Tomosynthesis: Is It What It's Stacked Up To Be?

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DISCLOSURES

L Fajardo

- Member, Scientific Advisory Board – Hologic, Inc
- Consultant, Siemens Tomosynthesis Reader Study
- Consultant & PI, FUJI Tomosynthesis Trial

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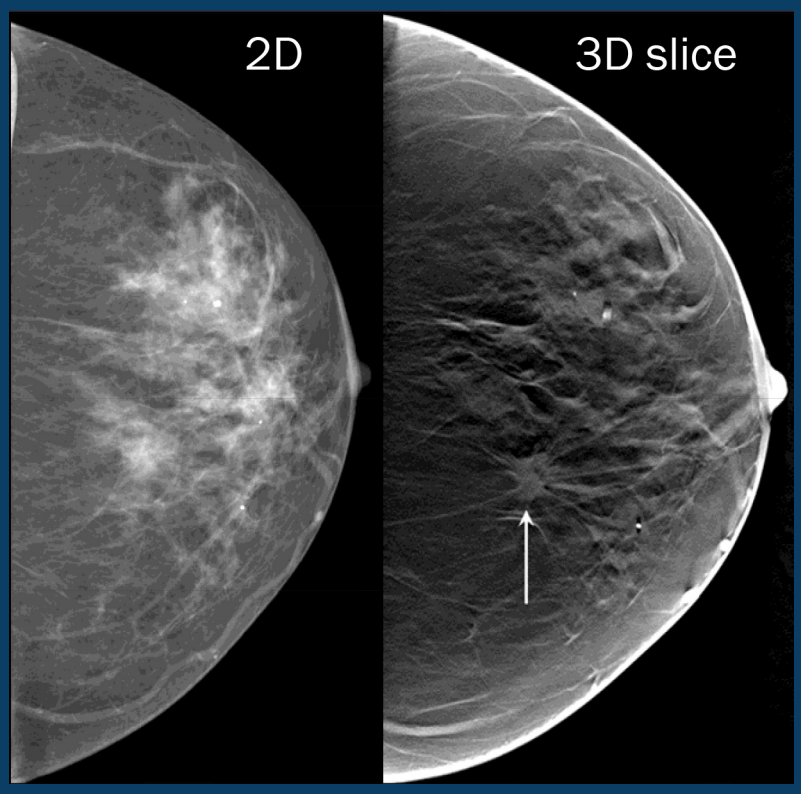
Outline

- Technology
- Clinical Trials & Economic Analysis
- Tomosynthesis (3D MG) Impact on
- Clinical Practice
- “Synthetic” 2D MG
- The Future



TECHNOLOGY

- • Hologic - approved
- • General Electric - approved
- • Siemens - submitted
- • Fuji – pivotal trial

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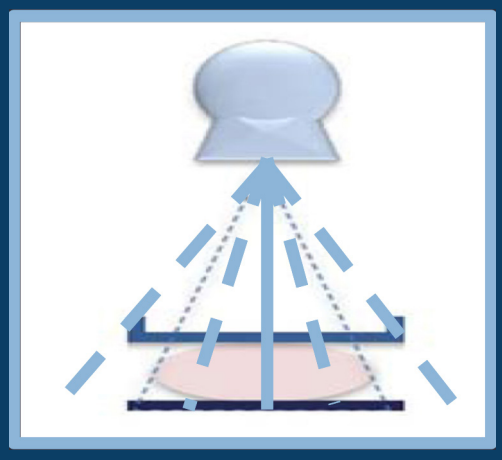
3D Basics: System Engineering &

HOLOGIC

- Amorphous selenium detector
- 150 acquisition; 15 projection images
- Continuous tube movement
- 4 sec acquisition
- No grid for 3D; retractable grid for 2D
- Original FDA approval for screening: 2D DM CC/MLO + 3D CC/MLO
- “C-View” now approved for screening: 2D SM CC/MLO + 3D CC/MLO
- 2D pixel size: 70µ
- 3D reconstructed pixel size: depends on paddle size used (95µ or 117µ)
- Reconstructed slice thickness: 1mm



