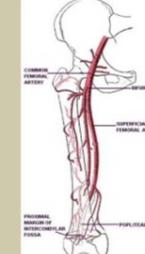


Supera Stent. Two years experience in severe femoropopliteal disease

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Introduction

The arterial femoropopliteal segment is characterized by anatomic features that limit the patency of endovascular treatments. The length, multiplicity and calcification of the lesions, added to flexion, traction and rotation forces affect the results on this territory.

The Supera stent is a self-expanding stent formed from six pairs of interwoven nitinol wires. This design avoids stent fracture by adapting to arterial anatomy through improved flexibility, kink resistance, and radial strength, making it more suitable to withstand dynamic forces such as compression, torsion, bending, shortening and pulsation.

Objective

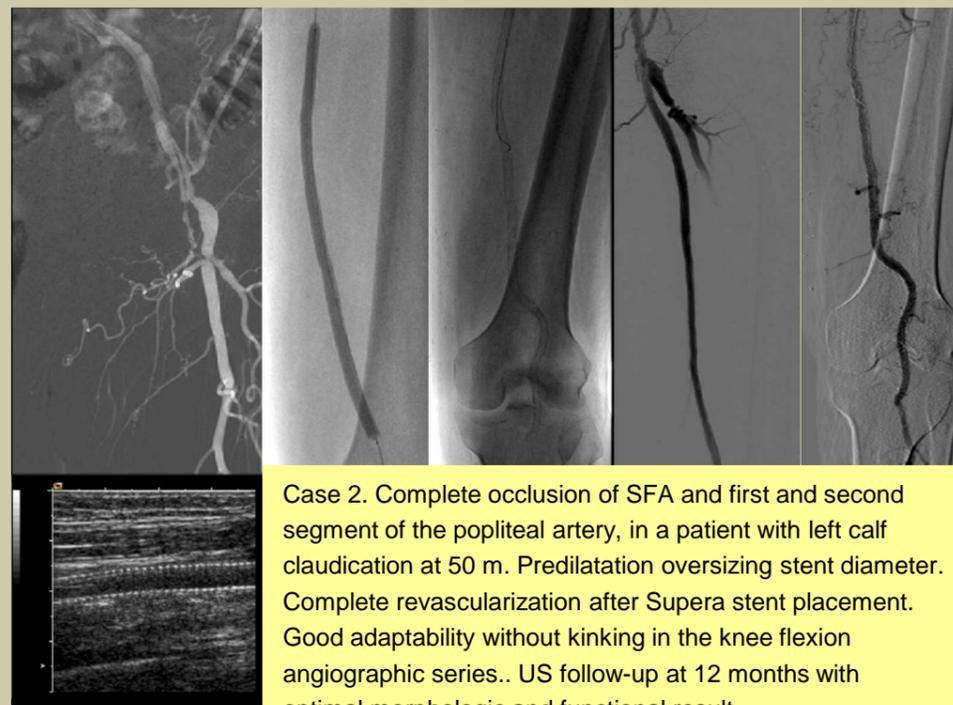
Analyze our two years initial experience with the Supera Stent in severe lesions in femoropopliteal territory.

Material and methods

From December 2013 we have treated 29 patients, implanting 47 stents. The mean age was 73.8, and 37% of the patients were between 79-84. 21 men and 8 women enrolled the study



Case 1. Patient with rest pain and a heel ulcer with intrastent SFA occlusion, with stent fracture due to a heavy calcified plaque. Recanalization and Supera deployment inside the fractured stent. Good angiographic result and functional success with no ulceration at the first month follow-up.



Case 2. Complete occlusion of SFA and first and second segment of the popliteal artery, in a patient with left calf claudication at 50 m. Predilatation oversizing stent diameter. Complete revascularization after Supera stent placement. Good adaptability without kinking in the knee flexion angiographic series.. US follow-up at 12 months with optimal morphologic and functional result.

About clinical stage, 38% presented critical limb ischemia and 58.6% referred severe claudication. Type of lesions is resumed in Table 1. 31% showed heavy calcified lesions, while 43.1% were complete occlusions. Follow-up at 1, 3, 6, 12, 18 and 24 months was performed, with clinical evaluation, ankle-brachial index measurement and doppler ultrasound.

TASC II	
Type A	0%
Type B	17%
Type C	32%
Type D	51%

Table 1. 83% were TASC C and D lesions

Results

Immediate clinical and technical success was 100%, with no initial complications.

Follow-up ranged between 6 and 24 months (mean 15 months).

After this two years experience with Supera stent, we obtained a cumulative primary patency of 89.9% with secondary patency of 93.1%.

At 12 months, primary and secondary patency were 91.6% and 95.8% respectively

90% of the patients upgraded their clinical stage at least one step. Only one patient, with 6 months stent occlusion, worsened his clinical signs.

No stent fracture was detected during follow-up

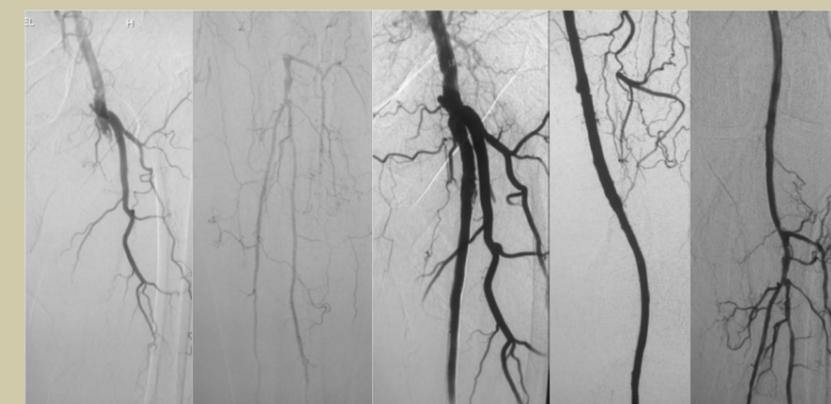
Discussion

Endovascular stents have significantly increased the patency rate in femoropopliteal lesions beyond that of balloon angioplasty alone. However, a notable complication of stent placement for arterial disease is stent fracture at flexion points. New generation laser-cut nitinol stents suggest lower fracture rate (5%). The series of Supera stent have shown great resistance to fracture, with promising patency rates (Table 2). Our results are similar to those published, keeping in mind that our series includes high rate of critical limb ischemia and complex arterial lesions.

In our two-year experience, predilatation with oversized balloon and precise deployment technique is essential for successful outcome.

SERIES	N	PRIMARY PATENCY 12 MONTHS
Scheinert, 2013	101	87.7%
Leon, 2013	39	79.2%
Chan, 2014	82	78.6%
Werner, 2014	492	83.3%
St. Louis, 2015	54	85.6%
Dumantepe, 2015	36	85.7%

Table 2. Primary patency at 12 months with Supera stent



Case 3. 84 year old smoker with rest pain in left foot. Complete occlusion from the origin of SFA. and popliteal artery, with two distal run-off vessels. Treatment of SFA and popliteal artery with Supera Stent, with good clinical outcome

Conclusions

Our initial results with Supera Stent are successful in terms of patency and safety, with promising results in complex and long femoropopliteal lesions.

In our experience, good pre-dilatation and tutored learning curve are necessary.

Longer follow-up and larger studies are needed.

References

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