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Initial Experience of an Automated Anastomotic Distal Device in Off-Pump CABG

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ABSTRACT

Background: Recent progress in minimally invasive technology in the field of coronary artery bypass grafting (CABG) stimulates interest in anastomotic devices used to facilitate distal coronary anastomosis. We assessed the feasibility of the automated anastomotic distal device (AADD) on arterial grafts in patients who underwent off-pump CABG (OPCAB) and evaluated the early anastomotic patency and clinical results of the AADD based on an elliptical nitinol ring with attached 8 pins.

Methods: Fourteen patients scheduled for multivessel OPCAB using arterial grafts between August 2003 and February 2004 were studied. Among 19 patients enrolled, 5 patients were excluded: 2 patients because of failure of graft flaring onto the implant pins, 2 because of small and diseased target coronary artery (<1.5 mm in diameter), and 1 because of conversion to cardiopulmonary bypass. The distal anastomosis using the AADD was performed for the nondominant coronary artery.

Results: The total number of distal anastomoses was 48 (34 hand-sewn sutures and 14 AADD sutures), and the average number of distal anastomoses per patient was 3.4 ± 1.0. The grafts used for the AADD were right gastroepiploic artery (RGEA) in 10 patients, saphenous vein anastomosed to the end of the RGEA in 2 patients, and internal thoracic artery in 2 patients. The average time required for distal anastomosis using the AADD (from arteriotomy to anastomosis completion) was 2.9 ± 0.7 minutes (range, 1.5-4 minutes). The mean flow and pulsatility index of the AADD grafts measured intraoperatively by transit time flow measurement were 20.0 ± 10.3 mL/min and 2.4 ± 1.2, respectively. Early postoperative coronary angiographies demonstrated widely patent grafts in 32 of 34 hand-sewn anastomoses and 13 of 14 AADD sutures. There were no adverse events related to the use of the device.

Conclusions: Our initial experience demonstrated that distal anastomosis using the AADD was feasible in most of the patients who underwent OPCAB using arterial grafts. Distal anastomosis using the AADD had the advantage of shortening the actual suturing duration and might provide a method for standardizing the anastomotic procedure.

INTRODUCTION

Construction of an accurate and patent distal anastomosis is a crucial step in coronary artery bypass grafting (CABG), especially in off-pump CABG (OPCAB). With the recent technological developments in CABG, new devices are being developed to substitute for hand-sewn sutures for proximal and distal anastomoses. Bar-El and colleagues demonstrated that the 6-month patency rate of the automated anastomotic distal device (AADD) (Bypass, Herzlia, Israel) was comparable with that of hand-sewing sutures in animal study [Bar-El 2003]. The AADD is an elliptical nitinol ring to which 8 pins are attached. The ring is capable of expanding and adjusting itself to the local coronary anatomy while the pins attach the graft and the vessel wall against the ring to create a rapid, sutureless, end-to-side anastomosis.

The aims of this study were: (1) to assess the feasibility of the AADD in patients who were scheduled for OPCAB using arterial grafts and (2) to evaluate the early anastomotic patency and clinical results of the AADD.

MATERIAL AND METHODS

Description of the AADD

The AADD implant (Figure 1) is a coupling device that is mounted external to the graft vessel and secures the vessel to the coronary artery. The implant is based on an elliptic nitinol ring, with attached 8 pins. The nitinol ring design consists of 2 sets of locks (4 locks in each set), symmetric over the long axis of the ellipse. A thin strut having the ability to rotate connects the locks. These 2 sets of locks are connected between them by a wider strut close to the symmetric axis (the toe and heel sides of the anastomosis), designed to create a large sealing surface at these sensitive areas. The 8 pins can be pulled and pushed through the ring according to a predestined path, until it locks into position. After locking is achieved, the pins are cut to decrease their profile in such a way that each pin is locked independently to the ring, creating hemostasis. The AADD is designed to accommodate a graft vessel with an outer diameter of 2.0 to 6.0 mm. There

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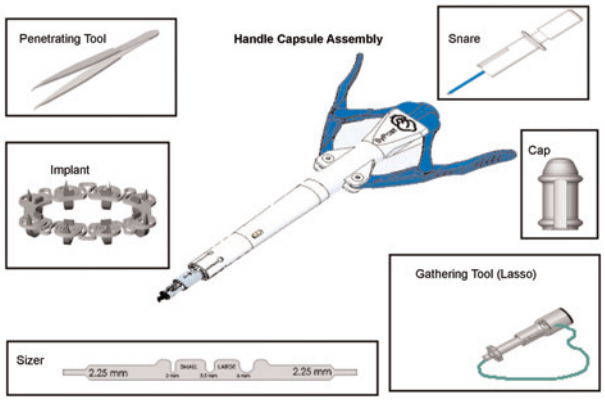

