Treatment of total SFA

Donghoon Choi MD, PhD
Severance Cardiovascular Center,
Yonsei University College of Medicine

Agenda

- Case
- Retrograde distal SFA approach
- Outback case
- DEB
- DES-Zilver
- Silverhawk in instent restenosis
- Our experience

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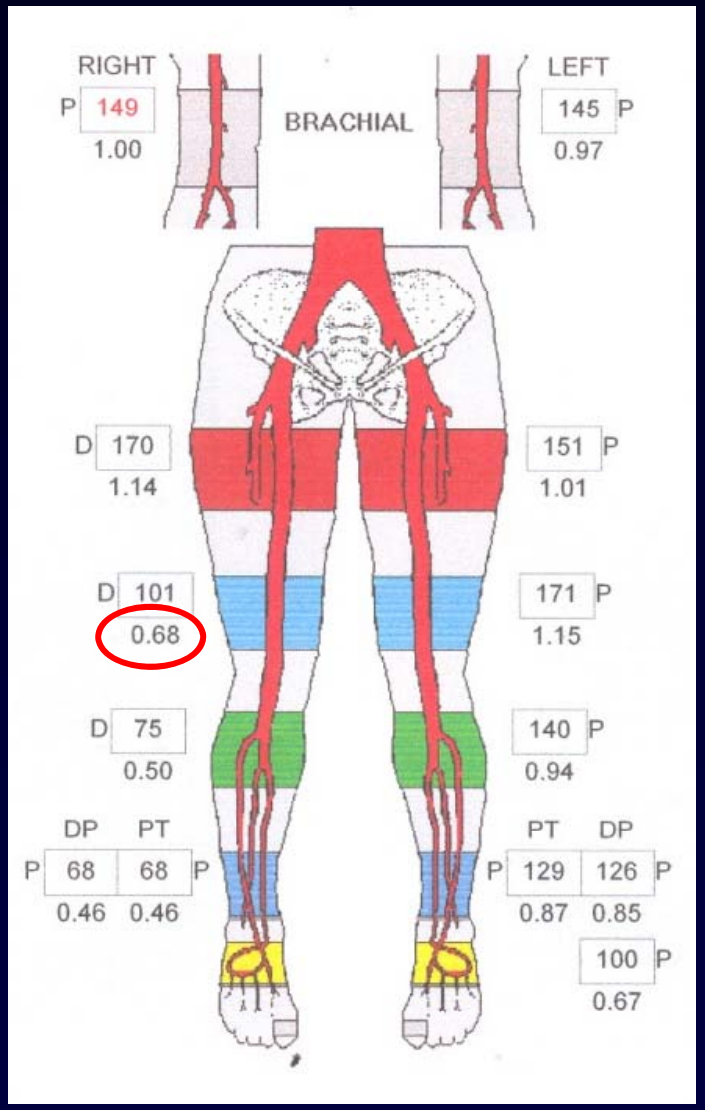
Case

Patient history

3761172 LJS

- Male / 75 year-old
- C.C: Right leg claudication
  (Fontaine classification: IIb)
- P.Hx: Hypertension, Diabetes melitus
  Old CVA (2001)
  CAD (2VD) (2007.12)
  s/p PTCA with stent insertion (RCA, LCX)

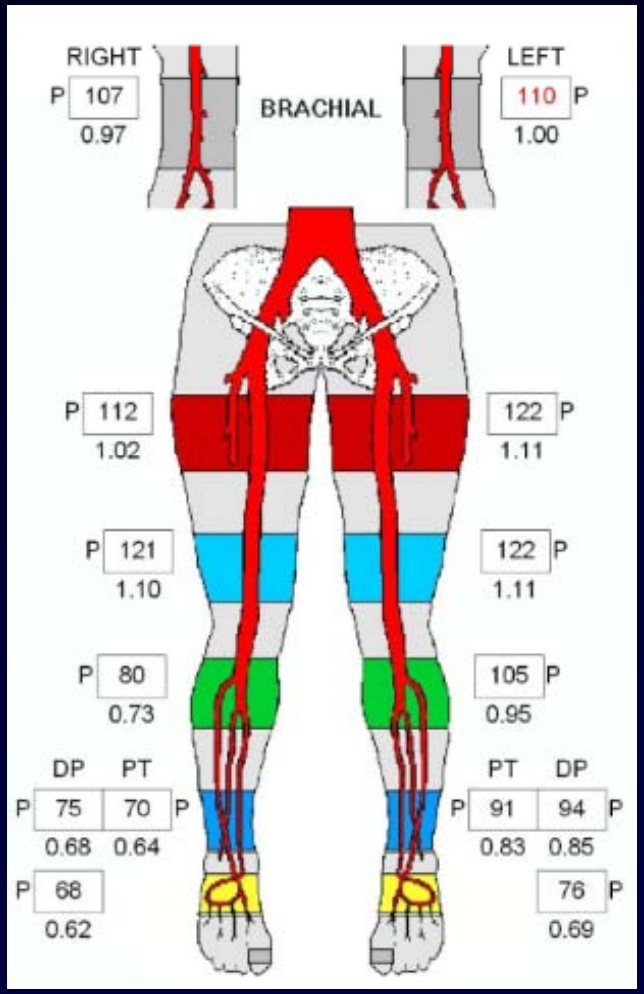
Peripheral CT (2011.5.20)



PTA

- Contralateral antegrade approach
- Balkin 7Fr sheath
- 035 hydrophilic Terumo wire
- Admiral 5 x 120 mm

PTA



•Complete SE 7 x 60 mm at pSFA

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Retrograde distal SFA approach

Patient History

- 81 year-old male
- C.C: Right leg pain (Fontaine classification III)
- Past History
  - Hypertension
  - Current smoker
  - Chronic kidney disease
  - NSTEMI, s/p PCI at RCA (2010.9)
  - Apical HCMP

Case

8Fr Balkin sheath
Balloon 6x40mm

Case

035 Terumo curved
→Subintimal approach

Case

Case

Roadmap flouroscopic imaging guided ; Micropuncture

→Distal SFA puncture

Case

5Fr sheath

035 Terumo

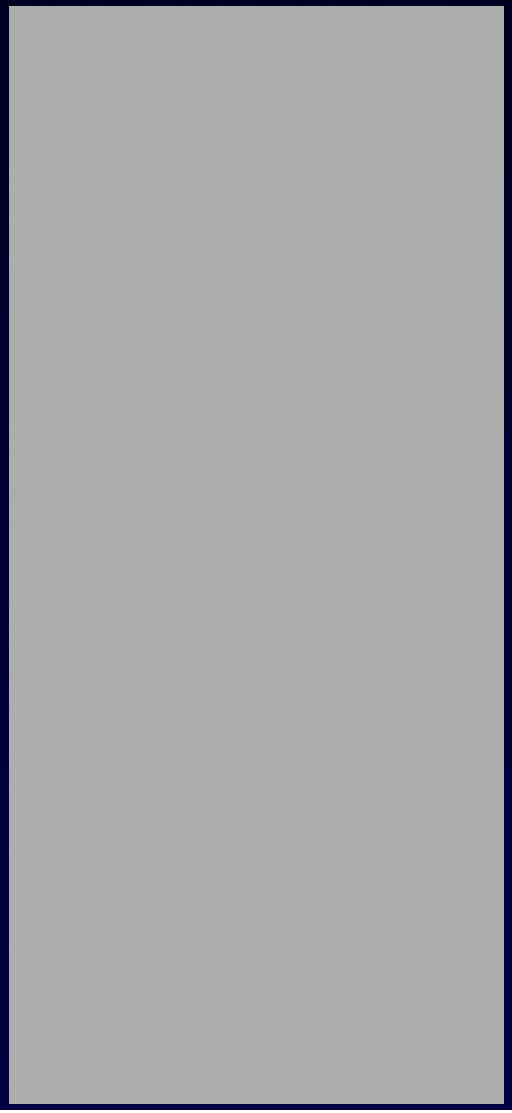
Case

Admiral 5 x 150mm

Case

Distal sheath was removed.
SMART 6 x 150mm, SMART 7 x 120mm

Case



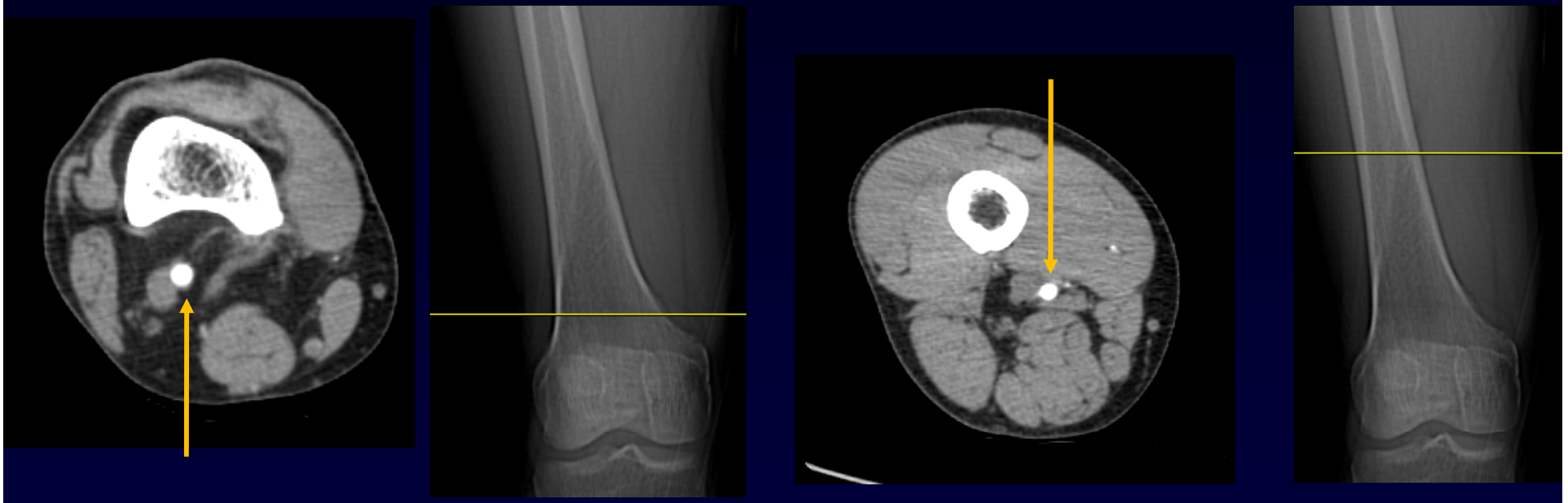
Good flow
No leakage

Why not prone position?

