Analysing the potential of Reveal® for monitoring cardiac potentials

Peter M. van Dam¹* and Adriaan van Oosterom²

¹Medtronic SQDM, Meander 1051, 6825 MJ Arnhem, The Netherlands; and ²Department of Cardiology, CHUV, Lausanne, Switzerland

Aims The implantable loop recorder (ILR) continuously monitors the heart’s electric activity by means of a subcutaneous bipolar electrogram (Elg). Currently, the relationship between the Elg and the surface electrocardiogram (ECG) has been poorly documented. This model-based study aimed at investigating the differences between the bipolar surface and subcutaneous signals, as well as the effect of the insulating boundary of the ILR on these signals. Additionally, the model is used for determining the optimal implant location of the device.

Methods and results Sinus rhythm ECG of a complete heart cycle was simulated by means of a biophysical model. Different volume conductors were created to investigate the effect of the insulating boundary of the ILR. The Elg closely matched the nearby bipolar ECG, both in morphology and in amplitude. The optimal localization and orientation of the ILR was found to depend on the Elg signal feature of interest, e.g. PQ, QRS, or STT waveforms.

Conclusion The differences between the bipolar ECG on the surface and the subcutaneous electrogram are negligible. The optimal implant location may be based on nearby surface recordings. The simulation model is an eligible tool for determining the optimal implant location for the ILR, for all signal features of interest.

KEYWORDS
Volume conductor models; Subcutaneous ECG; Implantable loop recorder

Introduction
In clinical practice, the 12-lead electrocardiogram (ECG) is commonly used for diagnosing specific electric malfunctioning of the heart. The normal recording practice provides snapshots of the electrical activity of the heart only. Rhythm disorders or the onset of acute myocardial infarction frequently remain unobserved. To capture such events, recording time can be prolonged, up to days, using a Holter system. Yet, despite the longer recording time, relevant clinical events are still frequently missed. In cases such as these, the heart may be monitored by an even more extended period (months) by an implantable loop recorder (ILR).

The Reveal, a commercially available ILR, is such a monitor. It is often implanted just below the subcutaneous fat in the left shoulder region. It monitors the heart rhythm by means of a bipolar electrogram with an electrode spacing of ~45 mm. To reduce the influence of myo-potentials, the electrodes are introduced facing the skin. Currently, the experience obtained from using the subcutaneous signals is still limited and the relationship between subcutaneous bipolar electrogram (Elg) and the nearby bipolar surface ECG is insufficiently documented. In this study, a computer model was used to quantify the differences between the two types of bipolar signals.

To simulate the type of signals involved, the electrical activities of both the atria and the ventricles need to be modelled. On the basis of a realistic source model and an MRI-derived volume conductor model, the bipolar ECG wave forms generated during sinus rhythm are compared with those of the IRL.

The boundary of the Reveal is a perfect insulator (with the exception of two small electrode contacts). The presence of such a non-conducting object might significantly influence the current density distribution within the torso, and hence also the potential field and in particular the potential difference between the electrodes of the ILR. This particular effect was studied by comparing the potential differences observed for the bipolar signals while either including or excluding the isolating properties of the device.

Finally, the suitability of the model for determining an optimal implant location was tested. At present, the optimal implant location in terms of signal amplitude remains to be determined.

Methods

Electrocardiogram simulation
Any description of the genesis of electrocardiographic potentials requires the specification of the current sources generated by the biochemical reactions at the cell membrane: the source model.
In addition, the conductive properties (extent and conductivity values) of the medium in which the potential field is set up need to be specified: the volume conductor model. The relevant geometry of the heart and the volume conductor as used in this study were derived from MRI images of a healthy 22-year-old human male. These were retrieved from images acquired during breath hold, half way expiration. The geometries of the atria and ventricles were reconstructed at the beginning of the P-wave, 165 ms before the QRS onset.

