

Proof-of-Concept Medical Robotic Platform for Endovascular Catheterization

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INTRODUCTION

In endovascular interventions, vessels serve as access routes to deep and remote anatomic regions [1]. Navigation through narrow, fragile, and deformable vessels in endovascular procedures requires considerable skill [2]. Robotic distributed control approaches could improve catheter navigation to bypass anomalies and prevent tissue damage [3]. For particularly narrow vessels, remote actuation through magnetic fields could help in performing complex coordinated motion in three-dimensional (3D) space as magnetic fields are safe and highly controllable [4]. Visualization during endovascular catheterization procedures mainly relies on fluoroscopy, an X-ray based imaging modality that only offers two-dimensional (2D) views of the interventional scene [5]. Conventional approaches are thus characterized by poor situational awareness as constructing a 3D representation from 2D views is mentally demanding. Generating a 3D view via a C-arm is time-consuming and can only be done sporadically to limit patient radiation. Intra-operative 3D vessel representations from non-ionising imaging sources could greatly improve ease of navigation of the medical instruments to target anatomic sites. Another challenge is to provide safe guidance when navigating in fragile vessels from a restricted access point [6]. This could be addressed by path planning to search for a feasible path connecting a start to a goal configuration, while considering the robotic systems constraints and characteristics.

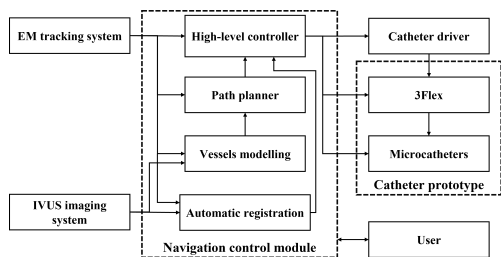


Fig. 1: Overall schematic of proposed medical robotic platform.

In this work, a prototype of a medical robotic platform aimed at endovascular catheterization is developed (Fig. 1). The system integrates several components: a multi-lumen catheter shaft, termed 3Flex, magnetically actuated microcatheter and a navigation control module conceived to help teleoperation and/or autonomous navigation of the 3Flex. This module comprises 3D vessel modelling, automatic registration, path planning, and catheter control. The 3Flex catheter is

designed to carry within it two 6 degrees-of-freedom (DOFs) electromagnetic (EM) tracking sensors, one intravascular ultrasound (IVUS) catheter, and two magnetically-actuated microcatheters envisioned to be controlled by a permanent magnet carrying KUKA robotic arm. However for this prototype, only one microcatheter was used.

MATERIALS AND METHODS

The 3Flex (Fig. 2) is a 3D printed catheter with an outer diameter of 12mm, a length of 500mm, and a 75mm long 2 DOF steerable tip actuated by four integrated pneumatic artificial muscles (PAMs). Its EM tracking sensors are located in two 10mm long sections proximally and distally adjacent to the steerable tip; both are fixed in place in their own lumens and provide position data to the control module. While the design can accommodate a coaxial Fibre Bragg Grating (FBG) for shape reconstruction of the distal segment, it was not implemented here.

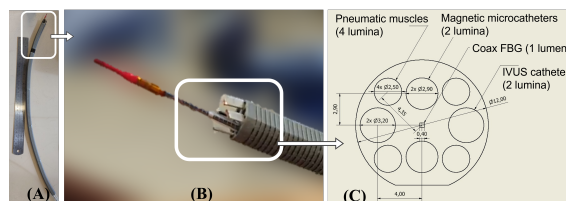


Fig. 2: A) 500mm long 3Flex system (beside a 300mm long ruler); B) view on tip of 75mm active distal section C) cross-sectional view showing embedded functionalities in the 3Flex’s lumina.

Autonomous trajectory planning is designed into the integrated system. Given the preferable anchor region, targets (i.e. two coronary ostia), and start region (patient groin), an optimal path and anchor pose were generated and forwarded to the user. During the trajectory planning, following constraints and system characteristics were incorporated: tip length, bending capability, 3Flex’s outer diameter, magnetic microcatheter length and offset between magnetic microcatheter and 3Flex catheter’s main axis. Real-time IVUS and EM tracking-based vessel modelling technology is integrated in this system. With it, a local representation of the vasculature of the vessel as a 10mm long cylinder-shape at the level of the catheter tip is estimated in real time. This 3D vessel modelling approach provides a 3D representation of the local vasculature for visualization and assists catheter navigation. Navigation assistance is achieved by outputting the 3D vessel model as well as its positioning relative to the 3Flex tip to the control strategy. Furthermore, an online automatic registration approach is implemented based on the intra-operative IVUS and EM tracking data. This registration method requires

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This work was supported by the ATLAS project. This project has received funding from the European Union’s Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 813782.

minimal user interaction by exploiting either a stochastic branch and bound method or an iterative closest point algorithm. It produces a transformation matrix between the EM tracker's coordinate frame and a pre-operative mesh frame [7]. This automatic registration runs continuously. Additional information regarding the vessels contour (points) are used to refine the registration between the pre-operative and the intra-operative (reconstructed) geometries. From the above IVUS-based strategies, enhanced catheter navigation is attained as the pre-operative geometry can be overlaid with the estimated local vessel models and the catheter pose. Consequently, the catheter pose and shape awareness can be significantly improved. To communicate this information the estimated local cylinder models and the reconstructed vessel registered with the pre-operative mesh was rendered both in a graphical user interface (GUI) based on the Unity engine (Fig. 3, left) and visualized in augmented reality using Microsoft's® HoloLens™ 2 (Fig. 3, right).

