



CONTROVERSIES & UPDATES
IN VASCULAR SURGERY

Critical appraisal of the endo-vascular technology in the SFA

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SUPERFICIAL FEMORAL

WILD WEST

AND CONGRESS OF ROUGH RIDERS OF THE WORLD.



COL. W. F. CODY
BUFFALO BIEF
WILL APPEAR

History of angioplasty in the SFA

- 1st femoral angioplasty:
16 Jan 1964 – Charles Dotter

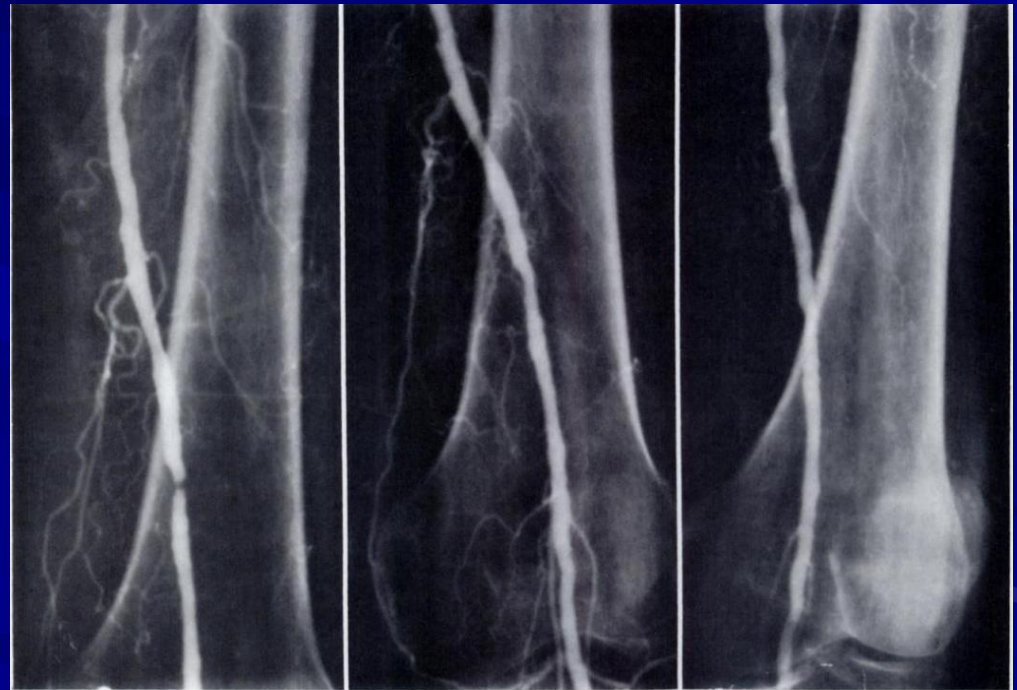
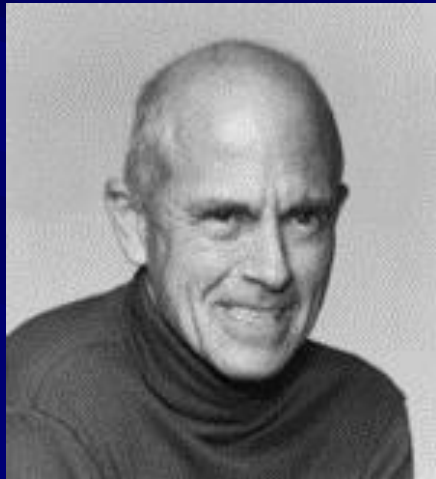
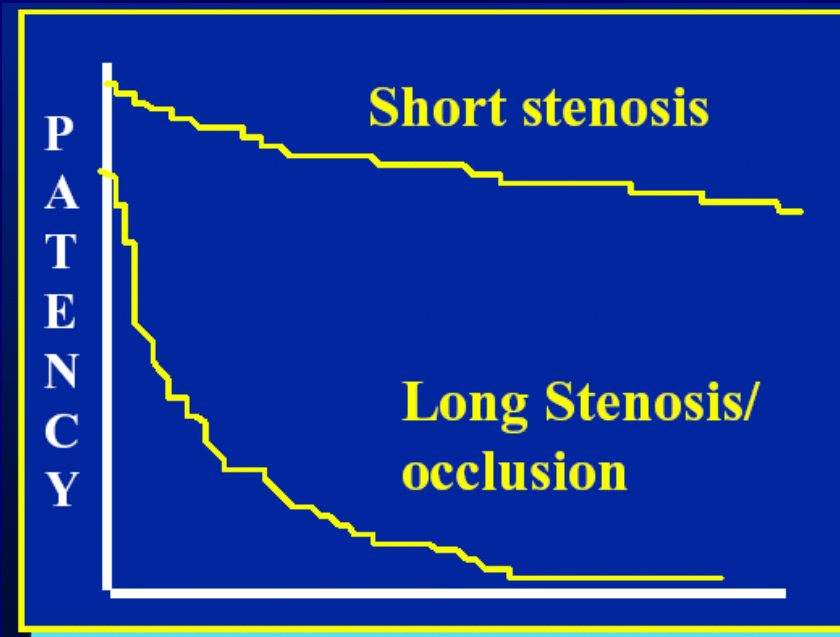


Fig. 2. Transluminal dilatation—the first case. A bedridden 83-year-old woman refused amputation for advanced gangrene due to a proximal popliteal stenosis and severe distal runoff disease. In January 1964, coaxial dilatation of the proximal stenosis was done with prompt improvement in blood flow to the foot.

- Before dilatation.
- Immediately after dilatation.
- Two and one half years after dilatation. The gangrene healed without surgery and the patient became ambulatory until her death of heart disease three years after the procedure.

