Relation of Stenosis Morphology and Clinical Presentation to the Procedural Results of Directional Coronary Atherectomy

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

Methods and Results. Four hundred stenoses from 378 patients consecutively treated at six major referral institutions were analyzed. Angiographic data were assessed at a central angiographic laboratory using standardized morphological criteria and computer-assisted quantitative dimensional analyses. Procedural success was achieved in 87.8% of stenoses, and major ischemic complications (death, myocardial infarction, and emergency bypass surgery) occurred in 6.3% of patients. Lesion success and complications were closely correlated with recognized modified American College of Cardiology/American Heart Association Task Force lesion morphological criteria. Observed for type A stenoses were 93% success and 3% complication rates; for type B1 stenoses, 88% success and 6% complication rates; and for type B2 stenoses, 75% success and 13% complication rates, respectively. There were too few type C stenoses treated to analyze. Furthermore, multivariate testing demonstrated stenosis angulation (multivariate $p<0.001$), proximal tortuosity ($p<0.001$), decreased preatherectomy minimum lumen dimension ($p=0.032$), and calcification ($p=0.041$) to correlate independently with adverse outcome and complex, probably thrombus-associated stenoses to have a favorable outcome ($p=0.055$). Operator experience ($p=0.020$) and a history of restenosis ($p=0.022$) also favorably influenced outcome.

Conclusions. The procedural outcome of directional coronary atherectomy is highly associated with coronary stenosis morphology. Furthermore, after appropriate stratification for morphology and clinical presentation, overall atherectomy procedural outcome may be similar to that achieved with coronary angioplasty. However, specific subsets of patients may have relatively better outcome with either atherectomy or balloon angioplasty. (_Circulation_ 1991;84:644–653)

Although percutaneous transluminal coronary angioplasty (PTCA) has revolutionized the treatment of patients with coronary artery disease since its introduction in 1977, the technique is limited by a 4–7% incidence of abrupt arterial closure[1,2] and a 28–38% incidence of restenosis.[3–6] Recently, several percutaneous techniques have been introduced with the hope that some of these limitations of PTCA may be overcome. Assessment of the proper role of these new techniques will require

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comparison of quality-controlled data analyzed in a standardized manner, followed by randomized trials comparing the most promising treatments.

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Computer-assisted quantitative coronary analysis has been found to be far superior to visual assessment of the severity of coronary stenoses because of greatly reduced interobserver variability and the ability to obtain quantitative absolute coronary dimensions.[7,8] To date, however, results with directional coronary atherectomy have not been assessed with such rigorous methods,[9–11] nor have the results been assessed with regard to coronary morphology, which is known to be a major determinant of procedural outcome with coronary angioplasty.[1,12]

Therefore, to aid in initial comparison of procedural outcome with standard coronary angioplasty and assess potential subgroups of patients who might have particularly good or poor procedural outcome with directional coronary atherectomy, we performed standardized morphological and computer-assisted quantitative coronary dimensional analysis on 378 patients with 400 consecutive stenoses treated with directional coronary atherectomy at one of six high-volume interventional centers.

Methods

Patient Population

Consecutive procedural cineangiograms from all patients with attempted directional coronary atherectomy using the Simpson Atherotome® (Devices for Vascular Intervention, Redwood City, Calif.) at six institutions (University of Michigan Medical Center, Mayo Clinic, St. Vincent's Hospital, Cleveland Clinic, Emory University Hospital, and Christ Hospital) were requested. No patient subgroup was excluded. The angiograms were collected and assessed until 400 attempted stenoses had been analyzed. Each site contributed 40 or more stenoses for analysis. These procedural cineangiograms reflected the relatively early experience with directional coronary atherectomy in 1988 through early 1990. Patient selection for atherectomy during that time varied somewhat from institution to institution, but patients and stenoses were generally considered for the technique if relatively proximal and eccentric stenoses were located in coronary arteries of sufficient caliber to allow passage of the atherectomy device (usually 2.5 mm or more in diameter). The procedure was performed after each patient had given informed consent under the guidelines of the individual institutional review boards.

