Initial Experience With Proximal Anastomoses Performed With a Mechanical Connector

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Background. **The Symmetry Bypass System Aortic Connector (St Jude Medical, Inc) is a novel device for the construction of sutureless proximal anastomoses. The connector allows attachment of saphenous vein grafts to the aorta without requiring aortic clamping. We report our initial clinical experience with this device.**

Methods. **In a 2-month period from May to July 2001, a total of 139 consecutive proximal anastomoses were performed in 67 patients using the connector. All procedures were performed on a beating heart without cardiopulmonary bypass or any aortic clamping. Intraoperative variables and postoperative results were prospectively collected and retrospectively analyzed.**

Results. **Of 139 consecutive proximal anastomoses 138 (99.3%) were successfully completed with the device. One anastomosis required suture revision because of misdeployment. Six anastomoses (4.3%) required an additional suture for leak. Predeployment problems included connector loading/preparation malfunction in 10 grafts (7.2%), five because of human error and five technical failure. There was no operative mortality, perioperative myocardial infarction, or stroke. Vessels bypassed included the circumflex system (n = 59), right coronary artery and branches (n = 48), diagonal branch (n = 26), and left anterior descending coronary artery (n = 6). At a mean follow-up of 7 months, survival was 94.1% and survival free of major adverse cardiac and cerebrovascular events (MACCE) was 88.1%.**

Conclusions. **Initial clinical experience with a sutureless proximal saphenous vein graft to aorta anastomosis performed with a mechanical connector demonstrates safety, reliability, and ease of use. Surmounting a brief learning curve improves the subtleties of device loading and deployment. Further benefits will be determined in an ongoing randomized study.**

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Extensive research into alternatives to the sutured anastomosis has recently culminated in the introduction into clinical cardiac surgery of a mechanical connector to perform an end to side anastomosis between saphenous vein grafts and the aorta [1]. With deployment of this connector, attachment of saphenous vein conduits to the aorta can be performed without the necessity of placing a clamp on the aorta ("clampless anastomosis"). We describe our initial clinical experience with a mechanical connector in beating heart coronary artery bypass surgery.

Material and Methods

In a 2-month period from May to July 2001, 139 consecutive proximal anastomoses of saphenous vein graft to aorta without suturing or aortic clamping were performed in 67 patients undergoing multivessel beating heart coronary artery bypass grafting. The patients were consecutive and nonselected, except for instances in which manufacturing issues precluded availability of the device for all patients. Exclusion criteria included patients who underwent all arterial grafting or in whom inadequate saphenous vein graft was available because the size was either larger or smaller than the available connector system. No patients were excluded because of aortic disease.

The Device

The Symmetry Bypass System Aortic Connector (St Jude Medical, St Paul, MN), is a device constructed of nitinol, a nickel–titanium alloy with unique shape memory characteristics that allows manipulation of the device into a "deployable" shape with return to its original shape after deployment. The connector has three key features (Fig 1): (1) internal and external struts to position the connector in the aorta, "sandwiching" the aortic wall between the sets of struts; (2) radially expandable "racetracks" to provide a hemostatic seal; and (3) six to eight vein hooks

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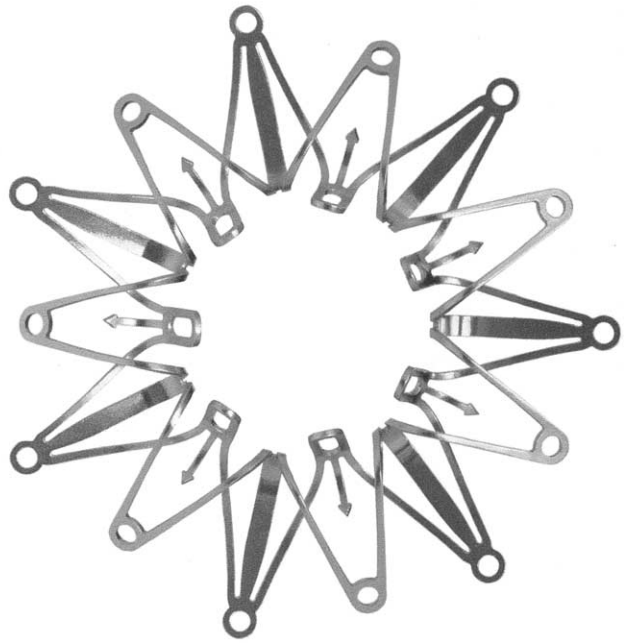

Fig 1. Symmetry aortic connector composed of nitinol memory shape metal.

