Cardioscopic Imaging to Guide Manual and Robotic Surgery Inside the Beating Heart

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INTRODUCTION

The transcatheter approach is gaining popularity for many cardiac procedures that have previously been performed as open-heart surgery. One of the major hurdles of transcatheter interventions, however, is providing imaging of sufficient quality for procedure guidance and monitoring.

Ultrasound and X-ray fluoroscopy are the most common modalities utilized for the image guidance. While both are noninvasive, each has limitations in guiding interactions between the catheter and the tissue. Ultrasound images are of limited resolution and suffer from high noise. Fluoroscopy provides higher resolution, but the images are 2D and contain the catheter, but not the tissue. In short, both modalities lack ability to provide high-resolution images at the interventional site.

Optical imaging at the tip of the catheter can augment the image guidance of these modalities by providing intuitive local images of the intervention site. The challenge of optical imaging inside the heart, however, is seeing through the blood. Three approaches have been attempted to overcome this challenge: infrared imaging [1], flushing with clear liquid [2] and introducing an optical window [3]. In the latter, a transparent optical window is pressed against the tissue to displace the blood so that the tissue becomes visible. The advantages of this approach are that it does not require continuous fluid injection into the bloodstream and also stabilizes the imaging location through the contact force for subsequent tool delivery.

This abstract describes two of our cardioscope designs for intracardiac imaging. The first is a handheld instrument for tissue removal. The second smaller design, mounted on a robotic catheter, is being developed for transapical aortic paravalvular leak closure.

MATERIALS AND METHODS

Figure 1 shows the two cardioscopes. Their diameters are 13mm and 6mm, respectively. The main component of both cardioscopes is the transparent optical window cast from RTV-2 silicone rubber (QSil 216, Quantum Silicones LLC). The optical window encloses the camera and LED light sources and incorporates a tool channel. The handheld design has an additional channel for flushing saline to clear the field of view.

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Imaging is performed using a 5mm CCD camera (Vividia Mini, Vividia Tech.) and 1mm CMOS image sensor (NanEye, Awiaba), respectively. The tool channels of the two systems were designed for passage of $\phi 1.8$ mm MEMS tissue removal tool [4] and 4Fr closure devices for sealing paravalvular leaks, respectively. The field of view of both cardioscopes is designed to enable visualization of devices extending from the tool channel.

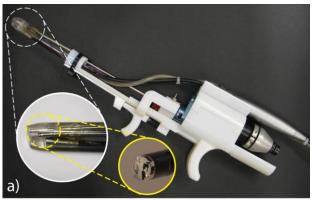




Fig 1. Cardioscope designs. a) Handheld tissue removal instrument. b) Robotic catheter for paravalvular leak closure.

RESULTS

The handheld cardioscope was tested in *ex-vivo* and *in-vivo* experiments. The goal of the both experiments was to remove tissue from the infundibulum region of the right ventricle, simulating the correction of pediatric outflow tract obstruction.

The *ex-vivo* experiments were performed on porcine hearts connected to a pulsatile pumping system to simulate the cardiac cycle. Prior to the experiments, a 15mm circle was marked on the tissue to specify the target for tissue removal, as shown in Figure 2a. The cardioscope was inserted through the free wall of the right ventricle and tissue was precisely removed from the target region as shown in Figure 2b.

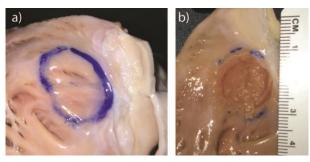


Fig 2. *Ex-vivo* experiment. a) Target region of interest marked on the inner surface of the heart. b) Target region after the experiment, showing precise removal of the tissue.

For the *in-vivo* experiment, a 65kg swine was anesthetized and the cardioscope was inserted through the right ventricular free wall. Figure 3 shows images of the ventricular wall during tissue removal. Clear visualization of the tissue was established as soon as the optical window contacted the tissue. Tissue was removed under visual guidance as shown in Figure 3c,d.

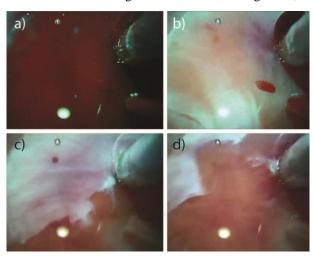


Fig 3. In-vivo View. a) Prior to tissue contact. b) At tissue contact. c) and d) Removal of the endocardium.

The robotic-catheter-mounted cardioscope has been tested in bench-top and *ex-vivo* experiments as shown in Figure 4. Figure 4a,b demonstrate navigation of the catheter tip inside a beaker of water to "read" lettering written on its exterior. In initial *ex-vivo* experiments, the catheter has been navigated inside a water-filled porcine heart (Figure 4c). As an on-going imaging demonstration project, current experiments involve constructing transcatheter valve models incorporating paravalvular leaks. The robotic catheter will be introduced transapically and the effectiveness of cardioscopically-guided navigation to each leak will be investigated.

DISCUSSION

This paper presents two cardioscope designs with the goal of providing tool-tip views inside the heart. The designs, which integrate camera, light source and tool channel as a single molded unit, are both simple and inexpensive to fabricate. As a milestone toward

percutaneous robotic interventions, a handheld instrument was developed and demonstrated in the context of beating-heart tissue removal. It successfully addressed two key problems: visualization of tissue removal and precise control of tool-tissue contact.

As described, its miniaturization for deployment on a robotic catheter has been demonstrated. In combination with robotic steerability, cardioscopic navigation is currently being explored for paravalvular leak closure.

It is anticipated that cardioscopic imaging can be combined with X-ray fluoroscopy and ultrasound, the traditional imaging modalities of intracardiac procedures. The 'local' optical image of the intervention area from the cardioscope can augment the more 'global' picture of catheter position from fluoroscopy and ultrasound. Together, such imaging may provide sufficient additional information to broaden the range of transcatheter interventions that can be performed.

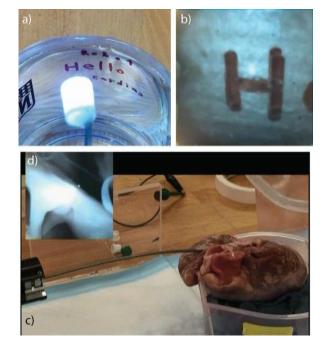


Fig 4. Initial testing of catheter-mounted cardioscope, a) Navigating to text on beaker, and b) Cardioscope image, c) *Ex-vivo* navigation into porcine heart, d) Image inside heart.

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