Nitinol stent implantation for femoropopliteal lesions: 12-month results

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Objective
To evaluate the 1-year efficacy and safety of the self-expanding nitinol stent in treatment of intermediate femoropopliteal lesions.
Patients and methods
This prospective study included patients with symptomatic (Rutherford grade 2–5) 5–15 cm femoropopliteal artery lesion between July 2014 and July 2016. Study end points were primary patency rate, improvement of Rutherford clinical criteria and ankle brachial indices, major adverse events (MAE), target lesion revascularization, and stent fracture.
Results
The study enrolled 45 patients. Technical success rate 100%. A total of 45 stents were implanted in 45 patients. A single stent was used for each lesion. The primary patency rate at 1 year was 75.5%. The mean Rutherford clinical criteria decreased from 3.84±0.85 at baseline to 0.71±0.84 at 1 year ($P<0.001$). Compared with baseline, a significant improvement in ankle brachial indices was found at 12-month (0.93±0.16; $P<0.0001$) follow-up visits. No MAE were present at 30 days. At 12 months, there was one MAE case that showed target vessel revascularization using angioplasty. Target lesion revascularization at 12 month was 8.9%. Stent fracture at 12 months was 4.4%. All stent fractures were type 1 fracture.
Conclusion
The outcome of the study demonstrates that the self-expanding nitinol stent is effective and safe device for treating intermediate femoropopliteal arterial lesions.

Keywords:
femoropopliteal artery lesion, nitinol stent, peripheral artery disease

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Introduction

Peripheral artery disease (PAD) is common, affecting between 8 and 12 million USA residents [1]. The lower limb is the most common site of PAD [2]. Femoropopliteal segment is the most common site for peripheral arterial atherosclerotic disease [3,4].

Endovascular treatment is commonly performed as an initial treatment of choice for PAD [5]. Endovascular therapy is established as the first-line strategy for femoropopliteal obstructive disease [6].

The femoropopliteal arterial segment is a particularly challenging location for implantation of a permanent endoprosthesis owing to the extreme mechanical forces exerted on these arteries during the activities of daily living [7].

Nitinol stent implantation after balloon angioplasty has been used for the treatment of longer and more complex lesions than in lesions treated with PTA alone [5].

Newer nitinol stents with enhanced flexibility have been developed for femoropopliteal use and may be associated with a reduced rate of stent fracture and improved long-term patency [7].

The aim of this study was to evaluate the 1-year efficacy and safety of the self-expanding (SE) nitinol stent in the treatment of intermediate femoropopliteal lesions.

Patients and methods

This prospective study was carried out in Vascular Surgery Department, Sohag Faculty of Medicine, following approval by the Scientific Ethics Commitee. The study included a series of 45 patients between July 2014 and July 2016.

Patient selection

Eligible participants had the following inclusion criteria:

A documented symptomatic (Rutherford grade 2–5) de-novo occlusion or 50% at least de-novo or restenotic

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stenosis in the superficial femoral artery (SFA) and proximal popliteal arteries with reference vessel diameters of 4–7 mm of an adult patient. The target lesion had to be located with its most distal point maximally 3 cm proximal to the knee joint. Lesion lengths had to be 5–15 cm, with a minimum of one patent runoff vessel present. Treatment of both legs was possible. The patient provides a written informed consent before enrolment in the study.

Patients were excluded if they had the following:

Significant stenosis (50%) or occlusion of the inflow tract (proximal ipsilateral, iliofemoral, or aortic lesions).
Previous stenting or bypass surgery of the target vessel.
No patent runoff vessel.
Aortic/iliac/popliteal aneurysms.
Acute thrombosis in the index vessel.
Venous thrombosis or thrombophlebitis.
Complications of arterial access site in legs within 30 days before the study procedure.
Life expectancy of less than 12 months.
Not completed our follow-up protocol.
Other factors making follow-up impossible.

