How to Manage Long SFA Lesions

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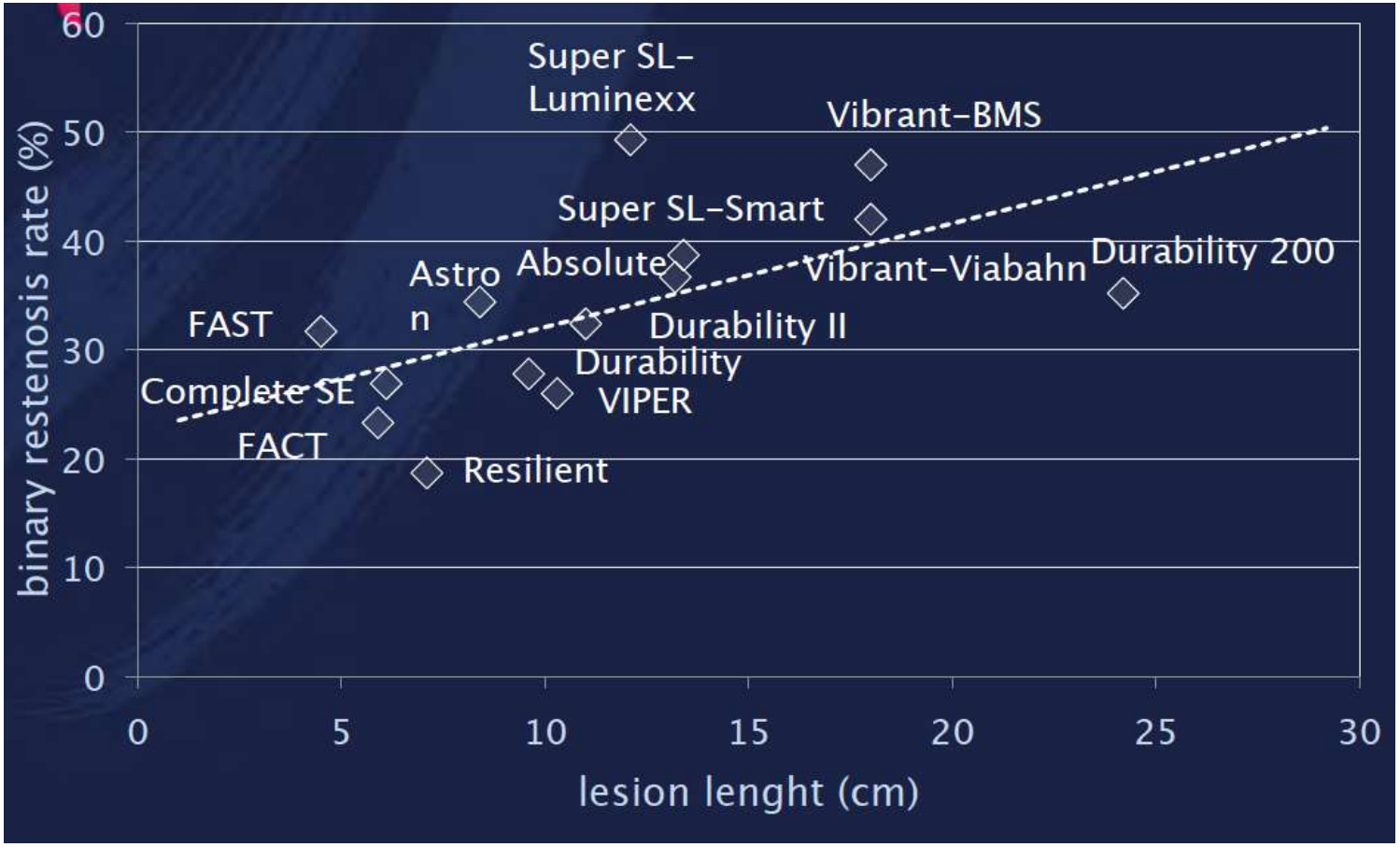
BMS Outcomes



Spot vs Long Stenting after Subintimal Angioplasty

Retrospective analysis: Between 2003 and 2013,
a total of 196 limbs in 163 patients with
stenting after SA for long CTOs (lesion length ~ 25 cm)

Spot stenting
129 limbs (66%)

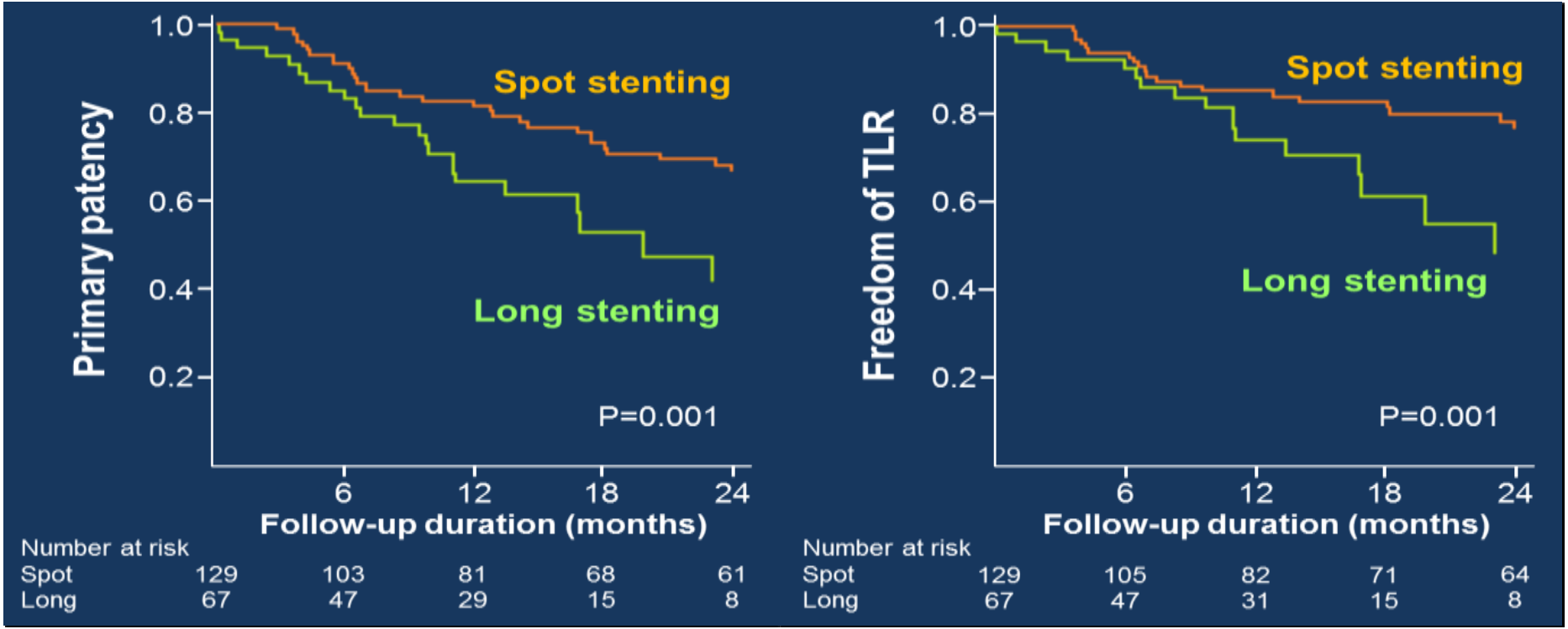
1) Routine stenting at proximal stump
2) Flow-limiting dissection
3) Significant RS >30%

