

SBI TURNS 40!

Celebrating 40 years of Impact & Innovation

SBI 40th Anniversary **Breast Imaging Historical Timeline**

Presented by: Shirley Chou, Yasmeen Fields, Michael Linver, Bonnie Joe

Thank you to all our contributors and SBI Presidents (see next slide), with special thanks to:

Dr. Marc Homer

Dr. Ed Sickles

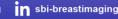
Dr. Val Jackson

Dr. Amy Patel

Credits to our wonderful SBI staff and SBI 2025 IT support!









SBI Presidents 1985-2025:

1985-1988 1990-1991 2001-2003 1993-1995 1997-1999 2005-2007 Marc Homer Barbara Monsees Ed Sickles Larry Bassett Bill Eklund **James Brenner** 1989-1990 1991-1993 1995-1997 1999-2001 2003-2005 Carl D'Orsi Valerie Jackson Steve Feig Carol Stelling **David Dershaw** 2007-2009 2011-2013 2015-2017 2018-2019 2020-2021 2022-2023 2024-2025 Carol Lee Debbie Monticciolo Liz Morris Jay Baker Jessica Leung John Lewin Linda Moy 2019-2020 2021-2022 2023-2024 2009-2011 2013-2015 2017-2018 Wendy DeMartini Rita Zuley **Emily Conant** Mimi Newell Phil Evans Murray Rebner







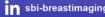




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Chronologic Timeline













Direct X-Ray Mammogram

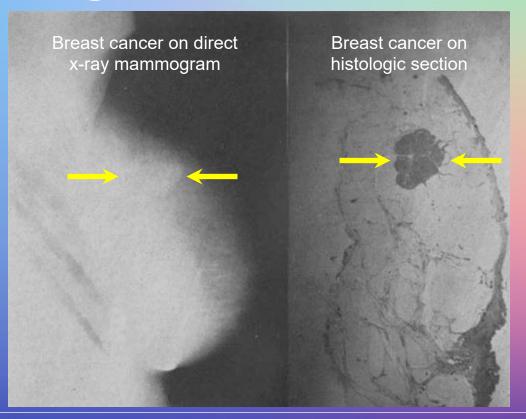
1934: INNOVATION

From: Lockwood H. Radiology 1934;23(2):202–207.

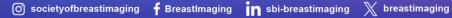
Published in: Bonnie N. Joe; Edward A. Sickles;

Radiology 2014, 273, S23-S44.

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Warren Direct X-Ray Mammogram

1939: INNOVATION

1939 Direct exposure mammogram (lateral view) From files of Dr. Stafford Warren

Courtesy of Dr. Larry Bassett, UCLA









Carbon Dioxide Insufflation

1939: INNOVATION



Published in: Bonnie N. Joe; Edward A. Sickles;

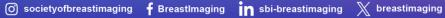
Radiology 2014, 273, S23-S44.

2014 by the Radiological Society of North America, Inc.









Ductogram 1939: INNOVATION

From: Hunt HB, Hicken NF. Radiology <u>1939;33(6):712–724.</u>

Published in: Bonnie N. Joe; Edward A. Sickles;

Radiology 2014, 273, S23-S44.

2014 by the Radiological Society of North America, Inc.











Egan's Mammographic Positioning

1960: INNOVATION



Positioning for the cranjo-caudad view. Identification marker is kept on the axillary side of breast for localization of the mammary quadrant.

Fig. 2. Oblique or lateral position. The cardboard film-holder is supported on a small wood block.

Fig. 3. Axillary view. The central beam is centered to the apex of the axilla and also parallel to the retromanmary space. This arm position provides maximum visualization of the axilla as it reduces the number of skin folds without superimposition of the scapula. Factors: 54 kv, 300 ma, 40 inches, three and a half seconds; in obese patients the distance is reduced to 30 in.

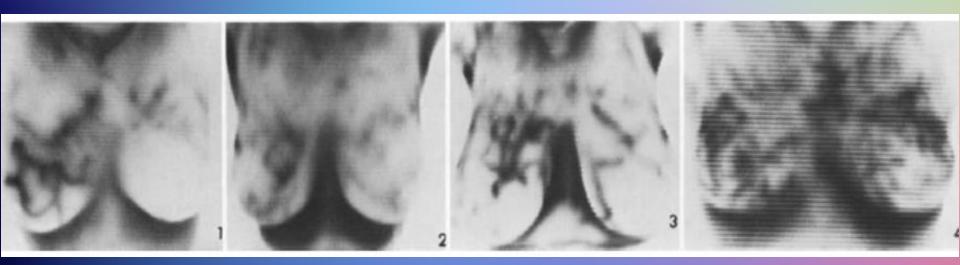
Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.







Thermography 1977: INNOVATION?

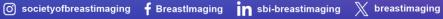


Positive thermograms in 4 women. Thermography ultimately proved insensitive as a screening exam.

From: Feig SA, Shaber GS, Schwartz GF, et al. Thermography, mammography, and clinical examination in breast cancer screening. Review of 16,000 studies. Radiology. <u>1977;122(1):123-7.</u>

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America. Inc.

