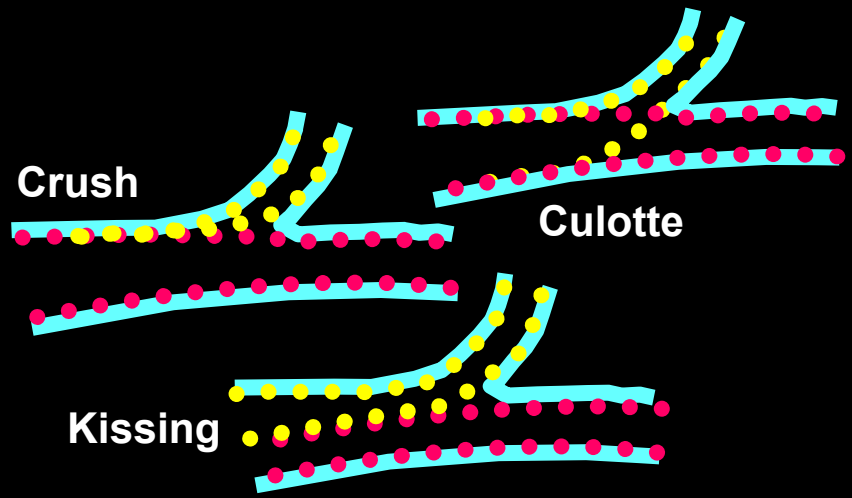
# Dedicated Bifurcation and Left Main Stents

**Eberhard Grube MD**

Intl. Heart Center Rhein – Ruhr, Essen, Germany
Hospital Oswaldo Cruz - Dante Pazzanese, São Paulo, Brazil
Stanford University, Palo Alto, California, USA

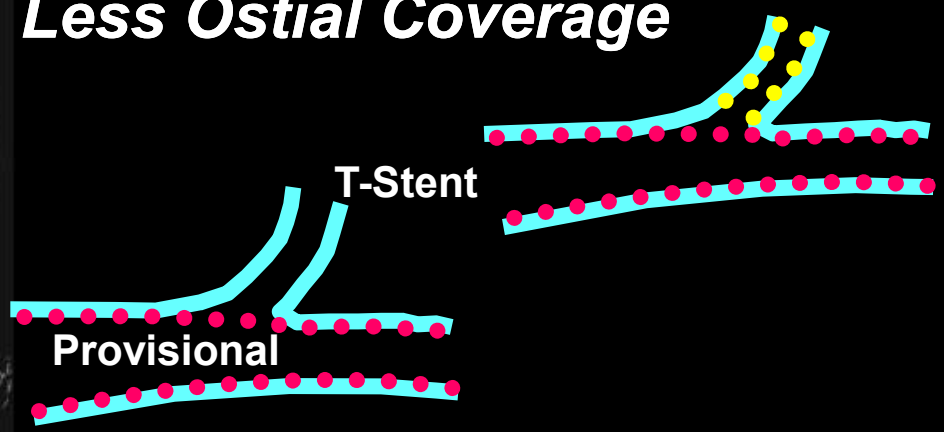
# Bifurcation Stent Techniques

*More Complex Technique*




*Less Ostial Coverage*

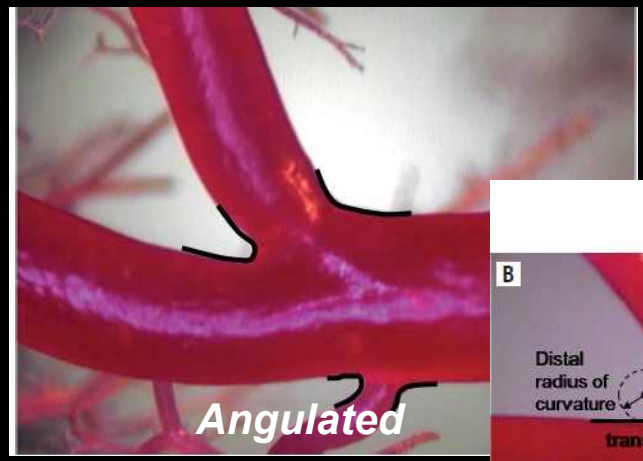
*More Ostial Coverage*

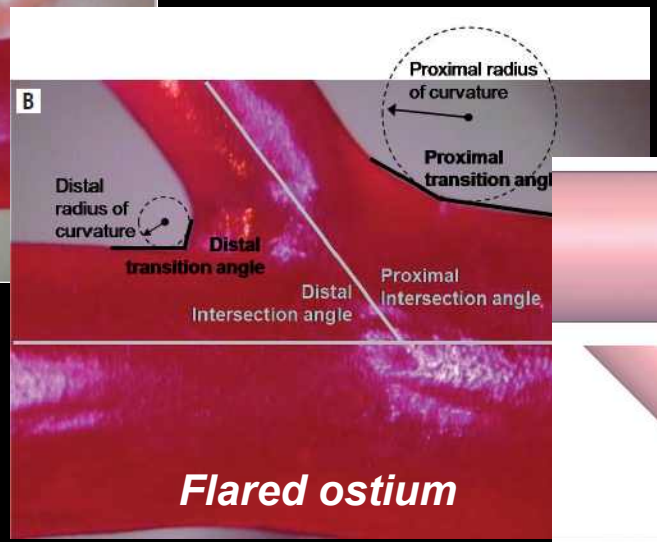


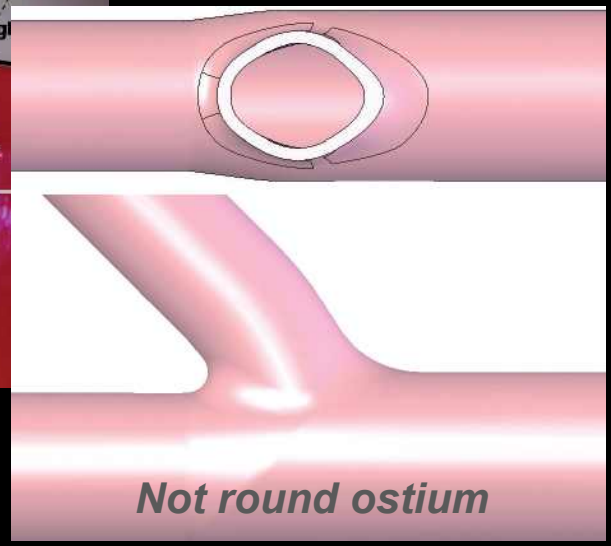

*Less Complex Technique*

# Understanding Ostial Morphology

**Bifurcation procedures are complicated, due to complicated anatomy**



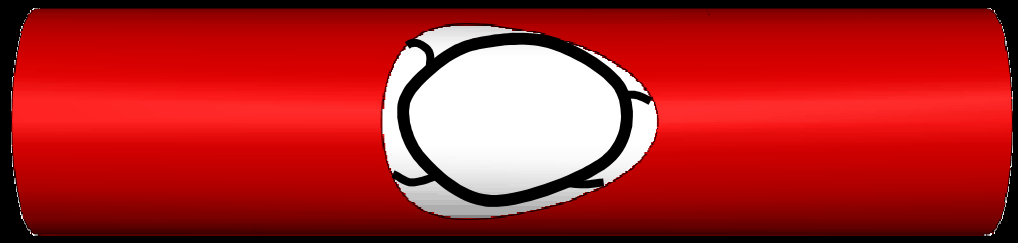




M.E. Russell et al, *EuroIntervention* 2009; 5:96-103

# In a perfect world, all stent struts should be in contact with the arterial tissue

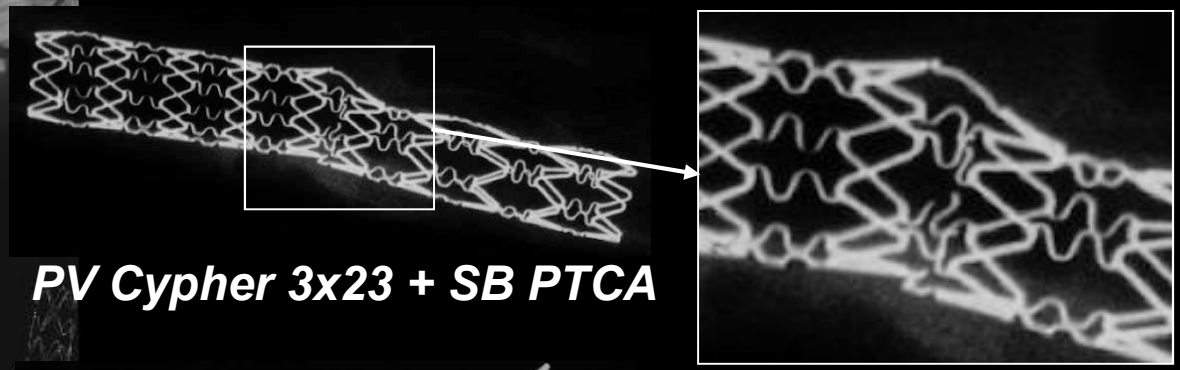
- Why?
  - To reduce the risk of stent thrombosis
  - To facilitate subsequent stent insertion in the side branch
  - To reduce the disturbance of the blood flow
  - To optimize drug delivery

- If the stent cells are too small, this is not possible!



