

ISSUE BRIEF



What You Need to Know About Breast Implants

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By Diana Zuckerman, PhD; Elizabeth Nagelin-Anderson, MA;
and Elizabeth Santoro, RN, MPH

In 2008, more than 300,000 women and teenagers underwent surgery to have their breasts enlarged with silicone or saline implants, and almost 80,000 breast cancer patients had reconstruction after mastectomy, often with implants.¹ The popularity of breast augmentation has more than tripled since 1997, when there were just over 101,000 of these procedures.²

More than 40,000 implant *removal* procedures were also reported in 2008.¹ Given these statistics, it is not surprising that in spite of the increasing number of women with breast implants, debate continues to swirl about their safety. Many women are justifiably confused by the conflicting information they hear. Here are the facts about what is known and not known about the risks of breast implants.

After a brief history of breast implants in the U.S., we will answer the following questions:

- What are the known risks?
- What happens when breast implants break?
- Do breast implants make women sick?
- What are other concerns?
- What if I need to get my implants removed?
- Are there newer, safer implants?

History of Implants in the U.S.

Breast implants made with silicone envelopes and filled with silicone gel or saline (salt water) were first sold in the United States in the 1960's, but sales were relatively slow until the 1980's. By 1990, however, almost one million women had undergone breast implant surgery, even though no safety studies had been published. Most of those women had silicone gel breast implants, which the plastic surgeons preferred.

Although most medical products must be proven safe and effective before they can be

sold in the U.S., that was not true for implanted medical devices sold before 1976. The Food and Drug Administration (FDA) did not require that companies selling silicone breast implants prove that their implants were safe until 1991 – after they had been in use for almost three decades. For the first time, the media started to report about women with implant problems, and quoted doctors who were concerned about implant safety. When the studies were provided to the FDA, the safety data were found to be inadequate to warrant FDA approval.

The FDA did not require implant makers to prove that their saline implants were safe until 2000, when, despite high complication rates, the FDA approved saline breast implants for the first time.

Silicone gel breast implants were approved for the first time in November 2006. Between 1992 and 2006, silicone implants were restricted to clinical trials that were primarily for cancer patients and women with broken implants. Patients were required to be informed that the implants were not approved by the FDA and to be regularly evaluated by their plastic surgeons as part of the study, in order to provide safety data intended to help all women with gel implants. Although silicone gel breast implants made by two manufacturers were approved in November 2006, there are still restrictions. For example, they are only approved for women over the age of 22, because younger women are still developing physically and emotionally and probably would not fully understand the risks.

What are the known risks?

Reports of complications among women with implants have been published in medical journals and discussed at public FDA meetings. There are a number of short-term and long-term risks that any woman thinking about getting breast implants or about removing or replacing older implants needs to be aware of.

"Local complications" refer to problems that occur in the breast area that are obviously related to the breast implants or the surgery. Common complications include infection and other surgical risks, chronic breast pain, breast or nipple numbness, capsular contracture, breakage and leakage, necrosis (skin death), the need for additional surgery, and "cosmetic" problems (such as dissatisfaction with how the breast looks with the implant).

Studies of saline breast implants and silicone gel breast implants conducted by implant manufacturers have shown that within the first three years, approximately three out of four reconstruction (breast cancer) patients and almost half of first-time augmentation patients experienced at least one local complication – such as pain, infection, hardening, or the need for additional surgery.³

For example, among reconstruction patients:

- 46% of women with silicone gel implants and 21% with saline implants underwent at least one re-operation within three years;
- 25% of silicone patients and 8% of saline patients had implants removed; and
- 6% of silicone patients and 16% of saline patients experienced breast pain.^{4,5}

Complication rates were lower, but still substantial, for augmentation patients. The FDA has a consumer handbook with descriptions of common complications as well as photographs, available to consumers at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064348.htm>

In addition to the risks from anesthesia, surgical risks include infection and hematoma (blood collecting around an implant), both of which can range from mild to severe. Surgical risks are highest immediately around the time of surgery, but complications can require additional surgery later, which will have similar risks. A woman may need to face these surgical risks several times if she needs surgery to correct implant problems or has broken or damaged implants replaced with new ones.

Common local complications include loss of nipple sensitivity or painfully sensitive nipples. Some women are dissatisfied with the cosmetic results of breast implants, because their breasts look or feel unnatural or asymmetrical, or they can hear a "sloshing sound" from saline-filled implants. Problems like these can interfere with sexual intimacy.

