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THE INFLUENCE OF TWO STEAM STERILIZATION PARAMETERS ON THE DIMENSIONAL STABILITY OF 3D PRINTED SURGICAL GUIDE (IN VITRO STUDY)

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ABSTRACT

BACKGROUND: Advanced manufacturing techniques, known as three-dimensional (3D) printing, use computer-aided digital design models to automatically produce customized three-dimensional objects.
OBJECTIVE: The purpose of this study was to evaluate the effects of two different sterilizing methods on the dimensions of a 3D-printed surgical guide for implant treatment.
METHODS: Based on the parameters of the sterilizing procedure, we conducted a controlled study with a prospective design on surgical guides, randomly dividing them into two groups of 13 specimens each. Group I underwent steam sterilization for 15 minutes at 121 °C, whereas Group II underwent sterilization for 10 minutes at 134 °C.
RESULTS: Before autoclaving, Group I and Group II have no statistically significant difference in area or perimeter ($p = 0.128$, p = 718). The percentage changes in the area and perimeter after autoclaving between Group I and Group II were found to have a significant difference ($p<0.0001$).
Conclusions: The results of this investigation show that steam sterilization procedures have a substantial impact on the area and perimeter of the 3D-printed surgical guides. It was found that the settings with the minimum dimensional changes and distortion were at 121°C for 15 minutes, of steam sterilization.
KEYWORDS: Steam Sterilization, Dimensional Stability, 3d Printed, Surgical Guide
RUNNING TITLE: Steam sterilization influence on stability (3D surgical guide)

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INTRODUCTION

Three-dimensional (3D) printing technologies are sophisticated manufacturing techniques that utilize computer-aided digital design models to automatically produce customized 3D objects (1, 2). Modern 3D imaging technologies and software can significantly assist in preoperative planning for dental implant surgery, by transferring the virtually planned position of the implant to the surgical site through the use of an implant-guided template, surgical guides are found to enhance procedure efficiency and minimize mistakes during insertion, particularly in flapless surgery (3,4). Surgical guides are created either through additive (3D printing) or subtractive (milling) methods where no disparity in accuracy between the two processes. "Critical A" medical equipment refers to devices, like the dental implant surgical guide, that come into contact with blood during invasive procedures. Furthermore, the manufacturer classifies surgical guides as class I medical devices under the EU Medical Device Regulation (Medical Device Coordination Group, n.d., for Hospital Hygiene and Infection).

Autoclaving with steam is the most common sterilization method. Despite the majority of rules, few manufacturers advise against disinfecting their resin only with alcohol, octenidine dihydrochloride, or chlorhexidine digluconate.

According to the Centers for Disease Control and Prevention (CDC), tested disinfection techniques involve immersing the fully assembled surgical guide in 70% isopropyl alcohol (IPA) for a maximum of five minutes.

However, this process may adversely affect the performance of the surgical guide. In addition, surgical guides can undergo sterilization by heating them to a temperature of 132°C/270°F for four minutes using a pre-vacuum steam sterilizer. Alternatively, you can heat them to 121°C/250°F for thirty minutes. However, it is important to ensure that the sterilization cycles do not exceed twenty minutes at a temperature of 134°C/273°F or thirty minutes at a temperature of 121°C/250°F.

To maintain accuracy, a desiccation process must be included in autoclave cycles (5). Multiple authors have examined the potential for microbiological contamination of acrylic surgical guides.

Surgical guides, produced in dental laboratories, are susceptible to contamination from various sources, including damp polishing stations, stagnant pressure spots, contaminated work surfaces, and laboratory personnel. The goal of this study was to assess the effects of two different sterilization methods on the size of a 3D-printed surgical guide for implant procedures.

Hypothesis

The null hypothesis of this study was that there are no significant differences in the dimensions of 3D-printed surgical guides before and after sterilization.

