

# Pulmonary Vein Isolation using a High Density Mesh Ablator Catheter: Incorporation of three-Dimensional Navigation and Mapping

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## Abstract

### Background

We evaluated the use of a novel High Density Mesh Ablator (HDMA) catheter in combination with three-dimensional navigation for the treatment of paroxysmal atrial fibrillation.

### Methods

The HDMA catheter was used to carry out pulmonary vein isolation in a consecutive series of patients. Three-dimensional geometry of the left atrial-pulmonary vein (LA-PV) junctions were first created with the HDMA catheter. Ostial, proximal and distal sites within the pulmonary veins were tagged with catheter shadows on the created geometry to allow for re-interrogation of these exact sites after ablation.

### Results

The HDMA catheter was successfully used to create three dimensional geometry of the LA-PV junction in a total of 20 pulmonary veins which involved 5 patients. In all cases, ostial ablation alone was sufficient to achieve electrical isolation. No significant pulmonary vein stenosis was seen acutely after ablation.

### Conclusion

We describe the successful use of the novel HDMA catheter to create three-dimensional geometry of the LA-PV junction to assist with pulmonary vein isolation.

**Keywords :** Atrial Fibrillation, pulmonary vein isolation, ablation

## Introduction

Since it was first described by Haissaguerre and colleagues,<sup>1,2</sup> catheter ablation of atrial fibrillation

(AF) has become an important treatment option in the management of this common arrhythmia. Then very first ablation procedures<sup>2</sup> described made use of conventional catheters with radio-

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frequency (RF) energy to deliver lesions point-by-point at sites at the left atrial-pulmonary vein (LA-PV) junction, aiming to isolate atrio-venous and venoatrial conduction i.e. pulmonary vein isolation.

Attempts to improve endocardial ablation efficacy have resulted in modifications to RF energy delivery with the use of irrigated catheter tips<sup>3,4</sup> and also application of pulsed RF energy<sup>5</sup>. Alternative energy sources that have been explored include cryotherm<sup>6</sup>, microwave<sup>7</sup>, laser<sup>8</sup> and ultrasound.<sup>9</sup>

To simplify and improve the efficacy of pulmonary vein isolation, several studies have evaluated different energy sources with novel catheter designs. Natale et al reported on the successful use of a through-the-balloon delivery of ultrasound energy for isolation of pulmonary veins.<sup>10</sup> Results of ablation using a high intensity focused ultrasound balloon catheter have also been recently reported<sup>11</sup> Endoscopic visualization to assist laser energy delivery through a balloon catheter is another technology that is currently being evaluated.<sup>12,13</sup>

Recently, an expandable multi-electrode HDMA catheter (High Density Mesh Ablator Catheter, Bard Electrophysiology, Lowell, MA, USA) was introduced as a one catheter solution to both mapping and ablation of the LA-PV junction with the use of pulsed RF energy. While it is possible to use the HDMA catheter with fluoroscopic guidance only, the addition of three-dimensional (3-D) navigation and mapping can provide further anatomical information to help guide catheter positioning and ensure delivery of ablation to optimal sites. We hereby describe our technique of using this new ablation catheter in combination with a 3-D navigation and mapping system, with the aim of assessing the technical aspects of using this catheter in this context, and at the same time evaluating acute results achieved with it.

## Methods

The HDMA catheter was used in a consecutive series of patients who had been referred for catheter ablation of paroxysmal AF. All antiarrhythmic therapies were discontinued for more than 5 half-lives prior to the procedure.

The HDMA catheter utilizes an expandable high

density array of wires arranged in 2 helices to form a mesh geometry, carrying a total of 36 electrodes.

