Microscopy Analysis of Breast Implant Rupture Caused by Surgical Instrument Damage

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Background: The mechanism of breast implant rupture has continued to be an important topic throughout the plastic surgery community and regulatory agencies, such as the US Food and Drug Administration. Retrieved ruptured implants returned to Allergan (Santa Barbara, CA; formerly Inamed Corporation) for analysis exhibit various modes of failure, which can include a small pinhole (approximately 1 to 2 mm in size) in the shell, a ruptured shell, or a severely fragmented shell.

Objective: The failure mechanisms and associated morphologic features for the modes of implant failure can be quite different. The objective of this study is to analyze and describe the rupture characteristics of silicone gel–filled implants that failed because of surgical instrument damage.

Methods: There are several types of diagnostic techniques available to analyze ruptured implants. Visual inspection, physical examination, and photographic analysis provided an overall description of the implant shape and gross features of the shell failure region. These techniques allowed categorization and documentation of the mode of failure and were quite useful as a supplemental tool in the diagnosis of implant failure mechanisms. Microscopy techniques provided details of the ruptured shell region and could be used to determine the cause of breast implant failure. This study involved the use of optical microscopy and scanning electron microscopy in the analysis of ruptured breast implants.

Results: Details of the geometry of ruptured shell regions are described. Illustrations are also presented in which 35-mm photography is used to assist in substantiating the cause of failure. Many of the ruptured regions exhibit striations across the thickness of the shell. Micrographs are presented that clearly show that the striations are due to lines in the cutting surface of the surgical instrument that were formed during the manufacturing process.

Conclusions: This article demonstrates that, with the proper background and experience in analyzing ruptured breast implant shells, the features at the failure site can be correctly interpreted and the corresponding failure mechanisms can be diagnosed. Breast implants are subject to surgical instrument damage during implantation, and this damage can develop into a shell rupture, with the failure mode identifiable via microscopy analysis. (Aesthetic Surg J 2007;27:239–256.)

Silicone gel–filled breast implants are presently marketed throughout the world. The Premarket Approval conditions of approval for marketing these implants in the United States were recently released by the US Food and Drug Administration (FDA). The conditions of approval include continued monitoring of the percent of ruptured implants and further characterization of the long-term modes and causes of rupture of explanted retrieved devices. The percentage of ruptured devices is being precisely determined during studies conducted for the FDA. The percentage of single-lumen silicone gel–filled breast implants that have ruptured is extremely low, amounting to less than 1% per year. This low percent of ruptured devices is less than the estimate from the Institute of Medicine. The Institute of Medicine report states that “the committee is of the opinion that, with a conservative guess at upward adjustment to account for under diagnosis, a modest number (perhaps less than 10%) of modern gel-filled implants will have ruptured by five years.” In spite of the low percent of ruptured devices, implant rupture is still a major concern, and retrieval and analysis studies are being conducted to determine the modes and causes of rupture.

Retrieval and analysis studies by Allergan (Santa Barbara, CA; formerly Inamed Corporation) have demonstrated that a considerable number of ruptured devices exhibit surgical damage. A variety of surgical instruments are used for both the implantation and explantation procedures for silicone gel–filled breast
implants. Contact of the surgical instrument with an implant can result in a cut through the entire shell thickness. On the other hand, minor contact during implantation surgery can cause a microscopic flaw in the shell surface that can eventually result in shell rupture in vivo.

An example of implant rupture caused by a surgical instrument is presented in Figure 1, which is an optical micrograph of a section of a ruptured silicone gel–filled breast implant shell. This is the type of shell failure that is considered in this study. The series of nearly parallel lines (striations) on the cut shell were caused by a surgical instrument. The striations were induced in the shell by the machining lines of a surgical device.

