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Superficial Femoral Artery Recanalization with Self-expanding Nitinol Stents: Long-term Follow-up Results

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Purpose. *Since long-term patency and device integrity of nitinol stents in SFA lesions are not well studied, we examined clinical outcome, patency and device integrity after stenting long lesions using a standardized implantation technique.*
Methods. *Between 2001 and 2006, 59 patients (74 lesions) were treated with the same nitinol self-expandable stent (Zilver, Cook, USA) and technique for SFA recanalization. Clinical charts and imaging were retrospectively reviewed for patency (primary and assisted-primary), and device integrity.*
Results. *Patients were 74.5 (10.9) years old (range 49 to 93), 64% male, 42% diabetic, 62% hypertensive and 67% current or former smokers. Lesions were 23% TASC B, 16% TASC C, or 61% TASC D. Mean recanalization length was 19 cm (range 3 to 53). Mean number of stents per patient was 2.8 (total 210). Mean follow-up time was 2.4 years (range 3 days to 4.8 years). Kaplan-Meier estimates for primary patency rates were 90%, 78%, 74%, 69%, and 69% at 1, 2, 3, 4 and 4.8 years, respectively. Ten restenoses at a mean of 500 (388) days (1–1251 days) were successfully recanalized. The assisted primary patency rates were 96%, 90%, 90%, 90% and 90% at 1, 2, 3, 4 and 5 years, respectively. Six complete occlusions could not be reverted by a second recanalization procedure, and were treated by surgical bypass (1 case), amputation (3 cases), or medical management (2 cases). One (1.04%) Class II stent fracture was noted.*
Conclusions. *SFA recanalization with a standardized implantation technique and nitinol stents provides good long-term primary and assisted-primary patency.*

Keywords: Superficial femoral artery; Lower limb revascularization; Atherosclerosis; Recanalization; Nitinol stent; Peripheral vascular disease; Intermittent claudication.

Introduction

Lower limb ischemia due to atherosclerotic disease remains a pressing clinical problem without optimal treatment. Bypass surgery is accepted as definitive, but morbidity and re-hospitalization rates can be significant, with re-operative rates nearing 50%.[1] Endovascular treatment of lower limb ischemia with unassisted balloon angioplasty has shown a disappointing patency rate of 61%, 51% and 48% at 1, 3 and 5 years, respectively.[2]

Based upon the improved outcomes in coronary lesions,[3,4] use of stents in treating lower limb lesions has increased.[5,6] However, the clinical outcomes have been disappointing in early SFA trials.[7–9] Several factors may influence the outcome of angioplasty and stenting for lower limb ischemia such as clot formation, intimal hyperplasia, negative remodeling, recoil, stent fracture and implantation technique. Technique variability and device-related problems such as hyperplasia and stent fracture have been associated with restenosis.[10] Consequently, prior studies have not adequately demonstrated that a combination of consistent technique and use of a reliable stent can together provide definitive long-term patency.

The stent designs used in the SFA have varied substantially, including stainless steel balloon-expanded and nitinol self-expanding stents, covered stents, drug-eluting stents, and biodegradable stents. Patency with stainless steel, balloon-expanded stents was reported at 54% to 80% at 1 year, and 28% at 3 years.[11–13] With nitinol, self-expanding stents, patency was reported to be 75% to 93% at 1 year

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and 73% to 76% at 3 years.[11,12,14,15] Treating vessel rupture, stenosis and occlusion with a covered stent, patency was reported to be 78% at 1 year and 74% to 87% at 2 years;[16,17] however, branch vessels are often lost when covered. Treating long, calcified occlusions or diffuse tandem lesions with subintimal angioplasty, patency was reported to be 51% at 6 months.[18] Drug-eluting and biodegradable stents remain under investigation.

These prior studies suggest that nitinol stents provide the most promising clinical outcomes, at least in the short-term. The results, however, vary widely suggesting that differences between nitinol stents may be important to clinical outcome.[4,10,12] These prior studies raise questions about the optimal stent design and the importance of implantation technique. While some report good short-term results, others report disappointing results.[12,19,20] Based upon one stent design, Greenberg *et al*.[21] suggested that stenting only increases the cost and not the long-term patency. However, most of the data are short-term. Few studies provide results with outcome beyond three years so the long term results are not well understood; studies with at least five-year results are needed.

