Outcome of stenting of long segment of superficial femoral artery lesions

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Abstract

Background: There for conflicting data regarding the benefits of primary stent implantation compared with balloon angioplasty with provisional stent implantation in SFA.

Aim: to evaluate the primary patency of long superficial femoral artery lesions treated by nitinol self-expandable stent after 12month follow-up as a primary end point. Secondary end -point was to evaluate clinical and hemodynamic improvement after 12 month follow-up.

Methods: The study group included 30 patients with chronic lower limb ischemia. The age of these patients ranged from 53 to 75 with a mean age of 64years. They were performed in the vascular and interventional Radiology Unit., Kasr El Aini Hospital, Cairo University and 6th O'ctober insurance hospital. Interventional procedures were performed in an angiographic interventional room with high resolution C- arm fluoroscopy, road mapping and digital subtraction capabilities. Parameters evaluated including: Rutherford category, walking distance, ankle –brachial index and preconditions for risk factor.

Results: Only one patient developed a small groin hematoma which didnot required evacuation and spontaneously resolved under conservative treatment. One patient developed contrast-induced nephropathy which required a single hemodialysis section. Kidney function improved thereafter. The improvement of ABI, walking distance and the Rutherford classification improvement showed high significance ($P < .001$). Follow-up time was 12 months. No patients died during follow-up.Follow-up ABI values were 0.89 ± 0.28.The improvement of the ABI went parallel to the increase of walking distance and Rutherford classification on a highly significant level ($P < .001$). After 24 months, primary patency was 86.66%. 4 cases restenosis (13.33 %) were found. Two cases of them occurred within the first six months. Endovascular recanalization was performed as stent in stent procedure, PTA alone for three cases .one femoropopliteal bypass as secondary procedure.

Conclusion: Long SFA lesions treated successful by nitionl stenting with primary patency rate 88%, and as a successful procedure for limb salvage. Clinical deterioration occurred in only a small number of patients, and all of them were retreated by endovascular therapy or underwent bypass surgery with supragenicularanastomosis. These observations confirm that the initial endovascular approach for long lesions did not complicate further patient management after clinical stent failure. Furthermore, at the time of follow-up, the patients had a sustained clinical and hemodynamic benefit compared to baseline.

Keywords: stenting, superficial femoral artery

Introduction

Lower limb peripheral arterial disease (PAD) is a common important manifestation of systemic atherosclerosis. Occlusion of superficial femoral artery (SFA) can lead to claudication and can contribute to chronic critical limb ischemia. **(1)**

Therapies for occlusive (PAD) include lifestyle modification, pharmacological agent, and revascularization by either percutaneous or an open surgical approach. Surgical bypass using autogenously vein (the gold standard) or synthetic graft has been the traditional treatment for several SFA diseases. **(2)**

The use of minimal invasive endovascular techniques, which entail less morbidity than the traditional surgical approach, has increased markedly in recent years. Endovascular intervention is considered first-line therapy for most superficial femoral artery occlusive disease **(3).** The most commonly employed endovascular procedure is percutaneous trans luminal angioplasty (PTA), other endovascular procedures include self-expanding bare metal stents and drug-eluting nitinol stents. **(2)**

There is uncertainty regarding the best endovascular treatment strategy for symptomatic patients with atherosclerosis disease of superficial femoral artery. **(4).**

The main limitation of endovascular treatment modalities in femoropopliteal tract patency of plain balloon angioplasty might be as low as 30%to40%, improved results have been reported with primary stenting approach **(5)**

Endovascular stent implantation was introduced to femoropopliteal procedures almost two decades ago. Stenting holds the promise of improving the results of SFA intervention by providing a better initial angiographic result, reducing elastic recoil, and scaffolding dissection. **(6)**

Initial results with first –generation stents, including the balloon-expanding stainless steel palmaz stent, were disappointing. **(7)**

Several randomized controlled clinical trials failed to demonstrate any benefit of balloon-expandable stents over angioplasty alone **(8).**

There for conflicting data regarding the benefits of primary stent implantation compared with balloon angioplasty with provisional stent implantation in SFA. **(9, 10)**

This conflicting result s has added to the uncertainty regarding the role of stents in SFA intervention.in addition, concerns exist about the potential for stent fracture and late stent restenosis. **(11)**

The study aimed to evaluate the primary patency of long superficial femoral artery lesions treated by nitinol self-expandable stent after 12month follow-up as a primary end point. Secondary end -point was to evaluate clinical and hemodynamic improvement after 12 month follow-up.

