

# Coronary Artery Bypass with the Use of a Magnetic Distal Anastomotic Device: Surgical Technique and Preliminary Experience

Thanos Athanasiou, MD, PhD, Hutan Ashrafian, MBBS, Brian Glenville, FRCS, Roberto Casula, MD, FECS

The National Heart and Lung Institute, Imperial College of Science, Technology and Medicine, Department of Cardiothoracic Surgery, St Mary's Hospital, London, UK



Dr. Athanasiou

## ABSTRACT

**Background:** At present there is little reported experience in the application of new technology in the performance of distal coronary anastomoses in the clinical setting. The aim of our study was to evaluate the feasibility of using the Ventrica magnetic vascular positioner (MVP) device for left internal thoracic artery (LITA)-to-left anterior descending (LAD) coronary anastomosis.

**Methods:** We present our preliminary experience of the first 14 coronary artery cases performed in the United Kingdom from April 2003 to December 2003. The selection criteria, surgical technique, clinical outcome, advantages or disadvantages, and future implications are all discussed.

**Results:** The device was used in 12 patients for LITA-to-LAD anastomosis and in 2 patients for the proximal anastomosis of a radial artery Y-graft from the LITA to the circumflex territories. The first 3 patients underwent coronary artery bypass graft with the use of cardiopulmonary bypass, and the remaining 9 underwent surgery performed using an off-pump coronary artery bypass technique. No mortality or device-related events were observed in these patients. The anastomosis time in our series was  $5.6 \pm 1.99$  minutes, and the blood loss was  $914 \pm 234$  mL. The mean length of stay was  $5.8 \pm 1.16$  days.

**Conclusion:** The MVP system is a novel distal coronary anastomotic device that is quick, simple, and effective, producing consistently reliable coronary anastomoses in a wide variety of coronary bypass procedures. Early results are encouraging, and further studies are required in order to evaluate long-term efficacy of this system in the rapidly changing world of coronary revascularization.

## INTRODUCTION

Hand-sewn anastomosis of the internal thoracic artery to significantly stenosed coronary targets is the gold standard of

surgical coronary revascularization with regard to long-term patency and survival [Lytle 1999]. Of late there has been a resurgence in the development of alternative methods for distal anastomoses in coronary revascularization. There are 2 main reasons for this resurgence. First, off-pump coronary artery bypass (OPCAB) and the development of minimally invasive and robotic coronary procedures have led to an increasingly complex suturing environment, which requires simple and rapid performance without compromising the reliability of the distal coronary anastomosis. Second, OPCAB techniques require temporary occlusion of coronary blood flow in a beating heart, resulting in regional myocardial ischemia.

Distal anastomotic devices using accelerated tissue-bonding techniques have been applied in clinical practice to reduce the required anastomotic time and therefore the ischemic time [Scheltes 2000]. We describe our experience with the Ventrica magnetic vascular positioner (MVP; Ventrica, Fremont, CA, USA) and demonstrate a step-by-step approach for use of this sutureless magnetic anastomotic device in coronary artery bypass surgery.

## PATIENT SELECTION AND EXCLUSION

All patients considered for MVP were awaiting first-time elective coronary artery bypass grafting (CABG). The following exclusion criteria were used: contraindication to antiplatelet therapy, ejection fraction less than 30%, and the presence of highly calcified, thickened, or friable coronary architecture. A relative contraindication to the use of the device was a history of neurologic or spinal disease, which is likely at some stage to require magnetic imaging, a procedure that may potentially disrupt the distal anastomosis.

In the selected patients the MVP device was used to perform anastomosis of the left internal thoracic artery (LITA) to the left anterior descending coronary artery (LAD). The remaining anastomoses were performed using a hand-sewn technique. Although patients were selected on the basis of their preoperative angiogram, if at the time of operation the quality of the LAD target was deemed to be unsuitable, a hand-sewn anastomosis was performed. We considered this to be a conversion to the traditional technique as per the intention to treat methodology.

Received May 24, 2004; accepted June 7, 2004

Address correspondence and reprint requests to: Mr. T. Athanasiou, Senior Registrar and Senior Clinical Fellow in Robotic and Minimally Invasive Cardiothoracic Surgery, 70 St Olaf's Road, Fulham, London SW6 7DN, UK; 44-0207-886-1147; fax: 44-0207-886-6777 (e-mail: tathan5253@aol.com).

## PREOPERATIVE AND POSTOPERATIVE

All patients received 150 mg of aspirin and 150 mg of clopidogrel 24 hours prior to the operation. Postoperatively patients were placed on a life-long dose of 75 mg aspirin and 75 mg clopidogrel.

