Long-Term Safety and Efficacy of Polyurethane Foam-Covered Breast Implants

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Background: Polyurethane foam-covered silicone gel-filled breast implants, introduced in the 1970s, were used in more than 110,000 American women. Because of concerns about possible toxicity, they were withdrawn from the US market in 1991. These implants remain popular in many parts of the world.

Objective: The goal of this study was to evaluate long-term experience with polyurethane foam-covered implants and compare outcomes and complication rates with other types of implants.

Methods: This population-based study was comprised of all individuals receiving either polyurethane breast implants (n = 568) or other types of silicone gel-filled breast implants (n = 963) for augmentation, reconstruction, or secondary revision surgery between 1981 and 2004 (23 years). A prospective implant database was established and maintained in Microsoft Excel (Redmond, WA). Data were extracted from chart review and questionnaires mailed to 719 patients (response rate, 48%). Various parameters, including infections, hematomas, excessive waviness, capsular contracture, rupture, systemic side effects, reoperation rates, and patient satisfaction were monitored. Statistical analysis was performed using SAS 9.1 (SAS Institute, Cary, NC).

Results: The incidence of capsular contracture was dramatically lower with polyurethane foam-covered implants compared to smooth or mechanically textured implants; this beneficial effect persisted at least 10 years after implantation. Aside from a transient skin rash, there was no increase in morbidity or complications associated with polyurethane implants.

Conclusions: Polyurethane foam-covered implants result in long-term reduction in the risk of capsular contracture and appear to have a safety profile similar to other silicone gel-filled devices. (Aesthetic Surg J 2006;26:265-274.)
June 2004 (the date when the study was terminated). All operations were performed by one of two board-certified plastic surgeons who used similar surgical techniques and followed the same protocols for postoperative management.

Implant recipients fell into one of three categories. “Augmentation” included all patients receiving implant(s) (with or without mastopexy) for cosmetic reasons. “Reconstruction” included patients receiving implants to restore a breast after cancer treatment. “Revision” included all patients undergoing secondary implant procedures, regardless of the original indication for surgery. To obtain maximum follow-up, implant recipients were provided with indefinite postoperative visits at no charge. Patients were never “discharged” or told to “return prn”; after the first anniversary of surgery, they were given annual follow-up appointments.

A prospective breast implant database was established in January 1990. To collect data on implants inserted prior to that date, charts of all patients implanted between March 1981 (first use of polyurethane implants) and December 1989 were reviewed. Information extracted included patient demographics, details of the surgical procedure, type of implant used, early and late complications, degree of contracture at intervals, and laboratory and mammographic findings. The database was updated in 2003 and 2004 by performing a comprehensive review of all available charts.

Implant recipients were invited to return annually for follow-up, but many patients from earlier years had not presented for recent examination. An “implant questionnaire,” designed in collaboration with the University of California–Los Angeles (UCLA) Department of Biomathematics, was sent out between May 2003 and May 2004. Questionnaires were mailed to 719 patients; 265 questionnaires were “nondeliverable,” 454 individuals received the mailing, and 216 (48%) returned the questionnaire.

Each implant was considered separately and tracked from insertion until the date of explantation or most recent follow-up visit. Capsular contracture was graded using the “Baker Scale.” Baker grade 1 or 2 capsules were defined as contracture-free and Baker grade 3 or 4 capsules, as having contracture. The date of onset was the date a Baker 3/4 capsule was first noted in the medical record. For patients who self-reported contracture (via the questionnaire), the date of onset was considered to be the date the questionnaire was completed. Contracture rates were expressed as incidence (Baker 3 or 4) per 1000 patient-months of observation.

