Endovascular treatment of long lesions of the superficial femoral artery: Results from a multicenter registry of a spiral, covered polytetrafluoroethylene stent

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Objective: **Information on outcome of patients with long superficial femoral artery (SFA) obstruction undergoing endovascular treatment is scarce. The present study reports results from a prospective multicenter registry designed to evaluate the safety, effectiveness, and patency of the aSpire self-expanding polytetrafluoroethylene covered stent (Vascular Architects Inc, San Jose, Calif) in patients with femoropopliteal occlusive disease.**
Method: **The aSpire Registry included 150 patients (166 limbs) enrolled in 16 centers during a 28-month period (2003 to 2005) for medium/long (>3 cm) occlusion (n = 115) or stenosis (n = 51) of the SFA (n = 51) or of the proximal popliteal (n = 115) arteries. Procedures were performed for intermittent claudication in 92, for rest pain in 33, and for limb savage in 41. The mean length of arterial segment covered was 107.35 ± 73.7 mm. Indications for treatment included 44 type B1, 57 type B2, 47 type C1, and 18 type D lesions according to TransAtlantic Inter-Society Consensus classification. Clinical and ultrasound evaluation was performed at discharge and at 1, 6, 12 months, and yearly thereafter. Mean follow-up was 13 months (range, 1 to 36). Primary end points were immediate technical success (vessel recanalization with residual stenosis ≤30%) and stent patency.**
Results: **Initial technical success was obtained in 162 (97.6%) of 166 procedures. More than one stent was applied in 48 procedures, for a total of 214 stents. No periprocedural deaths occurred. Procedure-related complications occurred in 22 of 166 procedures, including 6 peripheral embolizations, 7 thromboses, 2 hemorrhages requiring revision, 1 vessel rupture, and 6 vessel dissections. Life-table estimates of primary patency at 12, 24, and 36 months were 64%, 59%, and 59%, respectively. Thirty-two reinterventions were performed during follow-up, resulting in secondary patency rates at 12, 24, and 36 months of 74.2%, 67%, and 67%, respectively. Amputation was required in six of 41 patients treated for limb salvage. At multivariate analysis, critical limb ischemia was the only significant predictor of late failure.**
Conclusion: **Endovascular treatment of SFA occlusive lesions provides interesting results. Length of lesion and clinical symptoms influence negatively the patency. The aSpire covered stent showed good mid-term results, but a number of reinterventions were necessary to obtain an optimal secondary patency. Risk of patency failure was related to critical limb ischemia as an indication for the procedure. Technologic and pharmacologic improvement and longer follow-up are needed to define the indications for the aSpire stent. (J Vasc Surg 2007;45:32-9.)**

During the last few years, the treatment of superficial femoral artery (SFA) occlusive disease has witnessed the introduction of more aggressive endovascular therapy. However, the efficacy of femoropopliteal endovascular treatment remains controversial because of inconsistent reporting standards. Cumulative patency rates of 26% to 90% over 1 to 5 years are evidence of the wide variability of the published results owing to differences in vascular anatomy, clinical presentation, and criteria used to define success.[1-3]

Reports from the last two decades suggested that SFA angioplasty might be an adequate short-term intervention, although long-term patency was poor. Randomized trials have shown that primary stenting does not add any benefit to percutaneous transluminal angioplasty alone.[4-6] In the meantime, technology and stent design for femoropopliteal occlusive lesions have continued to change, and the possibility for treating SFA obstruction has dramatically increased. Balloon-expandable stents associated with late stent deformation and mechanical compression resulting in late clinical failure have been replaced mainly by newer self-expanding stents and stent grafts that have shown improved initial results but late mechanical fatigue and associated restenosis. The use of nickel titanium (nitinol) offered the theoretic possibility of superior patency because of its self-expandable form, continued radial force, and ability for crush recovery.

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Currently, no long-term or comparative data exist on the role of newer endovascular techniques for treating SFA obstruction, and factors that are predictive of success or failure of these interventions remain to be defined. This report outlines the experience of a registry designed to evaluate safety, effectiveness, patency, and factors influencing failure of the aSpire, a self-expanding spiral nitinol stent covered with expanded polytetrafluoroethylene (ePTFE) (Vascular Architects Inc, San Jose, Calif), in patients with femoropopliteal occlusive disease.

