One hundred and thirteen attempts at directional coronary atherectomy: the early and combined experience of two European centres using quantitative angiography to assess their results

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Directional coronary atherectomy has been introduced as an alternative to conventional balloon angioplasty when treating coronary artery stenoses with complex lesion morphology. To determine the immediate efficacy of coronary atherectomy in patients with such lesions, the first 113 attempts at directional atherectomy in two centres using quantitative angiography were reviewed in 105 patients. The lesions were classified as complex stenosis since 95% had a symmetry index < 1·0, a length of 6·83 ± 2·55 mm on average and an area of plaque of 9·77 ± 6·69 mm². Procedural success defined as a residual stenosis ≤50% after tissue retrieval was obtained in 90 (85·7%) of 105 patients. The primary angioplastic success rate, combining atherectomy and balloon angioplasty in case of failed attempt of atherectomy was 95·2%.

Coronary atherectomy was unsuccessful in five patients; three were referred for emergency coronary artery bypass grafting. Major complications (death, emergency surgery and transmural infarction) were encountered in 5·7% of the patients.

Assessed by quantitative coronary analysis, a residual minimal luminal diameter of 2·42 ± 0·52 mm and a diameter stenosis of 26 ± 12% were obtained immediately after directional coronary atherectomy. We conclude that directional coronary atherectomy is particularly suitable for the treatment of stenosis with complex lesion morphology and is associated with acceptable complication rates. Randomized trials comparing atherectomy with balloon angioplasty are warranted to clarify the role of atherectomy in the treatment of lesions in the proximal part of the three major epicardial coronary arteries.

Introduction

Percutaneous transluminal coronary angioplasty was reported in 1978 by Gruentzig[1] as a non-operative technique for the treatment of single, discrete and proximal coronary artery stenosis in patients with symptomatic ischaemic heart disease. Over the past decade, improved technology and operator experience have led to a greater use of conventional balloon angioplasty with an excellent immediate success rate[2,3]. As indications for coronary angioplasty expand and more difficult anatomy is approached, the likelihood of acute complications has increased. Potential causes of an initial suboptimal and unsatisfactory angiographic result after conventional balloon angioplasty include arterial recoil, dissection and presence of thrombus. In the past 4 years, interventional cardiologists have designed new devices aimed at debulking the atherosclerotic plaque. Directional coronary atherectomy is such a new technique having the potential advantage of creating a smooth luminal surface by removing rather than remodelling the plaque.

We report the immediate quantitative angiographic results of the initial 113 clinical applications of directional coronary atherectomy in two European centres using the same methodology to assess the efficacy of intra-coronary interventions. Patients were referred for elective transcatheter treatment of an angiographic complex lesion and selected for directional coronary atherectomy when they presented with a suitable coronary anatomy (a stenosis in the proximal part of a coronary artery with a reference diameter ≥ 2·5 mm). Quantitative coronary angiographic analysis (CAAS) was used to evaluate the immediate efficacy of directional atherectomy.

Methods

PATIENT SELECTION

From September 1989 to April 1991, 105 patients underwent 113 attempts at directional coronary atherectomy at the two participating centres. Both medically stable and unstable patients were considered candidates for directional atherectomy when they presented with a large and eccentric coronary artery stenosis in the proximal part of an epicardial coronary artery with an anticipated reference diameter of at least 2·5 mm.

