Ultimate Strength Properties of Control and Explanted Silastic 0 and Silastic I Silicone Gel-filled Breast Implant Shells

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Background: The effect of in vivo implantation on breast implants is important to both physicians and patients, but little information about the in vivo aging process of silicone gel-filled breast implants has appeared in the literature. The effects of the in vivo aging process could affect the durability of breast implants.
Objective: The purpose of this study was to investigate changes in the mechanical and chemical properties of breast implant shells as a function of implantation time.
Methods: The ultimate mechanical properties of the shells from single-lumen silicone gel-filled Silastic 0 and Silastic I explants with in vivo duration times ranging from 6 to 28 years were measured and compared with the corresponding properties of unimplanted control single-lumen silicone gel-filled implants. Ultimate tensile strength, elongation-to-failure, and tear resistance were measured for both explant and control shells through use of identical testing protocols. In addition, the tensile strength and elongation-to-failure of shells extracted with hexane to remove non–cross-linked silicones were measured for both explants and control implants. The ultimate strength data were plotted as a function of implantation time, along with data from other research institutions.
Results: Statistical analysis of the data indicated that the ultimate mechanical properties of tensile strength, elongation-to-failure, and tear resistance are not functions of implantation time for up to 28 years of implantation.
Conclusions: The results of this study show that there is no significant degradation of the mechanical properties of the elastomeric shell as a function of time.

The effect of in vivo implantation on breast implants is of concern and interest to the medical community as well as to breast implant users. The primary concerns are the overall safety, long-term stability, durability, and aesthetic value of the device. The present study focuses on the durability of the device, which depends on the long-term stability of the mechanical properties of the shell in vivo. Our study is primarily concerned with the strength characteristics of Silastic 0 and Silastic I implants (Dow Corning, Midland, MI). The Silastic 0 implants were manufactured from approximately 1969 to 1974, and the Silastic I implants were manufactured from approximately 1975 to 1986. We analyzed these implant shells together because they are composed of the same silicone elastomer. The primary difference between the 2 implants is in the

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viscosity of the gel. The influence of the different gels on the long-term mechanical properties of the shells appears to be negligible for these 2 types of implants.

Little information about the in vivo aging process of silicone gel-filled breast implants has appeared in the literature, and that which has appeared has generally not accounted for variability among different manufacturing lots, types, or manufacturers.[1-4] A previous study[5] has shown that it is desirable to compare the properties of explants with those of lot-matched controls, or at the very least with the control property ranges. However, these types of comparisons have been made in only a few studies. In one such study,[6] the shell property data of 2 Dow Corning explants were compared with the minimum-to-maximum ranges of properties of similar controls; the results showed that the implant shells had undergone no significant degradation during 28 years of implantation.

Failure to compare explant data with the proper control data can result in incorrect observations and conclusions. For example, Marotta et al[2] measured the mechanical properties of 10 Dow Corning explants and 3 unimplanted controls without regard to implant type or manufacturing lot. Comparing the explant data with limited control data, the authors concluded that there was a significant degradation of the implant shells, which they regarded as an important factor in the high rupture/failure rates reported for silicone gel-filled breast implants as a function of implantation time. However, all of the tensile stress and elongation measurements for the Silastic 0 and Silastic I explants reported by Marotta et al[2] fall within the range of controls reported by Brandon et al.[5]

The ability to determine the aging characteristics—ie, the durability—of any system is directly dependent on a knowledge of the parameters of interest at the onset of the aging process, which in this case is the time of implantation. The primary properties of interest for this study are tensile strength, elongation-to-failure, and tear strength, inasmuch as any factors affecting these parameters may directly affect the life of an implant. It is important to measure the properties of interest after a given aging interval using the same methods and techniques as those used to determine the initial values. Ideally, unaged lot-matched control implants should be compared with their matched explants. However, lot-matched controls for Silastic 0 and Silastic I explants are generally not available. In the absence of lot-matched controls, we have compared the mechanical property measurements of the explants with the mechanical property ranges of unimplanted Silastic 0 and Silastic I controls.

