Totally Endoscopic Atrial Septal Defect Repair With Robotic Assistance

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Background—Computer (robotic) enhancement had emerged as a facilitator of minimally invasive cardiac surgery, and has been used to perform portions of intracardiac procedures via thoracotomy incisions. This report describes the next step in this progression—the first U.S. application of robotic technology for totally endoscopic open heart surgery.

Methods and Results—Seventeen patients underwent repair of a secundum-type atrial septal defect (n=12) or patent foramen ovale (n=5) by a totally endoscopic approach, utilizing the Da Vinci robotic system. Cardiopulmonary bypass (CPB) was achieved peripherally. Cardioplegia was administered via the distal port of the arterial cannula after endo-balloon inflation. Via three port incisions in the right chest, pericardiotomy, bicaval occlusion, atriotomy, atrial septopexy, and atrial closure were performed by a surgeon seated at a computer console. A fourth 15-mm port was utilized for suction and suture passage by a patient-side assistant. The mean age of the patients was 47 years (range, 22 to 68). Aortic crossclamp time was 32 minutes (median), and CPB time was 122 minutes. In 16 patients, transesophageal echocardiography after 30 days confirmed successful repair. In one patient, a recurrent shunt was identified and repaired on postoperative day 5. Median length of stay (LOS) in the intensive care unit was 20 hours, and median hospital length of stay was 4 days.

Conclusions—Robotic technology can be utilized to perform open heart procedures safely and effectively via totally endoscopic approaches. This technique represents an option for patients seeking a reliable ASD repair but wishing to avoid sternotomy or thoracotomy. **(*Circulation*. 2003;108[suppl II]:II-191-II-194.)**

Key Words: minimally invasive cardiac surgery ■ robotics ■ ASD repair

In the past decade, the field of cardiac surgery has been influenced by a number of technologic advances. Notable among these has been the development of minimally invasive techniques, including minimally invasive direct coronary artery bypass (MIDCAB), off-pump coronary artery bypass (OPCAB), and minimal access valve surgery. During the early days of minimally invasive cardiac surgery, attempts to operate through small incisions were hindered by the absence of appropriate accessory technology, such as visualization systems, retractors, stabilizers, and alternate methods of vascular cannulation and cardiopulmonary bypass. With the evolution of these technologies, surgeons have been increasingly able to perform complex cardiac procedures, including coronary artery bypass, mitral and aortic valve replacement, and atrial septal defect (ASD) closure, through smaller and smaller incisions. Nonetheless, in many cases, the extent to which incision size has been reduced by these minimally invasive approaches has been matched by a corresponding increase in technical difficulty and operative time—and a potentially decreased safety margin—because of the constraints imposed by limited or incomplete cardiac exposure.

Recently, computerized robotic enhancement has emerged as a potential facilitator of minimally invasive surgical procedures. Initially, this technology was utilized to maximize visualization of intracardiac structures by providing enhanced (including voice-activated) endoscopic camera control.[1] In the last few years, robotic surgical systems have permitted the manipulation of surgical instruments through limited thoracic incisions.[2] This report describes the next step in this progression: the performance of atrial septal defect repair entirely through thoracoscopic port incisions. Torracca and colleagues[3] have recently reported a small series of patients undergoing this operation in Europe. Our series of robotic ASD repairs supplements this experience. The first case of our series was performed in July 2001,[4] and represents the first U.S. application of robotic technology for totally endoscopic open heart surgery.

Methods

Robotic Surgical System

The Da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) consists of two primary components: the surgeon's viewing and control console and the surgical arm unit that positions and maneuvers detachable surgical EndoWrist instruments (Figure 1). These pencil-sized instruments, which possess small mechanical wrists with 7 degrees of motion, are designed to provide the dexterity of the

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***Circulation* is available at http://www. circulationaha.org** **DOI: 10.1161/01.cir.0000089043.82199.2f**

