Comparing the performance of conventional and robotic catheters in transcatheter aortic valve implantation

E. B. Mazomenos*, P.-L. Chang *, A. Rolls†, C. D. Bicknell † C. V. Riga†, and D. Stoyanov*
*Centre for Medical Image Computing, Department of Computer Science, University College London,
London, WC1E 6BT, U.K. email:{e.mazomenos, ping-lin.chang, danail.stoyanov}@ucl.ac.uk
† Division of Surgery, Department of Surgery and Cancer, Imperial College London,
London, SW7 2AZ, U.K. email:alex.rolls1981@googlemail.com,{colin.bicknell, c.riga}@imperial.ac.uk

Abstract—**In this paper we investigate the performance of a recently developed robotic catheterization platform in comparison to conventional surgical equipment. Transcather aortic valve implantation (TAVI) was chosen as the test case and 12 interventionists (6 experts and 6 novices) participated in experiments with a silicon aorta model. Video sequences of the fluoroscopic monitor, used for guiding the instruments, were captured and processed with specialized software. To evaluate and compare the two systems the 2-D position of the catheter/guidewire tip is tracked and the shape of the phantom model is extracted in the video frames. In our analysis, we focus on three metrics; the procedure time, the average speed and the average distance to the vessel wall. The obtained results show that procedure time is capable of discriminating the participants of the different experience groups, achieving p=0.008 in the first stage of the experiment. In addition, experts consistently exhibit a higher average speed than novices. Ultimately, the increased average distance to the vessel wall demonstrated by the robotic system is an indication of improved precision and safer catheter/guidewire navigation.**

I. INTRODUCTION

Minimally invasive surgical (MIS) procedures are nowadays the preferred form of treatment for a number of vascular conditions. Transcatheter aortic valve implantation (TAVI) is an MIS approach for valve replacement that allows patients, previously deemed unsuitable for open heart surgery to undergo treatment [1]. Despite its clear advantages, of minimum incision and smaller recovery time, over open surgery, TAVI faces a number of challenges stemming from the restricted operating environment and the danger for calcium dislodgement. These factors raise the risk for intraoperative human errors occurring.

In recent years the field of MIS has been revolutionized from the development of surgical robotic instruments and platforms. In the endovascular domain, many studies assessed robotically-controlled surgical systems for a number of different procedures [2]. In general, they were found to be capable of reduced operation time, increased precision and safety in terms of decreasing the risk for vascular damage, compared to conventional catheters [3], [4]. Subsequently, there has been increasing interest for employing these systems in TAVI operations.

TAVI procedures can also benefit from an improved surgical training paradigm. Recent studies have introduced the video-based analysis of the catheter's motion for evaluating endovascular surgical skills [5], [6]. In traditional methods for endovascular skills assessment (e.g. global rating scales, checklists), one aspect that characterizes surgical competency is the ability to demonstrate a high level of respect for tissue damage [7]. Surgeons must be able to operate the surgical instruments in such a way that no danger for tissue damage (e.g. vessel rupture) arises. This is of particular importance for TAVI that presents a high risk for calcium dislodgement due to calcification deposited in the vasculature.

In this work we investigate potential benefits of a robotic catheter system over conventional surgical equipment. We present TAVI experiments on a phantom model with 12 surgeons of different experience (6 novices, 6 experts) and analyze their operational characteristics. Our analysis is performed on recorded video sequences of the fluoroscopy screen used in the experiments. A semi-automated algorithm is used to track the tip of the catheter/guidewire in the video frames. We use this information to calculate the average speed during the operation as the ratio of the total path length travelled over the procedure time. Furthermore, we segment the aorta model in the video frames and introduce the distance to the vessel wall as a metric to evaluate how safe the navigation of the catheter is with the respect to adjacent vascular tissue. The remaining of the paper is organized as follows. Section II gives the details of the experimentation and the equipment used, while in Section III we present the data analysis methods and the obtained results. Conclusions follow in Section IV.

II. EXPERIMENTAL METHODS

A. *Inanimate model of the aorta*

For simulating the TAVI procedure a silicon-based aorta model (Elastrat Sàrl, Geneva, Switzerland) was used. It was constructed from CT recordings in humans and represents a type I aortic arch. The opening of the aortic valve was reduced to 0.6cm^2 so as to resemble stenosis and has been used before in TAVI experiments [8]. The left ventricle was custom-modelled and attached to the proximal end of the arch.

