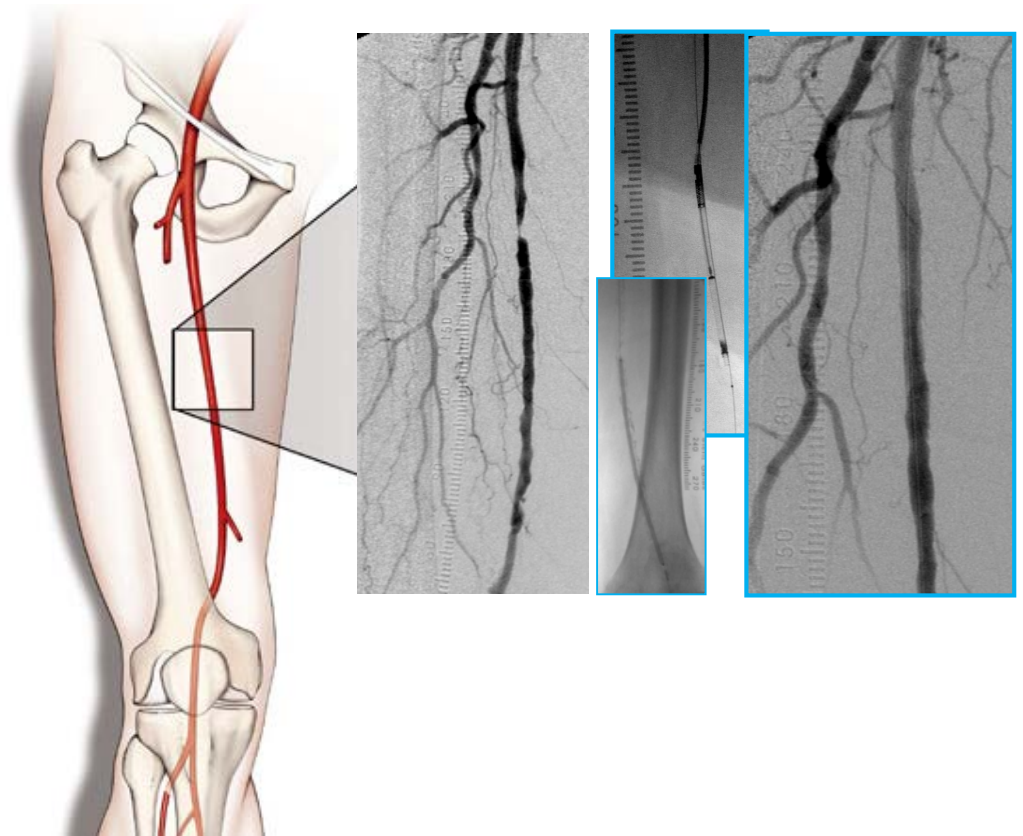


My most promising perspective with new concept for SFA (endo)treatment

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My most promising perspective with new concept for SFA (endo)treatment

Disclosure

Speaker name: *Prof. Mauro Gargiulo*

I have no potential conflicts of interest to report

PERSPECTIVES 2017

December Friday 15 - BORDEAUX

Organization: E. Ducasse, M. Sibé



www.congresperspectives.com



Vascular Surgery – University of Bologna

SFA Endo Treatment



Patients (2010-2012)	122
Limbs	136
Men	72-59%
Mean age	71.9 years (40-87)
Hypertention	84.4%
Coronary artery disease	53.3%
Diabetes Mellitus	65.5%
End-Stage-Renal-disease	32%



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Clinical Characteristics	N
CLI	122-89.7%
TUC grade III	65 - 47.8%
TUC stage D	40 - 29.4%



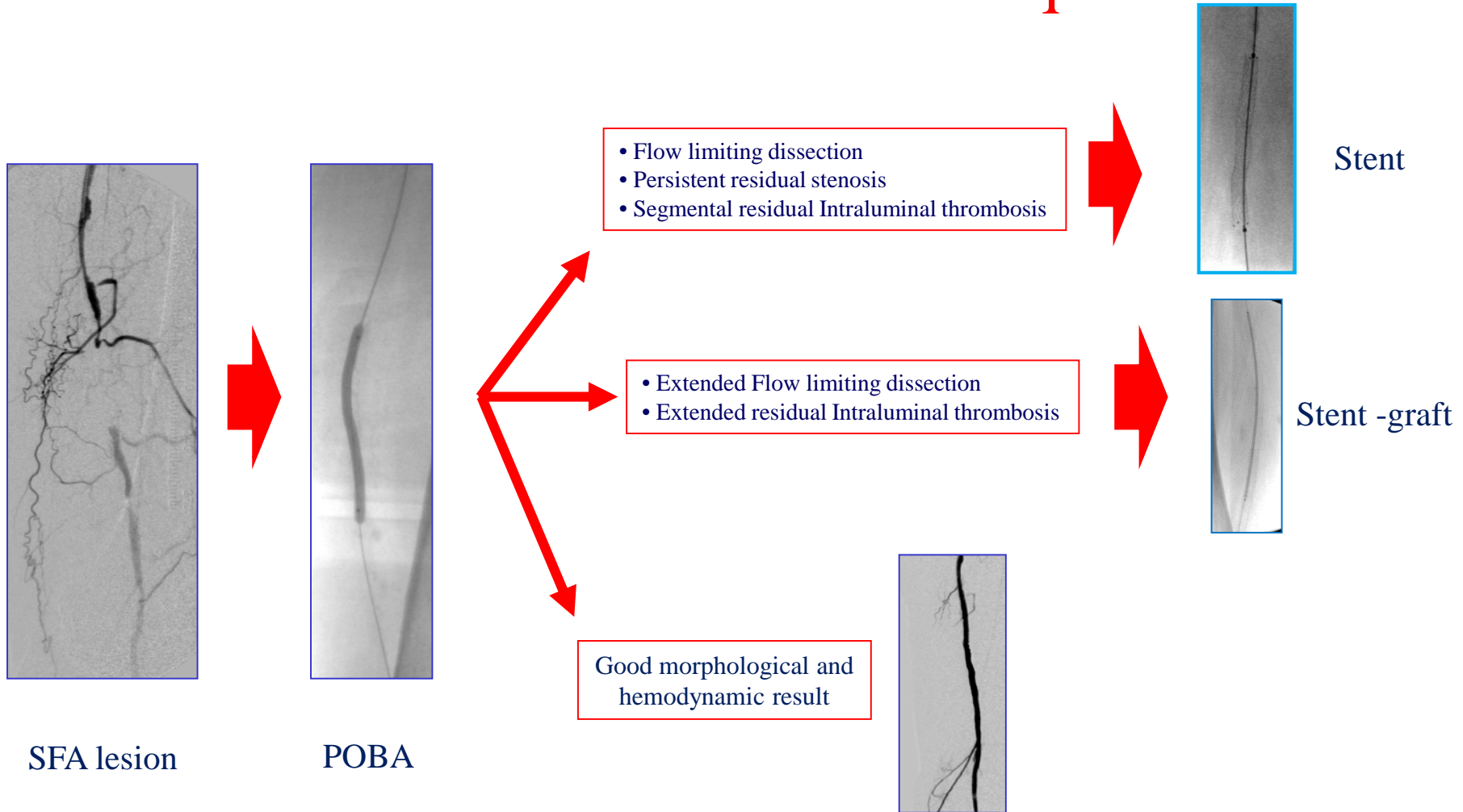


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Type of lesions	N	
Stenosis	100 (73.5%)	
Occlusion	36 (26.5%)	
< 5 cm	8	
5-10 cm	15	
> 10 cm	13	



SFA - Endovascular Techniques





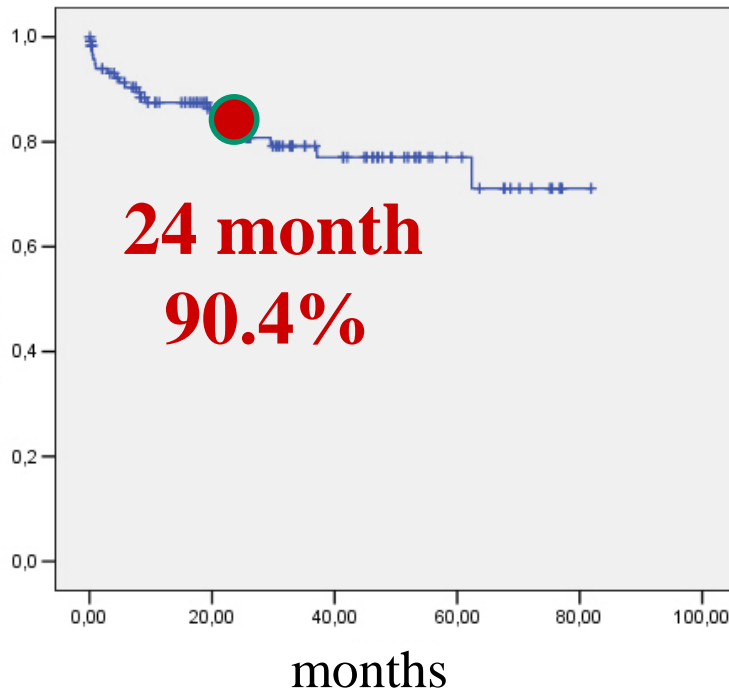
Endovascular Techniques

- PTA: 89 limbs (65.4%)
- PTA+ Stent: 29 limbs (21.3%)
- PTA+ Stent-Graft: 18 limbs (13.2%)



