Panoramic atrial mapping with basket catheters: a quantitative analysis to optimize practice, patient selection and catheter choice.

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ABSTRACT

Background:
Panoramic mapping with basket catheters have been used in persistent atrial fibrillation (AF) mapping. However, limited contact and coverage achieved with the basket catheter has raised concerns about the validity of these technologies.

Method:
Patients undergoing catheter ablation for atrial tachycardia (AT) and persistent AF were prospectively recruited. Unipolar signals were recorded with the Constellation or FIRMap catheter. The total and distribution of LA coverage and contact achieved was determined. The impact catheter position and patient-specific sizing had on LA coverage was evaluated.

Results:
Thirty patients were included in this study (15 Constellation and 15 FIRMap). The LA coverage achieved with the FIRMap catheter was significantly greater than that achieved with the Constellation catheter (76.9 ± 13.1% vs. 49.9 ± 11.8%; p<0.001) particularly that of the septum (56.4 ± 18.1% vs. 15.7 ± 13.1%; p<0.001). This was also the case in regards to LA contact whereby greater number of electrodes was within 10mm of the geometry surface (88.6% vs. 78.1% of electrodes; p=0.002) and had peak-to-peak amplitude of ≥0.5mV (52.1 ± 8.6 (81.4%) vs. 39.2 ± 7.9 (61.3%); p<0.001). Catheter position, LA size despite basket specific sizing and bipolar voltage had a significant impact on the LA coverage and contact achieved.
Conclusion:

FIRMap catheter is a superior basket catheter to the Constellation catheter allowing for better coverage and contact. Through taking on board practical considerations including catheter position, LA size and bipolar voltage it will allow for the best mapping results to be achieved with these basket catheters.
INTRODUCTION

Identification of drivers in persistent atrial fibrillation (AF) is an ongoing challenge. ‘Panoramic mapping’ of the left atrium (LA) using basket catheters has been the foundation of recent mapping systems aiming to identify drivers in AF (1-4). However, whole-chamber mapping with basket catheters can be limited by the electrodes being positioned in the blood pool thereby reducing tissue contact and clustering of the basket splines leading to a reduction in LA coverage (5, 6).

To date, published studies using basket catheters have used the Constellation catheter (Boston Scientific Ltd, Natick, MA). This 64-electrode catheter consists of eight evenly spaced splines, each with eight electrodes spaced 5mm apart. The Constellation catheter is available in four sizes (35, 45, 60 and 75mm) however the 60mm catheter has been used in a majority of studies. The flaws seen with interspline bunching resulting in loss of coverage and contact and the lack of electrode poles proximally resulting in loss of septal coverage have been considered in the development of newer basket catheters. The FIRMap catheter (Topera, Abbott, CA, USA) has stiffer splines to minimize distortion and bunching. Electrodes are also spaced further apart, with more proximal electrodes to improve LA septal coverage.

This study aimed to characterize optimal practice for atrial mapping with the basket catheter. LA coverage, electrode-tissue contact and catheter stability were examined to allow (i) an analysis of the optimal catheter position, (ii) to study the impact of increasing atrial size and scarring thus informing patient selection, and (iii) the first direct comparison of the functionality of the Constellation and FIRMap catheters.
METHOD

Patient selection

Patients that were prospectively enrolled in the STAR study, which utilizes panoramic mapping with a basket catheter to identify and characterize drivers in AF, were included in this study. In brief patients with symptomatic persistent AF (<24 months) and no previous ablation and those with suspected left sided atrial tachycardia (AT, de novo or with a history of pervious AF ablation) were prospectively enrolled. All procedures were performed on uninterrupted oral anticoagulation with either warfarin or a novel oral anticoagulant. Heparin was administered during the procedure to ensure an ACT >300s. Procedures were performed under conscious sedation or general anesthetic. All patients provided informed consent for their involvement in the STAR study. Ethical approval was granted by the UK National Research Ethics System (London- Bloomsbury Research Ethics Committee, 16/LO/1379) and the study was prospectively registered on clinicaltrials.gov (NCT02950844).