CORONARY ATHERECTOMY

The atherectomy procedure was carried out as previously described[4]. Briefly, all patients were pretreated
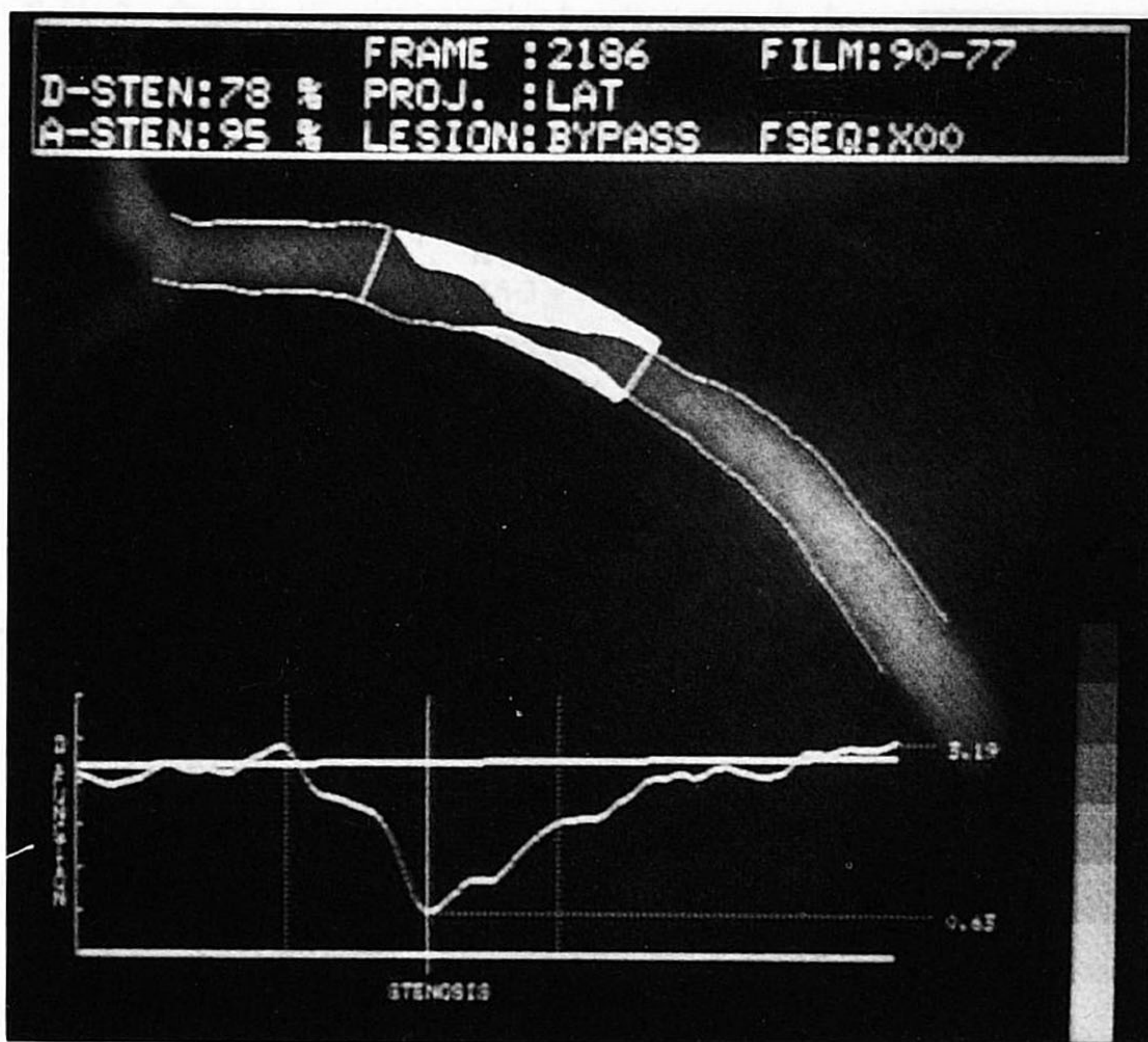
Figure 1 Detected contours superimposed on the original video image of a complex lesion within a stent in a venous bypass graft, filmed in lateral projection before directional atherectomy. The diameter function is shown at the bottom. The white area is a measure of the 'atherosclerotic plaque'. The minimal luminal diameter (vertical line) is 0·63 mm, corresponding to a diameter stenosis of 78% and an area stenosis of 95%.

with 250 mg acetylsalicylic acid and 10 000 U heparin intravenously. To prevent coronary spasm, intra-coronary isosorbide dinitrate was given. Following the initial angiograms, the atherectomy device was advanced using the over-the-wire technique and positioned across the stenosis. After proper positioning the support balloon was inflated up to 2 to 3 atm, the driving motor activated and the rotating cutter slowly advanced to cut and collect the protruding intimal lesion in the collecting chamber located at the tip of the catheter. After each pass, the balloon was deflated and either removed or repositioned. Atherectomy was considered successful when the residual stenosis was less than 50% and plaque material was present in the collecting chamber. Following atherectomy, the patients were monitored for 24 h and electrocardiograms and cardiac enzyme levels were obtained twice a day. Nifedipine or nitrates were given every 2 h for 24 h after the procedure, and aspirin was given for one year. All atherectomy procedures were performed after obtaining informed consent.