Technique of Directional Coronary Atherectomy

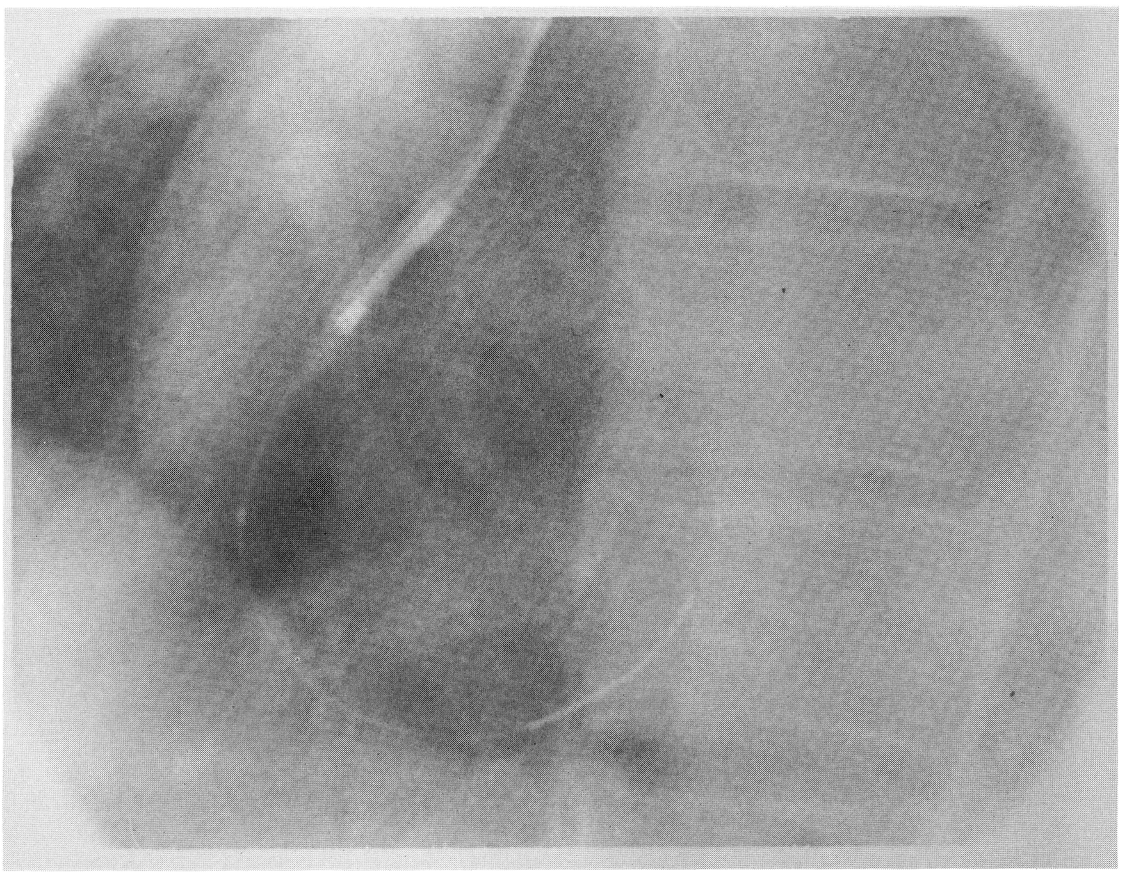
The technique of directional coronary atherectomy has been previously described.[13] Briefly, after pretreatment with 80–325 mg aspirin and a calcium channel blocker, a 10F or 11F sheath is placed percutaneously into the femoral artery system using standard Seldinger technique. The specially designed (Devices for Vascular Intervention) guiding catheter is advanced into the ascending aorta over a 0.035-in. guide wire and an 8F introducing catheter. The coronary ostium is then gently intubated, with care taken to not abruptly or deeply enter the ostium and risk injury with the relatively stiff guide catheter. Next, a 0.014-in. coronary guide wire is steered through the stenosis and positioned distally in the artery. The atherectomy catheter is then advanced across the stenosis and aligned directionally toward the stenosis by a gentle torquing of the catheter. Predilatation using standard balloon techniques is occasionally required to allow advancement of the 5F, 6F, or 7F atherectomy device across the stenosis. The cutter is then manually retracted proximally in the housing, exposing the cutting window. After balloon inflation to 15–60 psi to stabilize the device within the artery and compress the atheroma into the cutting window, the motor drive unit is activated, and the rotating cutter is advanced manually. The atheroma is thus excised and displaced into the nose cone. The balloon is then deflated, the atherectomy device is reoriented, and the procedure is repeated three to 10 times before the device is removed from the coronary artery. Thereafter, angiography is performed to determine whether additional passes are required. The end point parameters varied during the course of study. Until November 1989, most investigators attempted to remove all angiographically visible atheroma to approximate a normal lumen dimension. Thereafter, because of a concern about rarely reported vessel perforation as well as because it was suggested that exuberant tissue removal evidenced by medial or adventitial excision might predispose to restenosis, most investigators chose a somewhat less aggressive approach to tissue removal. The technique was modified by lowering the peak balloon inflation pressure to 30 psi and by no longer attempting to remove all angiographically apparent stenosis.

After completion of the procedure, patients were monitored in an intensive care unit or postprocedural ward. Patients were medicated with oral aspirin and a calcium channel blocking agent and/or a nitrate preparation. A 12-lead electrocardiogram was obtained immediately in the event of chest pain suggestive of ischemia; if ischemia was suspected, the patients were usually returned for cardiac catheterization, and creatine kinase levels were followed. Patients were routinely discharged from the hospital 1–2 days after atherectomy.