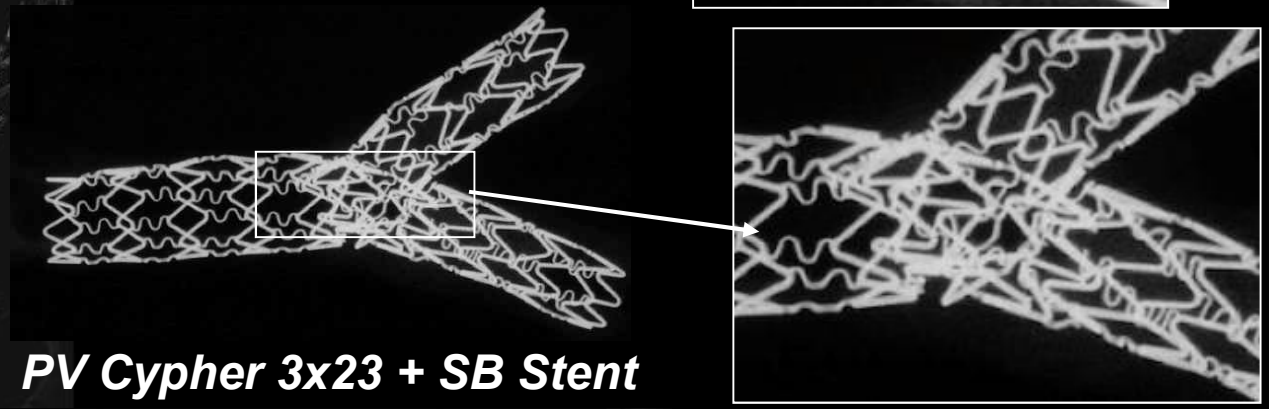
# Issues with 2 Stent Techniques

**Images from *in vivo* provisional stent studies at 180 days:**



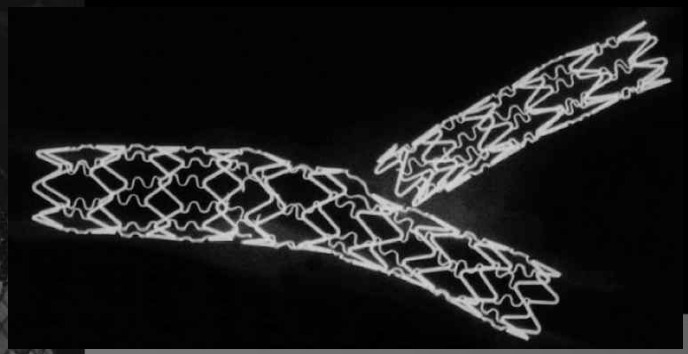
***PV Cypher 3x23 + SB PTCA***

PTCA in SB distortion, fracture dissection at SB ostium



***PV Cypher 3x23 + SB Stent***

Excessive overlap, obstructed lumen

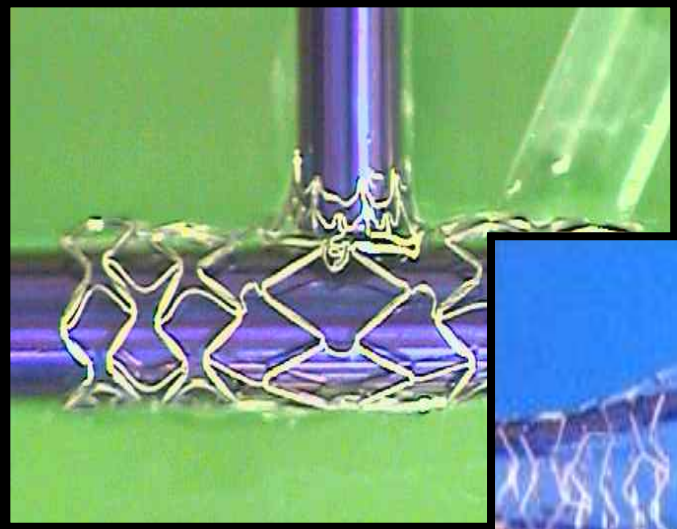


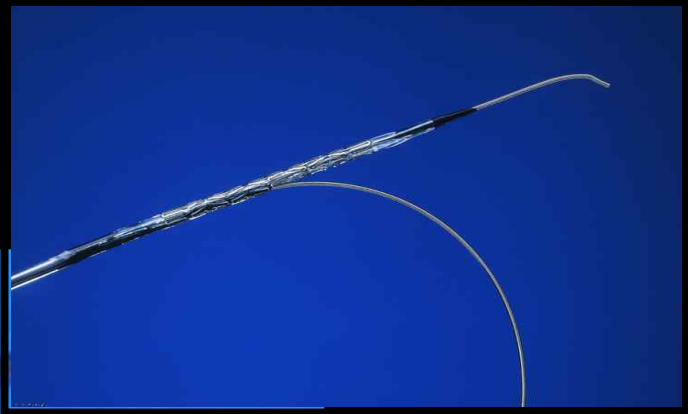
Ostial gaps, persistent flow restriction, restenosis

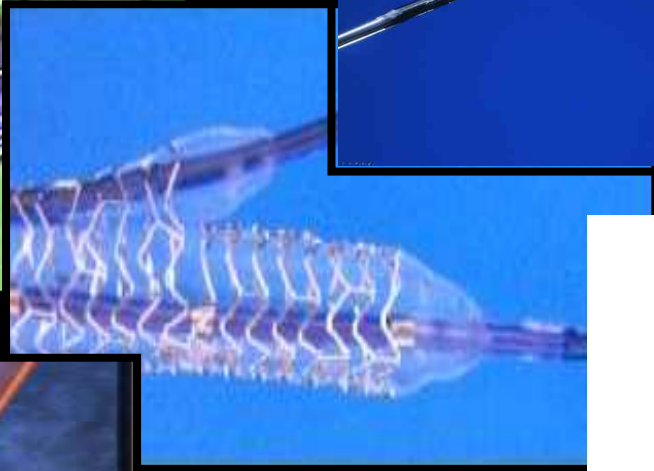
# Example of Stent Conformity

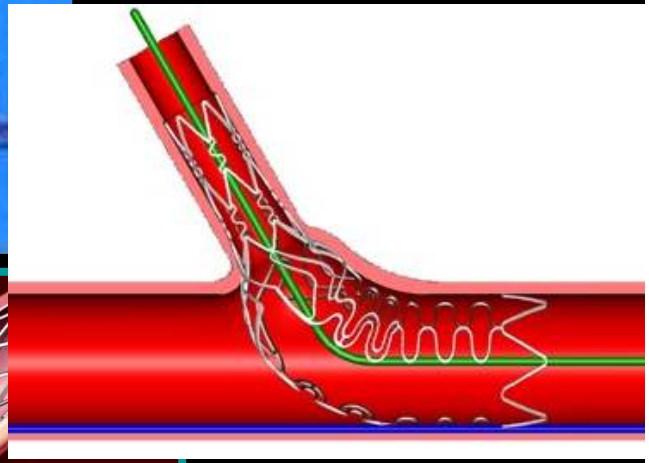
Stent Boost Imaging shows
SB ostial coverage

