Innovations and Applications of Tomosynthesis

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Acknowledgements of Support

- Grant support from the Komen Foundation, DOD, NIH, and Hologic.
- Dr. Maidment is a scientific advisor to and shareholder of Real Time Tomography, LLC.
- Dr. Maidment is a member of the Scientific Advisory Board of Gamma Medica, Inc.

FDA Statement

 This presentation will include off-label uses and applications and devices not yet approved for human use in the United States.

Tomosynthesis Pedigree

Linear Tomography



Simple Tomosynthesis



Acquisition geometry

Backprojection image formation

22 deg.

11 deg.

3 deg.



45 Views

23 Views

12 Views

6 Views

Computed Tomography



Breast Tomosynthesis



Courtesy J. Boone

Tomosynthesis Reconstruction

Sampling geometry



- → sampling is incomplete (in Fourier space)
- approximative inversion only
- artifacts

Siemens Medical Solutions that help

<u>B.3 - 3D spatial frequency domain</u>

 ω_z

<u>CT</u>

Modern Multi-slice VCT scanners have nearly isotropic response with maximum spatial frequencies of .8 to 1.0 cycles/mm



O,

 ω_{x}





Maidment et al. SPIE 6142 Physics of Medical Imaging 2006



Tissue Imaging



Angular Spacing, $\Delta \theta = 2^{\circ}$

Courtesy M.J. Yaffe

Dose Determines Lesion Detectability



Determinants of Dose



Projection Factors

- Number of projections
- mAs per projection
- Technical Limitations (det./gen.)

Tomosynthesis



Mammogram



Clinical applications

- Breast
- Chest
- Muskuloskeletal
- Head and Neck
- Angiography
- Dental imaging
- Radiation therapy

Breast Imaging

Hologic Selenia Dimensions Tomosynthesis



- 2D and 3D Imaging under same compression
- W Tube with Rh, Ag and Al Filtration
- 15 degree continuous sweep, 15 images, 3.7 s acquisition
- 200 mA generator, 0.1/0.3 mm focal spot
- 70 cm source-to-detector distance
- Retractable High
 Transmission Cellular grid
- 24 x 29 cm Selenium Direct Detector, 70 µm pixels

GE Senoclaire Tomosynthesis



- 2D or 3D Imaging under one compression
- Mo/Rh Tube with Mo and Rh Filtration
- 15 degree step and shoot sweep, 9 images, 9 s acquisition
- Grid to reduce scatter
- 24 x 30 cm Csl Indirect Detector, 100 µm pixels
- Iterative Reconstruction

Siemens Mammomat Inspiration With True-Breast Tomosynthesis



- Mo/W Tube with Mo and Rh Filtration
- 50 degree continuous sweep, 25 images, 25 s acquisition
- Retractable grid, with optional digital scatter removal software (mammo)
- 24 x 30 cm Selenium Direct Detector, 85 µm pixels



LMLO



Tomosynthesis Slice (Z = 24mm)

Invasive Carcinoma

Courtesy of Tao Wu, Ph.D.



Tomosynthesis Mammography Reconstruction Using a Maximum Likelihood Method





Invasive Ductal Carcinoma









Pooled ROC curves for 2 reader studies



Area under the ROC curve						
	DM	DM [†] plus Tomo	Difference	p-value	95% CI	
Reader Study 1	82.1	89.4	7.2	< 0.001	3.7, 10.8	
Reader Study 2	82.8	89.5	6.8	< 0.001	4.1,9.5	

Using probability of malignancy scores; curves represent average ROC performance for 12 readers in study 1 and 15 in study 2.

