Clinical and Angiographic Results of Transluminal Extraction Coronary Atherectomy in Saphenous Vein Bypass Grafts

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Background Transluminal extraction coronary (TEC) atherectomy is a relatively new device that has recently been approved by the Food and Drug Administration. Because of its ability to aspirate clot and atheromatous material, TEC atherectomy may be useful in patients with stenoses in saphenous vein bypass grafts.

Methods and Results TEC atherectomy was performed on 158 saphenous vein graft lesions in 144 consecutive patients with a mean age of 65±8 years (78% men). Clinical indications for atherectomy included stable angina (37%), unstable angina (54%), and postinfarction angina after recent (<1 month) myocardial infarction (8%). Patients with acute myocardial infarction and target vessels <2 mm in diameter were excluded. The mean age of the bypass graft was 8.3±3.0 years, and 17% were diffusely diseased and degenerated. Complex lesion morphology included total occlusion (6%), eccentricity (65%), ulceration (18%), and thrombus (28%). The TEC atherectomy cutter was successfully advanced through 144 lesions (91%), but technical failures occurred in 14 lesions (9%), and these were subsequently managed by successful balloon angioplasty. Quantitative angiography revealed an increase in lumen diameter from 0.9±0.5 mm to 1.5±0.7 mm after TEC atherectomy, to 2.3±0.8 mm after percutaneous transluminal coronary angioplasty (PTCA) (P<.001), which corresponded to decreases in diameter stenosis from 75±14%, to 58±20% after TEC atherectomy, to 36±22% after PTCA (P<.001). Device success was achieved in 39.2% (post-TEC atherectomy decrease in diameter stenosis ≥20%), and procedural success was achieved in 84% (final diameter stenosis <50% in the absence of a major complication). Angiographic complications were evident in 33 lesions (20.7%) immediately after TEC atherectomy and in 8 lesions (5%) after PTCA, including distal embolization (11.9%), no-reflow (8.8%), and abrupt closure (5.0%), but no perforations. Adjunctive PTCA (and other medical therapy) successfully managed 61% of angiographic complications. Serious clinical complications included in-hospital death in 3 patients (2.0%), emergency bypass surgery in 1 patient who died (0.7%), Q wave myocardial infarction in 3 patients (2.0%), non-Q wave myocardial infarction in 4 patients (2.7%), vascular injury requiring surgical repair and/or blood transfusion in 9 patients (6.1%), and hemorrhagic cerebral infarction in 4 patients (2.7%). Using a composite clinical end point defined as in-hospital death, emergency bypass surgery, or myocardial infarction, the strongest independent correlate (P<.001) of a severe clinical complication was the development of one or more serious angiographic complications (no-reflow, distal embolization, or abrupt closure) immediately after TEC atherectomy. Complete clinical follow-up was available in 118 (92%) of 128 eligible patients at an interval of 6.0±2.5 months after discharge. Late cardiac outcome included recurrent angina treated with medical therapy (18%), repeat percutaneous intervention on the original target lesion (26%), repeat coronary artery bypass surgery (5%), Q wave myocardial infarction (4%), and late cardiac death (7%). Angiographic follow-up in 105 (80%) of 132 eligible lesions revealed a restenosis rate of 69% (defined as a diameter stenosis >50%), including 30 lesions (29%) with total occlusion of the original lesion.

Conclusions In patients with stenoses in saphenous vein bypass grafts, TEC atherectomy is limited by the frequent need for adjunctive balloon angioplasty to achieve adequate lumen enlargement and to manage TEC atherectomy-induced complications. Although the incidence of serious clinical complications is similar to that of other percutaneous interventions in vein grafts, there is a high incidence of restenosis and late vessel occlusion. Prospective randomized studies are needed to determine the best revascularization strategy for high-risk patients with old degenerated vein grafts. (Circulation. 1994; 89:302-312.)

Key Words • atherectomy • veins • bypass for lesions in which PTCA is expected to result in suboptimal immediate or long-term results. Within the last 5 years, several new lasers, stents, and atherectomy catheters have undergone clinical investigation to determine their relative merits compared with PTCA. Transluminal extraction coronary (TEC) atherectomy is a relatively new device that has recently been approved by the Food and Drug Administration.1 Because of its ability to cut and aspirate clot and atheromatous material, TEC atherectomy may be potentially useful in patients with occlusive disease in saphenous vein bypass grafts, in which conventional PTCA and other devices may be limited by distal embolization, no-reflow, and a...
high incidence of restenosis. The purpose of this study is to evaluate the clinical and angiographic results of TEC atherectomy followed by adjunctive PTCA in saphenous vein bypass grafts.

Methods

Patient Population

Between December 1988 and June 1992, TEC atherectomy was performed on 158 saphenous vein graft lesions in 146 consecutive patients with a mean age of 65±8 years (78% men). Anginal symptoms were classified as I (1%), II (4%), III (47%), or IV (45%) according to the Canadian Cardiovascular Society classification. Clinical indications for atherectomy included stable angina (37%), unstable angina (54%), and postinfarction angina after recent (<1 month) myocardial infarction (8%). Prior PTCA or other percutaneous intervention had been performed in 22% of lesions. Patients with acute myocardial infarction and target vessels <2 mm in diameter were excluded from this study.

