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Magnetic Resonance Imaging Surveillance Study of Silicone Implant-based Breast Reconstruction: A Retrospective Observational Study

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Background: This study aimed to evaluate the results of magnetic resonance imaging (MRI) surveillance of implant-based breast reconstruction in patients with breast cancer.

Methods: This retrospective observational study analyzed patients who underwent implant-based breast reconstruction and MRI surveillance by a single surgeon from March 2011 to December 2018, in a single center. All patients were informed about the recommendation of the Food and Drug Administration for MRI surveillance, and they choose to undergo MRI 3 years after surgery.

Results: The compliance rate for MRI surveillance was 56.5% (169/299). MRI surveillance was performed at a mean of 45.8 (4.04 years) ± 11.5 months after surgery. One patient (0.6%) showed an abnormal finding of an intracapsular rupture of the silicone implant.

Conclusions: MRI surveillance for implant rupture in implant-based breast reconstruction showed a low incidence of silent implant rupture (0.6%), whereas the compliance of MRI was relatively high (56.5%). These results raise questions about whether taking an MRI in 3–4 years is suitable for imaging surveillance of breast silicone implants. Screening recommendations should be more evidence-based, and more studies are needed to prevent unnecessary screening and patient burden.
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INTRODUCTION

Since the introduction of silicone breast implants by Cronin and Gerow in 1962, silicone breast implants have been improved and developed with modifications of the implant shell and filler.[1] However, in the 1980s, the main concern of silicone breast implant-induced illness resulted in a moratorium on the use of silicone implants by the US Food and Drug Administration (FDA) and Health Canada in 1992. In the twenty-first century, after 2006, the FDA-approved silicone gel-filled breast implants for breast augmentation and reconstruction. The FDA stipulated that manufacturers conduct large postapproval studies to monitor outcomes for imaging surveillance, long-term safety and outcomes, and possible silicone-induced systemic harms.[2] For MRI surveillance, the FDA-approved labeling for silicone gel-filled implants recommended that women get their first breast MRI 3 years after they receive the implants and every 2 years thereafter to detect silent ruptures.[3] Recently, the FDA changed the rupture-screening recommendations of performing the first ultrasonography or MRI to 5–6 years after the surgery and every 2–3 years thereafter.[4]

Diagnostic imaging plays an important role in the follow-up of breast implants and detection of early or late complications.[5–7] Among imaging modalities, MRI plays a crucial role in detecting complications of breast implants with a detailed, artifact-free resolution.[7] MRI enables the visualization of the implant, surrounding tissues, and axilla. MRI could detect early or late peri-implant fluid collection, masses, and intracapsular/extracapsular implant ruptures. However, MRI is a finite healthcare resource that may not be performed on all patients. An MRI is notoriously expensive; thus, patients may not agree to screen for the breast implant.

This study aimed to evaluate the results of MRI surveillance of implant-based breast reconstruction in

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patients with breast cancer. In our center, all patients who underwent implant-based breast reconstruction were informed about breast implant surveillance 3 years after the surgery. In South Korea, all patients with breast cancer are financially supported by national medical health insurance for 5 years after their diagnosis; therefore, patients can obtain MRIs at low cost. To the best of our knowledge, this study is the largest on MRI surveillance of implant-based breast reconstruction in the Asian population.

PATIENTS AND METHODS

This retrospective study, approved by the institutional review board (No: 2022-0970), analyzed patients who underwent implant-based breast reconstruction and MRI surveillance in Asan Medical Center from March 2011 to December 2018 by a single surgeon (J.S. Eom). Data were collected until May 2022. During the study period, surgeons preferred anatomic textured implants and single-stage reconstructions. Therefore, we excluded the small number of cases in which round implants and staged reconstructions were used.

MRI SURVEILLANCE

All patients were informed about the recommendation of the FDA for MRI surveillance, and they agreed to MRI 3 years after surgery. Patients who agreed to the MRI surveillance were included. MRI examinations were performed at our center. Images were evaluated by board-certified radiologists. Radiologists reported on the status of the implant, intra-/extracapsular rupture, fluid collection, and intact implant.

SURGICAL TECHNIQUES

All patients underwent immediate breast implant reconstruction combined with surgery by an oncologic surgeon. All patients underwent the same surgical technique with subpectoral breast implant insertion using acellular dermal matrices. The pectoralis muscle was elevated, and the silicone implant was placed under the pectoralis muscle. Acellular dermal matrices were used for the coverage of the lower pole and sutured between the muscle and inframammary fold. Commercially available silicone gel-filled implants were implanted for breast reconstruction.