MATERIALS AND METHODS

The aSpire Registry is a multicenter prospective registry specifically designed to assess the applicability of aSpire stenting during a 28-month recruitment period (January 2003 to April 2005). Sixteen centers participated in the study. The database included demographic information, cardiovascular risk factors profile, clinical presentation, lesion characteristics according to the Trans-Atlantic Inter-Society Consensus classification (TASC),[7] and preprocedure and postprocedure hemodynamics, including ankle-brachial pressure index (ABI), operative, and follow-up data. Patient risk factors and comorbidities, including age, gender, smoking history, diabetes, hypertension, and end-stage renal disease, were determined according to The Society of Vascular Surgery reporting standards.[8] The primary end point of the registry was primary and secondary stent patency. Secondary end points were technical success, limb salvage, and complications occurring ≤30 days or during follow-up.

Inclusion criteria were SFA and/or above knee popliteal artery stenosis or occlusion >3 cm with vessel diameter of 5 to 10 mm, presence of critical limb ischemia (CLI) (Rutherford stages 4 to 6) or disabling intermittent claudication (Rutherford stage 3) persisting for ≥6 months after best medical treatment (including walking exercise, antiplatelet therapy, and risk factors amendment), patient compliance with treatment, and informed consent. Patients in whom revascularization included concomitant suprainguinal or distal procedures were included, but patients with an immediate need for revascularization (acute ischemia), a functionally useless limb, or crossing knee joint lesions were excluded. The study was performed according to the Declaration of Helsinki, and the registry was approved by the Review Boards of the Coordinating Center.

Device description. The aSpire covered stent is made of nitinol shaped in a double spiral and fully encapsulated with a thin layer of ePTFE, so that there is no tissue-to-metal or metal-to-blood contact. The stent is deployed through a delivery catheter consisting of two independent shafts (one within the other) that can be rotated in opposite directions to coil and uncoil the stent. When deployment is not optimal, the stent can be recoiled, repositioned, and re-expanded to precisely locate the stent. The final open spiral configuration is designed to maintain compliance, promote laminar flow, and preserve collateral vessel. For the purpose of the registry, the stent graft was available in lengths of 50, 100, and 150 mm, with diameters of 6 to 8 mm.

Preoperative and intraoperative management. Before the procedure, all patients underwent preoperative ultrasound evaluation, including ABI index measurements and color duplex examination to visualize the extension and morphology of the femoropopliteal lesion. Angiography was performed before operation or directly in the operating room during the procedure.

Routinely an anterograde puncture was used to access the common femoral artery (CFA), except in cases of severe obesity or lesions at the origin of SFA, where the approach was contralateral. In cases of diffuse lesions or severe calcifications of CFA, a surgical approach through a small groin incision under local anesthesia was used. For TASC type D lesions, a debulking technique, remote superficial femoral artery endarterectomy (RSFAE) using a ring stripper (Vollmar Dissector; Aesculap, South San Francisco, Calif; Martin Dissector, Vascular Architects Inc), and a ring strip cutter (MollRing Cutter, Vascular Architects Inc) was used.

After intraluminal catheterization with a 0.035-inch hydrophilic guidewire, insertion of a 7F or 8F introducer sheath, and performance diagnostic angiogram, intravenous heparin (100 UI/kg) was administered. After recanalization of the SFA with balloon angioplasty, the aSpire stent was deployed to cover all plaques compromising luminal diameter in the area of the target vessel and then remodeled by balloon. The balloon diameter corresponded to the proximal undiseased vessel diameter, and stent diameter was oversized ≤10%. Stent implantation was never performed in the middle or distal third of the popliteal artery. A completion angiogram concluded the procedure.

Follow-up. All patients were discharged with oral antiplatelet therapy consisting of aspirin indefinitely and clopidogrel (75 mg per day) or ticlopidine (250 mg twice daily) for at least 1 month after the procedure. Anticoagulant therapy was initiated in selected patients. Patency during follow-up was evaluated with color duplex examination, including ABI measurements when assessable, at 1, 6, 12 months, and yearly thereafter. Angiography or computed tomography angiography were performed when indicated. The follow-up period extended from February 2003 to March 2006 (mean, 13 months; range, 1 to 36 months).

