Long Superficial Femoral Artery Stenting With SuperA® Interwoven Nitinol Stents

STELLA SuperA trial one-year clinical outcome

Yann Gouëffic, Flora Gouailler, Olivier Marret, Marie Guillou, Philippe Chaillou, Blandine Maurel, Béatrice Guyomarc’h, Bahaa Nasr

Vascular center, Groupe hospitalier Paris Saint Joseph
Paris, France

ClinicalTrials.gov Identifier: NCT03020290
Pl: Prof. Yann Gouëffic
Y. Gouëffic reports:

- **Research funding** from Bard, Medtronic, Terumo, WL Gore

- **Personal fees and grants** from Abbott, Bard, Biotronik, Boston Scientific, Medtronic, Terumo, Vygon, WL Gore (medical advisory board, educational course, speaking)
Long femoropopliteal lesions: challenging cases

- >15-cm Popliteal involvement
- De novo - restenosis
- Calcifications

CLI by alteration of the re-entry

- Entry / Re-entry
- Intra and subintimal
- Long balloons - stents
### ESC-ESVS guidelines

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Level&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
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<tbody>
<tr>
<td>In patients who are not at high risk for surgery, bypass surgery is indicated for long (i.e. ≥25 cm) superficial femoral artery lesions when an autologous vein is available and life expectancy is &gt; 2 years&lt;sup&gt;c&lt;/sup&gt;.</td>
<td>I</td>
<td>B</td>
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<td>The autologous saphenous vein is the conduit of choice for femoro-popliteal bypass&lt;sup&gt;284,315&lt;/sup&gt;.</td>
<td>I</td>
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<td>When above-the-knee bypass is indicated, the use of a prosthetic conduit should be considered in the absence of any autologous saphenous vein&lt;sup&gt;284&lt;/sup&gt;.</td>
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<td>In patients unfit for surgery, endovascular therapy may be considered in long (i.e. &gt; 25 cm) femoro-popliteal lesions&lt;sup&gt;312&lt;/sup&gt;.</td>
<td>IIb</td>
<td>C</td>
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</table>

<sup>a</sup> Class of recommendation.  
<sup>b</sup> Level of evidence.  
<sup>c</sup> These recommendations apply for patients with intermittent claudication and severe chronic limb ischaemia.
## Evidence for long femoropopliteal lesions

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<tr>
<th>Devices</th>
<th>DURABILITY 200</th>
<th>STELLA</th>
<th>STELLA ptx</th>
<th>Zilver ptx registry</th>
<th>DCB vs DES</th>
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*Medtronic; £ Bard; ° Boston Scientific; # WL Gore; $ Supera; PR: prospective registry, RR: retrospective registry; RCT: randomized clinical trial; BMS: bare metal stent; DES: drug eluting stent; DCB: drug coating balloon; CS: covered stent

**STELLA trials**

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Davaine, Eur J Vasc Endovasc Surg, 2012; Davaine, Eur J Vasc Endovasc Surg, 2012;

£ Bard; & Cook; PR: prospective registry, BMS: bare metal stent; DES: drug eluting stent; CD-TLR: clinically driven target lesion revascularization stent
STELLA SuperA®

Prospective single center registry for long superficial femoral artery stenting with SuperA® Interwoven nitinol stents

Nantes University hospital

PI: Prof. Yann Gouëffic

From December 2016 to October 2018

Patients were asked to give their oral authorization to participate in the study by their surgeon.

Pre-operative exams were collected

Patient were followed in the study during 2 years.

Sponsor Nantes university hospital

STELLA SuperA® ClinicalTrials.gov number, NCT03020290
SuperA® stent (Abbott)

The SuperA® bio-mimetic vascular stent incorporates a wire interwoven nitinol biomimetic stent

SuperA®, a low COF stent*, could decrease in-stent restenosis and improve patency rate?

