Strength of Silicone Breast Implants

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Abstract

Rupture and leakage are recognized problems associated with silicone breast implants. Data are scarce about the durability of the silicone shell, and the life span of this device is unknown.

The purpose of this study was to investigate the strength of silicone breast implants. Thirty implant shells were subjected to mechanical testing. Twenty-nine of the shells were tested after explantation and one unused implant served as a control. Implantation time varied from 4 months to 20 years and all shells were tested, regardless of condition. Fourteen implant shells were intact, 8 were leaking and 7 were ruptured. All ruptured implants had been in place for 10 years or longer.

Specimens from the control shell required 15.5 to 25.6 N (3.5 to 5.8 lb) of force to fail. The breaking force of all other specimens ranged from 1.3 to 15.6 N (0.3 to 3.5 lb). The weakest group of specimens was from thin-shelled implants between 10 and 16 years of age. More than half of these specimens failed with less than 1 lb of force. The average breaking force of ruptured shell material was less than that of intact shells.

A comparison of strength data in this study with manufacturers' data suggests that breaking force is dependent on implant type, shell thickness and implantation time.

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Introduction

Recent reports of rupture of the silicone gel breast implants[1] have prompted scientific inquiry into not only the strength of the shells, but also the effect of usage age on the material itself. In a clinical study on 51 implants, de Camara et al.[2] found that all implants older than 10 years were either ruptured or leaking silicone gel. In another study, van Rappard et al.[3] found that the pressure resistance of intact implants decreased with implantation time. The literature that is readily available on the implant shells has been prepared by the manufacturers and reflects properties of unused shell material.[4,5,6] Such data are pertinent for comparison of one manufacturer's unused product with another, but give little insight into the *in vivo* behavior of the product.

The purpose of this study was to investigate the mechanical properties of the shell of silicone breast implants after explantation. Implants were subjected to mechanical testing to determine the strength of the implant shell. The techniques used in this study were applied to intact, leaking, and ruptured implants.

Materials and methods

The 29 implant shells tested in this study had implantation times between 4 months and 20 years. Causes for removal included implant rupture, capsular contracture, and personal request. Sixteen of the implants could be identified by manufacturer. Removal was performed by two plastic surgeons at a large multi-specialty clinic during the years 1990–1992. The implants were stored in saline and transported to the laboratory in individual containers. General observations were made on the condition of the implant shells prior to testing.

One or more specimens were then prepared from each implant shell and individually tested for strength. A total of 198 specimens were tested from the 29 shells. All implants were tested, regardless of condition. If the implant had a double lumen, both inner and outer shells were tested.

For comparison purposes, 9 specimens from an unused Dow Silastic II were also tested and results compared with industry standards to validate our testing methods. The mechanical testing was performed using guidelines outlined by the American Society for Testing and Materials.[7]

Specimen preparation

The breast implant was placed on a smooth, firm surface with the seal patch in mid-position posteriorly. An X-Acto blade was used to incise each implant in a circumferential manner, leaving about 20 percent of the circumference intact. The implant shell was then opened and the gel gently removed with a plastic spatula; remaining gel residue was removed with paper towels. Care was taken not to damage the shell surface in any way, particularly those shells that were already torn.

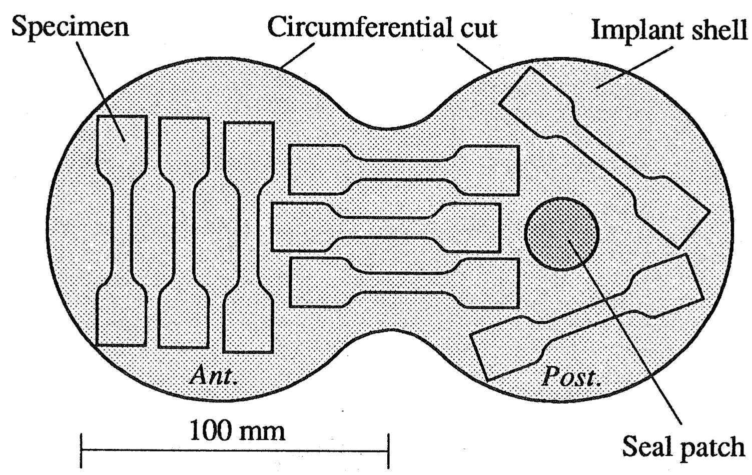


Fig. 1. Typical arrangement of specimens in an implant.