Definitions. Arterial disease extension and severity were graded using the TASC score.[7] *Vessel calcification* was classified as moderate/severe (circumferential and diffuse calcifications) or mild (not circumferential, spot calcifications). *Technical success* was defined as SFA recanalization with residual stenosis <30%. Clinical success was intended as symptom improvement and healing of necrotic lesions when present. *Primary patency* was defined as a patent SFA segment without recurrent stenosis or the need for further intervention. *Secondary patency* was defined as a SFA segment with hemodynamic failure that underwent further intervention within the inflow, the treated vessel segment, or outflow of the treated vessel segment to improve or restore patency. A secondary bypass graft performed after

Table I. Demographic and clinical data

Characteristic	*N*	*%*
Male	119	71
Mean age (range)	70.4 (40-88)	
Smoking	77	46.3
Diabetes	85	51.2
Hypertension	120	72.2
Coronary disease	54	32.5
End-stage renal failure	7	4.2
Cerebrovascular disease	8	4.8

Table II. Clinical category of treated limbs and anatomic and angiographic lesion characteristics

Characteristic	*N*	*%*
Disabling claudication*	92	55.4
Critical limb ischemia†	74	44.6
Type of lesion		
Stenosis	51	30.7
Occlusions	115	69.3
Site of lesion		
Proximal SFA	51	30.7
Distal SFA/AK PA	115	69.3
Calcification		
Moderate/severe	88	53
Mild/none	78	47
Run off vessels		
1	67	40.3
2	70	42.1
3	29	17
Target lesion length, mean mm (range)	107 (30-450)	

SFA, Superficial femoral artery; *USAK PA,* above-knee popliteal artery.
*Rutherford stage 3.
†Rutherford stages 4-6.

Table III. Procedural data on 166 saphenofemoral arteries with aSpire stenting

Procedure	*N*	*%*
Surgical approach	50	30
RSFAE	18	11
Percutaneous approach	116	70
Homolateral	106	64
Contralateral	10	6
Stented artery length, mean mm (range)	116.56 (5-300)	
Fluoro time, mean min (range)	24 (7-180)	
Associated procedures	44	26.5
Inflow	15	9
CFA endarterectomies	12	
Proximal SFA angioplasty	3	
Outflow	29	17.5
Popliteal-tibial bypass	1	
Tibial trunks angioplasty	28	
Procedural time (min)		
<60	90	
60-120	47	
120-180	22	
>180	7	
Contrast media, mean mL (range)	110 (30-400)	

RSFAE, Remote superficial femoral artery *(SFA)* endarterectomy; *CFA,* common femoral artery.

permanent occlusion of the treated SFA was considered a failure that allowed for tertiary patency.

Statistical analysis. Patency rates were calculated using life-table estimates. The univariate influence of dichotomous variables on patency was determined. The χ^2 test or Fisher's exact test was used for comparisons. The influence of the 10 variables of male gender, smoking habit, hypertension, diabetes, run-off status, length of stented artery, symptoms, concurrent vascular procedures, target lesion >10 cm, and stenting at the above-knee popliteal artery affecting secondary and primary patency was tested by multivariate analysis using Cox proportional hazards regression model. Statistical analysis was performed with SPSS software (SPSS Inc, Chicago, Ill). $P \leq .05$ was considered statistically significant.

