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POSTGRADUATE DENTAL COLLEGE  
SOUTHERN REGION OFFICE  
2787 WINFIELD SCOTT ROAD, SUITE 220  
JBSA FORT SAM HOUSTON, TEXAS 78234-7510  
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## THESIS APPROVAL PAGE FOR MASTER OF SCIENCE IN ORAL BIOLOGY

Title of Thesis: "CEREC Primescan Image Quality Following Multiple Cycles of Dry Heat Sterilization of Primescan Sleeves"

Name of Candidate: David A. Dantes  
Master of Science Degree  
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DATE:



Dr. Robert E. Masterson  
PROGRAM DIRECTOR FORT HOOD AEGD-2  
Committee Chairperson



Dr. John Kreider  
ASSISTANT PROGRAM DIRECTOR- FACULTY MENTOR  
FORT HOOD AEGD-2

10 March 2021

20210313

COL Stefan S. Olpinski  
COMMANDER, US ARMY DENTAL HEALTH ACTIVITY, FORT HOOD  
Dean, Fort Hood AEGD-2



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Name of Candidate: David A. Dantes  
Master of Science Degree  
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THESIS/MANUSCRIPT APPROVED:

DATE:

\_\_\_\_\_  
Dr. Robert E. Masterson  
PROGRAM DIRECTOR FORT HOOD AEGD-2  
Committee Chairperson

\_\_\_\_\_  
Dr. John Kreider  
ASSISTANT PROGRAM DIRECTOR FORT HOOD  
AEGD-2

\_\_\_\_\_  
COL Stefan S. Olpinski  
COMMANDER, US ARMY DENTAL HEALTH ACTIVITY, FORT HOOD  
Dean, Fort Hood AEGD-2

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David Dantes  
Uniformed Services University  
22 Feb 2021

# **CEREC Primescan Image Quality Following Multiple Cycles of Dry Heat Sterilization of Primescan Sleeves**

David Dantes, DDS

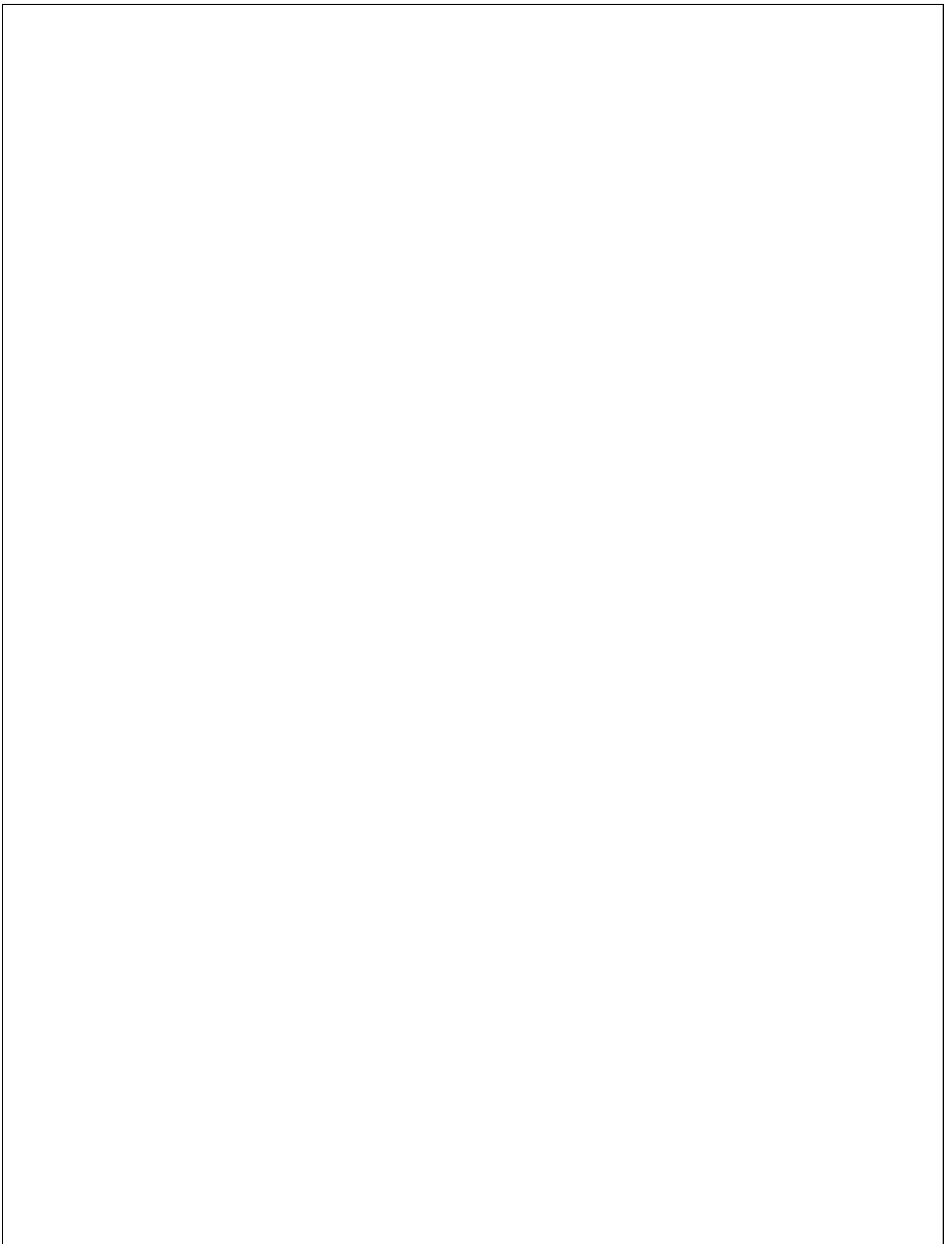
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AEGD2yr

