



Breast Implants: The View From the FDA

Binita Ashar, MD, MBA, FACS, David Krause, PhD, Laurie Scudder, DNP, NP

Jul 17, 2013

Editor's Note: *In June 2013, the US Food and Drug Administration (FDA) approved the most recent [silicone gel-filled breast implant](#), bringing the total number of approved products to 5. Although the FDA believes that approved breast implants have a reasonable assurance of safety and effectiveness when used as labeled, the agency emphasizes that breast implants are not lifetime devices and that women should be provided with essential information about the unique features of each device. The FDA issued a comprehensive [Update on the Safety of Silicone Gel-Filled Breast Implants](#) in 2011, which includes results of the studies the FDA required of the manufacturers at the time of approval as well as a review of other available scientific data. This detailed report is a must-read for breast surgeons.*

However, women's health and primary care providers are also key players in educating women about these options and monitoring those who have already received implants. Medscape spoke with Binita Ashar, MD, MBA, FACS, and David Krause, PhD, from the FDA's Office of Device Evaluation to review and summarize important information for clinicians and to highlight resources for both healthcare providers and consumers.

Medscape: Can you review the features and safety profile of silicone implants in comparison with older saline devices?

Dr. Ashar: There are no long-term studies directly comparing the safety profile for patients with silicone gel-filled breast implants vs saline-filled breast implants. Although there are no direct studies comparing these devices, there are some notable differences that should be considered by both patients and providers as they decide which type of implant should be used.

These include differences in the feel and shape of the implant and the recommendations in monitoring for breast implant rupture. There are also some unique characteristics associated with some of the newer silicone gel-filled breast implants. Some of these newer implants are filled with a more cohesive (firmer) silicone gel that can potentially fracture. To reduce the risk for gel fracture, it is recommended that the surgeon use longer incisions when inserting these implants. Some of the newer silicone gel-filled breast implants are not round but rather teardrop shaped. Insertion of a teardrop-shaped implant requires the surgeon to position the implant so that it does not appear rotated.

Local Adverse Events

Medscape: Can you summarize some of these key points from the safety update with regards to the specific local risks of devices -- not only device rupture, but also persistent breast pain and the potential need for future surgery?

Dr. Ashar: When the FDA approved silicone gel-filled breast implants in the United States in 2006, it recognized that there were limited data on rare events and long-term outcomes. To better understand

the long-term performance and identify any previously unrecognized adverse events, the FDA required the manufacturers to conduct a number of postapproval studies.

In June 2011, FDA issued a safety update regarding silicone-filled breast implants and the preliminary findings from the ongoing long-term clinical studies of implants approved at that time (Natrelle® [Allergan; Irvine, California] and MemoryGel® [Mentor; Santa Barbara, California]). The key points from the FDA's report are that patients and providers should be aware that breast implants are associated with significant local complications, and the longer the devices remain implanted, the more likely a patient is to experience a complication. Local complications and adverse outcomes include capsular contracture, reoperation, removal, and implant rupture. Many women also experience breast pain, wrinkling, asymmetry, scarring, and infection.

Since the June 2011 safety update, FDA approved 3 more silicone-gel filled breast implants and has looked closely at the local risks of these devices. The analysis performed for each of these devices is detailed in the Summary of Safety and Effectiveness Data (SSED) for each of these products. The SSED represents a detailed review of the data that FDA considered in making its device approval decision. Because the SSED is an FDA document that is not updated as new information is obtained, the SSED is different from the product labeling.

The data summarized in the SSED for the newer silicone gel-filled breast implants provides Kaplan-Meier cumulative risk tables for each adverse event as documented on an annual basis. In general, the rate of all of these adverse events increases over time. Some of them go up at a faster rate, and others increase and then stabilize and remain unchanged. The cumulative rates for various adverse events is different for the different implants.

If a woman or her clinician wanted to understand, for example, the risk for capsular contracture with a given implant, they could review detailed, device-specific information in the breast implant labeling. Labeling together with the SSED for more recently approved silicone gel-filled breast implants includes very detailed reviews and specific information about risk, based on time since implantation.

