

Analysis of Risk Factors Associated with Rupture of Silicone Gel Breast Implants

Lu-Jean Feng, M.D., and Saeid B. Amini, Ph.D., M.B.A., J.D.

Cleveland, Ohio

Despite many recent studies on breast implant rupture, there is no general consensus on causation or incidence. Existing studies have not reported a multivariate analysis of risk factors associated with breast implant rupture. Most studies lack adequate sample size to study the effect of implant type, manufacturer, and other patient-related factors that might affect rupture. This study addresses all of these shortcomings.

Patients undergoing implant removal by a single surgeon between 1990 and 1996 were examined for rupture and for 16 potential risk factors. The association between rupture and various factors was analyzed by univariate and multivariate analyses.

A total of 842 patients underwent removal of 1619 implants. Increasing age of implant [$p < 0.0001$; adjusted odds ratio (OR), 1.20; 95% confidence interval (CI), 1.15 to 1.23], retroglandular location ($p = 0.0002$; OR, 1.93; CI, 1.37 to 2.71), Baker contracture grades III and IV ($p = 0.005$; OR, 1.52; CI, 1.14 to 2.03), and presence of local symptoms ($p = 0.05$; OR, 1.37; CI, 1.00 to 1.89) were associated with rupture. When different implant types were compared with smooth gel implants, after adjustment, double-lumen ($p < 0.0001$; OR, 0.33; CI, 0.22 to 0.50) and polyurethane-covered implants ($p < 0.0002$; OR, 0.33; CI, 0.20 to 0.57) had significantly lower rupture rates. When various manufacturers were compared with Dow Corning after adjusting for other factors, rupture rates were significantly lower for McGhan ($p < 0.0001$; OR, 0.41; CI, 0.26 to 0.65), whereas higher for Surgitek ($p < 0.019$; OR, 1.52; CI, 1.05 to 2.18).

Significant risk factors for breast implant rupture were identified: older implants, retroglandular implant location, implant contracture, local symptoms, certain implant type, and certain manufacturer. Although the results of this study are based on a nonrandomized explant population from a single surgeon's practice, knowledge of these risk factors will permit better interpretation of future data on rupture. The knowledge will enable the medical community to better advise their breast implant population regarding durability and appropriate time for removal or replacement. (*Plast. Reconstr. Surg.* 104: 955, 1999.)

Silicone gel-filled breast implants have been used for breast augmentation and reconstruction since 1962. Long-term durability of these implants has remained controversial. The gold standard for identifying implant rupture has been removal and examination of the implant.¹ Reported rates of rupture have varied from 4 percent² to 63 percent.³ One reason for the wide variability has been variable definitions of rupture.^{3,4} One study included only large tears in its definition of rupture,⁴ whereas another study excluded both large and pinhole ruptures.³ Differences in the length of implantation at the time of the implant study have been another source for variability. Duration of implantation has been implicated in several studies as a factor contributing to rupture.³⁻¹¹ Studies with younger implants (mean, 4 years) have lower rates of rupture,^{2,12} whereas studies with older implants (mean, 11 years) have higher rates of rupture.³⁻¹¹

Another source for variability has been the implantation year of the removed implants. There has been an evolution in the design and manufacturing of single-lumen, smooth-shell, silicone gel-filled implants (smooth gel) since 1962.¹³ The first-generation implants were composed of a firm gel with a thick elastomeric wall. Because of high contracture rates in these implants, a second generation of implants was introduced in 1972, which had a softer gel and a thinner wall. Because surgeons observed greater rupture and bleed from them,¹⁴ the manufacturers responded with a number of third-generation implants after 1979, which

From the Section of Microvascular Surgery/Division of Plastic Surgery, Mount Sinai Medical Center, and the Department of Epidemiology and Biostatistics, Case Western Reserve University School of Medicine. Received for publication January 7, 1999; revised March 3, 1999.

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had a stronger shell.¹³ No previous study has had sufficient sample size to stratify these implants into different generations to study their life span. In addition, previous studies did not have sufficient sample size to study the effects of different types and manufacturers³ on rupture.

Causes of rupture could depend on patient, implant, and environmental factors in varying degrees. When a number of factors were examined for their relationship to rupture in previous studies,^{3,5} none had used the appropriate multivariate analysis based on the Generalized Estimation Equation. This analysis allows for examination of multi-level association among factors and adjustment of confounding factors such as length of implantation. In the present study, we have used a large sample size, applied a consistent definition of rupture, stratified the database into different implant groups, and used both univariate and multivariate regression analyses to examine 16 potential risk factors and interactions simultaneously for the purpose of determining the factors contributing to rupture.

