A Long-Term Study of Outcomes, Complications, and Patient Satisfaction with Breast Implants

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Background: Breast implants have been used worldwide for more than 40 years. Despite extensive clinical experience, there is continued concern about the safety of these devices. The purpose of this study was to compare the efficacy, complication rates, frequency of reoperation, and degree of patient satisfaction with different types of implants.

Methods: This is a consecutive, population-based study consisting of all patients receiving implants at a multidisciplinary breast center between 1979 and 2004 (25 years). A prospective implant database was constructed and maintained in Excel, and statistical analysis was performed using SAS 8.2. Various outcomes, including infections, hematomas, undesirable waviness, capsular contracture, deflation, rupture, reoperation, and patient satisfaction, were monitored.

Results: Data were collected on 3495 implants in 1529 women. The longer implants were in place, the greater the cumulative risk of developing contracture; hematoma significantly increased the risk of contracture; smooth and textured implants had similar contracture rates; polyurethane foam–covered implants had a reduced risk of contracture persisting for at least 10 years after implantation. There was a relatively high rate of reoperation and a relatively short interval between primary surgery and reoperation; the most common indication for reoperation was capsular contracture. Implant recipients expressed a high overall level of satisfaction.

Conclusions: Breast implants are associated with a significant rate of local complications and reoperation. There are marked differences in outcomes as a function of implant surface type and surgical indication. Despite relatively frequent complications and reoperations, implant recipients are largely satisfied. (Plast. Reconstr. Surg. 117: 757, 2006.)

Silicone breast implants have been widely used in the United States and throughout the world for more than four decades. During this time, there has been growing concern about the safety of these devices, with regard to both local complications and possible systemic effects. A large body of scientific literature has been published addressing a possible association between silicone implants and cancer.1–6 There is overwhelming epidemiologic evidence that women with implants are not at increased risk for primary or recurrent breast cancer or other tumors.7–11 In fact, some studies suggest a lower rate of breast cancer in augmented women.12–16 Similarly, there is abundant literature demonstrating lack of an association between silicone breast implants and immune diseases or any systemic illness.17–24

In contrast, recent studies have documented a significant incidence of local complications and side effects from breast implants.25–45 It has also been determined that a relatively large proportion of implant patients require revisional surgery.46–51 Long-term follow-up of breast implant recipients is difficult for several reasons. Patients who believe they are doing well have little incentive to return for routine reexamination. Patients who are dissatisfied often seek opinions (and subsequent treatment) from another physician. Also, the population in the United States is mobile; thus, over time, patients frequently relocate and may be difficult to contact. Implant registries and large-scale manda-
tory trials have only recently been established. Even in national manufacturer-sponsored studies, only a relatively small proportion of patients complete the desired follow-up.\textsuperscript{52–54} For all these reasons, our knowledge of complication rates and outcomes following breast implant surgery remains imprecise. The purpose of the current study was to investigate long-term outcomes, complications, reoperation rates, and patient satisfaction among breast implant recipients treated in a single practice and followed for as long as 25 years.

**PATIENTS AND METHODS**

This is a population-based study consisting of all implant recipients operated on at a multidisciplinary breast center (The Breast Center, Van Nuys, Calif.) and in a subsequent solo plastic surgery practice. The population consists of a consecutive series of women undergoing breast implant surgery during the 25-year period between June of 1979 and June of 2004. All patients receiving implants for cosmetic, reconstructive, or revisional surgery were included. Reconstructive surgery was defined as any case where an implant was used (with or without preceding tissue expansion) to restore a breast disfigured by cancer treatment. Revisional surgery included all patients (cosmetic or reconstructive) undergoing secondary implant procedures, regardless of the indication for surgery. Women who were evaluated or treated at our center for conditions related to breast implants inserted elsewhere were excluded because of the difficulty in obtaining reliable information about implant procedures performed at other facilities.

All surgical procedures were performed by one of two board-certified plastic surgeons working as part of an integrated, multidisciplinary “team.” There was consistency in the care provided, both from surgeon to surgeon and over time (e.g., the two surgeons used similar operative techniques, administered antibiotics uniformly, applied similar dressings, used the same postoperative instructions, and scheduled follow-up visits in a consistent manner). Implant patients were never “discharged” or told to “return prn”; all patients were given appointments for follow-up indefinitely over the course of this study. Patients were not charged for follow-up visits.

A prospective breast implant database was established in January of 1990. To incorporate data relating to implants inserted before inception of the database, information was obtained from chart review of all patients who underwent implantation between June of 1979 and December of 1989 (1122 implants in 508 women). The protocol for chart review called for extraction of data relating to patient demographics, details of the surgical procedure, type of implant, early and late postoperative complications, degree of capsular contracture at intervals, and laboratory and mammographic findings. As charts were reviewed, findings were entered onto custom-designed data sheets and subsequently transferred into a computerized database.

