

What Do Women Need to Know and When Do They Need to Know It?

Susan F. Wood, Ph.D.
Scott L. Spear, M.D.
Washington, D.C.

When a woman enters a physician's office considering silicone breast implants, both the surgeon and the patient have certain hopes and expectations. Effective communication about risks and benefits, both known and unknown, is critical for the woman to make an informed decision. In this age of makeover television programs, enormous media attention regarding plastic surgery, high rates of long-term survival after mastectomy, and direct-to-consumer advertising, it is especially important that physicians work to ensure patients understand the information, some of which is complex and not intuitive. What women learn from the World Wide Web, advertising, or word of mouth is quite often incorrect and misleading. Whether they are potential augmentation patients or reconstruction patients, women need to consider their own medical history, their own economic circumstances, and other personal considerations, as well as the potential risks and complications of breast implants in general and silicone gel implants in particular, as part of the process of exploring the possibility of breast implants. It falls on plastic surgeons as well as other physicians and trusted sources to provide this information.

The decision about breast implants is a lifelong decision, even though the implants are unlikely to last any given patient's lifetime.¹⁻³ Silicone gel breast implants have been approved for reconstruction for women of all ages and for augmentation for women only aged 22 years and older, to allow them to achieve both the physical and emotional maturity necessary before making this lifelong decision. It is clear that the process of informed consent continues to be highly variable depending on who is giving and who is receiving

and processing the information. What have women and surgeons said about their previous experience with informed consent?

One surgeon said, "I give [patients] what I consider my informed consent . . . I go through all the features like the position, . . . whether to have a smooth or textured implant, and all of those issues such as carcinogenicity, altered mammography, capsular contracture, rupture, bleeding, infection . . . And then I give them the [FDA] booklet to go home and read."⁴

One augmentation patient said, "My doctor told me that these implants would go with me to my grave."⁵

A second surgeon said, "As a surgeon, it is my responsibility to help my patients decide what treatment is best based upon an intelligent risk-benefit analysis. By and large, the women that I consult with every day are smart, well informed, careful to make wise decisions."⁴

One breast cancer reconstruction patient said, "There were many risks with the implants that I did not know about."⁵

Women seeking augmentation are usually significantly different from women seeking breast reconstruction after breast cancer surgery; they are typically younger and healthier, with expectations of benefit that will last for many decades.⁶ For either augmentation or reconstruction, women need to be informed in clear language what the short- and long-term expectations are of local complications, surgical risks, and long-term health and financial implications. It also needs to be clear

From the George Washington University School of Public Health and Health Services and Georgetown University Hospital.

Received for publication July 24, 2007; accepted August 2, 2007.

Copyright ©2007 by the American Society of Plastic Surgeons

DOI: 10.1097/01.prs.0000286742.75755.eb

Disclosures: *Dr. Wood's salary is provided by the project on Scientific Knowledge and Public Policy (SKAPP) at George Washington University. Major support for SKAPP is provided by the Common Benefit Trust, a fund established pursuant to a court order in the Silicone Gel Breast Implant Products Liability litigation. Dr. Spear is a paid consultant to Ethicon, Inamed, and Lifecell.*

that although we know some things about breast implants, there is still much that is unknown, and that unknown risk is not necessarily the same as no risk. This is a difficult challenge for healthcare professionals, to honestly and ethically convey useful information to patients. It is also a challenge to women to seek information, ask good questions, and carefully consider the answers.

START WITH WHAT WE KNOW

Breast implants will not last forever, but what does that mean to the woman? It means that she is likely to need or choose to have one or more reoperations on her breasts, some within just a few years.¹⁻³ As most women might anticipate having the implants for many decades, this reality must be communicated directly and clearly.

Rupture of silicone gel breast implants is usually silent and may have consequences. Currently, magnetic resonance imaging is the most accurate way to detect a rupture. Two studies have examined clinical examination and magnetic resonance imaging and concluded that only 30 percent of plastic surgeons familiar with a patient and her breast implants detected a silicone gel rupture,⁷ compared with 89 percent detection with magnetic resonance imaging.^{2,3,8} 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.^{1-3,9} With rupture, removal is recommended, because the loss of shell integrity results in the loss of a key barrier preventing migration of silicone into the patient's adjacent tissues. Replacement after removal is an option, but replacement is not necessarily a requirement.¹⁻³ Removing both implants at the same time may be a reasonable option even if only one is ruptured. Women need to know that silent rupture is just that, silent, and in this case ignorance of rupture is not bliss. Women have the right to know if their implants have ruptured (whether silent or symptomatic), so that the next decision about removal and replacement can be made with that information in hand. If a magnetic resonance imaging scan shows possible rupture or leakage or if a woman is experiencing symptoms that may be caused by her silicone gel implants, she should schedule an appointment with a plastic surgeon familiar with breast implants, including their removal and replacement.