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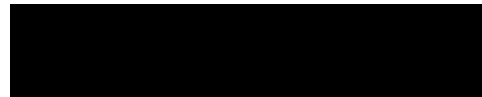


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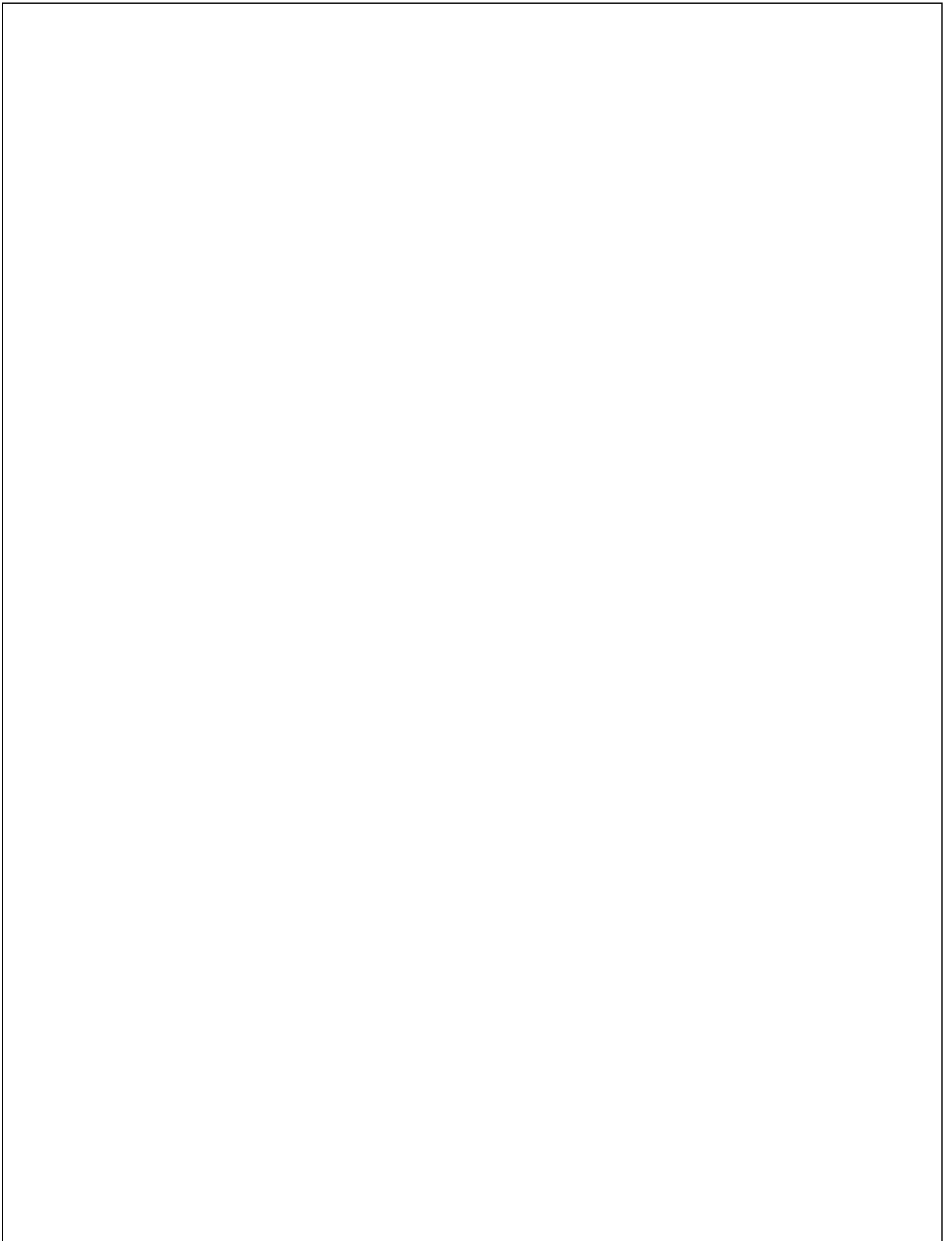
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David Dantes, D.D.S  
LTC, DC USARMY  
Fort Hood AEGD-2 Residency



