MEET2015

Nice, June 8-9 2015

TASC A/B femoropopliteal lesions treatment DES should be the first line treatment

Jos C. van den Berg, MD PhD
Ospedale Regionale di Lugano, sede Civico
Lugano
Switzerland

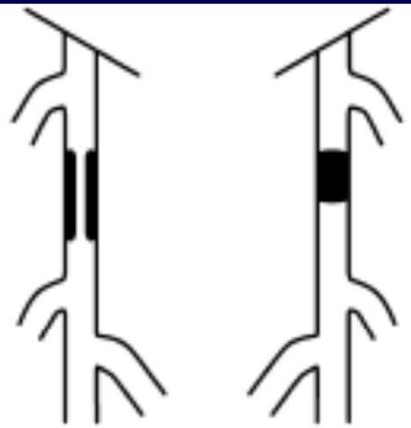
TASC II femoral popliteal lesions

- Type A lesions
  - Single stenosis ≤10 cm in length
  - Single occlusion ≤5 cm in length
- Type B lesions
  - Multiple lesions (stenoses or occlusions), each ≤5 cm
  - Single stenosis or occlusion ≤15 cm not involving the infra geniculate popliteal artery
  - Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
  - Heavily calcified occlusion ≤5 cm in length
  - Single popliteal stenosis

TASC II femoral popliteal lesions Type A and Type B

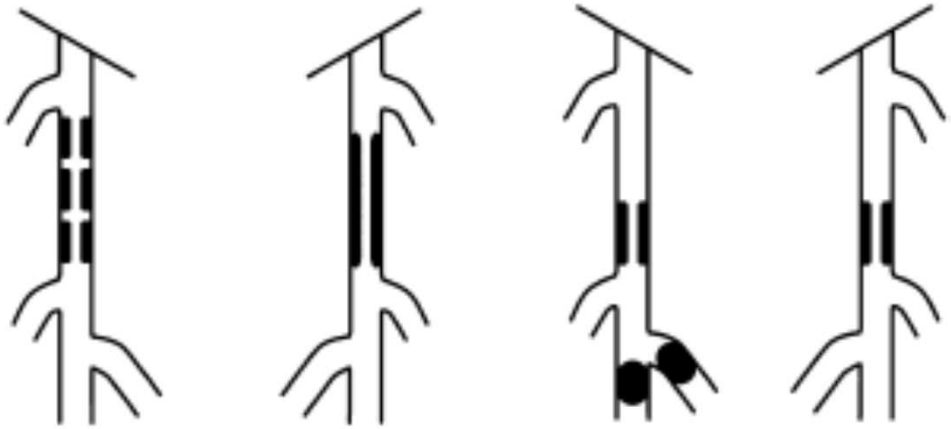
Type A lesions

- Single stenosis ≤10 cm in length
- Single occlusion ≤5 cm in length



Type B lesions:

- Multiple lesions (stenoses or occlusions), each ≤5 cm
- Single stenosis or occlusion ≤15 cm not involving the infrageniculate popliteal artery
- Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
- Heavily calcified occlusion ≤5 cm in length
- Single popliteal stenosis



Treatment options

- POBA
- BMS
- DCB
- DES

BMS-RCT’s

- ABSOLUTE
- FAST
- RESILIENT

BMS-12 months

	ABSOLUTE	FAST	RESILIENT
Mean lesion length (mm)	101/92	45/44	71/64
Primary patency (PTA)	50%/37%	66.4%/62.2%	53.8%/36.7%
Primary patency (stent)	75%/67%	76.2%/67%	84%/81.3%
# stents used	1.7	1	1.6
Stent fractures	2%	12%	3.1%

Stent/PTA
6months/12 months
Patency per protocol (except 12 month ABSOLUTE)

Schillinger M et al,NEJM 2006;354:1879-1888
Krankenberg H et al, Circulation 2007;116:285-292
Laird JR et al, Circ Cardiovasc Interv 2010;3:267-276

ABSOLUTE @ 24 months

- Restenosis rate
  - Intention-to-treat
    - PTA 69.2%
    - Stent 45.7% (p=0.03)
  - Treatment-received analysis
    - PTA 74.3%
    - Stent 49.2%
- Trend toward clinical benefit

Schillinger M et al, Circulation 2007;115:2745-2749

RESILIENT

Chronic Effectiveness Measures				
	Stent (n=134)	Balloon (n=72)	Difference, %	p
12 Months				
Freedom from TLR, %	87.3	45.2	42.1	<0.0001
Primary patency, %	81.5	36.7	44.8	<0.0001
Clinical success, %	72.3	31.8	40.5	<0.0001
24 Months				
Freedom from TLR, %	77.8	41.8	36.0	<0.0001
Clinical success, %	68.6	25.4	43.2	<0.0001
36 Months				
Freedom from TLR, %	75.5	41.8	33.7	<0.0001
Clinical success, %	63.2	17.9	45.3	<0.0001

Laird JR et al, Circ Cardiovasc Interv. 2010;3:267-276
Laird JR et al, JET 2012;19:1-9

