Silent Rupture of Silicone Gel Breast Implants: High-Resolution Ultrasound Scans and Surveys of 584 Women

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Background: Patient compliance has been low for U.S. Food and Drug Administration–recommended magnetic resonance imaging scans to screen silicone gel breast implants for silent rupture. High-resolution ultrasound scans are a convenient, in-office alternative that may improve screening compliance; however, women’s attitudes and feelings about silent rupture and their desire for rupture screening are unknown.

Methods: Plastic surgeons and staff in nine private practices received 1-day training in high-resolution ultrasound scanning, then screened women with silicone gel implants implanted since 2000. Suspect scans were reviewed by a high-resolution ultrasound–experienced plastic surgeon to determine if they showed ruptures. Surgical and scan findings were correlated. To learn attitudes and feelings about silent rupture, women took surveys before and after the scan.

Results: Of 584 women screened, 82 (14.0 percent) had scans showing ruptures; of 1153 implants, 92 (8.0 percent) showed ruptures. Forty women with scans showing ruptures underwent surgery, of which 30 (75 percent) had their ruptures confirmed. Surveys found 99.5 percent of women want to know if they have a rupture and 95.2 percent want the ruptured implant removed. If the scan showed no rupture, women felt relieved and 95.5 percent would get future high-resolution ultrasound screening for silent rupture. If a rupture was found, women expressed various concerns and 87.8 percent would remove the ruptured implant within 12 months.

Conclusions: Surveys show that women with silicone gel implants have concerns and feel anxious about possible silent rupture. Based on 14 percent of women showing a ruptured implant on high-resolution ultrasound scans and 75 percent of ruptures on high-resolution ultrasound scans surgically confirmed, 10.6 percent of women in this study have a silent rupture. (Plast. Reconstr. Surg. 149: 7, 2022.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Diagnostic, IV.

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A Video Discussion by Amy Colwell, M.D., accompanies this article. Go to PRSJournal.com and click on “Video Discussions” in the “Digital Media” tab to watch.
that an implant has ruptured and why it is called a “silent rupture.” The ruptured implant may remain in place for years until discovered at a subsequent implant procedure, such as a size change, or diagnosed during evaluation of signs or symptoms, such as capsular contracture, pain, a lump, change in shape, or abnormal mammogram. At this time, the U.S. Food and Drug Administration recommends magnetic resonance imaging or ultrasound scans of silicone gel implants to screen for silent rupture at 5 to 6 years after implantation and then every 2 to 3 years thereafter. The very low rate of patient compliance with magnetic resonance imaging screening, less than 5 percent, is attributed to the high cost and inconvenience of obtaining magnetic resonance imaging scans.

A low-cost, convenient alternative to magnetic resonance imaging scans is high-resolution ultrasound scans that can be performed in an office setting. High-resolution ultrasound scans have also proven to be as accurate as magnetic resonance imaging scans for detection of silent rupture of silicone gel implants. In 2012, Bengtson and Eaves showed that magnetic resonance imaging scans, surgeon-performed high-resolution ultrasound scans, and radiologist-performed high-resolution ultrasound scans were all accurate in predicting implant shell integrity in 29 of 29 imaged breasts (100 percent) as confirmed at the time of surgery. In 2020, the author (M.J.S.) reported on more than 1000 women with high-resolution ultrasound scans of their breast implants and showed a positive predictive value of 87 percent for women who had a confirmed rupture at surgery. There were no false-negative scans in his report.

In addition, in a 2018 study, the sensitivity and specificity of ultrasound scans were 90 and 80 percent, respectively, and the sensitivity and specificity of magnetic resonance imaging scans were 87 and 85 percent, respectively. The authors concluded that ultrasound evaluation may be the first-level examination in case of suspicious symptomatic breast implant rupture. In 2014, Rietjens et al. showed that the negative predictive value of ultrasound when evaluating breast implants for r uptures was 85 percent, meaning that in the case of negative ultrasound findings, magnetic resonance imaging scans may be avoided.

Unlike magnetic resonance imaging scans of an implant that is stationary, ultrasound scans are of an implant that is being manipulated by the operator to reveal shell details in real time that can confirm a rupture and minimize possible confusion with a shell fold. There are clear visual indicators on ultrasound images of a ruptured silicone gel implant. As with magnetic resonance imaging scans, high-resolution ultrasound scans can have false-positive and false-negative findings, so a plastic surgery consultation to discuss future monitoring or surgical options is essential when a ruptured implant is detected.