Preprocedural assessment

All eligible patients underwent a baseline clinical examination with Rutherford clinical category, ankle brachial indices (ABI) measurement, duplex ultrasound examination, and computed tomography angiography.

Preprocedural medication

Patients received clopidogrel (75 mg/day) for at least 3 days before the intervention, otherwise loading dose of 300 mg was given immediately before the procedure.

Procedure

Under local anesthesia, 6-Fr sheath was placed by an antegrade ipsilateral approach or cross-over technique via retrograde contralateral femoral approach. Intravenous bolus of 5000 IU of heparin was administered. The lesions were crossed endoluminally or subintimally with 0.035-inch Glidwire (Terumo Medical Corporation, Somerset, UK) together with 4 or 5-Fr multipurpose diagnostic catheter. Then, the lesions were dilated using an optimally sized balloon. Lastly, nitinol stent deployment was carried out. The stents used for this study were complete SE SFA stent (Medtronic Vascular, Santa Rosa, California, USA). The deployed stents were 1 cm proximally and distally from the target lesion, and the stent sizes were selected to be 1–2 mm larger than the diameter of the reference vessel. Following stent deployment, postdilation was performed according to the physician's discretion. Completion angiography was done to verify technical success of the procedure.

At the end of the procedure, manual compression at the puncture site of the femoral artery was done for inducing hemostasis.

Postprocedural medication

The patients were given aspirin 75 mg/day and clopidogrel 75 mg/day for 3 months.

Follow-up

All patients were evaluated at discharge, 1, 3, 6, and 12 months following intervention by Rutherford categorization, ABI, and duplex scanning. Plain radiograph in straight and bent knee configurations was done for all patients at 12 months to asses stent fracture.

Definitions

Technical success was defined as the ability to implant the stent with angiographic evidence of less than 30% final residual stenosis.

Primary patency refferred to uninterrupted patency with no procedures performed on or at the margins of the treated segment as documented by a peak systolic velocity ratio (PSVR) of more than 2.0 on duplex.

Major adverse events (MAEs) were defined as device-related and/or procedure-related death (or any death occurring through 30 days), as well as target limb loss and target vessel revascularization.

Clinically driven target lesion revascularization (TLR) was defined as procedures (angioplasty or bypass surgery) for ischemic symptoms referable to the target lesion as demonstrated by a decrease in the Rutherford scale by at least one category or at least 0.15 decrease in ankle brachial index (ABI)/toe brachial index (TBI).

End points

The effectiveness end points were as follows:

(1) Primary patency at 1 year.
(2) Clinical improvement that is evident by improvement of Rutherford clinical criteriaby at least one category and ABI by at least 0.15 increase in ABI reading at 12 months.

The safety end points were as follows:

(1) The MAE at 30 days and 1 year.

(2) TLR at 30 days and 1 year.
(3) Stent fracture (assessed by radiography in straight and bent knee configurations) at 12 months.

Statistically analysis

Data are presented as mean±SD for continuous variables and as counts (percentages) for categorical variables. IBM SPSS, (version 19: IBM Coporation, Somer, NY, USA) was used to measures change over time using test for repeated measures. *P* value was considered significant if less than 0.05. The primary patency rates were estimated using Kaplan–Meier method.

Results

Between July 2014 and July 2016, 45 patients with SFA and proximal popliteal artery lesions met the inclusion criteria and were enrolled in the current series.

The baseline characteristics of the study patients

The baseline characteristics of the study patients are shown in Table 1. The mean age of the study population was 67.3±9.3 years. There were 31 (68.9%) men and 14 (31.1%) women.

Baseline vascular risk factors

Vascular risk factors were prevalent. History of smoking was reported in 29 (64.4%) patients, 25 (86.2%) of which were still current smoker. Eighteen (40%) patients had arterial hypertension. Diabetes mellitus was present in 28 (62.2%), hypercholesterolemia in 19 (42.2%), renal insufficiency in four (8.9%), and cerebrovascular stroke in three (6.7%) patients (Table 1).