QUANTITATIVE CORONARY ANGIOGRAPHY

Quantitative analysis of the coronary segments was performed with the computer based Coronary Angiography Analysis System (CAAS), previously described in detail[4–8]. In essence, boundaries of a selected coronary artery segment are detected automatically from optically magnified and video digitized regions of interest (512 × 512 pixels) of a cine-frame (Figs 1 and 2). The absolute diameter of the stenosis in mm is determined using the guiding catheter as a scaling device. Calibration of the catheter in absolute values (mm) is achieved by comparing the mean diameter of the guiding catheter in pixels with the measured size in millimeters. Each individual catheter is measured by a micrometer. To correct the detected contour of the arterial and catheter segments for pincushion distortion, a correction vector is computed for each pixel based on a computer-processed cineframe with a centimeter grid placed against the input screen of the image intensifier. Since the functional significance of a stenosis is related to the expected normal cross-sectional area of a vessel at the point of obstruction, we use a computer-estimation of the original dimension of the artery at the site of the obstruction to define the interpolated reference diameter. The percentage diameter and area stenosis as well as the cross-sectional area (mm^2) are then calculated. The length of the lesion (mm) is determined from the diameter function on the basis of a curvature analysis. Symmetry is defined as the coefficient of the left hand distance between the reconstructed interpolated reference diameter and actual vessel contours and the right hand distance between reconstructed and actual contours at the site of the obstruction. The symmetry index ranges from 0 (totally eccentric stenosis) to 1 (symmetric). The degree of coronary bend is assessed by the curvature value at the obstruction site. This parameter is computed as the average value of all the individual curvature values along the centre line of the coronary segment, with the curvature defined as the first derivative of the tangent as it moves along the centre line which, for a
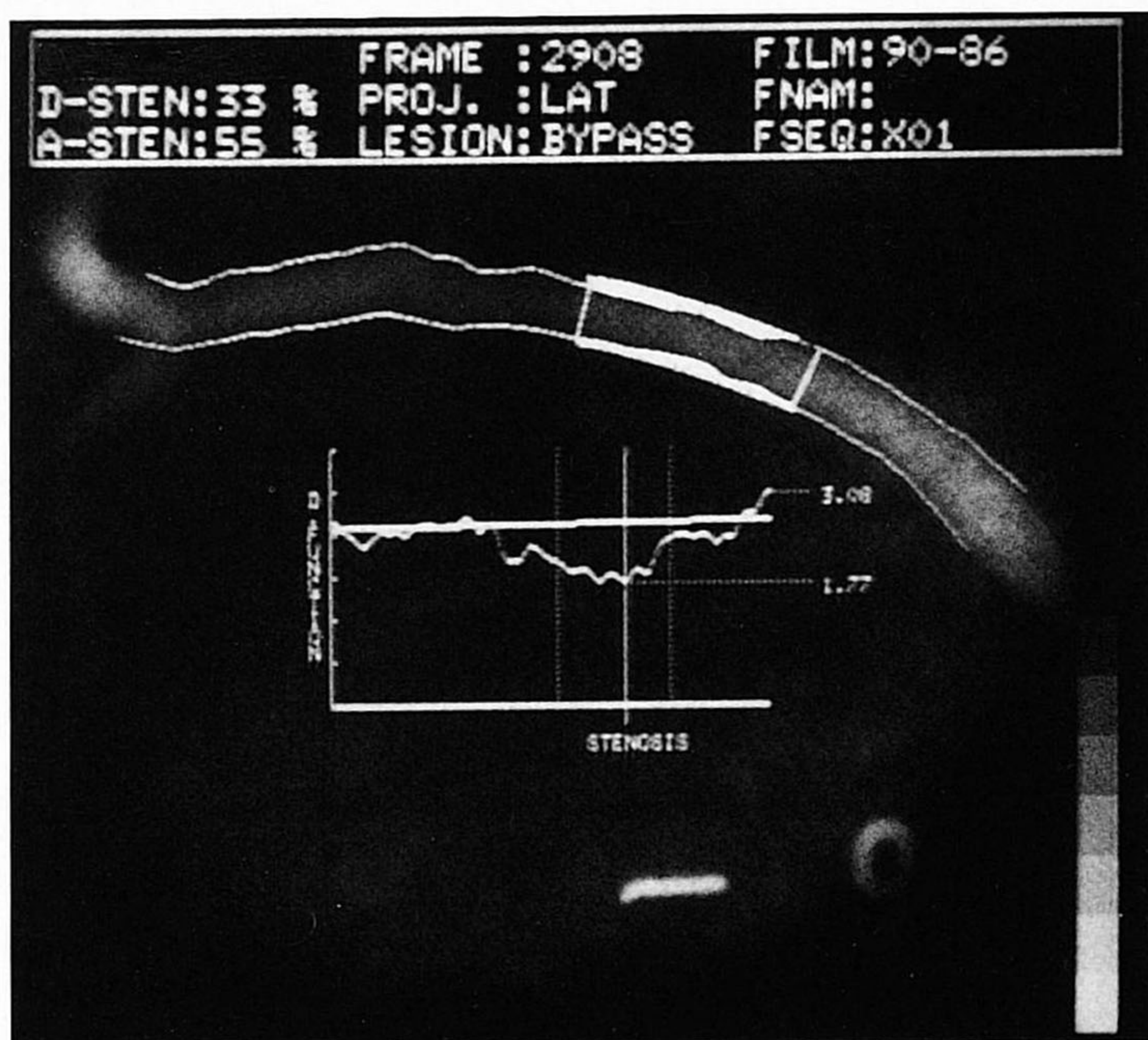
Figure 2   A single-frame angiogram of the venous bypass graft filmed in lateral projection after directional atherectomy. The minimal luminal diameter increased to 1·77 mm, corresponding to a diameter stenosis of 33% and an area stenosis of 55%.

