Long Segment Stenting with Woven Nitinol Stents: The New Endoluminal Bypass

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

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Endoluminal Bypass with Woven Nitinol Stents

What Is Endoluminal Bypass?

- Establish new pathway of blood flow following same principles exhibited in surgical bypass
- Must be able to traverse all disease and extend from healthy inflow to healthy outflow
- Endoluminal bypass conduit takes an anatomic route through the vessel lumen (unlike subcutaneously tunneled route as some bypass grafts)
- Must exclude all plaque burden and mechanical forces that exert themselves on it
- Must handle tortuosity and torsion forces across Hunter’s canal or knee joint
Properties of an Ideal Endoluminal Bypass Conduit

- Compression / crush resistance
- Flexibility and fracture resistance
- Resistance to kinking / torsion
- Exclusion of tissue ingrowth / intimal hyperplasia (although anastomotic stenosis occurs even in surgical grafts)

Tradeoffs involved with any device selection

Endoluminal Bypass with Woven Nitinol Stents

What Is Endoluminal Bypass?

Tigris Stent (WL Gore)

Viabahn (WL Gore)

Supera Stent (Abbott Vascular)
Endoluminal Bypass with Woven Nitinol Stents

“Traditional” Endoluminal Bypass w/ Covered Stents

Viabahn (WL Gore)

PTFE covering prevents tissue ingrowth

Contoured edges designed to reduce edge stenosis

Heparin bonding to prevent thrombosis
Endoluminal Bypass with Woven Nitinol Stents

“Traditional” Endoluminal Bypass w/ Covered Stents

Viabahn at SFA origin

Extending to reconstitution at Hunter’s canal
Endoluminal Bypass with Woven Nitinol Stents
“Traditional” Endoluminal Bypass w/ Covered Stents

VIASTAR Trial – 12-mo Outcomes
(Lammer J, et al. JACC 2013)

- 141 patients randomized to Viabahn vs BMS
- Lesion length: 19.0cm VIA, 17.3cm BMS
- Patency rates (12mo, intention to treat analysis):
  - VIA: 70.9%
  - BMS: 55.1% (NS)
  - Primary (>20cm): VIA 71.3%, BMS 36.8% (p=0.01)
- Significant difference in PP for all-comers when analyzed by per protocol basis (78.1% vs 53.5%, p=0.009)
Endoluminal Bypass with Woven Nitinol Stents
“Traditional” Endoluminal Bypass w/ Covered Stents

VIASTAR Trial - 2-year Outcomes

- Patency rates at 24 months:
  - VIA BMS
    - Primary: 63.1% 41.2% (p=0.04)
    - Freedom-TLR: 79.4% 73.0% (ns)
- Also no difference in ABIs between groups at 2 years
Endoluminal Bypass with Woven Nitinol Stents

“Traditional” Endoluminal Bypass w/ Covered Stents

SuperB Study

- 125 patients randomized to covered stent vs vein (n=42) or PTFE (n=20) bypass
- Mean lesion length 23cm
- Patency rates at 12 months:
  
  **VIA Bypass**
  
  - Primary 64.8% 63.6% (ns)
  - Secondary 85.9% 83.3% (ns)
  - FF-TLR 72.1% 71.05 (ns)
Endoluminal Bypass with Woven Nitinol Stents
“Traditional” Endoluminal Bypass w/ Covered Stents

SuperB Study

Early improvement (30-day) in QOL scores identical at 1 year
Endoluminal Bypass with Woven Nitinol Stents

Properties of the Supera Stent

- Flexibility and crush resistance required to withstand mechanical forces of residual plaque burden and dynamic forces across joints.
- While it cannot exclude tissue as a covered stent, it appears to have less tendency to trigger intimal hyperplasia due to lack of chronic outward radial force.
Endoluminal Bypass with Woven Nitinol Stents

Properties of the Supera Stent
Endoluminal Bypass with Woven Nitinol Stents

Properties of the Supera Stent

5.5x150 Supera (x3)
Endoluminal Bypass with Woven Nitinol Stents

Properties of the Supera Stent
Endoluminal Bypass with Woven Nitinol Stents

Properties of the Supera Stent

SUPERB Trial (Supera IDE Study)

Primary Patency at 12 months:
- 83.3% (p=0.480) for Moderate (21-40%) with n=6
- 81.8% (p=0.268) for Minimal (11-20%) with n=22
- 90.5% (p=0.026) for Nominal (± 10%) with n=74
- 73.7% (p=0.029) for Minimal (11-20%) with n=38
- 74.4% (p=0.029) for Moderate (21-40%) with n=39
- 57.7% (p<.001) for Severe (>40%) with n=26

By Percent Compression/Elongation at 12 months:
- Compressed
- Nominal
- Elongated
Endoluminal Bypass with Woven Nitinol Stents
Properties of the Supera Stent

SUPERB Trial (Supera IDE Study)

Freedom from Restenosis at 12mo by Lesion Length

- Shortest Lesions (35.4 ±12.3 mm) n=87: 88%
- Middle Lesions (73.5 ±10.8 mm) n=88: 85%
- Longest Lesions (126.1 ±33.4 mm) n=87: 88%
Endoluminal Bypass with Woven Nitinol Stents

**Properties of the Supera Stent**

- Consistent data from multiple centers demonstrating excellent results that are independent of lesion length or implant length

**Patency:** 80-94%

**Lesion Length:** 5-28cm%
Tips for Endoluminal Bypass with Woven Nitinol Stents

- Aggressive predilation with balloon 0.5-1.0mm larger than stent diameter
- Focal balloon use over long balloons
- Healthy inflow to healthy outflow; use of IVUS to guide this
- Slow deployment on high magnification, watch stent geometry
Surgical bypass has been effective in large part due to the ability to use a large-bore conduit from healthy artery to a healthy target.

Endoluminal bypass involves following these same principles with an endovascular approach.

There are several components to the ideal conduit in endoluminal bypass, which include compression resistance, flexibility and resistance to fracture, and minimal thrombogenicity.

Both covered stents and woven nitinol stents can be effectively used for these procedures and have been shown to have patency rates that are relatively independent of lesion length.
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