

Breast Augmentation Today: Saline versus Silicone—What Are the Facts?

Rod J. Rohrich, M.D.
Edward M. Reece, M.D.,
M.S.
Dallas, Texas

Controversy breeds excitement, and the epic saga of breast prosthesis in the United States has been no exception. In 1992, U.S. plastic surgeons began what can be considered an experiment. With new U.S. Food and Drug Administration restrictions, saline breast implants became the only option available to patients seeking breast augmentation surgery. This restriction spanned the course of almost 15 years. Initially, when we treated patients desiring breast augmentation, we were hopeful that one day silicone implants would be available again to provide our patients with a variety of options and choices.

In 2006, the experiment ended as the Food and Drug Administration approved silicone implants for general clinical use in breast augmentation. A vociferous buzz surrounding silicone implants ensued, resulting in new interest and questions from our patients. With the promise of “new cohesive gels” and better durability, the floodgate was opened, and many of us have again embraced the use of silicone gel implants for breast augmentation. A recent survey conducted by the American Society of Plastic Surgeons revealed that the majority of responding members felt that many primary augmentation patients would return to exchange their saline implants for silicone implants.¹ Further, members anticipated that more than 60 percent of future primary augmentation candidates would request silicone implants.¹ Underneath all of this enthusiasm, have we found ourselves “back to the future”?

If it were not for the health concern controversies surrounding silicone implants, which have been largely unsubstantiated in the scientific literature, it is conceivable that saline implants would never have been thoroughly investigated in the United States. The controversies led to multicenter trials and Food and Drug Administration endorsement of the safety of saline implants.² With the reintroduction of silicone implants, com-

parisons between silicone and saline are inevitable. Although there is an abundant amount of general data concerning silicone implants, the relative brevity of follow-up for the current silicone implants approved recently by the Food and Drug Administration makes the analysis between saline and silicone implants unbalanced. We are now told about the “new generation” of silicone gel implants, but long-term data are not yet available. Although the current data are alluring, we must remember a straightforward fact: the data from the latest generation of silicone implants are approximately 3 to 4 years old. As physician and scientists, we know that long-term, verified, scientific knowledge is needed on potential changes in the contracture and rupture rates of these implants. One advantage of the moratorium on silicone implants was the long-term collection of data on saline implants. This data collection period spanned more than 15 years in the United States, and the information gathered substantiated that saline implants are safe and effective in our patients.

Despite the uncertainty of outcomes with silicone implants, a plethora of data exists. What are the data and what should we discuss with our patients in consultation? The data we currently have are less than clear. With regard to rupture rates, studies have shown an 8- to 13-year average for silicone implants; corporate data also cite a 0.5 to 3 percent 3- to 4-year rupture rate.³⁻⁶ In their 2006 study, Hedén et al.⁵ found that the rupture rate was 8 percent for silicone implants; this was contrasted with a rupture rate of 4.3 percent for saline implants,⁷ which increased with variance in time (Table 1). At 10 years, third-generation silicone gel implants are projected to maintain integrity at a rate of 83 percent to 85 percent; this estimate,

Disclosure: *Neither author has any financial interests to disclose.*

Copyright ©2008 by the American Society of Plastic Surgeons

DOI: 10.1097/01.prs.0000298115.96337.72

Table 1. Primary Breast Augmentation Data*

	Silicone	Saline
Rupture rate		
1 to 2 years	8% (2 yrs) ⁸	1% (1 yr) ¹⁸ 4% (1 yr) ¹⁹
3 years	0.5% ¹³	3% (3 yrs) ¹³ 5% (3 yrs) ²⁰
4 years	2.7% ¹⁶	10% (4 yrs) ¹³
5 years	1% ¹¹	16% ¹⁰
9 to 10 years	10% (9 yrs) ¹⁷ 8% (10 yrs) ⁵	7% (10 yrs) ²⁰
Contracture rate		
1–3 years	8.1% (3 yrs) ¹⁸	5% (1 yr) ¹⁸ 4% (1 yr) ¹⁹ 9% (3 yrs) ²⁰
4 to 5 years	13.2% ¹⁶	10% (5 yrs) ⁶ 11% (5 yrs) ²⁰
7 years	5.6% ¹¹	11% (7 yrs) ¹⁸ 16% (7 yrs) ²¹
10 years	No comparison 38.5–90% ^{12,13}	16.6% (10 yrs) ¹⁰
Patient satisfaction	97% (6 yrs) ¹¹	95% (5 yrs) ²⁰ 93% (6 yrs) ⁷ 87% (7 yrs) ²¹
Implant removal (1 to 4 years)	5.1% (3 yrs) ¹⁸ 7.5% (4 yrs) ¹⁶	6% (1 yr) ¹⁹ 8% (3 yrs) ²⁰ 12% (4 yrs) ²⁰
Detection of rupture	Physician/patient inaccurate (12.5% sensitivity, 84.2% specificity) ⁵ MRI at 3 yrs then every 2 yrs (recommended by the FDA)	Physician/patient able to detect rupture
Deflation rate	0.308/1000 implants ¹⁴	0.34/1000 implants ¹⁴
Implant cost (range)	2×	1×
Incision size	6–8 cm	3–4 cm
Integrity at 10 years	Not collected	96.9–98% ¹⁰
Implant removal	Complicated (capsulotomy)	Simple (replacement)

MRI, magnetic resonance imaging; FDA, U.S. Food and Drug Administration.

