MENTOR GEL-FILLED MAMMARY PROSTHESIS

EXPLANT ANALYSIS – PHYSICAL TESTING OF THE SHELL

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I. PURPOSE

This report analyzes changes in shell physical properties over time implanted of Mentor Gel-filled Mammary Prostheses by looking at the shell properties of primarily ruptured explanted devices from Mentor's Texas Product Evaluation (TX PE) data base and all explanted devices (ruptured and intact) from Mentor's Core Clinical Study. The latter devices are the subject of Mentor's Gel-filled Mammary Prosthesis PMA.

II. INTRODUCTION

The physical testing of explanted gel-filled mammary prostheses should provide helpful data to better understand why these devices might rupture after implantation in patients. Since the shell and patch are the components involved in any device rupture, physical properties related to these components are most appropriate for testing. In addition, since the shell material is involved with vastly more ruptures than the patch material, most of the testing will focus on the shell and its material properties. Since there are standardized shell tests and methods for unimplanted finished device testing (e.g., ASTM F 703 Standard Specification for Implantable Breast Prostheses[1]), these standards were primarily used as a basis for deciding what tests should be performed on explanted devices.

Device rupture failures involving the shell can be classified as iatrogenic (induced inadvertently at the time of surgery and usually by instrument or handling damage of some sort) and non-iatrogenic (which could include wear, abrupt rupture of a normal shell due to excessive stress, shell weakening due to an inadvertent stress followed by wear or too excessive of a subsequent stress, etc.). In the case of an iatrogenic rupture, the physical properties of the shell may not be of primary importance because the failure is induced by an outside agent, most often a surgical instrument. Usually, the device is not in the body long enough for the shell physical properties to change. In the case of non-iatrogenic ruptures, however, devices can be in the body for days to years and any changes in the device shell physical properties could be a major contributor to device shell or patch-to-shell joint failure.

III. METHODS

ASTM F 703 Standard Specification for Implantable Breast Prostheses contains physical tests appropriate for assessing the physical properties of these finished devices. Mentor used these tests to help assess the acceptability of gel-filled mammary finished devices in normal production and during qualification of new vendors for mammary prosthesis materials, new materials, and new and modified manufacturing processes. Using the ASTM tests as a reference, the following physical tests were performed on explanted devices:

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[1] ASTM F703-96 Standard Specification for Implantable Breast Prostheses (approved 1996).

Shell Stress at Ultimate
Shell Break Force
Shell Elongation
Shell Tension Set
Patch-to-shell Joint Strength

The stress at ultimate (also called ultimate stress or tensile strength) of shells, while not mentioned in the ASTM standard, was also analyzed because it provided a thickness normalized strength measurement for the shell (unlike the break force measurement). As a result, this quantity is a direct measurement of the shell silicone material's property as compared to shell break force (which depends on the silicone's property and the thickness of the shell).

The physical tests were performed per ASTM F 703, Mentor's TM 000019 (Determination of Tensile/Elongation Properties of Elastomeric Materials), Mentor's TM 000401 (Determination of Joint Bond Strength), and Mentor's TM 000406 (Determination of % Tension Set of Elastomeric Materials).

At first, fifty devices were randomly chosen from the Mentor Texas Product Evaluation (TX PE) data base after sorting for devices with "Complaint 1: Rupture" and "Failure: Rent – UNK Cause" (or RUC which is a non-iatrogenic rupture failure mode). Having already been ruptured, these devices would most likely exhibit physical property changes if they occurred. They consisted mostly of Siltex Moderate Profile Gel-filled devices (forty devices) and a few Smooth Moderate Profile Gel-filled devices (ten devices). The number of devices chosen for testing was greatly influenced by the original number of smooth and textured devices in the RUC category of the data base and the number of each device type which had already been used or might be needed for other explant testing being performed at the same time. As a result, to supplement the smooth physical testing data, seven additional smooth devices were tested. These included two devices with no abnormalities because there were so few remaining ruptured smooth RUC devices available for physical testing. Because all Mentor textured device shells from different Siltex product lines are made with the same materials and basic processes and all smooth shell product lines are made with the same shell materials and processes, the physical property trends seen in any one textured or smooth product line is expected to be applicable to other similar product lines.

A second source of explanted devices for this report was Mentor's Core Clinical Study of Gel-filled Mammary Prostheses. This study began September 2000 and only utilized devices made since early 2000. Because the TX PE data base receives devices from physicians on a voluntary basis, any corroboration of TX PE explant physical testing results from a controlled clinical study, such as the Mentor Core Study, was considered to be valuable.

Explanted Low Bleed Gel-filled devices from Texas's PE database were manufactured at any time from the mid 1980's through 2003. During this time period, Mentor used ---------------------------- gel filler material, -------------- each of shell -------------

-------------------------- -- materials to dip shells, and ------------------ silicone sheeting materials. By contrast, the Core Study Gel-filled devices used --------------------------- ---------------- shell silicone dispersion materials, and primarily -------------------------- sheeting materials. As a result, the properties of the Core Study ----------------------- --- be more similar prior to implantation than the Texas PE data base devices, and the latter's explanted physical properties must be analyzed in light of their varying initial unimplanted physical properties. (Lot matched controls for these explanted devices do not exist; therefore, this type of control data does not exist for purposes of comparison.)

Finally, because of the small number of data points in some of the figures and the large data spread in other figures, a statistical assessment of the data and its suggested trends was obtained. The analysis was used to understand how the small incremental changes in the device raw materials over many years might influence the meaning of the explanted device data and whether trends were statistically significant based upon various potential models to fit the data. The analysis by Prof. Doyle Hawkins (Department of Mathematics, University of Texas, Arlington, TX) can be found in Appendix A. His final analysis used a quadratic regression model.

IV. RESULTS

A. Texas PE Explants (the raw testing data can be found in Appendix C)

1. Siltex Gel-filled Explants (see Table 1 for a data summary)
    a. Stress at Ultimate - The ultimate stress (or ultimate tensile strength) measurements of device shells implanted for about six months to nine and one half years is shown in Figure 1. The trend of the data suggests that the ultimate stress of devices remains, on average, unchanging at about 600 psi during the nine and one half years of implantation.
    b. Break Force - Figure 2 shows the trend in the explanted shell break force for implantation times out to nine and one half years. The explanted shell break force appears to show a gradual reduction; however, statistically this is not a significant change over time. On average the break forces are in the 2.5 – 4.0 lb range.
    c. Percent Elongation - Figure 3 shows the trend for shell percent elongation out to nine and one half years of implantation. On average, there appears to be a small decrease in the property over the time of implant, with the shell elongation being about 450% at the shortest in vivo time and dropping to about 350% by nine and one half years of implantation. The statistical analysis suggests that the property is leveling off by the longer implant times.
    d. Patch-to-Shell Joint Strength - Figure 4 shows the trend for the patch-to-shell joint strength of explants implanted for as long as nine and one half years. The trend shows a gradual reduction in

strength from about 3.5 lbs at the shortest implant period to about 2.5 lbs at the longest implant period. The statistical analysis suggests that the property is leveling off by the longer implant times.

e. Tension Set – Figure 5 shows the trend for shell tension set measurements of explants implanted for as long as about seven years. Although the data is very scattered, the trend of the tension set property is statistically leveling off (or increasing slightly) by the longer implant times.

2. Smooth Gel-filled Explants (see Table 2 for a data summary)

   a. Stress at Ultimate – Figure 6 shows the trend for tensile strength over about seven and one half years of implantation. Tensile strength values appear to decrease from about 1400 psi but statistically this is not a significant decrease.

   b. Break Force - Figure 7 shows the trend in the explanted shell break force for implantation times out to about seven and one half years. The explanted shell break force appears to show a statistically significant reduction from about 6.0 lbs with a leveling out at about 3 lbs.

   c. Percent Elongation - Figure 8 shows the trend for shell percent elongation after about seven and one half years of implantation. The trend is a statistically significant reduction in property with the property leveling off at about 400%.

   d. Patch-to-Shell Joint Strength – Figure 9 shows the trend for patch -to-shell joint strength out to about seven and one half years of implantation. The trend line shows a statistically significant reduction in property with a leveling off at about 2 lbs after a period of years in vivo.

   e. Tension Set – Figure 10 shows the trend for the shell tension set. Although the statistical analysis indicates a significant leveling off of the property, the data are widely scattered resulting in an uncertain overall trend meaning.

B. Core Gel Study Explants (the raw testing data can be found in Appendix D)

1. Siltex Gel-filled Explants (see Table 3 for a data summary)

   a. Stress at Ultimate – Figure 11 shows that the shell ultimate stress property of the explanted Core Gel-filled Prosthesis Study devices changes a small amount during their initial implant period, followed by a period where the property remained fairly constant, and a final small reduction in property at the end of the implant period. The property change over time was determined to be statistically significant.

   b. Break Force - Figure 12 shows that the shell break force of the explanted Core Gel-filled Prosthesis Study devices has a statistically significant small rise over the initial implant period, a leveling off period followed by a small drop in the property at the end of the implant period.

c. Elongation - Figure 13 shows that the shell ultimate elongation of the explanted Core Gel-filled Prosthesis Study devices have shown a statistically significant decrease over a period of approximately three years of implantation. Explant elongation appears to have dropped to the 400% range after three years of implantation.

d. Patch-to-Shell Joint Strength - Figure 14 shows that the patch-to-shell joint strengths of the explanted Core Gel-filled Prosthesis Study devices have increased during an early implantation period but decreased by the end of the approximately three year implantation period. These statistically significant patch-to-shell joint strength changes occur around the 4 lbs. joint strength level.

e. Tension Set - Figure 15 shows that the shell tension set of the explanted Core Gel-filled Prosthesis Study devices have remained fairly constant over a period of a little more than three years of implantation. There is statistically no change in the property at about the 3.0 - 3.5% tension set level.

2. Smooth Gel-filled Explants (see Table 4 for a data summary)

a. Stress at Ultimate – Figure 16 plots the tensile strength of the explanted devices versus years implanted. The property has statistically remained unchanged at about 1400 psi over a period of three years of implantation.

b. Break Force - Figure 17 shows that the shell break force of the explanted Core Study Gel-filled Prostheses has remained statistically unchanged over a period of three years of implantation. On average, the explanted shell break force was about 5 lbs.

c. Elongation - Figure 18 shows that the shell ultimate elongation of the explanted Core Study Gel-filled Prostheses has statistically remained unchanged over an implant period of three years. On average, the elongation properties of the explanted devices have remained close to 600%.

d. Patch-to-Shell Joint Strength - Figure 19 shows that the patch-to-shell joint strength of the explanted Core Study Gel-filled Prostheses has remained statistically unchanged over a period of three years of implantation. On average, the explanted shells have retained a joint strength close to 4 lbs.

e. Tension Set - Figure 20 shows that the shell tension set of the explanted Core Study Gel-filled Prostheses have remained statistically unchanged over a period of approximately three years of implantation. (It should be noted that these tension set measurements have a very wide range.)

V. DISCUSSION

A. Shell ultimate stress property

The measurement of shell ultimate stress is not a physical parameter called for in ASTM F703 or Mentor's own device finished product specifications. It is not a measurement of the whole shell's ability to withstand stress, but rather a measurement of a normalized amount (or unit thickness) of the shell's material to withstand force. This type of normalized property is more appropriate to analyze for silicone material changes over time implanted (as compared to break force) because it eliminates fluctuations in shell properties directly related to differences in shell thickness. In order to calculate shell ultimate stress, the cross-sectional area (thickness times the width) of a tensile testing sample must be calculated. For textured (Siltex) shell samples, thickness measurements are not highly accurate measurements of the cross-sectional area being stressed. The hills and valleys of the texturing make measuring the actual sample thickness being stressed somewhat inexact. As a result, the ultimate stress data for Siltex shell samples are more imprecise than the other measurements analyzed in this report. On the other hand, ultimate stress measurements of smooth shells will result in much more accurate analyses because their thickness measurements do not have the same measurement difficulties as with textured shells.

B. Physical property trends over time implanted

1. TX PE explants

The physical property trends for TX PE Smooth Gel-filled Mammary Prostheses are not well established due to the small number of explanted devices available for testing, especially the lack of longer term implants. Historically, domestic customers had a general preference for textured devices from the late 1980's through the 1990's. For those smooth devices that were implanted, Mentor's Gel-filled Mammary Prosthesis class action lawsuit settlement prevented testing of class action devices (i.e., devices implanted prior to June 1, 1993). These impediments, along with the need to use explanted smooth gel-filled devices for other types of explant failure analyses, greatly restricted the number of smooth devices available for physical testing. As a result, the best that can be discerned from the data is that most of the physical properties become constant after some period of implantation.

The physical property trends for textured devices over time implanted are clearer due to the larger number of devices which were tested. Shell ultimate stress changes a little during initial implantation but becomes constant after a few years suggesting that the shell material is not appreciably weakening during the time implanted.

With respect to the other Siltex device properties, the relatively unchanged shell ultimate stress and break force suggest that the shell and the shell silicone material are not weakening over time implanted. The other properties show initial reductions but then stop changing after a few years in vivo.

2. Core Gel Study explants

Mentor's Core Gel Study began in September 2000. Explanted Siltex devices from that study had been implanted for almost three and one half years and explanted smooth devices for as long as three years. The number of Siltex device explants (fifteen) was much smaller than the number of smooth device explants (forty-two) because of the larger number of smooth gel-filled devices which were implanted and the smooth device's slightly higher explant rate.

Some Siltex device physical properties (ultimate stress, break force, and joint strength) showed a change shortly after implantation but then exhibited a period of little change (or little data to accurately assess the nature of the change). Tension set was unchanged from its early implant values. Only the elongation showed a statistically significant reduction in property. However, it should be noted that Prof Hawkins in his statistical analysis indicated that the Core Clinical explanted Siltex shell physical data exhibits the most unusual characteristics in term of identifiable trends of all the analyzed data, possibly because this group had the fewest data points to analyze.

