ACUTELY IMPLANTED CARDIAC LEAD SHAPE MEASUREMENT: PHYSICIAN PREFERENCE ONLY?

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INTRODUCTION

Cardiac leads are implanted in over 300,000 patients each year and form a major engineering challenge to manufacturers [1]. A distinct lack of accurate implanted lead shape data forces design and test engineers to rely upon indirect assumptions to predict how differences in patient anatomy and implant technique will affect lead deformation *in vivo*. We sought to address this problem by measuring the shape of a single lead model in patients for the purpose of providing feedback to engineers; therefore, the objective of this study was to estimate the maximum curvature of an intracardiac defibrillator lead within three days post-implant and correlate maximum lead curvature with three clinically relevant parameters: patient body surface area (height and weight), left ventricular ejection fraction, and physician implant preference.

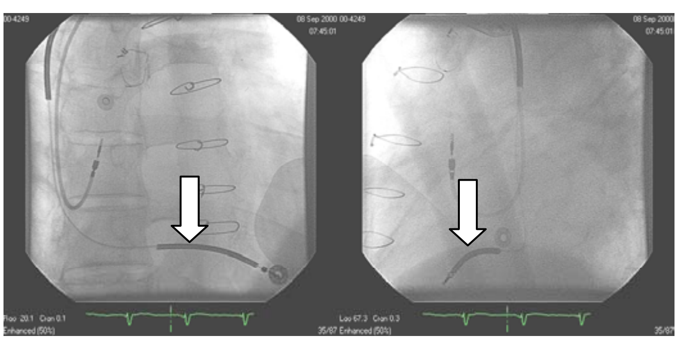

Figure 1: Biplane fluoroscopic images of the defibrillator lead (white arrow). All patients received the same lead.

METHODS

A total of twenty patients were enrolled in four U.S. centers (n=8, 7, 4, and 1, respectively), and were imaged within three days of implant. All patients filled out a complete demographic and cardiovascular history questionnaire. Nearly simultaneous biplane radiographic images of the heart (Figure 1) and a calibration cylinder were recorded either digitally or using custom video recording chains. Each patient was imaged for approximately five seconds while supine and holding their breath at end-expiration to minimize respiratory motion artifact. In 16/20 patients, an ECG tracing was superposed on the image permitting temporal registration of the two video streams and also allowing shape to be related to the cardiac cycle. Lead motion was used as a registration marker for the system without ECG display capabilities.

Using an active contour reconstruction technique described elsewhere [2], principal curvatures were calculated along the lead centerline at each time point throughout a representative cardiac cycle. Lead centerline curvatures were sampled along the lead arclength for each time point, and these values were sorted to find the overall curvature maxima across all time points in the cardiac cycle for each patient.

Using the demographic information that was collected, each patient's height and weight was converted into a body surface area (BSA) using Dubois and Dubois' classic formula [3]:

$$BSA\ (m^2) = 0.007184 * [Weight(kg)^{0.425} * Height(cm)^{0.725}] \quad (1).$$

Correlations were calculated between maximum lead curvature and both BSA and ejection fraction. To examine the effect of physician implant preference, we grouped the data at centers with multiple implants. We used an ANOVA with Bonferroni correction for comparison of multiple groups to test for statistically relevant differences between the groups.

RESULTS

Seventy percent (70%) of the patients were male, the mean age was 64.8 years (10.5 yrs. SD), and ninety percent (90% of the patients presented with ventricular tachycardia as primary indication for implantable cardioverter defibrillator implant. Eighty-five percent (85%) of the patients experienced compromised cardiac function (70% New York Heart Association class II, 15% NYHA class III), eighty percent (80%) of the population had coronary artery disease (60% with at least one myocardial infarction), and seventy percent (70%) of the patients suffered from congestive heart failure.

The mean maximum curvature was 0.48 cm^{-1} (0.18 cm^{-1} SD) and curvatures ranged from 0.27 cm^{-1} to 0.78 cm^{-1}. As shown in Figure 2, there was no correlation between body surface area and maximum lead curvature (R^2 = 0.17). Similarly, we found no correlation between left ventricular ejection fraction and maximum lead curvature (R^2 = 0.17) as shown in Figure 3.

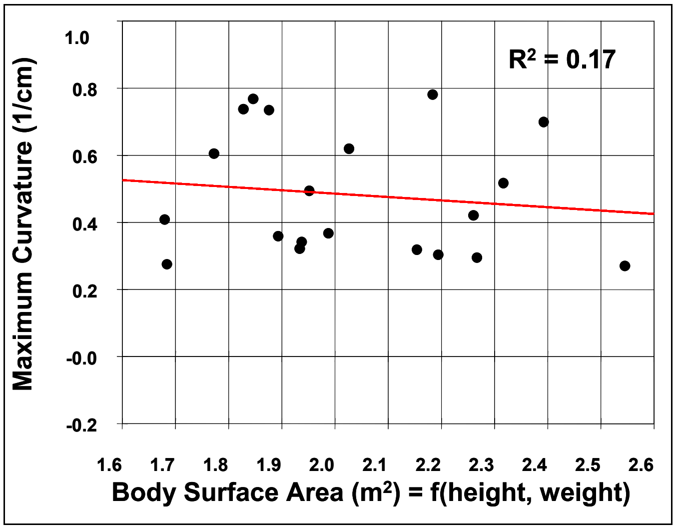

Figure 2: Patient body surface area does NOT correlate with maximum lead curvature in this study