**Source model**

The model of the cardiac current generator used was the equivalent double layer (EDL), located at the closed surface \( S_h \) bounding the myocardium, comprising the epicardium and the endocardium. The double layer may be viewed as a sheet of current dipoles directed along the local surface normal of \( S_h \). This source model has a direct link with electrophysiology and has previously been shown to be very effective in the simulation of the potentials during depolarization and repolarization of the atria and ventricles. The MRI-derived geometries of atria and ventricles are shown in Figure 1D. The endocardial segments of \( S_h \) bordering the cavities are shown alongside.

The time course of the local strength of the double layer is that of a stylized version of the transmembrane potential (TMP) of healthy myocytes. It is specified by the local magnitude of the upstroke of the TMP at node \( n \) of the surface \( S_h \), its timing of depolarization \( t_n \) and its timing of repolarization \( r_n \). The latter is defined as the timing of the inflection point of the repolarization sequence (Figure 2). Accordingly, the source strength at node \( n \) at time instant \( t \) can be denoted as \( s_n(t, t_n, r_n) \). For discrete time steps, the entire source may be denoted by \( S \), the columns of this matrix represent the instantaneous strengths of the source elements:

\[
S = s_n(t, t_n, r_n)
\]

**Volume conductor model**

To quantify the differences between the bipolar surface ECG and the \( Elg \), three volume conductor models were created: a basic model that does not take into account the insulating properties of the ILR, and two variants in which the insulating effect was incorporated.

The basic volume conductor model used consisted of triangulated versions of the atria, the ventricles, and the surfaces bounding the major volumes that influence the morphology of the ECG signals, e.g. the torso, lungs, and blood cavities (Figure 1). Additionally, a local subcutaneous fat layer was included under the complete body surface. The assigned thickness of the layer was 8 mm, the approximate value of the subcutaneous fat in the left shoulder region of the lean subject studied. The conductivity values assigned to the individual compartments were: thorax, atrial, and ventricular muscle: 0.2 Sm\(^{-1}\), lungs: 0.04 Sm\(^{-1}\), fat: 0.07 Sm\(^{-1}\), and blood cavities: 0.6 Sm\(^{-1}\). The triangulated atria consisted of 1504 nodes, and the triangulated ventricles consisted of 1500 nodes. For the torso, 501 nodes were used; for the left and right lung, 486 and 259 nodes were used, respectively.
Additionally, two variant volume conductor models were considered in which the insulating properties of the ILR were incorporated, placed in either a horizontal (slightly oblique) or a vertical orientation (Figure 1). The size of the ILR model was taken from the Reveal, length: 60 mm, width: 20 mm, and thickness 8 mm, with an electrode spacing of 45 mm. In both cases, ILRs were positioned ~10 mm under the skin, i.e. just below the subcutaneous fat layer.

**Forward computation**

From the source and volume conductor descriptions as specified above, the potential field throughout the volume conductor can be computed by means of the boundary element method. The transfer from all source elements on the nodes, \( n \), to any set of field points, \( \ell \), considered can be expressed by a transfer matrix \( A \), with elements \( a(\ell,n) \).

In this study, three different transfer matrices were computed, specific for different volume conductor models and field points considered. For each of the transfer matrices, the potential \( \psi(\ell,t) \) at field point \( \ell \) was then computed as

\[
\psi(\ell,t) = \sum_n a(\ell,n)s(t, \tau_n, p_n)
\]  

Simulated electrocardiogram during sinus rhythm

The source elements are located at all nodes of the triangulated surfaces specifying the geometry of the atria and the ventricles. Time was discretized at 1 ms interval. The timings of local depolarization and repolarization for the atria and ventricles were estimated by a dedicated inverse procedure. The resulting isochrones for the depolarization are depicted in Figure 3.

The simulated 12-lead ECG based on the standard volume conductor model is shown in Figure 4 (blue traces). The quality of this simulation can be judged by comparing the simulated signals (red traces) with the ones measured on the subject involved.

