

## Supplementary Issue: Vascular Disease

### Evaluation of the 4-French Pulsar-18 Self-expanding Nitinol Stent in Long Femoropopliteal Lesions

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#### ABSTRACT

**PURPOSE:** To evaluate the patency and the freedom of target lesion revascularization of the 4-French Pulsar-18 self-expandable (SE) nitinol stent for the treatment of long femoropopliteal occlusive disease in a two-center, prospective, all-comers registry with a follow-up period of 12 months.

**METHODS:** This registry enrolled 36 patients with symptomatic femoropopliteal long lesions for recanalization and implantation of the 4-French Pulsar-18 SE nitinol stent. Routine follow-up examination including duplex ultrasound was performed after 6 and 12 months. Primary patency was defined as no binary restenosis on duplex ultrasound (Peak systolic velocity ratio (PSVR) <2.5) and no target lesion revascularization was performed within 12 months' follow-up. No drug-eluting devices were allowed in this registry.

**RESULTS:** Average lesion length of the femoropopliteal segment was  $182.3 \pm 51.8$  mm. Mean stent implantation length was  $181.5 \pm 35.4$  mm. Total occlusion was present in 46 of the 48 (95.8%) treated lesions. Involvement of popliteal segment I–III was present in 3 (6.3%) lesions. The primary patency after 6 and 12 months was 87.5% and 85.4%, respectively. The clinically driven overall freedom from target lesion revascularization (fTLR) was 89.6% after 6 months and 87.5% after 12 months. ABI, pain-free walking distance and Rutherford category, all improved significantly ( $P < 0.001$ ) after 6 and 12 months. The primary patency rate in patients with diabetes ( $P = 0.18$ ) and renal insufficiency ( $P = 0.3$ ) was not significantly lower as compared to the overall primary patency.

**CONCLUSIONS:** In this two-center, all-comers registry, the use of the Pulsar-18 SE nitinol stent for endovascular intervention of femoropopliteal disease with a mean lesion length of  $182.3 \pm 51.8$  mm showed promising primary patency and fTLR rates after 6 and 12 months. Diabetes and renal insufficiency had no negative impact on the patency rate.

**KEYWORDS:** device evaluation, superficial femoral artery, self-expanding nitinol stent, 4-French device, endovascular therapy

**SUPPLEMENT:** Vascular Disease

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#### Introduction

The increasing prevalence of peripheral artery disease has expanded the use of endovascular therapy with nitinol stent implantation for femoropopliteal lesions during recent years.<sup>1,2</sup> This is reflected in international guidelines such as the TASC II<sup>3</sup> document for endovascular therapy and the European Society of Cardiology<sup>4</sup> recommendations, which underline the benefits of nitinol stents as treatment options in intermediate femoropopliteal lesions.

One of the major advantages of endovascular stent placement over balloon angioplasty is the prevention of elastic recoil of the dilated vessel, the limitation of residual stenosis, and the lower risk of vessel dissection. First-generation nitinol stents had the drawback of stent fractures with high rates of restenosis. Modern-generation nitinol stents for the treatment of femoropopliteal lesions have shown encouraging 12-month patency rates (Resilient trial,<sup>5</sup> MISAGO I<sup>6</sup> and MISAGO II<sup>7</sup> trials, Supera SFA registry,<sup>8</sup>



Zilver PTX Trial,<sup>9</sup> Durability I,<sup>10</sup> and Durability II<sup>11</sup> trials) and long-term freedom from restenosis rates in different prospective trials.

There is also increasing evidence for interventions with modern nitinol stents in long femoropopliteal lesions (TASC C and D lesions according to the TASC II classification) with encouraging patency and safety rates (Durability 200 trial,<sup>12</sup> TASC D – Pulsar-18 registry<sup>13</sup>), including in patients with critical limb ischemia. An intensive discussion regarding stent design is ongoing, where one of the central questions being addressed is whether the 4-French stent systems are equivalent to 6-French systems when treating complex and long femoropopliteal lesions. The use of the Pulsar-18 self-expanding (SE) nitinol stent for endovascular intervention of femoropopliteal disease was investigated in the PEACE I all-comers registry.<sup>14</sup> Patients with a mean lesion length of 111.5 mm showed promising primary patency and freedom from target lesion revascularization (fTLR) rates after 6 and 12 months. These very positive data of this all-comers registry led us to perform a prospective all-comers registry to analyze the patency rate and fTLR rate of this nitinol stent in patients with long SFA lesions.

