Newest technology in the SFA: the future is now

In-stent restenosis: hopes from new therapies

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Faculty Disclosure

Pr Yann Gouëffic

I disclose the following financial relationships:

Consultant for Medtronic and Cook

Employee /

Receive grant/research support Medtronic, Cook and Bard

Advisory board /

Paid speaker /

Major stockholder /

ISR and TLR rates @ 12 months are still high

	Vienna	Durability	Resilient
ISR @ 12 mo	37%	27.8%	31.7%
TLR @ 12 mo	22%	20.9%	20%

The fight against restenosis

Failure of systemic treatment

Local disease, local treatment:

-PTA

-Artherectomy

-Cutting Balloon

-Scoring Balloon

-Cryoplasty

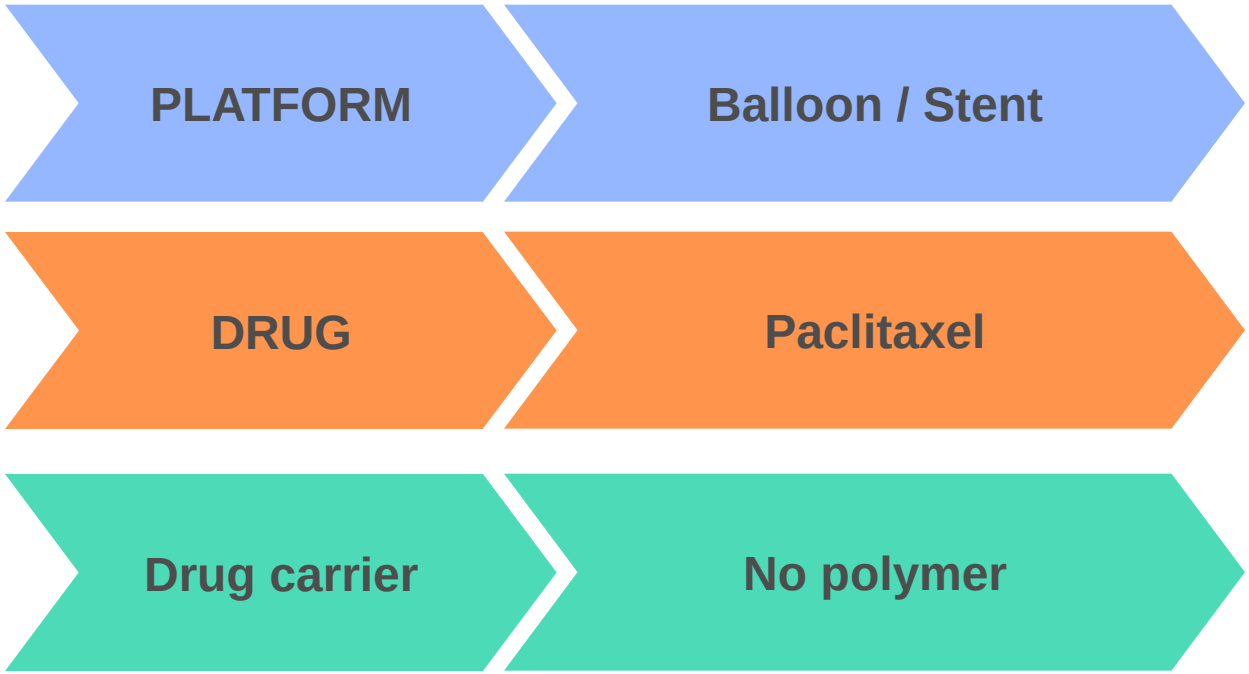
-Brachytherapy (b,g)

