Post-sterilization Dimensional Accuracy of Methacrylate Monomer Biocompatible Three-Dimensionally Printed Mock Surgical Guides

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Abstract

Objectives The aim of this study was to evaluate the post-sterilization dimensional accuracy of a standardized drilling guide, three-dimensionally printed using biocompatible methacrylate monomers.

Study Design A mock surgical guide was designed and printed in five resins ($n = 5$/material) using a commercially available desktop stereolithography printer. Pre- and post-sterilization dimensions were measured for each sterilization method (steam, ethylene oxide, hydrogen peroxide gas), then statistically compared; p-value less than or equal 0.05 was considered significant.

Results While all resins produced highly accurate replicas of the designed guide, the amber and black resins were unaffected by any sterilization method ($p \geq 0.9$). For other materials, ethylene oxide produced the largest dimensional changes. However, mean post-sterilization dimensional changes for all materials and sterilization methods remained less than or equal to 0.05mm

Conclusion This study demonstrated that post-sterilization dimensional change of evaluated biomaterials was minimal, and less than previously reported. Additionally, amber and black resins may be preferred to reduce post-sterilization dimensional change, as they were unaffected by any sterilization method. Given the results of this study, surgeons should feel confident using the Form 3B printer to create patient surgical guides. Furthermore, bioresins may provide safer alternatives for patients compared with other three-dimensional printed materials.

Keywords
- 3D printed
- surgical guide
- sterilization
- orthopaedic surgery
- patient-specific guides

Introduction

Three-dimensionally (3D) printed patient-specific guides are becoming increasingly popular in veterinary medicine.[1–6] Indeed, as the availability and affordability of desktop printers have improved, veterinary surgeons' interest in these tools is gaining momentum.[7–9] From a clinical standpoint, since desktop printers have been shown to produce highly accurate replicas with only sub-millimetric dimensional errors,[6] surgeons should feel confident utilizing such printers in clinical cases.

In human medicine, patient-specific instrumentation has been shown to improve procedural precision, as well as to reduce both patient morbidity and operating times.[10,11] However, since patient-specific instrumentation contacts patient tissues, they are subject to the same safety standards as other medical devices, including sterilization practices.[12–15] Common methods of sterilization for medical devices include

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steam, ethylene oxide or chemical germicides such as hydrogen peroxide gas.[15]

Steam sterilization, which has been used for over a century, has three critical components to ensure efficacy: time, temperature and pressure. General recommendations to achieve 10^{-4} remaining organisms are 121°C for more than or equal to 20 minutes, requiring 103 to 117 kPa of pressure.[16] However, the ubiquitous use of heat or moisture-sensitive medical prostheses requiring sterilization has led to an increasing desire for alternative methods.[15]

Ethylene oxide is a direct alkylating agent, reacting with cellular components of organisms (e.g. nucleic acids or functional proteins), resulting in denaturation.[17] One benefit is the option for cycle parameter adjustments to account for material sensitivities, thereby preserving device integrity. However, concerns about ethylene toxicity have resulted in many jurisdictions restricting the use of this process.[18]

Unlike ethylene oxide, hydrogen peroxide gas is non-toxic and has the added benefit of leaving sterilized instruments with a residue-free surface.[19] Hydrogen peroxide sterilization is achieved by injecting liquid hydrogen peroxide into a vacuum chamber. Following radiofrequency wave application, free radicals are produced which invade the bacterial cell wall, and kill the bacteria.[19]

While effective sterilization is critical for patient-specific instrumentation, there are concerns regarding the possibility of dimensional changes during the process, which could have a deleterious impact on the accuracy of implant placement and, therefore, on surgical outcome.[20] Yet, only a few studies have evaluated the post-sterilization effects on patient guides,[21–26] the majority of which focus on steam methods using polymers such as polylactic acid and acrylonitrile butadiene styrene.[21–25] However, these polymers are not always considered biocompatible and the long-term effects of contact with patient tissues are unknown.

