Stent vs. Non-Stent strategies for Peripheral Interventions

***Dallas Cardiovascular Innovations* 2015**

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What is the Strategy in Question?

Stent vs no stent strategy?

STENT STRATEGY:

- Primary stenting
  - BMS
  - DES-nonpolymer based
  - DES-polymer based*
  - DES-bioabsorbable scaffolds*

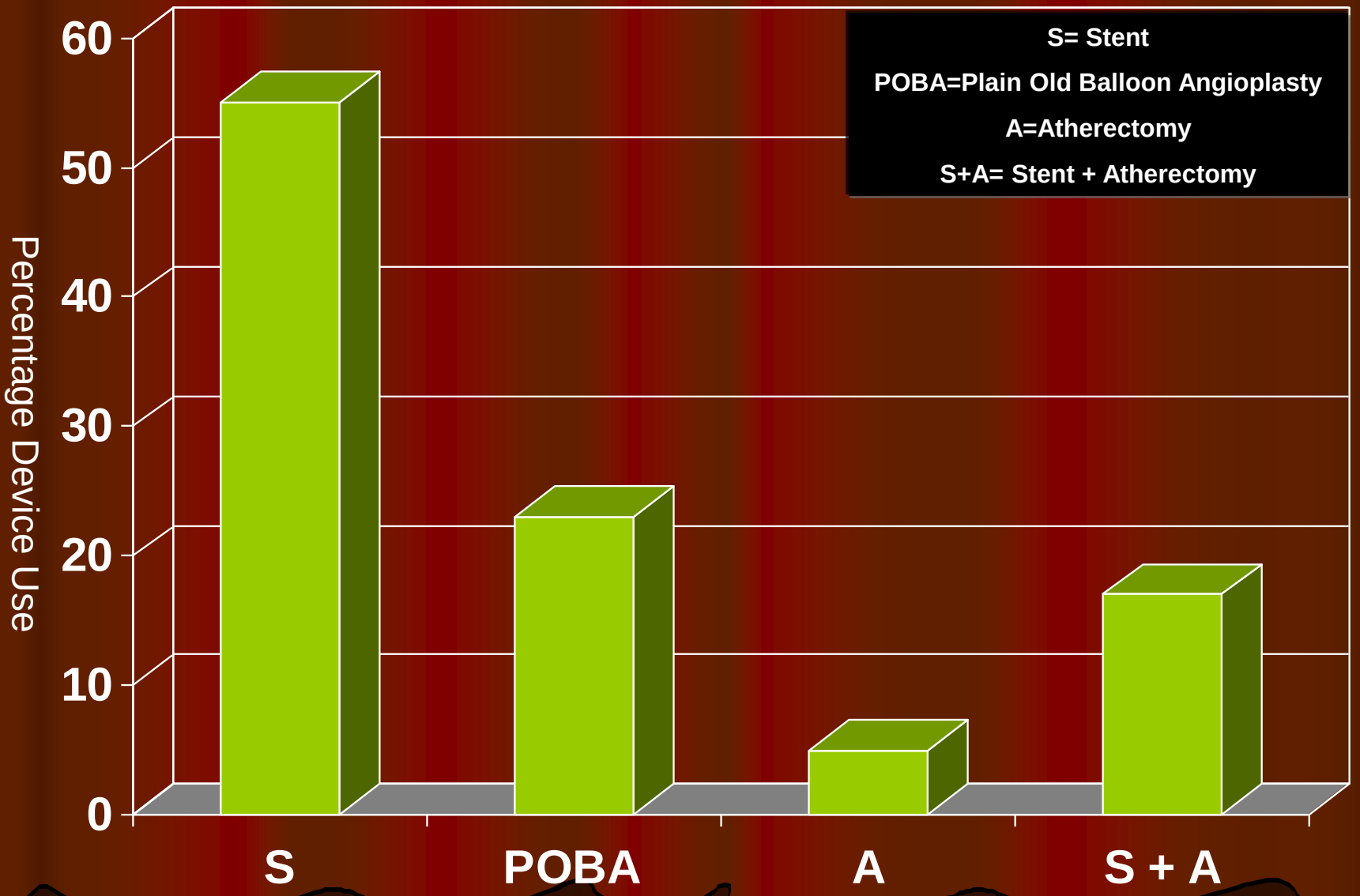
*Not available.

Non Stent Strategy:
(Provisional stenting strategy)

After POBA
After DCB
After Atherectomy+ adjunctive POBA
After Atherectomy + adjunctive DCB
After Scoring + Adjunctive DCB
After Chocolate + Adjunctive DCB

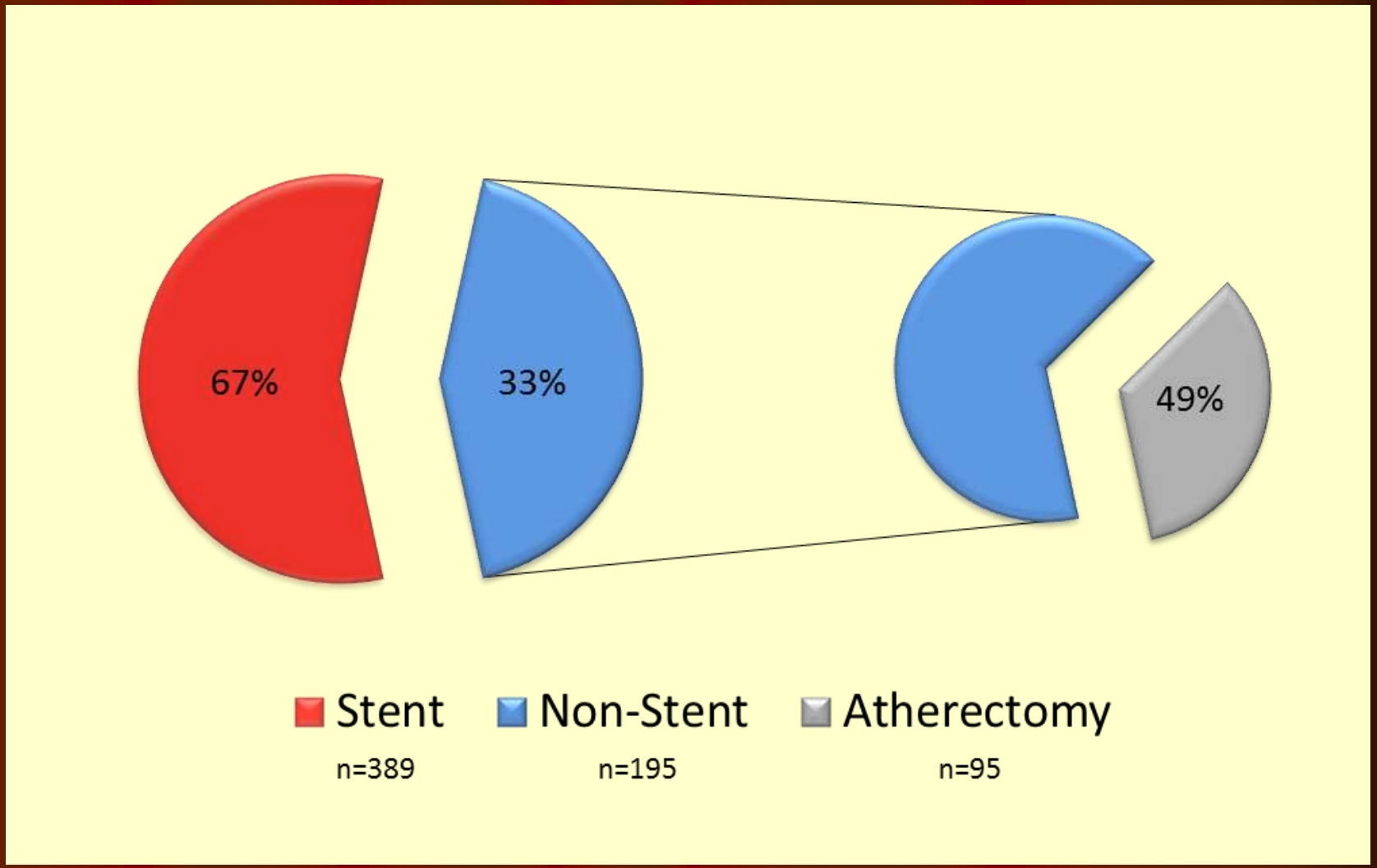
After Drug Coated Scoring balloons*
After Drug Coated Chocolate balloon*
* not available

