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REPORT M 041

IATROGENIC EFFECTS ON GEL-FILLED MAMMARY IMPLANT  
FATIGUE LIFETIME

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FATIGUE LIFETIME

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1.0 TITLE

IATROGENIC EFFECTS ON GEL-FILLED MAMMARY IMPLANT  
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2.0 ABSTRACT

This report presents a study of iatrogenic effects on Smooth Round Moderate Profile Gel-Filled Mammary Implants. Devices were subjected to simulated surgical and diagnostic procedures to determine the affect upon cyclic fatigue lifetime. That included mammary surgical insertion procedure, inadvertent scalpel damage and suture needle puncture and mammography induced compression. Subsequently devices were tested with servohydraulic instrumentation to measure cycles-to-failure for comparison to control devices that had not been subjected to iatrogenic events. Results are used for partial fulfillment of Premarket Approval application. Simulated surgical insertion procedure and mammography diagnostic procedure did not affect the device fatigue lifetime. Induced suture needle puncture damage through the device shell resulted in immediate failure of the implant or a loss of ~99 % of fatigue lifetime. Induced scalpel damage of the device shell with and without penetration through the shell also resulted in a variety of failures of the implant yielding no effect on fatigue lifetime and a loss of ~99 % of the fatigue lifetime.

3.0 INTRODUCTION

Mentor Corporation manufactures a variety of mammary prostheses including Smooth and Siltex Round Moderate and High Profile and Moderate Plus Profile Gel-Filled Mammary Implants. All devices are composed of a shell assembly and gel filler. The shell assembly is primarily a smooth low bleed envelope. The minor components include patches, fill reinforcement patch (button), dipcoat for -----, and a Siltex<sup>®</sup> model -----  
----- The raw materials of ----- imarily  
----- materials are highly crosslinked dimethylsiloxane and  
----- polymers with silicone dioxide filler and the gel is a  
-----thylsiloxane material.

Interest has developed regarding mammary implant failure analysis that involves product evaluation and testing of explanted devices and subsequent categorization of failure modes.<sup>1</sup> In some instances explants may have exhibited premature failure. Several failure modes have been identified and include events such as sharp instrument damage conceivably resulting from scalpel and suture surgical

instrument procedures. Accordingly iatrogenic events, inadvertently induced by a physician or surgeon or by medical treatment or diagnostic procedures, may contribute to premature implant failure. This study was intended to evaluate iatrogenic events and subsequent affect on cyclic fatigue behavior. Several events are considered such as surgical insertion procedure of the implant resulting in stress and deformation, sharp instrument damage resulting in puncture or incision of the implant shell and mammography diagnostic procedure resulting in repeated compression of the implant. The effect of implantation surgery on the strength properties of implant shells has been reported and concluded that "the surgical procedure of implanting a breast implant has a small but statistically significant effect on the average strength properties of the elastomer shell of the implant. It is unlikely that this small reduction is sufficient to be a factor in implant durability."<sup>2</sup> The effects of sharp instrument damage have also been reported in the literature and concluded the surface morphology of failed implants and artificially damaged implants are sufficiently similar to indicate surgical and diagnostic procedures could predispose the device to fail prematurely.<sup>3</sup> The results of the current study will be used for partial fulfillment of Premarket Approval (PMA) application for Gel-Filled Mammary Implants.<sup>4</sup>

#### 4.0 EXPERIMENTAL

A detailed description of the experimental procedure is compiled in Appendix A Protocol. Sample identification and traceability data are listed in Appendix C Sample Information. Smooth Round Moderate Profile Gel-Filled Mammary Implants, 100 cc, were used for this study. Devices were representative of sterile finished ----- cated with all recommended manufacturing processes utilizing - ----- raw materials and assembled with the thinnest smooth shell thickness--- -----The shell thickness requirement was chosen to fulfill criteria for direct ----- n to a previously acquired database. All devices were obtained from the same manufacturing lot.

