



False-positive diagnoses of damaged breast implants on imaging: a report of two cases

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Background: Silicone breast implants (SBIs), used in breast reconstruction, are durable and resistant to breakage and internal gel leakage. However, regular imaging examinations are crucial, as symptoms may not be apparent even if the implant ruptures. There are several known imaging findings that suggest SBI failure. Although artifacts such as moisture and air bubbles or substances similar to the gel extending outside the shell may appear on imaging, no reports have demonstrated false-positive diagnoses of damaged SBIs in detail. Hence, we present two cases in which failure was suspected based on the imaging results but not confirmed.

Case Description: In case 1, at the 4-year follow-up after implant-based breast reconstruction, ultrasonography revealed a stepladder sign, and magnetic resonance imaging (MRI) revealed the salad oil sign. Although SBI failure was suggested, intraoperative examination revealed only a small amount of fluid retention within the capsule and no SBI fractures. Consequently, the imaging results were proved to be artifacts. In case 2, at the 7-year follow-up after implant-based breast reconstruction, ultrasonography revealed a subcapsular line sign, and MRI confirmed a keyhole sign. Although SBI failure was suggested, intraoperative examination revealed no implant fractures. Hematogenous serous effusion was found within the capsule, and blood clots and a large amount of fibrinous mass were found deposited at the bottom of the capsule. These findings caused false-positive diagnoses on imaging.

Conclusions: In cases of suspected fractures, patients may opt for either observation or surgical removal, or replacement of the implant. When choosing the latter, it is important to inform patients of the possibility of an unbroken implant.

Keywords: Breast implant; case report; false-positive; magnetic resonance imaging (MRI); ultrasonography

Submitted Jun 16, 2023. Accepted for publication Oct 12, 2023. Published online Oct 26, 2023.

doi: 10.21037/gs-23-255

View this article at: <https://dx.doi.org/10.21037/gs-23-255>

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Introduction

Reconstruction after total mastectomy can be achieved through autologous reconstruction or using silicone breast implants (SBIs) (1). The most commonly used SBI has a three-layered outer shell and contains a cohesive silicone gel that is highly viscous and difficult to break (2). Subjective symptoms such as redness and swelling may not be apparent if the implant breaks. In rare cases, however, the leaked gel can cause severe inflammation that is difficult to treat if it escapes the capsule.

Ultrasonography and magnetic resonance imaging (MRI) are recommended every 2 years after reconstruction in Japan to detect early signs of implant failure. Although artifacts such as moisture and air bubbles may appear on imaging (3), no reports have demonstrated false-positive diagnoses of damaged implants.

In this report, we present two cases in which an SBI fracture was suspected based on imaging studies, and surgical intervention was performed. However, the implants were found to be intact. We discuss the reasons for the false-positive diagnoses and potential solutions for future cases. We present these cases in accordance with the CARE reporting checklist (available at <https://gs.amegroups.com/article/view/10.21037/gS-23-255/rc>).

Highlight box

Key findings

- We report two cases in which failure of silicone breast implants was suspected based on the imaging results but was not intraoperatively confirmed.

What is known and what is new?

- Regular imaging examinations, including ultrasonography and magnetic resonance imaging, are crucial, as symptoms may not be apparent even if the implant ruptures. There are several known imaging findings that suggest the failure of breast implants.
- No reports have demonstrated false-positive diagnoses on imaging of damaged breast implants in detail.

What is the implication, and what should change now?

- Even if breakage of breast implants is suspected on the basis of imaging findings, the possibility that they are not actually broken should always be considered.
- Report here about implications and actions needed.

Case presentation

Case 1

A 70-year-old female patient underwent primary two-stage reconstruction with a textured implant (Natrelle 410[®]; Allergan, Dublin, Ireland, LX-570) following a total mastectomy for right breast cancer in 2016. At the 4-year follow-up, the patient had no subjective symptoms, and there was no apparent change in appearance (*Figure 1A*). However, ultrasonography revealed hyperechoic changes inside the implant (stepladder sign) (*Figure 1B*), suggesting SBI failure. MRI further supported the diagnosis with a high signal change (salad oil sign) on T2WI (*Figure 1C*). The patient strongly requested a check, so we decided to perform the surgery with the policy of reinserting the SBI if it was not damaged. This was because there was no suitable size for the smooth type and she had already accepted the risk of developing breast-implant associated anaplastic large cell lymphoma (BIA-ALCL).

Intraoperative examination revealed only a small amount of fluid retention within the capsule and no SBI fractures (*Figure 2*). Therefore, the SBI was reinserted, and the surgery was completed.