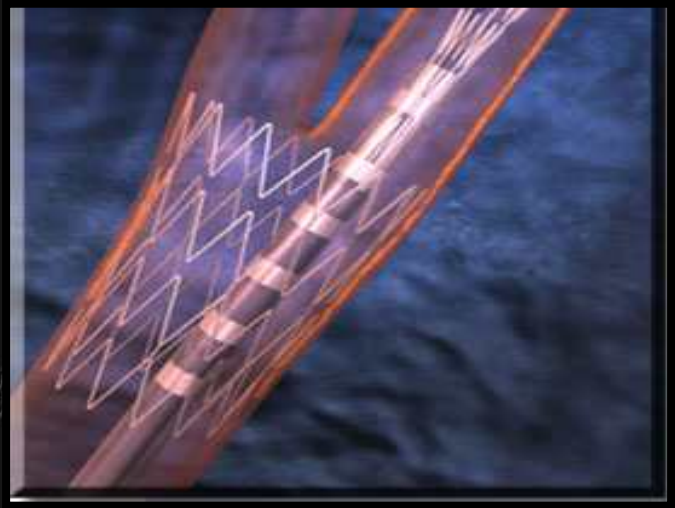
# Dedicated Bifurcation Stents

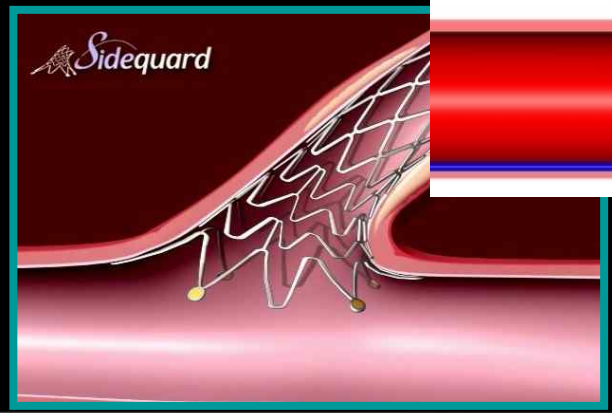




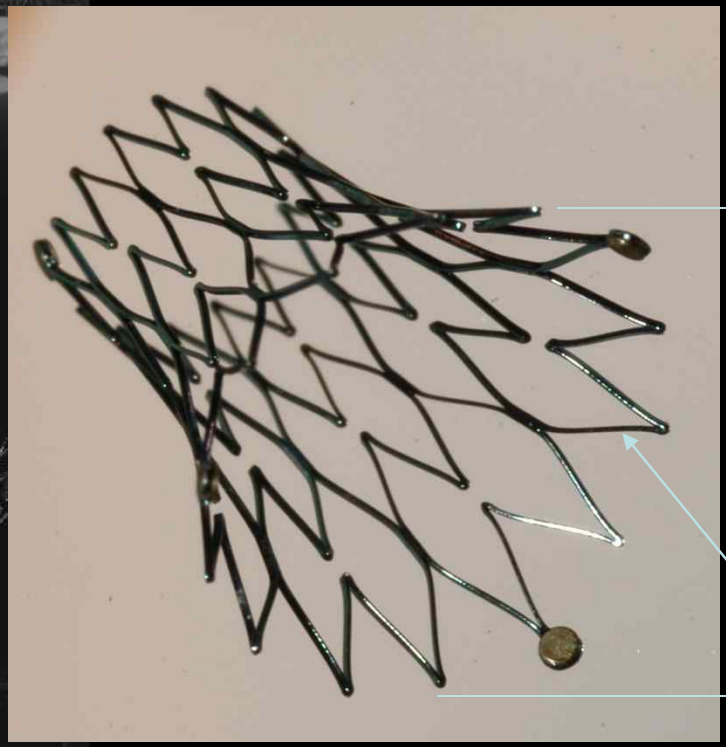








# AXXESS PLUS LM System

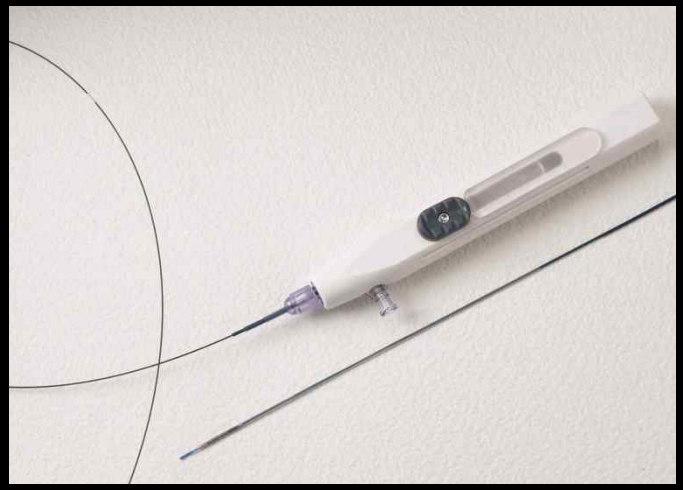


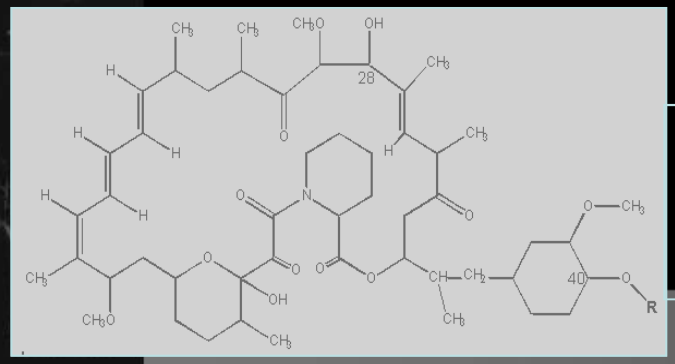
Flared Distal-End Stent Design

Self Expanding Nitinol Material

6, 8, 10, or 12 mm flare diameter

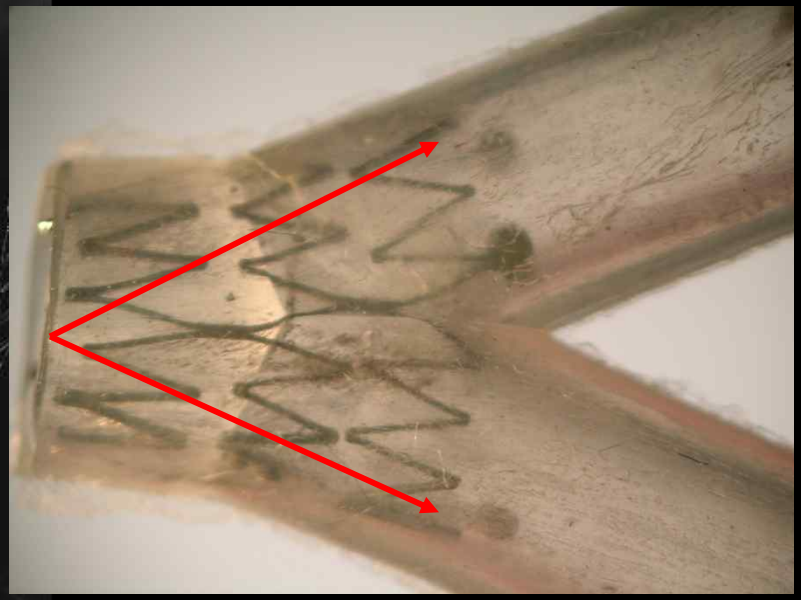
4.8F Rx Delivery System



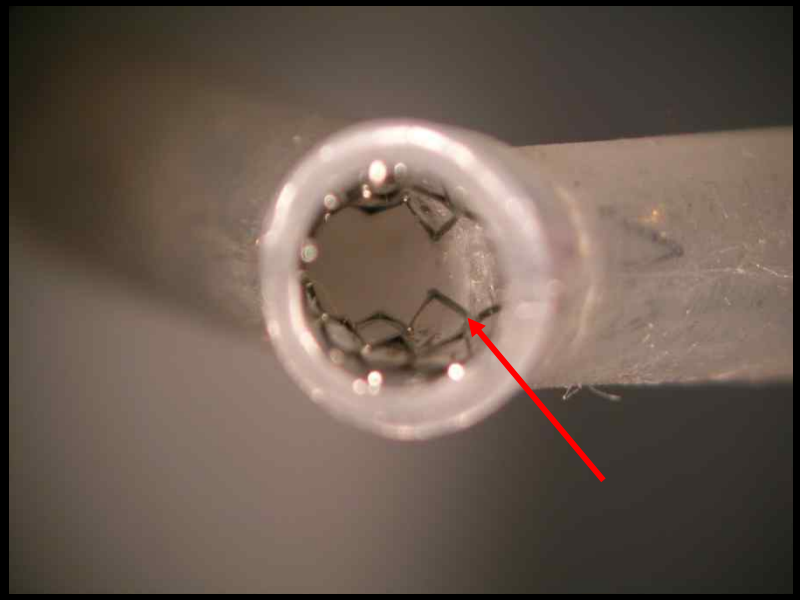


Biolimus A9 antiproliferative strut coating

# Complete Ostial Coverage

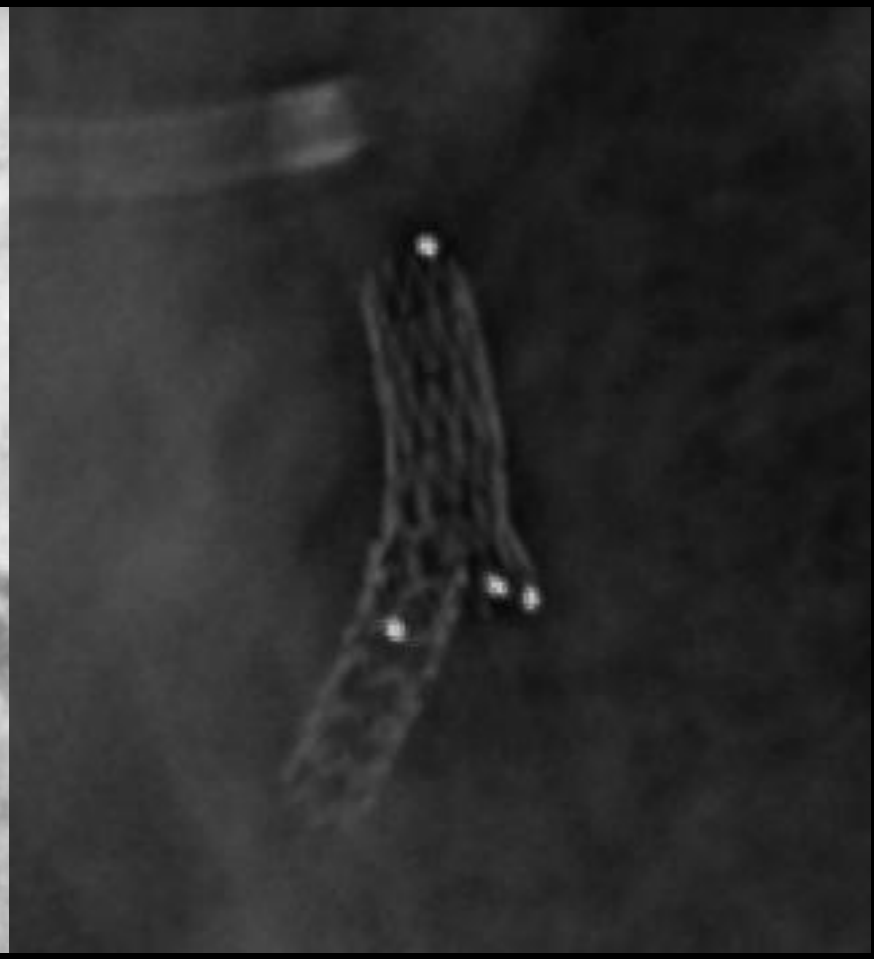


Stent flares to cover ostia of
Both branching vessels



Carina area is covered
By stent struts

# Example of Stent Conformity



Final Angiogram
PV: Axxess + Cypher
SB: PTCA

Stent Boost Imaging shows
SB ostial coverage

# AXXESS Clinical Experience

**AXXESS**
**n = 43**

- Bare metal version of Axxess Stent
- Safety and effectiveness study
- Six-month follow-up completed

**AXXESS PLUS**
**n = 139**

- Evaluated drug-eluting Axxess stent to bare metal stent
- Safety and effectiveness study
- Follow up through 3 years complete

**DIVERGE**
**n = 302**

- International safety and effectiveness study
- Evaluated best practices from AXXESS PLUS