STATISTICAL ANALYSIS

Statistical analysis was performed using IBM SPSS version 21 (IBM Corp., Armonk, N.Y.). Continuous values were presented as mean ± standard deviation. Categorical values were presented as numbers with percentages.

RESULTS

A total of 299 patients who underwent implant-based breast reconstruction in the study period were reviewed in this study. Of those patients, the authors enrolled 175 patients who had MRI surveillance postoperatively. Six patients were also excluded because they were already diagnosed with ruptures in another imaging study [ultrasonography, n = 5; computed tomography (CT), n = 1]. The implants that ruptured in six patients are Mentor CPG[5] and Natrelle 410[1] implants. Therefore, 169 patients were finally included in this study (Fig. 1). The patient compliance rate for MRI surveillance was 56.5% (169/299).

Takeaways

Question: Is magnetic resonance imaging (MRI) surveillance for implant rupture in implant-based breast reconstruction in a 3- to 4-year time interval suitable for an imaging surveillance tool?

Findings: Our results showed a low incidence of silent implant rupture (0.6%), whereas the compliance of MRI was relatively high (56.5%) in MRI surveillance.

Meaning: These results raise questions about whether taking an MRI in 3–4 years is suitable for imaging surveillance of breast silicone implants. Screening recommendations should be more evidence-based, and more studies are needed to prevent unnecessary screening and patient burden.

The age of the patients was 43.1±8.4 years, and the body mass index was 21.6±2.7 kg/cm^2. The duration of follow-up was 56.5±16.3 months; 21.3% of the patients underwent adjuvant radiation therapy, and 52.7% underwent adjuvant chemotherapy. Table 1 summarizes the demographic data.

One hundred thirty-five (79.9%) patients underwent nipple-sparing mastectomies, while 34 (20.1%) patients underwent skin-sparing mastectomies. All patients underwent single-stage reconstructions, and subpectoral plane breast reconstruction was performed using acellular dermal matrices as a lower pole support; 69% of the patients received Mentor implants, and 57.4% received Allergan implants. All implants used were anatomic and textured. The Mentor CPG (Mentor Worldwide LLC, Santa Barbara, Calif.) (n = 69, 40.8%), Natrelle 410/510 (Allergan Inc., Irvine, Calif.) (n = 97, 57.4%), and BellaGel anatomic textured (HansBiomed Co. Ltd., Seoul, Korea) (n = 3, 1.8%) were used (Table 2).

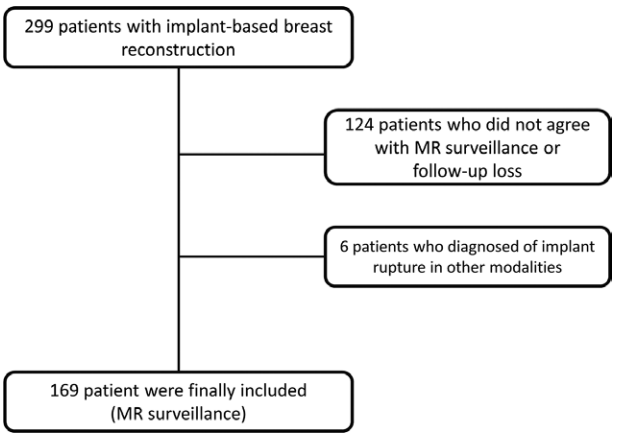

Fig. 1. Patient-inclusion process.

Table 1. Patient Demographics

	Values
No. patients	169
No. breasts	185
Age (mean ± SD)	43.1±8.4
BMI (mean ± SD)	21.6±2.7
Follow-up (mo, mean ± SD)	56.5±16.3
Hypertension (N, %)	14 (8.3%)
Diabetes (N, %)	3 (1.8%)
History of smoking (N, %)	3 (1.8%)
History of radiation therapy (N, %)	36 (21.3%)
History of chemotherapy (N, %)	89 (52.7%)

Table 2. Surgical Techniques and Implant Characteristics

	Values
Manufacturer	
Mentor CPG (N, %)	69 (40.8%)
Allergan 410/510 (N, %)	97 (57.4%)
Bellagel anatomic textured (N, %)	3 (1.8%)
Shape of implant	
Anatomic (N, %)	169 (100.0%)
Round (N, %)	0 (0.0%)
Surgical technique	
Subpectoral with ADM (N, %)	169 (100.0%)

