Hemodynamic and Vascular Effects of Ventricular Sourcing by Stent-Based Ventricle to Coronary Artery Bypass in Patients With Multivessel Disease Undergoing Coronary Artery Bypass Surgery

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Background—The hemodynamic and vascular effects of ventricular sourcing by a stent-based (VSTENT, Percardia) left ventricle-to-coronary artery bypass were studied in a patient subgroup of the European multicenter ADVANTAGE study (ADjunctive treatment with the VCAB/VSTENT myocardial implant system in coronary Artery bypass Graft patiEnts).

Methods and Results—Twelve patients who underwent VSTENT implantation in addition to coronary artery bypass surgery were studied up to 12 months after the procedure. The VSTENT was implanted distal to a hemodynamically relevant coronary artery stenosis. Coronary flow velocity was assessed at rest and during dobutamine stress. Intraoperative VSTENT implantation was successful in 11 of 12 patients. Early postoperative angiograms showed patent VSTENT in 8 of 11 patients, with predominantly systolic flow distal to the VSTENT. Coronary flow velocity reserve induced by dobutamine stress was 1.7±0.1 (P<0.006). VSTENT patency at 2- to 6-month follow-up was present in 5 of 11 patients, with concomitant VSTENT stenosis in 4 of those 5. In all patients, coronary flow velocity increased 3- to 4-fold proximal to the VSTENT, which was associated with a moderate degree of arterial remodeling. Except for target vessel reintervention (n=5), no other major adverse events were observed in 11 of 12 patients. One patient died on the second postoperative day, though the cause was probably not related to the VSTENT implantation.

Conclusions—VSTENT implantation seems to be safe in the mid-term follow-up and leads to a predominantly systolic coronary flow pattern in the vessel supplied by the VSTENT, with a flow reserve similar or close to that seen with conventional bypass. VSTENT patency rate, however, was unacceptably low at 3- to 6-month follow-up and needs to be improved. (Circulation. 2005;112[suppl I]:I-304–I-310.)

Key Words: ventricles ▪ stents ▪ bypass ▪ coronary disease

In patients with coronary artery disease, current myocardial revascularization strategies consist of restoring coronary artery blood flow by percutaneous angioplasty and stenting or coronary artery bypass surgery. 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.1-4 Using a stent-based approach for ventricle-to-coronary-artery bypass,1 a surgical implantation procedure (VSTENT Myocardial Implant, Percardia) was developed, which allows placement of the VSTENT distal to a high-grade coronary artery stenosis without obstructing the proximal part of the vessel. Under these conditions, VSTENT was able to provide capillary blood flow sufficient to supply ischemic myocardium in preclinical experiments.5 VSTENT changes coronary artery flow pattern toward predominantly systolic instead of diastolic forward flow and is accompanied by diastolic sink into the left ventricle. Interestingly, this type of coronary artery flow pattern was associated with significant shear stress induction and subsequent arterial remodeling in nondiseased coronary arteries.1,5

In this study, we sought to characterize the acute and mid-term hemodynamic and vascular effects of myocardial revascularization by surgical VSTENT implantation in a patient subgroup of the European multicenter ADVANTAGE study (ADjunctive treatment with the VCAB/VSTENT myocardial implant system in coronary Artery bypass Graft patiEnts) studied at the Grosshadern/Munich Medical Center.

Methods

Between February and September of 2003, 12 patients (mean age 61±13 years) underwent implantation of a VSTENT procedure in
adjunct to multivessel coronary artery bypass grafting (CABG) for myocardial revascularization at the Ludwig-Maximilians-University Grosshadern/Munich Medical Center. These patients were part of the European multicenter ADVANTAGE study. The primary end points of the ADVANTAGE study were device-related major adverse cardiac events at up to 6 months, acute device performance, and VSTENT implant patency at 6 months. Secondary end points determined only in this subgroup of 12 patients were the assessment of coronary artery flow velocity before and after VSTENT implantation, as well as regional myocardial function at rest and during dobutamine stress.

The study was approved by the local institutional ethics 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. Written informed consent was obtained from each patient at least 24 hours before surgery. Inclusion and exclusion criteria are given in Table 1.

