Does Low-Temperature Sterilization Affect the Geometrical Properties of 3D Printed Models and Surgical Guides from a Reconstruction of CT Images using the Mimics Innovation Suite?

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Research

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Abstract

Background: Fused deposition anatomical models and surgical guides are the embodiment of digital surgical planning. Although the models are primarily produced for training or simulation, they often touch the patient tissues and fluids while the guides are always in close contact with the patient. Therefore, sterility is a requirement but not at the expense of losing dimensions and shape. In the present study, we assessed the effects of sterilization with vaporized hydrogen peroxide on the geometrical properties and accuracy of 3D-printed pieces reconstructed and processed using the Mimics Innovation Suite.

Methods: computer tomography (CT) scan images from 16 patients were selected, eight from patients with maxillary and mandibular defects for the anatomical models, and eight from patients with mandibular defects for the cutting guides. The devices were manufactured in medical-grade acrylonitrile butadiene styrene from the primary files of the CT scans reconstructions. Two scanning processes were repeated after the production, one before and the other after sterilization. The dimensional error was estimated in each step of the process by comparing the scanned images of the printed pieces between before and after the sterilization process with the original design.

Results: The average of the estimated mean differences between the printed pieces before and after sterilization were -0,011 ± 0,252 mm (95%CI -0,011; -0,010) for the models and 0,003 ± 0,057 mm (95%CI 0,002; 0,003) for the guides. Regarding the dimensional error of the sterilized parts compared to the original design, the estimated mean differences were -0,082 ± 0,626 mm (95%CI -0,083; -0,081) for the models and 0,126 ± 0,205 mm (95%CI 0,126; 0,127) for the cutting guides.

Conclusion: The geometrical properties of the 3D-printed anatomical models and cutting guides designed with the Mimics Innovation Suite and manufactured in ABS was not affected after the process of low-temperature sterilization. The devices maintained dimensional stability after the sterilization but also showed high reliability relating to the original design.

Background

Digital Surgical Planning (DSP) is widely used for the presurgical design of complex cases in areas such as orthopedic, orthognathic, and facial reconstructive surgery, among others (1–5). The DSP provides the surgeon with an opportunity to plan, calculate, and predict surgical complications, avoiding improvisations during the procedure (1, 3–5).

Hand in hand with the DSP are the plastic anatomical models obtained through three-dimensional (3D) printing techniques, which constitutes the embodiment of digital planning (3, 4, 6). Additionally, computer-aided manufacturing techniques are used to prepare cutting guides based on preoperative imaging (3–5).

The 3D printing technology has allowed the DSP transfer into the patient's anatomical model, aiding the surgeon with a better visualization intraoperatively (3, 6). Likewise, with the 3D printing process, the digital guides are converted into physical devices through a layer-by-layer fabrication process (3, 5).

Fused deposition modeling (FDM) is the most common 3D printing method, primarily because of the simple processing and cost-efficiency. One of the most frequently used manufacturing materials in FDM 3D printers is acrylonitrile-butadiene-styrene (ABS) (2, 3, 6–8). ABS is a cost-effective polymer that is easy to manage; it has good resistance, strength, and stiffness (1, 3–5, 9).

When intrasurgical manipulation is needed, the models and guides printed in ABS must be sterilized before entering the operating room (7–10). The ABS devices can be sterilized by low-temperature hydrogen peroxide gas plasma (vaporized hydrogen peroxide, VH2O2), a method appropriate for sensitive instruments as the temperature cycles does not exceed 50 °C (7–10). However, whether or not the sterilization process could influence the geometrical properties and affect the precision and accuracy of the anatomical models and surgical guides is still under consideration.

For this reason, the purpose of this study was to evaluate the dimensional stability of 3D printed anatomical models and surgical cutting guides designed by using the Mimics Innovation Suite and manufactured in ABS, before and after the low-temperature sterilization process. We also aim to evaluate the accuracy of the models and guides to the original design.

Methods

Anatomical models and cutting guides design

The precision and dimensional stability were analyzed in two separate processes; one for anatomical models and another for cutting guides.

Computer tomography (CT) scan images of 8 patients with maxillary and mandibular defects were used to design the anatomical models. For the cutting guides, CT scan images from 8 patients with mandibular defects that needed correction using fibula segments were utilized.

