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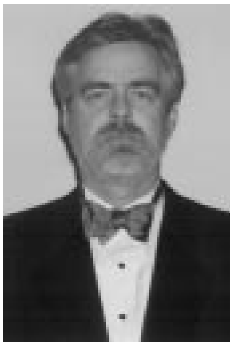
Off-Pump Multivessel Coronary Artery Bypass Utilizing the Octopus® Tissue Stabilization System: Initial Experience in 374 Patients from Three Separate Centers



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ABSTRACT

Background: Renewed interest in coronary artery bypass without heart-lung support has lead to the development of specialized instrumentation to permit surgical exposure and grafting in all territories of the beating heart. This report summarizes the results of a multicenter, prospective trial using a single system of mechanical stabilization for multivessel revascularization without cardiopulmonary bypass.

Methods: Three principal investigators at different institutions performed off-pump coronary grafting utilizing the Medtronic Octopus® suction stabilization system which provides a motionless region encompassing the target coronary artery. Positioning and stabilization strategies evolved during the trial but eventually lead to a consistent approach for accessing all regions of the heart. Clinical data sets were collected prospectively and pooled for evaluation of early and short-term endpoints of success.

Results: A total of 374 patients underwent beating heart coronary bypass procedures with only a single death for an in-hospital 30-day mortality rate of 0.26%. There were 140 single-vessel revascularizations (37.4% of patients), 119 double coronary grafts (31.8%), 90 triple-vessel grafts (24.1%), and 25 four-vessel grafts (6.7%), for a mean of 1.96 grafts per patient. If the single vessel cases are removed from analysis, the mean number of grafts performed in the multivessel cohort was 2.6 grafts per patient. All anatomic regions of the heart were successfully grafted including traditionally difficult locations such as the obtuse marginal branches of the circumflex and posterior descending branches of the right coronary artery. Only one patient suffered a new neurologic deficit which occurred 15 days postoperatively, for an overall incidence of only 0.26%. No patient required a new intra-aortic balloon pump or dialysis for renal insufficiency. The incidence of atrial fibrillation (12.8%) was age related and essentially unchanged from the overall incidence observed in patients operated at the same institutions using conventional techniques.

Conclusions: Multivessel grafting on the beating heart using the Octopus® stabilization system results in remarkably low perioperative mortality and morbidity, with very low incidences of cerebrovascular, renal, and respiratory complications. However, the incidence of postoperative atrial fibrillation is not reduced. Expanded clinical use of beating heart surgery with suction-based stabilization appears to be a promising technique for achieving global revascularization without the need for cardiopulmonary bypass.

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INTRODUCTION

Coronary artery bypass grafting (CABG) assisted by extracorporeal circulation has been an accepted standard for more than 30 years. Steady improvement in surgical technique, anesthesia, cardiopulmonary bypass, and perioperative care have lowered the mortality rates for elective CABG to very admirable levels. In current practice, most centers utilizing the traditional methods of cardioplegic arrest and

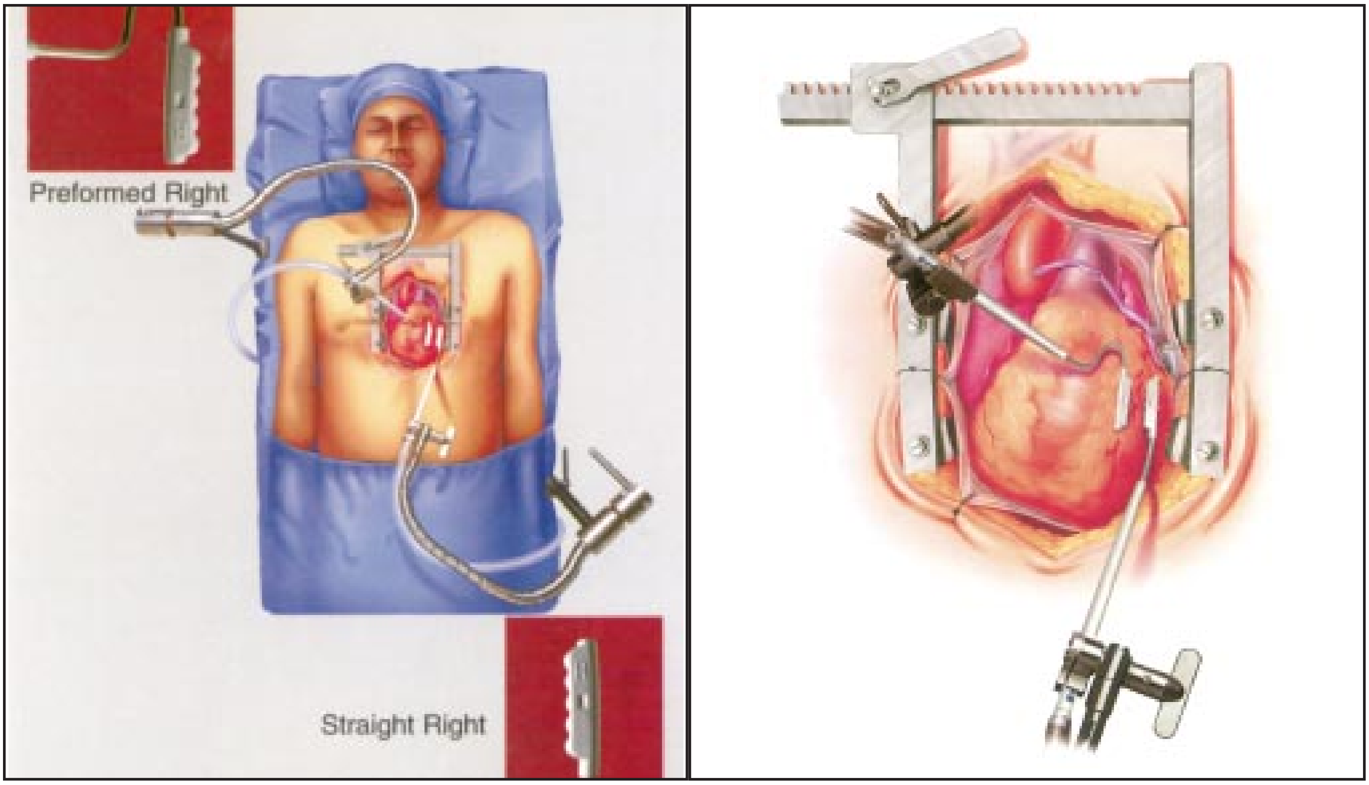

Figure 2. LAD stabilization (Option 1): Articulating arms are mounted at the patient's right shoulder and left hand. Tissue stabilizers: Preformed Right and Straight Right. Heart is elevated on lapartomy pack.
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cardiopulmonary bypass (CPB) can achieve a perioperative 30-day mortality rate of less than 5% in average or low risk patient categories [Edwards 1994]. Despite these accomplishments, there remain serious concerns about the morbidity of CABG in the increasingly elderly and fragile group of patients currently being referred for revascularization. Extensive comorbidity is now common in the presurgical referral population and the effects of cardiopulmonary bypass are no longer passively tolerated by such patients.

Recent interest in less invasive forms of surgery has lead cardiac surgeons to investigate possible means of reducing surgical trauma during CABG. The two most obvious sources of trauma are the incision (median sternotomy) and the side effects the cardiopulmonary bypass. To reduce the invasiveness of CABG, surgeons have recently developed an off-pump strategy through limited access incisions, now known as MIDCAB (minimally invasive direct coronary artery bypass). Variations of the MIDCAB approach have been performed through a small anterior thoractomy, a partial sternotomy, or subxyphoid incision [Subramanian 1995, Calafiore 1996, Arom 1996, Diegeler 1997]. MIDCAB has been shown to reduce perioperative morbidity, mortality, and hospital costs when compared with traditional CPB-based operations [Zenatti 1997, Del Rizzo 1998].

One of the keys to achieving such results is the use of mechanical stabilizers to immobilize the region of the target coronary artery. Adequate immobilization of the target vessel is a crucial part of the operative technique. For single-vessel beating heart anastomosis to the left anterior descending (LAD) using left internal mammary artery conduits (LIMA), the reported angiographic patency rates were 92.5% before the advent of mechanical stabilizers and 98.8% following the introduction of stabilizers [Calafiore 1998a, Diegeler 1998, Douville 1999]. These results actually match or exceed the angiographic patency rates reported in historical studies of conventional LIMA to LAD anastomoses performed on the arrested heart [Mack 1998].

Despite the sudden popularity and appeal of MIDCAB, this procedure is basically a single vessel operation in an era where single vessel disease is managed almost exclusively by interventional cardiology. To achieve a truly significant impact on perioperative morbidity and mortality in the majority of current surgical referrals, off-pump revascularization to all regions of the heart must be accomplished. Effective strategies for presentation and immobilization of all coronary targets must be developed before multivessel off-pump grafting will become a reality.

