

The St Jude Medical symmetry aortic connector system for proximal vein graft anastomoses in coronary artery bypass grafting

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Objectives: A new device designed to create proximal vein graft anastomoses to the aorta in coronary artery bypass grafting was recently developed by the St Jude Medical Anastomotic Technology Group (Minneapolis, Minn). This new anastomosis system consists of a nickel-titanium (nitinol) connector, an aortic cutter, and a delivery device.

Methods: The loading of the vein on the aortic connector and its delivery to the aorta are described. In 43 consecutive patients (mean age 68 ± 10 years, age range 33–91 years), 65 proximal vein graft anastomoses were performed with the new system. Intraoperative flow rates were assessed for all grafts according to the transit time principle.

Results: All connector anastomoses were performed without the use of any aortic clamp. Times to complete these mechanical anastomoses were less than 10 seconds in all cases. Hemostasis was instantaneous in all cases, with only 3 system failures. These connectors were easily removed so that the anastomoses could be performed with standard suturing technique through the same aortotomy without complications. All vein grafts were patent at the end of the procedure, and there were no intraoperative or postoperative complications related to the device.

Conclusions: The aortic connector system was easy to handle and allowed quick creation of reliable, reproducible, and uniform anastomoses. In addition, anastomoses could be done without any clamping of the aorta, which is especially attractive for off-pump procedures, because aortic manipulation and therefore the risks of embolism and aortic dissection would be further minimized. In on-pump cases this technique would facilitate the single-clamp technique, again minimizing aortic manipulation.

Since the first description of a vascular anastomosis with sutures by Alexis Carrel in 1902,¹ this technique has become the criterion standard for connecting vessels during surgery. Alternative methods that have been developed include glues, staples, clips, intraluminal stents, mounting systems, laser-assisted procedures, and other techniques. Recent progress in coronary artery bypass grafting (CABG) and initiatives toward reducing morbidity through the use of less invasive approaches have led to a growing interest in alternative facilitated anastomosis techniques.

Recently a new device designed to create proximal vein graft anastomoses to the

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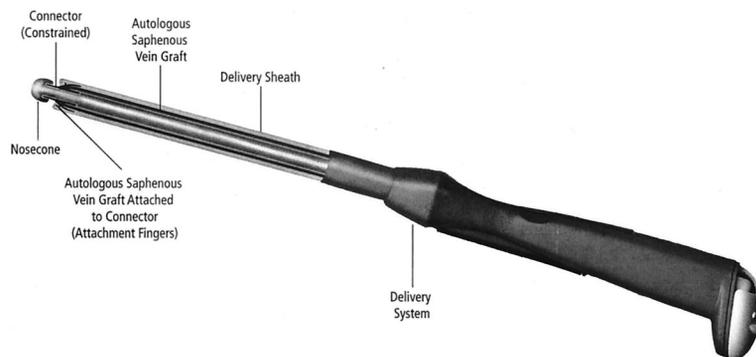


Figure 1. Aortic connector with loaded vein graft.

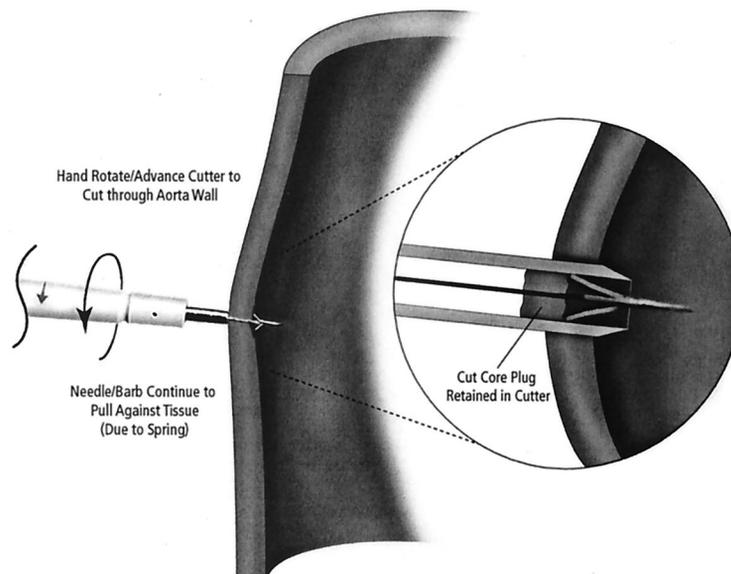


Figure 2. Aortic cutter with puncture needle with barbs and round, rotatable cutter blade creating hole through aorta.

aorta in CABG procedures (Symmetry Bypass System Aortic Connector, CE Mark) was developed by St Jude Medical Anastomotic Technology Group Inc (Minneapolis, Minn). This aortic connector system consists of a nickel-titanium (nitinol) connector, a delivery system, and an atraumatic aortic cutter with a rotatable blade to create a precisely sized, round hole without the need of an aortic partial occlusion clamp. This nitinol connector was extensively tested in the dog model under Food and Drug Administration Good Laboratory Practice regulations by Bonilla and colleagues (unpublished data) for use in autologous vein-to-aorta anastomoses. The CE Mark was obtained in May 2000, and since then more than 1200 implants have been performed in Europe. Food and Drug Administration approval was received in May 2001.

