

“Review of Recently Published Literature on the
Durability and Rupture Characteristics
of Silicone Gel Breast Implants”

Harold J. Brandon
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1. SUMMARY

The Mentor Corporation contracted with the author to prepare this document on the topics of silicone gel breast implant durability and rupture characteristics with emphasis on 3rd generation devices. The document is primarily based on literature on silicone gel breast implants published since the IOM study¹ (1999) and the IRG² (1998). The author's training, education and experience are primarily in the areas of mechanical engineering and plastic surgery research. He holds degrees through the D.Sc. in Mechanical Engineering and is a Registered Professional Engineer in Missouri. He is currently an Affiliate Professor of Mechanical Engineering, an Assistant Research Professor of Plastic Surgery, the Director of the Center for Implant Retrieval and Analysis at Washington University, and a consulting engineer. He has more than 35 years of industrial and academic experience. He has been a college professor since 1969 and has developed four graduate mechanical engineering courses at Washington University. He has been involved in the analysis of silicone gel breast implants since 1992. He has published papers on breast implants in plastic surgery and biomaterials journals and has presented papers at national and international plastic surgery and biomaterials conferences. He has been awarded grants from the Plastic Surgery Educational Foundation, the National Endowment for Plastic Surgery, and the Aesthetic Surgery Education and Research Foundation for analysis of breast implants. He has also been awarded contracts and grants from breast implant manufacturers. He served as the Chairman of the Symposium on Biomaterials in Plastic and Reconstructive Surgery at the 6th World Biomaterials Congress in 2000 and at the 7th World Biomaterials Congress in 2004. His background and experience qualified him to prepare this document.

The recently published literature reviewed during this study demonstrates that all three generations of silicone gel breast implants manufactured from the 1960s to the present exhibit

long-term material stability. The literature also demonstrates that the rupture characteristics are strongly dependent on implant generation. Second generation implants exhibit a much higher frequency of failure. The durability and rupture characteristics are significantly improved for third generation implants. These results are consistent with the low percent of failed devices reported by Mentor for the third generation implants submitted in their PMA application.

2. IMPLANT CLASSIFICATION

Peters *et al.*³ describe the evolution of silicone gel breast implants from the 1960s to the 1990s and divide the implants into three generations. First generation implants had a thick shell and a viscous gel. Second generation implants had a thin shell and a gel of much lower viscosity. Third generation implants had a strong shell with an inner surface "barrier coating". The generational dates most often used in the United States are as follows: first generation, 1964 to 1972; second generation, 1973 to 1987; and third generation, 1988 to present. Various designs were introduced by manufacturers in different years. Hence, it is impossible to discern the generation of a silicone gel breast implant based on its placement date alone. Accurate categorization of an implant into a certain generation requires knowing the specifics of the implant, such as the manufacturer and lot number.⁴ Unless silicone gel breast implants are properly identified, the "generational" classification scheme can easily lead to inaccurate and confusing data. The silicone gel breast implants considered in the Mentor PMA application are 3rd generation implants.

There can be significant differences in the properties of the various types of silicone gel implants manufactured from the 1960s to 2004.⁴ In addition the properties of many types of implants can vary considerably from lot to lot.⁵ Hence, any investigation of durability and rupture of implant shells should separate the implants according to type. This is necessary because the strength of implant shells can vary according to the manufacturer, the implant type, and the lot-to-lot variability for the given type. Ideally, explants should be compared with lot-matched controls prepared from the same batch of material as the explants. Unfortunately, lot-matched control specimens are rare. Only two studies in which explants were compared with lot-matched controls have been reported.^{6,7} In those two studies, one SILASTIC[®] 0 explanted

shell and 16 SILASTIC[®] II explanted shells were compared with lot-matched controls. If lot-matched controls are not available, then the explants should be separated according to implant type, so that the shell properties can be compared with the expected ranges of properties for that particular type of implant. If control property ranges are not available, then explants should be compared with all control specimens of the same type that have been tested. In such cases, assessment of the effects of *in vivo* aging on the durability of implant shells is limited.