After the visible gel was removed from the shell surfaces, the shell was cut into individual specimens, as illustrated in Fig. 1. A thin, smooth, stainless-steel, dumbbell-shaped template (Fig. 2) was gently secured on top of the shell with clamps. The template was then carefully traced all the way around with an X-Acto blade, thereby creating one specimen. From 1 to 13 specimens were cut from each implant shell, depending on the size of the shell and the presence of tears. An average of 7 specimens were cut from each implant.

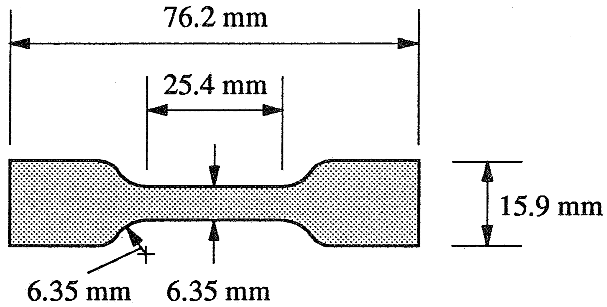


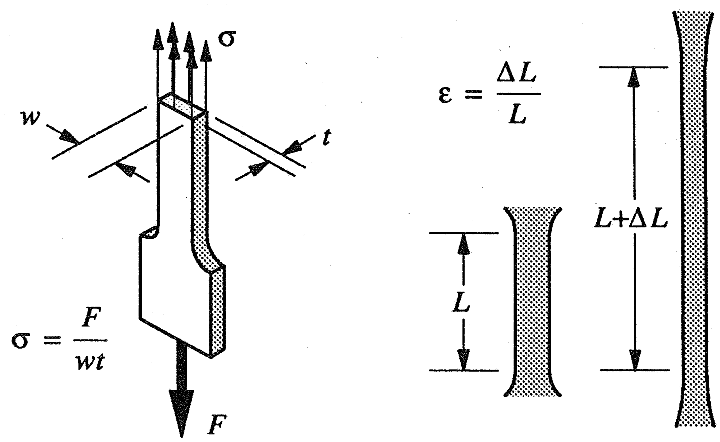
Fig. 2. Metal template used to cut specimens.

Specimens were first cut from the remaining circumferential portion of the shell. Additional specimens were cut from the rest of the shell, avoiding the seal patch. The thickness of each specimen was measured to the nearest 0.01 mm using a digital Vernier caliper before testing was performed. Three thickness measurements were taken within the mid-portion of the specimen and averaged to obtain the mean thickness value t. Similar measurements were made of the actual width w of each specimen. (Due to the compression of the template on the specimen, the actual specimen width tended to be slightly less than the template width.) Specimens were moistened with saline solution and stored in individually labeled zip-lock plastic bags prior to testing. Specimens judged to be defective for any reason were excluded from testing.

Testing procedure

Strength testing was done with a large-capacity universal testing machine (MTS, Minneapolis, Minn., model 312.21). The upper end of the specimen was secured in a fixed position and held by a fixed load cell (MTS, Minneapolis, Minn., model 3170-101). This load cell measured the force F that was applied to the specimen. The lower end of the specimen was clamped in a grip attached to a movable piston (hydraulic ram). Downward motion of the piston caused a displacement ΔL of the specimen. Rubber pads about 2 mm thick glued to the gripping surfaces completely secured the enlarged ends of the specimen.

With this apparatus, the force–displacement data were collected. Piston speed was set to 10 mm/second, with a maximum excursion of 120 mm. A typical test was completed in about 12 seconds. Force and displacement data were taken at 40 millisecond time intervals, resulting in about 300 data points for each specimen.



(a) Stress σ (b) Strain ε

Fig. 3. Nomenclature used in the definitions of stress and strain.