This study was prepared to assist the scientific community in understanding that surgical instruments used by plastic surgeons do have machining lines on the cutting surface and that these instruments can induce striations on a shell during a single surgical cut or nick. The article was also prepared to demonstrate that striations appearing on the ruptured shell of an explant indicate the rupture could have been caused by a surgical device. No previously published article has demonstrated a link between striations on a ruptured breast implant shell and machining lines on a surgical instrument.

**Material and Methods**

Microscopy analysis was conducted on explanted silicone gel–filled breast implant shells manufactured by Allergan. Explanting surgeons had returned the implants to Allergan for retrieval and analysis studies. The retrieved implants were first sterilized, and then the shells were cleaned by use of appropriate laboratory techniques.

There are various types of surgical instruments used in breast implant surgery. These include scalpels, needles, scissors, clamps, rakes, hemostats, forceps, and retractors. However, only Bard-Parker disposable scalpels (no. 15 surgical blade and no. 11 surgical blade; BD Medical Systems, Franklin Lakes, NJ) and an Ethicon cutting nee-

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**Figure 1.** Optical micrograph of ruptured breast implant shell.
dle (PS-2; Ethicon, Somerville, NJ) are considered in this study. A few unfilled control shells intentionally damaged with surgical instruments were also analyzed. The surfaces of damaged shell regions were examined by use of a field-emission scanning electron microscope (Model S-4500; Hitachi, Tokyo, Japan). Two optical microscopes were also used to analyze ruptured shells. The first was a Wild Stereomicroscope equipped with an Olympus 5-megapixel camera (model Camedia C-5050 zoom). The second was a Hirox KH-2200 Hi-Scope video microscope equipped with a 20-100× zoom lens. The camera’s output was to a color video monitor and a color video printer.

In some cases, it is difficult to determine whether surgical damage occurred during implantation or explantation. For an explant with a single or multiple suture needle cuts, it can be stated unequivocally that surgical damage occurred during implantation. On the other hand, a single or multiple cuts from a scalpel can occur during implantation or explantation surgery. Classifying a retrieved implant as having ruptured because of contact with a surgical device during implantation surgery is suspect if there is a single surgical cut on a shell with multiple tear sites. In such a case, there is the possibility that the surgical damage occurred during explantation. This was not the case for any ruptured devices classified as having a surgical mode of failure in this study. Each retrieved device that was classified with a surgical mode of failure had a single shell cut or multiple shell cuts caused by a surgical device.

Results and Discussion

Analysis of surgical instruments

A no. 15 surgical blade is the scalpel most commonly used in plastic surgery. In this study, a new no. 15 blade manufactured by Bard-Parker was analyzed. With the proper lighting, parallel machining lines could be seen on the cutting surface of the surgical blade with the unaided eye. The lines on the cutting surface of the blade are illustrated in Figure 2, a 35-mm photograph of the no. 15 scalpel. The lines appear only on the cutting surface of the blade and are created during the finish machining process to sharpen the blade. The lines can be called grind lines and are the result of the blade being sharpened by a grinding wheel during the last phase of the manufacturing process. The machined tracks, caused by the grains used in grinding wheels, are well known and documented.

**Figure 2.** Thirty-five-millimeter photograph of no. 15 scalpel.
in the manufacturing industry. The spacing between the grind lines will vary according to the grinding process.

A more detailed view of the grind lines is shown in Figure 3, an optical micrograph of the scalpel. The spacing between the grind lines was measured by use of a scale bar on a similar optical micrograph obtained with much greater magnification. The spacing between the grind lines varied from approximately 4.9 \( \mu m \) to 29.4 \( \mu m \) (0.20 to 1.2 thousandths of an inch).

