

First Clinical Results With a New Mechanical Connector for Distal Coronary Artery Anastomoses in CABG

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Background—Coronary anastomoses are currently primarily carried out with the use of running nonabsorbable sutures. Recently, a renewed interest has developed for facilitated mechanical anastomotic devices especially for minimal invasive techniques or limited access surgery. The initial experience with the first successful creation of mechanical vein-to-coronary artery anastomoses in humans is reported.

Methods and Results—Between November 2000 and June 2001, 14 patients scheduled for multivessel coronary artery bypass grafting (CABG) procedure were investigated. One vein graft-to-coronary artery anastomosis per patient was performed with the St. Jude Medical ATG Symmetry coronary connector system (stainless steel investigational device, not yet commercially available). We evaluated the overall performance of the device. Intraoperative flow measurements of the grafts using transit time methods were measured. A postoperative angiographic control was performed immediately after the procedure in all patients. Hemostasis was instantaneous in all cases and all anastomoses (mechanical n=14, sutured n=40) were patent. Mean intraoperative flow measurements for the mechanical anastomosed vein grafts was 75 ± 25 mL/min. Three month angiogram or MRI angiography is available to date in 11 patients. Ten connector grafts were patent and 1 was occluded. There were no cardiac-related adverse events or return of angina; exercise tolerance tests and stress electrocardiograms were normal in all patients.

Conclusions—The St. Jude Medical ATG Symmetry coronary connector system is a new device for sutureless distal vein graft-to-coronary artery anastomoses in CABG. This system allows the construction of geometrically perfect anastomoses. This technology represents a further step in a new era of sutureless anastomoses in cardiac surgery. (*Circulation*. 2002;106[*suppl I*]:I-1-I-4.)

Key Words: cardiovascular diseases ■ bypass grafting ■ mechanical anastomoses

In coronary bypass surgery, the anastomoses between the graft and the ascending aorta and the graft and the target coronary artery are currently carried out primarily through the use of running nonresorbable sutures. Suturing is an effective means for attaching vessels together, however, the quality of the anastomosis is human-dependent, in that each anastomosis will be different depending on skill level, experience, exposure, visualization, and time permitted. Over the last years, there has been several developments in cardiac stabilizers for CABG procedures on the beating heart. However, coronary anastomoses is the area in which technologic and engineering advancements are needed most. Recently, St. Jude Medical Anastomotic Technology Group (ATG) has developed a family of connectors that allow a facilitated mechanical anastomosis between a saphenous vein graft (SVG) and the ascending aorta^{1,2} and an SVG to the coronary artery.^{3,4}

The vein graft-to-coronary artery connector (stainless steel investigational device, not yet commercially available) cre-

ates a round side-to-side anastomosis, the diameter of which matches the internal diameter of the target coronary artery. After extensive evaluation of these connectors in cadavers and animal models,³ the first human implant was performed successfully in November 2000 in our institution.⁴ The present study was conducted to evaluate the feasibility and the early patency of this novel technology in humans.

Methods

The protocol of this study was reviewed and approved by the Local Ethical Committee of the University of Bern, (approval no. 182/2000, Oct. 11, 2000), Bern, Switzerland. Informed consent for a mechanical vein graft-to-coronary connection was obtained for all patients. The study is a prospective, nonrandomized, open label, single center registry with patients undergoing first-time coronary artery bypass graft surgery. The coronary connector will be used for 1 anastomosis with an autologous saphenous vein graft. The coronary artery outer diameter must be <3 mm at anastomosis site estimating an inner diameter <2.5 mm. The vein graft internal diameter must be <3.5 mm at anastomosis site.

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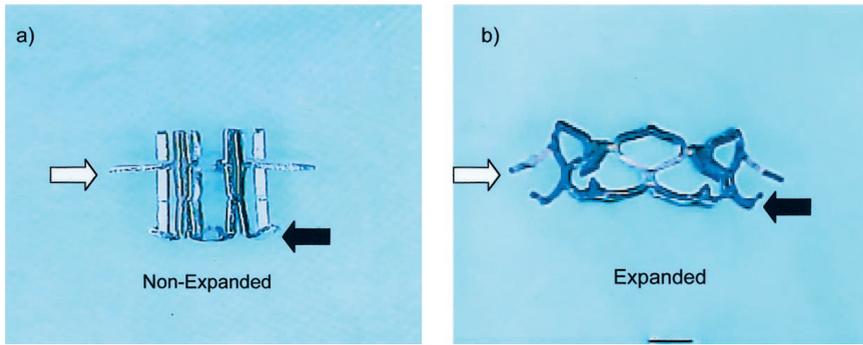


Figure 1. Design of the St. Jude Medical stainless steel connector nonexpanded (a) and expanded (b) after delivery. The vein is pierced on the upper small hooks (white arrow). After deployment the lower hooks secure the vein in the coronary artery.