Cyclic fatigue testing was conducted on control devices that were not subjected to iatrogenic events to establish a basis for comparison to devices subjected to iatrogenic events described below. In addition it was necessary to demonstrate that the manufacturing lot used for iatrogenic events exhibited a fatigue lifetime similar to a previous manufacturing lot for which complete testing had been performed and resultant lifetime estimated.<sup>5,6</sup> In this manner a direct calculation could be utilized to determine the effect of an iatrogenic event on the lifetime of an implant.

Simulation of surgical insertion procedure was performed by a trained plastic surgeon using a simulation insertion fixture.<sup>7</sup> This apparatus consists of a test stand with retainin----- cm diameter) in which a sheet of nylon reinforced silicone elastomer ----- is mounted. An incision ~2.5 cm was prepared in the center of the el----- -----t using a #15 scalpel blade. The surgeon lubricated

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the device with water and inserted using an index finger and repeatedly pressing the implant radius through the incision.<sup>8</sup> Simulated surgical insertion was performed with three replicate devices.

Sharp instrument damage was simulated with scalpel in the radius region of the device. The scalpel damage was placed on shell parallel to the radius using a #15 scalpel blade (Bard-Parker). Two variations of scalpel damage were induced. Minor scalpel damage was achieved with a surface scratch ~1.0 in length and ~0.0005 in depth. Major scalpel damage was achieved with puncture through the shell ~0.25 in length. One replicate device was subjected to each variation of this iatrogenic event.

Suture needle puncture was performed to penetrate the device shell. A precision cosmetic PC-3 suture needle (Ethicon) was used to place the puncture on the radius region of the device shell.

Mammography was simulated using a mammograph (Philips Diagnostic Model 3000) and repeatedly performed on an implant to accumulate 40 events. A trained radiology technician performed the diagnostic procedure.<sup>9</sup> Accordingly mammography simulation would represent device implantation of 40 years if the diagnostic procedure were performed annually. A craniocaudal bilateral view and mediolateral bilateral oblique view were obtained for each event representing horizontal and vertical compression on the radial axis of the implant respectively. Since the device cannot be supported for the vertical projection a 90° rotation was performed to obtain compression for the mediolateral view. Paddle compression load and gap were measured and recorded for each event. An x-ray was photographed for the first event for each view. Simulated mammography was performed for three two devices.

Following simulated iatrogenic events devices were subjected to fatigue testing to measure cycles-to-failure. This test was chosen to facilitate the effect on implant fatigue lifetime. Previously devices fabricated with minimal shell thickness have been characterized with cyclic fatigue analysis to generate complete cycles-to-failure and endurance limit behavior.<sup>5,6</sup> Results were used to calculate a fatigue lifetime for the implant combined with in vivo stress and estimates of physical activity. Accordingly a database has been developed for direct correlation to results obtained from this study. Fatigue testing was performed with a servohydraulic tester equipped with in vitro test chamber and parallel plate fixture. Fixture and device were immersed in saline at 37 °C. Polyurethane foam was placed between the fixture parallel plates and device to minimize abrasion. The instrument was operated in load control with 40 lb maximum load at frequency  $f=1$  and 5 Hz. Cycles-to-failure were measured for each test. Failure mode was recorded including shell thickness at failure location. Cycle dependent load and position were monitored for each test. The percent change for cycles-to-failure compared to control devices was applied directly to the previously calculated fatigue lifetime.<sup>6</sup> Statistical calculations for mean, standard deviation

and coefficient of variation were performed for replicate determinations. Statistical comparison of variance and mean (F-test and t-test) for control and iatrogenic event device data was also calculated.

## **5.0 RESULTS**

Cyclic fatigue test raw data is compiled in Appendix D Raw Data (Section 1 Cyclic Fatigue Test Raw Data for Control Implants, Section 2 Cyclic Fatigue Test Raw Data for Surgical Insertion Procedure Implants, Section 3 Cyclic Fatigue Test Raw Data for Scalpel Damage Implants, Section 4 Cyclic Fatigue Test Raw Data for Suture Needle Damage Implants and Section 5 Cyclic Fatigue Test Raw Data for Mammography Implants). This includes a listing of experimental parameters for instrument control and data acquisition, plots of position and load dependent cycles-to-failure and an illustration of device failure conditions (mode, location and shell thickness). In addition photographs of scalpel and suture needle sharp instrument damage prior to and following fatigue testing and x-ray photographs from mammography obtained from the first event are included in the relevant appendix sections.

