# Evaluation of long superficial femoral artery stenting in a critically ischemic limb Osama Ismail

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#### Aim

The aim of the study was to evaluate 1-year efficacy and integrity of long stents implanted in the superficial femoral artery (SFA) in a critically ischemic limb.

## Patients and methods

A prospective study was carried out between July 2012 and September 2014 on 25 patients (19 men and six women, mean age 58 years, range 52–65 years) suffering from critical limb ischemia (Rutherford classification 4 or 5) caused by a long SFA lesion who underwent stenting of the targeted segment at the 6th October Insurance Hospital (Dokki, Cairo, Egypt). Patients were scheduled to receive a single stent and were evaluated for 1 year. An overall 60% (15 patients) had occluded segments and 40% (10 patients) had multiple stenotic lesions. Thirteen (52%) patients had three-vessel distal run-off to the foot, seven (28%) patients had two-vessel, and five (20%) patients had single-vessel run-off. The mean lesion length was 13 cm (range 12–18 cm).

#### Results

Twenty-five stents were implanted in 25 patients. Technical success was achieved in all patients. Primary patency was achieved in 17 (68%) patients, whereas restenosis occurred in eight (32%) cases. Of these eight cases, four patients were treated with angioplasty, one patient was treated with a femoropopliteal bypass, two cases were treated medically, and the last patient developed extensive necrotizing fasciitis that ended in limb amputation.

#### Conclusion

Management of long SFA lesions with a nitinol stent is effective and safe in patients with critical limb ischemia as there is still the opportunity to receive bypass surgery or endovascular reinterventions.

#### Keywords:

critically ischemic limb, evaluation, long, stenting, superficial femoral artery

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# Introduction

The superficial femoral artery (SFA) and the proximal popliteal artery are the most common diseased segments, being involved in more than 50% of cases of peripheral arterial disease [1]. Trans-Atlantic Inter-Society Consensus (TASC II) identified endovascular treatment as the preferred method for multiple lesions (stenoses or occlusions) measuring 5 cm or less and for single stenoses/ occlusions less than or equal to 15 cm not involving the popliteal artery. There is evidence that longer lesions with a mean length of 10 cm treated with stents show improved 12-month freedom from restenosis compared with percutaneous transluminal angioplasty (PTA) [2]. Nitinol self-expanding stents seem to be a good choice for older patients with long SFA occlusions, with acceptable short and midterm results [3]. Soga et al. [4] reported the clinical efficacy of nitinol stents in long femoropopliteal lesions. PTA and stenting of SFA become challenging as restenosis is the main drawback, especially in long lesions [5]. Many studies have supported the effectiveness of angioplasty in the treatment of patients with critical limb ischemia (CLI), with lower morbidity and acceptable results, compared with surgical bypass [6]. Scali *et al.* [7] had reported that critically ischemic limb and renal insufficiency were predictors of failure for any intervention, whether bypass or angioplasty, whereas claudication was considered a predictor of success for SFA stenting.

## Patients and methods

This prospective study was carried out from July 2012 to September 2014 on 25 patients (19 men and six women, mean age 58 years, range 52–65 years) at the 6th October Insurance Hospital (Dokki, Cairo, Egypt). The inclusion criteria for this study were as follows:

- (1) Incidence of CLI caused by a long SFA lesion categorized under Rutherford classification as 4 or 5.
- (2) Location of the SFA lesion 1 cm below the origin of the profunda femoral artery and its distal end at least 3 cm above the knee joint.

- (3) Lesion length between 12 and 18 cm, to be covered with a single stent.
- (4) Patency of at least one-vessel distal run-off to the foot.

Exclusion criteria were as follows:

- (1) Presence of a nonsalvageable limb or lifethreatening infection.
- (2) Presence of multilevel occlusions.
- (3) Total occlusion that cannot be crossed by a wire.
- (4) Previous bypass surgery in the same limb.
- (5) Requirement of more than one stent to cover the lesion.

All patients were admitted and had to sign a written informed consent form before undergoing treatment. Patients were evaluated by full clinical assessment, including detailed history taking and examination, including history of diabetes mellitus (DM), smoking, hypertension, cardiovascular diseases, cerebrovascular diseases, renal insufficiency, previous endovascular intervention, and bypass surgery. All patients were subjected to thorough physical examination, ankle brachial pressure index (ABI) measurement, and duplex ultrasound imaging. Computed tomography angiography was performed in all cases for diagnosis, for identification of the character of the lesion, and for distal run-off vessels. All patients had undergone full laboratory investigations with special emphasis on renal functions and coagulation profile.

