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Clinical Management After Rupture of Silicone Gel-Filled Breast Implants in a Surgically Treated Cohort: A Retrospective Study

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ABSTRACT

Objective: Breast implant rupture is clinically significant complication that is often asymptomatic making diagnosis challenging. The primary objective of this study was to describe the clinical presentation, preoperative imaging findings, and operative findings in this surgically selected cohort. A secondary objective was to assess the apparent concordance of magnetic resonance imaging (MRI) and ultrasound findings with intraoperative rupture status in this surgically selected cohort. Additional exploratory analyses examined symptom categories, implant age, and implant placement in relation to operative and imaging findings.

Materials and Methods: This retrospective observational study evaluated a cohort of women with suspected or confirmed silicone breast implant rupture who underwent operative management at the Department of Plastic Surgery, Faculty of Medicine, Comenius University, University Hospital Bratislava, Ružinov, between 2020 and 2025. Because only patients who proceeded to surgery were included, the cohort represents a selected referral population rather than an unselected surveillance population.

Results: The mean patient age was 50.6 years, with a mean implant age of 14.7 years. Within this surgically selected cohort, MRI demonstrated higher apparent sensitivity and positive predictive value than those of ultrasound; however, diagnostic performance varied across subgroups and the findings should be interpreted cautiously because of the small sample size and selection bias. In patients with local symptoms, the apparent diagnostic performance was lower, particularly for ultrasound.

Conclusion: Breast implant rupture showed heterogeneous clinical presentations in this retrospective cohort of surgically treated patients, ranging from asymptomatic, imaging-detected rupture to cases associated with local symptoms, capsular contracture, or systemic complaints. MRI showed a higher apparent concordance with intraoperative rupture status than ultrasound in this selected cohort; however, the findings are limited by selection and verification bias. Subgroup analyses were exploratory, and clinical management should remain individualized; prospective studies are needed to guide evidence-based imaging and treatment strategies.

Keywords: Breast implant; implant rupture; magnetic resonance imaging; ultrasonography

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KEY POINTS

- Breast implant rupture frequently remains asymptomatic and is often detected incidentally on imaging, underscoring the importance of reliable diagnostic tools.
- Magnetic resonance imaging howed higher apparent diagnostic performance than ultrasound, but these findings are limited by selection and verification bias.
- In patients with local symptoms, apparent diagnostic performance was lower, particularly for ultrasound.
- Clinical management should remain individualized, and prospective studies are needed to guide evidence-based imaging and treatment strategies.

Introduction

Breast implants are among the most commonly used medical devices in plastic and reconstructive surgery (1). Despite continuous technological progress, a breast implant remains a foreign object within the body and carries a risk of complications. The most frequent include capsular contracture (CC), seroma, hematoma, infection, implant migration or malposition, and implant rupture (2, 3). Implant rupture is a clinically important complication whose incidence increases with the length of time since implantation. Reported rates range from 1–10% within the first 10 years, with a marked rise in risk after 15 years (4). Implant rupture involves a breach of the implant shell, allowing silicone gel or saline to escape into the periprosthetic space and surrounding tissues. Rupture of saline implants is usually easy to recognize because it results in a sudden loss of breast volume. In contrast, ruptures of silicone implants often present with subtle or absent clinical signs. They are frequently detected incidentally during imaging examinations such as magnetic resonance imaging (MRI) or ultrasound, since many cases remain asymptomatic (5).

A frequent underlying cause is the gradual wear of the implant shell. Repeated micro-deformations, friction against the periprosthetic capsule, and external forces can weaken the capsule's structure and lead to micro-tear formation. Another factor that can lead to rupture is trauma, such as a direct impact on the chest, injury from a car accident, or iatrogenic damage during procedures such as breast biopsy or mammography; these events may cause abrupt shell failure (6).

