Technique and early results of percutaneous femoropopliteal bypass with stent graft

Pierre Sarradon, MD,[a] Baris Ata Ozdemir, MD, PhD,[b] *and*
Jean Pierre Becquemin, MD,[c] *Monte Carlo, Monaco; Bristol, UK; and Champigny sur Marne, France*

ABSTRACT

Objective: We describe the technique and early results of lower extremity revascularization with total percutaneous bypass using extravascular placement of a stent graft (percutaneous prosthetic bypass).

Methods: Patients with severe chronic limb threatening ischemia for whom open or endoluminal repair was either not feasible and or had failed were selected for a pilot study using percutaneous prosthetic bypass. The procedure requires placement of three introducer sheaths in the contralateral common femoral artery, and the ipsilateral proximal and distal superficial femoral arteries (SFAs). A guidewire is placed from the contralateral sheath to the ipsilateral popliteal artery via the two ipsilateral sheaths. Two self-expanding polytetrafluoroethylene-covered stents are then placed from the proximal SFA to the distal SFA.

Results: A total of 30 bypasses were performed in 28 patients aged 71 ± 3 years. Of the 28 patients, 16 had severe claudication (Rutherford class 3; 53%) and 14 had critical ischemia (Rutherford class 4-6; 47%). The early results were excellent, with no deaths and one occlusion successfully treated with thrombolysis. No other complications requiring reintervention occurred. The mean follow-up was 25.4 months (range, 3-36 months). The 12- and 36-month Kaplan-Meier survival curve was 100% and 81%, respectively. The primary patency, secondary patency, and freedom from amputation rates were 75% and 75%, 78% and 75%, and 100% and 91%, respectively.

Conclusions: For patients with long lesions and/or failed endovascular treatment, the described technique offers the advantage of a total percutaneous procedure with acceptable early results. If these favorable outcomes are confirmed in larger series with longer follow-up, percutaneous extravascular bypass of the SFA will represent a complementary tool for infrainguinal arterial repair. (J Vasc Surg Cases Innov Tech 2023;9:101317.)

Keywords: Endovascular; Lower limb revascularization; Percutaneous bypass graft

The prevalence and incidence of peripheral arterial disease have been increasing, affecting >10% of the population aged >60 years, smokers, and patients with diabetes.[1] For patients with disabling claudication or chronic limb threatening ischemia (CLTI), restoring blood flow in the limb enhances patients' quality of life, prevents amputation, and improves their life expectancy. The superficial femoral artery (SFA) is the most common location of peripheral arterial lesions.[2] Revascularization procedures use either venous or prosthetic bypass or endovascular techniques that, with the technological advances, have become predominant in the therapeutic arsenal. The indications are relatively well defined and have been included in the recommendations from the major vascular societies.[3] In general, femoropopliteal bypass is recommended for long lesions and endovascular treatment for shorter lesions. The benefit of bypass surgery is the better long-term patency at the cost of higher perioperative morbidity mortality and longer hospital stays. In contrast, endovascular techniques can be performed in outpatient settings with a low rate of immediate complications but lower medium- and long-term patency.[4]

Recent tools that have successfully increased the feasibility and improved the outcomes of endovascular technique in the SFA area include drug-coated balloons and stents, atherectomy devices, and total occlusion crossing devices. However, long lesions and occlusions that cannot be crossed remain limitations, and investigators have explored various surgical innovations for new methods to overcome these issues. These are all based on placement of a covered stent from the groin to the distal SFA or popliteal artery. However, they differ in the

From the Hôpital Privé Saint Jean Toulon-Hyères, Centre Cardio-Thoracique de Monaco, Monte Carlo[a]; the North Bristol NHS Trust, University of Bristol, Bristol[b]; and the Private Hospital Paul D'Egine – Ramsay Santé Group, Champigny sur Marne.[c]

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Correspondence: Jean Pierre Becquemin, MD, Private Hospital Paul D'Egine – Ramsay Santé Group, 35 rue de Musselbourgh, Champigny sur Marne 94500, France (e-mail: jpbecquemin@gmail.com).

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chosen access approach, including endovenous access through the superficial femoral vein or through the surrounding soft tissue of the vessels in the thigh.[5-7] Performing percutaneous bypass has the potential to combine the benefits of the two techniques, including minimally invasive treatment and increased long-term patency.

The aim of the present study is to describe an innovative original technique for percutaneous vascular bypass and present the first early clinical results.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective analysis of prospectively collected registry data
- **Key Findings:** Total percutaneous femoropopliteal bypass (n = 30) was performed in 28 patients with lower limb ischemia. No early deaths and no complications occurred. One occlusion was successfully treated by thrombolysis. The 12- and 36-month Kaplan-Meier survival curves were 100% and 81%, respectively. The primary patency, secondary patency, and freedom from amputation rates were 75% and 75%, 78% and 75%, and 100% and 91%, respectively.
- **Take Home Message:** Percutaneous extravascular bypass is feasible and offers promising midterm results.

METHODS

Technique. Percutaneous prosthetic bypass (PEB) was performed in a hybrid operating room (Artis Zee; Siemens Healthineers) equipped with a sterile intraoperative duplex ultrasound machine (Sonosite S-Nerve; GE HealthCare). The anesthesia technique (ie, general anesthesia, epidural anesthesia, or local anesthesia with mild sedation) chosen was determined by the general condition of the patient and the complexity of the procedure. The patient was placed in the supine position. The operative limb and contralateral inguinal region were disinfected with chlorhexidine 0.5% and draped in sterile sheaths.

The skin and subcutaneous tissue of the thigh at the level of the passage of the graft were infiltrated with lidocaine hydrochloride 10% and 10 mg/mL of ropivacaine (Naropin; Fresenius Kabi). Aspirin was not discontinued preoperatively. The common femoral artery (CFA) contralateral to the bypass was punctured under ultrasound guidance. A 5F, 10-cm sheath, followed by a 4F, 65-cm angulated catheter, was used for the cross over. Once the wire was in place, it was exchanged for a 90-cm, 8F sheath with a removable valve (Destination; Terumo Europe; Fig 1) and placed in the iliac artery. A 0.035-in., 300-cm, angled stiff guidewire (Terumo Europe) was inserted into the contralateral iliac artery using a 4F, 65-cm angiographic catheter (Contra Flush; Boston Scientific), the long sheath was inserted over the stiff wire, and the tip of the sheath was placed at the level of the iliofemoral junction.

Angiography was performed to identify the proximal and patent distal segments of the SFA with anteroposterior and oblique views to identify the ostium of the profunda femoral artery and the origin of the SFA. These images were stored for later use with the road mapping technique to accurately deploy the proximal stent graft. After placement of the stent, it is no longer possible to inject contrast medium, because the introducer is obstructed by the sheath and the not yet deployed stent graft. Heparin, 50 IU/kg, was injected intravenously.

