Early Patency Evaluation of New Distal Anastomotic Device in Internal Mammary Artery Grafts Using Computed Tomography Angiography

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Introduction: Traditional coronary artery bypass grafting is performed using a hand sewn technique. The C-Port xA and Flex A anastomotic stapling devices (Cardica Inc., Redwood City, CA) were cleared by the Food and Drug Administration for use in distal coronary anastomoses in November 2006 and April 2007, respectively. They provide the ability to create a compliant, consistently reproducible, and automated anastomosis. Multidetector computed tomography (CT) has been shown to be effective in evaluating coronary artery bypass graft patency.

Methods: The first 24 patients to undergo internal mammary artery (IMA) anastomosis using the automated device in our practice were included in the study. Twenty-five IMA grafts (24 left IMA and 1 right IMA) were created using the C-Port xA or Flex A anastomotic device as part of multivessel off-pump coronary revascularization by sternotomy. Graft patency was evaluated at 30 days in the first 10 grafts and at 90 days in the next 15 grafts using multidetector (64 slice) CT.

Results: There were no device failures. There were no perioperative strokes, myocardial infarctions, or deaths. All 10 IMA grafts evaluated at 30 days were patent using multidetector CT. One of the 15 IMA grafts studied at 90 days was occluded using multidetector computed tomography.

Conclusions: The C-Port xA and Flex A distal anastomotic devices provided a safe and effective means to create a left IMA-left anterior descending artery anastomoses in coronary bypass surgery with excellent short to midterm patency in this early experience. Long-term follow-up is warranted. These findings will have important implications for future sternal sparing coronary bypass surgery.

Key Words: Coronary bypass graft, Distal anastomotic device, Internal mammary artery, C-Port, Multidetector CT angiography.

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METHODS

We conducted an observational study to evaluate the early to midterm patency of LIMA to LAD bypass grafts created using the C-Port xA and C-Port Flex A. The patient population consisted of 24 patients who underwent off-pump coronary bypass grafting using the C-Port xA or C-Port Flex A anastomotic device. All first-time CABG patients requiring
at least 1 IMA graft and had a LIMA vessel size of $\geq 2.5$ mm were treated with the C-Port xA or C-Port Flex A device. The MediStim flow measurement system was used in all procedures to measure the flow and pulsatility index (PI) in each bypass graft. Perioperative and postoperative outcomes through hospital discharge were recorded.

Graft patency was determined by qualitative analysis of images created from 64-slice rotational CT. A 64-detector Phillips Brilliance CT scanner was used. Patients were administered 80 mL of Visipaque 320 contrast media and sufficient $\beta$-blockers to achieve a heart rate of 60 to 65 beats per minute. Grafts were ranked on the appearance of the anastomosis and visualization of distal flow from the graft. The following number scale was used to define the patency of each graft: 0: occluded, 1: widely patent, 2: patent. A score of 1 or 2 was considered patent for analysis.

RESULTS

A total of 25 grafts were evaluated in 24 patients. One patient received bilateral mammary artery bypass grafts with the right IMA grafted to the first obtuse marginal branch of the circumflex coronary artery. All CABG procedures were performed off-pump. Five of the procedures were concomitant with aortic valve replacement or mitral valve repair (4 and 1, respectively). The average coronary vessel diameter was 1.69 mm ($\pm 0.19$). The average flow rate was 82.0 mL/min ($\pm 15.9$) with an average PI of 2.0 ($\pm 0.3$). All grafts were determined, patent and no grafts required intraoperative revision. Twenty-three of the 24 were male patients with an average age of 63 years ($\pm 5.1$ years). The number of patients presenting with triple vessel disease was 66.7%, and 58.3% of the population had a history of coronary artery disease.

The C-Port xA device was used to create 7 of the bypass grafts studied. C-Port Flex A was used to create the remaining 18. Thirteen of the 25 anastomoses required 1 or more repair stitch to achieve hemostasis. The majority of repair stitches were placed in the anvil insertion site as opposed to the actual anastomosis. Table 1 summarizes the number of stitches required for each anastomosis and location of each repair suture. There were no perioperative strokes, myocardial infarctions, or deaths. Postoperative complications were minimal. One patient required surgical intervention for postoperative bleeding. The location of the bleed was unrelated to the C-Port device anastomosis. One patient, with concomitant aortic valve replacement, suffered a postoperative cerebral vascular accident. Three patients had postoperative acute renal failure that resolved without requiring hemodialysis. All 24 patients were discharged home with an average postoperative hospital stay of 4.2 days.