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Mean follow-up
 28.34 ± 22.4 months (range 6-81.8)

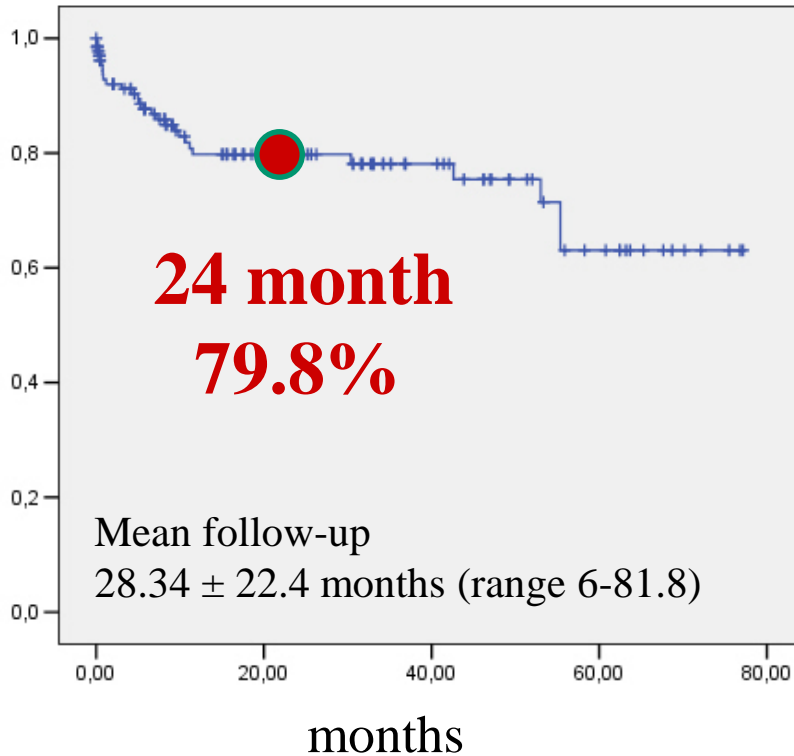


VARIABLES	p	HR (95%CI)
Demographics		
age	ns	
women vs men	ns	
Risk Factors		
hypertension	ns	
CAD	0.043	2.65 (1.03-6.81)
diabetes mellitus	ns	
cerebrovascular disease	ns	
ESRD	0.001	6.88(2.62-18.04)
ex-smoker	Ns	
Fontaine stage		
IV vs III-IIB	ns	
TUC		
IIID vs < IIID	ns	
III vs < III	ns	
Stage D vs C	ns	



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Limb Salvage %



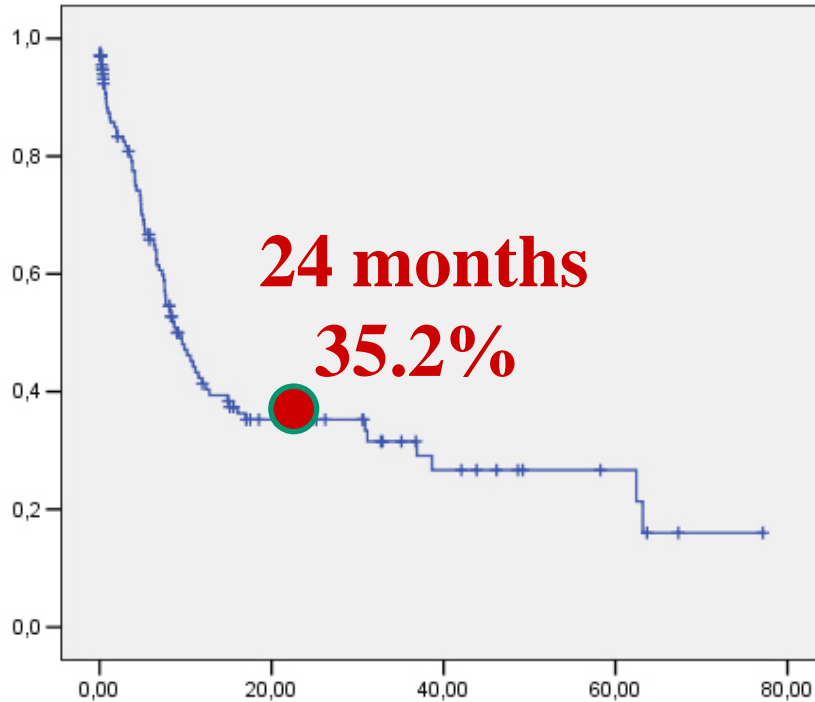
VARIABLES	p	HR (95%CI)
Demographics		
age	ns	
women vs men	ns	
Risk Factors		
hypertension	ns	
CAD	ns	
diabetes mellitus	ns	
cerebrovascular disease	ns	
ESRD	ns	
ex-smoker	ns	
Fontaine stage		
IV vs III-IIB	ns	
TUC		
III D vs < III D	ns	
III vs <III	0.054	2.04 (1.06-3.90)
Stage D vs C	0.048	2.27 (1.24-4.16)
Type of SFA lesions		
Stenosis vs Occlusion	ns	



Vascular Surgery – University of Bologna

Restenosis 24 months: 64.8%

Primary Patency %



months

Mean follow-up

28.34 ± 22.4 months (range 6-81.8)

VARIABLES	p	HR (95%CI)
Demographics		
age	ns	
women vs men	ns	
Risk Factors		
hypertension	ns	
CAD	ns	
diabetes mellitus	ns	
cerebrovascular disease	ns	
ESRD	ns	
ex-smoker		
Fontaine stage		
IV vs III-IIB	ns	
TUC		
IIID vs < IIID	ns	
III vs < III	ns	
Stage D vs C	ns	
Type of SFA lesions		
Stenosis vs Occlusion	0.049	1.63 (1.00-2.65)



Vascular Surgery – University of Bologna

2014-2016: 51 pts – SFA treated with DCB

Patient demographics and characteristics	Mean, %		
Age (mean ± SD)	68.9 ± 11.6 years		
Male gender	76.5		
Coronary Artery Disease (CAD)	47.1		
Renal Insufficiency	41.2		
	- Dialysis: 11.8		
COPD	15.7		
Blood Hypertension	96.1		
	80.4		
Diabetes Mellitus	- Insulin		
	dependent: 37.3		
Obesity	29.4		
Dyslipidemia	72.5		
Smoke	53		
		Clinical stage (Rutherford)	- 3: 4%
			-4: 3.9%
			-5: 49%
			-6: 43.1%
		Trophic lesion (TWC)	-III: 60.8%
			-D: 40%
		Arterial Lesions	De novo: 65%
			Ristenosis: 35%



Vascular Surgery – University of Bologna

2014-2016: 51 pts – SFA treated with DCB

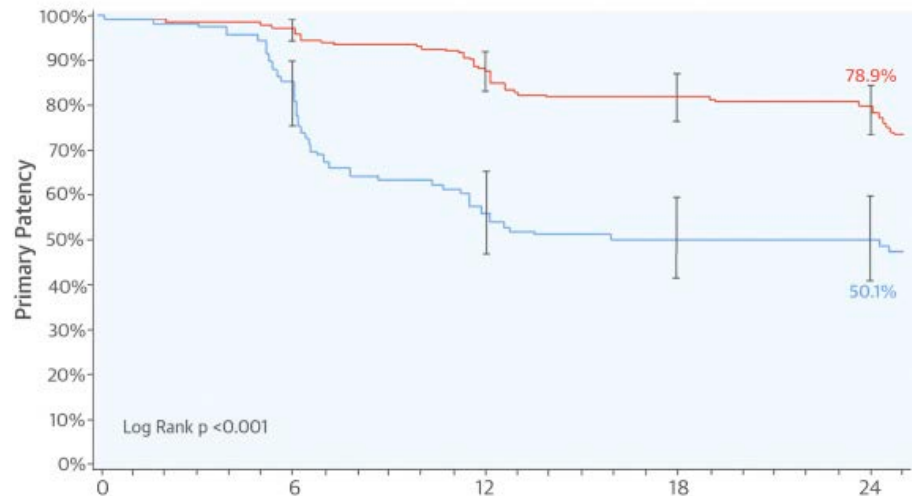
Technical Success: 98%

Results (mean F-U 18.4 months)	%
Survival 1 year	92.2%
Limb salvage 6 months	97%
Limb salvage 1 year	95%
Primary patency 6 months	89.9%
Primary patency 1 year	86.3%