The preintervention symptoms assessment according to Rutherford clinical category of the limbs

A total of nine (20%) patients had a walking distance 100–250 m (Rutherford category 2), seven (15.5%) patients had a limited walking distance less than 100 m (Rutherford category 3), 13 (28.9%) had rest pain (Rutherford category 4), and 16 (35.5%) had nonhealing arterial ulcers (Rutherford category 5) (Table 1).

Angiographic findings of the study patients

Angiographic findings of the study patients are summarized in Table 1, with 13 (28.9%) cases involving the proximal SFA, 15 (33.3%) cases involving the mid-SFA, 11 (24.4%) cases involving the distal SFA, and six (13.3%) distal SFA lesion extended to proximal popliteal lesion. The lesion length ranged from 8 to 15 cm. Occlusions were present in 53.3% of patients. Calcification was present in 60% of patients.

Procedural results

Technical success was achieved in all 45 patients, and 45 complete SE stents were used to treat the 45 lesions. A single stent was used for each lesion.

Effectiveness assessment

The primary patency rate at the 1 month was 93.3%, at 3 months was 88.9%, at 6 months was 80%, and 12 months was 75.5%. The primary patency rates were estimated using Kaplan–Meier method (Fig. 1).

Clinical improvement determination

It was estimated through improvement of Rutherford class by at least one category, which was 91.1% at 12 month, and through the improvement of ABI by at least 0.15 increase in ABI reading at 12 month, which was seen in 86%.

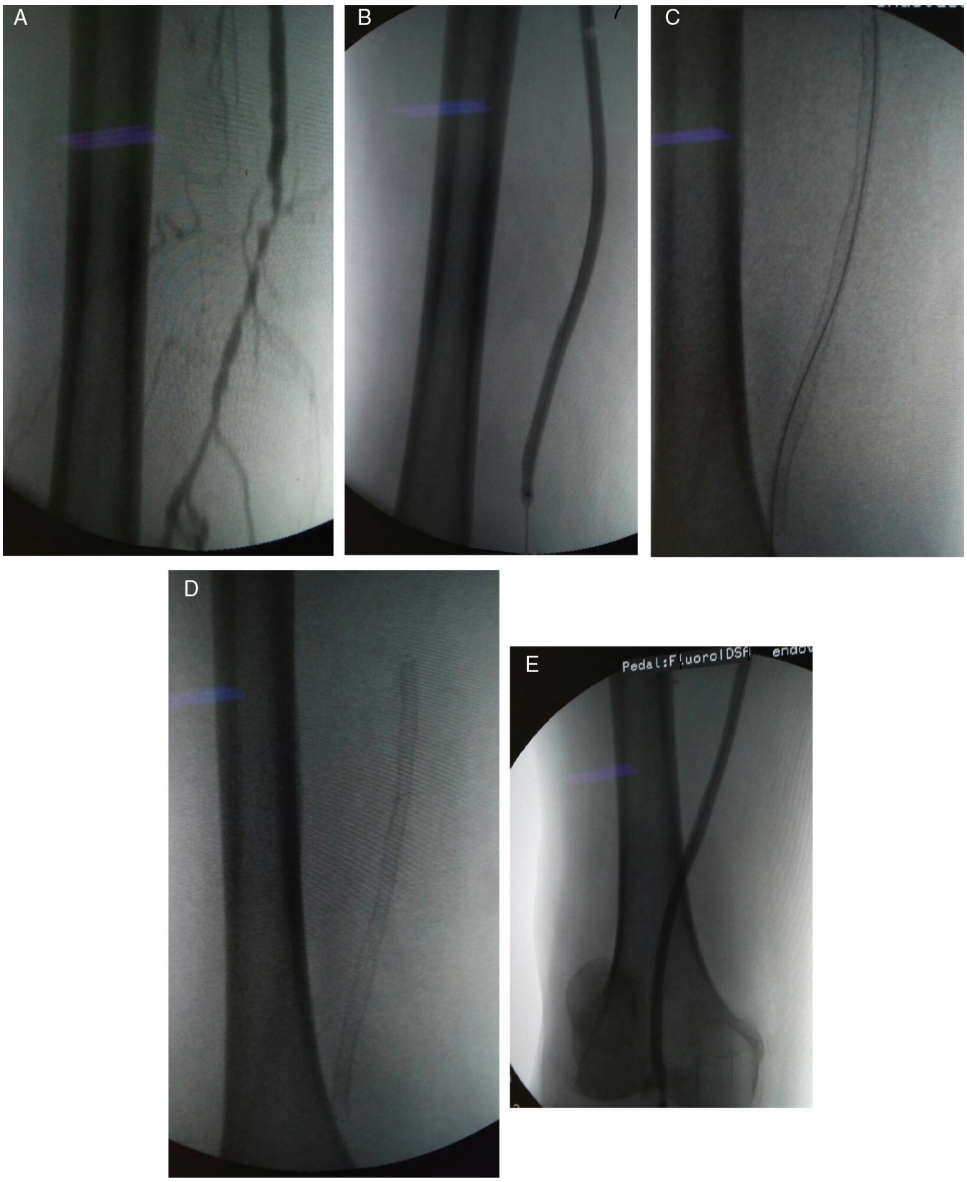
Changes in ABI and Rutherford clinical criteria are summarized in Table 2. Compared with baseline, a significant improvement in ABI was found at the 1-month (0.98±0.12; $P<0.0001$), 3-month (0.97±0.14; $P<0.0001$), 6-month, (0.94±0.15; $P<0.0001$), and 12-month (0.93±0.16; $P<0.0001$) follow-up visits. The mean Rutherford clinical criteria decreased from 3.84±0.85 at baseline to 0.71±0.84 at 1 year ($P<0.001$).

