

# Initial Experience with the Enclose Proximal Aortic Anastomosis Device during Off-Pump Coronary Artery Bypass: An Alternative to Aortic Side Clamping

Robert S. Boova,<sup>1</sup> Candace Trace,<sup>1</sup> Bradley G. Leshnower<sup>2</sup>

<sup>1</sup>Department of Cardiac Surgery, The Bryn Mawr Hospital, Main Line Health System Hospitals, Bryn Mawr; <sup>2</sup>Department of Surgery, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania, USA

## ABSTRACT

**Background.** The utilization of off-pump coronary artery bypass surgery (OPCAB) has resulted in the development of new technology to facilitate the creation of aorto-coronary graft anastomoses. Proximal aortic devices (PADs) enable the construction of a proximal aortic anastomosis without the use of a side-biting aortic clamp, thus reducing the risk of neurologic injury from particulate embolization.

**Methods.** One hundred ninety-seven patients underwent OPCAB at our institution between January 2003 and December 2004. Sixty (30.5%) patients had proximal aorto-coronary graft anastomoses constructed with the Novare Enclose PAD. The remaining 137 (69.5%) patients had graft construction with a standard aortic side-clamp technique. We compared the outcomes of these 2 cohorts to evaluate the safety and efficacy of the Novare Enclose PAD.

**Results.** One hundred seven proximal anastomoses were constructed in the PAD group, and 199 proximal were constructed in the side-clamp group. Three patients (1.5%), all in the side-clamp group, sustained permanent neurologic deficits after OPCAB. There were 2 cases of device malfunctions. There were no anastomotic thromboses, no reoperations for anastomotic hemorrhage, and no patients required anastomotic revision. Of the 197 patients in the series, there were 4 deaths, 2 in each group, resulting in an overall mortality rate of 2%.

**Conclusion.** The Novare Enclose PAD is a safe device that facilitates suture construction of proximal aorto-coronary graft anastomosis. In a select group of patients, the use of this device may reduce the risk of neurologic injury when compared to the application of an aortic side-biting clamp for coronary bypass surgery.

## INTRODUCTION

The utilization of off-pump coronary artery bypass surgery (OPCAB) for myocardial revascularization in recent years has resulted in the development of new technology to facilitate the creation of aorto-coronary graft anastomoses. These devices have been labeled aortic connector devices, aortic anastomosis devices, or proximal anastomosis devices (PAD), and are designed to create an automatic coronary anastomosis or to facilitate suture construction of a proximal anastomosis [Carrel 2004].

The conventional technique of creating a proximal aorto-coronary anastomosis involves partial occlusion of the ascending aorta with a side-biting clamp. Application of an aortic clamp is not without risk and has been associated with aortic dissection and local particulate embolization resulting in neurologic injury [Barzilai 1989; Blauth 1992; Barbut 1994; Chavanon 2001]. The use of a PAD facilitates the construction of a proximal aortic anastomosis without the use of a side-biting clamp, thus reducing the risk of neurologic injury from particulate embolization.

In this study, we report our experience with the Novare Enclose (Novare, Cupertino, CA, USA), a novel PAD that facilitates suture construction of proximal coronary graft anastomoses. To evaluate the safety and efficacy of this device, we compared patients undergoing OPCAB who had proximal graft anastomoses with the Novare Enclose PAD to a separate cohort of patients who had graft anastomosis with a conventional side-biting aortic clamp.

## PATIENTS AND METHODS

### Patients

Two hundred twenty patients underwent coronary artery bypass surgery at the Bryn Mawr Hospital between January 2003 and December 2004. One hundred ninety-seven patients (89.5%) underwent OPCAB during this period and are the subject of this review, thus eliminating cardiopulmonary bypass as a potential factor in patient outcomes.

Proximal coronary artery graft anastomoses were constructed either by conventional side-clamp and suture technique, or with the Novare Enclose manual PAD (Figure 1). Patients were selected for either technique in a nonrandom-

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Address correspondence and reprint requests to: Robert S. Boova, MD, Suite 203, 830 Old Lancaster Rd, Bryn Mawr, PA 19010, USA; 1-610-527-1600; fax: 1-610-527-0824 (e-mail: [rsboova@comcast.net](mailto:rsboova@comcast.net)).

