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REPORT M 028 FINAL

**PARALLEL PLATE CYCLIC FATIGUE ANALYSIS OF GEL-FILLED
MAMMARY IMPLANTS**

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1.0 TITLE

PARALLEL PLATE CYCLIC FATIGUE ANALYSIS OF GEL-FILLED MAMMARY IMPLANTS

2.0 ABSTRACT

Cyclic fatigue analysis of Siltex[®] and Smooth Round Moderate Profile Gel-Filled Mammary Implants is conducted using a servohydraulic tester equipped with *in vitro* test chamber and fixture. The resulting data are used to estimate a fatigue lifetime for these devices related to *in vivo* load and stress associated with physical activity.

Experimentation includes monotonic servohydraulic testing and cyclic servohydraulic testing of devices and electromechanical stress-strain testing of the material composing the device shell. Monotonic servohydraulic testing of devices is conducted to identify the appropriate conditions for cyclic testing. In addition, the monotonic servohydraulic testing provides calibration data that are needed for interpreting the results of the cyclic tests. Cyclic servohydraulic testing is conducted to evaluate the fatigue behavior of devices and the results are used for estimation of a device fatigue lifetime. Electromechanical testing of the material composing the device shell is undertaken to provide data on its stress-strain behavior.

Cyclic fatigue testing of devices is performed under load control at several load levels to define the cycles-to-failure behavior. These tests are continued until the device fails by rupture or until 10^7 cycles of load have elapsed. The test fixture and chamber used for cyclic fatigue testing is designed to provide *in vitro* stressing of the devices at 37 °C. A uniaxial compression parallel plate test fixture is used to compress the device and therefore cause tensile stress at the outer radius of the device. Cyclic testing is performed in most cases at a frequency of $f=1$ Hz, considered to be representative of *in vivo* loading of devices. In addition, some tests are performed at an accelerated frequency ($f=5$ Hz) to minimize experimental time requirements. Comparison of the results from testing at $f=1$ Hz and $f=5$ Hz is undertaken at a moderate stress level for validation of the accelerated frequency condition.

Monotonic servohydraulic testing reveals that cyclic testing is performed in the regime of prosthesis behavior involving limited nonlinear response. Cyclic results indicate that cyclic fatigue data for mammary implants can be used to estimate a

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fatigue lifetime for devices *in vivo*. Comparison of $f=1$ Hz and $f=5$ Hz data shows no frequency dependence.

The *in vivo* stress amplitude in device shells associated with the most common physical activity of walking, jogging and running is estimated to be as high as 8.6 psi. Load amplitudes associated with activities such as lying face down, embracing another person, *etc.* are estimated to cause compressive loads of 5 lb *in vivo*. The possibility of wrinkles forming at the outer radius of the prosthesis is considered and the action of such wrinkles appearing and disappearing is estimated to cause tensile stress amplitudes of 20 psi. Wrinkling and unwrinkling is considered to accompany other physical activities such as walking.

A Basquin-Gerber equation, a log-log relationship between the load or stress amplitude during cycling and the number of cycles to failure, is established for the implants and the material composing their shells. This relationship can be used to determine the fatigue lifetime at any specified level of device loading or stressing. It is found that the fatigue lifetime of the devices is 8.07×10^8 to 1.44×10^9 cycles of loading by walking, jogging and running and 4.87×10^9 to 1.25×10^{11} cycles of lying face down, embracing and similar activities. On the assumption that an implant recipient walks at most 10 hours per day at 1 pace per second and goes through no more than 1,000 actions per day of lying face down, embracing and related activities, it is determined that the fatigue life of an implant *in vivo* based on these assumptions is 61 to 109 years.

3.0 INTRODUCTION

Mammary implants experience various modes of mechanical loading, impact, and fatigue during their service life. Loads caused by normal everyday activities are a result of routine oscillatory movements like walking and jogging. These movements subject the shell of the implant to fatigue that occurs when it is repeatedly stressed or strained. This behavior can be investigated by cyclic fatigue testing, in which a cyclic compressive force is repeatedly applied to and removed from an intact, filled mammary implant until the device ruptures. The number of cycles a device can endure prior to rupture *in vitro* is an indication of the time the device can remain intact in the body. Thus, the experimental data, defining cycles-to-failure for a device, can be used for calculation of fatigue lifetime estimates for *in vivo* loading of the device. Moet and Hamdy *et al.* have reported studies conducted on silicone gel and saline-filled mammary prostheses which present an approach to implant lifetime estimation.¹⁻³ In addition, an FDA regulatory guidance document for breast implant device Premarket Approval (PMA) application recommends *in vitro* cyclic fatigue testing for estimation of the useful lifetime or long term reliability of implants.⁴

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In this report, results from *in vitro* mechanical tests carried out on Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Impl-----
----- r products manufactured with -----
----- raw materials representing the minimum model volume and shell thickness. Experimentation includes monotonic loading servohydraulic testing and cyclic loading servohydraulic testing of devices and electromechanical stress-strain testing of the material composing the device shell. Monotonic loading servohydraulic testing is conducted to identify the appropriate conditions for cyclic testing and to measure device dimensions at various compression loads. Cyclic loading servohydraulic testing is conducted to evaluate device fatigue behavior. An *in vitro* test chamber equipped with a uniaxial compression parallel plate fixture is used for compressive monotonic and cyclic fatigue testing. Electromechanical stress-strain testing of the material composing the device shell is undertaken to provide data on its mechanical behavior.

The resultant data are utilized for calculation of implant fatigue lifetimes. A Basquin-Gerber equation,⁵ a log-log relationship between the stress or load amplitude and the number of cycles to failure, is established as a lower bound to the experimental data. The Basquin-Gerber equation allows extrapolation of the measured fatigue data to cyclic load or stress levels encountered *in vivo* due to physical activities and thus can be used to estimate the fatigue life of the implanted device in response to these physical activities. The assessment requires the derivation of an *in vivo* model that estimates the stress and frequency of physical activity such as walking or jogging, and such models are presented.

4.0 EXPERIMENTAL

A detailed description of the experimental procedure is listed in Appendix A (Section 1 Protocol M 028). All sample identification and preparation information is compiled in Appendix B (Sample Information Section 1 Sample List and Section 2 Manufacturing Quality Control Data). Analysis samples are selected from Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants (100 ----- es are manufactured with ----- shell dispersion and gel filler-----bly are fabricated with the minimum shell thickness specification ----- Devices represent sterile finished products that have undergone all ----- ded manufacturing processes.

4.1 Electromechanical Stress-Strain Testing

Electromechanical stress-strain testing of the material composing the device shell is performed to determine shell tensile properties. Test specimens are prepared

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from three devices in duplicate (n= 6). Instrumentation (Instron 4200), grips, extensometer and experimental conditions are described in Test Method 348.⁶

4.2 Monotonic Servohydraulic Compression Testing

Monotonic servohydraulic compression testing is performed to determine the response characteristics of devices. The parallel plate compression test fixture is used for monotonic testing. Foam sheeting is placed between the device and the parallel plates to minimize abrasion of the device surface during the test.

Monotonic compression testing is conducted in load control until failure occurs. The load range used is ~0-500 lb at a loading rate of 0.25 lb/s. Load and parallel plate positions are monitored during the test. Three replicate devices are tested for Smooth and Siltex Round Moderate Profile Gel-Filled Mammary Implants. The failure mode, failure location and envelope thickness at failure site are recorded in addition to the applied compressive load and the relative displacement of one parallel plate towards the other. In some tests, device dimensions (outer diameter, contact diameter and parallel plate gap) are measured during monotonic compression testing relative to the applied load.

4.3 Cyclic Servohydraulic Compression Testing

Cyclic servohydraulic compression testing is conducted to determine the number of fatigue cycles-to-failure for devices at various cyclic loads. Experimental design is achieved with reference to Society of Automotive Engineers and American Society for Testing and Materials practices.⁷⁻⁹ The servohydraulic instrument (Instron 8511 and 8872), consisting of load frame, actuator, hydraulic pump, load cells, control panel and data station, is described in Protocol M 028 (Appendix A). The tester is equipped with an *in vitro* test chamber. A uniaxial test fixture is used with the test chamber and is illustrated in Figure 1. The uniaxial fixture is comprised of stainless steel parallel plates between which the device is compressed. A Plexiglas chamber houses the fixture and contains circulated physiologic saline at T= 37 °C to simulate *in vivo* thermal effects. Devices are thermally equilibrated for four hours prior to commencement of a test. Foam sheeting is placed between the device and fixture to minimize abrasion and simulate *in vivo* tissue effects. The chamber is mounted on the load cell attached to the load frame and the upper parallel platen is attached to the load frame actuator.

The servohydraulic compression tester is operated in load control at a frequency $f= 1$ Hz. Several cyclic load amplitudes are investigated and cyclic loading continued until device failure occurs or until 10^7 cycles of loading have elapsed. The peak loads for cyclic compression are selected from 20 lb, 25 lb, 30 lb, 40 lb, 50 lb, 60 lb, 80 lb and 100lb. A 10 lb holding load is imposed for each experiment

to prevent movement of the device during testing and this represents the minimum compression during load cycling. The load amplitude during cycling is therefore the peak load for the cycle minus 10lb. Prior to each test, the feedback waveform is optimized to reproduce the command waveform through proportional integral derivative adjustment. The peak load, the maximum and minimum gap between the parallel plates during cycling and the number of cycles-to-failure are monitored. The failure mode, failure location and shell thickness at the failure site are also recorded. The protocol calls for a minimum of three devices to be tested at each load level, but in some cases only 1 or 2 tests are completed. Complete cycles-to-failure testing or testing to 10^7 cycles is conducted on Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants.