In this substudy of the ADVANTAGE trial, intracoronary Doppler flow wire measurements were taken at rest and during intracoronary adenosine administration for assessment of flow reserve (adenosine 160 μg/min intracoronary; Flow Map, Cardiometrics) distal to the coronary artery stenosis of the target vessel for VSTENT implantation. A flow reserve <2 was required for inclusion into the substudy. Patients’ characteristics are given in Table 2.

### VSTENT Implantation Procedure
The surgical VSTENT implantation procedure (Figure 1) has been described in detail elsewhere. After the VSTENT procedure, CABG was completed in all patients receiving at least 1 and up to 3 conventional bypasses (Table 2). Postoperatively, in all patients discharged with a patent VSTENT, antiplatelet therapy consisted of clopidogrel 75 mg daily and aspirin 100 mg daily for at least 6 months.

### Angiographic and Hemodynamic Assessments
VSTENT patency was confirmed by coronary angiogram before discharge from the hospital in all patients. Follow-up coronary angiograms were obtained at 3 to 6 months in all patients with patent VSTENT before discharge (n=8). Assessment of 12-month coronary angiograms was performed if patency was assured at 3 to 6 months. All coronary angiograms were analyzed by quantitative coronary angiography (QCA). In case of intravascular ultrasound imaging, a motorized pullback at 0.5 mm/s with an electronic 20 MHz ekg view transducer (Volcano Therapeutics) was used.

Left ventricular angiograms at rest and during dobutamine stress (5 to 40 μg·min⁻¹·kg⁻¹ body weight) were obtained before discharge and at 3 to 6 months if the patients were suitable for dobutamine stress testing. Left ventricular ejection fraction was calculated, and regional myocardial function was determined by centerline analysis.

Postoperatively, flow wire measurements were repeated before discharge and at 3 to 6 months and 12 months if appropriate. Intracoronary flow was determined distal and proximal to the VSTENT implantation site. During dobutamine stress (5 to 40 μg·min⁻¹·kg⁻¹ body weight) intracoronary flow was measured distal to the VSTENT implantation site.

Transthoracic echocardiography was performed in all patients preoperatively and postoperatively as well as 3, 6, and 12 months after surgery. New York Heart Association classification was assessed by a standardized questionnaire. The study was monitored externally and all adverse events were reported. Major adverse events were reviewed and classified by an independent clinical event committee.

### Statistics
All data are presented as the mean±SEM and were analyzed using SPSS statistical software. Data obtained before and after VSTENT implantation were compared using Mann-Whitney U-test. A probability value <0.05 was considered to be statistically significant.

### Results

#### Preoperative Results
In the 12 patients studied, all of whom were included into the ADVANTAGE study at our hospital, the mean degree of stenosis by visual estimate was 74%±4% (QCA analysis: 61%±4%) in the target vessel for VSTENT implantation, and adenosine induced flow reserve was <2 in all patients (mean 1.5±0.3) preoperatively. Baseline QCA data are given in Table 3.

#### Intraoperative and Early Postoperative Results

### Clinical Events
A detailed description of the intraoperative and early postoperative results has been given elsewhere previously. Briefly, a successful VSTENT implantation into the coronary artery was achieved in 11 of 12 patients. One patient died on the second postoperative day, as the circulatory conditions worsened because of a systemic inflammatory response.