It is designed to provide high density mapping of the LA-PV junction by being able to conform to different shapes to suit any variation in anatomy. In its low profile configuration, it is able to enter and interrogate within the pulmonary vein itself. In its fully deployed and expanded profile, it adopts a circular, disc shape (30 mm diameter) to fit securely around the pulmonary vein ostium or antral region (Figure 1). It is non-steerable, and is capable of simultaneous delivery of pulsed RF energy at 5ms cycles alternating between its even and odd electrodes to achieve circumferential pulmonary vein ablation. The array of wires is divided into 4 quadrants with a thermocouple at each quadrant to allow for energy delivery under temperature control.

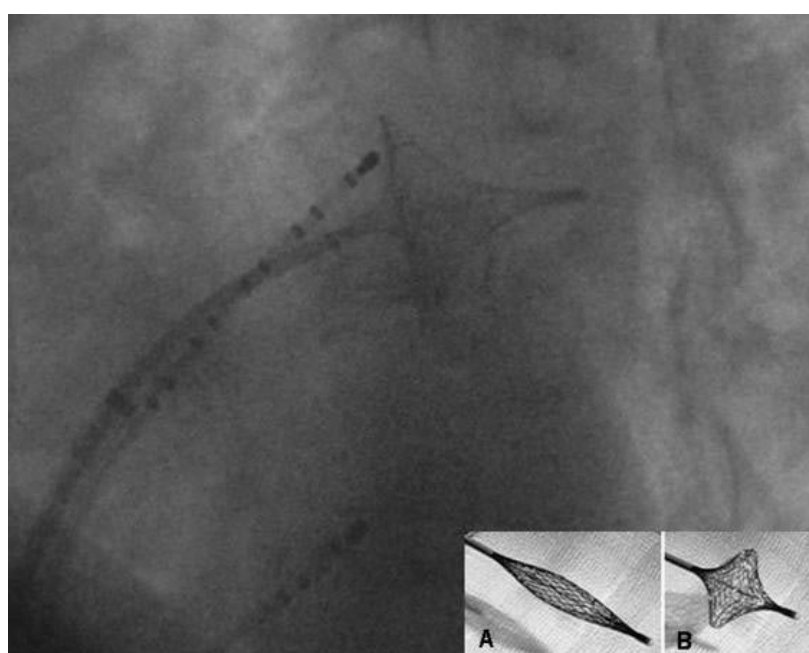
All procedures were carried out with the use of local anaesthesia under conscious sedation. Bilateral femoral venous access was used in all cases. Under fluoroscopic guidance, a steerable decapolar catheter and quadripolar catheter were positioned in the coronary sinus and His position respectively.

After baseline electrophysiology study, a single transseptal puncture was carried out using a steerable 9F transseptal sheath (Channel sheath, Bard Electrophysiology, Lowell, MA, USA) to gain access to the left atrium. Following pulmonary vein angiography, the HDMA catheter was advanced into the left atrium via the transseptal sheath. 3-D geometry of the pulmonary veins and the left atrium were created using the Ensite NavX system version 7.0 (St. Jude Medical Inc, St. Paul, Minnesota USA) by moving the HDMA catheter, focusing on the pulmonary vein antral and ostial regions. The HDMA catheter was semi-deployed to enter the pulmonary veins with gradual deployment allowing contact with the pulmonary vein wall on pull-back whilst the ostial / antral / atrial geometry was created with the catheter fully deployed as a circular disc. Due care was taken to ensure that the HDMA catheter was lined up with the long axis of the pulmonary vein to facilitate ease of deployment. This was done by first keeping the HDMA catheter in the transseptal sheath, before cannulating the pulmonary vein with the steerable sheath. The HDMA catheter was then advanced to the tip of the sheath, and gradual withdrawal of the