Mammography to detect breast cancer is complicated by all breast implants and will require extra radiographic views of the breast.^{2,3} All breast implants, whether silicone or saline, interfere with mammograms, and the larger the implants, the

more likely they are to obscure some of the breast and potentially hide cancerous tumors.^{1-3,10} The additional views of the breast with implants require a specially trained technician and will cost more, take more time, and expose the woman to more radiation. Mammography may also lead to rupture, especially if the implants are older.^{1-3,9} For young women in particular, it is difficult to communicate the importance of routine screening mammography, which may not be recommended to them for 20 or more years in the future after their breast augmentation. Most will not have experienced having a mammogram and do not know the compression involved during the procedure nor how different views of the breast are taken. The benefit of routine screening mammography in early detection of breast cancer for women over 40, and even more so for women over 50, must be discussed, along with the real need to take special care and extra effort and cost to ensure it will be done properly.

Breast implants may eventually feel hard and become painful (i.e., capsular contracture), and this is not uncommon. Along with this, the breasts may look abnormal. As such, capsular contracture is the most common cause of reoperation and implant removal.¹⁻³ Since many women seek implants for reasons associated with appearance, this is a critical fact to convey.

Women are likely to feel better about the appearance of their breasts in the years right after getting breast implants, but implants do not address underlying psychological issues, ranging from improving self-esteem to treating body dysmorphic disorder.¹¹ Physicians need to conduct a careful and thoughtful evaluation of the patient, as those with body dysmorphic disorder or other mental disorders, including depression and eating disorders, are not good candidates for breast implants. In addition, there are no long-term data on the effect of breast implants for improvement of overall body image.

Removal can be difficult if an implant is ruptured and if the gel has migrated outside the capsule. With removal of the implants, the resulting stretching and sagging which may have occurred may be "cosmetically unacceptable."^{2,3} If it occurs, silicone leakage into the tissue may result in removal of breast tissue, so that even with replacement, women's breasts may not be fully restored. It is important for women to know that after a second surgery, the risk of more complications, especially capsular contracture and rupture, is higher than before. Revisions or secondary corrections do not reduce the need or likelihood of future surgery.

The financial and health insurance issues are real and lifelong. Breast implants for augmentation are not usually covered by health insurance, but patients may not be aware that follow-up operations, removal and replacement, and additional costs for mammography and magnetic resonance imaging are also not likely to be covered. For women expecting to live at least 15 years, these financial costs are likely to go far beyond the initial charges of implant surgery. Also, insurance companies may drop coverage or raise premiums for women who have undergone breast implant surgery.¹⁻³ These personal financial expenses are critical facts women need to consider.

WHAT WE DO NOT KNOW

As important as it is to advise women about what is known about silicone breast implants, it is perhaps more important to convey to them what is unknown. It is difficult for a woman to give true informed consent when there are unknown risks associated with breast implants. This is true of most procedures or medications, but in the case of a lifetime decision for an elective procedure, this becomes even more difficult. The consent a woman is giving has to be made with clear understanding that the unknown risks may be quite real, even if they are not currently identified. The studies carried out on the newly approved products provide little information after 3 to 4 years for an implant that is expected to be in the body much longer than that. Although Mentor provided the U.S. Food and Drug Administration with 10-year data for 100 European augmentation patients (no reconstruction patients), this study included just a few implant styles, and the plastic surgeons used surgical techniques that are somewhat different from those common in the United States.¹² Longer studies are ongoing, but it will be some years before the quality and outcomes of those studies are known. And with each new product that comes on the market with claims of being new and improved, the comparisons once again will be based on short-term studies.

Women need to know that we do not know how long implants last. For some women, it may be only a few years; for others, it may be much longer. The implant company data provided to the Food and Drug Administration by Mentor and Allergan indicated that 0.5 percent (primary augmentation) to 7.7 percent (revision) of implants broke within the first 3 years, and the rupture rate is expected to continue to increase substantially after that.^{2,3} We do not have data on long-term implantation of these products in the body, so it cannot be honestly predicted. Particularly for

young women seeking augmentation who will be responsible for paying for any additional operations, this may be problematic, and this reality must be emphasized.

We do not have good long-term data on outcomes for women undergoing reconstruction after breast cancer surgery. Women with breast cancer are known to have higher risks of complications. Unfortunately, the studies that have been performed and submitted to the Food and Drug Administration for approval did not include many breast cancer survivors; in the case of Mentor, none of the women had implants for more than 3 years.¹² Women with breast cancer need to know all of the surgical and nonsurgical options after breast cancer surgery, and not be left with the misconception that surgical reconstruction is actually a necessary part of their cancer treatment.

As in most other drug and device studies, we do not have specific data collected and analyzed on women of different races and ethnicities. Differences in keloid formation, scarring, capsular contracture, and other complications in African-American women are a potential problem that has not been studied in breast implants and thus remains an unknown.