Long stenting
67 limbs (34%)

The entire lesion was covered with overlapping stents

Hong SJ, Ko YG, JACC Intv 2015;8:472

Late Outcomes



Hong SJ, Ko YG, JACC Intv 2015;8:472

Old Endovascular Treatment Options

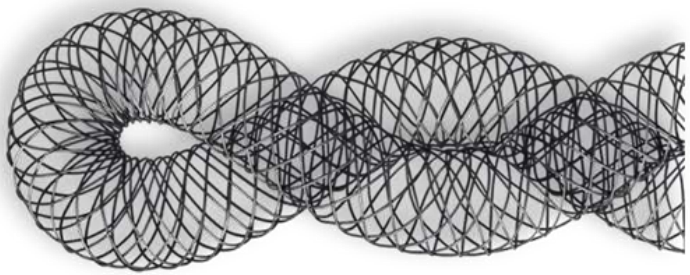
- Conventional balloons and BMS

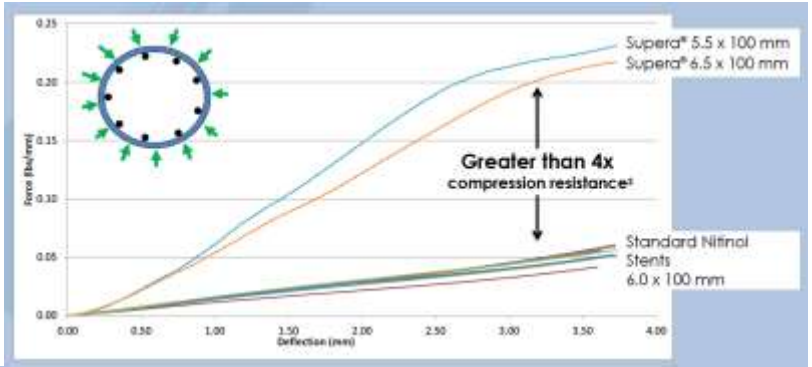
  => not good enough!

Newer Options for Long SFA Lesions

- Interwoven nitinol stent
- Covered stent
- DEB ± pretreatment with atherectomy
- DES