BMS-RCT's

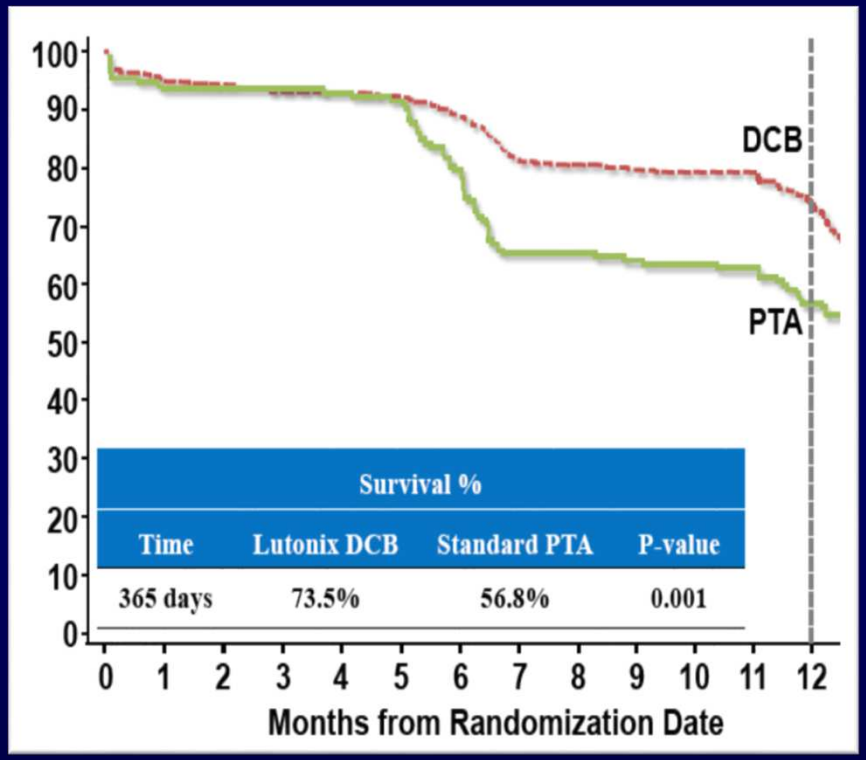
- ABSOLUTE
- FAST
- RESILIENT

NO LONG-TERM PRIMARY PATENCY DATA

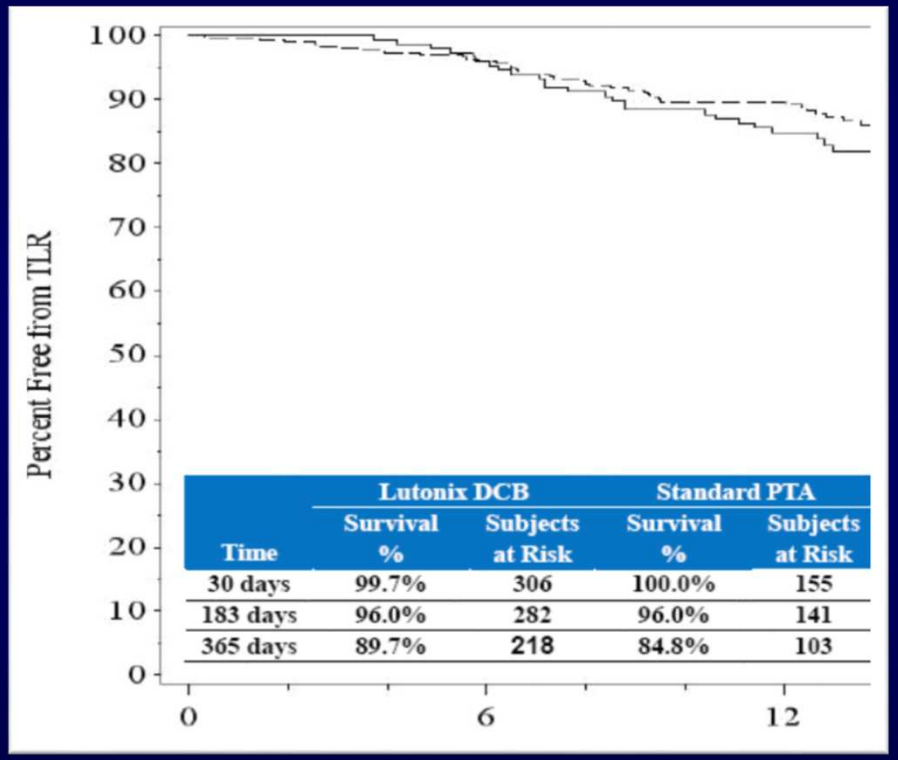
DEB-RCT's

- LEVANT 2
- INPACT SFA I-II

LEVANT 2



Survival %			
Time	Lutonix DCB	Standard PTA	P-value
365 days	73.5%	56.8%	0.001

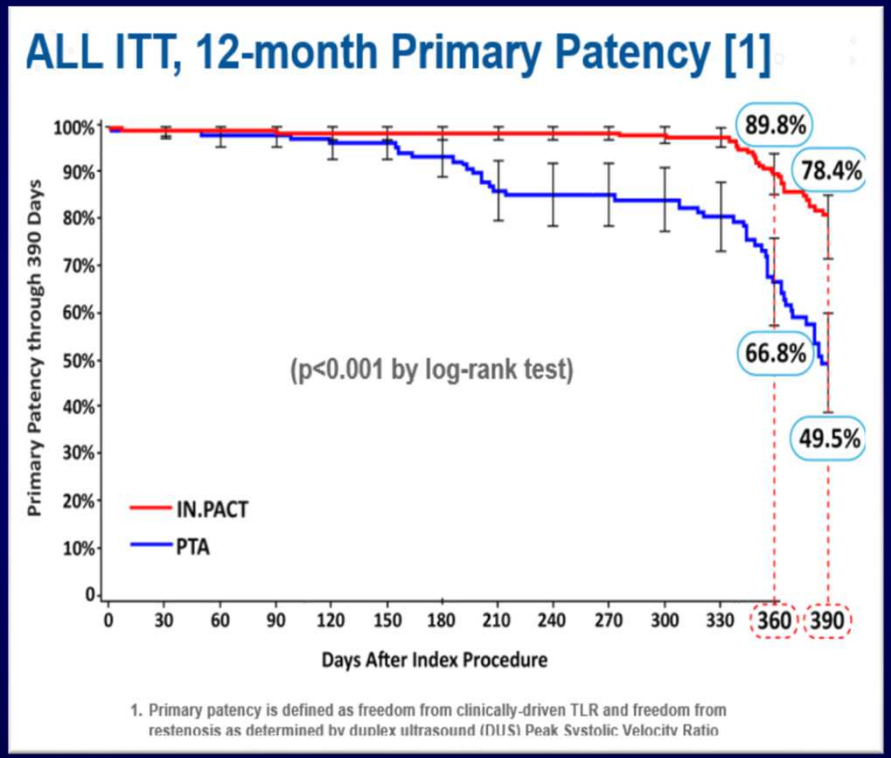


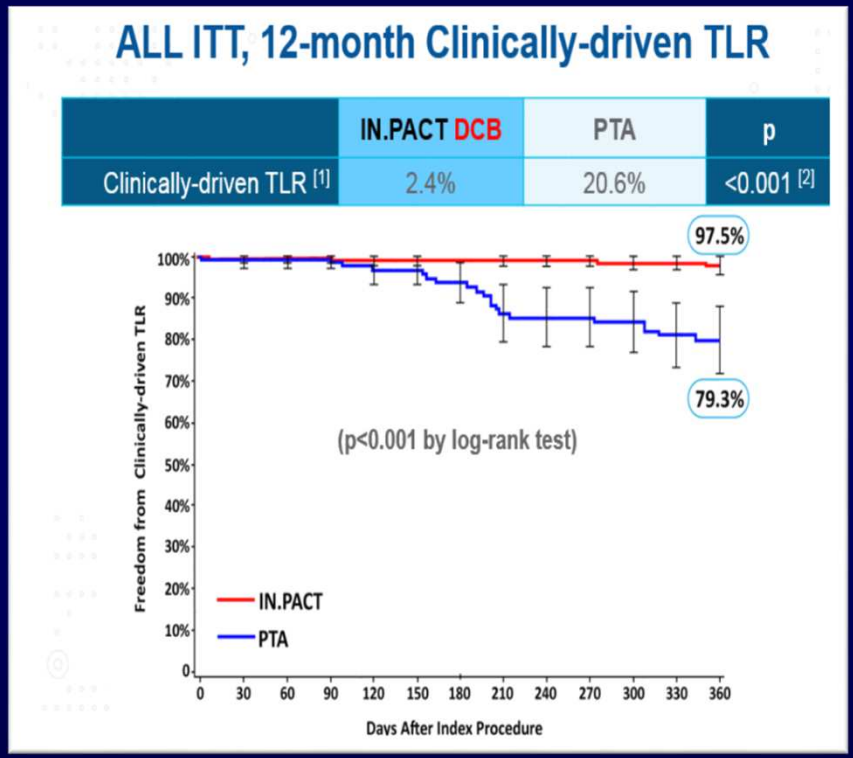
	Lutonix DCB		Standard PTA	
Time	Survival %	Subjects at Risk	Survival %	Subjects at Risk
30 days	99.7%	306	100.0%	155
183 days	96.0%	282	96.0%	141
365 days	89.7%	218	84.8%	103

