A new mechanical connector for distal coronary artery anastomoses in coronary artery bypass grafting: A randomized, controlled study

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Objective: A new mechanical anastomotic device was evaluated, aiming at its future use in minimally invasive techniques or limited access surgery in patients undergoing coronary artery bypass grafting.

Methods: Between April and December 2002, a total of 60 patients scheduled for elective multivessel bypass grafting were randomly assigned. One vein graft–coronary artery anastomosis per patient was either performed with the St Jude Medical ATG coronary connector system (n = 30; St Jude Medical Inc, St Paul, Minn) or hand sewn (n = 30). Selective coronary angiography or coronary magnetic resonance imaging of the studied graft and vessel was included in the 6-month follow-up.

Results: Twenty-eight of the connectors were successfully implanted. Two patients were excluded from the study because of conversion to hand-sewn anastomoses. Six connector-made anastomoses were bleeding at the anastomotic site. At the time of follow-up (190 postoperative days), all control anastomoses and grafts were patent, whereas 26% of the connector anastomoses were occluded. One graft in each group was patent but with stenosis.

Conclusion: The St Jude Medical ATG coronary connector system for distal anastomoses represents a new concept for sutureless anastomoses in cardiac surgery. This randomized, controlled study shows lower graft patency for anastomoses performed with the connector than for hand-sewn control anastomoses. It illustrates the importance of controlled studies when evaluating new technical equipment in medicine.

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Financially and technically supported by St Jude Medical, Inc, St Paul, Minn.

Received for publication Dec 16, 2003; revisions received Feb 22, 2004; accepted for publication Feb 26, 2004.

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J Thorac Cardiovasc Surg 2005;129:146-50
0022-5223/\$30.00

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doi:10.1016/j.jtcvs.2004.02.027

The most common and effective way of creating an anastomosis between grafts and the aorta or coronary arteries in coronary artery bypass grafting (CABG) is by a running hand-sewn suture with nonresorbable material. However, the success of this technique is dependent on various factors related to surgical experience and skill. During the past decade, a rapid development in off-pump CABG has made the exposure and visualization of all aspects of the heart possible, thereby creating the potential for less invasive techniques. In parallel, a need for semiautomatic anastomosing devices has grown.

The St Jude Medical Anastomotic Technology Group has developed a family of connectors for both proximal (vein grafts to the aorta)¹⁻³ and distal (vein grafts to the coronary artery)⁴ anastomoses. Recently, Eckstein and colleagues^{5,6} demonstrated the feasibility of using the new coronary connector for distal anastomoses in CABG. To investigate the St Jude Medical stainless steel 2.0 distal connector (St Jude Medical ATG coronary connector; St Jude Medical Inc, St Paul, Minn), we designed a prospective, randomized study. Patients were studied regarding cardiac events and graft patency 6 months after CABG.

Material and Methods

The protocol of this study was reviewed and approved by the local ethical committee of The University of Göteborg (Göteborg, Sweden; approval S 263-01, Aug 7, 2001). Informed consent for a single mechanical vein-to-coronary connection was obtained from each patient. The protocol of the study was also reviewed and approved by the Medical Product Agency (Uppsala, Sweden; approval 461:2001/046032).

The coronary connector was used for a single anastomosis in each patient. Inclusion criteria required a coronary outer diameter greater than 2.5 mm at the anastomotic site, corresponding to an estimated inner diameter greater than 2.0 mm. The vein graft's internal diameter had to exceed 3.5 mm. The random assignment took place at the time of inspection and measurement of the target vessel. In the preoperative angiographic screening, care was taken to choose patients with comparable distributions of target vessels in the two groups. Patients were excluded for the following criteria: emergency procedures, reoperative CABG, recent neurologic events, significant comorbidities (such as peripheral vascular disease, renal insufficiency, severe chronic obstructive pulmonary disease), left ventricular ejection fraction less than 25%, pregnancy or nursing, and requirement of chronic anticoagulation other than acetylsalicylic acid in the postoperative period.

