ANALYSIS OF EXPLANTED SILICONE/SILICA COMPOSITE BREAST IMPLANTS

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SUMMARY: A study was conducted to examine the physical, mechanical, and chemical properties of composite (silicone/silica) breast implants as a function of implantation time. In the study the properties of SILASTC®II gel-filled explants with in vivo duration times ranging from 4 months to 10 years were compared to lot-matched control (unimplanted) samples. Tensile strength properties were measured for both explant and control shells using identical testing protocols. The tensile strength properties of shells which were extracted with hexane to remove non-cross linked silicones were also measured. In addition, swelling measurements were used to determine the average molecular weight between cross-links (and/or entanglements). The tensile strength properties obtained from the present study were correlated with implantation time. The results of the study suggest that the silicone elastomer shells do not undergo appreciable degradation during in vivo aging.

KEYWORDS: biomedical, durability, mechanical properties, breast implants, silicone/silica, gel implants.

INTRODUCTION

Advanced polymeric and composite materials are used extensively in the biomedical field. The biomedical application considered in this study is silicone breast implants. The breast implant shell which contains the fluid or gel is a composite composed of a cross-linked silicone rubber containing a fine amorphous silica filler. The silicone/silica composite shell of a breast implant is filled with lightly cross-linked silicone gel, saline solution, or soybean oil. Only silicone gel implants are considered herein. In general, silicone gel implant shells fall into two broad classes typified by Dow Corning SILASTIC®I and SILASTIC®II implants. SILASTIC®I implants contain only the silicone/silica shell while SILASTIC®II implants contain an additional fluorosilicone elastomeric barrier coating. The barrier coating layer is added to minimize the permeation of gel fluid components, typically low molecular weight silicones, through the shell. A previous study [1] considered the long-term aging of both SILASTIC®I and SILASTIC®II implant shells. The present study focuses on the long-term durability and characterization of the physical and mechanical properties of the silicone/silica

composite shell for SILASTIC® II gel-filled implants with implantation times ranging from 4 months to 10 years.

For a silicone gel implant the primary properties of interest are the tensile strength, tensile elongation, moduli, tear strength, and crosslink density. Any factor that affects these parameters could directly affect the life of an implant. Furthermore, it is important to determine the properties of interest after a given in-vivo interval by the same methods and techniques that were used to determine the initial values. Since physical and analytical methods have changed so much during the 30-year history of silicone implants, it is necessary to compare the values obtained from control samples with in vivo aged samples (i.e., explants) by identical experimental methods. The ideal control is a lot matched implant prepared from the same batch of material as the explanted sample.

There are many factors which affect the strength of the elastomeric shell, but two of the most important factors are: 1) the nature of the coupling between the silica and the elastomer and 2) the degree of crosslinking of the elastomer. Any changes in either of these two properties will markedly affect the strength, i.e., mechanical properties, of the elastomer. The crosslink density, which is inversely proportional to average molecular weight between crosslinks and/or entanglements, is directly related to the mechanical properties of the polymer: a low crosslink density indicates a more open highly elastomeric molecular chain structure while a high crosslink density indicates a more brittle material. Crosslinked unfilled elastomeric silicones are relatively weak materials. However, their tear strength can be increased a factor of 30-40 upon the addition of finely divided silica [2]. The reinforcing effect of finely divided particulate matter in elastomers is well-known in the rubber industry. Any long-term aging factors, such as interaction of the silicone/silica shell with biological fluids or swelling from the sorption of low molecular weight compounds from the gel could lead to changes in both mechanical properties and crosslink density of the elastomeric shell.

The chemical properties of the silicone elastomeric shell and silicone gel are nearly identical: the primary difference is due to the higher degree of crosslinking in the shell compared to the gel. Therefore, one expects and observes that the low molecular weight components of the gel diffuse into and swell the shell.