Popliteal Puncture with
Patient Supine

US guided puncture via postero-medial approach

Pop vs d-SFA puncture



Popliteal puncture

distal SFA puncture

Distal SFA puncture

- Benefit
  - Supine position; patient does not need any motion.
  - Able to insert stent; Not bending portion, in case of vessel injury
- Limitation
  - Hard to puncture; Roadmap flouro-guided
  - Hemostasis??, muscle damage??

Possibly useful way > dangerous attempt

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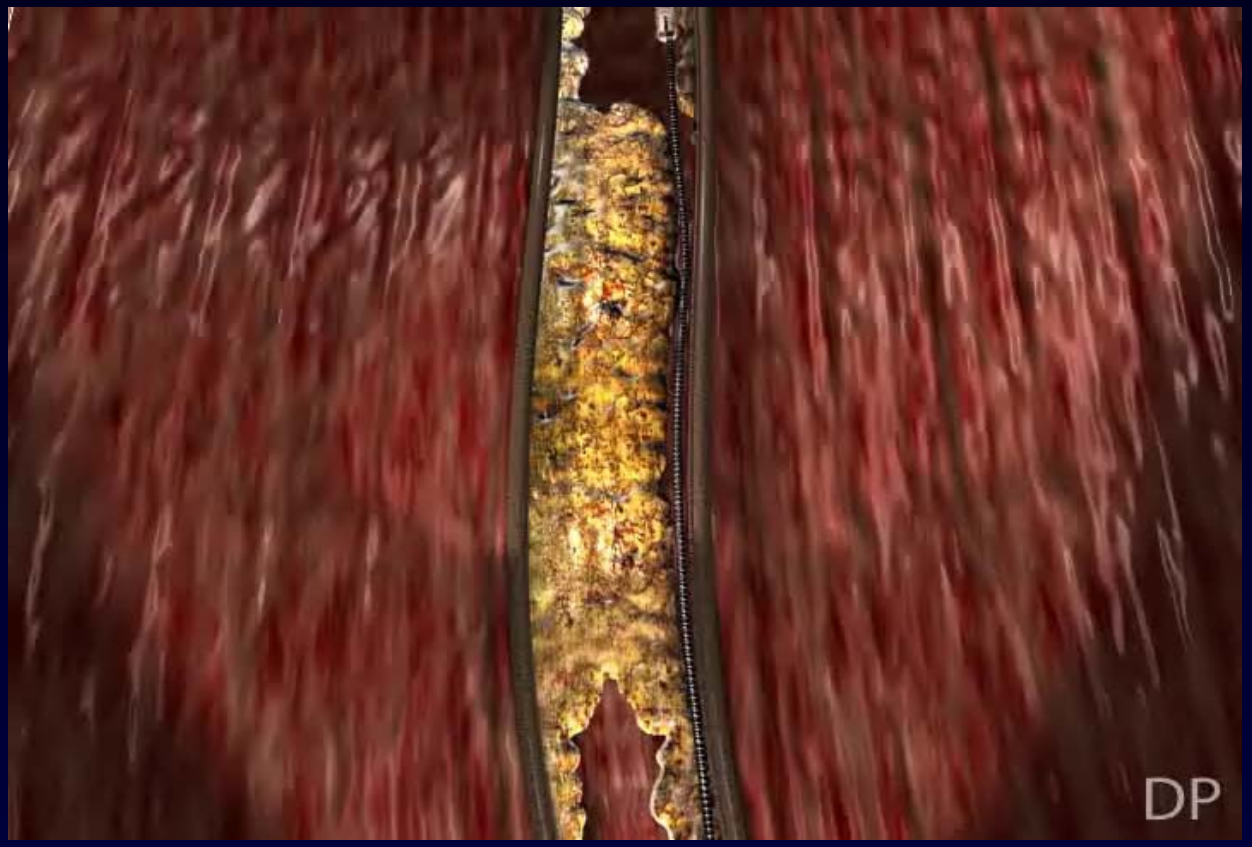
OUTBACK® LTD® Re-Entry Catheter



The OUTBACK® LTD® Re-Entry Catheter is a single lumen catheter designed to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature.

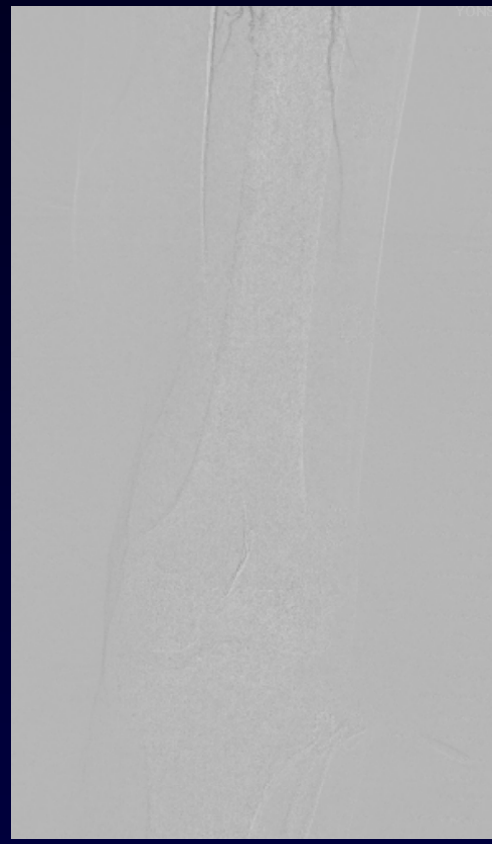
Patient history

- Male / 86 year-old
- C.C: Delayed wound healing on left lower leg
- P.Hx: Hypertension
  Atrial fibrillation
  s/p partial gastrectomy d/t bleeding

Case

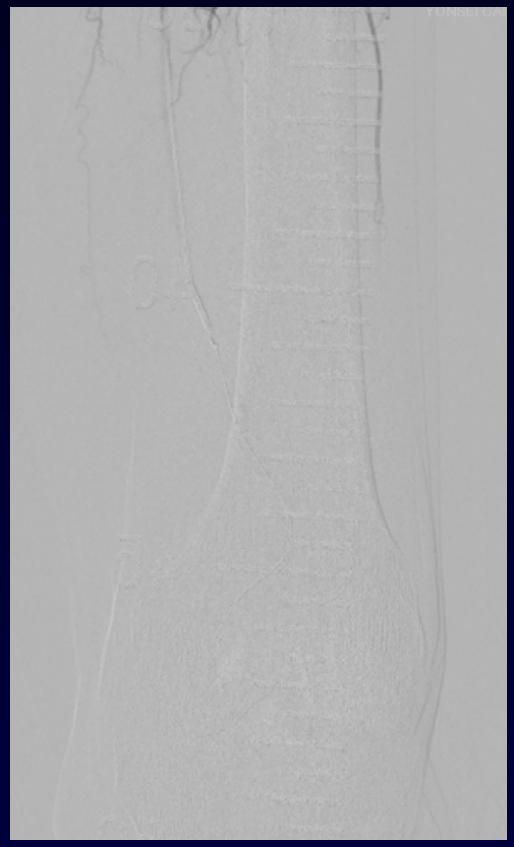
Contralateral approach

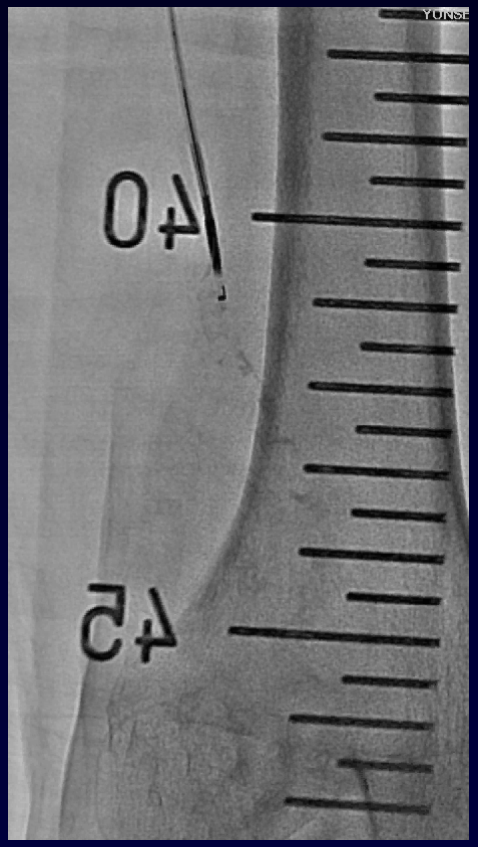
Subintimal angioplasty



Failed to find re-entry

Case



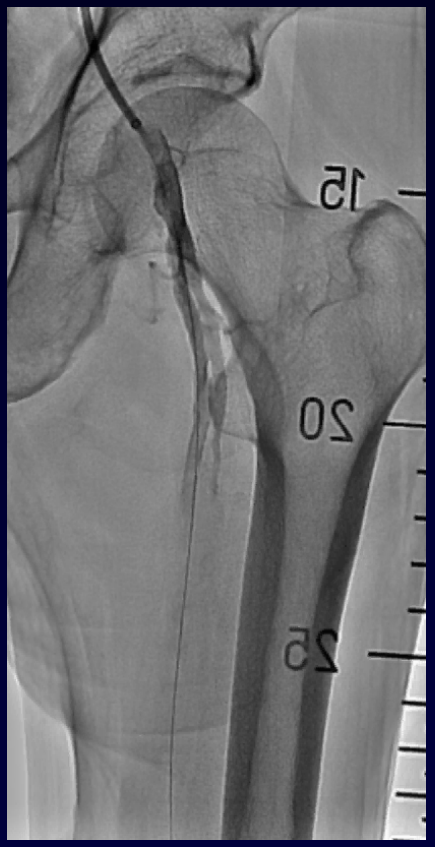


OUTBACK® LTD® Re-Entry Catheter

Admiral 6 x 150 mm

Case

SMART 6 x 80 mm



Final angiography

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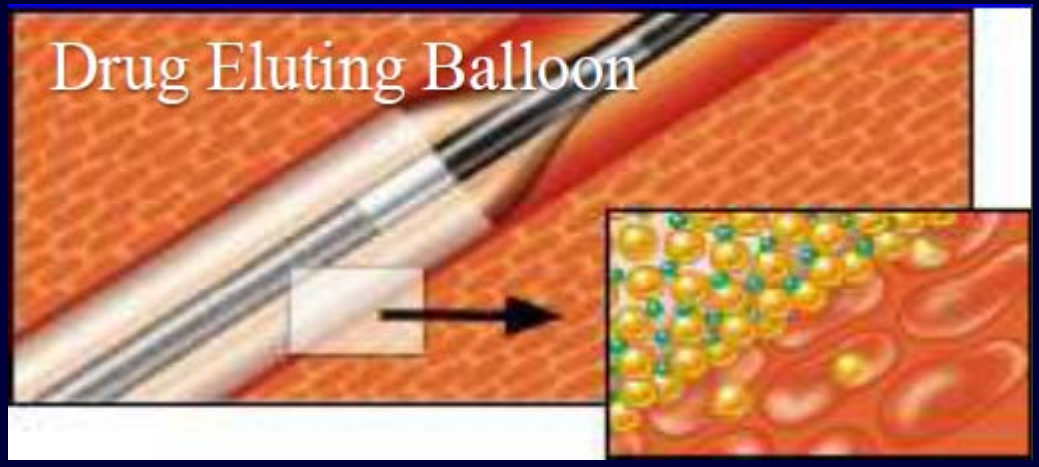
Drug coated balloon in SFA lesion



