Mentor Report Number M 052

AN INVESTIGATION OF THE MODES AND CAUSES OF FAILURE OF GEL-FILLED BREAST IMPLANT DEVICES IN THE "RENT-UNKNOWN CAUSE" AND "NOT APPARENT-ETIOLOGY UNKNOWN" CATEGORIES OF THE PRODUCT EVALUATION DATABASE

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August 15, 2004

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Executive Summary

The Product Evaluation (PE) Database is the repository for information on Mentor gel-filled implant devices for which complaints have been received. The database contains complaints on both devices that have failed (ruptured) and those that have not. It is important to define the mechanisms of failure for the failed devices, because this understanding can lead to ways of reducing or eliminating those failures.

The cause of failure for some devices in the database has been well defined. For example, devices that are categorized under the failure code of "Iatrogenic (User Related)" failed as the result of cuts or punctures from sharp instruments. The initial laboratory examination of returned devices for two specific failure categories did not yield a determination of failure mode. These devices are listed under the failure codes "Rent-Unknown Cause" and "Not Apparent-Etiology Unknown" in the database. The "Rent-Unknown Cause" population was chosen for the initial, detailed study. There were two main reasons for this choice. First, this failure code was established in 1994. This means that failures of any second generation devices would be minimal in this group. This is important because it has been well established in the literature that third generation products are more robust. Therefore, the selection of this population will provide a better view of the third generation products. Secondly, this population was small enough to allow a detailed analysis in a reasonable period of time. The conclusions from the study of this population should be directly applicable to the closely related population in "Not Apparent-Etiology Unknown" since the latter category was used to record data on the devices with similar failure modes prior to 1994.

After the investigation of the "Rent Unknown Cause" (RUC) category was completed, the decision was taken to perform the same analysis on the "Not Apparent-Etiology Unknown" (NAEU) category in order to make the investigation as comprehensive as possible and to provide assurance that the results from the investigation of the "Rent-Unknown Cause" population were representative. The results of both studies are included in this report.

The objectives of this study on gel-filled implants were (1) to identify modes of device failures, (2) to postulate mechanisms of failure and test whether the mechanisms matched the data and, finally, (3) to provide a rough approximation for the mean time to failure for devices based upon the failure modes combined with implantation time. The procedure for this was to first perform a detailed physical examination on each device in the population, record data that would allow computer searches and correlations of findings and, finally, analyze the information in an effort to meet the specified objectives. The population of re-examined devices from the two populations (RUC and NAEU) covered by the investigation represented a substantial portion, but not all, of all failed devices within that population.

This study identified three modes of failure: (1) localized shell fatigue, (2) thin line failures and (3) delamination of the shell/patch bond area.

Delamination of the shell/patch bond area results when the bond between the shell and patch fails. There were 12 instances of this failure across both re-examined populations

consisting of 203 total failed devices. This amounts to approximately 6% of all failures (12 out of 203) in the two categories.

Localized shell fatigue failures result from folds in the shell. Flexing of this fold creates a small area of fatigue in the shell elastomer. Over time this develops into a shell failure. This failure mode is distinctive and easily recognized. Essentially all of these failures are textured products.

Thin line failures can be subdivided into failures in the shell and at the shell/patch interface. The shell/patch interface thin line failures extend from the radius of the patch perpendicular to the shell and down through it. This mode is distinct from delamination at the shell/patch bond as described above. The delamination type failure extends along the shell between the patch and shell. Both the shell and shell/patch interface thin line failures are characterized as a failure extending through the shell. If the two sides of a thin line failure are brought back together, they will match precisely, i. e., they are reverse images of one another. Thin line failures at the patch/shell junction are most likely the result of flexing in this junction area. These failures occur predominately on textured devices. Textured devices have patches that extend close to the periphery of the device. Flexing in this area may play an important role in these failures.

Thin line failures of the shell result from either local stress on the shell applied during insertion of the device during the implantation procedure or sharp instrument cuts. A published study by Brandon, *et al.* confirms that small tears develop in implant shells over time for no apparent reason.[1] These ruptures could have resulted from localized stress applied during implantation of the device. Another study by Dr. Brandon et al. demonstrated that shell damage can result from contact with surgical instruments during implantation and explantation surgeries.[2]

No matter how these failures are initiated, they appear to propagate over time in the body. This propagation, if it proceeds to produce a long failure line, makes it very difficult to determine the exact area of initiation along the line or even the initiating factor (localized stress or cut) for the failure.

During the investigation an attempt was made to determine whether surface characteristics (smooth or textured) influence device failure. Specifically, was there a greater tendency for devices with smooth surfaces to fail as compared to those with textured surfaces or *vice versa*? Except for devices that fail by localized shell fatigue or by thin lines at the shell/patch junction, no strong bias was detected for the failure of one surface type over the other. In the case of localized shell fatigue failures, only two devices with smooth surfaces failed compared to 18 with textured surfaces within the total examined population (examined devices from Rent-Unknown Cause plus Not Apparent-Etiology Unknown categories).

During the analysis of the data from device examinations, it was noted that shell failures tended to be clustered in the area at the radius and on the anterior region of the device just

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[1] Brandon HJ, Jerina KL, Wolf CJ, Young VL, "Biodurability of Retrieved Silicone Gel Breast Implants," *Plat And Reconstr Surg.*, Vol 111, No. 7, June 2003.

[2] Brandon HJ, Young VL, Jerina KL, Wolf CJ, "SEM Characterization of Surgical Instrument Damage to Breast Implants," *Plast Reconstr. Surg*, Vol. 108, No. 1, July 2001.

above the radius. Iatrogenic damage is more likely to occur in these areas for the following reasons: (1) During closure of the wound after the device implantation, there is a higher probability that the device will be punctured. During closure, suturing will be done at the periphery of the device for the inframammary and transaxillary surgical approaches. (2) If a doctor elects to remove an implant, for example, as the result of capsular contracture, the incision for that removal will, in most cases, be at the periphery of the device based upon fact that inframammary and transaxillary placements are used more frequently than periareolar placement. This location presents the greatest likelihood for a scalpel nick or cut in preparation for the removal. (3) The device placement procedure used by surgeons involves pushing the device through the incision using one or two fingers to force the device into the surgical pocket. For transaxillary and inframammary approach to placement, this technique results in localized stress being applied to the area on the anterior surface just above the radius or at the radius of the device. This localized, weakened area may result in failure by fatigue over a longer period of time.[3]

There will be a propensity for non-iatrogenic failures in or close to the radius. Non-iatrogenic failures related to folding or wrinkling of the shell and resulting in localized fatigue failure will most likely be more prevalent in the radius region. Inspection of the devices included in this investigation revealed that, in those cases where shell wear was detected, the wear pattern indicated that the device had a fold and that the fold usually extended from somewhere on the anterior surface and terminated at or near the radius of the device. The pattern was a narrow "V" shape with the base of the "V" being on or near the radius region. Where abrasion lines were detected with the localized shell stress failure mode, the failure occurred at the base of the "V" at or near the radius.

Other non-iatrogenic failures are not necessarily located in this radius region. For example, failure of the shell/patch bond area can only occur at this bond area on the posterior of the device. The frequency of these particular failures was very low in the total population of failures in this group of devices. Other potential manufacturing related failures, such as thin shells, bubbles in shells or any other defects in the shell, would appear at random locations on the shell. No such failures were detected during this investigation.

Observed failures of devices with time were similar for both populations (RUC and NAEU) reviewed in this study. In all populations there were elevated numbers of intraoperative failures and subsequent elevated numbers of failures up through year 2. It is believed that these are related to iatrogenic failures. After this initial period, there is a lower number of failures per time interval. This lower rate of failure reaches a maximum among the failure distributions in the 6 to 9 years time frame. The number of failures then decreases to essentially zero over a period of a few years. The Rent-Unknown Cause population had no failures after 10 years. The Not Apparent-Etiology Unknown population expressed the same general shape and had no failures after about 12 years.

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[3] Wolf, CJ, Brandon, HJ, Young, VL, "Effect of Surgical Insertion on the Local Shell Properties of Silastic® II Silicone Gel Breast Implants," J. of Biomaterials Science Polymer Edn, Vol. 11, pp. 1007-1021.

This implication is that the implanted devices must fail in a bimodal distribution. A small number are failing fairly early, up to approximately 15 years. There is a decreasing number of failures after about 10 to 12 years. In order for a substantial number of devices to fail over a period of time, the rate of failures must increase at some point in time. The second failure mode in the bimodal distribution of the large *in vivo* population has not yet begun. Its initiation will be characterized by a monotonic increase in cumulative failures. This is the classic failure pattern for elastomers (and most other devices either medical or non-medical). The onset of the second part of the bimodal failure can not be predicted from the information available. But when it does begin, it will likely take several years for a significant number of devices to fail. It is impossible to predict a median life for the devices with any precision based strictly on the available data from this study, because, until the monotonically increasing failures begin to occur, there is no way of extrapolating a meaningful device life.

A reasonable conjecture is that, once this second failure mode begins, the failure of all devices will be defined by some distribution over time. It is inconceivable that all devices will fail simultaneously. If one assumes that the failure curve will follow a normal distribution, that the final distribution will be broad (have a large standard deviation) and that the final failure mode is initiated within the next two years or so, then, a minimum mean average device life is very roughly estimated to be 25 years or greater. The span of time to the median failure time will depend upon the precise shape of assumed the normal distribution curve, i. e., narrow with a rapid depletion of the devices or broad with a gradual failing of devices. This qualitative estimate is based upon the overt failures that were investigated in this study and the failure rate for Mentor devices that has been reported to the FDA --------)[4]. The potential impact of silent ruptures on this device life estimate cannot be addressed here. The inclusion of populations of silent failures in any attempt to predict a median device life must await the results of the MRI studies from the Mentor Core Clinical Study.

[4] PMA P030053, Section 8.2, Volume 13, December 11, 2003

Introduction

When a customer complaint is received by the Mentor Product Evaluation (PE) Group, a file is opened for that complaint and a record is added to the PE Database. When a complaint device is returned to the group, it is matched with the complaint, an "as received" photograph is taken of the device and the device is physically evaluated for cause of failure. All observations relative to the complaint device are entered into the database.

At the end of September 2003 there were ------ records on gel-filled complaint devices. The reported complaints range from cosmetic defects to actual ruptures of devices. Once a determination is made that the device is, in fact, ruptured, a mode of failure is assigned when possible. It should be noted that, in some cases, the physician's complaint is a ruptured device, but, upon examination, the device will be intact. Also, in some instances a mode of failure cannot be determined. These devices will be assigned to categories that signify that a mode of failure could not be determined. The headings for the "Failure" field in the database that contain most of the complaint population are listed in Table 1.

Table 1. Failure Categories that Contain Most of the PE Database Records

PE Database Category	Number of Complaints	Percent of Total Complaints
---------- ---------- --	----	------
---------- ---------	——	------
----------	------	-------
----------	----	------
---- ------	----	------
Iatrogenic (User Related)	----	------
Rent-Unknown Cause	----	------
Not Apparent-Etiology Unknown	------	-------
Total of Selected Categories	------	-------

The categories shown in Table 1 represent about ----- of the total complaints. In some cases, the Failure Designation indicates the status of the device, e. g., ---------- ----------. In many instances, a complaint was recorded, but no device returned to Mentor for examination. This category, ---------- represents approximately ----- of all complaints. ---------- ---------- ---------- ----------

i---------- Obviously, no detailed evaluation that would result in an assignment for cause of failure could be made on these complaint devices.

For ------ of the database population the PE personnel detected no failure in the returned device (No Abnormality). Cosmetic defects, but no device failure, were determined for ------ of the total population. ---------- of the devices listed in the ---------- failure category were shown, after examination, to be intact (no ruptures). Examples of ---------- defects are small bubbles in the silicone gel or minor damage to outer packaging of device that was probably sustained during shipment and that did not impact sterility of device.

Where possible, a cause is assigned to a failed device. This is the case with "---------- ----------. Examination of these devices has revealed characteristics, such as, parallel striations, that are a clear indication of cuts or punctures with sharp instruments. A review of the statistics provided in the database verifies the accuracy of the laboratory determination. Below is a tabulation of those statistics.

Table 2. Statistics of ------ ---------- Failures

Item	Number of Devices	Percent of Total Population
Total Population in Database	----	
No Abnormality	---	------
In Vivo Time Unknown	----	-------
Population Remaining for Analysis	----	-------

Population Remaining for Analysis		
Intraoperative Failure	312	61.4%
In Vivo Time 0 - 1 year	101	19.9%
In Vivo Time 1 - 2 years	29	5.7%
In Vivo Time 2 – 3 years	19	3.7%
In Vivo Time > 3 years	47	9.3%
Total	508	100.0%

A small number of the returned devices in the ---------- failure category had no abnormality, i. e., had not failed. Missing implant and/or explant date did not allow calculation of *in vivo* time for about ----- of the population. However, a significant number of devices remained after eliminating these two groups from the analysis.

If instrument damage is inflicted on a device during implantation, it would be expected that the device will fail quickly. This is, in fact, substantiated by the data. About ----- (--- devices) of the population that could be analyzed (--- total devices) failed intraoperatively. Another approximately -- percent failed within the first year of implantation. These short-term failures account for about ----- of all failures in this category. It is also reasonable to assume that instrument damage might be difficult to

detect intraoperatively. Detection would be possible after the initial damage became more severe through propagation of the cut. This would account for the failures in the 1-3 year period. The longer term failures (> three years) are most likely the result of instrument damage to the device during explantation for other reasons, such as, a desire for a size change or the alleviation of capsular contracture. Instrument damage to devices during explantation is identifiable because the failure line has not had time to propagate, i. e., the cut area will encompass the length of the failure line. The identification of these explanted devices can be made difficult if the shell is torn during the removal process. If this happens, the failure line will probably be indistinguishable from a failure line that has propagated over time.

Two populations in the PE Database do not have definitive causes of failure assigned to returned devices: "Rent-Unknown Cause" and "Not Apparent-Etiology Unknown". Any returned device that is examined by the PE personnel and for which a cause of failure cannot be ascertained will be assigned to either the "Rent-Unknown Cause" or "Not Apparent-Etiology Unknown" populations. The "Rent-Unknown Cause" category was established in 1994 after the PE group moved from Goleta, California to the Irving, Texas location. The pre-1994 data under the old category of "Not Apparent-Etiology Unknown" was later added to the database in Texas, but the original designation for that category was retained.

In the FDA's draft guidance for breast implants, the agency states that "The modes and causes of rupture should be characterized so that the rate of rupture and the rate of change of rupture over time can be minimized to establish reasonable assurance of device safety." [5] In response to this guidance, Mentor undertook a detailed physical re-examination of the devices related to domestic U. S. complaints for rupture included in the "Rent-Unknown Cause" population of the PE Database. Of the ---- devices in the category, 125 were available in the domestic complaint category and were re-examined. Some devices had been selected for alternate studies to determine mode of failure or physical properties post-implantation. This involved the identification and recording of modes of failures, number of failures per device, location of failures and characteristics of the failures. The data were captured in a format that allowed computer analysis of the results. Unusual characteristics of failures were recorded in text format and entered into a computer database. Limited examination by optical microscopy was performed on devices of special interest after completing the physical examination.

The "Not Apparent-Etiology Unknown" population was examined by the same procedures as applied to the "Rent-Unknown Cause" population. This was done as a verification of the results from the RUC population were typical. A discussion of these results is included later in this report.

[5] FDA, Draft Guidance for Saline, Silicone Gel and Alternative Breast Implants, January 8, 2004, Section 7. "Modes and Causes of Rupture"

Rent-Unknown Cause Database Population: Results and Discussion of Re-Examination of Devices Related to Domestic U. S. Complaints[6]

Overview of Total Sample Population

The population of re-examined devices is characterized in Table 3.

Table 3. Re-examined Devices from Rent-Unknown Cause Population and with Complaints Resulting from Domestic U. S. Sales

Description of Population	Number of Devices	Percent of Total Population
Number of Examined Devices for which *In Vivo* Time could not be determined because either Implant or Explant Date is Unknown	10	8%
Number of Examined Devices with 0 Days *In Vivo*, i. e., Intraoperative Failure	31	25%
Number of Examined Devices that could be used to Determine *In Vivo* Time for Various Failure Modes	80	64%
Subtotal of Examined Devices with Failures	121	97%
Devices with No Failure in Examined Population	4	3%
Total Examined Devices with and without Failures	125	100%

A total of 125 devices were examined to determine their mode of failure. Four (4) of these were found to be intact. A failure mode was assigned to the remaining 121 devices (97% of the population). Thirty-one (31) devices, 25% of the population, failed intraoperatively (0 days *In Vivo*). The *In Vivo* Implantation Time for 10 of the devices could not be determined since either the implantation or explantation date, or both, was not available. Obviously, these devices could not be used to determine failures versus time. The remaining 80 devices could be used in this determination of time to failure.

