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Transluminal Extraction Catheter Atherectomy Followed by Immediate Stenting in Treatment of Saphenous Vein Grafts

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Objectives. **The purpose of this study was to evaluate the effectiveness of transluminal extraction catheter (TEC) atherectomy followed by immediate Palmaz-Schatz coronary stenting of coronary bypass vein grafts.**

Background. **Degeneration of saphenous vein coronary bypass grafts has become a common problem. Repeat bypass surgery is associated with greater risk and a poorer outcome than the initial operation. Moreover, percutaneous interventional procedures in vein grafts have been associated with high procedural complication rates, including distal embolization, and high restenosis rates. TEC atherectomy may reduce distal embolization, and stenting may reduce restenosis rates.**

Methods. **We evaluated the procedural, hospital and clinical outcomes of TEC atherectomy followed by immediate Palmaz-Schatz coronary stenting of 53 vein grafts in 49 consecutive patients. The strategy was to limit instrumentation to extraction debulking and to stabilizing the site with stent deployment before using balloon dilation for optimal gain in lumen diameter.**

Results. **Results are shown as mean value (95% confidence interval [CI]). The mean graft age was 9.2 years (95% CI 7.9 to 10.5), and 1.0 (95% CI 1 to 1) TEC cutter (2.2 mm [95% CI 2.1 to 2.3]) and 1.7 (95% CI 1.4 to 2.0) Palmaz-Schatz coronary stents/vein graft were used. The procedural success rate was 98%, with a minimal lumen diameter at baseline of 1.3 mm (95% CI 1.1 to 1.5), increasing to 3.9 mm (95% CI 3.6 to 4.2) ($p < 0.05$) after the TEC–stent procedure. Procedural complications occurred infrequently: graft perforation in 1 (2%) of 53 patients and distal embolization in 1 (2%) of 53 (same patient). In-hospital complications included non–Q wave myocardial infarction in two patients and death after a successful procedure in three (6%) (n = 1 each: massive bleeding from the catheter site; sepsis; and acute myocardial infarction with asystole in the distribution of the stented vessel). The event-free survival rate to hospital discharge was 90%. Clinical follow-up (13 months [95% CI 11 to 15]) was available for all patients. There were five (11%) revascularization procedures (three bypass grafts and two percutaneous transluminal coronary interventions), four (9%) nonfatal myocardial infarctions and five (11%) deaths, for a cumulative rate of 28% for any adverse outcome occurring in 13 of 46 patients.**

Conclusions. **TEC atherectomy followed by immediate Palmaz-Schatz coronary stenting of stenoses in old (>9 years) saphenous vein grafts can be successfully performed, with a low incidence of procedural and hospital complications. Clinical restenosis rates are low and less than those previously reported; however, late morbid cardiac events are still frequent in this high risk group of patients. These observational findings suggest that this technique may improve percutaneous management of vein graft disease, but optimal long-term management strategies remain to be determined.**

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Coronary artery bypass graft surgery (CABG) using autologous, reversed saphenous vein grafts (SVGs) has been one of the mainstays of the treatment of symptomatic coronary artery disease. However, the SVGs used in the bypass procedure develop significant diffuse atheromatous disease within 5 to 7 years of implantation, often with progression to severe obstruction or occlusion (1–3). Repeat revascularization is often performed in these cases, but repeat CABG is associated with increased morbidity and mortality (4–6).

Standard balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA]) of vein grafts has been shown to be feasible but provides less than optimal acute and late outcomes, primarily as a result of a significant incidence of acute complications secondary to distal embolization. High restenosis rates have been observed after PTCA of vein grafts as well (7–13). Directional coronary atherectomy treatment of significant obstructive disease in SVGs has been reported; however, it has not resulted in substantially better results than those achieved with balloon angioplasty alone and has also been associated with a high acute complication rate (14–17). Transluminal extraction catheter (TEC) atherectomy has been used in treating vein graft disease because of its ability to aspirate thrombus and friable material present in diseased vein grafts (18,19). Initial results have suggested (18,20) that a significant incidence of distal embolization occurs, often as a

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Abbreviations and Acronyms

CABG = coronary artery bypass graft surgery
CI = confidence interval
ECG = electrocardiogram, electrocardiographic
LAD = left anterior descending coronary artery
MI = myocardial infarction
MLD = minimal lumen diameter
PTCA = percutaneous transluminal coronary angioplasty
SVG = saphenous vein graft
TEC = transluminal extraction catheter
TIMI = Thrombolysis in Myocardial Infarction

result of adjunctive balloon angioplasty used to provide a greater lumen gain after TEC atherectomy alone. In an attempt to lower the high rate of restenosis, intracoronary stents have been used in vein grafts (21–25). However, because of the need for predilation with balloon angioplasty, as well as adjunctive balloon angioplasty to fully deploy and expand the stents, distal embolization has remained a significant problem (23).