Some testing is performed at an accelerated frequency of $f=5$ Hz to minimize experimental time requirements. For example, the cyclic compression testing at a load level that does not result in device failure within 10^7 cycles of loading is carried out at a frequency of $f=5$ Hz. Three devices each were tested at $f=5$ Hz at load amplitudes low enough to allow them to survive without failure to 10^7 cycles for Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants. To validate the accelerated testing, some cyclic compression experiments are carried out at $f=5$ Hz to measure the number of cycles-to-failure at moderate loads, repeating some of the evaluations already carried out at $f=1$ Hz. Three replicate devices were tested at $f=5$ Hz to obtain results for comparison to those obtained at the lower frequency.

In addition to the monotonic compression and cyclic compression testing of Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants, testing is also being carried out on Siltex and Smooth Round High Profile Gel-Filled Mammary Implants. The testing of Siltex and Smooth Round High Profile Gel-Filled Mammary Implants work is in progress. However, results available so far from the testing of Siltex and Smooth Round High Profile Gel-Filled Mammary Implants are included in the appendices below for informational purposes. These data are not analyzed in this report but only included in the appendices for completeness.

5.0 RESULTS

Electromechanical stress-strain test data are compiled in Appendix C Raw Data Section 1 (Electromechanical Testing of Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants). These data include ultimate tensile strength and elongation, stress at 100 %, 200 % and 300 % elongation, rupture energy and Young's modulus. Load dependent displacement is plotted with modulus assignment. Statistical calculations for mean, standard deviation and coefficient of variation are compiled in Appendix D Results and Calculations

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Section 2 (Electromechanical Testing of Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants).

Monotonic servohydraulic compressive test data are compiled in Appendix C Raw Data Section 2 (Monotonic Compression Testing of Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants). These data include a listing of experimental parameters and position dependent load plots and an illustration of the device failure condition (mode, location and thickness). Statistical calculations for mean, standard deviation and coefficient of variation are listed in Appendix D Results and Calculations Section 2 (Monotonic Compression Testing of Siltex Round Moderate Profile Silicone Gel-Filled Mammary Implants). In addition, load dependent data acquired for device dimensions including outer diameter, parallel plate gap and contact diameter pertaining to each cyclic load utilized with fatigue testing are presented.

Cyclic servohydraulic compressive test data are compiled in Appendix C Raw Data Sections 3-6 (Cyclic Fatigue Testing of Siltex and Smooth Round Moderate Profile and High Profile Gel-Filled Mammary Implants). These data include a listing of experimental parameters concerning instrument control and data acquisition, plots of position and load dependent cycles-to-failure and an illustration of the device failure condition (mode, location and thickness). Statistical calculations for mean, standard deviation and coefficient of variation pertaining to $f=1$ Hz and $f=5$ Hz frequency testing and data set comparisons (F-test and t-test) are listed in Appendix D Results and Calculations Section 3 (Cyclic Fatigue Testing of Siltex and Smooth Round Gel-Filled Mammary Implants).

5.1 Results from Electromechanical Stress-Strain Testing

Tensile test results for the material composing the device shells are listed in Appendix D Section 1 Tables I and II for Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants respectively. Tensile strength and Young's modulus (at zero strain) are approximately 850 psi and 225 psi respectively for Siltex Round Moderate Profile Gel-Filled Mammary Implants. Tensile strength and Young's modulus (at zero strain) are approximately 1750 psi and 450 psi respectively for Smooth Round Moderate Profile Gel-Filled Mammary Implants.

5.2 Monotonic Servohydraulic Compressive Testing

Monotonic compression test results for devices are listed in Tables I and II and illustrated in Figure 2 for Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants. Devices are assembled in the parallel plate fixture and compressed until failure occurs. Failure is observed at approximately 450 lb and

375 lb for Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants respectively. The plot shown in Figure 2 provides the compressive load during the test as a function of the position (*i.e.* relative displacement) of the actuated parallel plate relative to an arbitrary datum above the test fixture (see Figure 1). Moderate nonlinearity is observed in the plot of load versus the relative displacement of the parallel plates for the load range 0-100 lb inclusive in all cases. Significant stiffening in the load-displacement response is observed at approximately 100 lb compression leading to an enhanced departure from linear behavior. Accordingly, the maximum load values chosen for cyclic compressive testing (20-100 lb) are within the regime of moderate nonlinearity of the device response in terms of the applied compressive load versus the displacement of the parallel plates. The standard deviation for replicate determinations for all these data is <10 %, indicating acceptable precision.

Additional monotonic tests are conducted to measure device dimensions at various compression loads. Device outer diameter and parallel plate gap are recorded for each load and used for stress calculations as described below. The results for Siltex and Smooth Moderate Profile devices are summarized in Tables III & IV, where, for each type of prosthesis tested, the measured device outer diameter D and the gap h between the parallel plates are listed as a function of the applied compressive load.

5.3 Cyclic Servohydraulic Testing

Cyclic fatigue test results are listed in Tables V-VIII and illustrated in Figures 3-6. A typical fatigue test result for the maximum and minimum compression as a function of the number of load cycles is shown in Figure 3. It can be seen that the maximum compression increases and minimum compression decreases during the early part of the test until device response attains a steady state at around 10^3 cycles. This phenomenon is attributable to adjustments of the device compliance during the initial cycles and the effect this has on the instrumentation and control system. This transient in the results establishes a criterion for acceptance of the results of a test: if device failure occurs before steady state behavior occurs, the result is rejected and not used in the fatigue lifetime study. Note, however that rejected results are included in the data provided in the appendices. After the initial transient in the device behavior has disappeared, the load control used during the experiment ensures that there is no further change of the minimum and maximum compression for the rest of the test, as can be confirmed from inspection of Figure 3.

Figure 4 shows the position of the plate at minimum and maximum compression during cyclic loading plotted against the number of elapsed load cycles for the same test used to provide the results illustrated in Figure 3. It can be seen that during the transient loading stage of about 10^3 cycles, the position of the plate at

minimum compression gradually rises while its position at maximum compression steadily falls. Comparison of Figure 4 with Figure 3 suggests that this behavior is largely tracking the load adjustments occurring during the transient loading stage. That is, as the minimum compressive load falls during the initial stage of the test, the effective strain across the device at minimum compression relaxes and as the maximum compressive load increases, the effective strain in the device at maximum compression increases in magnitude. However, after steady state loading behavior has been achieved at around 10^3 cycles, the position of the plate at maximum compressive loading continues to fall and the position of the plate at minimum compressive loading now also falls, with both phenomena occurring steadily during the remainder of the test. Such behavior during steady state loading indicates that device compliance is increasing as a result of fatigue.

Fatigue failure in cyclic compression testing is characterized by a macroscopic rupture (~0.5-2.0 in) located at the prosthesis outer radius and propagating towards anterior and posterior regions of the device. The number of cycles-to-failure data for $f=1$ Hz frequency testing are summarized in Table V for Siltex Round Moderate Profile Gel-Filled Mammary Implants and Table VI for Smooth Round Moderate Profile Gel-Filled Mammary Implants. The number of cycles-to-failure data for $f=5$ Hz frequency testing are summarized in Table VII for Siltex Round Moderate Profile Gel-Filled Mammary Implants and Table VIII for Smooth Round Moderate Profile Gel-Filled Mammary Implants.

Figures 5 & 6 show the load amplitude from the cyclic compression tests as a function of the number of cycles-to-failure. The data are plotted on logarithmic axes. Tests for which no failure occurred within 10^7 cycles of loading are plotted at $N=10^7$ where N is the number of cycles and these data points are marked as runouts. Figure 5 provides the results for Siltex Round Moderate Profile Gel-Filled Mammary Implants, Figure 6 is for Smooth Round Moderate Profile Gel-Filled Mammary Implants.

6.0 ANALYSIS OF RESULTS FROM CYCLIC COMPRESSION TESTING

It is commonly accepted that high cycle fatigue behavior of polymers, including silicone elastomers, can be represented by the Basquin relationship⁵

$$(1) \quad S_o = bN^c$$

where S_o is the applied load or stress amplitude, b and c are constants and N is the number of load or stress cycles at which fatigue failure occurs. However, the Basquin relationship is strictly for completely reversed cyclic loading in which the minimum load or stress is the negative of the maximum load or stress and the

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mean load or stress is zero. The cyclic experimental testing carried out for this report did not involve complete reversal of the applied load. However, the Gerber relationship⁵ and variants on it⁵ provides an equivalence between completely reversed cyclic loading and other types of cyclic loading such as is carried out for this report. Thus the Gerber relationship can be combined with the Basquin equation to provide a relationship that has the form of (1) but now allowing for load or stress cycling with a non-zero mean value. Thus equation (1) can be used to evaluate the experimental results presented in Section 5 of this report even though those data were obtained from cyclic compressive loading having a non-zero mean load. For this purpose, equation (1) will be termed the Basquin-Gerber relationship.