Hematoma was diagnosed when there was significantly greater than expected bruising, swelling, and firmness of the breast, or if surgical exploration revealed excessive blood around the implant. Infection was diagnosed if abnormal swelling, erythema, tenderness, and fever were present that either resolved with antibiotics or required explantation. Culture and sensitivity studies were obtained when possible to confirm suspected infections. The diagnosis of skin rash was based on clinical observation. Untoward outcomes, such as excessive waviness or

Figure 1. A, Polyurethane foam-covered silicone gel-filled breast implant. B, Scanning electron microscopic view of the open-cell polyurethane foam.
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rippling, were diagnosed when the degree of deformity was beyond what would normally be expected in a particular setting, required surgical revision, or was reported by patients as being problematic. Implant rupture was based on direct observation of leaking silicone gel at the time of explantation. The diagnosis of gel-implant rupture was not made from mammography, ultrasound, or magnetic resonance imaging (MRI) findings.

Reoperation rates, as well as indications for revision, were determined from chart review. Patient satisfaction was ascertained from medical records and responses to the questionnaire. Patients were asked to rate their overall satisfaction on a 5-point scale (1, least satisfied; 5, most satisfied).

The database was constructed and maintained in Microsoft Excel (Redmond, WA) and statistical analysis was performed using SAS 9.1 (SAS Institute, Cary, NC). Outcomes were compared among surgical procedures as well as different surfaces, including smooth, mechanically textured, and polyurethane foam-covered. For comparing the incidence of contracture over time, the Kaplan-Meier method of survival analysis (the log-rank test) was used. The assumption was made that when implants are placed bilaterally, each is independent of the other with regard to the risk of contracture; this is in accordance with the current prevailing view.8 Because there were multiple levels of procedures and surfaces, the overall log-rank tests did not spotlight where differences occurred. Additional log-rank tests were made to compare only 2 of the groups at a time. These are reported after the overall tests among the multiple groups.

For short-term outcomes such as infection, overall comparisons were made using chi-square tests for differences in percentages across the multiple groups. For these outcomes, 2 of the groups were compared by using contrast statements in logistic regression. The P values from these contrasts are reported after the overall chi-square tests, showing one P value for each 2-group comparison. For patient satisfaction, measured on a 5-point scale, nonparametric statistics were used. For the overall model, the Kruskal-Wallis test was used. Additional comparisons between 2 groups were made using the Wilcoxon rank sum test.

Results
This study yielded information on 719 patients who received 1531 breast implants. Five hundred sixty-eight polyurethane foam-covered implants were used in 305 patients, 345 smooth gel-filled implants in 156 patients, and 618 mechanically textured gel-filled implants in 289 patients (Table 1). In some patients, multiple implants of one type or implants of differing types were used successively. Occasionally, an analyzed measure had missing data for a few implants, which were therefore excluded from counts as deemed appropriate. Follow-up ranged from zero to 236 months (19.6 years), with a mean follow-up (per implant) of 37.3 months.

The incidence of contracture was studied as a function of implant surface type for all surgical procedures combined and for various subcategories (augmentation, reconstruction, and revision). The contracture rate (number of Baker 3/4 capsules per 1000 patient-months) for all procedures combined was 6.29 with smooth implants, 3.03 with textured implants, and 2.19 with polyurethane foam-covered implants. The combined contracture rates and rates by subcategories are summarized in Table 2. The risk of developing contracture over time is depicted using the Kaplan-Meier method (Figure 2).

Polyurethane foam conferred a significant reduction in risk of developing capsular contracture compared to smooth or textured implants; there was no significant difference in contracture rate between smooth and textured implants (log-rank test, \( P < .0009; \) polyurethane vs smooth, \( P = .0003; \) polyurethane vs textured, \( P = .0159; \) smooth vs textured, \( P = .1093 \)).

Hematoma occurred in 3 of 345 (0.9%) smooth implants, 10 of 618 (1.6%) textured implants, and 13 of 568 (2.3%) polyurethane foam-covered implants.
implants. Chi-square analysis and pairwise tests showed no significant difference in the incidence of hematoma as a function of implant surface texture (chi-square, $P = .2686$). Infection occurred in 4 of 345 (1.2%) smooth implants, 20 of 618 (3.2%) textured implants, and 11 of 568 (1.9%) polyurethane implants; there was no significant difference in the risk of infection as a result of surface texture (chi-square, $P = .0922$).

