

CTO vs. non-CTO lesions: What are the lessons learned from the Real-PTX trial and the concept of the BEST-SFA trial?

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest**

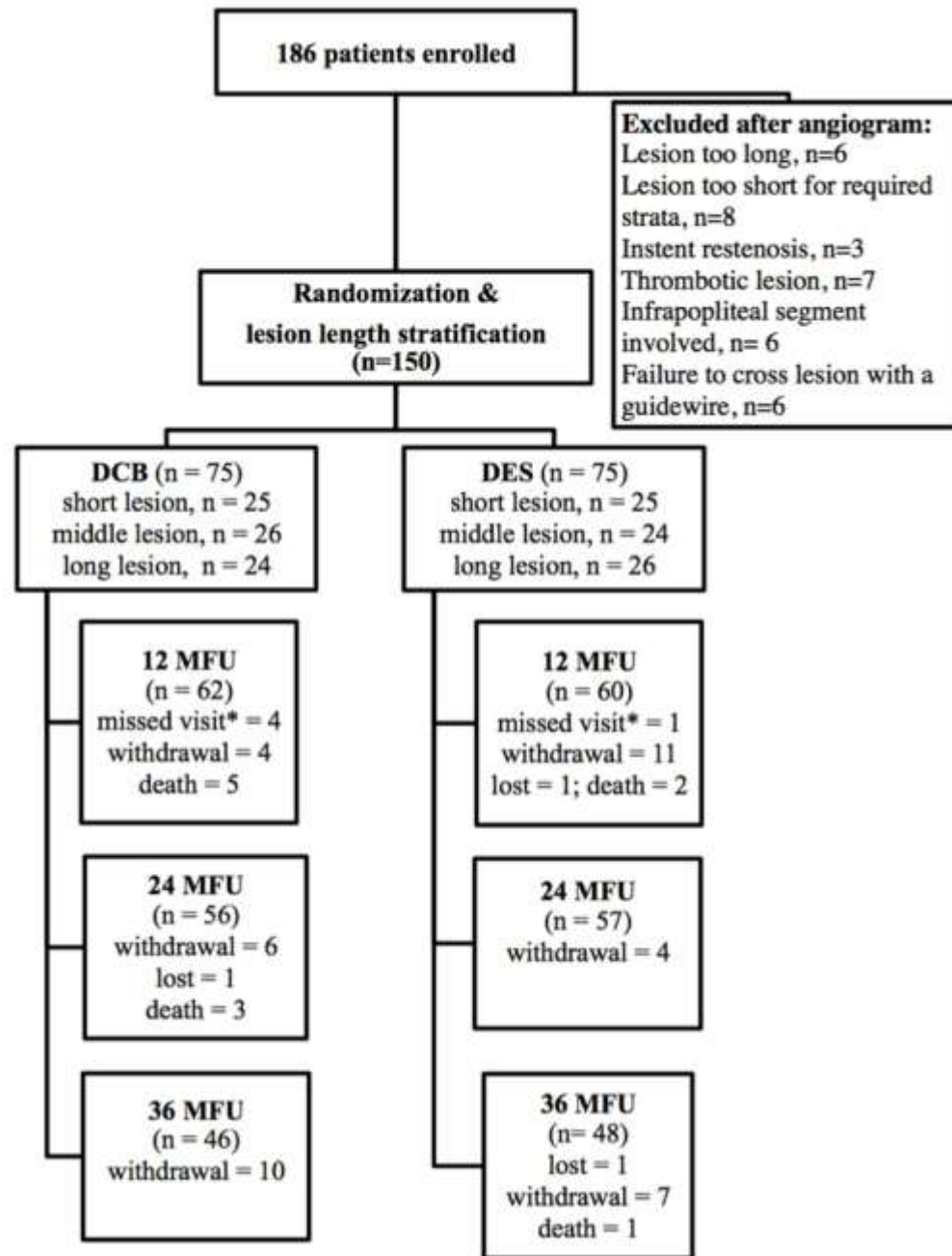
REAL PTX study

Drug-Eluting Stent

vs.