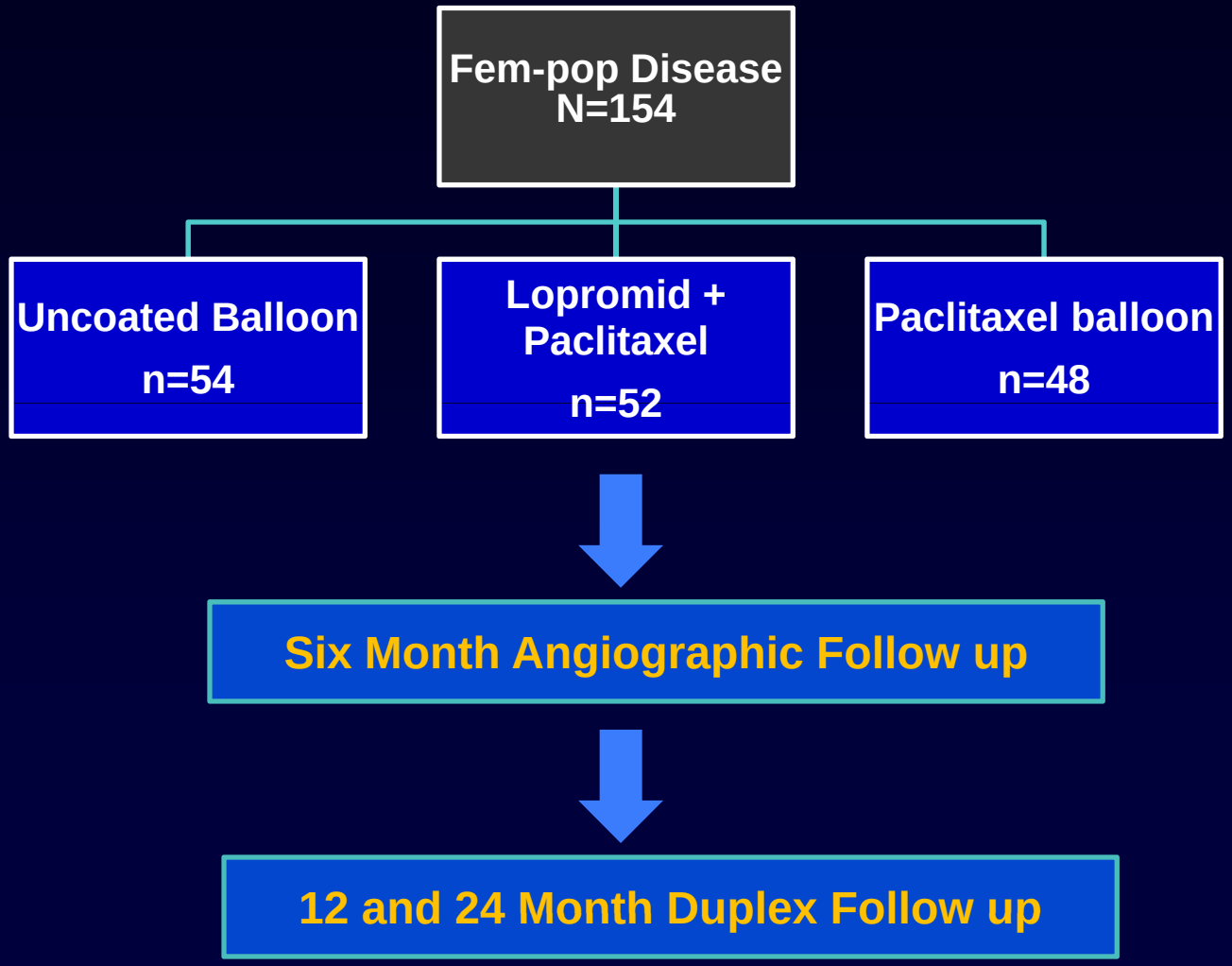
DEB clinical trial: THUNDER

- 3 arm randomized multicenter trial
  - Rutherford 1-5
  - SFA and/or popliteal lesion > 2 cm (mean 7.5cm)
    - De novo/restenotic lesions (~20%) including ISR (~15%)
  - Randomized 1:1:1
    - Conventinal balloon
    - Conventional balloon with 17.1 mg paclitaxel/100ml contrast
    - Paclitaxel coated balloon 3mg / mm
    - 1 minute inflation
  - 6 month primary endpoint: late lumen loss

N Engl J Med 2008;358:689-99

THUNDER Trial

: DEB clinical trial



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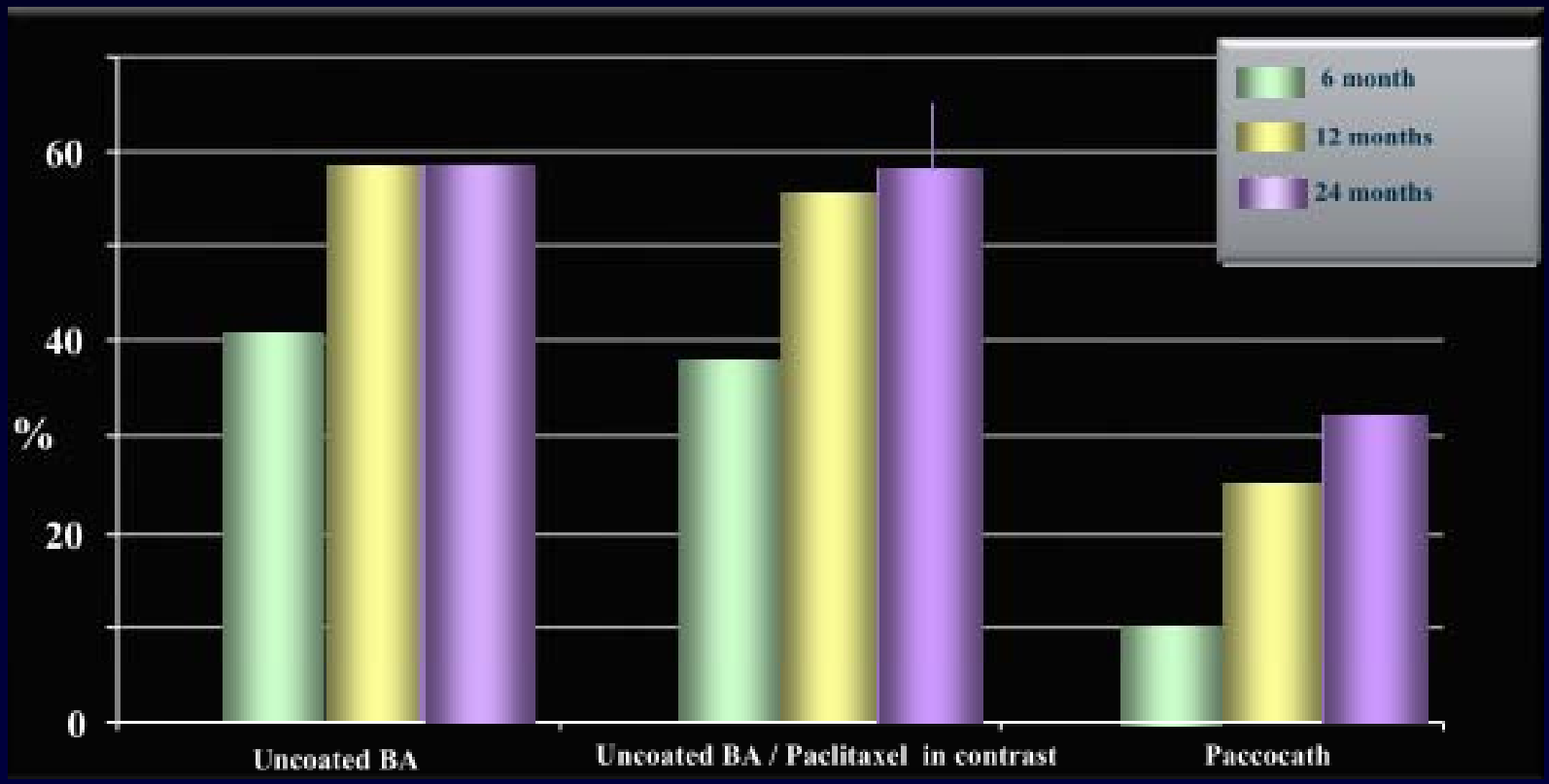
THUNDER Trial

