Mentor Report Number M 051

ADDENDUM

Analysis of In Vivo Failure Mechanisms of Mentor Silicone Gel Breast Implants* (Core Gel Coupon)

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Executive Summary

This study is a microscopy analysis of explanted silicone gel breast implants manufactured by the Mentor Corporation. Scanning electron microscopy (SEM) was used to examine failed explants to categorize the failure mechanisms. The Mentor Corporation provided cleaned explant shells. Electron microscopy provided visualization of morphological features or of a failure mechanism not readily apparent with optical microscopy.

In electron microscopy of the explant shells, failure can be categorized as one of five mechanisms.

a. sharp instrument damage (needle or blade)

Sharp instrument damage includes both blade and needle damage. Parallel striations are clearly evident on the electron micrographs of explant shells with simulated blade damage. When parallel striations are present, it is strong evidence that the device was damaged with a sharp blade. However, absence of parallel striations cannot eliminate the possibility of iatrogenic damage since tears initiated from needle punctures may not present parallel striations.

b. localized shell fatigue

Localized shell fatigue damage is the result of localized flex fatigue or fold flaw mechanisms. The damage is characterized as a tapered or feathered opening, material cracking, parallel feathering lines, and in some cases, shell layer delamination. In some cases, exterior surface abrasive wear is evident due to abutment, folding and rubbing contact of the exterior surface. When it is present, this failure mode is quite

distinctive and easily identifiable in the explant samples.

c. long failure lines for which an initiating cause could not be determined

Long tear failures result from a specific initiation point and propagation from that point. In some cases, since the failure lines are long, it is not possible to locate and analyze the initiation point. The initiating incident could be iatrogenic (sharp blade cut or needle puncture), localized stress resulting from placement of the device during the implantation procedure, or a manufacturing defect. Localized stress could give rise to a shell failure after exposure to cyclic failure *in vivo*. The failure lines have the appearance of tear propagation as is seen with control samples subjected to tear test procedures.

d. miscellaneous failures

Miscellaneous failures include patch/shell junction failures, and surface defects on the inside surface of the shell near the failure site.

e. unknown cause

The two devices that fell into the category of "unknown cause" had relatively short failure lines. This allowed a thorough examination of the failure lines with SEM. For devices that fell into the category of "long failure lines for which an initiating point could not be determined", a précise SEM examination could not be made because the failure lines were long. It would've required a very large number of SEM micrographs to

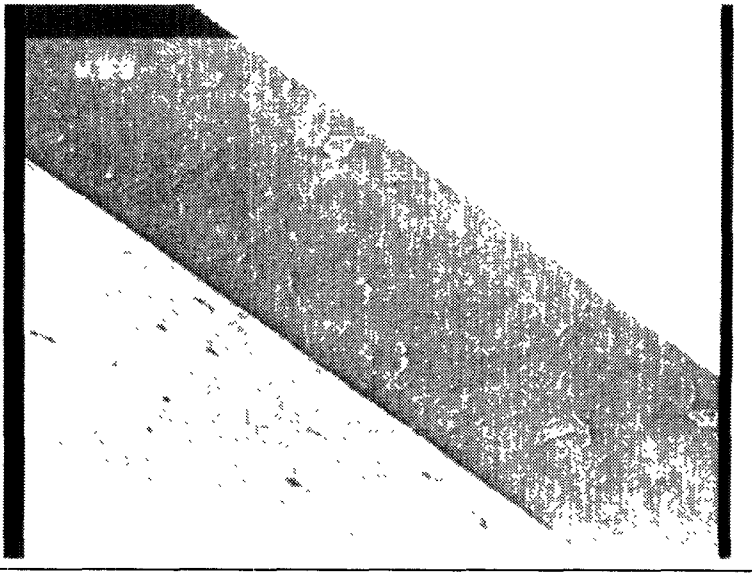
cover the length of the failure lines. Conversely, with short failure lines a thorough examination could be and was made via SEM and no initiation point was identified. This examination almost certainly eliminates iatrogenic failures (sharp blade cuts or needle punctures) since these would have been identified with a high degree of certainty, through the view of SEM micrographs. It is reasonable to speculate that the unknown failures could have resulted from localized stress introduced during the implantation procedure, a micro-flaw from a surgical instrument, or from an unobservable manufacturing defect that resulted in a weakened area of shell. None of these would necessarily result in an observable physical signature along the failure line. Because of the lack of any specific identifying characteristic, a precise designation of cause of failure was not possible.

The primary failure mechanism for each shell, as determined by electron and optical microscopy, is summarized in the following table.

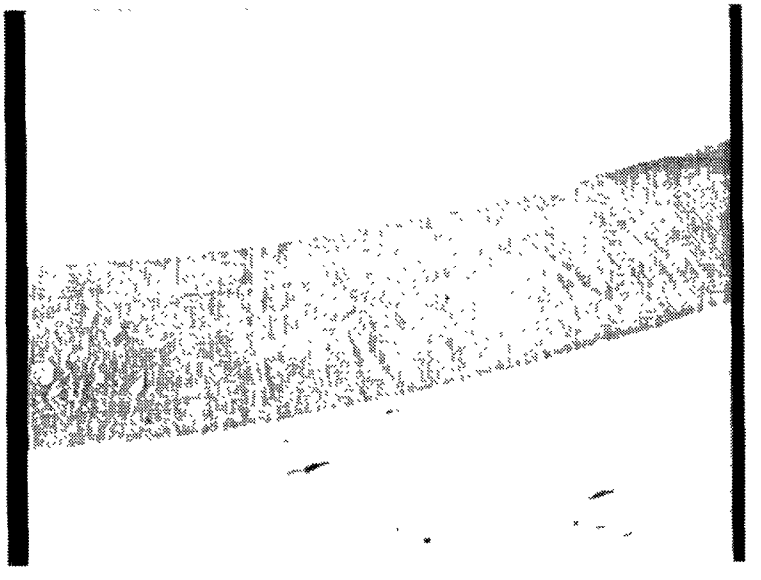
Shell	Figure	SEM	Comment
14185 left	1A	a. instrument	striations
	1B		striations
	1C		striations
	1D		striations
14185 right	2A	e. unknown	hole A
	2B		edge
	2C		hole B
	2D		inside surface
	2E		edge
	2F		edge
200010-0202	3A	a. instrument	needle hole X70
	3B		X298
	3C		X806
200101-0655	4A	a. instrument	hole A X50
	4B		striations
	4C		hole B
	4D		striations
200102-0308	5A	e. unknown	rent edge A
	5B		rent edge B
	5C		rent edge C
	5D		rent edge D X100
	5E		X200
	5F		tear pattern
	5G		tear pattern
	5H		tear pattern
200107-0413	6A	a. instrument	rent edge
	6B		striations
	6C		striations
200205-0417	7A	a. instrument	hole A edge
	7B		hole A surface
	7C		hole B edge
	7D		hole B surface