Drug-Coated Balloon Revascularization in Patients with Femoropopliteal Arterial Disease

JACC 2019; in press



Patient Characteristics

	DCB (n=75)	ZilverPTX (n=75)	p-value
Age in years (\pm SD)	68.2 \pm 9.6	69.5 \pm 9.5	0.4
Gender (male %)	45 (60.0)	57 (76.0)	0.05
BMI, mean (\pm SD)	26.5 \pm 4.3	27.5 \pm 3.9	0.1
Myocardial Infarction, n (%)	11 (14.7)	9 (12)	0.6
Heart Failure, n (%)	6 (8.0)	1 (1.3)	0.1
Cerebral Vascular Disease, n (%)	12 (16.0)	9 (12.0)	0.6
Hyperlipidemia, n (%)	51 (68.0)	56 (74.7)	0.3
Hypertension, n (%)	59 (78.7)	61 (81.3)	0.9
Renal Insufficiency, n (%)	16 (21.3)	14 (18.6)	0.8
Smoking, n (%)			0.5
Current, n (%)	32 (42.7)	29 (38.7)	
Previous, n (%)	22 (29.3)	29 (38.7)	
Diabetes, n (%)	25 (34.7)	23 (30.7)	0.7
Type 1, n (%)	1 (1.3)	1 (1.3)	
Type 2, n (%)	24 (32.0)	22 (29.3)	
Claudication (RC 2-3), n (%)	67 (89.3)	63 (84.0)	0.5
Critical limb ischemia (RC 4-5), n (%)	8 (10.7)	12 (16.0)	

Data are given as mean \pm std or number (%).

Lesion Characteristics

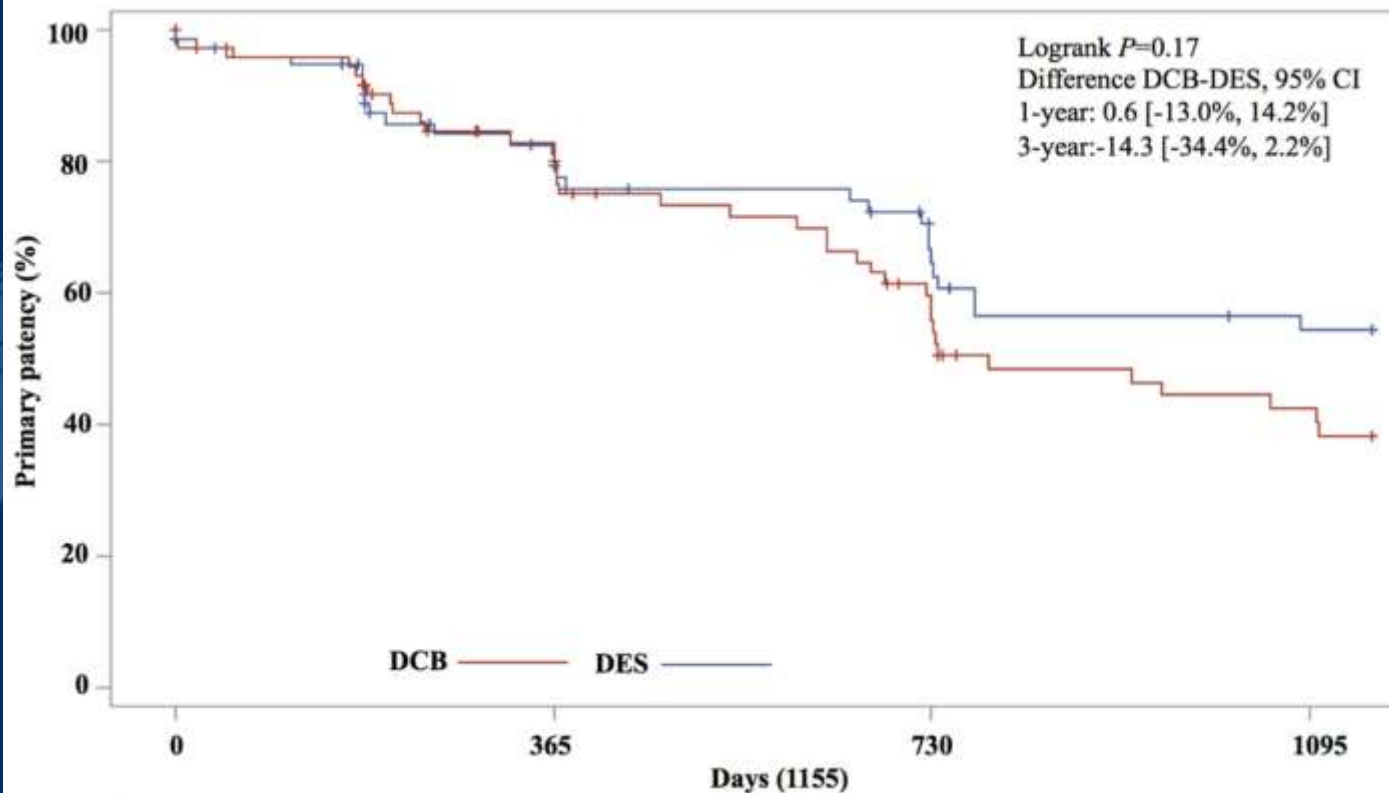
	DCB (n=75)	DES (n=75)	P-value
Target lesion length, mm	149.7 ± 87.4	155.5 ± 89.4	0.3
Diameter stenosis	87.4 ± 16.8	86.9 ± 15.2	0.8
Chronic total occlusions	40 (53.3)	39 (52.0)	0.9
Popliteal involvement	15 (20.0)	12 (16.0)	0.5
Calcification			0.09
None – mild	41 (54.6)	28 (37.3)	
Moderate – moderately severe	17 (22.7)	21 (28.0)	
Severe	17 (22.7)	26 (34.6)	

