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Clinical Investigations

Evaluation of Directional Atherectomy Studied by Intravascular Ultrasound in Femoropopliteal Artery Stenosis

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Abstract
Purpose: To evaluate the role of intravascular ultrasound (IVUS) before and after directional atherectomy (DA) in the treatment of femoropopliteal artery stenosis.
Methods: In 12 patients with 16 stenoses IVUS was performed before and immediately after an angiographically successful DA. This was defined as a diameter reduction (DR) ≤ 50%, which was calculated using the minimal lumen diameter compared with the diameter of a nearby ''normal'' segment. In the presence of residual plaque on IVUS an additional DA was performed. Endpoints studied were DR ≤ 30% on IVUS compared with the IVUS findings of the angiographically normal reference segment, or when no additional atherosclerotic material could be removed by further DA passages.
Results: Additional DA (mean 1.6 per lesion) had to be performed in all patients. Initial DA increased the cross-sectional free lumen area (FLA) from 3.8 ± 2.0 mm^2 to 8.1 ± 2.7 mm^2 ($p = 0.0004$). Additional DA increased FLA to 9.3 ± 2.3 mm^2 ($p = 0.002$) after the second passage and to 9.8 ± 2.4 mm^2 ($p = 0.09$) after the final DA run. The plaque area (PLA) before DA decreased from 18.1 ± 4.2 mm^2 to 15.4 ± 4.8 mm^2 ($p = 0.002$) after the first passage, and to 13.5 ± 5.0 mm^2 ($p = 0.004$) and 12.8 ± 4.4 mm^2 ($p = 0.07$) after the second and final DA runs, respectively. PLA of the reference segment (9.5 ± 5.7 mm^2) was significantly smaller ($p = 0.006$) than the final PLA of the treated lesion, indicating a large amount of retained plaque. As a result of DA there was an increase in the area bordered by the medial layer, i.e., the total vessel area (from 21.9 ± 4.7 mm^2 to 23.0 ± 4.7 mm^2), significantly in eccentric and soft lesions. On IVUS, dissection and plaque rupture after the final passage was seen in 12 of 16 stenoses; two dissections were seen on the completion angiogram. After the final passage in all stenoses except three, the DR with IVUS was ≤ 30%.
Conclusion: Lumen enlargement following DA is predominantly due to plaque excision. Vessel expansion combined with plaque excision varies in different stenoses and is an important factor in eccentric and soft lesions. Despite additional DA considerable plaque remains.

Key words: Atherectomy—Intravascular ultrasound—Arteriosclerosis—Arteries, extremities—Femoral artery

Balloon angioplasty of femoropopliteal stenosis is still hampered by a high percentage of restenosis [1, 2]. To improve the results new techniques, such as directional atherectomy (DA), were introduced in which atherosclerotic material could be removed instead of being pushed aside [3, 4].

Although the theoretical mechanism of DA is simple and the complication rate is low, little is known about the in vivo mechanism [5, 6]. Effects ascribed to DA include ''ploughing'' caused by the stiff and relatively large device itself, ''dilatation'' caused by the one-sided low-pressure balloon, and ''shaving'' caused by the rotating cutter [7]. It has not been established whether an initial passage into a vessel is equally effective as subsequent passages in debulking the atheromatous plaque. Up to now arteriography has been the

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method of choice to assess the results of percutaneous intervention. However, because arteriography visualizes the inner contours of the lumen only as a two-dimensional silhouette, the mechanism of DA is not precisely known. Although there are some insights into the mechanism of DA [8–11] most of these studies have dealt with coronary DA.

With the introduction of angioscopy and intravascular ultrasound (IVUS) it is now possible to understand the underlying mechanism of endovascular interventions. Angioscopy is an efficient technique for studying the vessel lumen in real-time, but lacks visualization of the vessel wall structures [12]. IVUS is a reliable method for investigating the different aspects of an atheromatous vessel wall both before and after vascular intervention [8, 13, 14]. The aim of this study was to investigate the mechanism of DA by IVUS and to evaluate the effect of additional DA passages on lumen enlargement.