MATERIAL AND METHODS

This in vitro laboratory experiment was carried out in the biomaterial department laboratories of the faculties of science and dentistry (Alexandria University). A dual scan for the fabrication of a surgical guide of an edentulous maxilla was done as follows:

a- CBCT scan for the patient wearing the denture

b- CBCT scan for the denture alone.

Alignment markers (using radiopaque composite resin markers) for the denture were done to appear while doing the CBCT for proper design to patients with missing teeth in the upper maxillary and mandibular An STL (standard tessellation language) file containing the scan data was exported. Using computer-aided design software that may be purchased commercially (Blue Sky Plan® program V4.7; BlueSky Bio L.L.C., Chicago, IL, U.S.A.).

An experimental surgical guide was created to mimic the insertion of four axial implants in the maxillary first molars and maxillary lateral incisors areas.

The surgical guide served as an example of a completely guided implant procedure for the maxilla that is edentulous. 26 guides were produced once the digital design was converted as an STL file using a 3D printing machine: (FORMLABS PRINTING MACHINE Formlabs Inc., Somerville, MA, USA).

UV-photopolymerizing resin was cured using digital light processing (DLP). The guides were produced using clear (FORMLABS SURGICAL GUIDE RESIN Formlabs Inc., Somerville, MA, USA)) in 50µm layers. At 385 nm, the angulation of printing was completely vertical where there was no deviation on the Z-axis, this material underwent photopolymerization. Following printing, the surgical guides were stripped of their supporting material and post-processed for ten minutes using 70% ethanol following the manufacturer's instructions.

A CBCT scan of the patient wearing the denture and a separate CBCT scan of the denture alone were used to create the surgical guidance.

Indicators (alignment markers) that indicate where the denture should show during the CBCT were used to ensure the correct design. The most well-recognized sterilizing process parameters are ISO 17665-2.

For the experiments, 13 identically sized and shaped dental implant guide templates were made. Using a MEDIT Scan ST dental scanner (MEDIT-SCANNER T710, Medit, South Korea, software version 1.2.7), the 3D-printed templates were digitally scanned, enabling the creation of 18-megapixel 3D models. The files in the stereolithography (STL) format contained the recordings. In the areas of the templates that are anticipated to be most vulnerable to damage, we took sub-millimeter measurements using MeshLab software (GNU General Public License Version 2.0).

Sample size estimation

The sample size was estimated assuming a 5% alpha error and 80% study power. The mean (SD) dimensional deviation after the normal sterilization cycle (121°C) was estimated to be 0.2735 mm (0.2129) (6) and it was 0.014 mm (0.068) for the flash sterilization (134 °C) (7). Based on the difference between independent means using the highest SD=0.2129 to ensure enough power, the minimum sample size was calculated to be 12 samples per group, increased to 13 samples to make up for processing errors. Total sample number per group x number of groups= 13 x 2 = 26 samples. The sample size was based on Rosner's method calculated by G*Power 3.1.9.7.

Group I: steam sterilization at a temperature of 121 °C for 15 minutes, Group II: at 134 °C for 10 minutes.

To assess the difference between the guide before and after sterilization, the hole area of the guide was measured in four separate locations using an (Olympus SZX 11 stereomicroscope, in Tokyo, Japan**) Figure (1, 2)**. The implant surgical guides' surface characteristics, geometric features, and dimensions were examined both before and after sterilization using (Olympus SZX 11 stereomicroscope, located in Tokyo, Japan) and results were analyzed according to changes in the perimeter and the area.

Statistical analysis

The normal distribution of dimensional stability parameters was checked using the Shapiro-Wilk test and Q-Q plots. Normality was confirmed for dimension perimeter thus it was presented using mean and standard deviation (SD). Area and percent change were not normally distributed thus median, minimum, and maximum were used for data summarization Percent change after autoclaving was calculated according to the following formula: [(Values after autoclaving – Values before autoclaving) / Values before autoclaving] x 100. Percent changes were compared using Kruskal Wallis tests followed by Tukey's and Dunn's post hoc test, respectively with Bonferroni correction to adjust for type I error. Paired t-test was employed to assess changes in all variables before and after autoclaving. All tests were two-tailed and the significance level was set at p-value ≤0.05. Data were analyzed using IBM SPSS for Windows version 23, Armonk, NY, USA.

