Scaffolds are here to stay

Michael K. W. Lichtenberg MD, FESC
## Conflict of Interest - Disclosure

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

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Honoraria for lectures:</td>
<td>CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan</td>
</tr>
<tr>
<td>2. Honoraria for advisory board activities:</td>
<td>Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific</td>
</tr>
<tr>
<td>3. Participation in clinical trials:</td>
<td>Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow, Terumo</td>
</tr>
<tr>
<td>4. Research funding:</td>
<td>Biotronik, Boston Scientific, Veryan, Veniti, AB Medica</td>
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Background
Mandate of Endovascular Devices

2 Targets:
1. **Make it Open**
2. **Keep it Open**

- Target 1) necessary but not sufficient to Target 2)
- Measure of success of Target 1 (lumen size, stability, ± presence of dissections) may influence degree of success in target
“Jailing” the natural behaviour
## Stents Have Significant Limitations

<table>
<thead>
<tr>
<th>Stent (study)</th>
<th>Re-stenosis</th>
<th>Stent Fracture Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilver</td>
<td>16% @ 1yr</td>
<td>0.9% RCT</td>
</tr>
<tr>
<td>Zilver PTX</td>
<td>10% @ 1yr</td>
<td>1.5% SAT</td>
</tr>
<tr>
<td>Supera (SUPERB)</td>
<td>13% @ 1yr</td>
<td>0.0% @ 1yr</td>
</tr>
<tr>
<td>Wallstent</td>
<td></td>
<td>Up to 19%</td>
</tr>
<tr>
<td>SMART (SIROCCO)</td>
<td>18% @ 6m</td>
<td>18.2% @ 6m</td>
</tr>
<tr>
<td>EverFlex (Durability)</td>
<td>28% @ 1yr</td>
<td>0.4%</td>
</tr>
<tr>
<td>LifeStent (Resilient)</td>
<td>19% @ 1yr</td>
<td>3.1% @ 1yr</td>
</tr>
<tr>
<td>Luminexx (FAST)</td>
<td>32% @ 1yr</td>
<td>12% @ 1yr</td>
</tr>
<tr>
<td>Dynalikn-E (STRIDES)</td>
<td>32% @ 1yr</td>
<td>2% @ 1yr</td>
</tr>
</tbody>
</table>

- Chronic inflammation
- In-stent restenosis
- Limited future treatment options
- Occasional fracture
Properties of an ideal SFA stent

### Low Chronic Outward Force (COF)

Chronic Outward Force is the force exerted on the vessel wall by a self-expanding (SE) stent to achieve its preset diameter. This can cause vessel injury, inflammation score and neointimal proliferation

The higher the force exerted on the vessel wall the stronger the inflammatory response is.

### Stent flexibility, Radial Resistive Force & Crush Resistance

- **High multidirectional flexibility**
- **Sufficient Radial Resistive Force (RRF)** (resistance to concentric compression)
- **Sufficient Crush Resistance (CR)** (resistance to eccentric compression)

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Paclitaxel Therapies Reduce Repeat Procedures Through 2 Years

2-Year Target Lesion Revascularization Rate


BMS, bare metal stent; DCB, drug-coated balloon; DCS, drug-coated stent; PTA, percutaneous transluminal angioplasty
Calcium and DCB Performance

- Calcification necessitates greater balloon pressures\(^1,2\)
- Calcified plaques are associated with dissections following balloon dilatation\(^3\)
- Calcification may interfere with DCB efficacy\(^4,5\)
  - Reduced patency, greater TLR rates\(^4\)
  - More late lumen loss (LLL) at 6 months\(^5\)

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6-month LLL and PACSS score\(^5\)

![Late Lumen Loss (mm) vs. Calcification Score (PACSS)](image)

- Median, interquartile range.

Stents used in DCB Studies

Longer mean lesion length in DCB studies correlates with higher provisional stenting rate

Provisional Stenting in Randomized Controlled Trials may not be representative of actual stenting in studies due to study design. Results from different trials are not directly comparable. Information provided for educational purposes.

FEMPAC- Werk M et al. Circulation 2008;
RANGER SFA-Bausback et al. J Endovasc Ther 2017;
IT Registry- Micari A et al. J Am Coll Cardiol Intv 2012;
IN.PACT SFA- Tepe et al. Circulation 2015;
CONSEQUENT- Tepe et al. Cardiovasc Intervent Radiol 2017;

ILLUMENATE EU RCT- Schroeder et al, Circulation 2017;
ILLUMENATE US RCT- Krishnan et al, Circulation 2017;
Lesions with dissections have a TLR rate 3.5 times higher than lesions without dissection\(^1\)