The most detailed description of the grind lines was obtained with scanning electron microscopy. A scanning electron microscopy (SEM) micrograph of the scalpel (Figure 4) showed the tip of the blade in the vertical direction. The specimen holder can be seen to the left of the blade tip. This micrograph also illustrates the curvature of the cutting surface near the tip of the blade. A scale (in micrometers) is shown in the lower right hand corner of the micrograph. On the basis of this photograph, the spacing between the grind lines varied from about 13 to 26 \( \mu m \) (0.5 to 1.0 thousandths of an inch). Other SEM micrographs taken at much higher magnification showed that the grind line spacing was as small as approximately 2 \( \mu m \) (0.10 thousandths of an inch). Hence, the spacing between the grind lines is not constant, but varies according to the size of the particles on the grinding wheel used during the finish machining process.

From Figure 4, the extreme end of the sharpened tip of the blade was measured to be approximately 1075 \( \mu m \) (42 thousandths of an inch) in length. The minimum length of the cutting surface of the scalpel determined from this micrograph was approximately 790 \( \mu m \) (31 thousandths of an inch), which appeared to be a representative length of the sharpened region along the entire blade surface. Since the blade was slightly tilted from the horizontal, the

\[ \text{Figure 3. Optical micrograph of no. 15 scalpel.} \]
actual length of the sharpened edge of the blade is slightly
greater than these measurements. The point is that the
length of the sharpened region containing grind lines is
greater than the thickness of a breast implant shell.

A no. 11 surgical blade is also a commonly used
scalpel in plastic surgery. A new no. 11 blade manufac-
tured by Bard-Parker was analyzed with the same
approach as the no. 15 scalpel. SEM analysis showed
that the grind line spacing varied from approximately
10.4 µm to 20.8 µm (0.41 to 0.82 thousandths of an
inch). As shown in Figure 5, the geometry of the extreme
tip of the no. 11 blade was quite different than the no.
15 blade, in that it was unsharpened and rough. The
length and width of the unsharpened end of the no. 11
scalpel measured from this micrograph was approxi-
mately 195 µm (7.7 thousandths of an inch) and 89 µm
(3.5 thousandths of an inch), respectively. The actual
dimensions would be slightly different because of the
effect of the tilt angle. Hence, if the no. 11 blade pene-
trated through less than approximately 40% of the shell
thickness, striations would not be formed and the cut
could appear to have a ragged surface mirroring the
rough surface of the no. 11 blade tip. Additional testing
is needed to determine the structure of such a cut. In
addition, if either a no. 15 or no. 11 blade cut the shell
such that the grind lines were nearly perpendicular to the
direction of motion, striations would not appear on the
cut shell. Further research is needed to determine the fin-
gerprint left by such a cut.

A new cutting suture needle manufactured by Ethicon
(PS-2) was also analyzed. This is a typical needle used by
plastic surgeons performing breast implantation surgery.
The optical micrograph in Figure 6 shows the tip of the
needle. A previous SEM analysis3 of a cutting suture nee-
dle showed the triangular configuration of the needle tip
and demonstrated that the imprint left on a damaged
shell can take one of several forms. The previous study
did not consider the roughness of the needle tip.

This microscopy analysis revealed that the tip of the nee-
dle was formed by the intersection of three surfaces. The
three surfaces did not have the same geometry, nor were they all planar. The geometrically simplest surface was the one along the inside curve of the needle (Figures 6 and 7). It was flat and fairly smooth. Each of the two outside surfaces was a cluster of three planes that intersected at low angles (producing a curved surface). The optical micrograph in Figure 8 shows one of the outside surfaces. So, the cross-sectional geometry of the needle was not simple. The optical micrographs in Figures 6 to 8 show that only fine-scale machining marks are on the tip of the needle surfaces.

From SEM micrographs, the spacing of the grind lines on the needle tip varied from approximately 2.3 µm to 8.4 µm (0.092 to 0.33 thousandths of an inch), which is considerably less than the range of grind line spacing on the scalpels. The spacing was difficult to measure on the optical micrographs. A typical spacing appeared to be approximately 11.9 µm (0.47 thousandths of an inch). The actual grind line spacing for the suture needle could be somewhat greater than the measurements presented herein because of tilt angle effects. The base and length of the needle tip were approximately 714 µm (0.028 inch) and 2930 µm (0.115 inch), respectively, where the length is defined as the distance to the base. The actual length would be slightly larger, because of the curvature of the needle tip. Hence, the length of the needle tip was greater than the thickness of a breast implant shell.

