Magnetic Vascular Port in Minimally Invasive Direct Coronary Artery Bypass Grafting

Uwe Klima, MD, PhD; Horace MacVaugh III, MD, FACS; Eric Bagaev, MD; Michael Maringka, MD; S. Kirschner, CM; J. Beilner, CM; Axel Haverich MD, PhD

Background—Minimally invasive direct coronary artery bypass grafting (MIDCAB) is a well-established operative procedure. However, it is technically demanding and is therefore somewhat underused. We evaluated the clinical and angiographic outcome of patients undergoing a MIDCAB procedure with the Ventrica Magnetic Vascular Port (MVP®) system.

Methods and Results—A Ventrica MVP® system was used in 10 of 11 selected MIDCAB patients. The system consists of 6 magnetic clips, with 3 clips forming a set. One magnetic clip set is positioned at the arteriotomy of the target artery and of the bypass graft using a preloaded delivery system. These ports then form an anastomosis by magnetic coupling. The mean age of the 10 patients (6 male) was 60.3±11.0 years. Three patients had an angiogram at the time of discharge and 8 returned for a 6-month angiogram. The total procedure time was 128.2±12.2 minutes. The mean anastomotic time was 199 seconds. The mean ischemic time during the anastomosis was 146±146 seconds. There were no in-hospital complications and no device-related adverse events. All 3 predischarge and all 8 6-month angiograms showed patent anastomoses.

Conclusions—The magnetic vascular port facilitates the MIDCAB procedure significantly and reduces the ischemic time during the anastomosis. This minimally invasive procedure has the potential to be an alternative to percutaneous transluminal coronary angioplasty and stenting in proximal left anterior descending (LAD) stenosis. It may expand the acceptance of hybrid procedures in which a left internal mammary artery (LIMA)-to-LAD graft optimally supplies the anterior wall and the septum while the circumflex and right coronary artery may be treated interventionally.

Key Words: bypass ■ revascularization ■ minimally invasive ■ automated anastomosis ■ magnetic

Modern medical management of coronary artery disease may involve several different modalities. Lifestyle modification, specific treatment of contributory coexistent conditions, interventional cardiology, coronary artery surgery, anti-lipid drug regimens, and although still investigational, the use of pharmacologic agents to reduce already formed intracoronary plaque. Each of these modalities has its advantages, disadvantages, benefits, and risks. The perceived risk relative to possible benefit often determines the sequence of therapies chosen for a patient, and yet the magnitude of those risks and benefits is constantly evolving and only imperfectly known. Our experience with a second-generation magnetic vascular port (MVP®) system may help evaluate the risks and benefits of a new method of coronary artery bypass surgery applicable to a large subset of patients with coronary artery disease. Standard coronary artery bypass surgery uses a midsternal incision, cardiopulmonary bypass, rotation and elevation of the heart, and venting of the left ventricle. Systemic hypothermia and coronary artery perfusion with a cold cardioplegic solution were added by most surgeons as operations became longer and the goal of “complete revascularization” was pursued. Each one of these factors in the standard operation adds its own subset of complications. Because every vessel is somewhat different, the skill required to operate successfully is only gradually developed. A hand-sewn coronary anastomosis is a relatively slow and tedious microsurgical operation that produces needle-hole trauma to the intima, risks plaque elevation and tears, and leaves a slightly irregular inner surface from the suture line itself.

We wished to show that using the MVP® system in a minimally invasive direct coronary artery bypass grafting (MIDCAB) series would reduce operating and myocardial ischemia times, would avoid cardiopulmonary bypass, and would therefore lead to fewer complications and more rapid recovery. We hoped that using a mini-thoracotomy rather than a mid-sternotomy might reduce morbidity and therefore appeal to patients considering surgical treatment. There has
been a concerted effort to find simpler, quicker methods to operate in restricted operative fields. The MVP® system has its major advantage during use in the restricted exposure of MIDCAB operations.

