Ablation of Atrial Fibrillation Using Novel 4-Dimensional Catheter Tracking Within Autoregistered Left Atrial Angiograms

Sascha Rolf, MD; Philipp Sommer, MD; Thomas Gaspar, MD; Silke John, MD; Arash Arya, MD; Gerhard Hindricks, MD; Christopher Piorkowski, MD

Background—We describe a novel fluoroscopy coregistered, 4-dimensional catheter tracking technology (MediGuide Technology [MGT]) used for treatment of patients with atrial fibrillation. The aim of the study was to investigate (1) the feasibility of nonfluoroscopic catheter manipulation within dynamic left atrial chamber models; (2) the integration of the technology into an established electroanatomical mapping system; and (3) potential clinical impact.

Methods and Results—Forty-nine patients received atrial fibrillation ablation using MGT-enabled NavX-EnSite. Matched patients ablated with a conventional NavX-EnSite system served as a control group. MGT was used for the deployment of diagnostic catheters within preacquired cine loops, for nonfluoroscopic chamber mapping within dynamic angiograms, and for 4-dimensional tagging of anatomical landmarks. Integration with the electroanatomical mapping system allowed correction of field distortions and a reference tool to detect and correct map shifts. Catheter ablation was done without MGT because the ablation catheter was not MGT enabled. MGT worked safely and stably in all 49 patients. Catheter deployment within the preacquired cine loops was successfully performed in 45 of 49 (92%) patients. Catheter tracking within dynamic left atrial angiograms allowed nearly nonfluoroscopic creation of NavX-EnSite geometries with subsequent computed tomography model registration in all 49 patients. Overall, MGT significantly reduced total procedural fluoroscopy time (median [quartiles]) from 31 minutes (25, 43 minutes) to 16 minutes (10, 23 minutes) and irradiation dose from 14,453±7,403 to 7,363±5,827 cGy*cm² (mean±SD), respectively (P<0.001).

Conclusions—MGT is a tracking technology that allows 4-dimensional visualization of dedicated catheters within moving chamber models. Integration of the MGT with an established electroanatomical mapping system provided algorithms to facilitate mapping in the electroanatomical mapping system environment. As a first measurable clinical impact, MGT was able to reduce fluoroscopy exposure by nearly 50%.

Key Words: ablation ■ atrial fibrillation ■ 4-dimensional mapping ■ image integration ■ nonfluoroscopic

Cardiovascular Medicine

Catheter ablation has become a successful treatment option for atrial fibrillation (AF) with an increasing number of procedures worldwide.1 Because of the complexity of the procedure, 3-dimensional (3D) mapping technologies are routinely used to facilitate catheter navigation, arrhythmia mapping, and strategic lesion creation. However, conventional fluoroscopy is still the backbone imaging technology for intracardiac catheter manipulation.

Clinical Perspective on p 690

Recently, a novel, sensor-based electromagnetic tracking system (MediGuide Technology [MGT], St Jude Medical, Inc, St Paul, MN) has been introduced. The MGT adds information of primary and secondary organ motion to established methods of 3D catheter localization (4-dimensional [4D] catheter tracking).2 As a further unique characteristic, it is coregistered with x-ray cine loops, allowing catheter tracking within dynamic cardiac chamber models.3 We report the first clinical experience with this tracking technology for catheter ablation of AF.

The objective of this study was to investigate (1) the feasibility of nonfluoroscopic MGT catheter manipulation within angiographic left atrial (LA) chamber models; (2) the integration of the novel tracking technology into an established electroanatomical mapping system (EAMS); and (3) the potential impact of MGT on clinical patient outcome.

Methods

A case-control study was conducted at our institution between June and November 2010. Ablation procedures were performed by 5 operators with different levels of clinical experience. The institutional review board approved the study, and participants provided written and verbal informed consent.

Background—We describe a novel fluoroscopy coregistered, 4-dimensional catheter tracking technology (MediGuide Technology [MGT]) used for treatment of patients with atrial fibrillation. The aim of the study was to investigate (1) the feasibility of nonfluoroscopic catheter manipulation within dynamic left atrial chamber models; (2) the integration of the technology into an established electroanatomical mapping system; and (3) potential clinical impact.