Rafferty E A et al. Radiology doi:10.1148/radiol.12120674

Radiology

Recall rates for individual readers



Case Type	Reader Study	Recall Rates (Average of Readers)						
		DM			DM plus Tomo			
		Mean	Range	SD	Mean	Range	SD	
Non- Cancer	1	55.1%	22.3% - 79.8%	16.3%	16.7%	7.6% - 28.4%	7.6%	
	2	48.8%	28.2% - 69.1%	12.3%	30.1%	19.8% - 41.3%	7.6%	
Cancer	1	87.2%	77.0% - 100%	6.5%	80.4%	64.6% - 93.8%	8.8%	
	2	84.8%	76.0% - 92.2%	6.1%	85.7%	78.0% - 92.2%	6.4%	

Rafferty E A et al. Radiology doi:10.1148/radiol.12120674



University of Pennsylvania 2010: 2D Mammo 2011: Combo-Tomo

Sept 2010-Sept 2011: 10814 patients Call- Back Rate: 10.33%

Cancer Detection Rate: <u>4.25/1000</u>

Sept 2011-Sept 2012 **11115 patients**

Call- Back Rate: **8.77**%

Cancer Detection Rate: 5.58/1000

Group Call-Back Rates (CBR) by Month



Cancer Detection Rate (cancers/1000)



CBRs pre and post Tomo implementation



Tomosynthesis Screening Outcomes

Individual CBR varied significantly

- 2010-11 (pre-tomo): from 5.5 to 15.5%
- 2011-12 (post-tomo) : from 4.4 to 12.2%

All Readers reduced their CBR

Reduction was not based on initial CBR or years in experience

• Group CBR went from 10.33 to 8.7%

- Largest reduction was from 8.5% to 5.8% (=31.2%)
- Smallest reduction was from 12.6% to 12.2% (=3.8%)

When controlled for variable reader volumes, OR = 1.24 (p=0.004) Therefore, the call-back rate decreased by 24% with DBT

		Mammography Alone					
Radiologist	Years of Experience*	False-Positive Rate [†]	Cancer Detection Rate [†]	No. of Known Cancers‡	Detected Cancers (%)§	No. of Patients	
1	8	110.7 (80)	6.9 (5)	6	83.3	723	
2	21	62.2 (175)	4.6 (13)	24	54.2	2812	
3	2	83.3 (131)	4.5 (7)	12	58.3	1573	
4	31	39.5 (64)	11.1 (18)	24	75.0	1622	
5	29	45.2 (106)	4.7 (11)	19	57.9	2346	
6	10	53.8 (78)	6.2 (9)	15	60.0	1451	
7	20	71.8 (67)	4.3 (4)	5	80.0	933	
8	6	60.3 (70)	8.6 (10)	16	62.5	1161	
All		61.1 (771)	6.1 (77)	121	63.6	12621	

		Mammography Plus Tomosynthesis						
Radiologist	Years of Experience*	False-Positive Rate ⁺	Cancer Detection Rate [†]	No. of Known Cancers‡	Detected Cancers (%)§	No. of Patients		
1	8	73.6 (46)	11.2 (7)	8	87.5	625		
2	21	68.3 (119)	7.5 (13)	15	86.7	1743		
3	2	55.3 (82)	4.7 (7)	9	77.8	1483		
4	31	44.4 (78)	5.1 (9)	10	90.0	1758		
5	29	52.7 (147)	13.3 (37)	43	86.0	2790		
6	10	50.6 (71)	5.7 (8)	14	57.1	1402		
7	20	52.4 (71)	8.9 (12)	14	85.7	1355		
8	6	38.2 (56)	5.5 (8)	8	100.0	1465		
All		53.1 (670)	8.0 (101)	121	83.5	12621		

Radiology

Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program, **Radiology**, **P**ublished online before print January 7, 2013
Pooled ROC by Lesion Type





ROC curves for average probability of malignancy



Zuley M L et al. Radiology doi:10.1148/radiol.12120552



Digital mammography image of an invasive ductal carcinoma.





Tomosynthesis image of an invasive ductal carcinoma.