sheath was then carried out to expose the HDMA catheter in the vein, which then allowed for pull-back and formation of its circular disc-shaped configuration. As the main areas of interest were around the LA-PV junctions, only limited left atrial wall geometry was created (Figure 2). A unipolar catheter that was actively fixed in the right atrium was used as reference for the geometry. Electrical signals were then recorded from proximal and distal sites within each pulmonary vein as well as at the pulmonary vein ostia using the HDMA catheter, during atrial pacing from the distal coronary sinus electrodes. Each of these sites were tagged by application of a catheter shadow on the 3-D geometry (Figure 3). Once the HDMA catheter was deployed at the LA-PV junction, RF energy was applied using a pulsed RF generator (Tempulse pulsed RF controller, Bard Electrophysiology, Lowell, MA, USA). Each application of energy continued for a total duration of 300 seconds whenever possible, aiming for a maximum target temperature of 58°C, with up to 100 W power output. Satisfactory contact with tissue was maintained by gentle pressure on the catheter or sheath. After ablation, mapping was carried out at each pulmonary vein at previously tagged ostial, proximal and distal sites as guided by the stored catheter shadows on the 3-D geometry to confirm pul-

monary vein isolation. The endpoint of ablation for each vein was elimination of all sharp signals (either in the pulmonary veins or at the ostia) suggestive of atrio-venous connection as mapped by the HDMA catheter. Electrical isolation was considered to have been achieved if there was evidence of entrance block or if dissociated pulmonary vein firing was seen.<sup>13</sup> Before ablation of the right sided pulmonary veins, pacing from the electrodes on the HDMA catheter was carried out to exclude any diaphragmatic stimulation. If this was evident, the HDMA catheter is rotated and re-orientated into a new position while ensuring adequate endocardial contact and repeat stimulation carried out. This manoeuvre is repeated until diaphragmatic stimulation was no longer possible. In our experience this is usually adequate to prevent phrenic nerve injury, which was not seen in any of the patients presented here. Pacing manoeuvres<sup>14, 15</sup> (using a steerable decapolar catheter in the left atrium) were also used to differentiate far-field atrial signals from local conduction when checking for pulmonary vein isolation. This was achieved by replacing the decapolar catheter with the quadripolar His catheter in the coronary sinus, followed by advancement of the decapolar catheter into the left atrium through the existing transseptal access. Once all pulmonary veins had been isolated, repeat pulmonary vein angiography in the same

**Figure 1:** Fluoroscopic image of the HDMA catheter deployed at the left upper pulmonary vein (left anterior oblique view) via a steerable transseptal sheath. A steerable decapolar catheter has been advanced into the left atrium and a quadripolar catheter is in the coronary sinus. A photograph of the catheter in its low (A) and expanded (B) profile is shown in the inset.



views was performed to assess for pulmonary vein stenosis. Heparin was administered throughout the procedure to maintain an activated clotting time of around 300s. All electrograms were recorded on an electrophysiology review and recording workstation (Labsystem pro, Bard Electrophysiology, Lowell, MA, USA).

All continuous variables are expressed as mean  $\pm$  standard deviation. Normally distributed paired data were analysed using paired Student's t-test. Full consent for the procedure was obtained in all patients.