Since our goal is to determine what changes, if any, occur in the properties of the elastomer shell due to implantation, it is necessary to compare the properties of the elastomer in the explant to those of the control. The specimens were compared two ways: 1) directly (after careful cleaning), and 2) without the complicating effect of the sorbed gel. For the later studies, the gel was removed by extraction with hexane. Thus, the properties of the shell and associated lot matched control were measured before and after the sorbed compounds or diluents were removed by extraction. We compare “as received” implants to “as received” controls with and without the diluent.

EXPERIMENTAL METHODS

The experimental results reported in this study are for SILASTIC® II controls and explants. All control implants were received in their original blister sealed packages. Eight explants from six different donors were retrieved intact and stored in non-sterile containers. A brief chronological description of the implants and controls used in this study is given in Table 1. These explants were removed primarily because of physical symptoms associated with capsular contracture or for augmentation replacement.

Table 1 SILASTIC® II Explants with Lot Matched Controls

Year Placed	Years of Implantation	Number of Explants Tested	Explant Status	Number of Controls Tested	Lot Numbers
1988	0.3	2	Intact	3	HH046269
1986	6	1	Intact	2	HH056366
1989	6	1	Intact	2	HH068335
1987	8	2	Intact	2	HH056302
1985	10	1	Intact	2	HH064983
1985	10	1	Intact	1	HH044027

The explants and control implants were prepared for testing by carefully removing the gel from the shell and subsequent gentle wiping of the shell with isopropyl alcohol moistened Kimwipes®. Eight ASTM D412 Die C half-scale tensile specimens, three ASTM D624, Die C half-scale tear resistance specimens, and two rectangular pieces approximately 30.5mm (1.2 in) x 30.5 mm (1.2 in) for swelling measurements 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 gage with a resolution of 2.54 μm (0.0001 in). Eight dogbone shaped samples from each shell were used for tensile testing; three of which were extracted with hexane prior to analysis. Extraction of these three dogbone samples was done with chromographic grade hexane (Fisher) at 60° C for a time of 96 hours. The samples were carefully dried to constant weight and used for subsequent analysis. The percent extractable was determined from the initial and final weights. Gas chromatograph mass spectrometric analysis of the extract indicated that it was primarily a complex of linear and cyclic silicones with molecular weights ranging from 294 to greater than 5000 daltons. All the mechanical tests were conducted using an Instron 5583 equipped with a video extensometer, which accurately measures the strain in the gage section of the specimen. The strain rate for all mechanical tests was 254 mm/min (10 in/min).

Crosslink Density

The crosslink density of the elastomer shells was determined by swelling measurements. After hexane extraction, which removes the low molecular weight diluents, shell samples were dried to constant weight and swollen in toluene to constant weight. The samples were removed from the toluene, patted dry, and placed in a tared glass weighing jar. The volume fraction polymer in the silicone/silica elastomer was determined by measuring the density of the elastomer (gravimetrically in ethyl alcohol) and correcting for the weight fraction of silica. The volume fraction polymer in the swollen elastomer was determined directly from the weight gain in the polymer fraction and the densities of toluene and the shell. The crosslink density was determined from the volume fraction of polymer according to the Flory-Rehner theory for polymer swelling [3].

RESULTS

The mechanical and chemical properties of SILASTIC® II prostheses which had been implanted for time periods ranging from 0.3 to 10 years were measured and directly compared with lot matched controls prepared from the same batch of elastomer at the same manufacturing time. The measurements included shell thickness, mechanical properties (stress-strain data, strength, elongation, moduli, and tear resistance), and chemical properties (crosslink density and percent extractables).

Previous studies have shown that these methods are applicable to the analysis of silicone breast explants [1, 4, 5].

Shell Thickness

The shell thickness of each implant and associated lot-matched control was measured in at least 33 locations around each shell. The results are summarized in Figure 1 where the maximum and minimum value for each shell are shown as a function of implantation time together with the values for the lot matched control. The thickness of a given shell can vary as much as 25% from the mean and the range of thickness for a given shell is as high as 50%. The variation in thickness between a particular explanted shell and its associated lot-matched control is small and well within the experimental error of measurements. These data indicate that little or no degradation has occurred on the surface of the explanted shell.

