Measuring Implantable Cardioverter Defibrillators (ICDs) during Implantation Surgery: Verification of a Simulation

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Abstract

Implantable cardioverter defibrillators (ICDs) are increasing used in abnormal configurations. We have developed a patient specific forward simulation model to predict efficacy of the defibrillation shock. Our goal was to develop a method of measuring the ICD surface potentials as the devices are tested during implantation surgery to use as verification of the simulation. A lead selection algorithm was used to develop a surface potential mapping system with 32 recording sites that do not interfere with implantation surgery. ICD discharge recordings were compared at similar locations to corresponding patient models.

The reconstructed simulated surface potentials showed < 1 % error, demonstrating an effective algorithm to recreate the potential distribution of an ICD. The reconstructed surface recordings showed errors in the magnitude of the potentials, yet demonstrated high correlation when compared to the simulation. Though refinement is needed, the simulation shows proper distribution of ICD potentials.

1. Introduction

Over 90,000 implantable cardioverter defibrillators (ICDs) were implanted in 2005[1] and the number is growing each year. Among the vast number of patients who benefit from ICDs are an increasing number of children. The physical size of pediatric patients as well as the anatomical abnormalities that they carry throughout life often lead to situations in which the standard locations of ICD device and lead placement are not possible and/or not optimally effective[2]. A second factor especially relevant to pediatric defibrillator placement and settings is that shocks can interfere with Ca^{2+} dynamics in cardiac tissue if the energy used is higher than that needed to defibrillate the heart[3]. Both of these factors provide motivation to determine the optimal locations for ICD placement in order to defibrillate the heart with the least amount of energy possible.

We have developed a patient specific computational simulation that predicts the potential distribution of an ICD as it is discharged. The simulation is based on a realistic torso geometry that includes structures and electrical conductivities of the body, placement of the ICD device and electrodes, and generates the resulting electric potentials throughout the torso. For each patient, various locations and settings can be tested to find the electric field throughout the heart and consequently evaluate the relationship between the ICD location and the energy requirement for defibrillation or defibrillation threshold[4]. To date, these simulations have shown encouraging accuracy in predicting the defibrillation thresholds when applied to a specific ICD patient[4]. However, defibrillation threshold is a single parameter that captures overall performance but does not reveal any details of accuracy of the simulations, for example, where and how simulation accuracy varies over the torso. Hence, a more comprehensive validation method in which full torso surface potentials generated by an ICD can be compared to the simulation is needed to provide deeper insight into the accuracy of the simulation and its reliability to predict the behavior of ICDs.

The nature of the measurements needed to obtain a full torso reading from an ICD present formidable obstacles because the only way to obtain electric potentials generated by the ICD is during implantation surgery when the device is tested for operability. One substantial limitation stems from the clinical reality that the area available for placing measurement electrodes is highly restricted. The nature of the surgery requires a sterile field where the ICD will be implanted and other areas are covered by safety and monitoring equipment so that large portions of especially the anterior chest are not available for recording electrodes. To overcome the spatial limitations, we have adapted a body surface potential mapping system and used the limited lead selection algorithm developed by Lux, et al [5] to determine the optimal set of 32 measurement lo-

cations which will enable a full torso mapping of the ICD distributions. With this system, we have carried out body surface mapping during ICD testing and compared preliminary surface recordings to determine the feasilbility of using such a method for validating the simulation.

2. Methods

Modification of the body surface potential mapping system for this application consisted of two components: 1) adapting the input to the amplifiers to accommodate the large (hundreds of volts) electric potentials from the ICD and 2) developing a novel electrode system that incorporates the clinical requirements of the ICD implantation.

The amplifiers in the 32 channel portable mux recording system are configured to measure cardiac surface potentials, four orders of magnitude smaller than typical ICD shocks. An attenuator was built that implements a voltage divider on each channel that scales down the voltage by 10,000, enabling the use of the cardiac measurement systems without clipping.

The basis for the new mapping electrode system was an adapted form of body surface estimation described by Lux, et al.[5]. This approach determines statistical relationships between a subset of spatially distributed, high resolution data and the remaining data based on a training phase. The resulting transformation then provides a means to expand subsequent measurements of the subset to the high resolution superset. The algorithm also provides a means of determining subsets of measurement locations that are optimal in terms of root-mean-squared errors between original and estimated data (limited lead set). The estimation and optimization algorithm was implemented using Matlab®to determine both optimal lead sets and the transformation matrix to predict the complete body surface potentials from the selected measurement electrodes.