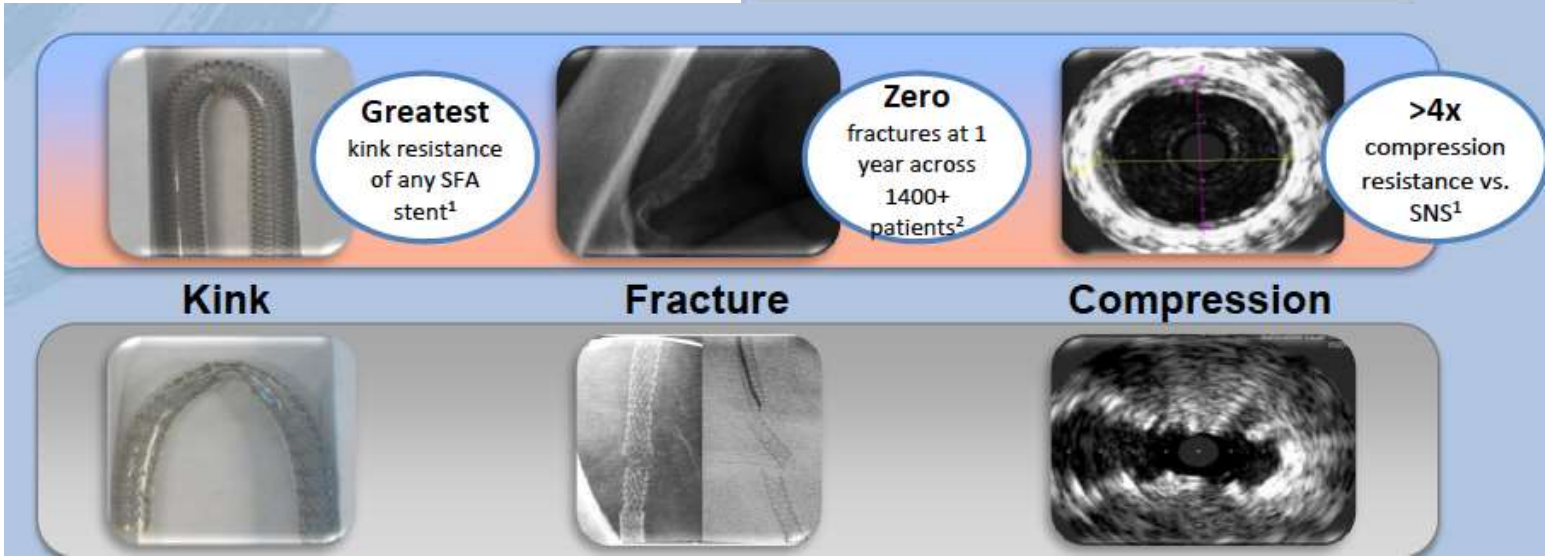
SUPERA: Interwoven Nitinol Stent





Supera

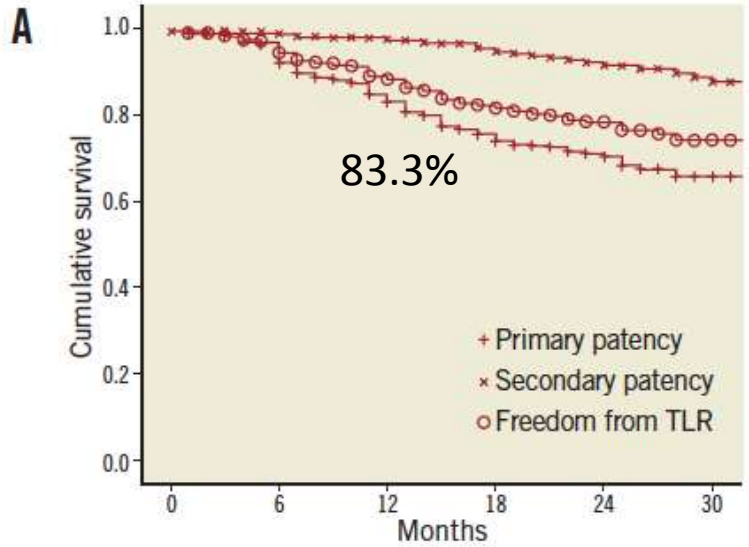
Standard Nitinol Stents



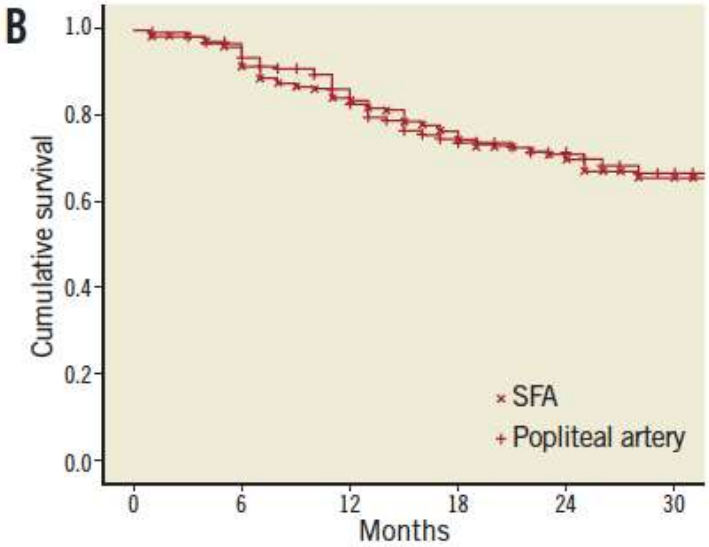
SUPERA 500: Leipzig Registry

N=470,

Mean lesion length 126.4 mm, total occlusion 52.6%



Limbs at risk	Baseline	12 months	24 months
Primary patency	412	280	129
Secondary patency	412	310	153
Freedom from TLR	492	341	148



Limbs at risk	Baseline	12 months	24 months
SFA	233	156	71
Popliteal artery	179	124	58

Werner M, EuroIntervention. 2014;10:861

SUPERA stent

- No RCT data
- No large-scale clinical study for lesion length > 20 cm

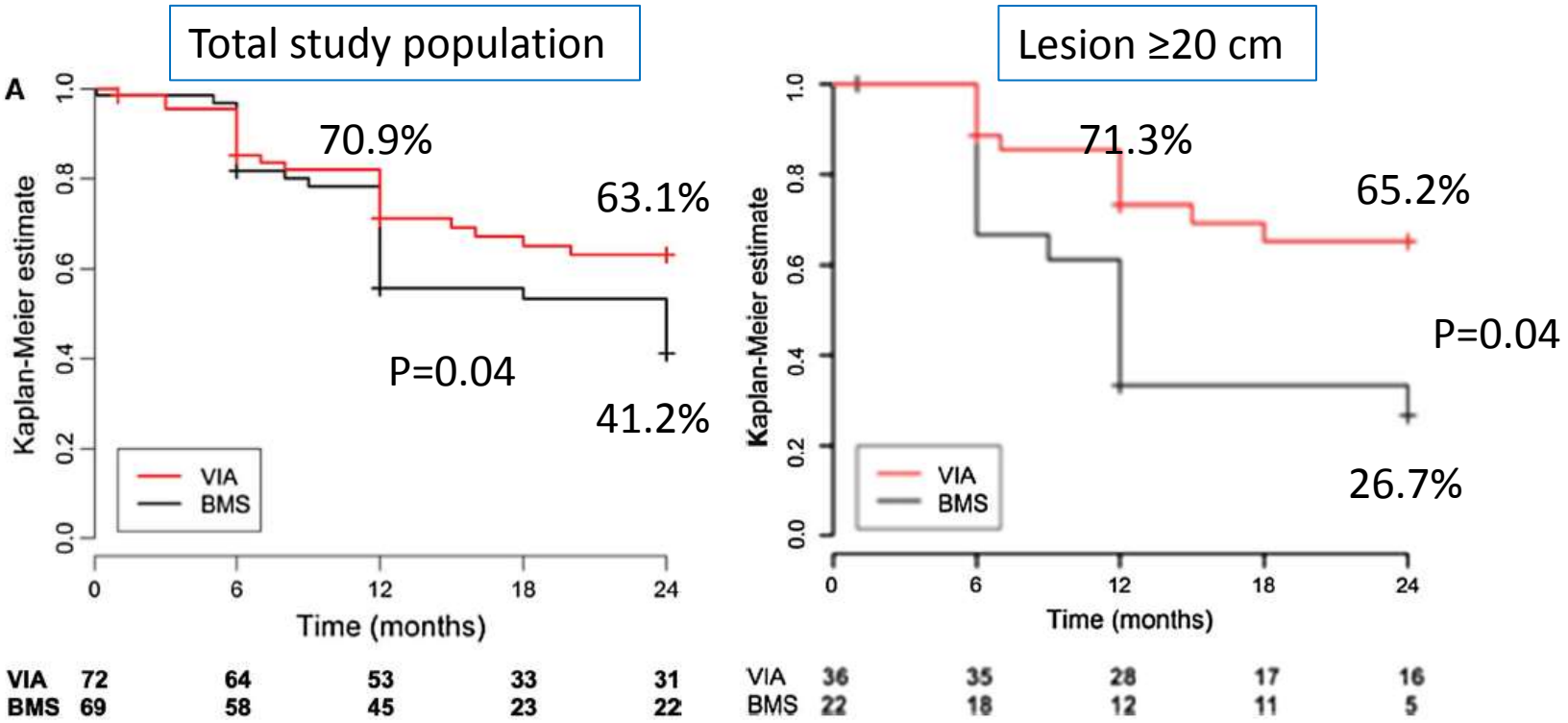
Table 1 Summary of studies of SUPERA stents