MATERIALS AND METHODS

Patient Population

This study included 842 consecutive patients, representing 1619 implants, from a single surgeon's practice. Patients underwent implant removal of a silicone implant from 1990 through 1996 by the same surgeon. None of the implants, except in two patients, were inserted by the removal surgeon. Removal of sponge implants and of other nonsilicone implants was excluded. Patients elected to undergo explantation for the presence of local symptoms (84 percent of patients), contracture (58 percent), suspected implant rupture (33 percent), and presence of systemic symptoms thought by the patient to be related to her implants (86 percent). Proportion of patients who had both local (breast) and systemic symptoms was 74 percent; 12 percent of patients had systemic symptoms only; 10 percent had local symptoms only; and 4 percent had no local or systemic symptoms. Patients with systemic symptoms usually requested bilateral implant removal. Patients with local symptoms on one side requested either unilateral or bilateral implant removal, depending on the aesthetic goals.

Implant Outcome Data

During implant removal, all patients underwent an extracapsular dissection to remove the implant and scar capsule together. Each implant was examined for rupture after removal of scar capsule on a specimen table in the operating room. This protocol was followed to prevent iatrogenic rupture of the implant during removal.

Diagnosis of implant rupture required two inclusive criteria: implants with gel present diffusely on the surface of the implant shell, and visualization of a tear in the implant shell. For double-lumen implants, both shells had to be ruptured before they could present a uniform layer of gel on their surfaces. This definition of rupture was applied to all implants removed since 1990.

Patient-Related Factors

A number of factors were hypothesized to be related to implant rupture. Data on these factors were collected during the patient's initial history and physical examination since mid-1991. Any missing demographic information from patients seen in 1990 to 1991 was collected subsequently during follow-up examinations and telephone interviews. Patients were asked during initial consultation to fill out a questionnaire regarding their significant local and systemic symptoms. Other patient-related factors documented were reason for implantation, incision type for original implantation, and location of implant. Contracture was graded preoperatively from I to IV, according to the Baker classification. Patients with contracture grades III and IV were considered to have significant contracture. Any tenderness on palpation of the breast implant was also recorded in the patient's chart.

Implant-Related Factors

These factors included implant insertion year, implantation length (from year of insertion to year of removal), and implant type. Implants were divided into nine types: single-lumen gel-filled smooth shell (56 percent of the implants), single-lumen polyurethane-covered (14 percent), double-lumen smooth shell (13 percent), single-lumen gel-filled with fixation patch (7 percent), single-lumen gel-filled textured shell (4 percent), single-lumen saline-filled smooth shell (3 percent), single-lumen saline-filled textured shell (2 percent),

double-lumen textured shell (1 percent), and others (1 percent). We were not able to identify the implant type in four implants (0.2 percent of implants). Saline implants (both smooth and textured) and textured double-lumen implants were excluded from the comparison of rupture rates of different type implants because of the small numbers present in the study.

Implant manufacturers included Dow Corning (32 percent of implants), Surgitek (16 percent), McGhan (13 percent), Heyer Schulte (12 percent), Natural Y (10 percent; Natural Y is a distributor name for several manufacturers of the polyurethane implant), Mentor (6 percent), Cox Uphoff (4 percent), Bristol Meyers (2 percent), and others (1 percent). Source of implant manufacturer information came from the operative record, attorneys' records, and direct identification of the removed implant by surgeon or outside expert. We were not able to identify the manufacturer in 80 implants (<5 percent of implants). Four of the unidentified implants were half of a pair of implants, with the source of the other half identified. In these four patients, the implants were inserted in different years, as a result of subsequent replacements. During comparison of different manufacturers, only the smooth gel implants were included in the comparison. Because both Natural Y and Bristol Meyers represented the polyurethane-covered implants, they were not included in the comparison.

Extrinsic Factors

These factors included all potentially traumatic factors extrinsic to the implant such as closed capsulotomy, compression mammogram, and trauma to the breast. We also included radiation and calcification of the capsule as extrinsic factors.