The lead selection process requires a set of training body surface maps at full resolution that covers the range of possible distributions. We simulated these data using the forward model of defibrillation over three patient geometries, two common ICD locations, and 60 conductivity variations in every permutation (360 potential fields) with the goal of sufficient variability. The surface potentials were obtained at 370 consistent measurement locations. Using the limited lead selection algorithm[5], each of the 370 locations were ranked by relevancy toward body surface reconstruction. The 32 higest ranked locations that complied with our space limitations (Figure 1) were said to be the optimal lead set. An electrode set was then fabricated at the Nora Eccles Harrison Cardiovascular Research and Training Institute (CVRTI) based on a simplified optimal lead set to be used to record ICD shock values. The lead set, the attentuator, and the mux recording system constitute the measurement system used to obtain ICD surface potentials.

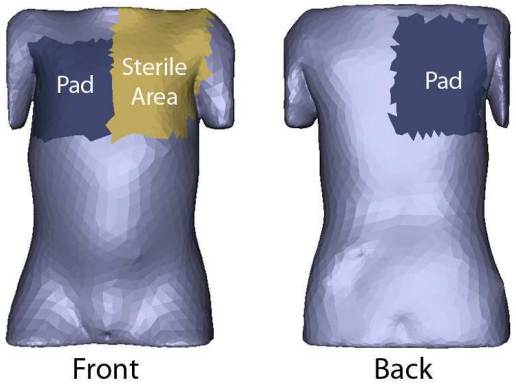

Figure 1. Constraints applied to the lead selection algorithm. The locations shaded are commonly used locations for defibrillator pads (dark gray) and implantation (tan).

Once the optimal lead set was found, a transformation matrix was generated using the covariance of the data set according to the potential mapping algorithm[5]. We then tested the resulting transform matrix on separate test datasets.

We then applied the entire processing pipeline to a patient receiving a first time ICD implantation. An MRI scan of the patient acquired before the implantation procedure provided the data for a tissue segmentation using Seg3D, a custom segmentation application (software.sci.utah.edu). Immediately prior to the procedure, the fabricated lead set was applied to the patient in the configuraton specified by the optimal lead set. The measmurement protocol included recordings from 32 body-surface leads for 30 seconds, which spanned the time required for inducing fibrillation, evaluating the detection of fibrillation by the ICD, and then defibrillating the heart. A fluoroscopic image of the location of the ICD obtained at the time of the implantation provided the position of the ICD for inclusion in the simulation. The simulated surface potentials were then compared to the recorded potentials by means of visual comparison of the spatial distribution and quantitative comparison of potential values at the measurement locations.

3. Results

The optimal lead set as calculated by the lead selection algorithm included measurement locations on the shoulders of the patient, the axillary areas, and the intercostal region as shown in Figure 2. The simplified optimal leads set fabricated for use in measurement is also shown.

The tests of accuracy of the body surface mapping algorithm illustrate high levels of accuracy (Figure 3). As shown in the figure, the absolute error in the reconstructed

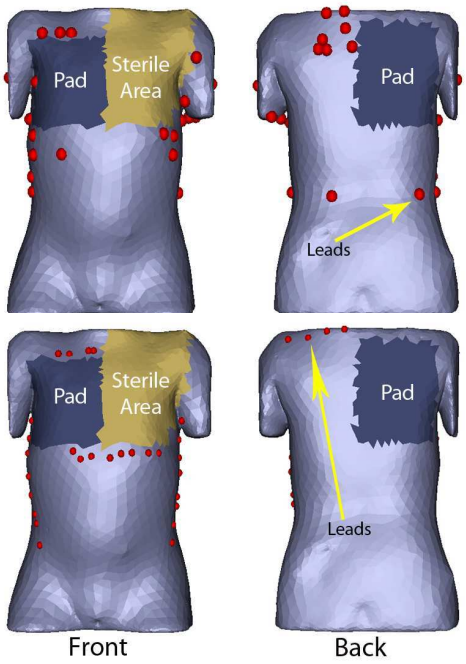

Figure 2. The optimum 32 locations of measurement determined by the algorithm with the applied constraints (top). Also shown is the simplified optimal lead set used to obtain surface recording (bottom). The constraints are shown on the surface of the torso: the dark gray represents the sterile area, and the tan represents the area of the defibrillation pads.

surface potentials were less than 1 V. From a simulated shock value of 500 V the surface potentials ranged from 150 V to 500 V, yielding a maximum error of .2 %.

The comparison of the surface recordings with the patient specific simulation demonstrated a discrepancy of the simulation and measured surface potentials. The raw voltage recordings and the simulated potentials at corresponding regions differed by factor of three (Figure 4). However, the scale between the two potential fields was consistent throughout the torso.

Similarly, the reconstruction of the ICD surface recordings demonstrated a significant difference in the magnitude of the potential from the patient specific simulation. As with the raw measurements, the distribution of the potentials were similar (Figure 5) demonstrating a correlation of .81, despite the magnitude difference.