## Methods

A two-center prospective registry study independent of the already published PEACE I Registry trial<sup>14</sup> was developed to evaluate the patency and fTLR rate of the Pulsar-18 SE nitinol stent in patients with long SFA occlusions >20 cm (TASC D lesions). The study was approved by the ethics committee of the Ärztekammer Westfalen-Lippe, and was conducted in accordance with the principles of the Declaration of Helsinki.

The nitinol stent used in this registry was the nitinol Pulsar-18 Self-Expanding Stent (BIOTRONIK AG, Buelach, Switzerland), which is premounted on a 4-F, 0.018-inch over-the-wire delivery system. The Pulsar-18 is a laser-cut, SE nitinol stent loaded on a low-profile 4F compatible over-the-wire coaxial delivery system. The stent has a flexible, thin-strut, open-cell design with helically aligned peak-to-valley crowns and has six radiopaque markers at each end. It is completely covered with PROBIO coating, an amorphous silicon carbide (a-SiC:H) coating. Revascularization of the occluded SFA was performed using either the subintimal recanalization technique or in the intraluminal way. After passing the guidewire into the true lumen in both recanalization techniques, a predilatation was performed using a correctly sized balloon to prepare for the Pulsar-18 SE stent implantation. After predilatation, stent deployment was successfully performed in all patients. Post implantation of the Pulsar-18 SE stent, all patients received at least clopidogrel and aspirin in combination for 4 weeks. Effective peri-interventional anticoagulation was mandatory with at least 5000 IU of heparin. The recanalization of the femoropopliteal culprit lesion was based on the standard of care of the center. Only the implantation

of the Pulsar-18 SE stent strictly followed the manufacturer's instructions for use. The stent extended over the proximal and distal part of the lesion. Stent overlapping was avoided whenever possible by using the appropriate stent length to cover the entire lesion with a single Pulsar-18 SE stent. As the Pulsar-18 SE is available in lengths of up to 200 mm, only lesions longer than 200 mm required overlapping stents. A successfully deployed stent was defined as a completely unfolded stent with a postimplantation residual stenosis of <30%. At least one patent crural outflow vessel and a noncompromised hemodynamic inflow had to be documented in the angiography to assess the patient's eligibility for this registry. If indicated, an intervention of the inflow and outflow vessel was allowed prior to femoropopliteal implantation of the Pulsar-18 SE stent.

Patients were enrolled in this registry if they met the following inclusion criteria:

- Signed informed consent,
- Patient age  $\geq 18$  years,
- Symptomatic de novo occlusion of the superficial femoral or popliteal artery (Rutherford  $\geq 2$  and  $\leq 5$ ) with occlusion length >15 cm, and
- Reference vessel diameter 4–7 mm.

There was no restriction on lesion length or the maximum number of Pulsar-18 SE implantations. Treatment of both legs was also allowed. Exclusion criteria were the following:

- Pregnancy or breast-feeding,
- Contraindication for postinterventional antiplatelet therapy,
- Treatment of a restenosis within a previously treated vessel segment,
- Target lesion located within a (synthetic) graft, and
- Use of a drug-eluting balloon (DEB) or drug-eluting stent (DES)

Examinations and follow-up were performed at baseline and at 6 and 12 months according to a standard protocol. For the baseline, standard physical examination, blood sampling, assessment of walking capacity, ankle-brachial index (ABI) measurement, and duplex ultrasound examination were performed. After performing a diagnostic angiography, the patient was included in the registry if the decision was made to implant a Pulsar-18 SE stent. Duplex ultrasound with peak systolic measurement, ABI and walking capacity assessment, and Rutherford categorization were required postprocedure and also for follow-up at 6 and 12 months. All complications and adverse events were recorded. The primary endpoints of the PEACE I registry were the primary patency of the Pulsar-18 SE stent at 6 and 12 months after the intervention, defined as a binary duplex ultrasound ratio (peak systolic velocity ratio) <2.5 at the stented target

lesion(s), and fTTLR. Secondary endpoints included determination of the Rutherford scale, measurement of the resting ABI, and assessment of the walking capacity at 6 and 12 months. Safety endpoints were death from any cause and limb amputation.