-Laser

-Nitinol Stent

-Covered Stent

Drug Eluting Balloons – Drug Eluting Stents

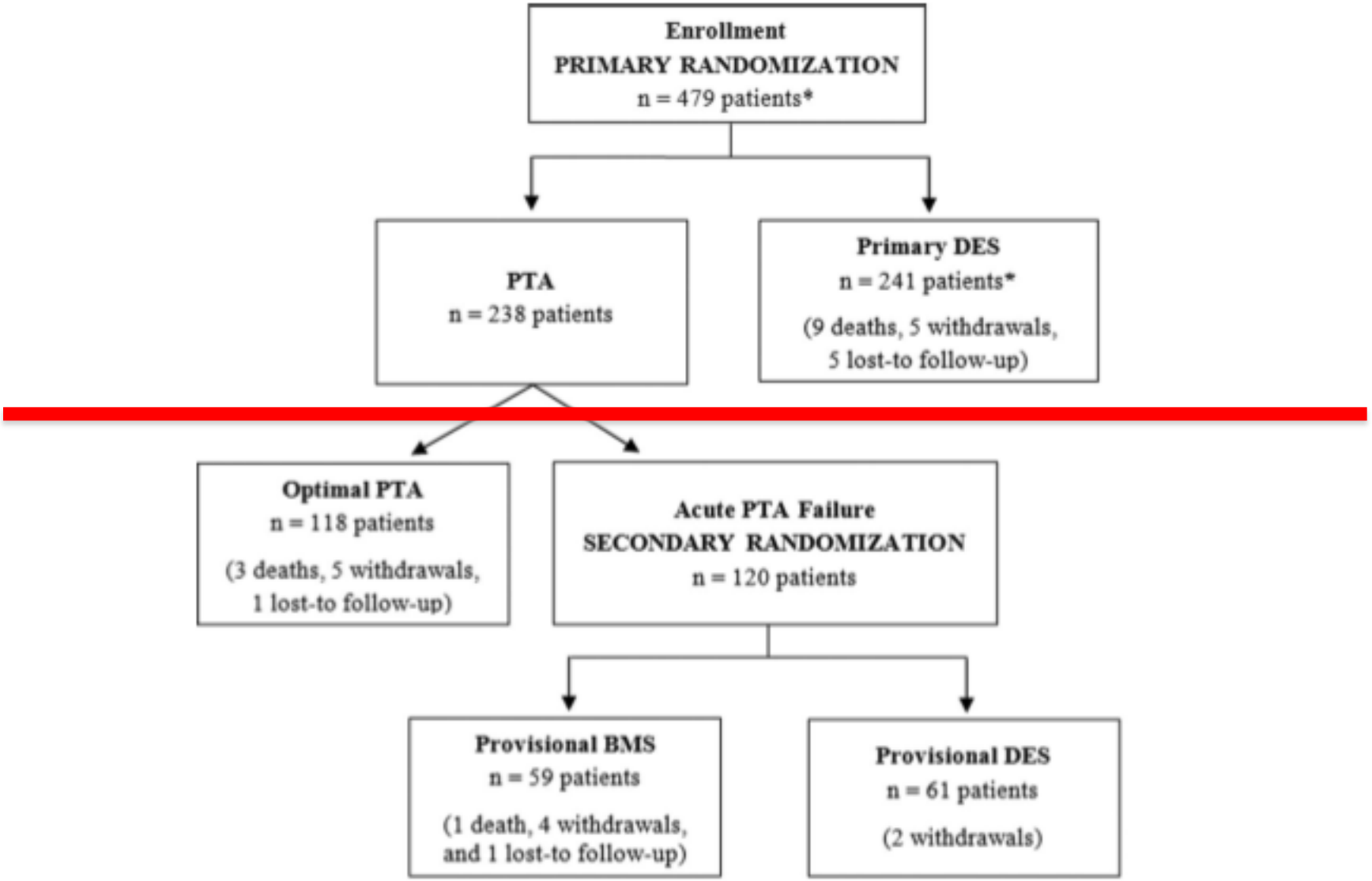


Rationale for the development of DES

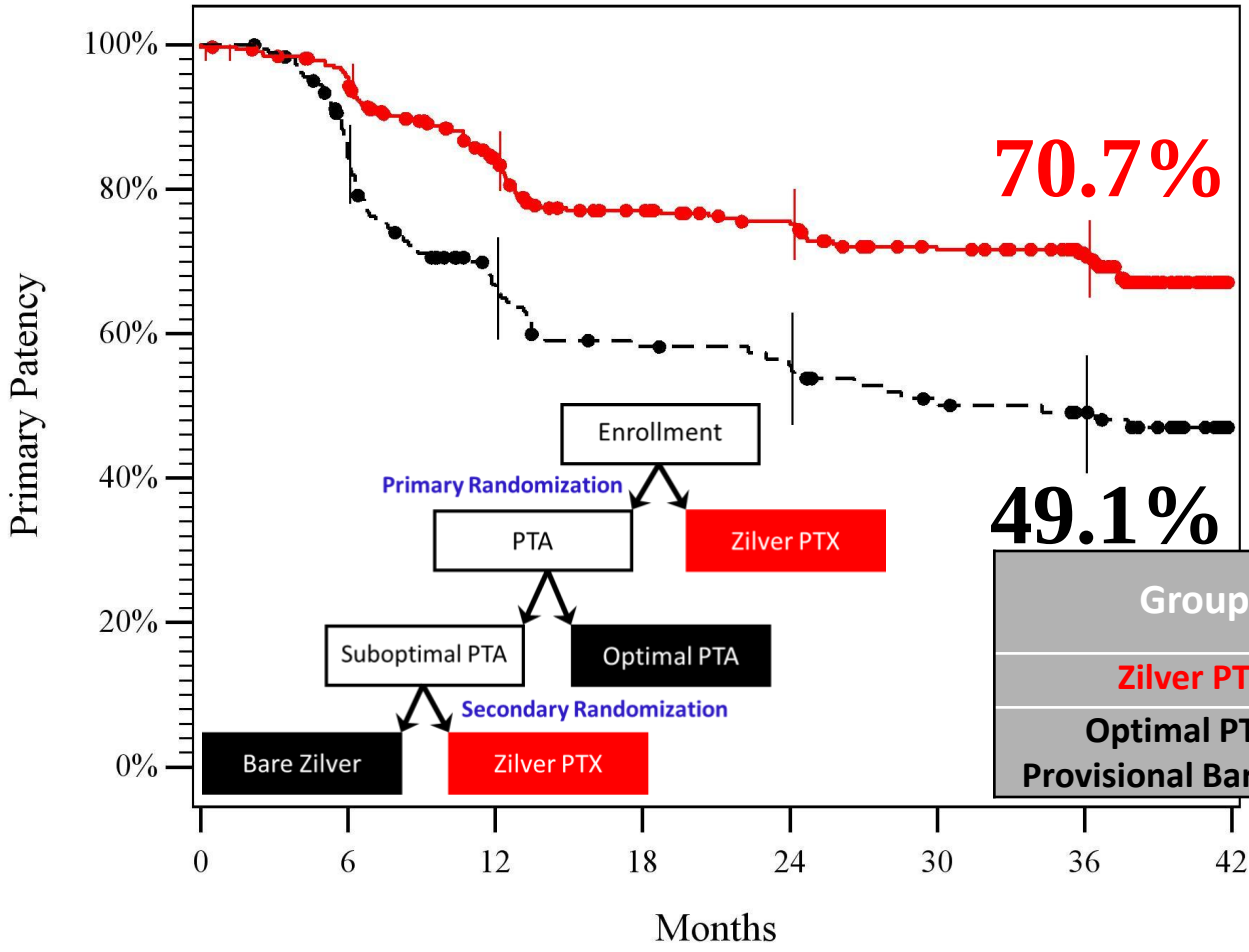
Rationale for the development of DEB derives from limitations of DES