Figure 1. Product components of the automated anastomotic distal device.

are 2 sizes of AADD, one with an internal diameter of 1.84 × 3.22 mm, intended for a graft vessel of 2 to 3.5 mm outer diameter, and the other with an internal diameter of 3.0 × 5.0 mm, for a graft vessel of 3.0 to 6.0 mm outer diameter. Both sizes are intended for use in all target coronary arteries that are suitable for conventional suturing.

Surgical Procedure

OPCAB was performed as previously described [Kim 2002]. A standard skeletonizing technique for harvesting the internal thoracic artery (ITA) was used. If use of bilateral ITAs as in situ or Y grafts was not adequate for complete revascularization, a short lower extension of the median incision was made to harvest the right gastroepiploic artery (RGEA) in a skeletonized fashion. The RGEA was used as an in situ or composite graft for additional revascularization. The patients underwent heparinization with an initial dose of 1.5 mg/kg of heparin and periodically received supplemental doses to maintain an activated clotting time of more than 300 seconds. In almost all the patients, the most critical vessel, the left anterior descending (LAD) coronary artery, was revascularized first to provide a backup to the less critical area. The distal anastomosis was constructed using a continuous technique with 8-0 polypropylene sutures.

Distal anastomosis using the AADD was performed for the nondominant coronary artery. The graft for the AADD was harvested without clipping the side branches at its distal segment. The graft was inserted through a side opening and pulled with a special snare through the central opening in the delivery capsule containing the AADD at its distal end. The graft was beveled at its distal end and flared with the aid of special forceps over the 8 circumferential pins that were designed to penetrate it. After penetrating all pins through the intima layer, pins were forwarded by pushing the graft backward. Convergence of all 8 pins with the assistance of a snare enabled the device to be inserted through a small coronary arteriotomy. When it confirmed that all pins were properly placed within the lumen, the handles were squeezed. The pins were diverged to approximate and fit the graft to the coronary artery. The side branches were then clipped after the deployment. Protamine was not given at the end of the procedure.

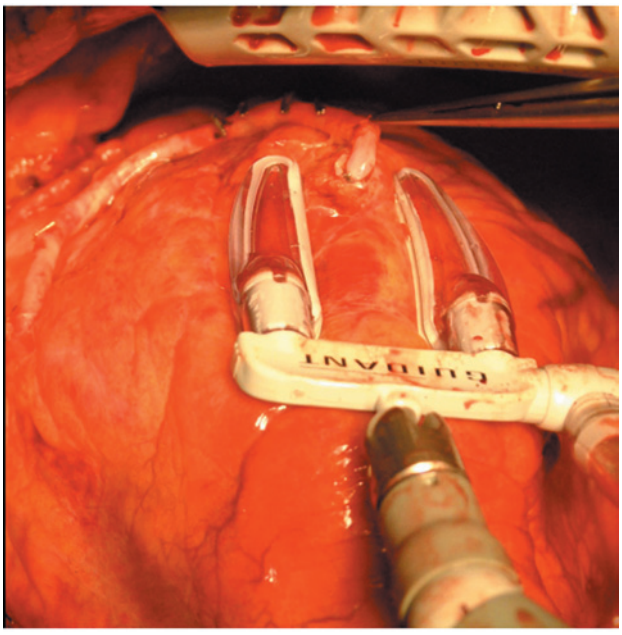

Figure 2. Surgical view after the anastomosis using the automated anastomotic distal device (AADD). During off-pump coronary artery bypass performed on this 77-year-old man with unstable angina, the right internal thoracic artery (ITA) was anastomosed to the left ITA as a Y-composite graft and then grafted to the diagonal branch (hand-sewn) and finally to the obtuse marginal branch using the AADD.

