ANALYSIS OF INTRACARDIAC LEAD BENDING STRESSES AND MOTION CHARACTERISTICS OF RVA VERSUS RVOS PACING LEADS USING AN INNOVATIVE 3-D RECONSTRUCTION TECHNIQUE

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INTRODUCTION

Numerous studies have demonstrated the hemodynamic superiority of right ventricular outflow septal (RVOS) pacing compared with right ventricular apical (RVA) pacing [1]. Stimulating at the right ventricular apex produces delayed contraction and could yield series of discrete and dispersed activation and contraction sequences that might lead to deterioration in global cardiac function. The RVOS pacing has been practiced as a suitable alternative to RVA pacing.

Before the RVOS pacing can be adopted throughout the medical community, the efficacy and performance of the pacing leads in such an application must be addressed. The lead is a critically important and the most chronic component in a pacemaker system. It is subjected to stresses that can lead to various complications if the lead system is not designed and tested to account for in the vivo motion and stresses. However, RVOS and RVA lead motion in vivo has not been studied to date. Thus, it is necessary to understand the RVOS lead motion characteristics. A novel technique was developed and employed to quantitatively assess the intracardiac motion comparing RVOS with RVA pacing leads in vivo.

METHODS

The process to reconstruct a 3-D moving pacing lead includes the following steps:

(a) Image acquisition A pair of fluoroscopic cine images of Guidant Sweet Picotip $Rx^{\textcircled{0}}$ leads with tip electrode placed sequentially at the RVA and RVOS was acquired from each of the 9 patients (4 males, 5 female, age 79.4 ± 8.1 year) who underwent routine pacemaker implantation. The images were acquired at 15 frames per second in each view with recorded electrocardiogram throughout the cardiac cycle using a single-plane imaging system.

(b) <u>Identification of 2-D pacing lead</u> A semi-automatic system based on the technique of deformation model and segmentation technique was employed for the identification of the 2-D pacing lead in the fluoroscopic images. The required user interaction involved indication of several points near the projection of lead centerline in the fluoroscopic images.

(c) <u>Calculation of transformation defining relative location and</u> <u>orientation of two views</u> The spatial relationship between any two views can be characterized by a transformation in the forms of a rotation matrix and a translation vector with the X-ray source (or focal spot) serving as the origin of 3-D coordinate space. A coarse-to-fine processing was employed to determine the transformation associated with each pair of fluoroscopic lead image throughout the cardiac cycle. By use of the corresponding landmark points and directional vectors of the lead extracted from the cardiac cycle, the global transformation in terms of a rotation matrix \mathbf{R}_g and a translation vector \mathbf{t}_g can be calculated. Based on the calculated global estimates, a refinement process is employed to calculate each local transformation \mathbf{R}_k and \mathbf{t}_k , where k = 1, ..., n defining the spatial relationship between each pair of views acquired throughout *n* time points from end-diastole to endsystole [2].

(d) <u>Modeling of the pacing lead</u> After the transformation $(\mathbf{R}_k, \mathbf{t}_k)$ that defines each pair of views in the image sequences is obtained, such information is used to establish the point correspondences on 2-D lead centerlines and calculate 3-D centerline of the cardiac lead based on the epi-polar constraints. The reconstructed 3-D lead was modeled on the basis of a sequence of cross-sectional contours to reflect variation at the lead distal segment. A d_i -mm circular disk centered at and perpendicular to the 3-D lead centerline point represents each contour V_i . The surfaces between every two consecutive contours V_i and V_{i+1} are constructed based on a number of polygonal patches.

(e) Establishment of temporal correspondence on a moving pacing lead To accurately characterize the movement of the cardiac leads, it is essential to obtain the temporal correspondence of each moving lead throughout the cardiac cycle. For each 3-D lead reconstructed at *k*-th time frame, the lead l_i^k can be modeled as a

sequence of n_k points $P_i^k = (x_i^k, y_i^k, z_i^k)$, where $i = 1, ..., n_k$. To perform the assessment on lead movements throughout the cardiac cycle, the correspondences of each pairs of 3-D pacing leads l^k and l_i^{k+1} moving between every two consecutive time frames k and k+1 must be established first by using the equation as fellows:

$$\min_{s_{i}^{k}} F(s^{k}) = \sum_{i=1}^{n_{k}} \frac{1}{2} m_{i}^{k} \left\{ \frac{\left[P_{i}^{k} - f_{k+1}(s_{i}^{k}) \right]}{\Delta t_{k,k+1}} \right\}^{2} + \frac{1}{2} K_{i}^{k} \left\{ \left| P_{i}^{k} - P_{(i+1)}^{k} \right| - \left| f_{k+1}(s_{i}^{k}) - f_{k+1}(s_{(i+1)}^{k}) \right| \right\}^{2} + \left[T_{i}^{k} - f_{k+1}^{(1)}(s_{i}^{k}) \right]^{2} + \left[N_{i}^{k} - f_{k+1}^{(2)}(s_{i}^{k}) \right]^{2} \tag{1}$$

subject to the constraints

 $0 \le s_1^k \le s_2^k \le \dots \le s_{n_k}^k \le 1$

where m_i^k and K_i^k denote the respective mass and module of elasticity at the lead segment P_i^k , $\Delta t_{k,k+1}$ is the elapsed time between the *k-th* and (*k*+1)-*th* time frames, $S_i^k = \{S_1^k, S_2^k, \cdots, S_{n_k}^k\}$ denotes the set of parametric variables corresponding to the 3-D lead centerline points of the lead l_i^k , T_i^k and N_i^k denote the tangent and normal vectors at point P_i^k , $f_{k+1}(S_i^k)$ is the parametric curve function defining the 3-D centerline points of a cardiac lead l_i^{k+1} , $f_{k+1}^{(1)}(S_i^k)$ and $f_{k+1}^{(2)}(S_i^k)$ denote the first and second derivatives of parametric curve function $f_{k+1}(S_i^k)$, respectively. The first two terms in the equation define the required minimal kinetic energy due to motion and minimal change in potential energy. The local shape similarity is characterized based on the last two terms by minimizing the differences of tangent and normal vectors at centerline points between the two reconstructed leads l_i^k and l_i^{k+1} .

(f) <u>Motion parameter and stress analysis</u> Based on the reconstructed 3-D moving lead from end-diastole to end-systole, the motion parameters including displacement, curvature, and curvature change were computed. Furthermore, using the curvature and curvature change data, lead bending stress evaluation was performed using finite element analysis for the inner conducting coil of the lead, since the inner coil had the higher stresses in this particular lead design.

RESULTS AND DISCUSSIONS

Figures 1(a) and (b) show a pair of images by superimposing the pacing leads (RVOS placement) in the corresponding fluoroscopic cine from end-diastole to end-systole. The 3-D moving pacing lead reconstructed by using Figures 1(a) and (b) is illustrated at two different gantry angles as shown in Figures 2(a) and (b).

RVOS leads had distinguishable orientation and shapes, and their motion characteristics were thus different. The RVOS leads had greater displacement in the right atrium and the right ventricle.

Distribution analysis was performed to compare the bending stresses in the RVA pacing lead with that of the RVOS placed lead. The lognormal distribution was found to be the most suitable model for these data. The 50th percentile value of the bending stress and the 90% tolerance interval were computed. Lead bending stresses in the right ventricle segment showed no statistical differences. However, the

bending stresses in the right atrium of the inner conducting coil were significantly different; higher stress values presented in the RVOS leads, though the higher values are within the expected range.

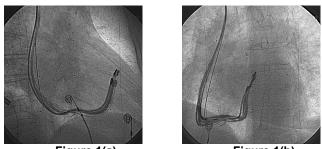


Figure 1(a) Figure 1(b) Figure 1: The pair of images of superimposed pacing RVOS leads extracted from fluoroscopic cine acquired at (a) RAO 30.0° CAUD 3.3° and (b) LAO 30.0° CAUD 2.4°.

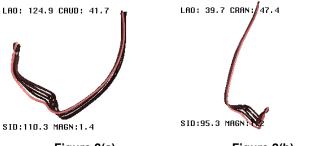


Figure 2(a) Figure 2: The reconstructed 3-D moving pacing lead at (a) LAO 124.9° CAUD 41.7° and (b) LAO 39.7° CRAN 47.4°.

CONCLUSIONS

The reconstruction technique developed permits 3-D visualization of cardiac lead motion in vivo and can be used to accurately quantify lead motion parameters.

The RVOS and RVA pacing leads had distinctive motion, lead orientation, and shapes. The RVOS leads had greater displacement in the right ventricle and the right atrium. In comparison with the RVA leads, RVOS lead right atrium segments had higher bending stresses though the higher stress values are within the expected range.

This in vivo information is important for lead stress analysis, design, and testing. Future chronic studies are needed to determine the effect of other factors such as cardiac anatomy, body habitus, and fibrosis on lead motion in vivo, and a study with a larger sample size is desirable.

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