The parameters b and c of equation (1) are obtained by applying a best fit straight line to a log-log plot of the load or stress amplitude versus the number of cycles-to-failure. In this fit, the parameter S_o in equation (1) is interpreted as the load amplitude from the test. The Basquin-Gerber parameters resulting from linear regression fits are provided in Table IX.

It is also of interest to analyze the cyclic compression tests in terms of the highest tensile stress amplitude experienced by material in the device during cycling as this is the parameter most likely to control fatigue failure in the prosthesis. During monotonic compression, the highest tensile stress in the device is at the outer diameter at the point marked A in Figure 7. Consequently, during load cycling the highest tensile stress amplitude is at this location as well. The derivation of the stress at this location for the uniaxial parallel plate fixture is given in Appendix D Section 4 Part B Uniaxial Fixture Stress Derivation and found to be:¹⁰

$$(2) \quad \sigma = F(D^2 - d^2) / \pi t D d^2$$

where F is the applied compressive load, D is the device outer diameter, d is the diameter of device contact with the platen, h is the plate displacement gap and t is the shell thickness at the point A (see Figure 7). Since the contact diameter, d , was not measured in the experiments, the approximate relationship

$$(3) \quad d = D - h$$

is used to obtain values for this parameter. The values for d obtained from this formula at various loads during monotonic compressive loading for each type of device are listed in Tables III and IV. Since each replicate is assumed to have the same values for D , d and h at a given compressive load F , it is useful to calculate the membrane resultant N_A (force per unit length) at location A for each type of device for various applied loads as

$$(4) \quad N_A = F(D^2 - d^2) / \pi D d^2$$

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The results of calculations of N_A for each device at various compressive loads are provided in Tables III and IV. The tensile stress at location A for each replicate of a given type at the given compressive load can then be obtained by dividing N_A by the measured value of the shell thickness t at the location A. In cases where failure occurs during the test, the shell thickness t is measured at the location of the rupture. In cases where no failure occurs (*i.e.* runouts) the shell thickness t is measured by sectioning the shell at the outer diameter of the device after the test.

Results for calculation of the stress σ for each replicate of each device at various compressive loads are provided in the Tables V-VIII. These results are then used to compute tensile stress amplitudes $\Delta\sigma$ at the location A shown in Figure 7 in each replicate of each device type during compressive load cycling. The stress amplitudes are calculated as the tensile stress at A at maximum compressive load minus the tensile stress at A at the minimum compressive load of 10 lb. These stress amplitudes are listed for each tested sample in Tables V-VIII.

Figures 8 and 9 are plots of the stress amplitude $\Delta\sigma$ at location A from each cyclic compressive test versus the number of cycles-to-failure. The data are plotted on logarithmic axes. Tests for which no failure occurred within 10^7 cycles of loading are plotted at $N=10^7$ where N is the number of cycles and these data points are marked as runouts. Figure 8 provides the results for Siltex Round Moderate Profile Gel-Filled Mammary Implants, Figure 9 is for Smooth Round Moderate Profile Gel-Filled Mammary Implants.

The Basquin-Gerber relationship of equation (1) is used next as a best fit to the data in Figures 8 and 9 and such lines have been drawn in these diagrams. In this fit, the parameter S_a in equation (1) is interpreted as the stress amplitude at location A from the test. The Basquin-Gerber parameters resulting from linear regression fits are provided in Table X.

Accelerated frequency ($f=5$ Hz) cycles-to-failure results obtained for a moderate load conducted on Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants are summarized in Appendix D Section 3 Part A Table IV and Part B Table V. Comparison of $f=1$ Hz and $f=5$ Hz frequency data is listed in Appendix D Section 3 Part A Table VII and Part B Table VI. The t-test assuming unequal variances as determined from F-test indicates indistinguishable sample populations. Accordingly the accelerated frequency was validated for subsequent measurement of the fatigue behavior at lower applied compressive loads and larger numbers of cycles with a maximum load of 30 lb and 20 lb for Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants respectively.

7.0 ESTIMATION OF *IN VIVO* LOADS AND STRESSES

A breast implant experiences a multitude of stresses resulting from normal activities and body movements that are difficult to account for in detail. The most common activity likely to cause fatigue of breast prostheses is walking and other similar motions such as jogging or running. Such activities would cause stressing of the breast implant by causing an oscillatory motion of the chest that would interact with the inertia of the breasts, leading to stretching and unstretching of the shell material of the prosthesis. Another set of repeated activities that would cause significant loads to be applied to the device is lying face down on a hard surface, embracing another person and related intimate activities. An estimate of the loads and stresses on the prosthesis caused by these activities is provided below. One can imagine other loads being applied to the prosthesis in unusual circumstances such as when a person is in a tightly packed crowd, experiences an accident involving a heavy fall or is impacted by a foreign object. However, these loads will not be repeated sufficiently often to cause fatigue damage to the device. Since the device burst load in compression in the monotonic compression tests is at least 348 lb, it is likely that other trauma would accompany incidents sufficiently severe to fail the prostheses and therefore the victim would be in need of medical attention that would ensure that any leaking prosthesis would be identified and attended to.

The actions of walking and similar activities plus lying face down and related actions cause a direct loading of the prosthesis and its shell. Another source of stressing of the shell material may be wrinkles that form naturally due to the position adopted by the prosthesis relative to the surrounding tissue in its resting position. One can imagine such wrinkles forming in a vertical plane relative to the diagram in Figure 7 where the prosthesis is being supported in the case of wrinkling not by the parallel plates but by tissue around it providing lateral forces resisting gravity forces acting in a horizontal direction relative to Figure 7. One can imagine such wrinkles folding the shell material flat so that it is bent through 180°. Activities such as walking, running and jogging or lying face down and related actions may then cause repeated stressing of the shell material by eliminating the wrinkles and allowing them to reform cyclically. This possible source of stress will also be considered and quantified below.

7.1 Stress Caused by Walking, Jogging and Running

Walking, jogging and running induce fatigue loads oscillating between a maximum stretching of the device as the breast achieves its lowest position and a minimum as it reaches its highest location. Consider a person moving in such a

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way that the prosthesis moves in an oscillatory manner so that the height y of its center of gravity above a horizontal datum is given by

$$(5) \quad y = y_o + y_a \sin \omega t$$

where y_o is the mean position of the center of gravity above the datum, y_a is half the amplitude of the motion of the center of gravity of the prosthesis, ω is the frequency of the motion and t is the elapsed time. It follows that the upward acceleration a of the center of gravity of the prosthesis is given by

$$(6) \quad a = -\omega^2 y_a \sin \omega t$$

At the apex of the motion, when $\sin \omega t = 1$, the prosthesis is assumed to be free of constraint and thus its center of gravity must then have a downward acceleration of magnitude g . Thus

$$(7) \quad \omega^2 y_a = g$$

for all amplitudes and frequencies of motion. Consequently, the maximum upward acceleration, a_{max} , occurring when $\sin \omega t = -1$, is given by

$$(8) \quad a_{max} = g$$

The force applied to cause this acceleration is the mass, m , of the prosthesis times this acceleration. Such a force is thus equal to the weight of the prosthesis but is in addition to the upward force that must be applied to support the device's weight. Consequently, the maximum force, F_{max} , applied in an upward direction to the prosthesis during the actions of walking, jogging and running is given by

$$(9) \quad F_{max} = 2 m g$$

Now consider a prosthesis that is supported from the top by adhering to tissue supported by the ribcage. Imagine that it is attached by a patch of contact of edge length s and supported uniformly around the edge. It follows that the load per unit length transmitted to the prosthesis through the edge of the patch of contact is given by F_{max} divided by s . This force per unit length supports the prosthesis through the shell having thickness t . Thus the maximum tensile stress σ_a applied to the shell material by the action of walking, jogging or running is

$$(10) \quad \sigma_a = 2 m g / s t$$

As noted above, at the apex of the motion, it is assumed that zero loads are being applied to the prosthesis. Thus the stress in the shell membrane at this stage is

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zero. It follows that the applied stress amplitude $\Delta\sigma_a$ experienced by the shell material due to the actions of walking, jogging or running is

(11)
$$\Delta\sigma_a = 2 m g / s t$$

The largest weights ($m g$) of a prosthesis are approximately

- (a) Siltex Moderate Profile: 0.25 lb
- (b) Smooth Moderate Profile: 0.24 lb

The smallest thicknesses (t) of the shell wall are

- (a) Siltex Moderate Profile: 0.0185 in.
- (b) Smooth Moderate Profile: 0.0085

It is assumed that the support patch for the prosthesis is of the same size as the area of contact with the platens at zero load in the monotonic compression tests described in Sections 4 to 6 with results summarized in Tables III and IV. The smallest diameter of contact at zero load is thus estimated to be 2.1 in. and therefore s is taken to be equal to 6.6 in. Thus the estimates of the applied stress amplitude in the shell of the prosthesis due to running jogging and walking are

- (a) Siltex Moderate Profile: 4.1 psi
- (b) Smooth Moderate Profile: 8.6 psi

This figure is an overestimate because it is unlikely that the prosthesis is supported only by a patch adhering to tissue adjacent to the ribcage. It is more likely that support will be provided by tissue from below as well as laterally from the ribcage.