# CEREC Primescan Image Quality Following Multiple Cycles of Dry Heat Sterilization of Primescan Sleeves

David A. Dantes, DDS; Jarred L. Price, DDS, MS; Robert Masterson, DDS, MS; John K. Kreider, DMD, MS; Michael R. Mansell, DDS, MS

## ABSTRACT

**Background.** The purpose of this study was to evaluate the effect of multiple cycles of dry heat sterilization on the accuracy of CEREC Primescan scans and the aim was to quantify any potential deviations in imaging.

**Methods.** A Nobel Biocare implant was placed in a prefabricated dental arch and a healing abutment with known measurement parameters was scanned using three separate CEREC Primescan sleeves, each divided into separate groups. After the initial (control) scan was obtained, the sleeves were processed once in a dry heat sterilization unit and another scan was obtained. This process was then repeated for a total of one hundred cycles. At the conclusion of the scanning process, the scans were then superimposed utilizing MeshLab 3D (CNR-ISTI, Pisa, Italy) software to evaluate any deviation from the control scan. Deviations were recorded and statistical analysis was carried out using SPSS Statistics (IBM, Armonk, NY). A paired samples t-test was performed for the first and one hundredth post-sterilization scans using the mean value between the three groups.

**Results.** After one hundred cycles of dry heat sterilization, a deviation range of 6-10 micrometers was recorded between the pre-sterilization and post-sterilization scans. A deviation range of 1-2 microns between the first and one-hundredth post sterilization scan among the three groups was noted.

**Conclusion.** No statistically significant deviation was found, however, further testing

may be required to determine if dry-heat sterilization limits the lifespan of the sleeves.

**Practical Implications.** It is important for the clinician to understand any potential effects that day to day clinical operations have on the effects on the lifespan of instruments. Scanning quality degradation following sterilization of CEREC Primescan sleeves would make their use cost-prohibitive. The increased upfront cost of digital impression-taking could indicate a poor investment if equipment performance was found to falter after following manufacturer recommended sterilization procedures.

**Key Words.** CAD/CAM, intraoral scanning, accuracy, CEREC, Omnicam, Primescan, dry heat sterilization

CAD/CAM (computer-aided design and computer-aided manufacturing) technology in dentistry offer a digital alternative for the creation and manufacturing of dental prostheses. The use of CAD/CAM technology to produce digital or “optical impressions” was first introduced in 1971.<sup>2</sup> With an increased demand over the past few decades for more efficient methods for the capture of intraoral structures, CAD/CAM technology has been forced to continually evolve. Currently, there are many different acquisition, design, and manufacturing options available to clinician. The most widely used intraoral scanning system in the U.S. Army is the CEREC Omnicam by Dentsply Sirona, but it is currently being phased out in favor of the CEREC Primescan. The CEREC Primescan