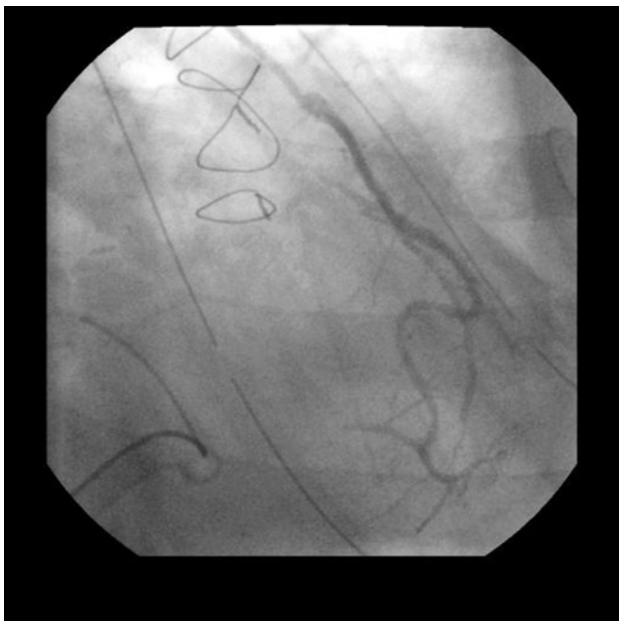

Figure 3. Postoperative angiography demonstrating a patent graft using the automated anastomotic distal device in the patient shown in Figure 2.

Table 1. Preoperative Patient Characteristics

Male:female, n	10:4
Age, y	65 ± 7
Left ventricular ejection fraction, %	58 ± 7
Unstable:stable angina, n	11:3
Risk factor, n (%)	
Smoking	8 (57.1%)
Hypertension	8 (57.1%)
Diabetes mellitus	8 (57.1%)
Hyperlipidemia	2 (14.3%)
Previous stroke	2 (14.3%)
Angiographic diagnosis, n (%)	
3-vessel disease	7 (50.0%)
2-vessel disease	2 (14.3%)
Left main disease (with or without peripheral coronary disease)	5 (35.7%)

This study was approved by the Institutional Review Board (approval no. 06-2003-079-0). Written, informed consent was obtained from each participating patient.

RESULTS

Nineteen patients who were scheduled for multivessel OPCAB using arterial grafts between August 2003 and February 2004 were initially enrolled in this study. Five patients were excluded intraoperatively because of failure of graft flaring onto the implant pins (2 patients), small and diseased target coronary artery (2 patients), and conversion to cardiopulmonary bypass (1 patient). In 14 patients (10 men and 4 women, mean age 65 ± 7 years; Table 1), 1 distal anastomosis was performed with the AADD. The total number of distal anastomoses in the 14 patients was 48 (34 hand-sewn sutures and 14 AADD sutures), and the average number of distal anastomoses per patient was 3.4 ± 1.0 (Table 2).

Table 2. Distal Anastomoses Performed in 14 Patients*

	Hand Sutures (n = 34)		AADD Sutures (n = 14)		
Grafts	Targets	No.	Grafts	Targets	No.
ITA	LAD	14	i-RGEA	PDA	3
	D	7		RCA	1
	OM	11	c-RGEA	OM	3
c-RGEA	OM	1		D	1
SVG	PDA	1		PLB	1
			f-RGEA	PDA	1
			ITA	OM	1
				PDA	1
			(i-RGEA)-SVG	PDA	2

*AADD indicates automated anastomotic distal device; ITA, internal thoracic artery; LAD, left anterior descending artery; i, in situ graft; RGEA, right gastroepiploic artery; PDA, posterior descending coronary artery; D, diagonal; RCA, right coronary artery; OM, obtuse marginal branch; c, composite graft; PLB, posterolateral branch; f, free graft; SVG, saphenous vein graft.

Table 3. Patency of Distal Anastomoses (n = 48)*

	Hand Sutures (n = 32/34)		AADD Sutures (n = 13/14)		
Grafts	Targets	No.	Grafts	Targets	No.
ITA	LAD	13/14	i-RGEA	PDA	3/3
	D	7/7		RCA	1/1
	OM	11/11	c-RGEA	OM	3/3
c-RGEA	OM	1/1		D	0/1
SVG	PDA	0/1		PLB	1/1
			f-RGEA	PDA	1/1
			ITA	OM	1/1
				PDA	1/1
			(i-RGEA)-SVG	PDA	2/2

*Abbreviations are defined in the Table 2 footnote.

