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Prototype Epicardial Crawling Device for Intrapericardial Intervention on the Beating Heart

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ABSTRACT

The development and preliminary testing of a device for facilitating minimally invasive beating-heart intrapericardial interventions are described. We propose the concept of an endoscopic robotic device that adheres to the epicardium by suction and navigates by crawling like an inchworm to any position on the surface under the control of a surgeon. This approach obviates cardiac stabilization, lung deflation, differential lung ventilation, and reinsertion of laparoscopic tools for accessing different treatment sites, thus offering the possibility of reduced trauma to the patient. The device has a working channel through which various tools can be introduced for treatment. The current prototype demonstrated successful prehension, turning, and locomotion on beating hearts in a limited number of trials in a porcine model.

INTRODUCTION

Minimally invasive cardiac surgery has become a major objective of the field because of the desire to avoid the morbidity associated with median sternotomy and cardiopulmonary bypass [Mack 2001]. The obstacles include not only miniaturization of instruments for endoscopic application and development of techniques for regaining dexterity lost by operating through small incisions but also gaining access to certain hard-to-reach parts of the heart. Current manual instrumentation generally relies on rigid endoscopes, which can reach only a limited area on the epicardial surface from a given incision. The multiarm robot systems that are commercially available (at prices of approximately US$1,000,000) provide much of the needed dexterity for the realization of endoscopic heart surgery, but access remains difficult for certain areas, such as the posterior wall of the left ventricle (LV) [Falk 2000].

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The challenges of minimally invasive access are further complicated by the goal of avoiding cardiopulmonary bypass, and this goal necessitates surgery on a beating heart. Thus instrumentation is needed that allows stable manipulation of an arbitrary location on the epicardium while the heart is beating [Zenati 2001a]. Local immobilization of the heart is the approach generally followed with endoscopic stabilizers such as the Endostab device [Falk 1999] and the endo-Octopus device [Gründeman 2003], which operate with pressure or suction. However, the resulting forces exerted on the myocardium can cause changes in the electrophysiological and hemodynamic performance of the heart, and there has been discussion in the literature regarding the care that must be taken to avoid hemodynamic impairment [Falk 1999]. As an alternative, several researchers in robot-assisted endoscopic surgery are investigating active compensation of heartbeat motion by visually tracking the epicardium and moving the tool tips accordingly [Çavusoglu 2003, Ortmaier 2003], but this research problem remains open. The motion of the beating heart is complex. In addition to the challenges of modeling or tracking the heart surface, active compensation will require considerable expense for high-bandwidth actuation to manipulate in at least 3 degrees of freedom over a relatively large workspace [Çavusoglu 2003].

All of these solutions address a problem that exists only because the tools are held by a surgeon or a robot that is fixed to the table or standing on the floor. We took a different approach: Rather than trying to immobilize the heart surface to stabilize it in the fixed frame of reference of a table-mounted robotic device, we mounted the endoscopic device in the moving reference frame of the beating heart. This task was accomplished with a miniature 2-footed crawling robotic device (HeartLander) designed to be introduced into the pericardium through a port, attach itself to the epicardial surface, and then, under the direct control of the surgeon, travel to the desired location for treatment. The problem of beating-heart motion was largely avoided by attaching the device directly to the epicardium. The problem of access was resolved by incorporating the capability for locomotion.

Improved access and precise manipulation are not the only benefits of this approach. Port access for minimally invasive cardiac surgery has typically been transthoracic, largely to accommodate the rigid endoscopes generally used for both

