Evolving Technology

Automated distal coronary bypass with a novel magnetic coupler (MVP system)

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Objective: We sought to assess the feasibility of performing sutureless distal coronary artery bypass anastomoses with a novel magnetic coupling device.

Methods: From May 2000 to April 2001, single-vessel side-to-side coronary artery bypass grafting on a beating heart was performed in 39 domestic white pigs (35-60 kg) without the use of mechanical stabilization, shunts, or perfusion bridges. Animals were divided into 2 groups. Seventeen pigs underwent right internal thoracic artery to right coronary artery bypass grafting through a median sternotomy (group 1) with a novel magnetic vascular positioning system (MVP system; Ventrica, Inc, Fremont, Calif). Twenty-two pigs underwent left internal thoracic artery to left anterior descending artery grafting with the MVP anastomotic device through a left anterior minithoracotomy (group 2). This system consists of 2 pairs of elliptical magnetic implants and a deployment device. One pair of magnets forms the anastomotic docking port within the graft; the other pair forms an identical anastomotic docking port within the target vessel. The anastomosis is created when the 2 docking ports magnetically couple. Anastomotic patency was evaluated by means of angiography during the first postoperative week and at 1 month. Histologic studies were performed at different time points as late as 6 months.

Results: Right internal thoracic artery to right coronary artery anastomoses and left internal thoracic artery to left anterior descending artery anastomoses were successfully performed with the system in all animals. The self-adherent and self-aligning properties of the implants allowed for immediate and secure approximation of the arteries (total anastomotic time between 2-3 minutes). Anastomoses were constructed without a stabilization platform. Five nondevice-related deaths occurred postoperatively. One-week angiography, performed in 35 surviving animals, showed a patent graft and anastomosis in all cases. The patency rate at 1 month was 97% (33/34). Histologic studies as late as 6 months demonstrated neointimal coverage of the magnets without any significant luminal obstruction. Histology also confirmed the presence of viable tissue between magnets.

Conclusion: The MVP anastomotic system uses magnetic force to create rapid and secure distal coronary artery anastomoses, which might facilitate minimally invasive and totally endoscopic coronary artery bypass surgery.

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Conventional coronary artery bypass grafting (CABG) with cardiopulmonary bypass is a reliable therapy for patients with multivessel coronary artery disease. For more than 2 decades, coronary anastomoses have been performed with a hand-sewing technique by using monofilament sutures. A bloodless operating field and motionless heart with cardioplegic arrest have been key requirements for accurate and safe vascular anastomoses. However, recent interest has focused on the development of new revascularization strategies on the beating heart in an attempt to decrease morbidity and mortality associated with conventional CABG. Minimally invasive direct coronary artery bypass with left internal thoracic artery (LITA) to the left anterior descending artery (LAD) anastomosis through a left anterior small thoracotomy and off-pump coronary artery bypass grafting (OPCABG) were first introduced to address these issues.[1-3] More recently, robot-enhanced single-vessel CABG has been performed endoscopically both on arrested and beating hearts through keyhole incisions.[4-6] The relatively recent introduction of mechanical stabilizers, positioning devices, and coronary occluders-shunts has facilitated the performance of OPCABG in patients with multivessel coronary artery disease,[7,8] as well as the construction of total endoscopic beating-heart coronary anastomosis. Nonetheless, a limiting factor in the broader adoption and further development of these procedures has been performing hand-sewn anastomoses in a confined space, on the beating heart, or both. A need exists for automated anastomotic technology, which would enable the creation of rapid, precise, and reliable distal anastomoses on the beating heart with limited exposure.[9] In our opinion the development of such a new device will be a significant step in the development of minimally invasive coronary bypass surgery (Figure 1).

Here we report our initial experience with a new automated anastomotic system (Magnetic Vascular Positioner [MVP]; Ventrica, Inc, Fremont, Calif), which uses magnetic forces to form a secure connection between blood vessels.