Methods

Patients

In 43 consecutive patients (mean age 68 ± 10 years, age range 33–91 years) 40 left internal thoracic arteries, 9 radial arteries, and a total of 72 vein grafts were used as bypass conduits. Sixty-five proximal vein graft anastomoses were performed with the St Jude Medical Aortic Connector System. Thirty-eight patients underwent CABG alone, 16 with cardiopulmonary bypass and 22 off pump. Five patients underwent concomitant valve replacements in addition to CABG, 4 aortic and 1 mitral. Informed consent was obtained from all patients. Intraoperative blood flow was measured for all grafts with the Cardiomed Flowmeter (Medi-Stim, Oslo, Norway) according to the transit time principle. Postoperative medical therapy included acetylsalicylic acid (100 mg/d) for all patients, with warfarin sodium (Coumadin) for patients with a valve replacement, atrial fibrillation, or both.

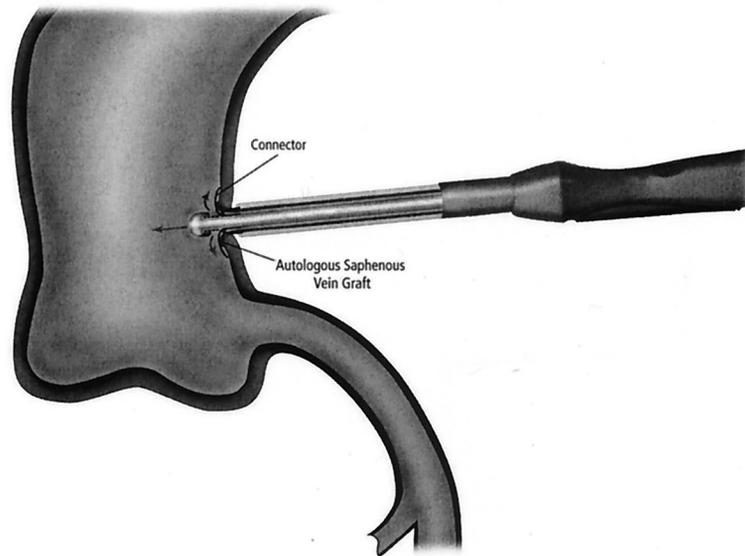


Figure 3. Insertion of aortic connector system into aortic hole. Internal struts are released by pushing button on top of handle.

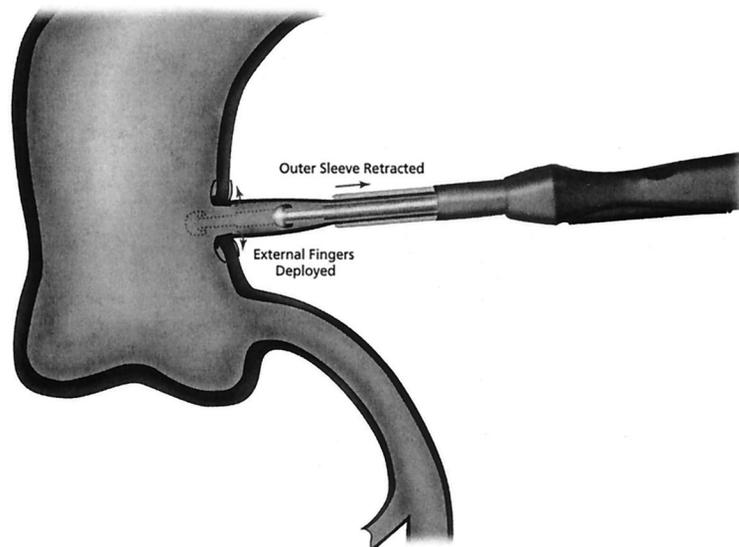


Figure 4. Aortic connector is pulled back. External struts are deployed.