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tbody>
<tr>
<td>Age ≥21 years</td>
<td>New York Heart Association functional class IV</td>
</tr>
<tr>
<td>Multivessel coronary artery bypass graft to be performed</td>
<td>Coronary artery disease amenable to primary revascularization of the target vessel using percutaneous intervention methods</td>
</tr>
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<td>High-grade stenosis on the left side of the heart that supplies a 15% or smaller localized region of the myocardium</td>
<td>Contraindications for cardiac surgery</td>
</tr>
<tr>
<td>VSTENT implantation target vessel diameter estimated to be 2.0 mm or greater</td>
<td>Q-wave myocardial infarction within 4 weeks of planned bypass surgery</td>
</tr>
<tr>
<td>Patient understands the nature of the procedure and provides voluntary informed consent before procedure</td>
<td>Ejection fraction less than 25%</td>
</tr>
<tr>
<td>Patient able and willing to participate in follow-up visits through 12 months after the procedure</td>
<td>Life expectancy less than 12 months</td>
</tr>
<tr>
<td>Planned or previous implantation of active leads in the left ventricle</td>
<td>Unstable arrhythmia</td>
</tr>
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<td>Contraindication for long-term antiplatelet therapy with aspirin and clopidogrel</td>
<td>Hypertrophic cardiomyopathy</td>
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<tr>
<td>Immune suppression because of long-term steroid use, concurrent radiation or chemotherapy treatment, or use immunosuppressive drugs</td>
<td>Known sensitivity to stainless steel, expanded polytetrafluoroethylene, or heparin</td>
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<tr>
<td>Known sensitivity to stainless steel, expanded polytetrafluoroethylene, or heparin</td>
<td>Pregnancy</td>
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<tr>
<td>Participation in another investigational protocol</td>
<td>Participation in another investigational protocol</td>
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syndrome, and the patient’s death was probably not related to the implantation procedure. In this patient, the VSTENT was implanted into the first diagonal branch without complications and the VSTENT was shown to be patent at autopsy. There were also no signs of myocardial infarction.

In 10 patients, an angiogram was performed 9/11006,5 days postoperatively, showing a patent nonobstructed VSTENT in 8 patients. All 8 patients with patent VSTENT in the early postoperative angiogram had an uneventful hospital stay and were discharged after 15/1006 days.

**Early Postoperative Flow Measurements and Regional Wall Motion**

In the 8 patients with nonobstructed VSTENT, coronary flow pattern distal to the VSTENT implantation site changed to predominantly systolic flow in contrast to the diastolic flow determined preoperatively (Figure 2 and Figure 3). Net distal flow velocity tended to be higher than values determined preoperatively (Figure 2). Under conditions of increased oxygen demand induced by dobutamine, net distal flow velocity increased 1.7/1006,0-fold from 19.8/1006,1.4 cm/s to 33.8/1006,3.8 cm/s (n=6). During dobutamine infusion, regional wall motion increased postoperatively (anterobasal 38.5/1006,3.9% to 50/1006,1.4%, P=0.03; anterolateral 45/1006,5% to 56.3/1006,2.7%), as did left ventricular ejection fraction (68.8/1006,3.7% to 75.4/1006,2.8%). No deterioration of regional wall motion was detected even at the highest heart rate (mean 130/1006,6.3 bpm). None of the patients experienced angina during dobutamine stress testing, nor did we observe any changes of the continuously monitored 12-channel ECG, which had an indication of ischemia.

Interestingly, a diastolic flow pattern was observed distal to the high-grade stenosis of the native vessel but proximal to the VSTENT. Diastolic flow velocity was increased markedly in all patients (Figure 4C), leading to a substantial increase in net flow velocity (90/1006,10.5 cm/s, n=8) compared with distal values (25.1/1006,2.8 cm/s, P<0.001). No significant change in the vessel diameter proximal to the VSTENT was observed compared with baseline values (Table 3).

**Mid-Term Angiographic Results**

At the 3- to 6-month follow-up, the overall patency rate after successful VSTENT implantation was only 45% (5 of 11
patients. In the 8 patients with a patent VSTENT in the early postoperative angiogram, 5 still had a patent VSTENT at 3 to 6 months. Moreover, most of these patent VSTENTs (4 of 5) had a significant stenosis (Figure 4A). In 3 of 4 patients, the morphology of VSTENT stenosis was studied by intravascular ultrasound (Figure 4B) before percutaneous implantation of a drug-eluting stent (Cypher, Cordis) of appropriate length to cover the VSTENT stenosis (Figure 4C).

**Mid-Term Flow Measurements**

We were able to assess flow wire measurements distal to a nonobstructed VSTENT in 5 patients. One patient had nonobstructed VSTENT to the diagonal branch at 6- and 12-month follow-up (Figure 5). In another patient, VSTENT to a marginal branch was not obstructed severely (<50%) at 3 months but closed up completely at 6 months. The 3 patients who were treated with sirolimus-eluting stents implanted into the high grade VSTENT stenosis were studied before and immediately after stent placement. In 2 of them, the VSTENT showed a moderate degree of stenosis after another 6 months of follow-up (Figure 4C), whereas 1 was completely occluded at that time.