The table below presents the mode of failure for the inspected devices. Thin line failures are those that could be created by cutting or tearing the device. Characteristically, if the two sides of the failure line are brought together, a precise match can be made. In other words, one side is a mirror image of the other. Thin line failures can occur on the shell of devices, on the surface area circumscribed by the shell/patch junction of patches on textured devices or at shell/patch junctions. About 80% of the failures are of the thin line variety.

[6] A glossary of terms is included in Appendix I of this report. Some terms are used in a specific, defined way. Therefore, in order to assure a clear understanding of the results that are presented, these definitions and explanation of terms should be read before proceeding with the rest of the report.

Localized Shell Fatigue accounts for 14% of all failures. Shell/Patch Delaminations comprise 3.3% of the total population. The occurrence of multiple (i.e., combination) failure modes in a single device constitutes only 3.2% of the total population. The significance of this is that the confounding effects of multiple failure modes acting on one device are infrequent in the population and is strong evidence that one type of failure is independent of others. Another way of stating this is that segregation and analysis of a single failure mode will provide valid conclusions about that mode.

Table 4. Characterization of Failures

Failure Characterization	No. of Failures by That Characterization	Percent of Actual Failures
Thin Line (Shell Only)	72	59.5%
Patch/Shell Junction (Thin Line)	21	17.4%
Localized Shell Fatigue	17	14.0%
Shell/Patch Delamination	4	3.3%
Patch Internal Only (Thin Line)	3	2.5%
Combination Failures		
Shell Fatigue/Patch Internal (Thin Line)	1	0.8%
Shell Fatigue/Thin Line	1	0.8%
Shell Fatigue/Patch Internal(Thin Line) /Patch-Shell Junction (Thin Line)	1	0.8%
Patch-Shell Junction (Thin Line)/Patch Internal (Thin Line)	1	0.8%
Total Failed Device Population	**121**	100%
No Failure	4	
Total Population	**125**	

The failed device population consisted of 98 with Siltex texturing (81% of total failed devices) and 23 smooth (19% of the total failed population). The locations of failures are shown in Table 5. The definitions of the various areas of the device are presented in the "Glossary of Terms" in Appendix I.

It is significant to note that 26% of the total number of the devices failed exclusively in the radius area. See Table 5. Another 39% of the failures involved the radius area. By definition for this investigation, the radius area consists of a strip of shell 0.75 inches wide and located along the periphery of the device (i.e., the circumference). This strip accounts for approximately 19 to 33 percent (~33% for 125 cc device and ~19% for an 800 cc device) of the total device surface. This means that 64% of the total failures occur entirely within or involve 19 to 33% of the surface area.

This propensity to fail in the radius area is not surprising if the modes of failure are examined. Iatrogenic damage is more likely to occur in these areas for the following reasons: (1) During closure of the wound after the device implantation, there is a higher

probability that the device will be punctured. During closure suturing will be done at the periphery of the device for the inframammary and transaxillary surgical approaches; (2) If a doctor elects to remove an implant, for example, as the result of capsular contracture, the incision for that removal will, in most cases, be at the periphery of the device based upon the frequency of inframammary and transaxillary placements versus periareolar placement. This location presents the greatest likelihood for a scalpel nick or cut in preparation for the removal; and (3) The device placement procedure used by surgeons involves pushing the device through the incision using one or two fingers to force the device into the surgical pocket, while squeezing the device in order to expand the portion of the device that has been squeezed into the surgical pocket. For transaxillary and inframammary approach to placement, this technique could result in localized stress being applied to the area on the anterior surface just above the radius or at the radius of the device. The degree of localized stress (and localized shell elongation) will depend heavily upon the surgical technique of the doctor. This localized, weakened area can result in failure by fatigue over a longer period of time. Published investigations by Brandon *et al.* provide supporting evidence for the proposed mechanism of localized shell damage during the implantation procedure.[7,8]

There may also be a propensity for non-iatrogenic failures in or close to the radius. Non-iatrogenic failures related to folding or wrinkling of the shell with resultant localized fatigue failure will likely be more prevalent in the radius region. Inspection of the devices included in this investigation revealed that, in those cases where shell wear was detected, the wear pattern indicated that the device was folded and that the fold usually extended from somewhere on the anterior surface and terminated at or near the radius of the device. The pattern was a narrow "V" shape with the base of the "V" being on or near the radius region. Where abrasion lines were detected with the localized shell stress failure mode, the failure occurred at the base of the "V" at or near the radius area.

Other non-iatrogenic failures may not be located in this radius region. For example, failure of the shell/patch bond area (delamination) can only occur at this bond area on the posterior of the device. The frequency of these failures is relatively low (3.3%) in the total population of failures in the populations studied. Other potential manufacturing related defects, such as thin shells, bubbles in shells or any other defects in the shell would appear at random locations on the shell. No such failures were detected during this investigation.

Except for the infrequent long failure line that can extend across the anterior region of a shell and in other cases can originate on the anterior area and extend across the radius into the posterior area and at times continue along the periphery of the shell/patch junction on the posterior, failure lines are usually relatively short and are most frequently located on the anterior region close to the radius region of the device. The very existence of these short failure lines in the general radius region strongly suggests that they are

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[7] Brandon HJ, Young VL, Jerina KL, Wolf CJ, "Effect of Implantation Surgery on the Strength Properties of SILASTIC® II Silicone Gel Breast Implant Shells," *Aesth Surg* J 1999, Vol. 19, No. 3, PP 197-204.
[8] Wolf CJ, Brandon HJ, Young VL, Jerina KL, "Effect of Surgical Insertion on the Local Shell Properties of SILASTIC® II Silicone Gel Breast Implants," *J. Biomater Sci Polymer Edn*, vol. 11, No. 10, pp 1007-1022, 2000.

involved in the inception of many failures. Over time, short failure lines may propagate into longer ones. Only in catastrophic situations where extreme stress is applied to the implant, such as in a car accident, will a long failure line be produced instantly. Obviously, the initiation point for the short line failure must be confined to that failure line. Thus, if there is a high frequency of short, thin line failures at or near the radius region as is observed, one can safely assume that this will be the location on the device for the inception of most failures.

The combination of failure areas in the table below, e. g., radius/posterior, simply signifies that more than one area of the failed device was involved. It is believed that the failure lines can propagate from one area to another. For example, a thin line failure could originate on the anterior surface and then pass through the radius and onto the posterior area of the device. This would constitute a combination failure involving different areas of the device. In a few cases the combination surface designation could mean that there were two separate failures on different surfaces of the device. An example of this could be two thin line failures, one on the radius and one in the anterior area. There were very few such examples.

Table 5. Location of Failures

Location	No. of Failures at Location in Population
Radius	32
Anterior	18
Posterior	23
Radius/Anterior	20
Radius/Posterior	8
Radius/Anterior/Posterior	19
Anterior/Posterior	1
Total	**121**
Devices with No Failure	4
Population Total	**125**

Location of Selected Failures	Number in that Location	Percent of Total
	7	
All Failures Involving Radius	9	65%
Failures Involving Radius	3	
Only	2	26%

As observed above, the total failure population consists of different failure modes. As will be shown later in this report, the individual failure modes will influence time to failure, selectivity to surface type and location of failure. For this reason, any further discussion of the influence of surface type on failures and the significance of failure location vis-à-vis failure mode will be done in relation to specific failure modes.

Table 6 lists the failure mode for all devices within the Rent-Unknown Cause population that failed intraoperatively. Note that all 31 devices that failed intraoperatively did so by the thin line mode. One would expect that essentially all intraoperative failures would be thin line failures that result from iatrogenic damage. Most of these failures will result from instrument damage (sharp blade cuts or needle punctures).

Table 6. Intraoperative Failures

Failure Mode	Number of Devices Failing by this Mode
Thin Line–Shell Only (Not Involving Patch)	30
Shell Fatigue	0
Shell/Patch Junction	0
Patch Internal (Thin Line)	1
Total	**31**
No Failure	1
Total Devices Failing Intraoperatively (0 Days *In Vivo*)	**32**

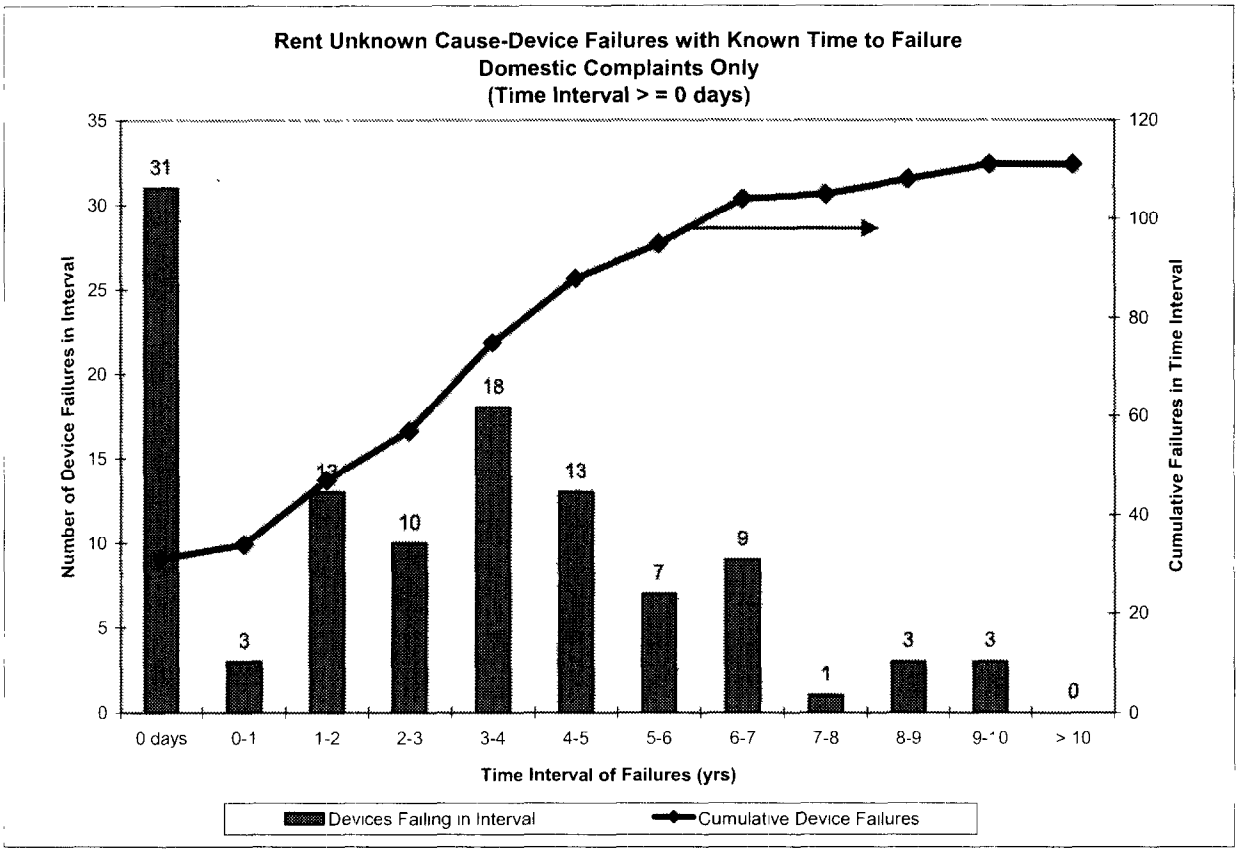

Figure 1. Total Failed Device Population in Rent-Unknown Cause versus Time to Failure Greater than or Equal to 0 Days

Figures 1, above, is a plot of all device failures in the Rent-Unknown cause population as a function of time interval to failure. The data on which the plot is based are included in Appendix II. Discounting intraoperative failures, this failure distribution is skewed

slightly toward 0 time with the maximum failures occurring in 1 to 5 years. There are no failures after 10 years. This figure includes devices (31) that failed intraoperatively. These comprise 25% of the total population. See Table 3.

Please note that there is an assumption concerning device life that will be made throughout this report. The assumption is that time *in vivo* (time *in vivo* equals explant date minus implant date) for a specific device is equal to the life of that particular device. The device may have failed before it was explanted, but the precise time cannot be ascertained. Thus, the foregoing assumption is the only logical one that can be made.

Thin Line Failures of the Shell

Proposed Mechanisms of Failure:

This population of thin line failures is restricted to failures of the shell area. It specifically does not include failures involving the patch, i. e., failures in the shell/patch bond area (bond delamination), patch/shell junction failures or thin line failures inside the periphery of the inner patch/shell junction (patch internal) in the textured area of a patch. It should be noted that textured devices have a large patch. The circular area inside the periphery of the bond area is essentially the same as the textured part of the shell. This means that under the right conditions, this area could be susceptible to the same failure/propagation mechanism as any other part of the shell. This is an infrequent occurrence for all textured devices examined. This is likely due to the fact that the patch bond area does not allow this region to bend or wrinkle (fatigue) as much as unconstrained areas of the shell. There were no failures inside the periphery of the patch. There were 2 patch/shell junction failures and 8 shell/patch delaminations in this examined population. It should be noted that the patch/shell junction failures are classified as thin line failures, but are not classified as thin line shell failures. Shell/patch delaminations are not classified as thin line failures since they do not comply with the specified definition. The analysis of the devices falling within the classification of shell/patch junction and shell patch delamination failure modes will be addressed separately.

This population of thin line failures is restricted to failures of the shell area. It specifically does not include failures involving the patch, i. e., failures at the shell/patch junctions or inside the periphery of the inner patch/shell junction in the textured area of a patch. Patch/shell junction failures will be treated separately. There were only 3 such patch internal failures in the total Rent-Unknown Cause These were not analyzed separately.

Thin line failures are almost certainly caused either by cutting or puncturing with a sharp instrument during the implantation or explantation of an implant or tears resulting from localized stress that extends the elastomer (shell) beyond its elastic limits (into the region approaching ultimate elongation). This localized stress could be induced by the surgeon during implantation, or it could result from repetitive bending of the shell elastomer at locations where the smooth transmission of stress is disrupted by an interface, such as, the shell/patch junction. A defining characteristic of the thin line failure mode is that each side of the failure is a mirror image of the other, and, if the sides are aligned in close proximity they will match. A picture of a thin line failure is shown below. Figure 2 is a

picture of a typical thin line failure. Figure 3 shows the edge of a failure line that resulted from tearing. Figure 4 shows a scalpel cut through a shell. Please note the parallel striations resulting from the cutting action of the scalpel.

Figure 2. Thin line failure in a textured shell.

Figure 3. Edge view of thin line failure resulting from a tear in a Siltex textured shell.

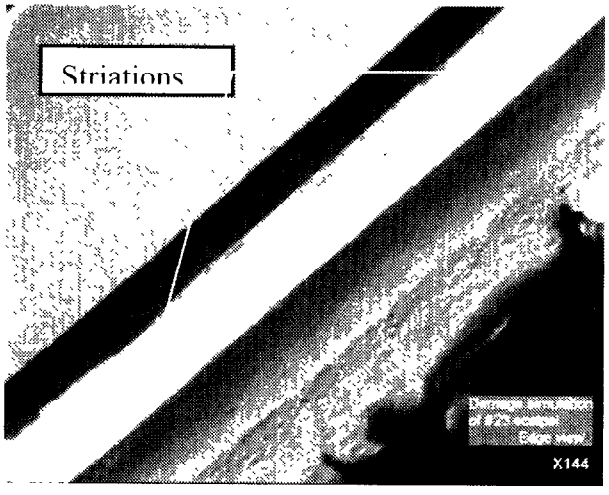

Figure 4. Edge view of a thin line failure in a Siltex textured shell showing parallel striations resulting from scalpel cut.

If created and not detected during implantation, it is postulated that instrument cuts or punctures will propagate as a tear over time. The amount of propagation will be determined by the periodic physical stress on the implant which is a strong function of the lifestyle of the patient. It is reasonable to assume that for the more active the person, input stress would be more frequent and perhaps greater in magnitude. Thus, the rate of propagation of a small failure will be dependent somewhat upon the lifestyle and personal habits of the implanted individual.

