EXPERT REVIEWS

EnSite Velocity™ cardiac mapping system: a new platform for 3D mapping of cardiac arrhythmias

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Accurate understanding and visualization of the mechanisms of cardiac arrhythmias originating from a complex 3D substrate are a prerequisite for successful treatment of such disorders. Nonfluoroscopic cardiac mapping systems are designed to provide the required spatial anatomical information in combination with local electrical information. During recent years, the EnSite system, with its EnSite NavX™ navigation and visualization technology, and CARTO have evolved as the main representatives. EnSite Velocity™ is the latest released platform of the EnSite NavX technology. It represents an open system enabling 3D visualization of multiple intracardiac catheters from different manufacturers. Fusion algorithms and respiratory compensation allow for model-guided therapy with real-time nonfluoroscopic visualization of intracardiac catheters within registered 3D CT/MRI images.

KEYWORDS: ablation • atrial fibrillation • mapping system • NavX™

Catheter ablation is a potentially curative treatment option for a wide range of cardiac arrhythmias. With a growing pathophysiological understanding, it is becoming increasingly important not only for a small population of patients with simple arrhythmias, such as atrioventricular nodal-re-entrant tachycardia (AVNRT) or accessory pathway, but it also offers a potential cure to patients suffering from endemic arrhythmias, such as atrial fibrillation (AF).

Accurate spatial, anatomical and electrical orientation is essential for the treatment of arrhythmias with a complex 3D substrate (e.g., AF, atrial macro-re-entrant tachycardia [MRT] or ventricular tachycardia). Owing to the limitations of 2D fluoroscopy to provide the required precision of 3D orientation, cardiac mapping systems have been developed to facilitate an accurate understanding of the electrical substrate within its anatomical boundaries. A realistic model of the individual 3D cardiac anatomy becomes even more important with the introduction of anatomically guided ablation line placement.

Any attempt of nonfluoroscopic intracardiac 3D orientation requires a technology for reliable, stable and reproducible visualization and 3D localization of intracardiac catheters. The concept of using transthoracic low-power electrical currents to enable localization of intracardiac electrodes was first published in 1999 [1]. In clinical practice that technology led to the development of the EnSite system (St Jude, St Paul, MN, USA). The EnSite system enables two types of cardiac mapping methodologies; one utilizes the EnSite Array™ noncontact mapping catheter and the other is the EnSite NavX™ mapping and visualization technology. The noncontact mapping system utilizes a multielectrode array catheter to simultaneously record multiple areas of endocardial activation. This facilitates performance of high-density maps from even a single beat of tachycardia. EnSite NavX features real-time 3D catheter localization and navigation using externally applied surface patches that generate transthoracic electrical fields in three orthogonal directions. The electric field can locate electrodes on catheters and render a catheter shape so that their spatial position within the cardiac chamber is known [1]. In addition, it allows superimposition of 3D anatomical positions with local electrical information (e.g., activation time, entrainment information, electrogram amplitude and special electrogram characteristics).

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Algorithms of image integration allow cardiac 3D images to be obtained from CT/MRI scans to be used within the 3D mapping system.

This article will focus on EnSite NavX with its new features.

Introduction to the technology

The general principle of electrical impedance-based intracardiac catheter visualization was validated initially in 74 patients. The study evaluated localization stability, localization accuracy, externally applied field strength and influences of cardiac and respiratory motion [1]. During a time interval of 128 ± 82 min, the electrode localization was stable with an average change in position of 0.2 ± 1.7 mm for the X, 0.1 ± 0.3 mm for the Y and 0.2 ± 0.6 mm for the Z direction [1]. In EnSite NavX the field frequency allows separation of biopotentials and the radiofrequency ablation current does not interfere with local electrogram quality and enables catheter tracking during ablation [2]. The transthoracic current does not create any patient discomfort.