- Follow up through 12 months complete

**AXXENT**
**n = 33**

- Multi-center pilot study for Axxess Left Main stent
- 12 months follow-up complete
- Study showed potential for effective LMCA intervention

***Over 500 Patients Studied***

Siegburg

# AXXENT LM Study
# Angiographic follow-up

| N=31 Patients with AFU (94%) | Left Main | Left Anterior Descending | Left Circumflex |
|---|---|---|---|
| Post Procedure | | | |
| MLD- mm | 3.63 ± 0.37 | 2.65 ± 0.41 | 2.47 ± 0.41 |
| %DS | 9.6 ± 5.3 | 13.7 ± 6.7 | 14.6 ± 6.6 |
| Acute Gain- mm | 1.80 ± 0.84 | 0.82 ± 0.71 | 0.96 ± 0.58 |
| 6 Month Follow Up | | | |
| MLD- mm | 3.59 ± 0.46 | 2.41 ± 0.62 | 2.03 ± 0.64 |
| %DS | 9.66 ± 8.5 | 20.6 ± 18.1 | 28.4 ± 21.5 |
| Late Loss- mm | 0.043± 0.32 | 0.24 ± 0.26 | 0.46 ± 0.69 |
| Binary Restenosis | 0% | 2 (6.9%) | 5 (16.1%) |

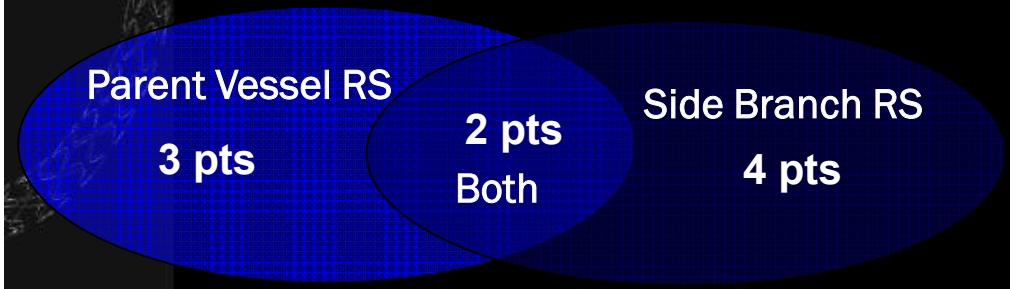
# AXXESS PLUS (Bifurcation) Results

| | |
|---|---|
| **Angiographic Follow Up** | 124/136 (91.2%) |
| **Binary Restenosis**<br>- Axxess Plus only<br>- All stents (Axxess + distal DES)<br>- In segment | <br>4.0%<br>5.6%<br>10.5% |

| | **Axxess Plus** | **Control** | ***p*** |
|---|---|---|---|
| **Angiographic Late Loss** | 0.11 ± 0.62 mm | 0.46 ± 0.51 mm | 0.002 |