**Patients.** This registry enrolled 36 patients at two clinical centers in 2011 and 2012, who were followed up after enrollment for 12 months. The patient cohort showed a high prevalence of cardiovascular risk factors, with hypertension in all patients and diabetes mellitus in eight patients (22.2%). Twenty-one (58.3%) patients were current smokers. More than two-thirds of the patients showed a clinical Rutherford stage  $\geq 3$  (Rutherford 3: 52.8%, Rutherford 4: 13.9%, and Rutherford 5: 16.6%). Baseline demographic and clinical characteristics are listed in Table 1.

The baseline angiographic data are summarized in Table 2. A total of 48 Pulsar-18 SE stents were implanted in the 36 enrolled patients. The average length of the target lesions was  $182.3 \pm 51.8$  mm. The mean Pulsar-18 SE stent length was  $181.5 \pm 35.4$  mm.

**Endpoints.** The primary endpoints of this registry were the primary patency of the Pulsar-18 SE stent at 6 and 12 months after the intervention, defined as a binary duplex ultrasound ratio (peak systolic velocity ratio)  $< 2.5$  at the stented target lesion(s) and fTTLR. Secondary endpoints included determination of the Rutherford scale, measurement of the resting ABI, and assessment of the walking capacity at 6 and 12 months. Safety endpoints were death from any cause and limb amputation.

**Statistical evaluation.** Using SPSS statistical analysis package, continuous data are presented as the mean  $\pm$  standard deviation; categorical data are given as percentages (counts/sample). An unpaired *t*-test or chi-square test was used to compare continuous variables or proportions between groups,

**Table 1.** Patients' demographics and comorbidities.

PATIENTS	N = 36
Male	18 (50%)
Age (min/max)	72.1 $\pm$ 10.6
Hypertension	36 (100%)
Dyslipidemia	32 (88.8%)
Current smoker	21 (58.3%)
Diabetes mellitus	8 (22.2%)
Obesity	13 (36.1%)
Renal Insufficiency	4 (11.1%)
Rutherford 2	6 (16.6%)
Rutherford 3	19 (52.8%)
Rutherford 4	5 (13.9%)
Rutherford 5	6 (16.6%)
Ankle – brachial index	0.60 $\pm$ 0.10
Walking capacity (m)	56.1 $\pm$ 34.9

**Table 2.** Lesion description and interventional data.

LESION CHARACTERISTICS	N = 48
Lesion length (mm)	182.3 $\pm$ 51.8
Implanted Pulsar-18 SE stents	48
Stent per patient	1.33
Stent implantation length (mm)	181.5 $\pm$ 35.4
Total occlusion (CTO)	46 (95.8%)
Popliteal segment (I–III)	3 (6.3%)

respectively; statistical significance was set at  $P < 0.05$ . Primary patency and fTTLR were estimated using the Kaplan–Meier method and compared using the log-rank test.

## Results

Between January 2012 and June 2012, a total of 36 patients with TASC D femoropopliteal lesions were successfully treated. In these patients, a total of 48 Pulsar-18 SE implants were implanted, giving a mean implantation rate in this cohort of 1.33 Pulsar-18 SE stents per patient (Table 3). Overall primary patency after 6 months was 87.5%; after 12 months, it was 85.4% (Fig. 1). The overall fTTLR rate after 6 months was 89.6%. After 12 months, the fTTLR was 87.5% (Fig. 1). Primary patency was assessed separately for diabetic and renal insufficiency patients, showing no significant differences in comparison to the overall primary stent patency rate. There was a trend toward higher restenosis rates after 12 months in overlapping stent implantation (Table 1). Clinical improvement was significant after stent implantation (Figs. 2 and 3). The ABI improved significantly after intervention, with an ABI of  $0.60 \pm 0.10$  before the intervention and  $0.92 \pm 0.05$  afterward ( $P < 0.0001$ ); the ABI remained stable after 6 months ( $0.87 \pm 0.11$ ;  $P < 0.0001$ ) and 12 months ( $0.88 \pm 0.08$ ;  $P < 0.0001$ ). In addition, the pain-free walking capacity improved significantly to  $594.1 \pm 339.5$  m ( $P < 0.0001$ ) after 6 months and  $654.2 \pm 419.1$  m ( $P < 0.0001$ ) after 12 months in comparison to the preinterventional walking capacity of  $56.1 \pm 34.9$  m. Likewise, the clinical Rutherford category improved significantly during follow-up (Figs. 4 and 5). Between patients with Rutherford  $< 3$  and  $> 3$  category, there was no significant difference in primary patency (Fig. 6). There were no deaths related to the intervention.

