Comparison of Breast Implant Deflation for Mentor Anterior and Posterior Valve Designs in Aesthetic and Reconstructive Patients

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Background: Saline breast implant rupture remains problematic after implan- tation. Company reports and previous studies implicate the valve as a common site of implant failure. This study evaluates the rupture rate of the Mentor posterior valve compared with the anterior valve in breast augmentation and reconstruction.

Methods: This is a retrospective analysis of consecutive breast implantations per- formed between 1992 and 2004 by two surgeons. All but two implants were filled at or above the manufacturer-recommended volume. Data were collected by chart review, telephone survey, and Mentor Corp. reports. Kaplan-Meier and Mantel- Haenszel analyses were used to compare rupture rate and relative risks, respectively. Results: Sufficient data were available for 516 implants in 325 women (average follow-up, 6.04 years). Overall, those implants with posterior valves had a lower rupture rate (0.007 versus 0.022). In the reconstructive cohort, the posterior valve implants had a lower rupture rate (0.011 versus 0.036), and the relative risk of rupture using an anterior valve versus a posterior valve was 3.387 ($p = 0.0154$). There was no significant difference in rupture rate between valve types in breast augmen- tation. A multivariate analysis showed that implant texture did not affect rupture rate.

Conclusions: The authors found a statistically significant decrease in implant rup- ture for Mentor posterior valve implants in the reconstructive cohort and no difference in the augmentation cohort. Thus, the authors conclude that at worst, the posterior valve is not more prone to rupture than the anterior valve model. Furthermore, the authors believe that the postoperative flexibility of the posterior valve implants makes them more useful clinically. *(Plast. Reconstr. Surg.* 122: 685, 2008.)

According to statistics from the American Society of Plastic Surgeons, hundreds of thousands of breast implants are placed for aesthetic and reconstructive purposes each year,' and along with their placement comes the complication of rupture. Despite their wide acceptance and usage, the rupture of saline *breast implants continues to be problematic in their clinical use.2 The rupture of saline implants, unlike their silicone predecessor, is always cosmetically obvious;

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ure,6 underfilling of the implant leading to fold flaw failure,7-13 and direct trauma to the implant.14 One factor that we believe has led to a decrease in the saline implant rupture rate and allowed for better postoperative flexibility in our clinical prac- tice is the use of a new valve type.

At Northwestern Memorial Hospital and Pren- tice Women's Hospital, we use primarily Mentor saline breast implants (Mentor Corp., Santa Bar- bara, Calif.) for aesthetic and reconstructive pur- poses. Originally, we only used Mentor anterior diaphragm single-valve implants (Fig. 1); however, starting in 1996, we began to use a Mentor pos-

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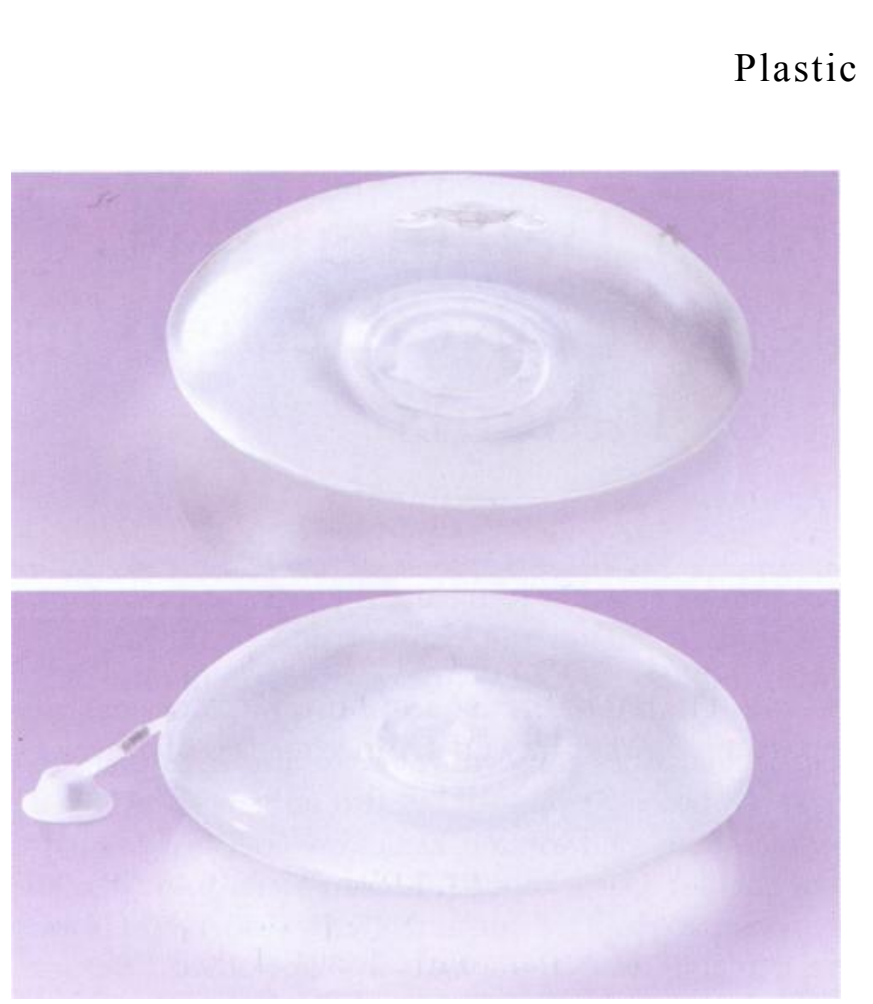

