Disclosures

John Sabol is an employee of GE Healthcare.
This is a scientific review of medical and physics literature on tomosynthesis imaging.
Some applications analysed for this presentation include off-label use of these medical devices. Regulatory agencies do not regulate medical practice, but they do regulate manufacturers. GE does not advocate for off-label use of GE products.
VolumeRAD is cleared by the FDA in the USA, and is intended for generating images of human anatomy including the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Furthermore, for patients undergoing thoracic imaging, it is indicated for the detection of lung nodules. VolumeRAD generates diagnostic images of the chest that aid the radiologist in achieving superior detectability of lung nodules versus PA and LAT views of the chest, at a comparable radiation level.
Competitive technologies, similar to GE’s, exist.
No medical practice recommendations will be given and nothing said should be considered medical advice.
Factors Determining Tomosynthesis Dose

X-ray Beam Quality Factors
- kVp
- Filtration

Angular Exposure Factors
- Change in SID
- Changes in organ dose
- Dynamic collimation
- Changes in scatter

Projection Factors
- Number of projections
- mAs per projection
- Dose Ratio
- Total mAs
- Standard mA range
- System technical limits (e.g., minimum mAs)

Legend
Black: Adjusted by users for each exam
Green text: Set by system

Monte Carlo Dose Simulation
- Use anthropomorphic chest phantom with additional 2.5 cm of Lucite
- Acquire PA and Lateral views to determine standard AEC technique
- Image at 90, 100, 110...150 kVp each with 0.0, 0.1, 0.2, 0.3mm of Cu
- Use 3 different dose ratios (5:1, 8:1, 10:1)
- Measure incident air Kerma (mGy) for all 84 techniques

Monte Carlo Simulations
- Use PCXMC 2.0 Monte Carlo tool
- Calculate effective dose for PA and Lateral Views
- Calculate effective dose for each projection of DTS scan
- Sum for total effective dose for DTS

Acquisition Factors Affecting Dose
- Change in SID
- Change in Collimation
- Variation in mAs
- Total mAs for complete sweep
- Ratio of total tomosynthesis mAs to standard view mAs (Dose Ratio)
**Absorbed Dose for Selected Organs**

![Graph showing absorbed dose for selected organs]

**Lung Nodule Detection Clinical Trial**

**Objectives**

**Primary Aim:**
- Improved Nodule Detection vs. CXR:
  - 3mm - 20mm diameter
  - <0.1 mSv effective dose

**Secondary Aims:**
1. Dual energy increases sensitivity & specificity
2. Increased agreement with CT for case management (actionability based on Fleischner Society recommendations)

**Study Details**
- 184 Subjects enrolled at 4 sites
- Duke University (J. Dobbins, P. McAdams)
- University of Washington (G. Reddy)
- Sahlgrenska University Hospital, Sweden (J. Vikgren)
- University of Michigan (E. Kazarooni)
- 3 ‘Truthers’
- 5 readers
- 3500 image reviews
- ~44000 Data points

**Effective Dose Comparison**

Tomosynthesis requires significantly less dose than CT, same Relative Radiation Level as 2-view CXR

Low Dose Tomosynthesis Techniques

Effective Dose per projection

<table>
<thead>
<tr>
<th>Volume Rad</th>
<th>Total Effective Dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>kVp</td>
<td>5:1</td>
</tr>
<tr>
<td></td>
<td>8:1</td>
</tr>
<tr>
<td></td>
<td>10:1</td>
</tr>
<tr>
<td>100</td>
<td>0.3</td>
</tr>
<tr>
<td>120</td>
<td>0.0</td>
</tr>
<tr>
<td>120</td>
<td>0.2</td>
</tr>
</tbody>
</table>


Thoracic Dose Optimization

<table>
<thead>
<tr>
<th>View Type</th>
<th>kVp</th>
<th>Additional Filtration</th>
<th>Dose Ratio</th>
<th>Volume Rad</th>
<th>Effective Dose per projection</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-View CXR</td>
<td>120</td>
<td>0.3mm</td>
<td>5:1</td>
<td>0.0504</td>
<td>~0.050 mSv</td>
</tr>
<tr>
<td>120 kVp, 0.0mm, 10:1</td>
<td></td>
<td></td>
<td></td>
<td>0.0504</td>
<td>~0.131 mSv</td>
</tr>
<tr>
<td>100 kVp, 0.3mm, 5:1</td>
<td></td>
<td></td>
<td></td>
<td>0.0504</td>
<td>~0.041 mSv</td>
</tr>
</tbody>
</table>

