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REVIEW ARTICLE

Mid and long-term results of the Supera® stent in femoropopliteal obstructive disease: a comprehensive analysis of the literature

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ABSTRACT

INTRODUCTION: The femoropopliteal biomechanical characteristics make the endovascular treatment of complex lesions particularly challenging. Despite several studies reporting longer patency of femoropopliteal stenting when compared to balloon angioplasty, long-term outcomes are still marginal due to the high rate of restenosis, stent fracture, and thrombosis. This study aims to review the current literature on the outcomes of the endovascular treatment of the femoropopliteal sector with the Supera® stent.

MATERIALS AND METHODS: A literature search was carried on the PubMed database using the search terms ["Supera" AND "femoropopliteal"]. Prospective and retrospective original studies were selected after title and abstract analysis. A comprehensive narrative review was constructed using the selected publications as references.

RESULTS: Thirteen studies were analyzed, comprising a total of 1441 limbs with femoropopliteal obstructive disease treated with the Supera® stent. The 12-month primary-patency rate (PPR) ranged from 72.6% to 94.1%, the 24-month PPR ranged from 60.8% to 83.1% and the 36-month PPR ranged from 69.5% to 76.7%. For high-complexity anatomies, including TASC C and D lesions, the 12-month PPR was >64%. There were no stent fractures reported in any of the included studies.

CONCLUSION: The Supera® stent showed promising results for the endovascular treatment of the femoropopliteal sector, highlighting its performance in high-complexity anatomic patterns.

Keywords: Endovascular; implantomimetic stent; peripheral artery disease; femoropoliteal

INTRODUCTION

The femoropopliteal biomechanical characteristics' make the endovascular treatment of complex obstructive lesions particularly challenging.[1-5] Among the diverse treatment options available, the biomimetic Supera® stent has shown promising results in improving patency rates and a compelling body of evidence has emerged in order to evaluate its efficacy.[4,6-9] The purpose of this review is to provide an overview of the existing evidence on the "real-world" performance of the implantomimetic stent Supera®, with liberalized treatment indications.

MATERIALS AND METHODS

A literature search was carried out on the PubMed database using the search terms ["Supera" AND "femoropopliteal"]. Only full-length articles published in English were considered. No period restrictions were imposed.

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Selection of relevant studies was performed by title and abstract analysis. After this first selection, full text reading was performed, and the inclusion and exclusion criteria for this review were applied. Inclusion criteria included 1) retrospective or prospective original studies regarding 2) patients with femoropopliteal obstructive disease 3) treated with the implantomimetic stent Supera, 4) reporting stent patency rates. Literature reviews, case reports, technical notes or studies not reporting patency rates were excluded.

The main outcome was the assessment of the global primary patency rate after stent deployment. Subgroup analyses of stent effectiveness in different anatomical disease patterns and rate of stent fracture were considered secondary outcomes

RESULTS

Thirteen studies published between 2014 and 2022 and encompassing 1441 limbs with femoropopliteal obstructive disease treated with the Supera® stent were considered. A summary of the main characteristics of each study is presented in Table 1.

Table 1. Characteristics of included studies, concerning patients with femoropopliteal lesions treated with the Supera® stent.

Authors	Year of publication	Study design	Sample size (n)	TASC C-D
George et al.[7]	2014	Retrospective single-center	98	38
Brescia et al.[14]	2015	Retrospective single-center	54	42
Garcia et al.[17]	2015	Prospective multicenter	243	15
Palena et al.[18]	2016	Prospective single-center	34	34
Montero-Baker et al.[15]	2016	Prospective single-center	147	90
Myint et al.[12]	2016	Retrospective single-center	111	58
San Norberto et al.[1]	2020	Prospective single-center	50	32
Low et al.[16]	2021	Retrospective single-center	72	35
Guzzardi et al.[3]	2022	Retrospective multicenter	105	60
Van Meirvenne et al[11]	2022	Retrospective single-center	136	86
Yang et al.[34]	2022	Retrospective single-center	260	166
Gostev et al.[19]	2022	Retrospective single-center	113	113
Nasr et al.[13]	2022	Retrospective multicenter	48	48

Fifty-three percent (n=767) of the lesions corresponded to TASC C and D disease patterns. By the 12th month of follow-up, the primary patency rate (PPR) ranged from 72.6% to 94.1%. The evaluation at the 24th month, conducted in five studies, revealed PPR values ranging from 60.8% to 83.1%. Additionally, four studies reported the 36-month PPR, which ranged from 69.5% to 76.7%, Table 2.

