

Multivariate Predictors of Intravascular Ultrasound End Points After Directional Coronary Atherectomy

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Objectives. This study attempted to identify the clinical, angiographic, procedural and intravascular ultrasound predictors of directional atherectomy results assessed by intravascular ultrasound.

Background. Several angiographic and intravascular ultrasound variables have been associated with the outcome of directional coronary atherectomy. No study has incorporated both modalities into a predictive model.

Methods. One hundred seventy patients were analyzed using preintervention and postintervention intravascular ultrasound and quantitative angiography. Clinical and procedural variables were collected by independent chart review. Quantitative and qualitative angiographic analysis was performed by a core laboratory in blinded manner. Intravascular ultrasound was performed using a transducer-tipped catheter, rotating within a stationary imaging sheath, and withdrawn automatically at 0.5 mm/s. Clinical, procedural, angiographic and ultrasound variables were tested in a multivariate linear regression model. Dependent

ultrasound variables included postatherectomy lumen cross-sectional area and percent cross-sectional narrowing (plaque plus media/external elastic membrane cross-sectional area) and, in a subgroup of 47 patients studied using volumetric analysis, percent plaque volume removal.

Results. By multivariate stepwise linear regression analysis, predictors of residual lumen cross-sectional area (correcting for reference lumen area) included arc of calcium and preatherectomy plaque plus media cross-sectional area; predictors of residual cross-sectional narrowing were arc of calcium, preatherectomy plaque plus media cross-sectional area and lesion length; and predictors of percent plaque volume removal were arc of calcium and atherectomy device size.

Conclusions. The preintervention lesion arc of calcium measured by intravascular ultrasound is the most consistent predictor of the effectiveness and results of directional coronary atherectomy.

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Several studies (1-3) have identified the baseline angiographic lesion characteristics that are useful in predicting the immediate procedural result of directional coronary atherectomy as determined by quantitative coronary angiography. However, unlike angiography, intravascular ultrasound provides transmural images of the coronary arteries in vivo. The normal coronary arterial wall, the major components of the atherosclerotic plaque, the changes that occur with the atherosclerotic disease process and the mechanisms and results of transcatheter therapy can be studied in humans in a manner previously not possible (4-6). The purpose of our study was to

use multivariate linear regression analysis to determine the clinical, procedural, angiographic and intravascular ultrasound predictors of directional coronary atherectomy mechanisms and results as assessed by intravascular ultrasound.

Methods

Study patients. Between October 10, 1991 and August 8, 1993, there were 170 patients (mean [\pm SD] age 58 ± 11 years) in whom a single target lesion was treated successfully with directional coronary atherectomy and in whom high quality intravascular ultrasound studies were available both before and after directional atherectomy. Sixty-seven patients (40%) were diabetic; 135 (80%) were male; and 113 (67%) had unstable angina. Target lesion location was saphenous vein grafts ($n = 7$) and the left main ($n = 3$), left anterior descending ($n = 84$), left circumflex ($n = 19$) and right ($n = 57$) coronary arteries. Sixty-seven target lesions were restenotic. The analysis of the clinical demographics, the proce-

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dural variables and the preintervention angiographic and intravascular ultrasound studies form the basis of this report.

Clinical variables. The hospital charts of all patients were reviewed independently by a registered nurse to obtain clinical demographics and laboratory results.

Angina was categorized as stable, accelerated, postinfarction or at rest. A recent myocardial infarction occurred within 6 weeks before the study; a remote myocardial infarction occurred >6 weeks before the study. In addition, a history of coronary artery bypass surgery and the presence of multivessel coronary artery disease (>50% diameter stenosis in two or more epicardial coronary arteries) were noted.

Risk factors for coronary artery disease that were tabulated included diabetes mellitus (medication dependent, including oral hypoglycemic drugs and insulin), hypertension (medication dependent only), hypercholesterolemia (medication dependent or serum cholesterol ≥ 240 mg/dl) and smoking (still smoking or having stopped smoking <6 months before the study). Laboratory data recorded included baseline admission hematocrit, platelet count and serum creatinine.