Confirmation of Implant Rupture

Most patients (91 percent) underwent either xeromammogram, ultrasound, or both studies preoperatively for diagnosis of implant integrity. The radiologist's diagnosis of implant integrity was made independently before the intraoperative diagnosis. There were two types of implant ruptures: intracapsular and extracapsular. Intracapsular rupture is rupture contained by the capsule. Extracapsular rupture is defined by a ruptured implant surrounded by silicone granuloma, which may be present contiguous to the capsule or distant from it. Dur-

ing analysis, implant rupture included both intracapsular and extracapsular ruptures. Radiologic and pathologic diagnoses on implant integrity were also collected and compared with the intraoperative diagnoses.

Statistical Analyses

The unit of analysis used was either patient or implant, depending on the hypothesis of interest. Demographic and patient-specific information such as age were considered patient based. Implant-related information such as type and manufacturer of implants, length of implantation, implant integrity, and presence of contracture were analyzed based on the implant level data. Rupture status, as diagnosed at the time of explantation, was considered as the dependent variable.

Both univariate and multivariate analyses were used. The continuous variables were described as the mean and standard deviation. The nominal and ordinal data were reported as proportions and percentages. Chi-square analysis was used to identify the univariate association between the rupture status and type, manufacturer, symptoms, contracture, and four implant generations. Mann-Whitney U and Kruskal-Wallis statistics were used for univariate association of continuous variables such as length of implantation. McNemar statistics were used to measure the association between rupture diagnosis by two methods (e.g., ultrasound versus at surgery).

The multivariate Generalized Estimation Equation¹⁵ logistic-regression analysis was used to identify independent predictors of implant rupture. This method allows for use of implant-level information while accounting for the correlation between two implants from the same patient. Specifically, by using the Generalized Estimation Equation, the multivariate association between implant integrity and 16 variables was assessed simultaneously by taking into account the dependency between the implants of the same patient. The multivariate analysis was also used to compare the implant rupture rates between manufacturers and implant types. In these analyses, we adjusted for implant type, manufacturer, duration of implantation, contracture, and other confounding variables. All statistical tests were two-sided, and a variable was considered statistically significant if the corresponding *p* value was less than 0.05. All statistical analyses were performed using main

frame computer Statistical Analysis System (SAS) version 6.12.¹⁶

RESULTS

Patient Profile

Mean age of patients who underwent explantation was 46 ± 9 years (range, 23 to 75 years). Mean length of implantation was 11 ± 6 years (range, 1 to 30 years). Year of implantation ranged from 1962 to 1995. Figure 1 shows the age distribution of the implants removed. Augmentation was the reason for implantation in 69.5 percent of implants; 30.5 percent were for reconstructive purposes (reconstruction after subcutaneous mastectomy, 22.4 percent; reconstruction after cancer mastectomy, 5.8 percent; and reconstruction for congenital hypoplasia, 2.3 percent). The retroglanular location was associated with 67.4 percent of implants; the rest of the implants (32.6 percent) came from a retropectoral location. One-third of implants (32.9 percent) had no contracture (Baker I or II); two-thirds of the implants had significant contracture (Baker III or IV). Eighty-seven percent of implants originated from patients with systemic symptoms; 71 percent from patients with local symptoms; 20 percent from breasts that were tender on examination; and 6 percent from patients with no local or systemic symptoms. Twenty-three percent of implants had a history of closed capsulotomy; 47 percent had a history of com-

pression mammogram; 6 percent had a history of blunt trauma; and 1 percent were implanted into irradiated tissue.

Confirmation of Implant Rupture

Among the 1619 implants removed, 57 percent were intact and 43 percent were ruptured (36 percent intracapsular, 7 percent extracapsular rupture). Preoperatively, 1303 implants were studied with a xeromammogram, and 816 implants were subjected to an ultrasound study. Xeromammographic diagnosis of implant integrity demonstrated an accuracy of 84 percent, positive predictive value of 93 percent, negative predictive value of 80 percent, sensitivity of 80 percent, and specificity of 93 percent. Ultrasound diagnosis of implant integrity demonstrated an accuracy of 86 percent, positive predictive value of 89 percent, negative predictive value of 82 percent, sensitivity of 72 percent, and specificity of 94 percent.