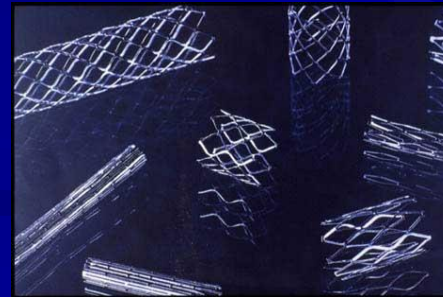
PTA of the SFA in the 80-90's

Results with PTA

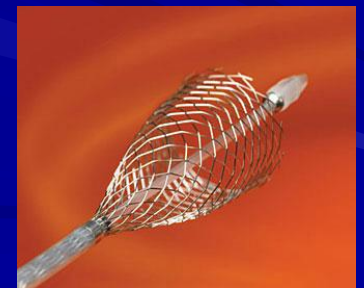


Stainless steel stents

- Palmaz stent (1991)
 - Balloon expandable
 - Rigid
- Wallstent (1986)
 - Self expandable
 - Flexible



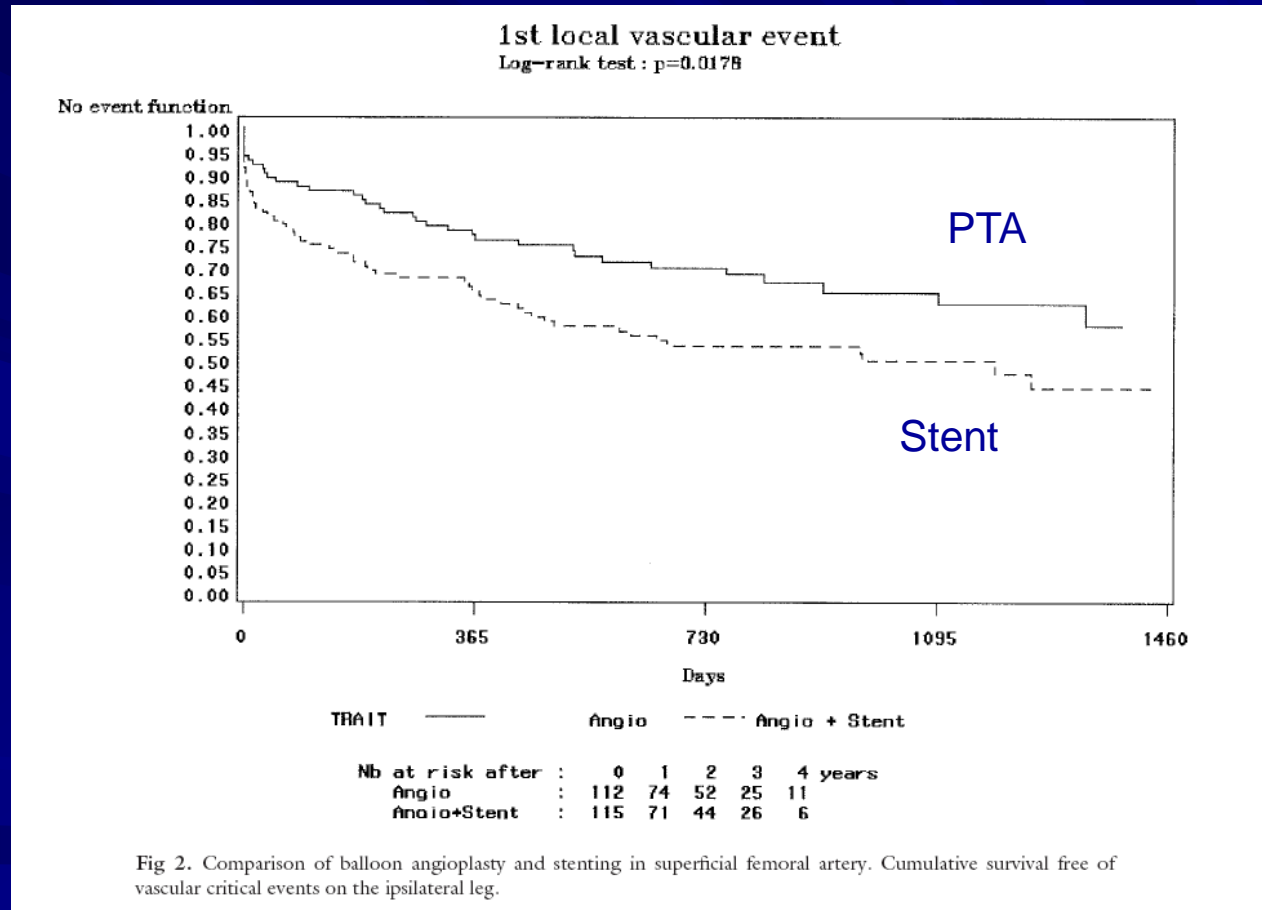
Palmaz stent



Wallstent

Primary vs selective stenting

Survival free of vascular events

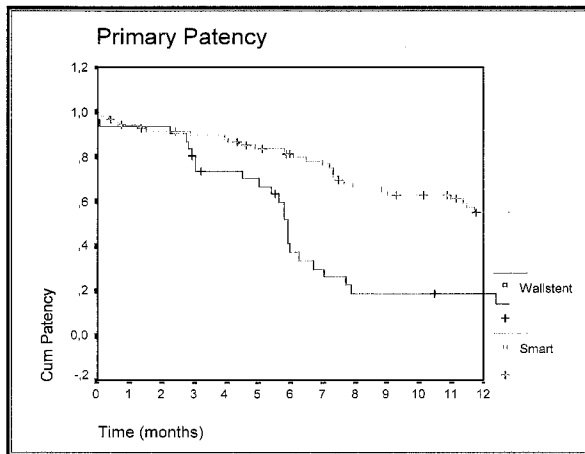


Becquemin (J Vasc Surg 2003)

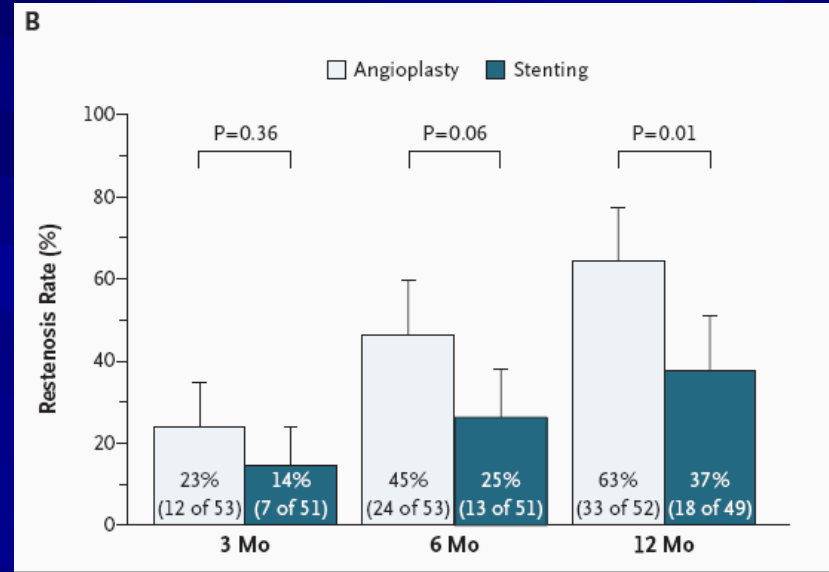
Nitinol stents

Nitinol vs stainless steel

Vienna - Absolute RCT



	<u>Smart</u>	<u>Wallstent</u>
6 months:	81.7±4.7%	37.2 ± 9.1%
12 months:	55.0 ± 6.5%	18.6 ± 7.4%
Log-rank test: P:0.0000		

