Eur J Vasc Endovasc Surg 9, 394–402 (1995)

Femorodistal Venous Bypass Evaluated With Intravascular Ultrasound*

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Objective: *To evaluate the feasibility of intravascular ultrasound imaging during femorodistal venous bypass procedures to assess qualitatitve and quantitative parameters of the greater saphenous vein and to detect potential causes for (re)stenosis and/or occlusion.*
Methods: *Intravascular ultrasound data obtained from 15 patients were reviewed and compared with angiographic data.*
Results: *Intravascular ultrasound enabled differentiation between normal and thickened vein wall. Venous side-branches could be located. Intact valves could be differentiated from valves disrupted by valve cutting. Patent anastomoses could be distinguished from anastomoses with some degree of obstruction. Intravascular ultrasound imaging of the inflow and outflow tracts revealed obstructive lesions, not evidenced angiographically. Quantitative analysis revealed that the median normal vein wall thickness (tunica intima and tunica media) was 0.25 mm (range 0.17–0.40 mm). The distinct vein wall thickening encountered in three patients measured 0.82, 0.95 and 1.06 mm, respectively, and was associated with narrowing in two patients. In five of 15 patients intravascular ultrasound findings altered surgical management.*
Conclusion: *Intravascular ultrasound is able to assess qualitative and quantitative parameters of the venous bypass and has the potential to influence surgical management based on morphologic and quantitative data.*

Key Words: Intravascular ultrasound; Venous bypass.

Introduction

Autogenous veins are the preferred graft material for femorodistal reconstruction. Although the results are reasonably good (1-year patency, 85%; 5-year patency, 70%),[1–3] much concern has focused on the prevention of graft failure because of the potential disastrous consequences for patients. Graft failure may be caused by several factors.[4] Within 1 month technical errors and poor choice of inflow and outflow sites are the predominant causes of graft failure. Failures during the subsequent 1-18 months have been attributed almost entirely to intrinsic vein graft stenosis at the proximal and distal anastomotic regions, but also in the vein conduit itself. Finally, failures after 18 months have generally been associated with progression of the underlying atherosclerotic process resulting in compromised inflow and/or outflow arteries. Intraoperative and postoperative monitoring using completion angiography, angioscopy and Duplex scanning do not predict all cases of graft failure.[5,6]

Recently, attention has focused on the quality of the venous bypass, as it became clear that morphologic changes such as fibrous thickening of the intima, calcification, media hypertrophy, mediasclerosis and luminal recanalisation may already be present before grafting.[7–14] The influence of these morphologic changes on bypass patency, however, remains unclear. At present, such morphologic changes are difficult to demonstrate prior to or during bypass surgery.[11]

With the introduction of intravascular ultrasound in 1989[15] a new diagnostic tool became available with the capability of identifying various components of vascular pathology and quantitating the mechanism of angioplasty devices. Since our first report on experience with intravascular ultrasound in femoropopliteal bypass surgery in 1991,[16] we have studied an additional group of patients undergoing venous

* Presented at the 8th annual meeting of the European Society for Vascular Surgery, Berlin, Germany (September 1994).
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bypass grafting. The objective of the present study was to elucidate our expanded experience with intravascular ultrasound in assessing qualitative and quantitative parameters of venous bypass grafts.

Material and Methods

Study Group

In 15 patients (12 males, three females) with a median age of 70 (range 55–83) years scheduled for routine below-knee femorodistal bypass procedure, intravascular ultrasound was used intraoperatively. The indication for operation was intermittent claudication ($n = 5$), rest pain ($n = 3$) and tissue loss ($n = 7$). This report contains data on three patients reported previously.[16]

An *in situ* bypass was performed in 11 patients (in two patients an extension with reversed vein was necessary), an *ex situ* non-reversed bypass in two patients, and a reversed bypass in two patients (a composite graft in one patient). The 11 *in-situ* bypasses were performed via an open technique ($n = 6$), or via a semi-closed technique ($n = 5$) in which the side-branches were closed by means of endovascular placed coils. In the *in situ* and *ex situ* non-reversed bypasses the valves were disrupted with a valve cutter (VaVaCut, William Cook Europe AS, Bjaeverskov, Denmark).