(depending upon the size) to attach the saphenous vein to the connector.

The connector is available in four, color-coded sizes based upon the outside diameter of the saphenous vein, ranging from 4.5 to 7.0 mm. The device received regulatory approval in Europe obtaining the CE Mark in May 2000, and in the United States receiving Food and Drug Administration clearance in May 2001.

The Procedure

All procedures were performed on a beating heart through a median sternotomy incision. Standard operative techniques for off-pump surgery were used including routine use of stabilization for distal anastomoses and suction positioners for access to all surfaces. A few specific changes from standard technique were necessitated for deployment of the connectors. The device as currently designed can only be used with saphenous vein grafts and not arterial conduits and it is necessary to perform the proximal anastomosis between saphenous vein graft and aorta first.

Once the saphenous vein graft has been harvested and target distal vessels identified, the saphenous vein segments are loaded into a delivery device. A color-coded caliper is available to size the saphenous vein graft and choose the appropriate size connector–delivery system. This portion of the procedure is typically performed by the surgical assistant and takes approximately 3 to 5 minutes per graft. Next the proximal anastomotic site on the aorta is chosen and the adventitia is cleared from this site. It is necessary to deploy the connector at a right angle from the aortotomy and therefore the usual anterior aortic graft sites cannot be used (Fig 2). Thus, grafts

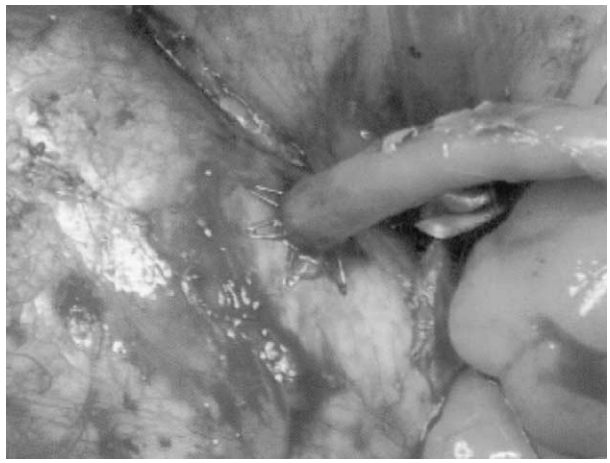

Fig 2. Saphenous vein graft attached to the ascending aorta with a connector.

to the right coronary artery are typically brought from the right side of the aorta, or low on the anterior aorta so that the grafts lies in the atrioventricular groove so that kinking does not occur. For the left coronary system vessels, the grafts are brought from the left side of aorta so that they course smoothly over the pulmonary artery (Fig 3).

Before deployment, the systolic blood pressure is lowered to less than 100 mm Hg with systemic vasodilators. The anastomosis is then performed without placement of a clamp on the ascending aorta in the following manner. A separate aortic punch is used to core an aortotomy site capturing the divot of aortic wall in the device at the chosen site and the surgeon's index finger is then placed over the aortotomy. The carrier with the loaded saphenous vein graft is then placed in the aortotomy and the device-saphenous vein graft composite is deployed. The average time of deployment is typically less than 1 minute per anastomosis. The site is immediately examined for hemostasis. On the rare occasion that leakage