4. Discussion and conclusions

The optimal lead set calculated by the lead selection algorithm generally determined most areas of significance to be as near he ICD and the associated leads as possible (Figure 2). In the original development of the algorithm for cardiac surface potentials, many leads calculated

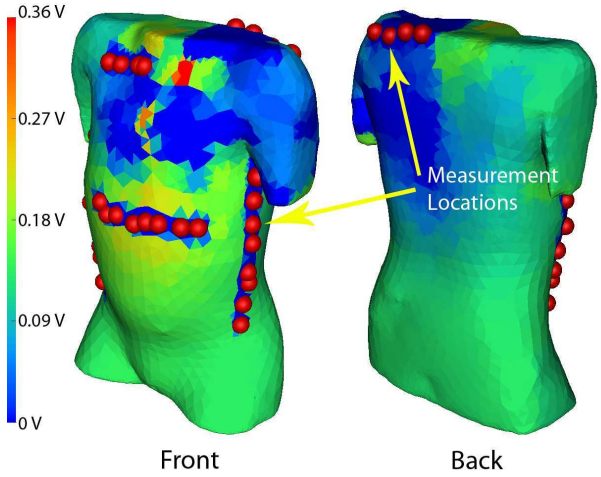

Figure 3. The absolute error of the reconstructed surface potentials using the measurement locations shown in Fig. 2. The largest error occurs in the area near the ICD ($<$ 1 V of 500 V or .2 %).

were located near the heart [5] indicating that solutions with many leads close to the source is expected of the algorithm. Furthermore, the reconstructions of the simulated data demonstrate the application of the body surface mapping algorithm with the simplified optimal lead set is a robust method for estimating simulated ICD torso surface potentials (Figure 3).

The reconstruction of the recorded surface potentials also supports the body surface mapping systems as a feasible method for obtaining ICD surface potentials (Figure 5). Though there are no full ICD surface potentials to compare with, the profile of the potential field is distributed as expected, with the highly positive potentials near the source of the voltage (the ICD) and the more negative potentials near the sink (epicardial coil), and a high correlation with the simulation. However, the reconstructed did express high differences from the simulation throughout significant regions of the torso, indicating an inaccurate reconstruction and/or simulation.

An analysis of the actual surface recordings provides is important in understanding the discrepancy between the simulation and the reconstructed ICD potentials. The surface recording potentials were smaller by about a factor of three than corresponding simulated potentials. This difference indicates that some physiologic complexity is missing from the simulation. The consistent scaling factor difference across the measurement locations indicate that the complexity missing could be from a physiological scaling factor such as conductivity differences or in the amount of voltage being delivered by the ICD. An analysis of the conductivity sensitivity of the simulation is required in order to test the former possibility, but the latter is much more

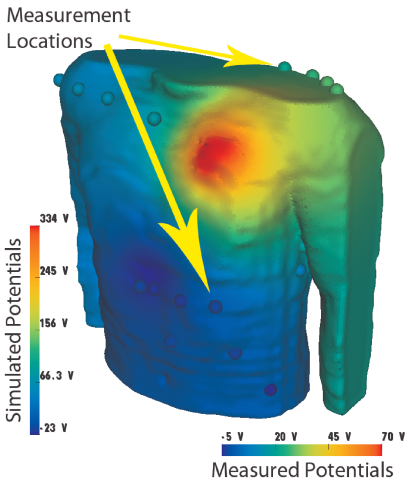

Figure 4. The comparison between the simulated surface potentials and the surface recordings without reconstruction. Though the magnitudes of the signals are different, the distributions follow a similar pattern. The image shows the surface recordings (bottom-right color scale) mapped on the simulation surface potentials (left color scale).

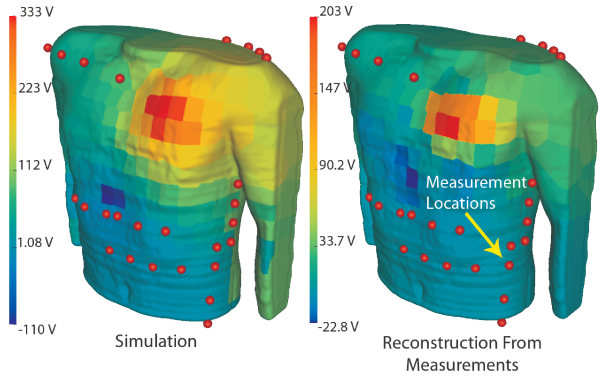

Figure 5. Comparison of the simulation potentials and the reconstructed potentials from surface recordings. The image on the left illustrates the potentials predicted by the simulation, the right illustrates the reconstruction of the surface potentials from surface measurements.

challenging and very impractical in a clinical setting due to the necessity of internal measurements located close to the ICD and leads, requiring animal models to determine the solution.

These early results suggest that measurements from the body surface are, indeed, possible during ICD testing and that with suitable reconstruction methods, even small lead sets can capture the necessary detail. Moreover, using these data to validate defibrillation simulations also appears to be feasible and thus a valuable adjunct to patient specific simulation and modeling studies.

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