Conventional fluoroscopy is the main imaging technology that allows for intracardiac device manipulation in a variety of interventional cardiovascular procedures. Besides the associated x-ray exposure for patients and staff, that technology only provides 2D orientations. Therefore, 3D mapping technologies have been introduced to facilitate spatial orientation within complex cardiac anatomies. Especially in interventional electrophysiology (EP), these technologies have become clinical routine applications. However, until today, such technologies represent independent systems unrelated to the most fundamental real-time catheter visualization provided by fluoroscopy.

We report the first in-human application of a new mapping technology allowing 3D EP catheter tracking in full integration with conventional fluoroscopy imaging.

Technology Description

The guided medical positioning system (gMPS System, St Jude Medical [SJM], St Paul, MN) consists of 3 components: (1) transmitters generating a set of low-intensity (<200 μT) alternating electromagnetic fields; (2) miniaturized passive single coil sensors (<1 mm³) assembled within intracardiac devices such as a conventional EP catheter (MediGuide Enabled Livewire, SJM); and (3) an electromagnetic field reference sensor attached to the patient’s sternum (patient reference sensor, PRS). The electromagnetic fields induce voltages on the passive device sensors. According to these voltages, the system computes position and orientation of each sensor within the 3D tracking volume with respect to the transmitter assembly with a time latency of <1 ms. The Mediguide quantitative accuracy data are based on in vitro testing, in which it is shown to have <0.5 mm positional error and <1° orientation error in a moving phantom imitating cardiac and respiratory motions. To compensate for cardiac and respiratory motion, the system continuously receives and stores data from all its active signal sources: PRS, sensor-enabled intracardiac devices, and real-time ECG. The system continuously computes cross-correlations between the motions of each sensor enabled device, the PRS and the ECG. The cross-correlation isolates the components of the devices’ motion that have high correlation to the ECG (hence, can be attributed to cardiac motion), components that have high-correlation to the PRS (hence, can be attributed to respiration related motion), and “other” motion components (actual device motion). This way, the temporal characteristics of PRS motion and ECG are being used to compensate cardiac and respiratory motion and to isolate the actual device maneuvering.

The electromagnetic field transmitters are mounted on the fluoroscopy detector of a conventional x-ray imaging system aligning the fluoroscopy space with the 3D electromagnetic sensor field. As a result, the sensor-equipped EP catheter can either be seen on fluoroscopy or tracked nonfluoroscopically at the identical position by the 3D electromagnetic sensor field. With the use of prerecorded fluoroscopy cine loops, real-time catheter location data obtained from the electromagnetic sensor field are visualized nonfluoroscopically within the x-ray environment. To adjust for cardiac cycle-dependent changes in catheter position, the speed of the cine loop is matched to the real-time ECG signal. The latency of the computation of the 3D gMPS tracking data are in the order of magnitude of <1 ms. However, there is a latency involved in the capture and display of the fluoroscopy image on the Mediguide system, which is approximately 80 ms. The system thus intentionally delays the tracking data display to match the underlying image’s latency. Hence, the overall latency of the 3D catheter icon display is approximately 80 ms.

The PRS, similar to an ECG electrode in size, functions as an anchor between the patient and the transmitters (hence, between the patient and the fluoroscopy detector, to which the transmitters are connected). Using the PRS, the system can project positions and orientations of sensor enabled intracardiac catheters on fluoroscopy images, even if the spatial relationship between the sensor and the fluoroscopy detector have changed with c-arm angulations, patient respiration, and patient and/or table movement.

Technology Application

After extensive in vitro and animal in vivo testing for the first time, the gMPS system was used to perform in-human
catheter tracking for a complete invasive EP study in a 26-year-old male patient.

The patient was enrolled in a respective clinical study with local ethics committee approval. In brief, the study tested clinical feasibility, stability, and accuracy of the gMPS system to perform nonfluoroscopic right and/or left atrial catheter positioning in patients presenting for diagnostic EP procedures, supraventricular tachycardia ablation, as well as treatment of atrial fibrillation or atrial macro-reentrant tachycardia. Live fluoroscopy was used to validate the gMPS catheter position and its in vivo alignment with the true catheter location.

The patient provided written, informed consent. The invasive EP procedure was performed for diagnostic workup of symptomatic tachycardia. Attempts of ECG documentation of the clinical tachycardia had been unsuccessful. During invasive EP study, the diagnosis of inappropriate sinus tachycardia was made.