Materials and Methods

From January 9, 2003 to May 23, 2003, a second-generation MVP® system called the MVP Series 6000 Distal Anastomosis System was used in 10 of 11 MIDCAB operations. This subset was part of a prospective, multicenter clinical trial with ethics committee approval. Reimbursement was provided to the institutions for clinical trial research. Patient demographic data, risk factors, and comorbidities are shown in Table. Inclusion criteria included patients with single vessel coronary disease, with a target artery stenosis of ≥80%, and free of plaque or calcification at the anastomotic site. Subjects were excluded from the study if the left ventricular ejection fraction was <35%, there was a contraindication to either aspirin or clopidogrel, the operation was an emergency or re-operation, or if additional noncoronary procedures were required.

Description of Device

The MVP® Series 6000 Distal Anastomosis System consists of 2 sets, 3 clips forming a set, of an elliptical-shaped intravascular magnet and 2 extravascular magnetic clips preloaded on a delivery instrument (Figure 1.1 and 1.2). One set of magnetic clips is deployed to form the anastomotic port in the graft vessel; the other set is deployed to form an identical anastomotic port in the target coronary artery. Once both ports are created, the instantaneous coupling occurs by simply bringing the 2 ports within close proximity to each other, forming a self-sealing anastomosis. (Figure 2.1. to 2.3). The MVP anastomosis has been tested by the manufacturer and shown to have an attachment strength that exceeds that of an 8-0 nonabsorbable suture when the anastomosis is created as per the instructions for use. The MVP® system is available in 2 sizes, the 1.5-mm device for vessels between 1.5 and 2.0 mm internal diameter, and a 2.0-mm device for vessels of 2.0 to 4.0 mm internal diameter. The device sizes refer to the approximate minor internal diameter (ID) of the device lumen (actual 1.6 mm and 2.1 mm, respectively).

Surgical Technique

Under general anesthesia and the use of a left main bronchus blocker, patients were placed in a 30-degree right lateral decubitus position. The left hemithorax was entered via a 6- to 7-cm anterolateral mini-thoracotomy in the fourth or fifth intercostal space. The left internal mammary artery (LIMA) was dissected as a pedicle under direct vision. All side branches were clipped. The length of the pedicle was usually between 10 and 15 cm, long enough to avoid

Patient Demographics (n=10)

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<td>Gender, % (n/N)</td>
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<td>Comorbidities, % (n/N)</td>
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<tr>
<td>Previous myocardial infarction</td>
<td>20.0 (2/10)</td>
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<tr>
<td>Previous angina</td>
<td>100 (10/10)</td>
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<tr>
<td>Hypertension</td>
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<td>Diabetes mellitus</td>
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<td>Hypercholesterolemia</td>
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<td>Smoker</td>
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<tr>
<td>Family history of coronary disease</td>
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<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>10.0 (1/10)</td>
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<td>Peripheral vascular disease</td>
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n indicates number of patients; N, total patient group; SD, standard deviation.
tension on the subsequent LIMA-to-left anterior descending (LAD) anastomosis. After completion of the LIMA harvest, papaverine was applied several times to the LIMA pedicle to prevent spasm of the vessel. Systemic heparinization (100 IU/kg body weight) was established. Additional heparin was given if necessary to maintain the activated clotting time >350 seconds at the time of the insertion of the MVP®. The LIMA pedicle was transected distally and its end occluded with 2 titanium clips. The pericardium was opened and the LAD target anastomotic site identified. A 5.0-mm incision was made in the distal LIMA and the first set of magnets was deployed. After confirming adequate blood flow through the port, the pedicle was wrapped in a papaverine soaked sponge and set aside. The LAD was encircled with a 4-0 polypropylene snare suture proximal to the selected anastomotic site. The anastomotic site must be free of plaque and have an intraluminal diameter of at least 1.5 mm. A commercially available blower mister system was used in all patients to help maintain a bloodless operative field. After closing the snare, a 2.0-minute stabilization phase followed before a 5.0-mm incision was made at the anastomotic site and the second set of magnets deployed. The 2 ports were then brought together, allowing their magnetic attraction to join them and form a reliable side-to-side anastomosis (functional end-to-side). Only 1 patient required additional mechanical stabilization of the operative field. After completion of the anastomosis, the pedicle was fixed with 2 tacking sutures between the pedicle and the epicardium to avoid rotation or twisting of the graft, as well as to provide additional security to the anastomosis as recommended by the manufacturer. Half of the administered heparin was reversed with protamine. A chest tube was inserted, pericostal sutures tied securely, and the thoracotomy was closed.