Univariate Analysis (Chi-Square)

Relation of time to rupture. Figure 2 shows the effect of length of implantation on rupture in all implants, with time expressed in multiple year intervals (unadjusted). Increasing rates of rupture were noted with increasing length of implantation. More than 50 percent of the implants were ruptured by the 10- to 14-year interval. The highest rupture rate occurred in the 15- to 19-year interval. This time corresponded

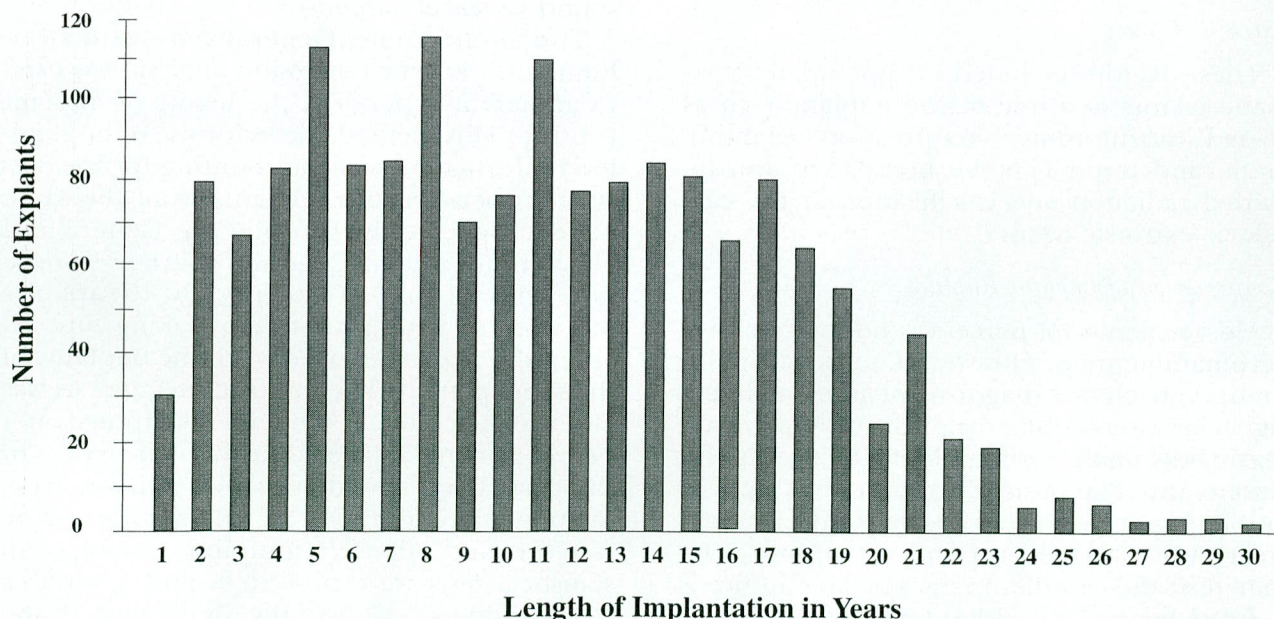


FIG. 1. Distribution of number of explants by length of implantation for the entire explantation series. Total number of explants = 1619.

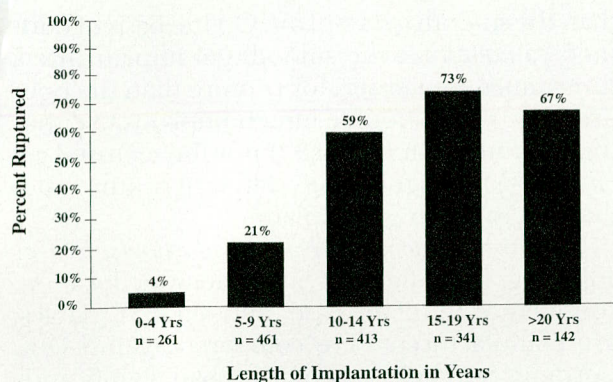


FIG. 2. Percentage of ruptured implants over five periods by length of implantation. Chi-square analysis demonstrates significant differences among different lengths of implantation ($p = 0.001$). n = number of implants. Total number of implants = 1618.

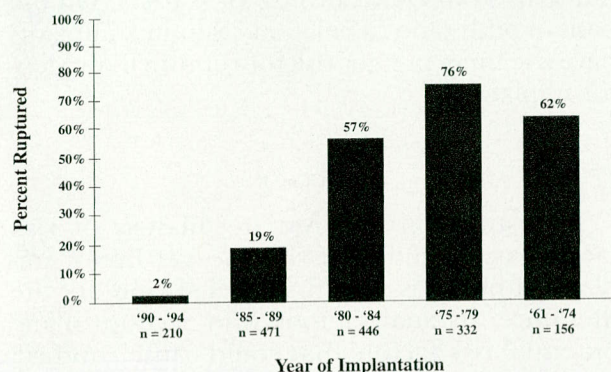


FIG. 3. Percentage of ruptured implants over 5-year intervals of implantation for all implants. Chi-square analysis demonstrates significant differences among different implantation year intervals ($p = 0.001$). Highest rupture rate occurred in the 1975 to 1979 year interval, probably because of the use of thinner shell implants at the time. n = number of implants. Total number of implants = 1615.

to the period when thinner shell implants were being implanted. Figure 3 shows the effect of year of implantation on rupture (unadjusted), demonstrating the increased rupture rates in the 1975 to 1979 implantation years.