To address this dilemma, we performed a systematic retrospective medical chart and imaging review of patients with lower limb ischemia treated with balloon angioplasty and self-expanding nitinol stents in femoropopliteal arteries. In treating these patients, a standardized, consistent technique for implantation was used and we explored the effect of technique. One specific stent design was used, and we explored the integrity of stents implanted in the femoropopliteal arteries including above, behind and below the knee through X-ray imaging to look for strut fractures in available patients. Follow-up extended up to the fifth year.

Methods

We performed a retrospective review of medical charts and imaging for patients treated between 2001 and 2005, to obtain patency rates of the stented femoropopliteal arterial segment and device integrity. Since 2001, it has been our practice to indicate primary angioplasty with stenting to all patients with Rutherford category 2 and above, and no patients have been referred to primary surgery. During this period, 59 consecutive patients (74 limbs, 210 stents) met the inclusion criteria for this retrospective analysis. Patient selection was based upon the following criteria: 1) the treated lesion was within the femoropopliteal artery, including the retropatelar region, 2) included patients received only the same model of stents (Zilver, COOK, USA), to exclude a possible influence from the different fracture, restenosis and occlusion rates from the different available stent models, 3) included patients had incapacitating claudication (Rutherford category 2 and above), not responsive to medical therapy for at least 6 months.

During the past five years, we have treated 121 patients that met the clinical criteria; however, most of these patients had different stent models within the same vessel, sometimes overlapping. This occurred mainly in those patients treated within the early years. We observed that the results were influenced by this, and justified selecting only those patients with one single model of stent. The selected model was the one we used most frequently, for two main reasons: 1) it is widely available and has good cost-effectiveness. This is crucial as the stents were paid by private medical insurance companies, and 2) we observed apparently good results with the selected model during the years of practice.

The diagnosis of obstructive arterial disease was confirmed largely by clinical history and duplex ultrasound examinations, performed pre-operatively. Diagnostic angiography was not considered necessary before the treatment procedure if the duplex ultrasound examination was adequate.

Because outcome is dependent upon technique, we adopted a standardized technique for recanalization of the femoropopliteal artery. The standardized technique is summarized in Table 1. Briefly, a contralateral approach to femoral access was chosen to isolate potential access complications, such as thrombotic occlusion or debris related to the percutaneous closure devices, from affecting the treated artery. Moreover, contralateral access allowed treatment of dissections or stenotic lesions proximal to the intended treatment site that are unappreciated pre-procedure. A hydrophilic wire guide and mammary catheter were advanced to reach the femoral bifurcation on the contralateral side. After exchanging the wire guide to a stiff wire guide, a long and flexible sheath was gently advanced into the common iliac as a workstation platform. This was important to provide support for advancement through the stenotic, and more importantly the occluded vessels. After wire exchange to a short tip hydrophilic wire, a mammary (or vertebral) catheter was advanced through the stenosed or obstructed femoropopliteal artery until the true lumen of the distal popliteal artery was reached. In several cases, but not all cases, the wire and catheter became subintimal and the wire guide was rotated to re-enter the true lumen at least by the end of the lesion. After exchanging to a stiff wire guide,