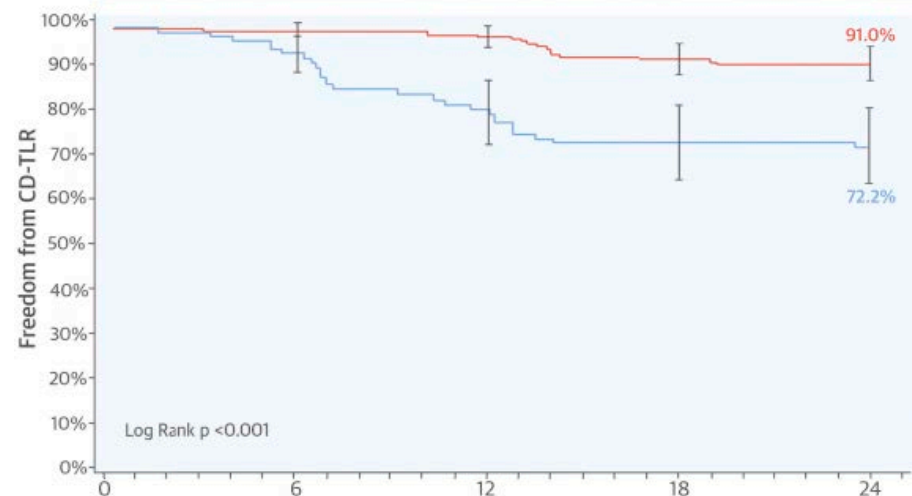
Durability of Treatment Effect Using a Drug-Coated Balloon for Femoropopliteal Lesions : 24-Month Results of IN.PACT SFA

Laird JR et al.
JACC 2015; 66: 2329-2338

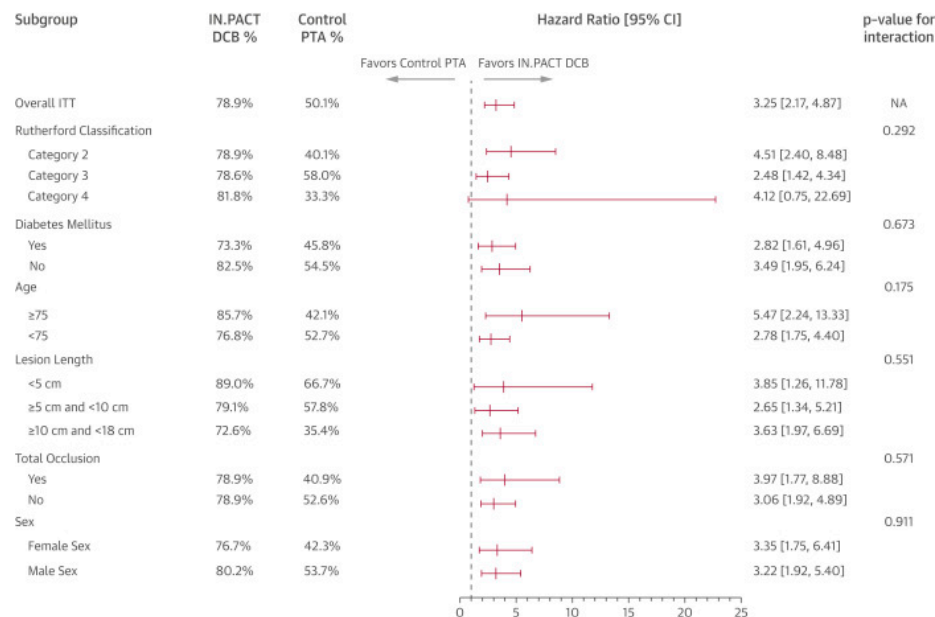
A. Primary Patency



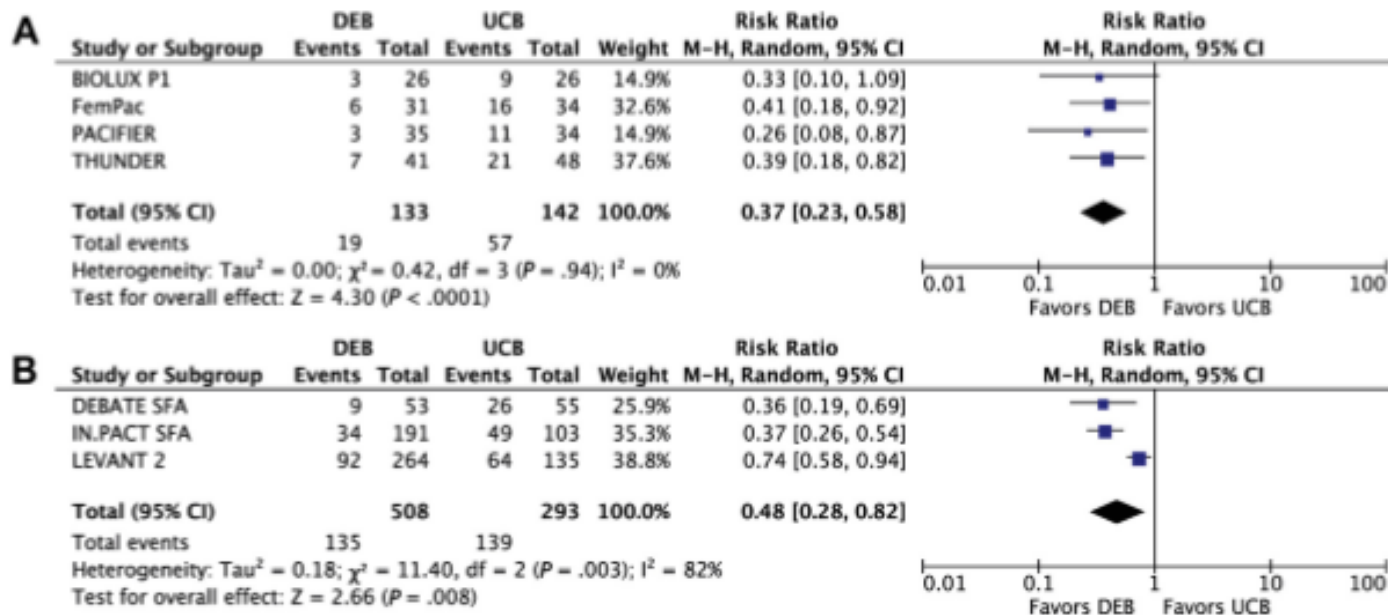
B. Freedom from Clinically Driven Target Lesion Revascularization