Relationship of contracture and location to rupture. Figure 4 shows the effect of increasing contracture grade of the implant on rupture rate of the implant. The rate of rupture among patients with contracture (grades III and IV) was significantly higher than that for patients without contracture ($p = 0.001$). Figure 5 shows the effect of implant location on rupture. Retroglandular location of the implant was significantly associated with greater rupture than the retropectoral location ($p = 0.002$).

Relationship of symptoms to rupture. Systemic symptoms were not shown to be associated with rupture ($p = 0.2$); neither was tenderness on

examination ($p = 0.2$) (Fig. 6). Local symptoms around the breast, experienced commonly as burning pain, were not shown to be associated with rupture by univariate analysis (chi-square test, $p = 0.7$), but they were shown to be associated with rupture in the multivariate analysis (Table I).

Relationship of implant type to rupture. Figure 7 shows the effect of length of implantation on rupture in three different types of implants, with time expressed in multiple-year intervals. All showed increasing rates of rupture with increasing length of implantation. Both the double-lumen and polyurethane implants had lower rates of rupture than the smooth gel implants. The Dacron patch implant (Fig. 8) was an exception. Its lowest rupture rate was in the >20-year interval. The lower rate for the >20-

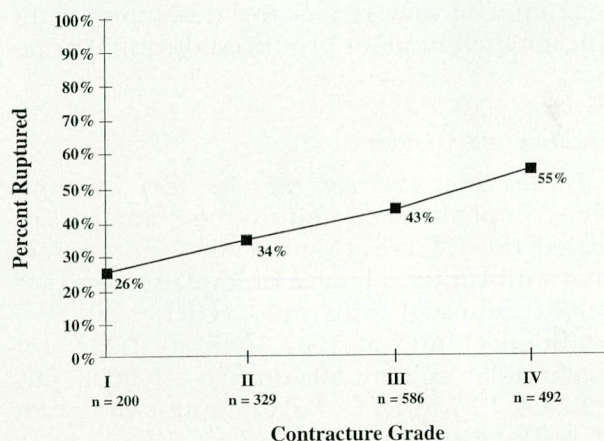


FIG. 4. Percentage of ruptured implants by contracture grade. There are increasing numbers of ruptures associated with greater contracture grades (chi-square analysis, $p = 0.001$). n = number of implants.

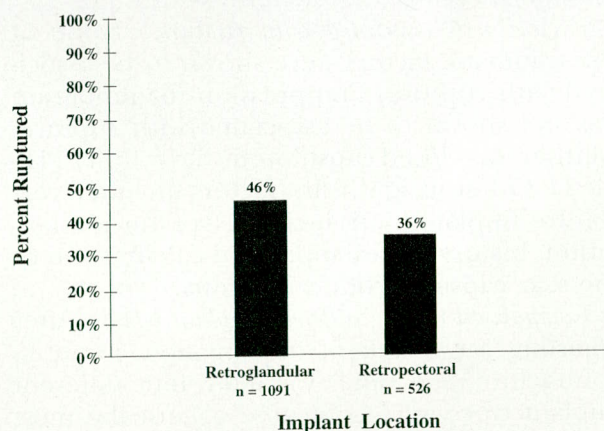


FIG. 5. Percentage of ruptured implants by location of implant. There is greater incidence of rupture associated with the retroglandular location (chi-square $p = 0.002$). n = number of implants.

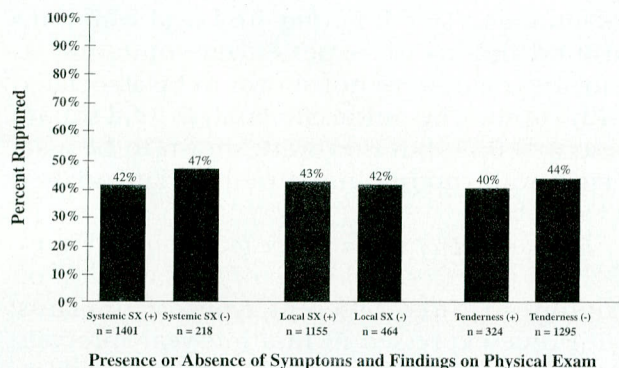


FIG. 6. Percentage of ruptured implants by presence (+) or absence (-) of systemic or local symptoms and local tenderness. Per chi-square analysis, there is no significant relation between presence or absence of systemic or local symptoms to rupture: systemic symptoms versus rupture, $p = 0.2$; local symptoms versus rupture, $p = 0.7$; tenderness versus rupture, $p = 0.2$. n = number of implants. SX, symptoms.

year interval may reflect the durability of the thicker shell implant produced during that period.

