

## ORIGINAL ARTICLES

# Quantitative angiography after directional coronary atherectomy

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## Abstract

**Objective**—To assess by quantitative analysis the immediate angiographic results of directional coronary atherectomy. To compare the effects of successful atherectomy with those of successful balloon dilatation in a series of patients with matched lesions.

**Design**—Case series.

**Setting**—Tertiary referral centre.

**Patients**—62 patients in whom directional coronary atherectomy was attempted between 7 September 1989 and 31 December 1990.

**Interventions**—Directional coronary atherectomy.

**Main outcome measures**—Increase in minimal luminal diameter of coronary artery segment.

**Results**—Angiographic success on the basis of intention to treat was obtained in 54 patients (87%). In four patients the lesion could not be crossed by the atherectomy device; all four had an uneventful conventional balloon angioplasty. Four of the 58 patients who underwent atherectomy were subsequently referred for coronary bypass surgery because of failure or complications; three of them sustained a transmural infarction. In the successful cases, coronary atherectomy resulted in an increase in the minimal luminal diameter from 1.1 mm to 2.5 mm with a concomitant decrease of the diameter stenosis from 62% to 22%. In the subset of 37 patients in which the changes induced were compared with conventional balloon angioplasty atherectomy increased the minimal luminal diameter more than balloon angioplasty (1.6 v 0.8 mm;  $p < 0.0001$ ). Conventional histology showed media or adventitia in 26% of the atherectomy specimens. In hospital complications occurred in six patients who had undergone a successful procedure: two transmural infarctions, two subendocardial infarctions, one transient ischaemia attack, and one death due to delayed rupture of the atherectomised vessel. All patients were clinically evaluated at one and six months. One patient had persisting angina (New York Heart Association class II), one patient sustained a myocardial infarction, one patient underwent a percutaneous transluminal coronary angioplasty for early restenosis, and one

patient underwent coronary bypass surgery because of a coronary aneurysm formation. At six months 80% (36/47) of the patients were symptom free.

**Conclusions**—Coronary atherectomy achieved a better immediate angiographic result than balloon angioplasty; however, in view of the complication rate in this preliminary series, which may be related to a learning curve, a randomised study is needed to show whether this procedure is as safe as a conventional balloon angioplasty.

Percutaneous transluminal coronary angioplasty was reported in 1978 by Gruentzig<sup>1</sup> 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 coronary angioplasty with an excellent immediate success rate.<sup>2,3</sup> As indications for coronary angioplasty expanded and more difficult lesions were attempted, the likelihood of acute complications increased. The most dangerous complication is acute occlusion which is encountered in 2–10% and frequently requires emergency surgical revascularisation.<sup>4,5</sup> Although acute occlusion is occasionally caused by thrombosis, it is usually caused by an intimal dissection.<sup>6,7</sup> In particular lesions with a complex shape have a greater tendency to occlude abruptly.<sup>4</sup> The use of new techniques might reduce acute complications after conventional balloon dilatation.<sup>8–11</sup> Although balloon angioplasty can efficiently dilate a stenosis, recoil is one of the immediate mechanisms that results in the loss of 50% of the balloon angioplasty result.<sup>12</sup> Several newly developed techniques have been designed to debulk coronary tissue thereby reducing the potential effect of elastic recoil.

Atherectomy is one such technique that might lead to fewer acute complications and less recoil because the plaque is removed rather than merely disrupted by the balloon inflation. There are published reports on the safety and short term results of atherectomy.<sup>13–16</sup>

We have assessed the immediate clinical and angiographic results of coronary atherectomy using quantitative coronary analysis as an objective method.

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from optically magnified and video digitised regions of interest ( $512 \times 512$  pixels) of a cineframe. The absolute diameter of the stenosis in mm was determined with the guiding catheter as a scaling device. Calibration of the catheter as an absolute value (mm) was achieved by comparing the mean diameter of the guiding catheter in pixels with the measured size in millimetres. Each catheter was measured individually. To correct the detected contour of the arterial and catheter segments for pincushion distortion, a correction vector was computed for each pixel based on a computer-processed cineframe with a centimetre grid placed against the input screen of the image intensifier. Because the functional significance of a stenosis is related to the expected normal cross sectional area of a vessel at the point of obstruction, we used a computer estimation of the original dimension of the artery at the site of the obstruction to define the interpolated reference area. The percentage diameter and area stenosis and the minimal luminal diameter (mm) and cross sectional area ( $\text{mm}^2$ ) were then calculated. The length of the lesion (mm) was determined from the diameter function on the basis of a curvature analysis. In addition, this technique allowed the assessment of the eccentricity of the lesion for a given view. The symmetry index ranged from 0 (totally eccentric stenosis) to 1 (symmetric). The degree of coronary bend was assessed by the curvature value at the obstruction site. This variable was computed as the average value of

all the individual curvature values along the centreline of the coronary segment, with the curvature defined as the first derivative of the tangent as it moves along the centreline, which for a circle is equal to the reciprocal of the radius.