To address the limitations of acute distal embolization and restenosis, we combined the TEC and stent procedures in 53 SVGs in 49 consecutive patients with stenoses in vein grafts. We evaluated the procedural and in-hospital success and complication rates, as well as the late clinical outcome of this combined procedure.

Methods

Patients. Between September 1994 and December 1995, the combined TEC–stent procedure was used in 49 consecutive patients and provides the basis for the study. Clinical indications for percutaneous revascularization were stable angina, unstable angina and angina after myocardial infarction (MI). Any lesion of the vein graft, except for distal anastomotic lesions, was considered suitable for the procedure. Angiographic presence of thrombus was not considered a contraindication to the procedure. Only patients with an acute MI were excluded from the study. The TEC–stent procedure was performed during the index hospital period in all 49 patients, with an average time from cardiac catheterization to the TEC–stent procedure of 1.8 ± 1.6 days.

TEC–stent procedure. The procedural strategy was to limit instrumentation to extraction debulking by TEC atherectomy and to stabilize the site with stent deployment before using balloon dilation for optimal gain in lumen diameter. The TEC atherectomy device (InterVentional Technologies, Inc.) was used in all patients in the study; 10F guiding catheters (DVI and InterVentional Technologies, Inc.) were used to cannulate the SVG. A TEC atherectomy guide wire (InterVentional Technologies, Inc.) was passed across the lesion and placed in a suitable distal position within the native coronary vessel. The TEC cutter size selection was empiric. In general, large cutters (2.1 or 2.3 mm) were used for vessels >3 mm if minimal angulation was present. The cutter was downsized if there was significant tortuosity of the vein graft. Cutting and aspiration were begun well proximal to the lesion site. The atherectomy device was advanced slowly across the stenosis and 1 to 2 cm beyond the stenosis. Multiple passes were made through the area of stenosis (usually three to five). Under most circumstances, withdrawal of the cutter was also done under active aspiration.

After TEC atherectomy, an appropriately sized Palmaz-Schatz coronary stent (Johnson and Johnson, Interventional Systems Co.) was selected and advanced into the area of stenosis. Stent size was chosen to match the distal reference segment diameter. After positioning the stent, it was deployed according to the manufacturer's specifications. All stents were postdilated with a high pressure, noncompliant PTCA balloon (SciMed, Cordis Corp or Schneider) to rated balloon burst threshold. Inflation to higher pressures was performed if stent expansion did not appear to be adequate angiographically. The postdilation high pressure balloon size was chosen to achieve a balloon diameter to distal reference segment ratio of 1.0:1.2.

Medications. All patients were pretreated with aspirin (325 mg) before the procedure. Aspirin (325 mg) was then given daily. Dextran infusions were given to the first two patients only. No patient received platelet glycoprotein receptor IIb/IIIa blocking agents. After sheath insertion, heparin was administered to achieve and maintain an activated clotting time ≥350 to 400 s. Intravenous nitroglycerin was begun during the procedure and continued until the following morning. Warfarin (10 mg) was given the night before the procedure when possible, and was given daily after the procedure to achieve an international normalized ratio of 2.0 to 3.0. Warfarin was used for 2 months after the procedure and then discontinued. Dipyridamole, and calcium and beta-adrenergic blocking agents were administered at the discretion of the primary cardiologist.

Angiographic analysis. Angiography was performed simultaneously from two orthogonal views. The view that identified the most severe stenosis was selected for quantitative analysis. Measurements of minimal lumen diameter (MLD) and percent diameter stenosis were obtained by computer-assisted quantitative coronary angiography (Sanders Data Systems) using the guiding catheter for reference measurement. Postprocedure angiograms were analyzed from the same projections as preprocedure films.

Flow characteristics were assessed using standard Thrombolysis in Myocardial Infarction (TIMI) criteria from the initial and final angiogram (26). The final angiogram was assessed for the presence of distal embolization, defined as the appearance of new filling defects or abrupt cutoff of vessels distal to the target stenosis, or both. The procedure was considered successful if the residual stenosis was ≤50% in the absence of procedure-related complications (distal embolization, slow flow, vessel occlusion or emergent CABG).