### **Procedure details**

Periprocedural medications included dual antiplatelet therapy in the form of 75 mg salicylates and 300 mg clopidogrel as a loading dose, followed by a daily maintenance dose of 75 mg clopidogrel continued postoperatively for at least 6 months in all cases. The procedure was carried out under local anesthesia in all cases. An ipsilateral antegrade femoral arterial puncture and a 6-F vascular sheath were used in 20 cases, whereas a contralateral approach using an 8-F sheath and a crossover guiding catheter was adopted in the other five cases where the SFA lesion was more proximal to its origin precluding optimum positioning of the sheath ipsilaterally. After sheath insertion, 5000 IU heparin was injected before starting the procedure. Preintervention angiography was performed to assess the lesion: its length, stenosis or occlusion, and distal run-off vessels. A 0.035 Terumo hydrophilic guide-wire (Radifocus, Terumo, Japan) or V-18 control guide-wire (Boston Scientific, USA) was used to cross the lesion either intraluminal or subintimally. After passing the wire, lesions were dilated using 4-5 mm low-profile balloons (Wanda balloon; Boston Scientific) for 1–2 min under nominal pressure. A self-expandable nitinol stent Protégé EverFlex (ev3 Inc., USA) was deployed using the road map technique to cover the whole length of the lesion and extending proximal and distal to the targeted segment. Poststent balloon dilatation was performed along the whole stented segment. Completion angiography was performed while the guide-wire remained in place to assess the technical success of the procedure.

After endovascular intervention, patients with ischemic foot ulcers or gangrene received standard wound care, debridement, and/or minor amputation until wounds were healed.

Follow-up was conducted daily during the period of admission and then in the vascular surgery outpatient clinic at 3, 6, and 12 months with respect to regaining pulse, ABI, disappearance of rest pain, wound healing, and complications. Any decrease in ABI measurement or recurrence of significant manifestations was an indication for duplex imaging to assess patency or stenosis. Restenosis was considered significant if more than 50% on duplex ultrasound, where peak systolic velocity ratio was greater than or equal to 2.4, as reported by Ranke *et al.* [8]. Repeated revascularization was performed on the basis of clinical manifestations, duplex scan, and angiography (Figs. 1 and 2).

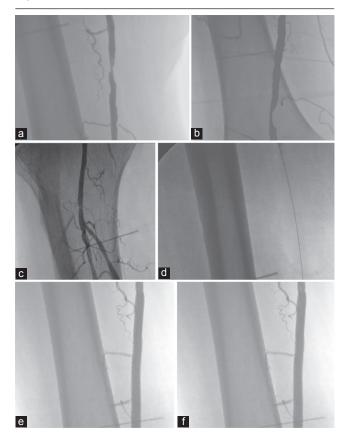
## Results

This study was performed on 25 patients with CLI caused by long SFA lesions categorized under Rutherford classification as 4 or 5 with a mean lesion length of 13 cm (range 12–18 cm). All patients received a single self-expandable stent of 15 or 20 cm, of a diameter of 6 mm. Major risk factors were diabetes and smoking, with incidences of 68 and 56%, respectively. All demographic data and patient criteria are summarized in Table 1. The majority of patients were classified as TASC B (16 patients, 64%). Totally occluded segments were observed in 60% (15 patients), whereas multiple stenosis was observed in 40% (10 patients). Nearly half of the patients (52%, 13/25) had three-vessel distal run-off to the foot (Table 2).

Regarding procedural complications, two patients developed groin hematoma, which resolved spontaneously, and one patient developed contrastinduced nephropathy, which was treated medically.

## Follow-up results

Technical success was achieved in all patients. Primary patency was achieved in 17 (68%) patients,



(a, b) Multiple stenotic lesions of a long superficial femoral artery SFA segment.(c) Distal run-off based on two vessels.(d) Crossing the lesion with a 0.035 wire.(e) After deployment of a long stent.(f) Completion angiography.