The studies performed for each implant were not designed to assess the effect of specific patient factors -- such as age, body mass index, or ethnicity -- on risk for complications. However, the risk for adverse events *is* stratified with respect to the reason that a woman received the implant: whether it was for augmentation, revision of an augmentation, reconstruction, or revision of a reconstruction. In general -- and this is just in general -- the safety profile was best for the cohort of patients that had augmentation surgery, and it was worst in the group that required revision of a reconstructed breast.

Dr. Krause: The SSED for these devices includes Kaplan-Meier curves for different adverse events in different populations of women based on annual data through 7 years. The local complications observed in the postapproval studies are consistent with complications noted at the time of approval for these devices, but data collection is ongoing and further analysis will be conducted at the conclusion of the 10-year postmarketing period.

Information in the SSED is very helpful for clinicians. It's the FDA's unbiased summary of all the information to date, and it includes information often not found in the medical literature. This summary, including device-specific patient and physician labeling, can be found on our [Website](#).

The Long-term View

Medscape: Can you discuss potential long-term, systemic safety concerns, including connective tissue disorders and malignancies?

Dr. Krause: The postapproval studies to date do not show evidence that silicone gel-filled breast implants cause connective tissue disease or reproductive problems. There does seem to be an association between breast implants and the development of lymphoma immediately surrounding the implant, but this is a very rare occurrence. In most of the reported cases, the lymphoma was detected by the patient when she noticed changes in the look or feel of the area around the implant. So we recommend that patients be aware and check for changes in this area, especially unilateral swelling or pain, and that they contact their healthcare provider if they observe such changes.

Dr. Ashar: More descriptive information about other potential complications, including difficulty with lactation, can also be found in the summary of safety and effectiveness in the labeling. (*Editor's Note: Links to the device-specific SSED can be found in the Table.*)

Table. Summary of Safety and Effectiveness Data for FDA-Approved Breast Implants

Device	Approval Date	Safety and Effectiveness Information
Saline-filled breast implants	May 2000	Mentor Saline Breast Implants
	May 2000	Allergan (formerly called McGhan and Inamed) Medical RTV Saline-Filled Breast Implant
Silicone gel-filled breast implants	November 2006	Allergan Inamed®
	February 2013	Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants
	November 2006	Mentor MemoryGel®
	June 2013	Mentor MemoryShape™ Silicone-Filled Breast Implants
	March 2012	Sientra Silicone Gel Breast Implants

FDA = US Food and Drug Administration

Monitoring

Medscape: What are the recommendations for monitoring women who have received breast implants? You alluded to differing recommendations in monitoring for rupture with these newer devices.

Dr. Ashar: Both patients with saline-filled and silicone gel-filled breast implants should continue routine mammography for breast cancer screening as recommended by their healthcare provider, based on age and risk factors. Patients with silicone gel-filled breast implants should also have periodic MRI screening examinations to detect "silent rupture" of the breast implant. The FDA's recommendation is that the first MRI screening should be conducted 3 years following implant placement, and then every other year after that. This is an across-the-board recommendation -- all women, regardless of the reason for the implant and personal factors, such as age, should receive

MRI screening on this schedule until enough scientific data are collected to determine a predictive timeline for rupture risk.

Medscape: What resources do you recommend for clinicians providing education and counseling to women considering breast implantation?

Dr. Krause: The FDA has a breast implants [Webpage](#) with resources that include:

- Links to patient information and data for each product;
- Information about risks and complications;
- Questions for patients to ask healthcare professionals regarding breast implant surgery; and
- [Contact information](#) for manufacturers of FDA-approved breast implants and related professional organizations.

Acknowledgment: *Drs. Ashar and Krause would like to thank Janette Alexander, MD, Plastic & Reconstructive Surgery Branch, Office of Device Evaluation, Center for Devices and Radiological Health, FDA; Plastic Surgeon (BC- ABPS), Clinical Reviewer for FDA, for her contributions to this article.*

Public Information from the FDA and Medscape

Information provided by FDA and/or its employees on this website is for educational purposes only, and does not constitute medical advice. Any statement or advice given by an FDA employee on this website does not represent the formal position of FDA. FDA and/or any FDA employee will not be liable for injury or other damages resulting to any individuals who view FDA-related materials on this website.

Cite this article: Breast Implants: The View From the FDA. *Medscape*. Jul 17, 2013.