Figure 1: 14185, left breast

Sample 14185, left breast was determined by Mentor to have 3 small holes that propagated into a long tear. Figure 1A shows the striations along hole A. Figure 1B shows the striations along hole B. Figures 1C-D shows striations along hole C. Between the holes, there were no striations.



(A) First set of parallel striations found along edge of rent.



(B) Second set of parallel striations found along edge of rent.

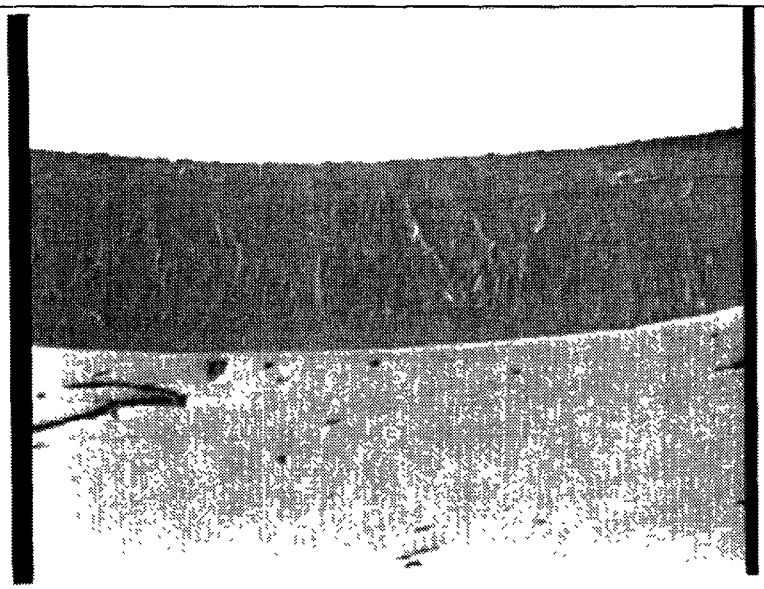
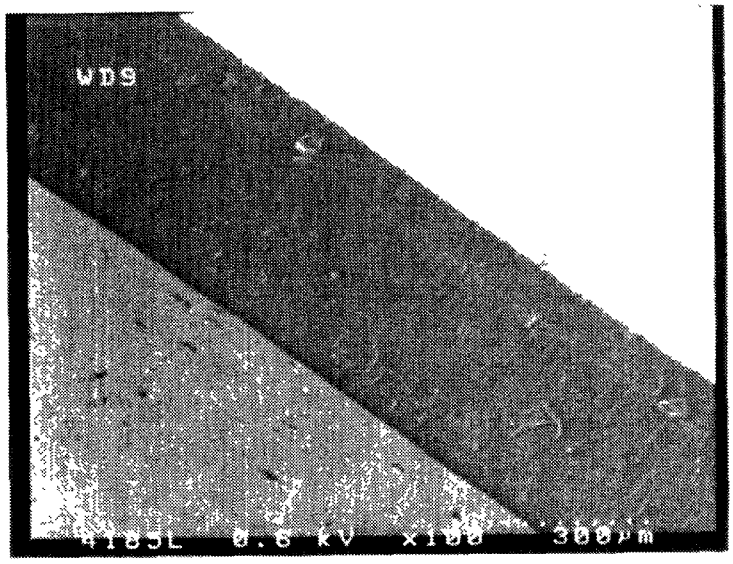
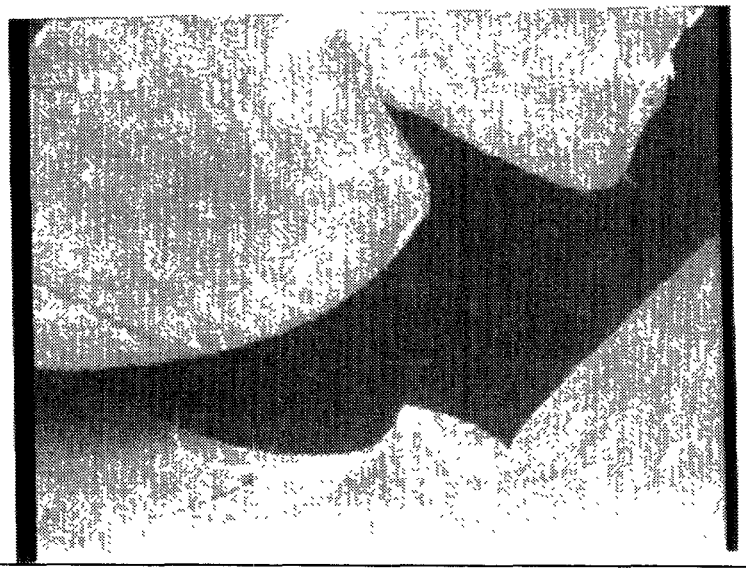
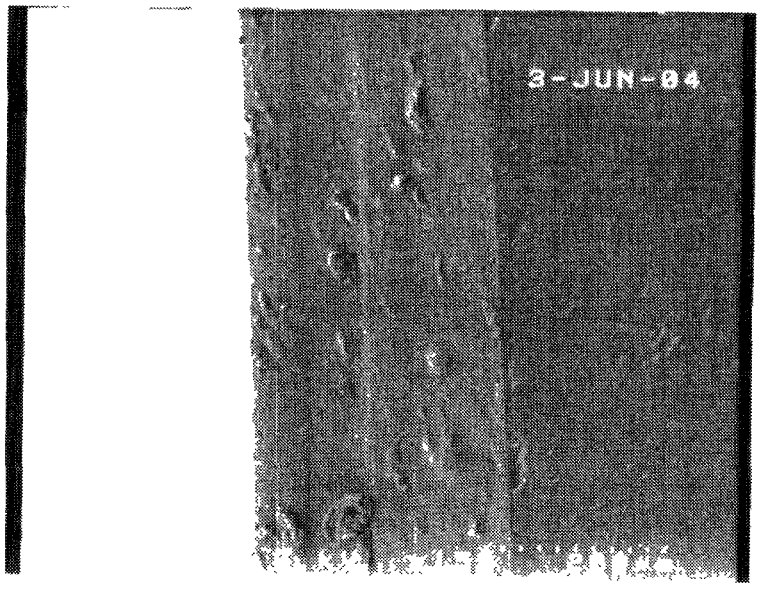
	(C) Third set of parallel striations found along edge of rent.
	(D) Third set of parallel striations found along edge of rent.