	Table 1	Demographic	data and	patients	criteria
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	n (%)
Age	58 (52–65)
Males/females	19 (76)/6 (24)
Risk factors	
DM	17 (68)
Smoking	14 (56)
Hypertension	12 (48)
Ischemic heart disease	12 (48)
Stroke	4 (16)
Renal insufficiency	4 (16)
Rutherford classification	
Rutherford category 4	6 (24)
Rutherford category 5	19 (76)

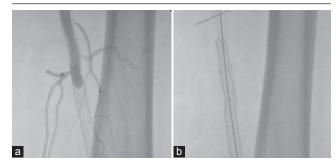
DM, diabetes mellitus.

Table 2	Angiographic	criteria
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TASC classification	n (%)
TASC B	16 (64)
TASC C	9 (36)
Distal run-off vessels	
Three vessels	13 (52)
Two vessels	7 (28)
One vessel	5 (20)

TASC, Trans-Atlantic Inter-Society Consensus.

Figure 2



(a) In-stent stenosis. (b) Crossing the occluded stent with a 0.035 wire. (c) Stent recanalization after balloon dilatation.

whereas restenosis occurred in eight (32%) cases. Six of them occurred within the first 6 months, whereas the other two cases occurred in the 8th and 11th month of follow-up. Four of these eight cases were treated with angioplasty, one patient was treated with a femoropopliteal bypass, and two cases were treated medically as they were claudicants without significant manifestations. The last patient had to undergo limb amputation because of the development of extensive necrotizing fasciitis along with poor general condition. The correlation between restenosis and associated risk factors revealed that DM was the most common risk factor for restenosis, seen in five of eight patients.

## Discussion

The femoropopliteal segment was the most common atherosclerotic lesion in the lower extremities [1,9]. Karch *et al.* [10] and Goshima *et al.* [11] confirmed that bypass surgery was the definitive strategy and the recommended procedure for revascularization of long femoropopliteal segment. However, its morbidity and possibility of reoperation are considerable drawbacks, reaching an incidence of ~50%. The main disadvantages of bypass surgery are wound complications, perioperative cardiac complications, and graft failure, with increased reoperation rate. All of these factors have to be considered when comparing surgery and endovascular intervention [11].

Improvement in short-term and midterm patency of SFA stenting has challenged the historical concept of bypass surgery when compared with endovascular therapy [12]. Van der Zaag *et al.* [13] have enumerated the advantages of endovascular therapy in terms of its ability to deal with complex and multilevel lesions, especially in patients with long diseased segments, previous revascularizations, advanced age, and unsuitable veins.

The study on bypass versus angioplasty in severe ischemia of the leg for patients with CLI showed that amputation-free survival and mortality among patients treated with angioplasty were similar to those treated with surgery [14].

The number of patients in this study was relatively small as it was carried out in a single center of an insurance hospital to which patients came from all across the governorate. This made follow up difficult, except for the small number of patients who lived closer to the hospital.

Most patients in this study were men, which matched the observation made by Laird et al. [15] that the prevalence of peripheral arterial disease is higher among men and increases with age. Diabetes and smoking were the main risk factors, seen in 68 and 56% of patients, respectively. Nearly similar incidences were observed in other studies [4,16]. Sabeti et al. [17] had reported in his series that DM was associated with an approximately four-fold incidence of in-stent stenosis. This could be explained by the influence of DM in hypertrophy of wound healing in areas of vessel wall trauma following stent implantation and then causing neointimal hyperplasia [18]. In contrast, Markose and Bolia [19] reported that endovascular therapy has many advantages among diabetic patients because of less invasiveness, absence of wound-related complications, lack of requirement for venous conduits, facilitation of simultaneous multiple vessel recanalization, and short hospital stay.

Sixteen (64%) patients were TASC B, nine (36%) patients were TASC C, and no patients were TASC A or TASC D. It was observed that primary patency was higher among patients with TASC B lesions compared with those with TASC C lesions. Baril *et al.* [20] published outcomes of endovascular interventions for TASC B and C lesions and found similar patency rates compared with femoropopliteal bypass surgery.

In this series, undersized balloon angioplasty was performed using 4–5 mm low-profile balloons before covering the entire target lesion with a long stent. This allows better deployment of the stent in its optimum position. Hu *et al.* [3] approved stent-supported angioplasty by using a balloon to dilate the whole lesion and then to implant short stents for the residual significant stenoses. Lenti *et al.* [21] commented upon this technique as it decreased the residual stenosis compared with postdilation, but it induced more distal embolization.