Excessive waviness and/or rippling occurred in 42 of 345 (12.2%) smooth implants, 80 of 618 (12.9%) textured implants, and 38 of 568 (6.7%) polyurethane implants; there was no significant difference in the risk of infection as a result of surface texture (chi-square, $P = .0922$).

Excessive waviness and/or rippling occurred in 42 of 345 (12.2%) smooth implants, 80 of 618 (12.9%) textured implants, and 38 of 568 (6.7%) polyurethane foam-covered implants (chi-square, $P = .0010$). Pairwise tests indicated that polyurethane implants were statistically different from each of the other 2 groups ($P = .0051$ vs smooth; $P = .0004$ vs textured) (Table 3).

Implant rupture occurred in 1 of 345 (0.3%) smooth implants, 6 of 618 (1.0%) textured implants, and 8 of 568 (1.4%) polyurethane foam-covered implants. When the incidence of rupture was divided by the duration of follow-up, the rate was 0.145 ruptures per 1000 patient-months for smooth implants, 0.308 for textured implants, and 0.260 for polyurethane implants (log-rank test, $P = .2730$).

The reoperation rate (for any reason) was 48 of 345 (13.9%) with smooth implants, 98 of 618 (15.9%) with textured implants, and 125 of 568 (22.0%) with polyurethane foam-covered implants. Mean duration between surgery and subsequent revision was similar for smooth implants (19.5 months) and textured implants (27.2 months), but significantly longer for polyurethane implants (47.8 months) (analysis of variance [ANOVA] $P = .0001$; pairwise $P = .0003$ for polyurethane vs textured) (Table 4).

Skin rashes, which occurred in association with only the polyurethane foam-covered implants, generally began within 2 weeks of surgery, were characterized by diffuse erythema and pruritis, and subsided spontaneously within 2 to 4 weeks. Skin rash occurred in association with 36 of 559 (6.4%) polyurethane implants.

Overall patient satisfaction was high, with the mean satisfaction score (scale of 1 to 5) being 4.1. There were no statistically significant differences in patient satisfaction across surface types (Kruskal-Wallis test $P = .0961$).

### Table 2. Contracture rates*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Smooth</th>
<th>Polyurethane foam</th>
<th>Textured</th>
<th>All surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmentation</td>
<td>6.63</td>
<td>1.29</td>
<td>0.90</td>
<td>1.72</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>6.67</td>
<td>2.81</td>
<td>3.79</td>
<td>3.07</td>
</tr>
<tr>
<td>Revision</td>
<td>6.14</td>
<td>2.58</td>
<td>3.94</td>
<td>3.64</td>
</tr>
<tr>
<td>All surgery types</td>
<td>6.29</td>
<td>2.19</td>
<td>3.03</td>
<td>2.96</td>
</tr>
</tbody>
</table>

*No. Baker 3/4 per 1000 patient-months follow-up.

### Table 3. Excessive waviness and rippling*

<table>
<thead>
<tr>
<th>Surface type</th>
<th>Number</th>
<th>No. wavy or rippling (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth</td>
<td>345</td>
<td>42 (12.2)</td>
</tr>
<tr>
<td>Textured</td>
<td>618</td>
<td>80 (12.9)</td>
</tr>
<tr>
<td>Polyurethane</td>
<td>568</td>
<td>38 (6.7)</td>
</tr>
</tbody>
</table>

*Overall, $P = .0010$; polyurethane versus smooth, $P = .0051$; polyurethane versus textured, $P = .0004$. 

**Figure 2.** Kaplan-Meier analysis of capsular contracture over time as a function of implant surface type.
Adverse outcomes related to breast implants may conveniently be divided into “local” complications and “systemic” side effects. Local complications include infection, hematoma, skin rash, capsular contracture, and abnormal skin rippling, implant rupture, and silicone leakage. Systemic complications include toxicity, allergic and immune reactions, and potential carcinogenicity.