- Stent malaposition
- Stent fracture
- Inhomogeneous drug transfer to the arterial wall
- Reendothelisation and antiplatelet treatment
- Foreign body
- Polymer

DES: Zilver ptx® trial



3-Year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care



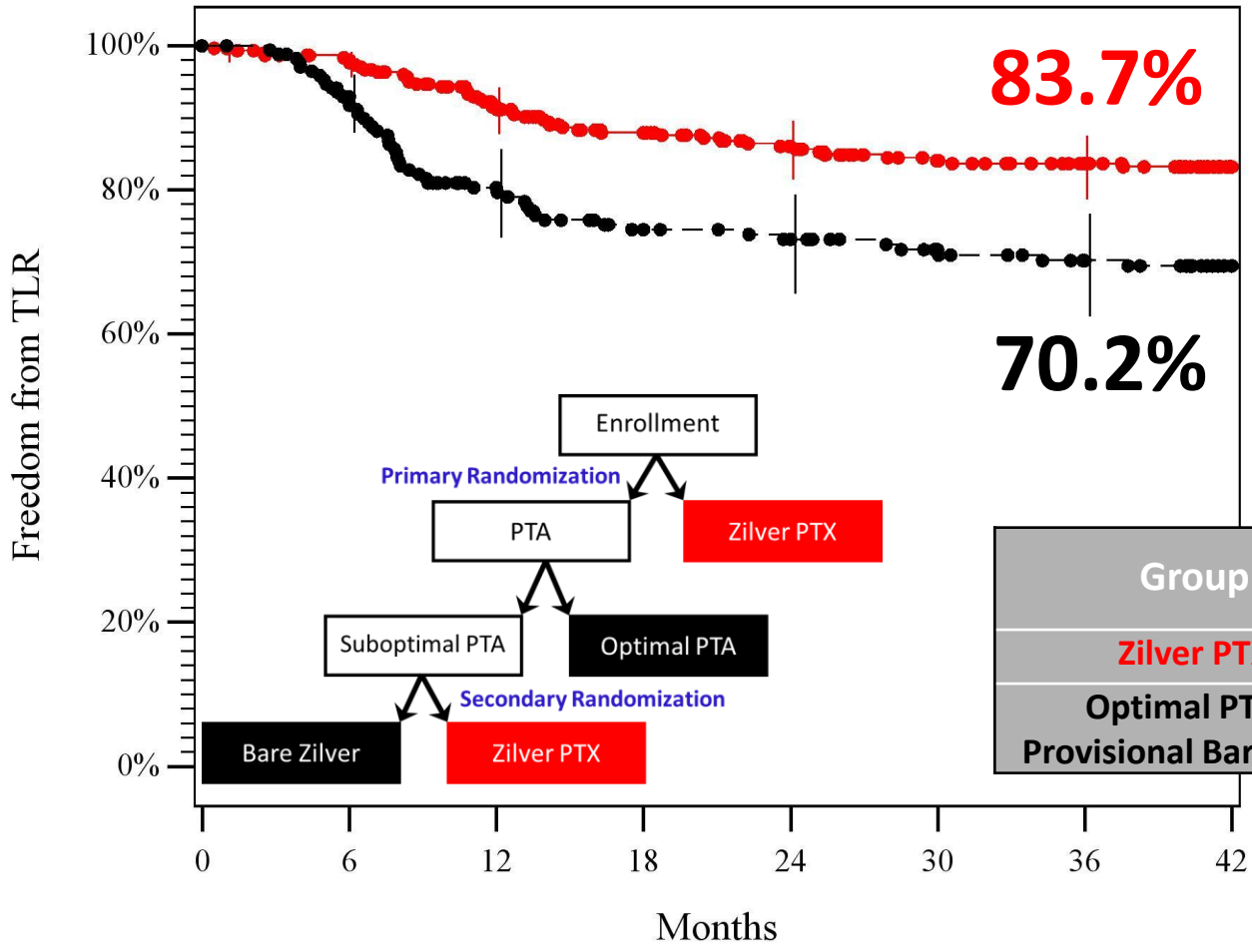
Zilver PTX
234 lesions

Optimal PTA
+ Bare Zilver
130 lesions

$p < 0.01$
log-rank