Multivariate Analysis

Factors associated with rupture. For the complete implant data, multivariate analysis revealed the following significant factors associated with rupture: length of implantation [$p < 0.0001$; adjusted odds ratio (OR), 1.20; 95% confidence interval (CI), 1.15 to 1.23], retroglanular implant location ($p = 0.0002$; OR, 1.93; CI, 1.37 to 2.71), Baker contracture grade III or IV ($p = 0.005$; OR, 1.52; CI, 1.14 to 2.03), presence of local symptoms ($p = 0.05$; OR, 1.37; CI 1.00 to 1.89), certain implant type, and manufacturer. Regardless of the implant type and manufacturer, the adjusted rupture rate of any implant increased significantly with time.

Factors not associated with rupture. None of the traumatic factors were shown to be associated with rupture. Compression mammogram was not shown to be associated with rupture. Neither was closed capsulotomy ($p = 0.11$) (Table I). Other insignificant factors included reason for implantation, incision type for implantation, history of radiation, and calcification of the scar capsule around implants.

Comparison among different implant types. After adjusting for length of implantation, location, contracture, and other variables, four different implant types were compared against the most common type, the smooth-shell single-lumen gel-filled type (smooth gel) (Table II). The polyurethane ($p < 0.0002$) and double-lumen implants ($p < 0.0001$) both had significantly fewer ruptures

than the smooth gel implant. On the basis of odds ratio calculations, the smooth gel implant has a three times greater risk for rupture than the polyurethane or the double-lumen implants. Neither the Dacron patch ($p = 0.33$) nor the textured gel ($p = 0.11$) had significantly different rupture rates than the smooth gel implants.

Comparison among different manufacturers. After adjusting for length of implantation, location, contracture, implant type, and other variables, five manufacturers were compared against Dow Corning. Surgitek ($p < 0.019$) had significantly higher rupture rates, whereas McGhan ($p < 0.0001$), Mentor ($p < 0.0004$), and Cox Uphoff ($p < 0.018$) had significantly lower rupture rates (Table III). Heyer Schulte was not significantly different from Dow Corning ($p = 0.41$). On the basis of odds ratio calculations, Surgitek implants have five times greater risk for rupture than Mentor implants.

DISCUSSION

This study on multivariate analysis of risk factors associated with silicone gel breast implant rupture is the first of its kind in the literature. Its analysis took into account many potential risk factors that could cause rupture: implant-related, patient-related, and extrinsic factors. The results of this study demonstrated that implant-related factors (length of implantation, implant type, and manufacturer) and patient-related factors (contracture, implant location, and local symptoms) are far more important than extrinsic factors (trauma, compression mammogram, closed capsulotomy) in predicting risk of rupture among patients who had their implants removed.

The implication of length of implantation as a risk factor for rupture is not surprising. Most studies on implant rupture, whether from a breast implant revisional series^{2,7-9,12} or explantation series,^{3-6,10} have demonstrated increasing rupture rates with older implants. There may be two explanations for this observation. Progressive lipid infiltration of the silicone shell in older implants has been implicated as a possible cause of implant aging.¹⁷ The older implant design from the second implant generation (1975 to 1979) involving the use of thinner shells has also been implicated as a cause for the rupture of older implants.

The exception is the Dacron patch implant, which had a thicker shell design between 1962 and 1974. The relative durability of this thicker

TABLE I
Multivariate Analysis: Significant Factors Associated with Rupture

Parameter	Odds Ratio	95% Confidence Limits		p Value
		Lower	Upper	
Time*	1.20	1.15	1.23	<0.0001
Retroglandular pocket	1.93	1.37	2.71	<0.0003
Contracture grade III/IV	1.52	1.14	2.03	<0.005
Local symptoms	1.37	1.00	1.89	0.05
History of closed capsulotomy	1.31	0.94	1.82	0.11
Systemic symptoms	0.74	0.49	1.12	0.15
Reason for implantation	0.83	0.59	1.16	0.27
Tenderness on physical examination	0.84	0.61	1.15	0.27

* Time is treated as a continuous variable with the unit of time being length of implantation in 1-year increments. It was measured as calendar year of implantation minus 1962. Time is treated as both an outcome and a confounding variable. When assessing the effect of other factors on rupture, time was considered as a confounding variable. Risk of silicone gel breast implant rupture is significantly associated with increasing length of implantation, contracture grade, retroglandular location, and presence of local symptoms.

