Early bypass occlusion after deployment of Nitinol connector devices

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Background: Reducing the negative side effects associated with extracorporeal circulation is the major advantage of off-pump revascularization. However, side clamping of a calcified aorta for proximal anastomoses can cause emboli, resulting in neurologic damage. This problem has been addressed by introducing a mechanical anastomosis device (Symmetry, St Jude Medical) that allows vein-to-aorta anastomosis without manipulating the aorta. This report describes our experience with this device.

Methods: Between June 2001 and April 2002, 77 connectors (1.3 per patient) were deployed in 61 patients (51 men and 10 women; mean age, 68 ± 8.6 years) undergoing off-pump coronary artery bypass grafting or beating-heart revascularization. Intraoperative quality assessment included transit-time flow measurement (Medistim) and indocyanine green–based angiography (Spy, Novadaq).

Results: The surgeons were meticulously trained in loading of the device. No postoperative neurologic deficits were detected. Fifty-three patients had an uneventful course. However, 8 (13.1%) patients with 12 implanted connectors were symptomatic within 8 months (1 day to 8 months). Angiography revealed significant (95%) stenosis or even occlusion of the proximal vein-to-aorta anastomosis at the level of all connectors. Four patients underwent reoperation (2 dilated-stented and 2 treated with drugs).

Conclusion: On the basis of these observations, the routine use of the connector was halted at our institution. At the moment, the use of this therapy is reserved for patients with severely calcified aortas with no technical alternative. Further investigations appear necessary to evaluate the clinical patterns of this otherwise promising technology.

Over the last years, off-pump coronary artery bypass (OPCAB) and minimally invasive cardiac surgery have been progressively performed. Especially in the elderly, the reduced morbidity and mortality of OPCAB surgery appears to be related to the avoidance of the negative pathophysiologic effects of extracorporeal circulation. In addition to the elimination of the complex systemic inflammatory response during and after extracorporeal circulation, a major concern with OPCAB surgery remains the manipulation of the ascending aorta, with
potential plaque mobilization and the subsequent increased risk of neurologic complications.

Recently, the Symmetry Aortic Connector System (SACS; St Jude Medical, Inc, Minneapolis, Minn) was introduced as a mechanical device to perform proximal vein graft anastomosis without the need for side clamping the aorta. With the first clinical testing of the SACS in early 2001, several groups reported its successful application in OPCAB surgery.2

Since June 2001, the SACS was routinely used in OPCAB surgery (less in beating-heart procedures) in our institution. The deployment was indicated when transesophageal echocardiography revealed calcification of the ascending aorta of grade II or more, digital examination of the ascending aorta showed severe calcification, or mean arterial pressure of less than 60 mm Hg could not be medically achieved for low-risk side clamping. The surgeons were meticulously trained in the mounting and deployment of the device before intraoperative application, and consequently, we rarely encountered any severe intraoperative malfunctions of the connector. Handling of the SACS is uncomplicated, and deployment time is reasonable. After loading the vein segment on the device, a hole is cut into the ascending aorta with the St Jude Medical cutter. Subsequently, the device is introduced, and the vein graft is fixed to the aortic wall with the Nitinol-based connector. Because of the perpendicular implantation of the vein segment to the aorta, it is crucial to determine the correct position to avoid any potential angulation and kinking of the bypass graft with subsequent early occlusion. Hence graft flow was routinely assessed by using a transit-time flow probe (Medistim, Norway) or the indocyanine green–based SPY system (Novadaq, Canada) after each anastomosis and before sternal closure.

Despite these measurements, we encountered several difficulties after the use of the connector system. We not only observed intraoperative malfunction but also, more importantly, early postoperative complications necessitating several emergency reinterventions. Given the relatively high