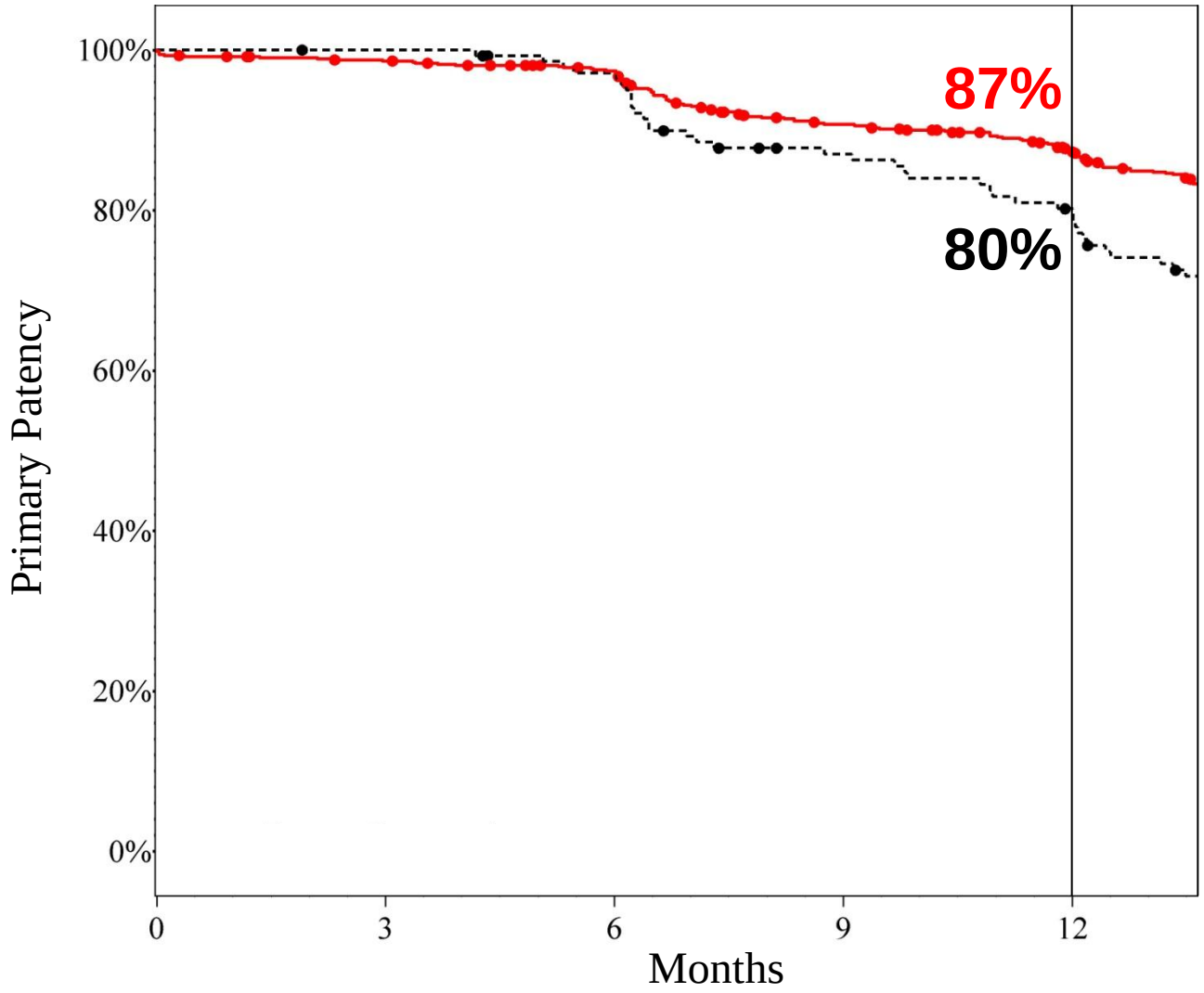
Group	3-year Restenosis	
	Rate	Reduction
Zilver PTX	29.3%	42%
Optimal PTA + Provisional Bare Zilver	50.9%	

3-Year Freedom from TLR
Zilver PTX vs. Standard Care



Group	3-year TLR	
	Rate	Reduction
Zilver PTX	16.3%	45%
Optimal PTA + Provisional Bare Zilver	29.8%	

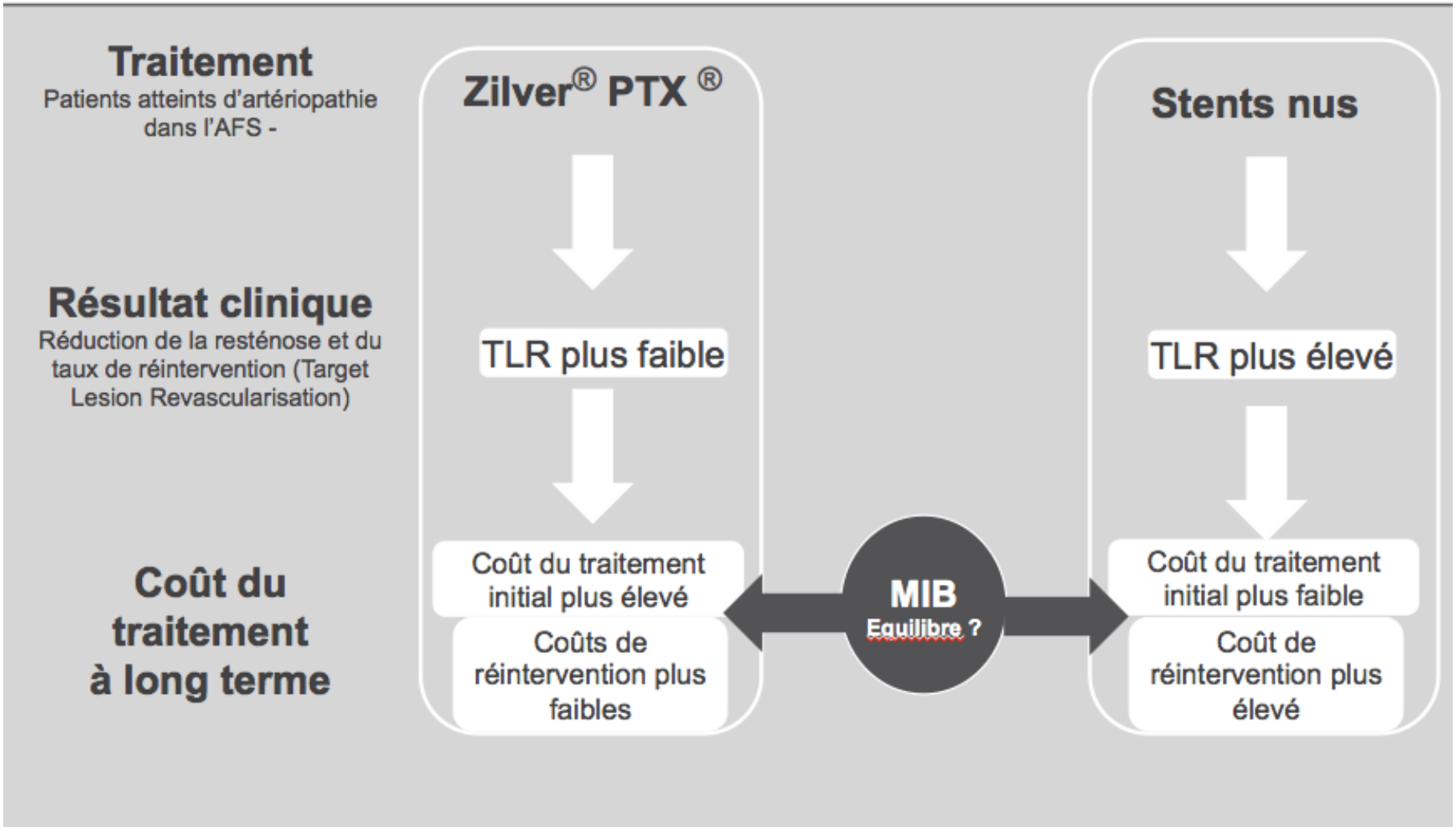
Zilver PTX® effectiveness in treating ISR
Primary Patency (PSVR < 2.5)