Fig. 1. *(Above)* Mentor anterior valve saline implant. *(Below)* Mentor posterior valve saline implant.

tenor self-sealing double-valve adjustable implant (Spectrum) because of its postoperative flexibility (Fig. 1). On changing to a posterior adjustable valve, we began to notice a decreased rate of implant rup- ture. Given that other variables remained con- stant, we hypothesized that the posterior valve de- sign was less prone to rupture than the anterior valve design. Furthermore, even if the rupture rate was equal to that of the anterior valve model, we felt their postoperative flexibility made them more useful in certain aesthetic and reconstructive situations.15,16 The Mentor posterior valve models have three sealing mechanisms: kink valve, leaf valve, and plug. The posterior valve also has a preplaced tube on the posterior side of the im- plant connected to a remote injection dome that is attached using connectors. This dome allows volume adjustment intraoperatively and postop- eratively. A plug cap fits into the end of the fill tube, and once the fill tube breaks from the cap and is removed, the valve kinks 4 cm inside the device (manufacturer-acquired information).

The anterior valve design, in contrast, has a sin- gle diaphragm valve. The fill tube has a small plastic tip that is inserted into the valve. When removed, the valve has a plug that closes automatically at the im- plant surface. An implant with a diaphragm valve can only be filled intraoperatively.

This study seeks to compare deflation rates between two different models of saline implants from the Mentor Corporation: a posterior self-

sealing double valve and an anterior diaphragm single-valve design. This study is based on the case- load of two experienced surgeons at a single in- stitution in both a cosmetic and reconstructive setting. Our hypothesis is that the posterior valve design model does not increase implant rupture rates in breast reconstruction or augmentation and offers the potential for postoperative adjust- ments because of its improved valve design.

PATIENT& AND METHODS

Study Design

This is a retrospective study consisting of con- secutive breast implantations by two attending sur- geons between January of 1992 and November of 2004 at Northwestern Memorial Hospital and Prentice Women's Hospital. Institutional review board approval was obtained before commence- ment of the study.

Follow-up on implant rupture was obtained by a combination of (1) a standardized telephone questionnaire to evaluate whether and when an implant rupture occurred, (2) office chart review, and (3) record of physician and patient self-re- ports of implant rupture to Mentor Corp. The telephone interviews included a standardized con- sent and questionnaire administered by a fourth- year medical student. Patients were told that their participation was optional. Next, all charts were reviewed to corroborate the phone data and to supplement information about those who were unreachable. Finally, a Mentor representative pro- vided a list of all ruptures reported by patient or physician. These Mentor data allowed the capture of patients who might not have felt comfortable reporting their rupture to their original surgeon or those seeking care at other centers. All of the data from these three sources were then trans- ferred to a master sheet that was coded in a man- ner to remove patient identities and ensure pa- tient confidentiality. These coded data were then reviewed with the principal investigator and epi- demiologists.

For breast augmentation patients who were not contacted or who did not follow up after 2 years, the Mentor reports were used as the defin- itive determination of rupture. This is based on the incentive of self-pay patients to report ruptures either to a physician or directly to Mentor Corp., whose policy is to replace ruptured implants free of charge. Patients having undergone reconstruc- tive operations do not share the same incentive for self-report of rupture, because their operations

were funded by insurance, and this assumption was not made.