Figure 2: 14185, right breast

Sample 14185, right breast had two small holes approximately 2 mm apart.
Figures 2A-C show the inside surface and edge of hole A, while Figures 2D-F show the inside surface and edge of hole B.

	(A) Micrograph of inside surface of hole A.
	(B) Micrograph of hole A edge does not show evidence of parallel striations.

	(C) Micrograph of inside edge of hole A. No clear evidence of parallel striations evident.
	(D) Micrograph of inside surface of hole B.

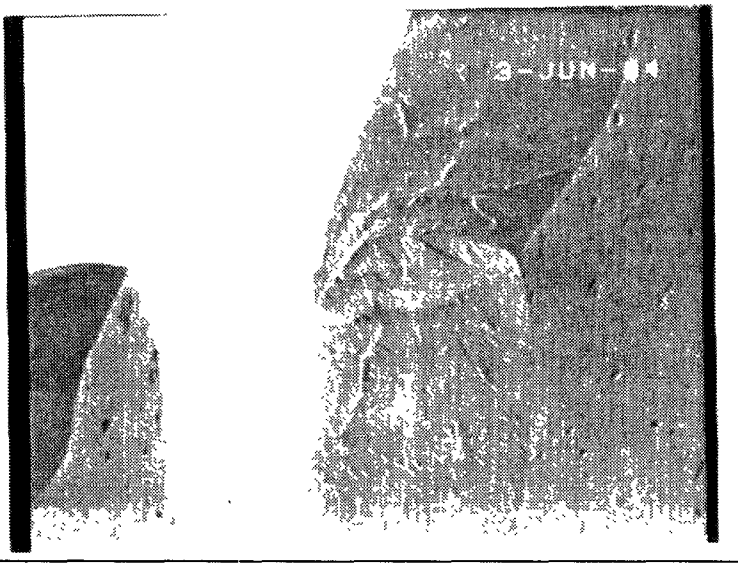
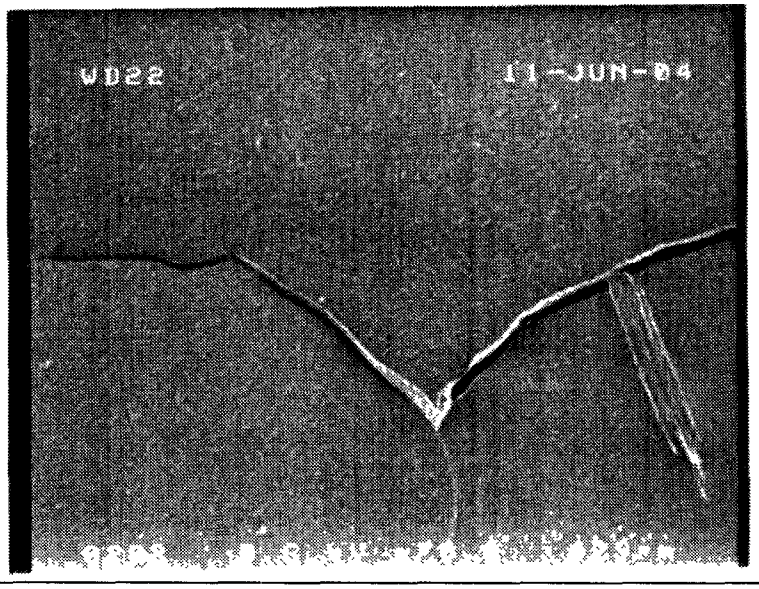
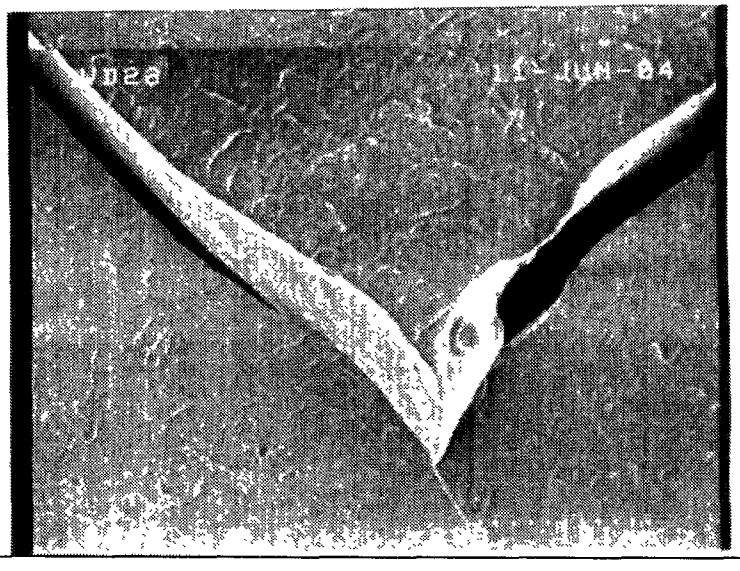
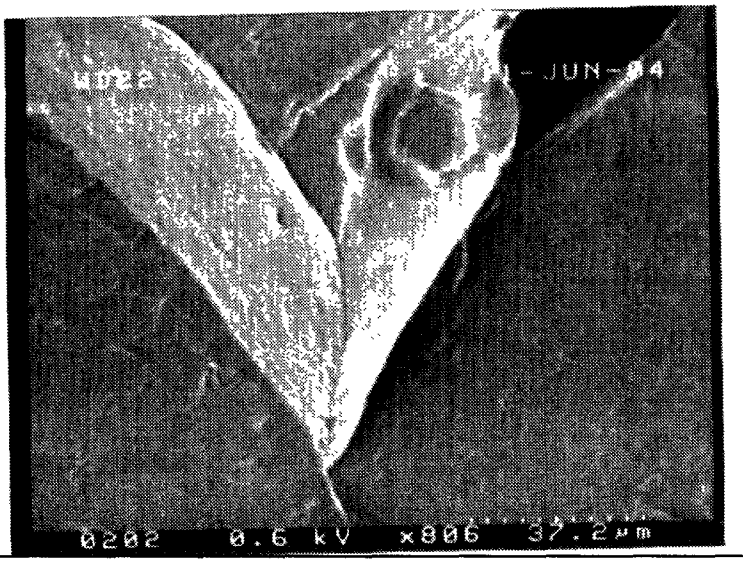
	(E) Micrograph of edge of hole B. No parallel striations evident.
	(F) Micrograph of edge of hole B.

