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RESEARCH ARTICLE

Residual properties of silicone (MED-4719) lead with leads from retrieved devices

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Abstract: Leads are designed for *in vivo* applications, however, for a definite period of time. *In-vivo* environment affects the mechanical behavior of implantable devices, therefore, there is a need to evaluate the residual properties of implantable leads used with pacemakers, defibrillator and neuro-stimulators. Silicone (MED-4719) lead is widely used in cardiac implantable electronic devices made by different manufacturers. . We collected 150 devices (with or without leads) from Anatomical Gift Program of the Wright State University. The objective of this study was to investigate the residual properties of Silicone (MED-4719) lead with different *in vivo* exposure time and compare the properties of a new, unused lead supplied by Medtronic for the purposes of this research. The tensile test was performed by applying specific load on the samples, percentage elongation at 5N and the corresponding displacement measured. Load to failure, percentage elongation, ultimate tensile strength, and modulus of elasticity were determined for each lead. Methods to collect and compile data were standardized, and statistical models were used to assess the sensitivity of measured parameters with *in vivo* performance. Load to failure, elongation to failure, ultimate tensile strength, and percentage elongation at 5N showed a significant decrease after 94 months ($P = 0.0063$), 8 months ($P = 0.0136$), 94 months ($P = 0.0244$) and 71 months ($P\text{-value} = 0.0326$) after implantation, respectively. On the other hand, modulus of elasticity was found proportional to the number of months device was exposed and showed significant increase after 71 months ($P = 0.0446$) of *in-vivo* environment.

Keywords: insulation, *in-vivo* study, load to failure, cardiac leads

1 Introduction

Insulation breach, though occur rarely, may result in short circuits, tissue damage and may lead to lead failure resulting in adverse clinical outcomes. In one of the product performance reports, nearly a thousand leads had experienced insulation breach. Therefore, there is a need to develop repositories of retrieved devices and integrity of lead insulation investigated. While retrieved devices are pulled out, it is often difficult to isolate the damage from retrieving the device and naturally occurring damage in the lead as a result of exposure. 5076 CapSureFix Novus MRI SureScan Lead has multi-length, active fixation, bipolar, coaxial design, with silicone (MED-4719) outer insulator and insulated between the two coils (Medtronic, Minneapolis, MN, USA). This lead received FDA in 2000 [1].

Silicone rubber was used during the 1960's for the first time in the cardiac devices as an insulator for leads. It is biocompatible and biostable. However, it can tear easily at the same time possesses a high coefficient of friction. The silicon rubber also has tendency to creep, which leads to insulation necking at the area of sustained stresses [1]. Silicon was modified to overcome abrasion, tear and creep with higher tensile strength and abrasion resistance. These include high-performance (HP) silicone, extra-tear-resistant (ETR) silicone, and Novus (Med-4719, Nusil Technologies, Carpinteria, Calif), produced by hybridizing HP and MDX4 silicone [2]. 5076 CapSureFix Novus MRI SureScan Lead uses Novus (Med-4719) as an insulator [3].

Determining the residual properties of leads were quite complex since there are no standards that one could follow. Literature presented how residual properties deteriorated with *in-vivo* environment. For instance, Wilkoff et al. [4] presented data on three different insulations- Optim, P55D, and silicone elastomer. These leads categorized into three different *in-vivo* years (zero-year, 2-3 years, and 4-5 years). Afterward, tensile test was performed to obtain the maximum load and extension. Results showed that Optim molecular weight decreased 20% after 2-3 years, then remained unchanged at 4-5 years. On the other hand, tensile strength decreased 25% after 2-3 years then became stable at 4-5 years. Furthermore, elongation did not change at all. Molecular weight of polyurethane was not exposed to any changes during that period. Silicone showed significant biostability compared to polyurethane and Optim.