While biocompatible 3D printed materials are available, few reports exist evaluating their accuracy following sterilization.[26–28] One group of investigators reported dimensional changes less than 0.2 mm, but used only one resin and sterilization method.[27] Another group of researchers similarly evaluated steam sterilization effects on surgical guide polymer replicas created by industrial printers not readily available in veterinary medicine.[26] Finally, while one study evaluated absorbable stents, such devices are not used in orthopaedic surgery.[28] Unfortunately, due to variations in methodology and types of polymers, these studies cannot be directly compared. Additionally, they do not provide substantial information for surgeons regarding the safety and reliability of orthopaedic PSIs created from biocompatible materials, intended for use in clinical patients. Furthermore, new materials have been introduced since the publication of these prior studies, and further investigation of their accuracy is warranted.

Therefore, the purpose of this study was to evaluate post-sterilization dimensional accuracy of biocompatible 3D printed resins using a standardized guide, and to assess the effect of three sterilization methods. The null hypothesis was that sterilization methods would have no significant effect on dimensional accuracy of 3D printed guides regardless of resin type.

Materials and Methods

Guide Design and 3D Printing

A mock surgical guide consisting of linear, circular as well as positive and negative depth features was designed (Fusion 360, Autodesk, San Francisco, California, United States; ►**Fig. 1**). Pre-determined morphometric measurements, chosen to replicate standardized distances, diameters and thicknesses across the guide are represented in ►**Fig. 1**.

A binary standard tessellation language file of the guide was uploaded into image processing software (3-Matic, Materialise, Plymouth, Michigan, United States) and name identification was created for each guide (►**Fig. 2**). Five biocompatible resins (various compositions of methacrylate monomers) were selected. Guides were printed using a desktop machine (Form 3B, Formlabs, Somerville, Massachusetts, United States), which was chosen based on the reported accuracy of a similar printer[6] and the available selection of biocompatible materials. Resins included surgical guide (SG), biomed amber (BA), biomed clear (BC), biomed white (BW, newly released) and biomed black (BB, newly released).

Files were then uploaded into printer-specific software (Preform, Formlabs, Somerville, Massachusetts, United States) and positioned with matching orientations on the build platform (►**Fig. 3**). Orientation was chosen to minimize part deformation during printing and surface quality disruption from support removal.[6,27] Automated supports were then generated using 'mini-rafts', a touchpoint density of 0.5 mm and touchpoint size of 0.4 mm. Five samples in each resin were printed for each of three sterilization methods, giving a total of $n = 15$ per material.

Post-processing

Following print completion, the printer platform was placed into the automated rinse station (Form Wash, Formlabs, Somerville, Massachusetts, United States) with prints still attached, then submerged in 99% isopropyl alcohol for 20 minutes. Following rinsing, guide supports were removed with tools provided by Formlabs. Briefly, 'flush cutters' were used to snip touchpoints on the guide as close as possible to the surface. Rafts were then removed from the print platform using the 'scraper' tool. The surface of the platform was cleaned with 99% isopropyl alcohol to prepare for the next print.

Once supports were removed, guides were placed in an ultraviolet curing tank (Form Cure L, Formlabs Somerville, Massachusetts, United States). Temperature and duration of curing was material dependent, based on manufacturer recommendations: SG (70°C, 30 minutes), BA (70°C, 30 minutes), BC (60°C, 60 minutes), BW (60°C, 60 minutes), BB (70°C, 60 minutes). The isopropyl alcohol was changed between each material.

