Exhibit K

silicone breast implants. Plast Reconstr Surg 1996;97: 1215–1225
11 Wolf C, Brandon H, Young V, et al. Physical and chemical analysis of explanted breast implants. Curr Top Microbiol Immunol 1996;210:25–38
12 Goldberg EP, Widenhouse C, Marotta J, et al. Failure of silicone gel breast implants: analysis of literature data for 1652 explanted prostheses. Plast Reconstr Surg 1997;100:281–284
13 ASTM D-412-92 standard test methods for vulcanized rubber and thermoplastic elastomers. 1992 Annual ASTM Standards 09.01:99–111
14 ASTM D-624-91 standard test methods for tear strength of conventional vulcanized rubber and thermoplastic elastomers. 1991 Annual ASTM Standards 09.01:115–125
15 Manikian M. Long term physical property evaluation of Silastic mammary prosthesis. Midland, MI: Dow Corning, 1971
16 Peters S. Physical properties versus time for Silastic-II and standard prosthesis. Hemlock, MI: Dow Corning, 1981
17 Peters S, Gant R. Fluorosilicone coated mammary prosthesis: gel bleed, physical properties and laminate integrity. Hemlock, MI: Dow Corning, 1983
18 Thompson RM, Howard CC, Brewer EJ, et al. Compositional analysis of silicone prostheses. 1979 Battelle report no. 233-77-5038 Task 8 to FDA. Columbus, OH: Battelle Memorial Institute, 1979
19 Picha GJ, Goldstein JA. Analysis of soft-tissue response to components used in the manufacture of breast implants: rat animal model. Plast Reconstr Surg 1991;87:490–500
20 Brown SL, Pennelo G, Berg WA, et al. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. J Rheumatol 2001:28: 996–1003

Invited Discussion

Harold J. Brandon, DSc *†
V. Leroy Young, MD *
Clarence J. Wolf, PhD †
Kenneth L. Jerina, DSc †
Marla E. Watson, MA *
Joseph K. McLaughlin, PhD ‡

The preceding article by Marotta and colleagues from the University of Florida updates the group's meta-analysis of failure data reported in the literature for nearly 9,800 explanted silicone gel breast implants. They also present results from their testing of 51 single- and double-lumen explanted silicone gel breast implants (with various implantation times, made primarily by three manufacturers) plus one Dow Corning Silastic II control implant (never implanted). Because the authors do not say how or why these explants were selected for testing, we cannot know whether the 51 explants are representative in any way of all breast implants. Were they chosen at random from a larger pool of explants or were they simply what were available? Aside from duration of implantation, we are not given important details on the tested devices, such as implant style and lot, status at the time of explantation, and differences between those not strong enough for testing and those tested.

Marotta and colleagues maintain that reductions in mechanical properties—tensile strength, breaking energy, and tear resistance—of breast implants lead to a "significant loss" in shell strength and toughness over time. They link the higher failure frequencies over time (shown in their Fig 12) to the effects of elastomer swelling and hypothesize that mechanical properties of elastomer degrade as noncrosslinked, low-molecular-weight silicone molecules diffuse from the gel into the shell. Without any scientific proof, the authors assert that early weakening of shells resulting from swelling is responsible for silicone gel breast implant failure. Our research indicates that implant rupture has numerous potential causes (not just one), including implant handling before surgery, in vivo processes, trauma to the breast, and unintentional surgical damage during implantation or explantation.

In their implant testing, Marotta and colleagues found no significant correlation between implantation time and shell strength properties. Our work at Washington University has produced similar findings. We are therefore puzzled as to why the authors neglected to reference almost all our published data.[1–8] Although not scientifically offensive, this "oversight" is perplexing because we have conducted a substantial amount of implant properties testing during the last decade. Although our work supports their *data*, it also refutes many of their *conclusions*. For example, our research has described various types of silicone gel breast implants that have remained intact with a large degree of shell swelling (20–40%) for implantation times ranging from 13 to 32 years.[1,3,5]