Primary patency 1 yr 73,5%

Freedom TLR 1 yr 89,7%

INPACT SFA I-II

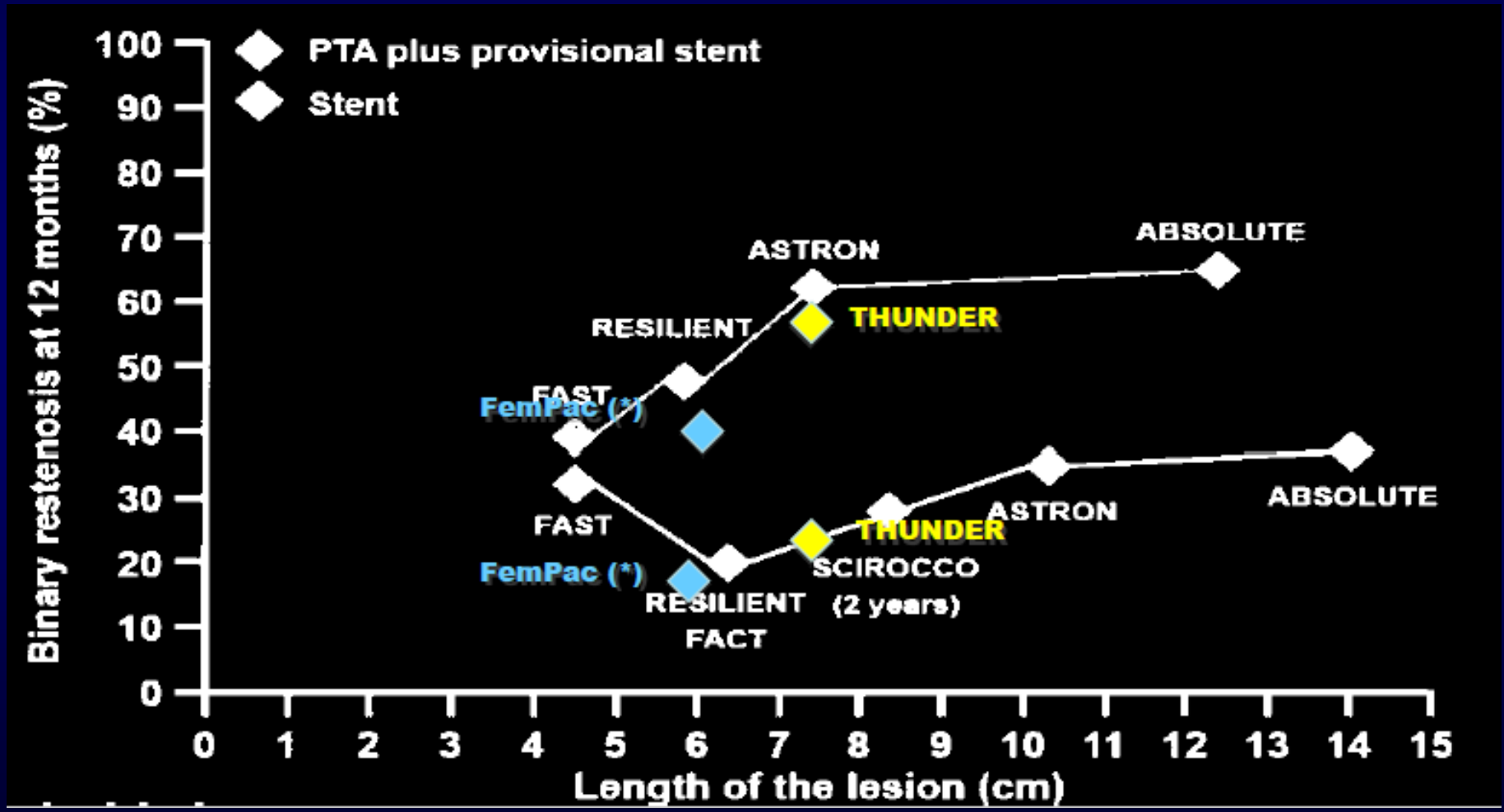




Primary patency 1 yr 89,9%

Freedom TLR 1 yr 97,5%

BMS vs. DEB


PTA plus provisional stent
Stent
Binary restenosis at 12 months (%)
100
90
80
70
60
50
40
30
20
10
0
ASTRON
ABSOLUTE
THUNDER
RESILIENT
FAST
FemPac (*)
FAST
FemPac (*)
RESILIENT
FACT
THUNDER
ASTRON
ABSOLUTE
SCIROCCO
(2 years)
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Length of the lesion (cm)