The primary factors affecting the strength of the elastomeric shell are the nature of the coupling between the silica and silicone and the degree of cross-linking of the elastomer. To determine what changes, if any, occurred in the elastomeric shell during the implantation interval, it is necessary to extract from the shell the low-molecular-weight silicones, which diffuse into and swell the shell. The actual amount of extractable material is highly variable; it depends on the (1) time of implantation, (2) cross-link density of the shell, and (3) actual composition of the filling gel. The extractable material from the shell is derived from 2 sources: (1) a small amount, typically 2% to 3% by weight, remaining from the preparation of the shell and (2) material that permeates the shell from the encapsulated gel. The extractable components consist of a complex mixture of linear and cyclic polydimethylsiloxanes with molecular weights ranging from 296 to greater than 5000 d.

Material and Methods

The experimental results reported in this study are for 7 single-lumen Silastic 0 and Silastic I controls, all received in their original sealed packages, and 18 single-lumen explants. The explants from different donors were retrieved by several plastic surgeons and stored in nonsterile containers before testing. The explants were removed primarily because of local symptoms associated with capsular contracture or for implant replacement.

The explants and control implants were prepared for testing by carefully removing the gel from the shell and gently wiping the shell with isopropyl alcohol-moistened Kimwipes (Kimberly-Clark Corporation, Roswell, GA). Eight American Society for Testing and Materials (ASTM) D412 Die C half-scale tensile specimens and 3 ASTM D624 Die C half-scale tear resistance specimens were cut from each of the cleaned shells, and their locations on the shell were recorded. The specimen thickness was measured with a digital thickness gauge with a resolution of 2.54 µm. Eight dog-bone-shaped samples from each shell were used for tensile testing; 3 of these were extracted with hexane before analysis to remove the non-cross-linked silicones from the elastomer. For extraction, these 3 dog-bone samples were gently refluxed with chromographic-grade hexane (Fisher Scientific, Pittsburgh, PA) at 60°C over a period of 72 hours and then carefully dried to constant weight. The percent extractable was

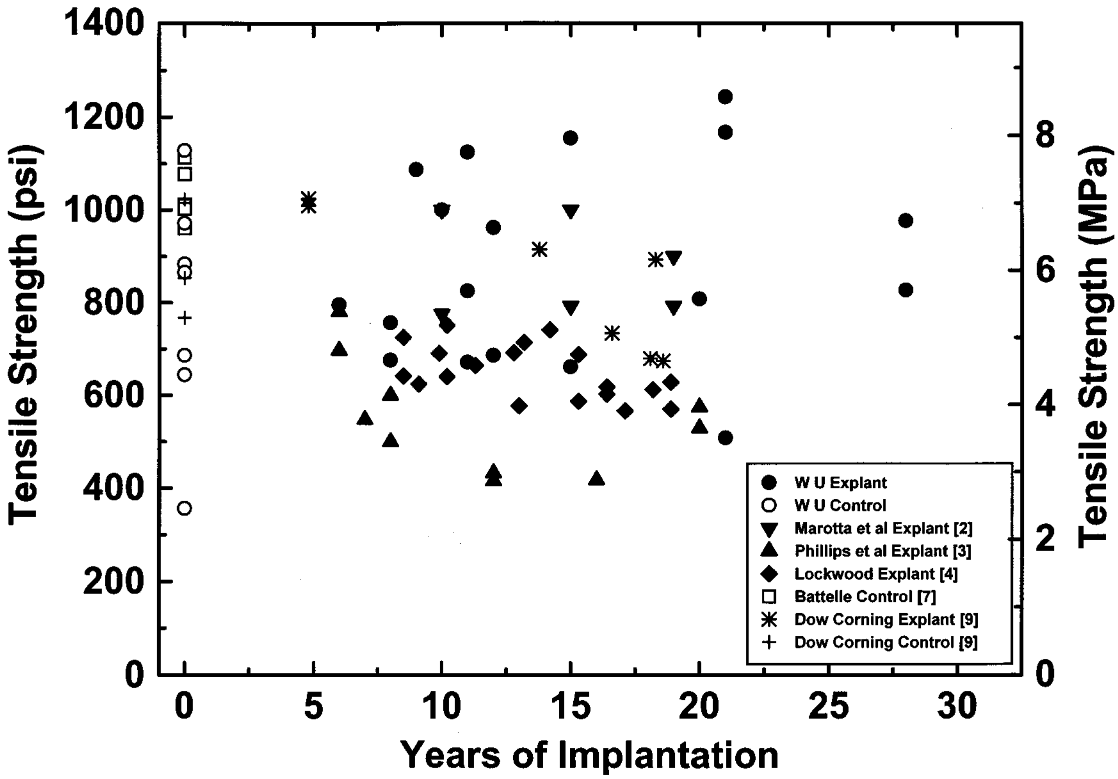

Figure 1. *Tensile strength of Silastic 0 and Silastic I implant shells as a function of time in vivo.*