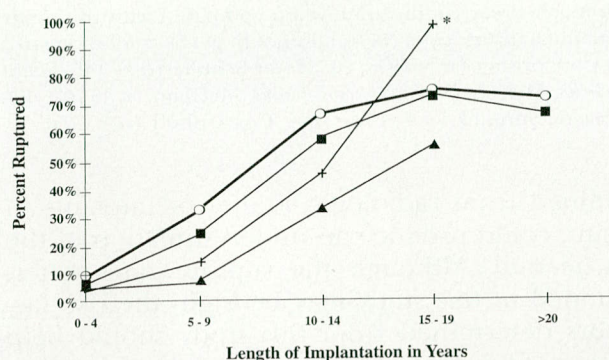


FIG. 7. Percentage of ruptured implants of different types and lengths of implantation. The asterisk denotes small sample size (two implants) of that particular data point. Rupture rates increase with increasing length of implantation for smooth gel, double-lumen, and polyurethane implants. The smooth gel implants have higher rates of rupture than the other two types. Circles, all implants ($n = 1618$); squares, smooth gel ($n = 899$); pluses, double lumen ($n = 210$); triangles, polyurethane ($n = 233$).

shell implant may be responsible for the drop in rupture rate in the >20-year and 1962 to 1974 implantation groups (Figs. 2 and 3, respectively, and 8). When the thinner-shell variety of the Dacron patch implant was introduced in the later years, it tore more easily. The rupture rate of this implant, which was made later, actually increased instead of decreased, as was the trend in all other types of implants (see Fig. 8).

Very little information has been published regarding the comparison of rupture rates among different manufacturers. The process of obtaining manufacturer information was difficult, until the filing of class action lawsuits that required information on manufacturers. Because the smooth gel implant remains the most common type in most published studies and in our sample group, we used this implant type to compare the rupture rate among man-

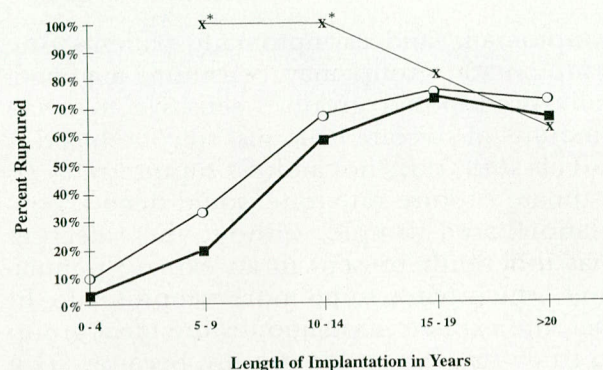


FIG. 8. Percentage rupture of Dacron patch versus smooth gel implants and length of implantation. An asterisk denotes small sample size (<10 implants) of that particular data point. Dacron patch implants seem to have a different rupture pattern with respect to length of implantation. The later Dacron patch implants have a thinner shell and tear frequently at the patch shell junction. The earlier Dacron patch implants have a much thicker shell and seemed to be more resistant to rupture. Circles, all implants ($n = 1618$); squares, smooth gel ($n = 899$); Xs, Dacron patch ($n = 108$).

ufacturers. This study shows that there are significant differences among manufacturers; however, implants from all manufacturers studied have increasing rupture rates with time (Fig. 9). Although in our study we were unable to determine the origin of these differences among manufacturers, the increase in rupture rate is most likely related to variations in implant design such as shell thickness and shell strength.