Description of Atherectomy Device

The TEC atherectomy device (Interventional Technologies, Inc, San Diego, Calif) consists of several components: a cutting catheter with a cone-shaped cutting head (5.5F, 6.0F, 6.5F, 7.0F, and 7.5F sizes) with two stainless steel cutting blades attached to the distal end of a hollow torque tube; a hand-held motor-drive unit that attaches to the proximal end of the cutting catheter; a battery pack that attaches to and serves as the power source for the motor-drive unit; and a vacuum bottle that attaches to the motor-drive unit for collection of aspirated blood and tissue. A trigger on the bottom of the motor-drive unit activates cutting-blade rotation (750 rpm) and a sliding lever on top of the handle permits advancement or retraction of the cutter. A specially designed rotating hemostatic valve with a sidearm adapter connects the guiding catheter to the manifold for contrast injections and also permits infusion of warmed (37°C), pressurized (300 mm Hg), heparinized lactated Ringer's solution, which creates a slurry of aspirated blood and tissue. The TEC atherectomy guide wire (Interventional Technologies, Inc) consists of a 300-cm-long 0.014-in stainless steel wire shaft, a 2-cm floppy tip, and a 0.021-in ball at the end of the wire to prevent wire entrapment in the cutter.

Device selection was largely empirical, but in general the largest device was 1.0 to 1.5 mm smaller than the reference diameter of the target vessel. For vessels >3 mm in diameter with large amounts of thrombus, large cutters (7F or 7.5F) were used if possible because of better ability to aspirate thrombus. In diffusely diseased vessels or subtotal stenoses, a smaller cutter (5.5F) was generally used first, followed by a larger cutter or PTCA to achieve a final residual diameter stenosis <50%.

Atherectomy Procedure

All atherectomy procedures were performed according to a protocol approved by the Human Investigations Committee of William Beaumont Hospital. A special 10F tungsten-braded soft-tip guiding catheter (Interventional Technologies, Inc) was recommended for all TEC atherectomy procedures, but a 9F guiding catheter (inner diameter ≥0.089 in) can be used with devices ≤6.0F. After the vessel ostium was engaged, the target lesion was crossed with the TEC atherectomy guide wire, and the floppy tip was positioned in the distal vessel so that the stiff portion of the wire was across the lesion. If difficulty in crossing the lesion was anticipated, a conventional 0.014-in angioplasty guide wire was used first, which was then exchanged for the TEC atherectomy guide wire by use of a 2.5F infusion catheter (Cordis, Inc, Miami, Fla). Once the wire was in position, the TEC atherectomy catheter was advanced up to the lesion, and lactated Ringer's solution was infused under pressure. By gripping the handle on the motor-drive unit, the operator depressed the trigger to activate cutter rotation and aspiration, and the lever was slowly advanced and retracted to traverse the entire lesion. In general, several (two to five) passes were made slowly (10 to 30 seconds per pass) through the lesion, until there was no further resistance to cutter advancement. Repeat angiography was performed after the cutter was retracted to assess the need for a larger device or for balloon angioplasty.

Medications

All patients were pretreated with aspirin at least 24 hours before the procedure. After the insertion of the arterial sheath, heparin 10 000 U was administered, and additional heparin was given to maintain the activated clotting time >300 seconds. After the procedure, patients were treated with overnight infusion of heparin, after which time the vascular sheaths were removed. For patients with visible thrombus, diffusely diseased and degenerated vein grafts, or total occlusion of the bypass graft, intracoronary urokinase was generally given before atherectomy (27 lesions, 17%), and oral coumarin was recommended for 6 to 8 weeks after intervention (82 patients, 56%), in addition to aspirin.

Angiographic Assessment

The single view that identified the most severe stenosis was selected for quantitative analysis. Measurements of minimal lumen diameter, reference diameter, and lesion length were obtained with electronic calipers (Chandler and Farquhar Co, Canton, Mass), using the guiding catheter as a reference object, as previously described. All views were selected with the target lesion and reference guiding catheter in the same plane, maximally elongated and centered to reduce vessel foreshortening and pincushion distortion. Intracoronary nitroglycerin (0.1 to 0.2 mg) was routinely administered before and after each intervention. In all cases, measurements were obtained immediately before and after atherectomy and after PTCA (all measurements were performed by R.D.S.). The ratio of the diameter of the final device to the diameter of the reference vessel (D/A ratio) was a measure of relative device sizing. The RLD/D ratio was defined as the ratio of the residual lumen diameter (RLD) immediately after TEC atherectomy to the final diameter (D) of the TEC atherectomy cutter (the diameter of the cutter [in millimeters] was calculated by dividing the French size by 3). The RLD/D ratio is a measure of the relative lumen diameter achieved, normalized for the size of the cutter, and is a direct measure of the mechanical efficiency of lumen enlargement.

