Non-fluoroscopic Catheter Tracking for Interventional Electrophysiology Procedures: The MediGuide System

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ABSTRACT. We describe our first experience with a new technological platform, the MediGuide™ (MG) technology, which allows non-fluoroscopic catheter tracking on prerecorded cine loops. Since 2011 we have treated over 200 patients with this technology; we report on our experiences working with the system with just diagnostic electrophysiology (EP) catheters available and on our first 25 cases treated for different arrhythmias with an MG-equipped ablation catheter. We also present some examples for left ventricular (LV) lead implantation using percutaneous coronary intervention (PCI) wires with a sensor at the tip. In the first analysis of our patients treated with MG technology, it was demonstrated that the efficacy of the procedures was identical to our standard approach and that the fluoroscopy time could be dramatically reduced. This has been shown for atrial fibrillation, typical atrial flutter, and LV electrode implantation. The reduction in fluoroscopy exposure was achieved by using a diagnostic MG catheter only. Our initial experience with a sensor-equipped ablation catheter shows that an additional reduction can be expected: atrial fibrillation cases with <2 min of fluoroscopy were performed first. MG is a tracking technology allowing visualization of dedicated catheters within chamber models on prerecorded cine loops. Integration with an established electroanatomical mapping system (EAMS) provided the first algorithms to facilitate mapping in the EAMS environment. As a first measurable clinical impact, MG was able to reduce fluoroscopy exposure dramatically for various EP indications.

KEYWORDS. ablation, atrial fibrillation, image integration, mapping, non-fluoroscopic.

MG: technology description

The MG technology has been described previously.2–5 The system consists of a transmitter unit generating a dynamic electromagnetic field and miniaturized by conventional fluoroscopy. Recently, a novel sensor-based 3D catheter tracking system has been introduced, integrating 3D non-fluoroscopic catheter navigation into the environment of prerecorded conventional two-dimensional (2D) fluoroscopy (MediGuide™ (MG) Technology, St. Jude Medical Inc., St. Paul, MN). A unique characteristic is that it is co-registered with fluoroscopy imaging, allowing catheter tracking within cardiac chamber models compensated for primary and secondary organ motion.2–5 We report the first clinical experience with this tracking technology for catheter ablation.
Figure 1: Three ways of displaying a catheter: “live” fluoroscopy in a left anterior oblique (LAO) 60° projection is shown on the left. Two diagnostic decapolar catheters are inserted: one is placed in the coronary sinus (yellow tip) and one is placed in the right ventricular apex (green tip). The catheters including the shaft are seen using fluoroscopy; the two catheter tips are additionally displayed by the MediGuide System. On the right side, a three-dimensional mapping system, EnSite™ Velocity™ system is shown in the right anterior oblique and LAO views, also showing the two catheters.

Figure 2: Coronary sinus (CS) catheter (yellow tip) and mapping catheter (green tip) displayed by the MediGuide System. Markers have been set for the superior vena cava (pink ring, blue arrow) and the inferior vena cava (pink ring, red arrow) and the CS ostium (pink ring, yellow arrow). The His position has been marked with a blue dot. The fossa ovalis has been marked with a yellow dot. On the right, the corresponding electroanatomical map is shown in a left anterior oblique projection with the tricuspid annulus (yellow dots), the right atrium (green shell), the inferior and superior vena cava (blue shells), the His (green dot), and the CS catheter (yellow).
single-coil sensors which can be tracked within that field. The sensors are mounted on intracardiac devices (such as diagnostic electrophysiology (EP) catheters). A reference sensor attached to the patient’s chest provides information about the spatial relationship between the patient and the tracking field. The transmitter unit is installed within the fluoroscopy detector of a conventional flat-panel X-ray imaging system (Siemens Artis Zee 20×20, Erlangen, Germany). Owing to this hardware set-up, fluoroscopy imaging and electromagnetic sensor tracking are pre-aligned and autoregistered. With three-dimensional (3D) localization of those sensors, a real-time visualization and navigation within a cardiac chamber on preacquired X-ray cine loops is provided. Built-in algorithms compensate catheter tracking and image display for respiration, cardiac motion, and patient movement.

**MG positional reference**
Integration of MG with the EnSite™ Velocity™ system allowed using the sensor equipped coronary sinus catheter as a positional reference for the 3D mapping system. The sensor’s 3D location was continuously monitored to detect map shifts which result from reference catheter displacement. These shifts can be managed at the operator’s discretion by repositioning the catheter into the initial MG recorded 3D location, or recalibrating the field and the map position towards the new location of the MG equipped reference catheter.