Directional coronary atherectomy procedure. Directional coronary atherectomy (Devices for Vascular Intervention) was performed according to standard protocols. Intravenous nitroglycerin was administered during the procedure, and 200 μ g of intracoronary nitroglycerin was administered before each intravascular ultrasound imaging run. Seventeen patients underwent preatherectomy balloon dilation with a 2-mm balloon. The maximal atherectomy cutter size was 7F in 129 patients (76%) and 6F in 41 (24%). The mean atherectomy balloon pressure was 31 ± 10 pounds per square inch (psi), and the mean number of atherectomy cuts was 14 ± 8 . Adjunct balloon dilation (mean balloon size 3.1 ± 0.7 mm, mean pressure 7.2 ± 2.2 atm) was used in 87 patients; in these 87, postatherectomy intravascular ultrasound imaging was performed before adjunct balloon angioplasty. Procedural variables were collected by independent review of technician records. Procedural variables tested in the model included the number of atherectomy cuts, maximal device size, maximal atherectomy balloon pressure and use of adjunct balloon angioplasty.

Primary operators were not blinded to the ultrasound images, and the information contained in the images was used routinely to guide the procedure. For example, ultrasound plaque distribution (eccentricity) was related to side branches, and this was used to direct the atherectomy cuts during the procedure. In addition, if heavily calcified lesions were identified by preintervention imaging, the use of directional coronary atherectomy frequently was abandoned.

Angiographic criteria. All target lesions were analyzed using a computer-assisted, automated edge detection algorithm (ARTREK, Quantitative Cardiac System) by a core angiographic laboratory blinded as to the ultrasound results. Using a contrast-filled catheter as the calibration standard, the reference segment lumen diameter and lesion minimal lumen diameter in diastole before intervention were measured from orthogonal projections; the results from the "worst" view were recorded; and the percent diameter stenosis was calculated.

Target lesion location was designated as ostial, proximal, mid and distal. Ostial lesions were those lesions that began within 3 mm of the major coronary or saphenous vein graft ostium. For purposes of analysis, proximal, mid and distal lesions were grouped together.

Lesion length was measured as the distance (in mm) from the proximal to the distal shoulder of the lesion in the projection that demonstrated the lesion with the least amount of foreshortening.

Qualitative lesion morphology was graded according to standard criteria (2). An eccentric target lesion had one of its lumen edges in the outer one-quarter of the apparently normal lumen.

To determine lesion angulation, the centerline through the lumen proximal to the lesion was compared with the centerline through the lumen distal to the lesion. Angulation was present if this angle was $>45^\circ$.

An irregular lesion had abnormal vessel margins. Specifically, an ulcerated lesion had a small crater or lumen flap, potentially with discrete lumen widening beyond a narrow mouth in the area of stenosis. An aneurysm had widening of the lumen beyond the apparent normal contour of the artery.

Calcification was identified as readily apparent radiopacities within the vascular wall at the site of the stenosis and was classified as none/mild, moderate (radiopacities only noted during the cardiac cycle before contrast injection), and severe (radiopacities noted without cardiac motion before contrast injection).

Because only few lesions contained thrombus ($n = 5$) or had proximal vessel tortuosity ($n = 2$), those two variables were not tested in the model.

Initial qualitative and quantitative readings were recorded by a single angiographic technician. Overreading of all cineangiograms was performed at a separate sitting by an experienced angiographer.

Intravascular ultrasound analysis. All intravascular ultrasound studies met the following criteria: a single target lesion and high quality intravascular ultrasound imaging using motorized transducer pullback through a stationary imaging sheath both before and after directional coronary atherectomy. Images with excessive nonuniform rotational distortion or significant sheath and catheter artifact were excluded from analysis.

Images were obtained using the CVIS/InterTherapy system. This system uses a 25-MHz transducer-tipped catheter rotating at 1,800 revolutions/min within a 3.9F stationary imaging sheath and withdrawn at 0.5 mm/s using a motorized transducer pullback. Planar two-dimensional images are formed in real time and recorded on a 0.5-in. high-resolution videotape for off-line analysis.

Validation of normal coronary artery anatomy, plaque composition and morphology, and measurements of external elastic membrane cross-sectional area, residual lumen cross-sectional area, plaque plus media cross-sectional area and total wall thickness by intravascular ultrasound have been reported elsewhere (7-14). Because media thickness cannot be mea-

sured accurately, plaque plus media cross-sectional area was used as a measurement of the amount of atherosclerotic plaque. Total wall (plaque plus media) thickness was used to calculate the eccentricity index.