## Discussion

The aim of our registry was to obtain information on the patency of the 4-French stent system in a daily routine setting in long (TASC D) femoropopliteal lesions. This daily routine registry demonstrated a primary patency rate of 85.4% and fTTLR of 87.5% in patients with long SFA occlusion during a follow-up period of 12 months after recanalization and nitinol stent implantation with the Pulsar-18 SE stent. Diabetes and renal insufficiency did not impact the patency rates during follow-up. Possible reasons for these

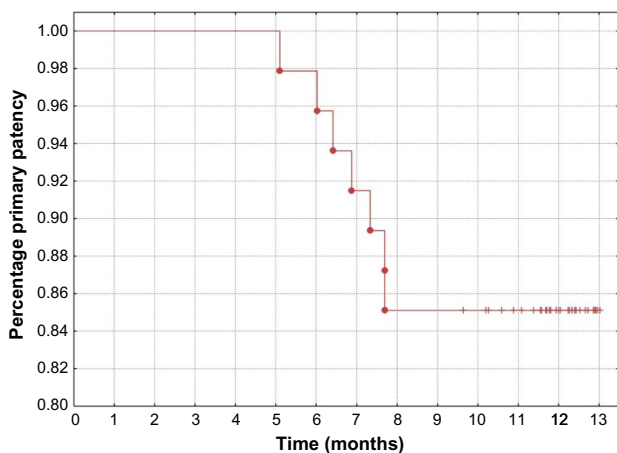


**Table 3.** Outcome measurement and efficacy endpoints.

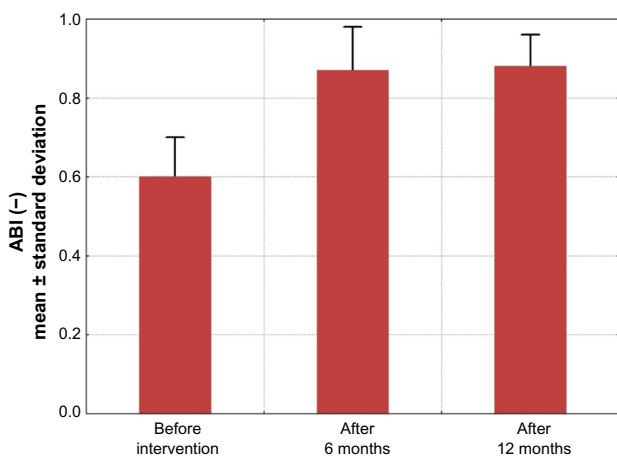
OUTCOME MEASUREMENT AND EFFECTIVENESS ENDPOINT ANALYSIS	6 MONTH FOLLOW-UP	12 MONTH FOLLOW-UP
Overall primary stent patency	87.5%	85.4%
Freedom from target lesion revascularization (FTLR)	89.6%	87.5%
Diabetic patients primary patency	83.8% ( <i>P</i> = 0.31)	81.1% ( <i>P</i> = 0.17)
More than 1 stent (overlapping stent)	81.3% ( <i>P</i> = 0.16)	78.1% ( <i>P</i> = 0.07)
Rutherford category <3	88.2%	85.7%
>3	85.3%	85.7%

encouraging data even in complex lesions in patients with diabetes and renal insufficiency could be partly explained by the thin-strut geometry of the 4-French system, which may reduce inflammatory vessel reaction after implantation. Another potential factor is the PROBIO coating, which reduces platelet activation and aggregation and promotes faster endothelialization. Recently published data of the PEACE I<sup>14</sup> and the 4-EVER<sup>15</sup> trial support our

