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Reprinted Article "Subintimal Angioplasty of Femoropopliteal Artery Occlusions: The Long-term Results"☆,☆☆

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Abstract The technique of subintimal angioplasty has been attempted on 200 consecutive femoropopliteal artery occlusions of median (range) length 11 (2–37) cm. The principle of the technique is to traverse the occlusion in the subintimal plane and recanalise by inflating the angioplasty balloon within the subintimal space. The technical success rate was 159/200 (80%) and was not significantly different for occlusions <10 cm (81%, $n = 73$), 11–20 cm (83%, $n = 63$) or >20 cm (68%, $n = 23$), $p = 0.20$. There were no deaths nor limb loss resulting from the procedure. The median (range) ankle-brachial pressure index increased from 0.61 (0.21–1.0) preangioplasty to 0.90 (0.26–1.50) postangioplasty. The actuarial haemodynamic patencies of technically successful procedures at 12 and 36 months were 71% and 58% respectively, the symptomatic patencies were 73% and 61%. A multiple regression analysis showed that smoking multiplied the risk of reocclusion by 2.70 ($p < 0.001$), each additional run-off vessel reduced the risk by 0.54 ($p < 0.001$) and the risk increased by 1.73 ($p = 0.020$) for every 10 cm of occlusion length. In conclusion, the technical success rate (80%) of subintimal angioplasty for femoropopliteal occlusions is unrelated to occlusion length and for all procedures, including technical failures, cumulative symptomatic and haemodynamic patencies of 46 and 48% can be achieved at 3 years. The factors influencing long-term patency were smoking, the number of calf run-off vessels and occlusion length.

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Introduction

We have previously described the technique of subintimal angioplasty for femoropopliteal artery occlusions and provided data on short-term patency (mean follow-up, 6 months) after 71 procedures.[1] The purpose of this paper is to describe our continuing experience and to review the long-term results of our first 200 consecutive attempted subintimal angioplasties of femoropopliteal artery occlusions.

Patients and Methods

Patients and technique of subintimal angioplasty

Patients undergoing subintimal angioplasty of femoropopliteal artery occlusions during the 64-month period January 1987 to April 1992 were prospectively studied. All procedures were performed by a single Vascular Radiologist (A.B.). The contraindications to subintimal angioplasty were acute thrombotic or embolic occlusions, the absence of a femoral artery "stump" (at least 0.5 cm) and extension of the occlusion below the infrageniculate popliteal artery.

The technique for subintimal angioplasty has undergone minor modifications since the original description.[1] After diagnostic arteriography, the ipsilateral common femoral artery is punctured and a size 5F (Van Andel type, Cook Ltd, Letchworth, U.K.) predilating catheter introduced antegradely up to the origin of the occlusion. Heparin (5000 units) and tolazoline (12.5 mg) are injected into the artery and a straight floppy guidewire (3 cm floppy, 150 cm long, 0.035 inch diameter; Meadox, Dunstable, U.K.) used to enter the occlusion. The tip of the wire is then directed towards the arterial wall and the subintimal space intentionally entered, taking care to avoid large collaterals. The wire/catheter combination is then advanced into the occlusion. Entry into the subintimar space is confirmed by injection of a small volume of dilute contrast medium (Fig. 1) and in addition the guidewire moves freely when the subintimal space has been entered. The straight guidewire is now replaced by a taper-tip J-wire (1.5 mm taper, 150 cm long, 0.035 inch diameter; Meadox). The occlusion is traversed either by forward pressure on the J-wire itself or by advancing the catheter with the J-wire protruding from it. When the catheter tip is 2—3 cm from the distal end of the occlusion, the J-wire is manipulated to form a large loop and the true arterial lumen re-entered by forward pressure on the loop. The Van Andel catheter is then replaced with a size 5F balloon catheter (Optiplast, Toronto, Canada) and the balloon (usually 5 or 6 mm diameter) inflated throughout the entire length of the subintimal passage at 10—12 atmospheres for 15 seconds (Figs. 2 and 3). If there is a residual stenosis of >30% then the dilatation is repeated using slightly higher pressures. All patients received a further intraarterial injection of tolazoline (12.5 mg) at the conclusion of the procedure. There was no defined policy concerning aspirin administration during the period of this study and those patients who were prescribed postangioplasty aspirin received a daily dose of 150 or 300 mg. Oral anticoagulants were not prescribed after the angioplasty procedure.

