HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2011; 3(4): 239-243

Vascular connector devices increase the availability of minimally invasive cardiac surgery to ischemic heart patients

M. Ramchandani, K. Bedeir

Methodist DeBakey Heart and Vascular Center, Houston, Texas

HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2011; 3(4): 239-243

ABSTRACT

The revival of off-pump cardiac surgery and the exploration of less invasive techniques for coronary artery bypass grafting, have lead to an increasing technical difficulty, as compared to conventional surgery using cardiopulmonary bypass. The moving target vessel in off-pump coronary artery bypass surgery, as well as the increasingly limited space in minimally invasive cardiac surgery were not convenient to many surgeons, a fact that lead many surgeons to deprive their patients the potential benefits of these techniques.

Since the 1950's, surgeons have attempted to make the anastomotic procedure less cumbersome and less time consuming. Many creative ideas and devices were made, but for many different reasons, they eventually faded away. Since then, hand-sewn anastomoses have been the standard of care in coronary artery bypass grafting. Today, with the obvious need for a facilitated and fast coronary anastomosis, interest in these anastomotic devices has been re-awakened. The exact geometry, physiology and dynamics of the perfect anastomosis have thus been studied, in an attempt to provide an understanding of reasons behind anastomosis and graft failure after coronary artery bypass surgery, and eventually design the best performing device. These devices would allow for a faster, more accurate and a more reproducible coronary anastomosis using minimally invasive techniques. Also, due to a short learning curve, the standardization of percutaneous devices would allow much more surgeons to more widely adopt less invasive techniques. In summary, we see anastomotic devices as a solution to the technical challenges surgeons encounter with minimally invasive coronary artery bypass grafting.

Keywords: *anastomotic devices, minimally invasive, cardiac surgery, coronary bypass, hybrid procedures.*

Presented at the Roland Hetzer International Cardiothoracic and Vascular Surgery Society 1st Expert Forum

In what is believed to be the first Soviet contribution to American medical literature, Pavel Androsov described the first vascular anastomotic device in 1956. After World War II, Androsov favored the use of his device over vascular ligation, citing reasons that would be still valid in our current day (1). Four years later, the first human coronary artery bypass (CAB) procedure took place, reported by Robert Goetz at Albert Einstein University. Interestingly, this first attempt (Right internal mammary artery to right coronary artery) was done using a tantalum ring anastomotic device with circumferential sutures. In Leningrad in 1964, Vasilii Kolesov performed the first hand-sewn clinical CAB, citing Goetz' work as a predecessor (2). Three years later, he performed the first, and for a long time the only, coronary anastomosis using a vascular stapler, and three years later, the patient remained free of symptoms (3).

Many anastomotic devices were designed

Corresponding author:
Mahesh Ramchandani MD, FRCS
Methodist DeBakey Heart and Vascular Center
6550 Fanninin Street, Suite 1401
Houston, Texas 77030, USA

and produced in the 1960's, but the advent of cardiopulmonary bypass (CPB) and its wide adoption made hand suturing on a motionless heart a more convenient option to surgeons. Vascular connector devices eventually faded away from the interest of surgeons, and hence manufacturers, and for a long time, the well established CAB technique remained – efficient but technically stagnant. In the 1990's, against the background of significant morbidities associated with the use of CPB and myocardial ischemic arrest, interest in off-pump CAB surgery (OP-CAB) was reawakened. This revival of interest re-established the same circumstances that brought interest to vascular connectors 40 years earlier. Not much later, the development of minimally invasive cardiac surgery - CAB (MICS-CAB) and totally endoscopic CAB (TECAB) made the hand suturing technique even more challenging and excessively time consuming, making connector devices, once again, an attractive option.

