

When will a Robot Outperform a Handheld Instrument? – A Case Study in Beating-Heart Paravalvular Leak Closure

B. Rosa, Z. Machaidze and P. E. Dupont

*Pediatric Cardiac Bioengineering, Boston Children's Hospital,
Harvard Medical School, Boston, USA*

pierre.dupont@childrens.harvard.edu

INTRODUCTION

Paravalvular leaks (PVLs) are a complication of valvular heart surgery, occurring in 5 to 17% of surgically implanted valves [1]. Identifying the leak and deploying a closure device during beating heart surgery is a difficult task that can only be carried out by a highly qualified interdisciplinary team of surgeons and imaging experts [2]. Recently, our group introduced a cardioscopic imaging device for beating heart surgery, which was successfully deployed for septal tissue removal [3]. The tip of the instrument comprises a chip-on-tip digital camera (Awaiba Naneye) and an LED embedded into a silicone optical window. Pressing the optical window against tissue displaces the blood, enabling visualization inside a beating heart. Using this technology, *in situ* high-resolution imaging could be used for precisely locating PVLs for controlled delivery of a closure device.



Fig. 1 Aortic PVL repair with a concentric tube robot.

Deploying such a device inside the heart however is complex, and requires a high degree of dexterity for navigating around the valve annulus inside the heart (Fig 1). Moreover, contact with the heart wall should be avoided so as not to cause arrhythmias.

While surgical robots, such as those comprised of concentric tubes [4], offer enhanced dexterity with reduced invasiveness, the use of any robot during a surgical procedure can lead to longer set-up times and higher costs compared to similar procedures performed with handheld instruments. Indeed, the question of robot superiority for a specific procedure can often only be addressed after the robot is designed and tested.

This paper attempts to address this question in the context of paravalvular leak closure during the design process by comparing the dexterity and collision avoidance capabilities of three systems: a straight handheld instrument, a manually steerable instrument

and a teleoperated robotic instrument. The surgical task and anatomic features are expressed as constraints in an optimization problem, where different robot architectures are optimized and compared. The optimized designs are then fabricated and evaluated in benchtop experiments on a 3D printed heart model.

DESIGN OF CARDIOSCOPIC TOOLS

In order to be able to compare several tool architectures, a constrained optimization framework is developed. Similarly to [4], constrained optimization is used in order to optimize the parameters of each tool in order to carry out the task while respecting anatomy constraints. The anatomical model is segmented from an anonymized patient MRI using the 3D slicer software.

The surgical task is expressed as constraints in the optimization framework. First, a positioning constraint is formulated, which consists of reaching 25 targets evenly spaced on the aortic valve annulus. Second, an orientation constraint is defined as a tip orientation difference being less than 20 degrees with respect to the valve plane normal. Similarly to [4], the structure of the tool/robot is optimized so as to respect the constraints while minimizing contacts with the anatomy.

Three type of architectures are compared. The first one is a simple straight handtool, similar to the one presented in [3] for septal tissue removal. Results show that it is able to reach the points around the valve annulus, but at the cost of significant collisions with the anatomy and of breaking the orientation constraint. The second structure is a steerable handtool. It consists of two concentric tubes, where the innermost tube is fixed and pre-bent, whereas the outer tube is moving over the inner one to straighten it. Optimization results show that a bending radius of 41 mm for the bent section allows it to reach every configuration around the valve annulus with minimal contacts with the anatomy and satisfactory orientations.

Finally, the last architecture is a three-tube concentric tube robot [4]. Optimization results show that the optimal design is with a variable curvature proximal section (minimal bending radius 150 mm, length 72 mm) and a fixed curvature distal section (radius of curvature 41 mm, length 35 mm). Configurations of the steerable handtool and the concentric tube robot reaching towards the targets inside the heart model are shown on Fig.2.

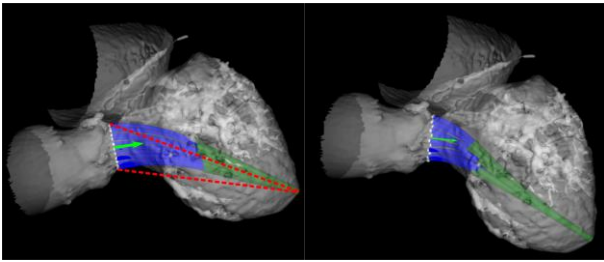


Fig. 2 Access to the valve annulus. Left: handheld instrument with a steerable tip section. Right: concentric tube robot. Green arrow: valve plane normal. Red dotted line: extreme configurations of the straight tool. White points: targets on the valve annulus.

