Revisiting of occluded native superficial femoral artery after femoropopliteal bypass occlusion in patients with critical limb ischemia using the endovascular approach

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Background
Patients with graft occlusion have poor outcomes, with increased amputation rates. Reoperation is not feasible in some patients with critical limb ischemia owing to high surgical risk, unsuitable target vessels, or lack of conduit. Pertinent progress in endovascular techniques has provided more therapeutic options for patients with critical limb ischemia.

Aim
This study aimed to assess the short-term outcome of native superficial femoral artery endovascular revascularization in patients with occluded bypass.

Patients and methods
This is a retrospective study that was based on a prospectively maintained database of patients who attended our hospital with signs of chronic limb ischemia owing to occluded previous femoropopliteal bypass during the period from January 2019 to June 2021. Patients were invited for follow-up visits at 6 weeks and then at 3-month intervals.

Results
Technical success was achieved in all patients. At the end of the follow-up period, the primary patency rate was 56.14%, the assisted patency rate was 82.5%, and the secondary patency rate was 87.7%. The amputation-free survival rate was 87.7%, and the limb-salvage rate was 96.5%.

Conclusion
Endovascular recanalization is a feasible, effective, and safe alternative treatment choice for patients with chronic limb ischemia and failed previous graft bypass. It offers high rates of technical success, assisted primary and secondary patency, limb salvage, and amputation-free survival.

Keywords:
critical limb ischemia, endovascular therapy, native superficial femoral artery, previous graft failure

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Introduction

Peripheral arterial disease (PAD) has become a considerable health problem owing to the high worldwide prevalence of related risk factors such as diabetes mellitus and smoking [1]. The clinical presentation of lower-extremity PAD is widely variable, ranging from silent disease to critical limb ischemia (CLI) [2].

Based on the Trans-Atlantic Inter-Society Consensus for the Management of PAD II (TASC II), the main treatment for chronic total occlusions of superficial femoral artery (SFA) is surgical revascularization with bypass graft [3]. However, the graft occlusion rate was reported to reach 10% early after surgery and up to 50% at 1 month postoperatively [4]. Patients with graft occlusion have poor outcomes, with increased amputation rates [5]. Reoperation is not feasible in some patients with CLI owing to high surgical risk, unsuitable target vessels, or lack of conduit [6].

Pertinent progress in endovascular techniques has provided more therapeutic options for patients with CLI [7]. Endovascular intervention advancements have expanded the treatment umbrella provided by TASC II guidelines to include some complex lesions, such as TASC C and D [8].

Percutaneous endovascular interventions have shown feasibility and success in the treatment of patients with CLI and graft occlusion [9,10]. However, given the patient's critical condition, this option represents a great challenge, as the risk of limb amputation is evolving in the case of failed endovascular intervention [6,10].

There is scarce evidence addressing the endovascular recanalization of native SFA after graft occlusion. This study aimed to evaluate the short-term outcome of native SFA endovascular revascularization in patients with occluded femoropopliteal bypass.

Patients and methods

The current study is a retrospective analysis of a prospectively maintained database of patients who attended our hospital with signs of CLI due to occluded previous femoropopliteal bypass during the period from January 2019 to June 2021. The study was commenced after the regional research ethics committee approval and following Helsinki declaration.

Patients were candidates for the study if they had failed conservative management and were ineligible for redo surgery owing to being surgically unfit, lack of an appropriate long saphenous vein, or lack of an adequate distal bypass target vessel. Patients with extensive tissue loss; acute limb ischemia; sepsis; allergy to heparin, antiplatelet, or contrast media; previous endarterectomy; chronic renal diseases; and not on hemodialysis were excluded from the study. Informed written consent was obtained from each included patient.

The endovascular intervention

All patients underwent routine workup before the procedure. All patients were evaluated by color Doppler ultrasound and computed tomography angiography. The ankle–brachial index (ABI) was evaluated preprocedurally and postprocedurally to assess hemodynamic improvement.