The SFA ipsilateral to the planned bypass was punctured under duplex ultrasound guidance, 4 to 5 cm below the femoral bifurcation, whether the artery was patent or occluded. An occluded artery was not a contraindication for the technique because the stent graft is deployed at the ostium of the SFA, and the occluded portion of the SFA can be punctured and crossed by the needle toward the patent CFA. An 18-guage, 7-cm echogenic needle (Cook Medical Europe) and a 0.035-in. Terumo guidewire were inserted into the same CFA. A 13-cm, 8F Terumo sheath was then placed in a retrograde direction toward the external iliac artery. The distal tip of the long sheath was pushed out through the skin (Fig 2), and the short sheath was removed. The third step includes antegrade puncture of the healthiest patent distal SFA or the popliteal artery under duplex ultrasound or arteriography guidance. A 13-cm, 8F peel-away sheath (Prelude SNAP; Merit Medical) was then placed (Fig 3).

The next step was to connect the two sheaths with a single guidewire (Figs 4-8). The 300-mm-long Terumo guidewire from the no. 1 sheath was introduced under radiographic guidance into the no. 2 sheath, with, if needed, the help of a 120-cm, 25-mm, 6F Amplatz goose neck snare (Medtronic). The tip of the guidewire wire was removed from the sheath and firmly held outside the patient's body. The no. 1 sheath was then pushed with the dilator over the wire through the arterial wall and the skin orifices of the puncture site of the no. 2 sheath, with the latter gradually removed. A retrograde tunnel close to the fascia, as identified by duplex ultrasound, was created between the puncture sites of the no. 2 and no. 3 sheaths using a tunneler (W.L. Gore & Associates) or a urology forceps (model 2703; Storz Medical). The wire was pulled through the tunnel, extracted at the level of the distal skin puncture, introduced into the no. 3 sheath, and then inserted into the popliteal artery and, whenever possible, down to the tibial artery. The 90-cm Terumo sheath with its dilator was pushed along the guidewire to the entry of the no. 3 sheath (Fig 5). The latter was peeled off and removed at the same time that the no. 1 sheath was inserted into the popliteal artery.

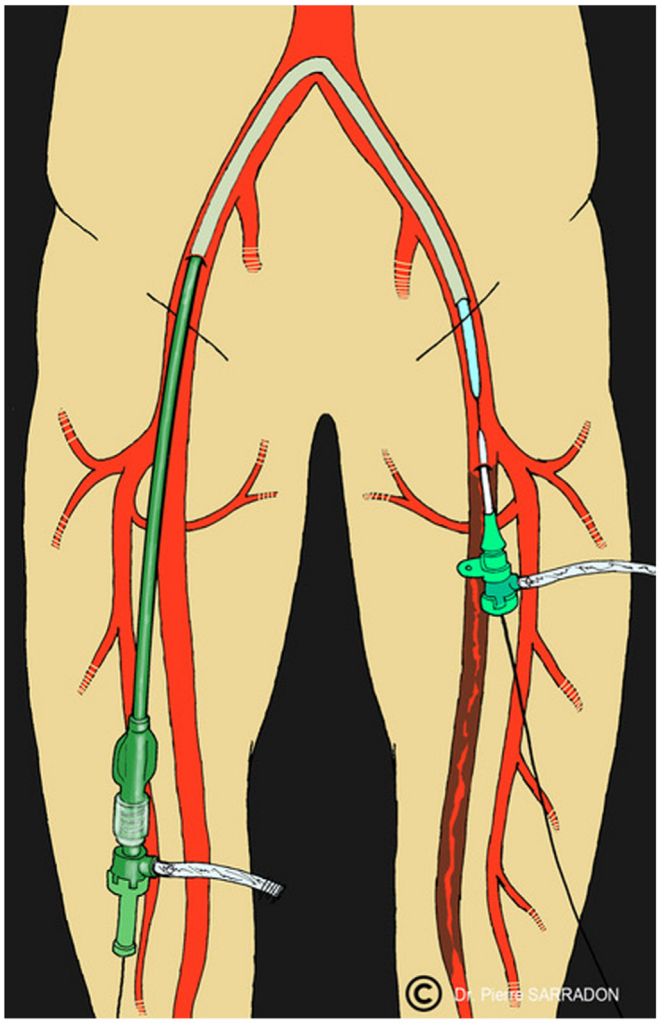

Fig 1. Diagram of total percutaneous bypass with long contralateral and short ipsilateral sheaths.

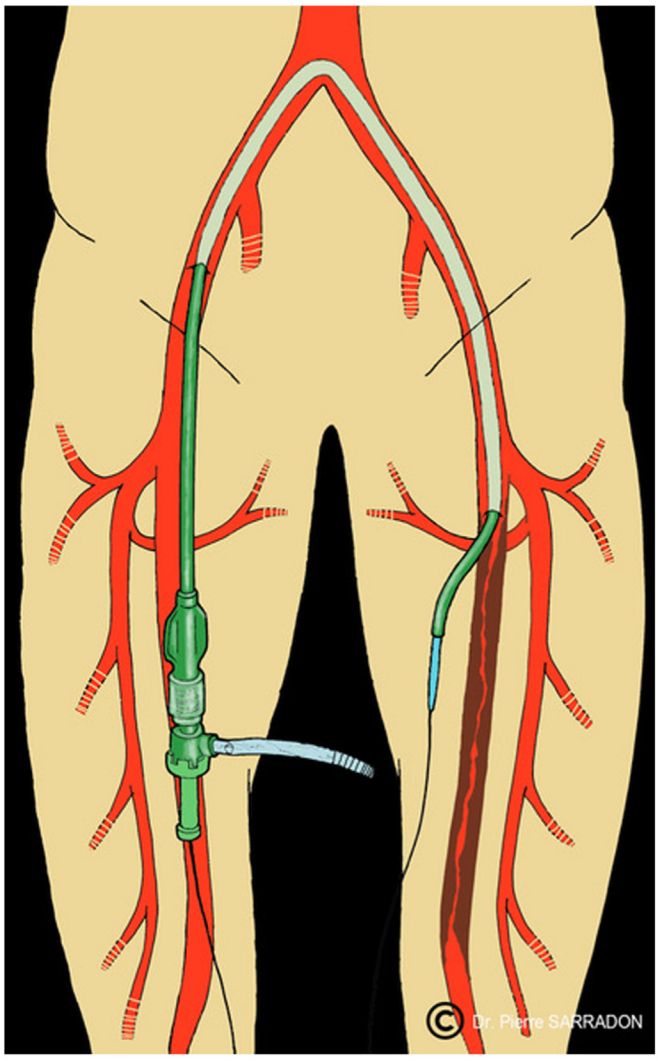

Fig 2. Diagram of total percutaneous bypass showing long sheath exiting percutaneously through the superficial femoral artery (SFA) puncture site of the ipsilateral sheath.