Current Device Application in Treating FP lesions

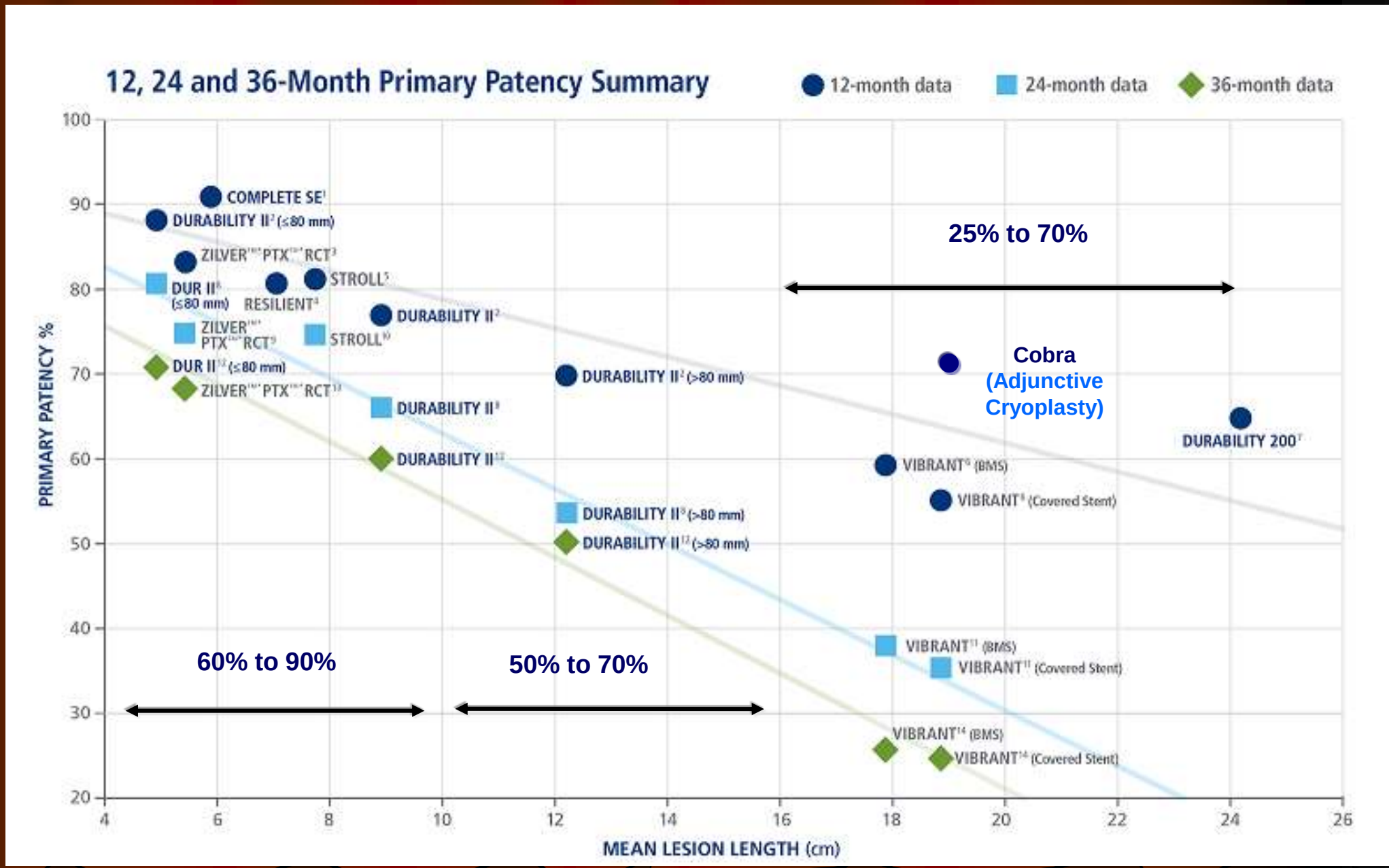


US Peripheral Device Market, 2012

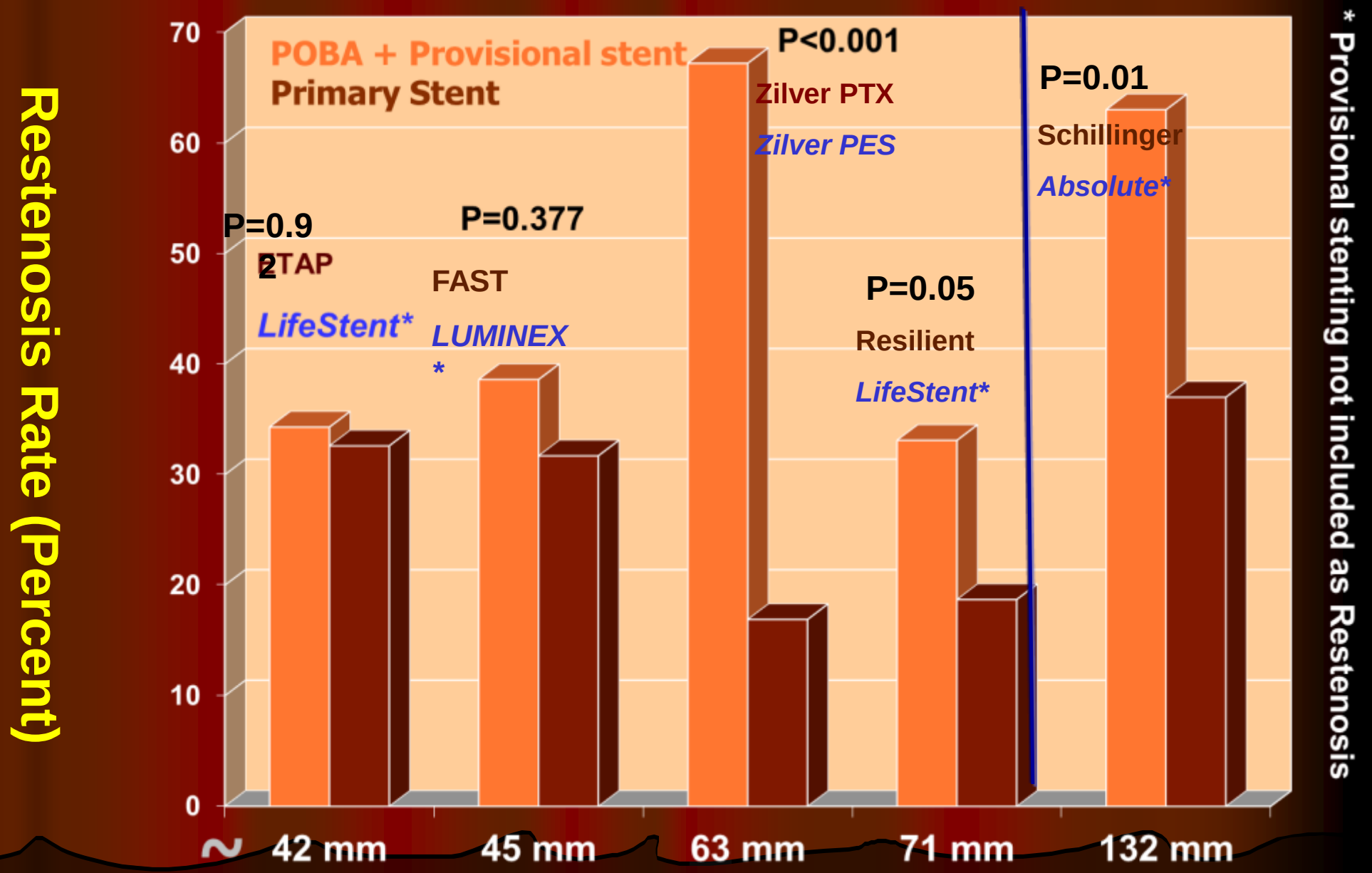
Treatment strategy distribution in the XLPAD registry



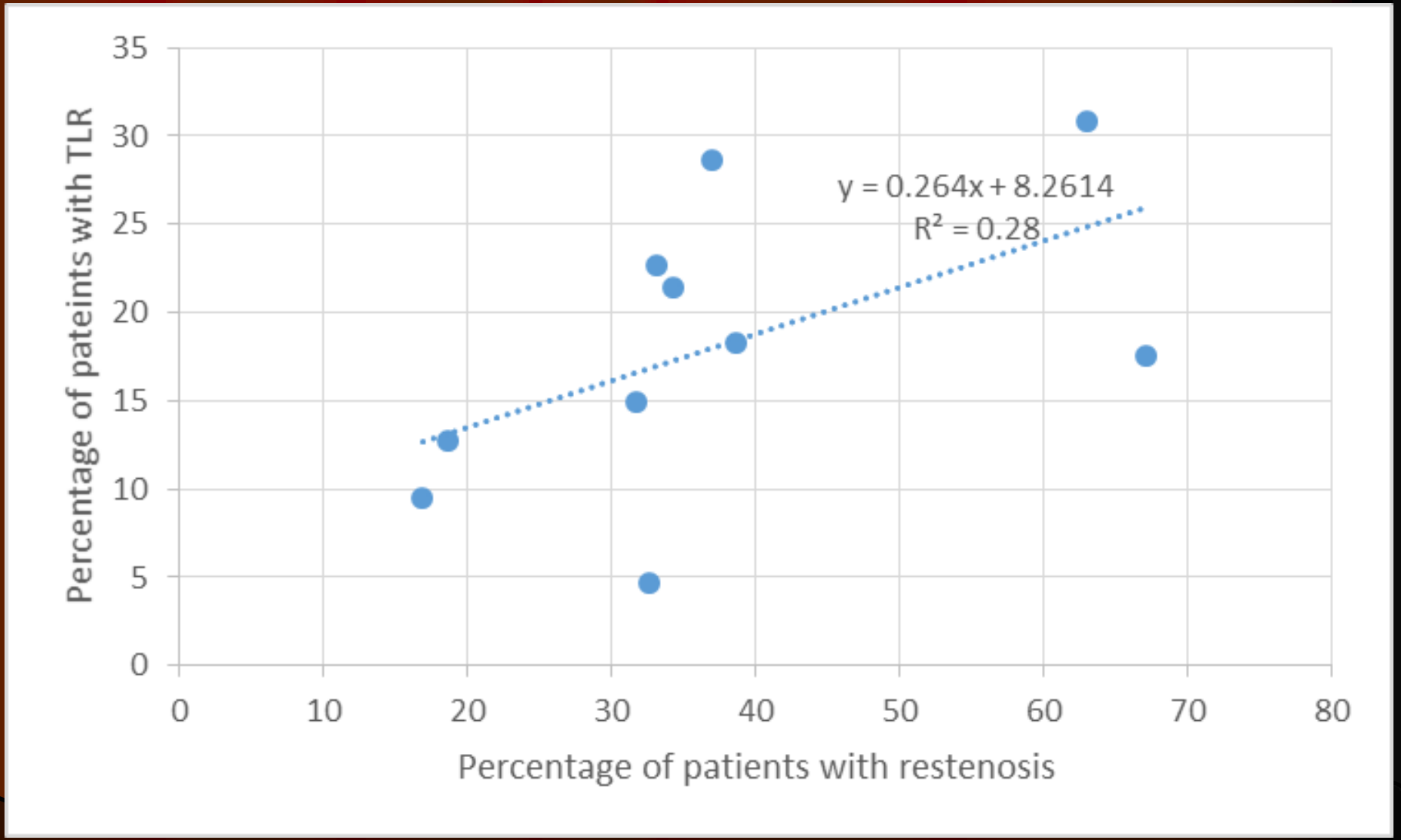
Banerjee S et al. JIC 2014 (in Print)


12, 24 and 36-Month Primary Patency Summary
12-month data
24-month data
36-month data
PRIMARY PATENCY %
MEAN LESION LENGTH (cm)
COMPLETE SE
DURABILITY II (≤80 mm)
ZILVER PTX RCT
DUR II (≤80 mm)
RESILIENT
STROLL
DURABILITY II
ZILVER PTX RCT
STROLL
DUR II (≤80 mm)
ZILVER PTX RCT
DURABILITY II
DURABILITY II (>80 mm)
DURABILITY II
DURABILITY II (>80 mm)
DURABILITY II (>80 mm)
25% to 70%
Cobra
(Adjunctive
Cryoplasty)
DURABILITY 200
VIBRANT (BMS)
VIBRANT (Covered Stent)
60% to 90%
50% to 70%
VIBRANT (BMS)
VIBRANT (Covered Stent)
VIBRANT (BMS)
VIBRANT (Covered Stent)

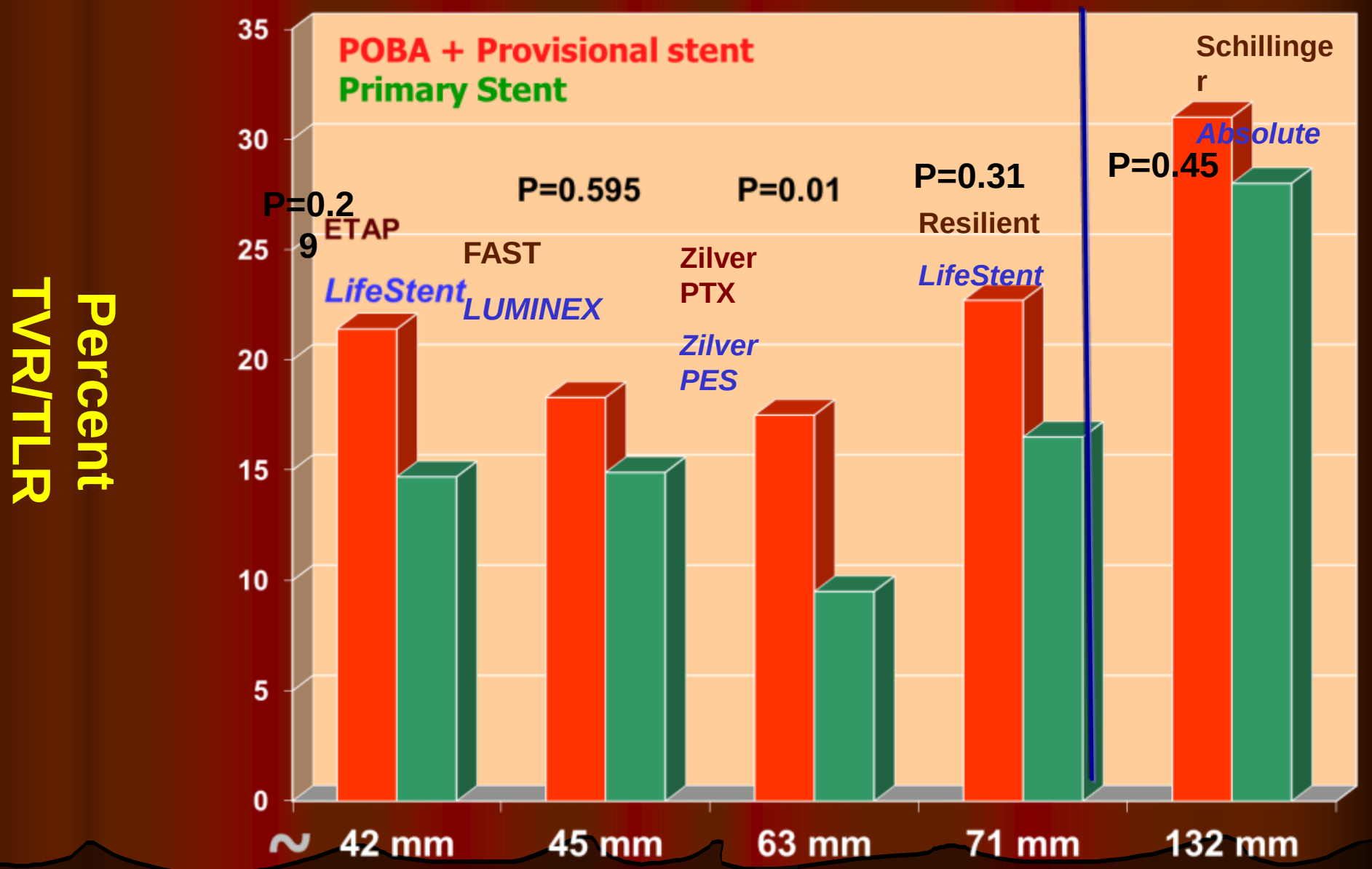
One-Year Restenosis Rate in Randomized Femoropopliteal trials