Another Study was performed to compare the tensile strength of insulation among three manufacturers by Chan et al. [5]. Boston Scientific - FINELINE II STEROX 4456, Medtronic - CAPSURE SENSE 4074, and Abbott=- ISOFLEX OPTIM 1948 were the three leads in this study. This study was done using in-vitro environment. They immersed the leads in 0.9 normal saline solution at room temperature for 10 days. Afterward, tensile test was performed. Boston Scientific and Medtronic lead showed same tensile strength; however, Abbott lead showed lower tensile strength than BSX and MDT leads ($p<0.001$).

Starck et al. [6] categorized the leads according to the method of performing tensile test. First group was without central supporting stylet, second group was with central supporting stylet, while third group was with supporting stylet in compression. Results showed tensile strength for group one was 28.3 ± 0.3 N, group two 30.6 ± 3.0 N, and group three 31.6 ± 2.9 N. Modulus of elasticity for group one was 22.8 ± 0.1 MPa, for group two 2830.8 ± 351.1 MPa, and for group three 2447 ± 510.5 MPa. This study introduced the supporting stylet that can enhance mechanical behavior of leads insulation.

2 Methods

Twenty-five 5076 CapSureFix Novus MRI SureScan pacing leads were used in the experiment. This lead is 52 cm active fixation, bipolar, coaxial design, with silicone (MED-4719) as an outer insulator and as an insulator between the two coils (Medtronic, Minneapolis, MN, USA). Two new, unexposed, leads were provided by Medtronic. The rest of the leads were received from the Wright State University Anatomical Gift Program. *In vivo* implantation duration was different for each lead with an average of 55.875 ± 49.04 months. Test Resources Q series system was used to perform the tensile test. Figure 1 demonstrates the test procedure including the sample preparation, length before and after the test, the fixture, and the cross-section of the sample under the microscope showing the coils and two insulators. Tests were run in compliance with ASTM Standard D 1708-02a [7] (Standard Test Method for Tensile Properties of Plastic by Use of Microtensile Specimens) and ASTM Standard D 412-06a [8] (Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension). The length of the samples was fixed to 38mm for all tested leads, 8mm in the grip and 22mm between the grips. The leads were tested with the coil inside the insulation. The lead was fixed in the grips by sandpaper to avoid slippage. The tensile test was performed by applying specific loads on the samples, and the corresponding displacement measured. The tensile test was repeated at least two to seven times and the average of the results was calculated. First, the diameter was measured for each specimen at three locations and the average diameter was calculated. A gage of 22 mm length was used for all the specimens. Also, all leads were examined under the optical microscope to investigate the damage before and after the tests as shown in Figure 2. The tensile load was applied at a rate of 1 mm/sec, and the body of the lead was observed for extension. In addition, load to failure, elongation to failure, percentage elongation at 5N, ultimate tensile strength, and modulus of elasticity were calculated after the lead insulation separated. Finally, the equivalent data were compared with respect to the *in-vivo* exposure in years.