DEB-RCT's

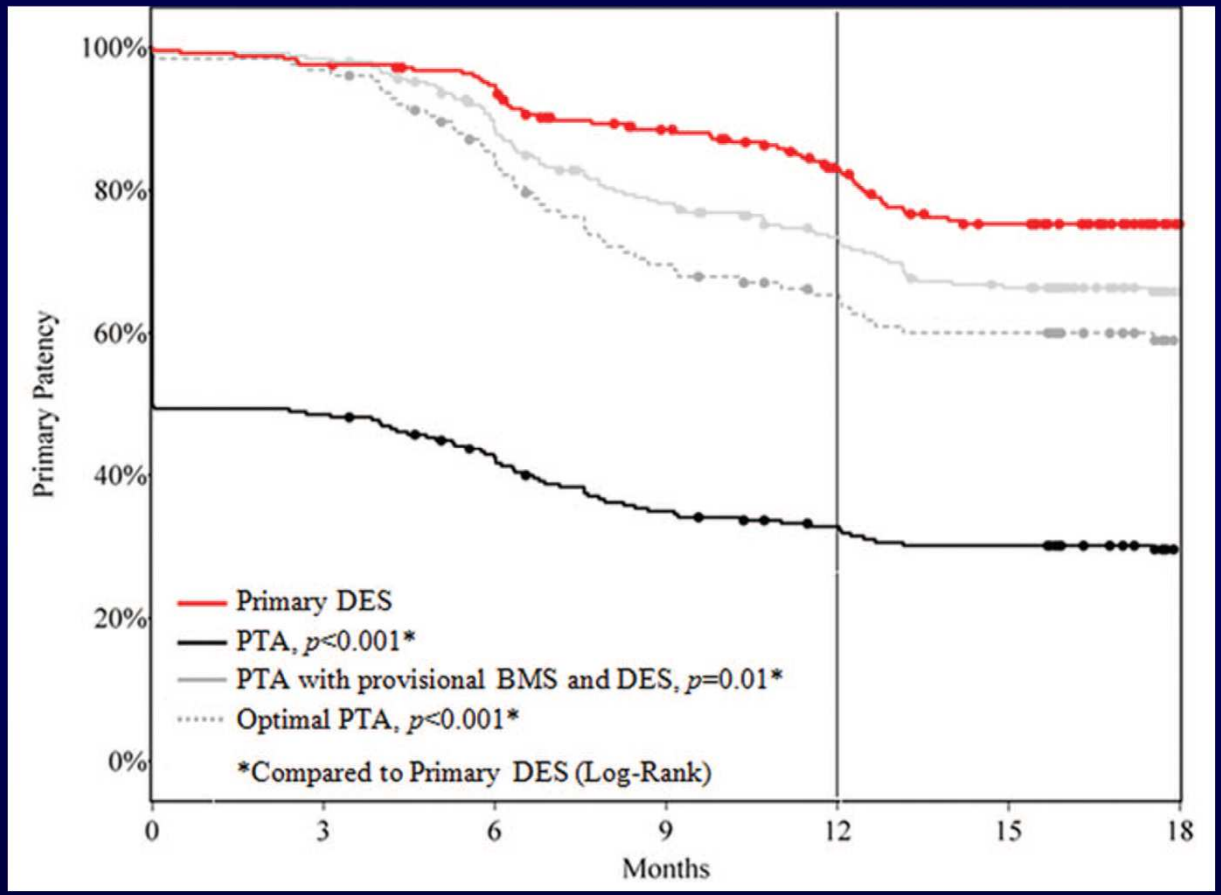
- LEVANT 2
- INPACT SFA I-II

NO LONG-TERM PRIMARY PATENCY DATA

DES-RCT's

- ZILVER-PTX

Zilver PTX-12 months



Primary patency primary DES 82.7%

Dake MD et al, Circ Cardiovasc Interv. 2011;4:495-504

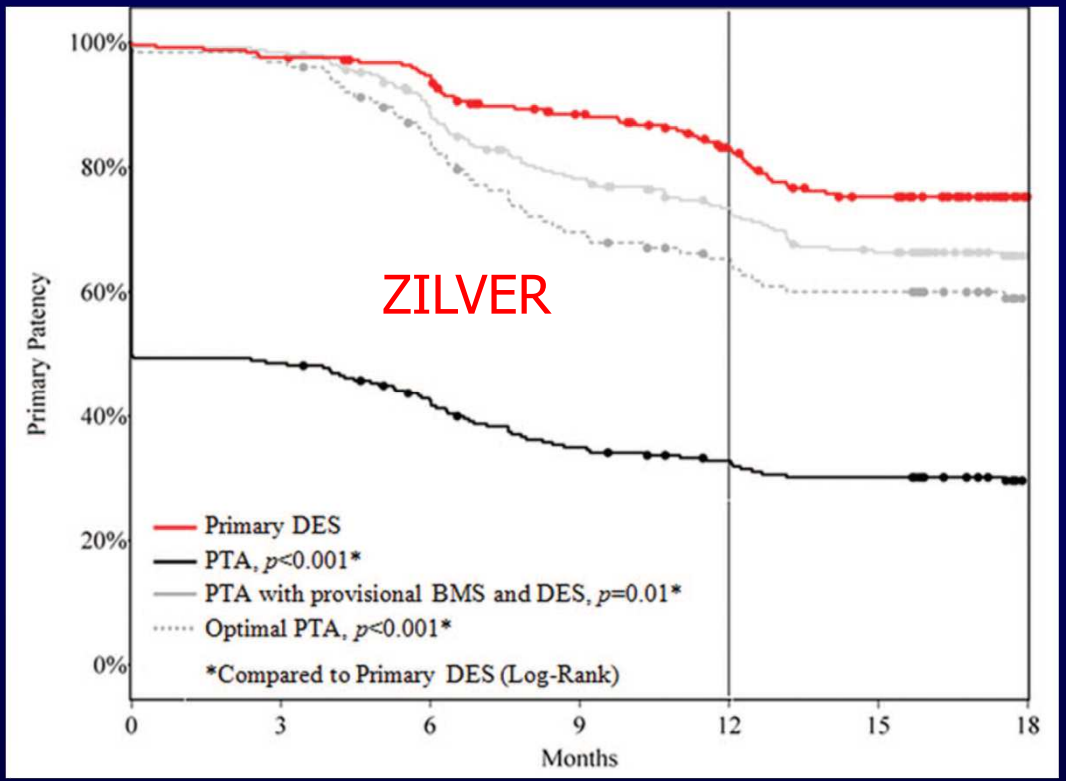
BMS vs. DES- 12 months

	ABSOLUTE	FAST	RESILIENT	Zilver PTX
Mean lesion length (mm)	101/92	45/44	71/64	53/54
Primary patency (PTA)	50%/37%	66.4%/62.2%	53.8%/36.7%	67%
Primary patency (stent)	75%/67%	76.2%/67%	84%/81.3%	82.7%
# stents used	1.7	1	1.6	1.5
Stent fractures	2%	12%	3.1%	0.9%

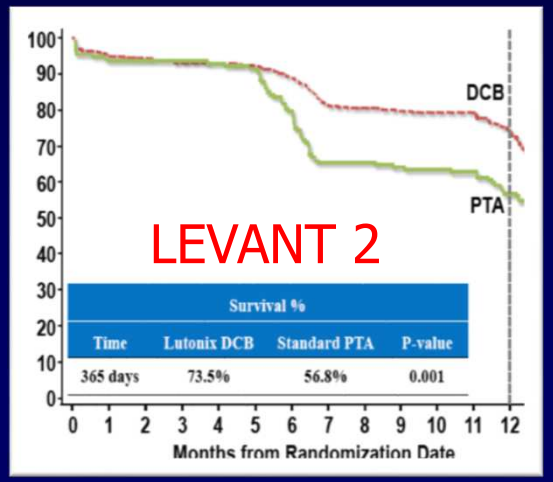
Stent/PTA
6months/12 months
Patency per protocol (except 12 month ABSOLUTE)

