Chapter 12
Enabling Medical Robotics for the Next Generation of Minimally Invasive Procedures: Minimally Invasive Cardiac Surgery with Single Port Access

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Abstract Minimally invasive cardiac surgery (MICS) is an evolving strategy aimed at delivering the desired form of cardiovascular therapy with the least change in homeostasis, ideally matching the same degree of invasiveness of percutaneous cardiac interventions. Cardiac surgery is different from other surgical procedures because the large sternotomy incision required to access the heart requires general endotracheal anesthesia (GETA) and the heart–lung machine that is required for open-heart surgery (e.g. valve repair) adds further morbidity. We have developed a novel, highly articulated robotic surgical system (CardioARM) to enable minimally invasive intrapericardial therapeutic delivery through a subxiphoid approach. The CardioARM is a robotic surgical system consisting of serially connected rigid cylindrical links housing flexible working ports through which catheter-based tools for therapy and imaging can be advanced. The CardioARM is controlled via a computer-driven user interface which is operated outside of the operative field. We believe single port access to be key to the success of the CardioARM. We have performed preliminary proof of concept studies in a porcine preparation by performing epicardial ablation.

Keywords Minimally invasive cardiac surgery · Single port surgery · Snake robotics · Surgical robotics

12.1 Introduction

Minimally invasive interventions have the potential to revolutionize surgical practice by offering reduced pain, faster recovery, and fewer complications. We believe the key to achieving such potential is to eliminate the need for multiple (up to 8) ports by using a single port entry. Single port access approaches may facilitate

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existing procedures but perhaps more importantly, they will enable new ones, and at a lower cost. This reduced cost has the added benefit of making therapies available to a larger portion of the general public.

A key feature requirement for single port entry is the need for dedicated robotic technology that can operate without access limitation and full feedback from a single entry point. Although they have great visual feedback, conventional surgical robots, such as the Intuitive Surgical's DaVinci SystemTM, are not adequate for single port entry because the three or four large robot arms manipulate linear chopstick laparoscopic-like devices which have limited access to line-of-sight regions from the ports. A small articulated device or a miniature mobile/crawling unit, not a conventional robot, is key to accessing many anatomical targets from a single port.

We have developed a novel, highly articulated robotic surgical system (CardioARM) to enable minimally invasive intrapericardial therapeutic delivery through a subxiphoid approach. The principle benefit of the CardioARM is that it has many internal articulated degrees of freedom to virtually provide unlimited but controllable flexibility which allows access to anatomic targets deep in the body without disturbing surround tissue. The CardioARM also has working channels through which catheter-based tools for therapy and imaging can be advanced. In six experimental subjects, CardioARM was introduced percutaneously via subxiphoid access. A commercial 5 Fr radiofrequency ablation catheter was introduced via the working port, which was then used to guide deployment. In all subjects, regional ("linear") left atrial ablation was successfully achieved, without complications. Based on these preliminary studies, we believe that CardioARM promises to enable deployment of a number of epicardium-based therapies. Minimally invasive cardiac surgery is one application for this technology; we are currently investigating the use of this robot for natural orifice transluminal endoscopic surgery (NOTES).

12.2 Relationship to Prior Work

12.2.1 Minimally Invasive Cardiac Surgery

Two approaches in the 1990s attempted to make cardiac surgery less invasive. First, the MIDCAB (Minimally Invasive Direct Coronary Artery Bypass) procedure involved a single vessel coronary bypass on the anterior surface of the heart on a beating heart through a small anterior thoracotomy [1]. Although the MIDCAB procedure catalyzed the minimally invasive movement in cardiac surgery, it now constitutes a minority of procedures; however, it did evolve into the current OPCAB (off pump coronary artery bypass grafting) procedure in which multivessel bypass is performed on a beating heart through a median sternotomy incision [2]. Second, the Port Access approach attempted totally endoscopic coronary artery bypass surgery on an arrested heart through ports but still using cardiopulmonary bypass [3]. Because of the complexities involved with the challenge of endoscopic

microvascular reconstruction of coronary vessels, the totally endoscopic approach was prohibitive.