During 3D mapping procedures, three different types of electrophysiological analyses are needed: activation/entrainment mapping, voltage mapping or purely anatomical maps. During sequential mapping, EnSite NavX allows acquisition of 3D anatomical points together with local activation time or local entrainment information. The points can be projected and color–coded on a preacquired 3D chamber anatomy (Figure 1). Currently, this technique represents the preferred approach to study inducible, sustained and hemodynamically tolerated arrhythmias. In patients with noninducible, nonsustained or hemodynamically unstable arrhythmias, information on local electrogram amplitude can be used to delineate diseased or even scarred myocardium in a 3D fashion, and to plan linear ablation strategies during sinus rhythm – so-called voltage mapping (Figure 2). The third type of mapping required commonly for ablation procedures is the pure reconstruction of a 3D chamber anatomy. This type of mapping procedure is mainly needed for anatomically based ablation concepts, such as the treatment of AF (Figure 3). For 3D anatomical maps, the focus lays on the accuracy and resolution of the map to enable a realistic anatomical orientation. When using EnSite NavX, reconstruction of cardiac chamber anatomies can be performed by moving multipolar catheters along the endocardial surface and collecting a 'cloud' of anatomical points from multiple electrode poles simultaneously. This technique, also called 'multipoint mapping', offers fast acquisition of 3D cardiac chamber geometries.

The EnSite system, using both EnSite NavX navigation and visualization technology, and/or the EnSite Array noncontact catheter, is an established technology for mapping and ablation in patients suffering from the aforementioned complex cardiac arrhythmias. However, limitations of the current EnSite system platform relate to technical handling, 3D accuracy and image registration and intracardiac electrogram quality. Regarding technical handling map stability, user interface design