Table 1. Status of Explants at Time of Analysis

	Washington University	Marotta et al[2]	Phillips et al[3]	Lockwood[4]	Dow Corning[9]
Intact	12	2	5	6	1
Ruptured	2	4	3	10	6
Pinhole leak	4	–	2	3	–
Totals	18	6	10	19	7

determined from the initial and final weights. Gas chromatograph mass spectrometric analysis of the extract indicated that it was primarily a complex mixture of linear and cyclic silicones with molecular weights ranging from 296 to 5000 d. All mechanical tests were conducted through use of an Instron 5583 (Instron Corp, Canton, Mass) equipped with a video extensometer, which accurately measures the strain in the gauged section of the specimen. The strain rate for all mechanical tests was 254 mm/min. Data from the 5 tensile specimens, 3 tear resistance specimens, and 3 extracted tensile specimens were individually averaged to determine the mean strength characteristics of each implant.

The implant mechanical property data obtained in this study are compared with data obtained from 5 other studies, all of which used different testing techniques. Some of the data scatter associated with the data plots presented herein is due to the different testing methods. For example, specimen preparation methods in the study of Phillips et al[3] used a metal template and X-Acto knife (Hunt Corporation, Philadelphia, PA) to cut specimens from the shell. Lockwood[4] points out that this technique of specimen preparation can lead to lower strength measurements. In addition, the surface finish and uniformity of the samples are not as consistent with a hand-tracing cutting method as they are with a standard cutting die.

