



Preliminary Report

High-Resolution Ultrasound in the Detection of Silicone Gel Breast Implant Shell Failure: Background, In Vitro Studies, and Early Clinical Results

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Abstract

Background: Magnetic resonance imaging (MRI) has historically been considered the “gold standard” for imaging silicone gel breast implants and is currently recommended by the US Food and Drug Administration for device surveillance. Recent studies, however, have questioned its accuracy as the best screening test for implant failure. In addition, the high cost of MRI is a significant deterrent to follow-up, especially among asymptomatic patients. Recent advancements in ultrasound technology have led to the development of high-resolution devices with the potential to accurately image breast implants and breast tissues.

Objectives: The authors evaluate the feasibility of portable, high-resolution ultrasound (HRUS) for imaging of silicone gel breast implants and perform preliminary comparisons of HRUS to MRI in the assessment of both intact and failed implants in a clinical setting by both radiologists and plastic surgeons.

Methods: Phase 1 was composed of in vitro and ex vivo scanning model assessments in a variety of implant models utilizing multiple HRUS hardware platforms (GE LOGIQ-9, LOGIQ-e, LOGIQ-i, and Venue-40 devices) and transducer heads (range, 8-16 MHz, mainly GE12ML transducer). In Phase 2, these technologies were applied clinically to provide imaging experience in three patients previously diagnosed with unilateral implant failure. Phase 3 was a preliminary prospective evaluation of HRUS of 29 implants in 15 consecutive patients for whom MRI and independent surgeon-performed and radiologist-performed HRUS scans were compared to subsequent surgical findings.

Results: In Phase 1, all hardware models easily detected both intact and intentionally damaged shells in currently marketed fourth-generation responsive gel implants and in investigational, fifth-generation highly-cohesive gel devices. Although multiple transducers were able to detect shell failure, the 12-MHz head produced the best images at the normal clinical depth range. In Phase 2, confirmatory HRUS scans correctly identified the side of rupture and were consistent with MRI and surgical findings in all patients. In Phase 3, MRI, surgeon-performed HRUS, and radiologist-performed HRUS scans were all accurate in predicting implant shell integrity in 29 of 29 imaged breasts (100%) as confirmed at the time of surgery in both symptomatic and asymptomatic patients.

Conclusions: Preliminary results with a variety of base and transducer systems demonstrated that HRUS provides excellent visualization of current fourth- and fifth-generation silicone gel implants both in the in vitro and ex vivo scanning models. In vivo surgeon-performed HRUS accurately identified implant status and correlated with radiologist-performed HRUS, MRI, and surgical findings. An ongoing Phase 4 prospective study is under way to help define the sensitivity and specificity of HRUS technologies in the evaluation of current implant designs. However, the relative affordability, accessibility, availability, and dynamic real-time visualization provided by HRUS represent significant potential advantages of HRUS over MRI in both the screening and future diagnosis of breast implant shell failure.

Level of Evidence: 2

Keywords

silicone gel, breast implants, shell failure, implant rupture, ultrasound, high-resolution ultrasound, HRUS, MRI, surgeon-performed ultrasound



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In November 2006, the US Food and Drug Administration (FDA) approved the marketing of silicone gel-filled breast implants manufactured by two companies for breast reconstruction in women of all ages and for breast augmentation in women ages 22 and older.¹ FDA approval was conditional upon the performance by each manufacturer of six postapproval studies, some of which stipulated periodic magnetic resonance imaging (MRI) surveillance for implant integrity. Contemporaneous with the 2006 marketing approval, the FDA also recommended routine MRI evaluations in all patients three years postoperatively

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and every two years thereafter. Current patient compliance with these MRI surveillance recommendations outside of the postapproval studies is unknown, but in 2011, the FDA released a report on the status of the postapproval studies, noting a deficiency in MRI surveillance (among other findings).² As plastic surgeons strive to assist the FDA in obtaining the requested data, it is clear that both the cost and inconvenience of MRI are impediments to postoperative implant evaluations, both for patients within mandated studies and for nonstudy patients, and that potential false-positive results raise the specter of unnecessary surgery in asymptomatic women. In August 2011, an FDA Advisory Panel considered the status of the postapproval studies, noting the current scientific data and recommendations for MRI screening for silent rupture and “question[ing] whether much was gained by this recommendation. There is a concern expressed about cost to patients and mentioned, false-positive findings and whether information about a silent rupture would change practice (such as decisions about removal of the device).”³

Essentially, by definition, Brown et al were correct in stating that “the gold standard for finding out whether an implant has ruptured is removal and examination of the implant.”⁴ There is less clarity, however, around which imaging technologies and strategies are best for the *noninvasive* assessment of implants under various conditions. With modified techniques to image breast parenchyma in patients with implants,⁵ mammography is a theoretically attractive option given its relative accessibility, affordability, and the potential contemporaneous evaluation of both parenchyma and implant. Unfortunately, mammography is of limited utility in imaging breast implants, failing to detect the more common intracapsular ruptures, thus exhibiting a low sensitivity in the detection of implant failure.⁶⁻¹² In addition, the examination can be painful, especially in the presence of capsular contracture (CC),^{13,14} and it exposes the patient to radiation. On the other hand, MRI is well suited to identify both extracapsular and intracapsular implant rupture.¹⁵⁻¹⁸ Following Gorczyca et al’s description¹⁹ of the “linguini sign,” pathognomonic for intracapsular shell collapse dispersed into the gel filler, MRI has been widely touted as the “gold standard” for noninvasive evaluation of silicone gel breast implants.

Several reports have challenged the role of MRI in the evaluation of breast implants, especially among asymptomatic patients.^{4,7,20-23} MRI is expensive, with the national Medicare Global Diagnostic Service Fee for bilateral MRI being 9.7 times that of a screening mammogram and 8.2 times that of breast ultrasound.²⁴ MRI is also inconvenient, requiring that the patient visit an imaging center or hospital radiology department apart from follow-up visits with her surgeon, and the presence of metallic implants (ie, surgical clips, pacemakers) or severe claustrophobia is a contraindication to MRI examination. Published MRI sensitivity and specificity for detecting implant failure shows that significant heterogeneity and interpretation discrepancies between radiologists commonly occur.^{9,21,23,25} Most studies favoring MRI in

the detection of implant failure have evaluated older implant models (first, second, or third generation), which have not been manufactured or implanted for decades^{7,10,18,26} and in which both advanced implant age and older manufacturing specifications may have contributed to a high incidence of failure.^{27,28} Furthermore, the vast majority of studies have been performed on women who are symptomatic, which may not correlate with the accuracy of MRI as a screening test. Given these concerns, extrapolating the existing MRI literature for screening asymptomatic women implanted with newer devices (fourth and fifth generation) is problematic.

Although standard ultrasonography (US) has been utilized for the evaluation of breast implants in the past,^{6,8,9,11,12,16,29,30} US has not been widely adopted as either a viable screening or diagnostic alternative to MRI. However, ultrasound—and especially newer high-resolution ultrasound (HRUS)—does have many attractive attributes with regard to its potential role in the imaging of silicone gel breast implants. It is noninvasive, relatively inexpensive, painless, and widely available. Higher-wave frequencies (eg, 12-18 MHz) produce higher image quality and resolution but are limited to more superficial scan depths due to increased attenuation. Ultrasound is therefore ideal for visualizing structures that reside just a few centimeters beneath the skin, as in the case of breast implants.³¹⁻³⁴ In addition, US does not expose the patient to ionizing radiation like mammography, nor does it have the metal foreign body restrictions of MRI. Recently, there have been significant improvements to ultrasound technology, including the development of handheld HRUS devices that are portable, reliable, and less expensive than older devices. Given these developments, the potential role of HRUS in breast implant imaging deserves further consideration.

METHODS

In order to study the feasibility of HRUS in the evaluation of silicone gel breast implant integrity, a three-phase preliminary study was undertaken. Phase 1 included in vitro examinations and ex vivo model comparisons of four currently-available HRUS hardware systems and transducer head combinations for the visualization of various normal and damaged implants. Phase 2 was a pilot clinical HRUS evaluation of implants in three patients previously scheduled for secondary breast implant surgical procedures. Phase 3 was a prospective comparison of portable HRUS and MRI in 15 consecutive breast implant patients who subsequently underwent secondary implant surgery. All in vitro, ex vivo, and in vivo plastic surgeon-performed HRUS studies were completed in an office setting, and a certified ultrasound trainer assisted with initial scanning techniques and instrument familiarity in Phases 1 and 2. All surgical procedures were performed in a certified outpatient surgical facility. Radiologist-performed ultrasound studies were completed in either a hospital setting or the same private office facility. MRI scans were performed at

several regional hospitals with breast coils in all cases, and interpreting radiologists were blinded to the HRUS findings. The study was performed under Spectrum Health Institutional Review Board (IRB) 2008-217.