Materials and Methods

Animal Model

From May 2000 to April 2001, 39 domestic pigs, weighing 35 to 60 kg, underwent single-vessel side-to-side OPCABG without mechanical stabilizers or shunts. Animals were divided into 2 groups. In group 1, 17 pigs underwent right internal thoracic artery (RITA) to right coronary artery (RCA) bypass with an MVP anastomotic device through a full sternotomy. In group 2, 22 pigs underwent LITA-to-LAD bypass with the MVP anastomotic device through a left anterior minithoracotomy. All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals."

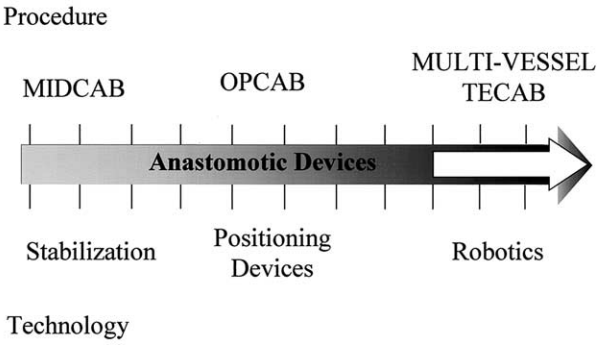

Figure 1. Enabling technologies that facilitate minimally invasive cardiac surgery. *MIDCAB,* Minimally invasive coronary artery bypass; *OPCAB,* off-pump coronary artery bypass; *TECAB,* total endoscopic coronary artery bypass.

Preoperative Treatment

Using guidelines consistent with the management of intravascular devices, antiplatelet therapy was administered to all animals. A loading dose of clopidogrel (300 mg) and aspirin (325 mg) was given by mouth from 1 to 3 days before the start of the procedure.

Intraoperative Treatment

Anesthesia was induced with an intramuscular injection of ketamine at a dose of 20 mg/kg. One percent to 5% isoflurane was given to maintain anesthesia. Lidocaine (100 mg/L) was administered by means of continuous infusion. Amiodarone (75 mg) or lidocaine (2 mg/kg) was administered by means of bolus infusion and used as a cardioprotectant before sternotomy or left thoracotomy, as well as before ischemic time. Intravenous heparin was used (100-300 IU/kg) to achieve an activated clotting time of greater than 400 seconds. Heparin was not reversed at the completion of the procedure.

Postoperative Treatment

Animals were treated with buprenorphine for pain. An intramuscular penicillin injection was given in the immediate postoperative period. Clopidogrel (75 mg) and aspirin (325 mg) were continued in each animal on a daily basis until death.

MVP System

The MVP system consists of 4 magnetic implants and a delivery device to facilitate placement (Figure 2). One pair of magnets forms the anastomotic docking port within the graft, and the other pair forms an identical anastomotic docking port within the target vessel (Figure 3). The 2 magnetic ports are then brought together to complete the anastomosis (Figure 3).

Operative Technique

Standard surgical instrumentation was used in all cases. Titanium forceps and clips were used in the immediate proximity of the magnetic implants. Mechanical stabilizers or shunts were not used.

A full median sternotomy (group 1) or left anterior minithoracotomy through the fourth intercostal space (group 2) was performed. The internal thoracic artery (ITA) was dissected as a

pedicle and ligated distally after the administration of heparin. Topical and intraluminal papaverine were administered to dilate the thoracic artery. The pericardium was opened longitudinally (group 1) or horizontally (group 2), and stay sutures were placed. The proximal segment of the RCA-LAD was selected for coronary artery bypass surgery.

Internal diameters of vessels in this study were in excess of 2.0 mm. The graft was prepared by tying or clipping the distal end of the ITA, and a conventional longitudinal arteriotomy (approximately 3.5 mm) was performed near its distal end. A pair of magnets was delivered with the MVP system by placing one of the magnets intraluminally and the other extraluminally, creating an anastomotic graft port. The target vessel was occluded proximal to the intended site of anastomosis with a 4-0 polypropylene suture. In our early experience, some animals underwent preconditioning by obstructing the proximal RCA-LAD for 3 periods of 30 to 90 seconds, which was later discontinued. A conventional arteriotomy (approximately 3.5 mm) was performed in the RCA-LAD just distal to the occlusion suture. The second pair of magnets was delivered in a similar fashion to form an identical target port. The 2 newly created ports were brought together to form the magnetically coupled anastomosis.