Women with autoimmune disease or a weakened immune system are not recommended by implant manufacturers to have breast implants,^{2,3} largely because these women were excluded from the clinical studies for these products. A question that has been raised many times is whether silicone breast implants have the potential to disrupt the immune system.¹³ Previous studies have generally excluded women who were already at risk for autoimmune diseases because of family history or personal history, and most of the studies have not included women who were known to have leaking silicone in their bodies. They also included very few African-American or Hispanic women, who are at higher risk for lupus and other autoimmune diseases than non-Hispanic white women are. Many studies to date have failed to identify a statistically significant increased risk of classic autoimmune diseases, except in some limited forms (the possible increased risk of fibromyalgia with extracapsular silicone and other potential autoimmune symptoms).^{1-3,14,15}

Regarding cancer, there is compelling evidence that breast implants do not increase the risk of breast cancer, but it is also known that breast implants may obscure the mammographic detection of breast cancer by reducing the sensitivity of mammography. Studies have not identified any related increased risks of other cancers, although there are limited data suggesting a higher risk of

cancers for augmentation patients as compared with other plastic surgery patients. A study carried out by the National Cancer Institute also found an increased risk of dying from brain cancer or lung cancer among breast augmentation patients compared with other plastic surgery patients, but the authors could not determine whether or not the latter is related to silicone gel breast implants or caused by increased smoking among women with breast implants.^{6,16,20}

Physicians need to be alert to the documented increased risk of suicide among women with breast implants, which was statistically significant in several large studies.¹⁷⁻²¹ With the increased rate of women with body dysmorphic disorder who seek breast implants and other plastic surgery, and the fact that implants will not improve this condition nor raise overall self-esteem, it is possible that mental health problems predate implants in some patients.

Young women who may decide to have children in the future also need to be told about the possibility of reduced success of breastfeeding among women who have undergone breast surgery, whether augmentation or reduction. They also need to be told about the need for research on possible leakage of silicone or other implant substances into breast milk, as this remains an unanswered question.¹³

CONCLUSIONS

Silicone breast implants recently approved for reconstruction in all age groups and for cosmetic augmentation in women 22 years old and older present a challenge to physicians and health educators. These products have been studied prospectively only for 3 to 5 years in the most recent studies submitted to the Food and Drug Administration. Women need to know and understand the known risks of rupture, capsular contraction, pain, and complications and the issues with mammography, as well as the likelihood of reoperation. Critically important is the need to understand that, as with all medical devices, these are not lifetime devices, and a small percentage of women will have ruptured implants within a few years. Therefore, proper follow-up to detect breakage will be necessary, and more than 15 percent should expect reoperations within 3 years. Women need to know that long-term studies with the newly approved devices have not been completed, and therefore, the expected lifetime and stability of implants are unknown at this time.

Questions will always remain that should be conveyed clearly to women considering breast implants, including the need for more information

about suicide, some cancers, autoimmune conditions, pain, and other nonspecific symptoms. Non-Caucasian women should be informed that adequate studies have not been done on women of their race or ethnicity. Breast cancer patients should also be informed that the Food and Drug Administration–sponsored studies on these devices did not include many breast cancer patients for more than 4 years. There are, however, several other long-term studies on reconstruction with large numbers of patients that provide useful information.²² Given the current knowledge, complication rates are significantly higher for reconstruction than they are for augmentation.

Given the breadth and depth of information that women must learn and understand before reaching this lifetime decision, adequate time and multiple perspectives should be provided to women. Women should take sufficient time, which is recommended to be 2 weeks after receiving information from the physician, from other health educators, and from written materials and other reputable sources, to consider this operation. For most women undergoing augmentation, this procedure is elective and not time-sensitive. Unlike many medical therapies, this educational and informed consent process should be not perfunctory and short-circuited but rather a time for physicians to carefully assess the mental health needs of the patient and to consider the appropriate use of mental health screening resources to ensure that she does not rush into an impulsive decision.

The challenge facing plastic surgeons and other physicians in educating their patients about silicone breast implants is one of clear and honest communication, time, and professional judgment: a challenge faced daily by health professionals for many procedures and treatments. The goal is to ensure that those women who ultimately choose to have breast implants do so with the full understanding of the known and unknown risks and costs, so that they can make this lifetime choice thoughtfully and clearly.

Susan F. Wood, Ph.D.

George Washington University
School of Public Health and Health Services
2100 M Street, NW, Suite 203
Washington, D.C. 20037
eohsfw@gwumc.edu

REFERENCES

1. U.S. Food and Drug Administration. *FDA Breast Implant Consumer Handbook, 2004*. Washington, D.C.: U.S. Food and Drug Administration. Available at <http://www.fda.gov/cdrh/breastimplants/indexbip.PDF>. Accessed July 23, 2007.