The Core Study smooth device explants showed the most unchanging physical property trends during the time implanted of all explant data. All measured properties showed no change over the three years of implantation.

C. TX PE compared to Core Gel Study explant data

The TX PE physical testing data suggests that the device shell properties remain either fairly constant during implantation or experience a reduction in their physical properties during an initial implantation period, but then usually level off and remain fairly constant out to nine and one half years of implant time.

In contrast to the TX PE explant data, the Mentor Core Gel Mammary Study smooth explant physical testing data shows explants with physical properties which are mostly unchanged over about three years of implantation. For several properties, Siltex devices show a change in property over an initial early time period but then become fairly constant for much of the rest of the time in vivo.

Unfortunately, comparing the two sets of explant data (TX PE and Core Clinical) to each other can only provide very general conclusions at best because each group was selected differently. The TX PE devices are almost all ruptured devices (i.e., devices having probably seen severe physical stresses which resulted in their rupture). Unruptured explanted devices are virtually absent from these test samples. The Core Clinical explanted devices are all explanted devices from the clinical study (i.e., a few ruptured but most unruptured).

In general terms, explanted smooth shells, show little changes during implantation or show a small change followed by a lack of further change in physical properties. TX PE explant shells exhibited this latter leveling off of properties over about seven years of implantation while the Core Clinical explant shells showed virtually no change over their three years of implantation.

Explanted Siltex shells tend to show this physical property leveling off characteristic no matter whether the data comes from the TX PE or Core Clinical Study.

D. Physical property reduction compared to the property level needed to prevent rupture

Even though devices may experience some loss in physical properties during their time implanted or compared to their unimplanted values, this does not automatically mean that a device will rupture. Mentor's gel-filled mammary prostheses have physical properties far exceeding the minimum requirements outlined by ASTM F703. If the loss of physical properties in the amounts observed during this study did directly result in device failures, one would have expected that Mentor's Texas Product Evaluation (PE) Department would have seen many more shell failures or patch to shell joint failures than the less than the --------------------- of domestic sales returned ruptured product observed through 2003. For those few properties which show a constantly decreasing trend over time, one might believe that they would eventually degrade enough to result in a failure. But when failure will occur is not known and depends on the level of the property when implanted, the rate of property decrease over time, and the minimum physical property required to maintain an intact device. Also, as seen in much of this data, properties can stop changing (i.e., level out) after a period of time in the body. All of these factors make predicting a time to failure based upon physical testing of explanted devices very questionable.

VI. CONCLUSIONS

Mentor's analysis of explanted devices from its Texas Product Evaluation data base and Core Gel Study database provided information on physical property changes over time implanted. However, a difference in the selection process of samples for testing makes a direct comparison between these two sets of explants tenous. TX PE explants were almost exclusively ruptured devices while the Core Clinical Study explants consisted of every explant from the study, some ruptured but most unruptured. With this in mind, data from shell ultimate stress, shell break force, shell elongation to failure, shell tension set and patch-to-shell joint strength were collected on the explants.

In general, the TX PE physical testing data suggests that the device shell properties remain either fairly constant during implantation or experience a reduction in their physical properties during an initial implantation period, but then usually level off and remain fairly constant out to nine and one half years of implant time. In contrast to the TX PE explant data, the Mentor Core Gel Mammary Study smooth explant physical testing data shows explants with physical properties which are mostly unchanged over about three years of implantation. For several properties, Siltex devices show a change in property over an initial early time period but then become fairly constant for much of the rest of the time in vivo.

TABLE 1 - SILTEX GEL EXPLANT PHYSICAL PROPERTY TESTING - TX PE

File Number	A or B	Catalog Number	Lot # Closing Date	Yrs In Vivo	Thickness (in)	JS Break Force (lbf)	Break Force (lbf.)	Ult. Stress (PSI)	% Elong.	Tension Set (%)*
200108-0364	A	354-3507	4/15/1991	8.2	0.0195	2.491	2.566	526.4	341.1	
200008-0183	A	354-4007	8/22/1991	6.4	0.019	1.885	2.674	562.9	342.8	
200005-0301	A	354-3007	10/4/1991	5.5	0.0175	2.336	2.056	470	307.9	
200305-0556	A	354-3504	10/31/1991	9.4	0.0185	2.687	2.413	521.8	336	
200103-0147	A	354-7007	10/13/1992	6.6	0.023	3.326	4.005	696.6	387.5	2.51
200108-0421	A	354-3507	11/17/1992	7.3	0.021	2.07	2.98	567.6	332.5	
200009-0060	A	354-4007	12/8/1993	6.6	0.0195	2.448	2.395	491.2	287.2	
200001-0082	B	354-4007	8/5/1993	5.2	0.0235	3.262	4.003	681.3	369	1.66
200101-0736	A	354-3007	6/18/1993	7.1	0.012	2.94	2.84	946.7	345.4	
200101-0736	B	354-3007	6/18/1993	7.1	0.014	2.558	3.401	1008	386.7	1.96
200005-0328	A	354-4007	11/12/1993	6.1	0.019	2.456	3.353	705.9	354.8	
200006-0702	A	354-3257	2/2/1994	6.2	0.0205	2.566	3.608	704	344.6	1.76
200111-0056	A	354-5004	3/3/1994	7.4	0.018	2.174	3.055	678.9	337.6	
200110-0236	A	354-3257	4/18/1994	7.4	0.0215	3.015	2.593	482.5	273.2	
200304-0633	A	354-5007	5/20/1994	6.6	0.0215	2.548	2.486	462.5	280.9	
200107-0409	A	354-2757	6/23/1994	6.7	0.018	3.791	3.136	696.8	361.7	
200107-0409	B	354-2757	6/23/1994	6.7	0.0175	2.424	2.956	675.6	346.8	
200107-0097	B	354-3007	5/24/1994	6.1	0.0185	2.848	2.569	555.5	335.3	
200103-0526	A	354-3507	6/20/1994	6.0	0.0215	2.349	2.776	516.4	321.3	
200102-0229	A	354-3507	8/1/1994	6.4	0.0195	2.891	3.009	617.3	346.6	1.71
200102-0215	A	354-5007	9/24/1996	2.4	0.0195	3.24	3.401	697.7	423.8	1.61
200103-0310	A	354-5007	9/24/1996	3.6	0.0205	2.276	2.341	456.8	344.6	
200012-0218	A	354-2007	9/26/1996	3.9	0.0195	2.276	2.746	563.3	361.9	1.66

TABLE 1 - SILTEX GEL EXPLANT PHYSICAL PROPERTY TESTING - TX PE (cont.)

File Number	A or B	Catalog Number	Lot # Closing Date	Yrs In Vivo	Thickness (in)	JS Break Force (lbf)	Break Force (lbf.)	Ult. Stress (PSI)	% Elong.	Tension Set (%)*
200106-0232	A	354-3757	10/17/1996	4.4	0.0205	2.322	2.797	545.8	396.6	1.51
200106-0232	B	354-3757	10/17/1996	4.4	0.023	1.992	3.291	572.4	366.8	1.51
200006-0264	A	354-7007	7/8/1997	2.8	0.02	3.173	2.829	565.9	381.9	1.96
200009-0086	A	354-4007	8/28/1997	1.1	0.0185	3.495	2.781	601.3	402.7	2.91
200007-0088	A	354-3757	11/22/1997	2.0	0.0225	2.827	3.417	607.5	395.6	0.5
200304-0540	A	354-3007	11/26/1997	5.2	0.0225	2.462	2.795	496.8	300.5	
200102-0576	A	354-4507	5/6/1998	2.7	0.0215	2.899	4.158	773.6	447.9	2.11
200012-0176	A	354-5507	7/31/1998	2.1	0.025	3.044	3.89	622.4	370.2	2.06
200108-0091	A	354-5507	12/10/1998	2.0	0.021	3.074	2.846	542	353.6	0.9
200108-0371	A	354-3507	8/19/1998	2.3	0.021	3.275	4.035	768.5	457.4	1.56
200111-0510	A	354-7007	8/28/1998	1.8	0.02	3.514	3.476	695.3	406.6	1.26
200108-0091	B	354-5507	3/9/1999	2.0	0.0315	3.962	4.856	616.7	435.3	1.41
200305-0566	A	354-3257	3/31/1999	4.1	0.03	3.291	3.949	526.5	375.6	1.96
200110-0361	A	354-3507	6/11/1999	2.2	0.022	2.625	2.446	444.7	279.9	
200304-0524	A	354-3257	8/20/1999	3.6	0.026	3.702	4.078	627.4	464.7	1.59
200104-0304	A	354-4007	1/3/2000	0.8	0.0245	4.123	4.564	745.1	532.9	3.21
200111-0366	A	354-3257	-----	2.9	0.0325	4.754	5.458	671.7	437.6	2.01

(* - blank entries signify sample could not complete the test)

TABLE 2 - SMOOTH GEL EXPLANT PHYSICAL PROPERTY TESTING - TX PE

File Number	A or B	Catalog Number	Lot # Closing Date	Yrs In Vivo	Thick. (in)	JS Break Force (lbf)	Break Force (lbf)	Ult. Stress (psi)	% Elong. At Ult.	Tension Set (%)*
200009-0004	A	350-7600BC	11/30/1990	6.3	0.008	1.366	2.113	1056	486.7	1.21
200008-0641	A	350-7275BC	3/25/1991	1.9	0.0085	1.936	2.781	1309	542.3	1.1
200107-0549	A	350-7200BC	Reworked 5/23/1994	7.5	0.0215	2.424	3.619	673.3	417.9	1.6
200011-0418	A	350-7550BC	4/23/1999	1.2	0.015	4.126	4.846	1292	560	1.51
200012-0061	A	350-7500BC	11/1/1999	0.8	0.0135	4.021	4.429	1312	690.5	1.96
200104-0084	A	350-7550BC	11/30/1999	0.7	0.018	4.711	5.535	1230	604.3	1.51
200110-0028	A	350-7800BC	2/17/2000	1.5	0.017	2.958	4.4	1035	553.3	2.31
200105-0246	A	350-7450BC	11/11/2000	0.4	0.0125	4.048	3.629	1161	552.5	1.46
200210-0025	A	350-7500BC	1/16/2001	0.4	0.0135	4.625	4.293	1272	578.8	2.11
200203-0641	A	350-7500BC	12/10/2001	0.0	0.0175	4.918	7.267	1661	702.8	1.91
983554	A	350-7400BC	5/29/1991	3.5	0.0120	1.764	2.741	913.6	353.8	
983554	B	350-7400BC	5/29/1991	3.5	0.0130	2.301	2.464	758.3	264.6	
200205-0624	A	350-7200BC	1/21/2000	2.1	0.0155	3.103	4.596	1186	475.3	4.45
200205-0624	B	350-7200BC	1/21/2000	2.1	0.0155	1.442	4.636	1196	449.5	4.08
200303-0859	A	350-7450BC	8/29/2000	2.4	0.0130	2.497	3.850	1184	540.9	4.44
200306-0232	A	350-7275BC	9/17/1999	3.4	0.0165	4.255	3.726	903.3	499.9	4.24
200306-0232	B	350-7275BC	9/17/1999	3.4	0.0155	3.946	3.511	906.2	413.0	4.53

(* - blank entries signify sample could not complete the test)

Table 3: 354-XXX7 Siltex Moderate Profile Gel Explant Physical Property Testing - CoreStudy

PE File Number	Mentor PN	Mentor LN	Volume (cc)	Years In Vivo	JS Break Force (lbf)	Tensile Break Force (lbf)	Stress @ Ultimate (PSI)	Percent Elongation (%)	Tension Set (%)
200112-0463	354-3257G	217513	325	0.7	3.863	3.949	734.7	459.3	3.50
200103-0005	354-4507G	217510	450	0.1	4.507	3.452	642.3	498.0	3.35
200106-0496	354-4007G	217007	400	0.6	3.866	4.470	794.6	542.3	3.50
20496	354-3007G	220197	300	0.6	3.216	3.302	677.3	496.6	3.11
25412	354-2757G	217004	275	1.3	4.789	4.540	789.5	503.4	3.86
200202-0352	354-5007G	221955	500	1.5	5.181	4.966	946.0	570.7	2.75
200204-0105 A	354-4507G	219164	450	1.9	4.526	3.831	712.7	471.5	3.60
200204-0105 B	354-4507G	219164	450	1.9	4.899	4.405	766.1	521.6	2.95
32557L	3545507G	217669	550	2.1	4.738	3.552	728.5	518.1	3.25
32557R	3545507G	217669	550	2.1	3.541	3.490	734.7	457 2	3.40
Device data acquired after 12/03 Report listed below									
36033L	354-3507G	217950	350	2.2	4.577	4.223	824.0	393.4	3.59
36033R	354-3757G	219708	375	2.2	4.899	4.945	1164.0	444.0	4.05
200404-0199A	354-3257G	217513	325	3.3	2.980	3.337	556.1	376.2	3.80
200404-0199B	354-3257G	217513	325	3.3	3.050	3.042	553.0	369.7	1.35
200303-0385	354-5007G	221955	500	1.6	5.278	5.984	920.6	574.8	4.86

Table 4: 350-7XXXBC Smooth Moderate Profile Gel Explant Physical Property Testing - Core Study