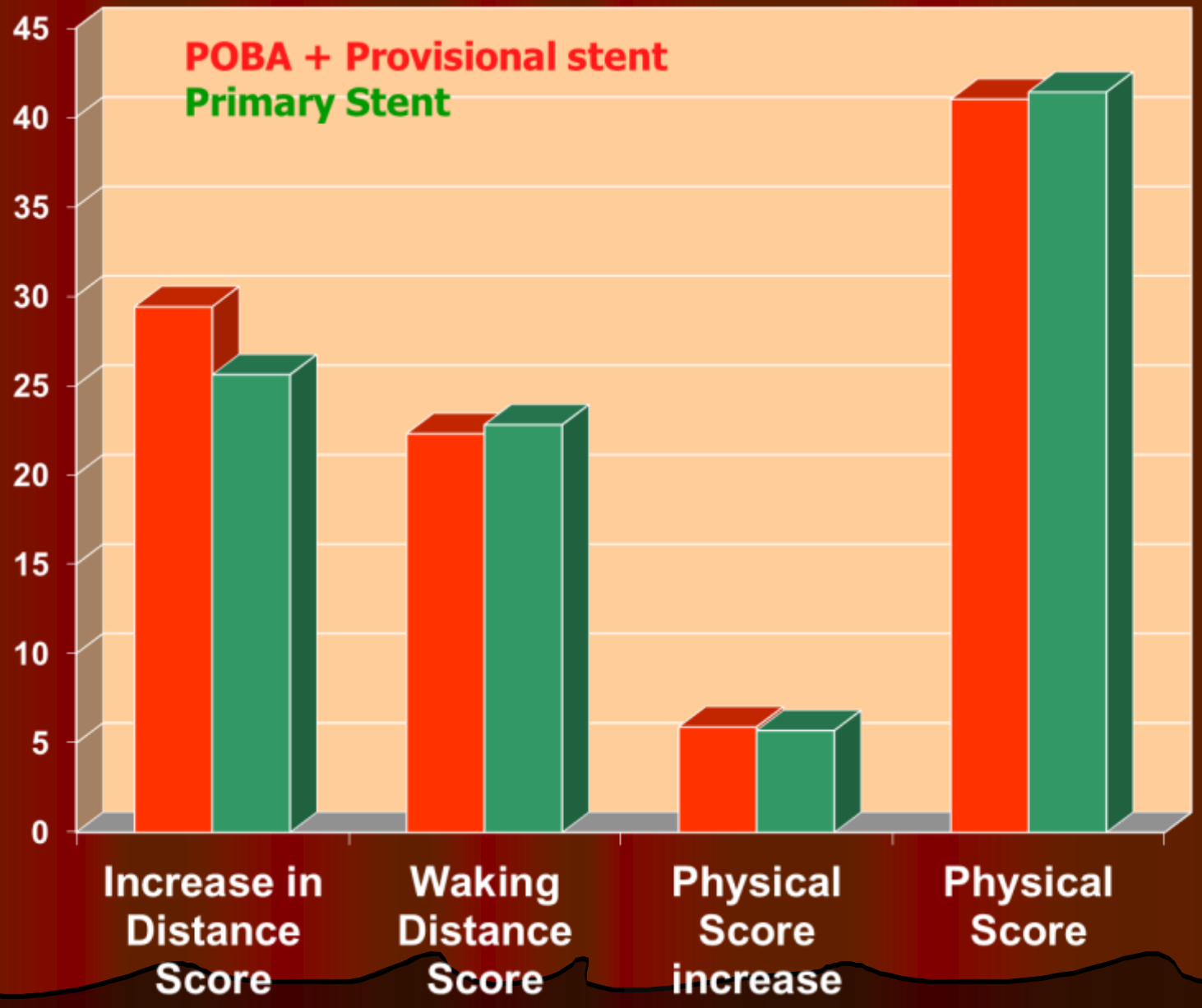
Restenosis rate vs TLR rate



One-Year TLR/TVR in Randomized Femoropopliteal trials



RESILIENT Trial QOL and walking scores (Stent vs Provisional Stent)



Clinical Outcomes and Posttreatment Clinical Benefit Index Results

Measurement	PTA Group		DES Group	
	Baseline	12 Months	Baseline	12 Months
ABI	0.68±0.2	0.89±0.20*	0.67±0.2	0.91±0.23*
Rutherford classification,† % of patients				
0	0%	45.4%	0%	44.7%
1	0.8%	21.7%	0.9%	20.9%
2	46.2%	20.3%	52.5%	23.3%
3	44.5%	10.1%	37.7%	9.2%
4	4.7%	1%	5.9%	1.9%
5	3.4%	1.5%	3%	0%
6	0.4%	0%	0%	0%
Walking scores, maximum possible=100%‡				
Walking distance	26.3±28.6%	57.7±36.9%*	25.0±27.6%	57.8±37.9%*
Walking speed	29.7±30.3%	58.2±35.7%*	27.5±27.1%	55.7±37.1%*
Climbing	38.7±32.5%	61.5±34.0%*	35.9±32.2%	55.6±37.3%*
Sustained posttreatment clinical benefit index,§ % of patients	N/A	75.8%	N/A	88.3%?

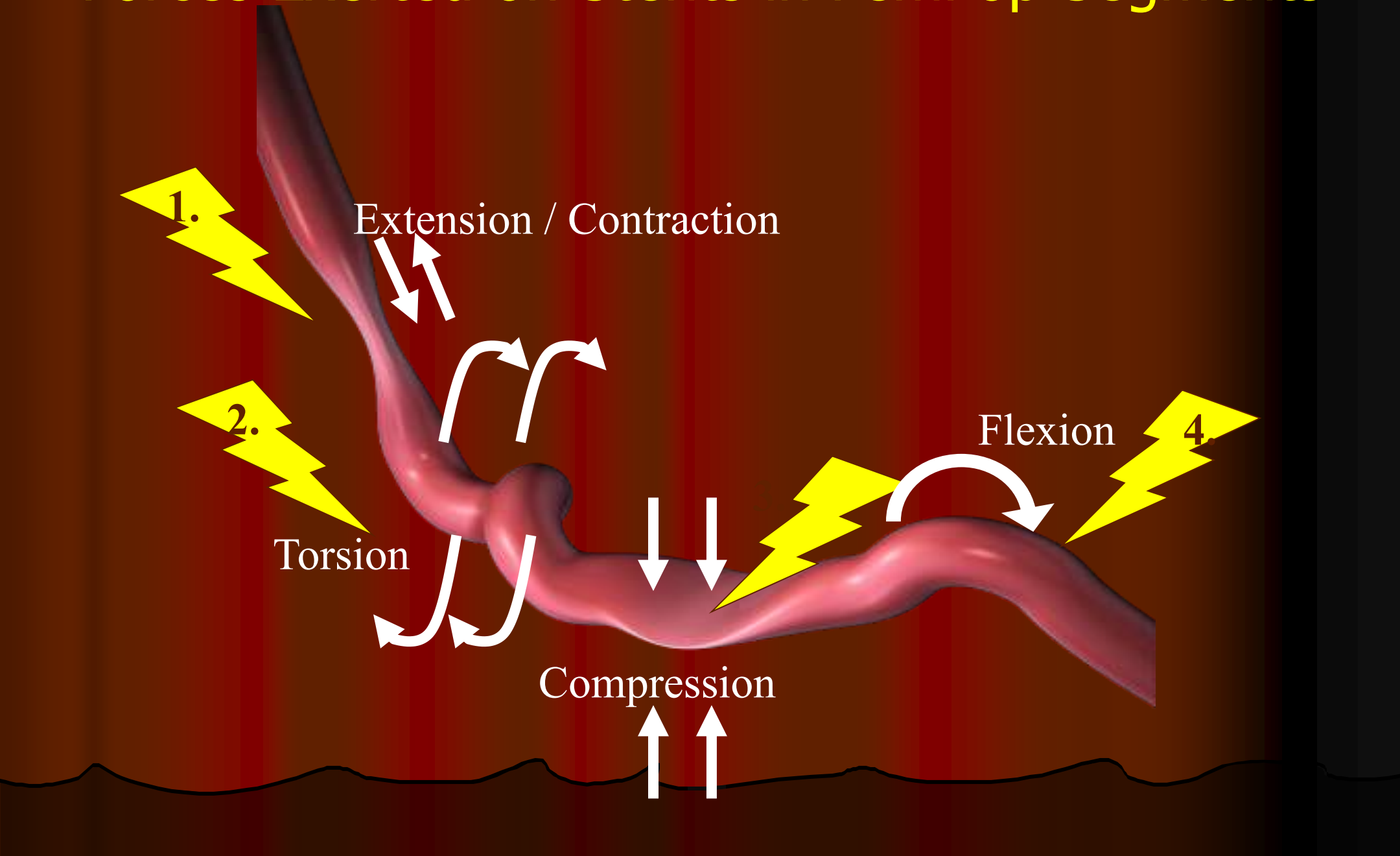
? § Posttreatment clinical benefit was defined as freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss after the initial study treatment.

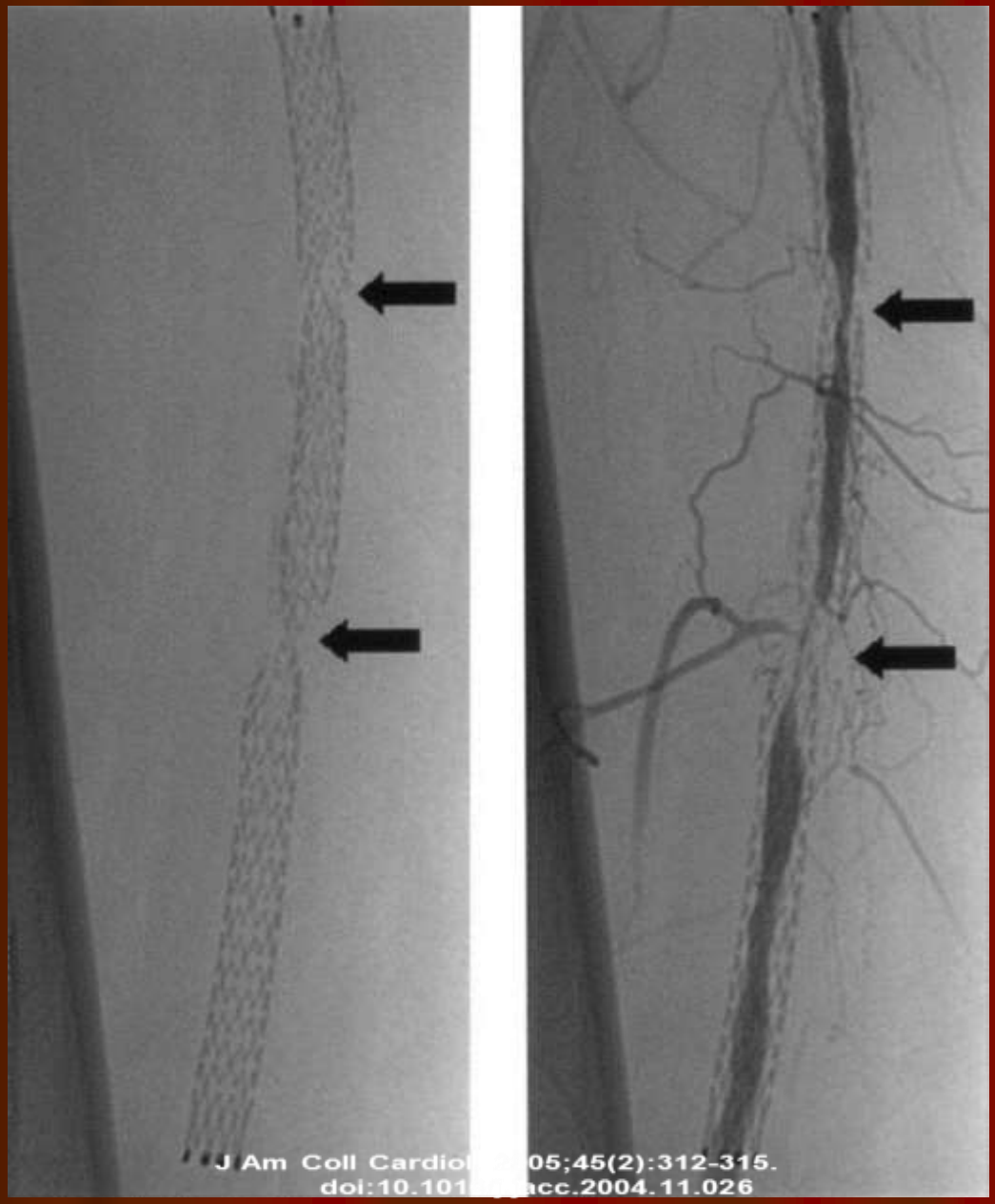
? ? $P<0.001$ compared with PTA group; paired t test.

