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Design and Performance Validation of Phantoms Used in Conjunction with Optical Measurement of Tissue II

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Introduction

This was the second conference on this subject to be held at the annual SPIE Photonics West BiOS Symposium. The first was two years ago (2008). As with the first meeting, this conference demonstrated that phantoms for optical devices are used for a variety of different measurements. For the most part, phantoms remain tools that are fabricated in individual laboratories to perform specific measurements during development or testing of optical devices. A noted exception to this, however, was the information presented by the group from the Institut National d'Optique (INO) in Canada. The group is commercializing fluorescent phantoms in polyurethane. This represents an encouraging move from individually constructed phantoms to commercial product.

So long as optical devices are being constructed and tested as one-of-a-kind instruments in laboratories and local clinical settings, the quality control defining the fabrication of the phantoms associated with the device can be low, without jeopardizing the results obtained by the device. However, when multi-site trials are undertaken, the necessity for several phantoms, each with well characterized and controlled performance characteristics is needed. The invited speaker, Dr. William Mantulin from the Beckman Laser Institute, spoke about the need for QC/QA to create success in providing "data insurance" when multiple devices are used. To quote Dr. Mantulin, "The QC/QA involves systematic assessment of testing materials, instrument performance, standard operating procedures, data logging, analysis, and reporting." This quality control starts with quality control of the phantoms that then provide a level of quality control for the multiple optical devices.

The conference had an exciting international component with seven of the twenty papers coming from outside the United States. These covered a number of different construction concepts and uses. Multi-layer phantoms and phantoms with known inclusions to simulate heterogeneities were presented. Skin simulation imaging and brain tumor simulations were prominent in this conference.

As optical devices progress down the pathway of translational research, issues of standardization and performance validation will have to be addressed. Phantoms will be an important part of that process. Phantoms will be used for both verification and validation. During verification, the investigator is questioning whether the device has been constructed to meet the design specification set forth at the beginning of the project. That is, verification is answering the question "Was the system made correctly?" Validation, on the other hand, is the process of testing if the device makes the intended measurement. That is, "Was the correct system constructed?" These are two

very different questions, and they imply very different levels of phantom construction and quality control. For verification, a number of simple targets can be used, so long as issues such as lifetime, batch homogeneity, and other physical issues are understood. For validation, however, more sophisticated phantoms will be needed to more closely mimic the tissue for which the optical device was designed to interrogate. These will be the challenges for those who create phantoms in the near future.

Robert J. Nordstrom