RESULTS

Group I, showed no significant difference in perimeter comparing before sterilization (916.5 ±39.2) and after sterilization (911.60±40.4) (p=0.497). However, there was a significant difference in Group II before (900.82 ±43.4) and after sterilization (913.5 ±42.5) (p=0.001)
(Table 1, Figure 3).

After autoclaving, Group I showed a percent change value of -0.5±1.1 while Group II showed a value of 1.5±4.8 having a significant difference of p <0.0001 between the two groups –
(Table 2, Figure 4).

For the area, Group I showed a significant difference comparing before sterilization (66492.7±5742) and after sterilization (65794.9±5929.9) (p<0.0001). Furthermore, Group II showed also a significant difference between before (64083.8±6392) and after sterilization (65313.2±6607) with p=0.026. It's interesting to note that after being sterilized Group I showed a significant decrease in the area (p<0.0001), in contrast to Group II which showed a notable increase in the area following autoclaving
(Table 3, Figure 5).

Comparing the two groups after sterilization, there was a highly significant difference in the % change in the area of value p< 0.0001 with values of -1.1±2.1 in Group I and 2.1±6.9 in Group II
(Table 2, Figure 6).

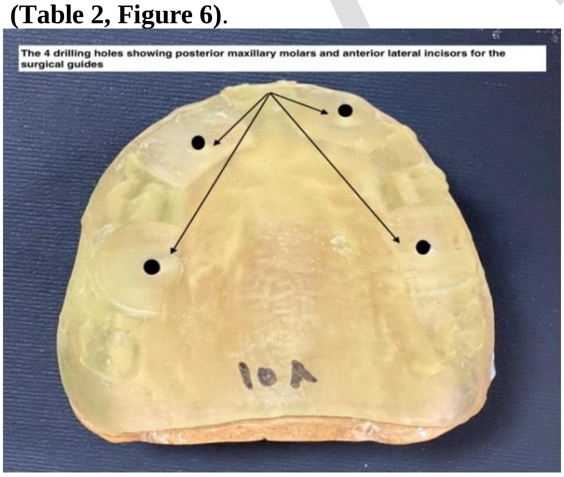

Figure (1): The 4 drilling holes showing posterior maxillary molars and anterior lateral incisors for the surgical guides

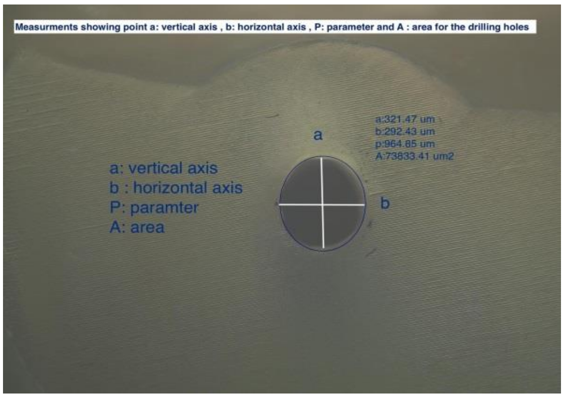

Figure (2): Showing measurements for the drilling holes under stereomicroscope

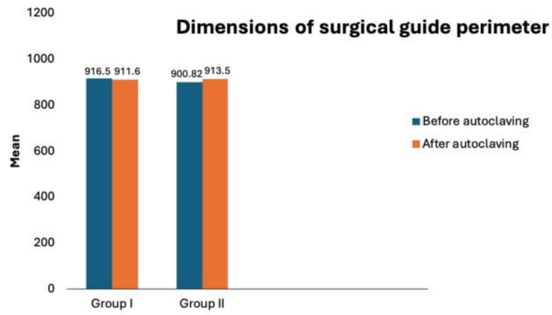

Figure (3): Shows the change in surgical guide perimeter among the study groups before and after autoclaving