Table 1 The baseline characteristics of the study patients

Total number of patients	45
Demographic characteristics of patients	
Age	67.3±9.3
Males	31 (68.9)
Females	14 (31.1)
Baseline vascular risk factors	
Smoking	29 (64.4)
Hypertension	18 (40)
Diabetes mellitus	28 (62.2)
Hypercholesterolemia	19 (42.2)
Chronic renal failure	4 (8.9)
Cerebrovascular stroke	3 (6.7)
Clinical category of limbs (*N*=45)[a]	
Rutherford criteria+ 2	9 (20)
Rutherford criteria+ 3	7 (15.5)
Rutherford criteria+ 4	13 (28.9)
Rutherford criteria+ 5	16 (35.5)
Angiographic finding of the study patients (*N*=45)	
Proximal SFA lesion	13 (28.9)
Middle SFA lesion	15 (33.3)
Distal SFA lesion	11 (24.4)
Distal SFA lesion extended to proximal popliteal lesion	6 (13.3)
Occlusion [*n*/*N* (%)]	34/45 (75.5)
Calcification [*n*/*N* (%)]	27/45 (60)

Data expressed as the mean±SD value or *n* (%) of patients. SFA, superficial femoral artery. [a]Rutherford classification reference [8].

Figure 1



Kaplan–Meier estimates of primary patency rate.

Safety assessment

The safety assessment measures are summarized in Table 3.

Major adverse events

There were no deaths and limb amputation over 30 days.

There were no deaths and limb amputation over 1 year, but there was one case that showed target vessel revascularization using angioplasty.

Target lesion revascularization

TLR at 12 month was 8.9%. Angioplasty was used for revascularization of three cases, and bypass surgery was used for revascularization of the fourth one.

Stent fractures

Analysis of straight and bent-knee radiographs indicated that there were two (4.4%) stent fractures at 12 months. All stents fractures were type 1 fracture.

Discussion

Endovascular technology has revolutionized the treatment of lower extremity arterial disease over the past decades [9,10].