All the DICOM (Digital Imaging and Communication in Medicine) files from the CT scans were imported into the Mimics Innovation Suite (Materialise NV, Leuven, Belgium) for the segmentation of the images and conversion into virtual 3D models in the stereolithography (STL) format (Fig. 1A). According to the DSP in each case, the needed subdivisions of the 3D anatomical model and design of the guides were also performed.

3D printing and processing

A print code (G code) was generated from the STL files, and using a high-performance desktop 3D printer, the models and cutting guides were manufactured in medical-grade ABS.

A high-resolution scanning protocol with the CT-scanner Bright Speed Elite (General Electric; Boston, USA) was used for the anatomical models, and the 3D optical scan Atos Core 80 with 0.03 mm resolution (GOM, ZEISS Group, Braunschweig, Germany) for the cutting guides after the 3D printing (Fig. 1B).

Sterilization process

The medical-grade ABS devices were subjected to low-temperature VH2O2 sterilization using a V-PRO® 1 Low-Temperature Sterilization System (STERIS Corporation, Mentor, OH), with the non-lumen cycle at 50 °C temperature.

3D scans of the models and surgical guides were taken after the sterilization process. The scanning protocol for the models and cutting guides was repeated after the sterilization (Fig. 1C).

Dimensional stability and statistical analysis

The dimensional error was calculated using the Analyze toolbox of the Mimics Innovation Suite. Three different sets of comparations were analyzed:

- "Comparison1" corresponded to the original design vs. the scans made before sterilization.
- "Comparison2", of the 3D-printed models and guides before and after sterilization.
- "Comparison3", corresponding to the original design vs. the scans after sterilization (Fig. 2).

The (.stl) files from the scans acquired before and after the sterilization process were digitally aligned, overlapped, and compared to the original design files. The dimensional error was estimated by comparing the difference between the overlapped images on a point-by-point basis; the distance amongst the points in the different coordinates in all the planes: X, Y, and Z, indicated the error. The software displayed these differences through a "color map" on the scanned model and guide.

Statistical analyses were performed with the IBM SPSS Statistics 25 software (Chicago, IL). After evaluating each data set's distribution, the averages, standard deviations (SD), and the 95%confidence intervals (95%CI) of the "Comparison2" differences were calculated and plotted to test the dimensional stability of the 3D-printed pieces after sterilization. The same applied to both "Comparison1" and "Comparison3" to evaluate the sterilized pieces' dimensional accuracy related to the original design. Additionally, a paired *t*-test was used to estimate the differences in mean distances (differences) after each process and the

correlation between those values. All parameters were measured in millimeters (mm). A *p*-value of less than 5% was considered significant.

Results

Dimensional stability of sterilized 3D-printed models and cutting guides

In the "Comparison2" of the 3D-printed models before and after sterilization, the average of the estimated mean differences was − 0,011 ± 0,252 mm (95%CI -0,011; -0,010). In this data set, the largest mean difference between the points of the superimposed scans of pre-sterilized and post-sterilized models was − 0,022 ± 0,295 mm (95%CI -0,025; -0,019). Regarding the cutting guides, the average of the estimated mean differences for the "Comparison2" was 0,003 ± 0,057 mm (95%CI 0,002; 0,003). In this series, the largest mean difference was 0,015 ± 0,050 mm (95%CI 0,015; 0,015). The mean differences between the non-sterilized and sterilized 3D-printed pieces (models and guides) are displayed in Table 1, and the median trends in Fig. 3.

Table 1
Estimated differences between the non-sterilized and sterilized 3D-printed pieces (Comparison2).

ModelNumber	Measured points (n)	Mean difference*	SD*	Lower 95%CI*	Upper 95%CI*
1	33615	-0,015	0,260	-0,018	-0,012
2	42059	-0,016	0,235	-0,018	-0,013
3	33125	0,004	0,255	0,002	0,007
4	35558	0,001	0,248	-0,002	0,003
5	33908	-0,022	0,295	-0,025	-0,019
6	76740	0,001	0,234	-0,001	0,003
7	76551	-0,012	0,255	-0,014	-0,010
8	91502	-0,021	0,250	-0,023	-0,019
Total	**423058**	**-0,011**	**0,252**	**-0,011**	**-0,010**
GuideNumber					
1	47785	-0,010	0,082	-0,010	-0,009
2	116214	0,002	0,071	0,002	0,003
3	192570	0,005	0,058	0,005	0,006
4	73695	0,012	0,048	0,012	0,012
5	138000	-0,010	0,052	-0,001	-0,001
6	108202	-0,005	0,041	-0,005	-0,004
7	69266	0,015	0,050	0,015	0,015
8	23114	-0,005	0,039	-0,006	-0,005
Total	**768846**	**0,003**	**0,057**	**0,002**	**0,003**