Subjects and Methods

The study group included 30 patients with chronic lower limb ischemia. The age of these patients ranged from 53 to 75 with a mean age of 64years. They were performed in the vascular and interventional Radiology Unit., Kasr El Aini Hospital, Cairo University and 6th O'ctober insurance hospital.

The patients were suffering from vascular lesions in a single or both lower limbs with lesions ranging from mild stenosis up to total occlusion at different levels of superficial femoral artery. Lesions where classified to B, C and D according to TASCII classification. **(12)**

Exclusion criteria included:

1-Type A TASC ll classification

2-Other types treated by angioplasty only.

3-Untreated inflow disease of the ipsilateral pelvic arteries (more than 50 percent stenosis or occlusion)

All patients underwent the following evaluations:

I. Clinical History:

• Complaint of the patient as (claudication, rest pain, ulcer, and gangrene and Tissue loss)

• Risk factors as (Diabetes Mellitus, hypertension, smoking, hyperlipidemia …etc.) was evaluated as well as prevalence.

•The associated diseases in the examined patients as (Ischaemic heart, Renal insufficiency, Carotid artery stenosis, COPD…etc.) was evaluated as well as prevalence.

II. Physical Examination:

General examination: included

- Vital signs
- All peripheral pulsations
- Abdominal and chest examination

Local examination:

Peripheral pulsations of both limbs were evaluated. Patients had ulceration or gangrene was evaluated as well as prevalence. Examination also included evaluation of sensory deficit and correlation it will prevalence of diabetes mellitus.

III Past History:

Reviewing the previous diseases, history of drug allergy.

IV. Arterial Assessment:

All patients had a vascular ultrasound evaluation (duplex) for both lower limbs for proper lesion analysis, hemodynamic assessment and as a base line study for follow up. Ankle brachial Index (ABI) was taken for all patients prior to intervention.

Diagnostic angiograms were also performed for all patients, either preprocedural or on a prior setting for proper assessment of ischemia and categorization of the lesions. Previous arteriograms were reviewed for the assessment of disease progression and were not considered for procedural planning.

Indications for interventional treatment:

1- Incapacitating claudication.
2- Limb-threating ischemia.

Patient preparation:

Patient were kept fasting for 6 hours.

Control of associated diseases e.g. (D.M, Hypertension, cardiac…etc.)

Patients were admitted the night before the procedure.

Proper sedation in anxious patient.

Laboratory Investigations included blood picture, kidney function test and coagulation profile.

II Procedure:

Interventional procedures were performed in an angiographic interventional room with high resolution C-arm fluoroscopy, road mapping and digital subtraction capabilities. (Philips)(maximus CRT 100and GE advantx AFM DX). Written consent was taken. Stents were used (Nitinol stent) ranging from (5-6) mm in diameter and their lengths ranging from 10-15cm.

Arterial access:

The arterial access whether ante grade for ipsilateral or retrograde for contralateral lesions access was done at superficial femoral artery; 5000 IU of heparin were administered.

Crossing the lesion:

After placing the introducer sheath, a multiple side hole straight or pigtail 6F high- flow catheter was introduced for diagnostic control angiogram. Then the lesion was negotiated by combination of a 5F straight catheter with a 0.035"j shaped terumo guide wire or a 5F j shaped catheter with a 0.018 straight Terumo guide wire. Subintimal passage of guide wire was required in 4 cases of occlusion.

Dilating the lesion:

After crossing the lesion, the balloon catheter was introduced and properly placed astriding the lesion. The inflation was done manually using a pressure of (8-10 atm or less) for 60 seconds each time observing the waist at the balloon produced by the lesion. This process may be repeated 2 or 3 times depending on the outcome after each time and till reaching homogenous inflation and deflation of the balloon.

Stenting the lesion:

The access was maintained (by guide wire) across the lesion to introduce the stent (primary stenting) or any diagnostic Catheter later on. After proper placement of the stent it was gradually deployed. Finally, a control angiogram is done to check the outcome and to exclude distal embolization.

Types of stents:

Nitinol stents were used in this study.