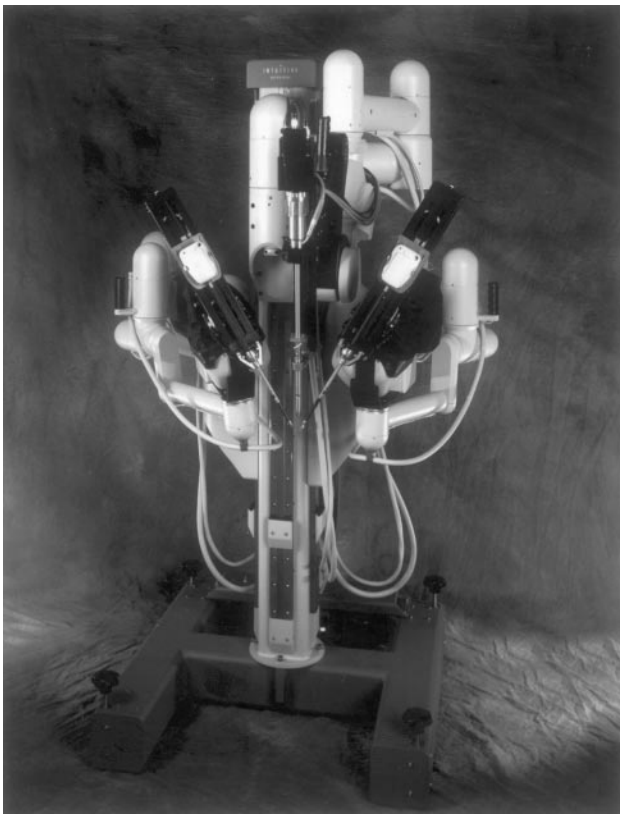

Figure 1. The Da Vinci system.

surgeon's forearm and wrist at the operative site through entry ports less than 1 cm in size. One port allows access for the endoscope, and the other two ports provide access for surgical instruments. The wrists of the surgical instruments mimic the motions made by the operating surgeon, who sits at a console away from the operating table. The surgeon peers through an eyepiece that provides high-definition, full-color, magnified, three-dimensional images of the surgical site provided by the endoscope, and controls the instrument arms in real time by manipulating modified joysticks.

Patient Selection

All patients in our series were enrolled in a U.S. Food and Drug Administration (FDA)-sanctioned trial, entitled "Atrial septal defect closure using Intuitive Surgical Inc.'s Da Vinci Surgical System" and gave informed consent. This study was approved by the Columbia University Institutional Review Board and received FDA Investigational Device Exemption (IDE # G010156, G010189). Intuitive Surgical, Inc. served as study sponsor for the multicenter IDE trial (G010189). This report comprises our single-institution experience from these two trials, in which a maximum of 25 patients could be enrolled and the primary endpoint was echocardiographic evaluation of residual interatrial shunt after 30 days. Inclusion criteria for the trial included age between 18 and 80 years, and the presence of a secundum type atrial septal defect with Qp:Qs ratio >1.5, or patent foramen ovale with a documented neurologic event. Patients were excluded if they could not tolerate single-lung ventilation or peripheral cardiopulmonary bypass, or otherwise were considered poor candidates for a thoracoscopic approach.

Operative Procedure

After induction of general anesthesia, a left-sided double-lumen endotracheal tube was positioned to allow single-lung ventilation. A transesophageal echocardiography probe and bilateral arterial pressure monitoring lines were inserted to facilitate monitoring of endoaortic balloon positioning later in the procedure. A 15- or 17-Fr.

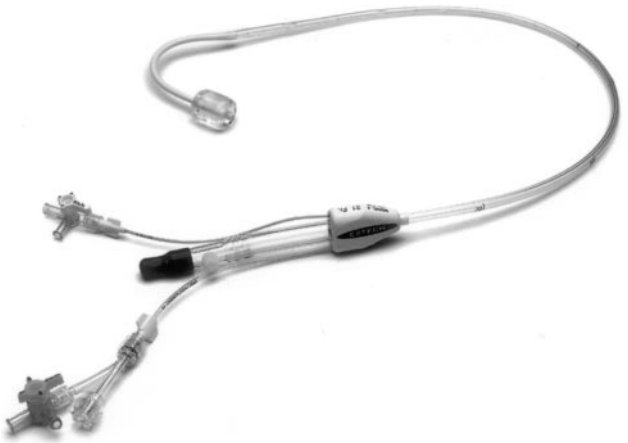

Figure 2. The RAP arterial perfusion cannula (ESTECH, Inc. Danville, CA), with endoaortic balloon clamp and distal cardioplegia lumen.