All procedures were performed according to our standard protocol with extracorporeal circulation (ECC) and cold blood cardioplegia. After harvest of the saphenous vein, the external diameter of the graft was assessed to ensure compliance with the connector system. When the patient was randomly assigned to receive a connector-created anastomosis, the vein was loaded onto the stainless steel clip system, which consisted of an implantable connector, a delivery system, a vessel-loading tool and transfer sheath, a venotomy and arteriotomy tool, and an artery and vein-dilating tool. The loading procedure was as follows: the connector was mounted on the delivery system as shown (Figure 1). The vessel-loading sheath was advanced into the distal end of the vein graft. The vessel-loading sheath supported the graft while an aperture was dilated in the side wall of the graft at the anastomotic site. The delivery system was then passed through the lumen of the vessel-loading sheath until the nose cone was advanced out through the aperture created in the side wall of the graft. The connector and delivery system were then ready for deployment into the target site (Figure 2). After pressurization of the coronary artery by blood cardioplegia, a small transverse incision at the target coronary artery was made with a small arteriotomy blade and dilated with a standardized dilating tool. The delivery system

was then introduced into the coronary artery until it was in contact with the coronary artery wall (Figure 3). With the device in place, the nose cone was advanced to uncover the internal fingers, and the delivery system was then positioned at 90° with respect to the coronary artery. The balloon was then inflated, expanding the clip (Figure 4). Once the clip was expanded, the delivery system was deflated and removed, and the vessel graft was ligated immediately distal to the anastomosis without compromising the vessel-anastomosis lumen (Figure 5). After completion of the distal anastomosis with the connector system, the subsequent operation was done as a standard procedure.

Intraoperative graft blood flow was measured with a transit time flowmeter (Medi-Stim AS, Oslo, Norway) in all studied grafts after weaning from ECC. All patients received acetylsalicylic acid (160 mg) daily starting on postoperative day 1, according to our clinical routine at that time. Six months after CABG, the patients were examined regarding physical status and chest pain and any cardiac or adverse events were registered. A selective coronary angiography of the studied anastomosed vessel was scheduled for the same time. A complete coronary angiography was performed if the patient had reported symptoms of chest pain. If the patients refused coronary angiography, coronary magnetic resonance imaging (MRI) was offered instead. Furthermore, 7 patients with occluded grafts on angiography were also examined with coronary MRI to verify the angiographic finding.

Results

Between April and December 2002, a total of 60 patients scheduled for elective first-time multivessel CABG were randomly assigned to receive either a hand-sewn vein graft–coronary artery anastomosis ($n = 30$) or a vein graft–coronary artery anastomosis performed with the St Jude Medical ATG coronary connector system. There were no significant differences between groups regarding preoperative demographic data (Table 1). One patient was excluded because of a plaque in the back wall, resulting in dislocation of the connector, and the anastomosis was eventually hand sewn. In another patient, the connector was successfully deployed but the graft was too short. The graft was exchanged and hand sewn. Six connector-made anastomoses were leaking from the anastomotic site, requiring one additional suture each with 7-0 polypropylene suture (Prolene; Ethicon, Inc, Somerville, NJ). One patient in the control group died on postoperative day 6 in arrhythmia. Another patient in the control group had a stroke develop early in the postoperative period. One patient who received a connector-created anastomosis underwent reoperation for bleeding, but no bleeding source was found at the anastomotic site.

All patients received complete revascularization (mean number of distal anastomoses 3 ± 0.7). Fifty-eight patients received an internal thoracic artery to the left anterior descending coronary artery. The target vessels of the studied grafts are shown in Table 2. The mean time required to load the vein graft onto the delivery system was 135 ± 11 seconds, and the time for deploying the connector was less

Figure 1. Schematic illustration of loaded vein on delivery system introduced into coronary artery. (Reprinted with permission of St Jude Medical, Inc, St Paul, Minn.)

Figure 2. Schematic illustration of connector and delivery system ready for deployment into target vessel. (Reprinted with permission of St Jude Medical, Inc, St Paul, Minn.)

Figure 3. Schematic illustration of connector and delivery system introduced into target vessel. (Reprinted with permission of St Jude Medical, Inc, St Paul, Minn.)

Figure 4. Inflation of balloon and expansion of clip. (Reprinted with permission of St Jude Medical, Inc, St Paul, Minn.)