All flow wire measurements of nonobstructed VSTENTs (n=7) at late follow-up time points revealed a predominantly systolic flow pattern at rest (diastolic/systolic velocity ratio=0.5±0.2). In addition, dobutamine stress resulted in an increase of flow velocity by 1.8±0.2.

At later follow-up time points (>3 months), coronary flow wire measurements in the native vessel proximal to a nonobstructed VSTENT (n=7) showed diastolic flow pattern with a net flow velocity of 70±12 cm/s compared with flow velocity in the distal vessel of 21±4 cm/s. Regarding all patients, there was no significant change in proximal or distal vessel diameter whether the VSTENT was closed or presenting with a stenosis.

In the only patient with nonobstructed VSTENT at 6- and 12-month follow-up (Figure 5), proximal vessel diameter tended to increase, whereas flow velocity tended to decrease (Table 4).

**Major Adverse Events and Clinical Outcome at Mid-Term Follow-Up**

None of the 11 patients with implanted VSTENT experienced myocardial infarction, ventricular arrhythmias, intraventricular thrombus formation, cerebral stroke, or other embolic events in 7 to 14 months of follow-up. Furthermore, echo-cardiographic studies provided no evidence for VSTENT displacement or the new occurrence of mitral insufficiency. Comparison of early and late angiograms did not show the formation of aneurysms at the site of the patch (Figure 5) that had been used to close the vessel at the site of the VSTENT implantation.

Of the 11 patients, 2 symptomatic patients were treated (one before discharge, one at 15 months after surgery) by stent implantation into the native stenosis of the VSTENT target vessel. Three asymptomatic patients were treated by percutaneous implantation of a sirolimus-eluting stent into the VSTENT stenosis at 3- to 6-month follow-up.

With regard to New York Heart Association classification, all patients improved from 2.3±0.4 before cardiac surgery to 1.3±0.3 (P<0.001) at 3 to 6 months after cardiac surgery, regardless of whether the VSTENT was patent or closed.

**Discussion**

This is the first study in patients that describes the acute and mid-term hemodynamic and vascular effects of a stent-based ventricle-to-coronary artery bypass (VSTENT). For feasibility reasons, the vessel diameter was chosen not to be less than 2 mm at the target site of VSTENT implantation. For safety reasons, however, the VSTENT was implanted in only one vessel which by visual estimate supplied not more than ≈15% of the left ventricle in these patients undergoing multivessel coronary artery bypass surgery at the same time. In addition, the VSTENT implantation was performed distal to a high-grade coronary artery stenosis and not distal to a total occlusion for 2 reasons. First, percutaneous access was

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**TABLE 3. QCA Analysis Before and After VSTENT Implantation**

<table>
<thead>
<tr>
<th></th>
<th>Stenosis of Native Vessel, %</th>
<th>Minimal Luminal Diameter, mm</th>
<th>Lesion Reference Diameter, mm</th>
<th>Vessel Diameter Proximal to VSTENT Site, mm</th>
<th>Vessel Diameter Distal to VSTENT Site, mm</th>
<th>VSTENT Stenosis, %</th>
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<tbody>
<tr>
<td>Before operation (n=12)</td>
<td>61±15</td>
<td>0.9±0.4</td>
<td>2.4±0.3</td>
<td>2.2±0.3</td>
<td>2.0±0.3</td>
<td>...</td>
</tr>
<tr>
<td>Pre-discharge follow-up (n=8)</td>
<td>60±13</td>
<td>1.0±0.5</td>
<td>2.3±0.5</td>
<td>2.3±0.4</td>
<td>1.8±0.4</td>
<td>9±7</td>
</tr>
<tr>
<td>2- to 4-Month follow-up (n=5)</td>
<td>75±6</td>
<td>0.6±0.1</td>
<td>2.2±0.4</td>
<td>1.9±0.3</td>
<td>1.5±0.4</td>
<td>70±18</td>
</tr>
<tr>
<td>6-Month follow-up (n=6)</td>
<td>66±17</td>
<td>0.9±0.5</td>
<td>2.2±0.5</td>
<td>2.0±0.5</td>
<td>1.4±0.7</td>
<td>67±35</td>
</tr>
<tr>
<td>After 6-month follow-up (n=4)</td>
<td>63±7</td>
<td>0.7±0.2</td>
<td>2.4±0.5</td>
<td>2.2±0.2</td>
<td>1.6±0.1</td>
<td>70±30</td>
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</table>
Can VSTENT Replace a Conventional Bypass Hemodynamically?