circle, is equal to the reciprocal of the radius. The area between the actual and reconstructed contours at the obstruction site is defined as the plaque area and is expressed in mm^2. The severity of a stenosis can also be expressed as a percentage area stenosis assuming circular cross-sections at the obstruction and reference position. Corresponding luminal areas (mm^2) were calculated by comparing the minimal area value at the obstruction with the reference value obtained following the interpolated diameter technique.

Results

Technical success in crossing the stenosis with the atherectomy device was achieved in 95 of 105 patients (90·5%). In 10 patients atherectomy was not performed since the stenosis could not be reached by the atherectomy device; twice the guiding catheter could not be placed selectively in the coronary ostium and eight times the lesion could not be crossed by the atherotome itself. Nine of these patients underwent a successful conventional angioplasty procedure while one patient was electively referred for coronary artery bypass grafting. These 10 patients belonged to the cohort of the initial 25 patients treated by atherectomy in each centre.

CLINICAL AND LESION CHARACTERISTICS

Of the 95 patients in whom directional coronary atherectomy was performed, 24% had a history of a previous balloon angioplasty (n = 15), stenting (n = 6) or coronary atherectomy (n = 2); 24% had two or three-

Table 1   Clinical and lesion characteristics of 95 patients treated successfully by directional atherectomy

Gender		NYHA classification	
male	81	I	1
female	14	II	26
Age (years)	58 ± 11	III	27
		IV	41
History		Vessel disease	
prior infarction	43	one	67
prior angioplasty	15	two	22
prior stenting	6	three	6
prior atherectomy	2		
Angina		Target vessel	
stable	54	LAD	63
unstable	41	LCX	12
		RCA	24
		graft	4

LAD = left anterior descending, LCX = left circumflex, NYHA = New York Heart Association functional class, RCA = right coronary artery.

vessel disease and 41% had a previous myocardial infarction (Table 1). Two patients had previously undergone a heart transplantation. At the time of atherectomy, 41 patients were in New York Heart Association functional class IV, 27 patients in class III, 26 patients in class II and one patient in class I. The target stenosis (n = 103) in these 95 patients was located in the left anterior descending artery in 63 cases, in the left circumflex in 12 cases, in the right coronary artery in 24 cases and four times in a venous bypass graft.

Table 2 Quantitative angiographic baseline stenosis characteristics of 113 successfully treated coronary artery lesions

	Pre-atherectomy	Post-atherectomy
Extent (mm)	6·83 ± 2·55	5·16 ± 2·46
Symmetry index	0·53 ± 0·25	0·59 ± 0·23
Curvature value	15·3 ± 7·50	11·6 ± 7·44
Plaque area (mm²)	9·77 ± 6·69	3·27 ± 2·32
Area stenosis (%)	85 ± 8	43 ± 18
Reference area (mm²)	8·25 ± 3·30	9·72 ± 0·60
Reference diameter (mm)	3·17 ± 0·64	3·26 ± 1·13
MLCA (mm²)	1·12 ± 0·75	4·48 ± 1·78
MLD (mm)	1·13 ± 0·38	2·42 ± 0·52
DS (%)	64 ± 11	26 ± 15

DS = diameter stenosis, MLCA = minimal luminal cross-sectional area, MLD = minimal luminal diameter.