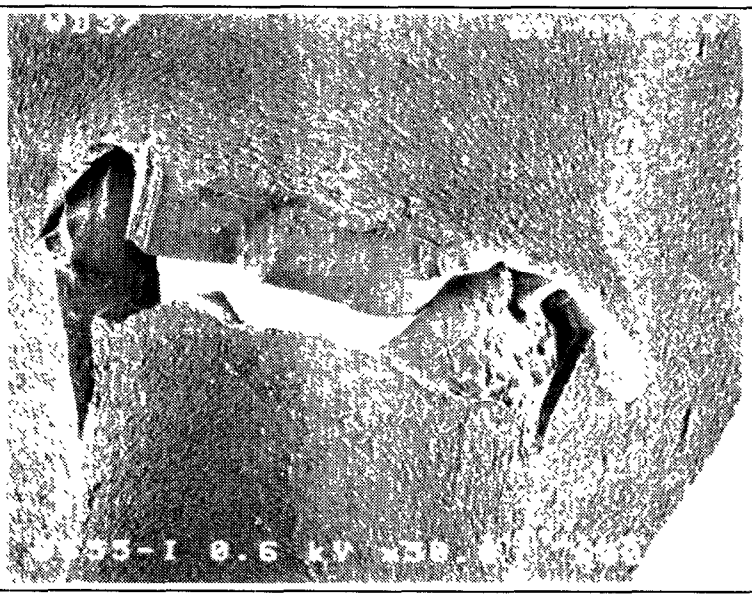
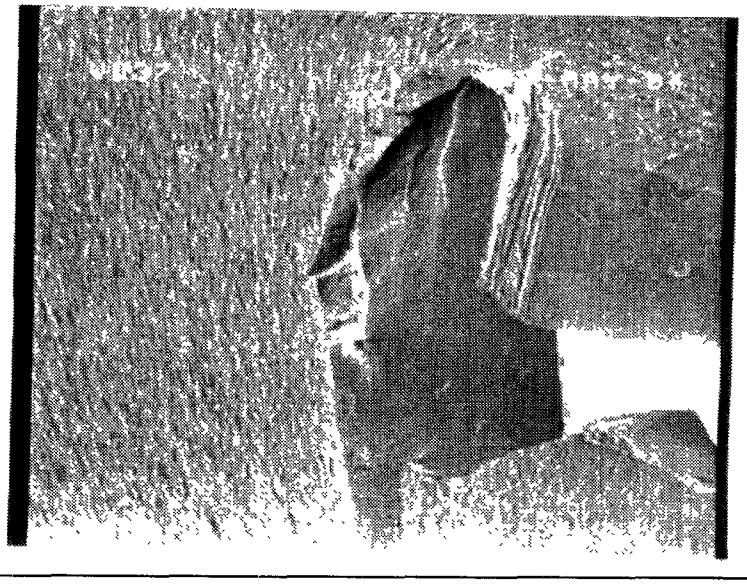
Figure 3: 200010-0202
Sample 200010-0202 has a long tear of approximately 3.5 inches. The edge of the tear was followed along both sides. No parallel striations were evident along either edge. However, Figure 3A shows a needle puncture. Figures 3B-C are enlarged views of Figure A.

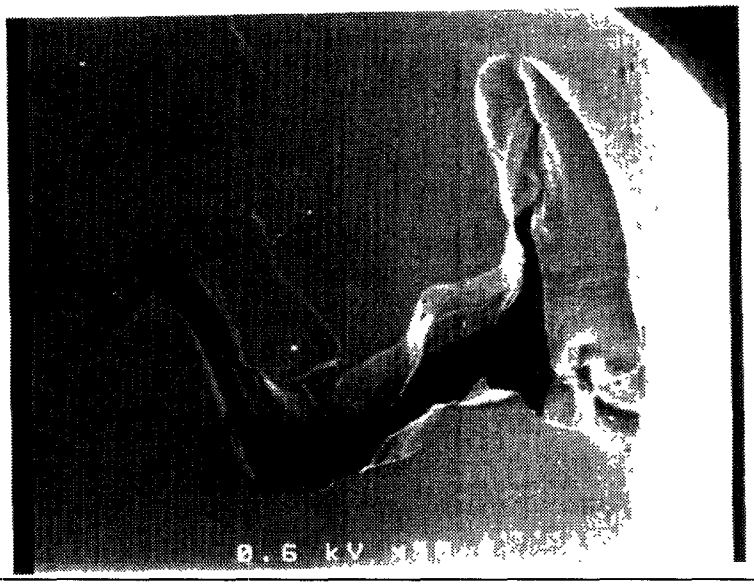
	(A) Micrograph of rent point of origin caused by needle puncture
	(B) Enlarged view of Figure A above.