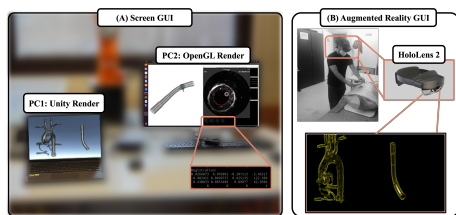


Fig. 3: Overview of GUI of intra-operative 3D vessel modelling, presenting (A) screen GUI including Unity rendering (PC1) and OpenGL rendering (PC2); (B) augmented reality GUI via HoloLens 2. The transformation matrix computed by the automatic registration strategy is also displayed in the middle.

The 3Flex has three DOFs of which two are catheter bending, while one is catheter insertion/retraction. Four PAMs are configured in two antagonistic pairs, allowing bi-directional bending of the 3Flex tip with a 80° maximum bending angle. To control the bending angle, input pressures to the four PAMs are modulated by four proportional air pressure valves (Festo group, Germany). These valves receive control signals from an analog output module NI-9144 (NI, Texas, USA). Currently tele-operated, 3Flex bending will be semi-autonomous in the future. A sleeve-based catheter driver, which has two pneumatically actuated grippers that grasp the catheter alternately and insert the catheter in a relay fashion, (Fig. 1, top right) is used to advance/retract the 3Flex.

The magnetic microcatheter carried by the 3Flex is composed of a soft polymer (UV Electro 225-1, Momentive, Germany) with embedded magnetic particles (MQFP-15-7, Magnequench, Germany). Once protruding from the 3Flex, it can be remotely actuated by a permanent magnet that is either robot-mounted or hand-held. The hollow microcatheter can introduce other sensors or guidewires for easier cannulation or for returning to earlier reached locations.

RESULTS

Trajectory planning was employed for the integrated system and the visualization of the inputs and outputs of the path planner is presented in Fig. 4. Fig. 3 depicts the output of the 3D vessel modelling approach and the online automatic registration strategy. The former determines, at each time step, an estimated local cylinder in the vicinity of the 3Flex tip. The latter helps to compute the transformation matrix of the intra-operative IVUS data with respect to the pre-operative geometry and overlay the estimated cylinder for catheter navigation. Both methods rely on the EM tracking data

relative to the 3Flex tip pose and the vessel lumen contours, segmented from IVUS images.

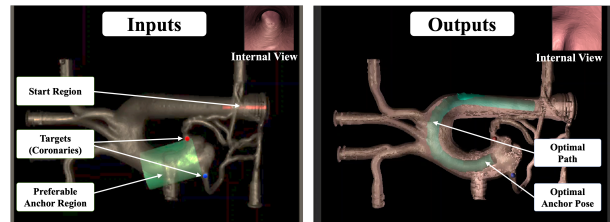


Fig. 4: Visualization of the inputs and outputs of the path planner.

To qualitatively evaluate the system, the 3Flex catheter was steered in an aortic phantom by using a joystick. The planned path was displayed to the user controlling the joystick. The catheter was successfully steered from the descending aorta to the coronary ostia (Fig. 5), by utilizing deflection from contact points. The optimal deflection points were determined by the navigation control module by considering the maximum bending angle/radius of the 3Flex. The magnetic microcatheter was guided to the right coronary artery (RCA) based on external visual feedback (Fig. 5) for now. However, in the future, integration of FBG- and EM- based shape reconstruction will replace the need for visual feedback.

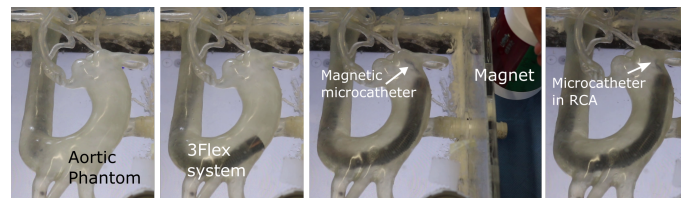


Fig. 5: 3Flex system being steered in the aorta and delivering the microcatheter to the aortic root from where the external magnet guides the magnetic microcatheter to the right coronary artery.

DISCUSSION AND CONCLUSION

The 3Flex was successfully tele-operated to the target site by joystick, further showing good stability during the manipulation of the magnetic microcatheter. Planned future work consists of integrating an autonomous control strategy of the 3Flex catheter to follow the pre-planned trajectories, while considering the intra-operative vessel model in the decision-making. Though only one microcatheter was used for this demonstration, the 3Flex has been designed to carry two within it which can be pushed one after the other and guided to both coronary arteries. Finally, while the proposed prototype is focused on endovascular catheterization, the developed technologies can be transferable to other intraluminal clinical scenarios, e.g. colonoscopy or ureteroscopy.

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