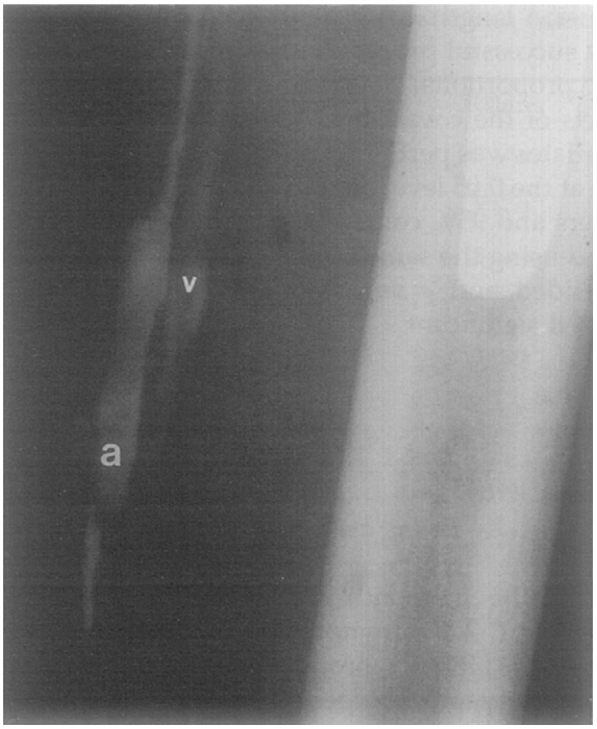

Figure 1 Showing injection of dilute contrast to confirm the subintimal location (a) of the catheter. The adjacent femoral vein (v) is often outlined with contrast during this procedure, presumably via venae comitantes.

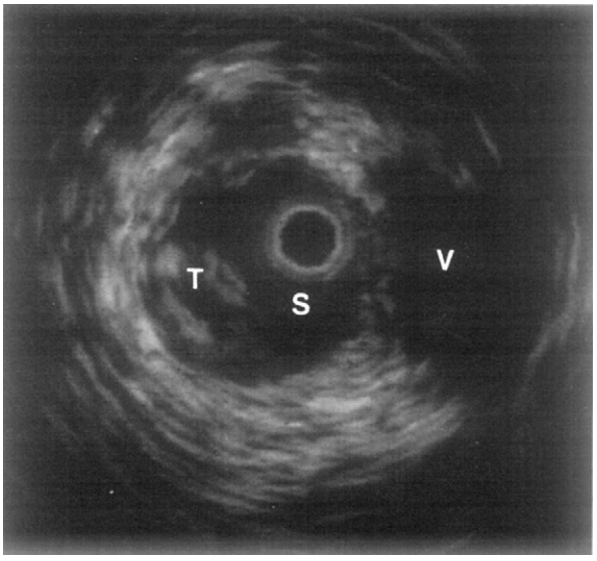

Figure 2 Endovascular ultasonography after completion of subintimal angioplasty of the right superficial femoral artery. The ultrasound probe is lying within the subintimal space (S), with the compressed true lumen (T) displaced laterally. The femoral vein (V) lies medially.

Definitions and data analysis

Success, failure, complications and long-term patency were analysed according to the guidelines provided by the