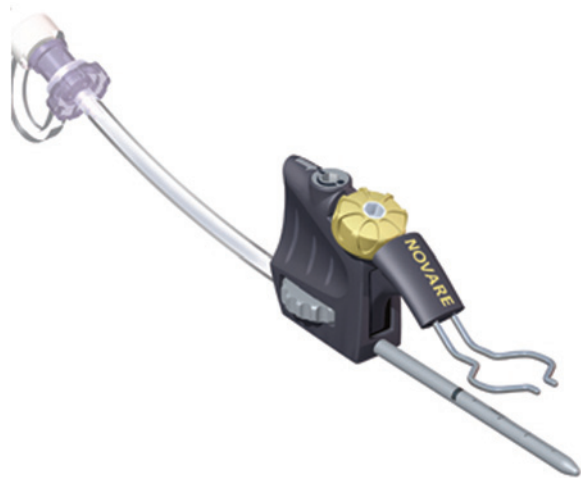


Figure 1. The Novare Enclose proximal anastomosis device (Novare, Cupertino, CA, USA): configuration prior to aortic insertion and deployment.

ized fashion. Those patients judged to be at higher risk for aortic atheromatous disease or stroke underwent proximal anastomosis construction with the PAD. Epi-aortic ultrasound of the ascending aorta was used selectively in patients with a history of stroke, transient ischemic attack, peripheral vascular disease, diabetes, or carotid endarterectomy. Of the 197 patients who underwent OPCAB, 60 patients (30.5%) had proximal graft anastomosis performed with the Enclose PAD, and the remaining 137 (69.5%) patients received the standard side-clamp technique.

Demographic profiles of the 2 patient cohorts are listed in Table 1. The groups were well matched with regards to age, sex, and body habitus. There was no difference in the inci-

Table 1. Patient Demographics\*

	Side Clamp (n = 137)	PAD (n = 60)	P
Mean age	68.9	69.4	.725
Female	41 (30%)	21 (35%)	.508
Obesity	44 (32%)	12 (20%)	.089
HTN	112 (82%)	44 (73%)	.187
CVA	11 (8%)	6 (10%)	.783
MI	62 (45%)	24 (40%)	.535
Recent MI, <21 days	29 (21%)	10 (17%)	.562
EF < 35%	31 (23%)	9 (15%)	.412
Renal failure	6 (4%)	1 (2%)	.678
COPD	34 (25%)	11 (18%)	.361
Carotid disease	21 (15%)	8 (13%)	.829
Diabetes	42 (31%)	21 (35%)	.619
CHF	19 (14%)	10 (17%)	.664
STS risk score	3.31	3.27	.960

\*PAD indicates proximal aortic device; HTN, hypertension; CVA, cardiovascular accident; MI, myocardial infarction; EF, ejection fraction; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; STS, Society of Thoracic Surgeons.

dence of diabetes, hypertension, stroke, chronic obstructive pulmonary disease, or renal failure between the 2 groups. Both cohorts had a  $\geq 40\%$  incidence of previous myocardial infarction, and the incidence of patients with a low ejection fraction ( $< 35\%$ ) (23% with OPCAB versus 15% with PAD,  $P = .412$ ) and congestive heart failure (14% with OPCAB versus 17% with PAD,  $P = .664$ ) was comparable between the 2 groups. The Society of Thoracic Surgeons (STS) coronary bypass risk score was 3.27% for all patients undergoing OPCAB, and there was no difference in STS risk scores between the 2 study groups (3.31% with OPCAB versus 3.27% with PAD,  $P = .960$ ). The mean coronary bypass risk score for the STS National Adult Cardiac Surgery Database is 2.4% [Edwards 2004].