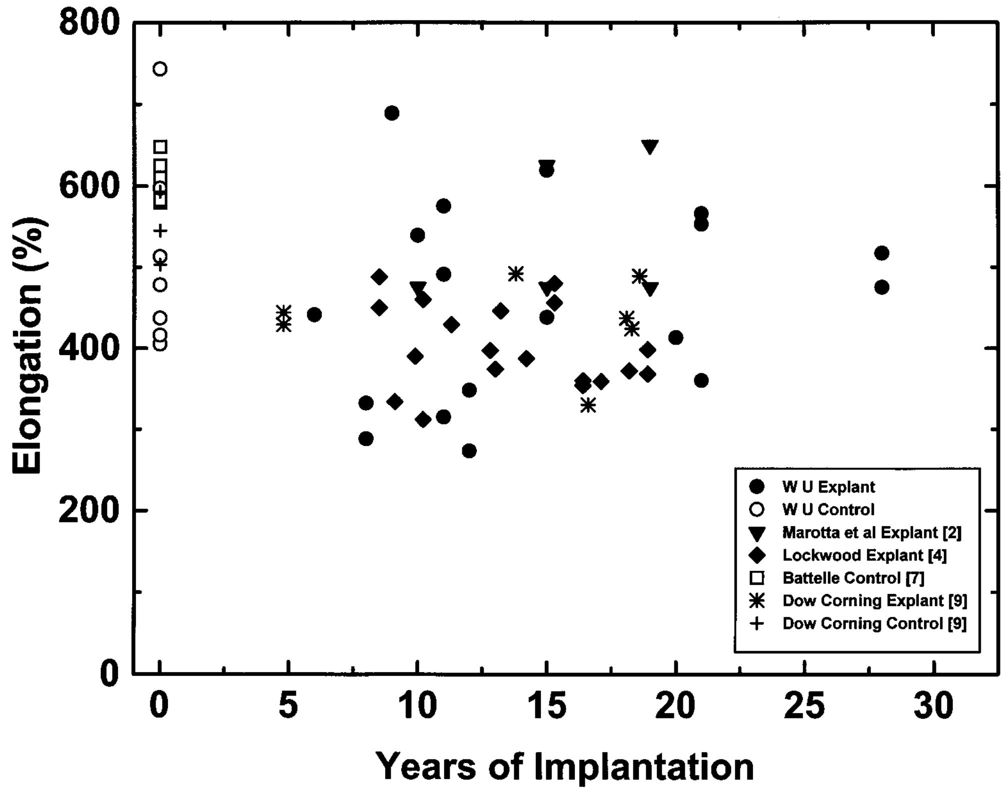

Figure 2. *Elongation of Silastic 0 and Silastic I implant shells as a function of time in vivo.*

Results and Discussion

Tensile stress data for Silastic 0 and Silastic I implant shells as a function of implantation time are summarized in Figure 1. The control data for unimplanted shells are plotted at time zero, and the explant data correspond to implantation periods ranging from 6 to 28 years. Data are for 15 single-lumen controls and 60 single-lumen explants tested at 5 different laboratories and published in 6 different studies.

The status of the explants at the time of analysis according to each of the investigators is summarized in Table 1. Twenty-six of the explants were intact, 25 were ruptured, and 9 had small pinholes. The explants tested by Phillips[3] and Lockwood[4] that were listed as leaking are categorized as pinhole leaks in Table 1. The cause of implant failure is not considered in any of the studies except that of Brandon et al,[6] where 1 explant with 28 years of implantation time had a pinhole caused by a scalpel nick during explantation surgery.

The large range in tensile strength of the control implants is primarily due to lot-to-lot variability among the shells.[5] The scatter in the explant data is also primarily due to lot-to-lot variability and the effect of different testing techniques used in the various studies. Nonetheless, the explant data from the 6 different studies are in general agreement; they indicate that there is no time-dependent degradation in the average shell tensile strength during 28 years of implantation. We also found no significant difference in the tensile strength of intact shells, ruptured shells, or shells containing a pinhole.

A summary of all of the published data from 15 controls and 50 explants on the elongation-to-failure of Silastic 0 and Silastic I implant shells as a function of implantation time is presented in Figure 2. Elongation data were not reported by Phillips et al.[3] Twenty-one of the explants were intact, 22 were ruptured, and 7 had pinholes. Again, we found no significant difference in the elongation of intact and failed implants and no significant shell degradation as a function of time in vivo. A considerable number of explants have elongations below the minimum control value of 405%. The explants with the 4 lowest elongation-to-failure values—3 samples measured in our laboratory (273%, 288%, and 315%) and 1 from Lockwood[4] (312%)—had implantation times ranging from 8 to 12 years; all of these were intact, even though

Figure 3. *Tear strength of Silastic 0 and Silastic I implant shells as a function of time in vivo.*

their elongation-to-failure values were below the ASTM-recommended value of 350%.[6] Because the mechanical properties do not degrade with time in vivo, some other factor or factors must cause the failure of Silastic 0 and Silastic I implants.

The data shown in Figures 1 and 2 represent the average tensile strength and elongation-to-failure of many specimens measured at different locations on the implant shell. Only average values for each implant were reported in the other studies; therefore, a complete statistical analysis of the data is not possible. However, 2 statistical analyses were carried out. First, a regression analysis on the data was performed, with robust standard errors and significance probabilities computed on the reported means of the ultimate stress, elongation, and tear properties. Second, a regression analysis on the ranked data was performed, with robust standard errors and significance probabilities. Using ranks reduces the effect of outliers without seriously affecting statistical power.

A comparison of average mechanical properties according to implant status shows an insignificant effect of implantation time on the mechanical properties of the elastomeric shell. The average tensile strength of the unimplanted controls is 889 psi, whereas that of the explants is 749 psi. The average tensile strength of the intact explants is 763 psi, whereas that of the ruptured/pinhole implants is 738 psi. The average strength of the explants is slightly lower than that of the controls. However, it is important to note that the average strength values for intact and ruptured implants are nearly identical. The results of the 2 statistical tests on strength indicate no difference in ultimate strength as a function of implantation time at a level of significance of .01. The average value of elongation-to-failure for the unimplanted controls is 552%, whereas that for the explants is 441%. As was the case for strength, the average elongation values for the intact and ruptured explants are nearly identical—428% and 451%, respectively. The results of the 2 statistical tests on elongation indicate no difference in ultimate elongation as a function of implantation time at a level of significance of .01. In fact, on close inspection, the average elongation-to-failure value for the visibly ruptured samples is seen to be slightly greater than that for the intact samples.