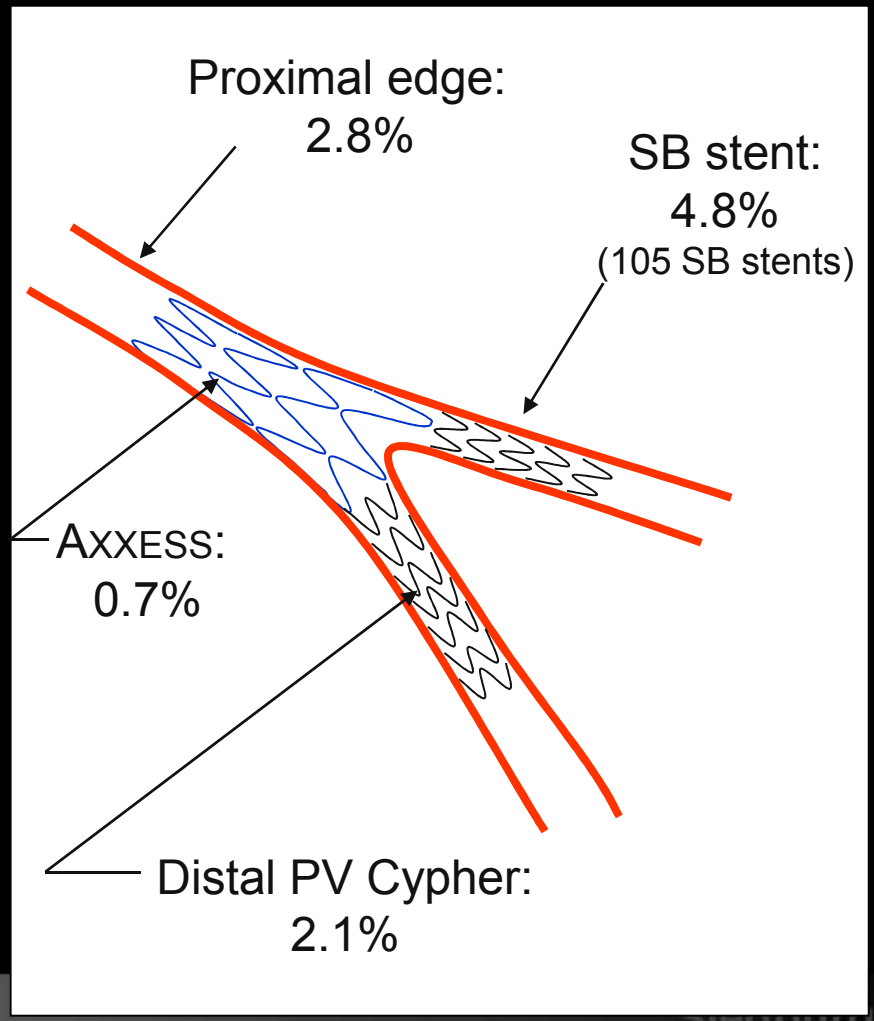
# Angiographic Outcomes

**Any in-bifurcation restenosis:**
***6.4% (9/140 at 9 months)***

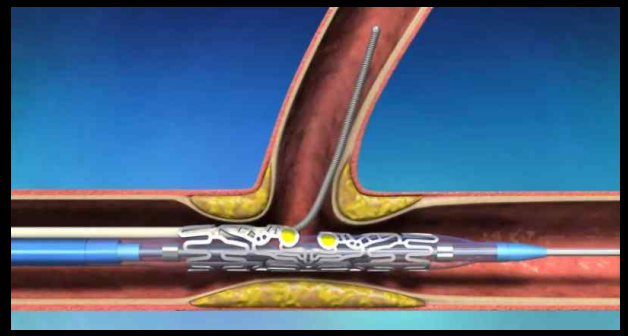



***Lowest restenosis rates ever reported in a bifurcation study of any kind***

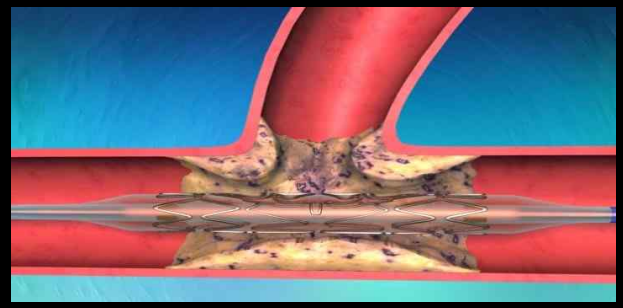
**Location Analysis:**



# Antares™ Family
## Treating Main Vessel with Side Branch Access



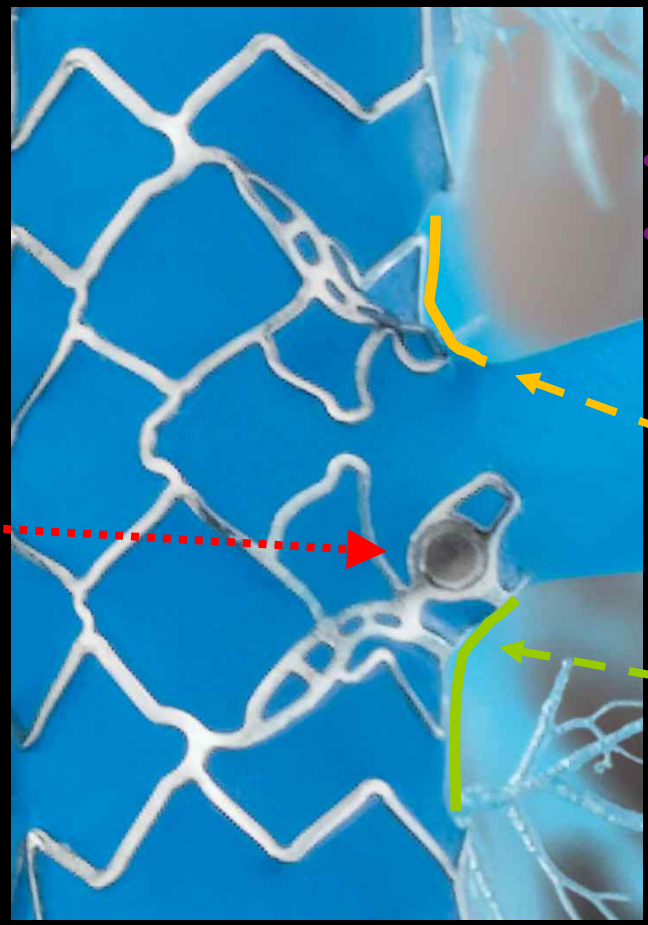
- Antares™ II
  *Continuous SB Access, Single balloon*
  - MV stent engineered for ostial scaffolding
  - Continuous SB access and no wire crossing by design
  - Can be considered for all anatomies and lesion types at or near bifurcations



- Antares™ Lite
  *Single wire, Single balloon*
  - MV stent engineered for ostial scaffolding
  - Ultra-low profile, single wire system (No SB wire required)
  - Stent crossing profile smaller than most regular stents (0.037”)

# Antares™ Design
## Tailored to the Asymmetric Ostial Geometry

- Varying strut lengths
- Independent ostial expansion



- Ostial scaffolding
- Asymmetric design

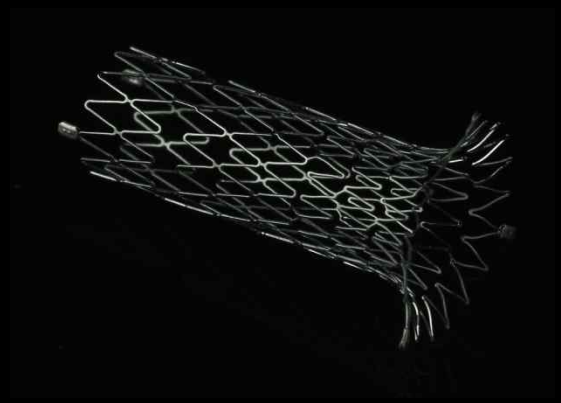
**Distal ∠ - acute**

**Proximal ∠-obtuse**

Ostial locators
- improves alignment
- provide structural support

- Advanced stent design allows for automatic deployment of ostial preservation structure upon expansion of main stent body with a single balloon

# Sideguard® Coronary Sidebranch Stent & Delivery System



- Self-expanding, Nitinol, ‘trumpet’-shaped sidebranch stent
- Delivers like a PCI catheter; Rx, low-profile, single wire
- A sheath encloses the stent, ensuring accurate placement of the device

# Cappella Sidebranch Stent *(ostial protection device)*

**Sideguard address the complexities associated with ostial and bifurcated lesions**

**Precise BE Delivery System**

**Peel-away Split Sheath, Balloon Expandable Delivery**

**Bare Metal Sidebranch Stent**

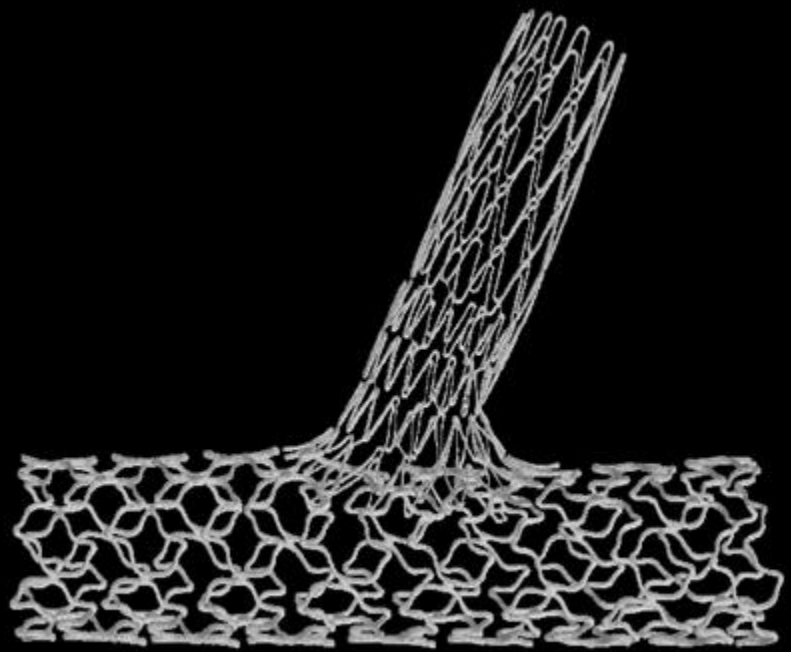

**Self-Expanding (SE) Stent**

- **Sideguard is a self-expanding, anatomically-shaped stent**
- **Target is a balloon-release delivery system for SE stents**