### Operative Technique

Patients undergoing OPCAB were anesthetized under general single lumen endotracheal anesthesia employing short-acting muscle relaxants, narcotics, and inhaled agents to facilitate intra-operative extubation at the completion of the operation (50% intra-operative extubation rate). Arterial and venous conduits were harvested endoscopically in the majority of cases. After median sternotomy, the left internal mammary artery (IMA) to left anterior descending coronary artery distal anastomosis was constructed first in all patients receiving an IMA graft. This step was followed by the completion of the remaining distal anastomoses. Proximal anastomoses were completed either by side clamping the ascending aorta or utilizing the Enclose PAD.

The Enclose PAD is designed to facilitate suture construction of a proximal coronary anastomosis. The device consists of dual internal and external assemblies that isolate the aortic wall. The internal assembly is a post with an expandable membrane, whereas the external assembly is a rigid wire frame (Figure 1). After placing a purse-string suture in the ascending aorta, the internal post is inserted through a needle aortotomy into the aorta. The post is converted to a diaphragm by rotating the lower dial on the device. Rotation of the upper dial approximates the rigid external frame to the internal diaphragm (Figure 2). This approximation creates an isolated segment of aorta with a hemostatic seal, allowing for bloodless aortic incision and punch aortotomy. The anastomosis is completed in a standard parachute fashion regardless of arterial or venous conduit, method of conduit harvest, or tributary ligation. A CO<sub>2</sub> and saline mister blower device is employed to facilitate exposure and provide a clear operating field.

### Statistical Analysis

All data are presented as means. Nominal data were compared between the 2 groups by a Fisher exact test. A Student *t* test was used to compare continuous data between the 2 groups. A *P* value less than .05 was considered significant.

## RESULTS

In the side-clamp group, 199 proximal (1.45/patient) and 406 distal (2.96/patient) anastomoses were constructed. In



Figure 2. The Novare Enclose proximal anastomosis device (Novare, Cupertino, CA, USA): configuration after aortic insertion and deployment of diaphragm and approximation with outer frame assembly.

the PAD group, 107 proximal (1.78/patient) and 205 distal (3.42/patient) were constructed. There was a significantly higher incidence of total arterial revascularization in patients undergoing conventional side-clamp anastomosis (27% with side clamp versus 13% with PAD,  $P < .05$ ; Table 2). At least 1 IMA graft was utilized in more than 87% of all patients and the overall use of IMA, bilateral IMA, and radial artery grafts was similar in both groups (Table 2).

The 2 major endpoints in this study were stroke and death. Three patients (1.5%), all in the side-clamp group, sustained permanent neurologic deficits after OPCAB (STS coronary bypass stroke occurrence is 1.5%; Table 3) [Edwards 2004]. Of the 197 patients in the series, there were 4 deaths, 2 in each group, resulting in an overall mortality rate of 2% (STS database coronary bypass mortality rate is 2.4%) [Edwards 2004].

There were 2 cases of device failure. One required conversion to conventional aortic side clamping, with anastomotic construction completed without adverse outcome. The other case of device failure resulted in completion of the anastomo-

Table 2. Coronary Graft Data\*

	Side Clamp (n = 137)	PAD (n = 60)	P
Proximals (range)	199 (0-4)	107 (1-3)	
Distals (range)	406 (1-5)	205 (2-5)	
1 IMA	122 (89%)	50 (83%)	.352
2 IMA	14 (10%)	10 (17%)	.238
2 IMA + radial	11 (8%)	8 (13%)	.295
All arterial grafts	37 (27%)	8 (13%)	.043

\*PAD indicates proximal aortic device; IMA, internal mammary artery.

Table 3. Stroke and Mortality Data\*

	Side Clamp (n = 137)	PAD (n = 60)	P
CVA	3 (2.2%)	0	.555
Mortality	2 (1.5%)	2 (3.3%)	.587

\*CVA indicates cardiovascular accident.

sis using the device with impaired visibility. There were no anastomotic thromboses, no reoperations for anastomotic hemorrhage, and no patients required anastomotic revision. There were no catheter-related re-interventions required for anastomotic failures, and no there was morbidity or mortality related to proximal anastomosis construction in either group.

