Axial Fatigue of MP35N Coils Used as Conductors in Implantable Medical Devices

Haitao Zhang[a)], Bernard. Q. Li, Peter Zhang, Bruce Behymer, Nu Zosel and Chris Canton
Medtronic Neuromodulation
7000 Central Avenue NE, Minneapolis MN 55432, USA

Summary Axial fatigue testing method was developed to evaluate fatigue characteristics of MP35N coils. Compared with the conventional rotary bending fatigue method, the new method enables coil tested to undergo plastic deformation. The stress and strain of the coils was analyzed with non-linear FEA software ABAQUS. Strain *vs* fatigue curve was obtained. The fatigue results were analyzed with a Coffin-Manson-Basquin approach. SEM was used to analyze the fatigue fracture surface of the samples.

INTRODUCTION

Neuromodulation is one of the fastest-growing areas of the medical device industry. Implantable Neurostimulators provide therapies to patients with chronic pain, movement disorders, overactive bladder, and psychiatric disorder symptoms. For these therapies, well-controlled stimulation current is delivered to the target nerves through implantable leads. The implantable leads must have sufficient fatigue durability to last for many years of implantation.

The implantable leads are composed of insulation polymer jackets and conductor coils/cables. Conductor coils/cables are generally made from low Ti MP35N alloys (Co-35Ni-20Cr-10Mo). These conductor coils are more susceptible to fatigue failure than the insulation polymer jackets.

Typical fatigue testing methods used to obtain material S-N curve typically involve using large coupon samples which has a characteristic size around several millimeters [1]. It has been shown that fatigue behavior of small medical wires can be significantly different from that of their base materials [2]. Some efforts have been made to characterize the fatigue of conductor coils in the elastic range with rotary bending method [3-5]. One of the limitations of rotary bending method is the coil tested can only have elastic deformation. It is desirable to develop fatigue test method to allow coil to undergo plastic deformation.

In this paper, an axial fatigue testing method was developed to evaluate fatigue characteristics of MP35N coils. Compared with the conventional rotary bending fatigue method, Compared with the conventional rotary bending fatigue method, the new method enables coil tested to undergo plastic deformation. The stress and strain of the coils was analyzed with non-linear FEA software ABAQUS. Strain *vs* fatigue curve was obtained. The fatigue results were analyzed with a Coffin-Manson-Basquin approach. SEM was used to analyze the fatigue fracture surface of the samples.

MATERIALS AND METHODS

Materials

Samples tested include low Ti MP35N (Co-35Ni-20Cr-10Mo) wire with diameter 0.102mm. The coil has four filars. The coil diameter is 0.686mm inch and the pitch is 0.686mm. Each filar is coated with ethylene tetrafluorethylene (ETFE) copolymer. Detailed metallurgy study of MP35N is available in the literature [6, 7]. The Young's modulus of the wire in coil is E = 193GPa.

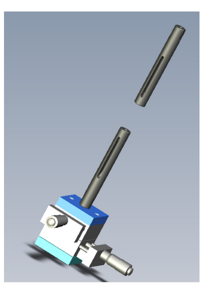

Fig. 1. Testing fixture design

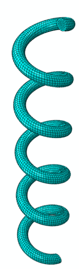

Fig. 2. Finite element model of coil

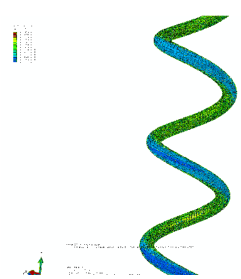

Fig. 3. Contour of maximum principal stress

Test method

Axial fatigue tests were conducted at a frequency of 30 Hz with a BOSE fatigue tester. Figure 1 shows the test fixture design. Lower fixture has a x-y stage to adjust the sample alignment. Each fixture has a cut-out slot to facilitate electric monitor of the filar fracture. During the testing, each filar was monitored individually. The testing sample has a gage length of 12.7 mm. The elongation selected are 11%, 12%, 13%, 15%, 16%, 17%, 18%, 19%, and 20%. The coil is mounted to the fixture through two lure fittings.