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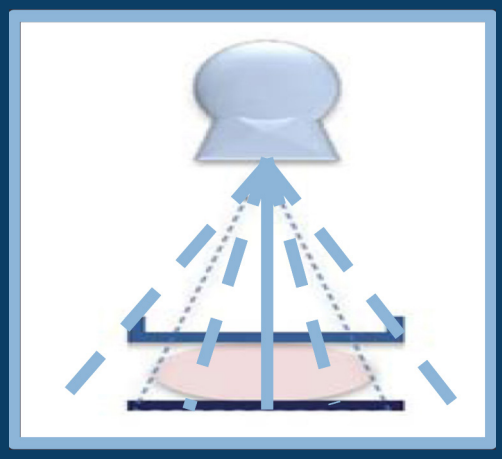

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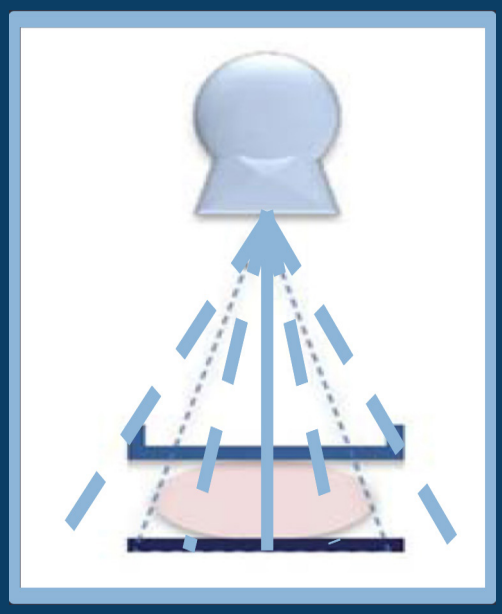
3D Basics: System Engineering & Physics

General Electric -

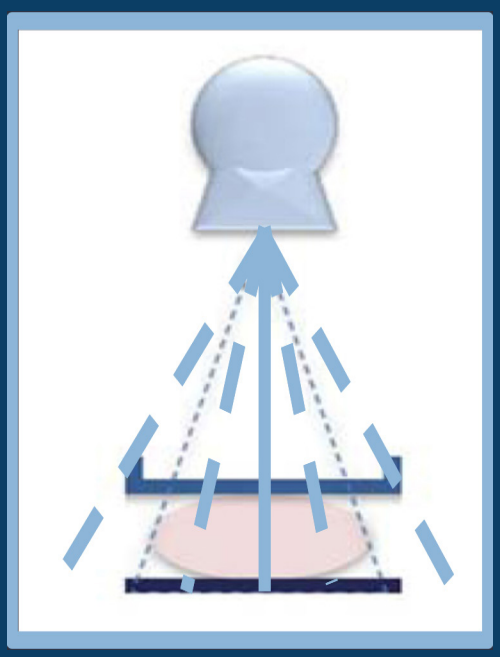
- Amorphous silicon; TFT read-out
- 250 acquisition; 9 projection images
- Step/shoot tube movement
- 10 sec acquisition
- 3D grid for TOMO
- FDA approval for screening: 2D DM CC + 3D MLO
- 2D pixel size: 100µ
- 3D reconstructed pixel size: 100µ (no binning)
- Reconstructed slice thickness: 0.5 or 1mm



3D Basics: System Engineering & Physics

SIEMENS - Not approved by FDA

- Amorphous selenium detector
- 50˚ acquisition 3D system acquires 25 projection images
- continuous tube movement
- 22 sec acquisition
- 2D pixel size: 85µ
- 3D reconstructed pixel size: 85µ
- Reconstructed slice thickness: 1mm
- No grid



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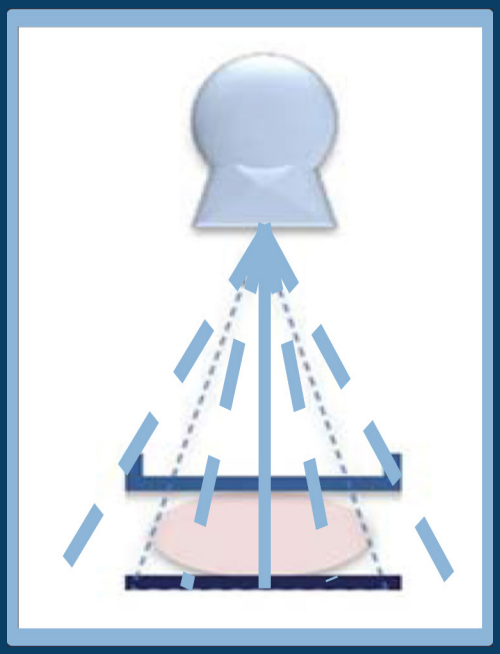
3D Basics: System Engineering & Physics