Angiography

An 18-gauge intravenous catheter needle was used to cannulate the femoral artery. A guide wire (0.038 in) was advanced through the iliac artery and into the descending aorta. A 6F ITA catheter was advanced over the wire and placed at the takeoff of the RITA-LITA. The guide wire was removed. Five to 10 milliliters of undiluted contrast was injected during fluoroscopy. Angiography was performed from 3 angles: anteroposterior, left anterior oblique, and right anterior oblique. The first angiogram was scheduled during the 7 days after the operation. A 1-month follow-up angiogram was performed in all surviving animals. Although 1-month graft patency rate was the primary endpoint, 10 and 6 animals were kept alive for histologic studies at 3 and 6 months, respectively.

Histology

The animals were killed with an overdose of sodium pentobarbital. The heart was removed, and the anastomotic device was examined in situ. The posterior wall of the coronary artery and the anterior wall of the ITA were incised to expose the anastomosis. Photographs of the anastomosis from both the coronary and graft sides were taken. The heart was fixed and immersed in glutaraldehyde (1%) for histologic examination. Before tissue explantation, vessels were perfusion fixed with 1% glutaraldehyde. Through slit incisions in the fibrous tissue pocket encapsulating the implants, the implants were removed. The remaining tissue was mounted in paraffin and then sectioned. Three serial cross-sections, 5- to 10-μm thick each, were taken every 0.5 mm across the longitudinal axis of the implants. The first of the 3 sections was stained with hematoxylin and eosin. The second and third of the serial sections was stained with a marked anti-Factor VIII antibody (specific to endothelial cells) and a negative control, respectively. Immunohistochemistry was performed by using the VectaStain Elite ABC Kit (Burlingame, Calif) in accordance with the manufacturer's directions. In brief, slides were cut on a 5-μm Leica microtome after formalin fixation and paraffin embedding. Slides were blocked for 1 hour. Protease K was applied for 10 minutes. Primary antibody to Factor VIII (Dako Corp, Carpinteria, Calif) was used at 1:100 in PBS-Tween (0.05%), and the secondary antibody was 1:1000. Slides were then incubated with avidin-biotin complex for 1 hour at room temperature, and diaminoben-

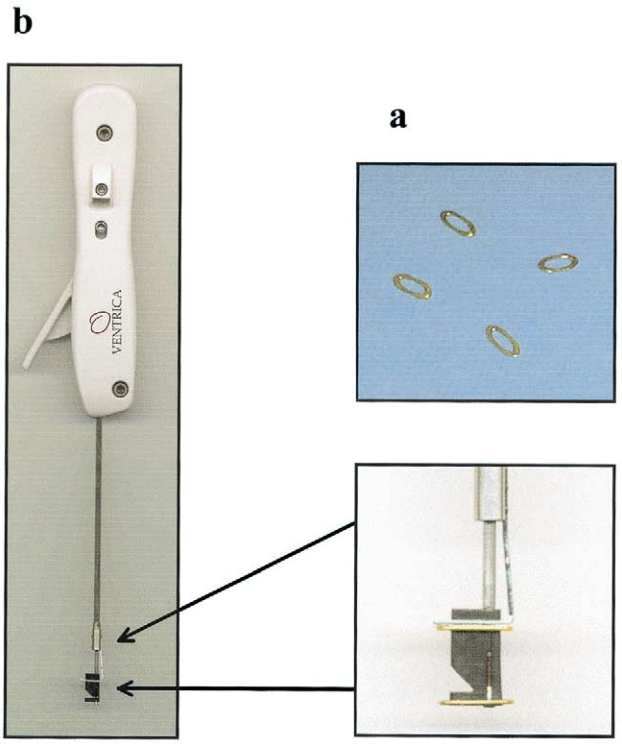

Figure 2. MVP system: A, elliptical magnets; B, delivery device.