DCB PTA



SFA DEB vs PTA - Ristenosis

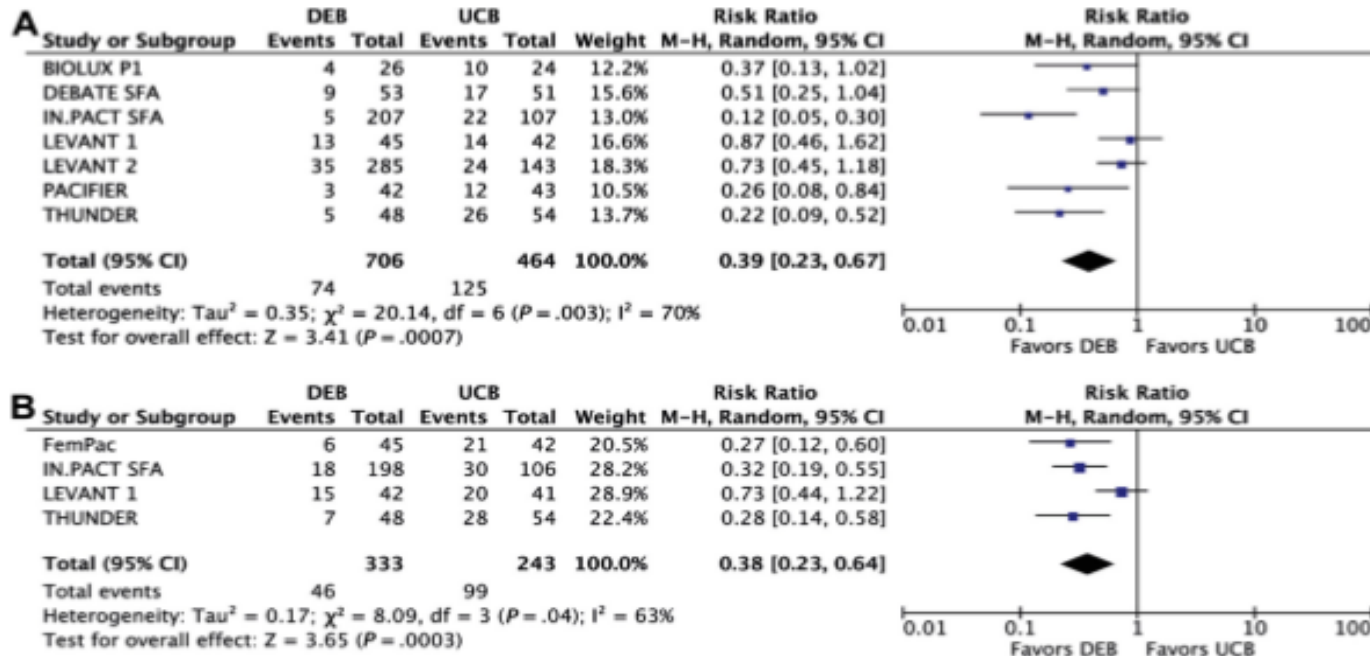


6 months

12 months

Fig 3. Binary restenosis **(A)** after 6 months and **(B)** after 1 year. The *solid squares* indicate the mean difference and are proportional to the weights used in the meta-analysis. The *horizontal lines* represent the 95% confidence interval (CI). The *diamond* indicates the weighted mean difference, and the lateral tips of the diamond indicate the associated 95% CI. The *solid vertical line* indicates no effect. DEB, Drug-eluting balloon; M-H, Mantel-Haenszel; UCB, uncoated balloon.

SFA DEB vs PTA - TLR



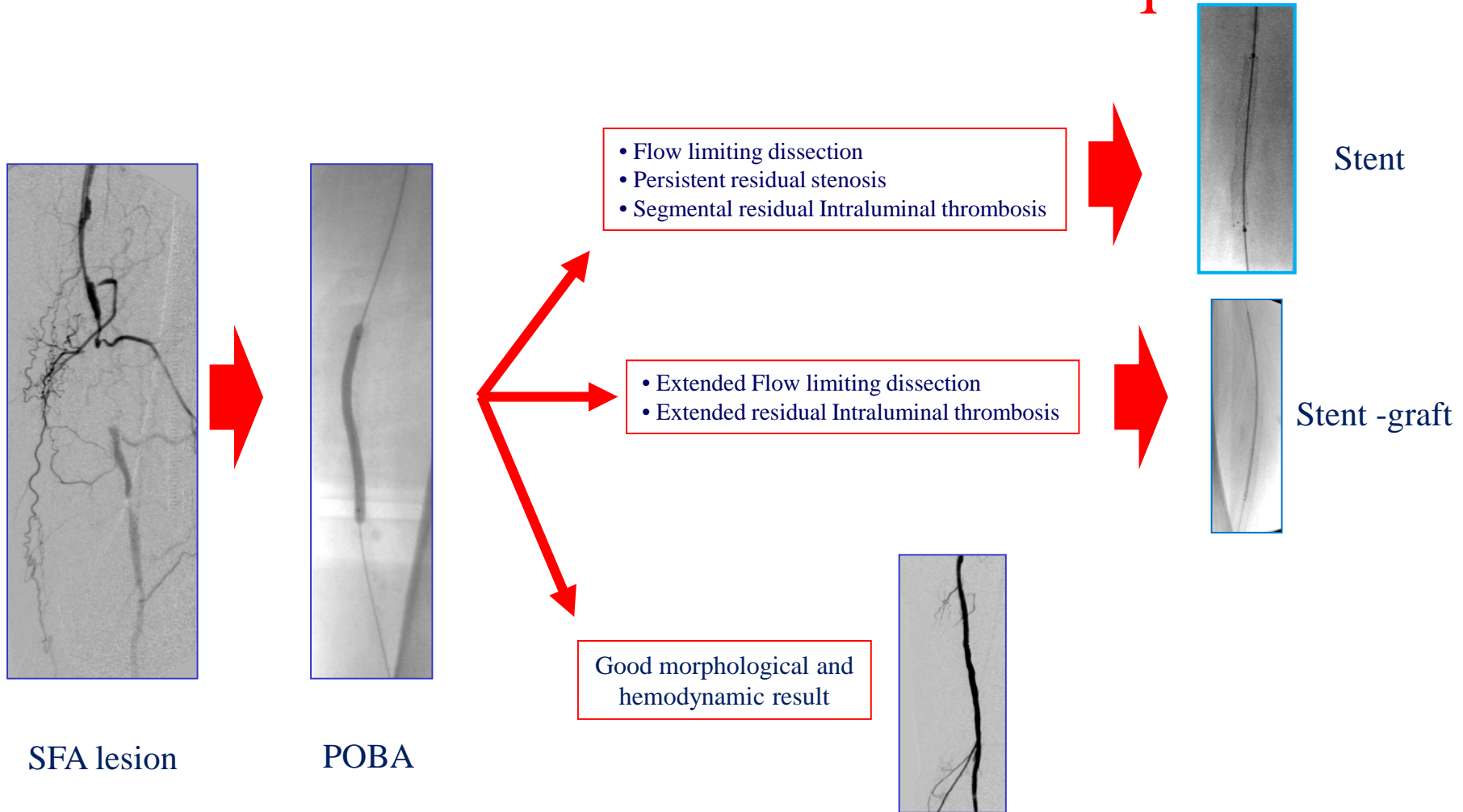
12 months

24 months

Fig 5. Target lesion revascularization (TLR) **(A)** after 1 year and **(B)** after 2 years. The *solid squares* indicate the mean difference and are proportional to the weights used in the meta-analysis. The *horizontal lines* represent the 95% confidence interval (CI). The *diamond* indicates the weighted mean difference, and the lateral tips of the diamond indicate the associated 95% CI. The *solid vertical line* indicates no effect. DEB, Drug-eluting balloon; M-H, Mantel-Haenszel; UCB, uncoated balloon.