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From the Department of Electrophysiology, University of Leipzig—Heart Center, Leipzig, Germany.
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Correspondence to Sascha Rolf, MD, Department of Electrophysiology, University of Leipzig—Heart Center, Struempellstr. 3904289 Leipzig, Germany.
E-mail sascha.rolf@web.de
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684
LVEF <45%.

Structural heart disease is coronary heart disease or valvular dysfunction or except for BMI, left atrial diameter, LVEF, diabetes mellitus, and history of AF.

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>All Patients (n=98)</th>
<th>MGT Group (n=49)</th>
<th>Control Group (n=49)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>60±10</td>
<td>60±10</td>
<td>60±10</td>
<td>0.37</td>
</tr>
<tr>
<td>Male (%)</td>
<td>78 (80%)</td>
<td>39 (80%)</td>
<td>39 (80%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Paroxysmal AF (%)</td>
<td>50 (51%)</td>
<td>25 (51%)</td>
<td>25 (51%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Arterial hypertension (%)</td>
<td>64 (65%)</td>
<td>32 (65%)</td>
<td>32 (65%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Structural heart disease (%)</td>
<td>12 (12%)</td>
<td>6 (12%)</td>
<td>6 (12%)</td>
<td>1.00</td>
</tr>
<tr>
<td>BMI*</td>
<td>28 (25, 31)</td>
<td>27 (25, 30)</td>
<td>28 (26, 32)</td>
<td>0.13</td>
</tr>
<tr>
<td>Left atrial diameter, mm</td>
<td>42±5</td>
<td>41±5</td>
<td>43±5</td>
<td>0.16</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>61±7</td>
<td>62±7</td>
<td>60±8</td>
<td>0.28</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>12 (12%)</td>
<td>8 (16%)</td>
<td>4 (8%)</td>
<td>0.22</td>
</tr>
<tr>
<td>History of AF (mo)*</td>
<td>60 (24, 122)</td>
<td>72 (31, 135)</td>
<td>50 (18, 119)</td>
<td>0.24</td>
</tr>
</tbody>
</table>

MGT indicates MediGuide Technology; AF, atrial fibrillation; BMI, body mass index; LVEF, left ventricular ejection fraction.

All parameters shown are matching criteria for case-control selection, except for BMI, left atrial diameter, LVEF, diabetes mellitus, and history of AF. Structural heart disease is coronary heart disease or valvular dysfunction or LVEF <45%.

*Non-Gaussian distribution.

Patients

Participants were adults (18–75 years of age) who had (1) paroxysmal or persistent symptomatic AF (documented on ECG); (2) a previously ineffective antiarrhythmic drug therapy (at least 1 antiarrhythmic drug); and (3) an LA diameter of <60 mm (parasternal long axis).

Forty-nine patients were prospectively included between June and November 2010. They received an AF ablation procedure using MGT-enabled NavX-EnSite Velocity (St Jude Medical, Inc; MGT group). Subsequently, these patients were retrospectively matched with 49 control subjects who were ablated without MGT using a conventional x-ray imaging system (Siemens Artis Zee 20×20 cm flat panel, Siemens, Erlangen, Germany) and a conventional EP catheter. The technology was used during the following stages of the catheter interventional procedure.

Image Acquisition of Cardiac Chamber Models

If allowed by renal function, LA angiograms were acquired in right anterior oblique (RAO) 20° to 30° and left anterior oblique (LAO) 50° to 60° before the introduction of the EP catheter. For each angiogram, 40 mL of nonionic iodinated contrast material (Ultravist 370) was injected through a pigtail catheter (Cordis, Bridgewater, NJ) into the common pulmonary artery trunk. Fluoroscopic image acquisition started after 4 seconds of lung passage time. Both angiography cine loops were recorded independently. For catheter tracking, the MGT was able to run both cine loops synchronously in a pseudobiplane mode aligned by real-time ECG and the respiratory phase.