The authors are consistently selective when citing published studies on the variability of mechanical properties of control implant shells. They ignore our data for Dow Corning control and explanted implant shells[1–6] and choose instead to reference studies of explants that did not characterize the devices according to manufacturer, specific type, or manufacturing lot, and did

not compare explants with proper controls.[9–11] Using these references, Marotta and colleagues conclude incorrectly that mechanical properties of all explanted prostheses are considerably poorer than nonimplanted controls. The consequence of not comparing explants with the proper controls is illustrated in their Figure 3. For the Dow Corning "standard" silicone gel explants they tested, the tensile strength of all four explants and the percent elongation of three fall below the control values published by Battelle Research in 1986. However, all the tensile strength and elongation data presented in Figure 3 fall within the determined ranges of control values for Silastic 0 and Silastic I implants.[2,6]

Along with selectively citing references, Marotta and colleagues refer only to those portions of publications with which they agree, even when that means misrepresenting other findings from the same study. As an example, they reference one of our papers that reported decreases of approximately 50% in tensile strength, 30% in elongation, and 40% in tear strength for implant shells after 8 years of implantation.[7] Marotta and colleagues neglected to mention that the same reference states: "a different implant shell type, also containing silicone gel, exhibited essentially no change in tensile strength and a small decrease in elongation as the implantation time increased."[7]

There are other examples of how the University of Florida investigators selectively use published literature to support their conclusions. They cite van Rappard and colleagues,[12] who investigated the pressure resistance of 50 explanted Dow Corning silicone gel breast implants. All 50 explants were intact at the time of removal and had an average implantation duration of 4 years (range, 0.1–8.0 years). This data point of 0% failure at 4 years does not appear in Marotta's meta-analysis (see their Fig 12), which predicts approximately 25% failure at 4 years. Although the study by van Rappard[12] is ignored in the meta-analysis, it is included as support for the proposition that explant strength is low compared with new, nonimplanted controls (and they do not acknowledge the control range tested by van Rappard and colleagues[12] was limited). We certainly do not believe the van Rappard data[12]—or any other selected data—can be considered as representative of all breast implants. Instead, we are troubled by the authors' willingness to use selected portions of the literature that bolster their theories and ignore whatever else does not.

Marotta and colleagues state, "various investigators have found consistently that the mechanical properties of explanted prostheses were considerably poorer than unimplanted controls." This conclusion is incorrect according to the literature and manufacturer data on Dow Corning "standard" gel implants. One of our studies summarized the published mechanical property data for Dow Corning Silastic 0 and Silastic I implants and showed that the tensile strength data for explants from six separate studies all fell within the data range for control implants.[2] In fact, the tensile strength data in the preceding article by Marotta and colleagues also fall within the published control range, as do their elongation data. Hence, we find no fault with Marotta's data for Dow Corning "standard" gel implants, only with the interpretation. Similarly, their data for Silastic II explants also agree with the explant and control data from our investigation and six other studies.[3] Silastic II explant shells exhibit a decrease in strength property values shortly after implantation but are essentially constant thereafter. This initial reduction in ultimate strength properties probably results from the enhanced diffusion of noncrosslinked silicones from the gel into the shell. Based on available information, the length of time needed to reach equilibrium swelling is uncertain, but it appears to occur within the first few years of implantation.

Many of our observations regarding Marotta and colleagues' conclusions on the mechanical properties of elastomer shells also hold for their swelling data. Interested readers should compare the preceding article's swelling data with our findings,[1,3,5,6,8] but a few key points are worth noting here. Marotta and colleagues say one of our studies[7] indicated that after the silicone oil that swells the shells is extracted, the mechanical properties return to the original strength values, which suggests that no chemical degradation of the elastomer shell occurs. They state further that patients are always exposed to implants with oil-swollen shells that have diminished mechanical properties. First of all, we have never sug-

Annals of Plastic Surgery Volume 49 / Number 3 / September 2002

gested that patients would be exposed to unswollen shells. Of course they are. More worrisome is that our data on the mechanical strength properties of extracted shells were not presented in the 1996 reference Marotta cited, but appeared in later publications.[1–3,5,6] From this mistake we can infer that the University of Florida group is indeed familiar with our research, even though they do not reference it.

Testing extracted implant shells did not become part of our study protocol until 1997, after Goldberg and coworkers[13] asserted "the notion that the elastomer and gel would be physically and chemically inert and indefinitely stable was naïve and without scientific bases." This statement prompted us to perform extraction studies on Silastic 0 and Silastic I controls and explants with implantation durations as long as 28 years, and Silastic II controls and explants with as long as 13 years of implantation.[1–3,5] (To our knowledge, these explants represent the longest implantation durations tested for both types of implants.) Our extraction studies found that the elastomeric shells of Dow Corning explants are not degraded chemically by the swelling process. We also demonstrated that the strength and elongation properties of these tested explants did not vary markedly with implantation time.