It will therefore be assumed that walking, jogging and running will cause stress amplitudes in the shell of the implant ranging from 4.1 psi or 8.6 psi, depending on device type.

7.2 Loads Caused by Lying Face Down, Embracing and Similar Actions

Clearly, it is possible to apply very large compressive loads to a breast implant by lying face down on a hard, flat surface, vigorously embracing another person and in related intimate activities. On the other hand, large loads will cause discomfort and the recipient of a prosthesis will avoid experiencing such loads repeatedly. Therefore, a reasonable estimate of repeated loadings possibly applied to the prosthesis in actions such as lying face down is the area fraction of the recipients

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weight projected through the implant. The planform area of an implant is approximately 9 sq. in., perhaps 5% of the silhouette area of a small person. This suggests a repeatedly applied compression of 5 lb is a reasonable figure for lying face down. It is assumed that other actions of a similar type such as embracing another person would lead to smaller compressive loads than 5 lb since deadweight is generally greater than forces that can be applied by muscular action.

It will therefore be assumed that actions such as lying face down, embracing and similar actions causes cyclic loads of up to 5 lb at maximum compressive load with zero minimum load. The compressive load amplitude is thus assumed to be 5 lb.

7.3 Stresses Caused by Wrinkling

The most severe wrinkle that can be created in a thin, flexible membrane is one in which material is folded sharply back upon itself. This deformation will cause extensional strains of order unity at the outside radius of the wrinkle. However, such severe wrinkles will be resisted by the bending stiffness of the shell membrane, which is small but sufficient to resist such severe bending of the material, especially since the loads causing the wrinkling are small. Therefore, we assume that the most severe wrinkle that will be repeatedly created and eliminated involves a strain of around 15%. Thus, wrinkles will be assumed to give rise to stress levels of 20 psi and a wrinkle will be assumed to cause 20 psi tension at the surface of the shell of the implant. When the wrinkle is flattened out, the stress in the material will fall to zero. It should be noted that this assumption implies that compressive stresses of 20 psi in magnitude will occur during wrinkling at the opposite surface of the shell membrane. Therefore, cycling as the wrinkle appears and disappears will involve tensile stress amplitudes in some locations and compressive stress amplitudes in other locations, but each of magnitude 20 psi. However, since silicone elastomer is a brittle polymer with little inelastic deformation, the compressive range of stressing is unlikely to be important in cyclic fatigue, in analogy to ceramics where compressive stresses are unimportant in the cyclic fatigue process.⁵

It will therefore be assumed that wrinkling and unwrinkling causes cyclic tensile stresses of 20 psi in amplitude.

8.0 ESTIMATION OF *IN VIVO* FATIGUE LIFETIMES

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The Basquin-Gerber relationship in equation (1) will be used to estimate the number of cycles the prosthesis can survive *in vivo* given the estimates of load and stress the implant experiences *in vivo* provided in the previous section.

8.1 Fatigue Lifetimes Calculated from Estimated *In Vivo* Loads and Stresses

8.1a Siltex Round Moderate Profile Silicone Gel Filled Implants

The load amplitude estimated for the implant for lying face down, embracing and similar actions is 5 lb (see Section 7.2). This value can be inserted as S_a in the Basquin-Gerber relationship, equation (1) and used to calculate a lifetime N in cycles that the implant can survive. With the Basquin-Gerber parameters for this implant taken from Table IX, the resulting lifetime estimate is 1.25×10^{11} cycles.

The stress amplitude estimated for this implant for walking, jogging and running is 4.1 psi (see Section 7.1). This value can be inserted as S_a in the Basquin-Gerber relationship, equation (1) and used to calculate a lifetime N in cycles that the implant can survive. With the Basquin-Gerber parameters for this implant taken from Table X, the resulting lifetime estimate is 9.94×10^{14} cycles.

The stress amplitude estimated for the implant for wrinkling and unwrinkling is 20 psi (see Section 7.3). This value can be inserted as S_a in the Basquin-Gerber relationship, equation (1) and used to calculate a lifetime N in cycles that the implant can survive. With the Basquin-Gerber parameters for this implant taken from Table X, the resulting lifetime estimate is 8.07×10^8 . This latter result is summarized in Table XI.

8.1b Smooth Round Moderate Profile Silicone Gel Filled Implants

The load amplitude estimated for the implant for lying face down, embracing and similar actions is 5 lb (see Section 7.2). This value can be inserted as S_a in the Basquin-Gerber relationship, equation (1) and used to calculate a lifetime N in cycles that the implant can survive. With the Basquin-Gerber parameters for this implant taken from Table IX, the resulting lifetime estimate is 4.87×10^9 cycles.

The stress amplitude estimated for this implant for walking, jogging and running is 8.6 psi (see Section 7.1). This value can be inserted as S_a in the Basquin-Gerber relationship, equation (1) and used to calculate a lifetime N in cycles that the implant can survive. With the Basquin-Gerber parameters for this implant taken from Table X, the resulting lifetime estimate is 4.13×10^{12} cycles.

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The stress amplitude estimated for the implant for wrinkling and unwrinkling is 20 psi (see Section 7.3). This value can be inserted as S_o in the Basquin-Gerber relationship, equation (1) and used to calculate a lifetime N in cycles that the implant can survive. With the Basquin-Gerber parameters for this implant taken from Table X, the resulting lifetime estimate is 1.44×10^9 . This result is summarized in Table XI.

9.0 DISCUSSION OF ESTIMATED *IN VIVO* FATIGUE LIFETIMES

Lifetimes are estimated in Section 8.0 for each of the device types for which fatigue data from the tests provide an adequate basis for estimation. The lifetimes are estimated in terms of numbers of cycles of two types of activities, namely running, jogging and walking on the one hand and lying face down, embracing and related intimate activities. The ancillary issue of wrinkling and unwrinkling of the shell of the implant is also considered; however the number of times that wrinkling and unwrinkling would occur is controlled by the prevalence of physical activities such as walking, jogging and running and lying face down, embracing and related activities. Therefore, it is necessary to make an estimate of how many paces per day are likely by an individual who is walking, jogging and running regularly and also how many times occur the actions of lying face down, embracing and related activities.

Consider a very active person who walks for 10 hours per day every day at 1 pace per second or runs 5 hours per day at 2 paces per second. This amounts to 1.31×10^7 paces per year. Therefore, with wrinkling taken to cause stress amplitudes of 20 psi, the fraction of the lifetime expended per year by the activities of this person walking, jogging and running is found to be:

- (a) Siltex Moderate Profile: $1.31 \times 10^7 / 8.07 \times 10^8 = 0.016$
(b) Smooth Moderate Profile: $1.31 \times 10^7 / 1.44 \times 10^9 = 0.0091$

If stress amplitudes due to wrinkling are absent or negligible wrinkling taken to be absent or negligible and therefore stress caused this activity is due to gravity and prosthesis acceleration, the fraction of the lifetime expended per year by the activities of this person walking, jogging and running is found to be:

- (a) Siltex Moderate Profile: $1.31 \times 10^7 / 9.94 \times 10^{14} = 1.32 \times 10^{-6}$
(b) Smooth Moderate Profile: $1.31 \times 10^7 / 4.13 \times 10^{12} = 3.17 \times 10^{-4}$

The activities of lying face down, embracing and related actions are more difficult to quantify. However, 10^3 times a day would seem to be a generous estimate for

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such activities, so this figure will be used. This amounts to 3.66×10^5 cycles per year, so that the fraction of the lifetime expended per year by the activities of this person lying face down, embracing and related activities is taken to be:

- (a) Siltex Moderate Profile: $3.66 \times 10^5 / 1.25 \times 10^{11} = 2.93 \times 10^{-6}$
(b) Smooth Moderate Profile: $3.66 \times 10^5 / 4.87 \times 10^9 = 7.52 \times 10^{-5}$

By the Palmgren-Miner linear damage rule⁵, the fraction of life expended in different stress and load conditions at a given material point can be simply summed. Furthermore, the process of wrinkling and unwrinkling will not occur where the gravity and acceleration loads during walking, jogging and running are highest because of the constraint of the tissue to which the prosthesis is attached. Thus the process of wrinkling and unwrinkling is the more critical fatigue process during walking, running and jogging because the stress amplitude so caused is assumed to be higher. On the other hand, wrinkling and unwrinkling will tend to occur at the prosthesis outer radius, where the stress amplitude due to compression loading will be greatest. Consequently, the Palmgren-Miner linear damage rule should be used to consider the combined effect of these 2 processes. Thus the fraction of life expended per year by a person who both walks, jogs and runs 10 hours per day and engages in 10^3 actions of lying face down, embracing and similar activities will exhaust the following fractions of the lifetime of a breast implant per year:

- (a) Siltex Moderate Profile: $0.016 + 2.93 \times 10^{-8} = 0.016$
(b) Smooth Moderate Profile: $0.0091 + 7.52 \times 10^{-7} = 0.0091$

Thus it can be seen that the exhaustion of the fatigue life is dominated by the more common activity of walking, jogging and running. Since the fraction of life used up by compression loading of the device is negligible, it follows that the fatigue lifetime can be considered solely in terms of the effects of wrinkling and unwrinkling. This situation is summarized in Table XII.

10.0 CONCLUSION

Cyclic fatigue testing of Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants has been completed using a servohydraulic tester equipped with an *in vitro* test chamber and fixture. Results indicate that the cyclic fatigue data can be used to estimate an implant fatigue lifetime. Conclusions are summarized below.