Dow Corning manufactured silicone gel breast implants which are representative of the various types of devices produced from the 1960s to the 1990s. The four major types of silicone gel-filled breast implants manufactured by Dow Corning and their approximate production dates are as follows: Cronin seamed (1964 to 1968), SILASTIC[®] 0 (1969 to 1974), SILASTIC[®] I (1975 to 1986), and SILASTIC[®] II (1981 to 1992). A significant amount of mechanical property data has been published on Dow Corning implants. On the other hand, data for only one Mentor explant has been published in the literature. Therefore, much of the Dow Corning data is reviewed in this study to demonstrate implant durability associated with the three major generations of silicone gel breast implants. The methods used to obtain the data have been shown to be applicable in the analysis of silicone gel breast implants.⁸

3. IMPLANT DURABILITY

3.1 Ultimate Properties

The ultimate properties of tensile strength, elongation, and tear resistance for all known Cronin seamed (1st generation) explants which have been tested and analyzed are presented by Brandon *et al.*⁴ for as-received shells and shells extracted with hexane prior to analysis. Data from one control are also shown. Implantation times for the explants ranged from 0.6 to 32 years. Two explants with thirty-two years of implantation time are the oldest known silicone gel explants that have been tested and analyzed to date. One of the explants with 32 years *in vivo* was damaged during explantation surgery. Since only one control shell was tested, the assessment of *in vivo* aging was limited for the explants. However, a qualitative assessment of the effects of *in vivo* aging was made. The most important observation is that there is no catastrophic decrease in the ultimate properties for an implantation time up to 32 years. The maximum reduction in tensile strength of an explant relative to the control is 35% for an as-received shell and 24% for a shell in which the non-cross-linked components were removed (extracted). A similar comparison for elongation yields reductions of 24% and 14% for as-received and extracted shells, respectively. These values are subject to interpretation since the effect of lot-to-lot variability is not known. Photographs of the implants show that the explants look very similar to the control even after 32 years implantation time.

The ultimate strength properties of SILASTIC[®] 0 and SILASTIC[®] I implant shells were recently analyzed by Brandon, *et al.*^{9,10} In the second study, both types of implant shells were analyzed together because the same basic process and elastomer were used to prepare the elastomeric shell. The difference between these two types of implants was the viscosity of the gel. The data reported consisted of 60 explants with implantation times ranging from 6 to 28

years together with 15 control samples. The data was taken at five different laboratories. On the basis of the data published to date on SILASTIC[®] 0 and SILASTIC[®] I implants, the results clearly indicate that the ultimate mechanical properties of the shell do not appreciably degrade *in vivo*. A recent study by Marotta, Goldberg *et al.*¹¹ evaluated the properties of four additional standard Dow Corning gel-filled explants with implantation times ranging from 10 to 15 years. The tensile strength and elongation data also fall within the control ranges published by the author and his colleagues.

All published data on the ultimate properties of SILASTIC[®] II implants (34 explants and 53 controls) were analyzed and reported by Brandon *et al.*¹² The explants had implantation times ranging from 0.3 to 13.2 years. The paper summarizes data from five different laboratories. The ultimate properties of SILASTIC[®] II explants were found to initially decrease after the implantation process, and then reach an equilibrium value. The initial reduction in the ultimate strength properties of SILASTIC[®] II explants compared with those of controls probably arises from the diffusion of the non-cross-linked silicones from the gel into the shell. It is uncertain how long it takes for the permeation process to reach equilibrium, but it appears to occur within the first few years following implantation. Once equilibrium swelling is reached in a SILASTIC[®] II shell, the ultimate shell strength properties are essentially unaffected by additional implantation time. The ultimate properties of SILASTIC[®] II shells from which the non-cross-linked material was extracted did not experience an initial decrease after implantation. Rather, the properties were essentially independent of implantation time. Marotta, Goldberg *et al.*¹¹ recently reported on the analysis of six SILASTIC[®] II explants with implantation times ranging from 5 to 8.5 years and one SILASTIC[®] II control. Their SILASTIC[®] II data agrees with the previous published investigation on SILASTIC[®] II implants.