Materials and Methods

Patients

Fifteen patients (age range 58–81 years, mean 70.5 years) with intermittent claudication due to one or two stenoses in the femoropopliteal artery were studied with IVUS and arteriography before and after consecutive DA passages. All patients were informed of the potential risks and benefits and had given consent for participation in the study.

Pre-intervention assessment included aortic and iliac arteriography using conventional screen film combined with digital arteriography studies of the femoropopliteal segment. The stenosis was imaged in two orthogonal directions and the diameter reduction (DR) was calculated using minimal lumen diameter, compared with the diameter of a nearby angiographically normal segment. The degree of stenosis was calculated from these measurements using the equation: % stenosis $= 100 \times [1 -$ (minimal diameter of diseased segment/normal diameter of this vessel)]. Stenoses before intervention ranged from 65% to 90% DR, ranging in length from 0.5 to 2.0 cm. The patients were treated with 80 mg aspirin daily, started the day before intervention and continuing indefinitely. During the intervention each patient received 5000 IU of heparin intraarterially.

Equipment

DA was performed via a 7, 8 or 9 Fr sheath, advancing the atherectomy catheter under fluoroscopic guidance. The maximum working diameter of the AtheroCath (Peripheral System Group, Mountain View, CA, USA) or the over-the-wire guided version, AtheroTrack (Peripheral System Group), ranged from 5.3 to 6.7 mm. All atherectomy catheters consisted of an extended collection chamber.

IVUS was performed using a comercially available ultrasound system (CVIS Inc., Sunnyvale, CA, USA). Peripheral imaging was performed using a 5 Fr, 30-MHz (radial penetration 7 mm) CVIS catheter. The mechanically driven mirror rotates with a speed of up to 30 frames per second. The IVUS catheter was advanced distally into the artery and images were recorded during manual pull-back of the catheter. The position of the ultrasound catheter tip within the artery was documented by a digital vascular mapping technique and compared with a radiopaque ruler. The IVUS and radiographic images were stored on an s-VHS video recorder for off-line analysis.

Technique of Intervention

After an antegrade puncture and introduction of a standard 7 Fr sheath (Terumo, Laméris Medical Products, Utrecht, The Netherlands; or Cordis, Rhoden, The Netherlands) into the common femoral artery, an arteriogram was made. The site of maximum stenosis was measured in different projections. By IVUS the working size of the DA catheter was chosen according to the mean diameter of the most normal segment nearby, proximal to the stenosis (reference segment, RF). When necessary an appropriate sheath (8 or 9 Fr) was positioned in the femoral artery to guide the DA catheter. Each DA passage consisted of rotating the catheter 8 to 10 times in the vessel lumen or until the collection chamber was filled with plaque debris. This latter was noticed when the cutter could not be fully advanced distally, which could easily be seen with fluoroscopy.

IVUS was performed for the second time when the residual stenosis was $\leq$ 50% DR angiographically. If atheromatous plaque was still detected on IVUS, additional DA passage(s) was performed. After each additional passage arteriography and subsequently IVUS was applied. The radiopaque ruler and anatomical markers such as sidebranches were used to identify the position of the previous stenosis. In eccentric lesions special attention was focused on the eccentric location of atheromatous tissue, by guiding the rectangular window against the plaque using a digital vascular mapping technique.

Procedural endpoints were defined when a residual stenosis $\leq$ 30% DR was achieved as monitored by IVUS, or when the removal of atherosclerotic material by additional DA proved impossible. This latter was noticed when the collection chamber of the DA device remained empty following subsequent DA passages. DR was calculated using the minimal lumen diameter (measured with IVUS) compared with the minimal lumen diameter of a nearby segment with the smallest plaque burden.