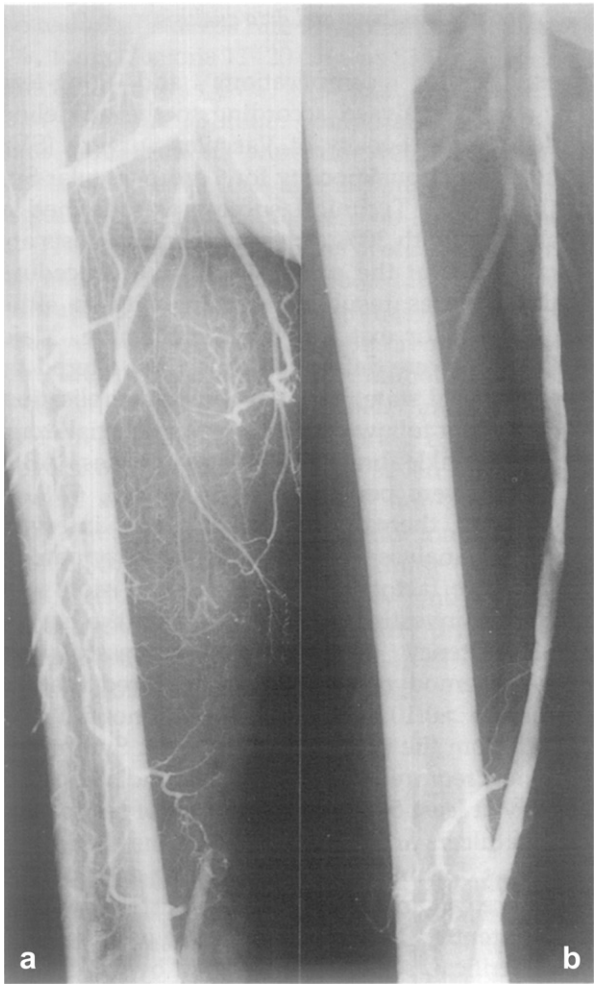

Figure 3 Showing a 25 cm superficial femoral artery occlusion before (a) and after (b) subintimal angioplasty. The smooth-walled 'spiral ribbon' appearance is characteristic of subintimal angioplasty.

Society of Vascular Surgery (SVS) and the International Society for Cardiovascular Surgery (ISCVS).[2–4] Technical success was defined as recanalisation with 30% or less residual stenosis and antegrade flow at the conclusion of the procedure. Technical failures resulted from inability to either enter, traverse or exit the subintimal space. Major complications were defined as those that altered the patient's clinical state, whereas minor complications did not. Patient follow up consisted of clinicial examination and ankle-brachial pressure indices (ABPI) only. These were performed at 24 h, 1, 3, 6, 9, 12 months and thereafter at 6-monthly intervals. Patency was analysed by looking at primary patency only, and the factors influencing reocclusion were examined by investigating their effect on the haemodynamic patency of technically successful procedures. Haemodynamic patency required that the ABPI rose by >0.10 within 24h and did not fall more than 0.15 from the post-procedure level. Symptomatic patency required that claudication distance improved by at least 50%, the resolution of rest pain or healing of ulcers and minor amputations. Peripheral run-off was documented by examining arteriograms of the entire calf and classified as 0-1 artery patent, 2 arteries patent or 3 arteries patent. We used the definition of critical ischaemia suggested by the Second European Consensus Document on Chronic Critical Leg Ischaemia[5] (rest pain for >2 weeks or ulceration or gangrene at the foot plus an ankle systolic pressure less than or equal to 50 mmHg).

Discrete variables were analysed with the Pearson chi-squared test with Yates' correction when the expected number of observations was small. Continuous variables were analysed by the Mann–Whitney U test. Patency was computed (Systat Survival package; Systat, London, U.K.) using the Kaplan–Meier method of life table analysis[6] and standard error calculations performed using the Greenwood formula.[7] Patients who died were censored at their last follow-up visit, no patients were lost to follow-up during the study. The minimum follow-up was 3 months, the maximum 60 months. The effect of variables on the haemodynamic patency of the technically successful procedures was compared in an univariate analysis with the Mantel-Haenszel log-rank test.[8] The variables examined in the univariate analysis were; gender, diabetes, hypertension, aspirin ingestion, smoking, clinical presentation, occlusion site, number of patent run-off arteries and occlusion length. Multivariate analysis of the technically successful procedures was performed using the Cox proportional hazards model[9] to analyse the effects of the covariates. A stepwise selection of the covariates was performed using the covariates significant at the 0.05 level on univariate analysis. Risk multipliers and 95% confidence intervals (CI) were computed using the same model. All statistical tests were two-sided and *p* values of 0.05 or less were considered significant.

Results

Patient and procedure details

During the 64-month study period, 176 patients underwent 200 attempted subintimal angioplasty procedures for femoropopliteal occlusive disease. During the same time period a total of 987 lower limb angioplasty procedures were performed on 831 patients, and 47 conventional intraluminal angioplasties were performed for femoropopliteal

Table 1 Details of all patients and those patients in whom subintimal angioplasty was technically successful.

	All patients	Technically successful patients
Number of patients	176	145
Median (range) age, yr	68 (22–92)	68 (22–92)
Males	130 (74)	108 (75)
Diabetes	33 (19)	26 (18)
Hypertension	62 (35)	48 (33)
Smoking[a]	61 (35)	57 (40)

Figures in parentheses are percentages.
[a] Refers to continued smoking after the angioplasty procedure.

Table 2 Details of the technically successful and failed procedures (total = 200).