Standard Catheter Deployment

Three sensor-equipped EP catheters were advanced into the heart, tracked, and 4D visualized within the preacquired cine loops. Based on 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 cm flat panel, Siemens, Erlangen, Germany). Because of this hardware setup, fluoroscopy imaging and electromagnetic sensor tracking are prealigned and autoregistered. Thus, sensor-equipped catheters can be localized in 3D in real-time resulting in 4D visualization within a moving organ image, such as preacquired x-ray cine loops. Built-in algorithms compensate catheter tracking and image display with respect to primary (ie, cardiac) and secondary (ie, respiratory) organ motion.

General Procedure Setup

Patients were studied under deep propofol sedation with continuous invasive monitoring of arterial blood pressure and oxygen saturation. After a single transfemoral puncture, mapping and ablation were performed under the guidance of NavX-EnSite Velocity (St Jude Medical, Inc), supplemented by 3D image integration. The algorithm to register the computed tomography (CT) model of the LA into the EAMS has been reported previously. Briefly, the 4 pulmonary veins (PVs) were reconstructed as individual NavX-EnSite anatomies and, subsequently, served as the anchor structures to register the 3D CT image. Fine adjustment of image integration was achieved with further fiducial points at predefined locations within the LA body.

In all patients, catheter navigation was facilitated using a steerable sheath (Agilis, St Jude Medical, Inc).

MediGuide: Technology Application

In the present study, the application of MGT was linked to the use of a diagnostic decapolar EP catheter (Livewire™, MediGuide Enabled™, St Jude Medical, Inc), which is the first clinically approved MGT EP catheter. The technology was used during the following stages of the catheter interventional procedure.

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on these dynamic models, the catheters were routinely, and if possible, nonfluoroscopically, positioned into the coronary sinus (CS), into the right ventricular apex and at the bundle of His (online-only Data Supplement Movie I). As a safeguard, in case of uncertainty, the operator was advised to use confirmatory live fluoroscopy of the in vivo situation of the MGT catheter.

**Placement of Intracardiac Location Markers**

To improve orientation, 1 of the sensor catheters was used to place 3D markers at dedicated intracardiac locations such as the bundle of His, the oval fossa, the superior/inferior caval vein, and the PV ostia (online-only Data Supplement Movie II and Movie IVa Vla). These markers allow real-time tracking of the targeted intracardiac location independent from C-arm angulations and compensated for table or patient motion. The location can be tracked on preacquired cine loops, as well as during live fluoroscopy (online-only Data Supplement Movie III; Figure 2).

**Registration of LA CT Model into NavX-EnSite**

Registration of the LA CT model into NavX-EnSite has been described above. Specific for MGT procedures, a sensor-equipped EP catheter was temporarily used in the LA. LA angiographies, which served as the background movies, were helpful in nonfluoroscopically navigating the catheter to the structures of interest in real time (online-only Data Supplement Movie IVa). The MGT-equipped catheter served to reconstruct the NavX-EnSite PV anatomies (online-only Data Supplement Movie IVb) and to locate the fiducial points (online-only Data Supplement Movie IVc).

**Field Scaling of NavX-EnSite Coordinates**

To integrate MGT with an existing EAMS, the 3D coordinate system is automatically aligned with NavX-EnSite Velocity coordinates. As a first clinical application, this combination of the coordinate systems leads to an algorithm that corrects impedance-based field distortions. The algorithm is based on pairs of MGT/NavX 3D points acquired for each 3D location, which is visited with a sensor-equipped MGT catheter. Combining the spatial information of such point pairs results in the so-called field scaling algorithm.

**MGT Positional Reference**

The sensor-equipped CS catheter was used as a positional reference for the EAMS. Integration of MGT with NavX-EnSite Velocity allowed the sensor’s 3D location to be continuously monitored to detect map shifts, which result from reference catheter displacement. These shifts could be managed to the operator’s discretion by (1) repositioning the catheter into the initial MGT-recorded 3D location; or (2) recalibrating the field and the map position to the new location of the MGT-equipped reference catheter.