For the proximal anastomosis the common femoral artery ($n = 11$) or the superficial femoral artery ($n = 4$) were used. For the distal anastomosis the below-knee popliteal artery ($n = 11$) and tibial arteries ($n = 4$) were used.

Preoperatively, diagnostic angiography was available in all patients. Intraarterial pressure measurements over the aortofemoral tract were available in seven of 15 patients. Following completion of the bypass, intraoperative angiography was performed in 14 patients. In one patient with renal insufficiency angiography was contraindicated.

Intravascular ultrasound investigation

A mechanical 30 MHz imaging system was used (DuMED, Rotterdam, The Netherlands). The first four patients were studied with a stiff 5F catheter; in the other 11 patients a 4.1F flexible catheter was used. The ultrasound catheters rotate up to 16 images per second. The axial resolution of the system is 80 μm. Lateral resolution is better than 225 μm at a depth of 1 mm. The resulting images were displayed on a monitor via a video-scanned memory and stored on a VHS recorder.

The non-reversed bypasses ($n = 13$) were imaged after completion of the proximal anastomosis and valve cutting. The ultrasound catheter was introduced distally into the vein graft and advanced beyond the proximal anastomosis to obtain images of the inflow tract from the anastomosis up to the aorta. After completion of the distal anastomosis, the vein graft and the distal anastomosis were imaged using a proximal side-branch for introduction. The reversed bypasses ($n = 2$) were studied after completion of the distal anastomosis and filled with heparinised saline to facilitate ultrasound imaging. The ultrasound catheter was introduced proximally and advanced to and beyond the distal anastomosis.

Intravascular ultrasound images were recorded during pull-back of the ultrasound catheter. The videotapes were reviewed immediately after imaging; an additional intervention was performed when intravascular ultrasound revealed unequivocal abnormalities in the vein graft, anastomoses or the inflow and outflow tract. The extended analyses were performed off-line.

Analysis

Intravascular ultrasound analysis included the venous bypass, the anastomoses and the inflow and outflow tract. The venous bypass was evaluated for the presence of wall thickening, side-branches, and intact or disrupted valves. Wall thickness in each vein graft was measured in three ultrasound cross-sections showing an apparently normal vessel wall and in those cross-sections showing a distinct wall thickening (Fig. 1). The thickness was calculated as the perpendicular distance between the leading edge from the lumen–intima interface to the leading edge of the outer echogenic layer. The ultrasound cross-section showing the smallest free lumen area of the vein graft was selected to measure the free lumen area and mean free lumen diameter. Free lumen area was defined as the area encompassed by the inner boundary of the intimal surface. Anastomoses were judged semi-quantitatively "sufficient" or "insufficient". The anastomosis was "insufficient" if the free lumen area of the anastomotic region was smaller than the free lumen area of the adjacent vein graft segment. Inflow and outflow tracts were analysed and the images showing the smallest free lumen area were selected to measure free lumen area, media-bounded area and percentage area stenosis.[17]

The measurements were performed with a digital video analyser as described previously.[18,19] Briefly, the analysis system was developed on an IBM PC/AT (IBM Corp. Boca Raton, U.S.A.) equipped with a framegrabber and a PC mouse device. Observer variability in quantitative measurements has been reported to be satisfactorily low.[18–20] All measured values are presented as median values and range.

Results

The intravascular ultrasound study was completed in 14 patients. In one patient, only a small part of the bypass was visualised as the ultrasound catheter could not be further advanced through the vein. In another patient the bypass was perforated by the ultrasound catheter; this was treated with simple closure. No other complications related to the intravascular ultrasound studies were observed. The median duration of the intravascular ultrasound investigation was 14 min (range 3–40 min).

Vein wall

It was noted that the vein wall presented as a two- or three-layered structure. The two-layered structure consisted of a hypoechoic inner layer, representing the tunica intima and tunica media, and a hyperechoic outer layer, representing the tunica adventitia (Fig. 1). When the vein wall presented as a three-layered structure a hyperechoic region was seen at the lumen-intima interface. Intravascular ultrasound images obtained during the open and semi-closed *in situ* technique differed in appearance. Exposure of the vein to air in the open technique caused a more hyperechoic outer layer than in the semi-closed technique (Fig. 2).