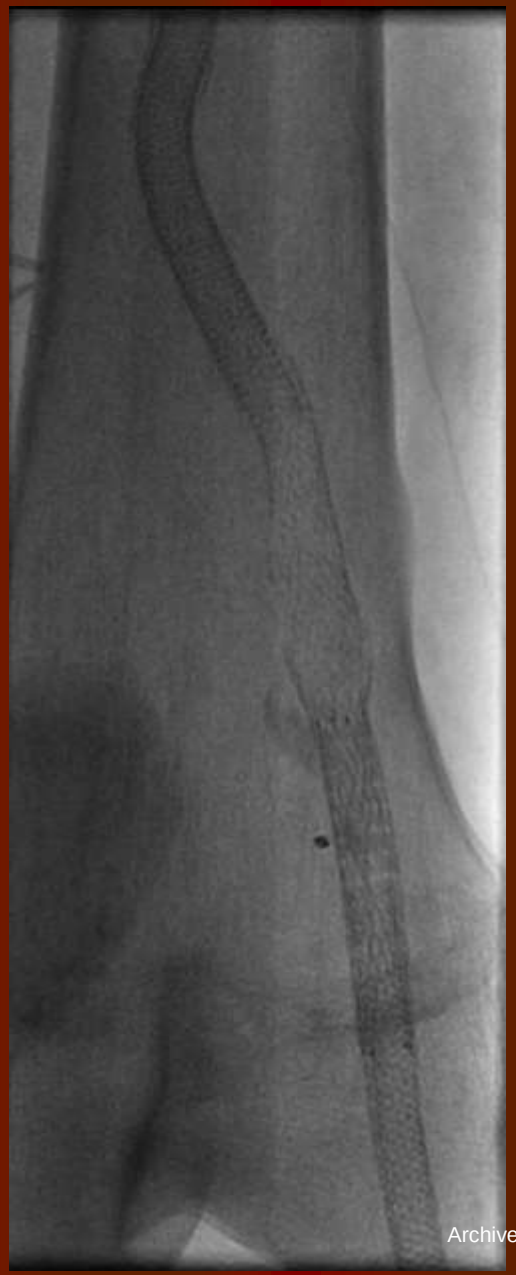
Revisit what is important…

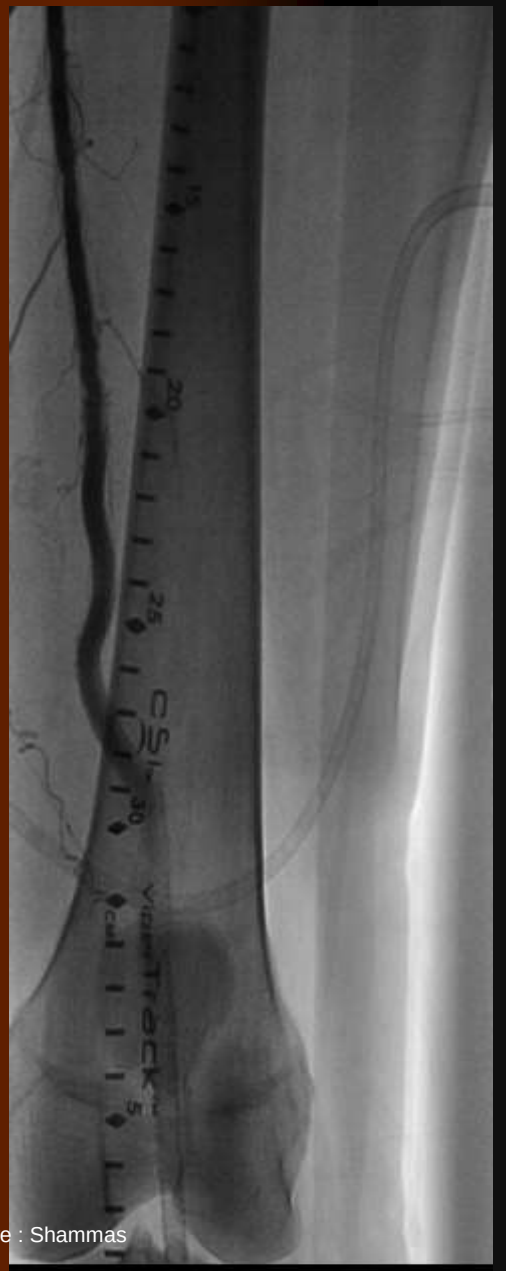
- Is Patency the endpoint that should be guiding our clinical trials?
- OR should we think about TLR/TVR and QOL as the ultimate goal???
- "**Déjà vu**" questions from coronary trials:
  - Coronary Trial has now clinical outcome endpoints before angiographic endpoints
  - Avoiding the "Occulo-stenotic reflex"
  - Patency or TLF? TLF for PAD=Vasc Death, Amputation and TLR

Forces Exerted on Stents in FemPop Segments









ISR treatment

- Long diffuse lesions
- High rate of embolizations
- Restenotic-thrombotic lesions
- Recurs very frequently
- No good way to treat it effectively
- More layers of stents may be needed
- Fracture rate 1-3% in newer generation stents
- May impede effectiveness of upcoming anti-restenotic treatment
- My impair future surgical targets

Stenting the FemPop Segment: Facts from Randomized Trials

- Stenting has lower restenosis at 1 year than PTA particularly in longer lesions . Longer lesions have a high rate of restenosis with both PTA and stent
- No difference in TLR with primary stenting vs provisional stenting using BMS
- Primary DES or provisional DES has lower TLR than PTA or PTA with provisional BMS stenting. Randomized data available for shorter lesions
- QOL, Walking distance, claudication are not consistently altered at 1 year by primary stenting vs provisional stenting
- FP stenting has its inherent problems relating to the nature of ISR lesions and stent fractures

How to avoid stent related problems?

Avoid Routine Primary Stenting

Consider Stenting :

- Provisional preferably with DES
- DES in Short lesions in proximal to mid SFA
- DES Stenting in advanced limb ischemia when feasible to maximize chance for wound healing
- Otherwise: our strategy is to reduce stenting and add adjunctive DCB

Optimal Strategy in Peripheral Arterial Revascularization

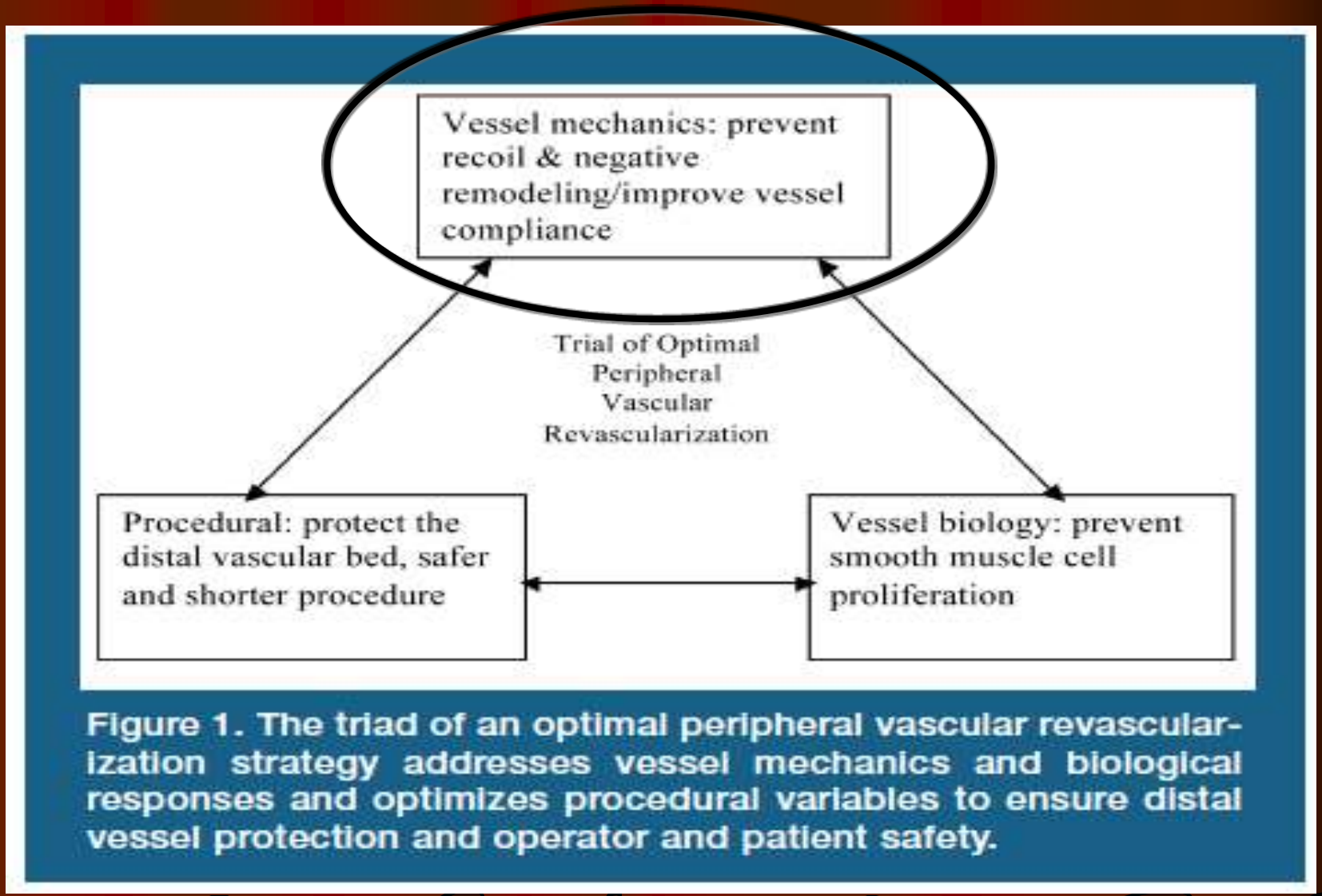
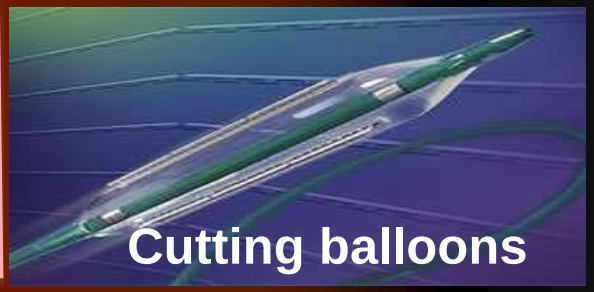


Figure 1. The triad of an optimal peripheral vascular revascularization strategy addresses vessel mechanics and biological responses and optimizes procedural variables to ensure distal vessel protection and operator and patient safety.

