alpha = 0.05) with a power (1-beta) of 80% using one-way ANOVA. All 96 samples were evaluated on the master die with 4.5x magnification for visibly large defect in marginal integrity. No large marginal gaps visible by the naked eye were noted and no samples were rejected.

VARIANCE WITHIN GROUP A (CONTROL GROUP)

Tests for normality of distribution of site measurements: Inspection of the distribution of the 32 crown measurements at the 10 sites around the margin revealed nothing unusual (Graph 4-1). The overall mean for Group A was 34.21$\pm$3.99 (SD).

Within Group A, the 32 measurements at 5 sites (MB, DB, MBB, ML, and DLL) passed both the D'Agostino & Pearson omnibus normality test and the Shapiro-Wilk normality test ($p>0.05$)(Table 4-1). Measurements at three sites (B, MLL, and DL) passed the D'Agostino & Pearson test, but not the Shapiro-Wilk test ($p\leq0.05$). Measurements at site DBB passed the Shapiro-Wilk test, but not the D'Agostino & Pearson test, while measurements at site L failed both tests.

Out of the 320 measurements, a ROUT test for outliers only found one high outlier under the relaxed condition of Q=5% (Crown #15, position L=49.00 μm). Therefore, there did not appear to be a prevalence of unusually high or low values.

Test for effect of matching: An F-test for the effect of matching on the partitioning of error within a repeat-measures ANOVA, was performed using the 10 sites as repeat measure groups. Sphericity was not assumed. The effect of matching was highly significant (F-test, $F=2.603$; $p<0.0001$), indicating correlation between measurements at the sites within one or more crowns. The Geisser-Greenhouse epsilon was 0.774, indicating minor deviation from sphericity.

A significant difference was found between sites (repeat-measures ANOVA, p=0.0001). Tukey's multiple comparisons test showed that the mean gap at MLL was significantly larger than at B, L and DL, ($p \leq 0.027$), and MBB was significantly larger than L (p=0.012).

To determine which crowns could have contributed to these results, the crowns were treated as groups and the sites treated as independent replicate measurements of gap width. Crowns 16 and 19 failed both tests for normality ($p \leq 0.044$), while crown 17 failed the D'Agostino & Pearson test (p=0.044). Crowns 16 and 17 showed substantial positive skewness and kurtosis, and crown 19 had a large negative kurtosis. Only crown 16 at position MLL was identified as an outlier using the ROUT test (Q=5%).

The 32 groups of site measurements showed no significant differences in variance (Brown-Forsythe test, p=0.80; Bartlett's test, p=0.95). A one-way ANOVA gave a highly significant p value (0.0001), indicated a difference between the mean marginal gap of at least one crown and the remainder. Tukey's multiple comparisons test identified the mean marginal gap of crown #2 as larger than crowns #5 and 16 ($p \leq 0.048$). No other differences were significant.

VARIENCE WITHIN GROUP B (SCANS CONVERTED TO STL)

Tests for normality of distribution of site measurements: Inspection of the distribution of the 32 crown measurements at the 10 sites around the margin revealed nothing unusual (Graph 4-2). The overall mean for Group B was 35.34 ± 3.15 (SD).

Within Group B, the 32 measurements at 8 sites passed both the D'Agostino & Pearson omnibus normality test and the Shapiro-Wilk normality test (p>0.05)(Table 4-2). Measurements at one site

(DLL) passed the D'Agostino & Pearson test, but not the Shapiro-Wilk test ($p \leq 0.05$). Measurement at site MB failed both tests. There was no consistent trend to skewness or kurtosis.

Out of the 320 measurements, a ROUT test for outliers showed no outliers under the relaxed condition of Q=5%. Therefore, there did not appear to be a prevalence of unusually high or low values.

Test for effect of matching: An F-test for the effect of matching on the partitioning of error within a repeat-measures ANOVA, which was performed using the 10 sites as repeat measure groups. Sphericity was not assumed. The effect of matching was significant (F-test, F=1.666; p=0.018), indicating correlation between measurements at the sites within one or more crowns. The Geisser-Greenhouse epsilon was 0.754, indicating minor deviation from sphericity.

