

**Original Article**

***Perfusion During Coronary and Mitral Valve Surgery Utilizing Minimally Invasive Port-Access Technology***

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Keywords: cardiopulmonary bypass, extrathoracic bypass, cardiac surgery, minimally invasive surgery

**ABSTRACT**

Minimally invasive surgery has been used in the treatment of some cardiovascular diseases. Port-Access surgery is a new minimally invasive technique that utilizes cardiopulmonary bypass and a specialized catheter system that provides cardiopulmonary support and myocardial preservation. Extrathoracic cardiopulmonary support is established with femero-femoral bypass with kinetic assisted venous drainage. An endovascular catheter system allows for all the benefits of mechanical support as well as myocardial preservation. This catheter system includes an endoaortic balloon catheter which functions as an aortic cross clamp and antegrade cardioplegia delivery catheter, endopulmonary vent, and endocoronary sinus catheter used for administration of retrograde cardioplegia. An initial cohort of 20 patients was treated by the Port-Access surgical approach with cardiopulmonary bypass. Ten patients had coronary artery surgery and 10 patients had mitral valve surgery. The average bypass times were 94.4 min (coronary artery) and 152.8 min (mitral valve). The mean aortic occlusion times were 49.7 min (coronary artery) and 112.6 min (mitral valve). All patients were weaned from bypass. This initial patient series demonstrated that Port-Access surgery was feasible in selected patients.

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## INTRODUCTION

New approaches to conventional surgery have revolutionized the practice of many general and thoracic procedures. Advances in endoscopy and instrumentation have led to the development of less invasive or minimally invasive techniques. It has been postulated that minimally invasive approaches would result in less morbidity, shorter hospital stays, quicker recovery, and be less costly compared to conventional operations. In traditional cardiovascular surgery, less invasive methods have not been as feasible, because most procedures require a median sternotomy and cardiopulmonary bypass. Due to morbidity related to a median sternotomy and some side effects of cardiopulmonary bypass, minimally invasive direct coronary artery bypass (MIDCAB) procedures have been reconsidered, and their use has increased in the past few years. Less invasive approaches utilize a smaller incision, which is usually a mini-sternotomy or small thoracotomy. Improvements in surgical technology and intraoperative management have allowed coronary artery bypass procedures to be done without the use of cardiopulmonary bypass. However, most minimally invasive procedures that do not utilize cardiopulmonary bypass are limited to epicardial procedures such as coronary revascularization of selected coronary arteries.

Reports of coronary bypass grafting without the use of a heart-lung machine were reported in the 1970's and 80's (1-4). Many of these procedures utilized a median sternotomy and saphenous veins as conduit. With the advent of better myocardial preservation techniques, cardiopulmonary bypass with cardioplegic arrest was used for myocardial revascularization and operations off bypass were used less frequently.

Since Kolessov's report of using the mammary artery in 1964 for treatment of angina pectoris (5), the internal mammary artery has been the vascular conduit with the longest patency rate. Normally, the internal mammary artery is harvested under direct vision with a median sternotomy but the vessel can also be harvested under direct vision with a mini-thoracotomy. Endoscopic techniques have also been used to dissect and isolate the internal mammary artery for MIDCAB procedures (6-8).

Minimally invasive coronary artery bypass has been performed without the use of cardiopulmonary bypass (9-14). The MIDCAB procedure is done by pharmacologic manipulation of the blood pressure and heart rate. Cardiopulmonary bypass is available on a standby basis. In the majority of patients, MIDCAB coronary revascularization can be completed without mechanical support, although cardiopulmonary bypass was used with a few patients (15, 16). A few reports have described reoperative myocardial revascularization being done without cardiopulmonary bypass (17, 18). New technological advances have allowed for coronary bypass procedures to be performed with devices that stabilize the anastomotic site (19). However,

it is unknown whether graft patency during a MIDCAB procedure is similar to that done with cardiopulmonary bypass (20).

Although there is an increasing trend to perform the MIDCAB operation off bypass, minimally invasive coronary bypass surgery has also been used in conjunction with femoro-femoral bypass. Robinson described myocardial revascularization in 6 patients using an anterior mediansternotomy with video-assisted thoracoscopy. Cardiopulmonary bypass was used while the heart was placed in ventricular fibrillation for anastomosis of the mammary artery to the left anterior descending coronary artery (21).

