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C.E. Credit. Effect of Steam Sterilization on Accuracy of 3D Printed Implant Surgical Guides: A Pilot Study

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ABSTRACT

Background: 3D printed implant surgical guides are designed to improve implant placement accuracy. However, they are a potential source of contamination during implant surgery and therefore require sterilization to prevent post-surgical infection. This study evaluated the effect that steam sterilizing 3D printed implant surgical guides has on the accuracy of fully guided implant placement.

Methods: 3D printed models were prepared with an edentulous site at the right maxillary central incisor. A surgical guide was designed and fabricated to place a bone level implant at this edentulous site. Ten implants were placed with surgical guides, followed by ten placed with the same guides after autoclave sterilization at 134°C for 6 minutes. Implants were scanned and analyzed using three-dimensional analysis software. The implant platform position, apex position, and angulation were evaluated before and after sterilization of the surgical guides.

Results: There were statistically significant deviations of implant platform and apex in the x-axis (buccolingual), y-axis (mesio-distal), and implant angulation (Wilcoxon signed-rank test, $p < .05$). There was no statistically significant deviation in the occluso-gingival height of the implant.

Conclusions: Steam sterilization has a statistically significant effect on the accuracy of fully guided implant placement using 3D printed surgical guides. The buccolingual deviation of the implant apex is clinically significant (mean = 1.22 mm).

Practical Implications: Dentists should exercise caution when using steam heat (i.e. autoclaving) to sterilize 3D printed implant surgical guides. Alternative options such as cold sterilization may be more appropriate.

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Introduction

Dental implants are an increasingly popular method of restoring function and esthetics for patients with missing dentition.[1] Many variables affect the success of implant surgery and restoration including skill level of the clinician, the use of prosthetic-driven implant planning, depth and angulation of the implant in bone, and type of surgical guide used.[2–4] Inaccuracy is defined as the discrepancy between the planned and final positions of an implant intraorally. While freehand placement can certainly be successful, utilizing custom computer-aided design/computer-aided manufacturing (CAD/CAM) surgical guides improves implant placement accuracy.[5–8] This holds true even for experienced clinicians.[9,10] Increasingly accessible software allows clinicians to incorporate data from a cone beam computed tomography (CBCT) scan and intraoral scan into the implant planning process.[11] In recent years, 3D printing has emerged as a fast and low-cost method of fabricating surgical guides. Several studies have analyzed the accuracy of these guides and found it comparable to that of guides prepared using traditional techniques.[2,4,6]

Despite their widespread use, there is no universally accepted best practice for sterilizing 3D printed implant surgical guides. The European Union classified surgical guides as class I "non-critical items" until the 2021 enaction of the Medical Device Regulation reclassified "all surgically invasive devices intended for transient use" as class IIa, requiring heat sterilization.[12,13] The American Dental Association considers any item which penetrates soft tissue or bone to be a critical item, necessitating heat sterilization. While flapless surgery is often facilitated by surgical guides, more extensive surgeries or unforeseen complications often require a flap to be placed for visualization.[12] In this case, the surgical guide is a critical item, making steam sterilization most appropriate.[14] The process of

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steam sterilization by autoclaving has the potential to distort surgical guides, resulting in inaccurate implant placement.[14]

A considerable breadth of literature covers changes to the mechanical properties of surgical guides, such as flexural strength and modulus of elasticity, after sterilization.[15,16] Notably, stereolithography-based surgical guides became brittle after steam sterilization, increasing risk of fracture during use.[15] However, only a few recent studies have quantified the distortion of surgical guides and the resulting change in implant placement accuracy due to steam sterilization. Several of these studies found statistically significant changes in linear dimensions.[17,18] However, the statistical significance of these results does not necessarily translate into clinical significance in the accuracy of implant placement. One study found no significant volumetric change but did find morphological deformity of stereolithography-based surgical guides after steam sterilization.[19] Other studies found no statistically significant effect on the dimensions of surgical guides sterilized with steam heat.[20,21] While the results of these studies vary, they all note that further research should be undertaken with larger samples sizes exploring different types of sterilization and various materials.

