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ENDOVASCULAR PROCEDURES USING A ROBOTIC SYSTEM

Lucian Gheorghe GRUIONU, Răzvan Sabin STAN, Anca Loredana UDRIȘTOIU, Andreea Valentina IACOB, Mircea Cătălin CONSTANTINESCU, Gabriel GRUIONU

Abstract: *The placement of stents can be difficult especially in elderly patients with complex vascular disease where error of navigation and poor placement can require open surgery to correct device shift. To place the catheter that contains the stent in the exact position depends significantly on the surgeon's skills. An improvement of precision can be obtained using medical robotics and image-guided navigation. Existing robotic solutions have several disadvantages like high equipment and procedure cost, size of the system, complexity of the procedure, accuracy to reach the target and necessity of new, customized instruments to cover all procedures.*

The scope of this project is to develop a robotic and surgical navigation solution for increased precision and accuracy of early diagnosis and treatment of cardiovascular disease and lung cancer, to increase success rate, decrease patient radiation and stress exposure, and substantially reduce the procedure cost. To accomplish this goal, we developed a working prototype of an endo-navigation robotic system, SAR-E (smart assisting robotic catheter for endovascular procedures) and tested it in a limited laboratory model for an initial proof-of-concept and safety of candidate demonstration.

Key words: *endo-navigation robotic system, endovascular procedures, SAR-E, smart assisting robotic catheter, image-guided navigation.*

1. INTRODUCTION

Compared to open surgery, endovascular procedures are associated with less complications, faster recovery and shorter hospitalization. To overcome the limitations of these procedures like cost, navigation challenges and radiation exposure, new solutions like robotic systems are developed as a new approach to treatment [1]. Using remote controlled robots with steerable or pre-bended tip catheters and tracking systems, the surgeon and patient are exponsed to less radiation during fluoroscopy usage. The position of the catheter tip within the volume is defined by the preoperative data resulting in more accurate positioning and navigation, together with increased stability. Robotic systems improve surgeon's performance, eliminate the effect hand's shaking, reduce the learning curve.

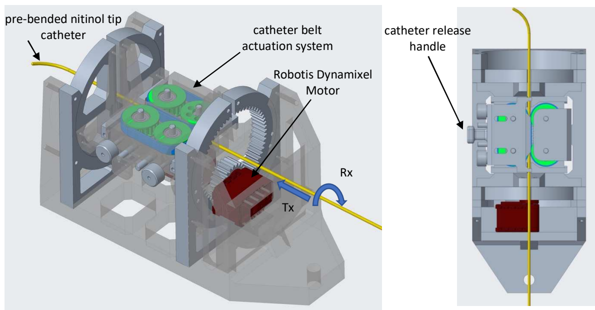
The robotic procedures present several complications like lack of distal catheter control, absence of force feedback with the risk of vessel perforation, high cost, size of the systems, set-up time, and complexity of the procedure [2,3,4]. Some robotic systems require large-diameter tools compared to standard catheters and sheaths [4]. The robotic catheters have limited compatibility with standard balloon and stent systems, therefore after the initial cannulation of blood vessels, the custom-made robotic catheter needs to be replaced with standard devices.

2. MATERIALS AND METHODS

To adress the high cost and complexity of the existing robotic catheter solutions, we developed a low cost, compact and simple to use smart assisting robotic catheter for endovascular interventions (SAR-E) system for endovascular interventions (Fig. 1).

The SAR-E robotic catheter includes a 2DOF robot that can be used with catheters or guide-wires with outer diameters in the range of 1-4 mm.

The robot performs translation/retraction and axial rotation of a pre-bended tip catheter to navigate tortuous anatomy.



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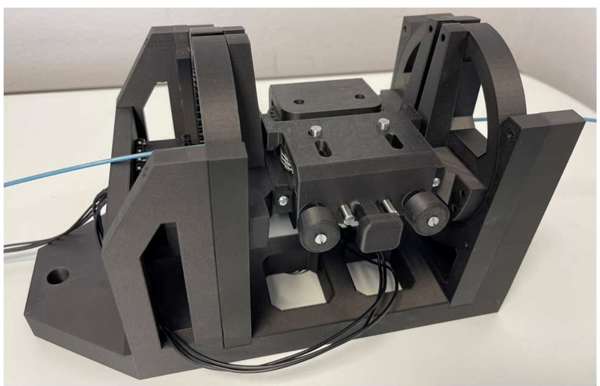

