Biomed Amber Sterilization Results

The purpose of this paper is to evaluate the compatibility of Formlabs Biomed Amber Resin with various biological sterilization methods: autoclave, gamma, e-beam, and ethylene oxide sterilization (EtO). Changes in mechanical properties will be presented pre- and post- sterilization. The results presented are intended to help inform potential uses, but should not be used as a substitute for application-specific testing.

Sample Preparation

Printing

All samples were printed on Form 3B SLA printers equipped with clean Build Platforms, Form 3 Resin Tanks and Biomed Amber Resin v1 cartridges. Part orientations and placement were kept constant for all samples.

Post Processing

After printing, testing samples attached to a build platform were washed twice in a Form Wash. The first wash was 10 minutes in <=95% IPA to remove the majority of uncured resin. The second wash was 10 minutes in >99% IPA to ensure removal of any residual uncured resin. Compressed air was used to dry the parts thoroughly. Parts were removed from supports and cured for 30 minutes at 70° C in a Form Cure.

Formlabs Form Wash, Form Cure, and finishing tools were used according to the recommended Instruction for Use to ensure optimal performance and biocompatibility compliance.

Results

Biocompatibility Testing

Printed and post-processed parts were provided to NAMSA for ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity study using the ISO elution method. The results show no evidence of causing cell lysis or cytotoxicity; with 0% lysis detected.

Results and conclusions of the cytotoxicity testing are based on a standard geometry and sample set per ISO 10993-5. Biocompatibility and sterilization compatibility results may vary if there are any deviations from the recommended Instructions for use. Formlabs is not responsible for any biocompatibility results except the one specified in this report. Users are responsible for confirming biocompatibility for their specific application.

Dimensional Testing

Dimensional coupons were printed and post processed using the process described above. The dimensional coupon includes features measuring 1, 4, 9, 27, and 50 mm. After printing and post

processing, the coupons' features were labeled and measured using a calibrated Coordinate Measuring Machine (CMM). These coupons were then sent to vendors for sterilization.

Mechanical Property Testing

Tensile Testing: Tensile bars (ASTM D638 Type I) were prepared as described in the "Sample Presentation" section. The samples were conditioned and tested according to ASTM D638.

Flexural Testing: Flexural bars were prepared as described in the "Sample Preparation" section. The samples were conditioned and tested according to ASTM D790 - Method B.

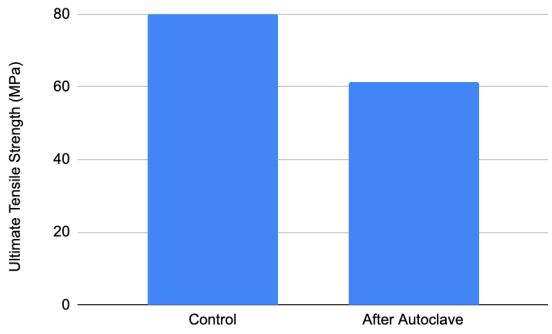
Parts printed and tested under different conditions, such as printer, storage conditions, etc. may produce different results.

Autoclave (Steam) Sterilization

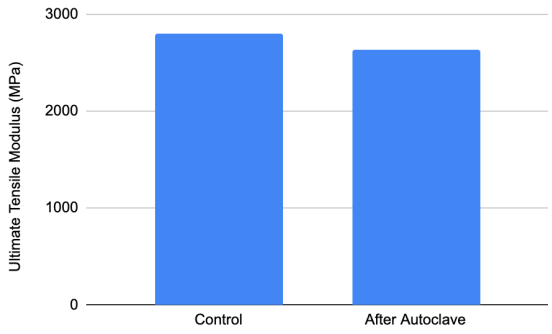
Tensile and flexural bar samples were provided to STERIS for autoclave processing. The parts underwent 5 cycles of pre-vacuum steam sterilization at 132° C with a 4-minute sterilization phase and 30 minutes dry phase. Parts were allowed to cool 30 minutes between cycles.

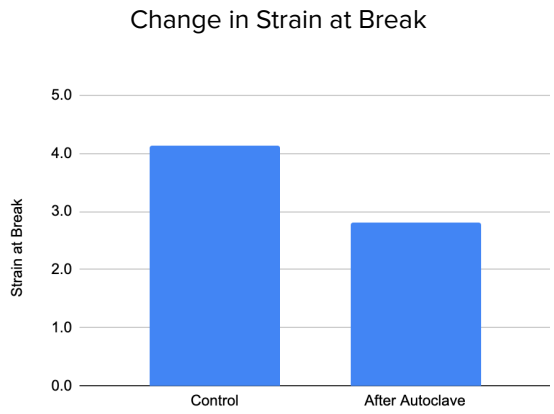
The mechanical property testing below shows the compatibility of Biomed Amber Resin printed parts with autoclave sterilization. No appreciable losses in material properties, deformations, cracking or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.