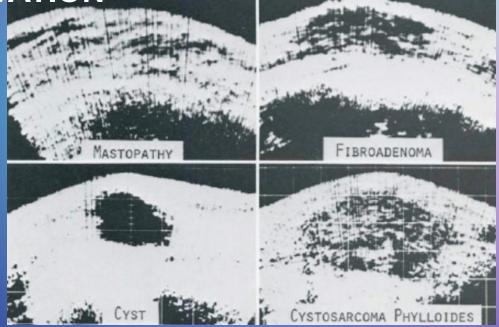






Ultrasound

1977: INNOVATION



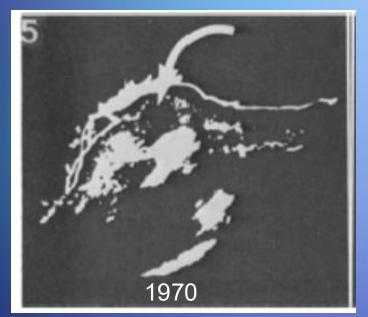
From: Kobayashi T. Gray-scale echography for breast cancer. Radiology. 1977;122(1):207-14.

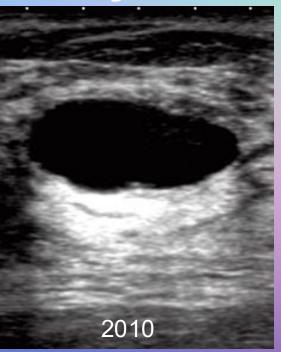
Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America. Inc.



Ultrasound of a Breast Cyst

1977: INNOVATION





From: Damascelli B, Musumeci R, Orefice S. Sonar Information About Breast Tumors. Radiology.

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.



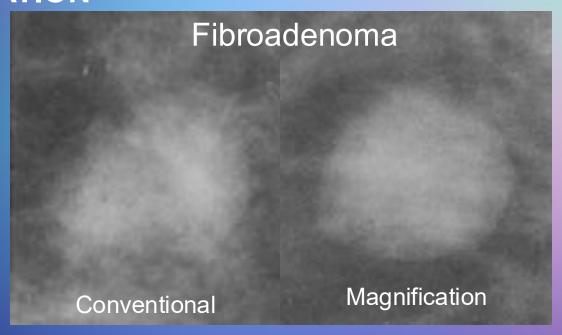








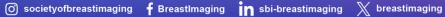
Magnification Improves Quality 1979: INNOVATION



From: Sickles EA. Microfocal spot magnification mammography using xeroradiographic and screen-film recording systems. Radiology.

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.

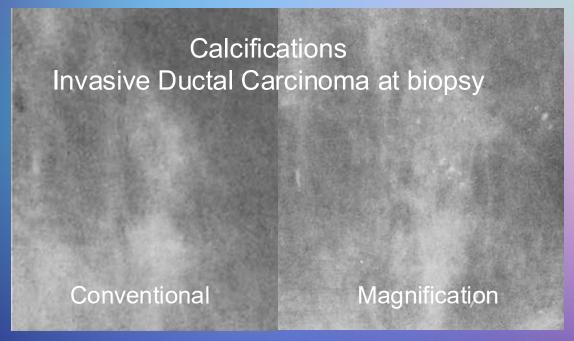






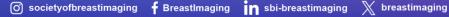


Magnification Improves Quality 1979: INNOVATION

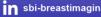


From: Sickles EA. Microfocal spot magnification mammography using xeroradiographic and screen-film recording systems. Radiology. 1979;131(3):599-607. Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.



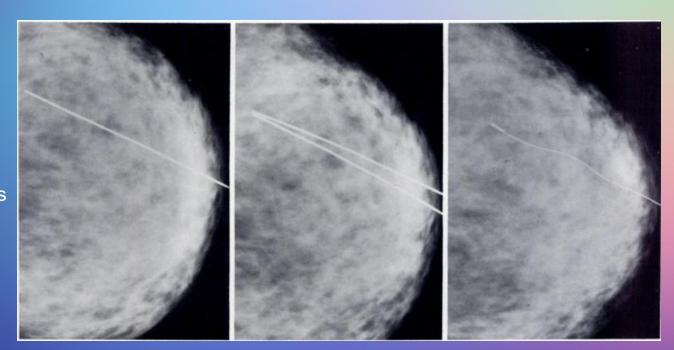






Freehand Needle Localization 1980: INNOVATION

- Iterative approximations to get close to target
- Risk of pneumothorax (needle pointing towards chest wall)













Grid Localization

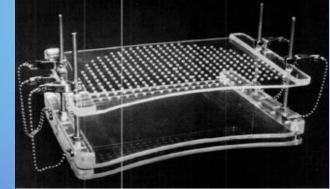
1983: INNOVATION

1-2 needles placed into grid openings closest to target (arrow) based on mammographic image

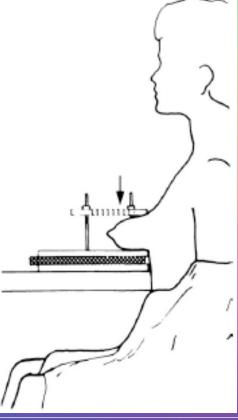
From: Goldberg RP, Hall FM, Simon M. Radiology <u>1983:146(3):833-839.</u>

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44.

2014 by the Radiological Society of North America, Inc.







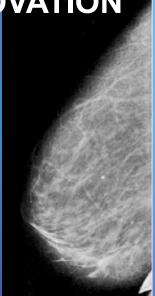




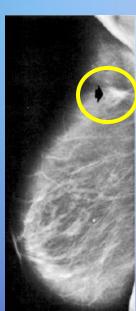
The Oblique View

1983: INNOVATION

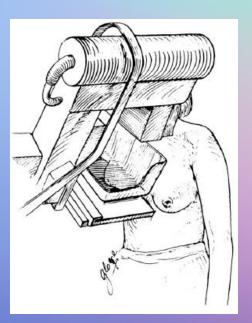
From: Bassett LW, Gold RH. Breast radiography using the oblique projection. Radiology. 1983;149(2):585-7.