For purposes of analysis, lesion characteristics were categorized as dichotomous variables (present or absent). Lesions were considered eccentric if they occupied the outer quarter of the vessel lumen, and ulcerated lesions were defined as those with definite overhanging edges (lesions with simple contour irregularity were not considered ulcerated). Thrombus was considered to be present if there was a definite circumscribed filling defect, whereas intraluminal haziness alone was not considered sufficient evidence for thrombus. Lesion angulation was graded as none, mild (<45° angle), moderate (45° to 60° angle), or severe (>60° angle). Vessel tortuosity proximal to the lesion was graded as none, mild (one bend ≤90°), moderate (two 90° bends), or severe (more than two 90° bends). Vein grafts were considered degenerated if diffuse atheromatous changes occupied more than 25% of the body of the graft.

Antegrade flow was graded after TEC atherectomy and after subsequent PTCA using standard TIMI criteria. Dissection grades were assigned on a scale of 0 to 4 (0, no dissection; 1, mild focal dissection; 2, moderate dissection with <50% diameter stenosis; 3, severe dissection with >50% diameter stenosis; 4, severe dissection with total occlusion).
Follow-up
Follow-up was performed by clinic visit or telephone contact with the patient or referring physician. Repeat angiography was recommended to all patients at 6 months, or earlier if necessary for recurrence of symptoms.

Definitions
For purposes of this study, “device success” was defined as a decrease in diameter stenosis ≥20% after TEC atherectomy, and “procedural success” was defined as a final diameter stenosis <50% (after TEC atherectomy alone or after TEC atherectomy and adjunctive PTCA) in the absence of a major complication (death, emergency bypass surgery, or Q wave myocardial infarction). Distal embolization was defined as the new appearance of circumscribed filling defects and/or abrupt cutoff of the vessel distal to the target lesion. No-reflow was defined as poor antegrade flow (TIMI ≤1) not explained by dissection or high-grade residual stenosis at or adjacent to the target lesion. If no-reflow was observed, it was not scored as distal embolization to eliminate “double counting.” Abrupt closure was defined as poor antegrade flow (TIMI ≤1) caused by acute occlusion of the target lesion. Non-Q wave myocardial infarction was defined as elevation of creatine kinase >3 times the upper limit of normal in the absence of pathological Q waves. Angiographic restenosis was defined as a diameter stenosis >50% at follow-up, and clinical restenosis was defined as revascularization of the target lesion (PTCA, another device, or coronary artery bypass surgery), myocardial infarction, or cardiac death.

Statistical Analysis
Data are reported as mean±SD. Comparisons were made with Student’s t test for continuous variables. χ² analysis was used to compare categorical variables, and logistic regression was used to determine associations between clinical factors and outcome. Statistical analyses were performed with available software (SAS Institute, Cary, NC). A value of P<.05 was considered significant.

Results
Baseline Angiography
The extent of coronary artery disease (defined as diameter stenosis >50%) was limited to one vessel (0.6%), two vessels (12.6%), or three vessels (86.8%). The mean left ventricular ejection fraction was 47±11%. Target lesions were located at the aorto-ostial anastomosis in 32 lesions (21%) and in the body of the vein graft in 126 lesions (79%). The average age of the bypass graft was 8.3±3.0 years. Twenty-seven vein grafts (17%) were diffusely diseased and degenerated, whereas 131 lesions (83%) were focal or tubular. Complex lesion morphology was frequently identified (Table 1), including total occlusion (9 lesions, 6%), eccentricity (101 lesions, 64%), ulceration (29 lesions, 18%), and intraluminal filling defects consistent with thrombus (45 lesions, 28%).

Immediate Results
The final TEC atherectomy cutter size was 5.5F in 24 lesions (15.9%), 6F in 32 lesions (21.3%), 6.5F in 7 lesions (4.7%), 7F in 49 lesions (32.7%), and 7.5F in 38 lesions (25.3%). The mean cutter diameter was 6.6±0.7F (2.2±0.2 mm), and an average of 1.4±0.5 cutters were used per lesion. The average D/A ratio was 0.6±0.1, consistent with relative undersizing of the TEC atherectomy cutters compared with the normal vessel reference diameter.