Preoperative and Postoperative Antiplatelet Regimen
Twelve to 24 hours preoperatively, patients received a single loading dose of 100 mg aspirin and 130 mg clopidogrel (Plavix®). On the day of operation, no concomitant antiplatelet therapy was administered. On the first postoperative day, patients started 75 mg of clopidogrel daily for 12 weeks and a chronic course of 100 mg of aspirin daily.

Angiographic and Clinical Follow-up
Flow assessment was determined as the best method for patency analysis as quantitative coronary angiography is difficult because of the radiopacity of the magnetic clips. Three of the 10 patients underwent predischarge angiographic follow-up between postoperative days 4 and 6. These patients were part of a subset of patients who were studied by early angiographic assessment. Eight patients were angiographically reevaluated 6 months after surgery. The 6-month clinical follow-up included a physical examination, an assessment of angina status, and a determination of the presence or absence of a major adverse cardiac event such as death, myocardial infarction, or reintervention.

Results
Intraoperative Data
There were no intraoperative or postoperative complications and no adverse events related to the use of the MVP® system. Mean stay in the intensive care unit was 1.4±0.4 days and total stay in the hospital was 6.4±1.2 days. The ischemic time during the anastomosis was 146.0±146.2 seconds. The total procedure time was 128.2±12.2 minutes. In 2 patients, the 1.5-mm system was used but the other 8 all had the 2.0-mm device. The mean LIMA graft diameter was 2.3 mm±0.3 (SD) with a range of 1.8 to 2.5 mm, and the mean LAD diameter was 2.5 mm±0.5 (SD) with a range of 1.8 to 3.5 mm. The 24-hour chest tube drainage was 529 mL±230 mL.

One patient, classified as “intention to treat” in this series, did not receive the MVP® anastomosis. At operation, the MVP® port was inserted into the LIMA graft, although the graft was noted to be in significant spasm despite papaverine usage. Although the graft was not received in the MVP® port, the chest tube was deployed uneventfully. The ports were then coupled. On inspection of the anastomosis there was a leak at the graft port site. The arterial spasm had caused the MVP® port to become dislodged from the LIMA. The device was removed and the anastomosis was successfully completed by the hand-sewn technique.

Angiographic and Clinical Follow-up
All 3 predischarge angiograms showed patent anastomoses. At 6-month follow-up, 8 of 10 patients returned for a study angiogram for patency evaluation. Two patients refused to undergo angiographic reevaluation. One of the patients was unable to be contacted and the other was reported to be doing well, without any clinical symptoms. The bypass grafts were graded as either patent or not patent based on evidence of flow through the anastomosis. All grafts were patent for a patency rate of 100%. All 8 anastomoses showed unrestricted flow through the device. Figure 3 illustrates a typical postoperative angiogram 6 months after the operation.

No serious adverse events occurred within the 30-day period. One minor adverse event was reported at the 30-day follow-up period. That patient had a minor wound infection. At 5 months postoperatively, 1 patient was found to have a stenosis in the LAD distribution with a patent MVP® graft. The stenosis was proximal to the MVP port and was not present on the preoperative angiogram. The stenosis may
Discussion

This study demonstrates the safety and efficacy, as well as the clinical and angiographic follow-up, of an automatic distal anastomotic connector—the Ventrica MVP® system, when used in a MIDCAB series. To our knowledge, this is the first reported series of patients undergoing “facilitated” automatic anastomosis in limited access surgery. Our experience has helped us form opinions on potential clinical advantages of the device and on the impact of the device on future revascularization strategies.