Vein Loading

The saphenous vein was explanted in a conventional fashion; small side branches could be clipped with titanium clips, whereas larger ones were ligated. After harvesting of the saphenous vein, the external diameter of the graft was assessed to match with the best-fitting size of the connector systems. Because the proximal anastomosis had to be performed first, the length of the vein had to be long enough to reach the appropriate anastomotic site. The vein was then put on a vein transfer sheath to guide the vein over the release tube until it contacted the aortic connector. The vein was carefully cleaned from surrounding tissue to avoid any difficulty

during the loading process. Thereafter the vein was equally distributed within the entire circumference of the aortic connector. With a fine-tipped forceps, the vein was brought over the hooks of the connector and then gently pierced through seven connector hooks with the vein punch. It was necessary to ensure that the vein had not been everted during these steps. After verification that every hook was pierced through all the vein layers, the handle was attached. The delivery sheath was then slid to cover the vein graft, and the nose cone was then placed to cover the connector hooks. The aortic connector was then ready for deployment and had to be kept wet to prevent the vein from becoming dehydrated (Figure 1).

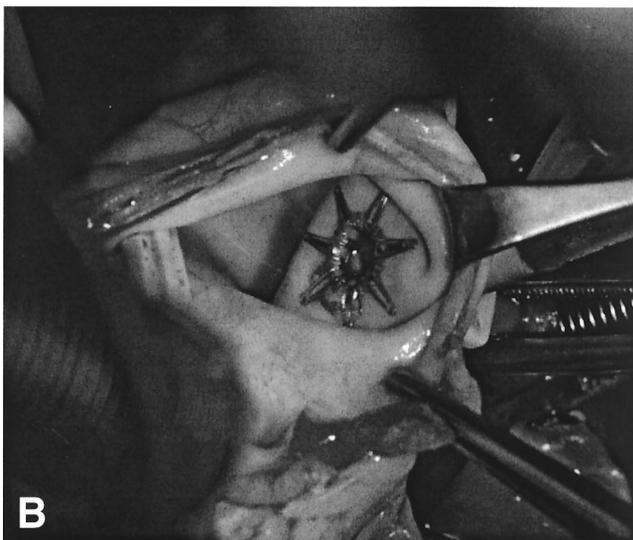
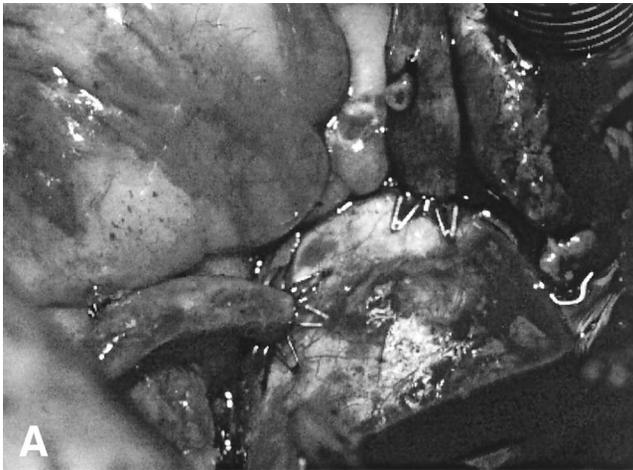


Figure 5. A, Intraoperative outside view of two proximal vein anastomoses. B, Intraoperative inside view of proximal vein anastomosis through aortotomy in patient with additional aortic valve replacement.

Aortic Cutter

The aortic cutter consists of a puncture needle, with barbs to fix inner layer of the aorta and a round, rotatable blade. Because of a 90° takeoff of the vein graft from the aorta, a site adjacent to the pulmonary artery or right atrium was chosen for the left- or right-sided grafts, respectively. The aortic site was then cleaned in the usual fashion. With the puncture needle fully advanced, the cutter was inserted into the aorta at a 90° angle. The needle was then released so that the barbs pulled back the aortic wall against the circular cutter. By rotating the circular cutter blade, a perfectly round aortotomy was performed (Figure 2). The cutter was then removed, and the neo-ostium for the subsequent connector anastomosis was covered with a finger to control bleeding.

Vein Deployment

The loaded aortic connector system was then inserted into the aortic hole until the delivery sheath was flush with the external

aortic wall. With the handle held at a 90° angle, the internal struts of the aortic connector were deployed on the inside of the aorta by pushing the button on the top of the handle (Figure 3). Pulling back the handle perpendicular to the anastomosis deployed the external struts of the aortic connector and removed all components from the inside of the vein graft (Figure 4). The anastomosis was completed in a few seconds (Figure 5).

