

## Spyder™ Proximal Coronary Vein Graft Patency over Time: The SPPOT Study

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### ABSTRACT

**Background:** Clamless proximal anastomoses are associated with fewer strokes in coronary artery bypass (CAB) graft surgery, but lack of patency of proximal grafts has been an issue. The Spyder™ (Medtronic, Minneapolis, MN, USA) is an “exoconnector” device that deploys a nitinol clamping mechanism to attach a vein onto the aortotomy and create the proximal anastomosis.

**Methods:** During a 22-month period we performed gated cardiac computed tomographic angiography on 38 patients who underwent off-pump CAB.

**Results:** Of the 49 proximal anastomoses created with the Spyder™, 44 (90%) remained patent at the time of study, with a mean follow-up period of 16.7 months.

**Conclusions:** The use of the Spyder™ exoconnector to create a clamless proximal anastomosis during off-pump CAB surgery is a reasonable strategy to improve graft patency.

### INTRODUCTION

To facilitate off-pump coronary artery bypass (OP-CAB), several methods have been developed to create a clamless proximal vein-to-aorta anastomoses. These types of connectors are quickly deployed and have been shown to facilitate the creation of anastomoses of vein grafts to the aorta, thus eliminating the use of an aortic clamp [Eckstein 2001; Eckstein 2002; Mack 2003; Scarborough 2003; Semrad 2003; Katariya 2004]. Early patency of proximal anastomoses created in this fashion has been questioned because of reports of thrombosis associated with these connectors [Donsky 2002; Cavendish 2004; Dietrich 2005; Kitamura 2005].

Interrupted nitinol sutures (U-Clip; Medtronic, Minneapolis, MN, USA) were developed to aid in the quick placement of secure surgical anastomoses without the need to tie knots. These types of clips have a potential advantage over more rigid anastomotic connectors because they have less material exposed to the bloodstream, these connectors could be less susceptible to acute thrombosis and/or long-term restenosis. Data are scarce regarding midterm patency rates of grafts for which this type of device has been used to create the proximal anastomosis.

Received October 8, 2008; accepted December 10, 2008.

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To facilitate off-pump anastomotic creation, the Spyder™ device (Medtronic) simultaneously deploys a ring of interrupted nitinol sutures (Figure 1). This procedure minimizes the need for aortic manipulation during off-pump coronary bypass (OP-CAB) and may reduce associated complications [Hamman 2005].

We evaluated midterm patency of proximal anastomosis of saphenous vein grafts that had been successfully created with the Spyder™ tool during OP-CAB. All studied grafts were older than 6 months in order to allow for adequate endothelialization and possible midterm restenosis.

### METHODS

Data were collected from retrospectively studied patients who underwent OP-CAB during which the Spyder™ was used to create the proximal anastomosis(es). The cohort of patients originated from one surgeon's practice during a 22-month period (August 1, 2003, to June 30, 2005). Use of the Spyder™ was always at the discretion of the surgeon. All OP-CAB procedures were performed via median sternotomy, and all proximal vein-to-aorta grafts were created on the ascending aorta.

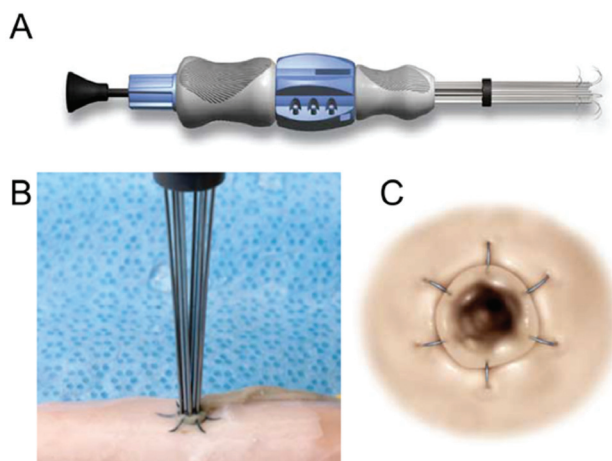


Figure 1. The Spyder™ device (panel A). Panel B demonstrates deployment of the interrupted ring of nitinol sutures, prior to releasing the clips. A view of the anastomosis seen from the lumen of the aorta (panel C) provides a close-up view of the ring of connectors. It is notable that very little of the metallic portions of the clips is in contact with the lumen of the vein graft (photos courtesy of Medtronic).

