Applications and Evidence for minimally invasive stenting

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Disclosure

Speaker name: Dr. Jingjun Jiang

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
The SFA is a challenge to treat

Shortening 23-25%¹

Compression > 1kg²

Torsion 60°³

Bending 64°⁴

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¹ Jonker et al., Dynamic Forces in SFA/Popliteal Artery During Knee Flexion, Endovascular Today. Buyer’s Guide 2009, pp. 54–59
«Dedicated stents» needed to tackle SFA lesions

Properties of an ideal SFA stent

- Accurate deployment
- High multidirectional flexibility
- Low Chronic Outward Force (COF)
- Sufficient Radial Resitive Force (RRF)
- Sufficient Crush Resistance (CR)
- Low profile

Source: SUPERB Study 12m data presented by Lawrence Garcia, MD at VIVA 2014.
Is Pulsar an ideal SFA stent?

**Pulsar-18 Specifications**
- 0.018” OTW Nitinol Stent
- Ø: 4.0-5.0-6.0-7.0 mm
- **Strut thickness 140µm**
- L: 30-40-60-80-100-120-150 mm
- proBIO coated (a-SiC:H)
- 4F Introducer Sheath compatible

**Pulsar-18 key features**
- Thin Struts and Low COF
- Low Profile 4F Delivery System
- Stent with multi-directional flexibility and peak-to-valley design
- Accurate stent deployment - one-handed stent release handle

**Thin Struts**

**Low COF**

**Clinically Proven**
Properties of an ideal SFA stent

Elongation/compression can impact patency

Pulsar has one-handed & accurate & easy stent release

Source: SUPERB Study 12m data presented by Lawrence Garcia, MD at VIVA 2014.
Properties of an ideal SFA stent

High multidirectional flexibility depends on the strut thickness and stent design

Source: 1. BIOTRONIK Data on file test report IIB(P)79/2016
Properties of an ideal SFA stent

- Low Chronic Outward Force (COF)
- High multidirectional flexibility
- Sufficient Radial Resisitive Force (RRF)
- Sufficient Crush Resistance (CR)
- Accurate deployment
  Elongation/compression can impact patency

RRF (resistance to **concentric** compression)

CR (resistance to **eccentric** compression)

TOO low...
Impossibility to open the lesion
Residual Stenosis

TOO high...
Chronic stent-vessel irritation
Intimal Hyperplasia
Pulsar vs. LifeStent® in animals

LOW COF stent shows significantly smaller area stenosis vs. HIGH COF stent

**28 days FUP**
- Astron Pulsar 8.78mm²
- Lifestent 17.02mm²

**90 days FUP**
- Astron Pulsar 6.9mm²
- Lifestent 19.32mm²

Funovic M. Oral presentation at LINC 2017

LOW COF stent shows significantly smaller area stenosis vs. HIGH COF stent.
Pulsar shows long term durability with sufficient Radial Resisitive Force (RRF)

Images courtesy of Prof van den Berg
**Pulsar-18 is less invasive 4F device**

Benefits of 4F intervention

<table>
<thead>
<tr>
<th>Patient</th>
<th>Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Smaller puncture hole:</strong></td>
<td>Technical success may be improved – low crossing profile</td>
</tr>
<tr>
<td>▪ Less wound complications</td>
<td>▪ Potential for reduced risk of distal thromboembolization -low crossing profile may reduce need for pre-dilation</td>
</tr>
<tr>
<td>▪ Day case intervention</td>
<td>▪ May permit Ambulatory treatment-potentially reducing hospital costs</td>
</tr>
<tr>
<td>▪ Vessel better preserved for future intervention</td>
<td>▪ May reduce need for Vascular Closure Devices</td>
</tr>
</tbody>
</table>

![Diagram showing comparison of 6F and 4F sheaths](source)

Source: 4EVER 24m CIRSE 2013
Technical Success Rate

Pulsar Clinical Studies: complex lesion rates

4EVER\(^1\)
- 100% technical success rate
- 31% calcified lesion

PEACE\(^2\)
- 100% technical success rate
- 56.7% CTO

TASC D\(^3\)
- 100% technical success rate
- 100% CTO
- Long lesions – Long stents