PE File Number	Mentor PN	Yrs. In Vivo	JS Break Force (lbf)	Tensile Break Force (lbf)	Stress at Ultimate (PSI)	Percent Elongation (%)	Tension Set
200012-0489	350-7350BCG	0.1	4.263	4.679	1497	601.6	4.00
200102-0308	350-7375BCG	0.0	4.072	5.103	1512	710.9	4.30
200101-0655	350-7375BCG	0.0	3.731	4.078	1255	594.6	3.95
200010-0202	350-7350BCG	0.0	4.161	5.353	1529	637.0	4.60
200103-0579	350-7550BCG	0.1	5.136	5.549	1644	728.1	3.45
200107-0413 L	350-7500BCG	1.0	4.279	4.601	1416	666.8	4.35
200107-0413 R	350-7500BCG	1.0	4.405	3.517	1563	696.4	4.55
16724	3507450BCG	0.3	4.145	4.131	1437	532.6	3.05
16678 L	3507350BCG	1.0	4.593	6.545	1540	659.1	2.10
16678 R	3507350BCG	1.0	4.921	5.181	1337	528.9	2.35
200202-0349	350-7350BCG	1.0	3.941	6.054	1468	578.3	1.35
11090	3507450BCG	0.0	4.011	4.341	1389	620.7	4.07
14185 L	350-7500BCG	0.3	4.483	4.977	1327	583.4	4.16
14185 R	350-7500BCG	0.3	4.985	5.592	1491	692.9	3.31
15968	350-7325BCG	0.3	3.809	5.050	1443	630.3	3.77
200209-0036 A	3507500BCG	0.9	N/A	3.785	1211	571.0	4.90
200209-0036 B	3507500BCG	0.9	3.189	4.059	1203	532.6	4.16
26770 L	3507275BCG	1.0	3.216	4.880	1627	594.4	3.25
26770 R	3507275BCG	1.0	3.850	4.679	1702	562.1	3.64
31405 A	350-7375BCG	2.3	3.450	3.648	1042	559.2	4.32
31405 B	350-7375BCG	2.3	3.219	4.118	1098	551.4	3.89
200301-0194	350-7450BCG	1.4	4.338	5.482	1512	657.2	3.05
200205-0417	350-7325BCG	1.1	3.927	4.421	1474	613.7	3.70
34127	350-7350BCG	2.6	4.220	4.660	1381	599.7	2.90
200307-0292	3507300BCG	2.0	5.141	4.682	1628	656.4	2.85
34218L	3507550BCG	2.3	4.639	4.843	1684	669.0	3.05
34218R	3507600BCG	2.3	3.157	5.860	1674	690.2	3.15
35298A	3507325BCG	2.1	4.046	5.968	1591	649.9	3.25
35298B	3507325BCG	2.1	4.199	4.330	1650	623.6	3.50

Table 4: 350-7XXXBC Smooth Moderate Profile Gel Explant Physical Property Testing - Core Study (cont.)

200305-0061L	3507500BCG	1.2	4.097	4.714	1508	638.7	2.80
200305-0061R	3507500BCG	1.2	3.578	5.484	1567	648.9	3.10
200010-0409	3507250BCG	0.0	4.421	5.399	1393	627.1	3.86
Device data acquired after 12/03 Report listed below.							
37240 L	350-7350BCG	-----	3.270	5.130	1465	477.3	3.55
37240 R	350-7350BCG	-----	4.090	4.430	1107	453.0	3.59
40015 A	350-7175BCG	1.6	4.010	4.420	1264	510.9	3.95
40015 B	350-7225BCG	1.6	2.620	5.350	1296	559.5	4.51
200405-0266B	350-7175BCG	3.0	1.920	4.320	1330	550.9	3.40
200405-0266A	350-7400BCG	3.0	4.550	5.420	1205	502.3	3.44
200401-0158A	350-7550BCG	2.6	4.110	4.690	1103	475.4	3.50
200401-0158B	350-7550BCG	2.6	4.420	5.020	1296	589.8	4.40
200204-0408A	350-7300BCG	0.6	4.745	5.740	1641	591.1	4.00
200204-0408B	350-7350BCG	0.6	3.870	6.590	1227	562.1	3.74

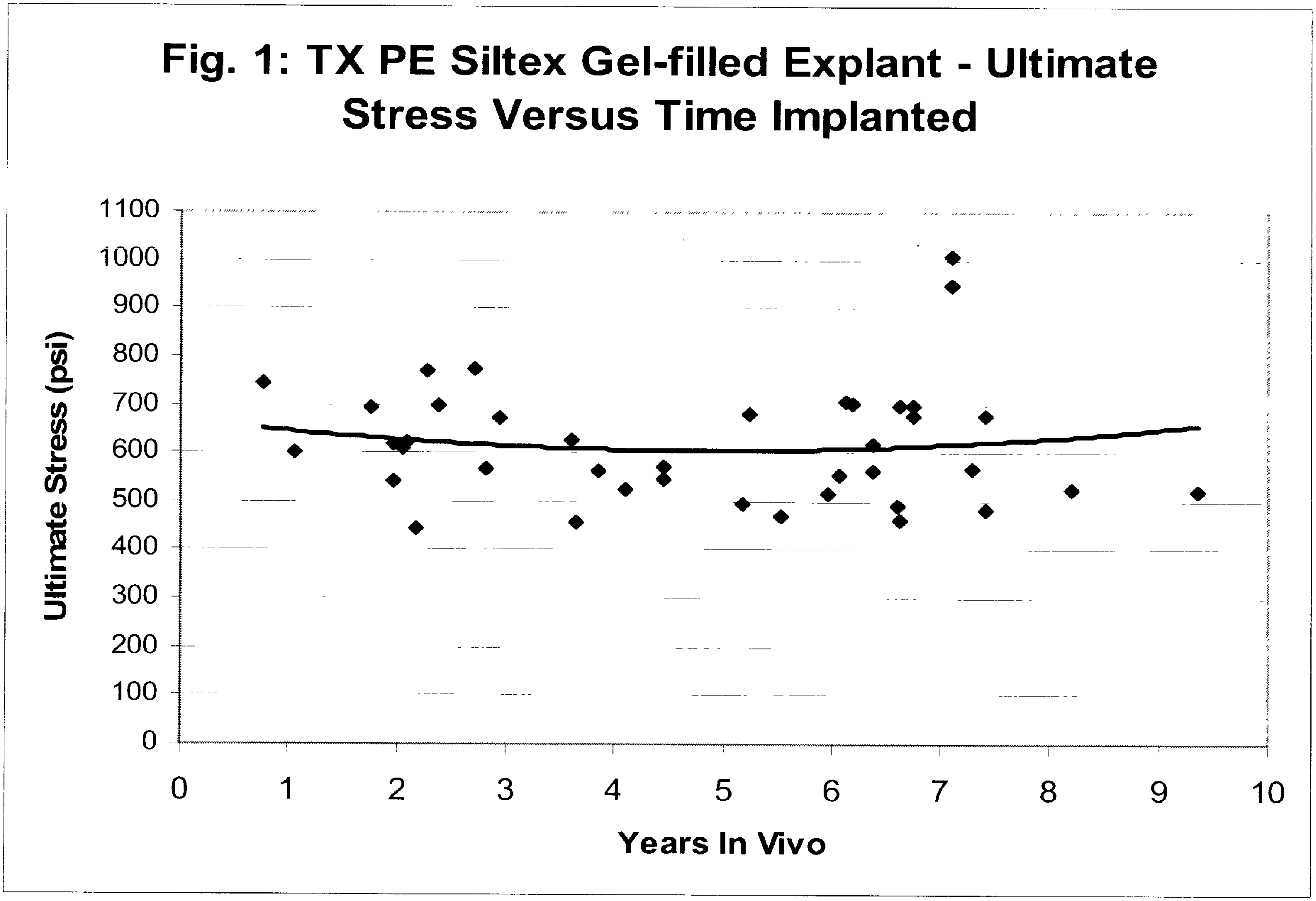
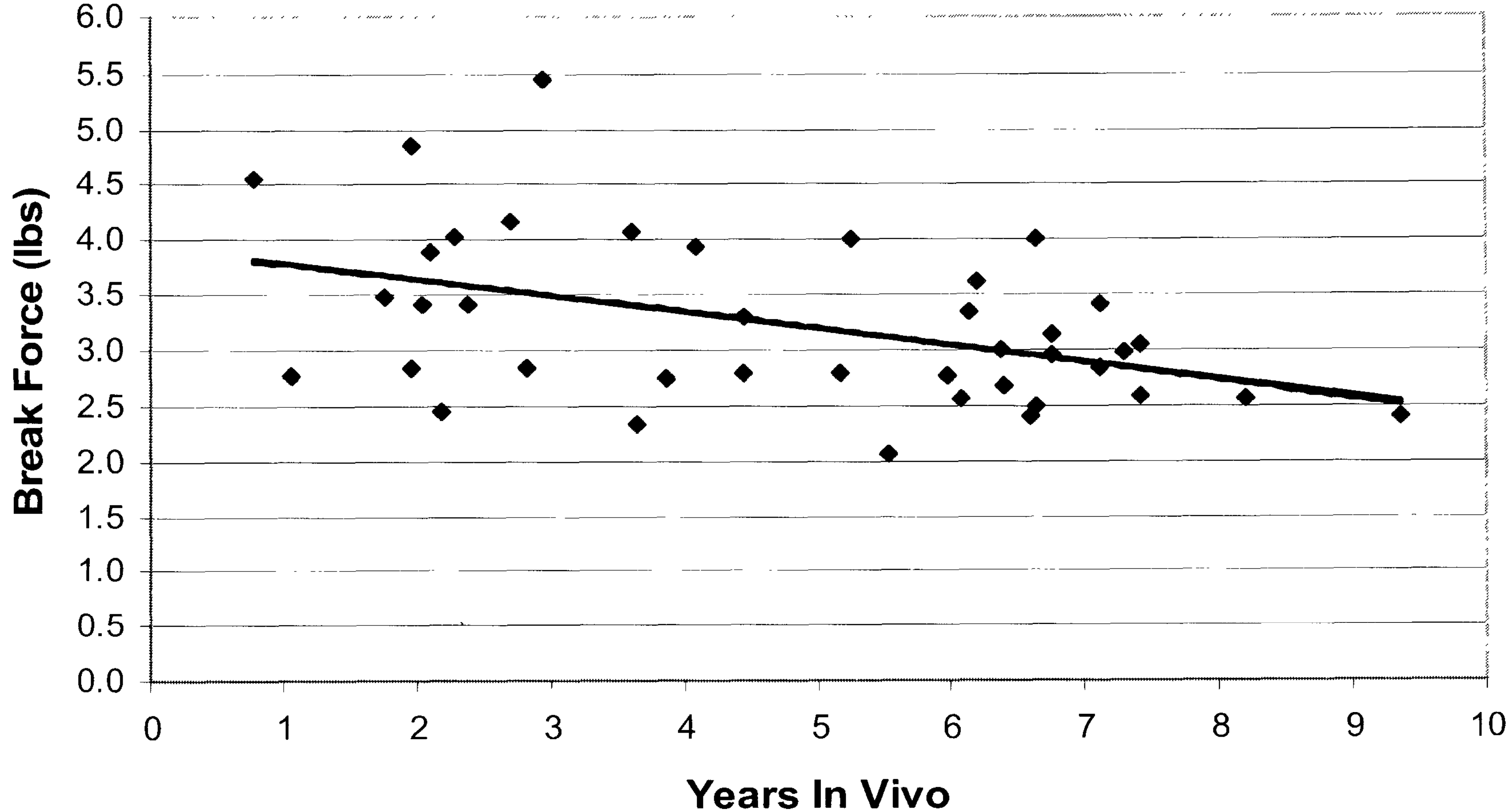


Fig. 1: TX PE Siltex Gel-filled Explant - Ultimate Stress Versus Time Implanted
Ultimate Stress (psi)
0
100
200
300
400
500
600
700
800
900
1000
1100
Years In Vivo
0
1
2
3
4
5
6
7
8
9
10

Fig. 2: TX PE Siltex Gel-filled Explant - Break Force Versus Time Implanted



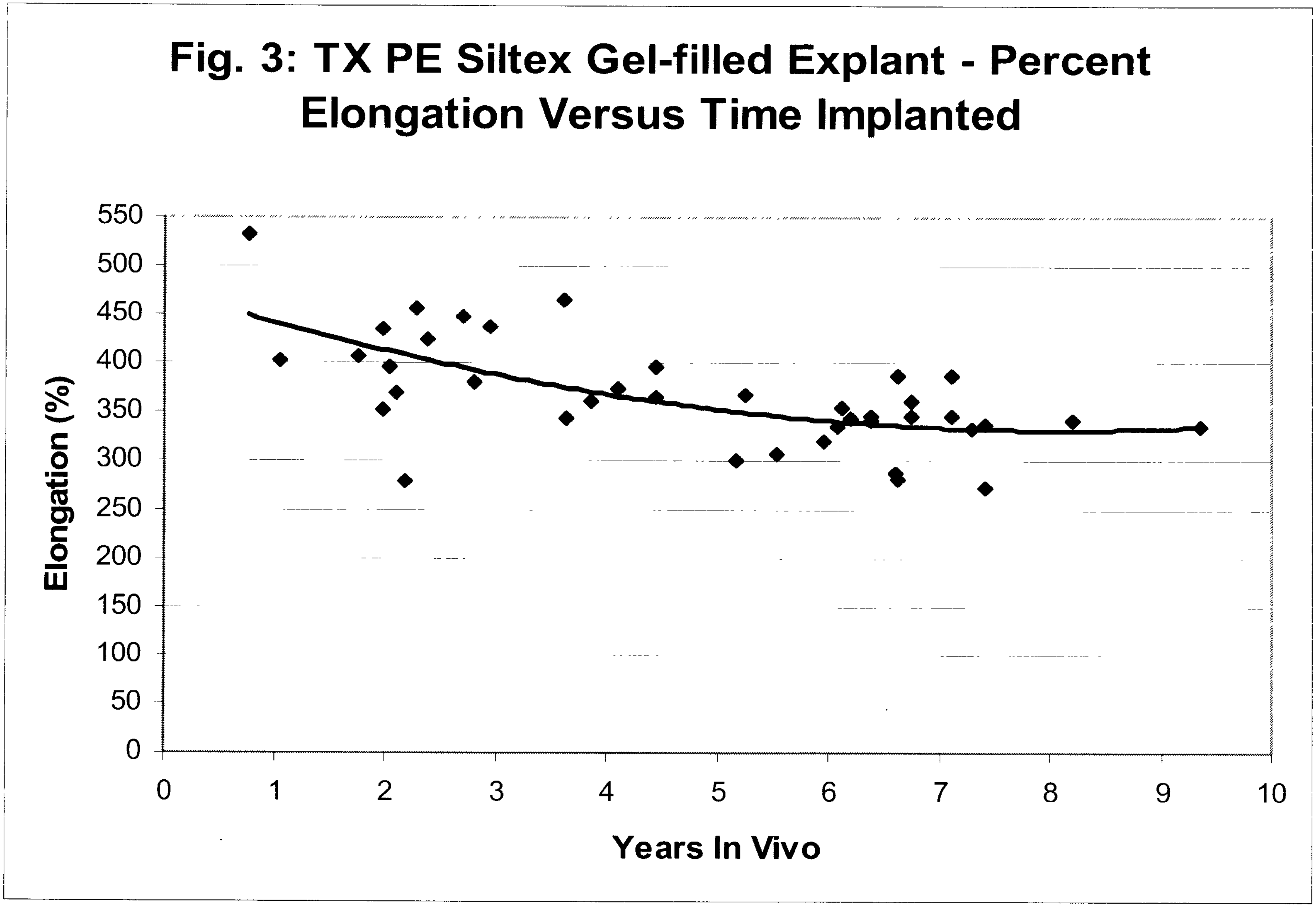


Fig. 3: TX PE Siltex Gel-filled Explant - Percent Elongation Versus Time Implanted
Elongation (%)
550
500
450
400
350
300
250
200
150
100
50
0
0
1
2
3
4
5
6
7
8
9
10
Years In Vivo

