NAVIGATION PLATFORM FOR ENDOVASCULAR PROCEDURES

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Abstract. To correct cardiac arrhythmias, a long catheter is inserted into an arm or leg artery or vein and navigated to the heart during a cardiac ablation procedure. Heat or cold energy is then used to create small scars in the heart tissue to block irregular electrical signals and restore a typical heartbeat. Medical robotics combined with image-guided navigation can overcome many of the challenges faced throughout classic procedures especially for patients with complex vascular disease by adding control, stability, precision to reach the target reduce learning curve and improving safety. The disadvantages of the existing robotic systems are the high equipment and procedure cost and necessity of customized instruments. The scope of this project is to develop a novel robotic catheter system to help doctors navigate with increased precision and accuracy to treat arrythmia especially for patient with complicated pathologies, increase success rate and decrease patient radiation exposure necessary for position confirmation. The working prototype in two versions, developed by our group and named SAR-E (smart assisting robotic catheter for endovascular procedures) was successfully tested for feasibility in a 3D vasculature model.

Key words: robotic catheter system, arrythmia, image-guided navigation, cardiac ablation.

1. INTRODUCTION

The heart arrythmia is a life-threatening condition caused by irregular heartbeats and problems with electrical signals that coordinate them. The treatment includes medication, catheterization, implanted devices, or surgery. Cardiac ablation is a common procedure to treat arrythmia by inserting a catheter through the veins of arms or legs and using heat (for radiofrequency ablation) or cold (for

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cryoablation) to create small scars in the heart which block irregular electrical signals and restore the normal heartbeat.

Compared to open surgery, this minimally invasive procedure is associated with less complications, faster recovery, and shorter hospitalization. It also includes navigation challenges and radiation exposure during X-ray scanning necessary to guide the catheter up into the heart. To overcome these limitations, robotic systems are developed as a new method of treatment [1] using steerable or pre-bended tip catheter and special tracking equipment to increase precision and decrease radiation exposure. With electromagnetic tracking systems, the position of the catheter tip inside the patient 3D model built from preoperative CT data is computed and used for the navigation of the instrument and accurate positioning to the ablation location. The robotic procedures however present several complications like low distal catheter control and force feedback with the risk of vessel perforation, the cost, set-up time and complexity of the technique [2–4].

2. MATERIALS AND METHODS

We developed an original (patent pending), easy to operate robotic system for endovascular interventions named SAR-E (smart assisting robotic catheter for endovascular procedures). With SAR-E we can improve surgeon capabilities to reach the target during a remote procedure from another room, decreasing his exposure to radiation when the instrument is guided inside the blood vessels.

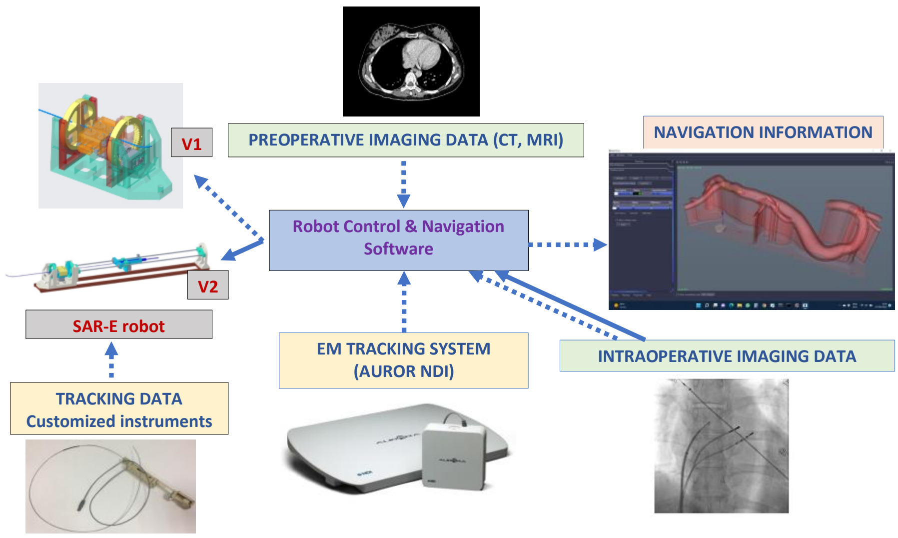
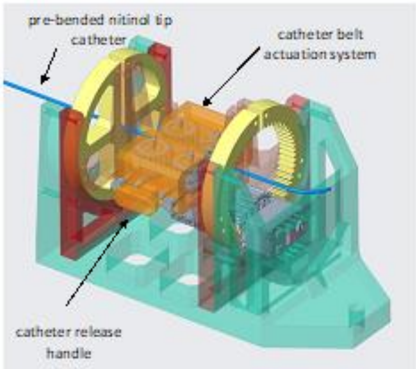