Scar tissue that forms around any implant or foreign body can become hard or tight around the implant. This common problem is called capsular contracture. The scar tissue is inside the body, but it can cause the breasts to become very hard and misshaped, and it leads to discomfort that ranges from mild to severely painful.

Researchers have shown that bacteria or mold can grow in saline implants,⁶ and have expressed concerns about the bacteria or mold being released into the body if the implant breaks. What effect that might have on a woman, or a nursing baby, has not been studied.

What happens when implants break?

All breast implants will eventually break, but it is not known how many years the breast implants that are currently on the market will last. Studies of silicone breast implants suggest that most implants last 7-12 years, but some break during the first few months or years, while others last more than 15 years.

In a study conducted by FDA scientists, most women had at least one broken implant within 11 years, and the likelihood of rupture increases every year.⁷ Silicone migrated outside of the breast capsule for 21% of the women, even though most women were unaware that this had happened.

Implant makers were required to study breakage and provide their studies to the FDA. Short-term studies of today's saline implants suggest that between 3-9% break within the first three years, and one implant manufacturer's study of their silicone gel implants found that between 3-20% break within three years.^{3,8} A Danish study of ruptured silicone gel implants suggests that most implants last for ten years, but by the time they are 11-20 years old, most will break, and after 20 years the few that are still intact will break.⁹

Many women with silicone gel implants are unaware that their implants are broken or leaking. Plastic surgeon Dr. Scott Spear and the former director of FDA's Office for Women's Health, Dr. Susan Wood, point out that "magnetic resonance imaging is the most accurate way to detect a rupture...Mammograms are often inaccurate in detecting rupture, and if an implant is already broken, the pressure from a mammogram could cause the silicone gel from the implant to leak outside the capsule."¹⁰

Silicone Migration: Research has shown that silicone gel in implants can break down to liquid silicone at normal body temperatures, and there are reports of silicone leakage and migration from implants to the lymph nodes and other organs.¹¹ What happens if liquid silicone migrates to the lungs, liver, or other organs? A study published by the Royal Academy of Medicine in Scotland found that a woman with a broken silicone gel implant in her calf was coughing up silicone identical to the kind in her implant.¹² This has potentially serious implications for women with breast implants, since silicone gel breast implants are considerably larger and closer to the lungs than calf implants.

Do breast implants make women sick?

A more controversial question is whether breast implants cause diseases or illnesses, and not just problems in the breast area.

Autoimmune diseases. Several reports have concluded that there is no evidence that implants cause systemic disease.^{13,14,15} These reports, however, relied on research that focused on autoimmune or connective-tissue diseases in women who had implants for a relatively short time -- ranging from a few months to a few years. Since connective-tissue and autoimmune diseases may take many years to develop and be diagnosed, studies that include women who had implants for such a short time cannot be used to determine whether or not breast implants increase the long-term risks of getting these diseases.

Studies conducted after these reports were published indicated that implants may be linked to autoimmune diseases. For example, FDA scientists conducted a study of women who had silicone gel breast implants for at least seven years and found that those with leaking implants were significantly more likely to report fibromyalgia, a painful autoimmune disease.¹⁶ The risk of fibromyalgia remained even after statistically controlling for patient's age, implant age, and implant manufacturer. These researchers also found that women with leaking silicone implants were significantly more likely to report a diagnosis of at least one of the following painful and debilitating diseases: dermatomyositis, polymyositis, Hashimoto's thyroiditis, mixed connective-tissue disease, pulmonary fibrosis, eosinophilic fasciitis, and polymyalgia.

Do implant patients who have autoimmune symptoms feel better if their implants are removed? A study of 95 women who had silicone gel-filled breast implants and rheumatologic symptoms such as joint pain, found that the symptoms improved in 97% (42 of 43) of the women who had their breast implants removed. In contrast, rheumatologic symptoms worsened in 96% (50 of 52) of the women who did not have their implants removed.¹⁷ In addition, a university researcher has reported that silicone stimulates an immune response, and cellular analyses indicate that these responses are associated with atypical forms of connective tissue disease.¹⁸

A study of Danish women who had breast implants for an average of 19 years found that they were significantly more likely to report fatigue, Raynaud-like symptoms (white fingers and toes when exposed to cold), and memory loss and other cognitive symptoms, compared to women of the same age in the general population.¹⁸

Despite reporting that women with implants were between two and three times as likely to report those symptoms, the researchers, who were funded by a silicone manufacturer, concluded that long-term exposure to breast implants "does not appear to be associated with" autoimmune "symptoms or diseases." However, the symptoms they reported can be from autoimmune diseases.

