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Evaluation of a Multi-Steerable Catheter for Cardiac Interventions in a 3D-Printed Heart Model

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1. Introduction

To overcome the challenges presented by complex 3-dimensional shapes and tortuous vasculature in the cardiovascular environment, we previously developed a prototype of a multi-steerable catheter having 4 DOFs controlled by two joysticks [1]. However, it remains unknown whether the added steering possibilities are beneficial in the cardiovascular anatomy. With this research we aimed to investigate the effect of 0-DOF, 2-DOF, and 4-DOF catheter systems on surgical performance in a cardiovascular model.

2. Methods

Catheter Prototype – The catheter prototype was modified to compare 0-DOF (no steering), 2-DOF (multi-directional steering with a single segment), and 4-DOF steering (multi-directional steering with two segments).

Heart Model & Pathways – A transparent, rigid 3D-printed heart model was fabricated by Materialise (Leuven, Belgium) based on patient CT-data. Three pathways were defined for the experiment, differing in level of complexity:

1. Endo-myocardial biopsy route: starting in the jugular vein to reach a specified location on the intraventricular wall of the right ventricle.
2. Aortic valve implantation route: starting from the femoral artery to reach a specified location past the aortic valve.
3. Trans-septal mitral valve route: starting from the inferior vena cava to reach a specified location past the mitral valve.

Test Setup – The three identified pathways were visibly marked on the heart model and an electrode was placed at the start and end points of each pathway. The electrodes were connected to a National Instruments LabVIEW box to record the elapsed time between the start and end of each test.

Test Procedure – 18 novices (all students and employees at Delft University of Technology) between 18 and 30 years old, participated in the experiment. Each participant conducted three experimental sessions. In each session, one catheter type was used to manoeuvre along each of the three pathways. This resulted in nine tests per participant. Catheter order and pathway order were randomized.

Performance measures – Performance was assessed using the following objective measures: 1) completion time of each of the nine tests, and 2) number and locations of errors (wrong branch or chamber, retraction of the catheter, catheter blocking). Moreover, the following self-reported measured were used: 1) task performance, 2) usability, 3) workload, and 4) catheter preference.

3. Results

General Observations – General observations gave insight in the methods the users applied to overcome difficulties in steering. These methods included rotation of the shaft, fast push-pull movements of the catheter as a whole, shaking movements to direct the catheter in a specific region, and making use of the cardiac wall.

Preliminary Results – Four participants have been tested so far, yielding a total of 36 tests (4 x 9). For both the 0-DOF and the 2-DOF catheters, 4 out of 12 tests succeeded within 5 minutes. With the 4-DOF catheter, the task was completed within 5 minutes in 8 out of 12 tests. From the tasks that were completed within 5 minutes, the average completion time was measured as 102 s for 0-DOF, 126 s for 2-DOF, and 118 s for 4-DOF. Additionally, all four users reported that they preferred the 4-DOF catheter over the other two.

4. Discussion & Conclusion

The preliminary results indicated that the 4-DOF catheter is able to overcome the challenges of the cardiac pathways better than the 0-DOF and 2-DOF catheters. The remaining 14 participants must be tested before any clear conclusions can be drawn from the results.

References

[1] A. Ali, A. Sakes, E.A. Arkenbout, P. Breedveld, "Design of a Multi-Steerable Catheter for Complex Cardiac Interventions," 28th International Conference of Society for Medical Innovation and Technology (SMIT), Oct. 5-8, Delft, The Netherlands.