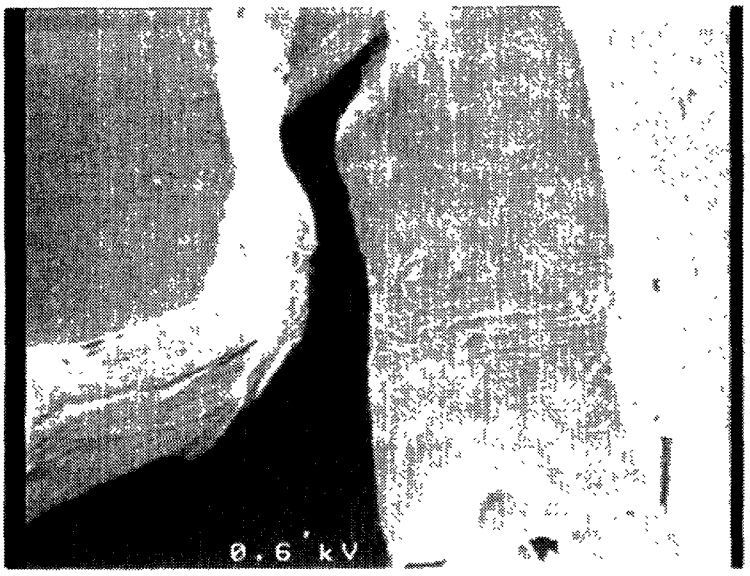
(C) Enlarged view of Figure B above.

Figure 4: 200101-0655
Sample 200101-0655 had two holes approximately ½ inch apart. Figures 4A-B show hole A. The holes were produced by a staple. Parallel striations were found on the edge of shell rent. Figures 4C-D show hole B. Evidence of parallel striations were found on the edge of rent (hole B).

	(A) Micrograph of hole A.
	(B) Enlarged view of hole A. Parallel striations are evident on shell flap.

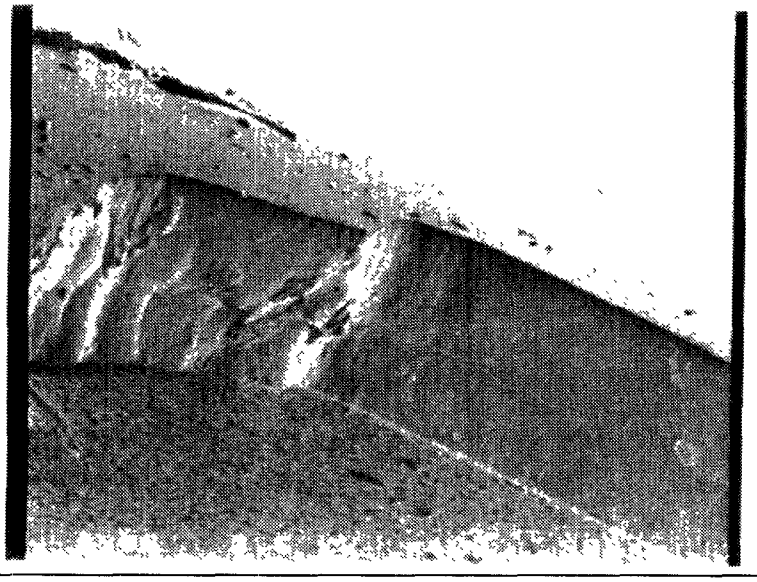
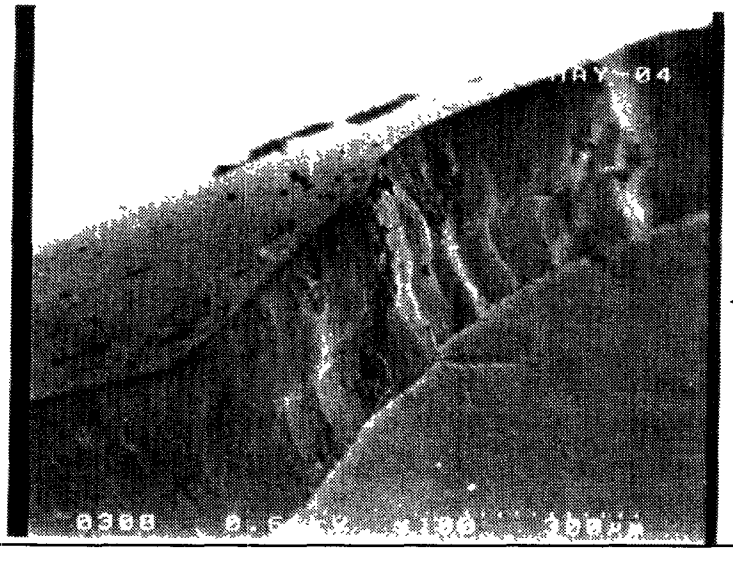


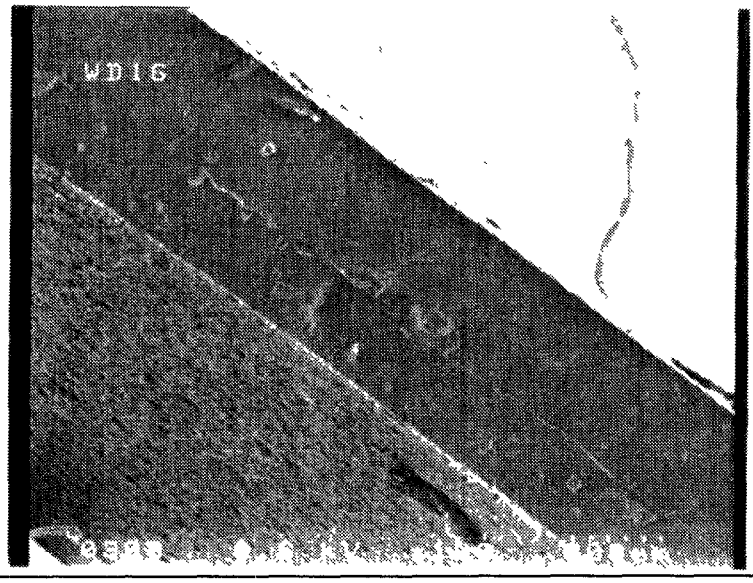
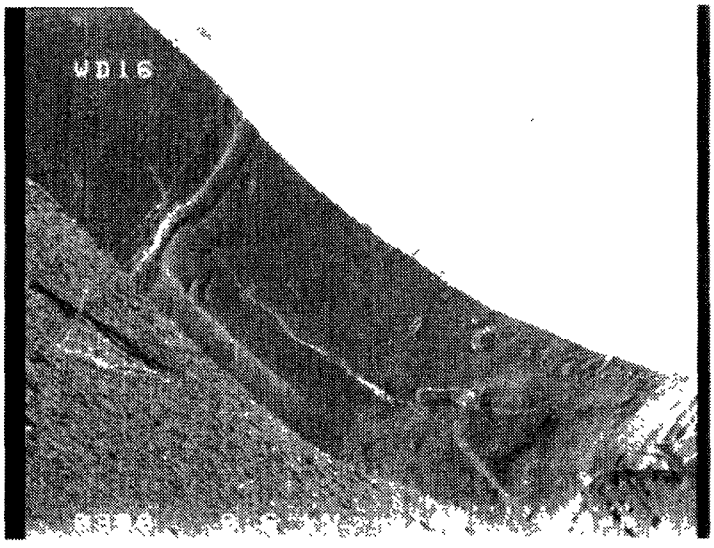
(C) Micrograph of inside surface of hole B.