Clinical and Procedural Variables

Clinical variables (patient age, diabetes mellitus, gender, history of restenosis, multivessel disease, patient sequence number, and unstable angina) and procedural variables (maximum balloon pressure [psi], device-to-artery ratio, and preatherectomy PTCA) were obtained from the case report forms provided by the individual investigators.

The device-to-artery ratio was measured by calipers as the ratio between the atherectomy device proximal or distal to the cutting window and a normal adjacent coronary artery for the largest device that crossed the stenosis. This was performed when the balloon was in its deflated state. A device-to-artery ratio with the balloon inflated could not be properly



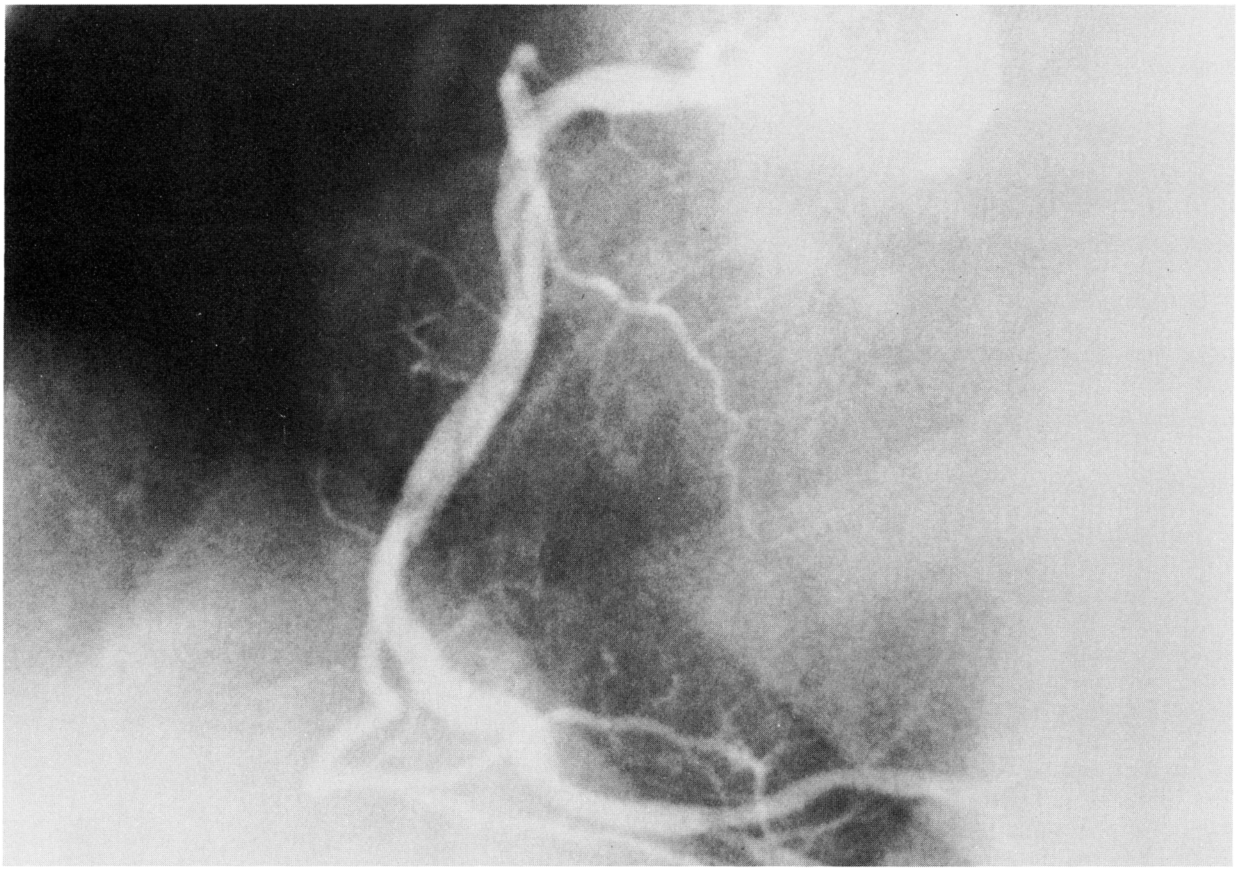


FIGURE 1. Top left panel: *Left anterior oblique projection of a 65% proximal right coronary artery stenosis located in an area of vessel angulation in a 45-year-old woman with unstable angina.* Bottom left panel: *Atherectomy device in place with balloon inflated to 4 atm pressure (device-to-artery ratio, 0.72).* Top right panel: *Resultant extensive spiral dissection. Patient required emergency bypass surgery but did not evolve a Q wave myocardial infarction.*

measured because of the eccentric location of the balloon relative to the catheter.

"Early atherectomy experience" referred to patient sequence numbers 1–20 for a given institution. Because these atherectomy procedures were typically performed, particularly in the early institutional experience, by two investigators and the assistant operator was not recorded on the case report form, this definition was chosen over that relating to the experience of an individual operator.

