# Percutaneous Subxiphoid Access to the Epicardium Using a Miniature Crawling Robotic Device

*Takeyoshi Ota,* Nicholas A. Patronik,† Cameron N. Riviere,† and Marco A. Zenati*†*

**Background:** To expand minimally invasive beating-heart surgery, we have developed a miniature 2-footed crawling robot (HeartLander) that navigates on the epicardium. This paradigm obviates mechanical stabilization and lung deflation, and avoids the access limitations of current approaches. We tested the locomotion of the device on a beating porcine heart accessed through a closed-chest subxiphoid approach.

**Methods:** HeartLander consists of 2 modules that are connected by an extensible midsection. It adheres to the epicardium using suction pads. Locomotion and turning are accomplished by moving the 2 modules in an alternating fashion using wires that run through the midsection between them. After a preliminary test with a plastic beating-heart model, we performed a porcine study in vivo. The device was inserted into the pericardial space through a subxiphoid incision, while the test was observed using a left thoracoscopy. The blood pressure and electrocardiogram were monitored, and vacuum pressure and driving forces on the wires were recorded.

**Results:** HeartLander traveled across the anterior and lateral surfaces of the beating heart without restriction, including locomotion forward, backward, and turning. The vacuum pressure was kept below 450 mm Hg at all times. The average maximum force during elongation was 1.86 ± 0.97 N, and during retraction was 1.24 ± 0.33 N. No adverse hemodynamic or electrophysiologic events were noted during the trial. No epicardial damage was found on the excised heart after the porcine trial.

**Conclusions:** The current HeartLander prototype demonstrated safe and successful locomotion on a beating porcine heart through a closed-chest subxiphoid approach.

**Key Words:** Robotic, Cardiac surgery, Beating heart, Minimally invasive, HeartLander.

(*Innovations* 2006;1: 227–231)

From the *Division of Cardiac Surgery, Heart, Lung and Esophageal Surgery Institute, University of Pittsburgh, Pittsburgh, PA; †The Robotics Institute, Carnegie Mellon University, Pittsburgh, PA.

N.A.P., C.N.R. and M.A.Z. are coinventors of the Heartlander and hold equity in Enhanced Medical Systems LLC (licensee of the IP from Carnegie Mellon University).

Supported by grants from the National Institutes of Health (grant no. 1- R01-HL078839), National Aeronautics and Space Administration (GSRP Fellowship), and National Science Foundation (grant no. EEC-9731748).

Address correspondence to: Marco A. Zenati, MD, Division of Cardiac Surgery, Heart, Lung and Esophageal Surgery Institute, University of Pittsburgh, C700 PUH, 200 Lothrop St. Pittsburgh, PA, USA; E-mail: zenatim@upmc.edu.



ISSN: 1556-9845/06/0105-0227

Minimally invasive surgery (MIS) on the beating heart has become popular over the past decade because of the desire to reduce morbidity, most significantly that associated with median sternotomy and cardiopulmonary bypass.[1] The lack of direct assess to the work space, however, reduces the visualization and dexterity of the surgeon. Additionally, surgery on the beating heart typically requires local immobilization of the heart, which may cause adverse changes in the electrophysiologic and hemodynamic performance of the heart.[2] The field of robotic-assisted MIS has shown exciting progress, using the multiarm teleoperated system (ie, da Vinci, Zeus) to address some of these limitations.[3] However, these systems still have difficulty accessing certain areas of the heart.[4] Robotic systems, such as the da Vinci and Zeus, also require several port placements to insert the rigid instrumentation. Alternatively, the subxiphoid videopericardioscopy (SVP) approach is appealing because it allows access to the pericardial space through a single subxiphoid port, does not require general endotracheal anesthesia, and facilitates epicardial interventions on the beating heart (eg, cell transplantation, lead placement, ablation).[5,6]

We have developed a miniature 2-footed crawling robotic device (HeartLander) that adheres to the epicardium using suction and crawls like an inchworm to any location on the surface of the heart.[7,8] The HeartLander will be placed into the intrapericardial space via subxiphoid minimally invasive approach that allows for percutaneous access to the pericardium through a 2 cm long incision below the xiphoid process.[5] The concept of the HeartLander could be expected to provide a complete solution to the problems of beating-heart motion, access insufficiency, and multiport invasiveness.

Early HeartLander prototypes were constructed and tested in open chest porcine model. The first prototype demonstrated its ability to navigate on the surface of a beating-heart porcine heart with the pericardium excised through full median sternotomy.[7] The second prototype traveled across the surface of beating porcine hearts with intact pericardia after median sternotomy, and performed successful myocardial injections of dye.[8] The third prototype obtained high quality of the visual feedback from a charge coupled device (CCD) camera located in the front section of the device.