Baseline characteristics were prospectively recorded in all patients including age, gender, hypertension, diabetes, cerebrovascular disease, ischemic heart disease, previous cardiac surgery, left ventricular systolic function, LA dimensions (diameter, area and volume). Details regarding previous catheter ablation were recorded in all patients.

Electrophysiological study

Mapping was performed with CARTOFINDER mapping system (CARTO, Biosense Webster, Inc, CA). All patients had RA and LA geometries created. A high-density bipolar voltage map was created in all patients using a 2-6-2mm spacing PentaRay®
NAV catheter (Biosense Webster, Inc, CA). Areas of low voltage were defined as <0.5mV (7, 8). Bipolar voltage points in the pulmonary veins and LA appendage were excluded to ensure these did not affect average voltage values for the body of the LA.

Either the Constellation or FIRMap whole-chamber basket catheter was used to record unipolar signals (Figure 1). For the first 15 consecutive cases the Constellation catheter was used and for the subsequent 15 cases the FIRMap basket catheter was used. The basket catheter was positioned in the LA through an 8Fr Mullens (Cook Medical, IN, USA) or 8.5Fr SL1 sheath (Daig Medical, MN, USA) under fluoroscopy guidance. Once in the LA the catheter was manipulated to position it in a stable position with visually optimal LA coverage and minimal interspline bunching. Unipolar signals were recorded through the BARD electrophysiological recording system (Labsystem Pro, Boston Scientific, Ltd, NA) by referencing to a decapolar catheter (Biosense Webster, Inc, CA) positioned in the IVC and filtering between 0.5Hz and 500Hz. Further recordings were taken with repositioning of the basket if the operator felt that better coverage could be achieved.

Unipolar signals were recorded over five minutes in AF, two minutes in AT, or 30 seconds during atrial pacing in sinus rhythm as per the STAR study protocol.

The performance of the basket catheters was assessed in several respects:

i) Atrial coverage
Coverage was defined as the percentage of the chamber surface within 10mm of a basket electrode. This is calculated by projecting points within 10mm of the geometry
onto its surface and assuming each electrode covers an area with a 10mm radius. The percentage coverage of the LA surface was then calculated using the LA geometry created in CARTO, with the exclusion of venous structures, pulmonary ostia, mitral and tricuspid valve annulus and LA appendage (11). These findings were verified using a custom written script in Matlab (Mathworks, MA, USA) whereby the anatomical shell was reconstructed and using the xyz coordinates the position of the electrodes <10mm from the shell was determined. Using the same method as above the LA coverage achieved was verified.

The LA was subdivided into anterior, posterior, lateral, roof and septum (Figure 2). The mean percentage coverage achieved for each of these sections was calculated.

The effect catheter positions had on the LA coverage achieved was also determined. Two common catheter positions in the LA were compared whereby in one the distal end of the catheter was positioned anterior to the appendage ridge (pointing laterally towards the LA appendage or lateral wall) and with the other the distal end was positioned at or posterior to the LA appendage ridge (so pointing towards the ridge or the left superior pulmonary vein (LSPV)).

**ii) LA size and LA coverage**

The basket catheter was sized from the transverse and longitudinal LA diameters obtained from the transthoracic echocardiogram performed on the day of the procedure as advised by the manufacturers. The basket size nearest to the largest LA dimension in the apical four-chamber view (whether septal to lateral wall or annulus to posterior wall) was selected.
It is intended that sizing the basket catheter based on LA dimensions should compensate for a dilated LA and still allow optimal coverage unconditional of LA size. Whether choosing the size of the basket based on the manufacturers recommendations prevented loss LA coverage was evaluated.

iii) Electrode-tissue contact

The proportion of electrodes with LA contact was determined for both basket catheters. Two surrogates for electrode-tissue contact were used:

a) Distance from the geometry

Utilizing the xyz coordinates and a custom written Matlab script the distance between the electrode poles and the atrial geometry was determined. A distance of ≥10mm from the geometry surface was defined as out of contact and was assumed to be in the blood pool. The number of poles on each catheter that were <10mm from the geometry were identified.