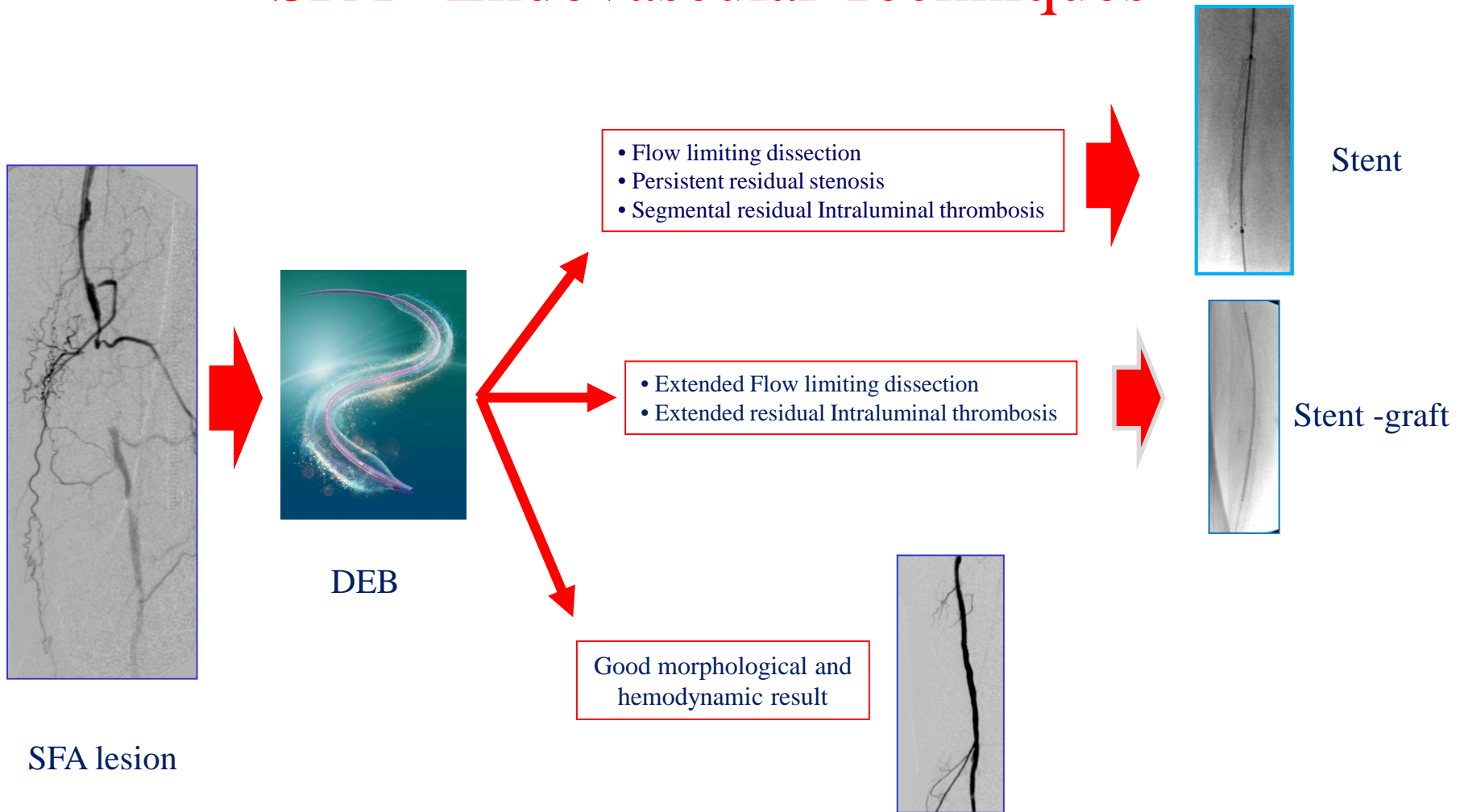


2010 - SFA - Endovascular Techniques





SFA - Endovascular Techniques



Cost-Effectiveness of Endovascular Femoropopliteal Intervention Using Drug-Coated Balloons Versus Standard Percutaneous Transluminal Angioplasty: Results From the IN.PACT SFA II Trial.

Salisbury AC et al.

JACC Cardiovascular Intervention 2016;9(22):2343-52

	DCB (n = 121)	Standard PTA (n = 60)	Difference (95% CI)	p Value
Length of stay (days)	0.65 ± 0.63	0.73 ± 1.21	-0.08 (-0.35 to 0.19)	0.56
ICU length of stay (days)	0.04 ± 0.30	0.10 ± 0.44	-0.06 (-0.17 to 0.05)	0.29
Non-ICU length of stay (days)	0.61 ± 0.60	0.63 ± 0.88	-0.02 (-0.24 to 0.20)	0.85
Nonprocedural hospitalization costs (\$)	1,774 ± 1,619	1,966 ± 2,041	-192 (-743 to 360)	0.53
Inpatient physician fees (\$)	566 ± 110	594 ± 193	-28 (-73 to 16)	0.30
Total hospitalization cost (\$)	8,293 ± 3,230	7,164 ± 3,325	1,129 (113 to 2,146)	0.03

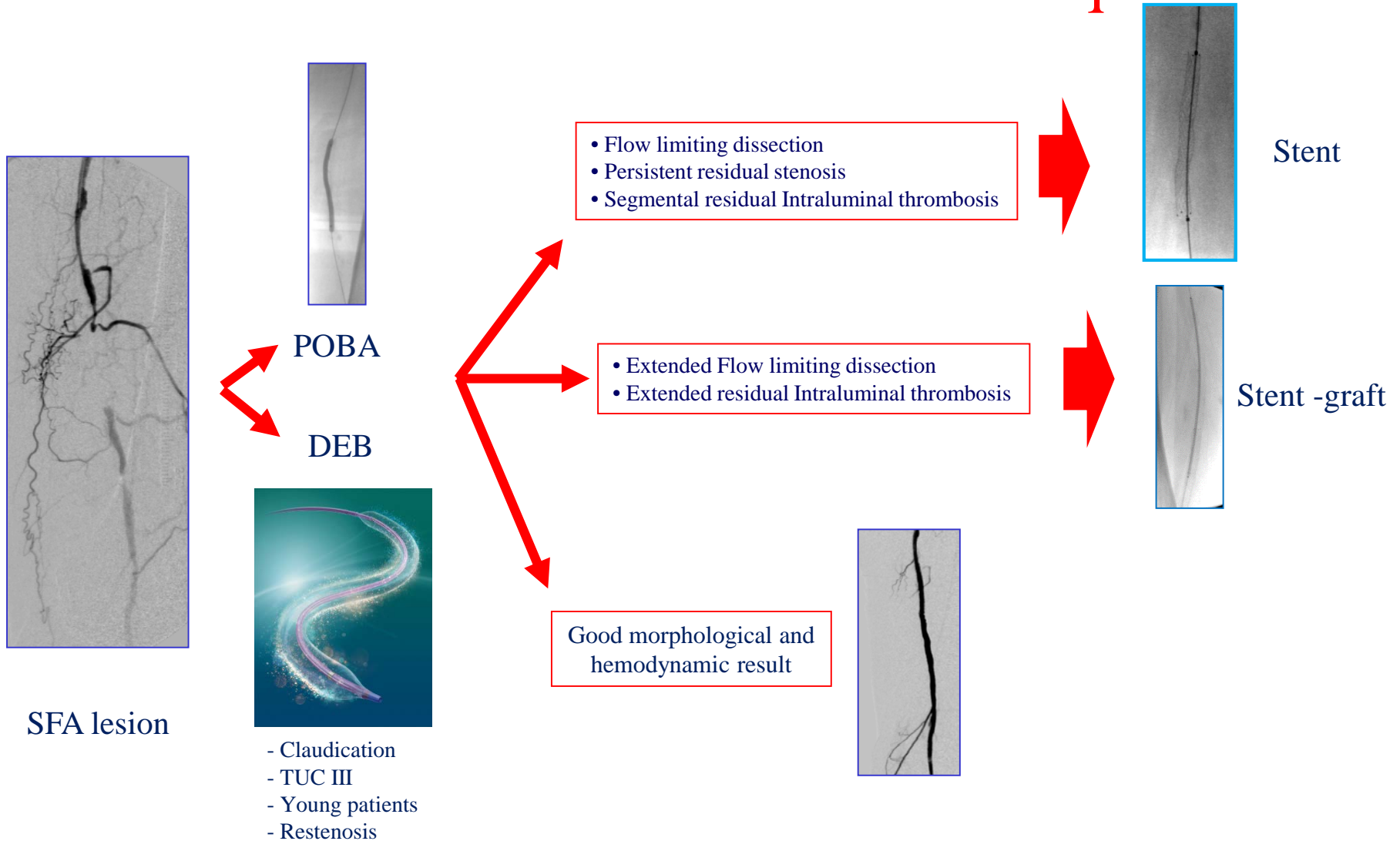
Costs (\$)	DCB (n = 121)	Standard PTA (n = 60)	Difference (95% CI)	p Value
Target limb vascular hospitalizations	2,171 ± 12,208	3,158 ± 7,143	-987 (-4,354 to 2,379)	0.48
Inpatient physician fees	208 ± 1,029	368 ± 933	-159 (-470 to 152)	0.30
Follow-up medications	605 ± 757	670 ± 776	-65 (-303 to 173)	0.54
2-year follow-up	2,984 ± 13,247	4,196 ± 8,251	-1,212 (-4,899 to 2,476)	0.44

Conclusions

For patients with femoropopliteal disease, *DCB angioplasty is associated with better 2-year outcomes and similar target limb-related costs compared with standard PTA.* Formal cost-effectiveness analysis on the basis of these results suggests that use of the DCB angioplasty is likely to be economically attractive.



