Forty-one-month follow-up of the Symmetry aortic connector system for proximal venous anastomosis

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Objective: Results of short- and midterm follow-up studies of the patency rate of the Symmetry aortic connector systems (St Jude Medical, Inc, Minneapolis, Minn) are controversial. Long-term follow-up studies are still lacking (so far, the longest mean follow-up period was 19 months). The aim of our study was (1) to evaluate the patency rate of this device over a longer time-period and (2) to analyze risk factors for graft occlusion.

Methods: Between November 2000 and July 2003, 76 Symmetry aortic connector systems were implanted in 42 patients. At follow-up, 24 patients with 44 mechanical connectors were studied with 64-slice cardiac computed tomography. Eight patients had died previously, 6 patients refused to undergo a computed tomographic scan, and 4 patients had to be excluded because of impaired renal function.

Results: From a total of 44 mechanical connectors studied, 24 (55%) were occluded, 20 (45%; confidence intervals 31%–61%) were patent, and 7 of these grafts showed stenosis in the area of the connector. Mean follow-up was 41 ± 10 months (18–52 months). Sex, age, left main stenosis, hyperlipidemia, hypertension, renal failure, target vessel, stenosis of the target vessel, diameter of the target vessel, type of surgical intervention, diabetes, ejection fraction, postoperative anticoagulation regimen, and the connector size showed no significant influence on the bypass graft patency ($P > .05$). The bypass graft flow was recognized to be the only risk factor for bypass graft occlusion ($P = .0256$).

Conclusion: Midterm follow-up data show a high number of occluded Symmetry aortic connector system vein grafts. On the basis of these observations, the use of the connector was abandoned at our institution.

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Since CE Mark and Food and Drug Administration market approval were granted in the years 2000 and 2001, more than 40,000 Symmetry aortic connector systems (SACSs; St Jude Medical, Inc, Minneapolis, Minn) for proximal venous aortic connection have been implanted worldwide. Results of short- and midterm follow-up studies on the patency rate of these devices are controversial, with some reports showing good results and some an incidence of graft occlusion as high as 50% with the SACS.^{1–16} Long-term follow-up studies are still lacking; so far, the longest mean follow-up period was reported by Kitamura and associates¹⁷ in October 2005. Twenty-seven SACSs were evaluated with

Abbreviations and Acronyms

AVR = aortic valve replacement
 CABG = coronary artery bypass grafting
 MSCT = multislice computed tomography
 SACS = Symmetry aortic connector system

multislice computed tomography (MSCT) by that group; the mean follow-up was 19 months and the 1-year patency rate of that mechanical device was 92.6%.

The goal of our study was (1) to investigate the patency rates of SACS grafts over a longer time period and (2) to analyze risk factors for graft occlusion.

Patients and Methods

From November 2000 to July 2003, a total of 42 patients at our institution received the SACS at the time of coronary artery bypass grafting (CABG) either alone ($n = 18$) or with aortic valve replacement (AVR) ($n = 24$). All proximal saphenous vein graft anastomoses to the ascending aorta were performed with the SACS ($n = 76$); conventional techniques were used for venous distal anastomoses and left internal thoracic artery grafts to the left coronary artery ($n = 22$). Indication for the use of the SACS was a localized calcification of the ascending aorta, which was identified by digital palpation of the aorta. Transesophageal echocardiography was done routinely. All operations were performed by the same surgeon, who had been certified after a St Jude Medical, Inc, course for the Symmetry device and had extensive experience with aortic valve, on-pump, and off-pump CABG surgery.

One of our patients had had a CABG operation 7 years earlier; none had undergone previous coronary stent implantation. A total of 4 patients underwent revascularization without cardiopulmonary bypass. Graft flow was always evaluated intraoperatively with a flowmeter (CardioMeds; Medi-Stim, Oslo, Norway) according to the transit-time principle. There were no device failures at the time of implantation.

Surgical Procedures

The saphenous vein was harvested by experienced surgeons using an open technique. Heparin was used to keep the activated clotting time in excess of 300 seconds. In off-pump CABG procedures, 150 to 200 IU/kg of heparin was given to reach a target activated clotting time of 300 seconds. In the on-pump cases and in combined AVR procedures, 300 IU/kg of heparin was administered. The veins were mounted on the correctly sized device by the trained surgeon depending on vein diameter. The proximal anastomoses were performed immediately after cardiopulmonary bypass was started, followed by crossclamping for the distal anastomoses or AVR. In on-pump CABG procedures, the proximal anastomoses were performed after heparin had been administered and the activated clotting time had reached 300 seconds.