b) Electrogram based

All atrial electrograms (EGMs) were effectively filtered in Matlab to disregard noise. A peak-peak amplitude of <0.5mV was set as the low voltage threshold (9). Electrode poles with peak-peak amplitude of ≥0.5mV were deemed to demonstrate atrial tissue contact. If the peak-peak amplitude was <0.5mV and the electrodes were within 10mm of the geometry, the bipolar voltage at the site of the electrode was determined using the voltage map (acquired separately using the Pentaray catheter). If the bipolar voltage was ≤0.2mV on the bipolar voltage map the electrode pole was deemed to be in contact and the absence of atrial signal was
assumed to be secondary to structural remodeling. The relationship between the proportion of electrodes with peak-peak amplitude of $\geq 0.5\text{mV}$ and the mean atrial bipolar voltage was also evaluated.

**iv) Catheter deformation**

The interspline spacing for the Constellation and FIRMMap catheter was determined ex vivo. This was defined as the distance between each equatorial electrode pair on adjacent splines under passive conditions. This was used for comparison to the interspline distances obtained in vivo.

To determine changes in the interspline distance once deployed in the LA the xyz coordinates for each catheter pole was determined from the location data obtained through CARTO. From this the Euclidean distance between each equatorial electrode on neighboring splines was calculated and the mean minimum and maximum equatorial interspline distance was determined.

The three surrogates for catheter deformation used were a) the minimum and maximum equatorial interspline distance and comparing this to the ex vivo equatorial interspline distance. b) The coefficient of variance for the eight equatorial interspline distances was determined for each recording. The mean of the coefficient of variance was then determined across all recordings in that patient. c) The proportion of splines with an equatorial interspline distance of either $\geq$ or $\leq$ than 20% of the equatorial interspline distance documented under passive conditions ex vivo.
Increased distortion of catheter shape and interspline bunching is believed to be a cause of decreased LA coverage. To evaluate the impact this has on LA coverage, in a proportion of patients the catheter shape was intentionally distorted. The LA coverage achieved was then compared to the prior recording with minimal catheter distortion.

v) Catheter stability

The xyz coordinates for the basket electrodes were obtained through CARTO at the start and end of the unipolar signal recordings. The coordinates were used to determine the position of the electrode on the LA geometry. The change in electrode position was calculated as a marker for catheter stability.

Statistical analysis

This was performed using SPSS (IBM SPSS Statistics, Version 20 IBM Corp, Armonk, NY, USA). Continuous variables are displayed as mean ± standard deviation (SD). Categorical variables are presented as a number and percentage. Chi-square was used for the comparison of nominal variables. The student t-test, or its non-parametric equivalent the Mann-Whitney U test when appropriate, was used for comparison of continuous variables. Spearman rank-order correlation was used to assess the strength and direction of association between LA volume and area with the LA coverage achieved. Coefficient of variance of the equatorial interspline spacing was determined. Results with p<0.05 were regarded as significant.
RESULTS

A total of 30 patients were included in this study (15 persistent AF and 15 AT). In 15 patients a 60mm Constellation catheter was used to record unipolar signals whilst in the subsequent 15 patients a 60mm and 50mm FIRMap catheter was used in 12 and three patients respectively (sized as per manufacturers instructions).

Baseline characteristics are demonstrated in Table 1. The mean age was 62.0 ± 11.4 yrs. and the cohort was predominantly of male gender (n=18, 60%). A majority of patients had preserved left ventricular systolic function with an ejection fraction of >55% (n=20, 66.7%) and a mean LA volume of 59.8 ± 8.1ml. The mean bipolar voltage in the LA body was 0.4 ± 0.1mV measured over a total of 19, 170 points (639 ± 217 points per patient). A comparison of the two basket catheters in terms of their performance mapping *in vivo* is summarized in Table 2.