#### ANGIOGRAPHIC MATCHING PROCESS

We compared the results of the first 37 successful consecutive patients of this series with the results of 37 individually matched angioplasty lesions in 37 other patients. To avoid patient selection bias we selected populations with comparable baseline stenosis characteristics. The coronary artery tree was subdivided into 15 segments according to the American Heart Association guidelines. The lesions were individually matched according to stenosis location and reference diameter. Matching was considered adequate if the mean difference of the reference diameter between the groups was zero.<sup>19</sup>

#### HISTOLOGY

Tissue samples were carefully removed from the collecting chamber of the atherectomy device. Part of the material was used for microscopical and morphological examination while the other part was processed for cell culture studies.<sup>20</sup> Specimens were fixed in 10% buffered formalin and embedded in paraffin. Tissue sections were cut and stained with haematoxylin-azofloxin. Light microscopical examination of each specimen was performed

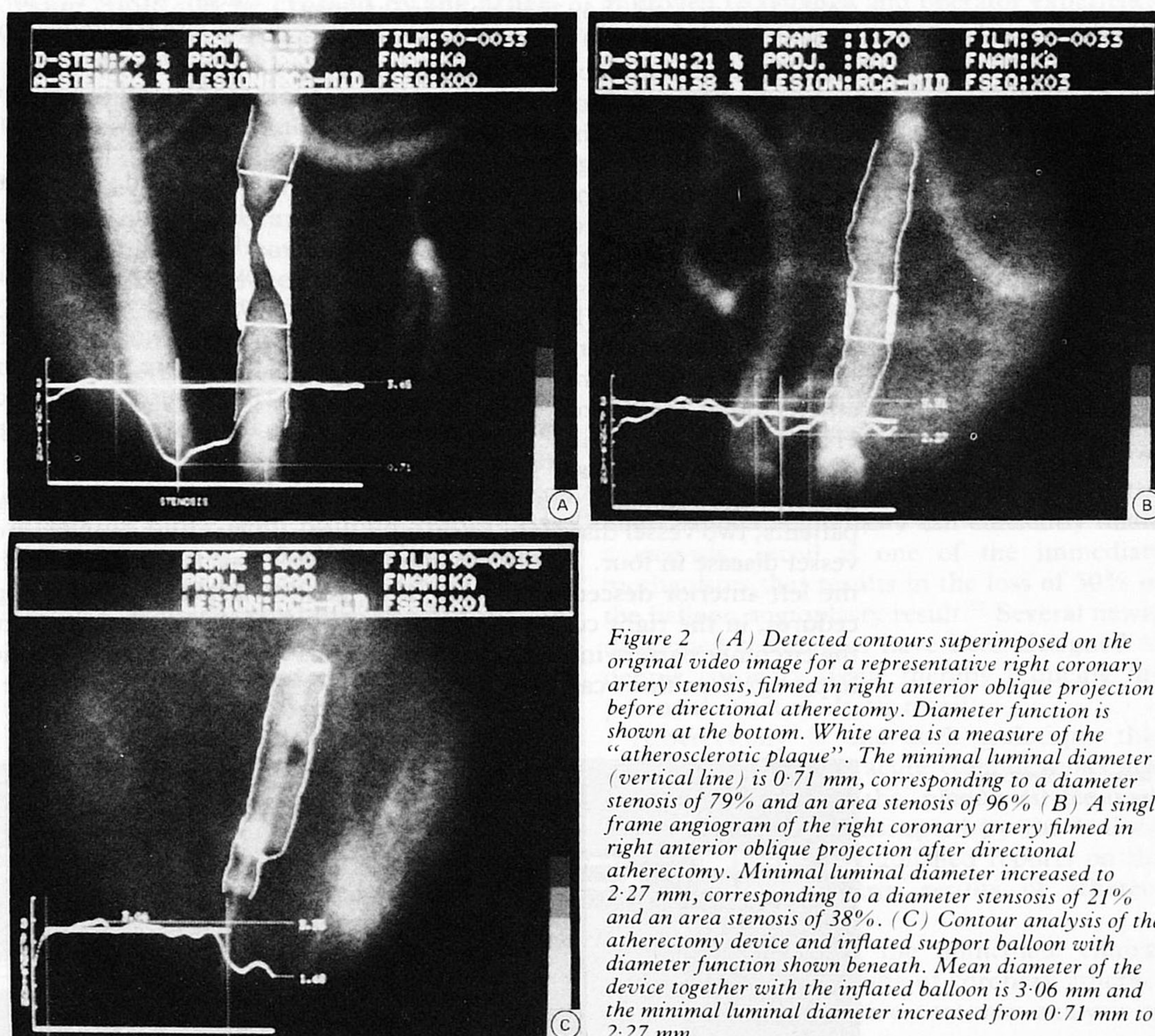


Figure 2 (A) Detected contours superimposed on the original video image for a representative right coronary artery stenosis, filmed in right anterior oblique projection before directional atherectomy. Diameter function is shown at the bottom. White area is a measure of the "atherosclerotic plaque". The minimal luminal diameter (vertical line) is 0.71 mm, corresponding to a diameter stenosis of 79% and an area stenosis of 96% (B) A single frame angiogram of the right coronary artery filmed in right anterior oblique projection after directional atherectomy. Minimal luminal diameter increased to 2.27 mm, corresponding to a diameter stenosis of 21% and an area stenosis of 38%. (C) Contour analysis of the atherectomy device and inflated support balloon with diameter function shown beneath. Mean diameter of the device together with the inflated balloon is 3.06 mm and the minimal luminal diameter increased from 0.71 mm to 2.27 mm.

were separately assessed by quantitative angiography. Such a study is precluded by ethical considerations.

Does the removal of atheromatous tissue explain the improvement in the luminal diameter? Rensing *et al* and others suggested that part of the luminal improvement is due to "facilitated angioplasty".<sup>25,26</sup> Our study helps to clarify this issue. The intracoronary quantitative assessment of the device size showed a mean diameter of 2.1 mm increasing to 3.4 mm after balloon inflation, while the minimal luminal obstruction diameter and reference diameter were 1.1 mm and 3.0 mm, respectively. The introduction of the atherectomy device itself has a "dottering" effect that is subsequently combined with an angioplasty effect when the support balloon is inflated.

Atherectomy was predominantly performed in long eccentric stenoses located in a proximal coronary artery containing a large atheromatous mass. Our primary angiographic success rate (87%), based on intention to treat analysis, is similar to the results reported so far.<sup>13-16</sup> The treatment of such a lesion is currently a major challenge in interventional cardiology because it is known that the risk of acute complication is high in these lesions. We need a randomised study to establish whether these lesions are more safely and successfully treated by atherectomy than by conventional balloon dilatation.