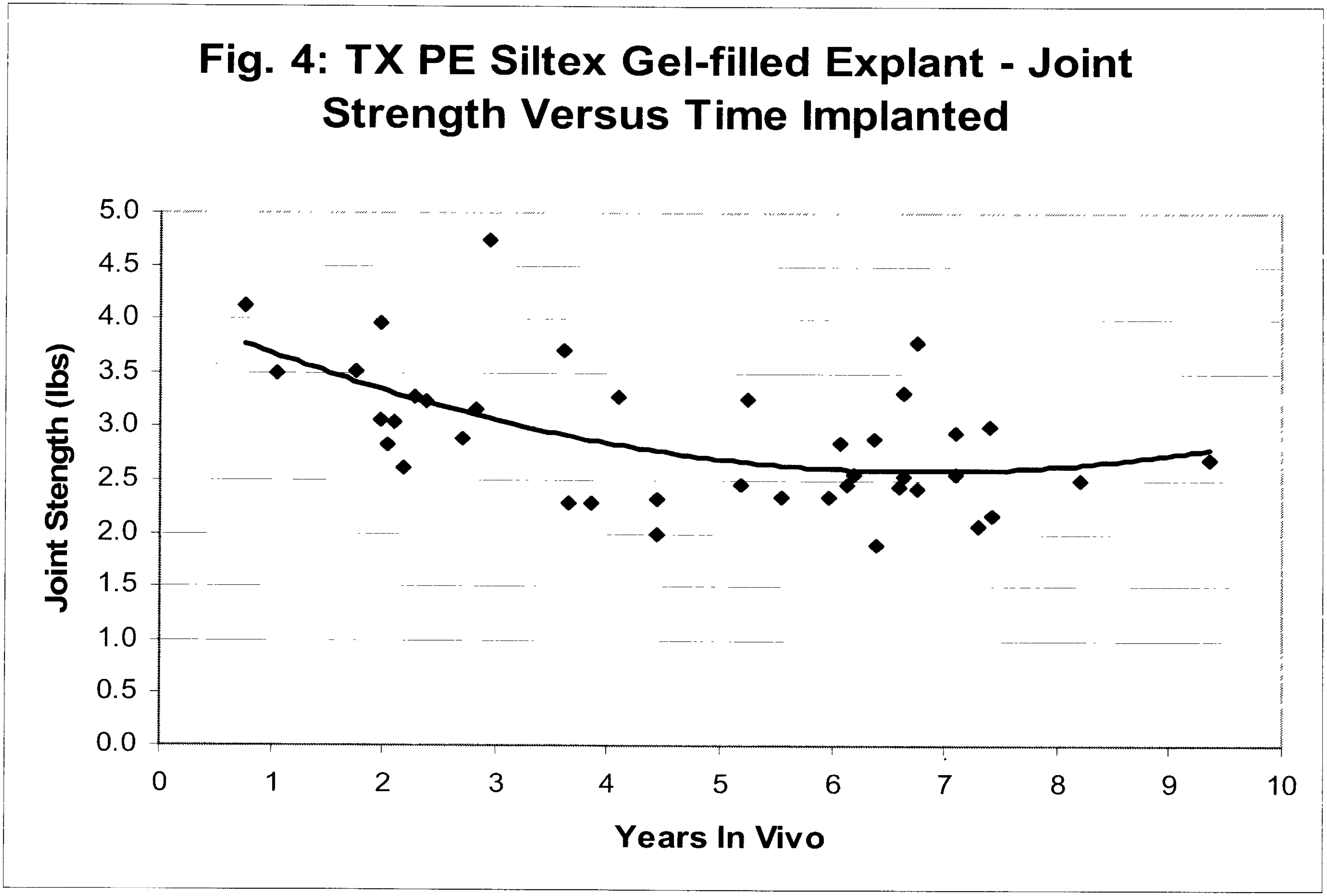
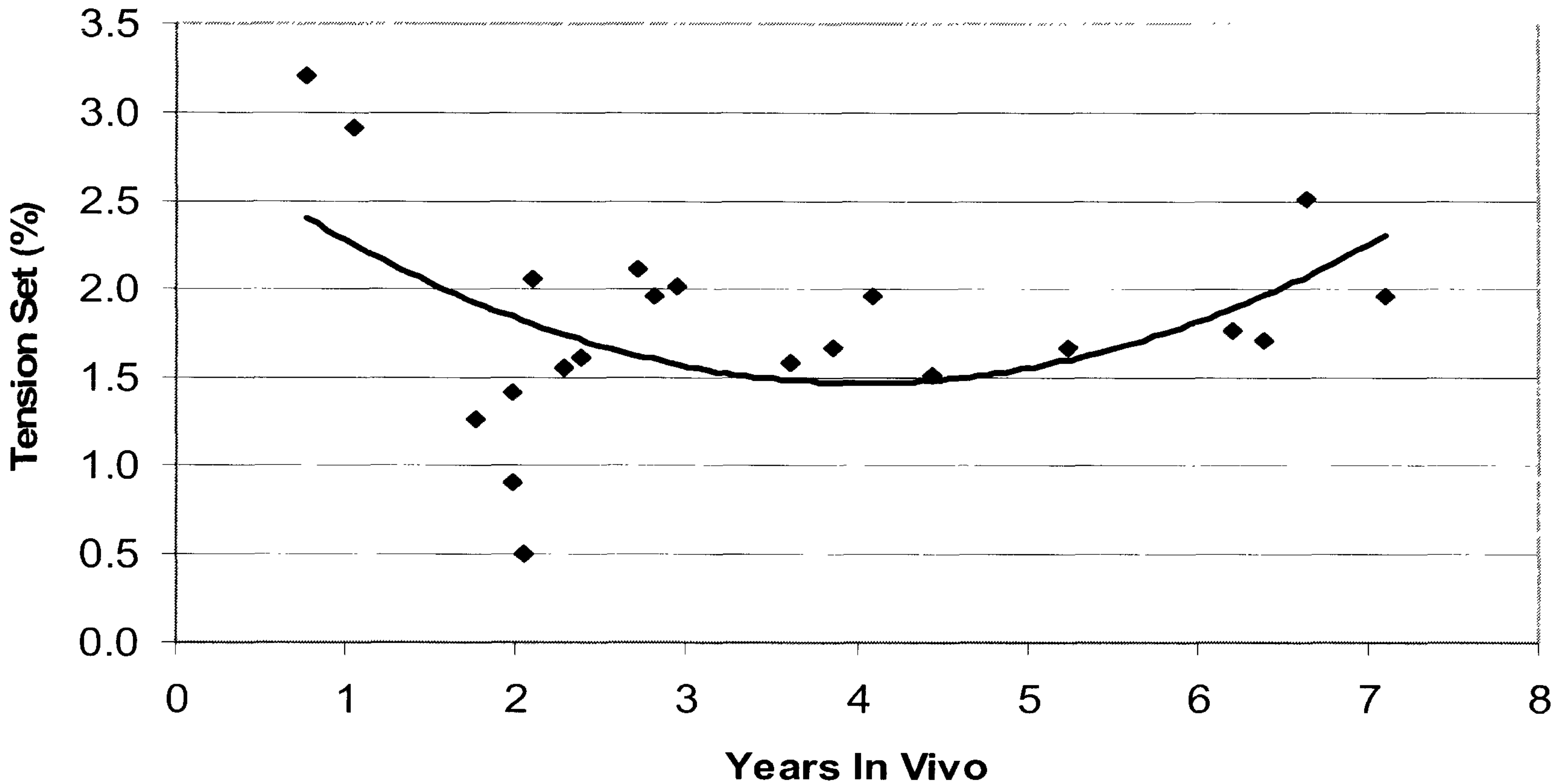


Fig. 4: TX PE Siltex Gel-filled Explant - Joint Strength Versus Time Implanted
Joint Stength (lbs)
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0
1
2
3
4
5
6
7
8
9
10
Years In Vivo

Fig. 5: TX PE Siltex Gel-filled Explant - Tension Set Versus Time Implanted



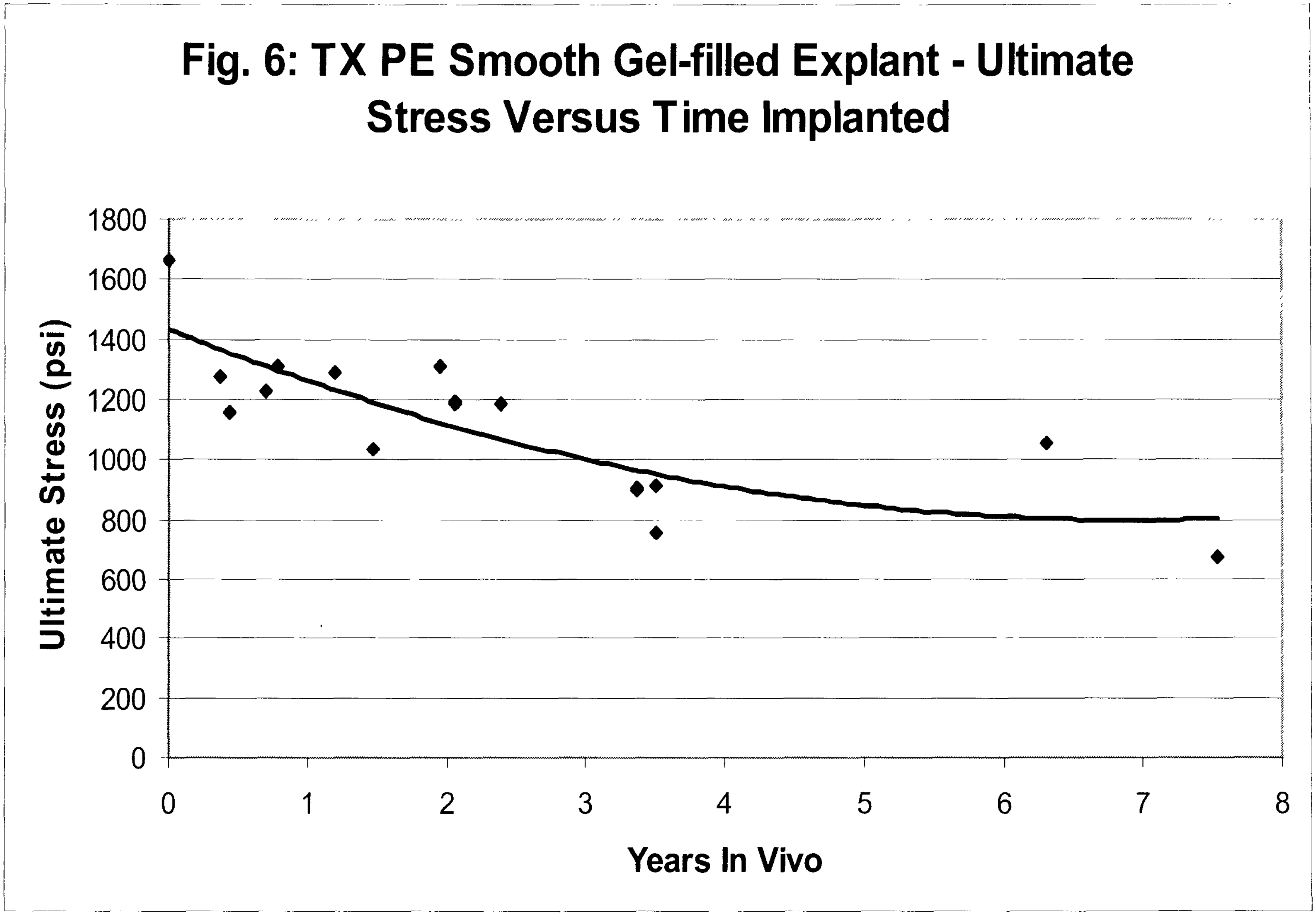


Fig. 6: TX PE Smooth Gel-filled Explant - Ultimate Stress Versus Time Implanted
Ultimate Stress (psi)
1800
1600
1400
1200
1000
800
600
400
200
0
0
1
2
3
4
5
6
7
8
Years In Vivo

