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Treatment of Complex Atherosclerotic Popliteal Artery Disease With a New Self-Expanding Interwoven Nitinol Stent

12-Month Results of the Leipzig SUPERA Popliteal Artery Stent Registry

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Objectives We examined the efficacy and durability of a new interwoven self-expanding nitinol stent system in the treatment of complex popliteal artery lesions in unselected patients.

Background The optimal endovascular treatment strategy for atherosclerotic popliteal artery disease is not known.

Methods We retrospectively analyzed the data gathered in 101 consecutive patients presenting with atherosclerotic, popliteal arterial disease, who underwent implantation of 125 stents. The patients were followed for 12 months by Doppler ultrasound examinations, stent roentgenograms, and estimation of Rutherford-Becker class (RBC) and ankle-brachial index (ABI).

Results The mean age of the patients was 73.1 years, and 52.5% were men. Total occlusions were present in 48 patients (47.5%). The mean stent length was 84.3 ± 45.1 mm (range 40 to 240 mm). A <30% residual stenosis was achieved in 98.0% of procedures. The 6- and 12-month primary patency rates were 94.6 ± 2.3% and 87.7 ± 3.7%, respectively, and the secondary patency rates 97.9 ± 1.5% and 96.5 ± 2.0%, respectively. Between baseline and 12 months of follow-up, mean ABI increased from 0.58 ± 0.15 to 0.97 ± 0.18, and mean RBC decreased from 3.1 ± 0.9 to 1.4 ± 0.8 ($p < 0.001$ for both comparisons). Radiographs performed on 51 patients, at a mean of 15.2 months, confirmed the absence of stent fractures in 100% of examinations.

Conclusions Over a 12-month observation period, the patency rate and durability of SUPERA stents implanted for severe popliteal artery disease were high. (J Am Coll Cardiol Intv 2013;6:65–71) © 2013 by the American College of Cardiology Foundation

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The recent guidelines formulated in the comprehensive American College of Cardiology/American Heart Association 2005 Practice Guidelines for the Management of Patients With Peripheral Arterial Disease (1) and the 2007 Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) (2) favored percutaneous transluminal angioplasty as the initial preferred option for endovascular treatment of symptomatic femoropopliteal arterial lesions, with bail-out stent placement after a suboptimal or failed result from balloon dilation. More recent data, however, suggest that particularly for longer lesions of the superficial femoral artery (SFA), patency rates after systematic primary stenting are significantly higher than after balloon dilation and provisional stenting (3). In fact, recent data from studies on nitinol stent implantation in the SFA have reported encouraging patency rates of 60% to 80% at 12 months (4–7).

On the basis of the available clinical evidence, implantation of nitinol stents into the SFA has become a widely used technique overall, resulting in improved clinical outcome of percutaneous procedures. By contrast, there is still a relative uncertainty about the role of endovascular stenting in the popliteal artery. Because scientific reports have traditionally combined the popliteal artery with the SFA, there is little scientific information available on the outcome of endovascular techniques in the popliteal artery. In fact, patients with isolated popliteal disease are largely underrepresented in the available literature.

Abbreviations and Acronyms

ABI = ankle-brachial index

RBC = Rutherford-Becker class

SFA = superficial femoral artery

The popliteal artery, unlike the SFA, has unique characteristics because it embryologically originates from the sciatic system (8,9). Most important, this arterial segment is highly exposed to biomechanical forces resulting from repetitive flexion of the knee (10–12). Concerns have been expressed that the implantation of stents, particularly in the popliteal artery, may be complicated by an unacceptable risk of stent fracture.

Although non–stent-based solutions for the popliteal artery may seem appealing, very few data are available, and stenting may still be required in a high percentage of patients after initial angioplasty procedures (8). We have recently reported 24-month results in the treatment of complex SFA lesions, using a novel, highly flexible, self-expanding interwoven nitinol stent (7). Over the 2-year follow-up, we observed a high patency rate together with significant clinical improvements. Most important, no stent fractures were observed over the 24-month surveillance period, which suggests that this stent may also be very suitable for implantation into the popliteal artery.