Definitions: Before Intervention

Free lumen area (FLA): Area bordered by the inner surface of the vessel lumen.
Media-bounded area (MBA): Area bordered by the inner side of the hypoechoic layer representing the media. The total vessel area is bordered by the adventitial layer of the vessel wall. The MBA is strongly related to the *total vessel area*, because the thickness of the media is small and the adventitia consists mainly of connective tissue [14].
Plaque area (PLA): Plaque area calculated by subtracting the free lumen area from the media-bounded area.
Soft lesion: A lesion having a homogeneous echo structure without shadowing (thickness exceeds 0.5 mm).
Hard lesion: A lesion having a bright echo structure casting peripheral shadowing, representing a calcified lesion.
Eccentric and concentric lesion: The thinnest and thickest segment of the vessel wall was identified at the site of the maximum stenosis [15]. The ratio of these two measurements > 2 defined an eccentric location of the plaque.

Definitions: After Intervention

Plaque rupture: Small echolucent separation of the intimal plaque not extending into the media.
Dissection: Echolucent space behind the surface of the plaque whose thickness was more than 0.5 mm, or if movement was seen as the plaque wavered in the flow of blood behind it [15].
Media rupture: Interruption in the internal elastic membrane and media that exposes the hyperechoic adventitia to the lumen.

Qualitative and Quantitative Analysis

Analysis was performed by two independent observers experienced in IVUS, without knowledge of the angiographic findings. The reference segment and site of maximum stenosis seen on IVUS before and after each additional passage were selected for analysis for free lumen area and media-bounded area. In order to assess the FLA site a number of adjacent cross-sections at the site of maximum stenosis were selected for analysis. If the media–intima interface was not clearly visible because of acoustic shadowing, contours were estimated by continuity from adjacent cross-sectional images. For quantitative findings the IVUS cross-sections, including the reference segments and sites of maximum stenoses, were measured.

Statistical Analysis

Results are expressed as mean ± SD. The Fisher exact test was used to compare discrete variables between groups. The Wilcoxon test was used for paired nonparametric observations. Continuous variables were compared using the Mann–Whitney test. A p value less than 0.05 was considered significant.

Results

Early Procedural Outcome

Fifteen patients were studied before and after DA. In one patient the IVUS study was inadequate due to video mismatch; in another there were mechanical problems with the DA catheter; and a third patient had a persistent arteriographic residual stenosis of $> 50\%$, which was a protocol reason for removing the patient from the study. After removal of these three patients, 12 patients with 16 stenoses remained. The total number of DA passages ranged from 2 to 3 (mean 2.6 per lesion). In two patients the collection chamber remained empty. IVUS studies showed no difference between the IVUS examination of the previous DA passage. After the final passage in all stenoses except three the DR with IVUS was $\leq 30\%$. No complications occurred during the procedures.

Qualitative IVUS Findings

Lesions involved were classified as eccentric in nine and concentric in seven cases. A soft lesion was seen in nine patients and hard lesions in seven patients. In 12 lesions dissection and/or plaque rupture were seen with IVUS. Media rupture was seen in one patient. Neither plaque rupture nor dissection were found in four lesions. On IVUS, dissection was seen in eight lesions whereas only two were seen on the completion angiogram. When dissection was seen with IVUS, it remained virtually unchanged after the subsequent DA passage. There was no relation between soft or hard lesions on the incidence of plaque rupture or dissection.

Table 1. Quantitative intravascular ultrasound findings obtained from 16 stenoses

	FLA	MBA	PLA
Pre-DA (mm^2)	3.8 ± 2.0	21.9 ± 4.7	18.1 ± 4.2
DA 1 (mm^2)	8.1 ± 2.7[a]	22.7 ± 5.3	15.4 ± 4.8[a]
DA 2 (mm^2)	9.3 ± 2.3	22.9 ± 4.7	13.5 ± 5.0[a]
DA 3 (mm^2)	9.8 ± 2.4	23.0 ± 4.7	12.8 ± 4.4
Reference (mm^2)	17.3 ± 3.7	26.9 ± 6.1	9.6 ± 5.7

Values are the mean ± SD
DA = directional atherectomy; FLA = free lumen area; MBA = media-bounded area; PLA = plaque area
[a] Significant value ($p < 0.05$)