Phase 1: In Vitro and Ex Vivo Studies

In vitro and ex vivo examinations were completed between June and July 2008. Various-sized implants ranging from 300 to 450 cc were studied, including samples of both currently-available, fourth-generation responsive gel implants (Natrele Style 10, 15, 20; Allergan, Inc., Irvine, California) and fifth-generation, highly-cohesive silicone gel implants currently under premarket approval (PMA) investigation with the FDA (Style 410, size range 300-450 cc; Allergan, Inc.). Implants were either scanned in an intact state or were purposefully altered with a 2-cm sharp incision on the anterior implant surface that extended, full-thickness, through the implant shell but not into the gel filler. Both intact and cut implants of each design were then scanned with four different HRUS hardware base unit designs: the LOGIQ-9 unit and the smaller, laptop-size LOGIQ-e, LOGIQ-i, and Venue-40 base units (General Electric Healthcare, Waukesha, Wisconsin). Multiple transducer heads ranging in frequency between 6 and 18 MHz (all General Electric Healthcare) were assessed in varying combinations with the base units.

In vitro scanning methods included direct transducer-to-implant, transducer-to-implant with Aquasonic-100 water-soluble ultrasonic gel (Parker Laboratories, Fairfield, New Jersey), transducer-to-water immersion, and transducer with lift models (Figure 1A-F). The transducer-to-water immersion model was created by placing the implant within a water-filled resealable standard kitchen polyethylene bag. The lift model utilized a standard training spacer (General Electric Healthcare) positioned between the transducer head and the implant. Scans were also completed in similar combinations of implant designs (intact and altered) positioned under ex vivo tissues, including meat samples or discarded abdominoplasty resection specimens, also with Aquasonic-100 gel. Compression or distortion of the implants was performed to simulate clinical maneuvers in an attempt to express the inner silicone gel filler through the shell defect (Figure 2A-D). Base unit and transducer head combinations were evaluated for their capacity to produce full visualization of the inner and outer shell surfaces, image resolution, clarity, and optimal visualization depth in the different scanning models tested.

Phase 2: Initial Clinical Pilot

In order to gain experience in the clinical application of HRUS, three consecutive symptomatic patients with an MRI scan positive for unilateral rupture and scheduled for

surgery agreed to undergo preoperative HRUS examination. All patients had bilateral fourth-generation silicone gel devices (one patient had Natrele Style 15 and two patients had Style 153) with intervals since implantation of four, six, and eight years. Two of the three patients presented with Baker Grade 3-4 CC, and one of the Style 153 patients presented with a softening change of the affected breast. Ultrasound technique training was initially provided to the surgeon-scanner by a nationally-certified ultrasound trainer. Both the affected and unaffected breasts were imaged in each of these patients with either the LOGIQ-i or LOGIQ-9 unit base models with M12L (12-MHz) and 16-MHz transducers. The surgeon performing the ultrasound was blinded as to which side was symptomatic or had a positive MRI. A diagnosis of “intact” or “failure” was made, and ultrasonographic images (still and video) were recorded. These results were subsequently compared to the MRI results and confirmed at surgery.

Phase 3: Preliminary Diagnostic Comparative Trial

In Phase 3, 16 consecutive patients were enrolled in a prospective study comparing HRUS to MRI in the evaluation of silicone gel breast implant status. Inclusion criteria were previous augmentation or reconstruction procedures with silicone gel breast implants, previous completion of or willingness to undergo an MRI examination, willingness to undergo HRUS examinations, and existing plans for secondary breast surgery due to elective aesthetic goals, clinical symptoms (CC, rotation, malposition), or for suspicious noninvasive imaging results. Patient ages ranged from 28 to 64 years, with interval from implantation ranging from three to greater than 26 years (mean, 8.5 years).

Two HRUS scans were completed for each implanted breast (total 58 HRUS scans), one radiologist-performed and one surgeon-performed. At the time that the HRUS scan was performed, the scanning surgeon was blinded to the MRI findings as much as possible, although the enrollment process did compromise the completeness of surgeon blinding to some details. The radiologist performing and interpreting the HRUS scans was fully blinded to the MRI results. Neither the surgeon nor the radiologist performing the separate ultrasound examinations discussed the MRI findings or symptoms with the patient prior to the HRUS exam. The radiologist-performed and surgeon-performed HRUS scans and interpretations were all mutually blinded. Both still and video ultrasonographic images were recorded. All HRUS and MRI interpretations were documented prior to surgical exploration and compared to findings during the subsequent surgical procedure. Of the 16 patients enrolled, 15 completed all required components of the study and were included in the analysis. One patient has yet to complete the final stage of surgical confirmation and will be included in a subsequent report. All surgical procedures were completed within 10 weeks of the HRUS examination.

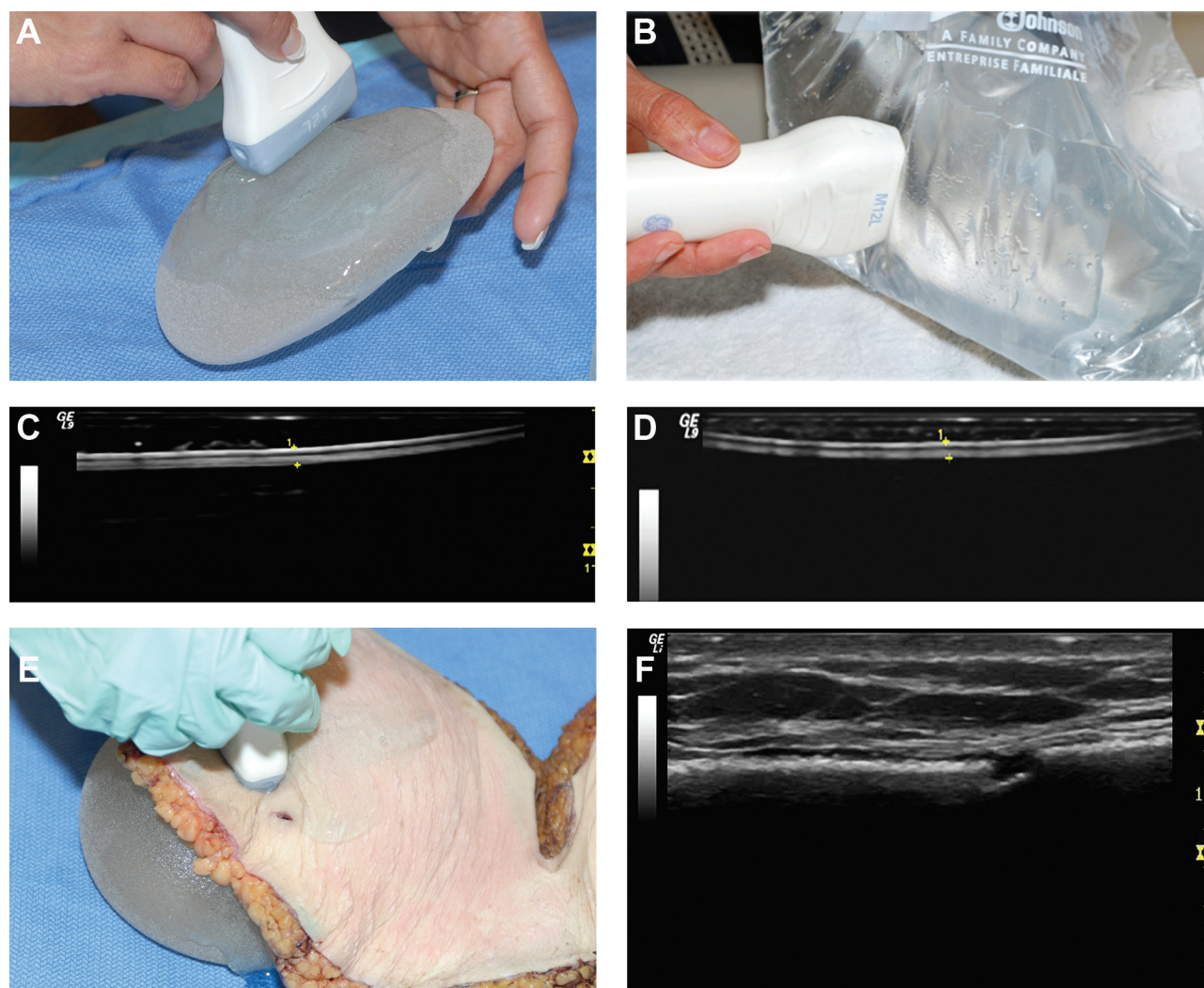


Figure 1. Representative in vitro and ex vivo, Phase 1 scanning models. (A) Direct scanning of a fifth-generation device (Natrele Style 410). (B) Indirect scanning of smooth-surface fourth-generation device (Style 15) through a plastic bag filled with fluid. (C) High-resolution ultrasound (HRUS) scan of a highly-cohesive implant (Style 410) with an intact shell. The shell is ~ 1.1 mm in thickness. (D) HRUS scan of a Style 15 implant. The “Oreo” look, which describes a clear central area on the scan, does not represent the barrier coating but the sound waves canceling themselves out as they impact the outer and inner shell, resulting in a hypoechoic area. (E) HRUS scanning of a fifth-generation (Style 410) implant through a discarded abdominoplasty specimen. (F) HRUS scan of purposefully-cut Style 410 implant imaged through a discarded abdominoplasty specimen. (All implant devices Allergan, Inc., Irvine, California; scanning technology—all General Electric Healthcare, Waukesha, Wisconsin, with 12-MHz transducer heads.)