Pooled ROC by Lesion Type







Visualization of micro-calcifications





Simulated pattern of clustered µCas (Pattern: Big Dipper and Pole Star)



Distribution along z-direction

Conventional mammography:

- Clustered µCa are projected onto a 2-D plane.
- The pattern of µCa distribution is obvious.
- The pattern of µCa distribution contains important diagnostic information.



Visualization of micro-calcifications









"Slab View" for showing clustered µCa:

- Combine multiple slices into a "slab"
- Maximum intensity projection (MIP) within the slab
- Slide the "slab window" through the reconstruction





Visualization of micro-calcifications





DBT reconstruction (1 mm slice)



Visualization of micro-calcifications





Slab View: 10 mm slab

Average Glandular Dose in Digital Mammography and Breast Tomosynthesis

Mittlere Parenchymdosis bei der digitalen Mammografie und der Brusttomosynthese

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Average Breast Thickness – 55 mm

Results – MGD and Thickness & Glandularity



Digital Mammography:

 MGD is dependent on <u>both</u> thickness and glandularity (p<0.001)



Tomosynthesis:

 MGD is dependent on thickness (p<0.001) but not glandularity (p=0.11)



Synthesized 2D





Synthesized 2D

True 2D

2D vs 3Ds

Hologic FDA data:

- 302 subjects
- 15 readers
- 3Ds superior to 2D alone
- △AUC = 0,04 (p=0.005)
- Recall Rate reduced by 30.2%



Mode	FFDM Views	DBT Views	Synthesized Views	Exam Dose per Breast
FFDM	MLO + CC	-	-	2.4 mGy
FFDM + 3D MLO	MLO + CC	MLO	-	3.85 mGy
FFDM + DBT	MLO + CC	MLO + CC	-	5.3 mGy
DBT + Synthesized 2D	-	MLO + CC	MLO + CC	2.9 mGy

Other Issues

- Reimbursement
- Computer-aided diagnosis (CAD)
- Automated density estimation (Quantra)
- Tomo-guided procedures

Thoracic Imaging



Experimental System



Computer-controlled tube mover
GE flat-panel detector
Matrix inversion tomosynthesis reconstruction algorithm (Duke)

Digital Tomosynthesis



Conventional tomography

Tomosynthesis

Images Courtesy J. Dobbins

Routine follow-up; history of breast Ca with right partial mastectomy

20-degree tube angle, 61 projection images, 5 mm slice spacing Total tomo exposure ≈ Lateral image exposure (screen film)



Analysis of the impact of digital tomosynthesis on the radiological investigation of patients with suspected pulmonary lesions on chest radiography



Emilio Quaia et al.

Eur. Radiol 2012

CXR	0.06 mSv (0.03 – 0.10 mSv)
Tomosynthesis	0.11 mSv (0.09 – 0.12 mSv
СТ	3.0 mSv (2-4 mSv)

Clinical Study of 339 Patients

Tomosynthesis is almost 30 times lower dose than CT

Pulmonary Mycobacterial Disease: Diagnostic Performance of Low-Dose Digital Tomosynthesis as Compared with Chest Radiography¹

Eun Young Kim, MD Myung Jin Chung, MD Ho Yun Lee, MD Won-Jung Koh, MD Hye Na Jung, MD Kyung Soo Lee, MD

Purpose: To compare the diagnostic performance of a low-radiationdose digital tomosynthesis (DTS) technique with that of conventional radiography in the detection of lung lesions in patients with pulmonary mycobacterial disease.

Materials and Methods: The institutional review board approved this study, and all patients provided informed consent. In this study, 100 patients (65 study patients, 35 control patients) underwent multidetector computed tomography (CT), chest radiography, and low-dose DTS (effective doses: 3.4, 0.02, and 0.05 mSv, respectively). Two radiologists evaluated radiographs and DTS images for the presence of parenchymal lesions and the number of cavities in each patient; CT served as the reference standard. Wilcoxon signed rank and McNemar tests and κ statistics were used.