Cancer missed on lateral



Cancer seen on MLO view



Positioning for oblique view

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.







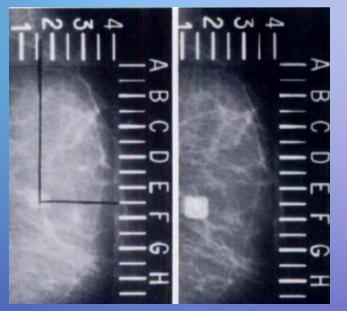


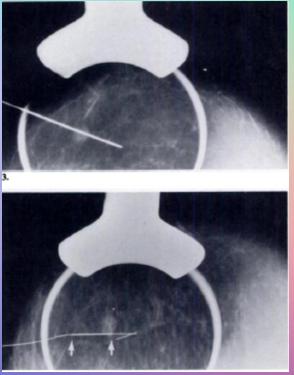


Grid Localization 1985: INNOVATION

System allowed for repositioning of needle before wire deployment

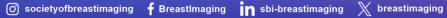
From: Kopans DB, Lindfors K, McCarthy KA, Meyer JE. Spring hookwire breast lesion localizer: use with rigidcompression mammographic systems. Radiology. 1985;157(2):537-8.





Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.





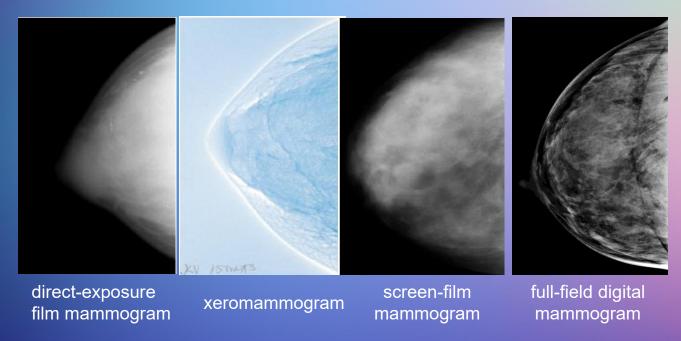






Evolution of 2D mammography

1930's-1990's: INNOVATION



Published in: Bonnie N. Joe; Edward A. Sickles; Radiology 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.







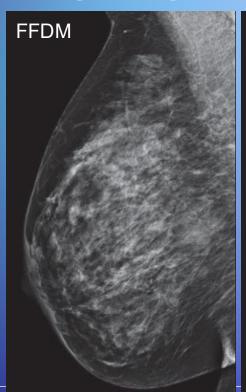


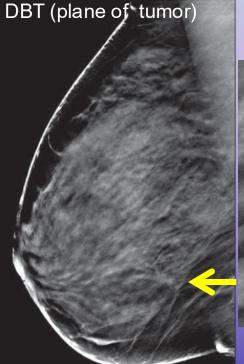


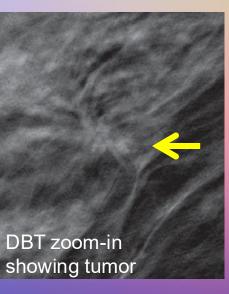
Digital Breast Tomosynthesis

1997-2010's: INNOVATION

Kopans DB. Digital breast tomosynthesis from concept to clinical care. AJR. 2014;202(2):299-308.



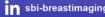














Computer-Aided Detection 1998: INNOVATION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

R2 Technology, Inc. c/o Howard M. Holstein Hogan & Hartson 555 13th Street, N.W. Washington, D.C. 20004

Re:

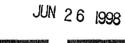
P970058

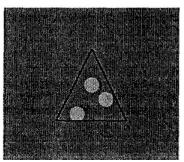
M1000 ImageChecker Filed: December 16, 1997

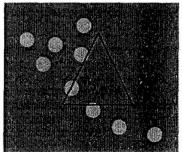
Amended: February 17, 1998, February 20, 1998,

April 10, 1998, April 22, 1998, and Ju

ImageChecker M1000 FDA PMA approval 1998







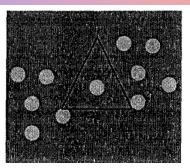
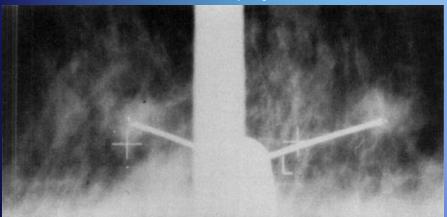


Figure 4. Marker positioning examples for microcalcifications

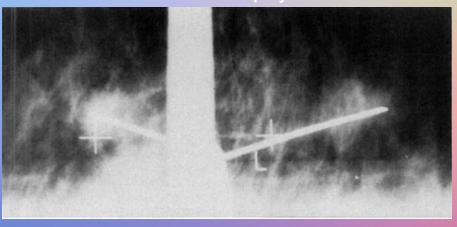


Stereotactic-Guided Breast Biopsy 1990: INNOVATION

Pre-biopsy



Post-biopsy



From: Parker SH, Lovin JD, Jobe WE, et al. Stereotactic breast biopsy with a biopsy gun. Radiology. 1990;176(3):741-7.

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.