Table 1. Patient Population Demographics\*

	All CAB	On-Pump CAB	OP-CAB	OP-CAB with Spyder	OP-CAB with Spyder Analyzed by CTA
n	234	108	126	70	38
Age, y	64.5 ± 10.8	63.9 ± 10.8	64.9 ± 10.6	66.9 ± 10.6	65.0 ± 9.5
Male sex	163 (70%)	80 (74.1%)	83 (66%)	45 (64%)	24 (63%)
Diabetes	110 (47%)	57 (52.8%)	53 (42%)	27 (37%)	14 (37%)
Previous stroke	36 (15%)	15 (13.9%)	21 (17%)	16 (23%)	9 (24%)
PVD	40 (17%)	16 (14.8%)	24 (19%)	12 (17%)	8 (21%)
PVD or stroke	62 (27%)	24 (22.2%)	38 (30%)	22 (31%)	13 (34%)
Hypertension	176 (75%)	83 (76.9%)	93 (74%)	51 (73%)	28 (74%)
Chronic renal failure (on hemodialysis)	5 (2.1%)	3 (2.8%)	2 (1.6%)	2 (2.9%)	0 (0.0%)
Renal insufficiency (creatinine >1.9, not on hemodialysis)	19 (8.1%)	9 (8.3%)	10 (7.9%)	5 (7.1%)	0 (0%)
Previous MI	108 (46%)	58 (53.7%)	50 (40%)	27 (39%)	12 (32%)
Low EF (<40%)	57 (24%)	31 (28.7%)	26 (21%)	16 (23%)	7 (18%)
History of CHF (grade III or IV)	47 (20%)	29 (26.9%)	18 (14%)	11 (16%)	3 (8.0%)
Low EF% or history of CHF	74 (32%)	42 (38.9%)	32 (25%)	20 (29%)	9 (24%)
Urgent/emergent surgery	37 (16%)	25 (23.1%)	12 (9.5%)	8 (11%)	4 (11%)
Previous CABG	22 (9.4%)	10 (9.3%)	11 (8.7%)	6 (8.5%)	3 (8.0%)
Use of LIMA	214 (91.5%)	100 (92.6%)	114 (90.5%)	63 (90.0%)	35 (92%)
Concomitant TMR	47 (20%)	21 (19.4%)	26 (21%)	15 (21%)	6 (16%)
Grafts, n	3.3 ± 1.1	3.8 ± 1.0	2.8 ± 1.1	2.9 ± 1.0	2.8 ± 1.0
Endoscopic vein harvest	81 (35%)	53 (49%)	37 (29%)	27 (39%)	24 (63%)

\*CAB indicates coronary artery bypass; OP-CAB, off-pump CAB; PVD, peripheral vascular disease; MI, myocardial infarction; EF, ejection fraction; CHF, congestive heart failure; CABG, CAB graft; LIMA, left internal mammary artery; TMR, transmyocardial revascularization.

Gated multislice cardiac computed tomography (CT) was used to evaluate the bypass grafts [Peterman 2007]. Inclusion criteria for the study were a regular heart rate of no greater than 80 beats/min at rest and ability to hold the breath for the duration of the scan. Each patient who met these criteria and consented to participate in the study then underwent 64-slice computed tomographic scanning (Lightspeed VCT; GE Healthcare, Milwaukee, WI, USA) for at least 6 months and up to 30 months after their surgery (Figure 2). Evaluation of the CT angiography (CTA) was performed by a reader with experience equivalent to level-3 training, based on American College of Cardiology/American College of Cardiology Foundation guidelines [Budoff 2005].

Patients who were not included in the statistical analysis were those who died before being contacted for CTA study, were lost to follow-up, could not safely undergo CTA for medical reasons, did not wish to participate in the research, and/or had a CTA that was not interpretable. The Society of Thoracic Surgeons database was used to analyze clinical demographics, operative variables, and outcomes.

## RESULTS

During the study period, 234 CAB graft surgeries were performed; 55% were performed as OP-CAB, and 56% of

the OP-CABs were performed with use of the Spyder™ anastomotic device. In no instance was an anastomosis started by using the Spyder™ and then aborted or discontinued. Some anastomoses were repaired in a minor way with suture. The majority of the patients were male, approximately half had diabetes, and slightly more than one-third had an ejection fraction <40%. The rates of low ejection fraction, previous stroke, congestive heart failure, or known peripheral vascular disease were similar in the patient groups who underwent CAB, OP-CAB, and clampless OP-CAB (Table 1).