Computer-assisted telemanipulation systems like Intuitive Surgical's DaVinci™ Surgical System are being evaluated in prospective randomized trials as potential enabling technology for endoscopic cardiac surgery for such procedures as closure of atrial septal defects, mitral valve repair and coronary artery bypass; however, the prohibitive cost and the complexity of the technology limit the potential for widespread adoption [4]. Furthermore, totally endoscopic cardiac procedures require multiple (3–4) ports in the left, right or both chest and require special anesthetic techniques with double-lumen endotracheal tubes in order to collapse alternatively the left or the right lung [5].

An innovative MICS approach for epicardial interventions is subxiphoid videopericardioscopy (SVP) pioneered by Zenati [6] (Fig. 12.1). The SVP is designed to minimize the changes in patient's homeostasis by: (1) requiring only one port (<20 mm diameter), (2) not requiring general endotracheal anesthesia (as no invasion of pleural spaces is necessary), (3) not requiring the use of the heart–lung machine. This new original approach has the potential for redefining MICS, allowing a truly minimally invasive access to the beating heart and bridging to interventional cardiologists and electrophysiologists as potential users as well as minimally invasive surgeons. Dr. Zenati has used this approach for epicardial left heart pacing lead implantation for resynchronization [6, 7].

The subxiphoid videopericardioscopy (SVP) device (Guidant Corporation, Santa Clara, California) is the only dedicated technology available for endoscopic video exploration of the pericardial cavity; Guidant received approval for clinical use of this device by the Food and Drug Administration (510k number K023629, November 12, 2002). The SVP device is an elongated instrument made of stainless steel that contains two contiguous circular lumens. Its aggregate maximal diameter is 16 mm. The superior lumen, 4.2 mm in diameter, is used to house a 4 mm diameter endoscope (Scholly Fiberoptic, Denzlingen, Germany) and is enclosed distally by a conical, transparent plastic tip. The inferior lumen, 7.3 mm in

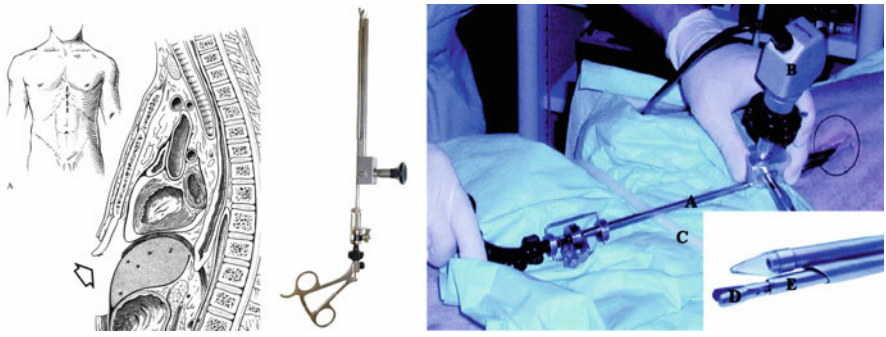

Fig. 12.1 (*left*) Subxyphoid access, (*middle*) Guidant's videopericardioscope (SVP), Images from SVP in porcine model

diameter, is open-ended and used as a "working port" with ability to accommodate a 7 mm diameter instrument.

One major problem associated with the present configuration of the SVP device is its rigidity and hence the significant potential for compression of the beating heart with trigger of life-threatening arrhythmia. Most of the anatomical targets for videopericardioscopy are located in remote areas of the pericardium, away from the entry point in the pericardium below the xiphoid process. A number of cardiovascular therapies based on the epicardium could be effectively delivered by the SVP approach if these physical constraints (rigidity, lack of maneuverability) could be solved, including but not limited to epicardial ventricular and atrial ablation for life-threatening arrhythmias [8, 9], left atrial appendectomy [10, 11], pulmonary vein electrical isolation [12], myocardial revascularization, cell transplantation [13, 14], injection of myocardial growth factors [15], gene therapy [16].

