Comparative Effects of Radiation Sterilization Modality on Medical PVC Tubing

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INTRODUCTION

As the production volume of single-use, polymer-based medical devices increases each year, so does the need for throughput capacity to sterilize the devices. Around 80% of radiation-sterilized devices are processed using gamma-ray radiation from industrial cobalt-60 sources. Supply chain, security, and disposal concerns are prompting manufacturers and contract sterilizers to explore alternatives to irradiation using cobalt-60 gamma-rays, such as electron beam (E-beam) and X-ray radiation. Advantages of these 'machine' sources over radioisotope-based sources are that they do not decay, a characteristic that requires cobalt-60 to be replaced over time, they can be turned off when not in use, and they do not represent the same level of concern regarding misuse.

One of the barriers to direct transition from gamma-ray sterilization to E-beam or X-ray sterilization is concern over the relatively unknown effects of sterilization dose of these alternative modalities on the performance of medical device polymers. Commercially available medical devices sterilized with gamma-ray irradiation exhibit acceptable device function, acceptable mechanical performance, and acceptable discoloration. To be viable, alternate sterilization methods must not only achieve acceptable sterilization, but the process must also result in a product with functional, mechanical, and visual effects acceptable to customers and the regulator.

Flexible polyvinyl chloride (PVC) is a plastic material that is commonly found in single-use medical devices and is known for its sensitivity to radiation processing. For instance, transparent PVC is known to yellow upon irradiation. To encouraging sterilization alternatives to cobalt-60 gamma-ray, we directly compared the effects of gamma-ray, E-beam, and X-ray radiation exposure at similar sterilization-relevant doses on key properties of medical grade PVC tubing.[a]

MATERIALS AND METHODS

PVC Tubing

The PVC tubing studied here, pictured in Fig.1, is from the VYSUN product line of Sunlite Plastics. It is a component of the Stryker Instrument MixEvac-III® Bone Cement Mixer (ME3) device used in orthopedic surgery. The ME3 is produced in high volume and is currently sterilized using cobalt-60 gamma radiation.

Radiation Processing

The PVC tubing was carefully removed from ME3 devices either before irradiation or following irradiation for evaluation. The tubing and devices were irradiated to target doses of 15, 25, 50, and 70 kGy using cobalt-60 gamma-ray (Sterigenics, Corona, CA), E-beam (Texas A&M University (TAMU), College Station, TX), and X-ray (Steri-Tek, Fremont, CA)[a] for direct comparison of modality effects. Testing of the tubing commenced no sooner than 1 week following irradiation to avoid dynamic material effects directly following exposure. Samples were stored enclosed in boxes at room temperature prior to testing.

Characterization

Tensile Testing

Standard tensile testing (ASTM D638) of the tubing specimens was performed at TAMU[a] on an Instron 5943 testing machine with testing speed of 200mm/min [1]. Prior to testing, samples were preconditioned at 43% relative humidity and room temperature for at least 48 hrs. Tensile strength, secant modulus, and elongation at break were calculated from the obtained stress-strain curves.

Yellowness Index

Yellowness index (YI), a standard method for quantifying visual color change (ASTM E313), was determined at TAMU[a] using a digital camera, a D65 standard light booth, a standard color pallet, and image conversion [2].

Fig. 1. Photo of PVC tubing from the ME3 device.

[a]The authors gratefully acknowledge: (1) the U.S. Department of Energy National Nuclear Security Administration and Lance Garrison for funding this work, (2) Mark Murphy for leading the Team Nablo that performed the work, (3) gamma sterilization and guidance provided by Rodney Parker and Erick Gustin of Stryker Instruments, (4) X-ray processing and input from Larry Nichols of Steri-Tek, (5) E-beam processing and input from Suresh D. Pillai of the National Center for Electron Beam Research at TAMU, (7) Matt Pharr, David Staack and their TAMU Mechanical Engineering students Md Kamrul Hasan and Min Huang for mechanical and color testing and input.