After care:

The patient after percutaneous angioplasty with or without stenting was maintained on anti-platelet agents (clopidogrel,) for 6 months. All Patients were kept for monitoring for a period ranging from 6 hours up to 24 hours for vital signs, proper hydration, medication intake and evaluation of distal pulses and circulations. Evaluation by duplex scanning was done the day after the procedure to acquire data regarding the procedures results and the patient was discharged with scheduled follow up at 3 months 6months and 1 year interval.

Follow-up

Patients were examined at 3, 6.12 months postinterventional. Follow up visits included questionnaire regarding clinical improvement (walking distance, improvement of rest pain…. etc.).Patients were evaluated using ultrasound including B-mode evaluation, waveform analysis and ankle brachial pressure indices

Definition and classifications

Parameters evaluated including: Rutherford category, walking distance, ankle –brachial index and preconditions for risk factor...

Endovascular procedure was considered technically successful when the treated lesion had no residual stenosis more than 30% on completion of the intervention.

Endpoints were primary patency at 3, 6,12months and occurrence of restenosis.

Primary patency was defined as the absence of restenosis or occlusion (>50% of the vessel diameter) in the treatment arterial segment. Restenosis was defined either as recurrence of patient's symptoms in conjunction with non-invasive examination, which confirmed recurrent disease, or based on duplex scan finding indicative of recurrent disease alone for select patients who had no clinical symptoms.

Statistical analysis

Statistical analysis was used basic computer program (SPSS)version (14.01), parametric variable was analyzed using one sample student T test, Nonparametric variable using (Chi-square test). measurement was expressed as mean ±standard deviation ,out -come was expressed as percentage.

Results

A total of 32 nitinol stents were deployed in 30 patients: an average of 1.06 stent per limb. Most of them received one single stent, in 2 patients a maximum of 2 devices per limb were implanted. Range stent length was 120-150 mm with a diameter of 5 -6mm to cover lesions range between10-23cm with average16. 5cm.Average age was 62.93 years (range 53 – 75y).Enrollment data showed the males constituted 86.7% of the study group.

Sixty percent of patient had occlusive lesions. And a total of 26.6 %were classified as Rutherford IV (Table 1). Indications for intervention were either life style limiting claudication (Rutherford III) or limb salvage (Rutherford IV/V).

Table (1): Baseline data: Rutherford categories

Rutherford category	**N / % of cases**
II/III	53.33%(n=16)
IV	26.66%(n=8)
V	6.6%(n=2)
VI	13.3%(n=4)

17 patients (56 %) suffered from a TASC B lesion, 11(36 %) ASC C, 2 (8 %) TASC According to TASCII classification in the following table (2).

Table (2). lesion classification according to TASCII classification.

TASC classification	Number of cases and its percentage
TASC B	17 (56 %)
TASC C	11(36 %)
TASC D	2 (8 %)

In Table (3) baseline data concerning patients 'risk factor underline a numerous part of hypertensive patients (70 %). 53.66 % were current smokers, and 24.2 % stopped smoking for more than one year.

Table (3): baseline data. Patients 'risk factor

Risk factor	Diabetes Mellitus	hypertension	smoking	Hyperlipidemia
prevalence	18	21	20	9

Table (4): Baseline data: Patients' comorbidities

Diabetes	60.33%(N=18)
Hypertensive disease	70.%(N=21)
Hyperlipoproteinemia	30%(N=9)
Renal insufficiency	13.33%(N=4)
Ischemic heart disease	30%(N=9)

Procedure complications are demonstrated in the following **table (5):**

Complication	Number of patient
Groin hematoma	1
Early thrombosis(<30 days)	-
Distal embolization	-
Amputation (major)	-
ARF	1
Stent fractures	1

Only one patient developed a small groin hematoma which did not required evacuation and spontaneously resolved under conservative treatment. One patient developed contrast-induced nephropathy which required a single hemodialysis section. Kidney function improved thereafter

Immediate outcomes

Technical success was achieved in100 % of stents deployed. There were neither periprocedural complications nor deaths. ABI increased 0.36; preinterventionally ABI was 0.559 ± 0.139 and after endovascular procedure 0.94 ± 0.11 ($P < .001$). Walking distances were improved from an average of 75m to more than 500mafter stent implantation. Rutherford improvement postinterventionally increased 2 classes. The improvement of ABI, walking distance and the Rutherford classification improvement showed high significance ($P < .001$).