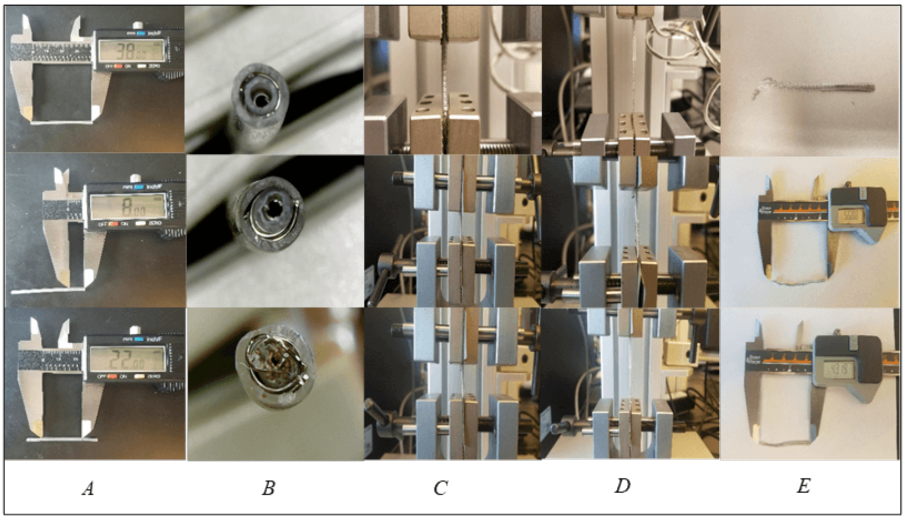

Figure 1 (A) Specimen measurement; (B) Cross-section of the lead; (C) During the test; (D) At the break point; (E) After deformation

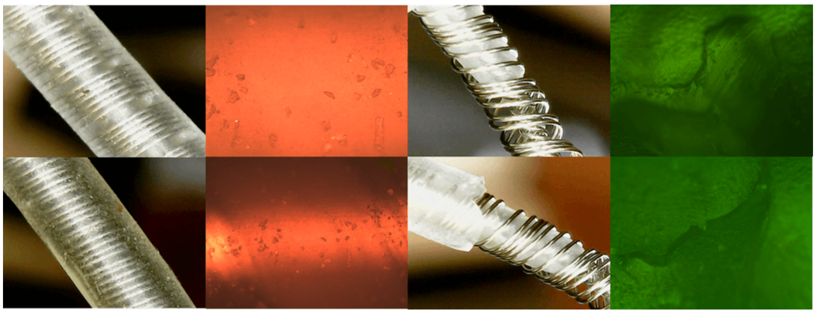

Figure 2 Microscopic inspection for the lead before and after tensile test

3 Results

3.1 Load to failure

The load to failure of the new lead was 21.9272N ± 4.3N. However, this value changed to 25.1678N ± 0.35 N after 6 months of *in-vivo* implantation. The maximum load had decreased slightly after 8 months to reach 21.05145 N ± 1.118N. Then the load to failure has declined to 19.59N ± 5.26 N after 18 months of implantation and continued decreasing slightly until it reached 12.02864N ± 1.999N after 132 months of *in-vivo* exposure, as shown in Figure 3. This deterioration did not affect the usability and the duration of the lead. The lead remained fully functioning for the 132 months of the *in-vivo* environment until extraction.

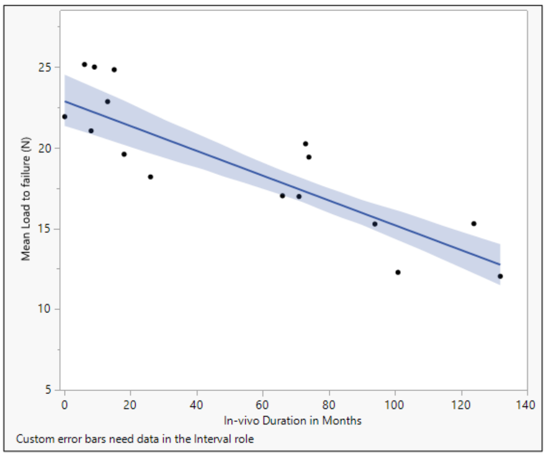

Figure 3 Representative Mean Load to Failure *vs in-vivo* months plot of 5076 CapSureFix Novus MRI SureScan pacing leads

A mathematical model developed to predict the maximum load with respect to the number of *in-vivo* months:

$$Load\ to\ Failure = -0.0767\tau + 22.88$$

Where τ represents number of months the lead was exposed *in-vivo*.

Statistical analysis performed to identify the significance of the maximum load to failure, and it was found that there is a significant difference in maximum load to failure after 94 months ($p = 0.0063$), this difference can be represented by the drop of the load from 21.9272N ± 4.3N to 15.27N ± 1.999.