We have developed a fourth HeartLander prototype which has smaller body sections while retaining the capabilities of previous prototypes. This article describes tests of the current prototype using a plastic beating-heart model and a porcine preparation.

## METHODS

### Design

The fourth-generation HeartLander prototype has 2 body sections, each containing an independent suction pad for prehension. Vacuum pressure is regulated by external computer-controlled valves and is supplied to the suction pads via vacuum lines. Outside the body of the device, the proximal portion of each vacuum line is fitted with a pressure sensor that provides data used to verify the vacuum seal with the surface of the heart. The total size of both body sections together in the retracted state is 17.7 (length) × 8.2 (width) × 6.5 (height) mm (Fig. 1b). Each suction pad has a rectangular shape of 4.9 × 6.5mm with 20 small openings, each 0.8 mm in a diameter. The device has a 1-mm diameter needle channel and a 2-mm diameter general working port. The front body is attached to 3 superelastic nitinol wires, each with a diameter of 0.2 mm, that pass freely through the rear body and connect to the drive belts of 3 motors. Each wire is contained within a flexible plastic sheath. One end of the sheath is attached to the rear body of the device, and the other to a stationary block located near the motors. Inchworm-like locomotion is accomplished through coordination between the motors controlling 3 wires and the solenoid valves that regulate the vacuum pressure in each of the suction pads. To move forward, the wires are pushed to advance the front body while the rear body is under active suction (Extend phase) (Fig. 1a). Pulling backward on the wires advances the rear body toward the front body while the front body is under active suction (Retract phase) (Fig. 1b). To move backward, the reverse process is done. Turning is achieved by advancing the 3 wires in different lengths (Turning phase) (Fig. 1c). This internal coordination is maintained by the software, while the physician controls the device with a joystick interface. The forces exerted on the 3 wires are recorded throughout the experiment using load cells incorporated into the mechanical transmission of the robot. Throughout the locomotive cycle, the software also monitors the readings from external pressure sensors attached to the vacuum lines to ensure that at least one suction pad maintains a grip on the heart surface at all times.

### Testing With a Plastic Beating Heart

As a preliminary trial, the HeartLander was tested using a plastic beating-heart model (The Chamberlain Group, Great Barrington, MA), which had a highly detailed exterior with the feel and movement of a live human heart. The pulse rate was set at 72 beats per minute. Locomotion on the surface of the heart model in various directions was tested with the plastic pericardium model in place. The vacuum pressure and force exerted on wires were measured when the device was moving.

### Testing With a Porcine Preparation

A large Yorkshire pig (47 kg) was anesthetized and placed in a supine position. A small skin incision was made below the xiphoid, and a 15 × 35 mm port was inserted (Fig. 2a). Through this port, the pericardium was incised to a length of 2 cm. The HeartLander was inserted into the pericardial space through the pericardial hole. Several trajectories of locomotion were tested, while the test was observed using a thoracoscope inserted from the left thoracic wall. The blood pressure and electrocardiogram were monitored, as well as the vacuum pressure and driving forces on the wires during locomotion.

## RESULTS

### Locomotion

Each test lasted approximately 30 seconds, and was repeated 4 times for each trajectory, yielding 2 minutes of data per trajectory. In the test with a plastic model, the HeartLander was able to travel across the surface without restriction from the tether. Locomotion forward, backward, and turning were achieved. Traveling from the anterior wall to the posterior wall near the AV groove through the acute margin (Fig. 3), from the anterior wall to the apex, and from the lateral wall to the apex was possible. During the trial, no significant slipping or detachment of suction pads was noted. The maximum speed of travel attained on the anterior wall of the right ventricle was approximately 18 cm/min. This successful locomotion was demonstrated with the plastic pericardium model in place. In the test with the porcine preparation, pathways from the apex to the left atrial appendage through the lateral wall and oblique sinus or through the anterior wall, and from the apex to the pulmonary arterial trunk coming across the left anterior descending coronary artery were successfully accomplished (Figs. 2b and 2c). No adverse hemodynamic or electrophysiologic events such as hypotension or fatal arrhythmias were noted (Fig. 4). Normal sinus rhythm was kept up through the trial.