After removal of the dilator, a 25-cm, 5- or 6-mm (determined by the recipient artery diameter) heparinized Viabahn stent (W.L. Gore & Associates) was introduced into the sheath and delivered in the patent distal SFA overlying 4 to 5 cm in the vessel lumen (Fig 6). The 90-cm sheath was partially withdrawn to enable deployment of the Viabahn stent. Back bleeding through the first Viabahn stent during placement and deployment of the second stent were prevented by a loop. The loop was placed around the long sheath, which required a 0.5- to 1-cm incision. The free ends of the loop were externalized through a drain, which allowed the loop to be tightened and held by a clamp during tunneling of the guidewire. The Viabahn stent was entirely released. Next, according to the length of the remaining arterial length requiring treatment, a 15- or 25-cm Viabahn stent was added proximally (Fig 7). Its tip was placed as close as possible to the ostium of the SFA, with respect to the profunda femoral artery. Once the two grafts were deployed, expansion of the stents was ensured by high-pressure balloon angioplasty (6 × 15 high-pressure Mustang balloon dilatation catheter; Boston Scientific), with close attention at the proximal and distal anastomosis levels. To prevent proximal clot formation because antegrade flushing was not possible, the introducers were repeatedly rinsed with saline solution and heparin, the back flow from the distal stent was controlled by the loop, the second graft was delivered with the loop released, and the 90-cm-long sheath was withdrawn such that its distal tip was at the level of the CFA.

The following technical details were of paramount importance. To prevent disconnection, we strove to achieve an ~4-cm overlap of the grafts at the distal and proximal sites and between the two stents. Also, whenever possible, the distal tip of the Viabahn stent

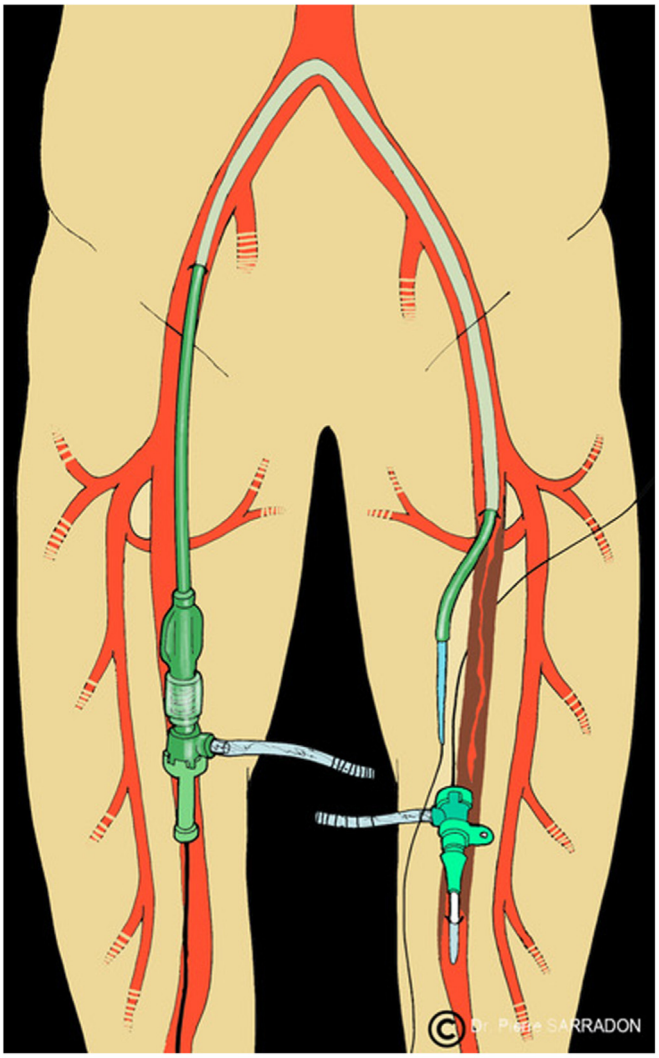

Fig 3. Diagram of total percutaneous bypass showing puncture of the distal superficial femoral artery (SFA).

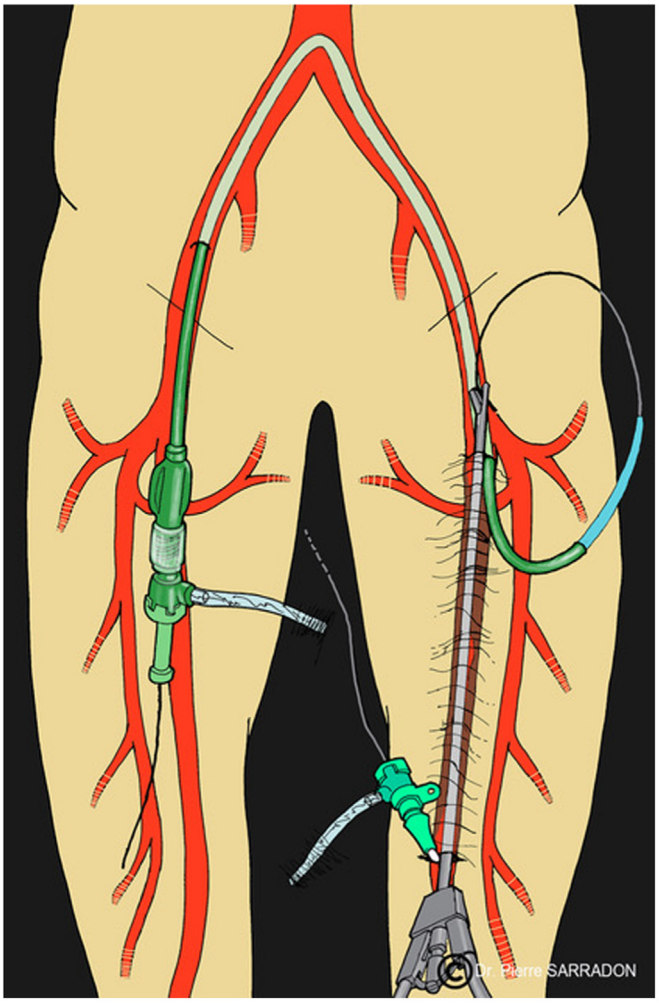

Fig 4. Diagram of total percutaneous bypass showing stiff wire from the long sheath caught with a urologic forceps introduced at the level of the distal superficial femoral artery (SFA) puncture site with a subcutaneous path.