Cardiopulmonary bypass used in conjunction with a minimally invasive approach would allow for both epicardial and intracardiac procedures to be conducted assuming a method of myocardial preservation could be implemented. Port-Access cardiac surgery is a technique that allows for such minimally invasive procedures to be conducted through a mini-thoracotomy and thoracic ports. The technique utilizes extrathoracic cardiopulmonary bypass and a special set of endovascular catheters that allows for complete cardiopulmonary support with antegrade or retrograde cardioplegic arrest. This system has been evaluated clinically and the perfusion data from the initial 20 patients presenting for coronary revascularization and mitral valve surgery are described.

## MATERIALS AND METHODS

Twenty patients presented for either single vessel coronary artery bypass grafting (CABG) (10) or mitral valve surgery (10) utilizing the Port-Access catheter system<sup>a</sup>. Informed consent was given by all patients following approval from the Food and Drug Administration and Institutional Review Boards for a Phase I clinical trial of the Port-Access system. Surgery was conducted at Stanford University Medical Center (10 coronary bypass, 3 mitral valve) and New York University Medical Center (7 mitral valve). There were 14 males (8 CABG, 6 mitral valve) and 6 females (2 CABG, 4 mitral valve). The patients ranged in age from 44-68 years in the CABG group (mean 55.6 years) and 28-73 years in the mitral valve group (mean 53.5 years). The CABG patients' height and weight ranged from 155-195 cm (mean 172.6 cm) and 55-98 kg (mean 79.0 kg) respectively. The mitral valve patients ranged in height and weight from 153-185 cm (mean 169.6 cm) and 55-95 kg (mean 69.4 kg) respectively.

In 3 CABG patients, endoscopic takedown of the left internal mammary artery occurred through 3-5 thoracic ports (5 mm) inserted into the left side of the chest. Partial endoscopic and direct takedown of the left mammary artery were performed through the thoracic ports and a left anterior mediansternotomy in the remaining 7 patients. In all mitral valve patients, a small right thoracotomy was performed through the fourth intercostal space to provide atrial access for valve surgery.

The Heartport EndoCPB<sup>TM</sup> system is a specialized set of instruments and endovascular catheters that allow for minimally

a Heartport, Redwood City, CA

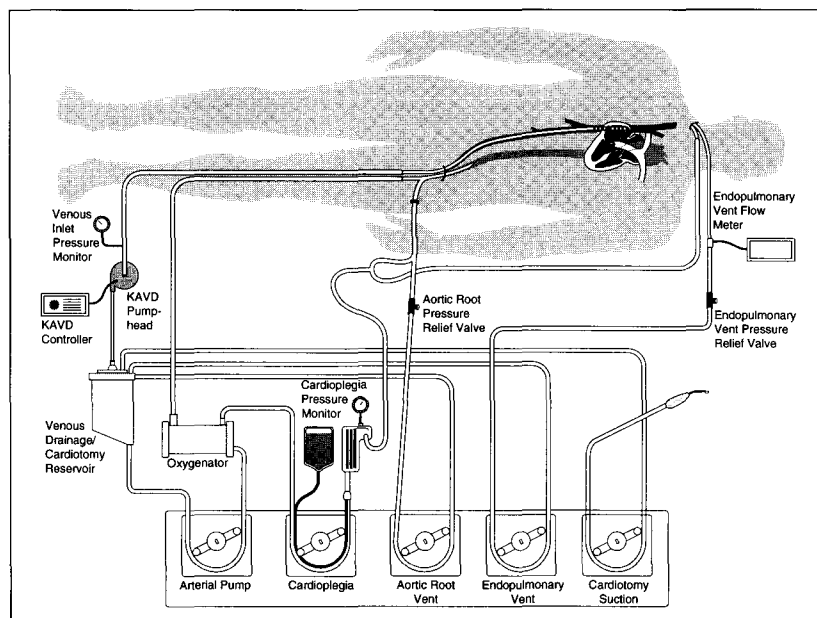
invasive cardiac procedures to be done with small modifications to a standard heart-lung machine (Figure 1). The description and management of the Port-Access cardiopulmonary bypass system has been described previously (22). The catheter system provides for complete extrathoracic bypass with cardioplegic arrest which mimics conditions during an open procedure. The catheter components consist of a long thin-walled femoral venous drainage catheter with multiple side holes, specialized femoral arterial reinfusion cannula, aortic balloon occlusion catheter, coronary sinus cardioplegia catheter for retrograde cardioplegia, and pulmonary artery vent (Figure 2).

The endoarterial reinfusion catheter (EARC) is a thin walled cannula designed to accommodate the reinfusion of the arterial blood from the heart-lung machine and the shaft of the endoaortic clamp (EAC). The cannula contains a "Y" connector on the end which connects to the arterial line on one side and allows for the EAC to be inserted through the cannula's lumen (through a hemostatic valve) from the other side of the "Y".