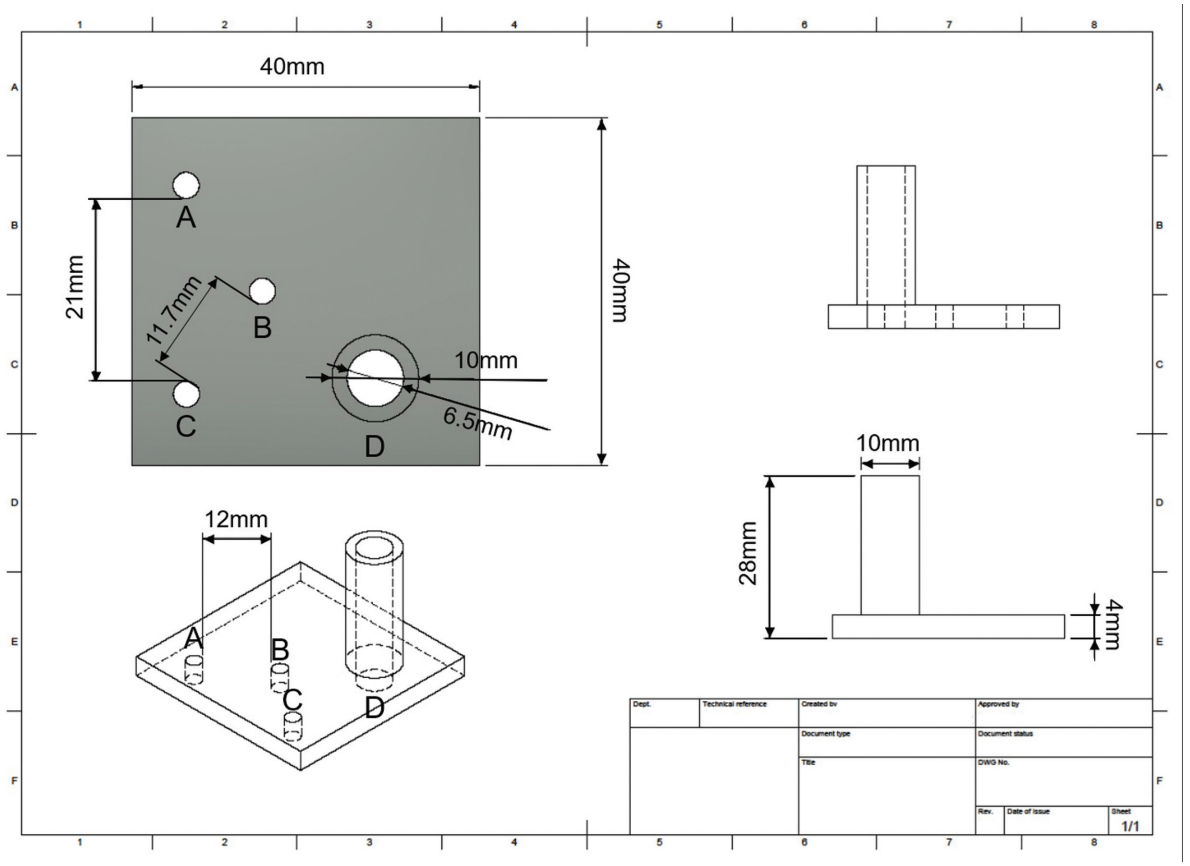

Fig. 1 Mock surgical guide with designed dimensions. Each measurement has been labelled with its corresponding letter. Designed dimensions were compared with post-print pre-sterilization dimensions to assess accuracy of each material.

Fig. 2 Mock surgical guide in 3-Matic showing imprinted guide label. Each guide was created with the material name, sterilization method and model number in the upper right corner. These 'negative' features were assessed subjectively for clarity pre and post sterilization.

Pre-sterilization Measurements

Following curing, measurements were obtained using a digital caliper (Mitutoyo America, Aurora, Illinois, United States) by a single investigator (DMM). All measurements were performed in triplicate and averaged for each sample. Measurements were taken from the following locations (►**Fig. 1**, designed dimensions in parentheses): (1) A to B (12 mm), (2) A to C (21 mm), (3) B to C (11.7 mm), (4) inner diameter of D (6.5 mm), (5) outer diameter of D (10 mm), (6) height from guide bottom to top of D (28 mm), (7) width and height of the guide base (40 mm for both), and (8) guide base thickness (4 mm). Measurements were reported as either a positive or negative value indicating magnification or reduction of the dimensions respectively.

Sterilization

Three methods of sterilization were chosen – steam, ethylene oxide and hydrogen peroxide gas. Cycle settings for each method were selected based on the standard operating procedures for our institution. Steam cycles (single door hinged autoclave, Consolidated Sterilizer Systems, Billerica, Massachusetts, United States) were run at 121°C for 20 minutes. Ethylene oxide cycles were run at 55°C for 60 minutes using a Steri-Vac GS5–1D (3M, Maplewood, Minnesota, United States). Hydrogen peroxide cycles were completed using a Sterrad 100S (Advanced Sterilization Products, Irvine, California, United States) with temperatures not