Table 2. Qualitative and quantitative intravascular ultrasound findings in 16 stenoses

	Free lumen area (FLA)	
	Before intervention	After final passage
Concentric vs eccentric lesions		
Concentric	3.3 ± 1.9 mm^2	8.9 ± 2.5 mm^2
Eccentric	4.2 ± 2.0 mm^2	10.7 ± 2.1 mm^2
p value[a]	0.22	0.14
Hard vs soft lesions		
Hard	3.4 ± 1.6 mm^2	9.6 ± 2.0 mm^2
Soft	4.1 ± 2.2 mm^2	10.1 ± 2.8 mm^2
p value[a]	0.56	0.83

[a] Paired Mann–Whitney test

Quantitative IVUS Findings

Quantitative findings obtained before and after DA at the reference site and the maximum stenotic site are listed in Table 1. A significant increase in FLA was achieved mainly during the first and second DA passage; the third run had little influence on FLA. The increase in MBA, representing a stretching effect, was not statistically significant ($p = 0.09$). The decrease in PLA was significant after the first and second passage but not significant after the additional third DA passage.

The qualitative and quantitative findings of concentric and eccentric lesions are shown in Table 2: these differences were not statistically significant. This was also noticed for hard versus soft lesions. The increase in FLA in both hard and soft lesions is comparable. However, the final FLA in all treated lesions is much smaller than the FLA of the reference segment (17.3 ± 3.7 mm^2) (Fig. 1).

In contrast to concentric lesions, eccentric lesions show a significant increase in MBA: from 22.1 ± 5.2 mm^2 to 24.4 ± 4.9 mm^2 ($p = 0.04$). Also in contrast to hard lesions, in soft lesions a significant increase in MBA was observed: 23.3 ± 4.2 mm^2 to 25.2 ± 4.5