*i) Atrial coverage*

The LA coverage was determined over an average of 4.4 ± 1.1 LA maps per patient. The mean LA coverage achieved with the Constellation catheter was 49.9 ± 11.8% whilst with the FIRMap catheter this was significantly greater at 76.9 ± 13.1% (p<0.001). This represents an average of 27.0% increase in coverage with the FIRMap catheter with an average area specific increase of 22.6 ± 8.3%. Arguably more importantly, the maximum coverage achieved with the Constellation catheter was 61.9 ± 11.0% compared to 83.1 ± 5.0% (p<0.001) with the FIRMap catheter.
The regional coverage achieved with each basket catheter is shown in Figure 2. The FIRMap catheter achieved better average coverage of the septum compared to the Constellation catheter (56.4 ± 28.1% vs. 15.7 ± 13.1%; p<0.001).

When comparing the position of either basket catheters and the LA coverage achieved, with the distal end of the basket catheter positioned at or posterior to the LA appendage ridge resulted in better coverage of the LA whilst positioning the basket catheter anterior to the appendage ridge resulted in reduced LA coverage predominantly due to the loss of anterior wall coverage (68.2 ± 16.7% vs. 39.5 ± 14.6%; p=0.001; Figure 3A-B). The effect catheter position had on LA coverage applied to both catheters.

**ii) LA size and LA coverage**

There was a negative correlation between the LA coverage achieved and the LA volume with both catheters (R= -0.9, p<0.001 Constellation and R=-0.8, p<0.001 FIRMap). This relationship was also consistently seen with LA area (R=-0.9, p<0.001 Constellation and R=-0.9, p<0.001 FIRMap) (Figure 4A).

There was an average of 30.2 ± 2.9% reduction in LA coverage when comparing the largest and smallest LA area pentiles despite the use of larger basket catheter sizes in those with larger LA sizes. A LA area of >28cm² was associated with LA coverage of ≤50% (PPV and NPV of 100%) and ≤60% (PPV 100.0% and NPV 66.7%) with the Constellation and FIRmap catheter respectively (Figure 4A).
In two out of the 15 patients that had mapping done with the FIRMap catheter the basket catheter appeared oversized (despite being sized according to manufacturer’s instructions), which resulted in difficult catheter manipulation and distortion to the shape of the basket catheter. In both of these patients the LA coverage achieved was 41.9 and 46.7%, which was significantly lower than the remaining cohort where the coverage was 71.1% (p=0.005).

iii) Electrode-tissue contact

With the FIRMap catheter there were significantly more electrodes of the basket catheter that was <10mm from the LA geometry surface compared to the Constellation catheter (88.6% vs. 78.1%; p=0.002).

The number of electrodes of the 64-pole basket catheter with atrial signal with a peak-to-peak amplitude of ≥0.5mV in the LA was significantly greater with the FIRMap catheter compared to the Constellation catheter (52.1 ± 8.6 (81.4 ± 13.4%) vs. 39.2 ± 7.9 (61.3 ± 14.8%); p<0.001), representing a 20.1 ± 6.9% increase in LA contact with FIRMap. This was also consistent when including the sites with peak-to-peak amplitude of <0.5mV in the context of a bipolar voltage of ≤0.2mV on the voltage map and <10mm from the geometry as sites of contact (54.5 ± 7.1 (85.2 ± 11.1%) vs. 46.2 ± 9.7 (72.2 ± 15.2%); p=0.036). If the mean bipolar voltage for the LA was <0.3mV the LA contact achieved was significantly less than the mean LA contact achieved with both the Constellation (40.7 ± 5.1% vs. 61.3 ± 14.8%; p=0.03) and FIRMap catheter (59.7 ± 4.5% vs. 81.4 ± 13.7%; p=0.017; Figure 4B). Taking both catheters on board those with a mean bipolar voltage of <0.3mV had a 21.2 ± 6.1% reduction in LA contact compared to the mean LA contact achieved (p=0.007).
iv) **RA coverage and contact**

In a subgroup of patients unipolar recordings were performed in the RA with the basket catheters (n=6 Constellation catheter and n=6 FIRMap catheter). The mean coverage achieved in the RA was significantly greater with the FIRMap catheter than with the Constellation catheter (69.9 ± 6.6% vs. 58.7 ± 7.7%; p=0.02). These findings also applied to tissue contact whereby significantly more electrodes were within 10mm of the geometry (60.2 ± 3.3 (94.1 ± 5.1%) FIRMap vs. 55.7 ± 3.7 (87.1 ± 5.8%) Constellation; p=0.02).