Both the accuracy of implant placement and the sterility of surgical procedures are of critical importance to clinicians.[22,23] This study aimed to contribute to the ongoing investigation into the effect of steam sterilization on the accuracy of fully guided implant placement using 3D printed surgical guides. This was accomplished by placing implants into models using 3D printed surgical guides, sterilizing the surgical guides, placing additional implants in new models with the same guides, and accurately comparing the positions of the pairs of implants. The null hypothesis adopted is that steam sterilization of 3D printed surgical guides will result in no statistically significant deviation in implant platform position, apex position, or angulation.

Materials and Methods

Fabrication of Typodont Models

The Institutional Review Board of Loma Linda University determined that this study does not meet the definitions of human subject research (IRB #5220366). Figure 1 provides a graphical representation of the study design. The right maxillary central incisor was removed from a Frasaco ANA-4 V typodont (Frasaco, Greenville, NC, USA). The socket was filled flush to the surrounding gingiva with wax and the typodont was scanned with a 3Shape Trios 3 intraoral scanner. This scan was imported to Autodesk® Meshmixer software (Autodesk, San Rafael, CA, USA) and digitally trimmed to include teeth #5–12. The area of the edentulous site was lowered by 1.5 mm to simulate reflection of a full thickness gingival flap. A consumer-grade high-resolution resin 3D printer, the Phrozen Sonic Mini 4K (Phrozen, Hsinchu City, Taiwan), was used to print 21 identical models with Phrozen Aqua 4K resin. These models were rinsed with isopropyl alcohol for 10 minutes and cured under ultraviolet light on a rotating platform for 15 minutes, as directed by the resin manufacturer.

Design and Fabrication of Surgical Guide

One copy of a NobelReplace® 4.3 × 13 mm tapered conical connection implant (Nobel Biocare, Kloten, Switzerland) was placed in the edentulous site, following the implant manufacturer's guidelines for freehand placement.[24] The implant was placed 1 mm supracrestal to improve scan resolution in the implant platform area. A scan body was attached to this model, and it was scanned using the TRIOS 3 intraoral scanner. Using Nobel DTX Studio™ Implant software (Nobel Biocare, Kloten, Switzerland), a surgical guide was designed to replicate the placement of this master implant. It has been shown that support from two adjacent teeth on either side of a single edentulous site provides stability equal to a full-arch guide.[25]

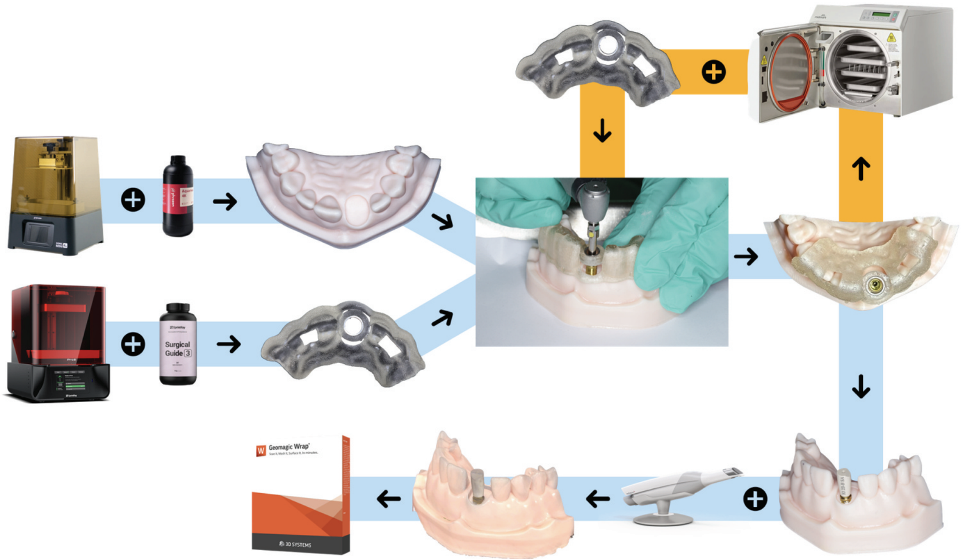

Figure 1. Flowchart of experimental design illustrating 3D printing of typodont models and surgical guides, placement of implants, sterilization of surgical guides, scanning of implant with scan body attached, and 3D analysis of scans. Orange pathway indicates sterilization of the surgical guides prior to reusing them to place a second set of implants.