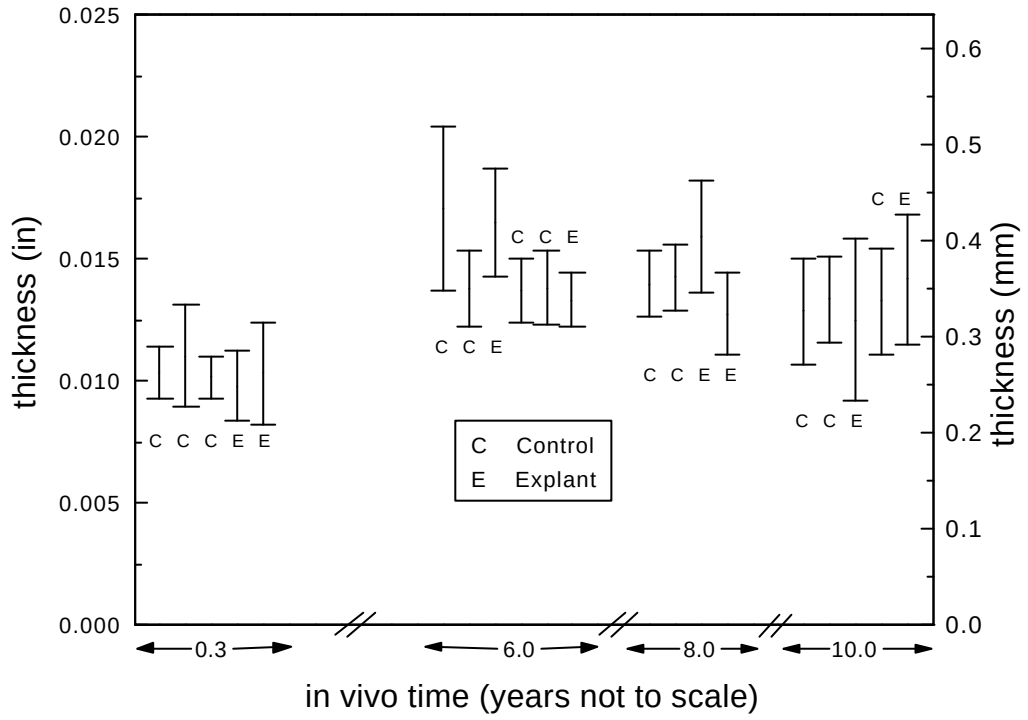

Fig. 1: Minimum to maximum shell thickness range of lot matched controls and explants as a function of in vivo time. Lot matched sets of data are grouped together.

Mechanical Properties

The results of the mechanical and chemical tests for explant HH056302, which had been implanted for 8 years, referenced to its lot matched control are shown in Figures 2 and 3 for the unextracted and extracted shells. The ratio of the explant property to the lot-matched control property for tensile strength, elongation, 200%, 400%, 600% moduli, and tear resistance are presented for the unextracted shell. The same properties except for the tear resistance are presented for the extracted shell together with the crosslink density. A ratio of 1.0 indicates no change in the measured value for the explant with respect to the same property measured for the control. For the "as received" shell, the ultimate properties (tensile strength, elongation, and tear resistance) show a marked effect due to implantation. However, elongation is still greater than the minimum acceptable value of 350% per ASTM Standard F703. For example even after eight years in vivo, the tensile strength and elongation are 3.69 MPa and 573%, respectively. The moduli and crosslink density are essentially independent of implantation time. The ultimate properties of the extracted shell are less affected by