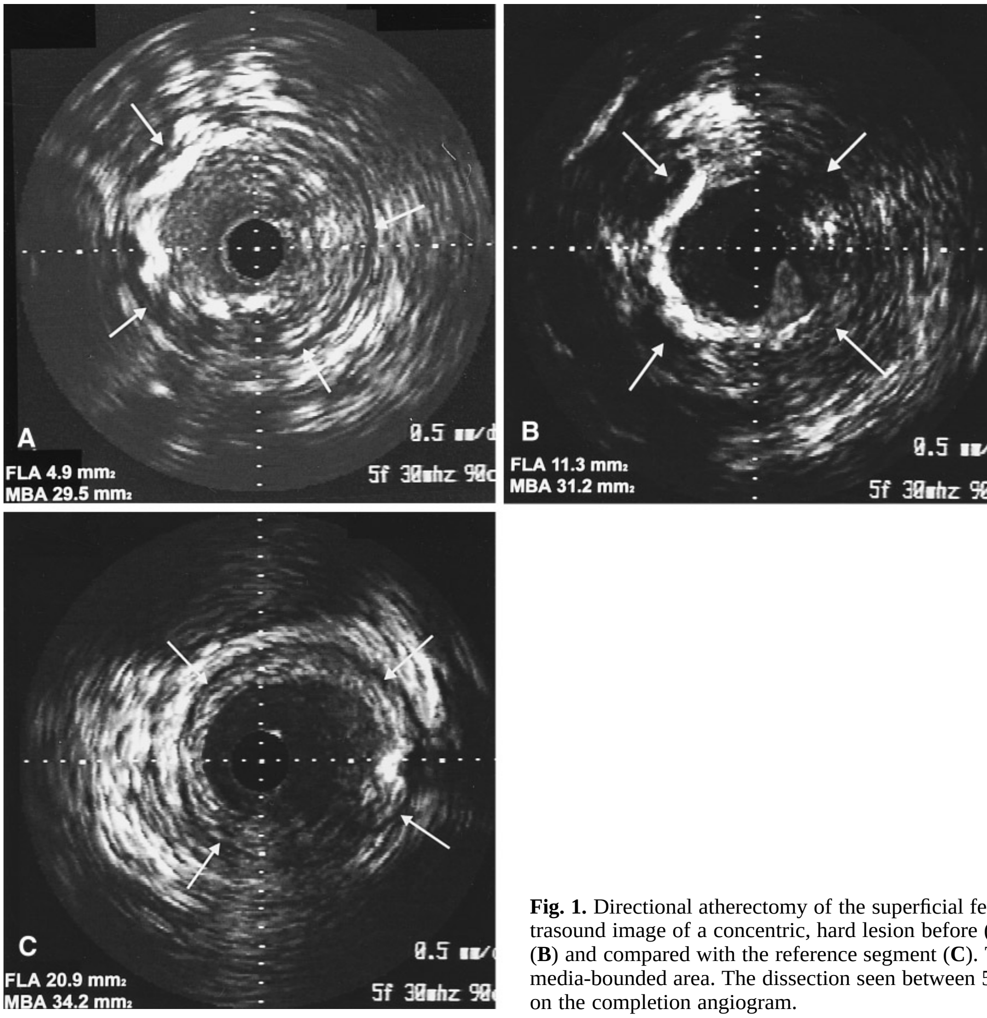

Fig. 1. Directional atherectomy of the superficial femoral artery. Intravascular ultrasound image of a concentric, hard lesion before (**A**) and after the final passage (**B**) and compared with the reference segment (**C**). The white arrows indicate the media-bounded area. The dissection seen between 5 and 6 o'clock was not seen on the completion angiogram.

mm^2 ($p = 0.02$). Although there was a slight stretching effect in both eccentric lesions and soft lesions, the final overall MBA (23.0 ± 4.7 mm^2) is significantly smaller ($p = 0.007$) than the overall MBA of the normal reference segment (26.9 ± 6.1 mm^2), suggesting geometric remodelling in severe atherosclerotic lesions (Fig. 2). There was a significant decrease in PLA in the lesions in all the different subgroups (concentric, eccentric, hard, soft). The overall PLA of the treated lesion after the final passage was significantly ($p = 0.006$) larger than that of the reference segment (9.6 ± 5.7 mm^2), which indicated considerable residual atherosclerotic plaque.

Discussion

Balloon angioplasty (PTA) has been the most frequently used technique for treatment of stenoses or short occlusions in the femoropopliteal artery. The effects of PTA, i.e., cracking, splitting, and remodelling, are caused by mechanical and high-pressure properties of the inflated balloon in the stenotic artery [14, 15]. These effects may injure the vessel, resulting in patency rates after 2 years ranging from 47% to 79% [16, 17]. Therefore, new devices have been developed to create a smooth vessel wall less susceptible to superimposed thrombus and myointimal hyperplasia. Directional atherectomy (DA) is the most used alternative and the patency rates for short lesions are equal to or even better than those for PTA [18–20].

It has been suggested that the gain in lumen enlargement by DA in coronary stenoses is achieved by ploughing and/or balloon effects and that tissue removal has only a minor influence [9, 21]. However, these suggested results were based only on the amount of atherosclerotic material removed. A more accurate method of studying the mechanism of DA is IVUS, which also has the possibility of comparing treated lesions with normal arterial segments. We studied 12 patients with IVUS before and after DA of the

