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Effects of Various Sterilization Protocols on the Dimensional Accuracy of 3D Printed Surgical Guides for Dental Implants

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Effects of Various Sterilization Protocols on the Dimensional Accuracy of 3D Printed Surgical Guides for Dental Implants

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Master of Dental Science Thesis

Effects of Various Sterilization Protocols on the Dimensional Accuracy of 3D Printed Surgical Guides for Dental Implants

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C. ABSTRACT

Statement of Problem:

Currently, there is limited research on the effects of various sterilization methods for 3D printed surgical guides on their possible distortion and dimensional accuracy.

Objective:

The primary objective of this study was to determine if there would be any change in physical dimensions or physical characteristics of 3D printed edentulous surgical guides before and after subjecting them to either traditional terminal steam sterilization (TTSS) or immediate-use steam sterilization (IUSS) (“flash cycle”). The secondary objectives were to compare differences in physical dimensions and subjective characteristics of surgical guides after steam sterilization in a large-scale, Hospital autoclave and a Dental Office autoclave.

Material and Methods:

A total of 45 standardized surgical guides were fabricated for an edentulous maxilla with 3-dimensional (3D) printing technology. The surgical guides were divided into three groups of 15 guides each: Hospital autoclave TTSS (121°C for 30 min), Hospital autoclave IUSS (135°C for 4 min), and Dental Office autoclave IUSS (135°C for 4 min). The intaglio surface of each surgical guide was recorded using optical surface scanning before and after being subjected to a steam autoclave cycle. The optical scans were subsequently registered using a surface inspection software and the mean differences in distortion between the two surfaces of each surgical guide were calculated. Each surgical guide was also visually inspected under 3x optical magnification for physical changes subsequent to sterilization.
Results:

TTSS (121°C for 30 min) in the Hospital unit produced a mean absolute surface distortion of 0.0093 (SD=0.097) mm. IUSS (135°C for 4 min) in the Hospital unit produced a mean absolute surface distortion of -0.0088 (SD=0.17) mm. IUSS (135°C for 4 min) in the Dental Office unit produced a mean absolute surface distortion of -0.0020 (SD=0.12) mm. These distortions were not statistically significant compared to the pre-autoclaved state in any of the groups (p>0.05). Cracking of the surgical guides was observed in 9 of 15 guides in the Hospital IUSS group, 7 of 15 in the Hospital TTSS group, and in 1 of 15 guides in the Dental Office IUSS group. However, no complete through and through fractures occurred in any of the surgical guides and no other physical changes were observed.

Conclusions:

There was an insignificant difference in distortion after various methods of steam autoclaving indicating that steam autoclaving is unlikely to affect the fit or clinical accuracy of implant placement through the 3D printed surgical guides. Therefore, immediate-use steam autoclaving can be safely used to decontaminate surgical guides if a surgical guide becomes contaminated immediately before or during a surgical procedure. However, depending upon the machine used, there may be a risk of cracking of the surgical guides.
D. INTRODUCTION

D1. Objective of research

This study investigated the dimensional changes of 3D printed, stereolithographic surgical guides resulting from: traditional terminal steam sterilization (TTSS) in an Hospital steam autoclave (121°C for 30 min, 30 min drying), immediate use steam sterilization (IUSS) in a Hospital steam autoclave (135°C for 4 min, 10 min drying) and immediate use steam sterilization (IUSS) in a Dental Office steam autoclave (135°C for 4 min, 10 min drying). The objectives were as follows:

1. To know if there are any differences in the dimensions of 3D printed edentulous surgical guides before and after TTSS or IUSS autoclave protocols.
2. To know if there are differences in the magnitudes of dimensional changes of 3D printed edentulous surgical guides between TTSS and IUSS autoclave protocols
3. To know if there are differences in the magnitudes of dimensional changes of 3D printed edentulous surgical guides between the two autoclaves tested
4. To observe any physical changes in the surgical guides following steam autoclave sterilization
5. To validate a method to digitally quantify surface topography changes of 3D printed surgical guides using optical scanning and surface inspection software.


**D2. Review of available literature**

For over a century, “oral sepsis” and pathogenic oral microorganisms have been linked with disease. Early literature recommended the application of chemical disinfectants directly to the diseased dentition and periodontium, and the heat-based disinfection of dentures by boiling. In the modern dental clinic, guided implant surgery is becoming increasingly common place. To minimize complications, implants are placed with a combination of aseptic/clean and sterile protocols that include preoperative oral disinfection, systemic antimicrobial agents, sterile surgical instruments, optimizing operating room environment, and sterile draping and operating technique. This combination of measures aims to minimize the colonization of the surgical lesion with exogenous and endogenous microorganisms and reduce risk of infections and/or implant failure. Due to the current lack of standardized sterilization protocols for surgical guides in implant dentistry, the dental laboratory-fabricated surgical guides represent a break in the chain of asepsis during dental implant surgery. If a surgical guide is utilized, it should conform to the same standards of asepsis.