3.2 Elongation to failure

Elongation to failure was investigated and found to decline from 167.556% ± 5.062% for the new lead to 137.5115% ± 8.413% after 8 months of implantation. The percentage elongation dropped to 130.39% ± 3.19% after 15 months. The results show that after 8 months, there was no significant difference in the percentage elongation compared to the new lead ($p = 0.0136 \sim < 0.0001$). These results showed a steady line between 8 months and 132 months, until it reached 109.479% ± 7.634% after 132 months. A mathematical model developed to predict the percentage elongation with respect to the number of *in-vivo* months exposure:

$$Elongation\ to\ Failure = -0.3634\tau + 144.95$$

Where τ represents the number of months. (see Figure 4)

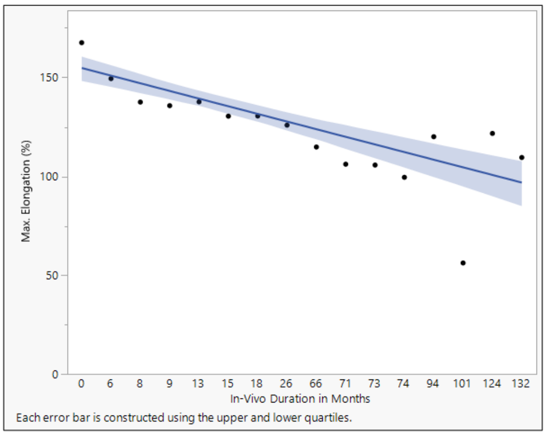

Figure 4 Representative Percentage Elongation *vs in-vivo* months plot of 5076 CapSureFix Novus MRI SureScan pacing leads

Statistical analysis performed for the elongation to failure. It was found that there is a significant difference in percentage elongation after 8 months (*p = 0.0136*), this difference can be represented by the drop of the elongation to failure from 149.376% $\pm$ 7.208 to 137.512% $\pm$ 7.208..

3.3 Percentage elongation at 5N force

The percentage elongation was investigated in this study with 5 N force applied, as literature showed that the maximum load that can be applied to the lead *in-vivo* is within the range of 5 N [9]. Percentage elongation at 5N force was similar to percentage elongation during load to failure and resulting percentage elongation after tests. It showed that there is a significant difference after 71 months of *in-vivo* exposure when compared to new lead (*P-value = 0.0326*). A mathematical model developed to predict the 5N force percentage elongation with respect to the number of *in-vivo* months:

$$5N\ Force\ Percentage\ Elongation = -0.0746\tau\ +\ 19.9176$$

Where τ represents the number of months. (see Figure 5)

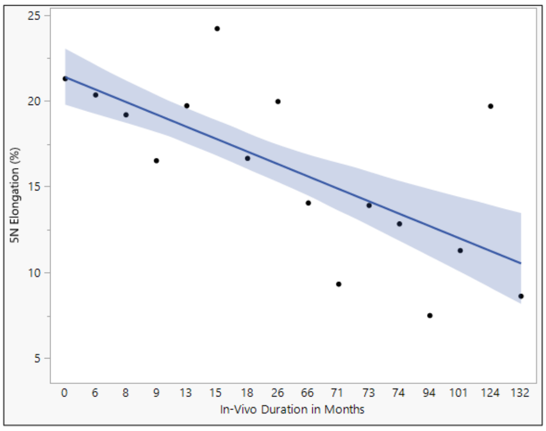

Figure 5 Representative Percentage Elongation at 5N *vs in-vivo* months plot of 5076 CapSure-Fix Novus MRI SureScan pacing leads

3.4 Ultimate tensile strength

Additionally, the ultimate tensile strength (UTS) was found to be 6.716 MPa $\pm$ 1.49 MPa for the new leads. The UTS has slightly decreased to 5.4303 MPa $\pm$ 0.22 MPa after 8 months of implantation, it continues decreasing until 94 months, which showed a significant decrement (*p = 0.0244*) compared to the new lead. A mathematical model developed to predicted ultimate tensile strength with respect to the number of *in-vivo* months:

$$UTS = \ -0.019615\tau\ +\ 6.8656$$

Where τ represents the number of months. (see Figure 6)