was deployed above large patent collateral arteries to maintain outflow in the case of occlusion. The final control angiogram was performed through the no. 1 sheath (Fig 8). Finally, the sheath was pulled out, and the puncture site was closed using a percutaneous closure system (Angioseal; Terumo Interventional Systems). In the case of significant associated stenosis of the iliac and/or popliteal arteries, concurrent angioplasty was performed. The below-the-knee popliteal artery was occasionally selected as the receptor artery when the distal SFA was not suitable. This approach presented two drawbacks. First, the femoral bone condyle made correct visualization of the artery using ultrasound difficult. Second, the short length of the receiving popliteal artery exposed the coverage of the ostium of the anterior tibial artery. Fig 9 shows the 1-month postoperative view of a patient's thigh. Fig 10 shows three-dimensional reconstruction of a computed tomography angiogram of bilateral PEB. Postoperatively, patients were prescribed aspirin 75 mg and clopidogrel 75 mg daily or, when anticoagulant therapy was needed, apixaban (Eliquis; Bristol-Myers Squibb) 2.5 mg $\times$ 2/d with aspirin 75 mg/d was prescribed.

Study indications. We included patients with severe claudication or CLTI (Rutherford class 3-6). SFA lesions consisted of persistent lesions after a previously failed attempt of endovascular repair with totally occlusion of $\geq$15 cm or tight (>75%) multifocal stenosis >25 cm. The popliteal artery was free of severe disease. Given the lesion severity, the use of endoluminal stent grafts was not considered feasible.

Data management. The clinical presentation, risk factors, procedures, and follow-up data were prospectively recorded and retrospectively analyzed.

Follow-up. Follow-up was performed via medical consultation with the responsible surgeon (P.S.) and

Doppler ultrasound by a certified angiologist at 1 and 6 months and then annually. In the case of ischemic recurrence, the patients underwent clinical evaluation and duplex ultrasound earlier, followed, if necessary, by computed tomography or arteriography.

Ethics. All the patients included in the study were informed that the technique used (percutaneous) was novel but that the grafts had the CE (Conformité Européene) mark, were approved by the French authorities, and were routinely used in vascular surgery. They provided written informed consent to participate and for the report of anonymized medical data for scientific purposes. The medical committee of the Hôspital Prive Saint Jean Toulon-Hyères approved the study and waived the requirement for ethical review owing to the retrospective nature of the study.

Statistical analysis. Statistical analysis was performed by one of us (B.A.O.) using R, version 4.4.2 (R Foundation for Statistical Computing), and RStudio, version 2022.12.0, Build 353 (Rstudio Team).

RESULTS

Between January 2018 and March 2021, 30 percutaneous bypasses were performed in 28 patients (22 men and 8 women). Their average age was 71.2 years (range, 56-91 years). Of the 28 patients, 16 had severe claudication (Rutherford class 3; 53%) and 14 had CLTI (Rutherford class 4-6; 47%). The patients' comorbidities are listed in the Table. The interval between the two bilateral procedures was 4 and 7 months. The indication for percutaneous bypass included previously failed endovascular recanalization for 19 patients (64%) and reocclusion for 11 patients (36%). Of the 30 lesions, 27 (90%) measured >25 cm on preoperative computed tomography angiography or perioperative arteriography, and 3 (21%) measured 15 to 25 cm but could not be crossed by a guidewire in a previous attempt. Associated procedures were performed in 13 patients (43%), including iliac angioplasty for 3 (10%), angioplasty of the profunda femoral artery for 3 (10%), and angioplasty of the popliteal artery for 7 (23%).

General anesthesia was used for 3 patients because technical difficulties were expected (n = 2) or patient preference (n = 1), with locoregional anesthesia used for 25 patients. The average duration of the intervention was 115 minutes (range, 58-300 minutes). The longest duration was related to a very complex procedure for a patient with SFA occlusion, iliac artery lesions, and tibial—popliteal lesions. In one case, retrograde dissection occurred from an SFA puncture that was corrected by changing the placement of the needle in the true lumen. In this series, no SAFARI (subintimal arterial flossing with antegrade-retrograde intervention) technique and no crossing devices were used. The radiation exposure was 1968.16 μg/m^2 (range, 1407-3339 μg/m^2). The mean amount of contrast medium used was 89 mL (range, 65-120 mL). The technical success rate was 100%.

Immediate postoperative complications included a retroperitoneal hematoma, which resolved spontaneously, two moderate thigh hematomas, and one immediate thrombosis that was successfully treated by in situ thrombolysis. A disconnection between two 15-mm Viabahn stents whose overlap was too short (2 cm) required realignment. No cases of lymphorrhea or local or general infection developed, and no patient required a blood transfusion.

On postoperative day 1, 21 patients had returned to ambulation, with 9 patients starting ambulation on postoperative day 2. The average length of hospitalization was 4.21 days (range, 3-13 days). The longest stays were mostly related to patients with CLTI who required care of foot or leg wounds. Duplex ultrasound before discharge showed 100% patency for the 30 grafts. All patients were discharged to home. The mean follow-up was 25.54 months (range, 3-48 months). No patient was lost to follow-up. The 12- and 36-month Kaplan-Meier survival curves and primary, secondary patency, and freedom from amputation rates are shown in Figs 11-13.

The three secondary interventions included one angioplasty for restenosis, one femoropopliteal saphenous vein bypass for an occluded graft, and one transtibial amputation for nonhealing gangrene of the toes despite a patent bypass. At 6 months after intervention, one stent graft was occluded and was treated successfully by thrombolysis and stenting of a tight stenosis caused by a calcified plaque at the distal anastomosis. Six months later, the graft had thrombosed again, and saphenous vein bypass was performed.

At 30 months after intervention, of the five patients available for follow-up, four were symptom free with a patent bypass and the fifth patient presented with Rutherford class 4 and a patent bypass but an occluded distal popliteal bifurcation treated with successful angioplasty. Of these five patients, three had presented with claudication and two with CLTI. At the last follow-up, all five available patients were symptom free with a patent bypass. Three-dimensional reconstruction of computed tomography angiography is shown in Fig 10. During follow-up, two patients died of unrelated causes. Of the 30 lesions, 4 had become occluded 3 to 18 months after intervention (13.3%), 2 had required saphenous bypass (6.6%), 2 had required complementary percutaneous transluminal angioplasty, and 1 had required an amputation (3%). The reasons for occlusion were poor out flow due to severely diseased tibial arteries in three patients and compression of the Viabahn graft by severe circular calcification at the distal anastomosis in one patient.