	Successful	Failures
Number	159 (80)	41 (20)
Diabetes[a]	28 (18)	9 (22)
Hypertension	57 (36)	18 (44)
Aspirin[b]	112 (70)	15 (37)
Smoking[b]	61 (38)	9 (22)
Critical ischaemia[a]	18 (11)	4 (10)
Site of occlusion[a]		
Femoral artery	120 (75)	34 (83)
Popliteal artery	39 (25)	7 (17)
Run-off		
0-1 arteries patent	41 (26)	12 (29)
2 arteries patent	62 (39)	15 (37)
3 arteries patent	56 (35)	14 (34)
Occlusion length[a]		
<10 cm	73(46)	17 (41)
10–20 cm	63 (40)	13 (32)
>20 cm	23 (14)	11 (27)
Occlusion length,[a] cm		
median (range)	11 (2–30)	12 (2–37)
ABPI, median (range)		
Pre-angioplasty	0.61 (0.21–1.00)	0.62 (0.23–0.76)
Post-angioplasty (24 h)	0.90 (0.26–1.50)	0.62 (0.31–0.81)

Figures in parentheses are percentages. ABPI: ankle-brachial pressure index.
[a] The values for these variables are not significantly different between the technically successful and failed groups.
[b] Refers to continued smoking or aspirin ingestion after the angioplasty procedure.

artery occlusions. Thus, the 200 subintimal angioplasties reported here represent 20% of all lower limb angioplasties and 81% of angioplasties for femoropopliteal artery occlusive disease. Details of all patients (176) and those patients in whom the angioplasty was technically successful (145) are given in Table 1. Details of the technically successful (159) and failed procedures (41) are given in Table 2. The difference between the number of technically successful patients (145) and procedures (159) arises because 14 patients underwent subintimal angioplasties on both limbs. Because none of these bilateral procedures were concurrent, and because the analysis considers only primary patency and does not consider repeat procedures on reoccluded angioplasty segments (secondary patency), 30-day mortality and patency calculations are based on the number of procedures performed, not the number of patients.

Technical success rate and complications

The technical success rate was 80% (159/200) and there were no significant differences between the technical success and failure groups with respect to the incidence of diabetes, critical ischaemia/claudi- cation, occlusion site or occlusion length (Table 2).The technical success rate for occlusions <10 cm was 81%, for occlusions 11–20 cm was

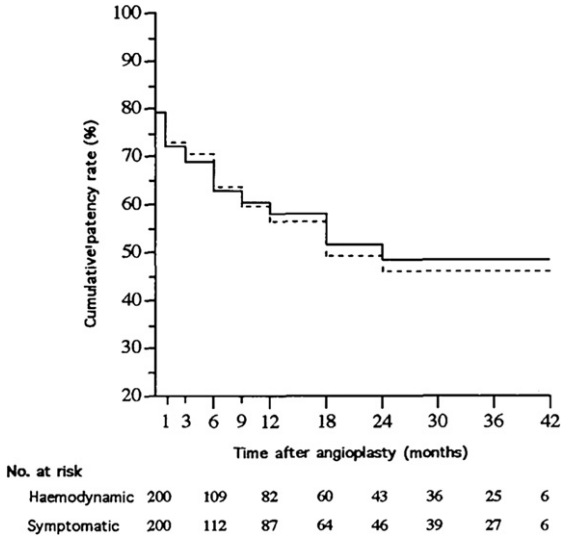

Figure 4 Cumulative haemodynamic (---) and symptomatic patencies (—) for all 200 attempted subintimal angioplasties (i.e. analysed on an intention-to-treat basis).

83% and for occlusions >20 cm was 68%, $p = 0.20$. There were two major (1%) and 13 minor complications (6.5%). The major complications were one retroperitoneal and one scrotal haematoma, and although both required surgical evacuation, there were no long-term sequelae. The minor complications were two groin haematomas, seven distal emboli and four vessel perforations. The groin haematomas resolved spontaneously. Two of the perforations required no treatment, and two were treated by embolisation using a 5F curved-tip non-tapered catheter and 3 mm diameter 1 cm long stainless steel spring coils (W. Cook, Bjaeverskov, Denmark). Of the seven distal emboli, six were aspirated using an 8F non-tapered aspiration catheter (W. Cook) and in addition one required regional fibrinolysis with streptokinase (5000 units/h) for 24 h. There were no deaths or limb