**TABLE 1. Baseline Morphology of 158 Saphenous Vein Bypass Graft Lesions Treated by Transluminal Extraction Coronary Atherectomy**

<table>
<thead>
<tr>
<th>Morphology</th>
<th>n</th>
<th>%</th>
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<tbody>
<tr>
<td>Total occlusion</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Aorto-ostial</td>
<td>32</td>
<td>21</td>
</tr>
<tr>
<td>Calcium</td>
<td>1</td>
<td>0.6</td>
</tr>
<tr>
<td>Eccentric</td>
<td>101</td>
<td>64</td>
</tr>
<tr>
<td>Ulcerated</td>
<td>29</td>
<td>18</td>
</tr>
<tr>
<td>Thrombus</td>
<td>45</td>
<td>28</td>
</tr>
<tr>
<td>Angulation</td>
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<td></td>
</tr>
<tr>
<td>None, mild</td>
<td>142</td>
<td>90</td>
</tr>
<tr>
<td>Moderate</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>Severe</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Tortuosity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None, mild</td>
<td>139</td>
<td>88</td>
</tr>
<tr>
<td>Moderate</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td>Severe</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Length</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focal</td>
<td>72</td>
<td>46</td>
</tr>
<tr>
<td>Tubular</td>
<td>59</td>
<td>37</td>
</tr>
<tr>
<td>Diffuse</td>
<td>27</td>
<td>17</td>
</tr>
</tbody>
</table>

*See text for definitions.

The TEC atherectomy cutter was successfully advanced through 144 lesions (91%). However, technical failures of TEC atherectomy occurred in 14 lesions (9%) and were due to failure to engage the vessel ostium with the guiding catheter in 1 lesion (0.6%), failure to cross with the TEC atherectomy device in 6 lesions (3.8%), and failure to treat the entire lesion in 7 lesions (4.4%). All technical failures were subsequently managed by successful balloon angioplasty.

Quantitative angiographic analysis revealed a reference diameter of 3.8±0.9 mm and a lesion length of 9.1±7.1 mm. Minimal lumen diameter increased from 0.9±0.5 to 1.5±0.7 mm after TEC atherectomy and to 2.3±0.8 mm (P<.001) after final treatment (Fig 1A). These absolute diameters corresponded to decreases in diameter stenoses from 75±14%, to 58±20% after TEC atherectomy and to 36±22% (P<.001) after final treatment (Fig 1B). The efficiency of lumen enlargement (RLD/D) was 0.69±0.33, indicating that the magnitude of luminal improvement was 69% of the final cutter diameter.

When acute results were evaluated in terms of diameter stenosis, device success after TEC atherectomy was achieved in 62 lesions (39.2%), based on a decrease in diameter stenosis ≥20%. In contrast, 96 lesions (60.1%) were considered device failures according to the diameter stenosis definition because of the development of abrupt closure (8 lesions, 5.1%), no-reflow (7 lesions, 4.4%), or a decrease in diameter stenosis <20% (80 lesions, 51.3%). Final procedural success was achieved in 84% of lesions (Fig 1B). After PTCA, TIMI grade 2 to 3 antegrade flow was observed in 147 lesions (93%), but poor antegrade flow (TIMI grade 0 to 1) persisted in
Adju nctive PTCA

TEC atherectomy was used as the only intervention in 14 lesions (8.8%). Adjunctive balloon angioplasty was used after TEC atherectomy in 144 lesions (91.2%) to further enlarge lumen dimensions (115 lesions, 72.8%), to salvage technical failure (14 lesions, 8.8%), and to manage TEC atherectomy-induced vessel occlusion caused by abrupt closure or no-reflow (15 lesions, 9.5%). Predilation (and postdilation) was required in 1 lesion (0.7%). For adjunctive PTCA, 1.2±0.5 balloons were used per lesion, and the average balloon diameter was 3.6±0.5 mm.

Lumen Morphology After Intervention

A smooth lumen contour was observed in 50 lesions (31.6%) after TEC atherectomy and in 78 lesions (50%) after final angiography (Fig 2). Angiographic evidence for dissection was detected in 54 lesions (34.5%) after TEC atherectomy, including mild or moderate dissection (grade 1 or 2) in 28 lesions (18%), severe dissection with high-grade residual stenosis (grade 3) in 18 lesions (11.4%), and severe dissection with total occlusion of the vessel in 8 lesions (5.1%). After final angiography, however, angiographic dissection was detected in 26 lesions (16.4%), including mild or moderate dissection in 24 lesions (15.2%) and severe dissection with high-grade residual stenosis or total occlusion in 1 lesion each (1.2%). New filling defects consistent with thrombus and/or dissection were identified by angiography in 22 lesions (13.9%), all after TEC atherectomy. These filling defects persisted in 5 lesions (3.2%) despite overlapping balloon inflations, intracoronary thrombolytic therapy, and intravenous dextran.