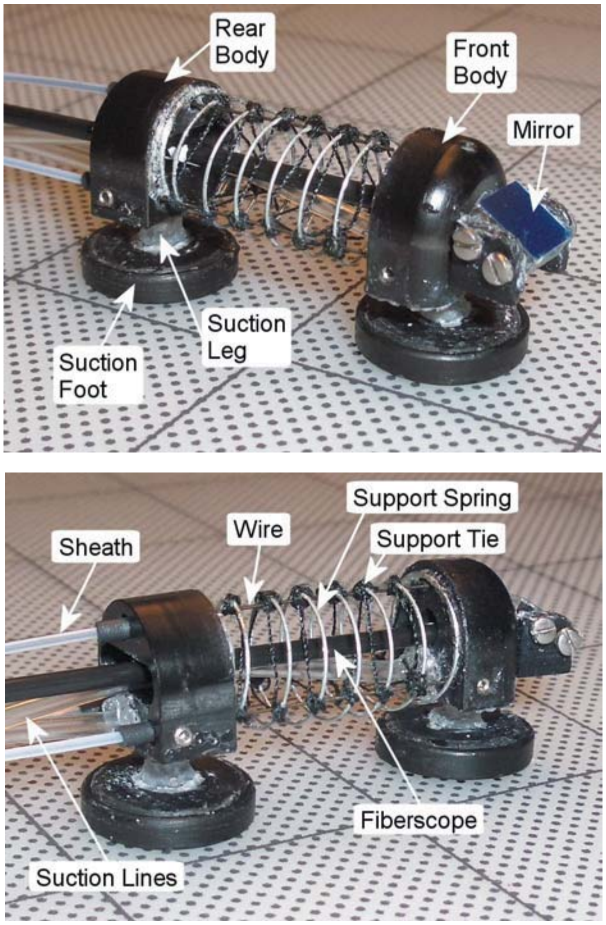

Figure 1. The HeartLander prototype. The device crawls like an inchworm, using wires to advance the front foot and then sheaths surrounding the wires to push the rear foot up to meet the front. The lines on the mat are 25.4 mm apart; the dots are 2 mm apart.

manual and robot-assisted procedures. Transthoracic access to the heart requires deflation of the left lung, general endotracheal anesthesia, and differential lung ventilation. A variety of current and upcoming procedures, however, can conceivably be performed transpericardially, without invasion of the pleural space, if appropriate instrumentation is made available. Examples include, but are not limited to cell transplantation [Li 1999], gene therapy for angiogenesis [Losordo 1999], epicardial electrode placement for resynchronization [Leclercq 2002], epicardial atrial ablation [Lee 1999], intrapericardial drug delivery [Gleason 2002], and ventricle-to-coronary artery bypass [Boekstegers 2002].

The ability of the HeartLander device to move to any desired location on the epicardium from any starting point enables minimally invasive cardiac surgery to become independent of the location of the pericardial incision. Use of the device also allows a subxiphoid transpericardial approach to any intrapericardial procedure, regardless of the location of the treatment site. As a result, deflation of the left lung is no longer needed, and it becomes feasible to use local or regional rather than general anesthetic techniques. These advantages have the potential to open the way to ambulatory outpatient cardiac surgery [Zenati 2001b].

A prototype of the HeartLander device was constructed, and preliminary tests were performed in vivo in a porcine model. We describe the design of the prototype and the initial results.

MATERIALS AND METHODS

Design

The HeartLander prototype (Figure 1) has 2 solid modules, each mounted on a suction pad for prehension. Suction has proven to be effective for prehension of the epicardium in surgical devices such as the Octopus and Starfish (Medtronic, Minneapolis, MN, USA), as well as in numerous mobile robots [Siegel 1998]. Vacuum pressure is regulated by external computer-controlled valves and is supplied to the suction pads via 2 vacuum lines. Outside the body of the device, the proximal portion of each vacuum line is fitted with a pressure sensor used to verify the vacuum seal with the surface when appropriate during locomotion.

Each module is 16.5 mm tall and has a circular footprint 13.2 mm in diameter, allowing the device to pass through a 20-mm cannula. The front body is attached to 3 highly elastic nitinol wires that pass freely through the rear body and connect to the drive pulleys of 3 motors in a box located at the bedside. The wires are spaced in a radially symmetric pattern at intervals of 120 degrees. Each wire passes through a flexible plastic sheath. One end of each sheath is attached to the rear module of the HeartLander device, and the other to a stationary block located near the motors. Inchworm-like locomotion is accomplished by a simple technique that requires only that slack be maintained in the wires and sheaths (ie, if the wires are completely straight, the device does not work) [Patronik 2004]. Pushing on the wires advances the front module while the rear module is under active suction. Pulling backward on the wires advances the rear module toward the front module while the front module is under active suction. Turning is achieved by advancing the 3 actuation wires different lengths, as shown in Figure 2. A spring connects the front and back modules, surrounding the wires to prevent them from bowing outward during sharp turns (Figure 2).

Locomotion of the device is controlled by a surgeon using a personal computer-based graphical user interface that provides video feedback. A joystick is used for control (Figure 3). Forward and reverse travel is accomplished by pushing the joystick forward and backward, respectively, and steering is accomplished by pushing the joystick left or right. Visual feedback is relayed to an external video camera by a 1.6-mm diameter fiberoptic endoscope running through the tether (Figure 4). This same joystick-based user interface will be used for operation of surgical end-effectors.

