Pulsar stent technology

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Disclosures

Speaker name: Michael Lichtenberg

I have the following potential conflicts of interest to report:

- Consulting (CR Bard, Biotronik, COOK, Optimed, Straub Medical, Terumo, Volcano, Boston, Veniti)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
Culprit Lesion Preparation SFA
(POBA, Cutting, Atherectomy, Laser)

Optimal POBA, 3 min, 1:1 RVD
= TASC A, no dissection
flow limiting dissection

Drug eluting Balloon

Optimal POBA, 3 min, 1:1 RVD

flow limiting dissection
flow limiting dissection
Bailout
Bailout

SE Nitinolstent
Spotstent
Bailoutstent
Radial force at expansion is also known as Chronic Outward Force (COF).

Radial force under compression is also known as Radial Resistive Force (RRF).

Crush Resistance (CR) is also force under compression but at a focal point.

A diseased vessel is not regular diameter
Oversizing always occurs at the site of the lesion

A stent implanted in a vessel without disease/lesion, the COF will be consistent value along the length of the stent

At the point of narrowest diameter, COF will be the highest value

Source: IIB(P)71-2011
Correct chronic outward force (COF)

Low COF = lower mechanical stress on vessel wall
Sufficient Crush resistance

If too low = stent collapse

IIB(P)71/2011-1 test report, Institute fuer ImplantTechnologie und Biomaterialien e.V., Rostock-Warnemuende
Link between scientific theory and proven clinical benefit: clinical trials

**Safety/Efficacy**
- Long term patency
- Low TLR rate
- 4 F device w/o need of closure device
- Low compression time

**Required stent design/characteristics**
- Ideal radial resistive force (RRF)
- Ideal chronic outward force (COF)
- Ideal crush resistance (CR)

**4EVER**

**PEACE**

**Pulsar in TASC D**
4-EVER TRIAL

Prospective non-randomized multicenter trial investigating the safety of the full 4F Endovascular Treatment Approach of Infra-Inguinal Arterial Stenotic Disease

SAFETY and EFFICACY Trial

- Multicenter prospective trial
- 120 patients
- Mean lesion length: **72.42 mm**
- 31% calcified lesions
- CTO: 20.8%

Journal of Endovascular Therapy 2013:20:746-56
4 – EVER TRIAL
Prospective non-randomized multicenter trial investigating the safety of the full 4F Endovascular Treatment Approach of Infra-Inguinal Arterial Stenotic Disease

SAFETY ANALYSIS

Compression time

Puncture site complication
- 3.33 % major hematomas
- 0.97 % in non coumarin pts.
PEACE I Trial

German prospective multicenter all comers efficacy registry to evaluate the one year patency of the 4F Pulsar 18 self expanding nitinol stent for treatment of femoropopliteal occlusive disease

- All comers multicenter registry
- 148 patients enrolled
- 1/2012 – 6/2012
- Mean lesion length: 111.5 mm
- 51.6 % TASC C and D lesion
- CTO 56.7 %
- fTLR 81.0 %
Evaluation of the 4-French Pulsar-18 Self-expanding Nitinol Stent in Long Femoropopliteal Lesions

- All comers prospective registry
- 36 non CLI patients
- Mean lesion length: 182.3mm
- CTO 95.8%
- 6 month PP 87.5%
- 12 month PP 85.4%
- fTLR 89.6%
Superficial femoral artery TASC D Registry:
Twelve-month effectiveness analysis of the Pulsar-18 SE stent in patients with critical limb ischemia

- 22 CLI pts. enrolled
- 12 months follow up
- Mean lesion length: 245 mm
- 100 % CTO
- fTLR: 86 %
CLINICAL EFFICACY CONCLUSION

4EVER

PEACE

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Rutherford Change</th>
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<tr>
<td></td>
<td>+3</td>
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<tr>
<td>6 months</td>
<td>1</td>
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<tr>
<td>(n=98)</td>
<td></td>
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<tr>
<td>12 months</td>
<td>0</td>
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<tr>
<td>(n=96)</td>
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79.8% improved at least 1 Rutherford Category

Painfree Walking Distance (m) Mean ± Standard Deviation

Before Intervention | After 6 Months | After 12 Months
CLINICAL EFFICACY CONCLUSION

Long SFA Trial

Pulsar in TASC D
<table>
<thead>
<tr>
<th>Study</th>
<th>DEVICE</th>
<th>Mean lesion length</th>
<th>Primary patency</th>
<th>Freedom from TLR</th>
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<tbody>
<tr>
<td>4EVER</td>
<td>Pulsar-18</td>
<td>72 mm</td>
<td>73.4 %</td>
<td>85.2 %</td>
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<tr>
<td>PEACE I</td>
<td>Pulsar-18</td>
<td>112 mm</td>
<td>79.5 %</td>
<td>81.5 %</td>
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<tr>
<td>TASC D Trial (CLI patients)</td>
<td>Pulsar-18</td>
<td>315 mm</td>
<td>77.0 %</td>
<td>86.0 %</td>
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<tr>
<td>Long SFA Trial (non CLI patients)</td>
<td>Pulsar-18</td>
<td>182 mm</td>
<td>85.4 %</td>
<td>89.6 %</td>
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<tr>
<td>Supera</td>
<td>Supera</td>
<td>90 mm</td>
<td>84.7 %</td>
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<tr>
<td>Resilient</td>
<td>Lifestent</td>
<td>62 mm</td>
<td>81.3 %</td>
<td>87.3 %</td>
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<tr>
<td>Zilver PTX</td>
<td>DES Zilver</td>
<td>63 mm</td>
<td>73.0 %</td>
<td>77.0 %</td>
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<tr>
<td>Durability</td>
<td>Everflex</td>
<td>96 mm</td>
<td>72.2 %</td>
<td>79.1 %</td>
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<td>Durability 200</td>
<td>Everflex</td>
<td>242 mm</td>
<td>64.8 %</td>
<td>68.2 %</td>
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<td>Viabahn 200</td>
<td>Viabahn</td>
<td>194 mm</td>
<td>78.0 %</td>
<td>85.0 %</td>
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# Further upcoming Pulsar efficacy studies