Case 2

A 37-year-old female patient underwent primary two-stage reconstruction with a textured implant (Natrelle 410[®]) following a total mastectomy for left breast cancer in 2015. The patient had a history of cellulitis of the reconstructed breast on several occasions. At the 7-year follow-up, the patient had gained >30 kg since SBI insertion and presented with contractures and color changes in the left breast (*Figure 3A*). Ultrasonography revealed fluid accumulation and sediment outside the outer shell of the implant (subcapsular line sign), and SBI failure was suspected. MRI confirmed fluid accumulation around the SBI, sediment in the fluid, and changes in the shape of the implant (keyhole sign) (*Figure 3B*). The radiologist suspected simple breakage, and the breast surgeon performed a puncture aspiration cytology of the reservoir under echocardiography but found no features suggestive of malignancy including BIA-ALCL. The patient strongly requested a check, and we decided to perform the surgery with the policy of reinserting the SBI

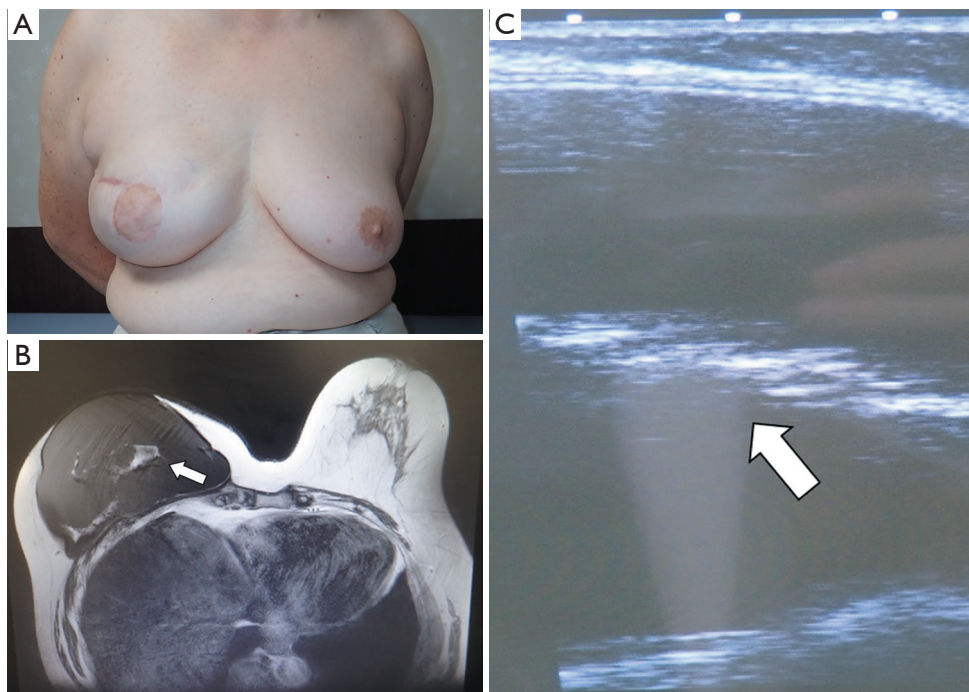


Figure 1 Clinical findings of case 1. (A) Picture of case 1 4-year postoperatively. No abnormal contour findings are observed. (B) Ultrasound finding of case 1. Hyperintense changes are observed inside the implant (arrow). (C) Magnetic resonance imaging findings of case 1. High signal changes inside the implant are observed (arrow).

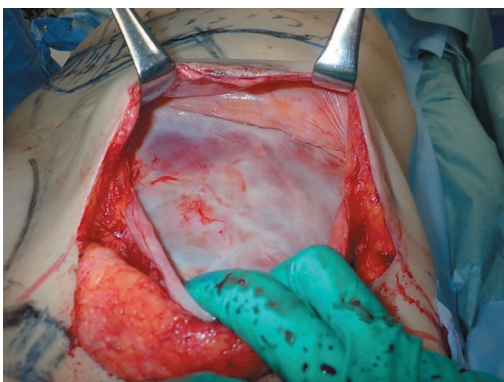


Figure 2 Intraoperative findings in case 1. Slight serous fluid retention in the capsule.

as follows. We explained that if there was a mass suspicious for BIA-ALCL, we would not reinsert the implant, and if reinserted, we would remove it immediately if a permanent postoperative specimen showed a diagnosis of BIA-ALCL.