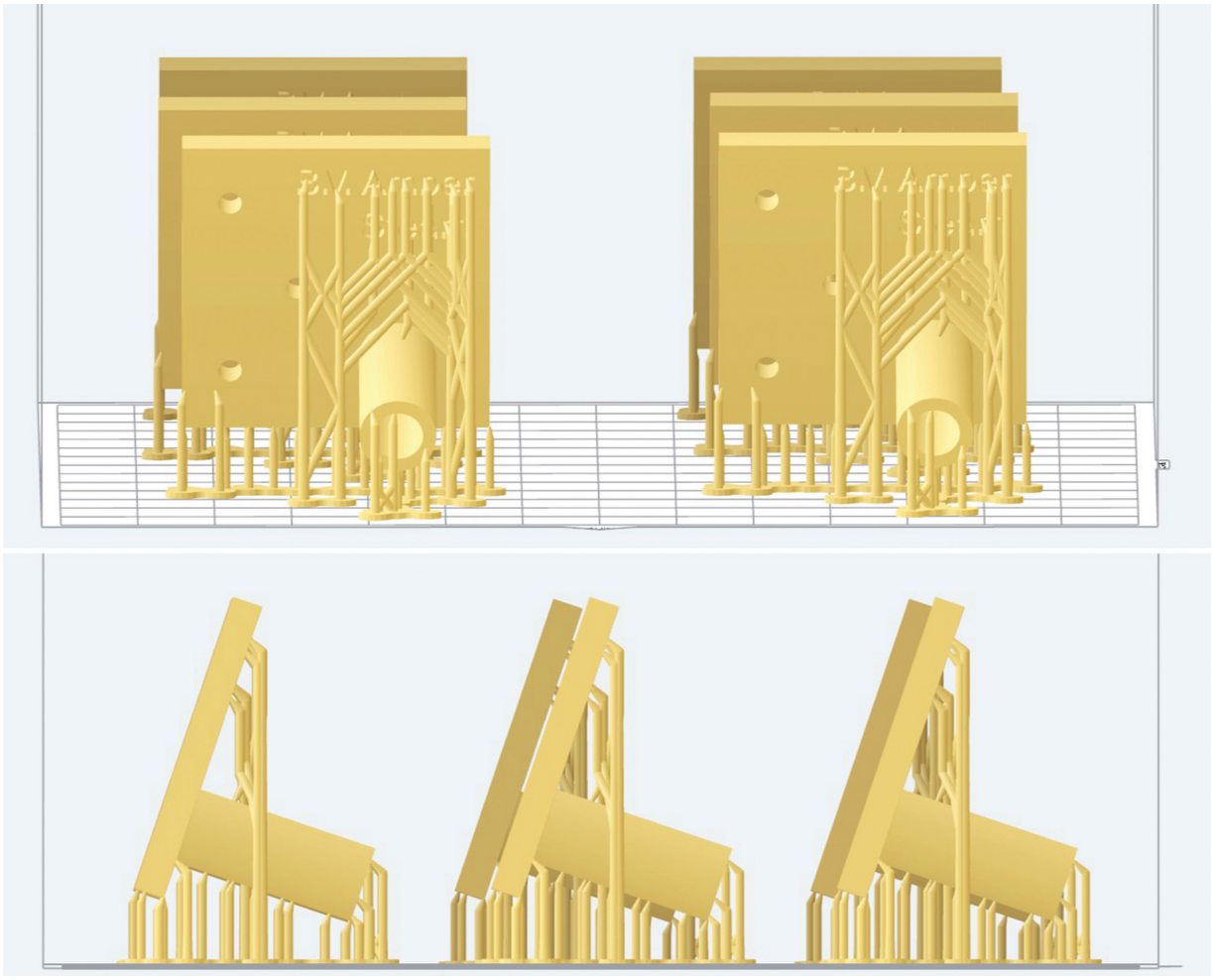

Fig. 3 Orientation of the mock guides on the Form 3B build platform. Guides were all oriented similarly to ensure homogeneity among samples.

exceeding 55°C for 48 minutes. Indicator tape or colour change markers on packaging were used to determine if sterility had been achieved (standard protocol for clinical cases at our institution).