"Patient sequence number" referred to the number of atherectomy procedures performed at the given institution at the time of the patient's procedure (inclusive of the procedure being evaluated).

Coronary Angiographic Analyses

Morphological analyses. An experienced angiographer at the Angiographic Core Laboratory reviewed the diagnostic and procedural cineangiograms to code for 13 lesion-related morphological variables (angulated stenosis, bifurcation stenosis, calcification, complex and probably thrombus-containing stenosis, diffuse proximal disease, eccentric stenosis, irregularly contoured stenosis, stenosis length of 10 mm or more, severe and lengthy [10 mm or more] stenosis, modified American College of Cardiology/American Heart Association [ACC/AHA] lesion criteria, proximal tortuosity, ostial location, and thrombus-associated stenosis).

Quantitative analyses. Selected end-diastolic cine frames from angiograms obtained before and after directional atherectomy were digitized using a cine-video converter interfaced with a computer-assisted automated edge detection system (ADAC Laboratories, Milipitas, Calif.[8]). Using the guiding catheter as the reference standard, absolute coronary dimensions including normal and minimal luminal diameters were determined. Normal and minimal cross-sectional areas, percent area stenosis, and mean diameter percent stenosis were calculated from orthogonal projections based on the geometry of an ellipse.

Angiographic definitions. The angiographic definitions used in this analysis have been used in evaluation of the results of coronary angioplasty and previously published.[12] New definitions or those particularly germane to the results of this analysis are described as follows.

A "bend stenosis" was present when the artery in the area of the stenosis to be excised was angulated 45° or more at end diastole in a nonforeshortened view (see Figure 1). A lesion was said to be complex

and probably thrombus containing when it had either an easily recognized filling defect or gross luminal irregularities (see Figure 2). "Diffuse proximal disease" was present when one third or more of the artery proximal to the stenosis to be treated had angiographically apparent luminal irregularities or stenoses. A "long and severely narrowed stenosis" was said to be present when its percent diameter stenosis was 70% or more and 10 mm or more in length. The original ACC/AHA lesion score of A, B, or C was modified as described by Ellis et al[12] to include categories B1 and B2, in which lesions were scored B1 when one class B characteristic was present and B2 when two or more class B characteristics were present. "Proximal tortuosity" was present when, to cross the stenosis to be treated, the atherectomy catheter had to traverse two or more areas of vessel angulation of 75° or more or one or more area of angulation of 90° or more as determined from nonforeshortened and end-diastolic projections. "Thrombus-associated stenosis" was present if an intraluminal filling defect, largely separated from the adjacent vessel wall, was clearly definable.

Outcome Variables

The variables of emergency bypass surgery or myocardial infarction consequent to ischemia, procedure-related death, and any major ischemic complication were obtained from the case report forms provided by the individual investigators. In addition, the presence of guide catheter–induced arterial closure and vessel perforation were obtained by the angiographic core laboratory.

The following definitions were used. "Lesion complications" were considered any major complication, reported on a per-lesion basis. "Lesion success" was defined as a final percent diameter stenosis of less than 50% (with or without ancillary use of balloon angioplasty), tissue removal, and no major ischemic complications and is reported on a per-lesion basis. "Major ischemic complications" were considered emergency bypass surgery, myocardial infarction, or death resulting from attempted coronary atherectomy. "Procedure-related emergency bypass surgery" was considered surgery required because of ischemia or hemodynamic compromise resulting from attempted atherectomy and, like all procedure-related definitions, is reported on a per-patient basis. "Procedure-related myocardial infarction" was defined by elevation of cardiac enzymes or as electrocardiographic changes diagnostic of infarction resulting from procedure-induced ischemia. "Procedure-related death" was defined as death from any cause during hospitalization after attempted directional atherectomy.

Statistical Analyses

Data are expressed as mean±1 SD unless otherwise indicated. χ^2 Analyses were used to test differences in categorical variables, with Yates' corrections where appropriate, and unpaired Student's t tests were used to assess differences in continuous variables. Relative risk data are also presented for each variable, with relative risk considered the number of events divided by the number of outcomes at risk when the variable in question was present divided by the number of events divided by the number of outcomes at risk when the variable in question was not present. Multiple stepwise logistic regression analyses were performed to determine the independent correlates of procedural outcome. Analyses were performed using SYSTAT software (SYSTAT, Inc., Evanston, Ill.)