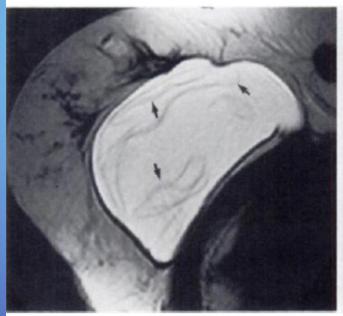


Breast MRI: Silicone Implant Evaluation

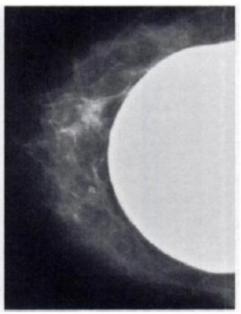
1992: INNOVATION

From: Gorczyca DP, Sinha S, Ahn CY, et al. Silicone breast implants in vivo: MR imaging. Radiology. 1992;185(2):407-10.

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.



"Linguine sign" of intracapsular rupture of silicone implant

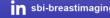


Implant apparently intact on mammogram





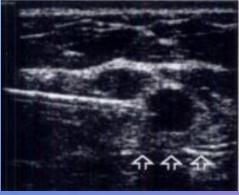


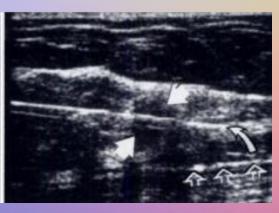




Ultrasound-Guided Breast Biopsy 1993: INNOVATION



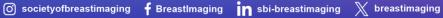


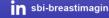


From: Parker SH, Jobe WE, Dennis MA, et al. US-guided automated large-core breast biopsy. Radiology. 1993;187(2):507-11

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.







Breast Cryoablation

2002: INNOVATION

Sabel MS, Kaufman CS, Whitworth P, Chang H, Stocks LH, Simmons R, Schultz M. Cryoablation of early-stage breast cancer: work-in-progress report of a multi-institutional trial. Ann Surg Oncol. 2004 May:11(5):542-9.

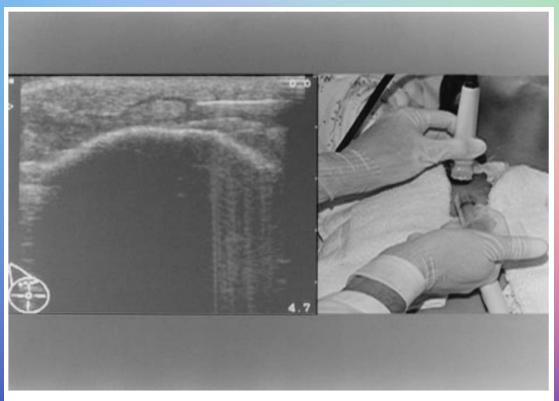


FIG. 4. Injection of saline between the ice ball and skin for skin protection during cryoablation.



FES-PET 1991: INNOVATION

McGuire AH, Dehdashti F, Siegel BA, Lyss AP, Brodack JW, Mathias CJ, Mintun MA, Katzenellenbogen JA, Welch MJ. Positron tomographic assessment of 16 alpha-[18F] fluoro-17 beta-estradiol uptake in metastatic breast carcinoma. J Nucl Med. 1991 Aug;32(8):1526-31.

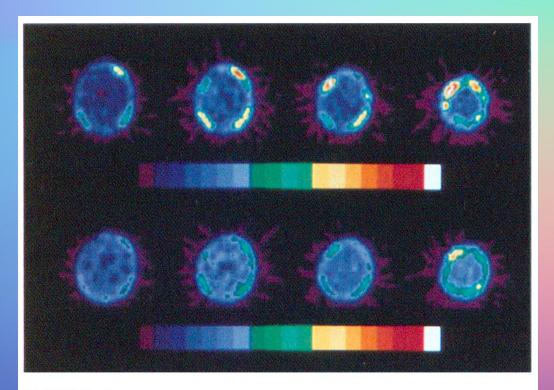


FIGURE 2. Multiple calvarial metastases (Patient 6). PET images obtained before antiestrogen therapy (top row) demonstrate multiple foci of radiopharmaceutical accumulation in the calvarium. The corresponding images obtained 14 days after initiation of antiestrogen therapy (bottom row) show a marked decrease in tracer uptake by these lesions.



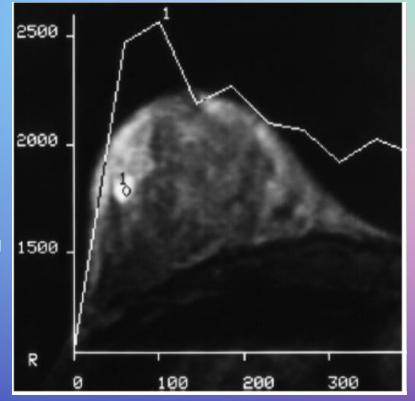
Breast MRI: Signal Intensity-Time Curve

1999: INNOVATION

"Type III" or "washout" curve of invasive ductal cancer

From: Kuhl, C.K., et al., Dynamic breast MR imaging: are signal intensity time course data useful for differential diagnosis of enhancing lesions? Radiology, 1999. 211(1): p. 101-10.

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.





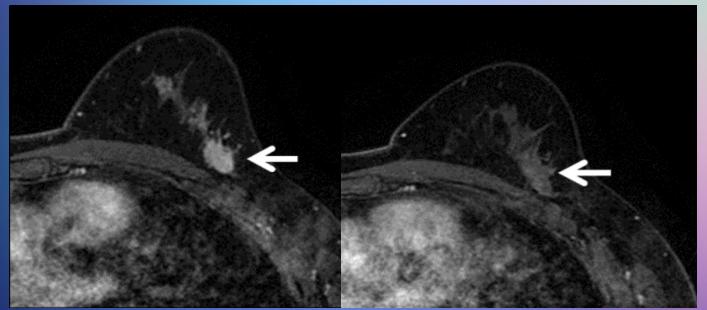






Breast MRI: Monitor Neoadjuvant Rx

2007: INNOVATION



Baseline

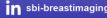
After chemotherapy

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.