During the experiments the phantom was perfused by a water and glycerol solution, circulated via a pump.

B. *Surgical equipment*

Conventional surgical equipment included typical catheters (5Fr pigtail, AL1 guide catheter), guidewires (0.032in J-wire, 0.018in glide-wire, 0.035in super-stiff wire) and medical balloons (22mm balloon). Fluoroscopic imaging was employed for navigating the surgical instruments. The Magellan$^{\text{TM}}$(Hansen Medical, Mountain View, CA, USA) system, specialized for peripheral vascular procedures, was employed as the robotic platform. We used the 6Fr Magellan$^{\text{TM}}$steerable robotic catheter with a 9.5Fr sheath. This catheter is capable of 180° multidirectional articulation while the sheath adds 90° articulation. The operator controls the robot and navigates the catheter remotely from a workstation using a joystick device, with the aid of fluoroscopy imaging and orientation information superimposed in the fluoroscopy screen. Standard endovascular instruments and devices (balloons, stents) can also be percutaneously inserted with the Magellan system. Video sequences of the fluoroscopy monitor were recorded during both robotic and conventional procedures for post-hoc analysis.

C. *Participants*

Twelve endovascular surgeons agreed to participate in this study. They were categorized into two groups based on their previous endovascular experience. The two groups were labeled as: the novices group (n=6) with no prior experience in endovascular interventions and the experts group that included individuals who had performed more than 100 operations. No individual had prior experience with the robotic system and no training before the execution of the experiments took place. Each participant was asked to perform two executions; one with the conventional equipment and one with the Magellan$^{\text{TM}}$robotic platform in random order. We focused on two specific stages of the TAVI procedure. Firstly, the navigation of the catheter/guidewire through the aortic arch, defined as the advancement from the descending aorta (at the point marked by the most proximal part of the left ventricle) into approximately 2cm proximal to the aortic valve. The second part was the crossing of the valve, considered as the advancement of the catheter/guidewire from the 2cm point proximal to the aortic valve, in the left ventricle.

III. DATA PROCESSING AND RESULTS

Captured video sequences were processed post-hoc and the total procedure time for each stage was extracted from these recordings. Video frame processing took place using custom software which implemented a semi-automated algorithm to track the 2-D location, in pixel coordinates, of the catheter/guidewire tip in the fluoroscopic image. The tip was manually annotated in the frame that appeared initially and then was automatically tracked in subsequent video frames. Obtaining the trajectory of the instrument's tip allowed us to investigate the kinematic pattern of the catheter/guidewire and compare both the conventional equipment to the robotic system as well as the different experience groups.

