European Heart Journal (1993) **14**, 505–510

The mechanism of directional coronary atherectomy

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KEY WORDS: Directional coronary atherectomy, quantitative angiography, Dotter effect.

An attempt was made to assess the mechanism of directional coronary atherectomy using different methods of analysis. Quantitative coronary angiography was used as the gold standard to assess the immediate results of atherectomy, and a comparative quantitative analysis of atherectomy and balloon angioplasty was made. To determine whether the post-atherectomy cross-sectional area is close to a circle, we compared the area measurements obtained by edge detection with those obtained by videodensitometry. Finally, the extent of a 'Dotter' effect was established by quantitative angiography following crossing the stenosis with the atherectomy device. For the purpose of this study, the results of the first 113 successful atherectomy procedures were reviewed. In matched lesions, directional atherectomy induced a greater increase in minimal luminal diameter than balloon angioplasty (1·6 mm vs 0·8 mm; P*<0·0001). However, this luminal improvement is due to a substantial 'Dotter' effect induced by the bulky atherectomy device. Following atherectomy, only a slight difference in cross-sectional area measurements between edge detection and videodensitometry (mean difference: 0·28 mm²) was found. Histologic examination of an atherectomized coronary artery showed a near-circular post-atherectomy area geometry. In conclusion, directional atherectomy is a very effective device with a substantially better initial result than balloon angioplasty. However, insertion of this bulky device itself causes an important 'Dotter' effect.*

Introduction

Directional coronary atherectomy has been introduced as a novel percutaneous technique for the treatment of coronary artery disease. The exact mechanism through which directional atherectomy enlarges the vessel lumen is under extensive investigation. As its name indicates, 'directional' atherectomy selectively removes the atheromatous plaque as the cutting device is directed towards the encroaching plaque. With plaque removal, instead of remodelling, a greater gain in luminal area is expected. Furthermore, the luminal lining may become smooth and the vessel wall may assume a more circular configuration. Based on quantitative coronary analysis, we[1] and others[2] have suggested that a significant 'Dotter' effect is part of the 'angioplastic' process. Whether this effect is an important determinant of the final result has not been firmly established. Together with quantitative coronary angiography, histopathological examination of atherectomy specimens and post-mortem examination may also shed light on the mechanism of directional coronary atherectomy.

For the purpose of this study, the quantitative coronary angiographic data (videodensitometry and edge detection) and histological information of two institutions were reviewed. In particular, the extent of the 'Dotter' effect and the post-atherectomy lumen area configuration were assessed to elucidate some of the mechanisms of directional coronary atherectomy.

Submitted for publication on 30 January 1992, and in revised form 9 October 1992.

This study was supported in a part by a grant from the Netherlands Heart Foundation. Technical assistance was by Eline Montauban van Swijndregt.

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Methods

ATHERECTOMY PROCEDURE

From September 1989 to July 1991, 113 patients underwent a successful directional coronary atherectomy at the Thoraxcenter and St Luc Hospital. A successful procedure is defined by tissue retrieval and a visually assessed post-procedural diameter stenosis <50%. Using a standard over the wire technique, an 11 French guiding catheter was positioned in the coronary ostium. All patients received 250 mg acetylsalicylic acid and 10 000 U heparin intravenously. Intracoronary injection of isosorbide dinitrate was performed to relieve any possible spasm. The atherectomy device, either 6 or 7 French, was advanced through the guiding catheter, slid over a guidewire and positioned across the stenosis. After proper positioning the support balloon was inflated up to 0·5 atm, the cutter was retracted and balloon inflation pressure was increased to 2 to 3 atm. The driving motor was activated and the rotating cutter was slowly advanced to cut and collect the protruding atherosclerotic lesion in the collecting chamber located at the tip of the catheter. After each pass, the balloon was deflated and either removed or repositioned. On average, 5·8 (3–14) passes were performed across a stenosis.