Although graft failure is probably multi-factorial, technical error still shares a good deal in this failure. Anastomotic connector devices decrease the error in hitting a moving target (OPCAB), as well as facilitate graft anastomoses in a restricted space (MICS-CAB). Other non-technical advantages are displayed as well. Eliminating the need for an aortic cross clamp has been achieved in OPCAB, but the proximal anastomoses still mandated a partial clamp application. This has been reported to consistently increase rates of stroke after CAB surgeries (4-7). Connector devices allow performing proximal anastomoses with minimal aortic manipulation, and thus improve neurological outcomes. Also, the supposedly reduced time needed to complete an anastomosis using a connector device would allow for less hemodynamic instability, when grafting posterior vessels off-pump, as well as allow for a shorter clamp time when using CPB and ischemic arrest, and thus would be associated with less morbidity and mortality (8, 9).

More than 60 connector devices have been designed and produced by several manufacturers for coronary bypass surgery alone, and due to different outcomes and economic reasons, only a few of them came to fruition (10,11). A perfect connector device should display a number of geometric, physiological, technical and outcome characteristics, in a cost effective context.

These characteristics would ensure patency rates that are at least, and adverse event rates that are at most, equal to standard hand suturing technique. An understanding of how this can be, invites an understanding of how failure happens. Altering flow dynamics and disrupting endothelial continuity may lead to thrombosis, intimal hyperplasia or both. The blood exposed non-intimal surface (BENIS), whether it be the media, adventitia or foreign material (suture, metal, etc) has been directly correlated to thrombosis (11). This is the reason why two distal connector devices are no longer available; the *Graft Connector of Jomed (*Jomed Inernational AB, Helsingborg, Sweden) and the *Magnetic Vascular Positioner MVP* (Ventrica Inc, Fremont, CA). Thrombosis is also increased with a stenotic anastomotic orifice. This was particularly relevant with the Spyder (Medtronic Inc, Minneapolis, MN), probably due to the lack of support from a connecting ring (12). Intimal hyperplasia for less than understood reasons was a main issue with the *Symmetry aortic connector system* (St. Jude Medical, St. Paul, MN), leading to a graft patency of 50 % at 3-5 months angiographic follow-up. Despite the early enthusiasm with this device, it was abandoned by SJM due to what the authors described as an unacceptably low intermediate result (13, 15).

Several technical factors share to connector-constructed graft failure. Excessive graft ma-

nipulation while loading on the connector is very likely to cause endothelial denudation, with subsequent thrombosis. Also, what seems to be inconvenient to many surgeons, is that most proximal connecting devices require that the proximal anastomoses be constructed before the distal ones. Most proximal connectors have a graft take-off angle from the aorta approaching 90°. These two issues require careful planning of graft length and position to avoid graft kinking and excessive wall stress. The *PAS-Port* device (Cardica Inc, Redwood, CA) overcomes the issue of kinking by having a low implant body height.

In summary, a perfect connector device should provide anastomoses with the least possible BENIS, the largest possible orifice area that is supported and compliant, a least possible chance to develop intimal hyperplasia, and should be "surgeon friendly" (graft loading and deployment that are easy, fast and reproducible). In addition, it should allow for graft anastomosis at all angles and in a confined space, and in proximal connectors, with minimal aortic manipulation. Of extreme importance, is the ease of recovery after unsuccessful deployment, leaving undamaged vessel edges that are still sewable. All these characters should interplay to make this "perfect" device display results that are non-inferior to standard technique.

Great discrepancies have been reported with different trials studying different graft materials. It is however, beyond any doubt, that internal mammary arteries (IMA) have a superior patency profile compared to any other graft material (16, 17). In some reports, the IMA patency after 10 years was better than saphenous venous graft (SVG) patency after 1 year (18). For this reason, comparing hand-sewn anastomoses to connector device anastomoses is more convenient using venous grafts, giving connector devices a potential to display patency superiority over a relatively short time frame. This is under investigation in the MAGIC trial (Multicenter Assessment of Grafts in Coronaries: Long-term Evaluation of the C-Port Device). Patency rates of SVGs to non-LAD vessels have also varied considerably, however, the widely accepted average is 85 % patency at 6 months, and 80 % at one year (17, 19). The cited patency rates over the past 20 years have shown a gradual decline in patency rates, which may partially be attributed to the more advanced vessel disease presenting to surgeons, in the presence of percutaneous coronary interventions as a first line. In general, the quality of anastomosis tends to affect early patency rates, while late patency rates are more governed by progressing atherosclerotic disease. This made most studies satisfied with comparing hand-sewn anastomosis to ones done by a connector device, only for a period of 6 months. Devices have attempted to approximate vessel edges and bond them in different mechanisms.

