Validation of Computed Tomography Image Integration into the EnSite NavX Mapping System to Perform Catheter Ablation of Atrial Fibrillation


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Validation of EnSite NavX Fusion. Introduction: The complex anatomy of the left atrium (LA) makes location of ablation catheters difficult using fluoroscopy alone, and therefore 3D mapping systems are now routinely used. We describe the integration of a CT image into the EnSite NavX System with Fusion and its validation in patients undergoing atrial fibrillation (AF) or left atrial tachycardia (AT) catheter ablation.

Methods and Results: Twenty-three patients (61 ± 9.2 years, 16 male) with paroxysmal (14) and persistent (8) AF and persistent (1) AT underwent ablation using CT image integration into the EnSite NavX mapping system with the EnSite Fusion Dynamic Registration software module. In all cases, segmentation of the CT data was accomplished using the EnSite Verismo segmentation tool, although repeat segmentation attempts were required in seven cases. The CT was registered with the NavX-created geometry using an average of 24 user-defined fiducial pairs (range 9 to 48). The average distance from NavX-measured lesion positions to the CT surface was 3.2 ± 0.9 mm (median 2.4 mm). A large, automated, retrospective test using registrations with random subsets of each patient’s fiducial pairs showed this average distance decreasing as the number of fiducial pairs increased, although the improvement ceased to be significant beyond 15 pairs. In confirmation, those studies which had used 16 or more pairs had a smaller average lesion-to-surface distance (2.9 ± 0.7 mm) than those using 15 or fewer (4.3 ± 0.8 mm, P < 0.02). Finally, for the 13 patients who underwent left atrial circumferential ablation (LACA), there was no significant difference between the circumference computed using NavX-measured positions and CT surface positions for either the left pulmonary veins (178 ± 64 vs. 177 ± 60 mm; P = 0.81) or the right pulmonary veins (218 ± 86 vs. 207 ± 81 mm; P = 0.08).

Conclusion: CT image integration into the EnSite NavX Fusion system was successful in all patients undergoing catheter ablation. A learning curve exists for the Verismo segmentation tool; but once the 3D model was created, the registration process was easily accomplished, with a registration error that is comparable with registration errors using other mapping systems with CT image integration. All patients went on to have subsequent successful ablation procedures. Where LACA was performed (13 patients), only four patients required segmental ostial lesions to achieve electrical isolation. (J Cardiovasc Electrophysiol, Vol. 19, pp. 821-827, August 2008)

atrial fibrillation, ablation, imaging, computed tomography, mapping systems

Introduction

In 2002, more than 5,000 patients underwent catheter ablation aimed at curing atrial fibrillation (AF), and each year this number continues to grow.1 Currently, the principal ablation strategies include electrical disconnection of the pulmonary veins (PVI)2 and left atrial circumferential ablation (LACA),3,4 with the addition of further linear lesions dependent on the underlying substrate and outcome of the initial procedure.5 The complex 3D geometry of the left atrium (LA) means that performing these procedures is difficult using fluoroscopy alone, and therefore they are now routinely performed with a 3D mapping system.6-9 Conventionally, a 3D model of the LA is generated using the mapping system, and then used to guide catheter ablation. However, the resolution of these models is defined by the number of points acquired sequentially to create them, and may not define important anatomical boundaries such as the venoatrial junctions with sufficient accuracy. The ability to integrate high resolution, 3D computed tomography (CT) or magnetic resonance imaging (MRI) models into a mapping system offers potential for greater accuracy of lesion placement.10 We have validated the integration of a CT model of the LA into an electroanatomical mapping system (CartomergeTM, Biosense Webster Inc., Diamond Bar, CA, USA) in patients with AF

Dr. Rajappan participated in a speaker’s bureau relevant to this topic from St. Jude Medical.

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also,¹¹ and demonstrated very acceptable success rates using this technology for AF ablation.⁹ We report the first use of CT model integration into another mapping system (St. Jude EnSite System™ incorporating the EnSite Fusion Dynamic Registration module, St. Jude Medical, St. Paul, MN, USA) and validation in patients undergoing AF ablation.