Postoperative Anticoagulation

Intravenous heparin was always administered from postoperative days 1 through 5 to maintain the partial thromboplastin time at a

value 2.5 to 3 times greater than the normal value. All patients undergoing CABG received long-term postoperative aspirin therapy (300 mg intravenously on the first postoperative day, then 100 mg/day orally). After biological AVR + CABG, patients received warfarin with an international normalized ratio target range of 2 to 2.5 for 3 months, followed by long-term aspirin treatment. Patients with mechanical AVR + CABG and those with permanent atrial fibrillation were put on a permanent regimen of anticoagulation.

Postoperative Follow-up and MSCT Evaluation

This study was approved by the institutional research ethics committee, and informed consent was obtained from all patients. In January 2005, all surviving patients who had received a SACS implant were contacted by telephone and invited to undergo a 64-slice MSCT (Siemens Somatom Sonata, Erlangen, Germany) to evaluate the bypass graft. Exclusion criteria were intolerance to contrast medium, creatinine clearance greater than 1.5 mg/dL, and claustrophobia. At that time, 8 of the 42 patients had already died, as will be described in detail below. Six patients refused to participate without giving reasons; all of them were under a cardiologist's regular care and were in New York Heart Association class I. Four patients had to be excluded because of impaired renal function. The remaining 24 patients with 44 SACSs (ie, the study group) underwent 64-slice MSCT to determine patency of the bypass graft. Collimation was 0.6 mm and rotation time 0.33 seconds at 120 kV and 750 ms. The dimeric non-ionic contrast medium Visapaque 270 USB (Amersham Health, London, United Kingdom) was applied intravenously via an antecubital vein. The circulation time was measured with a 10-mL bolus injection before the main scan. The total contrast dose for the main scan was 80 mL. Each scan took 10 to 12 seconds; during this time the patients had to hold their breath, but this was never a problem. The complete examination took 10 to 15 minutes.

The raw data were reconstructed routinely in 1-mm slices showing 55% to 65% of the R-R intervals using retrospective electrocardiogram-gated reconstruction at 25 cm of the displayed field of view. The reconstructed images were transferred to a workstation (Wizard Siemens Medical Solution, Erlangen, Germany) for postprocessing. Axial, 3-dimensional volume-rendered, and maximum intensity projection reconstructed images were analyzed to evaluate the number, location, and patency of the bypass grafts. Graft occlusion was diagnosed if the graft was not visualized. The connector itself, however, was always visible.

Statistical Analysis

Numeric data were analyzed with the t test. Categorical data were analyzed by the Fisher exact test and χ^2 analysis. Results are expressed as mean $\pm$ SD.

Results**Clinical Outcomes**

Of the 42 patients, 3 died within the first 30 postoperative days; 2 of them, aged 80 and 81 years, underwent combined AVR and CABG and died of multiorgan failure in the intensive care unit. In both cases, autopsy showed all bypass grafts to be patent and valve function after biological AVR to be unimpaired. The third patient, aged 82

TABLE 1. Clinical profile of the study group (n = 24 patients with 44 SACSs)

Age (y)	
Mean $\pm$ SD	70.9 $\pm$ 7.8
Range	54–88
Female (No. of patients)	9
Ejection fraction (%)	
Mean $\pm$ SD	63.0 $\pm$ 12.3
Range	35–80
Left main trunk stenosis (No. of patients)	5
Three-vessel disease (No. of patients)	6
Two-vessel disease (No. of patients)	3
One-vessel disease (No. of patients)	1
Aortic stenosis + 3-vessel disease (No. of patients)	5
Aortic stenosis + 2-vessel disease (No. of patients)	5
Aortic stenosis + 1-vessel disease (No. of patients)	4
Coronary artery stenosis 75%–90% (No. of Cv)	21
Coronary artery stenosis > 90% (No. of Cv)	23
Old myocardial infarction (No. of patients)	8
Diabetes mellitus (No. of patients)	5
Hypertension (No. of patients)	18
Chronic renal failure (No. of patients)	5
Hyperlipidemia (No. of patients)	8

SACSs, Symmetry aortic connector systems; SD, standard deviation; Cv, Coronary vessels.

years, died 21 days after CABG of a pulmonary artery embolism at a rehabilitation center after he had been discharged from the hospital in good condition on the ninth postoperative day.

Five of the remaining 39 patients died within the average observation period: 1 patient died of uterine carcinoma 20 months after surgery; 1 patient of a cerebrovascular accident 43 months postoperatively; 2 patients of myocardial infarction 3 and 11 months after surgery; and the fifth patient died of unknown cause 32 months after CABG. Nothing can be said about the patency of those bypass grafts. The study group comprised 24 patients (15 men and 9 women); their average age at the time of surgery was 70.9 $\pm$ 7.8 years. The clinical profile of the study group is summarized in Table 1. Among them, 44 SACSs and 10 left internal thoracic artery grafts were anastomosed. Twenty-one months after mechanical AVR + CABG with 3 mechanical connectors, 1 of these patients had to be reoperated on because all of the bypass grafts using a SACS were occluded. The redo procedure was performed off pump with 2 venous grafts to the left anterior descending and circumflex arteries. Proximal and distal anastomoses were performed with conventional hand suture.

