MammoGRIP®

The Invisible Glove

Disruptive Technology

LIFT. STICK. **GRIP**

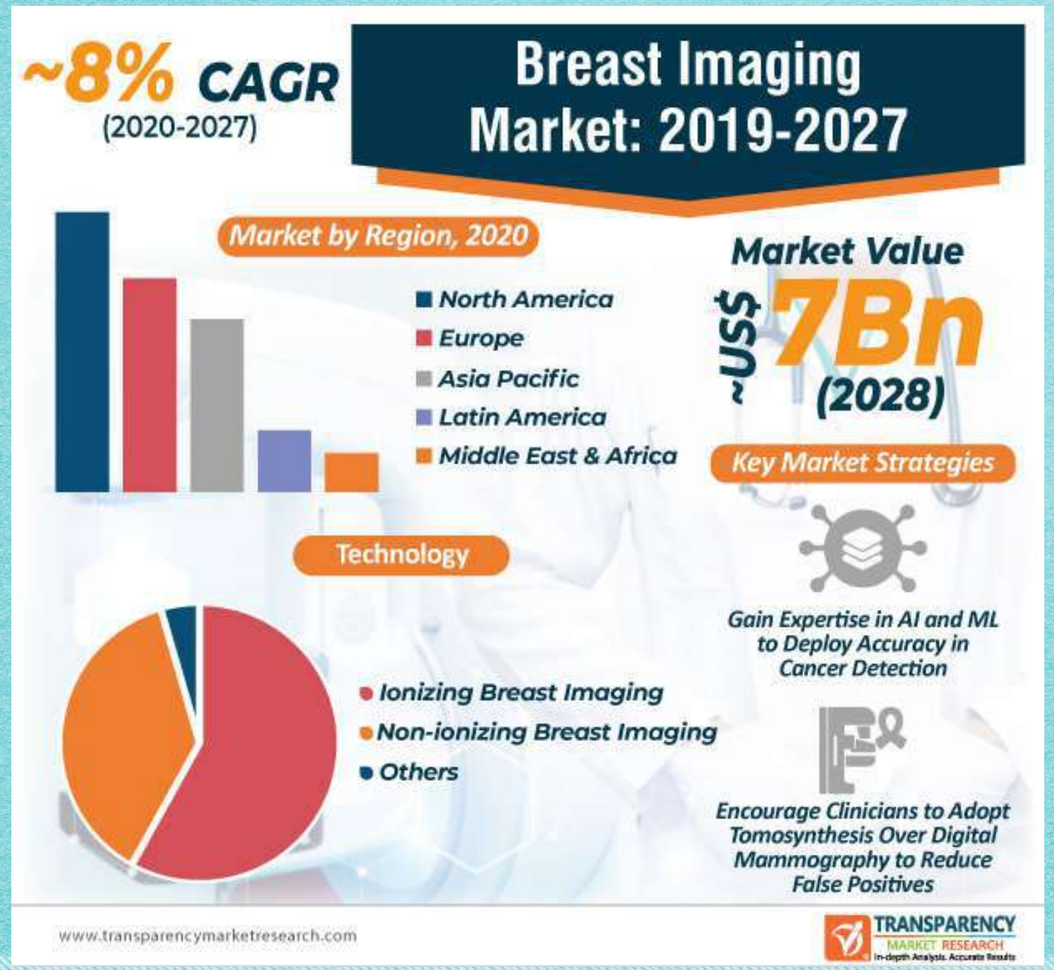
BIOFLEX

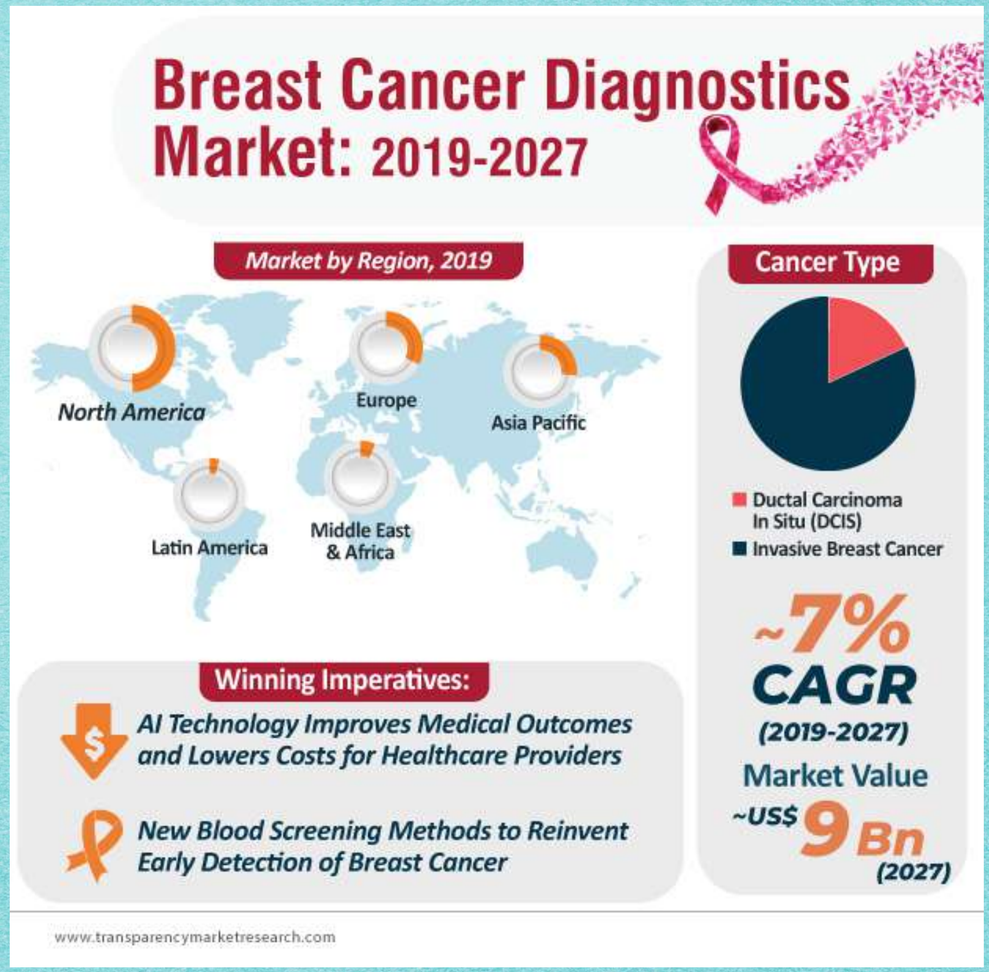
Age vs. Probability of breast cancer Development in %*

Birth to 49	1.9 (1 in 52)
50 to 59	2.3 (1 in 43)
60 to 69	3.4 (1 in 29)
≥70	6.8 (1 in 16)

Birth to death 12.4 (1 in 8)

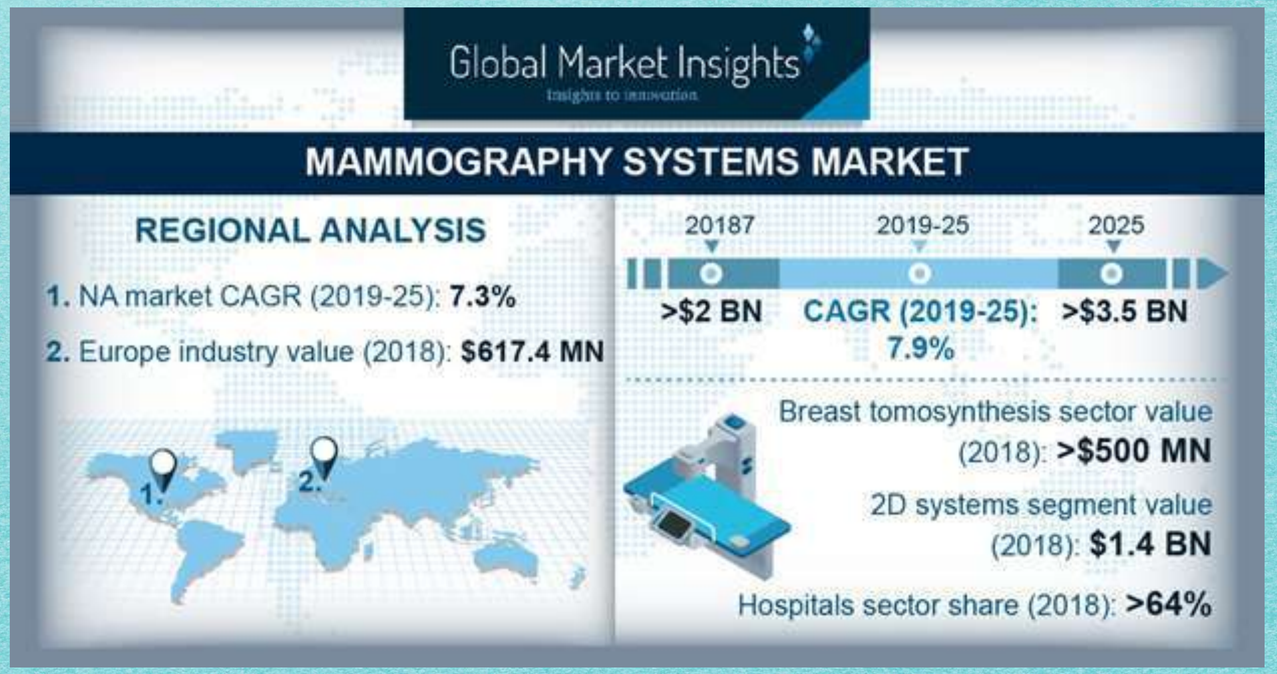
Market


~8% CAGR
(2020-2027)
Breast Imaging Market: 2019-2027
Market by Region, 2020
North America
Europe
Asia Pacific
Latin America
Middle East & Africa
Market Value
~US$ 7Bn
(2028)
Key Market Strategies
Technology
Ionizing Breast Imaging
Non-ionizing Breast Imaging
Others
Gain Expertise in AI and ML to Deploy Accuracy in Cancer Detection
Encourage Clinicians to Adopt Tomosynthesis Over Digital Mammography to Reduce False Positives
www.transparencymarketresearch.com
TRANSPARENCY MARKET RESEARCH


Breast Cancer Diagnostics Market: 2019-2027
Market by Region, 2019
North America
Europe
Asia Pacific
Latin America
Middle East & Africa
Cancer Type
Ductal Carcinoma In Situ (DCIS)
Invasive Breast Cancer
~7% CAGR
(2019-2027)
Market Value
~US$ 9 Bn
(2027)
Winning Imperatives:
AI Technology Improves Medical Outcomes and Lowers Costs for Healthcare Providers
New Blood Screening Methods to Reinvent Early Detection of Breast Cancer
www.transparencymarketresearch.com

Market

MammoGRIP®
The Invisible Glove



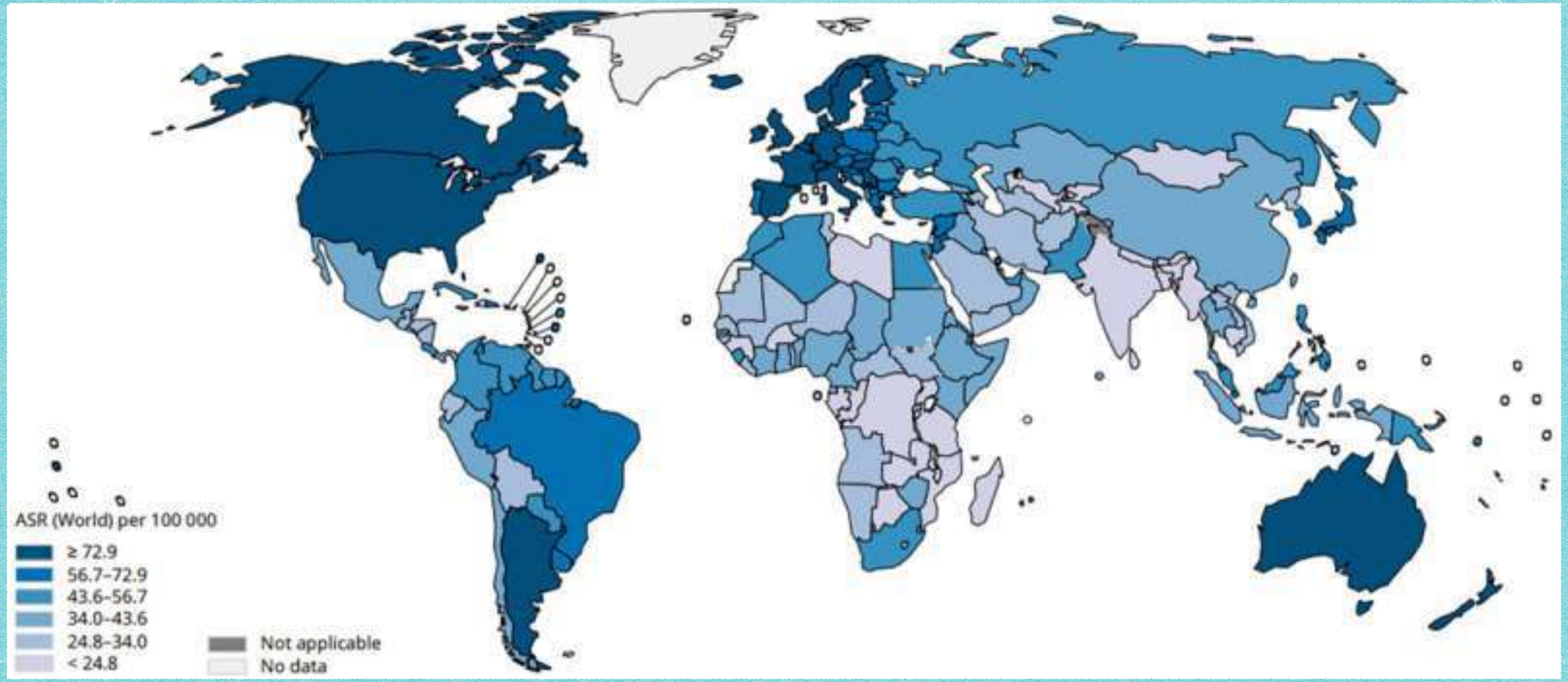
The American Cancer Society's estimates for breast cancer in the United States for 2020 are:

- About 276,480 new cases of invasive breast cancer will be diagnosed in women.
- About 48,530 new cases of carcinoma in situ (CIS) will be diagnosed (CIS is non-invasive and is the earliest form of breast cancer).
- About 42,170 women will die from breast cancer.

