

# Recent Advancements in Devices for Off-Pump Coronary Artery Bypass Grafting

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According to the annual registry of the Japanese Association for Coronary Artery Surgery, the percentage of off-pump coronary artery bypass grafting (CABG) procedures performed in Japan in recent years has increased rapidly, comprising of more than 60% of all CABG procedures in 2004. This widespread use of off-pump CABG is mostly owing to the recent technological advances in devices that are specifically designed for beating heart surgery.

## Stabilizers and Positioners

To accomplish accurate anastomoses on the beating heart, local stabilization of cardiac wall motion is extremely important. The invention of the stabilizer in the late 1990's significantly improved anastomotic quality on the beating heart.<sup>1)</sup> Initially, a compression stabilizer with a horseshoe-shaped metal blade was commonly used. However, the pressure applied to the ventricle by this device adversely affected ventricular function.

Borst et al.<sup>2)</sup> introduced the concept of the suction stabilizer. Recently, various sophisticated suction stabilizers such as the Octopus® (Medtronic Inc., Minneapolis, MN) and ACROBAT™ (Guidant Corp., Cupertino, CA) are commercially available. These advanced stabilizers provide almost complete immobilization of the target vessel on the beating heart. The suction paddles are malleable so as to conform to the epicardial surface of the heart and immobilize it in the horizontal (X, Y) plane by lifting the epicardium with vacuum pressure, thereby reducing pressure on the ventricle. An articulating arm minimizes movement in the vertical (Z) plane.

The most challenging step in performing a beating heart anastomosis is in positioning the heart so that all coronary artery targets are well visualized and accessible, while at the same time maintaining hemodynamic stabil-

ity. The heart can be elevated and rotated by pulling on multiple sutures that are placed in the posterior pericardium. These sutures are referred to as Lima sutures after Ricardo Lima from Brazil.<sup>3)</sup> Although this technique enables access to all coronary territories, displacement of the heart using deep pericardial sutures typically results in some degree of hemodynamic compromise.<sup>4)</sup>

Apical suction heart positioners such as the Starfish™ (Medtronic Inc.) and Xpose™ (Guidant Corp.) were invented to displace the heart by holding the apex with a compliant suction cup and fixing the position with an articulating arm.<sup>5)</sup> Clinical and experimental studies showed less hemodynamic changes due to vertical heart displacement with the use of an apical suction device when compared to the deep pericardial sutures technique.<sup>4,6,7)</sup> However, because the whole weight of the heart is suspended only at the apex, possible myocardial injury or spontaneous detachment during anastomosis makes such devices controversial. Spontaneous atrioventricular groove disruption during use of the apical suction positioner has been reported.<sup>8)</sup> Severe ischemia of the suctioned apical myocardium induced by the collapse of coronary vessels due to vacuum pressure has also been observed.<sup>9)</sup>

More recently, a multi-suction heart positioner, TENTACLES™ (Sumitomo Bakelite Co., Ltd., Tokyo, Japan) has been invented in Japan.<sup>10)</sup> This unique positioner consists of three small independent suction cups with vacuum tubes and elastic traction strings and no articulating arm. Each suction cup is small so that it can be applied to avoid compression of the surface coronary artery. Cardiac weight is dispersed over multiple suction sites, thus minimizing the possibility of myocardial disruption and accidental detachment.

## Shunts and Coronary Occlusion

Two major advantages of the shunt are myocardial protection and the hemostatic effect.<sup>11,12)</sup> The shunt allows for distal perfusion while maintaining hemostasis of the anastomotic site. With use of either an intraluminal or external shunt, the distal coronary artery is perfused pas-

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sively depending on the patient's arterial pressure.<sup>13)</sup> A shunt is particularly effective during anastomosis of the right coronary artery because simple occlusion of this artery often leads to critical hemodynamic compromises such as bradycardia and hypotension.

However, because the driving pressure of the shunt is passive pressure, the perfusion flow obtained by shunting is limited. For example, the perfusion flows obtained by external shunts of 1.7- and 2.0-mm diameter under normal arterial blood pressure are only 13 and 22 ml/min, respectively.<sup>14)</sup> Although this flow rate is less than that of the normal coronary artery flow, it is usually sufficient to prevent an ischemic event during the short period of coronary anastomosis. If the blood pressure is very low, however, a sufficient flow rate may not be obtained. Theoretically, shunt flow is determined by the blood pressure and the internal diameter of the shunt. According to the Hagen-Poiseuille equation, flow rate is proportional to the perfusion pressure and to the 4<sup>th</sup> power of the internal radius of the shunt. The internal diameter of commercially available 2-mm shunts is about 1 mm. If this internal diameter narrows by even 0.1 mm, the theoretical flow reduction becomes 34%. Therefore, effective flow cannot be expected when a small shunt of less than 1.5 mm is applied. The only effect of a small-sized shunt is to create hemostasis. To solve these limitations associated with shunts, an active perfusion system has been advocated by some researchers.<sup>15,16)</sup> Although active perfusion is effective even during hypotensive situations, this technique has not yet gained popularity due to the complexity of the perfusion circuit and higher cost.