12.2.2 Snake Robots

The highly articulated mechanism development in our work is born out of Hirose's seminal 1972 work in which he developed mechanisms to crawl like snakes [17]. Inspired by this work, others developed the hyper-redundant manipulator and some basic techniques to position the end-effector (i.e., perform inverse kinematics) [18]. These works, and others that followed, were generally limited to one plane and could not travel in three-dimensional volumes.

Many spatial snake robots have a fixed based and typically are a serial chain of linearly actuated universal joints stacked on top of each other. Takanashi developed at NEC a new two-DOF joint for snake robots that allowed a more compact design. This joint used a passive universal joint to prevent adjacent bays from twisting while at the same time allowing two degrees of freedom: bending and orienting. This universal joint enveloped an angular swivel joint, which provided the two degrees of freedom. The universal joint being installed on the outside rendered the joint too bulky. Researchers at Jet Propulsion Laboratory (JPL) "inverted" Takanashi's design by placing a small universal joint in the interior of the robot. This allowed for a more compact design, but came at the cost of strength and stiffness (backlash). A small universal joint cannot transmit rotational motion at big deflection angles nor can withstand heavy loads.

Over the past 5 years, our group has developed a family of "snake robots" (Fig. 12.2), both fixed-base elephant trunk-like probes [19] and free-crawling robots [20]. The development of these robots was geared toward urban search-and-rescue in collapsed buildings [19, 21]. One robot is a series of innovative two-degree-of-freedom universal joints with a camera at its distal end to report imagery to remote users. The efficacy of this snake robot has been demonstrated in urban search and rescue training scenarios with the Chemical Biological Response Force (Marines) and the Center for Robotics Assisted Search and Rescue (see http://snakerobot.com).

Fig. 12.2 (*left*) Fixed base "elephant trunkbot" on a mobile base (*right*) Free crawling snake robot

12.2.3 Novel Forms of Actuation

For MICS, a snake robot would require an outer diameter of less than 10 mm. The many degrees of articulation that furnish a small snake robot with its enhanced capabilities also offer its main research challenges: constructing a maneuverable device with many degrees of freedom in a small space. Much prior work, therefore, has been geared toward developing novel actuators that are small and hopefully strong and robust to operate an articulated device.

Numerous works have been presented on active catheters and endoscopes, most actuated by non-conventional actuation technology such as shape memory alloys (SMA) actuators (Tohuko University, Olympus Optical Co). SMA spring and wire actuation has been implemented by Hirose to detect contact forces; the overall accuracy of the device is 2.3 mm [17]. Another endoscopic active device developed was an 8-mm diameter worm-like mechanism formed by a sequence of segments articulated to each other by SMA driven pin joints [22]. This device was specifically designed to explore the intestine with a camera. A 2.8-mm diameter active catheter was developed based on silicon micromachining [23]. This multilane manipulator is connected by joints made of SMA, fixed at equilateral triangular locations to allow bending in several directions. Unfortunately, SMA-based designs generate indirect heating, which can cause collateral tissue damage. Several other papers have reported additional endoscopic, SMA-based, tools [24–29]. However, disadvantages of these tools include its relatively low stiffness and its requirement of high activation voltage causing heat to be generated.

An alternative to SMAs are electrostrictive polymer artificial muscles (EPAM), which have been used to create snake-like endoscopic robot composed of several blocks joined by a concentric spine [30]. In addition, another snake-like manipulator using EPAM has been designed with a special actuator design, allowing control of curvature [31]. A different activation concept involves a 5 mm diameter two-degrees-of-freedom tool driven by super-elastic nitinol (NiTi) wires [32]. However, wire actuation, SMA, and EPAM actuation all become a challenge with robots having multiple degrees of freedom due to limited space inside the robot's mechanical

envelope. For this reason, the previous work was not able to achieve a complex curve, such as an "S" shape, in a three-dimensional space and therefore was limited to a confined luminal tube-like environment.