The Glossary of Prosthodontic Terms defines a surgical guide as “a guide used to assist in proper surgical placement and angulation of dental implants”. The current Centers for Disease Control and Prevention (CDC) guidelines divide point-of-care medical equipment into three categories based on the classification by Spaulding et al. They are critical, semi-Critical, and non-Critical. Critical items enter normally sterile sites or the vascular system and pose a high risk of surgical site infection if contaminated. Semi-critical devices contact non-intact skin or mucous membranes. Non-critical items only contact intact skin. Based on this classification, the dental implant surgical guide is considered “critical”. Critical surgical instruments are recommended to be sterilized with approved protocols, either steam-based or if heat sensitive,
via ethylene oxide gas or peroxide gas plasma. Cold chemical sterilants such as glutaraldehyde or peracetic acid may also be employed as an alternative.²

Steam autoclaving protocols achieve microbial sterilization as a function of high temperature and time². Two common steam autoclave sterilization protocols are currently active in dentistry. The first is 121°C (249.8°F) for 30 minutes defined as traditional terminal steam sterilization (TTSS), and the second is 135°C (269.6°F) for 4 minutes defined as immediate-use steam sterilization (IUSS)². 3D printed surgical guides are most commonly manufactured from photopolymerized or thermoplastic acrylic resin deposited in layers. Additive manufacturing techniques using photopolymerized resins are known as stereolithography, while techniques utilizing thermoplasticized materials are known as “fused deposition modelling” (FDM)⁹. A survey of 3D printing devices on the market available to dentists and laboratories currently suggests that stereolithography is the most common manufacturing method for 3D printed surgical guides. A limitation of stereolithographic resins is their limited temperature stability in the polymerized state ¹³. Any polymerized acrylic-based surgical guide, whether 3D printed or produced with traditional pouring methods, is generally considered inappropriate for steam sterilization due to the glass-transition temperature (T_g) of methacrylic resins ranging from 85°C-157°C, approximating that of the sterilization temperature ¹¹,¹². Heating of surgical guides to the T_g may initiate changes in physical dimensions, potentially leading to poor fit and compromised implant placement. Indeed, many 3D printed materials are rated to be only dimensionally stable up to 50-60°C by virtue of their T_g.¹²

Despite the several reports in the literature indicating the apparent dimensional stability of surgical guides following steam autoclave, this resistance to distortion is material and manufacturer specific. The potential heat-related distortion of acrylic resin-based surgical guides
has encouraged dentists to opt for low temperature sterilization such as ethylene oxide gas, hydrogen peroxide gas plasma, or chemical disinfectants (“cold sterilization”) \(^8\). Chemical disinfectants are typically the most accessible in the dental office. In a survey performed by Sennhenn-Kirchner et al\(^7\), chlorhexidine and alcohol were the most common dental office chemical disinfectants employed. Neither of these agents provide sterility as recommended for critical surgical equipment according to current CDC healthcare facility disinfection and sterilization guidelines \(^2,4,7\).

The possibility of microbial contamination of acrylic surgical guides has been investigated by several authors.\(^4,7\) Fabricated in the dental laboratory, surgical guides can be inoculated by multiple sources including laboratory personnel, contaminated bench surfaces, stagnant pressure pots, and wet polishing stations \(^4,6,7,13\). Specifically, 3D printed surgical guides can be contaminated during manual post-processing in the dental laboratory to clean excess resin, remove supporting structure, and polish. Estimates suggest that at least two-thirds of all materials received by dental laboratories are contaminated, leading to possible cross infection if adequate disinfection is not performed.\(^7\) Dental acrylic resin-based prostheses have porous and rough surfaces which are not easily decontaminated by chemical disinfectants or running water.\(^6\) Furthermore, bacterial pathogens including Acinetobacter, Micrococcus, Pseudomonas, Moraxella, Klebsiella, Staphylococcus, and Alcaligenes have been demonstrated to contaminate the polishing stations of commercial dental laboratories.\(^13\) Smith et al investigated the microbial load on commercially fabricated and in-house laboratory fabricated acrylic surgical guides.\(^4\) Microbial contamination was found in both groups, with in-house guides yielding significantly higher colony forming units (CFU) during cell culture. These microorganisms are exogenous risks to the surgical site if introduced even by a “clean” acrylic resin surgical guide.\(^4\)
The need for dimensional accuracy of surgical guides has been widely studied in implant dentistry literature\textsuperscript{14-18}. Deviations from the planned implant positions result from the sum of all errors from initial imaging to final implant placement.\textsuperscript{15} These errors can include, but are not limited to: 1) inaccurate data acquisition from distorted impressions or 3D scanning artefacts; 2) dimensional changes in the surgical guide during fabrication; 3) inaccurate seating of the surgical guide during surgery; 4) poor fit of components and instruments to the guide; and 5) surgical errors\textsuperscript{14-18}. Verhamme et al\textsuperscript{15} investigated the clinical accuracy of fully-guided implant placement in edentulous maxillary arches compared to the computer-aided virtual plan. Mean translational inaccuracies of 2-4mm and mean rotational inaccuracies of 1-2 degrees in the positioning of the surgical guide were found. These errors were correlated with statistically and clinically significant deviations in implant angulation, depth, and positioning. In contrast, an analysis by Cassetta et al\textsuperscript{17,18} investigating the effect of guide malpositioning on implant placement accuracy found no significant errors with implant angulation and significant translational errors of only <0.5mm. Regardless of the magnitude of the errors observed in previous studies, it can be concluded that inaccurate guide positioning does frequently occur and can contribute to the total positioning error in dental implant surgery. It follows that distortions of the surgical guide introduced by its manufacturing or preparation for surgery could interfere with its seating intraorally, thus resulting in inaccuracies.