: DEB clinical trial

Long-term Follow up



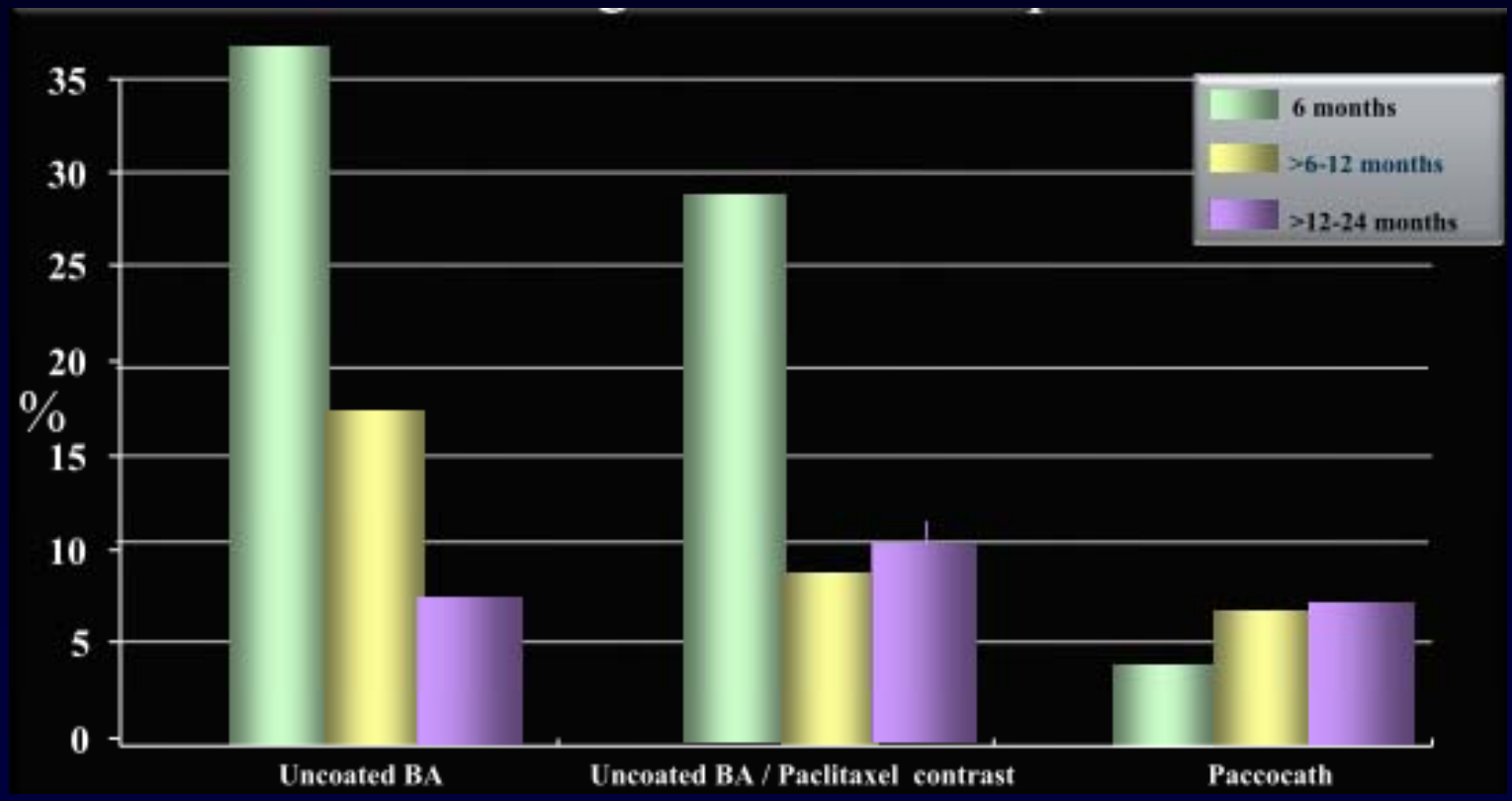
Binary restenosis rate

N Engl J Med 2008;358:689-99

THUNDER Trial

: DEB clinical trial

Long-term Follow up



TLR, amputation or death

FemPac trial

: Drug coated balloon in FP lesion

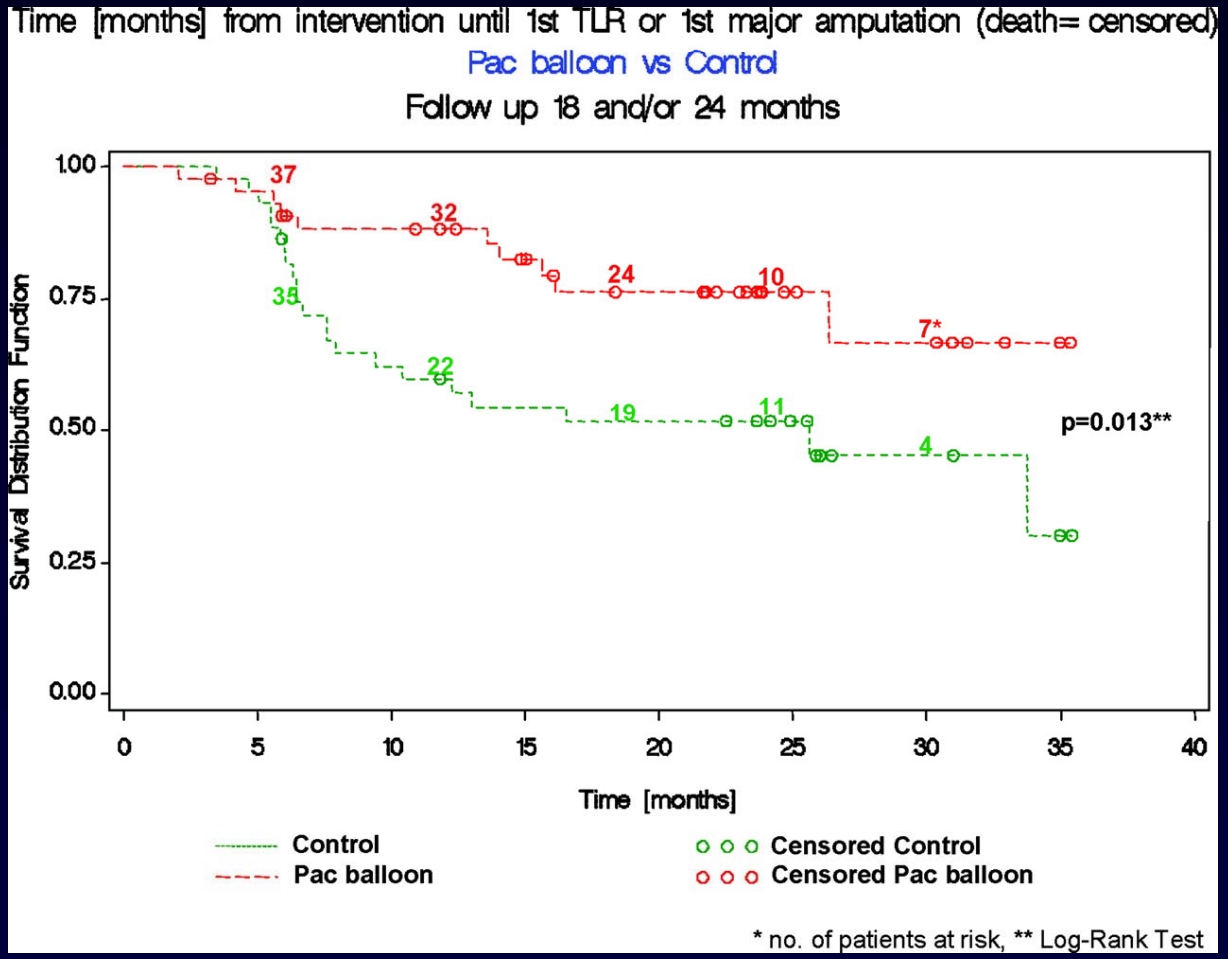
Preinterventional Angiographic findings	Uncoated Balloon Group	Paclitaxel-Coated Balloon Group	p-value
Reference diameter(mm)	5.0/4.7-5.6(41)	5.2/4.9-6.2(43)	0.23
Total occlusion, n(%)	8/42(19)	6/45(13)	0.56
Degree of stenosis, %	85/80-90(42)	85/75-90(45)	0.55

Values are median/25th-75th percentile(n)
or number of patients/total number of patients

Werk, M. et al. *Circulation* 2008;118:1358-1365

FemPac trial

Survival distribution function up to 24 months



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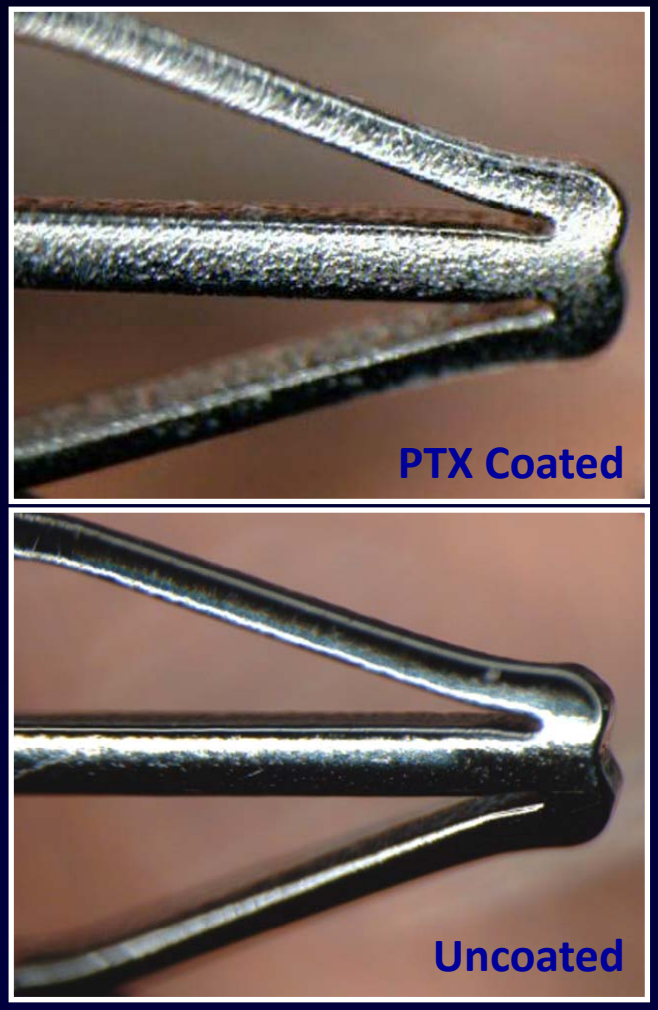
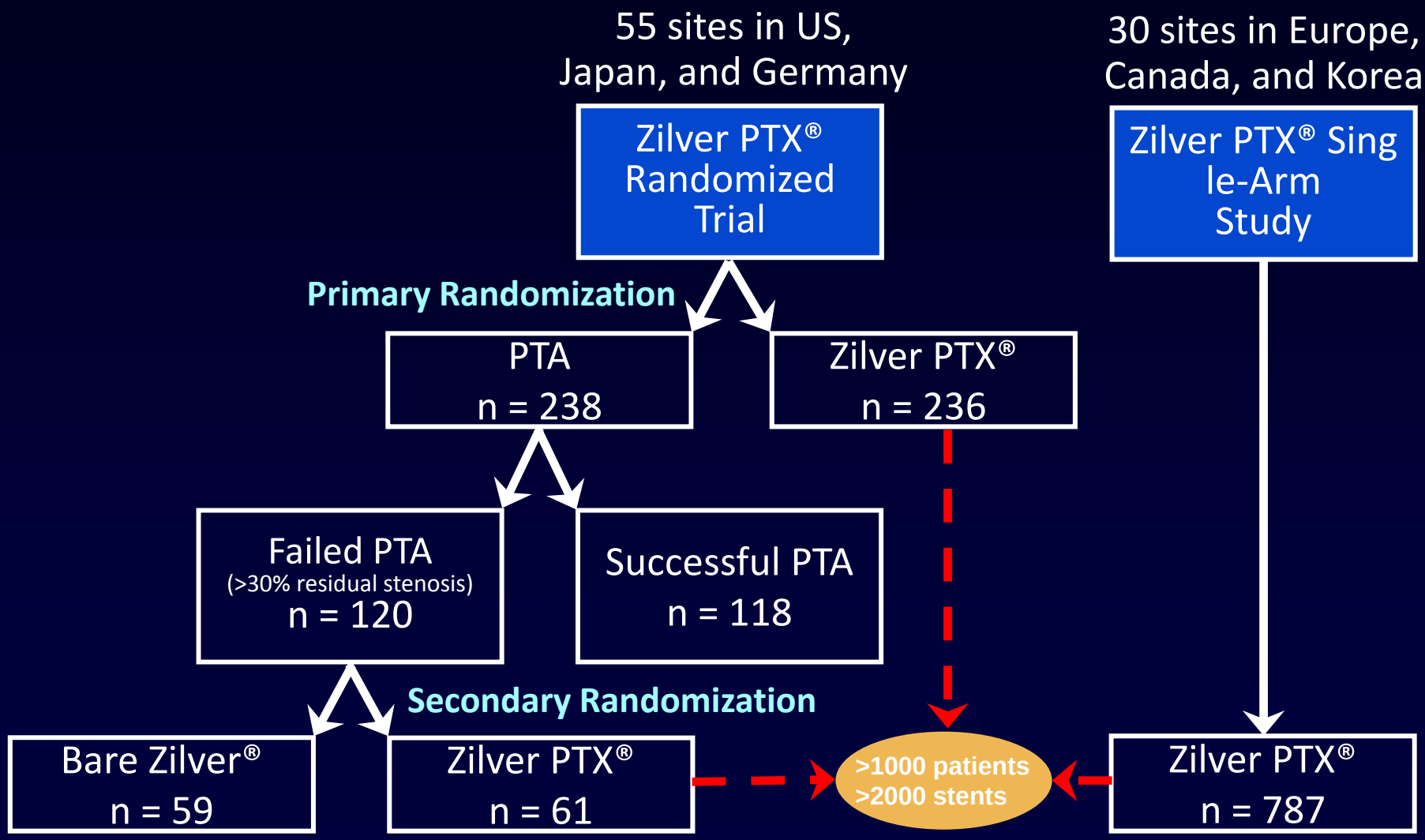
- Parade Study

