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Contact Force Assessment In Catheter Ablation Of Atrial Fibrillation

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Abstract

The efficacy of catheter ablation of atrial fibrillation (AF) remains limited. Increase of success would require more durable lesions without increased risk steam pop and cardiac perforation. Recently, novel technologies have been developed to estimate real-time catheter-tissue contact force (CF). This paper reviews three available tools for assessment of CF and data on experimental or clinical experience. Experimental data with open-irrigated catheter showed that lesion size was greater with applications of lower power (like 30 W) and greater CF (e.g. 30 to 40 g) than with high power and low CF. Impedance drop in the first 5 seconds was significantly correlated to catheter CF. Perforation was achieved more rapidly with the ablation catheter in a sheath despite the same CF because the sheath prevents catheter buckling. Clinical experience confirmed poor relationship between CF and either unipolar amplitude, bipolar amplitude, or impedance. Within the left atrium, the most common high CF site was found at the anterior/rightward LA roof, directly beneath the ascending aorta. Importantly, several studies showed that the use of CF leads to shorter procedure with less fluoroscopy time and less RF applications. CF assessment was also found to be associated with higher proportion of durable lesions. Finally, pilot studies showed that CF measurement could be associated with better clinical efficacy AF ablation.

Introduction

During the last decade, pulmonary vein isolation (PVI) has been accepted as a method of choice for management of atrial fibrillation (AF) resistant to antiarrhythmic drug therapy.[1,2] In addition, this technique could be offered in selected cases as the first line therapy of AF.[3] According to recent European registry, the vast majority of PVI procedures are performed using radiofrequency current.[4] However, long-term clinical efficacy is limited and arrhythmia recurrences are frequent (from 20% to 55%).[5,6] Although the mechanisms of recurrences are not fully understood, most patients have documented conduction gaps within the previous isolation line.

The problem of current technologies for RF ablation is that we are balancing between lower efficacy and risk of complications.

Key Words:
Catheter Ablation, Atrial Fibrillation, Contact Force, Pulmonary Vein Isolation.

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To be effective, catheter electrode should be in a good contact with the tissue. Low electrode contact with the tissue is likely to increase probability of being ineffective. High electrode contact may increase substantially risk of steam pop and cardiac perforation. Recently, several technologies have been developed to estimate real-time catheter-tissue contact force (CF). This paper reviews current experience with the use of CF assessment in catheter ablation of AF.

Technology

Currently, three novel technologies are available to assess real-time catheter-tissue CF. The first one, called Intellisense, is implemented in electromechanic robotic system Sensei (Hansen Medical, inc,, Mountain View, CA).[7] In principle, it uses indirect assessment of catheter tip-tissue contact while measuring friction in the proximal part of catheter shaft. Small dithering movement of the catheter inside the robotic sheath Artisan is induced and the amount of friction is then proportional to the level of catheter contact with the tissue.

Two other technologies use direct assessment of the catheter tip contact. One type employs 3 optical fibers to measure microdeformation of a deformable body in the catheter tip (TactiCath; Endosense SA) (Figure 1).[8,9] The second type of catheter uses a small spring connecting the ablation tip electrode to the catheter shaft with a magnetic transmitter and sensors to measure small deflections of the spring (Thermocol SmartTouch; Biosense Webster, Inc) (Figure 2).[10,11] Both latter systems have CF resolution <1 g in bench testing.

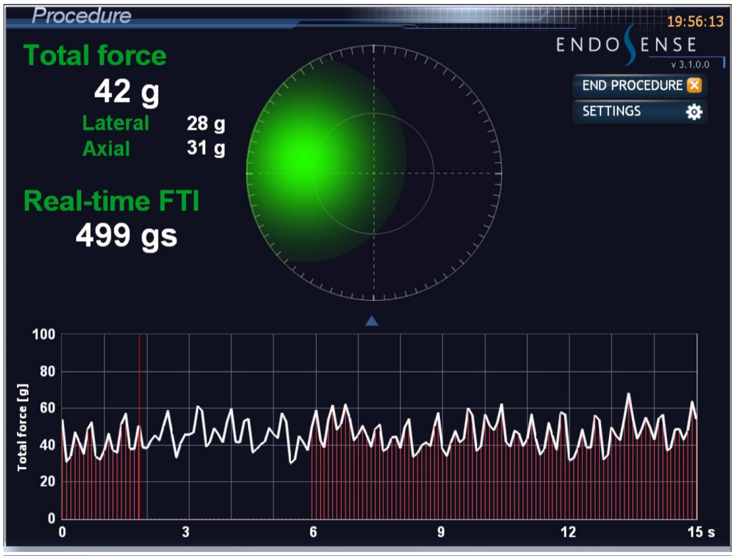

Figure 1: TactiSoft® screen (Endosense SA, Geneva, Switzerland) showing real-time Contact Force in g and Force Time Integral data in gs in the EP laboratory. Green ball depicts proportionally the amount of the contact force (the more contact force, the larger diameter of the ball) and its spatial distribution related to the center of the graph (that would correspond to perpendicular catheter contact with the tissue). Graph at the bottom shows instantaneous contact force in grams and the area under the curve shows force time integral.