Early follow-up was performed in 10 patients with a total of 15 grafts. The average time of follow-up from date of surgery was 126.2 $\pm 25.7$ days. Fourteen of the 15 grafts evaluated were patent (93%). The occluded LIMA-LAD graft was a sequential graft to a first diagonal branch and then to the LAD. This patient also received a concomitant mitral valve repair. Combined analysis of both cohorts (early and midterm follow-up) results in a patency of 96%.

DISCUSSION

The C-Port distal anastomotic system is a highly engineered, fully integrated anastomotic device designed to create vascular anastomoses. It simultaneously creates an arteriotomy and attaches the conduit loaded into its cartridge to the recipient target vessel using multiple individual small stainless steel clips. The original C-Port device was cleared by the Food and Drug Administration for use in the United States in November 2005 and was suitable for most vein-to-coronary artery bypasses with the creation of an end-to-side anastomosis. This approval was based on evaluation of outcomes in a

### TABLE 1. Technical Aspects of Intraoperative Device Performance in 25 IMA Grafts

| Off-pump bypass | 25/25 | 100% |
|-----------------|-------|------|
| Device failures | 0/25  | 0%   |
| No. grafts not requiring repair suture | 12/25 | 48% |
| No. grafts requiring repair suture | 13/25 | 52% |
| Site of repair suture | | |
| Toe | 5/25 | 20% |
| Heel | 1/25 | 4% |
| Anvil site (extra adventitial stitch) | 11/25 | 44% |

**FIGURE 1.** C-Port x A device.

**FIGURE 2.** C-Port Flex A device.
multicenter European trial, which demonstrated a 92% angiographic patency at 6 months in grafts constructed with this device. Since then the device has been used clinically in the United States for coronary bypass grafting; however, there has been limited reported data.

In November 2006, the next generation anastomotic device (C-Port xA) was cleared for use in the United States. The xA system is suitable for creating vein-to-artery bypasses and artery-to-artery bypasses. This next generation device was also intended to alleviate the need for heel and/or toe stitches by adding extra clips not present in the previous device.

The next generation (Flex A) C-Port system, which became available in April 2007, is a flexible model of the xA device designed for remote activation and introduction through ports for sternal sparing approaches during CABG.

These devices are the first of their kind (automated single shot anastomotic devices) to be cleared for use in the United States. Previous devices have had significant barriers to entry for various reasons including technical, regulatory, and cost issues.

The active component of the C-Port devices is a CO2-powered cartridge that fires multiple individual small stainless steel clips that attach the 2 vessels in an end-to-side fashion once the device is fired resulting in an interrupted anastomosis (Fig. 3). The clips are made to form by compression around an anvil that houses a small knife. This knife is also actuated when the device is fired and creates a 4.2-mm arteriotomy in the recipient vessel. The device functions somewhat similar to a gastrointestinal anastomosis stapler and requires only closure of the anvil insertion site at completion of the anastomosis. This is usually achieved with an adventitial stitch.

The device is suitable for coronary targets as small as 1 mm in diameter because this is the diameter of the anvil to be inserted into the coronary artery. Conduits as small as 2.5 mm (outer diameter) IMA grafts can be used once adequate experience with loading the device has been achieved. The conduit should have a double-wall thickness of <1.4 mm to allow adequate penetration of the clips and safe disengagement of the device from between the cartridge limbs once the anastomosis is completed.

We have used the various iterations of the C-Port anastomotic devices for creation of the distal anastomosis in off-pump coronary bypass since they first became available in the United States in December 2005. We started with selective vein graft-coronary pairings with the original C-Port system and moved on to using it on the majority of most vein anastomoses with the advent of the C-Port xA.

Midterm outcomes in our practice using this device on saphenous vein grafts have been excellent as demonstrated by Cai et al. We are in the process of evaluating long-term patency for these early saphenous vein grafts some of which are over 2½ years old.

With the introduction of the C-Port xA device (Fig. 1) came the ability to perform IMA anastomoses in an automated fashion, and we started using the device for selected LIMA-LAD anastomoses. The flexible device (C-Port Flex A) (Fig. 2) adds to the accuracy and maneuverability in tight spaces by substituting the rigid shaft with a flexible cable connected to the handle, thereby decoupling the loading and insertion process at the cartridge from the firing maneuvers at the handle. Since it became available we have been performing the majority of IMA anastomoses with this device.

This report concerns the evaluation of intraoperative and clinical outcomes and early to midterm patency in the first 25 of such procedures using the xA and Flex A devices on IMA grafts. Although these grafts were completed using a sternotomy approach, we believe that this validation is a necessary step in moving toward sternal sparing platforms for coronary bypass. This approach can be highly facilitated by introduction of remotely activated devices.