Zilver® PTX® Drug-Eluting Stent

- Designed for the SFA
- CE Marked
  - Investigational in the US and Japan
- Dual therapy stent
  - **Mechanical support:** Zilver® Flex™ Stent Platform
  - **Drug coating:** Paclitaxel only
    - No polymer or binder
    - 3 µg/mm^2 dose density
- Sponsor: Cook Medical



Complementary Zilver PTX® Clinical Studies



Zilver PTX® Randomized Trial

- **Prospective, multinational trial**
  - Protocol approved by FDA, PMDA and German regulatory authorities
- **CEC and DSMB** oversight, and imaging **Core Lab** analyses
- **Key inclusion/exclusion criteria**
  - Rutherford classification ≥ 2
  - Reference vessel diameter 4-9 mm
  - Lesion length ≤ 14 cm
  - *De novo* or restenotic lesions (no in-stent restenosis)
  - > 50% diameter stenosis
  - One lesion per limb (bilateral treatment allowed)

Zilver PTX® Randomized Trial

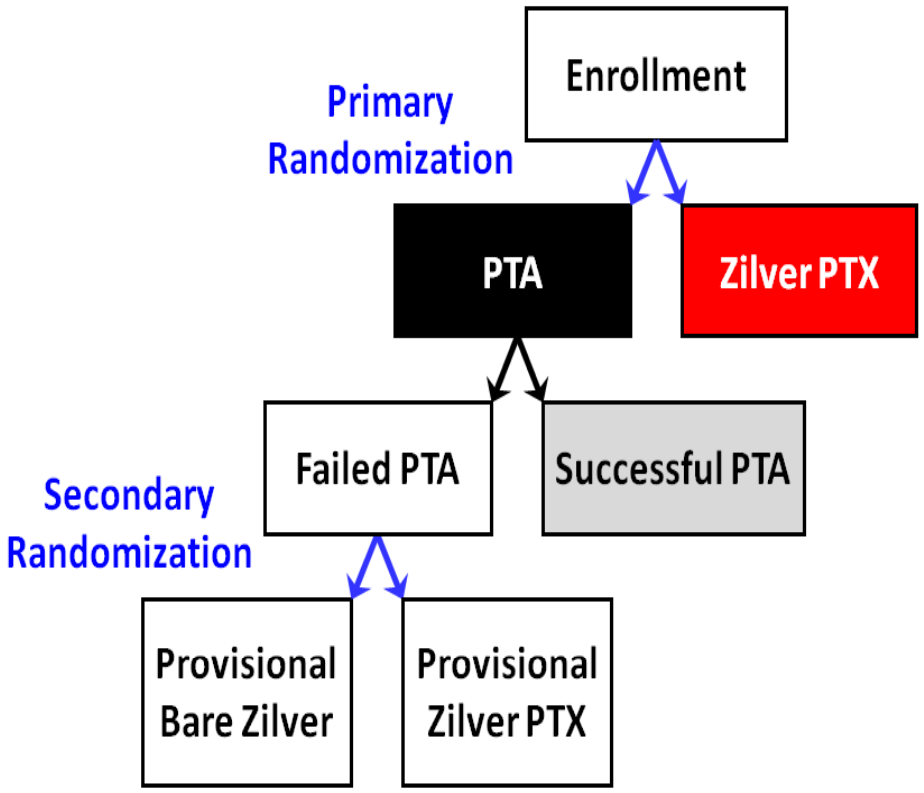
- **12-month event-free survival –** Primary safety endpoint
  - Per patient freedom from death, amputation, target lesion revascularization, or worsening Rutherford score (by 2 classes or to class 5 or 6)
- **12-month primary patency –** Primary effectiveness endpoint
  - Per lesion patency by duplex ultrasonography, patent = PSVR < 2.0 (or angiography if available, patent = diameter stenosis < 50%)
  - One lesion per limb, bilateral treatment allowed
- **5 year** ongoing follow-up
  - 2, 3, 4, and 5 year patency evaluations for all stent patients and a randomly selected subset of patients with acutely successful PTA
  - 3 and 5 year stent radiographs

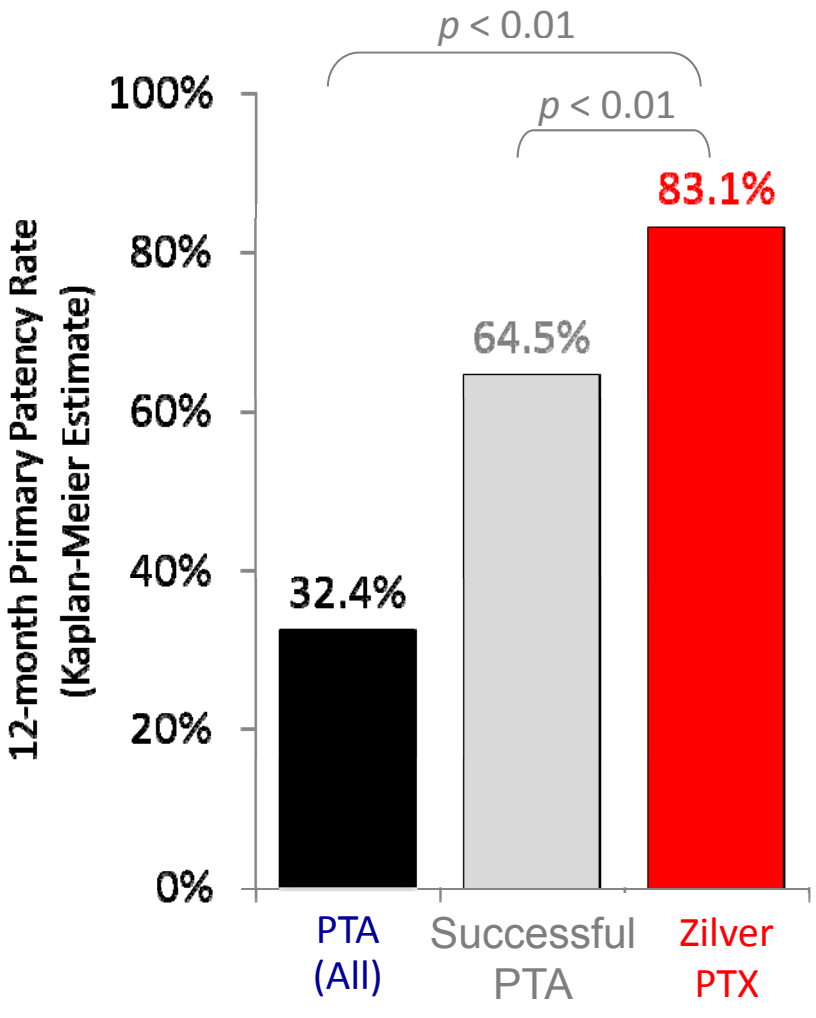
Patient Demographics and Comorbidities

	PTA	Zilver PTX®	*P*-value
Patients	238	236	
Age (years)	68 ± 11	68 ± 10	0.88
Male	64%	66%	0.70
Height (in)	66 ± 4	67 ± 4	0.55
Weight (lbs)	179 ± 44	180 ± 40	0.62
Diabetes	42%	49%	0.13
High cholesterol	70%	76%	0.12
Hypertension	82%	89%	0.02*
Past/current smoker	84%	86%	0.70