Results

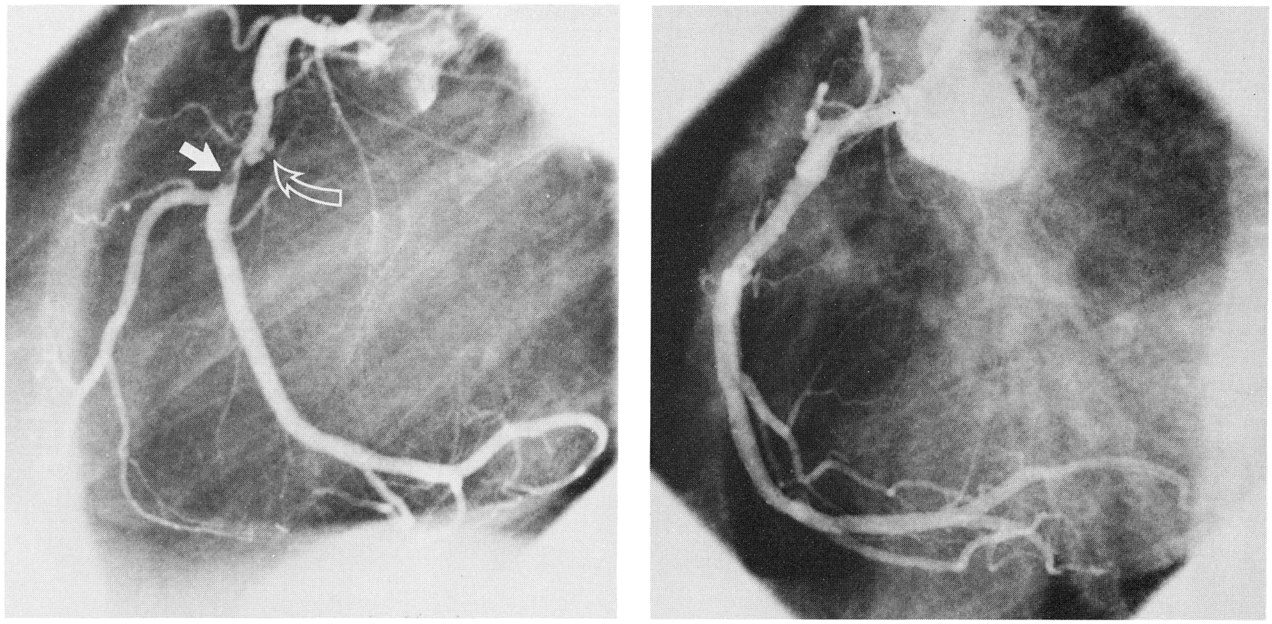
Patient Demographics

Four hundred stenoses from 378 patients were analyzed. The baseline patient and lesion information for the patients treated early in the atherectomy experience (patient sequence numbers 1–20 at each institution), patients treated later, and the entire population analyzed are enumerated in Table 1. There were no differences between the patients treated early and those treated later, except that patients treated later had a lower incidence of prior restenosis (42% versus 60%, $p=0.003$).

Procedural Characteristics and Results

Limited procedural characteristics are also described in Table 1. Preatherectomy and postatherectomy balloon dilatations were seldom required. Patients treated later in the experience tended to have lower atherectomy balloon pressures used (36±10 versus 47±12 psi, $p<0.001$).

Lesion and procedural success and complication data for the early and later treated patients as well as the overall group are also listed in Table 1. A successful result was obtained in 351 of 400 stenoses attempted (87.8%). When successful, the minimum luminal dimension increased from 1.1±1.0 to 2.6±2.3 mm ($p<0.001$). Major ischemic complications occurred in 24 of 378 procedures (6.3%). Complications of emergency bypass surgery, myocardial infarction, and death occurred in 5.5%, 1.8%, and 1.0% of patients, respectively. Guide catheter–induced closure occurred in 0.8% of stenoses attempted, and vessel perforation occurred in 0.3% of vessels attempted. Reasons for lesion failure other than complications were failure to cross the stenosis with the atherotome (4.2%), failure to engage the coronary ostium with the guide catheter (1.2%), failure to cross the stenosis with the guide wire (0.5%), and failure to achieve a final less-than-50% diameter stenosis (0.3%). Differences in outcome were noted based on institutional experience. Although rates of lesion success did not differ between patients treated later in the experience and those treated earlier (89% versus 86% success), fewer complications occurred in patients treated later in the experience compared with those treated relatively early (4.6% versus 10.0% success, $p=0.04$). This was particularly