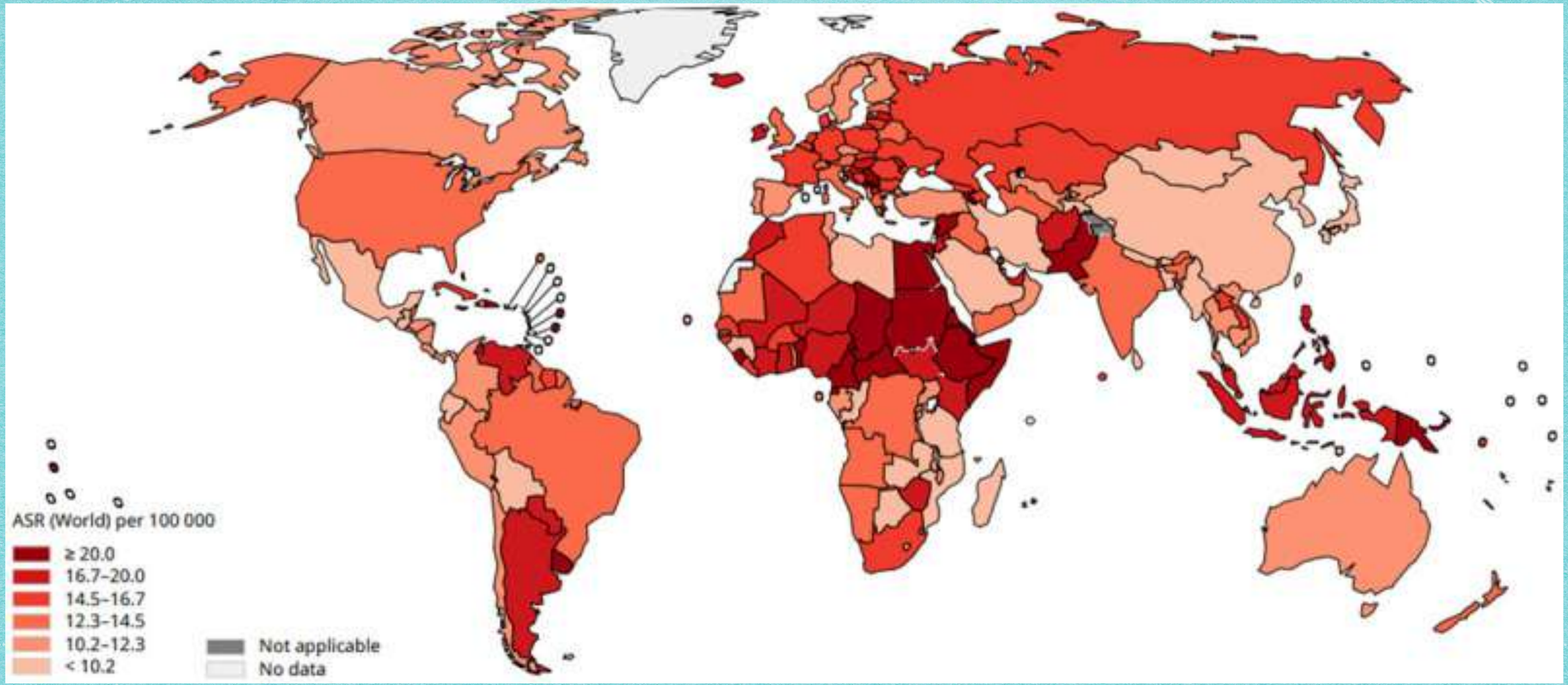
Hope

Since 2007, breast cancer death rates have been steady in women younger than 50, but have continued to decrease in older women. From 2013 to 2017, the death rate decreased by 1.3% per year. These decreases are believed to be the result of finding breast cancer earlier through screening and increased awareness, as well as better treatments.

Global Breast Cancer Incidence



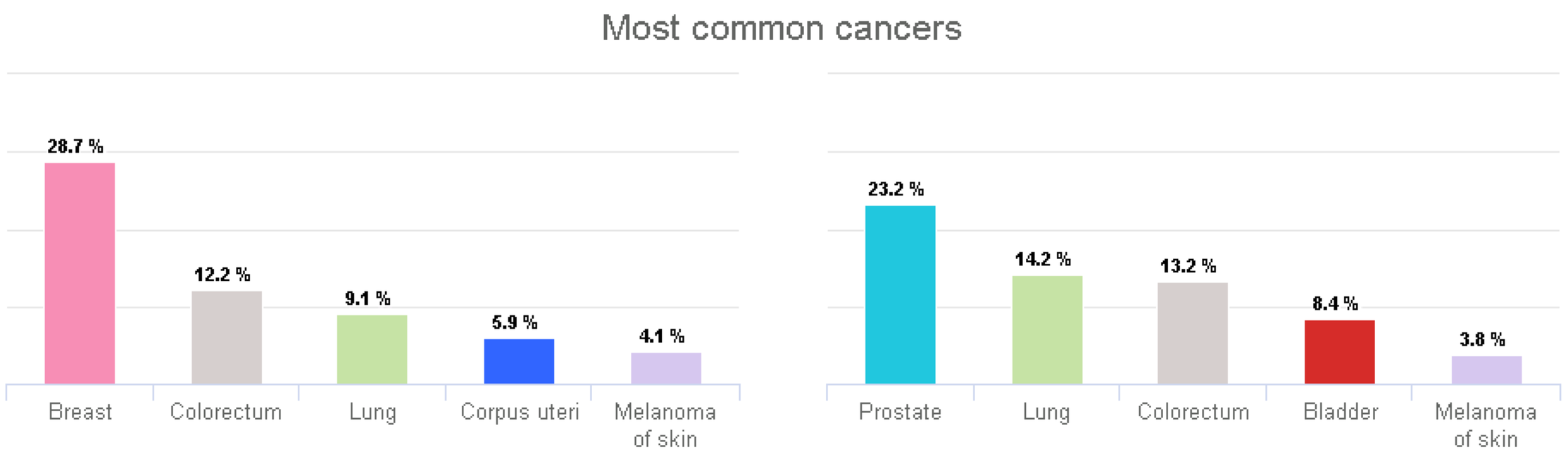
Global Breast Cancer Mortality



European Union

1 237 588 new cases

1 444 949 new cases



ECIS - European Cancer Information System (2020)

- Breast Cancer 2020 - 29.2%
- Estimates that increased rates (COVID 19 role as well*)
- 2.7 million new cases of all types of cancer (excluding Melanoma)
- over 1.3 million deaths only in 2020

ECIS - European Cancer Information System

"How is the COVID-19 pandemic affecting the burden of cancer?

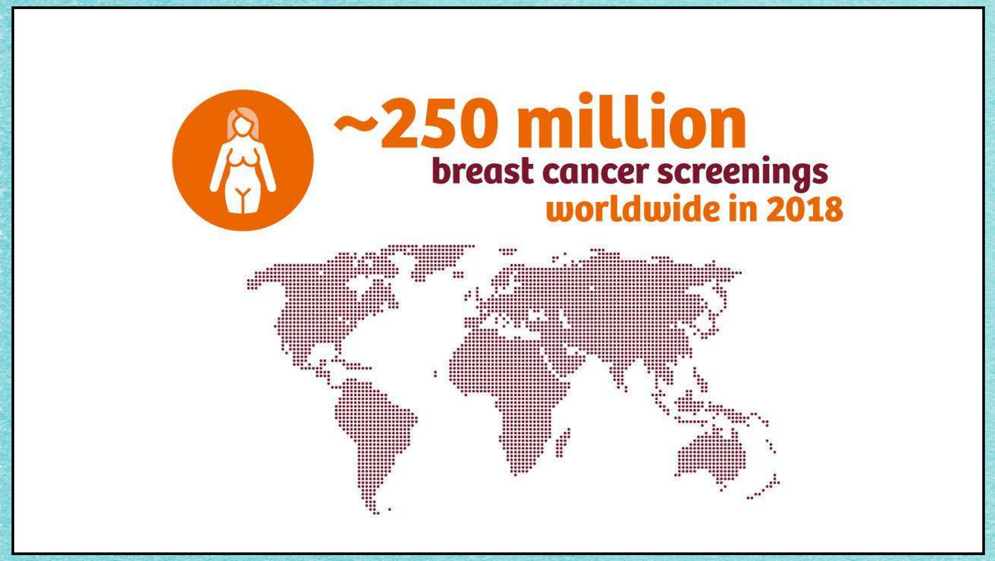
This is not clear yet, especially considering the geographical variations and irregular evolution of the pandemic across countries.
However, there have been reported delays in cancer screening and diagnoses. Yet in some countries, there have been reports that cancer diagnoses have picked up after the lockdown ended.
Unfortunately, the effects of this pandemic is not reflected in these 2020 estimates because they are based on incidence trends from past years.
Therefore, we might even observe a possible overestimation of 2020 incidence rates in some countries.
We will however be able to account for this bias through detailed analyses when such data become available."

PORTUGAL

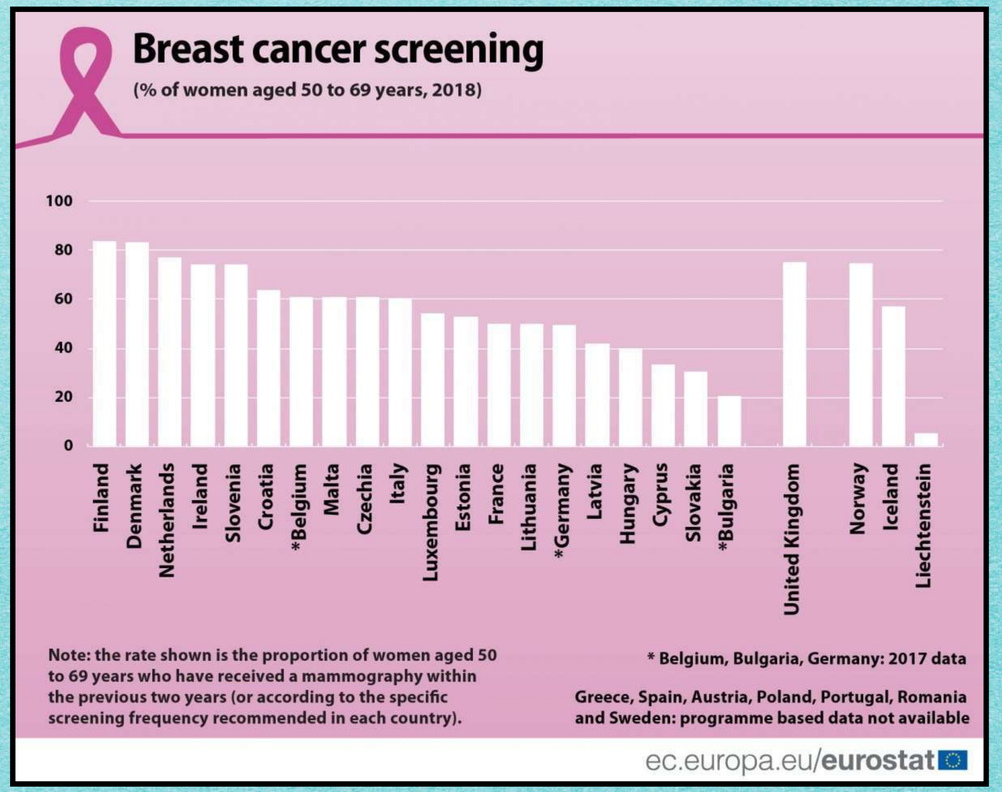
- **TOP 5 - Breast Cancer in Europe**
- **6,000 new cases every year**
- **1,000 women die annually**

The Lancet, 2020

Mammograms performed per year



Only for screening in the US
37 million/ year
Cost - about $100



Mammogram Anxiety

WHY Some Women May Not Schedule a **Mammogram**

- Fear of Having Cancer
- Scared of Radiation
- It Can Be Uncomfortable
- There Is an Expense
- Takes Too Much Time
- Believe They're Not at Risk

4 MAMMOGRAM MYTHS

MYTH: Mammograms don't help.

TRUTH: Regular mammograms are the best tests doctors have to find breast cancer early, sometimes up to three years before it can be felt.[12]

MYTH: Mammograms cause cancer.

TRUTH: Mammograms utilize very small doses of radiation—it's like getting an x-ray.

MYTH: Mammograms are inaccurate.

TRUTH: Although they are not perfect, mammograms are the best tool we have in early detection.

MYTH: Mammograms are painful.

TRUTH: Everyone's pain threshold is different, but the compression involved in a mammogram is more often described as temporary discomfort.

FDA approved

MammoGRI™

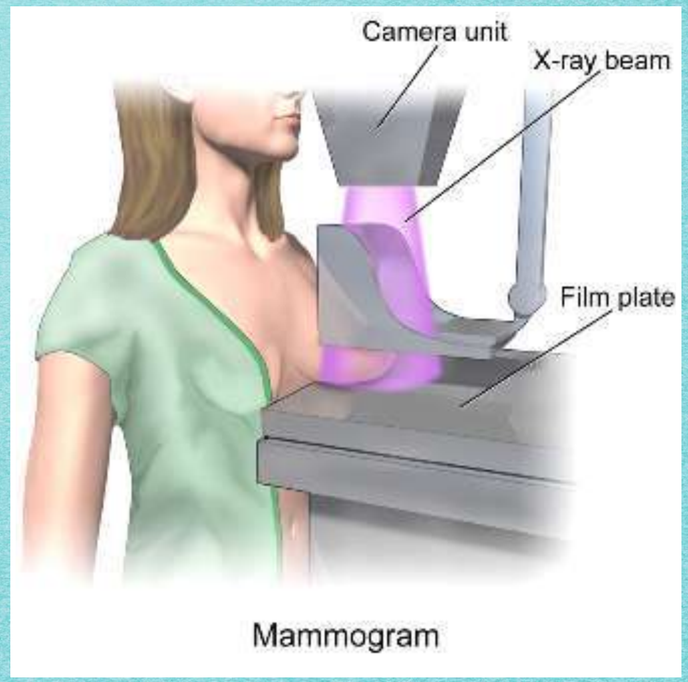
Created by technologists for technologists: For *every* patient with *every* image.