The endovascular intervention was performed under local anesthesia in dedicated angiography suites with a mobile C-arm having vascular imaging capabilities. The target vein was accessed via the contralateral common femoral artery through a retrograde puncture in all cases. A 6-Fr vascular sheath was inserted, and an angiography was performed. Systemic administration of heparin (50 IU/kg) was secured during the procedure. For endoluminal recanalization, in addition to the conventional intraluminal techniques, we used subintimal techniques, including the subintimal arterial flossing with antegrade-retrograde intervention (SAFARI). We used a 0.035-inch hydrophilic guide wire (Radifocus, Terumo, Tokyo, Japan) to cross the lesion. For infrapopliteal arteries, 0.018-inch hydrophilic guide wires (Boston Scientific, Natick, Massachusetts, USA) were used. Then, a 4–5-mm balloon (Sterling SL Monorail Balloon Directed Catheter by Boston Scientific or Armada XT; Abbott Vascular, Redwood City, California, USA) was positioned. Self-expanding stents were routinely placed to prevent restenosis in all cases. Stents were either EluviaTM (Boston Scientific) or LifeStent (Bard Inc., Murray Hill, New Jersey, USA).

Two antiplatelet medications [clopidogrel (75 mg/day) and aspirin (100 mg/day)] were administered for at least 1 year.

Follow-up of patients

Patients were invited for follow-up visits at 6 weeks and then at 3-month intervals. During the follow-up visit, all patients underwent complete physical examination and duplex ultrasound to assess vessel patency.

Study outcomes

The primary outcomes were technical success (native SFA recanalization with a $<30\%$ residual stenosis and ≥ 1 patent runoff tibial artery) and patency rates (primary, assisted, and secondary), and the secondary outcomes were limb-salvage rate (LSR; the interval between the procedure and major amputation) and amputation-free survival (AFS; the time between the procedure and major amputation or death).

Primary patency refers to the time from the intervention to the re-occlusion of SFA. Assisted primary patency is defined as the re-intervention to treat SFA critical stenosis and preclude pending occlusion. Secondary patency is defined as the duration from patency of the SFA after revascularization till its re-occlusion.

Statistical analysis

The patients' data were analyzed using the statistical package SPSS, version 26. After normality testing, comparisons between variables were made using the appropriate tests. Kaplan–Meier analysis was used to assess the cumulative patency rates, LSR, and AFS. Cox regression analysis was performed to identify predictors for primary patency loss. P values less than 0.05 were considered statistically significant.

Results

The present study included 57 patients with chronic limb ischemia who had previously failed femoropopliteal graft bypass. The patient's age ranged from 48 to 73 years with a mean of 62.18 ±8.26 years. Males were slightly predominant,

constituting 56.1% of the study patients (32 patients). Patients' associated comorbidities were diabetes mellitus, hypertension, dyslipidemia, chronic renal disease, and ischemic heart disease. A total of 28 (49.1%) patients had a history of smoking, and of them, 10 (17.5%) patients were current smokers (Table 1).

As for clinical data, the duration of the previous graft insertion ranged from 2 to 54 months, with a mean of 24.84±11.34 months. Three (5.26%) patients presented with incapacitating claudication, 38 (66.7%) patients presented with rest pain, four (7.01%) patients presented with major tissue loss, and 12 (21.05%) patients had ulcers. Regarding the TASC grade, 15 (26.3%) patients were of TASC C and 42 (74.7%) patients were of TASC D (Table 2).

A total of 36 (63.2%) patients had the previous graft to the above-knee popliteal artery, whereas 21 (26.8%) patients had the grafts to the below-knee artery. Grafts were synthetic expanded polytetrafluorethylene in 17 (29.8%) patients and great saphenous vein conduit in 40 (70.2%) patients. Overall, 26 (45.6%) patients had distal anastomotic occlusion, 23 (40.4%) patients had proximal anastomotic occlusion, and eight (14%) patients had both (Table 2).

The preprocedural ABI ranged from 0.3 to 0.8, with a mean of 0.62±0.14. Vein access was obtained in all patients through the contralateral femoral artery. The retrograde popliteal puncture was performed in 45 (78.9%) patients when the antegrade procedure was not possible owing to the difficult crossing of the previous anastomotic sites. Intraluminal technique was used in 11 (19.3%) patients, whereas the subintimal angioplasty was used in 46 (80.7%) patients, and of them, the SAFARI technique was used in 39 (88.4%) patients. Simultaneous treatment of the infrapopliteal arteries was done in 42 (73.7%) patients to provide a minimum of one patent run-off artery to the foot (Table 3).