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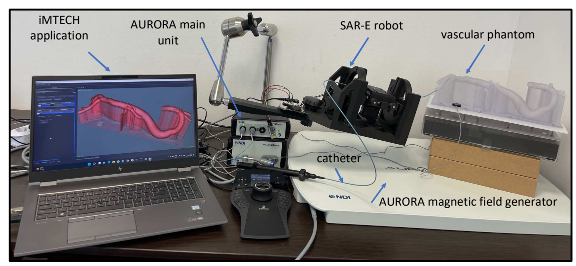
Fig. 1. CAD assembly of the robotic solution SAR-E (a) and the physical prototype (b).

The components of the robotic system are:

- A gear-belt assembly for catheter translation
- A gear assembly for catheter rotation
- An electric motor for catheter translation Robotis Dynamixel AX-12A,
- An electric motor for catheter rotation Robotis Dynamixel AX-12A,
- A handle for catheter loading/release
- chassis
- A microcontroller OpenCM9.04,
- expansion board OpenCM 485,
- A bluetooth module,
- A raspberry PI4 micro-computer (optional)
- The SAR-E Control – the robot control application,
- The image-guided navigation application iMTECH, to use the system without fluoroscopy.

To reduce the number of intraoperative fluoroscopy scans, the image guided navigation software developed in our lab, iMTECH is used together with AURORA electromagnetic (EM) tracking system, and a customized catheter including an EM sensor mounted close to the tip [5,6]. Compared to fluoroscopic imaging that provides a 2D representation of target vessels, endovascular navigation using electromagnetic tracking present in our system offers a 3D visualization which improves catheter manipulation and reduces the number of radiographic scans.

The SAR-E robot is actuated by two Robotis electric motors Dynamixel AX-12A, connected to a microcontroller OpenCM9.04, and an expansion board OpenCM 485.



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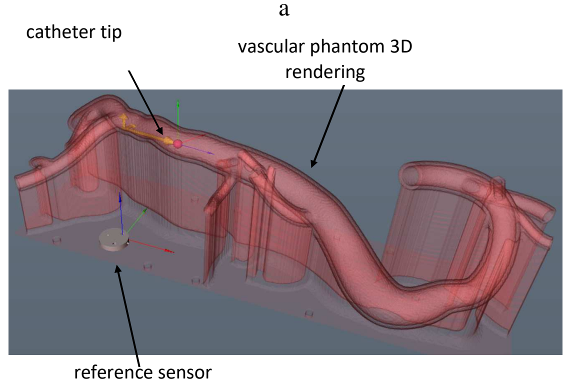

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Fig. 2. Testing environment setup of the SAR-E robotic system manipulating a catheter for cardiac ablation (a), and part of iMTECH screen presenting a rendering of an aorta phantom and the position of the catheter tip in quasi-real time (b).

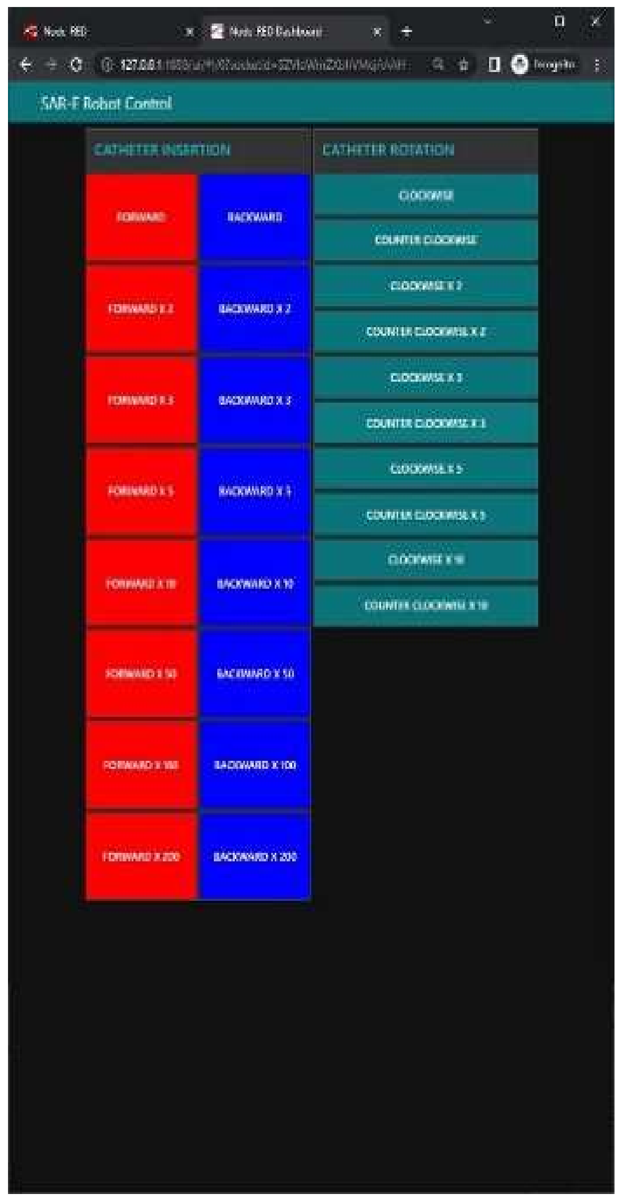
To control the movements of the SAR-E robot, an application using Node-RED framework was developed to command the system from another room using a joystick/mouse or remotely via Bluetooth connection. In addition to the low cost, the software offers the surgeon the ability to control the SAR-E robot from anywhere, using any type of computer. The software can be used with operating systems as Mac-OS, Windows or Linux, and several web browsers such as Safari, Chrome, Opera, Microsoft Edge or Chromium.