12.3 CardioArm Mechanism

The CardioARM is composed of 50 rigid cylindrical links serially connected by four cables. Two adjacent links can rotate approximately $\pm 10^{\circ}$ relative to each other. The current distal apparatus is 10 mm in diameter, 300 mm in length with 105 degrees of freedom. A novel feature of this mechanism is that all of the links do not have to be individually controlled and hence this device is sometimes called a "follow-the-leader" mechanism. When the user specifies inputs for the distal tip of the robot, all the other links follow its location. Since the distal apparatus is capable of preserving its previous three-dimensional (3-D) configuration, in a sense the CardioARM traces a curve in three dimensions. The radius of curvature of the distal apparatus is 35 mm at minimum. The maximum speed of forward and reverse movement is up to 20 mm/s. See Fig. 12.3.

A feeding mechanism, rigidly attached to the operating room table via an adjustable support mechanism, inserts the CardioARM through a small incision

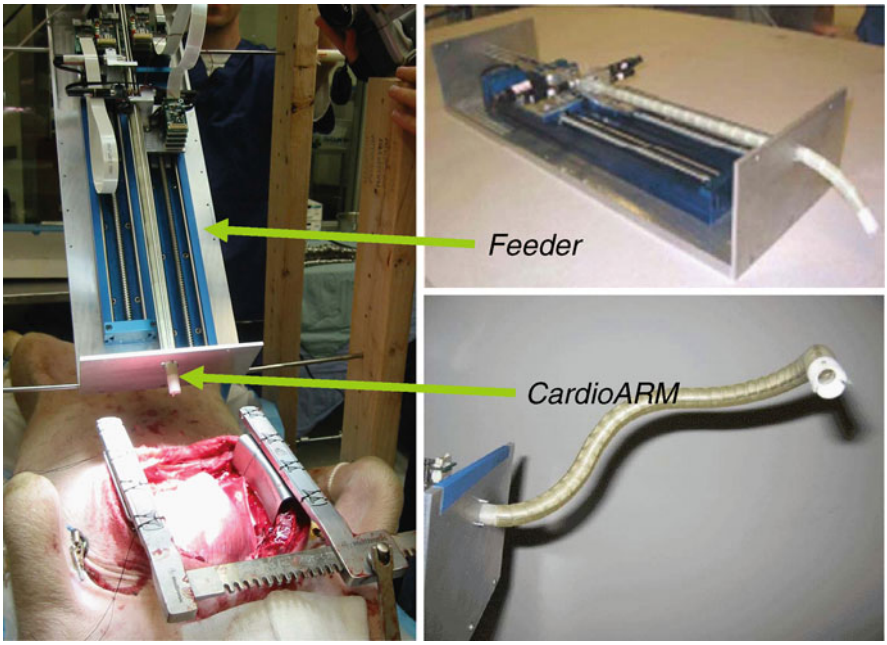

Fig. 12.3 Feeder mechanism (*upper left and right*) inserting CardioARM (*lower right*) into a pig (*lower left*)