FUJI - Not approved by FDA

- Amorphous selenium detector
- 15˚ (St) (15 projection images) or 45˚ (HR) (15 projection images)
- Continuous tube movement
- 4 sec/11 sec acquisition
- Grid for TOMO
- St & HR modes with L/N/H dose modes
- 2D pixel size: 50µ
- 3D reconstructed pixel size: 100µ
- (St – binned)/(HR ? 50µ)
- Reconstructed slice thickness: 0.5 or 1mm



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CLINICAL TRIALS DATA

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Clinical Trials
Major European Prospective Trials

STORM Trial: Ciatto 2013[1]

Cancer detection increase: 51%

Decrease in false positives: 17%

Oslo Trial: Skaane 2013[2]

Cancer detection increase (overall): 27%

- Invasive cancer detection increase: 40%

Decrease in false positives : 15%

Study Population: 12,631 women

[1] Ciatto S, Houssami N, Bernardi D, Caumo F, Pellegrini M, Brunelli S, Tuttobene P, Bricolo P, Fantò C, Valentini M, Montemezzi S, Macaskill P. Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. Lancet Oncol 2013 Apr 24.

[2] Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, Izadi M, Jebsen IN, Jahr G, Krager M, Niklason LT, Hofvind S, Gur D. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. Radiology 2013

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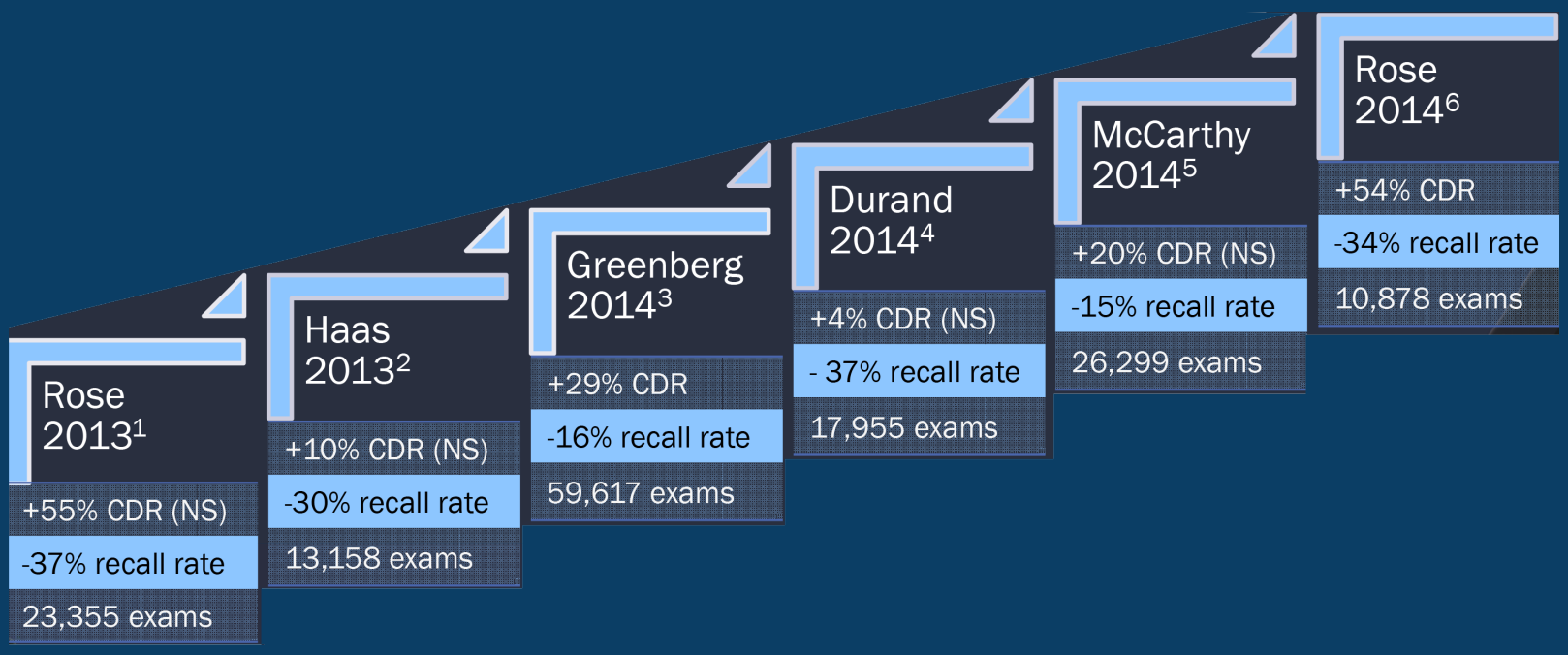
Publications from U.S. Trial Sites



