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First Clinical Experience With the VSTENT: A Device for Direct Left Ventricle-to-Coronary Artery Bypass

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Background. Stent-based left ventricle-to-coronary artery stent (VSTENT) is a newly developed, alternative surgical revascularization procedure (VCAB). We present here our initial experience using this technique.

Methods. Twelve patients (10 male and 2 female, mean age 61 ± 13 years) underwent a VCAB concomitant to coronary artery bypass surgery. Myocardial revascularization was performed on-pump with arrested heart in 4 patients, on-pump with beating heart in 6 patients, and off-pump in 2 patients. Average number of coronary anastomoses per patient was 2.4 ± 0.8. In all cases left internal thoracic artery-to-left anterior descending was used. In each patient only one VSTENT was implanted. Target artery for the VCAB was a diagonal branch in 5 patients, an intermediate branch in one patient and a marginal branch in 6 patients. Mean time for the VCAB was 23 ± 5 minutes (17 to 30 minutes).

Results. An immediate procedural success was observed in 11 of 12 cases. In one case VCAB was not successful and conventional aortocoronary bypass was performed. One patient died on the second postoperative day due to a systemic inflammatory response syndrome. Autopsy demonstrated a patent VSTENT. Angiography was performed in 10 patients 2 to16 days (9 ± 5 days) postoperatively showing a patent VSTENT in 8 patients.

Conclusions. The VCAB was feasible and potentially safe in the short-term postoperative follow-up, particularly with increasing experience after the first patients. Though the VSTENT is a promising tool for myocardial revascularization, long-term safety, patency, and performance of the device needs to be determined.

Traditional myocardial revascularization involves either surgical restoring of coronary blood flow, using a conduit, or percutaneous treatment of the native coronary artery stenosis using balloon angioplasty and stenting. Bypass conduits establish a new pathway for the blood to supply the ischemic myocardium. In case of saphenous vein graft, the source of arterial blood is the ascending aorta whereas in case of "in situ" internal thoracic artery the source of blood is the subclavian artery. In both situations graft-to-coronary blood flow occurs almost exclusively during diastole similar to native coronary circulation. In contrast, ventricular sourcing is an alternative approach to myocardial revascularization based on the concept of systolic filling of the epicardial coronary arteries serving as a reservoir to deliver arterial blood to the capillaries. Recently, a stent-based approach for surgical implantation of an expanded polytetrafluoroethylene (ePTFE) membrane covered stent (VSTENT) to provide a left ventricle-to-coronary artery bypass (VCAB) was developed (Percardia, Inc, Merrimack, NH). The VSTENT was able to maintain regional myocardial blood flow at rest and under conditions of increased oxygen consumption distal to a high grade coronary artery stenosis in preclinical experiments in pigs [1]. Based on these observations, the clinical phase I/II European multicenter ADVANTAGE (adjunctive treatment with the VCAB/VSTENT myocardial implant system in coronary artery bypass graft patients) study was initiated. We report here on the results of the pilot phase in 5 patients followed by another 7 patients included into the ADVANTAGE study at Großhadern University Hospital in Munich.

Material and Methods

Patients

Twelve patients (mean age, 61 ± 13 years) underwent a VCAB concomitant to coronary artery bypass grafting (CABG) for myocardial revascularization at our institution. The study was approved by the Munich Ethics

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Drs Vicol and Boekstegers disclose that they have a financial relationship with Percardia, Inc.

Table 1. Preoperative Data of the Study Population

Age (years)	61 ± 13	41–76
Female sex	2	16.7%
Diabetes mellitus	3	25%
Obesity	6	50%
Hypertension	12	100%
Smoking history	1	8.3%
Hyperlipidemia	10	83.3%
Previous myocardial infarction	4	33.3%
Previous PTCA	2	16.7%
Peripheral vascular disease	1	8.3%
NYHA class		
II	6	50%
III	6	50%
CAD 3 vessel disease	12	100%
LVEF	70% ± 10%	59%–90%

LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PTCA = percutaneous coronary angioplasty.