EXCLUSIVE AND PATENTED PRODUCT

The Challenge that Inspired MammoGRIP®

The Invisible Glove

- Mammograms are likely to miss small tumors near the chest wall where 70% * of breast cancers are found
- Excessive manipulation of the breast is more uncomfortable for the patient and can tear the skin under the breast
- Results can be inconclusive



Mammogram

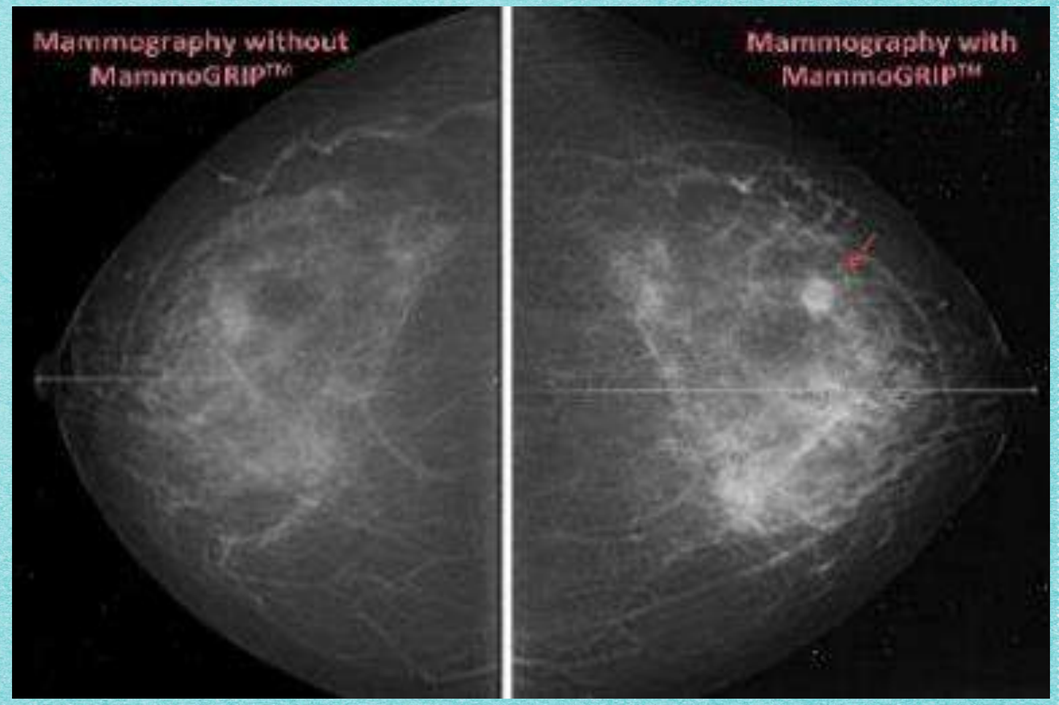
Dr. Daniel Kopans, Breast Imaging 3rd Edition, p 392

What is MammoGRIP®

The Invisible Glove

MammoGRIP® :

- is a non-medicated skin foam solution used when conducting mammograms
- when applied to the technician's hands, MammoGRIP® imparts a slightly tacky or sticky surface which allows a better grip of the breast tissue, thereby allowing more tissue to be pulled into the field of view.



Solution To The Problem ~ MammoGRIP® allows:

- For a better grip of the breast
- For a technologist to obtain more breast tissue into an image
- An improvement in quality of images assisting in earlier detection of cancer

Benefits

- NO modification of existing equipment
- Patented product and methodology: PCT_US2012_050585
- Less manipulation of the breast equals less discomfort and anxiety
- Better first time success
- Less repeats & recalls
- Less exposure to radiation

Facts about Breast Cancer for Radiologists

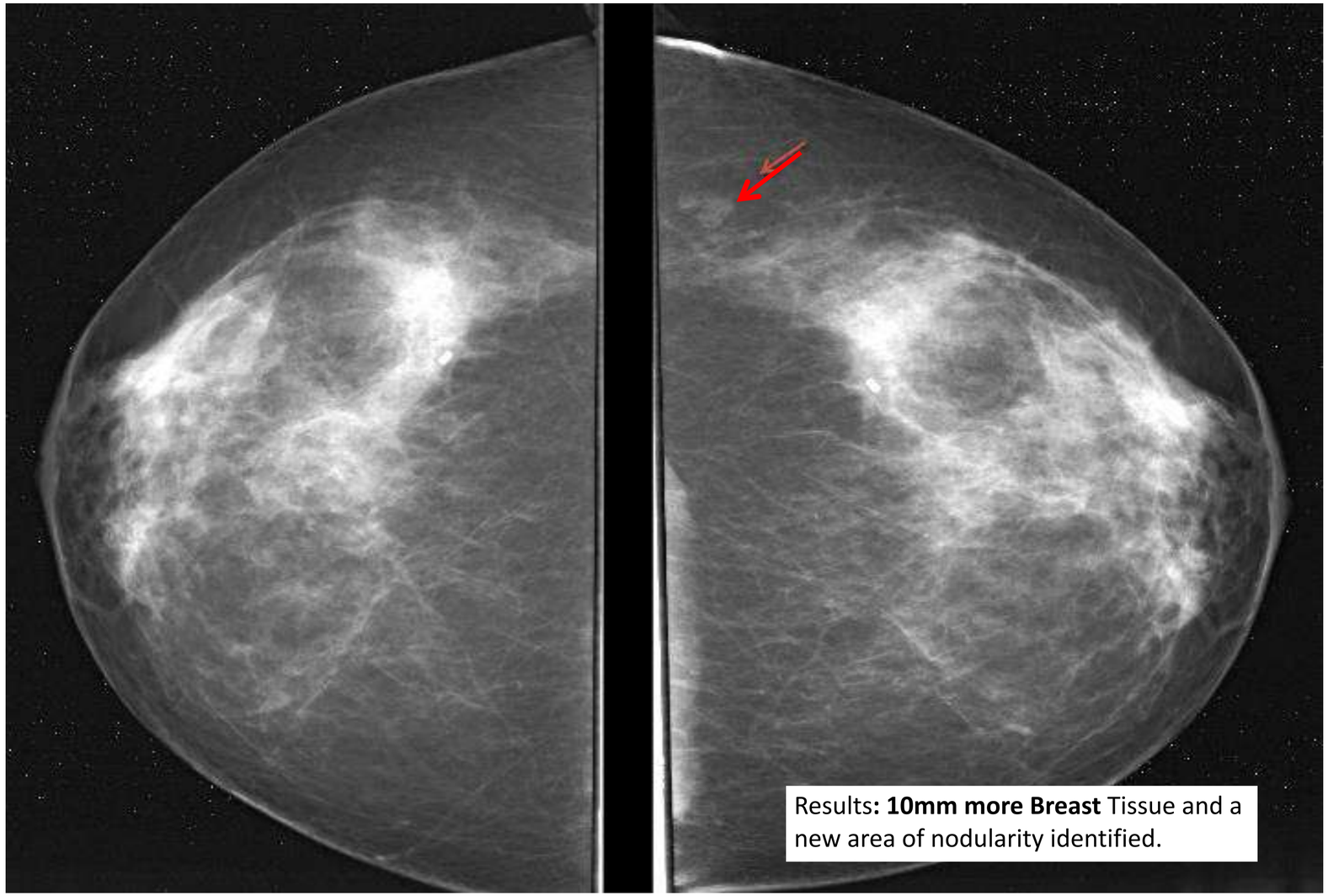
- The average Size of Malignant Calc's (cluster): 6mm
- The average Size of non-invasive cancers such as DCIS: .8cm (8mm)
- The average Size Breast Cancer Found on Mammogram: 1.1cm (11mm)
- The smallest Size of Breast Cancer visible on a Mammogram: .2 - .3cm (2 – 3mm)
- According to the National Breast Cancer Society over 85% of women who get breast cancer DO NOT have a family history
- 70% of breast cancers detected by mammography are developed at the periphery of the breast parenchyma, between the subcutaneous fat or retromammary fat and the breast cone of the breast, which includes the area close to the chest wall
- Frequent screening & earlier detection can lower mortality rate by 30 %.

