

Featured Review



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The Role Of Contact Force In Atrial Fibrillation Ablation

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Abstract

During radiofrequency (RF) ablation, low electrode-tissue contact force (CF) is associated with ineffective RF lesion formation, whereas excessive CF may increase the risk of steam pop and perforation. Recently, ablation catheters using two technologies have been developed to measure real-time catheter-tissue CF. One catheter uses three optical fibers to measure microdeformation of a deformable body in the catheter tip. The other catheter uses a small spring connecting the ablation tip electrode to the catheter shaft with a magnetic transmitter and sensors to measure microdeflection of the spring.

Pre-clinical experimental studies have shown that 1) at constant RF power and application time, RF lesion size significantly increases with increasing CF; 2) the incidence of steam pop and thrombus also increase with increasing CF; 3) modulating RF power based on CF (i.e, high RF power at low CF and lower RF power at high CF) results in a similar and predictable RF lesion size.

In clinical studies in patients undergoing pulmonary vein (PV) isolation, CF during mapping in the left atrium and PVs showed a wide range of CF and transient high CF. The most common high CF site was located at the anterior/rightward left atrial roof, directly beneath the ascending aorta. There was a poor relationship between CF and previously used surrogate parameters for CF (unipolar or bipolar atrial potential amplitude and impedance). Patients who underwent PV isolation with an average CF of <10 g experienced higher AF recurrence, whereas patients with ablation using an average CF of > 20g had lower AF recurrence. AF recurred within 12 months in 6 of 8 patients (75%) who had a mean Force-Time Integral (FTI, area under the curve for contact force vs. time) < 500 gs. In contrast, AF recurred in only 4 of 13 patients (21%) with ablation using a mean FTI >1000 gs. In another study, controlling RF power based on CF prevented steam pop and impedance rise without loss of lesion effectiveness.

These studies confirm that CF is a major determinant of RF lesion size and future systems combining CF, RF power and application time may provide real-time assessment of lesion formation.

Introduction

During radiofrequency (RF) catheter ablation, electrode-tissue contact force is one of the primary determinants of lesion size.¹⁻⁷ No effective lesion is formed without adequate contact force, and excessive contact force is associated with excessive deep tissue heating and an increased risk of deep steam pop (and perforation) and injury outside the heart, such as esophageal, pulmonary and phrenic nerve injury.^{6,7}

Previously, electrode-tissue contact force could not be measured directly during ablation. Ablation catheters using two different technologies have been developed recently to measure real-time catheter-tissue contact force during mapping and RF ablation. One catheter uses three optical fibers to measure the microdeformation

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Corresponding Author: Hiroshi Nakagawa, MD, PhD Heart Rhythm Institute, University of Oklahoma Health Sciences Center 1200 Everett Drive (TUH-6E-103), Oklahoma City, Oklahoma 73104 of a deformable body in the catheter tip (TactiCath, Endosense SA), which correlates with tip force.⁸⁻¹⁶ The second catheter uses a small spring between the ablation tip electrode and catheter shaft, with a tiny magnetic transmitter in the tip and magnetic sensors proximal to the tip to measure microdeflection of the spring (ThermoCool SmartTouch, Biosense Webster, Inc), corresponding to tip force.¹⁷⁻²³ Both systems have high resolution (< 1 gram) in bench testing and accurately display the direction of force.^{8,21-23} These two catheters, equipped with saline irrigated tip electrodes, underwent extensive pre-clinical studies and were introduced for clinical use, beginning in 2010.