**Ablation**

In both patient groups, ablation was performed using a conventional irrigated tip ablation catheter (M-Curve IBI Therapy CoolFlex™, St Jude Medical, Inc) because MGT-enabled ablation catheters are not yet available for clinical use (Figure 2). Radiofrequency alternating current was delivered in a unipolar mode between the tip electrode and an external back plate electrode. The standard ablation setting consisted of an upper temperature limit of 45°C, a power of 40 W, and an irrigation flow rate of 17 mL/min. Near the esophagus, power delivery was reduced to 25 W and was further adapted according to the actual temperature increase recorded on an intraesophageal temperature probe (Sensitherm, St Jude Medical, Inc).

**Ablation Strategy and Procedural End Point**

In all patients, circumferential ablation around both ipsilateral PVs was performed at the atrial side of the PV antrum. In addition, patients with persistent AF received a box lesion electrically isolating the posterior LA and a mitral isthmus line extending from the left lower PV to the mitral annulus. Ablation of the right atrial cavitricuspid isthmus was performed in patients with clinically documented, isthmus-dependent right atrial flutter only. The procedural end point was electrophysiologically proven bidirectional conduction block for the PV encircling ablation lines and the posterior box lesion. Gap detection and line verification were performed using the pace-and-ABLATE approach, as described previously. Results were confirmed in all patients with a circular mapping catheter (Optima, St Jude Medical, Inc).

**Postprocedure Care and Follow-Up**

Serial 7-day Holter ECGs (Lifecard CF, DelmarReynolds Medical Inc, Irvine, CA) were recorded immediately after ablation and at 3 and 6 months postablation. The initial 3 months were defined as the blanking period. Episodes of AF and macroreentrant tachycardia qualified as arrhythmia recurrences if they were documented on ECG and lasted longer than 30 seconds. Antiarhythmic medication was discontinued after ablation and patients received a β-blocker. In case of symptomatic arrhythmia, recurrences medication was allowed to be adapted according to the investigator’s discretion. Starting the day after the ablation procedure, patients received oral anticoagulation with an international normalizes ratio of 2-3. Anticoagulation was discontinued after the 6-month follow-up, according to the CHADS2 score.

**Data Analysis**

Data were tested for normal (Gaussian) distribution using Kolmogoroff–Smirnov test. Normally distributed continuous variables are presented as mean±SD. In case of a non-Gaussian distribution, median (quartiles) are given. Categorical variables are expressed as number and percentage of patients.

Differences of continuous, normally distributed data between the case and the control groups were tested for statistical significance using the t test for paired data. In case of continuous data with a non-Gaussian distribution (history of AF, body mass index, fluoroscopy time), Wilcoxon matched pairs test was used.
Table 2. Procedural Parameters and Follow-Up Data

<table>
<thead>
<tr>
<th></th>
<th>All Patients (n=98)</th>
<th>MGT Group (n=49)</th>
<th>Control Group (n=49)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy time, min*</td>
<td>24 (16, 33)</td>
<td>16 (10, 23)</td>
<td>31 (25, 43)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Irradiation dose, cGy*cm²</td>
<td>10 835±72509</td>
<td>7363±5827</td>
<td>14 453±7403</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedural time, min</td>
<td>166±48</td>
<td>174±43</td>
<td>157±51</td>
<td>0.06</td>
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<tr>
<td>RF time, s</td>
<td>2067±1014</td>
<td>1900±799</td>
<td>2250±1191</td>
<td>0.19</td>
</tr>
<tr>
<td>RF pulses, n</td>
<td>34±21</td>
<td>31±16</td>
<td>38±25</td>
<td>0.16</td>
</tr>
<tr>
<td>Documented PVI</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>1.00</td>
</tr>
<tr>
<td>AF/AT freedom at 6 mo (%)</td>
<td>67 (68%)</td>
<td>33 (67%)</td>
<td>34 (69%)</td>
<td>0.83</td>
</tr>
</tbody>
</table>

MGT indicates MediGuide Technology; RF, radiofrequency; PVI, pulmonary vein isolation; AF, atrial fibrillation; AT, atrial tachycardia.