Early Detection Can Result in FULL Cure

30% Improved Images
25% Assertive Diagn osis

LIFT. STICK. **GRIP**

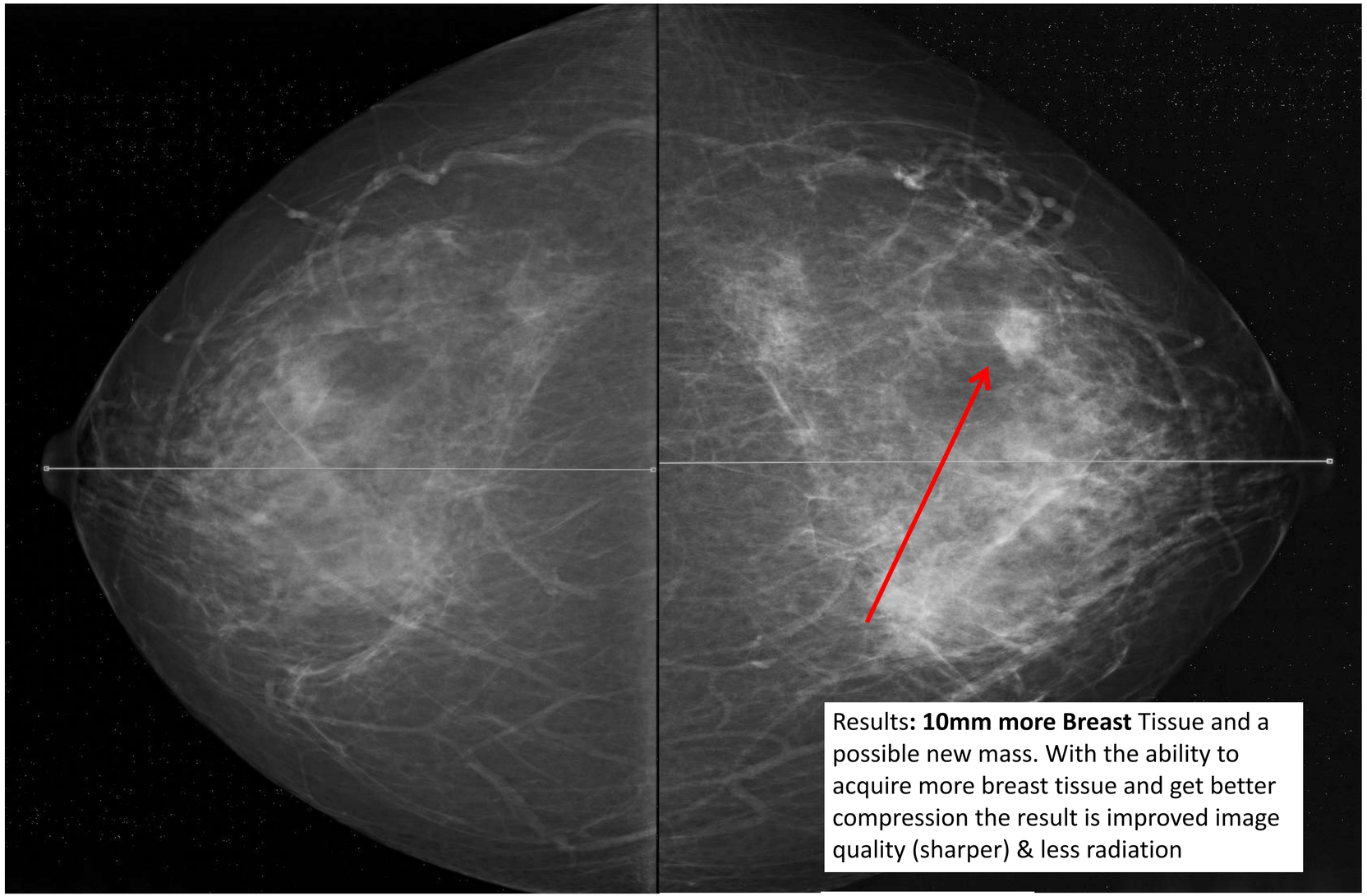
Image Analysis – Patient 1



Year 1
11.1 cm

w/MammoGRIP™
Year 2
12.1 cm

Image Analysis – Patient 2

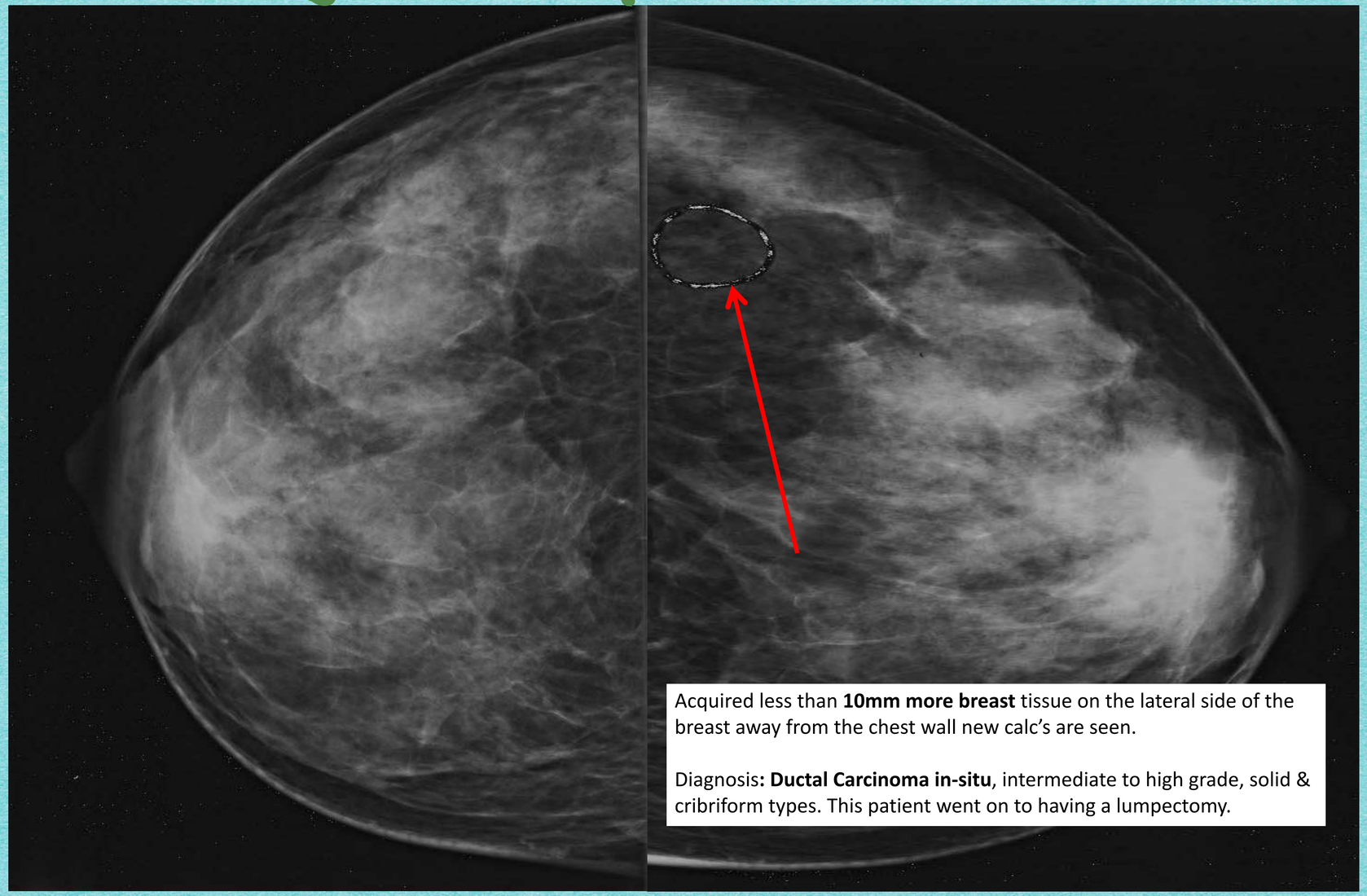


Results**: 10mm more Breast** Tissue and a possible new mass. With the ability to acquire more breast tissue and get better compression the result is improved image quality (sharper) & less radiation

Year 1
13 cm

w/MammoGRIP™
Year 2
14 cm

Image Analysis – Patient 3



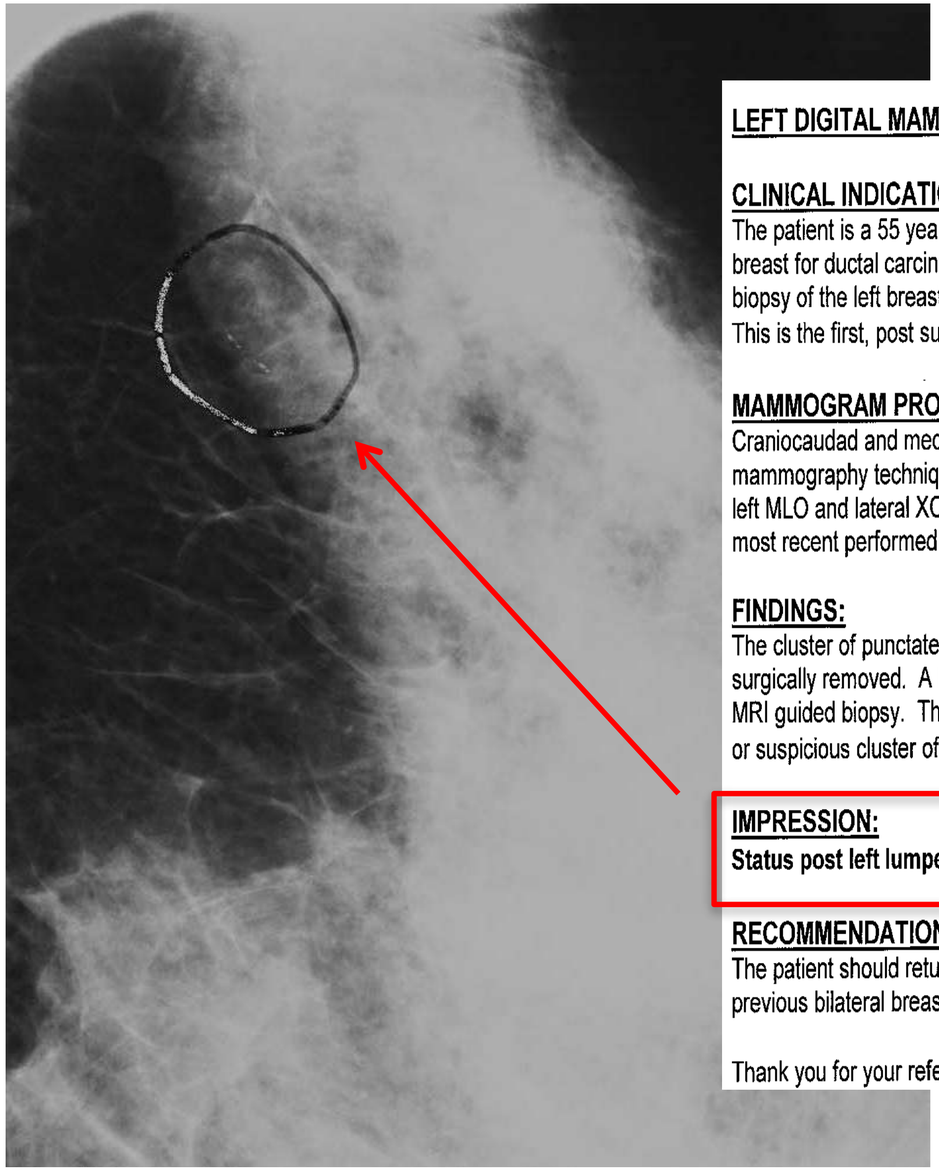
Acquired less than **10mm more breast** tissue on the lateral side of the breast away from the chest wall new calc's are seen.

Diagnosis**: Ductal Carcinoma in-situ**, intermediate to high grade, solid & cribriform types. This patient went on to having a lumpectomy.

Year 1

w/MammoGRIP™
Year 2

Image Analysis – Patient 3 (continued)



LEFT DIGITAL MAMMOGRAPHY WITH CAD (COMPUTER AIDED DETECTION)-04/19/2011

CLINICAL INDICATIONS:
The patient is a 55 year old female who is status post stereotactic biopsy followed by lumpectomy of the left breast for ductal carcinoma in-situ, intermediate to high-grade, solid and cribriform-types. An MRI guided biopsy of the left breast performed on 11/16/10 was benign. No radiation therapy has been administered. This is the first, post surgical mammogram.

MAMMOGRAM PROCEDURE:
Craniocaudad and mediolateral oblique views of the left breast were performed, utilizing full field digital mammography technique, as well as the iCAD Second Look Computer Aided Detection system. Additionally, left MLO and lateral XCC magnification views were obtained. Comparison is made to the prior studies, the most recent performed on 10/27/10.

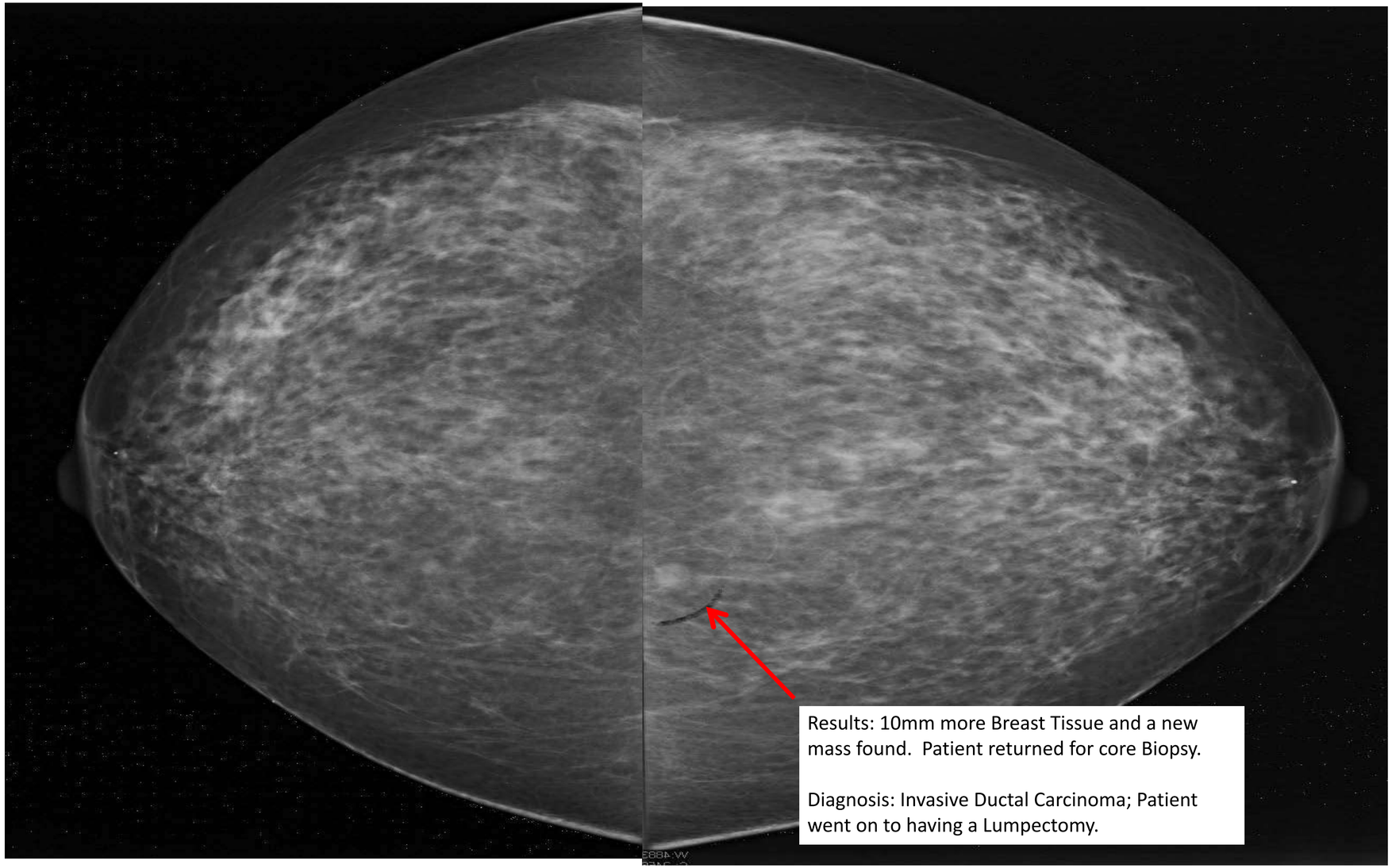
FINDINGS:
The cluster of punctate calcifications previously noted in the upper, outer quadrant of the left breast have been surgically removed. A biopsy clip is noted in the central, retroareolar aspect of the breast, placed during the MRI guided biopsy. There is no evidence of significant architectural distortion, a significant parenchymal mass or suspicious cluster of microcalcifications.

IMPRESSION:
Status post left lumpectomy for DCIS.

RECOMMENDATIONS:
The patient should return for a bilateral mammogram and breast ultrasound in 10/11, the anniversary of the previous bilateral breast imaging study. BIRADS 2, benign. The patient was given/mailed a layman's report.

Thank you for your referral.

Image Analysis – Patient 4



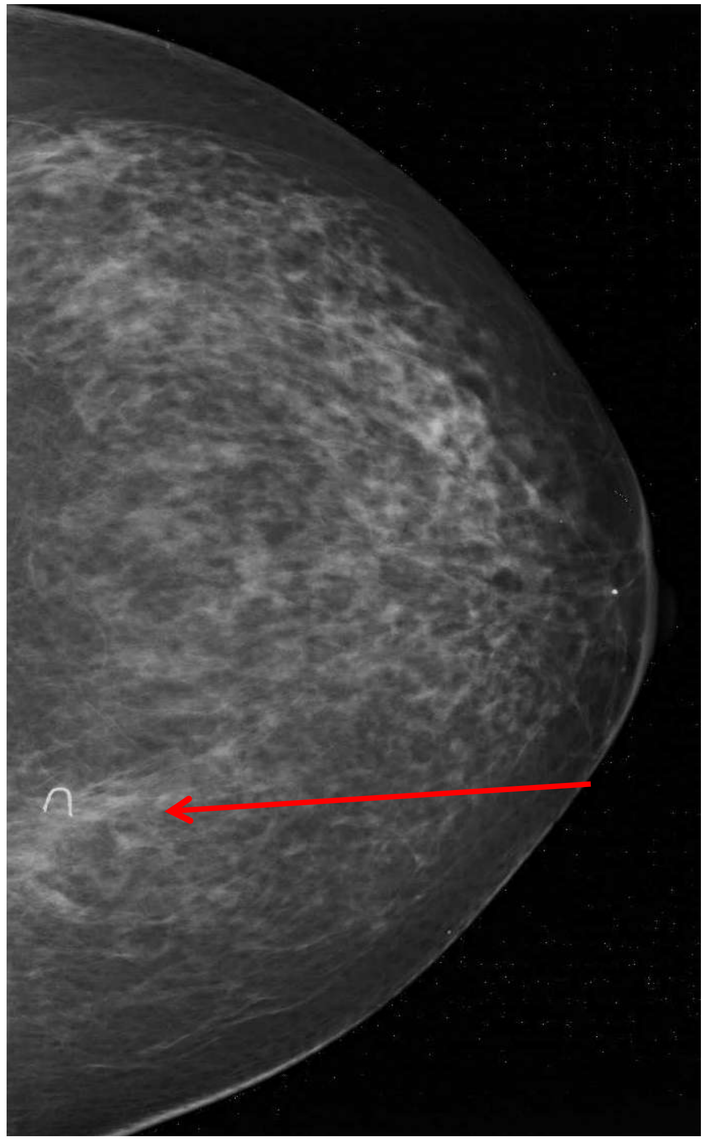
Results: 10mm more Breast Tissue and a new mass found. Patient returned for core Biopsy.