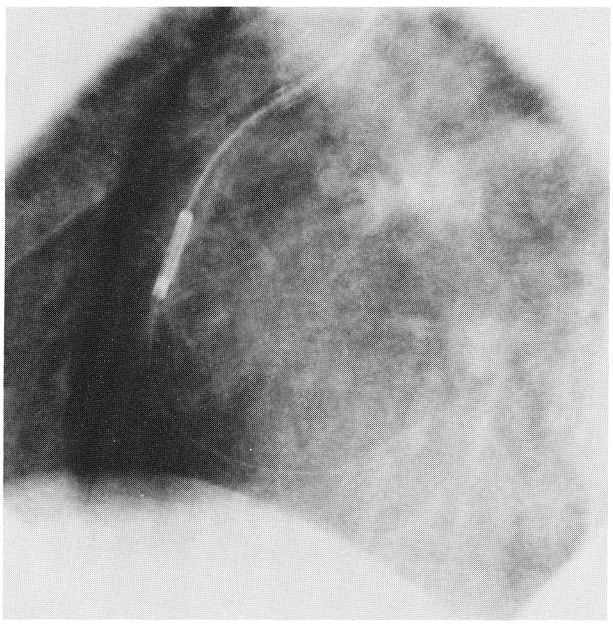


FIGURE 2. Top left panel: *Lateral projection of an 83% mid right coronary artery stenosis with an area of ulceration (open arrow) and a filling defect suggesting thrombus (closed arrow) in a 55-year-old man with postinfarction angina.* Bottom left panel: *Atherectomy device in place with balloon inflated to 2 atm (device-to-artery ratio, 0.58).* Top right panel: *Resultant 36% stenosis in left oblique projection. Fourteen specimens were retrieved, with six having thrombus present on microscopic examination.*

notable with regard to the need for emergency bypass surgery (3.5% versus 10.0%, p=0.008).

Correlates of lesion success. The relations between the modified ACC/AHA lesion scores and outcomes are shown in Table 2, both for the group as a whole and for the relatively later experience (institutional cases 21 and later). For the overall experience, success was closely related to the modified ACC/AHA score. Class A stenoses were associated with a 93% success rate. The success rate diminished with increasing score such that class B1 stenoses had an 88% success rate, class B2 stenoses had a 75% success rate, and the relatively limited number of class C stenoses had a 75% success rate ($p \leq 0.001$). This relation was also apparent for stenoses treated in the relatively later experience. The relative risk of procedural failure on a per-lesion basis, the associated univariate p value, and the multivariate p value for the individual correlates of lesion success are shown in Table 3. There were four statistically significant independent adverse risk factors for lesion success: bend stenosis, proximal tortuosity, preatherectomy minimum lumen dimension, and stenosis calcification. There were two correlates of improved lesion success: history of prior restenosis at the site of atherectomy and presence of a complex, probably thrombus-containing stenosis. The presence of thrombus in the excised portion of these stenoses was confirmed in 72% of those in whom pathology reports were available. The relative risk for procedural failure for each of the independent predictors of outcome for the entire group

Table 1. Overall Patient, Procedural, and Outcome Characteristics

	Early experience (n=124 lesions)	Later experience (n=276 lesions)	Overall experience (n=400 lesions)
Clinical characteristics*			
Age (yr)	58±10	59±11	59±11
Diabetes mellitus (%)	13.6	15.7	15.0
Diameter stenosis (%)	77±13	74±13	75±13
Male gender (%)	79.5	78.4	78.7
History of restenosis (%)	59.8	42.4	47.8
Multivessel disease (%)	44.2	48.1	47.9
Unstable angina pectoris (%)	49.5	48.8	49.0
Artery treated			
Left main (%)	0.8	1.1	1.0
Left anterior descending (%)	58.1	55.4	56.3
Left circumflex (%)	3.2	7.2	6.0
Right coronary artery (%)	21.8	25.0	24.0
Saphenous vein graft (%)	16.1	11.2	12.8
Procedural characteristics			
Preatherectomy angioplasty (%)	12.3	16.4	14.9
Postatherectomy angioplasty (%)	12.9	10.0	10.9
Device-to-artery ratio	0.71±0.09	0.71±0.13	0.71±0.12
Atherectomy balloon pressure (psi)	47±12	36±10	40±12
Procedural outcome			
Lesion success (%)	85.5	88.8	87.8
Myocardial infarction (%)*	1.7	1.9	1.8
Emergency bypass surgery (%)*	10.0	3.5	5.5
Procedure-related death (%)*	2.5	0.4	1.0
Major ischemic complications (%)*	10.0	4.6	6.3

*Reported on a per-patient basis.

did not differ from that in the later treated group by more than 0.50, except for the risk for proximal tortuosity (4.16 in the later group). Success was achieved in three of four (75%) left main stenoses, 200 of 225 (88.9%) left anterior descending stenoses, 22 of 24 (91.7%) left circumflex stenoses, 82 of 96 (85.4%) right coronary stenoses, and 44 of 51 (86.3%) saphenous vein graft stenoses (p=NS).