A shell cut with a needle would reflect some aspect of the shape and cross-section of the needle tip. A cut through a breast implant shell with a scalpel or suture cutting needle could potentially produce some type of imprint caused by the grind lines unless the direction of the movement of the surgical instrument were nearly perpendicular to the grind lines. Whether the effect of the grind lines on the shell can be detected with microscopy is a separate issue, which is considered in the remaining portion of this study.

**Analysis of simulated surgical damage**

It is difficult to use 35-mm photography to determine the cause of breast implant rupture. This analysis tech-
**Figure 6.** Optical micrograph of inside surface of cutting needle.

**Figure 7.** Optical micrograph of inside surface of cutting needle, higher magnification view.
nique has primarily been used to describe the gross features of breast implants.\textsuperscript{4-7} An experiment was conducted to demonstrate the limitations of this technique. The no. 15 surgical blade analyzed in this study was used to damage a control textured shell with a single cut through the shell. A specimen surrounding the damaged region was removed from the shell, folded at the cut, and analyzed with 35-mm photography. A mark was placed at the cut as an aid to locate the damaged region. Figure 9 presents a 35-mm photograph of the specimen. Striations at the end of the cut can barely be seen and can hardly be distinguished from the surface texturing. This example demonstrates the difficulty in the use of 35-mm photography to diagnose breast implant surgical damage.

The no. 15 scalpel blade was used to make another single cut through the control textured shell. An optical micrograph of the damaged shell region is shown in Figure 10. The striations induced in the shell by the surgical blade are evident. The striation pattern is very similar to the grind line pattern on the cutting surface of the blade. These lines represent the boundaries of the surface roughness in the shell, which mirror the marks machined on the cutting edge of the blade. The width and depth of the grooves on the blade are determined by the grain size on the grinding wheel. With the scale bar on this and other micrographs, the striation spacing was measured and related to the spacing of the grind lines on the scalpel. The spacing of the striations varied from about 8.9 $\mu$m to 20 $\mu$m (0.35 to 0.79 thousandths of an inch), which is consistent with the spacing of the grind lines. Other features observed in Figure 10 include the texturing on the outer surface of the shell and white spots at various locations on the shell caused by reflection of the incident light.

The cutting needle was also used to simulate surgical damage to a control shell. Striations were not detected with optical microscopy. Rather, the small cuts and holes
produced by the needle reflected some aspect of the shape and cross-section of the needle. This result is consistent with the previous study, which characterized needle damage to breast implants.3

**Explant analysis**

Optical microscopy is a reasonable approach to analyze modes and causes of shell rupture. However, for many cases the more sophisticated technique of field emission scanning electron microscopy is needed to confirm or refute questionable failure sites and failure mechanisms determined by optical microscopy. SEM can often be used to determine a failure mechanism by providing additional morphologic features of failure sites. The approach taken in this study was to use SEM to substantiate and verify failure modes and mechanisms determined with optical microscopy for a selected number of retrieved devices with ruptured shells. Another objective of the SEM analysis was to demonstrate the usefulness of the technique to view morphologic features of failure sites not obtainable with optical microscopy. The SEM technique used to analyze ruptured explants has previously been described in the literature.3,8

Four ruptured devices manufactured by Allergan were analyzed in this study with optical microscopy and SEM analysis. All four devices were silicone gel-filled breast implants. Three of the implants had a textured shell, and one had a smooth shell. For all four devices, shell schematics and optical micrographs were first used to investigate the failure mode. Shell schematics were prepared to document the number, location, and size of the rupture sites on the shell. The schematics are not presented herein. The optical micrographs are presented. The Allergan implant identification numbers are given in the upper left hand corner of the optical micrographs. The SEM micrographs for each implant are located immediate-
ly after the optical micrographs. A micron scale is given in the lower right hand side of each of the SEM micrographs.