Despite thin strut, low COF design, high technical success\(^4\) can be achieved with Pulsar

\(^1\) Bosiers M. 4EVER, JEVT 2013;20:746–756. \(^2\) Lichtenberg M. PEACE 12m results, J ENDOVASC THER 2014;21:373–380. \(^3\) Lichtenberg M; TASC D, J. Cardiovasc Surg 2013; 54: 433-9. \(^4\) Technical success: defined as the ability to cross and stent the lesion and achieve angiographic residual stenosis, 30% and residual stenosis, 50% by duplex imaging
Pulsar-18 in calcified lesions: 4EVER 24m results

Pulsar demonstrated a non-significant difference in long-term (24m) results in calcified vs. non-calcified arteries.

Patients at risk (n)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>24m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcification</td>
<td>37</td>
<td>27</td>
</tr>
<tr>
<td>No calcification</td>
<td>83</td>
<td>62</td>
</tr>
</tbody>
</table>

Cumulative Primary Patency Rate [%]

- **Calcification**: 76.7%
- **No Calcification**: 66.8%

\[ p = 0.485 \]

Pulsar-18 in patients with CLI
TASC D 12m results

**DESIGN:**
Single Center, prospective registry,
22 patients

**PRINCIPAL INVESTIGATOR:**
Dr. M. Lichtenberg (Arnsberg, Germany)

**ENDPOINTS:**
Primary Patency (PP) at 6 and 12 months
Freedom from Target Lesion Revascularization (TLR) at 6 and 12 months

**Lesion Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N= 22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Ankle Brachial Index (ABI)</td>
<td>0.44 ± 0.18</td>
</tr>
<tr>
<td>Average lesion length</td>
<td>24.5 cm</td>
</tr>
<tr>
<td></td>
<td>(21.5 – 31.5 cm)</td>
</tr>
<tr>
<td>Chronic Total Occlusion</td>
<td>100%</td>
</tr>
<tr>
<td>Sub-intimal recanalizations</td>
<td>81.8%</td>
</tr>
<tr>
<td>Stent ration per patient</td>
<td>2.4</td>
</tr>
</tbody>
</table>

**Results**

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>77%</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>86%</td>
</tr>
<tr>
<td>Mean ABI</td>
<td>0.85 ± 0.2</td>
</tr>
</tbody>
</table>

BIOFLEX PEACE - evaluating Pulsar in a real world setting

DESIGN:
All-Comers registry. Prospective, multicenter, for the treatment of atherosclerotic disease of the femoropopliteal arteries using the 4F Pulsar-18 stent.

PRINCIPAL INVESTIGATOR:
Dr. M. Lichtenberg (Arnsberg, Germany)

PRIMARY ENDPOINT:
Primary Patency (PP) at 12 months

SECONDARY ENDPOINT:
Primary Patency at 6 & 24 months
Freedom from clinical driven Target Lesion Revascularization (cd-TLR) at 6, 12 & 24 months

Lesion Characteristics | N=160
---|---
Lesion length, cm (mean ± SD) | 11.6 ± 10.3
Mean ref. vessel diameter | 4.97 mm
Mean implanted stent diameter | 5.77 mm
TASC C | 34 (18.3%)
TASC D | 40 (21.5%)

Results 24 months

<table>
<thead>
<tr>
<th></th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>78.0 %</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>92.4 %</td>
</tr>
</tbody>
</table>
Pulsar clinical results

- Pulsar has demonstrated consistent clinical performance in several clinical studies.
- Results are consistent across a range of lesion lengths.

Conclusions

- Pulsar stent is specifically designed for the SFA treatment

- High multidirectional flexibility and low COF are given by very thin strut thickness and special stent design

- Pulsar as a low COF stent shows significantly smaller area stenosis than high COF LifeStent in animal study

- Pulsar shows long term durability with sufficient Radial Resisitive Force which has been demonstrated in several clinical studies

- Pulsar outcomes are consistent across a range of lesion lengths
Applications and Evidence for minimally invasive stenting

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