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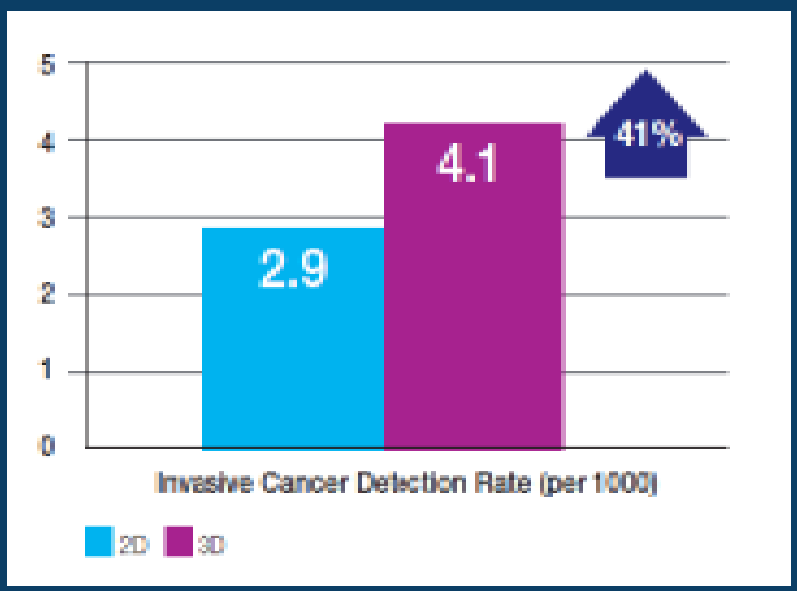
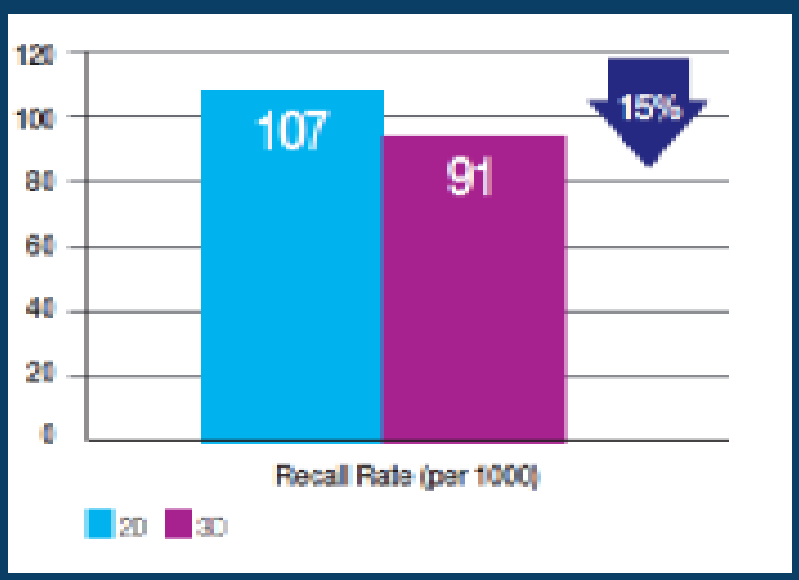
Clinical Evidence
Friedewald et al (JAMA 2014)[1]

- Multicenter: 13 sites, 139 radiologists
- Comparison of 454,850 exams
  - 281,187 DM alone (1 yr prior to BT implementation)
  - 173,663 DM + Tomo (3-22 months)





[1] Friedewald SM, Rafferty EA, Rose SL, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. *JAMA* 2014;311(24):2499-2507