The Dynamixel servomotors used to actuate the robot are designed for robotic applications with a compact and very flexible structure. Each servomotor includes a gearbox with a transmission ratio of 254: 1, with a high stall torque of 1.5 Nm at a supply voltage of 12 V and a current of 1.5 A and reduced dimensions (32 x 50 x 40 mm and 55 g weight). For a power supply of 12 V, in the absence of any load, the servomotor shaft reaches a speed of 59 rpm, which means almost 1 rotation every second. Other advantages of this servomotor consist in its control and modes of operation. The servomotors can be used in two ways: with continuous rotation, respectively in positioning mode. The configuration commands, controlling the movement at the motor shaft are sent in digital format, in the form of data packets, through a TTL Level Multi Drop Bus interface. When used in positioning mode, the range allows for movement from 0 to 300°, with the resolution of 0.29°. For continuous movement the number of rotations is not limited in any direction. The high transmission rate of the control packets (up to 1 Mbps) gives the servomotors the ability to react quickly in control. The interface of the servomotors and the connectivity available at each servomotor allows the control on a common bus of all servomotors from a robotic structure (2 in this case) by using a daisy chain connection.

The software developed in Node-RED uses the client-server model, being composed of the following elements: a web server, a backend component for the application logic and a frontend component for the interaction with the users. In the frontend component (Fig. 3, a) there are several buttons available for inserting and retracting the catheter (available variants: from one movement to 200 continuous movements) but also for catheter rotation (available variants: from one movement to 10 continuous movements). The backend component (Fig. 3, b) has server-side logic, here there is a module for each button in the frontend and a module for the serial port. This component receives requests from the user, processes and then sends it to the robot via the serial port.

The robot design is compact with parts printed from nylon with carbon micro-fiber insertions on a FDM Onyx Pro printer from Markedforged. The catheter is translated using one motor and a double belts system and it can be easily released/replaced during the procedure.

In case a pre-operative CT scan of the patient is available, iMTECH navigation software can be combine with the robot to increase precision and reduce patient and doctor exposure to fluoroscopy radiation.