Zilver PTX®
No in-stent restenosis

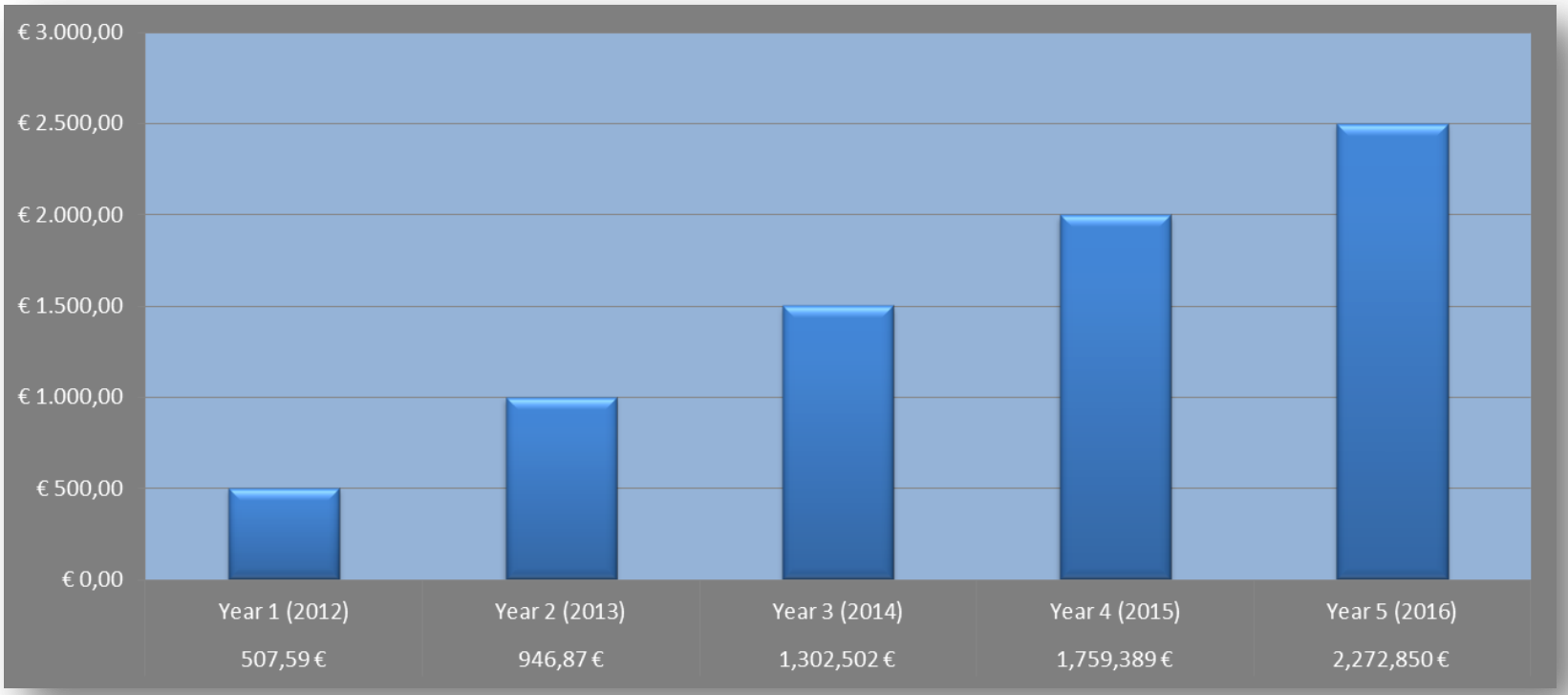
Zilver PTX®
In-stent restenosis

Modèle d'impact budgétaire (MIB) – En bref



De Cock, Cardiovasc Intervent Radiol, 2012

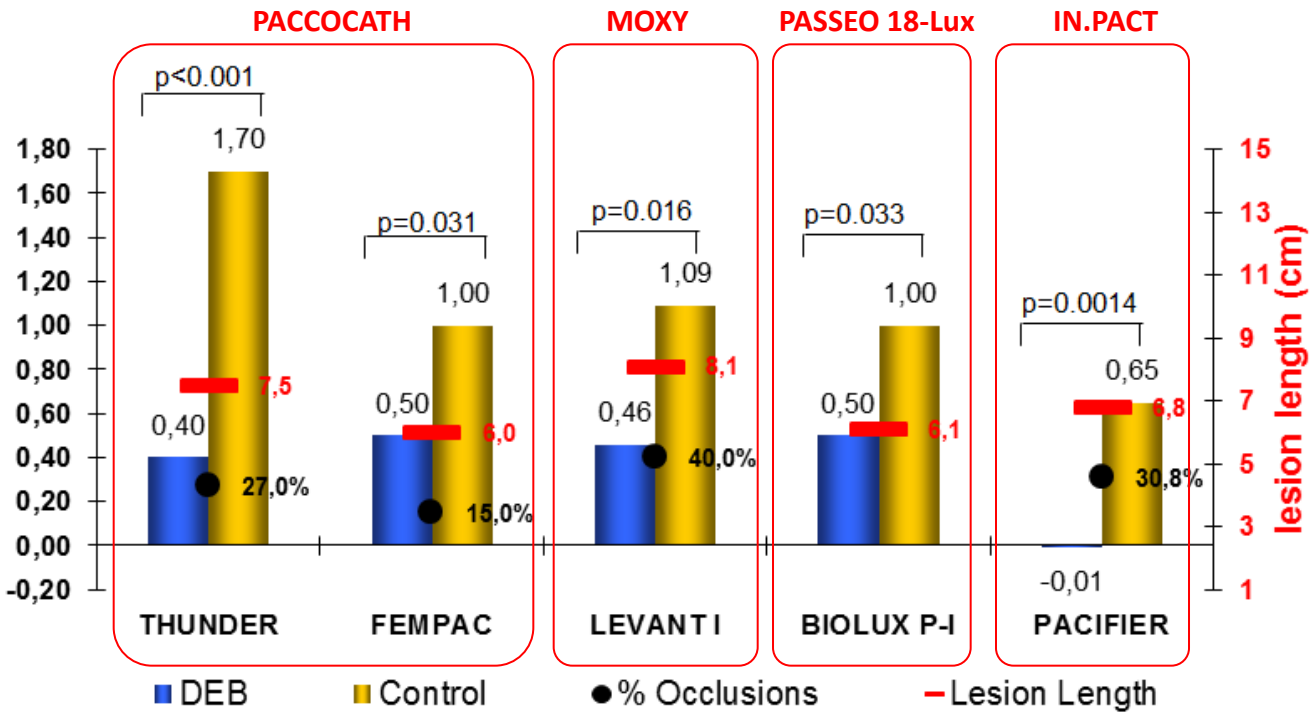
Saving: 6,807,202 €



De Cock, Cardiovasc Intervent Radiol, 2012

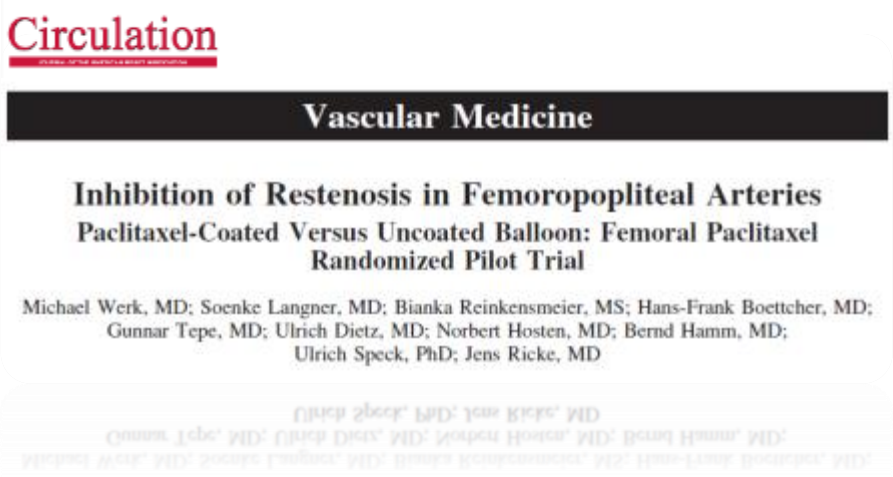
DEB in SFA: Proof of Concept Studies

Consistent demonstration of significant reduction of Late Lumen Loss and Restenosis Rates vs. PTA at 6-month



- G.Tepe et al. N Engl J Med 2008;358:689-99; M.Werk et al. Circulation. 2008;118:1358-1365; D.Scheinert TCT 2010 Oral Presentation; D.Scheinert EuroPCR 2012 Oral Presentation; M.Werk Charing Cross 2012 Oral Presentation