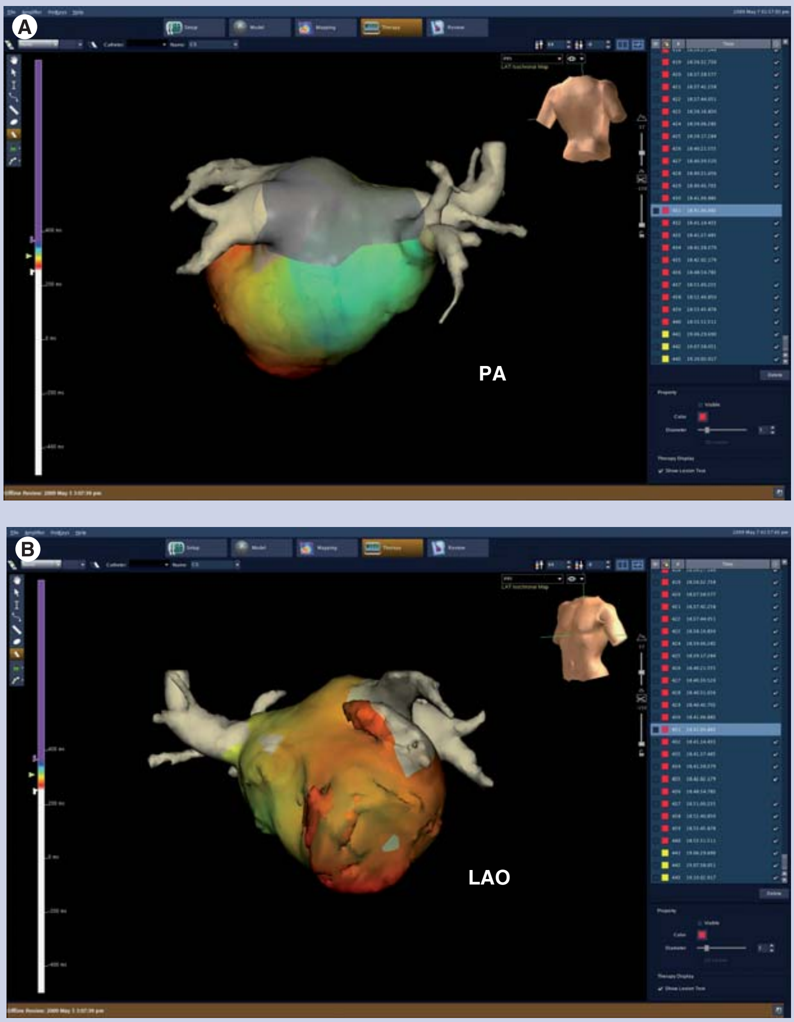

Figure 1. 3D entrainment map with EnSite Velocity™ in a patient after previous ablation of persistent atrial fibrillation (pulmonary vein isolation, box lesion, mitral isthmus line) and recurrences of symptomatic macro-re-entrant tachycardia. (A) Persistent isolation of pulmonary veins and the posterior box lesion is shown as scar area (gray) in a posteroanterior projection. **(B)** Entrainment mapping revealed a perimitral macro-re-entrant tachycardia (color-coded in orange) that terminated after placement of an endocardial mitral annulus line (left anterior-oblique projection).
LAO: Left anterior-oblique; PA: Posteroanterior.

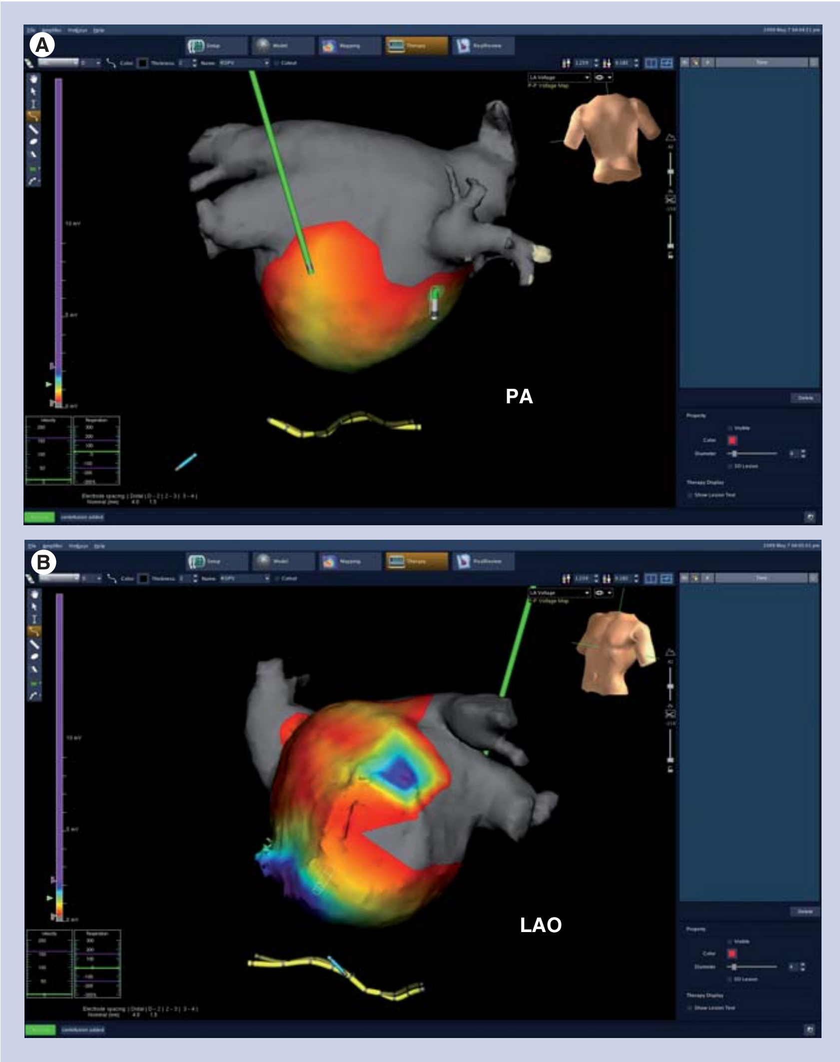

Figure 2. Voltage mapping using EnSite Velocity™ in a patient with previous cardiac surgery (aortic valve replacement, closure of left atrial appendage) and concomitant ablation of atrial fibrillation. Here the patient presented with symptomatic macro-re-entrant tachycardia. **(A)** Changing macro-re-entrant tachycardias and degeneration into atrial fibrillation prevented activation or entrainment mapping. Therefore, voltage mapping of the left atrium was performed during sinus rhythm showing absence of pulmonary vein reconduction, as well as complete box isolation. **(B)** Consecutively, lesions were placed between the left atrial appendage and the mitral annulus. Ablation was performed in the coronary sinus and the superior vena cava was isolated.
LAO: Left anterior-oblique; PA: Posteroanterior.