Implant rupture can occur in two forms: intracapsular, in which the silicone remains confined within the fibrous capsule, and extracapsular, in which the gel escapes into surrounding tissues. If an intracapsular rupture is identified, surgical removal and replacement of the implant are generally advised, even in asymptomatic patients, due to the risk of progression to extracapsular rupture and related complications, such as granulomatous reactions or silicone nodules (4, 7). An extracapsular rupture is a more severe form of implant damage in which silicone gel escapes from the periprosthetic capsule into the breast tissue or the lymphatic system. Patients may report breast enlargement, changes in shape, pain, localized induration, or palpable nodules in the breast or axilla. In some cases, an inflammatory reaction may occur, accompanied by redness and tenderness in the affected area. A typical finding is the presence of so-called silicone nodules (siliconomas), which develop as a granulomatous response to the leaked silicone (4). Silicone may migrate to regional lymph nodes, particularly the axillary nodes, leading to a condition known as silicone lymphadenopathy. The prolonged presence of silicone in these tissues can complicate differential diagnosis, as palpable nodes may resemble malignancy (8).

A related phenomenon, known as "gel bleed," refers to the microscopic leakage of silicone molecules through an intact implant shell. This process has been linked to the development of granulomatous inflammation and CC (7, 9). With long-term exposure, gel bleed can lead to the accumulation of silicone in regional lymph nodes, resulting in silicone lymphadenopathy (8). In some cases, gel bleed is believed to play a role in the development of systemic symptoms, such as those described in breast implant illness (BII) or in the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). BII refers to a cluster of systemic symptoms that patients associate with the presence of breast implants, including fatigue, muscle and joint pain, brain fog, and depressive symptoms. ASIA syndrome is a broader term describing autoimmune or inflammatory manifestations triggered by an adjuvant, including silicone (10, 11). Accompanying complications significantly increase the risk of implant rupture. CC can increase mechanical stress on the implant shell (9), while recurrent seromas and hematomas may foster an environment that promotes fibrosis and gradual weakening of the implant structure (12, 13). The management of implant rupture primarily relies on surgical intervention. Treatment options include simple implant removal, capsulectomy, or replacement with a new implant, depending on the presence of complications, the patient's overall clinical condition and individual preferences (2, 14).

The primary objective of this study was to describe the clinical presentation, preoperative imaging findings, and operative findings in this surgically selected cohort. A secondary objective was to assess the apparent concordance of MRI and ultrasound findings with intraoperative rupture status in this surgically selected cohort. Additional exploratory analyses examined symptom categories, implant age, and implant placement in relation to operative and imaging findings.

Materials and Methods

This retrospective observational study evaluated a surgically treated cohort of women with suspected or confirmed silicone breast implant rupture who subsequently underwent operative management at the Department of Plastic Surgery, Faculty of Medicine, Comenius University, University Hospital Bratislava, Ružinov, between 2020 and 2025. The study was approved by the Ethics Committee of University Hospital Bratislava in November 16, 2022 under reference number EC/158/2022. Because only patients who proceeded to surgery were included, the cohort represents a selected referral population rather than an unselected surveillance population.

Patient Selection

Eligible patients were women aged 18 years or older who had a history of breast augmentation or implant-based breast surgery, had suspected or documented implant rupture on preoperative imaging or clinical evaluation, and subsequently underwent surgery. Patients were included only if operative records were available for review. Histopathology data were collected when available as part of routine clinical management. Patients were excluded if they were younger than 18 years or if the surgery was performed for reasons unrelated to suspected implant rupture, such as elective cosmetic revision performed without concern for implant rupture, or surgery performed solely for acute infection. A total of 43 women met the inclusion criteria and were included in the analysis.

Data Collection

Clinical data were retrospectively extracted from the Medea hospital information system at UNB Ružinov. Sources included outpatient records, preoperative imaging reports, operative reports, discharge summaries, and follow-up documentation. The following variables were collected when available: patient age, indication for surgery, presenting symptoms, implant age, implant placement, imaging modality used before surgery, intraoperative findings, and histopathologic findings.

