### Development of a New Soft Tissue Breast Radiographic Marker for Breast Biopsy and Other Soft Tissue Tumors

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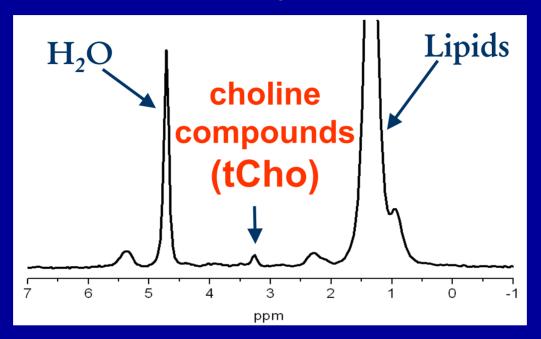
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- Breast Radiographic Markers (RMs)
  - Surgical localization after biopsy
  - Follow up neoadjuvant chemotherapy
  - Marking lesion site for boost field irradiation

RM composition - Stainless Steel Alloy or Titanium Alloy

- Diagnosis and management of breast cancer
  - Mammography / Ultrasound
  - MRI
  - > in vivo <sup>1</sup>H MR Spectroscopy

#### <sup>1</sup>H MR spectrum

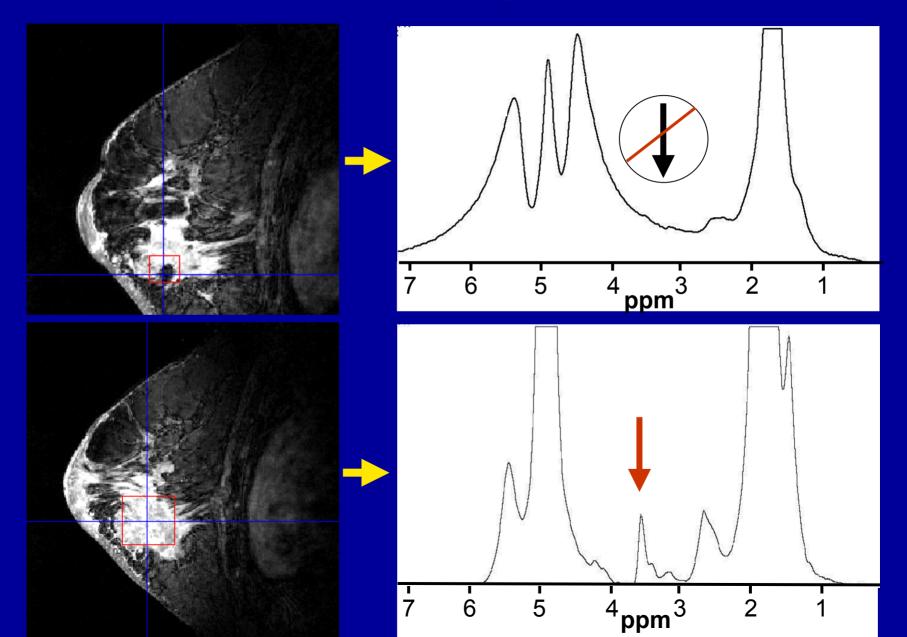


#### Neoplastic breast tissue produces a signal from tCho

- Roebuck et al. Anticancer Res 1999
- Kvistad et al. J Magn Reson Imaging 1999
- Gribbestad et al. Anticancer Res. 1999
- Katz-Brull et al. Natl Cancer Inst 2002
- Bolan et al. Mag Res Med. 2003

- Stainless Steel and Titanium Alloy RM
  - Movement
    - Rosen et al Radiology 2001
    - ➤ Harris et al Radiology 2003
    - ➤ Birdwell et al Radiology 2003
    - Esserman et al Radiographics 2004
  - Breast MRI void artifact
    - > Lanner et al AJR 2004
    - Kubota et al Breast Cancer 2004
  - ➤ Breast <sup>1</sup>H MRS spectral artifact
    - U of Minnesota / Center for Magnetic Resonance Research