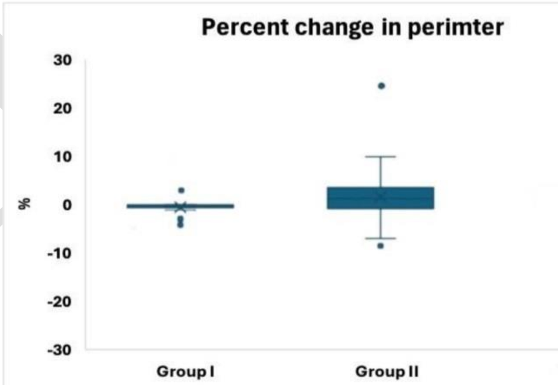

Figure (4): Shows the percentage change in perimeter between the study groups before and after autoclaving

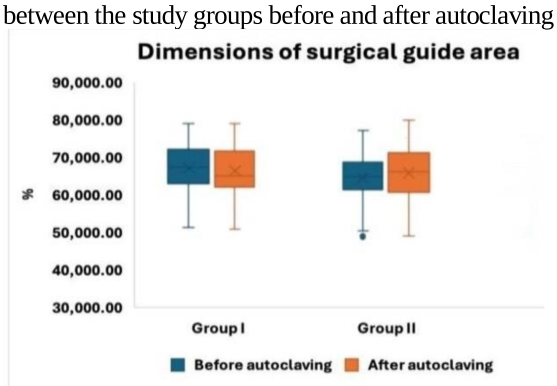

Figure (5): Shows the change in area between the study groups before and after autoclaving

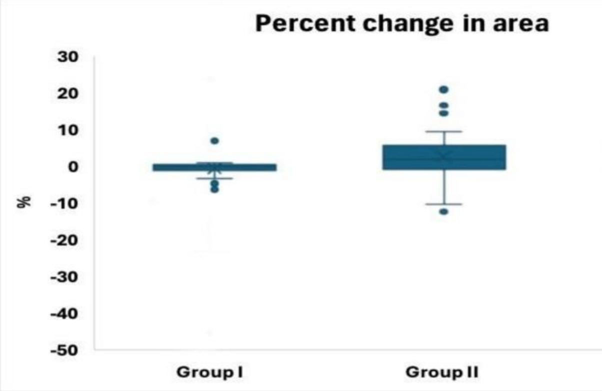

Figure (6): Shows change in surgical guide area among the study groups before and after autoclaving

Table (1): Comparison of change in surgical guide perimeter among the study groups before and after autoclaving

		Group I (n=13)	Group II (n=13)
Before autoclaving	Mean ±SD	916.5 ±39.2	900.82 ±43.4
	Median	917.1	901.9
	Min – Max	804.6 – 989	799.2 – 996.4
After autoclaving	Mean ±SD	911.60±40.4	913.5 ±42.5
	Median	906.4	916.3
	Min – Max	803 – 989	811.5 – 994.8
***p* value#**		0.497	0.001*
% Change	Mean ±SD	-0.5±1.1	1.5±4.8
	Median	-0.2	1.1
	Min – Max	-4 – 2.8	-8.1 – 23.3
***p* value¥**		<0.0001*	

*Statistically significant difference at p value≤0.05, #Paired t-test, ¥Kruskal Wallis test

Table (2): Pairwise comparison regarding the change in perimeter and area between the study groups

Parameter	Groups	Compared to	*p*-value
	Group I	Group II	<0.0001*

*Statistically significant difference at p value≤0.05

Table (3): Comparison of change in surgical guide area among the study groups before and after autoclaving