PROCEDURAL RESULTS

In all but four patients a 6 French atherectomy device was used. One patient was treated with a 5 French and in three patients a 7 French atherectomy device was used. On average 5·8 ± 2·8 passes in multiple directions were performed. The primary success rate as defined by a residual stenosis < 50% and tissue withdrawal was 85·7% (90 of 105 patients). The primary angioplastic success rate, combining atherectomy and balloon angioplasty in case of failed attempt at atherectomy was 95·2% (100 of 105 patients). Among the five patients with a final failure, one had an obstructive dissection which was successfully treated by a stent implantation, a second patient presented with an unexpected total occlusion. Despite

pre-dilatation and subsequent atherectomy, the coronary artery remained occluded and the patient was referred for elective coronary bypass grafting. Three patients were referred for emergency coronary artery bypass surgery because of guiding-catheter induced dissection of the right coronary ostium (n = 1), a total occlusion 1 h after the atherectomy procedure which persisted despite emergency balloon angioplasty (n = 1) and because of an obstructive dissection induced by the manipulation of the device into a curved coronary artery (n = 1).

QUANTITATIVE ANGIOGRAPHY

Quantitative angiographic analysis was performed on all successfully treated coronary lesions. The quantitative angiographic parameters which describe the complexity and the severity of the lesions are tabulated in Table 2. With respect to lesion complexity, the length of the stenosis was on average 6·83 ± 2·55 mm while all but five lesions were found to be eccentric (symmetry index < 1·0) according to quantitative angiographic definitions. The mean curvature value for all analysed segments was 15·3 ± 7·5. The lesion severity can be characterized by the plaque area, area stenosis and minimal cross-sectional area. The mean value for the area plaque was 9·77 ± 6·69 mm² while the area stenosis averaged 85 ± 8% and the minimal cross-sectional area was 1·12 ± 0·75 mm².

The sequential changes in angiographic parameters before and after coronary atherectomy are shown in Figs 3 and 4. The reference diameter did not change significantly. As expected, the minimal luminal diameter and mean cross-sectional area increased significantly
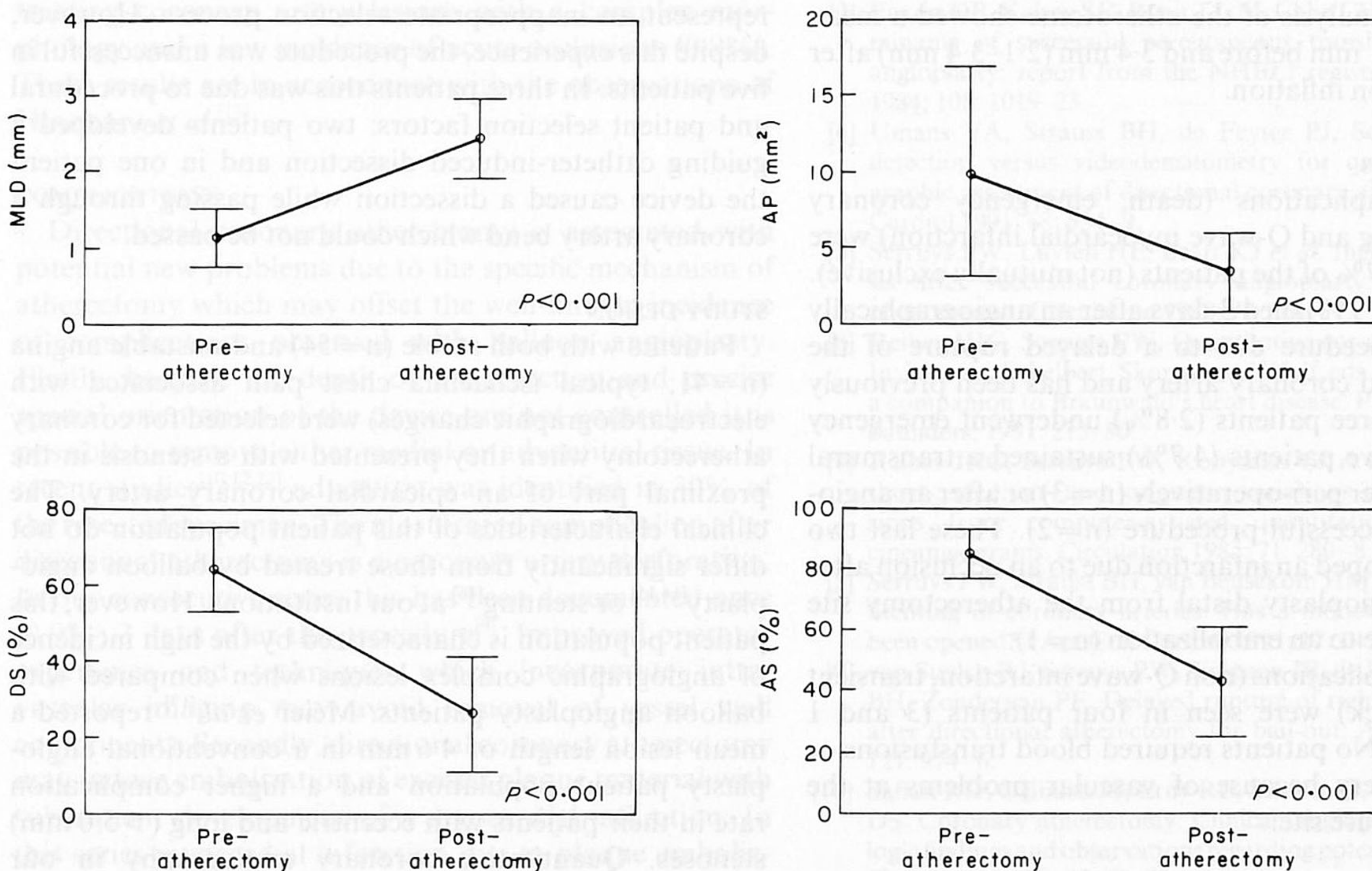