*Composite data from the plastic surgery literature.

however, needs to be verified with long-term studies,⁸ as other studies have shown the implant rupture rate to be 60 to 85 percent at 10 years.⁹ Saline implants have been shown to remain 96.9 to 98.9 percent intact at 10 years.¹⁰ Capsular contracture with silicone implants after 5 years is on the order of 5.6 percent¹¹; this rate approaches 38.5 to 90.7 percent at 10 years in the historic data.^{12,13} Saline implants were associated with a 5-year capsular contracture rate of 10 percent.⁶ After 10 years, this rate increased to 16.6 percent.¹⁰ Deflation rates for the two types of implants have been comparable over a limited follow-up time (0.308/1000 implants with silicone and 0.34/1000

implants with saline).^{14,15} Consideration of incision size between the two types of implants is significant: saline implants can be placed through a 3- to 4-cm incision, whereas silicone implants must be placed through an incision almost twice that length, depending on the size of the implant used. Cost is also a factor. In 2007, the cost of saline implants was approximately 50 percent less than that for silicone implants. Finally, satisfaction rates were high for both silicone (97 percent)¹¹ and saline (93 percent)⁷; these rates decrease moderately over time. These data are summarized in Table 1.^{16–21}

The data presented in Table 1 represent a veritable mire of information that is difficult for a practicing plastic surgeon, let alone a patient, to unravel. When considered in the light of historical data, it is difficult to fervently adopt silicone gel data. Further, it is unrealistic to think that patients will be able to discern a balanced understanding from these data to give informed consent. It is important for plastic surgeons to understand this information when consulting with patients.

The experience of plastic surgeons has proven that breast augmentation is not an isolated surgery for either saline or silicone implants and that implant replacement is to be expected. Given this reality, changing silicone implants in a revisional procedure is a more challenging operation than changing saline implants. The practicing surgeon must inform the patient of the suggested magnetic resonance imaging surveillance protocol for silicone implants to meet Food and Drug Administration recommendations. The Food and Drug Administration recommends a magnetic resonance imaging scan at 3 years after surgery and then every 2 years thereafter. This is certainly an expensive method of follow-up and one that is not covered by standard insurance plans.

Finally, Food and Drug Administration approval of silicone implants was not meant to encourage the use of silicone implants over saline breast implants. To the contrary, the Food and Drug Administration has moved to inform patients about safe options for breast augmentation, whether they include saline or silicone implants. This is a laudable endeavor which we should encourage to continue.

Plastic surgeons must consider the invaluable lessons learned from our recent use of saline implants in primary breast augmentation. First, saline implants have a greater than 93 percent satisfaction rate. Second, saline implants are easier to exchange in revisional procedures. Third, they have a lower rupture rate, as validated by substan-

tial data, and rupture is detectable without an expensive work-up. Fourth, saline implants probably have less of an effect on mammography detection of breast cancer compared with silicone implants. Breast implants interfere with mammography detection of breast cancer and require additional views and skilled technologists to compensate. Finally, saline implants have a proven safety record and are approved by the Food and Drug Administration. These implants have earned the right to remain a suitable and excellent option for patients desiring breast augmentation. Plastic surgeons must use facts from supportive data to help their patients make appropriate choices and provide informed consent.

What should we tell our patients to give them the most balanced and accurate information about the differences between silicone and saline implants? There is no question that silicone implants simulate the feel of breast tissue and are therefore perceived as more natural to some patients. Further, there is less palpable rippling and less potential for visible rippling. These cosmetic differences become more apparent in patients with less breast tissue and skin turgor. Although saline implants may feel less natural in thinner women, they have a much lower risk of capsular contracture and a lower rate of rupture. In addition, when revisional surgery is required with either implant, it is less extensive, with a shorter recovery time and less expense, when saline implants are used. Therefore, consideration of “maintenance” issues should be part of the initial decision-making process for patients choosing between saline and silicone.

It would be unrealistic to inundate patients with all of the corporate literature, albeit scientific data, and not expect them to be confused and overwhelmed. Physician-led teaching about the differences between saline and silicone implants is a mandatory adjunct to help patients select proper implants.

Through informed plastic surgeons, patients can make confident decisions about breast augmentation surgery. We are at a disadvantage when accurately describing the outcomes of using silicone implants when quoting data that extend, at best, for only 4 years. Plastic surgeons have learned much about the use of saline implants: specifically, that they have proven to be safe and reliable and are associated with a high rate of patient satisfaction, a low contracture rate, and a low deflation rate. This has been a pleasant surprise in plastic surgery. Although we were forced into a noble experiment with saline implants, we must not dis-

card the information obtained from the past 15 years. We should use this information wisely to educate our patients.