The grafts used for the AADD were RGEA in 12 patients, ITA in 2 patients, and saphenous vein anastomosed to the end of in situ RGEA in 2 patients. There was difficulty in flaring of the RGEA graft onto the implant pins in 2 patients in whom the saphenous vein was used as a composite graft. Repeated trials of flaring the graft onto the implant resulted in a short length of RGEA, which needed an additional segment of saphenous vein anastomosed to the end of the in situ RGEA to reach the target coronary artery. The small-sized device (2 mm) with an internal diameter of 1.84 × 3.22 mm was used in all patients. The internal diameter of the target coronary artery and the external diameter of the graft used for the AADD sutures were 1.9 ± 0.3 mm (1.5-2.5 mm) and 3.0 ± 0.5 mm (2-3.5 mm), respectively.

The average time required for distal anastomosis using the AADD (from arteriotomy to anastomosis completion) was 2.9 ± 0.7 minutes (1.5-4 minutes). The mean flow and pulsatility index of the AADD grafts measured by the transit time flow measurement intraoperatively were 20.0 ± 10.3 mL/min and 2.4 ± 1.2, respectively. All 14 AADD were released perfectly, and 1 of these anastomoses required an additional stitch for hemostasis.

Postoperative coronary angiographies were performed in all patients at 1.5 ± 1.3 days (range, 1-6 days) postoperatively. Postoperative angiographies demonstrated widely patent grafts in 32 of 34 hand-sewn anastomoses and 13 of 14 AADD sutures (Table 3). One ITA anastomosed to the LAD after coronary endarterectomy and the other saphenous vein anastomosed to the diffusely atherosclerotic posterior descending coronary artery were occluded in the 34 hand-sewn anastomoses; 1 Y-composite RGEA anastomosed to the diffusely atherosclerotic diagonal branch was occluded in the 14 AADD sutures.

There were no adverse events related to the use of the AADD device.

DISCUSSION

This study demonstrates the feasibility of the AADD in most of the patients who undergo OPCAB using arterial grafts. Distal suture performed using the AADD

revealed excellent early patency with shortening of the actual anastomotic duration and the period of myocardial ischemia associated with local occlusion of a coronary vessel in OPCAB.

Although avoidance of the potentially detrimental effects of cardiopulmonary bypass and elimination of intraoperative global myocardial ischemia are demonstrated advantages of OPCAB, hemodynamic instability during displacement of the heart and local coronary occlusion of 10 to 25 minutes during distal anastomosis are current limitations of OPCAB procedures. Development of a suturing device that allows the creation of an accurate, rapid, and patent distal anastomosis may shorten the anastomotic duration and decrease those limitations of OPCAB. Such a device may provide a method for standardizing the anastomotic procedure and further improve the surgical outcomes of OPCAB. Several different anastomotic devices have been proposed in the field of CABG, including laser [Bass 1989], clip [Nataf 1998], stapler [Chavanon 1999, Eckstein 2002], glue [Gundry 2000], intraluminal stent [Solem 2000], mounting device [Scheltes 2000], ventriculocoronary shunt [Emery 2001], and magnetic device [Filsoufi 2004].

The AADD implant is a coupling device mounted external to the graft vessel, allowing an end-to-side anastomosis of oval shape. The implant is based on an elliptic nitinol ring, with attached 8 pins. The nitinol ring design consists of 2 sets of locks (4 locks in each set), symmetric over the long axis of the ellipse. These 2 sets of locks are connected by a wider strut close to the symmetric axis (the toe and heel sides of the anastomosis), designed to create a large sealing surface at these sensitive areas.

To demonstrate the feasibility of the AADD suture in patients undergoing OPCAB with arterial grafts, 19 patients were initially enrolled in this study. However, 4 patients were excluded because of technical difficulties: failure of flaring of the graft onto the implant pins in 2 patients and small (inner diameter of less than 1.5 mm), atherosclerotic target coronary artery in 2 patients. The AADD was used successfully for arterial grafts in 12 patients (RGEA in 10 patients and ITA in 2 patients). All 14 AADD were released perfectly, and the time required for distal anastomosis using the AADD (from arteriotomy to anastomosis completion) was 2.9 ± 0.7 minutes on average. Postoperative angiographies revealed widely patent grafts in 13 AADD sutures except 1 Y-composite RGEA anastomosed to the diffusely atherosclerotic diagonal branch.

To load the graft onto the AADD, the graft had to be flared over the 8 circumferential pins. This somewhat cumbersome procedure often caused lacerations in the intimal layer of arterial graft. Failure to flare arterial graft onto the pins occurred in 4 of 19 patients, and in 2 of these patients we had to use an additional segment of saphenous vein to compensate for the short length after repeated trials. This limitation is being resolved in the newer generation of AADD devices that are under development.

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