v) **Catheter deformation**

The Constellation catheter demonstrated greater deformation of the catheter in vivo compared to the FIRMap catheter whereby a greater proportion of splines demonstrated an interspline distance of ≤ or ≥20% of the baseline interspline spacing (67.5 ± 25.1% vs. 6.7 ± 13.3%; p<0.001) and a greater coefficient of variance of the equatorial interspline spacing (0.5 ± 0.1 vs. 0.4 ± 0.1; p=0.02).

In 10 out of the 30 patients the basket catheter shape (5 Constellation and 5 FIRMap catheters) was intentionally distorted to result in interspline bunching. This resulted in an average LA coverage of 32.1 ± 16.1% which was an average reduction of 28.6 ± 15.0% compared to the preceding non-distorted position (p=0.002).

vi) **Catheter stability**

The mean variation in the position of the electrode poles on the LA geometry from the beginning of the recording to the end was 1.10 ± 0.5mm for 30 seconds, 1.4 ± 0.7
2 min and 1.6 ± 0.7 mm for 5 min for the whole cohort. There was no difference in catheter stability between the two catheters (p=0.96).

DISCUSSION

This is the first study that has quantitatively analyzed optimal practice for atrial mapping with the basket catheter. The optimal catheter position was pointing towards the LA appendage ridge or LSPV. Increasing atrial size reduced LA coverage and electrode-tissue contact, which was not fully mitigated by increasing basket size as per manufacturer guidance. More than moderate LA dilatation resulted in poor LA coverage and electrode tissue contact. Likewise, a mean LA voltage <0.4 mV was associated with a low proportion of electrodes yielding interpretable electrograms. The first direct comparison of the Constellation and FIRMap catheters showed greater LA coverage particularly at the septum, a higher proportion of electrodes in tissue contact, and less bunching of splines with the FIRMap catheter compared to the Constellation.

A) Atrial coverage

Previous studies have shown that LA coverage achieved with the Constellation catheter is limited to approximately half of the LA (5, 6, 9). These findings were consistent with what was seen in this study with the Constellation catheter. We have shown that the differences implemented in the FIRMap catheter, including wider spaced and stiffer spines, results in not only an increase in overall LA coverage by almost 30% but also 40% greater coverage of the LA septum which has been documented as a blind spot of the Constellation catheter (10). The improved coverage
owes partly to the reduction in interspline bunching and distortion in basket shape seen with the FIRMap catheter, which we showed reduced LA coverage by almost 30%. Previous studies have documented more than one AF driver per patient (11, 12) with these distributed throughout the LA (13, 11) but in small discreet locations (11). As a result when mapping these drivers using basket catheters any loss of coverage could have a significant impact on the identification of drivers in AF. The FIRMap catheter therefore provides an advantage on these grounds, with better coverage of both the LA and RA compared to the Constellation catheter.

B) Atrial contact

A previous study reported that approximately 50% of 64-electrodes of the Constellation catheter were >10mm from the geometry and thereby floating in the blood pool (7). In this study a significantly larger proportion of electrodes of the Constellation catheter (78.1%) was within 10mm of the geometry. Nevertheless this was significantly greater with the FIRMap catheter (88.6%; p=0.002).

A previous study concluded that only two third of basket electrodes were in tissue contact, since this was the proportion of recorded atrial signals that met the peak-to-peak voltage criteria used in the study (8). However, when determining the atrial contact the underlying bipolar voltage was not taken into account. In this study we ensured that if the electrode was within 10mm of the geometry and the underlying bipolar voltage was ≤0.2mV that it was counted as being in contact. This showed that a higher proportion of electrodes were in contact than previously thought. The proportion of electrodes in contact as well as the proportion recording a peak-to-peak
amplitude of >0.5mV were also greater with the FIRMap (80% and 85% respectively) compared to the Constellation catheter (65% and 72% respectively).