Post-sterilization Measurements

To minimize bias, measurements were performed by a single author (DMM) without viewing pre-sterilization data. Measurements were also made at least 1 week after pre-sterilization data were collected so that the investigator could not remember previous results. Measurements were completed as described for pre-sterilization samples.

Statistical Analysis

Sample size ($n = 5$ / material / sterilization method) was based on previous studies using 3D printed or machined models.[6,29–31] Data distribution was evaluated for normality using the Shapiro–Wilk test. Mean dimensional differences (absolute value) between the designed guide and pre-sterilization models were first compared using a paired student *t*-test ($n = 15$ / material). Then, pre- and post-sterilization groups were compared using a two-factor repeated measures analysis of variance. Post-hoc Tukey tests were performed when significant differences were identified. Significance was set at *p*-value less than 0.05. Descriptions of printing time and resin volume were also recorded.

Results

Pre-sterilization Dimensional Analysis

Linear Dimensions

A-B: Differences between designed and post-print dimensions were identified in the SG ($p < 0.0001$), BA ($p = 0.02$) and BC ($p < 0.0001$) materials.

B-C: No significant differences were identified in any material.

A-C: All materials had significantly different dimensions. The most accurate mean was observed in the BA ($+0.01 \pm 0.01$ mm, 0.05% Δ), while the least accurate was the SG ($+0.04 \pm 0.04$ mm, 0.2% Δ).

Width: Significant differences were identified in SG (-0.02 ± 0.03 mm [-0.05% Δ], $p = 0.009$), BA ($+0.01 \pm 0.02$ mm [0.03% Δ], $p = 0.006$) and BB (-0.01 ± 0.01 mm [-0.03% Δ], $p < 0.001$).

Height: The only difference identified was in the SG material ($+0.04 \pm 0.04$ mm [0.1% Δ], $p = 0.002$).

Tube and Thickness Dimensions

Tube Inner Diameter (ID): Differences were identified in the BA ($+0.01 \pm 0.01$ mm [0.15% Δ, $p = 0.03$), BC (-0.03 ± 0.04 mm [-0.47% Δ], $p < 0.0001$) and BB (-0.01 ± 0.01 mm [-0.15%], $p < 0.001$) materials.

Tube Outer Diameter (OD): The SG (-0.03 ± 0.02 mm, -0.3% Δ) and BB (-0.02 ± 0.02 mm, -0.2% Δ) were the only materials with differences ($p < 0.001$ for both).

Tube Height: The only material with significantly different dimensions was the BB (-0.03 ± 0.03 mm [-0.11% Δ], $p = 0.008$).

Thickness: The SG (-0.04 ± 0.03 mm, -1% Δ) and BB (-0.02 ± 0.02 mm, -0.5% Δ) were the only materials with differences noted ($p < 0.001$ for both).

Post-sterilization Dimensional Analysis

Linear Dimensions

A-B: Neither material type nor sterilization method had a significant effect.

B-C: Material type had a significant effect when using steam sterilization only. The SG resin was the least accurate (-0.4% Δ) when compared with the BA ($p = 0.02$), BC ($p = 0.003$) and BB ($p = 0.03$) resins, all of which had a 0% change. The type of sterilization did not have a significant effect.

A-C: Material type had a significant effect when using ethylene oxide sterilization only. The BC resin was less accurate (-0.29% Δ) than SG (0.05%, $p = 0.04$), BA (0% Δ, $p = 0.01$) and BB (-0.05% Δ, $p = 0.005$). Sterilization method affected only the BC resin, with steam more accurate than ethylene oxide ($p < 0.001$).

Width: Material type had a significant effect when using ethylene oxide sterilization. The BW resin was less accurate (0.51% Δ) than SG, BA, BC and BB ($p < 0.001$ for all, range: -0.05% to -0.1% Δ). Similarly, sterilization method had an effect only on the BW material, with steam and hydrogen peroxide gas more accurate than ethylene oxide ($p < 0.001$ for both).

Height: Material had a significant effect for ethylene oxide and peroxide gas. For ethylene oxide, BW was more accurate than BC ($p < 0.001$). For peroxide, BW was less accurate than SG and BB ($p = 0.005$ and $p = 0.04$ respectively). Sterilization method affected only BW with hydrogen peroxide gas showing more accuracy than ethylene oxide ($p = 0.003$).