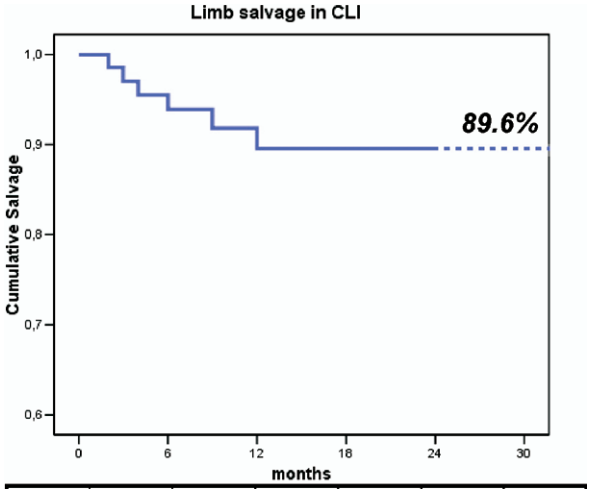
RESULTS

Patient population. The study included 150 patients for a total of 166 limbs. Mean age was 70.4 years (range, 40 to 88 years), and 119 (79.35%) were men. Demographic data, risk factors, and comorbidities are summarized in Table I. There were high rates of diabetic patients (51%) and smokers (46%). Indications for treatment are reported in Table II. Procedures were performed for claudication in 55% (n = 92), and 45% (n = 74) were for critical limb ischemia, including 20% (n = 33) for rest pain (Rutherford stage 4) and 25% (n = 41) for tissue loss (Rutherford stages 5 to 6).

Anatomy. The mean length of the artery target lesion was 107.35 mm (range, 30 to 450 mm). All treated lesions were in TASC B, C, or D groups. Specifically, there were 44 category B1 (27%), 57 category B2 (34%), 47 category C lesions (28%), and 18 category D (11%). Type of lesions, including calcification and run-off status, are reported in Table II. More than one stent was applied in 48 procedures, resulting in a total of 214 aSpire stent implants.

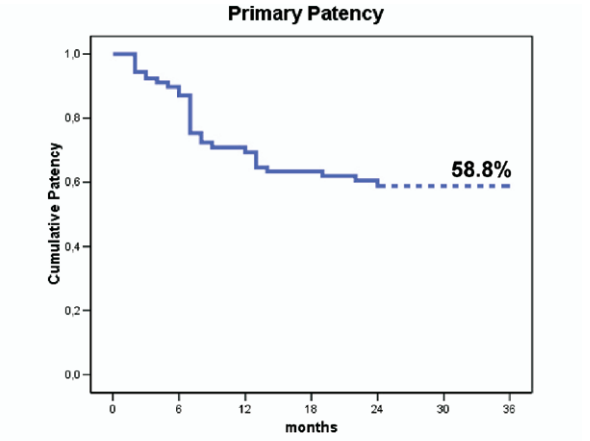
Immediate outcome. An antegrade percutaneous puncture was used in 106 procedures, and in the remaining 10 cases (6%), the access was through the contralateral femoral artery owing to the presence of lesions involving the proximal SFA or severe patient obesity. In 50 patients (29.4%), an ipsilateral surgical approach through a small groin incision was performed for severe vessel calcification or diffuse CFA disease (n = 32) or when RSFAE was required (n = 18).

Operative data are summarized in Table III. No perioperative deaths occurred. Technical and clinical success was obtained in 162 (97.6%) of 166 procedures. Procedure-related complications occurred in 22 procedures, including 6 peripheral embolizations, 2 hemorrhages requiring surgical revision, 1 vessel rupture, 6 vessel dissections, and 7 intraoperative thromboses. All complications were successfully treated at the time of the primary procedure, with preserved stent patency except for three persistent thromboses and one vessel rupture requiring surgical by-pass. One thrombosis, one vessel



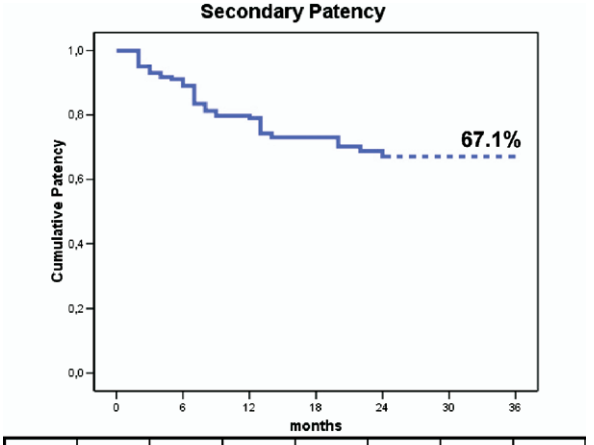
months	0	6	12	18	24	30
n°	74	58	40	18	11	1
salvage%	100	93.2	89.6	89.6	89.6	89.6