The EAC functions as an aortic cross clamp, antegrade cardioplegia infusion site and aortic root vent catheter. The EAC is passed through the EARC and positioned into the ascending aortic arch by fluoroscopy and/or transesophageal echocardiography. The EAC contains separate lumens for balloon inflation, cardioplegia delivery-aortic root venting, and distal tip pressure monitoring. The cardioplegia-aortic root vent lumen is shared and a "Y" adapter allows infusion or aspiration to be controlled by separate roller pumps. Blood or crystalloid cardioplegia solution can be administered through the cardioplegia-aortic root vent lumen from any cardioplegia infusion source. The aortic root vent line has a -80 mmHg pressure relief valve which allows the aortic root to be vented by a roller pump without exerting excessive negative pressure on the aortic root. Cardioplegia can be delivered and recirculated through the aortic root vent line to prime the cardioplegia line. Following infusion of the cardioplegia, the aortic root can be vented.

Cardioplegia can also be delivered retrograde through the endocoronary sinus catheter (ECSC). The ECSC catheter is inserted through a jugular venous sheath and utilizes fluoroscopy or transesophageal echocardiography to properly guide the catheter's tip into the coronary sinus. Once positioned, the catheter is connected to the cardioplegia delivery line. The cardioplegia reinfusion line can be divided to allow for either antegrade or retrograde cardioplegic delivery.

Figure 1: EndoCPB system



Antegrade cardioplegia is directed through EAC while clamping off the aortic root vent pump and retrograde cardioplegia delivery line. Retrograde cardioplegia is administered by clamping the antegrade delivery arm and directing cardioplegia flow towards the ECSC.

The endopulmonary vent (EPV) acts to return any blood not drained by the femoral venous catheter to the heart-lung machine. The EPV is inserted through a second jugular venous sheath and positioned into the main pulmonary artery. Fluoroscopy or transesophageal echocardiography can be used to position the catheter if necessary. The EPV is also connected to a roller pump. A -80 mmHg pressure relief valve is inserted a few inches from the EPV catheter, so once the roller pump is engaged, an air-blood mix is aspirated from the pulmonary artery without exerting a large negative pressure of the vent. A blood flowmeter can be positioned between the catheter and pressure relief valve to quantitate the amount of blood passing through the EPV.

Cardiopulmonary bypass with extrathoracic vascular access was used in all patients. The heart-lung machine and disposables were slightly modified at each institution to integrate with the Port-Access system. Commercially available tubing sets and membrane lungs with open (Stanford) or closed (New York University) venous reservoirs were used. Venous drainage was accomplished by inserting a long thin walled 28F x65 cm catheter<sup>b</sup> into the right atrium via a femoral vein. The arterial and venous access catheters were connected to the heart-lung machine and bypass was begun by gravity drainage. Kinetic assisted venous drainage (KAVD) was used to increase venous drainage by inserting a Biomedicus BP-80 pumphead<sup>c</sup> into the venous line and regulating the siphon pressure between 40-90 mmHg. The siphon pressure was measured proximal to the kinetic pump's inlet.

Once venous blood has been collected into the venous res-

b Medtronic DLP, Grand Rapids, MI  
c Medtronic Biomedicus, Eden Prairie, MN

ervoir, it was pumped, oxygenated and reinfused through the arterial cannula into the arterial circulation by a standard roller or kinetic blood pump at a prescribed blood flow rate. Normal extracorporeal management and cardioplegia protocols were utilized.

In the CABG patients cardioplegic arrest was achieved by antegrade cardioplegic infusion (4:1 blood) through the EAC. An arresting dose of 1000-1800 ml was used. Additional doses of 250-500 ml were administered if necessary.

Retrograde cardioplegia was used in each of the 10 mitral valve patients. In 3 patients (Stanford) antegrade arrest was followed by an additional volume of 500-1000 ml administered through the ECSC at a coronary sinus pressure no greater than 40 mmHg. In the other 7 patients (New York University) antegrade arrest was not used. Primary retrograde arrest was achieved by infusing 700-1500 ml of cardioplegia solution through the ECSC. Additional retrograde cardioplegia was administered at 20-30 minute intervals.