Magnetic devices have been used in various applications in medicine and surgery for many years. There are reports describing use in orthodontics, prosthodontics, otology, for certain hearing aid uses involving sound transmission across the middle ear, endoscopic gastrointestinal surgery as an aid in forming gastroenterostomies, and transhepatic cholecdochoenterostomy. In urology there has been work on a device to enable magnetic urethral compression for stress incontinence. Data from the first clinical experience using magnetic vascular positioning in coronary artery bypass grafting were collected in a multicenter trial using the generation I device: the Ventrica Series 4000 Magnetic Vascular Positioner. Results of the Generation I study were excellent, but there were some deficiencies. The Series 4000 Magnetic Vascular Positioner comprised 2 small, flat, oval, gold-plated, magnetic rings, which were placed by a delivery system inside and outside an axial vascular incision in a graft vessel and in a target coronary artery. The Series 4000 device was made in only 1 size, which, unfortunately, was too large for 1.5-mm arteries. There was no tissue contact between the 2 elements, although endothelium did quickly bridge the junction. The stack of 4 magnets was bulky. The reengineered Series 6000 device comprises a set of 6 magnetic clips. The inner oval ring magnet has a relatively larger orifice than the earlier device, and its curved cross-section conforms to the internal convex curve of the vessel wall. The completed stack has a lower profile. There is a 1.5-mm size for 1.5- to 2.0-mm vessels and the standard 2.0-mm size for 2.0- to 4.0-mm vessels. The design of the MVP Series 6000 clips enables adventitia-to-adventitia apposition sealing the anastomosis. These modifications facilitated our use of the system in MIDCAB procedures in which hand-sewn techniques are sometimes slow and cumbersome, particularly so on the beating heart. Other distal anastomotic devices have also been used for coronary artery bypass grafting, but not in minimally invasive surgery.

The short time required to perform these anastomoses is a major advantage in off-pump coronary artery bypass grafting and MIDCAB procedures because regional coronary artery flow is interrupted a relatively short time (146 seconds in this series) while inserting the device. Even in standard operations, morbidity is reduced because of the shortened duration of cardiopulmonary bypass. In our experience, the time required to perform a hand-sewn anastomosis averages 6 minutes but may reach 15 minutes in difficult situations. In our series of patients the mean MVP® anastomosis time, defined as the sum of the graft port creation time, the target port creation time, and the coupling time, was 199±191 seconds. This mean MVP® anastomosis time, even though compiled during our “learning curve,” is significantly shorter than our anastomotic time in hand-sewn anastomoses. This should decrease ischemia-related complications such as arrhythmia during beating heart surgery. In using the MVP®, preparation of the graft port takes place leisurely at the chest wall level. Exposure of the target coronary vessel may be limited yet be adequate for placement of temporary hemostatic snares, incision of the target artery, and creation of the port. The malleable handle adds remarkable positional versatility and helps significantly during insertion of the LIMA port in MIDCAB procedures. In 9 of our 10 patients, we used no additional mechanical stabilization. Not having a stabilizer in the field is an advantage in exposing the target artery and allows a more flexible, unobstructed surgical approach.

An advantage of the MVP® over other automated devices is that even if the insertion attempt fails, the device may be removed and the vessel wall will be found to have remained intact and the intimal surface undamaged.

Increased Acceptance of MIDCAB Surgery

Diegeler et al. have proven in their study that in patients with isolated high-grade lesions of the proximal LAD the clinical and angiographic outcome after MIDCAB operations is superior to percutaneous transluminal coronary angioplasty (PTCA) and stenting. However, even though the MIDCAB procedure is a well-established operative procedure, it is technically demanding and has not gained widespread acceptance. Automatic anastomotic devices like the MVP® system facilitate the operative procedure and may increase the acceptability of MIDCAB among surgeons. The LIMA-to-LAD connection is the most important anastomosis for long-term clinical outcome. As described by Diegeler, MIDCAB is superior to PTCA and stenting when comparing repeat intervention rate, restenosis, and clinical outcome. It may be hypothesized that by simplifying the MIDCAB procedure with anastomotic devices, we may develop an even better alternative to PTCA and stenting for proximal LAD lesions. In addition to the potential benefits in using the MVP...
system in a MIDCAB procedure alone, a combination MIDCAB and PTCA/stent or “hybrid” procedure using both surgical revascularization and interventional procedures may also become more accepted. Our experience with the hybrid approach to myocardial revascularization suggests that this concept is a safe and effective method for complete revascularization for selected patients with multivessel disease. 23–24