Change in Ultimate Tensile Strength (MPa)

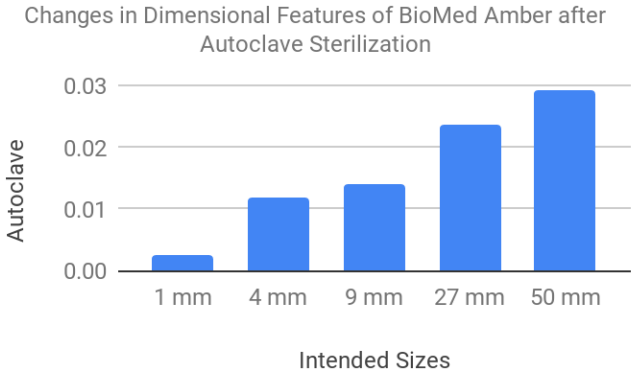


Change in Ultimate Tensile Modulus (MPa)





Dimensional coupons were provided back to Formlabs for dimensional measurements using the same CMM as used in the pre sterilization measurements. The data shows a uniform increase in size across the measured size spectrum. All size differentials were below 100 micron which indicates that autoclave sterilization of Biomed Amber Resin parts is viable for a large number of applications.

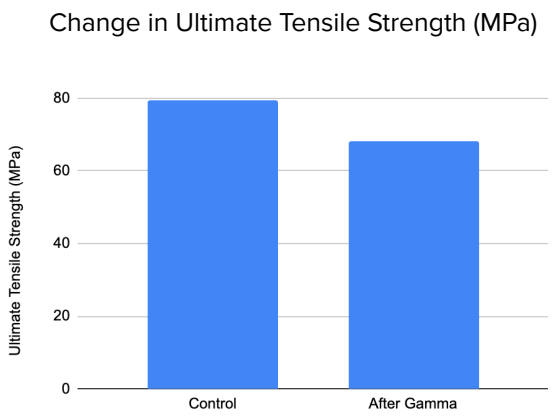


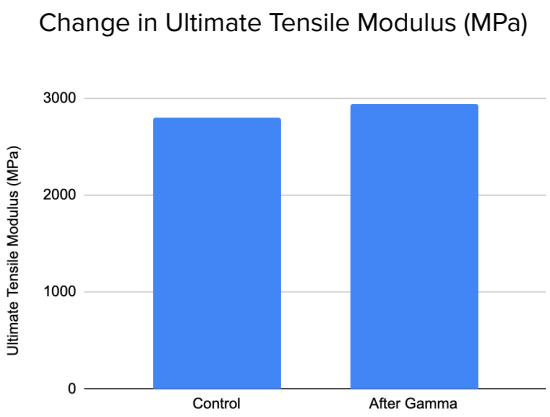
Samples were tested by NAMSA for cytotoxicity per ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity evaluation. The results show that post-autoclave sterilization, there is no evidence of causing cell lysis or cytotoxicity.

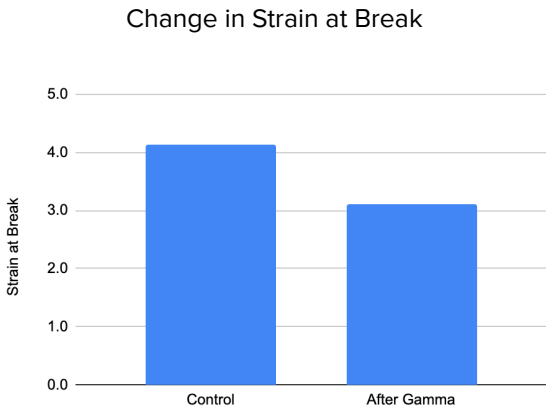
Gamma Sterilization

Tensile and flexural bar samples were prepared and provided to Sterigenics - Rockaway, NJ for Gamma processing. The samples were exposed to 29.4-31.2 kGy of gamma radiation.

