Novel Contact Force Sensor Incorporated in Irrigated Radiofrequency Ablation Catheter Predicts Lesion Size and Incidence of Steam Pop and Thrombus

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Background—An open-irrigated radiofrequency (RF) ablation catheter was developed to measure contact force (CF). Three optical fibers measure microdeformation of the catheter tip. The purpose of this study was to (1) validate the accuracy of CF sensor (CFS) (bench test); and (2) determine the relationship between CF and tissue temperatures, lesion size, steam pop, and thrombus during RF ablation using a canine thigh muscle preparation.

Methods and Results—CFS measurements (total 1409) from 2 catheters in 3 angles (perpendicular, parallel, and 45°) were compared with a certified balance (range, 0 to 50 g). CFS measurements correlated highly ($R^2$=0.988; mean error, ±1.0 g). In 10 anesthetized dogs, a skin cradle over the thigh muscle was superfused with heparinized blood at 37°C. A 7F catheter with 3.5-mm saline-irrigated electrode and CFS (Endosense) was held perpendicular to the muscle at CF of 2, 10, 20, 30, and 40 g. RF was delivered (n=100) for 60 seconds at 30 or 50 W (irrigation 17 or 30 mL/min). Tissue temperature (3 and 7 mm depths), lesion size, thrombus, and steam pop increased significantly with increasing CF at each RF power. Lesion size was greater with applications of lower power (30 W) and greater CF (30 to 40 g) than at high power (50 W) with lower CF (2 to 10 g).

Conclusions—This novel ablation catheter, which accurately measures CF, confirmed CF is a major determinant of RF lesion size. Steam pop and thrombus incidence also increases with CF. CFS in an open-irrigated ablation catheter that may optimize the selection of RF power and application time to maximize lesion formation and reduce the risk of steam pop and thrombus. (Circ Arrhythmia Electrophysiol. 2008;1:354-362.)

Key Words: catheter ablation ■ fibrillation ■ tachyarrhythmias ■ radiofrequency ■ ventricular tachycardia

Several experimental studies have suggested that during radiofrequency (RF) catheter ablation, electrode-tissue contact force (CF) is a major determinant of lesion size.1–7 Despite its importance, CF cannot be measured directly with available ablation catheters. Therefore, surrogate measures of CF have been proposed, including baseline impedance and changes during ablation in electrode temperature (ET) and impedance.1,3,4 The accuracy of these surrogate measures has not been extensively validated.

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A CF sensor (CFS), using 3 optical fibers to measure microdeformation of the catheter tip, has been developed for use in an RF ablation catheter. The sensor was incorporated into an ablation catheter with a saline-irrigated tip electrode (TactiCath, Endosense SA). The purpose of this study was to (1) validate the accuracy of the CFS measurements in a bench test; and (2) determine the relationship among CF, impedance, ET, tissue temperatures, lesion size, and the incidence of steam pop and thrombus during saline-irrigated RF ablation using a canine thigh muscle preparation.

Methods

CFS and Ablation Catheter

The 7 Fr quadripolar ablation catheter had a 3.5-mm tip electrode. For saline irrigation during ablation (open irrigation), the catheter had a central lumen and the tip electrode had 6 small irrigation holes (0.4 mm diameter) around the circumferrence, located 1.2 mm from the tip (Figure 1). The tip electrode also contained a thermocouple for measuring the ET.

A force sensor was incorporated into the distal part of the ablation catheter (TactiCath, Endosense SA), between the second and third electrode. The force sensor (Touch+, Endosense) consisted of a deformable body (elastic polymer) and 3 optical fibers (diameter of 0.125 mm) to measure microdeformations that correlate with force applied to the catheter tip (Figure 1). Infrared laser light (wave
The red bands depict the boundaries of the RF lesions. Figure 1A. Schematic representation of the distal end of the force sensing ablation catheter. The force sensor includes 3 optical fibers attached distally with fiber Bragg gratings to a deformable body. Force on the deformable body changes the periodicity of the fiber Bragg gratings refractive index pattern, which changes the reflected wavelength of light in the 3 optical fibers. The consequent change of the reflected wavelength is proportional to the CF applied to the tip. By monitoring the reflected wavelength in the 3 optical fibers (attached at 3 sites spaced circumferentially around the deformable body), the system is able to calculate and display the vector of the CF (magnitude and angle) at intervals of 100 ms (Figure 1). The CF (magnitude and angle) at time intervals of 100 ms (Figure 1).