Committee and the Freiburg International Independent Ethics Committee and conducted according to the European standard EN 540 (Clinical Investigation of Medical Devices of Human Subjects) and the Declaration of Helsinki. All major adverse cardiac events that occurred during the study were reviewed by an independent clinical event committee. Written informed consent was obtained from each patient at least 24 hours before surgery. Patients had to be 21 years of age or older and required nonemergency, multivessel CABG with or without cardiopulmonary bypass (CPB). Inclusion criteria for the VCAB target vessel were a high grade proximal stenosis, a diameter of 2 mm or greater, a viable supplied region less than 15% of the left ventricle myocardial mass, and no evidence for atherosclerotic plaque formation at the site of the VSTENT implantation. In addition, myocardial wall thickness had to be less than 23 mm at the implantation site determined by echocardiography. Exclusion criteria were New York Heart Association class IV, coronary artery disease that is amenable to primary revascularization using a percutaneous catheter procedure, contraindications for cardiac surgery, Q-wave myocardial infarction within 4 weeks of planned surgery, ejection fraction less than 25%, life expectancy less than 12 months, contraindication for long-term antiplatelet therapy, pregnancy, and known sensitivity to stainless steel, ePTFE, or heparin. Patients' baseline characteristics are given in Table 1.

Device Description

The VSTENT surgical delivery system consists of five main components: VSTENT, delivery device, guidewire, access needle, and inflation device. The VSTENT is an ePTFE membrane covered, heparin-coated stent and available in five different lengths (14, 18, 21, 25, and 28 mm). The VSTENT is premounted on a noncompliant 3.0 mm coronary angioplasty balloon and deployed by inflating the balloon at about 16 atm for 30 seconds. The VSTENT has 2 tabs, which create an angle of 90 degrees to the axis of the stent. The function of the tabs is to anchor the device on the floor of the target coronary artery. The delivery system consists of the seating tool with the premounted VSTENT at the distal end. The VSTENT myocardial implant system runs on a 60 cm long floppy guidewire. The floppy end of the guidewire is inserted into the ventricle using the access needle. The shaft of the access needle is marked to determine the thickness of the myocardial wall at the site of VSTENT implantation. The 5 marks correspond to the 5 available VSTENT lengths. The inflation device is used to inflate and deflate the instent balloon during the VSTENT deployment procedure.

Implantation Procedure

Surgery was performed on-pump with arrested heart in 4 patients, on-pump with beating heart in 6 patients, and off-pump in 2 patients. At the planned VSTENT implantation site, epicardial echocardiography (HP Sonos 5500 system, with a 2.0 to 2.5 MHz transducer; Hewlett Packard, Andover, MA) on the beating heart was used to visualize intracardiac structures such as the papillary muscles, chordae tendinae, and mitral valve leaflets. In addition, myocardial wall thickness was determined which had to be less than 23 mm to fulfill the inclusion criteria. Thereafter, the positioning of the heart was performed using the Starfish device (Medtronic, Inc, Minneapolis, MN) and the target artery was exposed using the Octopus Tissue Stabilizer (Medtronic, Inc). A bloodless surgical field was ensured by a Goretex 5.0 suture (WL Gore & Assoc, Inc, Flagstaff, AZ), which gently occluded the artery proximal to the planned arteriotomy site. Occasionally, a second, distal suture was used to stop excessive retrograde bleeding. In most of the cases the use of the blower ClearView (Medtronic, Inc) was sufficient and the distal suture was not necessary. A 10 mm long incision was performed in the target coronary artery. After exposure of the posterior wall of the vessel the access needle was advanced through the myocardium towards the ventricular cavity until there was backflow. Keeping the access needle in this position, the black band on the needle, which was located directly above the surface of the posterior wall of the artery, was used to choose the corresponding length of the VSTENT. In case of an on-pump and arrested heart procedure, the left ventricle was pressurized before inserting the needle. After positioning of the access needle, the guidewire was inserted into the ventricle and the access needle was removed. The delivery device was loaded onto the guidewire and advanced into the myocardium until the seating tool reached the floor of the target artery and the tabs of the VSTENT were aligned parallel to the long axis of the vessel. Once alignment was confirmed, the balloon was inflated to 16 atm for a minimum of 30 seconds to deploy the VSTENT and the seating tool was removed. After deflation of the balloon, systolic backflow through the VSTENT confirmed successful implantation. Reinflation of the balloon within the VSTENT stopped backflow from the ventricle and allowed closure of the arteriotomy by a patch (Fig 1). In 11 cases a saphenous vein patch, and in