The prevalence of silent rupture among women who currently have silicone gel implants is unknown. The Core clinical trial data from the three U.S. manufacturers of silicone gel implants indicates that approximately 10 percent or more of women had an implant rupture during the 10 years after implantation (Table 1), but rupture data are not available beyond 10 years. The availability of high-resolution ultrasound scanning provides an opportunity to study a large number of women with silicone gel implants to determine the prevalence of silent rupture. In conjunction with scans, these same women can be surveyed to document their concerns and feelings about silent rupture, desire for rupture screenings, and choices for future implant surgery, which is information not previously reported.

### PATIENTS AND METHODS

#### Study Design

This was a prospective, multicenter study in a large population of women to determine the prevalence of silent rupture of current types of silicone gel breast implants by screening with a high-resolution ultrasound scanner. Commercially available Allergan and Mentor silicone gel implants were implanted for their Core clinical trials in 1998 and 2000 respectively, resulting in U.S. Food and Drug Administration approval in 2006. Therefore, this study of current types of silicone gel implants included those from Allergan and Mentor implanted after January 1, 2000, and those from Sientra implanted after U.S. Food and Drug Administration approval in 2012; all were implanted before December 31, 2015. The first high-resolution ultrasound scans were performed in April of 2019 and the last in March of 2020.
so the implants studied had been in place a minimum of 3 years and a maximum of 20 years.

Ultrasound scans were performed using a U.S. Food and Drug Administration–cleared, hand-held, high-resolution ultrasound scanner with a 7- to 13-MHz linear probe (Clarius Mobile Health Corp., Burnaby, British Columbia, Canada) that transmitted images to a tablet screen for visualization. The scans were standardized across all study sites to ensure methodical and consistent collection of data and electronic storage of implant images. All women received the same high-resolution ultrasound scans with similar high-resolution ultrasound technology.

Screening scans were performed at nine private practice study sites by the plastic surgeon principal investigator, plastic surgeon subinvestigators in the practice, and registered nurses or certified medical assistants under their supervision. All were taught the basics of high-resolution ultrasound scans to detect a ruptured implant in a 1-day office training session conducted by an experienced ultrasound training consultant (S.A.C.). All ultrasound scans were initially analyzed by the investigator for possible rupture and stored electronically for reference. Implant scans that were interpreted by the investigator as not ruptured were secondarily analyzed by the ultrasound training consultant. Scans initially interpreted as a suspected rupture by the investigator or secondarily interpreted as a suspected rupture by the ultrasound training consultant were sent for final interpretation to the plastic surgeon reviewer, who was experienced with high-resolution ultrasound detection of silicone gel implant rupture (M.J.S.). Based on this final review of the still and video images taken by the investigators, these suspected ruptures were determined to be either ruptured or not ruptured. Investigators were notified of the final interpretation of the scan by the plastic surgeon reviewer.

If a woman had a scan interpreted by the plastic surgeon reviewer as ruptured, her office medical records were reviewed to learn whether she had chosen to undergo surgery and to correlate the surgical findings with the high-resolution ultrasound scan final interpretation. The investigators began obtaining scans in April of 2019, then slowly ramped up so that most scans were obtained in late 2019 through March of 2020; the medical records were reviewed and surgical results were recorded in early September of 2020. In the time interval following their scans, women may have delayed their decision to have explantation surgery waiting for final interpretation of their scans by the plastic surgeon reviewer, and then may have delayed further because of health and financial concerns related to the coronavirus disease of 2019 pandemic.

To document women’s concerns and feelings about silent rupture of silicone gel implants, in-person surveys were administered by the office staff: one before the high-resolution ultrasound scan and another immediately after the scan that was specific to the investigator’s initial interpretation of the scan, either not ruptured or a suspected rupture.

All data were collected on standardized case report forms in paper and/or electronic format. The study was approved by a central investigational review board (Salus IRB, Austin, Texas), because all investigators conducted study procedures in their private practice offices.

**Subjects**

Women aged 18 years or older were eligible to enroll. Informed consent was obtained in writing. Inclusion criteria were that they had one or two silicone gel breast implants implanted between January 1, 2000, and December 31, 2015, and had access to their breast surgery record or device card to verify the manufacturer, type of surface, shape, and implant date. Women with a known ruptured implant were excluded. The study population consisted of women within the practice at the study sites who were invited to participate during an already-scheduled office visit and/or through practice communications, such as e-mails and social media.