In-hospital outcomes. The hospital course of all patients was followed for occurrence of procedure-related complications. Electrocardiograms (ECGs) were reviewed for the oc-

Table 1. Clinical Characteristics of 49 Study Patients

Mean age (yr)	67
95% CI	64–70
Men/women	30/19
CAD risk factors (% of pts)	
Diabetes	29%
Hypertension	56%
Dyslipidemia	46%
Family history	48%
Current smoker	44%
Indications (% of pts)	
Post-MI	12%
Stable angina	24%
Unstable Angina	64%
Mean age of grafts (yr)	9.2
95% CI	7.9–10.5
Range	0.3–19
No. of vessels treated (n = 53)	
SVG–LCx	2
SVG–diag	4
SVG–LAD	15
SVG–OM	17
SVG–PDA	3
SVG–RCA	12

CAD = coronary artery disease; CI = confidence interval; diag = diagonal branch; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; MI = myocardial infarction; OM = obtuse marginal; PDA = posterior descending artery; pts = patients; RCA = right coronary artery; SVG = saphenous vein graft.

currence of new Q waves at 24 to 48 h after the procedure. Creatine kinase values were obtained in all patients at 8, 16 and 24 h, with MB subfractions determined in those with elevated total creatine kinase levels. Q wave MI was defined as the presence of new Q waves present on the ECG with elevated CK levels. Non–Q wave MI was defined as the presence of elevated creatine kinase levels greater than or equal to three times normal with positive MB fractions in the absence of Q waves.

Clinical outcomes. The clinical outcomes of the patients discharged from the hospital were assessed by a review of the medical records from the primary care physician and cardiologist or by phone interview.

Statistical analysis. Results are reported as mean value (95% confidence intervals [CI]). Comparisons between angiographic measurements were made by the paired *t* test. A p value <0.05 was considered statistically significant.

Results

Baseline characteristics. The demographic and clinical characteristics of the 49 patients are shown in Table 1. The mean age of the patients was 67 years (95% CI 64 to 70, 30 men, 19 women). The mean age of the bypass grafts was 9.2 years (95% CI 7.9 to 10.5, range 0.3 to 19). The indication for the procedure was stable angina in 12 patients (24%), unstable angina in 31 (64%) and ischemia after a recent MI (<1 week) in 6 (12%). The duration from cardiac catheterization to the TEC–stent procedure was 1.8 days (95% CI 1.4 to 2.2), which was performed during the index hospital period in all 49 patients.

The distribution of SVGs treated was SVG to left anterior descending coronary artery (LAD) in 15 patients, SVG to diagonal branch in 4, SVG to circumflex coronary artery in 2, SVG to obtuse marginal in 17 and SVG to right coronary artery in 15. There were 50 primary lesions and 3 restenotic lesions. The preprocedural stenosis rate averaged 65% (95% CI 61% to 69%), including two lesions with total occlusions. Thrombolysis in Myocardial Infarction flow grade averaged 2.8 (95% CI 2.6 to 3.0), with 10 of 53 lesions with TIMI flow grade <3. Reference diameter before the procedure was 3.5 mm (95% CI 3.2 to 3.8) by quantitative coronary angiography.

Procedural outcomes. Angiographic images of the vein graft before and after the TEC–stent procedure in one patient are shown in Figure 1. Despite significant disease, the vein grafts were successfully stented with excellent angiographic results and without evidence of distal embolization. The equipment used for the procedures is shown in Table 2. The average TEC cutter size was 2.2 mm (95% CI 2.1 to 2.3). In all but one patient a single cutter was used before stent placement. An average of 1.7 (95% CI 1.4 to 2.0, range 1 to 6) stents/vessel, were placed and 35 (66%) of 53 vein grafts were treated with a single stent, with an average stent size of 3.8 mm (95% CI 3.7 to 3.9). The average balloon size used for post-stent deployment dilation was 4.0 mm (95% CI 3.9 to 4.1, range 3.25 to 5.0).