The database was updated in 2003 to 2004 by performing a comprehensive record review of all implant recipients for whom charts were available. Data extraction forms were created in collaboration with the Department of Biomathematics at the University of California, Los Angeles School of Medicine. The data abstraction forms were designed to collect demographic information, confirm details of the surgical procedure, and monitor postoperative complications. The database was further enhanced with information obtained from a comprehensive patient questionnaire. The breast implant questionnaire, also devised in collaboration with the University of California, Los Angeles Department of Biomathematics, consisted of a 21-question instrument designed to solicit information about patient demographics, implant-related complications (including degree of capsular contracture), and level of patient satisfaction. Because many patients in this series had multiple implants over time, the questionnaire called only for information relating to the current implant(s) or, in the case of explanted patients, the most recent implant(s). The date of implantation of the device in question was provided on the questionnaire to avoid ambiguity. In cases of bilateral implants, information was collected separately for the right and left sides.

A total of 1555 questionnaires were mailed between May of 2003 and May of 2004. The post office returned 702 questionnaires (nondeliverable/incorrect addresses). It is believed that 853 questionnaires were delivered to recipients. A persistent effort was made to encourage patients to complete and return questionnaires. This included remailing questionnaires in all cases where the original questionnaire was not returned by the post office or completed by the patient, and telephone calls to patients who failed to return questionnaires. As a result of these measures, a total of 429 patients (50 percent) ultimately completed and returned questionnaires.

For purposes of this study, each breast implant was considered separately and its history tracked.
from the date of insertion until the date of explantation or the last follow-up visit. In patients who underwent revisional surgery with insertion of a new implant, a new record was created to track complications and outcomes related to the new device. If the relatively few cases where surgery (e.g., capsulotomy) was performed and the same implant was reinserted, the prior record pertaining to that device was terminated (censored) and a new record was created to track the implant from the date of reinsertion.

Patients with Baker grade 1 or 2 capsules were defined as free of contracture, and patients with Baker grade 3 or 4 capsules were considered to have significant contracture. The date of onset of contracture was defined as the date a Baker 3 or 4 capsule was first documented in the medical record. In the case of patients who self-reported significant contracture (by means of the breast implant questionnaire), the date of onset was considered to be the date the questionnaire was completed. Contracture rates were expressed in terms of incidence per 1000 patient-months of observation. In addition, the incidence of contracture over time was evaluated using the Kaplan-Meier method of survival analysis. In applying the Kaplan-Meier method to the study of capsular contracture, 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.

Complications that tended to occur over a discrete time frame in the early postoperative period (e.g., hematoma, infection) were evaluated based on occurrence as a function of the total number of cases (raw rate), whereas complications that occur over a longer time frame (e.g., implant deflation, rupture, contracture) were calculated in relation to the total number of patient-months of risk.

Hematoma was diagnosed if there was significantly greater than expected bruising, swelling, and firmness of the breast or if surgical exploration revealed the presence of excessive blood around the implant. Infection was considered to have occurred if there were symptoms of abnormal swelling, erythema, tenderness, and fever that either resolved with antibiotics or required explantation. Culture and sensitivity studies were obtained when possible to confirm suspected infections. Untoward outcomes such as excessive waviness or rippling were considered to have occurred when the degree of deformity was beyond what would normally be expected in a particular clinical setting, required surgical revision, or was self-reported by patients as being problematic.

Rupture of silicone gel implants was based on clinical confirmation at the time of explantation. The diagnosis of gel implant rupture was not made on the basis of mammography, ultrasound, or magnetic resonance imaging findings. The diagnosis of saline implant deflation was made from physical examination and was confirmed at the time of implant replacement.

The rates of reoperation, and the indications for revisional surgery, were determined from review of progress notes and operative reports. Patient satisfaction was ascertained from medical records and from responses on the breast implant questionnaire. Patients were given the opportunity to rate their overall satisfaction on a five-point scale, with 1 being least satisfied and 5 being most satisfied.

The database was constructed and maintained in Excel (Microsoft Corp., Redmond, Wash.) and statistical analysis was performed using SAS 8.2 (SAS Institute, Inc., Cary, N.C.). Outcomes were compared among surgical procedures, different surfaces, and different fillers. For comparing the incidence of contracture over time, the Kaplan-Meier method of survival analysis (the log rank test) was used. This methodology is ideal for studying progressive phenomena such as contracture because it allows for staggered entry of cases into the trial and irregular loss to follow-up. With the Kaplan-Meier method, only actual observations are used to determine contracture rates; implants are eliminated from consideration (censored) as of the date contracture occurs or beyond the date of the last follow-up visit. Because there are multiple levels of procedures, surfaces, and fillers, the overall log rank tests do not spotlight where differences occur; thus, additional log rank tests were performed to compare only two of the groups at a time. These are reported after the overall tests among the multiple groups.

For shorter term outcomes such as infection, overall comparisons were performed using chi-square tests for differences in percentages across the multiple groups. For these outcomes, two 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 two-group comparison. For patient satisfaction, measured on a five-point scale, nonparametric statistics were used. For the overall model, the Kruskal-Wallis test was used. Additional compari-
sons between two groups were made using the Wilcoxon rank sum test.