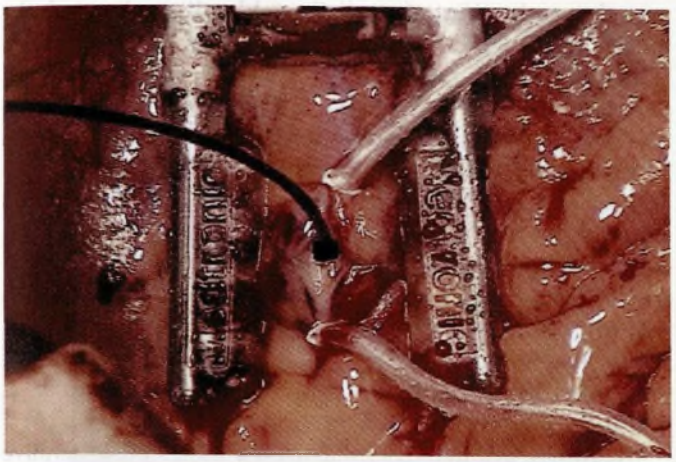

Fig 1. Ventricle-to-coronary artery stent (VSTENT) implanted into an intermedius branch. To stop coronary blood-flow, proximal and distal snaring of the target artery is used. The balloon is inflated within the VSTENT to stop backflow from the left ventricle.

one case a radial artery patch, were implanted by a 7.0 polypropylene running suture. After removal of the deflated balloon and the guidewire, the suture of the patch was finished and tied down.

After the VCAB procedure, CABG was completed with all patients receiving at least one up to four conventional grafts. An important aspect of the VCAB is the concomitant antiplatelet therapy. Our initial protocol consisted of preloading with clopidogrel (Plavix, Sanofi Berlin, Germany) 3 to 24 hours before surgery. Due to severe postoperative bleeding in the first patient, however, preloading with clopidogrel was abandoned. Instead a GPIIb/IIIa inhibitor (tirofiban) was given intravenously (Aggrastat MSD, Haar, Germany) one hour before VSTENT implantation as a bolus of 15 μg/kg body weight during 3 minutes followed by a continuous infusion of 10 μg/kg body weight. In case of an on-pump procedure the infusion was terminated 2 hours after VSTENT implantation and heparin was given so that the prothrombin time was prolonged more than 60 seconds. Clopidogrel loading was performed at the earliest time point based on a clinical decision using 300 mg followed by a daily application of 75 mg. The heparin infusion was continued 8 hours after clopidogrel loading. In case of an off-pump procedure tirofiban was given for 48 hours and replaced by clopidogrel starting with a 300 mg loading dose on the second postoperative day. Clopidogrel was continued at a daily dosage of 75 mg. After the first 6 cases the antiplatelet therapy was changed again. In the last six patients antiplatelet therapy was not started before 6 to 8 hours after the end of the operation and limited to clopidogrel 150 mg followed by 75 mg and 100 mg aspirin daily. In all discharged patients with a patent VSTENT the antiplatelet therapy consisting of clopidogrel 75 mg daily and aspirin 100 mg daily was continued for 6 months.