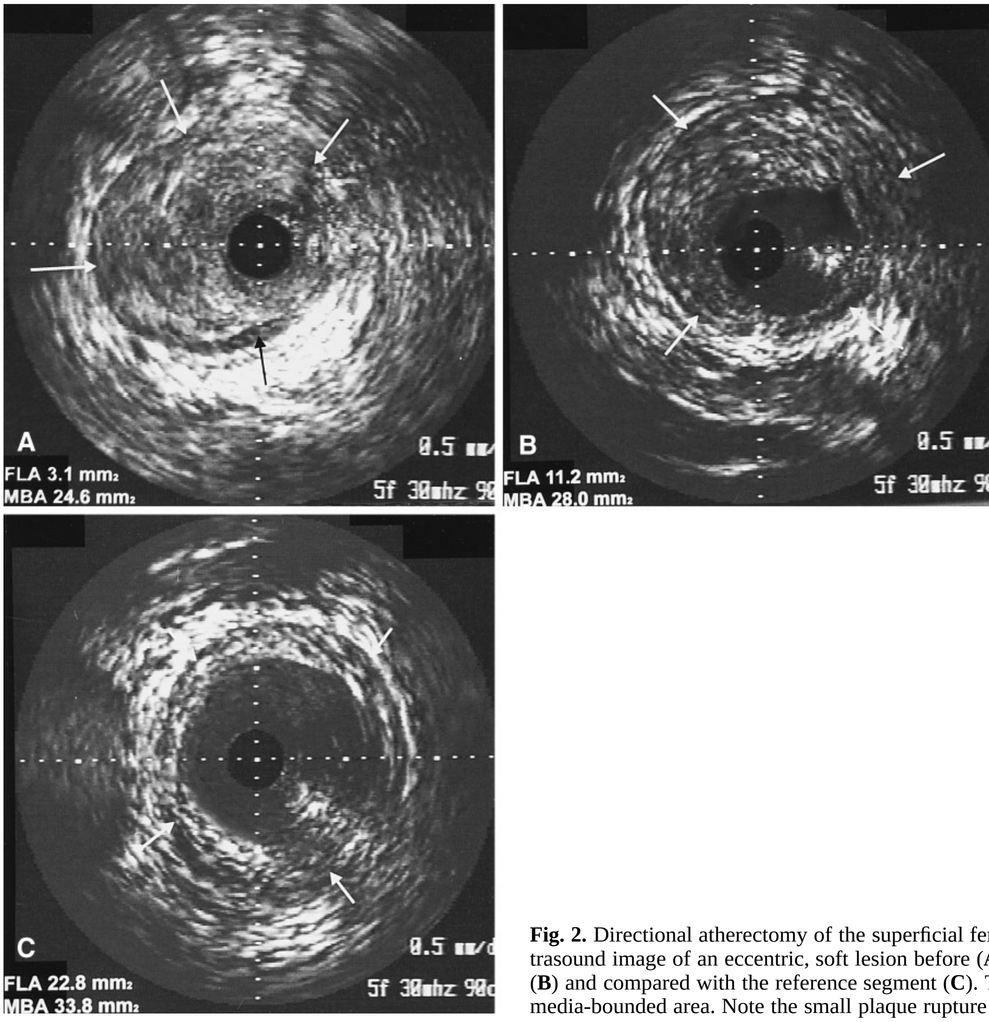

Fig. 2. Directional atherectomy of the superficial femoral artery. Intravascular ultrasound image of an eccentric, soft lesion before (**A**) and after the final passage (**B**) and compared with the reference segment (**C**). The white arrows indicate the media-bounded area. Note the small plaque rupture (**B**) at 2 o'clock.

femoropopliteal artery and concluded that, on the basis of comparison with the reference segment, plaque excision is the main factor in lumen enlargement, with vessel stretching playing a minimal role. This is in agreement with the findings of several other IVUS-controlled studies in the coronary artery [22, 23]. Moreover, in coronary arteries it was observed that plaque containing calcium is more difficult to resect than homogeneous plaque [24, 25]. However, comparison of the working mechanism in coronary arteries with results in peripheral arteries is not always justified. Although the cutting action is similar, the coronary DA catheter (6 or 7 Fr) is much larger in relation to the coronary artery (2.5–3.5 mm) than is the peripheral DA catheter (7 or 8 Fr) in relation to the femoral artery (4.5–6.5 mm). Therefore ''ploughing'' effects are more likely to occur in coronary arteries.

Suneja et al. [26] and Sharaf et al. [27], on the basis of removed volume of coronary atheroma, found that ''compression'' of plaque is an important factor in DA. Compression effects were also described as an important factor in PTA [14]. However, according to Castañeda et al. [28] and Waller et al. [29] it is unlikely that ''compression'' of plaque plays an important role in PTA.