3.2 Moduli and Cross-link Density

The durability of breast implant shells is a function of their mechanical and chemical properties. Ultimate mechanical properties (tensile strength, elongation, tear) can depend upon material flaws and their subsequent propagation in the shell. On the other hand, moduli values are dependent on the bulk structure of the material. For this reason, moduli values tend to be more reproducible than ultimate properties. Moduli values were examined by Brandon *et al.*⁴ to investigate the bulk material stability of explanted breast implant shells. The 200% and 400% moduli for unextracted and extracted SILASTIC[®] I/ SILASTIC[®] 0 implant shells and the 200%, 400%, and 600% moduli for unextracted and extracted SILASTIC[®] II implant shells are presented. This data represents all the known moduli data obtained on these types of implants. Most of the explant data for unextracted and extracted SILASTIC[®] I/ SILASTIC[®] 0 shells fall within the ranges measured for the unextracted control shells. This signifies that neither swelling nor *in vivo* aging affects the lower portion of the stress-strain curve. Swelling was found to affect the 600% modulus for SILASTIC[®] I/ SILASTIC[®] 0 shells. Unlike the ultimate properties, the moduli values for SILASTIC[®] II explants do not decrease after the implantation process. The 200%, 400%, and 600% moduli for SILASTIC[®] II shells do not vary with implantation time. This demonstrates that a significant portion of the stress-strain curve is not affected by swelling or *in vivo* aging. The moduli properties are essentially not affected by implantation for time periods up to 13 years for SILASTIC[®] II implants and up to 28 years for SILASTIC[®] I/ SILASTIC[®] 0 implants. The moduli properties for Cronin implants exhibited a similar result. The fact that the explant moduli values are essentially independent of implantation time provides evidence of long-term stability of the mechanical properties of these breast implants. The 200% and 400% moduli properties are insensitive to long-time exposure to a biological environment.

If the silicone elastomer in an implant shell undergoes a chemical reaction during implantation, one would expect to observe a change in the cross-link density of the elastomer. An increase in cross-link density should be accompanied by an increase in Young's modulus and an associated embrittlement of the shell; a decrease in cross-link density suggests degradation of the elastomer and an overall loss in strength. The cross-link densities, determined from swelling measurements, as a function of implantation time for SILASTIC[®] I/ SILASTIC[®] 0 and SILASTIC[®] II implant shells are also presented by Brandon, *et al.*⁴ All the explant data fall within the ranges for the control implants and indicate that the polymer does not degrade. Hence, the cross-link densities are essentially independent of implantation time for 13 years for SILASTIC[®] II implants and 28 years for SILASTIC[®] I/ SILASTIC[®] 0 implants. This suggests that the cross-link density of the silicone elastomer undergoes little or no change during implantation.

3.3 Lot-Matched Control Studies

Only two studies have been published comparing explants with lot-matched controls. In the first study⁶, one SILASTIC[®] 0 explant shell with 18 years *in vivo* was compared with a lot-matched control. Chemical analysis revealed little difference between the gel extract from the explant and its lot-matched control. The tensile strength of the explant was approximately 20% less than the lot-matched control. In the second study⁷, the mechanical and chemical properties of 16 SILASTIC[®] II prostheses which had been implanted for time periods ranging from 0.3 to 13 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 tensile strength, elongation, moduli, tear resistance, crosslink density, and percent extractables.