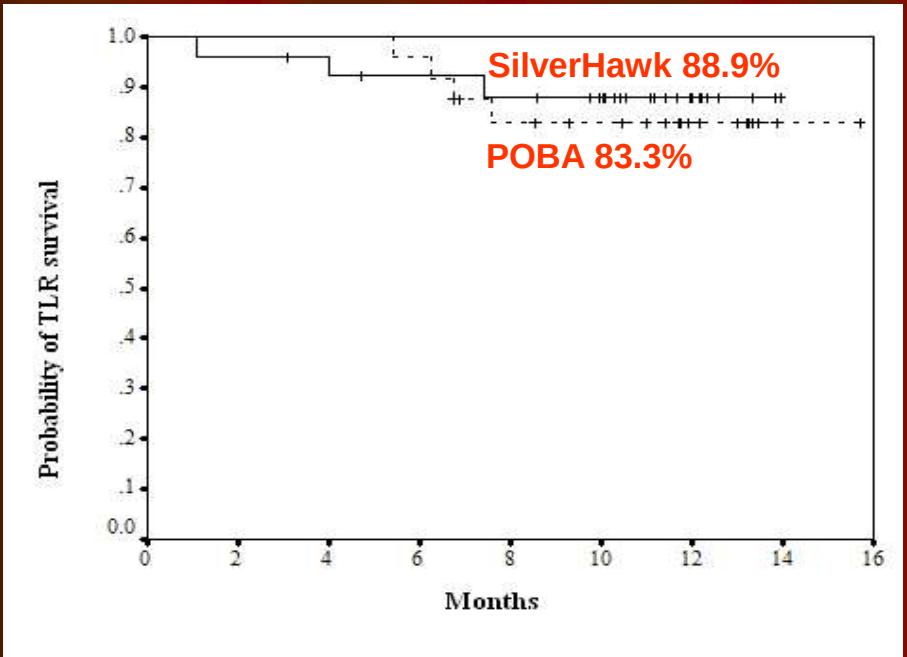
Shammas NW, Vascular Disease Management, 2009;6:36-40

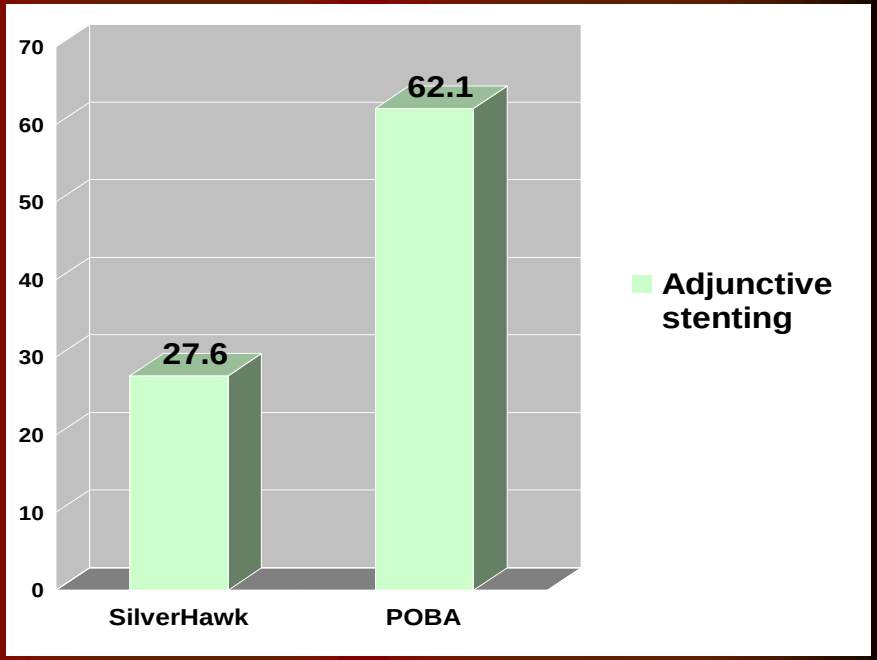
Atherectomy Devices

Specialized Balloon



Angioplasty versus SilverHawk Atherectomy





1. No change in TLR
2. Reduction in stenting by > 50%
3. Very high rate of distal embolization

distal macroembolization in 64.7% treated with atherectomy versus none of 10 in the PTA group (P < .001).

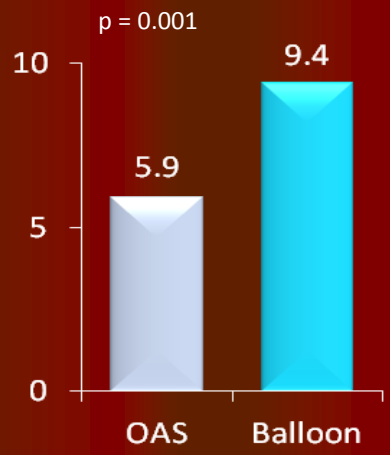
Shammas et al. J Vasc Interv Radiol. 2011; 22(9):1223-8. Epub 2011 Jul 14.

CALCIUM 360° STUDY
OAS Outperforms Balloon Angioplasty in BTK Lesions

- Prospective, multi-center
- Randomized
- 95% severe and moderate calcium
- Below the Knee lesions

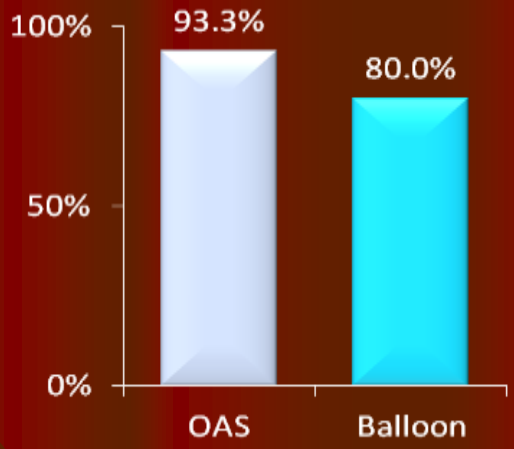
Max Balloon Pressure

Average Max Balloon Pressure (atm)

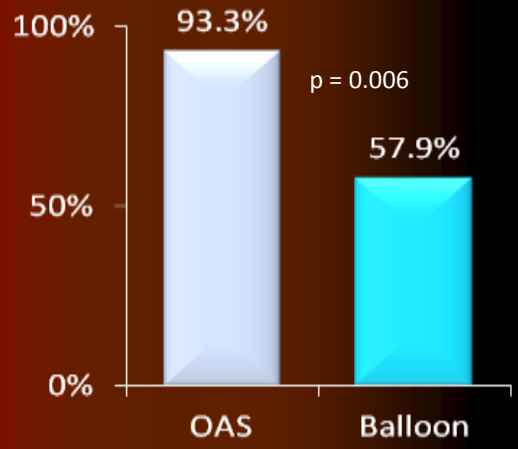


Results at 12 Months

Freedom From Restenosis



Freedom From Major Adverse Events*



Shammas, N. *J Endovascular Ther*, 2012; 19:480-488.

Slide courtesy CSI

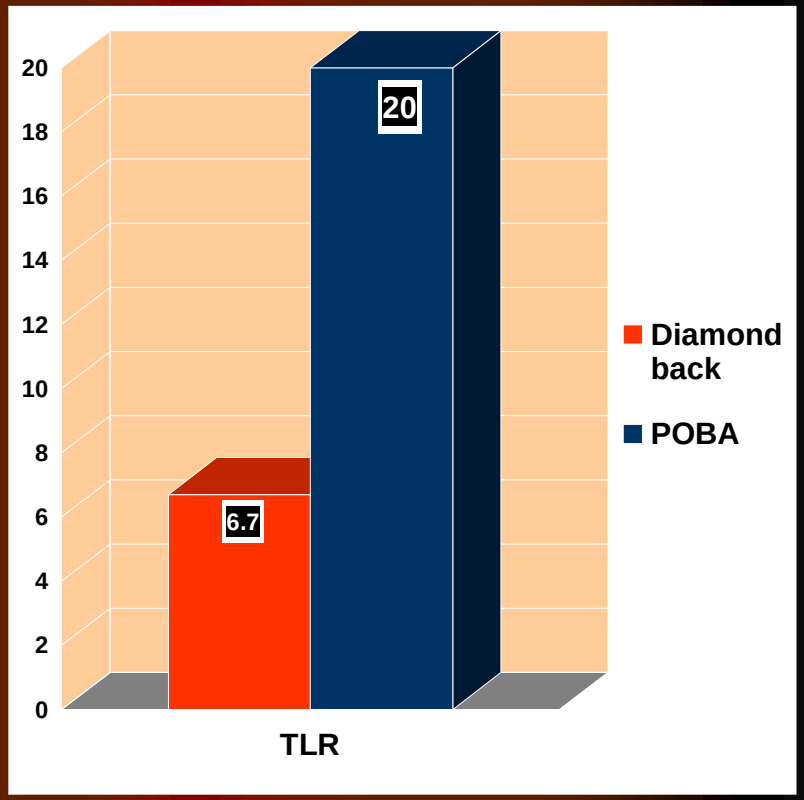
- Major adverse events: major amputation (above-the-ankle), death and TLR/TVR

CALCIUM 360° Study

Dissection, Bailout stenting,TLR

	Diamond-back 360°	Balloon Angioplasty
Dissections*	**3.3%**	**11.4%**
Bail-out stenting*	**2 (6.9%)**	**5 (14.3%)**

- Trend toward lower TLR
- Lower dissection rate and bail out stenting
- Higher freedom from major adverse events

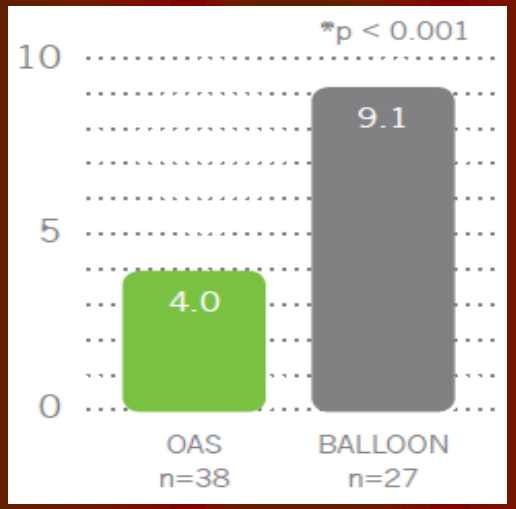


Shammas NW et al. J Endovasc Ther 2012;19(4):480-8

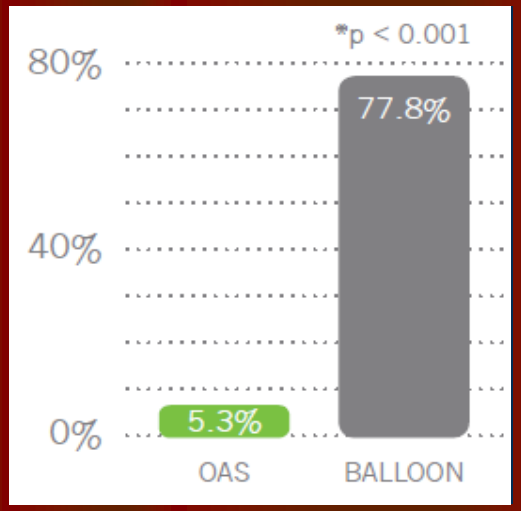
COMPLIANCE 360º Study[1]
OAS Outperforms Balloon Angioplasty in ATK Lesions