The effects of the steam autoclave on 3D printed specimens has been reported by 4 groups at the time of this review. Torok et al\textsuperscript{19} fabricated tooth-borne surgical guides using a poly-jet type 3D printer. The guides were subjected to either chemical disinfection, gas plasma sterilization, TTSS autoclaving at 121°C for 20 min, or IUSS steam autoclaving at 134°C for 10 mins. Optical surface scanning was used to make selected point-point measurements on the
guides before and after disinfection. The samples were further analyzed by scanning electron microscopy and by material properties testing. No significant differences were identified between groups regarding dimensional changes. Shaheen et al used a similar poly-jet printer to produce a representative dental splint, a surgical guide, and a tooth. These samples were subject to either flash steam autoclaving (134°C) or peroxide gas plasma sterilization. Each sample was scanned with Cone Beam Computer Tomography (CBCT) before and after sterilization. Surgical guides and teeth showed a negligible mean dimensional change of up to 0.014 mm. While the full-arch dental splints showed much larger changes, up to 1.7 mm at the most distal extensions, after steam autoclaving. The large distortion rendered the splint clinically unacceptable. Marei et al compared the dimensional accuracy of dental office-fabricated tooth-borne 3D-printed surgical guides with commercially-fabricated 3D-printed guides after steam autoclaving at 121°C for 20 min. The dental office printer utilized stereolithography and photopolymerized resin. Optical scanning before and after sterilization indicated no significant distortions between the axes of the guide sleeves with the mean distortions being all <0.02 mm. Boursier et al examined the effects of steam autoclaving at 121°C for 20.5 min on the width of a 3D-printed feline femur model produced by fused-deposition-modelling (FDM). The linear distortions caused by steam autoclave never exceeded 1% and ranged from -0.07 mm to 0.35 mm.

Presently, no published scientific literature exists specifically addressing the dimensional accuracy of edentulous, 3D-printed surgical guides following disinfection or sterilization procedures. Edentulous maxillary surgical guides are typically mucosa-supported, and thus extend over the entire palate. The effects of steam autoclaving on a surgical guide that encompasses the palate and implants on both sides of the maxillary arch have not been studied. However, the effects of heat-based denture disinfection on the fit and dimensional stability of
acrylic resin denture bases have been extensively studied\textsuperscript{23-25}. Although not constructed of the same photopolymerized methacrylate resin, traditional denture base resins are methacrylate based. Lorton et al\textsuperscript{24} examined the effect of water bath immersion from 70°C-100°C on denture bases. Point-to-point measurements were made across the molar regions of standardized representative dentures. Measurement differences never exceeded 1.5% even in the most extreme conditions tested. Denture base misfits was assessed subjectively and were found to increase in number and magnitude as temperature increased, especially when above 90°C. A poor correlation was found between subjective assessment of misfit and changes in inter-molar distance. Polukoshklo et al\textsuperscript{26} investigated the effect of repeated heat processing at 60°C to 70°C on denture bases via direct point-to-point measurements at standardized positions in the horizontal plane. Measurement differences all were <0.15mm. Seo et al\textsuperscript{25} compared the dimensional changes caused by heat-based microwave disinfection protocols on dry and soaked denture bases, again by horizontal plane, point-to-point direct measurements. Dimensional changes up to 2.3% were recorded in the most extreme disinfection protocol and up to 0.8% in the control group. Regarding the distribution of distortion within denture bases, Kim et al\textsuperscript{27} studied the effect of auto-polymerized and heat processed relines on the posterior palatal seal by measurement of fit-checking silicone. The greatest mean distortions were observed in heat processed relines at the distobuccal flanges and the mid palatal. These results suggest that these are regions of interest in assessing the response of denture bases to heat, and that dentures distort heterogeneously across their surface. Horizontal plane measurements, measuring global changes near the denture borders, may not capture the full three-dimensional, localized nature of distortion. Furthermore, distortions of denture bases in response to polymerization stresses and moderate heat are typically small and subject to measurement error, especially if done manually.
It can also be argued that slight changes in physical dimensions of dentures are likely more clinically significant for denture retention than in the accurate seating of implant surgical guides. However, as the goals for precision increase with guided implant surgery, surgical guide distortion may add significantly to the summation of errors.