and mapping point access have to be considered. In particular, the inability of simultaneous chamber reconstruction and electrical mapping point acquisition represent an unmet need. Regarding 3D accuracy, electrical field distortions are an inborn limitation of the technology. The accuracy of integration of preacquired 3D cardiac images is ultimately linked to the quality of the registration process, which is highly operator-dependent and requires a significant amount of experience.

Components & new features of EnSite Velocity

EnSite Velocity consists of four hardware components: mapping catheter, patient interface unit, computer workstation with user interface and a small 'NavLink' or 'ArrayLink' to facilitate connections. A breakout box known from older EnSite system platforms is no longer part of the hardware setup.

The technology is based on the principle that when an electrical current is applied across two electrodes a voltage gradient can be measured along the electrode axis. With a pair of electrodes placed on the thorax, EnSite NavX measures the local voltage on the electrode and calculates the electrode position along the axis. In clinical practice three pairs of surface electrodes are placed opposite the thorax in anterior–posterior, left–right and cranio–caudal positions (Figure 4). The electrodes are connected with EnSite NavX alternately emitting a 5.6-kHz current signal and creating a corresponding voltage gradient [3]. In the EnSite Velocity platform the sampling rate has been increased to 8.136 kHz in order to improve the 3D localization accuracy. With older EnSite versions, 3D localization repeatability was measured to be 0.7 ± 0.5 mm in animal studies [4]. Currently, comparative data for EnSite Velocity do not exist.

Similar to older EnSite system platforms, EnSite Velocity represents an open system, where different types of electrode catheters manufactured by different medical device companies can be used and visualized without fluoroscopy. The system is compatible with catheters for cryoablation and radiofrequency ablation. In older EnSite versions up to 12 catheters with a total of 64 electrodes can be located simultaneously and displayed in real-time. In EnSite Velocity the number of visualized electrodes has been increased to 128 and the number of catheters that can be displayed is, in principle, unlimited.

As a unique feature, the EnSite NavX technology provides an algorithm for compensation of catheter shifts due to respiratory motion. It is based on the identification of breathing-dependent changes of transthoracic impedances. Respiratory compensation is one of the prerequisites for successful image integration and subsequent 3D model-guided therapy, where planning and placement of ablation lines is being performed within the integrated 3D image