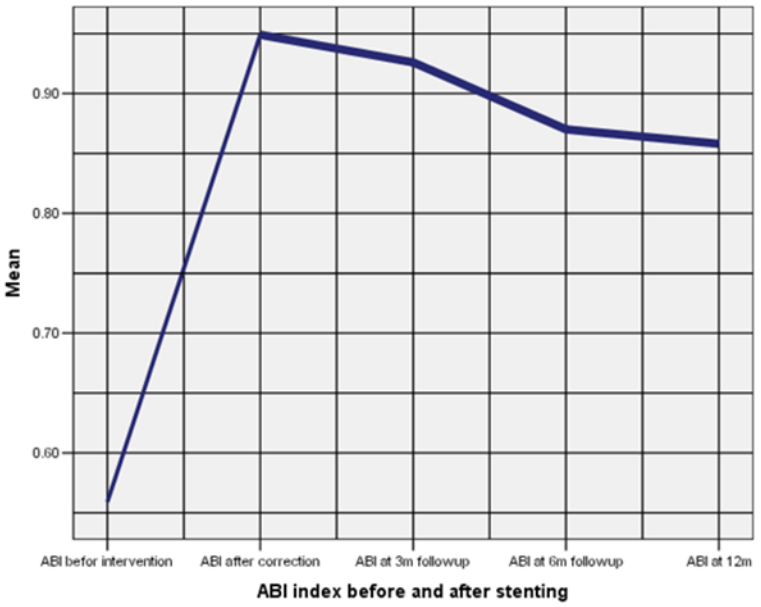
Follow up

Follow-up time was 12 months. No patients died during follow-up. Follow-up ABI values were 0.89 ± 0.28.The improvement of the ABI went parallel to the increase of walking distance and Rutherford classification on a highly significant level ($P < .001$).

Ankle Brachial Index **table (6):**

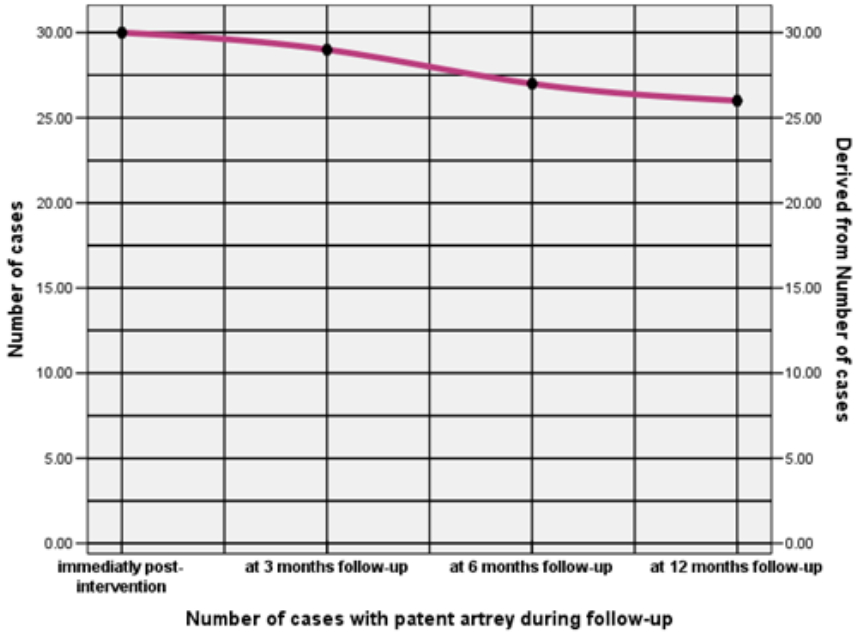
	Mean	**St. deviation**	**Significance**
ABI before intervention	0.559	±0.1392	0.000**
ABI immediately post-stenting	0.949	±0.1386	0.000**
ABI at 3 months followup	0.926	±0.18614	0.000
ABI at 6 months followup	0.870	±0.3172	0.000
ABI at12 months followup	0.858	±0.3128	0.000

*There is highly significant difference between ABI before intervention and ABI immediately post-correction and at 3, 6 and 12 months follow up



Patency:

After 24 months, primary patency was 86.66%. 4 cases restenosis (13.33 %) were found. Two cases of them occurred within the first six months. Endovascular recanalization was performed as stent in stent procedure, PTA alone for three cases .one femoropopliteal bypass as secondary procedure.