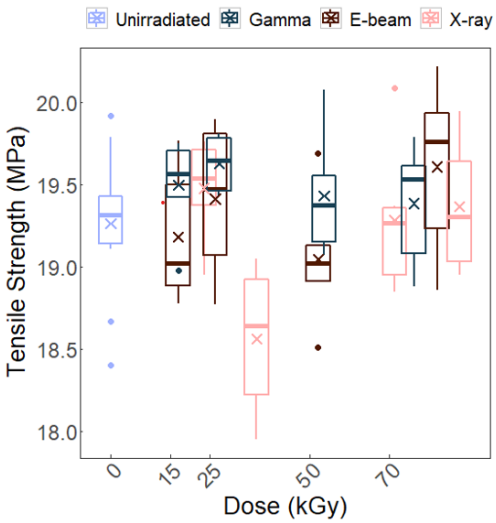

Fig. 2. Tensile strength of PVC tubing.

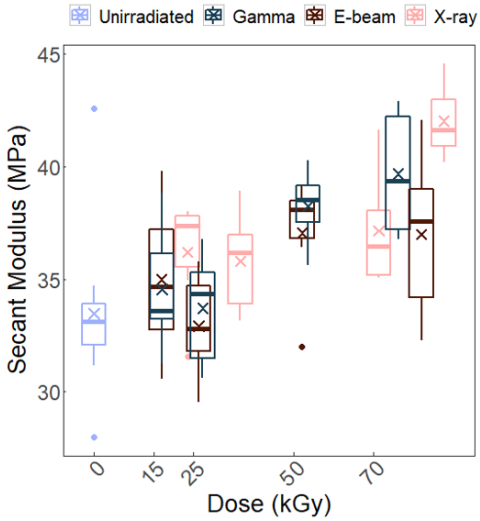

Fig. 3. Secant modulus of PVC tubing.

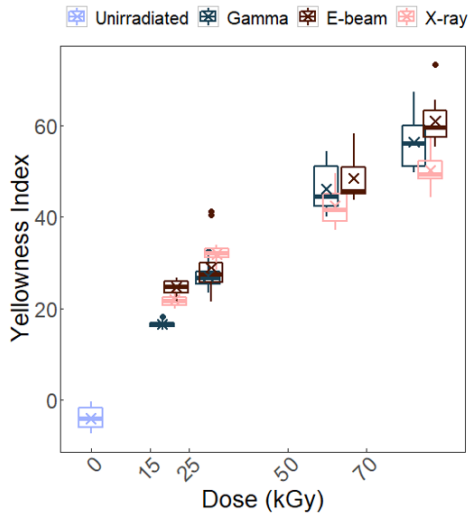

Fig. 4. Secant modulus of PVC tubing.

RESULTS AND DISCUSSION

The tensile strength of the PVC tubing was not observed to vary significantly with irradiation at the doses explored, as shown in Fig.2. Within the scatter of the data points, tensile strength values of irradiated tubing were similar to those of unirradiated tubing other than the anomalous X-ray irradiated specimen at 30 kGy. No clear difference in effects was observed among the modalities.

The secant modulus of the PVC tubing was observed to increase with dose for all three modalities, as seen in Fig.3. However, no statistically significant differences were observed between the results of E-beam or X-ray irradiation and those of gamma irradiation.

The yellowness index of the PVC tubing was also observed to increase with dose for all three modalities, as seen in Fig.4. Small differences were observed between the effects of the modalities, with E-beam and X-ray radiation producing slightly less yellowing than gamma-ray radiation at higher doses.

CONCLUSION

Flexible PVC tubing from a high volume, single-use medical device was studied to directly compare the relative effects of the three investigated sterilization modalities, gamma-ray, E-beam, and X-ray. Tensile strength was not found to be significantly affected by the radiation processing. Conversely, both secant modulus and yellowness index were found to increase with radiation processing for all three modalities. Differences were observed in yellowness index values for E-beam and X-ray processed tubing at higher doses, a slightly more severe effect for E-beam and a slightly less severe effect for X-ray relative to the incumbent gamma-ray radiation processing.

Based on the results observed here of the relative effects of irradiation modality on flexible PVC tubing, E-beam and X-ray appear as viable alternatives to cobalt-60 gamma-ray radiation for sterilization of single-use medical devices.

REFERENCES

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