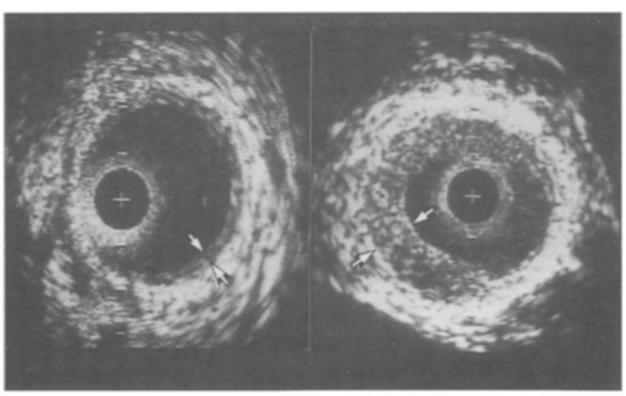

Fig. 1. Intravascular ultrasound cross-sections showing a normal venous bypass (left panel) and a venous bypass with thickening of the vein wall (right panel). + = Catheter; calibration = 1 mm.

Although the free lumen diameter seen with intravascular ultrasound varied along the length of the bypass, the wall thickness (tunica intima and tunica media) remained practically unchanged. Thickening of the vein wall was usually seen in the proximity of the valves. The median thickness of the apparently normal vein wall was 0.25 mm ($n = 45$; range 0.17–0.40 mm) (Figs 1,3). Statistically significant differences were found between the thickness of a vein wall with a two-layered appearance ($n = 20$; median 0.21 mm, range 0.17–0.29 mm) and that with a three-layered appearance ($n = 25$; median 0.28 mm, range 0.17–0.40 mm) ($p < 0.001$, Mann-Whitney test).

A focal, eccentric thickened vein wall, different from the thickening seen in the proximity of the valves, was observed in three patients. This thickening appeared as a homogeneous soft structure superimposed to the outer hyperechoic layer and measured 0.82, 0.95 and 1.06 mm, respectively (Fig. 1). In two of these patients, intimal thickening was associated with free lumen area narrowing (mean diameter 2.4 and 3.1 mm, respectively) (Fig. 1). These abnormalities were not seen with intraoperative angiography.

Free lumen area and diameter

During pull-back of the ultrasound catheter it was noted that the size of the free lumen area of the venous

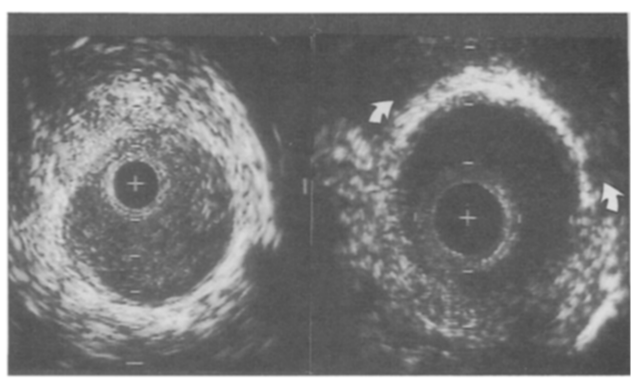

Fig. 2. Intravascular ultrasound cross-sections showing the differences between images obtained during the semiclosed and the open technique. Left panel: Using the semiclosed technique the tissue surrounding the vein wall can be identified completely. Right panel: Using the open technique the effect of exposure of the vein to air is seen on ultrasound between 9 and 3 o'clock (arrows) as a more hyperechoic outer layer than seen between 3 and 9 o'clock. + = Catheter; calibration = 1 mm.

bypass changed markedly. Proximal to the valve leaflets the lumen size sometimes increased. Similarly, the free lumen area decreased when imaged distal to large side-branches. The median smallest free lumen area measured was 6.5 mm^2 (range 2.5–19.0 mm^2). The median smallest free lumen diameter was 2.9 mm (range 1.8–4.9 mm) (Fig. 3). In one patient, intra-operative angiography revealed a short local stenosis in the venous bypass, not sufficiently alarming to warrant re-exploration. Intravascular ultrasound revealed a narrowed elliptic lumen as a result of external compression of the vein graft. At surgical inspection it was found that the tendon of the gastrocnemius muscle compressed the venous bypass, caused by a false route during tunnelling of the bypass. After tendon division the intravascular ultrasound image showed a normal circular lumen (Fig. 4).