#### Sample Case – Metallic RM



### Purpose:

Evaluate the effects of a new FDA approved radiographic marker on:

- Mammography
- Ultrasound
- Breast MRI (1.5 T and 4T)
- Breast MRS (1.5 T and 4T)

### **Materials and Methods:**

#### New FDA approved breast RM

- ➤ Biomarc ® (Carbon Medical Inc.)
- Composition: Pyrolytic Carbon Zirconium Oxide
- Size: 3 mm X 1 mm
- Color: Black

#### 40 Biomarc ® RM in 33 patients (BIRAD 4/5)

- > 25 ultrasound guidance (14 gauge trocar)
- > 11 stereotactic guidance (11 gauge needle biopsy)
- > 4 MRI guidance (Daum titanium trocar)

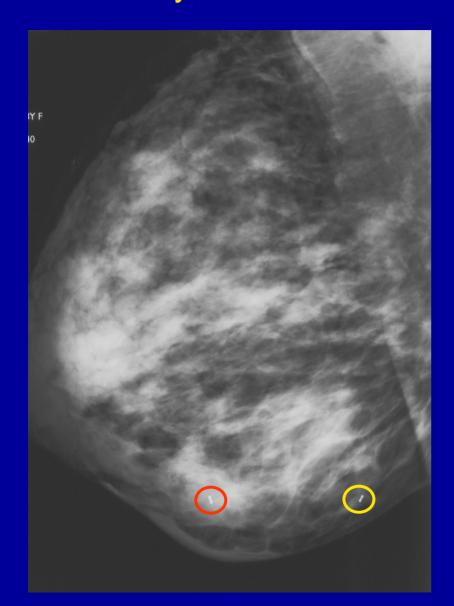
#### **Materials and Methods:**

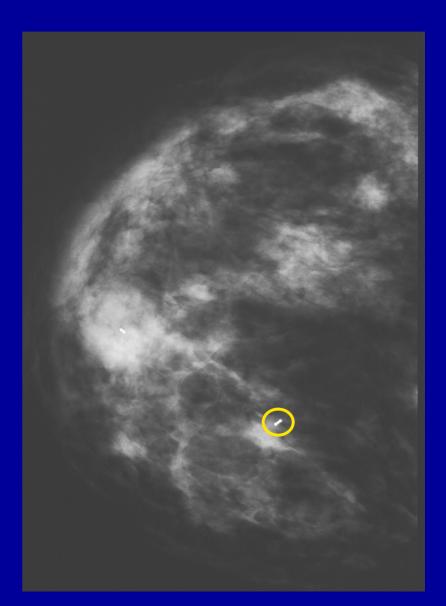
- All RM evaluated for visibility at time of deployment:
  - Mammography
  - Ultrasound
- 15 RM evaluated for migration and visibility on follow up:
  - > 5 mammography at 6 month follow up
  - > 10 ultrasound at 3 wk, 6wk, and 24 wks
- 5 RM were check for void and spectral artifact at 1.5 T and 4T
  - ► [tCho] quantified with <sup>1</sup>H MRS at 4T (Bolan et al. MRM 2003)

#### **Results:**

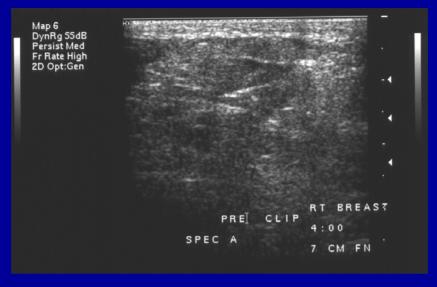
- All 32 RM placed within 4 mm of biopsy site
- All 32 RM visible on mammography / ultrasound deployment.
- 5/5 RM visible at 6 month follow up on mammography
- 8/10 RM visible on follow up ultrasound
- 3/5 RM visible on MRI at 1.5T
- 5/5 RM visible on MRI at 4T
- 5/5 RM adequate MRS at 4T