- Monotonic compression testing indicates that the cyclic compression testing carried out for this report is performed in the regime of device

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response in which the nonlinearity of response is moderate. Ultimate compression strength of the devices is approximately 450 lb and 375 lb for Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants.

- Cyclic fatigue testing at frequency $f=1$ Hz and $f=5$ Hz shows no significant differences.
- Cyclic compression testing of devices at low amplitudes of load is used to establish the load and stress amplitudes for which no failure occurs within 10^7 cycles of compression.
- A Basquin-Gerber relation is fitted to the cycles-to failure data for Siltex Round Moderate Profile Silicone Gel filled Implants and for Smooth Round Moderate Profile Silicone Gel filled Implants.
- Load and stress amplitudes *in vivo* are estimated for the activities of walking, jogging and running and lying face down, embracing another and related activities and due to the process of wrinkling and unwrinkling at the outer radius of the device.
- The Basquin-Gerber relations are used to show that based on the assumed *in vivo* load and stress amplitudes, the fatigue lives for Siltex and Smooth Round Moderate Profile Gel-Filled Mammary Implants are respectively 8.07×10^8 and 1.44×10^9 cycles of loading by walking, jogging and running and respectively 1.25×10^{11} and 4.87×10^9 cycles of lying face down, embracing and similar activities.
- On the assumption that an implant recipient walks at most 10 hours per day at 1 pace per second and goes through no more than 1,000 actions per day of lying face down, embracing and related activities, it is determined that the expenditure of fatigue life is dominated by walking, jogging and running.
- Based on the above experimental findings, analysis and assumptions, it is deduced that the fatigue life of an implant *in vivo* is from 61 to 109 years.

11.0 ACKNOWLEDGMENTS

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Table I Monotonic Compression Test Results: Siltex Round Moderate Profile Gel Mammary Implants

Sample Number	Maximum Load (lb)	Load Rate (lb/s)	Failure Mode				
			Failure Orientation			Description (in)	Thickness (in)
			Top	Radius	Bottom		
CV	0.07						0.02

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Table II Monotonic Compression Test Results: Smooth Round Moderate Profile Gel Mammary Implants

Sample Number	Maximum Load (lb)	Load Rate (lb/s)	Failure Mode				
			Failure Orientation			Description (in)	Thickness (in)
			Top	Radius	Bottom		
---	---	---	---	---	---	---	
---	---	---	---	---	---	---	
---	---	---	---	---	---	---	
---	---	---	---	---	---	---	
s	30					0.0000	
CV	0.08					<0.01	

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Table III Compression Dependent Device Diameter and Membrane Axial Resultant Force per Unit Length (N_A)
Siltex Round Moderate Profile Gel-Filled Mammary Implant

Applied Load (lb)	Device Diameter (D) (in)	Displacement Gap (h) (in)	d= D-h (in)	N_A (lb/in)
30	4.15	0.525	3.74	0.715
40	4.25	0.510	3.97	0.873
60	4.44	0.475	3.97	1.091
80	4.56	0.435	4.13	1.240
100	4.63	0.420	4.21	1.443

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Table IV Compression Dependent Device Diameter and Membrane Axial Resultant Force per Unit Length (N_A)
Smooth Round Moderate Profile Gel-Filled Mammary Implant

Applied Load (lb)	Device Diameter (D) (in)	Displacement Gap (h) (in)	$d = D - h$ (in)	N_A (lb/in)
20	4.11	0.538	3.57	0.502
30	4.21	0.510	3.70	0.668
40	4.32	0.480	3.84	0.784
50	4.42	0.452	3.97	0.866
60	4.53	0.423	4.11	0.913

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Table V Results of Cyclic Compression Tests on Siltex Round
Moderate Profile Gel-Filled Mammary Implants
Frequency 1 Hz

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Maximum Stress (psi)	Stress Amplitude (psi)
028904	909,231	60	50	57	42
028905	3,230,153	60	50	57	42
028906	1,625,707	60	50	57	42
028907	243,215	80	70	64	49
028908	145,172	80	70	60	46
028909	180,711	80	70	67	49
028910	71,112	100	90	72	58
028911	67,877	100	90	78	63
028912	79,493	100	90	78	63

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Table VI Results of Cyclic Compression Tests on Smooth Round Moderate Profile Gel-Filled Mammary Implants
Frequency 1 Hz

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Maximum Stress (psi)	Stress Amplitude (psi)
028934	16,527	60	50	101	68
028936	24,108	60	50	96	66
028937	8,482	60	50	96	66
028938	62,000	40	30	87	55
028939	418,773	40	30	83	53
028940	205,683	40	30	78	49
028942	326,656	30	20	61	35

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Table VII Results of Cyclic Compression Tests on Siltex Round
Moderate Profile Gel-Filled Mammary Implants
Frequency 5 Hz

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Maximum Stress (psi)	Stress Amplitude (psi)
028913	181,854	80	70	60	46
028914	308,098	80	70	64	49
028915	229,983	80	70	64	49
028916	6,949,964	40	30	47	32
028917	10,008,881 ^a	30	20	35	21
028918	10,070,029 ^a	30	20	39	24
028919	10,000,000 ^a	30	20	39	24

^a Runout

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Table VIII Results of Cyclic Compression Tests on Smooth Round
Moderate Profile Gel-Filled Mammary Implants
Frequency 5 Hz

Sample Number	Cycles (N)	Maximum Load (lb)	Load Amplitude (lb)	Maximum Stress (psi)	Stress Amplitude (psi)
028947	6,502,240	20	10	53	23
028949	1,228,684	40	30	92	58
028950	653,126	40	30	82	52
028952	754,300	40	30	75	48
028953	5,736,552	30	20	74	42
028941	10,269,871 ^a	20	10	53	30
028943	10,000,000 ^a	25	15	61	31
028948	10,099,402 ^a	20	10	53	23
028954	10,000,000 ^a	30	20	70	40

^a Runout

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Table IX Basquin-Gerber Parameters for Cyclic Compression Tests
Load Amplitude, ΔF , versus Cycles-to-Failure, N

Device	$\Delta F = bN^c$	
	b (lb)	c
Siltex Moderate Profile	828	-0.200
Smooth Moderate Profile	271	-0.179

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Table X Basquin-Gerber Parameters for Cyclic Compression Tests
Stress Amplitude, $\Delta\sigma$, versus Cycles-to-Failure, N

Device	$\Delta\sigma = bN^c$	
	b (lb)	c
Siltex Moderate Profile	203	-0.113
Smooth Moderate Profile	187	-0.106

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Table XI Fatigue Lifetime in Cycles

Based on Stress Amplitudes of 20 psi due to Folding
Calculated form the Basquin-Gerber Equation

Device	Cycles
Siltex Moderate Profile	8.07×10^8
Smooth Moderate Profile	1.44×10^9

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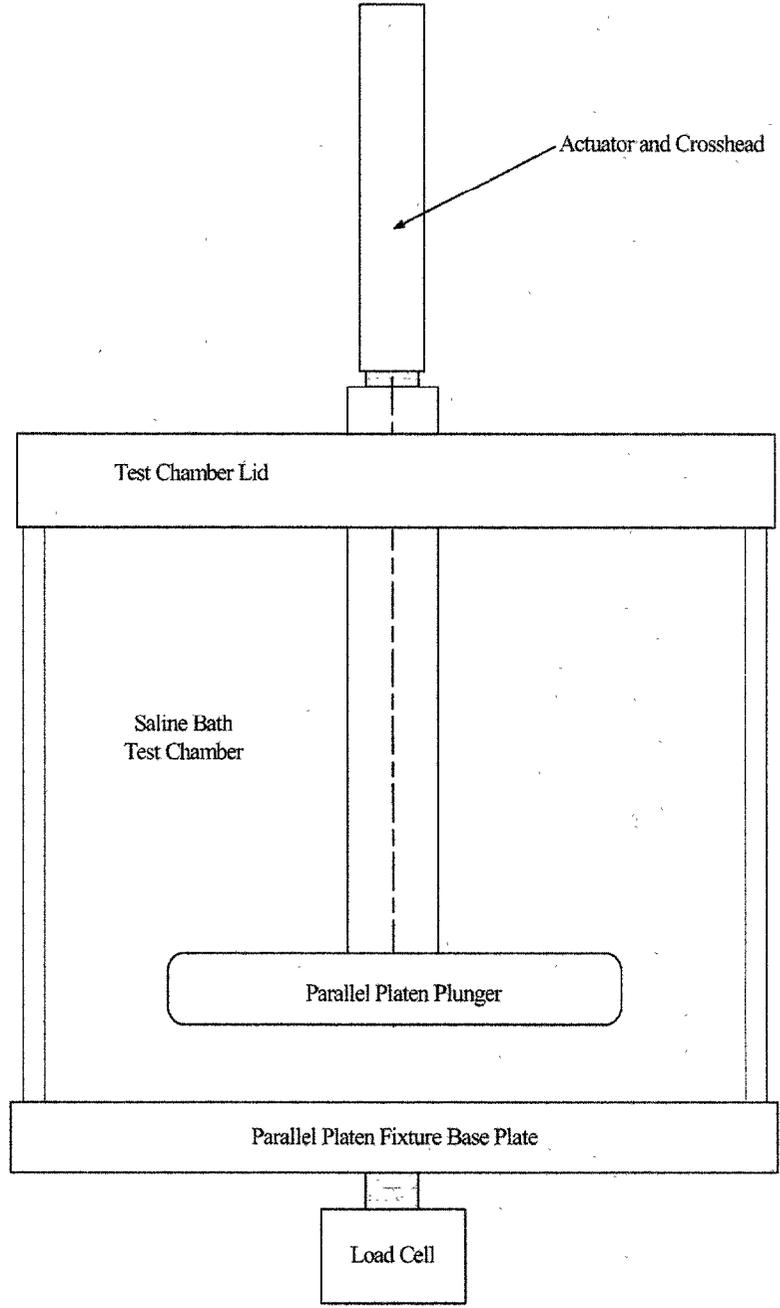
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Table XII Fatigue Lifetime in Years for a Very Active Person
Walking 10 hours per Day
Based on Stress Amplitudes of 20 psi due to Folding