Because most patients were referred from external institutions, imaging examinations were performed using heterogeneous protocols. Detailed technical parameters, including MRI field strength, coil type, imaging sequences, slice thickness, ultrasound probe frequency, and radiologist subspecialty expertise, were not consistently available and therefore could not be analyzed in a standardized manner.

Imaging Assessment, Reference Standard, and Histopathology

Preoperative imaging consisted of MRI, ultrasound, or both, depending on the referring pathway and clinical context. Imaging classification was based on the final preoperative radiologic report available in the medical record. Cases were categorized as imaging-positive when rupture was described or suspected in the report, and as imaging-negative when rupture was not reported. Given the retrospective, multicenter nature of imaging acquisition, standardized rereading of all original imaging studies using a uniform protocol was not feasible. Therefore, the imaging analysis reflects real-world preoperative assessments rather than controlled diagnostic imaging studies.

The reference standard for implant rupture was the intraoperative finding documented in the surgical report. Rupture status was classified as “confirmed” when rupture was identified intraoperatively, and as “not confirmed” when the implant was found to be intact.

Histopathologic examination was evaluated separately from the confirmation of implant rupture. Histology was used to document, when present, silicone leakage, siliconomas, granulomatous reactions, or related tissue changes , but it was not used as the primary reference standard for diagnosing implant rupture.

Statistical Analysis

Analyses were performed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Descriptive statistics were used to summarize patient demographics, implant characteristics, presenting symptoms, imaging findings, operative findings, and histopathologic results. Continuous variables are presented as means (with ranges) and categorical variables as counts and percentages. For preoperative imaging, intraoperative findings were used as the reference standard. Because the study included only surgically treated patients with suspected or clinically relevant pathology, the dataset is affected by selection bias and verification bias, and is enriched for positive cases. As a result, specificity and negative predictive value could not be reliably estimated, and any measure of overall diagnostic accuracy must be interpreted with substantial caution. Accordingly, imaging results are presented as an apparent within-cohort concordance with intraoperative findings, rather than as estimates of performance in routine screening or surveillance practice. Given the limited sample size, all subgroup analyses were considered exploratory and hypothesis-generating. No multivariable modeling was performed because the sample size was insufficient to allow robust adjustment for confounding.

Results

A total of 43 women were included in the study. Age at the time of surgery ranged from 26 to 77 years, with a mean age of 50.6 years. The interval between implantation and surgical intervention ranged from 2 to 39 years, with a mean duration of

14.7 years. Preoperative imaging consisted of MRI in 25 patients, ultrasound in 16 patients, and both modalities in 1 patient. One patient underwent emergency surgery for systemic symptoms and had no prior imaging. Implant placement was reported as subglandular in 11 patients, submuscular in 17 patients, and dual-plane in 4 patients. In 11 patients (25.6%), implant placement was not documented in the surgical reports.

Fourteen patients were asymptomatic at presentation, and implant rupture was detected incidentally on imaging in all of them, including 10 cases identified by MRI and 4 by ultrasound. All 14 cases were confirmed intraoperatively. Histologic evidence of silicone leakage into the capsule was present in 8 of these 14 patients. Fifteen patients presented primarily with CC. In this subgroup, preoperative imaging suggested implant rupture in 13 cases, including 7 identified by MRI and 6 by ultrasound. Intraoperative rupture was confirmed in 11 of these patients, whereas 4 implants were found to be intact at surgery. Eleven patients presented with local symptoms, including breast pain, swelling, or redness. Fever was present in 3 of these 11 patients, with temperatures of up to 38 °C in 2 patients and of 39 °C in 1 patient. In this subgroup, MRI suggested implant rupture in 5 patients, of whom 3 had rupture confirmed intraoperatively. Ultrasound suggested rupture in 4 patients, of whom 2 had rupture confirmed intraoperatively. Histologic evidence of silicone leakage into the capsule was found in 4 patients.