RESULTS

Phase 1

In the in vitro studies, all of the base units and hardware systems performed well, with no significant differences noted among them concerning their ability to accurately evaluate implant shell integrity. Of the transducer heads evaluated, the 12-MHz standard, 12L Matrix Array, and 16 3D/4D L heads (all General Electric Healthcare) had the greatest degree of clarity and visualization, with higher-frequency heads utilized when imaging more

superficially. All scanning models, both in vitro and ex vivo, allowed clear visualization of the anterior and lateral implant surfaces and were able to determine implant integrity. Both the meat and abdominoplasty ex vivo models provided a more realistic simulation of in vivo scanning and represent a potential model for surgeon-HRUS training. In the ex vivo models, diagnostic maneuvers may be used to simulate changes seen during in vivo examinations, such as applying pressure displacing the implant and accentuating the defect or flattening potential folds.

Phase 2

Of the six implants evaluated in the three patients, both MRI and surgeon-performed HRUS correctly demonstrated implant status as confirmed at the time of surgical exploration. Each patient had one intact and one ruptured implant. These initial evaluations supported progression to Phase 3 of this study and further helped to refine the hardware selection, with the more portable LOGIQ-i model and the 12ML transducer producing the best image quality.

Phase 3

Of the 15 patients completing the study, 14 (93.3%) had bilateral breast implants originally placed for aesthetic reasons; the remaining patient (6.7%) had a unilateral device only, which had been placed for breast reconstruction. Patients were classified as “symptomatic” if the clinical presentation was suspicious for implant rupture (ie, CC extracapsular mass or changes in feel, shape, position, or appearance of the breast) or “asymptomatic” if symptoms were not suspicious for implant failure (ie, elective size change, longstanding implant malposition, or postpartum parenchymal involution). Seven patients (46.7%) were considered asymptomatic; these patients presented for elective size change (three), positive screening MRI for rupture (three), or revision of reconstruction (one). Eight patients (53.3%) were symptomatic, presenting with either increased softness or a change in appearance of a breast (five) or with CC (three).

On a per implanted breast basis, 18 of 29 breasts were asymptomatic (62.1%) and 11 (37.9%) were symptomatic. Specific implant model information was available for 25 (86.2%) of the implants studied, with 16 (55.2%) fifth-generation Style 410 highly-cohesive gel implants (textured surface), six (20.7%) fourth-generation Style 15 gel implants (smooth surface), one (3.4%) fourth-generation Style 10 gel implant (smooth surface), two (6.7%) Style 153 (textured), and four (13.8%) smooth-surface gel implants of unknown design (all known designs were Allergan, Inc.). No patient complained of pain or discomfort during the course of the HRUS examination. Completion times for HRUS scanning for the surgeon-performed HRUS scans were typically less than 10 minutes per breast.

There was 100% concordance of the MRI, surgeon-performed HRUS, radiologist-performed HRUS, and surgical findings (Table 1, Figures 3 and 4) in this preliminary study group. A total of 10 (34.5%) of the implants were ruptured, with six of the 15 patients (40%) demonstrating unilateral rupture and two (13.3%) demonstrating bilateral rupture. Eight of 16 Style 410 implants were ruptured (median time from implantation, 8.25 years; range, six to 10 years), and eight were intact (median time from implantation, 6.75 years; range, three to 10 years). None of the Style 10 and 15 implants were ruptured (median time from implantation, 5.9 years; range, four to nine years), none of the Style 153 implants were ruptured,

and two of the four implants of unknown origin were ruptured. All implant ruptures were intracapsular. Surgical procedures included implant exchange in all studied breasts, combined with either capsulotomy or partial or complete capsulectomy. All patients underwent reimplantation with fourth-generation, smooth silicone gel implants (24 Style 15, 82.8%; five Style 20, 17.4%). All patients successfully underwent breast revision with no secondary complications at a median follow-up of eight months. Of note, none of the ruptures were located on the deep or posterior aspect of the shell only. A series of videos of these scans is available at www.aestheticsurgeryjournal.com. You may also use any smartphone to scan the code on the first page of this article to be taken directly to the first video on www.youtube.com.

Of the 11 symptomatic breasts, five (45.5%) were ruptured and six (54.5%) were intact. Of note, all symptomatic breasts with ruptured implants had been augmented with Style 410 implants, and the symptoms in each case were a complaint that the implant had shifted, rotated, or become “softer” to the patient. Of the Style 410 implants considered as a group, all five symptomatic implants were ruptured, but only three of eight (37.5%) in the asymptomatic breasts were ruptured. Of the symptomatic breasts that had unruptured devices, all six presented with CC and had been implanted with smooth-surface devices. Of the 18 asymptomatic breasts, five (27.8%) contained ruptured implants and 13 (72.2%) contained unruptured implants. Both of the two women with bilateral rupture were asymptomatic on both sides. Of the 13 asymptomatic breasts with intact implants, all patients were undergoing surgery to treat symptoms of the opposite breast or other symptoms unsuspecting for implant rupture, such as malposition or a desire for implant size change (Table 2).

DISCUSSION

When considering any test such as MRI or current HRUS, it is important to understand the purpose of the test (whether the test is intended to be screening or diagnostic) and how it will alter patient care; it is also important to be familiar with the characteristics of the condition, the population, and the test itself. Surveillance is screening over time, as in the FDA recommendation for repeated MRI examinations of the breast,¹ and the principles of screening and surveillance have been eloquently expressed for decades by the World Health Organization³⁵ (Table 3). Current recommendations for screening asymptomatic women for rupture do not appear to be in alignment with these principles, even beyond the issues with MRI such as expense, acceptance, and accessibility. Prospective trials have not demonstrated significant systemic health risks (such as autoimmune disease) associated with silicone gel implants.³⁶⁻⁴⁰ In addition, the clinical significance and natural history of a silent implant rupture (the “latent phase”) are unknown, and women followed prospectively with untreated implant failure do not appear to experience significant elevated health

Table 1. Presenting Symptoms, Implant History, Imaging Results, and Surgical Findings on a Per Breast Basis

Patient Side	Presenting Signs and Symptoms	Imp	Age, y	MRI	Surgeon HRUS	Radiologist HRUS	Surgical Findings	Procedure
Pt 1 R	Increased softness	410	10	Ruptured	Ruptured	Ruptured	Ruptured, anterior linear shell tears	Capsulectomy/exchange to Style 15
L	Asymptomatic	410	10	Intact	Intact	Intact	Intact	Capsulectomy/exchange to Style 15
Pt 2 R	Asymptomatic, elective size change	410	3	Intact	Intact	Intact	Intact	Capsulotomy/exchange to Style 15
L	Asymptomatic, elective size change	410	3	Intact	Intact	Intact	Intact	Capsulotomy/exchange to Style 15
Pt 3 R	Asymptomatic	410	8	Intact	Intact	Intact	Intact	Capsulotomy/exchange to Style 15
L	Implant rotated postpregnancy	410	8	Ruptured	Ruptured	Ruptured	Ruptured, minor radial tear	Partial capsulectomy/exchange to Style 15
Pt 4 R	Capsular contracture (Baker IV)	15	7	Intact	Intact	Intact	Intact	Capsulectomy/exchange to Style 15 with Strattice
L	Capsular contracture (Baker IV)	15	7	Intact	Intact	Intact	Intact	Capsulectomy/exchange to Style 15 with Strattice
Pt 5 R	Asymptomatic	410	9	Rupture	Rupture	Rupture	Rupture, minor radial tear	Capsulotomy/exchange to Style 15
L	Asymptomatic	410	9	Rupture	Rupture	Rupture	Rupture, minor radial tear	Capsulotomy/exchange to Style 15
Pt 6 R	Postreconstruction asymmetry	10	9	Intact	Intact	Intact	Intact	Partial capsulectomy/Style 20
L	No implant	NA	NA	NA	NA	NA	NA	Revision reconstruction
Pt 7 R	Increased softness, implant rotated	410	6	Ruptured	Ruptured	Ruptured	Ruptured, multiple linear cracks in anterior surface	Partial capsulectomy/exchange to Style 15
L	Asymptomatic	410	6	Intact	Intact	Intact	Intact	Capsulotomy/exchange to Style 15
Pt 8 R	Change in feel and look	410	6	Ruptured	Ruptured	Ruptured	Ruptured, radial tear at apex of implant	Partial capsulectomy/exchange to Style 20
L	Asymptomatic	410	6	Intact	Intact	Intact	Intact	Capsulotomy/exchange to Style 20
Pt 9 R	Capsular contracture (Baker IV), pain	UKS	>26	Intact	Intact	Intact	Intact	Total capsulectomy with acellular matrix/exchange to Style 15
L	Capsular contracture (Baker IV), pain	UKS	>26	Intact	Intact	Intact	Intact	Total capsulectomy with acellular matrix/exchange to Style 15
Pt 10 R	Asymptomatic	410	10	Ruptured	Ruptured	Ruptured	Ruptured, minor radial tear	Capsulotomy/exchange to Style 15
L	Asymptomatic	410	10	Intact	Intact	Intact	Intact	Capsulotomy/exchange to Style 15
Pt 11 R	Capsular contracture (Baker III), firmness	15	5	Intact	Intact	Intact	Intact	Capsulectomy/exchange to Style 15
L	Capsular contracture (Baker III), firmness	15	5	Intact	Intact	Intact	Intact	Capsulectomy/exchange to Style 15
Pt 12 R	Asymptomatic, elective size change postpregnancy	15	4	Intact	Intact	Intact	Intact	Capsulotomy/exchange to larger Style 15