Before catheter introduction, 2 cine loops with a length of 3 cardiac cycles were recorded in standard right anterior oblique 30° and left anterior oblique 60° projections (Figure 1). These cine loops served as the background image for nonfluoroscopic catheter tracking. The system allows both cine loops to run simultaneously and therefore to visualize the catheter position in 2 projections (similar to a conventional biplane x-ray mode). For the clinical procedure, 3 catheters were introduced nonfluoroscopically to the right ventricular apex (online-only Data Supplement Movie 1), to the His-bundle position (online-only Data Supplement Movie 1), and into the high right atrium (online-only Data Supplement Movie 1). As a safeguard, the operator was advised to stop catheter manipulation and to perform live fluoroscopy in case of any uncertainty of the anatomic in vivo position or in case of difficulties to mechanically maneuver the catheter. None such situation occurred. After nonfluoroscopic catheter placement, the precise intracardiac position of all catheters was confirmed on x-ray (Figure 2 and online-only Data Supplement Movie 2). During the invasive EP study, the electrode catheter from the His-bundle was nonfluoroscopically repositioned into the coronary sinus and confirmed on fluoroscopy (Figure 3 and online-only Data Supplement Movie 3). To test rhythm-dependent catheter visualization, coronary sinus pacing was applied at a cycle length of 500 ms. With the onset of pacing, the speed of the cine loop automatically adjusted to the cycle length of the real-time ECG signal (online-only Data Supplement Movie 4). Compensation for

Figure 1. Display of the guided medical positioning system (gMPS), user interface. Several cine loops can be stored to be used for catheter localization. A, List of prerecorded fluoroscopic cine loops. In the present example, 2 cine loops have been stored. The system allows independent loops to be run simultaneously on 2 display monitors; B and C, pseudobiplane mode. In the present example, right anterior oblique 30° is selected for the left screen (B) and left anterior oblique 60° for the right screen. The ECG signal used for adjustment of the cine loop speed to the actual rhythm is displayed in D. The type and status of intracardiac devices equipped with gMPS sensors and connected to the system are displayed in E, F. Different 3D markers that can store a specific intracardiac sensor position within the fluoroscopic images.

Figure 2. Confirmation of catheter position on fluoroscopy. Pre-recorded cine loops are stored in A. The fluoroscopy image displays real-time fluoroscopy, indicated by the red signal in B. The catheter position is visualized conventionally on live fluoroscopy, together with the nonfluoroscopic catheter localization provided by the guided medical positioning system (color-coded catheter icons). The overlay of the fluoroscopic catheter image and the nonfluoroscopic catheter icons indicate the accuracy of the system for catheter localization (C indicates high right atrium; D, His bundle; and E, right ventricular atrium).
patient movement was tested by sudden displacement of the patient position relative to the fluoroscopy detector by approximately 20 cm; for this, the patient table was suddenly shifted. The patient remained stable with stable intracardiac catheter locations. According to a moved PRS, the displacement is recognized by the system and the tracked catheter icons return to their actual intracardiac location and are subsequently compensated for the shift during further catheter visualization (online-only Data Supplement Movie 5).

With the use of the gMPS System, all catheters were positioned entirely nonfluoroscopically at the clinically dedicated intracardiac location. Radiography was only used for initial cine loop acquisition and later on for confirmation of the catheter position according to the clinical research protocol. Total fluoroscopy time measured 30 seconds.

Limitations
No complication was observed during and after the procedure. The patient did not have any discomfort beyond the typical pain and sensations associated with an invasive EP study. Theoretically, however, certain limitations and caveats must be considered when using the gMPS system: (1) Accurate nonfluoroscopic catheter tracking depends on a stable position of the external PRS. In obese patients or patients with loose skin, PRS movement may affect tracking accuracy. (2) Deformation of cardiac structures caused by mechanical catheter forces, which can be picked up by changes of the fluoroscopic cardiac silhouette, may be missed when solely relying on nonfluoroscopic gMPS catheter tracking. In last consequence diagnosis and treatment of cardiac tamponade may be delayed if the operator is inattentive to other signs of pericardial effusion rather than only the fluoroscopic alterations. (3) The functionality of the system in structurally abnormal hearts such as in patients with corrected or uncorrected congenital cardiac malformations or in patients with artificial valves remains to be further evaluated. (4) Availability of the gMPS real-time ECG on both screens instead of one system screen might be beneficial for the physician to control the system’s compensation of catheter tracking during arrhythmia or extrasystole.

Summary and Future Implications
The first clinical application of the gMPS technology in electrophysiology revealed feasibility of nonfluoroscopic catheter visualization within the workflow of conventional invasive diagnostic EP procedures. Future system and catheter developments need to extend into actual catheter ablation, especially for the treatment of complex arrhythmias. Alignment of the 3D working space of the gMPS system with the 3D working space of other established cardiac mapping systems could open the opportunity for (1) enhanced mapping accuracies, (2) automatic image registration, and (3) reduction of periprocedural fluoroscopy needs. Eventually, the technology may have the potential to be implemented in other fluoroscopy-based cardiovascular interventions outside EP, such as lead placement, cardiac/valvular implants, and coronary/peripheral target vessel revascularization.

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References

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Christopher Piorkowski and Gerhard Hindricks

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