Figure 3 Minimal luminal diameter (MLD); plaque area (AP), diameter stenosis (DS) and area stenosis (AS) before and after coronary atherectomy. The minimal luminal diameter increased from 1·13 ± 0·38 mm to 2·42 ± 0·52 mm, the plaque area decreased from 9·77 ± 6·69 mm² to 3·32 ± 2·56 mm², and the diameter stenosis decreased from 64 ± 11% to 26 ± 15% and the area stenosis decreased from 85 ± 8% to 43 ± 18%.
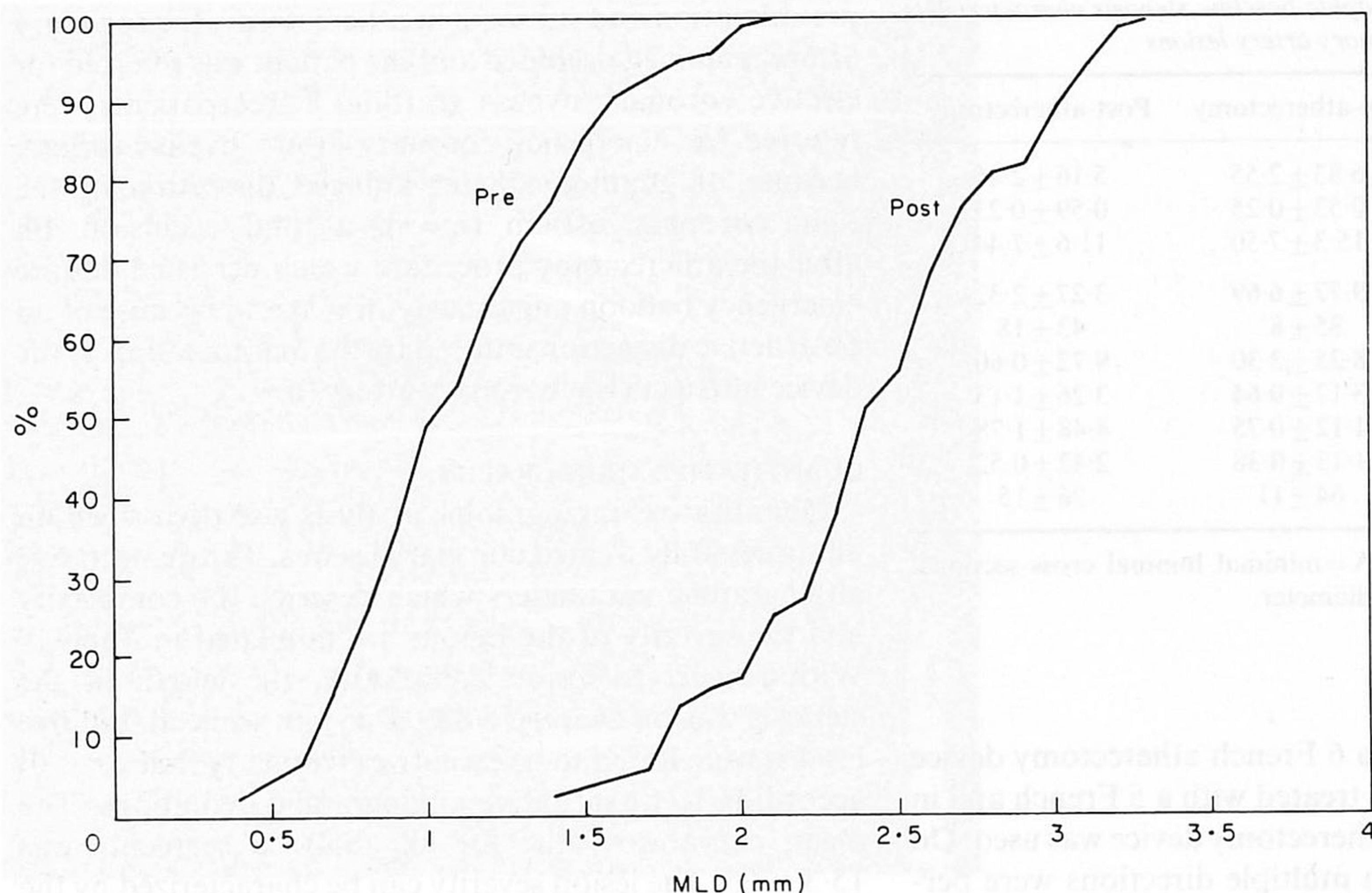
Figure 4 Cumulative frequency in minimal luminal diameter (MLD). Directional coronary atherectomy resulted in an increase of the minimal luminal diameter from $1·13 \pm 0·38$ mm to $2·42 \pm 0·52$ mm. Pre = before atherectomy, post = after atherectomy.