Figure 5. Schematic illustration of completed side-to-side anastomosis. (Reprinted with permission of St Jude Medical, Inc, St Paul, Minn.)

than 1 minute. The intraoperative graft blood flows after weaning from ECC were a mean of 47 ± 8 mL/min in the connector group and a mean of 46 ± 4 mL/min in the control group, indicating that all anastomoses were patent at the end of the procedure. The mean ECC times were 65 ± 4 minutes in the connector group and 59 ± 3 minutes in the control group. There were no differences in mean ischemic time between the connector and the control group (37 ± 2 and 35 ± 2 minutes, respectively). At the 6-month follow-up, 59 patients had had no chest pain or cardiac-related adverse events. One patient had chest pain 3 months after the operation, and coronary angiography revealed an occluded graft to the right coronary artery (not a studied graft) and a significant stenosis at the connector-made anastomosis to an obtuse marginal branch. The patient underwent reoperation through a left thoracotomy, receiving a vein graft between the descending aorta and the obtuse marginal branch. The anastomosis to the descending aorta was performed with the St Jude Medical proximal connector (Symmetry; St Jude Medical Inc), which facilitated the anastomotic procedure in the deep wound.

Fifty-seven patients were scheduled for a 6-month follow-up with either coronary angiography or MRI (2 patients were excluded because of conversion to hand-sewn anastomoses and 1 patient had died). Coronary angiography was performed 179 days after CABG in 46 patients (23 in each group). MRI was performed 255 days after CABG in 8

patients (4 in each group). Three patients (5.3%) were unavailable for follow-up; 1 in the connector group who had moved abroad and 2 patients in the control group who were doing well but refused both coronary angiography and MRI.

TABLE 1. Selected preoperative demographic data

	Connector	Hand sewn
Male/female ratio	57:3	51:9
Age (y, mean and range)	69 (43-83)	67 (42-81)
Hypertension (No.)	19 (63%)	13 (43%)
Diabetes (No.)	6 (20%)	9 (30%)
History of smoking (No.)	12 (40%)	12 (40%)
Stroke or transient ischemic attack (No.)	4 (13%)	2 (7%)
Hyperlipidemia (No.)	16 (53%)	12 (40%)
Chronic obstructive pulmonary disease (No.)	—	3 (10%)
New York Heart Association functional class (No.)		
I	23 (77%)	26 (87%)
II	4 (13%)	1 (3%)
III	2 (7%)	2 (7%)
Myocardial infarction (No.)	14 (47%)	12 (33%)
Peripheral vascular disease (No.)	—	4 (13%)
Percutaneous coronary intervention (No.)	—	1 (3%)

All studied grafts in the control group were patent. Seven of the grafts performed with the connector were occluded (26%), as verified by both coronary angiography and MRI. One patient in each group had a significant stenosis at the anastomotic site (Table 3). Of the 7 occluded grafts, 3 required an extra suture because of bleeding.

Discussion

There are several reasons for the vast interest in developing new technology for vascular connections. With the increasing popularity of beating-heart CABG, the need to develop the anastomotic technique increases. The final goal for this technique is the use of a simple mechanical anastomotic device inserted through a small skin incision. Now that percutaneous coronary interventions are developing rapidly, it is important to simplify the CABG procedure to make it more appealing for both the referring cardiologist and the patient, especially in the light of the good long-term results of the CABG procedure. There is also an industrial interest in the profit of developing new products in new fields of medicine.

A limitation of this study lies in its variability among the individual patients. Size of the coronary arteries, morphologic and pathologic properties of the arterial wall, and other factors differ among patients however well they are chosen. A larger random sample of patients would reduce this phenomenon; however, in the light of our results it would raise ethical objections.

The rather strict selection of patients with regard to exclusion criteria was based on our efforts to limit variations among patients and also to avoid possible effects of medication on grafts and coronaries. Low ejection fraction,

TABLE 2. Distribution of target vessels (studied grafts)

	Connector	Hand sewn
Obtuse marginal branch I	10	11
Obtuse marginal branch II	2	2
Right coronary artery	2	2
Posterior descending artery	7	9
First diagonal artery	1	4
Second diagonal artery	2	1
Intermediate artery	4	1
Total	28	30

TABLE 3. Postoperative graft findings at coronary angiography or coronary MRI

	Connector	Hand sewn
Patent	20 (74%)	27 (100%)
Occluded	7 (26%)	0
Total	27	27

reoperative procedures, and emergency surgery were considered as complicating factors when trying out this new equipment and were therefore avoided.