The flow wire measurements enabled us to characterize coronary flow pattern and functional flow reserve in the distal part of the vessel supplied by the VSTENT before and after implantation. In addition, the flow wire approach is relatively independent from the effects of concomitant bypass grafting of other vessels in these patients in contrast to perfusion techniques such as single photon emission computed tomography or positron emission tomography. Similar to preclinical studies, we observed a change in coronary flow pattern from diastolic to predominantly systolic flow in the vessel supplied by the VSTENT in all patients. A predominantly systolic flow pattern after VSTENT implantation distal to a coronary stenosis argues for the hemodynamic relevance of the stenosis because we did not observe such a flow pattern if the coronary artery stenosis was below 70% in pig experiments. If oxygen demand was increased by dobutamine stress, an appropriate increase of net distal flow velocity was observed in the VSTENT-dependent vessel, and the patients did not experience angina, nor did regional wall motion deteriorate. We decided to use dobutamine stress to determine functional flow reserve in our patients because intracoronary adenosine, which we administered before surgery, was not suitable under conditions of VSTENT perfusion after surgery.

Furthermore, the combination of the flow wire measurements under dobutamine stress with contrast ventriculography enabled us to determine regional wall motion at the same time in catheterization laboratory. The observed maximal increase in distal flow velocity during dobutamine stress is almost in the range reported for positron emission tomography investigations and transthoracic Doppler flow velocity measurements in patients.

Figure 3. Original recordings of coronary artery flow velocity in (A) distal native vessel before VSTENT implantation, (B) distal native vessel after VSTENT implantation, and (C) proximal vessel after VSTENT implantation. S indicates systole; D, diastole.

Figure 4. Morphology of VSTENT stenosis. A, Angiogram 6 months after VSTENT implantation showing a stenotic process over the whole length of the VSTENT, with the highest degrees of stenosis at the ventricular side and at the junction to the native vessel. B, Intravascular ultrasound imaging of VSTENT stenosis showing very low but homogenous echogenicity of the stenotic material. Left panel, cross section; right panel, longitudinal 2-dimensional reconstruction. C, Angiogram 5 months after percutaneous treatment of VSTENT stenosis with a sirolimus-eluting stent. Moderate luminal obstruction was seen at both ends of the VSTENT at the sites where the implanted sirolimus-eluting stent did not completely cover the VSTENT.
Although we observed an appropriate increase in regional wall motion in the myocardial regions supplied by the VSTENT during dobutamine infusion, this does not exclude completely functional deterioration, as the spatial resolution of the centerline method is limited and overlapping perfusion areas are present after bypass surgery.

From a hemodynamic perspective, the findings mentioned above argue for the ability of ventricular sourcing to provide nutritive blood flow similar or close to that with a conventional bypass. Whether this holds true for vessels supplying large perfusion areas has not been addressed in this study. Moreover, long-term hemodynamic effects of ventricular sourcing need to be evaluated with regard to progression of atherosclerosis and collateral development.

Can VSTENT Replace a Conventional Bypass With Regard to Patency?

Apparently, a 3- to 6-month VSTENT patency rate of 63% was unacceptably low in our patients. Hence, VSTENT certainly cannot replace a conventional flow similar to that with a conventional bypass. Only 1 of 8 patients had a nonobstructed VSTENT after 6 and 12 months of follow-up and probably will continue to be without stenosis. In the other patients (n=7), the reintervention rate was high (71%), as they were either treated by percutaneous implantation of a sirolimus-eluting stent\(^\text{15,16}\) into the native stenosis \((n=1)\) or by percutaneous implantation of a sirolimus-eluting stent into the VSTENT stenosis \((n=3)\). Except for the patient who received a sirolimus-eluting stent into the native stenosis, all patients were asymptomatic at the time of intervention, as were the 3 patients with a completely obstructed VSTENT without intervention. These observations argue for the safety of the study design as well as for the safety of the VSTENT application in general. The high incidence of VSTENT stenosis and occlusion, however, warrants further development of the VSTENT device.