A significant difference was found between sites ($p<0.0001$). Tukey's multiple comparisons test showed that the mean gap at B was significantly larger than at MB, DB, ML, DL, and DLL ($p \leq 0.049$). Site L was significantly larger than DB, ML, DL, and DLL ($p \leq 0.037$). Site MBB was significantly larger than DB and DLL ($p \leq 0.020$). Site MB was significantly larger than DB (p=0.049), and DBB was significantly larger than DLL (p=0.038). Collectively, sites B, L and MBB tended to a relatively larger size, and conversely dorsal sites tended to a relatively smaller size.

To determine which crowns could have contributed to these results, the crowns were treated as groups and the sites treated as independent replicates. All crowns passed both tests for normality except #18, which failed both tests ($p \leq 0.005$). Crown 18 showed substantial negative skewness and positive kurtosis. Crown 18 at position DBB was identified as a low value outlier using the ROUT test (Q=5%), while crowns 10 and 13 showed a high value at position B.

The 32 groups of site measurements showed no significant differences in variance (Brown-Forsythe test, p=0.98; Bartlett's test, p=0.98). A one-way ANOVA gave a non-significant p value (0.13), indicated no difference between the mean marginal gap of at least one crown and the remainder.

VARIANCE WITHIN GROUP C (RESTORATION CONVERTED TO STL)

Tests for normality of distribution of site measurements: Inspection of the distribution of the 32 crown measurements at the 10 sites around the margin revealed nothing unusual (Graph 4-3). The overall mean for Group C was 34.92 ± 2.37 (SD).

Within Group C, the 32 measurements at 7 sites passed both the D'Agostino & Pearson omnibus normality test and the Shapiro-Wilk normality test ($p>0.05$)(Table 4-3). Measurements at one site (DLL) passed the D'Agostino & Pearson test, but not the Shapiro-Wilk test. Measurement at sites DL and DBB passed the Shapiro-Wilk test, but failed the D'Agostino & Pearson test. There was no consistent trend to skewness, but the three sites showed a negative kurtosis.

Out of the 320 measurements, a ROUT test for outliers showed no outliers relative to the mean site value under the relaxed condition of Q=5%. Therefore, there did not appear to be a prevalence of unusually high or low values.

Test for effect of matching: An F-test for the effect of matching on the partitioning of error within a repeat-measures ANOVA, which was performed using the 10 sites as repeat measure groups. Sphericity was not assumed. The effect of matching was not significant (F-test, F=1.442; p=0.066), indicating no correlation between measurements at the sites within one or more crowns. The Geisser-Greenhouse epsilon was 0.784, indicating minor deviation from sphericity.

A significant difference was found between sites (p=0.013). Tukey's multiple comparisons test showed that the mean gap at MBB was significantly larger than at DL, (p=0.008), but no other significant differences were found.

To determine which crowns could have contributed to these results, the crowns were treated as groups and the sites treated as independent replicates. Crown 12 failed both tests for normality ($p \leq 0.006$), while all other crowns passed. Crowns 12 showed substantial negative skewness and positive kurtosis. Crown 12 at position DL was identified as a low value outlier relative to the mean crown value using the ROUT test (Q=5%).

The 32 groups of 10 site measurements showed no significant differences in variance (Brown-Forsythe test, p=0.87; Bartlett's test, p=0.96). A one-way ANOVA gave a non-significant p value (0.10), indicated no difference between the mean marginal gaps of any crowns.

ANALYTICAL STATISTICS OF MARGINAL GAP MEASUREMENTS

COMPARISON OF MEAN MARGINAL GAPS

All three group datasets passed both tests for normality. However, the datasets failed both the Brown-Forsythe and Bartlett's test for homogeneity of variance (p=0.040 and 0.018 respectively), consistent with differences in the precision of manufacture between the groups. The standard deviations for groups A, B and C were respectively 3.99, 3.15 and 2.37. Since these were well within a four-fold range, and parametric ANOVA is relatively robust to minor differences in standard deviation, the data were considered suitable for ANOVA, with a caution regarding weakly significant results.

