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High Risk Breast Cancer Patient with Silicone Breast Implant and Q Inside Safety™ Micro Transponder

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Abstract

Motiva Implants® (Establishment Labs Holdings Inc., NY, USA) contains a RFID micro transponder RFID(RT) (RT = registered trademark) known as Q Inside Safety Technology which provides an added safety feature embedded in the shell of the Motiva breast implant [1] [2]. Because this RFID micro transponder has Ferric components, a concern over breast MRI imaging susceptibility artifact has arisen. Among breast images, a single high risk breast cancer patient was imaged at our institution (January 2018). All breast imaging modalities were used to determine if this high risk patient had a recurrence of her cancer or any new breast cancer. The MRI showed a susceptibility artifact on the posterior margin of the implant but breast ultrasound showed no abnormalities in the area of the susceptibility artifact. By using high risk screening including Mammography, Tomosynthesis, Breast Ultrasound and Breast MRI, an adequate survey of the high risk patient was completed [3]. Our high risk clinic examined the patient and the imaging results and came to the following conclusion: This patient showed no evidence of recurrent cancer and no new masses were identified. The conclusion was BIRADS 2 benign: normal findings post-mastectomy and implants. Recommendation was for routine high risk screening at yearly interval.

Keywords

Breast MRI, Ultrasound, Mammography Implants, Radiofrequency Identification Device [RFID]

1. Introduction

We present a 55-year-old female, G3P2 with first birth at age 31 and menarche

at 11 who has a history of breast cancer. The patient underwent bilateral mastectomy in 2010 for left breast cancer with breast implant placement and chemotherapy. In 2017, the patient has breast surgery revision with new silicone implants. The new silicone breast implants contain a radio frequency identification device micro-transponder (RFID-M), known as the Q Inside Safety Technology™, as an added safety feature embedded in the shell of its breast implant. This RFID-M device allows for the rapid unique identification of implants through a three-point authentication system that contains important information about the implants manufacturing date, serial number, volume, and size [4] [5]. The patient underwent routine mammography, breast ultrasound, and breast MRI without and with contrast as a part of her routine annual surveillance (**Figures 1-3**).

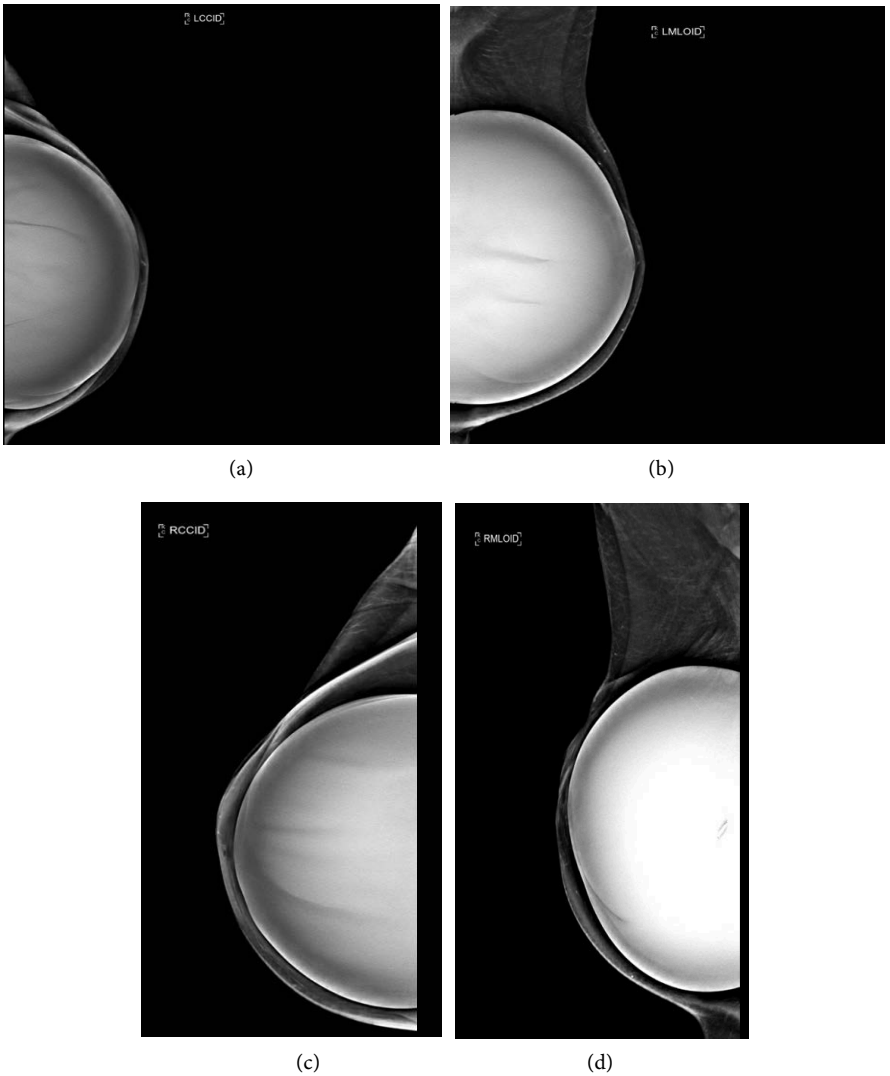
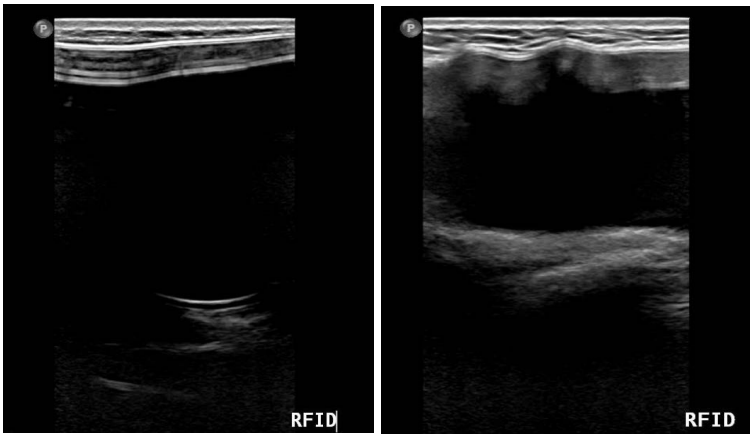
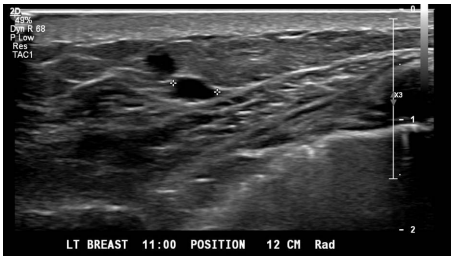