*Values are expressed in millimeters. SD: Standard deviation; CI: Confidence interval

Dimensional accuracy of sterilized 3D-printed models and cutting guides

In the “Comparison1” and “Comparison3” of the original design vs. the 3D-printed models before and after sterilization, the averages of the estimated mean differences were − 0,095 ± 0,536 mm (95%CI -0,096; -0,094) and − 0,082 ± 0,626 mm (95%CI

-0,083; -0,081), respectively. The largest mean differences between the points of the superimposed scans of “Comparison1” and “Comparison3” were − 0,168 ± 0,469 mm (95%CI -0,170; -0,166) and − 0,179 ± 0,737 mm (95%CI -0,182; -0,176). Regarding the cutting guides, the averages of the estimated mean differences for the “Comparison1” and “Comparison3” were 0,141 ± 0,240 mm (95%CI 0,140; 0,141) and 0,126 ± 0,205 mm (95%CI 0,126; 0,127), respectively. The largest mean differences were 0,244 ± 0,355 mm (95%CI 0,244; 0,245) for Comparison1” and 0,238 ± 0,259 mm (95%CI 0,237; 0,240) for Comparison3”. The mean differences between the original design and scans of non-sterilized and sterilized 3D-printed parts (models and guides) are displayed in Table 2.

Table 2
Estimated differences between the original design and the 3D-printed pieces before (Comparison1) and after the sterilization process (Comparison3).

ModelNumber	Measured points (n)	Mean difference Comparison1*	SD*	Lower 95%CI*	Upper 95%CI*	Mean difference Comparison3*	SD*	Lower 95%CI*	Upper 95%CI*
1	168098	-0,019	0,467	-0,021	-0,017	0,017	0,529	0,015	0,020
2	144685	-0,037	0,398	-0,039	-0,035	-0,023	0,452	-0,025	-0,020
3	242098	-0,168	0,469	-0,170	-0,166	-0,165	0,516	-0,167	-0,163
4	114841	-0,072	0,529	-0,075	-0,069	-0,071	0,623	-0,073	-0,066
5	100099	0,021	0,570	0,017	0,024	0,074	0,719	0,069	0,078
6	128057	-0,111	0,506	-0,114	-0,108	-0,075	0,630	-0,078	-0,071
7	215781	-0,139	0,620	-0,141	-0,136	-0,179	0,737	-0,182	-0,176
8	171893	-0,134	0,643	-0,138	-0,131	-0,097	0,723	-0,100	-0,094
Total	**1285552**	**-0,095**	**0,536**	**-0,096**	**-0,094**	**-0,082**	**0,626**	**-0,083**	**-0,081**
GuideNumber									
1	47785	0,115	0,189	0,114	0,117	0,119	0,198	0,117	0,121
2	116214	0,091	0,207	0,090	0,092	0,100	0,194	0,099	0,101
3	192570	0,162	0,210	0,161	0,163	0,116	0,193	0,115	0,116
4	73695	0,100	0,184	0,098	0,101	0,083	0,174	0,082	0,084
5	138000	0,244	0,355	0,244	0,245	0,238	0,259	0,237	0,240
6	108202	0,118	0,188	0,117	0,119	0,092	0,175	0,091	0,093
7	69266	0,071	0,175	0,070	0,073	0,098	0,140	0,097	0,099
8	23113	0,093	0,195	0,091	0,096	0,071	0,170	0,069	0,073
Total	**768845**	**0,141**	**0,240**	**0,140**	**0,141**	**0,126**	**0,205**	**0,126**	**0,127**

*Values are expressed in millimeters. SD: Standard deviation; CI: Confidence interval

The mean differences between “Comparison1” and “Comparison3” for the models and guides were − 0,013 ± 0,672 mm (95%CI -0,014; -0,012) and 0,015 ± 0,299 mm (95%CI 0,014; 0,015). The correlations between the two sets of camparisons were of 0,399 for the models and 0,106 for the guides (both with $p < 0,05$) (Table 3 and Fig. 4).