Statistical Analysis

Statistical analysis was performed using Stata version 9.2 (Stata Corp., College Station, Texas) and SPSS version 15.0 software (SPSS, Inc., Chi- cago, Ill.). Survival time analysis was used to cal- culate the rupture rate per total number of years at risk for all implants. Kaplan-Meier analyses were used to determine anterior and posterior valve implant actuarial survival at given years out from the date of surgery. For deflation analysis, the data were divided into reconstructive implants and aug- mentation implants. The anterior and posterior valve implants were then compared under each of these subdivisions. All comparisons of Kaplan- Meier curves were performed using the log rank test. A life table of cumulative freedom from rup- ture was also calculated for each yearly interval. This Kaplan-Meier and log rank analysis allowed us to control for the differences in average fol- low-up between valve types. A Mantel-Haenszel es- timate of the rupture rate relative risk ratio was also calculated along with the p value. Finally, a multivariable Cox regression analysis was per- formed to evaluate the relative risk of rupture when taking implant texture into account. Signif- icance was set at $p < 0.05$. Statistical analyses were performed in the Biostatistics Core Facility of the Robert H. Lurie Comprehensive Cancer Center and at the University of Michigan M-Score Center (Michigan Surgical Collaborative for Outcomes Research and Evaluation).

Surgical Methods

All expander reconstructions were performed using textured, anatomically shaped expanders placed immediately after a skin-sparing mastec- tomy. At the second stage, a complete capsulot- omy was performed as necessary and the final implant was placed. All final implants placed were filled enough to remove all visible wrinkling. With the exception of two implants, all implants were filled to 100 percent or more of their recom- mended fill volume as set by Mentor. For patients with a posterior valve, the volumes were often ad- justed after the exchange in a clinic setting to improve symmetry or eliminate wrinkling. The pa- tients who had an implant placed after a latissimus or transverse rectus abdominis myocutaneous (TRAM) flap procedure had either a single-step reconstruction performed or an adjustable port added to the posterior valve Spectrum implant to allow for later adjustment. When adjustable ports were used, they were removed at the time of nipple reconstruction.

RESULTS

Based on our inclusion criteria, a total of 676 women were identified who had surgery between January of 1992 and June of 2004. To ensure at least 2 years' follow-up, all women who had surgery after June of 2002 were removed. Of this original capture set, 325 women and 516 implants had sufficient follow-up by the methods listed above (Table 1). Each breast implant was considered separately and followed from the day of implan- tation until the end date of the study or the date of explantation. Consistency of treatment was pro- vided between both surgeons, who used similar operative techniques and postoperative protocols. Both implant models had identical shell compo- sition and filler and nearly equal fill volumes (av- erage fill volume, 110.0 percent for posterior valve and 107.3 percent for anterior valve implants). All patients were given similar postoperative instruc- tions regarding follow-up and signs of implant rupture.

Anterior and posterior valve implants were stratified into those used for breast augmentation and those used for breast reconstruction. Three hundred forty-one implants were placed for aes- thetic purposes and 175 were placed for recon- structive purposes (Table 1). Reconstructive im- plants were those placed to correct a breast disfigured by cancer surgery. Reconstructive cases included three types: (1) implant placement fol- lowing tissue expander (n = 116 implants), (2) implant use in latissimus dorsi breast reconstruc- tion (n = 31 implants), and (3) implant use in TRAM flap breast reconstruction (n = 16 im- plants); 12 were unknown based on our records. Reconstructions with muscle coverage were di- vided evenly between the anterior and posterior valve groups. Follow-up ranged from 2 to 12 years, with the median time to follow-up of our entire cohort being 6.04 years.

In total, there were sufficient data on 43 im- plants that had ruptured. Analyzing all implants, there was a higher rupture rate in those patients

	Posterior Valve	Anterior Valve	Total
Aesthetic	258	83	341
Reconstructive	92	83	175
Total	350	166	516

with the anterior valve of 2.2 ruptures per 100 implants (0.022) versus the posterior valve of 0.7 ruptures per 100 implants (0.007) (Table 2). We then used a Mantel-Haenszel analysis to calculate the relative risk of a rupture when using an ante- rior valve instead of a posterior valve, which was 2.996 ($p = 0.001$) (Table 3). A log rank test for survival by valve type shows that the difference in rupture rate over time is statistically significant (Fig. 2). Whereas the Mantel-Haenszel calculation analyzes relative risk overall, a Cox regression anal- ysis allows us to look at different variables simul- taneously, such as valve type and texture. Our mul- tivariable Cox regression analysis looked at valve type and texture type and showed that the anterior valve did have a 3.82 higher rate of rupture than the posterior valve when controlling for the texture ($p = 0.05$) (Table 4). At the same time, it shows that the risk of rupture using a smooth implant is only 1.25 higher than with a Siltex implant, and this did not reach statistical significance ($p = 0.71$).