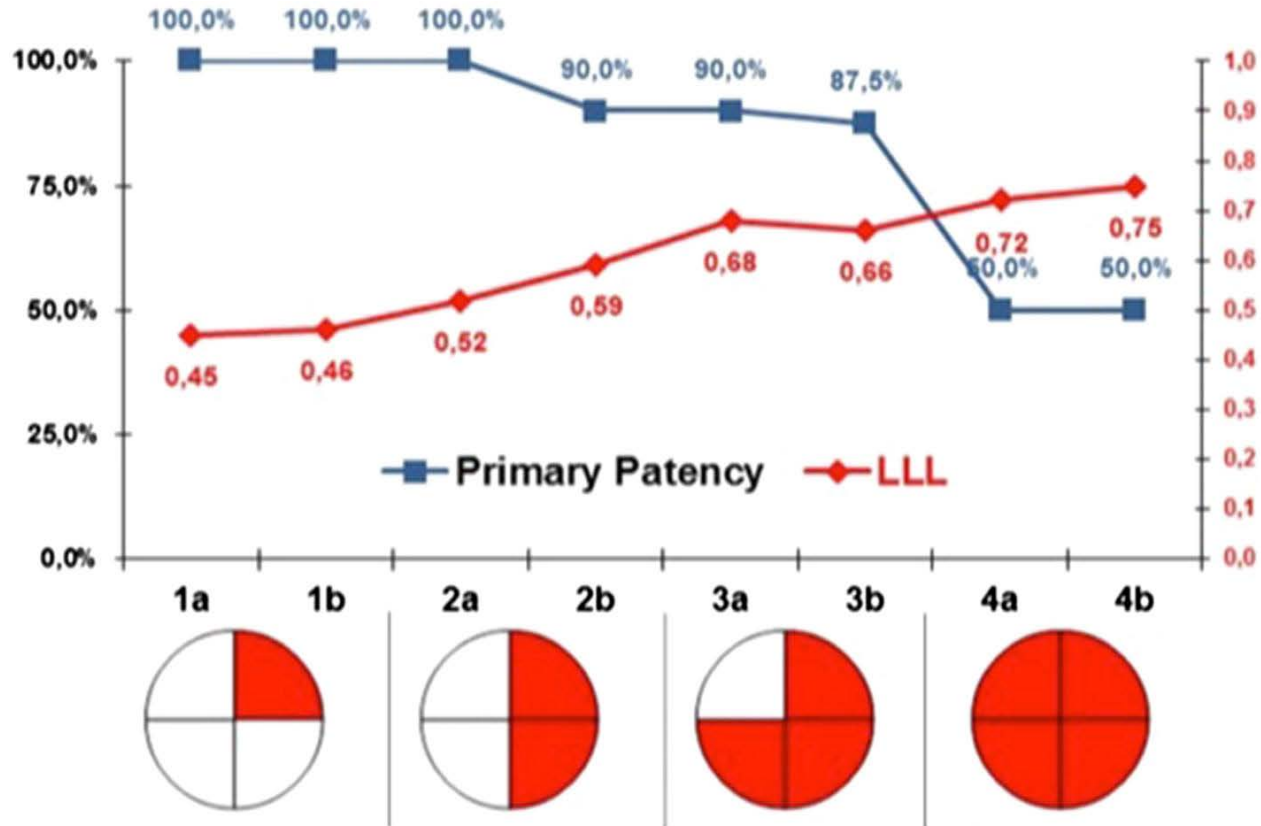
2016 - SFA - Endovascular Techniques



Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease

Fanelli F et al.

Cardiovasc Intervent Radiol 2014; 37: 898-907



A strong correlation between LLL, PP and the severity of calcium was clearly evident with the progressive worsening of both endpoints when calcium grade increased



Vascular Surgery – University of Bologna

SFA Occlusion (5-20 cm) with calcified plaque



Three-Year Results After Directional Atherectomy of Calcified Stenotic Lesions of the Superficial Femoral Artery

P. Minko · A. Buecker · S. Jaeger · M. Katoh

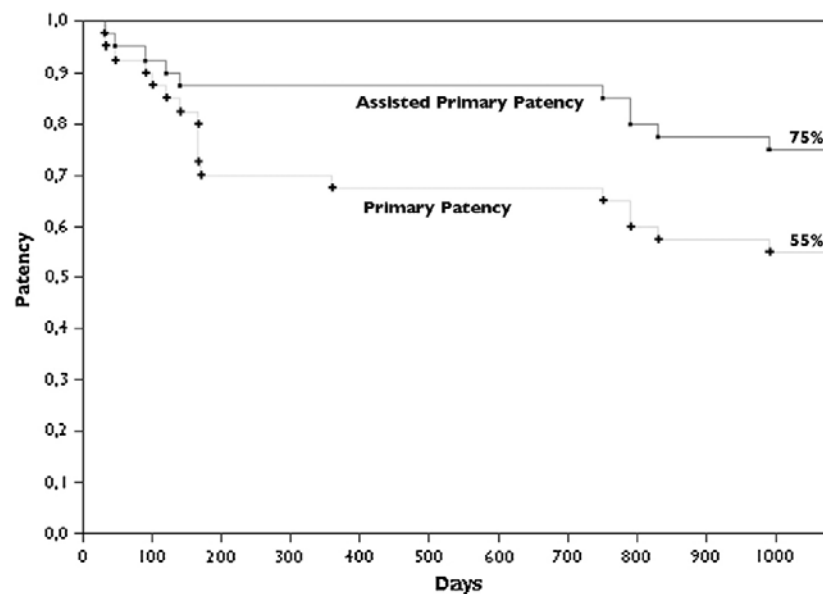
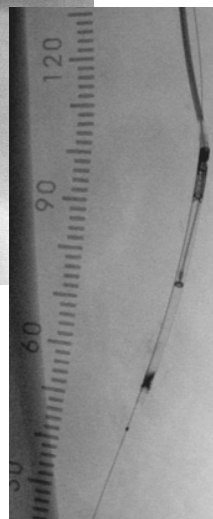
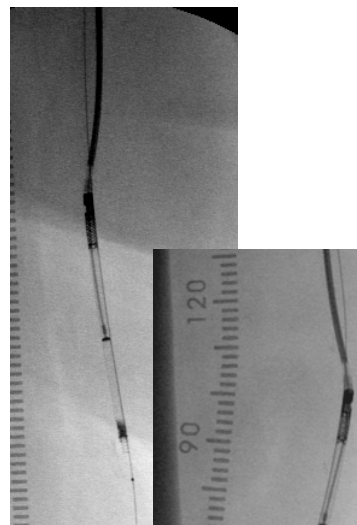


Table 3 Summary of Rutherford score and ABI

	Initial	6 mo	12 mo	18 mo	24 mo	30 mo	36 mo
Rutherford score (median) (IQR)	5 (3)	1 (3)	1 (3)	1 (3)	1 (3)	0 (1)	0 (1)
ABI (mean \pm SD)	0.65 (\pm 0.38)	1.07 (\pm 0.41)	0.97 (\pm 0.37)	0.99 (\pm 0.21)	0.92 (\pm 0.47)	0.97 (\pm 0.30)	1.12 (\pm 0.33)

Median Rutherford score decreased significantly from 5 to 0 ($p < 0.001$), whereas mean ABI increased from 0.65 to 1.12 ($p = 0.162$) after 36 months

2015 – Debulking + PTA



Result

Lower Extremity Revascularization Using Directional Atherectomy

12-Month Prospective Results of the DEFINITIVE LE Study

James F. McKinsey, MD,* Thomas Zeller, MD,† Krishna J. Rocha-Singh, MD,‡ Michael R. Jaff, DO,§ Lawrence A. Garcia, MD,|| on behalf of the DEFINITIVE LE Investigators

DEFINITIVE LE demonstrates that the TurboHawk device achieves:

- Stent-like results without leaving a stent behind
- Bail-out stent rate was only 3%
- 1-year patency rate for popliteal lesions of 77% in claudicant
- Limb salvage rate of 95% in CLI patients
- Device is effective in moderate and soft plaque
- DEFINITIVE LE demonstrates that claudicants with eccentric lesions had 86% patency at one year