<table>
<thead>
<tr>
<th>Product /Study</th>
<th>Study Design</th>
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<tbody>
<tr>
<td><strong>USA &amp; Europe</strong></td>
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<td>Burket US</td>
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<td>Brodmann AT</td>
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<td><strong>Europe</strong></td>
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<tr>
<td><strong>BIOFLEX PEACE</strong></td>
<td>All-Comers Registry Pulsar-18 500 subjects</td>
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<td><strong>BIOFLEX PEACE</strong></td>
<td>Registries 100-500 per Satellite</td>
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<td>Satellites</td>
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<tr>
<td><strong>OCT</strong></td>
<td>Single-arm, SFA Pulsar stents 40 subjects</td>
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<td>Brodmann AT</td>
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<td><strong>Combination Therapy</strong></td>
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<tr>
<td><strong>BIOLEX 4EVER</strong></td>
<td>Single-arm, SFA Passeo-18 Lux+Pulsar-18 120 subjects</td>
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<td>Bosiers BE</td>
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*PRO- Patient Related Outcomes e.g. quality of life, pain score
Objective: Evaluation of safety and performance of Pulsar-18 in treatment of subjects with atherosclerotic disease
Design: Prospective, non-randomized, multi-centre All Comers Registry with follow-up investigations at 6, 12 and 24 months
Indication: Subjects with infrainguinal atherosclerotic disease eligible for stent implantation

Dr. Michael Lichtenberg (PI), Arnsberg
Prof. Dr. Guenther Wittenberg (Bielefeld)
Dr. Tessarek (Lingen)
Prof. Holger Reinecke (Münster)
Dr. Stefan Betge (Jena)
Dr. Torsten Fuss (Suhl)
Dr. Ralf Langhoff (Berlin)
Prof. Dr. Sigrid Nikol (Hamburg)
Prof. Dr. Claus Nolte-Ernsting (Mülheim)
Dr. Jawed Arjumand (Wuppertal)
PD Dr. med. Ulrich Sunderdiek (Osnabrück)
Prof. Dr. Birgit Hailer (Essen)
Dr. Jawed Arjumand (Wuppertal)
Prof. Martin Andrassy (Rastatt)
BIOFLEX PEACE Registry
Subgroup analysis

• Type of stenosis (e.g. de novo, restenotic, etc.)

• Lesion length, location, degree of stenosis, calcification

• TASC classification

• Lesion preparation (e.g. scoring balloons, cutting balloons, atherectomy devices, etc.)

• Use of Drug eluting balloons
  
  for predilatation
  for postdilatation

• Stent characteristics (diameter, length, stent size vs. RVD etc.)

• Treatment approach (e.g. sub-intimal, intra-luminal, etc.)

• Stenting strategy (e.g. spot stenting, etc.)

• QoL (e.g. pain level, WIQ, SF-12)
BIOFLEX PEACE Registry

December 2014: 101 patients with 111 lesions enrolled

Mean target lesion length: 124.9 mm

Mean Pulsar-18 SE stent length: 92.5 mm
BIOFLEX PEACE Registry

December 2014: 101 patients with 111 lesions enrolled

Lesion pretreatment

Efficacy difference?

Post stent treatment
Conclusions

• Important stent characteristics
  – Correct „chronic outward force“
  – Correct „radial resistive force“
  – Sufficient „crush resistance“

• Because of correct COF the 4 F Pulsar SE Stent has a high clinical efficacy potential

• Equal efficacy to 6 F stent devices

• Advantage: Reduced manual compression time and access complication rates – no/reduced need for closure devices
Thank you for your attention
9TH HERDRINGER VASCULAR COURSE
April 24-25, 2015

Invitation

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• Herzzentrum Bad Krozingen, Bad Krozingen, Germany
• Vascular Center, Arnsberg Clinic, Arnsberg, Germany

Faculty:
Prof. Marianne Brodmann, Prof. Thomas Zeller
Dr. Michael Lichtenberg, Dr. Wilhelm Stahlhoff
PD Dr. Andrej Schmidt, Prof. Giovanni Torsello
Prof. Karl-Ludwig Schulte

Location:
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Zum Herdringer Schloss 7
59757 Arnsberg

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www.klinikum-arnsberg.de/ib-termine

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Supported by: incathlab
the interactive cardiovascular channel
Pulsar stent technology

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