Data given as mean and SD.

*Data given as median and quartiles.

Continuous, normally distributed parameters were compared between the 2 groups using the t test for paired samples. Continuous parameters with a non-Gaussian distribution (*) were compared using the Wilcoxon matched pairs test. Categorical data were compared using the McNemar test.

All P values are unadjusted for multiple testing.

Differences of categorical data between the case and the control group (ie, rhythm outcome, completeness of PV isolation, antiarrhythmic drug usage) were tested for statistical significance using χ² test. Group comparisons listed in Table 2 were revised regarding Bonferroni correction. Because significances would not change, the more instructive unadjusted P values are reported. All analyses were performed using SPSS for Windows, release 17.0 (SPSS Inc, Chicago, IL). A 2-sided P<0.05 was considered statistically significant.

Results

A total of 98 patients, 78 men and 20 women (20%), with a mean age of 60±10 years, were included in the study. All patients completed the study to the end of the 6-month follow-up. Seven-day Holter ECG recordings were available for 98 of 98 (100%) patients after ablation, 98 of 98 (100%) patients at 3 months, and 94 of 98 (96%) at the 6-month follow-up. Patient demographics are shown in Table 1. Fifty (51%) patients suffered from paroxysmal AF and 48 (49%) from persistent AF. Structural heart disease was present in 12 (12%) patients, and 64 (65%) patients had a history of arterial hypertension. Thirty-four (35%) patients had so-called lone AF. Left ventricular ejection fraction and LA diameter measured 61%±7% and 42±5 mm, respectively. The median history of AF was 60 months (range, 24 months to 10 years). Baseline characteristics did not differ between the MGT and control groups (Table 1).

MediGuide: Technology Performance

The MGT technology was easily integrated into the workflow of the EP procedure. Fluoroscopic image acquisition, real-time aligned image display, and nonfluoroscopic 4D catheter tracking were feasible in all 49 patients of the MGT group.

Intracardiac catheter positioning was successfully achieved without any further fluoroscopy in 49 of 49 (100%) of the right ventricular apex catheter positions, 49 of 49 (100%) of the His catheter positions, and 45 of 49 (92%) of the CS catheter positions.

Communication between MGT and NavX-EnSite Velocity could be established and remained stable throughout the procedures. MGT-based LA/PV mapping allowed creation of NavX anatomies and subsequent CT model registration in all 49 patients. The registration process required a residual amount of live fluoroscopy (fluoroscopy time, ≥2 minutes). Additional fluoroscopy was needed (1) to understand the position and orientation of the steerable transseptal sheath, which cannot be tracked on MGT or NavX; (2) to confirm intracardiac locations, which are critical for the registration process; and (3) to verify the catheter situation in case of safety concerns.

In the MGT environment, catheter shifts did not occur. In the NavX-EnSite environment map, shifts were observed in 8 of 49 (16%) patients. All of these shifts were caused by displacement of the CS reference catheter. They were successfully detected and compensated by the positional reference tool.

Procedural Data

For the procedural end point, complete PV isolation with bidirectional conduction block was achieved in 49 of 49 (100%) patients from the MGT and the control group. In addition, for persistent AF patients, the posterior LA wall was successfully isolated in 24 of 24 (100%) patients from both groups, whereas a complete mitral isthmus line could be created in 18 of 24 (77%) in the MGT group versus 19 of 24 (79%) patients in the control group (P=0.83).

For procedural characteristics, the total fluoroscopy time was significantly reduced from a median of 31 (25, 43) minutes in the control group to 16 (10, 23) minutes in the MGT group (P<0.001). Among 15 of 49 (31%) MGT patients, the total fluoroscopy time was <12 minutes. The MGT-associated fluoroscopy reduction led to a significant decline in radiation dose delivery from 14453±7324 to 7363±5768 cGy*cm² (P<0.001). In the presented MGT version and workflow, MGT usage was associated with a nonsignificant trend toward longer procedure duration, a decreased number of radiofrequency pulses, and a reduced duration of radiofrequency energy delivery (Table 2).