- Prospective
- Multi-center
- Randomized (1:1)
- Calcified ATK Lesions

Max. Balloon Pressure



Bail-Out Stenting



Revascularization at 12 Mos

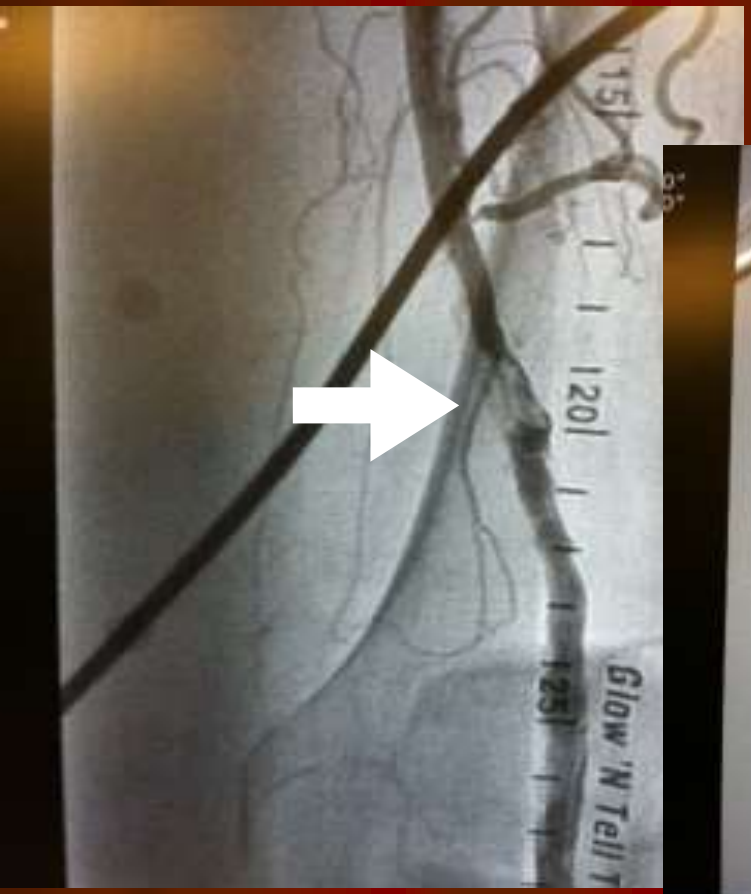
18.8% OAS
21.7% PTA

Similar patency despite large difference in stent usage

Slide courtesy CSI

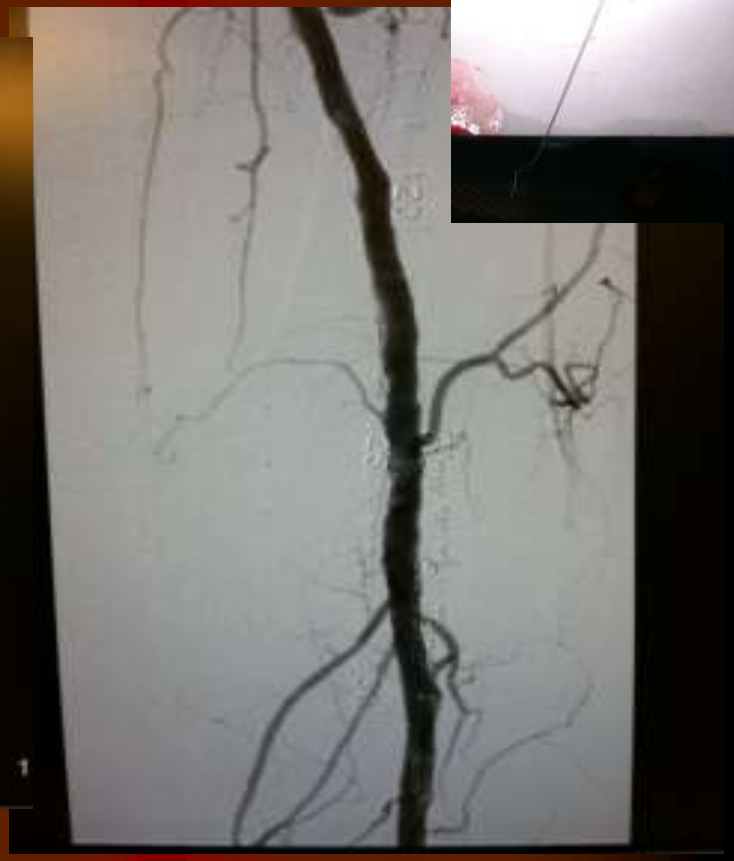
1. COMPLIANCE 360 Clinical Study. Data on File.

Case 1: 73 year-old male with Severe claudication and ABI of 0.55 at rest (LLE) treated with SilverHawk atherectomy



95% heavily calcified left distal SFA

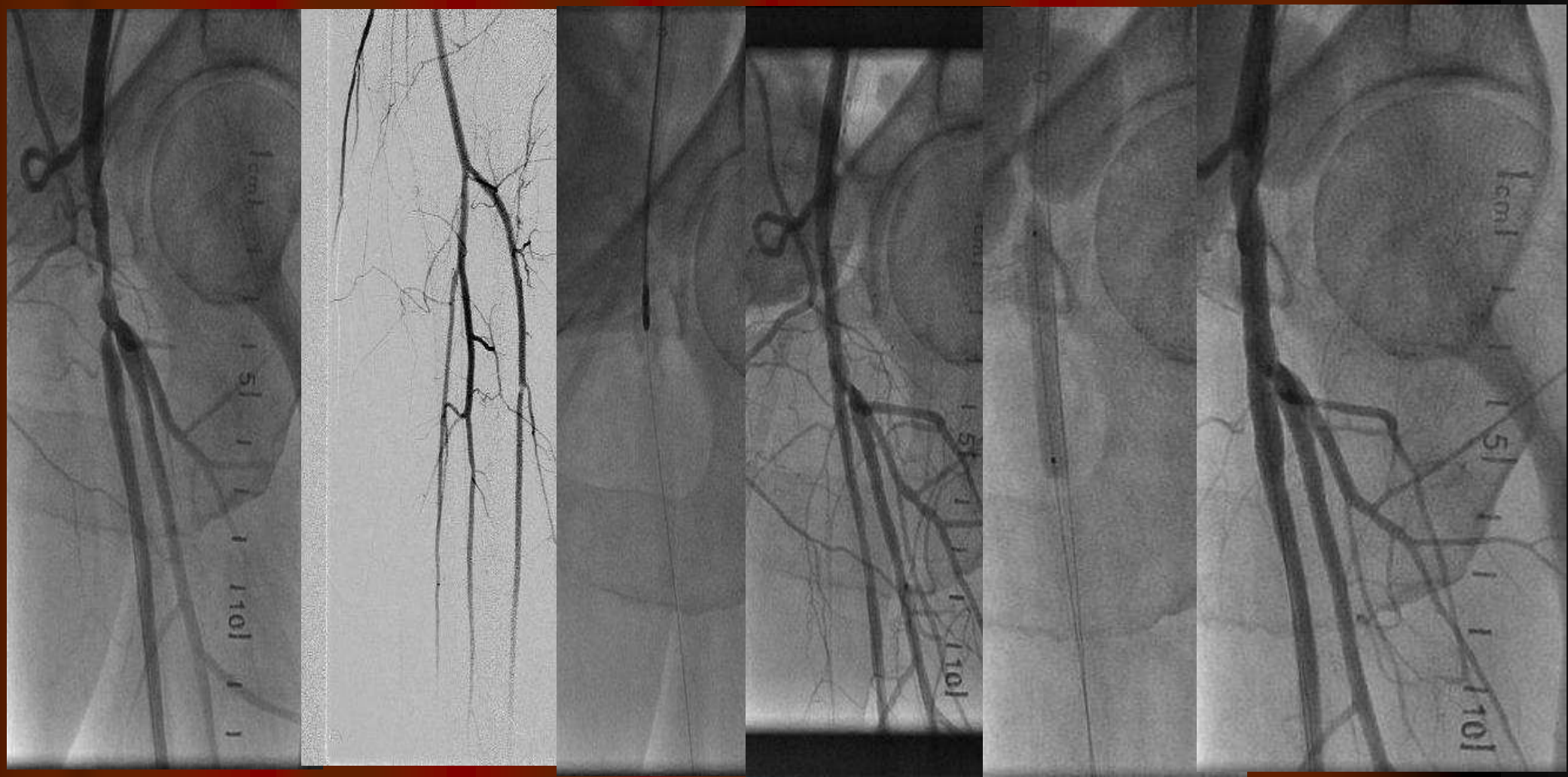
40% residual post atherectomy with LX-C Turbohawk & 6 mm Spider Wire



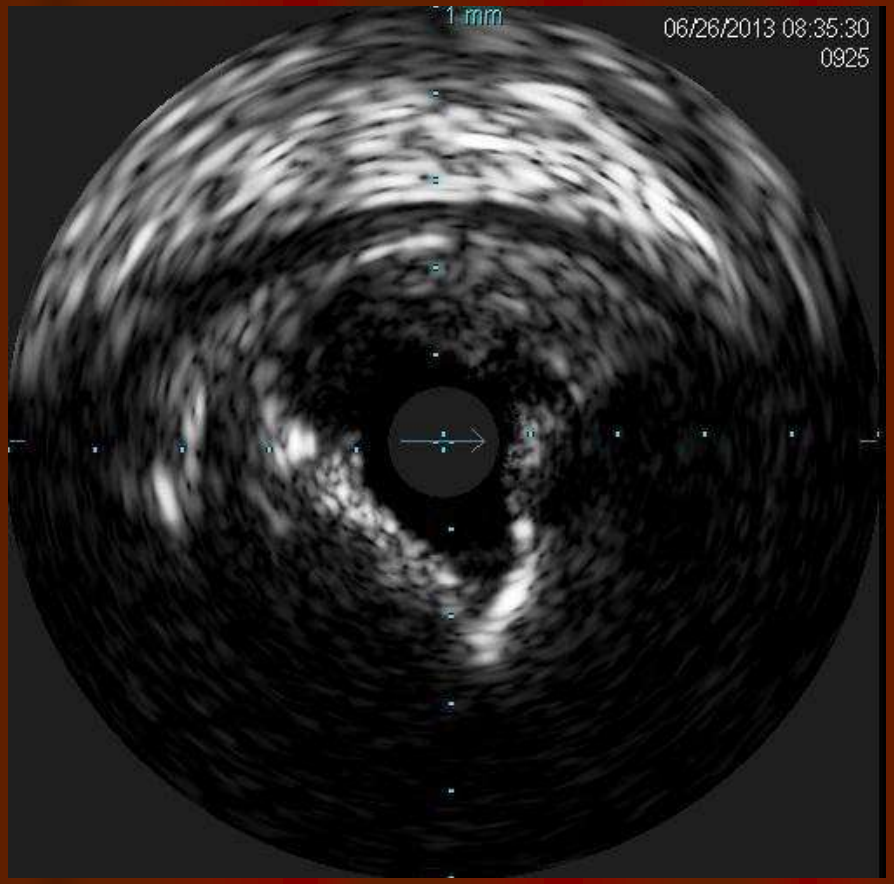
Postdilate with 6 mm balloon showed less than 10% residual