The data were further substratified to look at the rupture rate for reconstructive and augmen- tation patients independently based on valve type. For reconstructive implants, the rupture rate in posterior valve implants was lower than that in the anterior valve model (Table 2). Overall, the Man- tel-Haenszel estimate, controlling for time, showed that the relative risk of using an anterior valve versus a posterior valve was 3.387 ($p = 0.001$) (Table 3). A Kaplan-Meier analysis demonstrated that rupture rates at all time periods were also greater in this case for patients who had an anterior valve implant (Fig. 3). A log rank analysis showed that this differ- ence was statistically significant (Fig. 3). These rup- ture rates compare favorably to rupture rates for breast reconstruction quoted by the Mentor-spon- sored studies in their patient handout (Table 5).17

A similar survival analysis was completed look- ing only at augmentation implants. The rupture rates per year for anterior and posterior valve im- plants were 0.006 and 0.010, respectively (Table 2). Overall, the Mantel-Haenszel estimate, control- ling for time, showed a relative risk of 1.704 ($p =$

Table 3. Relative Risk of Rupture of Anterior versus Posterior Valve Implants for Implants Controlling for Time

Implant Cohort	Relative Risk*	χ^2	p Value	95% CI
All implants	2.996	10.83	0.001	1.507–5.953
Reconstructive implants	3.387	5.87	0.015	1.187–9.670
Aesthetic implants	1.704	1.06	0.303	0.609–4.735

CI, confidence interval.
*Man tel-Haenszel estimate.

0.303) of rupture when using anterior as opposed to posterior valve design (Table 3). When com- paring the rupture rate at various time points, there is little divergence between the two valve designs, and a log rank analysis of the survival curves failed to show a statistically significant dif- ference (Fig. 4). Again, the survival data can be compared with the data originally reported by Mentor for augmentation implants (Table 5).

DISCUSSION

It was our hypothesis based on clinical expe- rience that Mentor adjustable self-sealing poste- rior valve implants were not more prone to rup- ture compared with the anterior valve implants in breast augmentation and reconstruction surgery. In our analysis, this hypothesis was confirmed when looking at the entire cohort and when look- ing specifically at the reconstruction-only or aug- mentation-only cohorts. By controlling for shell texture, filler material, fill volumes, and tech- niques, we believe the valve was the main differ- ence between the two models. Thus, we believe our data prove that the posterior valve design was at least equal to the anterior valve design with respect to the complication of implant rupture in breast reconstruction and augmentation.

Previous studies have shown that similar ad- justable implants can be used in single-stage re- construction with reasonable outcomes.18-2° This is the first study that we

Table 2. Rupture Rate Based on Valve Type

Implant Cohort	Valve Type	No. of Ruptures	Rupture Rate*	95% CI
All implants	Posterior	13	0.007	0.004–0.013
	Anterior	30	0.022	0.015–0.032
Reconstructive implants	Posterior	5	0.011	0.0046–0.026
	Anterior	23	0.036	0.0239–0.054
Aesthetic implants	Posterior	8	0.006	0.003–0.013
	Anterior	7	0.010	0.005–0.021

CI, confidence interval.
*Rupture rate is based on total number of years at risk.

