

Preliminary Report

Acceleration of Textured Saline Breast Implant Deflation Rate: Results and Analysis of 645 Implants

W. Grant Stevens, MD; David R. Fellows, MD, MFA; David A. Stoker, MD; and Elliot M. Hirsch

Drs. Stevens, Fellows, and Stoker are in private practice in Marina del Rey, CA.
Mr. Hirsch is at the Keck School of Medicine, University of Southern California, Los Angeles, CA.

Background: Although inflatable saline implants have been in use since 1965, few studies have examined their deflation rates over time.

Objective: We conducted a retrospective study to analyze the deflation rate for Mentor inflatable Siltex saline implants (Mentor Corp., Santa Barbara, CA) for a period of 5 years following implantation.

Methods: The study group included 645 Siltex inflatable implants placed in 324 patients for primary breast augmentation between 1992 and 1997. The implants were placed by a single surgeon using the same surgical technique. Implant data were obtained from the operative log and patient charts for a 6-year period from 1992 to 1997. All patients were followed for 5 years.

Results: The deflation rate of the implants was 0.3% within the first year of implantation, 2.2% within the first 3 years, and 5.3% over 5 years. The rate of spontaneous deflation per implant year was 0.3% at 1 year, 0.7% at 3 years, and 1.0% at 5 years. The deflation rate was lower than the expected deflation rate reported in the manufacturer's product insert data sheet.

Conclusions: The rate of spontaneous implant deflation per year was demonstrated to increase with time. Further studies are needed to ascertain the long-term deflation rates for each type of breast implant. (Aesthetic Surg J 2005;25:37-39.)

Inflatable saline implants have been in use since 1965. Although a potential complication associated with these implants is spontaneous implant deflation, few studies have been conducted to determine their deflation rate over time. There is wide disparity in implant deflation rates reported by researchers and thus no definitive data on implant longevity.¹⁻⁷

The manufacturer's product insert data sheet for the Mentor Siltex adjustable saline-filled mammary prosthesis (Mentor Corp., Santa Barbara, CA) states that the deflation rate is 1% after the first year of implantation, 3.3% within the first 3 years, and 10% within the first 5 years.⁸ It does not address the rate of deflation over more extended periods, and it is not clear whether one can

extrapolate these data over ensuing years. The product insert data sheet also does not address the difference in deflation rates between smooth and textured surface implants.⁹

Overall, the deflation rate for inflatable saline implants has been expressed variously, ranging from 1% to 34%,^{1,2,5-7,10} in reports on implants placed from 1 to 20 years. There is little data on implant deflation rates expressed as a function of years after placement. We observed that deflation of saline breast implants seemed to increase with time and designed this study as a retrospective analysis to quantitate this observation and investigate how the deflation rate of Siltex saline breast implants changes over time.

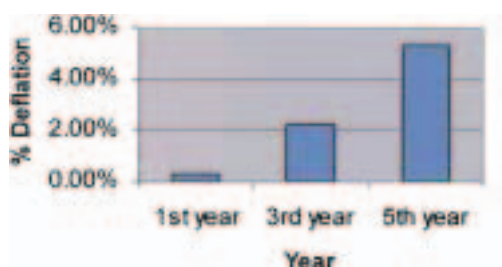


Figure 1. Implant deflation rate 1, 3, and 5 years after implantation.

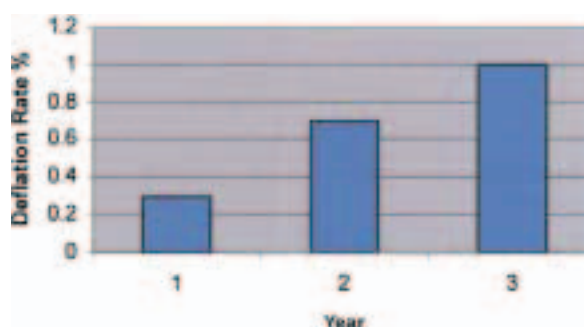


Figure 2. Implant deflation rate per implant year.

Table 1. Number of deflations within 1, 3, and 5 years after implantation

Year	Number of implantations performed	Number of deflations		
		1st Year after implantation	3rd Year after implantation	5th Year after implantation
1992	80	0	0	4
1993	66	0	3	7
1994	70	0	0	0
1995	122	0	0	0
1996	139	1	4	10
1997	168	1	6	12

Table 2. Outpatient surgery center (OSC) deflation rates versus Mentor insert data deflation rates

Year after implantation	OSC deflation rate (%)	Mentor insert data deflation rate (%)
1st Year	0.3	1
3rd Year	2.0	3
5th Year	5.1	10

Methods

Patients

This study was a retrospective analysis of 645 Siltex saline implants used for primary augmentation over a 6-year period and was conducted at a single outpatient surgery center. A single surgeon performed the primary breast augmentations, utilizing the same technique in all procedures. Data on 324 patients aged 18 to 52 years who underwent breast implant placement from January 18, 1992 to December 17, 1997 was gathered and evaluated over a 5-year period (Table 1).

Surgical technique

All surgeries were performed at an outpatient ambulatory surgery center under general anesthesia. Intravenous antibiotics were given preoperatively. Surgical incisions were made at the periareolar margin. Mentor Siltex saline implants were used in all cases. Implant size ranged from 175- to 475-cc fill volumes. Each implant was filled according to the manufacturer’s recommended volume. None of the implants was underfilled.

The implants were placed deep to the pectoralis muscle and then inflated with saline to the upper limits of the manufacturer’s recommended filling range. The pocket was then irrigated with saline and the incisions were closed in layers. The patient was placed in a supportive bra postoperatively. Strenuous activity was limited during the first 2 weeks following surgery.

Data collection

Implant data were obtained from the operative log and patient charts for Siltex saline implants placed over the 6-year period from 1992 to 1997. All patients were followed for 5 years.

Results

Of 645 implantations performed, we found an overall deflation rate of 0.3% over the first year ($P < 0.03$, Fisher exact test), 2.2% over the first 3 years ($P < 0.05$, $\chi^2 = 4.306$) and 5.3% deflation rate over 5 years ($P < 0.01$, $\chi^2 = 10.81$) (Table 1, Figure 1). All deflations were unilateral, except for 2 patients in whom implants deflated bilaterally but at different times. The earliest deflation occurred at 685 days postoperatively and the latest deflation occurred at 1666 days.

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Discussion

Our deflation rate was lower than the manufacturer's expected deflation rate (Table 2). Possible explanations for this discrepancy may include the parameters of the study, the type of implant, the surgical technique, and the 100% follow-up. Despite the lower deflation rate, however, the rising risk of deflation over time was demonstrated.

The rate of deflation per implant year increases with time, as demonstrated in Figure 2. The implication is that the Siltex saline implant deflation rate increases as the implants age and may lead to a corresponding increase over time in the rate of secondary surgical procedures, such as implant replacement or removal.

Conclusion

This study confirms that the saline implant deflation rate increases over time. Further studies are needed to ascertain the long-term deflation rates for each type of breast implant. The patient population in this study will continue to be followed in an effort to gather longer-term data.

Plastic surgeons and their patients should have accurate information regarding the anticipated longevity of inflatable saline breast implants. Discussions concerning future surgery and costs due to spontaneous deflation are an integral part of preoperative discussions. Hopefully, this study, now and in the future, will provide an addi-

tional basis for dialogue between surgeons, patients, and manufacturers.

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Reprint requests: W. Grant Stevens, MD, 4644 Lincoln Boulevard, Suite 552, Marina del Ray, CA 90292.

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