Therefore, the surgical guide covered teeth #6–10. Twenty copies of this surgical guide were printed using a SprintRay Pro 95 dental resin 3D printer and SprintRay Surgical Guide 3 resin (SprintRay, Los Angeles, CA). These surgical guides were post-processed as directed by the resin manufacturer and metal sleeves were luted in place using cyanoacrylate glue.[26]

Implant Placement and Surgical Guide Sterilization

An experienced clinician (>100 implants placed) used 10 copies of the surgical guide to place 10 NobelReplace® 4.3 × 13 mm tapered conical connection implants into individual typodont models. The NobelReplace® Procedures Manual was followed. Compressed air was used to keep the implant site clear of debris during the sequential drilling process. These 10 surgical guides were sterilized in a Midmark M11® tabletop autoclave (Midmark, Dayton, OH) at 134°C for 6 minutes as directed by the surgical guide resin manufacturer.[26] Care was taken to avoid any forces on the surgical guides during or immediately after sterilization to avoid introducing distortion. Ten new implants were placed in new models using the same surgical guides after sterilization. A scan body was attached to each implant and the models were scanned with the TRIOS 3 intraoral scanner (3Shape, Copenhagen, Denmark).

Scan Interpretation

The scans of all 20 implants placed were imported to 3D Systems Geomagic Wrap® three-dimensional analysis software (3D Systems, Morrisville, NC) to compare each pair of implants placed before and after sterilization of the surgical guide. Axes were assigned to the long axis of the implant, the top of the scan body, and the flat back of the model. The models were then aligned, and a scan of a dummy implant attached to a scan body was superimposed on the model. The three-dimensional coordinates of the implant platform center, implant apex, and the implant angulation were recorded. Figure 2 provides several illustrations of this process. The linear distances between each pair of implants (placed before and after sterilization of the surgical guide) were calculated for each axis: bucco-lingual (BL), mesio-distal (MD), and occluso-gingival (OG).

Statistical Analysis

Given the small sample size of this study, the Wilcoxon signed-rank test was used to determine if the linear and angulation deviations were statistically significant. The angulation of each implant placed after sterilization of the surgical guide was recorded and compared to the angulation