#### POTENTIAL RISKS

This new and vigorous technique produces a larger luminal diameter than any other intracoronary interventional technique.<sup>25,27</sup> Because the depth of the resection and precise spacial orientation of the device are not controlled, it is possible to remove both medial and adventitial tissue. In one study adventitia was identified in 30% of the resected specimens.<sup>28</sup> The 26% incidence of media in our specimens supports these findings.

In one of our patients coronary perforation occurred three days after a bail-out atherectomy. Conventional angioplasty had led to an obstructive dissection which was removed by atherectomy; three days later the patient died of cardiac tamponade. In one patient formation of a coronary aneurysm occurred after the use of a relatively oversized 7 F atherectomy device. Embolisation of atheromatous material from the plaque to the periphery of the treated vessel occurred in two patients resulting in a non-Q wave infarction. Side branch occlusion was noted once. With the use of an 11 French sheath, major groin complications may occur; however, none of our patients developed a haematoma requiring blood transfusion or vascular surgical repair. These cases underline the risks associated with the aggressiveness of atherectomy. In future the device will undoubtedly be modified to produce smaller, more flexible, and less traumatic systems.

#### ATHERECTOMY AS A BIOPSY TECHNIQUE

Recently Johnson *et al* reported their histological observations on excised peripheral arterial tissue from atherectomy procedures.<sup>29</sup>

They found that 75% of restenosis showed intimal fibrous proliferation compared with 9% in primary atherectomy lesions which consisted predominantly of typical atherosclerotic plaque.<sup>29</sup> Our results are consistent with theirs: 89% of restenoses showed intimal hyperplasia compared with 24% of primary stenoses.

In our study atherectomy was performed within a stent on five occasions. The tissue excised resembled that of other restenosis specimens. Microscopy showed intimal hyperplasia and capillary ingrowth. Immunohistochemical staining showed that most of these cells were smooth muscle cells. We and others are currently investigating the behaviour of smooth muscle cells in culture from atherectomy material.<sup>20,30</sup> Thus atherectomy can be used to obtain material to throw light on the development of restenosis or to monitor pharmacological treatments.

Directional coronary atherectomy is an effective non-operative treatment of coronary artery lesions. It is particularly effective in removing atheromatous tissue specimens from eccentric lesions which are not particularly amenable to conventional balloon angioplasty. Quantitative analysis of the immediate results after coronary atherectomy shows a greater gain in minimal luminal diameter than with balloon angioplasty. Using quantitative analysis we found evidence that a facilitated angioplasty effect partly accounts for the luminal improvement. Because the depth and site of the resection is not controlled, atherectomy can lead to serious complications. Atherectomy is a method of obtaining human (re)stenosis tissue which can be used to study the causes of restenosis. Despite the encouraging short term results, however, we need further studies of the ultimate indications and long term follow up.

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