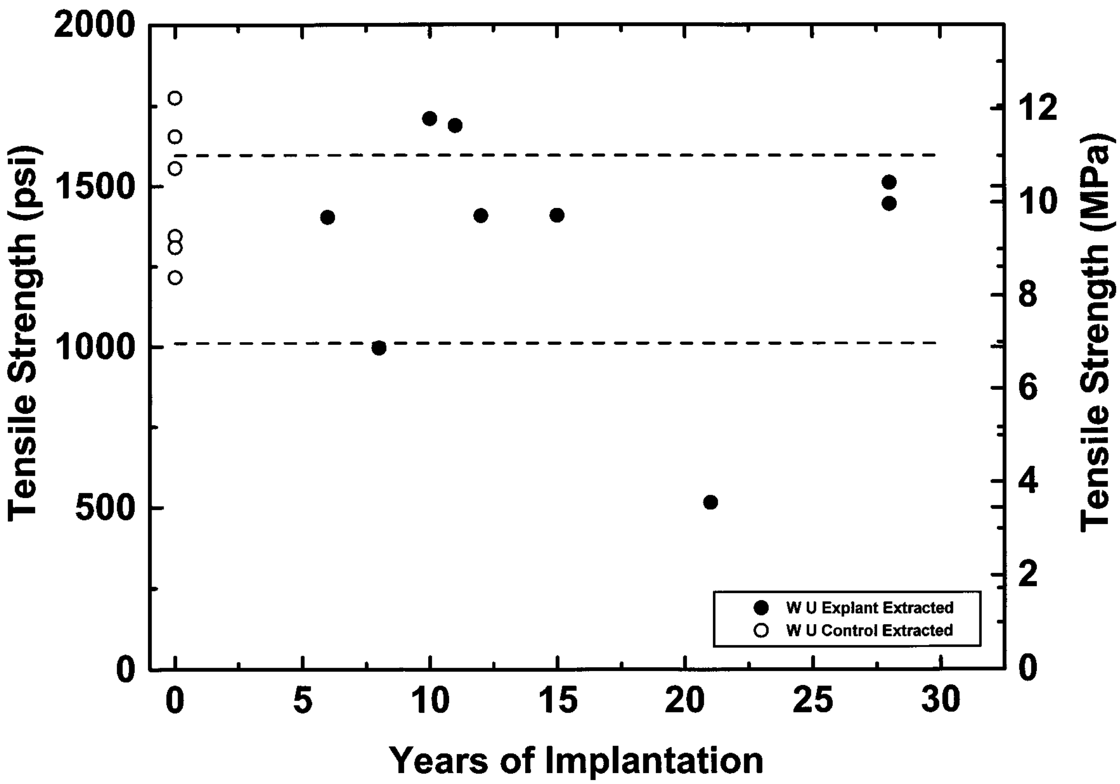

Figure 4. *Tensile strength for extracted Silastic 0 and Silastic I implant shells as a function of time in vivo.*

The tear strength data for 7 controls (plotted at implantation time zero) and 17 explants as a function of implantation time is shown in Figure 3. All of the data were taken at Washington University. The tear resistance data published by Marotta et al[2] and Morey and North[7] are not included inasmuch as those data were obtained through use of a different test protocol that does not allow a direct comparison with the present data.[8] The explant data have implantation times ranging from 6 to 28 years. On the basis of a regression analysis, the tear strength is independent of implantation time at a level of significance of .01. Eleven of the explants were intact, 2 were ruptured, and 4 had pinholes. As with tensile stress and elongation, the tear data are not a function of whether the explant was intact, was ruptured, or had a pinhole. The explants with the lowest values for tear resistance were intact, nonruptured implants.