**MG for typical atrial flutter (using 3D mapping systems)**
When the ablation catheter was not available, two diagnostic sensor-equipped catheters were used for these procedures. First, two cine loops were recorded, each of them 2–3 s. Those loops were constantly displayed; the position of the sensors are calculated and superimposed to create a “virtual” biplanar view. One catheter was placed in the coronary sinus, the other catheter was used for mapping right atrial structures (Figure 1). After electroanatomical reconstruction of the right atrium, the superior and inferior vena cava, the coronary sinus, and the tricuspid annulus, an ablation line on the cavotricuspid isthmus was drawn using a conventional ablation catheter. Using this method, the fluoroscopy time could be reduced to 2.4 min in a series of 10 consecutive patients (Figure 2). In a case-control group of 10 patients being treated with the 3D mapping system “only,” we observed a reduction from 10.5±6 to 2.4±2 min (p=0.001) by the additional use of the MG system.

**MG system for typical atrial flutter (as “stand alone”)**
Since ablation catheters are also available with MG technology, EP procedures like isthmus ablation for typical flutter can be performed with the MG system as a
stand-alone support. After acquisition of the two cine loops, the two diagnostic catheters were inserted and an open-irrigated tip ablation catheter with an MG sensor was used to achieve bidirectional isthmus block. Besides 6 s of fluoroscopy (prior femoral puncture), no additional fluoroscopy was used and the operator was able to work without lead protection (Figure 3).

**MG system for atrial fibrillation**

We have recently demonstrated that by using diagnostic catheters with MG sensors, the fluoroscopy time for AF ablation could be reduced by 50% (from 31 min to 16 min).\(^5\) Our initial experience using the irrigated-tip ablation catheter showed even further reduction, with a minimum fluoroscopy time of <2 min.

In AF procedures, it is very helpful not only to have native cine loops serving as a background for the catheter display, but to perform angiographies of the left atrium. In most of our cases, we inserted a pigtail catheter in the pulmonary artery and injected contrast dye (approximately 50 ml); loop acquisition was started 4–5 s after the onset of the injection. During the entire procedure, all MG catheters were permanently shown as an overlay on these angiographies, which facilitates the procedure significantly, particularly in inexperienced hands (Figure 4).

Besides a decrease in radiation exposure, there is a second important advantage of the system, which is improved spatial resolution of the 3D mapping systems. The EnSite Velocity system has a second source for catheter localization, i.e., the sensor-derived data. This improves the quality of the 3D electroanatomical reconstruction and facilitates precise registration of 3D computed tomography models (Figure 5).

**MG for ventricular tachycardia ablation**

Owing to distortions in border regions of the electromagnetic field, geometries of the ventricles sometimes looked unrealistic. This weakness is overcome with the introduction of MG: also in ventricular tachycardia (VT) procedures the 3D mapping systems profits significantly from the additional localization information related to sensor technology. The maps are much closer to reality and again, permanent catheter tip visualization on left ventricular angiography improves the quality of 3D

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**Figure 4:** Right anterior oblique view showing the coronary sinus catheter (yellow tip) with an additional marker at the tip (pink) and at the ostium (yellow), markers for inferior and superior vena cava (pink ring), markers for the pulmonary vein ostia (Left Inferior Pulmonary Vein: brown; Left Superior Pulmonary Vein: blue; Right Inferior Pulmonary Vein: red; and Right Superior Pulmonary Vein: green), the mapping catheter with MG sensor is displayed with a green tip (located in the left inferior pulmonary vein). Additionally the pigtail catheter for contrast dye injection can be seen in the pulmonary artery. During the injection the right coronary artery can be seen (yellow arrows).
understanding of the underlying substrate (Figure 6). Substrate analysis with voltage mapping can be performed without fluoroscopy under permanent guidance of the sensor-equipped catheters (Figure 7). The rate of complications in our VT patient cohort is comparable with conventional procedures; in particular, no increase in the rate of perforations or tamponades were observed.

**MG for CRT implantation**

The implantation of devices for cardiac resynchronization therapy (CRT) is demanding and is often associated with high radiation exposure due to long fluoroscopy times and being positioned very close to the radiation source. In the field of CRT implantations, the MG system has two advantages: first is the possible reduction in fluoroscopy time, and second is the option to follow the devices in the left anterior oblique projection, but having the C-arm in a comfortable anterior-posterior or even right anterior oblique projection.

Special tools are required for CRT implantations such as subselectors and wires. In a series of 15 patients we were able to work with 0.14mm percutaneous coronary intervention (PCI) wires that were equipped with MG sensors (Figures 8 and 9). In all patients, we succeeded to implant the LV electrode using the MG system. The average fluoroscopy time was <3 min for LV placement only, and <6 min for the entire procedure.