Efforts to better appreciate the complex nature of denture distortion have included standardized radiographic tomography, moiré topography analysis, and surface scanning. Artopoulos et al. utilized a computerized contact measurement scanner to generate digital surface models of the intaglio surfaces of denture bases fabricated with different resins and polymerization methods. These surface data were compared via 3D inspection software to determine the location and magnitude of the distortions compared to the master cast. A color map was generated to visually indicate the differences. More recently, Goodacre et al. employed a novel technique of optical surface scanning and surface inspection software in a similar study that compared four methods of maxillary complete denture fabrication. Like Seo et al., statistically significant surface differences were observed at the apex of the denture border and the posterior palatal seal. Discrepancies also presented 6mm from the denture border, at the crest of the ridge, and the palatal vault. Most recently, Norvell et al. employed optical scanning to compare the differences between a master wax pattern and final dentures processed by traditional compression molding and injection molding. Standardized points on the cameo surface and cusp tips were selected for quantitative positional analysis. These studies validate the use of surface scanning and digital surface comparison for investigating the complex nature of denture base distortions.

Based on published literature, it can be concluded that 3D printed surgical guides are becoming increasingly common in the dental implant practice as a means of improving surgical
outcomes and patient satisfaction. Due to their method of fabrication in the dental laboratory, microbial contamination of these appliances has shown to be inevitable⁴,⁶,⁷,¹³. These guides should be treated as critical surgical instrumentation, and thus be subject to accepted sterilization protocols prior to use². Several options exist including chemical disinfectants, steam autoclave, and gas sterilization. Each method has limitations such as processing time required, accessibility to the clinician, and effects on the guide’s accuracy. There are currently few scientific guidelines specifically pertaining to the preparation of 3D printed surgical guides for surgery. Previous studies²³-²⁵ suggest that acrylic resins used for complete dentures can tolerate moderate heating with minimal measurable dimensional changes. No study has compared the effects of different sterilization protocols, including steam autoclaving, on the deformation of 3D printed surgical guides for the edentulous maxilla.
D3. Rationale

Presently, no published scientific literature exists specifically addressing the dimensional accuracy of edentulous maxillary 3D printed surgical guides following disinfection or sterilization procedures. While reports discussing the steam sterilization of 3D-printed surgical guides exist\textsuperscript{19-21}, the existing data are material and manufacturer specific. These reports pertain to surgical guides designed for placement of implants in a partially-dentate single quadrant. Due to the greater dimensions and full palatal coverage of edentulous maxillary surgical guides, different degrees of distortion that may affect the outcome of subsequent implant placement are possible.

Quantifying the effects of common sterilization protocols on surgical guides will provide guidance to the clinician on the best method to select in practice. Chemical disinfectants may require long soak times to achieve adequate disinfection, but will not induce heat related distortion. Steam autoclaving is accessible to all clinicians and rapid, but may lead to larger deformations. Ethylene oxide gas and peroxide gas plasma sterilization are effective and eliminate the risk of temperature distortion, but are expensive, can require exceedingly long processing times and are typically inaccessible to clinicians outside of healthcare institutions. Even when low temperature modalities are available, long processing times preclude them when rapid sterilization is necessary, such as if a surgical guide becomes accidentally contaminated immediately before or during a surgical procedure. Identifying a convenient, effective, and economical means of surgical guide sterilization will advance the standard of care of guided implant surgery.
E. HYPOTHESES

The null hypotheses of this study were as follows:

1) There are no differences in the dimensions of 3D printed surgical guides before and after steam autoclaving with either of the 2 cycles tested (IUSS at 135°C for 4mins, TTSS at 121°C for 30mins)

2) There are no differences in physical dimensions of 3D printed surgical guides between the 2 sterilization cycles tested (IUSS at 135°C for 4mins, TTSS at 121°C for 30mins).

3) There are no differences in physical dimensions of 3D printed surgical guides between the two autoclaves tested (Hospital IUSS at 135°C for 4mins and Dental Office IUSS at 135°C for 4mins).

4) There are no differences in physical changes of 3D printed surgical guides between each tested sterilization (Hospital TTSS at 121°C for 30mins, Hospital IUSS at 135°C for 4mins, Dental Office IUSS at 135°C for 4mins).
F. MATERIALS AND METHODS

Experimental Design Overview

This in-vitro study was conducted at the Division of Post-Graduate Prosthodontics Dental Laboratory at the University of Connecticut School of Dental Medicine. The main experiment involved measuring the surface distortion that occurred in 45 surgical guides which were fabricated through 3D printing technology, after being subjected to one of three sterilization protocols: Hospital TTSS, Hospital IUSS, and Dental Office IUSS. Distortion was assessed by comparing pre- and post-autoclave optical surface scan data of the intaglio surfaces of each surgical guide. Each guide’s pre-autoclave scan served as a control. The primary objective of these analyses was to determine the amount of distortion introduced by each method of sterilization and to compare the distortions induced by each method of sterilization. After sterilization, each sample was visually inspected under 3x optical magnification.