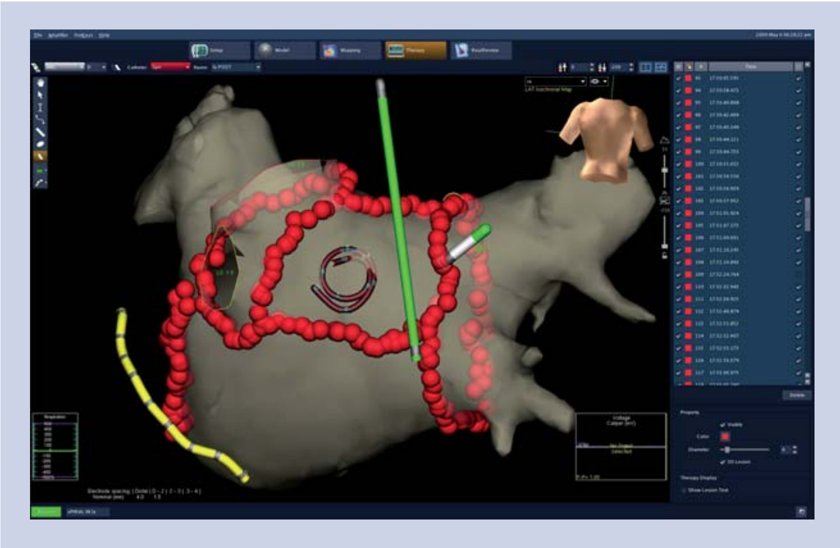

Figure 3. Anatomically guided lesion line concept applied in a patient with persistent atrial fibrillation guided by EnSite Velocity™ (posteroanterior view). The procedure was performed within an integrated 3D computerized tomography image of the left atrium without further chamber reconstruction. Red-colored lesion points display 3D ablation lesions. Circumferential left atrial lesions were deployed around the antrum of the left- and right-sided pulmonary veins and additional linear ablation lines were placed in the left atrium for further substrate modification (box isolation of the posterior left atrium, mitral isthmus line). Electrical isolation was tested with a multipolar mapping catheter. The coronary sinus catheter (yellow) and the intraesophageal temperature probe (green) are also shown.

of the respective cardiac chamber without the need for catheter-based 3D anatomy reconstruction. For left atrial procedures, experience only exists to reconstruct the pulmonary vein anatomy with a multipolar mapping catheter and to use this information as a landmark surface for the registration of the entire left atrium (Figure 5) [5].

By aligning early and late activation points within a re-entrant circuit, the 'Re-entrant Map' feature, already available in the older version, is designed to enhance the understanding of activation maps during MRT. However, EnSite Velocity is the first version to allow simultaneous collection of chamber model points and electrical information. This feature, called the 'OneMap tool', allows chamber electrical information to be collected from all of the electrodes on the active catheter.

New important features of EnSite Velocity contain a wider user interface monitor with a new user interface surface aiming to improve handling and procedural workflow. 'RealReview' allows simultaneous analysis of the live procedure on one side of the screen and a prerecorded segment in the other. New noise filters have been introduced to improve the quality of intracardiac electrogram recordings. Owing to an increased usage of robotic catheter navigation, EnSite Velocity will be integrated with Hansen technology. In the 3D map it will allow display of the mechanical contact force, which is measured through a sensor within the Hansen sheath (Figure 6). Currently, this technology is not available commercially.

Clinical profile & postmarketing findings

Owing to the recent release, clinical data with EnSite Velocity are still lacking. Published work on the clinical value of EnSite NavX was performed with older platforms of the technology.

In 2004 and 2005, initial studies described the use of EnSite NavX for nonfluoroscopic anatomical orientation for ablation of simple arrhythmias, such as AVNRT, accessory pathways or isthmus-dependent right atrial flutter [2,6]. Since activation mapping was not available at that time, the utility of EnSite NavX was limited to 3D nonfluoroscopic catheter orientation and chamber model creation. Concordantly, through all publications, the system could significantly reduce radiation exposure. That benefit was further supported by two studies describing complete mapping and ablation of supraventricular arrhythmias without any fluoroscopy in an infant population [7,8].