Using computer planimetry, the target lesion was analyzed using the following measurements: 1) lesion site external elastic membrane cross-sectional area (mm^2); 2) lesion site lumen cross-sectional area (mm^2); 3) minimal lumen diameter (mm); 4) plaque plus media cross-sectional area (mm^2) equals external elastic membrane cross-sectional area minus lumen cross-sectional area; 5) percent cross-sectional narrowing equals plaque plus media cross-sectional area times 100 divided by external elastic membrane cross-sectional area; 6) eccentricity index equals maximal total wall thickness divided by minimal total wall thickness. An eccentricity index of 1.0 would indicate purely concentric target lesion plaque distribution. In many of the preatherectomy imaging studies, the ultrasound catheter was wedged into the stenosis. The lumen cross-sectional area at such sites was considered to be equal to 1.3 mm^2 , which is the cross-sectional area of the imaging sheath.

Target lesion and reference site plaque composition were assessed visually. The presence of significant amounts of calcium, dense fibrous tissue, and soft plaque were tabulated independently for each lesion; mixed lesions containing more than one type of atherosclerotic plaque were tabulated as containing each plaque type. Calcium produced bright echoes (brighter than the reference adventitia) with acoustic shadowing of deeper arterial structures and was quantified by measuring its circumferential arc (in degrees) with a protractor centered on the lumen.

Dense fibrous tissue produced echoes that were as bright as or brighter than the reference adventitia but without acoustic shadowing. The absence of acoustic shadowing differentiated dense fibrous tissue from calcium.

Soft (less intensely echogenic) plaque was less bright than the reference adventitia. This may contain heterogeneous amounts of loose connective tissue, lipid, intimal hyperplasia or thrombus.

Target lesion calcium was analyzed further as follows. The *arc of target lesion calcium* was quantified in degrees using a protractor centered on the imaging sheath. The *number of calcified arcs* within the target lesion were counted. *Calcium location* was classified as superficial or deep depending on its location within the plaque. Superficial calcium was less than half the depth of the plaque, that is, closer to the plaque-lumen border than to the media-adventitia interface. Deep calcium was more than half the depth of the plaque, that is, closer to the media-adventitia interface than to the plaque-lumen border. Absence of calcium was coded as 0; deep calcium (in the absence of superficial calcium) was coded as 1; and the presence of any amount of superficial calcium was coded as 2. *Target lesion calcium length* was measured by adding the number of calcium-containing contiguous frames spaced at 1-mm intervals. *Target lesion superficial calcium length* was measured by adding the number of superficial calcium-containing contiguous frames spaced at 1-mm intervals.

Although acoustic shadowing caused by lesion calcification can make measurements of external elastic membrane cross-sectional area difficult, two types of extrapolation were used. Briefly, because the cross section of a coronary artery is more or less circular, extrapolation of the circumference is possible provided that each calcific deposit did not shadow $>60^\circ$ of the adventitial circumference. Also, real-time axial movement of the transducer just distal or proximal to a calcific deposit (or to find the smallest arc of calcium within a large calcific deposit) unmasked and filled in contiguous parts of the adventitia that were otherwise shadowed.

Reference site lumen cross-sectional area was also measured using computerized planimetry. The reference segment was selected as the most visually normal cross section within 10 mm proximal to the target lesion but distal to a major side branch. In circumstances where a proximal reference segment could not be identified (e.g., ostial lesion location or diffuse disease, as noted previously), then a distal reference (also within 10 mm of the target lesion but proximal to a major side branch) was analyzed.

Volumetric intravascular ultrasound analysis. Of the 170 patients, we selected 47 studies on the basis of good image quality and limited calcification throughout the length of the vessel. The plaque plus media volumes of the 47 lesions were measured before and after directional atherectomy. Histologic validation of this method of measuring plaque plus media volume has been reported previously (15). In brief, on playback of the recorded studies, an end-diastolic frame was selected every 1 mm of axial lesion length. Because the ultrasound images were not gated, end-diastole was determined when the vessel lumen was at its largest during the cardiac cycle. The external elastic membrane and lumen cross-sectional areas were traced manually at 1-mm axial intervals (with a pullback speed of 0.5 mm/s, each 2 s of video playback corresponds to 1 mm of axial lesion length). The length of the atherectomy site was determined by comparing the ultrasound images before and after atherectomy and by noting both the increase in lumen area and the typical postatherectomy findings of new plaque defects, fissuring and dissection planes. To ensure that the same segment was analyzed in the preatherectomy and postatherectomy studies, major branches and large calcific deposits were used as axial reference points.