TASC II classification:

No correlation was found between primary patency and lesion morphology according to TASC II classification this might be due to the limited number of patients.

Table (7): Rate of restenosis among TASC group

TASC II classification	Rate of restenosis
TASC B	(1) 3.33%
TASC C	(2) 6.66%
TASC D	(1)3.33%

Risk factors

The analysis of influencing factors for restenosis showed no significance for diabetes and nicotine abuse. But hypertension was borderline significant (P = 0.06) as a risk factor. Statistical multivariate analysis included all comorbidities, previous interventions and anatomical and hem dynamical features.

Runoff:

Primary patency was significant diminished in patient with impaired tibial runoff (lower than three tibial vessels) as group A compared to patient normal tibial run off (three tibial vessel) group B.

Table (9) Binomial Test

		Category	N	Observed Prop.	Test Prop.	Asymp. Sig. (2-tailed)
runoff	Group 1	good runoff	18	.60	.50	.362(a)
	Group 2	impaired runoff	12	.40		
	Total		30	1.00		

Procedure risk factor

As regard to technique; four cases stent was implanted subintima group A. Other cases wereimplanted intraluminal as group B.

Table (10): Relation between primary outcome and the approach used

approach	No. of cases	Occluded
Sub-intimal	4(13.33%)	1(25%)
Intra-luminal	26(86.67%)	3(15.3%)

Discussion

Atherosclerotic lesions arise more frequently in the femoropopliteal segment than in any other area of the lower extremities, and surgery was the standard treatment until the 1980s. **(13)**

Endovascular interventions offer minimally invasive alternative therapies that have proven efficacious in most circulatory beds for an ever-growing array of pathologies. For aortoiliac lesions, a triad of endovascular techniques, including balloon angioplasty, thrombolysis, and stenting, comprise the treatment of choice; both immediate and long-term outcomes are identical or superior to surgery, and the morbidity and mortality rates are lower, the costs less, and the hospital stays short **(13)**.

At the present time, the majority of authors agree that the primary indication for stenting is angioplasty failure or suboptimal angioplasty results. These were the indications primarily used in their study, though elective stenting was performed for chronic, calcified occlusions in which recoil was judged likely to occur. Because the use of multiple stents has been associated with higher restenosis rates, we have accordingly implanted the minimum number of stents to adequately cover a lesion or dissection. **(14)** In the present study all patients were prepared for primary stenting.

Nevertheless, decision to best treatment develops towards increased endovascular interventions. But literature results on long stents in the femoropopliteal artery are still few. For that the presented trial may underline and answer remaining questions **(15)**. The trial shows the effectiveness of a long self-expanding nitinol stent being an adequate tool to treat different femoropopliteal lesions. It becomes obvious that primary and secondary patency's are comparable or even better than long-term outcomes after bypass implantation**. (16)** Primary patency after 12months was 88 % versus bypass procedures with five-year patency rates between 57.4 % and 77.2 % in met analyses in the literature.

In the study of Larid and colleagues in 2010 ,the clinical criterion for study entry was symptomatic peripheral-artery disease which included of incapacitating intermittent claudication and critical limb ischemia(Rutherford stage 3,4,5).The anatomical inclusion criteria, based on biplane digital subtraction angiography (DSA) performed at the time of intervention, were stenosis of more than 50 percent or occlusion of the ipsilateral superficial femoral artery, a target-lesion length of more than 30 mm, and at least one patent (less than 50 percent stenosed) cural runoff vessel. The exclusion criteria were acute critical limb ischemia, previous bypass surgery or stenting of the superficial femoral artery, untreated inflow disease of the ipsilateral pelvic arteries (more than 50 percent stenosis or occlusion), and known intolerance to study medications or contrast agents **(15)**. In the present study clinical presentation encompass Rutherford stage 2.3.4.5and 6 .and the exclusion criteria similar to this study. However, the rate of restenosis at 12 month follow up was37%.but in the present study rate of restenosis at 12month follows up was 13.3%.

