Robotic Surgery

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Abstract

Currently available robotic surgical and catheter-based systems have limited application in pediatric cardiac procedures. For surgical systems, the main obstacles include extended setup time and complexity of the procedures, as well as the large size of the instruments with respect to the size of the child. For intracardiac surgery, while the main advantage of robotic systems is the ability to minimize incision size, use of cardiopulmonary bypass is still required. Catheter-based robotic systems, on the other hand, have been expanding rapidly in both application and complexity of procedures and lesions treated. However, despite the development of sophisticated devices, robotic systems to aid catheter procedures have not been commonly applied in children. There are a few transcardiac and percutaneous robotic delivery platforms currently under development. These systems aim to facilitate safe navigation through confined spaces and, combined with novel instruments and devices, enable complex repairs, such as tissue approximation and fixation, and tissue removal, inside the beating heart under image guidance. Promising solutions for image-compatible and multifunctional robotic tools are also described.

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Introduction

In the last two decades, minimally invasive image-guided techniques have been gradually adapted to cardiac surgical specialties, from the initial attempts of video-assisted procedures through small incisions, toward fully endoscopic complex reconstructive procedures using telemanipulation systems and specialized instruments and devices. Among the advantages over conventional open-heart surgery, robotically assisted techniques offer less trauma to neighboring structures, which leads to less patient discomfort postoperatively and faster recovery. In addition, newly available specialized surgical tools and imaging aids provide the surgeon the ability to operate precisely in confined spaces and then assess the results of repair in physiologic conditions, which results in safe and effective repairs.

Robotic Surgical Systems

Currently, the da Vinci® Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) is the only FDA-approved system for intracardiac procedures. It consists of several components that include a surgical console, a patient-side cart, four interactive robotic arms, a 3D vision system, and proprietary EndoWrist® instruments. The surgeon operates from a console that is located remotely from the patient while using the 3D high-definition high-magnification endoscopic vision system for imaging. The patient-side cart is where the patient is positioned during surgery. It includes four robotic arms that accept the EndoWrist® instruments and a dual-camera endoscope. These 7-degree-of-freedom instruments essentially represent mechanical wrists and are designed to function as the surgeon's forearm and wrist but with dexterity provided at the operative site through the entry ports. While the surgeon operates using the master control clutches at the console, a computer system causes the robot arms to transmit the surgeon's hand motions to the instruments while also enabling the features of tremor elimination, motion scaling, and motion indexing.

Robotically Assisted Pediatric Cardiac Surgery

The first report of robotically assisted cardiac surgical procedure was published in 1998 by Carpentier and colleagues [1]. The authors used a prototype of the current da Vinci® Surgical system and performed successful closure of an atrial septal defect (ASD) in a 52-year-old woman. Shortly thereafter, Mohr and colleagues performed the first coronary artery bypass in five patients, which was reported in 1999 [2]. Initially, the procedures were performed through small thoracotomy incisions. In the following years, the da Vinci® Surgical system has gained acceptance among adult cardiac surgeons and, with the improved instruments and visualization system, has been used in patients undergoing totally endoscopic coronary artery bypass or mitral valve repair [3, 4]. Despite increasing reports in adults, there is limited experience with robotically assisted procedures in children.

Pediatric Extracardiac Procedures

Le Bret and colleagues first reported robotically assisted patent ductus arteriosus (PDA) ligation in 2002 [5] using the discontinued ZEUS® Surgical System (Computer Motion, Inc., Goleta, CA, USA). The authors compared a robotically assisted technique for PDA closure with the standard video-assisted thoracoscopic surgery technique in 56 patients weighing 2.3–57 kg (mean = 12 kg), 28 patients per group. The robotic group ranged from 2 months to 5.5 years in age and from 3.2 to 22.5 kg in weight. The investigators found that the operation time was significantly longer in the robotically assisted group because of the incremental complexity, but no complications were noted. Suematsu and colleagues reported the successful use of the da Vinci® Surgical System for PDA closure in nine patients and vascular ring division in six patients weighing 14.1–77.0 kg (mean = 35.5 kg) [6]. It was found that, despite the long operative times, the robotic procedures were feasible and safe, largely due to advantage of 3D visualization and dexterous manipulation afforded by the surgical robotic system. The conclusions of these reports and others [7, 8], however, are that due to the large instrument size and need for entry port sites that are relatively far apart to avoid interference between the robotic arms, use of this system in children less than about 30 kg is quite difficult. For these reasons, most surgeons who have utilized the da Vinci® Surgical system in children believe that a robotic approach is comparable but has no major advantages over non-robotic thoracoscopic instruments using video-assisted techniques.

