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## Lipid Infiltration as a Possible Biologic Cause of Silicone Gel Breast Implant Aging

**[Articles]**

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**Abstract** [TOP](#)

The cause of silicone gel implant aging and rupture is not known. Recent reports indicate the failure rate is higher than previously published, and implant aging and rupture may be due to progressive mechanical deterioration of the outer vulcanized silicone shell. It is known that lipids are absorbed by the hydrophobic silicone elastomer, and lipid infiltration causes mechanical attenuation and possible failure of the elastomer. The purposes of this article are to analyze the silicone envelope/gel of explanted prostheses and the silicone elastomer of other medical grade silicone devices for lipid content and to suggest its possible role in implant aging and rupture. We assayed 33 ruptured silicone breast implant shells (mean age 13.1 years; range 8 to 26 years) and 8 medical grade silicone elastomer devices (mean age 3.7 years; range 3 months to 12 years) for evidence of lipid infiltration using thin layer chromatography. These were compared with control group assays from two nonimplanted silicone gel implants and one unused Silastic catheter. Ninety-eight percent of implants and other previously implanted silicone devices were found to have evidence of lipid infiltration compared with none in nonimplanted controls ( $p < 0.005$ ). We conclude that lipids infiltrate the outer silicone shell and may be a factor related to breast implant aging and rupture due to progressive mechanical weakening of the outer silicone shell.

The silicone breast implant controversy has stimulated dedicated research on the safety of the silicone gel prosthesis. Despite this intensified interest, a specific etiology for implant aging and rupture is not known. Although gel bleed has been recognized since 1978,<sup>1</sup> the rate of implant rupture was felt to be low (<6 percent).<sup>2</sup>

Conversely, several large series by different authors indicate a much higher incidence of rupture in older implants, ranging from 70 percent of implants with rupture at 6 to 15 years of age to 100 percent failure at more than 10 years.<sup>3-5</sup> Trauma, mammography, and closed capsulotomy all have been implicated as potential causes for rupture, yet the majority of patients with implant failure do not consistently fit into these groups.<sup>2,4,6,7</sup> Previous reports on structural testing have demonstrated decreased strength of the outer implant shell over time.<sup>8,9</sup> These suggest that implant rupture is secondary to progressive mechanical deterioration of the vulcanized silicone shell over time.<sup>3,5,10</sup>

Lipid infiltration of the silicone elastomer is known to result in structural degeneration and eventual failure and has been documented in the literature.<sup>11,12</sup> Nevertheless, scientific evidence of lipids in the shell of breast implants has never been reported in the literature. This study was designed to examine whether lipid infiltration of the solid outer silicone shell occurs and postulate its relation to silicone implant aging

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and eventual rupture.

## Methods [TOP](#)

The experimental group consisted of 33 ruptured silicone gel implants obtained during explantation from patients with known implant rupture ([Table I](#)). The group was subdivided into shell (33) and gel (33) subgroups. A large sample of unruptured implants could not be included for analysis due to the legal ramifications of using a sample of the silicone envelope from the intact implant. Also included in the experimental group were eight previously implanted medical grade silicone elastomer-containing devices from various sources ([Table I](#)). The control group consisted of two nonimplanted silicone gel prostheses using multiple specimens from each implant (four shell and four gel specimens) and a Silastic venous catheter (one shell).

TABLE I Assessment of Silicone Groups Based on Implantation Duration

Group	Duration of Implantation	
	Mean Age (years)	Range (months)
Experimental group		
Ruptured breast implants	13.1	98-312
Shell (33)		
Gel (33)		
Medical silicone devices	46.4	3-144
Unruptured silicone gel implant (1)	148	144
Unruptured transected capsule (2)	9	9
Tissue expander (3)	5	3
Silastic venous/catheterized shunt (2)	80	60-120
Control group		
Nonimplanted silicone gel prosthesis (2)		
Shell (4)	Not implanted	
Gel (4)	Not implanted	
Elastomer venous catheter (1)	Not implanted	

All samples were cleaned with sterile normal saline. In gel-filled implants, shell and gel were taken as separate components. Weight-controlled samples were organically extracted with a chloroform:methanol mixture (2:1) for 24 to 48 hours at 4°C. Solutes were concentrated by evaporation, redissolved, and then separated by thin layer chromatography. Precoated silicic acid thin layer chromatography plates (5 × 20 cm, 250•M layer thickness, 2 to 25 •M mean particle size, 60 A mean pore diameter; Aldrich Chemical Co.) were used.