The distal coronary connector (Figure 1) is stainless steel and contains small external hooks that are necessary to hold the vein graft and internal fingers to engage in the internal coronary lumen and secure the vein on the coronary. After harvesting of the vein graft, a transfer sheath is introduced into the vein and, at the presumed site of the anastomosis, the graft is pierced from the outside and dilated in the center of the area stretched over the end of the vein transfer sheath (Figure 2). Through the vein transfer sheath an expandable balloon delivery catheter with the connector mounted on it is introduced backward through the distal end of the graft up to the stainless steel connector until the nose cone protrudes through the orifice created in the vein. Then the delivery system is pressurized to 1 atmosphere (Figure 3a). The entire circumference of the vein is distributed equally around the stainless steel connector, ensuring that the intimal layer of the vein is overall the external connector hooks. The vein is then pierced through these small 6 hooks and finally a small rubber ring is slid over the nose cone and placed over the external hooks (Figure 3b). The system is now ready for deployment.

After pressurizing the coronary artery either by native blood flow or by cardioplegia a small arteriotomy blade is inserted in the coronary artery tangentially at the presumed anastomosis site. The incision is dilated by a standardized dilating tool that creates a small hole matching to the size of the pre-inflated catheter with the connector. Then the nose cone of the delivery catheter is inserted into the arteriotomy as axially as possible until the coupling device adapts to the borders of the arteriotomy on the coronary artery. The delivery system is orientated in a perpendicular angle relative to the coronary artery and, by holding the delivery device in position, it is pressurized to 18 atmospheres. During pressurization of the balloon of the delivery catheter, the connector expands and creates the anastomosis. At the same time it reduces its length compressing the vein graft to the coronary artery, creating a hemodynamic seal and a firm attachment of the 2 vessels (Figure 4).

Results

Between November 2000 and June 2001, we enrolled 23 patients scheduled for multiple CABG procedures. Intraop-

eratively, 9 patients were excluded because of the diameter of the coronary target vessels (outer diameter <3.0 mm). In 14 patients (mean age 63 ± 8 years) 1 distal SVG anastomosis was performed with the mechanical device. All patients were operated on using standard extracorporeal circulation (ECC) and myocardial protection techniques. All patients received complete revascularization (mean distal anastomoses $n=3.9 \pm 0.6$ with: left internal thoracic artery $n=13$, A. radialis $n=7$, SVG $n=23$), and connector anastomoses were performed to the right coronary artery (RCA) in 10 patients, to the posterior descending artery in 3 patients, and to the obtuse marginal branch in 1 patient. The required time to load the vein graft onto the delivery system was between 6 and 8 minutes and this part of the procedure was performed during internal thoracic artery harvesting and cannulation for ECC. Time to deploy the connector and to create the mechanical anastomosis at the coronary site was less than 2 minutes. Hemostasis was instantaneous in all cases and all mechanical anastomoses were patent at the end of the procedure, as measured by intraoperative flow measurement with the transit time method (Cardiomed Flowmeter, Medi-Stim, Oslo, Norway) mean flow of 75 ± 25 mL/min. Postoperative angiography was performed in all patients at the end of the operation before the admission to the intensive care unit. Patent anastomoses were demonstrated in all patients (Figure 5), although in 1 patient a mechanical anastomosis showed distal flow only while retrograde proximal flow to the native coronary artery was restricted. This patient underwent immediate reexploration, the connector was removed, and the anastomosis was performed with a running suture at the same site. Three-month angiogram ($n=2$) or MRI angiography