Table 3
Overall results of the dimensional differences and correlations between the three sets of comparisons.

Models	Mean difference*	SD	Lower 95%CI*	Upper 95%CI*	Correlation	*P*-value
Comparison1 vs. Comparison2	-0,043	0,522	-0,045	-0,042	-0,004	< 0,05
Comparison2 vs. Comparison3	0,037	0,571	0,035	0,039	-0,004	
Comparison1 vs. Comparison3	-0,013	0,672	-0,014	-0,012	0,339	
Guides						
Comparison1 vs. Comparison2	0,138	0,247	0,138	0,139	-0,002	
Comparison2 vs. Comparison3	-0,123	0,213	-0,124	-0,123	0,013	
Comparison1 vs. Comparison3	0,015	0,299	0,014	0,015	0,106	

*Values are expressed in millimeters. SD: Standard deviation; CI: Confidence interval

Discussion

In the present study, we assessed the effect of the sterilization process on the dimensional stability of FDM 3D printed anatomical models and cutting guides and accuracy to the original design. The mean differences in dimensional stability after sterilization with VH2O2 in both groups, models, and guides, were under ± 0,5 mm and ± 0,05 mm, respectively. The analysis revealed that the low-temperature hydrogen peroxide sterilization effect over the medical-grade ABS models and guides was sub-millimetric, assuring the dimensional stability after the process. Likewise, the mean differences in the accuracy of the models and guides after sterilization to the original design were under ± 1 mm and ± 0,25 mm, respectively. These findings indicated that even though the 3D-printing and posterior sterilization process could have caused dimensional errors in the models and guides, the fidelity to the original design was maintained. The shape and dimensional accuracy remained high.

The stereolithographic anatomical models are generally used for surgical preparation, training, and educational and consultation purposes. Yet, they are often needed in the operating room as a visual aid for the surgeon and are often in contact with the patient (11–14). Cutting guides are used in both the surgical simulation and the actual procedure. These guides come in contact with the bone, blood, and fluids of the patients during the surgeries (11–13, 15).

FDM printed models and guides are prone to contraction and distortion during the thermoplastic cooling process leading to geometric inaccuracies (16). Several studies have assessed the dimensional accuracy of FDM pieces, biomedical and non-biomedical, manufactured in ABS after the 3D-printing process. Popescu et al. (8), as mentioned above, evaluated several dimensions of a non-biomedical ABS test part, measuring and comparing it to the nominal values in different sections. They found divergence values of +/−0.27 mm with mostly positive deviations in comparison with the nominal part. On the other hand, E-Katatny et al. (14) and Hsu et al. (17), using anatomical models of a mandible and a canine fibula, respectively, found surface deviations of 0,159 mm and 0,121 mm to the original design. In our study, the mean differences between the printed pieces and original design were within the 95%CI of -0,096 to -0,094 mm for models and 0,140 to 0,141 mm for guides. It showed that our manufacturing parameters are accurate and very close to those reported in the other studies.

FDM 3D printing is likely to produce devices with some degree of sterility, given the high temperatures used during the manufacturing process (18). However, handling in non-sterile conditions contaminate the devices and lead to an intraoperative infection (7). Therefore, the sterility of those models and guides is critical during surgery but without sacrificing the accuracy of the devices.

The sterilization methods adequate for different 3D-printing materials have been tested in terms of infection rate, mechanical performance, and dimensional stability, or, on the contrary, geometrical deformation (7, 9, 15, 19–21). Low-temperature hydrogen peroxide gas plasma has been an optimal sterilization procedure for printouts produced by FDP in ABS. They show a low infection rate with the preservation of the geometrical dimensions (7, 8, 17). In a recent publication, Shea et al. (7) evaluated

the infection rate of 124 pieces (59 models and 55 guides) 3D-printed in ABS and reported an overall infection rate of 7%, mostly associated with age and long surgical times. The authors stated the infection rate was comparable to that reported by others using traditional surgical techniques and sterilization processes (7). On the other hand, Popescu et al., in two different publications (7–9), have demonstrated that low-temperature gas plasma sterilization does not influence the tensile and flexural strength of ABS specimens (9) nor the dimensions of the geometrical features remained stable (8). However, it has been indicated that for more multifaceted structures, mostly containing large surfaces of low depth, sterilization with VH2O2 could significantly impact the accuracy (22).