The objective of this registry was to evaluate the efficacy and integrity of this new nitinol stent system in complex popliteal artery obstructions, implementing a clinically established systematic follow-up regime with stent fracture screening and evaluation for restenosis. To derive both scientifically and clinically meaningful information, the registry intentionally allowed enrollment of a wide range of obstructions, including long lesions, total occlusions, and highly calcified vessels, without pre-specified inclusion and exclusion criteria.

Methods

Patient population. The medical records of 101 consecutive patients who had undergone implantation of SUPERA stents (IDEV Technologies, Webster, Texas) for the treatment of popliteal artery disease between January 2008 and April 2010, at Park Hospital, Leipzig, Germany, were retrospectively reviewed to collect clinical information between study enrollment and 12 months of follow-up. This represents about one-third of all popliteal interventions performed during that period. The decision to implant a stent was left to the operator's judgment, although the general indications after primary percutaneous transluminal angioplasty were followed, including hemodynamically severe residual stenosis, flow-limiting dissection, or elastic recoil.

All patients underwent baseline physical examinations with a focus on manifestations of lower limb ischemia, classified according to Rutherford et al. (13). Patients were assessed for the pain-free walking distance while walking fast. According to our institutional routine, patients were classified to Rutherford-Becker class 1 (RBC 1) if walking distance was more than 300 m and to RBC 3 if walking distance was <100 m. RBC 2 was determined if the walking distance was between 100 and 300 m. In indecisive situations, a treadmill test was performed.

The ankle-brachial index (ABI) was measured, and duplex ultrasound studies were performed, followed by selective angiography of the popliteal artery to outline the vascular anatomy and define the lesion characteristics. In accordance with the institutional and local regulatory policies, all patients signed a written informed consent form before undergoing the procedure.

Inclusion and exclusion criteria. There were no formal inclusion or exclusion criteria specified for this analysis other than a SUPERA stent was implanted into the popliteal artery to treat symptomatic de novo or restenotic (outside a previously implanted stent) popliteal artery lesion. Recipients of other stents were excluded from the analysis. The popliteal artery segments are defined as follows: P1 segment, from intercondylar fossa to proximal edge of patella; P2

segment, from proximal part of patella to center of knee joint space; and P3 segment (below knee popliteal artery), from center of knee joint space to origin of anterior tibial artery.

Stent procedure and medication regimens. The SUPERA stent system includes a 7-F coaxial delivery system with the pre-mounted stent. A detailed description of the system and of its deployment method has been published previously (7). Since 2011, the SUPERA stent has had an improved delivery system. However, in this study, all stents were still equipped with the first-generation delivery system. All lesions were pre-dilated, and balloon size was determined by visual estimation. Stents were not post-dilated, because further stent expansion cannot be achieved by post-dilation. Additional devices used were up to the investigators' discretion: Rotarex catheters (Straub Medical, Wangs, Switzerland) and thrombolysis were used in lesions with thrombotic material. The outback device was used if crossing the lesion was not possible by conventional means. Inflow and outflow lesions were treated if they were significant. Outflow lesions were treated to establish straight-line flow through at least 1 vessel to the foot.

The antithrombotic regimen was administered according to the usual institutional practices. Periprocedural anticoagulation with ≥5,000 U of heparin was recommended. Dual antiplatelet therapy with ticlopidine or clopidogrel and aspirin was administered for at least 4 weeks after the procedure, with the recommendation to continue aspirin indefinitely.