Schillinger M et al,NEJM 2006;354:1879-1888
Krankenberg H et al, Circulation 2007;116:285-292
Laird JR et al, Circ Cardiovasc Interv 2010;3:267-276
Dake MD et al, Circ Cardiovasc Interv. 2011;4:495-504

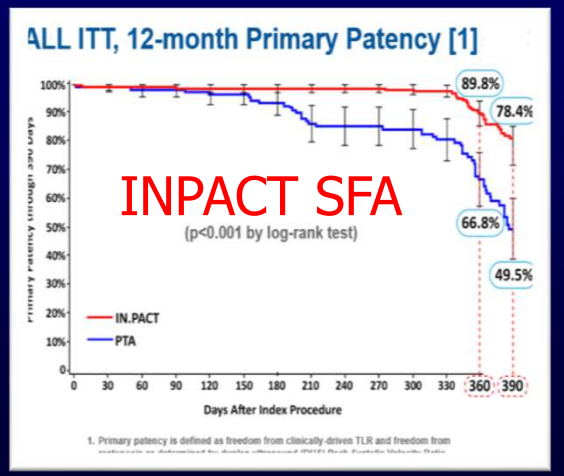
DEB vs. DES-12 months



Primary patency primary DES 82.7%

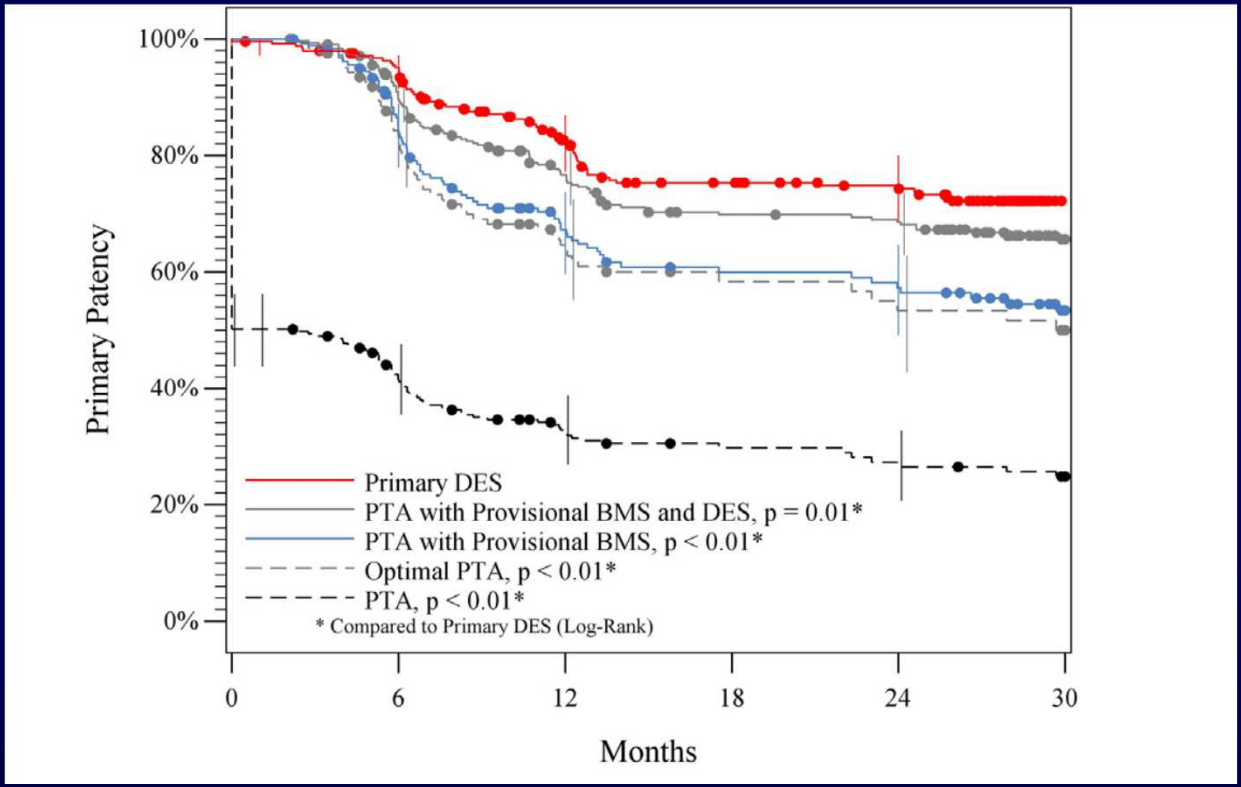


Primary patency 1 yr 73,5%



Primary patency 1 yr 89,9%