Correlation of the Intellisense system with direct CF measurement has been studies less extensively. In our pilot study, we compared Intellisense with TactiCath catheter in 3 patients undergoing AF ablation guided by robotic system. Importantly, the TactiCath was fully compatible with Artisan robotic sheath and performed similar as to manual operation. Direct comparison between both CF systems was performed showing a mean difference of 10±8 g (Table 1, unpublished data).

Group from Charlottesville did similar comparison using in vitro model of the left atrium.[12] After a total of 151 min of robotic manipulation, 33 episodes of excessive CF were detected with mean CF of 153 g. While all episodes of excessive CF on the posterior wall were detected by both techniques; only 10/15 of excessive CF on the roof were detected by Intellisense. Overall CF and lateral CF measured by Tacticath correlated poorly with CF measured by Intellisense (Spearman's correlation coefficient: 0.36, -0.44, respectively). These studies suggest that for accurate assessment of CF in electromechanic robotic system, direct sensor catheter could be preferable.

Experimental Studies

Several experimental studies suggested that electrode-tissue CF is a major determinant of lesion size.[13,14] Novel CF catheter allowed for the first time to determine the relationship between CF and tissue temperatures, lesion size, steam pop, and thrombus during RF ablation using a canine thigh muscle preparation.[15] RF was applied at 20 or 30 W for 60 seconds in low (0.1 m/s) or high (0.5 m/s) pulsatile blood flow. Temperatures were measured in the electrode, electrode-tissue interface, and within the tissue at 3- and 7-mm depths. With closed loop catheter, interface temperature and thrombus incidence were greater at 30 W and low blood flow. With open irrigation, interface temperature remained low (less than 71°C) with no difference between 20 and 30 W or between low and high blood flow. Steam pop occurred at 20 W in 4 of 35 closed loop and 0 of 30 open irrigation and at 30 W in 15 of 28 closed loop and 4 of 28 open irrigation applications ($P<0.05$). In another study with similar experimental setup,[8] RF was delivered at 30 or 50 W (irrigation 17 or 30 mL/min), using different CF values from 2-40 g. 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).

Further experience with direct CF assessment described the area under the CF curve and expressed as the force time integral (FTI).[9] Measured FTI was highest in constant contact, intermediate during variable contact and lowest during intermittent level of catheter contact. Importantly, FTI correlated linearly with lesion volume ($P < 0.0001$ for 20 and 40 W). Constant contact produced the largest and intermittent contact the smallest lesions despite constant RF power and identical peak contact forces. The other study with ex vivo model of freshly excised hearts from pigs showed that the impedance drop in the first 5 seconds was significantly correlated to catheter CF.[16] Of a total 101 ablations, no thrombus formation was noted but popping was seen in 17 lesions.

Another important experimental evidence was obtained by Shah et al[17] who studied right atrial free wall lesions in pigs. The intact heart was removed and the CF sensor-equipped catheter was used to mechanically perforate (without RF delivery) the free walls of both atria and ventricles. Perforation was also performed through epicardially visible RA lesions and adjacent unablated tissue.

Table 1: Head to head comparison of contact forces measured by Tacticath (Endosense SA) and Intellisense (Hansen Medical, Inc) in a pilot study in 3 patients undergoing catheter ablation in the left atrium for atrial fibrillation. N denotes number of mapping points.