We have recently investigated the effects of swelling on lightly crosslinked polydimethylsiloxane films and found that swelling can have a pronounced effect on the material's mechanical properties.[14] However, because this effect is completely reversible, the mechanical forces involved in the swelling process do not degrade the polymer network. Although the amount of swelling in many explanted implants can be notable, as high as 20 to 40%, our experiments found that, in general, the observed mechanical properties of swollen implants were still higher than the minimum acceptable ASTM values.

One major conclusion reached by Marotta and colleagues is that breast implant rupture relates to weakening of the shells via elastomer swelling by noncrosslinked silicone fluids from the gel. They believe this weakening begins when the shell is filled initially with gel and continues over time, whether an implant is sitting on a shelf or implanted in a patient. To support their conclusion, they reference a 1971 report by Manikian that reported decreases in tensile strength, elongation, and tear strength (43%, 4%, and 46% respectively) for nonimplanted Dow Corning silicone gel implants when measured 3.5 years after manufacture. In reality, Manikian compared the nonimplanted control implants with the elastomer dispersion material used to manufacture the shells—not to other implants produced at the same time. Marotta and colleagues ignore an important statement in the Manikian report: "there is a strong indication that, after the changes induced by the gel contact have been completed, the shell [bag] remains essentially stable." Also, the University of Florida researchers seem not to have noticed that their explant data either agree with or are higher than the control data by Manikian, which correspond fairly closely with published control range data for tensile strength and elongation.

Another contradiction in the Marotta article pertains to what happens to a silicone gel implant after it is manufactured. On the one hand, they state that the decrease in shell properties resulting from swelling begins once the implant is filled with gel and continues whether the implant is stored or implanted. On the other hand, they admit their data show no significant correlation between implantation duration and degradation of implant strength. We know of no scientific evidence supporting the contention that silicone gel implant shell strength declines throughout the life span of implants. To the contrary, the published data (including that of Marotta and colleagues) demonstrate that once an equilibrium swelling has been achieved, the mechanical properties of shells without a barrier coating remain relatively constant over time, no matter where the implants are (sitting on a shelf or implanted in a patient). Shells with a barrier coating (such as Dow Corning Silastic II implants) also achieve equilibrium swelling when they are stored. However, once implanted, additional swelling occurs in barrier-coated shells, and it may take a few years before equilibrium swelling is reached.

We have investigated the effect of aging on stored control implants. Specifically, in 1997 we tested Dow Corning control implants from the same manufacturing lots as those tested by Battelle in 1986. The Table compares the tensile

strength and elongation for the controls tested at Battelle and at Washington University. The mechanical property values measured by both groups are very similar for both types of implants after an additional 11 years of storage. We attribute the differences between our data and the Battelle data ranges primarily to variability within a lot and the effects of different testing techniques. Regardless, there is no evidence that these stored implants continued to weaken over time. This comparison supports the idea that once an implant shell achieves equilibrium swelling, the properties remain relatively constant thereafter.

One observation presented by Marotta and colleagues is difficult to understand in view of their silicone oil penetration hypothesis. They found the amount of extractable silicone from the inner and outer shells of McGhan double-lumen explants to be essentially the same: approximately 20% (see their Fig 9). The double lumen contains an inner shell filled with silicone gel and a second intermediate region containing saline solution surrounded by a second shell. When originally packaged, i.e., in the control state, the intermediate region is void of saline solution and the inner and outer shells are in contact. When the device is implanted, saline solution is added and the inner and outer shells are separated and are no longer in contact (except for a few regions where they may touch). Thus, it is difficult to explain why the two shells would have the same amount of sorbed silicone fluid. Furthermore, Marotta et al report that the mechanical properties of the inner and outer shells are essentially the same, which supports their hypothesis that "permeation from the gel decreases the mechanical properties of the silicone shell." These observations required further explanation.

