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Clampless Anastomosis: Novel Device for Clampless Proximal Vein Anastomosis in OPCAB Surgery—The Initial Spyder Experience

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ABSTRACT

The Spyder is a novel device that enables the attachment of a vein to the aorta by compliant, interrupted anastomosis; this minimizes aortic manipulation during off pump-coronary artery bypass (OPCAB) surgery. Its use may reduce transcranial Doppler signals recorded during CABG. We performed 250 anastomoses in 160 OPCAB cases in many centers and recorded efficiency and efficacy data. There were no adverse events noted during the operative period. In a subset of patients in one center, flow (n = 48) and transcranial Doppler signals (n = 22) were measured. We found the device to be a useful adjunct for minimally invasive CABG surgery.

BACKGROUND

It is widely accepted that peripheral emboli are a common cause of neurological injury incurred during CABG surgery [Loop 1979; Loop 1986; Berger 1999]. Most agree that atherosclerotic plaque on the ascending aorta is the most likely source of emboli in this scenario. The brain and other organs are at risk for injury [Kouchoukos 1994; Barbut 1996; Stamou 2002; Lee 2003]; their injury pattern of frequency and severity correlates to the extent of aortic atherosclerotic disease [Kouchoukos 1994].

Barbut et al showed that transcranial Doppler (TCD) signals correlate with adverse neurological outcomes in CABG during use of the cardiopulmonary bypass pump [Barbut 1996]. The severity of neurological injury correlates with the number of emboli measured during a traditional (on-pump) CABG operation [Kouchoukos 1994; Barbut 1996; Stamou 2002]. There are fewer TCD signals recorded during OPCAB as compared to CABG [Lee 2003]. Most TCD signals are recorded near the time of partial occlusion clamp or cross clamp release in OPCAB [Kouchoukos 1994; Barbut 1996; Stamou 2002; Lee 2003]. Clampless anastomosis of a vein to the aorta during OPCAB may lead to fewer peripheral emboli and consequently to lesser neurological events during OPCAB.

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Several strategies for "clampless" proximal aorto-vein anastomoses have been developed. Intra-aortic barriers are marketed as Novare's Enclose II (Cupertino, CA, USA) and Guidant's HeartString (Santa Clara, CA, USA). Both require the introduction of a shield or barrier into the aorta to shield the aortotomy from intraluminal blood, then creation of the anastomosis, and finally retrieval of the barrier. St. Jude Medical developed a true "clampless" aorto-vein connector that does not touch the intima like the shields, but utilizes a stent-like apparatus inside the vein to affix the vein to the aorta [Traverse 2003].

The Spyder is a novel device that employs both the "no touch" attributes of the Symmetry (St. Jude Medical, St. Paul, MN, USA) method without the introduction of a metal stent into the anastomosis [Fitzgibbon 1996; Cavendish 2004; Ballyk 1998; Wolf 2003]. Its use enables automatic reproducible creation of an aorta to vein anastomosis by placement of nitinol clips through the vein into the aorta in such a way that the vein is affixed onto the aorta by 6 separate clips [Wolf 2003; Hill 2001; Hamman 2003]. The connection is a compliant, interrupted anastomosis. The precursor device, the IPAD, has been shown to be safe and effective in allowing such an anastomosis to be created by hand [Hill 2001; Hamman 2004a; Hamman 2004b].

METHODS

Patients undergoing OPCAB, in whom a vein graft from the aorta to a distal target was indicated were studied in 5 centers. The Spyder was used to create proximal aorto-vein anastomoses. Technical details of the Spyder use were entered into a registry to evaluate efficiency and performance of the anastomoses.

In a selected subset of patients at one center (Baylor University Medical Center), clinical data was obtained regarding TCD signals recorded during the operation. Doppler flow data was recorded after the operation was complete. The proximal anastomoses were created before the distal anastomoses because of surgeon preference though the reverse order is feasible.

