Magnetic catheterization using a medical robotic platform

M. H D. Ansari^{1,2,3,*}, D. Wu^{3,4}, F. Trauzettel^{3,4}, Z. Li^{4,5}, B. F. Barata^{3,6}, X-T. Ha^{1,2,3}, D. Dall'Alba⁶, G. Borghesan³, M. Ourak³, V. Iacovacci^{1,2}, S. Tognarelli^{1,2}, J. Dankelman⁴, E. De Momi⁵, P. Breedveld⁴, P. Fiorini⁶, J. Vander Sloten³, A. Menciassi^{1,2}, and E. Vander Poorten³

¹The BioRobotics Institute, Scuola Superiore Sant'Anna, Italy

²Department of Excellence in Robotics & AI, Scuola Superiore Sant'Anna, Italy

³Department of Mechanical Engineering, KU Leuven, Belgium

⁴Department of Biomechanical Engineering, Delft University of Technology, Netherlands

⁵Department of Electronics, Information and Bioengineering, Politecnico di Milano, Italy

⁶Department of Computer Science, University of Verona, Italy

*hasan.mohammad@santannapisa.it

INTRODUCTION

A Chronic Total Occlusion (CTO) is a type of arterial blockage, which has persisted for more than three months, affecting the coronary arteries of the heart. Traditionally, CTO is treated by making a large incision in the chest area. This is a highly invasive procedure. Instead, catheter based approaches offer smaller incisions and exploit the vessels as access routes to remote anatomic regions [1]. Navigating catheters through narrow, fragile, and deformable vessels requires considerable skill [2]. Robotic distributed control approaches could potentially improve catheter navigation to bypass anomalies and prevent tissue damage [3]. However, when handling relatively stiff instruments, avoiding tissue damage remains difficult. For particularly tortuous vessels, remote actuation through magnetic fields could help in performing complex coordinated motion in three dimensional (3D) space. Magnetic fields are safe and highly controllable [4], and magnetic catheters can be made soft and compliant [5]. A good understanding of the catheters whereabouts remains important. Visualization during endovascular catheterization procedures mainly relies on fluoroscopy, a harmful X-ray based modality that only offers two dimensional (2D) views [6]. Instead, Augmented Reality (AR) assisted 3D visualization can limit exposure to harmful radiation.

In this work, a prototype of a medical robotic platform aimed at magnetic catheterization for CTO treatment is developed (Figure 1). The system integrates several components: a multi-lumen guide catheter, termed 3Flex, a magnetic catheter (MC), a catheter driver, and a navigation control module conceived to help teleoperation of the 3Flex. The 3Flex catheter [7] is designed to carry within it an MC controlled by an External Permanent Magnet (EPM) carrying KUKA robotic arm. The system is designed to operate through a two-stage

approach: 1) initially, navigating the 3Flex from the groin incision to predefined positions in the ascending aorta, followed by 2) extending the MC from within the 3Flex, continuing under magnetic navigation to reach the blockage site located in the Left Coronary Artery (LCA). The details of the control module and the first stage involving a successful positioning of the 3Flex in the ascending aorta, and the characterization of the MC have been outlined in previous works [8][9][10]. The robotic control of a magnetic catheter for catheterization of the coronary arteries has not yet been shown for this platform, which is the second stage of the procedure. This abstract concentrates on detailing the second stage of the procedure and also evaluates the optimal position of the 3Flex catheter for effective treatment.

MATERIALS AND METHODS

A soft magnetic tip was custom fabricated using the extrusion process shown in [5] and extensively characterized in [10]. The resulting axially magnetized tip is a hollow cylinder of 7 mm length, 2.3 mm outer diameter and has a 0.9 mm inner diameter lumen. It was glued (Loctite Super Attak®) to a 65 cm long 4Fr medical catheter (Radifocus® Glidecath™ C2) such that their axes align and the assembly was used as a steerable MC. The 3Flex is also 3D printed with an outer diameter of 12mm, a length of 500mm, and a 75mm 2 Degrees of Freedom (DOFs) steerable tip. It is actuated by four Pneumatic Artificial Muscles (PAMs) placed symmetrically along its periphery in their offcentred lumens which are 90° apart from each other. The EM sensor, placed at the tip of the 3Flex, provides the position data to the control module.

The 3Flex carrying the MC within one of its lumens was inserted into the aortic phantom using a catheter driver [11]. The tip of the 3Flex was steered to reach the desired location using EM based positioning and AR assisted 3D

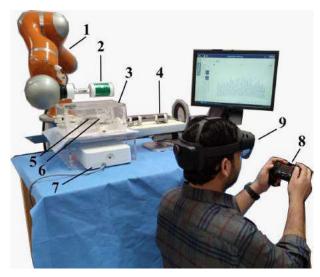


Fig. 1 The robotic platform for magnetic catheterization: 1 -KUKA robot; 2- EPM; 3- aortic phantom; 4- catheter driver; 5- 3Flex; 6- MC; 7- Electro-Magnetic (EM) field generator; 8gamepad; 9- head-mounted display.