Complications

Procedure-related minor complications postablation were observed in 2 of 49 (4%) patients in the MGT group and in 2
of 49 (4%) patients in the control group. In the MGT group, 1 patient suffered from a groin pseudoaneurysm, which was conservatively treated. In the control group, 1 patient suffered from pericardial effusion without hemodynamic relevance, which resolved spontaneously. In 1 patient of each cohort, a thermal esophageal lesion was detected by endoscopy, which was routinely scheduled whenever luminal esophageal temperature exceeded 41°C during the intervention. Both lesions resolved within 1 week. None of the patients developed esophageal perforation, cardiac tamponade, thromboembolic events, or PV stenosis.

Clinical Patient Outcome
All patients completed at least 6 months of follow-up. The clinical outcome was comparable between the MGT and control groups. Without concomitant antiarrhythmic drug therapy, 33 of 49 (67%) and 34 of 49 (69%) patients remained free from recurrences of AF and macroreentrant tachycardia after 1 procedure, respectively (P=0.83).

Discussion
Main Findings of the Study
Our study has used a novel, catheter-tracking technology for the treatment of patients with complex arrhythmias, whereby we were able to demonstrate feasibility of nonfluoroscopic 4D catheter tracking within dynamic angiographic cardiac chamber models and to clinically evaluate the integration of that technology into an established EAMS. As a first potential clinical impact, a case-control analysis demonstrated a nearly 50% reduction in fluoroscopy time and radiation exposure at otherwise unchanged procedural and outcome characteristics.

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 toward the moving target organ. However, besides the associated x-ray exposure, that technology only provides 2-dimensional orientation. For the treatment of complex cardiac anatomies and substrates encountered in interventional EP, 3D mapping technologies have been introduced to facilitate spatial anatomical and electrical orientation.10,11

Although a technological milestone, these EAMS technologies carry 2 principal limitations. First, they are independent systems unrelated to the standard working environment of live fluoroscopy. Second, they provide only 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. It is known, for instance, that respiratory and cardiac motion components differently affect atrial and ventricular chamber movement.12 The inability to describe such time-dependent motion of catheter positions together with the target anatomy limits the in vivo accuracy of established 3D mapping systems.

MGT represents a novel, catheter-tracking technology, which, for the first time, allows 3D localization of a catheter tip over time and instantaneously separates 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. Following appropriate image acquisition, 4D catheter tracking can be performed and visualized in dynamic images of cardiac anatomy.

Catheter Tracking in Our Study
In our study, we have applied MGT tracking technology for complex ablation procedures in patients with AF. MGT was used for diagnostic catheters and was implemented into our procedural workflow at several steps.

First, standard catheter deployment within the preacquired cine loops was successfully performed in 92% of the patients. In 4 patients, the CS could not be engaged that way, primarily because of mechanical catheter properties rather than catheter tracking.

The second, and clinically more relevant, step was MGT implementation for mapping of the LA and the PVs. The aim was to create limited anatomies of the PVs and to register a 3D CT model into NavX-EnSite. The MGT enabled us to perform anatomy creation and mapping, while the catheter was tracked within multiprojection preacquired LA angiograms. Clinically, this carried the benefits of (1) being nonfluoroscopic; and (2) improving operators’ orientation by showing significantly more cardiac anatomy compared with plain live fluoroscopy. Scientifically, it showed feasibility of catheter 4D tracking within moving cardiac chamber models. In future, 4D tracking may be extended clinically into other cardiac chambers, such as in VT patients, and, technologically, into better and potentially 3D dynamic chamber models.