Fig 1. Limb salvage in 74 superficial femoral artery aSpire stents in patients with critical limb ischemia *(CLI)* by life-table analysis. *Dashed line* indicates SE >10%.



months	0	6	12	18	24	30	36
n°	166	129	89	45	33	2	1
Patency%	100	75.3	64.6	61.9	58.8	58.8	58.8

Fig 2. Primary patency by life-table analysis. *Dashed line* indicates SE >10%. The number of patients at risk for each interval is recorded.



months	0	6	12	18	24	30	36
n°	166	131	101	52	38	2	1
Patency%	100	83.5	74.3	73.1	67.1	67.1	67.1

Fig 3. Secondary patency by life-table analysis. *Dashed line* indicates SE >10%. The number of patients at risk for each interval is recorded.

distal embolization, one distal dissection, and one vessel perforation occurred during procedures in which RSFAE techniques were used.

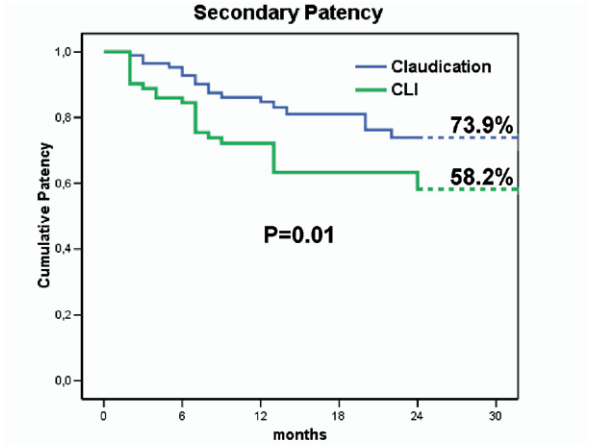
Mid-term and longer-term results. Mean follow-up was 13 months (range, 1 to 36 months). Six late deaths occurred from myocardial infarctions (n = 4), cancer (n = 1), and cerebral hemorrhage (n = 1).

During follow-up, there were 15 restenoses and 41 occlusions, of which only four occurred after the first year. In the CLI subgroup, 24 occlusions and five restenosis occurred. Overall, 32 reinterventions for revascularization were performed: 16 used catheter-based techniques and 16 were with bypass surgery.

The 41 late occlusions were managed conservatively in the case of nondisabling symptoms (n = 18), or with fibrinolysis and secondary angioplasty (n = 2), bypass surgery (n = 15), or major amputation (n = 6). All but one restenoses (14/15) were successfully treated by balloon angioplasty, the remaining were treated by bypass graft. After reangioplasty, 11 arteries remained patent during the subsequent follow-up, but three developed recurrent complete occlusion. At 36 months, amputation was required in 6 (8%) of the 74 patients treated for CLI. Actuarial limb salvage for CLI was 89.6% (Fig 1).

According to life-table estimates, primary patency rates at 12, 24, and 36 months were 64%, 59%, and 59%, respectively (Fig 2). Secondary patency rates at 12, 24, and 36 months were 74.2%, 67%, and 67%, respectively (Fig 3). Secondary cumulative patency rates were significantly different between the subgroup of patients affected by critical limb ischemia and those with claudication (58% vs 74%; $P = .001$; Fig 4).

Risk factor analysis. Results of univariate analysis to identify the association of periprocedural factors with primary and secondary patency are summarized in Table IV. None of the overall 10 variables tested with multivariate analysis was found to be a significant predictor of primary patency. The presence of CLI (hazard ratio [HR], 2; 95% confidence interval [CI], 1.067 to 3.957; $P = .03$) was the only negative predictor of secondary patency. Length of stented artery showed a trend to negatively influence both primary (HR, 1.005; 95% CI, 1 to 1.009; $P = .04$) and secondary patency (HR, 1.006; 95% CI, 1.01 to 1.011; $P = .03$).



	months	0	6	12	18	24	30
Claudication	n°	92	74	61	34	27	1
	patency%	100	90.2	83.1	81	73.9	73.9
CLI	n°	74	57	40	18	11	1
	patency%	100	75.4	63.3	63.3	58.2	58.2

Fig 4. Secondary patency by clinical category. Critical limb ischemia *(CLI)* and claudicant patients determined by life-table analysis. *Dashed line* indicates SE >10%. The difference between groups was significant ($P = 0.01$, log-rank test). The number of patients at risk for each interval is recorded.