The procedural outcomes are summarized in Table 3. The combined TEC–stent procedure was successful in 52 (98%) of 53 SVGs. The MLD increased from 1.3 mm (95% CI 1.1 to 1.5) to 3.9 mm (95% CI 3.6 to 4.2, $p < 0.05$) (Fig. 2). The mean residual stenosis was −28% (95% CI 26% to 29%). Angiographically apparent flow abnormalities occurred in only one patient who had perforation of the SVG to the LAD during TEC atherectomy and distal embolization observed after percutaneous repair of the vein graft. Distal embolization was not visualized in any of the other 52 vessels of the remaining 48 patients.

In-hospital outcomes. The mean peak creatine kinase level was 149 U/liter (95% CI 81 to 217) before the procedure and 145 U/liter (107 to 183, p = NS) after the procedure (Table 4). Two patients (4%) had a non–Q wave MI. One of these patients had perforation of the SVG to the LAD by a 1.8-mm TEC catheter; the other was clinically asymptomatic, and the non–Q wave MI was detected solely by a rise in creatine kinase. The patient with perforation of the SVG had bleeding into the mediastinum. Two 4.0 Palmaz-Schatz coronary stents covered with a vein segment harvested from the patient's antecubital fossa were used to percutaneously repair the perforation. After repair of the perforation, embolization of the native coronary artery supplied by the SVG was noted. No repeat angiography, repeat procedures or CABG was necessary in any patient during the hospital stay. Three patients (6%) died after a successful procedure: One patient had an acute MI in the distribution of the stented vessel, with resultant asystole and

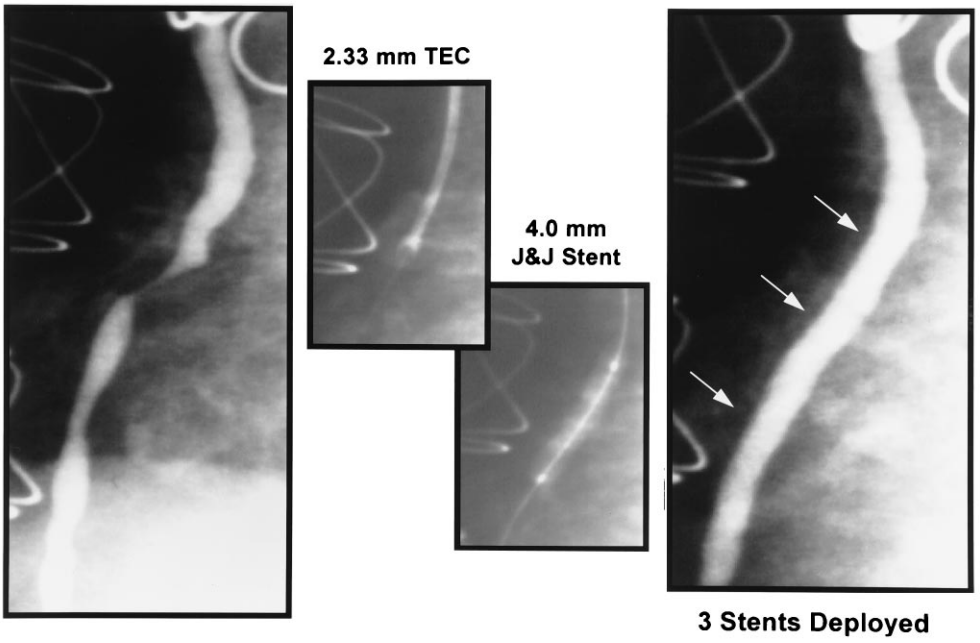

Figure 1. Angiographic images obtained from one patient showing a diffusely degenerated vein graft with high grade stenosis of the body of the graft **(left panel),** the TEC atherectomy device and coronary stent used for the procedure **(center panels)** and the final result after deployment of three Palmaz-Schatz coronary stents **(right panel).** J&J = Johnson & Johnson Interventional Systems.

unsuccessful resuscitation; one patient had massive bleeding from the catheter site the day after the procedure and died in the operating room during attempted vascular repair; and one patient had sepsis after the procedure and died after a protracted hospital stay of complications of sepsis. The event-free survival rate to hospital discharge was 90% (44 of 49 patients).

Late clinical outcomes. Clinical outcomes of repeat revascularization, MI and death were available for all patients at an average follow-up of 13 months (95% CI 11 to 15) (Table 5). Five patients underwent revascularization procedures after the TEC–stent procedure, including CABG in three and repeat percutaneous transluminal coronary intervention, yielding a target vessel revascularization rate of 11% in two. Four patients (9%) had a nonfatal MI.