Some of the specimens were very resilient and their change in length (displacement) exceeded the excursion capacity of the MTS testing machine. When this situation arose, the remaining specimens from these samples were tested by hand in a different machine (ATS, Butler, Pa., model 910-36) with a different load cell (Interface, Scottsdale, Ariz., model SM-100), maintaining the same testing rate.

Data analysis

The raw data gathered in this study were the force F and the corresponding displacement ΔL, both as functions of time, for each specimen. The *maximum force* F_{max} that the specimen withstands before failure is one measure of strength of a specimen. In the metric system, the unit of force is the newton (N), which is equal to about 0.225 lb. Another commonly used measure of strength is the *maximum stress* σ_{max} that the specimen withstands before failure. The stress σ is given by the quotient F/A, where A is the original cross-sectional area; a specimen having width w and thickness t has a cross-sectional area A given by the product $w \times t$. See Fig. 3(a). In the metric system, the unit of stress is the pascal (Pa), which is one newton per square meter.

Table 1. Summary of test data

Shell number	Manufacturer	Condition of implant	Age (yrs)	Average thickness t (mm)	Avg. max. force F_{max} (N)	Avg. max. stress σ_{max} (MPa)
1	Dow Silastic II	Intact	0.3	0.26	14.78	9.05
2	McGhan	Intact	1	0.31	11.62	5.82
3	Surgitek	Intact	2	0.31	8.27	4.21
4	Surgitek†	Intact	2	0.67	22.37	5.33
5	Dow Silastic II	Intact	4	0.25	7.00	4.50
6	Dow Silastic II	Leaking	5	0.37	13.42	5.87
7	Dow Corning	Intact	6	0.21	6.72	5.38
8	Dow Corning	Intact	6	0.23	7.04	4.80
9	Dow Corning	Intact	7	0.26	6.15	3.77
10	Dow Corning	Intact	8	0.25	6.39	4.13
11	Dow Corning	Intact	8	0.24	5.20	3.44
12	Unknown	Leaking	10	0.21	3.31	2.40
13	Unknown	Leaking	10	0.20	3.46	2.80
14	Unknown	Intact	10	0.16	4.25	3.82
15	Unknown†	Leaking	10	0.16	4.27	4.25
16	Unknown	Intact	10	0.13	4.92	5.84
17	Unknown†	Leaking	10	0.16	4.87	4.82
18	Unknown	Intact	11	0.17	3.08	2.90
19	Unknown	Ruptured	11	0.16	2.64	2.65
20	Unknown	Leaking	12	0.35	7.94	3.59
21	Dow Corning	Ruptured	12	0.21	3.83	2.86
22	Dow Corning	Leaking	12	0.26	4.77	2.98
23	Unknown	Intact	15	0.19	4.94	4.20
24	Dow Corning	Leaking	16	0.18	3.70	3.29
25	Unknown	Ruptured	16	0.24	9.49	6.23
26	Unknown	Ruptured	16	0.18	4.49	3.59
27	Unknown	Ruptured	19	0.43	11.47	4.23
28	Dow Corning	Ruptured	20	0.52	12.47	3.65
29	Dow Corning	Ruptured	20	0.46	11.73	3.96

†Inner shell

To compensate for small variations in width w, we multiplied the raw F_{max} value found for each specimen by a correction factor equal to (6.35 mm)/w to determine the value of F_{max} which *would* have occurred in a specimen having a width of exactly 6.35 mm (1/4 in.). All F_{max} data reported in this paper have been corrected using this procedure.

Since all the specimens in this study have nominally the same shape, maximum force data may be used directly for certain comparative purposes. However, maximum stress data provide a measure of the intrinsic strength of the material itself, without regard to specimen size or shape.

Results

Implantation times in this study varied from 4 months to 20 years. A summary of the test data, including manufacturer, implantation time, condition of implant, average thickness, and strength values, appears in Table 1.