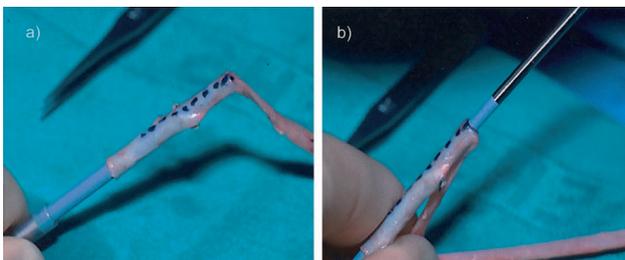


Figure 2. The coupling device is introduced backward from the distal end into the vein graft (a). A small incision (site of the future anastomosis in the vein) is made from the outside and dilated in the center of the area stretched over the end of the vein transfer sheath (b).

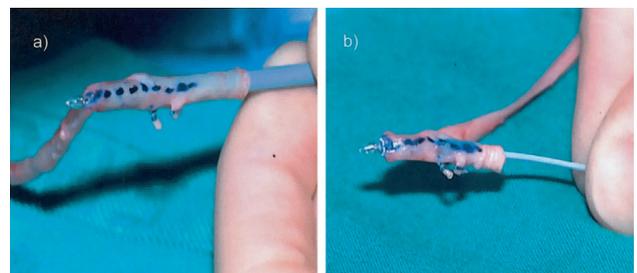


Figure 3. Through the vein transfer sheath the delivery device with the stainless steel connector mounted on it is introduced into the graft until the nose cone protrudes through the orifice created in the vein (a). The vein is then attached to the external hooks and finally secured by a small rubber ring under the microscope. The system is ready for deployment (b).

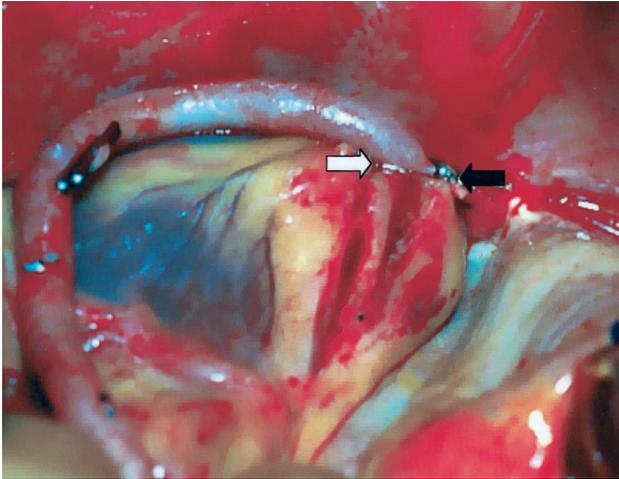


Figure 4. Intraoperative view of a side-to-side mechanical connection between an SVG and the right coronary artery (white arrow). The distal end of the graft has been closed with a connector after retrieving the delivery catheter (black arrow).

(n=9) (Figure 6) follow-up was available in 11 patients, 2 patients refused invasive follow-up investigation. Ten grafts with the mechanical connector were patent and 1 was occluded. In the patient with the occluded graft, poor run-off as the reason for occlusion was excluded by good intraoperative flow result. In 3 patients with a patent graft, a smooth narrowing at the anastomosis site was observed. In 1 patient, PTCA and stent implantation of the native RCA was performed. There were no cardiac-related adverse events or any return of angina. Exercise tolerance tests and stress electrocardiograms were normal in all patients.

Discussion

The ultimate goal of less invasive coronary bypass procedure is to achieve surgical revascularization with a maximum of arterial grafts through the smallest incision. Although mechanical stabilizations have played a major role in enabling surgeons to perform running coronary sutures on the beating heart, the next major hurdle is at the level of the coronary anastomosis. Recent technology likely to have a great impact on the adoption of beating heart bypass surgery is the development of mechanical anastomotic devices to facilitate and fasten all vascular connections. Anastomotic devices

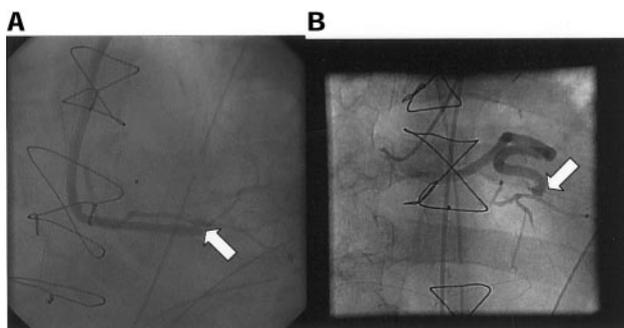


Figure 5. Postoperative angiography of 2 mechanical anastomoses (white arrows) with bidirectional native flow to the distal parts of the right coronary artery (a) and to the obtuse marginal branch (b).

