Radiopacity

Introduction

Radiopacity is the ability of a material to impede the passage of x-rays, thus allowing for visibility in an x-ray. This allows for devices to be tracked in vivo during a medical procedure. Radiopacity of a test article can be determined either qualitatively or quantitatively. Qualitative radiopacity compares visibility of a test article to a reference, such as a predicate device. Quantitative radiopacity calculates the difference in pixel intensity between the test article and the reference. Pixel intensity is defined as the greyscale value of a pixel between 0 and 255, with 0 representing black and 255 representing white. The lower the pixel intensity, the higher the radiopacity, and the more visible your device [1]. Evaluating the radiopacity of medical devices is important to the development process since it verifies that the device will be adequately visible during a procedure. **Figure 1** shows an example of the of medical devices arranged on a phantom, which mimics a portion of the body during radiopacity evaluation.

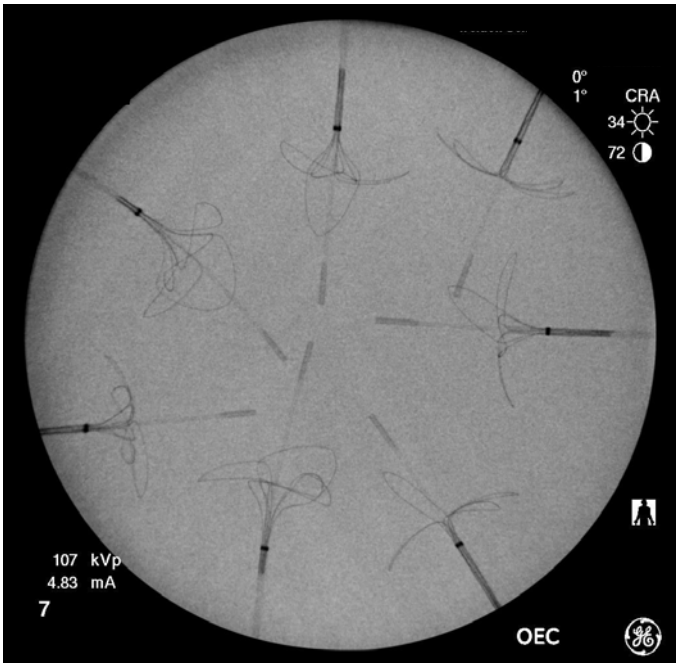

Figure 1. Sample of image used in radiopacity evaluation

Clinical Relevance

Radiopacity of medical devices is applicable in various clinical settings; the most prominent is fluoroscopy. Fluoroscopy is used for procedures in cardiology, gastroenterology, and orthopedic surgery, among others [2]. During fluoroscopic procedures, clinicians have to consider the radiation dose to the patient and the operator from x-ray exposure, while obtaining images of sufficient quality.

Radiation dose, as well as image quality, can be altered by changing the settings for tube current and tube voltage of a c-arm. Tube current is measured in milliamperes (mA) and determines the amount of x-ray photons produced. If there are not enough photons, an x-ray image appears too grainy. Tube voltage is the energy of photons measured in kilovolts (kV) and determines the likelihood that the photons will be absorbed by the patient's body. Additionally, the voltage affects image contrast between types of tissue composition. Increasing either current or voltage will increase patient radiation dose [3].

The patients' physiology and health are another determinant for the c-arm settings. For thin patients, low current and voltage can be used. However for heavy patients, the voltage and current have to be increased to achieve a similar image quality [2]. Additionally, settings vary for different parts of the body. Since image quality will always be further limited by "As Low as Reasonably Achievable" principles, resulting clinical images will rarely be 100% ideal. This means your devices will likely not be imaged under the most optimal settings for visibility in a clinical setting. Through the use of a mass-attenuating body phantom and clinically relevant imaging settings, we can provide a realistic representation of your device visibility.

Our Method

Our lab is ISO17025 accredited in regards to radiopacity testing. We perform both qualitative and quantitative radiopacity evaluations in accordance with ASTM standard F640-12 and can accommodate other standards as needed for your device.

Our Services

At MED Institute, we have the tools and experience to help with your radiopacity evaluation needs. Contact us so that we can work together to make products and therapies that will improve patient outcomes.

If you have any questions or need any additional information, please contact:

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References

[1] ASTM F 640-07. Standard test Method for Determining Radiopacity for Medical Use. March 1, 2007.

[2] W. J. Davros, "Fluoroscopy: basic science, optimal use, and patient/operator protection.," *Techniques in Regional Anesthesia and Pain Management,* vol. 11, no. 2, pp. 44-54, 2007.

[3] C. M. Anderson and E. M. Leidholdt, *An Introduction to Fluoroscopy Safety,* 2013.