

A Comparison of 500 Prefilled Textured Saline Breast Implants versus 500 Standard Textured Saline Breast Implants: Is There a Difference in Deflation Rates?

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Background: This study provides the first large-volume (1000 implant) comparison of the deflation rates of Poly Implant Prosthesis prefilled textured saline breast implants versus a control group of Mentor Siltex textured saline implants.

Methods: A consecutive series of 500 Poly Implant Prosthesis prefilled textured saline breast implants was compared with a consecutive series of 500 Mentor Siltex breast implants. Each breast implant was evaluated for a 4-year period, and the annual deflation rate (number of deflations during a given year divided by the total number of implants) and cumulative deflation rate (cumulative total of deflations through a given year divided by the total number of implants) were recorded. Statistical significance was calculated using the Fisher's exact test at year 1 and the chi-square analysis at years 2 through 4.

Results: The cumulative deflation rates of the Poly Implant Prosthesis implants was as follows: year 1, 1.2 percent; year 2, 5.6 percent; year 3, 11.4 percent; and year 4, 15.4 percent. The cumulative deflation rates of the Mentor implants was: year 1, 0.2 percent; year 2, 0.6 percent; year 3, 1.6 percent; and year 4, 4.4 percent. At year 1, the difference between deflation rates was not statistically significant (Fisher's exact test, $p > 0.05$). However, at year 2 (chi-square, 13.29; $p < 0.001$), year 3 (chi-square, 37.91; $p < 0.001$), and year 4 (chi-square, 32.69; $p < 0.001$), the difference was statistically significant.

Conclusions: There was a statistically significant difference between the overall deflation rates of Poly Implant Prosthesis prefilled textured saline breast implants and Mentor Siltex breast implants at year 2, year 3, and year 4. After 4 years, the 15.56 percent cumulative deflation rate of Poly Implant Prosthesis implants was over 3.5 times higher than the 4.31 percent deflation rate of the Mentor Siltex implants. There may be several factors contributing to the higher deflation rate seen in Poly Implant Prosthesis implants, including possible in vitro deflation before implantation and silicone shell curing technique. Nevertheless, this statistically significant deflation difference must be taken into account when balancing the risks and benefits of Poly Implant Prosthesis breast implants. (*Plast. Reconstr. Surg.* 117: 2175, 2006.)

Throughout the nearly 40 years during which breast implants have been available to the public, there has been much debate over which materials and design constitute the best implant. In the mid 1990s, a French company named Poly Implant Prosthesis introduced prefilled, textured saline implants. These implants were appreciated by some surgeons and patients as having a softer, more natural feel. In addition, the fact that

they were prefilled was believed to save time in the operating room¹ and remove a risk factor for deflation by eliminating the "posterior plug" in the implant.²

Despite these theoretical advantages, concerns were raised with Poly Implant Prosthesis implants, especially with regard to their deflation rate. In 2000, citing "incomplete data for both the preclinical and clinical aspects of their product,"¹ the U.S. Food and Drug Administration chose to withdraw Poly Implant Prosthesis implants from U.S. markets,³ with the exception of compassionate-use protocols or revisions of previous Poly Implant Prosthesis implants.⁴ Nevertheless, the use of Poly Implant Prosthesis implants has remained popular worldwide, and Poly Implant Prosthesis is currently

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petitioning the U.S. Food and Drug Administration to permit their reentry into the United States.

At this time, there has not been a published study evaluating the deflation rates of Poly Implant Prosthesis implants against the deflation rates of other breast implants. As a comparison, previous studies of Mentor saline implants have demonstrated a 1-year deflation rate of 1.4 percent,⁵ a 3-year deflation rate of 3.3 percent,⁵ and a 5-year deflation rate between 5.5 and 8 percent.⁵⁻⁸ The goal of this study was to provide information regarding the deflation rates of Poly Implant Prosthesis prefilled textured saline breast implants as compared with standard Mentor Siltex textured saline implants.

PATIENTS AND METHODS

A consecutive series of 500 Mentor Siltex textured saline breast implants (size range, 175 to 475 ml) was compared with a consecutive series of 500 Poly Implant Prosthesis prefilled textured saline breast implants (size range, 155 to 610 ml). All implants were placed between 1996 and 2000, and each breast implant was evaluated over a 4-year period to maintain a consistent length of follow-up.