In this study the major effect of the DA device was due to the rotating cutter, while the other effects (ploughing and dilatation) play a minor role. In the present study, when performing a sub-analysis for soft and eccentric lesions, a combined effect of plaque extirpation and stretching was found. This is supported by a significant increase in FLA and MBA combined with a significant decrease in PLA. Vessel stretching, i.e., increase of the MBA, is probably due to the mechanical (''Dotter'') effect of the device, which is more likely to occur in soft lesions which have less radial strength than hard lesions.

It is noteworthy that the present study revealed that the mean MBA of the treated lesions was significantly smaller than the mean MBA of the reference segments.

This is in contrast to other studies in which compensatory enlargement of the artery was observed as a response to atherosclerosis [30, 31]. Our results support the findings of Pasterkamp et al. [32] who reported that arterial wall shrinkage in femoral arteries may contribute to luminal area narrowing.

IVUS studies on peripheral DA are scarce; moreover, these studies do not discriminate between the different factors of the device responsible for lumen gain, nor is the influence of additional DA passages in the removal of any residual plaque discussed [8, 10, 11, 33]. Yock et al. [33] discuss the theoretical and practical applications of IVUS as a guide to tissue removal. They postulated that combined ultrasound imaging and atherectomy would provide more accurate tissue removal and produce a smoother inner lumen by precise circumferential cutting. Isner et al. [8] reported IVUS findings in two patients undergoing DA of the femoral artery and, in contrast to our study, plaque rupture and dissection were not seen. Tobis et al. [10] reported preliminary data which demonstrate that plaque reduced from 13.3 mm^2 to 10.5 mm^2 in peripheral arteries, which is comparable with our results. In addition, they found an 18% increase in vessel diameter, indicating an expansion effect—however, without differentiating between different types of lesions. Korogi et al. [11] reported ''significant morphological changes in the vessel due to inflation of the positioning balloon alone in the absence of cutting.''

Although dissections are commonly seen with IVUS after PTA of peripheral stenoses [14, 30, 34], we found dissection in 50% of DA-treated stenoses. In only two stenoses were dissections visible on the completion angiogram. It was somewhat disappointing that it was not possible to extirpate these dissections by additional DA passages monitored by IVUS. One may speculate that these dissections are caused by the ploughing effect of the device itself, as in contrast to PTA the DA device has a single-sided low-pressure balloon. Another reason might be the damage to the vascular wall caused by rotating the catheter, resulting in plaque ruptures and dissections.

The present study also evaluated the influence of additional DA on plaque removal after an angiographically residual stenosis of $\leq$ 50%. The extirpation of atheromatous plaque is mainly achieved during the first two DA passages, as is supported by a significant decrease in PLA compared with only a slight decrease in PLA after the final passage. Although additional passages decrease the plaque area in most stenoses, a large amount of residual plaque was still registered with IVUS after the final passage compared with the reference segment. The possible reasons for diminished plaque removal following DA passages support the hypothesis that removing fibroatheroma may alter plaque compliance which results in inadequate pressure of the cutter on the remaining plaque [35]. Other possibilities are the tendency of this device to orientate into the same direction once an initial cut is made, or torsion of the vessel caused by rotation of the relatively large device in narrowed vessels. The necessity of performing additional DA despite an angiographically successful result was also observed by others [10, 12, 24]. In the study of Bauriedel et al. [12] additional DA in femoropopliteal stenoses was necessary in 10 of 39 (26%) patients, to remove significant residual plaque as detected by angioscopy.

In conclusion, IVUS analysis before and after additional DA passages in the femoropopliteal artery showed that lumen enlargement is predominantly based on plaque excision. However, vessel expansion combined with plaque excision varies in different stenoses and is an important factor in eccentric and soft lesions. The amount of plaque removal decreases significantly after the first and second DA passages, although significant amounts of plaque remain.

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