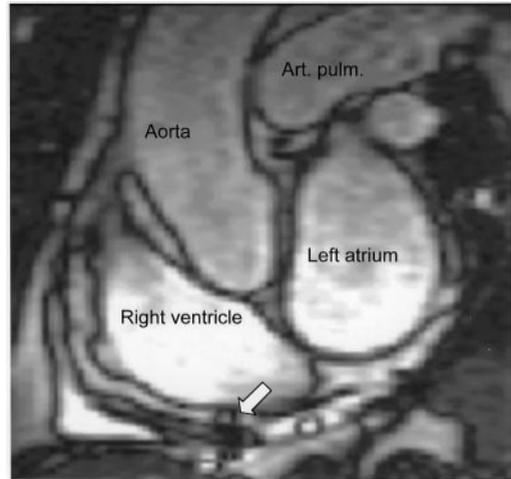


Figure 6. Three-month postoperative high-resolution MRI of a vein graft to the RCA with signal void due to coronary connector (white arrow).

must be simple to use and provide precise and effective outcomes.⁵ Several anastomotic devices have been proposed for potential use in coronary locations, including glues,^{6,7} staples,^{8–10} clips,¹¹ coupling devices,^{12,13} intraluminal stents,¹⁴ mounting devices,¹⁵ or laser-assisted procedures,^{16,17} and, to a certain extent, the so-called ventriculo-coronary shunts.^{18,19} However, the long-term success of any of these devices has yet to be proven.

The St. Jude Medical ATG coronary connector system is part of a family of connectors made of stainless steel. It was developed recently to facilitate the creation of a vein graft-to-coronary anastomosis for CABG. The connector is mounted in a compressed fashion on a balloon catheter, which, when pressurized, expands it and instantaneously creates the anastomosis. It produces a morphologically round anastomosis that matches the internal diameter of the target coronary artery. In the present study, all anastomoses were performed in a side-to-side fashion and then the distal end of the graft was ligated. Although all anastomoses were patent, 1 had only a unidirectional flow to the distal part and a restricted flow to the proximal part of the coronary artery. This happened early in our experience and was caused by a proximal back-walling of the coronary artery by the internal hooks of the clip. Immediate reexploration confirmed this finding, the connector was removed, and the anastomosis was performed at the same site with a running 7.0 polypropylene suture.

One limitation of this mechanical connector was the necessity of a 3.0-mm outer diameter of the target vessel, which is not encountered frequently in the present era of CABG surgery; this led to the implantation in the right coronary artery in the majority of cases. A new system for smaller coronary arteries is under investigation and will help to resolve this issue. The connector presented herein had to be loaded under a microscope and this was always performed on a separate side table. This somewhat cumbersome procedure restricted the application and did not allow combination of a distal and a proximal vein graft connector. This is also being resolved in the newer generation mechanical connectors that

are under development. Contrary to the use of clips made of metal with a memory function such as Nitinol the use of stainless steel for coupling devices facilitates the more careful handling of the system during loading and delivery to avoid irreversible distortion.

These mechanical anastomoses are round and not oval-shaped, leading to the observation at angiography that mechanical anastomoses appear smaller (limited by the size of the connector) than hand-sutured ones and look unusual while being a side-to-side connection even at the end of the vein graft. The observed narrowing in 3 anastomoses did not restrict flow characteristics and were hemodynamically not significant. However, 1 patient was treated with PTCA and stent implantation of the native RCA during 3-month post-operative catheterization. The significance of these findings should better be understood on longer-term follow-up (6 months) in future studies.

There might be some concern with the fact that foreign material is introduced through the intima of the vessels and might induce intimal hyperplasia already observed after intracoronary stent placement. This has not been observed in long-term animal studies, and might be at least partially a result of the fact that the device is introduced at a healthy area and not at the level of a freshly dilated stenotic lesion.