Case TurboHawk Atherectomy: Shammas NW

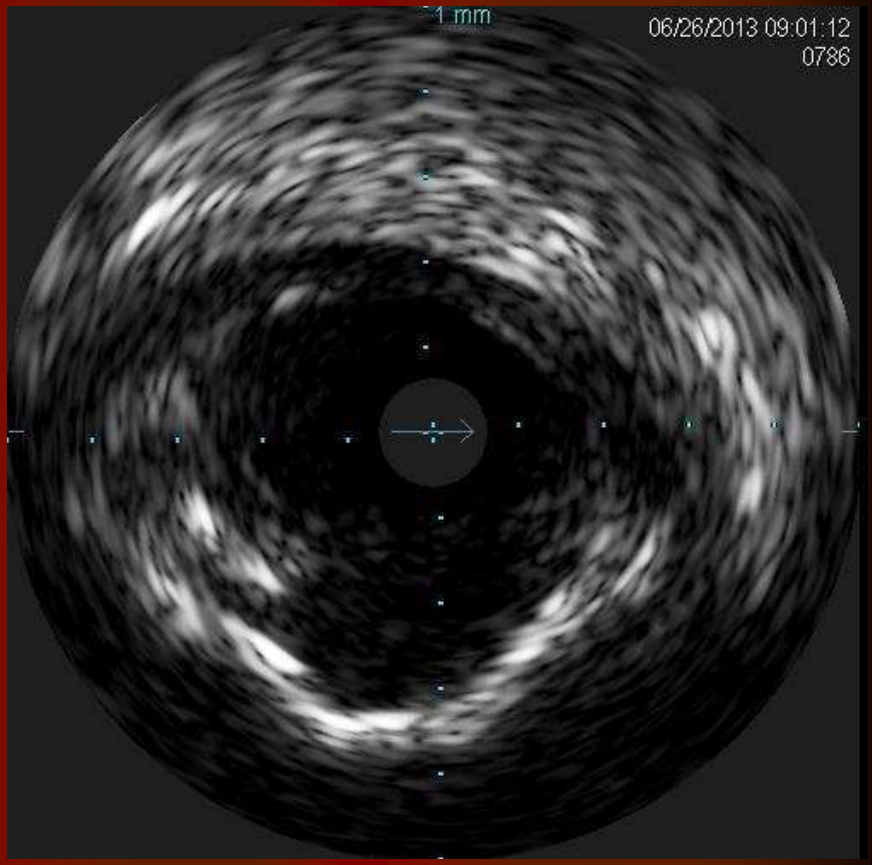
Case 2



Case 2 IVUS



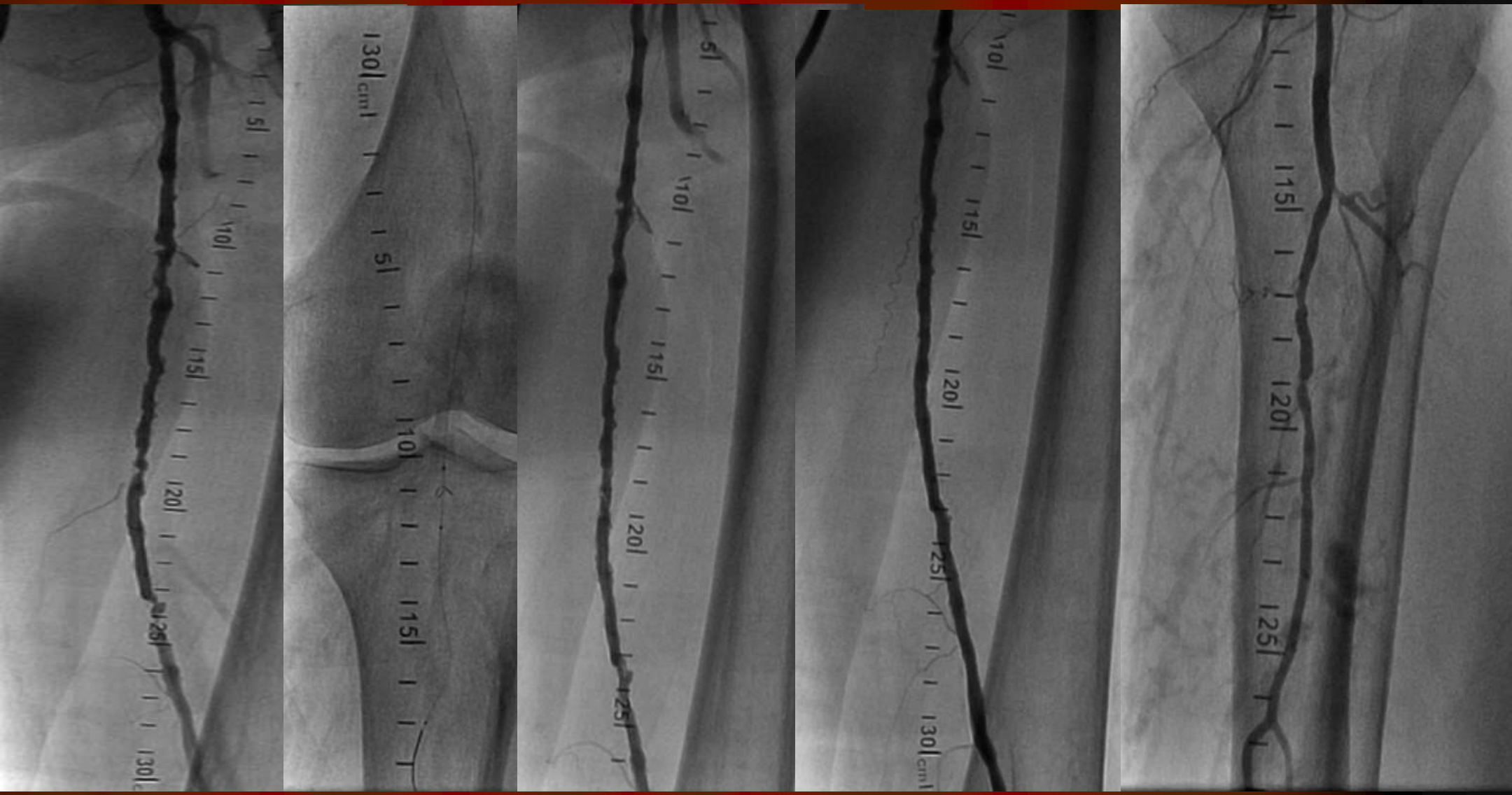
Pre treatment IVUS



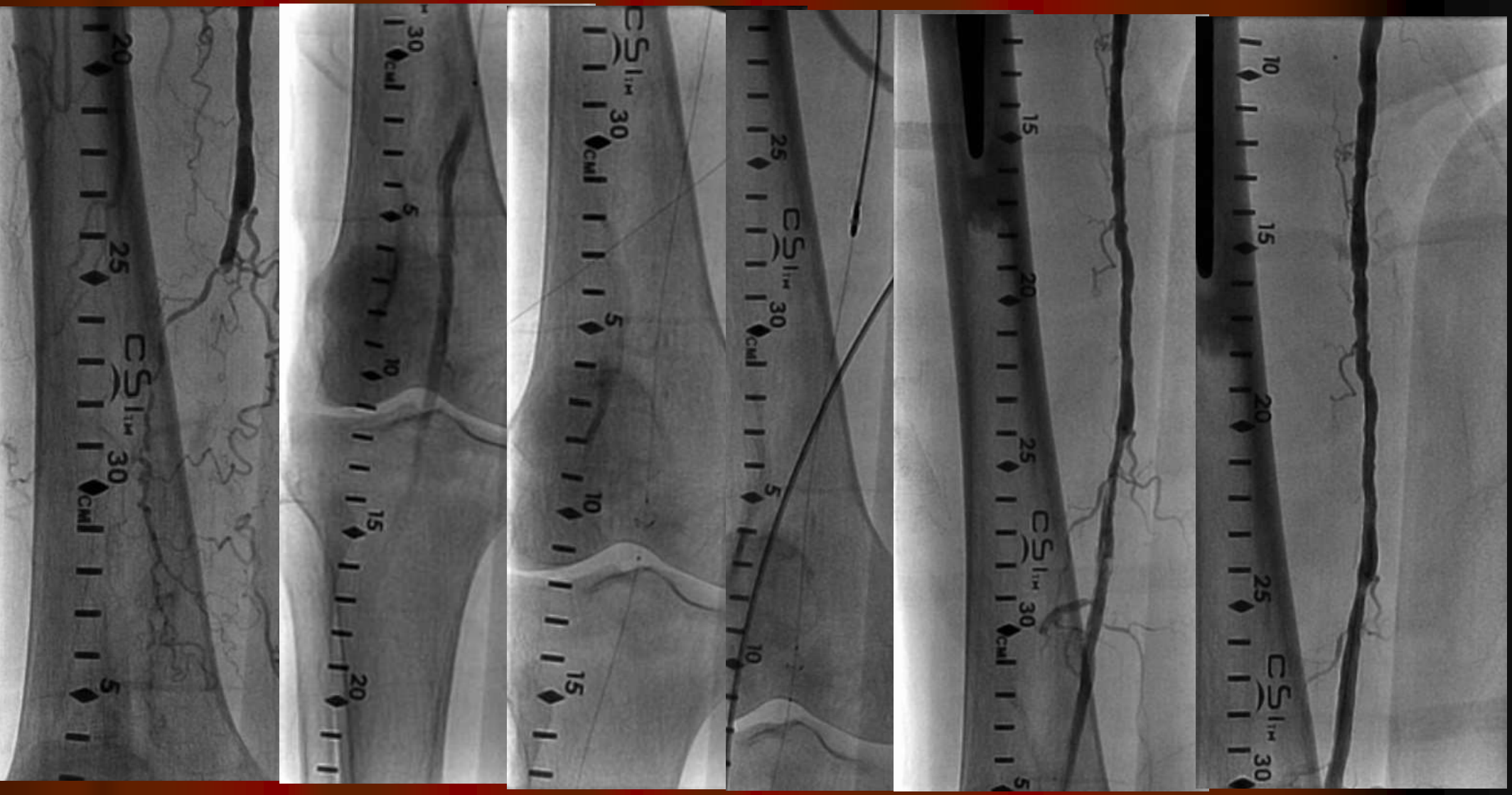
Post treatment IVUS

Case IVUS pre and post Jetstream Atherectomy:
Shammas NW

Case 3



Case 4



Optimal Strategy in Peripheral Arterial Revascularization

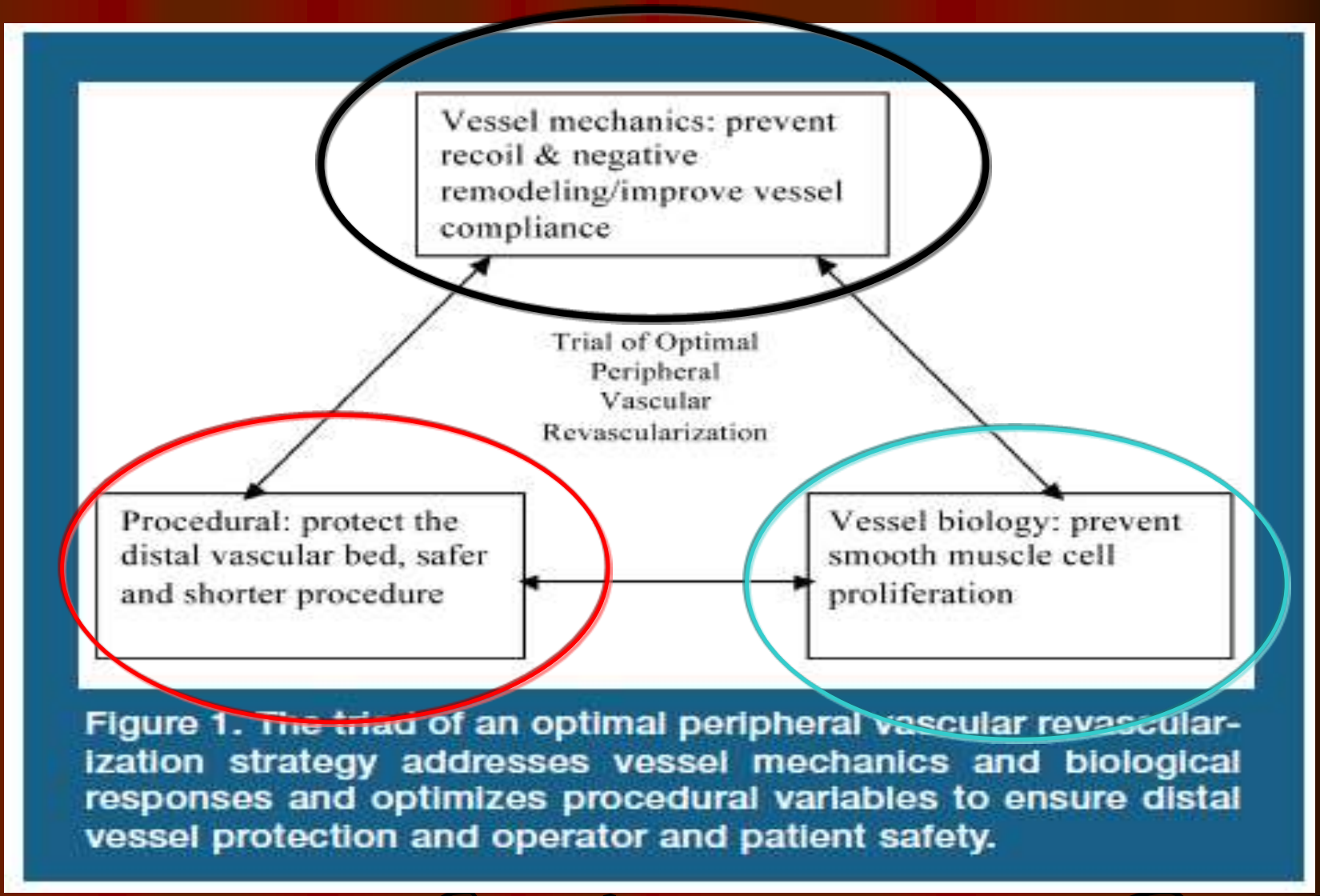
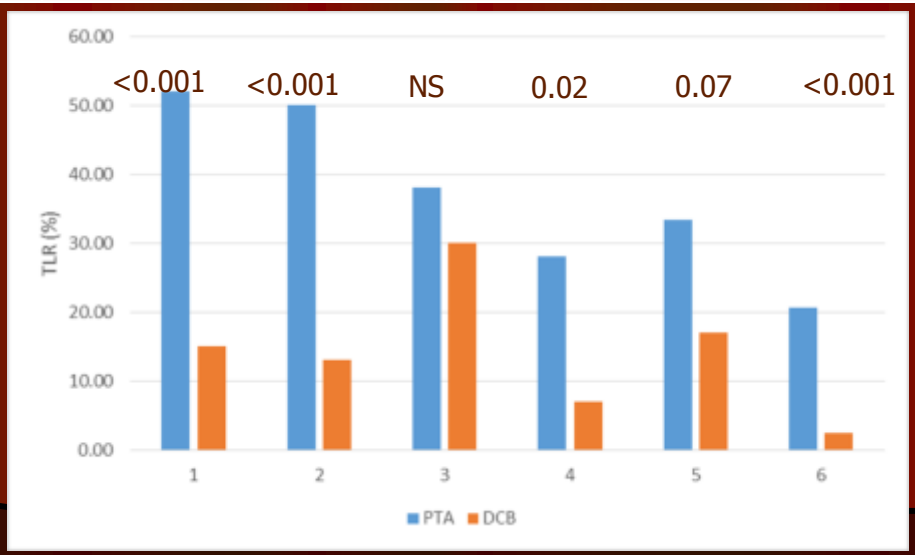


Figure 1. The triad of an optimal peripheral vascular revascularization strategy addresses vessel mechanics and biological responses and optimizes procedural variables to ensure distal vessel protection and operator and patient safety.