There were 5 deaths (11%) after the TEC–stent procedure, ranging from 1 to 7 months after the procedure. In three patients an MI preceded death that may have been related to stent occlusion, whereas in the remaining two patients, death was most likely not due to a stent-related problem. The average age of these five patients (72 years [95% CI 68 to 76]) was greater than that of the group as a whole, and three of the five patients had reduced left ventricular function. Thirteen (28%) of the 46 patients experienced one or more of these major adverse cardiac events.

Table 2. Transluminal Extraction Catheter Atherectomy–Stent Equipment

	Mean (95% CI)
TEC catheter size (mm)	2.2 (2.1–2.3)
Stent size (mm)	3.8 (3.7–3.9)
No. of stents/vessel	1.7 (1.4–2.0)
Postdilation balloon size (mm)	4.0 (3.9–4.1)
Max inflation pressure (atm)	14.8 (13.9–15.7)

CI = confidence interval; Max = maximal; TEC = transluminal extraction catheter atherectomy.

Discussion

Study findings. *The principal finding of our study* was that the combined TEC–stent procedure, used to treat obstructive disease in old (>9 years) SVG, was associated with a high success rate and a low incidence of procedural and in-hospital complications. Despite an average vein graft age >9 years, we observed angiographic evidence of distal embolization in only one patient and no slow flow and no emergent CABG. Cardiac enzymes were significantly elevated in only two patients after the procedure. There were three in-hospital deaths after the procedure, only one of which was clearly attributable to the coronary intervention itself. At an average of 13 months of follow-up, 13 (28%) of 46 patients experienced a major adverse cardiac event, including repeat revascularization, nonfatal MI or death. Although these represent observational findings, we believe that our results indicate that the TEC–stent procedure for degenerated vein graft stenosis may significantly reduce the acute complication rates previously associated with percutaneous revascularization attempts in these conduits. Moreover, target vessel revascularization rates may be reduced by this combined procedure. However, significant postprocedural morbidity in these high risk patients still occurs, and the optimal strategy for management of vein graft disease remains to be determined.

Comparison with previous studies. Reports of balloon angioplasty (7–13) and directional atherectomy (14–17) in

Table 3. Procedural Outcomes

	Pre [mean (95% CI)]	Post [mean (95% CI)]	p Value
MLD	1.26 (1.24–1.28)	3.94 (3.64–4.24)	<0.001
% stenosis	64.5 (60.0–69.0)	−27.7 (21.5–33.9)	<0.001
TIMI flow grade	2.74 (2.54–2.94)	3.0 (3.0–3.0)	NS
Distal emboli	—	1	NS

CI = confidence interval; MLD = minimal lumen diameter; Post = after the procedure; Pre = before the procedure; TIMI = Thrombolysis in Myocardial Infarction.

Table 4. In-Hospital Outcomes in 49 Study Patients

Event	No. (%) of Patients
Non–Q wave MI	2 (4%)
Death	3 (6%)
CABG	0
Q wave MI	1 (2%)
Perforation	1 (2%)
Vascular repair	1 (2%)

CABG = coronary artery bypass graft surgery; MI = myocardial infarction.

degenerated vein grafts have indicated that the acute complication rate, attributed to distal embolization, is substantially higher than that in native coronary arteries, suggesting that the atheromatous process responds differently to interventions in these two vascular structures (4–6). The incidence of embolization and associated non–Q wave or Q wave MI after PTCA in vein grafts ranges from as low as 2% to 10% to as high as 20% to 30% in patients with angiographic evidence of thrombus (20,27). Moreover, there is often substantial morbidity and mortality associated with the embolic event (20,28). In contrast, the TEC device may reduce, and possibly eliminate, distal embolization in vein grafts. Although initial experience with the TEC system was not entirely favorable (20), most likely because of adjunct PTCA used to achieve a more optimal lumen, more recent data suggest (29) that TEC atherectomy can be performed with a low rate of distal embolization (3.9%). Although TEC atherectomy appears to reduce distal embolization rates, it is primarily an adjunctive technique because it leaves an average residual stenosis ≥50% (20).