Further steps of MGT implementation into our procedural workflow were based on the integration of that tracking technology into the NavX-EnSite Velocity mapping platform. For initial clinical use, 2 integration algorithms were applied in our study. First, we routinely performed MGT field scaling. With this tool, impedance-based field distortions could be corrected by simultaneous 3D coordinates acquired from the aligned sensor tracking field. Clinically, it influenced and improved the shape and proportion of the respective NavX-EnSite geometries. Second, we routinely used the MGT positional reference, whereby the sensor-equipped CS catheter simultaneously served as a NavX-EnSite reference. During the procedure, catheter displacement detected by MGT tracking was successfully used to identify shifts of the NavX-EnSite map and to subsequently correct them (even without repositioning the reference catheter). Catheter tracking during the ablation process was done without MGT because the ablation catheter was not MGT enabled.

MediGuide: Clinical Impact of Our Study
Although early in its clinical use, we tried to investigate the potential impact of MGT on clinical patient care with respect to procedural and outcome characteristics. For that purpose, we performed a case-control analysis comparing the MGT-treated patient group against a matched control patient population with similar baseline characteristics and ablated over a similar time period using the same ablation approach and workflow but without MGT.
Currently, the most visible and best measurable procedural benefit was a near 50% reduction in fluoroscopy time and radiation exposure for the entire procedure. Two factors are likely to be responsible: First, in the MGT group, standard catheter placement and CT model registration were performed almost completely nonfluoroscopically. Second, the field scaling algorithm of the integrated MGT/NavX-EnSite platform improved the quality of the NavX-EnSite model, which in turn increased operator confidence and reduced the need for confirmatory live fluoroscopy during mapping and actual ablation.

Despite a considerable shift in the model-based nonfluoroscopic working environment, the technology demonstrated safe clinical use without an increase in complication rate. The procedures tended to be slightly longer; however, the difference failed statistical significance. The reasons for prolongation may be (1) the time needed to acquire the LA angiograms; (2) a learning curve with the technology and its features; and (3) the clinical study setup with time needed for documentation and data acquisition. The procedural end point was adequately reached with and without MGT. Accordingly, the clinical success was similar in both treatment groups.

### Future Technological Developments

Our study describes the first clinical use of MGT for the treatment of patients suffering from complex arrhythmias. From our perspective, future developments may broaden the implementation of the technology into procedural workflow with a clinical impact beyond fluoroscopy reduction. With today’s experience, 2 areas seem to be clinically relevant. First, development needs to provide more sensor-equipped catheters and intracardiac working tools, such as a MGT-enabled ablation catheter. With that, MGT also has the potential to be used as standalone tracking technology for the treatment of simple arrhythmias, such as atrioventricular nodal reentrant tachycardia or atrioventricular reciprocating tachycardia. Second, the unique capabilities of tracking and model registration of the combined MGT/NavX-EnSite platform may be used for software developments that allow (1) autoregistration of rotational angiography models into the EAMS; (2) extended catheter tip and shaft visualization in the MGT cine loop environment; and (3) use of dynamic cardiac chamber models within the EAMS.

Extending beyond interventional EP and implementing more sensor-equipped working tools, MGT carries the potential to provide relevant clinical applications for other fluoroscopy-based cardiovascular interventions, such as device therapy, interventional valve treatment, as well as coronary and peripheral vascular interventions.

### Limitations

Our study was not randomized. It retrospectively compared the MGT group against a control population. However, we recruited our patients over a short period of time, and the control patients, ablated during the same time period, were matched with regard to the most relevant clinical characteristics. Eventually all baseline data were equally distributed between both patient groups, so they are not expected to have influenced the results of the study.

### Conclusions

The first in-human application of MGT for AF catheter ablation was feasible and safe. The technology represents an innovative tracking tool allowing 4D visualization of sensor-equipped catheters within moving cardiac chamber models. The integration of MGT with an established cardiac mapping system provided the first algorithms to facilitate mapping and ablation in the EAMS environment. Even with a diagnostic sensor catheter only, MGT implementation was already able to significantly reduce fluoroscopy exposure.