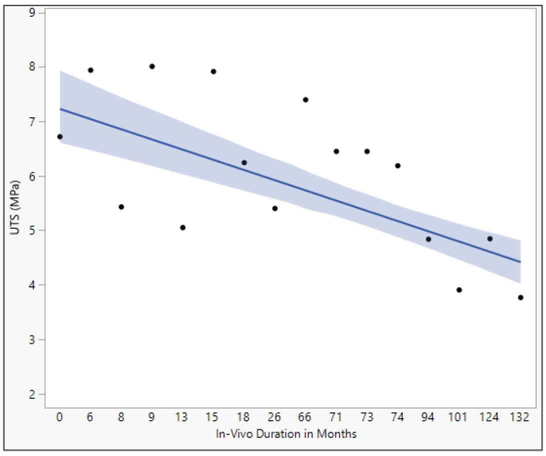

Figure 6 Representative Ultimate Tensile Strength *vs in-vivo* months plot of 5076 CapSureFix Novus MRI SureScan pacing leads

3.5 Modulus of elasticity

Finally, the modulus of elasticity was calculated and statistically analyzed. It shows direct proportionality between the modulus of elasticity and the number of *in-vivo* months as shown in Figure 7. The statistical analysis showed a significant increase in modulus of elasticity after 71 months($p = 0.0446$). A mathematical model developed to predict the modulus of elasticity with respect to the number of *in-vivo* months:

$$E = 0.058079\tau + 8.0443$$

Where τ represents the number of months.

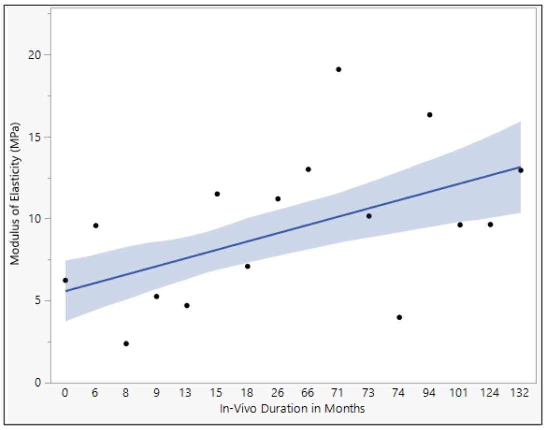

Figure 7 Representative Modulus of Elasticity *vs in-vivo* months plot of 5076 CapSureFix Novus MRI SureScan pacing lead

All residual properties are summarized in Table 1. Duration of *in-vivo* environment, load to failure, elongation to failure, 5N percentage elongation, ultimate tensile strength, and modulus of elasticity were tabularized with the area where the insulation broke.

4 Discussion

Residual tensile properties of 25 retrieved leads were investigated and compared with unused leads donated by Medtronic. Number of tests varied since each retrieved lead was of different length ensuring that no prior damage continue through. Insulation with the coil were tested as a composite. Since the insulator outer wall was mounted in the sand paper and the grip, the insulator carried the load. Prior to testing individual devices were examined for surface defects, both on the leads and pacemakers [11, 12] and data developed into a survival model. Understanding the deterioration, how residual properties with exposure time change is critical to prevent unwanted insulator breach and resulting tissue damage, sort-circuit resulting in unable to deliver the therapy and in extreme cases death. The residual properties of the Medtronic 5076 CapSureFix Novus MRI SureScan lead compared with new lead, Table 1, Figure 8. The results showed that load to failure, elongation to failure, ultimate tensile strength, and percentage elongation at 5N showed a significant decrease after 94 months (*P = 0.0063*), 8 months (*P = 0.0136*), 94 months (*P = 0.0244*) and 71 months (*P-value = 0.0326*) after implantation, respectively. This is due to the effect of internal body environment on the insulator (silicone (MED-4719)). Longer exposure does not lower the mechanical properties at the same rate as it does the first few years of exposure. Finally, a significant drop in the residual properties occurred after 71 months of implantation, which is probably as a result of creep, abrasion, tear, and environmental interaction [2, 11, 12].