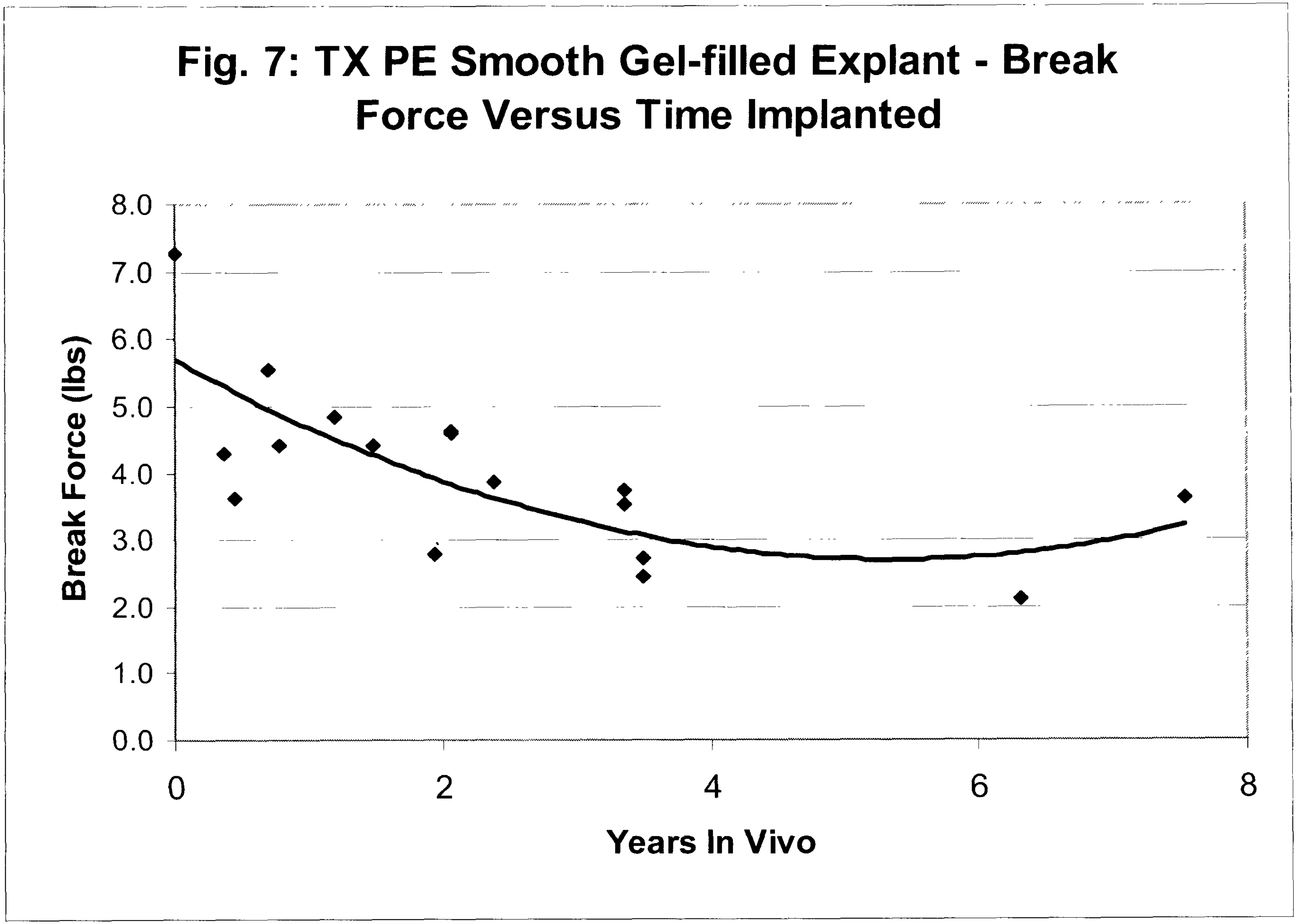


Fig. 7: TX PE Smooth Gel-filled Explant - Break Force Versus Time Implanted
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
Break Force (lbs)
0
2
4
6
8
Years In Vivo

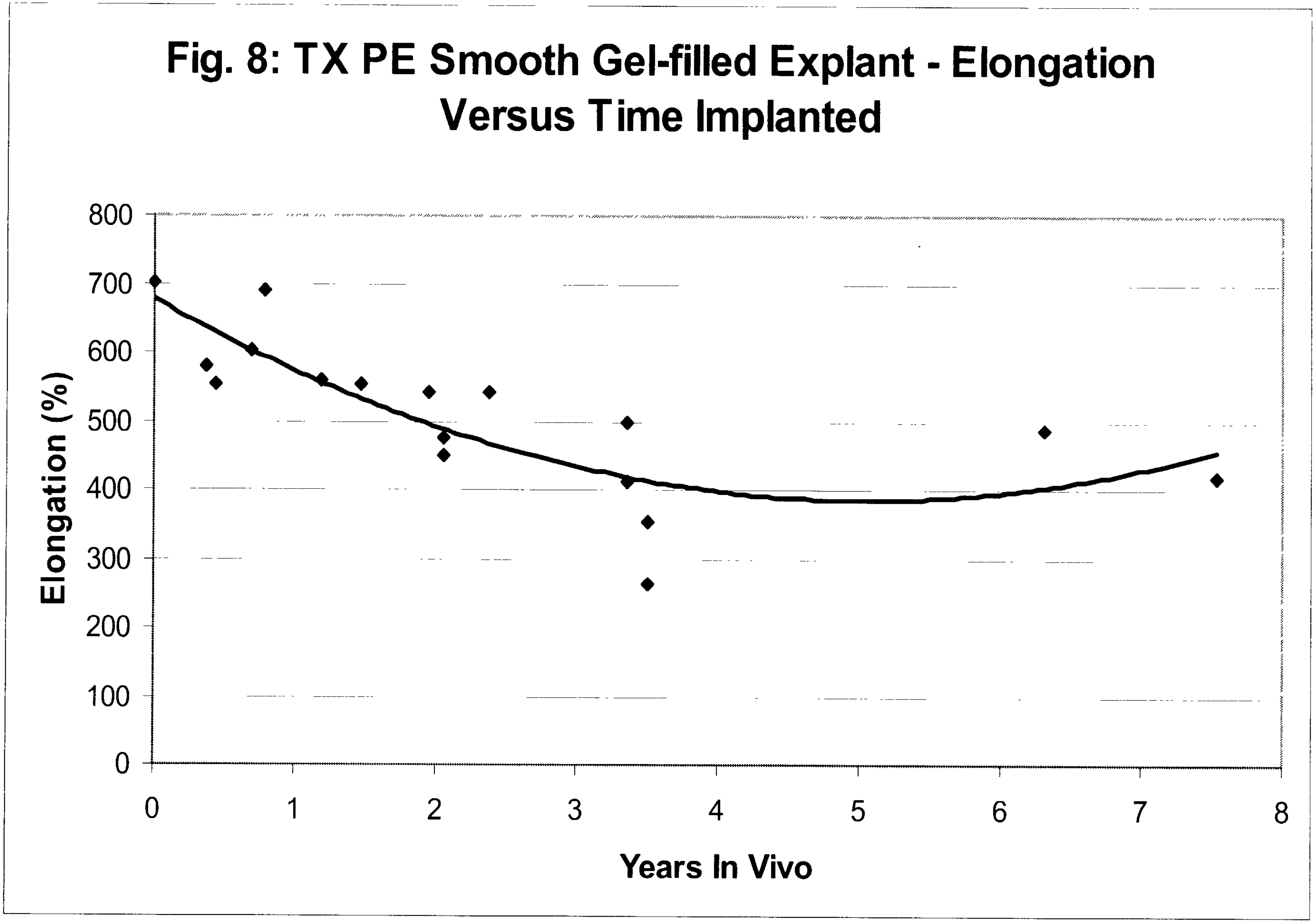


Fig. 8: TX PE Smooth Gel-filled Explant - Elongation Versus Time Implanted
Elongation (%)
800
700
600
500
400
300
200
100
0
0
1
2
3
4
5
6
7
8
Years In Vivo

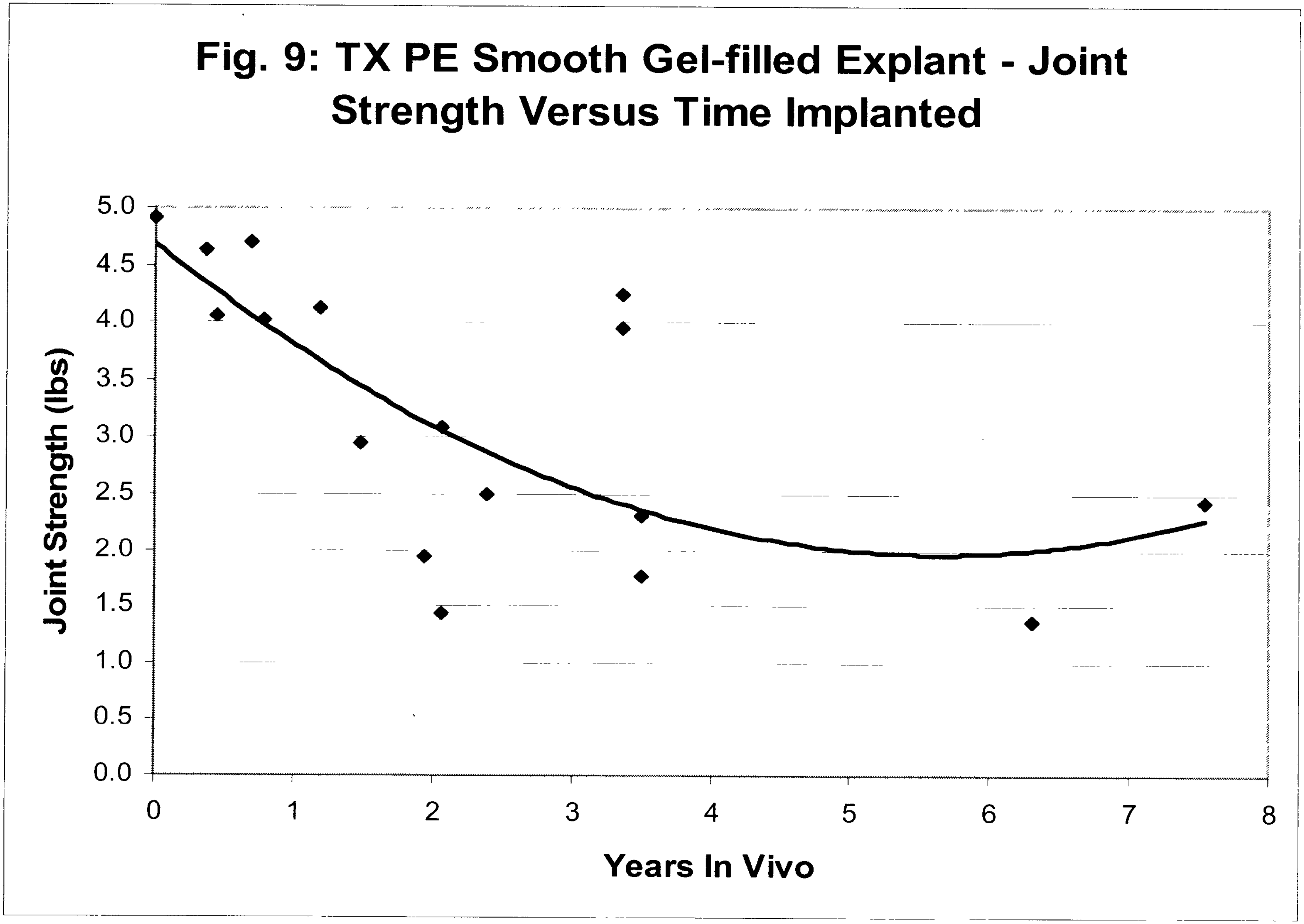


Fig. 9: TX PE Smooth Gel-filled Explant - Joint Strength Versus Time Implanted
Joint Strength (lbs)
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0
1
2
3
4
5
6
7
8
Years In Vivo