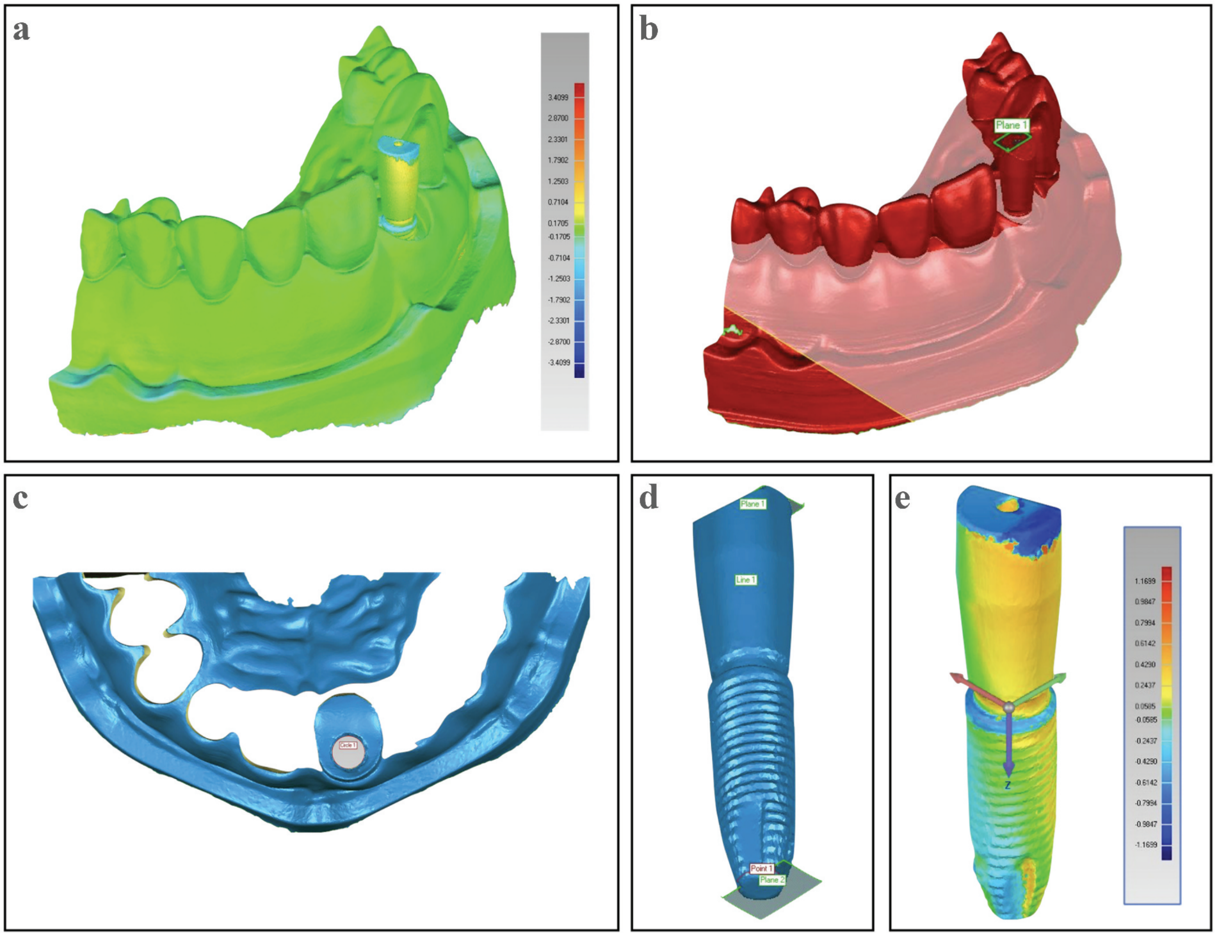

Figure 2. 3D analysis using Geomagic wrap software. 2(a). Heat map showing dimensional differences for models with implants placed before and after sterilization of surgical guide. 2(b). Slicing model using plane parallel with implant platform. 2(c). Determining implant platform center. 2(d). Determining implant apex. 2(e). Heat map showing differences in implant position before and after sterilization of surgical guide.

of each implant placed before sterilization of the corresponding surgical guide. Jamovi statistical software (Jamovi, Sydney, Australia) was used to compute all statistical measures.

Results

Implant Platform

Analysis shows a statistically significant mean deviation of the center of the implant platform after surgical guide sterilization of 0.578 mm in the X-axis (BL)($p = .006$, Wilcoxon signed-rank test) and 0.169 mm in the Y-axis (MD)($p = .037$, Wilcoxon signed-rank test).

Implant Apex

For the implant apex, statistically significant mean differences of 1.22 mm in the X-axis (BL)($p = .01$, Wilcoxon signed-rank test) and 0.458 mm in the Y-axis (MD)($p = .006$, Wilcoxon signed-rank test) were found.

Implant Depth

No statistically significant deviation was found in the Z-axis (OG). The mean deviation was 0.0934 mm ($p = .232$, Wilcoxon signed-rank test).

Implant Angulation

A statistically significant mean deviation of 3.57 degrees in the long axis of the implant was found ($p = .002$, Wilcoxon signed-rank test).

Figure 3. shows deviation in millimeters for the implant platform and apex in all three dimensions. Each diamond represents the difference between one pair of implants (one placed before sterilization of the surgical guide and one after).

Table 1. Statistical analysis of implant platform, apex, and angulation deviation. Statistically significant deviations are highlighted in green.

Axis	Mean Deviation	*p*-value
Platform X (BL)	−0.578 mm	.006
Platform Y (MD)	−0.169 mm	.037
Platform Z (OG)	−0.0861 mm	.375
Apex X (BL)	−1.22 mm	.01
Apex Y (MD)	−0.458 mm	.006
Apex Z (OG)	−0.0934 mm	.232
Angulation	3.57 degrees	.002

Table 1 summarizes the mean linear and angulation deviations, with statistically significant values highlighted in green.