The physical properties of the two explants with 13 years *in vivo* were compared with the lot-matched control values. With the implants placed on a horizontal surface, the average diameter of the two explants with 13 years *in vivo* is 8% greater than the lot-matched control diameter. The weights of the two explants are within 1% of the lot-matched control weight, and the shell thickness ranges of the two explants are comparable to the control range. The shell thickness ranges were obtained from the thicknesses of the test specimens cut from the shells. The strength properties of the two explant shells with 13 years *in vivo* and the lot-matched control shell were compared. The tensile strength, elongation, and tear resistance of the explant shells fall below the control values. The reduction in the ultimate properties is due to the increased swelling of the explant shells which is about 2.5 times greater than the control shells. After extraction, the ultimate properties of the explant shells are much closer to the control values. The 200% and 400% moduli of the explant and lot-matched control shells are nearly identical for both the unextracted and extracted samples. The moduli values, i.e., the portion of the stress-strain curve up to 400%, are essentially independent of both swelling and implantation indicating that the implants were not damaged *in vivo*. The author and his colleagues have previously shown that the stress-strain curve in the damaged region of a SILASTIC[®] II implant is different than that observed in an undamaged region.¹³ In the damaged region, the stress for a given strain is significantly lower than in the undamaged material.

Similar results have been obtained for all 16 explant shells and their lot-matched controls for both the unextracted shells and for extracted shells. The mean ratio of the explant property to the corresponding lot-matched control property for tensile strength elongation, tear resistance, 200% and 400% moduli for the unextracted shells were plotted and tabulated. The mean ratio values for the same properties, except for the tear resistance, were presented for the extracted

shells together with the cross-link density. For the unextracted shells, the ultimate properties of tensile strength, elongation, and tear resistance of the explants are on the average 18% to 27% below the lot-matched control values. The reduction in the explant ultimate property values is primarily due to the increased swelling of the explant shells compared to the control shells. On average, the percent extracted from an explant shell is approximately 2.0 times greater than its lot-matched control value. The author and his colleagues¹² previously reported that SILASTIC[®] II implant shells exhibit a decrease in strength property values shortly after implantation and are constant thereafter. The amount of time required for the properties to reach equilibrium is not known. However, the reported data suggest that it occurs within the first few years of implantation. The initial reduction in the ultimate strength properties of the explants in comparison with those of the lot-matched controls probably arises from the enhanced diffusion of the non-cross-linked silicones from the gel into the shell. The elongation for the 16 explants ranged from 413% to 918%. Even though the elongation of the explants decrease during implantation, the elongation for each of the explants is still greater than the minimum acceptable value of 350% per ASTM Standard F703. The ultimate properties of the implanted shells return to nearly their original value after the low molecular weight silicones that have permeated into the shell are removed. Extracted explant shells are less affected by implantation than those of the unextracted explant shells. For the extracted shells, the tensile strength and elongation of the explants are within 5% to 7% of their original values. On average, the 200 and 400% moduli of the explanted shells are within 2% of the control values for both unextracted and extracted shells. The crosslink density of the explanted shells is also within 2% of the lot-matched control shells.

Breast implants are subjected to some degree of stress and deformation during the surgical procedure of insertion. A recent study¹⁴ has shown that the surgical process of

implanting a breast implant can have a small but statistically significant effect on the average strength properties of the elastomer shell of the implant. Another factor which could explain some of the differences in the mechanical properties of the explants and their lot-matched controls is property variation within a lot which was not considered in the study.

In addition to comparing the physical, mechanical, and chemical properties of explant and lot-matched control shells, the morphological features of the explant and control shells were also compared using scanning electron microscopy (SEM). SEM has previously been shown to be a useful technique in analyzing explanted breast implant shells.¹⁵ SEM analysis showed that there is essentially no change in the outer surface of the explant shell exposed to a biological environment for 10 years compared to the unimplanted control shell manufactured at the same time and from the same lot of silicone elastomer. Changes were observed on the inner surface of implanted shells, i.e. in the barrier coat region.

