21st CardioVascular Summit
TCTAP 2016 April 26-29, 2016
Coex, Seoul, Korea

Dedicated Stents for Bifurcation Lesion: What We Really Need

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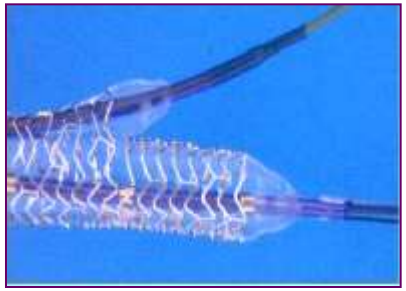
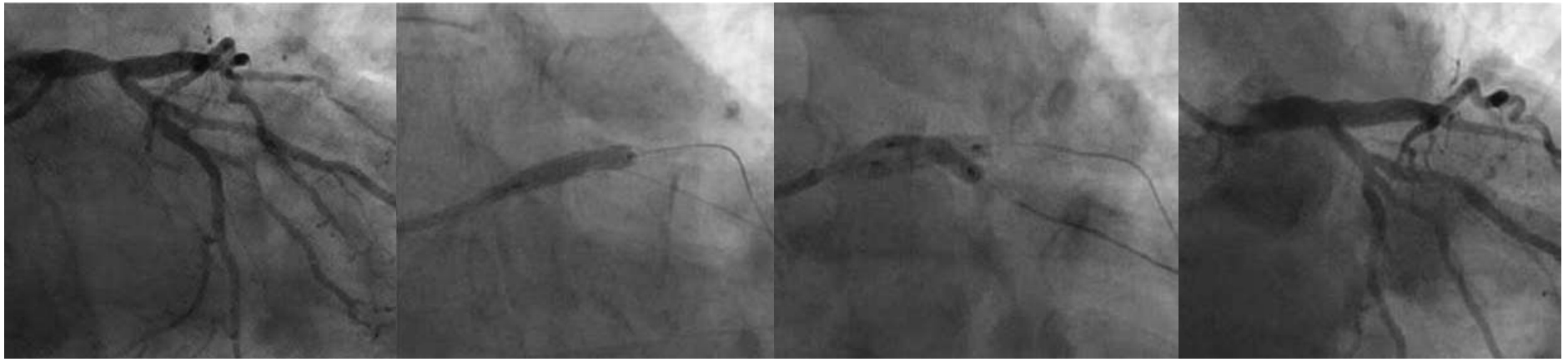
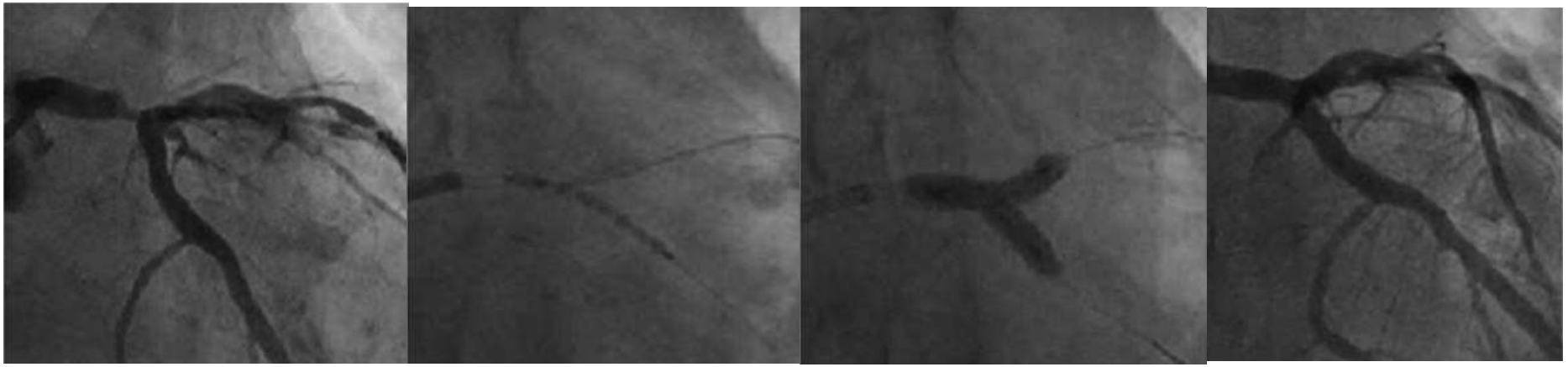


Single stent : « Provisional T Stenting «

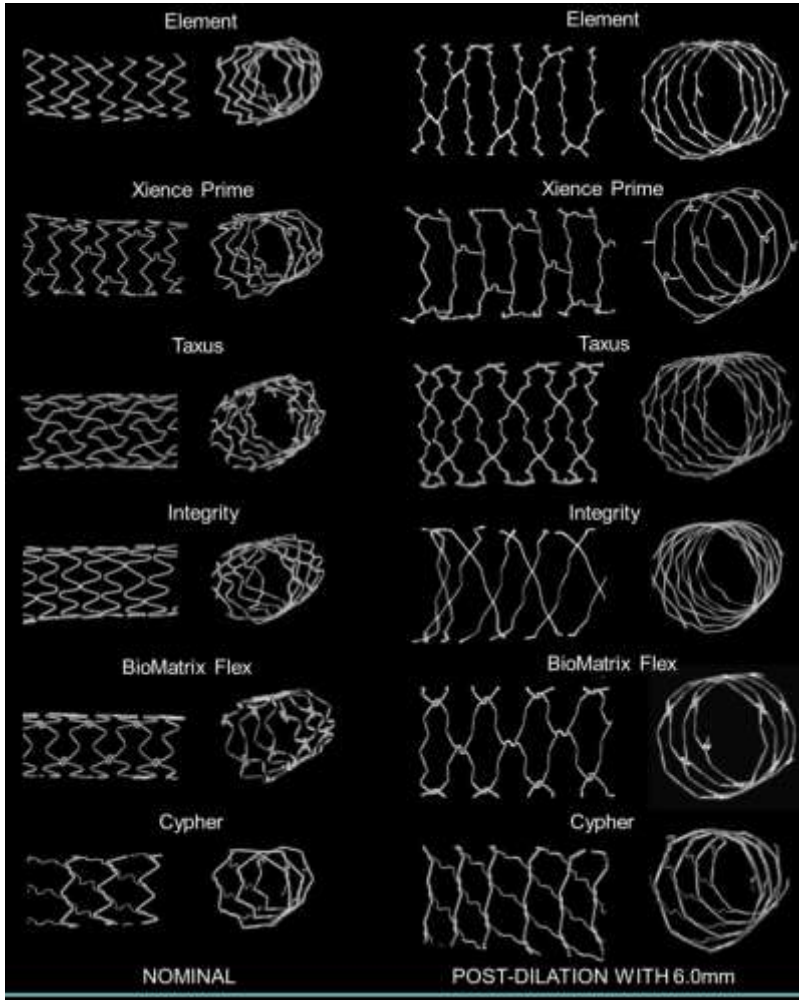


Double–stent approaches (T stenting, Crush, Mini-cruch , DK Cruch, TAP ,Coulotte, V stenting …)



- The defualt approach for BL is single stenting (70 t0 80% of cases)

Stent Deformation with overexpansion



Stent deformation with over-expansion is a common problem in treating bifurcation lesions affecting both the side branch origin and the proximal main vessel (Markedly exaggerated in LM lesions)