Study name	Number of patients	SFA, %	Popliteal, %	Claudicant, %	CLI, %	Mean lesion length, mm	Moderate or severe calcification, %	Occluded segment, %	Primary patency at 1 yr, %	Primary patency at 2 yr, %	Stent fracture at 1 yr, %
Scheinert (2011)[9]	107	100	–	82	17	90	54	31	85	76	0
Goltz (2012)[23]	40	0	100	25	75	–	–	88	68	–	0
George (2014)[15]	80	91	22	68	31	143	–	39	86	–	0
León (2013)[24]	34	0	100	26	74	119	–	44	79	–	0
Scheinert (2013)[21]	101	0	100	67	23	58	52	48	88	–	0
Werner (2014)[12]	439	59	42	82	18	126	52	53	81	62	0
Chan (2014)[14]	78	100	54	59	47	126	–	–	79	–	0
Brescia (2015)[22]	48	100	69	54	46	240	–	–	80	83	0
Dumantepe (2015)[13]	36	–	–	–	–	105	64	33	86	–	0
Garcia (2015)[11]	264	98	13	95	5	78	73	25	79	–	0

Abbreviations: CLI, critical limb ischemia; yr, year; SFA, superficial femoral artery.

Covered Stent: VIASTAR Trial

Heparin-bonded Viabahn
A RCT (N=141), lesion length 19 cm



DCB: Advantages

- "Leaving nothing behind"

  - *good for "no-stent zones"*
  - *no stent-related complications*
  - *Not interferes with future interventions*

IN.PACT Global Long Lesion Imaging Cohort

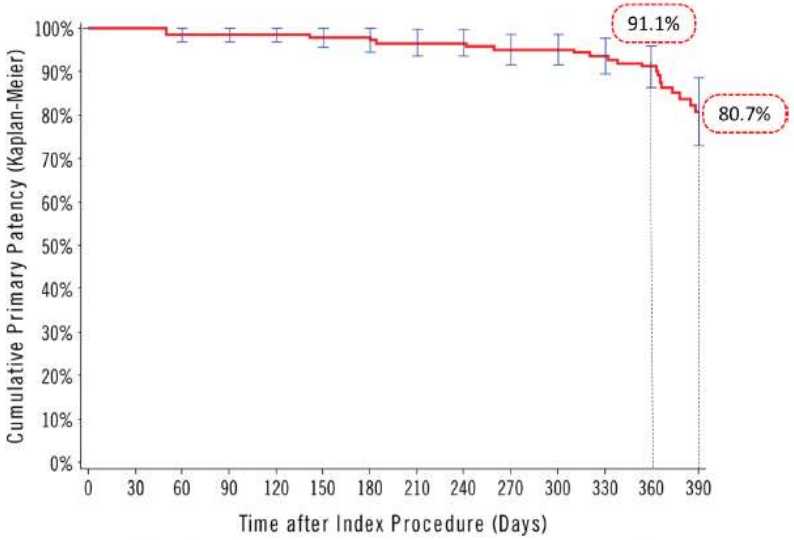
Lesions (N)	164
Lesion Type:	
de novo	83.2% (134/161)
restenotic (no ISR)	16.8% (27/161)
ISR	0.0% (0/161)
Lesion Length	26.40 ± 8.61 cm
Total Occlusions	60.4% (99/164)
Calcification	71.8% (117/163)
Severe	19.6% (32/163)
RVD (mm)	4.594 ± 0.819
Diameter Stenosis (pre-treatment)	90.9% ± 14.2
Dissections: 0	37.9% (61/161)
A-C	47.2% (76/161)
D-F	14.9% (24/161)

Procedural Characteristics	
Device Success [1]	99.5% (442/444)
Procedure Success [2]	99.4% (155/156)
Clinical Success [3]	99.4% (155/156)
Pre-dilatation	89.8% (141/157)
Post-dilatation	39.1% (61/156)
Provisional Stent	40.4% (63/156)
LL 15-25 cm:	33.3% (33/99)
LL > 25 cm:	52.6% (30/57)

1. **Device success:** successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP
2. **Procedure success**: residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
3. **Clinical success:** procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge

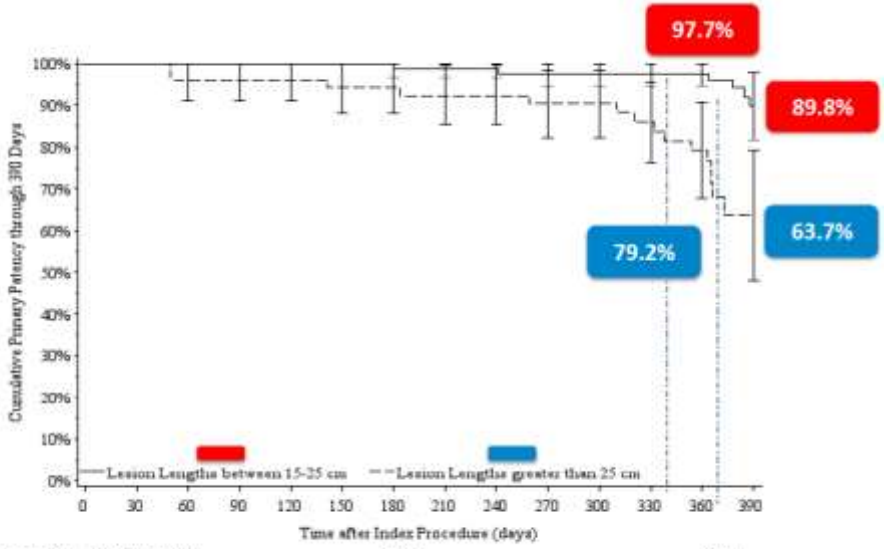
IN.PACT Global Long Lesion Imaging Cohort

