Supera stent implantation for the treatment of isolated popliteal artery disease – systematic review and evaluation of current endovascular strategies

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ABSTRACT:
Introduction: The anatomical location of the popliteal artery is one of the greatest challenges for percutaneous interventions. The biomechanical attributes of the vessel lead to higher rates of restenosis, stent fracture, and occlusion. Some surgeons consider the popliteal artery as a “no stenting zone”. Many specialists favor percutaneous transluminal angioplasty to be the first line of endovascular treatment in the popliteal artery with bail-out stent implantation if the results are suboptimal. The Supera peripheral stent system is a novel stent that has been manufactured with a high degree of flexibility and supposedly might be appropriate for implantation in the popliteal artery.


Methods: As many as 92 articles were found in the databases and after full-text review, 4 studies matched the inclusion criteria and were evaluated.

Results: Primary patency rates of Supera implantation in an isolated popliteal artery at 12 months ranged from 68% to 90%. In all four studies, no stent fractures were observed. Only one study provided longer follow-up than 12 months and evaluated the performance of the Supera stent 36 months after implantation.

Conclusion: In conclusion, mentioned studies show promising and superior to other stent patency rates of the Supera stent regarding popliteal artery lesions. What is more, no stent fracture is promising regarding longer follow-up. However, more studies with longer follow-ups and direct comparison to other methods are required to fully evaluate Supera’s performance in the popliteal artery.

KEYWORDS: endovascular, isolated popliteal artery disease, popliteal artery, Supera stent

ABBREVIATIONS
ABI – Ankle-brachial index
CAD – Coronary artery disease
CLITI – Critical limb-threatening ischemia
DAART – Directional atherectomy with antirestenotic therapy
DCB – Drug-coated balloon
IC – Intermittent claudication
IPAD – Isolated popliteal artery disease
PAD – Peripheral artery disease
PRISMA – Preferred Reporting Items for Systematic Reviews
PTA – Percutaneous transluminal angioplasty
RBC – Rutherford-Becker class
SENS – Self-expanding nitinol stents
TLR – Target lesion revascularization

INTRODUCTION
Peripheral artery disease (PAD) of the lower extremities is the third cause of atherosclerotic morbidity. The first two leading causes are coronary artery disease (CAD) and stroke [1]. The prognosis of untreated critical limb-threatening ischemia (CLTI) remains poor. Even up to 38% of patients left without revascularization require a major amputation (an above-the-knee or below-the-knee amputation) 12 months after diagnosis [2]. The importance of minimally invasive, percutaneous, endovascular treatment is incessantly increasing in order to lower complication rates associated with open surgeries [3, 4]. In the extending list of cases of intermittent claudication (IC) and CLITI endovascular procedures become the first line of treatment. Endovascular devices are being constantly improved and experience is enhancing. As a result, technical and clinical success rates are increasing combined with lower complication rates. Today, not only basic but also combined cases of PAD are performed using endovascular treatment [5]. The femoropopliteal lesions are unique, because of the femoropopliteal artery’s placement in the adductor canal and its intersection with two joints (hip and knee joint). Due to these two factors, the biomechanical stress of the artery is increased. The increased biomechanical stress worsens patency rates. The femoropopliteal segment includes a specific type of lesions which are called isolated popliteal artery disease (IPAD). This anatomical location is one of the most challenging for percutaneous interventions [6]. The biomechanical attributes of the vessel are induced by dynamic flexion of the knee joint and lead to higher rates of restenosis, stent fracture and occlusion. Some interventionists consider the popliteal artery as a “no stenting zone”. Many specialists favor percutaneous transluminal angioplasty to be the first line of endovascular treatment in the popliteal artery with bail-out stent implantation if the results are suboptimal. A major disadvantage of such a procedure is a high rate of restenosis due to neointimal proliferation.
This concept influenced investigators to use self-expanding nitinol stents (SENS) in the popliteal artery as new-generation devices improved the outcomes of this therapy [7–9].

