RESEARCH ARTICLE


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Abstract:

Background: Computer-guided surgical templates are considered critical instruments and are proposed to be sterilized before surgery. However, steam heat sterilization process may result in volumetric changes in the acrylic resin materials and this may compromise the accuracy of the drilling process during surgery.

Objective: The aim of this in vitro study was to investigate the effect of steam heat sterilization on the volumetric and morphological dimensions of 3D printed surgical guides that could affect the accuracy of guided implant surgery.

Methods: A total of fifteen templates of the same size and shape were printed from three different resin materials (five templates from each material) based on digital data of a clinical case previously planned with a special implant planning software. Following the printing procedure, all templates were digitally scanned using an intraoral scanner before and after steam heat sterilization at 121°C for 20 minutes. The scan data were saved in STL files and volumetric and morphological changes were evaluated before and after sterilization process by using appropriate software.

Results: The results showed dimensional alterations within the three tested materials, before and after the sterilization process. Mean percentage of volumetric change was -1.53% for Visijet, 0.50% for MED610 and 1.9% for eResin. A larger deformation of the surgical guides at the sleeve and buccal wire areas was also observed.

Conclusion: We can conclude that low steam heat sterilization seems to affect differently the three investigated implant template materials. Visijet and eResin showed a significant difference between the initial and the final volume of the surgical guides. This could possibly decrease the accuracy of computer guided surgery.

Keywords: Computer guided implant surgery, 3D printing, Steam heat sterilization, Surgical templates, Volumetric stability.

1. INTRODUCTION

Computer-guided implant placement is a rapidly grown method for an accurate implant placement among dental practitioners [1, 2]. The implants are placed with the aid of a surgical template, designed digitally through an appropriate planning software and produced by 3D printing of acrylic resin. Accuracy in guided implantology is particularly important for the success of the surgical procedure [2, 3]. Among several parameters that may affect the accuracy, the disinfection-sterilization method of the surgical template has been examined in recent studies [4 - 7].

Based on the current guidelines from the Center for Disease Control and Prevention (CDC), dental implant surgical templates are considered “semi-critical” devices, as in most cases, they fit only on teeth or mucosa in case the implant surgery is performed flapless [8]. However, there are cases in which the template comes in contact directly with alveolar...
bone, as well as with bone grafts or barrier membranes which are used during the operation. In such cases, the surgical templates could be considered as “critical devices” since they enter sterile sites and pose a higher risk of surgical site contamination [7 - 10]. In both scenarios, the templates are recommended to be sterilized with approved protocols, such as steam heat, ethylene oxide gas and peroxide gas plasma [7, 8, 11 - 13]. Steam heat is considered the most common sterilization method used for dental instruments since autoclave is a standard equipment in all dental offices. Two common steam autoclave sterilization protocols are currently available in dentistry. The first is 121°C for 20-30 minutes, defined as low heat steam sterilization, and the second is 135°C for 4 minutes, defined as high heat steam sterilization [8, 10, 12].

3D-printed surgical guides are usually made of photopolymerized or thermoplastic acrylic resin applied in layers [7, 14]. Additive manufacturing techniques that use photopolymerized resins are known as stereolithography (SLA), while techniques that use thermoplastic resins are known as “fused deposition modeling (FDM) [7, 15]. Recent studies of 3D printing equipment available to dentists and laboratories indicate that stereolithography is currently the most common manufacturing technique for 3D-printed surgical guides [16, 17]. A limitation of SLA is its limited temperature stability in the polymerized state [7, 16]. Any photopolymerized acrylic-based surgical guide, whether 3D-printed or manufactured by conventional casting methods, is generally considered unsuitable for steam sterilization because the glass transition temperature of methacrylic resins ranges from 85 °C to 157 °C, which is approximately the sterilization temperature [7, 18]. Heating of surgical templates can lead to a change in physical dimensions, possibly resulting in a poor fit and subsequently impaired implant placement [7, 9, 10, 13].