4.0 RUPTURE CHARACTERISTICS

4.1 Breast Implant Failure Mechanisms

Based on the breast implant data published in the literature, implant failure cannot be explained based on *in vivo* degradation of the shell mechanical properties associated with the exposure to a biological environment. Implant failure has been shown to be associated with several failure mechanisms that have been identified and documented using scanning electron microscopy.¹⁵ Failure can be attributed to manufacturing defects, implant handling prior to surgery, implantation surgery, *in vivo* processes, mammography, trauma, and explantation surgery. In addition explant shells have been analyzed that failed due to an unknown failure mechanism. These implants developed small tears in the shell *in vivo* for no apparent reason. There was no sign of abrasion or wear in the shell in the vicinity of the failure site. This type of failure needs further investigation.

Marotta, Goldberg, *et al.*¹¹ have proposed a failure mechanism associated with shell material degradation *in vivo*. They recently concluded that a primary mechanism for rupture must be the progressive cyclic mechanical stress induced creation and enlargement of tears in weakened silicone fluid swollen silicone elastomer shells. This proposed failure mechanism is unsubstantiated. The shell extraction values measured by Marotta, Goldberg *et al.* for Dow Corning explants was about 20%. A study by the author and his colleagues⁴ has shown that various types of silicone gel breast implants can remain intact *in vivo* for percent swelling ranging from approximately 20 – 40%. Another recent study¹⁶ has shown that the mechanical forces involved in the swelling process do not degrade the silicone shell even when the elastomer is cycled through five swell-extract cycles with an aggressive swelling agent. The hypothesis that the material chemical bonds are not broken due to swelling is also supported by the fair

agreement of the ultimate properties of the extracted shells and the elastomeric dispersion used in the manufacture of SILASTIC[®] I/ SILASTIC[®] 0 and SILASTIC[®] II shells.^{10,12}

A potential failure mechanism that can occur during implantation surgery has recently been investigated.^{13,14} Weakening of the implant shell can occur during implantation surgery because the implant is subjected to some degree of stress and deformation during insertion. The insertion process can result in a reduction of some of the average strength properties of the elastomer shell of the implant. It is unlikely that the small reduction in the overall strength of the shell is significant enough to result in implant failure. More important is the local weakening of the shell where the surgeon's fingers force the implant through the breast incision. The implant shell can be locally damaged due to the implantation process. This shell weakening process would be more pronounced for thin shells. Perhaps this mechanism was a cause of the high percent of the second generation (thin shell) implant failure reported by Peters *et al.*³ Francel¹⁷ recently addressed the question of silicone gel implant longevity based on implant generation. First and third generation implants were more likely to be intact than second generation implants. All third generation implants with thick textured shells were removed intact. These included 52 consecutively explanted intact implants with an average of 8 years of implantation. Francel's results support the hypothesis that local shell damage during implantation surgery could be a failure mechanism for thin shell implants. The detailed relationship between implant failure, shell thickness, and the surgeon's implantation technique is the subject of ongoing research.

Contact with instruments or needles is much more traumatic to an implant shell than finger touching. Unless a surgeon is fortunate enough to know that he or she has damaged an implant during insertion or closure, instrument injury will go undetected until the breast changes shape, a granuloma develops, or an imaging study detects a problem. To explore the types of

instrument trauma that could occur, the author and his colleagues intentionally damaged implant shells with surgical instruments commonly used in breast augmentation and breast biopsy and then examined the damaged sites with SEM.¹⁵ This examination showed that scanning electron microscopy could identify specific patterns of instrument damage. The author and his colleagues have developed a catalog illustrating the kinds of damage caused by different surgical instruments that they now use when microscopically analyzing failure sites in their explant inventory. It is clear that unintended damage from instruments occurs during implantation, but it is not known how often. Non-breast-related surgical procedures, such as chest tube insertion, also can lead to implant damage.

During explantation, the greatest risk for implant damage probably occurs when the surgeon is trying to remove an implant and capsule *en bloc*. The frequency of damage during explantation undoubtedly is underreported. For example, Slavin and Goldwyn¹⁸ stated that 11 of 46 patients in 1 year had their implants broken during removal. Not all surgeons report this important detail. The fact that there are so many potential sources of surgical damage confounds the collection of accurate data on implant status at removal, especially if surgeons are unaware of damage they have caused or fail to note it in operative reports. It is unknown how many implants are classified as failed when in fact they have been damaged during surgical procedures.