It is likely that shell tearing results from stresses applied to the device during implantation. First, as the surgeon forces the implant through the incision and into the surgical pocket with his fingers, localized stress is placed on the device, especially in the radius area. In addition, after inserting a segment of the device through the incision, the device is squeezed to expand it into the pocket. This expansion of a small portion of the device at the radius area stresses that area. The amount of stress required for implantation of a device is dependent on the size of the incision through which the device is being implanted and the local force applied to the device over a small area. The stress required to implant a device is inversely proportional to the size of that incision. This means that the maximum stress level is independent of the surgical approach, (with the possible exception of the periareolar approach), transaxillary or inframammary fold and depends only upon the size of the incision provided for the implantation and the localized stress that the surgeon applies as a result of his/her own insertion technique.

If the applied stress causes localized stress on the shell resulting from pushing with fingers or by local expansion of the shell from squeezing the device (both actions are used to insert the device through the incision) to a point close to the ultimate elongation limit for the material, the shell of the device in the radius area could be permanently deformed and weakened with the resultant potential for producing a thin line tear in the device after implantation.[9] The surgeon must strike a balance between the desire to produce a small incision for aesthetic reasons and the need to guard against excessive stress on the device. Mentor provides the following caution statement in its current Product Insert Data Sheet (PIDS):

> "Implant size and the firmer nature and higher profile of the Siltex shell should be a consideration when choosing optimum incision size and surgical approach. Avoid too small an incision; a larger incision than is normally used for other smooth-surface gel-filled implants may be required to facilitate insertion and to avoid damage to the device."[10]

The mechanisms of failure described above will lead to a higher probability of failures in the radius area. This tendency will be exacerbated by the fact that the thinnest area on a shell is at the radius. The anterior surface close to the radius area would also be expected to be the target of thin line failures. The reason for this is that surgeons, during implantation procedures, hold the device with the posterior surface towards the patient while applying force with their fingers to the radius area or the anterior surface just above this area as they insert the device through the incision. After a small failure in the shell is produced, that failure may propagate over time. As described above, the rate of propagation will depend somewhat on the lifestyle of the patient. If the proposed mechanisms are valid, during the early period of implantation, failures should be grouped on the anterior area close to the radius of the device and within the radius area. Over time and with propagation, the failures can grow and encompass more of the anterior region or even proceed into the posterior region.

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[9] Wolf, CJ, Brandon, HJ, Young, VL, "Effect of Surgical Insertion on the Local Shell Properties of Silastic® II Silicone Gel Breast Implants," J. of Biomaterials Science Polymer Edn, Vol. 11, pp. 1007-1021.

[10] Product Insert Data Sheet, 102748, Rev. D. Effective Jan 2001.

Location of Failures: According to the mechanism proposed for most failures, iatrogenic-related factors (scalpel cuts, suture needle punctures and localized stress during implantation) account for most short term failures. By the proposed mechanism these failures will be concentrated on the anterior area close to the radius area and in the radius area itself. Over time these small failure lines could propagate into longer failure lines that can extend across the anterior region and into the posterior area of the device, even extending to and along the periphery of the patch/shell junction. The location of short term failures and the inclusion of other shell surface areas over time should provide support for the proposed mechanisms.

We see in Figure 5 that there are 30 intraoperative failures. Failures involving only the radius and anterior areas account for 90% of all failures that occurred intraoperatively (*in vivo* time =0). The 90% for the intraoperative failures is revealing and probably provides the purest view of these failures, because they are discovered immediately and not confounded by any influences after the failure is formed. On the other hand. the failures that are not detected intraoperatively or, more likely, form postoperatively as thin line tears in localized regions of shell stress, have had time to propagate under stress. These failure lines can propagate until they involve other regions on the device.

As time progresses (*in vivo* time to failure) from the period of intraoperative to one year compared to the period of greater than one year, failures involving

* the radius area only increases from 27% in the intraoperative to one-year period to 31% in the greater than one year time period (Note that this is a change of only 2 devices)
* the radius and anterior areas combined drops from 37% to 16%
* the anterior area only drops from 27% to 19%
* the radius/anterior/posterior areas combined increases from 10% to 22%
* the radius/posterior combination increases from 0% to 6%

Thus, it can be seen that, over time, failures encompass a larger number of regions. This is substantiation that failure lines that are present early during implantation do propagate to longer failures that involve more shell surface areas.

It is recognized that the device populations (early versus later failures) obviously involve different devices—a device can only fail and be removed once. Nevertheless, the populations are large enough to provide a solid basis for conclusions based upon the fact that, when larger populations are considered, overall failure results will become more representative of the total population. Resting on this logic, these statistics provide strong support for the proposed mechanisms.

Table 7. Postulated Effects of Time on Location of Failures

LOCATION	Intraoperative Failures (In Vivo Time = 0)		Postoperative Failures (In Vivo Time >0)	
	Number of Failures at Location	Percent of Total Locations	Number of Failures at Location	Percent of Total Locations
Radius	8	27%	10	31%
Radius/Anterior	11	37%	5	16%
Radius/Posterior	0	0%	2	6%
Radius/Posterior/Anterior	3	10%	7	22%
Anterior	8	27%	6	19%
Posterior	0	0%	2	6%
Total	30	100%	32	100%

Time to Failure: Thin line failures of the shell of implants dominate the overall population of failed devices in the Rent-Unknown Cause population that was investigated. They account for 72 (about 60%) of the 121 failed devices in the population. Figure 5 is a plot of the individual and cumulative thin line failure device populations versus time (*in vivo* Time = or > 0).

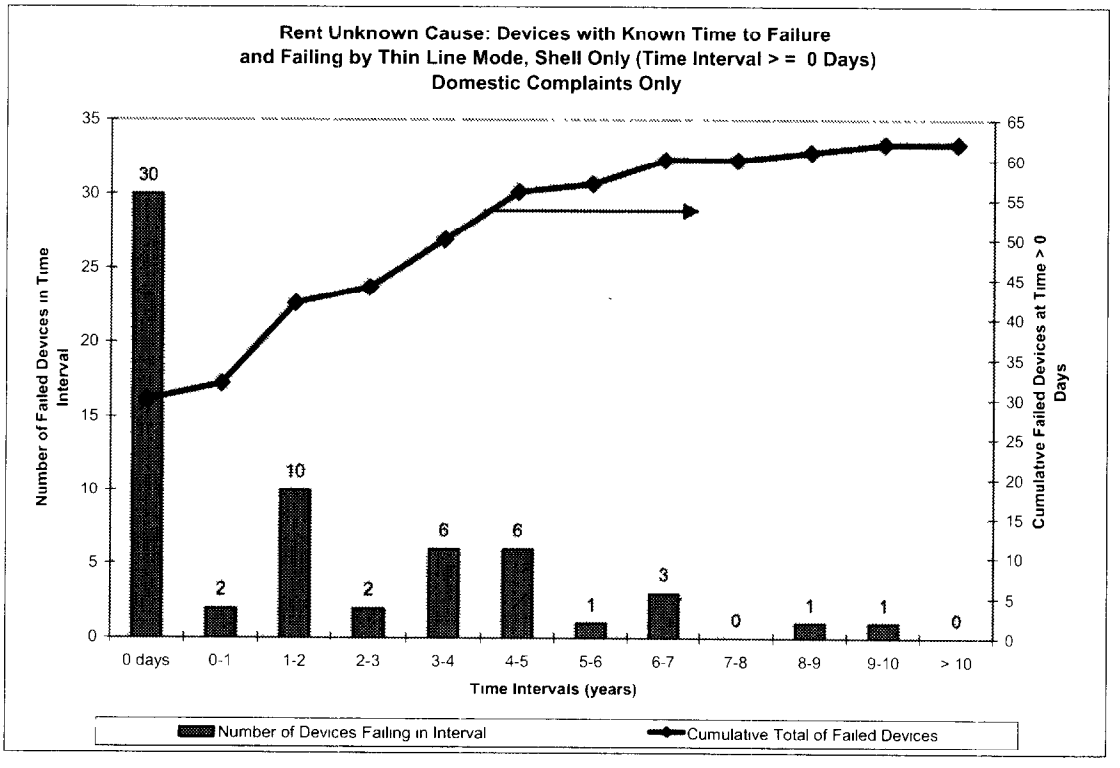

Figure 5. Individual and Cumulative Number of Devices Failing with Thin Line Intraoperatively and Postoperatively (*In Vivo* Time = or >0)

As can be seen in the figure and, as expected from the mechanism of failure discussed above, postoperative failures for this population are skewed towards time equal zero. The bulk of the failures occur within 1 to 5 years. There are no failures after 10 years. From Figure 5 we see that intraoperative failures are at least 3.0 times those in any other

individual time interval. Intraoperative failures account for 48% of the cumulative population.

It is interesting to compare the number of failed devices in the individual time intervals from intraoperative (0) through 2 years for the Thin Line failure mode to the total device population in Rent-Unknown Time. The numbers of devices in these intervals are almost identical. For intraoperative failures the failed device numbers are 30 and 31, respectively, for the Thin Line versus the total Rent-Unknown Cause population; for the 0-1 year interval it is 2 and 3; and for the 0-2 year interval it is identical at 10. The point is that thin line failures account for essentially all of the early failures. As pointed out before, these failures result from iatrogenic damage.

Surface Characteristics Effect on Failure:

For thin line failures of shells the ratio of surface characteristics of failed devices is shown in Table 8. Although the ratio of textured-to-smooth devices was calculated for Intraoperative and Postoperative failures the calculated values are rendered essentially useless for attempting to assess any relationship between surface characteristics and tendency to fail because the distribution of failures at Unknown Time to these populations cannot be determined. The ratios in these categories would change significantly depending upon how the failures in the Unknown In Vivo column were distributed to the other columns. The implantation dates of this population of the Rent-Unknown Cause category range from 1993 to 2003. The ratio of textured-to-smooth devices sold during the period 1993-2003 was -----.[11] See Appendix V. The textured to smooth ratio for the total population of failed devices is 2.6. Thus, this would suggest that there is a bias that favors the failure of textured devices (ratio of 2.6 for failed devices versus a global population of sold devices of -----). Based upon the proposed mechanisms for failure, these failures should result from damage to the device (instrument damage or localized stress) during implantation. Damage by instruments should be a random event, and, therefore, the failed population should reflect the population of implanted devices when large populations are considered.

Another factor that could alter this random selection process would be a bias that would be introduced by the practitioner. For example, if one or a small group of surgeons accounted for a large number of the failures and these same surgeons strongly preferred one shell characteristic over the other, then these factors would bias the results. During the investigation, an inquiry was made to determine if a single or few surgeons account for most of the failures in the Rent-Unknown Cause. It was confirmed that this was not the case.

Localized stress related failures would present a bias only if one or the other surface characteristics (smooth or textured) are more subject to stress damage. This then leads to the obvious conclusion that the stress-related mechanism for failure must be biased towards failing textured devices. The reason for this might result from the fact that the textured devices have an extra layer of elastomer (texturing layer) compared to a smooth device. The incremental local stress that is required to overcome the resistance of this extra material as the device is deformed during the insertion procedure might be the source of the higher failure rate for textured devices.

[11] Sales data presented in PMA Submission P030053, Section 8.2. Volume 13. December 11. 2003.

The hypothesis for stress-induced failures that would favor textured devices is not supported by other evidence. Later in this report, an analysis of the effect of surface characteristics of a device on failures rates within a population (Not Apparent-Etiology Unknown) that is closely related to the Rent-Unknown Cause population yielded the diametrically opposite conclusion, i. e., there is a bias for smooth, rather than textured devices, to fail more often as thin line failures of the shell. With the above arguments and the conflicting results from analyses on closely related populations, it was concluded that any tendency imparted from surface characteristics for a device to fail, could not be reliably determined from these data.

Table 8. Surface Characteristics of Devices Failing by Thin Line Mode on the Shell of the Device Only

Surface of Failed Devices	Intraoperative Failures (Time = 0)	Known Postoperative (> 0 DAYS)	Unknown (> or = 0 DAYS)	Total Number of Devices with Thin Line Failure	Each Surface Type as a Percent of Total Population
Textured	21	22	9	**52**	72%
Smooth	9	10	1	**20**	28%
Total	**30**	**32**	**10**	**72**	100%
Ratio of Surfaces	**2.3**	**2.2**	**9.0**	**2.6**	

Shell/Patch Junction Device Failures

During device assembly, a patch is attached to the posterior of a shell as a means of closing a hole that is created as part of the production process. The patch is attached to the outside of the shell and overlaps the shell for the full circumference of the patch. In the overlap area the thickness of the device consists of the shell and the patch assembly. At the outer periphery of the patch the thickness drops from the thickness of this combination to that of the shell. When a given stress is applied to this area, the shell will elongate at a much greater extent than the shell/patch combination. This causes a stress concentration precisely at the shell/patch junction and may give rise to a failure in this area over time. The likelihood of failure is increased by an increase in cyclic stress, i. e., the more stretching and movement of this junction, the higher the probability of a failure. Figures 6 and 7 are pictures of a shell/patch junction failure.

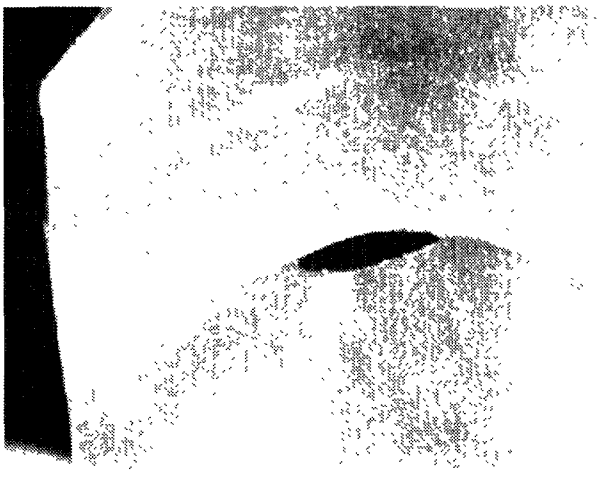

Figure 6. Shell/Patch Junction Failure on a Siltex Textured Device.

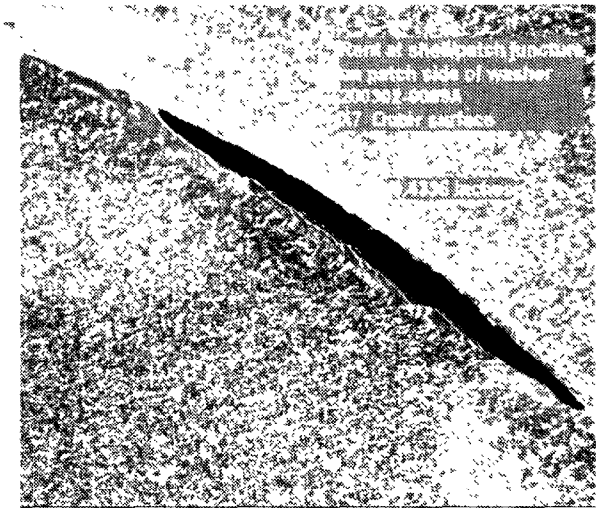

Figure 7. Magnified View of Shell/Patch Junction Failure on Siltex Textured Device.

Since shell/patch junction failures have all of the characteristics of a thin line failure, they are classified as a subset of thin line failures. The relationship between shell/patch junction and other thin line failures can be seen from the following discussion.

The shell/patch junction population being discussed here is restricted to that failure only and does not contain combination failures. For example a thin line shell tear could, and the results from the re-examination of devices suggest that some probably do, propagate to the shell/patch junction and proceed along the periphery of the patch precisely on the shell/patch junction. Conversely, it is possible that a failure at the shell/patch junction could propagate into the shell and involve the radius or even the anterior area. In these combination failures, it is impossible to determine the true source of the failure. Therefore, the population for analysis was restricted to failures at the shell/patch interface only.

Figure 8 is a plot of the individual and cumulative devices that fail at the shell/patch junction over time. The total population is 21 devices. The failure distribution appears to very roughly approximate a normal distribution with a mean average time to failure in the 3-4 year time interval. There are no failures beyond 8 years. As expected, there are no intraoperative (*In Vivo* Time = 0) failures. Time is required to develop this cyclic flexural stress mode of failure.

Twenty (20) Siltex textured devices and 1 smooth device comprise the total population. This is logical since the textured patch is large and extends much closer to the periphery of the device than does the smaller patch on smooth devices. The central region of the posterior of devices lies against the rib cage of the patient, and, therefore, should be more stable and subjected to less movement and flexural stress. Conversely, the region closer to the radius area of a device is subject to flexing as the result of body movement. This will result in a higher incidence of flexural stress. Thus, there will be a greater propensity for textured devices with their larger patches to fail by shell/patch junction mode.