unit consists of the Primescan camera for image capture and an acquisition computer for the design of the intended prosthesis. The Primescan camera has a reusable stainless-steel sleeve with a glass insert that must be sterilized between patients. Sirona provides two types of re-useable sleeves: autoclavable and dry-heat sterilization. According to Sirona, there are two accepted means of sterilization of the Primescan dry-heat sleeve: high level disinfection and dry-heat sterilization. Current U.S. Army sterilization guidelines only allow for FDA approved sterilization practices. At this time, high level disinfection has not been approved by the FDA. Therefore, dry-heat sterilization is the only method currently used in U.S. Army dental clinics. The dry heat sterilizer accessible to most dental clinics in the U.S. Army is the Cox RAPIDHEAT sterilizer, which was incorporated into this study based on its availability.

Several studies have assessed the accuracy of the CEREC Omnicam compared to other intraoral scanners in different clinical scenarios.<sup>5-7</sup> One study conducted by Price et al (2020) did evaluate the effect of multiple dry-heat sterilization cycles on the CEREC Omnicam sleeves and found no significant effect on image quality. However, given the recent introduction of CEREC Primescan to the marketplace, to date there is limited data available regarding its durability. To the author's knowledge, no studies exist that have evaluated image quality consistency following multiple cycles of dry heat sterilization on Primescan sleeves. Therefore, as a pilot study for Primescan, the research design was derived and based from the study conducted by Price et al (2020) on Omnicam sleeves. The purpose of this study was to evaluate the effect of multiple cycles of dry heat sterilization on the accuracy of CEREC Primescan scans and the aim was to quantify any potential deviations created. The null hypothesis was that the dry-heat sterilization of the Primescan sleeves would not significantly impact scanning accuracy and that

any potential deviations created in the imaging would be deemed negligible. The alternative hypothesis was that the dry-heat sterilization process would significantly impact scanning accuracy and results in unacceptable distortion of the images generated.

## **MATERIALS AND METHODS**

### **Testing model, reference dataset, and direct digitization of model**

A Biomet 3i T3 4.1 x 10 mm implant (Zimmer Biomet, Warsaw, IN) and a Bellatek Encode 4.1 (D) x 5.0 (P) x 4.0 (H) mm healing abutment (Zimmer Biomet, Warsaw, IN) was placed in a prefabricated plastic model to be scanned. The Encode healing abutment was selected to serve as a known quantifiable landmark for calibration and analysis within Meshlab software. CEREC AC Primescan and three new, never before used, CEREC Primescan stainless steel sleeves with sapphire glass inserts were utilized. Three groups (grp 1, grp 2, and grp 3) were formed for each sleeve. A group consists of a control, a first post-sterilization, and a one-hundredth post-sterilization scan. The control scan was obtained prior to the first sterilization cycle. The sleeves were then placed in a Steri-Dent Self-Seal Nylon Pouch and processed using a Cox RapidHeat Sterilizer (CPAC, Leicester, NY). The manufacturer's pre-programmed cycle III was selected for sterilization, which consists of a 12 minute heat cycle at 375°F (195°C). After sterilization, the sleeves were allowed to cool for twenty minutes prior to use for a single scan.

### **Alignment of datasets**

Once obtained, scans were then exported onto a flash drive as highest resolution standard tessellation language (STL) files and assigned to their respective group. This process was repeated for one hundred cycles with each sleeve. The STL datasets were then imported into MeshLab for analysis.