# Cappella Sidebranch Stent

## *Anatomic Molding to SB Anatomy*

***Stent architecture provides scaffolding throughout bifurcation***

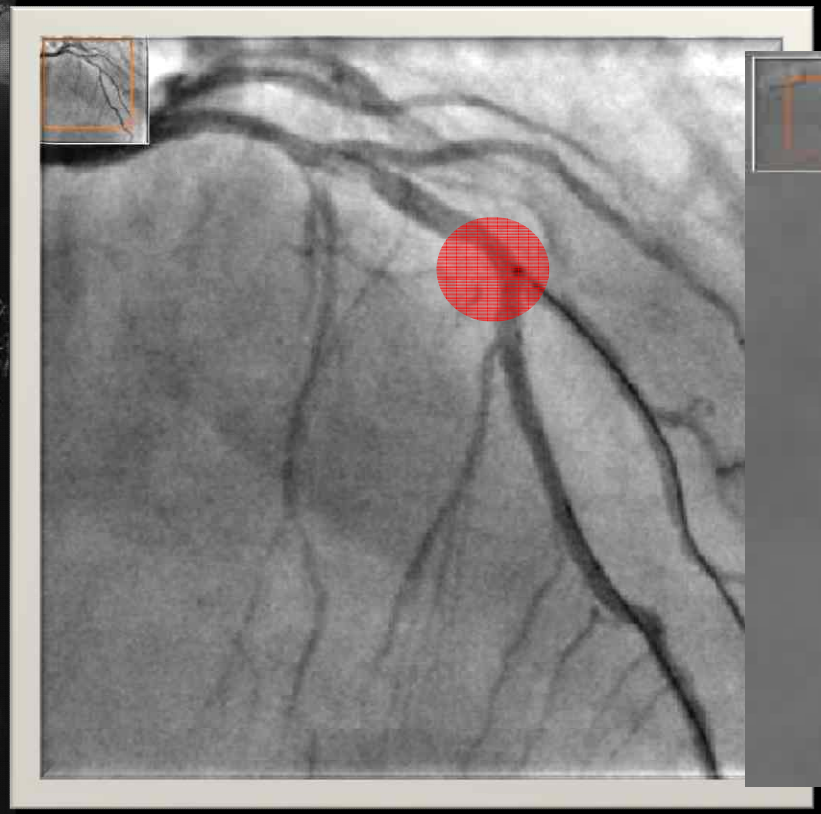


***Self Expanding Trumpet design opens the SB ostium***

**J. Ormiston, micro CT of Sideguard plus Liberte**

Siegburg

# T-Stenting Technique



*Positioning of ostial marker at sidebranch ostium*

*Position and deploy Sideguard® at ostium*

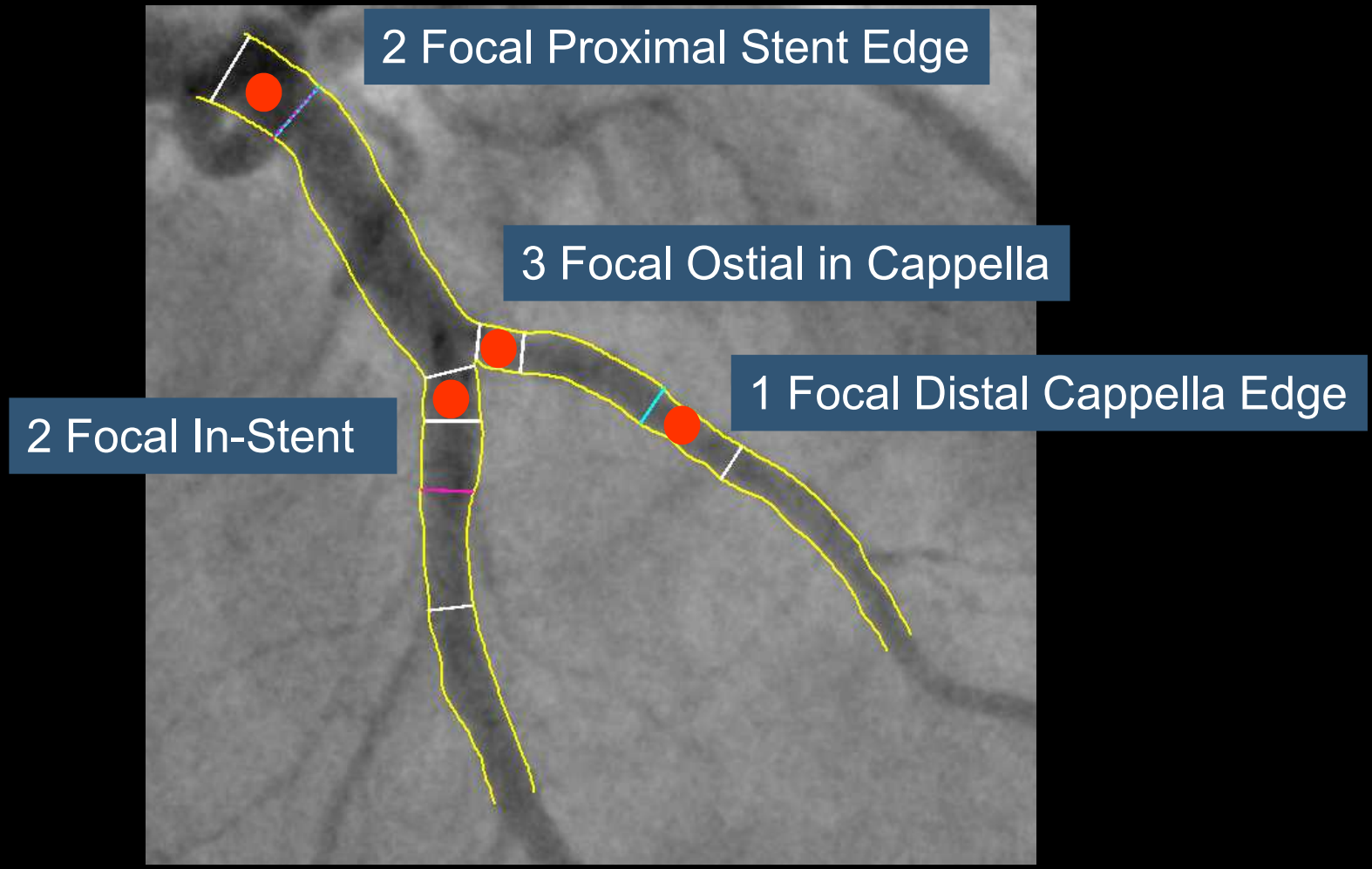
# Sideguard I and II
## *Clinical Outcomes*

| MACE (all) | All Patients (90 pts) | Sideguard (80 pts) |
|---|---|---|
| Up to 30 Days | 4.4% (4/90) | 3.8% (3/80) |
| Up to 6 Mos | 11.1% (7/63) | 10.2% (6/59) |
| **MACE Events @ 6 mos** | | |
| Cardiac Death | 1.6% (1/63) | 1.7% (1/59) |
| Myocardial Infarction | 4.8% (3/63) | 3.4% (2/59) |
| Target Lesion Revascularization | 4.8% (3/63) | 5.1% (3/59) |
| **Other Revascularizations @ 6 mos** | | |
| Ischemia Driven TVR | 6.3% (4/63) | 6.8% (4/59) |
| **Stent Thrombosis*** | | |
| Up to 30 Days | 3.3% (3/90) | 2.5% (2/80) |
| Up to 6 Mos | 4.8% (3/63) | 3.3% (2/59) |

*One ST @ 10 days in MV

# Sideguard I and II

## *Pattern & Location of Restenosis*



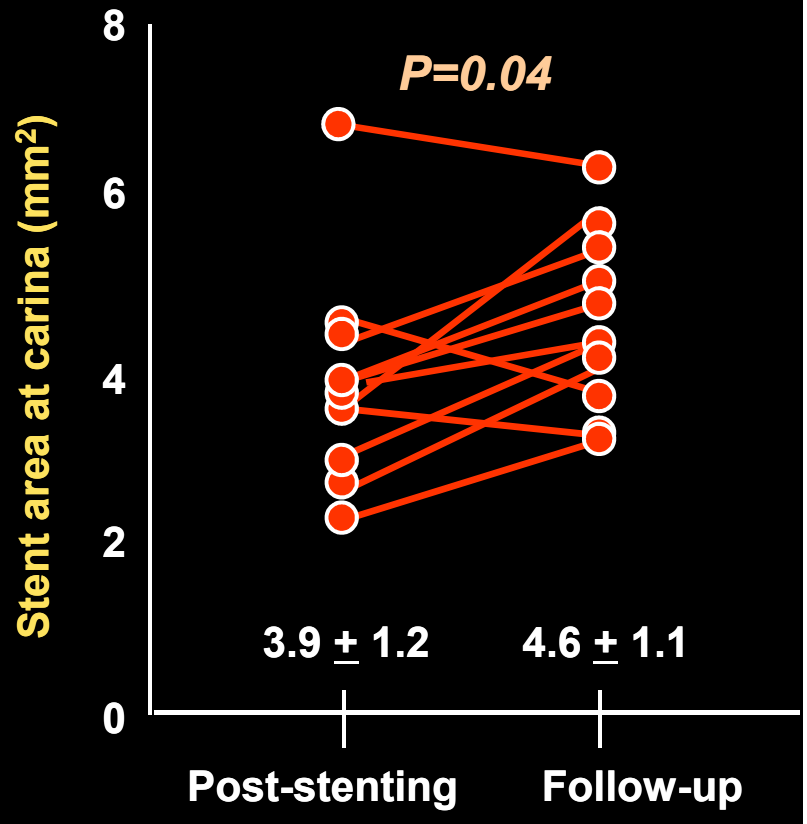
# Sideguard I and II
## *QCA @ 6 mos*

| | MV (50 pts) | SB (47 pts) |
|---|---|---|
| **MLD (mm)** | | |
| In-stent | 2.59 ± 0.50 | 1.83 ± 0.53 |
| In-segment | 2.20 ± 0.46 | 1.69 ± 0.49 |
| **% DS** | | |
| In-stent | 14.00 ± 14.34 | 18.60 ± 21.06 |
| In-segment | 27.44 ± 14.75 | 26.93 ± 18.06 |
| **Late Loss (mm)** | | |
| In-stent | 0.28 ± 0.50 | 0.38 ± 0.50 |
| In-segment | 0.23 ± 0.60 | 0.38 ± 0.50 |
| **Binary Restenosis** | | |
| In-stent | 4.0% (2/50) | 6.4% (3/47) |
| In-segment | 8.0% (4/50) | 8.5% (4/47) |

# Sideguard I and II
## *IVUS Substudy (11 pts)*

(1) Sidebranch stent area (at the carina) increased from 3.9±1.2 to 4.6±1.1mm² (p=0.04, Figure) resulting in no change in lumen area (3.9±1.3 vs. 4.0±1.3 mm², p=0.77) despite an intimal hyperplasia area of 0.6±0.7mm² (Figure).