The purpose of this in vitro study was to examine the effect of steam heat sterilization on the volumetric and morphological dimensions of 3D printed surgical guides that could affect the accuracy of guided implant surgery. Thus, the null hypothesis was the mean volumes of the surgical templates that did not differ before and after the sterilization process within or between the three tested materials.

2. METHODS

The study was conducted at the Department of Dentoalveolar Surgery, Implantology & Radiology of Aristotle University of Thessaloniki, Greece. The digital data from a single clinical case previously planned was used to prepare a series of identical surgical guides. The digital implant planning was performed on a special software MSOFT64 2.15.0 (MIS Implants Technologies, Bar lev, Israel). The planned template was full-arched tooth-supported and had three implant positions (#36, #37, #46) (Fig. 1).

![Study flow-chart](image)

Fig. (1). Study flow-chart.
A total of fifteen templates were printed with three different resin materials (five templates from each material). The first material was VisiJet M2R-CL (3D System Inc., Rock Hill, South Carolina) which is a USP (United States Pharmacopeia) Class VI certified resin material with ISO 10993 biocompatibility, dedicated for medical applications. The second material was MED610, which is a transparent, biocompatible PolyJet™ material medically approved for body contact. This material is designed for both medical and dental applications and is approved for permanent skin contact (more than 30 days) and limited mucosal membrane contact (up to 24 hours). The third template material was the SG100 Surgical Guide e-Resin (Shenzhen eSUN Industrial Co., Ltd.) which is a dental resin material suitable for printing implant templates. All templates were printed by ProJet® 3510 DPPro3D printer (3D Systems, Rock Hill, South Carolina, USA) with SLA method.

Following the printing procedure, digital impressions of the templates were taken by using an intraoral scanner (TRIOS 3, 3Shape, Copenhagen, Denmark), with the same methodology for all cases, according to the company’s instructions for use. All templates were scanned again with the same protocol after the sterilization process. The scan data were exported as a standard tessellation language (STL) file.

The sterilization process included placement of the templates into separate self-adhesive sterilization pouches (Eurosteril®, Euronda SpA, Vicenza, Italy) and they were all sterilized into an autoclave water steam sterilizer (Domina Plus B, DENTAL X S.p.A., Dueville, Italy) simultaneously. The sterilization built-in parameters, which were by default set by the manufacturer to warranty effective sterilization and proper loading conditions were 121°C for 20 minutes of three pre-vacuum pulses and 11 minutes of drying (7 minutes vacuum and 4 minutes of ventilation). The efficiency of the sterilization process was checked by using special steam sterilization strips (Sterilization control strips complying with ISO 11140-1, Bastos Viegas, Portugal), which were placed into the autoclave chamber.

The volumetric measurement of the templates before and after the sterilization process was saved in STL files with Rhino 6 SR22 Software. Moreover, colored visualization of the volumetric changes was done using CloudCompare (Version 2.10.2).

Statistical analysis was performed with IBM SPSS Statistics (Version 25) software. Comparison of mean volume of the templates before and after sterilization process performed separately for all three materials with Wilcoxon test, since data did not follow the normal distribution criterion as indicated by Shapiro-Wilk test. Mean percentages (%) of volumetric change were calculated for all three materials and they were compared by One-Way ANOVA test and Tukey HSD/Tukey Kramer. The level of significance was set at p = 0.05.

![Boxplots of templates volumes (in mm) before (blue) and after (green) sterilization process for Visijet (*P = 0.043), MED610 (**P = 0.225) and eResin (**P = 0.043).](image)
3. RESULTS

The results of the present study showed dimensional differences between the three template materials before and after the steam heat sterilization process (Fig. 2). Templates from Visijet had a constant volumetric decrease, while those from eResin had a constant volumetric increase after sterilization (Figs. 3 and 4). Templates from MED610 had either increase or decrease in volume (Fig. 5). Means of volume before and after sterilization differed significantly in templates from Visijet and eResin (Table 1). Mean percentage of volumetric change was -1.53% for Visijet, 0.50% for MED610 and 1.9% for eResin (Fig. 6). It was found that the mean percentage of volumetric change did not differ significantly between MED610 and eResin, while mean percentage of volumetric change of Visijet differed significantly from the other two materials (Table 2).