Condition of implants

Of the 29 used shells tested, 7 were ruptured with tears in the shell, 8 were obviously leaking silicone gel, and 14 were intact. As indicated in Table 2, most of the intact shells had been implanted less than 9 years, and most of the leaking and ruptured shells had been implanted for 9 years or more. Ruptured shells were generally torn along the circumference. No ruptures were observed to emanate from the edges of the seal patches.

Table 2. Correlation between implantation time and condition of implant

Implantation time	Condition of implant		Total
	Intact	Leaking or ruptured	
< 9 yr	10	1	11
≥ 9 yr	4	14	18
Total	14	15	29

Shells were found to be of varying thickness, not only among implants, but also among specimens cut from a single shell. Specimens cut from the circumference were generally thinner than those cut from the anterior and posterior surfaces. The average thickness t of all implant shells was 0.27 mm, with a standard deviation of 0.12 mm (44 percent). Excluding four unusually thick shells (shell numbers 4, 27, 28, 29), the average thickness t was 0.23 mm ± 0.06 mm (26 percent).

Typical force–displacement plot

A typical result of the mechanical testing is seen in Fig. 4. This figure illustrates the response of one specimen from an 8-year-old implant during the test. The force F is plotted as a function of the displacement ΔL of the piston with loading of the specimen. Note that for this specimen the force is essentially proportional to displacement; that is, the silicone shell remained linear elastic to failure. At failure, the specimen tore into two pieces; that is, there was complete disruption of the implant shell specimen. Failure occurred when the shell specimen had been elongated by 76 mm, at which time the force was 4.9 newtons (slightly more than one pound).

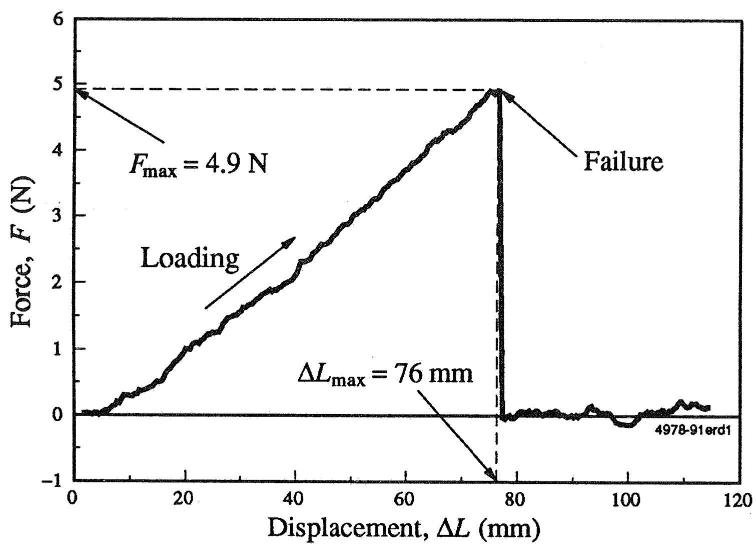


Fig. 4. Typical implant shell force–displacement plot for a specimen.

Test method corroboration

Our test results for an *unused* Dow Corning Silastic II implant shell[8] are compared with existing manufacturers' data in Fig. 5. The authors' maximum force of 21.1 N ± 2.8 N compares favorably with data for the Silastic II published by Surgitek.[4] The authors' maximum stress of 9.92 MPa ± 1.35 MPa also compares favorably with data for the Silastic II published by Surgitek,[4] Dow Corning,[5] and Battelle.[6] As seen in Fig. 5, there is a wide variation of initial strengths among the selected manufacturers' products—maximum stress values range between about 6 MPa and about 12 MPa.