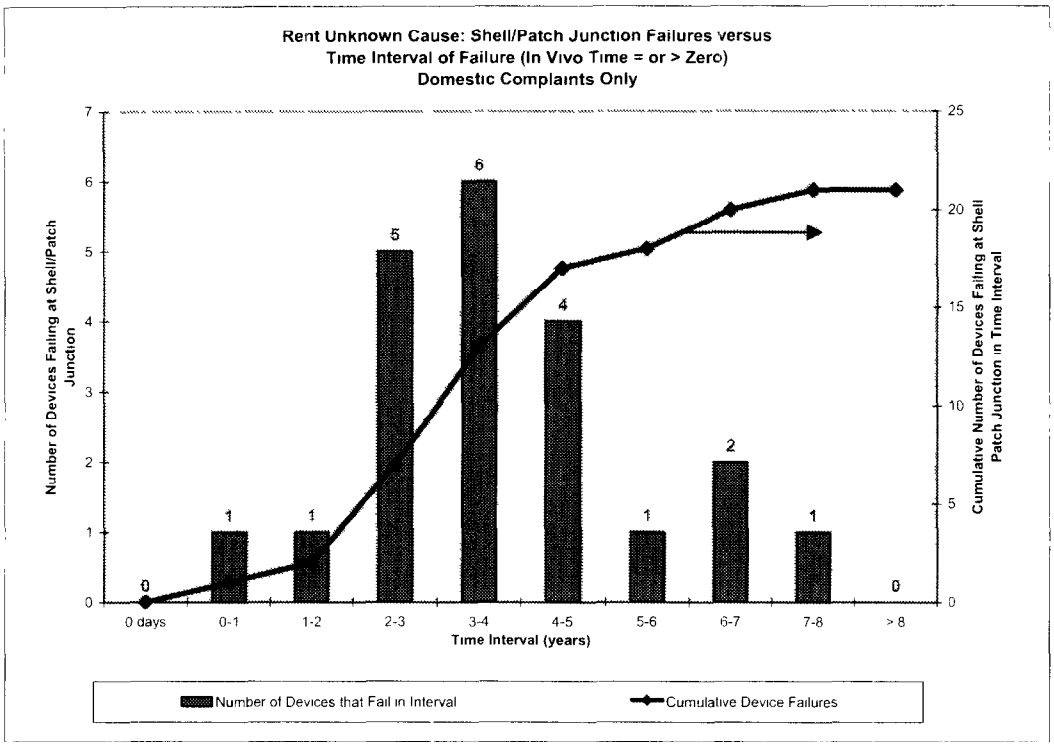

Figure 8. Individual and Cumulative Device Failures by the Shell/Patch Junction Mode versus Time Intervals

Localized Shell Fatigue Failures

There is strong evidence provided by the direct examination of failed devices that this type of failure results from folding of the shell. If a shell folds in the anterior surface and that fold extends close to or into the radius area of a device, a high stress area will be formed at the end of the fold close to the periphery of the device. The stress will be exacerbated due to the contour of the device where the radius area curves toward the posterior region. Flexing of the device at the radius will cause the high stress area at the end of the fold to "roll" as the flexural stress is applied and removed. Over time, this cyclic stress may cause the shell material to fatigue and fail. These failure areas are characterized by a localized white appearance surrounding the failure site on the shell. See Figures 9 and 10.

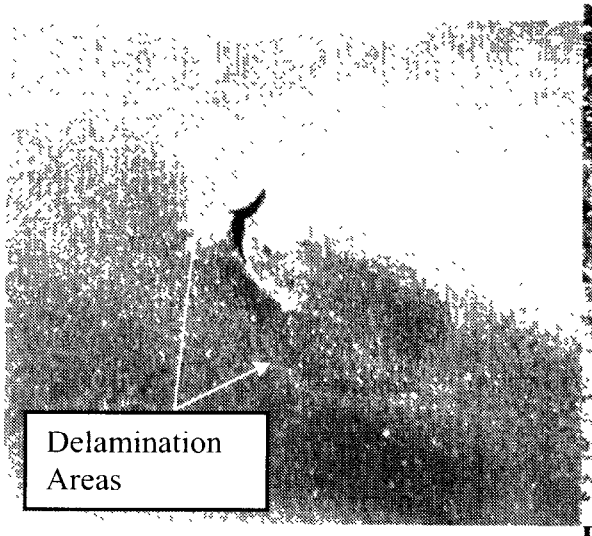

Figure 9. Shell Fatigue Failures. Note white appearance surrounding the failure site.

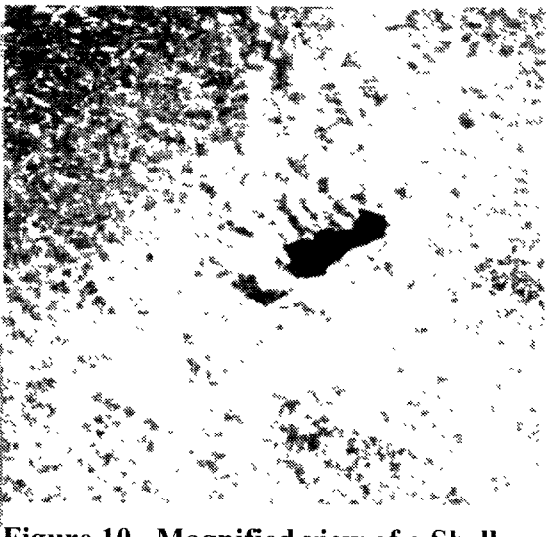

Figure 10. Magnified view of a Shell Fatigue Failure Site. Note white appearance surrounding failure.

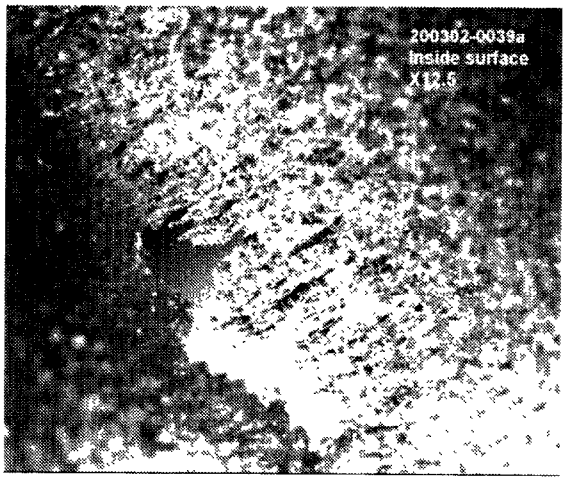

Figure 11. Shell Fatigue Failure. Note pattern of fatigue ridges extending from failure and nodules of silicone extending from side of failure.

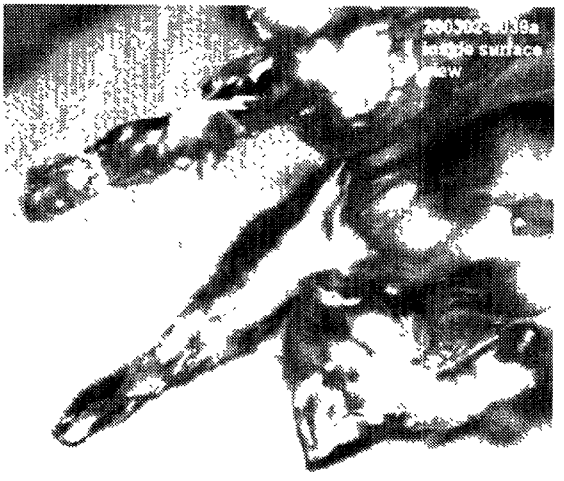

Figure 12. Silicone nodules protruding from margins of Shell Fatigue Failure.

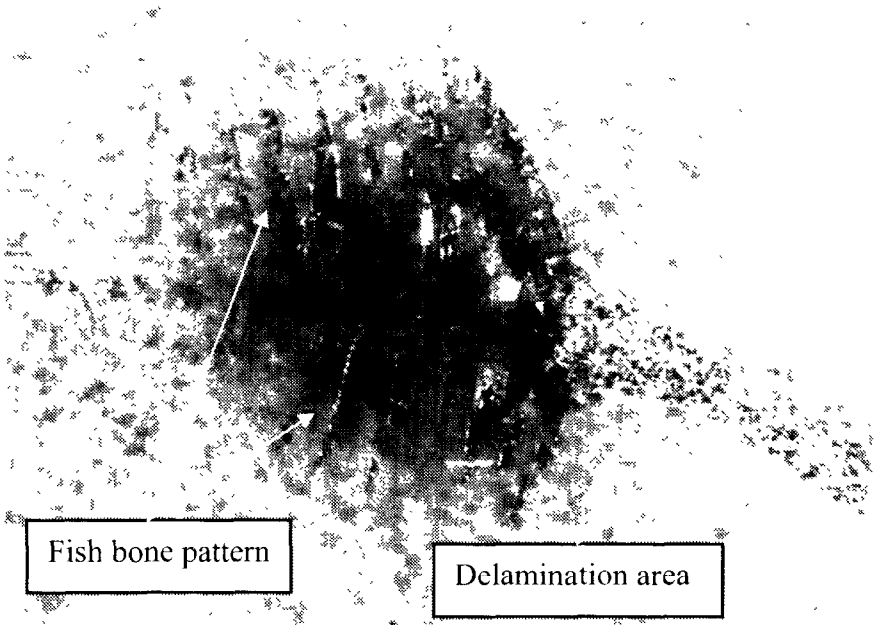

Figure 13. Shell Fatigue Failure with distinctive fish bone pattern of shell fatigue lines. Note shell wear extending off to the right of the failure.

Inspection of failed devices shows that small holes form in the failure area. With time these holes will consolidate into a larger opening. Many of the failures have elastomer fatigue lines that have the appearance of ridges radiating from the failure area and are in a configuration similar to a fish bone pattern. Such fatigue patterns have been noted in articles published by other researchers.[12] See Figures 11 and 13. The failure area is ragged and disorganized. In many cases, translucent nodules extend inwards from the sides of the failure. See Figure 13. Figure 12 provides a magnified view of the nodules that protrude from the sides of the failure. In a few cases, delamination of the inner layer of the shell is evident around the failure. In still fewer cases, delamination of the outer layer of the shell was noted. These delaminations extend over a small area, a few millimeters at most. Evidence of small delaminations can be seen to the lower right and upper left of the failure area in Figure 9. The lower right delamination was on the outer surface of the shell and the upper left on the inside.

Shell abrasion was seen in the proximity of many, but not all, shell fatigue failures. Similar abrasion patterns have previously been observed on failed devices by other researchers.[13] When present, these abrasion marks typically were in a "V" pattern with the failure at the point of the "V". The folds generally extended from the apex region of the anterior surface and terminated at or near the periphery of the device in or near the radius area on the external surface of the device. As explained above, this would be an area of maximum stress as the device periphery flexes. The actual wear on the shell texture was superficial. The shell abrasion itself was not a factor in the failure, but was an artifact of the failure mode. It is evidence that a fold formed, but there are no failures directly within the abrasion lines that extend away from the failure area.

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[12] Brandon, HJ, Young, VL, Jerina, KL, Wolf, CJ, "Scanning Electron Microscopy Characterization of Surgical Instrument Damage to Breast Implants," Plastic and Reconstruction Surgery, Vol. 108, No. 1, pp. 52-61, July 2001.
[13] Brandon *et al.*, *ibid.*

Figure 14 is a plot of the number of individual and cumulative devices failing by the shell fatigue mechanism. The shell fatigue population contains 17 failed devices. No devices with a combination of failures are included in the population. This restriction removes any confounding of data from other failure modes.

Fatigue failure takes time to develop. For this reason, there were no failures up through 1 year. Only one device/year failed by this mechanism in each of the time intervals 1-2 and 2-3. The profile of the population is skewed to longer failure times. The mean average life of a device for this failure mode with its skewed distribution is roughly estimated to be from 4 to 6 years.

All 17 failed devices were textured. Please note that in a later investigation of the Not Apparent-Etiology Unknown population two devices with smooth surfaces that failed by this mechanism were identified. There is a strong selectivity towards textured devices for those failing by this mode. The identification of these two devices is important, because it suggests that the failure mechanism is most likely related to the mechanical action of bending or folding the shell of a device and that the selectivity can be attributed to differences in shell thickness between textured and smooth devices.

As discussed above, creation of a wrinkle or fold in the shell is a prerequisite for shell fatigue failure. There are two, independent causes for creation of wrinkles or folds. First is the volume of gel in the shell. The volume of gel should be sufficient to inhibit the formation of a fold or small wrinkle in a shell. The second is the size and shape of the surgical pocket that is created during the implantation procedure. The prevention of this source of fold creation is directly dependent upon the skill, training and knowledge of the surgeon performing the implantation procedure.

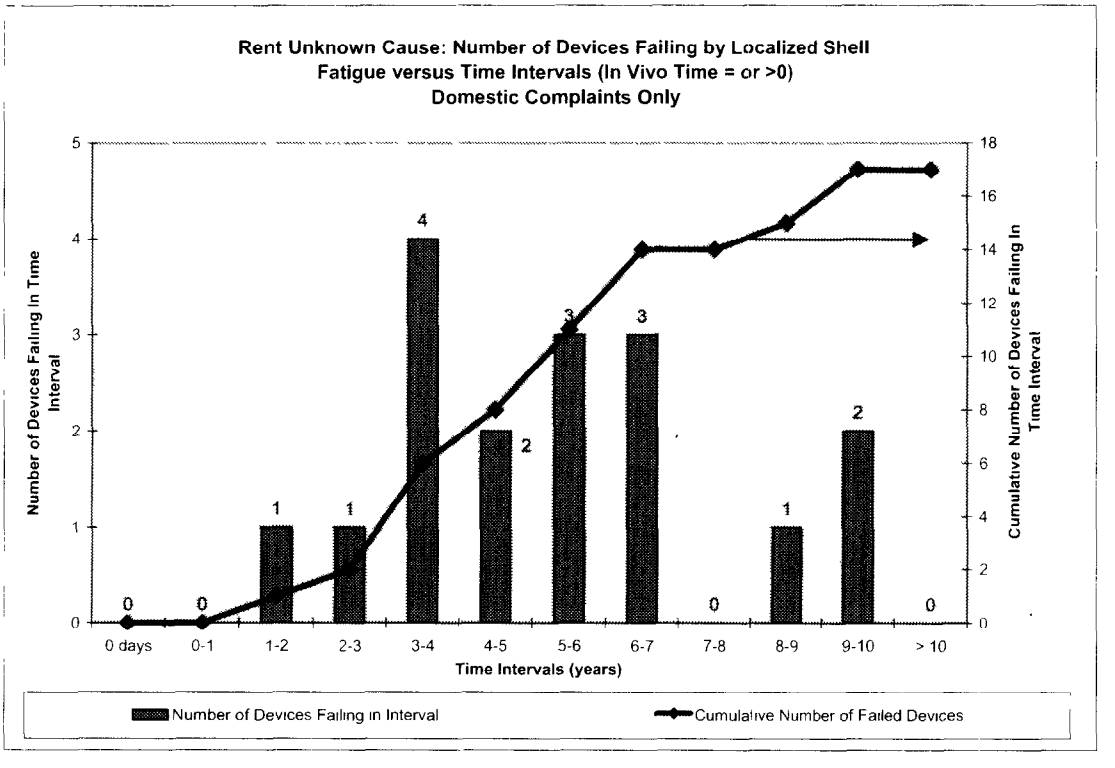

Figure 14. Individual and Cumulative Number of Devices Failing by the Shell Fatigue Mode versus Time to Failure.

Table 9 provides data on the location of localized shell fatigue failure on devices. As expected from the proposed mechanism for this failure mode, all failures are within or close to the radius area.

Table 9. Location of Shell Fatigue Failures on Device

Location of Failure	Number of Failures
Radius	11
Radius/Posterior	4
Radius/Anterior	1
Radius/Posterior/Anterior	1
Total	**17**

Shell/Patch Delamination

There were 4 devices that failed by this mechanism. All had textured surfaces. This failure mode comprises about 3% of the overall re-examined failure population for the Rent-Unknown Cause population.

Bond failure between the shell and patch of a device results in this failure mode. The strength and permanence of this bond is directly related to the vulcanization process for producing the bond. The fact that all failures involved textured surfaces suggests that the larger patch on those devices may be somewhat more difficult to bond to the shell.

Table 10 below provides the time to failure for the 4 failed devices. This type of failure requires time. No failure by this mode occurred in less than 2 years. The longest time to failure was in the 5-6 year interval.