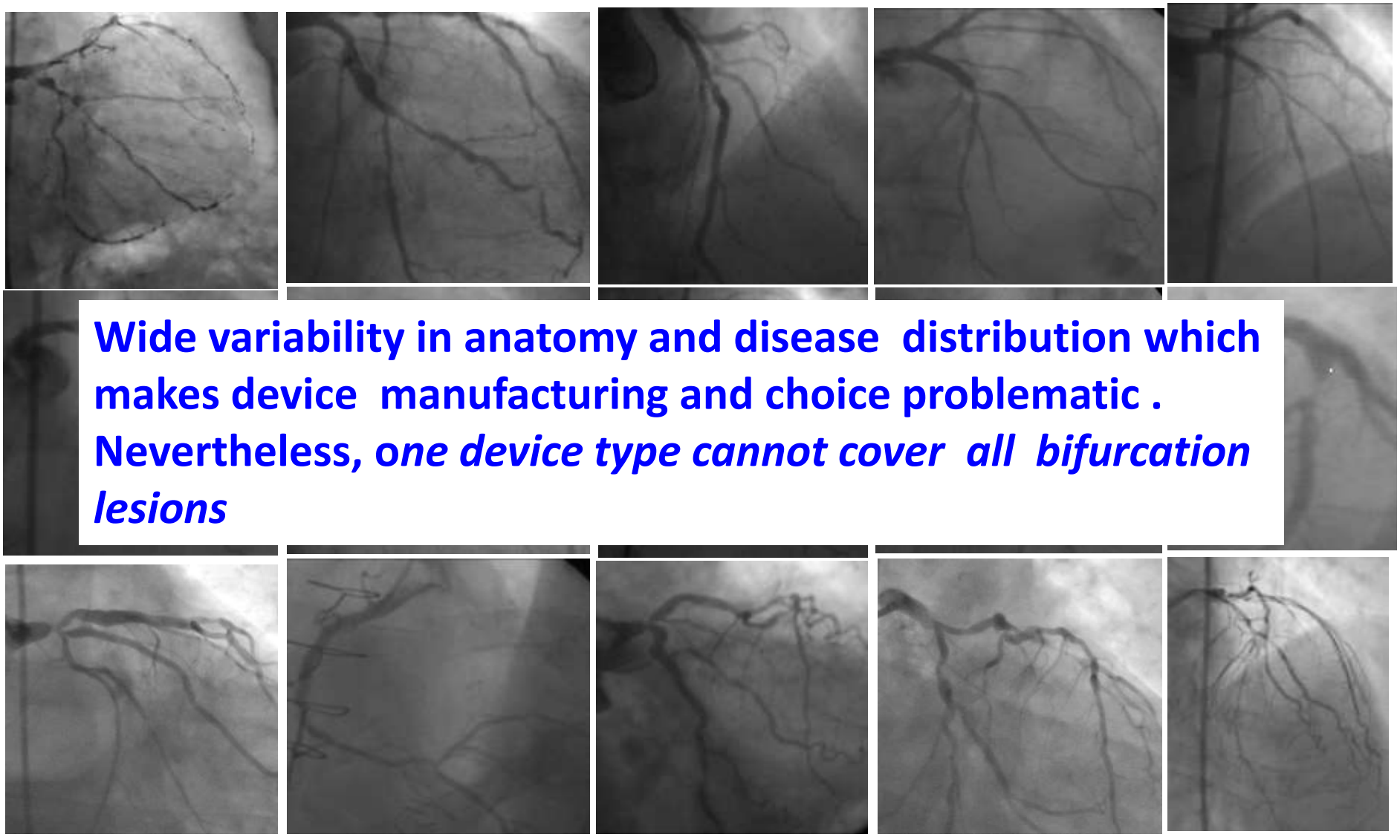
N. Foin , EuroInterv

Stent Deformation with SB dilatation or KB

Stent designs is important in stent selection for bifurcation lesions

N. Foin , EuroInterv

Not all bifurcations are equal …



Wide variability in anatomy and disease distribution which makes device manufacturing and choice problematic .
Nevertheless, o*ne device type cannot cover all bifurcation lesions*

Dedicated stents for bifurcation

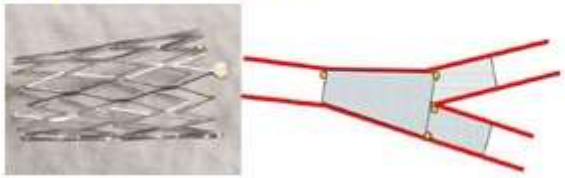
- **Dedicated bifurcation stents technology is an attempt to find solutions to a challenging subset of coronary lesions.**
- **The expectation from these devices is to simplify the technical challenges in bifurcation and possibly to improve clinical outcomes in this lesion subset.**

Requirements of a Dedicated Bifurcation Stent:

- ***Protecting high-risk side branches (complex or diffuse disease) and more user friendly***
- ***Appropriate stent size for the anatomy (diameter, length and taper)***
- ***Full apposition for variable anatomy, particularly at the bifurcation side branch ostium***
- ***Protection and full ostial coverage of side branches***
- ***Improvement of patient safety and clinical efficacy***

Dedicated Bifurcation Stents

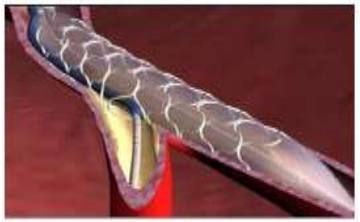
AXXESS (Biosnsors)



