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Highly Articulated Robotic Probe for Minimally Invasive Surgery

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Abstract

We have developed a novel highly articulated robotic probe (HARP) that can thread through tightly packed volumes without disturbing the surrounding tissues and organs. We use cardiac surgery as the focal application of this work. As such, we have designed the HARP to enter the pericardial cavity through a subxiphoid port. The surgeon can effectively reach remote intrapericardial locations on the epicardium and deliver therapeutic interventions under direct control. Our device differs from others in that we use conventional actuation and still have great maneuverability. We have performed proof-of-concept clinical experiments to give us preliminary validation of the ideas presented here.

Keywords

Cardiac Surgery; Medical Robot; Minimally Invasive Surgery; Snake Robot

I. Introduction

Antiseptic techniques, introduced by Lister 150 years ago, have been by far the greatest single improvement in the art and science of surgery. This has enabled the core surgical task of "cutting and sewing" with hand instruments, allowing direct visualization and contact. The next great improvement, which will have a far greater impact than antiseptic techniques, has begun. This improvement lies in minimally invasive surgical approaches where a small incision is made and the surgeon performs the operation through specialized tools inserted through the incision. Many areas of surgery have been revolutionized by the development of minimally invasive surgical procedures developed after the introduction of fiber optic technology (i.e. endoscopy, laparoscopy, etc.)

Conventional minimally invasive surgical devices are either 1) rigid and straight, or 2) flexible and buckle easily. This paper describes our initial efforts in developing a new medical device which has the best of both worlds; it is both rigid and flexible and therefore well suited to minimally invasive surgery. The mechanism described in this paper can be viewed as a snake robot, but we prefer to call it a highly articulated robotic probe or HARP, for short.

We have chosen the cardiac domain as a focal application because the challenges faced in cardiac surgery are representative of challenges faced in other procedures. Moreover, according to a recent Gallup Poll, heart disease and heart attack are ranked second, after cancer, as a major health concern for Americans, preceding other diseases such as arthritis, stroke, high blood pressure and diabetes. The Center for Disease Control and Prevention

concluded in their 1996 report that cardiovascular diseases (principally ischemic heart disease and stroke) are the nation's most common cause of death among both men and women of all racial and ethnic groups. This trend is supported by the 2004 annual statistical report of the American Heart Association which indicates that since 1900 cardiovascular disease has been the number one killer in the United States every year but 1918.

Cardiac surgery is different from other surgical procedures because the large sternotomy incision required to access the heart requires general endotracheal anesthesia. The heart-lung machine that is required for open-heart surgery (e.g. valve repair) adds further morbidity. If for that reason only, performing an epicardial intervention in a less invasive manner will dramatically improve recovery and decrease risks involved with the current procedures.

The HARP mechanism, described in this paper, differs from previous devices in its ability to form a curve in a three-dimensional space with only six actuators. We present an overview of existing medical devices, show the mechanical design of the HARP and report experiments on pig models.

II. Overview

A. Minimally Invasive Surgery

It is almost self-evident that minimally invasive procedures have clear clinical benefits to patients when compared to "open" procedures. By virtue of the minimal invasion, performing any procedure less invasively results in less soft tissue disruption, with the effects of reduced pain, faster healing and better recovery. It has already been documented that less invasive procedures which include smaller incisions and fewer injuries to major blood vessels and nerves improves patient care [1]. As a byproduct of minimally invasive techniques, patients require shorter hospital stays and faster return to normal activity [2].

B. Minimally Invasive Cardiac Surgery

We believe that the HARP will be ideally suited for minimally invasive cardiac surgery (MICS). The HARP can enter the pericardial cavity through a subxiphoid port, reaching remote intrapericardial locations on the epicardium without causing hemodynamic and electrophysiologic interference while delivering therapeutic interventions under the direct control of the surgeon (Fig. 1). Some of these potential intrapericardial therapies include: cell transplantation by intramyocardial injection, epicardial ablation, and epicardial lead placement for resynchronization.

The subxioid route is an ideal point of entry for cardiac procedures because its use avoids the need for a large sternotomy incision. Dr. Zenati pioneered this approach for epicardial left heart pacing lead implantation for resynchronization [3]. The subxiphoid videopericardioscopy (SVP) device (Guidant Corporation, Santa Clara, California) is the only dedicated technology available for endoscopic video exploration of the pericardial cavity. One major problem associated with the present configuration of the SVP device is its rigidity and the significant potential that the compression of the beating heart will trigger a 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. Our 12mm in diameter HARP can get to those hard to reach anatomical targets by using its high redundancy and maneuverability while minimally interacting with the environment along its path.