Table 2. Relation of Modified American College of Cardiology/American Heart Association Criteria to Lesion Success and Complications

ACC/AHA Score	n	Lesion success (%)		Complications (%)	
Overall experience					
Type A	176	93.2		3.4	
Type B1	148	87.8		6.1	
Type B2	72	75.0	(p=0.002)	12.5	(p=0.076)
Type C	4	75.0		0.0	
Overall	400	87.8		6.0	
Later experience					
Type A	124	92.7		3.2	
Type B1	100	90.0		4.0	
Type B2	49	75.5	(p=0.021)	8.2	(p=NS)
Type C	3	66.7		0.0	
Overall	276	88.7		4.3	

Correlates of lesion complications. The relation between the modified ACC/AHA lesion score and complications is shown in Table 2. Complications increased with increasing score such that in the entire experience, type A lesions had a 3.4% risk, type B1 lesions had a 6.1% risk, and type B2 lesions had a 12.5% risk (p=0.076). There were too few type C lesions to adequately assess the risk of complications in this group. The risk of complications was similarly related to the modified ACC/AHA score in patients treated in the relatively later experience, but the overall incidence of complications declined. The relative risk for complications, the associated univariate p value, and the associated multivariate p value for the individual correlates of complications are shown in Table 4. Only three variables were independently correlated with the likelihood of complications: early institutional experience (relative risk of complications, 6.6; p=0.020), no history of prior restenosis (relative risk, 3.2; p=0.022), and bend stenosis (relative risk, 2.7; p=0.046). To a lesser extent, the risk of complications was also related to the presence of stenosis calcification and increased atherectomy balloon pressure. Complications occurred in none of four (0%) left main stenoses, 16 of 225 (7.1%) left anterior descending stenoses, none of 24 (0%) left circumflex stenoses, seven of 96 (7.3%) right coro-

TABLE 3. Correlates of Lesion Success

Characteristic	n	Univariate p	Relative risk of failure (95% confidence intervals)	Multivariate p*
Proximal tortuosity	19	<0.001	7.25 (2.50–21.28)	<0.001
Bend stenosis	35	<0.001	4.81 (1.89–12.34)	<0.001
History of restenosis	200	0.008	0.37 (0.18–0.80)	0.010
Eccentric stenosis	230	0.106	1.96 (0.94–4.06)	0.029
Preatherectomy minimum lumen diameter	...	0.055	...	0.032
Calcification	47	<0.001	1.98 (0.85–4.56)	0.041
Complex, probably thrombotic stenosis	30	0.032	0.00 (0.00–13.50)	0.055

*Log likelihood, −109.78.

nary artery stenoses, and one of 51 (2.0%) saphenous vein graft stenoses (p=NS).

Discussion

The concept that coronary stenosis morphology is a major predictor of the likelihood of the procedural success and complications of coronary angioplasty is not new[14] and is well substantiated by many reports.[1,12,14,15] A widespread acceptance of this concept is reflected by the formalization of standard criteria by ACC/AHA in 1988.[16] In that report, the task force put forth a formal classification scheme of type A for high-success, low-risk stenoses; type B for moderate-success, moderate-risk stenoses; and type C for low-success, high-risk stenoses. That scheme has been validated recently by two reports—one by Cragg et al[15] in a low-risk population and one by Ellis et al[12] in a population of patients with multivessel disease. The procedural success and complication rates in those two reports for type A, B, and C stenoses were 92–94% and 0–2%, 84–91% and 3–7%, and 61–89% and 9–21%, respectively. Ellis et al[12] suggested that type B stenoses be further subdivided into type B1 (one adverse characteristic) and type B2 (two or more adverse characteristics) based on a statistically significant difference in procedural outcomes between these two classes of stenoses. In that study, the procedural success and complication rates for type B1 stenoses were 84% and 4% and 76% and 10% for type B2 stenoses.

The recent rapid proliferation of new devices capable of achieving percutaneous revascularization that may eventually compete with or supplement standard balloon angioplasty has raised many questions about how physicians might appropriately compare the results with these devices in a practical and representative manner short of the performance of large-scale and expensive randomized trials. A consensus appears to have arisen for the need for standardized definitions and methodology to allow appropriate comparisons. Without randomized trials, however, comparison of results will be difficult, particularly given the potential for patient selection bias and for the possibly confounding influence of "learning curves."[17,18] A comparison of results in well-defined patient subsets may in part obviate the concerns regarding the problem of patient selection bias and serve as a reasonable prelude to randomized trials of devices showing the most promise.

The present study is the first to report the results of such a subset analysis for the technique of directional coronary atherectomy in which objective computer-assisted quantitative coronary dimensional analyses served to assist in the definition of the procedural success. As such, these results should be differentiated from preliminary reports of the results with this technique[9,10] that, although useful, did not focus on subset analyses based on coronary morphology or use computer-assisted quantitative coronary angiography.