Between April of 2019 and March of 2020, a total of 584 women were enrolled at nine study sites, with a range of 11 to 199 at each site (mean, 65). Bilateral implants were present in 569 women and only one implant was present in 15 women; thus, a total of 1153 implants were scanned. Both implants were from the same manufacturer in all but two women. These 1153 implants had the characteristics shown in Table 2.

**RESULTS**

Of the 584 women who received screening scans, 115 women had scans interpreted by the investigator as a suspected rupture, comprising 141 implants. The other 469 women had scans interpreted by the investigator as not ruptured, but on secondary analysis by the ultrasound training consultant, 16 women had scans interpreted as a suspected rupture, comprising 19 implants. These suspected rupture scans were sent to the
plastic surgeon reviewer who determined that 82 of the 584 women (14 percent) had a high-resolution ultrasound scan showing a ruptured implant, comprising 92 of the 1153 implants (8 percent). Table 2 shows the characteristics of these 92 ruptured implants.

Table 3 stratifies all 1153 implants scanned and the 92 ruptured implants by the year implanted. For each year, the number of implants ruptured is shown as a percentage of the number of implants scanned.

Table 2. Implant Characteristics

| Indication    | Screened (%) | HRUS-Ruptured (%) |
|---------------|--------------|-------------------|
| No.           | 1153         | 92                |
| Cosmetic      |              |                   |
| Primary       | 833 (72.2)   | 66 (71.7)         |
| Revision      | 152 (13.2)   | 16 (17.4)         |
| Reconstruction|              |                   |
| Primary       | 130 (11.3)   | 7 (7.6)           |
| Revision      | 38 (3.3)     | 3 (3.3)           |
| Surface       |              |                   |
| Smooth        | 954 (82.7)   | 78 (84.8)         |
| Textured      | 199 (17.3)   | 14 (15.2)         |
| Shape         |              |                   |
| Round         | 1049 (91.0)  | 82 (89.1)         |
| Shaped        | 104 (9.0)    | 10 (10.9)         |
| Placement     |              |                   |
| Submuscular   | 1059 (91.8%) | 86 (93.5)         |
| Subglandular  | 77 (6.7)     | 5 (5.4)           |
| Unknown       | 17 (1.5)     | 1 (1.1)           |
| Manufacturer  |              |                   |
| Allergan      | 450 (39.0)   | 36 (39.1)         |
| Mentor        | 608 (52.7)   | 53 (57.6)         |
| Sientra       | 95 (8.2)     | 3 (3.3)           |

HRUS, high-resolution ultrasound.

Table 3. Scanned and Ruptured Implants versus Year Implanted

| Year Implanted | Implants Scanned | HRUS-Ruptured Implants | Ruptured Implants of Implants Scanned (%) |
|----------------|------------------|------------------------|------------------------------------------|
| 2000           | 4                | 0                      | 0                                        |
| 2001           | 4                | 0                      | 0                                        |
| 2002           | 8                | 2                      | 25.0                                     |
| 2003           | 8                | 3                      | 37.5                                     |
| 2004           | 12               | 6                      | 50.0                                     |
| 2005           | 25               | 2                      | 8.0                                      |
| 2006           | 16               | 0                      | 0                                        |
| 2007           | 61               | 9                      | 14.8                                     |
| 2008           | 96               | 6                      | 6.3                                      |
| 2009           | 118              | 16                     | 13.6                                     |
| 2010           | 136              | 12                     | 8.8                                      |
| 2011           | 125              | 11                     | 8.8                                      |
| 2012           | 152              | 8                      | 5.3                                      |
| 2013           | 119              | 4                      | 3.4                                      |
| 2014           | 156              | 7                      | 4.5                                      |
| 2015           | 113              | 6                      | 5.3                                      |
| Total          | 1153             | 92                     |                                          |

HRUS, high-resolution ultrasound.

DISCUSSION

Compared to the inconvenience and high cost of magnetic resonance imaging equipment and scans, a plastic surgery practice can offer women the convenience of in-office high-resolution ultrasound scans for a modest investment (up to $10,000 for equipment and training) and a low cost per scan (up to $250). This would allow plastic surgeons to follow and screen their silicone gel implant patients for silent rupture according to U.S. Food and Drug Administration recommendations, or more frequently if desired by the patient.