C. Related Work in Medical Devices

Endoscopic instruments are the main tools used today in minimally invasive surgery (MIS). A typical endoscope consists of a long 10mm in diameter tube with a length of 70 to 180 mm. Although these devices have a steerable tip which allows them to be directed inside the body, current endoscopic tools cannot maneuver in very small and geometrically complex spaces. To overcome this problem numerous works have been presented on active catheters and endoscopes which try to increase their maneuverability. Much of these works have focused on developing a new form of actuation, such as shape memory allows (SMA) [4] and electric polymer artificial muscles (EPAM) [5].

Hirose [6] used an SMA spring and wire actuation to make a small surgical device; the novelty of his mechanism is that it overcomes hysteresis commonly found in SMA's. Although SMA's offer a compact alternative to conventional actuators, virtually all SMA tools have relatively low stiffness, and require high activation voltage. This high activation voltage then makes removing heat difficult

A different activation concept is presented in [7]. In this work the authors presented snakelike tools using super-elastic NiTi which has higher stiffness than other SMAs but the heating problem and complexity of multiple DOF is still relevant, resulting in limited DOF mechanisms. Lately there has been an increase interest in Electrostrictive polymer artificial muscle (EPAM) for medical applications. An EPAM based snake-like endoscopic robot was developed at Stanford Research Institute (SRI). The device is composed of several spherical joints attached serially around a concentric spine [5]. Another popular actuation scheme is wire actuation, such as the arthroscope tool developed at the Santa Anna laboratory in Pisa, Italy, [8]. The 25-mm long distal section of the arthroscope has a 1-DOF with an angle range of 0° to 110° .

Perhaps the biggest drawback to wire actuation, SMA, and EPAM actuators is that they do not have the strength to "hold" the device in three dimensions. This means that they cannot form a true three-dimensional curve. These devices, for which they were most likely originally designed, can only operate inside a luminal or tube-like environment.

III. Harp Design and Operation

A prototype of the highly articulated robot for minimally invasive surgery has been built and tested in our lab. The current prototype is 12mm in diameter, and 300mm in length. The choice of 12mm is based on available ports. With the feeder mechanism, described below, the overall dimensions of the mechanism are approximately 500mm length, 170mm width, 100mm height.

Four cables actuate the probe. The source of actuation is off-board which means that no electric power, heat dissipation, etc. occurs inside of the HARP, and hence inside the body, when the HARP is inserted into a patient.

Visual feedback from the distal link is relayed by a 2mm diameter fiber optic endoscope attached to the outer snake, and displayed on a monitor.

IV. Preliminary Experiments

We have performed bench testing with an anthropomorphic beating heart model (Chamberlain Group, Barrington, MA) in which the probe is outfitted with a 1.2mm image fiber scope (Myriad Image Fiber Tech., Dudley, MA), a 5Fr ablation catheter (Biosense Webster, Diamond Bar, CA), and an irrigation line to deliver saline. A mark was made on the epicardial surface of the LAA and the heart model covered with a thoracic phantom that

simulated a subxiphoid approach. Using only the direct visualization to identify anatomical landmarks, the probe was piloted to the target region where the ablation catheter was deployed and ablation simulated. The mark used to indicate the target site was clearly visible in the image window, as was the catheter manipulation. More insightful heart model testing will be possible when we have fully integrated the electromagnetic tracking system.

V. Experiments

Large healthy Yorkshire swine of either sex (N = 5, body weight 40-45 kg) were anesthetized and laid in supine position. A 20 mm skin incision was made at the subxiphoid. Then, the pericardium was incised in 2 cm length. The HARP advanced into the pericardial space through the pericardial hole, while the test was observed using a thoracoscope inserted from the left thoracic wall (Fig. 2A, B, C). Operations of pathways from the subxiphoid to the left atrium through the anterior wall of the heart and through the oblique sinus were tested several times repeatedly. Once the tip of the robot had reached the left atrium, 8 Fr. catheter with an irrigated radiofrequency tip (Biosense Webster, Diamond Bar, CA) was guided through the working port of the robot. Epicardial ablation (40W, 15 seconds) was performed three times in each point. Two or three points of ablation were carried out in every animal. The blood pressure and electrocardiogram were continuously monitored to evaluate hemodynamic and electrophysiological influences of the robot and the ablation procedure. All animals survived until elective sacrifice at the end of the trials, and the heart was excised for triphenyltetrazolium chloride (TTC) stain.

The thoracoscope inserted from the left thoracic wall provided adequate visualization of the left aspect of the heart through the pericardium. Two pathways from the subxiphoid to the left atrium through the anterior wall of the heart and through the oblique sinus were successfully accomplished in all cases without interference with the beating heart. The HARP was precisely navigated by the surgeon to pre selected remote locations. Series of epicardial ablation were successfully performed under a beating heart with the thoracoscopic view (Fig. 3A, B). Throughout the trials, hemodynamic status was stable and there were no adverse events such as fatal arrhythmia including multiple premature ventricular contractions, injury to the heart and malfunction of the robot in all cases.