Multiple studies have evaluated the limitations of SENS. Traditional SENS obtain a suitable diameter by inducing exerting outward stress on an artery wall. Additionally, those stents are oversized to make sure that they properly adhere to the vessel wall. These two factors combine with constant irritation of the vessel which can lead to restenosis in the stent [10, 11]. Standard stents are also associated with relatively high rates of fractures especially in the popliteal artery due to little compression resistance. Many vascular specialists do not accept implanting a stent at the popliteal artery because of the risk of stent fracture and restenosis [12].

Although some studies have evaluated placing stents in the popliteal artery, the follow-up time was not sufficient to determine cases appropriate for popliteal artery stenting.

The Supera peripheral stent system (Abbott Vascular) is a novel stent that has been manufactured with a high degree of flexibility and radial strength in comparison to traditional SENS. The implantation of the stent needs no oversizing. Instead, the lesion is oneto-one predilated before placement of the stent. These factors enable implantation of the Supera stent in a challenging environment with an open round lumen and unique mechanical benefits [7]. The Supera stent adjusts better to arterial kinking with knee flexion due to supreme relative radii of curvatures [13]. With one of the greatest distances of translocation, this stent has better resistance to deformation, especially in knee flexion. Although the stent is less deformed during knee flexion, the real-life patency duration and clinical performance must be established.

Most of the studies investigate the patency rates of the Supera stent implanted into the femoropopliteal artery, without highlighting the popliteal artery. The popliteal artery remains underrepresented in those studies. Nevertheless, the results of Supera stent implantation into the popliteal artery were published [8, 14–17].

**OVERVIEW OF THE SUPERA PERIPHERAL STENT SYSTEM**

The Supera peripheral stent is a nitinol interwoven self-expanding stent. It is constructed from six pairs of closed-ended interwoven wires arranged in a helical pattern. Such a construction makes the stent both resistant to fracture and flexible. The stent is premounted on a 6 Fr or 7 Fr delivery system with shaft lengths of 80 cm and 120 cm respectively. The Supera peripheral stent system is compatible with 0.014 or 0.018 guide wires. Four diameters of the stent are manufactured: 4.5 mm, 5.5 mm, 6.5 mm, and 6.5 mm. The reference vessel diameter is respectively 4–4.5 mm, 4.6–5.5 mm, 5.6–6.0 mm, and 5.6–6.5 mm. The lengths of the Supera stent are from 20 mm to 150 mm. Oversizing during deployment is not required and the diameters of the stent match the reference vessel luminal diameter in a 1:1 ratio. Before deployment, the lesion must be pre-dilated. During implantation, special care is required not to elongate the stent, because elongation of the Supera stent leads to reduced compression resistance and, as a result, higher rates of restenosis and target lesion revascularization [18]. The stent implantation system is unique and the stent might be stacked in certain lesion locations. Before implantation, the stent is three times longer inside the catheter and during deployment the Supera stent foreshortens significantly. The delivery system contains a stent driver which enables the contact of a distal end of the stent with the target vessel. The stent is deployed out of the sheath due to further manipulation and the delivery catheter translocates proximally. For detachment of the stent from the delivery catheter, a final deployment stroke is required.

**METHODS**

A systematic review was established according to the 2009 Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement. The literature search included Embase, Cochrane, and PubMed/MEDLINE databases.

The keywords used to search studies were: “supera stent”. The literature search was concluded on 30 November 2021. There were no language limitations.

Two investigators (SS and HS) independently conducted searching of the literature, study selection, data extraction, and quality evaluation.

Criteria of inclusion in the review were:

- original cohort studies,
- isolated lesions in the popliteal artery,
- patients with LEAD, excluding studies with popliteal artery aneurysms.

Studies without information about the characteristics of the population were excluded. Some studies that included both SFA and PA lesions were excluded because information about the characteristics of the population was given in total, without the PA population separately. The results of the literature review are summarized in Fig. 1. An amount of 92 articles were found in the databases and after full-text review, 4 studies matched the criteria mentioned previously.