DISCUSSION

Performance and efficacy of endovascular procedures in the treatment of SFA lesions is still controversial, and the use of stents has not given adequate answers. The reported 1-year patency rates vary between <50% and 81%[5,9,10] for femoropopliteal non-nitinol stents and from 58% to 90% with nitinol use.[11-15] Nonetheless, intimal hyperplasia causing stenosis, inadequate stent surface healing allowing thrombosis, or stent fracture, or a combination of these, are major problems. The ideal stent should provide adequate radial force to resist external compression while avoiding a dense metal skeleton that promotes luminal thrombosis. Different materials, covering surfaces, and stent configurations are suggested solutions to overcome these difficulties.

The aSpire stent has a unique design consisting of a nitinol double-spiral frame covered in a thin layer of ePTFE. The hypothesized benefits of this design are high radial force and longitudinal flexibility that allow effective placement in an area of excessive movement, such as in the femoropopliteal segment. The spiral-shaped nitinol frame was designed to ensure conformability to the vessel lumen without occluding important collaterals. The particular ePTFE covering provides enhanced luminal coverage compared with other nitinol stents.

The aSpire Registry has proven most of these supposed advantages and shown that stenting of the SFA using this new type of nitinol covered spiral stent may be performed with minimal morbidity and is associated with reasonable patency rates in TASC B, C, and D lesions. In this multicenter experience nitinol stents demonstrated 24-month primary patency and secondary patency rates of 59% and 67%, respectively. Limb salvage rates in patients with CLI were also good (89.6%), in part as a result of the spared collateral flow depending on the spiral shape of the aSpire being able to ensure viability of the limb in case of acute occlusion. Indeed, no secondary intervention was performed in 18 of our late occlusions because there was no recurrence of disabling symptoms. Only six amputations were required in patients with history of stage 5 to 6 CLI. The results of SFA stenting were, however, highly dependent on the clinical presentation; the presence of CLI was associated with lesser patency with respect to claudicant patients (58% vs 74%, respectively, $P = .01$). Multivariate analysis confirmed CLI as the only significant factor affecting secondary patency (HR, 2; 95% CI, 1.067 to 3.957; $P = .03$).

Our data indicate the presence of CLI might signal caution when challenging SFA stenting procedures are attempted. On the other hand, it is well known that lower extremity ischemia is a marker for cardiovascular mortality, and treatment is associated with substantial morbidity, mortality, and expenditure of health care resources. Although bypass grafting with 5-year limb salvage rates of >80% is still considered by most vascular surgeons the gold standard of treatment for most infrainguinal lesions, systemic and local complications may occur in up to 25% of patients, and the associated morbidity may compromise functional outcomes, as 50% of patients report a return to normal functional status by 6 months.[16-19] In this regard, the good limb salvage rate for patient with CLI and tissue loss may let us consider the aSpire stent as an option for patients with CLI at high surgical risk, even if patency rates may be reduced during time.

Despite material characteristics that were suggested to play a role in maintaining patency in femoropopliteal lesions, the aSpire Registry showed that a number of catheter-based secondary procedures (n = 16) were needed to preserve good secondary patency during follow-up. However, 14 of the 15 restenoses that caused failure were amenable to additional percutaneous interventions, with minimal morbidity and durable results: 78% were still patent at 36 months.