Angiographic Complications

Significant angiographic complications were evident in 33 lesions (20.7%) immediately after TEC atherectomy, and additional angiographic complications were directly attributed to PTCA in 8 lesions (5%) (Table 3). Distal embolization (of atheromatous debris in 15 lesions and air embolism in 4 lesions) occurred in 19 lesions (11.9%): immediately after TEC atherectomy in 18 lesions (11.3%) (Fig 3) and after adjunctive PTCA in 1 lesion (0.6%). Despite further balloon inflations, intracoronary nitroglycerin, and thrombolytic agents, angiographic evidence for distal embolization persisted in 5 lesions (3.2%) and was associated with myocardial infarction in 3 patients. No-reflow was observed in 14 lesions (8.8%): immediately after TEC atherectomy in 7 lesions (4.4%) and after adjunctive PTCA in 7 lesions (4.4%) (Figs 3 and 4). Normal antegrade flow could not be reestablished in 10 lesions (6.3%) despite further balloon inflations, large doses of intracoronary nitroglycerin (0.2 to 1.2 mg), thrombolytic therapy, intravenous low-molecular-weight dextran, and intracoronary verapamil in several cases. Severe dissection leading to abrupt closure occurred in 8 lesions (5.0%), all imme-

<table>
<thead>
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<th>Table 2. Assessment of Antegrade Flow in 158 Saphenous Vein Graft Lesions After TEC Atherectomy With or Without PTCA</th>
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<tbody>
<tr>
<td><strong>TIMI Grade</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

TEC indicates transluminal extraction coronary; PTCA, percutaneous transluminal coronary balloon angioplasty; and n, number of lesions.

*See Reference 5 for definitions.
TABLE 3. Cause and Outcome of Angiographic Complications in 158 Saphenous Vein Graft Lesions After TEC Atherectomy and Adjunctive PTCA

<table>
<thead>
<tr>
<th>Complication</th>
<th>Due to TEC Atherectomy</th>
<th>Due to PTCA</th>
<th>Persist After PTCA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>18</td>
<td>11.3*</td>
<td>1</td>
</tr>
<tr>
<td>No-reflow</td>
<td>7</td>
<td>4.4</td>
<td>7</td>
</tr>
<tr>
<td>Abrupt closure</td>
<td>8</td>
<td>5.0</td>
<td>0</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tamponade</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>20.7</td>
<td>8</td>
</tr>
</tbody>
</table>

TEC indicates transluminal extraction coronary; PTCA, percutaneous transluminal coronary balloon angioplasty; and n, number of lesions.

*Distal embolization of atheromatous debris (n=14) and air (n=4).

Clinical Complications

Among 146 patients treated with TEC atherectomy in saphenous vein grafts, there were 3 in-hospital deaths (2.0%), all in patients with target lesions in degenerated saphenous vein bypass grafts (mean age, 9 years). One of these patients died despite emergency bypass surgery, and the other 2 patients (who were not felt to be candidates for emergency surgical revascularization because of poor LV function and lack of suitable conduits) died despite institution of emergency percutaneous cardiopulmonary support (CPS). Coronary artery bypass surgery was performed in 1 patient who died (0.7%), as described above. Abrupt closure or no-flow resulted in Q wave myocardial infarction in 3 patients (2.0%) and non-Q wave myocardial infarction in 4 patients (2.7%). (See Table 4.)

Percutaneous hemodynamic support was required in 10 patients (6.8%), including emergency placement of an intra-aortic balloon pump in 7 patients (4.7%), emergency CPS in 2 patients (1.4%) as described above, and planned CPS in 1 patient (0.7%) with congestive heart failure and poor left ventricular function. Vascular injury occurred in 9 patients (6.1%), requiring vascular surgical repair in 2 patients (1.4%) and blood transfusion in 7 patients (4.7%). Hemorrhagic cerebral infarctions occurred several days after successful atherectomy in 4 patients (2.7%) with poor LV function and severely degenerated vein grafts who required adjunctive intracoronary urokinase during atherectomy. Transient ventricular tachycardia or fibrillation occurred in 4 patients (2.7%) and was managed successfully by electric shock. Contrast-induced renal failure occurred in 2 patients (1.4%) who did not require dialysis.

Correlates of Angiographic and Clinical Complications

Univariate analysis was performed on 40 demographic, clinical, and angiographic variables to identify correlates of angiographic and clinical complications. Univariate correlates of no-reflow included thrombus (P<.05) and baseline TIMI flow ≤1 (P<.05), and univariate correlates of distal embolization included de novo lesion (P<.05) and lesion location in the midbody of the vein graft (P<.05). There were no univariate correlates of abrupt closure. However, none of these lesion characteristics were significantly correlated with these angiographic complications when analyzed with multivariate techniques. If a composite angiographic end point was considered to be the development of one or more of these complications (no-reflow, distal embolization, or abrupt closure), de novo lesion, lesion location in the midbody of the vein graft, and the presence of thrombus (all P<.05) were all correlated with the composite angiographic end point by univariate techniques, but none of these characteristics were statistically significant by multivariate techniques.

According to a composite clinical end point defined as in-hospital death, emergency bypass surgery, or myocardial infarction, independent correlates of adverse clinical outcome included female sex (P<.01) and history of hypertension (P<.05). However, the strongest independent correlate (P<.001) of a severe clinical complication was the development of one of the composite angiographic end points (no-reflow, distal embolization, or abrupt closure) immediately after TEC atherectomy.