Table 1 Residual properties of the tested leads with corresponding area of insulation break

In-vivo Duration in Months	Load to failure (N)	Max. Elongation (%)	5N Elongation (%)	UTS (MPa)	Modulus of Elasticity (MPa)
New Lead	26.477	186.684	20.733	8.761	7.453
New Lead	17.141	169.052	21.580	5.459	4.572
New Lead	26.477	162.732	21.312	8.432	7.971
New Lead	18.277	165.380	22.115	5.821	5.335
New Lead	22.324	168.198	21.230	5.512	9.356
New Lead	27.511	176.540	22.768	8.761	5.278
New Lead	19.833	163.463	18.763	6.316	4.817
6	24.918	148.387	19.984	7.777	9.561
6	25.418	150.365	20.711	8.095	9.624
8	21.842	143.461	16.830	5.682	2.153
8	20.261	131.562	21.550	5.179	2.572
9	24.754	131.884	20.855	7.964	5.959
9	25.263	139.500	12.177	8.045	4.518
13	22.576	134.785	20.180	4.960	1.438
13	22.932	129.754	18.984	5.074	3.202
13	23.078	148.346	19.986	5.121	9.423
15	24.174	132.650	24.394	7.699	11.307
15	25.513	128.132	24.034	8.125	11.662
18	26.723	136.309	19.650	8.511	16.627
18	23.758	125.895	18.412	7.566	12.682
18	16.196	148.197	20.839	5.158	2.595
18	15.468	114.227	13.092	4.926	1.300
18	15.843	127.791	11.263	5.046	2.168
26	19.550	124.045	19.550	5.442	9.419
26	16.836	127.650	20.380	5.362	12.958
66	16.826	114.795	13.794	7.394	16.751
66	17.217	114.795	14.308	7.394	9.221
71	16.976	106.100	9.320	6.447	19.078
73	18.885	113.329	19.559	6.014	8.841
73	21.539	102.973	10.933	6.860	10.389
73	20.310	100.710	11.230	6.468	11.191
74	19.421	99.450	12.833	6.185	3.966
94	16.334	105.893	7.240	5.075	19.174
94	15.788	137.893	7.822	5.028	18.013
94	16.334	105.893	7.793	5.202	18.736
94	13.723	128.676	7.675	4.370	11.678
94	14.174	121.628	6.916	4.514	13.962
124	16.406	117.195	20.850	5.225	6.456
124	15.222	138.550	24.500	4.848	5.759
124	15.291	102.673	9.023	4.780	20.386
124	14.245	128.260	24.394	4.537	5.891
132	13.368	101.236	8.060	3.977	21.764
132	11.413	115.998	8.473	3.635	15.385
132	13.221	112.696	9.163	4.184	13.518
132	8.773	116.231	8.485	2.794	1.505
132	13.368	101.236	8.906	4.257	12.475

The modulus of elasticity on the other hand showed an increase in residual tensile properties as the number of *in-vivo* months increased and reached maximum modulus of elasticity at 132 months of *in-vivo* exposure. Since we do not know the right mechanism of this behavior it may be speculated that longer exposure increased crystallinity and oxidation. It is also possible that under these conditions the insulator may become susceptible to cracking causing the breach. *In-vivo* contacts and loading may raise temperature due to high coefficient of friction between the lead, lead and coil, and lead and tissue [10]. The glass transition temperature *in vivo* is several times higher than the insulator, high temperature deformation mechanisms such as creep may become active by global damage development, cavities and linking to cracking may result.