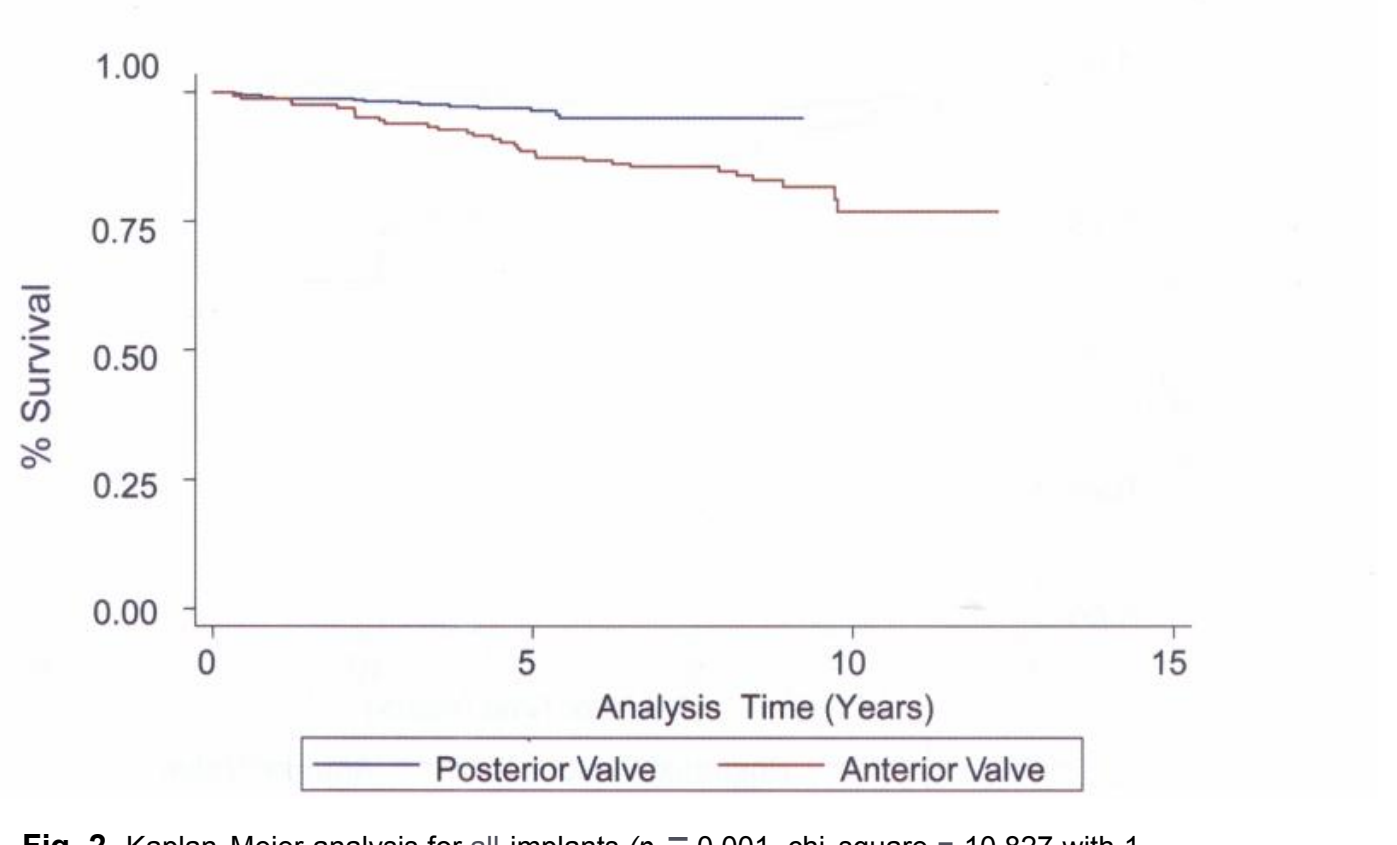

Fig. 2. Kaplan-Meier analysis for all implants ($p = 0.001$, chi-square = 10.827 with 1 degree of freedom).

Table 4. Multivariable Cox Analysis of Valve Type and Texture Type

	B	SE	p	Exp (B)
Posterior valve	0.00			1.00
Anterior valve	1.34	0.69	0.05	3.82
Siltex	0.00			1.00
Smooth	0.22	0.584	0.71	1.25

B, parameter estimate; SE, standard error; p, significance; Exp (B), risk ratio.

tenor valve implants to Mentor anterior valve im- plants for reconstructive and aesthetic purposes. Previous reports of saline implant rupture rates have ranged from 5.5 to 23.9 percent, with differences in follow-up ranging from 1 to 10 years.15'21-25 We be- lieve our 7-year rupture rates with our posterior valve model of 5.8 and 4.95 percent for recon- structive and augmentation operations, respec- tively, compare well with previous studies.