QUANTITATIVE CORONARY ANALYSIS

Edge detection

Quantitative analysis of the stenotic coronary segments was carried out with the computer-assisted Cardiovascular Angiographic Analysis System (CAAS), which has been described in detail elsewhere[3–7]. 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

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Table 1 Matched pre-procedural stenosis characteristics of 51 patients with successful coronary atherectomy compared to successful balloon angioplasty

	Pre-atherectomy	Pre-angioplasty
Reference diameter (mm)	3·0 ± 0·6	3·0 ± 0·6
Minimal lumen diameter (mm)	1·1 ± 0·4	1·1 ± 0·3
Diameter stenosis (%)	64 ± 10	63 ± 9
Area plaque (mm^2)	9·1 ± 6·0	8·4 ± 4·6
Curvature value	15·9 ± 7·0	22·2 ± 13·1*
Symmetry index	0·5 ± 0·3	0·5 ± 0·4

**P* value $<$0·02.

a cine-frame. Each individual catheter is measured by a micrometer and used as a scaling device. Correction for pincushion distortion was performed. The computer estimation of the original dimension of the artery at the site of the obstruction was used to define the interpolated reference diameter. The percentage diameter and area stenosis as well as the minimal cross-sectional area of the narrowed segment were then derived by assuming a circular model and comparing the observed stenosis dimensions to the reference values. The angiographic analysis was done using the average of multiple matched views with orthogonal projections whenever possible.

Videodensitometry

To determine the changes in cross-sectional area of a coronary segment from the density profile within the artery, the calibration of the brightness levels in terms of the amount of X-ray absorption (Lambert Beer's Law) is required. Details of this technique have been described elsewhere[3–7]. Calibration of the densitometric area values is accomplished by comparing the reference area calculated from the diameter measurements (assuming a circular cross-section) with the corresponding densitometric area value. The complete procedure has been evaluated with the cine-films of perspex models of coronary obstructions[6].

Matching process

The matching process has been described earlier[1]. Briefly, the coronary artery tree was subdivided into 15 segments according to the American Heart Association guidelines and the lesions were individually matched according to stenosis location and reference diameter. The principles of matching are threefold: the angiographic dimensions of matched lesions are assumed to be 'identical', the observed difference between the two 'identical' lesions must be within the range of the CAAS analysis reproducibility of 0·1 mm (= 1 SD)[5] and finally the reference diameter of the vessels to be matched are selected within a range of ±0·3 mm (= 3 SD; confidence limits 99%).

PATIENTS

Group A

Out of the initial cohort of 113 patients, 51 atherectomy patients were individually matched with 51 patients who underwent conventional balloon dilatation.

Group B

In 29 patients, edge detection and videodensitometry were used to evaluate the immediate results of the atherectomy. The change in minimal cross-sectional area before and after the procedure was determined by both methods and subsequently compared.

Group C

In 10 consecutive patients quantitative coronary angiography was performed before atherectomy, after crossing the stenosis with the device and after directional atherectomy ('sham atherectomy').

Histopathology following atherectomy

Post-mortem examination was available from one patient who died 2 days after a successful atherectomy procedure as a result of a delayed rupture of the right coronary artery which resulted in a tamponade leading to death[8]. Post-mortem histological cross-sections revealed a fissure of the atherectomized vessel.

Results

ATHERECTOMY VS BALLOON ANGIOPLASTY

The pre-procedural stenosis characteristics of the matched patients (group A) are summarized in Table 1. The immediate efficacy of atherectomy and angioplasty, as assessed by quantitative angiography, are detailed in Fig. 1. As expected, atherectomy and balloon angioplasty significantly improved the minimal lumen diameter (1·1 ± 0·4 mm to 2·7 ± 0·4 mm; $P<0{\cdot}0001$ vs 1·1 ± 0·3 mm to 1·9 ± 0·4 mm; $P<0{\cdot}001$). Immediately following atherectomy, the increase in minimal lumen diameter was superior compared to conventional balloon angioplasty (1·6 vs 0·8 mm; $P<0{\cdot}0001$).