Restenosis remains the main challenge in endovascular interventions of the infrainguinal level, unless further surgical options are not jeopardized **(17)** Stent procedures are still limited by significant rates of recurrent stenosis and stent fractures. Stents themselves contribute to intimal hyperplasia. Treatment is possible but complex because of the involvement of variable vessels and the unique forces from flexion, torsion, and compression in the region **(18).**

In the RESILIENT trial in 2010, a cross-sectional survey of males aged 65 to 85 in Western Australia reported that the age-standardized prevalence of PAD is 15.6 percent (95% Confidence Intervals:14.5-16.6%), The prevalence of PAD is higher among males and increases with age. Rates of PAD in persons over the age of 65 were reported to be between 12 and 15 percent.in our study males constituted 86%of the study group. **(4).**

Bariland colleagues in 2008, published outcomes of endovascular interventions for TASC B and C lesions, extending the indication for endovascular procedures in the SFA**. (8)** They found similar restenosis rates compared with open femoropopliteal bypass surgery. The secondary (or primary assisted) patency rates were excellent, underlining the presented findings. Bari supported treating lesions longer than≥ 10 cm, because immediate subjective benefit is realized by the patient and contributes to patient satisfaction. RESILIENT and Conformexx Trial included shorter obstructions, **(19,20)** with good results, respectively. The presented article supports the use of long devices, even in TASCC and D lesions: long segment stents obtained sufficient results with patency rates for TASC C and D of 87.3 %after 21 months. Even the involvement of the popliteal artery led to a beneficial patency rate of 84.3 %. It was one of the major limitations that only one stent was analyzed: the ev3Protégé Everflex stent. It would be interesting, and data will follow, to report overall patencies independent of the implanted stent device. FESTO Trial utilized a variety of 3 stents (SMART – Cordis; SelfX –Abbott/Jomed and Luminexx – Bard) **(15, 19).** They treated lesions with an average length of 16 cm. ZILVER and STRIDEStrial proposed better outcomes than SIROCCO I **(21,22).** Comparing these trials to the present study; we treated lesions with an average length 16,5cm by long nitinol stents with primary patency rate 88%after 12months follow-up.

In the present study we found that the primary patency though 12month was 88% follow-up similar to Brial et al in 2010 and Schoenefeld et al.in 2012, in the study by Larid and colleagues in 2010 primary patency at 12 month was 81.3%.

At present, the usual method of treating significant intimal growth within a stent is balloon dilation, which has resulted in good secondary patency rates for others **(23).** In the present study, we followed the same technique in treatment of in- stent restenosis, only one case, (out of 4 requiring reintervention),during intervention the lesions could not be crossed by a guide wire and the patient required a femoropopliteal bypass.

In the present study, as regard to analysis of the risk factors it has been found that the effect of hypertension is similar to that observed the study of Schoenefeld and coworkers in2012, it has also been observed that the state of run off affected the primary patency where primary patency is reduced in bad run off (less than three tibial vessel) in comparison to patients with good distal run-off (three tibial vessel). **(23)**

In the study of Ersan and colleague in 2014. 74 patients were presented by claudication and critical limb ischemia due to femoro-popliteal occlusions were treated by percutaneous subitimal angioplasty and stenting, primary patency rate at 6months was 94% with immediate technique success rate 97% **(24).** In the present study, it was found that primary patency was reduced in patients where subintimal route was used when compared to other where the intraluminal method was utilized.

Laridand colleagues in 2010, in a study of 206 adult's patients (234 lesions) in multiple centers across USA and Europe, including only patients with claudication (Rutherford categories 1 to 3) for intervention. Patients with critical limb ischaemia (Rutherfordcategories4-6) were not included in their study **(4).** In the present study, patients with both intermittent claudication and critical limb ischaemia were included.

Acute lesion success was defined as ≤ 30 percent stenosis of the treatment post intervention. Acute hemodynamic success was defined by more than a 0.15 improvement in the ankle brachial index from pre-procedure to discharge. Clinical success was an improvement of baseline symptoms by at least one Rutherford category, sustained through follow-up with no additional intervention. In RESILIENT study, clinical success rate at 6-month effectiveness measured81.4% and 12-month effectiveness was 72.3% **(25).** In comparison to the present study clinical success rate at discharge was 100%, at 6month 86.7% and at 12month 83%.