Procedural Outcome

	DCB (n=75)	DES (n=75)	P-value
Bailout Stenting CoreLab	19 (25.3)	NA	
Dissection	54 (72.0)	29 (38.7)	< 0.001
Type A/B	19 (25.3)	11 (14.7)	
Type C-F	35 (46.7)	18 (24.0)	
Diameter stenosis postprocedure	26.0 ± 14.9	15.6 ± 16.3	< 0.001
Residual stenosis ≥ 30%			
by site estimation	2 (2.7)	1 (1.3)	1.0
by core-lab analysis	32 (42.7)	12 (16.0)	< 0.001

Data are given as mean ± std or number (%).

REAL PTX study results – full cohort



Kaplan Meier Estimates of Event-free Survival (EFS), Values Represent Patients								
Days Post-Procedure	EFS (%) \pm Standard Error		Cumulative Failed (n)		Cumulative Censored (n)		Remaining at risk(n)	
	DCB	DES	DCB	DES	DCB	DES	DCB	DES
0	100 \pm 0	100 \pm 0	0	0	0	0	75	75
180	93.1 \pm 3.0	94.6 \pm 2.6	5	4	3	5	67	66
365	79.9 \pm 4.8	79.3 \pm 5.0	14	14	11	13	50	48
730	56.0 \pm 6.4	64.6 \pm 6.2	28	22	16	20	31	33
1095	42.4 \pm 6.6	56.7 \pm 6.6	35	26	19	22	21	27
1155	38.4 \pm 6.5	54.5 \pm 6.7	37	27	20	22	18	26