They can be generally classified to self-expanding, mechanically-expanding and non-expanding devices. The *CorLink device* (Bypass Ltd, Herzelia, Israel) utilized a nitinol self-expanding mechanism.

Mechanically expanding devices utilize stainless steel expandable connectors. The *SJM distal device* (St. Jude Medical, St. Paul, MN), the *PAS-Port system* (Cardica Inc, Redwood, CA), the *Automated Anastomotic Distal Device* (AADD, Bypass Ltd, Herzelia, Israel) and the *Spyder device* (Medtronic Inc, Minneapolis, MN), all rely on the same concept of mechanical expansion. Creative ideas have been implemented in other non-expanding devices to perform the task. The *Converge Coupler* (Converge Medical, Sunnyvale, CA), the *Symmetry II* (St. Jude Medical, St. Paul, MN), and the *Magnetic Vascular Positioner* (MVP, Ventrica Inc, Fremont, CA) are examples of the non-expanding group. Out of the - more than fifty - designs, only 2 devices for proximal anastomosis, and one device for distal anastomosis

earned the Food and Drug Administration (FDA) approval. The two proximal devices are the *PAS-Port* and *Spyder*. The latter uses circumferential nitinol anchors that are not connected. This lack of support might be behind the high rates of stenosis (52.7%) after 6 months (20). On the other hand, the *PAS-Port* utilizes connecting ring-supported stainless steel tines. Worth noting, the supporting ring in the *PAS-Port* lies outside the vessel, with no blood contact thus minimizing BENIS, in contrast to the earlier *Symmetry* device.

The EPIC trial was a randomized controlled, prospective, multi-center trial that evaluated the *PAS-Port* device. Comparing patency rates at 9 months, and comparing mean aortic take-off angles both showed no statistical significance between the device constructed anastomoses and the hand-sewn ones (21).

The FDA approved connector device for distal anastomosis comes from the same manufacturer; the *C-Port*. It is available in slightly different modifications, with versions allowing for port access coronary anastomosis. On the target coronary vessel, proximal to the area of the anticipated anastomosis, a small stab is made, the anvil of the device is passed through the stab and the device is deployed, forming an end-to-side anastomosis. A previously placed purse string suture at the site of the stab should not compromise the proximal coronary lumen. Matschke and colleagues (22) reported a patency of 96%, with a Fitzgibbon A patency in 91.7%, 6 months after using the *C-Port*. Patency rates using the *C-Port* and standard techniques lacked any difference as reported by Suyker and colleagues (23).

Minimally invasive cardiac surgery (MICS) saves the patient a number of morbidities associated with classical sternotomies. With less surgical trauma, MICS is associated with significantly less pain, less transfusion requirements, a shorter hospital stay, a faster recovery, reduced costs, enhanced cosmesis and a consistently higher patient satisfaction (24-29). Minimally invasive cardiac surgery - CAB and TECAB proved to be safe and feasible for multivessel coronary disease (30-32). With the expanding reach of percutaneous interventions, surgeons should be striving for less invasive techniques that would be more appealing to the patients. Despite these facts, MICS-CAB does not seem to be gaining the expected popularity among cardiac surgeons. Reasons behind this reluctance are different with different surgeons, but all revolve around two main factors; technical difficulty and prolonged time.