External elastic membrane and lumen volumes (in mm^3) were calculated using Simpson's rule, and the plaque plus media volume (also in mm^3) was calculated as follows:

$$\text{External elastic membrane cross-sectional volume} \\ - \text{Lumen cross-sectional volume.}$$

Percent plaque volume removal was calculated as follows:

$$\frac{(\text{Plaque} + \text{Media volume preatherectomy} - \text{Plaque} \\ + \text{Media volume postatherectomy}) \times 100}{\text{Plaque} + \text{Media volume preatherectomy}}$$

Dependent variables. Three dependent intravascular ultrasound end point variables of the directional coronary atherec-

Table 1. Angiographic Lesion Morphology and Quantitative Angiographic Results

Ulcerated	19
Eccentric	105
Bend	21
Irregular	26
Calcified	31
Lesion length (mm)	7.91 ± 4.54
Reference lumen diameter (mm)	2.93 ± 0.51
Pre-DCA %DS	69 ± 15
Pre-DCA MLD (mm)	0.89 ± 0.39
Post-DCA %DS	21 ± 18
Post-DCA MLD (mm)	2.33 ± 0.51

Data presented are mean value ± SD or number of lesions. DCA = directional coronary atherectomy; DS = diameter stenosis; MLD = minimal lumen diameter.

tomy procedures were selected for analysis: two planar and one volumetric. The two dependent planar intravascular ultrasound variables were 1) the postatherectomy target lesion cross-sectional area, and 2) the postatherectomy target lesion percent cross-sectional narrowing. The latter has also been termed the residual plaque burden. In the 47 patients for whom volumetric measurements were available, the percent plaque volume removal was the third dependent variable.

Statistical analysis. Results were expressed as mean value ± SD. Dichotomous variables were expressed as frequencies. Relations between variables were examined using linear regression analysis. Clinical, procedural, angiographic and ultrasound variables with $p \leq 0.2$ were entered into a stepwise multivariate linear regression analysis to detect the independent variables that were significantly related to the postatherectomy lumen cross-sectional area, percent cross-sectional narrowing and percent plaque volume removal. Statistical analysis was performed utilizing the SAS statistical software program (16). Statistical significance was accepted as $p \leq 0.05$.

Results

Quantitative angiographic lesion characteristics and results. Qualitative and quantitative angiographic lesion characteristics are shown in Table 1. After atherectomy, the angiographic minimal lumen diameter increased from 0.89 ± 0.39 to 2.33 ± 0.51 mm, and percent diameter stenosis decreased from 69 ± 15% to 21 ± 18%.

Quantitative and qualitative intravascular ultrasound lesion characteristics and results. The lumen cross-sectional area increased from 1.7 ± 1.0 to 6.6 ± 2.0 mm² after directional atherectomy ($p < 0.0001$); this was primarily the result of a decrease in plaque plus media cross-sectional area (from 18.3 ± 6.1 to 14.0 ± 5.6 mm², $p < 0.0001$) but also a result of a small increase in external elastic membrane cross-sectional area (from 20.0 ± 6.5 to 20.6 ± 6.2 mm², $p < 0.0001$). The ultrasound variables that were significantly related to either the postatherectomy lumen cross-sectional area, percent

Table 2. Quantitative and Qualitative Intravascular Ultrasound Variables That Were Predictive of Any of the Three Indexes of Directional Atherectomy Results Using Univariate Analysis

Arc of Ca (deg)	69 ± 78 (0-360)
Arc of superficial Ca (deg)	30 ± 58 (0-360)
Ca location (nonc/superficial/deep)	67/52/51
Ca length (mm)	2.0 ± 2.2 (0-10)
Superficial Ca length (mm)	0.8 ± 1.7 (0-10)
Number of Ca arcs	0.7 ± 0.7 (0-3)
Reference lumen CSA (mm ²)	10.7 ± 4.1 (3.7-22.0)
Pre-DCA P+M CSA (mm ²)	18.3 ± 6.1 (6.2-38.6)
Eccentricity index	3.3 ± 2.6 (1.0-21.8)

Data presented are mean value ± SD (range) or number of lesions. Ca = calcium; CSA = cross-sectional area; DCA = directional coronary atherectomy; P + M = plaque + media.

cross-sectional narrowing or percent plaque volume removal ($p \leq 0.2$) are shown in Table 2. These variables were entered into the multivariate models.