Every patient whose surgery was performed with the use of the Spyder™ device (n = 70) was included in a demographic report, but only 38 patients were included in the patency analysis. Of the original cohort of 70 patients, 7 were lost to follow-up and 7 died prior to CTA analysis. Four patients did not qualify for the CTA scan, 12 patients refused to participate in the research study, and 2 had CT scans with nondiagnostic results. Clinical event rates for the different selected surgical strategies are presented (Table 2).

### Graft Patency Results

The 38 patients included in this analysis received CT scans to verify late graft patency at an average of 16.7 months postoperatively. Of the 49 proximal anastomoses created with

the Spyder™ all could be located, and 44 (90%) remained patent during the mean follow-up period of 16.7 months. Although the study was not powered to detect patency differences in various ostiae sizes, it did not appear that there was a greater likelihood that small-sized ostiae were associated with a higher chance of closure (Table 3).

In the patient group with anastomoses created with the Spyder™ there was low hospital mortality and few adverse central nervous system events. The low incidence of perioperative stroke, seizure, and transient ischemic attack in the Spyder™ group is consistent with decreased embolic strokes attributable to less aortic manipulation. Incidences of myocardial infarction and repeat intervention for all on-pump and OP-CAB procedures were nominal. Those incidences were equally low in the group receiving anastomoses created with the Spyder™ device.

A single-operator, single-center series study such as ours is limited in many ways. To provide the best care, we did not randomize the patients in the study. All OP-CAB procedures were performed only on those patients considered by the surgeon to be best served by use of this procedure. Scans and follow-up data were not blinded.

**DISCUSSION**

CAB surgery has a low but measurable incidence of complications and stroke [Hogue 1999; Roach 1996; Stamou 2001]. Emboli dislodged from the ascending aorta are thought to be the etiology of most strokes in patients undergoing CAB [Bar-El 1992; Blauth 1992; Barbut 1994; Pugsley 1994; Aranki 1995; Ascione 2005]. To reduce patient morbidity, off-pump techniques for CAB have been created [Hartman 1996; Antunes 2003; Patel 2003; Bucnerius 2004; Lev-Ran 2005; Sedrakyan 2006; Hammon 2006].

Surgeons have developed 2 general strategies for performing clampless proximal vein-to-aorta anastomoses. Some problems with devices invented to create clampless proximal anastomoses have dampened enthusiasm for the technique

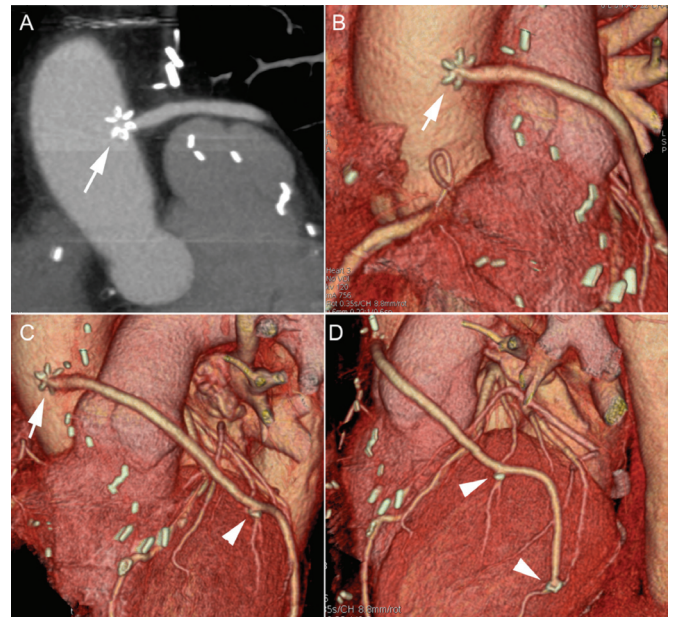


Figure 2. A 64-slice computed tomographic coronary angiogram of a patent vein graft. The maximum intensity projection view (A) clearly demonstrates the ring of interrupted nitinol clips that make up the proximal anastomosis. The graft itself is seen to be patent in the 3-dimensional views (B-D). This graft has distal anastomoses with obtuse marginals 2 and 3 (C-D).

[Donsky 2002; Carrel 2003; Carrel 2004; Dewey 2004; Hamman 2005]. In certain cases, because the devices still disrupt the aortic endothelium, clampless devices have failed to prevent the dislodging of atherosclerotic debris from the inside of the aorta [Kanemitsu 2006].