	N	Force variance between systems [g]	St dev [g]	Max difference [g]
Pt 1	68	8.3	6.7	31
Pt 2	63	7.7	6.5	27
Pt 3	79	15.0	10.1	36

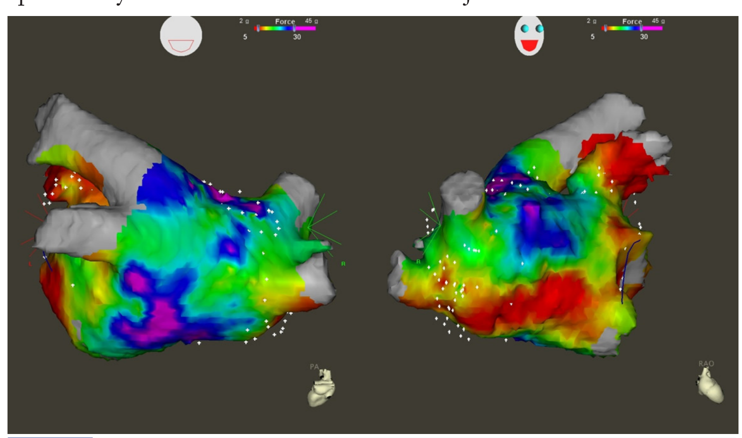

Figure 2: An example of image integration of contact force data in color (2 g lower limit, 30 g upper limit) with CT angiogram of the left atrium and pulmonary veins. Left panel shows posterior view and right panel right anterior view. Color scheme depicts typical distribution of contact forces with the highest values in the region of the roof and upper septum (where aortic root overlies the atrium).

Importantly, perforation force through transmural RA lesions was lower than through unablated RA tissue (172.4±79.1 vs. 300.6±116.8 g, P<0.0002). Perforation was achieved more rapidly with the ablation catheter in a sheath despite the same CF because the sheath prevents catheter buckling.

Clinical Experience

The first clinical experience with indirect CF measurement was assessed in non-randomized comparison of conventional and robotically assisted AF ablation.[18] A robotic catheter control system was used for remote navigation-supported PVI in 22 patients (mean age = 55 +/- 9 years, 16 males, study group). An irrigated-tip catheter with estimate of CF on the tissue was used. This was compared in nonrandomized fashion with conventional hand-controlled catheter ablation in 16 patients (mean age = 55 +/- 9 years, 13 males, control group). The procedures were performed under guidance of Ensite NavX navigation system (St. Jude Medical, St. Paul, MN, USA) and intracardiac echocardiography. Robotic navigation with CF measurement was associated with significantly shorter overall duration of radiofrequency delivery (1,641 +/- 609 vs 2,188 +/- 865 seconds, P < 0.01), shorter total procedural time (207 +/- 29 vs 250 +/- 62 minutes, P = 0.007), fluoroscopy exposure (15 +/- 5 vs 27 +/- 9 minutes, P < 0.001), and lower radiation dose (1,119 +/- 596 vs 3,048 +/- 2,029 uGy.m2, P < 0.001). No complication was observed in either the study or the control group.

In another study from our lab,[19] 100 patients with paroxysmal AF (29 women, age 56.5 ± 10 years) were ablated using electromechanic robotic system and Intellisense CF assessment. CF assessment allowed safe catheter manipulation and resulted in low fluoroscopic time (mean 11.9 ± 7.8 minutes). There were no major procedure-related complications. After a median follow-up of 15 months (range 3-28 months), 63% of the patients were free from any atrial arrhythmias ≥ 30 seconds after the single procedure. Success rate increased to 86% after 1.2 procedures.

Several clinical studies used Endosense catheter Tacticath with direct CF assessment. The first multicenter study, the Toccata clinical trial,[20] showed a significant inter-investigator variability (P < .0001) in CF values with mean CF values during mapping ranging from 8 ± 8 to 60 ± 35 g and from 12 ± 10 to 39 ± 29 g in the supraventricular tachycardia group and the AF group, respectively. Interestingly, high transient CFs (>100 g) were noted in 27 patients (79%) of the AF group with one device-related complication (tamponade, 3%). Subsequent analysis of Toccata trial data[21] revealed that besides average CF above 20 g, the number of RF applications with low CF (<10 g) was a predictor of clinical outcome at 12 months in patients with paroxysmal AF. Low CF applications appeared to be related to incomplete, non-transmural lesions resulting in gaps and long-term treatment failure. Finally, the study showed correlation between FTI and patient outcome at 12 months.

EFFICAS I was the subsequent study with the objective to correlate occurrence of PVI conduction gaps with CF parameters used during ablation while the operator was blinded to information on CF.[22] The study population comprised 46 patients with paroxysmal AF. At follow-up, remapping of the pulmonary veins was performed to assess gap location and correlate with the index procedure ablation parameters. Altogether, 65% (26/40) of patients presented with ≥1 gaps. Analysis of procedural parameters revealed that RF applications with minimum Force-Time Integral (FTI) <400 gs were associated with increased likelihood for reconnection (P<0.001). Gap occurrence showed a strong trend with lower average CF and average FTI.

