Use of the INTELLANAV STABLEPOINT™ Ablation Catheter for a Highly Symptomatic Paroxysmal Atrial Fibrillation, *a technical note*

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Introduction

Radiofrequency (RF) ablation has become an increasingly accepted treatment modality for the treatment of atrial fibrillation (AF). The advent of contact force (CF) sensing ablation catheters has significantly advanced the ability to create durable RF lesions by confirming mechanical contact, supporting both the efficacy and safety of the procedure. However, a major limitation of CF-sensing catheter technology to date has been the inability to provide direct tissue feedback in response to applied RF energy. This has led to the widespread adoption of a one-size-fits-all approach to RF parameter selection. The result is possibly unnecessary over-ablation. Further technology refinements are needed to better tailor lesion creation.

DIRECTSENSE™ Technology in conjunction with the RHYTHMIA HDx™ Mapping System and the INTELLANAV MIFI™ OI Ablation Catheter (Boston Scientific) uses highly localized impedance measurements at the catheter tip to provide insight into tissue characteristics. DIRECTSENSE™ Technology also provides direct tissue feedback which can be monitored during all aspects of an electrophysiology procedure including RF delivery, thereby, providing the opportunity for more precise ablation for creation of ablation lesions. There have been encouraging reports demonstrating successful application for AF ablation.

Previously physicians could choose from CF-sensing or INTELLANAV MIFI™ OI that featured DIRECTSENSE™ Technology. While each of these catheters provided unique and valuable capabilities during ablation procedures, operators were forced to choose between them. No single catheter was equipped with both features. However, the new INTELLANAV STABLEPOINT™ Ablation Catheter (Boston Scientific) incorporates both capabilities. This case illustrates application of INTELLANAV STABLEPOINT™ with DIRECTSENSE™ during catheter ablation of paroxysmal AF.

Patient history

A 58- year-old male with a history of highly symptomatic paroxysmal AF refractory to drug therapy was listed for catheter ablation. The patient had previously undergone coronary artery bypass surgery 2 years ago and had well-preserved left ventricular function. The strategy was to perform pulmonary vein isolation (PVI) using the INTELLANAV STABLEPOINT™ Ablation Catheter featuring DIRECTSENSE™ Technology in combination with the RHYTHMIA HDx™ Mapping System with SW4.0 featuring AutoTag (Boston Scientific).

Procedure

The procedure was performed under general anesthesia. A decapolar catheter was used to cannulate the coronary sinus (CS). A single transseptal puncture was performed using a large-curve steerable sheath and a 98 cm Brockenborough-1 needle. An INTELLAMAP ORION™ Mapping Catheter (Boston Scientific) was introduced into the left atrium (LA). The mapping catheter was used with the RHYTHMIA HDx™ Mapping System to create an electroanatomical map of the LA while pacing from the CS at a cycle length of 600 ms. A total of 7,664 points were obtained in 15 min. Standard pulmonary vein (PV) anatomy was confirmed along with well-preserved underlying LA bipolar voltages in the main (>0.5mV) (Figure 1).

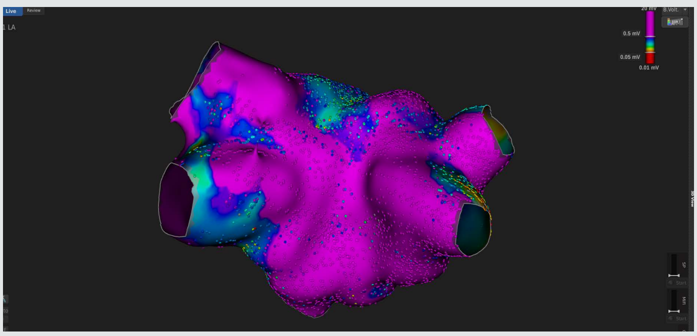

Figure 1. Baseline voltage map of the left atrium (LA). Collected with coronary sinus (CS) pacing at a cycle length of 600 ms. A total of 7664 points were obtained in 15 min. This confirmed a standard pulmonary vein (PV) arrangement and well-preserved underlying LA bipolar voltages in the main (> 0.5 mV).