In summary, there are several salient points to convey to patients:

1. Saline implants have an overall decreased capsular contracture and rupture rates compared with silicone breast implants.
2. Saline implants require a smaller incision for placement than silicone implants.
3. Rupture detection for silicone implants depends on magnetic resonance imaging, which the Food and Drug Administration recommends be performed periodically and which is likely not reimbursed by insurance. Saline implant rupture can be detected by the physician and patient.
4. Primary breast augmentation surgery is not an isolated operation and implants will need to be replaced. Revisional surgery is easier with saline than with silicone gel implants.
5. Patient satisfaction is high with both types of implant.
6. The cost of saline implants is roughly half that of silicone gel implants.
7. Both implant types require additional views to adequately image the breast.

Rod J. Rohrich, M.D.

Editor-in-Chief

University of Texas Southwestern Medical Center

5309 St. Paul's Hospital, HD1.544

Dallas, Texas 75235

rjreditor_prs@plasticsurgery.org

REFERENCES

1. American Society of Plastic Surgeons. Breast Implant Survey Results, 2007. Available at www.plasticsurgery.org/medical_professionals/publications/members/psn0607/survey-reveals-acceptance-of-silicone-implants.cfm.
2. Rohrich, R. J. The FDA approves saline-filled breast implants: What does this mean for our patients? *Plast. Reconstr. Surg.* 106: 903, 2000.
3. de Camara, D. L., Sheridan, J. M., and Kammer, B. A. Rupture and aging of silicone gel breast implants. *Plast. Reconstr. Surg.* 91: 828; discussion 835, 1993.
4. Rohrich, R. J., Adams, W. P., Jr., Beran, S. J., et al. An analysis of silicone gel-filled breast implants: Diagnosis and failure rates. *Plast. Reconstr. Surg.* 102: 2304; discussion 2309, 1998.
5. Hedén, P., Nava, M. B., van Tetering, J. P. B., et al. Prevalence of rupture in Inamed silicone breast implants. *Plast. Reconstr. Surg.* 118: 303; discussion 309, 2006.
6. Mentor Corporation. *Saline-Filled Breast Implant Surgery: Making an Informed Decision*. Product Insert; Mentor Corporation, Santa Barbara, California: 2004.
7. Gutowski, K. A., Mesna, G. T., and Cunningham, B. L. Saline-filled breast implants: A Plastic Surgery Educational Foundation multicenter outcomes study. *Plast. Reconstr. Surg.* 100: 1019, 1997.

8. Hölmich, L. R., Friis, S., Fryzek, J. P., et al. Incidence of silicone breast implant rupture. *Arch. Surg.* 138: 801, 2003.
9. Rohrich, R. J., and Clark, C. P., III. Controversy over the silicone gel breast implant: Current status and clinical implications. *Texas Med.* 89: 52, 1993.
10. Cunningham, B. L., Lokeh, A., and Gutowski, K. A. Saline-filled breast implant safety and efficacy: A multicenter retrospective review. *Plast. Reconstr. Surg.* 105: 2143; discussion 2150, 2000.
11. Hedén, P., Boné, B., Murphy, D. K., Slicton, A., and Walker, P. S. Style 410 cohesive silicone breast implants: safety and effectiveness at 5 to 9 years after implantation. *Plast. Reconstr. Surg.* 118: 1281, 2006.
12. Fiala, T. G., Lee, W. P., and May, J. W., Jr. Augmentation mammoplasty: Results of a patient survey. *Ann. Plast. Surg.* 30: 503, 1993.
13. Cairns, T. S., and de Villiers, W. Capsular contracture after breast augmentation: A comparison between gel- and saline-filled prostheses. *S. Afr. Med. J.* 57: 951, 1980.
14. Handel, N., Jensen, J. A., Black, Q., Waisman, J. R., and Silverstein, M. J. The fate of breast implants: A critical analysis of complications and outcomes. *Plast. Reconstr. Surg.* 96: 1521, 1995.
15. Handel, N., Cordray, T., Gutierrez, J., and Jensen, J. A. A long-term study of outcomes, complications, and patient satisfaction with breast implants. *Plast. Reconstr. Surg.* 117: 757; discussion 768, 2006.
16. Allergan Corporation. Allergan Core Study. Product Insert; Allergan Corporation, Irving, California: 2006.
17. Sharpe, C. UK Sharpe and Collis study. Unpublished data from Mentor supplemental insert, 2006.
18. Mentor Corporation. Mentor core study results. Product Insert; Mentor Corporation, Santa Barbara, California: 2006.
19. Inamed Corporation. The large simple trial (LST). Product Insert; Allergan Corporation, Irving, California: 2002.
20. Inamed Corporation. The 1995 augmentation study (R95). Product Insert; Allergan Corporation, Irving, California: 1995.
21. Inamed Corporation. The post approval survey study (PASS). Product Insert; Allergan Corporation, Irving, California: 2005.