Relation of Clinical Presentation, Stenosis Morphology, and Operator Technique to the Procedural Results of Rotational Atherectomy and Rotational Atherectomy–Facilitated Angioplasty

Stephen G. Ellis, MD; Jeffrey J. Popma, MD; Maurice Buchbinder, MD; Irving Franco, MD; Martin B. Leon, MD; Kenneth M. Kent, MD; Augusto D. Pichard, MD; Lowell F. Satler, MD; Eric J. Topol, MD; Patrick L. Whitlow, MD

Background  Rotational atherectomy using the Rotablator has recently become available to treat coronary stenoses. This study was performed to determine the relation of patient characteristics, stenosis morphology, and operator technique to procedural outcome to gain insight into which patients might be best treated with this device.

Methods and Results  Four hundred stenoses from 316 patients randomly selected from the initial Rotablator experience at three major referral institutions were analyzed. Angiographic data were assessed at a central angiographic laboratory using standardized morphological criteria and caliper measurement. Patients were somewhat more elderly than most percutaneous transluminal coronary angioplasty (PTCA)-treated groups (mean age, 64±11 years), 74% were men, and the lesions treated were often complex (modified American College of Cardiology/American Heart Association lesion type A, 24%; B1, 40%; B2, 30%; and C, 6%). Elective adjunctive PTCA was used for 82% of stenoses treated. Procedural success was achieved in 89.8% of stenoses (93.5% if results with creatine kinase two to three times normal are not counted as failures), and major ischemic complications (death, 0.3%; non-Q-wave myocardial infarction, 5.7%; Q-wave myocardial infarction, 2.2%; or emergency bypass surgery, 0.9%) occurred in 8.9% of patients. Complications were due to epicardial coronary obstruction in 3.8% of patients and to delayed coronary runoff (“slow reflow”) in 5.1% of patients. Procedural failure was correlated independently with outflow obstruction (success rate, 64%; odds ratio for failure, 5.4; multivariate P=.002), lesion irregularity (76%; odds ratio, 3.3; P=.003), stenosis bend ≥60° (73%; odds ratio, 3.7; P=.03), and female sex (84%; odds ratio, 2.4; P=.03). Ischemic complications were correlated independently with lesion length (≥50% narrowing) ≥4 mm (complication rate, 12%; odds ratio, 3.6; multivariate P=.005), right coronary artery stenosis (13%; odds ratio, 2.4; P=.02), stenosis bend ≥60° (27%; odds ratio, 6.1; P=.03), and female sex (13%; odds ratio, 3.0; P=.04). Slow reflow was correlated with total burling duration (odds ratio, 1.005/s; multivariate P=.001), right coronary artery stenosis (incidence, 17%; odds ratio, 4.5; P=.009), and to a lesser extent with recent myocardial infarction in the treated territory (44%; odds ratio, 4.3; P=.08).

Conclusions  The procedural outcome of rotational atherectomy is highly correlated with stenosis morphology and location and sex of the patient. After stratification for these parameters, overall outcome with the Rotablator appears to be similar to that with balloon angioplasty and other competing techniques. Short-term outcome with specific subsets of patients may be superior with the Rotablator (calcified stenoses), but this technique might best be avoided in some patients (those with irregular or possibly thrombus-containing stenoses, highly angulated stenoses, and possible right coronary artery stenoses or those associated with impaired distal runoff caused by a recent myocardial infarction or manifest by a fixed thallium defect). (Circulation. 1994;89:882-892.)

Key Words  • angioplasty • stenosis

Although percutaneous transluminal coronary angioplasty (PTCA) has revolutionized the treatment of patients with coronary artery disease since its introduction in 1977, recent studies suggest that the technique is limited by a 6% to 7% incidence of abrupt coronary closure and a 38% to 50% incidence of late restenosis.3,4 Recently, several percutaneous atherectomy, stent, and laser devices have been introduced with the hope that these limitations of PTCA might be overcome. Although final assessment of the potential benefit of these devices must await results of randomized trials, such trials and initial patient treatment are best guided by unbiased assessment of procedural and long-term outcome from multiple centers in a standardized manner. To date, the results with rotational atherectomy have not been so analyzed.