arterial cannula (Medtronic Bio-Medicus, Eden Prairie, MN) was placed percutaneously into the right internal jugular vein and passed into the superior vena cava with echocardiographic guidance. This cannula was heparinized before and after insertion to avoid thrombus formation. The patient was placed in a modified left lateral decubitus position, with the right arm either suspended above the head (n=7) or tucked at the side (n=10) and the pelvis relatively flat to facilitate femoral cannulation. After sterile preparation and draping, the right femoral vessels were accessed through a 2-cm oblique incision along the inguinal crease. After systemic heparinization, the right common femoral artery was cannulated with a 17- or 21-Fr. remote access perfusion cannula with endoaortic balloon (ESTECH, Inc., Danville, CA) (Figure 2). The distal tip of the arterial cannula was passed under echocardiographic guidance into the ascending aorta, approximately 3 cm from the aortic valve. The bypass circuit was completed by inserting a 19- or 21-Fr. venous cannula (Medtronic Bio-Medicus) into the right common femoral vein and passing it into the inferior vena cava, with its tip just inferior to the inferior vena cava-right atrium junction.

After establishment of selective left lung ventilation, a port incision was made in the fourth intercostal space, in the midclavicular line, and a 12-mm endoscopic trocar (Ethicon, Inc., Somerville, NJ) was placed into the pleural space. The endoscopic camera was inserted and after pleural adhesions were ruled out, the pleural space was insufflated with carbon dioxide to a maximum pressure of 8 mm Hg. Two additional 8-mm port incisions were made in the third and sixth intercostal spaces, in the anterior axillary line. The Da Vinci Surgical Cart was positioned at the operating table, and the left and right robotic arms inserted into the pleural space. A fourth port incision (15 mm) was made in the fifth intercostal space, in the posterior axillary line, for use as a service entrance.

Next, the operating surgeon moved from the operating table to the surgeon's console, and began the intrathoracic portion of the operation by controlling the robotic camera and surgical instrument arms. A pericardiotomy was made using the "long-tip forceps" and "cautery" attachments, and pericardial stay sutures placed, with traction provided by passing the sutures out of the chest through the service port (posteriorly) or by sewing the suture to the inside of the chest wall (anteriorly). Caval snares were placed using the long-tip forceps and passed out of the service entrance port. Cardiopulmonary bypass was initiated, with kinetically assisted bicaval venous drainage, and the patient was cooled to 32 degrees. Atrial stay sutures were placed. The perfusion pressure was reduced, and the endoaortic balloon inflated to a pressure of 250 to 300 mm Hg. Antegrade cold blood cardioplegia (4:1) was administered through the distal cannula port, and a satisfactory cardiac arrest was confirmed.

Using the round-tip scissors attachment, a right atriotomy was created, and the right atrium explored. Cardiotomy suction was

provided by a specially modified instrument (the "Flora sucker"), which was passed through the service entrance port by the patient-side surgeon. In each case, anatomic landmarks, including the fossa ovalis, coronary sinus ostium, and eustachian valve, were identified. Whether the pathology involved a large ASD or PFO with or without a septal aneurysm, we closed the entire fossa with a double layer primary suture technique (4−0 polypropylene or braided polyester). Before tying the atrial septopexy suture, the left atrium was de-aired by inflating the left lung. After the suture was tied, the endoaortic balloon was deflated, and the patient was rewarmed. The atriotomy was closed with two layers of running suture, and the patient was weaned from cardiopulmonary bypass. Integrity of the septal closure was conformed by transesophageal echocardiography, and protamine was administered. After adequate hemostasis was achieved, the robotic arms were removed from the chest, and a small flexible drainage tube placed in the pericardium and one or two conventional chest tubes placed in the right pleural space, all through existing port incisions. The femoral vessels were decannulated, and the percutaneous catheter removed from the internal jugular vein. All incisions are closed in layers with absorbable suture material.

Postoperative Regimen

The patients were transported to the intensive care unit where they remained until extubated. On extubation, patients were transferred to the general postoperative unit. Chest drains were removed when drainage subsided. Anticoagulants were administered only for patients with specific postoperative indications such as atrial fibrillation. On discharge, patients were given an appointment for a clinical visit and a transthoracic echocardiogram approximately 1 month postoperatively. At this visit, patients underwent physical examination, electrocardiography, chest radiography, and transthoracic echocardiography. All data, including adverse events, were collected and recorded prospectively.