Side-branches and valves

Side-branches in venous bypasses were seen with intravascular ultrasound as an interruption of the vessel wall (Fig. 5). The median number of side-branches seen per bypass was 10 (range 1–14). In the *in situ* bypass detection was facilitated by blood flow in the side-branches, as imaging was performed before ligation. Both large and small tributaries were detected.

The intact valves in the reversed bypasses were detected as straight echogenic lines. After valve cutting in the *in situ* bypasses, intravascular ultrasound enabled demonstration of the remnants of the valves and differentiation between (partially) intact and totally disrupted valves (Figs 6,7). The presence of blood flow seen with real-time imaging facilitated identification of the valve patency. An intact valve was seen as a straight structure behind which stagnant blood created a higher echogenicity than normal blood flow (Fig. 7). Another way to demonstrate complete or incomplete disruption of the valves was by flushing saline through the bypass, which eliminated the blood and clearly visualised the valve leaflets.

The median number of locations with valves (intact or disrupted) seen per bypass was 5 (range 1–8). A persisting intact valve was detected in two patients after valve cutting which resulted in an additional valve-cutting procedure. An additional 12 (partially) intact valves were detected by off-line analysis in seven patients. Five valves were not imaged on angiography as only the distal anastomosis and the outflow were imaged. The other seven partially intact valves were seen on angiography as an irregular luminal contour in three cases, and were not visualised in the remaining four cases.

Finally, intravascular ultrasound enabled detection of a dissection in the vein wall in three patients, probably caused by the valve cutter (Fig. 8). These were not visible angiographically.

Proximal and distal anastomoses

The proximal anastomosis was studied with intravascular ultrasound in 12 patients and the distal anastomosis in ten patients. In four patients, the ultrasound catheter could not be advanced beyond the distal anastomosis. The vein wall and arterial wall could be distinguished based on anatomic characteristics evidenced on intravascular ultrasound (Fig. 9).

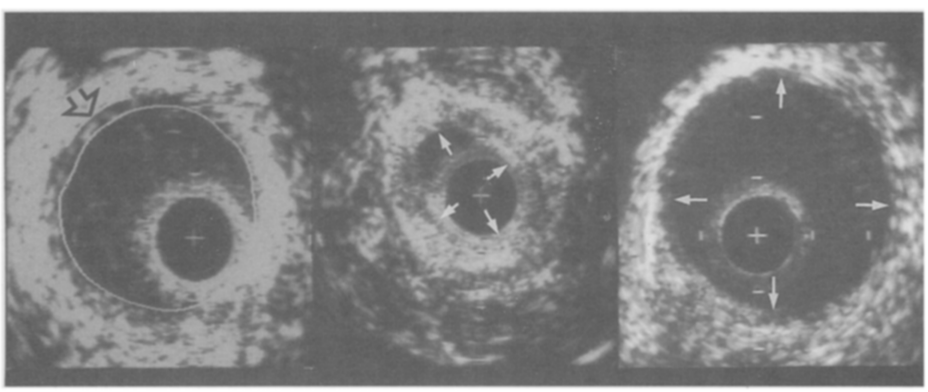

Fig. 3. Intravascular ultrasound cross-sections of venous bypasses showing differences in lumen areas. Left panel shows the contour of the free lumen area (FLA) and the vein wall thickness (open arrow). Middle panel: example of a small lumen (FLA = 5.6 mm^2). Right panel: example of a large patent lumen (FLA = 12.1 mm^2). + = Catheter; calibration = 1 mm.

All anastomoses, except one, were semi-quantitatively judged "sufficient". One distal anastomosis was judged "insufficient" as intravascular ultrasound revealed an intraluminal structure proximal to and within the anastomotic region, suggestive of thrombus. Angiography revealed a stenotic lesion just proximal to the anastomosis. Reexploration was deemed unnecessary because pedal pulsations were present. Perfusion of the patient's leg continued to decline progressively during the following days and reoperation was necessary 1 week later. The graft was thrombosed and a small distal part of the venous bypass was considered insufficient and resected after thrombectomy of the bypass.