## DEVICE DESCRIPTION

The Ventrica MVP is a recently designed sutureless distal coronary anastomotic device of the continuous mechanical bonding category. It uses magnetic attraction to form an instantaneous self-aligning, self-sealing connection between 2 blood vessels.

The MVP 6000 system currently exists in 2 sizes, the series 6150 for target vessels with a diameter of up to 2.0 mm and the 6200 for vessels with a diameter larger than 2.0 mm. Each system comprises a magnetic clip set with a clip applicator (Figure 1). Each clip set contains 2 groups of a 3-subunit magnet ring. This ring conformation is then applied with the clip applicator (Figure 2A) to the intra- and extravascular segments of one vessel at the site of the anastomotic incision (Figure 2B). Each 3-subunit ring (consisting of a central intravascular ring and 2 extravascular arms) is attached to the wall of a conduit vessel and then applied to its counterpart 3-subunit ring on a corresponding coronary vessel wall to form the complete magnetic anastomosis.

## SURGICAL TECHNIQUE

After undergoing routine cardiac anesthetic preparation, each patient was administered 15,000 units of heparin for anticoagulation. The surgical technique was as follows:

1. The distal LITA is harvested in a nonskeletonized fashion (distal 2 cm) to allow suturing of the fascia onto the epicardium following completion of the anastomosis. The LITA is then ligated distally.

2. The left anterior descending artery is identified and mobilized circumferentially by 270 degrees.

3. Preparation of the LITA for deployment of the MVP: A 4- or 5-mm long arteriotomy (for the series 6150 or 6200, respectively) is performed on the LITA and flow is assessed visually. The internal diameter of the vessels to be anastomosed is then evaluated in order to select the appropriately sized system (series 6150 for vessel diameter <2.0 mm and 6200 for vessel diameter >2.0 mm). In order to prevent attraction to the MVP devices, from this point only titanium instruments are used.

4. Deployment of MVP onto LITA: The clip applicator and its handling stem are adjusted into a position that best allows clip function. The toe of the clip applicator delivery shoe is then inserted at the tip of the incision, and once in place, the heel of the applicator shoe is pressed down. With the magnetic ring underneath and abutting the vascular wall, the delivery shoe is then lifted vertically upward, facilitating its removal (the ring remains in the vessel wall). The ring applicator is then deployed, adhering the external wall ring

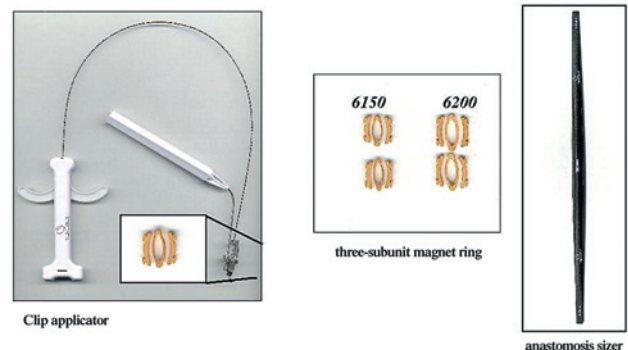


Figure 1. The Ventrica MVP (magnetic vascular positioner) distal anastomosis device system.

components to the internal ring component (already in situ). This process forms 1 of the 3-part rings that comprise half of the magnetic anastomosis.

5. Deployment of MVP onto LAD: The entire procedure is repeated for the corresponding coronary artery (Figures 2A and 2B). It is important to note that great care is taken to position the incision so as to avoid any deformity in the bypassed conduit once final apposition is achieved.

6. Apposition of the 2 LITA and LAD components: On completion of application of the 3-part ring to each vessel wall, the magnetic faces are carefully brought together, aligning the central lumen. At close range, these 2 come together as a result of magnetic attraction, and the anastomosis is complete.

Magnetic and metallic objects in proximity to these systems may affect function and therefore their deployment may be limited by the use of items such as pacemakers, implantable defibrillators, and ventricular assist devices. The manufacturer advises that pacemakers and implantable defibrillators should be more than 2.5 cm from the MVP device, and external magnetic devices used in conjunction with pacemakers and implantable defibrillators should be more than 5 cm from the device.

On-the-table inspection should be carried out to ensure good graft alignment, positioning, and flow. This inspection includes routine measures such as checking hemodynamic status, performing electrocardiographic monitoring, and ensuring that there is no para-anastomotic leak. If there is failure of hemostasis despite good graft alignment, the device must be removed and replaced. A single 6-0 polypropylene tacking stitch can be applied on each side of the anastomosis between the apposing extravascular arms of the device, incorporating local adventitial tissue. Finally, because positioning of the MVP system is carried out through a standard incision, the magnet can be removed at any time, and the anastomosis performed with the traditional hand-suture technique.