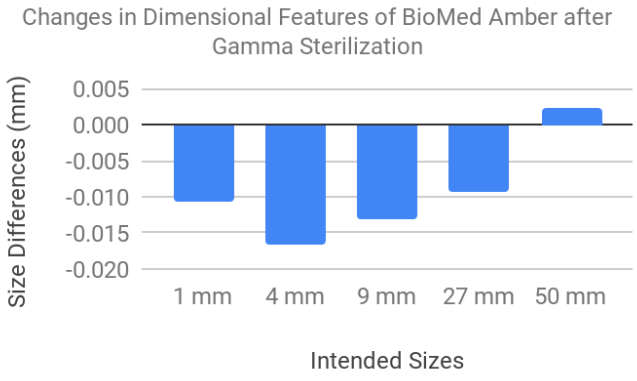
Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Biomed Amber Resin printed parts with gamma sterilization. No appreciable losses in material properties, deformations, or cracking were observed after processing. The material exhibited an increased yellowing after processing. Flexural properties were tested and followed similar trends as tensile testing.







Dimensional coupons were provided back to Formlabs for dimensional measurements using the same CMM as used in the pre sterilization measurements. The data shows a decrease in size for the 1, 4, 9, and 27 mm features, and a very slight increase in the 50 mm feature. All size differentials were below 100 micron which indicates that gamma sterilization of Biomed Amber Resin printed parts is viable for a large number of applications.

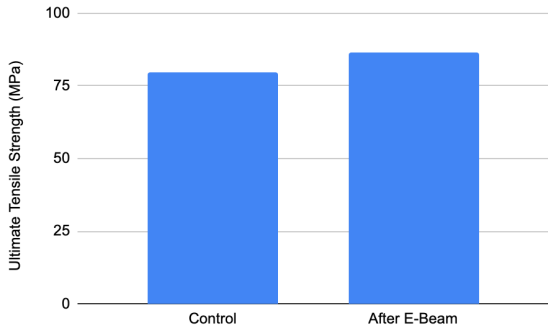


E-beam Sterilization

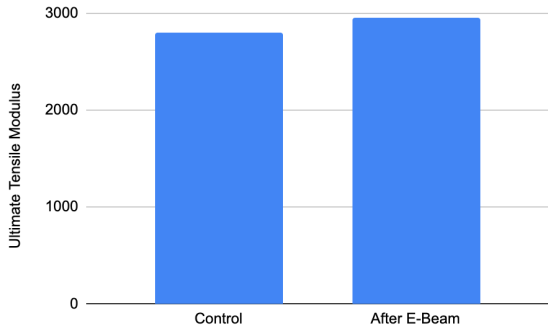
Tensile and flexural bar samples were prepared and provided to Sterigenics - San Diego, CA, for e-beam processing. The samples were exposed to a surface dose of 35 kGy of e-beam radiation.

Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Biomed Amber Resin printed parts with e-beam sterilization. No appreciable losses in material properties, deformations, or cracking were observed after processing. The material exhibited an increased yellowing after processing. Flexural properties were tested and followed similar trends as tensile testing.

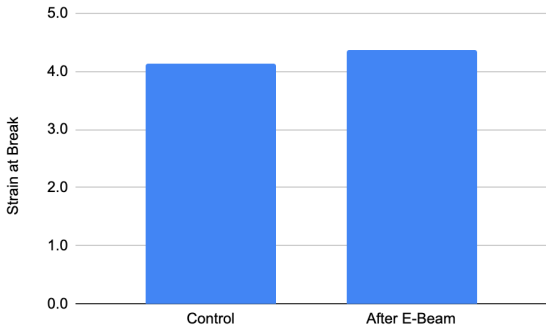
Change in Ultimate Tensile Strength (MPa)



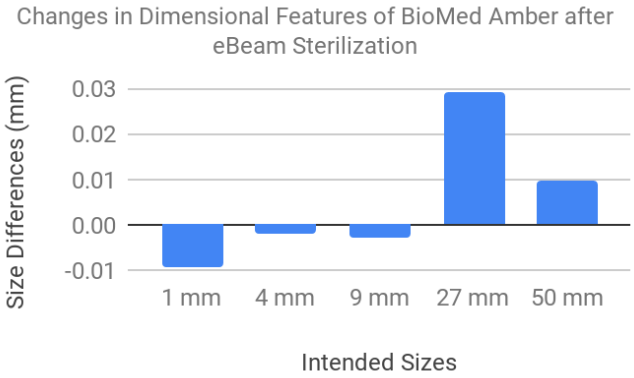
Change in Ultimate Tensile Modulus (MPa)



Change in Strain at Break



Dimensional coupons were provided back to Formlabs for dimensional measurements using the same CMM as used in the pre sterilization measurements. The data shows a decrease in size for the 1, 4, and 9 features, and increase in the 27 and 50 mm features. The variation could represent a random pattern centered around 0 or there could be a more global dimensional mutation (i.e. warping, curling) that gives rise to this size pattern. Additional testing would need to be completed to determine the cause of the variation, however all size differentials were below 100 micron which indicates that e-beam sterilization of Biomed Amber Resin printed parts is viable for most application designs without warping challenges.