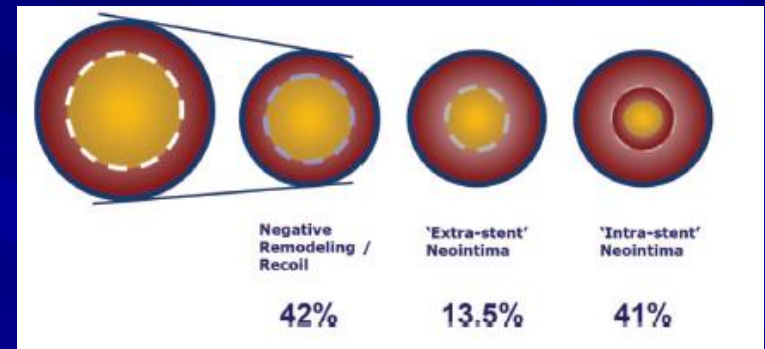
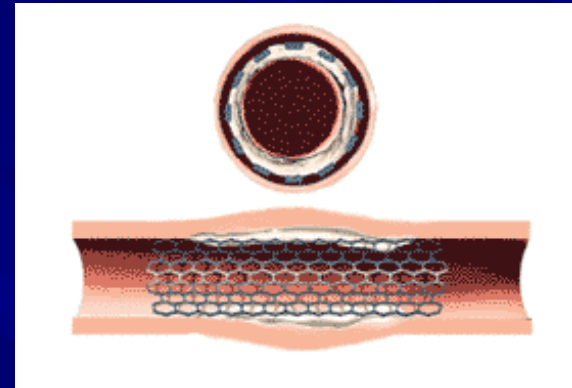


Hayerizadeh – Biamino 2003

Schillinger 2006

Reasons for Restenosis

- Early recoil, dissection
- Negative vessel remodelling
- Neo-intimal hyperplasia



Resilient trial

Actual Enrollment Pattern

Intention to Treat - ITT Analysis

n=206 patients
randomly allocated
1:2

PTA Only
Control Arm
n=72 (81 lesions)

PTA + LifeStent
Test Arm
n=134 (153 lesions)

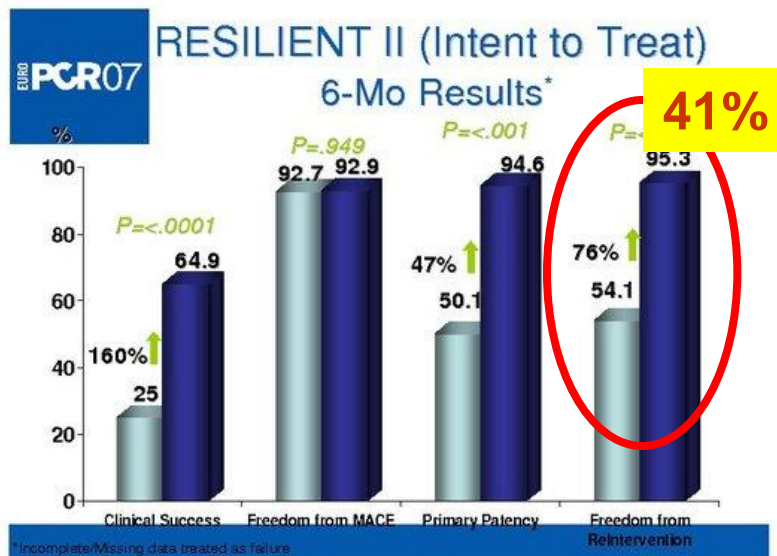
PTA
Only
n=43

PTA+
Stent
n=29

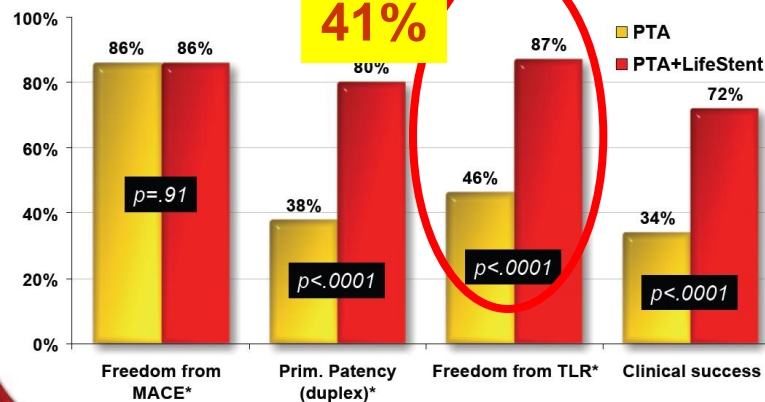
Cross Over
bailout + Stent
n=29 (40.2%)
(34 lesions)