Inclusion Criteria

No Stent Zones

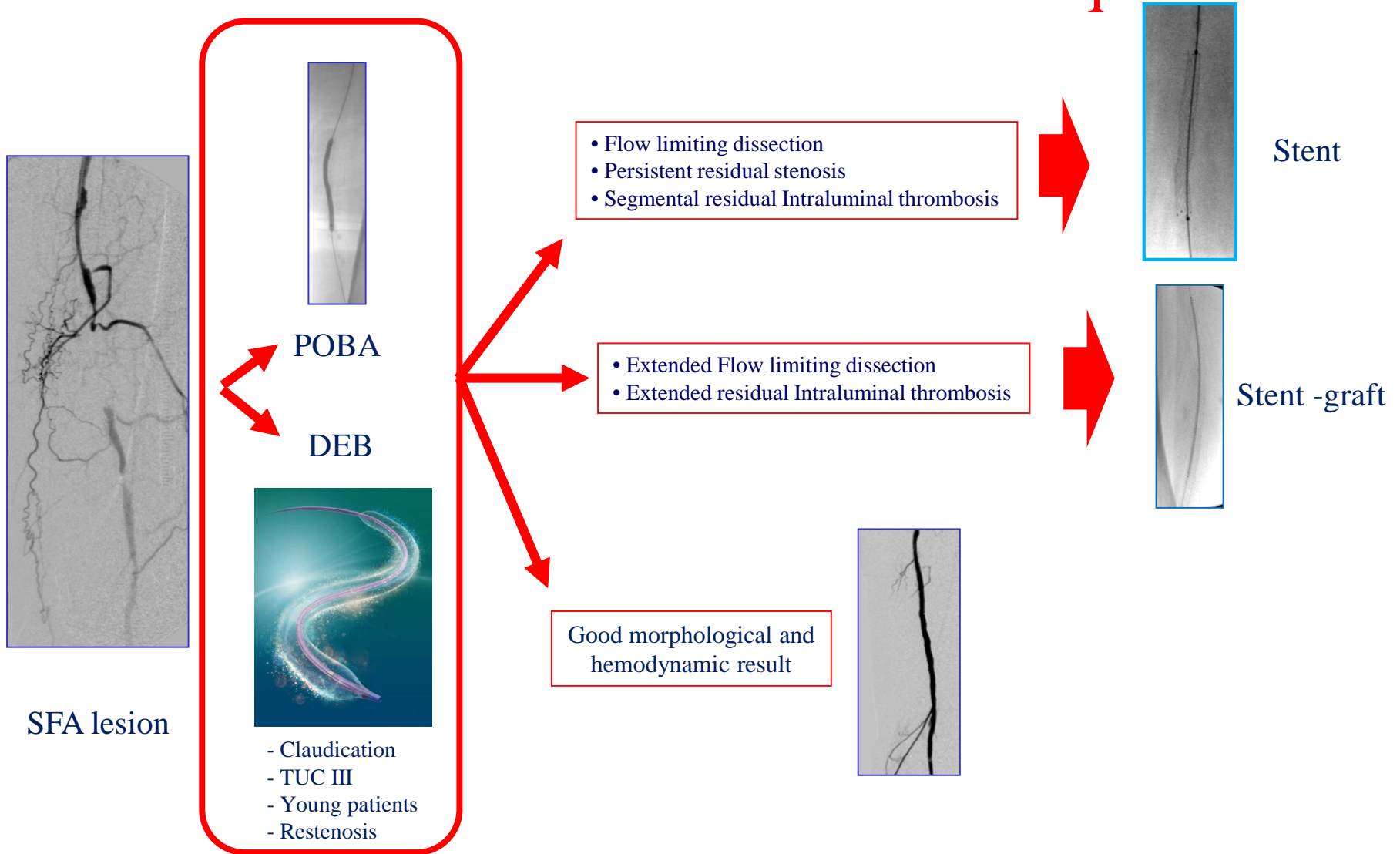
Moderate / Soft
Plaque

Eccentric Lesions

Calcium ATK

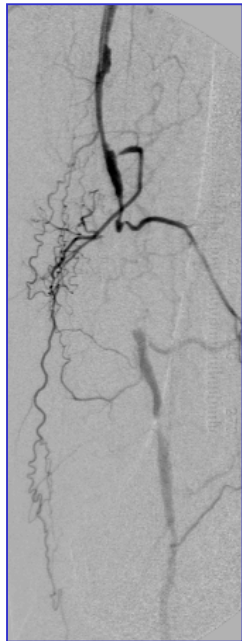


2016 - SFA - Endovascular Techniques

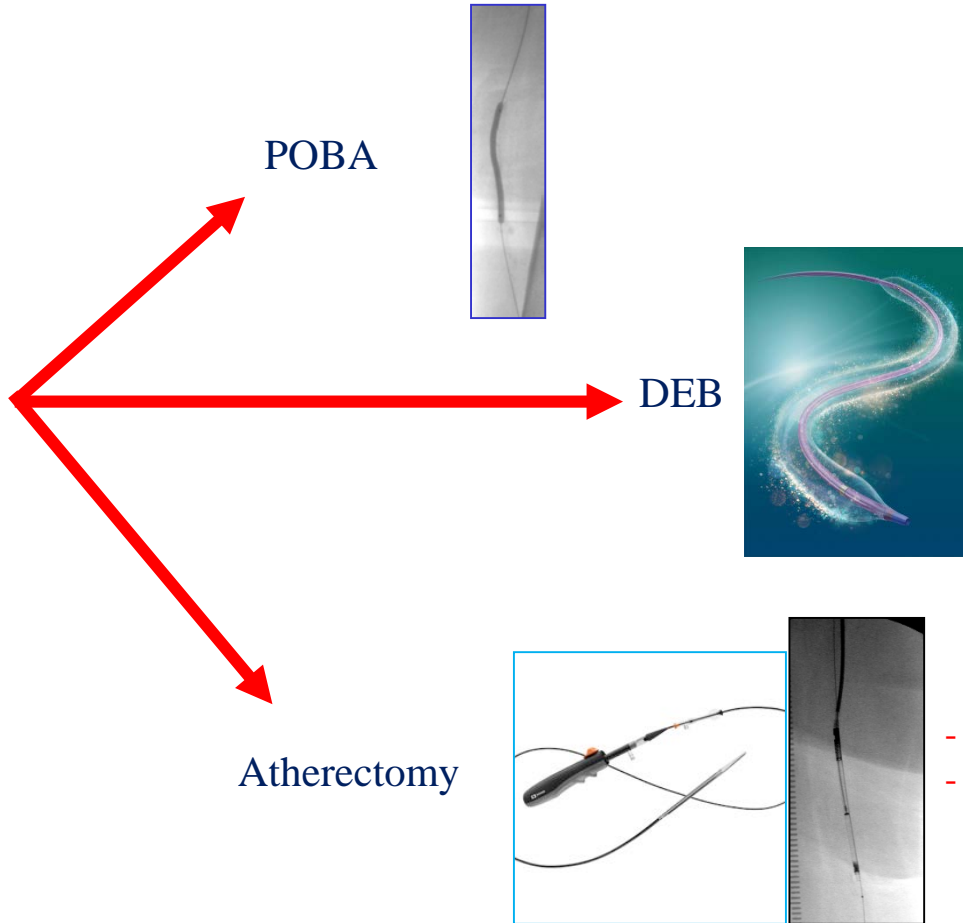




SFA - Endovascular Techniques



SFA lesion



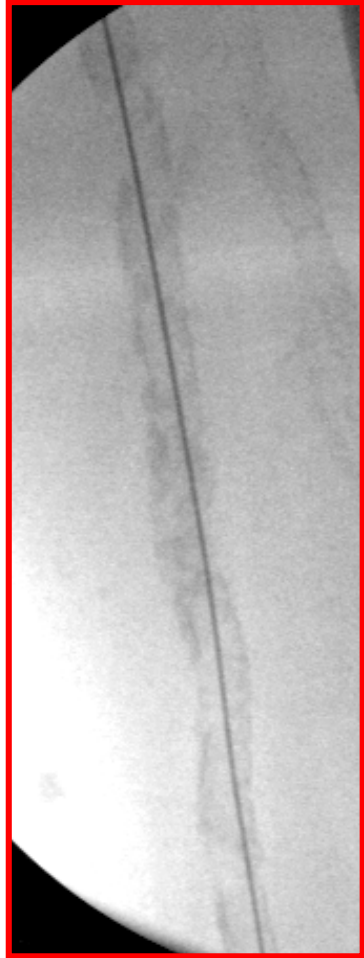
- Claudication with lesion in no stent zone/ no calcified plaque
- TUC III with lesion in no stent zone/ no calcified plaque
- Young patients with lesion in no stent zone/ no calcified plaque
- Restenosis

- **Calcified lesions**
- **Non calcified plaque – no stent zone**

Drug-Eluting Balloon Therapy for Femoropopliteal Occlusive Disease: Predictors of Outcome With a Special Emphasis on Calcium.

Tape G et al.

J Endovasc Ther 2015; 22(5): 727-33



PURPOSE:

To assess the association of patient, lesion, and procedure variables, including calcification, with late lumen loss (LLL) after use of drug-eluting balloon (DEB) therapy in patients with femoropopliteal arterial disease.

METHODS:

In this retrospective study, **91 patients** (mean age 72.0 ± 8.62 years; 50 men) were analyzed at 6 months after DEB treatment. Lesions were located in the superficial femoral artery (SFA, $n=68$) and popliteal artery ($n=23$). **Lesion calcification was graded by a core laboratory using 2 published scoring indices:** the peripheral artery calcification scoring system and a grading system based on circumference (arc) and length of calcium.