Technical success was gained in all cases. The postprocedural ABI ranged from 0.8 to 1.2, with a

Table 1 Sociodemographic data of the study patients

	Study patients (*N*=57) Mean±SD (minimum–maximum)
Age (years)	62.18±8.26 (48–73)
	n (%)
Sex	
Female	25 (43.9)
Male	32 (56.1)
Comorbidities	
Diabetes mellitus	49 (86)
Hypertension	35 (61.4)
Dyslipidemia	42 (73.7)
IHD	23 (40.4)
ESRD	24 (42.1)
Smoking	
Smoker	28 (49.1)
Current smoker	10 (17.5)

ESRD, end-stage renal disease; IHD, ischemic heart disease.

Table 2 Clinical and surgical data of the study patients

	Study patients (*n*=57) Mean±SD (minimum–maximum)
Duration from the previous graft (months)	24.84±11.34 (2–54)
Preprocedural ABI	0.62±0.14 (0.3–0.8)
	n (%)
Clinical presentation	
Incapacitating claudication	3 (5.26)
Rest pain	38 (66.7)
Major tissue loss	4 (7.01)
Ulcers	12(21.05)
TASC II category	
C	15 (26.3)
D	42 (74.7)
Previous bypass graft	
Above-knee popliteal artery	36 (63.2)
Below-knee popliteal artery	21 (26.8)
Graft	
ePTFE	17 (29.8)
Great saphenous vein	40 (70.2)
Site of occlusion	
Distal anastomotic	26 (45.6)
Proximal anastomotic	23 (40.4)
Both	8 (14)

ABI, ankle–brachial index; ePTFE, expanded polytetrafluorethylene; TASC, Trans-Atlantic Inter-Society Consensus for the Management of PAD II.

Table 3 Procedure-related data of the study patients

	Study patients (*N*=57) Mean±SD (minimum–maximum)
Duration of follow-up (months)	21.4±5.4 (2–26)
Postprocedural ABI	0.99±0.09 (0.8–1.2)
	n (%)
Vein access	
Contralateral femoral artery	57 (100)
Retrograde popliteal puncture	45 (78.9)
Angioplasty technique	
Intraluminal	11 (19.3)
Subintimal	46 (80.7)
SAFARI	42 (74.7)

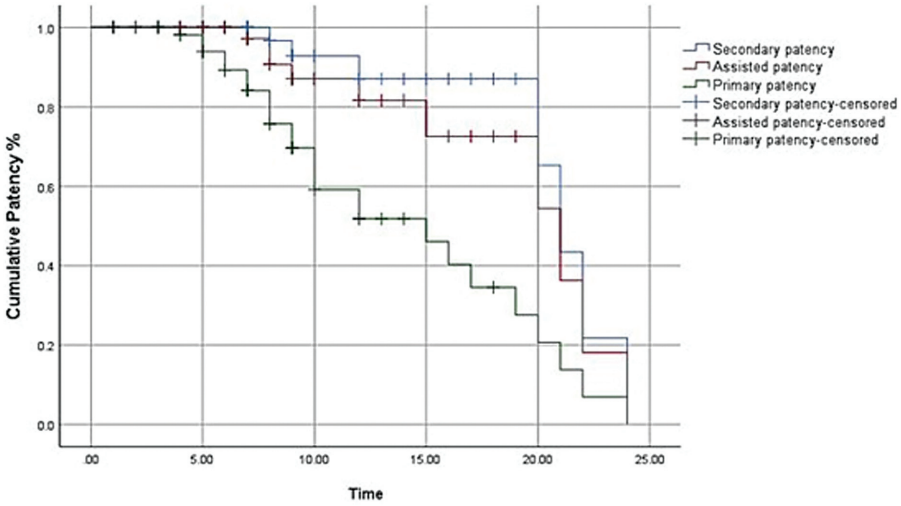
ABI, ankle–brachial index; SAFARI, subintimal arterial flossing with antegrade-retrograde intervention.

mean of 0.99±0.09, denoting a significant increase in comparison with the baseline values ($P<0.001$). The follow-up period ranged from 2 to 18 months, with a mean of 21.4±5.4 months. At the end of follow-up period, Kaplan–Meier analysis revealed that the primary patency rate was 56.14%, the assisted patency rate was 82.5%, and the secondary patency rate was 87.7% (Fig. 1). Six mortality cases were encountered during the follow-up period owing to unrelated causes, and four cases dropped out during the follow-up period. The AFS rate was 87.7% (Fig. 2), and the LSR was 96.5% (Fig. 3). Cox regression analysis showed that current smoking was the only significant predictor for loss of primary patency ($P=0.001$).

