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

Organizers:
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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.

FOCUS OF AAPM TG 234

• www.aapm.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.
Development of a Virtual Breast Phantom from a Multi-Modality Perspective

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- Experiences developing a multi-modality breast phantom
- Virtual Imaging Clinical Trials for Regulatory Evaluation

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

- Adipose tissue (AT): Simulated adipocytes
- Fibroglandular tissue (FGT): Fibers follow equipotential lines

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- Dr. D. Pokrajac, Applied Math, Delaware State Univ.
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- Dr. A. D. A. Maidment, Radiology, Univ. of Pennsylvania

DBT APPLICATIONS OF A FEATURE ADAPTIVE VISUAL SEARCH MODEL OBSERVER

Mini Das, AAPM (2016)
Current implementation

“Towards an anthropomorphic model observer,” Ali Avanaki

Office of Science and Engineering Laboratories
Excellence in Regulatory Science

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Computational Models for Medical Devices


- 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?

Medical Device Innovation Consortium
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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...

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