We found that use of the newer xA and Flex A devices in IMA coronary anastomosis fairly easy to master with a relatively short learning curve. It was helpful that we gained experience using saphenous vein grafts before performing the procedure on the more delicate IMA conduits. Skeletonizing the IMA for a certain length at the distal end and avoiding clips are necessary to facilitate loading and disengaging the device after completion. There were no device failures or need for intraoperative graft revisions. The majority of the single repair sutures required was to the anvil insertion site. Importantly, the follow-up CT angiographic (CTA) studies did not reveal any significant stenosis at the anastomotic heel as a result of this.

The Medistim flowmeter used in our study affords several parameters for assessing intraoperative graft patency using transit time measurements including mean flow, percentage of diastolic flow, and a calculated PI. These param-
eters have been shown to correlate with intraoperative graft patency.\textsuperscript{10} Our evaluation of intraoperative flows indicated excellent patency as seen by the individual graft mean flows and pulsatility indices (Table 2). This is consistent with the improved graft flows seen in our practice when switching from a hand sewn anastomosis to an interrupted anastomosis with U clips (Medtronic, Minneapolis, MN) several years ago. This was also demonstrated in a multicenter trial of an interrupted coronary anastomotic technique.\textsuperscript{11} We believe that checking intraoperative graft flow is a necessary step in any procedure and especially if new devices and techniques are being used.

Newer generation CT scanners can give an excellent evaluation of the coronary vessels and grafts. The use of 64-slice CTA in the postoperative setting is far less invasive than traditional cardiac catheterization.\textsuperscript{12} Recent studies indicate 100\% correlation between traditional angiographic patency assessment and CTA.\textsuperscript{13}

This study used 64-slice CTA as a means to determine graft patency of the C-Port and C-Port xA connectors when used in IMA anastomosis. All patients were scanned using a 64-detector Philips Brilliance CT scanner after administration of 80 mL Visipaque 320. Standard $\beta$-blockers protocol was administered to achieve a heart rate of 60 to 65 beats per minute. Data were recorded to a CD with digital imaging and communications in medicine standard (DICOM) data for interpretation and determination of graft patency (qualitative data assessment). The images obtained easily demonstrated the course of the grafts and native coronaries and allowed for accurate assessment of the anastomotic site (Figs. 4 and 5). All the grafts in both the early and the midterm follow-up groups were patent except for 1 sequential LIMA graft to a diagonal branch and then to the LAD. The segment to the LAD was occluded possibly for reasons of competitive flow. The segment to the diagonal branch was patent.

Since completing this study, we have become very comfortable with the Flex A device in creating an IMA anastomosis and prefer it to a hand sewn technique in the end to side configuration. It creates a reproducibly perfect arteriotomy and stapled connection as long as the conduit double wall thickness is $<1.4$ mm, and the wall of the coronary target is not calcified or sclerotic. This results in an interrupted, mechanically governed, compliant anastomosis. The device is helpful in deep vessels especially in the off-pump setting, and it further facilitates off pump coronary artery bypass (OPCAB) by virtually eliminating ischemia time, because the device can be loaded with the heart in a neutral position, and proximal snares are rarely required.

| Flow (cc/min) | PI | Flow (cc/min) | PI |
|--------------|----|---------------|----|
| 80           | 1.8| 30            | 2.2|
| 71           | 2.2| 60            | 2.5|
| 82           | 2.4| 200           | 1.5|
| 80           | 1.6| 40            | 2.0|
| 81           | 1.6| 41            | 1.3|
| 38           | 1.6| 50            | 2.2|
| 45           | 1.5| 77            | 4.5|
| 80           | 1.3| 120           | 1.6|
| 147          | 1.5| 50            | 1.9|
| 60           | 1.9| 65            | 3.0|
| 100          | 1.6| 100           | 2.0|
| 160          | 2.3| 90            | 1.6|
| 100          | 1.9|               |    |
It is widely believed that one of the reasons of poor adaption of off-pump CABG is the demanding nature of the anastomoses in the beating heart compared with the arrested heart and the hemodynamic compromise of prolonged compression of the myocardium and snaring of the coronary vessel. The ability to perform the anastomosis quickly without significant interruption of native flow or prolonged displacement of the heart, especially in posterior wall vessels, may enhance OPCAB adaption once surgeons become familiar with the use of these devices.

What remains to be seen is whether the long-term outcomes of grafts created with these devices will continue to be similar to or better than grafts constructed using traditional techniques. We are in the process of evaluating our long-term patency data in both vein and IMA grafts using the C-Port devices in coronary bypass grafting and have had excellent long-term clinical outcomes thus far.