**Methods**

**Study Population**

The study population consisted of 23 consecutive patients who underwent catheter ablation of AF (16 male; aged 61 ± 9 years). All patients gave written informed consent. All patients had symptomatic documented AF and had failed 2.1 ± 0.8 antiarrhythmic drugs. Twelve patients were undergoing ablation for the first time and 11 patients were having repeat procedures. Fourteen had paroxysmal AF; eight had persistent AF, and one persistent atrial tachycardia (AT).

**Computed Tomography**

A multislice helical contrast CT was performed using GE Light-speed Ultra 8-slice scanner (GE Healthcare Technologies, WI, USA). The technique used for the CT has been previously described.¹¹ The CT was performed 2 weeks prior to the ablation procedure. We have previously demonstrated that the time between procedure and CT or rhythm during CT has little influence on registration.¹¹

**Electrophysiological Study and Radiofrequency Ablation**

Electrophysiological study was performed in the postabsorptive state under conscious sedation. Oral anticoagulation was administered for at least 4 weeks prior to the procedure, and transesophageal echocardiography was performed within 24 hours of the procedure to exclude left atrial thrombus. LACA was performed using an irrigated tip catheter with power limited to 30 W and temperature to 50°C, with the endpoint PV electrical isolation determined by a circular PV catheter. Linear ablation was then performed with additional ablation of fractionated potentials in patients in whom AF persisted. This has been described previously.⁹ Briefly, in those undergoing their first procedure, LACA was performed to encircle the left and right-sided PV in pairs, 1–2 cm from their ostia as defined by PV angiography, using 3.5 mm irrigated tip radiofrequency ablation catheter, with electrical isolation of the PV being the electrophysiological endpoint. If AF persisted, a combination of the following was performed: (i) roof line, (ii) mitral isthmus line, and (iii) complex fractionated electrograms. If at any stage AF organized into AT, activation and entrainment mapping was performed. If AF continued following the linear ablation and targeting of fractionated electrograms, internal DC cardioversion was performed. In all patients requiring cardioversion and where typical atrial flutter had been previously documented, cavotricuspid isthmus ablation was performed. Where the patient was undergoing any procedure other than their first AF ablation, electrical isolation of the PV was first confirmed and, where necessary, reisolation performed, usually by identification of breakthrough(s) in the original LACA line. Subsequently, the procedure continued as for a first-time procedure. In the single patient with AT at the start of the case, segmental ostial ablation of right inferior pulmonary vein (RIPV), LPV, and LAA ridge was performed successfully using the EnSite NavX System with Fusion, followed by activation and entrainment mapping.

**Mapping System**

The EnSite NavX System (St. Jude Medical) was used with the Investigational Registered Digital Image Fusion Software (v7.0 RDS). The EnSite System consists of three major components: the EnSite NavX Patch Kit, the Display Workstation (DWS) and the Patient Interface Unit (PIU). The EnSite NavX Surface Electrode Kit consists of six patches that are placed on the skin of the patient to create electric fields along three orthogonal axes (x, y, & z). The patches are placed on both sides of the patient (x-axis), the chest and back of the patient (y-axis), and the back of the neck and inner left thigh (z-axis). Electrical fields are created in the heart by emitting low-intensity 5.68 kHz signals through these patches. Each catheter or other electrode within the patient is located within these fields by sensing the 5.68 kHz signal through the electrode. This signal is detected in three dimensions, locating the catheter in space. The EnSite NavX Surface Electrode Kit also includes a System Reference patch that is placed on the patient’s abdomen and serves as the electrical reference for the system. The PIU is connected via a fiber optic network cable, and converts all analog signals from the patient into digital signals that are then displayed on the DWS. All electrical interfaces with the patient including intracardiac catheters, surface ECG leads, connected pacing leads, the EnSite NavX Surface Electrode Kit, and connection to other EP equipment are connected to the PIU through the Breakout Box. The DWS is the computer interface of the EnSite System; it displays catheters, 3D geometry, and electrical signals gathered by the catheters.

**Integration of CT Image into Mapping System**

The contrast enhanced CT image in standard Dicom format was imported into the mapping system using the EnSite System software tools for digital image fusion.