The veins were removed from the patients' legs using an endoscope, and then they were evaluated for Spyder use. Patients whose outer vein diameter measured from 2.8 mm to 7.0 mm and in whom Spyder proximal anastomoses were attempted were included in the study.

The vein was loaded onto the Spyder device by pushing it through the legs about 2 mm beyond the edge of the device

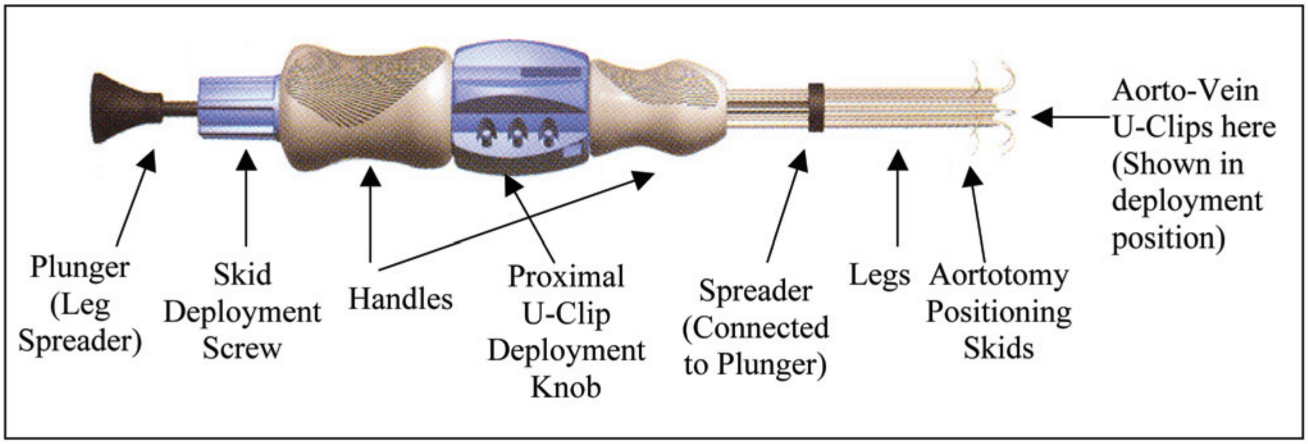

Figure 1. The Spyder anastomotic device.

(Figure 2). A loader tool (Figure 2A and 2B) or a triangulation technique (Figure 2C and 2D) was used to evert the end of the vein over the end of the legs. Skids (Figure 2E) were extended about one millimeter from the vein (Figure 2E) edge to capture the end of the vein. The skids later serve as stops to prevent pushing the as-yet connected vein into the aorta.

Full-dose heparin (300 mg/kg) was given and an activated clotting time was measured. A cut-out hole in the ascending aorta was made with the circular aortic core cutting device while the systemic blood pressure was maintained at 90 mm Hg ± 15. Digital pressure over the hole maintained hemostasis during the vein to aorta transfer. The skids were fully extended for optimal and consistent positioning of the vein onto the device. The skids also served to limit or stop the depth that the Spyder could be inserted into the aortotomy.

After the ready device was transferred to the aortotomy, the plunger was pushed forward to spread the legs and maximize the aorto-vein inner diameter. The small vein eversion served initially to seal the vein to aorta connection. The veins were automatically attached to the aorta with interrupted nitinol U-Clips (Medtronic, Minneapolis, MN, USA) by twisting the deployment knob while holding the handle. The U-Clips were released through the ends of the legs of the Spyder mechanism. The U-Clips completely penetrated the vein and then the aorta for a secure attachment (Figure 3).