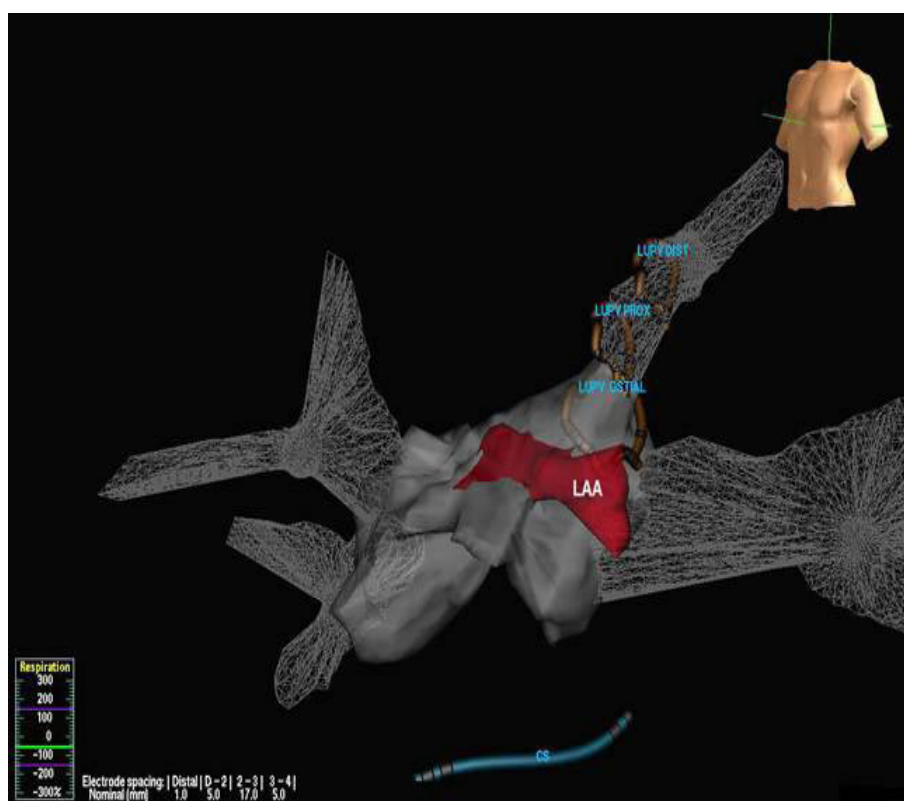
## Results

A total of 20 pulmonary veins in 5 patients were ablated with the HDMA catheter (Table 1). High density mapping and 3-D pulmonary vein and limited left atrial geometry creation with the HDMA catheter were successfully carried out in every patient. No pulmonary venous anomaly or common ostia were noted in any of the patients. All patients had a history of paroxysmal AF and mean left atrial dimensions on echocardiography

was  $40 \pm 5$  mm, measured in the parasternal long axis view; all patients were in sinus rhythm at the start of the procedure. One patient developed sustained AF during catheter manipulation in the atrium but this reverted to sinus rhythm during circumferential pulmonary vein ablation. All 20 pulmonary veins were successfully isolated. The number of energy applications per patient was  $13.6 \pm 4.2$  and duration of total energy delivered was  $3093 \pm 622$  s. Number of energy applications per vein was  $3.4 \pm 1.05$  and duration of energy application per vein was  $773 \pm 156$  s. Two patients developed transient bradycardia and lowering of blood pressure consistent with a significant vagal response during ablation of the left upper pulmonary veins but this resolved without the need for specific intervention. Mean fluoroscopy time was  $68 \pm 97$  minutes and procedure duration was  $286 \pm 30$  minutes. Pulmonary vein ostial dimensions before and after ablation showed no statistical difference when comparing measurements obtained from fluoroscopy (Table 2).

In all cases, pulmonary vein signals which were mapped and tagged at proximal and distal por-

**Figure 2:** High density 3-D geometry of the LA-PV junctions (with limited LA geometry) created with the HDMA catheter using Ensite NavX. The left atrial appendage is labelled LAA and the pulmonary veins are shown as grids. HDMA catheter shadows in the left upper pulmonary vein (LUPV) and its ostium indicate sites mapped by the catheter





tions of each pulmonary vein, were completely abolished after delivery of pulsed RF energy with the HDMA catheter at the pulmonary ostia alone. Examples of intracardiac signals before and after pulmonary vein isolation are shown in Figure 4. Apart from minor groin haematoma in 1 patient, no other significant procedure-related complications were encountered acutely in patients reported in this study.