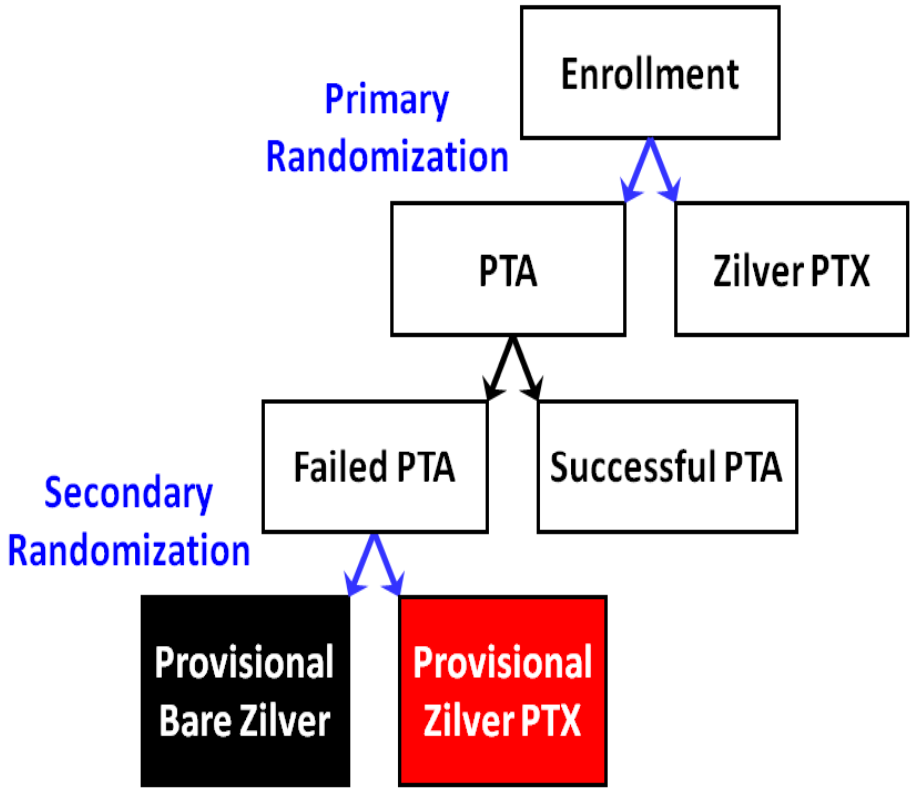
* Statistically significant

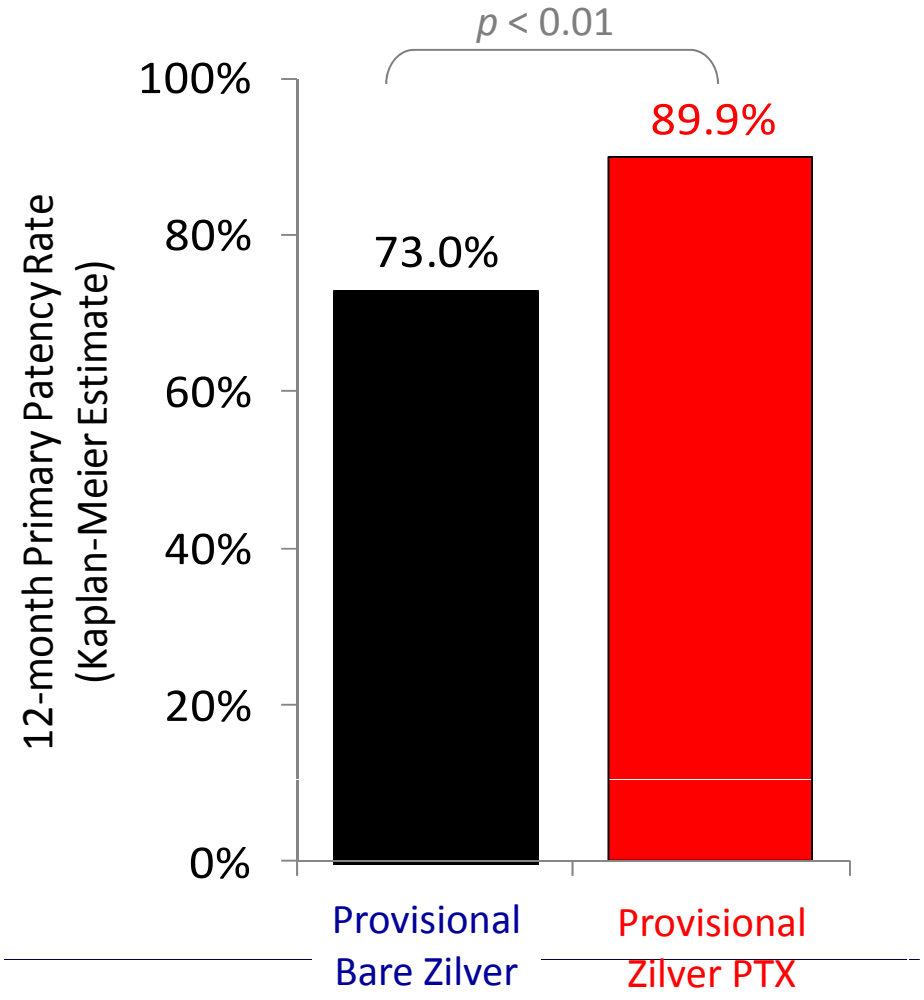
12-Month Effectiveness
Primary Patency (PSVR < 2.0): Zilver PTX vs. PTA