In 1996, Gründeman, Borst and colleagues at the University of Utrecht, Netherlands developed a unique suction-based stabilizing system for beating heart multivessel grafting [Borst 1996]. Unlike pressure foot stabilizers introduced for MIDCAB, the use of deforming pressure was obviated by the use of suction pods attached to the epicardial surface and anchored to an articulating, table-mounted arm. Experimental work in the porcine model has shown trivial movement of the target vessel (around 1 mm displacement) and excellent stabilization for difficult regions

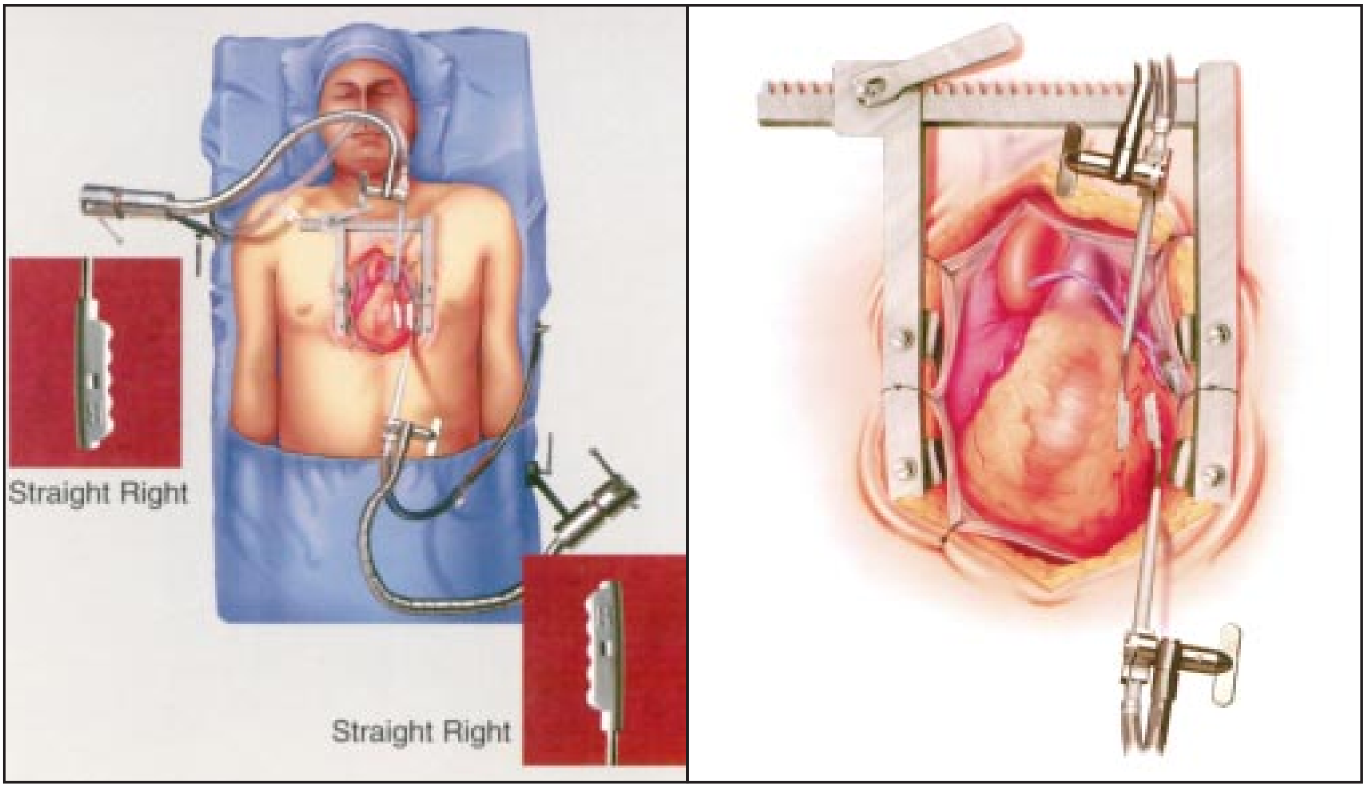

Figure 3. LAD stabilization (Option 2): Articulating arms are mounted at the patient's right shoulder and left hand. Tissue stabilizers: Two Straight Rights. Heart is elevated on laparotomy pack.
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such as the circumflex branches [Jansen 1997]. Refinement of this concept has lead to the commercial introduction of the Medtronic Octopus® stabilization system. This report outlines the results obtained by three separate investigators using only the Octopus® stabilization system for multivessel beating heart CABG at separate institutions.

MATERIALS AND METHODS

Enrollment

A prospective non-randomized trial of beating heart grafting was performed in a continuous series of patients using a single method of anastomotic stabilization. Patients were enrolled based on acuity of clinical presentation, coronary artery anatomy, and co-morbidity. An attempt was made to perform complete revascularization whenever possible. Angiographic characteristics of distal vessels deemed suitable for beating heart techniques are outlined below:

1) Vessel diameter ≥ 1.5 mm
2) Epicardial (not intramyocardial) location
3) Absence of diffuse or distal disease
4) Absence of vessel wall calcification at the proposed target site

With experience, vessels of greater difficulty were successfully grafted. Initially, patients with poor left ventricular (LV) function were excluded but with further experience, this proved to be unnecessary. Patients with lower ejection fractions (EF) were found to tolerate positioning and stabilization just as well as patients with normal EF. However, patients with cardiomegaly were more difficult to position for lateral wall grafting.

All patients who met pre-operative and intra-operative criteria were included in this analysis if OPCAB was attempted. The reported results are thus presented on an "intent to treat" basis. Pre-operative demographics and clinical descriptors were prospectively recorded, as were intra-operative variables. Post-operative data were collected and analysis supplemented by retrospective chart review and telephonic contact when necessary.

Operative Techniques

The Medtronic Octopus® tissue stabilizing system utilizes two independent pods secured to a tension flexor arm which in turn is anchored to the side rails of the operating table. The cable within the articulating arm is tightened to provide a rigid delivery platform for the pod. Each pod contains a row of 5 suction ports. Separate pods are connected to a bifurcated one-half inch PVC tube into which 400 mmHg suction is applied. A trap is placed in the suction system to capture moisture, blood, or condensation that is drawn through the suction tubing. Separate snap clamps or pump tubing clamps are used to independently control suction to each pod.

Clinical pods are manufactured in three shapes ("Preformed", "Offset", and "Straight"), each with a left- and