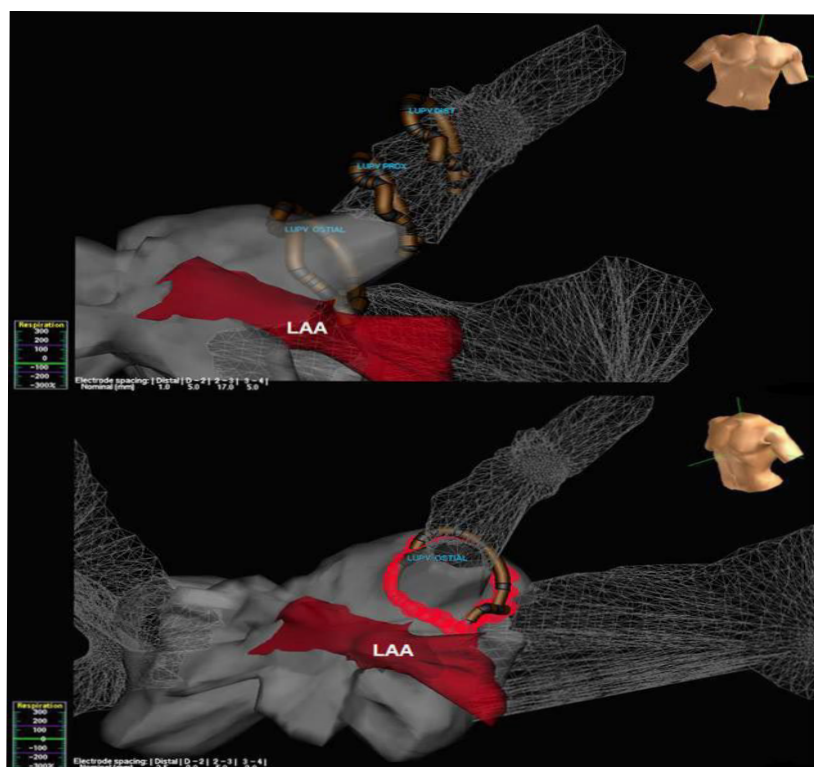
At the time of writing, 4 out of the 5 patients reported in this series had reported significant symptomatic improvement and were free of AF as assessed by routine 24 hour Holter monitoring more than 3 months after the ablation (3 off antiarrhythmic medication). One patient had documented recurrence of symptomatic, paroxysmal AF at 3 months post-procedure. No long term procedure-related complications were encountered. Mean duration of follow-up for all patients was  $112 \pm 19$  days.

## Discussion

We have hereby described our technique of using the novel High Density Mesh Ablator catheter in

conjunction with 3-D navigation and mapping using the Ensite NavX system. While the catheter has been developed with the intention for it to be used as a single mapping and ablation catheter for pulmonary vein isolation without employing 3-D mapping assistance, the HDMA catheter is still a relatively new product and published experience of its use in humans is limited. In our group of patients, we successfully used the HDMA catheter to create high density 3-D geometries of the pulmonary veins and the ostial / antral regions to help guide catheter manipulation and also to re-check specific sites in and around the pulmonary veins when assessing for electrical isolation. Although not encountered in our series, 3-D navigation will be especially useful in the delineation of any anomalous venous anatomy or common ostia which may limit the ability of the catheter to deliver effective lesions at desired sites. This is particularly relevant as the shape of the expanded HDMA catheter is designed to fit normal pulmonary venous ostia and could have difficulty conforming to anatomical variation. Having a 3-D geometry will help guide positioning of the HDMA catheter. In all cases, ablation was limited to only to the LA- PV junction as non-pulmonary vein

**Figure 3:** HDMA catheter shadows marking ostial, proximal and distal left upper pulmonary vein (top) and demonstration of lesions delivered by the HDMA catheter (bottom)