Overall primary patency



Number of subjects at risk*	Baseline (day 0)	6 mo	12 mo
IN.PACT™ DCB	157	142	119

Primary patency: long vs. very long

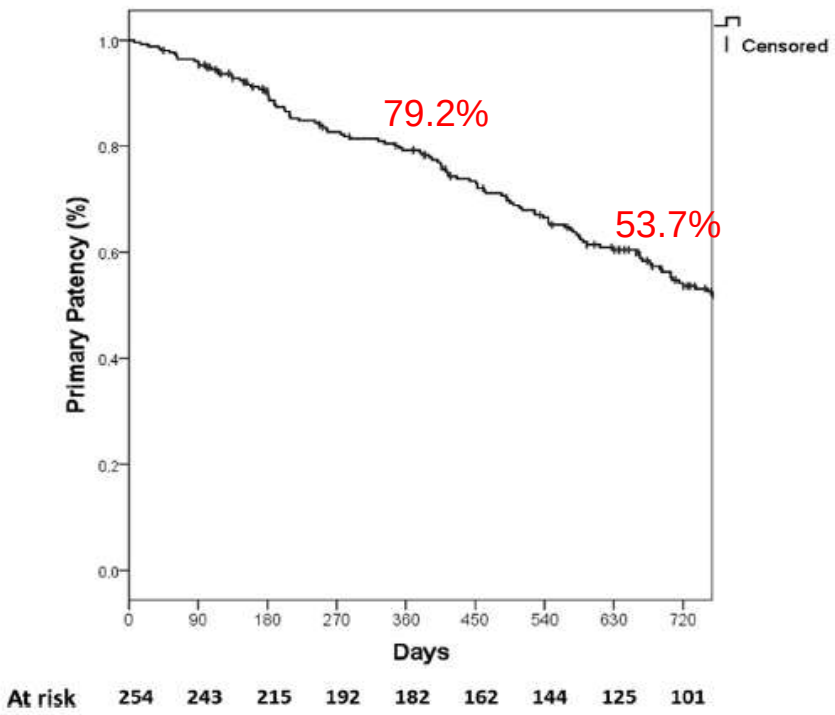


Number of subjects at risk	Baseline (day 0)	6 mo	12 mo
Lesion Length 15-25 cm	100	92	81
Lesion Length >25 cm	57	50	38