We performed standardized morphological and quantitative coronary dimensional analysis on 316 patients with 400 treated stenoses treated with the Rotablator (Heart Technology, Bellevue, Wash) at one of three high-volume interventional centers (1) to assess potential subgroups of patients who might have particularly good or poor procedural outcome with rotational atherectomy and to aid in initial comparison of proce-
dural outcome with PTCA and other increasingly well-characterized alternative procedures and to assess technical factors possibly related to outcome.

Methods

Patient Population

A registry of consecutive Rotablator procedures performed at each of the three participating institutions (Cleveland Clinic Foundation, University of California at San Diego, and Washington Hospital Center) was obtained. No patient subgroup was excluded except for the first 20 procedures performed at the University of California at San Diego when the device was undergoing its first very early clinical testing. Four hundred target stenoses were then randomly selected by random number generator for review. Analysis of this number of stenoses has been shown by this core laboratory to provide sufficient numbers for morphological subset analysis. Each site contributed 80 or more treated stenoses for analysis. These procedural results reflected the relatively early experience with the Rotablator from October 1989 through April 1992.

Patient and lesion selection for treatment during that time varied somewhat from institution to institution, but stenoses were most often considered for the technique if they contained angiographically apparent calcium or had restenosis after PTCA. The procedure was performed after each patient had given informed consent under the guidelines of the individual institutional review boards.

Technique of Rotational Atherectomy

The technique of rotational atherectomy with this device has been described previously. Briefly, after pretreatment with 80 to 325 mg aspirin and a calcium channel blocker, an 8-10F sheath is placed percutaneously into the femoral artery and a 6-8F sheath is placed in the femoral vein using standard Seldinger technique. Heparin (usually 10 000 to 15 000 U bolus and 800 to 1200 U/h infusion) is administered and titrated to achieve an activated clotting time of >300 seconds. A 5-8F temporary pacing wire is inserted into the right ventricular cavity, and adequate pacing thresholds are obtained before all right coronary artery procedures and some left coronary artery procedures to treat possible transient bradycardias during treatment. A standard high-flow 8-10F guiding catheter is then used to intubate the appropriate coronary ostium. Next, a specially designed, 300-cm-long, 0.009-in.-diameter guide wire (Heart Technology) is steered through the stenosis and positioned distally in the artery. A 1.25- to 2.5-mm-diameter, air-turbine driven, abrasive burr (Rotablator), designed to rotate at 180 000 to 200 000 rpm, is advanced over the guide wire and positioned proximal to the stenosis to be treated. Sometimes, before activating and advancing the burr, a dopamine infusion of 3 to 10 \( \mu \text{g} / \text{kg} \cdot \text{min}^{-1} \) is begun to increase the blood pressure to potentially optimize clearance of the particulate debris from the artery treated. The stenosis is then crossed with the activated Rotablator, and device time is withdrawn into the guiding catheter. Angiography is then performed to determine adequacy of the treatment result. In general, a 0% to 30% residual diameter stenosis after intracoronary nitroglycerin (100 to 200 \( \mu \text{g} \)) was sought. Larger burrs and/or balloon angioplasty is often required to achieve this result and can be delivered to the stenosis without removing the exchange-length guide wire. Most operators considered balloon angioplasty (as a final treatment to optimize the dimensional result) to be an integral part of the usual procedure. See Figs 1 and 2.

After completion of the procedure, patients were monitored in an intensive care unit or postprocedural ward. Patients were medicated with oral aspirin, a calcium channel blocking agent, and/or a nitrate preparation and received continued intravenous heparin overnight. Creatine kinase levels with isoenzyme determination were obtained several times in the first 24 hours after the procedure, usually immediately thereafter and for every 6 to 8 hours and also in the event of symptoms suggestive of ischemia afterward. A 12-lead ECG was obtained immediately after, 12 to 24 hours after, and in the event of suspected coronary ischemia.

Clinical and Procedural Variables

Clinical variables (patient age, current smoking, diabetes, sex, hypercholesterolemia, hypertension, patient sequence number, prior myocardial infarction in the distribution of the treated stenosis, prior restenosis at the treatment site, reversible or fixed thallium defect corresponding to the treated stenosis, unstable angina) and procedural variables (adjunctive use of PTCA, burr sizes, and Rotablator activation times [first pass, maximum, and total duration]) were obtained from the case report forms provided by the individual investigators.