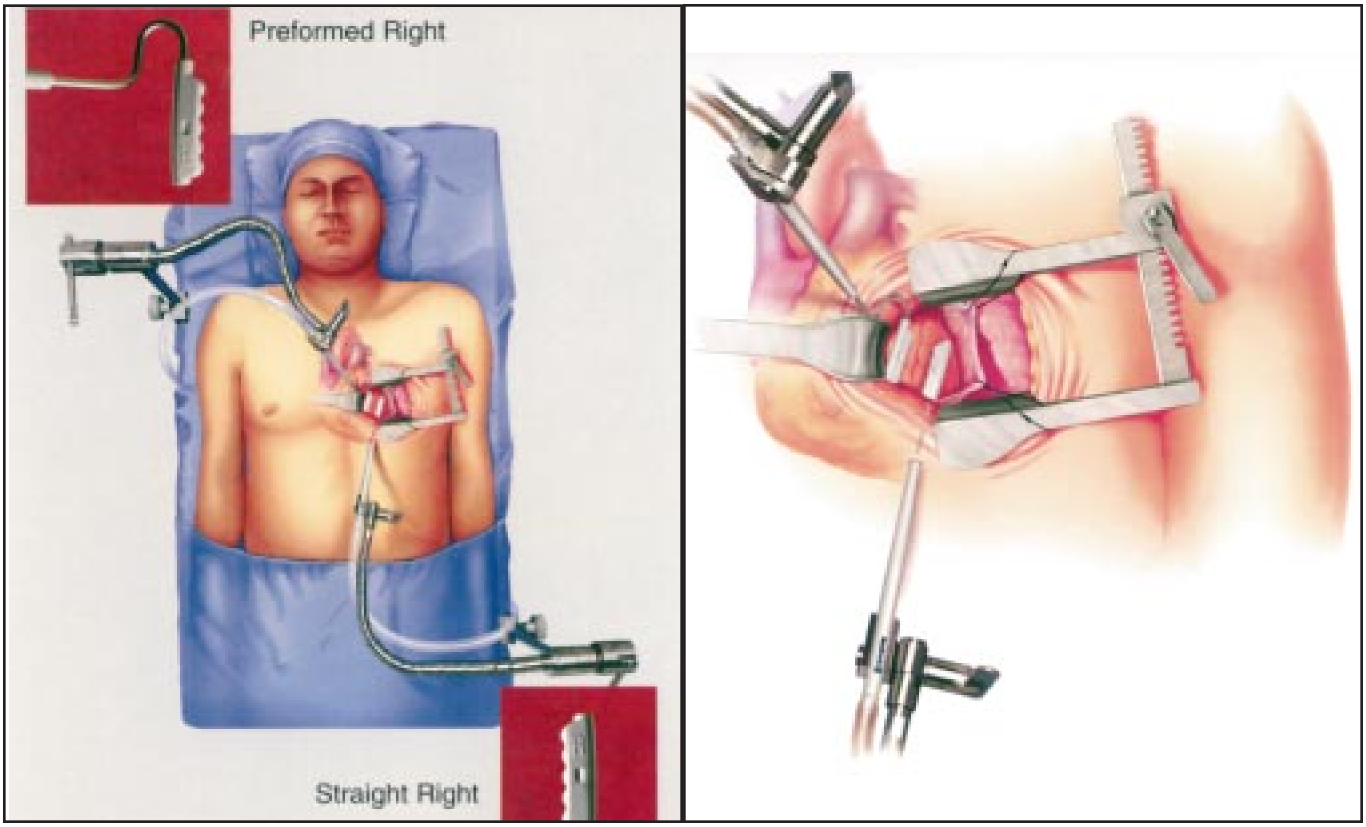

Figure 4. LAD MIDCAB through small anterior thoracotomy: Articulating arms are mounted at the patient's right shoulder and left hand. Tissue stabilizers: Preformed Right and Straight Right. The left-sided stabilizer is inserted through the chest tube incision and drawn into the chest using a 1-inch Penrose drain to cover the side holes. The pod is directed over the rib for additional stability.
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right-handed variant (see Figure 1 ◎). The proximal stem is very rigid and provides strong mechanical coupling to the articulating arm. The intermediate stem of each probe is malleable enough to allow for shape customization according to the needs of the exposure and anatomy.

In the initial series of patients, the placement of the articulating arms and pods was not standardized in any way. As the trial progressed, each surgeon gradually developed a system of flex arm and pod positioning suitable for each region of the heart, (see Figures 2 through 9 ◎ which represent artist drawings of the most common Octopus® positions developed by the investigators in this trial). The majority of coronary targets could be served with one flex arm near the patients right shoulder and one near the patients left wrist. Variations were commonly employed as dictated by the needs of the anatomy. One of the strengths of the Octopus® system is the ability of the surgeon to reshape the pods as needed. Pods could be bent using the heal of another pod or using a standard pump tubing clamp. A soft foam pad over the patient's face was used to protect from accidental injury by the heavy weight of the articulating arm. When limited access incisions were used, the pods occasionally were brought through separate stab incisions (later used for chest tube placement). In this instance, a 1-inch Penrose drain was used to cover the pods and guide the device through the chest wall.

Epicardial stabilization suitable to perform coronary grafting was achievable in all cases. However, the Octopus® device is designed mainly for stabilization and does not provide sufficient grip to lift and retract the cardiac mass by itself, except in some minor instances [Janzen 1997]. Specific maneuvers were thus necessary to deliver the heart into position prior to application of the stabilizing system. For exposing the LAD, a posterior pericardial cotton pack or laparotomy tape was usually sufficient. Left-sided pericardial traction sutures in addition to the posterior pack would usually provide adequate exposure to the diagonal branches.

For lateral wall exposure, elevation and rotation of the heart was possible using a series of 3 or 4 deeply placed pericardial traction sutures (see Movie 1 ◎). These sutures are placed in the deep recess of the lateral pericardium near the left pulmonary veins and oblique sinus. Traction on these sutures causes the apex to rotate medially and raises it into the wound (see Figures 6, 7 and 10 ◎). Additional rotation of the apex occurs if a laparatomy pack is then placed behind the back of the heart. Finally, lateral rotation of the operating table to the patient's right makes it possible to expose obtuse marginal branches as high up as the atrioventricular groove (see Movie 1 ◎). The Trendelenburg position was usually effective in correcting hypotension due to cardiac displacement [Gründeman 1997].

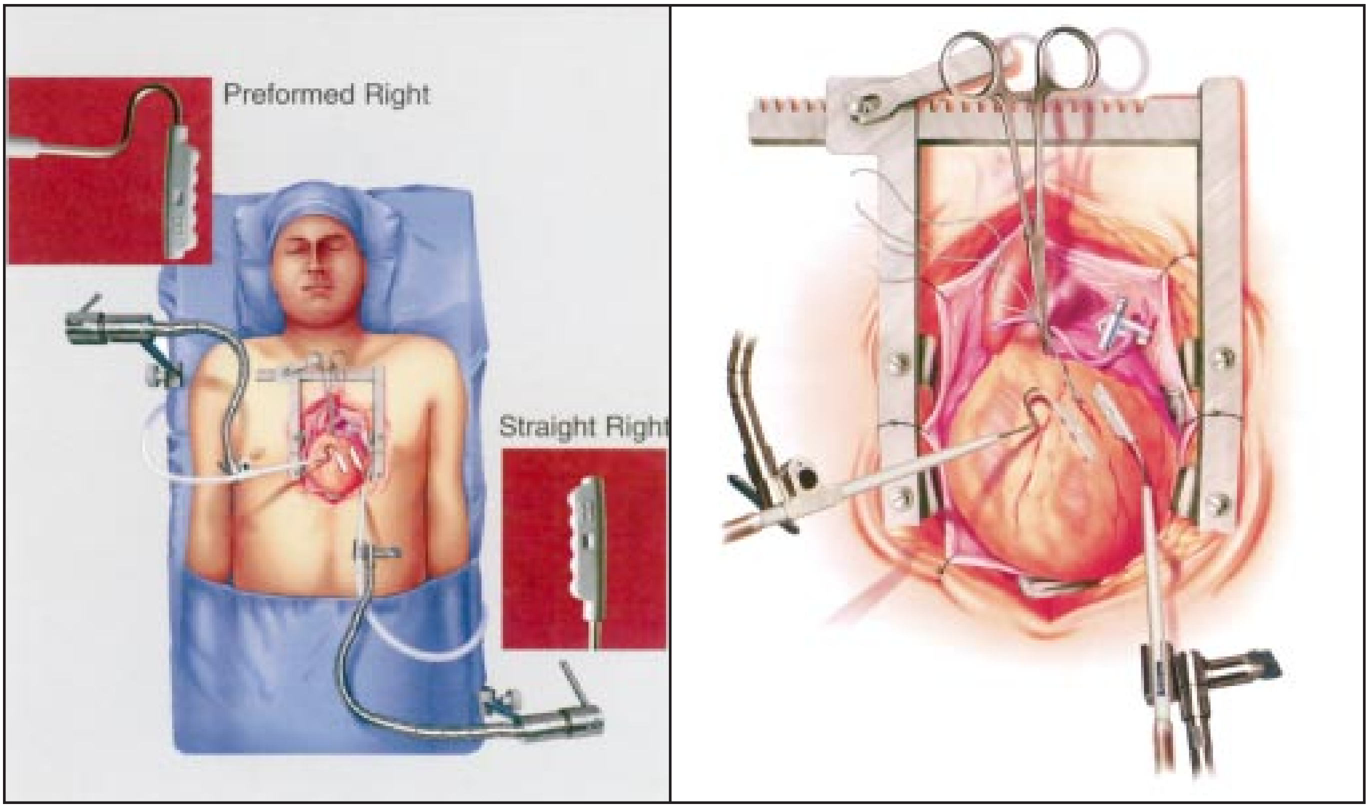

Figure 5. Diagonal stabilization: (Skip grafts should be performed prior to the LAD anastomosis.) Option 1: Articulating arms are mounted at the patient's right shoulder and left hand. Tissue stabilizers: Preformed Right and Straight Right pods. Heart is elevated on lapartomy packs. Option 2: Articulating arms are mounted at the patient's right and left hands. Tissue stabilizers: Straight Right and Straight Left.
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Another important maneuver to improve lateral wall exposure is counter tilt of the right hemisternum. The pericardium is incised along the right diaphragmatic reflection down to within a few centimeters of the inferior vena cava (see Movie 1 ◎). The right pleura is widely detached from the back of the sternum. Pericardial sutures on the right side are removed when exposing the left lateral wall. As the left pericardial sutures are placed under tension, the apex of the heart rotates towards the right and often comes to lay underneath the right hemisternum or inside the anterior portion of the right pleural space (see Figures 6, 7 and 11 ◎). This brings the lateral wall vessels to the midline and within easy reach of the surgeon. The Chaux retractor (Pilling Instruments) has been used to elevate the right hemisternum in some cases to make additional room for the apex of the heart to flip into the right pleural space.

Exposure of the right coronary artery in the atrioventricular groove usually did not require special maneuvers for positioning. Exposure of the posterior descending artery (PDA) was best achieved by elevation of the apex towards the head (see Figure 12 and Movie 2 ◎). Deep pericardial retraction sutures near the IVC help to elevate the apex sufficiently to expose the PDA.