40%

THE RESILIENT TRIAL



12-Month Results



*Data from Kaplan-Meier Survival Analysis

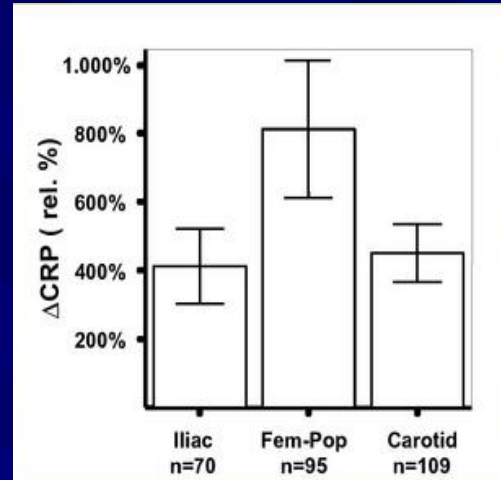
THE RESILIENT TRIAL

Factors eliciting restenosis in SFA

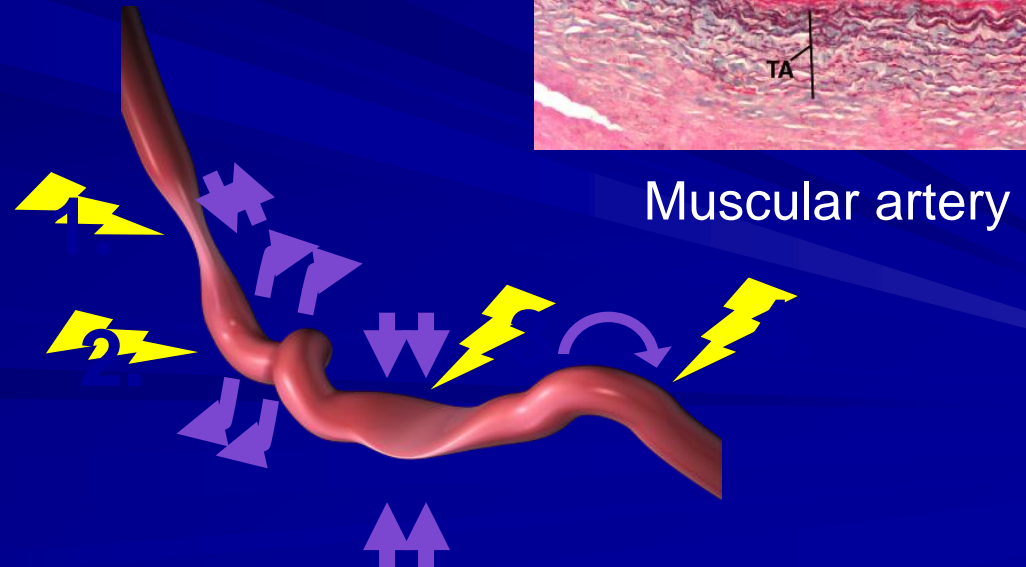
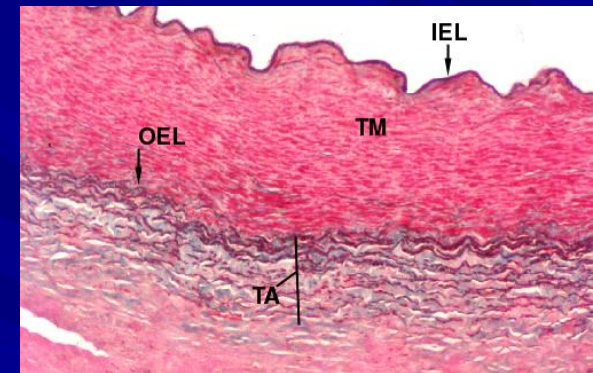
■ Biochemical

■ Histological

■ Biomechanical



Inflammatory response after PTA



Strategies to prevent restenosis

Laser

Debulking

Drug-eluting stents

Better stents

Coated balloons

Coated balloons

Brachytherapy

Cryoplasty

Endografts

Cutting balloon

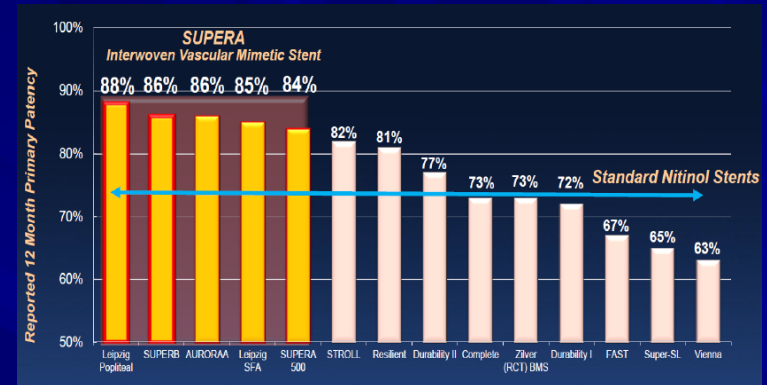
Better stents - Techniques

■ Improved stent design

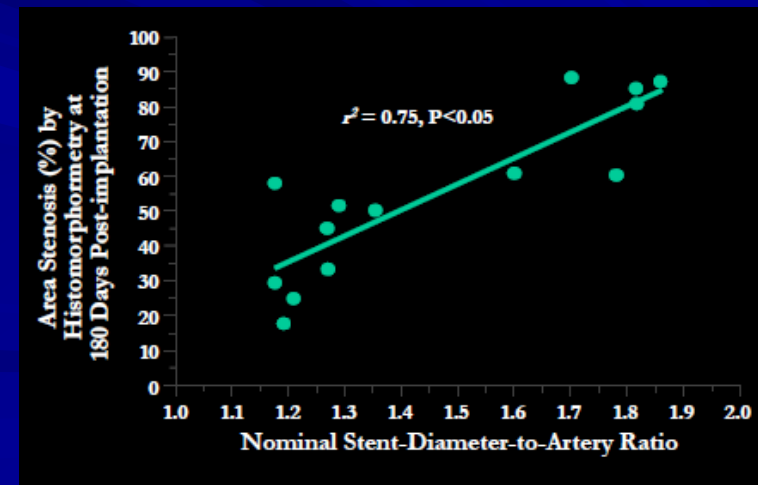
- Biocompatible
- Thrombo resistant
- Fracture resistant
- Flexible (all directions)

