

*Woodruff Nuclear & Radiological Engineering and Medical Physics
Programs Seminar*

“Future of Breast Care, Mammographic Screening”

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Thursday, April 2, 2009

Manufacturing Research Center (MARC, Room 114)

(813 Ferst Drive – Corner of Hemphill Avenue/Ferst Drive)

11:00am to 12:00 Noon

REFRESHMENTS WILL BE SERVED

Abstract

Roughly 1 in 10 US Women are afflicted with breast cancer annually. Though this represents a relatively consistent incidence rate, mortality from the diseases has steadily decreased in the developing world. This is largely due to the early diagnosis afforded by national x-ray mammography screening programs. During my Ph.D. at GaTech, my work centered on this area of radiological physics. In the intervening 15 years, x-ray mammography has become standardized and optimized largely by the MQSA of 1994 and technological innovations have been developed and become standardized into typical imaging centers [today](#). The single largest of these innovations has been the digitization of the imaging chain and the obsolescence of film/screen and processor. My employer, Hologic was the first company to successfully launch "Digital Mammography" utilizing amorphous silicon solid state flat panel imagers substituting for the screen/film almost decade ago. [Today](#) the market is 50% converted to digital mammography systems from all major vendors and growing.

Now the industry is looking to an area where digital mammography does not perform as well as it should: younger fibrodense breast patients have a significantly lower sensitivity (<50% in screen/film, <60% in digital) compared to older, non-dense breast patients (> 90% for both screen/film and digital). As other technologies for breast imaging have been introduced to help with this problem (ultrasound and MRI) they too have helped but not to the degree desired. Because while Ultrasound and MRI both improved sensitivity, they also can produce too many false positives (specificity ~ 50%). While the proponents of MRI and Ultrasound are actively attempting to address these issues, the mammography vendors are considering ways to address the original problem, decreased sensitivity in fibrodense breasts, by utilizing x-ray tomography for the breast. A third modality is also being investigated, nuclear medicine, or as it is also known, Scintimammography, SPECT or Molecular Breast Imaging (MBI). Stand-alone MBI created at Mayo Clinic has recently reported not quite the sensitivity of mammography but near perfect specificity (> 95%) which amounts to almost no false positives.

Hologic is currently almost 2 years into an FDA Pre-Market Approval (PMA) process whereby we are the only major vendor attempting to modify the standard X-ray mammography gantry to produce 3D Tomographic images by a process known as Tomosynthesis (Tomo). Tomo works by moving the source and/or detector in a know fashion around the object being imaged and then mathematically reconstructing a 3D image set from the resulting acquisitions. This has never been done clinically in an FDA approved device for any body site. Mammography is potentially the perfect application of this form of Tomography because the breast and the detector both ideally should remain stationary and only the x-ray tube has freedom to move during a routine exam time. While Tomo gains market approval and we understand the improved level of specificity Tomo alone provides, we are expecting that a fused Tomo and MBI machine concept will possibly produce the next new standard in breast cancer imaging, possibly obviating MRI for these patients and providing a one-stop imaging machine for all breast cancer patients.

Biosketch

Kenneth Brooks is the Vice President of New Technology Development at Hologic, Inc. in Boston, MA. He reports to the COO, CTO and Head of Business Development working with research partners and performing due diligence for potential acquisition or commercial interests. He also participated in diligence for Biolucent (\$100MM, 9/07) and Cytoc acquisitions (\$6.3 B, 12/07). Currently he is actively managing several future opportunities by providing technical, clinical and marketing diligence for these potential partners. Additionally, he is working with Marketing and R&D to secure IP positions including creating our own for the markets and products in our roadmap. Ken received his BS, degree in Nuclear Engineering from the University of Tennessee in 1987, his MS degree in Nuclear Engineering from MIT in 1989 and his PhD degree in Medical Physics/Radiological Engineering from Georgia Tech in 1993.