

# A system for in vitro evaluation of magnetic and manual catheter navigation for cardiac ablations

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# A system for in vitro evaluation of magnetic and manual catheter navigation for cardiac ablations

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## INTRODUCTION

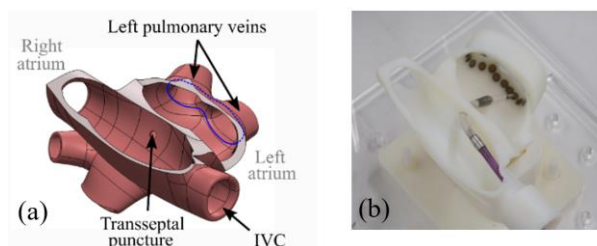
Radiofrequency (RF) cardiac ablation is currently the treatment of choice for many types of cardiac arrhythmias [1]. As an alternative to manually guided catheter used to deliver the RF energy, an emerging technique known as remote magnetic navigation uses a magnetic catheter, which is remotely manipulated by a controlled magnetic field [2]. This approach enables a robotic approach to performing the ablation, with an expected gain in the procedure safety, time-efficiency, and precision. Despite preliminary evidence of the benefits of magnetic manipulation in some difficult ablation cases [3], the advantages of the robotic magnetic approach over the manual one are still to be investigated. In this work, we propose a further step toward this investigation by developing a dedicated setup for an in vitro evaluation of cardiac ablations. We focus on the design of realistic geometries and ablation trajectories in order to assess navigation performance and catheter manipulability. We aim at providing a platform to evaluate and improve the design of magnetic catheters and allow for a comparison with manual catheters for specific navigation tasks. To this extent, we designed and 3D-printed heart models corresponding to common ablations cases. We also developed dedicated control software to perform the magnetic manipulation. We report preliminary results of a user-study to evaluate a magnetic versus a manual manipulation procedure. Since atrial fibrillation (AF) is the most common cardiac arrhythmia, we focus on the pulmonary vein isolation (PVI) procedure that is commonly performed to cure AF [4].

## MATERIALS AND METHODS

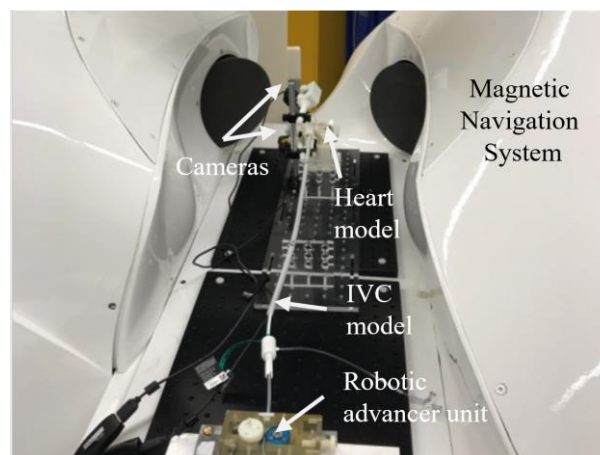
Our goal is to design a setup to simulate the navigation in one or more of the heart chambers with an ablation tool. We focus on designing geometries that are realistic enough to evaluate the ability of a catheter to follow a realistic trajectory.

In the case of PVI, ablation points are located along a circular trajectory around one or several pulmonary veins located in the left atrium, as depicted in Fig. 1(a). Therefore, we designed a heart model that is 3D-printed in a rigid polymer material and that allows for access with a standard introducer sheath from the inferior vena cava (IVC). The ablation trajectory is represented in our heart model by 19 fiducial marks placed that define a trajectory around the two left pulmonary veins. The

points are intended to be touched with the catheter tip as depicted in Fig. 1(b). The model is cut open on the opposite side of the trajectory in order to allow for a visual inspection of the ablation targets.