A 1.0 to 2.0 mg/kg bolus of heparin was administered prior to the start of grafting with a target ACT of two times baseline [Spooner 1998]. For vascular control of the target vessel, silastic vessel tapes (Quest Medical Inc, Allen, Texas) were passed underneath the proximal vessel and threaded through a Teflon® pledget (see Figure 13 ◎). Distal tapes were avoided in most instances. A five-minute test occlusion was performed while observing for signs of ischemia. Routine use of transesophageal echo was not done. Most coronary arteries with a high-grade proximal stenosis did not demonstrate acute ischemia during temporary occlusion. However, the right coronary artery artery appeared to be more vulnerable, with third degree atrioventricular block and hypotension as a consequence of trial occlusion. Intracoronary shunts [Rivetti 1998] were found to be useful for preventing ischemia particularly in the territory of main right coronary artery.

After a three-minute period of reperfusion, the vessel was again controlled proximally and the coronary opened. Conventional anastomotic suturing techniques were used with visualization aided by the use of a misted blower device [Teoh 1991]. In most cases, the LAD was grafted first to provide septal and anterior wall perfusion with expected collateralization to other territories. For anterior skip grafts, the diagonal was performed first followed by the LAD anastomosis. In general, major vessels with severe stenosis or occlusion were grafted before minor vessels or those with moderate lesions [Spooner 1998]. The distal anastomoses were usually completed first followed by proximal anastomoses of vein graft segments to the

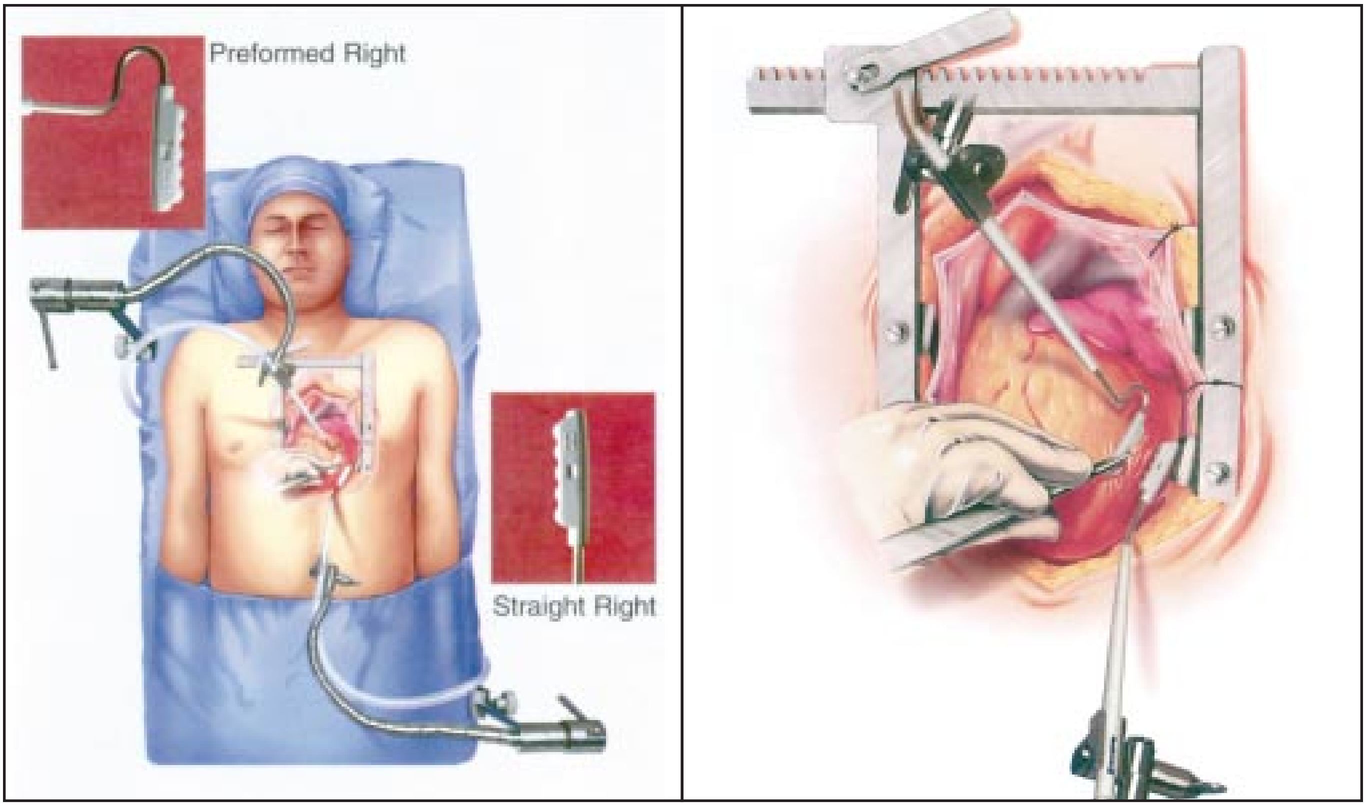

FIGURE 6. Proximal Obtuse Marginal stabilization: Articulating arms are mounted at the patient's right shoulder and left hand. Tissue stabilizers: Preformed Right and Straight Right. Heart is rolled to the patient's right side, with or without laparotomy packs. Further exposure can be achieved by elevating the right hemisternum and allowing the apex to enter the front of the right pleural space. All right sided pericardial sutures are removed and the pleura is widely incised.
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ascending aorta under a single period of partial occlusion. Heparin reversal with protamine was used in all cases.

In most cases, cell scavengers were not assembled in anticipation and only used if needed. However, as more multivessel cases were performed later in the series, back bleeding from the distal portion of the open coronary artery became cumulative enough that significant blood loss occurred. This has prompted one of the authors (JCH) to reconsider using cell scavengers for multivessel OPCABs. At this time, cell scavengers are not necessary for single or double vessel cases.

Anesthetic Management

Perioperative anesthetic management is key to the success of the procedure as a whole. In addition to ensuring the basic elements of general anesthesia, there are additional concerns typical of OPCAB such as maintenance of core temperature, optimization of respiratory status, pain control, and ischemia detection. Transient arrhythymias when maneuvering the heart are common. Lifting of the heart from the pericardial cradle can be associated with loss or alteration in QRS and T-wave components of the electrocardiogram (ECG) leading to difficulties in diagnosing ischemia. In some cases, ischemic ECG patterns may also be due to the axis shift of cardiac displacement. Hypotension from kinking of the venous return, right ventricle or pulmonary veins can occur [Gründeman 1997]. Multivessel off-pump grafting is very different from the comfort and familiarity of CPB and requires both experienced anesthesia support and close cooperation in each step of the operative sequence.

Table 1. Study Centers

Center	Cohort Size(N)	Principal Investigator	Institution	Dates
A	182	James Hart, MD	Pinnacle Health, Harrisburg, Pennsylvania	06/97 to 12/98
B	157	Ted Spooner, MD	Park Nicollet Health Center, Minneapolis, Minnesota	03/97 to 12/98
C	35	James Edgerton, MD	St. Marys Medical Center, Racine, Wisconsin	10/97 to 12/98
Total	374			