Table 1. Standardized Recanalization Technique

SFA Recanalization Technique

1 Via contralateral retrograde femoral access, advance a 100 cm mammary beacon tip catheter (HNBR, COOK) over a hydrophilic wire guide (0.035 × 260 Road Runner, COOK, USA) to the femoral bifurcation proximal to the lesion.
2 Exchange the wire guide to a stiff wire (0.035 × 260 Amplatz Stiff Wire Guide, COOK, USA) and sheath to a 70 cm long 6F sheath (6F × 55, 70, or 90 Flexor Raabe Sheath, COOK, USA), and gently advance the sheath over the wire to the common femoral artery.
3 Exchange the wire to a short taper hydrophilic wire guide (.035 × 260 Roadrunner RPC, COOK, USA), and exchange the dilator for the mammary catheter and gently advance the mammary catheter and wire into the obstructed SFA, until the true lumen of the distal popliteal artery is reached, sometimes but not always passing through a sub-intimal path.
4 Exchange the wire guide to the stiff wire, and advance the sheath into the SFA.
5 Exchange the mammary catheter for a 4 mm × 10 cm or 6 mm × 10 cm balloon (Pursuit Balloon Catheter, COOK, USA), advance the balloon catheter to the lesion and inflate to 8 atm for 3 minutes. For lesions longer than the balloon, inflations were repeated as necessary.
6 Over the same wire guide, the entire length of the dilated segment of the artery is then covered with self-expanding nitinol stents (Zilver, COOK, USA). If multiple stents are required to cover the dilated segment, overlap stents by at least 5 to 10 mm.
7 After an angiographic control, as necessary, the stent is post-dilated within its margins with a new balloon.
8 A percutaneous closure device is used to close the contralateral femoral artery.
9 During follow-up, patients are treated with acetyl salicylic acid, 300 mg per day, continuously, and 75 mg daily clopidogrel, for at least six months, to prevent clot formation.
10 A control duplex ultrasound exam is performed before hospital discharge and every six months.

a 6 mm × 10 cm balloon catheter (or a 4 mm × 10 cm in a small diameter popliteal), was advanced into the lesion and the vessel was pre-dilated at 8 to 10 atmospheres for 3 minutes. Following initial balloon angioplasty, self-expanding nitinol stents (Zilver, COOK, USA) were implanted to cover the entire dilated segment. The stents were submitted to a post-dilatation. When more than one stent was needed to cover the lesion, the most distal stents were placed first and adjacent stents were overlapped by 10 mm to avoid interstent focal stenosis due to unstented vessel recoil, flow disturbance or stent misalignment. Final angiograms were taken after wire guide removal to document patency. After the procedure, patients were treated with aspirin (300 mg QD) indefinitely, and clopidogrel (75 mg QD) for at least six months, to prevent clot formation.

During follow-up, patients were assessed for clinical outcome, image-based patency and stent integrity. The diagnosis of obstructive arterial disease post-operatively was confirmed largely by duplex ultrasound examination, performed at 6 month intervals after recanalization or at the presentation of post-operative symptoms. When the duplex ultrasound exam indicated restenosis of >50% or occlusion, a second recanalization procedure using angioplasty was considered when a 50% or higher stenosis was evident on the angiogram. If the second recanalization was successful, the result was considered an assisted-primary patency, but not a primary patency.

Standard X-ray flat films were not sufficient in most cases for detailed examination of the stent struts for evaluating device integrity. Therefore, available patients underwent additional good resolution X-rays adjusted to specifically highlight stent structure. All efforts were made to obtain unobstructed images free of bone artifact of each implanted stent. However, at the time of this retrospective analysis no X-rays were available for 11 patients (41 stents) that had died prior to having a good resolution X-ray, and for 21 patients (59 stents) that did not return for an X-ray either because the patient chose not to or was unable to return, or our staff was unable to contact the patient in sufficient time to be included within this analysis, or the patient was lost to follow-up. Additionally, eight of the 27 patients with good resolution X-rays had at least one stent that was unable to be assessed. Of these eight patients, 14 stents could not be assessed because: 9 stents had a complete overlap within another stent; 3 stent X-rays were disqualified because of bone artifact and poor resolution, one stent was superimposed over bone on the X-ray, and one stent X-ray was of poor resolution. All of these factors prevent proper strut by strut analysis; however, all available X-rays were assessed for type IV fracture. Each evaluable image was examined for broken struts.

All patients treated in our practice for lower limb ischemia were screened for the inclusion criteria and patients meeting the criteria were identified. The clinical outcome, imaging and device integrity data were obtained from a retrospective review of clinical charts and images. The data were maintained in a de-identified database. With the de-identification of retrospective chart data, individual informed consent was not required.