Follow-up and study endpoints. All patients were evaluated before their discharge from the hospital, and were scheduled to return for ambulatory follow-up visits according to our institutional standards at 6 and 12 months after the index procedure, at which times they underwent physical examinations, estimates of RBC, ABI measurements, and duplex ultrasound studies for the detection of restenoses. Not all patients were willing to return for the follow-up examinations: Duplex ultrasound and clinical assessment were available for 90 and 72 patients after 6 and 12 months, respectively. The duplex ultrasound recordings were analyzed by an investigator who was not involved in the initial treatment procedure. A peak systolic velocity ratio ≥2.4 (corresponding to a ≥50% decrease in vessel diameter) (14) was used for the diagnosis of binary restenosis. To confirm the integrity of the stent, plain roentgenographic images of the stented segment were obtained. These assessments are part of our routine follow-up protocol and are typically performed at around 12 months after the index procedure.

The primary efficacy endpoint of this analysis was stent patency, defined as absence of binary restenosis on duplex ultrasound examination without repeat target lesion interventions The secondary endpoints included: 1) procedural success, defined as a <30% residual vessel stenosis; 2) clinical status according to the RBC; 3) ABI measurements; 4) incidence of stent fractures on radiographic screening; and 5) rate of target lesion revascularization.

Statistical analysis. Descriptive statistics were used to present: 1) mean values and standard deviation (SD) for continuous variables; 2) median values (range); and 3) counts and percentages for categorical variables. Cumulative patency rates and standard errors (SE) were estimated, using Kaplan-Meier analyses. Between-group comparisons were made with the log-rank test. Mean ABI and RBC were compared at various time points, using the Student *t* test for dependent samples. Statistical significance was defined as $p < 0.05$. Analyses were performed using SPSS software, version 11 (SPSS, Chicago, Illinois).

Results

The analysis included 53 men (52.5%) and 48 women (47.5%), whose mean age was 73.1 ± 10.1 years. The baseline clinical characteristics of these 101 patients are shown in Table 1. Cardiovascular risk factors were highly prevalent, including hypertension in 99.0%, current or former smoking in 40.6%, and diabetes in 49.5% of patients. Furthermore, 46.5% of patients presented with severe claudication (RBC 3), and 22.8% presented with critical limb ischemia (RBC 4 to 5). The mean ABI at rest was 0.58 ± 0.15.

Angiographic and procedural characteristics and immediate results. A total of 125 stents, 4 to 6 mm in diameter and 40 to 150 mm in length, were implanted in the 101 patients, representing a mean stent length of 84.3 ± 45.1 mm (range 40 to 240 mm) implanted in a mean lesion length of 58.4 ± 34.3 mm (range 10 to 200 mm). The angiographic and procedural characteristics and the immediate procedural

Table 1. Clinical Characteristics of 101 Patients With Popliteal Artery Disease

Age, yrs	73.1 ± 10.1
Men	53 (52.5)
Medical history	
Smoking	41 (40.6)
Active	22 (21.8)
Previous	19 (18.8)
Diabetes	50 (49.5)
Insulin-dependent	24 (23.8)
Oral medication	26 (25.7)
Hypertension	100 (99.0)
Hyperlipoproteinemia	63 (62.4)
Coronary artery disease	60 (59.4)
Cerebrovascular disease	15 (14.9)
Rutherford-Becker class	3.1 ± 1.0
Ankle-brachial index at rest	0.58 ± 0.15

Values are mean ± SD or n (%) of observations

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Table 2. Angiographic and Procedural Characteristics in 101 Recipients of 125 Popliteal Artery Stents

Treated leg	
Right	46 (45.5)
Left	55 (54.5)
Stented arterial segment	
P1	39 (38.4)
P2	48 (47.5)
P3	14 (13.9)
Total occlusion	48 (47.5)
Stenosis	53 (52.5)
Calcifications	
None	20 (19.8)
Mild	29 (28.7)
Moderate	21 (20.8)
Severe	31 (30.7)
Vessel run-off	
0 or 1 vessel	41 (40.6)
2 or 3 vessels	60 (59.4)
Lesion length, mm*	58.4 ± 34.3 (10–200)
Stent length, mm	84.3 ± 45.1 (40–240)
Number of stents implanted per patient	
1	78 (77.2)
2	22 (21.8)
3	1 (1.0)
Additional procedures	
Inflow	23 (22.8)
Iliac arteries (all bare-metal stents)	3 (3.0)
Superficial femoral artery	21 (20.8)
Standard balloon angioplasty only	4 (4.0)
Drug-coated balloon angioplasty	2 (2.0)
Bare-metal stents	12 (10.9)
Drug-eluting stents	5 (5.0)
Outflow (tibial arteries)	24 (23.8)
Standard balloon angioplasty only	15 (14.9)
Drug-coated balloon angioplasty only	5 (5.0)
Drug-eluting stents	4 (4.0)
Special devices or procedural techniques	
Outback	4 (4.0)
Atherectomy	2 (2.0)
Rotarex	3 (3.0)
Lyse	5 (5.0)
Procedural success†	99 (98.0)