Correlates of the postatherectomy intravascular ultrasound lumen cross-sectional area. The minimal residual lumen cross-sectional area was 6.6 ± 2.0 mm² (range 2.1 to 11.9). Univariate correlates included atherectomy device size, number of atherectomy cuts, reference lumen cross-sectional area, preatherectomy plaque plus media cross-sectional area and angiographic lesion length (Table 3). By stepwise linear regression analysis, reference lumen cross-sectional area was associated with a larger residual lumen cross-sectional area ($p = 0.0001$), whereas lesion length was associated with a smaller residual lumen cross-sectional area ($p = 0.0001$). To correct for vessel size, the same linear regression model was rerun, but reference lumen cross-sectional area was eliminated. After correction for vessel size, the arc of calcium was associated with a smaller residual lumen cross-sectional area ($p = 0.02$), and preatherectomy plaque plus media cross-sectional area was associated with a larger residual lumen cross-sectional area ($p = 0.0003$).

Correlates of postatherectomy intravascular ultrasound percent cross-sectional narrowing. The postatherectomy percent cross-sectional narrowing ranged from 21.0% to 90.0% (mean 67.9 ± 11.3%). Univariate correlates included angiographic lesion length, arc of calcium, calcium location, calcium length, reference lumen cross-sectional area, preatherectomy plaque plus media cross-sectional area and preatherectomy percent cross-sectional narrowing (Table 4). By stepwise linear regression analysis, arc of calcium ($p = 0.0002$), preatherectomy plaque plus media cross-sectional area ($p = 0.0001$) and lesion length ($p = 0.01$) were associated with a larger postatherectomy percent cross-sectional narrowing.

Correlates of ultrasound-measured percent plaque volume removal. In 47 patients in whom volumetric ultrasound analysis was performed, mean percent plaque volume removal was 19.7 ± 9.5% (range 2.6% to 45.8%) (Table 5). Univariate correlates included atherectomy device size, atherectomy bal-

Table 3. Clinical, Angiographic, Procedural and Intravascular Ultrasound Correlates of Intravascular Ultrasound Postatherectomy Minimal Lumen Cross-Sectional Area Before and After Forced Removal of Reference Lumen Cross-Sectional Area From the Model

	Univariate Analysis		Multivariate Analysis		Repeat Multivariate Analysis*	
	Coefficient	P Value	Coefficient	P Value	Coefficient	P Value
Clinical factors						
Age	0.028	0.09				
Unstable angina	0.409	NS				
Angiographic factors						
Pre-DCA %DS	1.05	NS				
Calcification	0.564	NS				
Lesion length	-0.088	0.06	-0.109	0.0001		
Bend	0.781	0.17				
Ulceration	0.465	NS				
Procedural factors						
Device size	1.265	0.005				
No. of DCA cuts	0.053	0.03				
DCA balloon pressure	0.009	NS				
IVUS factors						
Arc of Ca	-0.004	0.15			-0.006	0.02
Arc of superficial Ca	-0.003	NS				
Ca location	-0.0002	NS				
Ca length	0.057	NS				
Superficial Ca length	-0.007	NS				
No. of Ca arcs	0.098	NS				
Reference lumen CSA	0.106	0.0002	0.136	0.0001	*	*
Pre-DCA P+M CSA	0.093	0.002			0.113	0.0003
Eccentricity index	0.110	0.15				
r value				0.49		0.41
p value				0.0001		0.0004

*Multivariate analysis was repeated after correcting for the reference lumen cross-sectional area (CSA). IVUS = intravascular ultrasound; other abbreviations as in Table 2.

loon pressure and arc of calcium. Angiographic calcification had a borderline correlation ($p = 0.07$). By stepwise linear regression analysis, arc of calcium ($p = 0.02$) was associated with a smaller percent plaque volume removal, and atherectomy device size ($p = 0.04$) was associated with a larger percent plaque volume removal.