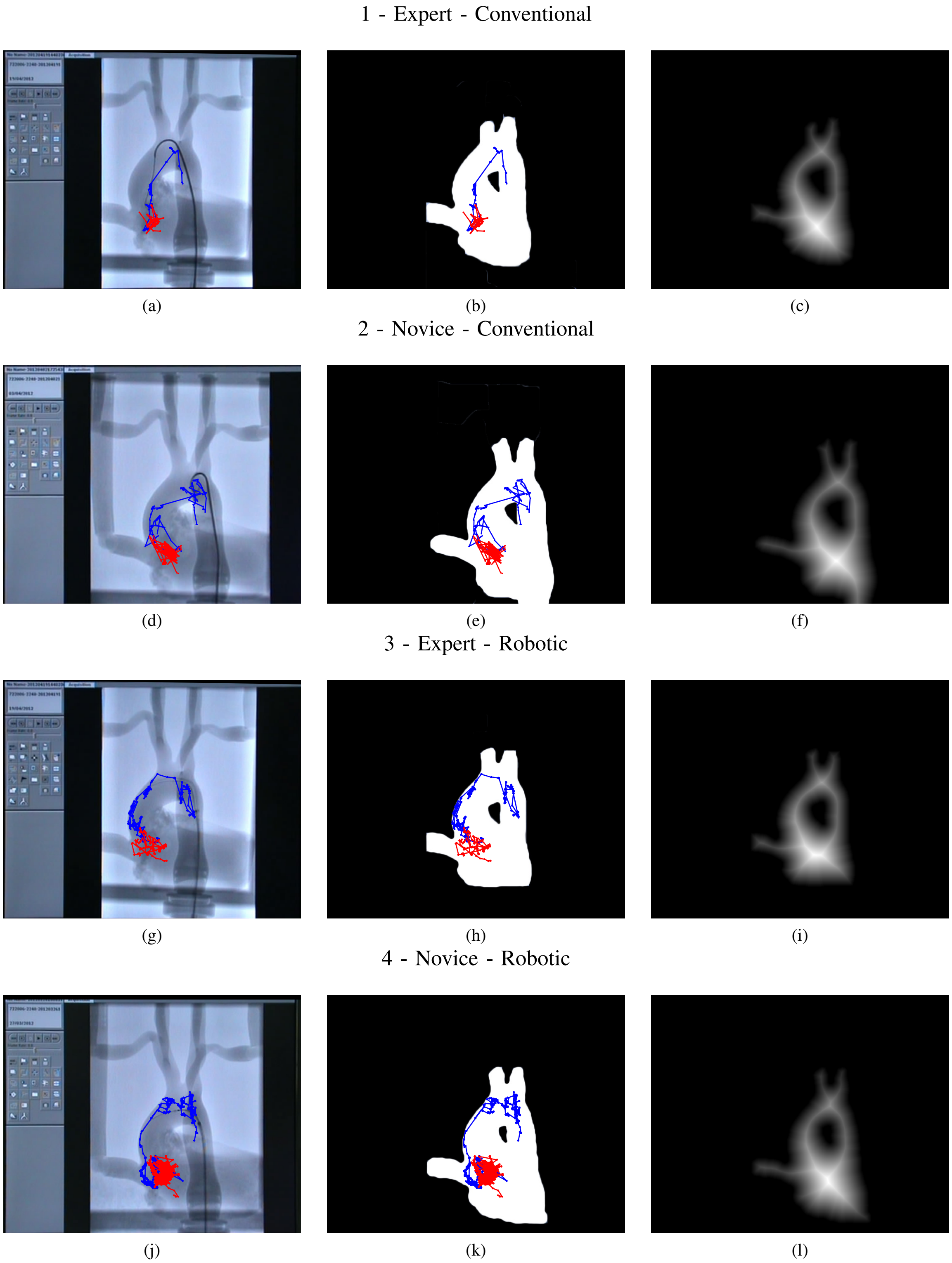
To evaluate the safe navigation of the catheter in a quantitative way, we elected to investigate the tip's trajectory with respect to its distance from the vessel wall. The first step was to segment the shape and geometry of the vasculature in the fluoroscopic image. To achieve this we manually isolated the portion of the image that contains the aorta model and transformed it into a grayscale image. Following, we extracted the shape of the vasculature by converting the grayscale image into a binary one using a cut-off threshold value. Pixels with grayscale value above the threshold were assigned value "1" while the ones below, the value "0". In the obtained binary image, the aorta model is delineated by the white pixels. We calculate the Euclidean distance of each white ("1") pixel, focusing on the pixels that correspond to the catheter's trajectory to the nearest black ("0") pixel, which in essence defines the edge of the vessel wall. This allows us to calculate the average distance of the tip's locations to the nearest point of the vessel wall. Our main hypothesis is that experienced interventionists should be able to maintain a relatively large distance from the vessel wall, thus minimizing the danger for potential tissue damage.

Fig 1 illustrates the three processing steps we followed (catheter/guidewire tip tracking, model segmentation, distance calculation) in representative experimental executions from an expert (rows 1 and 3) and a novice participant (rows 2 and 4) with both the conventional catheter (rows 1 and 2) and the robotic system (rows 3 and 4). The higher efficiency of the expert surgeon, in terms of time and movement, is evident by the trajectory of the tip particularly during the first stage. It is also clear that the two operators required more steps to complete the procedure when using the robotic catheter.

Median values for procedure time (sec), average speed (calculated as total path length/procedure time) and average distance to vessel wall (px) are listed in Table I. The box plots of the three features are illustrated in Fig. 2. To compare results between the two experience groups we use the Mann-Whitney U-test (M-W) while to compare the two types of catheter (robotic, conventional) in each participant we use the Wilcoxon signed-ranked test (Wi). Statistical significance is considered when p-value<0.05.

