Lessons Learned When Treating Complex Lesions Using An Endoluminal Bypass

Darren B. Schneider, MD
Associate Professor of Surgery
Chief, Vascular and Endovascular Surgery

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Boston Scientific - consulting; medical advisory board
Medtronic - medical advisory board
Bard – consulting; medical advisory board
Traditional SFA Treatment Strategies

Angioplasty
• High initial success
• Up to 75% restenosis at 1 year

Nitinol stents
• Improved patency compared to PTA
• In-stent restenosis remains common, occurring in about 30% of patients
• Treatment of ISR remains challenging and is costly
New Generation Treatments to Reduce Restenosis
# Reported Patency of Viabahn Covered Stents in the SFA

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Journal</th>
<th>Lesion Length</th>
<th>% Occlusions</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Primary Patency (years / %)</th>
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<td><strong>Average / Total</strong></td>
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<td><strong>1103</strong></td>
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NR = Not Reported

*Randomized studies

**Total limbs corrected for repeated data from Saxon 2007 & 2008**
SFA Covered Stent 1-Year Patency

![Graph showing the relationship between lesion length (cm) and patency (%). The graph displays a scatter plot with data points and a line of best fit. The x-axis represents lesion length in cm, ranging from 0 to 35, and the y-axis represents patency in %, ranging from 0 to 100. The data points show a trend that is relatively consistent across different lesion lengths.]
US, multicenter, prospective, randomized
Viabahn (Pre-Heparin-Bonded) n=72 vs. BMS n=76
TASC I C&D lesions; Rutherford 2-5
Average lesion length, 18cm
Primary endpoint: 3-year primary patency by CDUS
3-Year Primary Patency

BMS 25.9%
Viabahn 24.2%  p=.392

Geraghty et al. JVS 2013
Post-VIBRANT Viabahn Design Modifications

Covalent Heparin Bonding

Scalloped Proximal Edge
10 Technical Considerations

1. Avoid excessive oversizing
2. Treat all of the disease
3. Prescribe appropriate antiplatelet therapy
4. Assure adequate inflow and outflow
5. Place device flush with SFA to cover disease
6. Overlap devices by at least 1 cm
7. Post-dilate
8. Do not use PTA outside of device
9. Use duplex ultrasonography follow-up
10. Treat progressing disease
Treat All of the Disease

- Disease not covered due to proximity to the SFA origin?
- Total occlusion at 203 days

Original pre-treatment angiogram  | Occlusion at 203 days

End of device
Place Device Flush with Origin if Disease is Present

Uncovered disease at the proximal edge can limit flow and propagate to failure.

May need to prepare a landing zone when flush occlusion.

Case 1

Case 2
Place Device Flush with Origin if Disease is Present

Proximal edge

Well positioned VIABAHN device at the SFA origin under ipsilateral angulated view (~25°)
VIPER Study

US, multicenter, prospective, single-arm
Viabahn (Heparin-Bonded) n=119
Femoropopliteal lesions
19cm mean lesion length
56% occlusions
Primary endpoint: 1-year primary patency by CDUS
VIPER One-Year Patency

12 month duplex follow-up available for 103/120 patients

- \( \leq 20 \text{ cm} \) (n=68) 75%
- \( > 20 \text{ cm} \) (n=51) 72%

Saxon JVIR 2013
Effects of Device Oversizing: Proximal Edge: *Results from the VIPER study*

% Free from Loss of Patency vs. Time Post Treatment (months)

- Oversized ≤20%
- Oversized > 20%

88% vs. 70% at 12 months, p<0.05

*Saxon JVIR 2013*
VIASTAR Study

European, multicenter, prospective, randomized
Viabahn (Heparin-Bonded)  n=72 vs. BMS n=69
Femoropopliteal lesions
Mean lesion length: 19cm Viabahn; 17.3cm BMS
Oclusions: 79% Viabahn; 70% BMS
Primary endpoint: 1-year primary patency by CDUS or CTA
1 Year Primary Patency (per protocol analysis)

All Lesions

Lesions > 20 cm

Patency benefit of Viabahn amplified in lesions ≥ 20 cm.

Lammer JACC 2013
Lesions ≥ 20 cm

All Lesions

Primary Patency (%)

Time Post Treatment (months)

P < 0.01

Lammer Cardiovasc Intervent Radiol 2015

Patency benefit of Viabahn persists at 2 years.
25 cm Viabahn Study

European, multicenter, prospective, single-arm Viabahn (25cm, Heparin-Bonded) n=71 Femoropopliteal lesions

Mean lesion length: 26.5cm
Occlusions: 92.9%

Primary endpoint: 1-year primary patency by CDUS

Most challenging SFA population studied
25cm Viabahn Study: 1-Year Results

Zeller J Endovasc Ther 2014
<table>
<thead>
<tr>
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<th>VIBRANT</th>
<th>VIPER</th>
<th>VIASTAR</th>
<th>25cm Viabahn</th>
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<td># Limbs</td>
<td>72</td>
<td>119</td>
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<td>Lesion Length (cm)</td>
<td>19 cm</td>
<td>19 cm</td>
<td>19 cm</td>
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<tr>
<td>CTO</td>
<td>61%</td>
<td>56%</td>
<td>79%</td>
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<td>% TASC C&amp;D</td>
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<td><strong>73%</strong></td>
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## Comparison of Viabahn Studies

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Improved Outcomes with Newer Generation Devices

Lesion Length (cm)

One-Year Primary Patency

- Multi-center, randomized
- Multi-center, single arm
- Dual-center, single arm, EU
- Multi-center registry
- Trend of randomized BMS studies

ZILVER PTX
ZILVER FAST
VIABAHN PMA
FACT
ASTRON
Absolute
Resilient
Durability I
Supera
VIBRANT (VIABAHN)
VIBRANT BMS
VAPIER
ZILVER PTX
25 cm

Durability 200
Improved Outcomes with Newer Generation Devices

One-Year Primary Patency

Lesion Length (cm)

- Multi-center, randomized
- Multi-center, single arm
- Dual-center, single arm, EU
- Multi-center registry
- Trend of randomized BMS studies

VIBRANT (VIABAHN)
VAPIER
VIASTAR
ZILVER PTX
ZILVER PMA
VIABAHN
ASTRON
Supera
Resilient
FACT
Durability I
Durability
200
25 cm
Summary

The evidence supports the use of heparin-bonded covered stents for treatment of long SFA lesions, especially occlusions

- **Patency is independent of lesion length**
- **Better patency than BMS**
- **No increased incidence of occlusions or ALI**

Covered stents can be considered primary treatment for occlusions > 10cm in length

Need to consider

- **Covering collaterals**
- **Cost**
- **Drug eluting technology (DCB w selective spot-stenting)**
DIVISION OF VASCULAR AND ENDOVASCULAR SURGERY
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