Results:

The accuracies of DTS and radiography in depicting mycobacterial disease were 97% and 89%, respectively, for observer 1 (P = .039) and 99% and 93%, respectively, for observer 2 (P = .031). The accuracies of DTS and radiography in depicting each lesion type were, respectively, 95% and 77% for bronchiolitis, 92% and 76% for nodules, 86% and 79% for consolidation, and 93% and 70% for cavities. Interobserver agreement with DTS ($\kappa = 0.62-0.94$) was superior to that with radiography ($\kappa = 0.46-0.62$). Of a total of 141 cavities found with CT, means of 27 (19%) cavities at chest radiography and 108 (77%) cavities at DTS (P < .01) were detected by the two observers.

Conclusion:

DTS performed with a low-dose technique is superior to radiography for the detection of lung lesions in patients with pulmonary mycobacterial disease.

^oRSNA, 2010

 Tuberculosis causes ~3 million deaths/yr globally

- Leading cause of death in HIV/AIDS population
- CXR is routinely used for detection but lacks both sensitivity and specificity
- Tomosynthesis showed statistically significant increase in sensitivity compared to CXR, without significant change in specificity

Radiol. 2010 257:269-277

¹ From the Department of Radiology and Center for Imaging Science (E.Y.K., M.J.C., H.Y.L., H.J., K.S.L.) and Division of Pulmonary and Critical Care Medicine, Department of Medicine (M.J.K.) Samsung Medical Center, Sungkyunkwan University Schol on Medicine, 50 Nuon-dong, Cangnam-gu, Socul 135-710, Korea. From the 2009 HSNA Annual Meeting, Received February 7, 2010; revision requested April 12, revision received April 25, accepted May 7; final version accepted May 19, Address correspondence to M.J.C. (e-mail: In: Inchang @asamurg.com).

© RSNA, 2010

BINAL RESEARCH

More Dose Studies

- M. Bath, *et al.*,
 - RPD 139: 144-152, 2010; RPD 139: 153-158, 2010
 - Clinical and simulation studies
 - Ave. tomosynthesis dose: 0.13 mSv
 - 2% of average Chest CT dose
- Y. Yamada, et al.,
 - Inv. Radiol 46: 471-477, 2011
 - Monte Carlo simulation based on 120 patients
 - Ave. tomosynthesis dose: 0.22 mSv

Muskuloskeletal Imaging

Muskuloskeletal Imaging

- Like radiology,
 - weight-bearing imaging is possible
 - multiple projections are necessary
 - new projections may be needed
 - Ideal for metal implants and hardware
 - Doses are relatively low
- Like CT,

- Superposition is largely eliminated





- The Shimadzu Sonialvision / Safire system integrates the digital detector within a radiographic tilt table.
- Shown in the tilt position for a lateral knee tomosynthesis acquisition (60°), the detector translates up and the x-ray tube moves downward.
- The x-ray central beam is directed at the joint surface with an angle that varies from -20 to +20 degrees



Nearly matched coronal planes from reformatted 3D CT (GE)









<u>B.3 - Frozen Cadaver – Tibial Plateau</u>

Nearly matched coronal planes from reformatted 3D CT (GE)





Shimadzu TS





Radiograph shows no obvious osteophyte in the right lateral femur (arrow).

Tomosynthesis demonstrates osteophyte

MRI also shows focal cartilage defect

Hayashi D et al. Radiology 2012;263:206-215









B.3 - Proximal Femur - ? Fx

reformatted coronal planes 3D CT (GE VCT, 64)



Standard



B.3 - Proximal Femur - ? Fx

Tomosynthesis Shimadzu Sonialvision/safire II



AP View

60-30 View

Multiple TS views are often used to obtain detail in planes of different orientation



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<u>B.3 - Reduced metal artifacts</u>



Delayed Union, Femoral Fractures



Coronal CT

Coronal Tomosynthesis



63-year-old man with RA show three erosions (arrows) of the second metacarpophalangeal joint