Results are compiled in Appendix D Results and Calculations (Section 1 Cyclic Fatigue Test Results for Control Implants, Section 2 Cyclic Fatigue Test Results for Surgical Insertion Procedure Implants, Section 3 Cyclic Fatigue Test Results for Scalpel Damage Implants, Section 4 Cyclic Fatigue Test Results for Suture Needle Damage Implants and Section 5 Cyclic Fatigue Test Results for Mammography Implants). Statistical calculations for mean, standard deviation and coefficient of variation for replicate determinations are included. Data set comparisons (F-test and t-test) are presented for control and iatrogenic device tests.

A summary of results is listed in Tables I-V.

## **6.0 DISCUSSION**

Cyclic fatigue test results for control implants are summarized in Table I. A mean cycles-to-failure of ~695,000 was measured. Relative standard deviation of ~56 % is typical of fatigue testing. Failure modes characterized by macroscopic tears located on the device radius are typical of fatigue testing. Statistical evaluation of cycles-to-failure data obtained with 40 lb maximum load showed no significant differences compared to data obtained previously with a different manufacturing lot. Previous testing entailed measurement of cycles-to-failure for several load amplitudes, determination of run out load amplitude and estimation of fatigue lifetime.<sup>6</sup> The results indicated a fatigue lifetime of ~109 years for Smooth Round Moderate Profile Gel-Filled Mammary Implants. These results are directly applied to results from the current testing such that any differences for cycles-to-

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failure can be used to estimate the affect on lifetime from iatrogenic events investigated. It is assumed that any reduction of cycles-to-failure observed for iatrogenic events is directly proportional to the fatigue lifetime of devices that have not been subjected to iatrogenic events. However it should be noted that the current test condition utilizing 40 lb maximum load is accelerated relative to the in vivo load estimated for calculation of a fatigue lifetime. Accordingly this represents a worst case assessment and resultant lifetime affects from iatrogenic events may be longer than estimated.

Cyclic fatigue test results for simulated surgical insertion procedure are summarized in Table II. A mean cycles-to-failure of ~935,000 was obtained. Relative standard deviation of ~47 % is typical of fatigue testing. Failure modes characterized by macroscopic tears located on the device radius are typical of fatigue testing. Statistical evaluation of cycles-to-failure data showed no significant differences compared to control implants. Accordingly simulated surgical insertion procedure does not affect the implant fatigue lifetime.

Cyclic fatigue test results for induced scalpel damage are summarized in Table III. Minor scalpel damage achieved with a surface scratch ~1.0 in length and ~0.0005 in depth yielded a cycles-to-failure of ~939,000. Failure mode was characterized by a macroscopic tear located on the device radius is typical of fatigue testing however the failure did not occur at the site of scalpel damage. Consequently this result is considered to show no difference compared to the control implant and no affect on fatigue lifetime. Major scalpel damage achieved with a puncture through the shell ~0.23 in length yielded cycles-to-failure of ~7,000. Failure mode was characterized by a macroscopic tear located on the device radius at the site of scalpel damage. Consequently this iatrogenic event yielded a loss of ~99 % of fatigue endurance resulting in a lifetime of ~1 year. Further testing is recommended to evaluate a variety of scalpel damage events.

Cyclic fatigue test results for induced suture needle damage are summarized in Table IV. Needle puncture yielded cycles-to-failure of ~2,400. Relative standard of ~10 % is typical of fatigue testing. Failure mode was characterized by a macroscopic tear located on the device radius at the site of suture damage. Consequently this iatrogenic event yielded a loss of ~99.6 % of fatigue endurance resulting in a lifetime of ~0.4 years.