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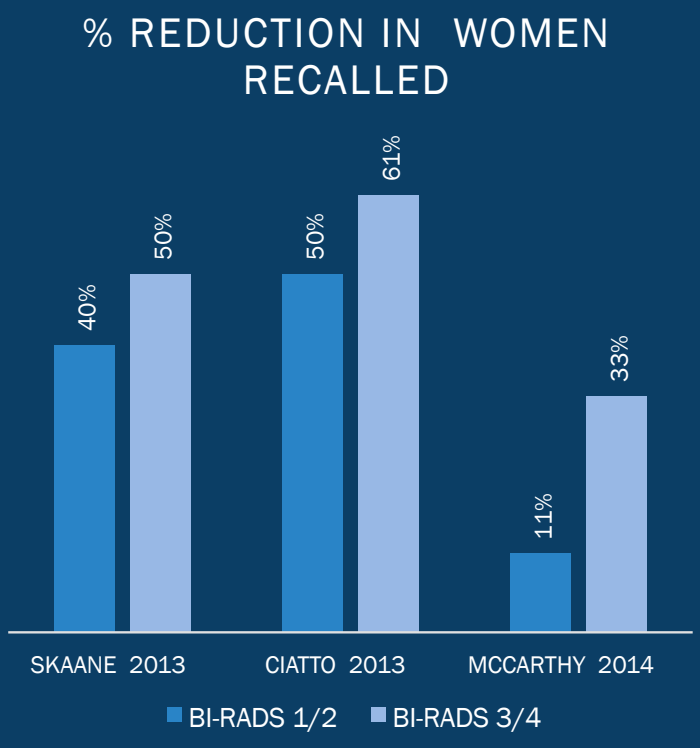
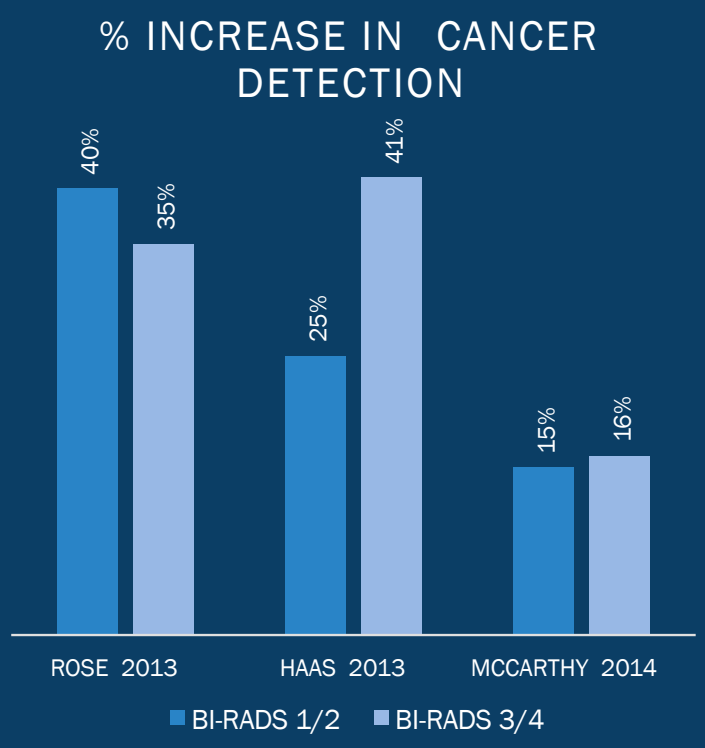
BT Effective Across All Breast Densities





[1] Skaane P, Bandos AI, Gullien R, et al. Radiology. 2013

[2] Ciatto S, Houssami N, Bernardi D, et al. Lancet Oncol. 2013 Apr 24.

[3] McCarthy AM, Kontos D, Synnestvedt M, et al. Journal of the National Cancer Institute. 2014;106(11)

[4] Rose SL, Tidwell AL, Bujnoch LJ, Kushwaha AC, Nordmann AS, Sexton R. AJR 2013;200(6):1401-1408.

[5] Haas BM, Kalra V, Geisel J, Raghu M, Durand M, Philpotts LE. Radiology. 2013;269(3):694-700.