Perioperative Assessments

Blood samples were obtained preoperatively, on arrival at the intensive care unit (ICU), every 6 hours postoperatively during the first 72 hours, at discharge, and at occurrence of adverse events. A 12 lead electrocardiogram (ECG) was performed on arrival at the ICU, 6 hours postoperatively, on the first and second postoperative days as well as at discharge and in the presence of arrhythmias. Diagnosis of myocardial infarction was based on ECG changes as new persistent Q wave and ST-segment elevation greater than 1 mm in two or more limb leads and/or greater than 2 mm in two or more precordial leads as well as a serum creatine kinase MB (CK-MB) activity greater than 40 IU/L 6 to 48 hours after operation. Normal range of CK-MB catalytic activity measured by standard methods was considered to be 0 to 10 IU/L. Echocardiography was performed transesophageally on arrival at the ICU and at occurrence of adverse events. A transthoracic echocardiography was carried out before discharge. Chest tube output was registered every hour postoperatively. Selective angiography of the native coronary arteries and the bypass conduits was performed before discharge from the hospital in all patients.

Left ventricular ejection fraction and regional myocardial function was determined preoperatively and before discharge by center-line analysis of the left ventricular angiogram [2]. Data are presented as mean ± standard deviation.

Results

Target coronary artery for the VSTENT was a diagonal branch in 5 patients, an intermediate branch in 1 patient, and a marginal branch in 6 patients. The diameter of the target vessel was 2.0 mm in 8 cases and 2.5 mm in 4 cases. The grade of stenosis of the target artery was higher than 75% and lower or equal to 95% by visual estimate in the preoperative angiogram in all patients. The length of the VSTENT used was 17 mm in one patient, 21 mm in 6, 24 mm in 1, and 28 mm in 4 patients. Mean time for the VCAB was 23 ± 5 minutes (17 to 30 minutes). Successful VSTENT implantation was achieved in 11 of 12 patients without complications. In one patient, the delivery of the VSTENT by balloon inflation was accompanied by the rupture of one margin of the vessel at the site of the VSTENT implantation. As a consequence, the target artery and the arterial end of the VSTENT had to be closed by a suture and an aortocoronary venous bypass was performed to revascularize the target artery distal to the failed VCAB. The further intraoperative course of this patient was uneventful. The CK and CK-MB determined at 6 hours postoperatively were 165 and 12.5 IU/L. They increased to a maximum of 433 IU/L and 33 IU/I without ischemic changes in the ECG on the first postoperative day. The patient was extubated 16 hours postoperatively. Due to pneumonia he stayed on the ICU for 6 days. The pneumonia resolved without the need of mechanical ventilation and the patient was discharged from the hospital 2 weeks after operation.

In addition to the VCAB, all patients received a left internal thoracic artery (LITA)-to-left anterior descending (LAD). In 2 patients a total arterial myocardial revascularization was performed and in 9 patients aorto-to-

coronary venous conduits were implanted. Mean number of anastomoses per patient was 2.4 ± 0.8 [1–4]. In case of an on-pump procedure (10 patients) the CPB time was 129 ± 24 minutes (100 to 164 minutes). In case of an on-pump arrested heart procedure (4 patients) the aortic cross-clamp time was 78 ± 38 minutes (35 to 109 minutes).

One patient died on the second postoperative day. In this patient the VSTENT was implanted into the first diagonal branch without complications and the VSTENT was shown to be patent at autopsy. The CK and CK-MB recorded 6 hours postoperatively were 186 and 30 IU/L, respectively, and increased to a maximum of 233 and 36 IU/L, respectively, on the first postoperative day. In this patient cardiocirculatory conditions worsened on the second postoperative day due to a systemic inflammatory response syndrome and the patient's death was probably not related to the VCAB.

Early postoperative angiograms 2 to 16 days (mean 9 ± 5 days) postoperatively were performed in 10 of the 12 patients to determine VSTENT patency (Fig 2). In 9 of 10 patients the VSTENT was widely patent showing systolic washout of the contrast agent into the distal target artery. In one of the 10 patients, the target vessel determined by the preoperative angiogram (first marginal branch) was missed intraoperatively because of an intramural course of the vessel. The second marginal branch was close to the first marginal branch but functionally occluded and collateralized in the preoperative angiogram. Intraoperatively, this vessel 2.0 mm in diameter was mistaken as the target vessel and the VSTENT was implanted without complications. In an early postoperative angiogram (second postoperative day) the malposition of the VSTENT was recognized and the high grade stenosis of the first marginal branch treated by percutaneous coronary angioplasty. The VSTENT in the functionally occluded second marginal branch was patent at this time but it closed up within 14 days probably due to poor distal runoff, as demonstrated by a second angiogram before discharge. All bypass conduits which the patients received in addition to the VCAB were patent in the postoperative angiograms and none of the 11 patients complained of angina at the time of discharge from the hospital.