![Fig. (3). Volumes of the five surgical templates before and after sterilization process fabricated from Visijet.](image)

![Fig. (4). Volumes of the five surgical templates before and after sterilization process fabricated from eResin.](image)

![Fig. (5). Volumes of the five surgical templates before and after sterilization process fabricated from MED610.](image)

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Fig. (6). Mean percentage (%) change in the volume of the surgical templates within the three tested materials.

Table 1. Mean volumes of the surgical templates before and after sterilization process within the three tested materials.

<table>
<thead>
<tr>
<th>Material</th>
<th>Mean ± SD Volume Before (in mm$^3$)</th>
<th>Mean ± SD Volume After (in mm$^3$)</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visijet</td>
<td>5574.85 ± 30.51</td>
<td>5489.49 ± 69.55</td>
<td>0.043</td>
</tr>
<tr>
<td>MED610</td>
<td>5672.00 ± 146.27</td>
<td>5700.37 ± 139.54</td>
<td>0.225</td>
</tr>
<tr>
<td>eResin</td>
<td>6040.50 ±307.32</td>
<td>6158.21 ± 327.2</td>
<td>0.043</td>
</tr>
</tbody>
</table>

Table 2. Results of Tukey HSD/Tukey Kramer test between the tested materials.

<table>
<thead>
<tr>
<th>Pair</th>
<th>Difference</th>
<th>Q</th>
<th>Lower CI</th>
<th>Upper CI</th>
<th>Critical Mean</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visijet – MED610</td>
<td>113.715532</td>
<td>4.649443</td>
<td>21.437670</td>
<td>205.993394</td>
<td>92.277862</td>
<td>0.0165440</td>
</tr>
<tr>
<td>Visijet – eResin</td>
<td>203.064108</td>
<td>8.302603</td>
<td>110.786246</td>
<td>295.341970</td>
<td>92.277862</td>
<td>0.000207270</td>
</tr>
<tr>
<td>MED610 – eResin</td>
<td>89.348576</td>
<td>3.653160</td>
<td>-2.929286</td>
<td>181.626438</td>
<td>92.277862</td>
<td>0.0579969</td>
</tr>
</tbody>
</table>

Colored visualization of the volumetric changes revealed that deformation was more pronounced in the buccal wire of the templates, affecting the area of the metallic sleeves (Fig. 7). This finding was common in all three materials.

Fig. (7). Colored visualization of the volumetric changes as conducted with CloudCompare software (red color indicates distortion sites of the template and yellow the sites remained stable).

4. DISCUSSION

Surgical guides for implant placement are considered semi critical or critical instruments and are proposed to be sterilized [8, 19]. These templates are fabricated from acrylic resins by the process of 3D printing, and steam heat sterilization may affect their dimensional stability [7, 9 - 11, 20]. Dimensional alterations of the surgical templates due to disinfection or sterilization processes have been considered as critical factor that may affect the fit of the template and finally the accuracy of drilling inclination [5, 21, 22]. The null hypothesis of the present study was rejected as all three tested materials had volumetric alterations after steam sterilization at 121°C for 20 minutes. The templates had either increase or decrease in their volume depending on the tested material, which ranged from 0 to 3% of the initial volume.

From the three tested materials, only one (MED610) is proposed by the manufacturer that it can be sterilized by steam heat, maybe due to higher glass transition temperature than the other two acrylic resins. This material was also found to have no significant volumetric alterations in the present study, which is also supported by the study of Török et al., who had used the same material [10]. The other two materials showed a significant increase (eResin) or decrease (Visijet) in volume. Although this increase or decrease did not exceed 3% of the initial volume, both alterations may affect the accuracy of the drilling procedure. In the case of an increased volume, the template may have micromovements during the surgical procedure. While in the case of decreased volume, the template may not fit accurately on the supporting teeth, which may result in differentiation of the inclination of the drill. However, Tallarico et al., who used Visijet, showed that any dimensional
CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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REFERENCES


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