Table 10. Number of Shell/Patch Delamination Failures versus Time Interval of Failure

In Vivo Interval	Number of Devices Failing in Interval
0 days	0
0-1	0
1-2	0
2-3	1
3-4	1
4-5	1
5-6	1
>6	0
Total Number of Failed Devices	**4**

Not Apparent-Etiology Unknown Database Population: Results and Discussion of Re-Examination of Devices Related to Domestic U. S. Complaints

Overview of Total Sample Population

The sample device population or re-examined devices is characterized in Table 11.

Table 11. Re-examined Devices from Not Apparent-Etiology Unknown Population and with Complaints Resulting from Domestic U. S. Sales

Description of Population	Number of Devices	Percent of Failed Population	Percent of Failed Population
Number of Failed Devices for which *In Vivo* Time could not be determined because either Implant or Explant Date is Unknown	16	20%	14%
Number of Failed Devices with 0 Days *In Vivo*, i. e., Intraoperative Failure	3	4%	3%
Number of Failed Devices that could be used to Determine *In Vivo* Time for Various Failure Modes	63	77%	55%
Total Failed Explants	82	100%	71%
Devices with No Failure in Examined Population	33		29%
Total Examined Devices with Failures	115		100%

A total of 115 devices were examined to determine their mode of failure. Thirty-three (33) of these were found to be intact. A failure mode was assigned to the remaining 82 devices (71% of the population). Three (3) devices, 3% of the population, failed intraoperatively (0 days *In Vivo*). The *In Vivo* implantation time for 16 of the devices could not be determined since either the implantation or explantation date, or both, was not available. Obviously, these devices could not be used to determine failures versus time. The remaining 63 devices (55% of total population) could be used in this determination of time to failure.

The table below presents the mode of failure for the inspected devices. Thin line failures are those that could be created by cutting or tearing the device. Characteristically, if the two sides of the failure line are brought together, a precise match can be made. In other words, one side is a mirror image of the other. Thin Line failures can occur on the shell of devices, on the surface area circumscribed by the shell/patch junction of patches on textured devices (inside the patch bond periphery) or at shell/patch junction. Devices that contained only thin line failures account for approximately 87% of the total population. Included in this number are failed devices that had a combination of single mode failures that were classified as thin line and combinations of modes of failure that included only thin line.

The other two components of the failures are localized shell fatigue and shell/patch delamination. Localized shell fatigue accounts for approximately 4% and shell patch delamination amounts to 9.8% of all failures, respectively.

Table 12. Characterization of Failures

Failure Characterization	No. of Failures by That Characterization	Percent of Actual Failures
Single Mode of Failure		
Thin Line (Shell Only)	60	73.2%
Patch Internal Only (Thin Line)	0	0.0%
Patch/Shell Junction Only (Thin Line)	2	2.4%
Shell Fatigue Only	3	3.7%
Shell/Patch Delamination	8	9.8%
Combination Modes of Failures		
Thin Line (Shell Only)/Patch Internal Only (Thin Line)	2	2.4%
Thin Line (Shell Only)/Patch/Shell Junction Only (Thin Line)	7	8.5%
TOTAL FAILURES	82	100%
No Failure	33	
TOTAL POPULATION	115	

The failed device population consisted of 39 with Siltex texturing (48% of total failed devices) and 43 smooth (52% of the total failed population). The locations of failures are shown in Table 13. The definitions of the various areas of the device are presented in the "Glossary of Terms" in Appendix I. It is significant to note that 13% of the total number of the devices failed exclusively in the radius area. A total of 60% of the failures involved the radius and anterior and/or posterior areas. Except for the infrequent long failure line that can extend across the anterior region of a shell and in other cases can originate on the anterior area and extend across the radius into the posterior area and at times continue along the periphery of the shell/patch junction on the posterior, failure lines are usually relatively short and are most frequently located on the anterior or posterior region close to the radius region of the device. The very existence of these short failure lines in the general radius region strongly suggests that it is involved in the inception of many failures. Over time, short failure lines may propagate into longer ones. Only in catastrophic situations where extreme stress is applied to the implant, such as in a car accident, will a long failure line be produced instantly. Obviously, the initiation point for the short line failure must be confined to that line. Thus, if there is a high frequency of short, thin line failures at or near the radius region as is observed, one can safely assume that this will be the location on the device for the inception of most failures. A discussion of the modes of failure with an explanation of why failures by these modes would occur more frequently in this radius region is presented in the discussion of the Rent-Unknown Cause examined population above.

The combination of failure areas in the table below, e. g., radius/posterior, in the table below simply signifies that more than one area of the failed device was involved. It is believed that the failure line propagated from one area to another. For example, a thin line failure could originate on the anterior surface and then pass through the radius and

onto the posterior area of the device. This would constitute a combination failure involving different areas of the device. In a few cases the combination surface designation could mean that there were two separate failures on different surfaces of the device. An example of this could be two thin line failures, one on the radius and one in the anterior area. There were very few such examples.

Table 13. Location of Failures

Location	No. of Failures at Location in Population	Percent of Total
Radius	11	13%
Anterior	21	26%
Posterior	12	15%
Radius/Anterior	5	6%
Radius/Posterior	3	4%
Radius/Anterior/Posterior	30	37%
Anterior/Posterior	0	0%
Total	**82**	**100%**
Devices with No Failure	33	
Population Total	**115**	
All Failures Involving Radius and Anterior and/or Posterior Combinations	**49**	**60%**
Failures Involving Radius Only	**11**	**13%**

As observed above, the total failure population consists of different failure modes. As will be shown later in this report, the individual failure modes will influence time to failure, selectivity to surface type and location of failure. For this reason, any further discussion of the influence of surface type on failures and the significance of failure location vis-à-vis failure mode will be done in relation to specific failure modes.

There were only 3 intraoperative failures in the sample population. All were thin line failures. There was one in the anterior region and two in the radius/anterior region combined. One would expect that essentially all intraoperative failures would be thin line failures and be iatrogenic. Most of these failures will result from instrument damage (sharp blade cuts or needle punctures).

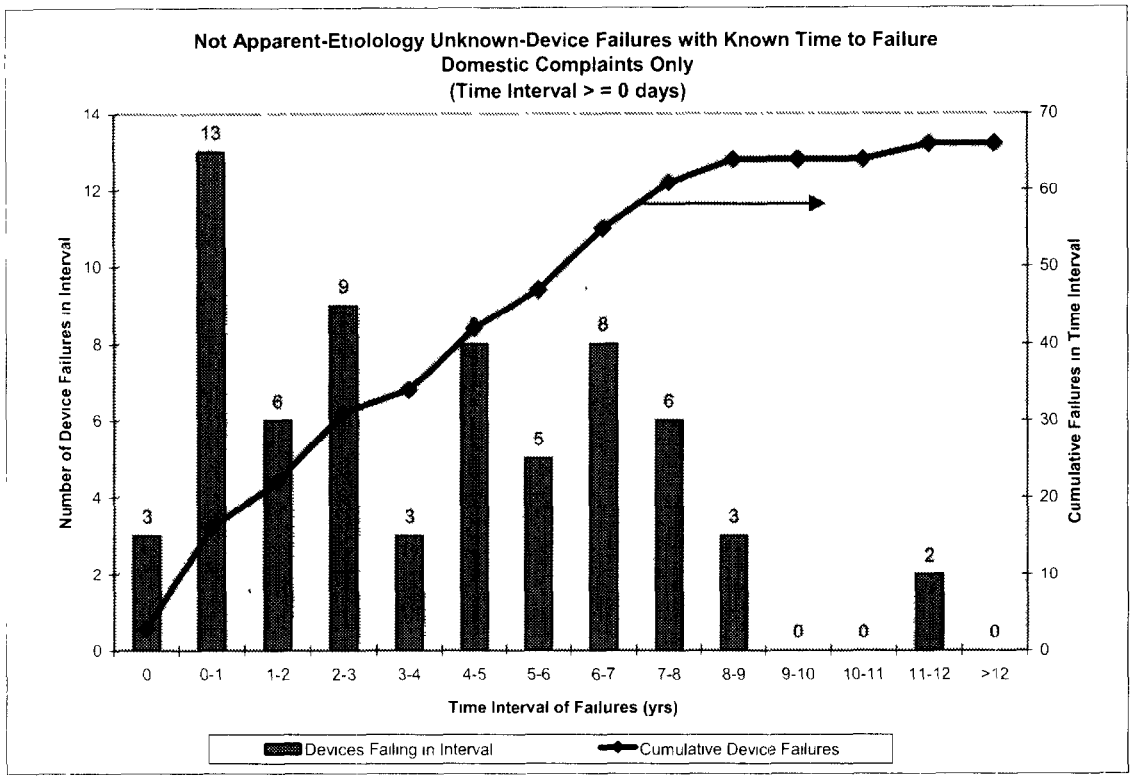

Figure 15. Total Failed Device Population in Not Apparent-Etiology Unknown versus Time to Failure Greater than or Equal to 0 Days (Intra- and Postoperative)

Figure 15, above, is a plot of all device failures in the Not Apparent-Etiology Unknown population as a function of time. It is a plot of the number of failed devices versus time (intra- and postoperative) to failure. The data on which this plot is based are included in Appendix III. The plot includes the numbers of devices failing in a specific time interval and the cumulative failures up through that interval. This failure distribution is skewed slightly toward 0 time with the maximum failures occurring in 1 to 7 years. There are only two failures with a time-to-failure greater than 9 years. Note the relatively large number of failures occurring in the interval 0-1 years. This is most likely the result of devices that had been damaged during implantation that failed shortly after being implanted.

Thin Line Failures of the Shell

Proposed Mechanisms of Failure: This population of thin line failures is restricted to failures of the shell area. It specifically does not include failures involving the patch, i. e., failures in the shell/patch bond area (bond delamination), patch/shell junction failures or thin line failures inside the periphery of the inner patch/shell junction (patch internal) in the textured area of a patch. It should be noted that textured devices have a large patch. The circular area inside the periphery of the bond area is essentially the same as the textured part of the shell. This means that under the right conditions, this area could be susceptible to the same failure/propagation mechanism as any other part of the shell. This is an infrequent occurrence for all textured devices examined. This is likely due to the fact that the patch bond area does not allow this region to bend or wrinkle (fatigue) as much as unconstrained areas of the shell. There were no failures inside the periphery of

the patch. There were 2 patch/shell junction failures and 8 shell/patch delaminations in this examined population. It should be noted that the patch/shell junction failures are classified as thin line failures, but are not classified as thin line shell failures. Shell/patch delaminations are not classified as thin line failures since they do not comply with the specified definition. The analysis of the devices falling with the classification of shell/patch junction and shell patch delamination failure modes will be addressed separately.

Thin line failures are almost certainly caused either by cutting or puncturing with a sharp instrument during the implantation or explantation of an implant or tears resulting from localized stress that extends the elastomer (shell) beyond its elastic limits (into the region approaching ultimate elongation). This localized stress could be induced by the surgeon during implantation, or it could result from repetitive bending of the shell elastomer at a location where the smooth transmission of stress is disrupted by an interface, such as, the shell/patch junction. A defining characteristic of the thin line failure mode is that each side of the failure is a mirror image of the other, and, if the sides are aligned in close proximity they will match.

If created and not detected during implantation, it is postulated that instrument cuts or punctures will propagate as a tear over time. The amount of propagation will be determined by the periodic physical stress on the implant which is a strong function of the lifestyle of the patient. It is reasonable to assume that the more active the person, input stress would be more frequent and perhaps greater in magnitude. Thus, the rate of propagation of a small failure will be dependent somewhat upon the lifestyle and personal habits of the implanted individual. A discussion of the mechanisms for creating and propagating thin line failures and the consequences from that on the location of failures over time was presented previously in the discussion of results from the investigation of the Rent-Unknown population. This discussion applies equally well to the Not Apparent-Etiology Unknown population and will not be repeated here.

Location of Failures: According to the mechanism proposed for most failures, iatrogenic-related factors (scalpel cuts, suture needle punctures and localized stress during implantation) accounts for most short term failures. By the proposed mechanism these failures will be concentrated on the anterior area close to the radius area and in the radius area itself. Over time these small failure lines could propagate into longer failure lines that can extend across the anterior region and into the posterior area of the device, even extending to and along the periphery of the patch/shell junction. The location of short term failures and inclusion of other shell surface areas over time should provide support for the proposed mechanisms. We see in Figure 16 that there are only 3 intraoperative failures. This is not a large enough sample size to reach any valid conclusion. But we also note from the figure that there is a relatively large number of failures in the first year. It is likely that implants damaged during implantation did not fail immediately or failures were not detected and that these weakened devices failed shortly after implantation. If this is true, it would be valid to combine the intraoperative and first-year failures. Table 14 shows the results of this approach.

Table 14. Postulated Effects of Time on Location of Failures

LOCATION OF THIN LINE FAILURES ON DEVICES

LOCATION	Intraoperative Failures (In Vivo Time = 0)		Postoperative Failures (In Vivo Time >0 and <=1 year)		Postoperative Failures (In Vivo Time >1 year)	
	No. of Failures at Location	Percent of Total Location	No. of Failures at Location	Percent of Total Location	No. of Failures at Location	Percent of Total Location
Radius	0	0%	3	19%	2	7%
Radius/ Anterior	2	67%	3	19%	0	0%
Radius/ Posterior	0	0%	1	6%	2	7%
Radius/ Posterior/ Anterior	0	0%	2	13%	17	59%
Anterior	1	33%	6	38%	7	24%
Posterior	0	0%	1	6%	1	3%
TOTAL	3	100%	16	100%	29	100%

Failures involving only the radius and anterior areas account for 78% of all failures that occurred intraoperatively through the first year of implantation. As time progresses (*in vivo* time to failure) from the period of intraoperative to one year compared to the period of greater than one year, failures involving

* the radius area only drops from 19 in the intraoperative to one-year period to 7% in the greater than one year time period,
* the radius and anterior areas combined drops from 19 to 0%
* the anterior area only drops from 38 to 24%
* the radius/anterior/posterior areas combined increases from 13 to 59%

It is recognized that the device populations (early versus later failures) obviously involve different devices—a device can only fail and be removed once. Nevertheless, the populations are large enough to provide a solid basis for conclusions based upon the fact that, when larger populations are considered, overall failure results will become more representative of the total population. Resting on this logic, these statistics provide strong support for the proposed mechanisms.

Time to Failure: Thin line failures of the shell of implants dominate the overall population of failed devices in the Not Apparent-Etiology Unknown population that was studied. They account for 60 (about 73%) of the 82 failed devices in the studied population. See Table 13 above. Figure 16 is a plot of the individual and cumulative thin line failure (shell) device populations versus time. It includes both intraoperative and postoperative failures (*In Vivo* Time = or > 0).