RESULTS

This study yielded information on a total of 1529 patients and 3495 implants. Occasionally, an analyzed measure has missing data for a few implants, which were therefore excluded from counts as deemed appropriate. The study included 825 augmentation patients who received 1601 implants, 264 breast reconstruction patients who received 352 implants, and 695 implant revision patients who received a total of 1534 implants. Follow-up ranged from 0 to 280 months (23.3 years), with a mean follow-up (per implant) of 37.4 months.

A variety of implants were used over the course of this study, including 1137 saline-filled devices, 778 double-lumen (gel/saline) prostheses, 1537 silicone gel-filled implants, and 38 implants with other fillers (e.g., Trilucent, Misti Gold). With regard to surface texture, there were 2067 smooth implants, 848 mechanically textured prostheses, and 568 polyurethane foam-covered devices (Table 1).

The occurrence of capsular contracture was studied as a function of the type of procedure performed and the surface texture of the implant. Contracture rate (Baker grade 3 or 4 per 1000 patient-months) was 1.99 after augmentation, 5.37 after breast reconstruction, and 4.36 after implant revision surgery. The rate of significant contracture was 3.85 with smooth implants, 3.23 with textured implants, and 2.19 with polyurethane foam-covered implants. Survival analysis curves were generated using the Kaplan-Meier methodology. These graphs depict the likelihood of remaining contracture-free over time as a function of type of surgical procedure and implant surface characteristics (Figs. 1 and 2). Reliable data were available out to 10 years of follow-up.

Hematoma was least frequent following breast augmentation, occurring in 24 of 1601 (1.50 percent) implants; more frequent after implant revision surgery, occurring in 29 of 1534 (1.89 percent) implants; and most common in association with breast reconstruction, occurring in 10 of 352 (2.84 percent) implants. Chi-square analysis and pairwise tests revealed no statistically significant difference in the incidence of hematoma as a function of the type of surgical procedure performed. Hematoma was also studied as a function of implant surface texture. Hematoma occurred in 35 of 2067 (1.69 percent) smooth implants, 15 of 848 (1.77 percent) textured implants, and 13 of 568 (2.29 percent) polyurethane foam–covered implants. Chi-square analysis and pairwise tests showed no significant difference in the incidence of hematoma as a function of implant surface texture.

The effect of hematoma on the risk of developing contracture was studied by comparing the contracture rate for implants with and without associated hematomas. Contractures occurred in 12 of 63 implants where there was a hematoma compared with 412 of 3432 implants without hematoma. The contracture rate (number of Baker grade 3 or 4 contractures per 1000 patient-months) was 7.17 for implants with hematoma and 3.27 for implants without hematoma. This was a significant difference (Kaplan-Meier log rank test, \( p = 0.0068 \)). The relative risk for contracture in the event of hematoma was 2.19.

Infection rates were determined in relation to procedure type and were noted to occur in 19 of 1601 implants (1.2 percent) used for augmentation, 16 of 352 of implants (4.6 percent) used for breast reconstruction, and 32 of 1534 of implants (2.1 percent) used for secondary revisions (Table 2). When infections were categorized as a function of implant surface texture, they were noted to occur in 30 of 2067 smooth implants (1.5 percent), 24 of 848 textured implants (2.8 percent),

<table>
<thead>
<tr>
<th>Texture</th>
<th>Augmentation ((n = 1601))</th>
<th>Reconstruction ((n = 352))</th>
<th>Revision ((n = 1534))</th>
<th>Total* ((n = 3495))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth</td>
<td>1138</td>
<td>206</td>
<td>717</td>
<td>2067</td>
</tr>
<tr>
<td>Textured</td>
<td>265</td>
<td>34</td>
<td>548</td>
<td>848</td>
</tr>
<tr>
<td>Polyurethane foam</td>
<td>194</td>
<td>107</td>
<td>266</td>
<td>568</td>
</tr>
<tr>
<td>Filler</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saline</td>
<td>743</td>
<td>64</td>
<td>324</td>
<td>1137</td>
</tr>
<tr>
<td>Double-lumen</td>
<td>398</td>
<td>144</td>
<td>236</td>
<td>778</td>
</tr>
<tr>
<td>Silicone gel</td>
<td>446</td>
<td>140</td>
<td>949</td>
<td>1537</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
<td>3</td>
<td>23</td>
<td>38</td>
</tr>
</tbody>
</table>

*The counts in the column for totals may exceed the row total because of a few implants with missing data. There were eight implants with missing surgery type, 12 with missing surface, and five with missing filler; some were missing two characteristics.
and 11 of 568 polyurethane foam–covered implants (1.9 percent) (Table 2).