**Segmentation**

Segmentation describes the process of separation of the CT image (or an MRI) of the cardiac chamber of interest, in this case the LA and pulmonary veins, from the other overlapping cardiac structures. A proprietary software tool (EnSite Verismo™, St. Jude Medical) allows segmentation of the cardiac image. Initially, it is necessary to accurately select the region of interest, containing the LA and associated structures. Once this region has been defined, it is possible to use boundary detection algorithms to define the blood pool, which will include not only the LA and pulmonary veins (PV), but also structures such as the right atrium, pulmonary arteries, aorta, both ventricles, and sometimes other structures not part of the blood pool. Further tools are then used to separate the LA and PV from the other structures. These include a separator tool that automatically defines different structures, again based on an edge detection algorithm, and a trace tool that allows the operator to define a traced region for inclusion or exclusion from a particular anatomical structure. Once the LA and PV have been satisfactorily defined, a 3D model is generated from the DICOM data (Fig. 1) and exported into the real-time mapping system for registration.
Registration

Registration describes the process of aligning a previously acquired 3D model with the NavX chamber geometry model and coordinate system. This was performed using an investigational version of DWS software that allowed the prospective registration of an imported model in the EnSite System. Prior to registration of the model, the EnSite System was calibrated with a stable intracardiac active fixation electrode, placed on the RA septum, as the positional reference electrode. This catheter (VascoStim Screw 2/6F, Vascomed, Binzen, Germany) is deployed after the two transseptal punctures have been performed, approximately 1–2 cm inferior to the punctures, using a combination of left anterior oblique/right anterior oblique fluoroscopic projections and electrograms to ensure it is attached to the muscular interatrial septum rather than other structures such as the tricuspid valve annulus. The catheters used during the procedure were defined, and the Respiration Compensation feature of the EnSite system was applied. A NavX geometry of the LA was created, ensuring that enough points were collected to provide sufficient definition. The LA geometry created consisted of separate geometries for each of the PV, the LA body, and the LA appendage, and included all major features of the LA so that corresponding locations on the NavX geometry and CT models were easily discerned in a side-by-side visual comparison. Finally, a scaling algorithm (Field Scaling) was applied to the completed detailed geometry in all cases. This algorithm adjusts for the nonlinearity of the geometry that occurs as a result of local changes in impedance fields. Field scaling is based on the measured interelectrode spacing for all locations within the geometry. Adjustments to the local strength of the navigation fields are made so that the computed catheter electrode positions match the known interelectrode spacing of the catheters used to create the geometry. The rest of the registration process could then be performed without further catheter manipulation. Fiducial point pairs were created by an operator identifying and selecting locations on the NavX geometry, and matching these on the CT model to the same anatomical location. Initially, three fiducial point pairs were identified at distinct locations around the LA chamber. These initial points spanned the LA and mostly were points at the ostia of the PVs and the base of the LA appendage. A registration algorithm then superimposed the NavX geometry onto the CT model (rigid registration, as shown in Fig. 2). Supplemental fiducial point pairs were then marked in regions where the NavX geometry differed from the CT model, mostly around the center of the LA body in all planes, but also on the PVs themselves, and the registration algorithm applied again. This process was continued, adding supplemental fiducial points pairs until good correspondence between the NavX geometry and CT models was achieved (dynamic registration, as shown in Fig. 2). The additional fiducial points allow the CT and NavX geometry to fit together by stretching the geometry as well as optimizing its rotation.

Validation of Registration

Validation of the accuracy and utility of CT registration was performed in three ways:

1. A comparison was made of the circumference of the ring produced by the LA circumferential ablation (LACA) 3D lesions and those marked when projected onto the CT surface (Fig. 3). Measurement of the circumferences was determined by summing the Cartesian distances between each successive pair of lesions in the LACA ring—first using their 3D positions, then using the positions of their CT-surface projections. The LACA ring was defined as the shortest distance that allowed isolation of ipsilateral
PVs as a pair (while maintaining a distance of 1 cm outside the PV ostia, except at the anterior aspect of the left PVs where ablation was performed along the ridge between the left atrial appendage and the PV ostia).