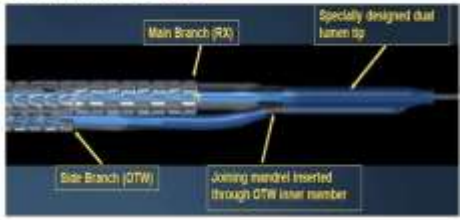
BIOSS – BIOSS Expert

Cappella Sideguard

Y-Med Side-kick

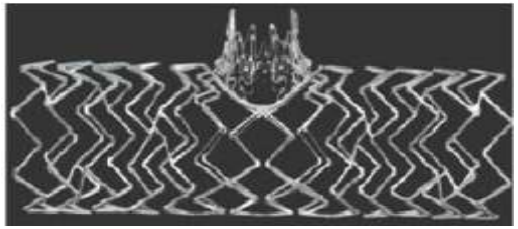


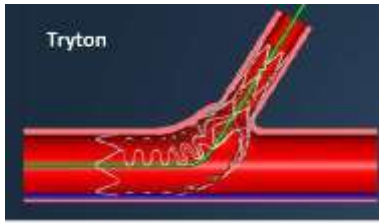
Multilink Frontier™



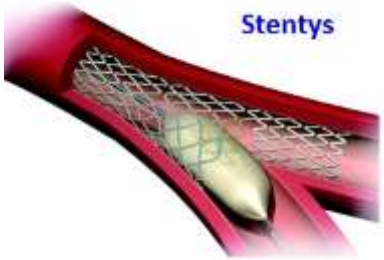
Medtronic Bifurcation Stent

BSC TAXUS Petal



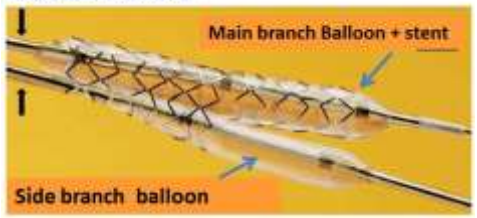


Stentys



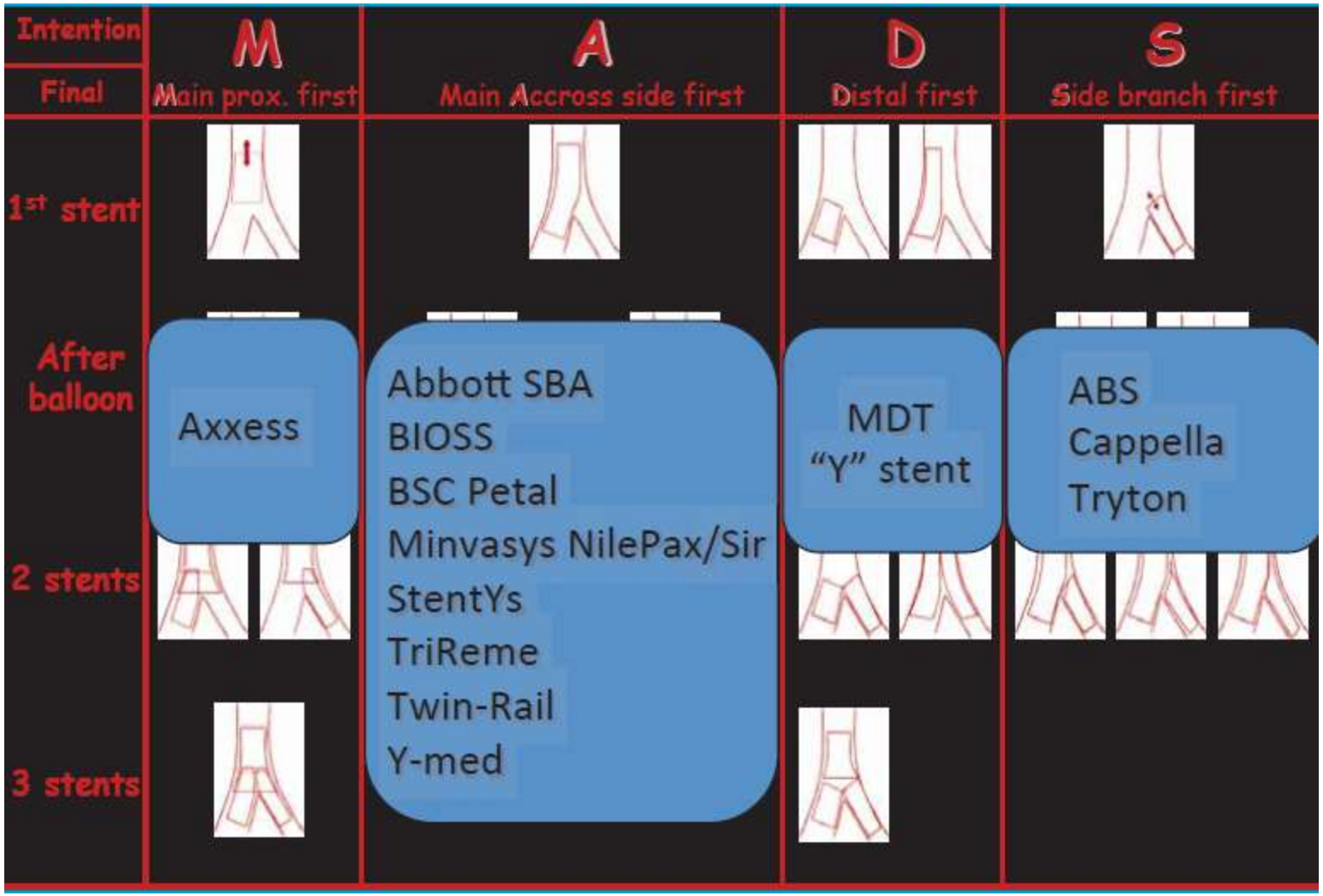
TriReme Bifurcation Stent - *TMI Antares™*

Nile Pax – Nile LM Sir



Twin Rail

Classification of Bifurcation Stent Strategies
Application to Dedicated Bifurcation Stents



Courtesy of Yves Louvard

Classification of Bifurcation Stent Strategies
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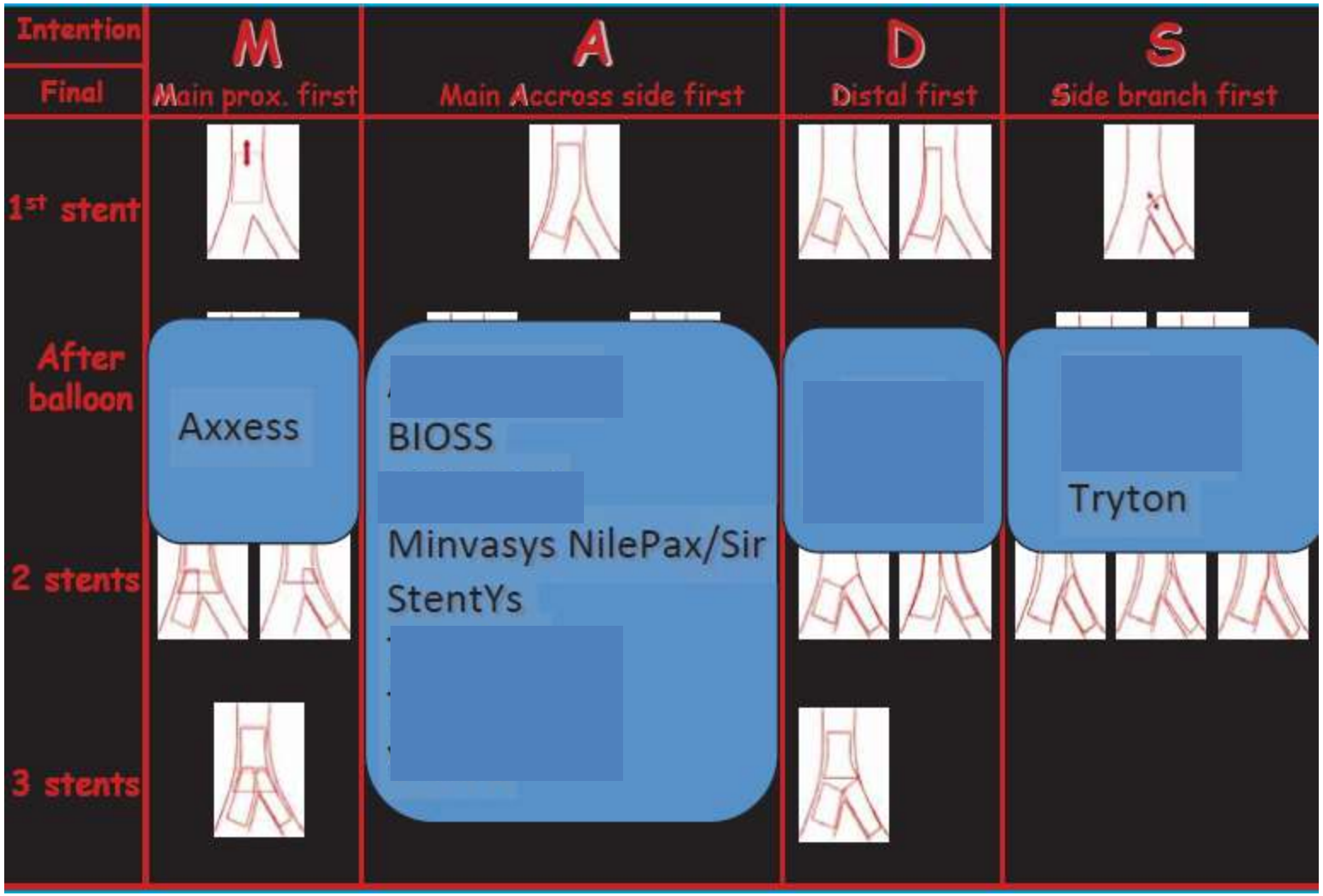
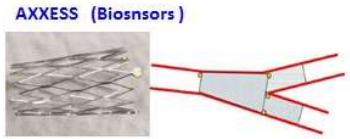


Courtesy of Yves Louvard

Clinical data ?