The first implant analyzed was diagnosed with a surgical rupture using optical microscopy. It had 0.30 years in vivo and ruptured because of a small tear on the anterior side. An optical micrograph for this implant is shown in Figure 11. The implant ID number, 2009253, is located in the upper left hand corner of the figure. Striations indicative of a surgical cut are evident in the figure.

SEM micrographs give views from the inside of the shell and show the beginning of the tear (Figure 12), a section of the cut edges with few striations in focus (Figure 13), and another section of the cut edges with many striations in focus (Figure 14). The geometry of the end of the tear was very similar to the geometry at the beginning of the tear. The minimum spacing of the striations that were in focus in Figures 13 and 14 was approximately 15.6 \( \mu m \) (0.61 thousandth of an inch), which conforms to the grind line spacing on a scalpel blade. For this implant, the SEM analysis verified the failure mechanism and provided further details of the failure site.

The second implant, ID 2004092, diagnosed with a surgical rupture using optical microscopy, had 2.5 years of implantation time. The shell schematic of this device revealed a series of tiny cuts at one location near the perimeter. The optical micrograph (Figure 15) from one of the cuts appears to show striations on a ruptured shell edge. Unfortunately, a scale bar was not placed on this micrograph, and so the apparent striation spacing could not be determined. SEM analysis of one of the cuts, which was most likely a different cut than the one analyzed with optical microscopy, revealed a sharp surgical tip cut in the outer surface with no striations in focus (Figure 16). Higher magnification views of the same cut did not contain striations. The width of the small hole in the shell is approximately 686 \( \mu m \) (0.027

![Figure 10. Optical micrograph of control textured shell specimen with scalpel cut.](image-url)
Figure 11. Optical micrograph of device with surgical rupture, 0.3 years in vivo.

Figure 12. SEM micrograph of device, inside view at the beginning of the tear.
Figure 13. SEM micrograph of device, view of cut edges with few striations.

Figure 14. SEM micrograph of device, view of cut edges with many striations.
inch), which is essentially the width of the base of the needle tip (0.028 inch or 714 µm). The manner in which the specimen was attached to the specimen holder probably affected the size and shape of the hole. Nonetheless, the shape and approximate size of the hole indicate surgical damage with a suture needle. Analysis of this second implant demonstrates that prior knowledge of the geometry of surgical instruments is very useful in diagnosing the failure mechanism associated with surgical instrument damage.

Both optical microscopy and SEM detected grind lines on a suture needle. However, optical microscopy of simulated suture needle damage and SEM of explants with suture needle damage failed to detect striations on the shell. There are two possible explanations why striations were not detected. First, the relatively small-scale roughness on the suture needle may not be transferred to a shell during a suture needle cut because of the elastic nature of the silicone shell. Second, the striation pattern associated with a suture needle cut could be beyond the resolution of the present microscopy techniques for silicone shells. We concluded that the apparent striation pattern shown in the optical micrograph (Figure 15) was caused by a scalpel or is an artifact in the shell generated during the tearing process that was initiated from the needle cut. It is suspected that a scalpel and a suture needle caused implant damage at the same shell location.