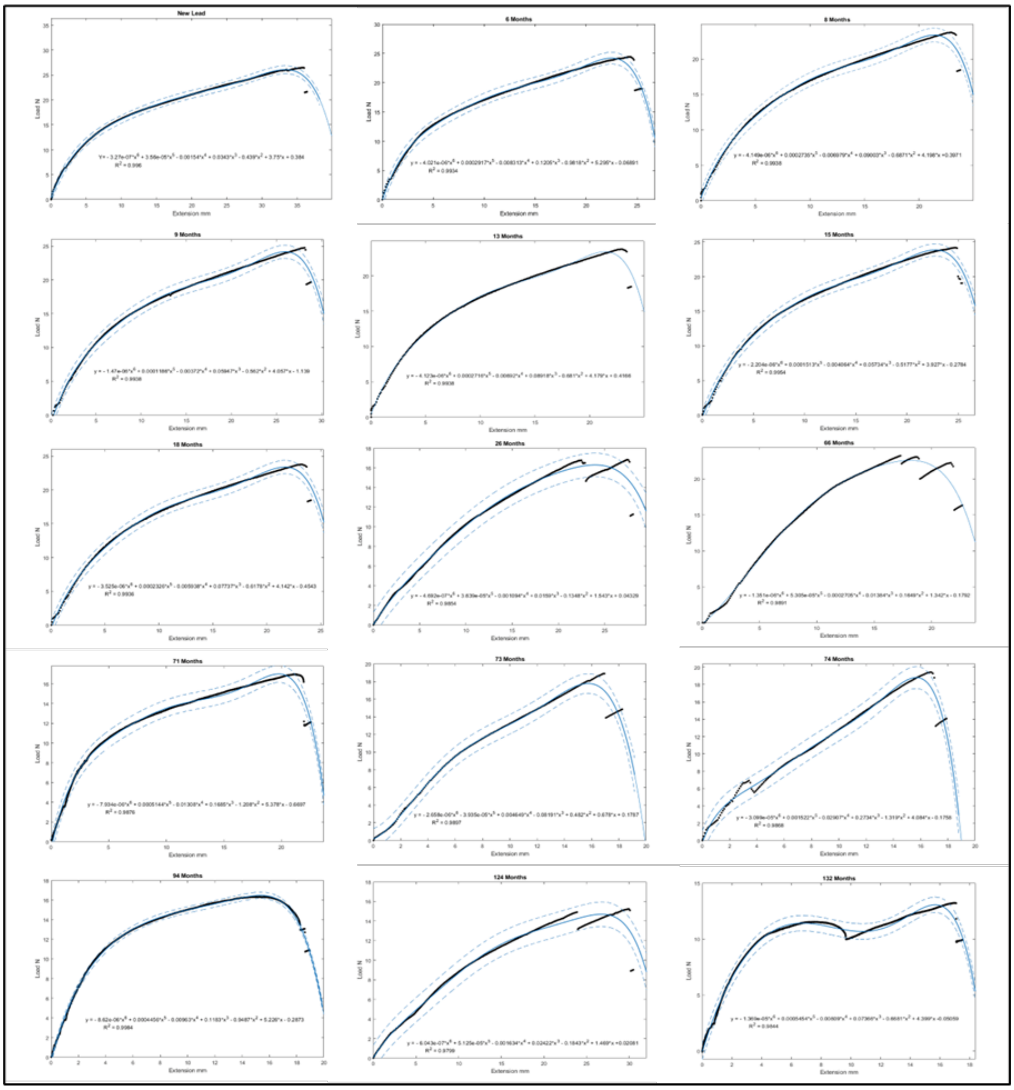

Figure 8 Representative Load *vs* extension plot for different *In Vivo* Implantation Durations

The sensitivity plot (Figure 9) shows a relation between load to failure, elongation, and *in-vivo* exposure in years. And it can be inferred that both load to failure and elongation decrease with the increase of *in-vivo* exposure. Figure 10 shows a mathematical relationship of the measured parameters with each other. A sensitivity plot indicates with the increase in *in-vivo* exposure the modulus of elasticity increases, and the ultimate tensile strength decreases and vice versa. Composite plots of the average tensile load versus elongation data shown in Figure 11. New lead accumulates higher strain and deformation than the exposed leads.