2. After the procedure, the average distance between NavX 3D lesion markers and the CT surface (after registration) was computed. Lesions that clearly were not intended to be on left atrial surface, for example, groups marking the coronary sinus, were excluded from the analysis. This average distance can be seen as an independent indicator of registration accuracy—the lesions were placed when the catheter tip was on the LA surface, located solely by NavX, and compared to their closest positions on the registered CT surface. While this distance metric is clearly weighted toward common ablation regions such as the LA roof and PV ostia, these are exactly the regions of clinical relevance, where good accuracy is required from a registration algorithm.

To remove any possible bias from the order in which the fiducial pairs were specified (for example, in some studies the first three fiducial pairs were all near the same PV, which is clinically convenient when moving a catheter but may not lead to good registration accuracy), the lesion-to-surface distance was computed as an average of all valid lesions and all possible registrations using any three fiducials (up to a maximum of 1,000 randomly chosen subsets of three). Each patient’s average lesion-to-surface distance was then averaged with those of other patients, to avoid biasing the statistics toward those patients having more lesions. These randomized registrations were also performed using fiducial-pair subsets of every size between three and the total number of fiducials defined for that patient, to quantify the improvement in registration accuracy when more fiducials are used (see Fig. 4).

3. Electrophysiological validation of the registration process was determined by the number of patients in whom LACA successfully achieved electrical isolation without the need for supplemental ostial ablation.

These indicators of registration accuracy and utility were also compared for patients who were in AF during the CT scan or at the start of the ablation with those patients in sinus rhythm to assess the influence on rhythm change.

Statistical Analysis

All variables are expressed as mean ± SD. Statistical comparisons between groups were made using a paired *t*-test or Wilcoxon rank sum test. For comparison between multiple regions a one-way ANOVA was used. A P value of < 0.05 was considered statistically significant.

Results

Procedure Characteristics

Total average procedure time was 207 ± 61 minutes, with a fluoroscopy time of 37 ± 12 minutes. The time taken to create the NavX geometry was 20 ± 9 minutes. To then register the NavX geometry and CT took a further 10 ± 7 minutes. Mean time for the entire process was 30 ± 11 minutes. There was no significant difference between the circumference of the LACA lesion lines using their 3D or surface positions for either the left PVs (3D NavX 178 ± 64 mm vs. CT surface 177 ± 60 mm; P = 0.81) or the right PVs (3D NavX 218 ± 86 vs. CT surface 207 ± 81 mm; P = 0.08). There was no difference between those patients who had their CT while in sinus rhythm (SR) and those who were in AF (Table 1). The close relationship between the 3D lesion and CT surface lesion circumferences, and the corresponding Bland-Altman plot, are shown in Figure 4.

There was a significant difference between the registration error using only three fiducial pairs (5.9 ± 0.8 mm) and all fiducial pairs (3.2 ± 0.9 mm; P < 0.001). Table 1 shows...
that these results were unrelated to the cardiac rhythm of the patient during the CT scan.

The relationship between the total number of fiducial pairs used and the registration error is shown in Figure 4. In Figure 4C, each patient is a single curve, plotting average lesion-to-surface distance of each 1,000 random registrations as a function of the number of fiducial pairs used in them. Figure 4D shows the simplistic average (plus median and maximum) curve over all patients, but it shows that at some point between 13 and 20 fiducial pairs, one reaches a “point of diminishing returns” in terms of accuracy. To quantify this number, Figure 4C also shows a cross at the smallest number of fiducials for which each patient’s average lesion distance falls very close to its minimum value (within 0.25 mm, chosen by inspection). The median of these values is 15 fiducials, and the 90th percentile is 26, suggesting that 50% to 90% of patients will reach an acceptable level of registration accuracy when 15 to 26 fiducial pairs are used.

When a value of 16 fiducials was used to divide the patients into two groups, there was a significant difference between the registration error with 16 or more fiducial pairs (2.9 ± 0.7 mm), compared with that using 15 or fewer fiducial pairs (4.3 ± 0.8 mm; P < 0.02). From Figure 4D, it can also be seen that when using 16 or more fiducial pairs, even the worst of the 1,000 random registrations produced an average lesion-to-CT distance of about 5 mm.