APPLICATION OF COMBINED CONTACT FORCE AND LOCAL IMPEDANCE DATA

Baseline impedance

The INTELLAMAP ORION™ catheter was exchanged for an INTELLANAV STABLEPOINT™ catheter. The catheter was initialized by placement inside the LA chamber for 2 minutes to warm-up to the patient's body temperature (required only at the first time that the catheter is inserted). The catheter was then "zeroed" while maintaining its position in the blood pool absent from any contact. The baseline local impedance value (blood pool) was obtained in the same position after confirming a contact force value of zero. The value of 155-160 ohms was used as the blood pool baseline reference for the rest of the procedure. It is important to note that as the INTELLANAV STABLEPOINT™ catheter lacks mini-electrodes, resulting in a larger local impedance circuit than that of the INTELLANAV MIFI™ OI catheter. Therefore, the local impedance values will be considerably higher in comparison, both at baseline as well as in response to ablation.

Tissue Characterization

The catheter was placed in contact with tissue at the anterior aspect of carina. The relationship between varying amounts of contact force (applied in a parallel direction to the tissue) and DIRECTSENSE™ values was then explored. As the applied contact force increased from 0g to 40g, the local impedance increased in parallel from 155 ohms to approximately 180 ohms. Therefore, the target CF boundary was set between 10-40 grams. We used a "traffic light" scheme for the CF and catheter tip widgets as follows: white was used for a target CF 0-10g (Figure 2a), green for a target CF 10-40g (Figure 2b), yellow for CF 40-50g (Figure 2c) and red for CF>50g (Figure 2d).

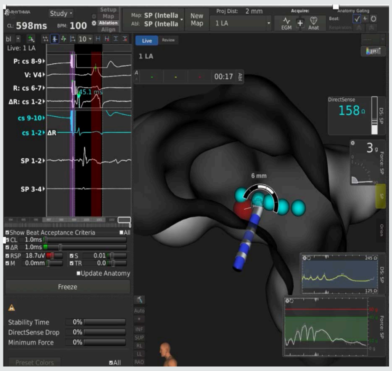

Figure 2a. Local impedance of 158 ohms and a force value of 3g. The contact force value is <10g. The white catheter tip widget displays 2/6 blocks filled and a white contact force value.

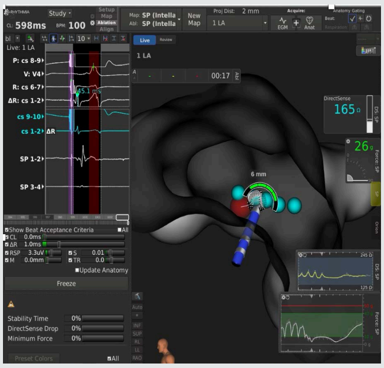

Figure 2b. Contact force of 26g with a local impedance reading of 165 ohms. A contact force in the range of 10-40g displays a green catheter widget with 4/6 blocks filled and a green force sensing value.

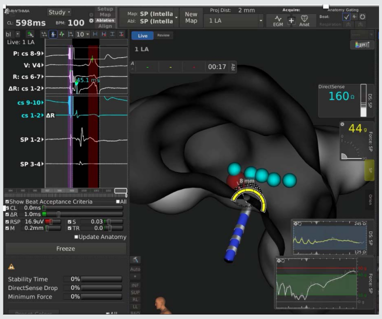

Figure 2c. Contact force value of 44g with a local impedance value of 160 ohms. The catheter tip widget displays yellow with 6/6 blocks filled. The contact force value is also now in yellow. Note that the local impedance value is lower at higher force value with the same catheter to tissue orientation of 90 degrees.

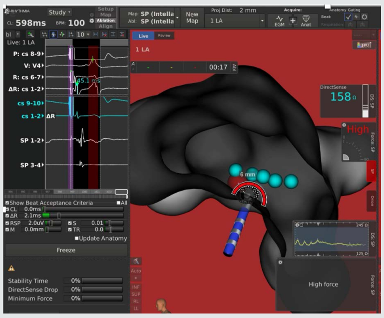

Fig 2d. Contact force value of >50g with a local impedance value of 158 ohms. The catheter tip widget >50g is shown in red with 6/6 blocks filled and the high force reading displayed in red. Note the local impedance value is lower than that seen at optimal force ranges.

