Prediction of radiofrequency ablation lesion formation using a novel temperature sensing technology incorporated in a force sensing catheter

Guy Rozen, MD, MHA,[*] Leon Ptaszek, MD,[*] Israel Zilberman, DVM,[†] Kevin Cordaro, BS,[*] E. Kevin Heist, MD, PhD, FHRS,[*] Christopher Beeckler, BS,[†] Andres Altmann, BSc,[†] Zhang Ying, MD,[*] Zhenjiang Liu, MD,[*] Jeremy N. Ruskin, MD, FHRS,[*] Assaf Govari, PhD,[†] Moussa Mansour, MD, FHRS[*]

From the [*]Heart Center, Massachusetts General Hospital, Boston, Massachusetts, and [†]Biosense Webster Inc, Diamond Bar, California.

BACKGROUND Real-time radiofrequency (RF) ablation lesion assessment is a major unmet need in cardiac electrophysiology.

OBJECTIVE The purpose of this study was to assess whether improved temperature measurement using a novel thermocoupling (TC) technology combined with information derived from impedance change, contact force (CF) sensing, and catheter orientation allows accurate real-time prediction of ablation lesion formation.

METHODS RF ablation lesions were delivered in the ventricles of 15 swine using a novel externally irrigated-tip catheter containing 6 miniature TC sensors in addition to force sensing technology. Ablation duration, power, irrigation rate, impedance drop, CF, and temperature from each sensor were recorded. The catheter "orientation factor" was calculated using measurements from the different TC sensors. Information derived from all the sources was included in a mathematical model developed to predict lesion depth and validated against histologic measurements.

RESULTS A total of 143 ablation lesions were delivered to the left ventricle (n = 74) and right ventricle (n = 69). Mean CF applied during the ablations was 14.34 ± 3.55*g*, and mean impedance drop achieved during the ablations was 17.5 ± 6.41 Ω. Mean difference between predicted and measured ablation lesion depth was 0.72 ± 0.56 mm. In the majority of lesions (91.6%), the difference between estimated and measured depth was ≤1.5 mm.

CONCLUSION Accurate real-time prediction of RF lesion depth is feasible using a novel ablation catheter-based system in conjunction with a mathematical prediction model, combining elaborate temperature measurements with information derived from catheter orientation, CF sensing, impedance change, and additional ablation parameters.

KEYWORDS Radiofrequency; Catheter ablation; Lesion assessment; Contact force sensing, Catheter orientation; Thermocouple

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Introduction

Numerous energy sources are currently used for catheter ablation of cardiac arrhythmias, including cryothermy,[1] high-frequency ultrasound,[2,3] laser,[4,5] and radiofrequency (RF) energy.[6,7] RF is the most commonly used energy source for ablation and has the advantage of creating ablation lesions rapidly and effectively.[8] One of the limitations of RF ablation is the inability to assess adequate lesion formation. Lesions deeper than clinically indicated can cause collateral tissue injury (eg, to the esophagus and phrenic nerve), whereas lesions that are too superficial can lead to gap formation and arrhythmia recurrence. As a result, assessment of RF lesion formation is considered one of the major unmet needs in cardiac electrophysiology.

Several techniques and technologies have been developed with the aim of estimating the creation of effective lesions. Tissue impedance measurement at baseline and subsequent change during ablation has been used as a surrogate marker for catheter–tissue contact and for predicting lesion efficacy in a number of studies.[9–14] Although the magnitude of the impedance fall early after RF ablation correlated with the imparted lesion depth,[14] diameter,[9] and volume[9,10,12,14] in animal models, it had only modest value in predicting the *in vivo* contact force (CF) in human studies.[15]

CF sensing recently has been introduced and shown to improve the efficacy of RF ablation.[11,12,14,16] Nevertheless, force sensing is yet another indirect predictor of proper energy delivery, incapable, by itself, of predicting ablation

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lesion creation without integration with input from other determinants.

Real-time subendocardial tissue temperature monitoring during RF energy application is a direct indicator of lesion formation.[17] However, temperature measured by sensors embedded in the catheter tip was shown not to be an accurate indicator of actual tissue temperature, especially with externally irrigated-tip catheters.[18–21]

The studies mentioned showed that catheter tip temperature measurement, impedance change, and CF sensing have been used individually to guide effective RF energy delivery. Yet no study to date used those parameters in combination to assess lesion formation.