### Contact Force

An example of the force exerted on the wires is presented in Figures 5a and 5b. In the plastic model, the mean force was 0.94 ± 0.38 N during elongation and was 0.79 ± 0.50 N during retraction. The maximum force measured, averaged over the cycles of locomotion, was 1.32 ± 0.10 N during elongation and 1.26 ± 0.18 N during retraction.

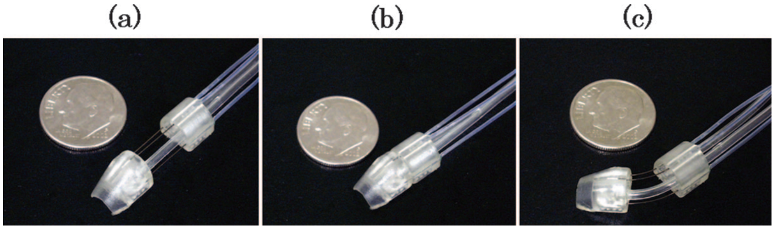


**FIGURE 1.** Photographs of the fourth-generation HeartLander prototype in (a) extend phase, (b) retract phase, and (c) turning phase.

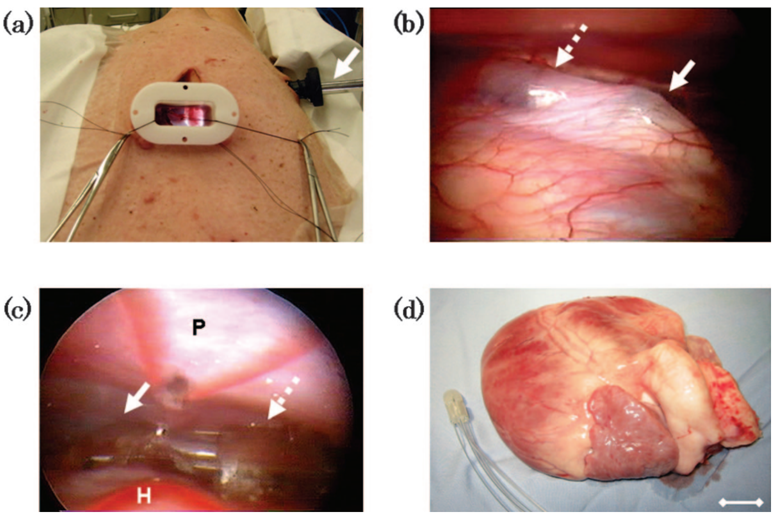


**FIGURE 2.** (a) Surgical view of the porcine trial. A 15 × 35 mm port was inserted through subxiphoid approach. A small incision was made in the pericardium and suspended open with sutures. Locomotion was visualized by a thoracoscope inserted from the left thoracic wall (arrow). (b, c) The view from the thoracoscopic camera inserted from the left thoracic wall (b) and intrapericardium (c). The HeartLander is seen through the pericardium (b). The solid line arrow shows the front body, while the broken line arrow shows the rear body. H, anterior ventricular wall of the heart; P, pericardium. (d) A picture of the excised heart with the HeartLander. There was no injury on the surface of the heart due to the HeartLander locomotion. (White scale bar: 20 mm)

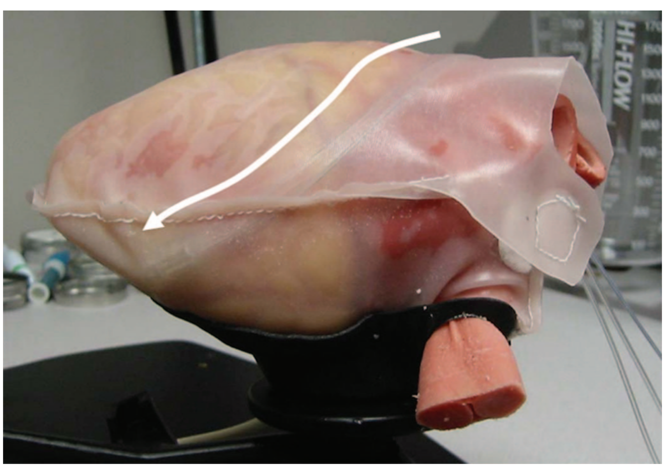

**FIGURE 3.** A lateral view of the plastic heart model with the pericardium showing that the HeartLander can travel from the anterior wall to posterior wall. The path is described by the white line.