Although failure after stenting may be related to progression of disease in the inflow and outflow vessels,[1] our data support the hypothesis that intimal hyperplasia is still a problem affecting mid-term results of nitinol stent for long SFA obstruction (>10 cm). Indeed, most of our failures occurred within the period of intimal hyperplasia response (52/56 ≤12 months, Figs 2 and 3). In any case, the number of failures after the first year was relatively low, suggesting a protective role of the stent favoring the healing of the treated segment. In fact, the cumulative secondary patency rate of 67% at 24 months is good if we consider the frequency of CLI, the multilevel occlusive vascular disease, the mean length of lesion, and TASC C and D prevalence. Larger studies with longer follow-up are needed to confirm the hypothesized long-term advantage of the aSpire stent.

Table IV. Univariate analysis of factors associated with primary and secondary patency

	Primary patency			*Secondary patency*		
	Yes (n = 110) n (%)	*No (n = 56) n (%)*	P	*Yes (n = 126) n (%)*	*No (n = 40) n (%)*	P
Male gender	80 (72)	39 (70)	1	90 (71)	29 (72)	1
Smoking habit	49 (44)	28 (50)	0.4	54 (43)	23 (57)	0.2
Hypertension	85 (77)	35 (62)	0.1	94 (75)	26 (65)	0.1
Diabetes	57 (51)	28 (50)	1	62 (49)	23 (57)	0.48
Run-off status*	46 (41)	21 (37)	0.87	51 (40)	16 (40)	1
End-stage renal disease	3 (2.7)	4 (7)	0.22	5 (4)	2 (5)	1
Moderate/severe calcification	61 (55)	27 (48)	0.62	68 (54)	20 (50)	0.59
CLI	45 (41)	29 (52)	0.24	50 (40)	24 (60)	0.047
AK popliteal site of lesion	76 (69)	40 (71)	0.47	86 (68)	30 (75)	0.7
Inflow/outflow procedures	39 (35)	16 (28)	0.6	43 (34)	12 (30)	0.57
Length of target lesion (>10 cm)	46 (42)	23 (41)	0.87	52 (41)	17 (42)	1

CLI, Critical limb ischemia; *AK,* above-knee.
*Run-off status: <2 run-off vessels.

The pattern of 56 late failures differed according to the severity of preoperative symptoms. Occlusion rates were found about twofold more frequently in the subgroup of 74 patients with CLI with respect to the 92 with claudication (18% vs 32%), while the reverse occurred for restenosis rates (11% vs 6.7%, respectively). Although there were no significant differences in primary patency rates between patients with claudication and CLI, secondary patency rates were significantly better for those with claudication (Fig 4). It could be hypothesized that most of the failures occurring in the claudicant patients may be caused by intimal hyperplasia leading to restenosis without occlusion that is easily and successfully manageable with redo treatment. On the other hand, patients with CLI presented with unviable occlusions (24 of 29 overall failures in this group), likely due to more aggressive, extensive vascular disease and the coexistence of multiple adverse factors such as poor run-off status, diabetes, and others.

In this regard, multiple factors have been shown to adversely affect patency rates of the treated artery, such as type (stenosis vs occlusion) and length of target lesion, distal runoff, and presence of diabetes or end-stage renal disease.[19-22] In the present study, regression analysis showed that above-knee involvement, target lesion length, and run-off status did not predict stent failure in SFA, although the total number of limbs treated per category was quite small. The same applies for diabetic and end-stage renal patients. Given our study population of 85 diabetic and seven end-stage renal patients, it is possible that such a conclusion may represent a type II error. Larger studies will likely allow firmer conclusions about the appropriateness of treating these lesions in patients as first-line endoluminal treatment.

The length of the stented artery more than the target lesion showed a tendency to negatively influence patency in the aSpire Registry, although the HR close to 1 at the multivariate analysis did not allow a relevant association (HR, 1.006; 95% CI, 1.001 to 1.011; $P = .03$). The length of the covered artery is probably a marker of technical difficulties and procedure complexity, because arterial dissection or rupture or unexpected lesions require longer stent coverage. Indeed, when we observe our patency curves (Figs 2 and 3), most of the failures occurred early, within the first 12 months, reflecting that in addition to intimal hyperplasia, a potential adjunctive negative effect on the outcome might be the consequence of a procedural challenging technique.