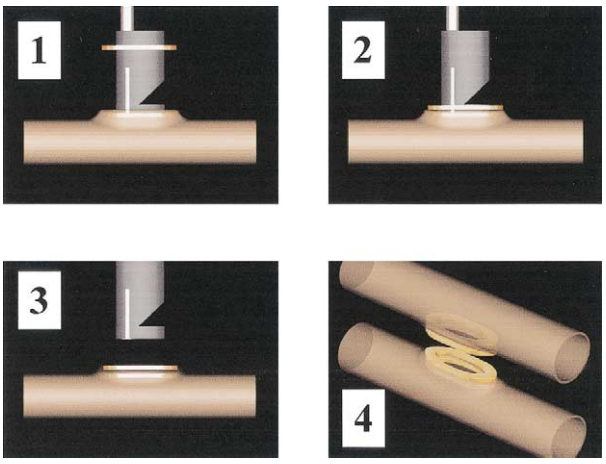

Figure 3. Illustration of the MVP system: 1, 2, and 3, Construction of anastomotic docking port; 4, creation of the anastomosis by approximation of the 2 magnetic ports. The device measures 3.0 mm at the minor axis and 7.0 mm at the major axis and is 0.4 mm thick.

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TABLE 1. Operative mortality

Cause	No.	POD
Premature extubation	1	0
Hemorrhage (ITA side branch)	1	1
Drug overdose (during transfer to angiography suite)	2	4 and 5
Mediastinitis	1	11

POD, Postoperative day; *ITA,* internal thoracic artery.

zidine was used to develop the slides. Slides were counterstained with Gill's hematoxylin for 1 minute, after which they were dehydrated and coverslipped.

Results

Operative Findings

RITA-to-RCA anastomoses and LITA-to-LAD anastomoses were successfully constructed in the 39 animals. Magnetic ports in both the graft and target vessel could be formed in less than 40 seconds. The self-adherent and self-aligning properties of the magnetic coupling device allowed us to rapidly secure a hemostatic anastomosis without using cardiopulmonary bypass or mechanical stabilizers. The average ischemic time was 60 seconds. In our experience, the size of the arteriotomy was critical in creating a perfect anastomotic port. If the arteriotomy was too small, there was a high risk of protrusion of arterial wall inside the new lumen after the magnets were inserted. This not only reduced the effective anastomotic orifice area but might also have produced turbulent flow with significant risk of early thrombosis. If the arteriotomy was too large, there was not enough tissue between the 2 magnets to achieve a perfect hemostatic seal. In this porcine model with normal compliant coronary arteries, the appropriate size of the arteriotomy was about 3.5 mm. During earlier feasibility studies done with the device, improper arteriotomy sizes at the time of graft preparation occasionally occurred. If the arteriotomy was too small, we were able to safely remove the magnets, enlarge the latter, and redeploy the pair of magnets. If the arteriotomy was too large, a new arteriotomy was performed more proximally. On the other hand, with the target vessel, we have favored an undersized arteriotomy, which could secondarily be enlarged. No cases in this experiment required conversion to a hand-sewn anastomosis because of excessive coronary arteriotomy.

Operative Mortality

The overall mortality was 13% (n = 5). These deaths were not device related. The cause and the timing of death are summarized in Table 1. The postmortem examination revealed a patent anastomosis in all 5 animals.