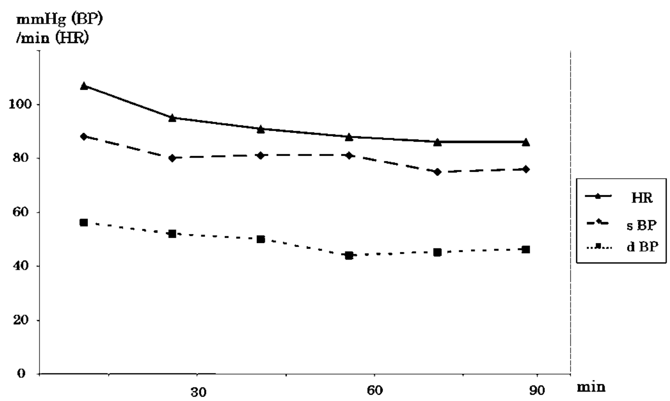


**FIGURE 4.** A graph of blood pressure and heart rate during the porcine trial. No hypotension and arrhythmia are seen. s BP, systolic blood pressure; d BP, diastolic blood pressure; HR, heart rate.

However, in the pig trial the mean force was 0.66 ± 0.50 N during elongation and 0.53 ± 0.27 N during retraction. The maximum force was 1.86 ± 0.97 N during elongation and 1.24 ± 0.33 N during retraction.

### Vacuum Pressure Level

The vacuum pressure supplied to the front and rear suction pads during the locomotion cycle is demonstrated in Figures 5c and 5f. We set the cycle of locomotion to have an overlapping phase (500 milliseconds) in each cycle during which suction was applied to both pads for stabilizing the prehension. The HeartLander could successfully travel with the active vacuum pressure below 400 mm Hg in the plastic model and below 450 mm Hg in the pig trial at all times. No epicardial damage was apparent on the excised heart, and no injuries to surrounding structures were noted at autopsy after the trial (Fig. 2d).

## DISCUSSION

The HeartLander is designed to be placed into the pericardial space using a SVP approach. This minimally invasive approach can be applied to many other applications from endoscopic ligation of the left atrium appendage[9,10] to pacing lead implantation.[6] The HeartLander methodology obviates sternotomy, cardiac stabilization, lung deflation, differential lung ventilation, and the insertion of additional ports to access other treatment sites of the heart or to insert multiple tools. Previous prototypes could travel on the surface of porcine hearts in vivo through a median full sternotomy without adverse hemodynamic or electrophysiologic events.[7,8] This study demonstrates that the device has the potential to reach everywhere on the surface of the beating heart in the closed-chest porcine model, including places such as the posterior wall that a surgeon has some difficulty accessing even under full median sternotomy. These experiments illustrate that the HeartLander concept successfully addresses the problems of the beating-heart motion, access insufficiency, and invasiveness of multiport placement.

 