DISCUSSION

In the present report, we describe a new technique for PEB. Considering the invasiveness nature of treatment of

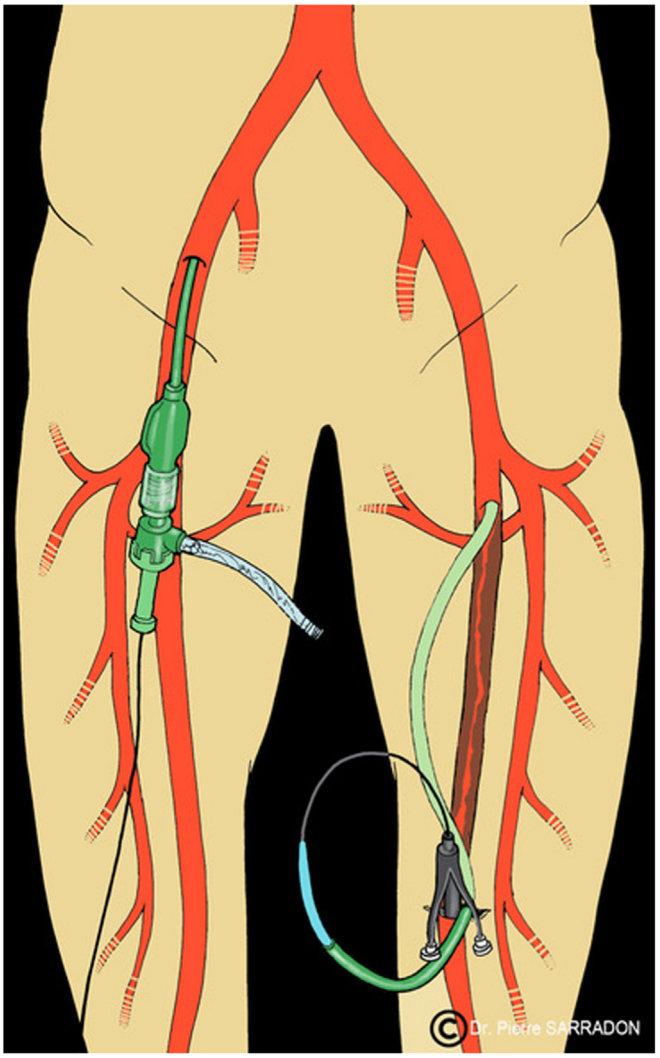

Fig 5. Diagram of total percutaneous bypass showing introduction of the stiff wire and distal tip of the contralateral sheath in the distal superficial femoral artery (SFA) sheath.

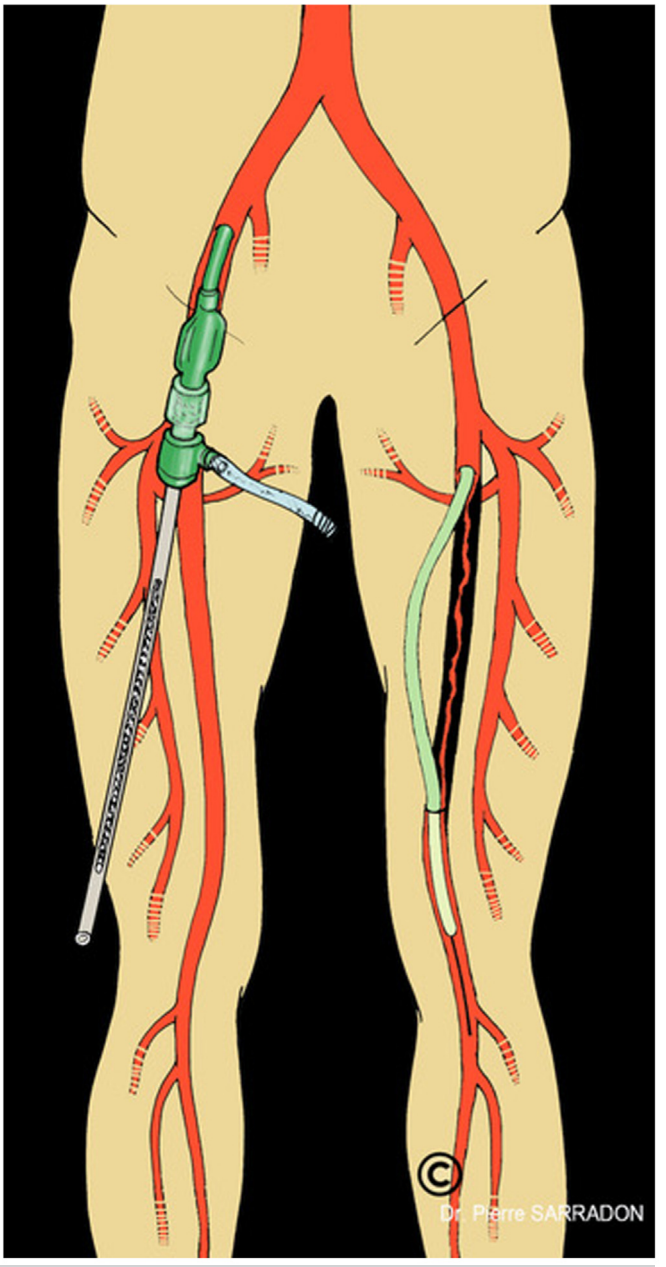

Fig 6. Diagram of total percutaneous bypass showing the distal superficial femoral artery (SFA) sheath peeled off and the dilatator of the contralateral sheath inserted into the popliteal artery. The Viabahn graft is inserted into the sheath.

patients with peripheral arterial disease, endovascular techniques are attractive because of the percutaneous approach. Situations exist, however, such as heavily calcified vessels, subintimal passage of the guidewire, and failure to reenter the true lumen distally, for which endovascular approaches are not feasible. Although various new devices might increase the early success rate, symptom recurrence has been reported to be as high as 68% at 2 years for those with claudication, and patency can be as low as 32% at 56 months.[8,9] In addition, long and severe restenosis or reocclusion remain challenging lesions to treat. Thus, at present, the current recommendation is to bypass long lesions.[3] Despite improvements in surgical and anesthesiology techniques, bypass is associated with significant morbidity in the range of 20%, mainly due to local complications such as delayed wound healing, skin and tissues necrosis, lymphorrhea, and infection.[10] The mortality after infrainguinal bypass is still in the range of 2.6% but is higher for frail older patients. Finally, longer in-hospital stays and the need for rehabilitation and wound care in specialized institutions increases the overall costs for the healthcare system. The use of a percutaneous bypass technique has the potential to avoid the limits and drawback of both techniques and to offer the benefits of minimally invasive treatment.