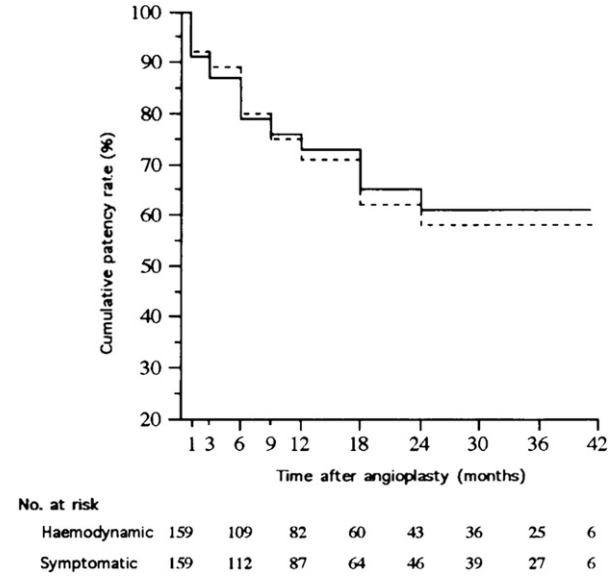

Figure 5 Cumulative haemodynamic (---) and symptomatic patencies (—) of the 159 technically successful procedures.

Table 3 Results of univariate analysis of variables influencing the long-term haemodynamic patency of technically successful procedures.

Variable	12-month patency (%)	Standard error of mean (%)	Number at risk	*p* value[a]
Gender				
male	72	5	63	
female	68	8	19	0.423
Diabetes				
present	61	10	13	
absent	73	4	69	0.063
Hypertension				
present	63	7	27	
absent	76	5	55	0.201
Aspirin				
prescribed	75	5	60	
not prescribed	62	7	22	0.031
Smoking				
smokers	61	7	24	
non-smokers	77	5	58	0.001
Presentation				
claudication	73	4	71	
critical ischaemia	60	12	11	0.144
Occlusion site				
femoral	73	4	62	
popliteal	66	8	20	0.413
Run-off arteries				
0-1 patent	56	9	14	
2 patent	67	7	32	
3 patent	85	6	36	0.014
Occlusion length				
<10 cm	77	5	46	
10–20 cm	71	6	36	
>20 cm	56	12	10	0.048

[a] Mantel-Haenszel log-rank test.

loss directly related to the subintimal angioplasty procedure. The 30-day mortality was 3/200 (1.5%), all three deaths resulting from myocardial infarction.

Patency

The long-term symptomatic and haemodynamic patencies of all 200 procedures (i.e. analysed on an intention-to-treat basis) and of the 159 technically successful procedures are shown in Figs. 4 and 5 respectively. The haemodynamic patencies at 12 and 36 months for all procedures were 56 and 46% respectively, the symptomatic patencies were 58 and 48%. The haemodynamic patencies at 12 and 36 months for technically successful procedures were 71 and 58% respectively, the symptomatic patencies were 73 and 61%. Five (3%) of the technically successful procedures failed within 24 h. The results of the univariate analysis of factors influencing patency of the technically successful procedures are given in Table 3. The significant variables at the 5% level were aspirin ingestion, smoking, number of patent run-off arteries and occlusion length. These covariates were entered stepwise into the Cox proportional hazards model and the results of this analysis are given in Table 4. It can be seen that smoking is estimated to increase the risk of reocclusion by a factor 2.70, each run-off artery reduces the risk by a factor of 0.54 and each 10 cm of occlusion length increases the risk by a factor of 1.73. Although aspirin was significant in the univariate analysis, this effect is lost in the multivariate model.

Table 4 Results of the Cox model for proportional hazards.

Variable	Estimated risk multiplier	95% confidence interval	*p* value
Smoking (smoking *vs.* non-smoking)	2.70	1.50–4.18	0.001
Run-off (risk per run-off artery)	0.54	0.37–0.85	0.001
Occlusion length (risk per 10 cm occlusion)	1.73	1.10–2.25	0.020

The variables entered into the model were aspirin ingestion, smoking, number of patent run-off vessels and occlusion length.

Discussion

During our early experience,[1] subintimal angioplasty was only performed if the guidewire entered the subintimal space accidentally. In recent years however, the subintimal space has been deliberately entered with the intention of performing subintimal recanalisation. Thus, although throughout the total duration of the study, 81% of angioplasties for femoropopliteal artery occlusions were subintimal, by the last two years of the study this figure had risen to 95%. Indeed, intraluminal angioplasty is now only used for very short (<2 cm length) occlusions, recent occlusions, or occlusions of very small femoropopliteal arteries (<4 mm diameter).