One particular stress on a valve that can cause failure is scar formation. Histologic examination of explanted breast implants has shown a dense collagenous capsule and alignment of the colla- gen fibers in the capsule.26 If the forces of the scar formation organize in a specific manner, it is pos- sible for this to create a stress on the valve. Saline implants can rupture because of a fibrous ring forming around the "valve sealing plug," putting force on the valve and allowing the saline to leak from the implant, as has been reported by Slavin and Kirkpatrick.27 The current posterior valve models have three sealing mechanisms: kink valve, leaf valve, and plug. Once the fill valve is removed,

we prefer the location of the valve in the posterior valve model because it is seated 4 cm inside the implant. This means the actual fill valve is 4 cm from the location of the anterior valve. For tissue ingrowth to occur, the tissue would have to travel 4 cm into the implant.

Scarring is also believed to exacerbate areas of stress, such as a fold flaw in the implant. We know from previous studies that underfilling implants is associated with an increased rupture rate likely sec- ondary to fold flaws.9"-15 For this reason, we rou- tinely fill our implants at or above the recommended fill volume. Although we do not know whether our ruptures were because of fold flaws, the fact that the two valve groups had similar fill volumes (110 per- cent for posterior valve and 107 percent for anterior valve implants) makes it unlikely that fill volume is a confounder. Furthermore, when reviewing our data, only two implants had volumes filled less than the manufacturer-recommended volume (neither of which ruptured). At the same time, however, signif- icant overfilling can create scalloping around the periphery of the implant, demonstrating the need for an "optimal" fill volume." Thus, we fill all of our implants to completely eliminate all visible wrin- kling. We also know that, even when we fill our implants to this volume, wrinkling can occur post- operatively. Thus, we feel that an added benefit of the posterior valve model is that volume can be added to or removed from the implant after it is placed to eliminate any folds that become apparent postoperatively.28

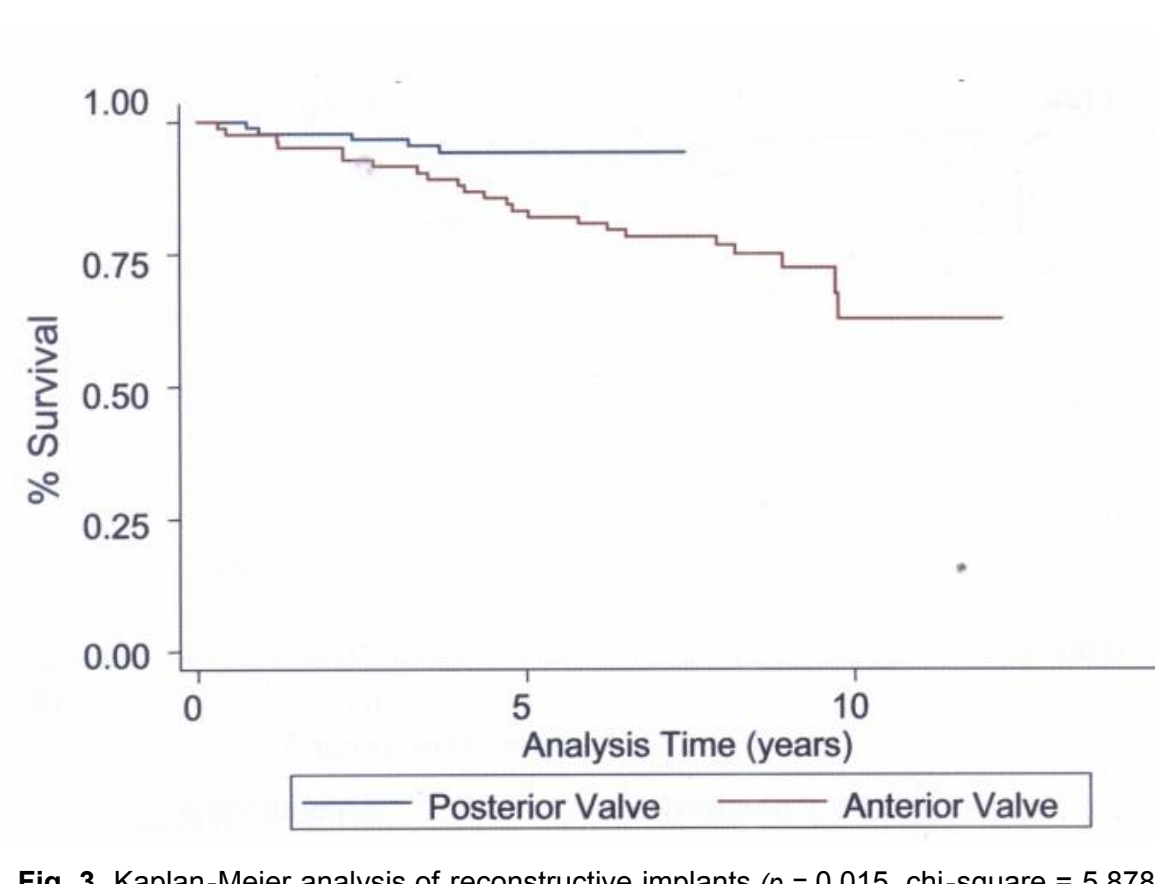

Fig. 3. Kaplan-Meier analysis of reconstructive implants ($p = 0.015$, chi-square = 5.878 with 1 degree of freedom).

