A Novel Method for Catheter–Tissue Contact Assessment During Atrial Fibrillation Ablation: The Electrical Coupling Index

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ABSTRACT. Interventional treatment of cardiac arrhythmias is in constant development. Percutaneous catheter ablation is the gold standard treatment for many types of arrhythmias, and its application is increasing significantly in regards to the treatment of atrial fibrillation (AF) and ventricular tachycardias. Adjunctive imaging technologies such as intracardiac echocardiography, three-dimensional mapping systems, and image integration contribute to a more precise understanding of the anatomy and thus, better treatment of arrhythmias. Efficacy and safety of ablation lesion formation are the main challenges in the interventional treatment of cardiac arrhythmias. Nowadays, it is a combination of physicians’ experience and subjective measures. There is a great need for a precise process to ensure catheter contact to the tissue, to control ablation lesions, and to deliver power to the endocardial tissue. The EnSite Contact technology appears promising and provides good feedback on catheter tip-to-tissue contact. This technology will be important for the management of AF ablation.

KEYWORDS. catheter–tissue contact, ablation lesion, atrial fibrillation ablation, contact technology.

Introduction
Cardiac arrhythmias are a major health-care problem and are responsible for a great number of hospital admissions and deaths.1 Over the past three decades, the art of treating these disorders has increasingly evolved in the fields of invasive cardiac electrophysiology and ablation strategies. Since the early 1980s, when ablation of the His bundle was performed with high-energy shocks delivered by a cardioversion unit connected to the catheter electrode,2 important advances have been made in targeting other sources of arrhythmias to make procedures safer using the best energy source and optimal power delivery to the tissue.

In the field of ablation therapy, outstanding development of energy sources has been observed. High-intensity focused ultrasound (HIFU), cryotherapy, laser, microwave, and radiofrequency (RF) energy are used nowadays for the interventional treatment of arrhythmias.

The most popular source is RF energy. It delivers high-frequency sinusoidal waves to the tissue, which is converted into thermal energy at the catheter–tissue interface, resulting in a necrotic lesion around the catheter tip.3 This is the most popular energy source and is used by the majority of services to perform cardiac ablation. A wide variety of catheters have been developed, e.g. catheters with different tip diameters, catheters with irrigated tips, balloon-shaped catheters, and double-curve catheters, in order to be more precise, to use less energy, to reduce the procedure time, to be safer, and to make the optimal lesion.

Following these developments, some questions arose: Is enough power being delivered to create the targeted lesion? How can ablation catheter tip-to-tissue contact...
and tissue damage be measured? What is the threshold between success and complications?

The standard ablative approach to atrial fibrillation (AF) is pulmonary vein isolation (PVI) with the possible addition of substrate modification lines, depending on the characteristics of patients and arrhythmias. Normally, monitoring techniques of RF ablation are based on indirect measures, such as assessment of the tissue temperature, power delivery, and impedance values provided by the ablation generator.

To guarantee the success of AF catheter ablation, the quality of catheter tip-to-tissue contact plays a major role. Electrophysiologists normally use a combination of qualitative measures, such as tactile feedback, fluoroscopic visualization, and electrical assessment of the quality of the electrograms. More recently, sensors have been incorporated into catheter systems to measure the force applied between the catheter tip and tissue. Although force sensors may provide additional feedback for catheter manipulation, force does not directly measure how well electrical energy is coupled between catheter tip and tissue.

The relation with the tissue damage is frequently controlled by the disappearance or lowering of local electrograms, subjective observation of impedance lowering, and assessment of the local pacing threshold. These monitoring methods can often result in delivering more RF lesions than necessary, which prolongs procedure time and therefore increases the risk of complications.

Some services use intracardiac echocardiography (ICE) to monitor real-time RF application, catheter contact to the tissue, and its angle. It is also used as anatomy guidance and to visualize complications during the procedure. However, ICE does not give an objective assessment of the catheter tip contact force or electrical coupling to the tissue, and it does not have sufficient contrast to visualize the formation of RF lesions.

Tissue lesion formation depends on the catheter tip-to-tissue electrical contact and is well correlated with local impedance variations. The recent development of a technology based on electrical contact between the catheter tip and tissue that calculates the complex impedance at the catheter tip-to-tissue area has shown positive results in predicting catheter tip-to-tissue contact and ablation lesion formation in animal ventricular wedge preparation and live models after intracardiac catheter ablation. The first study of contact technology validation in humans in whom AF ablation PVI was performed showed good results in predicting catheter tip-to-tissue contact.

Technology features

Aimed first at AF ablation, EnSite Contact technology (EnSite NavX system, St. Jude Medical Inc., St. Paul, MN) is a system based on the calculation of the real-time complex impedance specific to the catheter tip-to-tissue interface using a three-terminal model, through which a small current runs in one of the circuit arms. It is integrated in the EnSite Velocity mapping system and estimates the ablation electrode contact with the endocardial surface based on local impedance measurements, as previously described. This calculation is expressed as a single measure, termed the electrical coupling index (ECI).

The ECI is a real-value metric derived from this complex impedance measurement. The ECI is displayed on the EnSite Velocity System and shows the tip beacon, the meter (displayed as ECI units), and the wave form (ECI over time; Figure 1).

Practice based on evidence

The first experimental study tested the potential clinical benefits of EnSite Contact in different animal models: 1) porcine thigh muscle, in vivo exposed thigh with blood pool; 2) arterially perfused porcine and canine ventricular wedge preparation; and 3) porcine and canine in vivo intracardiac catheter procedures. The EnSite Contact signals were compared with endocardium electrogram (EGM) analyses and the force contact was with ECI (Figure 2a) and EGM analyses (Figure 2b). In this work, the correlation with pops in the wedge preparation was also better with the EnSite Contact system.

