The AURORAA registry: 4 year results using interwoven nitinol stents for extensive distal femoropopliteal occlusive disease

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Introduction

Endovascular treatment of **popliteal and distal superficial femoral artery** lesions is increasingly growing.(1) Popliteal stenting was limited by insufficient radial strength/flexibility to maintain vessel patency and scaffolding and to prevent recoil, stent kinking and fractures (with high prevalence of in-stent-stenosis, restenosis and occlusion). (2)

There was a need for **“dedicated” stents**, that provide the combination of sufficient strength and flexibility and that can deal with high mechanical stress, created by the flexion-extension, compression, elongation and rotational forces; especially at the level of the joint. (Fig.1)(3-4)

For this reason **the Supera device** (Fig.2) , a 0.014/0.018-inch guidewire compatible, sheath based delivery system is already been tested and investigated on safety and durability.(5,6) The retrieved data showed a superior radial strength, flexibility, durability, conformability, scaffolding and fracture resistance in combination with excellent patency rates compared to the“classic bare slotted nitinol tubed”stents.(7-9)

The aim of this survey was to see if those results could be reproduced in “real world” conditions with patients with extensive atherosclerotic lesions.

Methods

Patients, after endovascular treatment of lesions at the level of the distal superficial femoral artery (SFA) and/or popliteal artery ,who needed stent placement due to flow limiting dissection, recoil or calcifications, were treated with a Supera implantation. Before device delivery, every patient received a proper vessel preparation with a 1-to-1 balloon angioplasty (2 min inflation time) to obtain sufficient space for a complete stent deployment.

The Supera has a new **unique design** with six pairs of closed-end, interwoven nitinol wires in a helical pattern, giving it extraordinary characteristics : **very flexible, kink, fracture and crush resistant** together with **great radial force and improved strength** .
The device is deployed by advancing a ratchet-type mechanism actuated by a thumb slide distally while the stent handle is held stationary. The stent is then pushed out,while the catheter is pulled back.This is completely different as the traditional“pull back systems”and makes the deployment “operator- depended”.

Results

From June 2010 till July 2012 we followed **117 patients** treated with the Supera stent in a single centre physician-initiated, prospective, non-randomised, follow-up study (patient characteristics : table 1). Most of the lesions were **TASC II C & D** lesions, with involvement of the distal SFA and popliteal artery and with occlusive and calcified disease. The average lesion length was 14 cm with an average stent length of 16 cm. Technical success rate was around 96 % (table 2).
Follow up done by Duplex ultrasound (PSVR : 2.5). Seven (5.9%) patients died of non-interventional causes and 2 (1.7%) patients needed a major amputation. Six months primary patency was more then 90%. Twelve months primary patency was around 81%. Primary patency rates remained high in longer follow up: 70,08% after 36 months. (table 3)
We observed further more **no stent fractures or flow limiting kinking** in this very difficult “to stent” area (distal superficial femoral artery & popliteal artery).

Male	63	53.8%
Age (years)	63 (44-87)	64 (±8.3)
Smoking	92	78.6%
Arterial hypertension	98	83.8%
Hyperlipidemia	94	80.3%
Diabetes mellitus (type 1+2)	63	53.8%
Coronary artery disease	74	63.2%
Neurologic disease	24	20.5%
Pulmonary disease	88	75.2%
Renal Disease	43	36.8%

Table 1: Patient Characteristics (n = 117)

Follow up	Primary Patency
6 months	91,9 %
12 months	80,8%
18 months	76,07%
24 months	73,5%
30 months	71,8%
36 months	70,08%

Table 3:Primary Patency up to 36 months

n = 117	n	
Involvement distal SFa + popliteal	104	88.89%
TaSC ii C & D lesions	93	79.48%
Calcifications	68	58.12%
Stenotic disease	56	47.86%
Occlusive disease (15-210 mm)	61	52.12%
Mean lesion length : (3 – 320 mm)	143,43 mm	± 35,6 mm
Mean Stent length : (6- 350 mm)	157,86 mm	± 42,8 mm
Mean number stents :	1,62	
Mean number outflow vessels :	1,46	

Table 2 Lesion & Procedure Characteristics

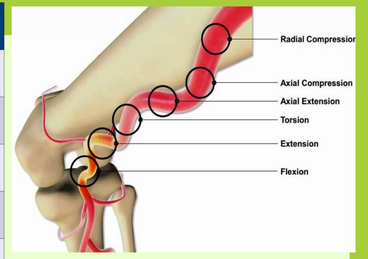

Figure 1: Anatomical challenges and forces acting in on the superficial femoral and popliteal artery

Figure 2: Supera stent

Conclusions

- The **Supera stent can be a solution** when the use of a “classic” nitinol stent is not indicated or favourable , especially in the **femoropoliteal area** or **areas with extreme mechanical stress**.
- Implantation of the Supera system is **safe and effective**, with high patency rates and **no stent fractures**, despite the very difficult regions to treat.
- This is of course highly important in patients with chronic CLI, the elderly, the chronic ill with high comorbidity, and those with extensive (calcified) plaque burden.
- This self-expandable system, that **mimics and adapts to the vascular features**, can be a necessary complement in your tool box due to its special characteristics.

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