Plastic surgeons, nurses, and medical assistants were able to quickly learn how to obtain high-resolution ultrasound scans of breast implants and analyze them for possible silent rupture, which is usually clearly shown by manipulating the implant while obtaining the scan. As expected, these investigators with limited experience had a tendency to overread scans (i.e., of the 141 implant scans they interpreted as a suspected rupture, only 73 were interpreted as a rupture by the plastic surgeon reviewer experienced with high-resolution ultrasound scans). If a plastic surgeon with limited high-resolution ultrasound experience has a scan that is suspicious but does not clearly show a rupture, before recommending surgery, the patient can be referred for a repeated high-resolution ultrasound scan by a high-resolution ultrasound–experienced surgeon or radiologist, or referred for a magnetic resonance imaging scan. In addition, during preoperative consultations, a surgeon can provide their rate of false-positive...
surgical findings in implants with high-resolution ultrasound scans that they interpreted as ruptured. The women could then proceed knowing the likelihood that an implant interpreted as ruptured on a high-resolution ultrasound scan will be confirmed ruptured at surgery. In contrast, of 1012 implant scans interpreted as not ruptured by these investigators with limited experience, only 19 scans were interpreted as a suspected rupture by the ultrasound training consultant, and then confirmed as ruptured by the plastic surgeon reviewer (i.e., 98.1 percent true-negative scans; 1.9 percent false-negative scans).

The number of false-positives decreases as one gains experience with high-resolution ultrasound scanning. For example, the plastic surgeon reviewer for this study has performed thousands of scans over 9 years and recently reported 47 surgically confirmed ruptures of 54 high-resolution ultrasound scans that were interpreted as a rupture (87 percent true-positive; 13 percent false-positive). In the authors’ experience, false-positive high-resolution ultrasound scans are almost always associated with implants in very tight, unyielding, often calcified capsules. When imaged with high-resolution ultrasound, these deeply folded implants appear to have the characteristics of ruptured implants. In these women, false-positive scan results are mitigated because they would typically undergo surgery anyway to remedy the severe capsular contracture and replace their implants. Because high-resolution ultrasound scans are dynamic scans, experience manipulating and observing the implant while performing the scan is key to accurate interpretation of a rupture. For this study, the plastic surgeon reviewer was limited to analyzing the still and video images captured by the investigators, which explains why only 75 percent of scans interpreted as a rupture on final review were found ruptured at surgery (75 percent true-positive).

Core clinical trial data show that the risk of rupture of silicone gel implants increases as the length of time implanted increases. The same trend was seen in this study, with 3.4 to 5.3 percent of the implants implanted at least 3 years but less
than 6 years (i.e., implanted 2012 through 2015) having a rupture on high-resolution ultrasound scans, compared to 25.0 to 50.0 percent of the implants implanted at least 14 years but less than 16 years (i.e., implanted 2002 through 2004) having a rupture on high-resolution ultrasound scans. The rupture percentages shown in Table 3 exemplify the overall trend of a higher prevalence of rupture as the time from implantation increases. These are not definitive rupture rates because this was not a controlled clinical trial and the sample sizes are small relative to the large number of implants implanted each year. Based on this study, at the initial U.S. Food and Drug Administration—recommended high-resolution ultrasound scan at 5 to 6 years, up to 5.3 percent of the women may already have a rupture; at the next U.S. Food and Drug Administration—recommended scan at 7 to 9 years, up to 13.6 percent of the women may have a rupture; and at the next scan at 9 to 12 years, up to 14.8 percent of the women may have a rupture.

Women’s concerns and feelings about silent rupture of their silicone gel implants have not been reported previously. Of the 584 women with silicone gel implants surveyed before their high-resolution ultrasound scan (Table 4), 70.9 percent had never been concerned that they may have a ruptured implant, 76.2 percent did not know the U.S. Food and Drug Administration recommends regular magnetic resonance imaging scans of silicone gel implants to screen for silent rupture, and 95.4 percent never had a magnetic resonance imaging scan of their implants. These responses are surprising in view of all the information provided for informed consent and the recent media attention directed at breast implant safety issues. Perhaps these women have been denying the possibility of having a ruptured implant, because when given the opportunity, 99.5 percent of women would like to know whether they have a ruptured implant and 95.2 percent would want a ruptured implant removed, even if asymptomatic. On learning that an implant has ruptured, most women reported that they would have a number of concerns: about silicone in contact with their tissues (76.9 percent), the expense or extent of revision surgery (72.9 percent), how long the implant had been ruptured (68.8 percent), and that the rupture was silent (63.4 percent). Only 1.7 percent of women responded that nothing would concern them.