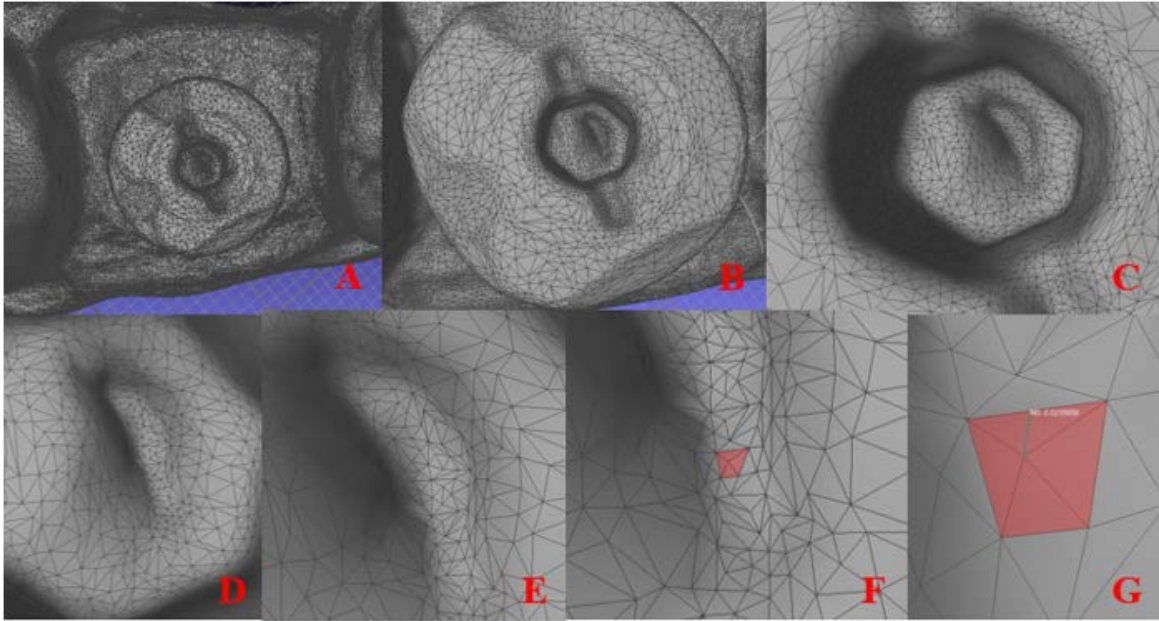


Figure 1. Highlighting STL file triangles aids in accurate measurement and alignment. As demonstrated here with increased magnification (alphabetically), triangles can be identified and highlighted. One triangle (G) was measured from base to apex at 0.02358mm (approximately 24 microns).