Seven patients required more than one attempt at segmentation to obtain an adequate 3D model for use in the procedure. The need for repeating the segmentation was obvious from the appearance of the final CT and indicated either by the truncated pulmonary veins/appendage or an inability to separate the LA from adjacent structures like the pulmonary arteries, requiring adjustment to the contrast and the edge detection of the segmentation software. As segmentation was performed before the ablation procedure, this did not impact on the registration process itself. A further attempt at registration was made in one case.

Technical Limitations

There are still limitations with this initial version of the software. Transparency of the CT model is controlled in a binary fashion, that is, on or off. When transparency is off, it is sometimes impossible to see the catheters if they are entirely within the CT model being viewed, as the walls of the CT are not translucent in this setting. However, with transparency on, the LA walls are difficult to visualize easily and differentiation of the near LA surface from the far surface is only possible when moving the geometry around. This version of the software is likely to be modified future versions.

Procedural Outcomes

Six patients required internal DC cardioversion during their procedure to convert to sinus rhythm; all of these patients had permanent AF. All patients were discharged at day 1 in sinus rhythm. Two patients required a single ostial lesion on the intervenous ridge to isolate the LPVs, and one patient required lesions across the intervenous ridge to isolate the RPVs. Another patient required a single ostial lesion to isolate the LPVs.

Complications

Pericardial effusions of 1 cm or less were detected in five patients, none of whom required any interventional treatment. Two patients developed a groin hematoma larger than is usually expected, with one being admitted to the local hospital,
but no pseudoaneurysm was detected on ultrasound. None of the complications above caused any delay in discharge post ablation.

### Discussion

CT model integration was performed with acceptable registration errors, and it was possible to use this technology to guide AF ablation in all of our patients.

### Registration of CT

The process of registration of the CT begins with segmentation as described. The software package for this process proved capable of generating a 3D model that could be used successfully. Given previous experience with other segmentation software, it was more time-consuming and sometimes required more than one attempt to complete. However, once this process was complete, creating the geometry and matching this to the CT took some time before ablation could be performed. Indeed, the initial fiducial point pairs were selected at anatomical points that were most reproducible on both the CT and NavX geometry, such as the PV ostia/left atrial junction (predominantly on the roof or at the level of the intravenous ridges anteriorly and posteriorly) and the base of the left atrial appendage. Subsequent placement of fiducial points was aimed to maximize closeness of fit, particularly around areas of interest, that is, PV/LAA junction. An integral part of the process of registration is the application of the field-scaling algorithm to the geometry created before matching to the CT model. It was possible to appreciate a significant difference visually between the geometry before and after field scaling, and also when comparing the fit with the CT model (Fig. 5). Based on this finding, although it is possible to register the CT to the geometry without field scaling, this would not be recommended.

### Clinical Use

The ultimate error between the NavX geometry and the CT model clearly represents a combination of the inevitable imperfection of the created geometry and the fact that the CT model may not exactly represent the LA at the time of the procedure (e.g., different volume loading conditions at the time that the CT was performed). Nonlinearity of the geometry that occurs as a result of local changes in impedance fields would also affect the error, but the field-scaling algorithm described adjusts the geometry for this, based upon the measured interelectrode spacing for all locations. Despite any registration error, it is clearly possible to use the CT model to perform catheter ablation successfully. There was no significant difference between the 3D lesion circumference for LACA and the CT surface circumference. However, as with other CT integrated mapping systems, it is important to note that the registered CT model remains a guide only, and a combination of fluoroscopy and the electrogram appearance must also be used in assessing contact with the LA surface and the true position of the catheter. Furthermore, the rigid registration of three fiducial pairs may allow orientation of the CT, but the registration error is high. It is necessary to add a number of fiducial pairs (our data would suggest 16 or more) and dynamically register the CT to gain acceptable accuracy.