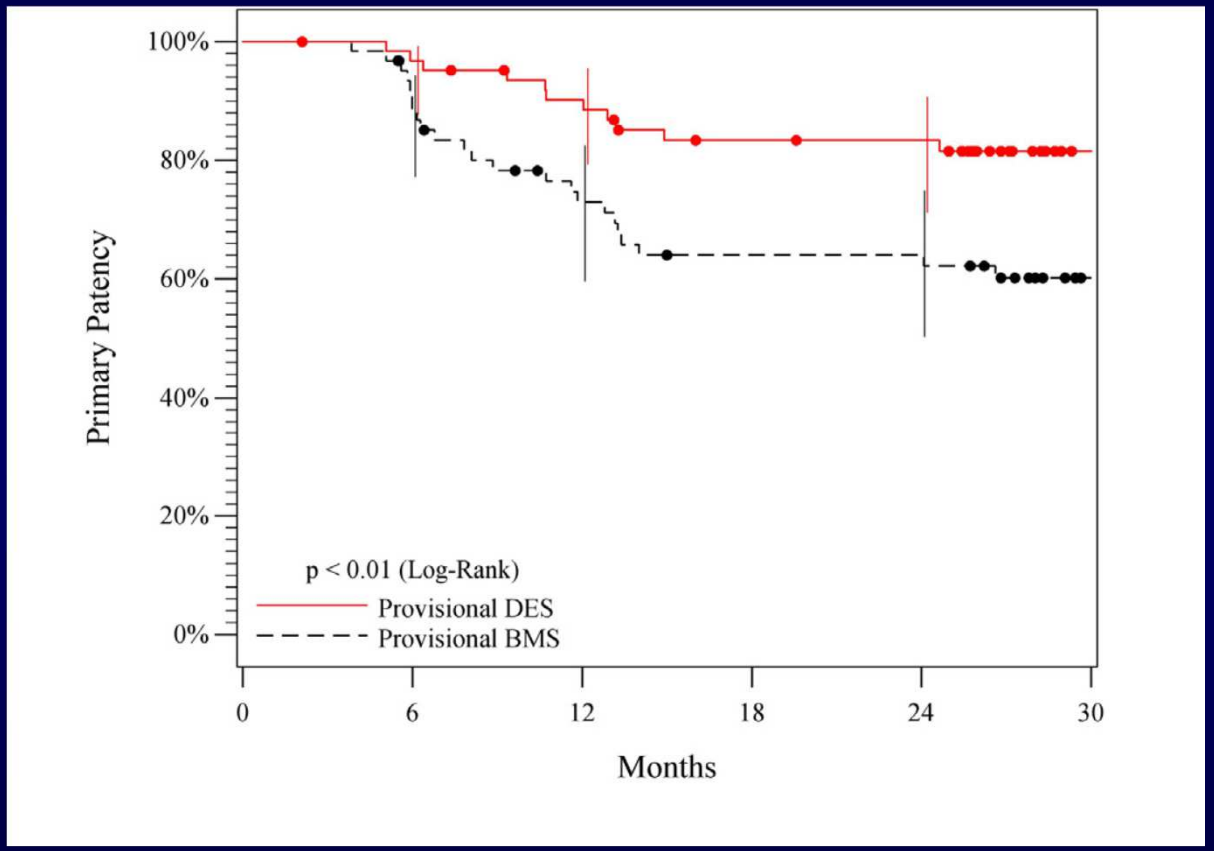
Zilver PTX-24 months



Primary patency primary DES 74.8%

Dake MD et al, JACC 2013;61:2417-2427

Zilver PTX-24 months



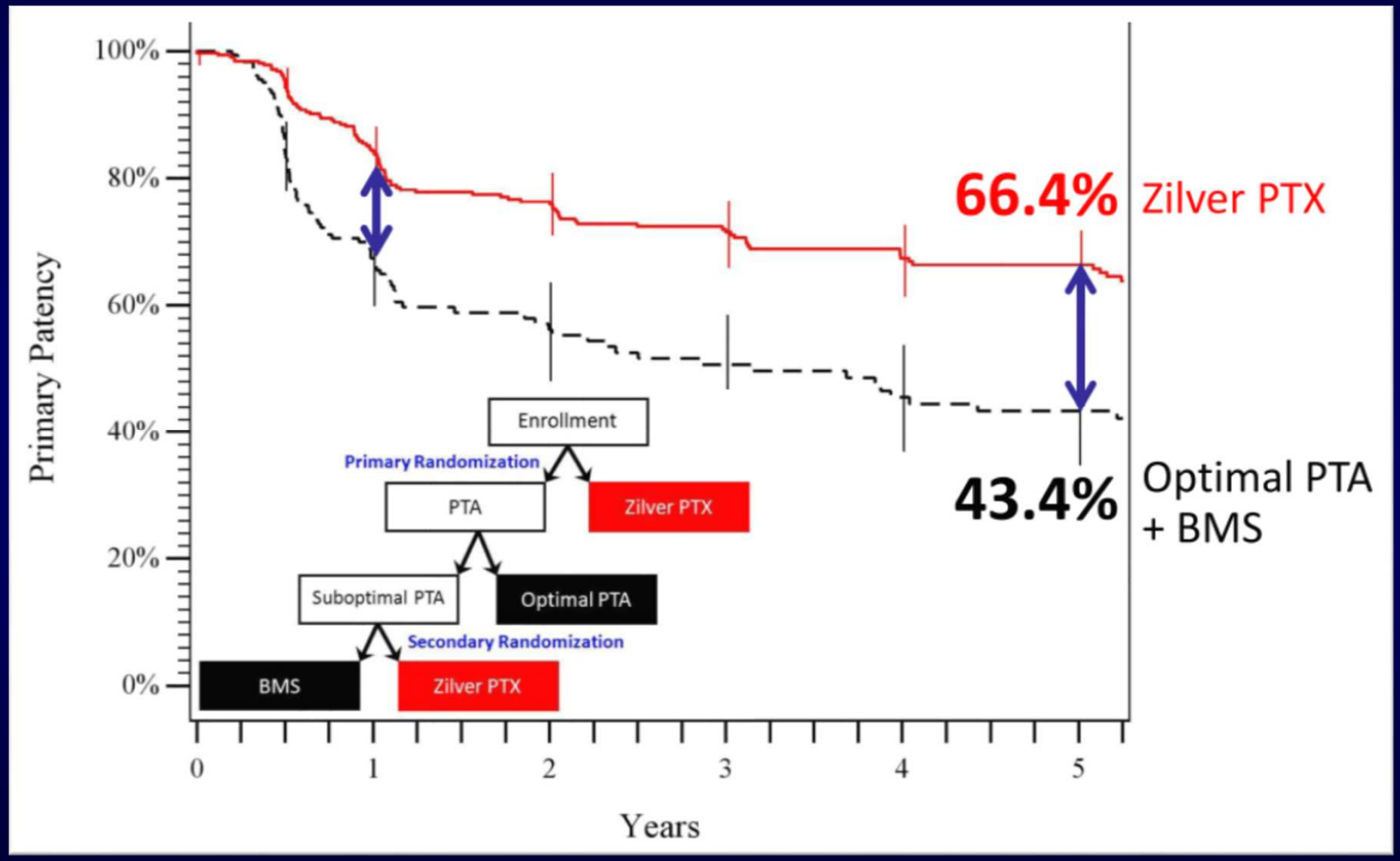
Primary patency provisional DES 83.4%

Dake MD et al, JACC 2013;61:2417-2427

BMS vs. DES vs. DEB-24 months

- Primary patency
  - Zilver PTX 83.4%
  - ABSOLUTE 50.8/54.3%
  - RESILIENT/FAST ?
  - LEVANT 2/INPACT SFA I-II ?