## POSTOPERATIVE PATIENT CARE

Routine post-CABG protocols were employed. However, the application of any mode of magnetic imaging or the presence of any strong magnetic field is contraindicated for life in these patients.

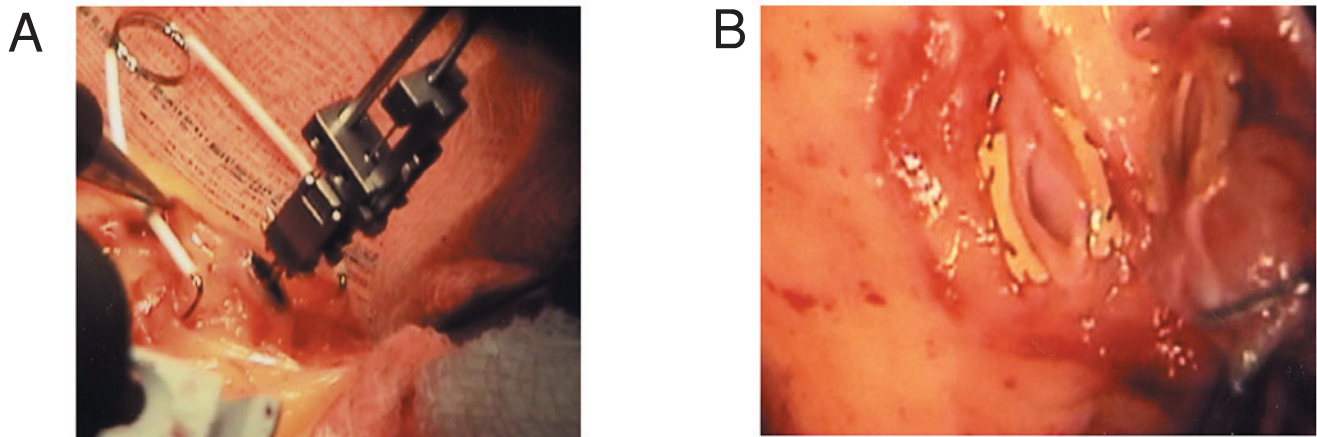


Figure 2. A, Insertion of the clip applicator into the left anterior descending artery (LAD) for deployment of the device. B, LAD coronary component of the device.

## RESULTS

We used the MVP device in 14 patients requiring CABG. The ratio of male to female patients was 13 to 1. The mean age was  $64.8 \pm 8.7$  years, with a Parsonnet score of  $8.07 \pm 6.4$  and a Euroscore of  $3.6 \pm 2.4$ . The first 3 patients underwent CABG with the use of cardiopulmonary bypass, and the remaining 9 underwent surgery performed using an OPCAB technique. In 1 of these 9 patients the LITA was harvested robotically. In this patient a 5-cm left anterolateral hemithorax incision was made, and without spreading the ribs access was gained to perform the distal (coronary) anastomosis, a process known as atraumatic coronary artery bypass grafting (ACAB).

Thirteen patients underwent sternotomy, and the mean number of grafts per patient was  $3.2 \pm 0.89$ . In 12 patients the MVP device was used for the LITA-to-LAD anastomosis, and in 2 patients the device was used for the proximal anastomosis of a radial artery Y-graft from the LITA to the circumflex territories.

No deaths or device-related events were observed in these patients. One of the patients developed a visual defect. Another patient developed postoperative ventricular fibrillation arrest, which required reexploration and additional grafting to the circumflex territory. Following this procedure this patient recovered fully and was discharged on postoperative day 7 without any evidence of myocardial infarction. None of the patients was reexplored for bleeding or developed myocardial infarction, ventricular arrhythmia, or recurrence of angina during the 4-month follow-up period. With regard to conversion to a hand-sewn technique, 16 patients were initially considered suitable candidates for the device, but at the time of operation, for the reasons previously mentioned, 2 of them were excluded. Angiography was performed in the first 2 patients and in the ACAB patient (Figure 3) and showed 100% patency in all 3 cases. The anastomosis time in our series was  $5.6 \pm 1.99$  minutes, and the blood loss was  $914 \pm 234$  mL. The mean length of stay was  $5.8 \pm 1.16$  days.

## DISCUSSION

Our preliminary experience with the use of the MVP device is very encouraging, particularly because none of the

patients that were operated on experienced any adverse events related to the use of the device. With regard to perioperative blood loss and length of postoperative hospital stay, we did not find any significant difference when comparing MVP patients to those undergoing routine CABG in our unit.