Bench Verification of the CFS Accuracy and Sensitivity

Two catheters were tested against an externally calibrated and certified balance (force sensor type 5N/0.001N, Mecmesin) to verify the accuracy and the sensitivity of the CFS. The CFS measurements were tested for 3 force angles: axial to the catheter (catheter perpendicular to contact surface, 90° angle), lateral to the catheter (parallel to contact surface, 0° angle), and at 45° angle. The catheters were mounted in a micrometric screw, exposing the distal 18 mm of the catheter, which is relatively rigid. At each of the 3 angles, the tip of the catheter was gradually advanced against the balance with increasing forces using the micrometric screw, starting at 0 g and increasing to a maximum force of 50 g. The force was then gradually reduced from 50 to 0 g. For each step, the CF readings from both the calibrated balance and the catheter CFS were recorded. This up-down sequence was repeated at least 10 times to ensure equal distribution of the force samples taken in the 0 to 50 g range.

Canine Thigh Muscle Preparation

The experimental protocol was approved by the University of Oklahoma Committee on the Use and Care of Animals. Ten mongrel dogs weighing 25 to 32 kg were anesthetized with sodium pentobarbital (25 mg/kg) and ventilated mechanically with room air. The right carotid artery was cannulated for monitoring arterial pressure.

The canine thigh muscle preparation has been described previously.7–14 Each dog was placed on its right side. A 20-cm skin incision was made over the left thigh muscle. The skin on each side of the incision was dissected free of the connective tissue. The skin edges were raised to form a cradle that was filled with heparinized blood (activated clotting time >350 seconds) from the same animal at 37°C to 38°C (Figure 2A).

The ablation catheter was held perpendicular to the thigh muscle. Pulsatile blood flow (Master Flex, Cole-Parmer Instrument) was directed at the ablation electrode from a plastic tube located approximately 1.5 cm from the ablation electrode. The device produced a peak flow velocity at the electrode of only 0.1 m/s, measured by pulsed Doppler (Figure 2A). A peak flow velocity of 0.1 m/s simulates ablation sites with low local blood flow.

ET was measured from the thermocouple within the tip electrode at 20 msec intervals. Two 0.3-mm diameter fluoroptic temperature probes (Luxtron model 3100, accuracy ±0.1°C at 0 to 160°C) were positioned on opposite sides of the electrode-tissue interface (Figure 2A). The electrode-tissue interface temperature (IT) was taken as the higher of the 2 temperatures. Two additional fluoroptic temperature probes were bundled together with shrink tubing and inserted into the thigh muscle adjacent to the ablation electrode, such that the 2 probes were located at 3 and 7 mm below the muscle surface. The electrode-tissue interface and 2 tissue temperatures were measured at 125-ms intervals (Figure 2B).

Ablation Protocol

Catheter-tissue CF was applied at separate sites in the thigh muscle at 2, 10, 20, 30, and 40 g as measured by the catheter contact sensor. In each of the 10 dogs, 1 saline-irrigated RF application was delivered at constant power of 30 W (17 mL/min irrigation13,14) at each of the 5 CF levels and 1 RF application was delivered at 50 W (30 mL/min irrigation14) at each of the 5 CF levels (10 RF applications per dog). The order of testing (CF and power) was randomized. RF energy (500 kHz) was delivered for 60 seconds between the ablation electrode and an adhesive electrosurgical dispersive pad (20 cm × 10 cm) applied to the shaved skin of the opposite thigh. The RF application was not terminated prematurely in the event of an impedance rise (≥10 Ω above the lowest impedance during the RF application) or a steam pop. A custom RF generator (Radionics, model RFG-3DJ) was used that allowed the recording of power, impedance, and ET at 20 msec intervals (Figure 2B). The root-mean-square power and impedance, and the ET, electrode-tissue IT, and tissue temperatures were monitored continuously and recorded (Bard LabSystem).
After each RF application, the catheter was left in place and the cradle was emptied of blood. The ablation electrode and the electrode-tissue interface were examined for thrombus.\textsuperscript{13–15} The electrode catheter was then removed, cleaned, and positioned at a new site for another RF application. RF current was delivered at 5 sites along the surface of the left thigh muscle. The skin incision was then closed, and the animal was rotated to expose the right thigh muscle. The right thigh muscle was prepared using the same procedure, and 5 RF applications were delivered.