Excessive waviness and/or rippling occurred least frequently with implants used for augmentation [91 of 1601 (5.7 percent)], more frequently with implants used for reconstruction [27 of 352 (7.7 percent)], and most frequently when implants were used in revision surgery [182 of 1534 (11.9 percent)] (Table 3). The risk of undesirable waviness was also related to implant surface texture, occurring in 143 of 2067 of smooth implants (6.92 percent), 38 of 568 of polyurethane foam implants (6.69 percent), and 120 of 848 of textured implants (14.15 percent) (Table 3).

Saline implant deflations occurred in nine of 943 smooth surface implants and 13 of 192 tex-

Fig. 1. Kaplan-Meier analysis of the risk of significant (Baker grade 3 or 4) capsular contracture as a function of the type of surgical procedure performed (all implant surfaces). Log rank test, $p < 0.0001$; augmentation versus reconstruction, $p < 0.0001$; augmentation versus revision, $p < 0.0001$; reconstruction versus revision, $p < 0.088$.

Fig. 2. Kaplan-Meier analysis of the risk of significant (Baker grade 3 or 4) capsular contracture as a function of implant surface characteristics (all surgical procedures). Log rank test, $p < 0.0009$; polyurethane foam versus smooth, $p = 0.0003$; polyurethane foam versus textured, $p = 0.0159$; smooth versus textured, $p = 0.1093$. 
The overall level of patient satisfaction was high. When gauged as a function of procedure type, mean satisfaction (scale of 1 to 5) was somewhat higher following augmentation (4.40) than following breast reconstruction (4.00) or implant revision surgery (4.02) (Table 9). There was no statistically significant difference in self-assessed patient satisfaction as a function of implant filler material (saline versus gel). Smooth implants received higher satisfaction scores than textured ($p = 0.0003$) and polyurethane foam–covered devices ($p = 0.0287$).

### DISCUSSION

This population-based, long-term follow-up study of implant recipients reveals significant differences in outcome as a result of type of procedure performed and type of implant used. Our findings confirm the widely held belief that capsular contracture is least frequent after breast augmentation, more frequent after revisional surgery, and most frequent after breast reconstruction.26,56–59 Curves from Kaplan-Meier survival analyses reveal that contracture is a progressive phenomenon, and the longer any group of patients is followed, the greater the cumulative risk of developing contracture. This contradicts the widely held belief that if patients remain contracture-free for a year or two they probably will not develop significant contracture.60 This finding may also have some relevance in understanding the cause of capsular contracture. If the risk of contracture persists for many years after implantation (as it appears to), it seems less likely that it is related to acute events such as bacterial contamination, surgical technique, drains, antibiotics, or other ancillary measures that have a short-term

### Table 2. Infection

<table>
<thead>
<tr>
<th>Implant Surface†</th>
<th>Procedure*</th>
<th>No. of Implants</th>
<th>No. of Infections</th>
<th>Implants Infected (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth</td>
<td>Augmentation</td>
<td>1601</td>
<td>19</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>Reconstruction</td>
<td>352</td>
<td>16</td>
<td>4.6</td>
</tr>
<tr>
<td>Textured</td>
<td>Revision</td>
<td>1534</td>
<td>32</td>
<td>2.1</td>
</tr>
<tr>
<td>Polyurethane</td>
<td>Smooth</td>
<td>2067</td>
<td>30</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Textured</td>
<td>568</td>
<td>11</td>
<td>1.9</td>
</tr>
</tbody>
</table>

*Overall $p < 0.0001$; pairwise: augmentation versus reconstruction, $p < 0.0001$; augmentation versus revision, $p = 0.0490$; reconstruction versus revision, $p = 0.0100$.
†Overall $p < 0.0437$; foam versus smooth, $p = 0.4095$; foam versus textured, $p = 0.2913$; smooth versus textured, $p = 0.0138$.

Reoperation rates (for any reason) were studied as a function of procedure type. For implants used in breast augmentation, 248 of 1601 (15.5 percent) required subsequent revision; when used for breast reconstruction, 125 of 352 (35.5 percent) underwent reoperation; and when used in revisional surgery, 336 of 1534 (21.9 percent) required subsequent reoperation (Table 6). The mean duration between operation and revision surgery was determined for various procedures. It was shortest (16.0 months) in breast reconstruction, longer (38.9 months) following breast revision surgery, and longest (49.1 months) after breast augmentation (Table 7). When the mean duration between surgery and subsequent revision was analyzed as a function of implant surface texture, it was approximately the same for smooth (36.9 months) and textured (35.5 months) implants but significantly longer for polyurethane foam–covered implants (47.8 months) (Table 7). The most frequent reasons for reoperation were capsular contracture (56 percent), size change (22 percent), and implant malposition (8 percent) (Table 8).
impact and more likely related to some chronic effect of implants on adjacent tissue.