Pediatric Intracardiac Procedures

The reports of robotically assisted intracardiac procedures have been limited to a small series of adult size patients undergoing ASD closure. Torracca and colleagues used da Vinci® Surgical System for the repair of ASD in seven patients [9]. In their report, five patients had ASD, whereas the other two patients had a patent foramen ovale (PFO) with atrial septal aneurysm. The authors established cardiopulmonary bypass (CPB) via peripheral cannulation and used an endoaortic balloon occlusion of the ascending aorta. All procedures were completed endoscopically; no conversion was needed. Argenziano and colleagues and Wimmer-Greinecker and colleagues reported a totally endoscopic ASD repair procedure using the da Vinci® Surgical system in 17 and ten patients, respectively [10, 11]. In the report by Argenziano et al., one patient required reoperation due to a recurrent shunt. In the study by Wimmer-Greinecker et al., no complications occurred, although conversion to a minithoracotomy was required in two patients due to endoaortic balloon failure. Bacha and colleagues reported closure of sinus venosus defect in 40-year-old patient via a 3-cm right anterolateral minithoracotomy [12]. Baird and colleagues reported closure of ASD using the da Vinci® system and hypothermic fibrillatory arrest in a 14-year-old female weighting 35 kg [13]. In all these reports, the operative times and CPB times still exceed those needed for a conventional procedure due to extended setup time and complexity of the procedure. In addition, in most of the series, 8 mm instruments were used, which have a larger working area and therefore limited the use of the robotic system in younger patients. Recently, Intuitive Surgical introduced a new 5 mm instrument set; however, there is limited experience with these instruments.

Despite the fact that the robotically assisted approach contributes to reduced invasiveness of the procedure, there is still a need for the use of CPB, which may potentially lead to neurologic among other complications [14]. Furthermore, since in most of these procedures bypass is achieved by peripheral vessel cannulation, the small size of children's vessels with respect to cannula size introduces the added risk of permanent vessel damage and its impact on limb growth [15].

Catheter-Based Robotic Interventions

Catheter-based percutaneous interventions have evolved significantly over the past decades and have become routine procedures in most centers [16]. Robotically assisted catheter-based interventions, however, are still early in development and have not been widely used in pediatric practice. Currently, there are two robotic catheter technologies available, an electromechanically based system and a magnetically controlled system. Hansen Medical (Mountain View, CA) offers the Sensei X robotic navigation system designed for electrophysiology interventions, while their novel Magellan system is a platform for peripheral vascular interventions. The Niobe magnetic navigation system (Stereotaxis, St. Louis, MO) is operated by a magnetic field created by two computer-controlled 0.08 T permanent magnets. The magnets are mounted on articulating arms that are enclosed within a stationary housing, with one magnet on either side of the patient table. By changing the positions of these magnets with respect to the patient, deflection of the magnetic tip of the catheter can be precisely controlled. Recently, a magnetically controlled system that utilizes a technology of dynamically shaped magnetic fields was introduced (Catheter Guidance Control and Imaging, CGCI, Magnetecs, Los Angeles, CA). Currently, robotic catheter applications in adults include electrophysiological procedures for arrhythmia ablation, peripheral vascular interventions and coronary interventions, and more frequently transcatheter valve interventions [17–25].

Despite recent development of novel technologies, most of the robotically assisted catheter interventions are still fundamentally device deployment or tissue ablation rather than tissue reconstructive procedures. The limitations of current robotic catheter design include inadequate ability for significant force application, especially in a lateral direction from the axis of the catheter, and, at the same time, stable tip position control that is sufficient for tissue manipulation. These limitations impair the surgeon's ability to grasp, plicate, approximate, and remove tissue as it is done during complex repairs in open-heart surgery.