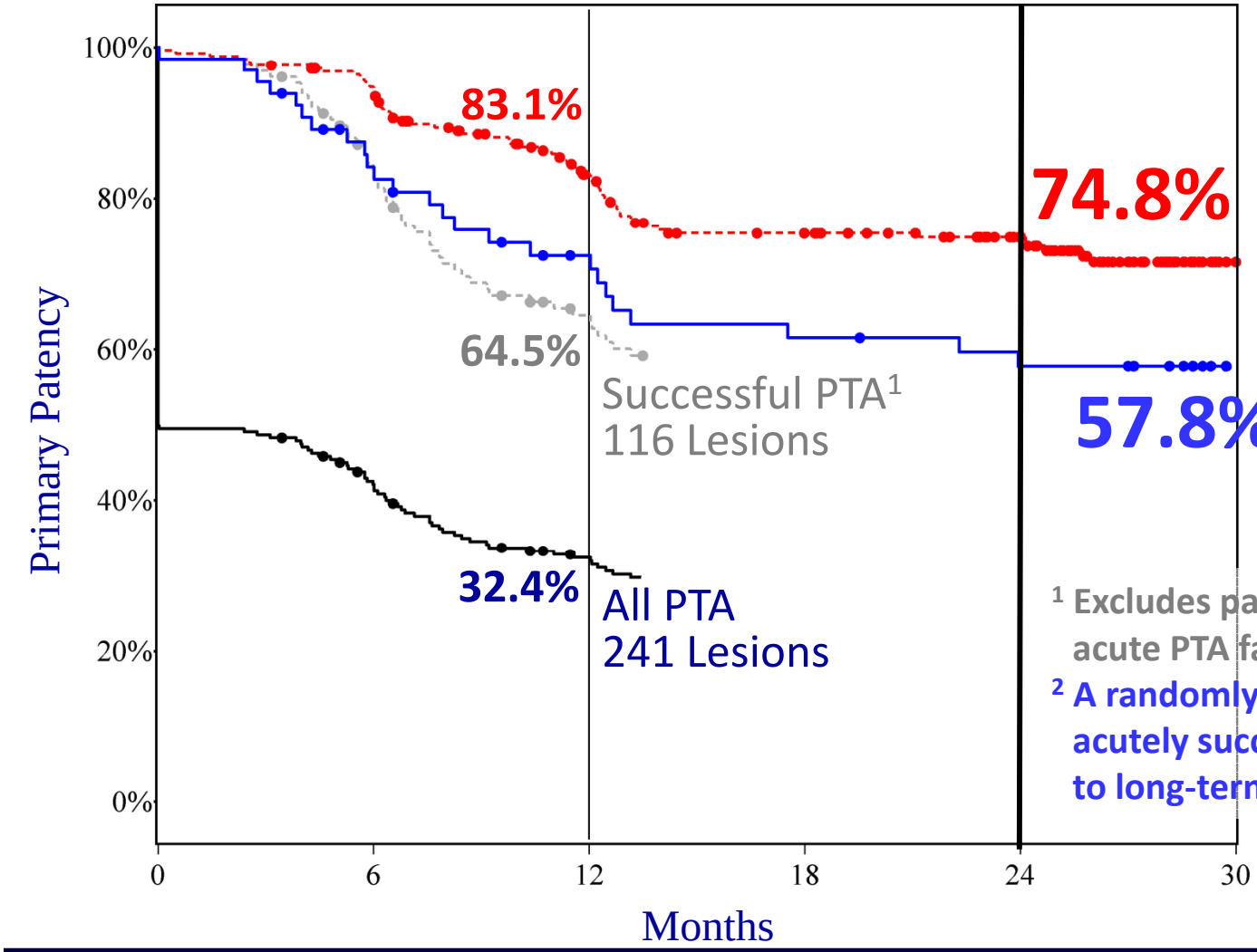


12-Month Paclitaxel Effect
Patency (PSVR < 2.0): Provisional Zilver PTX vs. BMS





24-Month Effectiveness
Primary Patency (PSVR < 2.0): Zilver PTX vs. PTA



Zilver PTX
187 Lesions

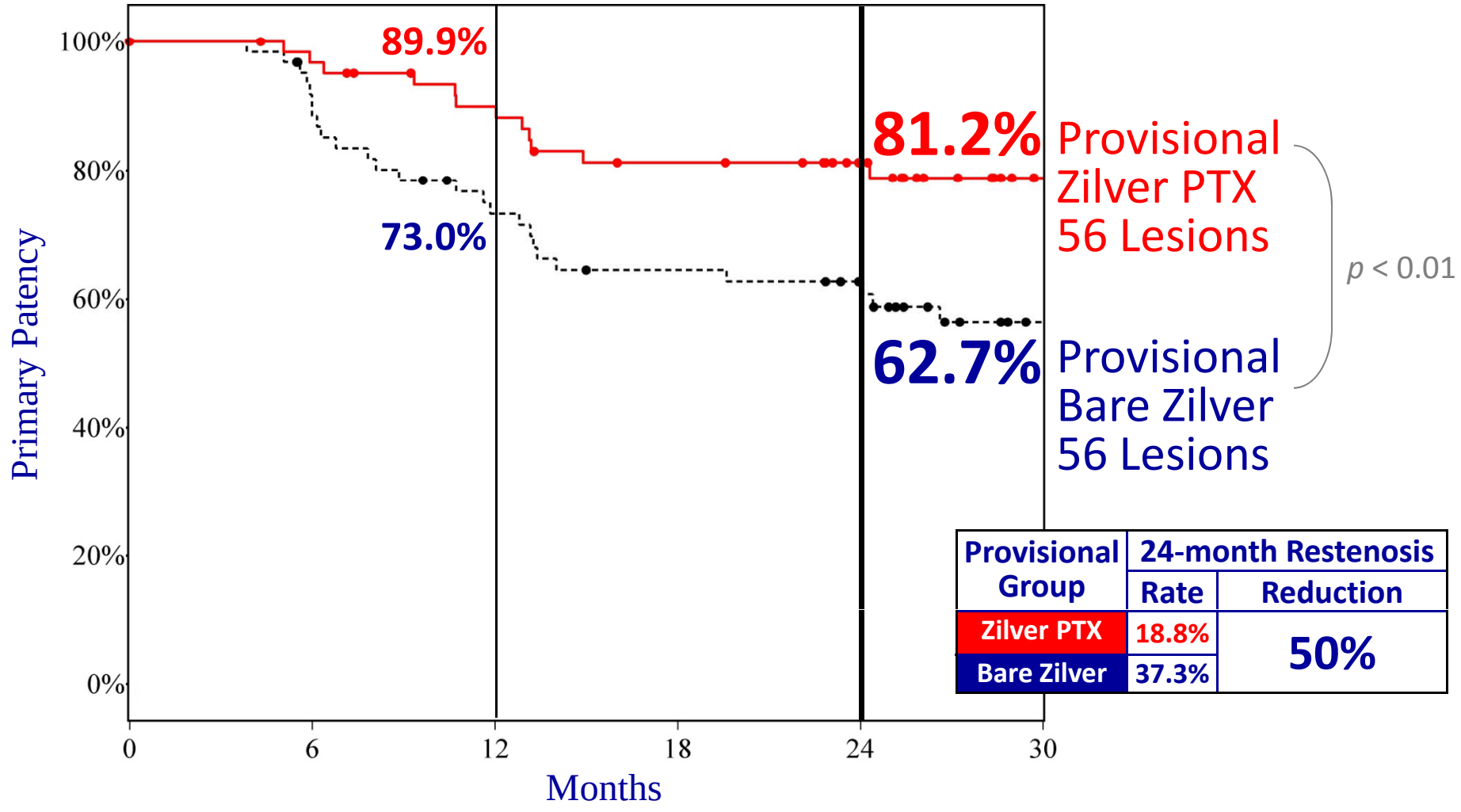
$p = 0.029$

57.8% Successful PTA long-term subset[2]
56 Lesions

[1] Excludes patients who experienced acute PTA failure

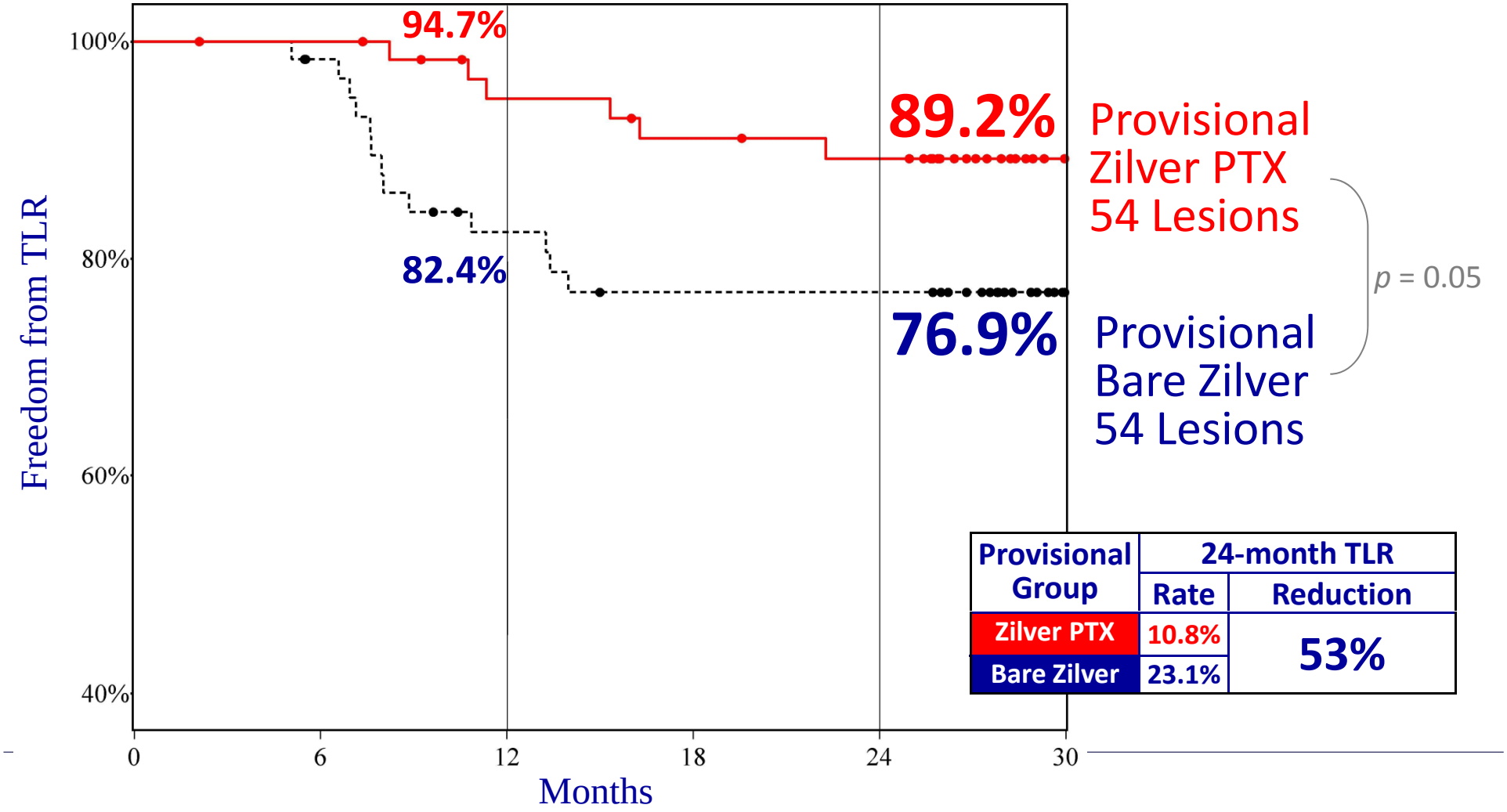
[2] A randomly selected subset of 56 acutely successful PTA patients assigned to long-term (> 12 mo) follow-up

24-Month Paclitaxel Effect
Patency (PSVR < 2.0): Provisional Zilver PTX vs. BMS



Provisional Group	24-month Restenosis	
	Rate	Reduction
Zilver PTX	18.8%	50%
Bare Zilver	37.3%	

24-Month Clinical Result from TLR: Provisional Zilver PTX vs. BMS



Provisional Group	24-month TLR	
	Rate	Reduction
Zilver PTX	10.8%	53%
Bare Zilver	23.1%	

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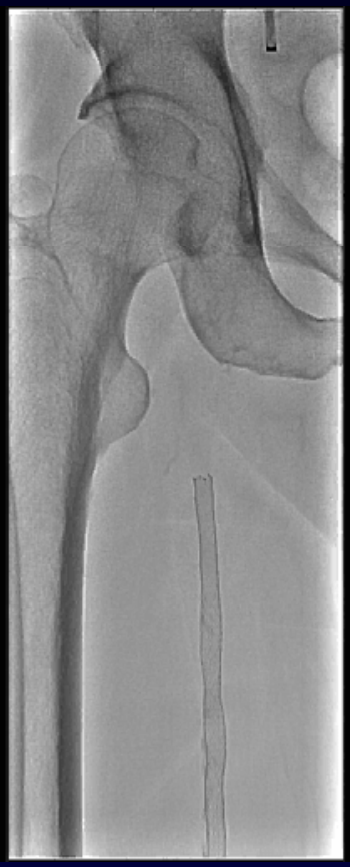
Patient history

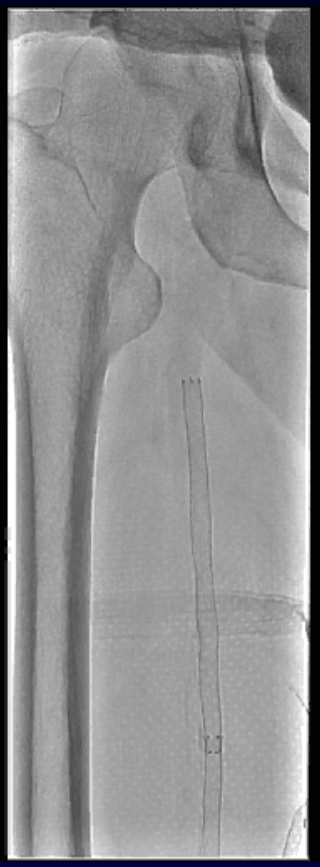
- Male / 56 year-old
- C.C: Claudication & Color change of Rt. Foot
- P.Hx: DM
  s/p PTA with stent insertion at Rt. SFA (8 months ago)

Case



Pre PTA

Silverhawk Atherectomy



Post PTA

Atheroma

Directional atherectomy using Silverhawk device

- Prospective single center study
- Rutherford 2-5
- 84 patients (100limbs), 131 lesions

- De novo lesions : 45
- Restenosis in a native artery : 43
- In-stent restenosis : 43

Zeller et al. J Am Coll Cardiol. 2006;48(8):1573-8

Atherectomy Results in SFA lesion

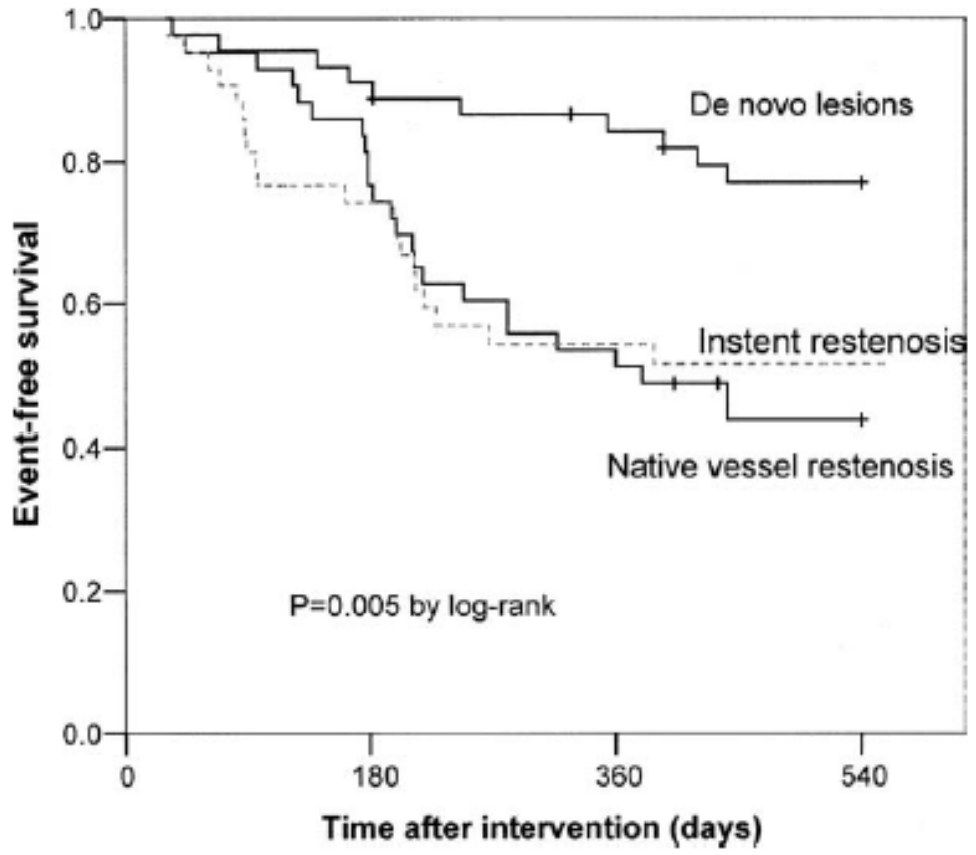


Figure 2. Kaplan-Meier event-free survival curves for survival without target vessel revascularization.