EDGE DETECTION VS VIDEODENSITOMETRY

In group B, the minimal luminal cross-sectional area (MLCA), as determined by densitometry, was compared with the minimal luminal cross-sectional area measurements from edge detection which assumes a circular configuration. Analysis of variance was performed to compare the area measurements derived from edge detection and densitometry before and after atherectomy, and when significant differences were found, two-tailed paired t-tests were applied. A statistical probability of <0·05 was

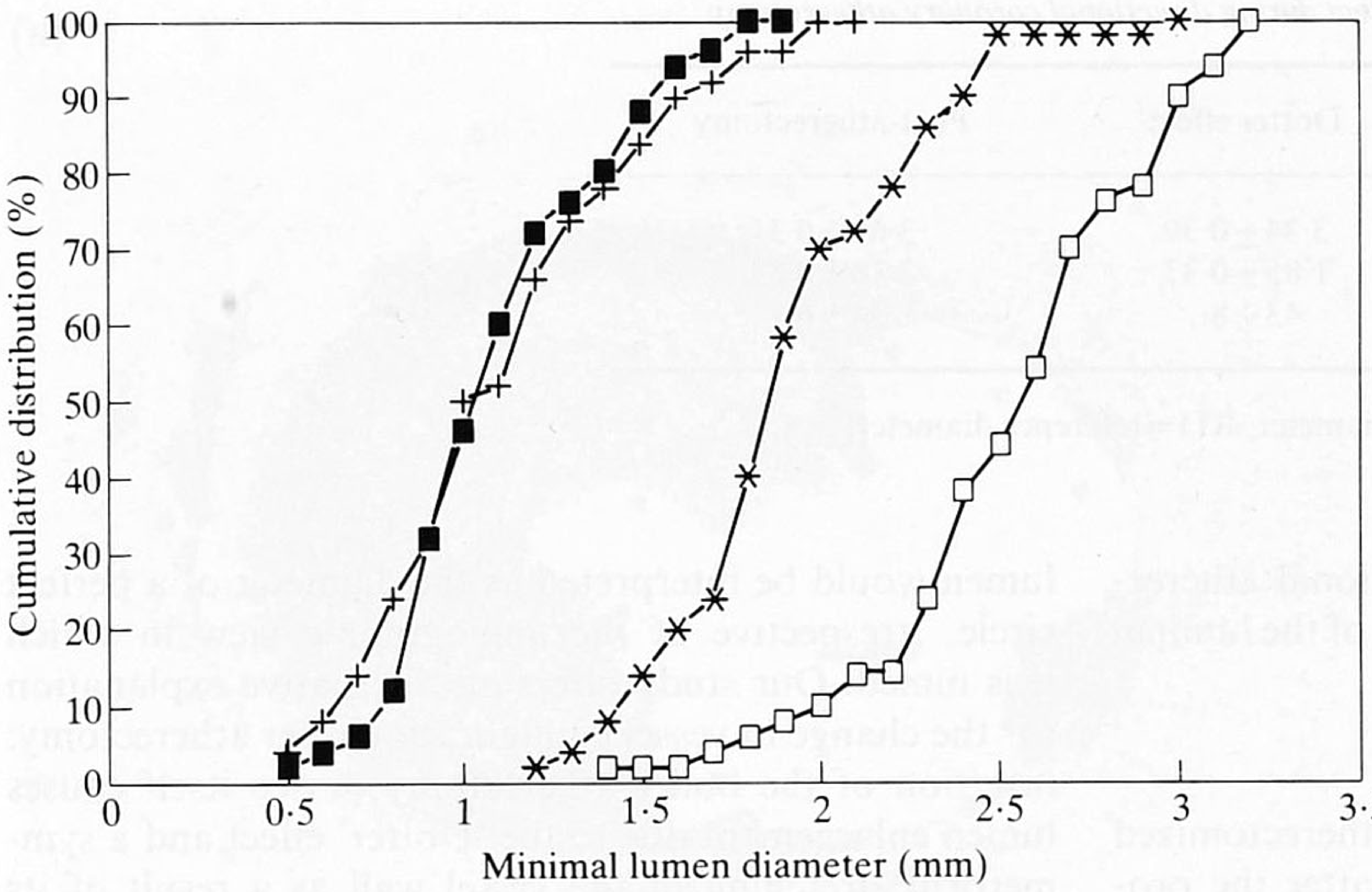


Figure 1 Cumulative distribution of the minimal luminal diameter in 51 patients who underwent either atherectomy or balloon angioplasty. Atherectomy resulted in a superior immediate luminal improvement. ■ = before percutaneous coronary angioplasty (PTCA); + = before atherectomy; * = after PTCA; □ = after atherectomy.