One hour after the ablation procedure, 20 mL of 10% triphenyl terazolium chloride was administered intravenously. Triphenyl terazolium chloride stains intracellular dehydrogenase a deep red color, distinguishing viable (red) and necrotic (pale) tissue. The animals were euthanized, and the thigh muscles were excised and fixed in 10% formalin. The thigh muscles were sectioned to measure lesion size.

**Measurements of Lesion Size**

The maximum depth (a), maximum diameter (b), depth at the maximum diameter (c), and surface diameter (d) of the lesion were measured. Lesion volume was calculated as: \( \text{volume} = \frac{1}{6} \times \pi \times (A \times B^2 + C \times D^2/2). \textsuperscript{12} \)

**Statistical Analysis**

Statistical analyses were performed using the SAS software (Version 9). For the bench test, the significance of the relationship between the force calculated by the catheter sensor and the force measured by the calibrated balance was assessed by a simple linear regression analysis. For the canine thigh muscle preparation, values are presented as median (50%) and 10%, 25%, 75%, and 90% values (box plot). Descriptive statistics were calculated for variables of interest. The significance of the relationship between the different levels of CF and the initial impedance, impedance decrease, ET, electrode-tissue IT, tissue temperatures at depths of 3 and 5 mm, and lesion size was assessed by using 2-factor repeated ANOVA. Repeated measures analysis of variance using SAS Proc Mixed was performed to account for the correlation among the observations from individual dogs. \( \chi^2 \) test for trend was used to test whether there is a linear relationship between the CF and the incidence of thrombus and steam pop. Fisher exact test was used to test the overall association between the CF and incidence of thrombus and steam pop. Nonparametric tests were used to compare the impedance decrease of RF applications with and without steam pop in the different levels of CF. A probability value of <0.05 was considered to be statistically significant.
The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

Bench Verification of the CFS Accuracy and Sensitivity
A total of 1409 catheter CFS measurements were obtained for the 2 catheters and the 3 angles (perpendicular, parallel, and 45°). The results were shown in Figure 3. The correlation between the force calculated by the catheter sensor and the force measured by the balance (measured CF) for 3 different angles (A, 90°; B, 0°; and C, 45°) for each of the 2 catheters (top and bottom). The CF calculated by the catheter contact sensor correlated very closely with the measured CF.

Relationship Between CF and Ablation Parameters in Canine Thigh Muscle Preparation
A total of 100 RF applications were delivered in the 10 dogs at power of 30 W at CF of 2 g (n=10), 10 g (n=10), 20 g (n=10), 30 g (n=10), and 40 g (n=10), and power of 50 W at CF of 2 g (n=10), 10 g (n=10), 20 g (n=10), 30 g (n=10), and 40 g (n=10).

The impedance at the onset of the RF application was not significantly different between the 5 CFs, but there was a trend toward higher impedance at higher CFs (Figure 4A). The magnitude of impedance decrease during RF applications (initial impedance minus minimum impedance) increased significantly with increasing CF at 30 and 50 W (Figure 4B). However, at the same CF, there was no significant difference in the magnitude of impedance decrease between 30- and 50-W RF applications. The occurrence of an impedance rise (impedance increase of ≥10 Ω above the lowest impedance during the RF application) increased significantly with increasing CF at 50 W (0/10 at 2 g, 0/10 at 10 g, 2/10 at 20 g, 3/10 at 30 g, and 6/10 at 40 g; P<0.01). At 30 W, only a single impedance rise occurred at the highest CF (40 g).