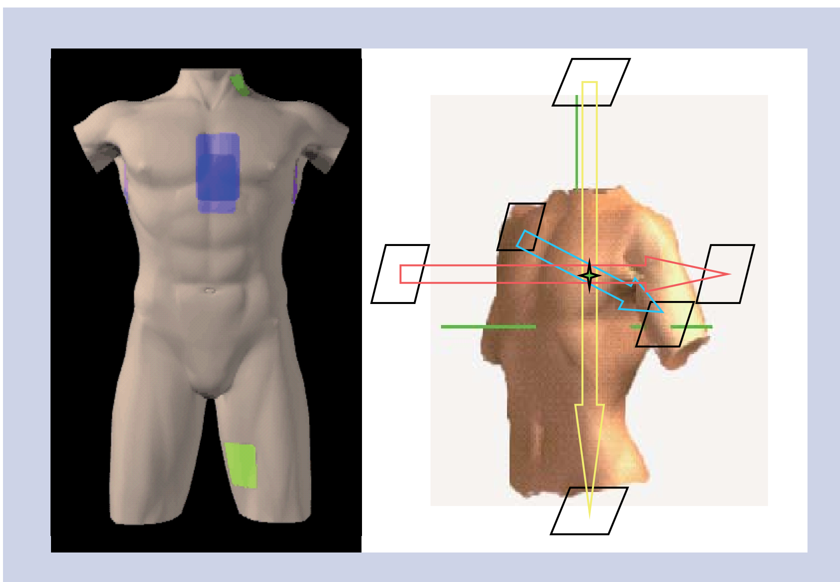

Figure 4. Placement of three pairs of surface electrodes opposite the thorax in anterior–posterior, left–right and cranio–caudal positions.

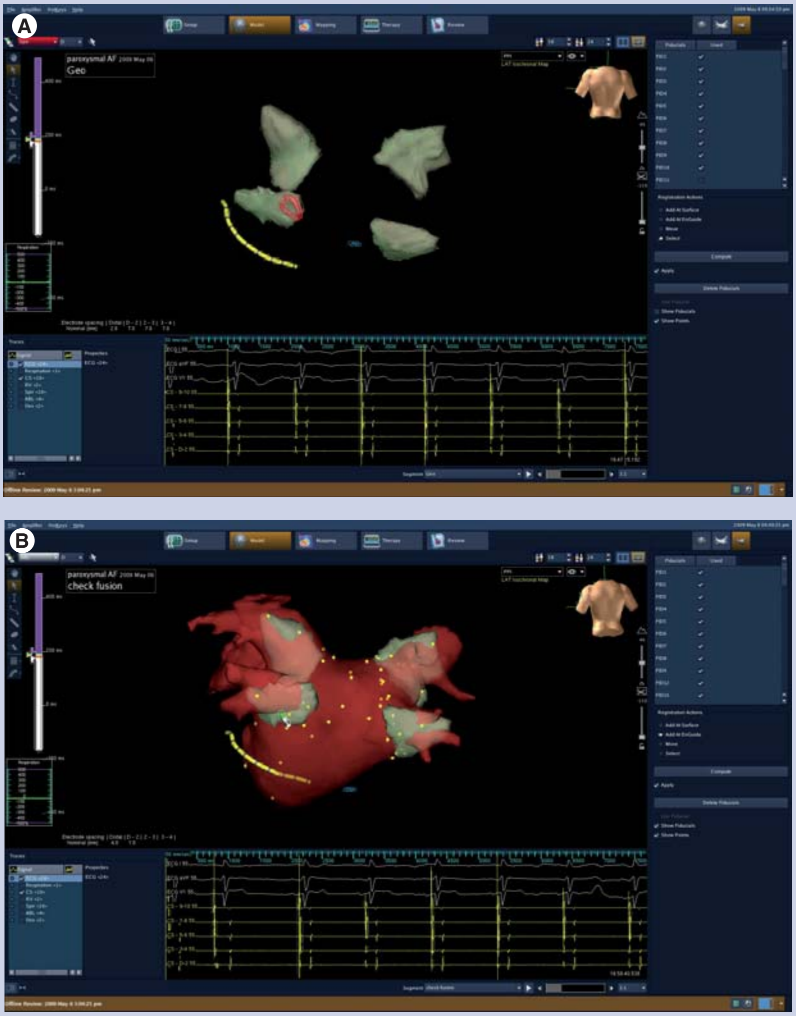

Figure 5. Registration of 3D computed tomography image of the left atrium into the real-time mapping system (EnSite Velocity™) based on reconstruction of the four pulmonary vein anatomies (posteroanterior view). (A) Pulmonary vein reconstruction was achieved through automatic anatomic point acquisition through all ten poles of a multipolar circular mapping catheter (red circle) while slowly withdrawing the catheter out of each pulmonary vein. In the picture, all four pulmonary veins have already been reconstructed, with the circular mapping catheter just being withdrawn from the left lower pulmonary vein. (The yellow line indicates the coronary sinus catheter). **(B)** The NavX™ reconstructed pulmonary vein anatomy was fused with the 3D computed tomography pulmonary vein images. After that main registration step, further fine adjustment was achieved through additional points visited with the ablation catheter (yellow points).