ABLATION

Ablation Strategy

We started ablation by placing location tags along both PV pairs using the INTELLANAV STABLEPOINT™ catheter at antral sites where a stable CF of greater than 10g was seen. This served as an easy roadmap for the subsequent lesion set and also provided insight into the baseline voltages of tissue underlying the planned RF lesions, thereby helping the operator tailor the individual lesions better. The goal was to deliver point by point lesions, ensuring contiguity between adjacent lesions (distance <6 mm).

Autotag Settings

We used the" Rule of 3" for settings to display tag drops as follows: lesion tag size 3mm; stability 3mm for 3 seconds; and a min 3g CF for 30% time. The tag size of 3mm ensured that we would quickly identify any visual gap between adjacent AutoTag lesions with an inter-tag distance >6mm. Although one can choose from a variety of parameters for the tag color of an AutoTag (time, DIRECTSENSE™ local impedance drop, average force, median power, or generator impedance drop), we chose the DIRECTSENSE™ local impedance drop for the simple reason that this variable was the best indirect marker of the quality of each RF lesion.

Ablation Settings

We used 50W for each RF application, as we have observed excellent efficacy, safety and efficiencies with this power setting on other platforms, provided that the local impedance drop is carefully monitored, and the duration of RF application is kept short. The target CF was 10-40g, with high emphasis on ensuring catheter tip stability. The Force Tip Widget was very beneficial to this end; our goal was to have it filled with green bars indicating within the ideal target range throughout a respiratory cycle before starting RF application (Figure 3). The angle indicator on the widget was useful in ensuring perpendicular contact with the tissue (angle 45-90 degrees). The following criteria were used to determine the duration of each RF application: 10 sec for the posterior wall or a maximum drop of 15 ohms in the DIRECTSENSE™ local impedance, whichever came first. For the anterior wall, we used a maximum RF application of 20 sec or a maximum drop of 30 ohms in the DIRECTSENSE™ local impedance, whichever came first. The AutoTag tool was set to change color from light pink to dark pink at a local impedance drop of 15 ohms and then to red if the local impedance drop was greater than 25 ohms. This ensured prompt discontinuation of RF application in real time as soon as the AutoTag changed color to dark pink on the posterior wall and to red on the anterior wall.

Furthermore, the light pink-colored tags enabled the rapid identification and localization of likely weak links in the chain in case of first-pass isolation failure or if acute reconnection was observed.

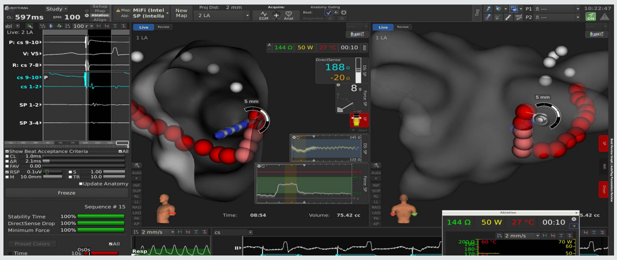

Figure 3. The role of the tip widget and tag coloring are shown. Before RF is initiated, we aim for a contact force value between 10-44g (displayed in the force graph). The catheter widget displays 4/6 blocks in green. RF delivery is tailored to the local impedance drop. For the posterior wall, 10 seconds or maximum local impedance drop of 15 ohms, whichever comes first. For the anterior wall, 20 seconds or a maximum local impedance drop of 30 ohms, whichever comes first. Tag coloring ranges from dark pink > 15 ohms and red > 25 ohms. Pale pink ablation tags display < 15 ohm drop in local impedance and quickly identify "weak links" in RF ablation application.

ESOPHAGEAL SAFETY

In our lab, we program the RF generator to cut off at 10 seconds while ablating on the posterior wall. We monitor the esophageal temperature throughout, stopping RF application if the temperature increases >1°C above baseline, recognizing that there may still be a temperature overshoot in spite of doing so. If any esophageal temperature increase is observed, we do not deliver any further RF in the vicinity unless the temperature returns to baseline. In the case under discussion, we observed an esophageal temperature increase from 35.6 °C to 38.0°C while delivering RF at the posterior aspect of the right wide antral circumferential ablation (WACA). RF delivery was terminated at 6-8 seconds, and we had to accept a local impedance drop of <15 ohms here.