Canella C et al. Radiology 2011;258:199-205



Other Tomosynthesis Dose Studies

Gislasson, King, Elbakri, and Reed, Winnipeg Children's Hospital:

- Tomosynthesis in pediatric spine, knee, facial, imaging
- 2-10 times dose of radiographic exam dose
- ~2-16% of CT exam dose
- Tomosynthesis dose less than total DR dose for some exams

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

Hayashi, Guermazi et al Boston University:

- · Clinical study of bilateral knee imaging
- 0.0072 mSv for DTS (~4X DR)

Mermuys et al :

- Clinical study of detection of urinary stones
- 0.85 mSv for DTS (~1.7 times DR, 7-34% of CT)

Canella et al Lille FR:

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



Gislasson et al, "Dose Assessment of Digital Tomosynthesis in Pediatric Imaging", Proc. of SPIE Vol. 7258, 72585V, 2009

R. E. Gazaille et al, "Technical Innovation: Digital Tomosynthesis of the Hip Following Intra-articular Administration of Contrast", **Skeletal Radiology 40**, 1467-1471, 2011

Hayashi et al, "Detection of Osteophytes and Subchondral Cysts in the Knee with Use of Tomosynthesis" Radiology 263:206–215, 2012

K. Mermuys et al, ""Digital Tomosynthesis in the detection of urolithiasis: diagnostic performance and dosimetry compared with digital X-ray using MDCT as a reference"" AJR **195**:161–167, 2010

Canella et al, "Use of Tomosynthesis for Erosion Evaluation in Rheumatoid Arthritic Hands and Wrists" Radiology 258:199–205, 2011

> J.M. Sabol, Ph.D. AAPM 2012 July 31, 2012

Head and Neck Imaging

European Journal of Radiology 81 (2012) 1140-1145



Contents lists available at ScienceDirect

European Journal of Radiology

RADIOLOG

journal homepage: www.elsevier.com/locate/ejrad

Radiation dose of digital tomosynthesis for sinonasal examination: Comparison with multi-detector CT

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Acute Maxillary Sinusitis



Tomosynthesis Image

MDCT MPR Coronal Image

Tomosynthesis in upright position delineates air-fluid level in left maxillary sinus

	MDCT (µGy)	DT (µGy)	MDCT/DT dose ratio
Еуе	$32,500 \pm 2500$	112 ± 6	290
Skin	$20,000 \pm 9300$	1160 ± 2100	17
Submandibular gland	17,000 ± 2300	1400 ± 80	12
Brain	$14,300 \pm 2200$	1770 ± 560	8
Thyroid gland	1230 ± 160	230 ± 90	5

- Sinusitis prevalence
 - 14% in general public
 - 32% in children
- 31 million diagnosed each year
- CT is definitive
- CT lens dose is high (33 mGy)
- Cataractogenesis has a deterministic threshold of 0.5 Gy



Comparison of Clinical Dose

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

Average	X-Ray	Tomosynthesis
Sensitivity	50%	79 %
Specificity	86 %	94 %
Accuracy	76 %	89 %



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Future Directions

Super-Resolution

Acquiring multiple low resolution images at sub-pixel spacing generates a high resolution (i.e., super-resolution) image.





Bar Pattern Phantom



The reconstruction can clearly distinguish frequencies higher than the detector alias frequency $0.5a^1$ (3.6 lp/mm). This ability is not present in acquiring the central projection alone.

Clinical Super-resolution



4x Mag

4x Super-resolution

Oblique Reconstructions



Oblique Reconstructions

Pitch 0°

Pitch 45°



Despite the backprojection artifacts, the reconstruction can clearly resolve the input frequency within the mid-thickness of the sine plate at both pitches.