After these initial clinical reports the technology was also applied for ablation of complex left atrial arrhythmias, such as AF. In a study using circular mapping catheter-guided pulmonary vein isolation (PVI) for treatment of AF the system helped to reduce procedure and fluoroscopy time at similar success rates [9].

Currently, EnSite NavX represents an established nonfluoroscopic 3D cardiac mapping system that is able to guide complex left atrial ablation procedures. The feasibility of successful placement of complex linear ablation line concepts guided by an integrated 3D image alone, rather than catheter-based virtual chamber surface reconstructions, could be demonstrated in two studies including patients with AF and atrial MRT [5,10].

Other areas of possible clinical use have been shown by case publications reporting on nonfluoroscopic pacemaker implantation using EnSite NavX [11]. However, more clinical data are necessary to be able to fully judge that approach.

Commonly used alternative technologies

As for cardiac 3D mapping systems, the CARTO technology (Biosense Webster, Diamond Bar, CA, USA) represents a second widely used approach to localize and visualize an intracardiac catheter in a 3D fashion without the use of fluoroscopy. The technology is based on three low-level electromagnetic fields delivered from three separate coils located underneath the patient's thorax. Using these fields, specialized catheters containing an embedded magnetic sensor can be located in 3D space. The system provides excellent precision in locating the catheter tip with an accuracy of 0.54 ± 0.05 mm [12]. Most recently, the CARTO technology has been widened by implementing current-based 3D catheter localization on top of the underlying sensor-based electromagnetic field localization principle (CARTO-3).

From a clinical electrophysiological point of view, CARTO provides comparable algorithms for color-coded 3D activation mapping, voltage mapping or purely anatomical chamber mapping. Image integration is also part of the CARTO technology.

The comparison between both technologies shows specific advantages and disadvantages. Most importantly, the EnSite Velocity system with EnSite NavX is an open system, where multiple catheters from different manufacturers can be visualized. Older CARTO versions were always dependent on a single specialized catheter with an embedded sensor. With the CARTO-3 platform the system has, in principle, also been opened to other catheter manufacturers. However, 3D visualization of catheters without a Biosense-sensor is limited to a 3D volume called 'matrix', which has to be predefined using a Biosense-catheter. Therefore, in clinical practice the system is not open.

Figure 6. EnSite NavX™ screen demonstrating a 3D map of the left atrium in a right posterior oblique view displaying the tip of the Hansen sheath measuring mechanical contact force. The sheath can be displayed on fluoroscopy simultaneously. Furthermore, intracardiac echo is displayed on the screen below. Indicators of mechanical contact force are available as real-time meters and in a trend diagram.

Location accuracy of the CARTO system is higher (3D localization repeatability in animal studies 0.54 ± 0.05 mm [12] vs 0.7 ± 1.5 mm [4]). Two factors are likely to contribute to this observation: first, CARTO not only shows location but also direction of the catheter tip; second, electrical field distortions seen with EnSite NavX do not occur with CARTO.

As an advantage compared with CARTO, EnSite NavX is the only 3D mapping system containing algorithms for respiratory compensation. Additionally, map dislocation following patient movement is less likely owing to firmly attached body patches. Furthermore, NavX EnSite is currently the only 3D mapping system allowing to simultaneously pace and ablate from the tip of the ablation catheter, which is an evolving end point for circumferential PVI in patients with AF [13–16].

Conclusion

During recent years the EnSite NavX technology has evolved as one of the main representatives of nonfluoroscopic 3D cardiac mapping systems. The ability to visualize multiple electrode catheters without the use of fluoroscopy together with accurate anatomical reconstructions and an advanced image integration technology have made EnSite NavX a helpful tool to understand and successfully treat simple and complex cardiac arrhythmias. EnSite Velocity represents the latest platform of the technology. Algorithms have been implemented to overcome limitations of older versions. These include new noise filters, the OneMap tool and the RealReview feature. Furthermore, EnSite Velocity will be integrated with Hansen technology displaying mechanical contact force. In clinical routine, the system is stable and reliable.