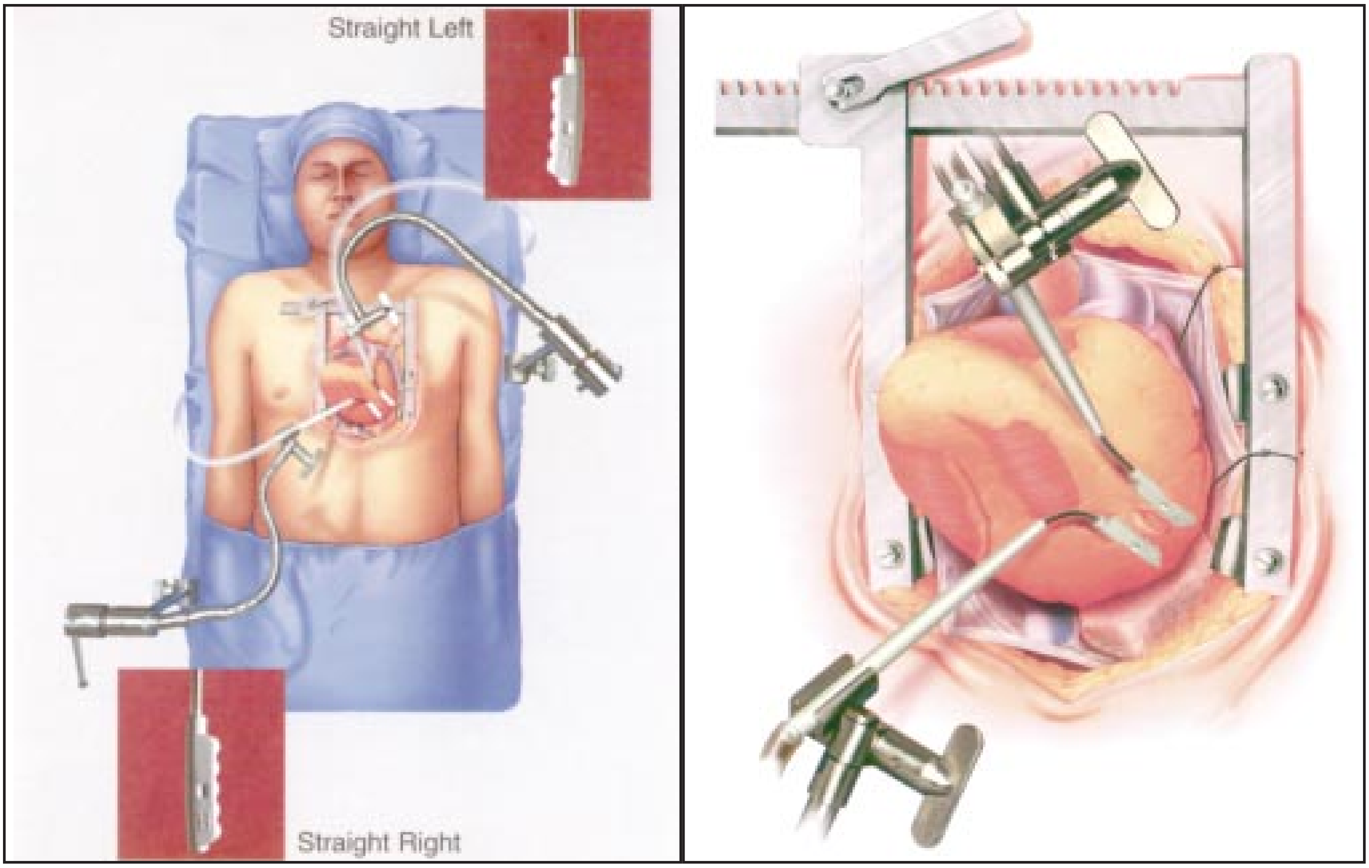

Figure 7. Distal Obtuse Marginal stabilization: Articulating arms are mounted at the patient's right hand and left shoulder. Tissue stabilizers: Straight Right and Straight Left. Heart is elevated on lapartomy packs with the apex pointing towards the sky. Further exposure can be achieved by elevating the right hemisternum and allowing the apex to enter the front of the right pleural space. All right sided pericardial sutures are removed and the pleura is widely incised.
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Standard cardiovascular monitoring including 5-lead ECG, radial arterial line, Swan-Ganz catheter, pulse oximetry, temperature, and urinary output were used in all patients. Transesophageal echocardiography was occasionally added. General anesthesia was maintained with a balanced technique using short acting agents whenever possible. Volatile agents supplemented with short acting narcotics and hypnotics were used with the intention to provide rapid wakening and extubation. Continuous low dose propafol drip supplemented the depth of anesthesia while also providing excellent amnesia and early arousal for immediate extubation. In patients who appeared to be candidates for early extubation, muscle relaxants were reversed after closure of the wound. Conservative intravenous fluid administration was necessary to prevent hemodilution, pulmonary congestion and permit early extubation. Occasionally bolus or drip milrinone proved beneficial for hypotension or low cardiac index during positioning.

Since these patients were not on extracorporeal circulation, specific strategies to prevent heat loss were an integral part of the operating technique. Patients were kept normothermic by keeping the surgical suite relatively warm, by utilizing a warming blanket on the operating table, by warming intravenous fluids, and by actively heating and humidifying respiratory gases.

Table 2. Patient Demographics

Center	N	Age Mean (range)	Gender (% Males)	Status (% Non-elective)	Reop (%)
A	182	64.1 (33-89)	73%	40%	10%
B	157	62.5 (43-85)	74.5%	21%	5.7%
C	35	62.6 (48-89)	79%	21%	0%
Means	374	63.2	74.2%	30.2%	7.2%

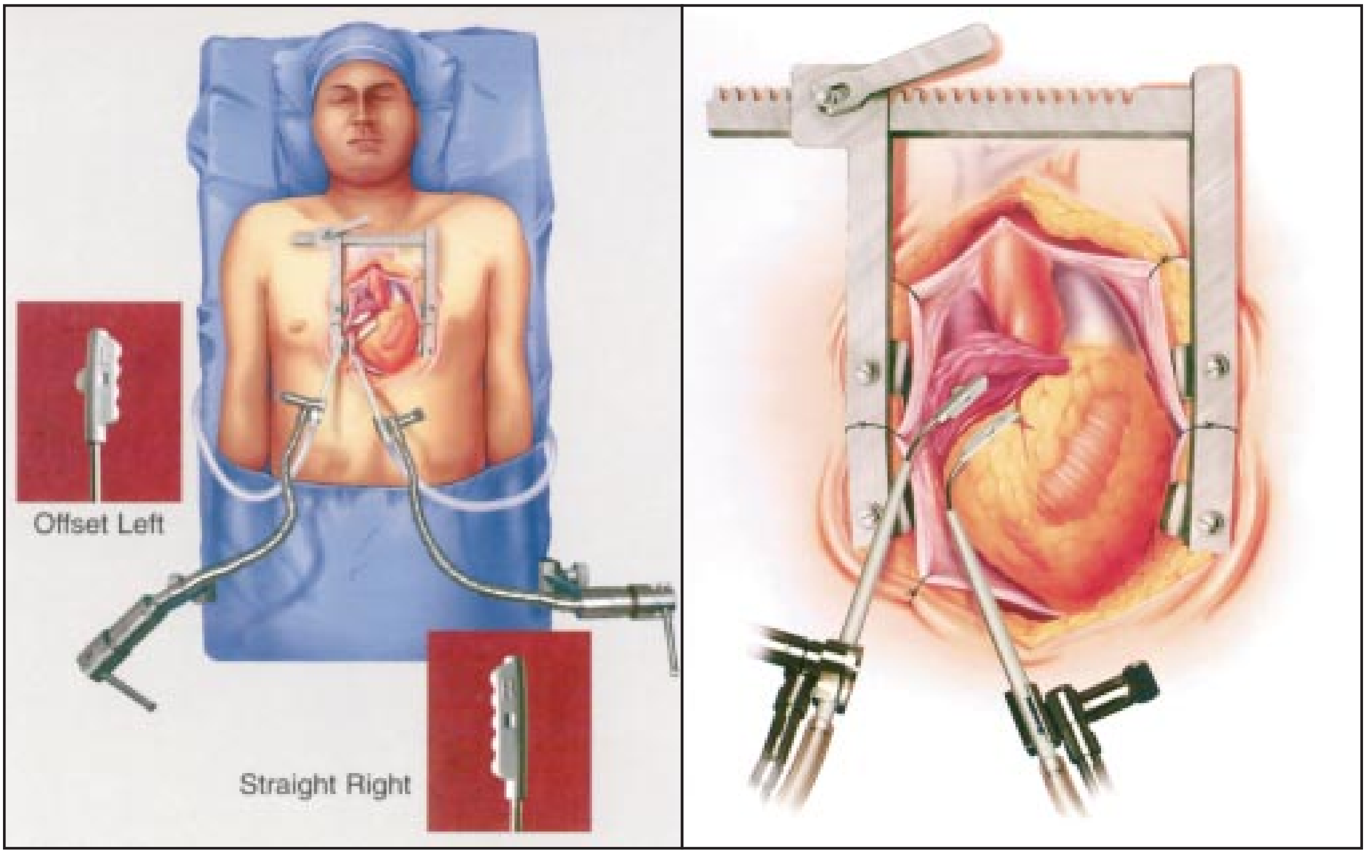

Figure 8. Right Coronary Artery stabilization: Articulating arms are mounted at the patient's right and left hands. Tissue stabilizers: Straight or Offset Left and Straight Right. Consider temporary pacing leads and/or intraluminal shunt to prevent bradycardia, heart block, or hypotension.
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Prior reports from non-US centers where beating heart surgery was pioneered included the use of bradycardia as a pharmacologic method of reducing motion. However, in our experience bradycardic pharmacotherapy frequently causes hypotension and further compromise in hemodynamics. The Octopus® provides target vessel stabilization without the need for beta blockade or calcium channel blockers and these drugs were avoided if possible [Spooner 1998]. Routine anesthetic management included low dose nitroglycerin drip for coronary artery vasodilation and the use of Trendelenburg positioning to augment venous return and cardiac output during displacement of the heart. Rarely, hypotension was treated with alpha vasopressors such as neosynephrine to maintain a systolic pressure of at least 100 mmHg .

Pain control strategies were equally important. At center A, most cases began with a single subarachnoid injection of 0.25-0.35 mg of preservative free morphine (Duramorph®). In the recumbant position, Duramorph® slowly ascends to the thoracic region of the spinal fluid compartment. This technique appeared to provide the dual benefit of improved intraoperative as well as early post-operative analgesia. At the conclusion of surgery, a long-acting local anesthetic was injected into the pre-sternal tissues and an intravenous does of Ketorulac tromethamine (Toradol®) was added for additional analgesic benefit.