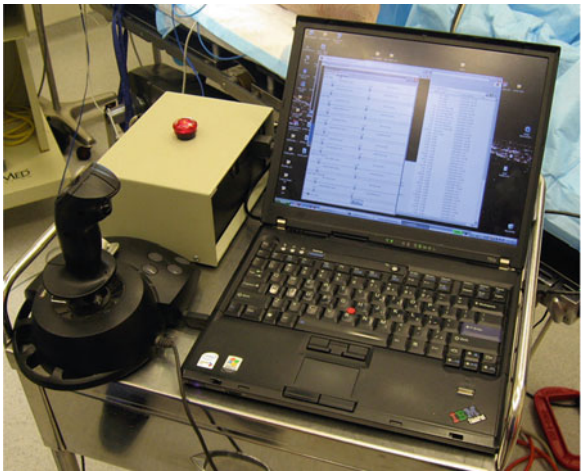

Fig. 12.4 CardioARM user interface

or port. The feeder contains four motors that pull on the cables to marionette the CardioARM. The feeder also has two motors to push and pull the CardioARM. Finally, the feeder houses all of the electronics that drive the probe and interface it with a user input device, such as a joystick, and computers to take high level commands to direct the CardioARM. See Fig. 12.4.

Control of the CardioARM requires a toggle and a straight-forward inverse kinematics procedure: The toggle selects direction with a button on the joystick to choose between forward or reverse motion. In forward mode, the joystick heading angle is converted into cable tensions via simple inverse kinematics to steer the CardioARM. The cable lengths are set via their associated motors as the motor pushing the mechanism engages. The process repeats as the joystick is in use. In reverse mode, the controller simply invokes the tensioning/advancing commands in reverse order causing the CardioARM to retract along the path it originally followed. The operator uses a 2-DOF joystick to control the distal link together with a button to control forward/backward motions.

We are able to pass catheter-based tools for therapy and imaging through the CardioARM. Visualization is provided by an on-board optical 15K bundle fiber scope with an integrated light guide, 65° FOV, 640 × 480 CCD camera. (fiber: FIGH-30-850N, Myriad Fiber Imaging Technology, Dudley, MA, camera: EO-2AN, Edmund Optics, Barrington, NJ).

12.4 Experiments

The CardioARM has been tested (Fig. 12.5) in 15 large (35–45 kg) healthy Yorkshire pigs of either sex at the Surgical Research Laboratory of the University of Pittsburgh [33, 34]. Initially, Zenati performed preclinical feasibility testing of

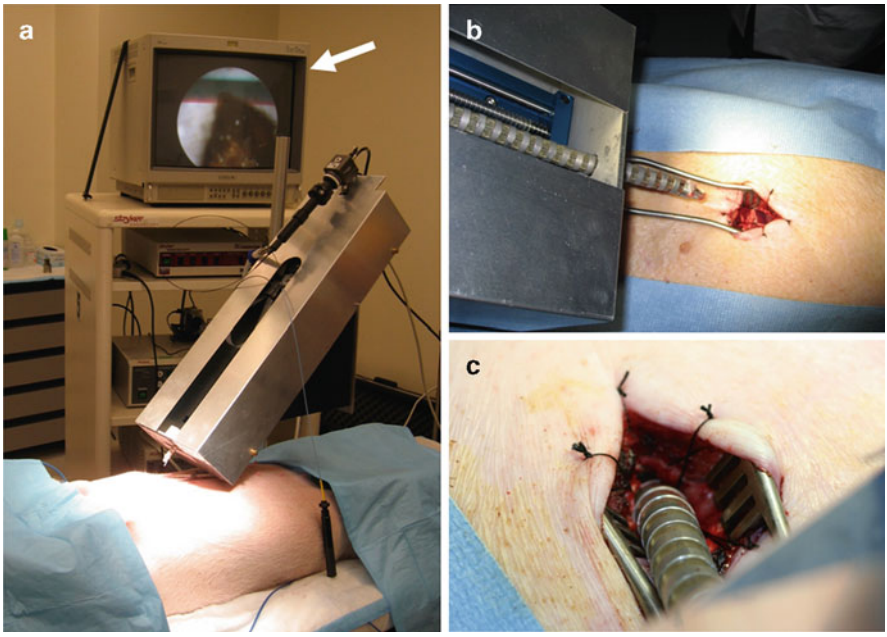

Fig. 12.5 CardioARM mount, display, and insertion into porcine model

the CardioARM prototype in the open-chest intrapericardial environment. We then performed preclinical testing accessing the intrapericardial environment through the subxyphoid.