Local complications associated with polyurethane implants

With the exception of capsular contracture and skin rashes, the profile of local side effects and complications was similar among smooth, textured, and polyurethane foam-covered implants.

Infection. Infections occur in less than 1% of breast augmentations and at a slightly higher rate in breast reconstruction and secondary revision surgery. Among our patients, we found no difference in the rate of infection as a function of surface texture. In a review of the literature, Brand found infection rates were similar regardless of surface, after both augmentation and breast reconstruction. There have been sporadic case reports of infections around polyurethane implants and concern that the porous foam might harbor pathogens and prove more susceptible to infection. Repeated studies, however, document that the infection rate associated with polyurethane implants is comparable to that associated with other devices.

Hematoma. The incidence of hematoma among our patients was similar regardless of implant surface texture. This is consistent with previous reports. Treatment of hematoma in a patient with a polyurethane implant poses no particular difficulty. Occasionally, blood will dissect between the elastomer shell and the overlying polyurethane, causing delamination of the foam layer.

Implant rupture. In our series, the risk of rupture of silicone gel-filled implants was unrelated to surface texture. This contrasts with saline inflatable implants, where textured prostheses have been shown to have a significantly higher rate of deflation than smooth implants.

Skin rash. We noted a distinctive skin rash occasionally occurring in association with polyurethane implants (Figure 4). Berrino et al reported that a rash developed...
in 4 of 70 implants used in 54 patients, an incidence of 5.7%. Eyssen et al. noted that 14 of 92 (15%) patients developed a skin rash after receiving polyurethane foam-covered implants. In the clinical study by Gasperoni et al., the allergic rash occurred in only 1% of cases. In all reported series, rashes resolved within 2 to 4 weeks, and no long-term sequelae were observed.

Capsular contracture. The benefit of polyurethane foam in reducing the risk of contracture has been previously reported. The current study further confirms this and demonstrates that the benefit is long lasting. Eight years following implantation, 80% of polyurethane foam-covered implants remain contracture-free (Baker 1 or 2) compared to 65% of textured implants and 50% of smooth implants. Breast-implant patients have a high rate of revision surgery, the most frequent indication being capsular contracture. Reduction in frequency and delay in onset of contracture translate into a diminished need for revisionary surgery in patients with polyurethane implants. In our population, the interval between the primary surgery and subsequent revision was significantly shorter for smooth implants (19.5 months) and textured implants (27.2 months) implants than for polyurethane implants (47.8 months).

Polyurethane foam stimulates formation of a unique scar tissue capsule, which differs histologically from the capsule around smooth or textured implants. Nonpolyurethane implants elicit a relatively short-lived, avascular, and acellular inflammatory response. Collagen fibers are deposited in a parallel, linear array (Figure 5). As contraction occurs, the parallel orientation of the collagen predisposes to linear contracture, resulting in spherical deformity and undesirable firmness of the implant. When polyurethane is implanted into animals or humans, it precipitates an intense, prolonged foreign-body reaction characterized by neovascularization with infiltration of large numbers of histiocytes and foreign-body giant cells. Collagen fibers are deposited in a configuration that mirrors the open-cell architecture of the foam. This results in a unique, sponge-like scar-tissue capsule (Figure 6). When the irregularly arrayed bundles of collagen contract, they do not produce the uniform linear forces that result in spherical contracture.
Systemic complications associated with polyurethane implants

The polyurethane used in the manufacture of breast implants is a polyesterurethane made from polyethylene glycol adipate (PEGA) and toluene diisocyanate (TDI). The TDI is comprised of a 4:1 isomeric mixture of 2,4-TDI and 2,6-TDI. TDI is unstable in an aqueous environment and converts slowly under physiologic conditions into toluenediamine (TDA). The major concerns with regard to safety of polyurethane relate to whether degradation products might pose a risk of toxicity or carcinogenicity.