Operative details of the study group are summarized in Table 2.

The mean follow-up was 41 $\pm$ 10 months (range 18–52 months). Twenty-four of 44 SACS grafts (55%) were occluded, 20 (45%; confidence interval 31%–61%) were

TABLE 2. Operative details for the study group (n = 24 patients with 44 SACSs)

CABG (No. of patients)	
On-pump	6
Off-pump	4
CABG + AVR (No. of patients)	
Biological AVR	11
Mechanical AVR	3
Skin-to-skin time (min)	
Mean $\pm$ SD	226 $\pm$ 61
Range	82–371
Bypass time (min)	
Mean $\pm$ SD	124 $\pm$ 48
Range	44–239
Crossclamping time (min)	
Mean $\pm$ SD	88 $\pm$ 41
Range	15–193
Left internal thoracic artery grafts (No.)	10
SVGs (No.)	44
Total distal anastomoses (No.)	54
Distal anastomoses per patient (No.)	2.25 $\pm$ 0.7
Range	1–3
SACS size (mm)	
4.5–5.0 (No.)	19
5.0–5.5 (No.)	23
5.5–6.0 (No.)	2
Intraoperative SVG flow (mL/min)	
Mean $\pm$ SD	51 $\pm$ 30
Range	17–152
Target coronary arteries for SVG (No.)	
Left anterior descending	11
Right coronary artery	16
Circumflex artery	15
Diagonal branch	2
Coronary artery size (mm)	
<2 mm (No.)	27
>2 mm (No.)	17

SACSs, Symmetry aortic connector systems; CABG, coronary artery bypass grafting; AVR, aortic valve replacement; SD, standard deviation; SVG, saphenous vein graft.

patent. All of the hand-sewn left internal thoracic artery anastomoses on the left anterior descending artery were patent (n = 10). Seven (35%) of the open bypass grafts showed a stenosis between 50% and 70%; these were located in the area of the connector. Eighteen patients were in New York Heart Association class I, 4 in class II, and 2 patients were in class III. One of them had to be reoperated on because of an occlusion of all venous grafts with symptomatic unstable angina pectoris. All the other patients are under regular care of a cardiologist.

The perioperative details of the occluded and patent venous grafts are shown in Table 3. Intraoperative graft flow proved to be the only variable exerting a significant influence on graft patency ($P = .0256$).

TABLE 3. Data of patent versus occluded venous grafts

Variable	Patent (n = 20)	Occluded (n = 24)	P value
Age (y, mean)	71.7 ± 6.9	70.9 ± 7.9	.7361
Ejection fraction (%)	60.3 ± 16.2	58.5 ± 15.6	.7170
Sex			
Male	9	15	
Female	11	9	.3627
Graft flow (mL/min, mean)	61.3 ± 34.8	41.2 ± 22.5	.0256
Intraoperative pulsatility index	2.69 ± 1.19	2.50 ± 1.05	.6953
Diabetes mellitus (No.)	2	4	.6731
Left main trunk stenosis (No.)	5	5	.999
Hyperlipidemia (No.)	9	11	.999
Hypertension (No.)	6	13	.1350
Value of coronary artery stenosis (%)			
75%-90% (No.)	12	9	
>90% (No.)	8	15	.2252
Chronic renal failure (No.)	0	5	.0534
Anticoagulation regimen			
Long-term aspirin (No.)	4	6	
Warfarin, then long-term aspirin (No.)	8	5	
Long-term warfarin (No.)	8	13	.3800
SACS size (mm, No.)			
4.5-5.0	9	10	
5.0-5.5	10	13	
5.5-6.0	1	1	.9603
Diameter of coronary artery (mm, mean)	1.73 ± 0.54	1.67 ± 0.48	.7093
Target coronary arteries (No.)			
Right	10	6	
Circumflex	4	11	
Left anterior descending	6	5	
Diagonal	0	2	.1094
Surgical intervention (No.)			
CABG	8	9	
AVR + CABG	12	15	.999

SACSs, Symmetry aortic connector systems; CABG, coronary artery bypass grafting; AVR, aortic valve replacement.