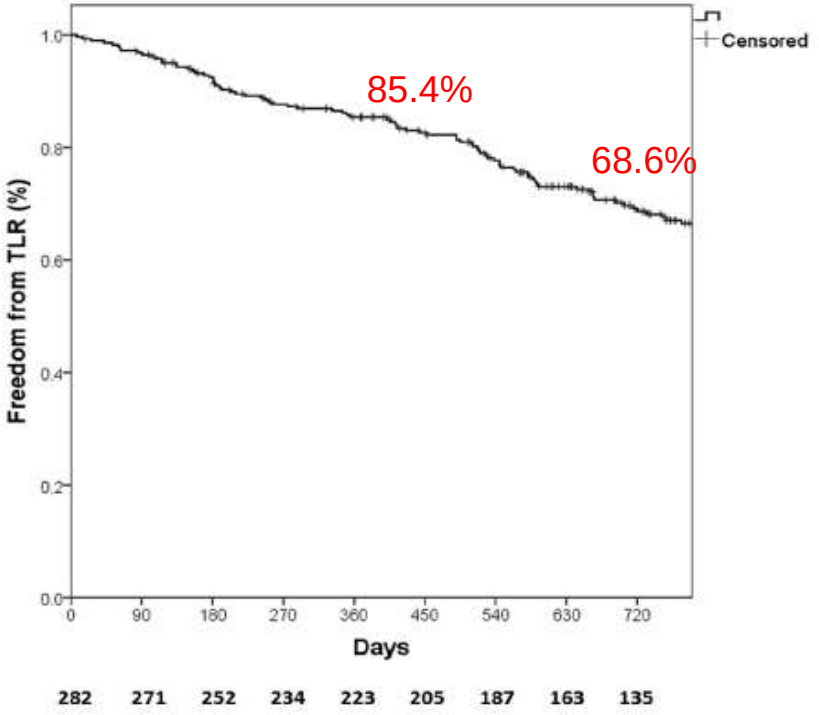
However, Leipzig Data …

288 limbs (260 patients), Lesion length 24 cm, CTO 65%, ISR 37%, InPACT DCB

Primary Patency



TLR-free Survival



Schmidt A, J Am Coll Cardiol Intv 2016;9:715

Challenges to DCB

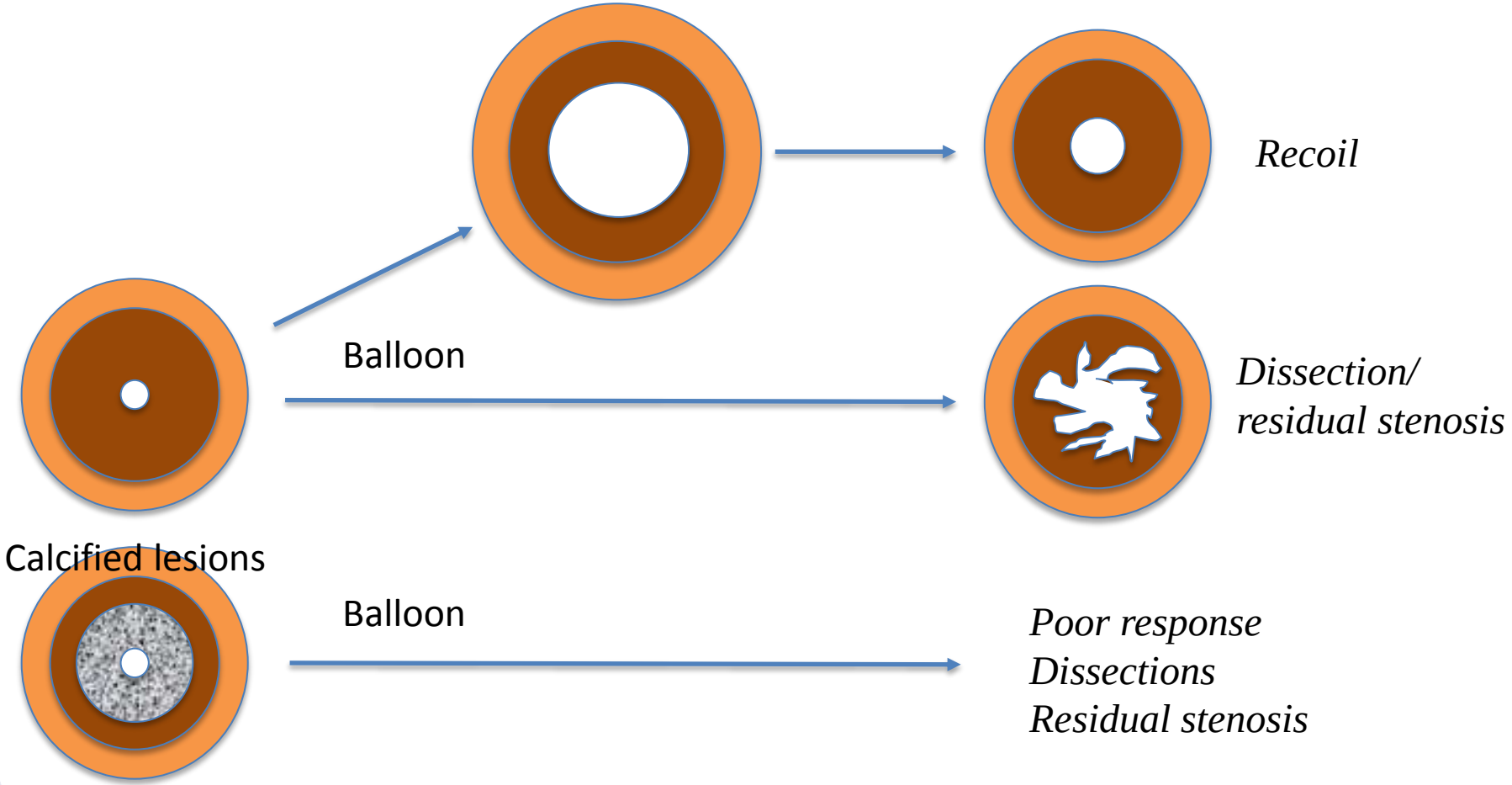
- Long lesions:

  - *more plaque burden, higher risk of dissection*

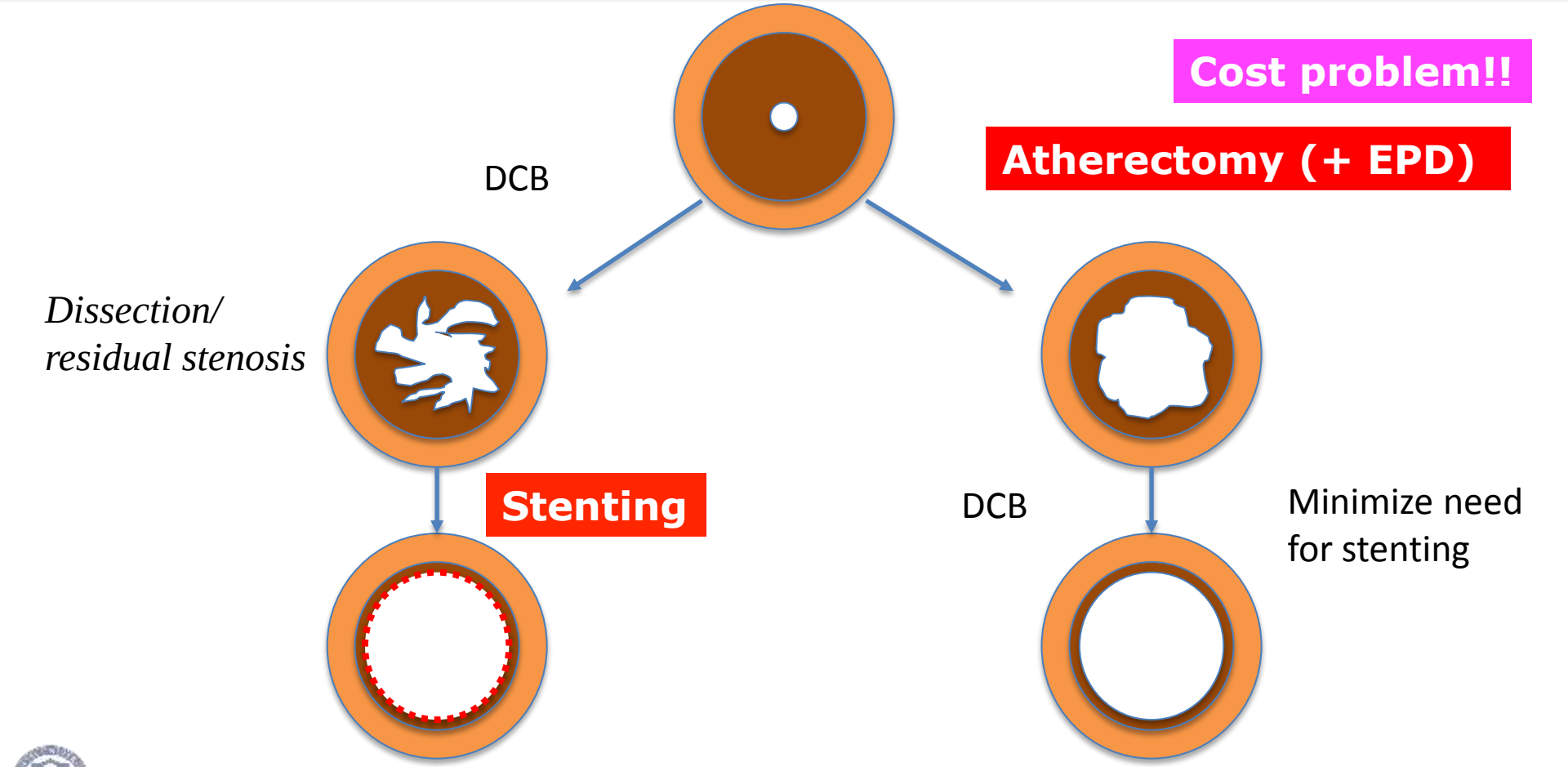
- Calcification:

  - *difficult to dilate, more residual stenosis, higher risk of dissection, insufficient drug delivery*