The updated meta-analysis presented by Marotta and colleagues continues to show that breast implant rupture is more likely the longer an implant is in place. Unfortunately, Marotta and colleagues continue to use the term "failure rate" in connection with their analysis when, in fact, this type of analysis cannot determine the incidence rate of silicone gel breast implant failure. The plot in their Figure 12 tells us something about rupture prevalence, but only that failure seems more frequent over time, as multiple authors have reported consistently. 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. 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 vs. implantation time does nothing to eliminate or even to reduce the underlying bias. We have discussed previously the kind of cohort study needed to determine accurately the prevalence and incidence rate of breast implant rupture.[15,16] 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 incidence rate of rupture is the probability of failure within a fixed length time period (e.g., *x* number of implants can be expected to fail at 1 year, *x* number at 5 years, etc.). This rate cannot be estimated from cross-sectional data. For one thing, we do not know when a silicone gel implant ruptured based on explantation or imaging studies. We know only that it was ruptured when

Properties of Stored Implants Measured 11 Years Apart

Laboratory	Tensile Strength, psi	Elongation, %
Silastic I control implant, lot no. HH 124437		
Battelle (1986)	960–1,113	580–648
Washington University (1997)	901	484
Silastic II control implant, lot no. HH 016121		
Battelle (1986)	1,578–1,888	1,092–1,133
Washington University (1997)	1,680	1,042

removed or imaged. Because the ruptures in the meta-analysis by Marotta and colleagues could have occurred anytime after implantation, the parameter estimated in the plot in their Figure 12 is closer to a cumulative probability of failure. By definition, cumulative probabilities increase over time. This type of analysis cannot support the conclusion that the rupture *rate* increases as the implantation time lengthens.

To determine the silicone gel breast implant rupture rate, the true patient base or population of interest we need to study is the universe of all women implanted by the same surgeon (or clinic), during the same time period, with the same type of implant, and with comparable surgical techniques. Ideally, this should be done for large numbers of implants made by each manufacturer to determine whether different manufacturers and models have different failure rates. The impact of not analyzing the correct patient base can be dramatic. Assume that 100 augmentation patients elect to undergo explantation, and that each of the 100 women is found to have one ruptured implant. Because 200 implants were evaluated, the rupture prevalence would be estimated at 50%. Assume that the true patient population base from which the 100 women came contained 1,000 women. The status of implants in the 900 women who did not undergo explantation is not known but is unlikely to be higher than that observed in the women electing surgery. Thus, the rupture prevalence in the true patient base could lie anywhere between 5% (assuming no ruptured implants in the 900 women) and the 50% observed in the self-selected group of explanted women. The only way to guarantee a valid estimate of the incidence rate of rupture would be to (1) evaluate all 1,000 women at the same time, preferably with a baseline magnetic resonance imaging examination; (2) remove implants identified as ruptured to confirm the diagnosis and/or to determine the number of false positives and false negatives; and (3) perform serial examinations of these women at regular time intervals (e.g., yearly) to reevaluate implant status. Only this approach would provide the incidence rate—based on timing—of breast implant failure.

Until we have these kinds of data, it makes no sense to offer a blanket recommendation for all women with silicone gel breast implants to undergo implant exchange within 6 to 8 years after implantation. We do not need higher reoperation frequencies among implant patients unless a recommendation for timed explantation is based on a scientifically determined failure rate.

Although the silicone gel breast implant mechanical and chemical property data presented by Marotta and colleagues supplement previous studies, these data do not support the article's conclusions, and the authors acknowledge this fact. Nevertheless, the article's conclusion asserts that their "explant rupture data are indeed representative of the implant aging properties and rupture characteristics of the general population of [silicone gel breast implants] that remain implanted." This assertion is insupportable. In the first place, their data cannot be representative of the general population because they are derived from a selected sample of failed implants. Their meta-analysis is not a properly designed investigation into the incidence rate of failure. In the second place, their data do not illuminate the question of implant aging. In fact, most of the measured properties shown in their figures demonstrate very little difference over time. In the third place, we need much more data on implant failure mechanisms before rupture characteristics can be defined. We are also concerned with the obvious selectivity Marotta and colleagues use when citing—or failing to cite—the published literature. This problem alone makes it hard to view their conclusions as anything but highly biased and unfounded.

This discussion was prepared by the Center for Implant Retrieval and Analysis, which is supported by the National Endowment for Plastic Surgery.