The strength and elongation-to-failure for 6 controls and 9 explants after the low-molecular-weight non-cross-linked silicones had been extracted from the shells are shown in Figures 4 and 5, respectively. Because this procedure was not always part of our testing protocol, only a limited number of implant shells were extracted. Seven of the explants were intact, and 2 had pinholes. The dashed lines in both figures represent the ranges of tensile strength and elongation-to-failure values reported by the manufacturer[9] for the elastomeric dispersion material used to prepare the implant shells. The 3 implants that fell outside the expected ranges were intact. Regression analysis at a significance level of .01 shows that the strength and elongation properties of the silicone elastomer shell are not a function of implantation time for up to 28 years of implantation.

The results of the present study, illustrated in Figures 1 through 5, are in sharp contrast to those presented in a recent publication by Marotta et al,[2] who concluded that mechanical property degradation of implant shells is an important factor in supporting the high rupture/failure rates recently reported for silicone gel breast implants as a function of implantation time.

Conclusion

The ultimate properties of tensile strength, elongation-to-failure, and tear resistance of Silastic 0 and Silastic I sili-

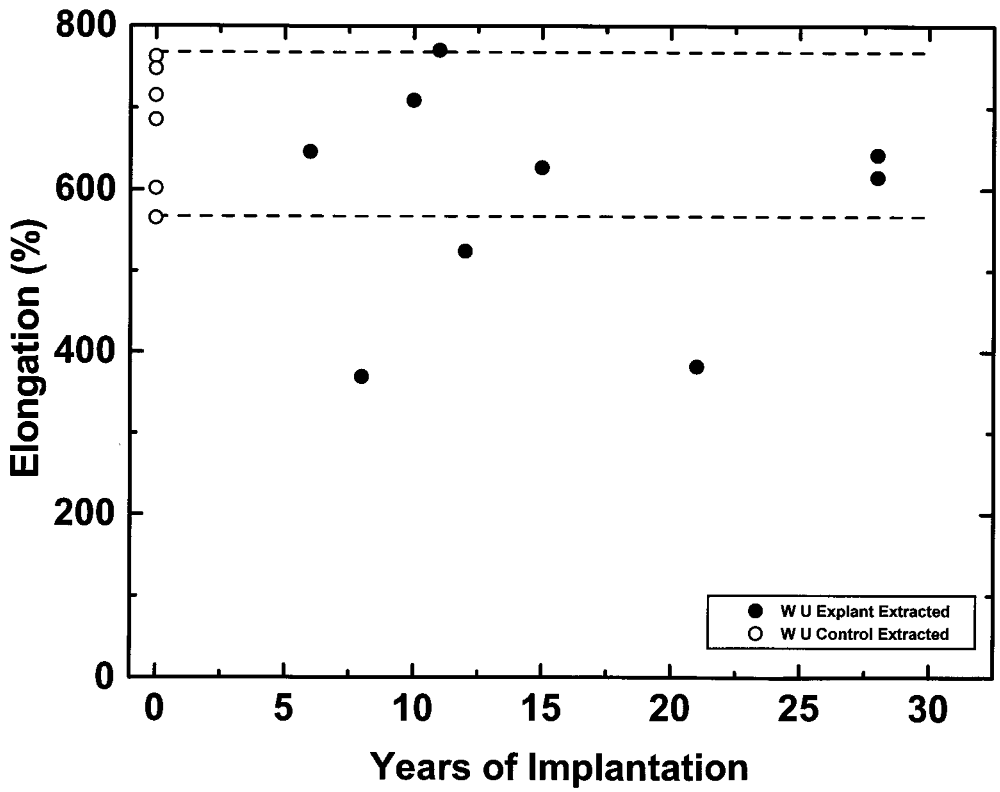

Figure 5. *Elongation for extracted Silastic 0 and Silastic I implant shells as a function of time in vivo.*

cone gel breast implants with implantation times ranging from zero (controls) to 28 years were measured and analyzed. The data obtained in this study were compared with explant and control data on the same types of implants from 5 other studies to determine the effect of long-term implantation. The results clearly indicate that the ultimate mechanical properties—tensile strength, elongation-to-failure, and tear resistance—do not appreciably depend on time in vivo. On the basis of all of the data published to date on Silastic 0 and Silastic I implants, we have concluded that implant failure is not the result of in vivo degradation of shell mechanical properties. ■

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