Cancers. A study by National Cancer Institute (NCI) scientists found a 21% overall increased risk of cancer for women who had implants for at least seven years, compared with women of the same age in the general population.²⁰ The increase was primarily due to an increase in brain, respiratory tract, cervical, and vulvar cancers. More research is needed to draw any conclusions, however. There is no research evidence that implants cause breast cancer.

Death. An NCI study found that women who had breast implants for at least 12 years were more likely to die from brain tumors, lung cancer, other respiratory diseases, and suicide compared with other plastic surgery patients.²¹ Augmentation patients were not more likely to smoke than other plastic surgery patients, so the difference in respiratory diseases did not appear to be due to smoking. However, more research is needed to better control for relevant health habits. Three Scandinavian studies have reported that women who had breast implants for augmentation were three times more likely to commit suicide compared to women in the general population.^{22,23,24}

What are other concerns?

Breastfeeding. According to the Institute of Medicine (IOM), women with any kind of breast surgery, including breast implant surgery, are at least three times as likely to have an inadequate milk supply for breastfeeding.¹³ Concerns about the safety of breast milk have also been raised, but there has not been enough research to resolve this issue. A study of a small number of women with silicone gel breast implants found that the offspring born and breastfed after the mother had breast implants had higher levels of a toxic form of platinum in their blood than offspring born before the same women had breast implants.²⁵

Breast Cancer Detection. Breast cancer is the most common type of cancer among women, and since mammograms have been shown to detect breast cancer earlier and thus save lives, the question of whether implants interfere with mammograms is very important.

There are several ways in which implants have the potential to delay detection of breast cancer:

- Although mammography can be performed in ways that minimize the interference of the implants, approximately 55 percent of breast tumors will be hidden in women with implants.²⁶

- FDA scientists report that silicone or saline implants can rupture when women undergo mammograms, and for this reason, women who fear implant rupture may forego mammograms.²⁷
- The accuracy of mammograms tends to decrease as the size of the implants increase in proportion to the size of the woman's natural breast.

Research findings on whether implants lead to a delay in breast cancer diagnosis have been inconsistent, but patients have reported such delays.²⁷ A delay in diagnosis could result in the woman needing more radical surgery or the delay could be fatal.

Problems with Memory and Concentration. Women with implants have raised concerns about memory loss, difficulties with concentration, and other cognitive problems. FDA's analysis of studies by implant companies found a significant increase in neurological symptoms, such as poor concentration, for women who had silicone implants for two years compared to their symptoms just prior to getting implants. These differences were maintained even when the women's ages were statistically controlled.²⁸ Some experts believe these symptoms could be related to the small amounts of platinum that are used to make silicone gel breast implants, since potentially toxic levels of platinum have been found in the blood and urine of women with implants.²⁵ Unfortunately, there is no well-designed published epidemiological research to determine whether there is an association between these complaints and breast implants.

Financial Costs. Breast implant surgery is not a one-time cost. On average, implants last 7-12 years, and each replacement adds to the cost. Even if the implant itself is replaced for free, or if the surgeon offers his or her services for free, the cost of the medical facility, anesthesiology, and other expenses can still cost many thousands of dollars for each surgery. These expenses are affordable for some women, but not for others, especially if the implant breaks after just a few months or years, or after a woman is divorced or loses her job.

When the FDA approved silicone gel breast implants in November 2006, it stated that women with these implants should have a breast MRI three years after getting silicone implants and every two years after that.²⁹ The purpose of the MRIs is to determine if the silicone gel breast implants are ruptured or leaking, because there are often no symptoms. Breast MRIs usually cost at least \$2,000, and at some facilities they cost more than \$5,000. It is important to remove silicone implants if they are ruptured, to avoid the silicone leaking into the breast or lymph nodes. That is an additional expense of at least \$5,000, and can be \$10,000 or more.

Saline implants do not require MRIs to check for leakage, and do not usually cost more than \$5,000 to remove. The cost of MRIs and the additional cost of removing leaking silicone makes silicone implants substantially more expensive than saline.