Diagnosis: Invasive Ductal Carcinoma; Patient went on to having a Lumpectomy.

Year 1
9.5 cm

w/MammoGRIP™
Year 2
10.5 cm

Image Analysis – Patient 4 (continued)



ULTRASOUND GUIDED CORE NEEDLE BIOPSY - RIGHT BREAST (X 1), ULTRASOUND GUIDED CORE NEEDLE BIOPSY - LEFT BREAST (X 2), ULTRASOUND GUIDED CLIP PLACEMENT - RIGHT BREAST (X 1), ULTRASOUND GUIDED CLIP PLACEMENT - LEFT BREAST (X 2), BILATERAL POST BIOPSY DIAGNOSTIC DIGITAL MAMMOGRAPHY WITH CAD (COMPUTER AIDED DETECTION), AND SPECIMEN RADIOGRAPHY - 12/06/2010

Following the procedure, a dressing was applied over each puncture site. The specimens were sent to the laboratory for pathologic analysis. The patient tolerated the procedure well.

BILATERAL DIAGNOSTIC DIGITAL MAMMOGRAM

A bilateral diagnostic digital mammogram was performed in the CC and 90 degree lateral projections, utilizing full field digital mammography technique, as well as the iCAD Second Look Computer Aided Detection system. The breast parenchyma is heterogeneously dense. A radiopaque clip is present in the upper inner 1:00 axis of the right breast, superimposed on the mass, which is now partially obscured by increased density, secondary to biopsy edema and possible small hematoma. Two radiopaque clips are present in the 11:00 and 12:00 axis of the left breast, at the middle depth. The clip in the 12:00 axis of the left breast is superimposed on the calcifications in question, confirming anatomic concordance of the sonographic lesion with the mammographic calcifications.

IMPRESSION/RECOMMENDATIONS:

Successful ultrasound guided bilateral core needle biopsies.

1. The pathology for the mass in the 1:00 axis of the right breast, demonstrates, "~~Invasive duct~~al ~~carcinom~~a, moderately differentiated (architecture:3, Nuclear grade:2, mitotic figures:1)." A surgical consultation is recommended.

2. The pathology for the hypoechoic lesion in the 11:00 axis of the left breast, demonstrates, "Fibrocystic changes, non-proliferative type."

3. The pathology for the core needle biopsy performed in the 12:00 axis of the left breast, demonstrates, "Fibroadenoma with associated calcifications."

Thank you for your referral.

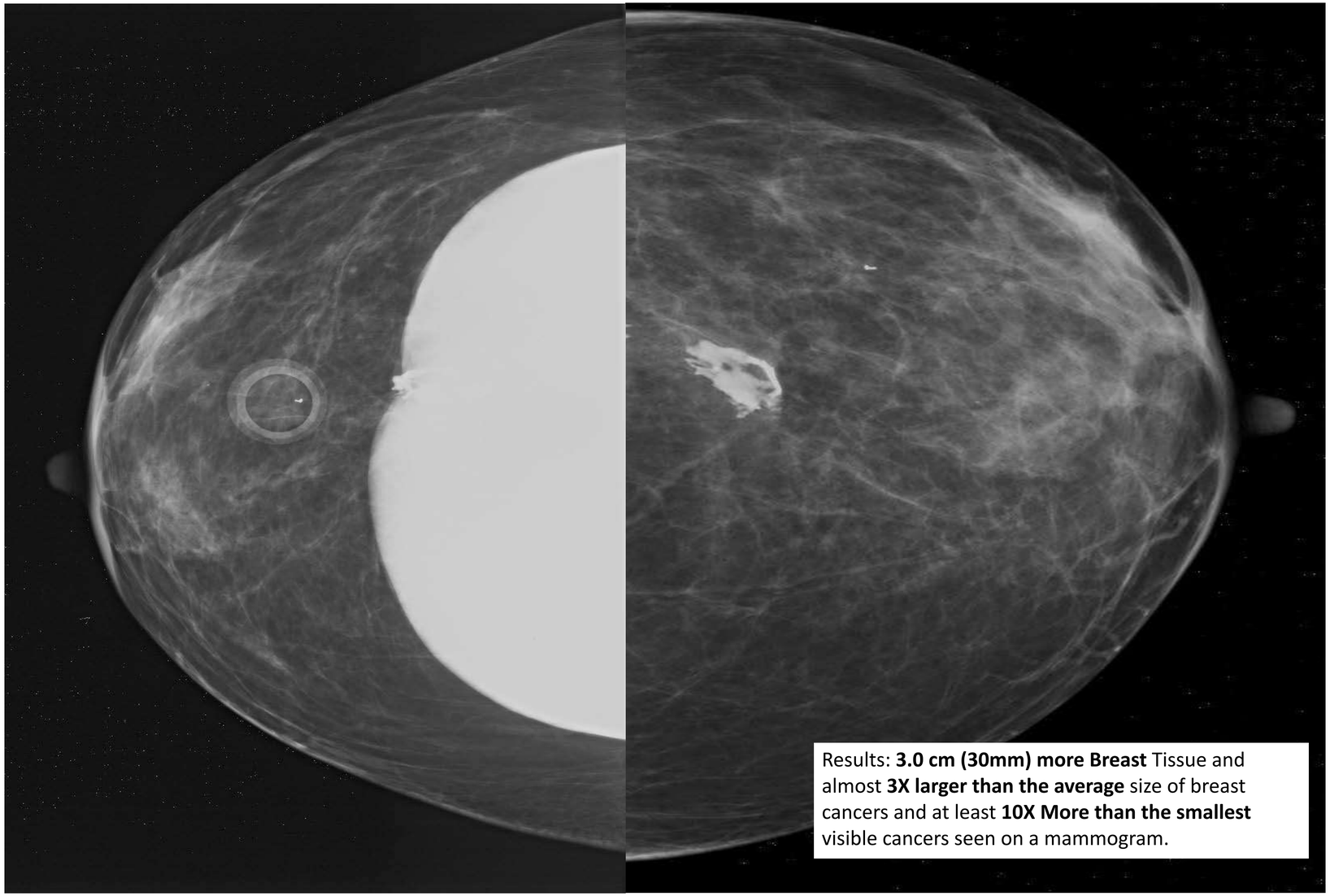
Mammograms with Implant Patients

- Probably least favorite exam for most radiologists to read and technicians to perform
- Because the x-ray beam is unable to penetrate implants special views are required
- One view requires the technician to manipulate the implant by pulling the breast forward to compress the breast tissue w/o the implant in view which not all technicians do well. I will teach you how with…

MammoGRI®

The Invisible Glove

Image Analysis – Patient 5

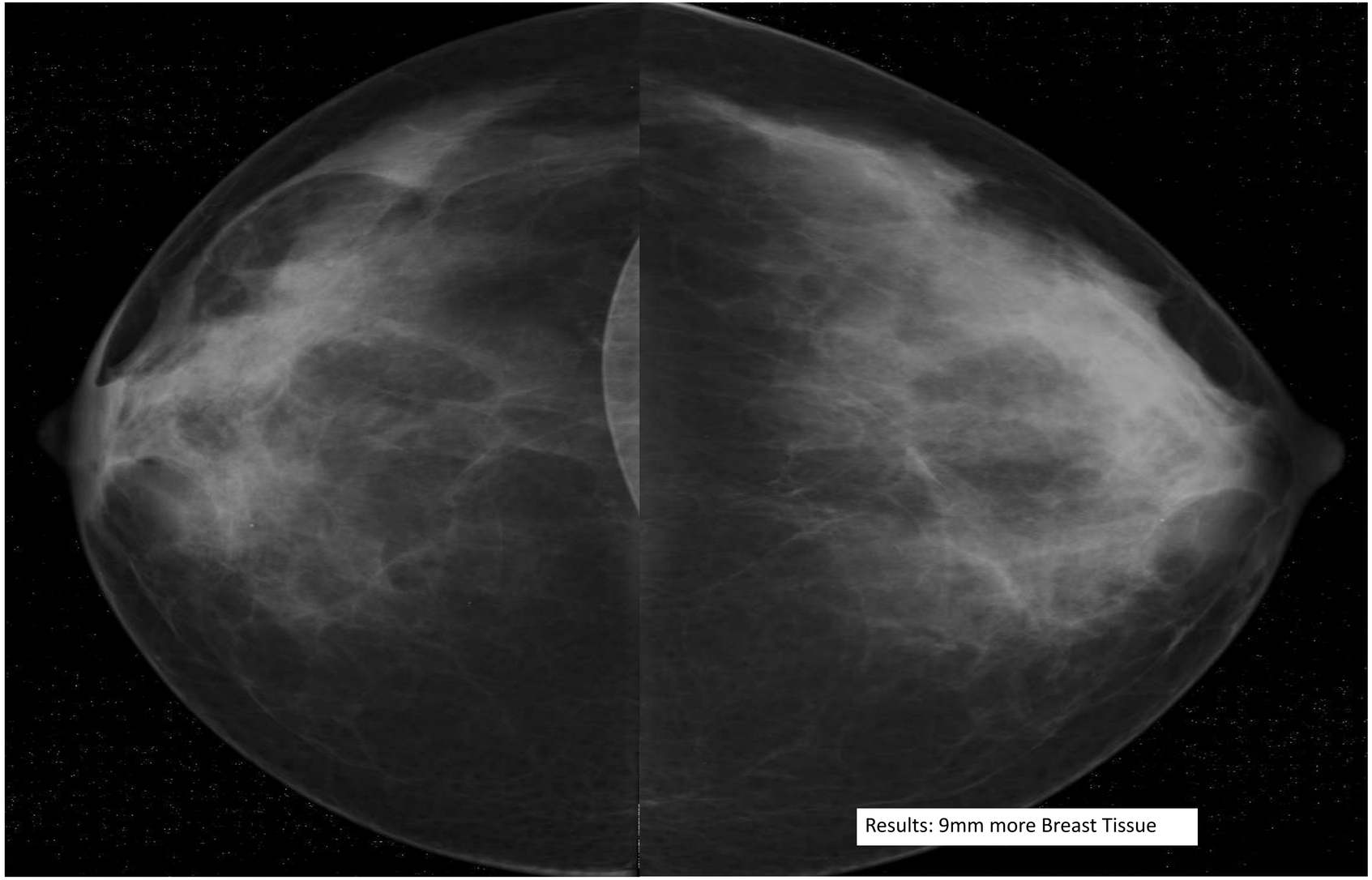


Results: **3.0 cm (30mm) more Breast** Tissue and almost **3X larger than the average** size of breast cancers and at least **10X More than the smallest** visible cancers seen on a mammogram.