Figure 1. (a)-(d): 1A is a CC view of the left breast; (b) is a LML view of the left breast; (c) is a CC view of the right breast. (d) is a MLO view of the right breast. Tomosynthesis images of the left and right breast shows subpectoral silicone implants with chip located on the posterior margin of the implant (not visible on these views). There are no suspicious mammographic findings. BIRADS 2—recommend annual breast cancer surveillance



(a) (b)



(c)

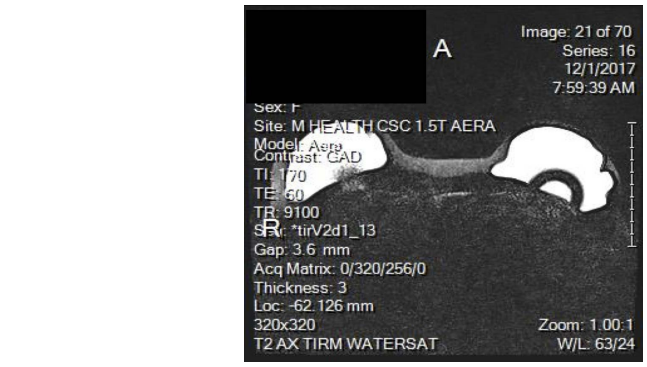
Figure 2. (a)-(c): Ultrasound image of the left breast at the site of the RFID micro-transponder (a) and (b). The posterior wall is visualized without artifactual distortion. There were two benign appearing cysts in the left breast of which the largest measures 4 mm in longest diameter at the 11 o'clock position 12 cm from the nipple. There are no suspicious sonographic findings. BIRADS 2—recommend annual breast cancer surveillance.

2. Conclusions

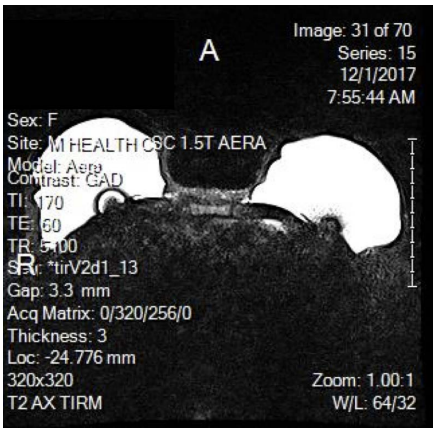
The purpose for reporting this case is to present a patient with silicone breast implants that contains an RFID device and how it impacts imaging surveillance. The RFID causes a susceptibility artifact that is cuboidal in shape and along the posterior wall of the breast implant near the region of the chest wall. This may reduce the accuracy of identifying recurrent cancer in this region on MRI. However, the addition of breast ultrasound to the breast MRI may help visualize this region and improve visualization of cancer recurrence.

