

In Vitro Deflation of Prefilled Saline Breast Implants

W. Grant Stevens, M.D.
 Elliot M. Hirsch, B.A.
 David A. Stoker, M.D.
 Robert Cohen, M.D.

*Marina Del Rey and Los Angeles,
 Calif.*

Background: The purpose of this study was to determine whether or not prefilled breast implants retain their volume in packaging.

Methods: This study examined 32 Poly Implant Prosthesis prefilled textured saline breast implants. All of these implants were within the manufacturer's expiration date at the time of weighing. No holes were visible on any of the implants. All were weighed on an electronic scale. The measured weight was compared with the expected weight (based on the implant size as specified by the manufacturer) and the percentage deflation was calculated. The manufacturer declined to provide specific information about the manufacture dates of the implants; thus, relative age (rather than absolute age) was examined with respect to percentage deflation.

Results: Of the 32 implants examined, all showed some degree of deflation (range, 8.84 to 57.14 percent; 95 percent confidence interval of the mean, 22.01 ± 4.17 percent). There was a moderate correlation ($r = 0.41$) between relative age of the implant and percentage deflation.

Conclusions: From these results, it is clear that this type of prefilled saline breast implant does not maintain its volume in vitro. If these implants are used, the underfilling could contribute to a higher deflation rate and cosmetic deformity. This risk should be taken into account by plastic surgeons who use this type of implant in breast augmentation procedures. (*Plast. Reconstr. Surg.* 118: 347, 2006.)

Prefilled saline breast implants are purported to have several advantages over standard saline breast implants. Because they are prefilled by the manufacturer, they do not have to be filled in the operating room and thus save time and expense.¹ In addition, unless there is a manufacturer defect, there is no chance of underfilling,¹ which should reduce the incidence of deflation.²

However, it has not been determined whether prefilled saline breast implants have a finite shelf life. It is important to know whether prefilled breast implants retain their volume in packaging, because underfilling has been reported as a significant cause of implant deflation.² By examining the volume of prefilled saline breast implants and comparing it with the manufacturer's stated volume, this study examined the incidence of in vitro deflation of these implants.

From Marina Plastic Surgery Associates and the Keck School of Medicine, University of California.

Received for publication March 29, 2005; accepted June 8, 2005.

Copyright ©2006 by the American Society of Plastic Surgeons

DOI: 10.1097/01.prs.0000227674.65284.80

MATERIALS AND METHODS

This study examined 32 Poly Implant Prosthesis (Poly Implants Protheses, La Seyne-sur-Mer, France) prefilled textured saline breast implants. The implants were purchased directly from the manufacturer for the purpose of implantation. They were stored alongside other breast implants in a secure, temperature-controlled location. Only the authors and their staff had access to these implants.

Repeated verbal and written inquiries were made to the manufacturer in an attempt to determine the manufacture dates of the implants in this study. Each time, the manufacturer refused to provide the requested information but did specify that the expiration date on the packaging extends 5 years from the manufacture date. All of these implants were within the manufacturer's expiration date at the time of weighing. No holes were visible on any of the implants. All were weighed on an electronic scale (Health-O-Meter Digital PE-6 Scale; Mettler-Toledo, Inc., Columbus, Ohio; weight graduation, 2 g) after being removed from the packaging. The actual weight was compared with the expected weight (based on the implant size as specified by the manufacturer) and the percentage deflation was calculated.

Table 1. Chart of Results

No. of implants	32
Maximum deflation	57.14%
Minimum deflation	8.86%
Mean deflation	22.01%
SD	22.01% ± 12.03%
95% CI of the mean	22.01% ± 4.17%

CI, confidence interval.

Because the manufacturer declined to provide the manufacture dates of the implants, it was not possible to examine the actual age of implant versus percentage deflation. However, the relative age of the implant versus percentage deflation was

examined by setting the expiration date of the oldest implant as the starting point and then counting the months between expiration dates to determine relative age. Only 22 of the implants in this study were labeled with expiration dates; thus, all implants could not be included in this analysis. These data were plotted on a graph with percentage deflation, and linear regression analysis was performed to identify any significant correlation.

RESULTS

The results of the study are shown in Table 1 and Figure 1. There was a moderate correlation