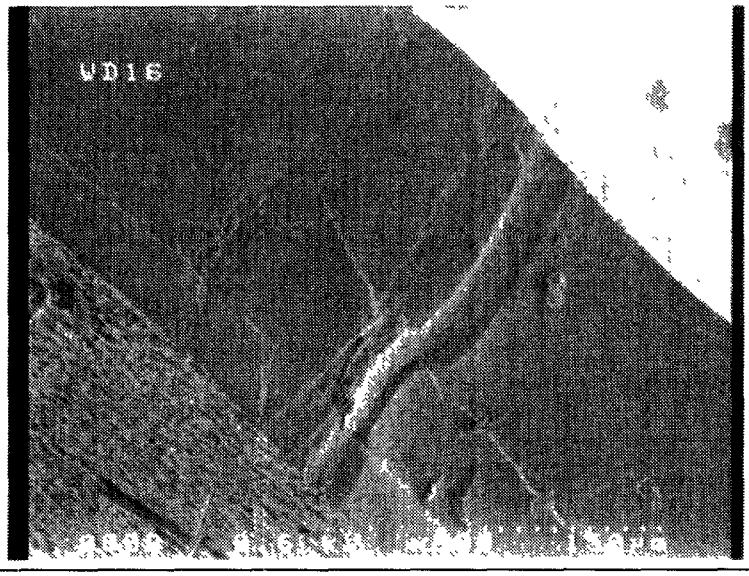
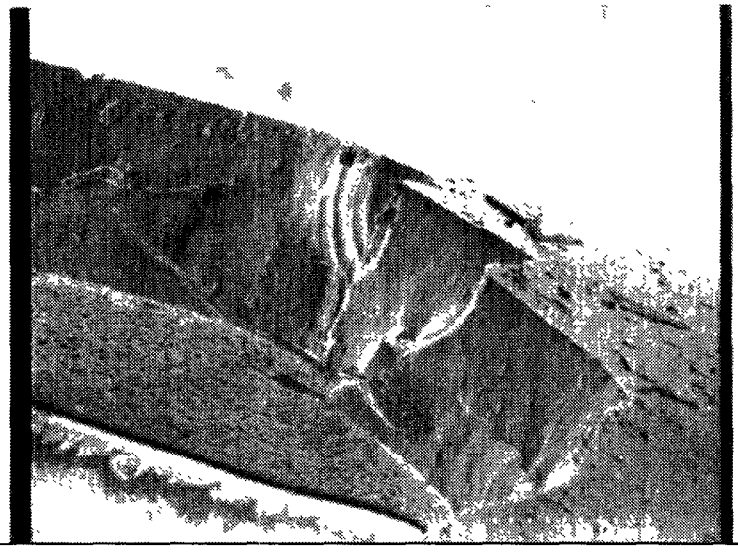


(D) Enlarged view of hole B. Parallel striations are evident on edge of rent.

Figure 5: 200102-0308
Sample 200102-0308 had a rent of approximately ½ inch. An SEM scan was performed along the rent edge. Figures 5A-B show the rent at the front edge of the failed region. No parallel striations are found. Figures 5C-D show the edge in the middle of the failure region, where no parallel striations were evident. Figure 5E is an enlarged view of Figure 5D. Figures 5F-H show the rent failure region at the opposite end of the sample. The failed region displays a curved pattern.

	(A) Micrograph of rent edge showing no evidence of striations.
	(B) Micrograph of rent edge showing no evidence of striations.

	(C) Micrograph further along rent. No evidence of striations.
	(D) Micrograph of rent edge showing no evidence of striations.

	(E) Enlarged view of Figure D above.
	(F) Micrograph of rent edge at other end of failed region. Curved tearing pattern evident.