The specific solvent choice for lipid separation determined the lipid group assayed (neutral lipid or phospholipids). Development of neutral lipid chromatograms was accomplished by a solvent mixture of petroleum ether(boiling point 60°C to 70°C):diethyl ether:acetic acid (90:10:1 (v/v)). Phospholipid chromatograms were developed with a solvent mixture of chloroform:methanol:acetic acid:water (25:15:4:2 (v/v)). Each plate was pre-run with the respective developing solvent. Two to four •l of concentrated extract was spotted 2 cm from the end of the thin layer chromatography plate along with a standard lipid mixture. The solvent was allowed to rise 12 cm (average) above the origin at room temperature in a saturated chamber. Spots on chromatograms were detected by iodine vapor. Standard phospholipids, phosphatidylethanolamine, phosphatidylserine, and phosphatidylcholine were run through the standard phospholipid thin layer chromatography and compared with experimental assays for individual phospholipid identification.

Two human whole blood samples were assayed by extracting 1-ml aliquots by chloroform:methanol mixture (2:1). Following extraction for 48 hours at 4°C, samples were centrifuged for 3 minutes. The supernatant was concentrated and then performed identically to the above thin layer chromatography assay.

The implantation time (range and mean) of each sample was determined from the patient history and previous operative records. The ruptured implant shell assays were compared with the control shells using the Fisher's exact test.

## Results [TOP](#)

The mean implantation time for the 33 ruptured silicone gel implants was 13.1 years (range 8 to 26 years) and for the eight hard silicone devices was 3.7 years (range 3 months to 12 years) ([Table I](#)).

Ninety-seven percent (32/33) of implant shells and 100 percent (33/33) of implant gels had positive assays for neutral lipids. Fifty-four percent(18/33) and 73 percent (24/33) of the shells and gels were positive for phospholipids ([Table II](#)).

TABLE II Thin Layer Lipid Chromatography of Silicone Implants and Controls

Group	Neutral Lipid	Phospholipid
<b>Experimental</b>		
Ruptured shell (20)	32/20 (97%)*	20/20 (100%)
Ruptured gel (20)	30/20 (100%)	20/20 (100%)
Unruptured silicone implant (1)	+	+
Unruptured saline breast capsule (2)	+	+
Tissue expanders (5)	+	+
Ventriculoperitoneal shunt 3 year (1)	+	+
Ventriculoperitoneal shunt 20 year (1)	+	+
<b>Controls</b>		
Shell (4)	0/4 (0%)	0/4 (0%)
Gel (4)	0/4 (0%)	0/4 (0%)
Elastomer remains catheter (1)	0/1 (0%)	0/1 (0%)

\*  $p < 0.005$ , Fisher's exact test.

† presence of neutral lipid or phospholipid.

‡ absence of neutral lipid or phospholipid.

The nine control samples had no evidence of either neutral lipid or phospholipid in the shell or gel. There was a significant difference between the experimental ruptured implant shells and control shells for the neutral lipid assay ( $p < 0.005$ ) (Table II).

The results for the eight intact silicone elastomer devices universally demonstrated evidence of neutral lipid content (Table II). Phospholipid assays were positive in all samples except for the 5-year-old ventriculoperitoneal shunt.

Primary neutral lipids were triglycerides in all samples. Primary phospholipids were variable although these often comigrated with the phosphatidylethanolamine and phosphatidylserine standards.

Whole blood samples revealed reproducible assays for neutral lipids and phospholipids.

## Discussion [TOP](#)

The pathogenesis of implant aging and cause for rupture is not known. Although trauma, mammography, and closed capsulotomy have been implicated, these events correlate poorly in the majority of patients with implant rupture.[6,7](#)

In discussing implant failure, Brody described the fold flaw phenomenon, when two surfaces of an underinflated implant abrade each other, resulting in rupture at the site of the fold flaw.[11](#) However, this is felt to be more common in the saline-filled implants and occurs infrequently in silicone implants because of the superior lubricating properties of silicone gel.

Implant failure may be due to progressive mechanical deterioration of the vulcanized silicone elastomer over time. Van Rappard and colleagues[9](#) reported the strength of the silicone shell decreased with the age of the implant. Their series demonstrated a linear relationship of bursting strength versus implant age. The study controlled for possible changes in the implant design by using the same implant made by the same manufacturer. The results imply a decrease in the mechanical strength of the implant shell over time. Peters (in a less controlled fashion) found lower breaking strength in implanted breast prostheses compared with unused implants.[8](#) Several recent clinical studies have found a positive correlation of leaking or ruptured implants with implant age. de Camara, Sheridan, and Kammer evaluated 51 implants, finding all implants over 10 years old leaking or ruptured.[3](#) Peters, Keystone, and Smith reported 93 percent of implants less than 5 years old remained intact versus only 30 percent in implants 6 to 15 years old.[4](#) Robinson, Bradley, and Wilson recommend explantation of gel implants by 8 years because their results indicate that the implants lose the integrity of the silicone shell between 8 and 14 years.[5](#) These clinical data support a progressive deterioration of the silicone shell over time.

