3-year results with heparin-bonded Viabahn stent-grafts to treat long SFA occlusions

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Infrainguinal arterial occlusive disease
- Venous femoro-popliteal bypass is considered the gold standard for extensive lesions in the superficial femoral artery
- Vulnerable patients with often multiple co-morbidities
- Bypass surgery related to complications, prolonged hospital stay and reinterventions

Why using SE covered stents?
- Endovascular strategy
- They may reduce the incidence of re-stenosis
- Reduce ISR to a focal edge stenosis:
  - Easier to treat
  - Incidence independent of lesion length

Endoluminal bypass
1. Gain access to lesion with the guidewire.
2. Pre-dilate with appropriately sized balloon.
3. Confirm initial landing zone before deployment.
4. Slowly pull deployment knob in a smooth motion.
5. Seat balloon well inside device during touch-up.
6. Land proximal edge at least 1 cm into healthy vessel when treating stenotic disease

Case example
Endoluminal SFA bypass
Clinical results

Review of 19 peer-reviewed articles
(789 treated legs)

• 1-year primary patency rate 44%-86%
• 1-year secondary patency rate 58%-95%

Large variation due to differences in:
  • Patient characteristics
  • Lesion characteristics
  • (Over) sizing
  • Medical treatment
  • Developments in stent design


Latest generation Viabahn

• Heparin-bonding technology
• Contoured proximal edge
• 25 cm long endografts

Heparin-bonded endograft
One-year outcome

<table>
<thead>
<tr>
<th>Author</th>
<th>Journal</th>
<th>Year</th>
<th>No. of Limbs</th>
<th>Lesion Length (cm)</th>
<th>Follow Up (yr)</th>
<th>Primary Patency</th>
<th>Secondary Patency</th>
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<tbody>
<tr>
<td>LENSVELT</td>
<td>Journal of Vascular Surgery, Vol 56, Iss 1, July 2012, P 118-125</td>
<td>2012</td>
<td>56</td>
<td>18.3</td>
<td>1</td>
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<td>80%</td>
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<td>VIPER</td>
<td>Journal of Vascular Interventional Radiology; 24: 165-173</td>
<td>2012</td>
<td>119</td>
<td>19</td>
<td>1</td>
<td>73%</td>
<td>92%</td>
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<tr>
<td>VIASTAR</td>
<td>Journal of the American College of Cardiology</td>
<td>2013</td>
<td>72</td>
<td>19.4</td>
<td>1</td>
<td>78%</td>
<td>90%</td>
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<tr>
<td>TOTAL weighted results</td>
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<td></td>
<td>247</td>
<td>19.0</td>
<td></td>
<td>75%</td>
<td>91%</td>
</tr>
</tbody>
</table>

73 SFAs in 70 patients April 2009 – December 2011
(Start inclusion in the SuperB trial)

Rutherford classification:
  • 3 51 (73%)
  • 4 7 (10%)
  • 5 11 (16%)
  • 6 1 (1%)

Risk factors:
  • Tobacco use 39 (56%)
  • Hypertension 59 (84%)
  • Hyperlipidemia 54 (77%)
  • Diabetes mellitus 30 (43%)
  • Renal failure 15 (21%)
  • Pulmonary disease 16 (23%)
  • Coronary artery disease 26 (37%)
  • Cerebrovascular disease 8 (11%)

Heparin-bonded endograft
Midterm outcome

• Mean lesion length 17.4 ± 7.0 cm
• Occlusion 40 (55%)
• Flush occlusion 21 (28%)
• TASC-2 C and D 61 (84%)
• Distal landing site:
  • P1 50 (89%)
  • P2 20 (27%)
  • P3 3 (4%)


Heparin-bonded endograft
Midterm outcome

• Concomitant procedures:
  • Endarterectomy CFA n=13
  • PTA iliac artery n=7
  • PTA popliteal artery n=3
  • EVAR n=2
Heparin-bonded endograft

Midterm outcome

- Two procedural complications
  - Thrombosis treated with thrombolysis
  - Dissection of the PA treated with SE stentgraft
- Admission 2 days (range 1-12 days)
- Overall 30 day morbidity 16%
  - Three hematoma’s groin, 2 requiring surgery
  - One unscheduled forefoot amputation

Midterm outcome

- Median follow-up 25 (2-55) months
- 17 (24%) died during follow-up

- At 3-year follow-up:
  - Primary patency 59%
  - Primary-assisted patency 71%
  - Secondary patency 82%
  - Freedom from amputation 100%

Heparin-bonded endograft

Midterm outcome

- 8 definitive failures; 5 requiring bypass surgery
- Cox regression analysis did not show any predictor of failure
- A non-significant trend in three-year patency was observed for the use of multiple stents
  - One stent 73%
  - Two stents 56%
  - Three stents 45%

Conclusion

- The use of the heparin-bonded Viabahn seems a good alternative to bypass surgery
- The use is related to a low morbidity and low amputation rates
- Randomized data are required; awaiting the final results of the SuperB trial comparing the heparin-bonded Viabahn with the (venous) bypass

SuperB trial

Design

- Multicenter randomized trial
- Designed to demonstrate an equality in patency and an improved QOL using heparin-bonded ePTFE covered stent compared to venous femoropopliteal bypass
- Primary end-points
  - Patency at 1-year
  - QOL at 30 days
- Inclusion November 2010- June 2015
- 6 Dutch centers
- Clinicaltrials.gov: NCT01220245

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