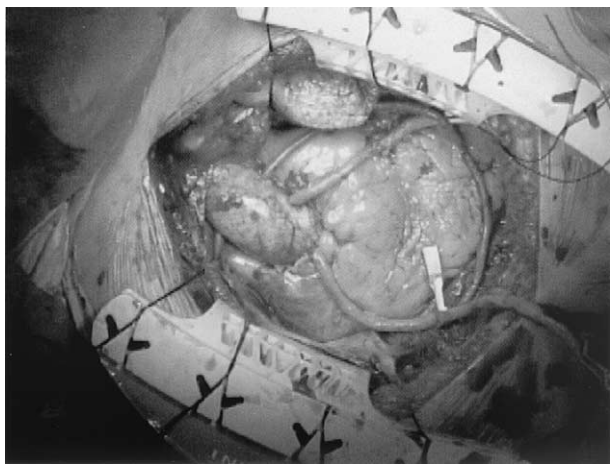

Fig 3. Typical location of grafts placed with the connector on the ascending aorta to avoid graft kinking.

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occurs, an additional hemostatic suture can be placed with care not to include the connector system in the suture. If nondeployment or mechanical failure should occur, the "bailout" maneuver is simple traction on the device to remove it followed by suturing. Upon proper deployment, the remainder of the operation is completed.

Postoperatively, patients were managed with an antiplatelet regimen of aspirin 325 mg/d and clopidogrel 300 mg immediately after surgery and 75 mg/d for 30 days.

Results

The connector was used in 67 patients at two institutions by six surgeons upon receiving regulatory approval for clinical use. There were 68% men and 32% women with a mean age 64 years range (31 to 84 years). All procedures were successfully completed on a beating heart. A total of 201 anastomoses (average 3.0 grafts/patient) were performed with 62 (30%) being arterial grafts. A total of 139 anastomoses were performed with the connector from saphenous vein grafts to aorta. During the same time period, an additional 14 patients underwent all arterial grafting and were thus excluded from the study. A total of 81 patients underwent isolated coronary artery bypass grafting in this period; 237 grafts were placed (3.1 grafts/patient), with 103 (43.5%) of all grafts being arterial (1.3 arterial grafts/patient). Of 139 anastomoses, 138 (99.3%) of the anastomoses were successfully performed with the connector. There was one misdeployment caused by failure to clear adventitia off the aorta with subadventitial firing and hematoma formation. Therefore, the anastomosis was completed with a partial occlusion clamp and suturing. The bypassed vessels included circumflex branches (n = 59), right coronary artery branches (n = 48), diagonal branches (n = 26), and left anterior descending coronary artery (n = 6) patients. No revision due to the lie of the conduits was necessary. Six anastomoses required an additional single suture for an anastomotic leak with care taken to avoid the struts of the device and all were successfully repaired. Additional problems included predeployment issues with loading the saphenous vein graft into the deployment device in 10 grafts (7.2%). The problems were due to human error (mixing the sizes of the connectors, dropping the device from the sterile field) in five grafts and technical failure while loading the vein into the device (premature deployment) in five other grafts. All 10 saphenous vein grafts were subsequently reloaded and successfully deployed.

There were no procedural complications related to the device. Three patients had detectable plaque by digital palpation in the ascending aorta. There was no operative mortality, perioperative myocardial infarction, or stroke. Complications included two sternal wound infections (2.9%), one leg incision infection (1.4%), one acute renal failure (1.4%), and one reoperation for bleeding (1.4%).

Six-month follow-up was attempted in all patients, with 63 of 67 (94%) successfully contacted. Survival at a mean of 7 months (range 6 to 8 months) was 94.1%. There were 4 deaths, 3 of noncardiac causes and one unknown. One death was due to late complications of sternal wound infection, one leukemia, and one unrelated sepsis. The 6-month survival free of major adverse cardiac and cerebrovascular events (MALLE), including death, myocardial infarction, stroke, and target vessel revascularization, was 88.1%. Two patients required stenting of native target vessels because of total occlusion of the connector–saphenous vein graft. Two other patients had proximal ostial anastomotic lesions successfully that were managed by a catheter-based approach. These lesions were treated with balloon dilation and stent placement.