*Test(s) performed by and data on file at Abbott.
Objectives

To evaluate safety and efficacy of implantation of SuperA® Interwoven nitinol stents for TASC C and D SFA atherosclerotic lesions at 12 months in a prospective single center registry for long superficial femoral artery stenting with

Primary endpoint

Primary sustained clinical improvement @ 12mo
(improvement by at least 1 Rutherford stage or healing of all skin lesions and resolution of ischemic rest pain + no need of repeated TLR in surviving patients)

Secondary endpoints

Morbi-mortality rates, MACE, Major amputations, ABI, ISR, TLR, TER, Stent fracture
# Patients

## Inc. criteria
- Age > 50 yo
- De novo atheromatous stenosis
- Rutherford stages 2, 3, 4, 5 and 6
- TASC C-D lesions
- Guidewire had passed through the target lesion
- Written informed consent

## Ex. criteria
- Restenosis
- No atheromatous disease
- Asymptomatic lesion
- Life expectancy < 1 year
- Pregnancy
- Patient involved in another trial
- Refusing patient
- No written informed consent
Follow-up

- Clinical research agents

- Clinical and duplex scan examinations
  (1, 3, 6, 9 and 12 months)

- Bi-plane X-ray @ 12 months
Procedures

Local anaesthesia + sedation

Antegrade/cross over approach

Vessel preparation (3mn with a balloon of 0.5mm diameter more than the SuperA to be implanted)

Stenting (SuperA®)

DAPT for 6 months
Flow chart

48 patients

- 3 deaths
- 2 withdrawal consent

43 Visits M12

No patient was lost of follow-up
48 patients - 49 limbs

| Age (y): | 71.9 ± 10 yo |
| Sex ♂ n (%) | 39 (81.2%) |

**Critical limb ischemia:** 29%

**Intermittent claudication:** 71%

| Dyslipidemia n (%) | 25 (52.1%) |
| BMI (kg/m²) | 25.8 ± 4.1 |
| Renal insufficiency n (%) | 6 (12.5%) |
Lesions and intraoperative results

Cross over: 93.9%
SUPER A stent: n=94
Other stents: n=10
Median stents per lesion: 2
Median diameter: 5.5mm

Mean total length of stented segment:

277 ± 128 mm
Primary sustained clinical improvement: 84.6%
Secondary sustained clinical improvement: 93.2%
Clinical Outcome @ 1 year

Death: 3 (6.3%)
Major amputations: 0 (0%)

p = 0.0168
TLR @ 1 year: 8.5%
Patency @ 1 year: 85.1%

In-stent restenosis: 12% (6/49)
In-stent thrombosis: 6% (3/49)
Hemodynamic outcomes @ 12 months

At baseline:
Median: 0.62 ± 0.15

At M12:
Median: 0.91 ± 0.17

p < 0.0001
Stent fractures
No fracture were observed
# Update of evidence for long femoropopliteal lesions

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Take home message

SuperA® (Abbott) is safe and efficient for long femoropopliteal lesions

In a non-controlled study, SuperA® achieves high primary patency rate and low TLR

SuperA® stent could be an alternative to open surgery treatment for femoropopliteal lesions superior to 25cm.
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Lesions and intraoperative results

Median stents SUPER A per lesion: 2 [min=1; max=4]

Mean total length of stented segment (n=104):

277 ± 128 mm
Clinical Outcome @ 1year

**MISAGO® (n= 85)**

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<tr>
<td>MACEs, n [1]</td>
<td>2</td>
</tr>
<tr>
<td>All-cause Death, n</td>
<td>2</td>
</tr>
<tr>
<td>Limb salvage, % [2]</td>
<td>100</td>
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<tr>
<td>Device- or Procedure-related Death, n</td>
<td>0</td>
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<tr>
<td>Mean hospitalization length, days ± SD</td>
<td>1.0 ± 1.1</td>
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<td>Rehospitalization (%)</td>
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**Major amputations:** 0 (0%)
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