Statistical analysis

Continuous data were provided as mean and standard deviation (in parenthesis). Dicotomous variables were listed in percent. Survival and patency rates (primary and assisted primary) are presented as plots of Kaplan-Meier estimates. All statistical analyses were performed using SAS (version 8.2).

Results

Patient demographics showed that 64% were male, 42% were diabetic, 62% had hypertension and 67%

were current or former smokers (Table 2). The mean age was 74.5 (10.9) years and the range was 49 years to 93 years. By Rutherford classification, the 59 patients were 22% Category 2, 63% Category 3, and 15% Category 4 or greater. There were 74 lesions [mean length = 19.2 cm (10.8 cm)] with a range of 3 to 53. Lesion classification was notably higher than in other studies with nearly 80% of patients having at least one class C or D lesion, and by lesion (limb) 23% were TASC B, 16% were TASC C, and 61% were TASC D. All patients selected received only one kind of stent (Zilver, COOK, USA), and patients with different stent models in the same vessel were excluded. A total of 210 Zilver stents was used in the 59 selected patients (74 limbs). The mean number of stents implanted per lesion was 2.8 (1.6) stents (range, 1 to 8 stents).

The implant results demonstrated successful recanalization for all treated lesions (100% technical success), although 2 cases required retrograde access from the popliteal artery under duplex scan guidance. There were no failures to access the lesion, deploy the stents, or achieve patency at the end of the procedure. However, extension or compression of cells of the stent during deployment was noted under detailed examination for some patients and felt to be associated with movement of the delivery system handle during retraction of the outer sheath to release the stent.

Table 2. Baseline Patient Characteristics

Characteristic	
Age (years)	
Mean ± S.D.	74.5 ± 10.9
Range	(49–93)
Gender (% male)	64.4
Rutherford Category	
1	0.0%
2	22.0%
3	62.7%
4	5.1%
5	6.9%
6	3.4%
Claudication (%)	97.8
Hypertension (%)	62.3
Hypercholesterolemia (%)	38.5
Diabetes Mellitus (%)	41.5
MI (%)	36.0
CHF (%)	36.0
Carotid Disease (%)	21.2
Renal Disease (%)	20.8
Pulmonary Disease (%)	19.2
Smoking Status (%)	
Current	11.5
Quit	55.8
Never	23.1
Unknown	9.6

The mean follow-up time was 29 (16) months (range 3 days to 58 months), and 58% of patients were followed for more than 2 years. The survival rates were 90%, 86%, 80%, 72%, and 64% at 1, 2, 3, 4 and 4.8 years, respectively (Fig. 1). Thirteen patients died after treatment. Three patients died within 30 days after surgery due to sudden death, pneumonia with multiple organ failure, and MI during dialysis for pre-existing renal insufficiency. Of the other 10 cases of death, 3 died within 31–180 days, none died within 6 months to 1 year, 2 died within 1 to 2 years, 2 died within 2 to 3 years, 2 died within 3 to 4 years, and 1 died within 4 to 4.8 years. Of the 13 patients, 11 patients maintained primary patency or assisted-primary patency in the last follow-up exam before death. However, one of the 11 patients died one day after the secondary procedure to maintain patency. Of the two patients that died without limb patency, one patient required amputation (died 1-month post-amputation) and one patient required bypass (died >2 years post-bypass).

During follow-up, there were 16 cases of restenosis (10 cases) or complete occlusion (6 cases). Of these 16 cases, 2 occurred within 30 days, 4 within 31–180 days, 1 within 6 months to 1 year, 5 within 1 to 2 years, 2 within 2 to 3 years and 1 within 3 to 4 years. There was one case of acute occlusion, occurring on post-operative day 2 (amputation was required). The primary patency rates were 90%, 78%, 74%, 69% and 69% at 1, 2, 3, 4 and 4.8 years, respectively (Fig. 2). There have been no reports of loss of patency beyond 4 years of follow-up. The assisted-primary patency rates were 96%, 90%, 90%, 90% and 90% at 1, 2, 3, 4 and 4.8 years, respectively (Fig. 3). Treatment failure, represented by an occlusion not treatable with an