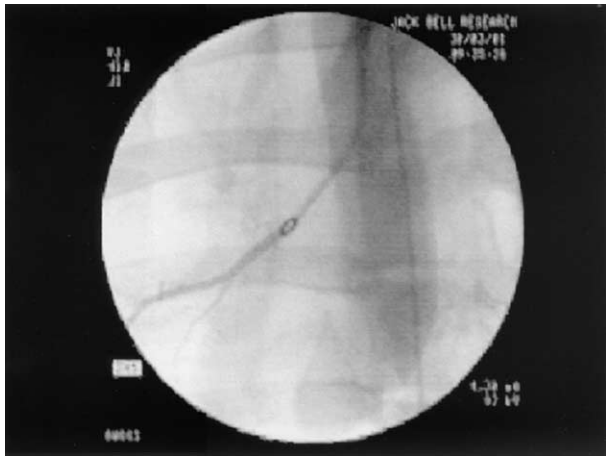


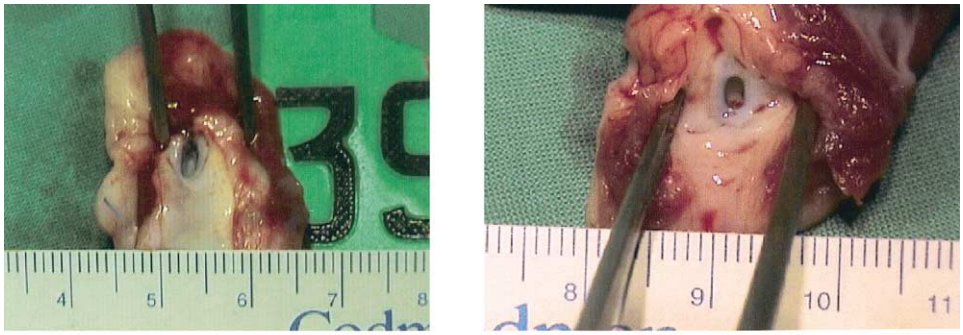
Figure 4. Angiography at 1 month: LITA-to-LAD anastomosis with MVP system.

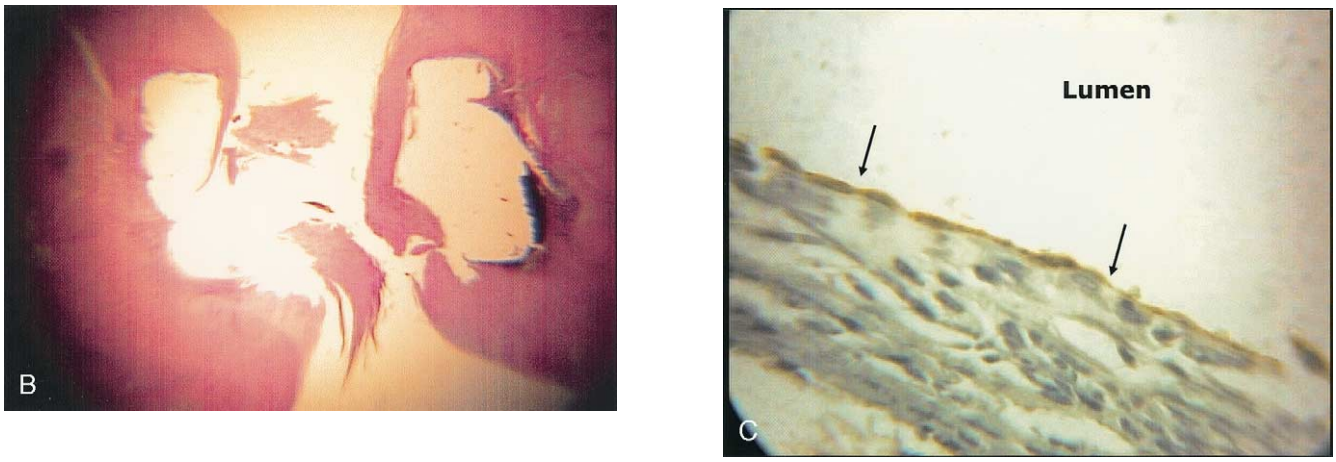
Angiograms

The first-week angiogram was performed in 35 animals, and all the anastomoses were patent. The 1-month angiogram was performed in 34 animals, which demonstrated a patency rate of 97% (33/34; Figure 4). The occluded graft was an RITA-to-RCA anastomosis. Although some test subjects were continued beyond the 1-month interval, it was not possible to perform additional angiograms because the animals quickly became too large for laboratory personnel to handle under labor guidelines at the sites. Furthermore, the radiopacity of the device made QCA and other methods of quantifying patency challenging in this model. We were, however, able to document TIMI-III flow in all patent subjects at 1 month. In addition, on explantation at every interval, we could confirm the absence of flow restriction by measuring the mean residual lumen narrowing (30% $\pm$ 0.06%).