Follow-up

Among the original cohort of 146 patients, 18 were excluded from clinical follow-up (11 patients had persistent total occlusion of the target vessel at the end of the initial procedure, and TEC atherectomy was not performed in 7 patients because of initial technical failure). Complete clinical follow-up was available in 118 (92%) of 128 eligible patients at an interval of 6.0±2.5 months after discharge.
According to the patients, anginal symptoms were reported as improved in 74 patients (63%), unchanged in 33 patients (21%), and worse in 19 patients (16%) compared with anginal symptoms immediately before atherectomy. According to the Canadian Cardiovascular Society classification, anginal symptoms were classified as class 0 (asymptomatic) in 54 patients (46%), class I in 8 patients (7%), class II in 16 patients (14%), class III in 22 patients (18%), and class IV in 18 patients (15%). Late cardiac outcome included recurrent angina treated with medical therapy in 21 patients (18%), repeat percutaneous intervention on the original target lesion (either PTCA or another new device) in 31 patients (26%), repeat coronary artery bypass surgery in 6 patients (5%), Q wave myocardial infarction in 5 patients (4%), and late cardiac death in 8 patients (7%). Therefore, clinical restenosis occurred in 50 patients (42%).

Among the original cohort of 158 lesions, 26 were excluded because of persistent total occlusion of the target vessel at the end of the initial procedure (11 lesions), initial technical failure (7 lesions), and patient death before follow-up angiography could be obtained (8 patients with 8 lesions). Angiographic follow-up was available in 105 (80%) of 132 eligible lesions. Quantitative angiography revealed a minimal lumen diameter of 1.3±1.0 mm, a reference diameter of 3.7±0.9 mm, a lesion length of 9±7 mm, and a diameter stenosis of 65±27%. If restenosis is defined as a diameter stenosis >50%, then 72 lesions (69%) had angiographic evidence for restenosis at the time of follow-up, including 30 lesions (29%) with total occlusion of the original target lesion (Fig 5). Among these patients with late total occlusion, only 19 required late revascularization (percutaneous intervention or bypass surgery), and there were no late myocardial infarctions. The only correlate of late total occlusion was the development of one of the composite angiographic end points immediately after TEC atherectomy ($P=.02$).

Discussion

Patients who have undergone previous coronary bypass surgery represent an increasing proportion of patients considered for percutaneous revascularization. Because of the disappointing acute and long-term results of PTCA, several new technologies are being considered as alternative strategies for revascularization of patients with stenoses in saphenous vein bypass grafts. Several randomized studies are either in progress or preparation to evaluate the merits of stents and directional atherectomy compared with balloon angioplasty. Although not currently being evaluated in a randomized trial, TEC atherectomy seems to offer many theoretical advantages over other percutaneous devices for treatment of stenotic vein grafts.

Mechanism of Action

TEC atherectomy relies on cutting and aspiration to remove atheroma, thrombus, and other debris (Fig 2) and therefore is unlike other atherectomy devices such as directional atherectomy (which relies on tissue cutting, storage, and retrieval) or high-speed mechanical rotational atherectomy with the Rotablator (which relies on tissue pulverization and abrasion). Unlike the discrete tissue fragments that are usually retrieved by directional atherectomy, TEC atherectomy results in a slurry of blood and debris that does not lend itself easily to tissue analysis to confirm removal of either atheroma or thrombus. Angiographically, it was frequently difficult to distinguish tissue removal from "Dotter" effect, and in one study, no tissue (except red blood cells) was identified in 93% of TEC atherectomy specimens analyzed by light microscopy. However, although another preliminary study using coronary angioscopy does not suggest a major role of tissue removal, TEC atherectomy does appear to be an effective device for aspiration of recent thrombus. In light of the ability of TEC atherectomy to aspirate thrombus,
the observation of new or persistent filling defects in 13.9% of lesions was confusing. However, further angioscopic observations suggest that TEC atherectomy frequently leads to intimal dissection and may "unroof" superficial atheroma and expose underlying organized thrombus.⁸ These angioscopic observations may explain the appearance of new filling defects and the potential for distal embolization immediately after TEC atherectomy or adjunctive angioplasty (or other devices such as directional atherectomy).
FIG 4. Angiogram of a saphenous vein graft to the distal right coronary artery in the left anterior oblique projection. Top left, Baseline angiography revealed total occlusion of the proximal portion of the graft (arrowhead). The occlusion was crossed with a guide wire, and the patient underwent an overnight infusion of urokinase (100 000 U/h) through an infusion wire (arrows). Top middle, After urokinase infusion, the graft remained occluded (black arrowhead), but distal injection through the infusion wire revealed a severe stenosis in the midbody of the vein graft with distal thrombus (white arrowheads). Top right, Transluminal extraction coronary (TEC) atherectomy was performed with a 7.5F cutter. Bottom left, After TEC atherectomy, there was improvement in the stenosis (black arrowhead) but poor distal runoff consistent with no-reflow (white arrowheads). Bottom middle, Multiple overlapping balloon inflations were performed throughout the entire graft, and additional urokinase was administered. Bottom right, After adjunctive percutaneous transluminal coronary angioplasty and urokinase, the bypass graft was patent with normal antegrade flow, but the distal vessel remained hazy. Several months later, follow-up angiography (not shown) revealed total occlusion of the graft.