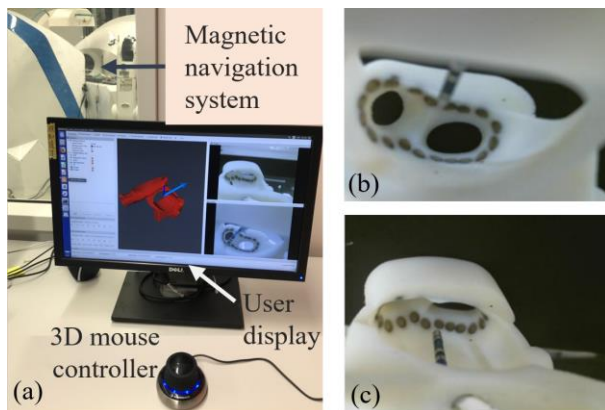
**Fig. 1** Heart model for PVI procedure. (a) Anatomy of the atria and trajectory for the PVI in blue, (b) 3D-printed phantom with ablation tool pointing at the target points in black



**Fig. 2.** Configuration of the evaluation setup in the magnetic navigation system

An overview of the setup is provided in Fig. 2. Visual feedback is performed via two cameras whose views are depicted in Fig. 3(b) and (c). The inferior vena cava is modeled as a flexible tube to access the heart model with standard introducer sheaths. A robotic advancer unit that is remotely controlled performs the catheter insertion within the sheath. The entire setup fits into a magnetic navigation system (CardioMag MNS, MSRL, ETH Zurich). This system can generate magnetic fields at a magnitude of 80 mT in any direction using eight current-controlled electromagnets without being affected by its ferromagnetic environment. The system is remotely controlled via a user interface depicted in Fig. 3(a). The interface displays the camera images and

the magnetic field direction with respect to a 3D-CAD model of the phantom geometry. The direction of the magnetic field and the insertion/retraction of the catheter are controlled by a joystick and the buttons of a 3D mouse controller (SpaceNavigator®, 3Dconnexion). The setup is also compatible with manual catheters by removing the robotic advancer unit and displaying camera images on a second screen at the bedside. The ablation task here consists in touching the 19 points of the heart model with the tip of an ablation catheter.



**Fig. 3** User interface (a) and camera views (b)-(c)

## RESULTS

As a preliminary result, we evaluated the feasibility of reaching the ablation points with both a magnetic and manual commercial catheter (ThermoCool® Navistar RMT and SF NAV, Biosense Webster Inc.). A commercially available standard SL1 introducer sheath is used to guide the ablation catheter up to the transseptal puncture. The time to reach all of the 19 points is considered as the performance criteria. A total of five users were selected for this study. Users include one electrophysiologist, as well as two medical students and two robotic engineers without experience with manual catheter manipulation. After an introduction to the setup and task, each user is given 15 min to test both magnetic and manual navigation on their own. The user is then told to touch all of the points as fast as possible. Each user is performing the magnetic approach first. Both videos and input from the joystick are recorded. The procedure is repeated three times for both magnetic and manual manipulation with 5 minutes break between each trial. The data of 30 trials have thus been collected.

All the 19 points could be reached by the 5 users with both manual and magnetic approaches and with a mean time of  $409 \pm 110$  s for magnetic and  $119 \pm 55$  s for manual procedure. Users reported that the magnetic manipulation is overall much less tiring than the manual one, since the magnetic field holds the tool in position when the controller is at a resting position.

The total time over the 3 trials is reduced by an average of 20% and 30% for the manual and magnetic procedures, which suggests a learning process for both modalities.

## DISCUSSION

This study shows the feasibility of simulating the navigation of an ablation catheter along a PVI trajectory with both a magnetic and manual approach. Preliminary results give a first comparison between manual and magnetic catheters. The same test procedure will be repeated in the future to monitor our magnetic navigation system performance as we refined our control algorithms and user interface.

The total time was the only performance criteria used. Other criteria could be considered such as repeatability, accuracy or muscle activity measures, which would require additional sensor-based monitoring. We also noticed the significant influence of the mapping between the 3D mouse controller motion and the magnetic field heading direction on the navigation performance. To this extent, further work could be performed on the analysis of the controller inputs and catheter kinematics to find an optimal mapping. Further improvements for the setup can be considered as well to include more realistic conditions of the real cardiac environment such as blood flow and tissue deformation.

The current setup can already be used as an in vitro training platform for both manual and magnetic navigation. Heart phantoms corresponding to several ablation cases have already been designed, such as for cavotricuspid isthmus ablation in the case of atrial flutter, or treatment of right ventricular outflow tachycardia. Our platform can also be used for the evaluation of new magnetic tools as we proposed in [4], and can lead to the design of the next generation of magnetic ablation catheters.

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