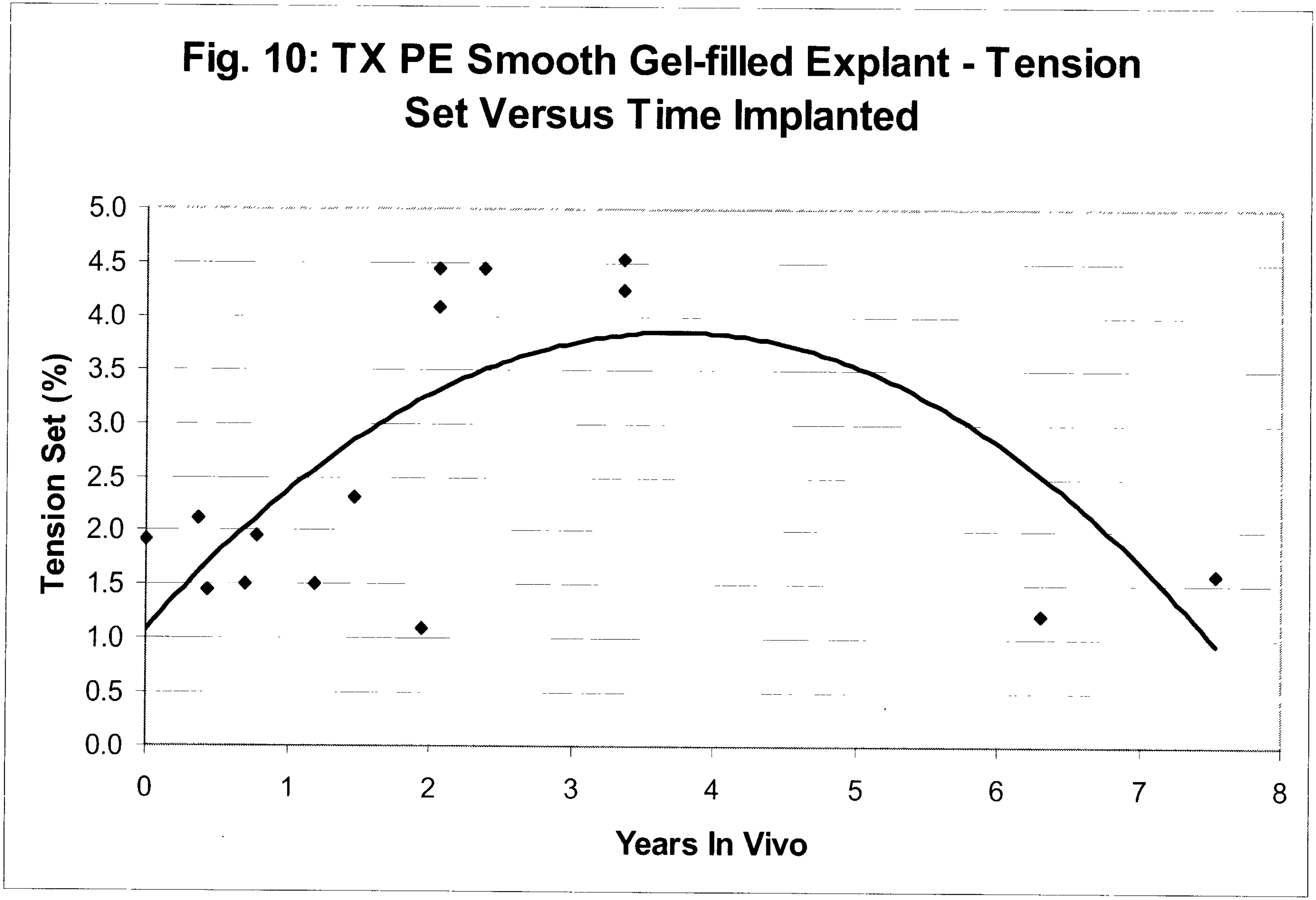
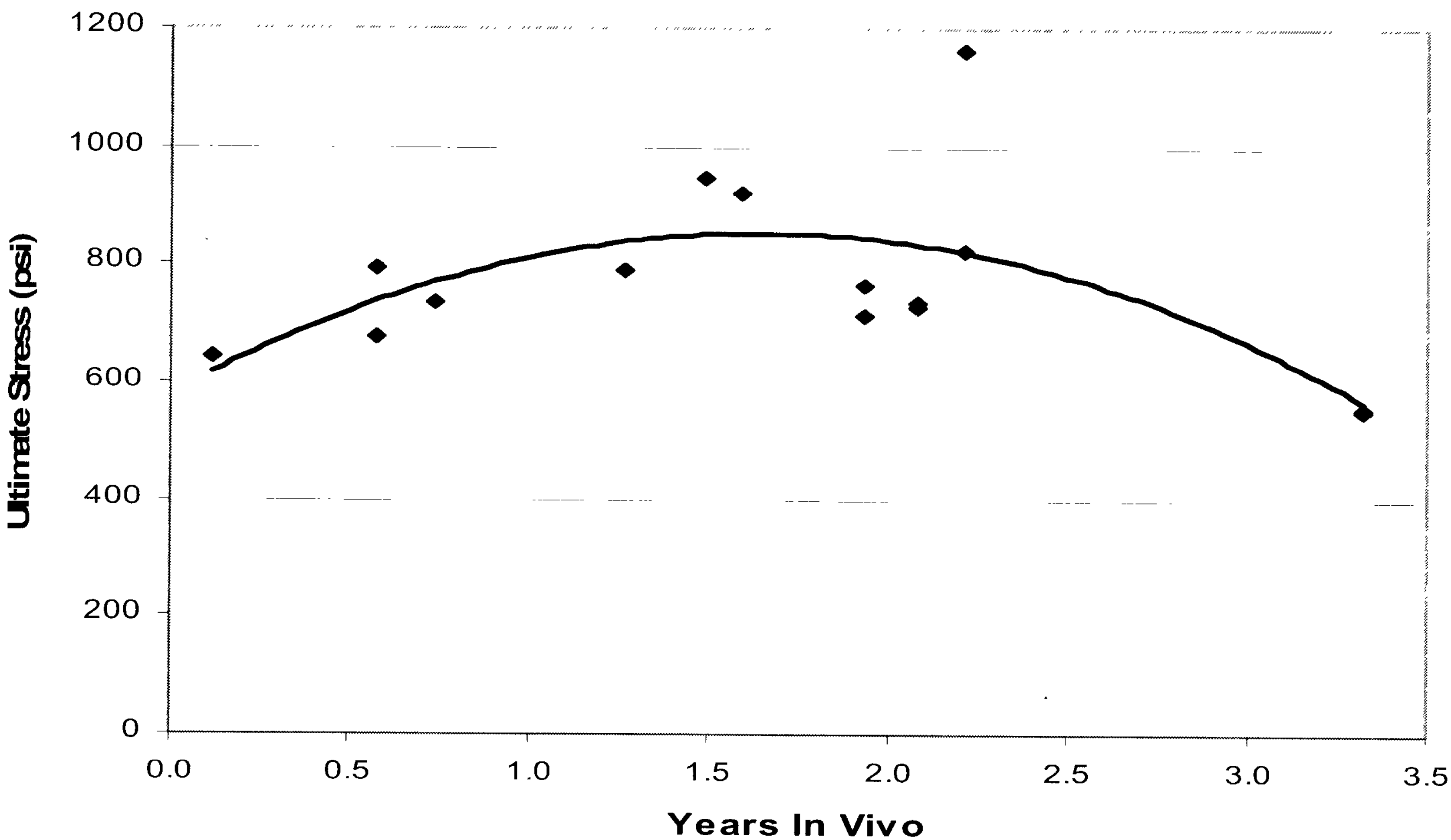


Fig. 10: TX PE Smooth Gel-filled Explant - Tension Set Versus Time Implanted
Tension Set (%)
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0
1
2
3
4
5
6
7
8
Years In Vivo

Fig. 11: Explanted Core Siltex Gels - Stress at Ultimate Versus Time Implanted



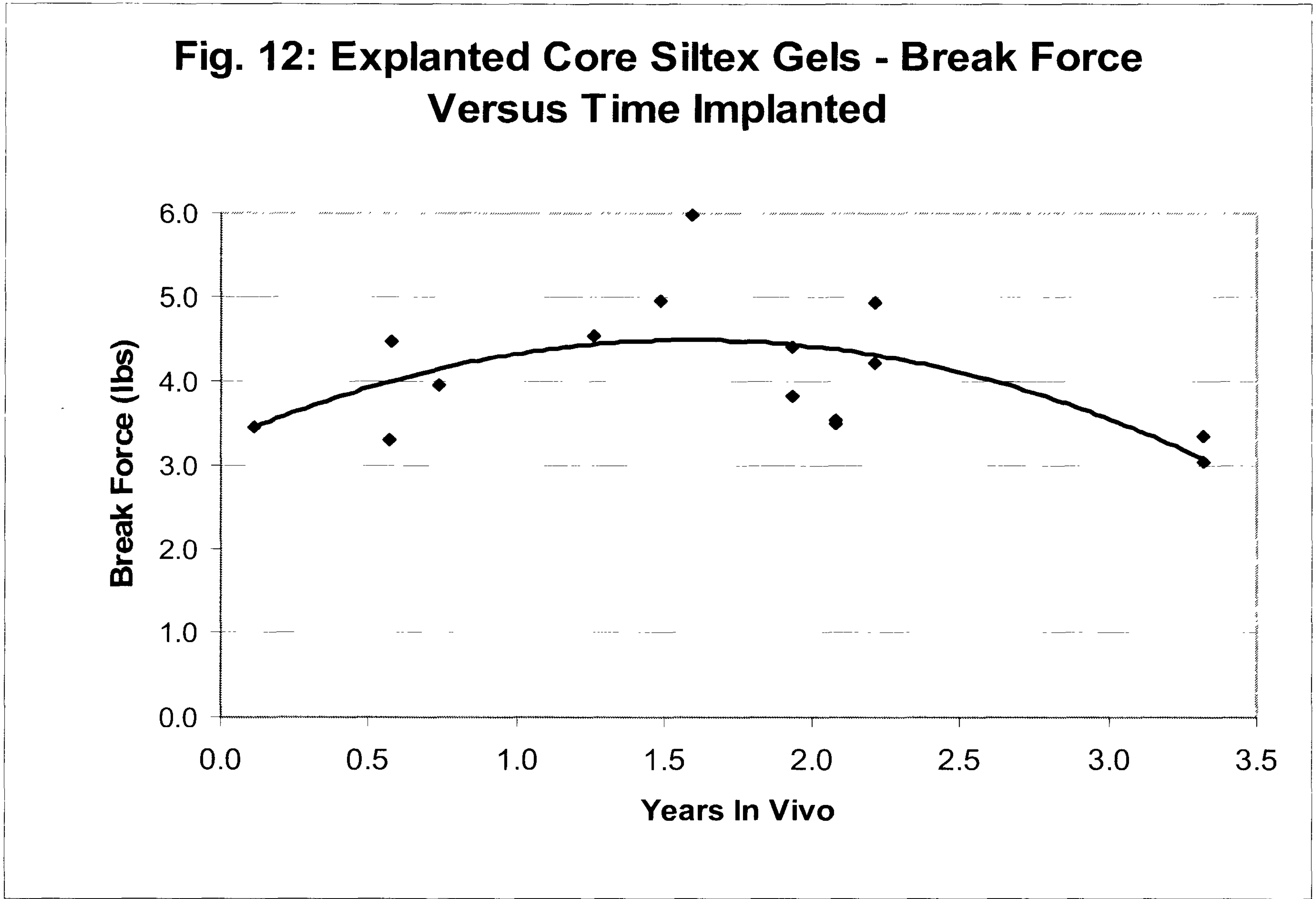


Fig. 12: Explanted Core Siltex Gels - Break Force Versus Time Implanted
Break Force (lbs)
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
Years In Vivo

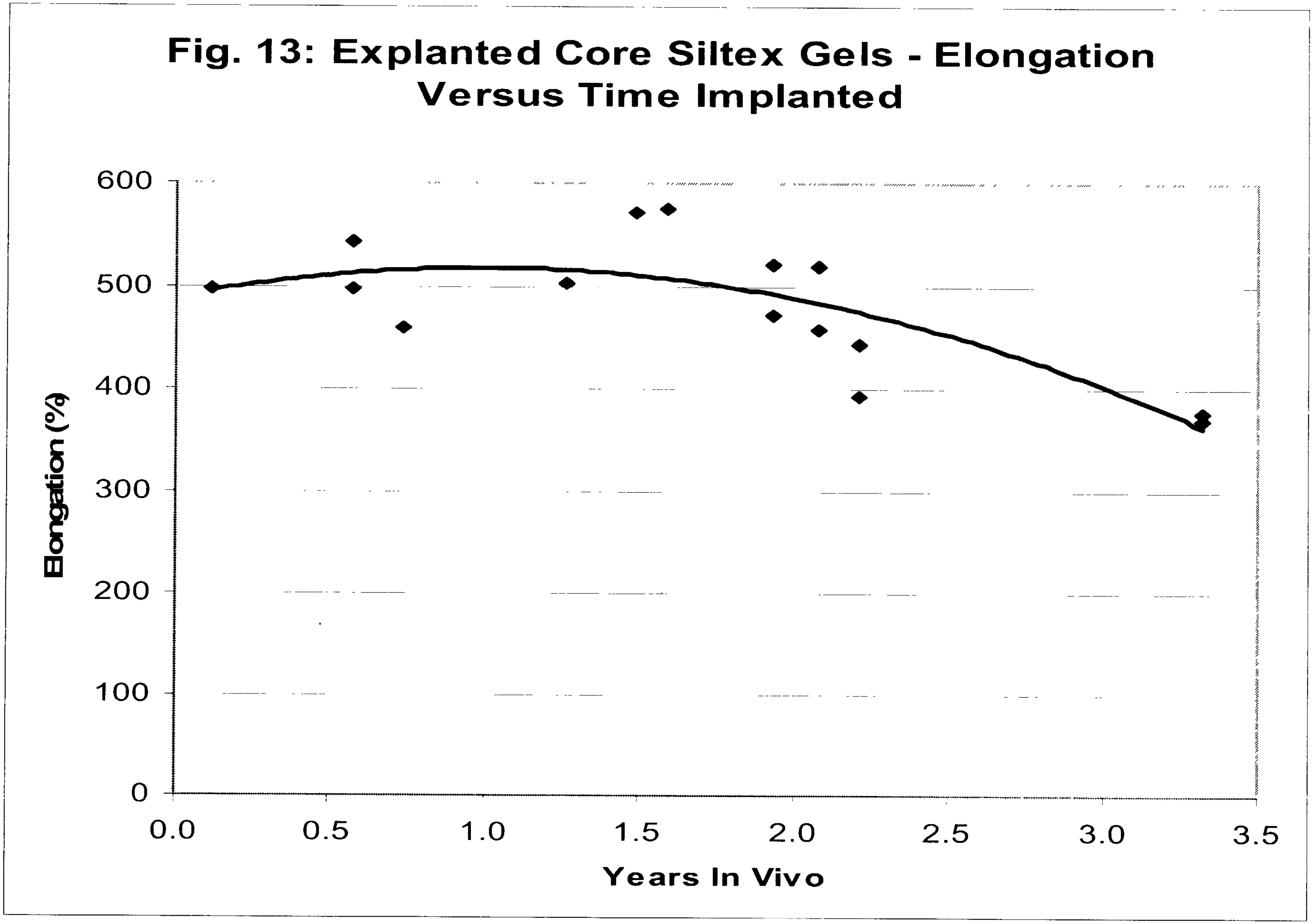
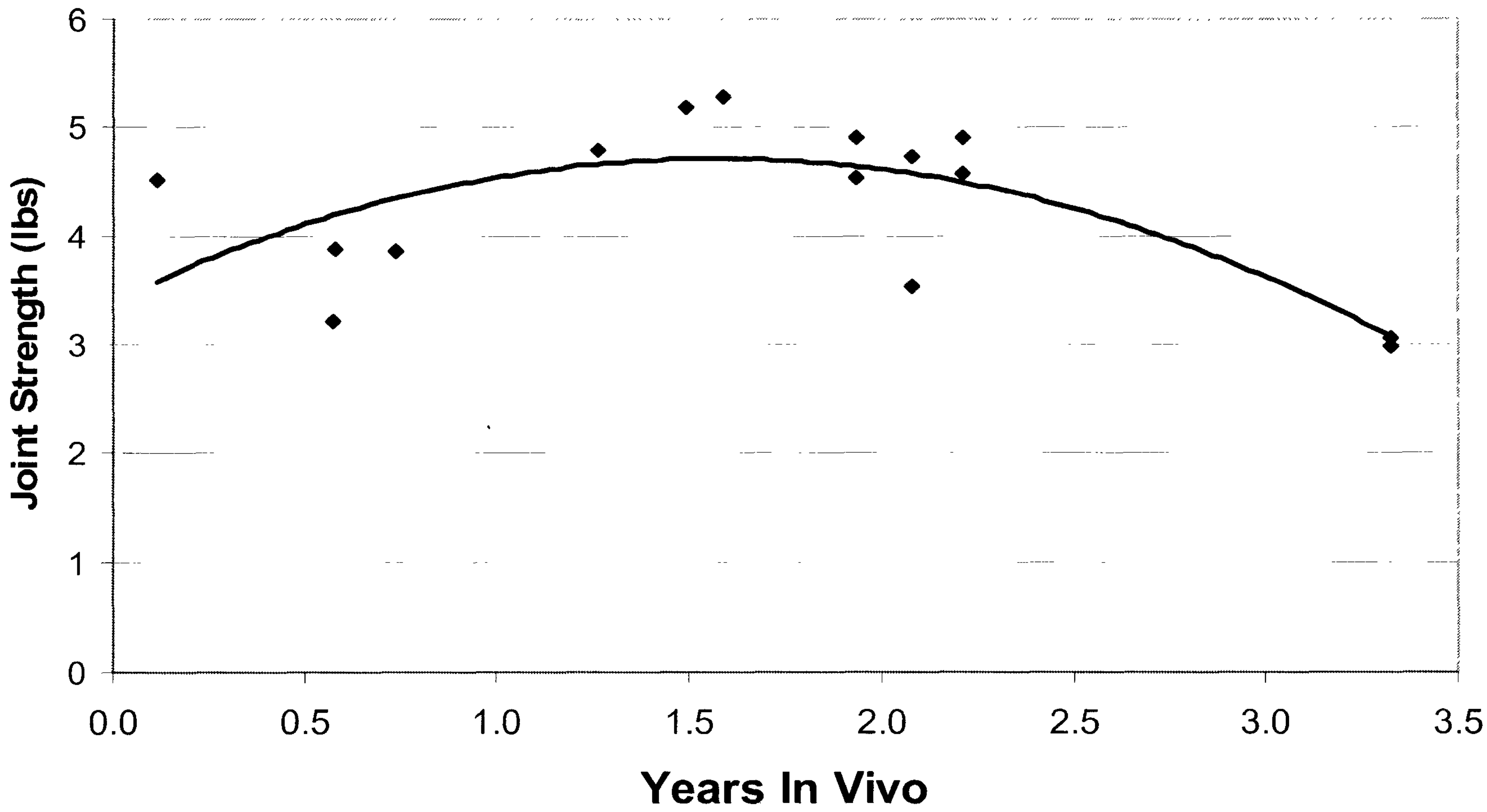