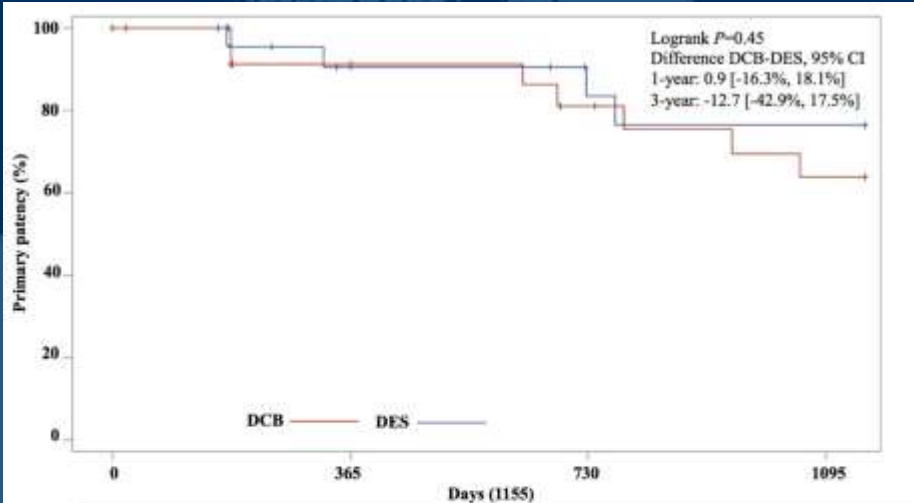
REAL PTX – Predictors of restenosis

Multivariate Cox Proportional Hazard Regression Analysis		
Predictor	Hazard Ratio	95% CI
Diabetes	1.9	1.1-3.3
Poor run-off (BTK vessels 0/1 vs 2/3)	2.0	1.2-3.3
Lesion length (per cm)	1.03	1.0-1.1
Chronic total occlusion	2.1	1.2-3.8

REAL PTX study results – lesion length

Short lesions ≤ 10cm (n=50)

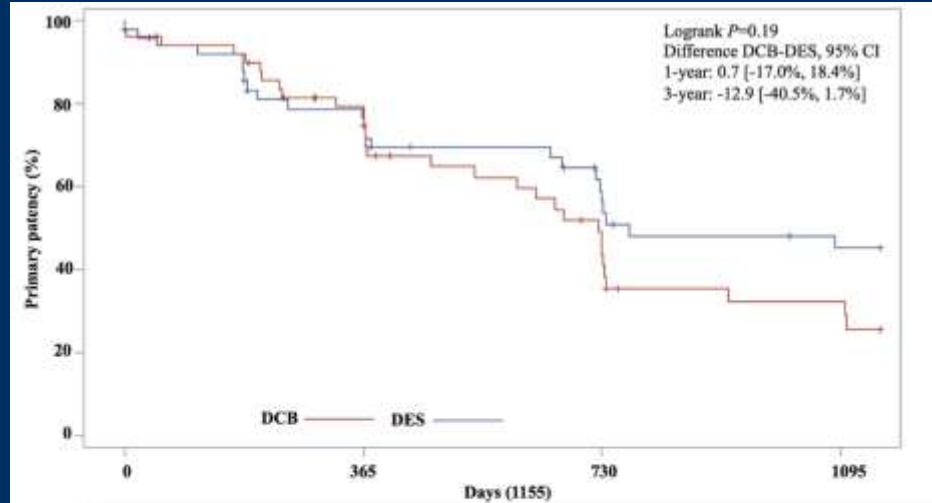
Middle and long lesions > 10cm (n=100)



Kaplan Meier Estimates of Event-free Survival (EFS), Values Represent Patients

Days Post-Procedure	EFS (%) ± Standard Error		Cumulative Failed (n)		Cumulative Censored (n)		Remaining at risk(n)	
	DCB	DES	DCB	DES	DCB	DES	DCB	DES
0	100±0	100±0	0	0	0	0	25	25
180	95.7±4.3	100±0	1	0	3	3	21	22
365	91.3±5.9	90.4±6.5	3	2	4	8	17	15
730	81.2±8.5	83.5±8.9	4	3	5	10	15	12
1095	63.8±11.2	76.5±10.6	7	4	6	10	11	11
1155	63.8±11.2	76.5±10.6	7	4	6	10	11	11