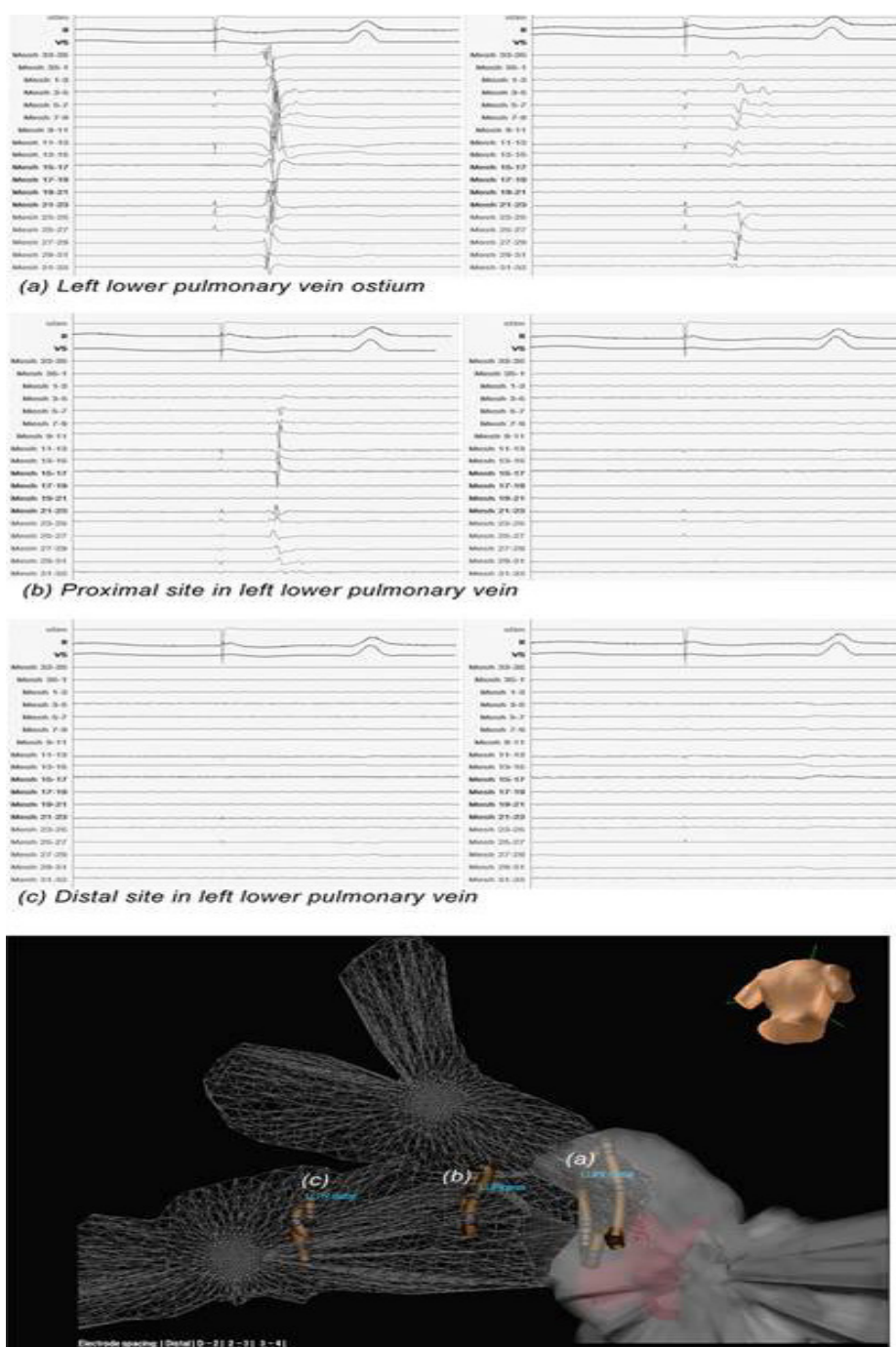


triggers of AF were not encountered in any of the patients. While the HDMA catheter is capable of ablation around pulmonary vein ostial and antral regions, we expect that ablation of non-pulmonary vein foci remote from the LA-PV junction will require the use of standard ablation catheters. These,

however, have previously been shown to occur less frequently than pulmonary vein triggers.<sup>2</sup>

The risk of pulmonary vein stenosis is reduced by ablating at the ostium or antral region rather than within the vein.<sup>18, 19</sup> The further the abla-