Values are mean ± SD (range), or n (%) of observations. Note: The same patient may have had >1 additional procedures. *Visual assessment. †Estimated post-procedural residual stenosis <30%.

results and complications are shown in Table 2. The degree of calcification, from mild for <5-mm calcium deposits in the vessel wall, to moderate for >5-mm deposits, to major for deposits filling up the entire vessel diameter, was graded on the basis of the amount of calcium deposits visible during fluoroscopy. Using this classification, more than 50% of the lesions were moderately to severely calcified.

A visually estimated, residual arterial stenosis <30% was achieved in 99 patients (98.0%).

Patient survival. Between their discharge from the hospital and 12 months, 10 patients died. One of these deaths occurred in a patient who initially presented with critical limb ischemia (RBC 5). The patient was readmitted at 6 months with an acute stent reocclusion. Despite an immediate reintervention, an amputation at the calf became necessary, and the patient died about 2 months later. No other individuals had minor or major amputations. All other deaths were unrelated to the vascular disease of the patients.

Stent patency. The rates of primary and secondary stent patency at 6 and 12 months of follow-up are shown in Table 3. The primary stent patency rate at 6 and 12 months were 94.6 ± 2.3% and 87.7 ± 3.7%, respectively. Of 10 patients who suffered in-stent occlusions (n = 4) or in-stent restenosis (n = 6), 7 were successfully recanalized percutaneously. The remaining patients were treated conservatively. Therefore, the secondary patency rate at 12 months of follow-up was 96.5 ± 2.0%.

The graphic displays of cumulative rates of primary and secondary stent patency up to 12 months of follow-up are shown in Figure 1.

RBC, ABI, and X-ray examinations. The mean RBC decreased from 3.1 ± 1.0 before the index stent implantation procedure, to 1.6 ± 0.9 at 6 months, and 1.4 ± 0.8 at 12 months (Table 4). The ABI increased from 0.58 ± 0.15 before the stent implantation procedure (Table 1), to 0.93 ± 0.19 at 6 months, and 0.97 ± 0.18 at 12 months (Table 3). These changes in RBC and ABI from baseline were highly statistically significant ($p < 0.001$). Follow-up radiographs of the stents, obtained in 51 patients at a mean follow-up of 15.2 months, confirmed the absence of stent fractures in 100% of examinations.

Table 3. Stent Patency Rates, ABI, and Cumulative Numbers of Adverse Events at 6 and 12 Months of Follow-Up

		Follow-Up (Months)	
	Baseline	6	12
Stent patency, %			
Primary	—	94.6 ± 2.3	87.7 ± 3.7
Secondary	—	97.9 ± 1.5	96.5 ± 2.0
Ankle-brachial index	0.58 ± 0.15	0.93 ± 0.19*	0.97 ± 0.18*
Cumulative adverse events			
Death	—	5	10
In-stent occlusion	—	3	4
>50% In-stent restenosis	—	3	6
Amputation	—	0	1
Repeat percutaneous recanalization	—	3	7

Values are mean ± SD (SE for stent patency results), or number of observations. Note: The same patient may have suffered >1 adverse event. *$p < 0.001$.
ABI = ankle-brachial index.