The aim of this study was to demonstrate the capability of a mathematical model that combines input from a novel catheter-based technology (allowing improved tip–tissue interface temperature measurements) with data regarding catheter orientation, CF sensing, impedance change, and additional ablation parameters to accurately predict ablation lesion formation in real time.

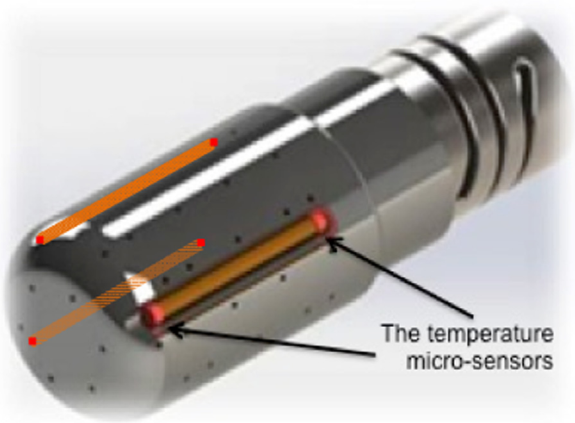

Figure 1 Qdot catheter tip. This novel catheter is based on the Biosense STSF catheter, with 56 irrigation holes but a wider tip shell (0.2 mm). The tip electrode embeds 6 thermocouples (TCs) drilled into the catheter's tip shell. The distance of the TCs from the outer surface is 75 μm (0.075 mm). Because the TCs are drilled into the metal tip, which acts as an ideal conductor, we were able to improve the catheter tip electrode temperature measurement to closer represent the electrode–tissue interface temperature.

Methods

Animal model setup

The study was performed at Massachusetts General Hospital (Boston, MA) in a previously described animal model.[22] The procedures were performed using a novel ablation system on 15 male Yorkshire pigs. The study protocol was approved by the Subcommittee of Research Animal Care, which serves as the Institutional Animal Care and Use Committee for the Massachusetts General Hospital, according to the American Association for Laboratory Animal Care standards for proper research animal care.

Thermocoupling technology

A novel irrigated-tip catheter (Biosense Webster Inc, Diamond Bar, CA) containing 6 miniature thermocoupling (TC) sensors measuring 1 mm in diameter (3 proximal and 3 distal), embedded at distinct locations within the outer metal shell of the catheter, just 75 μm underneath the tip surface was used (Figure 1). This catheter also incorporated force sensing technology. The reasoning behind the design was to obtain more accurate local temperature readings from the parts of the catheter tip in direct contact with the tissue, as opposed to the conventional average tip temperature measurement that is "diluted" by the cooler parts of the tip that are not touching the tissue.

Electroanatomic mapping and radiofrequency ablation

Electroanatomic mapping of the right atrium, right ventricle (RV), and left ventricle (LV) was performed using the experimental catheter with an electroanatomic mapping system (CARTO-3, Biosense Webster Inc, Diamond Bar, CA).

RF energy was delivered using the catheter in conjunction with an NMARQ RF generator and a CoolFlow irrigation pump (Biosense Webster). Positional stability and CF were measured and recorded continuously during lesion delivery.

All lesions were created using predetermined criteria for positional stability (≤2-mm deviation from the starting position of the catheter during RF application) and CF thresholds (10*g* or 20*g* of CF sustained for 60 seconds). The ablation was performed using predefined power for RF delivery in the different locations within the heart: 25 W for RV free wall, 30 W for RV septum, and 35 W for LV lesions (septum and free wall).

Lesion depth prediction model

Preliminary experiments were performed at previous stages using earlier prototypes of the catheter to deliver a large number of ablation lesions. The information gathered from these experiments was used to develop the mathematical prediction model for ablation lesion depth (Figure 2). The optimal values of the constants a and b were derived via numerical optimization of the measured vs estimated lesion size in the sense of least square error. The study described here was designed to test the final prototype of the catheter and confirm its lesion assessment capability using the mathematical model.

The ablation parameters recorded for each ablation lesion included time, power, irrigation rate, impedance drop, temperature from each sensor, and CF. Prior published reports showed that energy delivery and lesion size were larger with parallel, compared to perpendicular, tip to tissue

$$Depth = a\left(1 - e^{-\frac{Index*}{b}}\right)$$

Figure 2 Mathematical model for ablation lesion depth prediction a, b are constants, as follows: a = 6.03039 b = 0.14606. *Index = (Average power) × (Average force) × (Time) × (ΔImpedance) × (ΔTemp) × (Orientation factor).