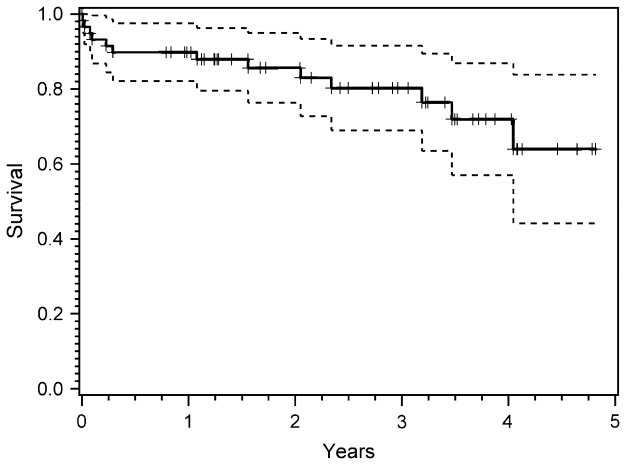

Fig. 1. Freedom from Death – 13 patients died during the time of the study.

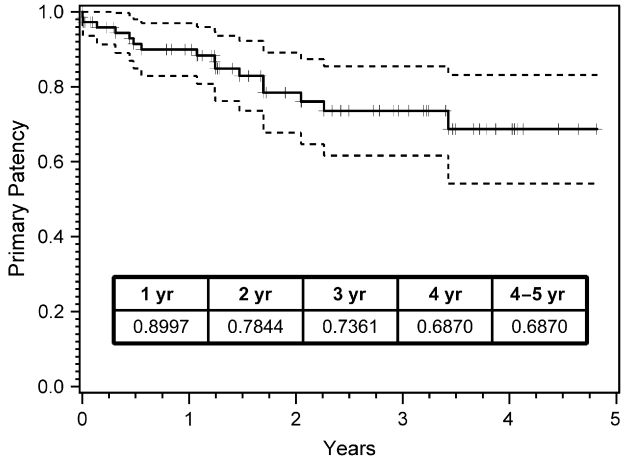

Fig. 2. Cumulative Primary Patency rates.

endovascular procedure, occurred in 6 patients (8.1% of limbs). These failures occurred at 2, 50, 161, 392, 454 and 537 days post-implant.

Each evaluable image was examined for abnormal stent deployment, broken struts and complete transsectional fracture. Of 96 stents with good resolution X-ray films, abnormal stent deployment was noted in 4 stents, and Class II (multiple single struts at different locations) fracture was noted in 1 stent (1%) (Fig. 4). No Class I (single strut), Class III (multiple strut fractures resulting in complete transaction of the stent) or Class IV (complete transaction of the stent and the two pieces of the stent separate from one another or spiral fracture) fractures were observed. Regarding only Class IV, 110 stents could be evaluated and none presented this type of fracture.

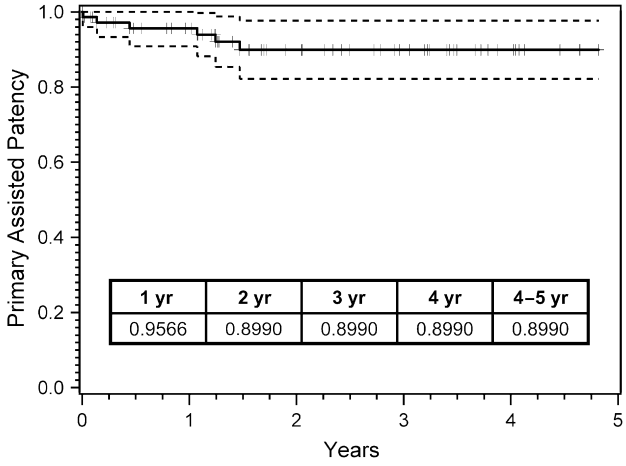

Fig. 3. Cumulative Assisted-Primary Patency rates.