Fig. 1 – Procedure diagram using SAR-E robotic catheter system: data flux for version 1 of the robot (dot arrows), with electromagnetic tracking, and for version 2 of the robot (solid arrows) working in client-server mode, without electromagnetic navigation.

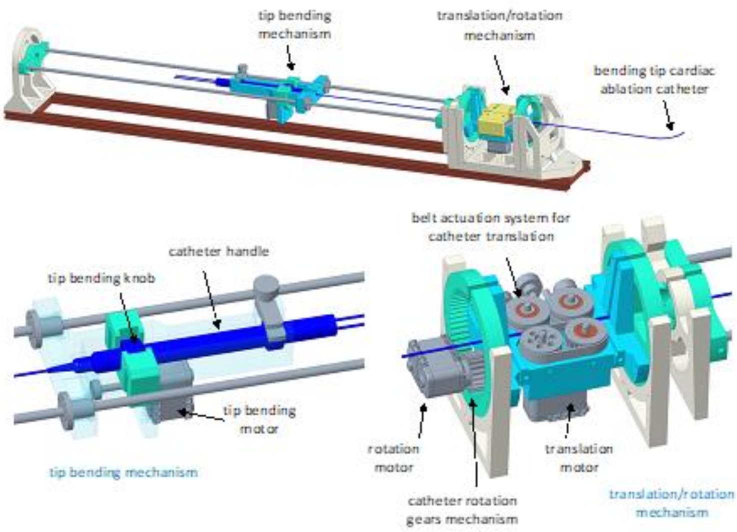
The medical procedure, Fig. 1, using SAR-E robotic catheter is performed with and without image guided tracking.

V1. With image tracking in the robotic master-slave mode, the path to target is computed from pre-operative data and, using a electromagnetic tracking system like Aurora from Northern Digital plus an electromagnetic sensor mounted in the catheter, to navigate to the ablation location using the robot software only, without X-ray scanning.

V2. Without tracking, in the robotic client-server mode, the surgeon controlling the system, from another room through a Bluetooth connection, using the robot control software on a tablet and using X-ray to guide the catheter position.



V1



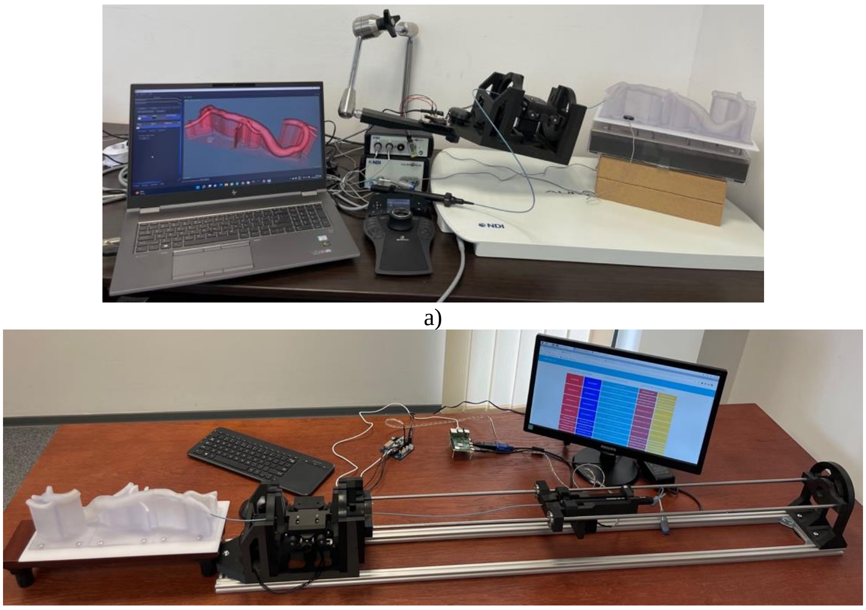
V2

Fig. 2 – CAD assembly of the robotic solution SAR-E: V1 – the version with electromagnetic tracking and 2DOF; V2 – the version without tracking, with 3DOF.