Tube and Thickness Dimensions

Tube ID: Material had an effect for ethylene oxide only. The BW resin was less accurate (2% Δ) than SG (0% Δ), BA (0% Δ), BC (-0.9% Δ) and BB (-0.16% Δ) with $p < 0.001$ for all. Sterilization method had a significant effect for BC and BW resins. Steam was more accurate for BC and BW than ethylene oxide ($p = 0.01$ and $p < 0.0001$ respectively). Peroxide gas was more accurate than ethylene oxide for BW resin ($p < 0.0001$).

Tube OD: Similar to tube ID, the material had an effect only with ethylene oxide. The SG resin was less accurate (-0.6% Δ) than BA (0% Δ, $p < 0.001$), BC (-0.1% Δ, $p = 0.007$) and BB (-0% Δ, $p < 0.001$). Only the SG material was affected by sterilization method. Similar to other measurements, steam was more accurate than ethylene oxide ($p < 0.001$).

Tube Height: Neither material nor sterilization method had a significant effect.

Thickness: Material type had an effect for ethylene oxide only. The BW resin was less accurate (2.4% Δ) than BA and BB (0% Δ, $p = 0.001$ and 0.2% Δ, $p = 0.02$ respectively. The BW resin was the only one affected by sterilization method, where steam was more accurate than ethylene oxide ($p = 0.02$).

Printing Times, Resin Use, Colour Change

Printing time for six guides (the maximum number of guides which fit on the build platform each printing session) was as follows: SG (4 hours), BA (5 hours, 15 minutes), BC (3 hours, 30 minutes), BW (7 hours, 16 minutes) and BB (5 hours, 20 minutes). The volume of resin used for six guides was similar among all materials (128.3 ± 2.7 mL).

Colour change following sterilization was noted for the SG and BA resins, with steam creating a lighter replica than ethylene oxide or peroxide gas when compared with initial post-print coloration.

Discussion

The results of this study demonstrate that each biomaterial produced highly accurate replicas, with mean post-sterilization dimensional changes for all materials and sterilization methods less than or equal to 0.05 mm. Despite these accurate results, significant differences were noted; therefore, part of the null hypothesis was rejected.

Some dimensional errors due to fabrication were noted. Indeed, pre-sterilization measurements revealed that percentage change was smaller for linear measurements (maximum of 0.2% change vs. a maximum of 1% for the thickness measurements). However, this still reflects highly accurate replicas across resin types. Interestingly, the BW resin failed on several samples to accurately print negative features, one of the measures of accuracy.[32] All other materials printed legible labels. While this would not have a clinical effect, it suggests that the BW resin may be a less desirable choice for surgeons considering the objective results of dimensional analysis for this material. Additionally, the majority of resins trended toward size over-estimation of printed replicas, which is different from other desktop printers and non-biocompatible resins.[6] Other post-sterilization dimensional studies do not directly report on under or over-estimation of measurements, which would be useful information for guide and instrument design. Indeed, while the magnitude of such changes is not likely to be a clinically relevant finding, it could be an important consideration when selecting tolerances in patient-specific guides.

Overall, the BA was subjectively assessed as being the most consistent resin. Out of nine measurements, the BA material produced replicas which over-estimated five, under-estimated one and was an exact match for three of these,

both before and after sterilization. Conversely, the BW resin was most affected by sterilization. Indeed, before sterilization this resin produced replicas with two over-estimated measurements, six under-estimated and one exact match. Following sterilization, these became two, one and six respectively. Furthermore, all tube and thickness dimensions showed an increase in size, which should be considered when designing guides and models. Given these results, one could suggest that the BA resin would be most suitable for institutions using a variety of sterilization protocols. Importantly, the largest absolute difference noted in a single sample for any material or sterilization method was 0.17 mm. This is notably smaller than an earlier report where the largest recorded absolute variation was 1 mm using desktop printers.[6] This may be, in part, due to the difference in model profile between studies. In the current investigation, measurements were comprised of simple geometric shapes, whereas the previous report evaluated a humeral replica with complex geometry. Printer accuracy may be improved with less intricate parts. Additionally, since the materials evaluated in the current study were not directly compared with the resin used in a previous study,[6] the possibility of differences in material accuracy cannot be excluded.