Table 2. Main outcomes of included studies, concerning patients with femoropopliteal lesions treated with the Supera® stent.

Authors	PPR12M	PPR24M	PPR36M	Amputation rate
George et al.[7]	85,80%	NR	NR	0
Brescia et al.[14]	85,60%	83,10%	76,70%	NR
Garcia et al.[17]	86,30%	NR	NR	0,4%
Palena et al.[18]	94,10%	NR	NR	12-month FDMA 97,1%
Montero-Baker et al.[15]	89,80%	NR	NR	5,4%
Myint et al.[12]	78,90%	NR	NR	2,2%
San Norberto et al.[1]	89,60%	72,30%	70,20%	NR
Low et al.[16]	85%	82%	75%	NR
Guzzardi et al.[3]	83,10%	74,30%	69,50%	NR
Van Meirvenne et al.[11]	72,60%	60,80%	NR	NR
Yang et al.[34]	80,60%		NR	NR
Gostev et al.[19]	72,70%	68,90%	NR	24-month LS 90,9%
Nasr et al.[13]	NR	77,90%	NR	NR

FDMA: freedom from death and major amputation; **LS:** limb salvage; **NR:** not reported; **PPR12M:** 12-month primary patency rate; **PPR24M:** 24-month primary patency rate; **PPR36M:** 36-month primary patency rate.

The influence of lesion complexity was evaluated in several studies. San Norberto EM. et al[10] identified TASC D lesions as a predictor for restenosis. Similarly, Van Meirvenne E et al.[11] reported reduced PPR for TASC C and D lesions when compared to TASC A-B (TASC A-B 12PPR of 86% and 24PPR of 75,4% vs. TASC C-D 12PPR of 64% and 24PPR of 51,1%, p=0,001). Myint M et al.[12] further demonstrated the negative impact of lesion length and complexity on prognosis, presenting lower PPR for stents deployed after chronic total occlusion (CTO) recanalization and for lesions with stent coverage exceeding 120mm (12PPR of 66,3% for >120mm stent coverage vs. 93,3% for <120mm; 12PPR of 84% for stents deployed after CTO recanalization vs. 93,1% after stenosis angioplasty). On the other hand, several other studies didn't find clear association between length and complexity of lesions and inferior outcomes. The recently published STELLA-SUPERA Trial[13] included exclusively TASC C and D lesions, with a 24-month PPR of 77,9%. Moreover, Brescia AA et al.[14] showcased a superior PPR for TASC C-D (80,1% PPR) lesions when compared to TASC A-B (75% PPR). Montero-Baker M et al.[15] and Low J et al.(16) also didn't find association between TASC staging and PPR and Guzzardi G et al.[3] described similar patency rates for longer lesions with stent coverage >180mm (PPR 87,5%, 72,4% and 68,9% by the 12th, 24th and 36th months, respectively). Only four studies[7,12,15,17] reported the amputation rate after treatment, ranging from 0 to 5,4%; Palena L et al.[18] reported a composite outcome of freedom from death and major amputation of 97,1% by the 12th month of follow-up and Gostev A et al.[19] reached a 90,9% 24-month limb-salvage rate. There were no stent fractures reported.

DISCUSSION

The compilation of results demonstrates high effectiveness of the interwoven nitinol stent Supera® in the treatment of femoropopliteal obstructive disease, including considerable number of TASC C and D lesions, with primary patency rates reaching 94% at 12 months and 77% at 36 months.