The SAR-E robot is used during the cardiac ablation procedure to manipulate the catheter for three types of movements: translation/retraction, axial rotation for version 1 and an additional movement that provides the tip bending for version 2. The robot in this configuration can be used with flexible instruments with 1–4 mm outer diameter and, with minor changes, can be adapted to any dimensions.

To control catheter advancing along the path to reach the target, version 1 of the SAR-E robot is using pre-bended tip catheter only, while in the second version, a bendable tip catheter (classic ablation catheter) can be used.

The components of the robotic system, Fig. 2, consist in three functional assemblies: a gear-belt mechanism for catheter translation and a gear mechanism for catheter rotation in version 1, and an additional screw-nut mechanism for tip bending by translating the catheter's handle knob in version 2, all of being actuated by three electrical motors Robotis Dynamixel AX-12A (Robotis Inc.). The motors are controlled by an OpenCM9.04 microcontroller board plus an OpenCM485 expansion board with a Bluetooth module, and a raspberry PI4 micro-computer.



a)

b)

Fig. 3 – Testing step-up for: a) version 1 with the robot, AURORA tracking system, the phantom the imaging and electromagnetic navigation software; b) version 2 with the robot, the phantom, the control boards, a Raspberry PI and the monitor with an application developed using Node-Red.

The first operation mode Fig. 3a of the SAR-E robot uses an image guided navigation software, iMTECH previously developed in our lab together with the AURORA electromagnetic (EM) tracking system, and a custom-made catheter with an EM sensor tip [5, 6]. Electromagnetic tracking with software reconstruction provides a 3D visualization of the pathway which improves catheter manipulation and reduces the number of radiographic scans compared to fluoroscopic imaging.

To test the second version of the robotic system SAR-E, a cardiac ablation catheter STABLEMAPRTM SM “Duodecapolar steerable atrial mapping” from Medtronic was loaded with the handle mounted in the tip bending mechanism carrier, Fig. 2, and the tube secured between belt and the pressure rolls of the translation/rotation mechanism.

A Node-RED application Fig. 3b was developed to control the SAR-E robot remotely with a joystick, computer mouse or a Bluetooth connection. The application runs on most commonly used operating systems (Mac-OS, Windows or Linux) and web browsers (Safari, Chrome, Opera, Microsoft Edge or Chromium).

The Dynamixel servomotors have small dimensions (32 × 50 × 40 mm) and weight (55 g), a gearbox with a transmission ratio of 254:1, a high stall torque of 1.5 Nm and use a supply voltage of 12 V, a current of 1.5 A and a speed of 59 rpm in the absence of any load. The servomotors can be controlled with a continuous rotation or in positioning mode. The motor shaft commands are processed in digital format via a TTL Level Multi Drop Bus interface. In positioning mode, the movement is 0 to 300° at a resolution of 0.29°. The continuous movement is not limited in any direction. The control packets have a transmission rate of up to 1 Mbps which makes the servomotors respond quickly.

The Node-RED is a client-server model with a web server, a backend and frontend components for the interaction with the users. Several buttons for the frontend component, Fig. 3b, are used for the translational move of the catheter from one step up to 200 or more continuous steps, catheter rotation from one to 10 continuous steps, and catheter bending. The backend component, Fig. 3b, has server-side logic with a module for the frontend and the serial port. The backend component processes the requests from the user and sends them to the robot for execution via the serial port.

The robot was built on a FDM Onyx Pro 3D printer Markedforged using nylon with carbon micro-fiber materials.