The great majority of patients managed in this fashion could be awakened and extubated immediately in the operating room and transported for observation to a general recovery area. Unlike other so-called "fast-track"

Table 3. Preoperative Risk Profile

Center	EF % (Range)	Left Main %	COPD %	Renal Insuff	CCVS III-IV
A	51.0 (17-73)	14%	9.3%	8.2%	93.4%
B	61.4 (20-80)	N/A*	N/A*	3.2%	85.9%
C	53.0 (30-75)	0%	14%	0%	93%
Means	55.5%	11.7%	9.9%	5.3%	90.2%

*N/A = Not Available

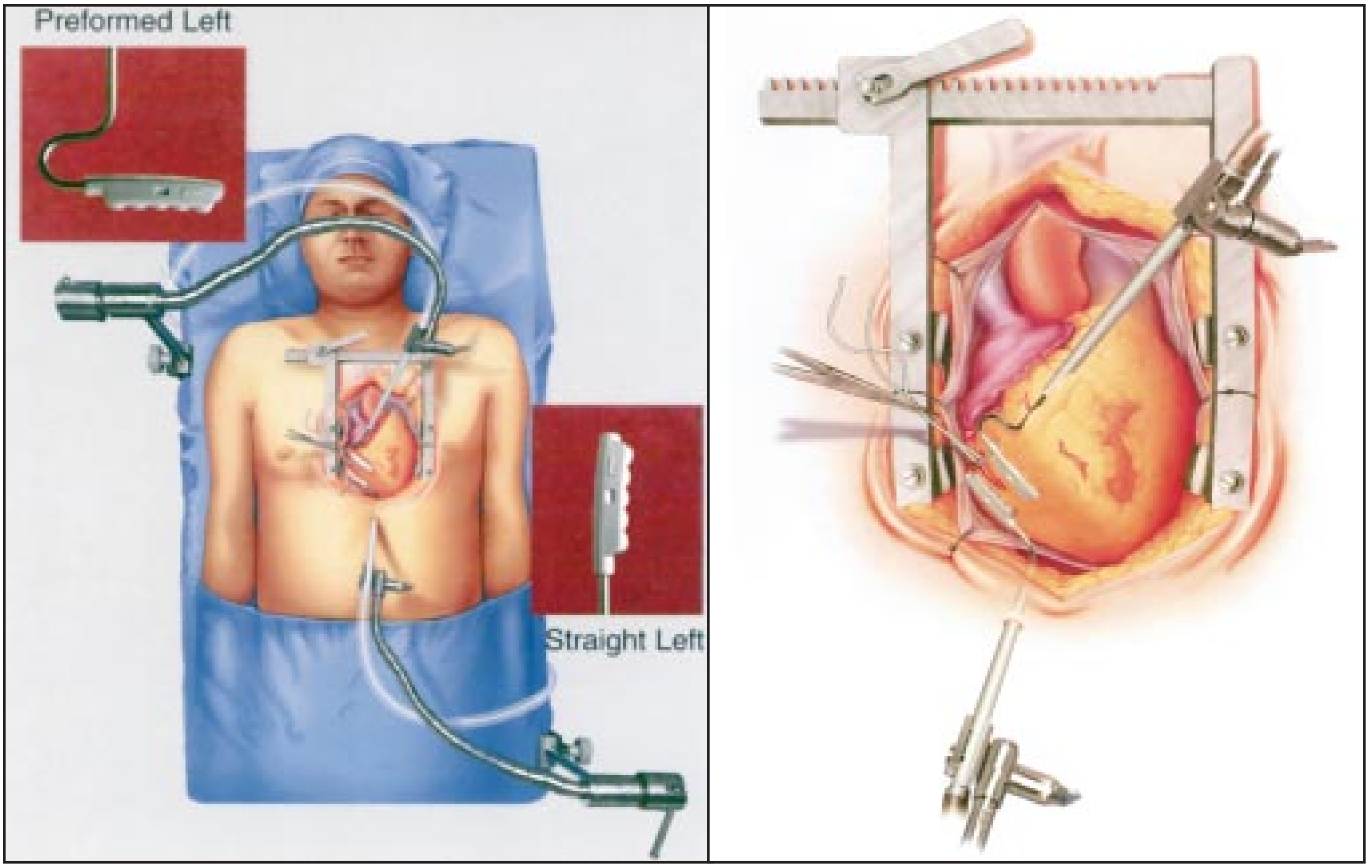

Figure 9. Posterior Descending stabilization: Articulating arms are mounted at the patient's right shoulder and left hand. Tissue stabilizers: Preformed Left and Straight Left.
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patients exposed to cardiopulmonary bypass, these patients did not suffer physiological insults such as hypothermia, hemodilution, or significant derangement of their hemostatic mechanisms and the risk of neurological impairment was extremely low. Therefore, OPCAB patients can be awakened from their anesthetic much like patients having non-cardiac procedures and may be extubated without fear of subsequent deterioration.

RESULTS

The principal investigators and respective institutions participating in this study are listed in Table 1 (◎). No patients who began the procedure with intent to perform OPCAB were excluded from analysis. Demographics of the patient population are summarized in Table 2 (◎). The incidence of preoperative comorbidity and surgical risk factors are summarized in Table 3 (◎). The average EF of the entire series was 55.5% (ranging from 17% to 80%). Over 90% of the patients were in clinical angina class III or IV as determined by the Canadian Cardiovascular Society scale.

There were a total of 728 distal anastomoses constructed in 374 patients for a mean of 1.96 grafts per patient. However, early in the series mostly single vessel cases were performed in order to provide a controlled situation in which to develop experience with the equipment and techniques before expanding to more complex cases. If the single-vessel cases are removed from consideration, the mean number of grafts performed in the multivessel cohort was 2.58 grafts per patient (see Table 4 ◎). A full breakdown of the number of grafts per patient and per center is provided in Table 5 (◎).

Using the exposure techniques described above, it was possible to graft all regions of the heart without serious hemodynamic instability. Distal anastomoses were successfully constructed to all target vessels of 1.5 mm or greater in diameter, including the obtuse marginal branches of the circumflex as well as posterior lateral and posterior descending branches of the right coronary artery. Table 6 (◎) provides a detailed breakdown of all

Table 4. Grafts per Patient

Center	Grafts per Patient (total)	Grafts per Multivessel Patient*
A	2.0	2.6
B	1.9	2.6
C	2.1	2.4
Means	1.96	2.58

*Excluding single vessel grafts done early in the series

Table 5. Number of Distal Anastomoses*

Center	1 Graft N (%)	2 Grafts N (%)	3 Grafts N (%)	4 Grafts N (%)
A	69 (37.9%)	52 (28.6%)	49 (26.9%)	12 (6.6%)
B	64 (40.8%)	47 (29.9%)	35 (22.3%)	11 (7.0%)
C	7 (20.0%)	20 (57.1%)	6 (17.1%)	2 (5.7%)
Means	140 (37.4%)	119 (31.8%)	90 (24.1%)	25 (6.7%)

* Expressed as a percent of the total number of patients operated on at each center

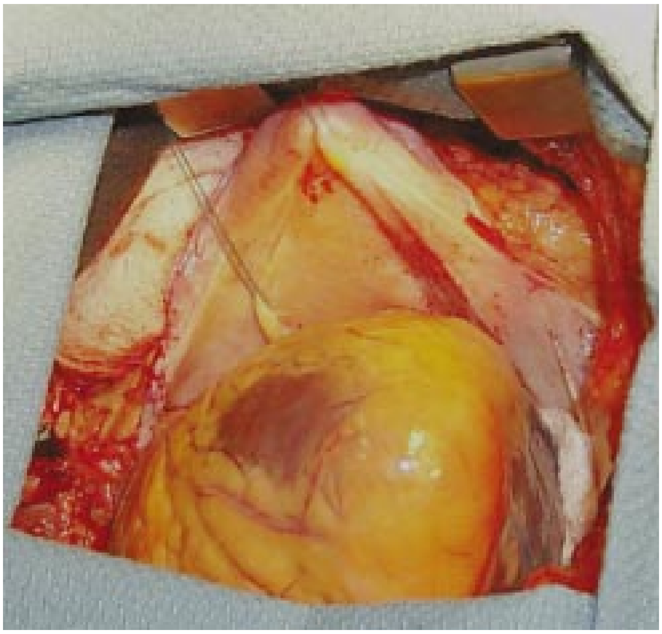

Figure 10. Medial rotation of the heart and exposure of lateral wall targets is facilitated by pericardial traction sutures placed near the pulmonary veins and the deep recess of the left pericardium.

distal anastomoses by target vessel location. A total of 225 grafts were constructed to non-LAD (or diagonal) branches, reflecting 30.6% of all grafts in this series.