Neither ET nor electrode-tissue IT increased significantly with increasing CF (Figure 5A and 5B), presumably attributable to cooling of saline irrigation. Tissue temperatures at depths of 3 and 7 mm increased significantly with increasing CF for 30- and 50-W RF applications (Figure 5C and 5D). Lesion depth, diameter, and volume also increased significantly with increasing CF for RF applications at both 30 and 50 W (Figure 6). Lesion depth, diameter, and volume were all greater for 30 W (moderate power) applications at 40 g CF.
than for 50-W applications (high power) at 10 g CF (median depth, 9.9 mm versus 8.5 mm; median diameter, 13.7 mm versus 11.9 mm; and median volume, 1052 mm³ versus 683 mm³; Figure 6).

Relationship Between CF and Incidence of Thrombus and Steam Pop

Thrombus did not occur with any RF application (30 or 50 W) at low CF (2 or 10 g). At greater CF (20, 30, and 40 g), thrombus occurred at the proximal edge of the electrode (not at the electrode-tissue interface) with RF applications at 30 and 50 W (Figure 7A). The incidence of thrombus increased significantly with increasing CF for 50 W. There was a trend (not significant) toward increased incidence of thrombus with increasing CF for 30-W applications (Figure 7A). Thrombus formation was associated with an impedance rise ($\approx$10 $\Omega$) in only 1 of the 7 RF applications producing thrombus at 30 W and 6 of the 11 RF applications producing thrombus at 50 W.

Steam pops were identified by an audible pop or small (3 to 5 $\Omega$) brief (usually in the range of 50 ms) increase in impedance. A steam pop occurred during 28 of the 100 RF applications at 11 to 57 (median 26) seconds after RF onset. At moderate RF power (30 W), steam pops occurred only with the largest CF tested (40 g; Figure 7B). At high RF power (50 W), steam pops occurred with CF as low as 10 g, and the incidence of a steam pop increased significantly with increasing CF (Figure 7B). A steam pop occurred during 7 of the 10 RF applications at 30 or 40 g CF and 50 W. The magnitude of impedance decrease during RF application was not a good predictor for the occurrence of a steam pop (Figure 7C). The impedance decrease associated with a steam pop was less at lower CF than the impedance decrease without a steam pop at higher CF (ie, median 10 $\Omega$ decrease for steam pop at 20 g CF and 50 W, compared with median 12 $\Omega$ decrease without steam pop at 40 g CF; Figure 7C).

Discussion

This novel catheter tip CFS (Figure 1) was found to be highly sensitive and accurate (mean error $\leq$1.0 g) in all 3 catheter orientations (perpendicular, parallel, 45°) in the bench tests (Figure 3). After validation by the bench test, this catheter was used to test the impact of CF (measured by the catheter force sensor) on RF lesion formation in the canine thigh muscle preparation. The force sensing ablation catheter was oriented perpendicular to the thigh muscle (Figure 2), and RF energy was delivered using saline irrigation to cool the electrode-tissue interface.

At constant RF power (30 or 50 W) and application time (60 seconds), increasing ablation electrode CF (2 to 40 g)
significantly increased tissue temperature at depths of 3 and 7 mm (Figure 5C and 5D), with significant increases in RF lesion depth, diameter, and volume (Figure 6A through 6C). The major impact of CF on lesion size is shown by the larger and deeper lesions produced by lower RF power (30 W) and greater CF (30 to 40 g) compared with lesions produced at high power (50 W) but lower CF (2 to 10 g; Figure 6). The price of higher CF is an increase in the incidence of steam pop and thrombus (Figure 7A and 7B). Therefore, the ability to measure CF before the onset of an RF application would allow the selection of an appropriate RF power and application time to maintain efficacy (deep lesion) and minimize risk of steam pop and thrombus.

Despite the increase in tissue temperature, there was no significant increase during ablation in ET or electrode-tissue IT with increasing CF (Figure 5). This differs from earlier studies using a nonirrigated electrode where ET did increase with increasing CF. Active cooling by saline irrigation prevents the temperature increase in the electrode and the electrode-tissue interface. With saline irrigation, RF lesion size correlates best with tissue temperature and not ET. The relationship between CF and lesion size is less evident when RF energy is delivered without irrigation in the temperature control mode. Because RF power is varied to maintain a constant ET (and the electrode is not actively cooled), the RF power is reduced with higher CF attributable to greater tissue heating. This reduces the increase in lesion size with increasing CF.

