Effect of Implantation Surgery on the Strength Properties of Silastic® II Silicone Gel Breast Implants

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Background: The causes of silicone gel–filled breast implant rupture are uncertain, and little research has been directed toward characterizing or quantifying the multiple factors that may contribute to device failure. Breast implants are subjected to some degree of stress and deformation during the surgical procedures of insertion. Thus implantation surgery itself could be a factor in affecting the durability of breast implants.

Objective: The purpose of this study was to investigate whether the surgical procedure of insertion affects the mechanical properties of the silicone elastomer shell of gel-filled implants. We wanted to determine whether the procedure of inserting a breast implant might cause a decrease in the strength properties of the shell.

Methods: Thirty-four Silastic® II gel-filled breast implants manufactured by Dow Corning were tested. All implants were from the same lot and had a volume of 300 cc. Twenty of 34 implants were tested without implantation to investigate variability within a lot and establish a baseline of control data for comparison with implanted implants. Fourteen of the 34 implants were implanted through an inframammary incision in the right breast of a cadaver. The effect of implantation surgery was investigated by comparing the mechanical properties of the anterior and posterior sides of the cadaver explants with those of the controls.

Results: Statistical analysis of the data indicated that the mechanical properties of elongation and tear resistance were essentially unaffected by implantation surgery. However, the average tensile strength of the explants was reduced 4.9% to 6.2% (for shells extracted with hexane and unextracted shells, respectively) compared with the controls. Breaking energy averages for the explants were also reduced 7.8% to 5.9% (for extracted and unextracted shells, respectively) when compared with the controls and average moduli decreased by a similar magnitude.

Conclusions: The surgical procedure of implanting a breast implant has a small but statistically significant effect on the average strength properties of the elastomer shell of the implant. It is unlikely that this small reduction is sufficient to be a factor in implant durability.
tigate the implantation procedure and attempt to quantify whether the surgical procedure of insertion might affect the mechanical properties of the silicone elastomer shell of gel-filled implants. Breast implants are subjected to some degree of stress and deformation during insertion. We wanted to determine whether the act of inserting a breast implant might cause a decrease in the strength properties of the shell. Thus implantation surgery itself could be a factor in affecting the durability of breast implants.

A study was designed to duplicate experimentally the surgical implantation of smooth silicone gel-filled implants for breast augmentation and to determine the effect of implantation on the mechanical properties of the shell material. The experiment was conceived to imitate a clinical implantation procedure as closely as possible in terms of incision, implant pocket creation, and placement of the implant by an experienced surgeon with more than 20 years’ experience in augmentation mammoplasty and breast reconstruction.

The gel contains a large mixture of cyclic and linear silicones with a solubility parameter nearly identical to that of the elastomeric shell. The overall composition of the low molecular weight silicones, that is, the non-cross-linked components, sorbed by the elastomeric shell can affect the mechanical properties of the shell, even when the basic structure of the elastomer does not change. Therefore we extracted the non-cross-linked material in the shells and compared the properties of the controls with that of the explants with and without the non-cross-linked silicones to estimate what, if any, changes occurred in the elastomer.

Material and Methods
Thirty-four Silastic® II silicone gel breast implants in their original packaging were obtained from Dow Corning Corporation, Midland, MI. All 34 smooth-surfaced gel-filled implants had a volume of 300 cc and were from the same manufacturing lot (HH 021104). It is important to consider implants only from a single lot because lot-to-lot variability in mechanical properties can mask the effect of property differences between the controls and explants if the difference is small. Twenty implants were not implanted and served as controls. The remaining 14 implants were surgically inserted, were immediately removed, and served as the explants. Mechanical property testing was conducted on all 34 implants. Variability of material property measurements (eg, minimum-to-maximum ranges) for this particular manufacturing lot and baseline data were obtained from the 20 controls. These data were then compared with mechanical property data for the 14 explants.

The experimental implantation portion of the study was conducted in April 1998, when the cadaver of a 49-year-old woman who died of malignant melanoma was obtained from the Anatomy and Neurobiology Department of the Washington University School of Medicine in St. Louis. The nonembalmed fresh-frozen cadaver was thawed to room temperature. Breast augmentation procedures were performed on the right breast of the cadaver with 14 different implants.