Optimal ballooning predilation more than postdilation is a key factor to obtain good technical success. Poor predilation may cause under-expansion of the stent and residual stenosis. Conversely, excessive ballooning after deployment may be dangerous, because this leads to arterial trauma, promotes intimal hyperplasia, and perhaps, favors stent restenosis. Postdilation limited in pressure and located within the confines of the stent to allow a controlled dissection plane is recommended. Similarly, unnecessary stent diameter oversizing (>10%) is to be avoided.

Perhaps a partial or complete debulking of the native vessel by removal of the atherosclerotic core rather than reshaping the lumen of a long arterial occlusion by angioplasty/stenting may reduce the restenosis coming from intimal hyperplasia. The hypothesis of complete SFA debulking in a remote SFA endarterectomy technique is appealing although not yet supported by convincing data.[23-26] Rosenthal et al[23] and Knight et al,[24] using remote endarterectomy with an aSpire stent in long SFA occlusions, reported an assisted primary patency rate of 88.6% at 18 months. More recently, Martin et al[25] reported primary patency rates of 70% and limb salvage rates of 94% at 30 months for >105 SFA remote endarterectomies. Similar better mid-term outcome was confirmed in our limited subgroup of 18 procedures where RSFAE technique was employed: primary patency was 67% at a mean follow-up of 9 months (range, 6 to 12 months). With a larger experience, a decrease in complication rates with this demanding procedure is to be expected.

Newer competitive treatment strategies combined with pharmacologic means of preventing the intimal hyperplas-

tic response have been suggested and are under study to improve the durability of endovascular treatment for long femoropopliteal lesions. Drug-eluting stents and cryoplasty have been introduced, but there is no evidence of clear benefit, as no comparative studies or long-term data are available. The final results of the cryovascular safety registry reported a primary patency rate of 82% in 102 patients at 10 months.[27] Duda et al[28] performed a randomized trial comparing the use of sirolimus-eluting shape-memory alloy recoverable technology (SMART) nitinol stents vs uncoated SMART nitinol stents in 36 patients with CLI and femoral artery stenosis or occlusion. At 6 months, the in-stent mean lumen diameter was 4.31 mm in the uncoated stent group vs 4.95 mm in the sirolimus group. No significant differences in patency or limb salvage were found in this study.[28,29]

Other techniques, such as subintimal angioplasty and excimer laser, that may ultimately be good alternative techniques to stents in long SFA occlusion (TASC C and D) are all still providing conflicting or disappointing results.[30-33]

Study limitations. This report does not address the assessment of patient satisfaction or the comparative application of surgical bypass grafting vs stenting. Stenting was used when anatomically feasible. However, studies on patients after surgery have shown up to 20% patients are dissatisfied with surgical outcome, even with an improved and normal postoperative ABI.[34,35]

Another limitation of this study is the limited number of patients who achieved the longest follow-up. Since the longer the follow-up, the greater the number of SFA stent failures there might be, aSpire patency rates could deteriorate when a larger number of stented patients are observed for a longer interval. Further studies are needed to confirm the good surface healing endorsed by aSpire stenting in a period >36 months.

Cost assessment was not a focal point of this analysis.

With the present report we could not assess true efficacy of aSpire stenting in SFA obstructive disease, as only randomized studies can ascertain, but we would like to provide an image of the common drawbacks and advantages in the use of this type of stent. The availability of the registry helped to obtain information from different centers and different patient populations, increasing the generalization of the results.

CONCLUSIONS

The decision to proceed with angioplasty and stenting to treat SFA occlusion, particularly for TASC C and D lesions, is challenging. Reasons usually include the preference of the patient or physician for minimally invasive treatment, the fact that surgery can usually proceed after the failure of endoluminal intervention, short-term tissue healing goals, patients at too high risk for open surgical procedure, or infection at the proposed surgical site. Quality-of-life issues need to be taken into account when treatment options are discussed with patients. This study suggests that SFA aSpire stenting is a reasonable and safe procedure with good patency and limb salvage rates. Clinical presentation may negatively affect the outcome, 24 months secondary patency rates being worse for patients with CLI: 58% vs 74% for claudication. However, limb salvage may be ensured in up to 90% of patients with CLI. Technologic and pharmacologic improvement, together with longer follow-up, are needed to define the indications for the aSpire stent.

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