RESULTS:

The median LLL after 6 months was 0.2 mm (interquartile range -0.5, 1.14) overall and varied significantly across lesions with differing severity of calcification ($p=0.042$). However, LLL did not differ based on calcium location (intimal, medial, or mixed) or calcium length ($p=0.351$ and $p=0.258$, respectively). Additional predictors of LLL after DEB treatment included diabetes ($p=0.034$), coronary artery disease ($p=0.024$), and prior intervention ($p=0.013$). Interestingly, the severity of residual stenosis after the intervention did not have any impact on the LLL during follow-up (Spearman $r = -0.238$).

CONCLUSION:

Severity of lesion calcification is associated with LLL after treatment with DEB. One possible approach to overcome this limitation might be plaque modification or removal prior to DEB usage. Nevertheless, clinical data that support this hypothesis are currently lacking.



Combined treatment of heavy calcified femoro-popliteal lesions using directional atherectomy and a paclitaxel coated balloon: One-year single centre clinical results [☆]

Angelo Cioppa ^{*}, Eugenio Stabile, Grigore Popusoi, Luigi Salemme, Linda Cota, Armando Pucciarelli, Vittorio Ambrosini, Giovanni Sorropago, Tullio Tesorio, Alessia Agresta, Giancarlo Biamino, Paolo Rubino

Table 3

Clinical results at one-year follow-up in patients treated with DA and DCB.

No. of patients	30
Follow-up completion	30 (100 %)
Clinical follow-up duration (days)	371 ± 115
Major amputations (above the ankle) in CLI patients	0
Minor amputations (below the ankle) in CLI patients	3
Limb salvage rate (CLI patients)	12/12 (100%)
Re-hospitalizations (any cause)	4 (13%)
Repeat percutaneous transluminal angioplasty	3 (10%)
Primary Patency at 1 year	27 (90%)
Secondary patency at 1 year	30 (100%)

My most promising perspective with new concept for SFA endovascular treatment

Eur J Vasc Endovasc Surg (2017) ■, 1–64

2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

Recommendations on revascularization of femoro-popliteal occlusive lesions^c

Recommendations	Class ^a	Level ^b
An endovascular-first strategy is recommended in short (i.e. <25 cm) lesions. ^{302,303}	I	C
Primary stent implantation should be considered in short (i.e. <25 cm) lesions. ^{287,302}	IIa	A
Drug-eluting balloons may be considered in short (i.e. <25 cm) lesions. ^{77,306–310}	IIb	A
Drug-eluting stents may be considered for short (i.e. <25 cm) lesions. ^{302,303,311}	IIb	B
Drug-eluting balloons may be considered for the treatment of in-stent restenosis. ^{312,313}	IIb	B
In patients who are not at high risk for surgery, bypass surgery is indicated for long (i.e. ≥25 cm) superficial femoral artery lesions when an autologous vein is available and life expectancy is >2 years. ³¹⁴	I	B
The autologous saphenous vein is the conduit of choice for femoro-popliteal bypass. ^{287,315}	I	A
When above-the-knee bypass is indicated, the use of a prosthetic conduit should be considered in the absence of any autologous saphenous vein. ²⁸⁴	IIa	A
In patients unfit for surgery, endovascular therapy may be considered in long (i.e. ≥25 cm) femoro-popliteal lesions. ³¹²	IIb	C

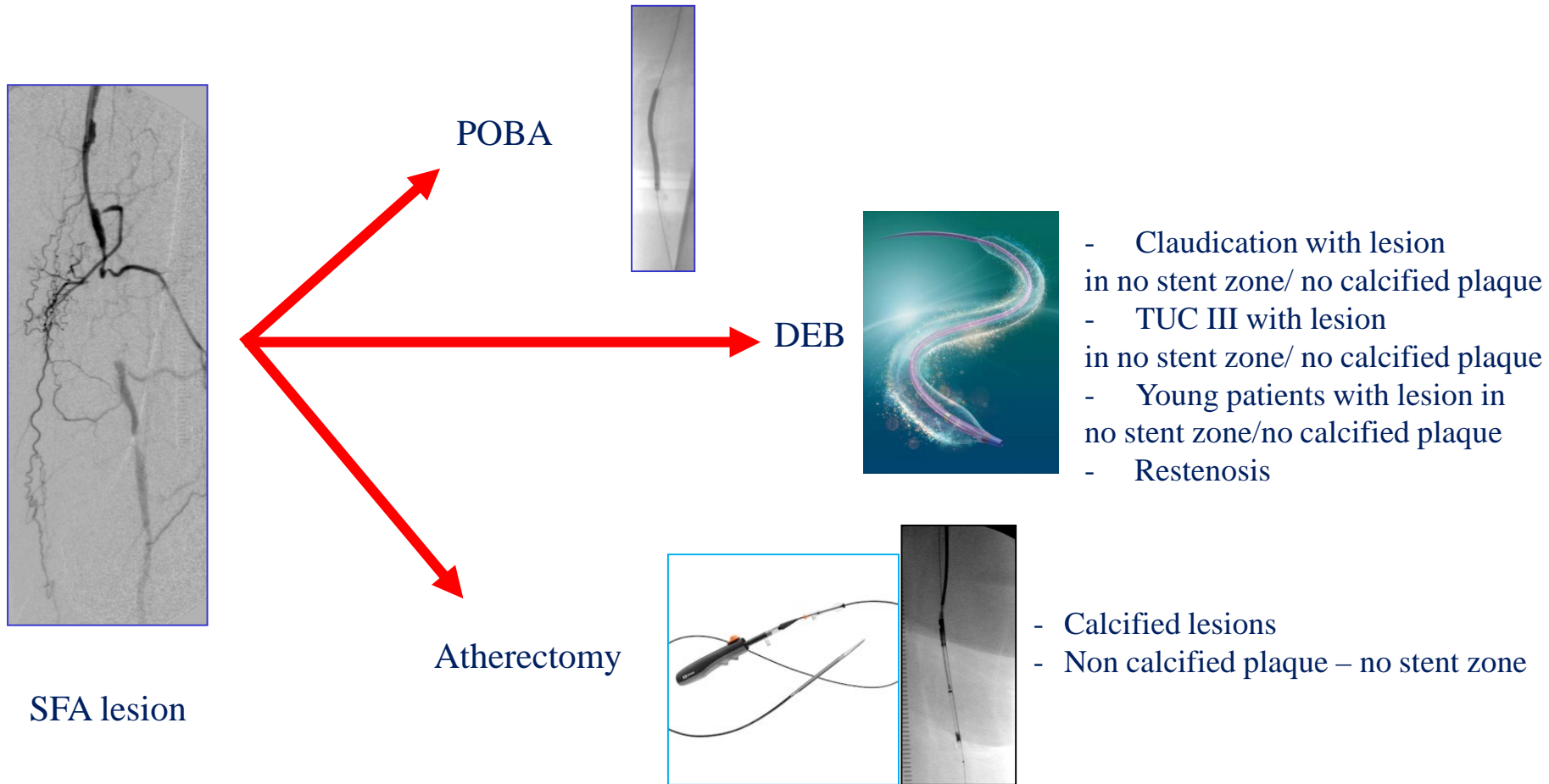
^a Class of recommendation.

^b Level of evidence.

^c These recommendations apply for patients with intermittent claudication and severe chronic limb ischaemia.

My most promising perspective with new concept for SFA endovascular treatment

2017 - SFA - Endovascular Treatment



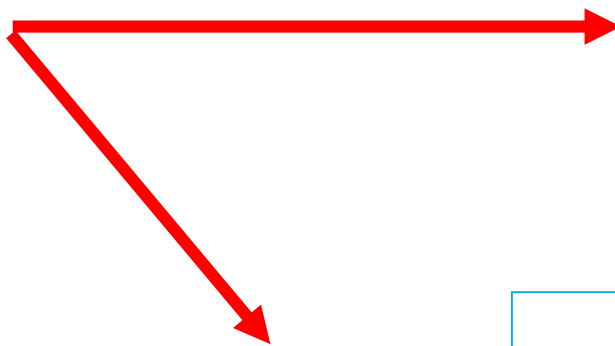
My most promising perspective with new concept for SFA endovascular treatment

Perspective 2018 - SFA - Endovascular Treatment



SFA lesion

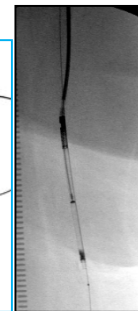
First choice



DEB



Atherectomy
± DEB
(DAART)



- Calcified lesions
- Non calcified plaque – no stent zone

My most promising perspective with new concept for SFA treatment

SFA Endovascular First: When ?

TASC A and B: always

TASC C and D: i have to evaluate:

- Anatomical complexity (occlusion vs stenosis, occlusion length)
- Calcifications (grade 3-4 Fanelli's classification)
- Patient Age
- Patient surgical Risk