Consistent with the relative similarity of the group means, one-way ANOVA found no significant difference between the group overall marginal gap means (p=0.37).

COMPARISION OF GROUP DISTRIBUTIONS

In all three groups the mean marginal gaps showed a good fit to a normal distribution, but significant differences in their standard deviations as determined by the Brown-Forsythe test and Bartlett's test.

An F-test (alpha=0.05) was performed for each pair of variances (df1=df2=31; critical F for two-sided test, df(30,30) = 2.07). Group A showed a significantly higher deviation than Group C (F=2.11), while Group A versus B and B versus C did not show a significant difference.

A two-sample Kolmogorov-Smirnov test was performed to compare the distributions for significant differences (alpha=0.05) from each other. All three comparisons gave a p value of 0.58, indicating no significant differences between the distributions.

THE EFFECT OF CHANGING THE BUR

For each group, non-linear regression using a line model was used to compare the pattern of marginal gap value changes from Crown 1-16, and from Crown 17-32. F-tests were used to determine if the null hypotheses that both sets of 16 values in a group fit the same line model, and if the line had a slope of zero.

For all three groups, the F-tests indicated that two sets of 16 crowns did not show a significant difference with regards to a fit to one line; both datasets fit the same line, with a slope not significantly different from zero. Treating each pair of crowns starting with 1,17 as replicate tests of the same amount of wear on the burr, the three groups were compared. Again, the p values from the F-tests did not support a different line model for the groups, and the slope did not differ significantly from zero.

THE EFFECT OF DIFFERENT EXAMINERS ON MARGINAL GAP WIDTH

A second examiner measured 7 crowns at the same margin positions for each group. The intraclass correlation coefficient (ICC) can be used to determine both the degree of correlation and the agreement between measurements by two or more examiners. In this study, two specific examiners tested the crowns. Therefore, a two-way mixed effect model was the model of choice, and the results reflect the reliability of the two specific examiners. The datasets for the two examiners are identical. Therefore, an ICC (3,1) test was used. ICC values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability. The ICC is calculated as a ratio ICC = (variance of interest) / (total variance) = (variance of interest) / (variance of interest + unwanted variance). Here, the unwanted variance is rater disagreement, and the intra-class correlation coefficient (ICC) quantifies the proportion of variance explained by a grouping (random) factor in multilevel/hierarchical data. The less the contribution of the examiner variance to the ICC value, the closer it will be to 1.

For Group A, The ICC (3,1) values and 95% CI intervals for Groups A, B and C were respectively 0.838 (0.751-0.897), 0.816 (0.719-0.882) and 0.479 (0.274-0.642). The lower reliability in Group C was likely due to the lower measured variance seen in this group, leading to random measurement error being less dominant in the comparison of examiners. Since the variance in Group C is small (CV=6.8%), the discordancy between the examiners must also be small. Consistent with this, the average difference between the 70 pairwise measurements in each group was 4.35, 5.02 and 5.33 μm for Groups A, B and C respectively.

CHAPTER 5: DISCUSSION

Prior to the release of software version 4.6, CEREC was a closed system. Any conversion of CEREC data to an open format required the use of third party software associated with a potential for degradation of the data [21, 22]. With the release of 4.6 and newer software versions, CEREC users have the ability to export data as a stl file. Now that the file conversion is occurring within the CEREC software, it is unknown whether the conversion leads to degradation of the data. affect the fit of the restoration. When a file is converted to stl, there is an inherent loss of data that occurs. A stl file is a 3-D representation of an object. All of the data that pertained to color, texture and other CAD model attributes is lost[23]. The aim of this study was to identify if the conversion process had an effect on the end product by evaluating the marginal gap.

A control group and two experimental groups were evaluated to test the effect of data conversion to stl at both the model and restoration phase. Each sample was evaluated at 10 different location as marked on the prepared typodont tooth. Each group was found to have only minor deviations from normal and was assumed to fit normally. Each measurement was evaluated per location and found to fit a normal distribution (i.e. the buccal measurement on crown #2 and crown #29 in Group A were similar). There was however a discrepancy found between the mean gap at different locations and the discrepancies were not consistent between groups. Within the limits of this *in vitro* study, every effort was made to mimic a clinical situation. The typodont tooth was prepared to ideal. A single master typodont tooth was prepared and used to collect the source data for each group to minimize potential distortions from die duplication. The automatic or magnetic margin detector was used to find the margin in each group. There was no correction made to the margin automatically generated by the software.