The above CF guidelines were prospectively applied in EFFICAS II to evaluate effective reduction of PVI gap rates.[23] Application of CF guidelines resulted in less variability in both CF and FTI in EFFICAS II compared to EFFICAS I. Continuity of each PV lesion was quantified using a "Jump index" that calculates how often the catheter moved to different segments of circumferential ablation line. Each jump to a non/adjacent site increases the value of jump index. There was significant reduction of PV lines with gaps during remapping study at 3 months from 29_ in EFFICAS I to 0 in EFFICAS II for PV lines with low jump index. For PV lines with high jump index, the gap rate was unchanged. This suggests that CF guidance is effective to ensure transmurality of lesions, however continuity is needed to minimize gap occurrence. The overal durability of PVI reached 72 % in EFFICAS I as compared to 85 % in EFFICAS II.

The first human experience with the Smart Touch catheter was obtained in our lab in Prague[24] A high-density map of the left atrium and pulmonary veins (median 328 sites) was obtained in 18 patients undergoing AF ablation. Average CF was displayed on the 3D map. For 5682 mapped sites, CF ranged 1–144 g (median 8.2 g). High CF (_35 g) was observed at only 118/5682 (2%) sites, clustering in 6 LA regions. The most common high CF site (48/113 sites in 17/18 patients) was located at the anterior/rightward LA roof, directly beneath the ascending aorta (confirmed by merging the CT image and map). Poor relationship between CF and either unipolar amplitude, bipolar amplitude, or impedance was observed. During ablation, RF power was modulated based on CF. In this pilot trial of RF adaptation according to CF, all pulmonary veins were isolated without steam pop, impedance rise, or pericardial effusion.

The first multicentre prospective study using Smart Touch CF catheter evaluated the effect of direct CF measurement on acute procedural parameters during catheter ablation of AF.[25] All the patients underwent the first ablation procedure for paroxysmal AF with antral PVI, aiming at entry and exit conduction block in all PVs.

Ninety-five patients were enrolled in nine centers. Overall procedure time, fluoroscopy time, and ablation time were 138.0 ± 67.0, 14.3 ± 11.2, and 33.8 ± 19.4 min, respectively. The mean CF value during ablation was 12.2 ± 3.9 g. Force time integral (FTI) analysis showed that patients achieving a value below the median of 543.0gs required longer procedural (158.0 ± 74.0 vs. 117.0 ± 52.0 min, P = 0.004) and fluoroscopy (17.5 ± 13.0 vs. 11.0 ± 7.7 min, P = 0.007) times as compared with those in whom FTI was above this value. Patients in whom the mean CF during ablation was >20 g required shorter procedural time (92.0 ± 23.0 vs. 160.0 ± 67.0 min, P = 0.01) as compared with patients in whom this value was <10 g.

The first prospective comparison of Smart Touch catheter with a non-CF open-irrigated catheter (EZ Steer Thermocool, Biosense Webster) (control group) was published more recently.[26] Overall, 30 patients were enrolled in each group, with a standardized 12-month follow-up, free of antiarrhythmic therapy. Demographic, cardiovascular and anatomic characteristics were similar in both groups. Though complete PVI was eventually achieved in all cases in both groups, success using an exclusive anatomic approach was 80.0% in CF group versus 36.7% in control group (P < 0.0001). CF use was associated with significant reductions in fluoroscopy exposure (P < 0.01) and RF time (P = 0.01). The incidence rates of AF recurrence were 10.5% (95% CI, 1.38-22.4) in the CF group, and 35.9% (95% CI, 12.4-59.4) in the control group (log rank test, P = 0.04). After adjustment on potential confounders, the use of CF catheter was found to be associated with a lower AF recurrence (OR 0.18, 95% CI 0.04-0.94, P = 0.04).

Conclusions:

Current technologies of CF assessment have allowed improvement of our knowledge regarding RF lesion creation. Lesion size was greater with applications of lower power and greater CF than vice versa. CF appears to be more important than impedance or temperature. In terms of safety, perforation force through transmural atrial wall lesions was approximately half of the CF needed for perforation of unablated tissue. The use of CF in clinical practice leads to lower variability of contact with the tissue. Clinical experience with CF assessment suggests that the use of CF results in faster procedure, shorter fluoroscopic time and less RF energy needed to perform PVI. The use of CF guiding appears to be associated with higher success rate of catheter ablation for AF. However, more robust data are needed.

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