(2) Post-stent malapposition was found in 2 patients, but only within the Cypher stent, not within the Cappella Sidebranch stent; and both resolved at follow-up.

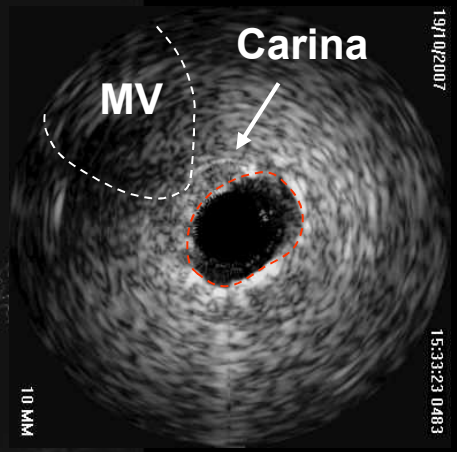



Hiroshi Doi, Akiko Maehara, Gary S. Mintz

# Sideguard I and II
## *IVUS Substudy (11 pts)*

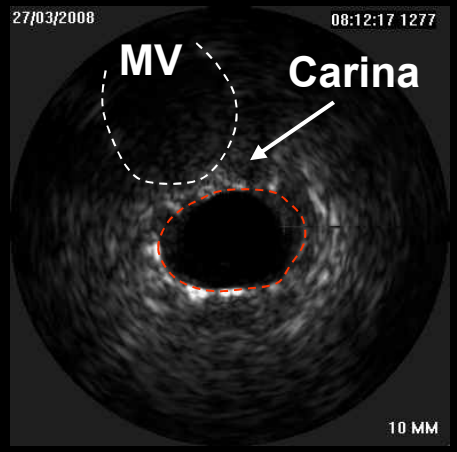
### Case in Group A

**Post-intervention**




Stent area=4.4 mm²
Lumen area=4.4 mm²

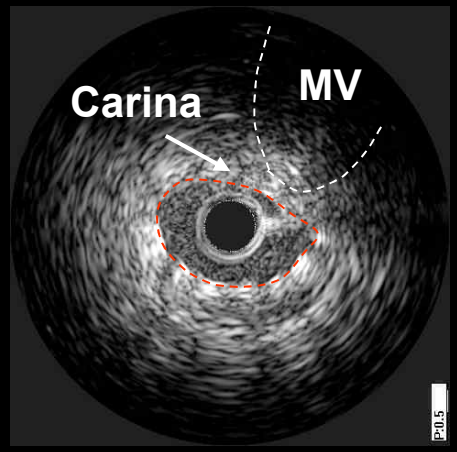
**Follow-up**




Stent area=5.7 mm²
Lumen area=5.7 mm²
IH area=0.0 mm²
ΔStent area=1.3 mm²
ΔLumen area=1.3 mm²

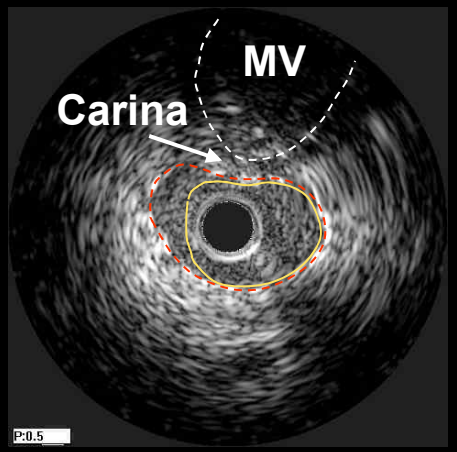
### Case in Group B

**Post-intervention**




Stent area=3.9 mm²
Lumen area=3.9 mm²

**Follow-up**




Stent area=5.1 mm²
Lumen area=3.9 mm²
IH area=1.2 mm²
ΔStent area=1.2 mm²
ΔLumen area=0.0 mm²

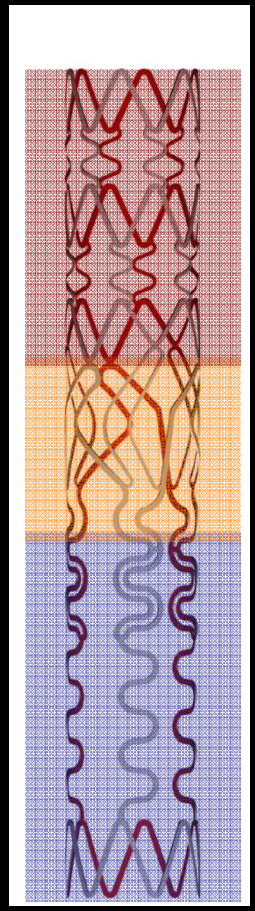
Hiroshi Doi, Akiko Maehara, Gary S. Mintz