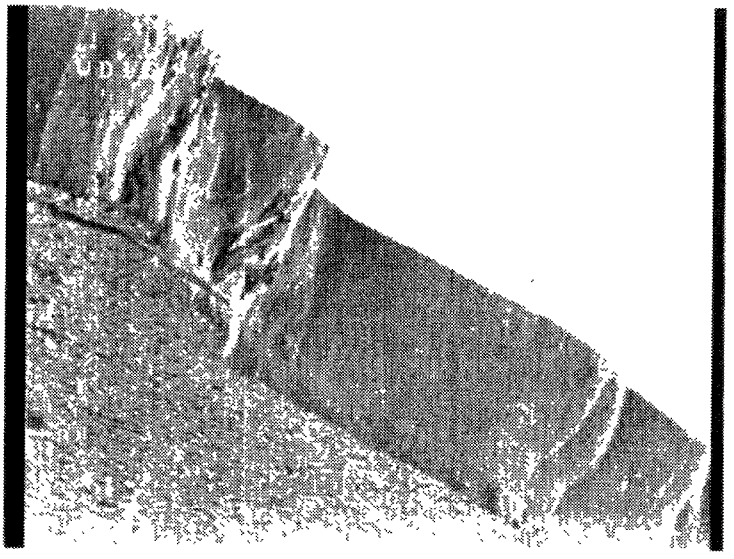
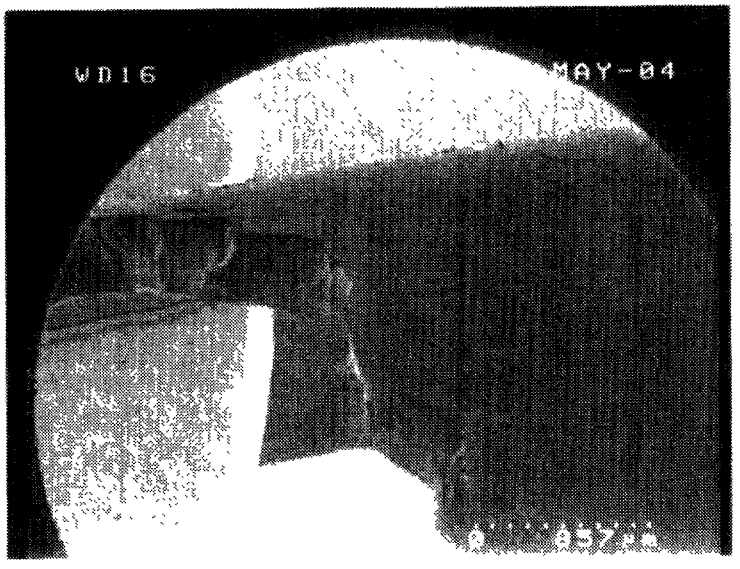
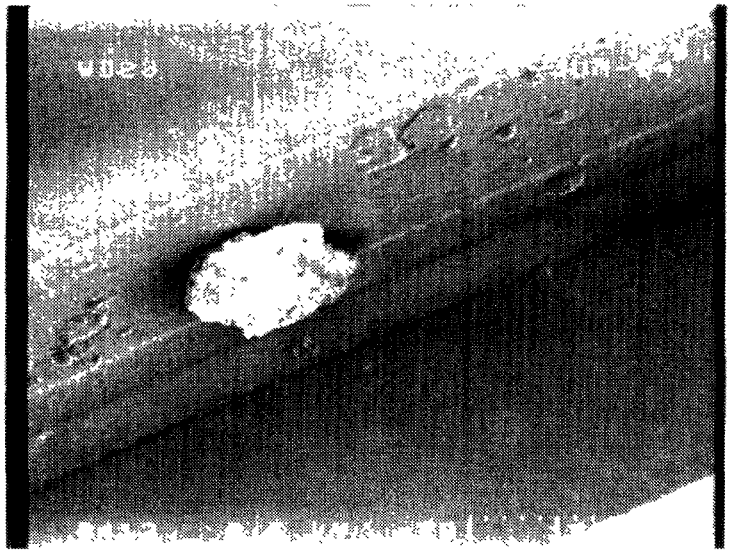
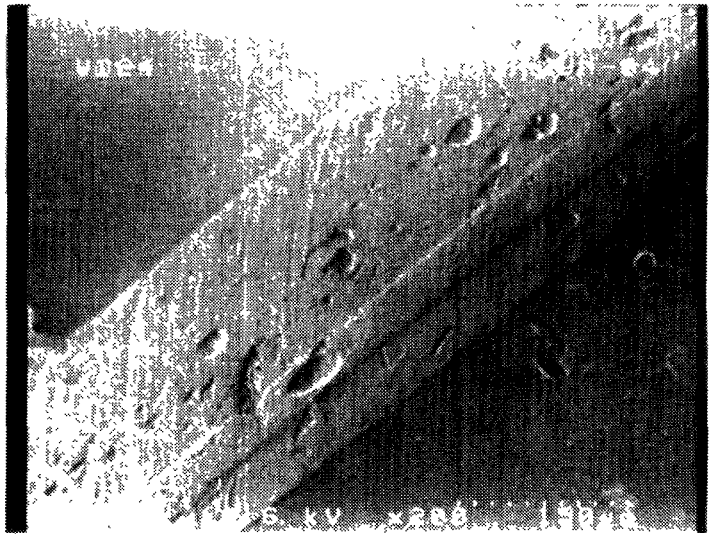
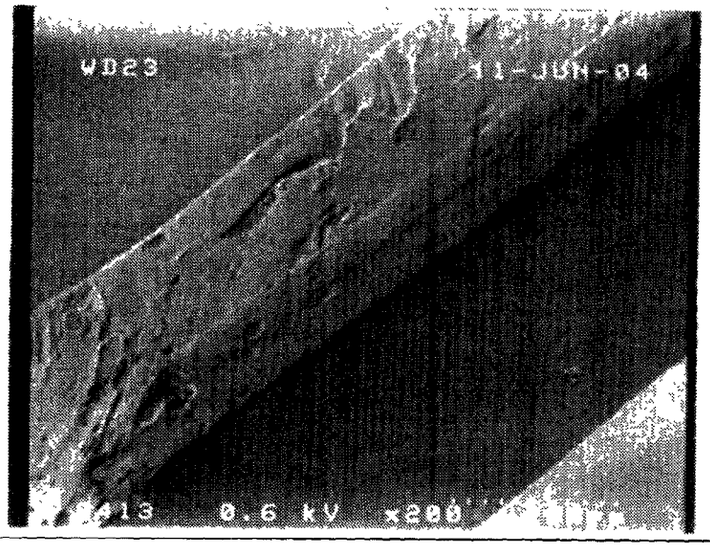
	(G) Micrograph of rent edge at other end of failed region. Curved tearing pattern evident.
	(H) Microograph of rent edge at other end of failed region. Curved tearing pattern evident.