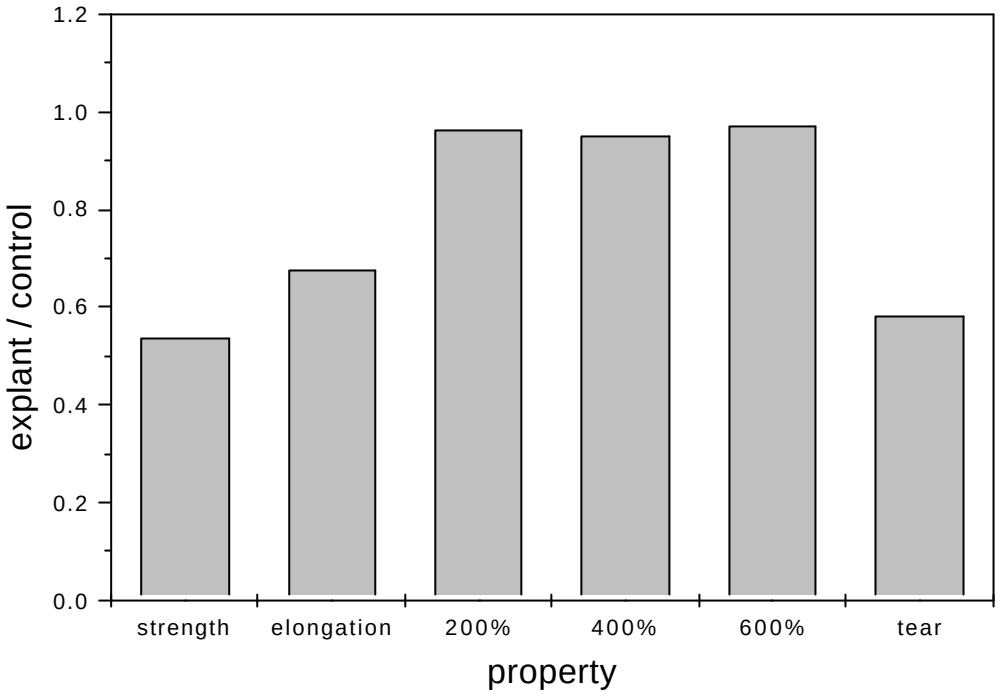

Fig. 2: Ratio of the mechanical properties of an eight years in vivo explant to the corresponding property of its control.