Of the 469 women who were told by the investigator that their scan did not indicate a suspected rupture (Table 5), 69.2 percent felt relieved and 70.7 percent reported now having peace of mind about their implants, indicating they previously must have felt anxious and had concerns about possible rupture of their silicone gel implants. This conclusion is supported by 95.5 percent reporting that in the future they would regularly get ultrasound scans to screen for silent rupture, with intervals ranging from every 3 months to every 2 years, which is a more frequent than every 2 to 3 years currently recommended by the U.S. Food and Drug Administration after an initial scan at 5 to 6 years.

The 115 women told by the investigator that their scan indicated a suspected rupture of at least one implant (Table 6) expressed concerns similar to those in the prescan survey: about silicone in contact with their tissues (70.4 percent), the expense or extent of revision surgery (69.6 percent), how long the implant had been ruptured (66.1 percent), and that the rupture was silent (64.3 percent). Only 4.3 percent of women responded that they were not concerned. Immediately after the scan, most of these women indicated they would like to remove the ruptured implant (78.3 percent), whereas some were initially undecided (19.1 percent), knowing that the scan would be reviewed again by a plastic surgeon

| Table 5. Postscan Survey*† | No. (%) |
|---------------------------|---------|
| 1. As your ultrasound scan did not show an implant rupture, which of the statements below apply to you? (check all that apply) |
| I feel relieved. | 324 (69.2) |
| I now have peace of mind about my implants. | 331 (70.7) |
| I am concerned the scan may be false-negative (looks intact on scan, but is ruptured). | 20 (4.3) |
| I am concerned about possible silent rupture in the future. | 93 (19.9) |
| 2. Going forward, would you get in-office ultrasound scans regularly to screen for silent rupture? |
| Every 3 mo. | 7 (1.5) |
| Every 6 mo. | 36 (7.7) |
| Every 1 yr. | 209 (44.6) |
| Every 2 yr. | 195 (41.7) |
| Would not do scans regularly to screen for silent rupture. | 21 (4.5) |
| 3. If you were getting breast implants for the first time today, which of the three different implant types would you consider? (check all options that you would consider) |
| Silicone gel; natural feel, MRI or ultrasound scans to detect silent rupture. | 378 (80.8) |
| Structured; natural feel, look in mirror to detect rupture so no scans, saline-filled. | 124 (26.5) |
| Saline; less natural feel, look in mirror to detect rupture so no scans. | 41 (8.8) |
| I would not choose to get breast implants. | 44 (9.4) |

*MRI, magnetic resonance imaging
*Scan interpreted by investigator (not ruptured); n = 468.
†One survey was lost.
experienced in interpreting high-resolution ultrasound scans. Only 2.6 percent would not remove the ruptured implant. The vast majority of women who decide to remove their ruptured implant would do so within 12 months (87.8 percent), supporting the conclusion that women feel anxious and have concerns about a ruptured silicone gel implant. Nevertheless, for replacement, 75.6 percent of women would choose a silicone gel implant, although 10.4 percent would choose a saline-filled implant and 13.9 percent would not replace the implant.

A suspected rupture of a silicone gel implant affected women’s attitudes about the implant types they would consider if getting implants for the first time today. Those who had a suspected rupture were less likely to consider a silicone gel implant today (73.0 percent) and more likely to consider no implant (17.4 percent) than those women who did not have a suspected rupture (80.8 percent and 9.4 percent, respectively). Women who had a suspected rupture and those who did not have a suspected rupture were about equally likely to consider a saline-filled implant type if getting implants for the first time today (33.9 percent and 35.3 percent, respectively).

**CONCLUSIONS**

Surveys of 584 women who had high-resolution ultrasound scans of their silicone gel breast implants show that they have concerns and feel anxious about having a silent rupture. Almost all would like to know whether their implant is ruptured, and most would replace it if ruptured. As an alternative to magnetic resonance imaging scans, high-resolution ultrasound scans are a convenient in-office way for plastic surgeons to monitor their silicone gel implant patients and screen for silent rupture. A plastic surgeon reviewer experienced with high-resolution ultrasound scans determined that 82 of the 584 women (14 percent) in this study had a ruptured implant on their scans. Based on 82 women showing a ruptured implant on high-resolution ultrasound scans and 75 percent of ruptures on high-resolution ultrasound scans in this study surgically confirmed, 10.6 percent of the 584 women in this study had...
a ruptured implant they were unaware of (i.e., a silent rupture). This study found a relatively high prevalence of silent rupture among women with silicone gel implants implanted for 3 to 20 years, with the rate of prevalence directly correlated to the length of time implanted.

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