### TABLE 1. Summarized data of presented cases

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Age/sex</th>
<th>Primary procedure</th>
<th>Performed bypasses</th>
<th>Affected graft at the level of connector</th>
<th>Time to clinical symptoms/diagnosis</th>
<th>Type of reintervention</th>
<th>Antiplatelet Therapy</th>
<th>Figure no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>57 y/M</td>
<td>OPCAB</td>
<td>LITA-LAD-D</td>
<td>V-RCA (o)</td>
<td>4 d</td>
<td>None</td>
<td>Aspirin 1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>76 y/M</td>
<td>Beating heart</td>
<td>LITA-LAD</td>
<td>V1-RCA (s, 95%) V2-intermedius (o)</td>
<td>5 wk</td>
<td>PTCA and stenting of RCA at level of connector</td>
<td>Aspirin 2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>67 y/M</td>
<td>OPCAB</td>
<td>V1-RCA</td>
<td>V1-RCA (s, 95%) V2-D-OM-Cx (s, 95%)</td>
<td>5 mo</td>
<td>PTCA of V1-RCA and PTCA and stenting of V2-D-OM-Cx at level of connector</td>
<td>Aspirin 3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>58 y/M</td>
<td>OPCAB</td>
<td>LITA-LAD V1-RIVP-RCA V2-intermedius-OM</td>
<td>V1-RIVP-RCA (o) V2-intermedius-OM (s, 80%)</td>
<td>6 mo</td>
<td>None (patient refused)</td>
<td>Aspirin 4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>64 y/F</td>
<td>OPCAB</td>
<td>LITA-LAD V-D</td>
<td>V-D (o)</td>
<td>3 d</td>
<td>CABG (V-D-LAD)</td>
<td>Aspirin 5</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>81 y/F</td>
<td>Beating heart</td>
<td>V1-OM1-OM2 V2-LAD-D-Intermedius</td>
<td>Dissected LITA-LAD V2-PDA (o)</td>
<td>7 d</td>
<td>OPCAB (LITA-V2)</td>
<td>Aspirin + Plavix</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>70 y/M</td>
<td>OPCAB</td>
<td>RITA-RCA V1-D-Cx</td>
<td>Intraoperative Reimplantation V1-D-Cx</td>
<td></td>
<td></td>
<td>Aspirin + Plavix</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>66 y/M</td>
<td>OPCAB</td>
<td>RITA-RCA V-Cx</td>
<td>V-Cx (s, 99%)</td>
<td>8 mo</td>
<td>Reoperation V-Cx-LAD</td>
<td>Aspirin + Plavix</td>
<td>7</td>
</tr>
</tbody>
</table>

incidence of these complications, we decided to summarize and present these complicated cases to stipulate a discussion regarding the routine application of connecting devices.

Case Reports
A brief summary of data is depicted in Table 1. Angiograms and further information are depicted in the corresponding figures (Figures 1-7).

Discussion
OPCAB surgery achieved increasing acceptance as an alternative to conventional coronary artery revascularization and its complications after cardiopulmonary bypass and
cardioplegic cardiac arrest. With the improvements in retractor and stabilization systems and exposure techniques, multivessel OPCAB is feasible in the majority of cases. Several studies have shown a decreased operative mortality and postoperative morbidity, decreased intensive care unit and hospital stay, and reduced costs.$^{3,4}$ OPCAB appears to be an especially attractive approach in the management of patients with a heavily calcified aorta. The prevention of neurologic problems after coronary artery revascularization represents a complex and multifaceted issue; however, a major contributing factor is the avoidance of manipulations of the aorta.

With the recent introduction of automated sutureless anastomotic devices, it is possible to eliminate aortic manipulation and to avoid crossclamping of the aorta. The St Jude Symmetry aortic connector system has gained increasing popularity as a mechanical anastomotic device by facilitating proximal vein-graft-to-aorta anastomoses. Several groups performed initial studies evaluating the safety and efficacy of the new mechanical anastomotic device. Verma and colleagues$^5$ showed no difference between saphenous vein graft segments after loading and deployment by using the aortic connector system compared with conventional techniques. A study by Eckstein and associates$^2$ demonstrated the safe and reliable application of the aortic connector system in 20 consecutive OPCAB procedures. However, all patients had only a 3-month follow-up that demonstrated no cardiac-related events. In contrast, a review by Hornik and coworkers$^6$ in 45 patients receiving 69 aortic connector devices during OPCAB and on-pump procedures with a follow-up of several weeks revealed stenosed grafts in 4 patients, requiring percutaneous transluminal coronary angioplasty (PTCA) or redo operations.

The present report showed comparable findings. The connector system was used in 61 patients during OPCAB

![Figure 5. Angiogram revealing occlusion of a vein graft to the diagonal coronary artery at the level of the device (circle).](image)

![Figure 6. Angiogram revealing occlusion of a vein graft to the posterior descending coronary artery. When pushing the catheter through the device, bypass could be exposed (circle).](image)

![Figure 7. Angiogram revealing 99% stenosis of a vein graft to the circumflex coronary artery at the level of the device (circle).](image)
and beating-heart surgery. All patients underwent close routine follow-up by the cardiologic referral centers of our institution. Seventy-seven aortic connectors (1.3 per patient) were deployed. After a mean follow-up of 88 days (1 day to 8 months), 8 patients demonstrated stenosed or occluded vein grafts. The situation was individually managed with reoperation in 4 patients, PTCA in 1 patient, and PTCA with subsequent stent implantation in 1 patient. Two patients refused any further intervention. All patients were undergoing antiplatelet therapy, consisting of 100 mg of aspirin alone (n = 5), and beginning in 2002, a daily dosage of 75 mg of clopidogrel bisulfate (Plavix; Sanofi-Synthelabo, Paris, France) (n = 3) was added to this regimen. The regimen has been changed for all coronary artery bypass grafting operations, regardless of the technique used for revascularization.