All breast implant operations were performed by the senior surgeon (W.G.S.) at the same outpatient ambulatory surgery center. All operations were performed under general anesthesia, and preoperative intravenous antibiotics were given in all cases. All implants were placed in a subpectoral plane by means of a periareolar or inframammary incision. Saline irrigation was used in each case, and contact of the implants with povidone-iodine was carefully avoided.

All of the Mentor Siltex implants were inflated to the upper limits of the manufacturer's guidelines by the surgeon to minimize rippling and fold flaws.⁹ The prefilled Poly Implant Prosthesis implants were assumed to be filled within the manufacturer's specifications and were not volumetrically evaluated at the time of implantation. The incisions were closed in layers using absorbable suture. Postoperatively, the patients

were placed in supportive bras and advised to avoid strenuous exercise for 2 weeks. All deflated implants were returned to the manufacturers for analysis. In the case of all Mentor deflated implants, the only cause of deflation was "fold-flaw failure." There were no instances of needle puncture or other means of deflation. The results of the deflated Poly Implant Prosthesis implant analysis was not returned to the authors.

The annual deflation rate was calculated by dividing the number of deflations during a given year by the total number of implants remaining at the beginning of that year. The cumulative total of deflations represents the sum of all deflations through a given year. The cumulative deflation rate was calculated by dividing the cumulative total of deflations through a given year by the total number of implants. Statistical significance was calculated with a Fisher's exact test at year 1 and with a simple chi-square analysis for the remaining years. To account for multiple testing and maintain the overall $\alpha = 0.05$ significance level, a Bonferroni correction factor was applied, and each individual test was evaluated at the $\alpha = 0.0125$ significance level to maintain an overall significance level of $\alpha = 0.05$ for the experiment.

RESULTS

The results of the Poly Implant Prosthesis implants are listed in Table 1 and the results of the Mentor series are listed in Table 2. The deflation rates are compared in Figure 1.

At year 1, the difference between the cumulative deflation rates is not statistically significant at the $\alpha = 0.0125$ significance level (Fisher's exact test, $p > 0.05$); however, at year 2 (chi-square, 13.29; $p < 0.001$), year 3 (chi-square, 37.91; $p < 0.001$), and year 4 (chi-square, 32.69; $p < 0.001$), the higher cumulative deflation rate at the end of each year of the Poly Implant Prosthesis implants versus the Mentor implants is statistically significant.

Table 1. Poly Implant Prosthesis Implants (n = 500)

Year	Deflations Each Year	Annual Deflation Rate (%)	Cumulative Total of Deflations	Cumulative Deflation Rate (%)
1	6	1.2	6	1.2
2	22	4.4	28	5.6
3	29	6.1	57	11.4
4	20	4.5	77	15.4

Table 2. Mentor Implants (n = 500)

Year	Deflations Each Year	Annual Deflation Rate (%)	Cumulative Total of Deflations	Cumulative Deflation Rate (%)
1	1	0.2	1	0.2
2	2	0.4	3	0.6
3	5	1	8	1.6
4	14	2.8	22	4.4

DISCUSSION

The results of this study clearly indicate that there is a statistically significant difference between the cumulative deflation rates of Poly Implant Prosthesis implants and Mentor Siltex implants at year 2 ($p < 0.001$), year 3 ($p < 0.001$), and year 4 ($p < 0.001$). At 4 years, the 15.56 percent deflation rate of Poly Implant Prosthesis implants is over 3.5 times higher than the 4.31 percent deflation rate of the Mentor Siltex implants.

It is unclear what accounts for the difference in deflation rates between Mentor and Poly Implant Prosthesis implants. The different silicone shell curing processes may represent one possibility. The Poly Implant Prosthesis shell is cured by high-temperature vulcanization,¹ whereas the Mentor implant shell is cured by room-temperature vulcanization.¹⁰ According to engineers at Mentor Corporation, silicone cured by high-temperature vulcanization results in a softer feel but has the unwanted potential of making the silicone abrasive and thus more prone to failure.¹⁰

Another possibility is that the Poly Implant Prosthesis implants are not retaining their volume

in vitro.¹¹ If this is indeed occurring, these implants would be underfilled at the time of implantation, which is a significant risk factor for deflation.⁹