The thoracic experiments were performed in the anesthetized animals following a median sternotomy. A 15 mm opening was created on the pericardium at the junction with the diaphragm; through this opening, the CardioARM was remotely guided to slide between the pericardium and the anterior wall of the right ventricle on the beating heart. After opening of the pericardium, the CardioARM was guided through the transverse sinus of the pericardium. This path was successfully completed both with the CardioARM entering through a subxiphoid access (Fig. 12.6), and from a right thoracic port. An endoscopic biopsy forceps was advanced through the CardioARM's working channel to simulate a pericardial biopsy; several specimens of pericardium were successfully harvested through the CardioARM (Fig. 12.6-left).

Furthermore, we were able to insert through the CardioARM's working channel a customized EndoloopTM (Ethicon Endosurgery), and simulate an LAA ligation (Fig. 12.6-right). The endoscopic biopsy forceps were found to be a useful adjunct to presentation of the LAA for optimal placement of the EndoLoop at its base. After the completion of the experiment, absence of any gross epicardial damage to the heart was confirmed by visual inspection. No adverse hemodynamic or electrocardiographic interference induced by the motion of the CardioARM was detected.

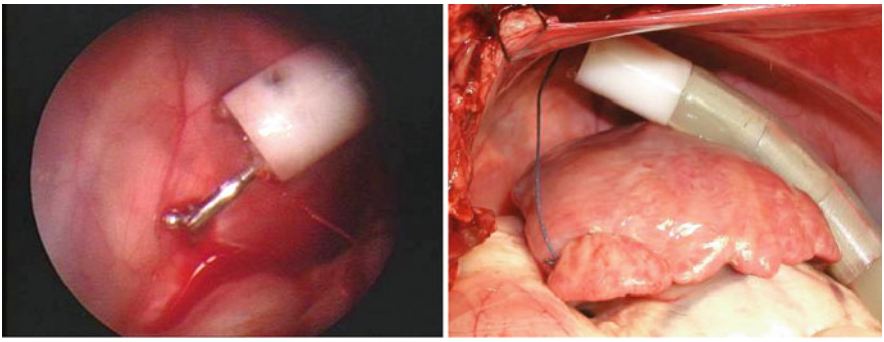

Fig. 12.6 Inserting tools through CardioARM's working channel: (*left*) Using biopsy forceps to perform pericardium biopsies; (*right*) Using Endoloop to ligate the LAA

Our initial experiments verified that we can indeed perform an ablation in hard to reach portions on a live beating heart (in a porcine model). The CardioARM system was introduced through a 15-mm subxiphoid incision into the pericardial space. Upon reaching the base of the left atrial appendage, a 7 Fr commercially available ablation catheter was introduced through one of the ports (Fig. 12.7), and under direct vision, epicardial ablation was performed. Epicardial transmural lesions were confirmed by histopathology. A detailed account of these experiments was published on the official journal of the International Society for Minimally Invasive Cardiac Surgery [35].

Further experiments entailed navigating to multiple portions of a live beating heart (in a porcine model) and performing ablations [36]. Six healthy large swine were anesthetized and placed in a supine position. A small subxiphoid skin incision (20 mm in length) and pericardiotomy (15 mm in diameter) were created under direct visualization. CardioARM was mounted on a surgical table (Fig. 12.5a) in a position for easy insertion through the subxiphoid incision. The distal apparatus of CardioARM was introduced into the pericardial space under the surgeon's control while watching a monitor display of the on-board optic fiber view (Fig. 12.5a). First, navigation trials to acquire several anatomical targets (i.e., right atrial appendage, superior vena cava, ascending aorta, left atrial appendage, transverse sinus from the left side, and atrioventricular groove in the posterior wall of the heart) were performed. When one target was acquired, the distal apparatus retracted to the initial position (i.e., the subxiphoid incision), then moved to another target. Following the navigation trials, left atrial ablation trials were performed. Once the tip of CardioARM was positioned at the vicinity of a target on the left atrium, a 5 Fr radiofrequency ablation catheter (Biosense Webster, Diamond Bar, CA) was passed through a working port of CardioARM, and a linear ablation lesion was created on the left atrial epicardium. A radiofrequency energy generator (Stockert 70, Biosense Webster) was set to deliver a power of 30 W for 30 s per lesion. Blood pressure and electrocardiogram were monitored throughout the trials. The animals were euthanized at the end of the trials, and postmortem examination was performed.