(continued)

Table 1. (continued)

Patient Side	Presenting Signs and Symptoms	Imp	Age, y	MRI	Surgeon HRUS	Radiologist HRUS	Surgical Findings	Procedure
L	Asymptomatic, elective size change postpregnancy	15	4	Intact	Intact	Intact	Intact	Capsulotomy/exchange to larger Style 15
Pt 13 R	Asymptomatic (Baker II)	UKS	7	Ruptured	Ruptured	Ruptured	Ruptured, radial tear intracapsular gel	Capsulectomy/exchange to Style 15
L	Asymptomatic (Baker II)	UKS	7	Ruptured	Ruptured	Ruptured	Ruptured, radial tear intracapsular gel	Capsulectomy/exchange to Style 15
Pt 14 R	Increased softness, change in shape	410	8	Ruptured	Ruptured	Ruptured	Ruptured, linear splits, gel in chunks	Partial capsulectomy/exchange to Style 15
L	Asymptomatic	410	8	Intact	Intact	Intact	Intact	Capsulotomy/exchange to Style 15
Pt 15 R	IMF malposition, elective size change	153	10	Intact	Intact	Intact	Intact	Fold repair, capsular flap/exchange to Style 20
L	IMF malposition, elective size change	153	10	Intact	Intact	Intact	Intact	Fold repair, capsular flap/exchange to Style 20

HRUS, high-resolution ultrasound; IMF, inframammary fold; L, left breast; MRI, magnetic resonance imaging; NA, not applicable; R, right breast; UKS, smooth silicone gel implant of unknown manufacturing origin. Age = implant age (time since implanted) in years. Baker Classification: Little G, Baker JL. Results of closed compression capsulotomy for treatment of contracted breast implant capsules. *Plast Reconstr Surg* 1980;65:30-33. 10 = Natrelle Style 10 implant (smooth), 15 = Natrelle Style 15 implant (smooth), 20 = Natrelle Style 20 implant (smooth), 410 = Style 410 implant (textured), 153 = Style 153 implant (textured). All known implants Allergan, Inc. (Irvine, California).

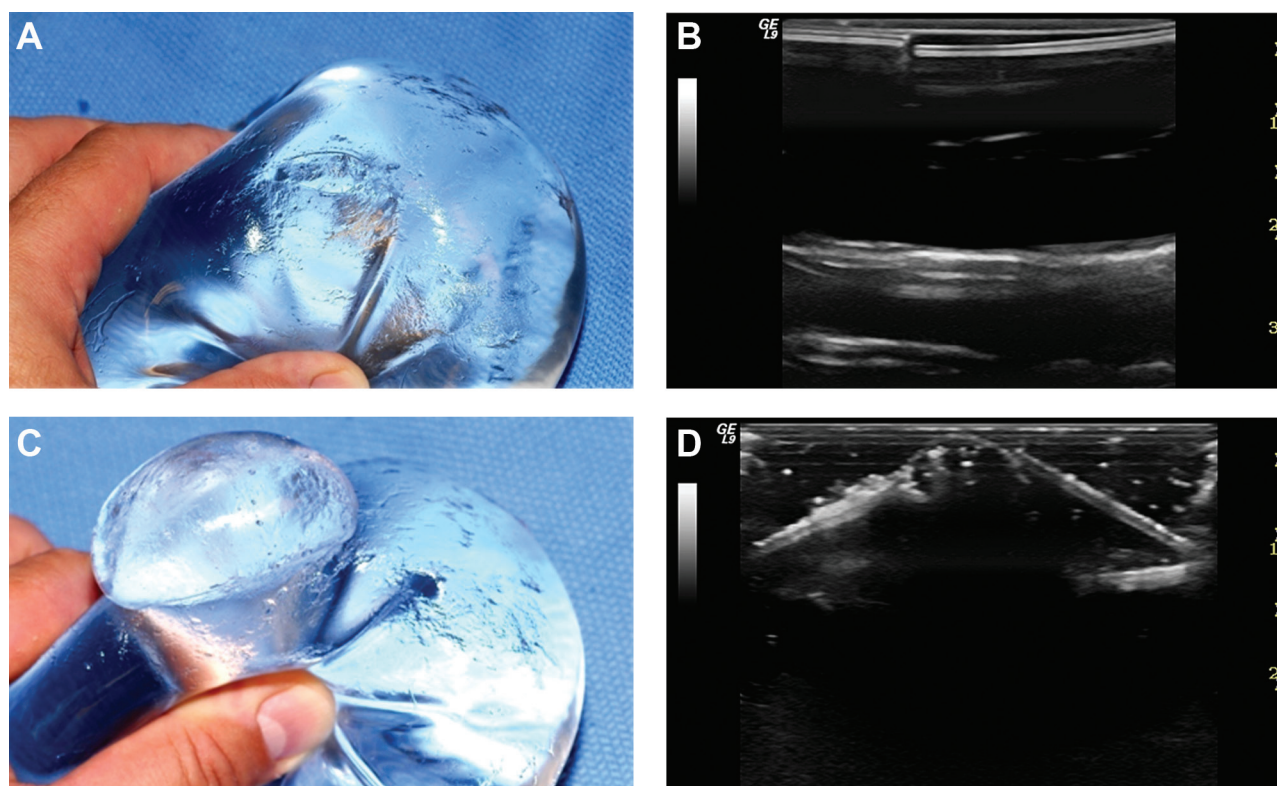


Figure 2. Intentionally-cut fourth-generation Style 15 implant. (A) Gross appearance after implant shell cut. (B) In vitro high-resolution ultrasound (HRUS) scan of implant in Part A showing the clear break in the implant shell. (C) Gross appearance with manipulation of the implant to accentuate the defect. (D) In vitro HRUS scan of same implant with manipulation to accentuate the defect. At the center top of the scan image, the gel fill can be seen projecting through the defect in the implant shell. (All implant devices Allergan, Inc., Irvine, California; scanning technology—all General Electric Healthcare, Waukesha, Wisconsin, with 12-MHz transducer heads.)