*Division of Plastic and Reconstructive Surgery
†Departments of Mechanical and Chemical Engineering
Washington University
St. Louis, MO
‡International Epidemiology Institute
Rockville, MD

References

1 Brandon HJ, Peters W, Young VL, et al. Analysis of two Dow Corning breast implants removed after 28 years of implantation. Aesthetic Surg J 1999;19:40

2 Brandon HJ, Jerina KL, Wolf CJ, et al. Ultimate strength properties of control and explanted Silastic I and Silastic 0 silicone gel-filled breast implant shells. Aesthetic Surg J 1999;19:381

3 Brandon HJ, Jerina KL, Wolf CJ, et al. Ultimate strength properties of explanted and control Silastic II silicone gel-filled breast implant shells. Aesthetic Surg J 2000;20:122

4 Jerina KL, Brandon HJ, Young VL, et al. In vivo aging characteristics of breast implants compared to lot-matched controls. In: Transactions of the 6th World Biomaterials Congress. Kamuela, Hawaii, May 15–20, 2000. 350

5 Brandon HJ, Young VL, Jerina KL, et al. Breast implants for plastic and reconstructive surgery—strengths and failures. In: Transactions of the 6th World Biomaterials Congress. Kamuela, Hawaii, May 15–20, 2000. 347

6 Brandon HJ, Young VL, Jerina KL, et al. Variability in the properties of silicone gel breast implants. Plast Reconstr Surg 2001;108:647

7 Brandon HJ, Young VL, Wolf CJ, et al. Mechanical analysis of explanted breast implants. In: Transactions of the 5th World Biomaterials Congress. Toronto, Canada, May, 1996. 302

8 Wolf CJ, Jerina KL, Brandon HJ, et al. Analysis of the extractable non-bound compounds from Silastic II silicone breast implants. In: Transactions of the 6th World Biomaterials Congress. Kamuela, Hawaii, May 15–20, 2000. 1143

9 Lockwood MD. Strength, strain, energy, and toughness of silicone breast implant shells. Master's thesis. University of Illinois. Chicago, IL: 1995

10 Marotta JS, Amery DP, Widenhouse CW, et al. Degradation of physical properties of silicone gel breast implants and high rates of implant failures. In: Transactions of the 24th Annual Meeting of the Society for Biomaterials, 1998. 374

11 Phillips JW, de Camara DL, Lockwood MD, et al. Strength of silicone breast implants. Plast Reconstr Surg 1996;97: 1215

12 van Rappard JHA, Sonneveld GJ, van Twisk R, et al. Pressure resistance of breast implants as a function of implantation time. Ann Plast Surg 1988;21:566

13 Goldberg EP, Widenhouse C, Marotta J, et al. Failure of silicone gel breast implants: analysis of literature data for 1652 explanted prostheses. Plast Reconstr Surg 1997;100: 281 [Letter]

14 Wolf CJ, Jerina KL, Brandon HJ, et al. The effect of cyclic swelling of octamethylcyclotetrasiloxane on the physical properties of silicone breast implant shells. J Biomater Sci Polymer Ed 2002;13(1):27–41

15 Young VL, Brandon HJ, Watson ME. Discussion. Silicone gel-filled breast implant integrity: a retrospective review of 478 consecutively explanted implants. Plast Reconstr Surg 2000;105:1986

16 Young VL, Watson ME. Discussion. Prevalence of silicone breast implant rupture among Danish women. Plast Reconstr Surg 2001;108:859

References

1 Marotta JS, Goldberg EP, Habal MB, et al. Silicone gel breast implant failure: evaluation of properties of shells and gels for explanted prostheses and meta-analysis of literature rupture data. *Ann Plast Surg.* 2002; 49:227–247.

2 Brown SL, Middleton MS, Berg WA, et al. Prevalence of rupture of silicone gel breast implants revealed on MR imaging in a population of women in Birmingham, Alabama. *AJR Am J Roentgenol.* 2000; 175;1057–1064.

3 Brown SL, Pennelo G, Berg WA, et al. Silicone gel implant rupture, extracapsular silicone, and health status in a population of women. *J Rheumatol.* 2001;28:996–1003.

4 Manikian M. Long term physical property evaluation of Silastic mammary prosthesis. *Dow Corning report.* July 7, 1971.

Reply

We were pleased to have the opportunity to respond (in the form of an Invited Discussion[1]) to the 2002 article by Marotta and colleagues (comments on March 23, 2003 Letter to the Editor by Marotta JS, Goldberg EP, Habal MB, Amery DP, Martin PJ, Urbaniak DJ, Widenhouse CW)[2] and also appreciate this chance to address their comments to us. Their letter does nothing to change our evaluation of their original article and the data selectivity, data omissions, and data misrepresentations it contains. We must first state that we received no funding from Dow Corning or any other commercial entity to support the preparation of our Invited Discussion or this letter. The Center for Implant Retrieval and Analysis at Washington University is supported by the National Endowment for Plastic Surgery and the Aesthetic Surgery Education and Research Foundation. In the past, we have received unrestricted gifts from Dow Corning to support our basic breast implant research, and this support has been denoted in our publications where applicable.