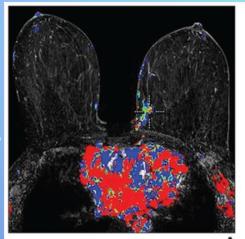


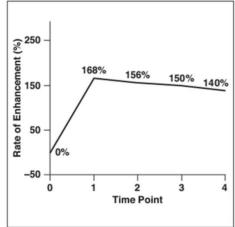


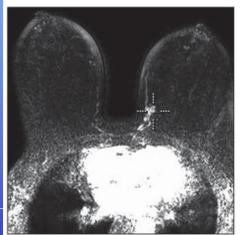
Ultrafast MRI 2014: INNOVATION

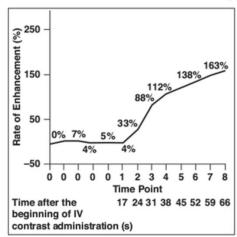
Mann RM, Mus RD, van Zelst J, Geppert C, Karssemeijer N, Platel B. A novel approach to contrast-enhanced breast magnetic resonance imaging for screening: high-resolution ultrafast dynamic imaging. Invest Radiol. 2014 Sep;49(9):579-85.

Figure from reference: Abe H, Mori N, Tsuchiya K, Schacht DV, Pineda FD, Jiang Y, Karczmar GS. Kinetic Analysis of Benign and Malignant Breast Lesions With Ultrafast Dynamic Contrast-Enhanced MRI: Comparison With Standard Kinetic Assessment. AJR Am J Roentgenol. 2016 Nov;207(5):1159-1166











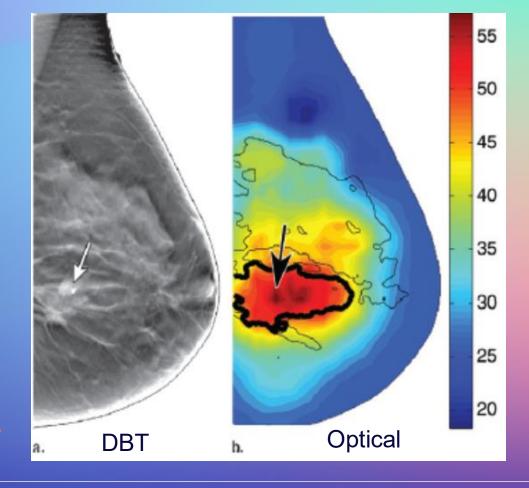


Optical Imaging 2011: INNOVATION

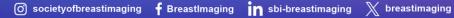
Invasive Ductal Carcinoma (arrow)

From: Fang Q, Selb J, Carp SA, et al. Combined optical and X-ray tomosynthesis breast imaging. Radiology. 2011;258(1):89-97.

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.









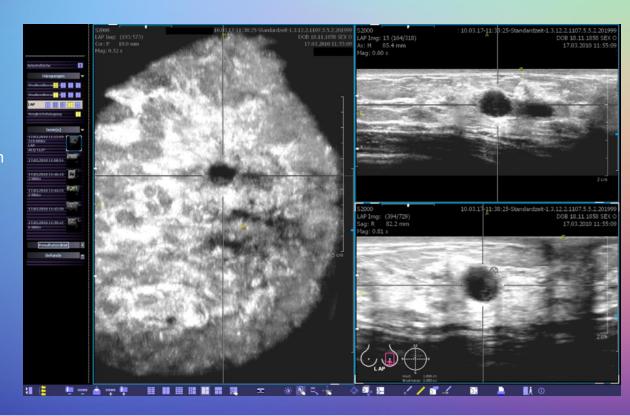




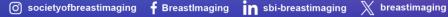
Automated Breast Ultrasound

2011: INNOVATION

Wojcinski S, Farrokh A, Hille U, Wiskirchen J, Gyapong S, Soliman AA, Degenhardt F, Hillemanns P. The Automated Breast Volume Scanner (ABVS): initial experiences in lesion detection compared with conventional handheld B-mode ultrasound: a pilot study of 50 cases. Int J Womens Health. 2011;3:337-46.









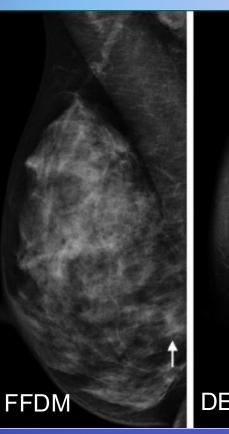


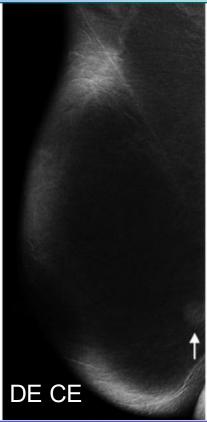
Contrast-Enhanced Mammography

2013: INNOVATION

From: Jochelson MS, Dershaw DD, Sung JS, et al. Bilateral contrast-enhanced dualenergy digital mammography: feasibility and comparison with conventional digital mammography and MR imaging in women with known breast carcinoma. Radiology. 2013;266(3):743-51.

Published in: Bonnie N. Joe; Edward A. Sickles; Radiology, 2014, 273, S23-S44. 2014 by the Radiological Society of North America, Inc.