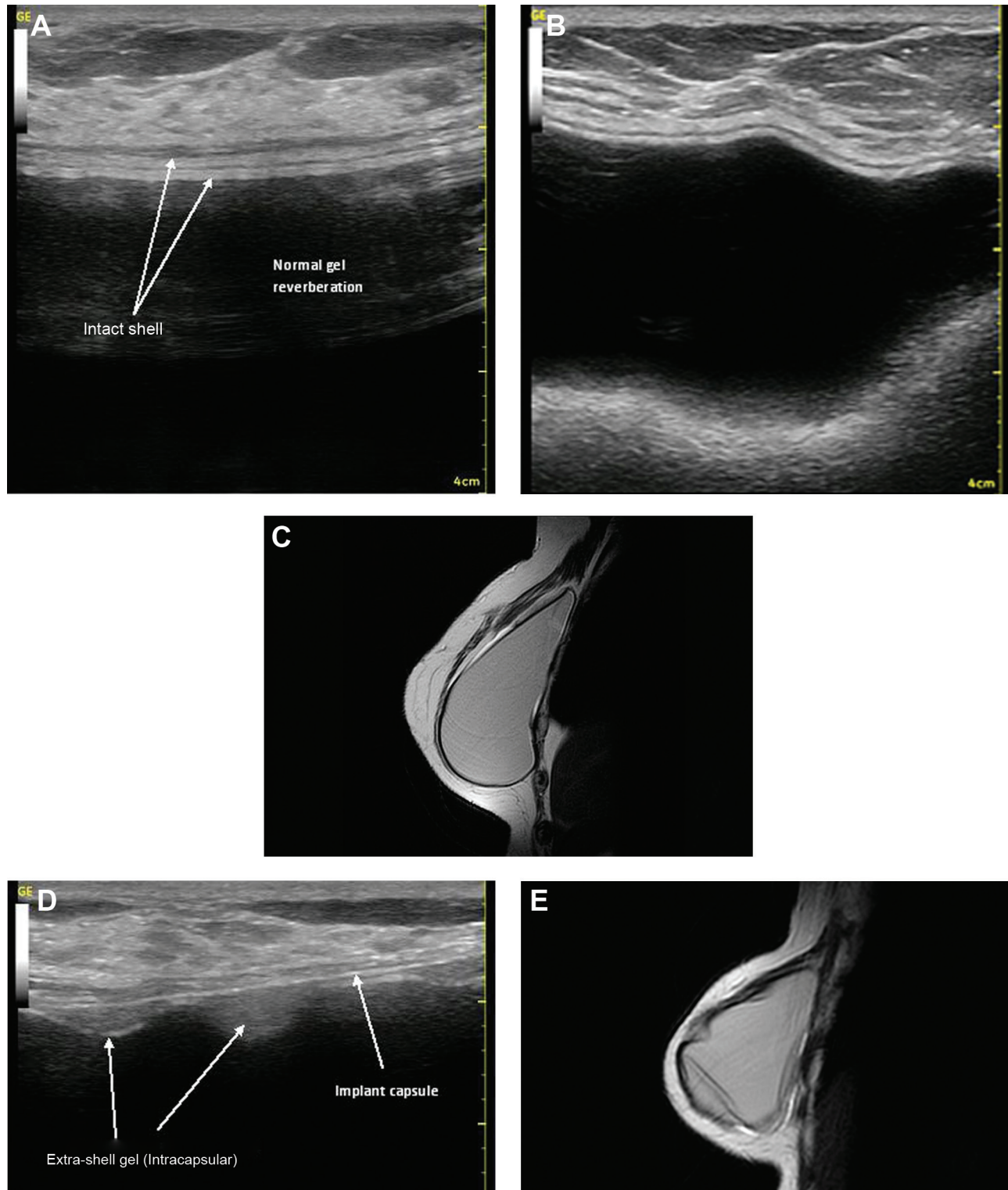


Figure 3. Patient high-resolution ultrasound (HRUS) and magnetic resonance imaging (MRI) scans. (A) In vivo HRUS of Style 15 intact device showing noninterrupted shell and a normal reverberation pattern. (B) In vivo HRUS Style 410 intact device is shown on HRUS. (C) In vivo, Style 410 device is shown on MRI, lateral view, in an asymptomatic patient presenting for elective implant size change. Intact implant status confirmed at surgery. (D) In vivo HRUS image of a ruptured silicone implant of unknown etiology. The presence of gel in the intracapsular space and the collapsed shell was confirmed at surgery. The extracapsular silicone demonstrates a typical “snowstorm pattern.” (E) In vivo, ruptured Style 410 implant visualized by MRI scan, lateral view. Intracapsular gel and irregularity of the implant shell are clearly visualized. The posterior capsule lights up and is attenuated but was not calcified.

Table 2. Symptoms vs Implant Status (Per Implanted Breast)

	Ruptured: Model (Number)	Unruptured: Model (Number)
Symptomatic (total = 11)	Total = 5 Style 410 (5)	Total = 6 Style 15 (4) Unknown (2)
Asymptomatic (total = 18)	Total = 5 Style 410 (3) Unknown (2)	Total = 13 Style 410 (8) Style 153 (2) Style 15 (2) Style 10 (1)
	Total ruptured = 10	Total unruptured = 19

Table 3. World Health Organization Criteria for a Screening Test

1. The condition sought should be an important health problem.
2. There should be an accepted treatment for patients with recognized disease.
3. Facilities for diagnosis and treatment should be available.
4. There should be a recognizable latent or early symptomatic stage.
5. There should be a suitable test or examination.
6. The test should be acceptable to the population.
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood.
8. There should be an agreed policy on whom to treat as patients.
9. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
10. Case-finding should be a continuing process and not a "once and for all" project.

Adopted from Wilson JMG, Jungner G. *Principles and Practice of Screening for Disease*. Geneva, Switzerland: World Health Organization; 1965.

risks.⁴¹ It also has not been demonstrated that elective removal of a failed silicone gel breast implant in an asymptomatic woman alters patient outcomes,^{26,42,43} and screening is not without potential harm (including patient anxiety, patient labeling, cost, and unnecessary surgery).⁴⁴ As opposed to screening tests, diagnostic exams are applied to targeted, at-risk populations such as patients with symptoms or a positive screening exam, and therefore higher costs, greater invasiveness, and increased inconvenience are more readily accepted. It would be unusual for a given test to function well *both* as a screening test *and* as a diagnostic test; in fact, "a screening test is *not intended* to be diagnostic."³⁵ Confusion can arise when these screening and diagnostic functions are comingled, as appears to be the case with MRI and breast implants.

Although augmentation with silicone gel implants was first reported in 1964,⁴⁵ imaging of breast implants for the detection of implant failure became the subject of significant focus after the FDA's controversial moratorium⁴⁶ on silicone gel implants in 1992. Accurate rupture rates can

Table 4. Silicone Gel Implant Generations Based on Manufacturing Time Period and Properties

Generation	Production	Characteristics
First generation	1960s	Thick shell (0.25 mm average) Thick, viscous gel Dacron patch
Second generation	1970s	Thin shell (0.13 mm average) Less viscous gel No patch
Third generation	1980s	Thick, silica-reinforced, barrier coat shells
Fourth generation	1992 to present	Stricter manufacturing standards Refined third-generation devices
Fifth generation	1993 to present	Cohesive silicone gel-filled Form stable

Adapted from Adams WP, Potter JK. Breast implants: Materials and manufacturing past, present, and future. In: Spear SL, Willey SC, Robb GL, editors. *Surgery of the Breast: Principles and Art*. Philadelphia: Lippincott Williams & Wilkins; 2006:426.

be difficult to determine⁴⁷ due to several factors, including the lack of a surgical "gold-standard" confirmation of negative imaging results and evaluation of symptomatic rather than screening populations. Rupture rates increase with time from implantation⁴⁸⁻⁵⁰ but also vary by model, materials, and manufacturing processes, by which "generations" of implants can be described²⁷ (Table 4). Older implant models (ie, first, second, and third generations) have higher reported rupture rates sometimes exceeding 60%,^{9,12,17,28} although the accuracy of the reported rupture rates is questionable due to study design and potential study inclusion bias.^{51,52} Currently-available, fourth-generation responsive gel devices have thicker, stronger shells and significantly greater gel cohesiveness than older implants. Reported rupture rates for these devices are 3.5% and 3.7% at six years postoperatively within mandated studies,^{53,54} and overall complications appear to be decreased with these devices as compared to earlier models.⁵⁵ The investigational fifth-generational, form-stable devices have rates reported at 0% to 1.7% (follow-up, two to 11 years).⁵⁷⁻⁶⁰

The *pattern or appearance* of failure seen with MRI or US imaging may vary significantly based on implant characteristics, compounding attempts to extrapolate studies of older implants to current models. Patients with thinner-shelled, less viscous, older devices may be more likely to present with extracapsular rupture or complete intracapsular collapse or may exhibit wrinkles or folds that may complicate image interpretation. Patients with newer, thick-walled, and more cohesive devices should be even

