What works best for long SFA disease?
A review of the evidence
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Disclosure slide

☐ I have the following potential conflicts of interest to report:
  ☐ Consulting
  ☐ Employment in industry
  ☐ Stockholder of a healthcare company
  ☐ Owner of a healthcare company
  ☐ Other(s)

☑ I do not have any potential conflict of interest
What are the options?

- NITINOL STENT
- DES
- VIABAHN
- SUPERA
- DCB
NITINOL STENT

• **DURABILITY 200**
  Physician initiated trial investigating the efficacy of the implant of EverFlex 200mm long nitinol stents in de novo TASC C&D femoropopliteal lesions

• **Main inclusion criteria**
  – 100 patients
  – Rutherford category 2 – 5
  – SFA stenosis > 50% or occlusion
  – Lesion length > 150mm (TASC C&D)
  – At least one-vessel run-off to the foot

• **Primary endpoint**
  Primary patency at 12 months, defined as no binary restenosis (>50%) on duplex ultrasound and no TLR performed within 12 months
NITINOL STENT


mean lesion length: 242mm

64.8%
**DES**

- **ZILVER PTX – long lesions**
  Prospective, single-arm, multicenter study evaluating the Zilver PTX drug-eluting stent for treating patients with symptomatic lesions in the above-the-knee femoropopliteal artery

- **Main inclusion criteria**
  - 135 patients
  - Rutherford category > 1
  - de novo or restenotic lesion with >50% stenosis
  - TASC C & D lesions
  - at least one-vessel run-off to the foot

- **Primary Patency at 12 months**
  Stent patency (<50% stenosis) was evaluated by **angiography or duplex ultrasound**; for this analysis, duplex threshold (<50% stenosis) was based on PSVR of 2.5

mean lesion length: 226.1mm

77.6%
**Zilver PTX post-market long lesions**

Post-market program to evaluate the Zilver PTX in long lesions in terms of safety, device integrity and primary patency

**Main inclusion criteria**
- 45 patients
- Rutherford category ≥ 2
- De novo or restenotic lesion with >50% stenosis
- Single segment ≥ 80 mm and ≤ 280 mm in length
mean lesion length: 189.3mm
• **VIABAHN-25 cm trial**
  Prospective, multicenter, single-arm study evaluating the 25cm Viabahn Endoprosthesis with Propaten Bioactive surface to treat de novo and/or restenotic lesions of the SFA

• Main inclusion criteria
  – 71 patients
  – Rutherford category 2 – 4
  – de novo, post-PTA or post-atherectomy stenosis (>50%) or occlusion of native SFA
  – lesion length 20-35 cm
  – at least one-vessel run-off to the foot

• Primary patency at 12 months
  No evidence of restenosis/occlusion within the originally treated lesion without TLR, based on Core Lab **duplex ultrasound** measuring a peak systolic velocity ratio ≤2.5

Zeller T. et al, J Endovasc Ther, 2014;21(6):765-774
VIABAHN

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mean lesion length: 265mm

67.0%
SUPERA

- **SUPERA long lesion cohort**
  Long lesion study to evaluate the Supera Veritas® peripheral stent system in femoropopliteal lesions

- **Main inclusion criteria**
  - 159 patients
  - Rutherford category 2 – 4
  - SFA plus proximal popliteal artery cohort

- **Results:**
  - mean lesion length: **240mm**
  - primary patency at 12 months: **73.7%**
SUPERA

- **SUPERA 500 registry - long lesions**
  Retrospective analysis of femoropopliteal lesions treated with the Supera stent between 2008 and 2011 to assess the efficacy of the Supera interwoven nitinol stent in a real world setting

- **Main inclusion criteria**
  - 495 patients
  - Rutherford category 2 – 5
  - femoropopliteal lesions
  - long lesion cohort: ≥ 150 mm
**Primary Patency**

- **12 months**
  - ≤ 70: 98.3%
  - > 70 < 150mm: 77.8%
  - ≥ 150mm: 67.9%

- **24 months**
  - ≤ 70: 82.2%
  - > 70 < 150mm: 73.5%
  - ≥ 150mm: 81.5%

**Mean lesion length:** 223.4mm

**81.5%**
• **DCB vs. DES retrospective trial**
  Propensity score retrospective analysis between May 2009 and October 2011 with patients treated with IN.PACT Admiral (DCB) and Zilver PTX (DES)

• Main inclusion criteria
  – 228 patients (131 DCB; 97 DES)
  – Claudication and rest pain
  – de novo and restenotic (non-ISR) femoropopliteal lesions
  – lesion length > 10 cm
DCB mean lesion length: 194.4mm

DCB mean lesion length: 194.4mm

81.5%

p=0.1334

(mean lesion length 19 cm)
• Cave: stent rate after DCB:
  - provisional stenting in 24 out of 131 patients (18.3%)
    • refractory stenosis: 5/131 (3.8%)
    • flow-limiting dissection: 13/131 (9.9%)
    • other: 6/131 (4.6%)
Conclusion

• Newest generation endovascular treatment options have promising results for long SFA lesions

• Randomized trials comparing the different treatment options need to be done
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