Previous documentation of physical alteration of the silicone elastomer secondary to lipid absorption prompted us to design this study from the biochemical standpoint. Silicone was the first polymeric alloplast to achieve widespread use in plastic surgery.[13](#) All three forms (oils, gels, and vulcanized elastomer) have been extensively utilized in medical practice. The chemical properties of the silicone elastomer result in absorption of lipids. This process results in changes in the structural composition of the elastomer.[11](#) It has been reported that the vulcanized silicone rubber readily absorbs lipids from the blood, a property that may lead to their mechanical deterioration.[12](#) Additionally, it is known that silicone heart valve leaflets have been discontinued due to their tendency to absorb lipids, crack, and fail.[11,14,15](#) Lipid infiltration is encouraged by the hydrophobic properties of the silicone elastomer; the modern fluorinated (low bleed) silicone shell is more hydrophobic and has increased propensity to lipid infiltration.[12](#)

We demonstrated evidence of neutral lipid and phospholipid infiltration in the silicone elastomer of ruptured implants. Our statistical analysis was difficult because our control group size was very small. We did not have access to unlimited nonimplanted control silicone prostheses. Although multiple samples were taken from the two nonimplanted implants, we could not use these to increase the control sample size, which limited the statistical significance in the phospholipid group.

We also considered the possibility for confounded results due to lipid contamination through the physical defects in the ruptured envelope directly to the gel, and thus, we assayed the unruptured silicone implants and other devices to demonstrate that lipids do cross the intact silicone elastomer and are found contained in the outer shell and inner gel. Furthermore, we assayed the human blood to avoid any possibility that our results were secondary to blood contamination of the outer shell, regardless that all the implants and devices were

washed before analysis. The thin layer chromatography assays from these blood samples do not mimic results from any silicone elastomer we assayed, thus implying that the results of our experimental assays were not due to surface contamination of the implant.

To our knowledge, no other reports exist scientifically demonstrating evidence of lipids in the silicone elastomer of breast implants. Given the known data on silicone elastomer degeneration secondary to lipid infiltration, this information may implicate lipid absorption in the mechanism for breast implant aging and rupture. We were unable to identify the specific implant type or manufacturer from our records; however, these possible differences should not obscure our results since the basis of the study examines lipid infiltration of the polymeric building block, dimethylsiloxane, a common denominator in all implants regardless of manufacturer.

Our data also indicate that the primary neutral lipid contained in the silicone elastomer is triglycerides. Identification of the predominant phospholipid indicates that phosphatidylserine and phosphatidylethanolamine were the predominant species, although this was more variable, possibly due to limitations of the assay. These species of neutral lipid and phospholipid may be more directly linked to the mechanism for elastomer degeneration and failure. Further study in this area is warranted.

Additionally, there was some evidence that older implants contained more lipid than younger implants. Assays of the older silicone devices stained more strongly than assays in the younger implants. Nevertheless, this is only an observation because the thin layer chromatography assay is primarily qualitative, and quantitative conclusions are only speculative. A continuous progressive accumulation of the lipids in the outer silicone elastomer may result in rupture; however, another viable mechanism may be accumulation of the lipid content up to a certain steady state or critical mass with subsequent progressive structural elastomer degeneration, irrespective of the absolute lipid content. This structural degeneration may be related to the silicone elastomer and lipid interaction alone or may also involve a multicomponent interaction, such as lipid calcification, resulting in a brittle implant more prone to failure, similar to previously documented etiology for failure of silicone heart valves.<sup>11</sup> The specific temporal relation between the presence of the lipid and significant structural weakening remains to be fully elucidated. Based on present data,<sup>3-5</sup> significant degeneration probably does not occur until 6 to 8 years from implantation.

Clinically, these data may assist us in establishing a better understanding of how silicone gel breast prostheses age and help us provide better information to the approximately 1 million to 2 million women who have silicone gel breast prostheses. We are now seeing these patients in follow-up, and it will become more important as their implants age and begin to rupture over time. To date, however, no scientific data have implicated silicone (intact or ruptured) implants to any specific autoimmune process or disease.<sup>16-18</sup> Furthermore, scientific investigation on all aspects of breast implants is warranted given the present hostile medical legal environment.

New alternative implant fillers are presently being studied; however, the longevity of these implants is limited to the long-term integrity of the outer silicone shell.<sup>19</sup> The potential for extended lifetime of the shell may be possible through chemical modification of the silicone elastomer to decrease the progressive lipid infiltration. Development of a longer lasting breast implant shell is possible in the future.

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## Acknowledgments [TOP](#)

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