In the study of Schoenefeld and coworker's in.2012, analysis of 103 patients who received 128 stents for endovascular treatment of femoropopliteal vascular stenosis or occlusion, found TASC C and D lesion had similar patency rates compared to TASC A and B lesions. **(23).** In the present study TASC A was excluded. It has been observed that primary patency rate was higher in patients with TASC B lesions than in patients with TASC C, D lesions. However, the limited number of patients prevented proper statistical analysis.
In a retrospective analysis of nitinol stent procedures performed at a single institution, Scheinert et al demonstrated a 37.2% stent fracture rate when performing long-segment SFA stenting with 3 different nitinol stents. The rate of fracture was related to the length of the stented segment and the number and type of stents implanted. In the study by Krankenberg et al, in 2007**(26)** 12% fracture rate was seen after stenting of shorter lesions. In the SIROCCO (Sirolimus-Coated Cordis Self-expandable Stent) I study, an 18.2% fracture rate at 6 months was identified with the SMART. stent when treating lesions with a mean length of 85 mm. In SIROCCO II, the 6-month fracture rate decreased to 8% as the lesion length was shortened to 81.5 mm and the number of stents implanted decreased. **(17,19)** the fracture rate with the Life Stent in that study was only 3.1% at 12 months. In the present study, stent fracture rate 3.33% at 12 months.
In the present study no drug eluting balloons or stents were available for use. however, the zilverptx randomized trials presented improved results in form of patency rates of long SFA lesions (89.95% at 12month).
The primary limitation of this multicenter study, single-arm study was the lack of a comparison group. Another limitation was the limited number of patients,which prevented proper correlation between lesion morphology (TASC classification)and patency rates .Finally longer follow-up periods are recommended.

Conclusion

Long SFA lesions treated successful by nitinol stenting with primary patency rate 88%, and as a successful procedure for limb salvage.
Clinical deterioration occurred in only a small number of patients, and all of them were retreated by endovascular therapy or underwent bypass surgery with supragenicularanastomosis. These observations confirm that the initial endovascular approach for long lesions did not complicate further patient management after clinical stent failure. Furthermore, at the time of follow-up, the patients had a sustained clinical and hemodynamic benefit compared to baseline.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. **Twine CP,Coulston J,Shandall A,Mclain AD,Angioplasty** versuse stenting for superficial femoral artery lesions. Cochrane Database Syst Rev ,2009;(2);CD006767.
2. **Gable D.**Role of total endoluminal superficial femoral aretery bypass.J Cardiovasc surg (Torino),2011;52(5):683-700.Gage A, Fazekas G, Riley E. Freezing injury to large blood vessels in dogs. Surgery. 1967;61:748–754.
3. **Baril DT,Rhee RY,Kim J.Makaroun MS,Chaer RA,Marone LK**.Duplex criteria for determination of in-stent stenosis after angioplasty and stenting of the superficial femoral artery.J Vasc surgery.2009:49(1):133-8.
4. **Laird JR,Katzen BT,Scheinert D,Lammer J,Carpenter J,Buchbinder M,Dave R,Ansel G,lansky A, Crisrea E,Coldstein J,Jaff MR:Resilient investigationrs** .nitinol stent implantation versuse balloon angioplasty for lesion in the superficial femoral and proximal popliteal artery :Twelve-Mouth results from the RESILENT Randamized trail circ cardiovascular Interv.2010:3:267-276.
5. **Rocha-Singh KJ.Jaff MR,Crabtree TR,Bloch DA, ansel G,** Performance goal and endpoint assessments for clinical trails of femoropopliteal bare nitinol stents in patients with symptomatic peripgeral disease .Catheter cardiovasc interv.2007;69:910-919.

6. **Minar, E and Schillinger, M.** New stents for SFA. J Cardiovasc Surg 2009; 50: 635 – 645.

7. **Muradin GS, Bosch JL, Stijnen T. et al**. Balloon dilation and stent implantation for treatment of femoropopliteal arterial disease: meta-analysis. *Radiology.* 2001;221:137–145.

8. Cejna M, Turnher S, Illiasch H, et al. PTA versus Palmaz stent in femoropopliteal artery obstructions:a multicenter prospective randomized study. J Vasc Interv Radiol. 2001;12:23–31.

9. **Schillinger M, Sabeti S, Loewe C, et al.** Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med 2006;254:18:1879–1888.

10. **Schillinger M, Sabeti S,Dick P,Amighi J,Mlekusch W,Schlager O, Loewe C,** Cejna M,Lammer J,Minar E,Sustained benefit a 2 years of primery femoropopliteal stenting compered with Balloon angioplasty with optional stenting.Circulation 2007;115:2745-2749.