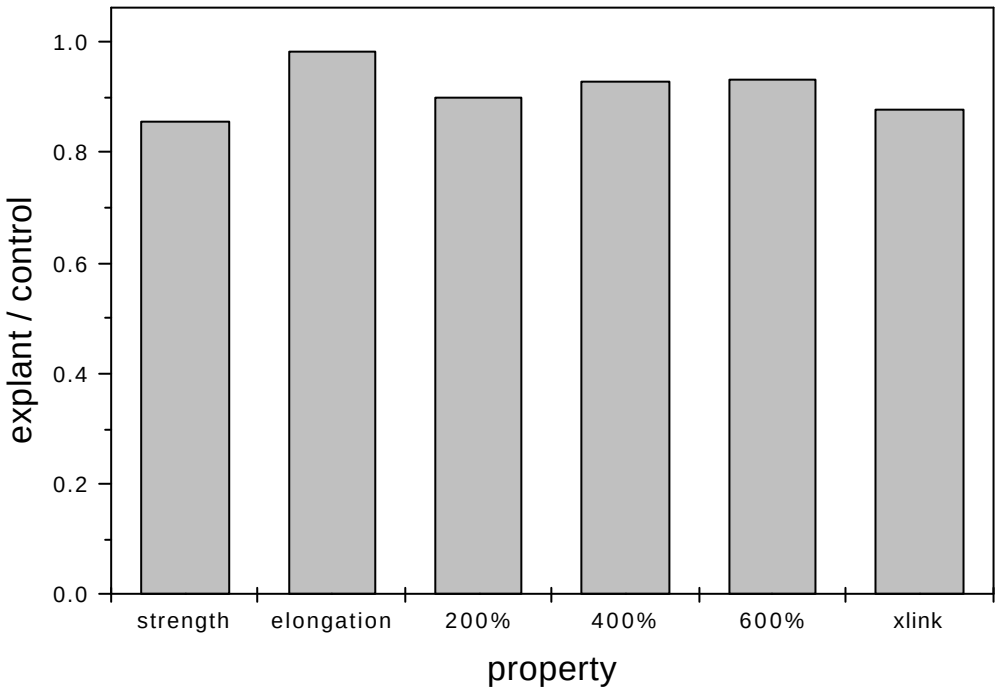

Fig. 3: Ratio of the mechanical properties of an eight years in vivo explant to the corresponding property of its control after diluents have been extracted.

implantation time than those of an unextracted implant specimen and as before the moduli are essentially independent of implantation time. The quantity of soluble material extracted from the implant shell was 30.2 ± 0.7 weight percent for the explant and 8.7 ± 1.4 weight percent for the control. The extract material is almost entirely a mixture of linear and cyclic silicones.

The diffusion of the low molecular weight compounds from the gel can have a significant effect on the elongation of the shell, as shown in Figure 4, which gives the ratio of the "as received" to the extracted (diluents removed) elongation as a function of the percent extracted. The explant and control data from this study are presented along with SILASTIC® II control data obtained from Ref. 5 which investigated the variability in shell properties for SILASTIC® I and II implants. Swelling of the elastomer by low molecular weight diluents significantly reduces the elongation. Results also showed that the tensile strength is more affected than elongation. Both the tensile strength and elongation decrease as the amount of diluent sorbed by the shell increases. In general, more material is extracted from the explant shell than from the corresponding lot-matched control.

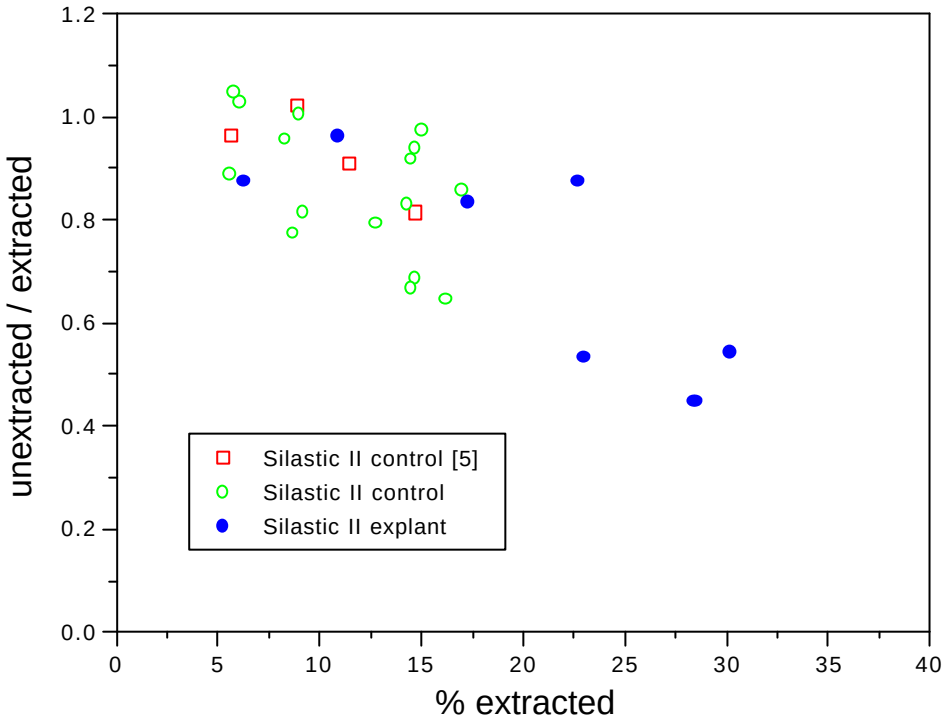

Fig. 4: Comparison of the elongation of shells before and after diluents have been extracted.