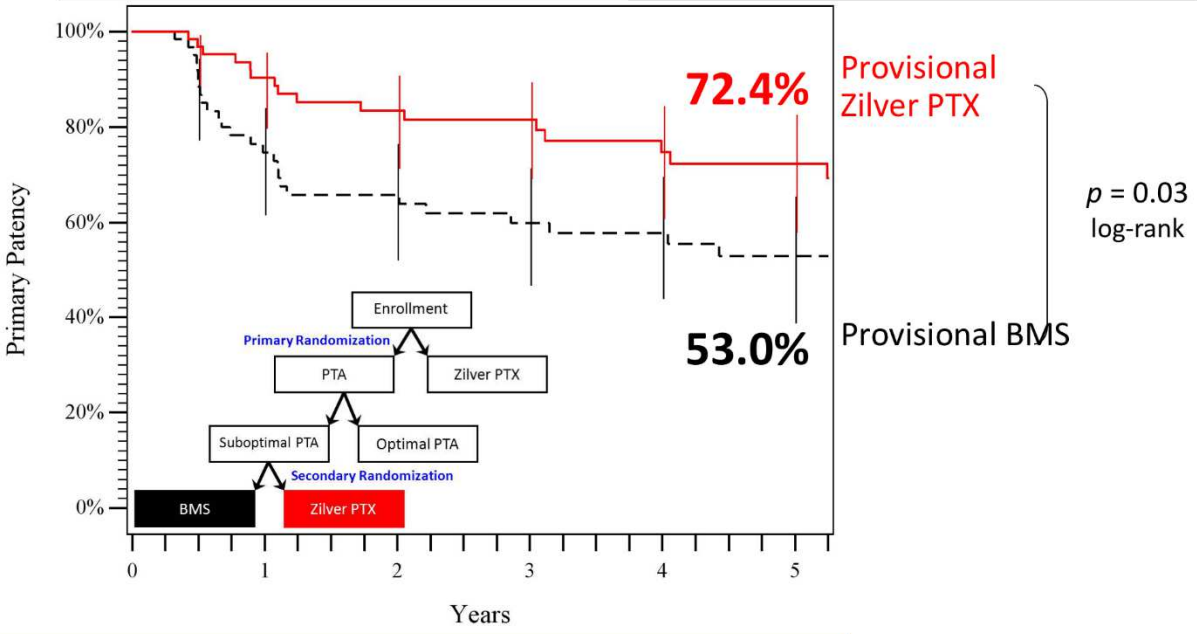
Zilver PTX-5 years



Dake MD et al, VIVA2014

Zilver PTX-5 years

5-year Primary Patency (PSVR < 2.0)
Provisional Zilver PTX vs. BMS

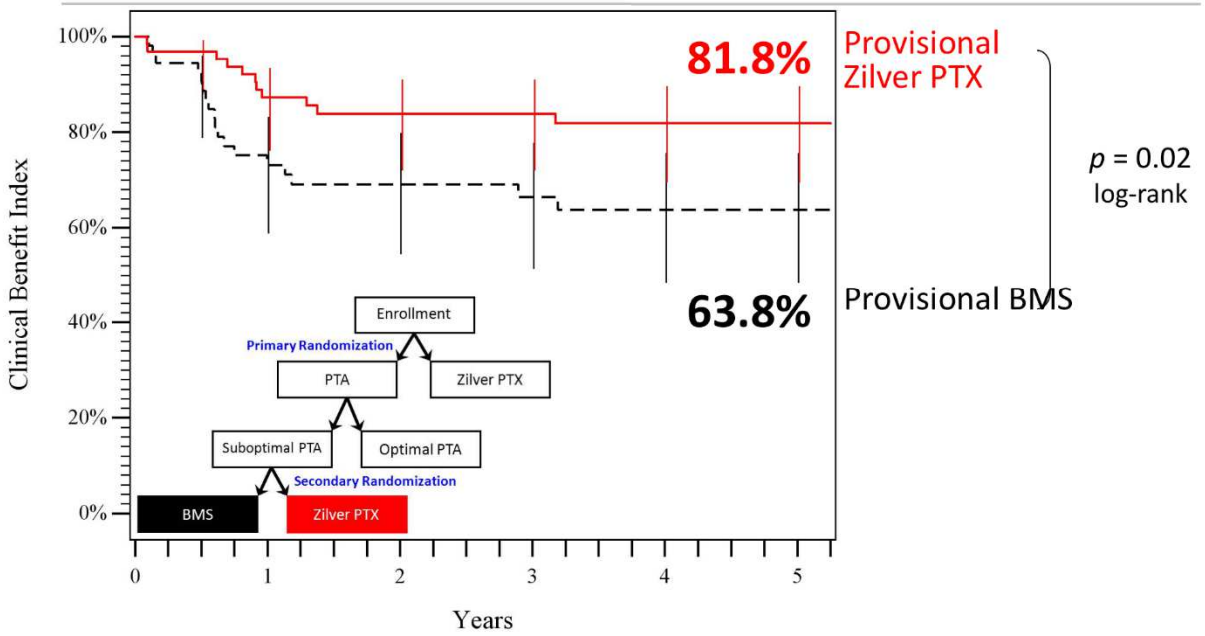


At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS

Dake MD et al, VIVA2014

Zilver PTX-5 years

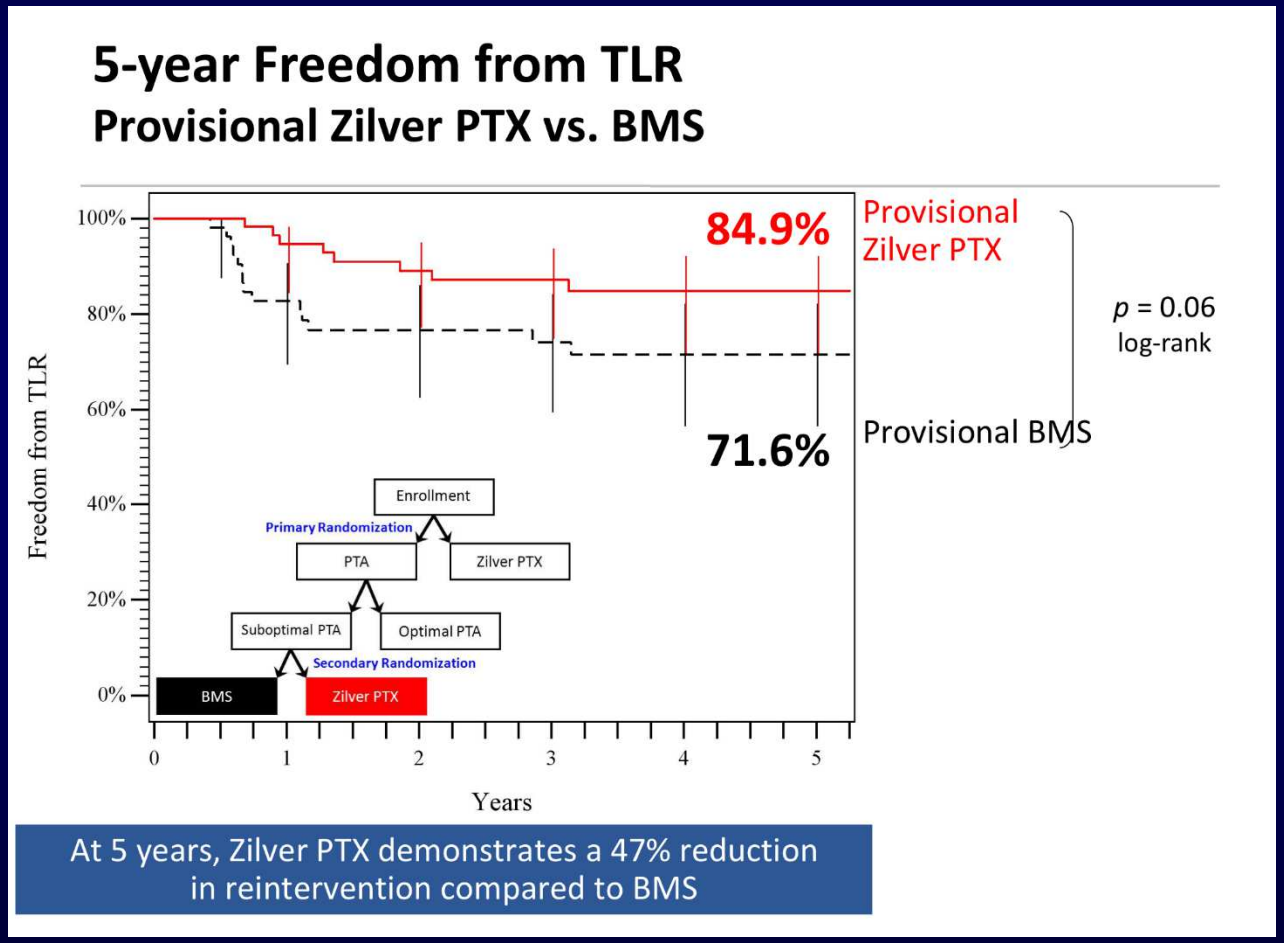
5-year Clinical Benefit Index
Provisional Zilver PTX vs. BMS