Limitations of DCB



DCB in Long Lesions May Require …



Zilver PTX

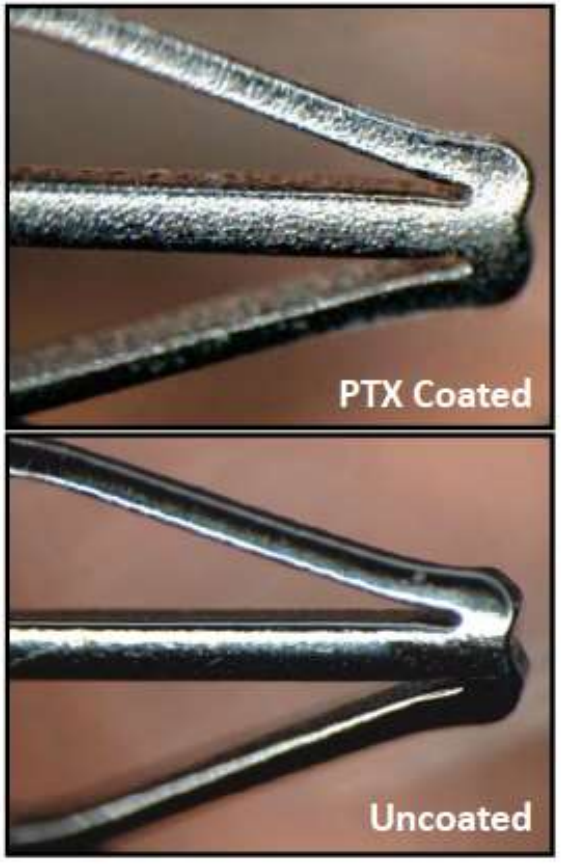
- Stent: Zilver

  - Self-expandable nitinol stent

- Drug: paclitaxel only

  - 3 μg/mm^2 dose density

- No polymer or binder



Zilver PTX Trials

Baseline Clinical Characteristics

	Zilver PTX RCT	Zilver PTX SAS	Zilver PTX Japan PMS
Patients	236	787	907
Age (years)	68 ± 10 *	67 ± 9 *	74 ± 9
Male	66%	73%	70%
Diabetes	50% *	36% *	59%
High cholesterol	76% *	58%	61%
Hypertension	89%	80% *	85%
Pulmonary disease	19% *	9%	8%
Renal Failure (eGFR< 60 and/or "on Dialysis")	0% (10% renal disease*)	Not assessed (11% renal disease*)	36% (44% renal disease)

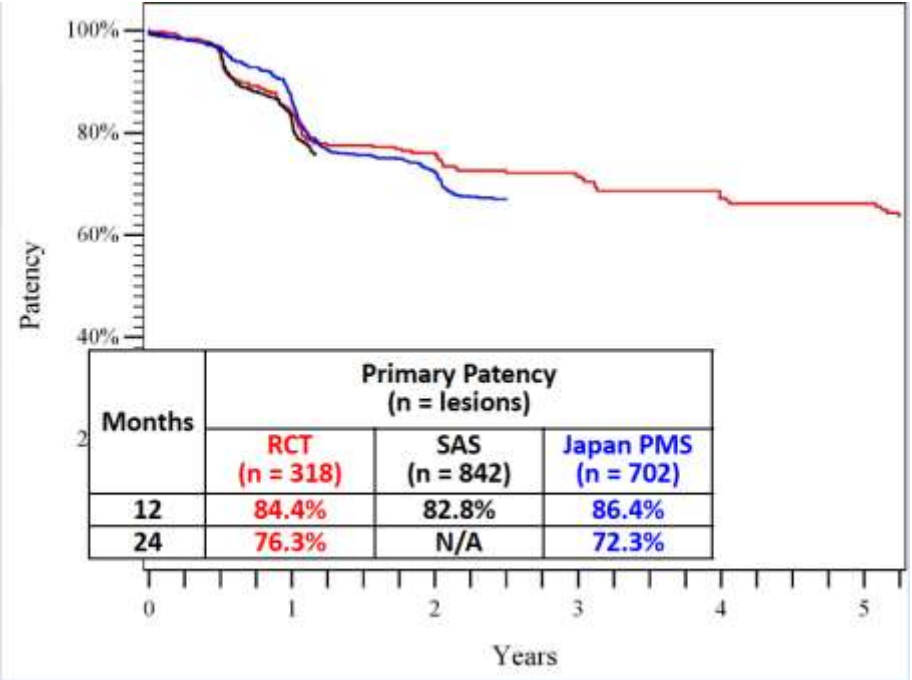
Procedural Data

		Zilver PTX RCT		Ziver PTX SAS		Zilver PTX Japan PMS
Lesions		247		900		1075
Lesion length (cm)		6.6 ± 3.9 *		10.0 ± 8.2 *		14.7 ± 9.7
Diameter stenosis (%)		81 ± 17 *		85 ± 16 *		92 ± 11
Total occlusions		33% *		38%		42%
In-stent restenosis		0% *		15%*		19%
Patent runoff vessels	0	0%		0%		7%
	1	22%	*	19%	*	32%
	2	35%		35%		32%
	≥3	42%		45%		29%