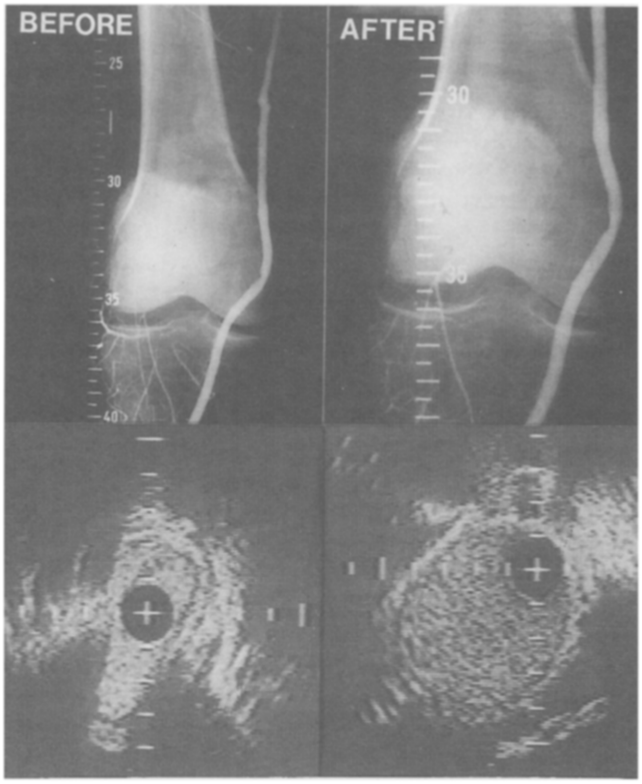

Fig. 4. Corresponding intravascular ultrasound cross-sections and angiograms of a venous bypass before and after cleavage of the tendon of the gastrocnemius muscle. Before intervention (right panel) an ambiguous stenosis is seen angiographically at level 34 that is no longer visible following cleaving (left panel). On ultrasound a local external compression of the bypass seen at level 34 changed the shape of the lumen elliptically (left panel). After cleaving (right panel) a normal circular shape is seen. + = Catheter; calibration = 1 mm. (Reprinted with permission of the *European Journal of Vascular Surgery* 1991; **5**: 523–526.)

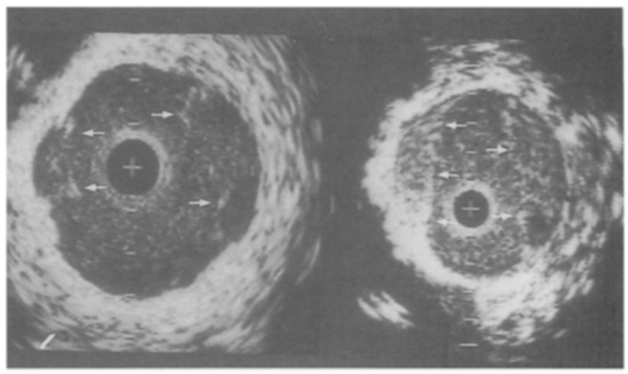

Fig. 6. Intravascular ultrasound cross-sections of a venous bypass showing differences between remnants of valve leaflets and an intact valve. Left panel: four remnants of valve leaflets are seen after valve cutting (arrows). Blood appears as a homogeneous echogenic medium in the lumen. Right panel: after valve cutting an intact valve leaflet (left: 3 arrows) and a disrupted valve leaflet (right: 2 arrows) are seen on ultrasound. The stagnant blood behind the intact leaflet causes a more homogeneous echogenic structure than blood flow in the lumen. + = Catheter; calibration = 1 mm.

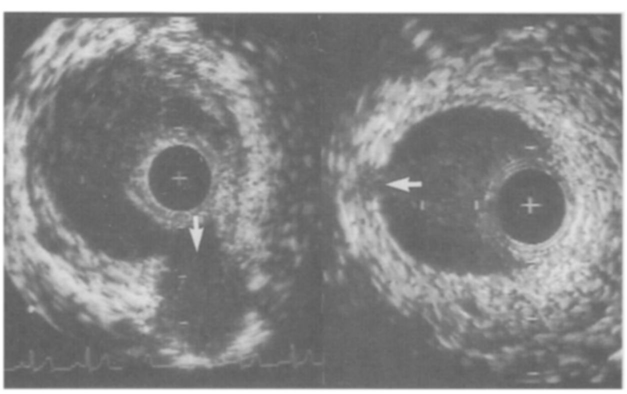

Fig. 5. Intravascular ultrasound cross-sections of a venous bypass showing a large (left panel) and a small (right panel) side-branch (arrow). + = Catheter; calibration = 1 mm.