Year 1 ID view
5.5 cm

w/MammoGRIP™
Year 2 ID view
8.5 cm

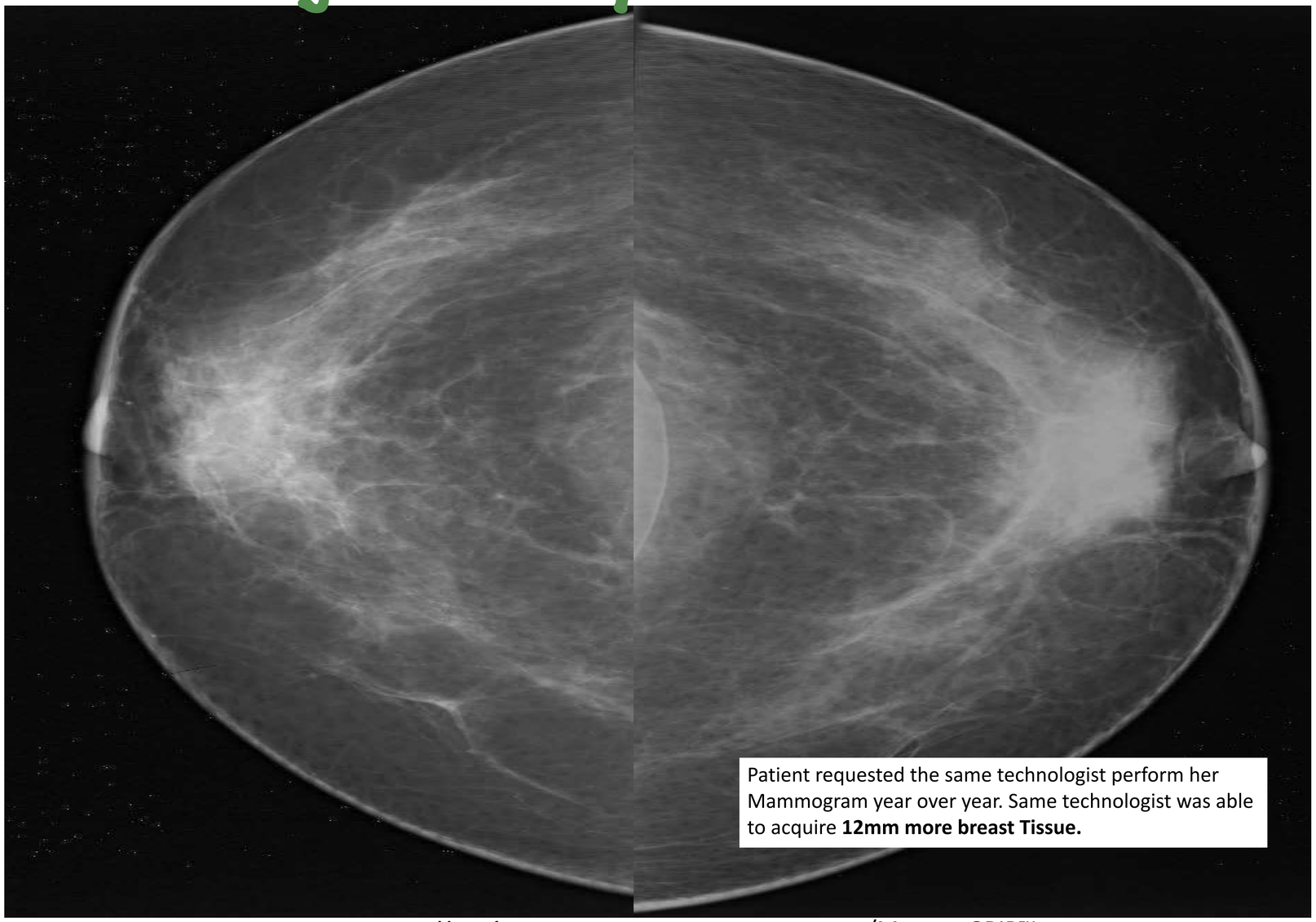
Image Analysis – Patient 6



Year 1
7.6 cm

w/MammoGRIP™
Year 2
8.5 cm

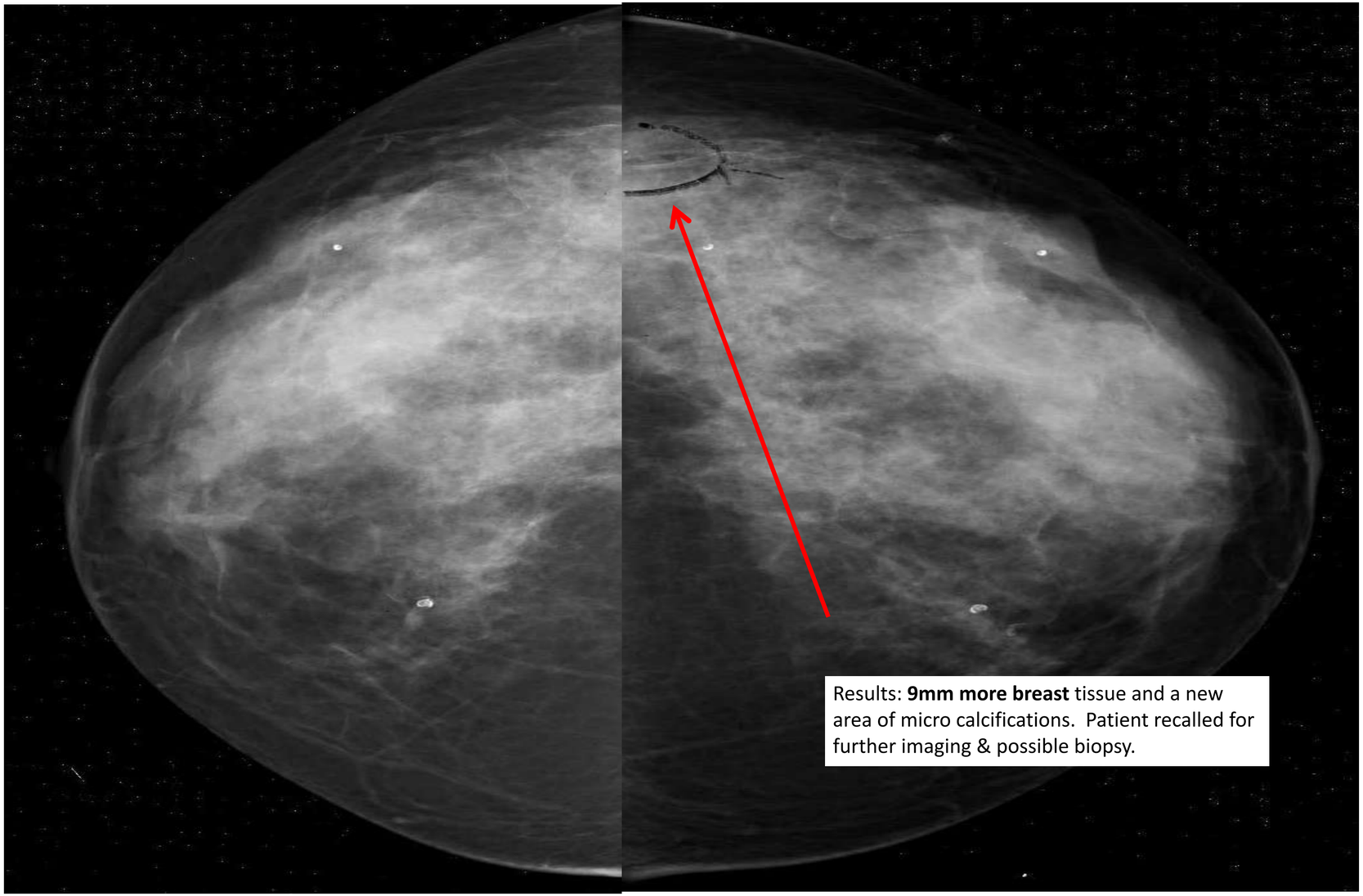
Image Analysis – Patient 7



Year 1

w/MammoGRIP™
Year 2

Image Analysis – Patient 8



Year 1
8.1 cm

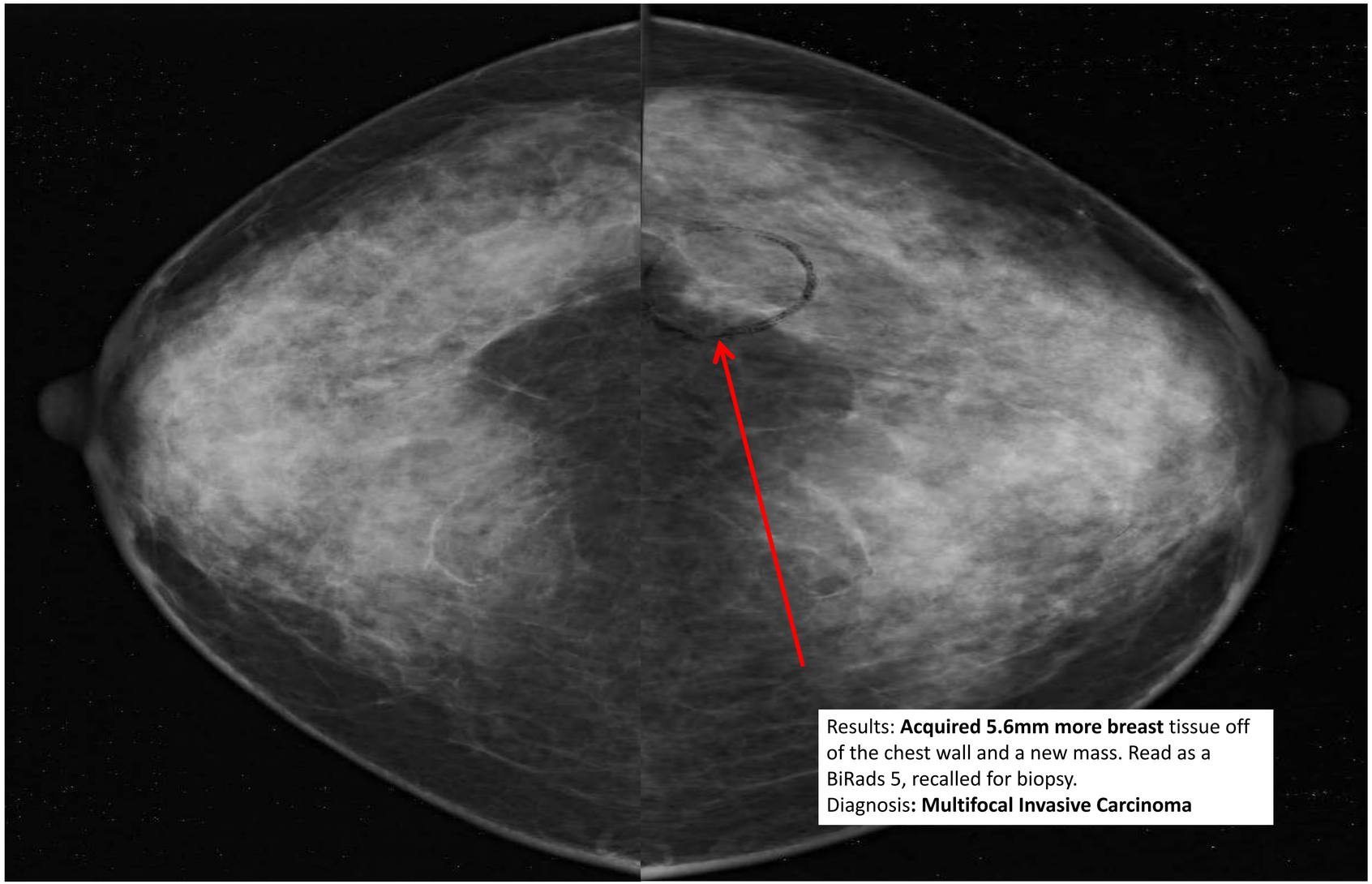
w/MammoGRIP™
Year 2
9 cm

Image Analysis – Patient 9

Year 1
14.2 cm

w/MammoGRIP™
Year 2
16.2 cm

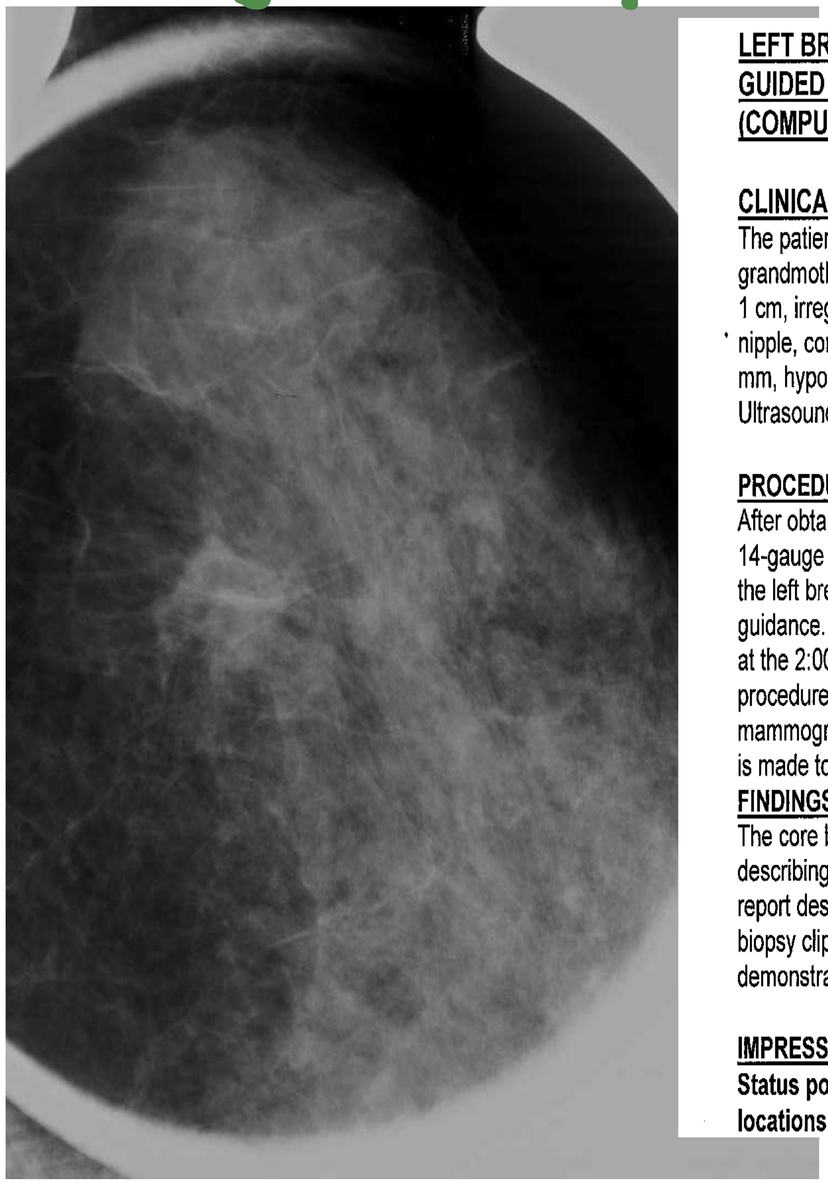
Image Analysis – Patient 10



Year 1
14.2 cm

w/MammoGRIP™
Year 2
16.2 cm

Image Analysis – Patient 10 (continued)



LEFT BREAST ULTRASOUND GUIDED CORE NEEDLE BIOPSIES (X 2), ULTRASOUND GUIDED CLIP PLACEMENTS AND FOLLOW-UP LEFT DIGITAL MAMMOGRAPHY WITH CAD (COMPUTER AIDED DETECTION) - 02/16/2011

CLINICAL INDICATIONS:

The patient is a 53 year old female with a positive family history of carcinoma of the breast (maternal grandmother diagnosed in her 40's), who had routine breast imaging performed on 2/14/11. On that study, a 1 cm, irregular area of focal asymmetry had been noted at the 1:00 axis of the left breast, 6 cm from the nipple, corresponding to a highly suspicious, irregular, hypoechoic, 1.1 cm mass sonographically. A second, 5 mm, hypoechoic area at the 2:00 axis of the left breast, 6 cm from the nipple, had also been noted. Ultrasound guided biopsy had been recommended.

PROCEDURE:

After obtaining informed consent, and utilizing 1% lidocaine local anesthesia and sterile technique, five, 14-gauge core needle biopsy specimens were obtained from the irregular, hypoechoic mass at the 1:00 axis of the left breast, 6 cm from the nipple. A biopsy clip was then inserted into the mass under ultrasound guidance. Five, 14-gauge core needle biopsy specimens were then obtained from the 6 mm, hypoechoic area at the 2:00 axis of the left breast, 7 cm from the nipple, followed by clip placement. The patient tolerated the procedures well. Post biopsy, CC and 90 ML views of the left breast were obtained, utilizing full field digital mammography technique, as well as the iCAD Second Look Computer Aided Detection system. Comparison is made to the pre-biopsy study dated 2/14/11.