Our response to the letter by Marotta et al. follows the order of their comments:

All the explant studies underlying the meta-analysis of Marotta and colleagues are biased by the self-selection of patients. Because patients who undergo explantation select themselves for surgery, they cannot be considered a random or representative sample of the population of all women with breast implants. Any investigation of explanted devices (many of which are removed because they failed) is inherently confounded by this same bias. The study of Brown et al,[3] which used MRI to assess implant status, used a less biased design to determine whether a breast implant has ruptured. Yet even this cross-sectional 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.[4] Another weakness with the Brown et al[3] study is that 92% of the implants imaged with MRI could be classified as "second-generation" devices, which are less likely to be intact than first- or third-generation implants.[5,6] 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.

Our problem with the way in which the University of Florida researchers refer to our work remains their selectivity, omission, and misinterpretation of data. We indeed looked very closely at the references cited by Marotta et al in their paper. They referred to none of our peer-reviewed publications, at least nine of which were available by the end of 2001 (when the original article was accepted). They did cite meeting presentations, two in the text and two (not one as stated in the preceding letter) in Figure 12. The Wolf reference (number 10) in Figure 12 is illustrative. They use that presentation as the basis for plotting a data point of 80% implant failure at 16 years when, in reality, that particular investigation examined gel viscosity, had nothing to do implant failure, and involved only five explants, four of which happened to be ruptured. Five intact explants could just as easily have been studied, but implant integrity was not our purpose. The use of these five explants as a data point for predicting failure versus implant duration is absurd. For anyone confused about our implant testing protocols, a recently published explanatory article describes how we analyze silicone gel and saline-filled breast implants.[7]

There is no need to repeat what was said in our earlier Discussion regarding implant shell weakening as a result of swelling with silicone fluid from the gel. Although shell swelling does reduce an implant's overall mechanical properties, we have seen no evidence that swelling is the major factor in the time-dependent cyclic stress-induced rupture of gel implants, as Marotta and colleagues assert. In fact, our studies have found that the effect of cyclic sorption stresses does not lead to an appreciable degradation of the basic shell structure. In addition, we have determined that various types of Dow Corning silicone gel explants have remained intact despite swelling of approximately 20% to 40% for implantation times ranging from 13 to 32 years.[8]

Our approach in conducting breast implant research is quite different from that of Marotta and colleagues. We find no value in plotting numbers of explants that have failed according to implantation duration. Our work has proven to us that erroneous conclusions can be drawn when explants are not compared with proper controls and when differences between manufacturers, implant models, and implant/patient history are ignored. We have focused our work on specific questions, such as testing explants and controls to determine what happens to the material properties when implant shells are exposed to a physiologic environment. These studies have covered the entire range of implantation times that are available to date and include the oldest known silicone gel explants from first, second, and third generations (including two Cronin seamed explants removed intact after 32 years). We have tested the largest known inventory of explants with lot-matched controls as well as the oldest

saline explants (removed intact after 22 and 23 years) that have been analyzed to date. These investigations have shown that variations in the original shell properties must be considered when analyzing explants implanted between the middle 1960s and early 1990s. We have also analyzed explants to demonstrate how surgical instrument damage during implantation and explantation surgery can cause or look like a rupture. We have studied the effect that implantation surgery itself (ie, placing an implant in the pocket) has on the strength properties of silicone gel breast implant controls.

We could plot the status of every explant in our inventory on a graph according to integrity status and time in vivo, but the result would not help determine the failure rate or identify when and why breast implants are likely to fail. Moreover, the explants in our inventory are a biased sample and certainly not representative of all explants, let alone all still-implanted implants. We therefore will not use rupture data from our inventory to predict the failure characteristics of the general population of silicone gel breast implants.