11. **Scheller B, Hehrlein C, Bocksch W, Rutsch W, Haghi D, Dietz U, Bohm M, Speck U.** Treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter. *N Engl J Med.* 2006; 355: 2113–2124.

12. **Tetteroo E, Haaring C, van der Graaf Y, van Schaik JP, van Engelen AD, Mali WP;** Dutch Iliac Stent Trial Study Group. Intraarterial pressure gradients after randomized angioplasty or stenting of iliac artery lesions. *Cardiovasc Intervent Radiol.* 1996; 19: 411–417.98-The Merck Manuals (2010). *Peripheral artery disease* [Internet]. The Merck.

13. **Haimovici, H. and F. J. Veith.** Femoropopliteal arteriosclerotic occlusive disease. In: Haimovici H, Callow AD, DePalma RG, et al eds. Vascular Surgery: Principles and Techniques 3rd ed. Norwalk, Appleton & Lange. 1989. 474–500.

14. **Diethrich, E. B. , O.** Santiago , and L. A. Lopez-Galarza . Endovascular stenting in the superficial femoral artery evaluated by angiography, intravascular ultrasound and angioscopy. (Abstr.). Circulation 1993. 88:I. 393.

15. **Sabeti, S, Mlekusch, W, Amighi, J et al.** Primary Patency of Long-Segment Self-Expanding Nitinol Stents in the Femoropopliteal Arteries. J Endovasc Surg 2005; 12: 6 – 12.

16. **Scali, ST, Rzucidlo, EM, Bjerke, AA et al.** Long-term results of open and endovascular revascularization of superfi cial femoral artery occlusive disease. J Vasc Surg 2011, article inpress.

17. **Schlager, O, Dick, P, Sabeti, S et al.**Long-Segment SFA Stenting – TheDark Side: In-Stent Restenosis,Clinical Deterioration, and Stent Fractures. J Endovasc Ther 2005.

18. **Tepe, G, Zeller, T, Albrecht, T et al**.Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. NEJM 2008; 358: 689 – 699.

19. **Scali, ST, Rzucidlo, EM, Bjerke, AA et al.** Long-term results of open and endovascular revascularization of superfi cial femoral artery occlusive disease. J Vasc Surg 2011, article inpress.

20. **Vroegindeweij D, Tielbeek AV, Buth J, Schol FP, Hop WC, Landman GH.** Directional atherectomy versus balloon angioplasty in segmental femoropopliteal artery disease: two-year follow-up with color-flow duplex scanning. *J Vasc Surg.* 1995; 21: 255–268.

21. **Bosiers, M, Deloose, K, Verbist,J et al.** Present and future of endovascular SFA treatment: stents, stent-graft s, drug coated balloons and drug coated stents. J Cardiovasc Surg 2008; 49: 159 – 165.

22. **Duda, SH, Bosiers, M, Lammers, Jet al.** Drug-Eluting and Bare Nitinol Stents for the Treatment of AtherosclerоticLesions in the Superfi cial Femoral Artery: Long-Term Results From Sirocco Trial. J Endovasc Ther2006; 13: 701 – 710.

23. **Eva Schoenefeld, Konstantinos P.** Donas, Th omas Schonefeld, Nani Osada, Martin Austermann, and Giovanni Torsello University Clinic of Muenster, Germany *Endovascular intervention in the SFADOI: 10.1024/0301 – 1526/a000163Vasa 2012; 41: 49 – 56.*

24. **Ersan Tatli, Ali Buturak, Osman Kayapınar,** EmirDogan,Mustafa Alkan,Yasemin Gunduz 1Subintimal angioplasty and stenting for chronic totalfemoropopliteal artery occlusions: Early and mid-term outcomes.Department of Cardiology, Duzce University.

25. **Laird, J. R., Katzen, B. T. et al (2012). '**Nitinol stent implantation vs. balloon angioplasty for lesions in the superficial and proximal popliteal arteries of patients with claudication: three-year follow-up from the RESILIENT randomized trial', *J Endovasc Ther*, 19, 1-9.

26. **Krankenberg H, Schluter M, Steinkamp H, Burgelin K, Scheinert DSchulte KL, Minar E, Peeters P, Bosiers M, Tepe G,**

Reimers B, Mahler F, Tubler T, Zeller TNitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: the femoral artery stenting trial (FAST). Circulation. 2007;116:285–292.