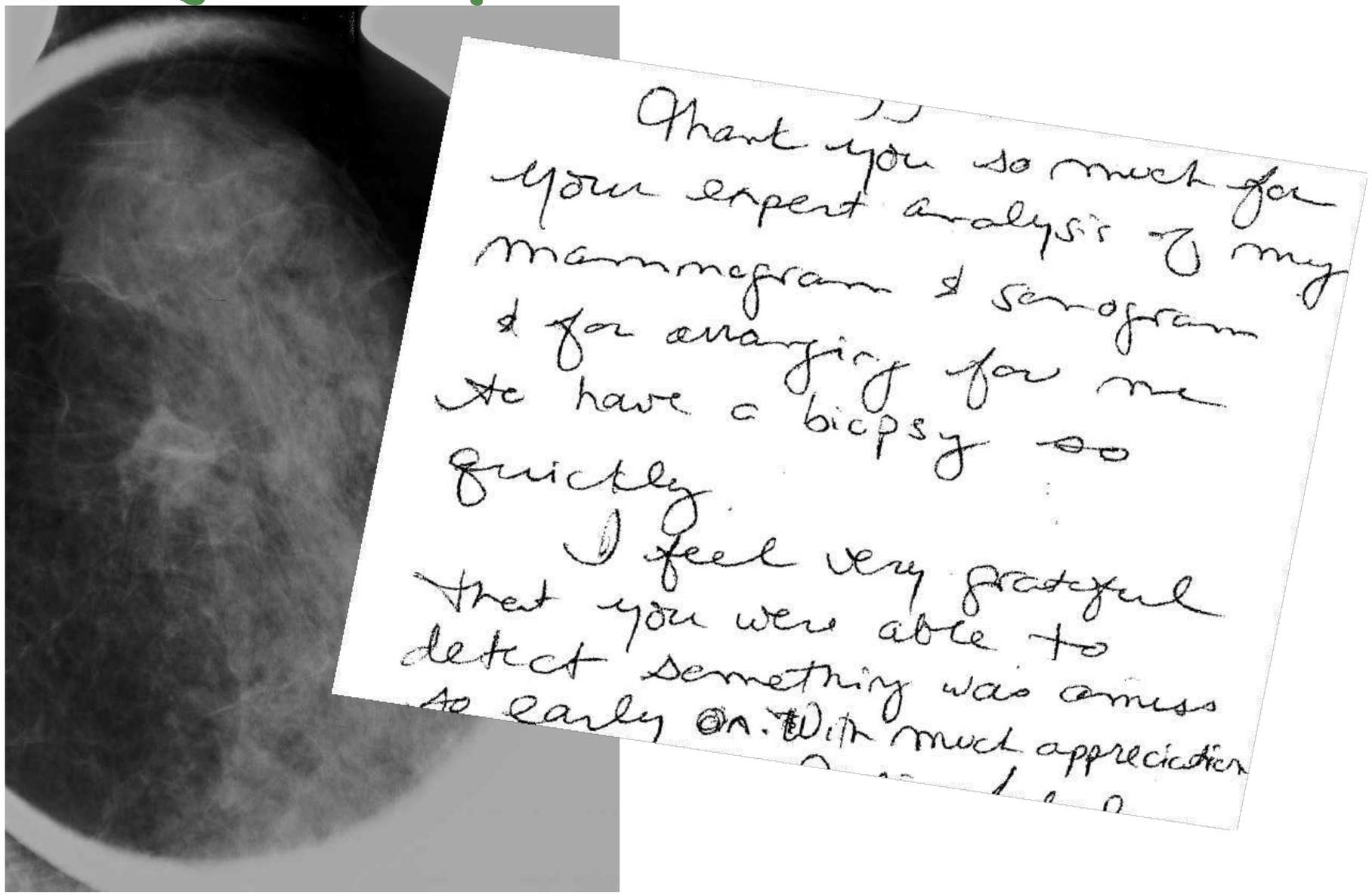
FINDINGS:

The core biopsy specimens have been sent to NYU Pathology Associates for assessment. The report describing the 1:00 mass reveals, "Invasive mammary carcinoma with mixed ductal and lobular features." The report describing the 2:00 mass reveals, "Small focus of invasive mammary carcinoma." Post biopsy, two biopsy clips are noted in the upper, outer quadrant of the left breast. No other significant change is demonstrable.

IMPRESSION:

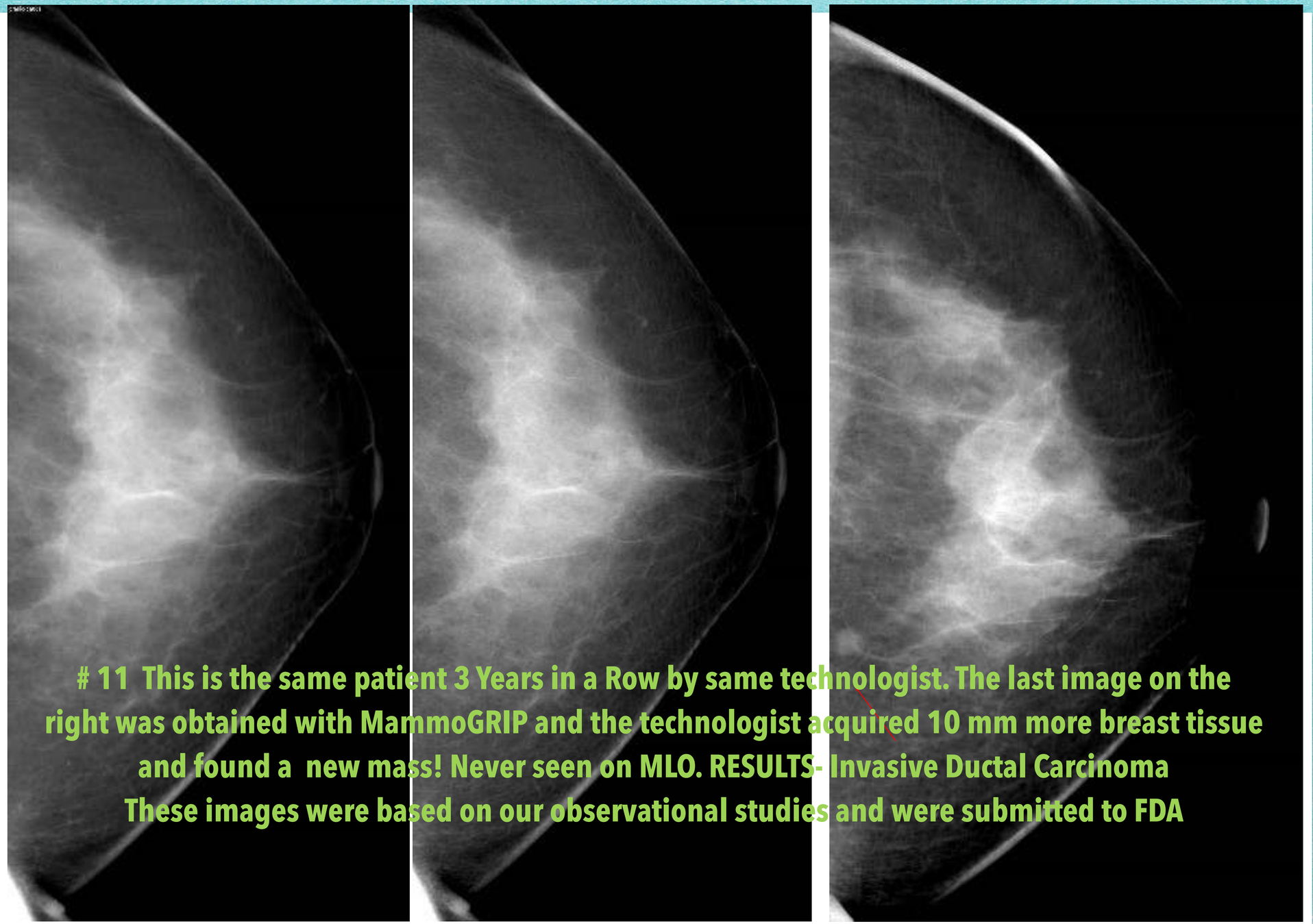
Status post ultrasound guided core needle biopsies of hypoechoic masses at the 1:00 and 2:00 locations in the left breast documenting multifocal invasive mammary carcinoma.

Image Analysis - Patient 10 (continued)



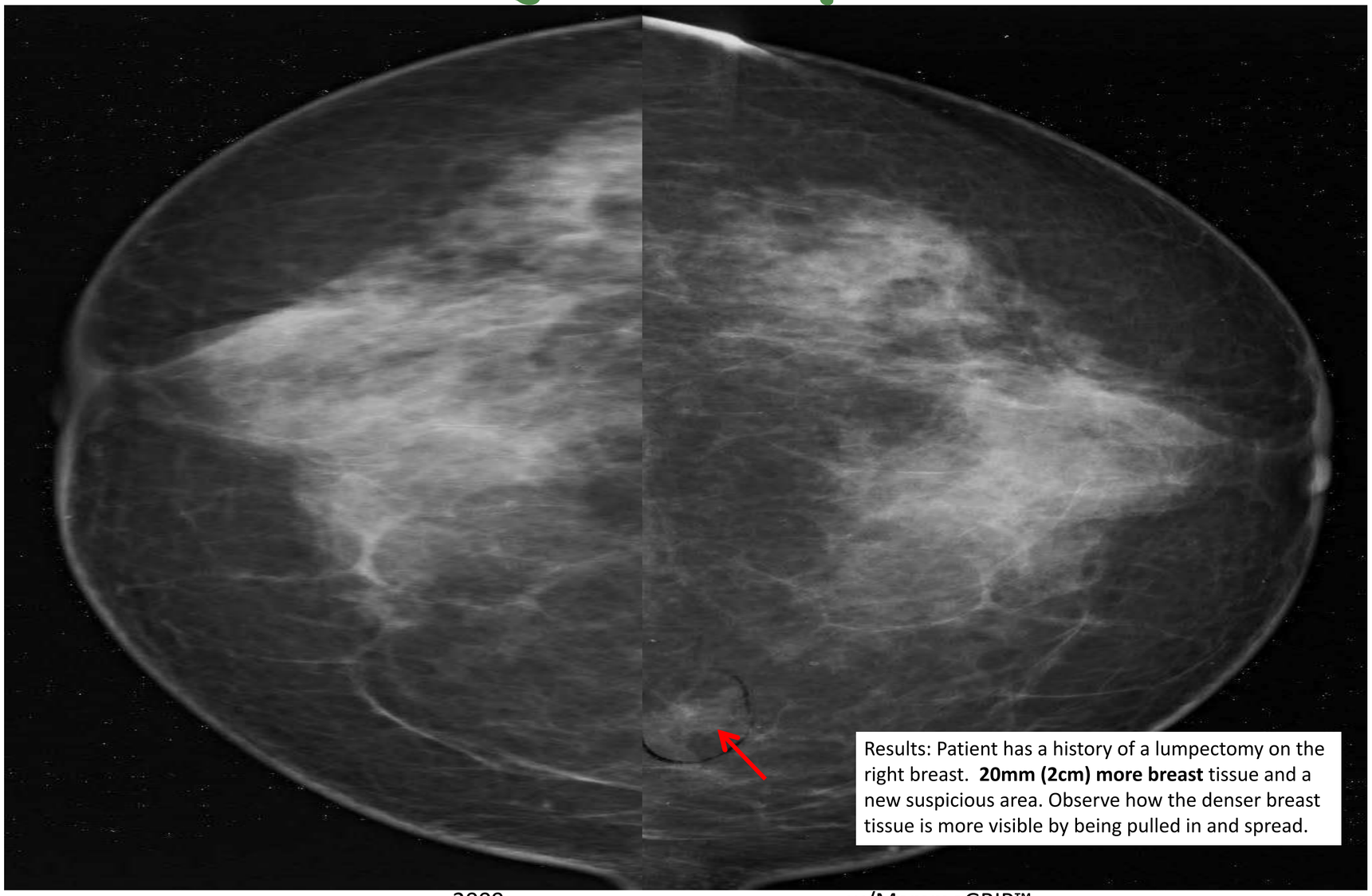
Thank you so much for your expert analysis of my mammogram & sonogram & for arranging for me to have a biopsy so quickly.