Device	Years
Siltex Moderate Profile	61
Smooth Moderate Profile	109

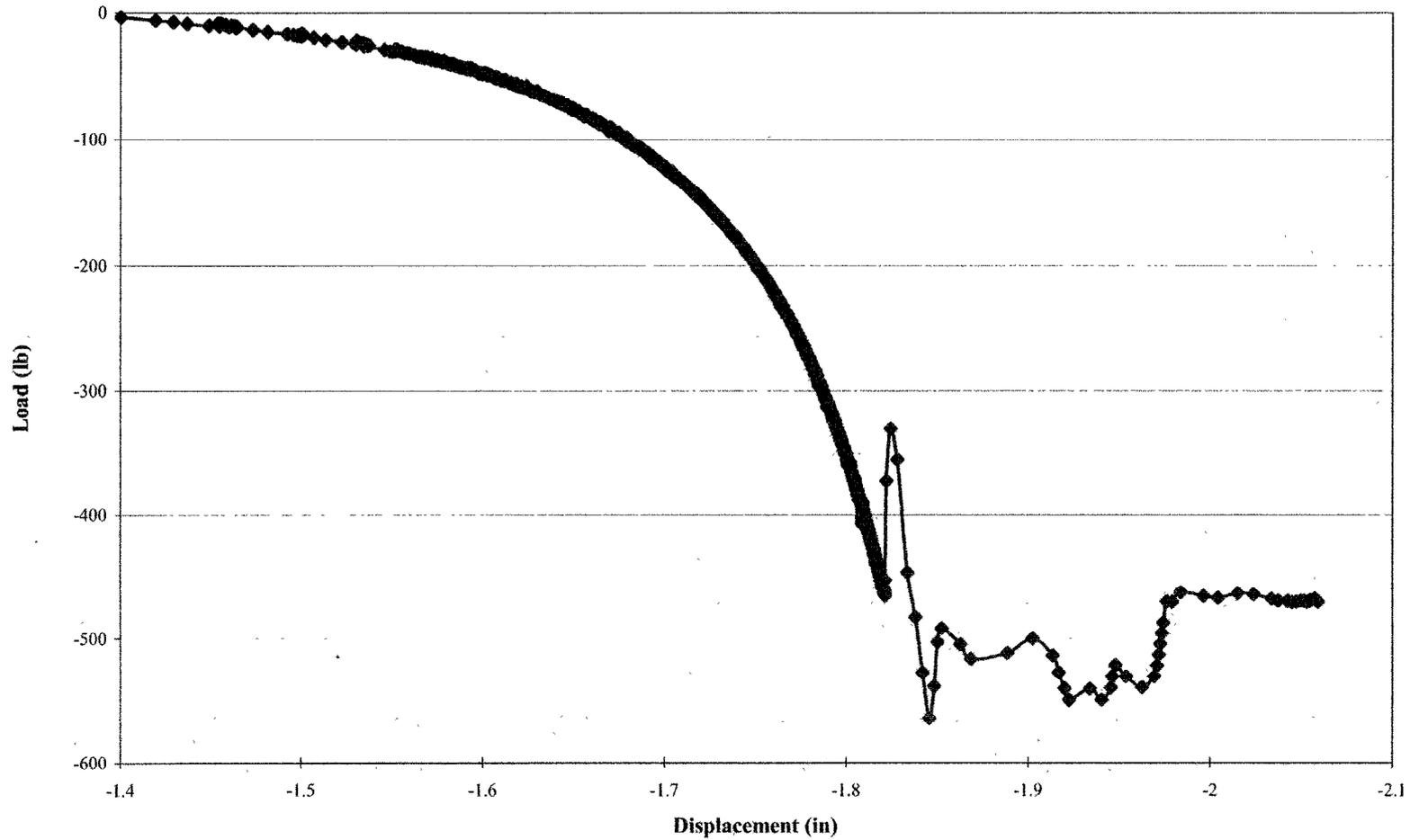
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Figure 1 Cyclic Fatigue Parallel Platen Test Fixture



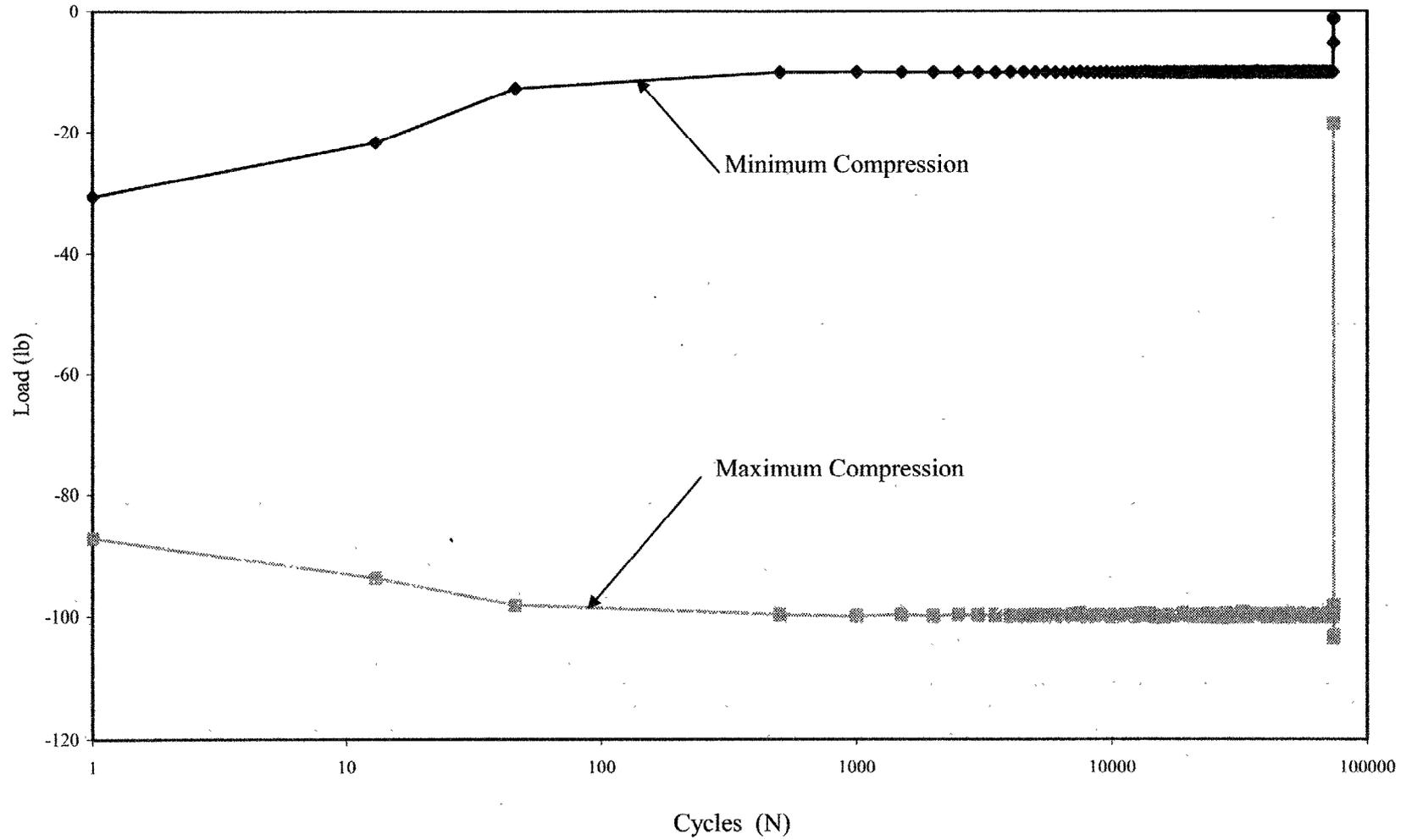
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Figure 2 Monotonic Compression Test: Plot of the applied compressive load as a function of the position of the actuated parallel plate. Position is measured relative to an arbitrary datum above the fixture (see Figure 1). Contact is made between the parallel plate and the device when the position is equal to -1.4 in.