Table 3. Results of MRI Surveillance

	Values
Interval of MRI after surgery (months, mean ± SD)	45.8±11.5
Abnormal findings in MRI (N, %)	1 (0.6%)
Implant silent rupture (N, %)	1 (0.6%)
Significant amount of seroma needs aspiration (N, %)	0 (0.0%)
Other abnormalities (N, %)	0 (0.0%)

MRI surveillance was performed at a mean of 45.8±11.5 months after surgery. One patient (0.6%) showed an abnormal finding of intracapsular rupture without symptoms, and the implant was changed (Table 3). Other local complications and reoperations are summarized in Table 4. In five patients, the implant was changed after surgery. The reasons for implant change were capsular contracture and infection.

Table 4. Local Complications and Reoperation

	Values
Rupture (N, %)	1 (0.6%)
Capsular contracture (III/IV) (N, %)	17 (10.1%)
Infection (N, %)	2 (1.2%)
Animation deformity (N, %)	9 (5.3%)
Reoperation	
Implant change (N, %)	6 (3.6%)

CASE OF A SILENT RUPTURE DIAGNOSED BY MRI SURVEILLANCE

A 46-year-old female patient was diagnosed with right-sided breast cancer. She underwent mastectomy, and the breast was reconstructed with an implant (Fig. 2A). She agreed to the MRI surveillance of the breast implant, and MRI was taken 53 months after the surgery. An intracapsular rupture with linguine sign was found in the MRI scan (Fig. 2B). The patient underwent capsulectomy and implant change with plane conversion. Symmetric breast was observed 6 months after implant change (Fig. 2C).

DISCUSSION

This study reports the results of MRI surveillance in implant-based breast reconstruction in a single center. Despite the long history (over 60 years) of breast silicone implant applications, no evidence-based recommendation about imaging for asymptomatic cases is available.[8] This study is one of the largest studies that focuses on the MRI surveillance of breast silicone implants in Asian patients with implant-based breast reconstruction.

In this study, only one patient (0.6%) was found to have breast implant abnormality in the MRI surveillance. These results raise questions about whether MRI is an appropriate test for follow-up after breast reconstruction using implants. These results also support the modified recommendation of the US FDA of performing ultrasonography or MRI in 5–6 years. The US FDA published in an advisory panel, "noting the current scientific data and recommendations for [magnetic resonance imaging] screening for silent rupture and questioning whether much was gained by this recommendation. There is a concern expressed about the cost to patients and mentioned,

Fig. 2. A case of positive result in MRI surveillance. A, A 46-year-old female patient who underwent implant-based breast reconstruction in her right breast. B, An intracapsular rupture with linguine sign in the MRI scan at 53 months after the surgery. C, Postoperative photograph taken 6 months after implant change with plan conversion.

false-positive findings and whether information about a silent rupture would change practice (such as decisions about the removal of the device)."[9]

Patient compliance is an important factor in surveillance. The large postapproval studies reported that the long-term MRI surveillance rate is less than 5%. In the present study, a higher compliance rate of 56.5% was observed. This is probably because the analyzed patients had breast cancer. Compared with patients who had implants for cosmetic purposes, patients with breast cancer had more concerns over their health and want to check the status of the implants and breast cancer using the most accurate diagnostic modality. Another reason is the low cost of MRI in Korea because of national medical insurance. All patients with breast cancer are financially supported by national medical health insurance for 5 years after the diagnosis of breast cancer.

Another important factor of compliance to the surveillance study is the recommending person. In breast implant surveillance, the board-certified plastic surgeon is the main recommending person. Interestingly, a study using a questionnaire from a board-certified plastic surgeon reported that less than 40% of the plastic surgeons recommended MRI screening for a breast implant.[10] In our center, we routinely recommend MRI surveillance of the breast silicone implant 3 years after surgery. This also increases the compliance for the MRI surveillance in this study.

Interestingly, in this study, six patients were diagnosed with implant rupture by other modalities (ultrasonography or CT) and then MRI was conducted for confirmation of implant rupture. Patients with breast cancer usually consider other imaging studies during follow-up for monitoring of cancer recurrence. Oncologic and plastic surgeons should discuss imaging for implant surveillance and cancer recurrence. This multidisciplinary approach could minimize unnecessary imaging and patient burden.