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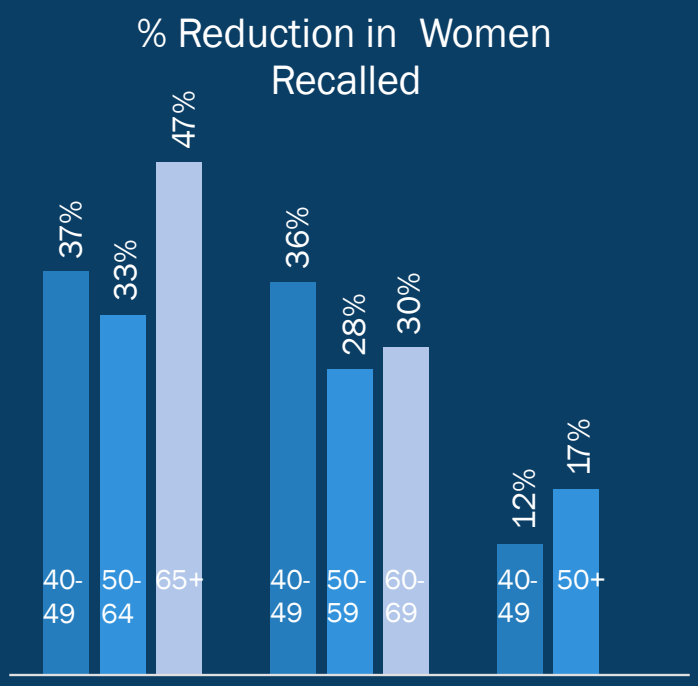
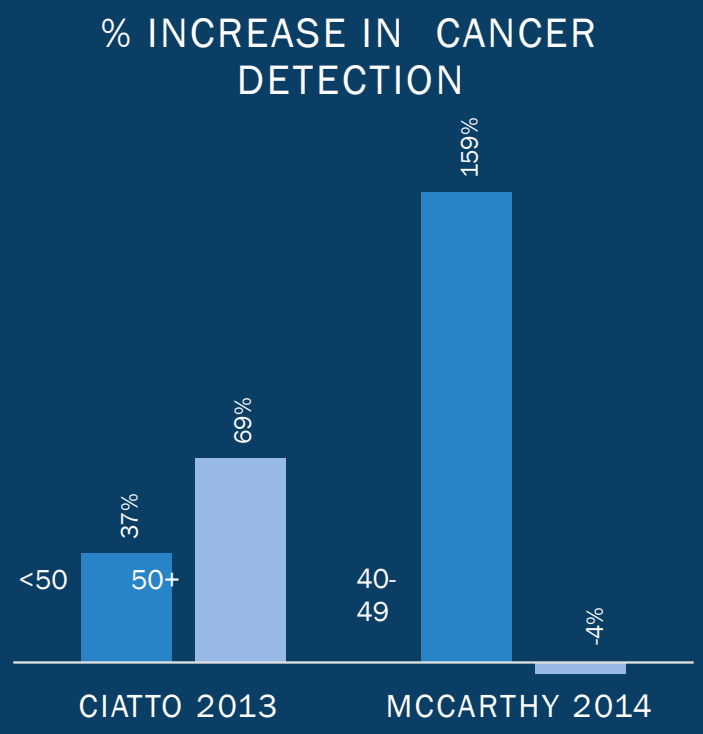
BT Effective Across All Age Ranges





[1] Rose SL, Tidwell AL, Bujnoch LJ, Kushwaha AC, Nordmann AS, Sexton R. AJR 2013;200(6):1401-1408.

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[4] Ciatto S, Houssami N, Bernardi D, et al. Lancet Oncol. 2013 Apr 24.

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ECONOMIC ANALYSIS

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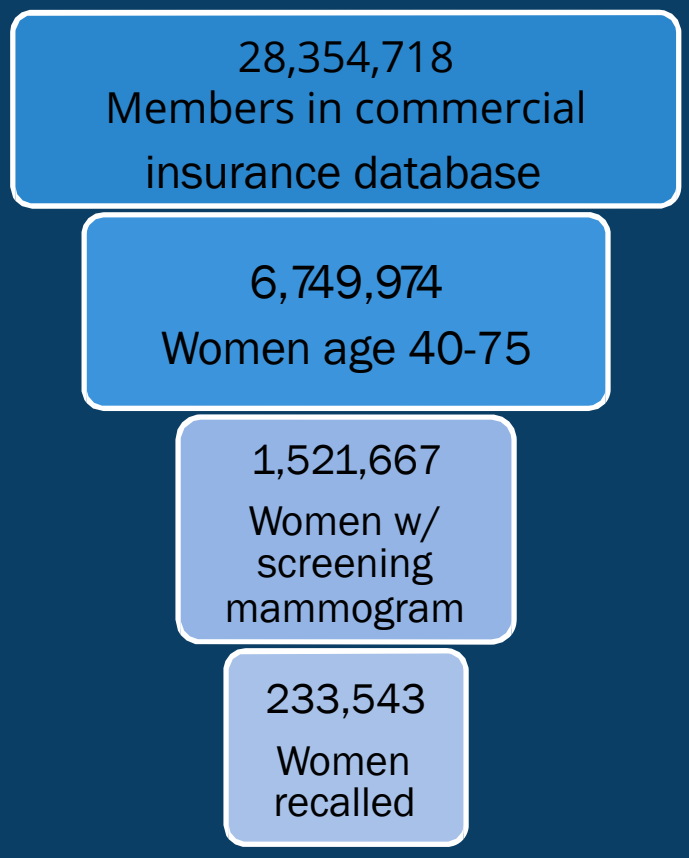
BT Economic Analysis
Bonafede et al (2015)[1]