**RESULTS**

Several retrospective studies were registered that investigated the outcomes of Supera stents’ implantation to the popliteal artery. Although none of these studies were randomized some conclusions can be drawn. Most of the studies including the Supera stent do not divide the group of patients with IPAD and investigate femoropopliteal disease.

Goltz et al. reported the outcomes of Supera implantation to the popliteal artery in 40 patients using 51 stents. All procedures were performed between February 2009 and March 2011. The mean ankle-brachial index (ABI) increased from 0.37 to 0.91 at 12 months’ follow-up. During the follow-up, two major and three minor amputations were performed which makes a rate of limb salvage of 95%. This study included many total occlusions of 87.5% which resulted in a low 1-year patency rate, of 68%. Additionally, after 1 year of follow-up, no stent fractures were observed [16].
The next study that was published in 2013 included 39 stent implantations between February 2008 and December 2010 in 34 patients. The stent length ranged from 40 to 240 mm with a mean value of 119 mm and 56.3% of patients had >100 mm of artery stenting. Mean ABI improved from 0.7 to 1 after the procedure. Primary patency rates and primary assisted patency rates were 79.2% and 88.1% respectively after 12 months of follow-up (6 patients were detected with occlusion of the stent). At 17.2 ± 6.2 months of follow-up, no stent fractures were found [17].

Leon et al. conducted a study with 101 patients who underwent procedures including the popliteal artery using 125 Supera stents. Stents with a mean length of 84.3 mm covered lesions with a mean length of 58.4 mm. The statistics of calcification of treated arteries were performed, dividing the calcification process into three degrees: mild, moderate, and severe. In 51.5% of the cases, calcification was either moderate or severe. The total occlusion rate of the lesions was similar to most of the described studies and was 47.5%. Technical success (<30% of residual stenosis) was observed in 98% of the patients. Ten patients died between stent implantation and 12 months after the procedure, with only one death related to vascular disease. The primary and secondary patency rates at 12 months were respectively 87.7% and 96.5%. The mean Rutherford-Becker class (RBC) decreased from 3.1 ± 1.0 before implantation of the stent to 1.4 ± 0.8 at 12 months. ABI increased from a mean value of 0.58 to 0.97. Changes of these two parameters were significant and the P-value was < 0.001. Radiographs of 51 patients after a mean of 15.2 months of follow-up revealed absence of stent fractures in all cases [8].

From studies describing implantation of the Supera stent in IPAD, San Norberto et al. achieved the longest follow-up, which was 3 years. Forty-six patients were involved in the study with 50 limbs treated with the Supera stent. The most popular indication for the procedure was tissue loss. In most of the cases, only one stent was implanted (61.7%), what is more, two stents were implanted in 11 cases and three stents in 7 cases, which gives a total number of 74 stents. At 12 months, a mean ABI improved to 0.63 in relation to 0.38 before intervention. Primary patency rates estimated by Kaplan Meier curves at 3, 6, 9, and 12 months were 95.9%, 91.7%, 89.6%, and 89.6%, and primary assisted patency rates were 95.9%, 93.8%, 93.8%, and 93.8%, respectively. Additionally, this study, as an exception, included data from a longer follow-up, which was 2 and 3 years, with primary patency rates of 72% and 70% respectively. Severe calcification was found in 40% of cases. In the most popular P3 segment of the popliteal artery, 64% of the stents were implanted. Similar to other described studies, 0 stent fractures were found at 1-year follow-up [14].

**DISCUSSION**

To date, treatment of isolated popliteal artery lesions remains unclear, with few studies evaluating endovascular options of therapy. The methods that have been evaluated in the literature are: percutaneous transluminal angioplasty (PTA), directional atherectomy with antirestenotic therapy (DAART), drug-coated balloon (DCB) angioplasty, cryoplasty and stent implantation. The strategy of, “leaving nothing behind” which includes: PTA, DCB angioplasty and DAART can be beneficial in the high-mobility region of the knee joint. Nevertheless, longer and calcified lesions might be less suitable for DCB and might require stent implantation.