When comparing steam and hydrogen peroxide gas methods, there was no difference in accuracy. However, ethylene oxide overall showed the largest dimensional changes for some materials. Therefore, the second part of our null hypothesis was partially accepted. Of the biocompatible materials evaluated, the only two unaffected by sterilization method were the BA and BB resins. Considering the pre-sterilization observations regarding the high accuracy and consistency of BA replicas, this finding further supports the use of BA for creating patient guides in clinical cases. Additionally, given the concerns of ethylene toxicity,[18] findings of this study may support the use of either steam or peroxide gas to sterilize printed guides or instrumentation. Indeed, previous apprehensions of using steam sterilization for moisture-sensitive materials[15] do not seem to be an issue for the biocompatible materials printed with the Form 3B desktop printer. Finally, from a clinical standpoint, these findings are relevant when considering 3D printed guide use because the two most accurate methods of sterilization (steam and peroxide gas) are also the quickest (20 and 49 minutes respectively). Additionally, steam is inexpensive and more accessible for many hospitals.[12] This means that surgeons could theoretically create a patient-specific guide from a CT scan, print and sterilize it for surgery the same or following day, which may be particularly useful for fracture fixation applications. The use of patient-specific instrumentation in joint replacement surgery could also become more mainstream, given the combined accuracy results from the biocompatible resins reported here and condylar accuracy results from a previous study.[6]

While not directly related to accuracy, printing times and resin volumes should be a consideration in pre-operative planning. Indeed, printing times will affect the rapidity with which guides can be created or surgical planning can be performed. Ultimately, this will determine when a case can be taken to surgery. Less concerning is the volume of resin required to complete the print. However, this becomes important when establishing a charging protocol for clinical cases. Variation in costs between resins is dependent on the additives for each material's composition, research and development costs, certifications and the supply chain (private communication with Formlabs). Since the results of this study indicate the BA resin to be overall the most accurate and unaffected by sterilization, in addition to most affordable, one may suggest this would be the resin of choice when creating patient guides.

Numerous factors have been shown to affect 3D print accuracy including model size, printer and material type, support materials and model orientation on the platform (additional factors such as imaging acquisition were not applicable in this study).[27,33–36] When considering custom guide function, its interface with the surface of the patient should fit as accurately as possible to prevent deleterious movement during surgery. Accordingly, surgeons should orient this surface away from the build platform (and thereby supports) to minimize inaccuracies.[27] While the ideal orientation angle has not been reported, the author typically places parts anywhere from a 25 to 60 degree angle relative to the build platform (depending on the part) to maximize print success and minimize warping, particularly with lengthy specimens. Indeed, van Dal noted parts placed at 0 degrees had more deformations than those placed at 90 degrees.[27] Causes of warping or failed prints vary based on printer type, but for stereolithography machines these are typically the result of 'cupping' in hollow regions that act as a suction cup and trap air while printing.

Some study limitations should be acknowledged. First, specimen blinding was not possible given the study design, and human error is possible. Second, this study evaluated biocompatible resins from one company using one desktop printer. Consequently, these results should not be extrapolated to other materials or printers. Finally, we used a simple method to obtain measurements which is similar to other published reports.[6,35–37] Other methods have been described[38] and future evaluations could consider use of these in their analysis.

This study demonstrated that mock surgical guides 3D printed in biocompatible materials using the Formlabs 3B desktop printer were highly accurate, with mean dimensional change following sterilization less than or equal to 0.05 mm. Furthermore, this study reports on two newly released biomaterials, the BW and BB resins and compares sterilization methods across numerous materials. Additionally, these results indicate that the BA and BB materials retained their dimensions post-sterilization. This suggests that surgeons should feel confident using such materials to create patient-specific instrumentation for use in clinical patients.

Authors' Contribution

D.M.M. contributed to the conception, study design, acquisition of data, data analysis and interpretation. L.M.D. contributed to study design. All authors drafted, revised, and approved the submitted manuscript and are publicly responsible for the relevant content.

Conflict of Interest

None declared.

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