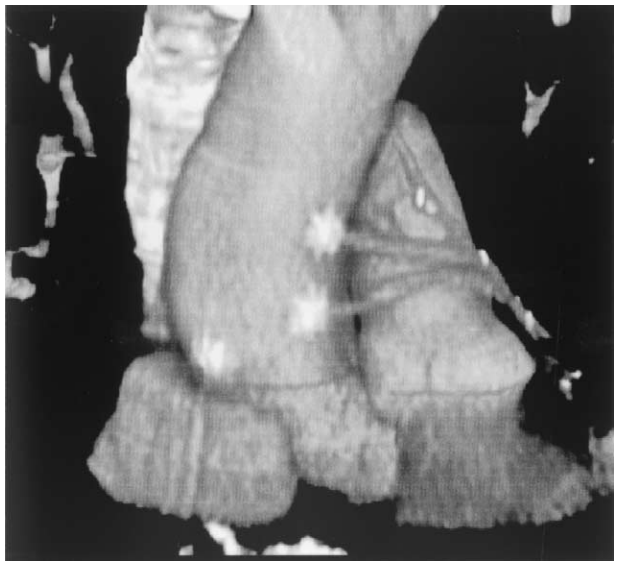

Fig 4. Electron beam angiography 6 months postoperatively, showing three connectors on the aorta with patent saphenous vein grafts.

A total of 20 patients (30%) agreed to undergo a contrast study, electron beam angiography to determine graft patency 6 months or more postoperatively (Fig 4). This technique involves infusion of 150 mL of contrast into a peripheral vein followed by a gated electron beam computed tomogram. After the 10-minute scan, three-dimensional reconstruction is performed. The test shows a good correlation with conventional coronary angiography for graft assessment [2, 3]. A total of 65 grafts were examined. All arterial grafts (20/20) were patent. In all, 47 saphenous vein graft attached to the aorta with connectors were examined. Two were unable to be evaluated for patency. Of the 45 evaluable grafts 39 (86.6%) were patent. Occluded grafts included four to the circumflex system, one to a posterior descending branch, and one to a diagonal.

Comment

Extensive research has been performed to find an alternative to suture for a "facilitated" anastomosis [4]. Alternatives investigated and developed include various mechanical connectors [5–8], nitinol sutures [9], suture devices [10], and biological glues [11].

Our initial clinical experience with a sutureless proximal saphenous vein graft–to–aorta anastomosis performed with a mechanical connector demonstrates safety, reliability, and ease of use. After completion of a training session mandated by the device manufacturer the successful sizing, loading, and deployment of the saphenous vein graft-connector system was not problematic. The few issues regarding loading were gradually resolved with experience.

The benefits of performing the proximal anastomosis with the connector include the ability to perform a "clampless" proximal anastomosis. With arteriosclerosis of the ascending aorta, placement of a partial occlusion clamp for suturing has been demonstrated to be a source of emboli [12]. Whether placement of the proximal anastomosis by a clampless technique results in fewer cerebral emboli by transcranial Doppler ultrasound has not yet been demonstrated; however, clinically there is less manipulation of the ascending aorta and, although our series is small, there have been no adverse neurologic events. Partial calcification of the ascending aorta was not a contraindication to use of connectors in our series. On the contrary, the device appears to offer an advantage in the diseased aorta because a clampless technique can be used. Although we used digital palpation only to detect ascending aortic disease in this series, we now routinely use epiaortic scanning for detection of plaque.

There have also been reports of aortic dissection related to beating heart surgery with placement of a partial occlusion clamp on a pulsatile aorta [13]. This risk is presumably eliminated with use the connector.

Another benefit of the device is a decrease in operative time, especially if the most time-consuming portion of connector use—ie, loading the saphenous vein graft into the device–is performed by an assistant. Three proximal anastomoses can be performed routinely in a total elapsed time of less than 2 minutes.