Angiographic Analyses

The following parameters were determined or measured with calipers using guide catheter calibration from a 7x optically magnified image of each stenosis treated at the central angiographic laboratory at the Cleveland Clinic Foundation: bend stenosis, bend stenosis with outwardly eccentric lumen, bifurcation, branch distribution score (each branchtery distal to the treated stenosis being scored as small, 1; medium, 2; large, 3), burr to “normal” artery ratio (first burr and maximum size burr), eccentricity, estimated left ventricular mass distal to the treated stenosis, calcium treated. Bradycardias (evaluated in location and severity: proximal or within the stenosis; none apparent; mild, artery motion required to visualize; moderate to severe, readily apparent on cineangiography; estimated atheroma burden [measured percent area stenosis times lesion length ≥50% diameter stenosis times normal artery diameter]), exit bend (≥45° bend in the artery in an unforeshortened projection immediately distal to the target stenosis such that the burr might impale the artery as it exits the treated stenosis), hinge stenosis (target stenosis located at a point where the artery appeared to bend between end systole and end diastole ≥15°), inflow obstruction (untreated stenosis ≥70% proximal to the target stenosis), irregular stenosis, stenosis length (measured in millimeters four different ways: shoulder-to-shoulder, length ≥50% diameter stenosis length ≥70% diameter stenosis, summed length ≥50% diameter stenosis in all stenoses in a given artery), modified American College of Cardiology/American Heart Association (ACC/ AHA) lesion score, myocardial infarction (creatine kinase changes) (evaluated because of any deviation from "normal" artery diameter, ostial stenosis, outflow tract obstruction (untreated stenosis ≥70%) distal to the target stenosis, pretreatment percent diameter stenosis, proximal tortuosity, stenosis location, and thrombus. All definitions were prospectively defined, and many have been published previously. Newly defined variables were usually evaluated because the anecdotial early experience with this device suggested a possible relation between the variable and complications.

Outcome Variables

The following outcome-related variables were obtained from the case report forms: procedure-related death while in-hospital, need for emergency bypass surgery, myocardial infarction (creatine kinase greater than twice the upper limit of normal with MB fraction ≥5% or development of pathological Q waves on ECG), Q-wave myocardial infarction, and ECG evidence of ischemia (ST segment elevation or depression, T-wave changes) immediately after the procedure. The following variables were evaluated at the central angiographic review of the participating patients corresponding to the treated arteries: death, abrupt closure, the next two pages. Angiograms from an 85-year-old woman with prior bypass surgery and restenosis of heavily calcified sequential left anterior descending coronary stenoses are shown on the following pages. A, Right anterior oblique view of the artery before treatment; B, Rotablator burr initiating treatment (arrow notes dense arterial calcification); C, follow-up balloon dilatation; and D, final satisfactory result.
laboratory: abrupt coronary closure (Thrombolysis In Myocardial Infarction [TIMI] flow ≤2 caused by increase in stenosis severity after treatment), cause of abrupt coronary closure (eg, guide wire, Rotablator, or PTCA balloon), coronary perforation, posttreatment percent diameter stenosis, and new “slow reflow” (delayed egress of contrast dye [contrast clearance ≥2 SD outside of vessel-specific post-PTCA normal range]. Dr Stephen Ellis, Cleveland Clinic Core Angiographic Laboratory, unpublished observations) noted on injection after Rotablator use in the absence of a proximal or distal ≥70% stenosis, left anterior descending (>2.0 cardiac cycles), left circumflex (>1.75 cardiac cycles), and right coronary artery (>2.25 cardiac cycles).

Primary end points of the analysis were prospectively defined as (1) procedural success (TIMI 3 flow, <50% final diameter stenosis and no death, emergency bypass surgery, or myocardial infarction), (2) procedural complications (death, emergency bypass surgery, or myocardial infarction), (3) slow reflow, and (4) coronary perforation. Any apparent possible discrepancies between angiographic findings and clinical end points were resolved by direct source documentation and discussion with the investigator involved.

