Office of Science and Engineering Laboratories
Excellence in Regulatory Science

MO-FG-209-0: SAM Imaging Education Course

Recent Advances in Virtual Tools for Validation of 3D/4D Breast Imaging Systems

Organizers:
Predrag R. Bakic (U Penn) and Kyle J. Myers (FDA/CDRH)

58th AAPM Annual Meeting & Exhibition, Washington, DC, August 1, 2016

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Motivation for Virtual Tools

- Clinical trials of imaging systems are limited by time, cost, and irradiation of subjects.
- This is especially true for novel 3D/4D x-ray imaging systems
  - large number of design parameters (x-ray spectrum, number of angles, angular range, dose, reconstruction algorithm, etc.)
- Simulation offers advantages over clinical studies in terms of reproducibility, reduced exposure, a known reference standard, and the ability to generate anatomical variations.

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Focus of AAPM TG 234

- www.aapm.org/org/structure/?committee_code=TG234
- The growing interest in the use of Virtual Clinical Trials (VCTs) for the evaluation of breast imaging systems has created a need for consensus on best methods for such simulation studies, including
  - Breast phantom specifications,
  - Simulated data representations,
  - Incorporation of phantoms into models for the imaging process
  - Statistical assessment methods that make use of the simulated images.

Today's symposium will review and discuss the state of the science of VCTs for novel x-ray breast imaging systems.

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Development of a Virtual Breast Phantom from a Multi-Modality Perspective

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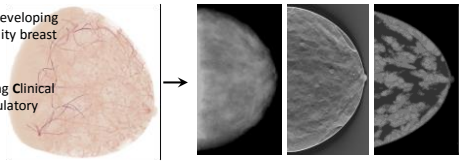
Division of Imaging, Diagnostics, and Software Reliability, OSEL, CDRH, FDA

- Experiences developing a multi-modality breast phantom
- **V**irtual **I**maging **C**linical **T**rials for **R**egulatory **E**valuation



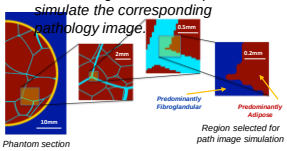
Simulation of Breast Anatomy and Pathology at the Cellular Level

Predrag R. Bakic, Ph.D., ***University of Pennsylvania, Philadelphia, PA***

Performed in 2 stages:

A. Generate a phantom @ radiological scale.

B. Select a region within the phantom & simulate the corresponding pathology image.

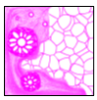


Phantom section @ radiology scale

Region selected for path image simulation

Adipose tissue (AT): Simulated adipocytes

Fibroglandular tissue (FGT): Fibers follow equipotential lines

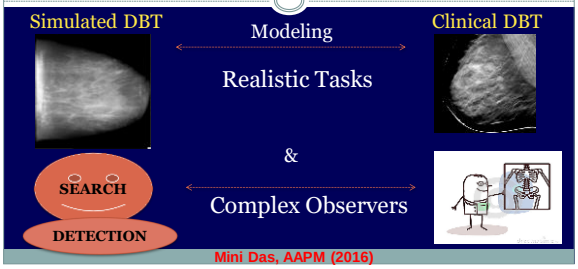


Path image simulated by combining AT & FGT portions

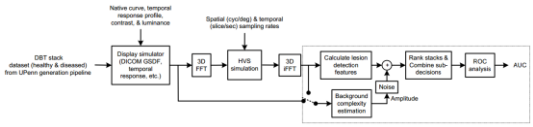
Acknowledgment
Dr. D. Pokrajac, *Applied Math, Delaware State Univ.*
Drs. R. Batiste and M. Feldman, *Pathology, Univ. of Pennsylvania*
Dr. A.D.A. Maidment, Radiology, *Univ. of Pennsylvania*

Perelman School of Medicine
University of Pennsylvania

DBT APPLICATIONS OF A FEATURE ADAPTIVE VISUAL SEARCH MODEL OBSERVER



Current implementation



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Mission

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health.

We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee.

We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

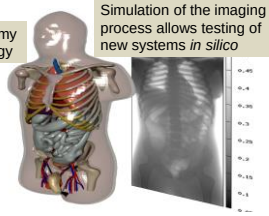
Computational Models for Medical Devices

"Reporting of Computational Modeling Studies in Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff" (issued January 2014).

- Fluid Dynamics and Mass Transport
- Solid Mechanics
- Electromagnetics and Optics
- Ultrasound

Virtual anatomy and physiology

Simulation of the imaging process allows testing of new systems *in silico*



Medical Device Development Tools

- A way for the FDA to qualify tools that medical device sponsors can use in the development and evaluation of medical devices.
- Qualification means that the FDA concurs with evidence that the tool produces scientifically-plausible measurements.
- Draft guidance available at: www.fda.gov/RegulatoryInformation/Guidances

Who will be first to demonstrate the ability to predict the performance of a new imaging system configuration via simulation?

And qualify that tool for public use?

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Medical Device Innovation Consortium
501(c)3 Public-Private Partnership
Members include FDA/CDRH, CMS, NIH, and Medical Device Industry

Computer Modeling and Simulation Project Vision

Quick and **Predictable** access for **Patients** to **Innovative** technologies enabled by Computation Modeling and Simulation as **Evidence** of safety and performance

- Increase Evaluation Confidence
- Faster Market Clearance
- Decrease Cost

The Future of Evidence

MDIC

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PANEL DISCUSSION

- Write down those provocative questions!
- Be a part of the conversation!!