The use of connector devices in this context might present a solution. The two Cardica connector devices (*PAS-Port* for proximal and *C-Port* for distal anastomoses) have a very favorable profile concerning these exact two factors. After a relatively short learning curve with these devices, the surgeon should be able to perform minimally invasive CAB anastomoses with more ease and in less time. Balkhy and colleagues (33) published a review of 120 cases integrating these connector devices with robotics towards a totally endoscopic beating heart approach, and results were impressing. At our institution, we performed 132 cases of MICS-CAB since August 2008, 52% of which were multivessel disease. Since September 2010, we performed 22 cases of MICS-CAB using connector devices, all using the *PAS-Port* of the proximal anastomoses, and the *C-Port* for the distal ones. Our experience with connector devices in MICS-CAB is favorable, with a very reasonable learning curve. We believe a wider scale adoption of connector devices would allow more surgeons to shift their practice towards less invasive cardiac surgeries. If this was to occur, a much larger number of patients will be offered the benefits of these techniques. Redefining the standard of care in CAB surgeries might well compete with newer percutaneous interventions for best results and patient convenience.

REFERENCES

1. Androsov PI. New method of surgical treatment of blood vessel lesions. AMA Arch Surg 1956; 73: 902-10.
2. Kolessov VI. Mammary artery-coronary artery anastomosis as method of treatment for angina pectoris. J Thorac Cardiovasc Surg 1967; 54: 535-44.
3. Olearchyk AS. Vasilii I. Kolesov. A pioneer of coronary revascularization by internal mammary-coronary artery grafting. J Thorac Cardiovasc Surg 1988; 96: 13-8.
4. Edelman JJ, Yan TD, Bannon PG, et al. Coronary artery bypass grafting with and without manipulation of the ascending aorta--a meta-analysis. Heart Lung Circ 2011; 20: 318-24.
5. Misfeld M, Brereton RJ, Sweetman EA, Doig GS. Neurologic complications after off-pump coronary artery bypass grafting with and without aortic manipulation: meta-analysis of 11,398 cases from 8 studies. J Thorac Cardiovasc Surg 2011; 142: 11-7.
6. Hassanein W, Hegazy YY, Albert A, et al. Short term outcomes of total arterial coronary revascularization in patients above 65 years: a propensity score analysis. J Cardiothorac Surg 2010; 5: 25.
7. Lev-Ran O, Braunstein R, Sharony R, Kramer A, Paz Y, Mohr R, et al. No-touch aorta off-pump coronary surgery: the effect on stroke. J Thorac Cardiovasc Surg 2005; 129: 307-13.
8. Weisel RD, Lipton IH, Lyall Rn, Baird RJ. Cardiac metabolism and performance following cold potassium cardioplegia. Circulation 1978; 58: 217-26.
9. Weisel RD, Goldman BS, Lipton IH, et al. Optimal myocardial protection. Surgery 1978; 84: 812-21.
10. Gummert Jf, opfermann U, Jacobs S, et al. Anastomotic devices for coronary artery bypass grafting: technological options and potential pitfalls. Comput Biol Med 2007; 37: 1384-93.
11. Scheltes JS, van Andel CJ, Pistecky PV, Borst C. Coronary anastomotic devices: blood-exposed non-intimal surface and coronary wall stress. J Thorac Cardiovasc Surg 2003; 126: 191-9.
12. Hamman BL, White CH, Fontes M, Labiche L. Clampless anastomosis: novel device for clampless proximal vein anastomosis in OPCAB surgery--the initial Spyder experience. Heart Surg Forum 2005; 8: 443-6.
13. Bergsland J, Hol PK, Lingas PS, et al. Intraoperative and intermediate-term angiographic results of coronary artery bypass surgery with Symmetry proximal anastomotic device. J Thorac Cardiovasc Surg 2004; 128: 718-23.