No sample measurements were recorded over the 120 μm threshold for clinical acceptability[14]. The largest marginal gaps noted for Groups A, B and C were respectively 53 μm (#21, MLL; #27 DLL), 55 μm (#3, B), and 50 μm (#3, MBB; #2, MLL; #19, DLL). The largest measured marginal gap for each method were all similar, and less than twice the mean marginal gap value.

The mean marginal gaps noted for Groups A, B and C were respectively 34.21 μm $\pm$ 3.99 (SD), 35.34 μm $\pm$ 3.15 (SD), and 34.92 μm $\pm$ 2.37 (SD). This is in good agreement with the result obtained by Oz *et al*[24]. They found the mean marginal gap of Empress onlays fabricated using the CEREC Omnicam and MCXL to be 33.54 μm.

The fit of most sample sets to a normal distribution with no evidence for marked outliers indicated that the mean of the marginal gap measurements on each crown would be a good estimate of the overall fit of the crown. Therefore, the mean marginal gaps for each crown were evaluated for suitability by one-way ANOVA. The ANOVA found no significant difference between the group overall marginal gap means ($p=0.37$). This contradicts the results of Erozan *et al*[3]. They found that there was a significant difference between crowns designed with proprietary and converted stl files. Erozan’s group did not manufacture their samples. They employed a superimposition technique to evaluate the fit digitally. Also, they did not specify how their proprietary data was converted. The conversion method used in this study was within the CEREC or InLab software. If Erozan utilized third party software for the data conversion, it could possibly be a reason for the different results obtained by their group and the current study. It is also possible that the measurement method (physical vs. virtual) could have also played a role in the differences.

All three groups showed good fit to a normal distribution, but significant differences were found in their respective standard deviations according to the Brown-Forsythe and Bartlett's tests. Using an F-test, Group A showed higher deviation than Group C, but no other differences were noted. The Kolmogorov-Smirnov test did not show any difference between the distributions. The sets of values for the mean marginal gaps of crowns produced by the three methods each fit a normal distribution, indicating an unbiased random variation, with Group C showing the lowest standard deviation, and a significantly lower value than Group A. This was consistent with Group C showing the fewest number of significant differences between site values.

Each of the samples were manufactured in order from number 1 to 32 for each group. The milling instruments (burs) were replaced in the MC XL mill prior to manufacturing sample number 1 and again before manufacturing sample number 17 to evaluate the effect of milling bur wear on the marginal gap. There was no evidence that the wear of the milling burs affected the mean marginal gap width with any method during the production of the 16 crowns per bur set, and there was no evidence of any difference between the groups, consistent with the results from the ANOVA.

Seven samples per group were randomly selected by a third party not involved with this study and were examined by a second examiner to confirm the principal investigator's marginal gap measurements. The second examiner was blinded to the sample number and workflow. An interclass correlation was used to compare the results. For Groups A (0.838) and B (0.816) there was a good agreement between the two examiners, indicating consistency in the measurements. While the low ICC value for Group C (0.479) was not consistent with good reliability, this was likely due to the low random error variance in the measurements.

In summary, the three methods all gave modest variance in crown marginal gap, either at the individual site or mean marginal gap level. Changing the milling bur after 16 crowns did not have a detectable effect. The agreement between evaluators was generally good, with a poorer ICC value in Group C likely being due to a relatively small random variance overall. Based on the data, the first and second null hypotheses of no difference between methods in the mean marginal gap cannot be rejected.

CHAPTER 6: CONCLUSIONS

Within the limitations of this *in vitro* study, exporting CEREC data to an open file type had no effect on the observed marginal gap. All three methods gave good precision in the mean marginal gap and clinically acceptable crowns with no evidence for a problematic failure rate. The largest measured marginal gap for each method were all similar, and less than twice the mean marginal gap value.