Fig. 13: Explanted Core Siltex Gels - Elongation Versus Time Implanted
Elongation (%)
600
500
400
300
200
100
0
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
Years In Vivo

Fig. 14: Explanted Core Siltex Gels - Joint Strength Versus Time Implanted



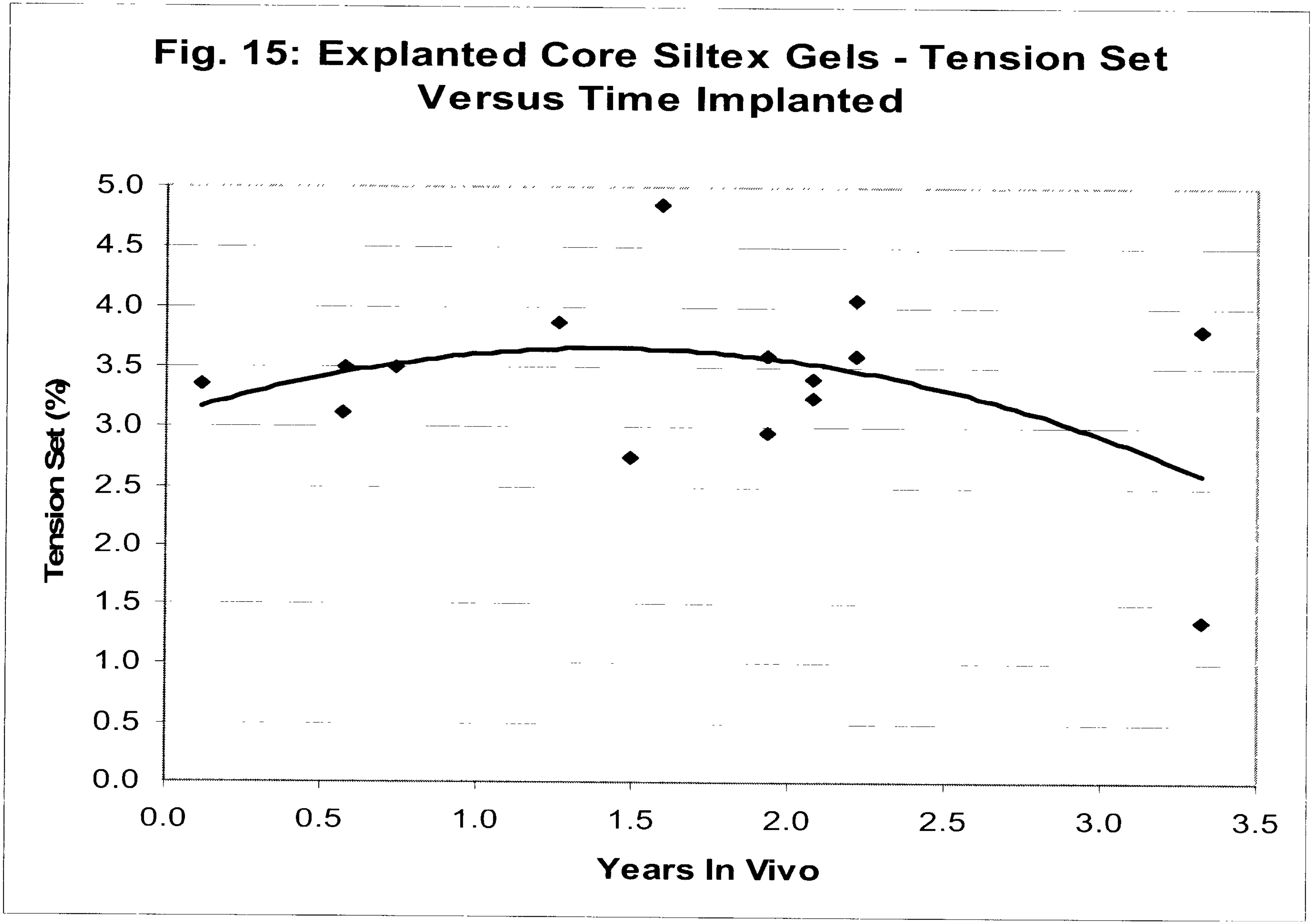


Fig. 15: Explanted Core Siltex Gels - Tension Set Versus Time Implanted
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
Tension Set (%)
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
Years In Vivo

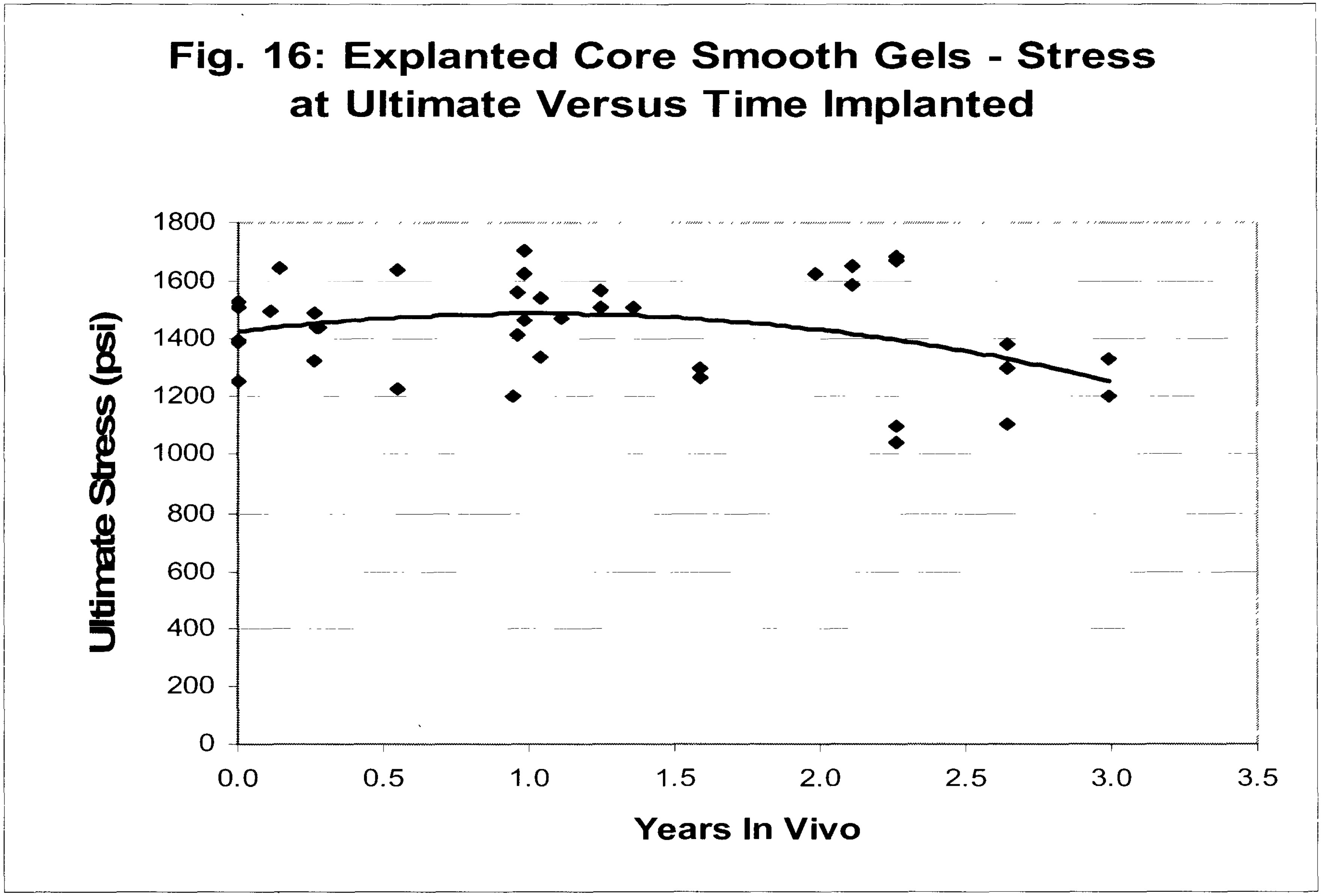


Fig. 16: Explanted Core Smooth Gels - Stress at Ultimate Versus Time Implanted
Ultimate Stress (psi)
1800
1600
1400
1200
1000
800
600
400
200
0
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
Years In Vivo

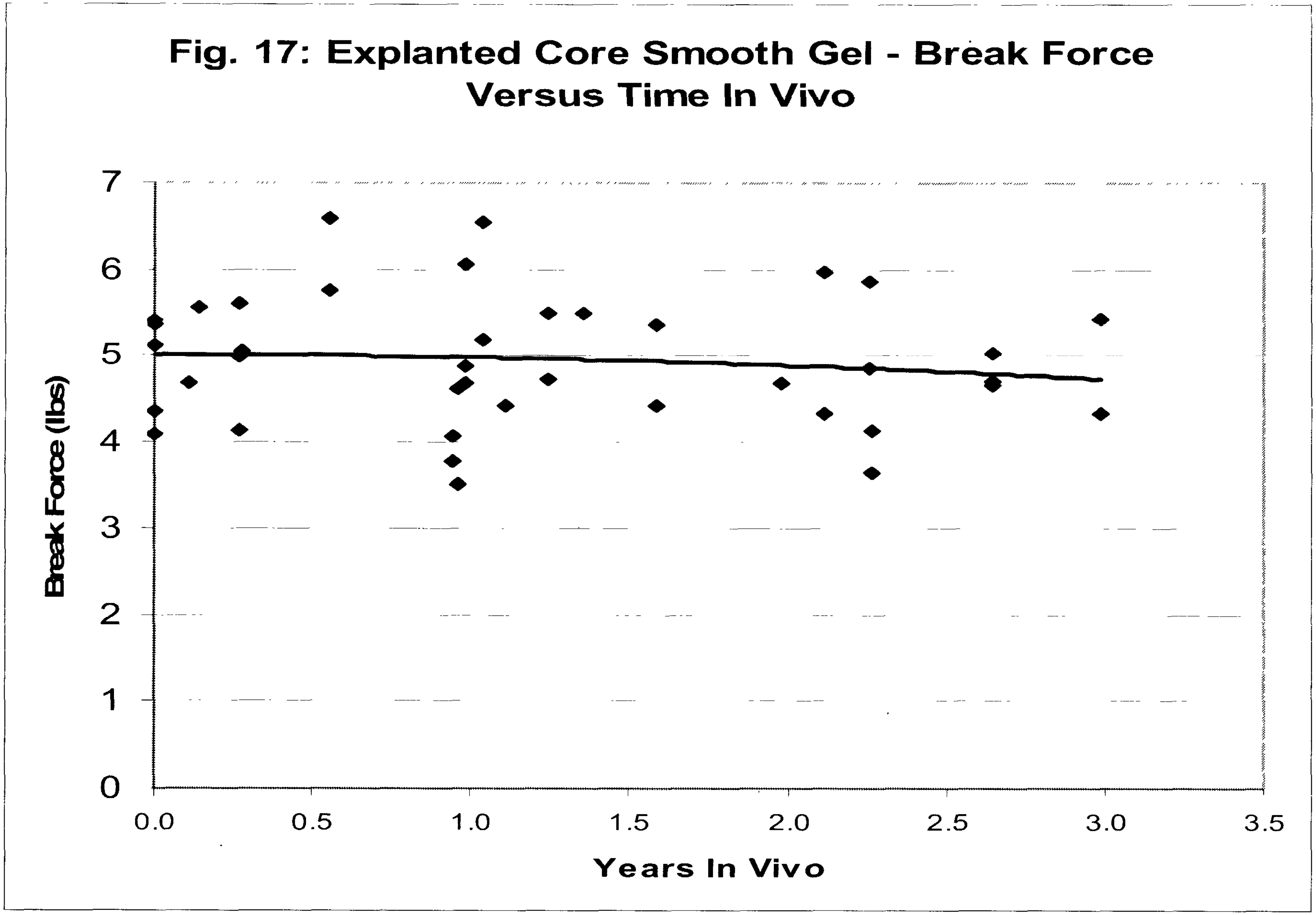


Fig. 17: Explanted Core Smooth Gel - Break Force Versus Time In Vivo
Break Force (lbs)
0
1
2
3
4
5
6
7
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
Years In Vivo