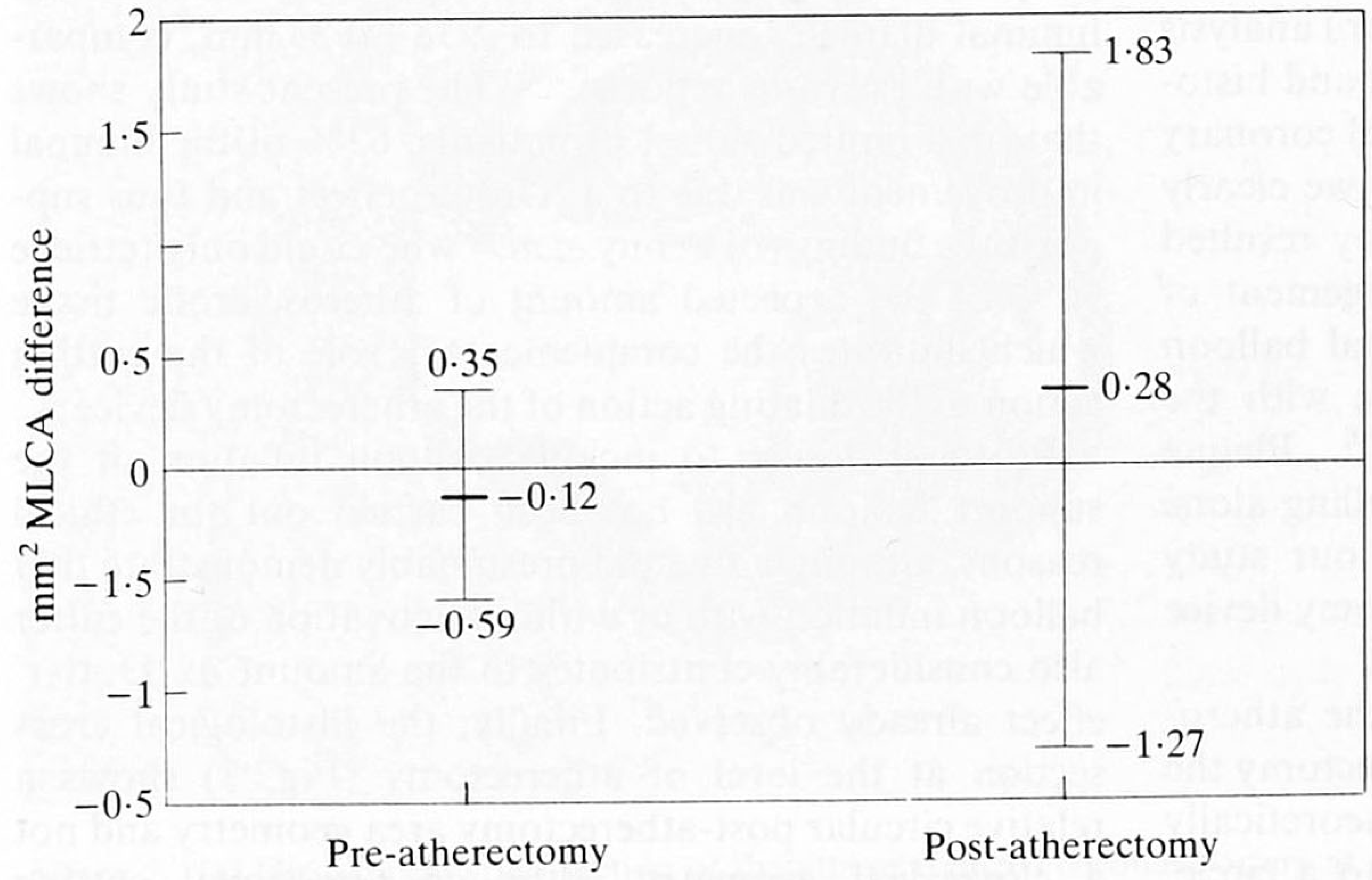


Figure 2 Individual data of the average minimal cross-sectional area (MLCA) before and after atherectomy assessed by edge detection and videodensitometry vs the difference in cross-sectional area between the methods. The mean difference before atherectomy was -0.12 mm^2; this slightly increased to 0.28 mm^2 after atherectomy.

considered significant. The agreement between the two methods was assessed by determining the mean and the standard deviation of the between-method difference, as suggested by Bland and Altman[9]. The comparative data before and after coronary atherectomy in group B are shown in Fig. 2. The minimal luminal cross-sectional area as determined by videodensitometry increased after atherectomy from 1.03 ± 0.77 mm^2 to 5.18 ± 1.64 mm^2 ($P < 0.0001$). The mean difference of the minimal cross-sectional area between the two methods before atherectomy was -0.12 mm^2, while this difference was slightly larger after atherectomy (mean difference 0.28 mm^2). The variability, as determined by the standard deviation of the between-method difference, was higher in the post-atherectomy analysis (1.55 mm^2) compared to the pre-atherectomy analysis (0.47 mm^2), suggesting that atherectomy induces a near-circular lumen area configuration. Quantitative analysis of the atherectomy device showed an increase of its diameter from 2.0 ± 0.2 mm to 3.4 ± 0.4 mm following inflation of the support-balloon.

'SHAM' ATHERECTOMY