Angiographic Results of TEC Atherectomy

Although the TEC atherectomy catheter successfully crossed 91% of lesions, the extent of lumen enlargement was disappointing. After TEC atherectomy, the average residual lumen diameter was 1.5±0.7 mm, which was similar to the residual lumen diameter of 1.6±0.6 mm reported by Popma and coworkers.9 Although the post-TEC atherectomy diameter stenosis of 58±20% was greater than the 50±22% residual stenosis reported by Popma, this difference is probably a result of the larger reference diameter in our study (3.8±0.9 compared with 3.2±0.6 mm).

In evaluation of the success of new devices in terms of residual diameter stenosis, it is important to consider the relative size of the device compared with the reference vessel (ie, D/A ratio).4,10 The D/A ratio of 0.6±0.1 is consistent with substantial undersizing of

<table>
<thead>
<tr>
<th>Complication</th>
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<th>%</th>
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<tr>
<td>Death</td>
<td>3</td>
<td>2.0</td>
</tr>
<tr>
<td>CABG</td>
<td>1</td>
<td>0.7</td>
</tr>
<tr>
<td>Q wave MI</td>
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<td>2.0</td>
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<tr>
<td>Non-Q wave MI</td>
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<td>2.7</td>
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<tr>
<td>CPS</td>
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<td>2.0</td>
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<tr>
<td>IABP</td>
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<td>4.7</td>
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<tr>
<td>Vascular repair</td>
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<td>1.4</td>
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<tr>
<td>Ventricular arrhythmia</td>
<td>4</td>
<td>2.7</td>
</tr>
<tr>
<td>Renal failure</td>
<td>2</td>
<td>1.3</td>
</tr>
</tbody>
</table>

TABLE 4. Clinical Complications After Transluminal Extraction Coronary Atherectomy and PTCA in 146 Patients

PTCA indicates percutaneous transluminal coronary balloon angioplasty; n, number of lesions; CABG, emergency coronary artery bypass graft surgery; MI, myocardial infarction; CPS, percutaneous cardiopulmonary support; and IABP, intra-aortic balloon pump.
TEC atherectomy cutters (because of the lack of availability of cutter diameters >2.5 mm) and the application of TEC atherectomy to large vein grafts (mean reference diameter, 3.8±0.9 mm). Nevertheless, when conventional definitions were applied, device success was achieved in only 39.2% of lesions (defined as a decrease in diameter stenosis ≥20%), and only 36% of lesions had residual stenoses ≤50% after TEC atherectomy (Fig 1B). However, the efficiency of lumen enlargement (RLD/D ratio, 0.69±0.33) for TEC atherectomy is similar to that reported for conventional PTCA but is less than the efficiency of Rotablator atherectomy (RLD/D ratio, 0.91), laser balloon angioplasty (RLD/D, 0.8), and stenting (RLD/D, 1.0).4,11

Role of Adjunctive PTCA After TEC Atherectomy

Despite the similar efficiency of lumen enlargement for TEC atherectomy and PTCA, the lack of availability of larger cutters mandates the frequent use of adjunctive PTCA. The frequency of adjunctive PTCA was 91.2%, which was similar to the use of PTCA in 86% of lesions in the study by Popma et al. However, PTCA was used to further enlarge lumen dimensions in 72.8% of lesions (Figs 2 and 3), to salvage technical failures in 8.8% of lesions, and to manage TEC atherectomy–induced vessel occlusion in 9.5% of lesions (Fig 4). Furthermore, PTCA resulted in improvement in lumen contour (Fig 2) and reduction in the incidence of severe dissection. Finally, angiographic success increased from 39% after TEC atherectomy alone to 84% after adjunctive PTCA (Fig 1B), which compares favorably with recent reports of balloon angioplasty of saphenous vein grafts.12-18

Safety of TEC Atherectomy in Vein Grafts

The complexity of lesions in this study is reflected in the baseline lesion characteristics, which include old (8.3 years) and degenerated grafts (17%) (Fig 2), aortostial location (21%), intraluminal filling defects consistent with thrombus (28%) (Figs 3 and 4), and abnormal contour with marked irregularity and ulceration (18%). In reviewing the available literature, it is difficult to find any reports of lesions with similar characteristics; therefore, the complications must be considered in light of the complexity of the target lesions. Furthermore, many of these patients were referred by other interventional cardiologists who refused to consider PTCA, directional atherectomy, or stenting for these stenoses.