Our findings further substantiate previous reports on the superiority of polyurethane foam–covered implants in reducing the risk of contracture compared with smooth or textured implants.\(^6\) At the end of 10 years of observation, among patients for whom data were available, 75 percent of those with polyurethane implants remained contracture free compared with 65 percent with either smooth or textured implants. In all categories considered—augmentation, revisional surgery, and breast reconstruction—polyurethane implants proved superior regarding reduction of contracture. These findings confirm earlier reports on the benefit of the polyurethane foam in reducing the incidence of contracture and document the long-term duration of this effect. Polyurethane-covered devices were voluntarily withdrawn by the manufacturer from the U.S. market in 1992; however, approximately 110,000 foam-covered implants were inserted in the United States before distribution was discontinued, and they continue to be widely used in Europe and South America.

In our study, textured implants had a slightly lower risk of developing significant (Baker grade 3 or 4) contracture than smooth implants. The difference, however, was not statistically significant, and as patients were followed for a longer periods of time, the difference became less apparent. Although there were initial reports in the literature that mechanical surface texturing of breast implants reduced the incidence of contracture, more recent studies have suggested that there is no significant difference between smooth and textured devices.\(^6\) Negative effects of textured breast implants include a greater propensity to cause visible rippling and waveliness and a higher rate of saline implant deflation. Both of these observations have previously been reported in the literature\(^2\) and are confirmed by the current study.

It has become increasingly apparent in recent years that breast implant recipients experience a significant incidence of complications and a relatively high rate of reoperation.\(^6\) In large-scale follow-up studies conducted by manufacturers, it was reported that by the end of 5 years, women undergoing augmentation with saline-filled implants had a 10 percent rate of significant (Baker grade 3 or 4) contracture, approximately a 10 percent incidence of deflation, and even higher rates of wrinkling and breast pain. Between 20 and 25 percent of saline-augmented patients underwent reoperation within the first 5 years.\(^5\) Complications associated with silicone gel implants were even more prevalent.\(^3\) According to manufacturers, at the end of 3 years, women undergoing gel implant reconstruction had a 20 percent risk of contracture (Baker grade 3 or 4), nearly a 30 percent risk of implant removal/replacement, and an overall reoperation rate of 45 to 50 percent.\(^5\)

The findings in our implant population were similar. We noted a high overall rate of reoperation. The lowest rate (15.5 percent) and longest mean duration to reoperation (49.1 months) was among augmentation patients; the highest rate (35.5 percent) and shortest mean duration to reoperation (16.0 months) was among breast reconstruction patients. The mean duration to reoperation also varied as a function of implant surface texture. The longest mean duration was with polyurethane foam–covered implants (47.8 months), and the mean duration was nearly identical with smooth (36.9 months) and textured (35.5 months) implants. It is likely that the longer mean duration until reoperation in cases with polyurethane foam–covered implants is related to the reduced tendency to develop clinically significant contracture.

### Table 4. Saline Deflation*

<table>
<thead>
<tr>
<th>Surface</th>
<th>No. Deflations</th>
<th>Rate per 1000 Patient-Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth</td>
<td>943</td>
<td>9</td>
</tr>
<tr>
<td>Textured</td>
<td>192</td>
<td>13</td>
</tr>
</tbody>
</table>

*\(p < 0.0001\).

### Table 5. Silicone Rupture*

<table>
<thead>
<tr>
<th>Implant Surface</th>
<th>No. Ruptures</th>
<th>Rate per 1000 Patient-Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smooth</td>
<td>1123</td>
<td>14</td>
</tr>
<tr>
<td>Textured</td>
<td>618</td>
<td>6</td>
</tr>
<tr>
<td>Polyurethane</td>
<td>568</td>
<td>8</td>
</tr>
</tbody>
</table>

*\(p = 0.1579\).

### Table 6. Reoperation Rates*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Total No.</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augmentation</td>
<td>1601</td>
<td>248</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>352</td>
<td>125</td>
</tr>
<tr>
<td>Revision</td>
<td>1534</td>
<td>336</td>
</tr>
</tbody>
</table>

*Overall \(p < 0.0001\); augmentation versus reconstruction, \(p < 0.0001\); augmentation versus revision, \(p < 0.0001\); reconstruction versus revision, \(p < 0.0001\).
The reasons for reoperation among our patients were similar to the reasons previously reported by manufacturers. In our series, the most common overall indication for reoperation was capsular contracture and the second most common was size change. In manufacturers’ studies, the most common reason for reoperation after breast augmentation was size/style change and the most common reason after breast reconstruction was capsular contracture.

Despite a relatively high rate of complications and the relatively frequent need for reoperation, breast implant recipients are largely satisfied. Among our patients, the highest level of satisfaction was in augmentation patients, but other categories reported favorable satisfaction rates as well. This high level of patient satisfaction among implant recipients has been observed and reported by others.40,75,76

**Limitations of This Study**

By their very nature, clinical studies have inherent limitations. Historically, it has been difficult to obtain long-term follow-up on implant recipients. As in all clinical trials, some of our patients were lost to follow-up. In this particular study, however, there were some unique advantages. The majority of our patients were treated at a multidisciplinary “breast center” where many of them returned annually for screening mammography. This provided an opportunity to evaluate their implants. The majority of cancer patients undergoing breast reconstruction received their medical and surgical oncology follow-up at our center. These patients were seen on a regular basis and the reconstructed breast was routinely evaluated. This unique clinical setting provided an opportunity for long-term follow-up not encountered in the typical clinical practice.