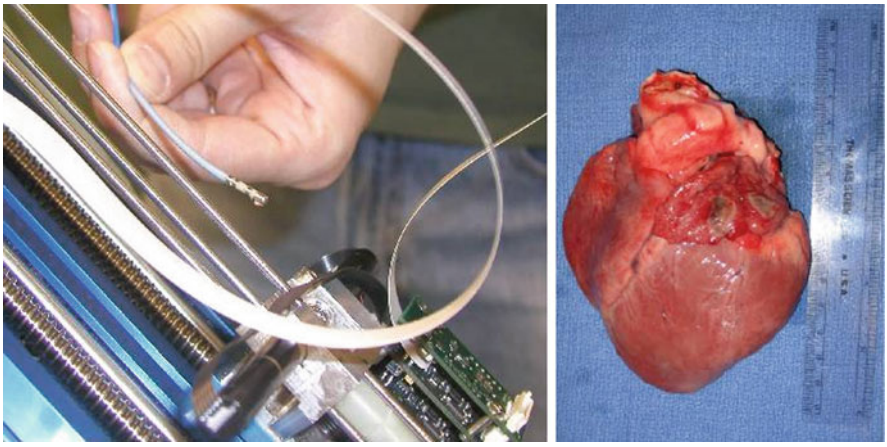

Fig. 12.7 (*left*) 7 Fr irrigated ablation catheter before insertion into CardioARM. (*right*) Two discrete ablation lesions are clearly visible on the LAA

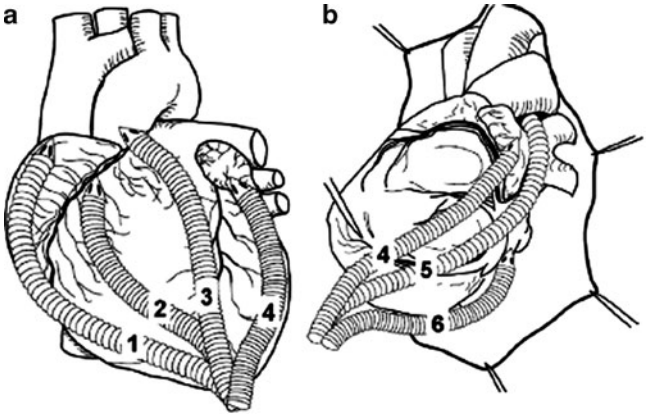

Fig. 12.8 The accomplished courses of the distal apparatus of CardioARM in the navigation trials. (**a**) Front view. (**b**) Left lateral view. #1: superior vena cava, #2: right atrial appendage, #3: ascending aorta, #4: left atrial appendage, #5: transverse sinus, #6: atrioventricular groove

All animals tolerated the procedures until their elective euthanasia. In the navigation trials, the distal apparatus of CardioARM followed a complex 3-D path from the subxiphoid incision along the ventricular wall to each target (Fig. 12.8). All navigation targets were acquired without complications (e.g., fatal arrhythmia, hypotension, bleeding). The on-board camera provided adequate visualization for navigation (Fig. 12.9a).