Pre-Clinical Experimental Studies

The initial pre-clinical studies were designed to test the relationship between contact force and RF lesion size in a controlled environment, using a canine thigh muscle preparation bathed in heparinized canine blood.⁸ The ablation catheter containing the optical fiber contact sensor (TactiCath, Endosense SA) was held perpendicular to the thigh muscle at contact force of 2, 10, 20, 30 and 40 g. RF energy was delivered at constant power (30 Watts or 50 Watts) for 60 seconds. Increasing contact force was associated with a progressive increase in lesion depth from 6.2 mm to 9.9 mm for 30 Watts and from 7.1 mm to 11.2 mm for 50 Watts (Fig 1A). Importantly, lesion depth was significantly greater at 30 Watts and moderately high contact force of 40 g than at 50 Watts and lower contact force of 10 g (median

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depth 9.9 mm vs. 8.5 mm depth, p<0.01).⁸ Lesion diameter increased similarly with increasing contact force (Fig 1B). These data provided the first suggestion that contact force had as much influence on lesion size as RF power. Increasing contact force also significantly increased the incidence of steam pop and thrombus (Figs 2A and 2B).

In a study using the same catheter, but adding dynamic contact (simulating the beating heat), RF energy (20 and 40 Watts for 60 seconds) was delivered to bovine skeletal muscles with a 20 g peak (systolic) and 10 g nadir (diastolic) at 50 and 100 catheter movements/min, or intermittent contact with a 20 g peak and 0 g nadir (loss of contact). Lesion depth and volume correlated linearly with the area under the contact force curve, known as the Force-Time Integral (FTI).¹¹

The relationship between contact force and RF lesion size was then explored in the canine beating heart using the catheter with the spring-magnetic force sensor (ThermoCool SmartTouch, Biosense Webster, Inc).^{17,18} RF energy was delivered to 3 separate sites in the right ventricle (25 W, 60 sec) and 3 separate sites in the left ventricle (40 W, 60 sec) at: 1) low average contact force (3-8, median 5.5 g); 2) moderate contact force (18-27, median 21.5 g); or 3) high contact force (40-62, median 45.5 g). Lesion depth and diameter increased significantly with increasing contact force (Fig 3). Lesion depth and diameter were greater for RF applications at 25 Watts at high contact force (\geq 40 g) than at 40 Watts at low contact force (<10 g), median depth 7.4 mm vs. 5.3mm and median diameter 11.4 mm vs. 7.5 mm, p<0.01.^{17,18} A steam pop occurred only with high contact force at 25 W in the right ventricle. The incidence of steam pop significantly increased by increasing contact force at 40W applications the in the left ventricle (Fig 4).

The feasibility of modulating RF power based on contact force to achieve desired lesion depth was explored in the canine right and left ventricles.¹⁹ To achieve lesions of similar moderate depth (approximately 6 mm) in the right ventricle despite variation in contact force, we delivered 40 Watts for 60 sec at sites of low contact force (4-10 g, median 8g), 25 Watts at sites of moderate contact force (15-26 g, median 20 g) and only 10 Watts at sites of high contact force (40-57 g, median 44 g). To achieve deeper lesions (approximately 8 mm) in the left ventricle, we delivered 50 Watts for 60 sec at sites of low contact force, 40 Watts at sites of moderate contact force and 25 Watts at sites of high contact force. The three combinations of



Figure 2:

Relationship between contact force and the incidence of steam pop and thrombus in the canine thigh muscle preparation. A. The incidence of steam pop increased significantly by increasing contact force at 30 Watts (left panel) and 50 Watts (right panel) RF applications (p=0.031 and p=0.0026, respectively). B. The incidence of thrombus formation also increased significantly by increasing contact force at 50 Watts applications (right panel, p=0.0044). At 30 Watts applications (left panel), there was a trend between the incidence of thrombus and contact force (p=0.0721). Modified with permission from reference.⁸





RF power and contact force resulted in similar lesion depth with relatively narrow range (median 5.2 mm, 5.2 mm and 5.0 mm in the right ventricle and 8.6 mm, 8.4 mm and 8.0 mm in the left ventricle, respectively, Fig 5)¹⁹ These results suggested that adjusting RF power based on contact force can produce the desired RF lesion depth.