Beating-Heart Intracardiac Image-Guided Surgery

In light of the deleterious effects of CPB and with growing availability of new imaging techniques and device development, there has been an ongoing interest in developing techniques to perform the same types of repairs currently done as open procedures but with the heart beating to avoid use of CPB. Initial attempts have been reported, mostly methods of septal defect closure and mitral valve repair. Warinsirikul and colleagues reported ASD patch closure in 76 patients, whereas the patch was attached with blind suture fixation followed by intra-atrial stapling under transesophageal echocardiography (TEE) guidance [26]. Beating-heart repair of mitral valve prolapse in an animal model has been reported by Seeburger and colleagues. The authors used a novel system developed by NeoChord (NeoChord, Inc. Minnetonka, MN) and were able to insert artificial chords via a transapical approach under echocardiography guidance [27].

Initial laboratory efforts have included direct image-guided approaches such as optical imaging with an endocardioscope in eight dogs for septal defect repair [28] and TEE-guided mitral valve suturing in a porcine model. Vasilyev and colleagues reported beating-heart ASD and ventricular septal defect (VSD) closure under image guidance in swine models [29, 30]. A patch delivery device and handheld anchor delivery system were utilized for atrial and ventricular septal defect closure under real-time 3D echocardiography. Video-assisted cardioscopy was used for intraoperative imaging and instrument navigation.

In order to bring these initial attempts to wide clinical practice, some major developments are required. New robotic delivery platforms need to be developed that provide steerability, precise repeatable motion control, and safe navigation and manipulation of rapidly moving intracardaic structures. In addition, new instruments and devices need to be developed that enable complex tissue manipulations inside the beating heart, limit interference with imaging techniques, and ideally can be integrated with a delivery platform.

Experimental Systems Under Development

Robotic Platforms for Beating-Heart Intracardiac Procedures

Concentric Tube Robots

Recently, a new class of robots for minimally invasive surgery has been developed called concentric tube robots [31–39]. While potentially appropriate for many types of minimally invasive surgery, their size and steerability make them particularly appropriate for intracardiac beating-heart surgery [37, 39–41]. These robots are similar in size to catheters but differ in construction since they are formed from the concentric, telescoping, curved superelastic metal tubes. The shape of the robots is a smooth three-dimensional curve that is controlled by rotating and translating the individual tubes within each other. While their construction makes these robots significantly stiffer than conventional catheters, the ability to precisely control robot shape enables safe navigation inside vessels and the heart. Tools and devices are deployed through the central lumen of the robot that serves as a working channel.

The family of shapes that a concentric tube robot can assume is determined by the shape and length of the individual tubes that comprise it. Sets of tubes for specific procedures can be designed that provide the robot shapes necessary to enable navigation to the surgical site as well as to perform the procedure [32, 39]. These tube sets can be made either for single use or for repeated use with sterilization. A motorized drive system, compatible with all tube sets, is used to control the motion of the individual tubes while the surgeon controls commands the overall motion of the robot using a joystick. Robot design algorithms are available to develop tube sets for new intracardiac procedures. These algorithms use image-based models of the anatomy together with geometric descriptions of the procedure to compute the appropriate lengths, shapes, and stiffness of individual tubes [39].

Robots similar to the design shown in Fig. 69.1 have been employed in percutaneous beating-heart tissue-to-tissue approximation for PFO closure in the right atrium [37]. Entry to the heart was gained via the internal jugular vein. For imaging, a combination of 3D ultrasound and fluoroscopy was employed. The stiffness and steerability of the robot enabled precise positioning on the septum and also the ability to "park" the robot in a particular shape and position so that imaging studies could be performed.