Group C showed a significantly smaller standard deviation than Group A, and fewer within-group significant differences than Group B, suggesting it had the best precision. That is, Group C appeared to give the most consistent marginal gap values.

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TABLES

Table 4-1: Descriptive statistics of 32 site measurements at 10 positions in Group A.

	MB	B	DB	MBB	MLL	ML	L	DL	DBB	DLL
D'Agostino & Pearson	Pass	Pass	Pass	Pass	Pass	Pass	p=0.024	Pass	p=0.044	Pass
Shapiro-Wilk	Pass	p=0.027	Pass	Pass	p=0.023	Pass	p=0.009	p=0.006	Pass	Pass
Skewness		0.477			-0.691	0.220	1.087	0.589	-0.177	
Kurtosis		-1.007			-0.337	-1.166	0.849	-1.015	-1.204	

Table 4-2: Descriptive statistics of 32 site measurements at 10 positions in Group B.

	MB	B	DB	MBB	MLL	ML	L	DL	DBB	DLL
D'Agostino & Pearson	p=0.022	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

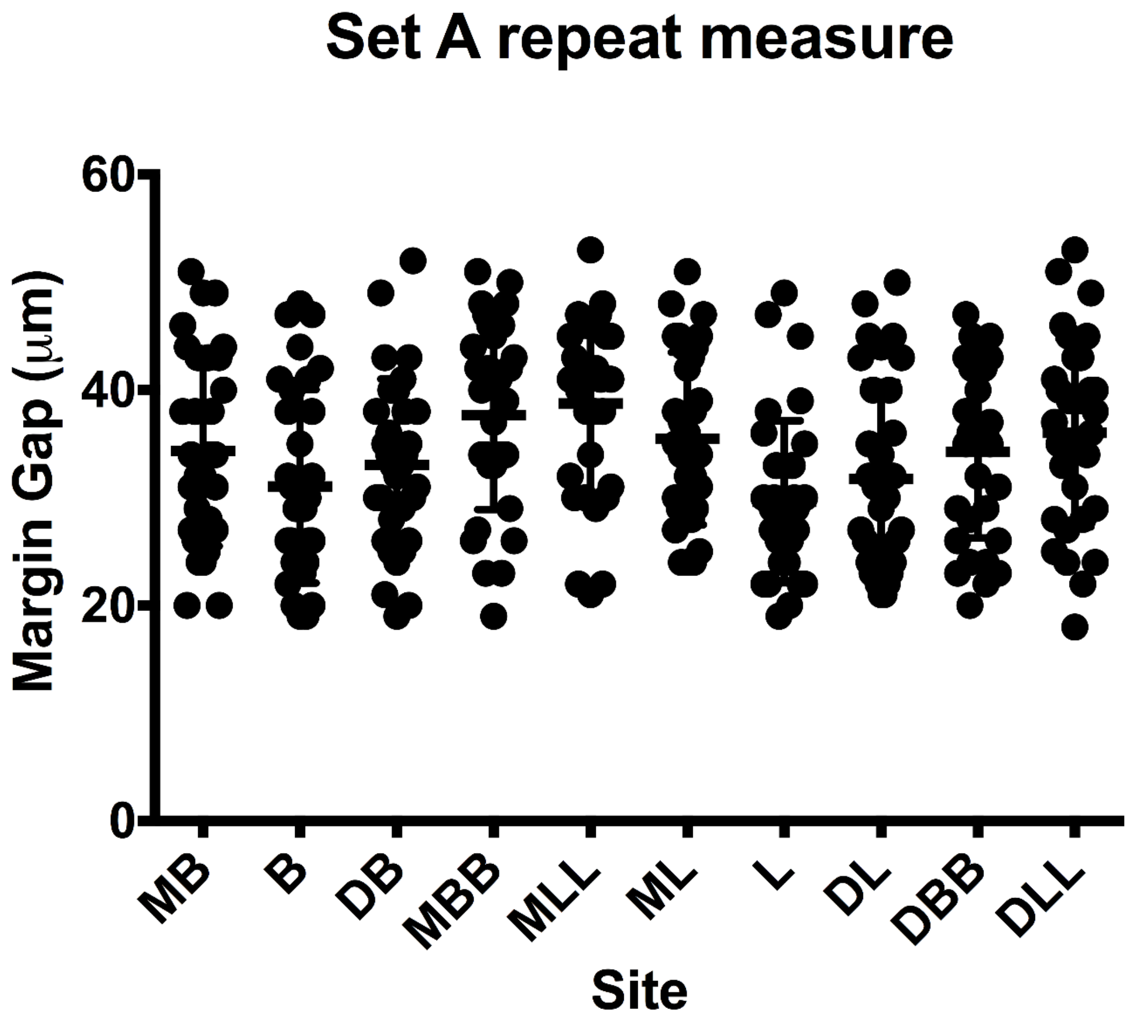
Shapiro-Wilk	p=0.045	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	p=0.040
Skewness	-0.057									0.841
Kurtosis	-1.277									0.373