One of the main purposes of MRI surveillance is to identify silent rupture. Patients with breast implant rupture do not manifest clinically significant signs or symptoms and are classified as having "silent" ruptures.[11–13] The prevalence of silent ruptures among women with silicone breast implants is unknown. Clinical data from USFDA breast implant postapproval studies indicate that the rupture rate is 1.0% of women with silicone implants 3 years after implantation.[2] In our study, the rate of silent rupture was low (0.6%) in a patient who underwent implant-based breast reconstruction within 3–4 years. These results raise questions about whether taking an MRI in 3–4 years is suitable for imaging surveillance of silicone gel-filled implants.

Recently, the US FDA recommends ultrasonography or MRI surveillance of silicone implants 5–6 years after surgery and every 2 years thereafter.[9] Imaging is a financial burden to patients, and tools such as MRI scanners are costly. Several studies have pointed out that ultrasonography is an optimal alternative under economic analysis. A recent systematic review reported a summary of 20 studies using ultrasonography, and they reported 79.5% of accuracy to detect implant rupture.[14] Recent advancements in ultrasound technology have led to the development of high-frequency, high-resolution devices, which may have more accurate results with lower costs in the future. Further investigations and evidence are needed to establish cost-effective and accurate imaging surveillance for silicone gel-filled implants.

In this study, one patient was diagnosed with implant rupture by CT. CT detected linguine sign and seroma around the implant (Fig. 3), which were confirmed by MRI. CT for screening has been considered a feasible alternative in several studies.[15–17] Katrina et al reported that dual-energy CT performs similarly to MRI for the detection of silicone gel implant rupture and the presence of silicone in regional lymph nodes.[15] However, the major limitation of CT is the need for ionizing radiation, whereas it is not required by MRI. The benefits and risks of CT as surveillance should be weighted through further studies.

Breast implant-associated anaplastic large cell lymphoma (BIA–ALCL) is a rare and distinctive type of T-cell non-Hodgkin lymphoma that occurs around textured implants.[18] In our study, we did not identify any cases of BIA–ALCL in MRI surveillance. According to a recent report, the principal signs of BIA–ALCL observable by MRI are the following: liquid-serous effusion, peri-implant- and capsule-related masses, enhancement of the capsule, irregular thickness of the capsule, and subcutaneous

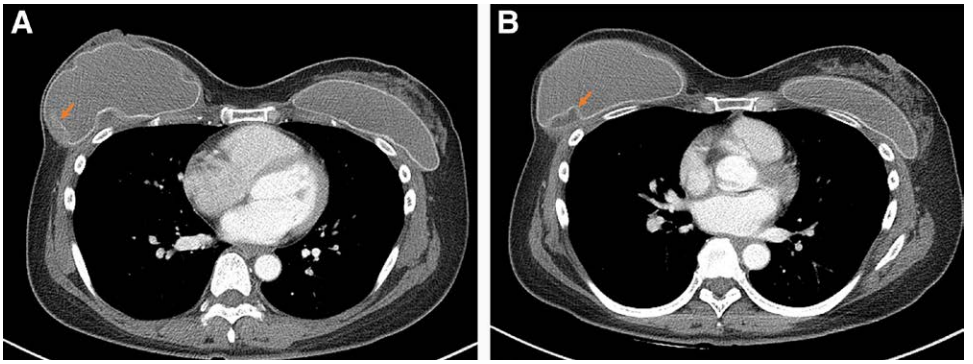

Fig. 3. CT of implant rupture. Linguini sign (A) and seroma (B) around the implant.

nodules.[19] However, there is still little evidence that surveillance imaging is helpful for detecting BIA–ALCL, and its use continues to be debated.

This study has several strengths. This study included a large number of patients who underwent implant-based breast reconstruction. The implant and surgical techniques were consistent because all procedures were performed by a single surgeon with a similar surgical technique. This fact could minimize the bias from different surgical techniques.

However, this study has several limitations. First, the retrospective study design may cause errors in data collection. Second, this study does not have follow-up loss data of patients. The results of this study should be interpreted considering this factor. Third, the study population is limited to Asians. This result does not represent the global population. Fourth, it is possible that false negatives were included.

CONCLUSIONS

This study revealed that MRI surveillance for implant rupture in implant-based breast reconstruction showed a low positive detection rate for implant rupture (0.6%), but the patient compliance rate was relatively high (56.5%). These results raise questions about whether taking an MRI in 3–4 years is suitable for imaging surveillance of breast silicone implants. Screening recommendations should be more evidence-based, and more studies are needed to prevent unnecessary screening and patient burden.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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