In the ablation trials, a linear lesion composed of several consecutive "dot-to-dot" lesions at the base of the left atrial appendage was successfully completed (Figs. 12.9b, c). No adverse event was noted during the trials. There was no injury

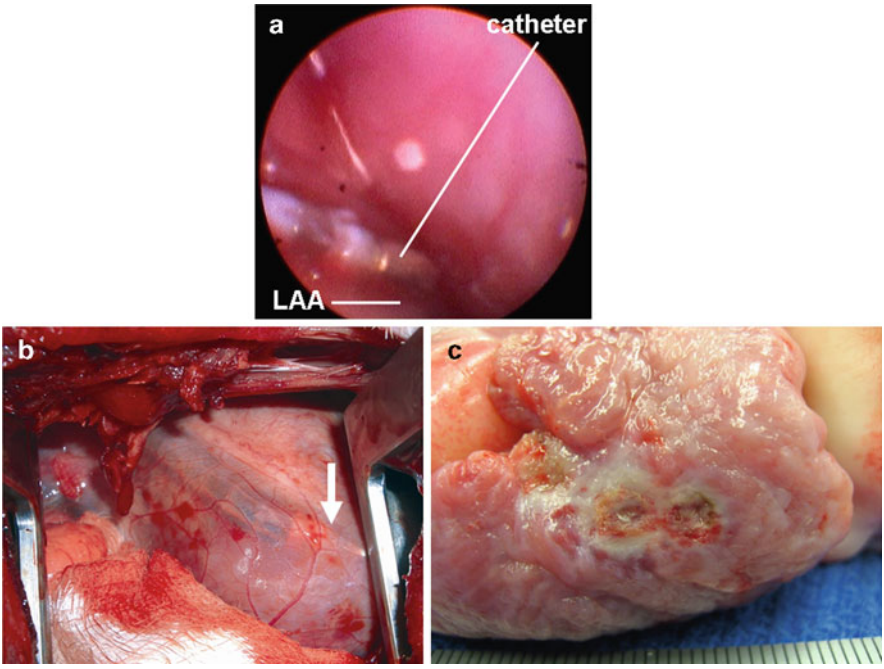

Fig. 12.9 (**a**) On-board view during the epicardial ablation trials (**b**) The distal apparatus of CardoARM is seen through the pericardium (*arrow*). The tip of the robot is navigated to the left atrial appendage. (**c**) A linear "dot-to-dot" lesion at the base of the left atrial appendage of the excised heart

due to the positioning of the robot and the tool's manipulation to the surrounding mediastinal structures (i.e., phrenic nerve, lung, pulmonary artery) upon postmortem examinations.

12.5 Conclusion

Despite the success of commercially available robotic systems aimed at minimally invasive cardiac surgery, current technology has significant limitations. The ability to operate in highly confined and dynamic spaces is of particular concern in cardiac surgery. The CardioARM was developed in an effort to provide dedicated intrapericardial therapeutic delivery with single port access (i.e., subxiphoid approach) and it has the potential to navigate the entire surface of the heart with visualization. Moreover, the CardioARM can accommodate any commercially available catheter-based tools through the working ports of the robot (up to 8 Fr for the current CardioARM model). Therefore, it is technically feasible to perform not only epicardial ablation but also epicardial injection, biopsy, mapping, and left atrial appendage ligation.

Perhaps the greatest feature of the CardioARM is its ability to preserve its shape in 3-D space during navigation. This feature is distinctively different from general endoscopic devices which rely on a static shaft and the ability to only control the tip. The "shape-keeping" ability of CardioARM is especially important in the pericardial space, where there is concern about interference with the beating heart.

Our future work will focus on improving the maneuverability of the device by decreasing the diameter and the radius of curvature of the mechanism. Moreover, haptic feedback will be incorporated to signal interaction between the device and its surrounding tissue to improve operator controllability. We are also seeking to develop new technology that will make the CardioARM a platform for natural orifice transluminal endoscopic surgery.

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