Nevertheless, the device creates an anastomosis equivalent to a hand-sutured one, in less time, and with minimal training required. It offers a valuable and alternative procedure to the standard suturing technique not only for coronary artery bypass grafting but also for peripheral vascular procedures. Mechanical vessel connections represent a further important step to facilitate telemanipulated surgery through limited access and will enhance the reproducibility, quality, and rapidity in the creation of vascular anastomoses.

References

- Eckstein FS, Bonilla LF, Englberger L, et al. Minimizing aortic manipulation during OPCAB using the Symmetry™ Aortic Connector System for proximal vein graft anastomoses. *Ann Thorac Surg.* 2001;72:S995–S998.
- Eckstein FS, Bonilla LF, Englberger L, et al. The St. Jude Medical Symmetry aortic connector system for proximal vein graft anastomoses in coronary artery bypass surgery. *J Thorac Cardiovasc Surg. J Thorac Cardiovasc Surg.* 2002;123:777–782.
- Schaff HV, Zehr KJ, Bonilla LF, et al. An experimental model of saphenous vein-to-coronary artery anastomosis with the St. Jude Medical stainless steel connector. *Ann Thorac Surg.* 2002;73:830–5; discussion 835–836.
- Eckstein FS, Bonilla LF, Meyer B, et al. Sutureless mechanical anastomosis of a saphenous vein graft to a coronary artery with a new connector device. *Lancet.* 2001;357:931–932.
- Werker PM, Kon M. Review of facilitated approaches to vascular anastomosis surgery. *Ann Thorac Surg.* 1997;63(6 suppl):S122–S127.
- Dumanian GA, Dascombe W, Hong C, et al. A new photopolymerizable blood vessel glue that seals human vessel anastomoses without augmenting thrombogenicity. *Plast Reconstr Surg.* 1995;95901–95907.
- Gundry SR, Black K, Izutani H. Sutureless coronary artery bypass with biologic glued anastomoses: Preliminary in vivo and in vitro results. *J Thorac Cardiovasc Surg* 2000;120:473–477.
- Androsov PI. New method of surgical treatment of blood vessel lesions. *AMA Arch Surg.* 1956;73:902–910.
- Chavanon O, Perrault LP. Favorable aspect of stapled anastomosis: an endothelial function study. *Ann Thorac Surg.* 1999;681443–681444.
- Inokushi K. Stapling device for end-to-side anastomosis of blood vessels. *Arch Surg.* 1961;82:337–341.
- Nataf P, Hinchliffe P, Manzo S, et al. Facilitated vascular anastomoses: the one-shot device. *Ann Thorac Surg.* 1998;66:1041–1044.
- Sasson HN, Stofman GM, Berman P. Clinical use of the 3M 2.5 mm mechanical microcoupling device in free tissue transfer. *Microsurgery.* 1994;15:421–423.
- Shennib H, Korkola SJ, Bousette N, et al. An automated interrupted suturing device for coronary artery bypass grafting: automated coronary anastomosis. *Ann Thorac Surg.* 2000;17:312–318.
- Solem JO, Boumzebra D, Al-Buraiki J, et al. Evaluation of a new device for quick sutureless coronary artery anastomosis in surviving sheep. *Eur J Cardiothoracic Surg.* 2000;17:1046–1048.
- Scheltes JS, Heikens M, Pistecky PV, et al. Assessment of patented coronary end-to-side anastomotic devices using micromechanical bonding. *Ann Thorac Surg.* 2000;70:218–221.
- McCarthy WJ, LoCicero J, Harzt RS, et al. Patency of laser assisted anastomoses in small vessels: one year follow-up. *Surgery.* 1987;102:319–326.
- Bass LS, Treat MR, Dzakonski C, et al. Sutureless microvascular anastomosis using the THC:YAG laser: a primarily report. *Microsurgery* 1989;10:189–193.
- Tweden KS, Eales F, Cameron JD, et al. Ventriculocoronary artery bypass (VCAB), a novel approach to myocardial revascularization. *Heart Surg Forum.* 2000;3:47–54.
- Emery RW, Eales F, Van Meter CH Jr, et al. Ventriculocoronary artery bypass results using a mesh-tipped device in a porcine model. *Ann Thorac Surg.* 2001;72:S1004–S1008.