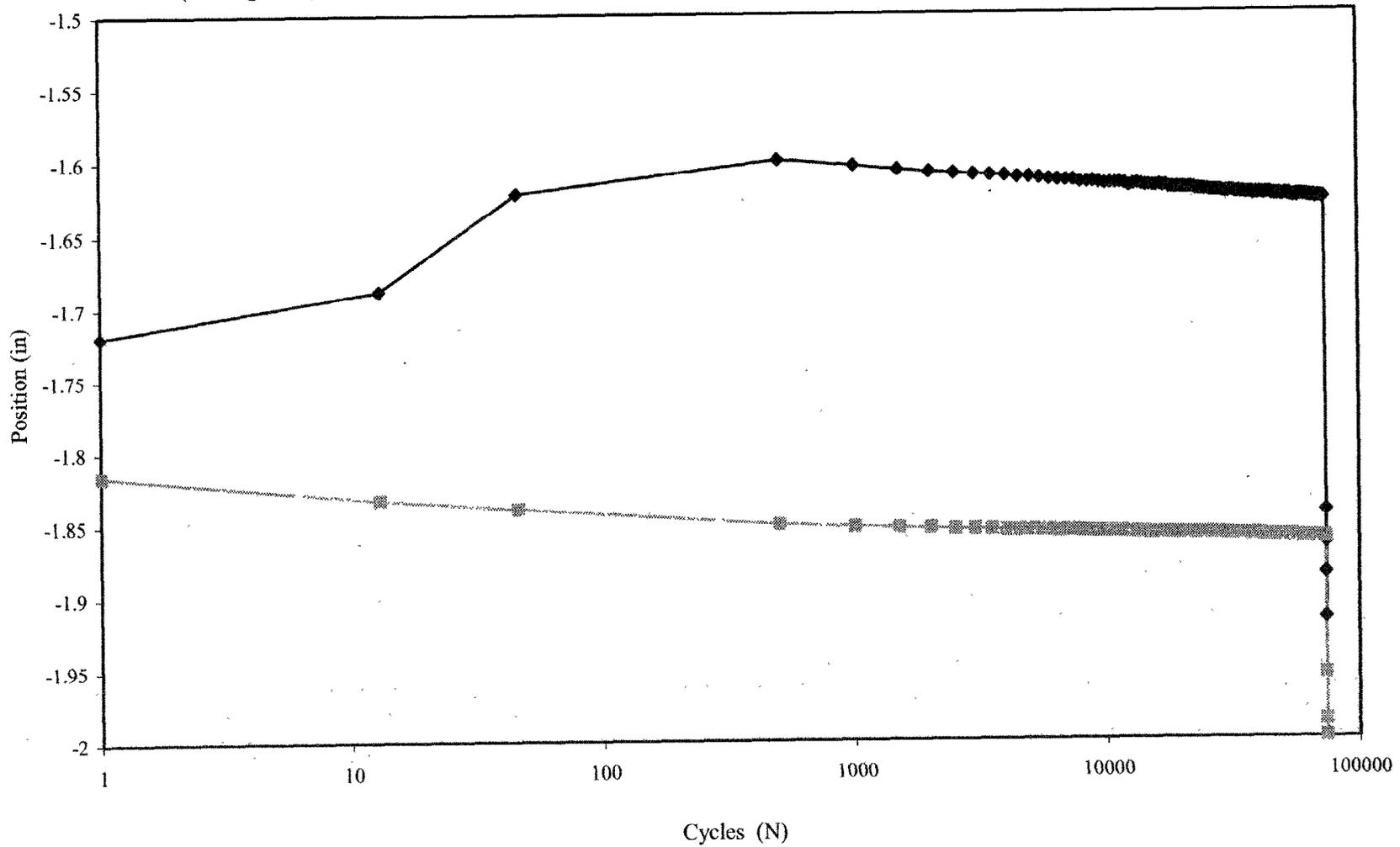
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Figure 3 Cyclic Fatigue Test: Plot of maximum and minimum compression load as a function of the number of load cycles.



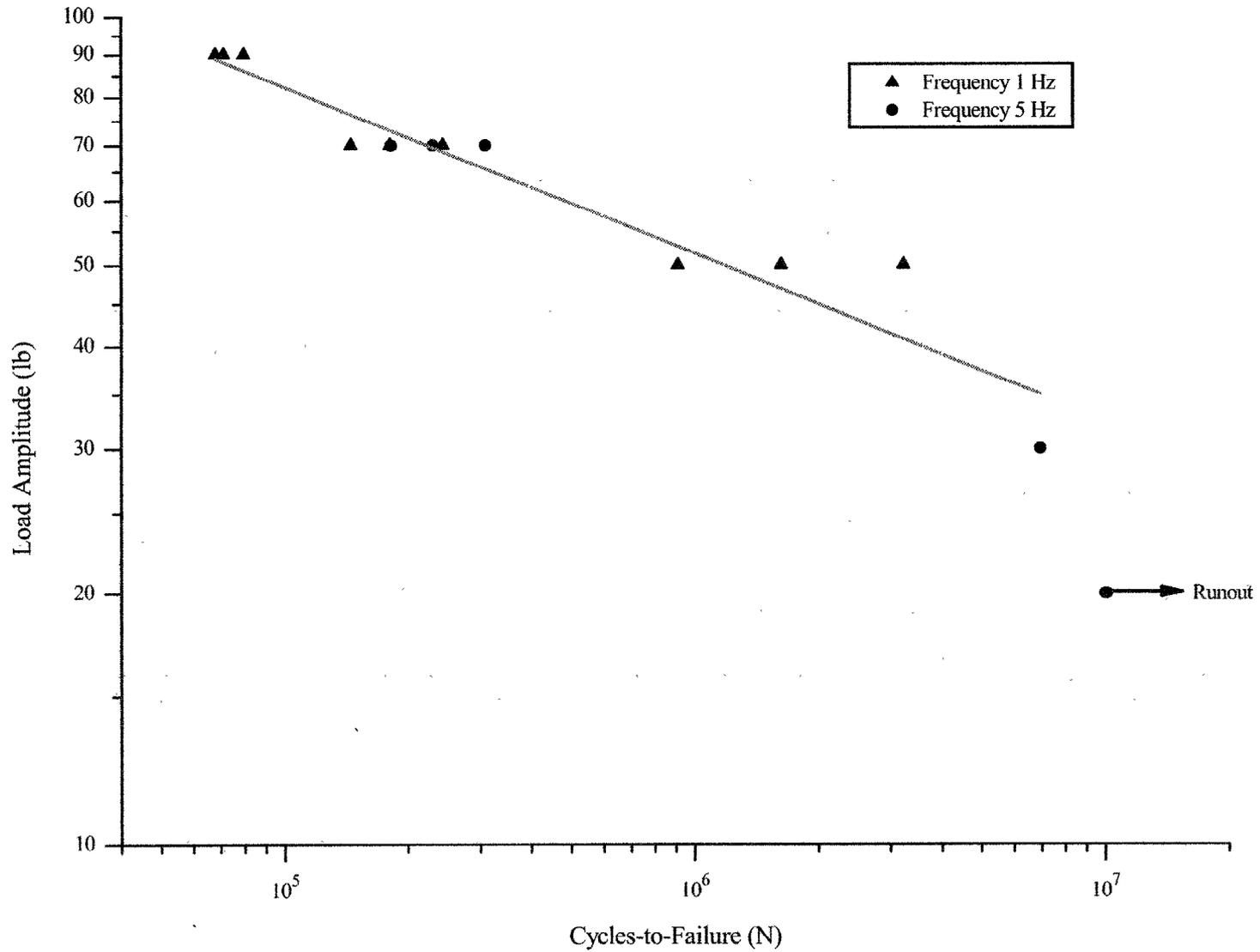
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Figure 4 Cyclic Fatigue Test: Plot of the position of the actuated parallel plate at minimum and maximum compression as a function of the number of load cycles. Position of the plate is measured relative to an arbitrary datum above the fixture (see Figure 1).



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Figure 5 Load Amplitude versus Cycles-to-Failure from Cyclic Compression Testing of Siltex Round Moderate Profile Gel-Filled Mammary Implants



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Figure 6 Load Amplitude versus Cycles-to-Failure from Cyclic Compression Testing of Smooth Round Moderate Profile Gel-Filled Mammary Implants