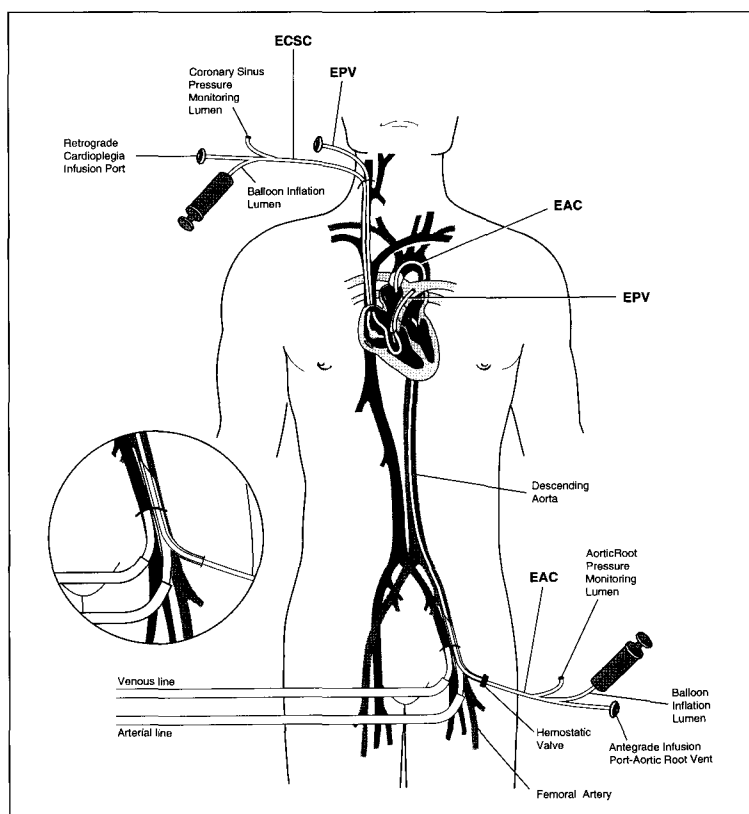
Surgical repair (CABG or mitral valve) was conducted under direct vision and by institutional protocols, except for the first 3 CABG patients in which the coronary anastomosis was conducted with the use of an endoscopic operating microscope.

## RESULTS

Systemic hypothermia, flow management, re-warming and patient management schemes followed the normal institutional protocols. There was no attempt to standardize perfusion methodology or practice techniques between the two institutions. All patients were supported on extrathoracic bypass with KAVD. Perfusion was deemed adequate based on observed flow rates and adequate blood gas values. No supplemental mechanical support devices were required in the postoperative period. Systemic hypothermia ranged from 28-34°C (CABG) and 25-30°C (mitral valve). Blood flow rates ranged from 3.0-5.5 L/min based on patient size, metabolic requirements and protocol.

In the CABG group, the total perfusion times ranged from 32-187 min (mean 94.4 min) with endoaortic occlusion times (myocardial ischemic time) ranging from 20-89 min (mean 49.7 min). All CABG patients had a graft placed to the left anterior descending coronary artery with the left internal mammary artery. In the mitral valve study group, 3 patients had valve replacements whereas the remaining 7 patients had valve repairs. The perfusion times ranged from 104-224 min (mean 152.8 min). The aortic occlusion times ranged from 65-161 min (mean 112.6 min).

**Figure 2: Endovascular catheter system**



The optimal position of each catheter is shown. The femoral venous drainage catheter tip is positioned at the atrio-superior vena cava junction by fluoroscopy and transesophageal echocardiography.

During these charter clinical trials, Port-Access technology was successfully implemented in 10 coronary artery and 10 mitral valve patients. All procedures were completed and each patient was weaned from cardiopulmonary bypass with little or no inotropic support. In the CABG group during immediate follow-up, 9 patients had patent coronary grafts, although 3 patients were ultimately reoperated on with a median sternotomy and had their internal mammary graft replaced with a saphenous vein graft because of technical problems with the internal mammary artery (23).

## DISCUSSION

The initial clinical use of Port-Access cardiac surgery demonstrated the feasibility of the catheter system. A learning curve was part of gaining experience using the technology. In these initial human trials, many intraoperative adjustments were anticipated. Special caution was observed during each step of the procedure to insure proper safety to the patients. Cardiopulmonary bypass times and aortic occlusion times were longer than

those observed during traditional open cases, but was related primarily to the newness of using the catheter system in a clinical setting as well as implementing and troubleshooting the catheter system. The use of the operating microscope during the first 3 CABG cases significantly lengthened the procedure time and was abandoned for a small anterior mediansternotomy for the later cases. In addition, transesophageal echocardiography was used and has been found to be beneficial in placing and monitoring the endovascular catheter system (24).