C) Practical considerations and implications of patient selection

i) Catheter position

The LA coverage achieved with either catheter is significantly influenced by the catheter position, whereby positioning the distal end of the basket catheter at or posterior to the LA appendage ridge resulting in a significant increase in the LA coverage achieved compared to a position pointing anterior to the appendage ridge. This was consistent with both catheters. Pointing the basket catheter at or posterior to the LA appendage allowed better coverage of the roof but particularly the anterior wall. Positioning the distal part of the basket catheter anterior to the appendage ridge increased the risk of the lower spines prolapsing across in the mitral valve orifice and as a result loss of LA coverage. With the splines of the Constellation catheter being less stiff they will be more at risk of prolapsing across in the mitral valve orifice, which could account for the more marked reduction in LA coverage seen with this catheter position with the Constellation catheter.

ii) Implication of patient selection

In previous studies using the basket catheter the 60mm Constellation catheter was used unconditional of the LA size (1, 13). In this study the basket catheter was sized based on the LA dimensions obtained from a transthoracic echocardiogram. This was to ensure that the coverage with larger LA sizes was not compromised and that there was no increase in interspline bunching with the smaller LA sizes. However, despite patient specified sizing in accordance with manufacturer’s instructions there was a
reduction in the LA coverage of around 30.2% when comparing the largest and smallest LA area pentiles. Oversizing basket catheter also has an impact on LA coverage. Therefore it is important that appropriate sizing is done and accepting that above certain LA dimension LA coverage will be compromised which will not be overcome by using larger basket catheters. We have further demonstrated that once the LA is moderately dilated the LA coverage achieved is less than 50% thereby indicating that whole-chamber basket catheter mapping should be limited to those with normal or mildly dilated LA. Further to this, in those patients with a mean bipolar voltage of <0.3mV there was greater than 20% reduction in the LA contact compared to the mean LA contact achieved. In patients where mapping with a basket catheter is being considered, it would be reasonable to perform a voltage map first to determine the feasibility of basket mapping.

**D) Catheter deformation**

The stiffer splines of the FIRMap catheter results, as expected in less variation in interspline spacing from the ex-vivo position, whilst with the Constellation catheter this variation was significant whereby more than 60% of splines demonstrated a 20% variation from baseline. In the two patients where the FIRMap catheter was oversized there was also marked interspline bunching resulting in a significant reduction in LA coverage. Together with the reduction in coverage seen with the catheter shape intentionally distorted it is clear that interspline bunching has a direct impact on LA coverage, which would account for the lower LA coverage achieved with the Constellation catheter.
E) Catheter stability

A range of mapping systems developed to detect drivers in AF either through mapping rotors (1, 2) or wavefront propagation (3) depend on recording unipolar data over a time period ranging between 30 seconds to 5 minutes. These systems utilize the location data obtained from the basket catheter at the start of recording where the assumption is that the basket catheter remains in a stable position. Variations in the catheter position over the recording will have a direct impact on the conclusions that can be drawn from these maps. Both basket catheters maintained good location stability with minimal variation in electrode position on the geometry. This was the case unconditional of the duration of the recording. The stability demonstrated provides reassurance that the atrial electrogram data obtained with the basket catheter during recordings could accurately be interpreted.

LIMITATIONS

This study only looked at practical considerations with mapping AF using basket catheters and did not evaluate whether either catheter was better in regards to detecting AF drivers. Better atrial coverage and contact would be expected to improve identification of AF drivers, although the minimum requirements for this process remain uncertain. In the Constellation catheter group the 60mm catheter was used in all patients so the impact other basket catheter sizes have on coverage and contact was not assessed in this study. However, the majority of studies have evaluated the 60mm Constellation catheter and all patients in this study had the catheter size chosen as per their LA size, where a 60mm catheter was a more appropriate size compared to a 45mm catheter which is the next available size for the Constellation catheter.
CONCLUSION