The HeartLander device is designed to be introduced through a pericardial incision via the working channel of a subxiphoid videopericardioscopy device [Zenati 2003] or similar instrument. After the treatment is complete, the device is retrieved simply by manually retracting the tether

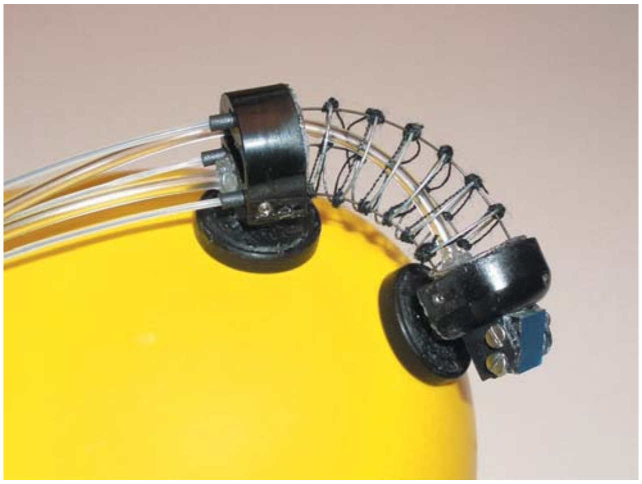

Figure 2. The HeartLander device is steered by advancing the 3 manipulator wires unequal amounts. With 3 wires spaced in a radially symmetric pattern, the device can steer not only left and right but also up and down. This method facilitates locomotion across the curved epicardium. The spring between the 2 solid modules prevents the drive wires from bowing outward during turns.

back through the cannula. This step also would serve as the recovery method for redeployment should the device become dislodged.

Testing

Three large (30-45 kg) crossbred swine were used. After standard single-lumen endotracheal intubation, a surgical plane of anesthesia was maintained with isoflurane, 1% to 3%. The animals were placed into the supine position. Invasive hemodynamic and arterial blood gas monitoring was performed throughout the procedure. Median sternotomy was performed, and the pericardial sac was opened. An apical suction positioner (Starfish; Medtronic) was used to present various areas of the right ventricle (RV) and LV to the center of the operative field. The HeartLander device was placed manually on the epicardium. Locomotion across the epicardial surface in various directions was tested for approximately 15 minutes.

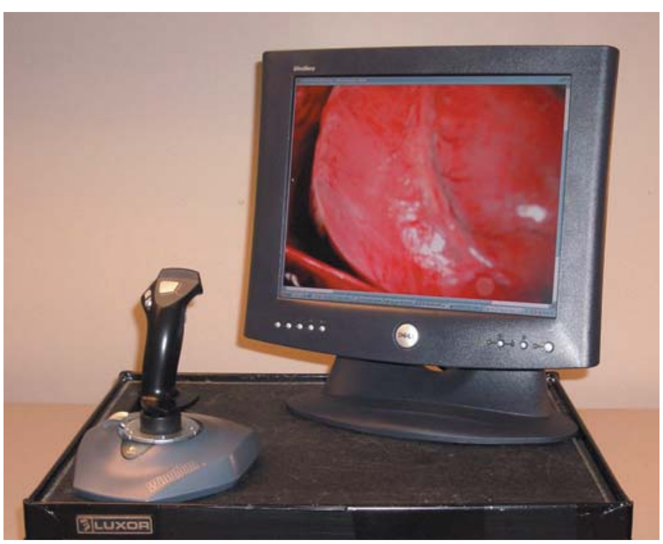

Figure 3. The HeartLander control interface. The joystick is used for control of locomotion, and the monitor is used to display video from the device camera.

RESULTS

Crawling on the epicardium was tested first on the anterior wall of the beating RV in each animal. Locomotion in a straight line was successfully accomplished without the scope inserted through the HeartLander device. When the scope was inserted, however, epicardial adhesion became inconsistent because the stiffness of the scope hindered the device in conforming to the shape of the heart. Therefore the HeartLander device subsequently was tested without the scope inserted. A curved trajectory was successfully reproduced on the anterior RV and allowed crossing of the left anterior descending coronary artery onto the anterior wall of the LV (Figure 5). No adverse hemodynamic or electrophysiologic events were observed during crossing over the coronary artery. No gross epicardial damage was observed along the trajectory of the HeartLander device.

After anterior RV crawling with the heart left in situ, the Starfish device was applied to the apex of the LV, and the beating heart was elevated and retracted laterally to the left as shown in Figure 6 to present the inferior wall of the RV to the center of the operative field. The HeartLander device was manually applied to the anterior wall of the beating RV and remotely directed to move inferiorly, crossing the acute margin of the RV onto the inferior wall. This task posed several challenges to the HeartLander device, which was required to crawl on diverse “terrain” with varying degrees of curvature (radius) and to make several changes of direction to complete a curved path. The HeartLander device successfully completed this experiment in all 3 animals. Occasional failures of

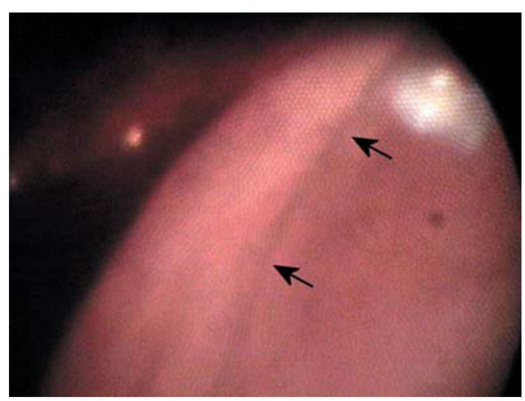

Figure 4. View through the scope on the HeartLander device shows the left anterior descending artery crossing the center of the image.