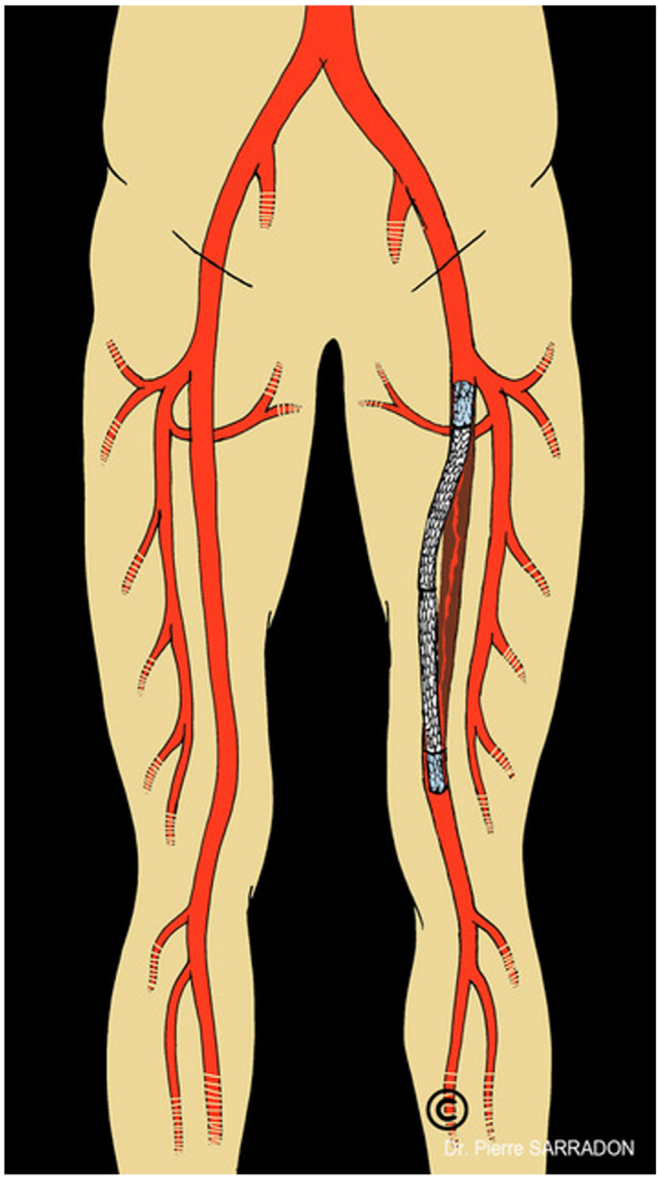

Fig 7. Final drawing of total percutaneous bypass procedure showing the Viabahn stent extending from the stump of the superficial femoral artery (SFA) to the popliteal artery via an extravascular route.

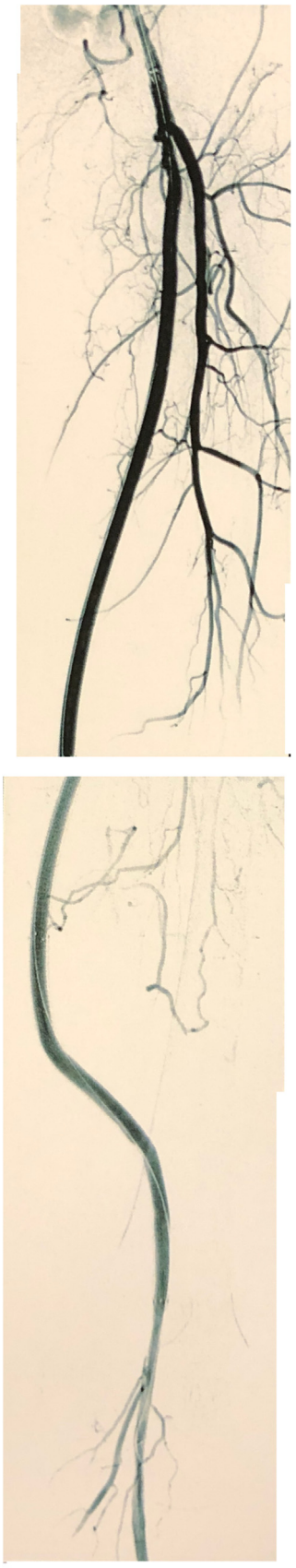

Fig 8. Intraoperative angiogram of total percutaneous bypass showing alignment of the grafts.

Furthermore, the percutaneous approach avoids the complications of a groin incision, especially in obese or diabetic patients.

The technique we describe in the present report differs from those reported previously. The DETOUR System (Endologix), whose results have been reported by Krievins et al,[5] is composed of a PQ crossing device, a PQ snare, and a Torus stent graft, which is a self-expanding nitinol wire frame encapsulated in expanded polytetrafluoroethylene. The delivery catheter is an over-the-wire 8F system. The crossing system allows for passage from the stump of the SFA into the

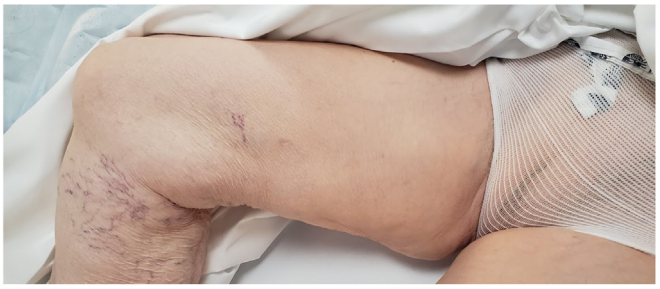

Fig 9. Photograph of the thigh at 1 month after total percutaneous bypass.

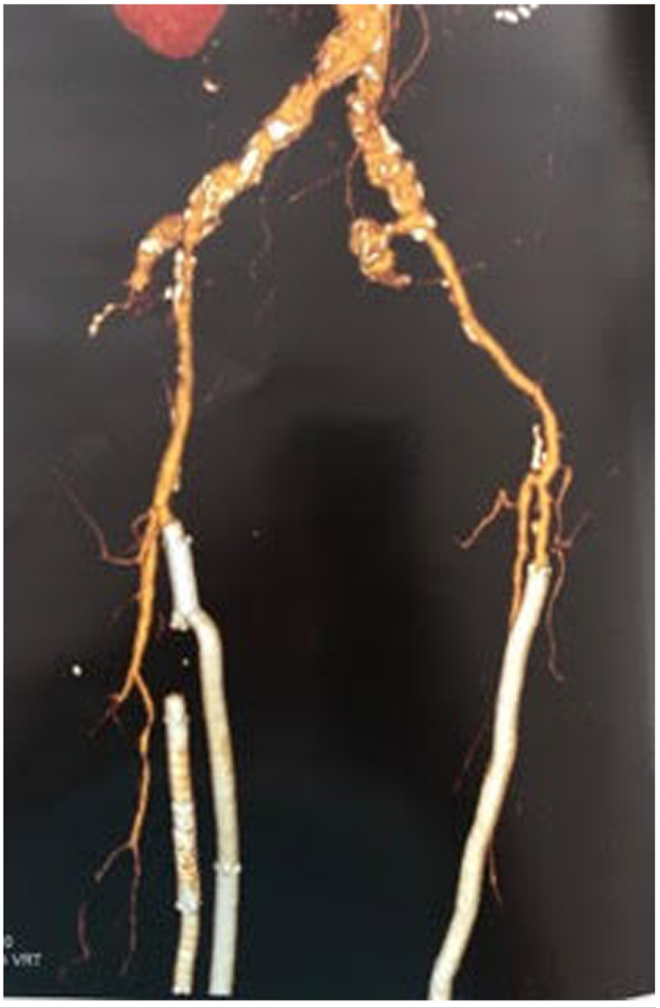

Fig 10. Three-dimensional reconstruction of 6-month computed tomography scan after bilateral total percutaneous bypass.