Statistical Analyses

Normally distributed continuous data are expressed as mean±SD. Non-normally distributed continuous data are expressed as median per interquartile range. χ² analyses were used to test differences in categorical variables, with Yates' corrections where appropriate, and unpaired Student's t tests and Mann-Whitney tests were used to assess differences in continuous variables. Risk of procedural failure and complications are expressed as an odds ratio with 95% confidence intervals (CI). To express odds ratios for continuous variables, they were dichotomized at their median value. Multiple logistic regression analyses were performed to determine the independent correlates of each of the primary study end points using SYSTAT software (version 5.03, SYSTAT, Inc, Evanston, Ill, 1990). Since procedural technique may have been in part determined by clinical and anatomic presentation, procedural variables were tested for independent correlation with outcome only after forcing significant clinical and anatomic correlates into the regression equation. Statistical significance was accepted at the P≤.01 level and possibly at the P=.05 level (two-tailed testing), but P values ≤.15 are reported.
Results

Patient Demographics

Patient and stenosis characteristics are enumerated in Tables 1 and 2. Patient characteristics are typical for reported angioplasty populations except for the apparently older age (64 ± 11 years) of this group. Treated stenoses are remarkable for a relatively high incidence of calcification (58%), prior restenosis (37%), and ostial location (17%). Stenosis complexity by the modified ACC/AHA score was quite varied, with 24% being simple type A, 40% being type B1, 30% being type B2, and 6% being complex type C lesions.

Procedural Technique

Procedural technique varied somewhat from operator to operator. Whereas first and maximum burr to artery ratios were generally similar throughout (0.61 ± 0.11 and 0.68 ± 0.13, respectively), speed of burr advancement was highly variable (10/4.25 seconds/mm length, 32/15.81 seconds maximum duration, and 99/56,246 total seconds). Ejective adjunctive PTCA to improve luminal results was used in 82% of lesions.

Total burring duration and adjunctive PTCA use decreased significantly with increased operator experience (246/122,294 seconds versus 94/56,228 seconds and 94% versus 81% for the first 20 cases at each site compared with the later experience, P = .004 for burring duration and P = .02 for PTCA use), but the other parameters did not change over time. Nonelective PTCA and stenting to treat threatened or true coronary closure were used in 9 (2.3%) and 2 (0.5%) stenoses, respectively.

Procedural Outcome

Procedural success and the incidence of major adverse outcomes are shown in Table 3. In general, complications were uncommon and success rates were high.

Correlates of Procedural Success

The relation between selected variables and procedural success is displayed in Table 4. There were 27 failures caused by complications and 14 failures without complications (failure to decrease stenosis to <50%, 5; failure to cross stenosis with a guide wire, 5; failure to cross the stenosis with the Rotablator, 4). Of the variables available before the procedure, outflow tract obstruction (multivariate P = .002), stenosis irregularity (P = .003), stenosis bend ≥60° (P = .028), and female sex (P = .035) were independent correlates of procedural failure. After accounting for the effect of these variables, no procedural variables correlated with outcome, although outcomes from the first 20 procedures at each institution were somewhat less satisfactory (success, 84%; complications, 16%; univariate P = NS and P = .04, respectively).

Correlates of Major Ischemic Complications

The independent preprocedural correlates of major ischemic complications (death, any myocardial infarction, or emergency bypass surgery) are outlined in Table 5 and were lesion length ≥4 mm (by the 50% definition) (P = .005), right coronary artery stenosis (P = .021), stenosis bend ≥60° (P = .033), and female sex (P = .044). Other variables approaching significant independent correlation were absence of stenosis calcium (odds ratio, 1.78; 95% CI, 0.94 to 3.35; P = .08) and the presence of a fixed thallium defect corresponding to the area treated (odds ratio, 8.07; 95% CI, 0.80 to 82.07; P = .08; data available for only 91 of 400 lesions treated). Once the significant preprocedural variables were
because

Age,

The variable

was

immediately

No

obstruction

confounding

emergency

proached independent

large

plications excluding non-Q-wave myocardial

infarction

into

forced into the regression equation, no procedural variable approached correlation with complications.

The independent correlates of major ischemic com-

plications excluding non–Q-wave myocardial infarction were lesion length ≥4 mm (odds ratio, 7.41; P = .04) and large normal vessel diameter (odds ratio, 4.64/mm; P = .04). The variable of “no stenosis calcium” ap-

proached independent correlation (odds ratio, 5.85; P = .08). Because of the infrequent occurrence of death, Q-wave infarction, and emergency bypass surgery, the power to detect meaningful correlations with this outcome is limited. See Fig 3.