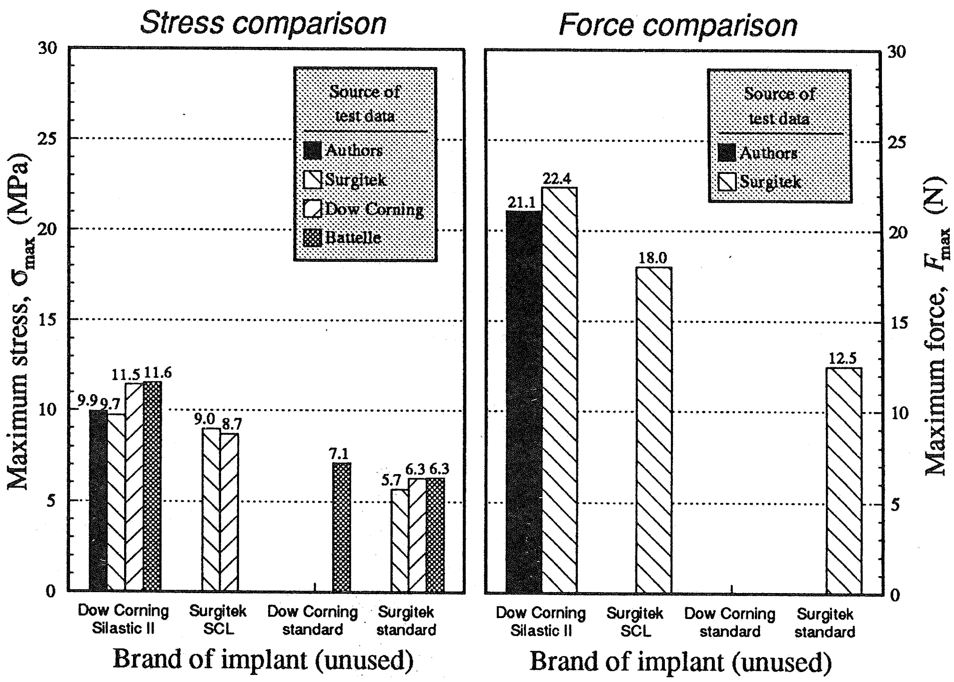


Fig. 5. Comparison of initial strengths of implants.

Strength as a function of implantation time

The dependence of maximum force F_{max} on implantation time is given in Fig. 6. Each plotted symbol represents the average value of strength F_{max} for all the specimens cut from one shell, and the error bars represent the standard deviation. Many of the specimens were either Dow standard or Dow Silastic II, and these are indicated with solid symbols.

Two of the ruptured implants at age 16 were calcified and very difficult to test because they were so fragile and brittle. The point annotated by a question mark corresponds to the only specimen (of 6 specimens) from one calcified implant that did not crumble during cutting or handling.

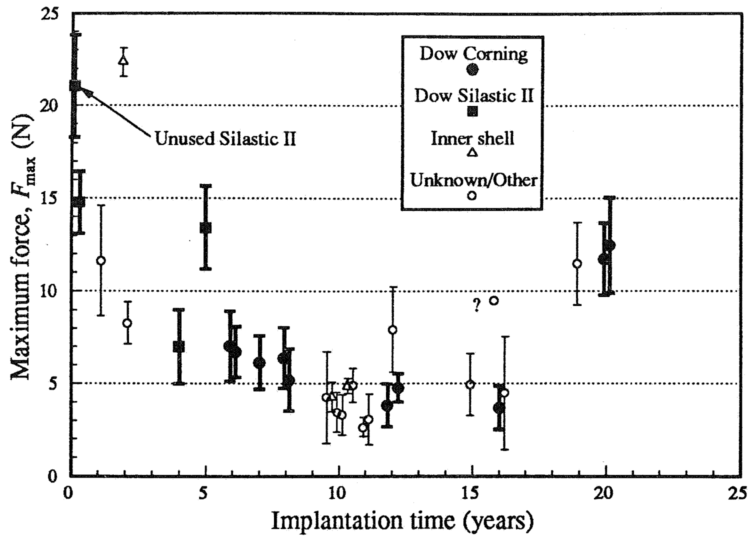


Fig. 6. Maximum force as a function of implantation time (by manufacturer).

A rather strong negative correlation is found between the maximum force F_{max} and implantation time for implants in the 1- to 18-year-old group. The three implants more than 18 years old, however, were comparatively strong; they had shell thicknesses about twice that of other specimens.