		Group I (n=13)	Group II (n=13)
Before autoclaving	Mean ±SD	66492.7±5742	64083.8±6392
	Median	66633	64247.8
	Min – Max	51513.4 – 77675.2	49148.1 - 75941
After autoclaving	Mean ±SD	65794.9±5929.9	65313.2±6607
	Median	64521.7	65560.1
	Min – Max	50977 – 77675.2	49274 – 78734.8
p value#		<0.0001*	0.026*
% Change	Mean ±SD	-1.1±2.1	2.1±6.9
	Median	-0.4	1.3
	Min – Max	-6.5 – 6.1	-12.2 – 20.3
***p* value¥**		<0.0001*	

*Statistically significant difference at p value≤0.05, #Wilcoxon Sign Rank, ¥Kruskal Wallis test

DISCUSSION

The field of dentistry has experienced a significant transformation due to the introduction of 3D printing technology. This advancement has enabled the creation of customized surgical guides for a wide range of dental procedures (8).

These guidelines are crucial for ensuring accurate and uniform outcomes during complex dental procedures. However, because 3D-printed objects are frequently sterilized before use, it is critical to understand the impact of high temperatures and pressures on the guides' dimensional stability (9).

Previous studies, like those by Sharma et al. and Popescu et al., which investigated the impact of steam sterilization on the dimensional alterations of 3D-printed surgical guides, have shown that the sizes of 3D-printed surgical guides change after they have been sterilized (10,11). Those findings fit with our results that showed statistically significant alterations in dimensions across both experimental groups, including changes in perimeter, area, and deviation from the initial measurements following the sterilization procedure.

The study findings indicate that the elevated pressure and temperature of the autoclaving procedure can alter the dimensions of 3D-printed guides. Modifications to the dimensions can potentially impact the fit, accuracy, and overall outcome of the surgical procedure. As a result, this is a significant concern for physicians and researchers who are using these customized surgical instruments.

One of the study's main findings was that prolonged exposure to higher sterilizing temperatures leads to the most significant decrease in guide diameters. Following the sterilization process, the guides belonging to Group I, which were subjected to a temperature of 121°C for 15 minutes, exhibited the smallest amount of dimensional alteration specifically, there was a 0.5% change in perimeter and a 1.1% change in area. This outcome underscores the importance of achieving a proper equilibrium between the duration and temperature of the sterilization process.

The observed shrinkage is likely a result of the photopolymer resin material degrading due to prolonged exposure to high temperatures. Studying the behavior of polymer materials at elevated temperatures can help us understand the fundamental process behind this change in dimensions. Under elevated temperatures, the polymer molecules exhibit enhanced mobility and vibrations due to the increased thermal energy, allowing them to approach each other more closely. This phenomenon, also known as thermal softening, can cause a decrease in the overall dimensions of the 3D-printed guides (12).

In contrast, the investigation revealed that the 3D-printed guides exhibited an apparent expansion when subjected to higher temperatures for shorter durations. When the guides were heated to 134°C for ten minutes, Group II showed a 1.5% increase in area and a 2.1% increase in perimeter according to the researchers. The guide material may have undergone thermal expansion due to a short exposure to elevated temperatures, which caused it to expand. Nevertheless, the rapid cooling and pressure fluctuations that occur during the sterilization process can induce physical modifications in the polymer chains, potentially leading to enlarged structures with increased overall size (13).

The increase in guide dimensions can be attributed to the interaction between thermal expansion and the impacts of sudden changes in temperature and pressure. According to Group I's findings, the employed method effectively reduces the deformation of the 3D-printed guides while ensuring sufficient sterilization at a controlled temperature and duration. This finding fits with what other research has found about how important it is to keep the shape stability of 3D-printed dental parts by making sure the sterilization conditions are just right (14, 15).

These findings are especially pertinent to scholars and physicians who utilize 3D-printed surgical guidance. Even minor dimensional variations in the guides can significantly impact the accuracy and comfort of the device during surgery (16).