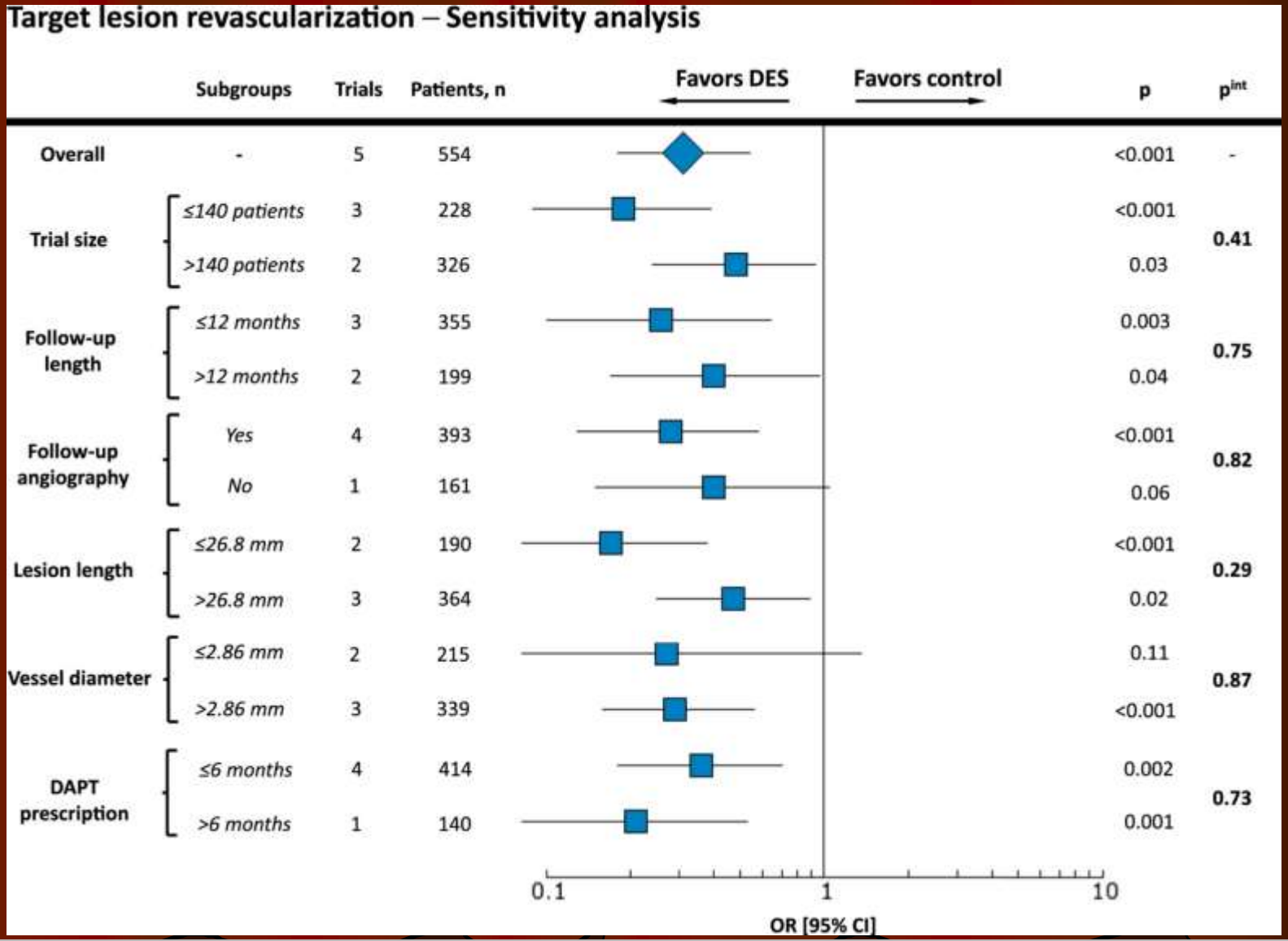
Shammas NW, Vascular Disease Management, 2009;6:36-40

TLR in Drug Coated Balloons Randomized trials

TRIAL	YEAR	DCB	Drug-Excipient	µg/mm2	Design	Location	FU duration	PTA	DCB	P
THUNDER	2008	Paccocath	Paclitaxel-Iopromide	3	PTA vs Paccocath	FP	24 mo	52.00	15.00	<0.001
FEM-PAC	2008	Paccocath	Paclitaxel-Iopromide	3	PTA vs Paccocath	FP	24 mo	50.00	13.00	<0.001
LEVANT-I	2010	Lutonix Moxy	Paclitaxel-Polysorbate/Sorbitol	2	PTA vs Lutonix	FP	24 mo	38.00	30.00	NS
PACIFIER	2012	In.PACT PACIFIC	Paclitaxel-urea	3	PTA vs In.PACT	FP	12 mo	28	7	0.02
DEBATE-SFA	2013	In.PACT Admiral	Paclitaxel-urea	3	PTA+BMS vs DCB+BMS	FP	12 mo	33.3	17	0.07
In.PACT SFA	2014	In.PACT Admiral	Paclitaxel-urea	3	PTA vs DCB	FP	12 mo	20.6	2.4	<0.001



From: Drug-Eluting Stents for Revascularization of Infrapopliteal Arteries: Updated Meta-Analysis of Randomized Trials



J Am Coll Cardiol Intv. 2013;6(12):1284-1293. doi:10.1016/j.jcin.2013.08.007

Drug-eluting balloon versus standard balloon angioplasty for infrapopliteal arterial revascularization in critical limb ischemia: 12-month results from the IN.PACT DEEP randomized trial

Prospective, multicenter, randomized, controlled trial
358 CLI patients were randomized 2:1 to IA-DEB or PTA.

2 co-primary efficacy endpoints at 12 months:

1. clinically driven target lesion revascularization (CD-TLR) and
2. late lumen loss (LLL).

Primary efficacy results of DEB versus PTA were CD-TLR of 9.2% versus 13.1% (p = 0.291)

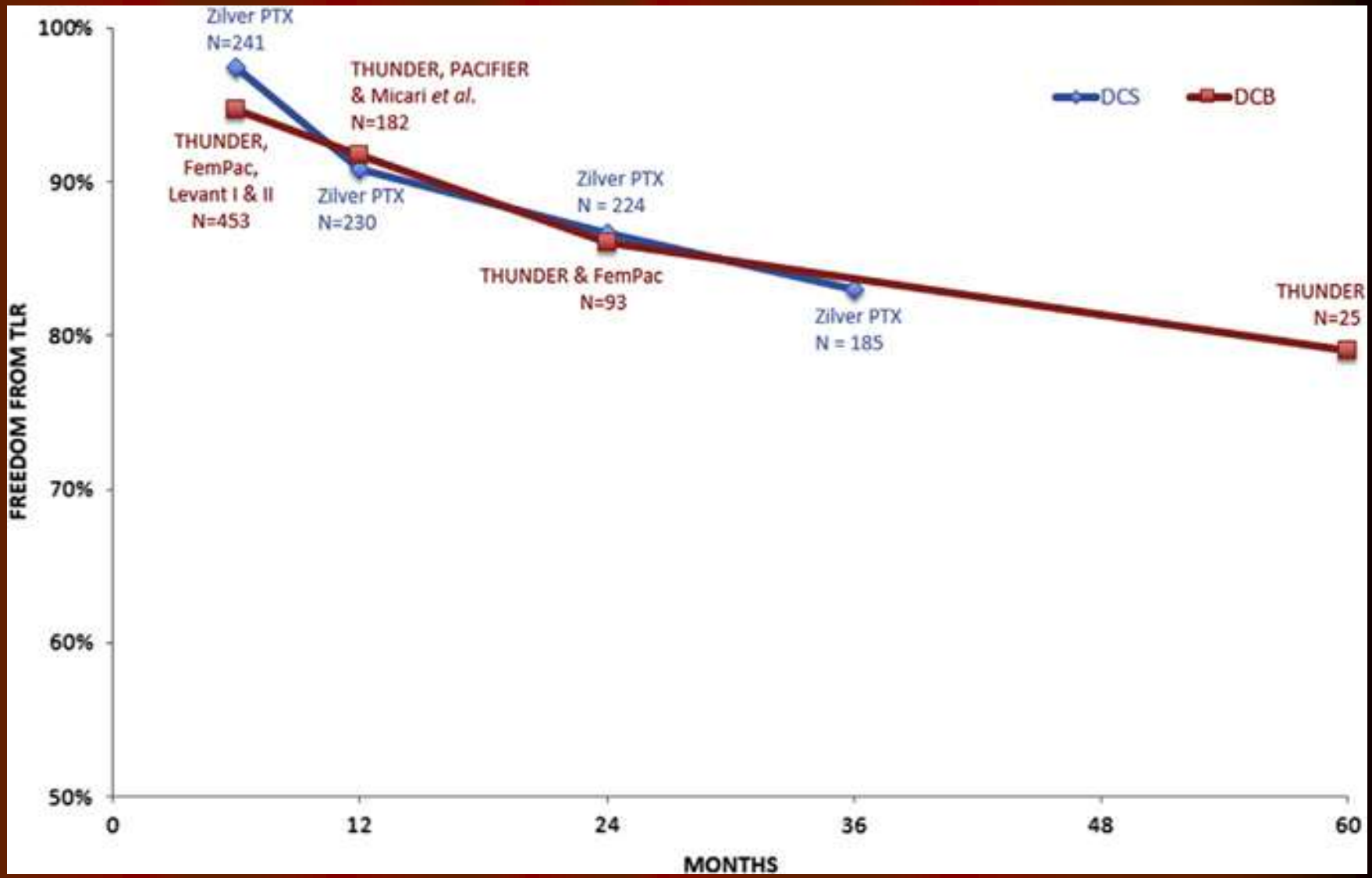
Primary safety endpoint through 6 months was a composite of all-cause mortality, major amputation, and CD-TLR.

Primary safety endpoints were 17.7% versus 15.8% (p = 0.021) and met the noninferiority hypothesis. Major amputations through 12 months was observed in the DEB arm versus the PTA arm (8.8% vs. 3.6%; p = 0.080).

Significant baseline differences between the DEB and PTA arms
impaired inflow (40.7% vs. 28.8%; p = 0.035),
previous target limb revascularization (32.2% vs. 21.8%; p = 0.047).

Zeller T et al. IN.PACT DEEP Trial Investigators. J Am Coll Cardiol. 2014 Oct 14;64(15):1568-76.

Drug Coated Balloons versus Drug Coated Stents



Sarode, K, Spelber D, Bhatt D…Banerjee S et al. JACC 2014

Summary

- Provisional stenting with BMS has same TLR and QOL when compared to Primary stenting of the FP segment
- Provisional stenting or primary stenting with DES has improved clinical outcomes compared to primary stenting with BMS or Provisional stenting with BMS. Data available for shorter lesions
- Atherectomy reduces dissection and stent rate and improves vessel compliance
- DCB are superior to POBA in reducing TLR and improves clinical outcomes
- *Combining Atherectomy with DCB likely reduces stent rate and reduces TLR*
- Potential disruptive technology on the horizon may include scoring drug coated balloons or drug coated Chocolate balloon (reduces both stent and TLR)

The optimal strategy in infrainguinal intervention will be a combination of reducing stenting, altering biology (antirestenotic drugs) and protecting distal vascular bed

THANK YOU