The third ruptured device that was classified as having a surgical rupture using optical microscopy was implant 2008071. This device had 3 years in vivo and ruptured because of a series of small cuts located around the perimeter. The optical micrograph (Figure 17) shows apparent striations along the edge of a cut. The SEM micrograph (Figure 18) shows another cut in the shell that is approximately 2 mm in length. Its shape is indicative of a surgical nick to the shell. The expanded views in Figures 19 and 20 are for one end of the cut. No significant striation pattern can be seen in the SEM micrographs. In Figure 20, there is a very small region in the upper right hand corner of the edge of the cut shell that could possibly contain striations. The parallel lines that can be seen in Figure 20 on the inside surface (gel side)

![Image](image_url)

**Figure 15.** Optical micrograph of device with surgical rupture, 2.5 years in vivo.
of the shell are replicas of the machining grooves from the shell manufacturing mandrel. The section of the textured piece cut from the shell had a width of approximately 548 \( \mu m \) (0.022 inch). This dimension is about 20\% of the length of the needle tip and about 50\% of the length of the extreme tip of a no. 15 scalpel. Hence, it appears that a needle tip or the tip of a scalpel moving in a direction almost perpendicular to the grind lines removed the piece of textured shell. Because either type of surgical instrument could have caused the shell damage, the SEM analysis neither confirms nor refutes the optical microscopy diagnosis but provides added morphologic features of the failure region.

The last implant analyzed had 2.3 years of implantation time and a shell failure region that was a 1.3-cm tear on the anterior side. The optical micrograph for the device (2009266) is presented in Figure 21. Lines across the edge of the torn shell are evident. Initially it was suspected that the lines were striations. After further analysis, it was uncertain whether the lines were striations made by a surgical instrument. So this device was chosen for SEM analysis, and a resulting micrograph for the torn edge is shown in Figure 22. This photo reveals that the lines associated with the deep grooves which were initially interpreted as striations were actually formed in the shell material during a tearing process. The cause of this unknown rupture could have been associated with a small microflaw that existed in the shell. The microflaw could have been introduced sometime between manufacturing and implantation surgery. As forces were imposed on the implant in vivo, the microflaw could have eventually propagated into a tear that was responsible for the shell failure. Hence, a microflaw could have acted as an initiation site for the development of the shell tear.

Conclusion

This study has demonstrated that a silicone gel-filled breast implant can be subjected to surgical instrument damage during surgery. After implantation, the implant is subjected to forces caused by daily activities. These forces
Figure 17. Optical micrograph of device with surgical rupture, 3 years in vivo.

Figure 18. SEM micrograph of device, outside view of surgical cut.
Figure 19. SEM micrograph of device, higher magnification outside view of surgical cut.

Figure 20. SEM micrograph of device, outside view of end of surgical cut.
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Figure 21. Optical micrograph of device with unknown failure mode, 2.3 years in vivo.

Figure 22. SEM micrograph of device, view of torn edge.
on the device in the vicinity of the flaw can cause the slight shell cut to propagate into a tear. Hence, even though surgically damaged silicone gel–filled breast implants can often function in vivo as intended for quite some time, any type of surgical damage should be avoided.

Machining or grind lines exist on the cutting edge of a scalpel used in breast implant surgery. The grind lines can be seen with the unaided eye, 35-mm photography, an optical microscope, and a scanning electron microscope. The geometry of the grind lines are a function of the grinding process used in manufacturing. The grind lines can induce striations on breast implant shells cut with a surgical blade. The striation geometry pattern is a function of the angle that the instrument impinges on the implant shell. Conversely, a slight nick to the surface of a breast implant with the extreme tip of a scalpel can produce a cut in the shell without striations. The striations can be detected using microscopy techniques. The spacing between grind lines and striations can also be quantified and correlated using microscopy analysis. Striations appearing in the shell are an indication that device rupture could have been caused by scalpel damage. Grind lines also exist on the tip of a cutting needle, but on a much finer scale. These lines can be seen by use of microscopy analysis.

Striations have not been detected on breast implant shells cut with a needle. This could be due to the elastic property of the silicone shell or the resolution of the microscopy techniques. However, shell cuts produced by a needle can mirror some aspect of the shape and cross-section of the needle. In summary, breast implants damaged by surgical instruments during implantation can develop ruptures in the shell, and the source of these ruptures can be identified via microscopy.

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