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Fracture prediction of cardiac lead medical devices using Bayesian networks

Tarek Haddad, Adam Himes*, Michael Campbell

Medtronic, Inc., 8200 Coral Sea St. NE, Mounds View, MN 55112, United States

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ABSTRACT

A novel Bayesian network methodology has been developed to enable the prediction of fatigue fracture of cardiac lead medical devices. The methodology integrates in-vivo device loading measurements, patient demographics, patient activity level, in-vitro fatigue strength measurements, and cumulative damage modeling techniques. Many plausible combinations of these variables can be simulated within a Bayesian network framework to generate a family of fatigue fracture survival curves, enabling sensitivity analyses and the construction of confidence bounds on reliability predictions.

The method was applied to the prediction of conductor fatigue fracture near the shoulder for two market-released cardiac defibrillation leads which had different product performance histories. The case study used recently published data describing the in-vivo curvature conditions and the in-vitro fatigue strength. The prediction results from the methodology aligned well with the observed qualitative ranking of field performance, as well as the quantitative field survival from fracture. This initial success suggests that study of further extension of this method to other medical device applications is warranted.

1. Introduction

The implantable artificial pacemaker enables patients with heart rhythm disorders to enjoy improved quality of life by electrically stimulating the heart to beat at a rate suitable for the activities of daily living. For patients at risk of developing life-threatening ventricular fibrillation or ventricular tachycardia, the implantable cardioverter-defibrillator (ICD) delivers current to the heart muscle at levels sufficient to interrupt the abnormal rhythms and restore cardiac function. The implanted hardware for modern pacemaker and ICD systems typically consists of a pulse generator under the skin in the shoulder region connected to one or more transvenous conducting leads that enter the vasculature and are anchored inside the heart at locations appropriate for delivering electrical therapy [1]. Cardiac leads are constructed of a variety of materials and structures; however a common element is a multi-filar conductor coil, most commonly used to deliver the electrical signal for pacing the heart [2,37]. Fig. 1 illustrates two modern cardiac leads for pace/sense applications in the left and right ventricles, and a defibrillation lead intended for right ventricular use. The coils are commonly placed within insulating tubes of polyurethane or silicone. In some cases, such as the defibrillation lead in Fig. 1, there are also wire rope cables for purposes such as sensing electrical activity in the heart and delivering defibrillation energy. Typical diameters for cardiac leads range from 2 to 3 mm. This paper will focus on reliability of a conductor coil.

Issues involving mechanical reliability of implanted medical devices may present problems beyond that of a typical engineering structure. Repair or revision commonly involves a surgery, which carries risks including complication from infection and anesthesia. Since the tortuous and mobile anatomy that a cardiac lead passes through poses considerable mechanical challenge, the reliability of cardiac leads asks for heightened. When it occurs, conductor fracture is widely recognized as a failure mode that can have serious implications [3–5]. Open or intermittent circuits in the pace/sense circuit can lead to missing or inappropriate therapy. Damage to the defibrillation circuit can potentially be life threatening. As discussed in [6], lead fracture is typically due to bending fatigue. Multiple researchers have presented methods for evaluating complication rates, including fracture, in large cohorts of patients [7,8]; however the published work in this area has been retrospective and based on risk factors rather than first principles. For example [9–15] found increasing risk of fracture in younger patients. Such publications to date have not linked study results to mechanics of fracture.

There is a recognized need for high quality data to assess the reliability of new lead designs [5]. In addition, the cost of developing and bringing new lead designs to market is expected to further increase as the awareness of cardiac lead failure modes increases, and higher reliability levels are requested by physicians

* Corresponding author. Tel.: +1 763 526 9414; fax: +1 763 526 5737.
E-mail address: adam.k.himes@medtronic.com (A. Himes).

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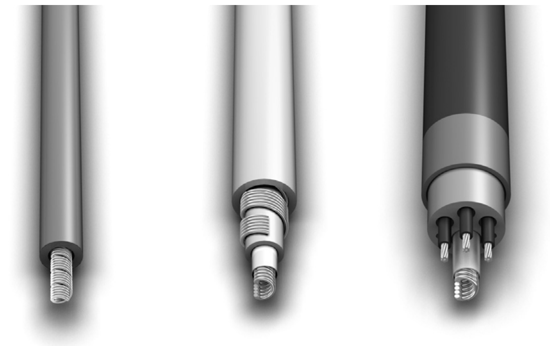

Fig. 1. Medtronic Lead Models 4193 (left), 5076 (center), and 6947 (right). From left to right, the leads are intended for pacing in the left and right ventricles, and for defibrillation in the right ventricle.

and patients. For lead manufacturers, there is a need to assess the performance of new designs prior to embarking on extensive clinical trials.