Hematogenous serous effusion was found within the capsule, and during the removal of the implant, blood clots and a brown muddy substance were found deposited at the

bottom of the capsule, which was highly constricted. No implant fractures were observed (*Figure 4*). The capsule was incised in a lattice pattern to release the contracture, the implant was reinserted, and the surgery was completed. Histopathologic examination revealed that the brown muddy material was suggestive of part of a hematoma, the capsule was fibrous tissue, and no malignant findings were noted.

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from all the patients prior to their participation in the study. A copy of the written consent is available for review by the editorial office of this journal.

Discussion

Since the introduction of the first-generation breast implants in 1962, there have been continuous improvements in terms of breakage and texture. The latest fifth-generation Natrelle 410 implant, introduced in 2012, has a three-layered outer shell containing a high-viscosity silicone gel

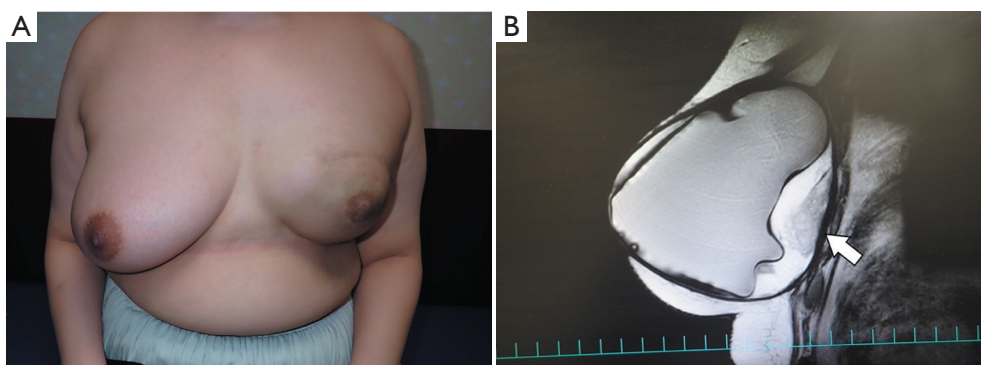


Figure 3 Clinical findings of case 2. (A) Picture of case 2 7-year postoperatively. Contraction and color change of the left breast are observed. (B) Magnetic resonance imaging findings in case 2. Fluid retention, including sediments around the implant, are observed (arrows), and implant shape changes are observed.



Figure 4 Intraoperative findings in case 2. (A) Blood clots and muddy material are seen in the capsule. (B) The capsule is highly constricted. (C) The implant is not fractured.

(cohesive silicone gel), which makes it difficult for the gel to break or leak. Even if the implant breaks, it is unlikely to cause subjective symptoms such as redness and swelling because of the surrounding fibrous capsule, which is the scar tissue.

However, periodic imaging is recommended for the early detection of silent ruptures that cannot be diagnosed based on changes in appearance. SBI failure that occurs without symptoms may present as siliconoma, silicone lymphadenopathy, or foreign body granuloma (4). Therefore, annual examinations and imaging studies with ultrasonography and MRI every two years are recommended by the Japanese Society of Breast Oncoplastic Surgery.

Ultrasonography findings that suggest SBI breakage include a high frequency of uniform or spotty echogenicity of the internal silicon and separation of the capsule from the outer shell. The former is thought to be the result of the SBI outer shell breaking and water entering the interior, reacting with the gel, and softening it, whereas the latter

is thought to be caused by the softened gel leaking out of the outer shell (5). *Table 1* shows the typical findings of SBI failure. MRI findings that suggest SBI failure should be diagnosed using T2-weighted and silicon-weighted images. *Table 2* shows the typical findings of SBI failure (3,6,7).

Previous reports have indicated that the sensitivity and specificity of MRI for SBI failure have been reported to be 72–94% and 85–100%, respectively. Palpation, ultrasonography, and MRI had sensitivities of 42%, 50%, and 83%, respectively, for implant failure, with specificities of 50%, 90%, and 90%, respectively (8). The agreement between ultrasonography and MRI findings was 87% (8).

Ultrasonography is superior to MRI for differentiating internal gel changes and is suitable for outpatient screening. However, the choice of test should take into account the above-mentioned considerations, and in some cases, a combination of tests may be necessary.