■ Avoid excessive oversizing

■ Avoid stretching



New stent design



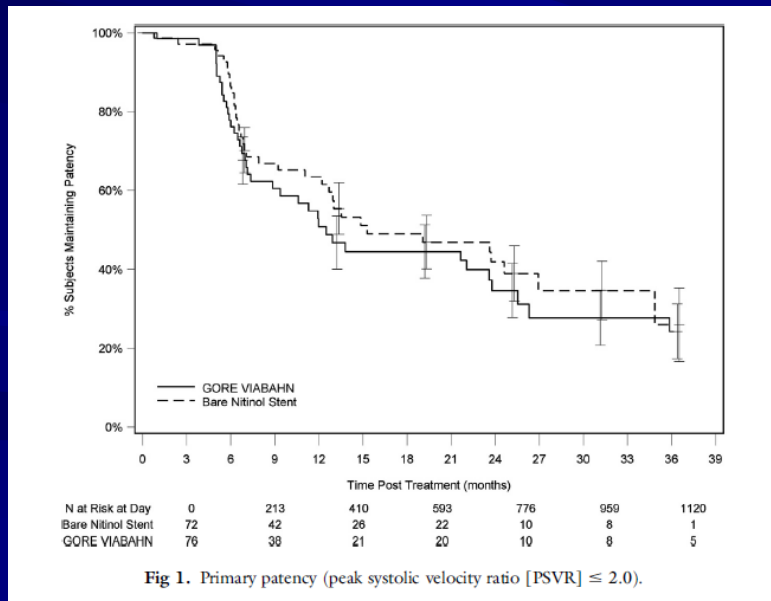
Effect of oversizing in swine

Covered stents

Prevent ingrowth through stent struts

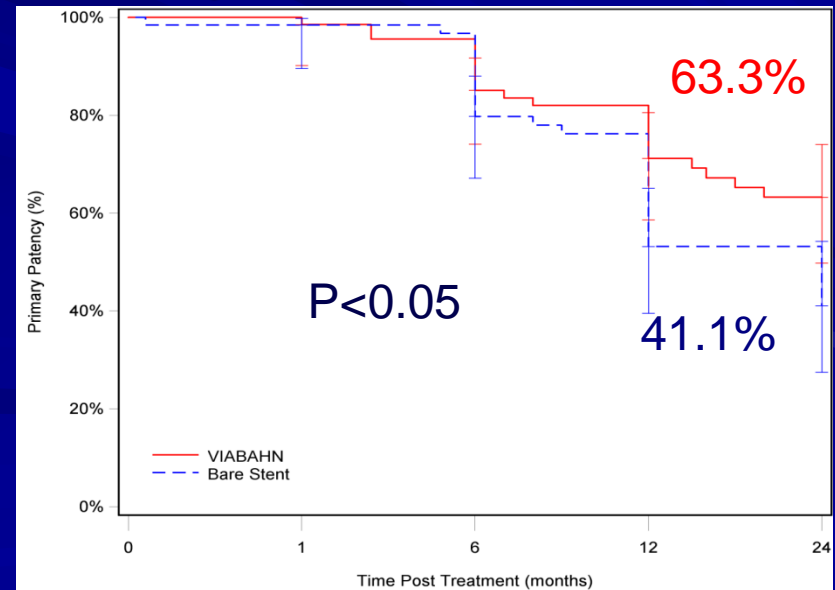
VIBRANT

- Viabahn vs bare stent
 - 3 year results



VIASTAR

- Heparin bonded Viabahn vs bare stent
 - 2 year results



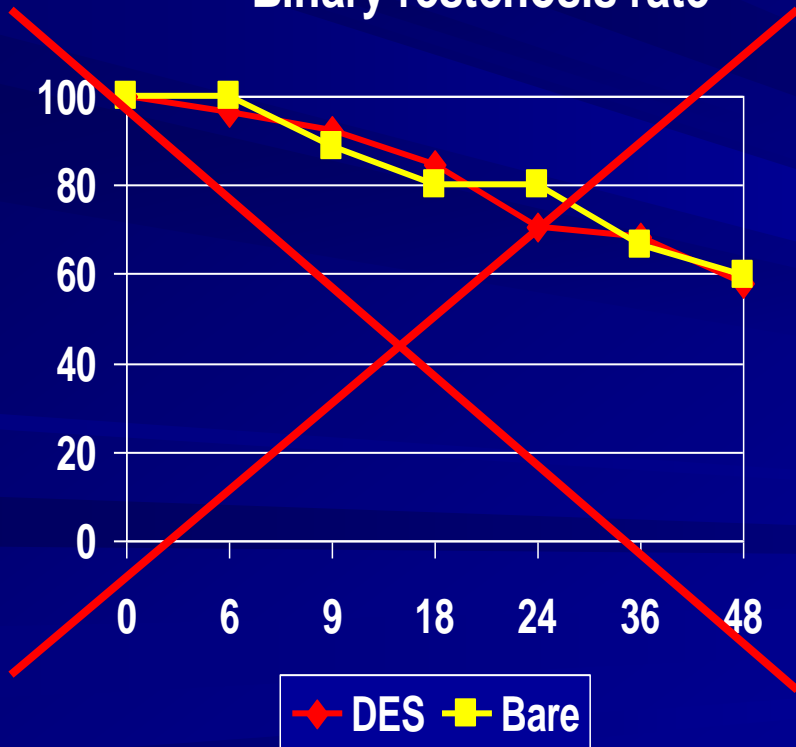
Drug eluting stents

Positive results in coronaries

Sirocco

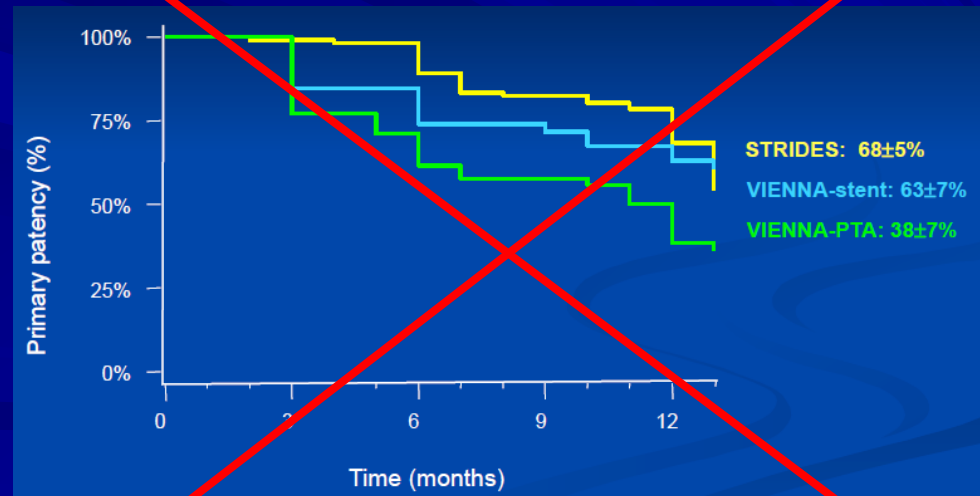
Sirolimus-eluting Smart

Binary restenosis rate



Strides

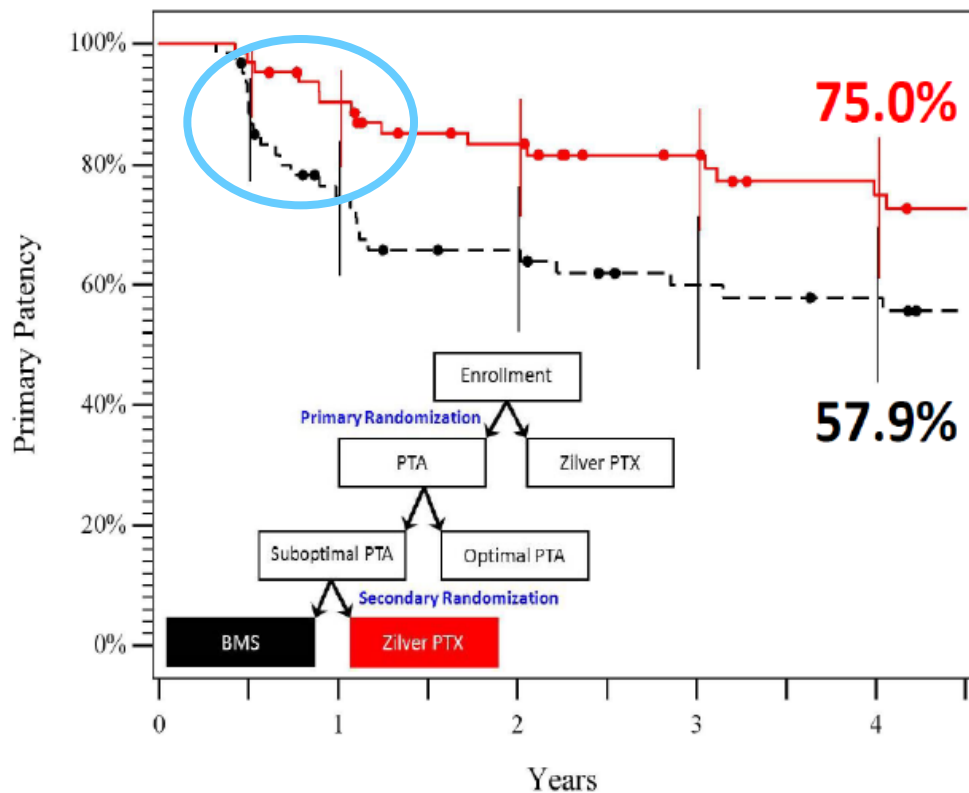
Everolimus-eluting Dynalink



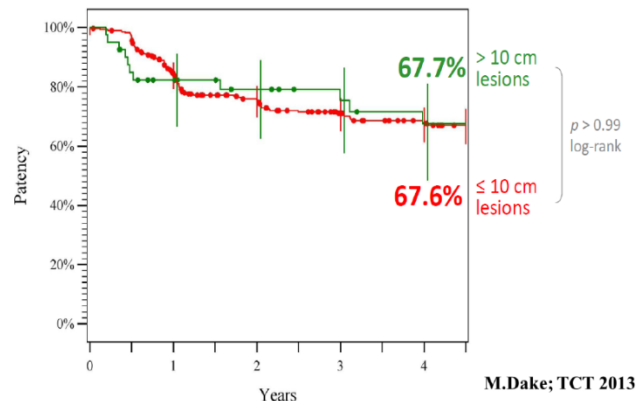
Drug-eluting stents Zilver PTX study

Proven Drug Effect at 4 Years

Patency (PSVR < 2.0): Provisional Zilver PTX vs. BMS



4-Year Primary Patency in > 10 cm Lesions



Metallic stents in the SFA

Short Term +++

- Eliminate acute thrombosis by dissection flaps
- Reduce vessel recoil and rest-stenosis
- Positive influence on early constrictive remodeling

Long Term - - -

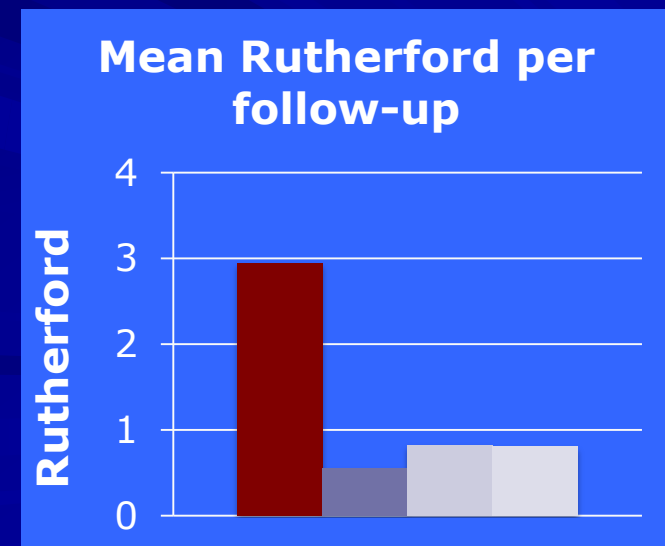
- Thrombogenic
- Continuous stress on the wall enhancing intimal hyperplasia