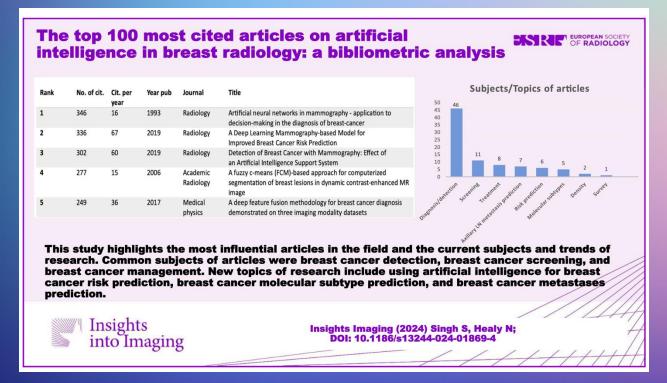








Artificial Intelligence 1990-2020's: INNOVATION













Artificial Intelligence 2022: INNOVATION – Deep learning simulated CE-MRI

Chung M, Calabrese E, Mongan J, Ray KM, Hayward JH, Kelil T, Sieberg R, Hylton N, Joe BN, Lee AY. Deep Learning to Simulate Contrast-enhanced Breast MRI of Invasive Breast Cancer. Radiology. 2023 Mar;306(3):e213199.

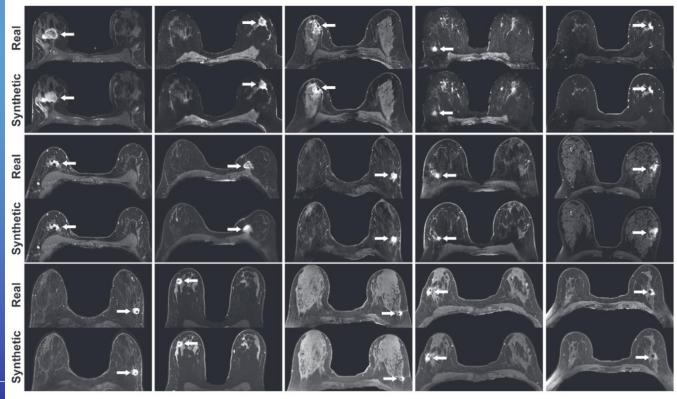




Figure 4: Real versus simulated (ie, synthetic) contrast-enhanced T1-weighted axial breast MRI scans of patients with invasive breast cancer. Pairs of real and simulated contrast-enhanced breast MRI scans from 15 patients with invasive breast cancer (arrows). Intrathoracic and extramammary structures were masked in all images.

ACR Mammography Accreditation Program 1987: IMPACT

The American College of Radiology Mammography **Accreditation Program**

Robert McLelland¹ R. Edward Hendrick² Marie D. Zinninger³ Pamela A. Wilcox³

This article discusses the background, goals, criteria, current results, impact, and future directions of the American College of Radiology's (ACR's) Mammography Accreditation Program. To date, approximately one half of the mammographic units in the United States have voluntarily applied for accreditation through the ACR program, with approximately one quarter of the units in the United States now accredited. Application rates have increased steadily since the start of the program in August 1987. The equipment performance criteria and professional criteria defined and employed in the ACR Mammography Accreditation Program have been adopted as standards for the performance of screening mammography by the ACR and have served as a basis for quality assurance standards in state and federal legislation on mammography.

AJR 157:473-479, September 1991



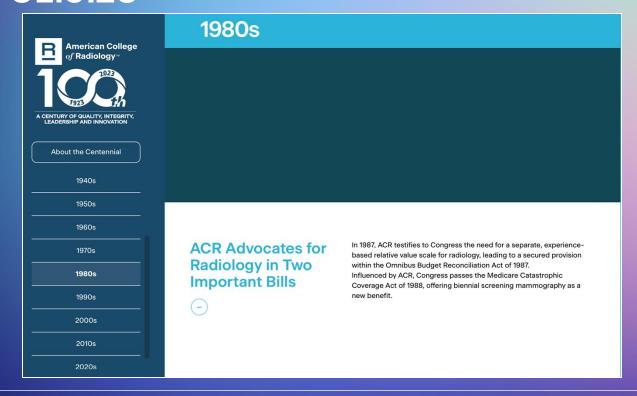








Medicare Catastrophic Coverage Act 1988: POLICIES











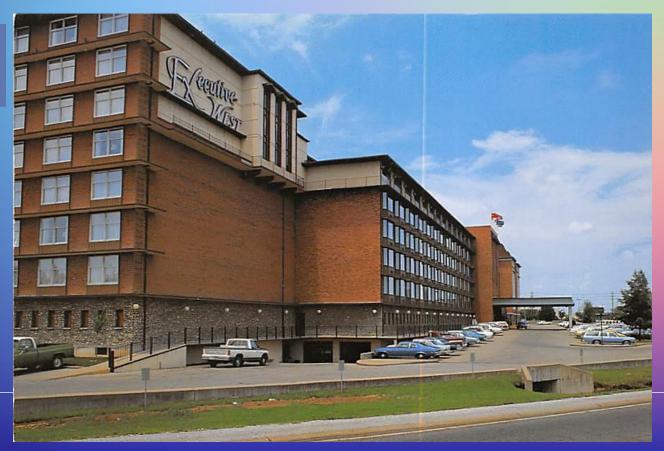


Breast Radiology Added to ABR Oral Board 1990: IMPACT

June 4-8, 1990 Executive West Hotel, Louisville, KY

"Please note category 10
Breast Radiology has been added. This will be a thirty minute examination period as are other categories of the examination."