The nondimensional modulus, that is the ratio of the "as received" modulus to the corresponding modulus of the extracted shell, as a function of the percent extracted are shown in Figure 5. In this figure the 200%, 400%, and 600% moduli are shown for both the explants and the lot-matched controls. The nondimensional moduli ratio for both the explants and the controls are essentially identical even though the explants sorbed significantly more than the control samples. The scatter of the 600% moduli data is larger than the other moduli. Furthermore, three of the explant samples failed at elongations less than 600%. The moduli ratios as a function of implantation time are shown in Figure 6. The ordinate shows the ratio of the explant modulus to that of its lot-matched control for both "as received" and extracted shells. Each data point represents the average of ten specimens for the "as received" shell and six samples for an extracted shell. The fact that the moduli are independent of implantation time and are essentially the same as that observed in the control samples strongly suggests that the silicone elastomer, i.e., the polymer, does not degrade or change during implantation periods as long as 10 years.

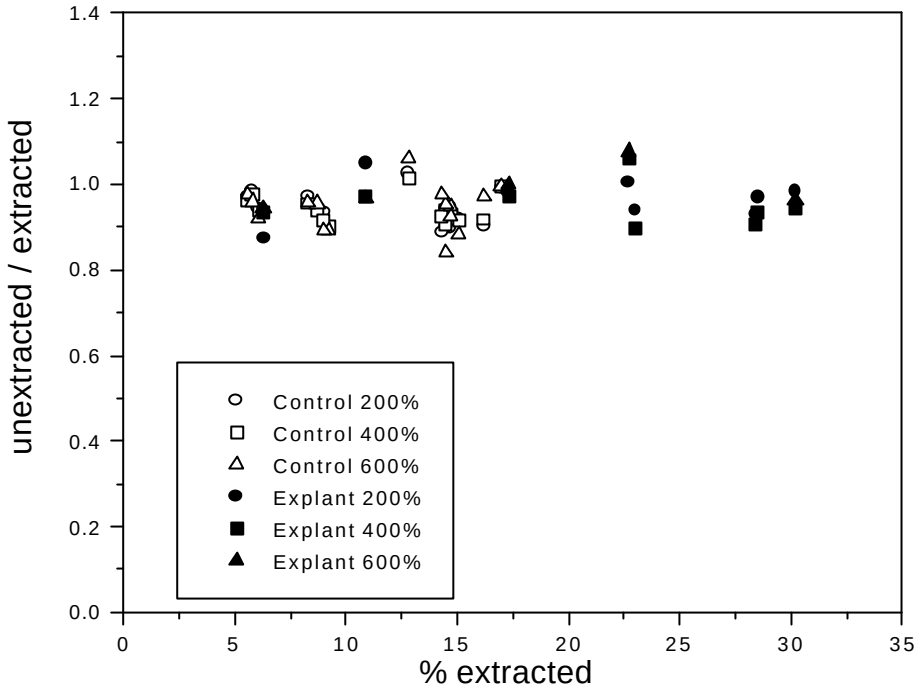

Fig. 5: Ratio of the modulus of Silastic II explants and controls to the modulus after diluents have been extracted from the shell.