- Alter mechanical properties of the vessel
- Impede late positive remodeling
- Promote difficult to treat in-stent restenosis

Bioabsorbable stents

Belgian Remedy study

- Remedy (Igaki-Tamai) stent
- Prospective multicentre registry in 12 centres – 100 patients
- Symptomatic (Rutherford 2-5) SFA-lesion ≤ 75 mm
- Results
 - 100 patients
 - Mean lesion length: 38 mm
 - Technical success (<30% stenosis) :95%
 - Primary patency 68%@6m, 58%@12m
 - Secondary patency 87%@6m, 89%@12m
 - Freedom from TLR: 79%@6m, 69%@12m

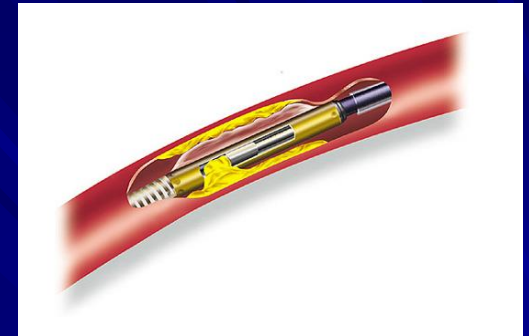
	6 M FU	12 M FU
1. Prim Patency	68 %	58 %
2. Sec. Patency	87 %	85 %
3. TLR	21 %	31 %
4. TVR	2.5 %	5.0 %
5. Amputation	1.2 %	1.7 %



Esprit – BVS study

- Single-arm multi-centre study in claudicants with single de novo-lesion in SFA or iliac artery
- Vessel diameter 5.5-6.5 cm
- Lesion length \leq 50 mm
- Treatment with one 6.0 x 58 Esprit BVS
- Angiographic FU @ 12 mth
- 35 patients
- 100% procedural success

Atherectomy



Simpson catheter

- Remove plaque burden
- Lowers stent-rate
- Embolization? Restenosis ? + DEB? Cost?
- Definitive LE – registry

