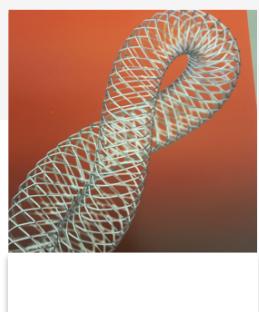


# Endovascular treatment of femoropopliteal disease with Supera stent: a real-world experience.

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**Objective:** To evaluate the safety and the maintenance of patency during one year of the Supera interwoven nitinol stent in a real-world population with superficial femoropopliteal arterial disease.



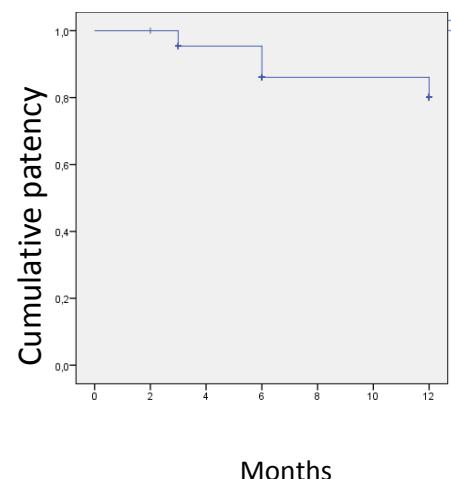
This interwoven nitinol stent is resistant to compression, and its helical shape is designed to adapt to arterial anatomy, making its use possible in difficult-to-treat femoropopliteal lesions, highly calcified vessels, and large lesions. The Supera stent offers outstanding flexibility and kink resistance to withstand the challenging environment of the SFA and proximal popliteal

**Methods:** This multicenter, non-randomized single-arm, prospective study included 110 patients (mean age 69.6±9.4 years) enrolled among 7 hospitals with lifestyle limiting claudication or ischemic rest pain in the femoropopliteal vessels lesions for stenoses or occlusions, including calcifications, previously evaluated with duplex ultrasound. Demographic features and risk factors were registered.

The inclusion criteria were patients with lifestyle-limiting claudication or ischemic restpain, ischemic ulcers [Rutherford-Becker classification (RBC) 3-6] in the femoropopliteal vessels, lesions, stenoses, or occlusions, including calcifications, previously evaluated with duplex ultrasound.

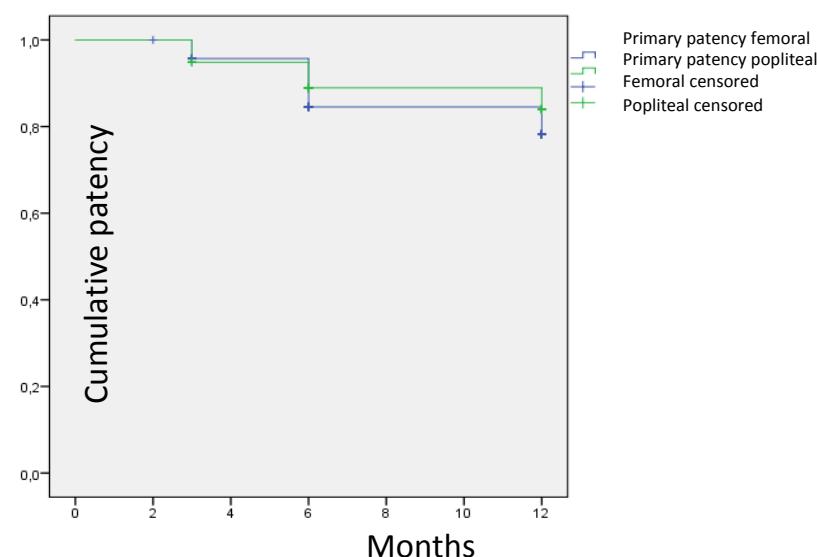
Months	0-<3	3-<6	6-<12	12
<b>N at risk</b>	110	104	83	54
<b>N lost</b>	5	9	4	0
<b>N censored</b>	1	12	25	54
<b>% patency</b>	95,4	86,1	80,1	89,1
<b>Std. Error</b>	0,02	0,035	,0,43	0,43

**Results:** The study results were analyzed by an independent data analyst with access to the primary data. The primary and safety endpoints were based on the intent-to-treat patient population.



Angiographic characteristics and procedure

N=110 patients	
<b>Vessel location</b>	
Distal SFA	56 (50.9%)
Middle SFA	13 (11.8%)
Proximal SFA	2 (1.8%)
Popliteal artery	39 (33.5%)
<b>Vessel run off</b>	
0	2 (1.8%)
1	31 (28.2%)
2	44 (40%)
3	30 (33%)



Mean lesion length was 105.6±52.9 mm. Primary patency rates at 3, 6 and 12 months were 95.4%, 86.1%, and 80.1%, respectively.

The mean ABI measurement increased from 0.27±0.19 before stent implantation to 0.81±0.28 at 12 months (P<0.001).

The mean Rutherford-Becker category decreased from 4.35±0.85 at baseline to 2.09±1.31 at 12 months (P<0.001).

Stent implantation was successful in all patients, no stent fractures were observed on follow-up in our serie.

Calcification	
No	0,9%
Mild	16,4%
Moderate	52,7%
Severe	33%

**Conclusions:** Based on our experience with seven operators at seven clinical centers over 1 year, the treatment of femoropopliteal artery lesions with the interwoven self-expanding nitinol SUPERA stent in patients with intermittent claudication or critical ischemia is a viable option, with better patency and symptom improvement, and without stent fractures.