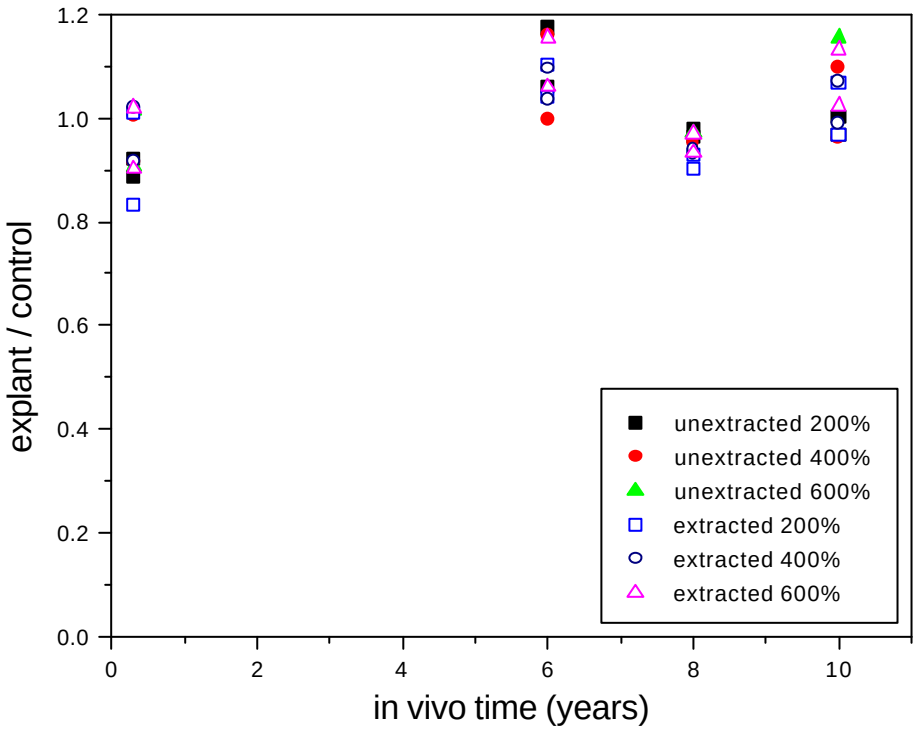

Fig. 6: Ratio of the modulus of Silastic II explants to the modulus of the control before and after diluents have been extracted.

The ratio of the crosslink densities, i.e. the crosslink density of the explant to those of the corresponding control, as a function of implantation time are shown in Figure 7. The ratio of unity coupled with the observation that the value does not change with implantation time strongly supports the hypothesis that the silicone elastomer does not degrade in vivo.

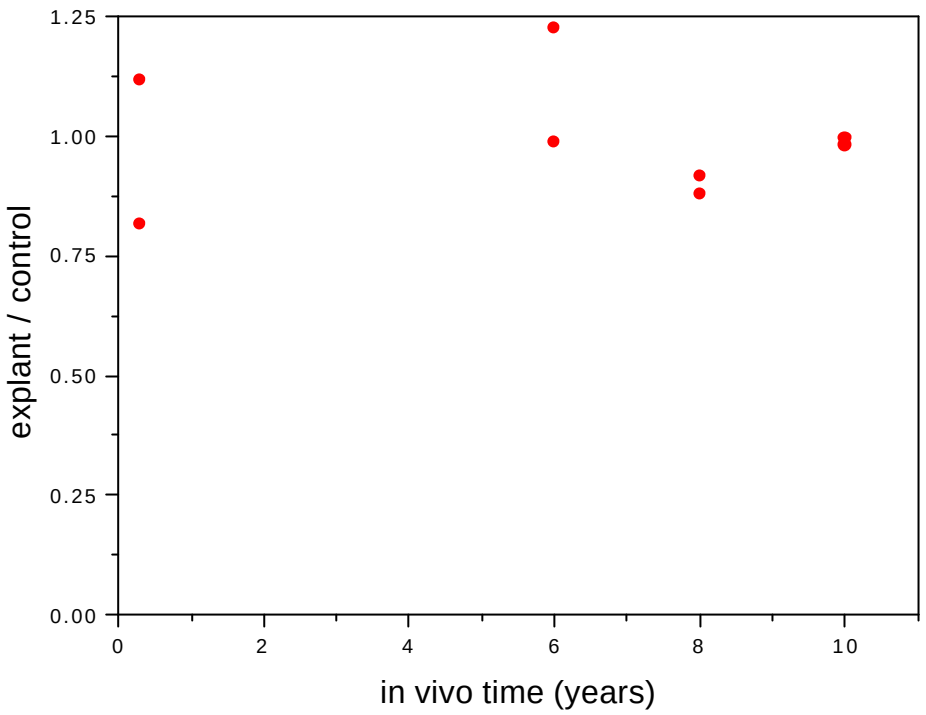

Fig. 7: Ratio of the crosslink density of Silastic II explants to the crosslink density of the control as a function of in vivo time.