The extent of the 'Dotter' effect as assessed by quantitative angiography in 10 consecutive patients of group C, is summarized in Table 2. The minimal lumen diameter increased from 0.97 ± 0.32 mm to

Table 2 Quantitative assessment of the 'Dotter' effect during directional coronary atherectomy

	Pre-atherectomy	Dotter effect	Post-atherectomy
RD (mm)	3·46 ± 0·36	3·34 ± 0·39	3·61 ± 0·31
MLD (mm)	0·97 ± 0·32	1·85 ± 0·37	2·38 ± 0·33
DS (%)	71 ± 8	43 ± 8	34 ± 6

DS = diameter stenosis; MLD = minimal luminal diameter; RD = reference diameter.

2·38 ± 0·33 mm ($P < 0·01$) following directional atherectomy. The 'Dotter' effect accounts for 62% of the luminal improvement.

HISTOPATHOLOGY

A histological cross-section of the atherectomized coronary artery of the patient who died after the procedure shows that all three layers of the vessel wall had been resected while the obstructive plaque remained unchanged (Fig. 3).

Discussion

In this report we used four different methods of analysis (edge detection, videodensitometry, matching and histology) to elucidate the mechanism of directional coronary atherectomy. Using our matching technique, we clearly showed that directional coronary atherectomy resulted in a superior immediate angiographic enlargement of the luminal area as compared to conventional balloon dilatation. These findings are in accordance with the observations reported by Muller *et al.*[10]. Plaque removal and remodelling rather than remodelling alone can account for this superiority. However, our study shows that introduction of the bulky atherectomy device is associated with a substantial 'Dotter' effect.

