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Combining Biocompatible Metallic Materials To Optimize Implanted Marker Visualization Across All Imaging Platforms For High Precision Radiotherapy

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Categories: Radiation Oncology
Keywords:

How to cite this poster
Sullivan T A (2013) Combining Biocompatible Metallic Materials To Optimize Implanted Marker Visualization Across All Imaging Platforms For High Precision Radiotherapy. Cureus 5(4): e556.

Abstract

Purpose/Objective: To determine the optimal biocompatible material(s) for an implantable marker that satisfies all of the current requirements for SRS, SBRT and IGRT that is clearly visible across all of the imaging platforms currently used to provide high precision stereotactic radiation therapy. We describe a uniquely distinctive implanted fiducial marker called the FusionCoil that images well across all of these platforms. Methods/Materials: A large variety of combinations of materials were tested for biocompatibility, and image performance. After the testing was concluded we settled on a patent pending combination of pure gold and surgical grade titanium. The final design is an open helix pure gold coil with securely segmented titanium nodes providing flexibility, nonmigrating characteristics and is optimized for visualization across all planning and localization imaging platforms. The marker was first tested for the potential corrosive nature due to the combination of dissimilar metals. Then a battery of imaging studies was performed including CT, MR, US, MV-CBCT, kV-CBCT, MV and kV planer images. Additional MR specific testing is required if the implanted device is to be labeled “MRI Safe”. Finally, (10) patients had this marker and a standard hollow gold coil implanted on the right and left sides of the prostate gland. Results: We utilized MTA Associates in Mt. View, CA to preform the cyclic polarization (ASTM F2129) corrosion testing; the marker did not exhibit any breakdown potential and was deemed safe from a corrosion perspective. The marker was then tested for MR compatibility using four separate tests that measure: - Magnetically Induced Displacement Force on Medical Device - Magnetically Induced Torque - Measurement of Radio Frequency Induced Heating - Evaluation of MR Image Artifacts The marker had acceptable reading for all four tests and was deemed MRI compatible. The marker was then placed in a tissue equivalent phantom and all of the aforementioned imaging studies were performed. The marker is clearly visible in each of the imaging platforms. In all cases (10) where the FusionCoil was implanted on the patient’s left side of the prostate gland it was readily visible for all of the imaging formats used while the hollow gold coil was not visible at all in the MR study. Conclusions: The combination of these biocompatible

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Published 04/05/2013

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materials has proved to produce the optimal implanted marker for all of the imaging formats currently used to plan and deliver image-guided radiotherapy. The marker has been cleared by the US FDA and carries the CE mark.

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