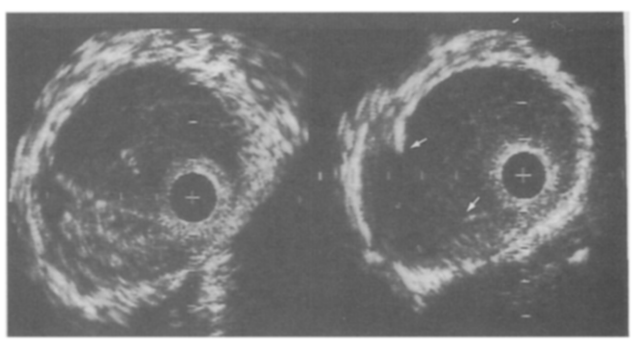

Fig. 7. Intravascular ultrasound cross-sections of a venous bypass showing an intact valve leaflet (left panel) and the remnants (arrows) of the same valve leaflet after an additional valve cutting procedure (right panel). Beyond the intact valve leaflet blood appears more echogenic than blood flow in the lumen. + = Catheter; calibration = 1 mm.

Inflow and outflow tracts

Intravascular ultrasound images of the iliofemoral inflow tract obtained in 12 patients revealed > 50% area stenosis in eight patients (56%, 61% and 70% in the iliac artery, and 50%, 52%, 60%, 72% and 77% in the common femoral artery). Preoperative angiography was normal in six patients and in two patients wall irregularities were seen. Intraarterial pressure measurements during angiography, performed in three patients, revealed no pressure drop, even with use of papaverine. Based on intravascular ultrasound, additional balloon angioplasty was performed in two patients (area stenosis of 70% in the iliac and 77% in the femoral artery)(Fig. 10). The intervention was deemed successful based on intravascular ultrasound data.

In two patients an atherosclerotic lesion with a dissection was seen in the common femoral artery, probably caused by clamping of the artery.

The outflow tract (popliteal artery and tibioperoneal trunk) was imaged in ten patients. An area stenosis > 50% was evidenced in four patients (54% and 62% in the popliteal artery, 60% and 70% in the tibioperoneal trunk). Only the stenoses in the tibioperoneal trunk were visible on angiography as a diameter stenosis < 50%. No additional angioplasty was considered because the anterior tibial artery was unaffected.

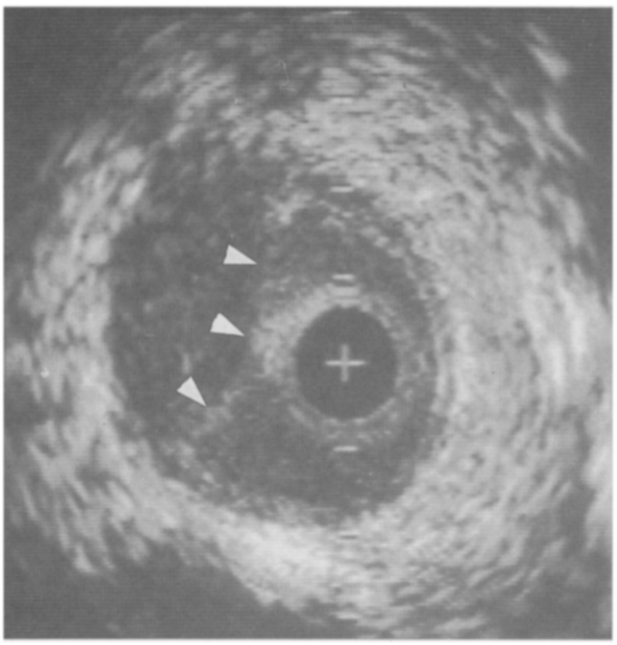

Fig. 8. Intravascular ultrasound cross-section of a venous bypass showing a dissection of the vein wall (arrows). + = Catheter; calibration = 1 mm.