Earlier studies have suggested that the initial impedance or the impedance decrease during an RF application may be used as a measure of CF. Higher CF would be expected to increase initial impedance by increasing the electrode-tissue interface area (higher impedance) and reducing the electrode-blood interface area (lower impedance). In this study, using an irrigated electrode, there was a trend toward higher impedance at higher CFs, but the relationship was not significant (Figure 4A).

The impedance decrease during the RF application is thought to result from the decrease in impedance at the electrode-tissue interface with tissue heating. In the present study...
study, there was a significant relationship between the magnitude of impedance decrease during RF and CF (Figure 4B), consistent with the increase in tissue temperature with increasing CF. However, there was significant overlap in the magnitude of impedance decrease, limiting its use as a measure of CF. Another limitation is that the measure of impedance decrease is not known before the onset of the RF application. It is desirable to have a measure of CF before the RF application to determine whether CF is adequate for ablation and to select an appropriate RF power.

The magnitude of impedance decrease during RF has been proposed as a predictor of steam pop. The decrease in impedance during RF failed to predict the occurrence of steam pop in the present study (Figure 7C).

**Study Limitations**

The primary limitation of this study is that it was performed in a canine thigh muscle preparation instead of a beating heart. This preparation was chosen to control electrode orientation, CF, and local blood flow, and allowed the correlation of ET with IT and temperatures within the tissue. This correlation would be very difficult in a beating heart because of limitation in measuring IT and tissue temperature. The thigh muscle preparation allowed the identification of thrombus on the electrode-tissue interface after each RF application. This preparation also provided the conditions of low blood flow, simulating a commonly encountered clinical condition (such as ablation of chronic atrial fibrillation or macroreentrant atrial tachycardia and ventricular tachycardia.
associated with prior myocardial infarction)\textsuperscript{21–25} in which maintaining RF power is difficult without saline irrigation.

Another limitation is that RF applications were tested only in a perpendicular catheter orientation. Positioning the electrode in an angled or parallel orientation might have different results by changing the electrode-tissue contact area or flow pattern of saline irrigation.

Conclusions
This novel irrigated ablation catheter with real-time CFS accurately measures tip CF. Using this catheter at constant RF power (saline irrigation) in the canine thigh muscle preparation, tissue temperature and lesion size increased significantly with increasing CF. The incidence of steam pop and thrombus also increased with increasing CF. The incorporation of real-time CF measurement in an irrigated ablation catheter may help to optimize the selection of RF power and RF application time to maximize RF lesion formation and reduce the risk of steam pop and thrombus in clinical application.

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Figure 7. Graphs showing the incidence of thrombus and steam pop as a function of CF. A, The incidence of thrombus formation increased significantly by increasing CF at 50-W applications (right, $p=0.0044$). At 30-W applications (left), there was a trend between the incidence of thrombus and CF ($p=0.0721$). B, The incidence of steam pop increased significantly by increasing CF at 30- and 50-W RF applications ($p=0.031$ and $p=0.0026$, respectively). C, The comparison of the impedance decrease for RF applications with steam pop (hatched box) and without steam pop (nonhatched box). There was no significant difference in the impedance decrease between RF applications with and without steam pop.

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Disclosures
Drs Nakagawa, Shah, and Jackman are consultants for Endosense SA. Lambert, PhD, Leo, MS, and Aeby, MS, are employees of Endosense SA. The other authors report no conflicts.

References

CLINICAL PERSPECTIVE
This study tested a saline-irrigated radiofrequency (RF) ablation catheter with a novel real-time contact force sensor in a bench test and a canine thigh muscle preparation. The bench test confirmed the accuracy (< 1 g) of the contact force sensor. The thigh muscle preparation was used to examine the impact of increasing contact force on RF ablation parameters and lesion size. Contact force was found to be a major determinant of RF lesion size. Larger and deeper lesions were produced by lower RF power (30 W) at greater contact force (30 to 40 g) than lesions produced at higher power (50 W) but at a lower contact force (2 to 10 g). The price of greater contact force is an increase in the incidence of steam pop and thrombus. Therefore, the incorporation of real-time contact force measurement in an irrigated ablation catheter should help to optimize the selection of RF power and RF application time to maximize RF lesion formation and to reduce the risk of steam pop and thrombus in clinical application.
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