Table 5. Cumulative Rupture Rate Organized by Years after Implantation for Breast Reconstruction and Breast Augmentation

		Current Study	
Time after Implantation (yr)	Mentor Study (%)*	Posterior Valve (%)	Anterior Valve (%)
Reconstructive implants			
1	NA	2.17	2.41
3	9	5.8	8.4
5	18	5.8	16.9
7	27	5.8	21.7
Aesthetic implants			
1	1	0.78	0
3	3	1.58	3.61
5	10	4.95	7.23
7	16	4.95	7.23

NA, not applicable.
*Mentor data from company-sponsored clinical trials.

Other benefits of the postoperative flexibility of the posterior valve have shaped our clinical practice. Such valve mechanisms allow saline to be added to or removed from the implant after sur- gery in the clinic. This is especially helpful for unequal size breasts or for the patient who changes her mind about the size with which she is comfortable.29-" Furthermore, we have found this useful in the following patient populations:

1. Patients after latissimus dorsi reconstruction for whom matching the breast to the oppo- site side is challenging because of swelling.
2. Patients with breast asymmetry (e.g., Poland syndrome and breast differences).

3. Patients with specific desires for symmetry.
4. Breast augmentation patients who are un- sure of the size they desire.
5. Patients who had removal of subglandular sil- icone implants because of contracture and now want submuscular saline breast implants.
6. Patients who want a single-stage reconstruc- tion with an implant.

A previous study discussed other instances where permanent expandable implants were ad- vantageous: pregnancy with capsular contracture, contralateral progressive ptosis, tubular breast, mammographic examination, and rippling.'7 Pre- vious studies published analyzing rupture rate of saline implants are multi-institutional and include multiple implants and techniques, leaving them open to selection bias. There is no true technique that is standardized for a breast implant; however, by analyzing the outcomes of only two surgeons using only two implant devices in this study, we feel that overall we have appropriate "standardization" and consistency.5'32

Despite general consistency in our procedures and the fact that most of the reconstructions were performed using tissue expanders, some of our implants were placed along with a TRAM recon- struction or latissimus reconstruction. We did not have large enough numbers to specifically analyze how the additional muscle coverage affected our outcomes. Interestingly, none of the posterior valve implants ruptured in the muscle coverage group, whereas close to half of the anterior valve implants