A clear technical operative benefit is in reoperative coronary procedures, especially with patent old saphenous vein grafts. The ability to perform a proximal anastomosis with minimal dissection and mobilization of the ascending aorta without placement of a clamp significantly facilitates this portion of the procedure. Circumflex revascularization through a lateral thoracotomy incision is significantly facilitated with the connector [14]. Placement of a proximal graft on the descending aorta just above the diaphragm is significantly facilitated by the connector system. Indeed, expanded use of anastomotic connectors may, in the long term, significantly facilitate limited access coronary revascularization.

Disadvantages to the use of the connector include the added cost of the device. At a current price of $450/connector, there is significant incremental cost added to the procedure. Whether this added cost can be offset with shorter operative time or possibly improved outcomes has not been demonstrated. Use in severely cost-constrained health delivery systems will be problematic. Whether the cost will eventually be lowered with the impending clinical introduction of competitive devices into the marketplace is also unknown.

Another significant disadvantage for many coronary surgeons is the requirement for the proximal anastomosis to be performed first. As most surgeons (ourselves included) routinely perform the distal anastomosis first, this change in technique requires some adjustment in the usual operative choreography. The major issue is judgment of graft length, but this can be surmounted with experience. Another change in operative technique is the requirement for placement of the graft from a different place in the ascending aorta. Because the graft emanates at a 90-degree angle from the aorta, placement in the usual anterior aspect of the aorta is not possible. However, one can quickly adapt to newer advantageous locations. Both of these disadvantages will soon be obviated, both by a second generation of the current device and by competitive devices soon to be released. The requirement for a "proximal first, right angle" anastomosis will be replaced by connectors that allow an "anatomic" side-to-side, "functional" end-to-side anastomoses.

Multiple significant questions still exist including long-term patency results with use of the device. Concerns have been raised regarding the nitinol connector material interfacing with the lumen of the blood vessel (similar to coronary stents), and whether the same propensity for intimal reaction to the intraluminal device exists. We routinely used antiplatelet therapy with aspirin and clopidogrel because of these concerns. In our series, we had two known occurrences of proximal anastomotic stenosis and two grafts totally occluded of undetermined cause in patients who presented with angina. An additional six grafts were found to be occluded in asymptomatic patients on angiographic follow-up. Loading the saphenous vein into the delivery system requires placement of a stainless steel rod through the lumen of the saphenous vein with a potential for endothelial injury. However, a recent study by Yau and colleagues [15] in which these saphenous vein segments were examined in an isolated tissue both showed no evidence of endothelial injury. This potential, however, will be obviated with newer generation systems. In our small subgroup of 20 patients who have undergone electron beam angiography for 6 months or more there is an 86.6% patency in grafts performed with a connector. This compares favorably with the "gold standard" patency of saphenous vein grafts. FitzGibbon and colleagues [16] reported an 81.1% patency rate in 5,065 saphenous veins at 1 year. Goldman and colleagues [17] reported an 88.8% graft patency in saphenous vein grafts placed only to the left anterior descending coronary artery, also at 1 year.

Other issues include determining whether there is any value other than time saving in arrested heart surgery especially when a single-clamp technique is used. It is also conceivable that because of a uniform, reproducible, quality controlled connector, a more reliable proximal anastomosis can be constructed. Obviously this will be difficult to answer and will require comparison of many thousands of anastomoses.

In an attempt to answer some of these questions we are currently undertaking a randomized study of traditional sewn versus mechanical connector anastomosis in beat-

ing heart surgery, with a primary endpoint being 6-month angiographic graft patency. Pending completion of this study, some of these issues and concerns may be more definitely answered.

The aorta–saphenous vein graft anastomosis is only the first to be performed with a mechanical connector. Although clinical experience now exists with mechanical connectors for distal anastomosis, many more issues must be addressed before clinical validation is demonstrated [18].

In conclusion, our initial clinical experience with the Symmetry Bypass System Aortic Connector has demonstrated clinical reliability, ease of use, and safety. This initial series has been further substantiated by our subsequent experience. Our total experience from May 2001 through March 2002 is placement of 444 connectors in 212 patients. Of these, 412 connectors have been placed in 198 beating heart coronary artery bypass graft patients. This subsequent experience reflects the findings of our initial experience with predeployment device problems in 4.7% of cases as well as three additional misdeployments (0.9% of the total), which were managed by reloading the vein on another connector and redeployment. If this experience is subsequently confirmed by others and with a larger experience, it may help to usher in a new era of facilitated vascular anastomoses.