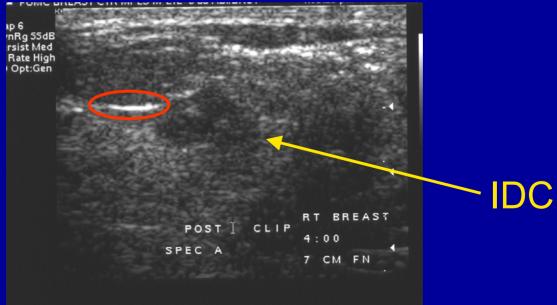
# BiomarC <sup>®</sup> - Mammography 38 year old female with invasive ductal carcinoma





# BiomarC ® - Ultrasound 38 year old female with invasive ductal carcinoma





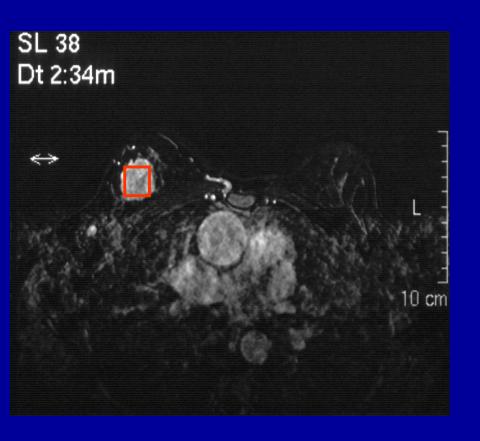
# BiomarC ® - Ultrasound 38 year old female with invasive ductal carcinoma 7 day follow up

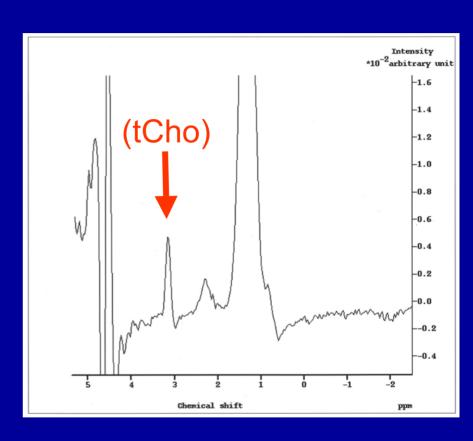


# BiomarC ® - Computed Tomography 38 year old female with invasive ductal carcinoma

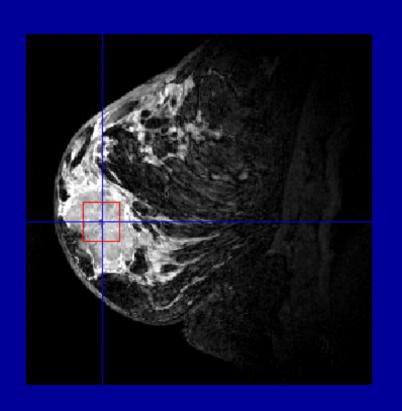


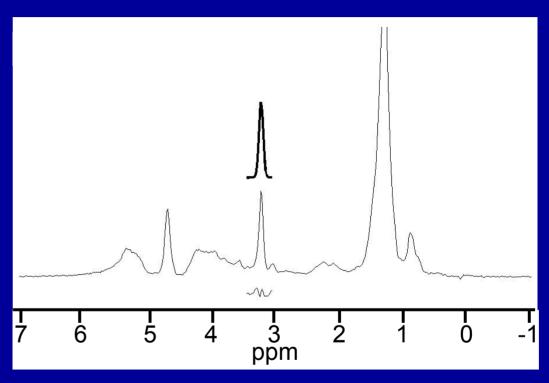
# BiomarC ® - 1.5T MRI / MRS 38 year old female with invasive ductal carcinoma