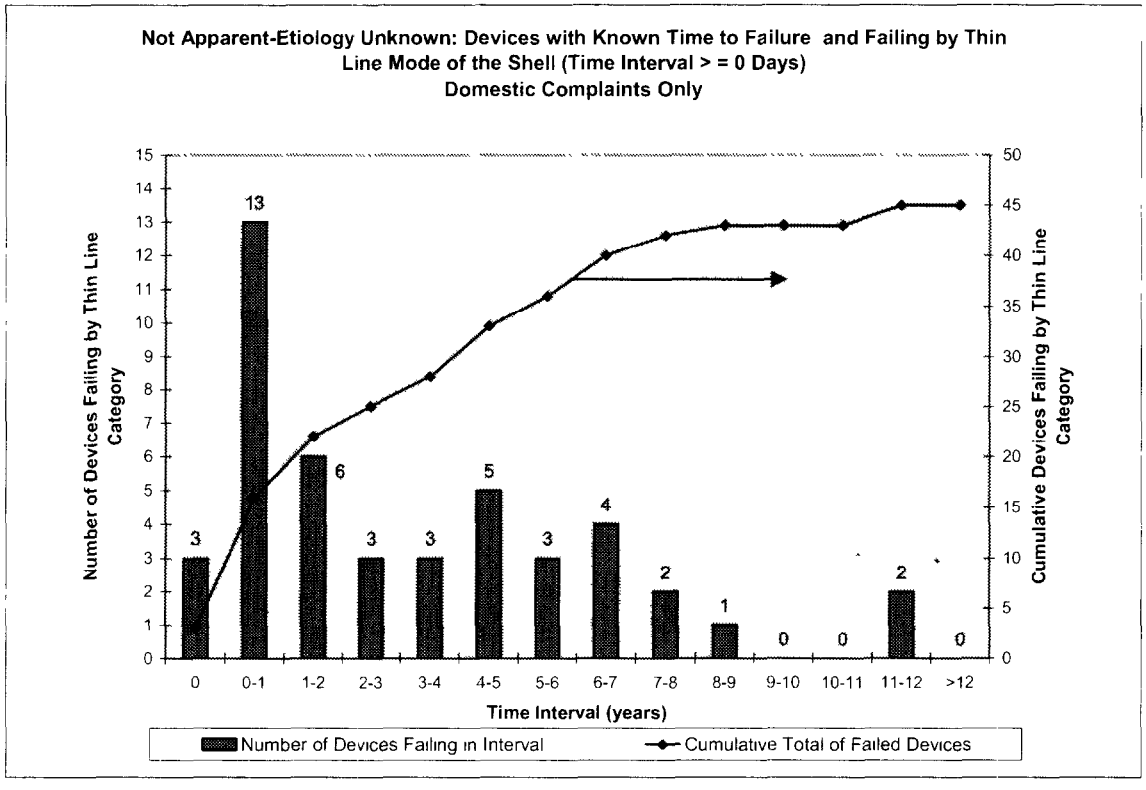

Figure 16. Individual and Cumulative Number of Devices Failing with Thin Line Intraoperatively and Postoperatively (In Vivo Time = or >0)

As can be seen from Figure 16, and as expected from the mechanism of failure discussed above, postoperative failures for this population is skewed towards time equal zero. The bulk of the failures occur within 1 to 5 years. After 9 years there are only two failures. From Figure 16 we see that the combined intraoperative plus failures through one year are 2.7 times those in any other individual time interval. The same population of failures accounts for 36% of the cumulative population. It is interesting to compare the number of failed devices in individual time intervals intraoperative (0) through 2 years in the total device population to the thin line failures of the shell. See Figures 15 and 16. The numbers of devices in these intervals are precisely the same for both populations, i. e., thin line failures of the shell are the only failures through year 2.

Surface Characteristics Effect on Failure: For thin line failures of shells the ratio of surface characteristics of failed devices is shown in Table 15. Although the ratio of textured-to-smooth devices was calculated for Intraoperative and Postoperative failures the calculated values are rendered essentially useless because the distribution of failures at Unknown Time to these populations cannot be determined. The ratios in these categories would change significantly depending upon how the failures in the Unknown In Vivo column were distributed to the other columns. The ratio for the total population is 0.9. The implantation dates of this population of the Not Apparent-Etiology Unknown category range from 1984 to 2003. The ratio of textured-to-smooth devices sold during the period 1984-2003 was approximately -----.[14] See Appendix V. Thus, this would suggest that there is a bias that favors the failure of smooth devices (ratio of 0.9 for failed

[14] Sales data presented in PMA Submission P030053, Section 8.2, Volume 13, December 11, 2003.

devices versus a global population of sold devices of -----). Please note that precisely the opposite conclusion was reached for the thin line failures of the shell for the population, Rent-Unknown Cause. Also, it is believed that these failures strongly reflect short term failures resulting from damage to the device (instrument damage or localized stress) during implantation. Damage by instruments should be a random event, and, therefore, the failed population should reflect the population of implanted devices when large populations are considered. Localized stress related failures would present a bias only if one or the other surface characteristics are more subject to stress damage. Since the results of the effects of surface characteristics on failures from the Rent-Unknown Cause and the Not Apparent-Etiology Unknown categories suggested diametrically opposite conclusions, it is reasonable to conclude that the attempt to determine this influence in this manner is not valid.

Table 15. Surface Characteristics of Devices Failing by Thin Line Mode on the Shell of the Device Only

Surface of Failed Devices	Intraoperative Failures (Time = 0)	Known Time *In Vivo* Postoperative (> 0 DAYS)	Unknown Time *In Vivo* (> or = 0 DAYS)	Total Number of Devices with Thin Line Failures	Each Surface Type as a Percent of Total Population
Textured	2	17	9	28	47%
Smooth	1	25	6	32	53%
Total	3	42	15	60	100%
Ratio of Surfaces	2.0	0.7	1.5	0.9	

Shell/Patch Junction Device Failures

Since shell/patch junction failures have all of the characteristics of a thin line failure, they are classified as a subset of thin line failures. The relationship between shell/patch junction and other thin line failures can be seen from the following discussion.

Shell/patch junction population being discussed here is restricted to that failure only and does not contain combination failures. For example a thin line shell tear could, and the results from the re-examination of devices suggest that some probably do, propagate to the shell/patch junction and proceed along the periphery of the patch precisely on the shell/patch junction. Conversely, it is possible that a failure at the shell/patch junction could propagate into the shell and involve the radius and/or the anterior area of the shell. In these combination failures, it is impossible to determine the true source of the failure. Therefore, the population for analysis was restricted to failures at the shell/patch interface only.

There were only 2 thin line shell/patch junction failures in the re-examined device population. Both of these were textured devices. Time to failure for the two devices was 2.9 and 4.3 years. Recall from the discussion of shell/patch juncture failures in the Rent-Unknown Cause population, the greatest number of failures occurred in the 3-4 year interval. These two failures fit within that time interval.

As explained before for failures within the Rent-Unknown Cause population, the patch on a textured device is large and extends much closer to the periphery of the device than does the smaller patch on smooth devices. The central region of the posterior of devices lies against the rib cage of the patient, and, therefore, should be more stable and subjected to less movement and flexural stress. Conversely, the region closer to the radius area of a device is likely subject to flexing as the result of body movement. This will result in a higher incidence of flexural stress. Thus, there will be a greater propensity for textured devices with their larger patches to fail by shell/patch junction mode. Even though the numbers are very limited (2 failures), these additional failures adds a little more credibility of the proposed mechanism for how these failures occur.

Localized Shell Fatigue Failures

There is strong evidence provided by the direct examination of failed devices that shell fatigue failure results from folding of the shell. If a shell folds in the anterior surface and that fold extends close to or into the radius area of a device, a high stress area will be formed at the end of the fold close to the periphery of the device. The stress will be exacerbated due to the contour of the device where the radius area curves toward the posterior region. Flexing of the device at the radius will cause the high stress area at the end of the fold to "roll" as the flexural stress is applied and removed. Over time, this cyclic stress will cause the shell material to fatigue and fail.

Shell abrasion was seen in the proximity of many, but not all, shell fatigue failures. When present, these typically were in a "V" pattern with the failure at the point of the "V". The folds generally extended from the apex region and terminated at or near the periphery of the device in or near the radius area on the external surface of the device. As explained above, this would be an area of maximum stress as the device periphery flexes. The actual wear on the shell texture was superficial. The shell abrasion itself was not a factor in the failure, but was an artifact of the failure mode.

There were only 3 failures by this mode in the examined population. Time to failure for these devices was 2.2, 2.3 and 6.5 years. Two of the devices were smooth and one was textured.

The time to failure for the 3 devices again emphasizes that time is required for failures by localized shell fatigue. The fact that two of the failed devices had smooth surfaces is significant. In the Rent-Unknown Cause population all devices that failed by this mode were textured. There was a concern that the reason for the extreme selectivity towards textured devices was because of some inherent characteristic in the texturing itself. The failure of two out of three devices having smooth shells provides proof that the characteristics of the textured surface *per se* is not integral to the failure mode. It suggests rather that some physical attribute that is integral to both surfaces is the ultimate determinate that provides a bias towards the textured devices. It is highly likely that the thickness of the shell itself is the key to the bias. Textured shells are thicker than smooth ones due to the added texturing layer. A fold in a thicker shell will produce greater stress, especially at the point of a tight fold, such as, at the tip of a V-shaped fold. Thus, this simple difference is the probable cause of the tendency for more devices with a textured shell to fail by the localized shell fatigue mode.

As discussed above, creation of a wrinkle or fold in the shell is a prerequisite for shell fatigue failure. There are two, independent causes for creation of wrinkles or folds. First

is the volume of gel in the shell. The volume of gel should be sufficient to inhibit the formation of a fold or small wrinkle in a shell. The second is the size and shape of the surgical pocket that is created during the implantation procedure. The prevention of this source of fold creation is directly dependent upon the skill, training and knowledge of the surgeon performing the implantation procedure.

Also, once a fold is formed, the amount and periodicity of the applied cyclic stress is most likely a strong determinant on how quickly or if a device will fail in this mode. For this reason, devices will be more likely to fail in a submuscular placement than if placed in a subglandular position. In the submuscular position the device will be tightly confined and periodic stress related to muscle movement will be more pronounced than if the device were placed in a subglandular position. These factors will favor a shorter device life. Further, thicker shells of textured devices, when placed sub muscularly, may exhibit tighter folds which may yield higher stress and shorter device life.

Shell/Patch Delamination

There were 8 devices that failed because of shell/patch delamination. All had textured surfaces. This failure mode comprises about 10% of the overall re-examined failure population for the Not Apparent-Etiology Unknown population.

Bond failure between the shell and patch of a device results in this failure mode. The strength and permanence of this bond is directly related to the vulcanization process for producing the bond. The fact that all failures involved textured surfaces suggests that the larger patch on those devices may be somewhat more difficult to bond to the shell.

The table below provides the time to failure for 7 of the failed devices. The time to failure for the one remaining failed device could not be determined because the date of implantation could not be obtained. No failure by this mode occurred in less than 2 years. The longest time to failure was 7-8 years.

Table 16. Time to Failure for Devices Failing by Shell/Patch Delamination Mode

Time Interval of Failure	Number of Devices Failing in Interval
2-3	3
4-5	1
6-7	2
7-8	1
Total	**7**
Unknown Time to Failure	**1**
Total Failed Devices	**8**

Examination of Larger Failure Population in the Not Apparent-Etiology Unknown Category

In this investigation we examined two populations of failed devices, Rent-Unknown Cause and Not Apparent-Etiology Unknown. Not all failed devices in either population were re-examined. Consequently, two questions arise: (1) Have all modes of failure been adequately identified? and (2) Are the examined populations representative of the larger failure populations?

With regard to the first question, we believe that the all modes of failure have been identified. First of all, the mode of failure is a function of individual devices. A large sampling of those failed devices was examined so that there is reasonable assurance that no unknown mode exists. In addition, the modes that were identified in this study match those identified in the literature. Furthermore, an outside expert was engaged to look at failed samples to determine modes of failure. The modes of failure identified in that study are congruent with the findings of this study. A broad sampling of failed devices were provided to the expert for examination, including some that Mentor was unable to classify with regard to the mode of failure. The results of that study are included in this submission to the FDA.[15] [16]

The best was to answer the second question is to examine a relevant larger population and demonstrate that the smaller population is representative of the larger one. We chose to examine the larger failure population in the NAEU category. The PE database provides the information required to calculate the time to failure for devices. There are a total of 838 total complaints from domestic U. S. physicians in the database. Within this population there were 300 devices for which in vivo implantation time could not be determined because either the implant or explant date was not available, leaving 538 complaint devices. Complaint devices that were either determined to be intact after inspection at Mentor or those with cosmetic or packaging complaints were excluded from the sample population (total of 509 of these devices). The remaining 329 complaint devices were included in the analysis. Of the 329 devices, 6 failed intraoperatively.

A plot of the individual and cumulative failed devices in the Not Apparent-Etiology Unknown category is shown in Figure 17. The failure pattern for this population is very similar to that for both the re-examined subpopulation of failed devices within NAEU and the re-examined failed devices in RUC. The highest numbers of failures occur within 7 years. There are some differences. The Intraoperative failures are disproportionately low compared to the Rent-Unknown Cause re-examined population. This low number of failure intraoperatively is offset by higher failures in the 1 and 2 year intervals. However, the cumulative Intraoperative and postoperative failures for the first two years for Rent-Unknown Cause and Not Apparent-Etiology Unknown Cause (larger sampled population) are 40% and 56%, respectively. This is good agreement across populations.

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[15] Report prepared for Mentor Corporation, Brandon, HJ, Savoy, TL, Wolf, CJ and Jerina, KL, "Analysis of In Vivo Failure Mechanism of Mentor Silicone Gel Breast Implants," June 2004.

[16] Report prepared for Mentor Corporation, Brandon, HJ, Savoy, TL, Wolf, CJ and Jerina, KL, "Analysis of In Vivo Failure Mechanism of Mentor Silicone Gel Breast Implants (Core Gel Coupon)," July 2004

The general shape of the failed device to failure time plots of the larger NAEU and its smaller subpopulation of examined devices from the NAEU category and the examined devices in the RUC category are very similar. Specifically, there are an elevated number of failures in the intraoperative to 3-year period. This followed by a period extending to about 9 years during which the number of failure per year are lower than the initial period but not insignificant. After 10 years the number of failure becomes quite low. The greatest difference is that the time to failure in the larger population extends to 14 years. But the number of devices that fail beyond 10 years in the larger NAEU population is only 11. The conclusion is that all three investigated populations (RUC re-examined population, NAEU re-examined population, and the larger NAEU population drawn from the PE database) have a similar time to failure distribution. Based upon the foregoing observations, it is concluded that the two smaller populations are representative of the larger one.

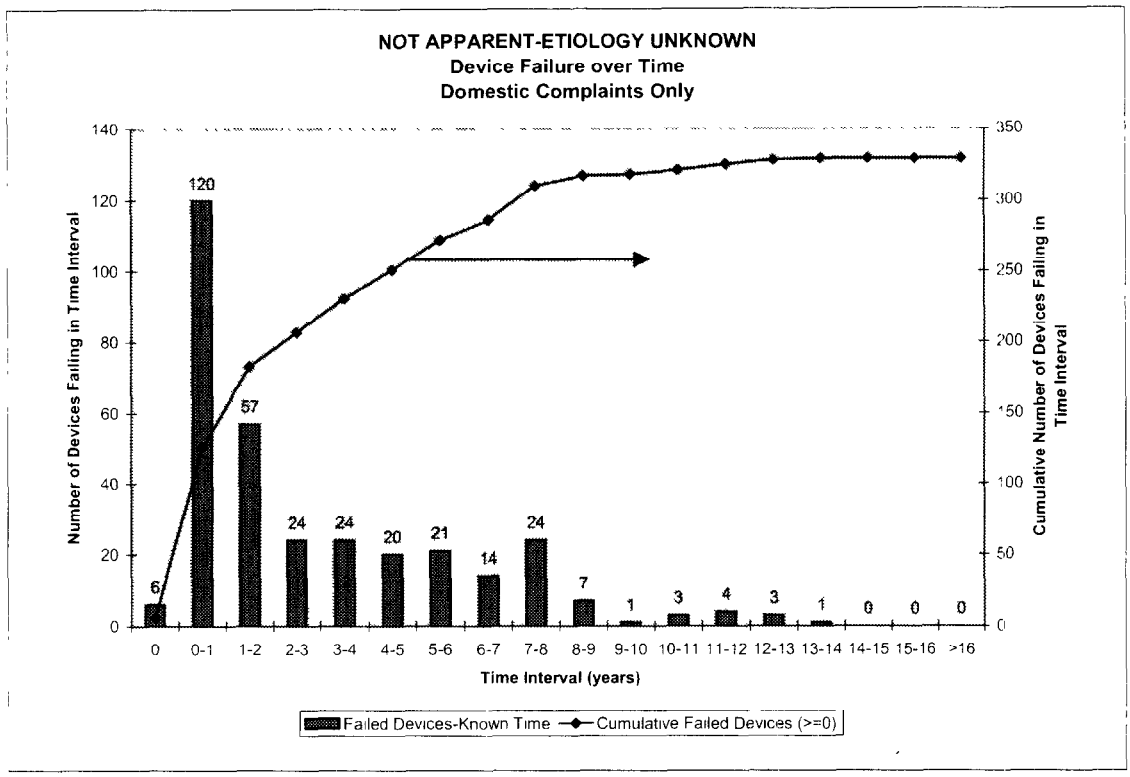

Figure 17. Failed Devices in Not Apparent-Etiology Unknown category versus Time to Failure.

Other Considerations that Could Affect Conclusions

If there were large populations of failed devices that are not accounted for in this analysis, the conclusions could be questioned. It has been suggested that two potential sources of devices that could be potential additions are the following:

- Failures not reported by physicians and
- Asymptomatic failures, so called, "silent ruptures".

There are two compelling reasons why a practitioner will report device failures. First, the reporting of failures and other complaints is a regulatory requirement. Secondly, it is in their self interest to do so. One facet of this is due to the threat of medical malpractice suits. The doctor wants an examination of any failed device to be done by the manufacturing company in order to learn as much as possible in case there is a suit. Through the examination process, the manufacturing company becomes involved with and knowledgeable about the specific complaint device. Facts and findings relating to the specific device and its history are recorded. These records become valuable during litigation, and the practitioner knows this. The doctor understands that the only source of the investigation and information is the manufacturing company.