Left ventricular ejection fraction did not change significantly postoperatively; 77 ± 3.3% before surgery versus 83 ± 4.1% after surgery. Regional myocardial function before and after operation is presented in Figure 3. None of the regional segments deteriorated postoperatively and we did not observe hypokinesia or akinesia in any of segments that were assigned to the VSTENT distal target vessel perfusion area.

A severe postoperative bleeding was observed in the first patient treated by preoperative clopidogrel loading. Though bleeding improved in the 5 consecutive patients with intraoperative administration of a tirofiban, the mean chest tube drainage on the operative day was still 1,276 ± 1,058 mL (440 to 3,040 mL) with a decrease to 557 ± 326 mL (100 to 1,000 mL) on the second postoperative day. The clinical consequence was a rethoracotomy without determination of a distinct bleeding site and the necessity of blood substitution in 5 of the first 6 patients. These consisted mainly of 3.8 ± 3.7 (0–10) red blood cell units, 3.3 ± 3.4 (0–10) fresh frozen plasma, and 0.7 ± 0.8 (0–2) platelet concentrate units. To reduce postoperative bleeding the antiplatelet therapy protocol was changed in the last 6 patients by starting antiplatelet therapy with clopidogrel no earlier than 6 to 8 hours postoperatively. Mean chest tube drainage decreased to 725 ± 609 mL (225 to 1,810 mL) on the operative day and 198 ± 162 mL (0 to 410 mL) on the second postoperative day. Blood substitution necessity decreased to 2.8 ± 3.8 (0–10) red blood cell units, 2.2 ± 5.3 (0–13) fresh frozen plasma, and 0.7 ± 1.6 (0–4) platelet concentrate units.

Mean CK-MB activity measured 6 hours postoperative was 19.7 ± 8.4 IU/L (9.2 to 31.7 IU/L), 24.6 ± 12.1 IU/L (2.7 to 34.2 IU/L) on the first postoperative day, and 24 ± 19.5 IU/L (8.9 to 75.1 IU/L) on the second postoperative day. Evidence for an ischemic myocardial injury indicated by a rise of CK-MB activity greater than 40 IU/L was observed in 3 patients. However, there was no correlation with ECG findings according to the definition of myocardial infarction in these patients. Mean postoperative ventilation time was 16.4 ± 20.7 hours (6 to 78 hours).

A transitory renal insufficiency (creatinine > 1.2 mg/dL) was treated by diuretics in 5 patients. In 4 patients transitory atrial fibrillation was treated by β-blockers. We did not observe any neurologic complications. Mean ICU stay was 3.4 ± 2.9 days (1 to 11 days).

Comment

Ventricular sourcing is an alternative concept of myocardial revascularization based on a direct connection between the left ventricle and the coronary artery through the heart wall. This approach was first proposed by Goldman in the 1950s [3] and studied in more detail by Munro and Allen [4] using a polymeric tube to provide a ventricle-to-coronary artery connection. Tweeden and colleagues [5] and Emery and colleagues [6] recently tested, in an animal experiment, a specifically designed titanium device for ventricle-to-coronary artery bypass. At the same time, physiologic studies demonstrated substantial preservation of regional myocardial blood flow by a ventricle-to-coronary artery bypass [7]. More recently, a surgically implanted but stent-based approach to ventricle-to-coronary artery bypass was introduced and shown to provide sufficient regional myocardial blood flow and function under conditions of increased oxygen demand, particularly in the presence of a high grade stenosis proximal to the VSTENT [1].