superficial femoral vein from the contralateral side. A 0.014-in. wire is snared by the PQ snare introduced from the tibial vein. Next, reentry from the vein to the artery below the occlusion is created, allowing for placement of the covered stent. A similar technique using

Table. Comorbidities of 28 patients

Comorbidity	Patients, no. (%)
Hypertension	16 (59.20)
Coronary artery disease	11 (40.70)
Arrhythmia	5 (19.50)
Pacemaker placed	4 (14.8)
IC	1 (3.7)
COPD	10 (37)
Diabetes mellitus	8 (29.60)
Carotid artery disease	7 (11.10)
Renal insufficiency	1 (3.70)
Smoker	12 (44.40)
Previous PAD treatment	16 (59.60)

COPD, Chronic obstructive pulmonary disease; *IC,* interstitial cystitis; *PAD,* peripheral arterial disease.

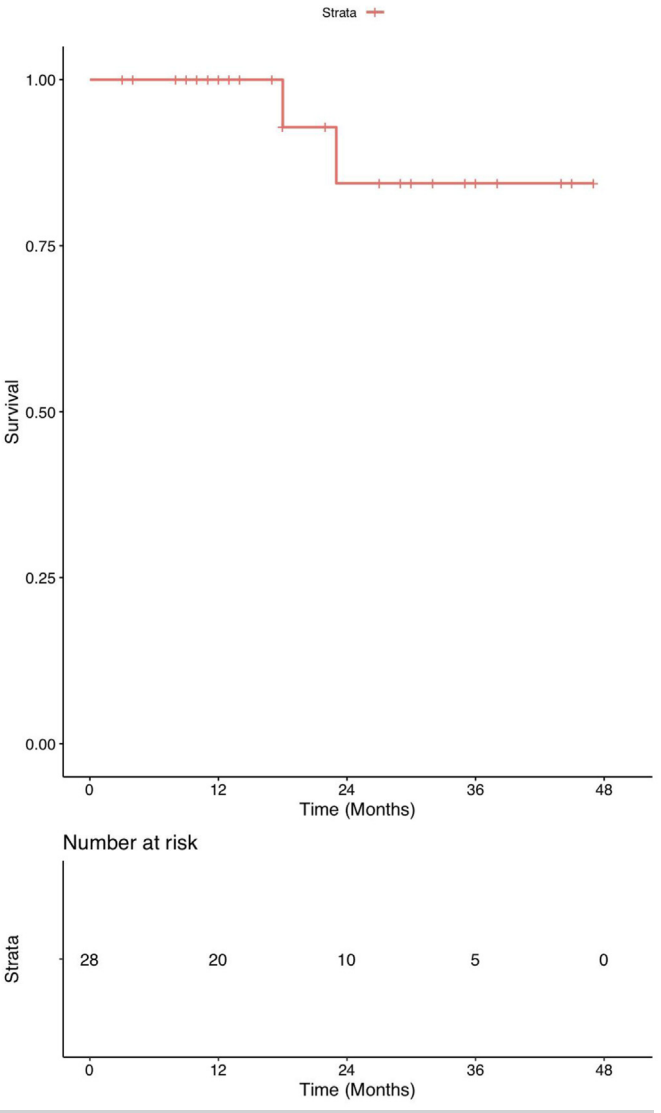

Fig 11. Kaplan-Meier survival curve.

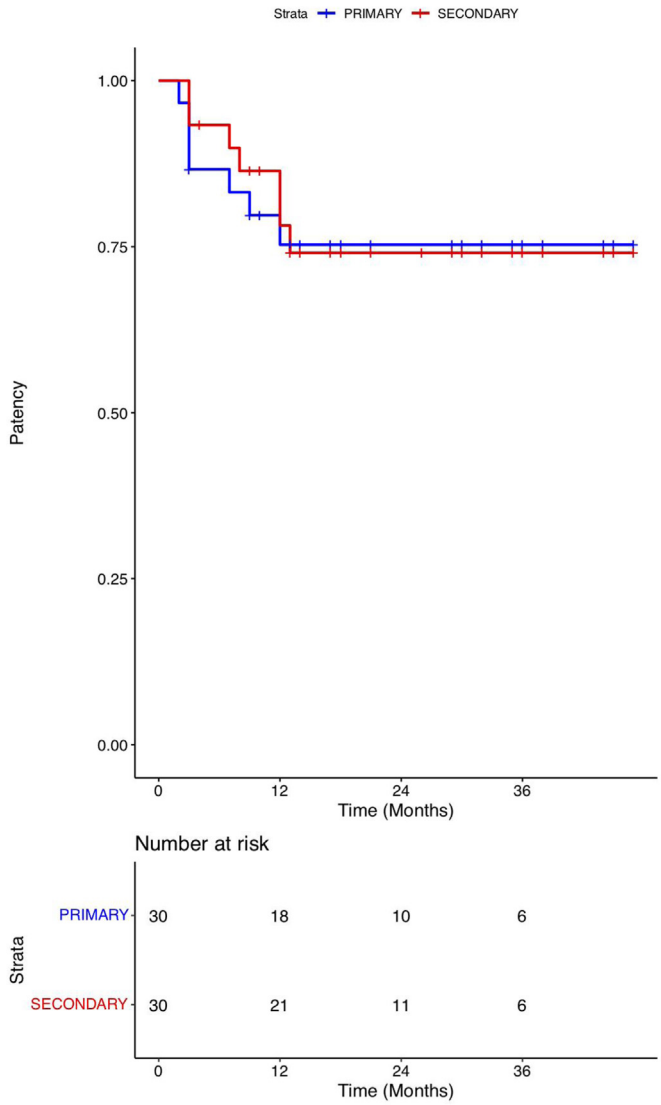

Fig 12. Kaplan-Meier curves for primary and secondary patency.