Cyclic fatigue test results for simulated mammography diagnostic procedure are summarized in Table V. A mean cycles-to-failure of ~952,000 was obtained. Relative standard deviation of ~109 % is greater than typical fatigue testing and further testing is needed to confirm this result. Failure modes characterized by macroscopic tears located on the device radius are typical of fatigue testing. Statistical evaluation of cycles-to-failure data showed no significant differences compared to control implants. Accordingly simulated mammography diagnostic procedure does not affect the implant fatigue lifetime.

## 7.0 CONCLUSION

The effect of iatrogenic events has been investigated for Smooth Round Moderate Profile Gel-Filled Mammary Implants. This entailed evaluation of surgical insertion procedure, scalpel damage, suture needle damage and mammography diagnostic procedure. Cyclic fatigue testing was conducted to determine the effect on implant fatigue lifetime. Conclusions are summarized below.

- Control devices used for this study showed no significant differences for cycles-to-failure compared to devices tested previously. Accordingly direct comparison to estimated fatigue lifetime for previously tested devices has been demonstrated.
- Simulated surgical insertion procedure showed no significant differences for cycles-to-failure compared to control devices. Accordingly the surgical procedure has no effect on fatigue lifetime.
- Minor scalpel damage to device shell showed no significant differences for cycles-to-failure compared to control devices. Accordingly minor scalpel damage has no effect on fatigue lifetime. Major scalpel damage showed a reduction of cycles-to-failure compared to control devices. Accordingly a loss of ~99 % fatigue lifetime was observed resulting in an estimated lifetime of ~1 year.
- Suture needle damage showed a reduction for cycles-to-failure compared to control devices. Accordingly a loss of ~99.6 % fatigue lifetime was observed resulting in an estimated lifetime of ~0.4 years.
- Simulated mammography diagnostic procedure showed no significant differences for cycles-to-failure compared to control devices. Accordingly the diagnostic procedure has no effect on fatigue lifetime.

## 8.0 ACKNOWLEDGEMENTS

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Table I Cyclic Fatigue Test Results for Control Implants

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Frequency (Hz)	Failure Mode				Principle Stress (psi)	
					Failure Location and Orientation			Description (in)		Thickness (in)
					Top	Radius	Bottom			
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
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-	-----	-	-	-	-	-	-	-	-----	-----
CV	0.56								0.06	0.06

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Table II Cyclic Fatigue Test Results for Surgical Insertion Procedure Implants

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Frequency (Hz)	Failure Mode				Principle Stress (psi)	
					Failure Location and Orientation			Description (in)		Thickness (in)
					Top	Radius	Bottom			
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
---	-----	---	---	--	-	-	-	-	-----	-----
-	-----	-	-	-	-	-	-	-	-----	-----
CV	0.47								0.03	0.03

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Table III Cyclic Fatigue Test Results for Scalpel Damage Implants

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Frequency (Hz)	Failure Mode				Principle Stress (psi)	
					Failure Location and Orientation			Description (in)		Thickness (in)
					Top	Radius	Bottom			
Minor Scalpel Damage Shell Surface Scratch ~1.0 in length ~0.0005 in depth										
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
Major Scalpel Damage Shell Puncture ~0.23 in length										
041009	7,000	40	30	5	Horizontal	Horizontal-	-----	-----	-----	

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Table IV Cyclic Fatigue Test Results for Suture Needle Damage Implants

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Frequency (Hz)	Failure Mode				Principle Stress (psi)	
					Failure Location and Orientation			Description (in)		Thickness (in)
					Top	Radius	Bottom			
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
---	-----	---	---	--	-	-	-	-	-----	-----
-	-----	-	-	-	-	-	-	-	-----	-----
CV	0.10								0.03	0.03

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Table V Cyclic Fatigue Test Results for Mammography Implants

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Frequency (Hz)	Failure Mode				Principle Stress (psi)	
					Failure Location and Orientation			Description (in)		Thickness (in)
					Top	Radius	Bottom			
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
041014	216,040	40	30	1	Verticle	Verticle	-----	-----	-----	
--	-----	---	---	--	-	-	-	-	-----	
-	-----	-	-	-	-	-	-	-	-----	
CV	1.09							0.07	0.07	