Stents are commonly used for treatment of femoral and popliteal occlusive disease, particularly for longer lesions [5].

Implantation of nitinol stents into the femoropopliteal segment has become a widely used technique, resulting

Table 2 Changes in ankle brachial indices and Rutherford clinical criteria from baseline to 12 months

	Changes in ankle brachial indices					*P* value
	Baseline	1 Month	3 Months	6 Months	12 Months	
Mean±SD	0.51±0.13	0.98±0.12	0.97±0.14	0.94±0.15	0.93±0.16	<0.0001
	Changes in Rutherford clinical criteria					*P* value
	Baseline	1 Month	3 Months	6 Months	12 Months	
Mean±SD	3.84±0.85	0.33±0.60	0.53±0.82	0.64±0.83	0.71±0.84	<0.0001

Table 3 Safety assessment

Safety assessment	
Major adverse events [*n*/*N* (%)]	1/45 (2.2)
Death	
Through 30 days	0
Through 1 year	0
Limb amputations	
Through 30 days	0
Through 1 year	0
Target vessel revascularization	
Through 30 days	0
Through 1 year	1
Angioplasty	
Target lesion revascularization [*n*/*N* (%)]	4/45 (8.9)
Through 30 days	0
Through 1 year	4
Angioplasty	3
Bypass graft	1
Stent fracture [*n*/*N* (%)]	2/45 (4.4)

in improved clinical outcome over other percutaneous procedures [11].

This article describes our experience on the primary stenting using nitinol stents for treating symptomatic patients with moderate length (5–15 cm) femoropopliteal atherosclerotic lesions. Occlusions were present in 75.5% of patients. Calcification was present in 60% of patients.

The technical success rate (<30% final residual stenosis) in the current study is 100%. The technical success rate in the current study compares favorably with the results in the MISAGO clinical trial, which is similar to our study in dealing with moderate femoropopliteal lesions. Schulte *et al.* [12] reported in MISAGO clinical trial that the technical success rate was 100%. MISAGO clinical trial enrolled implantation of 81 stents in five centers across Europe. Average lesion length was 85± 50 mm, and 64% of the lesions were totally occluded. The technical success rate in the current study is more than that reported in other literature studies [7,13] dealing with similar moderate femoropopliteal lesion length. Larid *et al.* [7] reported in a study, which including 196 patients from 28 centers, dealing with complete SE nitinol stents for obstructive lesions of the SFA or PPA with lesion length of 4–14 cm, acute lesion success rate (<30% residual stenosis) of 90.4%. This may be explained by the presence of moderate to severe calcifications in 91% of lesions. Larid *et al.* [13] reported in RESILENT randomized trial that the acute lesion success rate (<30% residual stenosis) was 95.8% for the stent group. The stent group includes 134 nitinol stents that were used for moderate length lesions (5–17 cm) in the SFA and proximal popliteal lesions.

The 12-month primary patency rate of the current study is 75.5%, which is comparable to the results in the studies by Sabeti *et al.* [14], Larid *et al.* [7,13], Rocha-Singh *et al.* [15], Bosiers *et al.* [16], and Werner *et al.* [11]. All these seven studies are similar in dealing with nitinol stent implantation for moderate femoropopliteal lesions, except for the study by Bosiers *et al.* [16], which dealt with moderate superficial femoral artery lesion only.

Sabeti *et al.* [14] reported that the primary patency rate after 52 nitinol stents implantation for moderate femoropopliteal lesion length 30–100 mm was 75% at 12 months. Overall, 54% of the lesions were occlusions. Primary patency was defined as PSVR more than 2.4.

Larid *et al.* [7] reported that the primary patency rate was 72.6% at 12 months. Primary patency was defined as PSVR more than 2.0. Use of the lower duplex PSVR threshold for restenosis would have no doubt resulted in a lower patency rate.