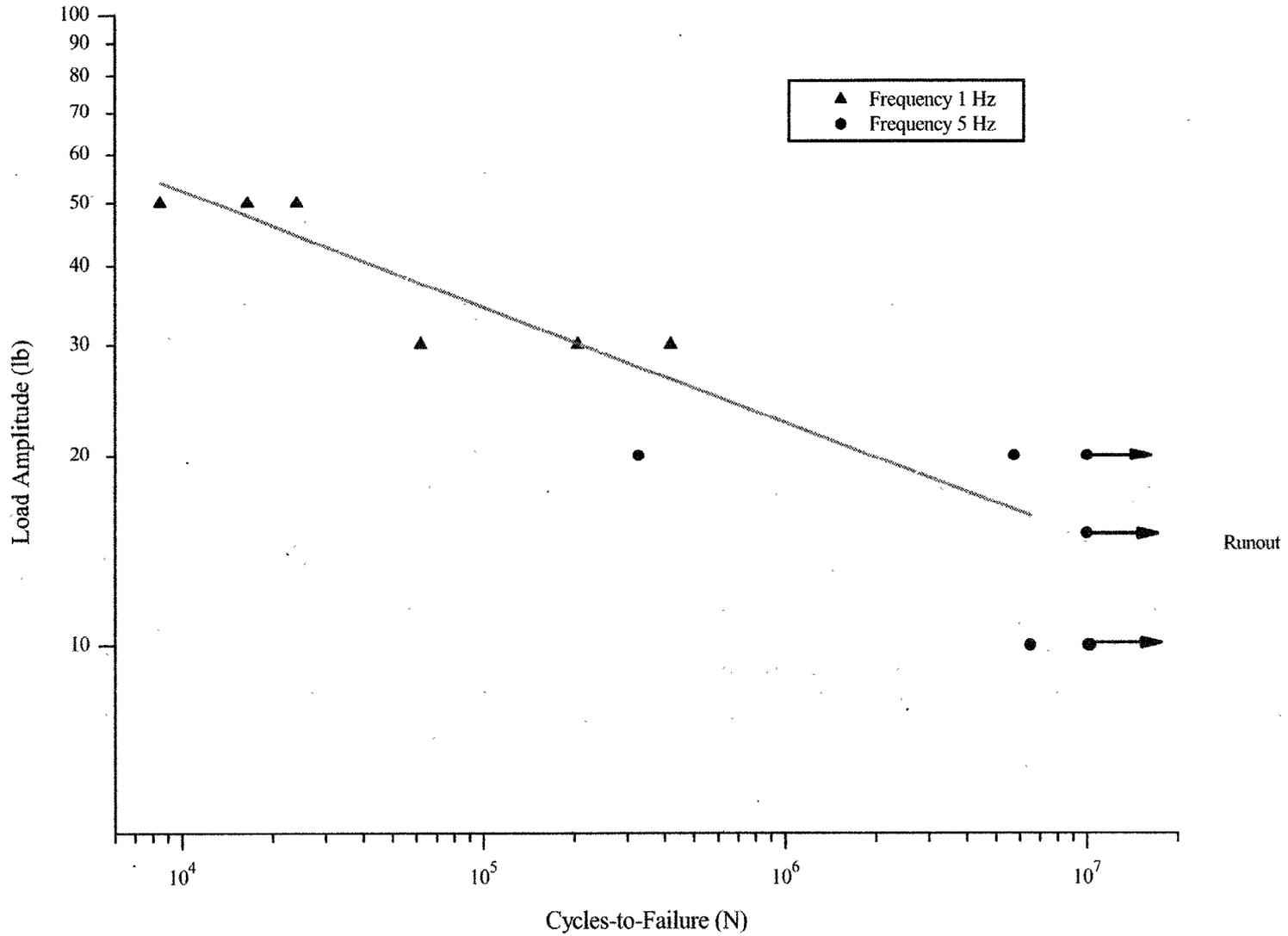
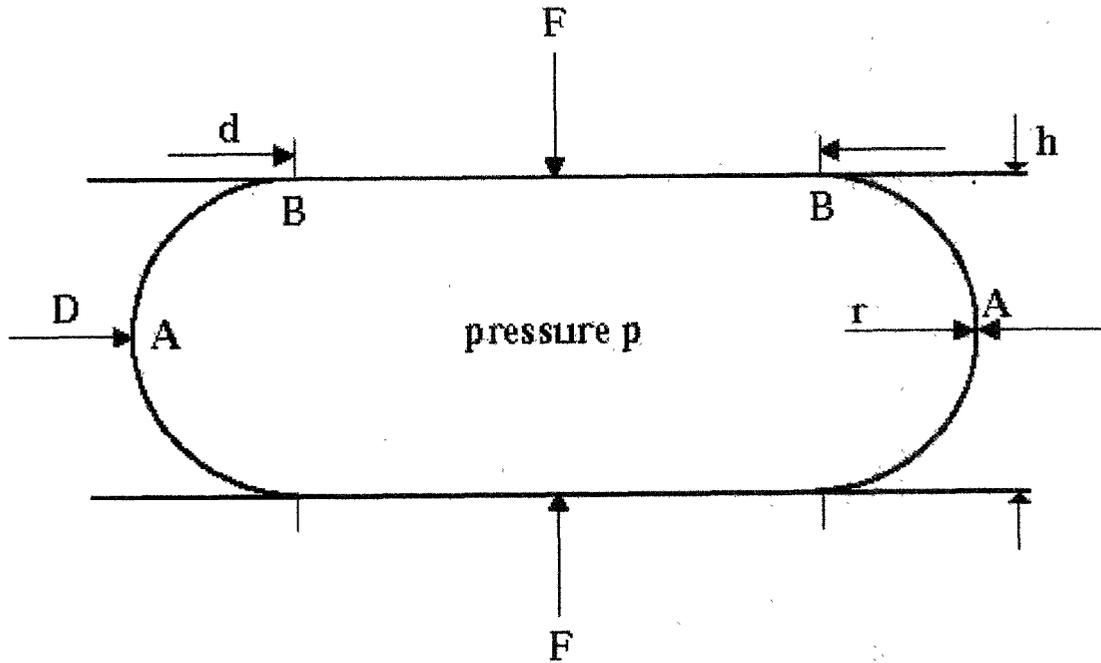
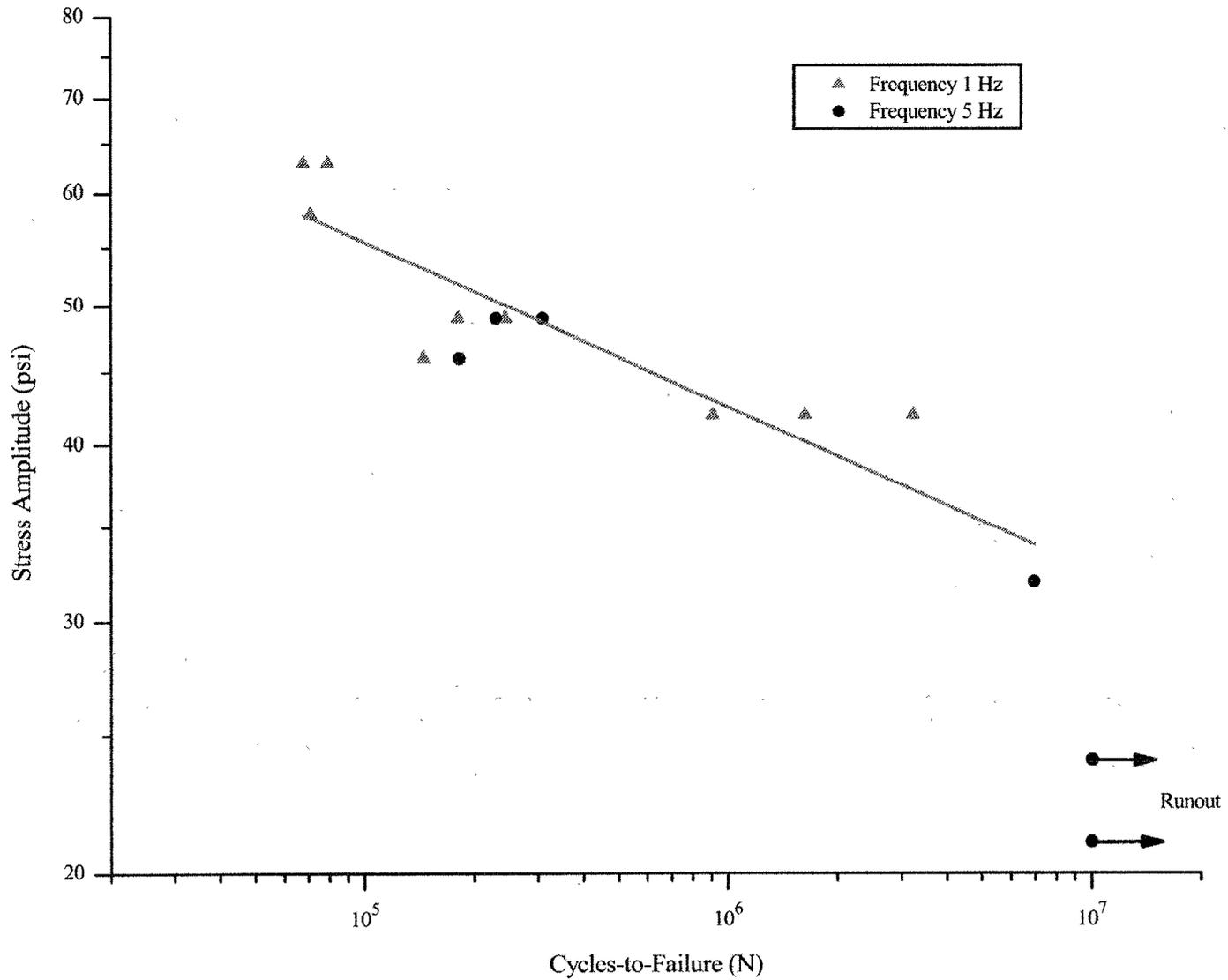


Figure 7 Prosthesis Compressed Between 2 Platens in the Uniaxial Loading Test



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Figure 8 Stress Amplitude versus Cycles-to-Failure from Cyclic Compression Testing of Siltex Round Moderate Profile Gel-Filled Mammary Implants



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Figure 9 Stress Amplitude versus Cycles-to-Failure from Cyclic Compression Testing of Smooth Round Moderate Profile Gel-Filled Mammary Implants