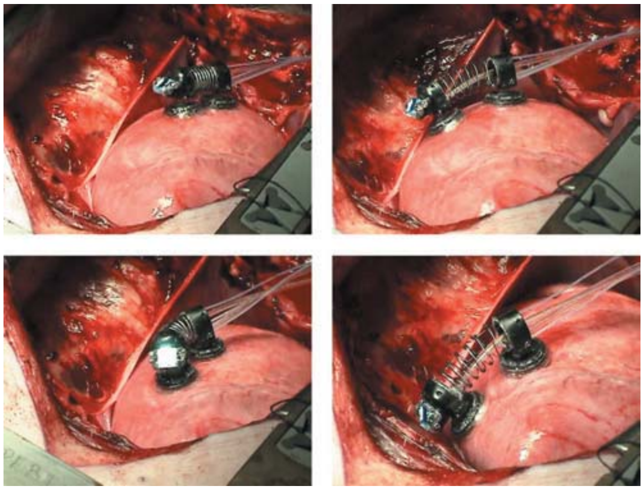

Figure 5. Time sequence shows the HeartLander device traveling across the beating porcine heart in situ, starting from a point near the anterior wall of the right ventricle and ending near the acute margin. The lower left image shows the steering capability of the device.

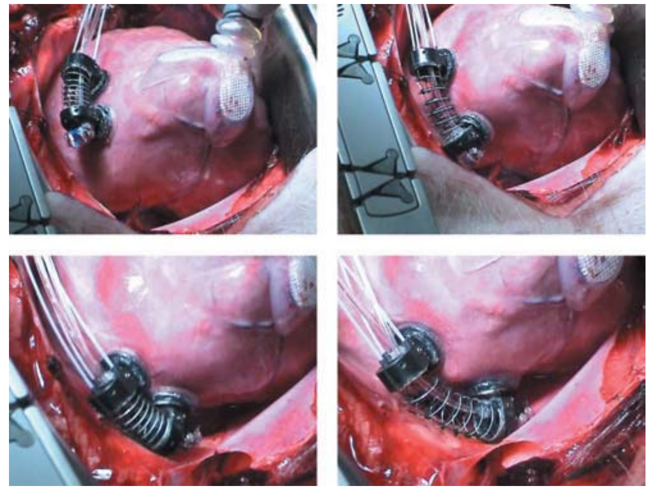

Figure 6. Time sequence shows the HeartLander device traveling from the anterior wall of the right ventricle (RV) across the acute margin and onto the inferior wall of the RV of a beating porcine heart repositioned with the Starfish device.

the front foot to make good contact with the epicardium in areas around the acute margin were encountered in the first 2 subjects. We eliminated these failures in the last experiment by decreasing the length of the step.

The speed of travel in these experiments was approximately 8 cm/min. The relatively high profile of the device did not allow access to parts of the heart that were still covered by the pericardial sac.

DISCUSSION

The results were an initial demonstration of the feasibility of adhering to and maneuvering on the epicardium of a beating heart with the HeartLander prototype. Further miniaturization of the device is needed to provide a lower profile, or reduced height, to facilitate travel within the pericardial sac. An alternative vision system also is needed, because the present fiberoptic scope made the device too stiff. After this redesign, evaluation will proceed from open-chest tests to minimally invasive tests via the subxiphoid approach in the porcine model. Additional testing will involve development of appropriate instrumentation to facilitate subxiphoid access.

The HeartLander vehicle is designed to be modular and compatible with a variety of types of intrapericardial intervention. The present prototype has a 3-mm working port, visible in Figure 1, through which tools can be deployed. The first application planned for evaluation is epicardial lead placement for resynchronization [Leclercq 2002]. As the research continues, we plan to develop end-effectors for the HeartLander device for more innovative procedures, such as epicardial delivery of myoblasts or stem cells for regeneration of the failing myocardium. Ultimately, we envision adoption of HeartLander-based intrapericardial therapies not only by minimally invasive cardiac surgeons but also by interventional cardiologists and electrophysiologists [Sosa 2000, Schweikert 2003].

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