Table 4-3: Descriptive statistics of 32 site measurements at 10 positions in Group C.

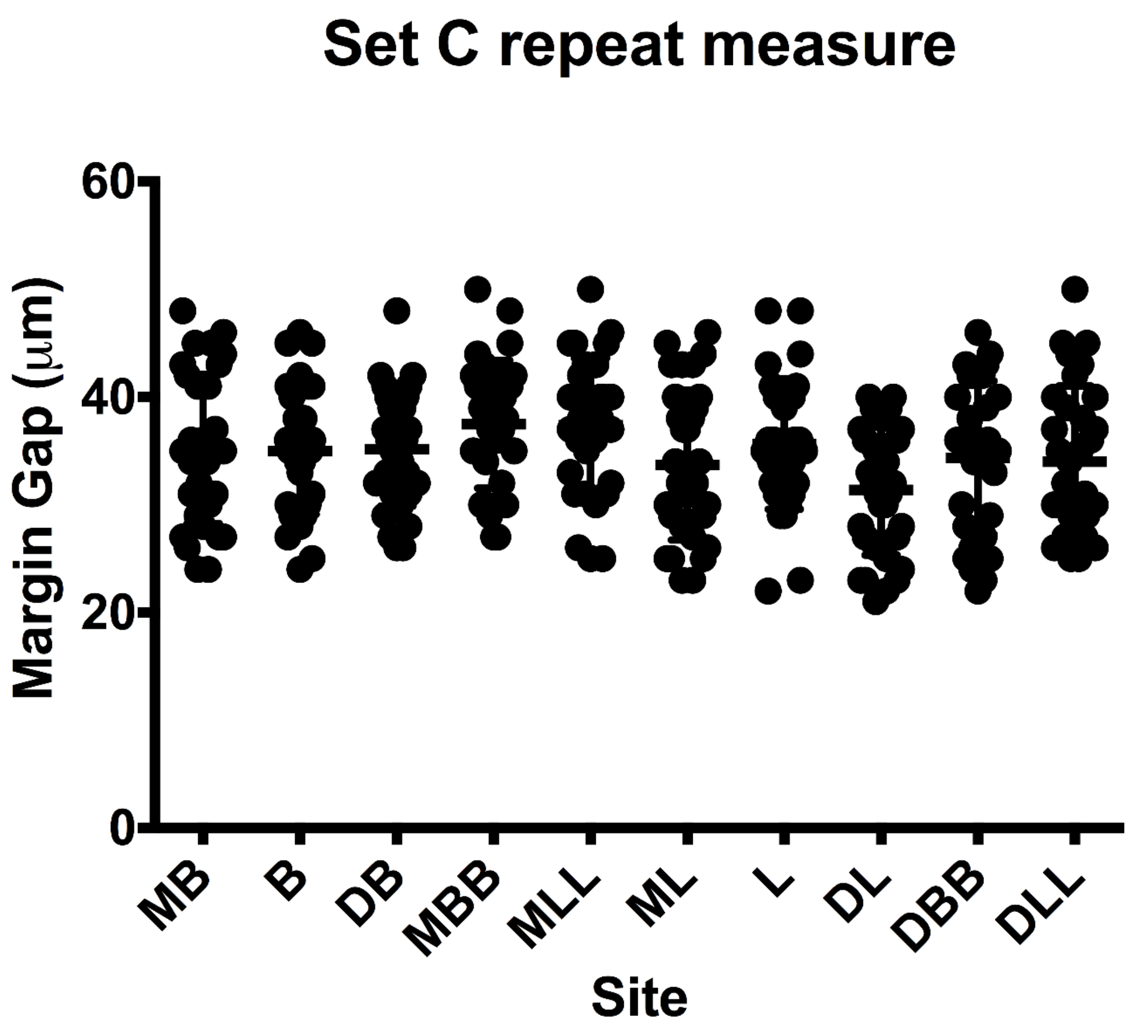
	MB	B	DB	MBB	MLL	ML	L	DL	DBB	DLL
D'Agostino & Pearson	Pass	Pass	Pass	Pass	Pass	Pass	Pass	p=0.014	p=0.037	Pass
Shapiro-Wilk	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	p=0.047
Skewness								-0.147	-0.208	0.484
Kurtosis								-1.308	-1.216	-0.810