---

a) Corresponding author. Email:haitao.zhang@medtronic.com

FEA stress analysis and fatigue analysis

Before filar fractures, filar to filar interaction is negligible. FEA stress and strain analysis can be conducted on a single filar. The length selected in the analysis is 5 revolutions. A finite element model of the spring was created as shown in Fig. 3. 17424 Quadratic hexahedral elements with 20 nodes each were used. The elastic-plastic stress analysis was conducted with FEA software ABAQUS.

The following Coffin-Manson-Basquin fatigue equation with Morrow mean stress correction is used to characterize the fatigue resistance of the coil:

$$\frac{\Delta\varepsilon}{2} = \frac{\Delta\varepsilon_e}{2} + \frac{\Delta\varepsilon_p}{2} = \frac{\sigma_f' - \sigma_m}{E}\left(2N_f\right)^b + \varepsilon_f'\left(2N_f\right)^c \qquad [1]$$

A least squares regression-analysis method was used to determine the fatigue parameters of Eq. [1].

RESULTS

The relation between the strain amplitude and reversals to failure ($2N_f$) obtained by axial fatigue tests conducted at various elongations is plotted in Fig.3. The strain endurance limit of the coil is at 0.003 as shown in Fig 3. The fatigue fractured surface of the filar in coil was examined in SEM. The SEM image, Figure 4, shows that each of the coil filars reveal crack initiation occurred at the inner diameter of the coil. The fracture surface of the filar indicates that the stresses on the filar is multiaxial which results in a slanted fracture surface a mixture of torsion and tension.

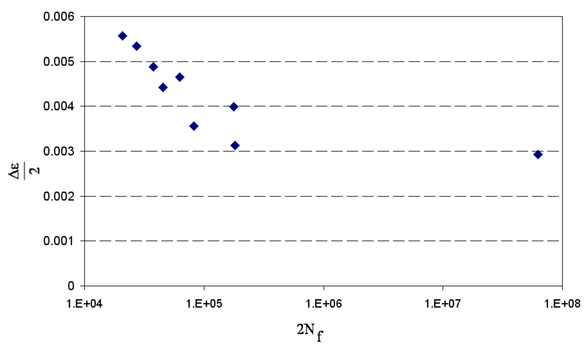

Fig. 3. Fatigue life of tensile coil

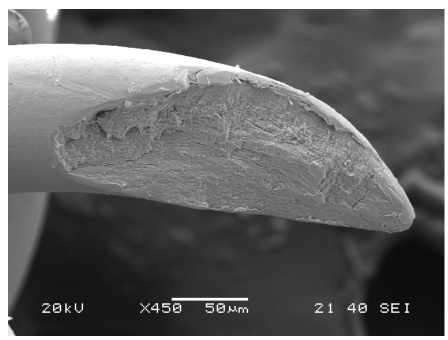

Fig. 4. SEM image of fatigue fracture surface

CONCLUSIONS

A novel axial fatigue testing method was developed to evaluate fatigue characteristics of MP35N coils. Compared with the conventional rotary bending fatigue method, the new method enables coil tested to undergo plastic deformation. The stress and strain of the coils was analyzed with non-linear FEA software ABAQUS. Strain *vs* fatigue curve was obtained. The fatigue results were analyzed with a Coffin-Manson-Basquin approach. SEM was used to analyze the fatigue fracture surface of the samples.

References

[1] Akiniwa Y., Stanzl-Tschegg S., Mayer H., Wakita M, and Tanaka K.: *International Journal of Fatigue* **30**:2057-2063, 2008.
[2] Li B. Q., Zhang H., and Wang L.: MPMD 2011, web site `http://asm.confex.com/asm/mpmd11/webprogram/Paper28326.html`.
[3] Altman P. A., Meagher J. M. , Walsh D. W., Hoffmann D. A. : *J Biomed Mater Res.* **43**:21-37, 1998.
[4] Scheiner A., Thomas J. M. , Kicher T. P.: *Journal of Biomedical Materials Research* **25**:589-608, 1991.
[5] Stokes B., Stephenson N. L.: The Third Decade of Cardiac Pacing, Advances in Technology and Clinical Applications. Futura Publishing, NY 1982.
[6] Li B. Q., Steigauf T., McIntyre P., and Sorensen D. : "Crystallography Texture of MP35N Wire" "Medical Device Materials V: Proceeding of Conference of Materials for Medical Devices, ASM, 2009, p111-114.
[7] Li B. Q., Steigauf T.: *Ceramic Transactions* **201**:627-635, 2008.