According to the Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia, in high-complexity lesions, classified by the Global Limb Anatomic Staging System (GLASS) as stage III, the endovascular treatment has an estimated immediate technical failure >20% and one-year limb-based patency <50%[20]. However, in the absence of an adequate autologous conduit or if high surgical risk, the endovascular treatment may be the only revascularization approach. In the setting of advanced lesion complexity (GLASS FP grade 2-4) adjuncts to balloon angioplasty (stents or drug-eluting devices) may be considered (recommendation 6, grade 2, level of evidence B).[20] Despite several studies reporting longer patency of femoropopliteal stenting when compared to balloon angioplasty[21-27], long-term outcomes are still marginal due to the high rate of restenosis, stent fracture, and thrombosis.[2,28-30] Grenville J et al.[31] reports a 12 and 24-months PPR of 55,3% and 38,2% for plain balloon angioplasty (PBA) as first strategy for TASC C and D femoropopliteal lesions and bare metal stents (BMS) have shown a 24-month PPR of 45%.[32] Drug-coated balloons (DCBs) and drug-eluting stents (DESs) may overcome those suboptimal results, but the long-term sustained benefit remains unclear. In a comparison between DESs and DCBs, Bausback Y et al.[33] reports a 12-month PPR of 79% for DESs and 80% for DCBs (with or without bailout stenting), but decreased to 54% and 38%, respectively, by the 36th month. The Supera® stent, with its biomimetic interwooven nitinol conformation, has shown promise in improving results.[4,6-9] The literature reports a 12-month PPR ranging from 72,6% to 94,1%[1,3,7,11-18,34], with sustained results by the third year of follow-up (PPR 69,5%-76,7%).[1,3,14,16] Despite some studies reporting worst outcomes for high-complexity anatomies[1, 11, 12], the 12-month PPR is still >64% for this subgroup. Those findings were not corroborated by other centers[3,14-16] and the "Supersub Study"[18], including exclusively TASC C and D lesions with a mean stented length of 279±12mm, reports a 12-month PPR of 94,1%; also, the recently published "STELLA-SUPERA Trial"[13] (exclusively TASC C and D lesions with a mean stented length of 273±127mm) reports a 24-month PPR of 77,9%. Nonetheless, a successful recanalization remains a major obstacle, requiring high technical skills; even in this scenario, the need for subintimal recanalization don't seem to impair the effectiveness of this stent.[18] A recently published observational study[19] comparing patients with symptomatic long (>20cm) occlusive lesions treated with Supera® (n=113) vs. bypass (n=263, with 71,1% prosthetic grafts) reports a 24-month PPR of 68,9% and 68,5%, respectively. Interestingly, the subgroup analysis showed similar results between Supera® (n=44, 24PPR 70,4%) , autologous vein bypass (n=13, 24PPR 67,5%; p=0,15) and PTFE graft bypass (n=67, 24PPR 67,2%; p=0,83) for above the knee interventions but a significant improved patency of the interwoven nitinol stent over the prosthetic graft bypass for below the knee revascularization (Supera®: n=30, 24PPR 66,7%; autologous vein bypass: n=22, 24PPR 77,2%, p=0,3; PTFE graft bypass: n=32, 24PPR 42,4%; p=0,046). The stent extension to the popliteal sector, under constant exposure to biodynamic forces (compression, torsion, rotation, flexion and extension) would presumably hold higher risk of stent stenosis, fracture and thrombosis. Supera®'s unique interwoven nitinol conformation provides greater radial strength, flexibility and fracture resistance[4, 6-9] and the stent extension to the popliteal sector appears to be safe without compromising efficacy.[1,15,16,19] The reported 2-year incidence of stent fracture ranges between 20-46%,[35] with an increased risk after chronic total occlusion (CTO) stenting.[32] There were no stent fractures reported among de 13 studies, which included 1441 treated limbs, supporting the advantages of the single string interwoven conformation over the conventional nitinol stents.

In conclusion, the Supera® stent showed promising results for the endovascular treatment of the femoropopliteal sector, highlighting its performance in high-complexity anatomic patterns.

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