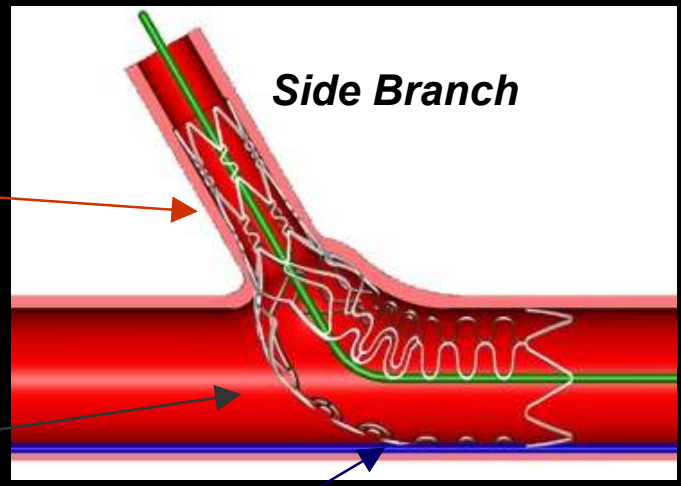
# Tryton Side Branch Stent

**Side Branch Region**
Standard Design

**Transition Zone**
Coverage
Hoop Strength

**Main Vessel Region**
3 Fronds - Minimal Coverage
Wedding Band

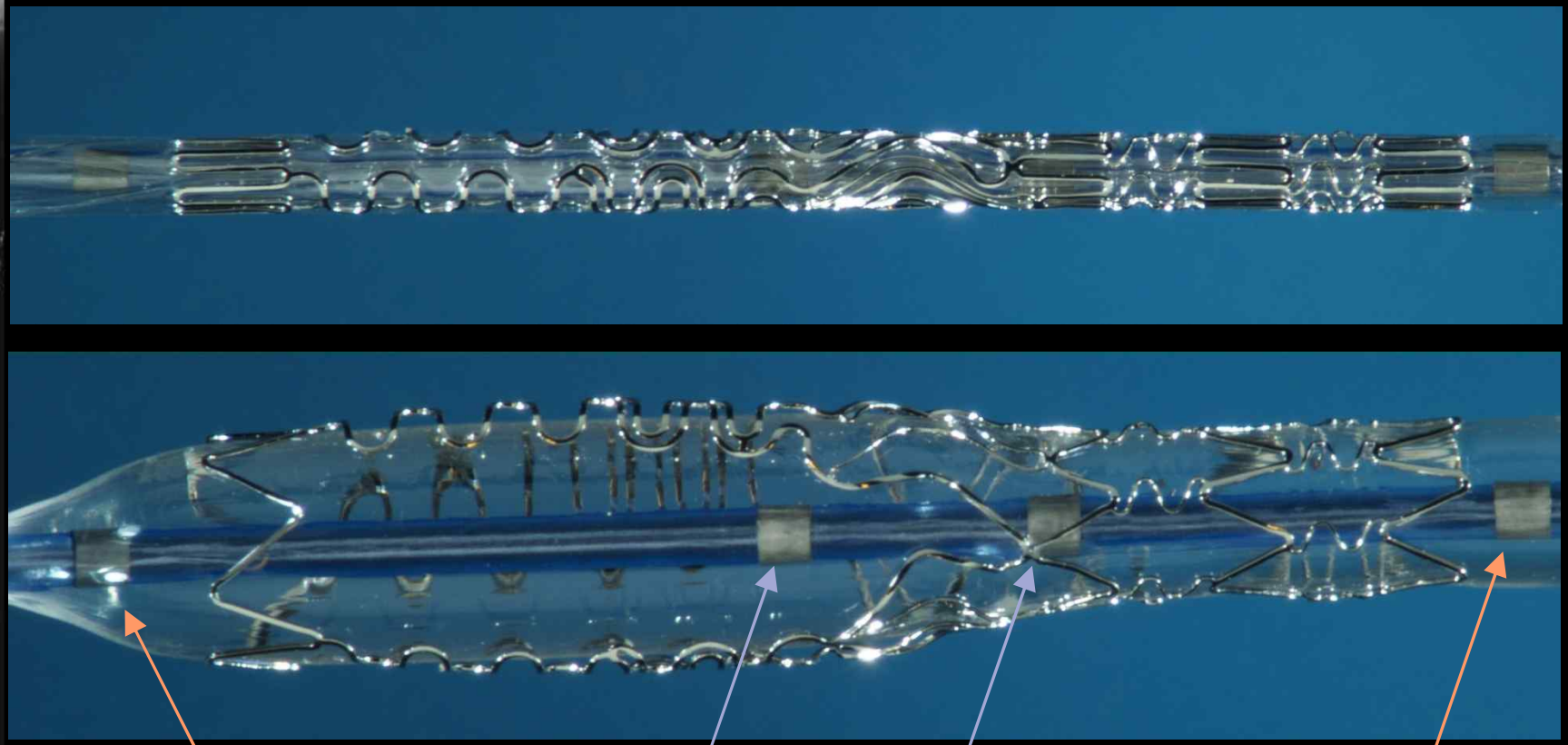





*Main Vessel*

**Cobalt Chromium**
**Strut Thickness: 0.003”**
**Diameter: 2.5 mm**

# Tryton Side Branch Stent
# Step Balloon Delivery System

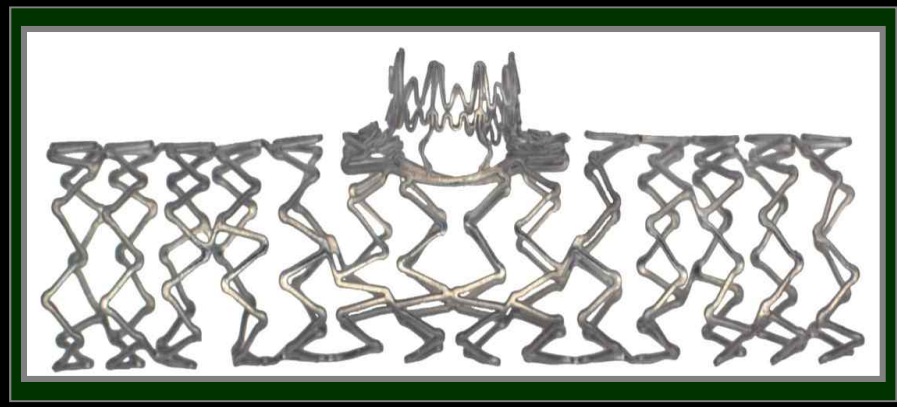


# Tryton Side Branch Stent Angiographic Results

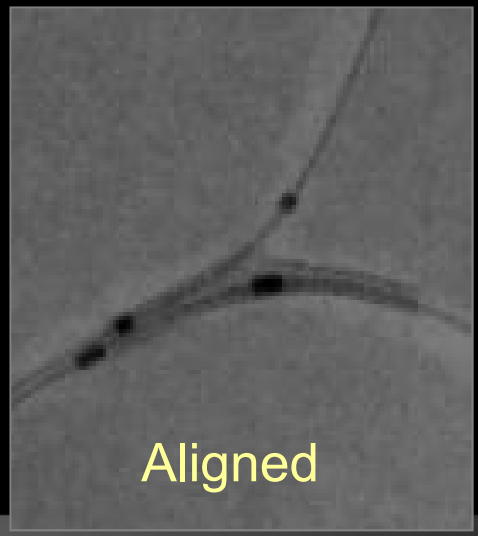
| N=30 | |
|---|---|
| PMB LLL (mm) | 0.25 +/- 0.43 |
| DMB LLL (mm) | 0.00 +/-0.31 |
| SB LLL (mm) | 0.17 +/-0.35 |
| In-stent binary restenosis | 0 |
| In-segment binary restenosis | 0 |

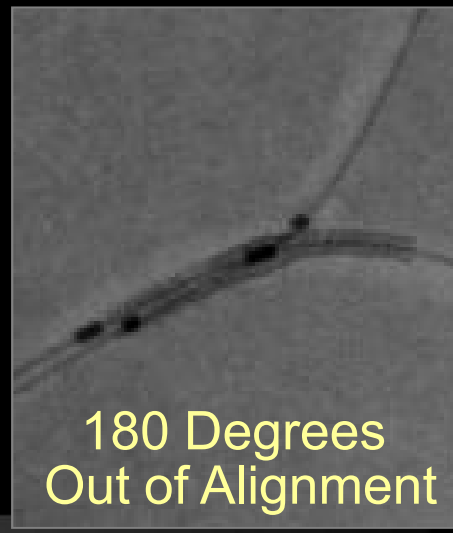
# TAXUS PETAL
## Coronary Bifurcation Stenting

- Conventional approach: higher risk of adverse events compared to non-bifurcation lesions
- TAXUS Petal paclitaxel-eluting bifurcation stent was specifically designed for bifurcation lesions



Dual balloon and dual wire system with 4 marker bands to ensure correct alignment



# Clinical Outcomes at 30 Days & 6 Mon
## Intent-To-Treat Analysis

| *Primary endpoint = 3.7%* | 30D (N=27) | 6M (N=26) |
|---|---|---|
| All death, MI, TVR (%) | 3.7% (1) | 11.5% (3) |
| All death (%) | 0.0% (0) | 0.0% (0) |
| Myocardial infarction (%) | 3.7% (1) | 3.8% (1) |
| Q-Wave MI (%) | 0.0% (0) | 0.0% (0) |
| Non-Q-Wave MI (%) | 3.7% (1)[a] | 3.8% (1)[a] |
| TVR (Overall) (%) | 0.0% (0) | 7.7% (2) |
| TLR (Overall) (%) | 0.0% (0) | 3.8% (1)[b] |
| TVR (Remote) (%) | 0.0% (0) | 3.8% (1) |
| Stent Thrombosis (%) | 0.0% (0) | 0.0% (0) |

a: Thought to be secondary to stenting over a second side branch. Data are binary rates.
b: TLR involved both main branch and side branch.

# Angiographic Outcomes

| *Analysis Segment* | *Main Branch Proximal* | *Main Branch Distal* | *Side Branch* |
|---|---|---|---|
| *Pre-Procedure (N=28)* | | | |
| RVD (mm) | 3.32±0.39 | 2.51±0.30 | 2.23±0.33 |
| Min Lumen Diam (mm) | 1.28±0.59 | 1.08±0.55 | 1.31±0.55 |
| % Diameter Stenosis | 61.72±16.70 | 56.72±20.74 | 41.59±20.77 |
| *Post Procedure (N=28)* | | | |
| RVD (mm) | 3.31±0.37 | 2.48±0.33 | 2.22±0.34 |
| Min Lumen Diam (mm) | 2.83±0.41 | 2.25±0.37 | 1.70±0.38 |
| % Diameter Stenosis | 14.48±7.58 | 9.53±7.20 | 23.08±13.66 |
| *6 Months (N=20)* | | | |
| RVD (mm) | 3.14±0.34 | 2.46±0.26 | 2.11±0.29 |
| Min Lumen Diam (mm) | 2.40±0.42 | 1.90±0.57 | 1.61±0.48 |
| Late Loss (mm) | 0.42±0.39 | 0.42±0.58 | 0.18±0.40 |
| % Diameter Stenosis | 23.84±11.49 | 22.86±20.83 | 23.95±20.39 |
| Restenosis (%, n) | 5.0 (1) | 10.0 (2) | 10.0 (2) |

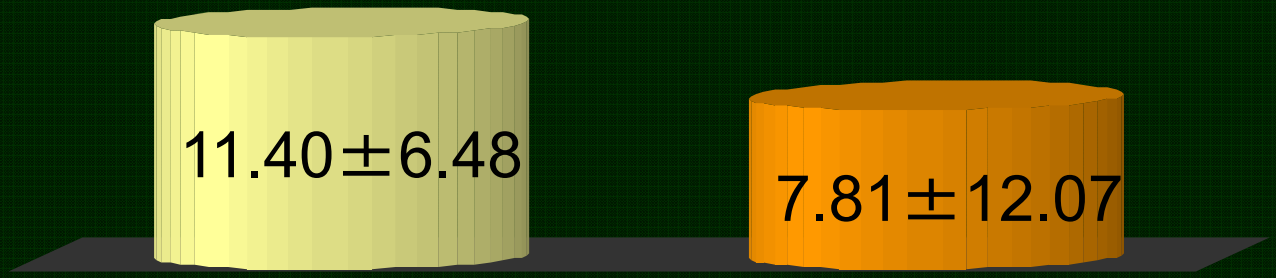
Data are mean±SD

# Intravascular Ultrasound Analysis

*Incomplete Apposition*

| | Main Branch | Side Branch |
|---|---|---|
| Post Procedure | 0.0% (0/23) | 0.0% (0/15) |
| 6 Months | 0.0% (0/19) | 0.0% (0/12) |

*% Volume Obstruction @ 6 months*



# Conclusion

- Dedicated bifurcation stents address ideally the specific needs of bifurcation lesions
- Due to the variable anatomy of bifurcation lesions, variable stent designs or deployment techniques are most likely needed
- Dedicated bifurcation DES are needed to combine the benefits of both technologies

# Thank you