Intravascular Imaging Insights into the Mechanism of Action of Focal Force Balloon Angioplasty

Sahil A. Parikh, M.D.
Assistant Professor of Medicine
Director, Research and Innovation Center
Director, Experimental Interventional Cardiology Laboratory
Director, Interventional Cardiology Fellowship Program

Harrington Heart & Vascular Institute
University Hospitals Case Medical Center
Case Western Reserve University School of Medicine
Disclosure

Speaker name:
Sahil A. Parikh, MD

I have the following potential conflicts of interest to report:

- Consulting: Angioscore/Spectranetics, TriReme, Cordis, St. Jude
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Short Segment Occlusion PTA: Satisfactory Angiographic Result?
OCT of TP Trunk Post PTA
**POBA Mechanism of Action**

**MoA 1:** Unfolding expansion results in:
- Shear stress

**MoA 2:** Uncontrolled expansion results in:
- Dilatation in “path of least resistance”

**MoA 1 + 2 = Vessel Trauma (torsional, radial, longitudinal)**

**Vessel trauma manifests as:**
- Severe dissections
- Elastic recoil
- Abrupt closure

**Today’s solution:** STENTS
Goal: Provide “stent-like” results without permanent implant

Design by TriReme Medical: Unique nitinol “constraining structure”

- Shields vessel wall from torsional shear stress caused by balloon “unfolding”
- Uniformly distributes longitudinal & circumferential forces
- Modifies plaque via:
  - “Modules”: Vessel dilatation without cutting or scoring
  - “Grooves”: Stress relief, plaque modification
- Reduces dissections
- Fast deflation, concentric secondary profile

“Grooves“

[Modules project beyond constraining structure]
Balloon Effect on Simulated Artery
Finite Element Analysis Computer Images

PTA Balloon

Chocolate Balloon

Scoring Balloon

Plaque

High Stress

Low Stress

Plaque

High Stress

Low Stress

Plaque

High Stress

Low Stress

FEA simulation shows significantly less vessel trauma vs. alternatives

Courtesy: TriReme Medical
## BTK Procedural Success

<table>
<thead>
<tr>
<th>No Flow Limiting Dissection</th>
<th>N=174</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieved &lt;30% Diameter Stenosis</td>
<td>99% (173/174)</td>
</tr>
<tr>
<td>physician visual estimate</td>
<td>94% (163/174)</td>
</tr>
</tbody>
</table>

### Dissection Rates

<table>
<thead>
<tr>
<th>Chocolate BAR</th>
<th>Odink, PTA Study</th>
<th>Bosiers, PTA Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1%</td>
<td>8%</td>
<td>12%</td>
</tr>
</tbody>
</table>

### Bail-Out Stenting Rates

<table>
<thead>
<tr>
<th>Chocolate BAR</th>
<th>Schmidt BTK DEB</th>
<th>Bosiers, PTA Arm</th>
<th>Schmidt BTK PTA</th>
<th>Odink, PTA Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>3%</td>
<td>5%</td>
<td>12%</td>
<td>14%</td>
<td>20%</td>
</tr>
</tbody>
</table>

### How does this compare?

**Odink, PTA**

**Bosiers, PTA Arm**

**Schmidt, BTK PTA**

**Schmidt, PTA Study**

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Courtesy: Tony Das and Jihad Mustapha, LINC 2014
Plaque Composition

Lipidic 1

Lipidic 2

Fibrotic 4

Calcified 3

Courtesy: Hiram Bezerra, MD and Marco Costa, MD, PhD
Angioplasty of Calcified Lesions: Fracture

No Fracture: Dissection

Partial Calcium Fracture

Complete Calcium Fracture

Courtesy: Hiram Bezerra, MD and Marco Costa, MD, PhD
Case Example: Lipid Rich Plaque with Medial Calcification
Treatment with Chocolate 4.0x40mm
Localized Dissection without Extension
Case Example: Calcified Lesion
Case Example: Fibrotic Lesion Anastomosis
Numerous Examples
CONCLUSIONS

• Focal Force Balloons have a unique mechanism of action compared to conventional PTA balloons.

• These devices demonstrate good acute performance in ATK and BTK lesions when looking at registry data in a representative group of patients.

• Heterogenous lesion composition confounds our ability to identify specific lesion types which may be particularly well-suited to treatment with these devices.

• Imaging analysis suggests less intimal disruption.

Chocolate OCT: ClinicalTrials.Gov: NCT02237066
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