Various incisions were utilized as outlined in Table 7 (◎). However, the vast majority of patients (91.9%) were approached through a full sternotomy or hemisternotomy. Only 28 patients underwent off pump revascularization using the Octopus® stabilizer through a non-sternotomy incision (either thoracotomy or subxyphoid approach).

Clinical endpoints monitored for the purposes of this study included 30–day in-hospital mortality as well as major morbidity (stroke, sternal wound infection, atrial fibrillation, reoperation for bleeding, renal function, and blood utilization). Mean postoperative hospital length of stays were calculated. Mortality rates were compared with published data from the Society of Thoracic Surgery database [Edwards 1994].

Only one patient died in the entire series for a 30–day in-hospital mortality rate of only 0.26% No randomization or historical controls were obtained, so statistical comparison was not possible. However, published mortality data from the Society of Thoracic Surgery database for the same level of operative risk were between 1.2% and 2.4% (see Table 8 ◎). We interpret our results as showing a meaningful reduction in mortality when compared to national figures available for conventional, arrested heart CPB techniques.

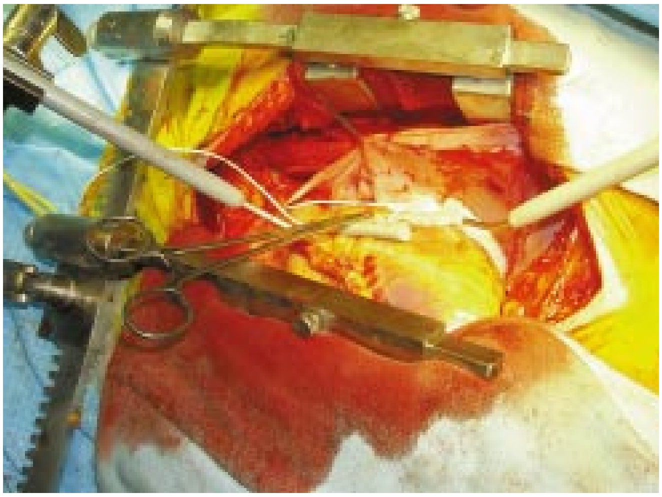

Figure 11. Wide incision of the right pleura and diaphragmatic pericardium allows the apex to rotate into the right pleural space, increasing exposure to the lateral wall vessels.

Table 6. Vessels Bypassed

Center	LAD	Diag	IR/OM	RCA	PDA	PLVBR	AM
A	167	40	78	24	53	3	3
B	136	49	41	37	20	3	1
C	28	10	11	12	10	2	0
Totals	331	99	130	73	83	8	4

LAD = left anterior descending; DIAG = diagonal branch of the anterior descending; IR = intermediate or ramus branch of the left main; OM = obtuse marginal; RCA = right coronary artery; PDA = posterior descending artery; PLVBR = posterior lateral ventricular branch; AM = acute marginal.

Table 7. Incisions

Center	Full Sternotomy	Hemi Sternotomy	Anterior Thoracotomy	Epigastric (subxyphoid)
A	155 (85.2%)	11 (6.0%)	14 (7.7%)	2 (1.1%)
B	121 (77.1%)	22 (14.0%)	12 (7.6%)	0 (0%)
C	32 (91.4%)	3 (8.6%)	0 (0%)	0 (0%)
Means	308 (82.3%)	36 (9.6%)	26 (6.95%)	2 (0.53%)

Figure 12. The posterior descending branch of the right coronary artery is best exposed and stabilized by elevating the apex skyward. This position is remarkably well tolerated without hypotension.

Additional benefit was evident by the exceptionally low perioperative morbidity observed in this series of patients. Requirement for inotropes beyond 24 hours was very low (Table 9). No patient in the entire series required the insertion of an intraaortic balloon pump during or after the procedure.

Only 15 patients (4%) were converted to cardiopulmonary bypass during the procedure. Rates of conversion to CPB ranged from 2.7% (Center A) to 5.7% (Center B) as shown in Table 9 (). Elective conversion to CPB was performed for technically difficult target vessels, intramyocardial vessels, local bleeding from coronary veins, vessels too small for OPCAB techniques, or vessels showing distal disease or calcifications. Only one patient (0.26%) required emergency institution of cardiopulmonary bypass for hemodynamic instability. The remaining patients were converted successfully and were completed without perioperative infarction or ventricular failure.

Only one patient demonstrated a new perioperative neurologic deficit for an incidence of 0.26% (see Table 10). This event occurred on the fifteenth postoperative day and following hospital discharge and thus was unrelated to the surgical technique per se. The neurologic risk of OPCAB in this series with the Octopus® is thus considerably lower than reported national average figures for stroke following CABG [Moody 1995, Roach 1996]. Blood product administration was used in 20.3% of patients (ranging from 20% to 28.5%).

No deep sternal wound infections occurred (0%) (see Table 11). Similarly, there were no instances of new onset renal insufficiency or renal failure requiring dialysis. The frequency of atrial fibrillation averaged 12.8%, which is just slightly lower than the frequency seen in standard CPB cases at the same institutions. Analysis of the incidence for atrial fibrillation in OPCAB using the Octopus® confirmed a direct relationship to advancing age similar to that reported in patients undergoing standard CPB techniques.

The average length of hospital stay following surgery was 4.97. days, with a total hospital LOS of 6.4 days (see Table 12). Cost figures were not obtained prospectively in this series. Due to constraints in reimbursement, routine angiographic followup or investigation of graft patency was not obtained.

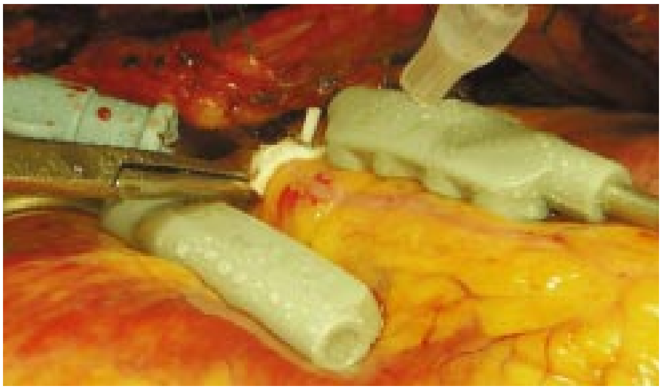

Figure 13. Close up of the left anterior descending with proximal control obtained by a subcoronary silastic tape threaded through a felt pledget, secured on one side with a clip and tightened as needed by traction against a right angle clamp. Five minutes of test occlusion is usually performed, especially on major coronary branches.

Table 8. Mortality

Center	Observed Mortality	Predicted Mortality (STS Database)
A	0/182 (0%)	2.4%
B	1/157 (0.6%)	1.4%
C	0/35 (0%)	1.2%
Total	1/374 (0.26%)	

Table 9. Operative Outcomes

Center	Conversion to CPB	Inotropes	New IABP
A	5 (2.7%) (none urgent)	3 (1.6%)	0
B	9 (5.7%) (one urgent)	N/A*	0
C	1 (2.9%) (none urgent)	3 (8.5%)	0
Totals	15 (4.0%)	6 (2.7%)	0 (0%)

*N/A = Not available

Table 10. Morbidity

Center	Stroke	Blood Products	Atrial Fibrillation
A	1/182 (0.6%)*	36 (20%)	18 (10%)
B	0/157 (0%)	30 (19%)	27 (17%)
C	0/35 (0%)	10 (28.5%)	3 (8.5%)
Totals	1 (0.26%)	76 (20.3%)	48 (12.8%)

* CVA occuring 15 days postoperatively

Table 12. Length of Stay

Center	Postoperative LOS(days)	Total LOS(days)
A	5.2	6.6
B	4.9	N/A*
C	4.1	5.4
Means	4.97	6.4

DISCUSSION

The risk of stroke or cognitive changes, renal insufficiency, coagulopathy, capillary leak syndrome, respiratory failure and multi-organ failure are known consequences of cardiac surgery and appear to be partly related to the physiologic stresses of cardiopulmonary bypass and exposure of the cellular elements of the blood to artificial surfaces. Extracorporeal circulation and blood-material contact is associated with diffuse activation of the early components of the coagulation cascade, platelet and white cell degranulation, and systemic release of the humoral mediators of inflammation. Although most patients tolerate these transient physiologic alterations, some patients suffer significant perioperative complications resulting in organ damage and possible death. In addition, disturbance of atheromatous material from the aorta and great vessels by the arterial cannula jet stream or aortic cross clamping accounts for the majority of embolic strokes occurring during CABG.