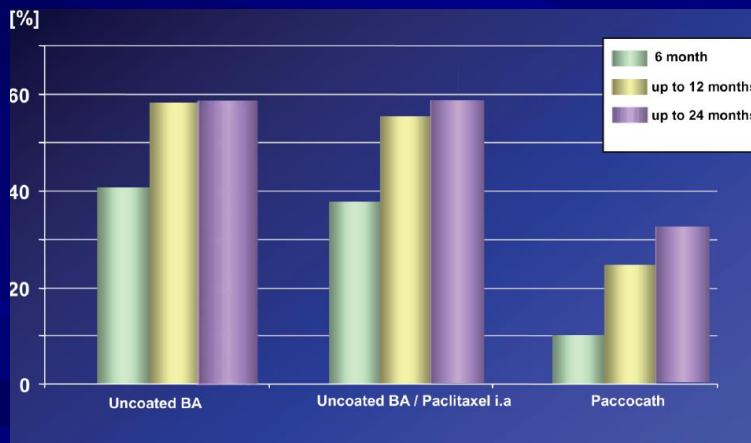
Claudicants	Primary Endpoint: Primary Patency at 12 Months (PSVR \leq 3.5)		Secondary Endpoint: Primary Patency at 12 Months (PSVR \leq 2.4)	
	Patency	LL (cm)	Patency	LL (cm)
All (n=743)	82%	7.5	78%	7.5
Diabetic (n=345)	80%	7.6	77%	7.6
Non-Diabetic (n=398)	83%	7.4	78%	7.4

- Definitive AR ?

Drug-eluting balloons

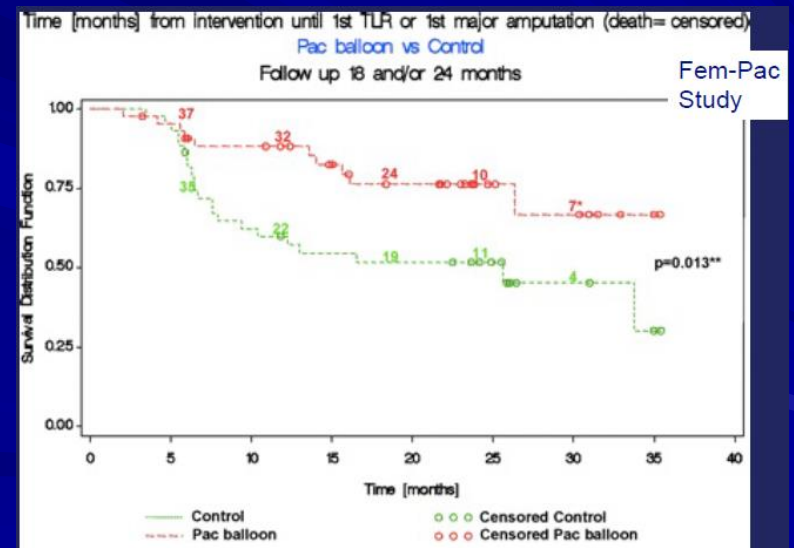
- Antiproliferative drugs prevent restenosis
- Balloon as drug-carrier