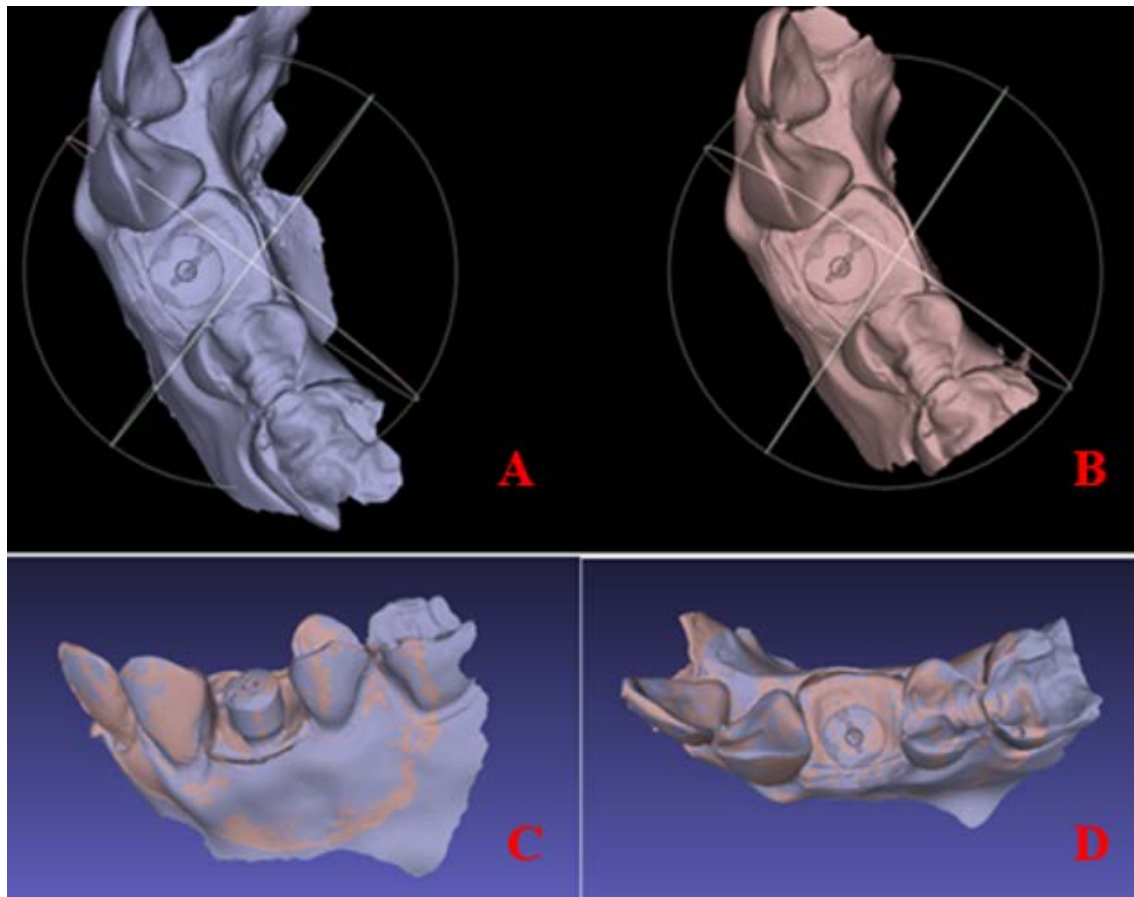


Figure 2. Pre-sterilization (A) and post-sterilization (B) models are processed for alignment (C and D).

Identifying and marking STL triangles (fig. 1) was done to aid in measurement and alignment (fig. 2).

Utilizing the control dataset, the software was calibrated to the 5 mm restorative profile of the Encode healing abutment. Thereafter, manual point-based alignment of the first and one-hundredth scan to the respective control scan was completed. Using the “Process” function within the software, the mean deviation of the post-sterilization scans from the control scans could be determined. In order to minimize user error during manual point-based alignment, the alignment and deviation processing was performed ten times for each scan and the lowest deviation, representing the most accurate alignment, was recorded.

### Statistical analysis

Using the mean deviation values obtained from the first and one-hundredth scans from all three groups, a paired samples t-test was performed using IBM SPSS Statistics software (IBM,

Armonk, NY) in order to assess the statistical difference between the two mean measurements. A p value <0.05 was established as the significance threshold

## RESULTS

The correlation between the amount of deviation for the first and one-hundredth post-sterilization cycle of each sleeve is shown in Figure 3. The overall deviation ranged between 6 to 10  $\mu\text{m}$ . Group 1 demonstrated a range of 8-10  $\mu\text{m}$ , Group 2 demonstrated a range of 6-8  $\mu\text{m}$ , and Group 3 demonstrated a range of 8-10  $\mu\text{m}$ . Individually, the groups demonstrated 1-2  $\mu\text{m}$  difference. The mean deviation value among all three groups for the first and one-hundredth post sterilization dataset was 7.333  $\mu\text{m}$  and 9  $\mu\text{m}$ , respectively. The paired samples t-test resulted in  $p=0.38$  ( $\alpha=0.05$ ), thus, the null hypothesis is retained and no statistically significant deviation was realized between the first and one-hundredth post-sterilization scan.