Discussion

3D printed implant surgical guides offer a convenient and affordable way to increase the accuracy of implant placement. However, they are a potential source of contamination during implant surgery and should be sterilized to avoid post-surgical infection or delayed osseointegration.[23] Many clinicians already have access to autoclaves, making steam heat sterilization a natural choice. In addition, the manufacturers of many resins marketed for use in surgical guide fabrication claim that steam heat sterilization will not affect the physical properties of their product.[26,27] This aim of this study was to design an accurate and fully replicable *in vitro* experimental process which mimics the clinical scenario as closely as possible.

Based on the results of this study, the null hypothesis was rejected. There was a statistically significant deviation in the position of implants placed after steam sterilization of the surgical guides. While both MD and BL deviations were statistically significant, the largest and most clinically relevant deviation was in the buccolingual axis of the implant apex. Implant surgeries are often carefully planned to avoid anatomical features such as the inferior alveolar nerve and the maxillary sinus. While a safety factor of 2 mm from these structures is commonly advised, an additional deviation of 1.22 mm (the mean deviation found in

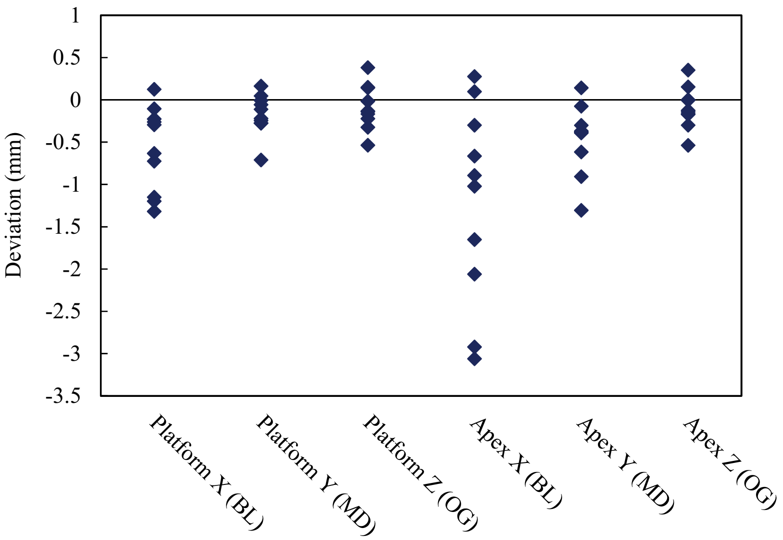

Figure 3. Linear deviations of implant platform and apex in three axes. Each diamond represents the linear difference between one pair of implants (one placed before sterilization of the surgical guide and one after).

this study) of the apex could result in anatomical impingement when combined with factors affecting accuracy such as errors in scanning, implant planning, and operator experience.[2,6]

Several studies have examined the mechanical and dimensional changes that surgical guides undergo during steam sterilization, with conflicting results. However, to the authors' knowledge no study has directly analyzed how implant position is affected by this process. It is important to note that deformation of the surgical guide does not necessarily correlate with deviation of the implant position. Likewise, implant deviation after steam sterilization could result from several variables including changes to the surface of the surgical guide which affect guide fit, increases in stiffness making complete seating more difficult, and alteration of the interface between the guide and metal sleeve. Also, if the metal sleeve is luted in place before sterilization, it is possible this bond could be altered by the process of steam sterilization.

The findings of this study support the conclusion of many other studies: that further research into the benefits and hazards of various methods for sterilization of 3D printed surgical guides is necessary.[18,19,21] Cold sterilization with antimicrobial solutions such as chlorhexidine, ethylene oxide sterilization, and various steam sterilization cycles should be investigated. Different resin formulations should also be tested. Larger sample sizes are needed to validate the statistical significance of the observed deviations in implant position. Analyzing the deformation of the surgical guides in conjunction with the deviation in implant placement after sterilization would offer greater insight into the relationship between sterilization, surgical guide dimensional change, and the resulting implant position. Adding an analysis of intra-operator error would also further elucidate the causes of implant deviation. Exploring these factors further will aid clinicians in selecting an appropriate sterilization technique which maximizes accuracy of implant placement while minimizing surgical contamination.

Conclusion

Within the limitations of this study, the results show that steam sterilization has a statistically significant effect on the accuracy of 3D printed implant surgical guides. This is especially apparent in the deviation of the implant apex in the bucco-lingual axis (mean = 1.22 mm).

Disclosure Statement

No potential conflict of interest was reported by the author(s).

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