Current animal research is focused on determining whether an online combination of the measurements of contact force, RF power and application time will predict RF lesion size. Based on initial



studies comparing lesion depth to various combinations of contact force, power and time,24 a logrhythmic formula was created (Force-Power-Time Index, FPTI). This formula is currently being tested



Similar lesion depth produced by RF power modulation based on contact force in the canine right and left ventricles. A. In the right ventricle, the lesion depth is almost identical between the three group ablation: 1) median depth of 5.2 mm with low contact force (4-10g, median 8g) at 40 Watt for 60 sec; 2) median depth of 5.2 mm with the moderate contact force (15-26 g, median 20 g) at 25 watts for 60 sec, and 3) median depth of 5.0 mm with high contact Figure 5: force (40-57 g, median 44 g) at 10 watt for 60 sec. Four of the RV lesions were transmural, preventing measurement of the depth. Therefore, these 4 lesions are excluded for data analysis. B. In the left ventricle, there is no significant difference in lesion depth for ablation with the low contact force - 50 Watt lesions (median depth 8. 6mm), the moderate contact force - 40 Watt lesions (median depth 8.4 mm), and high contact force - 25 Watt lesions (median depth 8.0 mm). Modified with permission from reference.¹⁹



prospectively to predict lesion depth in the beating canine heart. Preliminarily, it appears the formula is able to indicate when to terminate the RF application to obtain lesions of 3, 5, 7 and 9 mm depth within a \pm 1 mm accuracy in the beating canine right and left ventricles.²⁵

Clinical Studies In Patients With Atrial Fibrillation

force. Modified with permission from reference.23

The first group of clinical studies was performed using the ablation catheter containing the optical sensor (TactiCath, Endosense SA). The first study (TOCCATA Study) was designed to explore the range of contact force during routine catheter mapping.¹⁴ Right or left atrial mapping was performed by 17 and 12 investigators, respectively, blinded to the value of contact force. The investigators

identified sites where they felt the contact force was within the desired range ("good contact"). The contact force varied widely between investigators (right atrium: mean 8 g to 60 g, p<0.0001; and left atrium: mean 12 g to 39 g, p<0.0001). For each investigator, the contact force varied between sites. In the right atrium, contact force was higher at the septum and the appendage. In the left atrium, contact force was higher on the septum and lower in the appendage than other sites.¹⁴

The second component of the TOCCATA Study examined the relationship between contact force during pulmonary vein (PV) isolation and the recurrence of atrial fibrillation (AF).¹⁵ Contact force was available to the investigator and measured at each ablation site. Acute PV isolation was achieved in all 32 patients with paroxysmal AF. During ablation, the average contact force was 17.2 ± 13.5g and the RF power ranged 15 - 40 Watts. The highest contact force (21.8 \pm 6.7 g) was applied at the anterior inferior region outside the right inferior PV. The lowest contact force was applied to the left atrial appendage ridge, anterior to the left inferior PV (10.5 ± 9.8 g) and the carina of right PVs (14.6 ± 8.5 g). At 12 month follow-up, all 5 patients who had ablation with an average contact force of <10 g experienced a recurrence of AF, whereas 8 of the 10 patients who had ablation with an average contact force > 20g were free from AF recurrence. AF recurred within 12 months in 6 of the 8 patients (75%) who had a mean Force-Time Integral (FTI, area under the curve for contact force vs. time) less than 500 gs. In contrast, AF recurred by 12 months in only 4 of the 13 patients (21%) with a mean FTI >1000 gs.15

The EFFICAS I trial was performed to determine the correlation between contact force during PV isolation and the incidence of gaps in the PV isolation lines (PV reconnection) at 3 months following ablation.¹⁶ The operators were blinded to contact force during PV



reference.23

Contact Force



Figure 9: Poor relationship between contact force and unipolar atrial potential amplitude during sinus rhythm (A, 10 patients) and AF (B, 8 patients), bipolar atrial potential amplitude during sinus rhythm (C) and AF (D), and impedance during sinus rhythm (E) and AF (F). AF, atrial fibrillation. Modified with permission from reference.²³