Financial self interest is also a powerful motivator for reporting. Mentor has a current warranty policy that provides approximately $1200 towards the cost of the surgical procedure for replacement of failed devices if the devices fail within the first five years of implantation. The devices themselves have a lifetime replacement warranty. This replacement warranty is currently worth about $750/device to the patient. This warranty policy does not require the return of the product for payment. Nevertheless, if a physician is receiving reimbursement for himself or on behalf of the patient, experience has shown that there is a very strong inclination to return the device. For all of the reasons outlined in the foregoing paragraphs, it is believed that a high proportion of failed devices are returned to Mentor.

The question of whether there are large numbers of ruptured implants still resident in patients who have no symptoms related to that rupture remains outstanding. The MRI study that is being conducted as part of the Mentor gel implant Core Clinical Study is an important step in providing a definitive answer. There are other potential sources of information that may provide valuable data. That population of patients who originally underwent implantation for augmentation and who later chose to undergo a revision for size adjustment offer an ideal group to study. First of all, this population is large. Secondly, direct examination of the explanted devices provides the most detailed and accurate information on the condition of those devices. This information is available from explanted devices from the ongoing Mentor Core Clinical Study.

Conclusions

The modes of failure seen in the Rent-Unknown Cause and Not Apparent-Etiology Unknown failed device populations were (1) Thin Line Shell, (2) Shell/Patch Junction Thin Line and (3) Localized Shell Fatigue. Most localized shell fatigue failures were found in textured devices. Shell/Patch Junction failures were found disproportionately in textured devices.

Localized Shell Fatigue and Shell/Patch Junction Thin Line failures are uniquely distinguishable upon examination. This is not true with Thin Line Shell failures. These failures are tears, instrument cuts and combinations of the two. For example, an instrument cut can propagate over time to become a combination of instrument cut and tear. If the tear propagation line is long, it is extremely difficult to find the initiating cut. For this reason, it is impossible to cleanly segregate this failure group into components.

The pattern of re-examined device failures within the categories Rent-Unknown Cause and Not Apparent-Etiology Unknown was that most devices failed within eight to nine years. After that, the failures decreased to zero after 10 years. In the larger population of

Not Apparent-Etiology Unknown derived strictly from the PE database and not through re-examination of failed devices, there were no failures after 14 years. The trend of failures declined after 9 years.

The percent of failed (leak/rupture) devices was reported in PMA submissions as ------- based upon total customer complaints.[17] This rate is conservatively high because devices that were not returned were counted as failures, even though these complaints could not be confirmed as failures. Actual examination of devices reveals that some complaint devices classified as failures are, in fact, returned intact with no abnormality. Therefore, the ------- figure is a maximum value. This relatively small percentage of failures has been used as a starting point in the logic to roughly estimate a median lifetime of gel implant devices. It should be remembered that this current study is based upon overt (observed) failures. The quantification of any silent rupture population that would have an impact on the estimated life of the devices is ongoing as part of the Core Clinical Study and other clinical studies that Mentor will report upon in the current submission. Until the total population (overt and silent rupture) of failed devices is known or can be estimated with reasonable accuracy, a more accurate estimate of device life cannot be made. A qualitative estimate of median device life is presented below based upon the available overt failure data.

As discussed above, failures of Mentor gel-filled breast implants are skewed towards time equal to zero with the failures tailing off after about 9 years. If we include the larger population, Not Apparent-Etiology Unknown derived strictly from the PE database, no failures occur after 14 years. The critical point is that overt device failures decrease to zero. The relatively small number of observed device failures to date means that there is a large reservoir of intact devices remaining. It is unrealistic to assume that the devices will never fail given enough time. The sales numbers in Appendix V shows that there are approximately --------- devices sold from 1985 through September 2003. Since they were sold, it is assumed that they were implanted. These sales numbers then quantify the remaining population (once ruptures are subtracted from the number) that could be candidates for failure in ensuing years. Since failures in all populations of failed devices decrease essentially to zero in 15 years, there is no evidence that failures of these implanted devices are starting to occur in significant numbers.

This analysis implies that the bulk of devices will fail during a later time period, if they fail during the patient's lifetime. The initiation of the failure distribution of the bulk of the implant population will be marked by monotonically increasing number of failures over a period of time, measured in years. This increased rate of device failure is not observed in the data. Therefore, this final failure mode has not yet begun in a significant population of devices with an implant life approaching 20 years.

Without specific knowledge of the shape of this ultimate failure distribution, it is not possible to project a device life accurately. But a qualitative estimate can be made based on simple logic. First, it is highly unlikely that the failures within the bulk population will take place in a short period of time. Significant numbers of failures will likely take a number of years for a population of this size. It is estimated that, even if an increased failure rate was seen immediately, the mean average age of those implants would be greater than 25 years. This very rough estimate is based upon the assumption that the

[17] PMA P030053, Section 8.2, Volume 13, December 11, 2003

failures will follow a distribution similar to a normal distribution and that the actual failure distribution will not be narrow, i. e., it will be broad with a sizeable standard deviation.

APPENDIX I: Glossary of Terms

Glossary of Terms

Anterior surface area: This is the front surface of the implant that is facing away from the patient's rib case after implantation. It consists of all of the frontal area except for the radius area strip at the circumference of the device.

Combination failures: Failures can occur in combinations. For example, a thin line shell/patch junction failure can extend into the posterior region and thence into the radius and anterior regions. All of these extensions would be thin line. In other instances, a device may have a shell fatigue failure in combination with a thin line failure.

Device failure: A device that has a breach in the outside covering (shell or patch), i. e., a device with a rupture.

***In Vivo* implantation time:** This is the elapsed time between the implantation and explantation of a device, i. e., the elapsed time that the device was in a patient.

Patch internal: This is a thin line failure that can occur on the surface of a patch of a textured device. The cause of these failures can be from any of the initiating factors discussed below under "Thin line failures". Few of these failures were detected during the examination of devices.

Patch /shell junction: This is a thin line failure running precisely along the patch/shell junction (outer or inner). The failure line extends approximately perpendicular to the shell outer surface and extends through the shell to the inner surface of the shell. This type of failure is almost certainly the result of abrupt changes in stress at the junction. This stress could be induced by folding or wrinkling of the shell.

Posterior surface area: This is the back surface area on the device closest to the rib cage after implantation. This region consists of that entire region except where the radius area extends slightly onto the posterior surface. The posterior region contains the patch of the device.

Radius surface area: This area is at the circumference of the device. It consists of a strip of the surface around the device at the circumference. It is 1.5 inches wide with half the strip on each side of the circumference. This artificial designation was made in order to categorize the density of device failures. It was found during device examinations that a significant percentage of shell failures occurred in this region. The radius area ranged from about 33% to 19% of the total surface area for 125 and 800 cc devices, respectively.

Localized shell fatigue: This type of failure almost certainly results from cyclic stress of a local area of shell. Essentially all devices that fail by this mechanism are textured. Texture wear is frequently, but not always, evident in the failure area. In many cases, the texture wear is in the form of a "V" with the point of the "V" in the proximity of the failure.

Shell fatigue is characterized by a white appearance in the failure area. The failure itself is disorganized in that initially several small holes develop and, over time, these small holes coalesce into a larger failure area. Usually, ridged fatigue lines radiate from the failure area. These lines are similar to a fish bone design. In many instances the inner layer of shell delaminates from the next layer at the failure site. This delamination can extend away from the failure site. Much less frequently, delamination of the outer layer of texturing can be seen. In many cases, nodules protrude from the sides of a failure towards its center. These nodules are translucent to transmitted light.

Shell/Patch delamination: Bond failure between the patch and the shell. This failure is parallel to the shell and extends along the boundary between the patch and shell.

Thin line failure: As the name implies, this mode of failure is characterized by the fact that, if each side of the failure is brought back together, each will match the other precisely. This type can result from instrument cuts, such as, with a scalpel, or from tearing the shell. Scalpel cuts are always short and straight and are easily identifiable microscopically. This kind of damage results in minute, parallel striations through the shell. The same is true for needle punctures. The only difference is that a needle punch involves a small, localized area.

Failures resulting from tears may be jagged, curved, straight and, in some instances, branched. Over time a thin line failure that was originally the result of an instrument cut may propagate by the gradual tearing of the shell. Shell stress may give rise to a thin line failure without any initiating event involving sharp instruments.

APPENDIX II: Calculated Information on Failures Categorized as "Rent-Unknown Cause" Based upon Re-Examined Devices

EXAMINED EXPLANT DEVICE POPULATION FROM RENT-UNKNOWN CAUSE DOMESTIC COMPLAINTS ONLY

Description of Population	Number of Devices	Percent of Total Population
Number of Examined Devices for which In Vivo Time could not be determined because either Implant or Explant Date is Unknown	10	8%
Number of Examined Devices with 0 Days In Vivo, i. e., Intraoperative Failure	31	25%
Number of Examined Devices that could be used to Determine In Vivo Time for Various Failure Modes	80	64%
Subtotal of Examined Devices with Failures	121	97%
Devices with No Failure in Examined Population	4	3%
Total Examined Devices with Failures	125	100%

EXAMINED EXPLANT DEVICE POPULATION FROM RENT-UNKNOWN CAUSE DOMESTIC COMPLAINTS ONLY

Failure Characterization	No. of Failures by That Characterization	Percent of Actual Failures
Thin Line (Shell Only)	72	59.5%
Patch Internal Only (Thin Line)	3	2.5%
Patch/Shell Junction Only (Thin Line)	21	17.4%
Shell Fatigue Only	17	14.0%
Shell/Patch Delamination	4	3.3%
Combination Failures		
Shell Fatigue/Patch Internal	1	0.8%
Shell Fatigue/Thin Line	1	0.8%
Shell Fatigue/Patch-Shell Junction	0	0.0%
Shell Fatigue/Patch Internal/Patch-Shell Junction	1	0.8%
Patch-Shell Junction/Patch Internal	1	0.8%
Total Failed Device Population	**121**	100%
No Failure	4	
Total Population	**125**	

EXAMINED EXPLANT DEVICE POPULATION FROM RENT-UNKNOWN CAUSE DOMESTIC COMPLAINTS ONLY

Surface Type	Failed Devices in Population	Percent of Failed Devices	In-Tact Devices in Population	Total	Percent Surface Type of Total
Textured	98	81%	4	**102**	82%
Smooth	23	19%	0	**23**	18%
TOTAL	**121**		**4**	**125**	

	Intraoperative Failures (In Vivo Time = 0)	Postoperative Failure (In Vivo Time > 0)	Unknown Failure Time (In Vivo Time > or = 0)	Total Failures
Textured	22	67	9	98
Smooth	9	13	1	23
TOTAL	31	80	10	121
Ratio of Textured to Smooth Devices	2.4	5.2	9.0	4.3

EXAMINED EXPLANT DEVICE POPULATION FROM RENT-UNKNOWN CAUSE DOMESTIC COMPLAINTS ONLY

Location of Failure	No. of Failures at Location in Population	Percent of Total
Radius	32	
Anterior	18	
Posterior	23	
Radius/Anterior	20	
Radius/Posterior	8	
Radius/Anterior/Posterior	19	
Anterior/Posterior	1	
Total	**121**	
Devices with No Failure	4	
Population Total	**125**	
All Failures Involving Radius	79	65%
Failures Involving Radius Only	32	26%

	Earliest	Latest
Implantation Date	7/26/1993	5/3/2002
Explantation Date	8/15/1996	6/5/2003

INTRAOPERATIVE FAILURES (ZERO (0) DAYS *IN-VIVO)*
RENT-UNKNOWN CAUSE
DOMESTIC COMPLAINTS ONLY

Failures at Zero (0) Days *(Intraoperative Failure)* **31**

Failure Mode	Number of Devices
Thin Line on Shell (Not Involving Patch)	30
Shell Fatigue	0
Shell/Patch Junction	0
Patch Internal (Thin Line)	1
Total	**31**
No Failure	1
Total Devices Failing Intraoperatively (0 Days *In Vivo*)	**32**

Location on Device	No. of Failures at Location
Anterior	8
Radius	8
Posterior	1
Radius/Anterior	11
Radius/Posterior	0
Anterior/Posterior	0
Radius/Anterior/Posterior	3
Total	**31**
No Failure	1
Population Total	**32**

		Percent of Total Failed Devices
Number of Failures Involving Radius	**22**	**71%**
Number of Failures Involving Only Radius	**8**	**26%**

INTRAOPERATIVE FAILURES (ZERO (0) DAYS *IN-VIVO)*
RENT-UNKNOWN CAUSE
DOMESTIC COMPLAINTS ONLY

Surface Characteristics

	Intraoperative Population of Failed Devices	Percent of Intraoperative Failure Population	Percent Intraoperative of Same Surface in Total Population	Total "Rent-Unknown Cause" Failed Devices Examined	Percent of Population of Total Failed Devices Examined
Textured	22	71%	22%	98	81%
Smooth	9	29%	39%	23	19%
Total	**31**			**121**	

EXPLANTED DEVICES-RENT UNKNOWN CAUSE
INTRAOPERATIVE AND POSTOPERATIVE FAILURES
(IN VIVO = > 0 DAYS)
DOMESTIC COMPLAINTS ONLY

In-vivo Time interval	Devices Failing in Interval	Cumulative Device Failures	Percent of Cumulative Devices
0 days	31	31	28%
0-1	3	34	31%
1-2	13	47	42%
2-3	10	57	51%
3-4	18	75	68%
4-5	13	88	79%
5-6	7	95	86%
6-7	9	104	94%
7-8	1	105	95%
8-9	3	108	97%
9-10	3	111	100%
> 10	0	**111**	100%

Unknown Time to Failure	**10**
Failed Population	**121**
No Failures	**4**
Total Devices	**125**

THIN LINE FAILURES OF DEVICES
RENT-UNKNOWN CAUSE POPULATION
DOMESTIC COMPLAINTS ONLY

Time Interval of Failure	Number of Devices Failing in Interval	Cumulative Total of Failed Devices	Percent Total of Cumulative Devices (Time >= 0 Days)
0 days	30	30	48%
0-1	2	32	52%
1-2	10	42	68%
2-3	2	44	71%
3-4	6	50	81%
4-5	6	56	90%
5-6	1	57	92%
6-7	3	60	97%
7-8	0	60	97%
8-9	1	61	98%
9-10	1	62	100%
> 10	0	62	100%
Total	62		
Unknown Interval	10		
Total Failed Devices	72		

THIN LINE FAILURES OF DEVICES
RENT-UNKNOWN CAUSE POPULATION
DOMESTIC COMPLAINTS ONLY

LOCATION OF THIN LINE FAILURES ON DEVICE

LOCATION	Total Population		Intraoperative Failures (In Vivo Time = 0)		Postoperative Failures (In Vivo Time >0)	
	Number of Failures at Location	Percent of Total Locations	Number of Failures at Location	Percent of Total Locations	Number of Failures at Location	Percent of Total Locations
Radius	20	28%	8	27%	10	31%
Radius/Anterior	19	26%	11	37%	5	16%
Radius/Posterior	2	3%	0	0%	2	6%
Radius/Posterior/ Anterior	11	15%	3	10%	7	22%
Anterior	18	25%	8	27%	6	19%
Posterior	2	3%	0	0%	2	6%
TOTAL	72	100%	30	100%	32	100%

	Total Population		Intraoperative Failures (In Vivo Time = 0)		Postoperative Failures (In Vivo Time >0)	
	Number of Devices	Percent of Total Failures	Number of Devices	Percent of Total Failures	Number of Devices	Percent of Total Failures
Failures Involving Radius and Anterior Surface	57	**79%**	27	**90%**	21	**66%**
Failures Involving Radius Only	20	**28%**	8	**27%**	10	**31%**
Total Population of Failures	72		25		32	

Surface Characteristics of Devices Failing by Thin Line Mode on the Shell of the Device Only

	Intraoperative Failures (Time = 0)	KNOWN Postoperative (> 0 DAYS)	UNKNOWN (> or = 0 DAYS)	TOTAL NUMBER OF DEVICES WITH THIN LINE FAILURES	Each Surface Type as a Percent of Total Population
Textured	21	22	9	**52**	72%
Smooth	9	10	1	**20**	28%
Total	**30**	**32**	**10**	**72**	100%
Ratio of Surfaces	**2.3**	**2.2**	**9.0**	**2.6**	

PATCH/SHELL JUNCTION FAILURES
RENT-UNKNOWN CAUSE POPULATION
DOMESTIC COMPLAINTS ONLY

Time Interval of Device Failures	Number of Devices that Fail in Interval	Cumulative Device Failures	Percent Cumulative Devices Failing
0 days	0	0	0%
0-1	1	1	5%
1-2	1	2	10%
2-3	5	7	33%
3-4	6	13	62%
4-5	4	17	81%
5-6	1	18	86%
6-7	2	20	95%
7-8	1	21	100%
> 8	0	21	100%
Total	21		
Unknown Time to Failure	0		
Total Devices	21		

SURFACE CHARACTERISTICS OF SHELL/PATCH JUNCTION FAILURES

Textured	20
Smooth	1
Total	21

NOTE: Preponderance of failures are textured devices.