Expert commentary

As first clinical evaluation we have used the EnSite Velocity platform in 213 patients (93 female, 120 male; aged 61 ± 9 years) with AF and atrial MRT. A total of 152 patients were treated during an initial ablation procedure and 61 patients presented with arrhythmia recurrences after previous ablation attempts. The clinical arrhythmia leading to ablation treatment was paroxysmal AF (n = 119), persistent AF (n = 56) and atrial MRT (n = 38). The treatment strategy consisted of wide circumferential PVI with proven bidirectional conduction block in patients with paroxysmal AF. In patients with persistent AF a 'box' lesion electrically isolating the posterior left atrium and a mitral isthmus line were also created. In patients with MRT, electrical analysis (3D color-coded entrainment mapping) and ablation line placement for treatment of all inducible re-entrant circuits was being performed.

Using EnSite Velocity, procedure duration and fluoroscopy time were measured as 118 ± 58 and 4 ± 17 min, respectively. The procedural electrophysiological end point was achieved in 117 out of 119 patients with paroxysmal and in 52 out of 56 with persistent AF, as well as in 34 out of 38 patients with MRT.

During the procedure, EnSite Velocity was stable and map shifts did not occur. Handling of the new user interface surface was easy. Using the described technique of pulmonary vein-based image integration and fully 3D model-guided therapy, 3D orientation was excellent.

Five-year view

Current developments of both of the most widely used 3D cardiac mapping systems converge by integrating both principles of electrical impedance-based and electromagnetic sensor-based 3D catheter localization technologies, a concept that has been indicated and has been followed with CARTO-3 most recently. Each localization principle carries specific advantages and disadvantages, which makes a combination clinically reasonable. As for the EnSite Velocity platform, the inborn limitations in field distortion and location accuracy are likely to be overcome with an adequate electromagnetic sensor technology. Incorporation of such a technology within a platform for clinical usage seems likely. That development does not only carry advantages of more precise catheter localization, but it also offers the possibility for further improved algorithms to compensate for cardiac and respiratory motion – one of the main limitations for 3D mapping and orientation in a moving organ, such as the heart. In the end it could provide the basis for automatic registration protocols after periprocedural 3D cardiac imaging, such as rotation angiography or 3D echocardiography, and it would pave the way for approaches of intraprocedural 4D imaging of cardiac anatomies together with the intracardiac catheters introduced for arrhythmia treatment.

Financial & competing interests disclosure

Gerhard Hindricks and Christopher Piorkowski have received lecture honoraria from St Jude Medical. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Key issues

- Catheter ablation is a potentially curative treatment option for a wide range of arrhythmias.
- Accurate spatial anatomical and spatial electrical orientation is essential for treatment of arrhythmias with a complex 3D substrate, such as atrial fibrillation.
- EnSite Velocity™ represents the latest platform of the EnSite NavX™ technology, an electrical impedance-based 3D cardiac mapping system.
- EnSite Velocity represents an open platform, enabling 3D visualization of multiple intracardiac catheters from different manufacturers.
- Fusion algorithms and respiratory compensation enable real-time nonfluoroscopic visualization of intracardiac catheters within registered 3D computerized tomography/MRI images.
- The 'Re-entrant Map' feature is designed to enhance the understanding of activation maps during macro-re-entrant tachycardia by aligning early and late activation points within a re-entrant circuit.
- Algorithms have been implemented to overcome limitations of older versions:
  - New noise filters have been introduced to improve the quality of intracardiac electrogram recordings
  - The chamber model can be created and electrical information simultaneously applied using the 'OneMap tool'
  - The 'RealReview' feature allows simultaneous analysis of the live procedure on one side of the screen and a prerecorded segment in the other
  - EnSite Velocity will be integrated with Hansen technology displaying mechanical contact force.

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