Histology

Gross inspection of implants demonstrated complete neointimal coverage at all time points (4 animals between 2 and 3 months and 7 animals at the 6-month interval, data not shown). Figure 5, *A*, shows the gross appearance of a typical explant on both the graft and coronary sides at 6 months. Histologic studies confirmed complete neointimal coverage of the endoluminal magnetic surface. We did not note any significant luminal obstruction as late as 6 months. Figure 5, *B*, documents a hematoxylin and eosin–stained luminal area, which has been created by using a magnetic couple (the incision was made vertically over the couple). As seen at higher magnification, there are foreign-body giant cells in contact with the magnets and mature collagen fibrils but very few signs of acute inflammation. There were no polymorphonuclear leukocytes or lymphocytes present. Figure 5, *C*, shows a tissue that has been immunohistochemically





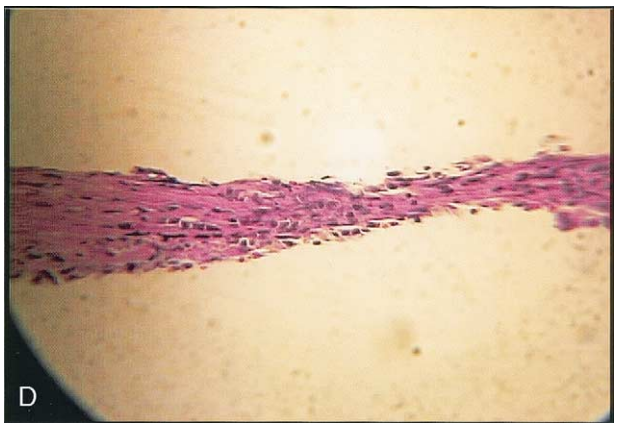


Figure 5. Histologic study. A, Internal gross appearance of the lumen of the implant at 6 months on both graft and coronary sides. B, Hematoxylin and eosin–stained section of tissue encapsulating outside and lumen of MVP implants. C, Factor VIII–stained section demonstrating a continuous single endothelial layer covering the MVP lumen. D, Hematoxylin and eosin–stained section (100×) showing viable tissue between MVP port implants.

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stained for Factor VIII. This tissue is in contact with the lumen and magnet. The luminal side is immunoreactive (brown) for Factor VIII antigen, demonstrating a continuous single endothelial layer. Figure 5, *D*, shows hematoxylin and eosin staining (100×) of tissue between a magnetic couple, which demonstrates the presence of viable tissue between magnets.

Discussion

In the rapidly evolving arena of minimally invasive CABG, the development of a simple and reliable facilitated anastomotic device remains a key to the wide adoption of minimally invasive and totally endoscopic multivessel CABG procedures. To date, efforts at developing proximal anastomotic devices have been more successful than efforts at

developing distal anastomotic systems. This might be because the ascending aorta is a more consistent target in terms of its caliber, wall thickness, and histologic characteristics. The recently introduced Symmetry Bypass System (St Jude Medical) is the only US Food and Drug Administration–approved proximal anastomotic device. This aortic connector uses a stent-like structure made of Nitinol to construct anastomoses with minimal manipulation of the ascending aorta. With respect to distal anastomotic devices, prior reports in animal models have used either intracoronary stents or nonpenetrating clips.[10-12] More recently, the Coalescent surgical U clip was introduced, enabling surgeons to construct coronary anastomoses using interrupted Nitinol clips.[13] This device, by eliminating knot tying and the need for suture management, facilitates the construction of distal coronary anastomoses, particularly during minimally invasive and robotically enhanced coronary surgery. The U-clip device, however, still requires the accurate placement of 8 to 12 bites through both the graft and the coronary artery. This process remains time consuming, particularly in an endoscopic environment, and the quality of the anastomosis is determined by the skill of the surgeon and not by the precision and effectiveness of a potential automated delivery system.

Our report represents the first successful attempt to use magnetic force to create vascular anastomoses. The MVP device facilitates rapid sutureless RITA-to-RCA or LITA-to-LAD coronary anastomoses without the need for cardiopulmonary bypass, mechanical stabilizers, or coronary shunts. The MVP system has multiple advantages, which include ease of use, reproducibility, and a brief learning curve. Also, the device does not exert radial stress on the vessel wall or the anastomosis, nor does it require vessel wall evertion, which could produce vessel distortion. We believe these design features contributed to our encouraging results. The deployment system is rapid, precise, and applicable to both venous and arterial conduits. One of the major benefits of this technology is that if, after completion of the arteriotomy, the placement of the magnets is not satisfactory, they can be removed atraumatically. In the majority of cases, the same magnets can be redeployed after the adjustment of the arteriotomy size, or the surgeon can revert to a hand-sewn anastomosis. Histology as late as 6 months confirmed complete neointimal coverage of the endoluminal magnetic surface without significant luminal obstruction. Excellent anastomotic patency on 1-week and 1-month postoperative angiograms was also very encouraging. The limitations of this study include the absence of a control group undergoing hand-sewn coronary anastomoses and the limited follow-up in an animal model with normal coronary arteries. However, the principal objectives of this study were to assess the feasibility, early angiographic results, and tissue-healing characteristics of the presence of magnetic coupling. Additional studies of this new technology are warranted to further define the role of magnetic coupling in advancing minimally invasive cardiac surgery.