GRAPHS

Graph 4-1: Mean and SD of 32 site measurements at 10 positions in Group A. Bars show the mean and standard deviation.



Graph 4-2: Mean and SD of 32 site measurements at 10 positions in Group B. Bars show the mean and standard deviation.



Graph 3: Mean and SD of 32 site measurements at 10 positions in Group C. Bars show the mean and standard deviation.

FIGURES

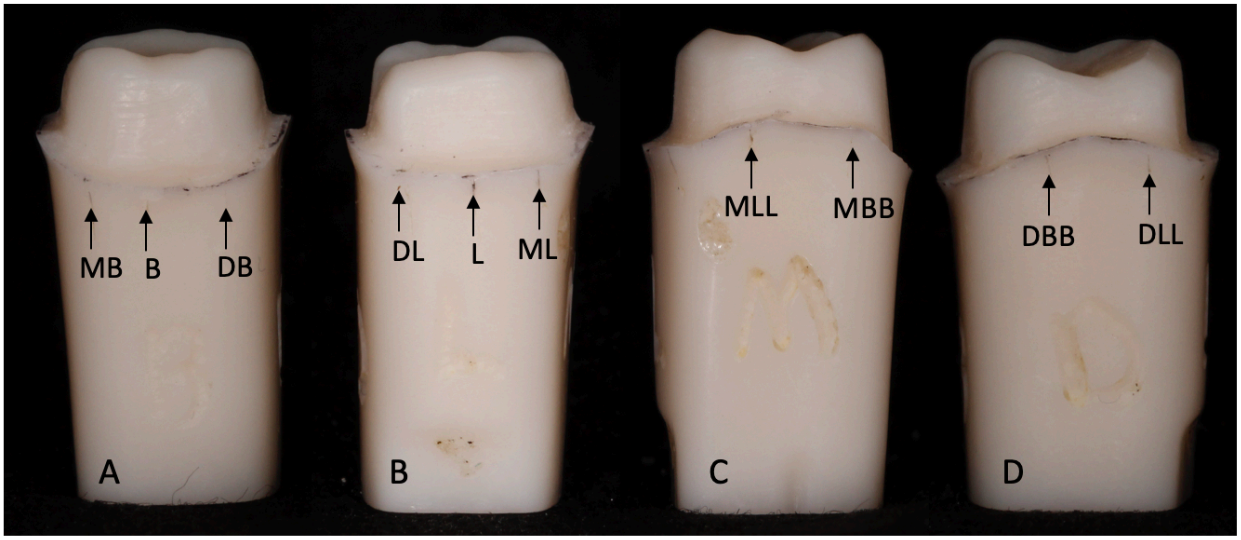


Figure 3-1: Prepared master typodont tooth. (A) Buccal surface with three measurement locations marked. (B) Lingual surface with three measurement locations marked. (C) Mesial surface with two measurement locations marked. (D) Distal surface with two measurement locations marked.