The initial experience with the Palmaz-Schatz intravascular stent in focal vein graft stenosis revealed a 99% success rate but a 10% incidence of non–Q wave MI (21–25). Friedrich et al. (21) were able to achieve a procedural success rate of 98.2%, with a non–Q wave MI rate of 12% and no reflow in ~10% of procedures. Procedural incidences of distal embolization and non–Q wave MI of 23% and 44%, respectively, have been reported (30) using biliary stents in degenerated SVG, suggesting that this technique may not reduce the acute complication rate and may be associated with substantial procedural morbidity. More recent data (31) suggest that stenting of vein grafts may be more optimal than PTCA. Although patients in this study were highly selected, it appears that stenting was associated with fewer non–Q wave MIs and a lower clinical event rate after the procedure than for standard PTCA (26% vs. 38%, $p < 0.05$). Whether similar favorable findings will be obtained when applied to a less select group of patients remains to be determined. The weight of experience suggests that the optimal treatment strategy of obstructive disease in vein grafts has yet to be determined.

In comparing our results with those of others, there are several factors that should be considered: 1) Patients were included in this study because their clinical symptoms were attributed to obstructive disease in a vein graft, with >75% of our patients presenting with an acute ischemic syndrome preceding their intervention, similar to previous studies. 2) Lengthy anticoagulation was not performed before the intervention. Thus, the clinical characteristics of our patients are similar to those of patients in previous studies. In an attempt to compare the extent and severity of disease in the vein grafts in our study with those of other studies, several lesion characteristics should be examined: 1) Our average graft age was >9 years, comparable to that of most other studies. 2) The average percent stenoses by quantitative coronary angiography was similar to that of previous studies (18,32). 3) Lesion length was <15 mm in two-thirds of our patients, whereas one-third had a lesion length >15 mm, also comparable to other reported values (18,32). Although direct comparisons to other studies are difficult, these lesion characteristics are similar to those

Figure 2. Cumulative frequency plot of MLD before **(circles at left)** and after the TEC–stent procedure **(circles at right)** as determined by quantitative coronary angiography.

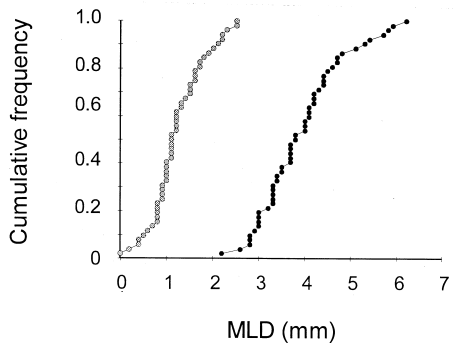

Table 5. Late Outcome in 46 Study Patients

Event	No. (%) of Patients
TLR	5 (11%)
Repeat PTCI	2 (4%)
Repeat CABG	3 (7%)
MI	4 (9%)
Death	5 (11%)
Cardiac	3 (7%)
Non–TLR related	2 (4%)
Event-free survival	33 (72%)

CABG = coronary artery bypass graft surgery; PTCI = percutaneous transluminal coronary intervention; TLR = target lesion revascularization.

observed in other trials of vein grafts. The mortality rate in our patient cohort was significant. Stent thrombosis was documented in only one patient but may have been responsible for, or contributed to, the death of three other patients. Significant mortality in patients treated with percutaneous revascularization has been previously reported (18,19,33). Our data, together with previous data, suggest that any patient with significant stenosis of a vein graft is at high risk. Although we cannot exclude selection biases inherent in studies of consecutive patients, these data suggest that our patients were not low risk and had significant obstructive disease of older vein grafts and that the favorable procedural outcomes did not occur because of our accepting a less than an optimal MLD during the procedure.

Clinical implications. The findings of this study may have important clinical implications. Management of obstructive disease in patients with a previous CABG is becoming an increasing problem as the number of such patients increases. The introduction and now widespread use of left internal mammary artery grafts, in addition to SVGs, in patients undergoing bypass operations may paradoxically magnify the problem. Because of the increased long-term patency of the left internal mammary artery conduit, many patients are now presenting with disease in vein grafts with widely patent left internal mammary artery grafts. Because of the reluctance, appropriately, of surgeons to reoperate on patients with patent mammary artery grafts, the management of the disease in SVGs is often referred for percutaneous management. Thus, the need to develop safer and more effective techniques of percutaneous management of this disease is important. Our findings suggest that the combined TEC–stent procedure may significantly reduce the procedural complications associated with percutaneous revascularization and may reduce the clinical event rate after the procedure in these patients. This technical approach, in combination with recent advances in platelet suppression, such as platelet glycoprotein receptor IIb/IIIa blockade, may further extend the number of obstructive vein grafts that may be safely and effectively treated with catheter-based interventions.

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