- ***There are limited clinical data with dedicated bifurcation stents and no RCT data compared with provisional and/or two-stent strategies using conventional DES, particularly with second generation DES***

The Axxess™ stent (Biosensors Europe SA, Morges, Switzerland)



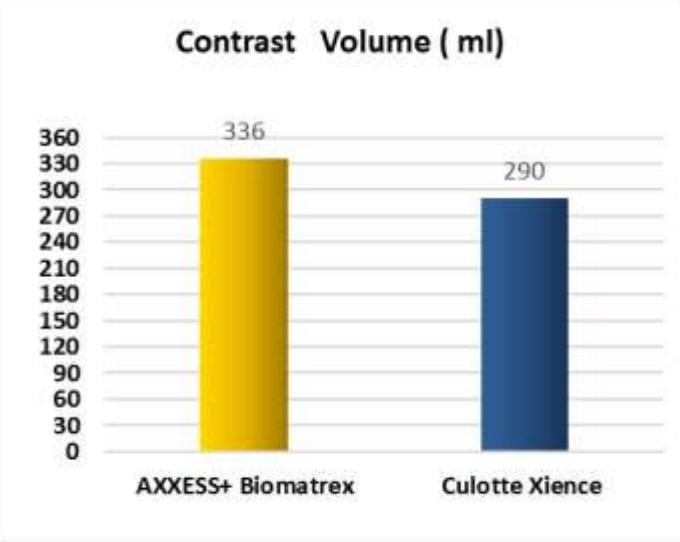
Pros

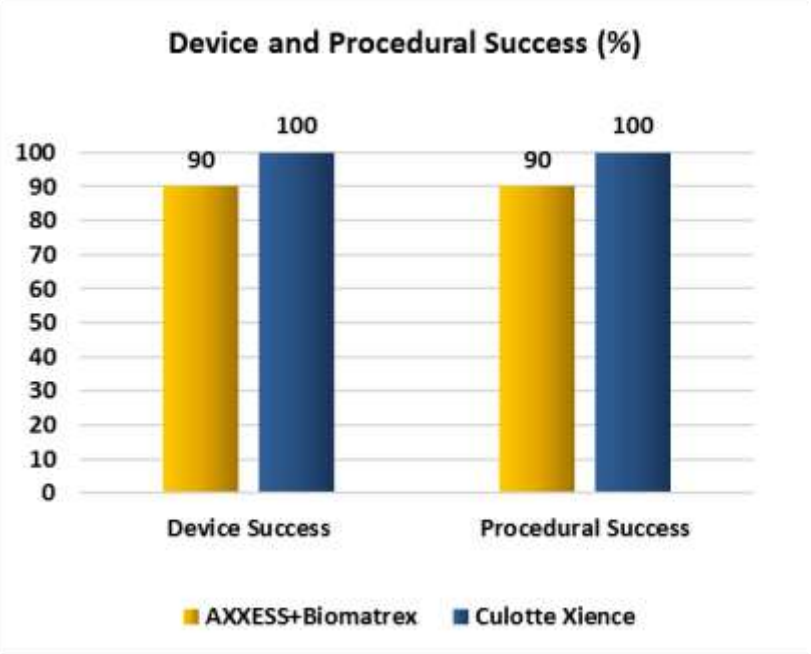
- ***Conforms to the natural anatomy of coronary bifurcation "flaring" into the distal main branch and side branch ostia***
- **Follows a provisional (proximal) main branch stenting strategy, without the commitment to additional side branch stents if not necessary.**
- **The ideal stent for Medina 1,0,0 bifurcation lesion with a narrow distal bifurcation angle**

Cons :

- ***Need for a good lesion preparation (self-expandable)***
- ***Large distal bifurcation angle is unfavorable toallow a full coverage of SB ostium***
- ***In the majority of cases need for additional stenting at least in MV distal to bifurcation with overlapping stents (potential gaps or excess of metal)***
- ***Need for 7F guiding catheter***
- ***Need for training***

Complex Coronary Bifurcation Lesions : Randomized Comparison of a Strategy Using a Dedicated Self-Expandable Biolimus-Eluting Stents Versus a Culotte Strategy Using Everolimus-Eluting Stents:Primary Results of the COBRA Trial





Ch Dubois et al; EuroIntervention 2015;11-online publish-ahead-of-print May 2015

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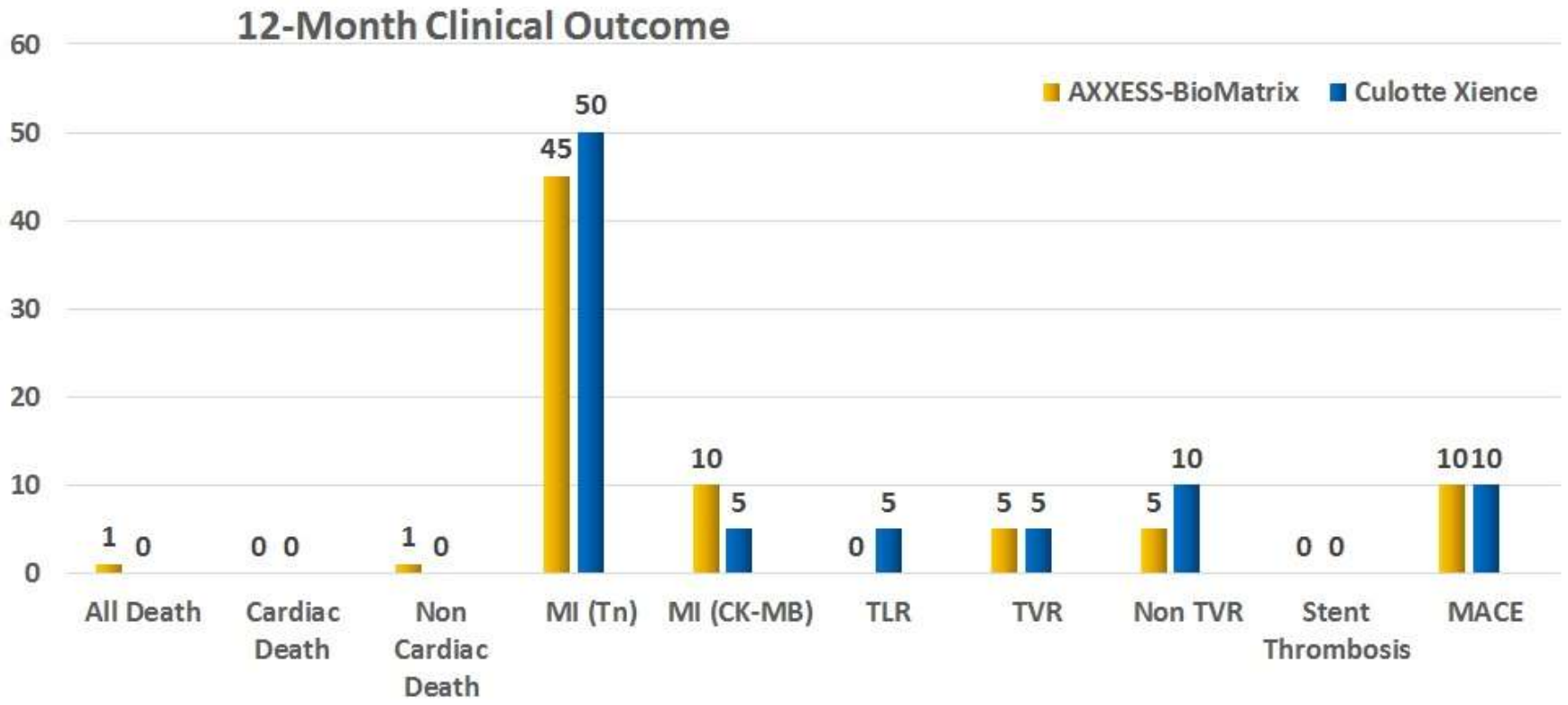
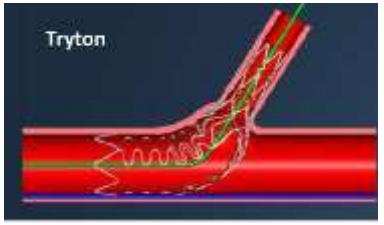


Ch Dubois et al; EuroIntervention 2015;11-online publish-ahead-of-print May 2015

The Tryton Side Branch Stent™ (Tryton Medical, Inc.)