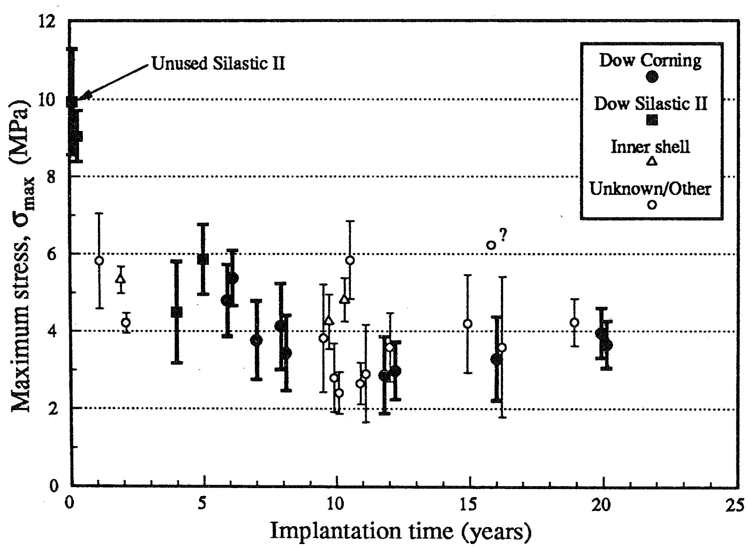


Fig. 7. Maximum stress as a function of implantation time (by manufacturer).

An investigation of the *stress* σ_{max} in each specimen at failure was also conducted. See Fig. 7. Compared with the maximum force data, the maximum stress data were better correlated with implantation time. The point annotated by a question mark corresponds to the calcified implant specimen just mentioned. As in Fig. 6, data are differentiated by manufacturer.

Another plot of some interest is that of stress σ_{max} vs. implantation time, with data differentiated by condition of implant. This plot appears in Fig. 8.

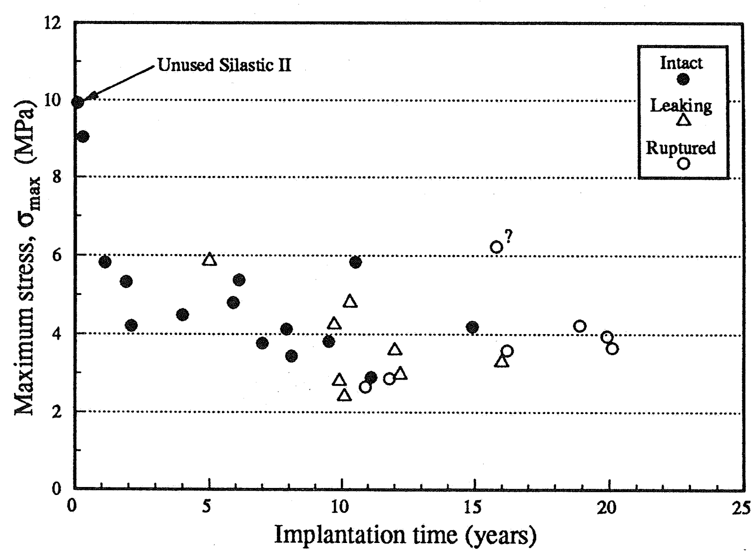


Fig. 8. Maximum stress as a function of implantation time (by condition).

The dependence of failure stress on position within each shell was also studied, but no significant trend was found, despite the observation that ruptured shells were usually torn along the circumference.

Discussion

Condition of implants

The results of this study suggest a strong correlation between the condition of silicone gel breast implant shells and implantation time. The implants that had been in place more than 9 years were generally either ruptured or leaking, and those in place less than 9 years were generally intact.

See Table 2. A chi-square analysis, with Yates' correction, of the data in Table 2 gives $\chi^2 = 10.3$, which is much larger than $\chi^2_{0.95} = 3.8$ for a one-degree-of freedom table, meaning that the correlation is very significant at the 0.05 level. These results are in general agreement with the earlier clinical study by de Camara et al.,[2] who found that the condition of silicone breast implants depended strongly on implantation time. Rolland et al.[9] also report similar results for 97 implants excised during the period 1979–84; they stated that torn prostheses had often been implanted for longer periods.