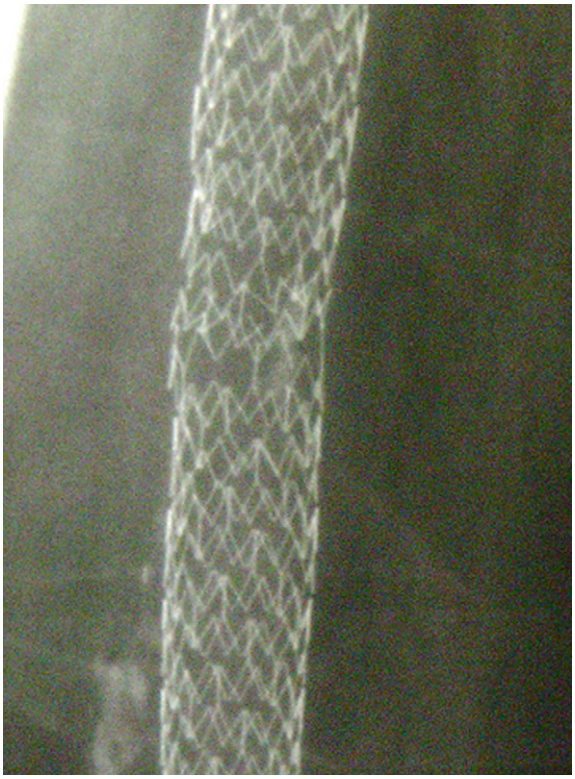

Fig. 4. Class II stent fracture – Multiple single struts at different locations.

Discussion

Our results corroborate growing literature suggesting that stenting of the femoropopliteal arterial segment can be safe and effective if the stent design and implantation techniques are appropriate.[10–13,15,16] In our opinion, the stent design in this study apparently did not exhibit a propensity for stent fracture and the details of the implantation technique were found to be important to longer term treatment success.

Our study confirmed that the stent design and treatment strategies must be adapted to the femoropopliteal arterial segment, such as the need for longer stents. While it seems reasonable to expect coronary-like results also in the femoropopliteal arterial segment, the femoropopliteal arterial segment lesion present a more complex situation. It is now widely accepted that the femoropopliteal arterial segment lesions are longer and subject to more stretching, twisting, bending and compression.[22] The extensive plaque is often intermittently calcified presenting the risk of further plaque rupture after intervention. Restenosis, occlusion and fracture rates have been directly related to mechanical factors such as material and design of stents, as well as its physical characteristics, markedly its radial force and flexibility.[22] The

stent implanted in all patients in this series has a specific design with strong radial force, flexibility and appropriate intra-strut spacing, probably responsible for a share of the good technical results. Appropriate intra-strut spacing provides spacing close enough to support vessel plaque flaps reducing restenosis but open enough to allow blood flow through small branch arteries, as seen in the control intra-operative angiography.

Early trials of nitinol stents in the femoropopliteal arterial segment reported stent fracture in 32% of limbs treated with the nitinol stents.[10] Patency at 12 months was reduced from 84.3% to 41.1% in lesions with fractured stents.[10] While the direct relationship between stent fracture and patency remains controversial, we did not experience the high fracture rate and the 12-month patency rate was excellent at 90% even with near 80% TASC C and D lesions.

Schlager *et al*.[12] evaluated restenosis, clinical deterioration and fracture rates between Wallstents (Boston Scientific, USA) and two different nitinol self-expandable stents, the SMART (Cordis, USA) and the Dynalink/Absolute (Guidant, USA). For patency and clinical deterioration, results were favorable for nitinol stents compared to the Wallstent. However, regarding stent fracture, the SMART stent fracture rate of 28% was significantly higher than the 2% rate for Dynalink/Absolute and fracture of the SMART stent was associated with restenosis. Comparing the Schlager *et al*.[12] study with our series, patients in the Schlager *et al*.[12] study were younger (67 vs. 74 years) and had a shorter mean lesion length (10 cm vs. 19 cm), yet the patency rates at 3 years were 47% and 51% for SMART and Dynalink, respectively, versus 74% in our series using Zilver stents.