Three additional patients presented with systemic symptoms that were clinically attributed to possible BII. Preoperative imaging suggested implant rupture in all 3 patients: 2 cases detected on MRI and 1 case on ultrasound. Intraoperative rupture was confirmed in 1 of 3 patients, and histologic evidence of silicone leakage was documented in 1 patient.

Possible ASIA syndrome was included in the differential diagnosis for one patient presenting with local symptoms, recurrent fever up to 39 °C, and enlarged left axillary lymph nodes. Although ultrasound suggested implant rupture, rupture was not confirmed intraoperatively. Histologic examination demonstrated a siliconoma. This individual case is presented descriptively and does not allow causal inference.

Imaging Findings and Intraoperative Confirmation

Within this surgically selected cohort, MRI showed higher apparent sensitivity and positive predictive value than ultrasound for intraoperatively confirmed implant rupture. Because the study included only surgically treated patients and lacked a non-operated comparison group, the specificity and negative predictive value could not be reliably estimated. The reported imaging metrics, therefore, reflect performance within a surgically selected population and should not be extrapolated to routine surveillance settings. Table 1 summarizes the comparison between MRI and ultrasound. MRI showed an apparent sensitivity of 95.0% and a positive predictive value of 79.2%, whereas ultrasound showed an apparent sensitivity of 80.0% and a positive predictive value of 57.1%. Within-cohort agreement was defined as the proportion of imaging assessments concordant with intraoperative rupture status among patients who underwent that imaging modality.

Imaging Findings According to Implant Placement

Exploratory subgroup analyses were performed based on implant placement. In the subglandular subgroup, MRI showed an apparent sensitivity of 87.5%, with 1 false-negative case. Ultrasound did not correctly identify implant rupture in this subgroup, resulting in 2 false-positive findings and 1 false-negative finding. In the dual-plane subgroup, all MRI-assessed cases were correctly identified. No patients in this subgroup underwent ultrasound examination. Because of the very small number of patients, these findings should be interpreted only descriptively. Among patients with submuscular implants, MRI showed an apparent sensitivity of 100%, although false-positive findings reduced agreement within the cohort. Ultrasound also demonstrated relatively high apparent sensitivity in this subgroup but lower within-cohort agreement. In the subgroup with undocumented implant placement, all surgically confirmed ruptures were detected preoperatively; however, false-positive findings were also present. No clear association between implant placement and imaging performance can be established from these data.

Table 1. Comparison of imaging method parameters: MRI *vs.* ultrasound

Statistics	Results (%)		
	MRI	Ultrasound	Total
Within-cohort agreement	76.0	50.0	65.9
Specificity	Not estimable		
Sensitivity	95.0	80.0	90.0
PPV	79.2	57.1	71.1
NPV	Not estimable		

Specificity and NPV are not estimable because there are no true-negative cases. PPV: Positive predictive value; NPV: Negative predictive value; MRI: Magnetic resonance imaging

Imaging Findings According to Presenting Symptoms

Exploratory analyses were also performed according to the presenting symptom category. In asymptomatic patients, no false-negative imaging findings were observed. In patients with local symptoms, apparent imaging concordance was lower, particularly for ultrasound. In patients presenting with CC, MRI demonstrated higher apparent sensitivity and greater within-cohort agreement than ultrasound. In patients with systemic symptoms, apparent sensitivity remained high, but within-cohort agreement was low due to false-positive findings. These subgroup findings are based on small numbers and should be considered descriptive and hypothesis-generating.

Impact of Implant Age on Presenting Symptoms

Implant age appeared to be associated with differences in clinical presentation. In our cohort, most individuals who reported localized symptoms (breast discomfort, shape changes, or palpable irregularities) had implants 15 years old or younger ($n = 9/11$). In contrast, patients who developed CC predominantly had implants older than 15 years ($n = 9/15$), indicating that longer implant duration may contribute to more advanced or structurally significant complications. This represents a descriptive observation without statistical testing and should therefore be interpreted cautiously.