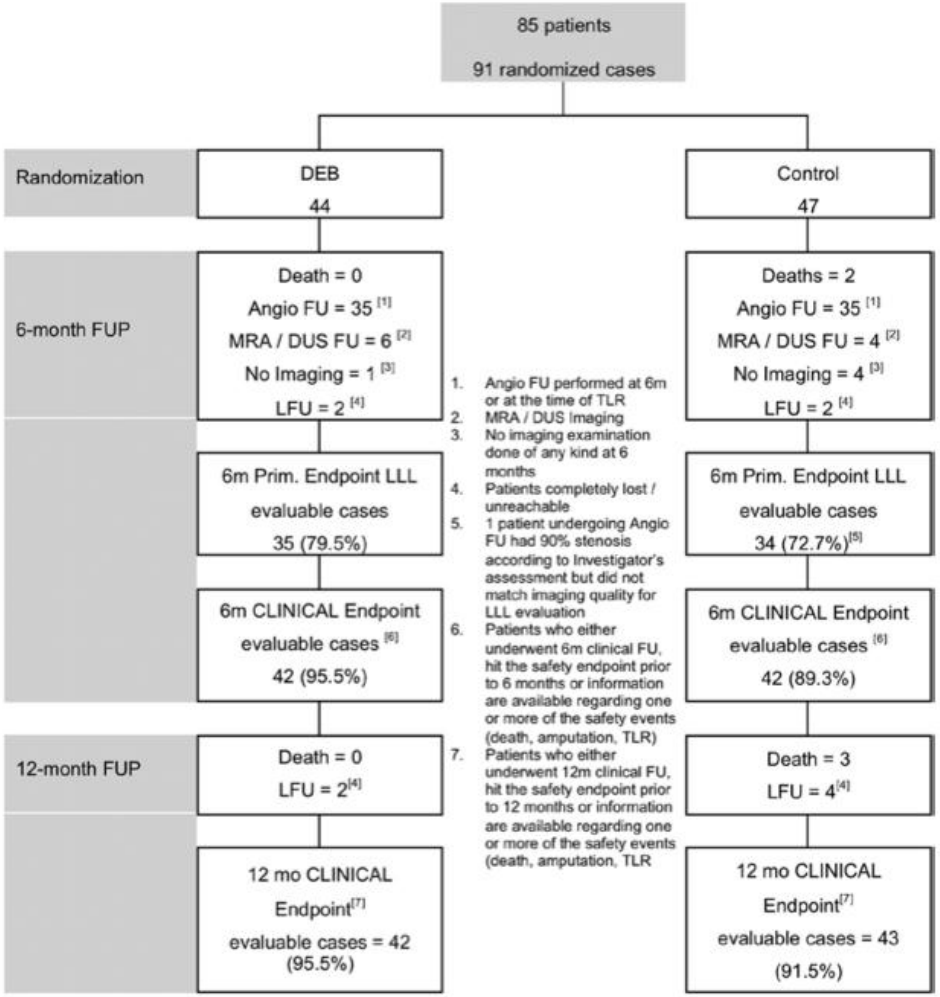
Early Evidence from Milestone DEB Trials



	THUNDER DEB group / Control	FEMPAC DEB group / Control
First TLR @ 24 mo	15% vs 52% (p=0.001)	13% vs 50% (p=0.001)

Pacifier

Werk, Circ Cardiovasc Interv. 2012



Investigator initiated

Multicenter Randomized (1:1)

Primary Endpoint: 6-month LLL

Inclusion criteria

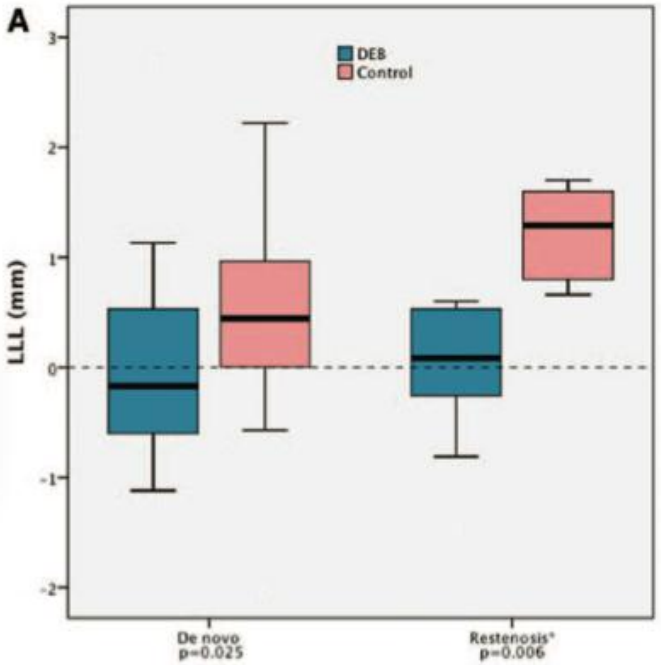
SFA and popliteal arteries

RC 2-3-4-5

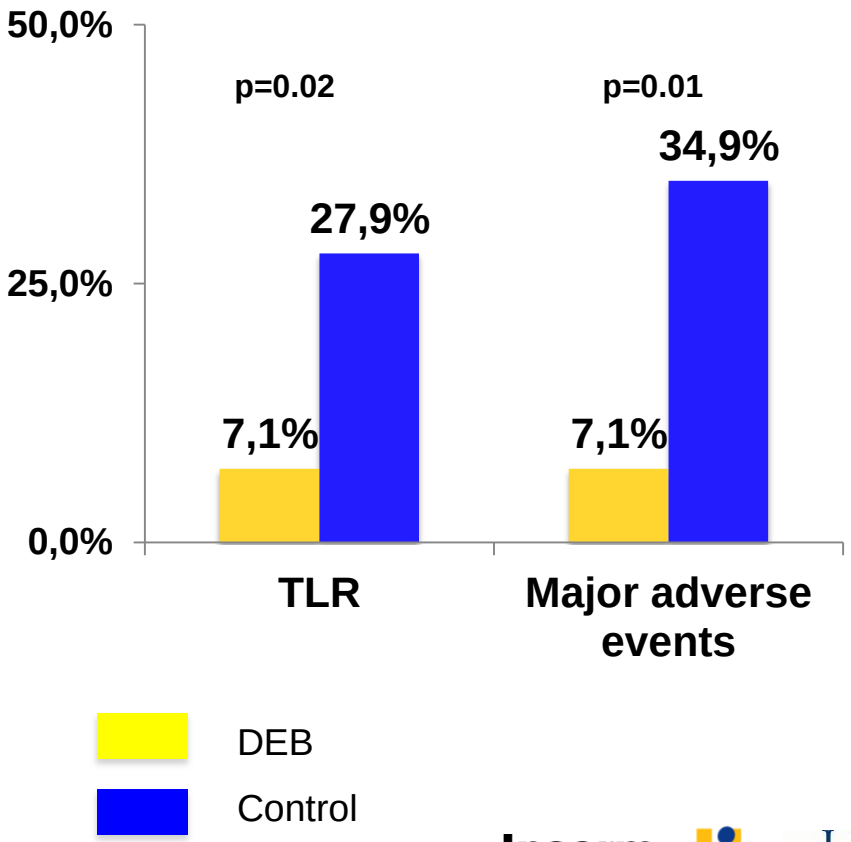
Lesions and/or occlusions

3 – 30 cm

6-month LLL sub-group analysis:



Cumulative 12-mo clinical events



Werk, Circ Cardiovasc Interv. 2012

DEB for treatment of SFA in-stent retenosis

Stabile, JACC, 2012

Single center prospective cohort (*39 patients)*

- ***LLC / CLI = 79.5% / 20.5%***
- ***Diabetics = 48.7%***
- ***Mean Stent length = 181.2 mm***

12-month TLR = 7.8%

12-month ISR rate = 7.8%

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Drug-Eluting Balloon for Treatment of Superficial Femoral Artery In-Stent Restenosis

Eugenio Stabile, MD, PHD, Vittorio Virga, MD, Luigi Salemme, MD, Angelo Cioppa, MD, Vittorio Ambrosini, MD, Giovanni Sorropago, MD, Tullio Tesorio, MD, Linda Cota, MD, Grigore Popusoi, MD, Armando Pucciarelli, MD, Giancarlo Biamino, MD, Paolo Rubino, MD

Mercogliano, Italy

Message to take home

- **Evidence exist** to prevent and to treat ISR using DES and DEB

-**Paclitaxe**l

-**Main limitation**: PTA is the control group

- **Indications should be clarify**: ISR lesion, long lesion, DEB or DES…

-**Devices reimbursement**

What next ?

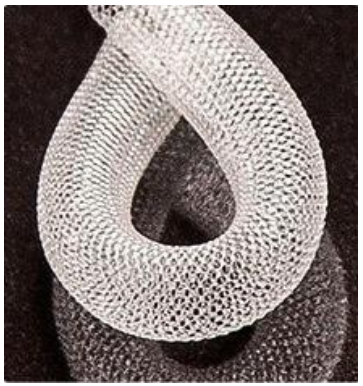
Bioresorbable scaffolds

Stanza® stent (480 Biomedical):

-Self expandable bioresorbable stent

- It dissolves over the six- to 12-month time period

- Stance trial (SFA; efficiency @ 6 mo) (2013)

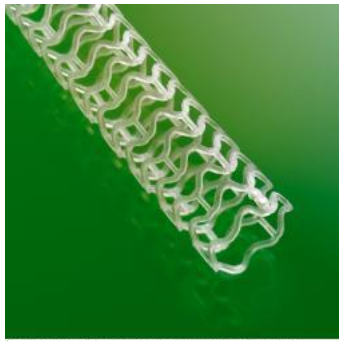


Stanza stent, 480 Biomedical)

ESPRIT® stent (Abbott)

-Drug eluting bioresorbable vascular scaffold
(everolimus, poly-L-lactide polymer)(balloon-expandable device)

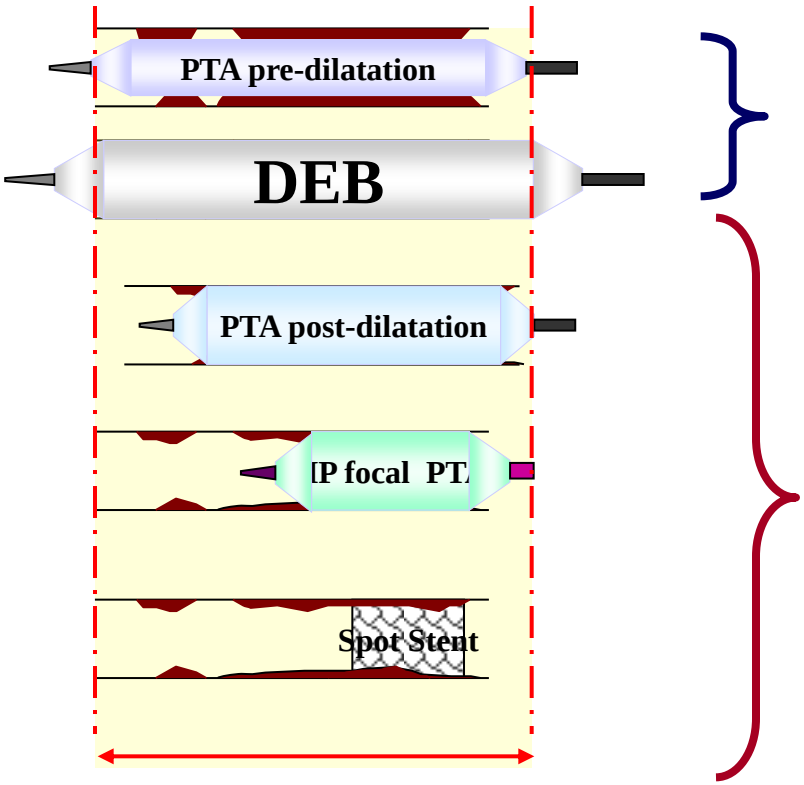
-Esprit trial (SFA+iliac, safety and efficiency) (2015)



Esprit, Abbott

DEB: the value of leaving nothing behind

To avoid geographic miss



DEB Area = Injured Area = working Area

1. **Any DEB pre-treatment (pre-dilatation) must fall within the DEB dilatation area**

2. **Any DEB post-treatment (post-dilat, spot stenting, ...) must fall within the DEB dilatation area.** *Should any DEB post- treatment be necessary that extends beyond the DEB area, a second DEB dilatation must be accomplished with a DEB length fully covering the post-treatment area*