Results

Demographics

Over 13 months, 22 patients were enrolled in the study and provided informed consent. Of these, five patients were excluded intraoperatively prior to initiation of the procedure. In one case, transesophageal echocardiography revealed a hypoplastic descending aorta, which was considered a contraindication to passage of the endoaortic balloon cannula. This patient underwent ASD repair via a minithoracotomy, with central vessel cannulation. In another case, the patient had an anaphylactic reaction on induction of anesthesia, with profound vasodilation, urticaria, and bronchospasm. After stabilization, this patient was awakened and the surgery deferred until appropriate allergic evaluation and testing. In a third case, there was difficulty in passing the internal jugular catheter during preparation, and the case was converted to an open procedure. Finally, in two cases, the femoral arteries were deemed too small for cannulation, and the patients underwent ASD repair by minithoracotomy and central aortic cannulation. The other 17 patients underwent the procedure robotically. The group of operated patients included 3 men and 14 women, with mean age 47±12 (mean ± SD). Twelve patients had secundum ASD, whereas 5 patients had PFO with septal aneurysm and a history of cerebrovascular accident not attributable to another cause.

Operative Results

In the 17 patients undergoing robotic surgery, all operations were completed robotically through four port incisions, with no intraoperative conversions to alternate techniques. All patients underwent primary suture repair of the ASD or PFO, and transesophageal echocardiography postoperatively (including bubble study) confirmed successful closure in all cases. Median cardiopulmonary bypass time was 122 minutes, and median crossclamp time was 32 minutes. In the last five cases of our series, median values for cardiopulmonary bypass and crossclamp times were 99 and 29 minutes, respectively. Postoperatively, all patients were extubated on the night of surgery, and median intensive care unit (ICU) length of stay was 20 hours. One patient remained in the ICU for 3 days for treatment of a postoperative pneumonia that was presumed to be related to aspiration, and recovered without incident. Hospital length of stay ranged from 2.5 days (our first patient) to 10 days (in a 68-year-old patient who developed postoperative atrial fibrillation and required several days to establish effective rate control), with a median value of 4 days. Cosmetic results were excellent in all cases (Figure 3).

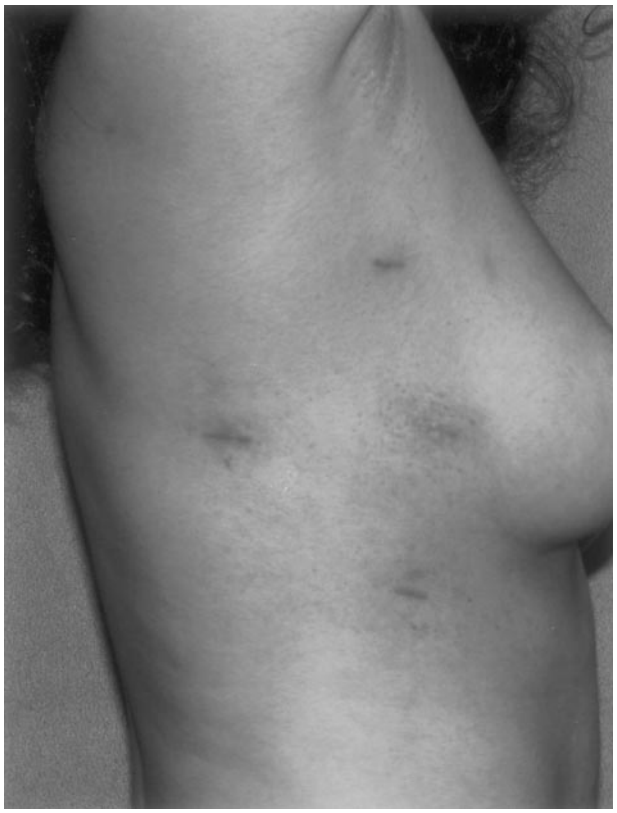

Figure 3. A robotic atrial septal defect repair patient, 30 days after surgery, with four well-healed port incisions.