The total observed restenosis-occlusion rate of 15.6% of connectors is comparable with the findings of Fitzgibbon and associates, who reported an occlusion rate of 12% for handsewn vein grafts within the first postoperative year. Antiplatelet therapy consisted of aspirin and dipyridamole handsewn vein grafts within the first postoperative year. Antiplatelet therapy consisted of aspirin and dipyridamole in this study. However, graft fate was primarily the result of distal anastomotic irregularities.

Reviewing our patients who had undergone revascularization in the same time period without the use of proximal connectors but with conventionally hand-sewn proximal anastomoses, none had to undergo reoperation because of proximal stenosis or occlusion of the graft.

In contrast to the comparable rate of restenosis, we observed the occurrence of stenosis-occlusion of the mechanically anastomosed bypass grafts at an early time point postoperatively. All patients were re-examined because of dyspnea, chest pain, or electrocardiographic changes, increase of enzyme levels, or both. Furthermore, angiographic and intraoperative findings located the restenosis-occlusion at the level of the device, whereas the location of spontaneous restenosis of saphenous bypass grafts is described to be located at the distal part of the anastomosis. Regarding timing and location of the stenosis process, a potential involvement of the device has to be taken into consideration.

The proximal vein–aorta anastomosis is performed by using a connector that is exposed to the blood flow on the edge of the aortic puncture side over a length of several millimeters along the intimal layer of the vein graft. The connector consists of Nitinol, an alloy of nickel titanium that shows favorable mechanical and physiochemical properties. Nitinol is already used in a variety of medical devices, such as vena cava filters and self-expanding coronary stents. In vivo studies demonstrated favorable patency rates for implanted Nitinol stents. Sutton and coworkers implanted 12 Nitinol stents with an internal diameter of 5 mm into the iliac and femoral arteries of dogs for 2 years. Patency rates were 100% at 2 years. Huang and colleagues implanted Nitinol stents into the external iliac arteries of dogs and pigs for 8 months and observed the formation of a smooth neointima with the absence of any inflammatory cell infiltration or foreign giant cell reaction. After these results, it appears that the observed early stenosis of the bypass grafts is not due to the application of Nitinol. However, long-term patency rates of the Symmetry Nitinol connectors are currently unknown, and angiographic long-term follow-up studies should be performed.

We have used the connector mainly in patients with severely calcified ascending aortas to prevent embolization by avoiding side clamping. These patients supposedly benefit most from the device. Considering the high costs per connector, we have restricted the application to patients with diseased aortas.

A major concern regarding stenosis of the Symmetry connector is the potential angulation and kinking of the vein graft distally to the device. In all cases special attention was paid to the accurate placement and length of the graft. Thus no immediate intraoperative angulation or kinking of the vein grafts was observed. In addition, all surgeons had to pass a short learning curve for managing the fast and reliable handling of the new connector device, but we did not observe any accumulation of early restenosis during this period. Furthermore, assessment of blood flow through the bypass grafts was routinely performed to confirm appropriate graft function. However, an impaired flow caused by slight kinking or angulation of the vein distally to the perpendicular implanted connector could result in an early stenosis. A further aspect of concern appears to be the transformation zone between the stiff vessel caused by the intraluminal part of the device and the beginning of the natural elastic part of the vessel wall at the end of the SACS. At this level, turbulence might lead to the induction of early proximal stenosis of the mechanically anastomosed vein grafts.

Another proposed reason for the occurrence of early stenosis might be the reduction of the effective orifice area of the proximal anastomosis by the vein connector mechanism. The Nitinol connector device invaginates the vein walls through the aortotomy and therefore can potentially cause a relative proximal stenosis intraoperatively.

In conclusion, the Symmetry connector system appears to be a promising new device facilitating OPCAB surgery without the need for side clamping the aorta. On the basis of the presented observations, a routine application of the SACS might not be advisable yet and might have to be reserved for patients with a severely calcified aorta for whom no other techniques are feasible. It has to be strongly emphasized that particular care has to be taken concerning appropriate placement of the connector to avoid any kinking of the vein graft. Future improvements of the device should
aim toward the development of a flexible stent device that would avoid any potential graft kinking and toward the elimination of any nonphysiologic intravascular surfaces. Furthermore, early angiographic follow-up studies appear to be clearly indicated for evaluation of the performance of this new device.

References