Nevertheless, despite these considerations, the overall incidence of complications was high (Table 3, Figs 3 and 4). Angiographic complications occurred in 25.7% of lesions, including 20.7% after TEC atherectomy and an additional 5% after adjunctive PTCA. The incidence of distal embolization was almost 12% (one quarter were due to significant air embolism, which may have resulted from improper technique in attaching and flushing the hemostatic valve and sidearm adapter), which was higher than after PTCA (3% to 7%).15,18 stenting (0% to 6%),19-22 and excimer laser angioplasty (4.4%)19 but similar to directional atherectomy (7% to 11.5%) in vein grafts.23,25,26 The incidence of acute graft occlusion due to abrupt closure (5%) and no-reflow (8.8%) was also higher than expected for PTCA in vein grafts but similar to other preliminary reports of directional atherectomy and TEC atherectomy in old vein grafts.27,28 Despite adjunctive PTCA, angiographic complications persisted in 10.1% of lesions (Table 3).

Despite these angiographic complications, the incidence of serious clinical complications compares favorably with recent reports of PTCA in vein grafts. The incidences of in-hospital death (2%), emergency bypass surgery (0.7%), and myocardial infarction (4.7%) are similar to the incidences of death (0% to 5%), emergency bypass surgery (0% to 3%), and myocardial infarction (0% to 9%) for PTCA.12-18 These clinical complications also compare favorably with those reported after stenting, directional atherectomy, and excimer laser angioplasty in vein grafts.19-26 Although repeat coronary artery bypass surgery appears to be an effective long-term strategy, perioperative mortality ranges from 2.0% to 11.7%, depending on the degree of left ventricular dysfunction and completeness of revascularization.29-36

Restenosis

Using the conventional dichotomous definition of restenosis, the 6-month angiographic restenosis rate after TEC atherectomy was 69% (Fig 5), which is considerably higher than the 22% to 55% restenosis rates reported for balloon angioplasty37,38 and the 21% to 47% restenosis rates for stenting.19-23 Although this restenosis rate is considerably higher than the 31% to 47% restenosis rates reported in some studies of directional atherectomy and excimer laser angioplasty in vein grafts,23,24 it is similar to the 60% to 63% restenosis rates reported in other studies.25,26 Randomized trials now in progress may provide additional information about the relative value of balloon angioplasty, directional atherectomy, and stenting. Although the perioperative mortality rates for repeat coronary artery bypass surgery are twofold to fourfold higher than for initial elective operations, 5- and 10-year survival rates are 84% to 94% and 75%, respectively.29-36 However, only 50% of patients are free of angina, and 5-year event-free survival (in terms of death, myocardial infarction, angioplasty, or third operation) is only 64%,30,33 A disconcerting finding was the observation that 30% of lesions were totally occluded at the time of angiographic follow-up (Fig 5), although none of these were associated with acute myocardial infarction. Although the need for target vessel revascularization and the general clinical status have been proposed as a superior method for assessing clinically significant restenotic lesions,39 target vessel revascularization was not required in one third of these total occlusions, and more than half of these patients were minimally symptomatic. The lack of need for late revascularization and the absence of symptoms in this subgroup may suggest that these lesions did not require initial revascularization by TEC atherectomy, that the occlusions were well collateralized, or that the concept of target vessel revascularization may be limited in the setting of postbypass multivessel disease.

Recommendations for the Use of TEC Atherectomy

This is a retrospective observational study; therefore, definitive recommendations about the use of TEC atherectomy cannot be made with certainty. However, although the theoretical benefits of the TEC atherectomy catheter suggest that this device could be the
treatment of choice for degenerated vein grafts, the frequent development of angiographic complications and the high incidence of restenosis raise a reasonable question as to whether any percutaneous technique should be applied to such lesions. Furthermore, the frequent need for adjunctive angioplasty (to enlarge lumen dimensions or to manage complications) will certainly raise procedural costs, and the combination of TEC atherectomy plus balloon angioplasty has not been shown to be superior to angioplasty alone. Until further randomized studies in vein grafts are available, TEC atherectomy might be considered for debulking large but focal thrombi, followed by either balloon angioplasty, directional atherectomy, or stenting, to achieve maximal lumen enlargement and provide the best opportunity for long-term benefit. However, the application of TEC atherectomy to diffusely diseased and severely degenerated vein grafts should be used cautiously and only after repeat bypass surgery has been strongly considered.

Limitations of the Study

This is a retrospective nonrandomized observational study, and as such, was not designed to identify the best treatment for patients with vein graft stenoses. Also, these data are based on the first generation TEC atherectomy cutters, and it is possible that future design modifications and increased operator experience may improve the immediate and long-term results and safety of the procedure.

Conclusions

In patients with stenoses in saphenous vein bypass grafts, TEC atherectomy is limited by the small size of the device and suboptimal angiographic results, often requiring adjunctive balloon angioplasty. Although the incidence of serious clinical complications is similar to that of other percutaneous interventions in vein grafts, there is a high incidence of restenosis and late vessel occlusion. In patients with old, diffusely degenerated vein grafts, TEC atherectomy may be considered if repeat coronary bypass surgery is not a reasonable therapeutic alternative. Prospective randomized studies are needed to determine the best revascularization strategy for these patients.

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References


Clinical and angiographic results of transluminal extraction coronary atherectomy in saphenous vein bypass grafts.

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