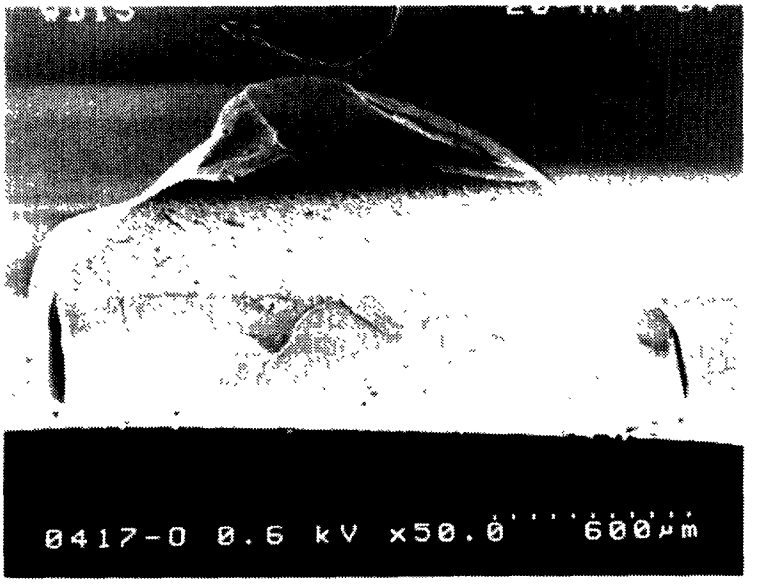
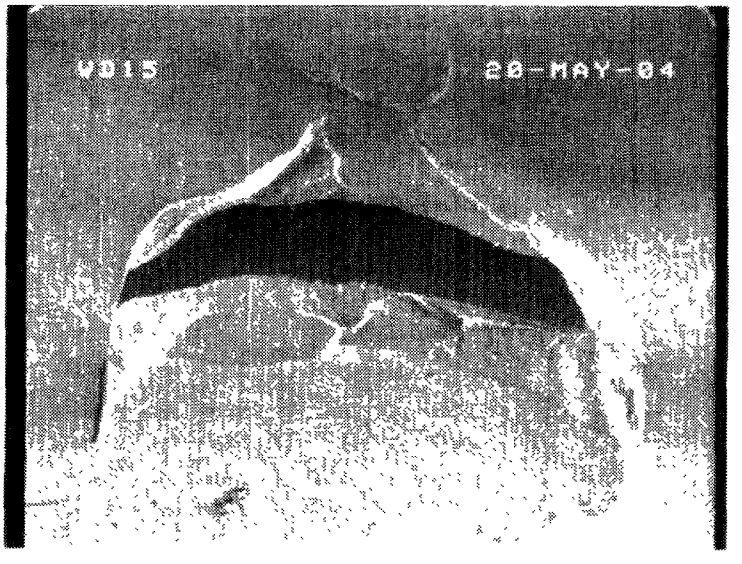
Figure 6: 200107-0413
Sample 200107-0413 had evidence of a rent approximately 1 inch long. An SEM scan was performed along the rent edge. Figure 6A shows the rent edge and no parallel striations are evident. Figures 6B-C shows the rent edge approximately 1/4-1/3 inch from beginning of rent. Parallel striations are evident on rent edge. The rest of the rent (1/3 – 1 inch) did not have any parallel striations.

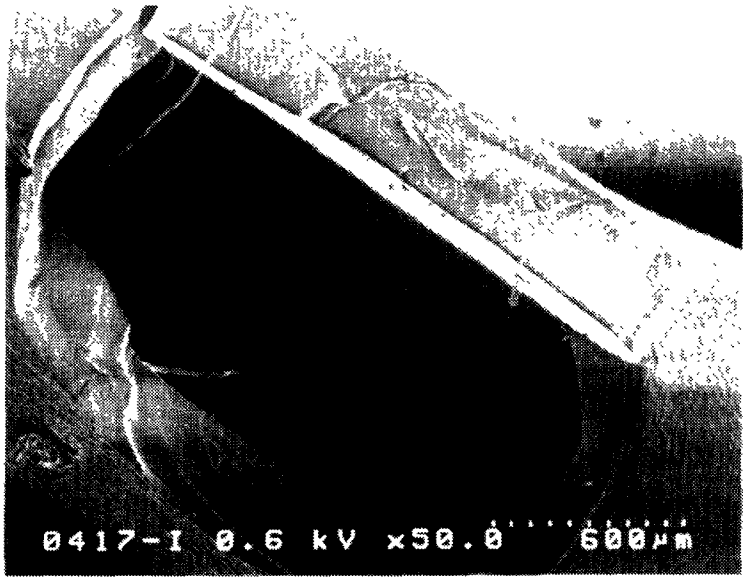
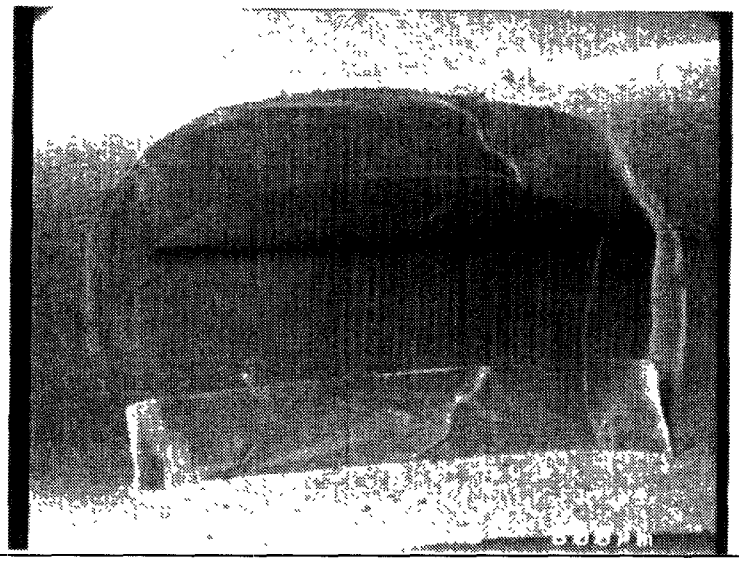
	(A) Micrograph along rent edge does not show evidence of parallel striations.
	(B) Micrograph of rent edge (approx. ¼ in from beginning of rent) with parallel striations.



(C) Micrograph of rent edge (approx. 1/3 in from beginning of rent) shows evidence of parallel striations.

Figure 7: 200205-0417
Sample 200205-0417 shows nine small holes. Mentor provided a failed region consisting of two holes. Figures 7A-B show hole A, while Figures 7C-D show hole B. Both holes were produced by surgical instrument.

	(A) Micrograph of hole A.
	(B) Micrograph of hole A.

	(C) Micrograph of hole B.
	(D) Micrograph of hole B.