## DISCUSSION

PADs were developed to facilitate proximal aorto-coronary bypass graft construction and to reduce aortic manipulation by eliminating aortic clamping. The risk of neurologic injuries may be reduced with the use of these devices. The first generation devices created automatic anastomoses by introducing nitinol or stainless steel into the aorta. These PADs required the construction of proximal anastomoses prior to distals, tributary occlusion with suture ties rather than metallic clips, and were limited to venous grafts only. Deployment of the first generation devices was associated with significant blood loss, and the overall initial results with these devices were mixed. Adverse outcomes included anastomotic leakage, anastomotic thrombosis, graft kinking, and aortic dissection at the deployment site. These complications have limited the use and availability of PADs [Carrel 2004; Lahtinen 2004].

The Enclose PAD is designed to facilitate suture construction of proximal coronary graft anastomoses. Deployment of the device results in minimal aortic trauma and blood loss. Its versatile design does not affect the construction sequence of proximal or distal anastomoses and allows the use of both arterial and venous conduits irregardless of harvest technique (endoscopic versus open, clips versus ligatures for tributary control). An additional advantage of this PAD compared to automatic PADs is that a single device can be used to create multiple proximal anastomoses through a single needle aortotomy. With our standard sequence of distal anastomosis construction first, the Enclose PAD also offers the advantage of immediate myocardial reperfusion following completion of each proximal anastomosis.

Ideal qualities of any new technology include safety, efficiency, reliability, predictable outcomes, and cost control. Our initial experience with the Novare Enclose PAD has been favorable and consistent with the aforementioned qualities. In 60 cases, we had only 2 incidences of device malfunction. Both of these malfunctions resulted in incomplete aortic isolation and suboptimal hemostasis that obscured the operating field. Neither of these incidences ultimately had an adverse impact on the quality of the anastomosis. The device is simple and requires a small area of normal aorta for deployment. This smaller area requirement is especially

advantageous in patients with diseased ascending aortas. The device eliminates the need for a side-biting aortic clamp for anastomosis construction, and therefore reduces the risk of aortic manipulation and aortic wall trauma. The reduction in aortic manipulation has been shown to reduce the risk of atheromatous embolization and end-organ injury, thus improving the safety of coronary bypass surgery [Eckstein 2001; Lev-Ran 2005].

Disadvantages of the Enclose PAD include the added expense of the device to the operation, a limited sewing area within the external assembly of the device, and the need for needle aortotomy, which creates a risk of embolization of atheromatous debris. The most important uncertainty regarding any new anastomotic device is long-term graft patency. As this device is used to facilitate suture construction of the proximal anastomosis, the concern is less than with devices that create automatic anastomoses, however long-term graft surveillance must be performed to validate the safety of the Enclose PAD.

Future technology will continue to improve the efficiency and safety of coronary bypass graft construction. In our initial experience with the Enclose PAD, there were no cases of stroke postoperatively in OPCAB patients who underwent proximal anastomosis construction with the device. We believe that in a subset of patients with severe atheromatous disease of the ascending aorta, deployment of this device with epi-aortic ultrasound guidance is a safer alternative than the application of a side-biting aortic clamp during creation of proximal coronary bypass graft anastomoses. Our experience with the Novare Enclose PAD is the largest to date, and adds to existing reports in the literature advocating use of the device [Akpınar 2005; Aranki 2005]. This tool and similar devices may ultimately replace aortic side clamping in coronary bypass surgery.

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## REVIEW AND COMMENTARY

### *Invited Commentary from Mark M. Levinson, MD, Hutchinson Hospital, Hutchinson, Kansas, USA*

The Enclose (Novare, Cupertino, CA, USA) is a new device that provides aortic isolation during construction of a proximal aortic graft anastomosis. Unlike some of the newer proximal anastomotic strategies that are derivatives of stent technology, the Enclose does not implant any foreign material into the conduit. The Enclose provides a blood-free space roughly the size of a standard punch hole without the use of deforming aortic clamps. Any type of conduit can be sewn to the aorta using conventional suturing techniques. It is very encouraging that Dr. Boova et al are now able to confirm the absence of graft complications in Enclose patients.