We can agree with the stated goal of Marotta et al when they say they want to "provide more scientific information to help improve patient counseling and preaugmentation-informed consent." We disagree, however, that their meta-analysis is based on sound scientific principles; it is fraught with bias and misrepresentation (eg, the Wolf example discussed earlier). Furthermore, how does the meta-analysis improve patient counseling today? Women who have received more recently designed silicone gel implants—and those who choose augmentation in the future—want to know how long their implants can be expected to last. The approach taken by Marotta and colleagues does not help answer that question.

We agree with the general observation that breast implants seem more prone to fail over time. However, time alone does not seem the most likely reason for failure. After many years of testing explanted devices and appropriate controls, we still cannot fully explain the mechanisms of failure, although we think that several mechanisms are probably involved, including in vivo processes such as abrasion, inappropriate handling of an implant prior to its placement, implantation and/or explantation surgery, and breast or implant trauma. It appears that the thinner elastomer shells characteristic of second-generation implants are more likely to fail than thicker-shell devices. The evolution of implant designs over time illustrates the danger of graphing failure versus time. Because all the data points plotted by Marotta and colleagues cannot be considered equal, we still contend their meta-analysis tells us very little about breast implant failure and creates more confusion than clarity.

Harold J. Brandon DSc†*
V. Leroy Young, MD‡
Clarence J. Wolf, PhD†
Kenneth L. Jerina, DSc†
*Marla E. Watson, MA**
Joseph K. McLaughlin, PhD§
**Division of Plastic and Reconstructive Surgery*
Washington University
St. Louis, MO
†Departments of Mechanical and Chemical Engineering
Washington University, St. Louis, MO
‡BodyAesthetic Plastic Surgery and Skincare Center
St. Louis, MO
§International Epidemiology Institute
Rockville, MD

References

1 Brandon HJ, Young VL, Wolf CJ, et al. Silicone gel breast implant failure: evaluation of properties of shells and gels for explanted prostheses and meta-analysis of literature rupture data [Invited Discussion]. *Ann Plast Surg.* 2002;49:242–247.
2 Marotta JS, Goldberg EP, Hebal MB, et al. Silicone gel breast implant failure: evaluation of properties of shells and gels for explanted prostheses and meta-analysis of literature rupture data. *Ann Plast Surg.* 2002;49:227–241.
3 Brown SL, Middleton MS, Berg WA, et al. Prevalence of rupture of silicone gel breast implants revealed on MR imaging in a population of women in Birmingham, Alabama. *AJR Am J Roentgenol.* 2000;175:1057–1064.
4 Feng L-J, Amini SB. Analysis of risk factors associated with rupture of silicone gel breast implants. *Plast Reconstr Surg.* 1999;104:955–963.
5 Peters W, Smith D, Lugowski S. Failure properties of 352 explanted silicone-gel breast implants. *Can J Plast Surg.* 1996;4:55–58.
6 Collis N, Sharpe DT. Silicone gel-filled breast implant integrity: a retrospective review of 478 consecutively explanted implants. *Plast Reconstr Surg.* 2000;105:1979–1985.
7 Brandon HJ, Young VL, Watson ME, et al. Protocol for retrieval and analysis of breast implants. *J Long-Term Effects Med Implants.* 2003;13:49–61.
8 Brandon HJ, Jerina KL, Wolf CJ, et al. Biodurability of retrieved silicone gel breast implants. *Plast Reconstr Surg.* 2003;111:2295–2306.

Re: Nodal Metastatic Melanoma in the Neck of a 4-Year-Old Girl After Diagnosis of Spitz Nevus of the Cheek

The report by Reynolds and colleagues (*Ann Plast Surg.* 2003;50:555–557) of nodal metastatic melanoma arising after the diagnosis of a Spitz nevus serves as an important reminder of the difficulties in histopathological diagnosis of melanocytic lesions. We think that proper nosology is of paramount importance in the medical literature. For this reason, we take exception with one phrase in the authors' otherwise well-written report. The last paragraph of the discussion starts with "Clearly, most Spitz nevi are entirely benign. . . ." We maintain that *all* Spitz nevi are benign.

If a melanocytic proliferation diagnosed as Spitz nevus metastasizes, it was diagnosed incorrectly. If the pathologist does not think a lesion is benign, the term "nevus" should not be affixed to it; rather, it should be diagnosed as a "melanocytic proliferation, see note" with an attached statement about one's uncertainty of its biology, or it should be referred for a second opinion to someone who might have more experience in diagnosing definitively such a lesion, or, in some cases, both.