Discussion and Conclusion

Breast implant ruptures showed heterogeneous clinical presentations in this surgically treated cohort, ranging from asymptomatic cases detected on imaging to patients with local complaints, CC, or systemic symptoms. In our patient group, clinical symptoms were often ambiguous, making both diagnosis and treatment planning more challenging. This aligns with existing literature, which describes a broad range of presentations, from asymptomatic implant ruptures detected only on imaging to cases in which patients report notable discomfort.

In the present study, MRI showed greater apparent concordance with intraoperative rupture status than ultrasound. This is in line with prior reports indicating that MRI is sensitive for detecting implant rupture, including intracapsular rupture that may occur without obvious clinical signs (4, 7). Similarly, the study by Secco et al. (15) describes MRI as a more reliable diagnostic modality than ultrasound.

However, not all studies have found a large difference between MRI and ultrasound. Spit et al. (16) reported that ultrasound was nearly as effective as MRI in detecting silicone leakage and proposed ultrasound as an initial imaging modality, with MRI reserved for inconclusive cases. Thus, diagnostic accuracy (as within-cohort agreement) depends not only on the imaging technique itself but also on the radiologist's level of experience. In our cohort, imaging was performed at multiple external institutions before referral, resulting in heterogeneous protocols and incomplete technical data that may have influenced the observed performance.

The study by Rukanskienė et al. (17) demonstrated that ultrasound reliably assesses breast implant integrity and can serve as the initial imaging modality in suspected rupture. In contrast, MRI is most appropriate when ultrasound results are inconclusive (17). Similarly, the study by Telegrafo and Moschetta (18) suggested that ultrasound may serve as the initial imaging modality in patients with breast implants. When an intracapsular rupture is suspected on ultrasound, additional assessment with MRI is recommended. In contrast, if ultrasound clearly identifies an extracapsular rupture, surgical removal of the implant can be considered without the need for further diagnostic examinations (18). Importantly, the diagnostic performance observed in this study must be interpreted within the context of a surgically selected cohort. Due to the absence of true negative cases, specificity and negative predictive value could not be reliably assessed. As a result, the reported accuracy and sensitivity reflect performance in patients already selected for surgical management and should not be directly extrapolated to routine clinical practice.

In our cohort, implant rupture was detected preoperatively in 14 asymptomatic patients and was confirmed intraoperatively, illustrating the recognized phenomenon of silent rupture. However, this study was not designed to evaluate surveillance strategies or screening policies. Current recommendations regarding imaging follow-up should therefore be interpreted based on external guidelines and outcome data rather than as conclusions drawn from this cohort (19, 20). Despite familiarity with Food and Drug Administration guidelines, the study by Henry et al. (21) found that surgeon adherence remains low, largely because the guidelines are often viewed as unnecessary or insufficiently supported by evidence. Similarly, patient compliance is poor. Mehta et al. (22) reported that only about 20% of patients underwent follow-up screening within 5–6 years after surgery, highlighting the challenges of screening.

In symptomatic patients, false-positive imaging findings were more common, particularly on ultrasound. This may reflect the operator-dependent nature of ultrasound as well as the influence of edema, fibrosis, or scarring on image interpretation. MRI also demonstrated false-positive findings but appeared to perform better overall in this cohort. These findings are consistent with the broader literature suggesting that MRI is often more reliable for assessing implant rupture, especially when ultrasound findings are inconclusive (23). The relationship between systemic symptoms and implant rupture remains incompletely understood and cannot be specifically evaluated within the design of this study.

The observed relationship between implant age and clinical presentation is also in line with previously reported trends. Local symptoms were more often observed in patients with younger implants, whereas CC was more frequent in those with older implants. This is consistent with evidence showing that both contracture and implant rupture are more likely with increasing time since implantation and that contracture reflects a chronic process of capsular remodeling rather than an immediate consequence of rupture (24-26). Another noteworthy finding concerns differences between implant generations. Patients with older implants (2nd- and 3rd-generation) experienced higher rates of both intracapsular and extracapsular ruptures than those with newer, highly cohesive 5th-generation implants. This supports the current preference for cohesive gel implants, which reduce the risk of silicone leakage into surrounding tissues and lower the likelihood of related complications (27-29). However, these findings should be interpreted with caution, as newer implant generations have shorter follow-up periods, limiting direct comparability.