Discussion

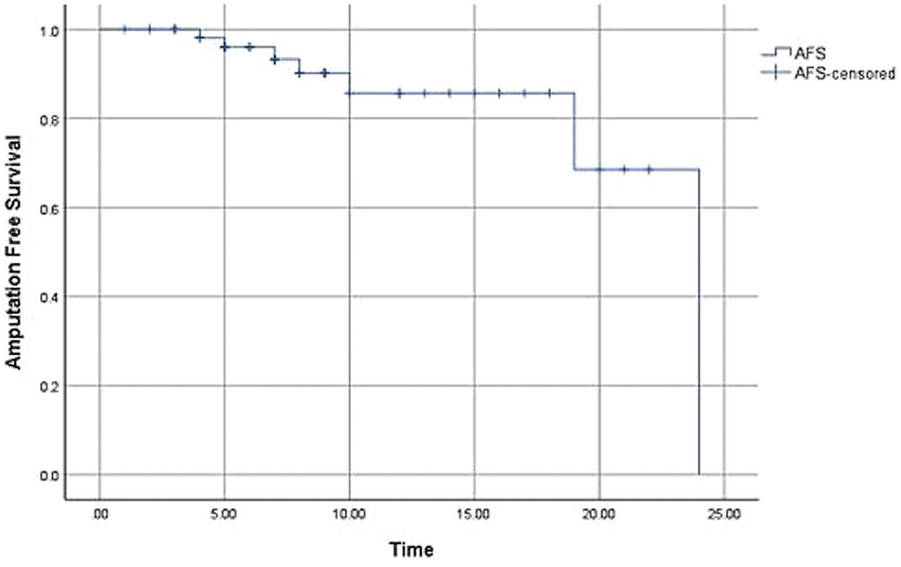
To date, management of lower limb occluded bypass graft remains a challenging dilemma. It has been estimated that patients with thrombosed graft have an LSR of about 50% at 24 months [11]. Proper treatment of failed bypass grafts would minimize patients' morbidity and allow higher LSR. Reoperation and thrombectomy have shown excellent immediate technical success. However, its effect on LSR is debatable. Advances in percutaneous endovascular intervention have provided an alternative management choice with acceptable outcomes. Nevertheless, there is still limited literature addressing recanalization of the

Figure 1



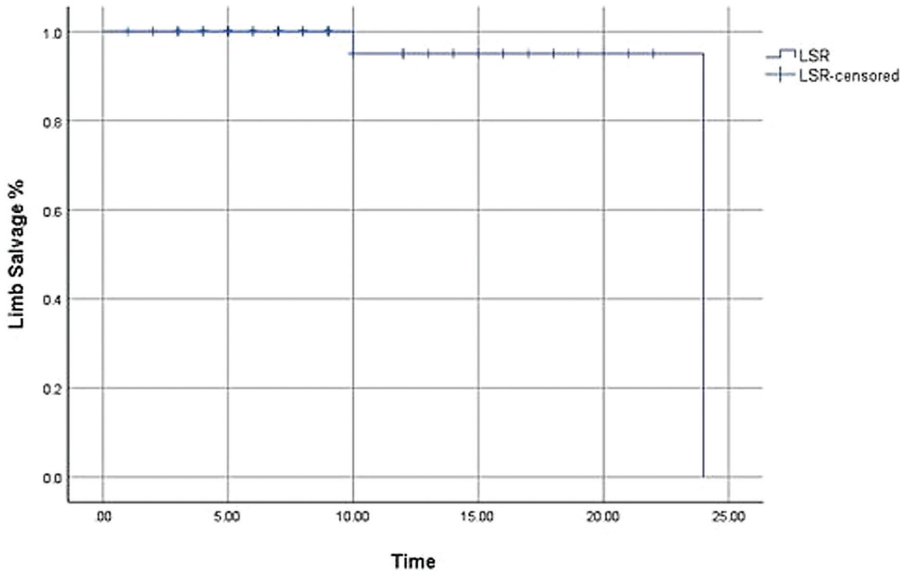
Kaplan–Meier analysis of cumulative patency rates after endovascular recanalization.

Figure 2



Kaplan–Meier analysis of amputation-free survival rates.