The angiographic manifestation of VSTENT stenosis (Figure 4A) revealed that in general, the stenotic process was present over the whole length of the VSTENT, with the highest degrees of stenosis either at the ventricular side or at the junction to the native vessel or both. These angiographic findings of a diffuse stenotic process were confirmed by intravascular ultrasound, which also showed the stenotic material to be of very low but homogenous echogeneity (Figure 4B) in all 3 patients examined. This kind of stenotic material within the VSTENT appeared to be different from material usually found in case of in-stent restenosis, which is of higher echogeneity. Because of the lack of histology, however, the actual nature of the stenotic material within the VSTENT could not be determined.

Interestingly, the placement of a sirolimus-eluting stent into a stenotic VSTENT seemed to slow down the stenotic process (Figure 4C), although it certainly did not eliminate it. The currently available sirolimus-eluting stent has not been designed for treatment of a membrane-covered expanded polytetrafluoroethylene stent\(^\text{15,16}\) like the VSTENT. Whether a complete coverage of the expanded polytetrafluoroethylene membrane with sirolimus or another immunosuppressive drug might prevent the stenotic processes in the VSTENT needs to be evaluated.

Vascular Effects of VSTENT Implantation

The impact of high shear stress\(^\text{17,18}\) present in the VSTENT itself, as well as in the vessel proximal to the VSTENT, may be beneficial or detrimental with regard to arterial remodeling or progression of arteriosclerotic processes.\(^\text{17–20}\) Although the low number of patent and nonobstructed VSTENTs in the

| TABLE 4. Coronary Artery Flow Velocity in the Proximal and Distal Native Vessel Before and After VSTENT Implantation in a Patient With Patent and Nonobstructed VSTENT With Up to 12 Months of Follow-Up: Development of Vessel Diameter in Relation to Coronary Artery Flow Velocity |
|-------------------------------|-----------------|----------------|----------------|----------------|
|                               | Before Surgery  | 7 Days After Surgery | 6 Months After Surgery | 12 Months After Surgery |
| Flow velocity proximal, cm/s  | 21              | 100             | 89              | 84              |
| Flow velocity distal vessel, cm/s | 20              | 25              | 28              | 30              |
| Vessel diameter proximal, mm  | 2.49            | 2.64            | 2.68            | 3.1             |
mid-term follow-up hampers a conclusive analysis, so far there was no evidence for a significant change in the degree of the native stenosis proximal to the VSTENT (Table 2).

According to the law of Hagen Poiseuille \( (r^4 \propto Q^2 / \rho \cdot r^4) \), the 3- to 4-fold increase in coronary flow velocity that we observed in the native vessel proximal to the VSTENT should result in a similar increase in shear stress. In the preclinical experiments, this was associated with a substantial enlargement of the vessel diameter by \( \approx 1.7 \) fold. In the patient with a nonobstructed VSTENT at the 12-month follow-up, only a slight increase in vessel diameter was observed, although coronary flow velocity was increased by 4-fold (Table 4). In accordance with the slight increase in vessel diameter, coronary flow velocity remained at a somewhat lower but still very high level after 12 months. The same trend was observed in other patients with a nonobstructed VSTENT at follow-up time points, suggesting that some arterial remodeling is taking place in the patients, but to a lesser extent than in nondoiseased porcine arteries.

**Limitations**

With regard to the hemodynamic and clinical performance of the VSTENT, several limitations have to be emphasized. A major limitation of this substudy of the ADVANTAGE trial is the small number of patients included and the low patency rate at 3- to 6 months, which made it difficult to assess the effects of VSTENT in a significant number of patients at follow-up time points. The primary end points of the European multicenter ADVANTAGE trial were the safety and patency. Therefore, the VSTENT was implanted in vessels of secondary importance and distal to a hemodynamically relevant stenosis. Hence, no conclusions can be drawn from our data with regard to the performance of VSTENT in larger vessels of primary importance or distal to a total occlusion.

**References**

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