$(1·13 \pm 0·38$ mm to $2·42 \pm 0·52$ mm; $P < 0·01$ and $1·12 \pm 0·75$ mm^2 to $4·84 \pm 1·78$ mm^2; $P < 0·01$ respectively). Accordingly, the diameter stenosis and area stenosis decreased significantly from $64 \pm 11\%$ to $26 \pm 15\%$ $(P < 0·01)$ and from $85 \pm 8\%$ to $43 \pm 18\%$ $(P < 0·01)$. Quantitative analysis of the atherotome showed a mean diameter of 2·1 mm before and 3·4 mm (2·1–3·4 mm) after support balloon inflation.

COMPLICATIONS

Major complications (death, emergency coronary bypass grafting and Q-wave myocardial infarction) were observed in 5·7% of the patients (not mutually exclusive). One patient (0·9%) died 3 days after an angiographically successful procedure due to a delayed rupture of the atherectomized coronary artery and has been previously reported[9]. Three patients (2·8%) underwent emergency surgery and five patients (4·7%) sustained a transmural infarction either peri-operatively (n = 3) or after an angiographically successful procedure (n = 2). These last two patients developed an infarction due to an occlusion after a balloon angioplasty distal from the atherectomy site (n = 1) and due to an embolization (n = 1).

Minor complications (non Q-wave infarction, transient ischemic attack) were seen in four patients (3 and 1 respectively). No patients required blood transfusions or vascular surgery because of vascular problems at the femoral puncture site.

Discussion

The data from this study show a primary success rate of 85·7% which is comparable with other reports[10–13]. This success rate did not differ between the two centres and was markedly influenced by the learning-curve effect since the 10 patients in whom the lesion could not be crossed by the device belonged to the cohort of the initial 25 patients treated by atherectomy in each centre and therefore represent an inappropriate selection process. However, despite this experience, the procedure was unsuccessful in five patients. In three patients this was due to procedural and patient selection factors: two patients developed a guiding catheter-induced dissection and in one patient the device caused a dissection while passing through a coronary artery bend which could not be passed.