GAP LOCALIZATION AND CONFIRMATION OF PV ISOLATION

Using the methods described, a total of 15 minutes of RF application was needed to achieve bilateral WACA. PV isolation was observed at the end of the first pass. After 15 minutes of waiting, we created an electroanatomical map with the INTELLAMAP ORION™ catheter. The map showed that while the left-sided veins remained silent, the right-sided PVs were reconnected through a localized gap on the posterior carina (Figure 4). Interestingly, this was the exact site at which the local impedance drop was <15 ohms (the esophageal temperature had increased and prevented the creation of therapeutic lesions initially).

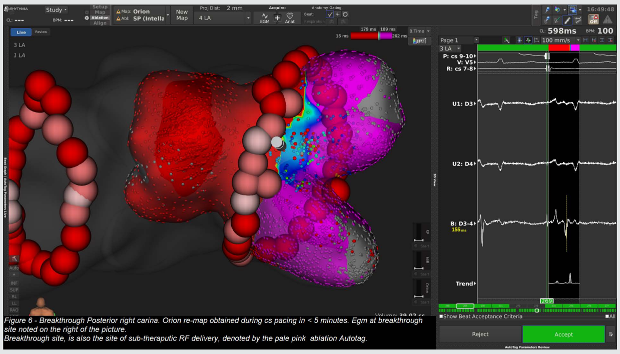

Fig.4 Breakthrough in the posterior carina is identified and remapped with the INTELLAMAP Orion™ during CS pacing in <5 min

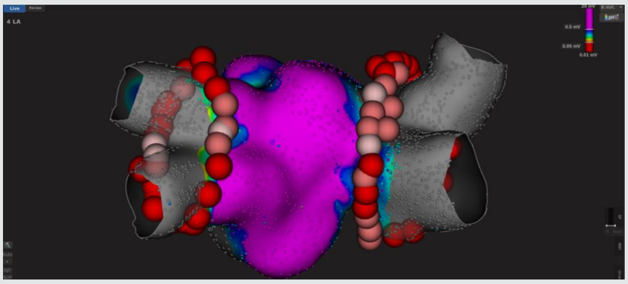

Figure 5. Remap with the INTELLAMAP ORION™ catheter in < 8 min. Both PV vein pairs appear to be isolated during RF delivery at the posterior breakthrough site on the right side.

The right-sided vein pair was isolated with a single RF application; we delivered another lesion adjacent to it. On further mapping with the INTELLAMAP ORION™ catheter, isolation of both pairs of PVs was confirmed (Figure 5). A total of 16 minutes of RF energy was delivered for the entire case.

Discussion

RF catheter ablation for AF has evolved dramatically over the past few years. Serial technology improvements such as CF-sensing catheters, automated RF tagging, intertag distance measurement tools and local impedance measuring capabilities (DIRECTSENSE™) have improved success rates and safety of the procedure, while decreasing procedure times, hence driving efficiencies. Simultaneously, the advent of ultra-high-density mapping with the RHYTHMIA HDx™ system has enabled rapid identification of gaps within the ablation lines, further streamlining the procedure. However, until now, no single system provided all of these capabilities, so operators were forced to make difficult trade-offs.

In the present case, we demonstrate how the novel INTELLANAV STABLEPOINT™ Ablation Catheter, enabled with both CF-sensing and DIRECTSENSE™ local impedance measurement technology facilitated a PVI procedure when used in conjunction with RHYTHMIA HDx ™ mapping.

In summary:

•The CF information facilitated better tissue contact for each RF lesion, and the DIRECTSENSE™ local impedance data allowed precise titration of RF to the underlying tissue with energy tailored to the evolving effects in real time. This ensured first-pass isolation of both vein pairs with a greatly reduced RF time of only 15 minutes, compared with 20 mins of RF time typically used during a de-novo PVI case.

•The RHYTHMIA HDx™ map allowed us to localize the site of an early reconnection very quickly, leading to focused additional ablation of just 1 minute to achieve complete isolation.

•The solitary site of reconnection was at the very same spot where an esophageal temperature increase had precluded the initial delivery of adequate RF energy; this was clearly highlighted with the AutoTag showing a low DIRECTSENSE™ local impedance drop.

We have subsequently used the INTELLANAV STABLEPOINT™ catheter in our lab for several de novo AF ablation cases. Operators have found the learning curve to be short, especially if they are already accustomed to using CF-sensing catheters, and they have achieved similar results.

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