**Correlates and Outcome of Coronary Perforation**

Coronary perforation occurred during treatment of 6 (1.5%) stenoses and resulted in abrupt coronary closure in 4 instances, tamponade in 4, emergency bypass surgery in 2, non–Q-wave infarction in 2, death in 1, and Q-wave infarction in 1.

Although the power to predict outcome was weak because of the low incidence of the event, multivariate logistic regression found that the variables appearing to correlate with perforation were right coronary artery stenosis (odds ratio, 7.3; 95% CI, 0.8 to 70.1; P = .08) and hinge stenosis (odds ratio, 4.0; 95% CI, 0.6 to 25.9; P = .14). Age, sex, burr size, and burring speed appeared to be less important.

**Correlates and Outcome of Slow Reflow**

Slow reflow was documented after treatment of 28 of 308 stenoses (9.1%) for which it could be evaluated. This variable could not be assessed for 92 stenoses because of failure to film for the 1.5 to 2 cardiac cycles after contrast injection requiring assessment of contrast egress in 73 (79%) and because of proximal coronary obstruction confounding flow evaluation in 19 (21%).

Slow reflow was associated with a 7% Q-wave infarction incidence and a 25.9% non–Q-wave infarction incidence. No patient with slow reflow died or required emergency bypass surgery, and the median and interquartile range of creatine kinase levels in these patients was 112 (59,215). ECG evidence of ischemia was evident immediately after the procedure in 42.8% of patients with angiographic slow reflow (25% ST depression with or without T-wave changes; 18% T-wave changes only) compared with 16.9% of patients without vessel closure or slow reflow (8% ST depression; 9% T-wave depression) (P ≤ .001).

Independent correlates of slow reflow by logistic regres-

sion are shown in Table 6 and were found to be total seconds of burring (P = .001) (see Fig 4), right coronary stenosis (P = .009), and to a lesser extent, myocardial infarction in the stenosis territory within 2 weeks of the procedure (P = .08). Burring to artery ratio (for first burr size, odds ratio was 0.04 to 9.8, P = .61; for maximum burr size, odds ratio was 0.03 to 11.6, P = .72), lesion length (for shoulder-to-shoulder measurements, odds ratio was 1.01 to 1.15/mm, P = .03; for length ≥50% stenosis, odds ratio was 1.0 to 1.2/mm, P = .02), estimates of atheroma burden (odds ratio, 1.01 to 1.09; P = .01) and the runoff bed size (branch distribution score) (odds ratio, 0.9 to 1.2; P = .84), and estimated left ventricular mass (odds ratio, 0.93 to 1.00; P = .05) were not highly correlated once other factors were considered.

**Relation of Modified ACC/AHA Lesion Criteria to Procedural Outcome**

Procedural success was achieved in 95.9% of type A lesions, 89.4% of type B1 lesions, 89.1% of type B2 lesions, and 70.0% of type C lesions (P = .013). Major ischemic complications occurred in 4.1% of type A lesions, 5% of type B1 lesions, 8.4% of class B2 lesions, and 26.1% of class C lesions (P = .008). However, after accounting for the individual predictive effect of the morphological variables described in the preceding paragraphs, the modified ACC/AHA lesion score did not add additional predictive value. See Fig 5.

**Discussion**

Recognition of the limitations of coronary angioplasty1–6 spawned the development, beginning in the mid 1980s, of many new devices to treat coronary stenoses. Generally favorable results with several of these devices9,10,18,19 have led to the release or imminent release of these products for widespread use and thus a heightened need to determine which device is best suited for each of the varied clinical presentations confronting the interventional cardiologist.