Degradation of polyurethane foam. Initial reports suggested the polyurethane foam fragmented and disappeared rapidly after implantation.30,32,33 Subsequent analyses revealed the material persists for a long time in the scar-tissue capsule (Figure 7). Szycher and Siciliano34 examined capsules ranging from 5 months to 9 years after implantation. Specimens were enzymatically digested, which removed the tissue but did not affect the polyurethane foam. Scanning electron microscopy (SEM) studies were performed; samples of foam from unimplanted prostheses were used as controls. Electron spectroscopy for chemical analysis (ESCA) was also performed on enzymatically digested specimens and control samples. It was determined that even 9 years after implantation, “surprisingly large amounts of unbroken polyurethane foam remain.” The ESCA analyses revealed the foam surface to be devoid of urethane linkages. The authors hypothesize that a “protective coating” forms in vivo, reducing surface hydrolysis and retarding further degradation of the polyurethane. This results in a very slow rate of bioresorption of the foam. Based on examination of specimens of polyurethane capsule obtained between 6 months and 4 years after insertion, Hester35 concluded that “there is ample histologic evidence to prove that implanted polyurethane foam is biodegraded but through a slow process.” Sinclair et al36 used spectroscopy to analyze the chemical composition of foam from unimplanted controls and from capsulectomy specimens; the reduction in mean strut width of explanted specimens compared to controls was considered further evidence that polyurethane undergoes slow in vivo degradation.

Toxic and carcinogenic byproducts. Some investigators have raised concerns that polyurethane foam might contain dangerous contaminants or could undergo in vivo degradation into toxic or carcinogenic byproducts. Chemical analysis using gas chromatography has confirmed the presence of small amounts of TDA in the polyurethane used in breast implants.37 This is of potential concern because 2,4-TDA is a known rodent carcinogen.38 Experimental studies demonstrate that polyurethane is susceptible to thermal and hydrolytic degradation under simulated physiologic conditions. Benoit39 showed that 2,4- and 2,6-TDA, 2,4- and 2,6-TDI and toluene isocyanate amine (TIA) are produced in low levels (1.5 ppm/day) when polyurethane foam is incubated at 37°C. Reports of TDA in the urine of a patient with a polyurethane foam-covered breast implant have been used as presumptive evidence that TDI is converted in vivo into TDA.40 A number of in vitro studies have addressed the question of TDA production in association with implanted polyurethane foam, and most results suggest that small amounts of 2,4-TDA are released.38 However, it has never been established that TDA is carcinogenic in humans.41

Figure 7. A, Capsule surrounding polyurethane foam-covered implant removed after 7 years. Significant amounts of polyurethane are still present. B, An enzymatically digested capsule from a polyurethane implant removed after 6 years. Nearly all the polyurethane is still present.
In response to concerns about potential adverse effects from even small amounts of circulating TDA, an FDA advisory panel was convened to consider the safety of polyurethane foam-covered implants. Even assuming TDA to be carcinogenic in humans, the FDA analysis revealed that in a woman with 2 polyurethane breast implants, the lifetime risk of developing cancer was so small that explantation would not be justified.7

To quantify in vivo release of TDA, Hester et al42 collected urine and serum samples from patients with polyurethane foam-covered implants (n = 61) and controls (n = 61). Free TDA was analyzed by gas chromatography combined with mass spectrometry. No measurable 2,4-TDA was detected in the serum of either group. Eighteen patients with polyurethane implants had detectable levels of free 2,4-TDA in their urine, compared to 7 control subjects. The authors estimated that the average lifetime dose of 2,4-TDA released from a pair of breast implants would be 5.06 × 10 minus 6 mg per kilogram per day. Based on the cancer potency of TDA established by the FDA, this would result in a theoretical 1:1.1 million lifetime risk of cancer from a single pair of polyurethane implants, a level considered inconsequential.

