THE USE OF NONLINEAR FEA MODELING TO DETERMINE THE *IN VIVO* CARDIAC PACING LEAD COILS FOR FATIGUE EVALUATION

Yong Zhao, Walt Baxter, Byron Johnson, Michael Schendel, John McCarty, Cathleen McMahon, Ryan Lahm, Hua Sun, Josee Morissette, Tim Laske, Jennifer Miller

Medtronic Cardiac Rhythm Management
7000 Central Avenue NE, Minneapolis, MN 55432, USA
E-mail: yong.zhao@medtronic.com

Abstract

Pacing leads, which are implanted in the heart to treat cardiac diseases for a typical lifetime of ten years, are the most strictly regulated medical devices for their quality and reliability to human health and safety. The resulting stress imposed upon the conductor coil filars of implanted leads can be an important determinant of long-term performance. Nonlinear finite element analysis (FEA) provides an efficient method for computing the stresses in the conductor coil filars of cardiac pacing lead bodies. This paper presents a numerical modeling approach in which the coil filar stresses are calculated for a prototype and a market released lead product, under prescribed deformations, as determined from *in vivo* (canine) radiography measurements of lead motion. From these stresses (locations and magnitudes), alternating stress amplitudes and mean stresses were computed and used to compare the fatigue conditions in the new and existing lead bodies.

Introduction

The fatigue failure mechanism of a structure is dominated primarily by the alternating strain or stress caused by the cyclic loads applied to the structure. *In vitro* physical tests are widely used in the cardiac pacing industry to quantify the fatigue resistance of the conductor coil of a pacing lead. These tests, however, can be time consuming and costly for the small-sized coil filars of a high strength alloy. It is therefore advantageous to use analysis to compare the fatigue resistance of different lead designs. Few references are available for analyzing lead stresses *in vivo*. In this paper, a 3-D nonlinear FEA approach was developed to evaluate and compare the *in vivo* coil stresses for a fatigue evaluation of a prototype and a commercially available cardiac pacing lead product.

Methods

The FEA models (Fig. 1) were developed with SDRC I-DEAS [1] software, and solved using the general purpose FEA software ABAQUS/Standard [2]. Models of two lead body designs were developed to focus on the coil filars of uniform (non-transition) portion of the leads. Other lead body components were included as original or simplified structures with appropriately calibrated material properties. The simulation was designed for leads implanted in the right atrium of a canine heart. A pseudo static, stress-strain analysis was used in the FEA analysis, which included all possible 3-D, deformable-to-deformable contact interactions between the coil filars, and between the coil filars and other components of the lead bodies. The FEA model was driven by 3-D translational displacements that were measured *in vivo*. The curvature of the deformed lead body model was calculated, and small adjustments to the driving displacement inputs were made until the curvature of the model fell within the error range of the measured *in vivo* maximum and minimum lead body curvatures. The location and value of the highest stress within the filars were identified as the maximum stresses of the cyclic stress field, and the stresses at the same location, for the minimum curvature configuration, were recorded as the minimum stresses of the cyclic stress field. These maximum and minimum stresses were used to compute a mean and alternating stress for the coil filars under the measured *in vivo* loading. These stresses for the two different lead configurations were compared.

Results and Conclusions

The finite element models of the prototype lead and the existing lead attained curvatures within 1.8% and 4.0% of the *in vivo* deformation targets respectively. Strong contact interactions between the model components were observed in the FEA results. Complicated stress status exhibit in the coil filars (Fig. 2).

The prototype lead body showed mean stresses 3.6 times lower than the stresses in the coil of the existing lead. Similarly, the alternating stress amplitude was 2.9 times lower in the coil of the prototype lead body. These relatively lower stress levels indicate that the coil within the prototype lead body should be less susceptible to fatigue fracture than the existing lead coil, which has had acceptable fatigue resistance performance in the clinical field for several years.

The nonlinear FEA approach developed is feasible and efficient for the fatigue evaluation of pacing leads *in vivo*.

References

1 Structural Dynamics Research Corporation, 2002, SDRC I-DEAS, Version 8.

2 Hibbitt, Karlsson & Sorensen, Inc., 2002, ABAQUS / Standard, Version 6.2.

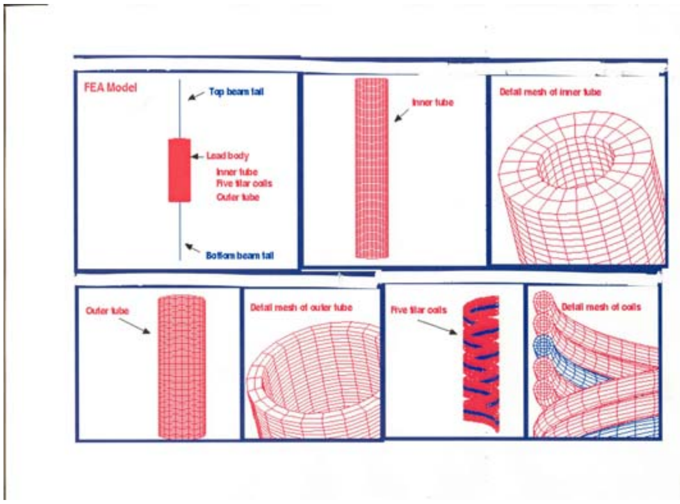

Figure 1 FEA Model with Multiple Components

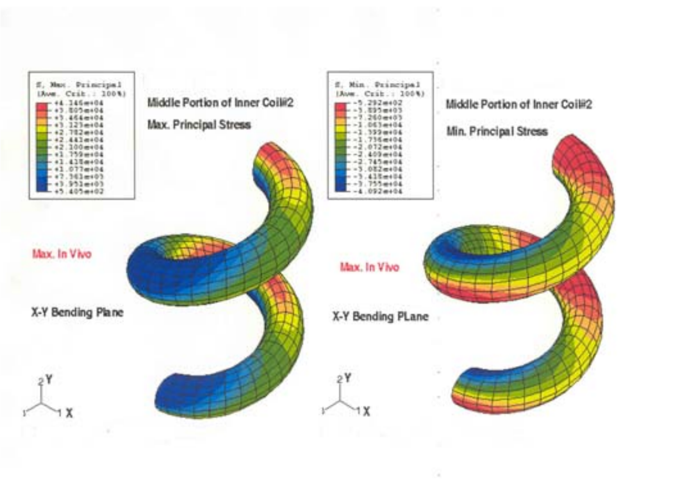

Figure 2 Stress Contours in Existing Lead Coil