What about health insurance? Typically, cosmetic surgery is not covered by health insurance, and problems resulting from cosmetic surgery are also not covered.¹⁰ Health insurance will not pay for MRIs to check for silicone leakage for augmentation patients. In some states, major health insurance providers do not insure women with breast implants.¹⁰ Some insurers will sell health insurance to women with implants, but charge

them more, and some insurers will not cover certain kinds of illnesses - or any problems in the breast area - for women with breast implants. Obviously, this can be a terrible problem for women who are diagnosed with breast cancer or any other illnesses that are excluded, whether or not those diseases are related to the implants.

What if I need to get my implants removed?

Women who have implants sometimes decide to have them removed because of complications, disappointment with how they look or feel, or concern about the long-term health risks. Some surgeons discourage patients from removing their implants. This may be because they don't share the patient's concerns, or because they know that some patients will be very unhappy with their appearance after the implant is removed. (See photo #3 at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064348.htm>) Women with ruptured silicone implants often lose breast tissue as part of the removal surgery. If silicone has leaked into the breast tissue, the resulting removal surgery may be similar to a mastectomy. (See second photo at www.breastimplantinfo.org/what_know/dz_fda_test_oct03.html.)

The plastic surgeon who performed the original surgery is not necessarily the best choice for removing the implant. Removal can be much more complicated and expensive than the original surgery, especially after a silicone gel implant has broken. Some plastic surgeons are very experienced at removal and are especially skilled at getting the best possible cosmetic result. Most surgeons who specialize in removal recommend removing the implants "en bloc," which means that the implant and the intact scar tissue capsule surrounding it are all removed together. This helps remove any silicone that may have leaked from a broken gel implant, and also helps remove silicone or other chemicals that may have "bled" from the silicone outer envelope.

Are there newer, safer implants?

As part of new research studies, plastic surgeons sometimes offer "gummy bear" breast implants, named after gummy bear candies because the implants are a thicker, more cohesive silicone gel. Since the shell and gel in these newer models are thicker than most other silicone gel implants, it is possible that they might be less likely to break or leak into the body.

However, new implants often have risks that are not immediately obvious. Unfortunately, no studies have been published in medical journals to show whether these new implants are proven safer than other silicone gel breast implants for long-term use. At this point, there is no way to know whether the thicker shell will last longer than other implants and if so, whether it will last one year longer or several years longer. Only when the cohesive gel implants are in women for 10 years or more will we know whether and how the implant deteriorates or changes when it is in the human body. These implants have not been approved by the FDA because even less is known about their safety than is known about the older styles of silicone gel breast implants.

Why long-term safety studies matter. In addition to silicone and saline implants, three other kinds of implants were developed and used primarily outside the United States: Trilucent implants (with soybean oil filler), and Novagold and PIP hydrogel implants,

which were filled with a plastic gel.

Although these implants were enthusiastically promoted by plastic surgeons and the media as a "natural" and safer alternative to silicone or saline implants, clinical trials were apparently never conducted on humans with these implants. By 2000, serious safety concerns resulted in the removal of all three from the market.^{30,31,32} The fact that they had been praised by doctors and patients when they were initially introduced serves as a reminder that the long-term risks of implants are not always obvious during the first few years of use. That is why studies of the risks of long-term use - which are still lacking for silicone implants - are essential to establish the safety of all kinds of implants.

Conclusions

Research clearly shows that implants are associated with significant health, cosmetic, and economic risks within the first few years and these risks increase over time. Unfortunately, long-term risks remain unknown because of a lack of careful scientific studies. FDA has required implant manufacturers to conduct additional research to determine why implants break, how long they can be expected to last, and what the longer-term health consequences of broken and leaking breast implants might be. Those studies, however, have not yet been made public.

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2 ASAPS Percent of Change in Select Procedures: 1997-2004. American Society for Aesthetic Plastic Surgery (ASAPS), 2005. www.surgery.org. ASAPS estimates approximately 70,000 more augmentation surgeries in 2004 than does ASPS.

3 FDA transcript of the Advisory Panel Meeting on Mentor Saline Breast Implants, testimony of Dr. Sahar Dawisha, pages 431-7, 441, at <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3596t1.rtf>; FDA transcript of the Advisory Panel Meeting on McGhan Saline Breast Implants, testimony of Dr. Sahar Dawisha, pages 129-148, at <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3596t2.rtf>. Local complications are even higher, and tend to be more serious, for women with silicone gel breast implants. See Inamed Corporation's McGhan, Silicone-Filled Breast Implants, October 14-15, 2003, slides 39-42 and 49-51, at <http://www.fda.gov/ohrms/dockets/ac/03/slides/3989s1.ppt>

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