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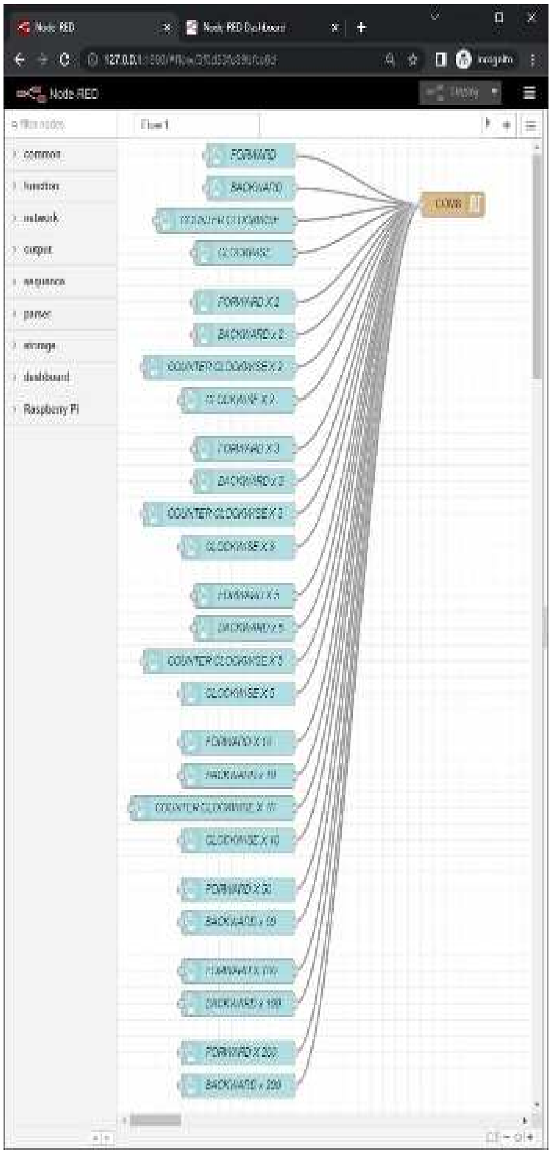

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Fig. 3. SAR-E Robot Control software application, frontend component (a) and backend component (b).

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In case a pre-operative CT scan of the patient is available, iMTECH navigation software can be combine with the robot to increase precision and reduce patient and doctor exposure to fluoroscopy radiation.

The software uses an electromagnetic system, AURORA developed by Northern Digital Inc. consisting in a table-top field generator, a system control unit, two sensor interface units and two sensors, one on the patient chest for registration and one mounted on the catheter tip, that offers to the system the 3D position in real time related to the field generator. The software creates the 3D rendering of the anatomy from the pre-operative CT scans and registers it with the patient before the procedure starts. During the procedure, iMTECH compute and display the position of the tools within the volume defined by the preoperative data, offering to the surgeon a navigation capability inside de vessels (Fig. 2, b).

5. RESULT AND CONCLUSION

SAR-E robot was successfully tested in the aorta phantom, in client/server mode, with and without image-guided navigation. The robot proved to be reliable in performing the two catheter movements, translation/retraction and axial rotation with no slippery, and includes the capability of changing the instrument during the procedure.

Starting from the femoral aorta, two instruments were used to reach the target, the aortic arch. One ablation catheter with tip bending control, and one custom made three-lumen carrier catheter developed in our laboratory for image-guided navigation systems testing.

This catheter includes a 5DOF Aurora electromagnetic (EM) tracking sensor mounted in a lumen and a bending controlled guide wire mounted in a second lumen, with a third lumen maintained free as working channel for additional instruments.

Table 1. The characteristics of the aortic branches and the performed measurements during the navigation process.

Path	**Model path length**	**Time to reach the target**	**Catheter length inside model**	**Nr of intersect.**
Left common illiacartery	475 mm	61,3 sec	499,8 mm	7
Right common illiacartery	465 mm	31,8 sec	471,6 mm	7

The robot can translate and rotate catheters or guidewires from 1 to 4 mm diameter, and allows an easy exchange during procedure. To avoid using fluoroscopy for navigation, the robot is used in conjunction with a special catheter with EM sensor, the AURORA tracking system and our image and EM guided application iMTECH, to successfully navigate in vascular system.

Table 2. Path simulation for accurate data collection

Path	ID Measurement	Time to reach the target	Catheter length introduced into the model	Nr of intersect
Left common iliac artery	L1	64,31 sec	501 mm	7
Left common iliac artery	L2	61,15 sec	497 mm	7
Left common iliac artery	L3	58,05 sec	504 mm	7
Left common iliac artery	L4	62,86 sec	521 mm	7
Left common iliac artery	L5	60,17 sec	500 mm	7
Right common iliac artery	R1	28,77 sec	475 mm	7
Right common iliac artery	R2	30,26 sec	467 mm	7
Right common iliac artery	R3	33,23 sec	475 mm	7
Right common iliac artery	R4	32,72 sec	466 mm	7
Right common iliac artery	R5	34,15 sec	475 mm	7

The SAR-E robot has the following features:

- The capacity of the rotation system is 360°, supporting 56 movements in steps ranging between 6.2° and 6.6°. The response time is instantaneous.
- The maximum capacity of the translation system is given by the length of the used catheter, having an unlimited number of steps, with an accuracy between 2.6 mm and 3 mm for each step.