STUDY DESIGN

Patients with both stable (n = 54) and unstable angina (n = 41; typical ischaemia chest pain associated with electrocardiographic changes) were selected for coronary atherectomy when they presented with a stenosis in the proximal part of an epicardial coronary artery. The clinical characteristics of this patient population do not differ significantly from those treated by balloon angioplasty[14,15] or stenting[16] at our institutions. However, this patient population is characterized by the high incidence of angiographic complex lesions when compared with balloon angioplasty patients. Meier *et al.*[17] reported a mean lesion length of 4·6 mm in a conventional angioplasty patient population and a higher complication rate in their patients with eccentric and long (> 5·0 mm) stenoses. Quantitative coronary angiography in our patient population demonstrates a 95% incidence of asymmetric coronary artery stenoses with a long lesion $(6·83 \pm 2·55$ mm), a large atherosclerotic plaque (plaque area = $9·77 \pm 6·69$ mm^2) which severely obstructs the

coronary artery lumen (area stenosis = 85 ± 8%). We confirm the result of Hinohara *et al.*[13] that coronary atherectomy achieves a high success rate in lesions with complex stenosis characteristics.

MECHANISM

Luminal improvement after conventional balloon angioplasty is created by compression or remodelling of the atheromatous plaque and by overstretching the vessel wall. Frequently many of the lesions are not effectively dilated because of elastic recoil of the vessel wall or incompressibility of the encroaching plaque. Furthermore, the barotrauma of the balloon may induce substantial damage to the vessel wall which may result in a dissection or total occlusion. Recent studies report an incidence of acute coronary artery occlusion of 2 to 11% following conventional balloon angioplasty[14,15,18,19]. These studies have demonstrated that unstable angina and the complexity of the coronary artery lesion are important factors associated with risk of coronary artery occlusion[15,19,20]. Therefore, new techniques like directional atherectomy which remove rather than remodel the atheromatous plaque have been introduced to supplement conventional balloon angioplasty, especially when treating complex lesions. Theoretically, these techniques have several advantages over dilating techniques. First, selective ('directed') plaque removal becomes possible with fewer dissections. Second, with directional atherectomy, plaque removal results in a superior luminal improvement when compared to balloon angioplasty[20,21] and finally, atherectomy induces less recoil of the arterial wall[20]. This study demonstrates the efficacy of directional atherectomy in treating coronary artery lesions with a complex morphology and a low incidence of acute occlusions (0·9%). These results are in accordance with the observations of Hinohara *et al.*[13].

COMPLICATIONS

Directional coronary atherectomy is associated with potential new problems due to the specific mechanism of atherectomy which may offset the well-known incidence of complications observed with balloon angioplasty. Firstly, because the depth of the resection and precise spacial orientation of the device are not controlled it is possible to remove either medial or adventitial tissue. In recent studies[10,12,22] adventitia was identified in 30% of the resected specimen. The most feared complication after directional atherectomy is a coronary artery perforation. In our consecutive series this has been documented once (0·9%) 3 days after the procedure[9]. Improved operator experience and techniques which incorporate intravascular imaging may avoid removal of vessel wall components. Secondly, directional coronary atherectomy may induce embolization of excised plaque material with subsequent development of a myocardial infarction. In this series myocardial infarction due to plaque embolization was observed in 3·7% of the patients (1 Q-wave infarction). This complication rate is not higher than that reported in large PTCA trials including stable and unstable patients[2,3,14,15,18,19]. Furthermore, acute coronary

occlusion at the site of atherectomy occurred in 0·9% of the patients. Finally, atherectomy was performed with larger guiding catheters due to the bulkiness of the atherotome. The use of these larger guiding catheters may enhance the complication rate both at the puncture site and at the coronary ostium due to its size, limited manoeuverability and stiffness.

CONCLUSIONS

We confirm the results of other studies[10–13]: directional coronary atherectomy is technically feasible, is particularly suitable for the treatment of stenosis with complex lesion characteristics as assessed by quantitative coronary analysis and is associated with low complication rates. Success rates are further improved with adjunctive use of conventional balloon angioplasty for a failed atherectomy attempt. Randomized trials comparing atherectomy with balloon angioplasty are mandatory to clarify the specific role of atherectomy in the treatment of coronary artery disease.

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