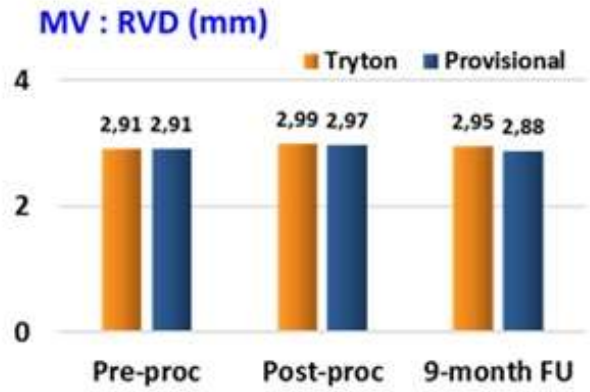
Pros

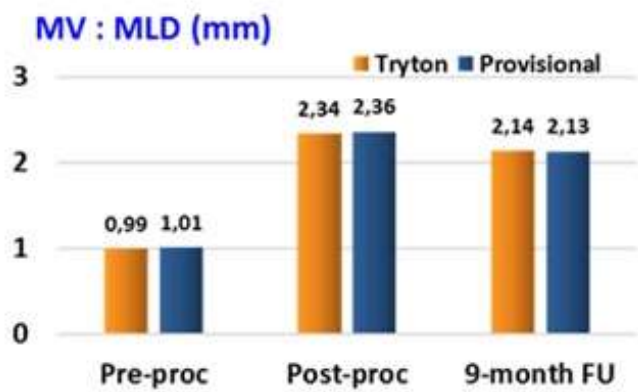
- **Accommodates the natural anatomy of the bifurcationc (step-down in diameters from proximal to distal)**
- **Suitable for a wide variety of BL (Bifurcation angle does not influence procedural outcomes**
- **Predictable outcome with side branch access during the procedure**
- **Semplifies the culotte technique with reduction of the amount of overlsapped metal in the proximal MV (compared with culotte with conventional DES)**

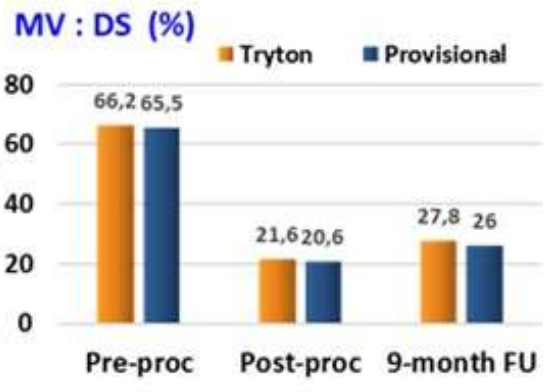
Cons :

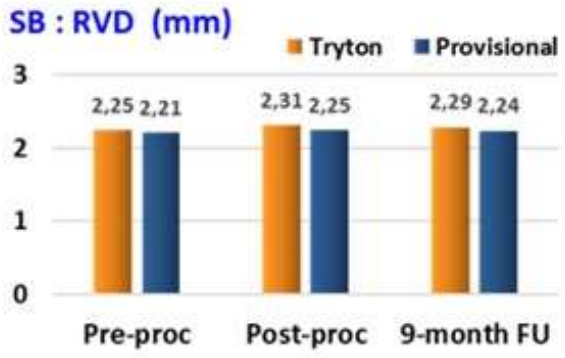
- **Need for rewiring the SB after stenting in MV with converntional stent (same limitations)**
- **DES version not available**
- **Need for precise postioning to fully cover the SB ostium**

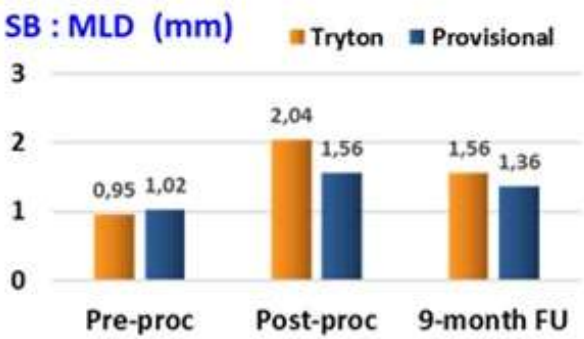
A Randomized Trial of a Dedicated Bifurcation Stent Versus Provisional Stenting in the Treatment of Coronary Bifurcation Lesions