Shell thickness between the two brands of implants is comparable (Poly Implant Prosthesis, 0.63 to 0.95 mm; Mentor, 0.38 to 0.86 mm)^{1,10}; thus, it is unlikely that this factor contributed to the different deflation rates. In addition, it is improbable that the elevated deflation rate in the Poly Implant Prosthesis implants is attributable to surgical bias, as the deflation rate of the Mentor implants is within the range suggested by current literature.⁵

CONCLUSIONS

In this large, consecutive case series, the deflation rate of Mentor Siltex implants increases with time and is consistent with previously published reports. In contrast, Poly Implant Prosthesis prefilled textured implants are 3.5 times as likely to experience rupture over a 4-year period. Further study is needed to determine the cause of this statistically significant difference in deflation rates. Until such information is available, this dif-

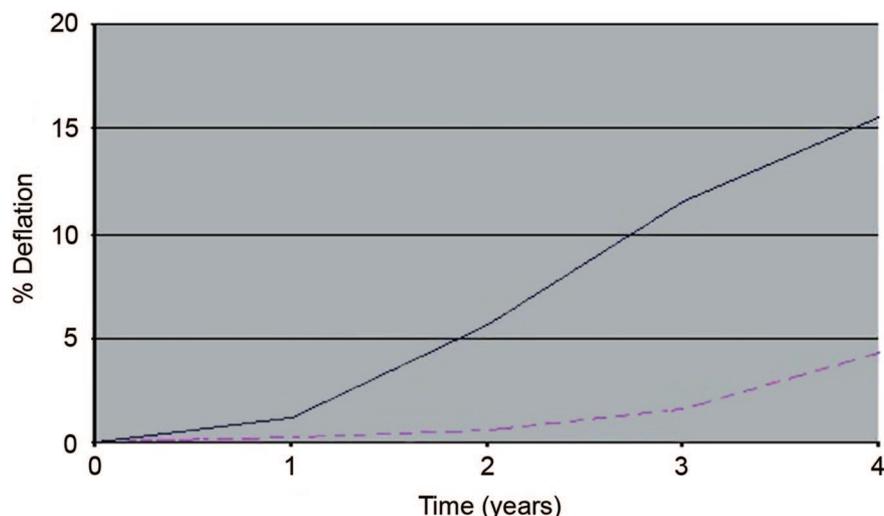


Fig. 1. Comparison of Poly Implant Prosthesis (solid blue line, n = 500) and Mentor implant (dashed pink line, n = 500) cumulative deflation rates.

ference in deflation rate must be taken into account when weighing the risks and benefits of Poly Implant Prosthesis implants.

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REFERENCES

1. United States Food and Drug Administration. Medical devices advisory committee: General and plastic surgery devices panel, minutes. Gaithersburg, Md., March 3, 2000.
2. Kirkpatrick, W., and Healy, C. Fibrous ring "pulls plug" on saline-filled implant. *Plast. Reconstr. Surg.* 108: 268, 2001.
3. United States Food and Drug Administration. FDA Breast Implant Consumer Handbook, 2004. Washington, D.C.: United States Food and Drug Administration, June 2004.
4. Poly Implant Prosthesis/PIP. America. PIP Saline Pre-Filled Breast Implants: Compassionate Use Study (Protocol #PP0201). December 2002.
5. Mentor H/S, Inc. Product insert sheet for Saline-filled and Spectrum mammary prosthesis. Mentor H/S, Inc. Santa Barbara, Calif., May 2003.
6. 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, 2000.
7. Gutowski, K. A., Mensa, G. T., and Cunningham, B. L. Saline-filled breast implants: A Plastic Surgery Educational Foundation multi-center outcomes study. *Plast. Reconstr. Surg.* 100: 1019, 1997.
8. Rheingold, L. M., Yoo, R. P., and Courtiss, E. H. Experience with 326 inflatable breast implants. *Plast. Reconstr. Surg.* 93: 118, 1994.
9. Lantieri, L. A., Roudot-Thoraval, F., Collins, E. D., et al. Incidence of underfilling on breast implant deflation. *Plast. Reconstr. Surg.* 100: 1740, 1997.
10. Stevens, W. G., and Hirsch, E. M. Personal correspondence with Mentor Corporation engineers, 2004.
11. Stevens, W. G., Hirsch, E. M., Stoker, D. A., et al. In vitro deflation of pre-filled saline breast implants. Accepted for publication in *Plast. Reconstr. Surg.*