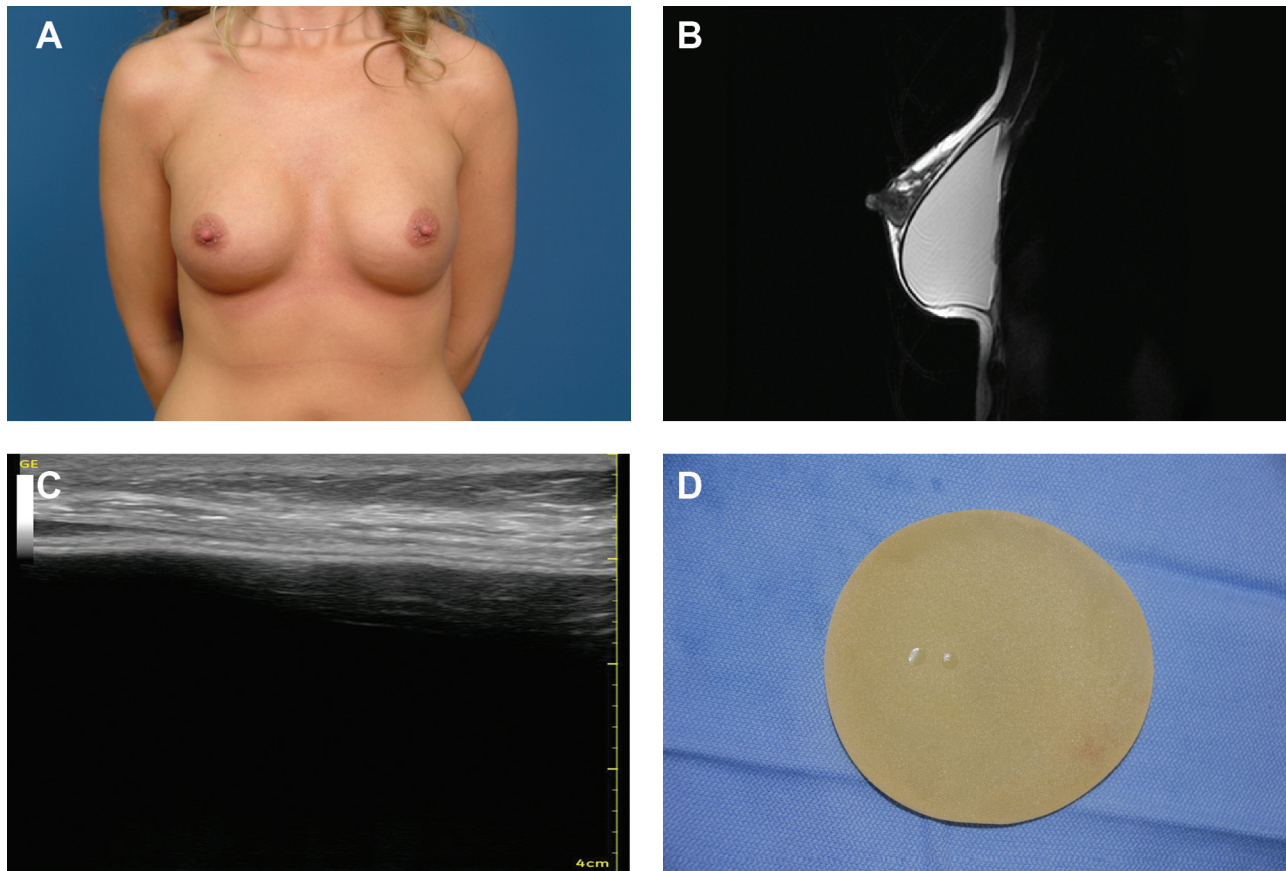


Figure 4. Study patient 7, 31-year-old woman six years following bilateral breast augmentation with Style 410 implants. The patient stated that the right breast implant had changed and felt softer than originally. The left breast was asymptomatic and unchanged. (A) Anterior view seen at time of presentation. On physician examination, the right implant appeared to have rotated and the right breast was softer. (B) Magnetic resonance imaging (MRI), lateral view of left breast demonstrating an intact Style 410 device. (C) High-resolution ultrasound (HRUS) of left breast showing intact tri-laminar shell. (D) Intact explanted left breast implant confirmed at the time of surgery. (E) HRUS of right breast demonstrating rupture. There is loss of the tri-laminar shell continuity seen in the upper right-hand portion of the scan. Shadowing within the underlying gel is indicative of fragmentation of the cohesive gel fill material. (F) MRI, lateral view, of right breast demonstrating implant rupture. The loss of shell integrity and intra-gel fractures are readily visualized. (G) The ruptured right implant is visualized through the inframammary approach upon initial opening of the implant capsule. A shell fragment is seen in the foreground. There is no visible inflammation within the capsule. (H) Ruptured explanted right implant. The rupture pattern of this highly-cohesive device demonstrates fractures within the shell with large resultant fragment sections.

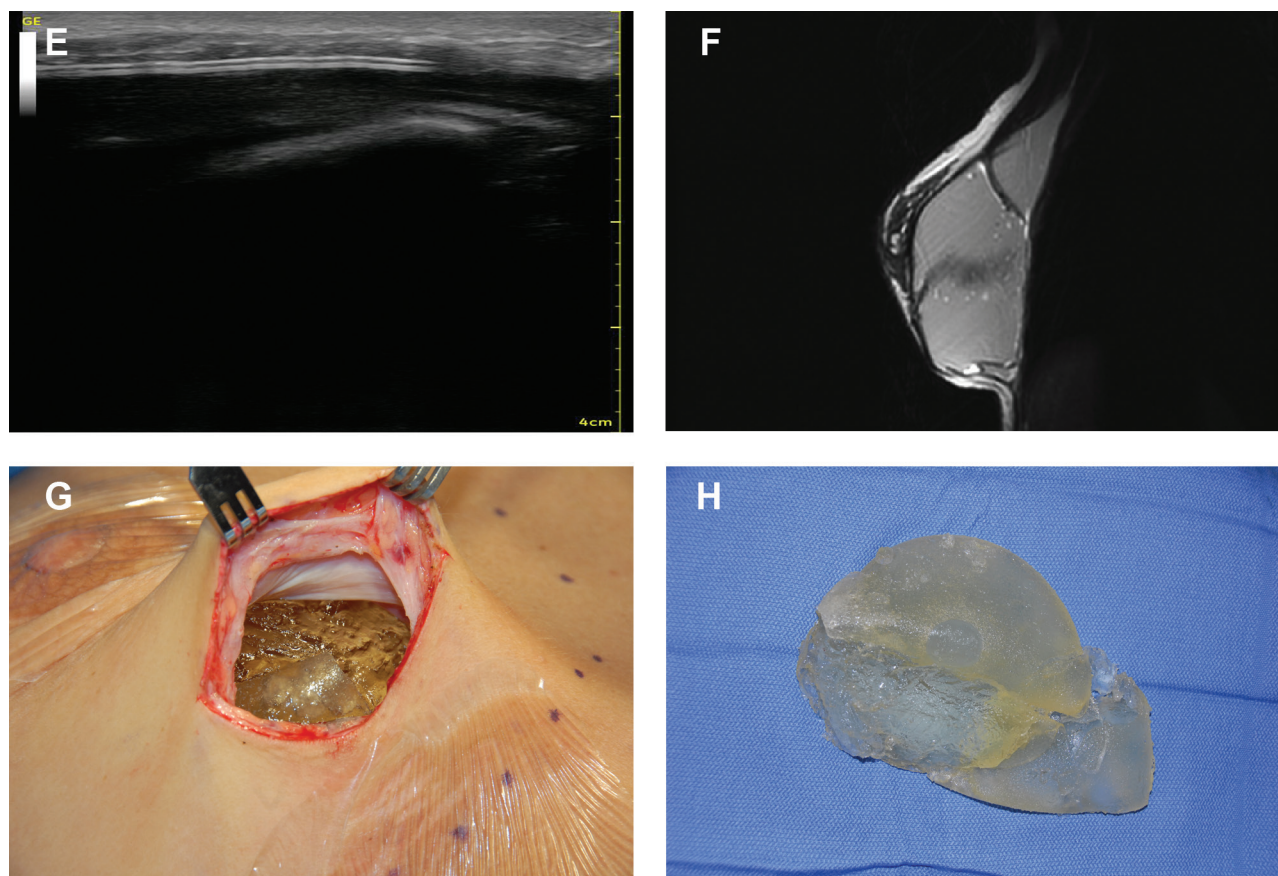


Figure 4.(continued) Study patient 7, 31-year-old woman six years following bilateral breast augmentation with Style 410 implants. The patient stated that the right breast implant had changed and felt softer than originally. The left breast was asymptomatic and unchanged. (A) Anterior view seen at time of presentation. On physician examination, the right implant appeared to have rotated and the right breast was softer. (B) Magnetic resonance imaging (MRI), lateral view of left breast demonstrating an intact Style 410 device. (C) High-resolution ultrasound (HRUS) of left breast showing intact tri-laminar shell. (D) Intact explanted left breast implant confirmed at the time of surgery. (E) HRUS of right breast demonstrating rupture. There is loss of the tri-laminar shell continuity seen in the upper right-hand portion of the scan. Shadowing within the underlying gel is indicative of fragmentation of the cohesive gel fill material. (F) MRI, lateral view, of right breast demonstrating implant rupture. The loss of shell integrity and intra-gel fractures are readily visualized. (G) The ruptured right implant is visualized through the inframammary approach upon initial opening of the implant capsule. A shell fragment is seen in the foreground. There is no visible inflammation within the capsule. (H) Ruptured explanted right implant. The rupture pattern of this highly-cohesive device demonstrates fractures within the shell with large resultant fragment sections.

more likely to present with intracapsular rupture only and should be less likely to have complete collapse or dramatic folds. These patterns may affect the sensitivity and specificity of MRI or US across implant models and generations.

Numerous studies have previously evaluated MRI and ultrasound in the detection of breast implant failure.* These studies exhibit common design trends that may affect not only the imaging accuracies reported but also

the relevance to current breast implant patient populations. First, prior studies have focused on symptomatic women rather than representative screening populations, thereby inserting a spectrum bias that can artificially elevate reported sensitivity and specificity.⁷⁴ Second, symptoms, imaging results, and surgical findings are often reported primarily on a *per patient basis* rather than on a *per implanted breast basis*, making it difficult to correlate presenting symptoms with implant status, particularly in women with unilateral symptoms. Third, the vast majority of the implants evaluated were older devices (first, second,

*References 6, 8, 11, 16, 19, 21, 22, 25, 29, 30, 60-73.