Fig. 2 The positions of the 3Flex inside a realistic aortic phantom for performing the catheterization using an MC.

visualization. The MC was then manually pushed out from it and steered to the LCA using the KUKA mounted EPM (outer diameter = 6cm, inner diameter = 1cm, length = 7cm, diametrically magnetized). A trajectory was defined using a few way-points for the EPM to follow and guide the MC to the LCA. Since the phantom was transparent, the KUKA was instructed to follow the pre-defined trajectory based on visual feedback by the operator. Further details about the robotic platform can be found in [8].

RESULTS AND DISCUSSION

The 3Flex was successfully advanced through the aortic phantom to each of the pre-defined positions: A, B, C, and D which are approximately 4 cm, 5 cm, 6 cm, and 7 cm from the aortic root, respectively (Figure 2). The MC could also successfully be advanced through the 3Flex. While the MC was advanced through the 3Flex, it was guided under the influence of the EPM to the LCA. The catheterization of the LCA was attempted ten times each from the four different positions of the 3Flex and the success rate of catheterization was found to be 0% from A and B, and 100% from C and D.

Due to bending limitations, the 3Flex always rested along the aortic wall close to the Right Coronary Artery (RCA). Improving the bending capabilities of the 3Flex could mitigate this limitation. It can be concluded that 3Flex has to be positioned such that its tip is at least 6 cm from the aortic root. This ensures that the length of the MC protruding from the 3Flex is enough to achieve a 90° bending to reach the LCA and, therefore, a 100% success rate is observed from positions C and D. If the 3Flex tip is too close to the aortic root, the length of the MC protruding out from it is not enough to achieve a 90° bending and, therefore, a 0% success rate is observed from positions A and B. From all four positions, it was not possible to achieve a successful catheterization of the RCA which is due to the insufficient bending radius exhibited by the MC. These limitations could be overcome by improving the bending capabilities of the MC. In future, Fiber Bragg Grating (FBG) based sensors could be used to reconstruct the shape of the MC and localize its tip in conjunction with the EM sensor based position data of the 3Flex. This would help in avoiding harmful X-rays and in teleoperation by eliminating the need for maintaining line of sight for visual feedback. Advancement of the magnetic catheter to the blockage site within the coronary arteries could be done in the future, bearing in mind the shortcomings of the present system and the requirements for the propulsive forces to overcome the friction.

ACKNOWLEDGEMENT

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 Sklodowska-Curie grant agreement No 813782.

REFERENCES

- [1] D. Guez et al., "Recent trends in endovascular and surgical treatment of peripheral arterial disease in the medicare population," Journal of Vascular Surgery, vol. 71, no. 6, p. 2178, 2020.
- [2] R. Aggarwal et al., "Virtual reality simulation training can improve inexperienced surgeons' endovascular skills," European Journal of Vascular and Endovascular Surgery, vol. 31, no. 6,
- Y. Yang et al., "Adaptive distributed control of a flexible manipulator using an iterative learning scheme," IEEE Access, vol. 7,
- [4] F. Carpi et al., "Stereotaxis Niobe® magnetic navigation system for endocardial catheter ablation and gastrointestinal capsule endoscopy," Expert Review of Medical Devices, vol. 6, no. 5,
- [5] M. H. D. Ansari et al., "3d printing of small-scale soft robots with programmable magnetization," Advanced Functional Materials, vol. 33, no. 15, p. 2211918, 2023.
- H. Rafii-Tari et al., "Current and emerging robot-assisted endovascular catheterization technologies: A review," Annals of Biomedical Engineering, vol. 42, no. 4, 2014.
- [7] F. Trauzettel et al., "Six smart guidelines for high-tech manufacture on low-tech 3d printers: the case of the 3flex," Journal of Engineering Design, pp. 1-20, 2024.
- M. H. D. Ansari et al., "Proof-of-concept medical robotic platform for endovascular catheterization," in Proceedings of the 11th Conference on New Technologies for Computer and Robot Assisted Surgery (CRAS), 2022.
- [9] D. Wu et al., "Comparative analysis of interactive modalities for intuitive endovascular interventions," IEEE Transactions on Visualization and Computer Graphics, pp. 1–18, 2024. [10] M. H. D. Ansari et al., "Characterization of a 3d printed
- endovascular magnetic catheter," Actuators, vol. 12, no. 11, 2023.
- O. Al-Ahmad et al., "Force control with a novel robotic catheterization system based on braided sleeve grippers," IEEE Transactions on Medical Robotics and Bionics, vol. 5, no. 3, pp. 602-613, 2023.