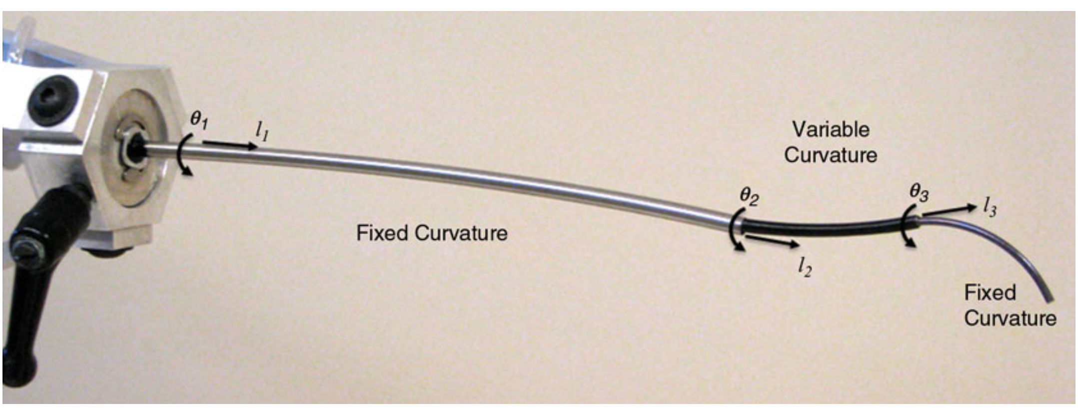

Fig. 69.1 Robot used for PFO closure. Design consists of three telescoping sections

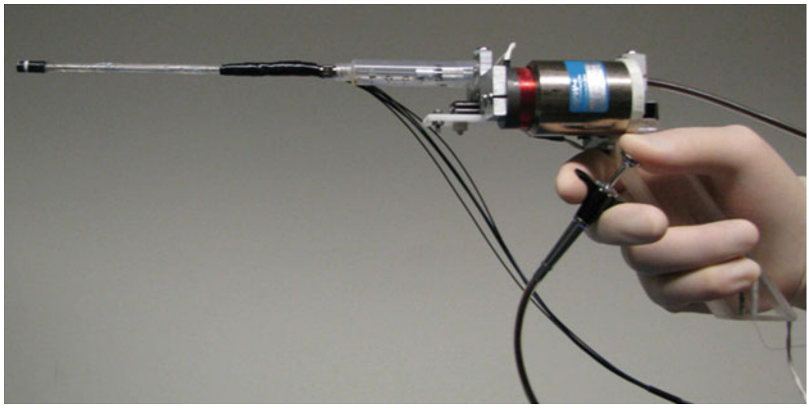

Fig. 69.2 Handheld 1-degree-of-freedom Motion Compensation Instrument

Robotically Assisted Motion Compensation Tools

While atrial septal motion over the cardiac cycle is modest, this is not true for other structures inside the beating heart. Interacting with valvar structures may not be achieved solely with robotically assisted tool tip stabilization, and a different method is required to avoid collision with such delicate structures. One option is to capture and immobilize a valve leaflet first, which then allows performing necessary manipulations with it. This approach is used in several tools for beating-heart mitral valve repair including MitraClip (Abbott Laboratories, Abbott Park, IL) and NeoChord (NeoChord, Inc. Minnetonka, MN), and others [27, 42]. An alternative approach is called robotically assisted motion cancellation, where the instrument moves in conjunction with the target tissue motion, which allows surgeon to approach and manipulate the tissue safely. The complexity of such a system depends on several factors including the precision of image-based tissue tracking; the motion profile of the tissue, i.e., how far and how rapidly it is moving in three-dimensional space; and the ability of the instrument positioner to move at the same rate in all three directions.

Such a device, a 1-degree-of-freedom robotic Motion Compensation Instrument (MCI), was developed (Fig. 69.2). The tool is initially operated by an image-based algorithm based on the real-time 3D echocardiography imaging [43]. The system identifies and tracks the position of the tissue target directly in front of the tool, and a linear motor moves the instrument shaft according to the target motion.

One of the limitations of image-based tracking is that once the surgical instrument tip comes into contact with the tissue target, the algorithm can no longer separate tissue movement from the instrument tip and therefore cannot control the instrument accurately. To address this limitation, a force control tracking algorithm is utilized in addition to the image-based tracking [44]. A force sensor, which is placed on the tip of the MCI, reads the force that the surgeon applies to the target tissue in real time. The force control algorithm thus enables maintenance of constant force against the tissue, which significantly increases the safety of the procedure. The MCI system was tested in an animal model where the movement is predominantly in one direction, such as with valve leaflets or valve annulus [43]. The system was able to achieve speeds up to 1.49 m/s, with accelerations of 103 m/s^2. In comparison, it was found that mitral valve annulus maximum speed in adult patients was only 0.21 m/s, with acceleration up to 3.8 m/s^2, which may make the MCI system well suited for pediatric procedures. It was shown that use of the MCI minimizes collisions with tissue and gives the surgeon precise control of the relative movement of the instrument tip with respect to mitral valve annulus. A catheter-based robotic MCI system is currently under development (Fig. 69.3).