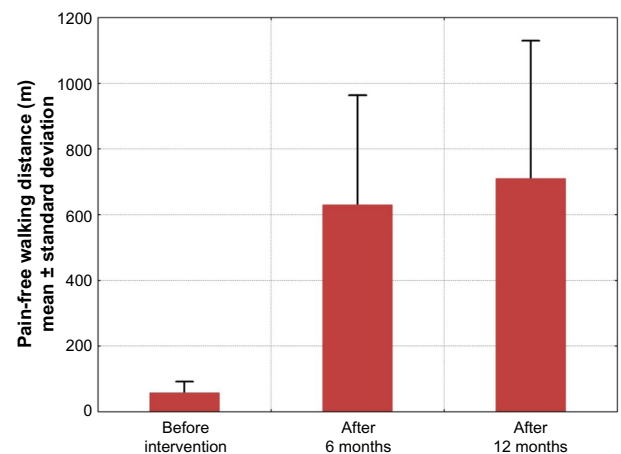
positive outcome data. The PEACE I trial was designed to assess more clinical performance data in an all-comers registry with almost no exclusion criteria besides the use of drug-eluting devices. The average lesion length of the femoropopliteal segment was 111.5 ± 71.4 mm with a primary patency rate after 6 and 12 months of 87.4% and 79.5%, respectively.



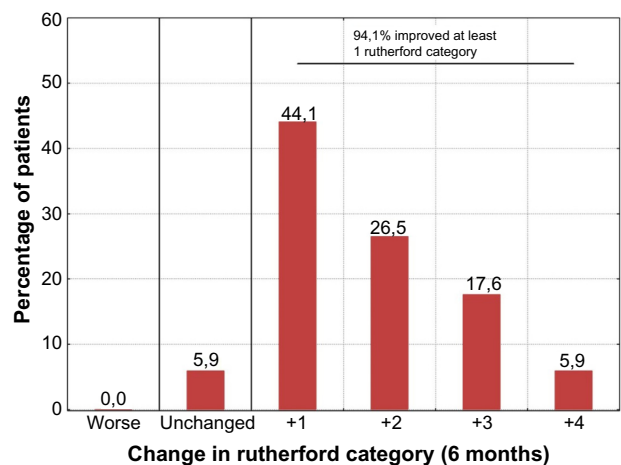
**Figure 1.** Kaplan–Meier estimates of overall primary patency.