Although it is standard teaching that inadvertent subintimal dissection during conventional intraluminal angioplasty is an indication to withdraw and relocate the guidewire or even abandon the procedure,[10] there are theoretical reasons why subintimal angioplasty might be advantageous. The subintimal lane is the path of least resistance[10] and surgeons who perform endarterectomy are familiar with the ease with which occluding atheroma can be excised in this plane. During subintimal angioplasty the occlusion is traversed in an extraluminal plane and this may explain why we found the technical success rate to be the same for long and short occlusions. Recanalisation in the subintimal plane can be likened to the situation in acute aortic dissection where the dissection either re-enters the true lumen spontaneously or is surgically fenestrated.[11] In this situation the false lumen is often larger and has a higher blood flow than the true lumen.

Another potential advantage of subintimal angioplasty is that thrombogenic, crushed atheroma, is displaced to one side of the new lumen, whereas in conventional intraluminal angioplasty the new lumen is entirely surrounded by thrombogenic material. A further theoretical advantage of subintimal angioplasty is that unlike rotary atherectomy or laser angioplasty, which use thermal, photoablative or mechanical injury to traverse the occluded lumen, the occlusion is traversed with minimal injury. This reduced injury might be expected to minimise the restenosis rate after angioplasty.[12] A potential complication of subintimal angioplasty is damage to collateral or main vessels distal to the occlusion if these may be included in the dissected portion. It is crucially important therefore that the dissection is not extended too far distal to the occlusion.

Because of widely differing patient and lesion characteristics, it is difficult to make meaningful comparisons between the results of the present study and other studies reporting the outcome of percutaneous transluminal angioplasty for femoropopliteal artery occlusions.[13–15] Published technical success rates vary from 26-91%.[16–20] Our technical success rate of 83% for occlusions of 10–20 cm length compares favourably with the figure of 67% reported by Lammer et al.[19] who used intraluminal angioplasty for occlusions of a similar length. Comparisons of long-term patency are also limited by the restrictions mentioned above and published 1-year patencies range from 25-73%.[13,21] Our 12-month haemodynamic patency (ABPI) of 71% for technically successful procedures compares favourably with the figure of 38% after intraluminal angioplasty reported by Lammer et al.[19] It should be noted that the longest occlusion treated in the latter study was 19 cm, whereas in the present study 14% of occlusions were >20 cm. Our finding that symptomatic patencies were slightly greater than haemodynamic patencies is in agreement with the results of other studies[19] and presumably reflects the development of collateral vessels in some patients.[4] The finding that the number of run-off vessels and occlusion length significantly influenced patency is not surprising and is in agreement with the results of previous studies of intraluminal angioplasty.[16,17,21,22] We found that smoking profoundly reduced patency after subintimal angioplasty and this underlines the importance of abstention in this group of patients.

Our 1% major complication rate is in keeping with reports of the complication rates after conventional intraluminal angioplasty.[13] The most serious complication we encountered was retroperitoneal haemorrhage after a high groin puncture. However, this complication is not specific to subintimal angioplasty and its potential dangers after all forms of vascular investigation and intervention through the common femoral artery have recently been highlighted.[23,24]

On the basis of the data presented in this paper, we conclude that subintimal angioplasty of femoropopliteal artery occlusions can be performed with a high technical success rate (80%) and a low major complication rate (1%). The haemodynamic patencies of technically successful procedures at 12 and 36 months were 71 and 58% respectively and although it is not possible to make strict comparisons with other studies, these results compare favourably with the published results of other forms of angioplasty. The specific advantages offered by subintimal angioplasty are that it does not require specialised equipment and is thus relatively cheap, it is not a technically difficult procedure, and it is relatively non-traumatic. Finally, although conventional teaching dictates that subintimal dissection should be avoided, it should be remembered that extensive subintimal dissection is frequently seen even after conventional intraluminal angioplasty.[25,26] We suggest therefore, that if the subintimal space is inadvertently entered during intraluminal angioplasty (as occurs in roughly 25% of cases)[19] that subintimal angioplasty is an excellent alternative to repositioning the guide-wire or abandoning the procedure. It is not known whether subintimal angioplasty is preferable to intraluminal angioplasty as a deliberate primary procedure and we have therefore recently begun a randomised prospective study to investigate this issue.

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