Yokoi H, 2016 LINC

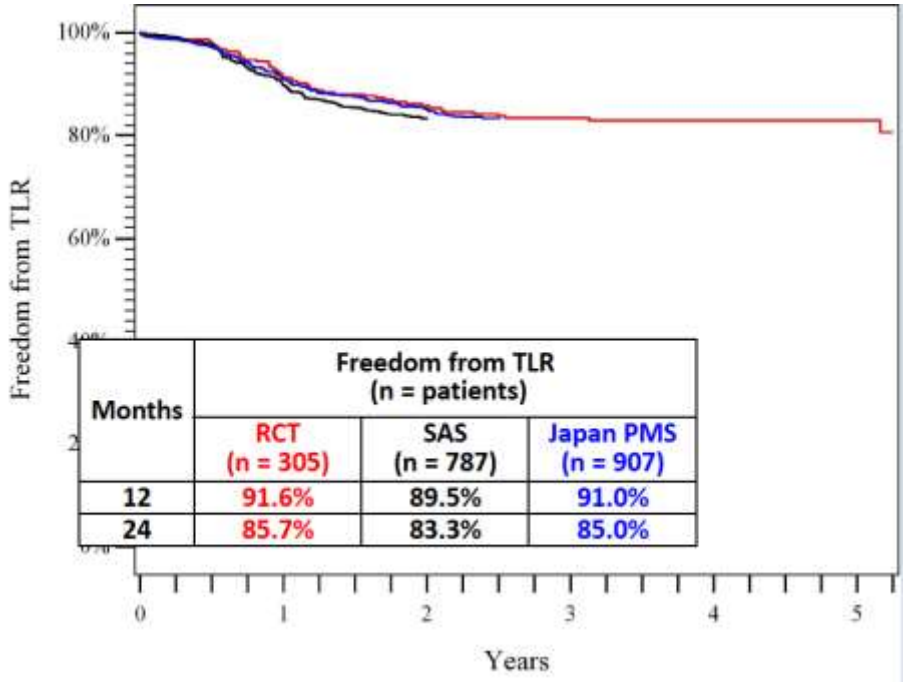
Late Outcomes

Primary Patency



Months	Primary Patency (n = lesions)		
	RCT (n = 318)	SAS (n = 842)	Japan PMS (n = 702)
12	84.4%	82.8%	86.4%
24	76.3%	N/A	72.3%

Freedom from TLR



Months	Freedom from TLR (n = patients)		
	RCT (n = 305)	SAS (n = 787)	Japan PMS (n = 907)
12	91.6%	89.5%	91.0%
24	85.7%	83.3%	85.0%

Yokoi H, 2016 LINC

Stent Integrity

	RCT (n=247)	SAS (n=900)	Japan PMs (n=1075)
Stent fracture rate at 1 year	0.9%	1.5%	1.5%

Zilver PTX

- Relatively simple procedures
- High patency rates
- Low stent fracture rates
- No late catch-up phenomenon

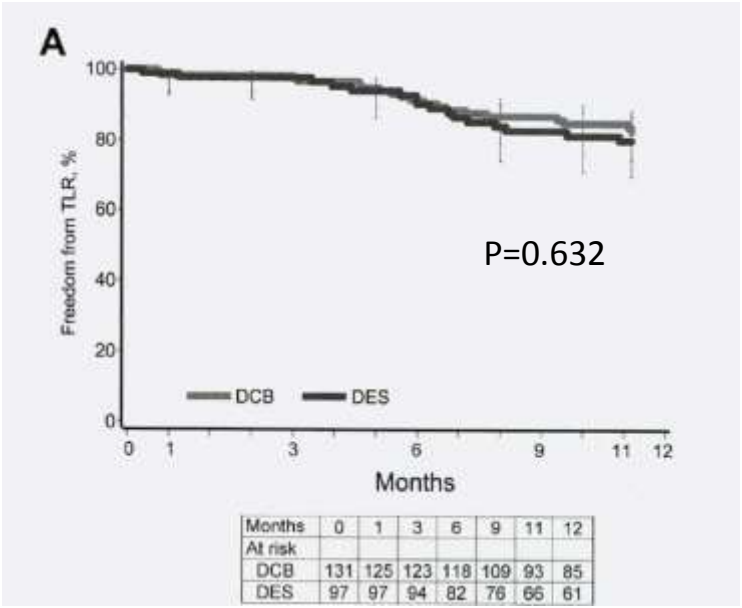
- *However, little data in very long lesions !*

DES vs DCB: Retrospective Data

Baseline Patient Characteristics

	DCB (n=131)	DES (n=97)	p
Patient characteristics			
Age, y	68.9±10.5 [69, 45–94]	68.2±8.0 [69, 48–85]	0.586
Men	77 (58.8%)	62 (63.9%)	0.432
Diabetes	53 (40.5%)	37 (38.1%)	0.724
End-stage renal disease	2 (1.5%)	2 (2.1%)	0.761
Renal insufficiency*	29 (22.1%)	18 (18.6%)	0.509
Hyperlipidemia	110 (84.0%)	79 (81.4%)	0.616
Past/current smoker	90 (68.7%)	66 (68.0%)	0.915
Hypertension	109 (83.2%)	78 (80.4%)	0.587
Rutherford class			0.052
1	3 (2.3%)	3 (3.1%)	
2	15 (11.5%)	14 (14.4%)	
3	88 (67.2%)	72 (74.2%)	
4	14(10.7%)	3 (3.1%)	
5	8 (6.1%)	4 (4.1%)	
Unknown	3 (2.3%)	1 (1.0%)	
Lesion characteristics			
Proximal SFA	66 (50.4%)	51 (52.6%)	0.743
Mid	92 (70.2%)	77 (79.4%)	0.119
Distal	100 (76.3%)	84 (86.6%)	0.052
P1	34 (26.0%)	17 (17.5%)	0.131
P2	14 (10.7%)	0 (0.0%)	<0.001
P3	10 (7.6%)	0 (0.0%)	0.005
Total length, mm	194.4±86.3 [160, 100–450]	195.0±64.5 [190, 100–350]	0.948
Restenotic lesion	68 (51.9%)	43 (44.3%)	0.258
Lesion calcification			0.527
None	41 (31.3%)	20 (20.6%)	
Slight	33 (25.2%)	47 (48.5%)	
Moderate	31 (23.7%)	21 (21.6%)	
Severe	26 (19.8%)	9 (9.3%)	
Diameter stenosis, %	93.5±8.6 [100, 70–100]	95.4±7.6 [100, 70–100]	0.073
Total occlusions	69 (52.7%)	61 (62.9%)	0.123
Subintimal	11 (8.4%)	17 (17.5%)	0.038
Re-entry device used	6 (4.6%)	9 (9.3%)	0.157

Freedom from TLR



Zeller T,
J Endovasc Ther 2014;21:359

Summary & Conclusions

- Conventional balloon and BMS have relatively high restenosis rates in long SFA lesions.
- Newer devices esp. drug-eluting technologies have shown promising data.
- DES and DEB have advantages and limitations.
- DEB may be not effective as a stand alone therapy in long SFA lesions. Stenting or atherectomy may be required as adjunctive treatment.
- Zilver PTX has shown excellent patency and safety data.
- We need RCTs and large-scale long-term comparing DES and DCB in long SFA lesions.


Thank you
for your attention!