Several anastomotic devices based on different techniques have been presented for trial and testing on coronary arteries.⁷⁻¹¹ In this study, the St Jude Medical stainless steel 2.0 distal connector had an early graft patency of 76%, which could be regarded as an acceptable result compared with early graft patency in vein grafts.¹² Compared with the control group in this study, however, in which all hand-sewn grafts were open, it is not acceptable. This stresses the importance of study design early in the developmental process of new technology to get relevant information. It is of utmost importance not only for the patient but also for the industry to get accurate information from clinical and scientifically correct studies.

Because the outer diameter of the target vessels in this study had to be greater than 2.5 mm and the coronary arteries were required to be without too much calcification, there was a clear selection of lightly diseased vessels, in which graft patency of sutured anastomoses can be expected to be high as found in the control group. There could be several reasons for the occlusions of the connector-made anastomoses. Foreign material is introduced into the intima of the vessels and might induce intimal hyperplasia, which has been described after intracoronary stent placement.¹³ This phenomenon has not been observed in long-term animal studies with coronary connectors; however, in those studies the device was introduced in a healthy area. Borst and associates¹⁴ presented a study in which the foreign material exposed in the lumen with different stents and coupling devices was quantified. The St Jude Medical con-

necter system (also used in our study) had a low proportion of foreign material exposed in the lumen, which makes this explanation less probable.

In our study, postoperative prophylaxis was attempted with acetylsalicylic acid only, according to our clinical routine after CABG at that time. It has been known for some time that the results after percutaneous coronary interventions have been improved with administration of clopidogrel,^{15,16} a drug with a wider and more complex effect on platelets. Considering our results, it can be discussed whether a more effective prophylaxis should have been used, along the lines of the routines used by percutaneous coronary interventionalists, but the question then arises as to whether to treat the control group as well, introducing an ethical aspect because clopidogrel is not a drug recommended after CABG in this country.

There could also be a mechanical reason for the occlusion of the connector-made anastomoses. After deployment of the connector, the vein has to be ligated, which creates a sac close to the anastomotic site in which a thrombus eventually will form. Studies have shown a remodeling of the intimal layer in such a sac as a result of the flow pattern.

In 6 connector-made anastomoses, an extra suture was placed at the anastomotic site to mobilize the adventitia and achieve a padding effect to stop ongoing bleeding. Even if the removal of a failing connector is feasible, the coronary artery will be traumatized, which will jeopardize the quality of the subsequent anastomosis. In the situation of a technical failure, such as a leaking anastomosis, we chose to add a suture carefully instead of anastomosing a damaged target vessel. In 3 of 7 occluded grafts, an extra suture had been placed for that reason. In 4 cases with occluded grafts, however, the deployment of the connectors was uneventful, indicating that an extra suture was not the only plausible cause of occlusion. The complexity of the whole connector system, in addition to biologic variations (graft and coronary quality, wall thickness, or a mismatch between the vein graft and coronary artery) may strongly contribute to the leakage. Another cause for leakage could be a deformation of the stainless steel connector during the deployment. This weakness could probably be avoided by using another material, such as nitinol.

Eckstein and colleagues⁶ recently reported only 1 occluded graft out of 11 at 3 postoperative months in anastomoses created with the St Jude Medical coronary connector. There could be several explanations for this discrepancy in results. They observed narrowing at the anastomotic sites in 3 cases, which could be interpreted as thrombus under formation. They were also using a larger connector, 2.5 rather than 2.0. In comparing their data with ours, we consider it a great challenge to construct connectors aimed

for vessels smaller than 2.5 mm with an acceptable occlusion rate.

In conclusion, the St Jude Medical ATG coronary 2.0 connector is not ready for clinical use. There is too high an incidence of leakage, and the graft patency is too low. This finding illustrates the importance of controlled studies when evaluating new technical equipment in medicine.

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