The cadaver’s breasts were approximately A-cup size. The first step in the operative procedure consisted of marking the midline of the sternum, the inframammary crease, and the lateral axillary line. An inframammary incision measuring 4 cm in length was made in the right breast of the cadaver. A 4-cm incision was chosen because it is typical for augmentation with that size (300 cc) of implant. The inframammary incision was located 8 cm inferior to the midline of the nipple and deepened to the chest wall. A subglandular pocket to receive the implant was created with sharp and blunt dissection between the breast parenchyma and the pectoralis major muscle. The pocket extended from approximately 1 cm lateral to the midpoint of the sternum medially at the level of the nipples, to 8 cm below the nipple inferiorly, to the anterior axillary line laterally, and to approximately 8 cm above the nipple superiorly. A separate incision measuring 16 cm in length was made in the infracavicular area and deepened to the pectoral muscle. A tunnel-like space approximately 16 cm wide was then dissected through the subcutaneous tissue to communicate with the implant pocket. This was done so the implants could be removed from the pocket without applying any significant additional stress to the devices after they had been inserted through the inframammary incision.

Each of the 14 Silastic® II implants was implanted in an identical manner during the course of a single day. As much as possible, each implantation procedure simulated a clinical breast augmentation with the same-size implant, incision size, and location. Before each implantation, the superior infracavicular incision that was made to communicate with the implant pocket was closed. As each test implant was inserted, it was gently squeezed with gloved fingers while a pushing and poking motion was gradually applied to work the implant.
through the inframammary incision and into the pocket. Each implant was inserted without difficulty. Once inserted, each implant was positioned with the fingers to lie flat on the chest wall with its center beneath the nipple. The inframammary incision was not closed after implant placement because the study focused on insertion through the incision and into the implant pocket.

After the device was satisfactorily placed and positioned, the superior infraclavicular incision was opened, the implant was removed with gloved fingers, and the superior incision was again closed. This implantation procedure was repeated until a total of 14 implants had been inserted and removed.

The effects of implantation surgery on the elastomer shells of breast implants were investigated by comparing the mechanical properties of the anterior and posterior sides of the 14 cadaver explants with those of the 20 control implants. Table 1 shows the number of specimens per implant tested, the testing protocols followed, and the properties that were measured. The shells were cut around the perimeter into a posterior and anterior hemisphere and cleaned by carefully removing the silicone gel and gently wiping the shell with isopropyl alcohol-moistened Kimwipes®. Our protocol for determining the strength of implants is to measure tensile and tear properties of specimens from the anterior and posterior sides of the cleaned shells. The anterior and posterior sections of the shell are nearly flat, and it is easier to prepare specimens from these sections than from the highly curved region around the periphery of the shell. Hence, the data for the 34 implants analyzed in this study were obtained in the same fashion as the data for implants from our previous study.¹

All the implants (explants and controls) were tested within a few weeks after the experimental implantation surgeries. Tensile experiments were conducted by use of an Instron® 5583 (Instron Corp, Canton, MA) equipped with a video extensometer. Half of the specimens from each implant were tested “as is,” and half were tested after being extracted to remove the non-cross-linked silicones from the elastomer. For extraction, the specimens were gently refluxed in chromatographic grade hexane (Fisher) at 60° C over a period of 72 hours and then dried to constant weight.

Tensile experiments were performed according to the ASTM D 412 protocol.² All tensile mechanical properties were derived from the stress strain data and are summarized in Table 2. Half of the specimens were obtained from the posterior and half from the anterior surfaces of the implant shells, for a total of 12 tensile specimens per implant (six unextracted and six extracted). In the experiment, the Die C half-scale tensile specimen was elongated at a constant displacement rate of 10 in/min until the specimen failed. The force and deformation at failure were determined and were used to calculate the tensile strength and percent elongation. The moduli and energy to failure were also computed from the stress strain data. The moduli are the stresses at strains of 100%, 200%, 400%, and 800%, respectively, and the energy to failure is the area under the force-grip extension curve.

Tear resistance was determined according to the ASTM D 624 protocol.³ Half the specimens were from the posterior and half from the anterior surfaces of the implant shells, for a total of eight specimens per implant (four unextracted and four extracted). To obtain tear resistance, a Die C half-scale tear specimen

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Table 1. Specimens from each of 34 Silastic® II implant shells from lot HH021104

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<th>Protocols</th>
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<td>Anterior unextracted*</td>
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<tr>
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<td>3</td>
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<td></td>
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<td>Posterior extracted*</td>
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<tr>
<td>Tear - ASTM D 624 Die C half-scale</td>
<td>2</td>
<td>Anterior unextracted†</td>
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<tr>
<td></td>
<td>2</td>
<td>Posterior extracted†</td>
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</table>

* Stress strain relation, tensile strength, elongation, breaking energy and moduli.
† Tear resistance.
was elongated at a constant displacement rate of 10 in/min, and the force required to tear the elastomer specimen was recorded.