Thunder trial



Tepe NEJM 2008

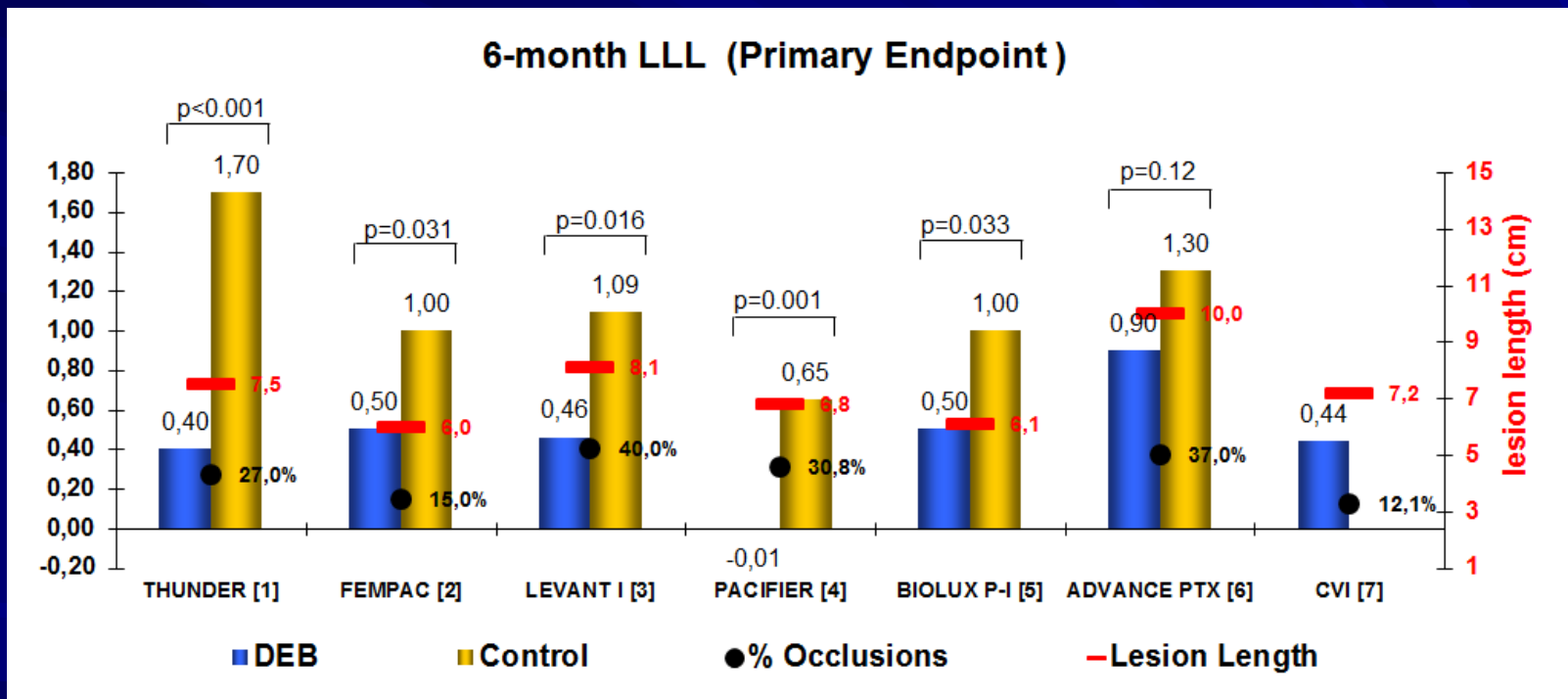
Fempac trial



Werk Circulation 2008

Short-term results

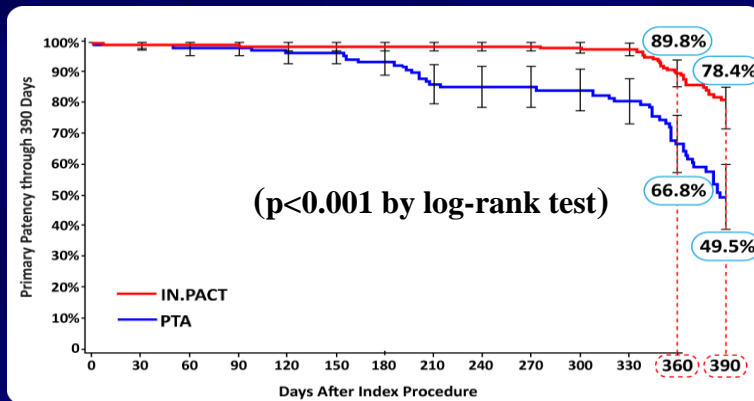
6 DEB Technologies / 7 Trials (6-month LLL Primary Endpoint)



[1] G.Tepe et al. - NEJM 2008; [2] M.Werk et al. - Circulation 2008; [3] D.Scheinert - TCT 2012 oral presentation; [4] M.Werk et al. - Circulation CI 2012; [5] D.Scheinert – EuroPCR 2012 oral presentation; [6] D.Scheinert – LINC 2013 oral presentation; [7] P.Peeters – LINC 2013 oral presentation

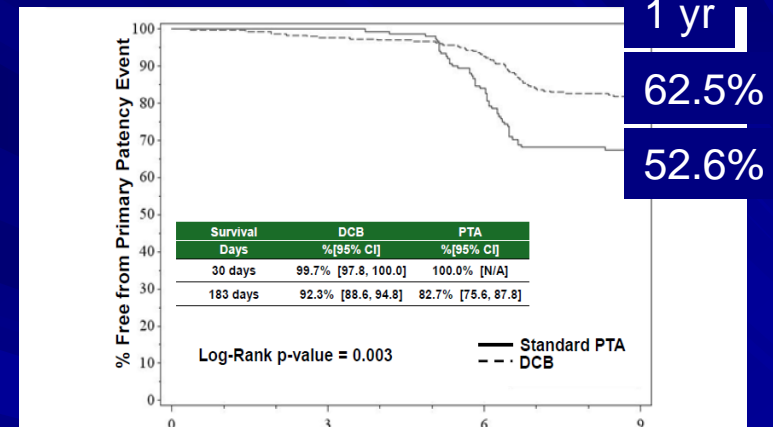
RCT 's 1 year results

In.Pact SFA



- IN.PACT admiral vs POBA
- 331 patients randomized 2:1
- Rutherford cat: 2-4
- Single de novo lesions > 70%
- 4-18 cm length (occlusions < 10 cm)
- SFA or prox. PA
- Mean lesion length: 8.9 cm

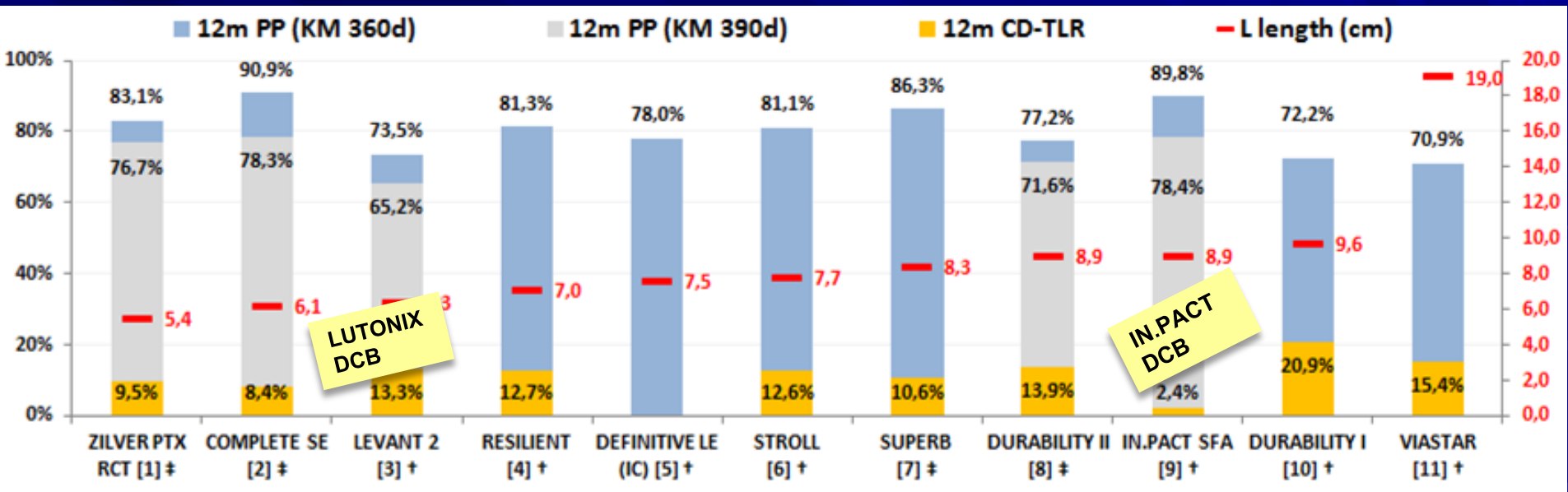
Levant II



- Lutonix DEB vs POBA
- 476 patients randomized 2:1
- Rutherford cat: 2-4
- Single de novo lesions > 70%
- < 15 cm length
- SFA or prox. PA
- Mean lesion length: 6.3 cm

Drug-eluting balloons

■ 1 y results compared to other techniques



Duplex derived Primary Patency based on PSVR ≤ 2.4 (†) or PSVR ≤ 2.0 (‡)

Conclusions

- The SFA remains a challenging area for endovascular treatment
- Results have improved over the last 20 years
- Role of POBA is probably limited to short lesions
- Stent design and implantation technique influence the results with stenting
- Stents remain to have indications but are only needed for a short term after implantation
- Bio-absorbable stents need drugs and are not there yet

Conclusions

- New generation covered stents might be an asset in long lesions
- Drug-eluting stents can offer an advantage (esp. In longer lesions?) but evidence remains limited
- Atherectomy only has a limited role
- Drug eluting balloons are a very interesting evolution and probably a game changer of which the precise place still needs to be determined