Perfusion management during these trials was more involved than a traditional open case. In addition to the normal perfusion monitoring parameters such as flow rates, reservoir volumes, cardioplegia, hemodynamic pressures and circuit pressures, additional monitoring of the Port-Access system was required. Special diligence was made to monitor venous assist pump, venous siphon pressure, endopulmonary and endoaortic root vent flows, endoaortic occlusion balloon pressure, and the relationship of the aortic root pressure and the systemic arterial pressure. Because of the extrathoracic catheter system, cardiopulmonary support management was more subtle; namely, manipulations to the circuit were done slowly and gradually. A sudden surge in systemic flow or cardioplegia flow had the potential to dislodge an endovascular catheter, which would require repositioning. In addition, troubleshooting the catheter system was necessary in order to diagnose situations where inadequate or excessive flows occurred in one of the catheters, inadequate endoaortic balloon occlusion occurred in the aorta, or a catheter was not placed properly.

Cardiopulmonary support was successfully implemented with only minor modifications of the existing extracorporeal circuit. Since the study was designed to evaluate whether the catheter system could be used during a minimally invasive surgical procedure, the optimal extracorporeal circuit configuration or design was not a major priority. Additional study will determine whether a more streamlined, reservoirless, closed circuit without any air-blood interfaces will improve patient care during Port-Access procedures. In addition, experience with the Port-Access endovascular catheter system should lead to improvements and additions to the existing system, which should positively impact patient care and lead to improvements in extracorporeal technology.

The feasibility of a peripheral endovascular non-invasive support system was first reported by Peters, who described a method in which extrathoracic cardiopulmonary bypass, cardioplegic arrest and aortic occlusion with an ascending aortic balloon catheter would be used during cardiovascular surgery (25). A multiple lumen catheter served several functions including: an aortic occlusion balloon to isolate the heart from the systemic arterial circulation, an administration site for cardioplegia, an aortic root vent and a cardioscopic source where laser therapy of valves or coronary arteries could be undertaken.

The current system used for Port-Access minimally invasive cardiac surgery was developed and evaluated in the experimental laboratory. The endoaortic occlusion balloon and cardiopulmonary

bypass system were developed and evaluated in a series of acute and chronic canine experiments where myocardial revascularization was performed. All animals were supported on endovascular cardiopulmonary bypass with KAVD. Hypothermic antegrade cardioplegic arrest was achieved through the endoaortic occlusion balloon. The endoaortic occlusion balloon was effective in occluding the aorta without damaging the aortic wall. An anastomosis with the left internal mammary artery was performed. The study demonstrated that complete cardiopulmonary support could be achieved with extrathoracic vascular access and adequate myocardial protection was achieved (26).

Port-Access mitral valve surgery was also shown to be feasible in an experimental setting. Fifteen dogs underwent successful valve replacement via femero-femoral bypass with assisted venous drainage. Cardioplegia was administered antegrade through an endoaortic occlusion balloon. The mean bypass time and myocardial ischemic times were 114 and 68 minutes respectively (27).

Good myocardial protection has been demonstrated using the endoaortic occlusion balloon clamp. The left ventricular function was compared in two groups of dogs, one group undergoing percutaneous cardiopulmonary bypass using an endoaortic occlusion balloon and the second group utilizing conventional open-chest cardiopulmonary bypass with aortic cross clamping. Antegrade cardioplegia was given in both groups and the aorta was occluded for 60 minutes. There was no difference in left ventricular function as measured by elastance and end-diastolic work length (28).

Based on experimental findings, the Port-Access approach integrating cardiopulmonary bypass with the endoaortic occlusion balloon clamp system was hypothesized to work in a clinical model. Based on a model developed in human cadavers, the left internal mammary artery could be safely harvested using endoscopic take down techniques (29). Access and visualization of the mitral valve was easily achieved through a small right thoracotomy. In addition, extrathoracic extracorporeal circulation with assisted venous drainage had provided adequate physiologic support during a mitral valve reoperation through a right thoracotomy (30).

An additional Port-Access CABG study showed the feasibility of the system in 12 coronary artery bypass patients. All patients were removed from bypass in normal sinus rhythm without inotropic support. Short-term follow-up revealed no complications (31).

Port-Access technology was deemed feasible and safe in 4 patients undergoing mitral valve replacement. Cardiopulmonary bypass time averaged 138 minutes and aortic occlusion time averaged 92 minutes. These times were similar to those observed in this evaluation (32).

Expanded clinical experience and additional human trials will determine the indications for Port-Access technology. Extracorporeal support allows for a minimally invasive approach to be undertaken in certain cardiovascular procedures, such as valve replacements, that cannot be done in a beating heart model.

Less invasive procedures with extracorporeal support may become more widely used as experience, improvements in circuit design and instrumentation and the catheter system occur.

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