Other devices have been developed that allow a strategy of “no touching” of the inside of the aorta, but affixing the vein to the aorta with these devices requires metal connectors. These have been associated with reduced patency [Donsky 2002; Dewey 2004].

Table 2. Clinical Events in Study Patients\*

	All CAB	On-Pump CAB	OP-CAB	OP-CAB with Spyder	OP-CAB with Spyder Analyzed by CTA
n	234	108	126	70	38
Perioperative death	8 (3.4%)	7 (6.5%)	1 (0.8%)	0 (0%)	0 (0%)
Myocardial infarction	3 (1.3%)	0 (0.0%)	3 (2.4%)	1 (1.4%)	1 (2.6%)
Stroke	5 (2.1%)	4 (3.7%)	1 (0.8%)	0 (0%)	0 (0%)
MACE (30 days)	14 (6.0%)	9 (8.3%)	5 (4.0%)	1 (1.4%)	1 (2.6%)
New-onset renal insufficiency	14 (6.0%)	8 (7.4%)	6 (4.8%)	3 (4.3%)	0 (0%)
New-onset hemodialysis	4 (1.7%)	4 (3.7%)	0 (0%)	0 (0%)	0 (0%)
Reoperation for bleeding	9 (3.8%)	4 (3.7%)	5 (4.0%)	3 (4.3%)	1 (2.6%)
New atrial fibrillation	64 (27%)	25 (23.1%)	39 (31%)	26 (37%)	12 (32%)
Initial ICU LOS, h	48 ± 61	60 ± 76	38 ± 41	35 ± 29	28 ± 16
Postoperative LOS, d	7.7 ± 4.5	7.9 ± 4.3	7.5 ± 4.7	7.4 ± 4.4	7.2 ± 4.7

\*CAB indicates coronary artery bypass; OP-CAB, off-pump CAB; MACE, major adverse cardiac events; ICU, intensive care unit; LOS, length of stay.



Table 3. Patency of Saphenous Vein Graft (SVG) by Size of Aortotomy Cutting Device (ACD)

ACD size	Patency*	Proximal SVG to left	Proximal SVG to right	Proximal SVG to any (all)
Red (3.25 mm)	Patent	1	0	1
	Total	1	0	1
Green (3.68 mm)	Patent	15	5	20
	Total	17	5	22
Blue (4.06 mm)	Patent	8	11	19
	Total	9	12	21
Yellow (4.65 mm)	Patent	3	1	4
	Total	3	2	5
All (3.25-4.65 mm)	Patent	27 (90%)	17 (89%)	44 (90%)
	Total	30	19	49

\*Patency determined by computed tomographic angiography.

In all, 7 types of devices have been invented to allow a surgeon to make a proximal anastomosis without clamping the aorta. These devices may be categorized into 2 groups, endoshields and exoconnectors, according to the strategy for making the bloodless operative field. The use of each device presents challenges. Endoshield devices such as Enclose™ (Novare, Atlanta, GA, USA) and Heartstring™ (Boston Scientific, Natick, MA, USA) attempt to create a dry operating field by using a shield that abuts the aortic endothelium and prevents blood from exiting the aortotomy. Exoconnectors such as the Spyder™, Symmetry™ (St Jude Medical, St Paul, MN, USA), and PassPort™ (Patton Surgical, Austin, TX, USA) devices deploy a clip system through or on top of a circular aortotomy to minimize the perturbation of the endothelium.

These exoconnector devices aid in increasing the speed at which proximal bypass grafts may be created and avoid perturbation of the endothelium. The more rigid, continuous iterations of these devices (eg, Symmetry) have been associated with problems with restenosis or occlusion. Interrupted nitinol sutures, deployed in a single simultaneous fashion, may be a significant step forward in facilitating creation of a clampless, proximal anastomosis.

## CONCLUSION

This study demonstrated that proximal anastomoses created with the Spyder™ exoconnector device have midterm patency comparable to that of traditionally created sutures, with mortality and morbidity rates on par with those of traditional techniques.

This type of device is a valuable addition to the surgeon's portfolio of strategies for minimally invasive CAB graft surgery. The Spyder™ device is relatively simple to deploy and creates reliable and reproducible anastomoses. Creation of this type of vein graft anastomoses may be increasingly helpful as surgeons move toward less invasive surgical techniques.

## DISCLOSURE

Baron L. Hamman is affiliated with Medtronic.

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