LOCALIZED SHELL FATIGUE FAILURES
RENT-UNKNOWN CAUSE POPULATION
DOMESTIC COMPLAINTS ONLY

In Vivo Interval	Number of Devices Failing in Interval	Cumulative Number of Failed Devices	Percent of Cumulative Failed Devices
0 days	0	0	0%
0-1	0	0	0%
1-2	1	1	6%
2-3	1	2	12%
3-4	4	6	35%
4-5	2	8	47%
5-6	3	11	65%
6-7	3	14	82%
7-8	0	14	82%
8-9	1	15	88%
9-10	2	17	100%
> 10	0	17	100%

NUMBER OF FAILED DEVICES WITH KNOWN TIME TO FAILURE	**17**

SURFACE	Number of Devices
Textured	**17**

Note: All Shell Fatigue failures involved textured devices.

LOCATION OF SHELL FATIGUE FAILURES ON DEVICE

Radius	11
Radius/Posterior	4
Radius/Anterior	1
Radius/Posterior/Anterior	1
TOTAL	**17**

NOTE: Failures always involve radius area where folds are most likely to terminate.

PATCH/SHELL DELAMINATIONS FAILURES
DOMESTIC COMPLAINTS ONLY

Total Number of Patch/Shell Delaminations: 4

In Vivo Interval	Number of Devices Failing in Interval	Cumulative Number of Failed Devices	Devices Failing in Time Interval as Percent of Total Failed Devices
0 days	0	0	0%
0-1	0	0	0%
1-2	0	0	0%
2-3	1	1	25%
3-4	1	2	25%
4-5	1	3	25%
5-6	1	4	25%
>6	0	4	0%

Number of Failed Devices with Known Time to Failure	4

Surface Characteristic	Number of Devices
Textured	4

Note: All Shell Fatigue failures involved textured devices.

APPENDIX III: Calculated Information on Failures Categorized as "Not Apparent-Etiology Unknown" Based upon Re-Examined Devices

EXAMINED EXPLANT DEVICE POPULATION FROM "NOT APPARENT-ETIOLOGY UNKNOWN"
DOMESTIC COMPLAINTS ONLY

Description of Population	Number of Devices	Percent of Failed Population	Percent of Total Population
Number of Failed Devices for which *In Vivo* Time could not be determined because either Implant or Explant Date is Unknown	16	20%	14%
Number of Examined Devices with 0 Days *In Vivo*, i. e., Intraoperative Failure	3	4%	3%
Number of Failed Devices that could be used to Determine *In Vivo* Time for Various Failure Modes	63	77%	55%
Total Failed Explants	82	100%	71%
Devices with No Failure in Examined Population	33		29%
Total Examined Devices with Failures	115		100%

Failure Characterization	No. of Failures by That Characterization	Percent of Actual Failures
Thin Line (Shell Only)	60	73.2%
Patch Internal Only (Thin Line)	0	0.0%
Patch/Shell Junction Only (Thin Line)	2	2.4%
Shell Fatigue Only	3	3.7%
Shell/Patch Delamination	8	9.8%
Combination Failures		
Thin Line (Shell Only)/Patch Internal Only (Thin Line)	2	2.4%
Thin Line (Shell Only)/Patch/Shell Junction Only (Thin Line)	7	8.5%
TOTAL FAILURES	**82**	100%
No Failure	33	
TOTAL POPULATION	**115**	

Surface Type	Failed Devices in Population	Percent of Failed Devices	In-Tact Devices in Population	Total	Percent Surface Type of Total
Textured	39	48%	19	**58**	50%
Smooth	43	52%	14	**57**	50%
Total	**82**		**33**	**115**	
Ratio	**0.9**				

EXAMINED EXPLANT DEVICE POPULATION FROM "NOT APPARENT-ETIOLOGY UNKNOWN" DOMESTIC COMPLAINTS ONLY

	Intraoperative Failures (In Vivo Time = 0)	Postoperative Failure (In Vivo Time > 0)	Unknown Failure Time (In Vivo Time > or = 0)	Total Post Operative Failures	Total Failures
Textured	2	28	9	37	39
Smooth	1	35	7	42	43
Total	3	63	16	79	82
Ratio of Textured to Smooth Devices	2.0	0.8	1.3	0.9	0.9

Location of Failures

Location	No. of Failures at Location in Population	Percent of Total
Radius	11	**13%**
Anterior	21	**26%**
Posterior	12	**15%**
Radius/Anterior	5	**6%**
Radius/Posterior	3	**4%**
Radius/Anterior/Posterior	30	**37%**
Anterior/Posterior	0	**0%**
Total	**82**	**100%**
Devices with No Failure	33	
Population Total	**115**	
All Failures Involving Radius	**49**	**60%**
Failures Involving Radius Only	**11**	**13%**

	Earliest	Latest
Implantation Date	6/20/1984	3/5/2003
Explantation Date	5/6/1991	5/23/2003

NOT APPARENT-ETIOLOGY UNKNOWN: INTRAOPERATIVE FAILURES
INTRAOPERATIVE FAILURES (ZERO (0) DAYS *IN-VIVO)*
DOMESTIC COMPLAINTS ONLY

Failures at Zero (0) Days *(Intraoperative Failure)*	**3**
Failure Mode	
Thin Line on Shell (Not Involving Patch)	3
TOTAL	**3**
No Failure	
Total Devices with 0 Days *In Vivo*	**3**

Location on Device	No. of Failures at Location
Anterior	1
Radius/Anterior	2
Total	**3**

	Number of Devices	Percent of Total Devices
Failures Involving Radius	**2**	**67%**
Failures Involving Only Radius	**0**	**0%**

Surface Characteristics

	Intraoperative Population of Failed Devices	Percent of Intraoperative Failure Population	Percent Intraoperative of Same Surface in Total Population	Total "Not Apparent-Etiology Unknown" Failed Devices Examined	Percent of Population of Total Failed Devices Examined
Textured	19	73%	49%	39	48%
Smooth	7	27%	16%	43	52%
Total	**26**		32%	**82**	

EXPLANTED DEVICES-NOT APPARENT-ETIOLOGY UNKNOWN
(*IN VIVO* TIME >= 0 DAYS)
DOMESTIC COMPLAINTS ONLY

In-vivo time interval	Devices Failing in Interval	Cumulative Device Failures	Percent of Failed Devices	Percent of Cumulative Failed Devices
0	3	3	5%	5%
0-1	13	16	20%	24%
1-2	6	22	9%	33%
2-3	9	31	14%	47%
3-4	3	34	5%	52%
4-5	8	42	12%	64%
5-6	5	47	8%	71%
6-7	8	55	12%	83%
7-8	6	61	9%	92%
8-9	3	64	5%	97%
9-10	0	64	0%	97%
10-11	0	64	0%	97%
11-12	2	66	3%	100%
>12	0	66	0%	100%
Devices with Unknown Failure Times		16		
Devices with No Failures		33		
	Total	115		

NOT APPARENT-ETIOLOGY UNKNOWN
THIN LINE FAILURES OF DEVICES (In Vivo Time >=0)
DOMESTIC COMPLAINTS ONLY

Total Failing Devices Categorized as "Thin Line Failures" **60**

Percent of Total Failures **73%**

Time Interval of Failure	Number of Devices Failing in Interval	Cumulative Total of Failed Devices	Percent Total of Cumulative Devices (Time >= 0 Days)	Cumulative Total of Failed Devices Failing (Time > 0 Days)	Percent Total of Cumulative Devices (Time > 0 Days)
0	3	3	7%		
0-1	13	16	36%	13	31%
1-2	6	22	49%	19	45%
2-3	3	25	56%	22	52%
3-4	3	28	62%	25	60%
4-5	5	33	73%	30	71%
5-6	3	36	80%	33	79%
6-7	4	40	89%	37	88%
7-8	2	42	93%	39	93%
8-9	1	43	96%	40	95%
9-10	0	43	96%	40	95%
10-11	0	43	96%	40	95%
11-12	2	45	100%	42	100%
>12	0	45	100%	42	100%
Total	45				
Unknown Time to Failure	15				
Total Failed Devices	60				

LOCATION OF THIN LINE FAILURES ON DEVICE—NOT APPARENT-ETIOLOGY UNKNOWN

Location	Total Population		Intraoperative Failures (In Vivo Time = 0)		Postoperative Failures (In Vivo Time >0and<1 Years)		Postoperative Failures (In Vivo Time 0-1 year)		Postoperative Failures (In Vivo Time >1 year)	
	Number of Failures at Location	Percent of Total Locations	Number of Failures at Location	Percent of Total Locations	Number of Failures at Location	Percent of Total Locations	Number of Failures at Location	Percent of Total Locations	Number of Failures at Location	Percent of Total Locations
Radius	10	17%	0	0%	3	23%	3	19%	2	7%
Radius/ Anterior	5	8%	2	67%	1	8%	3	19%	0	0%
Radius/ Posterior	3	5%	0	0%	1	8%	1	6%	2	7%
Radius/ Posterior/ Anterior	21	35%	0	0%	2	15%	2	13%	17	59%
Anterior	19	32%	1	33%	5	38%	6	38%	7	24%
Posterior	2	3%	0	0%	1	8%	1	6%	1	3%
TOTAL	60	100%	3	100%	13	100%	16	100%	29	100%
Failures Involving Radius and Anterior or Combinations	34	57%	3	100%	9	31%	12	41%	9	31%
Failures Involving Radius Only	10	17%	0	0%	3	10%	3	10%	2	7%
Total-All Locations	60		3		12		15		11	

Surface Characteristics of Devices Failing by Thin Line Mode on the Shell of the Device Only

Surface of Failed Devices	Intraoperative Failures (Time = 0)	Known Time *In Vivo* Postoperative (> 0 DAYS)	Unknown Time *In Vivo* (> or = 0 DAYS)	Total Number of Devices with Thin Line Failures	Each Surface Type as a Percent of Total Population
Textured	2	17	9	28	47%
Smooth	1	25	6	32	53%
Total	3	42	15	60	100%
Ratio of Surfaces	2.0	0.7	1.5	0.9	

NOT APPARENT-ETIOLOGY UNKNOWN
PATCH/SHELL JUNCTION FAILURES
DOMESTIC COMPLAINTS ONLY

Total Shell/Patch Junction Failures	2
Surface Characteristics of Shell/Patch Junction Failures	
Textured	2
Smooth	0
TOTAL	2

NOTE: Preponderance of failures consists of textured devices.

NOT APPARENT-ETIOLOGY UNKNOWN
LOCALIZED SHELL FATIGUE FAILURES
DOMESTIC COMPLAINTS ONLY

Total Number of Devices with Localized Shell Fatigue Failure	**3**
Number of Failed Devices with Known Time to Failure	**3**

Surface Characteristics of Localized Shell Fatigue Failures	**Number of Devices**
Textured	1
Smooth	2
Total	3

NOTE: These are the first instances where Localized Shell Fatigue Failures were Identified on Devices with Smooth Surfaces

Location of Localized Shell Fatigue Failures on Device	**Number of Failures at that Location**
Radius	1
Anterior	2
TOTAL	**3**

NOT APPARENT-ETIOLOGY UNKNOWN
PATCH/SHELL DELAMINATION FAILURES
DOMESTIC COMPLAINTS ONLY

Total Number of Patch/Shell Delaminations **8**

Time Interval of Failure	Number of Devices Failing in Interval	Cumulative Total of Failed Devices	Percent Total of Cumulative Devices (Time >= 0 Days)
0	0	0	0%
0-1	0	0	0%
1-2	0	0	0%
2-3	3	3	43%
3-4	0	3	43%
4-5	1	4	57%
5-6	0	4	57%
6-7	2	6	86%
7-8	1	7	100%
>8	0	7	100%
Total	**7**		
Unknown Time to Failure	**1**		
Total Failed Devices	**8**		

Surface Characteristics of Failed Devices

Textured	8
Smooth	0
Total	8

APPENDIX IV: *Information Derived from Product Evaluation Database* on Failures Categorized as "Not Apparent-Etiology Unknown"

PE DATABASE INFORMATION ON EXPLANT DEVICE POPULATION FROM "NOT APPARENT-ETIOLOGY UNKNOWN" DOMESTIC COMPLAINTS ONLY

	Total Population	Non-Failed Devices			Failed Devices
		No Abnormality	Cosmetic	Packaging	
Number of Devices for which In Vivo Time is Unknown (Implant or Explant Date Unknown)	300	44	11	4	241
Intraoperative Failure (Devices In Vivo Time = 0)	9	3			6
Postoperative Device Failures with Known In Vivo Time > 0	829	506			323
Total Failed Devices	1138				570
Devices with No Failure in Population			568		

RANGE OF IMPLANT AND EXPLANT DATES IN NOT APPARENT-ETIOLOGY POPULATION DOMESTIC COMPLAINTS ONLY

	Earliest	Latest
Implantation Date	6/20/1989	5/29/2003
Explantation Date	10/23/1989	7/11/2003

FAILED DEVICES VERSUS TIME INTERVAL
NOT APPARENT-ETIOLOGY UNKNOWN (*In Vivo* Time >=0)
DOMESTIC COMPLAINTS ONLY

Time Interval	Total No. of Devices in Interval	No Abnormality	Cosmetic	Packaging	Failed Devices-Known Time	Cumulative Failed Devices (> 0)	Cumulative Failed Devices (>=0)
Unknown	300	44	11	4	241		
0	9	3			6		6
0-1	328	208	0	0	120	120	126
1-2	122	65			57	177	183
2-3	62	38			24	201	207
3-4	75	51			24	225	231
4-5	63	43			20	245	251
5-6	50	29			21	266	272
6-7	48	34			14	280	286
7-8	39	15			24	304	310
8-9	14	7			7	311	317
9-10	8	7			1	312	318
10-11	7	4			3	315	321
11-12	6	2			4	319	325
12-13	3				3	322	328
13-14	2	1			1	323	329
14-15	0				0	323	329
15-16	2	2			0	323	329
>16					0	323	329
Totals	829	553	11	4	323		
Total Devices with no failures			568				

APPENDIX V: Breast Implant Sales Data

APPENDIX VI: Date of Implantation of Devices in Rent-Unknown Cause and Not Apparent-Etiology Unknown Categories

Number of Devices Implanted by Year for Rent-Unknown Cause and Not Apparent-Etiology Unknown Populations

Implantation Year	Rent-Unknown Cause				Not Apparent-Etiology Unknown			
	Number of Devices	Percent of Total	Cumulative	Cumulative Percent	Number of Devices	Percent of Total	Cumulative	Cumulative Percent
1983	0	0%	0	0%	0	0%	0	0%
1984	0	0%	0	0%	4	1%	4	1%
1985	0	0%	0	0%	11	2%	15	3%
1986	0	0%	0	0%	17	3%	32	6%
1987	0	0%	0	0%	16	3%	48	9%
1988	0	0%	0	0%	9	2%	57	11%
1989	0	0%	0	0%	15	3%	72	13%
1990	0	0%	0	0%	15	3%	87	16%
1991	0	0%	0	0%	7	1%	94	18%
1992	0	0%	0	0%	7	1%	101	19%
1993	8	7%	8	7%	44	8%	145	27%
1994	11	10%	19	17%	41	8%	186	35%
1995	13	12%	32	29%	32	6%	218	41%
1996	9	8%	41	37%	24	4%	242	45%
1997	25	23%	66	60%	61	11%	303	56%
1998	14	13%	80	73%	31	6%	334	62%
1999	13	12%	93	85%	49	9%	383	71%
2000	10	9%	103	94%	58	11%	441	82%
2001	6	5%	109	99%	74	14%	515	96%
2002	1	1%	110	100%	18	3%	533	99%
2003	0	0%	110	100%	4	1%	537	100%