and third generations) that have not been manufactured or marketed for decades, and the implant model, surface design, generation, and brand are generally not reported. Fourth, most studies do not provide specific information that would be deemed essential by plastic surgeons to interpret results or guide patient management; these missing details include indication for implantation (immediate or delayed reconstruction vs aesthetic enhancement), primary versus secondary procedures, implantation technique, insertion route, anatomical position, concurrent procedures (ie, mastopexy), or history of irradiation, CC, or perioperative complications. Fifth, as only patients with a positive MRI typically underwent explantation, false-negative studies were not identified, and thus a partial verification bias may have elevated sensitivity and decreased specificity.²³ In some publications, MRI interpretations by multiple radiologists may have altered accuracy compared to what would typically occur in clinical practices. For example, in a report specifically evaluating asymptomatic women, separate radiologist interpretations demonstrated sensitivities of 86% and 71% and specificities of 48% and 95% when considered individually, but these were 90% and 43%, respectively, when combined.²¹ Hölmich et al^{17,25} used four independent radiologists to evaluate the images, and disagreement—which occurred in 21% of cases—was resolved by consensus. Other concerns also exist: the majority of study cohorts were composed of nonconsecutive patients, which can insert a selection bias, and the time interval from imaging to surgery was typically not disclosed, although a median interval up to 297 days has been reported.²⁵ Even the definitions for “rupture” were not consistent across the studies, with some considering presence of a silicone gel “bleed” to constitute rupture, whereas others did not consider that a rupture,⁸ called it “indeterminate,” or labeled it “minimal.”⁶¹ Only rarely did authors comment on how imaging results might affect decision-making.^{8,20}

At least three different meta-analyses involving these MRI, ultrasound, and/or mammogram studies for the diagnosis of implant integrity have been undertaken. In 1997, Goldberg et al⁵¹ analyzed 65 articles from 1994 to 1997, of which nine were included in the meta-analysis. Pooled sensitivity and specificity were calculated for mammography (28.4% and 92.9%), ultrasound (50.0% and 76.8%), and MRI (78.1% and 80.0%). Goldberg et al did not recommend ultrasound or MRI as a screening tool, concluding that it would take 8.1 implants tested by ultrasound to find a single confirmed rupture and 6.1 implants examined by MRI to find a single confirmed rupture. In 2001, Cher et al⁷ performed a meta-analysis evaluating the accuracy of MRI in screening for device rupture. They noted that the quality of the study reports was generally poor and that there was significant heterogeneity across the studies. The authors calculated a summary sensitivity of 78% and a summary specificity of 91%. On the basis of resultant summary receiver operating characteristic (ROC) curves, the authors concluded that although the positive predictive value (PPV) of MRI for the detection of rupture was fairly high among symptomatic women, the PPV of

MRI among lower prevalence populations was insufficient to warrant utilization as a screening tool. Cher et al concluded that MRI should remain a confirmatory diagnostic test and should not be used as a screening test.

The most recent and systematic examination of the existing data was completed by Song et al²³ in 2011 and specifically compared MRI and ultrasound in the diagnosis of silicone gel implant failure. Using meticulous search criteria, specific inclusion criteria, independent reviewers, and validated analysis tools, the authors identified 1175 topic-relevant articles, of which 21 met inclusion criteria (such as surgical confirmation). Eight of the 21 studies considered MRI only, five evaluated ultrasound only, and eight examined both, with a total of 1098 implants in 615 women in the MRI group and 1007 implants in 577 women in the ultrasound group. Studies were noted to be heterogeneous and data deficits were significant, exemplified by the median or range of implant ages not being reported in eight articles. Multiple sources of potential bias related to study design were identified. For example, only three articles reported consecutive patients, potentially interjecting a selection bias, and 14 studies evaluated only symptomatic patients, creating a potential spectrum bias. In addition, funnel plots were developed that demonstrated a publication bias favorable toward MRI studies ($P = .01$), but no similar bias existed for ultrasound ($P = .87$). Although the pooled sensitivity and specificity as calculated by logistic regression modeling were 87.0% and 89.9% for MRI and 60.8% and 76.3% for ultrasound, the authors found that accuracy was overestimated secondary to study design flaws and biases, particularly for MRI. Cumulatively, the MRI studies reported a 14-times-higher diagnostic accuracy in symptomatic women compared to asymptomatic women and a two-times-higher diagnostic accuracy when compared to a screening population, with the authors concluding that “although the diagnostic performance of magnetic resonance imaging in detecting silicone gel breast implant ruptures in a symptomatic sample may be quite good, we find that its accuracy is magnitudes lower in detecting rupture in asymptomatic and screening samples.” This article is an excellent example of the application of evidence-based medicine (EBM) principles and clear explanations of how biases can be identified and quantified.

Current Study

Although preliminary, the current study differs from prior studies comparing ultrasound and MRI for implant integrity in several significant ways, related not only to the patients and devices but also to technology and technique. First, primarily newer implants were evaluated, and implant model and surgical history were known for the majority of study participants. The vast majority (25/29; 86.2%) of the devices studied were either highly-cohesive, textured-surface fifth-generation devices (14; 48.3%) or current smooth-surface, fourth-generation devices (nine; 39.1%). In this manner, the implant mix correlates with

both current and future clinical practices more closely than previous studies. Second, the study population was a mixture of symptomatic and asymptomatic patients and therefore perhaps more closely resembles a screening population. Third, symptoms, implant models, imaging results, and surgical findings were stratified on a *per breast* basis, potentially elucidating certain relationships that may have been missed in prior pooled samples. For instance, in this series, all of the Style 410 devices in patients who presented with a complaint that the particular implanted side had become softer or shifted were confirmed to be ruptured. Stratification by laterality represents an important opportunity to study asymptomatic breasts or negative test results against the surgical “gold standard” without subjecting women to unnecessary surgery, since women who have one symptomatic breast often undergo surgical exploration of both breasts as a routine part of surgical care. Although the asymptomatic opposite breast may not represent a perfect screening model since it is subject to the same previous surgical techniques, external factors, and biological milieu as the side that is symptomatic, the opportunity to address a partial verification bias that could skew sensitivity, specificity, and predictive values of imaging in asymptomatic populations is significant.

In addition to these patient and device factors, another significant difference of this study is that the HRUS evaluations were office-based and surgeon-performed, and they utilized small, portable, high-resolution devices as opposed to traditional radiologist-interpreted, hospital-based tests. Other studies have shown that surgeon-performed ultrasound often correlates well with tests performed by radiologists, and surgeon-performed ultrasound has shown significant utility in diverse situations, including localization of parathyroid tumors,⁷⁵⁻⁷⁹ flexor tendon injuries,⁸⁰ tumors for fine-needle biopsy,⁸¹ and the diagnosis of appendicitis⁸² and trauma.⁸³⁻⁸⁶ In addition, the real-time characteristic of surgeon-performed ultrasound makes these studies an extension of the physician examination, not unlike a stethoscope. As such, the surgeon can simultaneously compare the images to symptoms and patient history, knowledge of the surgical presentations and procedures, and clinical experience. Much larger studies will be required, however, to fully compare the accuracy of surgeon-performed ultrasound to radiologist-performed ultrasound and MRI, in this setting and with these implant designs. There are also potential medicolegal reasons that plastic surgeons should consider having the ultrasound findings confirmed by a radiologist, at least until more data are collected to confirm surgeon accuracy.

Despite these benefits, this study does have significant limitations in assessing the role or accuracy of breast implant imaging by MRI or ultrasound. First, the clinical presentation and enrollment pattern meant that the surgeon could not be fully blinded to the results of MRI or patient symptoms in all cases, which could have inserted an interpretation bias. In addition, if the patient was aware of the MRI findings prior to her visit with the surgeon, this may have influenced the way in which she interpreted,

weighed, or described her symptoms, producing a potential reporting bias. The issue with blinding the physician to patient symptoms reflects the very nature of real-time imaging. In clinical practice, imaging is an extension of the physical examination, and the surgeon seeks this clinical information rather than wanting to be blinded from it; this will undoubtedly happen even more in the future. Nonetheless, knowledge of symptoms could also insert an interpretation bias of scan results. However, the fully-blinded, radiologist-performed HRUS findings correlated well with those of the surgeon-performed HRUS, and even when some clinical information was known, the surgeon and radiologist performing the HRUS examinations were unaware of the actual side of the reported MRI abnormality or clinical symptoms. Future studies will attempt to address these potential bias sources through more rigorous blinding processes and full recording of patient symptoms prior to any studies.

Another limiting factor is that this study considers only a small sample size and is not amenable to detailed statistical analysis. Larger studies of sufficient calculated sample size and power⁸⁷ will be necessary to achieve statistically-valid calculations of sensitivity, specificity, predictive values, and accuracy of the imaging studies or correlations between symptoms and implant status. The design of this study does provide a relatively high level of evidence (LOE; Level 2) in the comparison of MRI and HRUS to surgical confirmation, suggesting that larger studies of similar design may provide valid answers to the question of HRUS accuracy. Evaluating the LOE of a study helps us to interpret and weigh the data and assess the validity of the conclusions in answering the question at hand.^{88,89} Although conveying similar meaning, it is helpful to realize that the scales for therapeutic studies differ from those of diagnostic studies.⁹⁰

In the present study, we found that the learning curve for HRUS was short and that the utilization of ex vivo or in vitro models with spacers and the assistance of a skilled ultrasound trainer helped to develop initial familiarity with the technology and imaging experience. Surface characteristics of the implants could usually be determined by the ultrasound appearance: a sharp echo pattern was seen in smooth-walled devices, and a slightly less sharp, “fuzzier” image was seen with textured devices. In this limited study, the difference in the image appearance between smooth and textured implants did not adversely affect the ability of HRUS to differentiate between intact and failed shells. Under HRUS imaging, the shells of fourth- and fifth-generation devices are approximately 1.1 mm in thickness. Typically, ultrasonic imaging of these implants produces a hypoechogenic area as the sound waves reflect off the inner and outer shell surface, canceling and creating a trilaminar “Oreo effect” (Figure 1C,D). Other colorful descriptors for ultrasound appearance have been published in studies imaging older implants, including the “black hole,”⁹¹ the “cobweb,”³⁰ the “stepladder sign” (which corresponds to the MRI “linguini” sign),⁶² and the “snowstorm” or echodense shadow.⁹² These signs concentrate on the appearance of the filler material, but with the latest generation of implants and

HRUS technology, attention is redirected to examining the shell to determine device integrity.