Other anastomotic methods such as tissue adhesives (laser or glue), interrupted bonding (clips or staples), intraluminal stents, and continuous mechanical bonding (intraluminal, extraluminal, or both), have all been considered. The reported experience with these devices in the literature is limited, making it difficult to pass judgment on their performance [Detweiler 1999, Scheltes 2000]. Magnetic vascular coupling with the MVP appears thus far to be safe, without compromise of clinical outcome in routine coronary surgery practice. A recent multicenter study with 32 patients demonstrated a 93.5% pre-discharge angiographic patency for patients receiving MVP anastomoses compared to 91.7% patency in patients whose surgery was performed using hand-sewn techniques. A median MVP anastomotic time of 137 seconds was also achieved in this study [Klima 2003]. Furthermore, a recent animal study has demonstrated the application of MVP anastomoses in the context of totally endoscopic coronary artery bypass, with only 1 reported thrombotic anastomotic occlusion, which was due to inadequate antiplatelet therapy [Falk 2003, Filsoufi 2004]. Intimal hyperplasia can also affect the long-term performance of the MVP device and is therefore an important consideration. Animal studies have previously shown the occurrence of complete endothelialization of luminal surfaces, with a cellular layer forming 6 weeks postimplantation [Adams 2002].

Our study highlighted a learning curve for the procedure, shown by an increased anastomotic time in the first 5 cases performed, a factor that improved significantly in the next 9 cases. We must also mention that when the device was used in OPCAB surgery the other anastomoses were performed first, leaving the LITA to LAD as the last anastomosis. This sequence avoids traction on the magnetically apposed anastomosis. In our routine practice, however, the LITA-to-LAD anastomosis is usually performed first.



Figure 3. Postoperative angiogram of patient who underwent atraumatic coronary artery bypass grafting with the use of the magnetic vascular positioner.

A major advantage of the MVP device is that it can be used with every type of incision, in a quick and reproducible manner. It can also be used to perform distal or proximal anastomoses of Y-grafts between internal thoracic and radial arteries. The application of the endoscopic version of the device has the potential to significantly improve the ease with which coronary anastomoses are performed during robotic surgery on the beating heart, for which the performance of a microvascular anastomosis remains a complex and time-consuming task.

The main limitations of these MVP devices are, first, that at present they are significantly more expensive than a 7-0 prolene stitch. Second, they require in the short term anticoagulation, which itself has clinical and financial consequences. Finally, caution is required with regard to exposure to a magnetic field for at least 6 months after the procedure. This precaution is particularly important as magnetic resonance imaging becomes more prevalent.

We acknowledge that because the number of patients in our series is limited and the mean length of follow-up is only

4 months, it is too early to draw any major conclusions. The MVP system is a novel distal coronary anastomotic device that is quick, simple, and effective and seems to produce consistently reliable coronary anastomoses in a wide variety of coronary bypass procedures. Early reports are encouraging and warrant further studies in order to evaluate the long-term efficacy of the MVP system in the rapidly changing world of coronary revascularization.

## REFERENCES

- Adams DH, Filsoufi F, Aklog L, et al. 2002. Automated distal coronary bypass using a novel magnetic coupler. American Association for Thoracic Surgery 82nd Annual Meeting, Washington, DC, May 5-8, 2002; T2(Abstract):230.
- Detweiler MB, Detweiler JG, Fenton J. 1999. Sutureless and reduced structure anastomosis of hollow vessels with fibrin glue: a review. *J Invest Surg* 12:245-62.
- Falk V, Walther T, Stein H, et al. 2003. Facilitated endoscopic beating heart coronary artery bypass grafting using a magnetic coupling device. *J Thorac Cardiovasc Surg* 126:1575-9.
- Filsoufi F, Farivar RS, Aklog L, et al. 2004. Automated distal coronary bypass with a novel magnetic coupler (MVP system). *J Thorac Cardiovasc Surg* 127(1):185-92.
- Klima U, Falk V, Maringka M, et al. 2003. Magnetic vascular coupling for distal anastomosis in coronary artery bypass grafting: a multicenter trial. *J Thorac Cardiovasc Surg* 126:1568-74.
- Lytle BW, Blackstone EH, Loop FD, et al. 1999. Two internal thoracic artery grafts are better than one. *J Thorac Cardiovasc Surg* 117(5):855-72.
- Scheltes JS, Heikens M, Pistecky PV, van Andel CJ, Borst C. 2000. Assessment of patented coronary end-to-side anastomotic devices using micromechanical bonding. *Ann Thorac Surg* 70:218-21.