Letter from the ABR
November 8, 1989





Robert G. Parker, M.D., President Los Angeles, California

Thomas F. Meaney, M.D., Vice President Cleveland, Ohio

Lee F. Rogers, M.D., Treasurer Chicago, Illinois

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The American Board of Radiology

OFFICE OF SECRETARY AND TREASURER

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> 300 PARK, SUITE 440 BIRMINGHAM, MICHIGAN 48009

> > PHONE (313) 645-0600 FAX (313) 645-0459

November 8, 1989

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John A. Kirkpatrick, Jr., M.D. Boston, Massachusetts

Eugene C. Klatte, M.D. Indianapolis, Indiana

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William E. Powers, M.D. Detroit, Michigan

Joseph F. Sackett, M.D. Madison, Wisconsin

Melvyn H. Schreiber, M.D. Galveston, Texas

TO:

All Program Directors of Diagnostic Radiology and Diagnostic Radiology with Special Competence in Nuclear Radiology Programs

FROM:

Kenneth L. Krabbenhoft, M.D.

SUBJECT:

Added Category for the ABR Oral Examination

Document courtesy of Dr. Marc Homer

SUBJECT: Added Category for the ABR Oral Examination

Enclosed please find an updated description of the categories of the oral examination for Diagnostic Radiology.

Please note category 10 Breast Radiology has been added. This will be a thirty minute examination period as are other categories of the examination.

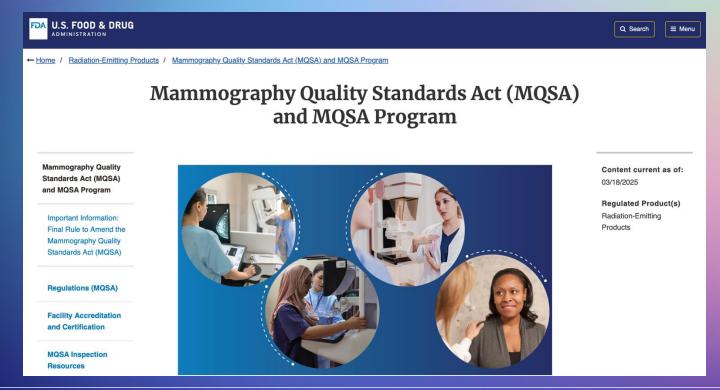
This category is described as follows:

Breast Radiology. This includes mammography, ultrasonography, contrast studies and special procedures related to the diagnosis of breast disease. A basic knowledge of the epidemiology and treatment of breast disease is also required.

This added category will be an integral part of the oral examination to be held June 4-8, 1990 for candidates in Diagnostic Radiology and Diagnostic Radiology with Special Competence in Nuclear Radiology.

Kenneth L. Frakbenhoft mb

Mammography Quality Standards Act (MQSA) 1992: POLICIES













1st Edition of the ACR BI-RADS Published 1993: IMPACT



American College of Radiology. Breast Imaging Reporting and Data System® (BI-RADS®).

Reston, Va: American College of Radiology

The ACR BI-RADS® Experience: **Learning From History**

Elizabeth S. Burnside, MD, MPH, MS^a, Edward A. Sickles, MD^b, Lawrence W. Bassett, MD^c, Daniel L. Rubin, MD, MS^d, Carol H. Lee, MD^e, Debra M. Ikeda, MD^d, Ellen B. Mendelson, MD^f, Pamela A. Wilcox^g, Priscilla F. Butler^g, Carl J. D'Orsi, MD^h

J Am Coll Radiol 2009;6:851-860. Copyright © 2009 American College of Radiology











ACR Accreditation for Stereo Biopsy 1996: IMPACT

With input from SBI members, the ACR institutes an accreditation program for practices performing stereotactic breast biopsy















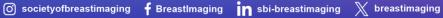
USPSTF Breast Screening Guidelines 2009: POLICIES

Recommendation Summary				
Population	Recommendation	Grade		
Women, Age 50-74 Years	The USPSTF recommends biennial screening mammography for women 50-74 years.	В		
Women, Before the Age of 50 Years	The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.	C		
All Women	The USPSTF recommends against teaching breast self-examination (BSE).	D		
Women, 40 Years and Older	The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older. Go to the Clinical Considerations section for information on risk assessment and suggestions for practice regarding the I statement.	I		
All Women	The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer. Go to the Clinical Considerations section for information on risk assessment and suggestions for practice regarding the I statement.	I	ARCHIVE	Ç
Women, 75 Years and Older	The USPSTF concludes that the current evidence is insufficient to assess the benefits and harms of screening mammography in women 75 years and older. Go to the Clinical Considerations section for information on risk assessment and suggestions for practice	I	PCK	
	regarding the I statement.		1	









SBI Position on 2009 USPSTF Guidelines **2009: IMPACT**

Breast Cancer Screening With Imaging: Recommendations From the Society of Breast Imaging and the ACR on the Use of Mammography, Breast MRI, Breast Ultrasound, and Other **Technologies for the Detection of Clinically Occult Breast Cancer**

Carol H. Lee, MD, D. David Dershaw, MD, Daniel Kopans, MD, Phil Evans, MD, Barbara Monsees, MD, Debra Monticciolo, MD, R. James Brenner, MD, Lawrence Bassett, MD, Wendie Berg, MD, Stephen Feig, MD, Edward Hendrick, PhD, Ellen Mendelson, MD, Carl D'Orsi, MD, Edward Sickles, MD, Linda Warren Burhenne, MD

J Am Coll Radiol 2010;7:18-27. Copyright © 2010 American College of Radiology







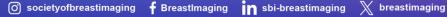


Mammography Saves Lives 2010: IMPACT

In collaboration with the American Society for Breast Disease and the SBI, the ACR creates this website













Protecting Access to Lifesaving Screenings (PALS) PALS Act of 2021: POLICIES

117TH CONGRESS 1st Session

S. 2412

To amend title XVIII of the Social Security Act to protect coverage for screening mammography, and for other purposes.