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DISCUSSION

DR HANI SHENNIB (Montreal, Quebec, Canada): This is an excellent paper by Michael Mack and, again, I would like to acknowledge your group's contributions to the validation of new cardiovascular technology. The premise of introducing new technology is to bring solutions to problems that we face in the operating room, and several issues related to proximal anastomotic devices need to be addressed.

The first issue that I would like to bring up is of the advantages of those devices. They are proposed to bring a potential decrease in neurological injury, a decrease in incidence of stroke and cognitive dysfunction, and potential decrease in aortic injury such as dissection. None of these so far have been validated. So as we assess this technology, we have to keep in the primary objective of bringing in this new technology and the importance of validating this.

The second issue is that, for every problem that we fix, there somehow are ascending to control and repair bleeding in the presence of those freshly deployed proximal anastomoses, knowing that the side-biting clamp might interfere with the device mechanisms?

More important, there is somehow sporadically an increasing verbal reporting of stenosis in the proximal site of the anastomotic devices, and we all know that nitinol-based technology is

not inert of the potential for restenosis, and I have noted from your own data there is an early incidence of proximal anastomotic stenoses. So in dealing with this and to create parallels with past catheter-based therapy for in-stent restenosis, angioplasty alone has been shown not to be effective long term without re-stenting. I would like to get your opinion as to the incidence of anastomotic stenosis and how we will ultimately deal with the potential problem of in-stent stenosis.

DR MACK: Regarding the first issue, the bailout maneuver for this device is connector grafts. Now in our own experience of over 400 of these connectors, that has not been necessary. So we are not fastidious about that aspect anymore.

Regarding the grafts that have leaked, it is usually due to an incorrect sizing of the connector versus the vein, particularly the smallest sized connector, which is 4.5 mm. Usually one simple suture, with care not to incorporate any of the device, is sufficient to manage any leak.

Regarding the incidence of in-stent restenosis, or more appropriately termed "anastomotic device stenosis" (ADS), there have now been approximately 13,000 implantations of this connector performed worldwide. The company has been notified of at least some of these restenosis, and there has been an incidence of 64 problems with vein grafts that have connectors in them. Thirty-eight of these 64 grafts were totally occluded, and 26 of these grafts clearly had anastomotic device stenosis. Now, whether the total occlusion of the grafts in our series or in other anecdotal reports are due to the connector or not, one does not know when it is totally occluded and, of course, there are a lot of reasons for a saphenous vein graft to occlude. But there clearly have been 26 cases that the company knows of that are anastomotic connector stenosis, and we have had two in our series. If you look at that total, 64 patients out of 13,000 implanted, that is an incidence of 0.5%. Now, we all know that there are a significant number of instances that the company is not aware of, but that is what the known experience is at the present time.

DR LISHAN AKLOG (Boston, MA): Did you have a specific anticoagulation or antiplatelet regimen and did it differ from your standard practice?

DR MACK: Regarding our anticoagulation regimen, we already had patients on an antiplatelet regimen for our beating heart surgery, which we had borrowed from cardiology stent protocols. Since all these patients underwent operation on a beating heart, we used that same protocol, and that is aspirin preoperatively and aspirin postoperatively, and then loading the patients postoperatively with clopidrogel 300 mg in the intensive care unit on the day of surgery and then clopidrogel 75 mg per day for 90 days.

Now, we all know that there are a significant number of instances that the graft occludes and it clinically is not apparent. Without complete angiographic follow-up, I feel that we do not know the true incidence of graft occlusion. We are currently undertaking a prospective, randomized study comparing saphenous vein grafts with a proximal anastomosis performed with connectors versus suturing. The endpoint of this study is 9-month angiographic follow-up. Hopefully, this will shed some light on the true incidence of the problem.