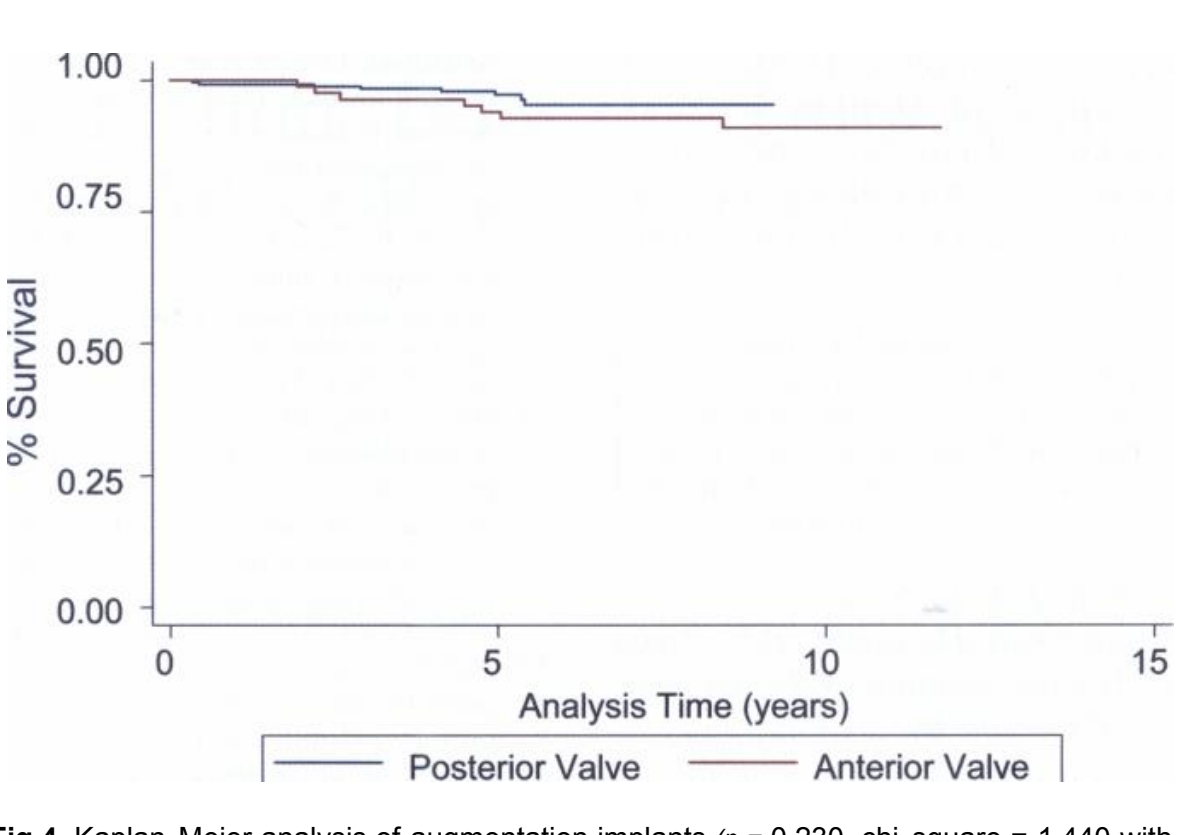

Fig.4. Kaplan-Meier analysis of augmentation implants ($p = 0.230$, chi-square = 1.440 with 1 degree of freedom).

with muscle coverage had a rupture, which may be an area to research further.

Another variable in this study was texture type, as both smooth and textured implants were used in our reconstructive cohort. When controlling for valve type, there was no statistical difference in the rupture rate between the two texture types (Table 4). Other larger studies, however, have shown texture to increase the rupture rate of sa- line breast implants.35

A problem with studies analyzing rupture rate (including this study) is that the rupture rate var- ies at different time points of the study.33-35 Be- cause the anterior valve models have been in use longer, we have more anterior valve implants with longer follow-up data. We believe we controlled for this by using a Kaplan-Meier and log rank analyses, which control for time (Figs. 2 through 4).

Another potential problematic issue is that our study is a retrospective review rather than a pro- spective, randomized, controlled study. Despite being a retrospective analysis, we do believe the insights this study offers are worthwhile. We un- derwent great efforts to overcome the limits of a retrospective study by using the experience of only two surgeons at one institution and requiring at least 2 years' follow-up. Also, we went beyond a patient questionnaire and used a total of three methods of data collection. At first, telephone questionnaires were administered to obtain the most recent status of the implant. We then verified and supplemented this information with patient charts. The third check involved going over Men-

tor records of implant ruptures that they receive regardless of the clinician they follow up with. We assume that, because Mentor offers free implants for a ruptured implant in aesthetic patients, the patients would have an incentive to report any rupture. In reality, however, it is possible that they would choose a different provider and ask for a different model without reporting this to anyone.

Finally, we feel that the data would be more meaningful if our database had more consistent fol- low-up on a greater number of patients. Perhaps in the near future, with larger national databases, we will be able to obtain a clearer conclusion.

CONCLUSIONS

This large, single-institution, retrospective study compares two different saline breast implant valve types to assess their effect on rupture rate. We found a statistically significant decrease in im- plant rupture for Mentor posterior valve implants in the reconstructive cohort and no difference in the augmentation cohort. Being a retrospective study, however, these findings may not be repro- ducible in a randomized controlled setting. We conclude that our findings support the belief that Mentor posterior valve implants are not more sus- ceptible to rupture than the anterior valve models in breast reconstruction and augmentation. We prefer the posterior valve model because we do not find a disadvantage with respect to rupture rate and it allows postoperative size adjustment. This postoperative flexibility is extremely useful in certain reconstructive and augmentation settings

and in decreasing implant rippling. Further stud- ies with larger numbers of Mentor implants, more involved tracking of patients, and longer follow-up would give us a better idea of the true relation and perhaps insight into the mechanics of a posterior valve.

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