I feel very grateful that you were able to detect something was amiss so early on. With much appreciation



11 This is the same patient 3 Years in a Row by same technologist. The last image on the right was obtained with MammoGRIP and the technologist acquired 10 mm more breast tissue and found a new mass! Never seen on MLO. RESULTS- Invasive Ductal Carcinoma
These images were based on our observational studies and were submitted to FDA

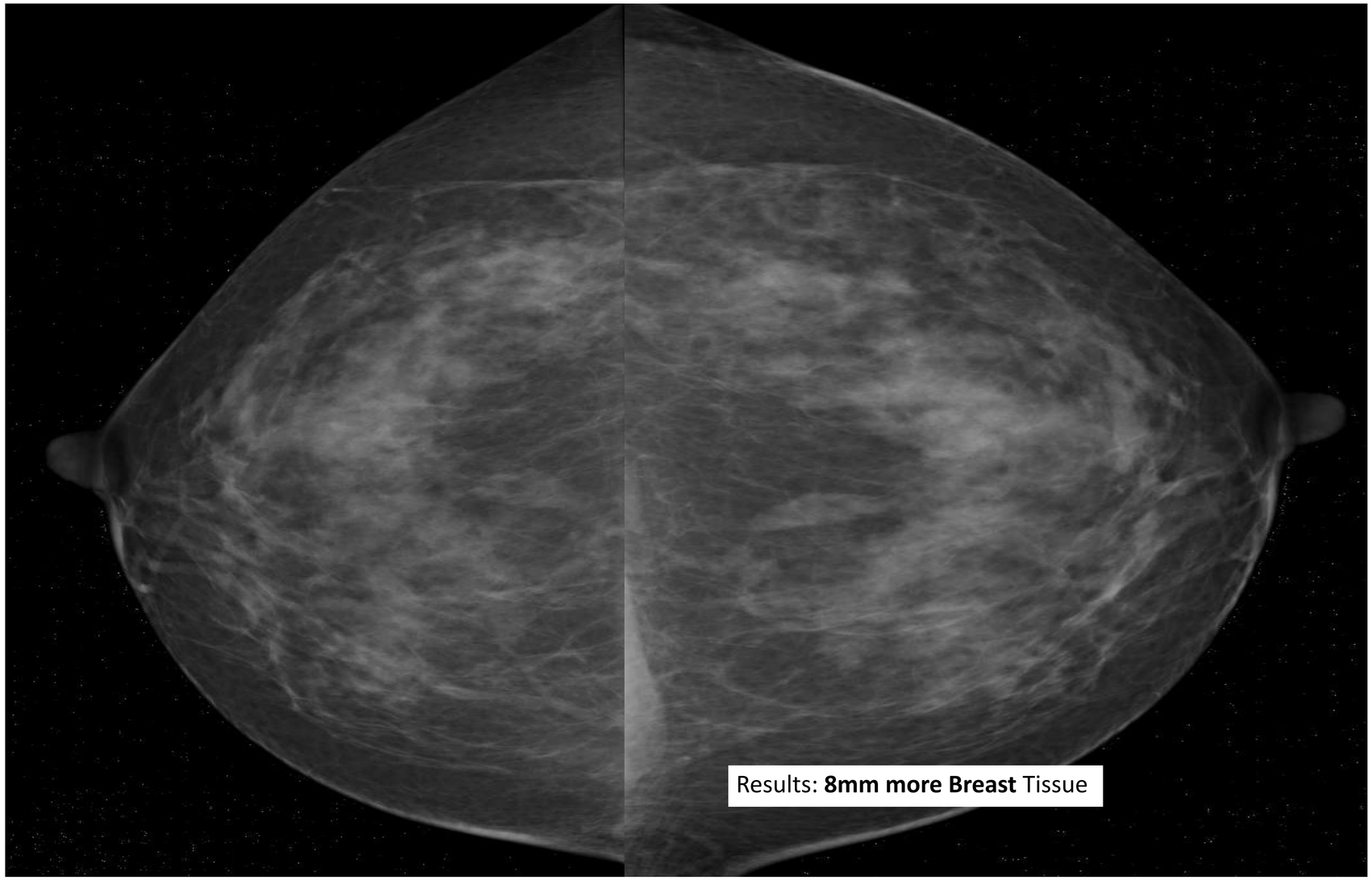
Image Analysis –



2009
6.8 cm

w/MammoGRIP™
2010
8.8 cm

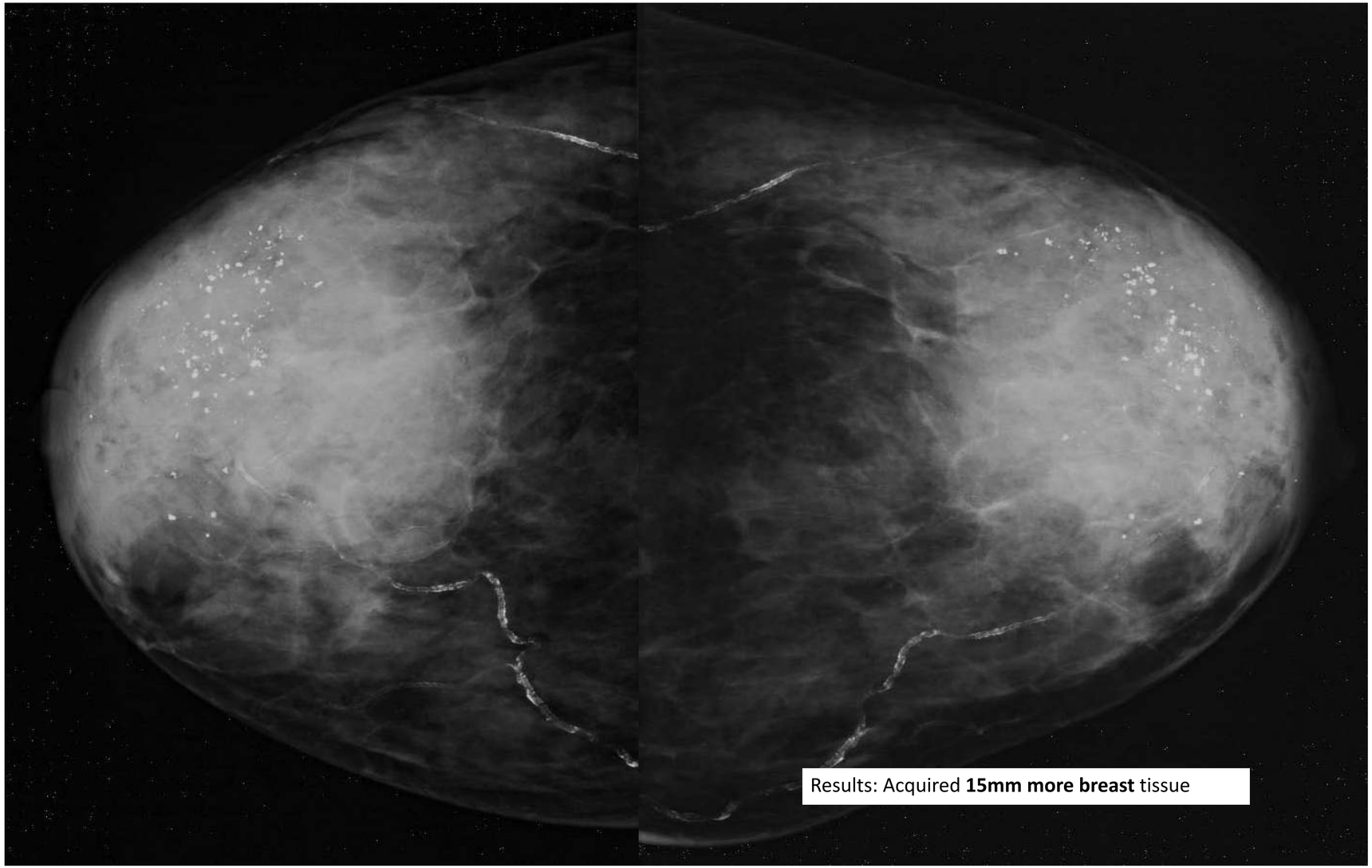
Image Analysis



Year 1
8 cm

w/MammoGRIP™
Year 2
8.8 cm

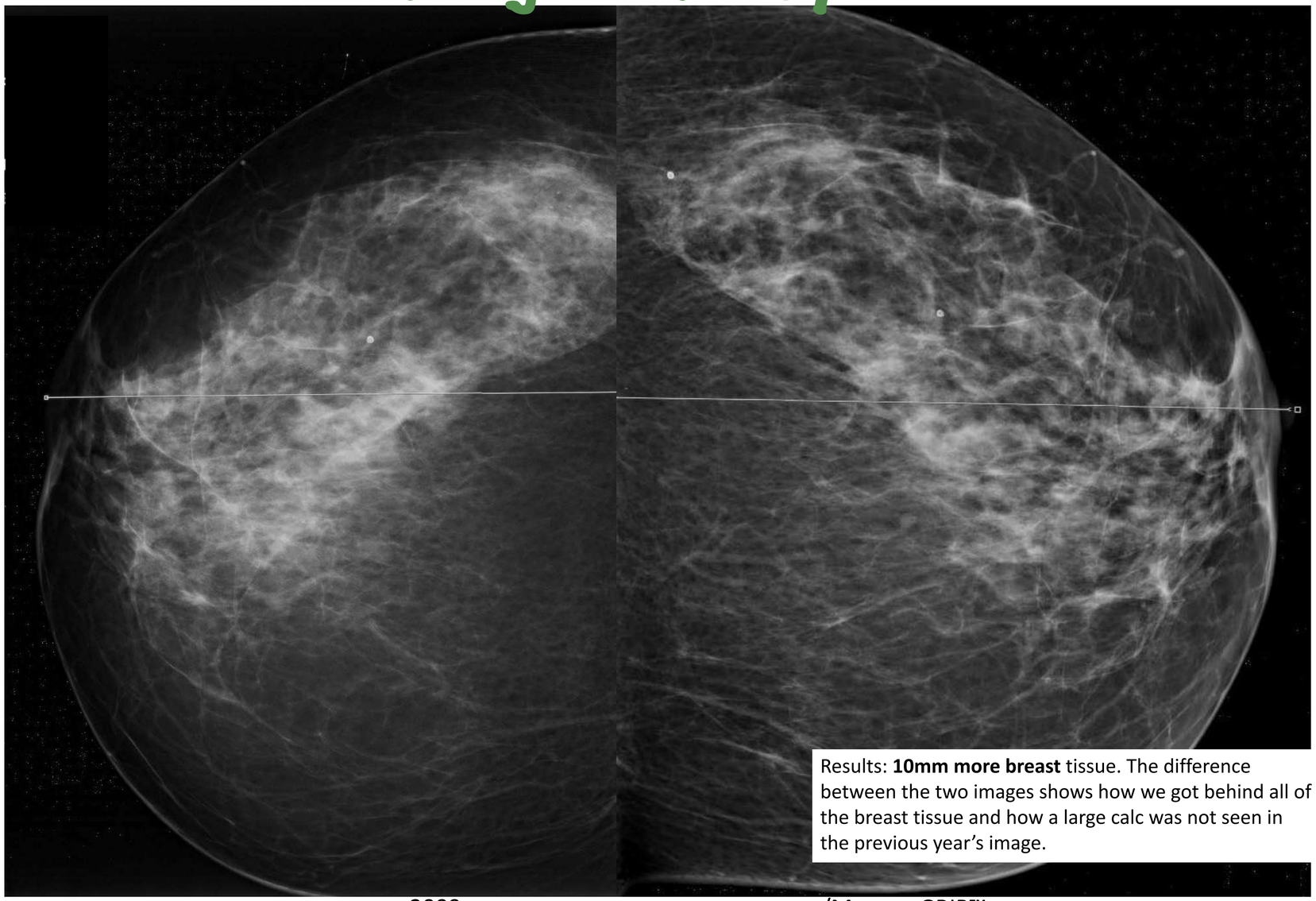
Image Analysis



2010
10.4 cm

w/MammoGRIP™
2011
11.9 cm

Image Analysis



Results: **10mm more breast** tissue. The difference between the two images shows how we got behind all of the breast tissue and how a large calc was not seen in the previous year's image.

2009
143.2 mm

w/MammoGRIP™
2010
153.7 mm

Image Analysis –

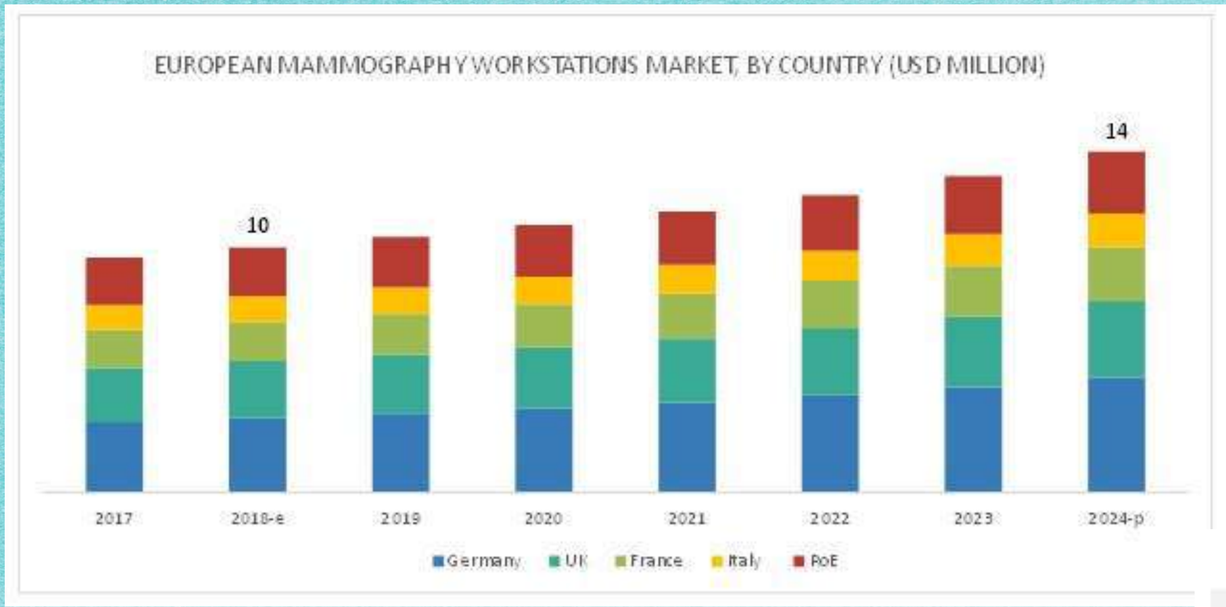
Results: Acquired **12mm more breast** tissue. Note how the breast parenchyma is pulled off of the chest wall which spreads the breast tissue out for better visualization, even with dense breast tissue..

2009
7.7 cm

w/MammoGRIP™
2010
8.9 cm

Business Model

- Representation by a few distributors in Strategic Markets
- Markets:
- 1. USA and Canada;
- 2. Brazil and LATAM;
- 3. Western Europe;
- 4. Eastern Europe
- 5. Asia (Ex-China);
- 6. Australasia;
- 7. Sub-Saharan Africa;
- 8. North of Africa;
- 9. Middle-East ;
- 10. China .



Number of Mammogram Machines tends to increase

The *Programa para as Doenças Oncológicas* (PNDO) from Portugal aims to achieve in 2020:

100% women population is covered - breast cancer screening

Gráfico 10. **Taxas de cobertura geográfica e de adesão no âmbito do Rastreio do Cancro da Mama**

Nota: Dados Provisórios de Portugal
Fonte: DGS – ARS 2020

Advantages for Imaging Services Providers

- Determines incisive increase in productivity (about 2X);
- Generates cost reduction
- Results in less liability
- Improves quality of the services provided