Current developments in drug eluting technologies for complex SFA treatment

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Disclosure

Speaker name:
.....Stefan Müller-Hülsbeck..........................................................

I have the following potential conflicts of interest to report:

☑️ Consulting:  Terumo, Boston Scientific, Eurocor Tech
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Complex SFA treatment?

- Objectives

  - Definition of complex SFA lesions
  - Introductory remarks
  - DISRUPT trial
  - LOCOMOTIVE trial
  - IMPERIAL trial – long-lesions
  - SPORTS trial
Definition of complex SFA lesions

- TASC C or TASC D lesion
- Lesion length >15cm (stenoses or occlusions)
- Calcified plaque burden
- Long-distant SFA re-occlusion after implants
Calcified plaque burden
Calcified plaque burden

Wire-Interwoven Nitinol Stent
Primary patency (KM)


Heparin-Bonded Stent-Graft – TASC II C and D (lesions longer than 20cm!)

In lesions ≥20 cm, the 24-month patency rates were **65.2** versus **26.7 %** for VIABAHN® versus BMS


<table>
<thead>
<tr>
<th></th>
<th>Viabahn™ Heparin-Bonded</th>
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<tbody>
<tr>
<td>Primary patency  @ 12month</td>
<td>67</td>
</tr>
<tr>
<td>Secondary patency @ 12month</td>
<td>96.9</td>
</tr>
</tbody>
</table>

Endovascular bypass concept

Leave nothing behind strategy


http://diako.de
Goal of Lithoplasty & DCB

- Obtain a better lumen with PTA
- Avoid stents – “leave nothing behind strategy”
- Overcome the main limitation of DCB: severe calcium
Next Steps in Shockwave Lithoplasty Clinical Development

Lithoplasty as primary therapy
Results:
- Low rate of vascular complications
  Provisional stenting (1.1%)
- Consistent effectiveness
  High acute gain (3.0 mm)
  Low residuals stenosis (23.8%)
  Sustained 6 month results

Combination therapy
- Goal is to assess the optimal therapy to dilate heavily calcified lesions.
- All patients who do not receive a stent will be treated with a drug-coated balloon.

DISRUPT PAD I
DISRUPT PAD II
DISRUPT PAD III
**Study Design**  Randomized study of the Shockwave Medical Peripheral Lithoplasty System with DCB versus standard balloon angioplasty with DCB to treat moderate and severely calcified femoropopliteal arteries (Disrupt PAD III).

**Objective:** The objective is to assess the optimal therapy to dilate heavily calcified lesions with Lithoplasty® versus traditional angioplasty, in achieving less than 30 % stenosis without the need for a stent. In addition, all patients who do not receive a stent will be treated with a drug-coated balloon.
Leave little behind strategy
Multi-Loc-Stent

LOCOMOTIVE study:

Multi-LOC for flow limiting outcomes after POBA and/or DCB treatment in the infrainguinal position with the objective to implant multiple stent segments.

<table>
<thead>
<tr>
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<th><strong>Multi-Loc</strong></th>
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<tbody>
<tr>
<td><strong>75 pts</strong></td>
<td></td>
</tr>
<tr>
<td>Primary patency @ 12month</td>
<td>85.7</td>
</tr>
<tr>
<td>TLR @ 12month</td>
<td>9.3</td>
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If there is a need for a scaffold?

“...if there is a need for an implant, all implants should be DES. This may be the end of the BMS era for femoropopliteal disease treatment.”

Any evidence?
# IMPERIAL Clinical Study Overview

| Primary Investigators | Global: William A. Gray, MD  
|                       | European: Stefan Müller-Hülsbeck, MD |
| Study Design | **RCT**  
|             | (Eluvia DES vs Zilver PTX)  
|             | • 2:1 randomized  
|             | • Single-blind  
|             | • Non-inferiority trial  
|             | **Long Lesion Sub-study**  
|             | (Eluvia)  
|             | • Single arm  
|             | • Lesion length 140 mm-190 mm  
|             | **Pharmacokinetic Sub-study** (Eluvia)  
|             | • Single-arm  
| Patients | N=465  
|             | Eluvia N=309 vs Zilver PTX N=156  
|             | N=50  
|             | N=13  
| Investigational Centers | 65 study centers: US, Canada, New Zealand, Belgium, Germany, Austria, Japan |

[http://diako.de](http://diako.de)
**IMPERIAL: Long Lesion Effectiveness**

**Primary Patency at 12 Months**

- Kaplan-Meier estimate: 87.9% at 12 months
- Observed rate: 87.0% (40/46)

1-year mortality 0%

Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or bypass of the target lesion, as assessed by the DUS core lab.
CTO stenting

- Inclusion criteria:
  
  Lesions > 15cm !!!

Started 2017: more than 100 pts. enrolled
CTO stenting

DES: Eluvia vs. BMS vs. DCB (bail-out stenting with Mulit-Lock)
Conclusions

• Drug-eluting technologies are expected to play an expanding role in endovascular treatment of PAD, also for complex SFA treatment

• Attempts combining drug-eluting technologies with others following the strategy “leaving nothing behind” are very promising and need further evaluation

• Attempts combining drug-eluting technologies with others following the strategy “leaving little behind” are very promising also and need further evaluation

• DES helps to provide a permanent scaffold in case of poor lumen gain, remaining plaque burden, recoil and/or flow-limiting dissection for complex SFA treatment as shown in the IMPERIAL long-lesion trial

• Data from the SPORTS trial are still pending
Barcelona, Spain  
September 7-11  
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