CONCLUSION

In conclusion, the C-Port xA and Flex A distal anastomotic devices (Cardica) are excellent options in arterial grafting especially in the off-pump setting. After a short learning curve, the loading and disengagement techniques can be mastered with minimal difficulty. Early and midterm patency as evaluated by multidetector CT scanning is excellent. Further follow-up to assess long-term patency is necessary. We expect that the flexible device will figure prominently in closed chest and sternal sparing coronary bypass grafting.

REFERENCES

1. Loop FD, Lytle BW, Cosgrove DM. Influence of the internal-mammary artery graft on 10 year survival and other cardiac events. N Engl J Med. 1986;314:1–6.
2. Fitzgibbon GM, Leach AJ, Kafka HP, Keon WJ. Coronary bypass graft fate: long-term angiographic study. J Am Coll Cardiol. 1991;17:10765–1780.
3. Matschke KE, Gummert JF, Demertzis S, et al. The Cardica C-Port System: clinical and angiographic evaluation of a new device for automated, compliant distal anastomoses in coronary artery bypass grafting surgery—a multicenter prospective clinical trial. J Thorac Cardiovasc Surg. 2005;130:1645–1652.
4. Hamon M, Lepage O, Malagutte P, et al. Diagnostic Performance of 16- and 64-section spiral CT for coronary artery bypass graft assessment: meta-analysis. Radiology. 2008;247:679–686.
5. Feuchter GM, Schachner T, Bonatti, et al. Diagnostic performance of 64-slice computed tomography in evaluation of coronary bypass grafts. Am J Radiol. 2007;189:574–580.
6. Uva MS, Mattas F, Mesquita A, et al. Sixteen-slice multidetector computed tomography for graft patency evaluation after coronary artery bypass surgery. J Cardiovasc Surg. 2008;23:17–22.
7. Falk V, Walthter T, Gummert JF, et al. Anastomotic devices for coronary artery bypass grafting. Expert Rev Med Devices. 2005;2:223–233.
8. Cai TH, Acuff TE, Bolton JWR, et al. Prospective evaluation of patency and early experience utilizing an automated distal anastomosis device (C-Port). Innovations. 2007;2:245–250.
9. D’Ancona G, Karmanoukian HL, Ricci M, et al. Graft revision after transit time flow measurement in off-pump coronary artery bypass grafting. Eur J Cardiothorac Surg. 2000;17:287–293.
10. Wallpoth BH, Bosshard A, Genyk I, et al. Transit time flow measurement for detection of early graft failure during myocardial revascularization. Ann Thorac Surg. 1998;66:1097–1100.
11. Wolf RK, Alderman EL, Caskey MP, et al. Clinical and six-month angiographic evaluation of coronary arterial graft interrupted anastomoses by use of a self-closing device: a multicenter prospective clinical trial. J Thorac Cardiovasc Surg. 2003;126:168–178.
12. Yoo KJ, Choi D, Choi BW, et al. The Comparison of the graft patency after coronary artery bypass grafting sing coronary angiography and multi-slice computed tomography. Eur J Cardiothorac Surg. 2003;24:86–91.
13. Song MH, Ito T, Watanabe T, et al. Multidetector computed tomography versus coronary angiography in evaluation of coronary artery bypass grafts. Ann Thorac Surg. 2005;79:585–588.
14. Raja SG, Dreyfus GD. Current status of off pump coronary bypass surgery. Asian Cardiovasc Thorac Ann. 2008;16:164–178.
15. El Hamamsy I, Cartier R, Demers P, et al. Long term results after systematic off-pump coronary artery bypass graft surgery in 1000 consecutive patients. Circulation. 2006;114:1486–1491.
16. Chang WI, Kim KB, Kim JH, et al. Hemodynamic changes during posterior vessel off pump coronary bypass: comparison between deep peri-cardial sutured and vacuum-assisted apical suction device. Ann Thorac Surg. 2004;78:2057–2062.

CLINICAL PERSPECTIVE

The development of a reliable coronary anastomotic device would greatly facilitate minimally invasive techniques for coronary artery bypass surgery. The Cardica C-Port devices have been cleared by the Food and Drug Administration for clinical use in creating a distal coronary anastomosis. In this single center experience, 25 internal mammary artery grafts were created using the C-Port anastomotic device as part of off-pump coronary revascularization. There were no device failures. All 10 of the internal mammary artery grafts evaluated at 30 days were patent using computed tomography angiography. At 90 days, 1 of the 15 grafts was occluded. This small experience demonstrates the feasibility of using these devices for the creation of a distal anastomosis. Large, multicenter trials will be needed to determine how these devices compare with standard hand sewn anastomoses. It should also be remembered that these cases were performed through a median sternotomy. Whether similar results can be obtained through a minimal access incision remains to be determined.