

Design of a head phantom for multi-implant image artefact testing in MRI

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Purpose

Image artefact testing for implantable medical devices currently is a two-step process:

1. Acquire images in an artificial phantom as per ASTM F2119 [1]
2. Acquire images in a human cadaver specimen to allow reporting on clinically relevant images in the safety sheet

Testing with cadaver heads is cumbersome and expensive. The presented research aims to integrate both steps into one by designing an MRI phantom with anatomically relevant features. This phantom can be used for any type of head-based implant.

As a use-case a middle ear hearing implant (Cochlear Ltd., Sydney, AU) and a prototype spinal cord stimulator (GTX medical, Eindhoven, NL) [2] will be used.

Method

A first version of the phantom was constructed with both bone and soft tissue mimicking structures:

- Bone: Skull and cylindrical neck
- Brain: 3D-printed brain model filled with CuSO₄-doped gel to mimic the signal properties of the brain
- Eyes: Silicone filled spheres
- Air-filled structures like the ear canal and the frontal sinuses

This phantom was used for acquiring T1- and T2-weighted images according to ASTM F2119-07 [1]. Implants were mounted in a clinically-relevant position using custom 3D-printed brackets

Currently, this prototype is being revised to contain:

- Bone: Plastic skull, mandible and spine (C1-T3 vertebrae)
- Brain: 3D models of white and grey matter were segmented from an available dataset (Brainweb). Models are hollowed out and 3D-printed to allow filling with a gel.
- No changes to the eyes and air-filled structures

Revised model is expected to allow acquiring images showing the bone, white and grey matter, CSF and the eyes.



Fig. 1: Picture of the first version of the head phantom, showing the skull (brown), brain (black), eyes (white) and implant holders mounted onto the skull (black)

References

- [1] ASTM F-2119-07 (2013)
[2] F. B. Wagner et al., Nature (2018)

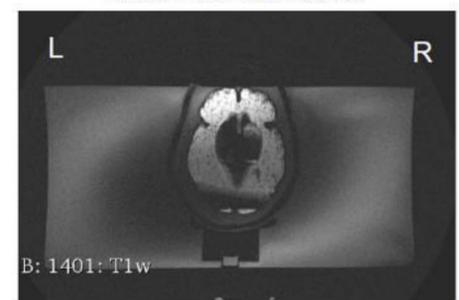
Results

Images were acquired on a phantom implanted with a Cochlear™ Carina® middle ear implant on the left side of the head. The presented T1-weighted image shows both the image artefact induced by the presence of the middle ear implant, as well as the phantom skull and brain.

Images can be acquired using the phantom that render realistic images based on the respective tissue type:

- Bony structures are not visible
- Brain structure provides image contrast similar to white matter both in T1- and T2-weighted images.
- Due to an air pocket inside the 3D-printed brain structure, there was no water in the ventricles creating a signal void in that region.

Axial view reference



Axial view implant

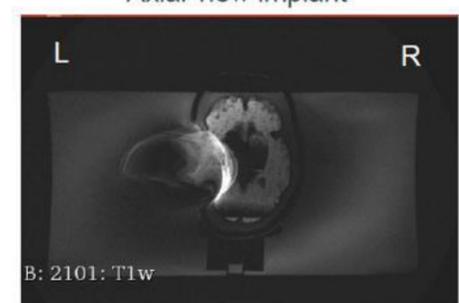


Fig. 2: Reference image (top). Image acquired when the phantom is implanted with a Cochlear™ Carina® implant on the left side of the head (bottom).

Conclusion

A prototype MRI phantom has been constructed that:

- contains both bone and soft tissue structures,
- allows measuring artefact dimensions,
- allows determining the anatomical regions obstructed by the image artefact, removing the need to do separate human cadaver testing.

Future work

Comparative study of the phantom with a cadaver head as a validation of the method.

Recommendation for use in future generations of ASTM F2119.

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