A NEW BIOMARC TISSUE MARKER FOR BREAST BIOPSY: CLINICAL EVALUATION IN ULTRASOUND, MAMMOGRAPHY, CT SCANNING AND BREAST MRI

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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 ¹H MR Spectroscopy

¹H 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 ¹H MRS - spectral artifact
 U of Minnesota / Center for Magnetic Resonance Research

Sample Case – Metallic RM





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 and 4 mm x 2 mm
- Color: Black

• 70 Biomarc [®] RM in 55 patients (BIRAD 4/5)
▶ 49 – ultrasound guidance (14 gauge trocar)
▶ 17 – 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 ¹H MRS at 4T (Bolan et al. MRM 2003)

BiomarC Pre-loaded Sideport Dry Delivery Device



BiomarC Pre-loaded Sideport Dry Delivery Device (1x3 Up-close)



BiomarC Pre-loaded Sideport Dry Delivery Device (2x4 Close-up)



Results:

- All 55 pts with 70 RM placed within 4 mm of biopsy site
- All 55 pts with 70 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[®] - 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

Large BiomarC Breast Marker

- 1. 4x 2 mm size
- 2. 3 x mass versus 1x3 marker
- 3. Easier to see on
 - Mammography
 - Ultrasound
 - MRI
 - Does not interfere with MR spectroscopy

45 year-old female with left breast mass on mammography showing atypia





45 year-old female with left breast mass on ultrasound showing atypia



CT scan of the chest showing two BiomarCs in left breast in 45-year old female



45-year-old female with right breast atypical ductal hyperplasia

Large BiomarC

SenorX, titanium

Right Breast CC view

Right Breast MLO view

45-year-old female right breast atypical ductal hyperplasia seen on ultrasound

Large BiomarC

MЗ

-2





+0.4cm

61-year-old female with right breast mass seen on mammography showing invasive lobular carcinoma

_Smal Biom<mark>arC</mark>

> Large BiomarC

Case #48 -Right Breast CC view

Right Breast ML view

61 year old female with invasive lobular carcinoma of the right breast seen on ultrasound

MЗ

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2**D** 59% C 60 P Low Res

P **Small BiomarC** Rt Breast CORE BX 12:00 Rad

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 ¹H MR spectroscopy (1.5 T or 4T) or PET scanning.