Determining the degree of capsular contracture is always subjective to some extent. The Baker grading system has been universally adopted for this purpose and is widely used in the published literature. In our study, Baker grade was ascertained by one of two board-certified plastic surgeons; determination of the degree of contracture was performed in accordance with the grading criteria specified by Baker.77 In an effort to obtain even longer term follow-up on patients who would not or could not return for personal examination, patients were canvassed with an implant questionnaire. Patients were asked to record the degree of contracture on each side; the criteria for the Baker grading system were clearly explained in lay terms on the questionnaire. However, there is always the possibility that the grade assigned by the patient might differ from that assigned by an independent trained examiner. It should be emphasized that these “self-evaluations” were not a substitute for examination by the plastic surgeon; they were used to obtain follow-ups of longer duration and supplement the data in the medical records. A number of the implant questionnaires were actually completed at the time of a follow-up visit, in which case the Baker grade was determined by the examining plastic surgeon and entered onto the questionnaire by the nurse.

There have been gradual changes in the design of implants over time. As a result, some of the groupings of implants designated for comparison

<table>
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<th>Table 7. Mean Duration between Surgery and Reoperation</th>
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<tbody>
<tr>
<td><strong>No. of Reoperations</strong></td>
</tr>
<tr>
<td>--------------------------</td>
</tr>
<tr>
<td>Procedure*</td>
</tr>
<tr>
<td>Augmentation</td>
</tr>
<tr>
<td>Reconstruction</td>
</tr>
<tr>
<td>Revision</td>
</tr>
<tr>
<td>Surface Type†</td>
</tr>
<tr>
<td>Smooth</td>
</tr>
<tr>
<td>Polyurethane</td>
</tr>
</tbody>
</table>

*Overall p < 0.0001; augmentation versus reconstruction, p < 0.0001; augmentation versus revision, p < 0.0001; reconstruction versus revision, p < 0.0001.
†Overall p < 0.0527; smooth versus textured, p = 0.7349; smooth versus polyurethane, p < 0.0257; polyurethane versus textured, p < 0.0280.

<table>
<thead>
<tr>
<th>Table 8. Reasons for Reoperation in 514 Implant Replacements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reason</strong></td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td>Contracture</td>
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<tr>
<td>Size change</td>
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<tr>
<td>Malposition</td>
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<tr>
<td>Waviness</td>
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<tr>
<td>Deflation</td>
</tr>
<tr>
<td>Infection</td>
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<tr>
<td>Ruptured gel</td>
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<tr>
<td>Palpability</td>
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<td>Anxiety</td>
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<table>
<thead>
<tr>
<th>Table 9. Patient Satisfaction*</th>
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<tr>
<td><strong>Procedure Type</strong></td>
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<tr>
<td>---------------------</td>
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<tr>
<td>Augmentation</td>
</tr>
<tr>
<td>Reconstruction</td>
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<td>Revision</td>
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*Patients ranked satisfaction on a scale of 1 to 5, where 1 = least satisfied and 5 = most satisfied. Overall p < 0.0001; augmentation versus reconstruction, p < 0.0029; augmentation versus revision, p < 0.0001; reconstruction versus revision, p < 0.0316.
in this study may be nonhomogenous. For example, there were changes in the design of the filler valve of saline implants that might have altered the rate of deflation; likewise, there have been changes in the characteristics of the elastomer shell of silicone gel implants that might affect the rupture rate. This study reports on actual clinical experience with breast implants over an extended period of time and reflects experience with products that have gradually evolved. The conclusions derived from our data are valid for the population of implants observed over this time frame. It is possible that our findings may not exactly predict the behavior of breast implants currently in use or implants that may be used in the future.

An implant questionnaire was mailed to all patients, and we achieved a 50 percent response rate, which is higher than the rate reported in most survey studies. We believe this high response rate was attributable to persistent efforts to contact patients and encourage them to complete and return the questionnaire. However, there is the possibility of some inherent difference between responders and nonresponders; for example, the level of satisfaction might affect the likelihood of a patient to respond. Although we believe the high overall response rate contributes to the credibility of our conclusions, we acknowledge the possibility of selection bias that might impact our findings.

CONCLUSIONS

Based on long-term follow-up of a large number of breast implant patients, we believe certain conclusions are warranted. Implant recipients have a significant incidence of local complications and a relatively high rate of reoperation. The most common overall indication for reoperation is capsular contracture. The incidence of symptomatic capsular contracture does not diminish after 1 or 2 years. The longer implants are in place, the greater the cumulative risk for developing contracture. The occurrence of hematomas significantly increases the risk of developing contracture.