Plaque morphology, clinical presentation, and perhaps sex of the patient have been repeatedly shown to strongly influence the outcome of treatment of coronary stenoses with PTCA,7,14,20,21 directional atherectomy,10 and excimer laser ablation.8 It would be surprising if these factors did not influence the procedural outcome with the Rotablator. Conversely, because of their varied manner of removing or displacing plaque, the precise clinical and morphological predictors of outcome with these devices might be expected to be different. The data reported herein, in conjunction with data previously reported by this and other laboratories, confirm these expectations and provide important preliminary evidence as to which patients and stenoses should and should not be treated with the Rotablator. Furthermore, because results of varied interventions to 2143 lesions have been analyzed in nearly identical fashion and reported from this core angiographic laboratory since 1988,8,10,14,12 some comparison of results with different treatments may be valid.
### Table 4. Relation of Variables to Procedural Success

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>Univariate P</th>
<th>Multivariate P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Restenotic lesion</td>
<td>2.17</td>
<td>1.0-4.7</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Male sex</td>
<td>1.84</td>
<td>0.9-3.6</td>
<td>.08</td>
<td>.035</td>
</tr>
<tr>
<td>Age ≤66 y</td>
<td>1.30</td>
<td>0.7-2.5</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.22</td>
<td>0.5-2.7</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>1.06</td>
<td>0.5-2.1</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>0.98</td>
<td>0.5-1.9</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Elevated cholesterol</td>
<td>0.98</td>
<td>0.7-1.4</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Prior MI in territory</td>
<td>0.96</td>
<td>0.4-2.1</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.76</td>
<td>0.4-1.5</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>MI in territory within 2 wk</td>
<td>0.56</td>
<td>0.1-2.6</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Fixed thallium defect</td>
<td>0.36</td>
<td>0.1-2.2</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td><strong>Angiographic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atheroma mass index ≤7.4</td>
<td>1.88</td>
<td>0.9-3.7</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>Modified ACC/AHA A or B1</td>
<td>1.85</td>
<td>0.9-3.5</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>Pre-Rx stenosis ≤69%</td>
<td>1.82</td>
<td>0.9-3.6</td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td>Length ≥70% ≤1 mm</td>
<td>1.80</td>
<td>0.9-3.5</td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td>Length ≥50% ≤3 mm</td>
<td>1.76</td>
<td>0.9-3.4</td>
<td>.09</td>
<td></td>
</tr>
<tr>
<td>Length (shoulder-shoulder) ≤5 mm</td>
<td>1.65</td>
<td>0.8-3.2</td>
<td>.14</td>
<td></td>
</tr>
<tr>
<td>Normal diameter ≤2.9 mm</td>
<td>1.35</td>
<td>0.7-2.6</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Bifurcation</td>
<td>1.29</td>
<td>0.5-3.4</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Ostial</td>
<td>1.22</td>
<td>0.5-3.0</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Stenosis calcium, moderate-severe</td>
<td>1.17</td>
<td>0.4-1.9</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Proximal calcium, moderate-severe</td>
<td>0.91</td>
<td>0.6-1.4</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Estimated LV mass ≤28%</td>
<td>0.86</td>
<td>0.4-1.6</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Branch distribution score ≤7</td>
<td>0.78</td>
<td>0.4-1.6</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Hinge stenosis</td>
<td>0.76</td>
<td>0.3-2.1</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Exit bend</td>
<td>0.74</td>
<td>0.3-2.0</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Multivessel disease</td>
<td>0.72</td>
<td>0.4-1.4</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Right coronary artery</td>
<td>0.63</td>
<td>0.3-1.2</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Eccentric lesion</td>
<td>0.61</td>
<td>0.3-1.2</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Proximal tortuosity, any</td>
<td>0.60</td>
<td>0.2-1.5</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Stenosis bend ≥45°</td>
<td>0.40</td>
<td>0.2-0.8</td>
<td>.01</td>
<td></td>
</tr>
<tr>
<td>Bend ≥45°+eccentric</td>
<td>0.36</td>
<td>0.1-0.9</td>
<td>.03</td>
<td></td>
</tr>
<tr>
<td>Stenosis irregularity</td>
<td>0.29</td>
<td>0.1-0.6</td>
<td>.002</td>
<td>.003</td>
</tr>
<tr>
<td>Stenosis bend ≥60°</td>
<td>0.27</td>
<td>0.1-0.7</td>
<td>.01</td>
<td>.028</td>
</tr>
<tr>
<td>Bend ≥45°+outer eccentric</td>
<td>0.24</td>
<td>0.1-0.8</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Outflow obstruction</td>
<td>0.18</td>
<td>0.1-0.6</td>
<td>.003</td>
<td>.002</td>
</tr>
<tr>
<td>Thrombus</td>
<td>0.18</td>
<td>0.0-0.8</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td><strong>Procedural</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small burr first</td>
<td>2.44</td>
<td>1.2-4.8</td>
<td>.009</td>
<td></td>
</tr>
<tr>
<td>Total burring time ≤99 s</td>
<td>2.29</td>
<td>1.1-4.6</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Maximum burring time ≤32 s</td>
<td>1.19</td>
<td>0.6-2.3</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>First burr: artery ≤0.60</td>
<td>0.84</td>
<td>0.4-2.0</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Burr speed (s/mm ≤10)</td>
<td>0.73</td>
<td>0.4-1.4</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>First 20 procedures</td>
<td>0.56</td>
<td>0.2-1.6</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Max burr: artery ≤0.67</td>
<td>0.22</td>
<td>0.1-0.5</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