Sample preparation

A surgical guide was digitally designed based on a representative master cast of an edentulous maxilla. The master cast was optically scanned and digitized with a Freedom HD dental laboratory scanner (DOF Labs, Seoul, Korea). This scan data was exported as an STL (standard tessellation language) file. Using commercially available computer-aided design software (Autodesk Meshmixer, San Rafael, CA), an experimental surgical guide was designed to simulate placement of 4 axial implants in the regions of the maxillary 1st molars and maxillary lateral incisors (Figure 1). The surgical guide was representative of a fully-guided implant surgery for the edentulous maxilla. The digital design was exported as an STL file and 45 guides were manufactured on an Asiga Max UV 3D printer (Whip Mix, Louisville, KY). This printer
utilized digital light processing (DLP) to cure ultraviolet-photopolymerizing resin. Guides were manufactured in 50µm layers with clear Veriguide resin (Whip Mix, Louisville, KY) (Figures 2-4). This resin was methacrylate-based and was photopolymerized at 385 nm. After printing, the surgical guides were trimmed of support material and post-processed according to manufacturer’s protocols with 70% ethanol for 10 min and ultraviolet light curing for 10mins (Whip Mix, Louisville, KY) (Figure 4).

**Sterilization protocols**

Three treatment groups were sterilized using the following methods: TTSS at 121°C for 30mins in a Hospital steam autoclave (700HC-E, Getinge, Wayne, NJ), IUSS at 135°C for 4 mins in a Hospital steam autoclave (533HC-E, Getinge, Wayne, NJ), and IUSS at 135°C for 4 mins in a Dental Office steam autoclave (MidMark M11 Steam Sterilizer, MidMark Corporation, Dayton, Ohio). TTSS involved a 30 mins drying time, while IUSS involved a shorter 10 mins drying time.

**Digital inspection of surgical guides**

The intaglio surfaces of surgical guides were optically scanned before and after sterilization with a Freedom HD lab scanner (DOF Labs, Seoul, Korea). Guides were lightly coated with scanning spray (Renfert, Hilzingen, Germany) prior to scanning. STL (standard tessellation language) mesh data were exported and trimmed to the borders of the surgical guides. After scanning, surgical guides were carefully cleaned under cool running water with detergent to remove scanning spray.

**Comparison of surface scan data**
Each pre- and post-treatment .STL mesh file was resampled into point-cloud data using open-source Cloud Compare v2.10 software (EDF R&D, Paris, France) for analysis. The pre- and post-treatment point-clouds were then aligned with the following protocol: initial coarse alignment was completed by manually selecting 4 common points on each surface, then fine alignment was completed using the software’s iterative closest point (ICP) algorithm excluding outlier points. This algorithm repetitiously performed a combination of rotations and translations to the aligned point cloud to minimize the root mean square of the distance between it and the reference point cloud. After alignment, the mean distance and variance between the 2 point clouds were computed on a random selection of 200,000 to 400,000 points. The distances between the pre- and post-treatment data sets were also used to generate a color-map to visually compare the location and magnitude of distortions in the surgical guides.

*Visual inspection of sterilized samples*

After sterilization, each surgical guide was carefully evaluated under magnification for any visible changes. These parameters included gross distortion, color, surface texture, and cracking. All changes were recorded in a descriptive manner.

*Statistical analysis*

The mean and standard deviation of distortion values from a random selection of 200,000 to 400,000 points were calculated per guide. As the number of selected points was large, the uncertainty or variation in guide-specific mean estimates was close to zero. Within groups, the mean distortions of the post-sterilized guides were compared to the controls (no distortion) using one-sample t-tests. The mean distortions and the mean standard deviations among point
distortion estimates between groups were compared using ANOVA F-tests. Pairwise comparisons were subsequently conducted using Tukey’s method.

For sensitivity analysis to the normality assumption, the Kruskal-Wallis test followed by Dunn Tests using the Benjamini-Hochberg method to adjust for multiple testing were completed. All of the statistical analyses were performed with the statistical software R 3.5.1 (The R Foundation, Vienna, Austria). An alpha value of 0.05 was chosen for all statistical analyses.
G. RESULTS

Surgical guide distortion

Hospital TTSS steam autoclaving (121°C for 30 min, 30 min drying) produced a mean surface distortion of 0.0093 mm (range [-0.0070, 0.026], SD=0.029). Hospital IUSS (135°C for 4 min, 30 min drying) produced a mean surface distortion of -0.0089 mm (range [-0.019, 0.0010], SD=0.018). Dental Office IUSS produced a mean surface distortion of -0.0020 mm (range [-0.0067, 0.0026], SD=0.029) (Table 1). The mean distortions were minimal in all three groups and were not statistically significant compared to the controls (p>0.05). The differences in distortion among all groups were also not statistically significant (p=0.059). In pairwise comparison, the 0.018mm difference in distortion between the Hospital TTSS and Hospital IUSS groups reached statistical significance (p=0.049) (Table 2). Differences were not statistically significant between Hospital IUSS and Dental Office IUSS groups (p=0.64) nor Hospital TTSS and Dental Office IUSS groups (p=0.29) (Table 2). The Kruskal-Wallis test (non-parametric alternative to ANOVA) was statistically significant (p=0.033) driven by the difference between Hospital TTSS and Hospital IUSS.