DCB cohort: 12% Bail-out stenting



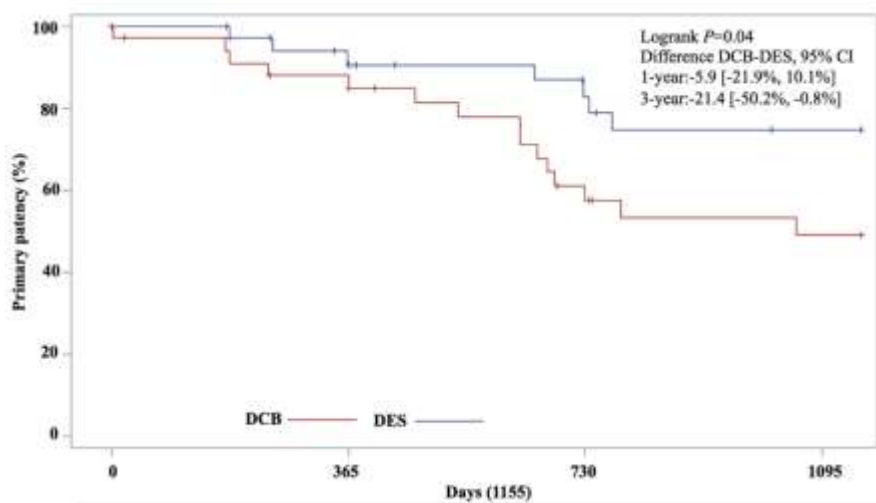
Kaplan Meier Estimates of Event-free Survival (EFS), Values Represent Patients

Days Post-Procedure	EFS (%) ± Standard Error		Cumulative Failed (n)		Cumulative Censored (n)		Remaining at risk(n)	
	DCB	DES	DCB	DES	DCB	DES	DCB	DES
0	100±0	100±0	0	0	0	0	50	50
180	91.9±3.9	91.8±3.9	4	4	1	2	45	44
365	74.7±6.3	74.0±6.5	12	12	5	6	33	32
730	43.7±7.8	56.4±7.7	24	19	10	10	16	21
1095	32.3±7.6	45.2±7.9	28	23	12	12	10	15
1155	25.8±7.3	45.2±7.9	30	23	12	12	8	15

DCB cohort: 32% Bail-out stenting

REAL PTX study results – CTO

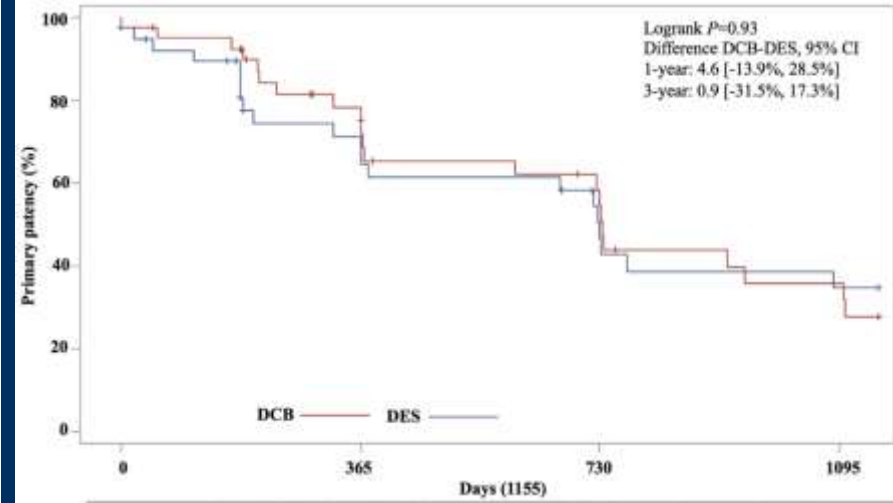
Stenotic lesions



Kaplan Meier Estimates of Event-free Survival (EFS), Values Represent Patients									
Days Post-Procedure	EFS (%) ± Standard Error		Cumulative Failed (n)		Cumulative Censored (n)		Remaining at risk(n)		
	DCB	DES	DCB	DES	DCB	DES	DCB	DES	
0	100±0	100±0	0	0	0	0	35	36	
180	94.0±4.1	100±0	2	0	2	1	31	35	
365	84.8±6.3	90.7±5.2	5	3	3	6	27	27	
730	57.5±9.0	82.9±7.0	13	5	6	10	16	21	
1095	53.4±9.3	74.8±8.4	14	7	8	12	13	17	
1155	49.3±9.4	74.8±8.4	15	7	8	13	12	16	