A challenge for reliability assessment of implanted medical devices, particularly for cardiac leads, is the complexity and variability of the human body. Loads and deflection in the implanted environment can be influenced by both physician and patient [16]. Physician training and patient factors may result in different implant locations [14,17,18]. Patient activity levels may range from completely sedentary to highly active [19].

Although quantitative life prediction of structures has been studied for many decades [20], incorporating uncertainty in the input parameters in order to make probabilistic calculations is relatively new [21–23]. It has only been in recent years that predictions for medical device reliability have begun to incorporate probabilistic inputs rather than fixed values for loading [24–26]. Areas of study for probabilistic life modeling of medical devices have been in the area of artificial knees and hips as well as dental implants [21,25]. Specific to medical devices, structural variability due to biomechanical factors has been studied in [22,25–27]. In recent work, quantitative life estimates have been given using Bayesian analysis methods to place confidence bounds on the predictions based on the uncertainty in input parameters [26,28–30,65]. This type of analysis for cardiac leads has not been found in the literature. Other researchers have presented stress analysis for cardiac leads due to in-vivo conditions, studied fatigue performance of coils from cardiac leads, and measured lead bending in-vivo [6,31–36]; however these elements have not yet been linked together to create reliability predictions.

The primary aim of this paper is to provide a method for utilizing data on fatigue strength and use conditions with statistical modeling to project the fracture survival of cardiac leads in their intended implant population. In order to account for uncertainty in the input parameters, Bayesian methods are used to generate confidence intervals on the output predictions, as well as to model sensitivity of lead fracture to various input conditions. A case study based on Medtronic lead models Sprint Quattro 6947 and Sprint Fidelis 6949 using newly available data is given as an illustrative example.

The overall methodology is given below. Each step will be discussed in detail further in this paper. The methodology employs two nested loops to account for natural variability due to population distributions and parameter uncertainty due to sampling error. Steps 1 and 5 account for parameter uncertainty and steps 2–4 account for natural variability.

1. Estimate population parameters (posterior parameter distributions) using a Bayesian approach (2.9)
2. Randomly generate use conditions (Sections 2.1–2.3)
3. Randomly generate fatigue strength (Sections 2.4–2.7)
4. Calculate time to fracture, competing risk and survival curve (Sections 2.8–2.10)
5. Repeat to simulate multiple patients and parameter uncertainty (Section 2.10).

2. Methodology

2.1. Implant geometry and loading

The implanted cardiac lead typically follows a tortuous path between the generator site and the heart. The x-ray image in Fig. 2 shows a typical tortuous path for a cardiac lead, following from the typical left-sided generator implant site. Of particular interest for this paper is the maximum curvature experienced by a lead in a zone near the shoulder. When coupled with highly mobile anatomical structures, cardiac leads can encounter potentially large amplitudes of bending around the shoulder region, as described in [35]. The curvature of the lead may vary considerably along the length [16,35] due to patient anatomy and implanter preference.

Measurement of time varying 3D cardiac lead paths has been well defined in the literature [31,32,39,40]. For the purposes of a coil fatigue example, the lead centerline curvature is an in-vivo measurement practical and useful to evaluate fracture reliability. Curvature is the reciprocal of radius and expressed in units of 1/length.

2.2. Effect of arm position

Data that correlates arm position and associated lead curvature is scarce; however there are simplifying assumptions that enable the analysis of the lead fatigue problem. Although there are infinite possible arm positions, we consider the most significant to be flexion of the humerus, measured in degrees from the plane of the torso (ϕ) and illustrated in Fig. 3. Unpublished measurements of lead curvature vs. humerus flexion angle have shown that curvature is frequently largest when $\phi > 0$. Several potential scenarios are illustrated in Fig. 4 below. Thus, given a random arm movement with a maximum and minimum arm angle, it is possible to directly calculate the curvature history associated with that movement.

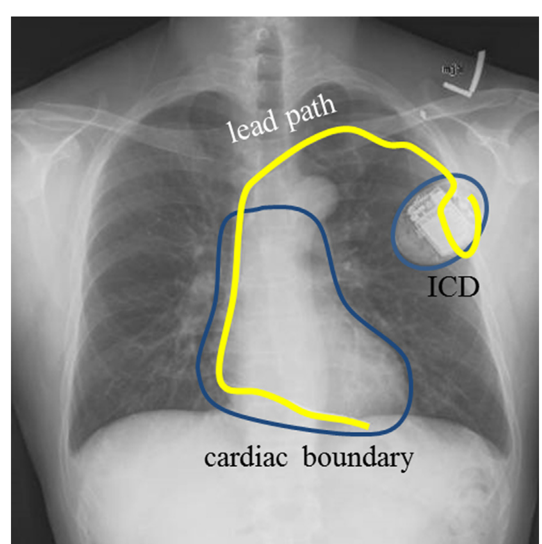

Fig. 2. Typical implant location and path for ICD and lead [38].