Results

The mean diameter of the 65 vein grafts in which the connector was used was 5.0 ± 0.3 mm (range 4.5–6 mm). Mean loading time for the connector was 4.6 ± 1.0 minutes. All connector anastomoses were performed without any clamping of the aorta. Times to complete these mechanical anastomoses were less than 10 seconds in all cases. Hemostasis was instantaneous in all cases, with only 3 system failures. These connectors were removed and the anastomoses were hand sewn with the same hole without complications. All vein grafts were patent at the end of the procedure. Flow measurements were 50 ± 27 mL/min for single-vein grafts and 83 ± 37 mL/min for sequential grafts. There were no intraoperative or postoperative complications related to the device, no myocardial infarctions, and no deaths.

Discussion

Manual suturing remains the criterion standard for the creation of vascular anastomoses. The quality of suture materials has improved considerably in the last decades, with polypropylene being cheap, simple to handle, and effective. Several attempts have been made to facilitate vascular anastomoses, including penetrating staples,^{2,3} nonpenetrating clips,^{4,5} coupling devices,⁶⁻⁸ tissue adhesives,^{9,10} and laser-assisted techniques.^{11,12} Most reports have focused on connectors allowing vein-to-coronary and other microvascular anastomoses, with only few assessing the possibility of a sutureless anastomoses of the aorta to saphenous vein grafts.¹³

The St Jude Medical Symmetry Bypass System Aortic Connector was recently developed to facilitate sutureless mechanical proximal anastomosis of autologous vein grafts to the aorta in CABG. This new device produces an anastomosis of the aorta to a saphenous vein graft that looks equivalent to a hand-sutured one but requires less time and minimal training. In our initial clinical experience this system was reliable, was easy to handle, and produced reproducible anastomoses. One further advantage is the minimization of aortic manipulation by avoiding clamping of the aorta. Atheromatous plaques in the ascending aorta or aortic arch may be mobilized during aortic manipulation (eg, cannulation, side-biting, clamping, or release of clamps) and are the most important factor for cerebral or peripheral embolism, contributing to perioperative neurologic morbidity.¹⁴ The new aortic cutter creates perfectly sized, round

holes, unlike the standard aortic punch. As the mechanical anastomosis device becomes unconstrained on deployment, it expands radially, bringing the vein wall firmly to the created aortic hole and creating a hemostatic seal. In addition, the mechanical anastomosis device body remains in place and adds structure to keep the anastomosis patent. The vein takeoff is at a 90° angle, mimicking the anatomy and geometry of the native coronary artery ostium. With this system the proximal anastomosis has to be performed first, and the length of the vein has to be checked out at the beginning of the procedure. This might be advantageous, especially to establish immediate flow in off-pump cases but also to perfuse cold or warm cardioplegia after performance of the distal anastomoses on-pump cases.

Hemostasis was instantaneous in all but 3 cases. In the first 2 cases the cause of failure was a small intimal tear caused by an inadequate angle during the creation of the circular aortotomy by the cutter. For safety reasons no attempts were made to repair the leaks with sutures, and the connectors were removed without difficulty. The anastomoses were sewn in a conventional way, but the aorta had to be tangentially clamped. In the third case the insertion of the device was after aortic clamping, while cold cardioplegic solution was being administered. The nitinol connector could not expand, because it loses its ability to spring back to its deployed configuration at temperatures lower than 15°C.

The connector system is especially attractive for off-pump procedures, because it reduces aortic manipulation and therefore the risk of embolism from mobilization of aortic wall debris. In on-pump cases there is an advantage in reducing the anastomotic time, even with a single-clamp technique. Further studies will show whether these advantages will outweigh the cost increment relative to the standard techniques. Although all the proximal anastomoses in this experience were performed on the ascending aorta, other aortic sites are possible. The delivery system also has the potential of being modified so it can be used with limited incisions, facilitating limited access surgery. Combining this technique with mechanical distal anastomoses¹⁵ could lead to a revolutionary new phase in CABG.

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Discussion

Dr Robbin G. Cohen (*Los Angeles, Calif*). Eckstein and colleagues are to be commended for their work with this interesting device. I have had no experience with this device and unfortunately saw none of the figures; however, I was able to search the on-line literature and find a nice video on the website of *The Wall Street Journal*. Eckstein and colleagues have described their early experience with the St Jude Medical Aortic Connector System, which is the first of many similar devices to be approved for commercial use in the United States. The need for such a device has been present for a long time, and in my opinion its importance cannot be underestimated. The complications during CABG that occur because of manipulation of the aorta are among the most dangerous, frightening and threatening, and this issue has become particularly germane with the increase in popularity of off-pump coronary surgery. There does not appear to be an increased stroke rate with off-pump CABG; however, there does appear to be an increase in the incidence of acute aortic dissection, as shown in the recent literature. In fact, we are personally in the process of reporting 3 fatal acute aortic dissections after off-pump surgery attributed to the side-biting clamp, as well as 1 false aneurysm that was not fatal.