The response time is instantaneous.

Table 1 shows the measurements made through the 2 navigable arteries (right common iliac artery and left common iliac artery) collecting information such as the time required to reach the target point, the distance traveled by the catheter and the number of intersections.

From Table 1, comparing the two paths, although the length of the route and the length of the inserted catheter are approximately equal, the time required to reach the target point is almost double for the left iliac artery, although the number of intersections reached is equal.

Data were obtained by performing 10 measurements and calculating the arithmetic mean (Table 2).

Test results show that the success of the procedure depends mainly on the maneuverability of the catheter and the precision of the registration when EM tracking is used for orientation.

A future version of the robot will include a mechanism to control the tip bending of the cardiac ablation catheter giving the surgeon the capability to control the procedure from another room with fluoroscopy or by using iMTECH for image-guided navigation.

6. AKNOWLEDGEMENT

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PROCEDURI ENDOVASCULARE FOLOSIND UN SISTEM ROBOTIC

Plasarea stenturilor poate fi dificilă, mai ales la pacienţii vârstnici cu boală vasculară complexă, unde eroarea de navigare şi plasarea necorespunzătoare pot necesita o intervenţie chirurgicală deschisă. Plasarea cateterului care conţine stentul în poziţia exactă depinde în mod semnificativ de abilităţile chirurgului, precizia se poate îmbunătăţi folosind robotica medicală şi navigaţia ghidată de imagini. Soluţiile robotizate existente au mai multe dezavantaje, cum ar fi costul ridicat al echipamentelor şi procedurii, dimensiunea sistemului, complexitatea procedurii, precizia de a atinge ţinta şi necesitatea unor instrumente noi, personalizate pentru a acoperi toate procedurile.

Scopul acestui proiect este de a dezvolta o soluţie de navigaţie robotică şi chirurgicală pentru a obţine o precizie şi acurateţe sporita a diagnosticului şi tratamentului precoce al bolilor cardiovasculare şi al cancerului pulmonar, pentru a creşte rata de succes, a reduce expunerea la radiaţii şi la stres a pacientului şi pentru a reduce substanţial costul procedurii. Pentru a atinge acest obiectiv, am dezvoltat un prototip de lucru al unui sistem robotizat de endo-navigaţie, SAR-E (cateter robotic de asistenţă inteligentă pentru proceduri endovasculare) şi l-am testat într-un model limitat de laborator pentru o demonstraţie iniţială a conceptului şi a siguranţei candidatului.

Lucian Gheorghe GRUIONU, PhD Eng. Habil., Professor, Faculty of Mechanics, University of Craiova, lucian.gruionu@edu.ucv.ro, 0721244200, Calea Bucureşti nr. 107 Cod. 200512, Craiova, Romania.

Răzvan Sabin STAN, PhD Student, Faculty of Mechanics, University of Craiova, stanrazvansabin@gmail.com, 0746055854, Calea Bucureşti nr. 107 Cod. 200512, Craiova, Romania**.**

Anca Loredana UDRIŞTOIU, Ph.D. Eng. Assoc. Prof. Faculty of Automation, Computers and Electronics, University of Craiova, Romania, anca_soimu@yahoo.com, 0741040508, Blvd. Decebal nr. 107, Craiova, România.

Andreea Valentina IACOB, PhD, Eng., Assist. Prof. Faculty of Automation, Computers and Electronics, University of Craiova, Romania, andr33a_soimu@yahoo.com, 0745100703, Blvd. Decebal nr. 107, Craiova, România.

Mircea Cătălin CONSTANTINESCU, Ph.D. Eng. Assoc. Prof. Faculty of Automation, Computers and Electronics, University of Craiova, Romania, catalin_1972@yahoo.com, 0723492338, Blvd. Decebal nr. 107, Craiova, România**.**

Gabriel GRUIONU, PhD. Eng. Assist. Prof., Indiana University School of Medicine, Indianapolis, United States of America, Faculty of Mechanics, University of Craiova, Craiova, Romania, gruionu@gmail.com, +1 (928) 863-8764, Krannert Cardiovascular Research Center 1800 N. Capitol Ave., E400 Indianapolis, IN 4620.