COMPARISON INSIDE A HEART MODEL

In order to validate the proposed designs, a benchtop setup is built. A soft model of the left ventricle of the heart is 3D printed in a soft material (VisiJet CE-NT, 3D systems, USA) and fixed to a support. Through a hole at the apex of the heart devices are inserted and navigated towards the aortic valve. For each experiment, an electromagnetic (EM) tracker (Trakstar, Ascension, USA) is fixed inside the operating channel of the tool to measure the tip position. The experimental setup is depicted on Fig.3.

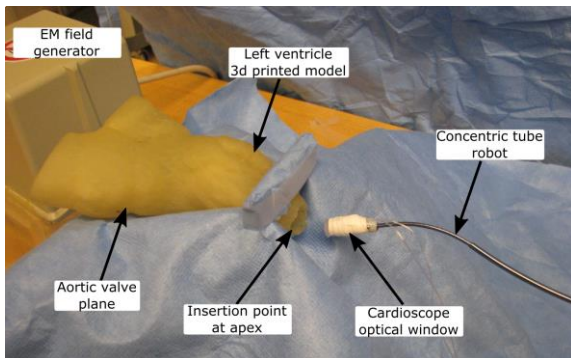


Fig. 3 Experimental setup, with robot about to be inserted.

Fig. 4 shows the results in terms of reachability of the different tools at the annulus. Since the heart model used is not as soft as real heart tissue, it is not possible to reach every point around the annulus with the straight and steerable handtools. This is however representative of the points which would be reached during surgery without touching the anatomy. Moreover, the areas around the annulus that present the highest risk of PVLs [5] can be reached successfully using both devices. The user is able to steer the robot around the valve annulus satisfactorily, showing good promise for *in vivo* experimentations. However, teleoperating the robot in order to follow the annulus shape is very difficult, mostly because the user has no feedback when touching the anatomy. Therefore in this experiment, points were reached one by one without following a smooth trajectory around the annulus. Smoother navigation is likely to require a large amount of training for the user.

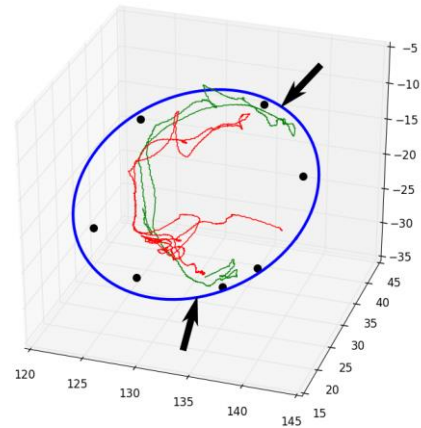


Fig. 4 Comparison of the workspace of the tools at the valve annulus (approximated as the blue ellipse). Red: straight handtool. Green: steerable handtool. Black dots: robot tip positions. Black arrows show zones of highest PVL risk [5].

DISCUSSION

The question of when a robot is truly needed is a recurring question in surgical robotics, mostly because of the costs associated with the introduction of such a device in the operating room. Therefore, identifying the least complex surgical tool able to carry out a given surgical task is a very important question. Through the example of paravalvular leak closure, this paper attempts to address this question, using design optimization before actually building the robot. Though experiments show that the robot is outperforming the handheld devices in terms of reachability, this is also at the cost of loss of haptic feedback, which causes difficulty in steering the robot. *In vivo* experiments are planned in the near future to assess performance of the different devices during a beating heart transapical paravalvular leak closure procedure.

ACKNOWLEDGEMENT

This work was supported by the the NIH under grant R01HL124020.

REFERENCES

- [1] K. Maganti, V. H. Rigolin, M. E. Sarano, R. O. Bonow, Valvular Heart Disease: Diagnosis and Management, Mayo Clinic Proc., vol. 85, n. 5, pp: 483-500, 2010.
- [2] Kumar, R., Jelnin, V., Kliger, C., *et al.* Percutaneous paravalvular leak closure. *Cardiology clinics*, 2013, vol. 31, no 3, p. 431-440.
- [3] A. Ataollahi, I. Berra, N.V. Vasilyev, Z. Machaidze, P. E. Dupont, Cardioscopic Tool-delivery Instrument for Beating-heart Surgery, *IEEE/ASME Trans. Mechatronics*, vol. 21, no. 1, pp. 584-590, 2016
- [4] C. Bergeles, A.H. Gosline, N.V. Vasilyev, P.J. Codd, P. J. del Nido, P. E. Dupont, "Concentric Tube Robot Design and Optimization Based on Task and Anatomical Constraints", *IEEE Trans. Robotics*, 33(1):67-84, 2015
- [5] Ruiz, C. E., *et al.* Clinical outcomes in patients undergoing percutaneous closure of periprosthetic paravalvular leaks. *J Am Coll Cardiol*. 58(21):2210-7, 2011.