There is historical evidence to support the safety of polyurethane foam in medical devices. Polyurethanes have been implanted for decades in various applications (eg, pacemaker connectors, fixation devices, hemodialysis tubing, percutaneous shunts, vascular patches, and grafts). This material is well tolerated, and there are no reports or published series to suggest any toxic or carcinogenic side effects. Before the introduction of the modern silicone gel-filled implant in 1963, a variety of porous sponge implants (polyurethane, polyether foam, polyvinyl alcohol) were used for breast augmentation. Harris43 reported on 16,600 implanted polymerized plastic breast implants and found no cases of breast malignancy. In a more recent review of the literature, McGrath and Burkhardt44 concluded there was no evidence to link breast implants of any kind with an increased risk of breast cancer. In a report prepared for the Canadian Minister of Health on the safety of polyurethane foam-covered implants, Kerrigan38 concluded that the claim that polyurethane implants can stimulate breast or other cancers “is not substantiated by the experimental and clinical literature.”

**Limitations of This Study**

Getting patients to return for long follow-up can be a problem with any longitudinal study. The FDA recently mandated that manufacturers collect data on complications and reoperation rates in patients receiving silicone gel-filled implants in the United States (adjunct clinical trial). One manufacturer, Inamed Corporation, reported that of patients receiving silicone gel-filled implants for reconstruction (N = 15,465) only 53.8% of those eligible for 1-year follow-up returned for evaluation, and at 3 years only 27% returned. The numbers were even worse for patients undergoing “implant replacement” (N = 9881), with 43.9% of those eligible returning at 1 year and only 19.9% returning at 3 years. The mean follow-up in our entire series was greater than 37 months, longer than in most published breast implant studies.

Determining the degree of capsular contracture is always subjective to some extent. The Baker grading system has been universally adopted and is widely used in the literature. In our study, the degree of contracture was determined by a board-certified plastic surgeon in accordance with the Baker criteria. To obtain longer follow-up on individuals who would not or could not return for personal examination, patients were canvassed with an implant questionnaire. The Baker grading system was explained in simple terms, and patients were asked to record the degree of contracture on each side. However, there is always the possibility that the grade assigned by the patient might differ from that assigned by an independent trained examiner.

As there have been gradual changes in the design of implants over time, some of the implant groups designated for comparison in this study may be nonhomogenous. For example, changes in the characteristics of the elastomer shell might affect the rupture rate; changes in the filler might affect the rate of silicone bleed, contracture, or other complications. Among our patients there was a great deal of internal consistency with respect to the type of implant used. Surgitek (subsequently Bristol-Meyers Squibb) manufactured all polyurethane foam-covered implants with no change in design over the period of this study. Different types of implants were combined (eg, all mechanically textured implants) for the purpose of analyzing a larger number of implants over a longer period to strengthen the statistical validity of conclusions. Our conclusions are valid for the population of implants used in this study. It is possible these findings may not precisely predict the behavior of breast implants currently in use, or of implants that may be used in the future.

An implant questionnaire was mailed to all patients, and we achieved nearly a 50% response rate. This high response rate is probably due to repeat mailing of questionnaires to nonresponders and telephone contact with patients to encourage them to complete questionnaires.
However, there is a possibility that some inherent difference between responders and nonresponders (eg, level of satisfaction) might affect the response rate and could bias results.

**Conclusion**

When evaluating any implantable medical device, it is necessary to monitor long-term safety and efficacy. The safety of breast implants is evaluated by determining the risk of local complications, the incidence of systemic effects (eg, carcinogenicity, toxicity) and the need for reoperation. Breast implants are intended to improve “quality of life,” so efficacy is best measured by determining patient satisfaction. The goal of the current study was to evaluate the safety and effectiveness of polyurethane foam-covered implants compared to other types of silicone gel-filled implants.

Based on analysis of our data, we conclude that the contracture rate after all types of breast surgery is dramatically lower with polyurethane foam-covered implants than with smooth or textured implants. This benefit persists long term, at least 10 years after implantation. Aside from a transient skin rash, there were no unusual side effects or complications associated with polyurethane implants. There is nothing in the experimental literature to suggest that polyurethane foam, or its in vivo breakdown products, pose a threat to the health or safety of patients. Polyurethane implants have measurable advantages over smooth and mechanically textured gel-filled prostheses and do not appear to be associated with an increased risk of complications or morbidity.

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