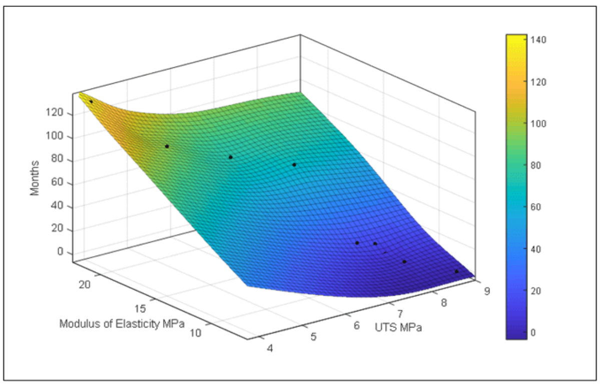

Figure 9 Sensitivity Plot representing Modulus of elasticity *vs* Ultimate tensile strength *vs* *in-vivo* months

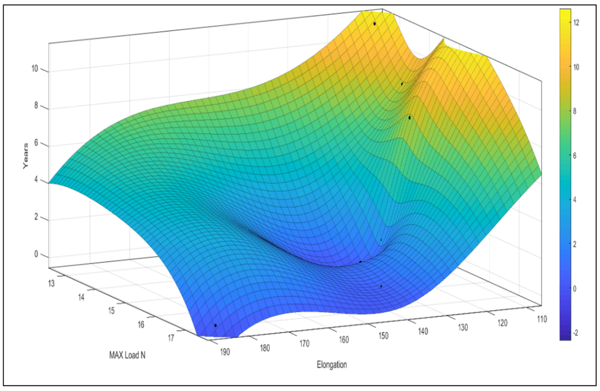

Figure 10 Sensitivity Plot representing Max. load *vs* Elongation *vs* *in-vivo* years

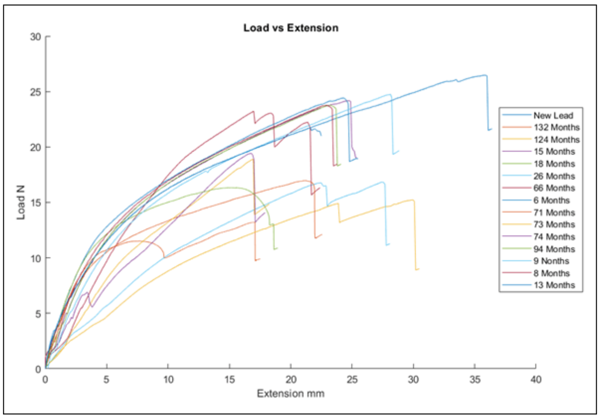

Figure 11 Representative Load *vs* extension plot of *in-vivo* years Combine

5 Conclusion

The silicone (MED-4719) demonstrates stable insulator for 132 month's exposure. Medtronic 5076 CapSureFix Novus MRI SureScan lead still continues to be used as the main lead. The materials used in the insulation are subjected to repeated cyclic loads and body temperature exceeding several times the glass transition temperature causing creep and wear. Load to failure showed a significant decrease after 94 months of *in-vivo* exposure (*P-value = 0.0063)*. Percentage elongation showed a significant decrease after 8 months of *in-vivo* exposure (*P-value = 0.0136*). However, the percentage elongation did not show any significant decrease between 8 and 132 months of *in-vivo* exposure. Ultimate tensile strength showed significant decrease after 94 months of *in-vivo* exposure (*P-value = 0.0244*) and percentage elongation at 5N force showed significant decrease after 71 months of *in-vivo* exposure (*P-value = 0.0326*). On the other hand, modulus of elasticity was directly proportional with the *in-vivo* exposure time and showed significant increase (*P-value = 0.0446*) after 71 months raising the stiffness and hardness of the insulator making them susceptible for cracking.

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