In this study, the 100% concordance between all three imaging modalities (MRI, surgeon-performed HRUS, and radiologist-performed HRUS) and the surgical findings is higher than the historically-reported sensitivity and specificity of MRI and ultrasound would predict. Several factors may have contributed to this finding, including small sample size or interpretation bias (as mentioned), but this high degree of accuracy may also be due in part to the characteristics of fourth- and fifth-generation implants, patterns of rupture, and the higher resolution scans. For instance, although HRUS allowed generally good visualization of all implant types, the highly-cohesive, form-stable fifth-generation gel implants were much easier to scan with HRUS than earlier models. In these newer devices, both the shell and gel appear more uniform; this, combined with a higher fill-volume-to-shell ratio, leads to a “cleaner” scan. This is in contrast to the appearance of second- and third-generation devices with thinner shells and lower fill-volume ratios that produce the marked shell redundancy and in-folding, leading to MRI and ultrasound misdiagnosis. As predicted, the pattern of rupture, especially for form-stable Style 410 devices, was different from that of earlier device models. Limited radial tears were more common than total device failure and, when total failure did occur, the remnants were large chunks and segments. As these older implants become less common and are replaced with newer generation devices, the accuracy of both HRUS and MRI may increase proportionally.

Compared to MRI and CT, which are static snapshots in time, a significant advantage of ultrasound is derived from it being dynamic, active, and real-time. While the exam is being performed, areas suspicious for rupture may be compressed, moved, or manipulated to either delineate the potential defect (by actively extruding the gel through the defect) or to flatten a fold in the shell that might be mimicking a defect. In addition, fine detail may be easier to see when scanning through thinner tissues, so displacing the implant away from the thicker upper and central segments and toward the thinner tissue inferiorly, medially, or laterally may help resolve areas of question. Radiologists often state that a disadvantage of ultrasound is the difficulty of visualizing the deep implant surface, which is true. However, in this study, the periphery of the deep shell surface could often be visualized through this same type of manipulation. Also, from a practical standpoint, rarely would a significant, minute shell failure on the deep surface of the device be the only sign of implant shell failure. Developing a systematic approach to the scan—for example, utilizing a grid or quadrant pattern—will help to ensure that all aspects of the implant are evaluated.

Many uses of ultrasound in plastic surgery have been described, including vascular identification in breast reduction,^{93,94} perforator identification in breast reconstruction,⁹⁵ evaluation and monitoring after reconstruction,^{96,97} intrauterine evaluation of cleft lip and palate,⁹⁸ flap monitoring,⁹⁹ and wound care.¹⁰⁰ Ultrasound has also

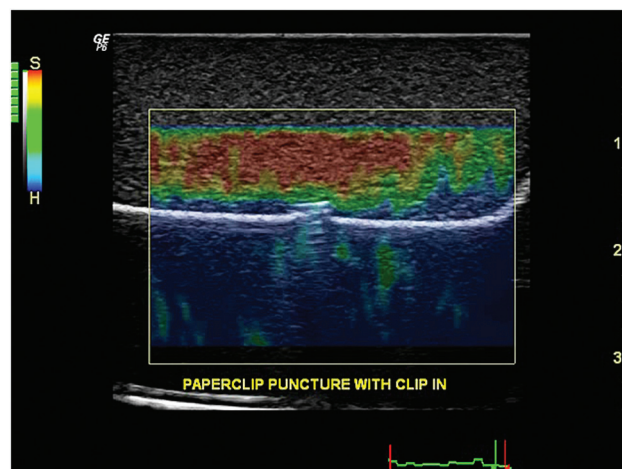


Figure 5. In the future, elastography and the application of different colors to various structures may allow for more accurate identification of shell failure in the future. For instance, by applying a white color to the implant capsule or acellular dermal matrix, a blue color to the implant shell, and a pink color to the inner gel, it may be easier to see shell failure, as in this image, where a paper clip was placed in and through the implant shell. A video of this scan is available at www.aestheticsurgeryjournal.com.

been applied both internally and externally for lipolysis and fat transfer follow-up.¹⁰¹⁻¹⁰³ The portable nature of newer HRUS base units makes office ultrasound evaluation a particularly attractive option for new applications. Patients may plan imaging as an extension of an examination with their surgeon, additional appointments for tests and follow-ups can be avoided, and cost can be kept comparatively low. In addition, there is benefit in having an ultrasound unit available for patient care even beyond looking for shell failure. For example, the lead author (BB) has utilized these units for multiple purposes, including visualization of registration tabs (in the Style 410) and lines (CPG) for shaped implant rotation, identification and management of postoperative seroma, adjustable gastric band or tissue expander port localization, and evaluation of swollen breasts to differentiate between a hematoma or seroma and parenchymal swelling. Portable HRUS is potentially applicable for other areas of plastic surgery, such as hand and facial fracture identification and treatment, vein surgery and ablation, and general breast evaluation (ie, breast cysts). This technology may be utilized to evaluate breast implant capsules, determine burn wound depth, and assess acellular dermal matrices in situ. Elastography,¹⁰⁴ wherein tissues and materials can be identified and enhanced (colored) on the basis of different elastic moduli such as implant shells versus internal gels, has shown particular promise and could further enhance the accuracy of ultrasound in the evaluation of breast implants (Figure 5) or provide a new way of studying CC. Although the base unit hardware models evaluated in this study functioned well, it is likely that new ultrasound

systems from a variety of manufacturers will be designed and built specifically for plastic surgery applications, and these will probably not require all of the radiological “bells and whistles” of the current designs. Smaller, less expensive, and less complex designs would facilitate the incorporation of ultrasound into the office setting and daily practice of plastic surgery.

Ultrasound is certainly not perfect in the evaluation of breast implants. The precise sensitivity, specificity, and predictive value of ultrasound in the various implant models have yet to be adequately quantified, and eventually false-negative and false-positive results will be produced. Compared to MRI, the technology is more examiner-dependent, even though the learning curve for ultrasound appears to be short. The entirety of the implant, particularly the deep surface, cannot be completely visualized. In addition, patients with CC can be more difficult to image, and older, thin-shell implants can exhibit significant artifacts, although MRI results can also be less reliable in these patients. As these older devices—typically now more than two decades from implantation—are replaced and have become increasingly rare, it is likely that the accuracy of breast implant imaging will improve. In addition, patients with these older devices often have other, additional clinical indications for secondary surgical procedures and removal or replacement of the devices, and in these cases, screening or diagnostic imaging generally would not alter surgical decision-making or patient care.

CONCLUSIONS

The FDA, manufacturers, plastic surgeons, and patients have long expressed an intuitive desire for a safe, fast, inexpensive, convenient, comfortable, and accurate screening and diagnostic method for determining silicone gel breast implant failure even though surveillance for implant integrity is of unproven benefit and potentially exposes patients to risks, including unnecessary surgery. For more than 20 years, MRI has been considered the “gold-standard” implant imaging modality and has thus been recommended by the FDA for device screening, yet MRI has not competently fulfilled this role. Despite the best intentions of the authors, the numerous methodological flaws and publication biases of existing studies—along with a focus on older devices and symptomatic patients—may have artificially elevated the published accuracy of screening MRI for implant failure among early-generation implant designs. Existing studies of ultrasound demonstrate similar flaws, yet the attributes of high-resolution ultrasound (such as cost, convenience, comfort, and ease) are more suitably aligned with the requirements of a screening exam than MRI. Given the significantly different characteristics of current implant designs compared to earlier generations, both MRI and HRUS should be reassessed, their accuracies should be recalculated for specific current implant models and in defined symptomatic versus screening populations, and their screening and diagnostic roles should be more clearly

defined. There may, in fact, be a “perfect storm” occurring where the newest generation of breast implants with thicker shells and more uniform gel along with innovations in the HRUS transducers and software imaging quality are emerging together in time that will allow for a greater degree of accuracy and sensitivity/specificity in the detection of shell failure. Future studies of both modalities should anticipate and address these potential bias sources; carefully stratify history, symptoms, devices, and results by laterality; and recognize the value of an opposite, asymptomatic implanted breast as an ethical model for evaluating breast implant integrity that includes surgical confirmation. Beyond advances in silicone gel breast implant imaging alone, a portable, surgeon-performed, high-resolution ultrasound has many broad potential applications within the practice of plastic surgery, and may in fact become a normal extension of our physical examination for breast implant patients in the future.

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