**Figure 2.** ABI before intervention and during follow-up.

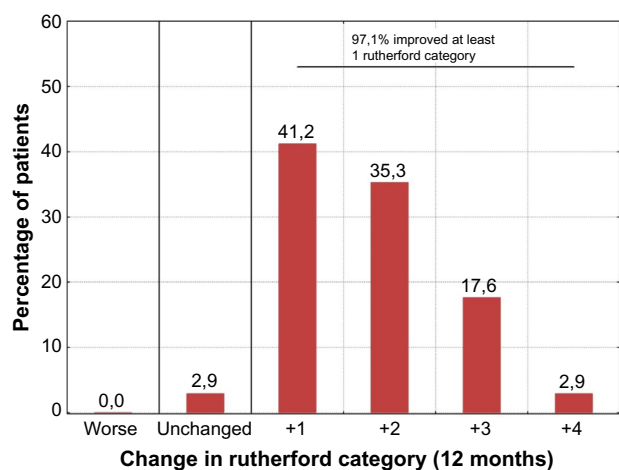


**Figure 3.** Pain-free walking distance before intervention and during follow-up.



**Figure 4.** Clinical improvement by Rutherford category after 6 months follow-up.

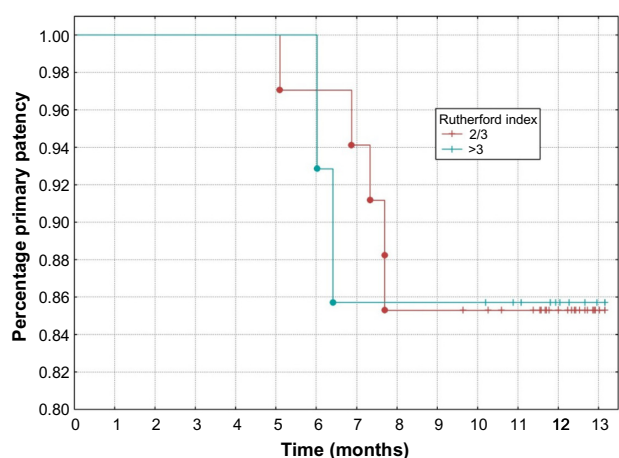




**Figure 5.** Clinical improvement by Rutherford category after 12 months follow-up.

The clinically driven overall fTLR was 93.2% after 6 months and 81% after 12 months. In the 4-EVER<sup>15</sup> trial recently published by Bosiers et al, a primary patency rate of 81.4% was observed excluding femoropopliteal TASC D lesion. A clear reduction in access site complications using the 4-French Pulsar-18 stent was documented in this trial, along with a reduced mean manual compression time of 8.1 minutes in comparison to compression times of 10–22 minutes with 6-French stent systems. Our study group recently published the Superficial femoral TASC D trial,<sup>13</sup> in which we showed that femoropopliteal lesions of up to 315 mm in patients with critical limb ischemia could be safely treated with the Pulsar-18 SE stent, with a primary patency rate of 77% and an fTLR rate of 86% after 12 months. A complete 4-French approach was possible in this trial in 7/22 patients.

Until now, endovascular treatment recommendations for patients with long SFA occlusion did not reach evidence level



**Figure 6.** Kaplan–Meier estimates of primary patency comparing patients with Rutherford category <3 versus patients with Rutherford category >3. No statistically significant difference was documented at 6 and 12 months follow-up.

in international guidelines (TASC II guidelines). On the other hand, recently published interventional registries and studies for different nitinol stent systems showed encouraging patency rates after reopening of SFA occlusions.<sup>5–12</sup> These trials did not focus on TASC D lesions in particular. TASC D lesions were only subgroups in a broad range of indications. The Durability II<sup>11</sup> clinical trial, presented recently, reported a proven stent patency rate of 69.6% in lesions longer than 80 mm with a 12-month stent fracture rate of 0.4%. This study, together with the Durability I<sup>10</sup> trial, clearly demonstrated that accurate stent implantation is imperative for avoiding stent fracture and subsequent associated restenosis. Overlapping stents are at risk for a higher fracture rate, which means that long nitinol stents should be preferred over short, multiple, overlapping stents. The Durability 200 mm trial<sup>12</sup> demonstrated a significant 12% decrease of the primary patency rate after implantation of more than two stents. This could be considered as supporting data to avoid overlapping stents and to use long stents, which are available today up to length of 200 mm, whenever possible. Although we did not analyze the fracture rate of the Pulsar-18 SE stent in our registry, we did not identify any stent fractures in those patients who had target lesion revascularizations. Regarding the potential lower radial force of a 4-F nitinol stent compared to a 6-F stent system especially in calcified lesions, there seems to be no disadvantages, which was proven in the 4-EVER<sup>15</sup> trial as there was no significant lower patency rate in calcified lesions. Lesion preparation (eg, atherectomy, cutting balloon angioplasty, prolonged balloon angioplasty) was mentioned as a key issue in calcified lesion to prepare a lesion for a 4-F, thin-strut nitinol stent. In our registry, every lesion was prepared for the Pulsar-18 SE stent. After successful implantation, the stents were postdilated to nominal diameter even with high-pressure balloons.

To determine if a combination of DEB plus nitinol stent could even increase patency rates, we recently initiated a multi-center prospective all-comers study, the BIOFLEX-PEACE study. We aim to find answer for the following questions: whether spot-stenting plus drug-eluting angioplasty with or without prior atherectomy in calcified lesions can enhance clinical outcomes in this trial. Patients will be followed for up to 24 months.

### Limitations

The limitation of this registry is the two-center design and the small number of patients, which does not allow significant subgroup analysis. We did not use core laboratories for angiography or duplex ultrasound.

### Conclusion

This all-comers registry for long femoropopliteal lesions with a mean lesion length of 182.3 mm proved a safe usage of the Pulsar-18 SE stent in this indication. Diabetes and renal insufficiency had no negative impact on primary patency and TLR rate.