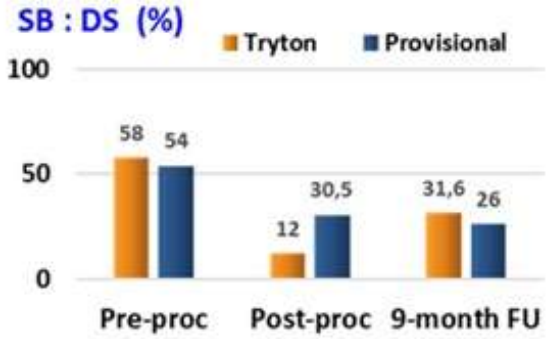






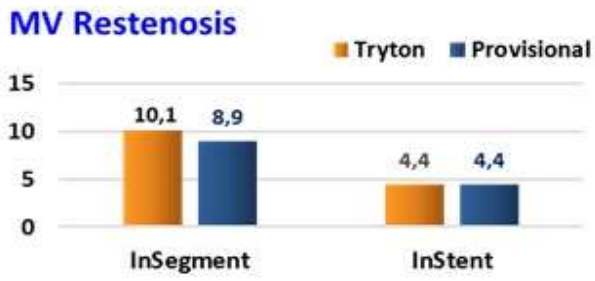


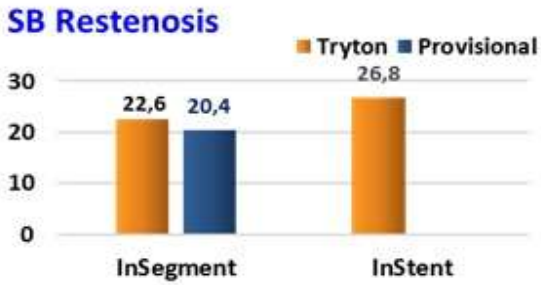


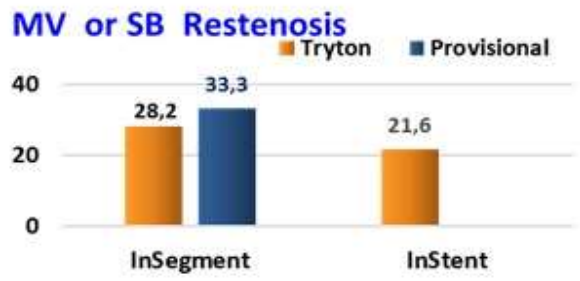


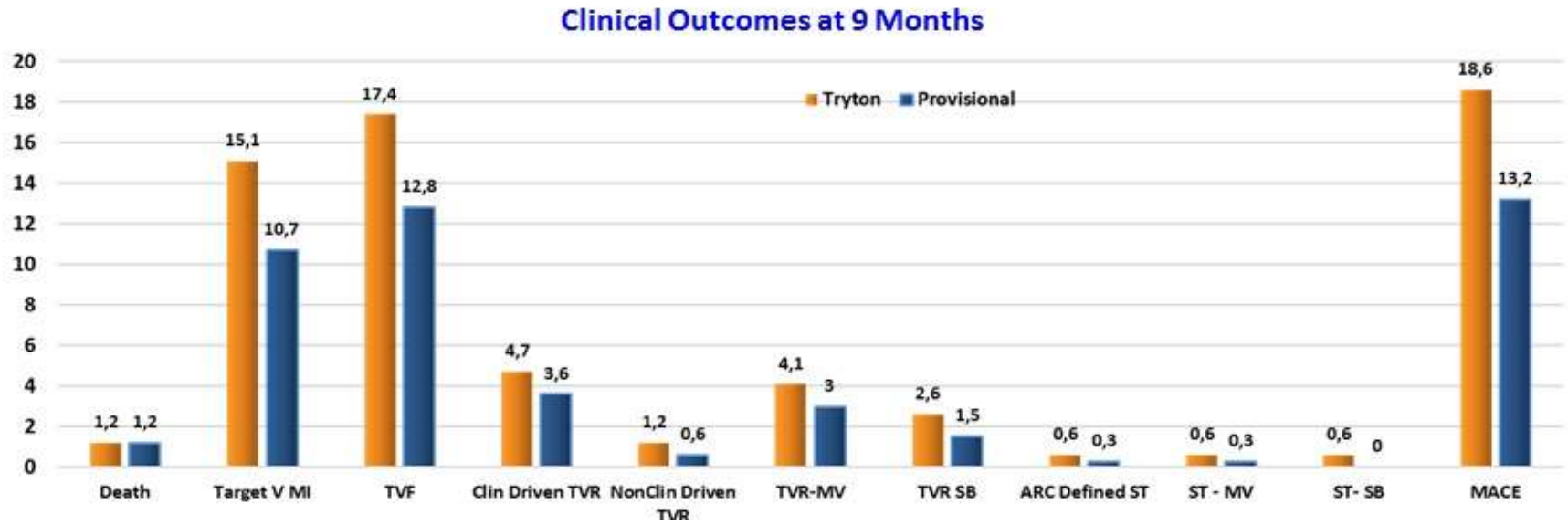
Ph Généreux, et al. JACC 2015 ; 65: 533-543

A Randomized Trial of a Dedicated Bifurcation Stent Versus Provisional Stenting in the Treatment of Coronary Bifurcation Lesions









Ph Généreux, et al. JACC 2015 ; 65: 533-543

The Bifurcation Optimisation Stent System (BiOSS®; Balton,Warsaw, Poland)

Pros

- **Conforms to the natural anatomy of the bifurcation (step-down in diameters)**
- **The stent design (stepped and large cell opening towards the SB) might decrease the need for POT and FKBD.**
- **Easy use as conventional stents**
- **DES version available**

Con

- **Distance (0.9-1.5 mm) between the proximal and distal stent parts potential risk for gaps particularly if MV is straight (angle around 180°)**
- **Access to SB is depending on postioning , easy if the stent is postioned appropriately**

CORONARY ARTERY DISEASE

Bioss Expert

Dedicated Bifurcation Paclitaxel-Eluting Stent BiOSS Expert® in the Treatment of Distal Left Main Stem Stenosis

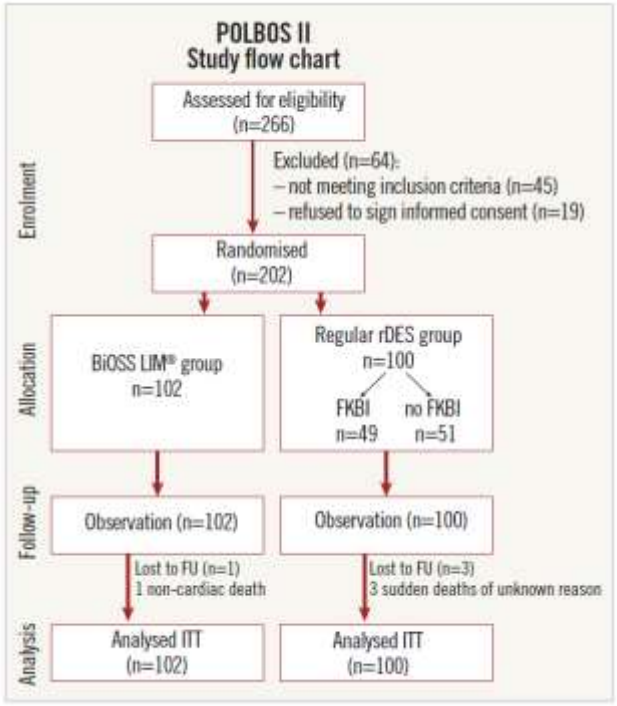
Table 6. Clinical Results

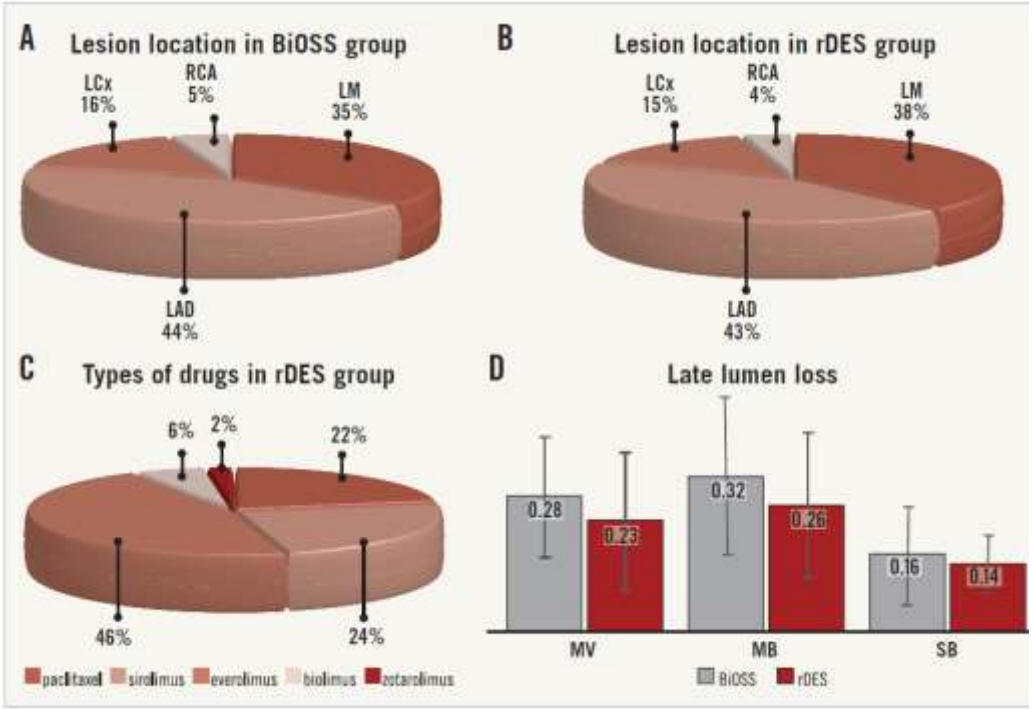
	30 Days			6 Months			12 Months		
	All	I Gr	II Gr	All	I Gr	II Gr	All	I Gr	II Gr
n	54	18	36	54	18	36	54	18	36
Death	0	0	0	0	0	0	0	0	0
MI	8* (14.8%)	3* (16.7%)	5* (13.9%)	0	0	0	0	0	0
Stroke	0	0	0	0	0	0	0	0	0
ST	0	0	0	0	0	0	0	0	0
TVR	0	0	0	0	0	0	0	0	0
TLR	0	0	0	0	0	0	5 (9.3%)	3 (16.7%)	2 (5.6%)

*Asymptomatic increase in TnI concentration. All, whole group; I Gr, BiOSS Ø ≤ 4.0 mm; II Gr, BiOSS Ø > 4.0 mm; MI, myocardial infarction; ST, stent thrombosis; TLR, target lesion revascularization; TVR, target vessel revascularization.