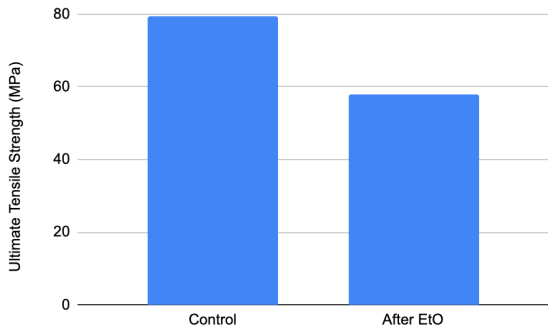


Ethylene Oxide (EtO) Sterilization

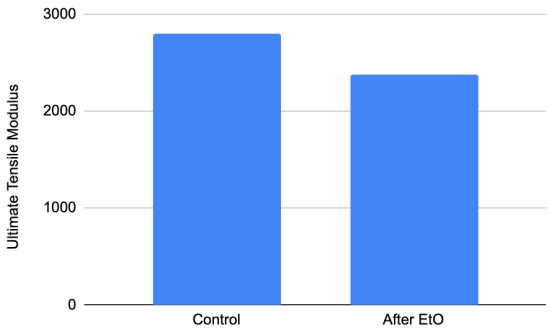
Tensile and flexural bar samples were prepared and provided to Blue Line Sterilization Services for EtO processing. The samples were conditioned at 55°C, 50% relative humidity, and 50 mbar for 78 minutes. The samples were then exposed to a single cycle of 100% EtO at 55°C for 180 minutes.

Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Biomed Amber Resin printed parts with EtO sterilization. No appreciable losses in material properties, deformations, cracking, or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.

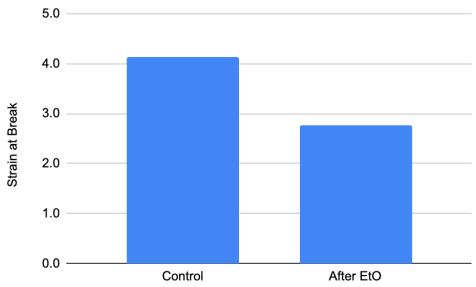
Change in Ultimate Tensile Strength (MPa)



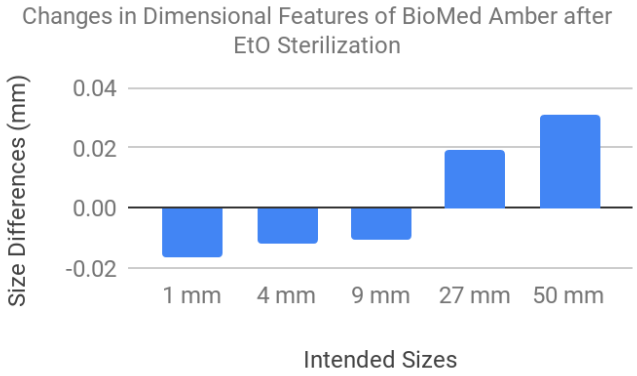
Change in Ultimate Tensile Modulus (MPa)



Change in Strain at Break



Dimensional coupons were provided back to Formlabs for dimensional measurements using the same CMM as used in the pre sterilization measurements. The data shows a decrease in size for the 1, 4, and 9 features, and increase in the 27 and 50 mm features. Similar to the e-beam results, the variation could represent a random pattern centered around 0 or there could be a more global dimensional mutation (i.e. warping, curling) that gives rise to this size pattern. Additional testing would need to be completed to determine the cause of the variation, however all size differentials were below 100 micron which indicates that EtO sterilization of Biomed Amber Resin printed parts is viable for a large number of applications. The effects of part design and geometry on EtO compatibility must be evaluated by the manufacturer based on application needs.



DISCLAIMER: The data presented in this report applies only to the articles tested by Formlabs. Formlabs takes no responsibility for testing completed on customer's products. Biocompatibility, sterilization, and mechanical compatibility results may vary depending on the test conditions and protocol used.