The overall efficacy of the treatment may be compromised by issues arising from an imprecise fit, such as the improper positioning of dental implants or other restorative elements, which may compromise the treatment's overall efficacy. Dental practitioners must thoroughly evaluate the sterilization methods employed for 3D-printed surgical guides to minimize the risks associated with dimensional alterations.

The study's findings suggest that the most effective approach for maintaining the guides' dimensional stability and ensuring proper sterilization is to heat them to 121°C for 15 minutes as part of a well-rounded strategy with a significant difference compared to other group using 134°C for 10 minutes ($p<0.0001$). Therefore, the null hypothesis of this study was rejected.

The resin's glass transition temperature (Tg) is a crucial parameter that dictates the mechanical response of the material when subjected to elevated temperatures, such as those experienced during sterilization. The glass transition temperature refers to the specific temperature at which a polymer material undergoes a transition from a rigid, brittle state to a flexible, elastic state. When the polymer's temperature exceeds its Tg, the polymer chains experience a significant increase in molecular mobility (17).

This increased mobility allows the chains to reorganize and potentially undergo dimensional changes thermal expansion or contraction when undergoing sterilization. This is because high-Tg materials have polymer chains that require a greater amount of thermal energy to surpass intermolecular interactions and undergo significant conformational alterations. According to Pop et al. (2022) (17), photopolymer resins commonly used in 3D printing may have glass transition temperatures that are lower than the standard sterilization temperatures of 121°C or 134°C. When subjected to autoclaving, they are susceptible to changes in size and shape.

The inherent qualities of the material and the 3D printing parameters, such as curing time and intensity, directly affect the crosslinking density and dimensional stability of the finished product.

The configuration of the 3D-printed surgical guide, along with the properties of the material, can also influence the extent of dimensional alteration during the sterilization process. The structure's susceptibility to warpage, expansion, or shrinkage can be influenced by a variety of factors, including the overall layout of the guide, the number of teeth it contains, the angulation of the guide, and the thickness of its walls.

Due to the high temperatures and pressures of the sterilizing process, larger guides with greater spans and surface areas are more prone to experiencing non-uniform deformation, which can lead to dimensional alterations. Similarly, guides that have thinner walls or more complex geometries may be more prone to deformation because the stresses generated during sterilization can more rapidly compromise their structural integrity (5).

Furthermore, the number of teeth in the guide design can potentially affect its dimensional stability. Heat-induced deformation can be magnified by the increased surface area and volume of guides with more teeth or a larger covering area, resulting in greater dimensional changes (5).

Several factors, including the physicochemical properties of the photopolymer resin, the structure and density of the printed material, the design and shape of the guide, and the specific sterilization procedure, influence the dimensional stability of 3D-printed surgical guides during sterilization (18).

By understanding and addressing these critical factors, dental professionals can optimize the manufacturing and sterilization processes to maintain the accuracy and reliability of 3D-printed surgical guides, ultimately ensuring the success of complex dental procedures.

Outcomes, it is critical to include sterilization-induced distortion in the digital workflow when making 3Dprinted guides.

A study examining the accuracy of guides after sterilization has found average differences of up to 0.2 mm in the vertical direction and 0.3 mm in the horizontal direction (16). Additionally, errors in the placement of implants range from 1.4 to 4.9 degrees compared to the intended angles (17).

Consequently, it is imperative to implement rigorous quality control measures. Recent research suggests that subjecting an object to a temperature of 121°C for 15 minutes may decrease any alterations in size or shape while still ensuring that it remains free from any microorganisms. However, from a clinical perspective, the dwell duration may be insufficient (19).

Increasing the duration to 20 minutes could provide a reasonable middle ground between precise and reliable sterilization. However, the optimal specifications should be tailored and verified based on the materials and guide design.

CONCLUSIONS

The outcomes of this study demonstrate that:

1- Steam sterilization procedures significantly affect the stability and dimensional accuracy of 3D-printed surgical guides.

2- While sterilization is critical, it is important to select settings carefully to minimize distortion.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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