There were also no statistically significant differences between the within-group mean standard deviations of distortions amongst the groups (p=0.12) (Figure 6). No between group pairwise comparisons were statistically significant (p>0.05) (Table 3). The parametric test results were consistent with non-parametric test results (Kruskal-Wallis test p=0.075 and none of the pairwise test results were significant). Although differences in mean standard deviation did not reach statistical significance, a greater amount of outlier distortion measurements were observed in the Hospital autoclave groups, in particular the Hospital TTSS group (Figure 5).
**Color Mapping**

A continuous color scale was assigned to all measured values between -1mm and +1mm away from the reference surface. Positive distortions above the reference surface were identified red, and negative distortions below the reference surface were identified blue. Zero distortion was identified as green. Areas with hues that tended towards red or blue were more affected by distortion. Corresponding histograms were generated to identify the distribution and relative frequency of values. The color mapping analyses showed that the majority of distortions occurred in the distal-buccal flange area when present. The remainder of the intaglio surface including anterior flange, crest of ridge, palate, and post-dam area appear better adapted (Figures 8-9). Even in the areas of greatest distortions, measurements did not exceed ±0.25mm (Figure 8-9) as indicated by the color scale and histograms.

**Visual inspection of surgical guides**

Cracking of the surgical guides was observed in 7 of 15 guides in the Hospital TTSS group, 9 of 15 guides in the Hospital IUSS group, and in 1 of 15 guides in the Dental Office IUSS group. This cracking ranged from minor, isolated crazing not extending through the full thickness of the material to a fine, reticular pattern of cracks extending through the full thickness through the guide material. Cracks were located primarily in the continuous areas of the palate and the flanges (Figure 10-11). No cracking through the drill sleeve areas was observed. Also, no surgical guide fully fractured during this experiment. No other physical changes were observed.
H. DISCUSSION

Maintaining asepsis within the surgical field is paramount to minimizing complications in dental implant surgery. Previous literature has asserted the presence of microbial contamination on surgical guides fabricated in the dental laboratory. There is no existing literature pertaining to the dimensional changes of 3D printed edentulous maxillary surgical guides after various sterilization protocols. This absence of literature has led to a lack of consensus regarding the preferred method of decontaminating surgical guides prior to surgery. Related studies in acrylic denture bases, suggest that heat-induced distortion is a concern, especially as temperatures rise above 90°C. Studies investigating the effects of polymerization stresses on dentures have also established exquisitely sensitive methods of characterizing and quantifying denture base distortion. It was the goal of the present study to combine these methods and observations to investigate the dimensional response of 3D printed surgical guides to sterilization protocols. Terminal sterilization protocols were selected based on current CDC guidelines regarding the sterilization of critical surgical equipment and also what is commonly available to the dental clinician in practice.

The protocol for optical scanning has been discussed by Goodacre et al. The Freedom HD scanner (Degrees of Freedom, Seoul, Korea) operates on the principle of “structured light scanning”. It consists of two 2-megapixel digital cameras and a light emitting diode (LED) light source. It has a reported scanning accuracy of approximately 10μm. Structured light scanning involves projecting a known pattern of light, often parallel bars, on the surface of the object to be scanned. This technology is an evolution of the “moire topography” technique previously used to study the contour of surfaces. The distortion of the pattern by the topography of the surface is recorded by the digital cameras from multiple angles. The
distortions can be subsequently measured, and combined with the known positions and
angulations of the cameras and light sources, be used to triangulate the distance between the
camera and a point on the surface. A “cloud” consisting of millions of points is used to digitally
reconstruct a 3D surface model.29 The surface model is subsequently exported as an STL file.

Although optical scanning is extremely sensitive, the scanner relies on cameras being
able to visualize patterns projected on the object to be scanned. Challenges arise with objects that
are reflective, transparent, or undercut. Reflections and transparency were mitigated with an
opaquing spray. Undercuts require repositioning of the object to allow adequate visualization by
the scanner’s cameras. The surgical guides being investigated in this study posed all three of
these challenges to the scanning process.

In this experiment, autoclaving induced minimal mean distortions to 3D-printed surgical
guides ranging from -0.019 mm to 0.026 mm. None of the experimental groups distorted in a
statistically significant manner compared to controls prior to autoclaving. Therefore, the null
hypothesis that steam autoclaving produced no significant distortions was unable to be rejected.
For a mucosa-supported guide as designed for this experiment, this degree of distortion observed
would likely be clinically insignificant due to the resilience of the oral tissues. As described by
Hanau, the oral mucosa is compressible and exhibits a “resilient and like effect” that would
compensate for minor degrees of surgical guide misfit.33 It is possible however that distortions
would be clinically relevant for a tooth-supported guide resting solely on the dentition. This data
suggests that edentulous 3D printed guides can be safely autoclaved without significantly
altering their fit or accuracy.