Using a pre-operative CT scan of the patient, the iMTECH navigation software is used in combination with the robot to reduce exposure to harmful X-ray radiation and increase procedure’s precision.

For navigation, the iMTECH software, Fig. 3a, is combined with the Aurora electromagnetic system with a table-top EM field generator and a system control unit. Two sensors are placed on the patient’s chest for position registration and on the catheter’s tip, which gives the 3D coordinates related to the field generator in real time. Based on the CT, the software generates the 3D model of the patient’s anatomy and registers it to the patient’s position. During the medical procedure, the iMTECH software, Fig. 4, computes and displays the position of the catheter’s tip within the anatomical volume and allows the surgeon to navigate inside the vessels.

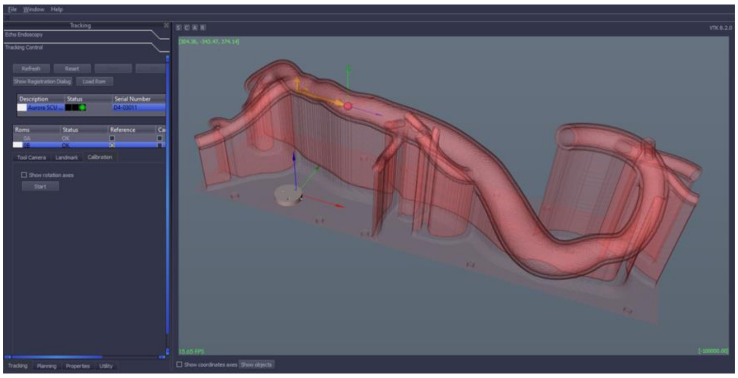


Fig. 4 – The navigation software presenting the 3D rendering of the model from CT scans and the catheter tip position displayed in quasi real time.

3. RESULT AND CONCLUSION

The SAR-E robot and catheter system was successfully tested without tracking in a transparent model of the aorta, in client/server mode, without any image-guided navigation and no X-ray scanning, using only direct visualization of the catheter for guidance. Starting from the iliac artery, a cardiac ablation catheter with tip bending control was inserted from the aorta and into the heart. The robot reliably performed translation/retraction, axial rotation, and tip bending, with no slipping. The design includes the ability of changing the instrument during the procedure, and bending the catheter's tip.

Table 1

Time, catheter inserted length and necessary movement steps from the entry point (iliac arteries) to the target (aortic arch)

Test No.	Left common iliac artery				Right common iliac artery			
	SAR-E Version 1		SAR-E Version 1		SAR-E Version 1		SAR-E Version 1	
	Time (s)	Length (mm)	Time (s)	Length (mm)	Time (s)	Length (mm)	Time (s)	Length (mm)
1	65.3	495	64,3	501	46.4	487	28,7	475
2	70	489	61,1	497	44.5	522	30,2	467
3	72.5	500	58,0	504	46.2	499	33,2	475
4	64.9	495	62,8	521	41.3	509	32,7	466
5	63.7	496	60,1	500	46.3	488	34,1	475
Avg.	66.92	495	61.26	504,6	44.94	501	31,78	471,6

The SAR-E robot rotated the catheter up to 360° in 3.5° steps. The translation movement was performed in 6mm steps. The maximum translation distance is only limited by the length of the catheter in use, having an unlimited number of steps, with 6 mm for each step. The response to the rotation and translation commands was instantaneous.

Table 1 lists the measurements made through the right and left iliac arteries. The recorded information included the time and distance and number of steps required to reach the. Each experiment was repeated 5 times and the average values were reported. When comparing the left and right access paths, although the lengths of the route and the catheter were approximately the same, the navigation time and steps to the target were longer for the left side because the catheter had to be retracted several times and replaced on the correct path.

Our results show feasibility of the robotic system with EM image guidance to perform the cardiac ablation procedure and potentially reduce the navigation time (Versions 1 and 2) and patient radiation exposure (Version 2). Future studies will continue testing the robotic system with an added tip bending feature of the cardiac ablation catheter therefore giving the surgeon the ability to control the catheter tip position remotely under fluoroscopy guidance or by using the iMTECH and EM platform.

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