Comparisons With Previous Angioplasty Studies

A comparison of the baseline patient demographics in this series with that reported from the 1985–1986 National Heart, Lung, and Blood Institute PTCA Registry may be highly informative in suggesting the initial biases and impression of efficacy for atherectomy of the investigators of directional coronary atherectomy. Such a comparison finds many similar patient characteristics (see Table 1) but also a higher incidence of bypass graft stenosis treatment

TABLE 4. Correlates of Lesion Complications

Characteristic	n	Univariate p	Relative risk of complications (95% confidence intervals)	Multivariate p*
Early experience	124	0.041	6.61 (2.70–16.20)	0.020
History of restenosis	200	0.005	0.31 (0.12–0.85)	0.022
Bend stenosis	35	0.036	2.66 (0.81–8.68)	0.046

*Log likelihood, −76.38.

with atherectomy and a lower incidence of unstable angina pectoris, multivessel coronary disease, and left circumflex coronary artery treatment in the atherectomy series.[19] Similarly, for comparison of results in which similar stenosis morphology grading systems has been used, patients in this series have a higher incidence of saphenous vein bypass graft treatment and a lower incidence of multivessel disease and left circumflex treatment than do those in the reports of Cragg et al[15] and Ellis et al.[12]

Recognizing the above-mentioned major limitations regarding comparisons of outcomes, the results reported herein suggest that directional atherectomy may be applied with success and complication rates similar to those achieved with the more mature technology of balloon angioplasty. Thus, with both techniques, the likelihood of procedural success and complications for type A stenoses appears to be 92–94% and 0–3%, respectively, and for type B stenoses, 83–91% and 3–7%, respectively. Type C stenoses were infrequently approached in this series, and therefore comparisons cannot be drawn between the results with atherectomy and angioplasty with these unfavorable stenoses. With both techniques, the stratification of stenoses by morphology appears to be highly predictive of outcome.

Favorable and Unfavorable Lesions

Based solely on initial procedural outcome, directional coronary atherectomy appears to be particularly well suited for treatment of restenoses and possibly for those that are complex and appear to contain thrombus. The relatively improved procedural results with stenoses that have been previously dilated may relate to their demonstrated accessibility to percutaneous instrumentation and perhaps to their more concentric or fibrotic nature.[20] Procedural success with repeat balloon angioplasty for restenotic lesions has also been reported to be high.[20] Results compared with standard balloon angioplasty appear to be improved for stenoses probably containing thrombus. The results in this series of 30 patients with these complex stenoses (100% procedural success and 0% complication rates) are remarkable. Such patients have been demonstrated to have a much higher than usual risk of procedural complications when treated with standard balloon angioplasty.[1,12,21] It may well be that the relatively soft nature of the stenosis and the removal of the nidus for thrombus formation by the atherotome make such lesions particularly well suited to treatment with directional coronary atherectomy. It should be noted, however, that lesions associated with large (2 mm or more) apparent thrombi were generally avoided. The procedural success and complication rates observed in the 35 ostial stenoses (91.4% and 5.7%, respectively) are also noteworthy compared with the results of standard balloon angioplasty in this setting.[22] Further comparisons of the results between directional atherectomy and standard balloon angioplasty must include recognition of the fact that although the initial dimensional result appears to be superior with atherectomy,[23] the overall long-term rates of restenosis thus far do not appear to be superior with this newer technology.[24]

Directional coronary atherectomy has a lower success rate and a higher complication rate in stenoses located at bends, with associated proximal tortuosity or calcification, and that are eccentric or severely narrowed. Bend stenoses are also poorly treated with standard balloon angioplasty.[1,12] The relative inflexibility of current atherectomy catheters and their inability to excise densely calcified atheroma may in part explain the relatively poor results with atherectomy in stenoses with proximal tortuosity and calcification. The reason for the lower success rate in eccentric and severe stenoses may relate to difficulty in atraumatically crossing such stenoses with a relatively bulky and rigid atherectomy device.

Limitations

In considering these results, certain limitations of the study should be kept in mind. First, the data reflect the early experience of the atherectomy operators who were otherwise highly skilled in balloon angioplasty. The importance of a learning curve with directional coronary atherectomy is highlighted in Tables 3 and 4. With increased experience, possibly improved technology, and better selection criteria, one must expect results with directional coronary atherectomy to improve. Second, there were some relatively minor modifications in the atherectomy device during the time reflected by this study. Minor changes in the nose cone configuration, the cutting device, and the balloon configuration were made in 1988 and 1989; hence, these results reflect those obtained with a changing technology. A similar limitation must be recognized for virtually all reports of the procedural results with balloon angioplasty. Third, multiple subgroup comparisons were made, and the possibility of a type II statistical error must be acknowledged. These results should, therefore, be recognized as exploratory and not definitive. Fourth, the long-term results of directional coronary atherectomy are not addressed in this report and, as such, any comparisons with recognized techniques must be limited. Finally, this is not in any sense a randomized treatment evaluation, and caution must therefore be urged in the comparison of these results with those achieved by other technologies.

Nevertheless, these data suggest that consideration of coronary morphological characteristics as predictors of outcome with directional atherectomy is extremely important; that initial results with coronary atherectomy, when stratified on the basis of coronary morphology, appear to be similar to those obtained with the more mature technique of balloon angioplasty; and that they provide initial data suggesting which patients may be best suited for treatment with this technique. Further study investigating the long-term treatment outcome after directional coronary atherectomy with a randomized control study design with other efficacious treatments will clearly be needed.

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Appendix

Investigators

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