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Discussion

Dr Anno Diegeler *(Bad Neustadt, Germany)*. I thank the Association for the privilege to discuss the article of Dr Filsoufi and Dr Adams' group with this new concept of a new device for automated distal coronary anastomosis in an animal trial. The evolution in coronary bypass surgery toward less invasive approaches, such as beating heart, off-pump, minimally invasive direct coronary artery bypass, or even endoscopically performed procedures, is a fact. This, however, is accompanied by some technical problems, particularly in performing the anastomosis under difficult circumstances.

During my experience with the group in Leipzig, namely it was Volkmar Falk, in developing the total endoscopic anastomosis technique using the da Vinci robot system, it became obvious that we reached a level of difficulties that

we could not overcome just with more training or more experience. We definitely asked for a totally new concept performing such anastomoses with other techniques than a running suture. This new concept of a magnetic coupler is fascinating because it is based on a very simple idea. The technique of application looks very easy, which is important for the surgeon and for those difficult approaches. This is the basis for a reproducible and standardized application. I want to congratulate Dr Filsoufi and Dr Adams' group for this important animal study, and I would like to thank the group for sending me the article in advance.

This is actually the first step to prove the feasibility and the safety of such a new device before entering a clinical trial. Those clinical trials are already under way in Hannover with Professor Haverich's group, in Frankfurt with Professor Wimmer-Greinecker, and in Leipzig with Professor Mohr's group. To my knowledge, 55 patients have been enrolled so far in these trials, and the predischarged patency rate of the LITA graft is 100%, as it is after 6 months for the thus far re-evaluated 7 patients. The venous graft patency in this group is a bit lower, but it is equal to that of a control group with hand-sewn anastomoses.

Apart from this very important information, I would like to ask Dr Filsoufi a question regarding the presented animal trial. The first question: Do you have information about the blind sac of the side-to-side anastomoses? Do you find thrombotic deposits in your histology and examination, which might be a source of microemboli and early occlusion of a vessel?

Dr Filsoufi. As you saw on the film, the distal end of the graft was occluded with a clip when the anastomosis was performed. Therefore we never left a pocket at the distal end of the conduit, and the histology did not show the presence of any clotting or any other deposit at this level in any animal.

Dr Diegeler. Because of the ring design, you might have some restricted area in the inflow tract. Did you perform flow measurements, including flow capacity, in your animal trial, and could you compare that with hand-sutured anastomoses?

Dr Filsoufi. I agree with you that flow measurements during the intraoperative period can provide valuable information. However, in this animal study our primary endpoint was the 1-month graft patency rate. This was evaluated by means of angiography, which is the gold standard. Thus we did not perform any flow measurements in these animals in the intraoperative period.

Dr Diegeler. As far as angiographic assessment is concerned, it seems to me that it is difficult to get the right information about your target area, which is within the metal ring.

Dr Filsoufi. I understand your concern about the anastomotic lumen at the level of the magnets, which cannot be visualized during angiography. We were able to determine whether the graft was patent. However, qualitatively, the coronary artery filled rapidly, indicating TIMI-3 flow, which is consistent with a widely patent anastomosis.

We were, however, able to assess the anastomotic lumen histologically. At 6 months, there was no luminal obstruction or any severe neointimal hyperplasia of the anastomosis in any animal. Specifically, the maximum decrease in anastomotic orifice area during the 6-month follow-up period was 13%.