From Table I we observe that procedure time, especially in the first stage, with the conventional catheter/guidewire discriminates among the two experience groups. Expert surgeons require less time to complete both stage 1 (34.9s, iqr (27 - 52.1) vs 239.1s, iqr (128.8 - 278.2), p=0.087) and stage 2 (111.2s, iqr (53.2 - 246.9) vs 208s, iqr (86.2 - 530.7), p=0.240). The use of the robotic system results in higher completion times by both groups in both stages and shows significance (p=0.03) for the experts group in stage 1. This can be attributed to the fact that all participants had no familiarity with the robotic system.

During the experiments we noticed that occasionally the instrument would remain stationary for a period of time. We therefore elected to calculate the average speed as an indication



1 - Expert - Conventional

(a) (b) (c)

2 - Novice - Conventional

(d) (e) (f)

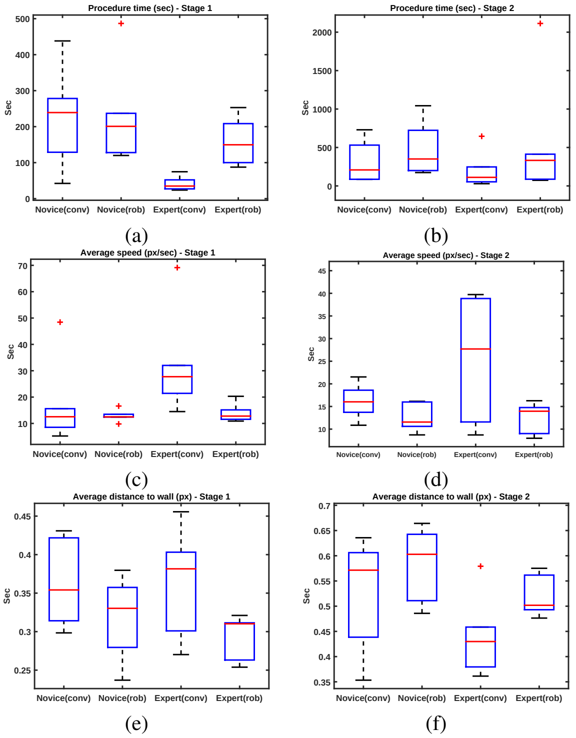
3 - Expert - Robotic

(g) (h) (i)

4 - Novice - Robotic

(j) (k) (l)

Fig. 1. Image processing steps; (a),(d),(g),(j) Original frames of the fluoroscopy monitor with tip's positions (blue - stage 1, red - stage 2); (b),(e),(h),(k) binary image with segmented aorta model; (c),(f),(i),(k) Image depicting the Euclidean distance of the each pixel of the model (white pixel) to the closest point on the vessel wall (first black pixel). Intensity of white color denotes higher distance value. Rows 1, 3 are from an expert participant and rows 2, 4 from a novice. Experiments in rows 1,2 are done with conventional equipment while the robotic platform is used in rows 3, 4. Comparing (b) and (e) we note the more efficient handling of the catheter by the expert, particularly in stage 1 (blue line).



(a) (b) (c) (d) (e) (f)

Fig. 2. Box plots of the three features for both stages: (a),(c),(e) - Stage 1 (Arch navigation); (b),(d),(f) - Stage 2 (Valve crossing)

TABLE I

PROCEDURE TIME, AVERAGE SPEED AND AVERAGE DISTANCE RESULTS (MEDIAN VALUES AND P-VALUES) FROM THE TWO STAGES OF THE TAVI EXPERIMENTATION

	Novices	Experts	p-value (M-W)
Procedure time (sec) - Stage 1 (Arch navigation)			
Conventional	239.1	34.9	0.008
Robotic	200.8	149.6	0.309
p-value (Wi)	0.687	0.031	
Procedure time (sec) - Stage 2 (Valve crossing)			
Conventional	208	111.2	0.240
Robotic	350.3	332.0	0.699
p-value (Wi)	0.312	0.562	
Average Speed (px/sec) - Stage 1 (Arch navigation)			
Conventional	12.5	27.7	0.064
Robotic	12.4	12.7	0.699
p-value (Wi)	1	0.031	
Average Speed (px/sec) - Stage 2 (Valve crossing)			
Conventional	16	27.7	0.309
Robotic	11.5	13.9	0.937
p-value (Wi)	0.1563	0.0938	
Average Distance to wall (px) - Stage 1 (Arch navigation)			
Conventional	0.354	0.399	1
Robotic	0.330	0.310	0.329
p-value (Wi)	0.218	0.312	
Average Distance to wall (px) - Stage 2 (Valve crossing)			
Conventional	0.571	0.430	0.246
Robotic	0.602	0.501	0.064
p-value (Wi)	0.562	0.125	