In comparing the TTSS and IUSS autoclave protocols in the Hospital autoclave, a
statistically significant difference of 0.018mm of mean distortion was found (p=0.049). This
difference represents a difference in the direction of distortion between the two groups. The TTSS group distorted +0.0093mm “above” the control group (range [-0.0070, 0.026], SD=0.029) and the IUSS group distorted -0.0088mm “below” the control group (range [-0.019, 0.0010], SD=0.018). In the context of generating misfit, the absolute values of distortion should be considered. Therefore, the distortions of these two groups should be considered equivalent. This finding suggests that the shorter, higher temperature autoclave cycle is not more detrimental to surgical guide dimensional stability compared to the longer, lower temperature cycle. Thus, the null hypotheses that there are no differences in degree of distortion between the two sterilization cycles and the two tested autoclaves was unable to be rejected.

Although there were no statistically significant differences in the mean standard deviations of distortion within each group, a greater presence of outlier data in the samples of the Hospital autoclave was observed compared to the Dental Office autoclave group (Figure 5). Furthermore, the presence of cracking was markedly greater in the Hospital autoclave groups (53%) compared to the Dental Office autoclave group (7%). Thus, the null hypothesis that there were no differences in physical changes between the experimental groups was rejected. A similar frequency of cracking was observed in both the higher and lower temperature groups using the Hospital autoclave. Two explanations could account for this observation. Firstly, locally higher temperatures may exist within regions of large-scale Hospital autoclave chamber during the cycle. These higher temperatures could account for the increased distortion and cracking observed in the Hospital autoclave group. Positioning of the individual guides at different locations in the autoclave chamber could have exposed them to unpredictably greater temperatures, and thus also account for the considerably greater number of outliers observed with this group (Figure 5). A second explanation could be an uncontrolled, extended drying cycle
in the Hospital autoclave. Following the high-temperature phase of the TTSS autoclave program, a drying cycle of 30 min begins to ensure that contents are dry and remain uncontaminated upon removal from the autoclave. IUSS uses an abbreviated 10 min drying cycle. Dental office, desktop autoclaves are typically designed for intermittent use. Their heating and cooling are relatively rapid, with the unit returning to room temperature shortly after the drying cycle is complete. Conversely, large hospital autoclaves with their long initial heating time maintain a standby temperature of 71°C, even after drying is complete. In a healthcare institution that relies on a centralized sterilization facility, the amount of time that instruments are left at the standby temperature could be variable. It is conceivable that this extended time at temperatures near the glass-transition temperature of the acrylic resin surgical guides could have caused the increase in outlier distortions and cracking compared to the Dental Office unit. Despite these factors, however, distortions were still minimal, with no significant differences in mean distortions between the Hospital TTSS, Hospital IUSS, and Dental Office IUSS groups.

The small magnitude of the distortions induced by autoclaving in this experiment agree with the findings of recent studies on 3D-printed specimens. While Shaheen et al20 tested a cross-arch dental splint and observed unacceptably large distortions, such large distortions that would affect the clinical performance of the surgical guides were not observed in this study. It is possible that the bulk of the palatal coverage serves to bolster the posterior aspect of the surgical guide to prevent distortion. This finding, combined with the greatest distortion being observed in the distal-buccal flanges could indicate an increased risk of clinically significant distortions in maxillary guides lacking palatal coverage, complete-arch edentulous mandibular surgical guides, and cross-arch tooth-supported guides.
On visual inspection, cracking was the only finding observed. This finding has not been reported by other authors. Cracks were most prevalent in the continuous areas of the surgical guides, namely the buccal and facial flanges and the palate. Few cracks involved the discontinuity areas where drill sleeves would be located. While no cracks caused total fracture of the surgical guides during handling, it is possible that fractures could occur in clinical use, rendering the surgical guide inoperable. This risk of total fracture would be greater in a guide lacking palatal coverage such as an edentulous mandibular guide or a tooth supported guide. This finding has important clinical relevance.

The applicability of the results of this study is limited by several factors: the specific model of autoclaves used, the specific properties of the 3D printing resin used, and the design of the surgical guides lacking cemented metal drill sleeves. The autoclaves selected for this investigation are representative of a hospital and a dental office autoclave, however results may differ with different autoclaves and autoclave loading protocols. It is also possible that the orientation and neighboring contents of the surgical guides during the sterilization cycle could affect distortion. Heat-related distortion is also specific to the 3D printing resin used in this study. Results may not be generalizable to other light-cured resins nor to surgical guides fabricated through other modes of 3D printing. Lastly, the surgical guides used for this study lacked cemented metal guide sleeves. While no major distortions or physical changes were observed, it is unknown whether steam autoclaving adversely affects guide sleeve retention.

The findings of this investigation suggest that edentulous maxillary surgical guides produced by stereolithography can be autoclaved with little to no distortion. Use of a Dental Office autoclave capable of a IUSS is standard practice to all dental clinicians. The finding that IUSS cycle at 135°C for 4 min does not produce significant distortion to surgical guides is
relevant to the clinician, as it allows a surgical guide to be rapidly sterilized should it become accidentally contaminated before, or during the surgical procedure. Cracking occurred in only 1 of the 15 guides autoclaved by IUSS in the Dental Office unit. While low temperature methods of sterilization such as ethylene oxide gas and peroxide gas plasma are still preferable to steam autoclaving to completely eliminate the risk of heat-induced changes, these technologies remain unavailable to the majority of dentists in private practice.
I. CONCLUSIONS

Within the limitations of the study, the following conclusions were drawn:

1. Steam autoclaving, whether TTSS or IUSS did not induce statistically significant distortions to 3D-printed edentulous maxillary surgical guides.