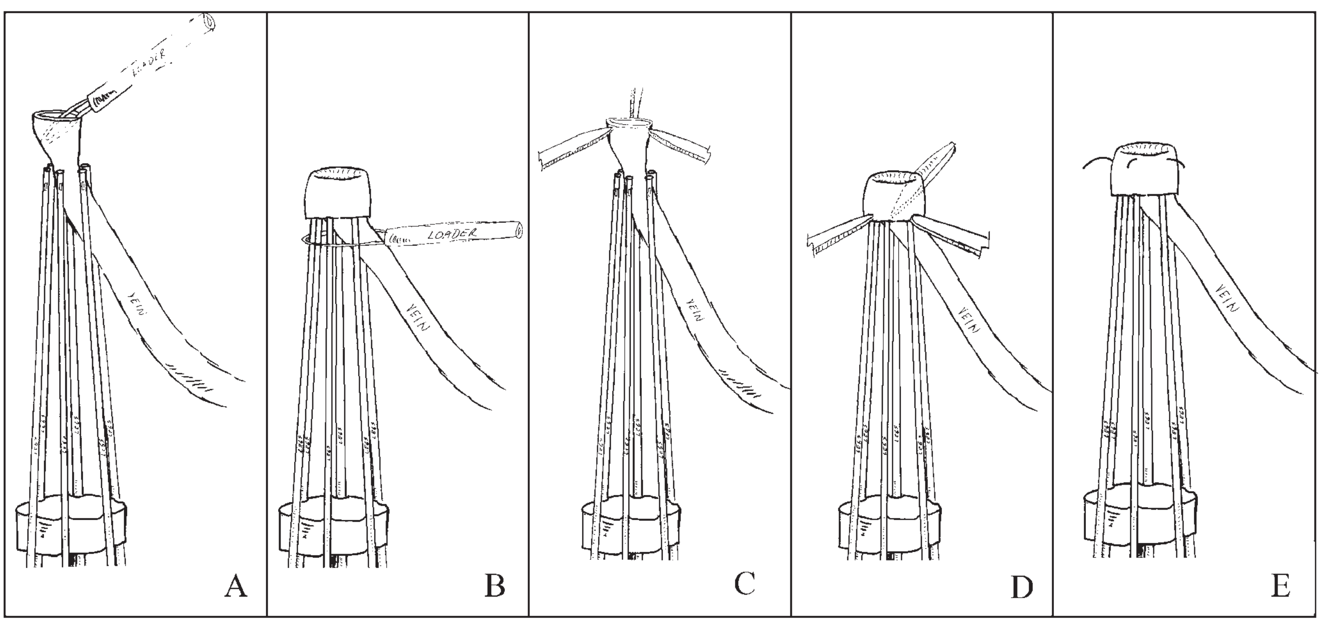

Figure 2. Loading a vein onto the Spyder. A, Placement of the loader tool into the lumen of the appropriately positioned vein. B, Eversion of the vein over the end of the collapsed Spyder by a gentle push. C, Alternative triangulation method of vein eversion by gently grasping the ends of the vein and simultaneously pulling downward to (D) evert the vein onto the Spyder legs. E, Skids are gently driven out to capture the vein ends optimizing the eversion and enabling a stop used when transferring the vein to the cut out aortotomy.