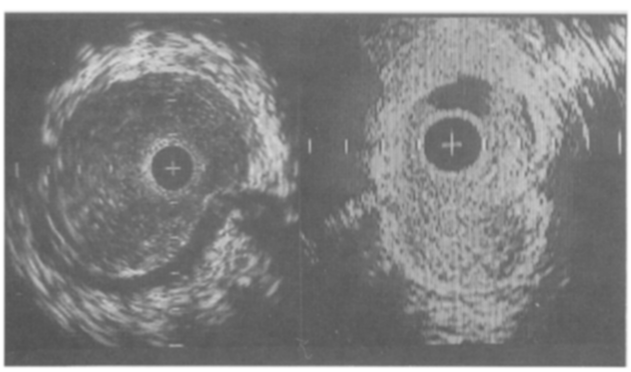

Fig. 9. Intravascular ultrasound cross-sections showing a patent end-to-end anastomosis (left panel) and an "insufficient" end-to-side anastomosis (right panel). In both panels the vein wall is at the top; the arterial wall is seen at the bottom as a three-layered wall with a hypoechoic middle layer representing the tunica media. The lumen in the right panel is severely obstructed by a soft lesion. + = Catheter; calibration = 1 mm.

Discussion

Since the introduction of intravascular ultrasound most emphasis has been on the investigation of atherosclerotic disease and the effect of balloon angioplasty. The number of studies performed on the venous part of the circulation is limited.

The study of The *et al.*[16] was the first to report on the use of intravascular ultrasound in the saphenous vein when used as a conduit in the arterial system.

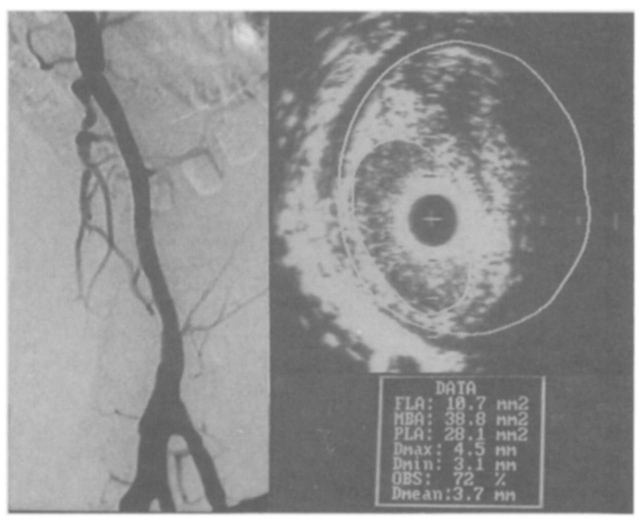

Fig. 10. Angiogram and intravascular ultrasound cross-section of the inflow tract. A 72% stenosis of the common femoral artery evidenced by intravascular ultrasound was not seen on angiography. + = Catheter; calibration = 1 mm.

Using the first generation intravascular ultrasound catheters they reported a homogeneous vein wall. As seen in *in vitro* studies, there was no differentiation between the tunica intima, media and adventitia.[15,20,21] The introduction of newly developed ultrasound catheters enables differentiation between a vein wall with a two- or three-layered appearance. *In-vitro* studies have shown that the inner layers represent the intima–media complex and the outer layer the tunica adventitia (unpublished observation). The difference in median thickness encountered in the present study between a two-layered (0.21 mm) and a three-layered (0.28 mm) vein wall indicates that the axial resolution is an important factor in imaging the vessel layers as distinct features. The intima–media thickness of the veins in this study (median 0.25, range 0.17–0.40 mm) are in the same order as those obtained by external ultrasound imaging with a 7.5 MHz probe of normal femoral (0.39 ± 0.031 mm) and popliteal veins (0.31 ± 0.33 mm).[22]

Visualisation of several layers provides the opportunity to differentiate between normal and thickened vessel walls. In the present study, distinct focal thickening of the intima–media complex evidenced by intravascular ultrasound in three patients was associated with free lumen area narrowing in two patients. In one of these patients, wall thickness was associated with subsequent significant luminal narrowing as Duplex scanning revealed a severe (> 50%) stenosis at 4 months follow-up. Although this finding is suggestive of a causal relation between intimal thickening and stenosis at follow-up, the clinical consequences of vein wall thickening remain to be determined.