With regard to clinical management, the findings of this study suggest that surgical treatment may be appropriate in selected patients with implant rupture, particularly those with symptoms. However, given the retrospective design and the surgically selected cohort, the data do not support definitive recommendations for routine explantation in all cases. Management should therefore remain individualized, taking into account symptoms, imaging findings, comorbidities, and patient preferences (30, 31).

This study has several important limitations. First, the retrospective design and the relatively small sample size limit the strength of the conclusions. Second, the inclusion of only surgically treated patients introduces selection bias and precludes the reliable assessment of specificity and negative predictive value. Third, the cohort was heterogeneous with respect to implant characteristics, clinical presentation, and available data. Additionally, implant placement was not documented in the operative report in 25.6% of patients, reflecting an inherent limitation of retrospective data collection, in which variables not considered relevant at the time of surgery were not consistently recorded. This is a recognized challenge in retrospective studies and underscores the need for standardized, prospective documentation of implant characteristics in future research. Moreover, the heterogeneity of imaging protocols is a significant limitation, as MRI examinations performed across multiple external institutions varied in field strength, coil configuration, and sequence selection, and were interpreted by radiologists with differing levels of subspecialty expertise in breast imaging. Similarly, ultrasound examinations were performed using various probe frequencies and techniques. This heterogeneity in protocols may have contributed to variability in diagnostic performance and may have limited the ability to draw conclusions about optimal imaging protocols. Furthermore, subgroup analyses were based on small numbers and should be considered exploratory. Finally, the absence of a non-surgical control group limits the ability to assess the broader clinical significance of imaging findings and systemic symptoms.

Taken together, these findings provide descriptive insight into the clinical and imaging features of breast implant rupture in a surgically managed population. Larger prospective studies that include both symptomatic and asymptomatic patients, as well as operated and non-operated controls, are needed to better define the role of imaging and to inform evidence-based management strategies.

Breast implant rupture showed heterogeneous clinical presentation in this retrospective cohort of surgically treated patients, ranging from asymptomatic imaging-detected rupture to cases associated with local symptoms, CC, or systemic complaints. MRI showed a higher apparent concordance with intraoperative rupture status than did ultrasound in this selected cohort. However, because the study included only patients who underwent surgery, the findings are subject to selection and verification bias, and should not be extrapolated to routine screening or surveillance populations. Subgroup analyses were exploratory and did not support definitive conclusions regarding imaging strategy or routine surgical management. Clinical decision-making should remain individualized, taking into account symptoms, imaging findings, comorbidities, and patient preferences. Larger prospective studies that include broader patient populations are needed to clarify the role of imaging and to guide evidence-based management of silicone breast implant rupture.

Ethics

Ethics Committee Approval: The study was approved by the Ethics Committee of University Hospital Bratislava in November 16, 2022 under reference number EC/158/2022.

Informed Consent: Given the retrospective observational nature of the study and the use of existing anonymized data, the requirement for informed consent was waived.

Footnotes

Authorship Contributions

Surgical and Medical Practices: M.T.T., M.C., D.M., M.B.; Concept: M.T.T., M.C., S.H., D.M., M.B.; Design: M.T.T., M.C., S.H., D.M., M.B.; Data Collection and/or Processing: M.T.T., M.C., S.H., D.M.; Analysis and/or Interpretation: M.C., S.H.; Literature Search: M.T.T., M.C., S.H., D.M., M.B.; Writing: M.T.T., M.C., S.H., D.M., M.B.

Conflict of Interest: The authors have no conflicts of interest to declare.

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