Two factors are essential when considering the use of a model or guide after the sterilization process. First, the dimensional stability in which the mean surface deviations of the pieces does not considerably alter the proportions, making them suitable for their use in the operating room and patients. Second, the devices' accuracy with a high level of conformity concerning the original design being truthful to the patient's anatomy (17, 22, 23).

The structural variations of VH2O2 sterilized FDM pieces produced in ABS have been previously addressed in various publications. Popescu et al. (8), as mentioned above, assessed a non-biomedical ABS part for dimensional accuracy following the printing and sterilization processes. After the latter, the dimensional changes were +/−0,20 mm, leading the authors to conclude that the sterilized part's dimensions were closer to the nominal design than the pre-sterilized one. Likewise, Kuczko et al. (22) evaluated the effect of VH2O2 sterilization over non-biomedical ABS 3D-printed pieces finding an average dimensional error of 0,036 mm (22). Hsu et al. (17) also tested the effect of low-temperature sterilization on the canine fibula model, getting a mean deviation of 0,043 mm (17).

We have shown that our 3D-printed models and cutting guides in ABS also maintained the dimensional stability after VH2O2 sterilization. First, the mean deviations on the 3D-printed pieces resulting from the low-temperature sterilization were low, with a 95%CI of -0,011 to -0,010 mm in models and of 0,002 to 0,003 mm in guides. Our values agree with those previously published, indicating that our sterilization process did not significantly affect the devices, making them suitable for intra surgical use. Second, the dimensional errors of the sterilized pieces compared to the original design were within a 95%CI of -0,083 to -0,081 mm in models and 0,126 to 0,128 mm in guides. Those values were smaller than those of the non-sterilized pieces, similar to what Popescu et al. (8) reported in their study.

In agreement, as shown in Fig. 4, the fidelity of the original design is preserved even after the 3D-printing and sterilization processes with significant correlations of 0,339 for models and 0,106 for guides.

In our ABS models and guides, the dimensional analysis indicated that errors that could occur during the manufacturing and sterilization processes were negligible. These results also indicate that the data acquisition procedure, the design, and manufacturing processes are reliable due to the final piece's accuracy.

A limitation of our study resides in that the results are only valid for FDM 3D printing technology and ABS devices. Therefore, there may exist other conditions under which these results are not reproducible. Identifying an FDM 3D printing material that deforms the least under the sterilization treatment is essential for clinical applications. The dimensional analysis was performed by one engineer, which could have introduced some bias on the measurements. However, the software provides programmed alternatives that assist in the device's alignments, eliminating manual errors and biases.

Conclusion

The dimensional stability of 3D-printed anatomical models and surgical cutting guides designed using the Mimics Innovation Suite and manufactured in ABS was not affected after the process of low-temperature sterilization. These results indicate that our ABS models and guides were fabricated with high accuracy and successfully sterilized using VH2O2 without significant effects on their surface shape and dimensions. The devices also showed elevated consistency regarding the original design being truthful to the patient's anatomy. Therefore, our models and guides are suitable for clinical use in surgery.

Abbreviations

DSP Digital Surgical Planning

3D Three-dimensional

FDM Fused deposition modeling

ABS acrylonitrile-butadiene-styrene

VH2O2 Vaporized hydrogen peroxide

CT Computer tomography

STL Stereolithography

SD Standard deviations

Declarations

Ethics approval and consent to participate: "Not applicable."

Consent for publication: Written consent, in a pre-established format used by our company, was obtained from the sixteen patients whose CT scans were used for this study. The consent forms were sent through email and returned, signed by each patient. The CT scans were part of the company's surgical planning service, and the study was a validation of our processes. No experimentation was carried out.

Availability of data and materials: The datasets generated and analyzed during the current study are not publicly available due to corporate policies but are available from the corresponding author on reasonable request

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Authors' contributions:

MT: Conception and design of the study, supervision of the study execution, and drafting and editing the manuscript.

AC: coordination of the entire study, drafting, and editing of the manuscript, corresponding author.

DR: Data acquisition, analysis, and interpretation writing and reviewing the manuscript.

LB: Design and writing of the study, informed consent forms procurement, data acquisition, and interpretation, reviewing the manuscript.

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