### TABLE 1

<table>
<thead>
<tr>
<th>CT and Cardiac Rhythm</th>
<th>CT scan in SR (n = 13)</th>
<th>CT scan in AF (n = 10)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean registration error (±SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 fiducial pairs (mm)</td>
<td>5.7 ± 0.6</td>
<td>6.1 ± 1.0</td>
<td>NS</td>
</tr>
<tr>
<td>All fiducial pairs (mm)</td>
<td>2.9 ± 0.7</td>
<td>3.7 ± 1.0</td>
<td>NS</td>
</tr>
<tr>
<td>Difference between 3 and all fiducial pairs (mm)</td>
<td>2.8 ± 1.0</td>
<td>2.5 ± 1.3</td>
<td>NS</td>
</tr>
<tr>
<td>PV ablation circumferences</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left PVs 3D geometry (mm)</td>
<td>163 ± 65</td>
<td>213 ± 53</td>
<td>NS</td>
</tr>
<tr>
<td>Left PVs CT surface (mm)</td>
<td>161 ± 58</td>
<td>214 ± 54</td>
<td>NS</td>
</tr>
<tr>
<td>Right PVs 3D geometry (mm)</td>
<td>209 ± 77</td>
<td>236 ± 114</td>
<td>NS</td>
</tr>
<tr>
<td>Right PVs CT surface (mm)</td>
<td>203 ± 78</td>
<td>217 ± 100</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = not significant; PV = pulmonary veins.

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Figure 4. Four graphs demonstrating assessment of registration error. The two top graphs show (A) a scattergram, and (B) a Bland–Altman plot of the PV circumferences measured with 3D lesions compared with CT surface lesions. The linear regression line and r value are shown. The lower two graphs show plots of the average lesion-to-CT distance. In (C) each curve is one patient, and each plot point is the average lesion distance when using up to 1,000 registrations using randomly chosen subsets containing that number of fiducial pairs. Crosses show where each curve falls to within 0.25 mm of its minimum value. In (D) the average, median and maximum curves for the entire group of patients are shown.
The benefits of CT image integration are not unique to the EnSite NavX Fusion software. We have previously described our experience with Cartomerge, another mapping system with CT image integration, and its possible advantages. Improved visualization of the mapping catheter within the atria may ensure closer apposition or “contact” with the atrial wall. A better appreciation of the atrial configuration also enables more accurate lesion placement, ensuring continuity of linear ablation that follows the patient’s own complex anatomy. These factors may be important in producing transmural conduction block, which results in an improvement in clinical outcome and a reduction in the incidence of recurrent atrial tachyarrhythmias, although this remains unproven in a randomized controlled trial (RCT). Although the principle of CT image integration is common to both the EnSite NavX Fusion and Cartomerge systems, there is a significant difference in how registration is achieved. As described previously, the EnSite system uses a dynamic registration process (with four or more fiducials) to optimize both rotation and stretching of the surface of the NavX geometry to match the CT. With the Cartomerge system the whole registration process is rigid with rotation of the CT to minimize distance between the surface of the anatomical model generated and that of the CT, but no stretching of the model itself. Despite this difference, the registration error is similar with both techniques (Cartomerge 2.3 ± 1.8 mm vs. EnSite NavX Fusion 3.2 ± 0.9 mm).

Comparison of the NavX fusion technology with Cartomerge, the alternative catheter location technology, is difficult to make in this validation study. Although it appears that the fluoroscopy times are long during this study, this is likely to be a reflection of the learning curve of the operators using this new technology. Randomized controlled studies are necessary to demonstrate equivalence or superiority of one of these technologies.

Conclusions

CT image integration into EnSite NavX Fusion was successful in all patients undergoing catheter ablation. To achieve successful registration and accuracy between the CT and NavX geometry, it was necessary to add 16 to 26 fiducial pairs. Occasionally, more than one attempt at segmentation of the CT scan was required. It is worth noting that the version of the software used in this study was the first limited market release, and hence it is expected that future versions will address the limitations identified, yet still provide equal accuracy. Despite this, validation of this version of EnSite NavX Fusion has shown a registration error comparable with other mapping systems with CT image integration. Although all procedures were completed successfully, the long term outcomes and clinical utility of this system remain unproven.

References