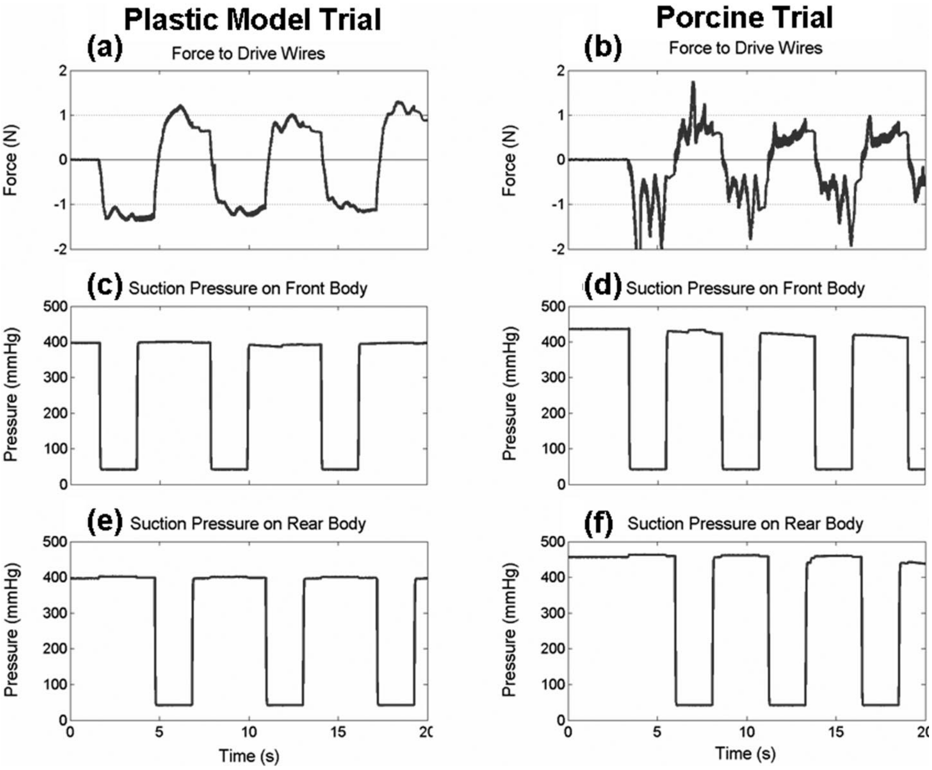


**FIGURE 5.** (a, b) Graphs of the force on drive wires. The force was a positive number during retraction and a negative number during elongation. (c, d) Graphs of the suction pressure on the front body. (e, f) Graphs of the suction pressure on the rear body.

The forth-generation HeartLander has been newly equipped with sensors that measure contact forces and applied suction level. These measurements will be important for testing the safety of the device. The vacuum pressure of the HeartLander is adjustable. We set the maximum vacuum pressure at 400 mm Hg in the plastic model trial, a level that has proven to be safe for use in mechanically stabilizing a beating heart using vacuum pressure.[11,12] The HeartLander could move with the vacuum pressure below 400 mm Hg in the plastic model without any failure such as a slip and a detachment. In the porcine trial, we set it at 450 mm Hg to test if the pressure level had an adverse influence on the living heart. Locomotion in the porcine preparation was successfully accomplished without any damage to the heart.

Regarding the force to drive wires, it was estimated as the aggregate force on the 3 drive wires, indicating the friction between the HeartLander body and the surrounding tissues. During the trial, the HeartLander was able to move and was not damaged in any trials. The maximum contact force of the porcine trial was higher than that in the plastic model trial, whereas the mean force of the porcine trial was lower. This is because the force pushing HeartLander into the heart surface is greater due to the surrounding organs, which are not present in the plastic heart model. It may be desirable to redesign the tether to reduce friction.

Previous prototypes were too large for the subxiphoid access method, and for easy navigation beneath the pericardium. The fourth-generation HeartLander was further miniaturized to resolve these problems. In speed of locomotion, the HeartLander is improved from 8 cm/min to 18 cm/min in comparison with the first prototype. It has a 2-mm diameter working port and a 1-mm diameter needle hole. A flexible needle injection system is available through the 1-mm needle hole, as described elsewhere.[8] This ability can be applied to therapies for myocardial infarction using stem cells, growth factor gene injection, and cell transplantation.[13–15] The effectiveness of these therapies was confirmed in the early clinical studies.[16] Administration of these therapies using HeartLander will be far less expensive and invasive than using multiarm robot systems. In the future, we plan on using the 2-mm working port for epicardial pacing lead placement for resynchronization,[17] epicardial atrial ablation,[18] and myocardial biopsy through the port.

Therefore, it is indispensable to develop exclusive devices for those clinical applications. The current HeartLander does not have on-board CCD camera like the third prototype because there is no suitable device that fits within the reduced body size. In addition, we need to develop strategies for coping with adhesions between the heart and the pericardium, which many targeted patients would be likely to possess. The locomotion results and force measurements collected during in vivo locomotion have provided the necessary information to design a future HeartLander prototype with on-board motors. By replacing the remote wire-driven mechanical transmission in the tether with a small number of thin wires for electrical power and motor controls, HeartLander will achieve greater flexibility and maneuverability. In the future, if more miniature devices are developed including motors, camera, and vacuum equipment, HeartLander can become a tetherless remote-controlled device that has all the required equipment in its body. In the future, HeartLander may also find applications in other spaces within the body.

Despite the contributions of this study, several limitations have to be addressed. First, only a limited number of trials have been performed to date. Continued study is necessary to demonstrate the safety of HeartLander. In addition, chronic studies are needed to investigate the safety and sequelae of applying HeartLander on the epicardial surface. Second, although the anatomy of the porcine heart closely resembles human anatomy, porcine hearts have several deferent points in its morphology. These include the amount of fat on the surface and the rightward rotation of the heart. We plan to test the next generation of the HeartLander with human cadavers and with a sheep model, which has an anatomy that is more similar to that of humans. Third, lack of proper visualization limited the locomotion tests in the porcine trial. Specifically, we did not perform locomotion tests on the right aspect of the heart (eg, the right ventricular acute margin).

In conclusion, the current HeartLander prototype demonstrated successful prehension, turning, and locomotion using a plastic beating-heart model and a beating porcine heart through a closed-chest subxiphoid approach. The sensors for contact forces and suction pressure levels will be useful for continued safety evaluation in vivo.

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