Bil et al , J Interv Cardiol 2014; 27 : 242-251

Regular Drug-Eluting Stents versus the Dedicated Coronary Bifurcation Sirolimus-Eluting BiOSS LIM® Stent: The Randomized ,Multicentre ,Open-Label controlled POLBOS II Trial





- **NO difference in fluoroscopy time , contrast , procedural time .**
- **Different rDES were used including differnt coating**

R. Gil et al EuroIntervention 2015;11-online publish-ahead-of-print November 2015

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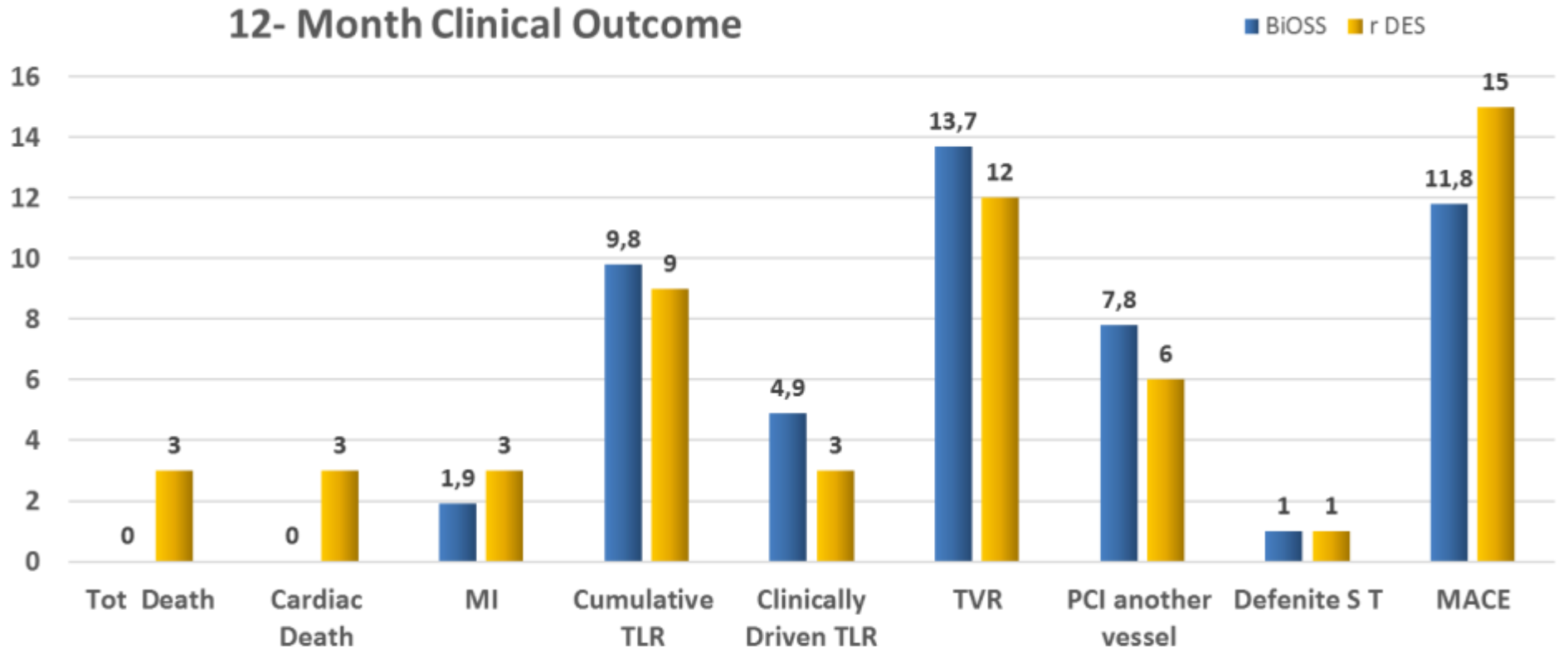


R. Gil et al EuroIntervention 2015;11-online publish-ahead-of-print November 2015

The STENTYS Self-Apposing® stent (STENTYS S.A., Paris,France)

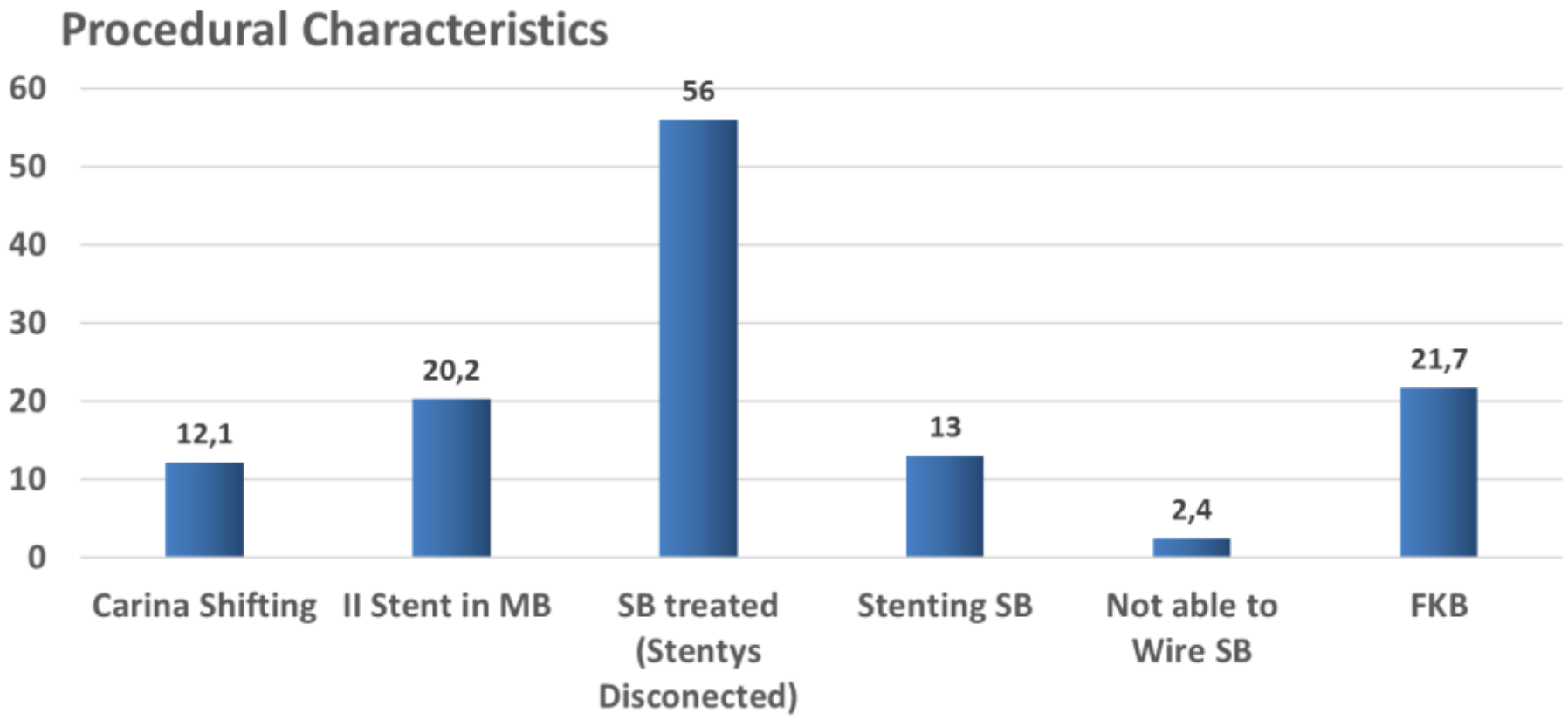
Pros :