**Figure 4:** Left lower pulmonary vein ostium (a), proximal vein (b), and distal vein (c) signals mapped from odd-numbered electrode pairs of the HDMA catheter before (left panel) and after (right panel) ablation, during distal coronary sinus pacing. The remaining electrical signals seen at the ostium after ablation were found to be from far-field sites by using pacing manoeuvres. Corresponding locations on the 3-D geometry are shown in the bottom panel.



tioncatheter is placed from the pulmonary vein, the lower the risk of pulmonary vein stenosis. The HDMA catheter was designed with this in mind and its configuration in the expanded profile prevents the catheter from entering the vein, and ensures that all ablation is delivered from the atrial aspect of the ostium. However, a potential problem with circumferential pulmonary ostial ablation is the persistence of LA-PV conduction. This would not be detectable by mapping the ostium alone and further interrogation within the pulmonary vein itself is desirable and often necessary. In our study the use of 3-D navigation and geometry tagging to mark proximal and distal pulmonary vein and ostial sites allowed these exact locations to be accurately re-visited and assessed post-ablation to ensure complete isolation. Our experience so far, using the above technique, indicates that ostial ablation alone with the HDMA catheter to eliminate ostial potentials can lead to successful isolation of the pulmonary veins, without causing any significant pulmonary venous stenosis. This is in agreement

with a feasibility study of a similar HDMA catheter carried out on canine hearts<sup>.20</sup> where it was used to successfully isolate the right superior pulmonary vein, without causing any significant pulmonary venous stenosis on both post-ablation and also on follow-up pulmonary vein angiography.

## Limitations

This report consists of a small number of patients with short term follow-up. However, we would like to stress that the intention of this paper is to document the feasibility of combining the HDMA catheter with 3-D navigation and mapping, and to highlight the possible advantages of such an approach. As this is a description of our early experience using the HDMA catheter, a considerable amount of time was spent on setting up equipment, manipulating the catheter, and also checking for pulmonary vein isolation. This will account for the fluoroscopy time and also overall procedure time reported in this study. With more operator experi-

Table 1

Procedural details of each patient

Patient No.	Left Atrial Size (mm)	No. of pulmonary veins isolated	Total RF delivery time (s)	Fluoroscopy time (minutes)	Total procedure time (minutes)
1	35	4	3417	66.7	325
2	47	4	3756	82.2	300
3	37	4	3296	73.6	290
4	42	4	2860	62.0	245
5	41	4	2138	57.5	270

Table 2

Comparison of pulmonary vein ostial dimensions on fluoroscopy pre- and post-ablation with the HDMA catheter (all measurements are in mm)

Patient No.	Pre-Ablation				Post-Ablation			
	LUPV	LLPV	RUPV	RLPV	LUPV	LLPV	RUPV	RLPV
1	16	23	25	12	16	21	22	13
2	28	24	34	28	27	24	30	27
3	24	28	19	14	23	26	16	12
4	30	24	29	26	29	24	29	24
5	30	20	27	18	24	20	27	14
Mean	25.6*	23.8†	26.8‡	19.6§	23.8*	23.0†	25.6‡	18.2§

\*P = 0.17, †P = 0.18, ‡P = 0.11, §P = 0.13

LUPV = Left upper pulmonary vein, LLPV = Left lower pulmonary vein, RUPV = Right upper pulmonary vein, RLPV = Right lower pulmonary vein

ence and familiarity, it is anticipated that the procedure time would be significantly reduced.

## Conclusion

We have demonstrated that pulmonary vein isolation can be carried out with the HDMA catheter in combination with 3-D navigation to create high density three-dimensional geometry of the LA-PV junction, and that this can assist with catheter placement and confirmation of pulmonary vein isolation. Using this technique, the HDMA catheter is capable of circumferential ostial isolation of the pulmonary veins without causing significant pulmonary vein stenosis acutely on angiography. Our data serves as a favourable feasibility assessment of the above technique and further evaluation of its safety and efficacy in a larger cohort of patients should be performed

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