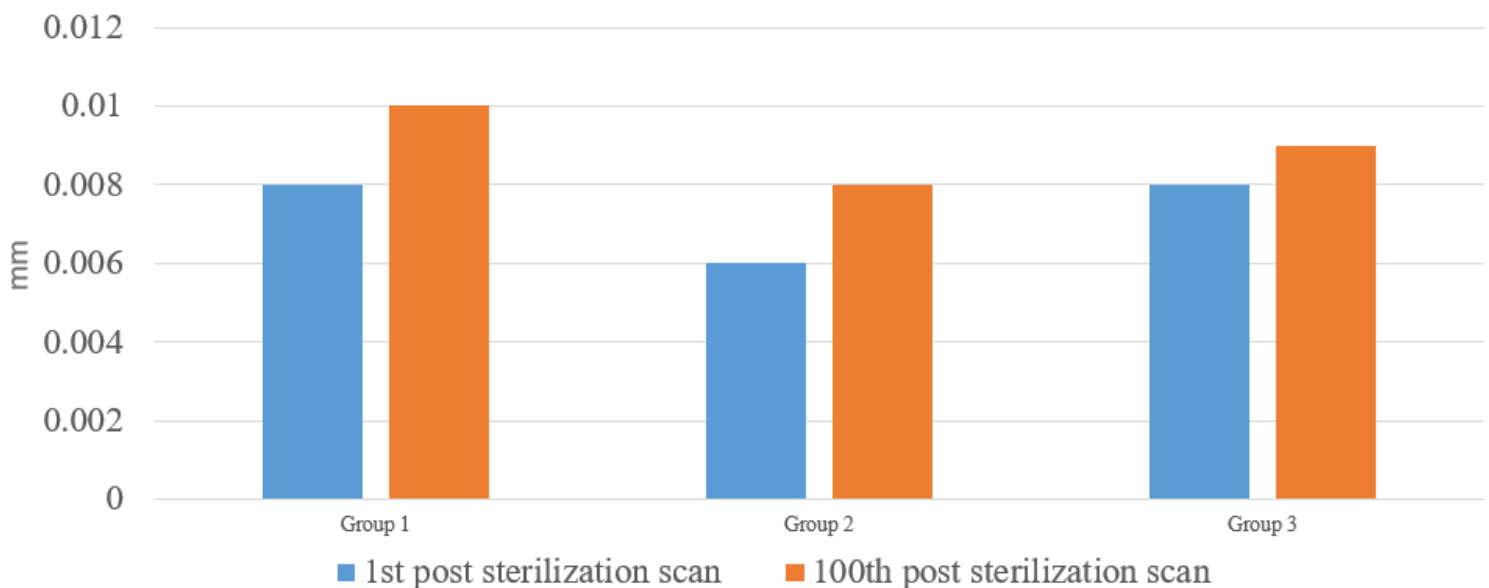


Figure 3. The amount of deviation of each post sterilization dataset from the control dataset is measured in millimeters (0.001 mm = 1  $\mu\text{m}$ ).

This is consistent with results obtained by Price et al (2020).

## DISCUSSION

The results of this study supports the null hypothesis. Deviations ranging in size from 6-10 $\mu$ m in the alignment of post sterilization scans to the control were encountered among the three groups. These deviations fall well below the tolerance range of 50-90 $\mu$ m for implant supported restorations (Braian et al, 2014) and 150 $\mu$ m for conventional fixed tooth supported restorations (Hayashi et al, 2013). The deviations encountered in this study are well below the most stringent tolerance reported in the literature and further lend support to a study by Ahrberg et al, concluding that digital workflow is more accurate than conventional workflow.

To ensure consistent analysis and to obtain alignment with the least deviation, use of known linear measurements of the Encode healing abutment, three dimensional manual point based referencing, and multiple alignments for the same dataset were utilized. This approach employs a method that is consistent with a clinical settings where clinicians use STL datasets for manual manipulation and point based alignment, such as the digital fabrication of surgical guides for implant placement. This study utilized only CEREC Primescan, however, different levels of accuracy among different scanners may be encountered. The findings of this study do not take into account the negative effect that mishandling the sleeves may impart. A potential follow-on project could study the potential negative effect of adding the application of disinfection wipes, e.g. Cavicide, to the sleeves while under this protocol. This study serves as a pilot study on the quality of imaging of the CEREC Primescan when re-usable dry-heat sleeves are subjected to standard sterilization procedures. This does not

investigate or compensate for potential design and fabrication processing errors.

## CONCLUSION

Within the limitation of this in vitro study, it can be concluded that multiple cycles of dry heat sterilization of CEREC Primescan sleeves has no significant effect on scanning and the quality of the images generated. All dataset deviation values obtained, ranging between 6-10 microns, were regarded as clinically acceptable. However, more research is needed to determine the life span of CEREC Primescan sleeves. It would be beneficial to expand this study by incorporating significantly more cycles of sterilization and subjecting the sleeves to different stresses in order to assess their lifespan.

None of the authors reported any disclosures or conflict of interests.

**Dr. Dantes** is a current resident, Advanced Education in General Dentistry 2-yr Program, Ft Hood, TX.

**Dr. Price** is a graduate, Advanced Education in General Dentistry 2-Year Program, Fort Hood, TX and is currently the 5<sup>th</sup> SFG Dental Surgeon, Ft Campbell, KY.

**Dr. Masterson** is the current Director, Advanced Education in General Dentistry 2-Year Program, Fort Hood TX

**Dr. Kreider** is the current Asst. Director, Advanced Education in General Dentistry 2-Year Program, Fort Hood TX

**Dr. Mansell** is the former Director, Advanced Education in General Dentistry 2-Year Program, Fort Hood TX

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