Results

The stress-strain properties of the Dow Corning Silastic® II implants are presented in Table 2. Implants from a single manufacturing lot were selected to minimize the variability in strength properties. The basic statistics for the mechanical property measurements of elongation, tensile strength, breaking energy, tear resistance, 100% modulus, 200% modulus, 400% modulus, and 800% modulus for the 20 controls and 14 explants are summarized in Table 2. The table shows the number of specimens tested, minimum, maximum, median, and mean values, standard deviation, and coefficient of variation for unextracted and extracted results.

For each of the 34 implants, mechanical tests were performed on 12 tensile specimens and eight tear specimens. In total, 408 tensile and 272 tear experiments were performed. Half of these specimens were unextracted and half were extracted in hexane to remove non-cross-linked...
silicones. The strength properties of an unextracted implant shell are generally less.

No significant differences were noted between the mechanical properties measured from the anterior and posterior surfaces of the shells. Consequently, we chose to combine all anterior and posterior control shell specimens into one group and all anterior and posterior explant specimens into a second group.

The mean unextracted and extracted properties for the 14 explants and 20 controls are quite similar because the percent extracted from all 34 implants was very small. The average percent extracted from the explant and the control specimens was identical, with 8.3% extracted from both groups of shells. The percent extracted is based on the weight of the unswollen elastomer after it has been extracted with hexane. If the amount of extractable material were larger, we would expect to see a greater difference in mechanical property data of unextracted and extracted shell specimens.

Nonparametric statistical methods were chosen for data analysis because nonparametric tests require relatively few assumptions about the nature of the data. The data for this class of statistical methods are not assumed to follow a specific probability distribution. However, these methods do allow the calculation of interval estimation and hypothesis testing. The variance estimator used in this study for confidence interval estimation is known by various names because it has been derived independently in different ways by different authors.4-13 The Huber4 and White5,6 estimator, the sandwich estimator of variance, and the robust estimator of variance are names associated with the estimator used in this study. One attractive feature of the robust estimator of variance is the ability to relax the assumption of independence of the observations. That is, it can produce correct standard errors even if the observations are correlated. This is accomplished by a cluster analysis with the individual shell as the cluster factor.

Extreme outliers were found in the data. The effect of these outliers could have been reduced by weighting or transformations. As an alternative the data were ranked, and the controls and explants were compared with nonparametric statistical tests. Some power is lost by use of a nonparametric test, but greater robustness is gained. Furthermore, if significant results are found with a nonparametric test, it is less likely that the results are influenced by scale artifacts or outliers.

Two sample Wilcoxon rank-sum14 (Mann Whitney15) test results for median comparison

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Two sample Wilcoxon rank-sum14 (Mann Whitney15) test results for median comparison

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<th>Observations</th>
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<tr>
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Figure 1. Elongation to rupture for the explant and control are not significantly different.
Figures 1 and 2 graphically illustrate the tensile strength and elongation data summarized in Table 2 in box plot form. Box plots, which are based on medians and quartiles, are a descriptive method of presenting statistics. The two-sample Wilcoxon rank-sum\textsuperscript{14} (or Mann-Whitney\textsuperscript{15}) tests comparing the median elongation and tensile strength of the explants and controls are tabulated below each graph. Similar tests were used to compare the mechanical property data for the 14 explants and 20 control implants. In a box plot, the center vertical line marks the median of the data. The length of each box shows the range within which the central 50% of the values fall, with the box edges at the first and third quartiles. The horizontal lines extending from the edges of the box show the range of data that fall within 1.5 times the interquartile range of the box edges. An asterisk, or outlier, marks an outside value that falls within 1.5 to 3 times the interquartile range of the box edge, and an open circle marks a far outside value that falls farther than 3 times the interquartile range from the box edge.

Three different statistical analyses were performed. In these analyses, we reject the null hypothesis at a 0.05 significance level if the observed test statistic (in absolute value) is greater than or equal to the test statistic for a probability of 0.05. First, a regression analysis on the original data was performed, with standard errors and significance probabilities adjusted for multiple observations per implant. The most dramatic difference is the tensile strength. The regression slope of \(-120.5\) psi (95% confidence interval from \(-175.6\) to \(-65.7\) psi) estimates the difference in mean tensile strength between explants and controls, with the explants weaker. Second, a regression analysis on the ranked data was performed, with standard errors and significance probabilities adjusted for multiple observations per implant. Use of ranks reduces the effect of outliers without seriously affecting statistical power. The tensile strength difference between the explants and controls remains statistically significant. Third, the data were reduced by taking medians, and then the medians were compared with the nonparametric Wilcoxon rank-sum tests.\textsuperscript{14,15} Taking medians coupled with use of a rank-sum test reduces the effect of outliers in two distinct ways, but with some loss of statistical power. There is only one observation per shell after the medians are computed, so there is no need to account for multiple observations per shell. Again, tensile strength differences remain statistically significant.