Off-Pump Coronary Bypass (OPCAB) avoids the unwanted sequelae of cardiopulmonary bypass (CPB). Without the systemic inflammatory response, hemodilution, and end-organ damage associated with CPB, coronary surgery may be offered with lower risk. OPCAB may also extend the patient range considered operable by offering surgery to patients not felt to be candidates for CPB. In a recent series of 505 off-pump multivessel patients operated on with the aid of pressure-plate stabilizers, Bergsland and colleagues reported fewer postoperative complications, a reduced incidence of stroke, and a shortened length of hospital stay when compared with a similar group operated on with CPB [Bergsland 1998].

The current resurgence in off-pump CABG renews the challenges faced three decades ago by the original pioneers of coronary artery surgery. If surgical revascularization of the heart is to be universally successful without the use of the pump oxygenator, several goals must be met. First, the operation must not compromise the expected clinical endpoints (mortality, morbidity, graft patency, and angina relief) that are presently obtained in the arrested heart. Second, modern OPCAB must permit full revascularization of all regions without encouraging inadequate or incomplete operations. Third, the procedure must be refined to permit all practicing surgeons, regardless of prior training, a reliable means of suturing on the beating heart without hemodynamic or ischemic compromise. Most surgeons practicing today were not trained in the era prior to the widespread use of the pump oxygenator and thus are not adept at sewing on the moving coronary target. Mechanical stabilization of the target vessel is one of the leading advances making off-pump grafting practical on a large scale [Calafiore 1998b, Diegeler 1998, Douville 1999].

Most currently available stabilizers provide relative freedom from motion at the coronary target by placing downward pressure on the surrounding epicardial zone [Boonstra 1997]. When these devices are applied to the region of the LAD, the septal muscle mass is a sufficient scaffold to prevent deformation of the anterior wall and impairment of ventricular function. Jurmann et. al. reported minimal decreases in left ventricular (LV) systolic and diastolic dimensions upon application of an epicardial compressive stabilizer during limited access thoracotomy (i.e., MIDCAB) [Jurmann 1998]. However, when using the same device on vessels located more laterally, the same authors noted more pronounced LV geometrical and hemodynamic changes [Jurmann 1998].

The strategy for immobilzation with the Octopus® system is different. Suction applied to the epicardium immobilizes the tissue in between the suction pods. Downward pressure on the ventricle is not needed to obtain motion

Table 11. Morbidity

Center	Reop Bleeding	Deep Sternal Wound Infection	New Renal Insufficiency
A	0 (0%)	0 (0%)	0 (0%)
B	4 (2.5%)	0 (0%)	0 (0%)
C	2 (5.7%)	0 (0%)	0 (0%)
Totals	6 (1.6%)	0 (0%)	0 (0%)

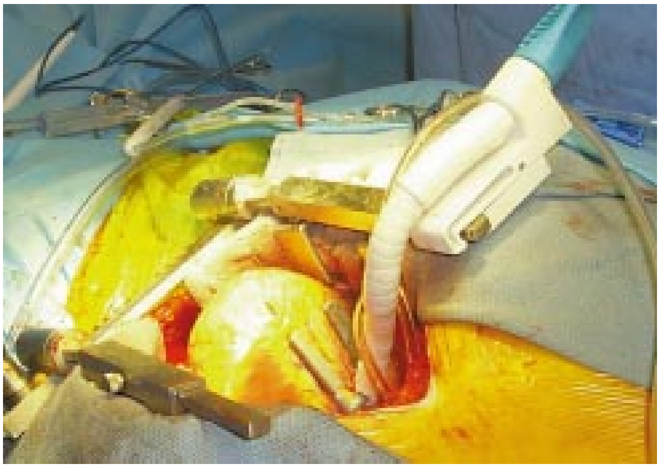

Figure 14. Exposure and stabilization of the posterior descending using the new retractor mounted Octopus® 2 device.

suppression. This means that the Octopus® is effective in all regions of the heart with minimal or no geometric deformation of the ventricle and less hemodynamic compromise.

The degree of immobilization obtained by the Octopus® was studied experimentally in a porcine model. Laser light was projected onto an epicardial beacon and the movement of the reflection was plotted as a function of the cardiac cycle. Without stabilization, the lateral wall of the porcine heart moves 10 to 15 mm with each cardiac cycle. Regional stabilization with the Octopus® reduces motion of the obtuse marginal target to a mean displacement of 1 by 1 mm [Borst 1996]. This effectively provides a regional "arrest" of the heart without the need for global arrest, cardiopulmonary bypass, or cardioplegia. The design of the Octopus® will permit stabilization even through the intact chest wall if the pods are placed through small, 7-mm stab incisions. This system is the only currently available stabilizer that can enter the chest through stab wounds or ports and thus provide stabilization for off-pump endoscopic or robotically assisted CABG.

Suction injury to the myocardium or underlying vascular structures (coronary arteries or veins) has not been observed in experimental models [Borst 1996]. Despite 400 mmHg of negative suction applied to the pods, only minimal surface interstital hemorrhage occurs and is usually limited to a depth of 1 to 2 mm [Borst 1996]. Epicardial suction marks appear grossly hemorrhagic at first, but often improve within minutes. Application of a pod to the epicardium over a coronary vessel does not damage the vessel wall.

One of the previous hurdles to multivessel OPCAB has been the hypotension associated with displacement of the heart from its natural position in the pericardial cradle. Classic teaching was that hypotension was solely due to compromise of left ventricular performance. However, the importance of right heart dysfunction during displacement was elucidated in recent studies performed by Gründeman and colleagues at the University of Utrecht [Gründeman 1997]. These investigators reported that displacement sufficient to view the circumflex branches caused a 44% mean decrease in left ventricular stroke volume with a simultaneous increase in right ventricular end diastolic pressure from 5 mmHg to 8 mmHg indicating a mild form of right heart failure [Gründeman 1997]. There was also a mean decrease in cardiac output of 33% and and a decrease in systolic blood pressure of 26%. These hemodynamic alterations were reversed by 20 degrees of Trendelenburg, presumably by volume loading of the right ventricle. These data are supported by our own observations that Trendelenburg is very effective in preventing hemodynamic stability during OPCAB. The Octopus® investigators also developed additional strategies to provide lateral and inferior wall exposure, including deeply placed left sided pericardal traction sutures, rightward table rotation, wide incision of the right pericardium and pleura, and countertilt of the right hemisternum. Even with these maneuvers, displacement and positioning of the heart must be performed gradually in order to maintain hemodynamic stability. It is recommended that the systolic pressure not be allowed to drift below 100 mmHg before or during the anastomosis.

The advent of MIDCAB has shown that temporary occlusion of a major coronary artery for beating heart CABG is not associated with dreaded complications in most cases. Severe ischemia, power failure, and death are not expected results of temporary coronary occlusion. It may come to the surprise of many surgeons new to off-pump grafting that the heart tolerates clamping or snaring of the target vessel rather well. However, there are consequences. When transesophageal echocardiography is performed during these cases, wall motion abnormalities in the region of the target vessel are often seen. Elevated ST segment changes can occur, but most of the time they are not associated with arrhythmias or power failure. Displacing the heart from the pericardium can diminish the ECG signal voltage displayed by surface leads and thus cloud the diagnosis of ischemia. Fortunately, the need for emergency measures for acute ischemia is very rare. In our series of 374 consecutive cases, only one patient was placed on bypass emergently. There were several patients with hypotension and/or bradycardia during acute clamping of the right coronary artery. These patients responded to the use of an intraluminal shunt [Rivetti 1998]. Preconditioning (trial clamping) for 5 minutes followed by 3 minutes of reperfusion prior to grafting was used by one investigator (JCH) and found to be a useful predictor of the need for shunting or cardiopulmonary bypass.

Off-pump coronary grafting is a new refinement of an old concept. The Octopus® provides a consistent and yet adaptable means to achieve regional mechanical stabilization for target vessels in virtually all regions of the heart. Many advantages and improved clinical outcomes have been detailed in our initial trials with this device. The one drawback of the current Octopus® design is the need for two sizable table mounted articulating arms which take up physical space and impede the operative field. The second generation, Octopus® 2, is now commercially available. In this device, both pods are mounted on a single flexor arm which attaches to the sternal retractor (see Figure 14). The Octopus® 2 is less bulky and thus easier to implement. The pods are attached to a ball joint which permits many angles of approach to the coronary target. As the flexor arm is tightened, the pods separate by up to 5 mm in order to provide lateral traction on the epicardium at the arteriotomy site. An initial experience with the Octopus® 2 in all three centers has demonstrated that this device can provide excellent stabilization in all regions of the heart (see Movie 3).

In conclusion, OPCAB surgery with the Octopus® stabilization system was utilized in 374 consecutive and diverse patients. All coronary arterial segments could be bypassed without significant hemodynamic instability. Anastomoses were constructed in a precise and unhurried manner. Urgent conversion to CPB was very infrequent. Mortality was extremely low and significant complications were rare. OPCAB surgery with the Octopus® appears to be safe and effective in a broad range of patients. Longer term follow-up and further investigation of this technique are warranted.

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