OCT Evidence of Reduced Thrombogenicity on Surface Modified FD

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Introduction

- In vitro- Pipeline Flex Embolization Device + Shield Technology TM (Shield)-surface modification consisting of a 3nm thick modified phosphorylcholine is less thrombogenic.¹

- **Hypothesis**- Shield has less thrombus formation in vivo as compared to uncoated Pipeline Embolization Devices (PED) regardless of dual antiplatelet therapy (DAPT)

Optical Coherence Tomography

- OCT - uses near infra-red light for HR imaging
- Catheter - DragonFly (St. Jude Medical) -
  - 54mm HR pullback
  - 20mm rapid exchange with 2.7F profile
  - 0.014’ guidewire and 6G guide catheter compatible
Comparison

**DSA**

**OCT**
Comparison

DSA s/p Angioplasty
Methods: study design, protocol

- Rabbit Elastase-aneurysm model
- 4 groups, 10 rabbits in each group: (cPED- Pipeline Classic, sPED- Pipeline Flex with Shield technology)
  - DAPT group - 10mg/kg/day clopidogrel and ASA, p.o. 5 days prior implant to 30 days
  - OCT used for assessing: Clot formation on the surface of device
## Baseline Data

<table>
<thead>
<tr>
<th>Aneurysm Characteristics (mean±SD)</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>cPED</td>
</tr>
<tr>
<td>neck size (mm)</td>
<td>no DAPT</td>
</tr>
<tr>
<td></td>
<td>DAPT</td>
</tr>
<tr>
<td>height (mm)</td>
<td>no DAPT</td>
</tr>
<tr>
<td></td>
<td>DAPT</td>
</tr>
<tr>
<td>parent vessel (mean±SD)</td>
<td>no DAPT</td>
</tr>
<tr>
<td></td>
<td>DAPT</td>
</tr>
<tr>
<td>proximal to aneurysm (mm)</td>
<td>no DAPT</td>
</tr>
<tr>
<td></td>
<td>DAPT</td>
</tr>
<tr>
<td>distal to aneurysm (mm)</td>
<td>no DAPT</td>
</tr>
<tr>
<td></td>
<td>DAPT</td>
</tr>
<tr>
<td>distal subclavian (mm)</td>
<td>no DAPT</td>
</tr>
<tr>
<td></td>
<td>DAPT</td>
</tr>
<tr>
<td>diameter size (mm)</td>
<td>no DAPT</td>
</tr>
<tr>
<td></td>
<td>DAPT</td>
</tr>
</tbody>
</table>

One-way ANOVA
Methods: imaging protocol

- **FD implant:**
  1) DSA: pre-implant
  2) VasoCT: pre-implant
  3) DSA: post-implant
  4) OCT: post-implant
  5) DSA: post-angioplasty
  6) OCT: post-angioplasty
  7) VasoCT: post-angioplasty

Blood clearance for OCT – power injection
  - 5ml/s, 3.5s, Omnipaque 240mgI/ml
Methods: Thrombus Quantitation

- After implant, optical coherence tomography (OCT, Dragonfly, St Jude) was performed before and after angioplasty, and at terminal follow-up.
- Thrombus formation was assessed at 4 locations along the implant as present or absent.
Results: procedure and complications

FD implant:
- 45 devices implanted,
  - 44 cases complete neck coverage (98%)
- no vessel perforation,
- 1 vessel dissection: innominate artery, proximal to FD (2%), blood flow not compromised – kept in study
- No visible thromboembolic complication on DSA
Results: clot formation

D - distal, DA - distal to the aneurysm, PA - proximal to the aneurysm, SBO - side branch origin

Score: 0-4

cPED – NO DAT, score: 4
Results: clot formation

Clot occurrence on the surface of the FD after angioplasty

<table>
<thead>
<tr>
<th>Treatment Groups</th>
<th>cPED no DAPT</th>
<th>cPED DAPT</th>
<th>sPED no DAPT</th>
<th>sPed DAPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Clot at the origin of 3 covered side branches

<table>
<thead>
<tr>
<th>Treatment Groups</th>
<th>cPED-no DAPT</th>
<th>cPED-DAPT</th>
<th>sPED-no DAPT</th>
<th>sPed-DAPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases</td>
<td>10</td>
<td>9</td>
<td>7</td>
<td>5</td>
</tr>
</tbody>
</table>
Results

- Animals receiving DAPT had a significant reduction in PRU values (69±28 vs 247±41, p=0.0039) and non-significant reduction in ARU (649±31 vs 659±9, p=0.2)
- **Shield significantly reduced the presence of clot formation (p<0.0001)**
- Clot formation was not associated with DAPT (p=0.4) or neck size (p=0.7).
Conclusion

- Shield technology reduces acute thrombus formation regardless of DAPT has been confirmed in vivo using OCT
- Shield reduces thrombus at SBOs
- OCT offers quantifiable insight into the device-anatomy interface
UMass Collaborations
- Marc Fisher, MD
- Neil Aronin, MD
- Alexei Bogdanov, PhD
- Greg Hendricks, PhD
- Guanping Gao, PhD
- Miguel Esteves, PhD
- Linda Ding, PhD
- Srinivasan Vedantham, PhD
- John Weaver, MD

Collaborations
- Youssef Wadghiri, PhD - NYU
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- Don Ingber, PhD – Harvard
- Netanel Korin, PhD - Technion
- Ricardo Hanel, MD and Eric Sauvageau, MD - Baptist
- Raul Nogueira, MD - Emory

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