The ratios of the tensile strength and elongation-to-failure of the explants to those of the corresponding lot-matched controls after the samples were extracted were computed as a function of implantation time. Although the value approached unity, it was always about 10 to 20% below 1.00. However, this indicates that a significant part of the properties of the elastomeric composite, i.e., the shell, is restored when the extractable material is removed. This again supports the hypothesis that the silicone shell undergoes little if any degradation due to implantation. There is little doubt that the diluents reduce the strength, elongation, and tear strength of the shell. However, these properties are essentially restored when the diluents are removed. It should also be noted that the ratios were determined from the actual thickness dimensions of the test specimens and do not reflect the dimensional changes of width and length, which occur during swelling.

In a separate study using both hexane and octamethylcyclotetrasiloxane (D4) as swelling agents, we observed that the swelling of both SILASTIC® I and II implants is isotropic, i.e., the coefficient of expansion is the same in the 3 principal directions. The dimensional changes can be significant. For example, an implant which sorbs 25 wt percent extractable compounds, would exhibit an 8% increase in length, width and thickness. Such a change in the thickness dimension is within the scatterband for the explant and control data presented in Figure 1. Although the amount of extractable material varies with each explant and control, its composition is essentially the same, a complex mixture of linear and cyclic silicones. The slight variation in thickness of the explant and control was considered in the stress calculation. However, changes in the length and width were not taken into account because all samples were cut from the same die. Thus, a sample containing a greater amount of swelling agent would contain a smaller number of polymer chains per unit width. Neither the width effect nor the slight strain due to swelling along the longitudinal axis of the dogbone shaped sample were specifically evaluated. However, these two factors can, at least partially, account for the decrease in the explant to control ratio noted above. The mechanical properties of shells in which the sorbed compounds were extracted do not appear to depend on implantation time.

However, the swollen elastomeric shell may experience different aging processes and failure mechanisms. A quantitative study of the effect of swelling on the mechanical properties of silica filled silicone elastomers and associated failure mechanisms is currently under investigation.

CONCLUSION

One of the primary objectives of this research was to determine the stability of the SILASTIC® II implant shell material as a function of in vivo implantation. This was accomplished by measuring various properties of explanted shells and comparing these properties with those for corresponding lot-matched controls. The study showed that the ultimate properties (tensile strength, elongation, and tear resistance) decrease due to implantation. The study also showed that the ultimate properties decrease as the amount of swelling agent, i.e., extractables, increases. The ultimate properties of the explant are restored to within 10 to 20 percent of their original values when the swelling agent is removed, which suggests that the silicone elastomer does not undergo appreciable degradation during in vivo aging. Implant samples exhibited a higher concentration of swelling agent than their corresponding lot-matched controls.

The 200%, 400%, and 600% moduli of both the extracted and "as received" (unextracted) shells are not appreciably affected by in vivo aging. The crosslink density of the extracted shells is also unaffected by in vivo aging. These two observations strongly suggest that the base silicone polydimethylsiloxane polymer does not change or degrade during in vivo aging. Furthermore, we observed no change in either the physical appearance, i.e. morphology, of the shell surface or shell thickness even after 10 years in vivo aging.

Further research is needed to determine the cause and overall effect of sorbed material on the mechanical properties of the shell. In future work the composition of the extractables will be analyzed to determine the quantity of sorbed silicones, biological diluents, and/or other components.

ACKNOWLEDGEMENTS

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