In this “we can do it” article, Eckstein and colleagues showed in a limited series that this device is certainly feasible for some patient types. They claimed that it requires almost no training, that it is quicker than conventional techniques, that it provides potentially a better anastomosis, and that it may be applicable to minimally invasive techniques, all of which would justify its significantly increased cost. Unfortunately, there was no comparison with any conventional techniques in this study, nor has there been

a prospective study, and there are no data to support these proposed advantages.

I do have a couple questions and concerns. My primary concern is that of the required 90° angle that the anastomosis has to come off of the aorta. I would think that there really are not that many places on the aorta that you can truly achieve this, and this would limit not only the number of grafts that you can place on the aorta but might increase kinking and decrease graft patency. Scientists in the flow laboratories at California Institute of Technology tell me that if you move an anastomosis in any direction more than 10° to 15° that this will significantly affect the amount of flow going through that graft. As a result, I was pleased to see that a protocol with angiographic follow-up has actually been started and that the results so far are good.

My first question is therefore about the technical factors involved in getting that 90° anastomosis into a graft that is not going to kink. My primary concern would not be when you are testing the flow when the chest is open. Rather, those grafts seem to kink as you pull the sternum together. Could you comment?

My second question is about timing. There are a couple of numbers in the article of great interest—that it takes less than 10 seconds to fire this device and that it takes less than 4 minutes to set it up. As a result, this device is expected to somehow decrease the operative time. Where is this time actually spent? With the use of endoscopic vein harvesting, we are finding that we are having to wait for the veins when we are ready to put them on. The fact that you are doing your proximals first would exacerbate that problem. If the person taking the vein out is doing it, and you have three grafts that you are going to use with your connector, that is going to add about 15 minutes of downtime to the procedure. I was just wondering how you have managed to affect the conduct of the operation with this device.

Finally, because reoperations would be one area that this device would be particularly attractive, I was just wondering what your experience with those is, and how many of those have you done?

Dr Carrel. Concerning the 90° angles, I think that the origin of the proposal to respect a 90° angle when looking at the possibility of creating the device was a study of the anatomy of the normal coronary ostia, which usually really are going 90° out of the aorta. We are still looking to see whether this is really a problem. I think that there will be a possibility of developing this device so that angulation to between 60° to 75° degrees should be possible. We have tried to do so in an ex vivo animal model, but it is difficult; if you cut the vein graft with a 75° angulation, it is difficult to

realize a technically perfect anastomosis. For this reason we try not just to put the anastomosis on the anterior part of the aortic wall but to place it really on the left side, because for the graft going to the circumflex supporting the initial course of the vein graft by surrounding structures (pulmonary artery) is of paramount importance. We were also concerned by the fact that closing the mediastinal fat tissue can really produce a kink. In the 1 case of stenosis we saw, it was probably not caused by the kink itself but by the turbulence that happened at the kinked place. When the cardiologist dilated this stenosis (which was located 1 cm distally from the anastomosis), it seemed not only to be a kink that was really smooth but to have some excessive tissue that could be felt during expansion of the balloon catheter. Even if this is only 1 case, it is unnecessary. We hope that the engineers will be able to give us a possibility to perform slightly angulated anastomoses.

With respect to the timing, actually the main operator is usually preparing both thoracic arteries or one thoracic and the radial, so it was not a problem to have at least one piece of vein graft ready at the moment it was needed to do the proximal anastomosis first. The loading process can be done with conventional 2.5 magnification surgical glasses, and the time needed to do it decreased fairly during the initial experience.

With respect to reoperation, we had none in the first series with 43 patients. Among the next 50 patients (not included in this series), we had 3 reoperations, with comparable results regarding the deployment of the device.

Dr Robert C. Robbins (*Stanford, Calif*). Can you comment on integration of this system into a single device, instead of introducing a cutter, pulling it out, and putting your finger on? Are there any plans for this particular device to be integrated into a single tool where you would just simply cut and make the anastomosis at one time? Also, when you do the distal anastomosis, is it possible to do a proximal anastomosis at the same time, because you have to do the proximal first with this before you do the hand-sewn anastomosis?

Dr Carrel. To answer your second question first, with this first generation of connectors for the proximal and distal anastomosis it is not possible to perform multiple anastomoses at once, but the next generation (called “Easy Load”) will include this possibility with the same graft, which would really then be a major advantage. Concerning the first question you had about integration of the cutter into the delivery system, I do not think that this will be possible with this device as currently designed.