2. There was no statistically significant difference in distortions caused by TTSS or IUSS protocols in a hospital autoclave.

3. There was no statistically significant difference in distortion whether IUSS is conducted in a hospital or dental-office autoclave indicating that IUSS can be safely used to decontaminate surgical guides if a surgical guide becomes contaminated immediately before or during a surgical procedure.

4. An increase in cracking was observed in surgical guides sterilized in the hospital autoclave compared to the dental-office autoclave. Cracking was mild to moderate in all cases and may not have compromised use of the surgical guide.

5. Optical surface scanning and surface inspection software are a viable means of analyzing the distortion induced by heat sterilization of surgical guides.
J. REFERENCES


12. Stereolithography Materials | SLA Material Properties:


K. Tables

Table 1:

Mean distortion and mean within-guide standard deviation for Hospital TTSS, Hospital IUSS, and Dental Office IUSS.

<table>
<thead>
<tr>
<th></th>
<th>Mean Distortion (mm)</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Mean within-guide SD (mm)</th>
<th>Lower limit</th>
<th>Upper limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital TTSS</td>
<td>0.0093</td>
<td>-0.0069</td>
<td>0.026</td>
<td>0.097</td>
<td>0.079</td>
<td>0.12</td>
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<tr>
<td>Hospital IUSS</td>
<td>-0.0088</td>
<td>-0.019</td>
<td>0.0010</td>
<td>0.12</td>
<td>0.098</td>
<td>0.14</td>
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<tr>
<td>Dental Office IUSS</td>
<td>-0.0020</td>
<td>0.0067</td>
<td>0.0026</td>
<td>0.119</td>
<td>0.10</td>
<td>0.14</td>
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Table 2:

Pairwise comparison of mean distortions between groups. (p<0.05). * represents statistical significance.

<table>
<thead>
<tr>
<th></th>
<th>Difference</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital IUSS/Dental Office IUSS</td>
<td>-0.007</td>
<td>-0.025</td>
<td>0.011</td>
<td>0.637</td>
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<td>Hospital TTSS/Dental Office IUSS</td>
<td>0.011</td>
<td>-0.007</td>
<td>0.029</td>
<td>0.290</td>
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<tr>
<td>Hospital TTSS/Hospital IUSS</td>
<td>0.018*</td>
<td>0.000</td>
<td>0.036</td>
<td>0.049</td>
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</table>

Table 3:
Pairwise comparison of mean standard deviations between groups.

<table>
<thead>
<tr>
<th></th>
<th>Difference</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital IUSS/Dental Office IUSS</td>
<td>0.002</td>
<td>-0.028</td>
<td>0.032</td>
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<td>Hospital TTSS/Dental Office IUSS</td>
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<td>-0.052</td>
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<td>0.202</td>
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<tr>
<td>Hospital TTSS/Hospital IUSS</td>
<td>-0.023</td>
<td>-0.054</td>
<td>0.007</td>
<td>0.155</td>
</tr>
</tbody>
</table>
I. Figures

Figure 1:

Digital design of experimental surgical guides based on a maxillary denture
Figure 2:
Digital nesting of individual surgical guide .STL parts prior to 3D printing
Figure 3:
3D printed surgical guide prior to removal from printer build platform, cleaning, and final curing.
Figure 4:
Intaglio surface of a 3D printed surgical guide prior to autoclave treatment.
Figure 5:

Mean distortions for Dental Office IUSS, Hospital IUSS, and Hospital TTSS groups.
Figure 6:

Mean within-guide standard deviations for Dental Office IUSS, Hospital IUSS, and Hospital TTSS groups.
Figure 7:

Color mapping indicating minimal distortions present. Green areas tend towards 0mm distortion. Color scale: -1.00mm to +1.00mm. Histogram indicating relative frequency and distribution of distortion values is indicated to the right of the scale.
Figure 8:

Color maps indicating negative direction distortion (blue) at the distobuccal flange areas. Green areas tend towards 0mm distortion. Color scale: -1.00mm (blue) to +1.00mm (red). Histogram indicating relative frequency and distribution of distortion values is indicated to the right of the scale.
Figure 9:

Color mapping indicating positive direction distortion (yellow) at the distobuccal flange areas. Green areas tend towards 0mm distortion. Color scale: -1.00mm (blue) to +1.00mm (red). Histogram indicating relative frequency and distribution of distortion values is indicated to the right of the scale.
Figure 10:
Cracks extending across the palate with minimal involvement of the drill sleeve areas.
Figure 11:

Fine reticular cracks involving contiguous areas of the buccal flanges.