## Author Contributions

Conceived and designed the experiments: ML, BH, MK, W-FS, DB, FB. Analyzed the data: ML, BH, MK, W-FS, DB, FB. Wrote the first draft of the manuscript: ML, BH, MK, W-FS, DB, FB. Contributed to the writing of the manuscript: ML, BH, MK, W-FS, DB, FB. Agree with manuscript results and conclusions: ML, BH, MK, W-FS, DB, FB. Jointly developed the structure and arguments for the paper: ML, BH, MK, W-FS, DB, FB. Made critical revisions and approved final version: ML, BH, MK, W-FS, DB, FB. All authors reviewed and approved of the final manuscript.

## REFERENCES

1. Bradbury AW, Adam DJ, Bell J, et al; BASIL trial Participants. Bypass versus angioplasty in severe ischemia of the leg (BASIL) trial: an intention to treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy. *J Vasc Surg*. 2010;51(5 suppl):5S-17.
2. Goltz JP, Ritter CO, Kellersmann R, Klein D, Hahn D, Kickuth R. Endovascular treatment of popliteal artery segments p1 and p2 in patients with critical limb ischemia: initial experience using a helical nitinol stent with increased radial force. *J Endovasc Ther*. 2012;19(3):450-6.
3. Norgren L, Hiatt WR, Dormandy JA, et al; TASC II Working Group. Inter society consensus for the management of peripheral arterial disease (TASC II). *Eur J Vasc Endovasc Surg*. 2007;33(suppl 1):S1-75.
4. European Stroke Organisation. ESC guidelines on the diagnosis and treatment of peripheral artery diseases: document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries: the Task Force on the diagnosis and treatment of peripheral artery diseases of the European Society of Cardiology (ESC). *Eur Heart J*. 2011;32:2851-906.
5. Laird JR, Katzen BT, Scheinert D, et al; RESILIENT Investigators. 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;3:267-76.
6. Schulte KL, Müller-Hülsbeck S, Cao P, et al. MISAGO 1: first-in-man clinical trial with Misago nitinol stent. *EuroIntervention*. 2010;5:687-91.
7. Schulte KL, Kralj I, Gissler HM, et al. MISAGO 2: one year outcome after implantation of the Misago self-expanding nitinol stent in the superficial femoral and popliteal arteries of 744 patients. *J Endovasc Ther*. 2012;19:744-84.
8. Scheinert D, Grummt L, Piorkowski M, et al. A novel self-expanding interwoven nitinol stent for complex femoropopliteal lesions: 24-month results of the SUPERA SFA registry. *J Endovasc Ther*. 2011;18(6):745-52.
9. Dake MD, Scheinert D, Tepe G, et al; Zilver PTX Single-Arm Study Investigators. Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. *J Endovasc Ther*. 2011;18(5):613-23.
10. Bosiers M, Torsello G, Gissler HM, et al. Nitinol stent implantation in long superficial femoral artery lesions: 12-month results of the Durability I study. *J Endovasc Ther*. 2009;16:261-9.
11. Matsumura JS, Yamanouchi D, Goldstein JA, 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(1):73-83.
12. Bosiers M, Deloose K, Callaert J, et al. Results of the Protégé EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions. *J Vasc Surg*. 2011;54(4):1042-50.
13. Lichtenberg M, Stahlhoff W, Boese D. Superficial femoral TASC D registry: twelve-month effectiveness analysis of the Pulsar-18 SE nitinol stent in patients with critical limb ischemia. *J Cardiovasc Surg*. 2013;54:433-9.
14. Lichtenberg M, Kolks O, Hailer B, et al. PEACE I all-comers registry: patency evaluation after implantation of the 4-French Pulsar-18 self-expanding nitinol stent in femoropopliteal lesions. *J Endovasc Ther*. 2014;21(3):373-80.
15. Bosiers M, Deloose K, Callaert J, et al. 4-French-compatible endovascular material is safe and effective in the treatment of femoropopliteal occlusive disease: results of the 4-EVER trial. *J Endovasc Ther*. 2013;20(6):746-56.