Because it applies a compressive load to the breast, mammography has been suggested as a potential cause of implant rupture. Experienced mammographers attempt to displace implants posteriorly and superiorly when performing mammography. They also stop applying pressure when the patient experiences discomfort. There is minimal information in the literature on the likelihood of rupture during mammography, although de Camara reported three mammography-

associated ruptures,¹⁹ and others have reported similar events.^{20,21} Nevertheless, the potential benefits of mammography far outweigh the risk for device failure.

Unexpected trauma to a breast implant can occur from a multitude of sources, including injuries to the chest area, auto accidents, falls, and possibly even vigorous hugs. These types of traumatic events can rupture breast implants or convert an intracapsular to an extra-capsular rupture. Because injuries are sufficiently rare, unique, and unpredictable, no meaningful data exists to predict risk.

4.2 Studies of Prevalence of Silicone Gel Implant Rupture

To date, no one knows the prevalence or incidence rate for rupture of silicone gel implants, although failure frequencies up to 77% have been reported. Young and Watson²² list the prevalence of silicone gel implant rupture reported by various researchers since 1989. To be included in their list, researchers had to report on a series of patients in whom implant status was confirmed by surgery. Consequently, most imaging studies were excluded because all patients in these cohorts rarely are explanted. Not all researchers correlated rupture with duration of implantation; of those who did, some determined that rupture was more likely with a longer implantation time, whereas others found a stronger association with implant type (specifically implant generation). Young and Watson point out that most data on gel implant failure comes from retrospective reviews of explantation patients and, therefore, represent a biased sample of self-selected patients. A large percentage of these patients sought implant removal because they had a symptom, were worried about their implants, or had an imaging study that suggested or diagnosed a rupture.

Although the studies summarized by Young and Watson give an idea of the cumulative failure prevalence of rupture among selected explanted implants, they reveal little about the

whole population of women with breast implants. In other words, it cannot be known whether the prevalence of implant rupture reported in explant studies reflects the condition of implants that remain implanted. To find an accurate incidence rate of rupture, studies must be based on the correct denominator, which is a representative sample of the entire population of implanted women, not just a selected sample of explanted women. Another weakness of silicone gel explantation studies is their inability to establish the timing of rupture; instead, explantation studies show whether an implant was ruptured at the time of removal but not when it actually failed.

Many studies have reported on explanted breast implants and the corresponding calculated percentage of implant failure verses implantation time. These published studies cannot establish the actual incidence rate of implant rupture. The sizes of the patient cohorts from which the explants were obtained were unknown as well as the time at which failure occurred. These studies have an inherent sample bias because the population of all women with breast implants is not represented. The type of study that is needed to accurately determine the incidence rate of implant rupture has recently been outlined.^{23,24}

4.3 Rupture Frequency

The meta-analysis presented by Marotta, Goldberg, *et al.*¹¹ shows that breast implant rupture is more likely the longer an implant is in place. Unfortunately, Marotta, Goldberg *et al.* use the term “failure rate” in connection with their analysis when, in fact, their analysis cannot determine the incidence rate of silicone gel breast implant failure. The Marrotta, Goldberg, *et al.* “master curve” tells something about rupture prevalence, but only that failure seems more frequent over time, as multiple authors have consistently reported. The analysis does not address failure in relation to critical questions such as different manufacturers, models, or generations of