of movement efficiency. Using the path length only would not be indicative of these pauses. Expert operators exhibited a higher average speed than novices in both stages, 27.7 px/s vs 12.5 px/s in stage 1 and 16 px/s vs 27.7 px/s in stage 2, when using the conventional equipment. For the robotic system the average speed was similar among the two groups in both stages.

In terms of the average distance to the vessel wall, both groups demonstrate similar performance in stage 1. However in stage 2 which, involves crossing of the valve, a higher average distance to the vessel wall was exhibited in both groups when using the robotic catheter. Although the p-values do not reveal statistical significance this observation may be indicative of the robotic system ability for more precise and safe navigation, thus limiting potential danger for vessel damage.

IV. CONCLUSIONS

This paper presented a comparative study between standard endovascular equipment and a robotic platform designed for endovascular intervention. A cohort of 12 participants, separated into two groups (novices, experts) performed two stages of a TAVI operation on a silicon model. Video sequences of fluoroscopy images were captured and used to track the 2-D position of the catheter/gruidewire tip as well as to segment the aorta model. Procedure time, average speed and average distance to the vessel wall, a metric we believe is indicative of safer catheter navigation, were the three parameters investigated. The two groups demonstrated different procedure times especially in the arch navigation stage (p=0.008). Moreover experts surgeons navigated the catheter in a faster pace than novices. Finally, the average distance to the vessel wall did not demonstrate statistical significance. This is an initial attempt to generate such metrics and errors may be introduced due to imperfect segmentation of the aorta model. Nevertheless, the segmentation result seems to be accurate enough and from the obtained results, the robotic system appears to facilitate safer catheter manipulation as indicated by a higher average distance to the vessel wall during stage 2.

REFERENCES

[1] R. R. Makkar, G. P. Fontana, H. Jilaihawi *et al.*, "Transcatheter aortic-valve replacement for inoperable severe aortic stenosis," *New Engl. J. Med.*, vol. 366, no. 18, pp. 1696–1704, 2012.

[2] H. Rafii-Tari, C. J. Payne, and G. Z. Yang, "Current and emerging robot-assisted endovascular catheterization technologies: a review," *Ann. Biomed. Eng.*, vol. 42, no. 4, pp. 697–715, Apr 2014.

[3] C. V. Riga, N. J. Cheshire, M. S. Hamady *et al.*, "The role of robotic endovascular catheters in fenestrated stent grafting," *J. Vasc. Surg.*, vol. 51, no. 4, pp. 810–819, Apr 2010.

[4] C. V. Riga, C. D. Bicknell, M. S. Hamady *et al.*, "Evaluation of robotic endovascular catheters for arch vessel cannulation," *J. Vasc. Surg.*, vol. 54, no. 3, pp. 799–809, Sep 2011.

[5] A. Rolls, C. Riga, C. Bicknell *et al.*, "A pilot study of video-motion analysis in endovascular surgery: Development of real-time discriminatory skill metrics," *Eur J Vasc Endovasc Surg*, vol. 45, no. 5, pp. 509 – 515, 2013.

[6] I. Van Herzeele, R. Aggarwal, I. Malik *et al.*, "Validation of video-based skill assessment in carotid artery stenting," *Eur J Vasc Endovasc Surg*, vol. 38, no. 1, pp. 1–9, Jul 2009.

[7] S. J. Hislop, J. H. Hsu, Narins *et al.*, "Simulator assessment of innate endovascular aptitude versus empirically correct performance," *J. Vasc. Surg.*, vol. 43, no. 1, pp. 47–55, Jan 2006.

[8] R. A. Rippel, A. E. Rolls, C. V. Riga *et al.*, "The use of robotic endovascular catheters in the facilitation of transcatheter aortic valve implantation," *Eur J Cardiothorac Surg*, vol. 45, no. 5, pp. 836–841, May 2014.