Phantom-based Performance Test Methods for Evaluating Emerging Photoacoustic Imaging Devices

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Abstract: Photoacoustic Imaging (PAI) is a rapidly emerging hybrid technology that combines pulsed laser excitation and acoustic sensors to enable deep-tissue imaging of light-absorbing molecules, including endogenous hemoglobin and exogenous contrast agents (dyes, plasmonic nanoparticles). Potential clinical applications include breast cancer detection, tissue oximetry, surgical guidance, and tumor margining. While commercial PAI devices are available for preclinical research, no PAI devices have been FDA-approved for clinical use. This may be due in part to a lack of well-validated test methods for objective and quantitative evaluation of device performance. The availability of standardized image quality test methods for PAI would hasten device optimization, clinical translation, and streamline regulatory evaluation. FDA researchers are addressing this need by developing bench tests based on tissue-mimicking phantoms made from novel materials that possess biologically relevant optical and acoustic properties. Image quality phantoms contain arrays of embedded targets inspired by established image quality standards for MRI, CT, and ultrasound. Oximetry phantoms include a series of fluid channels connected to a flow circuit that allows for tunable blood oxygen saturation via a membrane oxygenator. We have developed a custom PAI system with modular hardware and software options and shown utility of these phantoms for assessing and comparing image quality and oximetry measurement accuracy between system configurations. These phantoms are also being proposed as candidate consensus test methods through the International Photoacoustics Standardisation Consortium (IPASC). We have also recently extended these phantoms towards evaluation of detectability and photostability of plasmonic gold nanorod-based contrast agents. The availability of well-validated, consensus-based performance test methods will help ensure U.S. patients have rapid access to safe, effective, and innovative PAI devices.

Biosketch: William C. Vogt received his BS in mechanical engineering from the University of Massachusetts Amherst in 2009 and his PhD in biomedical engineering from Virginia Polytechnic Institute and State University in 2013. Since 2013, he has conducted photoacoustic imaging research at FDA’s Office of Science and Engineering Laboratories. He is also Co-Chair of the International Photoacoustics Standardisation Consortium (IPASC), a community-led effort to promote standardization of PAI performance testing. His research interests include photoacoustic imaging, phantom-based image quality testing, plasmonic nanoparticles, laser-tissue interactions, standardization, and medical device performance evaluation.