Another experimental study compared EGMs to ECI during closed chest animal ablation; the best correlation with force contact was with ECI (Figure 3a). ECI in the post-ablation substrate showed the ability to reflect catheter contact, whereas atrial electrogram amplitude did not (Figure 3b).

The first human study of clinical validation of ECI in AF ablation, the ECI I Trial, showed good correlation with EGMs and pacing thresholds (Figure 4), and also high sensitivity, specificity, and positive predictive value to tissue contact when the ECI threshold was set 5 units above the “true non-contact” area. It proved to be a safe indicator of catheter tip-to-tissue contact.

The ECI II Trial (in preparation) enrolled 40 patients with paroxysmal or persistent AF submitted to circumferential PVI with or without additional linear lesions. The patients were randomized to ablation of one ipsilateral PV pair with ECI displays on and the other ipsilateral PV pair with ECI displays off. The primary endpoint is isolation without the need for “touch-up.” Preliminary data suggest that with displays on, touch-up is required less, and the secondary endpoints (procedural times, clinical outcome, safety, and number of RF applications) seem to be favorable for the ECI system activated.

Leipzig experience in AF ablation with ECI

During the procedure, after reconstruction of the PVs and their integration with the computed tomography...
(CT) left atrium model, the operator moves the catheter to a non-contact area. In this position, an averaged ECI is computed as the baseline of “non-contact.” Afterward, the catheter is positioned in a place with firm contact with the atrial endocardium and is set at the “maximum contact line” (Figure 5).

After set-up, according to a color-coded threshold, the tip beacon turns green when it makes contact with the
tissue, and turns orange if there is excessive contact (Figure 5).

In the following case study example, a 63-year-old man underwent a PVI procedure in 2010 because of high symptomatic persistent AF. He had no major structural heart disease, with a left atrium (LA) of 38 cm and a CHADS2 score of 1 (hypertension).

Sedation was performed, and catheters were placed in the coronary sinus (CS) and right ventricle. After one transseptal puncture, the LA was mapped and integrated with the CT image previously acquired and segmented. In the sequence, the ECI validation was performed and started ablation per se. The patient was in sinus rhythm.

During ablation, the ECI threshold confirmed a contact moment within the inferior aspect of the right inferior pulmonary vein (RIPV), observed with the tip beacon and the ECI curve responses (Figure 6). During ablation, a decrease in the ECI curve was observed following a decrease in local potential (Figure 6). After successful PVI, a voltage map was performed and showed low voltage potentials at the roof of the LA (probably the insertion of Backmann’s bundle (BB)) and the anterior aspect of the right superior PV (Figure 7). An atrial macro re-entrant tachycardia was induced and terminated during ablation at BB insertion (Figure 7). Finally, no other sustained arrhythmia was induced, and the PVs were still isolated.

Interestingly, as normally observed, in the region of the ablation lines there were no more ECI signals while there was catheter contact.

Discussion

For many years, the treatment of AF was based only on antiarrhythmics to control the rhythm, or on chronotropic medications, such as beta-blockers, to control the heart rate. In the early 1990s, an evolution in the concepts of invasive treatment for AF boosted advances in technology, therefore making it more effective and less harmful for patients.
Ablation lesions in AF treatment aim to disconnect the triggers and modify the substrates that maintain AF. Therefore, measurement of catheter tip contact and lesion formation has become extremely important, not just to achieve the primary endpoint, but also to avoid excessive energy delivery to the tissue and thus procedure complications.

The purpose of indirect monitoring is unclear and lacks the sensitivity, specificity, and positive predictive value to detect catheter tip contact and lesion accomplishment.

Tissue impedance is a biophysical property that can be measured to predict catheter contact against the tissue and also to predict lesion formation during ablation.\textsuperscript{12,13}

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**Figure 4:** Validation of the contact and no contact areas with pacing threshold and comparison of atrial endocardium electrograms.\textsuperscript{11}

**Figure 5:** The menu options for the electrical coupling index (ECI) evaluation (left), and an example of a patient who underwent pulmonary vein isolation (PVI). There is “excessive contact” with the posterior aspect of the left inferior pulmonary vein (LIPV) ostium shown on the tip beacon (right).
thus, real-time measurement would be undoubtedly useful. EnSite Contact technology shows a valid way to ensure catheter tip-to-tissue contact using ECI. The preliminary data from one center suggest good clinical outcomes during AF ablation when compared with normal indirect parameters.

We believe that this technology adds better capability to confirm good catheter tip-to-tissue contact while avoiding excessive injury during AF ablation. The experimental data suggest that this technology may play a role in measuring ablation lesion formation and might be clinically relevant to ablation outcomes, as well as reducing peri- and post-procedural complications. Larger multicenter studies with wider populations are needed in order to assess the benefit of adding this technology to the clinical routine.

Figure 6: (Top) Observation of good catheter tip-to-tissue contact with the inferior aspect of the right inferior pulmonary vein shown by the electrical coupling index (ECI) curve and the tip beacon. (Bottom) Decreasing ECI during ablation of this spot (posterior-anterior from right and inferior view).
Figure 7: Voltage map showing “low voltage” area in the Backmann’s bundle region, where the induced atrial tachycardia terminated (green marker). Purple: electrograms higher than 0.5 mV.

References


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