Some patients with breast implants are those with reconstruction for treatment of breast cancer. The risk of cancer recurrence is uniform along the chest wall and therefore this is directly impacted by the size of the susceptibility artifact on MRI.

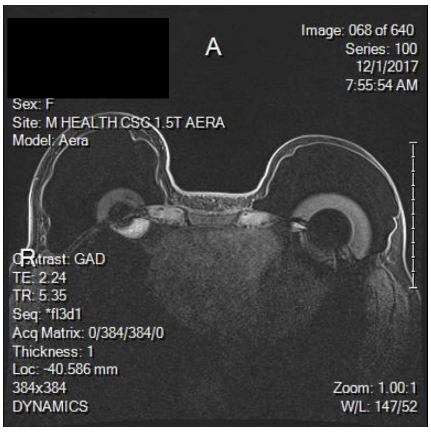
Currently, the FDA does not specify a method to directly mark a device for identification [1] [2]. We believe that a unique device identifier such as the one in this patient will provide a method to improve the identification of medical devices in a more rapid and accurate format for its safety and effective use. In 2014, a publication in the Breast Journal described the critical importance of



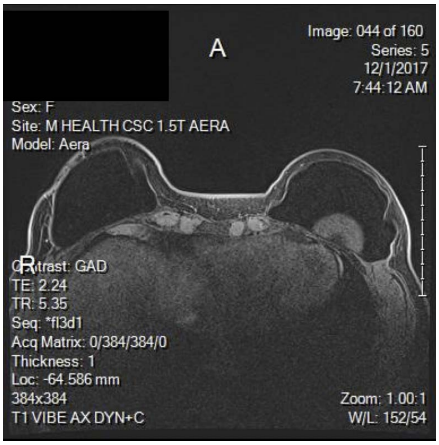
(a)



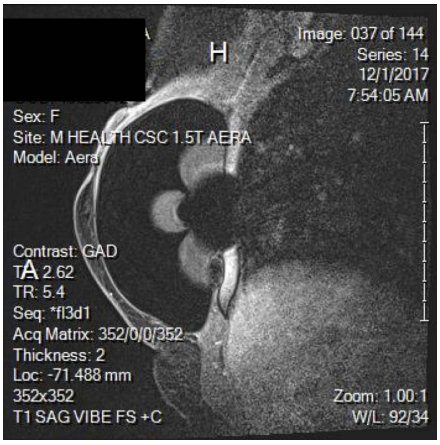
(b)



(c)



(d)



(e)

Figure 3. (a)-(e): Bilateral breast MRI without and with contrast on a 1.5 T MRI scanner. The images show minimal background breast parenchymal enhancement (**Figure 3(c)**). No abnormal suspicious areas of enhancement are seen. No evidence of lymphadenopathy. Bilateral subpectoral silicone implants with susceptibility artifact along the posterior margin of the right and left implant due to RFID device (**Figures 3(a)-(e)**). There are no suspicious MRI findings. BIRADS 2—recommend annual breast cancer surveillance. (a) Axial T2-WI TIRM sequence with water saturation; (b) Axial T2-WI TIRM sequence with water saturation and artifact reduction software applied; (c) Axial T1-WI subtraction image after administration of gadolinium contrast; (d) Axial T1-WI with fat saturation after administration of gadolinium contrast; (e) Sagittal T1-WI VIBE sequence after administration of gadolinium contrast.

robust breast device registries (Cooter *et al*. Breast. 2014). They concluded that breast implants are high risk devices that are distributed internationally. Failure to maintain an adequate registry of such devices can have a global impact with potential risk of becoming an international crisis. The *Poly Implants Prothèse* (PIP) case has had a large global impact at an international level which impacted nearly 400,000 patients raising concerns on the regulatory and quality control procedures that failed to safeguard many women from health risks associated with PIP breast implants (Berry *et al*. A product recall study) [5].

We believe that the value of the RFID device on the breast implant outweighs the detrimental effect of the susceptibility artifact on MRI. Furthermore, we feel that the use of breast ultrasound in addition to the breast MRI will improve a radiologist accuracy for assessing the posterior region of the implant and chest wall in patients undergoing surveillance.

Using all breast imaging modalities: digital mammography, tomosynthesis, dedicated breast ultrasound, and contrast subtraction MRI were all completed in this case for this patient with high risk screening [6] [7]. The imaging results were negative for breast mass or cancer. Our high risk clinician agreed with these results and recommend continued high risk screening.

Disclosure

Dr. Michael Nelson and Dr. Sina Meisamy are paid consultants from JAMM Technologies, Inca subsidiary of Establishment Labs; however, neither Dr. Nelson nor Dr. Meisamy has any conflicts of personal interests in the material and conclusions of this paper. Neither physician has any stock or ownership in ELabs or JAMM Technologies, Inc.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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