At present several methods are available to detect pre-existing venous disease including macroscopic external inspection, histology and angioscopy. Generally, on macroscopic external inspection most veins appear normal, masking underlying abnormalities.[12] Moreover, if endovascular occlusion of side-branches becomes more extensively used, external inspection of the venous bypass will no longer be possible.[23,24] As thickening of the vein wall may be both generalised and focal, histology of remnants of the saphenous vein used for bypass is not sufficient to assess the overall quality. Obviously, histologic processing cannot be performed "on-line" and, therefore, cannot be used as a clinical decision-making device. Angioscopy may demonstrate abnormalities in the venous bypass but wall thickness cannot be established by this technique.[14] In contrast, intravascular ultrasound has the potential to assess wall thickness along the entire length of the bypass.

The influence of diameter on graft patency has been reported.[25] During intravascular ultrasound imaging, on-line information on free lumen area and diameter can be obtained semi-quantitatively. It is noteworthy that in the present study semi-quantitative intravascular ultrasound data on free lumen area influenced surgical management in two patients. Although the quantitative measurements in this study were performed off-line, automatic contour detection may enable these measurements to be performed online in the near future. Another issue to consider is the time at which the ultrasound data are collected during the study. In this study most of the veins were examined both in a pressurised condition (after completion of one anastomosis) as well as after restoration of blood flow (after completion of both anastomoses). In the latter instance an increase in free lumen area was experienced. Ligation of side-branches causes an additional increase in free lumen area in the distal part of the graft. Most of the measurements were performed on cross-sections obtained after restoration of blood flow but before ligation of side-branches.

It was possible to detect both the location and size of side-branches. This observation could become important with the introduction of endovascular techniques for occlusion of venous side-branches in which case external inspection of the saphenous vein, including localisation of side-branches, is no longer possible.[23,24] Cikrit *et al.*[23] reported that only side-branches with a diameter larger than 1.5 mm could be cannulated; therefore intravascular ultrasound may be useful to determine the location and size of side-branches.

With the introduction of *in situ* bypass in surgical practice, valve cutting became an important procedure. Angiography and angioscopy have both been used to assess the result of this procedure. The result of valve cutting can also be demonstrated by intravascular ultrasound. A patent valve leaflet detected in two patients resulted in an additional passage of the valve cutter. However, reviewing the videotapes off-line, additional partially intact valves were detected; most of these retained valves were not detected by intraoperative angiography. Although the influence of these retained valves on patency remains unclear, it is generally considered as a possible cause of graft failure.

Normally, venous bypass procedures are performed after diagnostic angiography which enables the proper inflow and outflow tract to be chosen. Apart from angiography, the quality of the inflow tract can be evaluated by pressure measurements in order to detect haemodynamic significant stenoses, which should be treated before performing a bypass. Despite this diagnostic work-up in the present study, intravascular ultrasound revealed obstructive lesions both in the inflow and outflow tracts, which were considered to warrant additional balloon angioplasty in two patients.

Our ability to image the bypass and to interpret the ultrasound images improved considerably during the study. Due to a learning curve, the intravascular ultrasound procedure used in the present study was not performed according to a standard protocol; for future applications it will be important to standardise the procedure as much as possible. Using off-line analysis, abnormalities were detected that were not apparent during the study. Bearing this in mind, the results of the present study should be interpreted with caution. This new technique has a high sensitivity for abnormalities (wall thickening, intact valves and inflow and outflow tract stenosis), but the clinical significance of these abnormalities remains unknown.

In conclusion, intravascular ultrasound provides qualitative and quantitative data on parameters which describe the condition of the venous bypass graft during surgery. To what extent these parameters are predictors of short and long-term patency of these grafts needs to be determined in a prospective study. The results of the present study indicate that intravascular ultrasound has the potential to compete with angiography in evaluating the quality of the bypass procedure intraoperatively.

Acknowledgements

This project was supported by a grant from the Netherlands Heart Foundation and the Interuniversity Cardiology Institute of The Netherlands.

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Accepted 8 November 1994