Primary stenting remains controversial [22]. Schillinger *et al.* [12] reported that primary stenting

was morphologically and clinically superior to balloon angioplasty with optional stenting but was associated with serious problems such as in-stent stenosis and stent fractures. With the development and progress of new-generation nitinol stents, there has been a marked increase in the number of patients treated with this technique [23]. Krankenberg *et al.* [2] and Lofberg *et al.* [24] concluded in their series that SFA stenting is recommended only after technical failure of PTA and for treatment of long lesions measuring more than 10 cm, as balloon angioplasty alone is associated with recurrence rates exceeding 60% at 1 year. Also, Mewissen [25] reported that the 2-year primary patency rates of nitinol stents for symptomatic femoropopliteal disease are superior to PTA.

In this series, SFA stents were preferred over PTA, with optional stenting. This could be attributed to many reasons; first, all patients in this study had CLI and thus our aim was to ensure optimal patency results, adequate restoration of perfusion, and consequently limb salvage. Second, Lumsden et al. [26] had stated that the 6-month patency rate for bare nitinol stents was very high but decreased with time, which is sufficient enough for healing of ischemic ulceration in patients with CLI. Third, as reported by Ferreira et al. [27], many investigators have concluded that long-term primary patency is not strictly necessary for limb salvage, as some patients with restenosis remain asymptomatic, and in such cases medical treatment is sufficient [28]. Finally, critically ischemic limb commonly occurs in elderly patients suffering from many medical comorbidities, such as coronary artery disease, and the mortality rate among them is  $\sim$ 50–70% at 5 years [29]. Therefore, we believe that long-term patency might not be needed in most cases.

Few studies have been found discussing the results of long stents in the femoropopliteal segment. Sabeti *et al.* [30] reported the effectiveness of a long nitinol stent as an adequate tool to treat variable femoropopliteal lesions. Also, Mewissen [31] had reported that stenting of the entire diseased segment is generally preferred over spot stenting to decrease the possibility of vessel recoil, plaque fracture, and consequent inflammatory reaction between stents. In contrast, deployment of a long stent rather than multiple overlapping stents is risky for stent fracture and for in-stent stenosis [5,31]. Also, Schlager *et al.* [32] had stated that midterm and long-term primary patency was inversely proportional to the length of the treated segment beyond 10 cm.

Bosiers *et al.* [33] published 1-year results of the 200 mm Protégé EverFlex stent to be 64.8%. In this study, the 1-year primary patency rate of nitinol stents (15 and 20 cm) was 68%. The FAST study reported a

similar result (68.3%) with 12 months of freedom from restenosis in the stent arm. Discrepancy in patency rates might be explained by the limited number of cases in this study. Davies *et al.* [34] had reported in his series that long-term patency following PTA varied according to the severity of the treated lesion; claudication versus CLI, stenosis versus occlusion, lesion length, run-off vessels status, and presence or absence of diabetes.

Balloon angioplasty is the traditional method for treating significant intimal growth within a stent with better secondary patency rates [35]. In this study, the same strategy was followed in the treatment of in-stent stenosis in four of eight cases. During reintervention, the lesion could not be crossed by the guide-wire in one patient and was treated by femoropopliteal bypass. There were two patients with restenosis without recurrence of significant manifestations who received conservative treatment. Laird and Yeo [36] reported that femoropopliteal in-stent restenosis was one of the most frustrating problems in endovascular intervention. It is relatively common and occurs in 18-40% of patients within the first year of femoropopliteal artery stenting. Stabile et al. [37] treated SFA in-stent restenosis by using a drug-eluting balloon and reported a 100% rate of secondary patency after 1 year; thus, he concluded that a drug-eluting balloon can change the paradigm for treatment of SFA in-stent restenosis.

Machan [38] and Rosenfield *et al.* [39] attributed the main causes of SFA restenosis to complex anatomical factors, as there were multiple mechanical forces acting on SFA during its passage through the adductor canal — for example, repetitive deformity by leg movement and exposure to compression, torsion, and elongation by interaction with the surrounding musculature.

In this series, 13 (52%) patients had three patent vessel distal run-off, seven (28%) patients had two-vessel, and five (20%) patients had only one patent vessel run-off. Norgren *et al.* [5] found that patency rate was affected significantly by poor distal run-off to the foot.

## Conclusion

Management of long SFA lesions with a nitinol stent is effective and safe in patients with CLI as there is still the opportunity to receive bypass surgery or endovascular reinterventions.

# Acknowledgements

Conflicts of interest None declared.

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