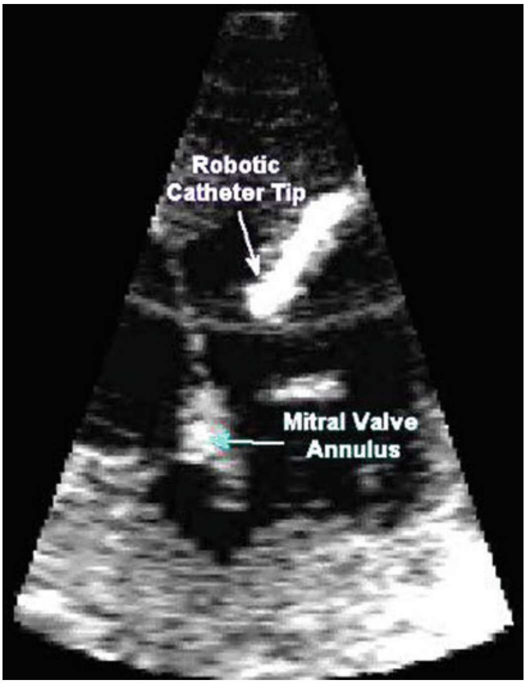

Fig. 69.3 3D-echocardiography image of the catheter-based Motion Compensation Instrument

Fig. 69.4 CardioARM robotic surgical

Other Platforms

Robotic platforms for extracardiac procedures have also been under development. The articulated robotic surgical system CardioARM (Cardiorobotics Inc., Middletown, RI) is a snake-type robot composed of series of rigid cylindrical links serially connected by three cables (Fig. 69.4).

The distal apparatus is 10 mm in diameter and 300 mm in length, with 105° of freedom, and is operated by a 2-degree-of-freedom joystick to control the most distal link together with a button to control forward/backward motions. All of the links are not individually controlled, as the robot employs the so-called "follow-the-leader" motion strategy. It possesses significant strength in the longitudinal direction but less so in the lateral direction. Catheter-based tools can be passed through the robot, and a fiber scope can be used for visible light pericardioscopy imaging. The robot was successfully tested in large swine animal model, where epicardial navigation and left atrial ablation trials were performed [45]. There are no reports, however, on possible use of such a system for pediatric extracardiac or intracardiac applications.

Instruments and Devices

In open-heart procedures, fundamental surgical maneuvers, such as tissue removal and approximation, are usually performed with standard surgical instruments. In cases of endoscopically guided minimally invasive procedures, long shaft endoscopic tools are used. However, both of these designs are not applicable inside the beating heart on rapidly moving structures in the presence of blood. The instruments also need to be compatible with the imaging modality used for procedure guidance and should be integrated with the robotic platforms.

Tissue Removal Tools

There are several clinical applications where precise tissue removal in confined spaces is required to relieve obstruction. These include discrete subaortic obstruction from a fibroelastic membrane or muscle, supra-valve mitral membrane, and abnormal muscle bundles in the right ventricle (RV) such as in double-chambered RV. In children, obstructions in the right or left ventricular outflow tract account for one of the more common causes of myocardial hypertrophy and subsequent dysfunction [46]. Currently, open-heart surgery to completely remove abnormal tissue or, in severe cases, to replace the abnormal structure is often the only option. Beating-heart tissue removal is an alternate approach that is currently being developed. Tissue removal in these applications utilizes the concentric tube robot to navigate to the area of interest, and a specialized microdebrider, which is made using metal micro electromechanical systems (MEMS) technology, is used to sculpt away excess tissue from the desired location [41].

To remove abnormal obstructions from the right ventricular outflow tract (RVOT), the concentric tube robotic system, similar to Fig. 69.1, is delivered percutaneously via a trans-jugular approach. The tool, containing rotating cutting blades, performs the combined functions of tissue cutting, morselizing, and particle entrainment as well as disposal (Fig. 69.5). The latter are implemented by including irrigation and aspiration channels inside the robot lumen. The results of ex vivo tests are shown in Fig. 69.6. As shown, this tool can be used to remove millimeter-thick surface layers of endocardium. It can also be used to create deeper cavities in the tissue. While aspiration removes the bulk of the tissue debris, a downstream embolization filter may need to be deployed into the main pulmonary artery to collect any particulate emboli that may be dislodged by the process of tissue removal.