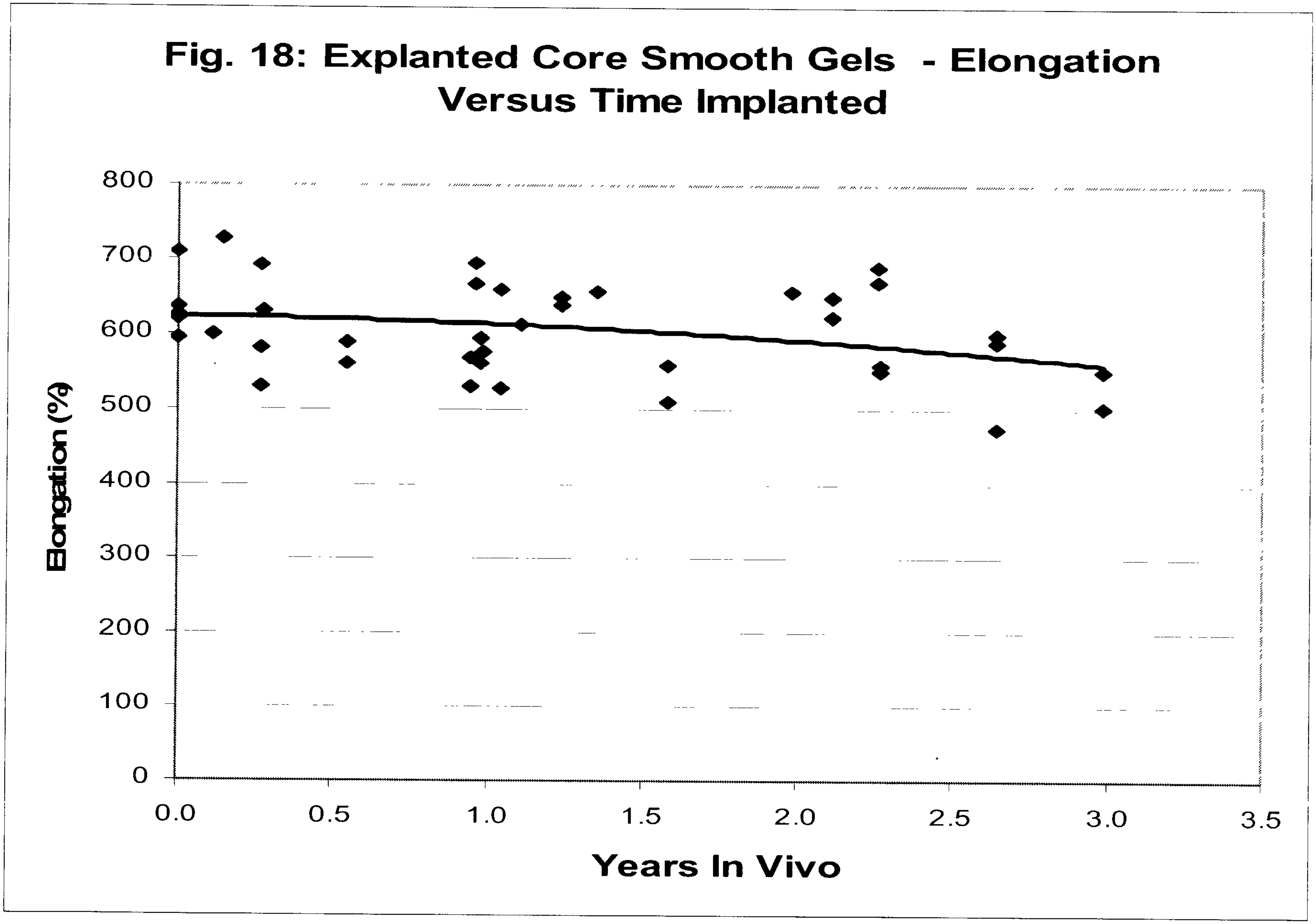
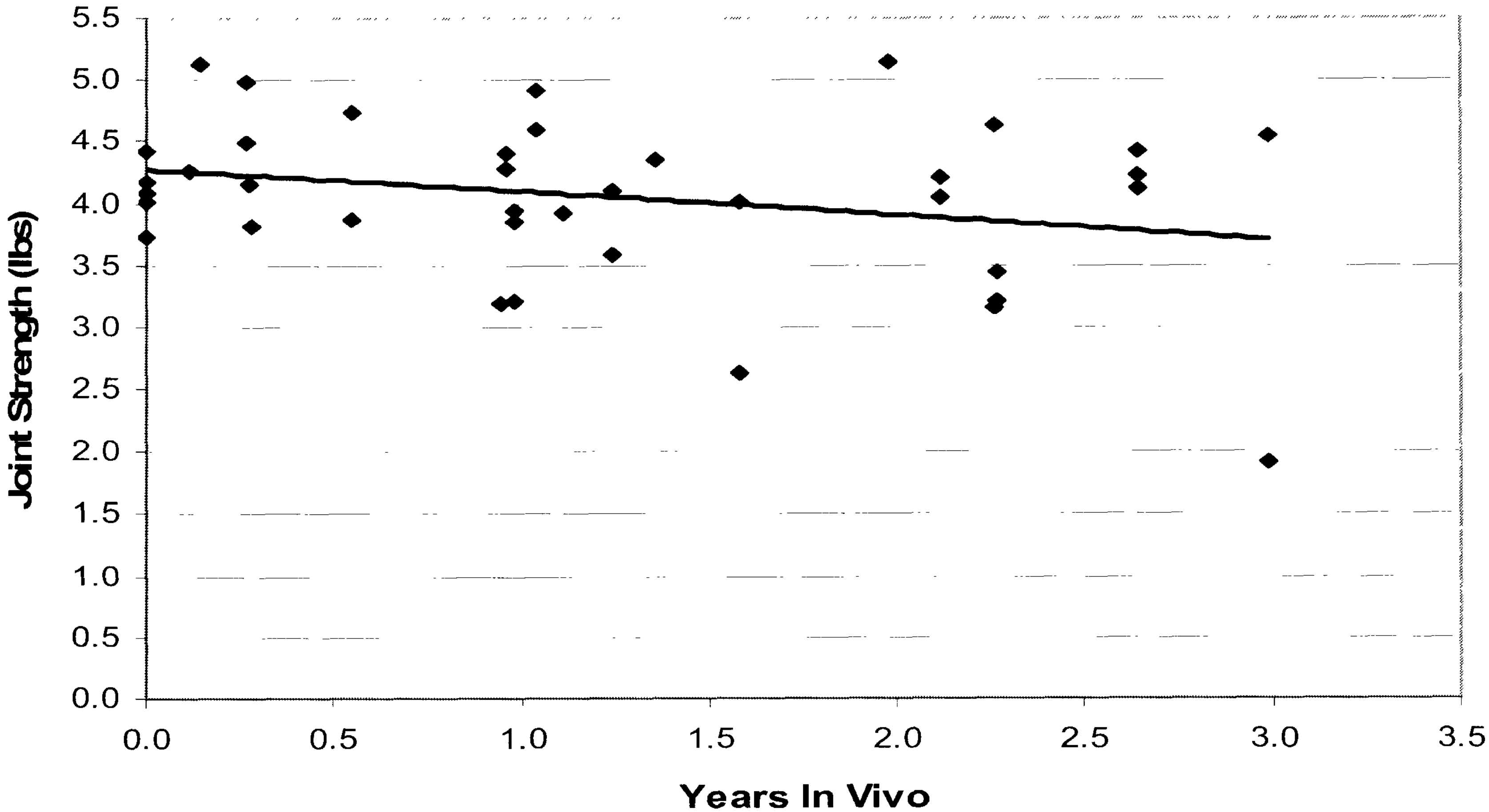


Fig. 18: Explanted Core Smooth Gels - Elongation Versus Time Implanted
800
700
600
500
400
300
200
100
0
Elongation (%)
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
Years In Vivo

Fig. 19: Explanted Core Smooth Gels - Joint Strength Versus Time Implanted



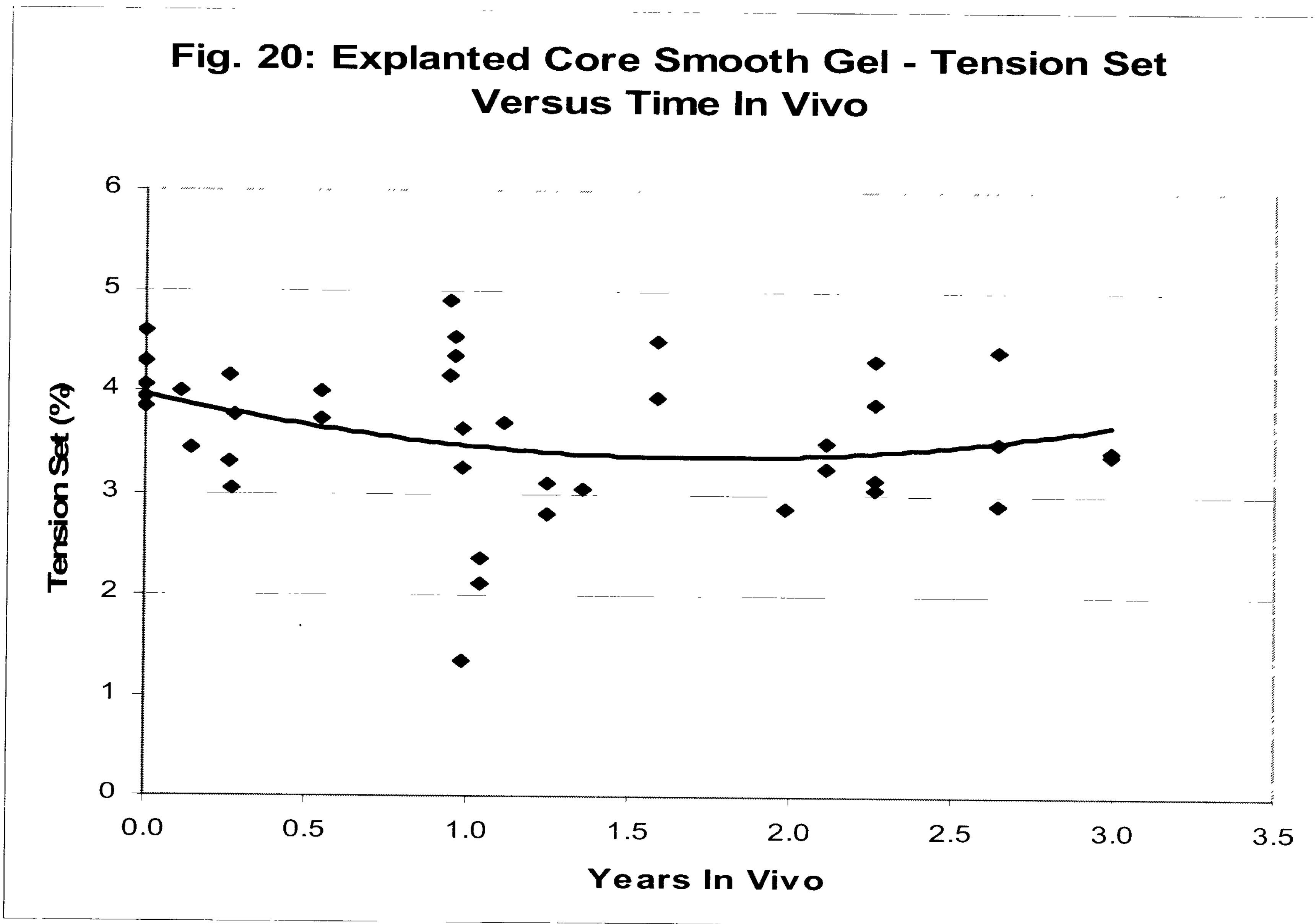


Fig. 20: Explanted Core Smooth Gel - Tension Set Versus Time In Vivo
Tension Set (%)
6
5
4
3
2
1
0
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
Years In Vivo