Sinus Imaging and Radiation Dose

- Prevalence of sinusitis is estimated to be ~14% of general population, ~32% in young children
- 31 million individuals diagnosed each year in US
- Definitive diagnosis and treatment recommendations are often based on CT findings
- Increasing recognition of sensitivity of the eye lens to radiation damage
- Radiation cataractogenesis is deterministic with threshold of 0.5 Gy (ICRP ref 482-3093-1464)
Sinonasal Exam Dose Measurement

- Alderson-RANDO phantom scanned covering frontal to maxillary sinus using the clinically routine protocol by MDCT and tomosynthesis
- Measured the dose of internal organs (brain, submandibular and thyroid glands) and on the surface at various sites including the eyes using glass dosimeters

<table>
<thead>
<tr>
<th></th>
<th>MDCT (µGy)</th>
<th>Tomosynthesis (µGy)</th>
<th>MDCT/DT Dose Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>32500 ± 2500</td>
<td>112 ± 6</td>
<td>290</td>
</tr>
<tr>
<td>Skin</td>
<td>20000 ± 9300</td>
<td>1160 ± 2100</td>
<td>17</td>
</tr>
<tr>
<td>Submandibular gland</td>
<td>17000 ± 2300</td>
<td>1400 ± 80</td>
<td>12</td>
</tr>
<tr>
<td>Brain</td>
<td>14300 ± 2200</td>
<td>1770 ± 560</td>
<td>8</td>
</tr>
<tr>
<td>Thyroid gland</td>
<td>1230 ± 160</td>
<td>230 ± 90</td>
<td>5</td>
</tr>
</tbody>
</table>


Clinical Dose and Performance

- 43 Patients
- X-ray (Caldwell and Water’s views)
- Single AP DTS acquisition
- MDCT standard clinical protocol

<table>
<thead>
<tr>
<th>Modality</th>
<th>Effective Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray</td>
<td>29 ± 6 µSv</td>
</tr>
<tr>
<td>Tomosynthesis</td>
<td>48 ± 10 µSv</td>
</tr>
<tr>
<td>MDCT</td>
<td>980 ± 250 µSv</td>
</tr>
</tbody>
</table>


Dose from Abdominal Exams

Mermuys et al, Clinical study of detection of urinary stones: 0.85 mSv for DTS (~1.7 times DR, 7.24% of CT)


Dose from MSK Exams

Two studies of lateral thoracic spine exam

Effective Dose (mSv)

<table>
<thead>
<tr>
<th>Svalkvist</th>
<th>Geijer</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP</td>
<td>0.07</td>
</tr>
<tr>
<td>LAT</td>
<td>0.13</td>
</tr>
<tr>
<td>Scout</td>
<td>0.05</td>
</tr>
<tr>
<td>Tomosynthesis</td>
<td>0.47</td>
</tr>
<tr>
<td>Total T-Spine Exam:</td>
<td>0.57</td>
</tr>
<tr>
<td>CT</td>
<td>6.6</td>
</tr>
</tbody>
</table>

Extremity Dose Results

Noël, A., Ottenin MA, Blum A. et al Nancy Université;

- Study of wrist imaging
- 2 tomo views, 5 conventional radiography views
- Tumo uses 25% of radiographic exam dose
- 20 times lower than CT exam dose

Canella et al Lille FR;

- Clinical study of rheumatoid arthritis of the wrist
- 0.1166 µSv (~2.6 times DR)

R.E. Gazaille, M. Flynn et al Henry Ford Hospital;

- Monte Carlo simulation of hip tomosynthesis
- 0.24 mSv per view, (typical exam of 3 views)
- ~3-4 times dose of radiographic exam dose
- ~10% of CT exam dose

AAPM TG#223

Dosimetry in Tomosynthesis Imaging

Charge: Develop methods to estimate dose from mammographic and radiographic tomosynthesis exams.