**Discussion**

*Catheter tracking in interventional EP*

Conventional fluoroscopy is the main technology for intracardiac device tracking in interventional cardiovascular procedures. For therapy delivery, it carries the strength to instantaneously localize the device and its spatial relationship towards the moving target organ. However, besides the associated X-ray exposure, fluoroscopy only provides 2D orientation. For treatment of complex cardiac anatomies and substrates such as in interventional EP, 3D mapping technologies have been introduced to facilitate spatial anatomical and electrical orientation.

These technologies carry two principal limitations. First, they are independent systems unrelated to the standard working environment of live fluoroscopy. Second, they only provide static maps and models of a moving target organ. However, over time intracardiac 3D locations are influenced by multiple components of primary and secondary organ motion.

The MG system represents a novel catheter tracking technology which, for the first time allows to localize three-dimensionally a catheter tip over time, and to instantaneously separate catheter movement caused by primary or secondary organ motion as well as the actual catheter manipulation. The tracking capabilities are autoregistered with an imaging system. Table 1 shows a comparison between conventional procedures in our
Figure 6: Left ventricular angiography serving as the background for catheter visualization. Standard positions for ventricular tachycardia cases with one catheter in the right ventricular apex (red tip) and one catheter in the coronary sinus (yellow tip). A pigtail catheter is placed in the left atrium via transseptal access with a long, steerable sheath. The left ventricle with a large anterior wall aneurysm is marked with a line.

Figure 7: Voltage map in the three-dimensional mapping system (b) shows a large apical aneurysm. The ablation around the scar tissue was performed with a MediGuide ablation catheter. This tip was visualized in green (a) in right anterior oblique (lower) and left anterior oblique (upper) using left ventricular angiography as a background. Intensive substrate modification around the scar area was performed. The procedure time was 180 min, and the fluoroscopy time was 2.6 min.
**Figure 8:** Cardiac resynchronization therapy implantation with MediGuide. The superior vena cava was marked with a yellow ring, the coronary sinus was intubated with a steerable diagnostic catheter (pink tip), the coronary sinus (CS) ostium was marked with a blue ring, the shaft of the CS sheath (yellow tip) is taken from an interpolation between the superior vena cava and the CS ostium. The CS sheath can easily be advanced over the CS catheter. Right ventricular and Right Atrial electrodes are already implanted.

**Figure 9:** Coronary sinus angiography serving as the background for MediGuide. A subselector was advanced in the ostium of the target vein (blue arrow) and a percutaneous coronary intervention wire was placed in a target position (red arrow). Over that wire a conventional left ventricular electrode is implanted.
Table 1: Comparison of procedural data of MediGuide-supported ablations and conventional procedures. Data are given as mean values ± standard deviation

<table>
<thead>
<tr>
<th></th>
<th>Procedure time</th>
<th>Fluoroscopy time</th>
<th>Success rate</th>
<th>Tamponades</th>
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<tr>
<td><strong>Atrial flutter</strong></td>
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<td>Conventional</td>
<td>55 ± 8</td>
<td>10.5 ± 6</td>
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<td>MediGuide; n=10</td>
<td>66 ± 16; n.s.</td>
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<tr>
<td>Conventional</td>
<td>157 ± 51</td>
<td>31</td>
<td>69%</td>
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<td>174 ± 43; n.s.</td>
<td>16; p&lt;0.001</td>
<td>67%; n.s.</td>
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<tr>
<td>Conventional</td>
<td>148 ± 50</td>
<td>32 ± 17</td>
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<td>12 ± 18; p&lt;0.05</td>
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<td><strong>CRT implantation</strong></td>
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<td>Conventional</td>
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Data for atrial flutter and atrial fibrillation are taken from two publications; data for conventional ventricular tachycardia are from a study cohort; data for cardiac resynchronization therapy were presented at Heart Rhythm Society Annual Meeting 2012 by S. Richter.

n.s.: not significant.

in institution and MG-supported ablations focusing on radiation time, procedure time, and complication rates. In all these preliminary data, we can observe that radiation exposure is reduced dramatically, the procedure time is slightly but not significantly increased, and no additional complications seem to occur, with the limitation of relatively small numbers (Table 1).

**MG: clinical impact**

This initial experience demonstrates that the system is working in a safe and reliable way. The catheters with sensor technology are precisely displayed, even in procedures lasting >180 min. Further developments such as sensor-equipped PCI wires will probably open new fields of application besides interventional EP. In EP, the system offers an option to dramatically reduce radiation exposure to both the patients and the physicians. In addition, sensor-based catheter tracking provides precise spatial resolution and helps to improve the quality of our procedures performed with 3D mapping systems. A decrease in fluoroscopy time can also be realized by applying 3D mapping systems; there are reports about “almost zero” fluoroscopy procedures. The difference is that the MG system offers a fully motion-compensated catheter visualization in a way that is familiar to most operators, i.e. on fluoroscopy loops.

**References**