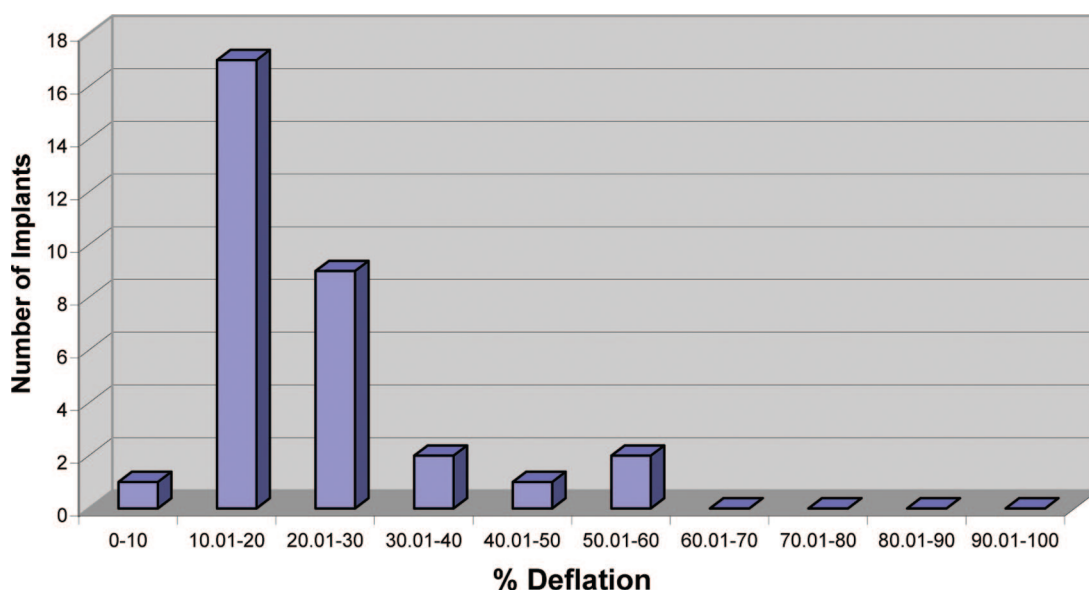


Fig. 1. Deflation distribution, blue series, Poly Implant Prosthesis implants.

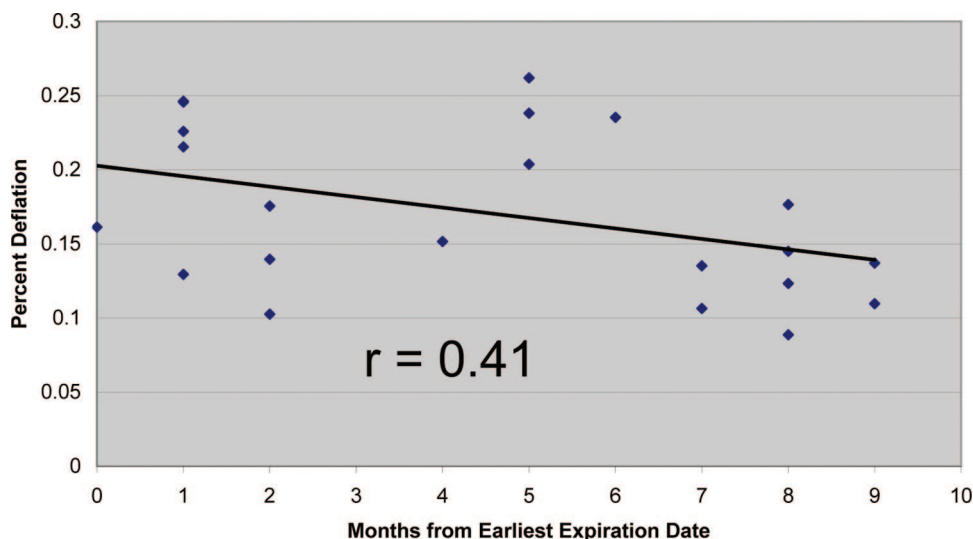


Fig. 2. Percentage deflation versus relative age. Relative age is given by months from earliest expiration date, with the earliest expiration date set as 0.

between relative age of the implant and percentage deflation, as demonstrated in Figure 2.

DISCUSSION

All of the implants in this study showed some degree of deflation (range, 8.84 to 57.14 percent). From these results, it is clear that this type of prefilled saline breast implant does not maintain its volume in vitro or is not filled properly at the factory. This in vitro deflation may occur if the packaging around the implant is not truly “air-tight.” In this situation, moisture would evaporate first through the implant and then through the packaging and the implant would lose its volume, just like any implant that is exposed to the air. The evaporation would probably not be visible within the package because it occurs relatively slowly over a period of several years. If this is indeed the cause of the volume loss, one possible solution would be to ship the implants in an isoosmotic saline bath.

CONCLUSIONS

It is important to be aware of the risk of in vitro deflation with prefilled implants. If this deflation

is not noticed and the implants are used, the underfilling could contribute to a higher deflation rate and cosmetic deformity. Plastic surgeons who use prefilled breast implants should consider this risk before using them in breast augmentation procedures.

W. Grant Stevens, M.D.

4644 Lincoln Boulevard, Suite 552
Marina del Rey, Calif. 90292
drstevens@hotmail.com

DISCLOSURES

The authors of this article have no financial interest in any of the products mentioned herein. The authors received no funding from the manufacturers of any products mentioned in this article, and have no corporate or financial affiliations with the manufacturers.

REFERENCES

1. United States Food and Drug Administration. Medical devices advisory committee: General and plastic surgery devices panel, minutes. Gaithersburg, Maryland, March 3, 2000.
2. Lantieri, L. A., Roudot-Thoraval, F., Collins, E. D., et al. Incidence of underfilling on breast implant deflation. *Plast. Reconstr. Surg.* 100: 1740, 1997.