**Results**

For all three volume conductors described, the resulting electric signals were simulated to investigate the differences between surface and subcutaneous signals as well as to study the influence insulating properties of the ILR. The subcutaneous electrograms were computed at the locations of the electrodes of the ILR (Figure 1), both while including or ignoring the insulating effect of the ILR (Figure 5). The
red lines relate to the simulated Elgs: the solid lines when incorporating the insulating effect, the dotted lines when disregarding it. In addition, Figure 5 includes the corresponding signals for field points on the surface of the thorax closest to the electrode positions of the ILR (blue lines).

The signals in Figure 5 demonstrate that the effect of the insulating properties of the ILR is very small, certainly compared with the inter-subject variability. At the locations of the ILR, the subcutaneous ECGs were found to be highly similar to the bipolar ECGs on the most proximal part of the body surface. Hence, the study of the optimal placement of the ILR may be carried out using the standard volume conductor, as reported in the remainder of this paper.

Three positions in the left side of the torso were selected to construct subcutaneous amplitude maps of the P-wave, the R-wave, and the T-wave: the first map was located above the heart, the next was located on top of the heart, and the last was located below the heart (see torso insets Figure 6). For each position within the map region, an Elg was generated between that point and the center of the map, which served as the potential reference for the Elg. All map positions were located 10 mm under the surface of
the torso. The maps in Figure 6 show that the maximum R-wave amplitudes were found in the region directly overlying the heart. Above and below the heart, the amplitudes were about half that size. For positions below the diaphragm, the P- and the T-wave disappeared almost completely. In all amplitude maps, a line could be found for which the amplitude is approximately zero. The difference in amplitude of the Elg features for different positions can best be observed in the signals shown in Figure 6.

Discussion

For the locations of the ILR selected, the subcutaneous Elg’s signals were found to be highly similar to those on the most proximal part of the body surface, both in morphology and amplitude. The effect of the insulating properties of the ILR on the Elg is negligible (Figure 5), certainly compared with the inter-subject variability. As a consequence, the study of the optimal placement of the ILR and the selection of its signal features may be carried out by using the surface signals.

In most mapping areas explored (Figure 6), the maximum amplitudes of the P-wave were found to be at least a factor 10 smaller than those of the R-wave, whereas those of the T-wave were about a factor less than four. From a practical implantation point of view, as well as by taking into consideration signal magnitude, the left shoulder region seems to be an appropriate implantation site. In order to determine the optimal orientation, the pattern of the local surface potentials has to be taken into account, e.g. both the maximum and minimum amplitude play a role.

As stated, the differences between the subcutaneous Elg and the bipolar surface ECG are very small. Initially, we compared both signals without the subcutaneous fat layer included in the volume conductor model (results are not shown). Even than the differences were very small, although slightly more compared with the signals with a subcutaneous fat layer included. This even smaller difference between both bipolar signals can, up to a certain extent, be explained by the fact that subcutaneous fat has a lower conductivity than the tissue underneath, thereby limiting the current flow across the layer of fat. As a consequence, the potentials on both sides of the fat layer are approximately the same. It is to be expected that for subjects with more subcutaneous fat the differences between the surface ECG and the subcutaneous Elg will, similarly, be small.

In clinical practice, the ILR sometimes fails to sense the R-wave, thereby failing to record the Elg during clinically relevant events. As the simulation results show, this can occur when the relative orientation of the ILR and the heart is such that the R-wave amplitude is ~0. For an optimal implant orientation, the line of minimal amplitude for certain Elg feature, e.g. PQ, QRS, or STT interval, should serve as guideline. The angle between the minimal amplitude line and the ILR should be large enough (~60°) in order to enable the recording of the selected feature despite changes in heart orientation because of posture changes. Unfortunately, the minimal amplitude line differs per Elg feature as shown in Figure 6. This may lead to conflicting implantation orientations for the ILR in cases where more than one feature requires to be monitored.

Conclusion

The bipolar EGCs sensed by the ILR closely match with the bipolar surface ECG, both in morphology and in amplitude. The optimal orientation of the ILR depends on the focus of interest, i.e. PQ, QRS, or STT interval. For optimal R-wave sensing, both ILRs location and its orientation for which the minimum R-wave amplitudes occur have to be considered.

Conflict of interest: none declared.

References