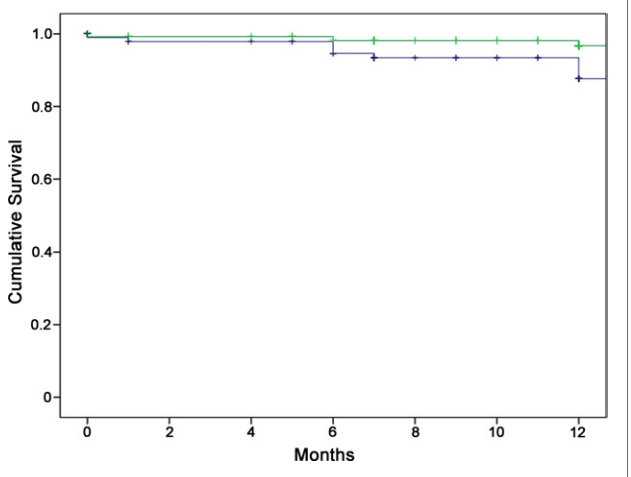

Figure 1. Cumulative Rates of Primary and Secondary Stent Patency up to 12 Months of Follow-Up

Blue line = primary patency. **Green line** = secondary patency.

Discussion

Non–stent-based solutions are currently favored as interventional treatment options for lesions affecting the popliteal arteries. Although dedicated data on the outcome of balloon angioplasty procedures in the popliteal segment are missing, reported patency rates after femoropopliteal balloon angioplasty are generally not convincing and may be as low as 30% to 40% (6). Alternative therapies, such as atherectomy procedures, have been applied in selected patients; however, no systematic reports specific to the use in the popliteal artery are available. A recently published small study comparing directional atherectomy treatment of the popliteal artery with balloon dilation found a somewhat better acute outcome after atherectomy procedures as expressed by a lower need for bail-out stenting. However, follow-up data after 1 year could not demonstrate a sustained benefit and showed identical re-obstruction rates as that of balloon angioplasty (8).

Table 4. RBC Before Intervention and at Follow-Up

RBC	Baseline (n = 101)	6 MFU (n = 90)	12 MFU (n = 72)
1	0 (0.0%)	56 (49.5%)	49 (48.5%)
2	31 (30.7%)	19 (14.9%)	16 (15.8%)
3	47 (46.5%)	12 (9.9%)	6 (5.9%)
4	9 (8.9%)	2 (2.0%)	0 (0.0%)
5	14 (13.9%)	1 (1.0%)	1 (1.0%)
6	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean (±SD)	3.1 ± 1.0	1.6 ± 0.9*	1.4 ± 0.8*

Values are n (%), except as noted. *$p < 0.001$.
RBC = Rutherford-Becker class.

The introduction of nitinol stents for treatment of the SFA has resulted in markedly improved acute and midterm results, at least for lesions with a length up to around 15 cm (3–7). For longer lesions, results were less convincing, and the reported issue of stent fractures with first-generation nitinol stents raised concerns about the suitability of stenting for those complex lesions (4,15). Clearly, these observations have also contributed to a widespread reluctance to implant stents into the popliteal artery. Indeed, due to its location across the knee joint and the fact that the artery is not contained in a muscular compartment, the characteristics of the popliteal artery are unique (10). Most important, the artery is highly exposed to mechanical forces and undergoes significant bending and foreshortening during knee movements (11,12). Due to their design characteristics, standard nitinol stents are mostly not suitable to fulfill these mechanical requirements, and significant stent fractures have been reported in the literature (16).