Figure 3



Kaplan–Meier analysis of limb-salvage rates.

native SFA recanalization for bypass graft failures [4,6,9,11–18].

This study presents our experience in managing graft failures with endovascular recanalization of native SFA over about 18 months. Our study revealed that such a management choice was feasible, with high immediate technical success (100%), and safe, with no perioperative major complications or death. This high success rate is likely attributed to proper patient selection, continuously advancing angioplasty techniques, and improving experience. We excluded patients with previous endovascular interventions on their native arteries. This decreased the potentiality of complex arterial lesions. Moreover, subintimal angioplasty and, in particular, the SAFARI technique have been adopted by our surgeons in many cases. This has enabled managing the furthermost complex arterial tracts. Our findings are comparable to the previously reported data. Simosa *et al.* [9] attained a technical success rate of 100%. Oguslu *et al.* [12], Li *et al.* [17], and Yin *et al.* [18] showed a technical success rate of 96.5, 95.6, and 92.9%, respectively.

The current study revealed significant improvement in the ABI after the endovascular intervention. The ABI is an indicator of the patient's overall atherosclerotic burden [19]. It has been reported that an elevation of the ABI by 0.15 or more after a successful endovascular intervention is an independent predictor for less incidence of morbidity and major amputation, irrespective of the preprocedural ABI [20–22]. In our study, the mean difference in ABI was 0.37, which indicates high procedure efficacy and promising patient outcome. This is in the range of the reported improvement in the ABI described by Oguslu *et al.* [12] and Minici *et al.* [4,12] (0.3), Wrigley *et al.* [14] (0.36), Li *et al.* [17] (0.4), Gandini *et al.* [11] (0.46), and Kawarada and Yokoi .[13] (0.47).

The major drawback related to endovascular intervention in treating patients with previous graft failure was the high rate of re-intervention. In this study, after 2 years of follow-up, the primary patency rate was 56.14%. This means that around half of the study patients had re-occluded native SFA at follow-up. Yet, this could be reasonable given the high assisted primary and secondary patency rates (82.5 and 87.7%, respectively). Our patency rates are consistent with previous studies, in which the primary patency rates ranged from 16% in the study of Wrigley *et al.* [14] to 76.7% in the study of Oguslu *et al.* [12], and the primary assisted patency rates ranged from 65% in the study by Minici *et al.* [4] to 88% in the study of Gandini *et al.* [11], and the secondary patency rates ranged from 32% in the study of Davies and El-Sayed [15] to 87.5% in the study of Oguslu *et al.* [12].

It appears that restenosis after endovascular treatment of native SFA does not negatively affect limb prognosis. Actually, in the current work, the AFS rate was 87.7%, and the LSR was 96.5%, denoting a high limb salvage performance. These encouraging rates are likely related to the preserved and enhanced collateral circulation during native SFA recanalization and subintimal techniques of angioplasty. The

improved collateral circulation helps to preserve tissue integrity, even if re-occlusion occurs. Furthermore, simultaneous treatment of the below-knee arteries could improve the outflow circulation. Our figures are congruent with the excellent LSR reported by previous studies [4,6,9,11–18].

Cox regression analysis in the present study demonstrated that current smoking was the only significant predictor for loss of primary patency. Smoking has been established to be associated with poor outcomes after surgeries [23]. Our findings are consistent with what has been reported that smoking is associated with negatively affected patency in patients with CLI [24].

Other risk factors were reported by previous studies. Diabetes mellitus, distal bypass target, hemodialysis, and dyslipidemia were reported to be associated with higher intervention rates [12,17]. To date, there are few studies assessing native SFA endovascular recanalization in patients with previous graft failure. Therefore, risk factors of patency loss have not been well-established. The limited sample size in the related studies could be another contributing factor to the difference in the concerned data.

This work is limited by being a single-center study, the relatively small sample size, limited follow-up period, retrospective design, and the absence of a group undergoing reoperation for comparison. However, our study adds evidence to the few studies searching for safe alternatives for reoperation in such risky patients.

Conclusion

Endovascular recanalization is an effective, feasible, and safe treatment choice for patients with chronic limb ischemia and occluded previous graft bypass. It offered high rates of technical success, assisted primary and secondary patency, limb salvage, and AFS.

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Conflicts of interest

There are no conflicts of interest.

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