The major drawback of the shunt is the endothelial injury induced by the shunt insertion procedure. Hangler et al.<sup>17)</sup> reported significantly higher endothelial injury after shunting compared with vessel loop occlusion in human coronary arteries. A safe occlusion technique using a spring-equipped, force-adjustable tourniquet would be less invasive to the coronary endothelium than is shunt insertion.<sup>18)</sup>

Understanding these advantages, disadvantages, and limitations, a shunt of the appropriate size can be applied selectively in patients in whom critical ischemia is expected during anastomosis; routine shunt insertion into the coronary artery should be avoided.

## **Automated Proximal Anastomotic Device and Proximal Anastomotic Assist Device**

Use of a side clamp for the performance of proximal anas-

tomoses in coronary artery bypass surgery may injure the ascending aorta and cause intimal tears, with subsequent dissection or debridement of atherosclerotic material and stroke. Various devices have been developed to perform proximal bypass anastomoses without the necessity of side clamping.

The Symmetry™ Aortic Connector System (St. Jude Medical, Inc., St. Paul, MN) first-generation device was the first commercially available automated proximal anastomotic device.<sup>19)</sup> Since receiving CE Mark and Food and Drug Administration (FDA) approval in May 2001, more than 40,000 of these devices have been implanted worldwide.<sup>20)</sup> However, its distribution has been suspended from December 2004, because of a high incidence of graft stenosis or occlusion.<sup>21)</sup>

Recently, Cardica, Inc. (Redwood City, CA) developed an anastomotic device called the PAS-Port™ System, which consists of a single tool that allows the surgeon to create the aortotomy and deploy the implant in one single action. The specific design of the PAS-Port™ device avoids exposure of foreign material inside the graft and minimizes the total amount of blood exposed to the nonintimal surface inside the aortic lumen. Gummert et al.<sup>22)</sup> reported promising short- and mid-term patencies of 100% and 98%, respectively. One disadvantage of automated anastomotic devices is the 90° take-off angle of the graft. Another limitation is that the proximal anastomosis must be performed before the distal anastomosis. More recently, Cardica Inc. has developed an innovative distal anastomotic device called the C-Port®, which received CE Mark approval in July 2006. These automated anastomotic devices may open the door to a new era of endoscopic off-pump CABG.

Another method of aortic anastomosis without the use of a side-biting clamp has been realized with proximal anastomotic assist devices such as the HEARTSTRING® proximal seal system (Guidant Corp., Santa Clara, CA)<sup>23)</sup> and the Enclose® II (Novare Surgical Systems, Inc., Cupertino, CA).<sup>24)</sup> These devices allow the surgeon to perform a clampless proximal anastomosis of either a vein or arterial graft using standard hand suturing techniques for which long-term patency is promising.

The HEARTSTRING® proximal seal is delivered into the aorta via a punch hole site and provides a sealed region to facilitate the proximal anastomosis. The proximal seal covers the punch hole from inside the aorta because the blood pressure pushes, and a tension spring mechanism pulls, the seal against the aortic wall. The major drawback of this device is that the seal does not

provide a completely bloodless field, and continuous oozing of blood is usually present. Combined use of a blower mister can provide a bloodless surgical field. However, a case of cerebral air emboli related to the use of the HEARTSTRING® device in combination with a blower mister has been reported.<sup>25)</sup> This is a new, device-related surgical complication.

The Enclose® II consists of a lower jaw with an expandable membrane and an upper jaw with a non-expandable wireform. The space between the lower jaw membrane and upper jaw provides an adequate bloodless area (1 cm<sup>2</sup>) for conventional suturing. The major drawback of the Enclose® II device is that it requires an alternate access site, and some degree of aortic trauma during insertion and manipulation of the device can occur. Nevertheless, being able to perform more than one proximal anastomosis through a single insertion port is an advantage over that of other anastomotic devices.

## Conclusion

Owing to various newly developed surgical devices, off-pump CABG has become a safe, reproducible, and technologically reliable procedure. Nevertheless, the surgeon must understand the advantages, disadvantages, and limitations of each device, and the most appropriate devices must be selected in each individual case. Improper device selection may lead to device-related complications. Another shortcoming of most of these devices is that they are single-use only, and this is likely increase surgical cost. However, I believe that compared to the high cost of implantation of multiple expensive drug eluting stents, multivessel off-pump CABG will become the most promising and cost-effective procedure for revascularization of ischemic myocardium.

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