**PTA**

This is an acceptable method to be performed in isolated PA lesions, thanks to its minimally invasive character. However, in many studies, patency rates remain unsatisfactory and inferior to stenting and DAART [19–21]. Primary patency rates of PTA at 1 year ranged between 45%- and 73%. What is more, DCB was found superior to conventional PTA in many randomized control trials involving femoropopliteal disease [6].
Cryoplasty

Cryoplasty is a technique that is based on delivering cold thermal energy during angioplasty to prevent initial technical failure by dissection or recoil and the late restenosis caused by negative remodeling and neointima formation. Midterm results of the COLD study established that cryoplasty as a primary treatment strategy in PA has a higher rate of dissection and lower initial anatomic success rate as compared to PTA with optional long-term dilation. Cryoplasty technique showed a tendency for increased long-term results but the differences were not significant and further studies are required to fully evaluate the technique [22, 23].

DAART

Several studies have been established to evaluate the performance of directional atherectomy, mainly in comparison to DCB. Those studies evaluated the safeness of directional atherectomy and the superiority of DAART over DCB. The superiority of DAART over DCB was exceptionally visible in long and highly-calcified lesions located in PA which was evaluated in the DEFINITIVE LE trial [19, 24]. What supposedly influences better patency rates in DAART, is the mechanism of better penetration of paclitaxel to the arterial wall due to primary preparation of the vessel. Moreover, despite the more invasive nature of atherectomy, a significantly higher incidence of complications, such as aneurysm formation, artery injury and distal embolization was not observed in the recent literature [6, 19, 20, 25].

DCB

Drug-coated balloons’ surface is covered with paclitaxel (with antiproliferative effects) which enables transfer of the drug to the arterial wall and inhibits restenosis with reduced loss of the lumen after the procedure [26, 27]. There is no much evidence on DCB angioplasty success in IPAD. However, DCB has been a part of some studies evaluating other methods of managing lesions in this region. DCB is considered as a part of “leaving nothing behind” strategy that increases the chances of future treatment options.

Popliteal artery stent occlusion can affect target vessels in patients who may require a subsequent lower extremity bypass. This should be considered when performing stenting [28]. According to Stavroulakis et al., DCB had lower 12-month primary patency rates than DAART, i.e. 65% vs. 82%, respectively. However, freedom from target lesion revascularization (TLR) was comparable in both groups [6]. More dedicated studies are required to fully evaluate DCB performance in IPAD.

Stenting

There is little evidence regarding stent implantation in IPAD, mainly due to the fact that most researchers combine SFA and PA in their reports: the RESILIENT [29], VIATOR [30], VIPER [31], ZILVER PTX trials [32]. Therefore, it is hard to extract data about stenting of PA. In a small study, with bailout (provisional) stent implantation in IPAD, encouraging results were achieved. One-year and two-year primary patency rates were 81% and 74% respectively, after implantation of balloon-expandable tantalum stents. The decision to perform stenting was based on maintained residual stenosis greater than 50% after PTA [33]. The first prospective, randomized trial comparing stenting and conventional PTA was the ETAP trial. As many as 246 patients were enrolled to ETAP, and 183 individuals were available for a 2-year follow-up. Primary patency rates were superior in the stent arm, however, no significant difference was achieved in freedom from TLR when provisional stenting was not considered as TLR. The stent used in this trial was self-expanding, nitinol Lifestent (Bard Peripheral Vascular, Tempe, AZ, USA). Nevertheless, 2-year results of this study suggest shift to higher patency rates in primary stenting. Furthermore, 2-year patency rates were unsatisfactory for Lifestent and PTA (64.1% vs. 56.1%, respectively) therefore supposedly novel stent studies are required [34]. Parthipun et al. evaluated the results of TIGRIS novel stent implantation in IPAD. A group of 48 individuals was enrolled in the study. The Gore TIGRIS stent (W.L. Gore & Associates, Inc., Flagstaff, Arizona, USA) is constructed from a single-wire nitinol stent interconnected by a durable, biocompatible, ePTFE structure. The interconnecting structure has a heparin-bonded surface. Primary patency rates achieved at

