Bioresorbable Radiopaque Markers for Visualization of Resorbable Polymer Spinal Implants

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Statement of Purpose

Bioresorbable polymer materials for spinal implants have numerous advantages, including minimizing stress shielding (elastic modulus is comparable to cortical bone), continually increasing load transfer to host bone as resorption occurs with replacement of the implant with remodeled bone. Bioresorbable implants obviate the donor site morbidity of structural autografts, and disease transmission and limited supply issues of allograft tissues. Unlike metals, bioresorbable materials are radiolucent on plain radiographs, and do not interfere with CT or MRI imaging. Therefore visualization of the surgical site is possible throughout the postoperative healing period. It is desirable to assess implant positioning immediately after surgery and postoperatively during healing, and since the implant is resorbable, it is also desirable to use a resorbable, nonmetallic radiopaque marker.

The purpose of this study was to evaluate nonmetallic, non-bone derived radiopaque markers for use with radiolucent bioresorbable implant materials. The markers were evaluated using plain radiography, CT, and MRI scans to assess visualization and any artifact possibly induced by the markers.

Methods

Markers were fabricated from USP grade barium sulfate ($BaSO_4$), a material with a long history of clinical safety in radiographic contrast applications. The markers are dense, consolidated $BaSO_4$, approximately 1.25 mm in diameter. Multiple markers are fully incorporated into the bioresorbable implant allowing radiographic visualization in all dimensions. Incorporation of the $BaSO_4$ markers into the implant does not affect the properties of either the polymer or the marker. Stability of the markers was assessed by in vitro ageing in phosphate buffered saline at 37 °C (ASTM F1635). To evaluate visualization, markers were incorporated into various implant forms made of 70:30 poly(L-lactide-co-D,L-lactide) including plates, screws, and interbody fusion devices. Devices with markers were implanted into cadaveric spines and evaluated using plain radiography. To assess intraoperative visualization, similar devices were evaluated using fluoroscopy (C-arm), and the possibility of artifact induced by the markers was assessed using both CT and MRI scans.

Results / Discussion

Stability of the markers was confirmed by in vitro ageing for time periods exceeding that required to degrade the polymer. The markers are consolidated into a dense spherical shape (not simply compacted powder), and there was no immediate breakdown or "wash out" of the $BaSO_4$ material after contact with simulated body fluid. Visualization of the implant position was achieved using plain radiography, fluoroscopy, and CT scans. The radiodensity of the markers was similar to that observed with metallic markers of equal size. The presence of the $BaSO_4$ induced no artifact in CT or MRI scans.

Conclusions

$BaSO_4$ markers provide visualization of polymer implant location both immediately and throughout the healing time period, and the small marker size does not obscure the healing site. The $BaSO_4$ material eliminates the potential of any long-term effects due to permanent metallic markers. Since the markers are not bone-derived, there is no possibility of disease transmission from human or animal bone sources. Marker degradation by the body´s fluids occurs after polymer degradation, minimizing interaction between the marker and surrounding tissues.

References

ASTM F1635, *Standard Test Method for In Vitro Degradation Testing of Poly(L-lactic Acid) Resin and Fabricated Form for Surgical Implants*.