Complications

There were no deaths in our series. There were no cerebrovascular accidents, myocardial infarctions, wound infections, or reoperations for bleeding. There were two cases of perioperative atrial fibrillation, one case of pneumonia, and one patient with temporary arm discomfort because of intraoperative arm positioning. One case was complicated by a right lower leg compartment syndrome, which required a local fasciotomy and delayed skin closure. In this patient, arterial perfusion and venous return were not impaired, leading to the conclusion that the compartment syndrome resulted from

ischemia-reperfusion syndrome. In one case, transthoracic echocardiography on postoperative day 5 revealed a 5-mm recurrent interatrial shunt, in a 58-year-old patient who had had a primary repair of a large secundum ASD. When this was confirmed by transesophageal echocardiography, the patient underwent reoperation via right minithoracotomy. At operation, the primary suture line was found to be intact, but a tear was noted in the septum medial to the repair. This was presumably induced by excessive tension on the septum postoperatively, and may have been prevented by a patch technique. A pericardial patch was used for this second repair, and the patient was discharged 4 days later without incident. Because the robotically placed sutures and the line of closure were intact, it is our conclusion that the failure of this repair was not related to the robotic procedure per se, but rather to the use of a primary suture repair technique. In the other 16 patients in the series, 30-day postoperative echocardiography confirmed successful repair.

Discussion

In the past several years, technical advances in peripheral cardiopulmonary bypass access and endoaortic balloon technology have allowed a number of intracardiac procedures to be performed through smaller than usual (but not necessarily small) incisions. The development of these procedures has required the adaptation of surgical instruments and techniques to the challenge of operating "in a deep hole," with less than optimal visualization. The least invasive of these procedures have required small thoracotomy or partial sternotomy incisions.[5,6] Although these approaches employ smaller than traditional incisions, they are still associated with significant perioperative pain, largely because of the division or retraction of intercostal muscles, ribs, and/or sternal bone. For these and other technical reasons, these procedures have been performed predominantly at selected centers, and have not gained widespread popularity.

The minimally invasive cardiac surgical movement has more recently been propelled by the introduction of a new category of technologic achievement: the computerized telemicromanipulator. Utilizing this device, also known as the surgical robot, surgeons can manipulate small instruments, which are inserted through small chest incisions, in tight spaces, achieving many of the technical maneuvers previously possible only with traditional open exposure. In 1997, the first intracardiac procedure—mitral valve repairs—were performed using a prototype of the current Da Vinci system.[7,8] These operations were performed through small thoracotomy incisions, since the "micro-wrists" allowed the surgeons to complete complex maneuvers without placing their hands within the chest. In December 2000, Chitwood and associates[2] reported the first such mitral valve operation performed in the United States, using an inframammary minithoracotomy.

The next step—a totally endoscopic intracardiac procedure—would wait until 2001, when closed-chest, robotically assisted atrial septal defect repairs would be performed, as described in this report. In addition to the six cases reported by Torracca[3] and the 17 cases performed by our group, an additional five procedures have been performed in Frankfurt, Germany (G. Wimmer-Greinecker, personal communication). By utilizing femoral cannulation and port incisions in the right chest, the Da Vinci surgical system is utilized to perform every step of the repair. By avoiding thoracotomy incisions and rib spreading, this procedure results in minimal pain and postoperative recovery time. Because this approach provides a time-tested method for ASD repair—suture closure under direct vision—it may represent an alternative for patients desiring a minimally invasive ASD repair but who are ineligible for (or reluctant to consider) catheter-based interventions.

Despite the impressive results in our series, and the potential advantages of this approach with regard to cosmesis and patient acceptance, it is currently unclear whether these benefits can be expected in all patients. For this reason, additional patients are being enrolled in our FDA-sanctioned clinical trial, to determine whether this technology will be of reproducible value in the management of patients with intracardiac disease on a larger scale. In addition, we are prospectively studying the effects of this approach on patient recovery, using well-established quality of life instruments to compare robotic and conventional approaches.

Furthermore, it is clear that the continued evolution of totally endoscopic cardiac surgery depends on the development of new accessory technology, such as retraction systems, perfusion catheters, noninvasive monitoring techniques, and sutureless anastomotic devices, and we are working with several industry partners in this area. Thus, although the surgical robot allows unprecedented closed chest access to the heart, it is only one of several tools that must be used to achieve the technical goals of a particular operation. In this respect, the immediate future of closed chest cardiac surgery depends on the ability of physicians and industry to work together to fill in the many technological gaps that are present in our current armamentarium of minimally invasive tools. With such advances, and continued success from pioneering centers, completely endoscopic cardiac surgery—literally an inconceivable notion only a few years ago—may become a widely available clinical reality in the near future.

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Circulation. 2003;108:II-191-II-194
doi: 10.1161/01.cir.0000089043.82199.2f
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 0009-7322. Online ISSN: 1524-4539