<table>
<thead>
<tr>
<th>STUDY NAME</th>
<th>NUMBER OF PATIENTS</th>
<th>CLAUDICANT, %</th>
<th>CLTI, %</th>
<th>MEAN LESION LENGTH, MM</th>
<th>MODERATE OR SEVERE CALCIFICATION, %</th>
<th>OCCLUDED SEGMENT, %</th>
<th>PRIMARY PATENCY AT 1YR, %</th>
<th>PRIMARY PATENCY AT 2YR, %</th>
<th>PRIMARY PATENCY AT 3YR, %</th>
<th>STENT FRACTURE AT 1YR, %</th>
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<td>25</td>
<td>75</td>
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<td>68</td>
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<tr>
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<td>26</td>
<td>74</td>
<td>119</td>
<td>-</td>
<td>44</td>
<td>79</td>
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<tr>
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<td>23</td>
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<td>36</td>
<td>64</td>
<td>112</td>
<td>64</td>
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CLTI—Chronic limb threatening ischemia

Tab. I. Summary of studies of SUPERA stents implanted in the popliteal artery.

Tab. II. Demographics and comorbidities in studied populations.

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<tr>
<th>STUDY NAME</th>
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<th>MEN</th>
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<th>CAD</th>
<th>HYPERLIPIDEMIA</th>
<th>DIABETES MELLITUS</th>
<th>CHRONIC RENAL FAILURE</th>
<th>CEREBROVASCULAR DISEASE</th>
<th>SMOKING</th>
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CAD—Coronary artery disease
12 months were 69.5 ± 10.2% with 86.1 ± 5.9% freedom from TLR and 87.0 ± 5.0% amputation-free survival [35]. In another study, researchers achieved superior primary patency rates at 12 months: 85.5%. However, most of the lesions in this research were located in SEA [36].

Open surgery

Our study focused mainly on endovascular treatment. However, open surgical methods are often the treatment of choice and should be assessed for complete description of the management of popliteal artery disease, including popliteal aneurysms. Open surgical repair can be divided into 2 methods: bypass grafting and endarterectomy. However, endarterectomy is performed less often [37]. When it comes to bypass grafting, the conduit that is used can be a vein graft or synthetic prosthesis. Nevertheless, vein grafts remain superior compared to PTFE grafts. Patency rates were significantly higher in vein bypass grafts compared to PTFE grafts, even if no great saphenous vein was used [38–40]. BASIL trial compared vein bypass surgery and PTA of lesions located in the femoropopliteal region in severe ischaemia patients. The conclusions from this study stated that patients with longer estimated survival time should be subjected to bypass surgery. On the other hand, patients without an available vein for bypass and shorter estimated survival time should have PTA first [41, 42].

When it comes to popliteal artery aneurysm repair, the primary patency rate of great saphenous vein bypass graft at 5 years was established to be between 77–100% [43]. Huang et al. compared vein bypass graft and PTFE bypass graft and established primary patency rate at 5 years to be 85% and 50% respectively [44]. Open surgical therapy is associated with higher 30-day mortality rate. However, long-term patency rates remain higher when compared to endovascular treatment [45]. To fully establish the treatment of choice (open surgery or endovascular treatment), prospective randomized trials are required.

CONCLUSIONS

In conclusion, the above mentioned studies show promising and superior to other stent patency rates of the Supera stent regarding popliteal artery lesions. However, all the data were gained retrospectively. What is more, the follow-up duration is unsatisfactory, and in most of the studies it was only 12 months. Only San Norberto et al. obtained 3 years of follow-up. No study directly compares the Supera stent with DAART, DCB or other stent platforms in popliteal artery disease. For better understanding of the discussed subject, some prospective studies are required, with longer follow-ups and comparing Supera stent implantation with DAART, DCB, and other stent platforms.

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