Cl indicates confidence intervals; MI, myocardial infarction; ACC/AHA, American College of Cardiology/American Heart Association lesion type; and LV, left ventricular.
TABLE 5. Correlates of Major Ischemic Complications

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>95% Cl</th>
<th>Multivariate P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length ≥4 mm</td>
<td>3.6</td>
<td>1.5-8.6</td>
<td>.005</td>
</tr>
<tr>
<td>(≥50% stenosis definition)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right coronary stenosis</td>
<td>2.4</td>
<td>1.0-5.8</td>
<td>.021</td>
</tr>
<tr>
<td>Stenoses bend ≥60°</td>
<td>6.1</td>
<td>2.1-17.0</td>
<td>.033</td>
</tr>
<tr>
<td>Female sex</td>
<td>3.0</td>
<td>1.3-7.0</td>
<td>.044</td>
</tr>
</tbody>
</table>

Cl indicates confidence intervals.

Correlates of Success and Complications

The overall procedural success rate (90%) with the Rotablator in this series reflecting the early experience with the device is similar to that reported with several other new coronary devices. The likelihood of success was strongly and negatively impacted by two factors: outflow tract obstruction (P = .002) and stenosis irregularity (P = .003); two other factors, stenosis angulation ≥60° (P = .03) and female sex (P = .03), were possibly related. In the absence of any of these factors, success was achieved in more than 95% of 240 lesions. Outflow obstruction, defined as an untreated 70% distal stenosis, was infrequently observed but was strongly correlated with procedural failure. Failures were due to coronary dissection and failure to cross the stenosis with a guide wire. Distal obstruction may simply reflect diffuse atheromatous disease, although it was included on this morphological analysis largely because of the concern that it might correlate with slow reflow. Stenosis irregularity, recently shown to correlate with mural thrombus in excised atherectomy specimens, was associated with failure most commonly caused by apparent thrombotic occlusion, coronary dissection, or slow reflow. Abrasion of such lesions with the rotating burr might reasonably be expected to promote thrombus propagation or emboli; hence, this may not be an altogether unexpected finding. Highly angulated stenoses (≥60°) were correlated with failure most commonly caused by dissection or perforation. Interestingly, although lesions at angles of 45° to 60° have a heightened risk with several other treatment modalities, such lesions were successfully treated in 35 of 41 instances (85%) in this series; hence, the flexibility of the Rotablator may lessen the straightening and tearing noted with PTCA and directional atherectomy for moderately angulated lesions. Finally, female sex, controversially an independent risk factor with PTCA, was found to independently correlate with failure in this series also.

Except for non-Q-wave infarction, which was due in two thirds of cases to slow reflow and not epicardial vessel closure, ischemic complications in this series were uncommon (3.7%). Given the uncertain prognostic importance of relatively small elevations of creatine kinase, the overall incidence of complications (8.7%) may be somewhat overstated. Long lesions (P = .005) and probably right coronary stenoses (P = .02) as well as the aforementioned stenosis angulation ≥60° (P = .03) and female sex (P = .03) were independent correlates of ischemic complications.