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### Disclosures

Drs Rolf, Sommer, Gaspar, and Arya have received modest lecture honoraria from St Jude Medical, Inc, Biosense-Webster, and Biotronik. Dr Hindricks has received modest lecture honoraria from St Jude Medical, Inc, Biotronik, Medtronic, and Biosense and is a member of the St Jude Medical, Inc, and Biosense advisory boards. Dr Piorkowski has received modest lecture honoraria from St Jude Medical, Inc, and Biotronik and is a member of the St Jude Medical, Inc, advisory board.

### References


**CLINICAL PERSPECTIVE**

Accurate anatomic guidance is important for atrial fibrillation ablation and is often achieved by registration of previously acquired computed tomography or magnetic resonance images into 3-dimensional electroanatomical mapping systems. We describe the first clinical use of a novel tracking technology that allows 4-dimensional visualization of sensor-equipped catheters within cine loops or angiograms taken at the time of the study, coregistered with the NavX-EnSite electroanatomic mapping system. Although ablation catheters with this sensor technology were not available for this study, a case-control study shows as a first clinical result that use of the system for diagnostic catheters while performing ablation with conventional catheters still reduced radiation exposure substantially. This system has the potential to facilitate anatomic-based mapping using procedure-acquired cineangiographic images while achieving low radiation exposure.
Ablation of Atrial Fibrillation Using Novel 4-Dimensional Catheter Tracking Within Autoregistered Left Atrial Angiograms
Sascha Rolf, Philipp Sommer, Thomas Gaspar, Silke John, Arash Arya, Gerhard Hindricks and Christopher Piorkowski

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SUPPLEMENTAL MATERIAL

Movie Legend

Movie 1: The movie shows non-fluoroscopic placement of sensor equipped standard EP catheters in the RVA (first yellow icon), and the CS (second yellow icon). Two cine loops displaying pre-acquired LA angiograms (pigtail catheter in the common pulmonary artery trunk) are running in non-fluoroscopic ECG-synchronized real-time tracking mode. These cine loops have been selected from the list of and stored cine loops on the left side of the screen. The cine-loops assigned to each of the two MGT screens are displayed together aligned by the real time ECG (lower right corner).

Movie 2: The movie shows annotation of intracardiac locations by placement of 3D markers which are displayed over time within the moving organ image (4D visualization). The catheter from the His bundle (green icon) is used to map the right atrium. The first 3D marker is placed at the AV node (blue 3D point). Subsequently the catheter visits the SVC and IVC (purple rings).

Note the green catheter icon on the initial attempt to access the SVC. The catheter diverts into the right atrial appendage; it is pulled back, turned around and successfully advanced into the SVC.

Movie 3: The movie shows the transseptal puncture illustrating that the MGT 3D markers can be used for 4D tracking of intracardiac locations not only within cine loops, but also during live fluoroscopy. Note the contrast staining of the intraatrial septum, which aligns with the yellow 3D marker in the oval fossa after the pressure from the needle is released. Also note the excellent temporal as well as spatial resolution of sensor and landmark tracking during angulation of the C-arm.
**Movie 4:** The sequence of movies illustrates the MGT based registration of the LA CT model into the NavX-EnSite environment.

**Movie 4a:** The green icon MGT catheter is advanced through the transseptal sheath into the left atrium. Note when the catheter passes through the yellow 3D marker at the oval fossa. In the LA the catheter is used to non-fluoroscopically access and map the PVs. Further 3D markers are placed at the PV ostia (shown for the left lower and left upper PV).

**Movie 4b:** Parallel to MGT based PV mapping, the NavX-EnSite geometries are created. MGT field scaling is frequently applied to optimize shape and proportion. Eventually four PVs have been reconstructed which realistically mirror shape, size and branching of the PVs seen in the CT model. These anatomies serve as the anchor structures for the CT model registration.

**Movie 4c:** After initial model fusion the registration is further improved by adding fiducial points within the LA body. For that the green icon MGT catheter is used to non-fluoroscopically map the LA within the pre-acquired angiograms. Fidcials are taken at the LA roof, at the posterior LA wall, around the mitral annulus and at the interatrial septum.