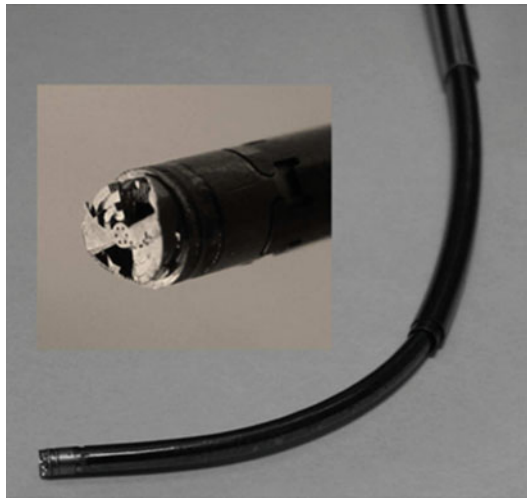

Fig. 69.5 Metal MEMS tissue removal device. Both irrigation and aspiration are incorporated into the design to remove tissue debris through the robot lumen

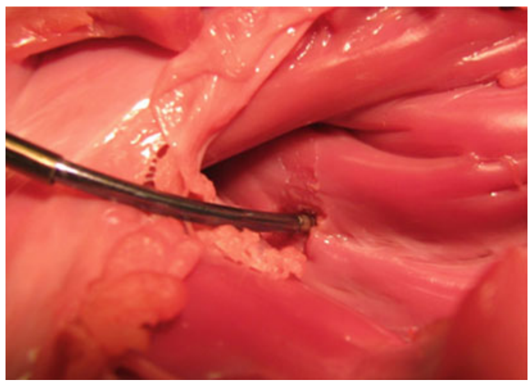

Fig. 69.6 Ex vivo example of tissue removal in the right ventricular outflow tract

Tissue Approximation Tools

Tissue approximation is a fundamental maneuver in surgical reconstruction and involves grasping one part of tissue and attaching it to another or to an artificial material. Novel devices have been under development that may enable these precise maneuvers during beating-heart procedures.

One specific example of tissue approximation is PFO closure. Current approaches to closure include open-heart surgery and catheter-based deployment of an occluder device. Experience with device closure, however, shows that serious complications such as hemorrhage, cardiac tamponade, the need for surgery, pulmonary embolism, and death occur in 1.5 % of patients and minor complications (arrhythmia, device fracture or embolization, air embolism, femoral hematoma, and fistula) in another 7.9 % [47]. Results with open-heart surgery indicate significantly lower risk of complications and no