The novel SUPERA interwoven self-expanding nitinol stent (Fig. 2), which has been studied in this analysis,

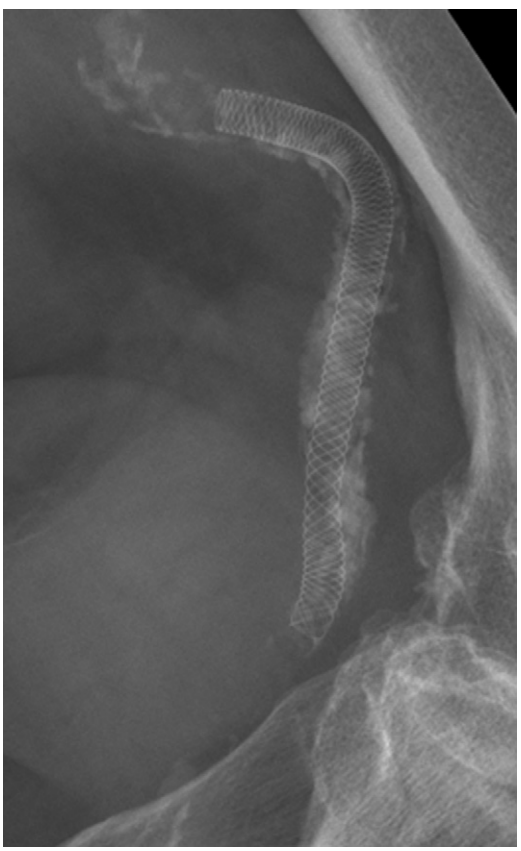

Figure 2. Bended-Knee X-Ray Image of a SUPERA Stent in the Popliteal Artery

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consists of woven nitinol wires braided in a tubular mesh configuration. The design configuration results in a stent that is flexible, compliant, and self-expanding and has a very high radial resistive strength. These features make the stent more suitable to withstand dynamic forces such as compression, torsion, bending, shortening, and pulsation. In a previous analysis of its use in the SFA, the device has been shown to have very good patency rates up to 2 years, as well as a complete absence of stent fractures (7).

In general, these encouraging results obtained in the SFA have been almost completely reproduced in the current analysis dedicated to the popliteal artery location. Patency rates after 1 year were almost identical to the results obtained with the SUPERA stent in the SFA at the corresponding time point (87.7% in the popliteal artery vs. 84.7% in the SFA) (7). Moreover, in the popliteal artery, a complete absence of stent fracture has also been demonstrated, offering reassurance that this novel stent design is durable and similarly suited for implantation into the popliteal artery as well as the SFA.

Although the mean length of the stented segment was somewhat shorter in the popliteal dataset (84 vs. 111 mm), from a clinical standpoint, patients with obstruction in the popliteal artery were generally more challenging compared with the reported SFA cohort. There were more patients with critical limb ischemia RBC 4 and 5 (22.8% vs. 16.8%), also shown by a lower baseline ABI (0.58 vs. 0.68). The likely explanation is that due to the more distal location of the obstruction, patients had poorer collateralization. In addition, the fact that in- and outflow interventions were performed in 22.8% and 23.8%, respectively, of the patients shows that multilevel disease is a typical disease pattern in patients with popliteal artery obstructions.

Despite these challenging clinical conditions, a good clinical effect of the treatment has been demonstrated by an improvement of the mean RBC class from 3.1 at baseline to 1.4 at 1-year follow-up. In fact, the clinical improvement after popliteal stenting was even higher as compared with the SFA cohort and was also supported by a greater improvement of the ABI value (7).

The question of how liberally these novel stents should be used in the popliteal artery is difficult to answer from this initial dataset and certainly requires a randomized head-to-head comparison to other available technologies and treatment strategies, including drug-eluting balloons, which have been shown to have great potential in other areas of the femoropopliteal tract (17–19).

Study limitations. Limitations of the presented data include the retrospective single-arm, single-center design of the analysis. However, the broad clinical spectrum of included cases without pre-specified inclusion and exclusion criteria gives a good "real-world" impression of the performance of the novel SUPERA stent in the popliteal location and is the largest reported cohort to date on stent-based treatment in this vascular bed. Further evidence, in the form of randomized controlled trials, is needed to confirm these first encouraging results.

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Key words: nitinol stent ■ peripheral artery disease ■ popliteal artery disease ■ popliteal artery stenting ■ stent fracture.