\begin{tabular}{|c|c|c|}
\hline
Observations & Rank sum & Expected \\
\hline
Control & 20 & 445 & 350 \\
Explant & 14 & 150 & 245 \\
\hline
Adjusted variance & 816.7 \\
Z & 3.324 \\
Probability > |z| & 0.001 \\
\hline
\end{tabular}
Statistical analysis revealed that the elongation and tear strength are not significantly different when the explant group and the control group are compared for both the unextracted and extracted specimens. For the other mechanical properties, there were small but statistically significant differences between the explants and controls, with the measurements indicating a decrease in properties for the explants. The regression analyses for the properties of the explants and controls are summarized in Table 3, along with the difference in the average value of the property and an estimate of the 95% confidence bounds on this difference. When compared with controls, the unextracted explant shells showed a decrease of 6.2% for mean stress to rupture; a decrease of 5.9% for energy to rupture; and 100%, 200%, 400%, and 800% moduli decreases of 7.5%, 3.3%, 2.5%, and 6.3%, respectively. When compared with controls, the extracted explant shells showed a decrease of 4.9% for mean stress to rupture; a decrease of 7.8% for energy to rupture; and 100%, 200%, 400%, and 800% moduli decreases of 8.2%, 4.6%, 3.2%, and 5.0%, respectively.

**Discussion**

The fact that several mechanical properties—such as tensile strength, breaking energy, and moduli—are less for the explants when compared with the controls (for both unextracted and extracted specimens) indicates a consistent decrease in the stress variable of the stress-strain response of the silicone elastomer after implantation. The strain data for the explants and controls are essentially identical, but there is a reduction in the stress for the explant at corresponding values of strain. The tensile strength of the explant compared with the control is less, but the elongation is nearly the same. The anterior and posterior sides of a breast implant do undergo some degree of damage or weakening during the implantation procedure that causes a small but statistically significant decrease in some of the strength properties of the elastomer shell. These real differences cannot be explained away by clustering or outlying observations. However, it is important to note that we do not consider this decrease in shell strength to be of practical importance. For example, the observed difference in tensile strength of –120.5 psi is only 6.2% of the mean stress for controls. If we use the 95% confidence interval (–175.4, –65.7 psi), we are 95% sure that the true difference is no less than 3% and no greater than 9%. Surely some degree of weakening is to be expected, and although the data establish that the weakening exists, they also place bounds on it that show it to be relatively small. Because the analysis of ranks
yields nearly the same results as the analysis of the original data, we believe we are justified in using the first analysis of the data to make such estimates of bounds.

Conclusion

The primary objective of this research project was to determine the effect of implantation surgery on the average mechanical properties of Silastic® II silicone gel–filled breast implants. Various strength properties of explants that were implanted in a cadaver breast were compared with those of controls from the same manufacturing lot. Statistical analysis of the data indicates that the mechanical properties of elongation and tear resistance are essentially unaffected. However, the average tensile strength of the explants was reduced 4.9% to 6.2% (for extracted and unextracted shells, respectively) compared with the controls. Breaking energy averages for the explants were also reduced 7.8% to 5.9% (for extracted and unextracted shells, respectively), and average moduli decreased by a similar magnitude. These reductions are quite small, though statistically significant, and refer to averages of the measurements obtained from hundreds of specimens taken from the 34 lot-matched implant shells.

In general we found that the surgical procedure of implanting a breast implant does have a small effect on the average strength properties of the elastomer shell of the implant. It is unlikely that this small reduction is sufficient to be a factor in implant durability. It should also be noted that we evaluated implants from one lot, one size, and one manufacturer. Other factors not addressed in this study that could potentially affect strength properties of implants after implantation surgery include lot variability, implant size, different manufacturers, the surgeon’s technique, the location and size of the incision, and whether the implant inserted is a patient’s first implant or a replacement.

We gratefully acknowledge the review of the statistical analysis in this study by Professor Edward Spitznagel of the Mathematics Department, Washington University, St. Louis, MO. His suggestions and assistance with robust estimators were valuable contributions to the data analysis.

References

15. Mann HB, Whitney DR. On a test of whether one of two random variables is stochastically larger than the other. Ann Mathematical Statistics 1947;18:50-60.