The distribution of the condition of the 29 shells tested (7 ruptured, 8 leaking, 14 intact) follows only roughly the distribution of 51 shells studied earlier by de Camara et al.[2] (27 ruptured, 7 leaking, 17 intact). The principal difference between the two studies is the absence of ruptured implants in the current study in the 1- to 9-year age group. However, the patient population in the earlier study were symptomatic women, many of whom had capsular contracture around the breast implants. The current work, in contrast, was not a clinical study, and concentrated on the mechanical properties of the shells after removal.

Strength as a function of implantation time

The data in this study also indicate a decrease in implant strength with implantation time. Strength was measured both in terms of the maximum force F_{max} that a 6.35 mm (1/4-inch) wide strip of the implant shell could withstand in tension, and in terms of the maximum stress σ_{max} characteristic of the material itself. The two measures of strength are related, as illustrated in Fig. 3(a), and both are relevant in this study: maximum force values provide a measure of *structural* strength of the shell (proportional to thickness), while maximum stress values provide a measure of *material* strength (independent of thickness).

The data in Fig. 7 indicate that the *material* strength of implanted shells decreases with implantation time. To test this hypothesis, we constructed a table like Table 2, again dividing the implants into two groups—those with implantation times less than 9 years, and those with implantation times of 9 years or more. In the first group, there were 2 implants with strength σ_{max}

< 4 MPa, and 9 with strength $\sigma_{max} \geq 4$ MPa, whereas in the second group, the numbers were 12 and 6, respectively. A chi-square analysis, with Yates' correction, of the resulting table gives $\chi^2 = 4.6$, which is slightly larger than $\chi^2_{0.95} = 3.8$, indicating that there is a significant correlation at the 0.05 confidence level. This correlation, however, is not as strong as the one previously noted between implantation time and condition of implant.

Perhaps the best evidence of strength reduction with time is provided by the Dow standard implants, which show a rather steady decline of about 40 percent in the 6- to 12-year implantation time period, from about 5 MPa to about 3 MPa. It is unfortunate that we did not have any unused Dow standard implant shells to test. However, Battelle[6] reports an original strength of 7.1 MPa for unused Dow standard shells. (See Fig. 5.) If both their data and our data are correct, then there is about a 50 percent decrease in material strength of Dow standard shells during the first 9 to 10 years of implantation. Thereafter, the strength seems not to decrease further. In fact, the two 20-year-old Dow standard implants had strengths closer to 4 MPa; perhaps the trend reversal is due to different chemical composition or to the fact that these older shells were very thick.

There is also the possibility of a rapid decrease in material strength within the first 1 to 2 years of implantation time. The control measurements on unused implants both in our lab and from the manufacturers' data indicate strength levels generally higher than those of even the youngest implants in our study. This finding may be consistent with data from Dow Corning on uncoated, unused, filled standard shells. These data show a decrease in strength of 17 to 20 percent after only 2 months, and a decrease of 32 to 34 percent after one year.[10]

For the Dow Silastic II "high performance" silicone shell[8] implants, there appears to be a significant decrease in material strength during the first 5 years of implantation, but it would be premature to make a strong statement because of the relatively few data points available. However, the 4- and 5-year-old Silastic IIs had strengths approximately equal to Dow standard implants of the same vintage.

The data in Fig. 6 indicate that the *structural* strength of implanted shells also generally decreases with implantation time, but the data are more widely scattered than the stress data (Fig. 7) because there is considerable variation in shell thickness. The Dow standard shells in the 6- to 12-year-old group all have approximately the same thickness, and thus show approximately the same percentage decrease in structural strength—about 40 percent—as is observed for maximum stress. The high structural strength of the two 20-year-old Dow standard implants is attributed primarily to the greater thickness of these shells.

The apparent significant decline in structural strength during the first 6 years is in agreement with the structural-strength results of van Rappard et al.,[3] in which Dow standard implants were pressure-tested within a blood-pressure device. Noting a 50 percent reduction in strength within the first 6 years, they concluded that "the pressure resistance of breast implants is negatively correlated with years after implantation" and "after prolonged implantation the pressure resistance of these prostheses may become critically low." Ruptured implants could not be tested with their apparatus. Our results show that there is a continued downward trend in maximum force values, regardless of implant condition, well beyond the first 6 years. (The three implants that were older than 18 years exhibited rather high maximum force values principally because they were about twice as thick as the average implant in the 0- to 18-year old group.)