It is of interest that the presence of systemic symptoms was not shown to be associated with rupture. Assuming that the systemic symptoms reported here by patients were uniquely associated with silicone gel breast implants, then our data suggest that development of systemic symptoms is not related to rupture of the implant. Because rupture can be present in both

TABLE II

Multivariate Analysis: Comparison of Smooth-Shell, Gel-Filled, Single-Lumen Implants with Other Implants Types

Parameter*	Odds Ratio	95% Confidence Limits		p Value
		Lower	Upper	
Smooth gel (899)	—	—	—	—
Double lumen (210)	0.33	0.22	0.50	<0.0001
Polyurethane (233)	0.33	0.20	0.57	<0.0002
Textured gel (60)	0.46	0.18	1.20	0.11
Dacron patch (108)	0.77	0.38	1.56	0.33

* Numbers in parentheses refer to number of implants in each category. All implant types were compared to the smooth gel implant, after adjusting for length of implantation, location, contracture, manufacturer, and other variables. The double-lumen and the polyurethane implants have significantly less risk of rupture than the smooth gel implants.

symptomatic and asymptomatic patients, the symptomatic group may constitute a genetically predisposed group,¹⁹ sensitive to small amounts of silicone from just silicone bleed.

This study does not address rupture rate. To estimate rupture rate, one would need a population-based sample, without the selection bias inherently present in an explant population, which tends to be more symptomatic. In fact, the explant population is the ideal group to study risk factors for rupture because (1) a more accurate diagnosis of rupture can be made by direct examination of the implant surgery, (2) there are more cases of rupture, and (3) information on the implants such as type and manufacturer can be ascertained more exactly. On the other hand, because the sensitivity of magnetic resonance imaging examination for both intracapsular and extracapsular ruptures is much lower than that of direct examination of the implant at surgery,¹⁶ any population-based study on rupture, deter-

TABLE III

Multivariate Analysis: Comparison of Dow Corning Implants with Other Manufacturers

Parameter*	Odds Ratio	95% Confidence Limits		p Value
		Lower	Upper	
Dow Corning (391)	—	—	—	—
McGhan (70)	0.41	0.26	0.65	<0.0001
Mentor (33)	0.29	0.12	0.69	<0.004
Cox Uphoff (37)	0.42	0.21	0.84	<0.018
Heyer Schulte (145)	1.15	0.75	1.77	0.41
Surgitek (158)	1.52	1.05	2.18	<0.019

* Numbers in parentheses refer to number of smooth-shell, gel-filled implants only. All five manufacturers were compared against Dow Corning. Only smooth gel implants are used in this comparison. After adjusting for length of implantation, implant location, contracture grade, and other variables, Surgitek had an increased risk for rupture, whereas McGhan, Mentor, and Cox Uphoff had significantly lower risk for rupture.

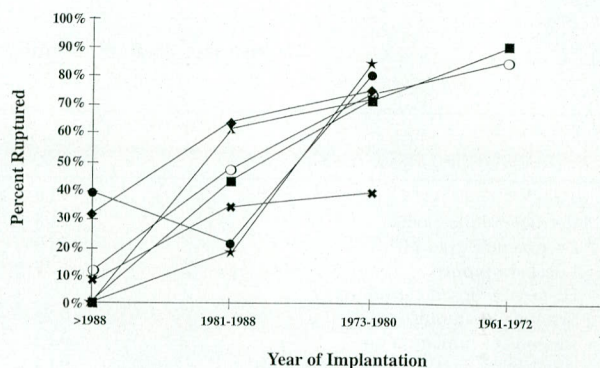


FIG. 9. Percentage of ruptured implants by manufacturer and implantation year in smooth gel implants, grouped by evolution in implant design. All manufacturers have increasing rupture rates with older implants. McGhan seems to have a much lower rupture rate when compared with the other manufacturers. Open circles, all smooth gel ($n = 899$); squares, Dow Corning ($n = 391$); Xs, Heyer Schulte ($n = 145$); filled circles, Mentor ($n = 33$); cross-marks, McGhan ($n = 70$); diamonds, Surgitek ($n = 158$); stars, Cox Uphoff ($n = 37$).

mined from radiologic studies of implants in situ, could produce an underestimation of the true rate. Although the rupture rates determined in this study may be high, the risk factors determined from this study should help patients and clinicians assess risk of implant rupture in a symptomatic patient and thus, determine the appropriate time for replacement or removal. For example, patients with greater than 10 years of implantation, implants placed before 1984, contracted single-lumen gel-filled implants located in retroglanular pocket whose manufacturers are Surgitek, Dow Corning, or Heyer Schulte will have a higher risk of rupture than those without these factors. This study should also help manufacturers better assess durability of different types of implants after long implantation times to improve future designs.

Lu-Jean Feng, M.D.
Division of Plastic Surgery
Mt. Sinai Medical Center
One Mt. Sinai Drive
Cleveland, Ohio 44106
drfeng@aol.com

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