IN THE SENATE OF THE UNITED STATES

July 21, 2021

Mrs. Feinstein (for herself, Mrs. Blackburn, and Mrs. Shaheen) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to protect coverage for screening mammography, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Protecting Access to Lifesaving Screenings Act of 2021" or the "PALS Act".

SEC. 2. PROTECTING COVERAGE FOR SCREENING MAMMOGRAPHY.

This bill makes a series of changes relating to health insurance coverage of screening mammography...

In addition, the bill preserves Medicare coverage for screening mammography, without a requirement for coinsurance, and expands the definition of screening mammography to include any digital modality of such a procedure. Further, the Centers for Medicare & Medicaid Services may not decrease the frequency with which screening mammography may be paid by Medicare for a woman over 39 years of age.









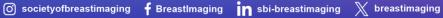


USPSTF Breast Screening Guidelines 2024: POLICIES

Recommendation Summary

Population	Recommendation	
Women aged 40 to 74 years	The USPSTF recommends biennial screening mammography for women aged 40 to 74 years.	
Women 75 years or older	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women 75 years or older.	
Women with dense breasts	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of supplemental screening for breast cancer using breast ultrasonography or magnetic resonance imaging (MRI) in women identified to have dense breasts on an otherwise negative screening mammogram. See the "Practice Considerations" section for more information on the patient population to whom this recommendation applies and on screening mammography modalities.	









Addressing USPSTF Guidelines 2023-2024: IMPACT

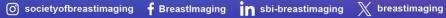
May 9, 2023

ACR/SBI Statement on New USPSTF Breast Cancer Screening Recommendations

The new United States Preventive Services Task Force (USPSTF) Breast Cancer Screening Recommendations are a step in the right direction. However, the American College of Radiology® (ACR®) and Society of Breast Imaging (SBI) urge the USPSTF to go further to recommend annual mammography screening for all average-risk women ages 40 and older.

The USPSTF, ACR, SBI, American Cancer Society and others all agree that the most lives are saved with this annual approach. Medical experts should clear the confusion caused by differing recommendations and agree to recommend yearly mammography for average-risk women starting at age 40.









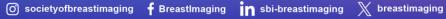


SBI & Prevent Cancer Foundation Capitol Hill Briefing 2015 IMPACT



SBI cohosts hearing on Capitol Hill with advocacy group, Prevent Cancer, and Congresswoman Debbie Wasserman-Schulz with panelists Drs. Elizabeth Morris and Murray Rebner, and breast surgeon, Dr. Regina Hampton









Breast Density and Mammography Reporting Act of 2015 2015: POLICIES





Dr. Bob Smith, ACS, Joan Lunden, Senator Dianne Feinstein, Dr. Nancy Cappello, Are You Dense Advocacy, Inc. and Kimberly Beers, Susan G. Komen.

Source: Are You Dense











FDA MQSA Mandate on Breast Density Notification 2023-2024: POLICIES

Issued Date: March 10, 2023

Effective Date: September 10, 2024







Mammography Quality Standards Act (MQSA) and MQSA Program / Radiation-Emitting Products / Regulations (MQSA)

Regulations (MQSA)

Regulations (MQSA)

Alternative Standards (MQSA)

The FDA issued a Final Rule to Amend the MQSA Regulations ("2023 MQSA Final Rule") on March 10, 2023. Facilities subject to the MQSA and its implementing regulations must comply with all the requirements, including the breast density notification, as of September 10, 2024. The information on this web page has been updated further to conform to the amended MQSA regulations, which are now in effect.

Content current as of:

10/03/2024

Regulated Product(s)

Radiation-Emitting Products







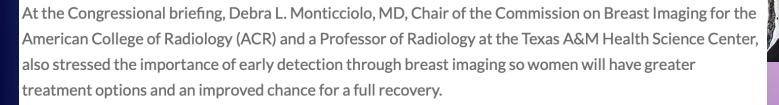




The Breast Cancer Patient Education Act of 2015 Photo courtesy of Dr. Mike Linver

2015: POLICIES

Left to right: Debra Monticciolo (14th SBI President), Pamela Plater, Yasmeen Fields in 2013 at the 11th SBI Postgraduate Course



"Breast cancer is a serious concern for all women but early detection and information on treatment options are powerful weapons for the best outcome," said Dr. Monticciolo. "It is extremely important that women have access to thorough and understandable information on their reconstructive rights."



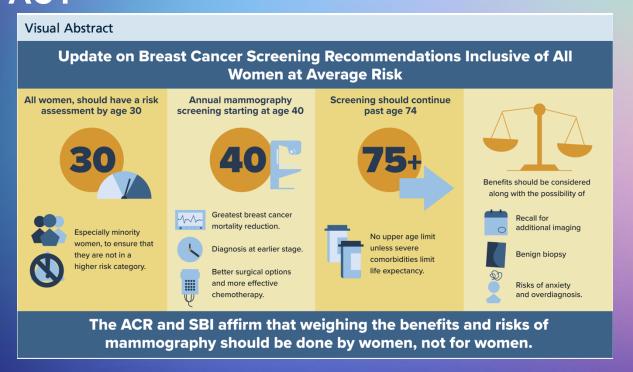






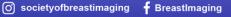


ACR/SBI Guidelines for Average-Risk Women **2021: IMPACT**



Monticciolo DL, et al. J Am Coll Radiol 2021:18:1280-1288.











SBI2025 BREASTIMAGING SYMPOSIUM