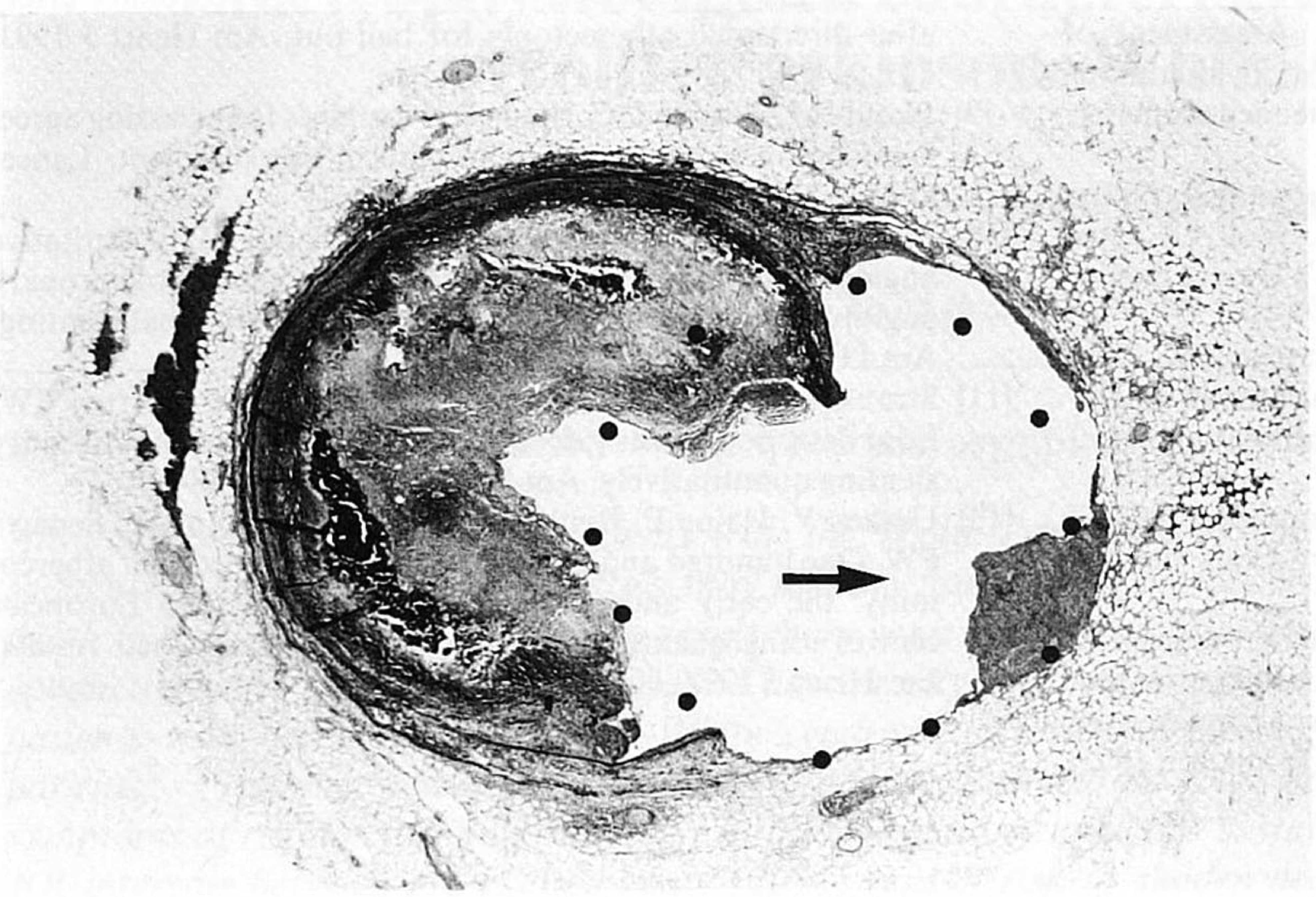
Because atherectomy selectively removes the atherosclerotic plaque, it is expected that after atherectomy the vessel wall will be disrupted and therefore theoretically may assume a configuration which is close to a circle. The comparison between edge detection and videodensitometry provides information regarding the luminal area geometry after an intracoronary intervention[5,11]. Discrepancies between these two techniques are most likely to occur when the cross-section of the vessel wall deviates most from a circular configuration since this is a basic assumption for the use of edge detection. Following atherectomy, only a small discrepancy in minimal luminal cross-sectional area between edge detection and videodensitometry was found, which suggests that the post-atherectomy vessel lumen was close to a circle. This finding is at variance with the clover-leaf post-atherectomy lumen area configuration as proposed by Penny *et al.*[2]. If this clover-leaf configuration was a predominant feature following atherectomy, then our cross-sectional area measure derived from videodensitometry would be inferior to the measurement derived from edge detection since edge detection would over-estimate the cross-sectional area: the largest diameter of this trilobated lumen would be interpreted as the diameter of a perfect circle, irrespective of the angiographic view in which it is filmed. Our study offers an alternative explanation for the change in vessel configuration after atherectomy: insertion of the bulky atherectomy device itself causes lumen enlargement due to the 'Dotter' effect and a symmetrical stretching of the vessel wall as a result of its cylindrical dimensions. Subsequent inflation of the support balloon with an increase in diameter from 2·0 mm to 3·4 mm and activation of the debulking device may lead to further luminal improvement by stretching of the non-diseased vessel wall and excision of the encroaching plaque. Ultimately, in these 10 patients, the minimal luminal diameter increased to 2·38 ± 0·33 mm, comparable with previous reports[1,12]. The present study shows that, in a limited subset of patients, 62% of the luminal improvement was due to a 'Dotter' effect and thus supports the findings of Penny *et al.*[2] who could only retrieve 30% of the expected amount of atherosclerotic tissue which indicates the complementary role of the cutting action to the dilating action of the atherectomy device.