Discussion

The results of the present study indicate that the arc of calcium measured by intravascular ultrasound was the single most consistent predictor of directional atherectomy results. The arc of calcium impacted negatively on all three measures of directional coronary atherectomy results: postatherectomy/residual lumen area, postatherectomy percent cross-sectional narrowing and percent plaque volume removal. Furthermore, by multivariate linear regression analysis, the overall arc of target lesion calcium was more important than its location within the plaque, its length or even the arc or length of superficial calcium.

Selection of directional coronary atherectomy end points. Intravascular ultrasound end points were selected for several reasons. Even with the use of orthogonal projections, angiog-

raphy cannot evaluate the lumen in cross section without invoking a number of geometric assumptions (17-22) that can both underestimate and overestimate the amount of lumen narrowing. More recent studies (23-26) have documented the poor correlation between quantitative angiography and intravascular ultrasound in measuring lumen dimensions after intervention. Furthermore, angiography cannot determine the residual plaque burden or the amount of plaque removed during the directional coronary atherectomy procedure. The purpose of the directional coronary atherectomy procedure is to improve coronary artery lumen cross-sectional area by removing atherosclerotic plaque and to leave behind a reduced plaque burden.

Target lesion calcium as a predictor of atherectomy result. Previous studies using angiography and intravascular ultrasound recognized the impact of lesion calcification on the result of directional atherectomy. In an angiographic study, Hinohara et al. (3) found that the atherectomy success rate of calcified lesions was only 52% compared with a success rate >80% for noncalcified lesions. Ellis et al. (2) demonstrated that angiographic lesion calcification was an independent predictor of lesion success. Using intravascular ultrasound before and after atherectomy, Suarez et al. (27) showed that

Table 4. Clinical, Angiographic, Procedural and Intravascular Ultrasound Correlates of Intravascular Ultrasound Postatherectomy Percent Cross-Sectional Narrowing

	Univariate Analysis		Multivariate Analysis	
	Coefficient	p Value	Coefficient	p Value
Clinical factors				
Age	0.0003	NS		
Unstable angina	0.010	NS		
Angiographic factors				
Pre-DCA %DS	0.124	0.09		
Calcification	-0.003	NS		
Lesion length	0.006	0.007	0.005	0.01
Bend	-0.042	0.15		
Ulceration	0.045	0.12		
Procedural factors				
Device size	0.027	NS		
No. of DCA cuts	0.0004	NS		
DCA balloon pressure	0.0002	NS		
IVUS factors				
Arc of Ca	0.0004	0.0008	0.0004	0.0002
Arc of superficial Ca	0.0003	0.07		
Ca location	0.024	0.04		
Ca length	0.009	0.05		
Superficial Ca length	0.008	0.16		
No. of Ca arcs	0.0186	0.16		
Reference lumen CSA	0.005	0.002		
Pre-DCA P+M CSA	0.008	0.0001	0.008	0.0001
Eccentricity index	-0.003	NS		
Pre-DCA %CSN	0.678	0.002		
r value				0.62
p value				0.0001

%CSN = percent cross-sectional narrowing; other abbreviations as in Tables 2 and 3.

plaque reduction was greater in echolucent than in echogenic calcified plaques.

In our study, intravascular ultrasound arc of target lesion calcium was superior to angiographic calcification in predicting atherectomy results. Angiography is insensitive in the detection of calcium. Mintz et al. (28) found that intravascular ultrasound detected calcium in 76% of patients undergoing transcatheter therapy, whereas fluoroscopy detected it in only 48%. In the current study, 61% were found to be calcified by intravascular ultrasound compared with 18% by angiography.

Angiographic lesion length as a predictor of atherectomy result. Lesion length was an independent predictor of postatherectomy lumen cross-sectional area and percent cross-sectional narrowing. Similarly, Popma et al. (1) found that angiographic lesion length was an independent predictor of angiographic final minimal lumen cross-sectional area, and Hinohara et al. (3) showed that long lesions were associated with suboptimal atherectomy results. Lesion length did not impact on percent plaque volume removal. Two explanations are possible: 1) volumetric analysis may factor in lesion length, or 2) volumetric analysis of percent plaque removal does not include the contribution of immediate vessel expansion to the postatherectomy result, which may be affected by lesion length.