breast implants. Furthermore, all the studies incorporated in the meta-analysis are comprised of biased samples, usually involving women who were concerned about their implant status or ruptured explants retrieved for study purposes. As an illustrative example, Marotta, Goldberg, *et al.* used a study conducted by the author and his colleagues at Washington University²⁵ as the basis for plotting a data point of 80% implant failure at 16 years. In reality, the Washington University investigation examined gel viscosity, had nothing to do with implant failure, and involved only five explants, four of which happened to be ruptured. Five intact explants with a 16-year implantation duration could just as easily have been studied, but implant integrity was not the subject of that study. The use of these five explants as a data point for predicting failure versus implant duration is absurd. Thus, the meta-analysis is not representative of all breast implants or all implanted women. Grouping many biased studies together to generate a plot of percent failure versus implantation time does nothing to eliminate or even reduce the underlying bias. Studies have outlined the kind of cohort study needed to accurately determine the prevalence and incidence rate of breast implant rupture.^{23,24} Although Marotta and colleagues say their failure analysis is based on a “large cohort,” their data do not represent a true cohort study but a compilation of many cross-sectional studies of a highly selected group of implants.

The author and his colleagues at Washington University recently published a critical evaluation of the Marotta, Goldberg, *et al.* master curve.²⁶ The Marotta, Goldberg, *et al.* response²⁷ to the critical evaluation cited the recent noninvasive MRI study of implant rupture status by Brown *et al.*²⁸ which was in complete agreement with the “master curve”. The author and his colleagues²⁹ replied to the Marotta, Goldberg, *et al.* response by pointing out that the study of Brown *et al.*, which used MRI to assess implant status, employed a less-biased design to determine whether a breast implant has ruptured. Yet even this cross-section MRI study suffers

from selection bias in that women volunteered themselves to participate and approximately 70% of their implants were Surgitek devices, which have been found more likely to fail than implants made by other manufacturers.³⁰ Another weakness with the Brown study is that 92% of the implants imaged with MRI could be classified as “2nd generation” devices, which are less likely to be intact than 1st or 3rd generation implants.^{3,31} Consequently, even this MRI study is limited because data are weighted toward a single manufacturer and implant generation and, therefore, cannot be considered an unbiased or representative sample of breast implants.

Peters *et al.*³ were the first researchers to show that device rupture characteristics are dependent on the generation of the implants. In their study of 352 explanted silicone gel breast implants, they found 0% of first generation implants were ruptured, 77% of second generation implants were ruptured, and 4% of third generation implants were ruptured. Collis and Sharpe³¹ conducted a retrospective review of the integrity of 478 silicone gel breast implants removed during an eleven year period. Their results showed that the percent of failed devices for first, second, and third generation devices was 33%, 65%, and 9%, respectively. While a Professor of Plastic Surgery at Washington University, Francel published a study¹⁷ which investigated implant longevity based on device generation. Francel found 50% of first generation implants and 66% of second generation implants were failed. Francel also found that all third generation implants he removed in the study were intact. These included 52 consecutively explanted intact implants with an average implantation time of eight years. In a recent study, Holmich, *et al.*³² used magnetic resonance imaging to demonstrate that silicone breast implant rupture varies with implant type and implantation time. The Holmich *et al.* study is the only published study that directly examines the incidence rate of implant rupture. Their study showed that for third generation implants intact 3 years after implantation, the estimated rupture-free survival is 98%

at 5 years and 83% to 85% at 10 years. Second generation implants had considerably higher rupture rates, and only 48% to 63% were estimated to be intact 15 years after implantation.

The low percent of failed devices reported in the literature for third generation implants is consistent with the rupture data submitted by Mentor in the PMA application. For example, the Mentor Core Study consisted of 1,896 implanted devices. After three years of follow-up, a total of 10 implants were suspected ruptures of which 2 were confirmed to be intact and 2 were confirmed ruptures. Therefore, a total of 8 implants (0.42%) were either confirmed ruptured or remain as suspected ruptures. It is interesting to compare the percent of failed devices for the Core Study with the "master curve" formulated by Marotta, Goldberg, *et al.*¹¹ to predict the percent of failed silicone gel breast implants as a function of implantation time. Marotta, Goldberg, *et als.* prediction for the percent of failed implants is 18.9% for an implantation time of three years. This prediction is an order of magnitude greater than the percent of failed Core devices. These results substantiate the critical evaluation of the Marotta, Goldberg *et al.* "master curve" which has previously been published by the author and his colleagues.²⁶

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