Discussion

Since the first clinical description of the SACS by Eckstein and associates¹⁸ in 2001, there have been highly varying reports in the literature on the patency rate for this mechanical connector device. There are reports of good results in short-term follow-up with patency rates of 96% on hospital discharge,³ 89% patency on 3-month follow-up,⁵ and 87% patency on 7-month follow-up.¹⁶ This corresponds to the development in the first month of early postoperative graft thromboses with conventional suture technique that is reported to be 5% to 10%.¹⁹ In contrast, there are also reports of graft occlusion or a high-degree graft stenosis of 31% to 54% in short-term follow-up,⁶⁻⁸ wherein these reports covered only symptomatic patients, so that nothing can be said about the

overall patency rate. A randomized study by Carrel and associates⁴ with a planned follow-up of 6 months was ended prematurely owing to a 38% incidence of stenosis in the proximal vein graft segment in those patients who received the SACS. Bergsland and colleagues⁹ showed an overall patency rate of only 50% after an average follow-up of 4.8 months. In contrast, 1-year patency rates of 80% to 86% were reported for conventional venous bypass grafts.^{19,20}

To our knowledge, the longest follow-up studies were those of Kitamura and coworkers¹⁷ (19-month follow-up with a 1-year patency rate of 92.6%) and Khan and associates²¹ (12-month patency rate of 84%). These studies, however, said nothing about the degree of stenosis of patent venous grafts. Long-term patency of venous bypass grafts stapled with the SACS has not as yet been reported in the literature.

In our average follow-up of 41 months, only 45% of the venous grafts created with the SACS were patent, and 35% of them showed stenosis of greater than 50% in the area of the device. All of the conventional left internal thoracic artery anastomoses on the left anterior descending artery were patent. Fitzgibbon and colleagues¹⁹ give the incidence of venous graft occlusions of conventional anastomoses after 1 year as 1% to 2.5% per year. Extrapolated for an average observation period of 41 months, this would be a patency rate of 71% to 92% for conventional grafts. Our results with venous grafts made with the SACS thus are poorer than would be expected with hand-sutured anastomoses.

Kinking of the graft has been mentioned as a possible reason for the high incidence of graft occlusion with the SACS.^{2,3,22} This is possible because the aortic connector is anastomosed at a 90° angle to the ascending aorta. Kinking can also be caused by an excessively long bypass graft inasmuch as, with mechanical anastomoses, unlike conventional ones, the proximal anastomosis must be created first, and so the length of the graft may be incorrectly estimated.²³ In our study group, there were never any technical complications with the implantation of the SACS and all the proximal SACS anastomoses were patent at the end of the operation. We cannot evaluate whether graft kinking led to occlusion of the graft, because occluded grafts are recognizable in the MSCT as a stoppage of contrast medium flow and a kink in the bypass graft is not seen. We were, however, aware of the problem, and to avoid it, we placed the device laterally on the aorta.

Spontaneous restenosis of hand-sutured saphenous bypass grafts is described to occur at the distal part of the anastomosis. All of the stenoses in the open bypass grafts that were identified in our study were in the area of the connector, and there was no kinking of the vessels with these grafts. Therefore, a potential involvement of the device in the stenosis process is plausible.

The histopathologic study of Farhat and coworkers²⁴ shows a further possible cause of graft occlusion. Connector

application caused complete alteration of the endothelium in 58%; more than 80% of those showed severe lesions of the vascular wall, in 42% there was dissection of the media, and in 5%, a complete thrombus on the vascular wall.

As far as medical treatment to avoid early thrombotic event is concerned, there is no uniform regimen. Some use aspirin alone, others use aspirin and clopidogrel, and still others use an anticoagulation regimen for 3 months.^{8,18,25} The manufacturer's recommendations for the SACS do not mention any antithrombotic treatment or anticoagulation after implantation. Our study did not show any significant difference in graft patency rate between antiplatelet or anticoagulant treatments, although it is uncertain whether clopidogrel would have influenced the occlusion rate.

Our study has some limitations. The patients in whom the connector device was used were not randomized; rather, they were chosen selectively on the basis of having partial arteriosclerosis of the ascending aorta. The reason for this was that this indication is mentioned in the literature and the use of the SACS was justified on the basis of good short-term follow-up results. Further, because of the high cost of the device, our division only had 80 SACSs at its disposal, which were applied selectively.

The expected patency rate for conventional hand-sutured proximal venous anastomoses was obtained from the scientific literature. Our historical controls of conventional anastomosis were similar to those results but were not published. Further, it remains unclear whether clopidogrel would have a positive influence on graft patency, as it does in interventional coronary stent application. None of our patients received this treatment and, to the best of our knowledge, there have been no relevant publications for SACSs up to this date.

Further, only 71% of the survivors underwent computed tomographic angiography, because 6 patients refused to participate and 4 patients had to be excluded owing to impaired renal function. These patients are under a cardiologist's regular care, but nothing can be said about the patency rate of the grafts.

In conclusion, despite the promising results reported in the literature for short-term follow-up with patency rates similar to conventional suture technique, our poor results for patency rates in longer-term follow-up led us to abandon use of this device at our institution.

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