The unique design of the Enclose provides some opportunities as well as challenges. In patients with focal atherosclerotic plaque in the ascending aorta, mechanical clamping may risk embolization and stroke. I compliment the authors on their use of epi-aortic ultrasound to examine the ascending aorta in all patients with risk factors. A finding of focal plaque implies that the surgical technique should be modified to avoid any trauma to these areas of potential emboli. It is theoretically possible to place the Enclose in a disease-free area and construct a proximal anastomosis without the risk of plaque trauma. In my experience, the Enclose does exert some deforming forces on the aorta if placed at right angles to the direction of flow, particularly on the lesser curve. The internal stem (which contains the occlusive membrane) is a stiff structure. When pressed up against the inside of the aorta as the device is tightened, I have occasionally observed a point-like indentation in the aorta. Fortunately, no intimal injury has occurred to date. However, I recommend that, whenever possible, the device be oriented parallel to the flow stream so the native aortic curvature is not draped over the internal stem.

After the internal membrane is deployed and the outer sealing band tightened to create a water-tight seal, it can be difficult to fully insert the aortic punch. In some cases, I have obtained a partial thickness punch of the aorta and it then becomes quite difficult to get the intimal remnant cleanly excised. It appears that once the device is fully deployed the internal stem blocks the entry of the punch anvil into the aortic lumen and predisposes to an intramural cut. A new

Enclose design was issued to lessen this problem, but I have not experienced much improvement.

There are 2 solutions. First, the initial knife hole should be gently dilated with a tine-tipped mosquito clamp to permit easy entrance of the punch anvil. The second solution is to loosen the occlusion pressure on the device using the rotary knob. This change allows the internal stem to be pushed away by the anvil. I have found it is not necessary for the device to be fully occlusive when inserting the punch. If a little bleeding occurs during this step, it is very tolerable and will disappear when tightening the device after a successful punch.

The author indicates that he experienced 2 device failures. These incidents are not a concern because the device can be easily replaced using the following technique. The external band is loosened until there is a little bleeding. Then the assistant covers the proximal anastomotic site with a finger while the internal membrane is collapsed and the device is withdrawn. The aortic entry is controlled with a purse string while a new device is inserted. When the device gets close to the aortotomy, the internal membrane is deployed and the device partially tightened to bring the membrane close to the intima. Then the device is slid into place under the aortic punch hole and tightened. Bleeding is transient and easily controlled with local pressure. Once the device is tightened, bleeding disappears entirely and suturing can resume.

One criticism I had initially with the Enclose was the small anastomotic window. This small window appears to mandate relatively thin bites of aortic tissue with each needle pass, particularly at the 3:00 and 9:00 positions (relative to the device mechanics). I have not experienced a suture tear-out or an

anastomotic disruption, but I have been concerned that someday the small bites taken inside the circumference of the device will not hold. Thus, I have developed some “tricks” to permit wider aortic bites. The first trick is similar to the one described above. Loosen the device and slide it from side to side. By shifting the device from side to side when needed, deeper bites can be placed at the crucial 3:00 and 9:00 positions.

Also, if the needle cannot exit on the inside of the metal bar, then loosen the clamping force of the device a little and swing the needle point through the aorta so that it exits outside (or external to) the clamping bar. It turns out that it is easy for the surgeon to “feel” the internal edge of the device with the needle point. An RB-1 or RB-2 needle curve invites a wider bite and will often spontaneously find its way outside the external bar. Next, just reverse the needle and sew back “inside the circle” at the same spot, coming just underneath the external bar with a superficial bite. Even though the needle exited the aorta outside the device, you can bring it back inside with a superficial reversal stitch whenever needed.

Finally, the device is more prone to a rocking motion from aortic pulsatility than a partial clamp. In a hyperdynamic heart, this motion can slow the pace of suturing. If so, apply your favorite coronary stabilizer to the nearby aorta. Suction-positioning devices (such as the Starfish or X-pose) will also work to reduce aortic motion and facilitate suturing.

The Enclose appears to be a versatile device and a true advance that every surgeon should know how to use. There are some “tricks,” but after a few cases it is clear that this device should be part of our everyday tools for coronary surgery. When the aorta is diseased, using the Enclose can be life saving.