Clinical MPR



Recon. at 0° Pitch





Recon. with 35 µm voxels at 0° pitch



Recon. with 35 µm voxels at 30° pitch

Clinical MPR





Recon. with 35 µm voxels at 0° pitch

Translation of Recon. Plane at 30° pitch

Hologic Prototype CE-DBT System



Target	W
kVp	49 (HE) / 32 (LE)
Filter	Cu (HE) / Al (LE)
SID	70 cm
Detector	3 fps, 2x2 binning
Angular Range	15°
Scan Time	7.3 seconds

- Separate calibrations for LE and HE images
- Manual technique, no AEC
- DE subtraction factor k derived from CIRS Model 20 BR3D phantom









Advantages of tomosynthesis

- Improves conspicuity by removing overlying structures
- Permits section imaging with high resolution in coronal view
- Easily performed on the high volume of radiography patients
- Lower radiation dose compared with CT
- Lower cost compared with CT
- Excellent platform for quantitative imaging

Special thanks to

- J. Boone
- E.F. Conant
- J.T. Dobbins
- L. Fajardo
- M. Flynn
- Z. Jing, T. Wu
- D. Kopans
- T. Mertelmeyer
- J. Sabol

UC Davis U of Pennsylvania **Duke University** U of lowa Henry Ford Hospital Hologic Mass. General Hospital Siemens GE

SAMs

- 1. Derive the central slice theorem from first principles
- 2. Prove that tomosynthesis demonstrates super-resolution using discrete and continuous integration
- Given the dose at the orthogonal ray, formulate a closed form approximation for the dose at all other obliquities

Q1: How does the radiation dose of tomosynthesis compare to other imaging modalities?

- 1. Slightly less than radiography
 - 2. Equal to radiography

2%

- 93% 3. Slightly more than radiography
- 4. Equal to computed tomography
- ^{1%} 5. More than computed tomography

Answer:

3. Radiation dose of tomosynthesis imaging is slightly higher than the dose for a comparable radiograph. The small increase in dose is necessary to overcome the impact of detector readout noise arising from acquiring multiple projection images.

H. Machida, T Yuhara, et al. Radiation Dose of Digital Tomosynthesis for Sinonasal Examination: Comparison with Multi-Detector CT, Eur J Radiol 81, 1140-1145, 2012

Q2: CT and tomosynthesis images are acquired as a series of projections. How does a projection image sample the Fourier domain of an object?

20%	1.	A line in the Fourier domain
55%	2.	A plane in the Fourier domain
18%	3.	A double-napped cone
<mark>7%</mark>	4.	It fully samples the Fourier domain

Answer:

2. A projection image samples a single plane in the Fourier domain. The greater the number of projections made, the more completely the Fourier domain is sampled.



J. Zhang, C. Yu, A Novel Solid-Angle Tomosynthesis (SAT) Scanning Scheme, Medical Physics, 37(8), 2010

Q3: How does spatial resolution of tomosynthesis compare to CT?

3%	1.	Poorer x, y, and z resolution
9%	2.	Poorer x & y resolution; better z resolution
7%	3.	Better x, y, and z resolution
81%	4.	Better x & y resolution; poorer z resolution
0%	5.	Same x, y, and z resolution

Answer:

 Like linear tomography, the x and y resolution of tomosynthesis is comparable (or superior) to radiography, and substantially superior to CT. The penalty of tomosynthesis is poorer z resolution than CT.

Acciavatti RJ, Maidment ADA. Observation of Super-Resolution in Digital Breast Tomosynthesis. Med Phys. 2012;39(12):7518-39.

Q4: The radiation dose in tomosynthesis is determinedly primarily by which factor?

- 18% 1. Body part thickness
- 1% 2. Angular range
- 27% 3. Number of projections
- 4. Number of reconstructed images
- 54% 5. Angular range AND number of projections

Answer:

 Like radiography, tomosynthesis dose is primarily determined by body part thickness. Dose does NOT depend upon the number of images reconstructed. Dose depends only minimally upon the number of images acquired (detector noise) or angular range (obliquity).

T. Olgar, T Kahn, and D. Gosch, Average Glandular Dose in Digital Mammography and Breast Tomosynthesis, Rofo, 2012

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