2. Mentor. Important information for augmentation patients about Mentor MemoryGel silicone gel-filled breast implants, 2006. Available at <http://www.mentor4me.com/pdf/approved/Augmentation.pdf>. Accessed July 23, 2007.
3. Allergan. Important information for women about breast augmentation with Inamed silicone-filled breast implants, 2006. Available at <http://www.breastimplantstoday.com/pdf/M1209-02SiliconeAugLabel.pdf>. Accessed July 23, 2007.
4. FDA Medical Devices Advisory Committee. General and plastic surgery devices panel, meeting March 2, 2000. Available at <http://www.fda.gov/OHRMS/DOCKETS/ac/00/transcripts/3596t2a.pdf>. Accessed July 23, 2007.
5. U.S. Food and Drug Administration. Making an informed decision about breast implants. *FDA Consumer Magazine*, Vol. 38, issue 5, 2004. Available at http://www.fda.gov/fdac/features/2004/504_implants.html. Accessed July 23, 2007.
6. Brinton, L. A., Brown, S. L., Colton, T., Burich, M. C., and Lubin, J. Characteristics of a population of women with breast implants compared with women seeking other types of plastic surgery. *Plast. Reconstr. Surg.* 105: 919, 2000.
7. Holmich, L. R., Fryzek, J. P., Kjoller, K., et al. The diagnosis of silicone breast-implant rupture: Clinical findings compared with findings at magnetic resonance imaging. *Ann. Plast. Surg.* 54: 583, 2005.
8. Holmich, L. R., Vejborg, I., Conrad, C., Sletting, S., and McLaughlin, J. K. The diagnosis of breast implant rupture: MRI findings compared with findings at examination. *Eur. J. Radiol.* 53: 213, 2005.
9. Brown, S. L., Todd, J. F., and Luu, H. D. Breast implant adverse events during mammography: Reports to the Food and Drug Administration. *J. Womens Health* 13: 371, 2004.
10. Miglioretti, D. L., Rutter, C. M., Geller, B. M., et al. Effects of breast augmentation on the accuracy of mammography and cancer characteristics. *J.A.M.A.* 291: 442, 2004.
11. Crerand, C. E., Franklin, M. E., and Sarwer, D. B. Body dysmorphic disorder and cosmetic surgery. *Plast. Reconstr. Surg.* 118: 167e, 2006.
12. U.S. Food and Drug Administration. FDA summary panel memorandum: Mentor P030053. Available at http://www.fda.gov/ohrms/dockets/AC/05/briefing/2005-4101b1_Tab-1_fda-Mentor%20Panel%20Memo.pdf. Accessed July 23, 2007.
13. Bondurant, S., Ernster, V., Herdman, R. (Eds.). *Safety of Silicone Breast Implants*. Washington, D.C.: Institute of Medicine. 1999.
14. Brown, S. L., Pennello, G., Berg, W. A., Soo, M. S., and Middleton, M. S. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. *J. Rheumatol.* 28: 996, 2001.
15. Brinton, L. A., Buckley, L. M., Dvorkina, O., et al. Risk of connective tissue disorder among breast implant patients. *Am. J. Epidemiol.* 160: 619, 2004.
16. Brinton, L. A., Lubin, J. H., Burich, M. C., Colton, T., Brown, S. L., and Hoover, R. N. Cancer risk at sites other than breast following augmentation mammoplasty. *Ann. Epidemiol.* 11: 248, 2001.
17. Jacobsen, P. H., Holmich, L. R., McLaughlin, J. K., et al. Mortality and suicide among Danish women with cosmetic breast implants. *Arch. Intern. Med.* 164: 2450, 2004.
18. Koot, V. C., Peeters, P. H., Granath, F., Grobbee, D. E., and Nyren, O. Total and cause specific mortality among Swedish women with cosmetic breast implants: Prospective study. *B.M.J.* 326: 527, 2003.
19. Pukkala, E., Kulmala, I., Hovi, S. L., et al. Causes of death among Finnish women with cosmetic breast implants, 1971-2001. *Ann. Plast. Surg.* 51: 339, 2003.
20. Brinton, L. A., Lubin, J. H., Burich, M. C., Colton, T., and Hoover, R. N. Mortality among augmentation mammoplasty patients. *Epidemiology* 12: 321, 2001.
21. Le, G. M., O'Malley C. D., Glaser, S. L., et al. Breast implants following mastectomy in women with early-stage breast cancer: Prevalence and impact on survival. *Breast Cancer Res.* 7: R184, 2005.
22. Spear, S. L., and Majidian, A. Immediate breast reconstruction in two stages using textured, integrated-valve tissue expanders and breast implants: A retrospective review of 171 consecutive breast reconstructions from 1989 to 1996. *Plast. Reconstr. Surg.* 101: 53, 1998.