Dr Diegeler. A study was performed under a strict protocol of a perioperative antiplatelet drug regimen, which might cause some clinical problems of bleeding in the clinical setting. Have you tried another regimen that you have data about, and what are your data about blood loss?

Dr Filsoufi. With regard to the antiplatelet regimen, all animals received a 300-mg loading dose of clopidogrel, followed by 325 mg of aspirin daily for 1 to 3 days before the operation. In the postoperative period, they received 325 mg of aspirin and 75 mg of clopidogrel each day. Bleeding was not a significant problem. We did not insert any chest tubes in these animals, and the only bleeding-related complication was from a side branch of the thoracic artery. Other animal studies have been performed with lower doses of clopidogrel in the preoperative period, and the patency rate in these animals at 1 month was also 100%. At this point, it is unclear what the optimal antiplatelet regimen will be in human subjects.

Dr Diegeler. Just a short closing remark. This concept meets one of the good surgical principles. The presented magnetic coupling device is very simple and easy to use. If it is linked with the good data we heard about, it is my opinion that it would have a successful future.

Dreat H. Walpoth *(Bern, Switzerland).* How is the use of magnetic resonance imaging? Are you thinking of a possible inference by using these devices with these high magnetic fields?

Dr Filsoufi. The effect of the magnetic resonance imaging on the magnets was not evaluated in this study. However, additional animal studies have been performed in another laboratory. At 3 months the magnetic resonance imaging did not have any negative effects on the anastomosis. There was no evidence of thermal damage or disruption of the anastomosis.

Draul F. Grundeman *(Utrecht, The Netherlands).* I have a question related to the size of the recipient artery in your model. What do you foresee to be the limiting diameter of the recipient artery in the clinical situation? That is the first question.

The second question is, you mentioned that there was no necrosis observed between the magnets. I have a question related to the presence of inflammatory cells. Did you observe any inflammation in the vicinity of the device?

Dr Filsoufi. Thank you very much for your questions. The coronary arteries in this animal model were 2 mm or more in diameter. However, as you can obviously understand, in the clinical setting coronary arteries are commonly smaller than this, and the company is currently working on decreasing the dimensions of the magnets to accommodate smaller coronary arteries.

Regarding the inflammatory reaction, we have done several histologic studies at different section points through the magnets. We have found minimal inflammatory reactions with few foreign-body giant cells and without the presence of any lymphocytes or polynuclear cells.

Dr Richard J. Shemin *(Boston, Mass)*. This is a beautiful study. One question I have is do you always get perfect coupling of the magnets, do they ever overlap? Also, can you speculate whether it has to be deployed at a site where you do not have a perfectly normal artery? Say you have residual atherosclerosis, would that interfere with the coupling?

Dr Filsoufi. The self-adherent and self-aligning properties of the magnets always resulted in perfect coupling without any overlap.

Regarding the coupling process in diseased arteries, I cannot answer because I do not have any clinical experience with this device.

Dr F. W. Mohr *(Leipzig, Germany)*. Maybe I can answer that from the clinical side. I think this is a concern one has to have if there is an irregular artery. We will see some problems and leaks. I think this has to be addressed with maybe a different design to overcome that.

Dr Javier Fernandez *(Moorestown, NJ)*. I worry about local thrombosis in the area of the metallic rings. This reminds me of our experience with the implantation of prosthetic heart valves, in which we observed that clot formation usually originated at the interface between the tissue and the exposed metal. My question is, do you see clot formation at the anastomosis, and would you anticoagulate these patients postoperatively as a precaution?

Dr Filsoufi. These magnets are completely covered at 1 month by endothelial cells, and this encapsulation remains stable over time. We did not note any thrombus anywhere in these anastomoses, including the distal end of the graft near the clip. Therefore we have no reason to recommend formal anticoagulation and believe that an antiplatelet regiment, as I previously described, will suffice.

Dr Michael J. Mack *(Dallas, Tex)*. When magnets attract, it seems to me they come together well this way and hold. Does lateral traction do anything in terms of potentially dislodging the anastomosis?

Dr Filsoufi. The anastomosis can, of course, be disrupted if enough force is applied to the graft in any direction. However, the coupling force at this point seems strong enough to prevent inadvertent disruptions.