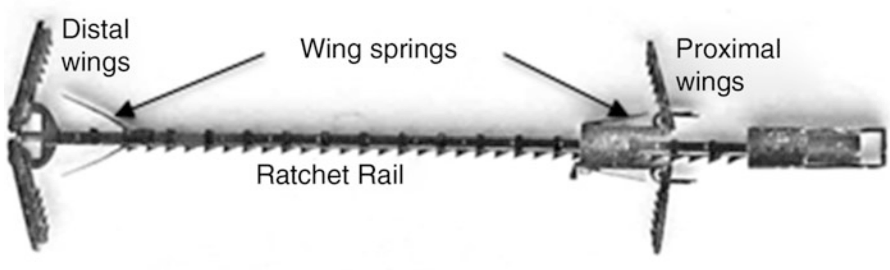

Fig. 69.7 Metal MEMS tissue approximation device

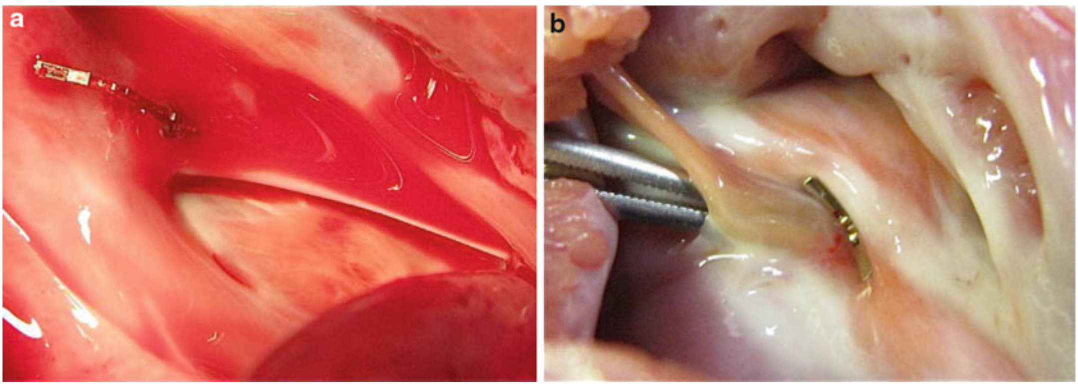

Fig. 69.8 Implanted tissue approximation device. (**a**) Right atrial view, (**b**) left atrial view

recurrence at 23 months of follow-up [48]. A device and technique of PFO closure that mimics surgical closure was developed (Fig. 69.7). The device is manufactured fully assembled using a metal MEMS fabrication process. It is comprised of two pairs of expanding spring-loaded wings that are used to pull the tissue layers together. The wing pairs are attached by a ratcheting mechanism that enables the tissue layer approximation distance to be adjusted with submillimeter accuracy. During device deployment, the robotic delivery platform enables accurate approximation of the septum secundum and primum by first piercing the secundum and then dragging it laterally to achieve the desired overlap with the septum primum (Fig. 69.8).

Successful PFO closure using the device has been demonstrated in porcine in vivo trials [37]. With further development, this device concept may serve as a platform for other procedures such as valve repair.

Imaging-Compatible Tools

For intracardiac robotically assisted beating-heart surgery, imaging plays a critical role. Real-time high-resolution imaging is necessary for the surgeon to navigate to the target, perform the required task, and then confirm adequate and accurate completion of the repair. In addition, imaging data often serves as an input for image-based robotic control algorithms. Therefore, its spatial and temporal resolution must meet the highest performance standards.

Recently, real-time 3D echocardiography has been gaining acceptance as often the sole imaging modality for guiding beating-heart intracardiac interventions given its relatively large field of view and its ability to image the surgical tool and the tissue structures simultaneously [49–53]. Most traditional surgical instruments, however, are made of hard materials with smooth surfaces, which produce a variety of image artifacts when ultrasound waves interact with their surfaces, and