After the epicardial ablation procedures, the animals underwent a full sternotomy for observation. Their diaphragms were not paralyzed under the spontaneous respiration, and no injury to the surrounding mediastinal structures (e.g. esophagus, pulmonary artery) and active bleeding caused by the HARP manipulation was noted. At gross examination, there was also no damage of both the heart and surrounding structures such as a pericardium, pulmonary veins, pulmonary arteries and the aorta (Figure 4A). Transmural ablation was confirmed by TTC stain in all points of all cases (Figure 4B, C).

The study protocol was approved by the Institutional Animal Care and Use Committee of the University of Pittsburgh. All subjects received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" published by the National Institutes of Health (NIH publication No.85-23, revised 1985).

VI. Conclusion

Recently, ablation therapies for AF have been well studied including energy sources, approaches, their efficacy and safety. Regarding epicardial ablation therapies on a beating heart, several minimally invasive trials such as robot-assisted or total endoscopic ablation were reported [9]. However, those studies still required more than 2 ports placement. We aim for achieving ablation therapy using the HARP with minimized port incision, that is, one port approach.

The HARP has been developed to facilitate therapeutic deliveries to the intrapericardial space for minimally invasive surgery [10]. The present prototype of the robot is the second generation which has smaller radius of curvature and increased speed in comparison with the first prototype (radius of curvature: 7.5 cm, speed: 5 mm/second).

The device is designed to be induced using a subxiphoid approach. Zenati et al. reported endoscopic ligation of the left atrium appendage and pacing lead implantation with the subxiphoid videopericardioscopy approach [11]. This minimally invasive approach is appealing because it allows access to the pericardial space through a single subxiphoid port while not requiring general endotracheal anesthesia and lung deflation.

The HARP has several advantages. The first advantage is maintaining its previous shape while moving forward or backward, which is the most different feature between this robot and traditional endoscopic devices. The body of a common endoscope would strike the surrounding structures when manipulated. In this study, the robotic manipulations did not trigger adverse events such as a fatal arrhythmia because the capability of keeping its previous configuration minimized contact of the robot with the heart. Second, the probe of the HARP can be made of any suitable, the Food and Drug Administration (FDA) approved material. The current probe is made of plastic. The probe will be able to be produced with quite low cost as a disposable product. Third, the large working port of the robot has a high utility to use off-the-shelf catheter devices. We have accomplished the left atrial appendage ligation with Endoloop® (Ethicon Endo-Surgery Inc., Cincinnati, Ohio) and a pericardial biopsy with an endobiopsy catheter using the first prototype of the HARP under the open chest porcine preparation (data not shown).

The present prototype had no built-in visualization, such as an on-board charge coupled device (CCD) camera. In addition, we will need to know the exact location and the physical relationship between the robot and the heart for a precise PV isolation. Electromagnetic tracking system or three-dimensional electroanatomic mapping system will be able to be incorporated for this purpose [12].

As for future works, we will focus on not only epicardial ablation but also the other epicardial interventions such as cell transplantation, epicardial lead placement, device-based mitral valve plasty using the Coapsys device (Myocor, Maple Grove, MN). Furthermore, endoluminal gastric surgery has been recently developed for minimally invasive surgery in the field of abdominal surgery. The HARP can also be utilized in this field. The development of dedicated instruments for surgery will enable the next HARP prototype to be inserted from the mouth without any skin incision and to perform surgery in the gastrointestinal tract.

Despite the contributions of this study, several limitations have to be addressed. First, because the sample size is small, further studies including chronic cases are needed to prove safety of the device and the procedure. Second, we need to test the robot in a diseased heart model (e.g. infarction) as a next step.

In conclusion, we have developed a novel articulated robotic medical probe and successfully performed epicardial left atrial radiofrequency ablation. Based on the feedback from these preliminary experiments, the radius of curvature and proper visualization of the device are being improved in the next prototype.

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Figure 1.

HARP is shown as a snake-like mechanism protruding from a current feeder mechanism rigidly attached to the operating table.



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Figure 2.

A, The robot is mounted on the table. A small incision is made at the subxiphoid (arrow 1). Visualization is achieved by a thoracoscope inserted from the left thoracic wall (arrow 2). B and C, The robot advances forward into the intrapericardial space through the subxiphoid incision.



Figure 3.

Tip of the robot and the ablation catheter (arrows) are seen through the pericardium. S indicates tip of the probe; LA, left atrium.

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Figure 4.

A, The excised heart. No injury is observed on the surface of the heart except ablated points (arrows). B and C, Triphenyltetrazolium chloride stain. Transmural ablation is confirmed (arrow).