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isolation. RF power ranged 10 - 40 Watts and mean contact force during ablation was 19.4 \pm 16.2 g. The average FTI for each ablation site was 730 \pm 773 gs. All PVs were successfully isolated. Forty of the 46 patients underwent repeat left atrial mapping at 3 months. At least one gap was present in 26/40 (65%) patients. Comparing continuously blocked segments (no gap) vs. segments with a gap, the minimum contact force applied was 8.1 g vs. only 3.6 g (p<0.0001) and the minimum FTI was 232 gs vs. 118 gs (p<0.001). Segments with a minimum FTI >400 gs had a 95% chance of remaining blocked, while those with a minimum FTI <400 gs had a 79% chance of remaining blocked (p<0.0001).¹⁶

Another study examined the range and spatial distribution of contact force during catheter mapping of the left atrium and PVs using the magnetic force sensor catheter (ThermoCool SmartTouch, Biosense Webster, Inc).23 Eighteen patients undergoing catheter ablation of paroxysmal AF were studied by 3 operators, blinded to the contact force measurement. There was a wide range of contact force during mapping and ablation for each of the 3 operators, but median contact force was similar (8.3, 7.3 and 9.3 g, Fig 6). High average contact force over a one second period (\geq 35 g) was observed at only 2% of mapped sites (118/5,682 sites). The sites of high contact force were clustered in 6 left atrial regions. The dominant high contact force region (present in 17 of the 18 patients) was the rightward-superior aspect of anterior left atrium, directly beneath the ascending aorta (Figs 7 and 8). High contact force at this site was usually transient, present mainly during inspiration, suggesting the ascending aorta exerts an external force against the left atrial wall and the catheter during inspiration (Figs 7 and 8).

RF power was adjusted based on contact force to reduce or prevent a steam pop, impedance rise, or pericardial effusion (and tamponade) without the loss of lesion effectiveness, measured as PV isolation. For low contact force (<10 g), the RF power was increased to 35-45 Watts. For moderate contact force (11-30 g), power of 25-34 Watts was used. For a contact force of 31-50 g, RF power was decreased to 15-24 Watts, and for high contact force (>51 g), the power was decreased to 5-14 Watts. All PVs were isolated without the occurrence of a steam pop, impedance rise or pericardial effusion.²³

Several clinical studies examined the accuracy of several surrogate parameters for contact force, such as atrial potential amplitude and impedance. Unipolar and bipolar atrial potential amplitude was relatively high with minimal contact (as low as 1 g) did not increase with higher levels of contact force (Figs 9A-F).²³ Impedance also poorly correlated with contact force.²³⁻²⁷ Decrease in impedance during the RF application modestly correlated with contact force. However, there was a large degree of overlap in impedance decrease between low, moderate and high contact forces. There was also significant overlap in electrogram amplitude attenuation during RF application as the Force-Time Integral (FTI) increased.²⁷ These results indicate the limited predictive value of these parameters for real-time contact force assessment. In summary, these parameters previously used as surrogate measure of contact force were found to correlate very poorly with contact force.²³⁻²⁷

Conclusion:

The pre-clinical and clinical studies indicate that electrode-tissue contact force is a main determinant of RF lesion size. These studies suggest that the degree of contact force is equivalent to the magnitude of RF power. At ablation sites where only low contact force can be maintained, increasing RF power and application time may allow an adequately deep lesion to be created. At sites of high contact force, decreasing RF power and limiting the application time may prevent excessive tissue heating and limit the incidence of complications.

The surrogate measures of contact force used previously, including the fluoroscopic appearance of catheter motion, intracardiac electrogram amplitude and impedance, have been found to be very poor predictors of contact force. There is no real substitute to directly measuring contact force during catheter mapping and ablation.

The addition of real-time contact force measurement is eliminating much of the uncertainty of RF lesion formation. It is likely that formulas combining contact force, RF power and application (such as the Force-Power-Time Index ²⁸) will provide real-time information on lesion depth and diameter in the near future, increasing the efficacy and safety of RF ablation.

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