Current tools for dissection repair (stents) have limitations

\(^1\)Kokkinidis, *Intervent Cardiol Clin* 2017
**Kobayashi Dissection Grading**


<table>
<thead>
<tr>
<th>Category</th>
<th>Width of Dissection</th>
</tr>
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<tbody>
<tr>
<td>Group A</td>
<td>None</td>
</tr>
<tr>
<td>Group B</td>
<td>&lt; 1/3 of lumen</td>
</tr>
<tr>
<td>Group C</td>
<td>&gt;1/3 of lumen</td>
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Dissections are divided into a three-part grading system analyzing the width of the remaining patent lumen in the dissected arterial segment.
Limited Options for SFA/Popliteal Dissection Repair

Prolonged Inflation\(^1\) (≥ 180 sec)
- Reduces number of dissections
- Does not prevent 100% of dissections

Stenting\(^2\)
- Impedes natural vessel movement
- High metal burden, high radial force
- Inflammation leads to challenging ISR
- Limits options for future treatment

\(^1\)Zorger, J Vasc Interv Radiol 2002
\(^2\)Garcia, Catheter Cardiovasc Interv 2017
Image courtesy of John Rundback, MD
Dissection analysis

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50% persistent stenosis

Group C dissection

Group B dissection
Renzan Concept

- Dual Layer Stent for Superior Femoral (SFA) and Popliteal Arteries
- Leverage Micromesh Protection Dual Layer Stent and Delivery System Design from Roadsaver
- Design for High Radial Strength, Low Chronic Outward Force
- Designed for Improved Fracture Resistance and Durability
- Braided Design for Superior Flexibility and Adaptation to FemPop Arteries
Stent Features & Benefits

Dual Layer Braided Stent with Micro-mesh Technology

**Inner layer**
- **Micro-mesh**: Very small cell size, designed to limit plaque prolapse and reduce distal embolization

**Outer layer**
- **Conformability**: Braided Nitinol design to allow for in-vivo stent tapering and conformability
- **Flexibility**: Closed cell stent designed to have similar flexibility to an open cell stent, resulting in excellent vessel wall apposition and adaptation to tortuous anatomy
- **Visibility**: Markers on stent end designed for improved visibility
Multi Axis Fatigue Testing

- MAPS Testing
  - Competitors: Renzan, Supera, Everflex, Smart Flex, Zilverflex
  - 10 Year=10 Million Cycles for Multi-Axis Loading
- Results
  - Competitor Bare Metal Stents: 3-16 Fractures
  - Renzan: 0 Fractures

Data on file at MicroVention. TR16-232, Renzan =11, TR16-172, other brand stents n=1
Chronic Outward Force Comparison

Data on file at MicroVention. TR17-120, TR16-272. Renzan stent (n=30), Supera stent (n=5), Other brand stents (n=2)
Radial Resistive Force Comparison

Data on file at MicroVention. TR17-120, TR16-272. Renzan stent (n=30), Supera stent (n=5), Other brand stents (n=2)
Renzan Ovine Study

➢ **Implant Summary:**
  ➢ 2 Ovine Models
  ➢ 3 Stents Implanted in SFA/Iliac Arteries
  ➢ 6,7,8mm OD Stents, 150mm Length

➢ **Follow-up Highlights: 60 Days**
  ➢ Good Stent Radiopacity
  ➢ No Flow Issues, Side Branches Patent
  ➢ Stents Well Apposed to Vessel Wall
  ➢ No Migration

➢ **Histology:**
  ➢ Minimal Vessel Injury
  ➢ Minimal Inflammation
  ➢ Minimal Uncovered Struts
  ➢ Stent Almost Completely Incorporated Into Vessel Wall
  ➢ Organized Neointima Composed of Smooth Muscle Cells

Data on file at MicroVention
The Prizer Study - Title

Prospective, Multicenter, Post-market, Single-arm study, to confirm the performance of the RenZan™ Peripheral Stent System in treating subjects with SupErficial Femoral and/or Popliteal artery disease

“PRIZER”
The Prizer Study - Design

- Prospective, Multicenter, Post-market Study, Single Arm

- To confirm the performance of the Renzan™ in treating Superficial Femoral and/or Popliteal artery disease

- Mandatory vessel preparation at least 1:1 stent to vessel sizing without the use of adjunctive debulking devices

- To confirm the safety and efficacy of the Renzan™
  Safety: freedom from Death, TLR, or any amputation of the index limb up to 30 Days.
  Efficacy: Patency of the artery at 12 months

- Number of Subjects: 135
CONCEPT OF HOT SPOT STENTING

«Lesion»

- de-novo
- ISR
- Ca++

Tosaka I
- Tosaka II / III

Debulking

pre-Dil (PTA)

DCB

>40/50% residual stenosis or flow limiting dissections?

if persistent

post-Dil (PTA)

>50% residual stenosis or flow limit dissections

spot-Stent
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