Limitations of Study and Device
In this study the MVP system was used in the distal position to form a functional end-to-side graft. One can also use the device in the proximal position as in a T-graft. For example, in the MIDCAB setting a surgeon may choose to use an MVP® device to anastomose the proximal end of a radial artery graft to the middle third of a LIMA-LAD graft2 as a “T.”-graft allowing the distal end of the radial artery graft to be oriented where needed, easily reaching the posterior left ventricle. Although using the MVP in an alternative position such as in a T-graft anastomosis is feasible, one can see the limitations in using the MVP system for sequential grafts. The sequential graft must be planned very carefully because the design of the MVP® requires the graft and each target artery to be close and axially oriented. A LAD and its narrowly divergent diagonal branch might be ideal for a sequential LIMA-Diagonal-LAD operation, but some variations of coronary anatomy may not be appropriate for sequential grafting. This is especially true in sequential grafting of obtuse marginal branches. Future designs of the anastomotic device should address the problem of making a right-angled sequential anastomosis.

The optimal site of the MVP anastomosis should be plaque-free, without major sclerosis or calcification. However, clinical experience has taught us that in many patients such an “ideal spot” does not exist. With an overall experience at our institution of >120 patients receiving single to multiple magnetic vascular ports with an MVP device, we exclude coronaries with a vessel wall thickness of >0.5 mm. If MVP® anastomoses are attempted in thick-walled vessels, then there is a tendency for the lateral extravascular magnets to flip toward the intravascular magnet, preventing the creation of a port. If there is no ideal target site at the coronary artery, then there is still the option of a hand-sewn anastomosis.

Vessel selection is important when using this technology. Coronary arteries with diameters <1.5 mm are unable to be treated with this technology. A vessel that is too small will not allow for adequate tissue drape on the intravascular magnet.

This technique demonstrates good early clinical and 6-month patency results; however, as with all new technologies longer-term data are desirable to make a comparison with the “gold standard” hand-sewn LIMA-to-LAD anastomosis. One design feature that may prove to be an advantage is that the MVP system design allows for a uniform and predictable orifice area, which may prove to be advantageous in creating the anastomosis in the off-pump, limited exposure procedures in which suturing is a challenge.

Antipla telet Regimen
Tissue in-growth and endothelialization occur within the luminal path, encapsulating the entire intravascular magnetic clip in ~2 months, as demonstrated in early animal studies, and there was no thrombus at the ligated end of the graft.25

To minimize concern about early localized thrombosis and late intimal hyperplasia causing restenosis, we have instituted a preoperative and postoperative antiplatelet regimen with a clopidogrel/asyrin combination. Clopidogrel is a platelet ADP receptor antagonist that effectively reduces platelet adhesiveness and aggregation.26 It has also been shown that the effectiveness of clopidogrel is enhanced by the addition of aspirin.27

Conclusions
The Ventrica MVP® system is an appropriate technique for performing a LIMA-to-LAD anastomosis in a MIDCAB procedure. Its use is associated with a reduction in myocardial ischemia time and the duration of the procedure. The 6-month angiographic follow-up has demonstrated excellent patency rates equal to hand-sewn anastomoses. The combination of a minimal access approach, the MIDCAB, with the use of an automated anastomotic method, the Ventrica MVP® system, may prove competitive to PTCA and stenting in proximal LAD lesions. Also, the MIDCAB-MVP operation may be useful in multivessel disease as the first stage of a hybrid procedure for complete revascularization.

References
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