14. Schoettle GP Jr. Use of a proximal anastomotic device in coronary artery bypass surgery: a word of caution. J Thorac Cardiovasc Surg 2004; 127: 269-70.
15. Carrel TP, Eckstein FS, Englberger L, et al. Pitfalls and key lessons with the symmetry proximal anastomotic device in coronary artery bypass surgery. Ann Thorac Surg 2003; 75: 1434-6.
16. Goldman S, Zadina K, Moritz T, et al. Long-term patency of saphenous vein and left internal mammary artery grafts after coronary artery bypass surgery: results from a Department of Veterans Affairs Cooperative Study. J Am Coll Cardiol 2004; 44: 2149-56.
17. Mack MJ, Osborne JA, Shennib H. Arterial graft patency in coronary artery bypass grafting: what do we really know? Ann Thorac Surg 1998; 66: 1055-9.
18. Sabik JF 3rd, Lytle BW, Blackstone EH, et al. Comparison of saphenous vein and internal thoracic artery graft patency by coronary system. Ann Thorac Surg 2005; 79: 544-51.
19. Fitzgibbon GM, Kafka HP, Leach AJ, et al. Coronary bypass graft fate and patient outcome: angiographic follow-up of 5,065 grafts related to survival and reoperation in 1,388 patients during 25 years. J Am Coll Cardiol 1996; 28: 616-26.
20. Biancari F, Lahtinen J, Ojala R, et al. Spyder aortic connector system in off-pump coronary artery bypass surgery. Ann Thorac Surg 2007; 84: 254-7.
21. Puskas JD, Halkos ME, Balkhy H, et al. Evaluation of the PAS-Port Proximal Anastomosis System in coronary artery bypass surgery (the EPIC trial). J Thorac Cardiovasc Surg 2009; 138: 125-32.
22. 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: 1645-52.
23. Suyker WJ, Borst C. Coronary connector devices: analysis of 1,469 anastomoses in 1,216 patients. Ann Thorac Surg 2008; 85: 1828-36.
24. Hamano K, Kawamura T, Gohra H, et al. Stress caused by minimally invasive cardiac surgery versus conventional cardiac surgery: incidence of systemic inflammatory response syndrome. World J Surg 2001; 25: 117-21.
25. Schmitto JD, Mokashi SA, Cohn LH. Minimally-invasive valve surgery. J Am Coll Cardiol 2010; 56: 455-62.
26. Chitwood WR Jr., Wixon CL, Elbeery JR, et al. Video-assisted minimally invasive mitral valve surgery. J Thorac Cardiovasc Surg 1997; 114: 773-80.
27. Yamada T, Ochiai R, Takeda J, et al. Comparison of early postoperative quality of life in minimally invasive versus conventional valve surgery. J Anesth 2003; 17: 171-6.
28. Dogan S, Aybek T, Risteski PS, et al. Minimally invasive port access versus conventional mitral valve surgery: prospective randomized study. Ann Thorac Surg 2005; 79: 492-8.
29. Casselman FP, Van Slycke S, Wellens F, et al. Mitral valve surgery can now routinely be performed endoscopically. Circulation 2003; 108: 48-54.
30. Mehran R, Dangas G, Stamou SC, et al. One-year clinical outcome after minimally invasive direct coronary artery bypass. Circulation 2000; 102: 2799-802.
31. McGinn JT Jr., Usman S, Lapierre H, et al. Minimally invasive coronary artery bypass grafting: dual-center experience in 450 consecutive patients. Circulation 2009; 120: 78-84.
32. Dogan S, Aybek T, Andressen E, et al. Totally endoscopic coronary artery bypass grafting on cardiopulmonary bypass with robotically enhanced telemanipulation: report of forty-five cases. J Thorac Cardiovasc Surg 2002; 123: 1125-31.
33. Balkhy HH, Wann LS, Krienbring D, Arnsdorf SE. Integrating coronary anastomotic connectors and robotics toward a totally endoscopic beating heart approach: review of 120 cases. Ann Thorac Surg 2011; 92: 821-7.

Cite this article as: Ramchandani M, Bedeir K. Vascular connector devices increase the availability of minimally invasive cardiac surgery to ischemic heart patients. HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2011; 3(4): 239-243

Source of Support: Nil. **Conflict of interest:** None declared.