- Goal
  - Model the financial impact of BT within a hypothetical US commercial health plan
- Data sources
  - Claims database
  - Published literature



[1] Bonafede MM, Kalra VB, Miller JD, Fajardo LL. Value analysis of digital breast tomosynthesis for breast cancer screening in a commercially-insured US population. *ClinicoEconomics and Outcomes Research*. Jan 2015;7:53-63.

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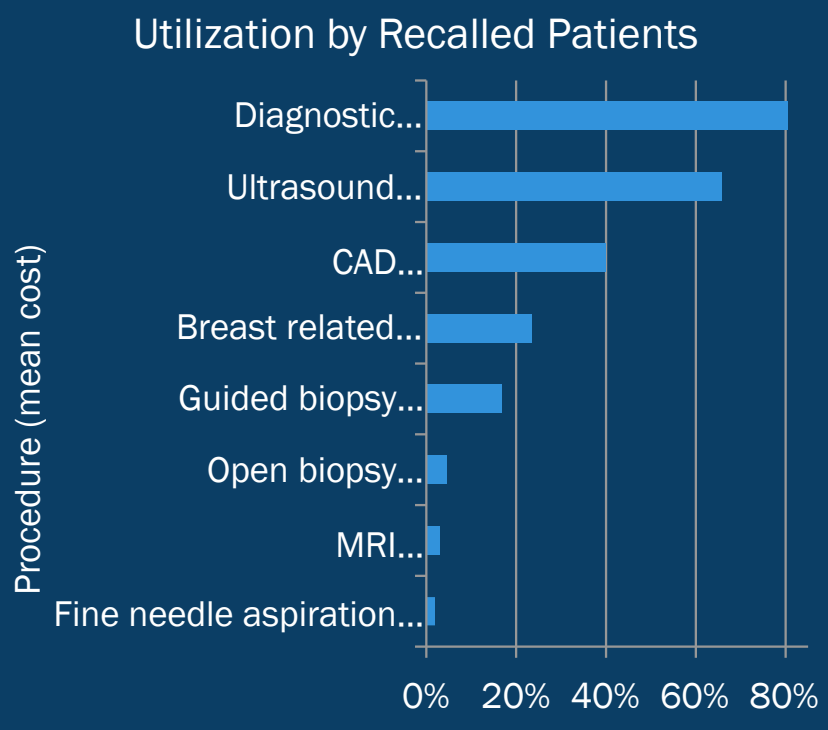
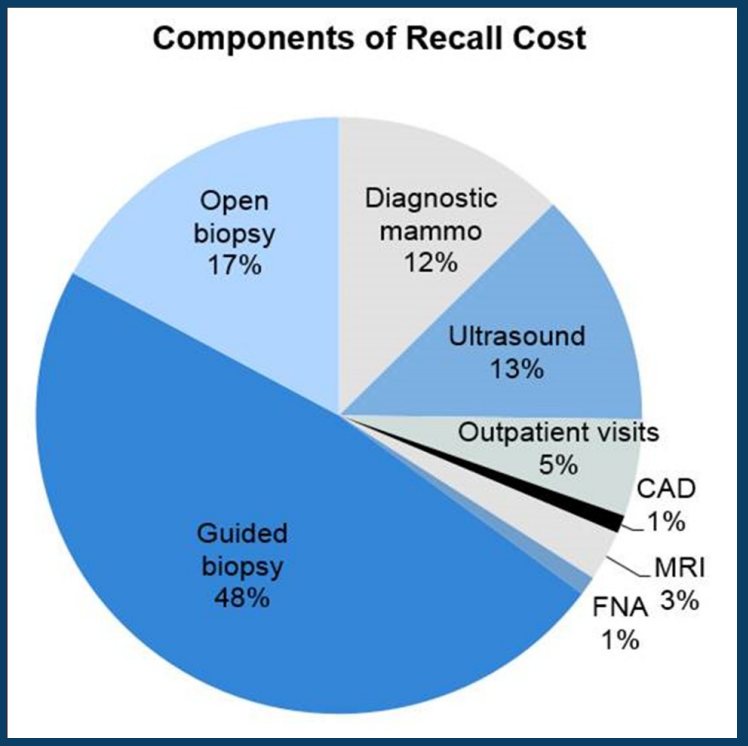
$1205 average cost per recall[1]