Schillinger *et al*.[20] reported a 2% fracture at 1 year in a nitinol stent (Dynalink) used in the femoropopliteal artery. Our results also indicate that a nitinol stent (Zilver) can be implanted in the femoropopliteal arterial segment without high fracture rates up to 4.8 years. Not all stents in our series had a good resolution stent X-ray for evaluation, and we recognize this as a limitation of the study. However, all patients were evaluated for clinical outcome. Thus, if stent fracture is somehow related to patency the good clinical outcome in our series provides further support for a low fracture rate.

Previous studies showed angioplasty success rates in the SFA around 40% of patients remaining asymptomatic after four years, and yet keeping the possibility of an endovascular re-intervention in about 50% of the patients with primary failure.[2] Predictors of immediate failure were found to be advanced age and final angioplasty quality, represented by residual stenosis or dissection. Final angioplasty quality was also a significant factor in long-term restenosis and occlusion.[2,23]

In our series, final angiographic quality was considered very important and efforts to optimize final angiographic results included angioplasty and stent coverage of the complete lesion including coverage of areas with threatening, but not tightly stenosed plaque such as the vessel segment between two serial stenoses. This resulted in longer recanalization lengths, post-stent dilatation within the stent for optimal expansion, and the use of more nitinol self-expandable stents. We believe that the selective use of stents only in residual stenoses remaining after angioplasty allows vessel recoil between stents reducing long-term patency. Although it is recognized that the use of more stents will increase the procedure cost, however, the cost of stents is decreasing, the hospital stay is shorter than open bypass surgery, and improved clinical outcome should reduce the re-intervention rates, offsetting the cost.

The experience in treating SFA by conventional surgery has taught us that atherosclerotic plaques are actually longer than the length localized by angiography. It is well known that serial lesions have higher restenosis rates. Therefore, long recanalization with stents avoids a potential fracture in the plaques and the related inflammatory reaction between adjacent stenotic segments.

Monitoring patency is also important. Clinical follow-up and duplex ultrasound exams were performed at six month intervals to identify restenosis and we re-intervened when indicated to optimize patency often before the patient became symptomatic or the vessel became totally occluded which would make the re-intervention more difficult. Consequently, the assisted-primary patency rates (endovascular re-intervention, but not open surgical bypass) were excellent out to near five years. Anti-platelet and anti-coagulants are also invaluable for maintaining patency, and therefore, methods to improve patient compliance are valuable.

Our experience with the SFA recanalization technique was very satisfactory, with long-term patency rates similar to those we achieved in our experience with femoropopliteal bypasses, without some undesirable complications seen with conventional surgery, such as infection of operative site or skin necrosis. In a few cases with complications, retrospectively, improved patient selection may have reduced the number of patients requiring amputation.

The TASC consensus recommendation that angioplasty is first choice for Classes A and B, but not for Class C and D lesions could be challenged by the

good results in Class C and D lesions in our series.[2] The percent of patients with at least one TASC C or D lesion comprised nearly 80% of our cohort. In the cases included in this study, the same technique was used independent of the TASC lesion classification. The only exception may be that the TASC C and D lesions required longer recanalization and more stents.

While skepticism around the SFA angioplasty still exists, continued improvements in endovascular devices and techniques may yield results similar to open bypass surgery without the morbidity. Our own daily experience has shown invaluable benefits and satisfaction to our patients, a reason why it has become our first choice for the treatment of inferior limb obstructive disease. We consider the SFA recanalization technique a safe and efficient treatment for inferior limb obstructive disease.

In summary, this study demonstrates the safety and effectiveness of stenting in the femoropopliteal arterial segment when nitinol self-expanding stent, a standardized implantation technique and periodic clinical follow-up are utilized. To corroborate these findings or compare these findings against other therapies or devices, a larger randomized clinical study is recommended.

Conflicts of interest

Marcelo Ferreira is a paid consultant for COOK Latin America.

Lori Nolte, PhD and Neal Fearnot, PhD are employees of MED Institute.

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