A high grade stenosis in the range of 70% to 95% was associated with high net flows distal to the VSTENT and almost complete elimination of diastolic backflow because of an increase in mean diastolic intracoronary pressure at the site of VSTENT implantation due to the residual diastolic flow through the high grade stenosis. Moreover, a diastolic steal affecting distal functional reserve was ruled out. Based on these experimental findings [1], a high grade stenosis of the VSTENT target

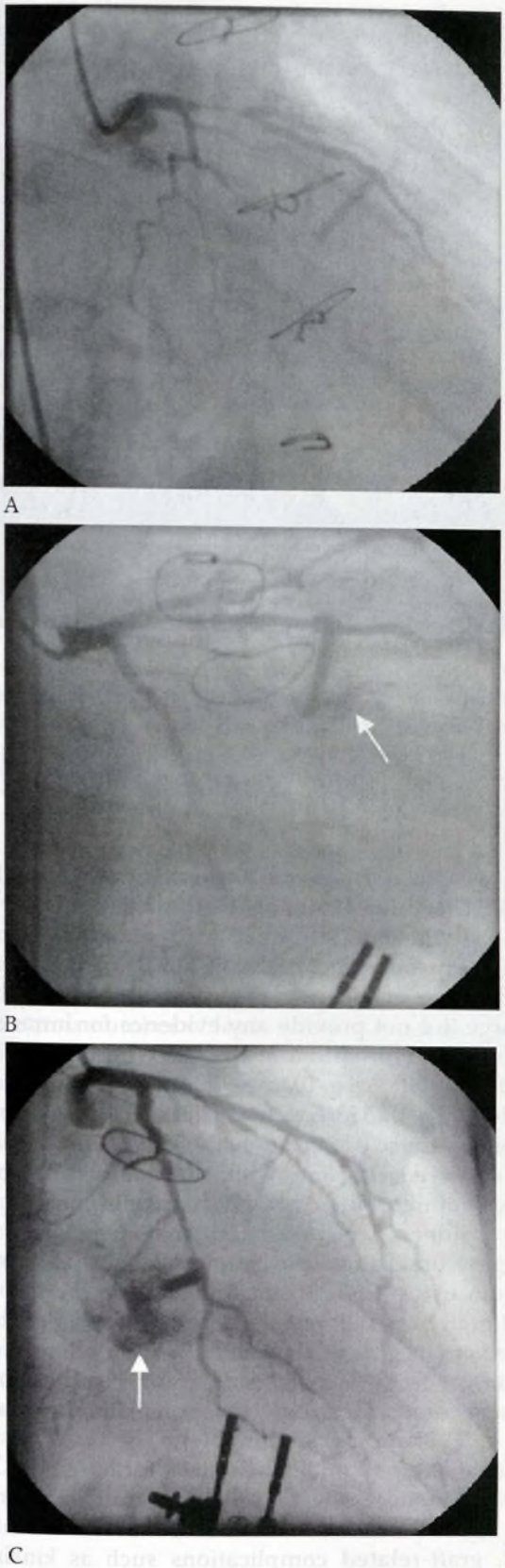

Fig 2. (A) Coronary angiography 16 days after VSTENT implantation into the first diagonal branch. (B) Coronary angiography 8 days after VSTENT implantation into the intermedius branch. Note the diastolic backflow into the left ventricle through the VSTENT (arrow). (C) Coronary angiography 12 days after VSTENT implantation into the first marginal branch. The arrow shows the diastolic backflow into the left ventricle through the VSTENT.