Polyurethane foam–covered implants are associated with a dramatically reduced rate of contracture for at least 10 years following implantation. Polyurethane implants do not appear to increase the risk of other complications such as infection or rupture. Textured implants do not afford significant protection against contracture and are associated with an increased risk of wrinkling and waviness and a higher rate of saline implant deflation.

Among all groups of implant recipients, the overall level of satisfaction is great despite a relatively high incidence of complications and relatively frequent need for revisions. We were unable to ascertain any difference in patient satisfaction as a function of filler material; smooth implants received a higher satisfaction score than textured implants but were not statistically different from polyurethane foam.

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Breast Implants


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A Long-Term Study of Outcomes, Complications, and Patient Satisfaction with Breast Implants

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I read with considerable interest the article by Dr. Handel and his fellow authors regarding long-term study of outcomes, complications, and patient satisfaction with breast implants. This topic is of particular interest to me and many other plastic surgeons because of the shortage of long-term data regarding how these devices perform in the local setting. The authors share with us a 25-year experience covering the years between June of 1979 and June of 2004. Patients reviewed included those undergoing cosmetic surgery, reconstructive surgery, and revisional surgery. The study included the practices of two plastic surgeons, both working within a well-integrated multidisciplinary team and thus providing a fair amount of consistency in terms of the type and quality of surgery performed. A prospective breast implant database was begun in January of 1990 and a retrospective database was obtained by chart review going back for the years between June of 1979 and December of 1989. Five hundred eight of the women with 1122 implants were collected in the retrospective database. The study, like many similar studies, is complicated by the fact that many of the patients had multiple implants over time, thus making the evaluation more complex. The authors therefore specifically looked at the experience of the patients with their most recent implant. It is of note that, in cases of bilateral implants, information was collected separately for the right and left sides, thus making double entries for all of the augmentation patients and single entries for most of the reconstruction patients.

The authors report that 1555 questionnaires were mailed and that the post office returned nearly half \( (n = 702) \) because they were nondeliverable. Of the 853 questionnaires believed to be deliverable, 429 were returned, for an approximate 50 percent response rate to the deliverable questionnaires. Response rate overall, however, was closer to 25 percent rather than 50 percent. In their study, each breast implant was considered separately and its history tracked separately from the date of insertion until the date of explantation or last follow-up. This is in contradistinction to the breast implant manufacturer’s Food and Drug Administration Premarket Approval data, which tracked patients rather than devices.

The data are reported in several ways, including complications that tended to occur over a discrete time frame that were reported as raw data, such as hematoma and infection, which almost always occur promptly after surgery. In contrast, events that occur over time were reported as incidents per 1000 patient-months. These included events such as implant deflation, rupture, and capsular contracture. Rupture required confirmation at the time of surgery and was not included if only suggested by magnetic resonance imaging, mammography, or physical examination.

One remarkable aspect of this study is the number of different statistical methods that were used, including the Kaplan-Maier method, the chi-square test, the Kruskal-Wallis test, and the Wilcoxon rank sum test. The authors report that the study yielded information on a total of 1529 patients and 3495 implants. This included 825 augmentation patients (1601 implants), 264 reconstruction patients (352 implants), and 695 revision patients (1534 implants). Follow-up averaged 37.4 months per implant. In terms of types of implants, there were 1137 saline-filled implants, 778 double-lumen implants, 1537 silicone gel-filled implants, and 38 implants with other fillers such as the Trilucent implant; 2067 implants were smooth, 848 were mechanically textured, and 568 had polyurethane covering.

The occurrence of capsular contracture was studied and revealed the figure of 1.99 capsular contractures per 1000 patient-months for the augmentation implants, 5.37 per 1000 patient-months after breast reconstruction, and 4.36 per 1000 patient-months after breast implant revision. When looking at types of implants, the numbers were 3.85 for smooth implants, 3.23 for textured implants, and 2.19 for polyurethane-covered implants. Hematomas were rare and did not vary particularly with either type of surgery or type of implant. One noteworthy aspect of the
study was the association of hematoma and the risk of developing capsular contracture. There was statistically significant evidence that hematomas increased the likelihood of capsular contracture. The contracture rate was 7.17 contractures per 1000 patient-months for patients with hematomas and 3.27 per 1000 patient-months for implants without hematoma. The relative risk of contracture in the event of hematoma was 2.19. Infections were relatively rare and were more common in breast reconstruction, but infections across the range of use of implants did not vary significantly with implant types. Excessive waviness or rippling, in contrast, was more frequent with textured implants and more common in revision than in reconstruction or augmentation.

Another notable aspect of the study was a deflation rate that occurred in nine of 943 smooth surface implants versus 13 of 192 textured implants. The rate of deflation per patient-month risk was 0.34 for smooth implants and 2.07 for textured implants. This difference was statistically significant. Among silicone implants, there was no difference with diagnosed ruptures between smooth, textured, and polyurethane implants.