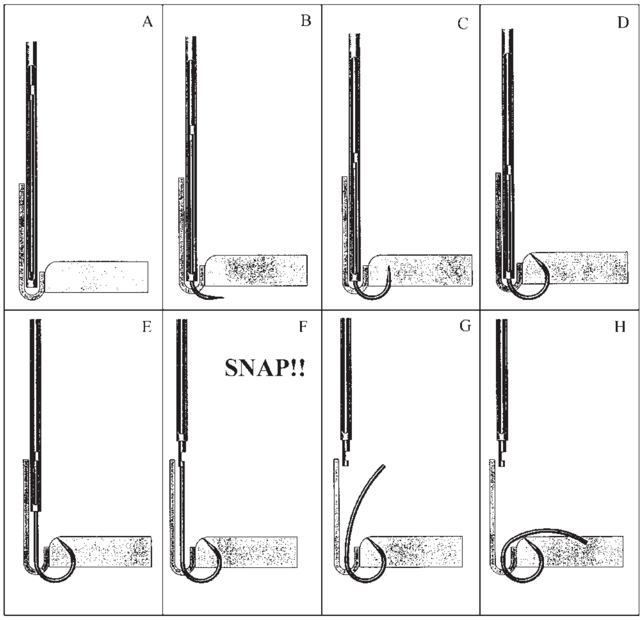

Figure 3. Creation of a Spyder U-Clipped proximal anastomosis. A, Approximation of vein into the aortotomy. B, Penetration of the U-Clip through the vein cuff. C, U-Clip penetrates the internal wall of the aorta. D, Internal position of the U-Clip complete [Hill 2001]. E, Begin Spyder outer tube removal. F, Spyder disengaged from U-Clip. G, U-Clip begins to "lay down" onto the aortic surface. H, Final U-Clip position–proximal anastomotic connection created.

In some patients, the anastomosis was optimized by gently and partially backing out or manipulating the deployed clips to reduce the eversion cuff. The perioperative measurements included the time for anastomosis completion and repairs; TCD signals and graft flows were evaluated with the Medi-Stem Butterfly Doppler Flow Analyzer (Medtronic) in the operating room before closure of the sternotomy. The patients were followed for 2 to 8 months postoperatively for signs of clinical complications.

RESULTS

Registry numbers are reported in Table 1. There were 250 Spyder proximal anastomoses created in 160 patients having OPCAB (mean, 1.56 anastomoses per patient). The length of time required to load the vein onto the Spyder averaged 2.8 minutes; the length of time to create the average anastomosis was 11.5 minutes, allowing an average anastomosis to be created in less than 15 minutes.

Table 1. Time for Anastomosis Completion and Repairs Were Recorded

Technical Data (n = 250)	
Vein Size (mm): Outer Diameter	3.6 ± 0.5
U-Clip Deployment	
Initial (by design)	6.0 ± 0.0
Augmentation clips	0.2 ± 0.2
Time to load Spyder, min	2.8 ± 0.25
Time to Secure Anastomosis, sec	11.5 ± 8.0

Table 2. Graft Flows in the Operating Room before Closure of the Sternotomy

Patency data:	Spyder–SVG, n = 32	Clamped–SVG, n = 16
Doppler flow (mL/min)	40.1 ± 18.7	36.13 ± 29.4
Pulsitility index	2.64 ± 0.69	2.31 ± 0.88

Table 3. TCD Signals Were Measured When Possible*

Transcranial Doppler Data	Spyder–SVG, n = 16	Clamped–SVG, n = 6
Average HITS per case	3.13 ± 4.90 ns	12.6 ± 21.1
Median (range) per case	2 (0-17)	8 (0-55)

*HITS indicates high-intensity transient signals.

Subset data from BUMC are shown in Table 2. Forty-eight patients were included in the comparison of Spyder versus clamped anastomoses. Graft flows were evaluated with the Medi-Stem Butterfly Doppler Flow Analyzer. Doppler flow signals showed satisfactory and equal flow in the grafts. The pulsatility indexes were satisfactory in both groups and not different.

In 22 patients, TCD was available and signals were interpretable (Table 3). Comparing the 2 groups, the average signals per case showed a trend toward lesser signals when the Spyder was used, but the result was not statistically significant. The range of TCD signals was much tighter in the Spyder compared to the hand-sewn group. The number of "Clamped-SVG" was too small to perform a *t* test.

CONCLUSION

The Spyder is easy, safe, and effective and can be utilized for making compliant proximal anastomoses in OPCAB surgery. Patency data suggests that the device is a useful adjunct for minimally invasive CABG. The trend toward fewer TCD signals in the Spyder cases suggests that emboli that could emanate from partial occlusion clamping of the aorta could be reduced by using this technique. Certainly, further study of this technique is warranted to move toward optimal minimally invasive CABG surgery.

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