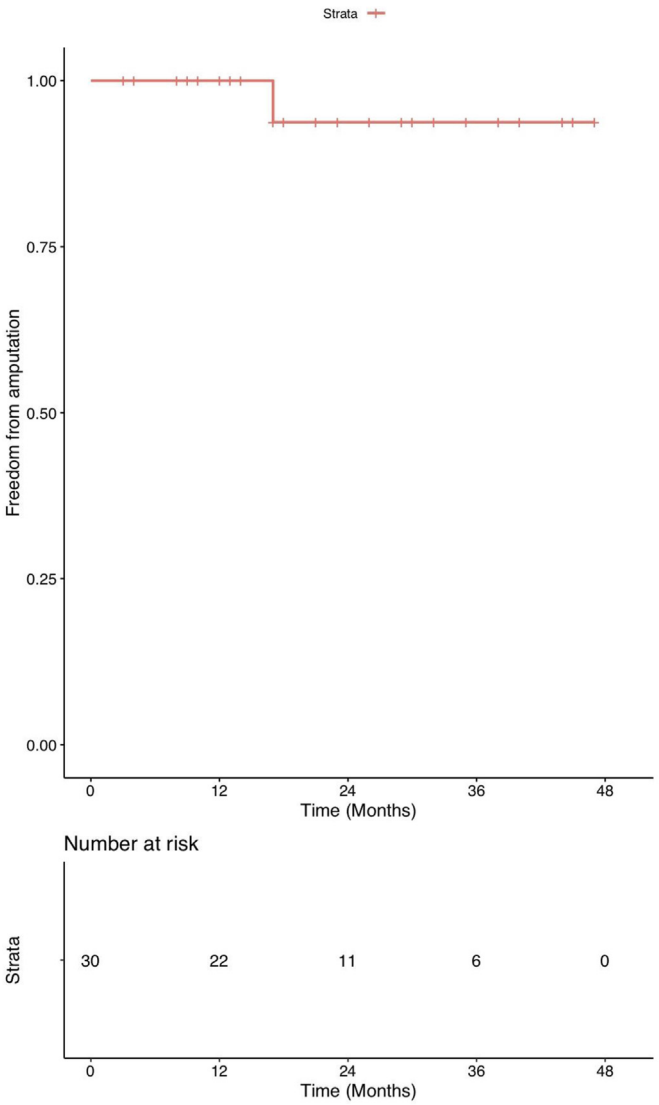

Fig 13. Kaplan-Meier curve for freedom from amputation.

the superficial femoral vein route but performed without a dedicated device and with a Viabahn stent graft has been reported by Touma et al,[6] with excellent early results. Di Primio et al[7] reported a technique in which the route was extravascular in the perivascular tissue, similar to our technique. The main differences were the proximal tip of the stent located in the deep femoral artery rather than in the origin of the SFA. Each technique has advantages and disadvantages. However, we believe that the DETOUR system, when available on the market, might be more expensive than the other three techniques. Also, the use of the deep femoral artery as the donor site exposes the limb to the risk of severe ischemia in case of bypass occlusion. In addition, the reported patency and limb salvage rates are inferior to our results.

Considering the short- and mid-term results reported by the three studies with significant numbers of patients and follow-up duration, the DETOUR technique showed 96% technical success, a Kaplan-Meier primary patency of 81% ± 4% at 1 year, and 94% ± 3% for secondary patency, with improved clinical status and few vein-related complications.[5] Di Primio et al[7] reported a 13% procedure-related complication rate, including one death and a rate of periprocedural hemorrhage at puncture sites requiring transfusion of 13%. The mean follow-up was 21 months, with amputation-free survival of 80% at 1 year and 53% at the last visit. The 1-year cumulative primary and secondary patency rates were 30% and 60%, respectively. These comparisons should be considered with caution before drawing firm conclusions, given the differences in patient selection, comorbidities, Rutherford status, and lesion type.

Our initial experience is very encouraging and compares favorably in demonstrating the feasibility of the technique, a low rate of early complications, and acceptable 25-month symptom-free, patency, and survival rates. The criteria for the inclusion of patients in our study were limited to primary lesions of the SFA of >25 cm and failure and/or recurrence after percutaneous angioplasty. We believe that shorter lesions that are not treatable by endovascular methods and for patients for whom general anesthesia and open surgery seems too risky, this technique could be a valuable option.

We do not recommend this technique for patients with poor runoff, which is a demonstrated risk factor for reduced long-term patency. The thrombosis observed in our series occurred in patients with stenosis of the popliteal artery or occlusion of the tibial arteries. Concomitant endovascular treatment of these lesions, which we performed in a few cases, improved the early results but raises the question of durability.

Technically, the learning curve was relatively short. One disconnection occurred in the very first patient, which was attributed to the lack of sufficient overlap between the two Viabahn stents. The lack was attributable in part to the unavailability at that time of the 25-cm graft. Compression of the graft when crossing the calcified wall of the artery highlights that the choice of the distal puncture site is essential. Preoperative analysis by computed tomography and/or duplex ultrasound of this distal puncture site is mandatory. In the case of stenosis detected by postprocedure angiography, high-pressure angioplasty, rather than placement of a short stent, is recommended. Finally, given the better long-term patency of venous substitutes with open repair, the choice of vein should be discussed. For percutaneous bypass, using a vein instead a graft poses unsolved problems, including that vein retrieval requires a long incision of the thigh or an endoscopic approach, which lengthens the operating time and most often requires general anesthesia. In addition, proximal and distal attachment of the vein is an unsolved issue. Also, twisting and/or plication of the conduit can be difficult to overcome. Finally, preservation of the vein when available does not compromise its future use in the case of occlusion of the bypass or the need for a tibial bypass.

Study limitations. This pilot study has several limitations. The number of cases is small, and follow-up is still relatively short. We report the experience of a single surgeon performing the procedure for patients whose vascular runoff was not always favorable. Larger series are needed to assess the patency according to the clinical stage and outflow. A multicenter study is underway to assess the validity of this new procedure compared with open femoropopliteal polytetrafluoroethylene bypass and, when feasible, advanced endovascular techniques such as SAFARI, intravascular lithotripsy, and/or crossing devices.

CONCLUSIONS

The results of our study show that the PEB technique is feasible with encouraging early results. It can be performed under local anesthesia and has low morbidity, no mortality, and acceptable short-term patency. The procedure can be considered for patients at significant surgical risk and patients with long lesions of the SFA, those lacking a saphenous vein, and patients for whom conventional endovascular techniques had failed or were not possible.

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AUTHOR CONTRIBUTIONS

Conception and design: PS, JB
Analysis and interpretation: BO, JB
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DISCLOSURES

None.

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