The authors reviewed the reoperation rates per implant and found that the per-1000 patient-month augmentation risk number was 15.5 percent; the rate was 35.5 percent for breast reconstruction and 21.9 percent for revision surgery. Of interest was the mean duration between operation and revision surgery, with it being shortest after breast reconstruction (16 months), longer after revision surgery (38.9 months), and longest after breast augmentation (49.9 months). The duration for revision surgery was longest in patients with polyurethane-covered implants. The most common reason for the operation was capsular contracture (56 percent), followed by size change (22 percent) and implant malposition (8 percent).

Despite the tremendous amount of work involved in putting this study together and the large amount of data presented, there are relatively few major new significant findings. The first is that capsular contracture in this authors’ study was a progressive phenomenon, with patients being at risk for capsular contracture throughout the length of the study. As the authors state, this contradicts the widely held belief that capsular contracture tends to be a short-term event. The authors argue, credibly, that for contracture to progress over years stands in opposition to the belief that acute events such as bacterial contamination or surgical technique are key players in the incidence of capsular contracture. Another key finding of this study was a higher rate of deflation with textured saline implants as compared with smooth saline implants.

The study included other findings that are consistent with previously published work including the fact that capsular contracture is less frequent in breast augmentation as compared with revision surgery and breast reconstruction. The authors also report that the patients with polyurethane-covered implants had a lower incidence of capsular contracture in the first several years as compared with smooth or textured silicone gel implants. Also in agreement with other studies, the authors report that rippling and waviness was more common with textured implants as compared with smooth ones.

This article comes at an interesting moment in our knowledge of breast implants. We have recently seen submitted by several implant manufacturers device-specific data to the Food and Drug Administration both on saline and silicone implants and in both textured and smooth varieties. The data in those Food and Drug Administration–sponsored Premarket Approvals are multiyear prospective population studies on thousands of women broken down into groups of those who have saline implants and those who have silicone implants used for augmentation, revision, and reconstruction. The studies are manufacturer-specific and device-specific and have follow-up at a minimum of 3 years and as long as 9 years in the cases of saline studies. The patients were enrolled prospectively at the beginning and have compliance in the 70 to 80 percent range in terms of follow-up. The data from those studies are per patient rather than per implant, which gives a higher rate or incidence of events because the denominator is smaller than it would be if it were per implant, which would be roughly double the number of implants as compared with per patient, particularly for augmentation.

What is interesting is the extent to which the data from those prospective Premarket Approval studies of thousands of patients from each manufacturer with both silicone and saline implants are in agreement with this 25-year retrospective study. Thus, in terms of the frequency of reoperation and the incidence of capsular contracture, there is general agreement between the studies. What is new in this study is the correlation between surface texture and saline device
rupture and the correlation between early hematoma and the eventual development of capsular contracture. The number and complexity of the statistical tests used in this article and the way the data are reported gives evidence of how complex and sophisticated this subject is and how difficult it may be to track large numbers of patients with disparate clinical stories for a long period. This is aggravated by the fact that the authors report some of their data in a relatively novel way, at least as compared with other implant studies. The use of occurrences as measured against 1000 patient implant months is a relatively uncommon method of describing the data. This makes it difficult to compare the authors’ results with those of other studies that report their data differently. Other issues with this study include the fact that it does not discriminate between different types of texturing and the different manufacturers of devices. This requires, to some extent, a leap of faith to believe that the various texturing processes would yield the same results or that the devices from different manufacturers would be homogeneous enough that they could be lumped together. The low rate of follow-up is another concern, with only approximately 25 percent of patients being available for follow-up.

This study raises the broader question regarding whether a long-term, large-patient-population study with relatively poor follow-up will provide more accurate or more useful data as compared with a smaller prospective study with better compliance such as those conducted by the manufacturers to obtain Food and Drug Administration approval. It also raises the question regarding the value of studies that go out 20 or more years in light of the fact that, by that time, the devices will have evolved and the data will be pretty much of historical interest only. Thus, for example, in the authors’ current study, the information regarding saline implants will probably become less relevant as saline implants are replaced by silicone implants with the impending U.S. Food and Drug Administration approval. Likewise, polyurethane implants, although performing well in the short run, are not on U.S. markets and are unlikely to return to the United States for some time, if ever. Finally, even many of the silicone implants discussed in this article are no longer used, such as double-lumen silicone implants, which are not available in the open market or core or adjunct studies in the United States at the present time. The information that plastic surgeons will be most interested in would be that regarding single-lumen textured and smooth silicone gel implants. The very best data regarding those devices are available from the core clinical studies that were submitted to the Food and Drug Administration over the last year as part of the Premarket Approval process by both Inamed and Mentor. As the breast implant industry, the Food and Drug Administration, and plastic surgeons consider how postmarket surveillance should be undertaken, the issue of what data should be collected on how many patients, and for how long, will become increasingly important. Articles such as this help remind us of the significance of ongoing study of these devices as they become used in a large number of patients.

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