## BiomarC ® - 4T MRI / MRS 38 year old female with invasive ductal carcinoma

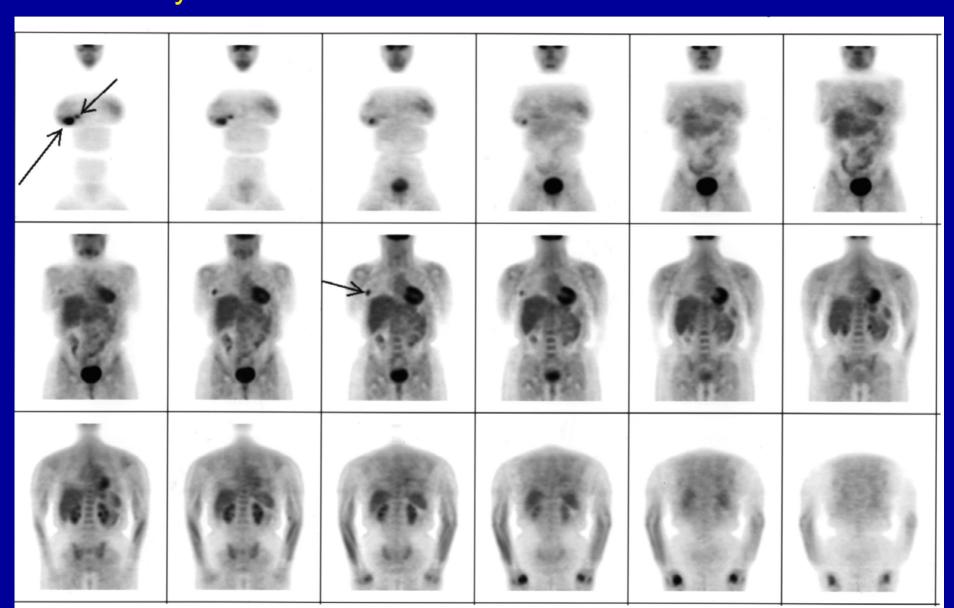




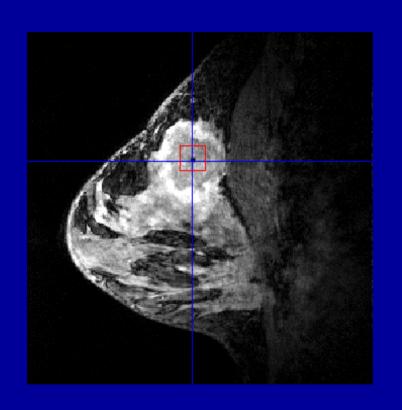
 $[tCho] = 4.85 \pm .07$ 

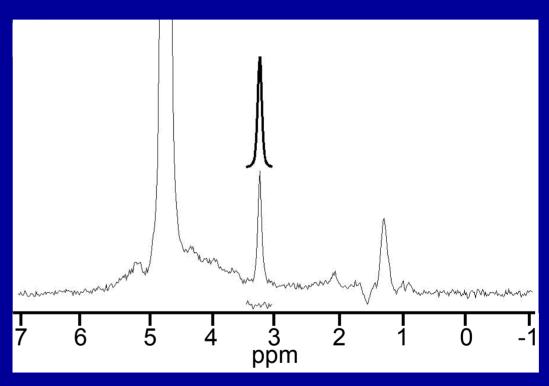
Highly consistent with malignancy

# BiomarC ® - PET Scan 38 year old female with invasive ductal carcinoma



## BiomarC ® - 4T MRI / MRS 47 year old female with invasive ductal carcinoma





 $[tCho] = 7.63 \pm 0.5$ 

Highly consistent with malignancy

#### **Conclusion:**

➤ RM (BiomarC ®) - deployed with accuracy (4mm) and was clearly visible under mammography, ultrasound, and MRI

Follow up studies after 12 weeks demonstrated no evidence of migration

RM did not interfere with <sup>1</sup>H MR spectroscopy (1.5 T or 4T) or PET scanning.