Zeller et al. J Am Coll Cardiol. 2006;48(8):1573-8

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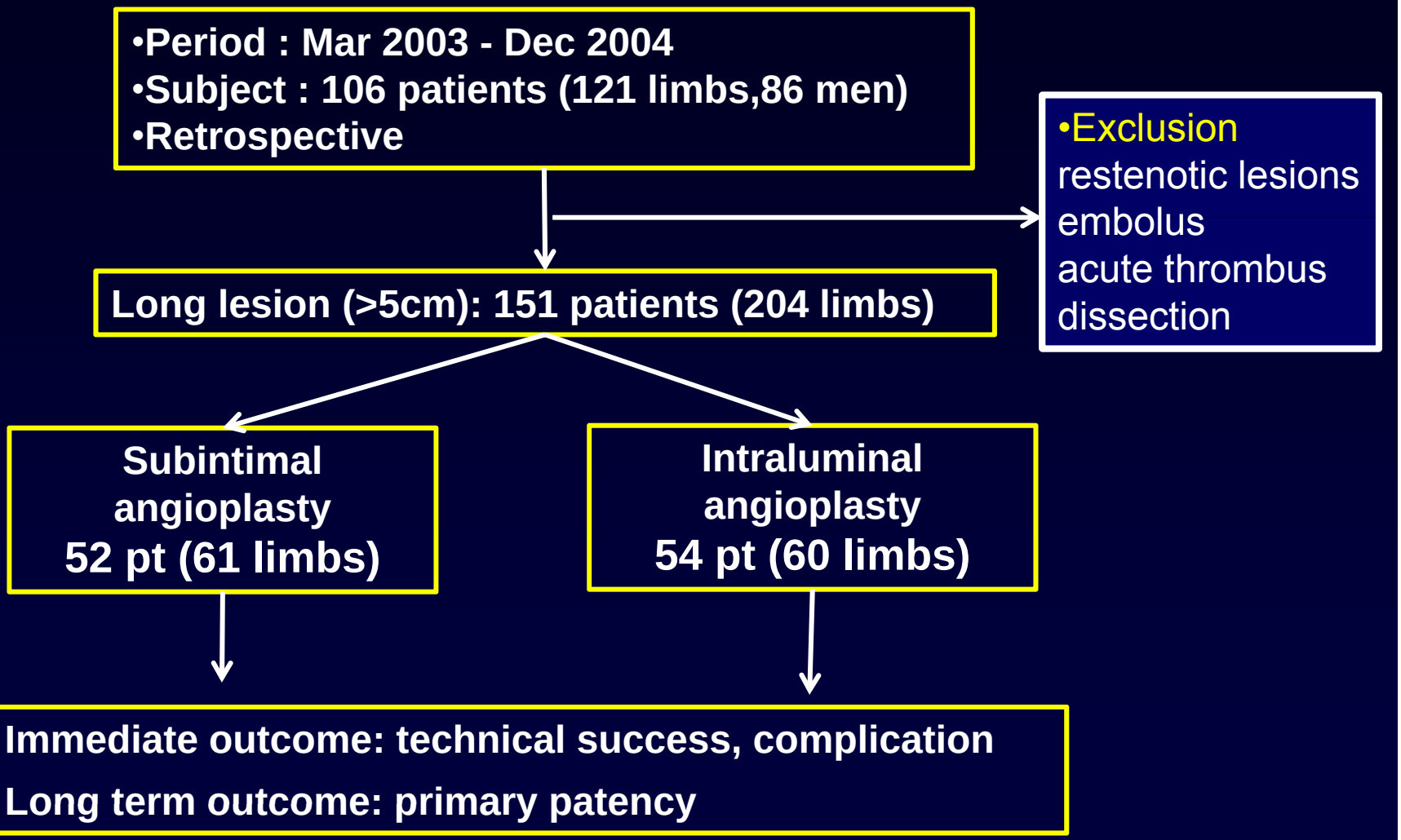
Method : Study design



Baseline characteristics

Variable	Intraluminal angioplasty	Subintimal angioplasty	P-value
Limbs	60	61	
Male	46 (85.2%)	40 (76.9%)	0.28
Age (years)	64.8 ± 8.2	65.6 ± 9.7	0.66
Diabetes mellitus	29 (60.4%)	27 (60%)	0.97
Hypertension	37 (77.1%)	31 (72.1%)	0.58
Current smoker	19 (35.2%)	20 (38.5%)	0.73
Hypercholesterolemia	17 (31.5%)	19 (36.5%)	0.58
Coronary artery disease	33 (61.1%)	33 (63.5%)	0.80
Fontaine stage			0.83
IIb	41 (68.4%)	41 (67.2%)	
III	5 (8.3%)	3 (4.9%)	
IV	14 (23.3%)	17 (27.9%)	

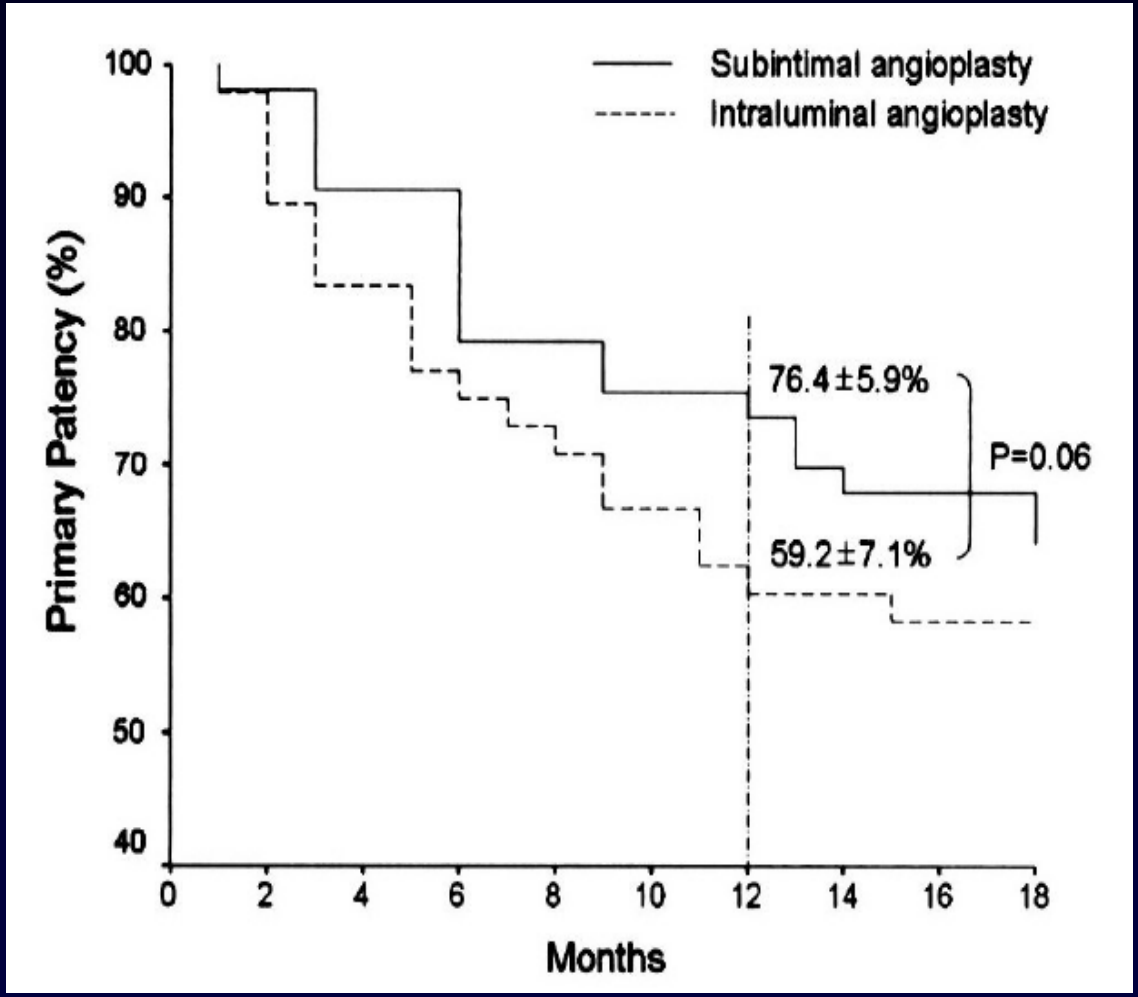
Baseline characteristics

Variable	Intraluminal angioplasty	Subintimal angioplasty	P-value
Limbs	60	61	
Occlusion length, cm	22.0 ± 8.5	22.7 ± 9.9	0.71
Additional lesions treated			
CIA	9 (15.0%)	7 (11.5%)	0.57
EIA	3 (5.0%)	8 (13.1%)	0.12
CFA	2 (3.3%)	4 (6.6%)	0.41
Tibial arteries	4 (6.7%)	8 (13.1%)	0.24
Number of runoff vessels			0.57
0	6 (10%)	8 (13.1%)	
1	17 (28.3%)	19 (31.1%)	
2	23 (38.3%)	22 (36.1%)	
3	14 (23.3%)	12 (19.7%)	
Pre-PTA ABI	0.51 ± 0.09	0.50 ± 0.14	0.79

Procedural data

Variable	Intraluminal angioplasty (n=104)	Subintimal angioplasty (n=100)	P-value
Technical success	52 (86.7%)	58 (95.1%)	0.11
Major complications	0	0	
Number of stents	12 ± 0.5	1.1 ± 0.3	0.08
Stent diameter, mm	7.4 ± 0.8	7.5 ± 0.9	0.56
Stented length, mm	74.5 ± 17.1	79.5 ± 16.9	0.12
Post PTA pressure gradient, mmHg	11.1 ± 6.6	8.7 ± 6.2	0.12
Post PTA ABI	0.84 ± 0.15	0.86 ± 0.15	0.62

Subintimal vs. Intraluminal



Ko YG, Kim JS, et al. J Endovasc Ther 2007;14:374-381

Conclusion

✓Subintimal angioplasty of long femoro-popliteal occlusions combined with primary stenting of the proximal entry point is safe and feasible, with a high success rate.