An explanation for the high incidence of leakage and rupture in the implants over 10 years old may simply be that the general decrease in strength with time leaves implants critically vulnerable to the forces generated by their environment. In Fig. 8 it is observed that implants older than 10 years have material strengths no higher than about 4 MPa; but new implants, as noted earlier, have material strengths between 5 MPa and 10 MPa.

Another finding was the variation in thickness at different sites in the implant shell. The periphery of a shell was generally thinner than the anterior and posterior portions. This variation in thickness is consistent with a report from Dow Corning[11] and may contribute to the peripheral ruptures that were observed in a previous clinical study[2] despite the fact that the material strength of specimens taken from the periphery was found to be about the same as that of specimens taken from anterior and posterior regions.

Testing method

The control implant selected in this study was an unused Dow Corning Silastic II. It was a readily available and commonly used implant. It provided us with a procedure for checking our testing method with those of other laboratories. Of all the products listed in the Surgitek,[4] Dow Corning[5] and Battelle[6] reports, the Silastic II had the highest original strength measurements; see Fig. 5. Our testing results on the Silastic II had comparable values.

The testing procedure in this study follows closely the standard method set by the American Society for Testing and Materials for tensile testing of rubber.[7] The template used to cut specimens has the same 1/4-inch (6.35 mm) gage width w that ASTM die "C" has. However, ASTM die "C" has an overall length of 114 mm, which is too long to allow a reasonable number of specimens to be cut from each implant shell. A smaller overall length of 76.4 mm was used in this study. The gage length L was also correspondingly reduced from 33 mm to 25.4 mm. (See Fig. 2.) These minor modifications should not significantly affect the results; and, even if they do, they would affect all the specimens in the same manner.

The rate at which the specimens were stretched in this study was 10 mm/second. This rate, which was selected to resemble the rapid changes in force applied to a breast implant during trauma, mammography, and closed capsulotomy, is slightly higher than the standard 8.3 mm/second (500 mm/min) value specified in Section 5.1 of the ASTM standard.[7] Silicone rubber exhibits increased strength with an increase in strain-rate,[12] the strength being roughly proportional to the logarithm of the strain rate. Tests by the authors on an unused Silastic II implant showed an increase in strength of 30 percent when the displacement rate was increased from 1 mm/second to 10 mm/second. Thus the values of strength reported in this paper are perhaps uniformly about 8 percent *higher* than those which would have been obtained at the ASTM rate.

Limitations

The currently available control data on breast implants have been taken from Surgitek,[4] Dow[5] and Battelle[6] reports, which compare properties of unused silicone shells between manufacturers. Emphasis in these reports was placed on the high-performance (Dow Silastic II and Surgitek SCL) implants; only 3 of our implants were high-performance and could be reasonably compared with these controls. The Battelle report[6] provided a datum for the original material strength of Dow Corning standard shells. However, unused implants of the same age and manufacture of those removed in this study were not available for comparison purposes. The lack of age-specific controls prevents us from distinguishing between the effects of shelf life and the effects of implantation time.

Although our study indicates a negative correlation between strength and implantation time, the possible *mechanisms* of strength loss have not been studied in any detail. The presence of fold flaws[9] in many excised implants raises questions about stress concentrations; this aspect is currently under investigation. Additional testing of the implant shells is needed, with particular emphasis on the newer high-performance and textured implants.

Conclusions

There is a negative correlation between material strength and implantation time. An even stronger negative correlation exists, however, between condition of the implant and implantation time, as observed earlier.[2] Although the newer high-performance implants appear to offer an improved initial mechanical strength, there is cause for concern for the standard types, particularly the thin-shelled ones, that have been implanted 10 years or more. Many of these shell samples broke with less than 1 lb of force.

Acknowledgments

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