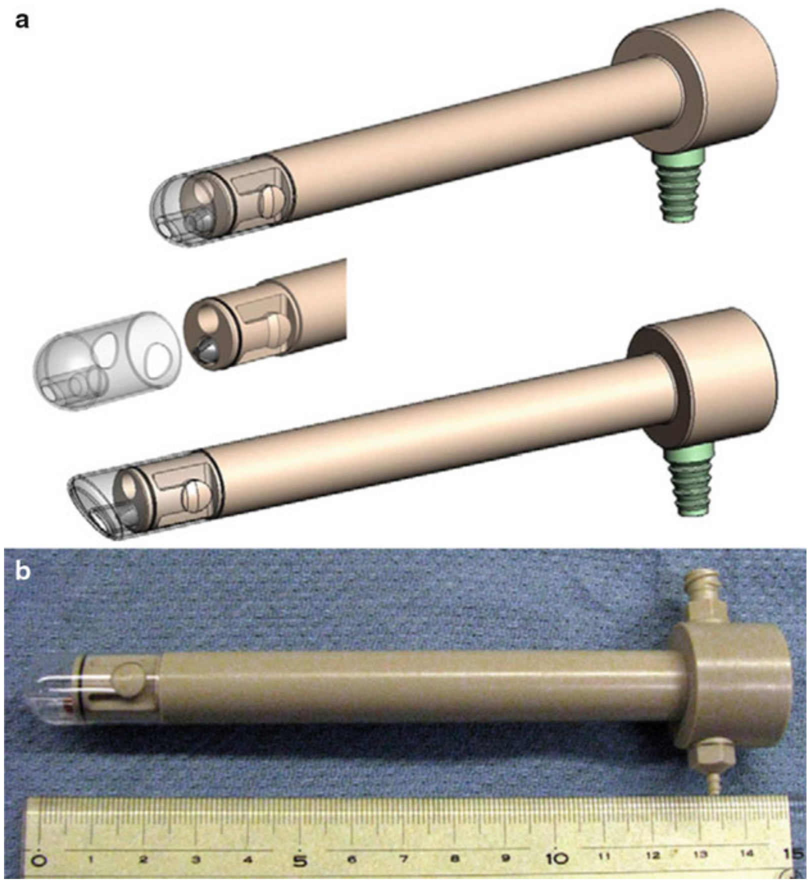

Fig. 69.9 The Cardioport. (**a**) Schematic drawing of the port showing exchangeable transparent plastic bulbs; the bulbs with various geometries can be mounted on the tip of the port depending on the procedure. (**b**) Actual port with the spherical bulb

can make it difficult to clearly visualize the instrument as well as nearby tissue [54, 55]. A variety of solutions to the artifact problem have been introduced. These include instrument modification, image processing techniques, active tracking sensors, and fiduciary markers. Instrument modification involves the application of coatings or surface modifications to reduce the specular reflectivity or to increase absorption [54–58]. Image processing methods apply search techniques to locate an instrument in an image [59–63]. Tracking sensors can also be placed on the surgical tool to detect instrument position and by registering the position relative to the ultrasound image provide real-time information as to the position of the tool within the image [64]. Fiduciary markers on the instruments that are strongly echogenic can also be used to enable the instrument position and orientation to be detected using image-based algorithms from the marker image [65, 66].

Multifunctional Tools

Most of the currently available instruments for minimally invasive surgery and catheter-based procedures are designed as single-function tools and have to be continually exchanged during the procedure. Although tool multifunctionality has the advantage of having a single tool for various tasks performed inside the heart, the design concept increases device complexity, particularly at the instrument tip and handle mechanisms. An intermediate step toward a fully multifunctional tool may be a single access multi-tool approach, where various tools are introduced via a single entry point into the patient's body significantly minimizing trauma and eliminating the need for instrument exchanges at the same time. There are new designs of such dexterous multifunctional robotic tools offered for endoscopic "single-port" surgical procedures. Intuitive Surgical has announced a single-port instrument set, which is not yet available on the market for cardiac procedures, and is undergoing feasibility studies in adult laparoscopic procedures [67]. It is yet to be seen, if such an approach is feasible for pediatric beating-heart interventions.

An additional feature to increase the functionality of the instrument is to incorporate an imaging modality. With recent technological developments for gastroenterologic natural orifice translumenal endoscopic surgical procedures, there have been a few commercially available systems that combine endoscopic imaging and dexterous instrumentation [68]. For cardiac applications, there is no commercially available multifunctional instrument. Vasilyev and colleagues reported development of a Cardioport that combines video-assisted optical cardioscopy and an instrument channel to access structures inside the beating heart [69] (Fig. 69.9).

The optical channel contained in the instrument is used to image the cardiac structure by pressing the scope against the tissue, displacing the blood, and permitting optical imaging of the heart surface. A fluid purging and valve system is utilized in the instrument channel, in order to prevent blood loss and air entry during instrument introduction and exchanges. In animal experiments, the Cardioport was successfully used for beating-heart atrial and septal defect closure and tricuspid valve annular dilation model creation [70].

Conclusion

Despite the fact that robotic systems have evolved significantly over the past decades, there is still limited application of these technologies in extracardiac and intracardiac pediatric procedures. Current clinically available systems have been designed primarily for adult surgical applications. Pediatric intracardiac interventions present an additional challenge, since the complex maneuvers required have to be performed in an even smaller space while operating on delicate tissue. In the research and development pipeline, there are promising platforms for robotically assisted beating-heart intracardiac procedures, which meet the challenges of accessing rapidly moving intracardiac structures. These nonrigid systems can be delivered either transcardiac or percutaneously, much like catheter-based interventions, but with the added functionality of providing a stable platform with the ability to manipulate tissue in a precise and controlled manner. Newly developed instruments combined with smaller, more steerable robotic delivery platforms and enhanced imaging form a single multifunctional tool platform technology, which may enable development of pediatric beating-heart reconstructive interventions currently not feasible with available robotic systems or by conventional catheter-based techniques.

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