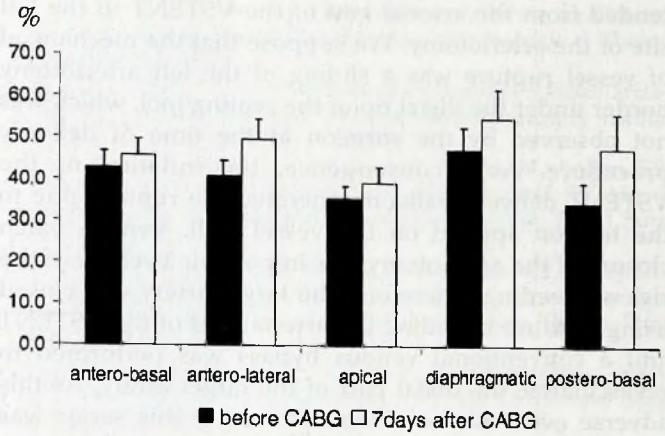

Fig 3. Regional myocardial function in 8 study patients before and after surgery. Mean shortening between the end-systolic and end-diastolic contour of 5 segments of the left ventricle (antero-basal, antero-lateral, apical, diaphragmatic, *and* postero-basal) *is expressed in percent. A trend in increase of regional myocardial function was observed in all segments after surgery.* (CABG = *coronary artery bypass grafting.*)

vessel was requested as an inclusion criteria of the clinical study, in order to have a high probability of sufficient regional myocardial blood flow in the VSTENT dependent area at rest and under conditions of increased oxygen demand such as exercise with increasing heart rate. Though the patients with patent VSTENT in the early postoperative follow-up (7 days) had no clinical evidence for ischemia and no wall motion abnormalities under resting conditions, stress testing is certainly mandatory to prove these assumptions during planned follow-up studies.

In this study, the clinical feasibility and potential safety of the VSTENT was demonstrated in a limited number of patients. However, several complications were also observed, of which most were probably related to the inherent learning curve using this new approach of VSTENT revascularization.

The mean time of 23 minutes needed for VSTENT implantation was acceptable in this first series of patients, but was longer than the time needed for a conventional distal coronary anastomosis. However, implantation times decreased with increasing experience to expose the target vessel, to place the device correctly aligned to the floor of the coronary artery, and to suture the patch. Of crucial importance, none of the patches to close the arteriotomy after VSTENT implantation showed intraoperative bleeding or required revision. Moreover, narrowing at the proximal or distal connection to the coronary artery was not observed in the postoperative angiograms.

In one patient, we experienced the inability to complete the VCAB procedure because of the rupture of one margin of the vessel at the site of the VSTENT implantation. At the time of delivery of the VSTENT the opposite implantation site to the surgeon could not be visualized. After removal of the seating tool the posterior wall of the coronary artery was ruptured. The rupture ex-

tended from the arterial end of the VSTENT to the left site of the arteriotomy. We suppose that the mechanism of vessel rupture was a sliding of the left arteriotomy border under the distal tip of the seating tool, which was not observed by the surgeon at the time of delivery procedure. As a consequence, the inflation of the VSTENT delivery balloon generated the rupture due to the tension applied on the vessel wall. Venous patch closure of the arteriotomy was impossible because of the risk of bleeding. Therefore, the target artery was closed using a suture including the arterial end of the VSTENT and a conventional venous bypass was performed to revascularize the distal part of the target artery. As this adverse event in the second patient of this series was probably related to the difficult exposure of the target coronary artery and the bad visibility of the vessel wall, the VSTENT was delivered in the following patients only if the margins of the vessel were clearly visible before balloon inflation. Implantation times, as well as the safety of VSTENT delivery, may improve further by a currently developed second generation of the device without the need of the patch closure.

Another important aspect of the VSTENT implantation is the selection of the basic surgical procedure. Shall we operate on or off-pump? In this series of 12 patients, most of the procedures were done on-pump for safety reasons. However, we experienced the impact of performing the VCAB procedure on the beating heart in contrast to the arrested heart. An important immediate feedback of a successful VCAB procedure was the systolic flow from the ventricle through the VSTENT, which was easier to assess on the beating heart. Furthermore, the determination of the systolic myocardial wall thickness, which is more relevant for the length of the VSTENT than the diastolic wall thickness, requires the beating heart assessment by epicardial echocardiography. Similarly, visualization of mitral valve structures on the beating heart is more relevant for determination of the site of VSTENT implantation. From our preliminary experience in 12 patients we infer that using the current VSTENT diagonal and intermediate branches may be treated off-pump whereas we would prefer an on-pump beating heart procedure for marginal branches.