Rocha-Singh *et al.* [15] reported in meta-analysis study dealing with nitinol stents implantation performed for femoropopliteal lesions a primary patency rate of 72.8% for lesions 43.7–76.8 mm and 69.1% for lesions 76.8–112.3 mm. Primary patency was defined as PSVR more than 2.0 for five studies and 2.5 for one study. Nearly two-thirds of patients had mild to severe calcifications.

Bosiers *et al.* [16] reported in DURABILITY 1 study that the rates for freedom from more than 50% restenosis (defined as PSVR ≥2.5 or angiographic

evidence of more than 50 stenosis) at 12 months were 72.2%. DURABILITY 1 study enrolled 161 stents which were implanted in 151 patients with 10–15 cm superficial femoral artery lesions. Occlusions were present in 40% of patients. Moderately calcified lesions were present in a third of the subjects.

Larid *et al.* [13] reported that the primary patency rate was 81.3% at 12 months in the stent group. Patency definition in this study was based on PSVR of at least 2.5 by duplex or freedom from restenosis more than 50% by arteriography. The stent group includes 134 nitinol stents that were used for moderate length lesions (5–17 cm) in the SFA and proximal popliteal lesions. Occlusions were present in (26/153) of lesions. Moderate and sever calcified lesions were present in (39/153) of lesions.

Werner *et al.* [11] reported in a multicenter nonrandomized SUMMIT study a primary patency rate (defined as PSVR ≥2.5) of 85.1% at 1 year. The SUMMIT study enrolled 100 patients with 9–15 cm femoropopliteal lesions that were treated with EPIC SE nitinol stents. Almost half of the lesions had moderate to severe calcifications.

Matsumura *et al.* [5] reported in Durability II study that the duplex ultrasound patency (defined as PSVR >2.0) rate was 67.7% in evaluable patients at 1 year. Durability II study included 287 patients with more than 4 cm and less than 18 cm SFA and proximal popliteal artery lesions, which were treated with Protégé EverFlex nitinol stent. Occluded lesions were 48.1%, and severely calcified lesions were 43%.

Clinical improvement in the current study was evident by significant improvement of ABI and Rutherford category after stent placement. Compared with baseline, a significant improvement in ABI was found at the 12-month (0.93±0.16; $P<0.0001$) follow-up visits. The mean Rutherford clinical criteria decreased from 3.84±0.85 at baseline to 0.71±0.84 at 1 year ($P<0.001$).

Freedom from TLR after 1 year was 91.1% in the current study. Freedom from TLR after 1 year in the current study lies within the range reported in Werner *et al.* [11] (92.3%), Larid *et al.* [7] (90.8%), Rocha-Sing *et al.* [15] (86.9%), Matsumura *et al.* [5] (86.8%), and Bosiers *et al.* [16] (79.1%).

Stent fracture rate in the current study was 4.4% at 1 year. All the stent fractures were type 1 fracture. Our 4.4% 1-year stent fracture rate falls in between the rates reported in Bosiers *et al.* [16] (7.7%), Larid *et al.* [7] (4.6%), Larid *et al.* [13] (3.1%), Schulte *et al.* [12] (1.7%), Matsumura *et al.* [5] (0.4%), and Werner *et al.* [11] (0%).

Limitations

Limitation included lesion length up to 150 mm only, so for lesions up to 150 mm in length, so the conclusion in this study is limited to this lesion length. Further studies are needed to be done in the future to evaluate nitinol stent for longer SFA lesions more than 150 mm. In addition, the patency rate definition (PSVR >2) may be oversensitive measurement for diagnosis of stenosis, which had a direct effect on the patency rate in this study, especially with presence of other studies that have suggested that a PSVR of more than 2.4 may accurately reflect more than 50% stenosis [17].

Conclusion

The outcome of the study demonstrates that SE nitinol stent is an effective and safe device for treating intermediate femoropopliteal arterial lesions. The results provide additional support for the use of nitinol stents in intermediate femoropopliteal arterial lesions.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Garcia L, Jaff M, Metzger CH, Sedillo G, Pershad A, Zidar F, *et al.* Wire-interwoven nitinol stent outcome in the superficial femoral and proximal popliteal arteries twelve-month results of the SUPERB trial. Circ Cardiovasc Interv 2015; 8:e000937.