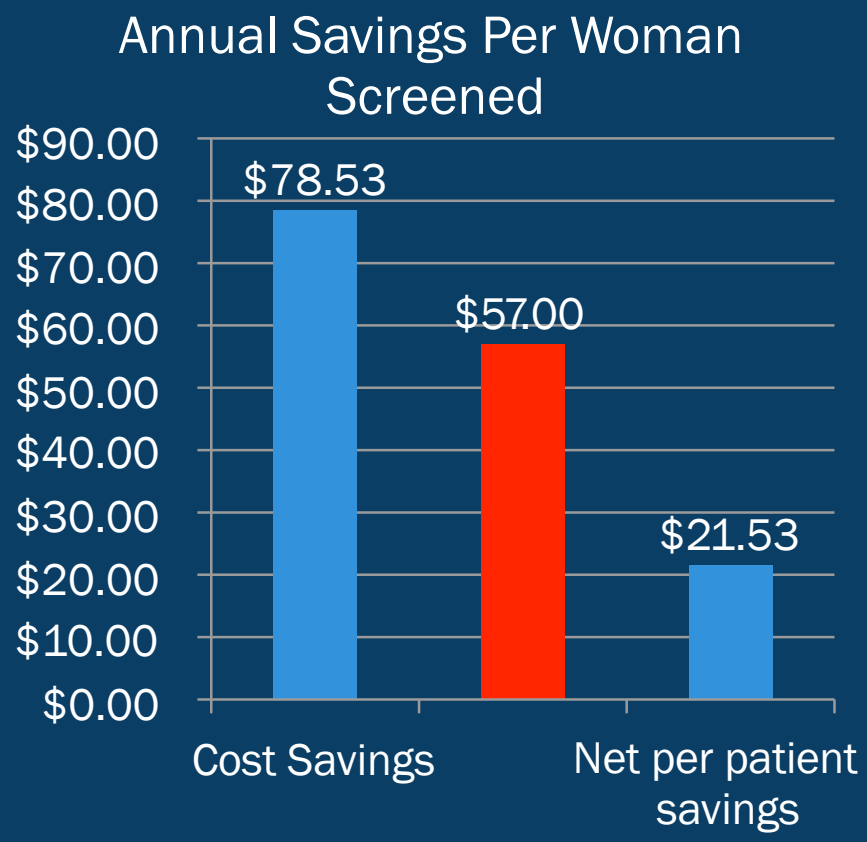
$1205 average cost per recall[1]

Base case

- $57 reimbursement
- 1M member health plan

Savings

- $21.53/woman screened
- $0.20/member/month



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Summary: Positive Impact on Breast

- ↑ CDR
- ↓ RR
- Improved performance across all BD & ages
- Value analysis modeling predicts ↓ screening costs
- No evidence for “OVERDIAGNOSIS”

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BT – IMPACT ON BREAST CARE
CLINICAL EXAMPLES

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BT: Clinical Challenges

- FPs: radial scars; sclerosing adenosis
- Expect a learning curve & practice variation
- Brown Paper
- Data on calcification performance: scant & varied – no evidence to suggest missed cancers, but more data needed
- NO BIRADS criteria to guide use of BT in clinical practice
- Dose concerns – reconstructed ("synthetic") 2D
- Improved QA needed – esp. for technologists

Reconstructed ('synthetic') 2D MG to ↓ BT Dose

- Cancers not seen on 2D have been shown to be visible on BT
- ↓ BT dose creates opportunity to improve 3D acquisition parameters
- BUT – many practice with synthetic 2D MG are still exposing conventional 2D MG as well
  - Different appearance
  - Image processing creates artifacts ("pseudocalcs")
  - If contrast is optimized for dense tissue, may appear "flat" on fatty breasts

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Summary

- Was TOMO really a positive step forward?
- Is it likely to decrease false positive exams?
- Will it pick up more cancers?

The Future.....

FUTURE

- ? Multi-institutional prospective clinical trial in the US?
- What if the tube did not have to rotate?
- What if the phase contrast imaging data could be used?

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