Table 5. Clinical, Angiographic, Procedural and Intravascular Ultrasound Correlates of Percent Plaque Volume Removal in 47 Patients Undergoing Volumetric Intravascular Ultrasound Analysis

	Univariate Analysis		Multivariate Analysis	
	Coefficient	p Value	Coefficient	p Value
Clinical factors				
Age	0.07	NS		
Unstable angina	2.5	NS		
Angiographic factors				
Pre-DCA %DS	8.9	NS		
Calcification	-7.69	0.07		
Lesion length	-0.219	NS		
Bend	4.30	NS		
Ulceration	-4.04	NS		
Procedural factors				
Device size	5.1	0.13	6.24	0.04
No. of DCA cuts	-0.283	NS		
DCA balloon pressure	-0.399	0.02		
IVUS factors				
Arc of Ca	-0.035	0.08	-0.04	0.02
Arc of superficial Ca	-0.034	0.19		
Ca location	-0.572	NS		
Ca length	-0.596	NS		
Superficial Ca length	-0.98	NS		
No. of Ca arcs	-0.465	NS		
Reference lumen CSA	0.44	NS		
Pre-DCA P+M CSA	0.196	NS		
Eccentricity index	0.682	0.09		
r value				0.48
p value				0.01

Abbreviations as in Tables 2 and 3.

Atherectomy device size as a predictor of atherectomy result. A larger (7F vs. 6F) atherectomy catheter was an independent predictor of percent plaque volume removal. By contrast, the atherectomy balloon pressure (which also influences the working diameter of the device) was not predictive; most of the devices used during the time course of this study were of the EX design, whose working diameter is less sensitive to balloon pressure. However, the contribution of tissue removal to lumen improvement after 6F versus 7F device use was similar. Using quantitative coronary angiography, Popma et al. (1) found that the atherectomy catheter size predicted the postatherectomy lumen cross-sectional area independently of the vessel size.

Comparison with other studies. A number of clinical and angiographic variables found by previous studies to be predictive of directional atherectomy results were not significant predictors in this study.

In the study by Ellis et al. (2), *proximal tortuosity, bend lesions, thrombus and preatherectomy minimal lumen diameter* were independent predictors of success, defined as a final percent diameter stenosis <50%, tissue removal and no major complications. Bend-point lesions and preatherectomy minimal lumen diameter are associated more with the success of delivering the atherectomy catheter to the lesion but not to its

ability to enlarge the lumen or remove plaque. In our study, only patients with procedural success were analyzed. Proximal tortuosity and the presence of thrombus were not tested because the number of patients with these variables was small.

Restenotic lesions were associated with a smaller post-atherectomy angiographic minimal lumen cross-sectional area in one study (1) but with a higher procedural success in another (2). Hinohara et al. (3) found that in restenotic lesions, the procedural success rate was high regardless of the number of complex lesion characteristics. In our study, a history of restenosis was not associated with any of the three dependent intravascular ultrasound variables tested.

Left circumflex coronary artery lesions were associated with larger final minimal cross-sectional areas in one study (1); however, in the current study, lesion location was not significantly associated with any of the dependent variables tested.

Study limitations. The current study has several limitations. 1) Despite the identification of several univariate and multivariate correlates of the atherectomy result, the correlation coefficients of the three models tested (0.41 to 0.62) suggest that a significant degree of variance cannot be explained by the presence or absence of the identified variables. 2) Only patients with successful procedures were studied; this study addresses the results of successful procedures, not the reason for procedural failure. 3) Because of the relatively small sample size, some angiographic factors, such as the presence or absence of thrombus and proximal vessel tortuosity, were not tested in the multivariate model. 4) Intravascular ultrasound was typically used to guide the directional atherectomy procedure. This may have biased the conclusions and, for example, may explain why plaque distribution (eccentricity) was not an important correlate of procedural results. 5) Volumetric analysis was performed for only 47 patients; this sample size may be too small for accurate analysis. However the results parallel the planar analysis performed in the larger patient cohort. 6) This study evaluated the results of primary directional atherectomy and did not take into account the contribution of adjunct balloon angioplasty to the final postprocedural results.

Conclusions. The preintervention target lesion arc of calcium measured by intravascular ultrasound (including angiographically invisible calcification) is the most consistent predictor of the effectiveness and result of directional coronary atherectomy. Long lesions adversely affect the final lumen cross-sectional area and the percent cross-sectional narrowing, whereas a larger atherectomy catheter size enhances the immediate atherectomy effects.

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