At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss

Dake MD et al, VIVA2014

Zilver PTX-5 years



Dake MD et al, VIVA2014

Zilver PTX-5 years

5-year Stent Integrity

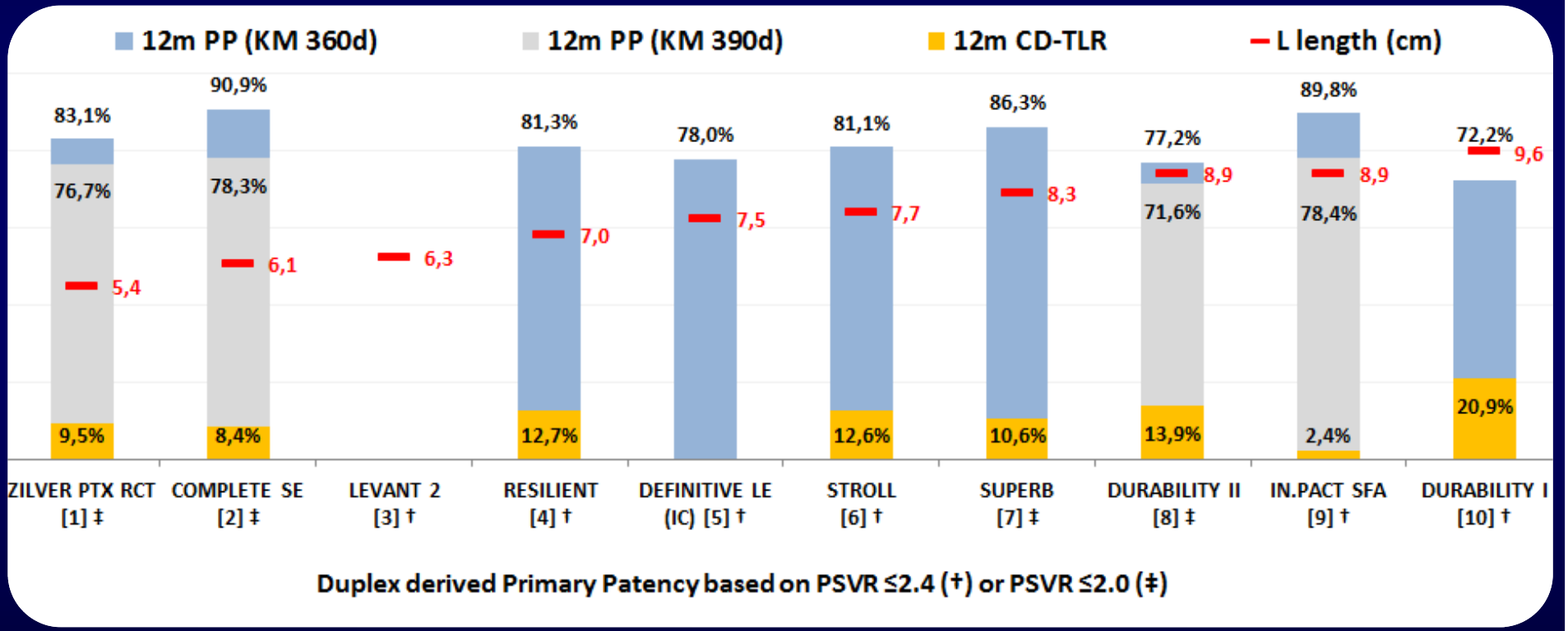
Study Period	Number of New Events	Fracture Rate[1]
Enrollment	0	0.0%
1-year	4	0.9%
3-year	3	1.9%
5-year	0	1.9%

[1] Kaplan-Meier estimates

Zilver PTX has excellent durability in challenging SFA environment

Dake MD et al, VIVA2014

DEB vs. BMS vs. DES



[1] Dake MD et al. Circ Cardiovasc Interv. 2011; [2] Scheinert D LINC 2013; [3] Rosenfield K TCT 2013; [4] Laird JR et al. Circ Cardiovasc Interv. 2010; [5] Garcia L LINC 2013; [6] Cordis SMART Control IFU 100000000922.1; [7] Scheinert D LINC 2014; [8] Matsumura JS J Vasc Surg. 2013; [9] G.Tepe Charing Cross 2014; [10] Bosiers M J Endovasc Ther. 2009

Role of PSV

	Lutonix	Control PTA	*P* Value
Primary composite safety endpoint (freedom from perioperative death and 12-month index limb amputation [above and below the ankle], index limb reintervention and index limb-related death)	83.9%	79%	0.005
12-month primary patency (Kaplan-Meier, PSVR = 2.5)	73.5%	56.8%	< 0.001
12-month primary patency (PSVR = 2.0)	53.2%	45%	0.13*
Total TLR at 12 months	12.3%	16.8%	0.208*

**No statistically significant difference.*

Conclusions

- In short term results seem to be equal, in long run differences appear

Conclusions

- In short term results seem to be equal, in long run differences appear
- If you want to avoid re-interventions and long-term benefits for your patients

Conclusions

- In short term results seem to be equal, in long run differences appear
- If you want to avoid re-interventions and long-term benefits for your patients
- The obvious choice is DES