Cambridge Polymer Group

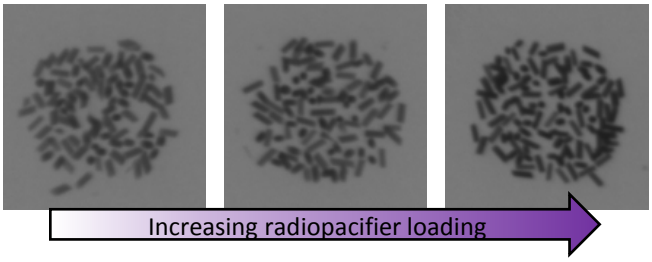
Custom Radiopaque Polymer Formulations

Summary

Polymers are increasingly replacing metallic components in medical devices. From both a cost and manufacturing perspective, polymers present an attractive substitute. Injection molding, extrusion, and now, 3D printing allow for rapid manufacture or customization of polymeric components. In medical applications, however, radiopacity is often a requirement for confirmation of correct device placement or in situ monitoring of position. Polymers inherently have poor radiopacity, as their primary constituent by weight is typically carbon, a relatively low atomic number element. Radiopacifiers such as barium sulfate, bismuth trioxide, and bismuth subcarbonate can be compounded with a polymer resin to enable x-ray detection of polymeric components.

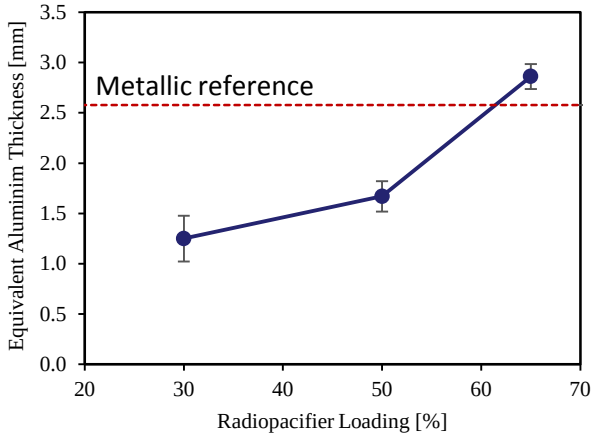
Description

Cambridge Polymer Group (CPG) was contacted for assistance in replacing a non load-bearing metallic element in an implantable medical device with a radiopaque polymer, with the requirement that the radiopacity meet or exceed that of the metallic component. Using a twin screw extruder, CPG compounded polymer formulations with various radiopacifier levels for comparative testing.



Analysis

Radiopacity testing per ASTM F640 Standard Test Methods for Determining Radiopacity for Medical Use was utilized to compare the x-ray attenuation of the custom radiopaque polymers with the metallic component. The radiopacity was quantified based on the difference in pixel intensity between the sample and the background, which was then converted to an equivalent aluminum thickness. At a radiopacifier loading of approximately 65 % by weight, the polymer radiopacity exceeded the metallic component. Improved radiopacity allows for more distinct identification of implanted materials.



Key Points

The properties of polymer resins can be tuned to meet requirements of a specific application through incorporation of various additives, including radiopacifiers, fillers, and stabilizers.

ANALYTICAL TESTING
BIOMEDICAL MATERIALS
MATERIALS CONSULTATION
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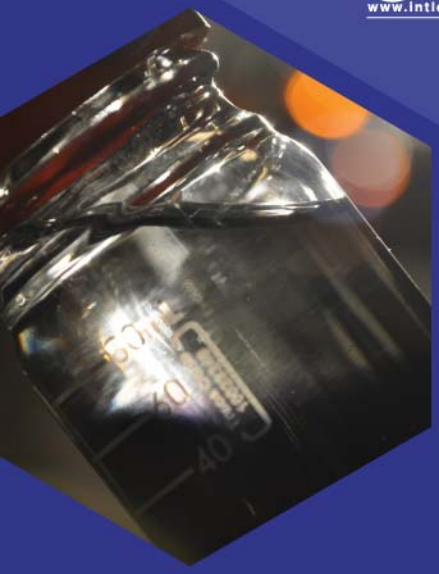

Cambridge Polymer Group, Inc. is a contract research laboratory specializing in materials. We partner with our clients to solve problems utilizing our multi-disciplinary research team and full service laboratory.

We work with clients throughout the product life cycle to:

- Develop new materials
- Design prototypes for proof-of-concept studies
- Create and execute experimental design
- Validate and verify manufacturing processes
- Perform root-cause analysis in product failures

Cambridge Polymer Group, Inc. was founded in 1996 to provide a cost-effective resource for testing, research and development to clients who need periodic access to Ph.D.-level scientists and their support structure. We have developed a host of testing methods and materials for our clients, which number more than 600.

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