The three centers that we pooled into separate groups had mean maximum curvatures of 0.34 cm^{-1}, 0.5 cm^{-1}, and 0.64 cm^{-1}, respectively. We found that the groups had equal variances (p=0.09) and that the mean maximum curvature of Center 1 was significantly lower than that of Center 3 ($P<0.05$). To illustrate the effect of physician implant preference, Figure 4 illustrates a histogram of the maximum curvatures color-coded by implanting center.

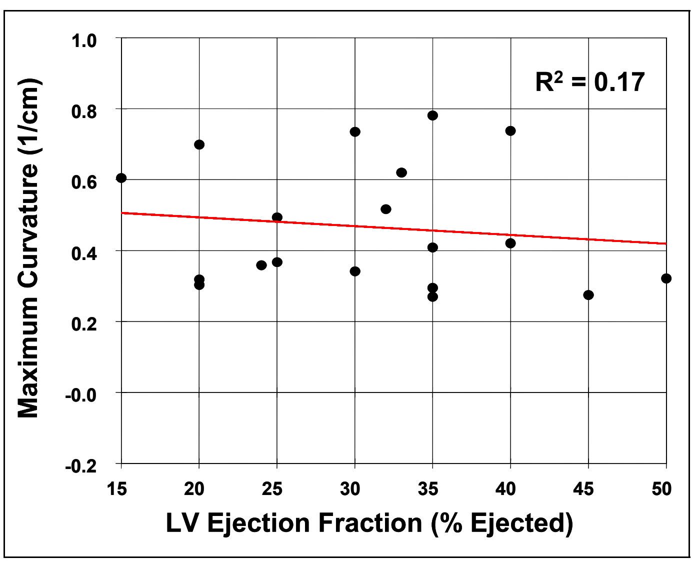

Figure 3: Patient left ventricular (LV) ejection fraction does NOT correlate with maximum lead curvature in this study

DISCUSSION

The maximum intracardiac curvature of the defibrillator lead we considered did not relate to either patient size or overall heart function within three days of implant. The results of this study imply that physician implant technique may have a larger impact on lead shape than previously believed and further exploration of this finding is warranted. Future studies might investigate possible correlations between implant technique and shape as well as the effect of chronic encapsulation and patient posture on implanted lead shape. In addition, the majority of this patient population suffered from early heart failure. Since previous researchers have reported chamber shape distortion and functional changes in hypertrophied hearts, this particular population may need separate consideration in a future study.

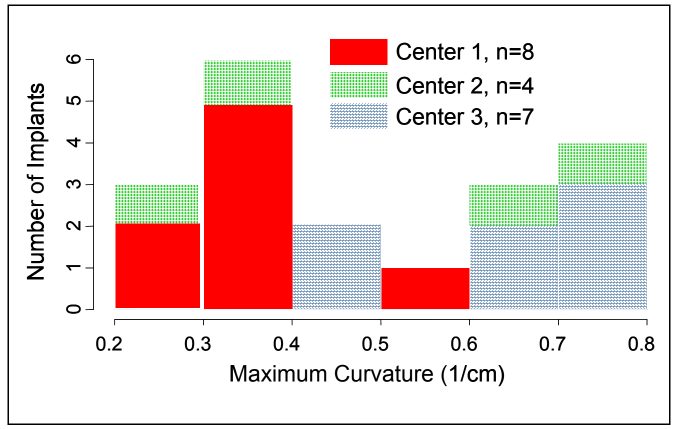

Figure 4: Physician implant technique had a large impact on maximum lead curvature in this study

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REFERENCES

1. Ellenbogen, K.A., Kay, G.N., and Wilkoff, B.L., "Preface" in Clinical Cardiac Pacing, Ellenbogen, K.A., Kay, G.N., and Wilkoff, B.L., Eds. Philadelphia, PA: W.B. Saunders Co., 1995, pp.xvi.
2. Baxter, W.W., and McCulloch, A.D.: A novel active contour method for reconstructing intravascular medical devices. Proceedings of the 1997 Annual Fall Meeting of the Biomedical Engineering Society. San Diego, CA, Oct. 4, 1997. In: *Annals of Biomedical Engineering*; 25 (suppl. 1), pg. S-29.
3. Dubois, D., and Dubois, E.F.: A formula to estimate the approximate surface area if height and weight be known. Archives of Internal Medicine, Chicago, IL, 1916, 17: 863-871.