The ultrasonography finding in case 1 was a stepladder sign. This finding has long been regarded as an indication

Table 1 Ultrasound findings suggesting breast implant failure

Sign	Findings
Keyhole sign, lasso sign, noose sign	The continuity of the outer shell is maintained, but microscopic perforations occur, and gel leaks out of the outer shell, loosening the shell and making it look like a keyhole, lasso, or fishing line
Sub-capsular line sign	A state in which gel is stored between the coating and the outer shell, and the two are no longer adjacent to each other
Stepladder sign	A condition in which the outer shell falls into the gel and is seen as multiple ladder-like steps because of a large amount of gel leaking out of the outer shell
Snowstorm sign	When an extracapsular rupture occurs, silicone gel disperses into the surrounding tissue and presents as a high-echoic lesion resembling a snowstorm

Table 2 Magnetic resonance imaging findings suggesting breast implant failure

Sign	Findings
Key hole sign, lasso sign	The continuity of the outer shell is maintained, but microscopic perforations occur, and gel leaks out of the outer shell, loosening the shell and making it look like a keyhole or lasso
Tear-drop sign	The continuity of the outer shell is maintained, but microscopic perforations occur, and gel leaks out of the outer shell, causing the outer shells to appear to be in contact with each other
Sub-capsular line sign	A state in which gel is stored between the coating and the outer shell, and the two are no longer adjacent to each other
Linguine sign	A state in which the shell has ruptured and is floating in the silicone gel
Salad oil sign	Small water droplets or gas images in silicone gel, findings that look like oil droplets floating in water

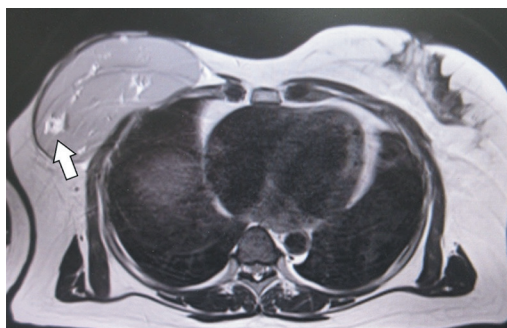


Figure 5 Case with actual breast implant fracture. Magnetic resonance imaging showing hyperintense changes inside the implant, similar to case 1 (arrow).

of implant failure. However, a pseudo-stepladder sign can be observed in cohesive silicone gels owing to the generation of bubbles and degeneration of the silicone gel over time (9). MRI showed a salad oil sign, which suggested implant breakage. However, this finding alone is not strong enough to diagnose breakage because water and air bubbles can collect inside the gel to produce similar findings (10).

We encountered a case in which the SBI was damaged with a salad oil sign, and the MRI findings were similar (*Figure 5*). Thus, we believe that it is difficult to determine the presence or absence of damage even with imaging studies.

In case 2, the ultrasonography finding was a subcapsular line sign, which suggested failure due to the accumulation of gel between the capsule and the outer shell. MRI also showed fluid accumulation around the implant, including solids, which suggested that the implant had failed and the gel had leaked out. However, in reality, a hematoma and brownish fibrinous precipitates accumulated, and the imaging diagnosis of SBI failure was falsely positive. Although hematomas can accumulate after breast implant insertion, delayed hematomas that appear more than 6 months after surgery, as in case 2, are rare (11,12). The cause is thought to be oral anticoagulants or trauma; however, the detailed mechanism remains unclear. In this case, the patient was sleeping with the affected side down to relieve the symptoms of left nasal obstruction, and we believe that chronic irritant pressure on the SBI and repeated cellulitis may have caused the capsular contracture

and chronic inflammation.

When breakage is suspected, and minor breakage is observed, follow-up may be an option because it takes time for the gel to leak out of the outer capsule. However, if the gel extends outside the capsule, surgical removal is recommended due to the risk of inflammatory foreign body granulomas.

Conclusions

We reported two cases in which failure of SBIs was suspected based on the imaging results but was not intraoperatively confirmed. We believe that even if SBI breakage is suspected on the basis of imaging findings, the possibility that the SBI is not actually broken should always be considered. It is essential to explain this possibility and what should be done before the SBI removal surgery.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the CARE reporting checklist. Available at <https://gs.amegroups.com/article/view/10.21037/gS-23-255/rc>

Peer Review File: Available at <https://gs.amegroups.com/article/view/10.21037/gS-23-255/prf>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://gs.amegroups.com/article/view/10.21037/gS-23-255/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from all the patients prior to their participation in the study. A copy of the written consent is available for review by the editorial

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Cite this article as: Shimabukuro M, Ishii N, Ko T, Ohta T, Matsuzaki K, Kishi K. False-positive diagnoses of damaged breast implants on imaging: a report of two cases. *Gland Surg* 2023;12(10):1434-1440. doi: 10.21037/gs-23-255