DCB cohort: 11% Bail-out stenting

Total occlusions



Kaplan Meier Estimates of Event-free Survival (EFS), Values Represent Patients									
Days Post-Procedure	EFS (%) ± Standard Error		Cumulative Failed (n)		Cumulative Censored (n)		Remaining at risk(n)		
	DCB	DES	DCB	DES	DCB	DES	DCB	DES	
0	100±0	100±0	0	0	0	0	40	39	
180	92.4±4.2	89.4±5.0	3	4	1	4	36	31	
365	75.2±7.2	67.9±8.1	9	11	6	7	25	21	
730	54.7±8.9	46.6±9.2	15	17	10	10	15	12	
1095	35.8±9.0	34.9±9.0	20	20	11	10	9	9	
1155	27.8±8.6	34.9±9.0	22	20	11	10	7	9	

DCB cohort: 37.5% Bail-out stenting

Cox regression: P-value for interaction = 0.09 -> signal for different treatment effect in stenotic vs occluded lesions

REAL PTX study – conclusions

- Direct comparison of DCB versus DES for complex femoropopliteal lesions up to 30 cm showed promising primary patency rates around 80% at 12 months for both treatment.
- Trend in favor of the DES beyond 12 months, but the study was not adequately powered to confirm this finding.
- Disappointing patency rates in long lesions, in particular in CTOs after 3 years.

**Is this the BEST we can do,
especially in complex SFA lesions?**

BEST SFA study

Best Endovascular Strategy for complex lesions of the Superficial Femoral Artery comparing a stent-avoiding versus stent-preferred approach

BEST SFA – Rationale

- Current clinical trials focus on patency rates for specific single devices.
- Complex SFA lesions
 - Combination of devices/technologies needed for optimal results and potentially improve outcome
 - Additive value of adjunctive therapy unclear
- **BEST SFA**: an exploratory pilot study to compare strategies rather than single devices .

BEST SFA –Study aim

- To evaluate patency rates in real-world complex SFA lesions without restricting the use of adjunctive devices.
- Study results could provide a benchmark for future trials in complex femoropopliteal disease with various technologies.

BEST SFA – Study design

- Prospective, multicenter German pilot study
- Investigator-initiated study; PI: Dierk Scheinert
- Funded by the Helmholtz Association of German Research Centres; industry-independent.
- Core lab adjudication of angios and duplex ultrasound.
- 100% source data verification

BEST SFA Study: Inclusion of 120 PAD patients
Rutherford category 2-4

Femoropopliteal lesions:
Stenoses >10cm, Occlusions >5cm;
Maximum length: ≤30cm

Both strategies
feasible at the
operator's
discretion

1:1 randomization

Stent-preferred strategy

Stent-avoiding strategy

Vessel preparation for plaque modification/minimizing bail out stenting:
Debulking devices, scoring/high pressure balloons

DES

DCB

Supera for focal severe calcification

Bail-out stenting: BMS, Supera for
focal severe calcification

BEST SFA – Study endpoints

- **Primary efficacy endpoint at 12 months: Primary patency** (absence of clinically-driven target lesion revascularization (CD-TLR) and/or restenosis defined as a peak systolic velocity ratio (PSVR) > 2.4 assessed by ultrasound
- **Assessment of safety through 24 months:** Freedom from device and procedure-related death, all-cause death, target limb major amputation and clinically-driven target lesion revascularization.
- **Key secondary efficacy endpoint(s) through 24 months:** Primary and secondary patency. Walking impairment questionnaire scores. Ankle-brachial index and Rutherford category.

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