- **Adjust itself (Selef-expandable) to the natural step-down of the MV The (STENTYS expands further than the its reference diameter)**
- **The disconnection of the connecting struts thus the proximal part to the disconnection "flares" and appose itself to the lateral vessel wall of the SB fully covering the ostium**
- **DES version is available**

Cons:

- **Need for a good lesion preparation for optimal self expansion , particularly at the ostium of SB**
- **-Need for precise crossing (distal strut) . Proximal cell crossing with a wire can leave uncovered the SB ostium**
- **Adjunctive intravascular imaging (OCT) to guide optimal cell re-crossing might be needed**

Final Results of a Self-Apposing Paclitaxel-Eluting Stent for the Percutaneous Treatment of *de novo* Lesions in Native Bifurcated Coronary Arteries Study



Ch Naber et al;EuroIntervention 2015;11-online publish-ahead-of-print June 2015

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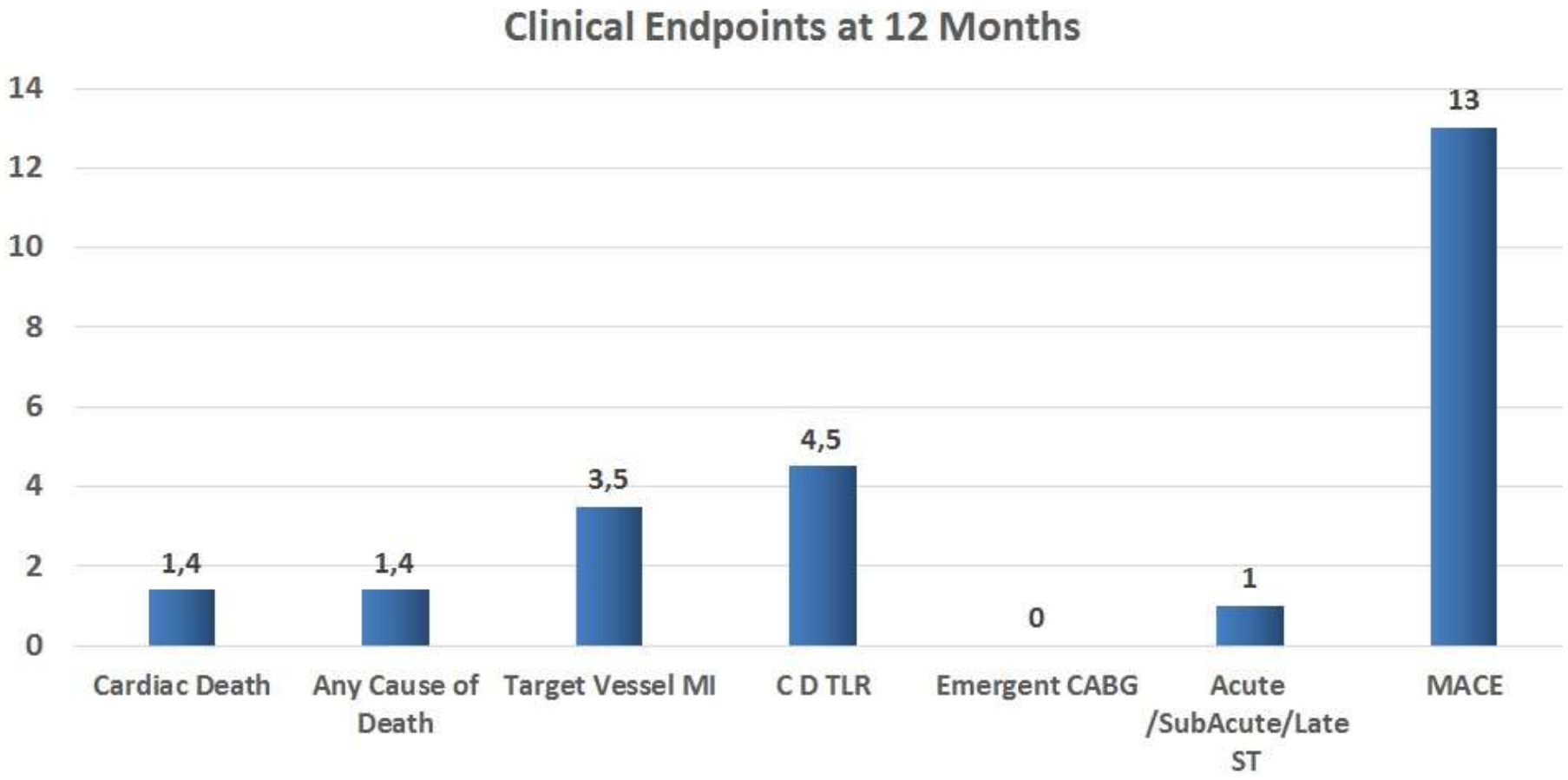

Ch Naber et al;EuroIntervention 2015;11-online publish-ahead-of-print June 2015

The Nile stent (Minvasys, Gennevilliers, France)

Pros :

-Permanenet access to MV and SB during the procedure.(no jailed wires) , thus no need for wire re-crossing

-SB wire and balloon are crossing distally and full caoverage of the SB ostium is presumed following stent expansion and KB

-Specific design of the proximal part of the SB balloon to prevent elliptical-shaped stent overexpansion in the proximal MV following FKB

-DES version is available

Cons

-The device is composed of two balloon catheters , advanced simultaneously on two wires , consequently wire wrapping is very frequent requiring re-wiring,

-Final POT is required since Nile stent is not stepped down (stent should be sized according to distal MV to prevent carina shift)

Procedural and early clinical outcomes of patients with *de novo* coronary bifurcation lesions treated with the novel Nile PAX dedicated bifurcation polymer-free paclitaxel coated stents: results from the prospective, multicentre, non-randomised BIPAX clinical trial

Ricardo A. Costa[1,2], MD, PhD; Alexandre Abizaid[1,2], MD, PhD; Andrea S. Abizaid[1,2], MD, PhD; Bruno Garcia del Blanco[3], MD; Jacques Berland[4], MD; Ivo Petrov[5], MD, PhD; Philippe Brenot[6], MD; Robert-Jan van Guens[7], MD; Thierry Royer[8], MD; Paolo Rubino[9], MD; Maciej Lesiak[10], MD, PhD; Jean Fajadet[11]*, MD; for the BIPAX Investigators

Multicenter Registry
101 patients
Acute and eraly (30 days) clinical outcome

1 MI during hospitalization
Device success 98%

EuroIntervention 2012;7:1301-1309

The Ideal Dedicated Bifurcation Stent

- Predictable and safe
- Easy and quick to use
- Simplify the procedure:
  - shorten procedural time
  - reduce x-ray exposure
  - reduce contrast media
- Allow continuous SB access with a non-jailed wire
- Predictable ostial side branch coverage after stenting
- Predictable long-term results (restenosis & ST rates, low)
- Able to treat all kinds of bifurcations
- Flexible during cardiac cycles after implantation

JF Lassen and G Stankovic ; EuroInterv2015; 11: 850-851

Final Considerations

- **The Ideal Dedicated Bifurcation Stent that we really need is unlikely to cover this wide variety of antatomy and disease distribution . O*ne device type cannot cover all bifurcation lesions***
- ***The real question is : do we really need a dedicated bifurcation stent given the huge improvement reached in recent times with regular stents designs and technology togother with the acquired experience and kwnoldge in bifurcation interventions and the excellent clinical outcomes using regular DES ?***
- ***Waiting for more clinical data and further technical improvments,we should keep going on with refining and optimizing what we have reached with the modern approaches in bifurcation interventions***

Thank You for Your Kind Attention !!

EuroIntervention 2013;9:148-156