Antiplatelettherapy was associated with serious bleeding in our first patients. The rationale to provide an aggressive antiplatelet therapy was to prevent subacute VSTENT thrombosis. However, preloading with clopidogrel in the first patient, as well as short-term intraoperative administration of tirofiban in the subsequent 5 patients, was associated with unacceptable high postoperative bleeding. Therefore, the beginning of antiplatelet therapy was postponed to 6 to 8 hours after operation in the last 6 patients at the risk of a higher incidence of subacute VSTENT thrombosis. The postoperative angiograms with patent VSTENTs in these patients argue against a substantial increase in the incidence of device thrombosis despite the less aggressive antiplatelet regimen. The significant reduction in chest tube drainage observed in the last 6 patients supports the safety of this approach to antiplatelet therapy after VCAB. Importantly, we did not observe any ventricular arrhythmias after VSTENT implantation in the early postoperative follow-up, which might be a concern due to the compression of the myocardium at the VSTENT implantation site. Postoperative echocardiography in all patients before discharge did not provide any evidence for intraventricular thrombus formation at the site where the VSTENT extended about 6 to 10 mm into the left ventricle as intended (Fig 4). Moreover, no mitral valve dysfunction or papillary muscle affected by the VSTENT implantation were observed. In line with these echocardiography findings, no neurologic complications nor embolic event in the postoperative course occurred.

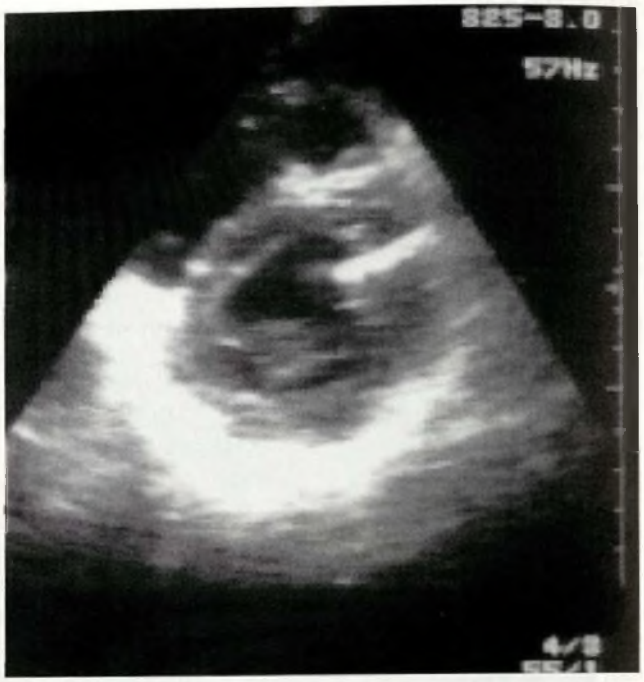

Fig 4. Transthoracic echocardiography 6 days after successful ventricle-to-coronary artery bypass. Shows procedure to the first diagonal branch and. parasternal short axis view of the left ventricle. The VSTENT (upper right area) is protruding into the left ventricular cavity. Note that no papillary muscle is seen in the vicinity of the VSTENT.

Potential indications for surgical myocardial revascularization using VSTENT technology are the following: lack of graft material, poor quality of graft material, high risk for venous graft occlusion, and arteriosclerosis of the ascending aorta (to avoid side clamping for proximal graft anastomoses) as well as porcelain aorta (which make side clamping impossible). The VCAB is well applicable and potentially beneficial for off-pump CABG avoiding the necessity of proximal graft anastomoses. Using the VSTENT as an alternative to conventional CABG, graft-related complications such as kinking or spasm may be avoided. The number of grafts could be minimized and harvesting complications such as wound healing and operation trauma could be reduced.

Our preliminary observations in 12 patients suggest that VCAB is feasible and potentially safe in the short-term postoperative follow-up, particularly with increasing experience. Though the VSTENT is a promising tool

for myocardial revascularization, long-term safety, patency, and performance of the device need to be determined.

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