Longer lesions have been reported previously by Teirstein et al. to be at higher risk during treatment with the Rotablator. Length can be measured in any of several ways. The shoulder-to-shoulder measurement in this study appeared to correspond best to the visual approximation of the investigators but was the weakest correlate of complications of the length measurements used in this study (see Fig 3). Complications after treatment of long lesions using the ≥50% diameter narrowing, the best correlate, usually were due to dissection, sometimes from slow reflow, and rarely by other mechanisms. Length continues to be correlated

![Graph](http://circ.ahajournals.org/)

Fig 3. Bar graph shows relation of stenosis length to procedural complications.
When Is Rotablator Treatment Preferred?

For simple ACC/AHA A lesions, based on a ≥97% success rate,7,8 speed, cost, and no evidence to suggest that other devices yield a lower incidence of restenosis, PTCA is preferred. However, for more complex lesions, the outcome with PTCA is less satisfactory.7,8 Although randomized trials will be required to better define treatment indications, the Rotablator is perhaps indicated for calcified lesions (91% success versus 81% with PTCA8 and 72% with directional atherectomy6-10 using identical definitions and the same angiographic laboratory and versus 85% with excimer laser, from other data sources9). The Rotablator also may be indicated for ostial lesions (91% success in this series), although high success rates have been reported with both excimer laser19 and directional atherectomy,29 for moderately angulated (45° to 60°) lesions (without the “hinging” appearance that may increase the likelihood of perforation) that do poorly with other percutaneous treatments,10,22 but had an 85% success (34 lesions) in this series, and for restenotic lesions (94% success), although such lesions may be well treated with many devices,10,29

Study Limitations

In considering these results, certain limitations of the study should be kept in mind. First, the data reflect the early experience of a group of operators who were otherwise highly skilled in balloon angioplasty and directional atherectomy. Although a statistically significant learning effect could not be demonstrated, the success and complication rates from the first 20 procedures were somewhat less satisfactory, and with increased experience and better selection criteria, the results with the Rotablator might be expected to improve. Second, multiple statistical comparisons were made, and spurious apparent correlations may be present. With an entirely new technology there exists the potential for new clinical, lesion-related, or procedure-related correlates of outcome such that a large number of variables needed to be assessed. In this context, these data should be considered exploratory and will require confirmation. Third, no late follow-up is presented, and judgments with regard to indications clearly must be made based on long-term risk and benefit. Fourth, whereas comparison of results with other devices was limited as much as possible to that from this angiographic laboratory to limit inconsistencies of definition, this is not a randomized treatment evaluation, and data from somewhat differing time periods and from different institutions were used. Such comparisons should be interpreted with the utmost caution. Finally, although the project was partially supported by the device manufacturer, the study design, data acquisition, data analysis, and presentation were performed in a completely independent fashion.

Conclusions

The results suggest that the Rotablator is an important addition to the device armamentarium of coronary interventionalists, with probable morphology-based indications. However, further controlled studies will be required to more exactly devise its proper usage.
Appendix

Investigators

Angiographic Core Laboratory, Cleveland Clinic Foundation, Cleveland, Ohio. Stephen G. Ellis, MD; Darrell Debowey, BS. Cleveland Clinic Foundation, Cleveland, Ohio. Patrick L. Whitlow, MD; Stephen G. Ellis, MD; Irving Franco, MD; Russell E. Raymond, DO; Eric J. Topol, MD; SueAnn DeLuca, RN.

University of California, San Diego. Maurice Buchbinder, MD; Joanna Fenner, RN.

Washington Hospital Center, Washington, DC. Martin B. Leon, MD; Kenneth M. Kent, MD; Augusto D. Pichard, MD; Lowell Satler, MD; Jeffrey J. Popma, MD; Regina Deible, RN.

Acknowledgments

This study was supported in part by a grant from Heart Technology, Inc, Bellevue, Wash. The authors wish to thank Patti Durnwald for her patience and expert secretarial support during the preparation of the manuscript.

References

Relation of clinical presentation, stenosis morphology, and operator technique to the procedural results of rotational atherectomy and rotational atherectomy-facilitated angioplasty.
S G Ellis, J J Popma, M Buchbinder, I Franco, M B Leon, K M Kent, A D Pichard, L F Satler, E J Topol and P L Whitlow

Circulation. 1994;89:882-892
doi: 10.1161/01.CIR.89.2.882

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1994 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/89/2/882

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org//subscriptions/