The FIRMap catheter is superior to the Constellation catheter in terms of coverage and contact achieved in both atriums. Optimizing catheter position and appropriate patient selection based on no more than moderately dilated or moderately scarred atria will also facilitate mapping with basket catheters. These practical considerations are vital to allow truly panoramic contact mapping in AF.
REFERENCES


spatial coverage and electrode contact for mapping atrial fibrillation in humans? Heart Rhythm 11, S20. 2014. Ref Type: Abstract


Table 1- Demonstrates the baseline characteristics of the cohort

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<th>Baseline characteristics</th>
<th>Constellation catheter n=15</th>
<th>FIRMap n=15</th>
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LA parameters mean ± SD

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Ablation indication

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Table 2- Demonstrates the practical differences between the Constellation and FIRMap catheter

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<td>Anterior LA appendage ridge catheter position</td>
<td>35.4 ± 5.0</td>
<td>56.8 ± 11.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Septal coverage</td>
<td>56.4 ± 18.1</td>
<td>15.7 ± 13.1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Electrodes with LA contact n (%)

| Atrial Peak-to-Peak amplitude ≥0.5mV                        | 52.1 ± 8.6 (81.4)  | 39.1 ± 7.9 (61.3) | <0.001  |
| Electrodes <10mm from the geometry (%)                     | 50.0 ± 5.3 (78.1)  | 56.7 ± 4.5 (88.6) | 0.002   |

Catheter deformation

<table>
<thead>
<tr>
<th>In vivo vs. ex vivo equatorial interspline distance, mm</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum mm mean ± SD</td>
<td>37.1 ± 11.9 vs. 21.0</td>
<td>22.5 ± 3.2 vs. 19.0</td>
<td></td>
</tr>
<tr>
<td>Minimum mm mean ± SD</td>
<td>10.1 ± 8.2 vs. 21.0</td>
<td>17.4 ± 3.4 vs. 19.0</td>
<td></td>
</tr>
</tbody>
</table>

^CV of equatorial interspline distances in vivo            | 0.5 ± 0.1          | 0.4 ± 0.1   | 0.02    |

Percentage of splines with an interspline distances of ≤ or ≥20% of ex vivo spacing | 67.5 ± 25.1 | 6.7 ± 13.3 | <0.001 |

Catheter stability (electrode position change from baseline) mm mean ± SD

<table>
<thead>
<tr>
<th></th>
<th>Constellation n=15</th>
<th>FIRMap n=15</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 seconds recording</td>
<td>1.3 ± 0.6</td>
<td>0.9 ± 0.4</td>
<td>0.33</td>
</tr>
<tr>
<td>2 minutes recording</td>
<td>1.4 ± 0.9</td>
<td>1.4 ± 0.5</td>
<td>0.91</td>
</tr>
<tr>
<td>5 minutes recording</td>
<td>1.4 ± 0.8</td>
<td>1.5 ± 0.3</td>
<td>0.75</td>
</tr>
</tbody>
</table>

^CV- coefficient of variance
FIGURE LEGEND

Figure 1A-B-
Ai-ii) Demonstrates a 60mm FIRMap catheter with eight evenly spaced spines, with eight electrodes on each spine that are spaced 9mm apart which allows for an electrode closer to the shaft of the catheter.
Bi-ii) Demonstrates a 60mm Constellation catheter with eight evenly spaced spines with eight electrodes on each spine spaced only 5mm apart which results in the absence of an electrode proximally and distally.

Figure 2A-B- Demonstrates the distribution of LA coverage achieved on a LA mesh in anterior and posterior views with
Ai-ii) FIRMap catheter
Bi-ii) Constellation catheter

Figure 3A-B- Demonstrates the FIRMap catheter on a LA geometry with Ai-ii) Anterior and lateral views showing the distal end of the catheter pointing at or posterior to the LA appendage ridge Aiii) LA coverage achieved in that position Bi-ii) Anterior and lateral views showing the distal end of the catheter pointing anterior to the LA appendage ridge Biii) LA coverage achieved in that position

Figure 4A-B- Demonstrates A) the correlation between LA coverage achieved and the LA area B) the correlation between LA contact achieved and the mean bipolar voltage