2 Zeller T. Current state of endovascular treatment of femoropopliteal artery disease. Vasc Med 2007; 12:223–234.

3 Hertzer NR. The natural history of peripheral vascular disease: implications of its management. Circulation 1991; 83(Suppl 1):I12–I19.

4 McDaniel MD, Cronenwett JL. Basic data related to the natural history of intermittent claudication. Ann Vasc Surg 1989; 3:273–277.

5 Matsumura J, Yamanouchi D, Goldstein J, Pollock C, Bosiers M, Schultz G, *et al.* The United States StuDy for EvalUating EndovasculaR TreAtments of Lesions in the Superficial Femoral Artery and Proximal Popliteal By using the Protégé EverfLex NitInol Stent SYstem II (DURABILITY II). J Vasc Surg 2013; 58:73–83.

6 Rastan A, Krankenberg H, Baumgartner I, Blessing E, Müller-Hülsbeck S, Pilger E, *et al.* Stent placement vs. balloon angioplasty for popliteal artery treatment: two-year results of a prospective, multicenter, randomized trial. J Endovasc Ther 2015; 22:22–27.

7 Laird J, Jain A, Zeller T, Feldman R, Scheinert D, Popma J, *et al.* Nitinol stent implantation in the superficial femoral artery and proximal popliteal artery: twelve-month results from the complete SE multicenter trial. J Endovasc Ther 2014; 21:202–212.

8 Rutherford RB, Baker JD, Ernst C, Johnston K, Porter J, Ahn S, Jones D. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997; 26:517–538.

9 Ansel GM, Lumsden AB. Evolving modalities for femoropopliteal interventions. J Endovasc Ther 2009; 16(Suppl 2):II82–II97.

10 Rogers JH, Laird JR. Overview of new technologies for lower extremity revascularization. Circulation 2007; 116:2072–2085.

11 Werner M, Piorkowski M, Thieme M, Nanning T, Beschorner U, A Rastan, *et al.* SUMMIT registry: one-year outcomes after implantation of the EPIC self-expanding nitinol stent in the femoropopliteal segment. J Endovasc Ther 2013; 20:759–766.

12 Schulte K, Müller-Hülsbeck S, Cao3 P, Becquemin J, Langhoff R, Charalambous N, *et al.* MISAGO 1: first-in-man clinical trial with Misago^{TM} nitinol stent. EuroIntervention 2010; 5:687–691.

13 Laird J, Katzen B, Scheinert D, Lammer J, Carpenter J, Buchbinder M, *et al.* Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery.twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv 2010; 3:267–276.

14 Sabeti S, Schillinger M, Amighi J, Sherif C, Mlekusch W, Ahmadi R, Minar E. Primary patency of femoropopliteal arteries treated with nitinol versus stainless steel self-expanding stents: propensity score-adjusted analysis1. Radiology 2004; 232:516–521.

15 Rocha-Singh K, Beckman J, Ansel G, Lyden S, Schneider P, Mehta M, *et al.* Patient-level meta-analysis of 999 claudicants undergoing primary femoropopliteal nitinol stent implantation. Catheter Cardiovasc Interv 2017.

16 Bosiers M, Torsello G, Gißler H, Ruef J, Müller-Hülsbeck S, Jahnke T, *et al.* Nitinol stent implantation in long superficial femoral artery lesions: 12-month results of the DURABILITY I study. J Endovasc Ther 2009; 16:261–269.

17 Schlager O, Francesconi M, Haumer M, Dick P, Sabeti S, Amighi J, *et al.* Duplex sonography versus angiography for assessment of femoropopliteal arterial disease in a 'real-world' setting. J Endovasc Ther 2007; 14: 452–459.