Protocol design to include balloon inflation of the support balloon has not been carried out for ethical reasons, although it would presumably demonstrate that balloon inflation with or without activation of the cutter also considerably contributes to the amount of 'Dotter' effect already observed. Finally, the histological cross section at the level of atherectomy (Fig. 3) shows a relative circular post-atherectomy area geometry and not a clover-leaf geometry, although directional cutting sometimes results in a small resection of quadrangular appearance.

LIMITATIONS

Several important limitations of the study should be acknowledged. First, quantitative coronary angiography may not be the most reliable method to detect post-interventional area geometry. Future studies, comparing intravascular ultrasound with quantitative coronary angiography are therefore mandatory. Second, the observations in the post-mortem examination are limited by the absence of precise information regarding device and cutting orientation vs the histological findings. Third, only a limited number of patients were studied with regard to the 'Dotter' effect. We acknowledge that the extent of the 'Dotter' effect may well be influenced by various other patient and angiographic variables (i.e. reference diameter).

(a)



(b)

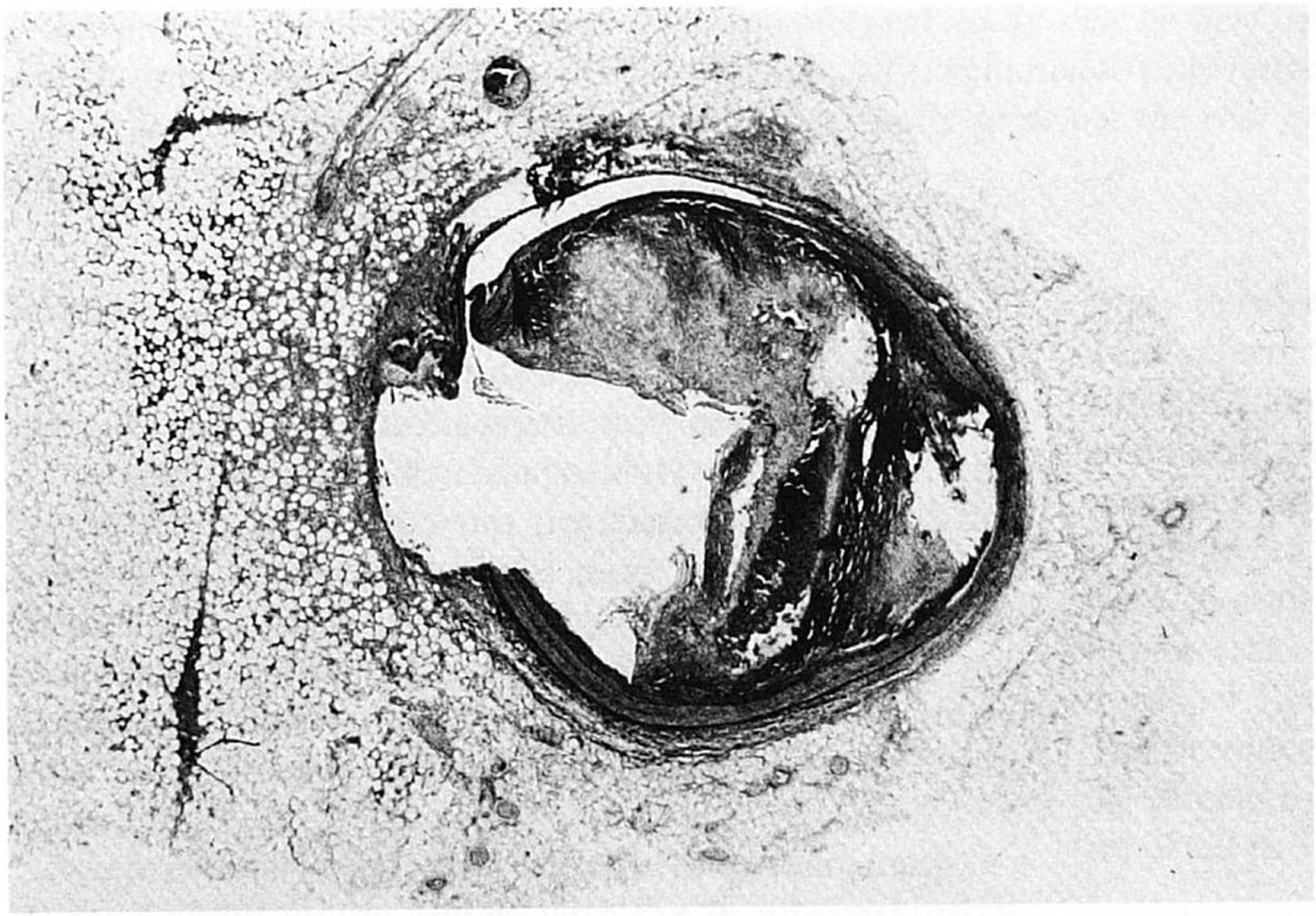


Figure 3 (a) Histological cross-section of the atherectomized coronary artery at the level of directional atherectomy (Hematoxylin-Azophloxine; original magnification × 12 and reproduced here at 60%). As indicated by the short and long axis measurements, there is only a slight deviation from a circle. The arrow indicates the thrombus at the site of the fissure. (Reproduced from [8] with permission). (b) Histological cross-section of the atherectomized artery following a single passage with the atherectomy device and subsequent excision of the atherosclerotic plaque (Hematoxylin-Azophloxine; original magnification × 12 and reproduced here at 60%). The directional cutting resulted in a small resection of quadrangular appearance. (Reproduced from [8] with permission).

Conclusions

Directional coronary atherectomy results in a superior immediate angiographic result when compared to conventional balloon angioplasty. However, using four different analytical approaches we demonstrate the importance of a 'Dotter' effect in luminal improvement following directional coronary atherectomy. Future developments should therefore be aimed at reducing the bulky design thereby limiting the need for balloon inflations.

We acknowledge Jaap Pameyer and the Cardialysis Core Laboratory for the quantitative angiographic analysis and Marjolein Wapenaar for her secretarial assistance.

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