- Compute normalized dose data for relevant acquisitions
- Obtain absolute dosimetry values for anthropomorphic phantoms
- Enable routine QC/QA measurements and information that can be communicated by physicist to physician/patient
- Mammography report released Sept. 2014
Body Exam Phantoms and Protocol

<table>
<thead>
<tr>
<th>Location</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head and Neck</td>
<td>PA Caldwell, Table Wallstand</td>
</tr>
<tr>
<td>Sinus/Facial Bones</td>
<td>PA Waters, Table Wallstand</td>
</tr>
<tr>
<td>Thoracic</td>
<td>Lateral, Table Wallstand</td>
</tr>
<tr>
<td>Lateral</td>
<td>PA Waters, Table Wallstand</td>
</tr>
<tr>
<td>Spine</td>
<td>C-Spine, AP, Left Lateral, Table Wallstand</td>
</tr>
<tr>
<td>T-Spine</td>
<td>AP, Left Lateral, Table Wallstand</td>
</tr>
<tr>
<td>L-Spine</td>
<td>AP, Left Lateral, Table Wallstand</td>
</tr>
<tr>
<td>Abdomen</td>
<td>Hip, AP Hip, Proximal Femur, Wallstand</td>
</tr>
<tr>
<td>Abdomen</td>
<td>AP Supine, Wallstand</td>
</tr>
<tr>
<td>Extremity</td>
<td>Knee, PA Bilateral, Wallstand</td>
</tr>
</tbody>
</table>

University of Florida Dosimetry

- Dr. Wesley E. Bolch’s ALRADS Research Group
  - Dr. Elliott J. Stepusin
- UF/NCI Library of Computational Phantoms
  - Hybrid computational phantoms with implicitly modeled lymph nodes and muscle

University of Florida Dosimetry

- Monte Carlo based dosimetry
  - Geometry modeled using custom Fortran 90 source subroutine in MCNPX (v 2.70)
  - University of Florida HiPerGator 2.0 (cloud computing resource) utilized for transport
- Post Processing
  - Organ doses normalized to reference air dose (@ 70 cm)
  - Projection data normalized by field size
Source Subroutine Geometry

Arbitrary Source Location
- Source \((x,y,z)\)

Trapezoid Center \((x,y,z)\)

Trapezoid Width Top

Trapezoid Width Bottom

Exam Modeling Flow Chart

Exam Description
- Used to define FOV
- Based on phantom's organ tags

Raytrace FOV
- Visually confirm the FOV is appropriate for the phantom

MCNPX Inputs
- Automatically generated
- Geometry information saved

Duke University Dosimetry

- Carl E. Ravin Advanced Imaging Labs (RAILabs)
  - Yakun Zhang, Greeshma Agasthya, Jocelyn Hove, Paul Segars, and Ehsan Samei

- XCAT Library of 4D Computational Phantoms
  - Hybrid computational phantoms, each based on its own set of patient CT data, covering a range of ages, heights and weights
Duke University Dosimetry

- Phantom voxel size = 3.45 mm
- Field of View (FOV) calculated to include relevant organs
- Positioning of anatomy was based on
- Monte Carlo Simulation Package: PENELOPE, version 2006
- Post Processing
  - Final organ doses normalized by exposure (mGy/mR)
  - Air exposure simulated in air at 70 cm from source

Abdomen exam 3D dose map

Proposed TG Report Contents

Data will be available for each phantom-exam combination
- Relative organ dose (per starting photon) for each organ at each projection
- Geometry data for each projection of the exam
- Normalization factor for the associated scout scan (dose at 70 cm from scout source)
- Organ doses (per measured dose to air) weighted based on projection geometry i.e. Organ dose for complete acquisition

Adult and pediatric Monte Carlo simulations are underway, at Duke and Florida – results to come!

Summary

The dose of body tomosynthesis exams is:
- Dependent on numerous acquisition factors that include:
  - The same factors that impact projection x-ray (spectra, technique etc)
  - Angular exposure factors (changes in SID, dynamic collimation, scatter)
- Total dose from all views is comparable for tomosynthesis and projection radiography for most exams
  - In a clinical trial, a chest tomosynthesis acquisition required ~2% of the dose of CT, comparable to a two-view x-ray exam
- More understanding, accuracy, and consistent reporting is required
  - AAPM TG#223 will provide data for research and clinical communication
Thank you, and thanks to many colleagues
for sharing of cases and data, collaborations, and helpful discussions

AAPM TG#223 Members
Dr. Myung Jin Chung, Samsung Medical Center, Seoul Korea
James DeBnis III, Duke University
Dr. Ali Guermazi, Boston University
Dr. Michael Lipkin and Rajan Gupta, Duke University
Dr. Haruhiko Machida, Tokyo Women's Medical University
Ioannis Sechopoulos, Radboud University Nijmegen Medical Center
The VORTEX Trial Team: D. Chakraborty, E. Kazerooni, P. McAdams, G. Reddy, & J. Vikgren,
Toshiyuki Yuhara, Tokyo Women’s Medical University

Gerhard Brunst, Katelyn Nye, Nahush Rao, Dharmandra Naskar, Rowland Saunders, GE Healthcare