One Year Results Of The SPORTs Trial: DCBs Vs. DES (Eluvia) VS. Bare Stents In Long SFA Lesions (TASC C AND D) - What Is Best?

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Disclosure

Study support by B.Braun, Biotronic, BSC, CVT, Philips, Medtronic, Shockwave

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	BSC, BBraun, Biotronic, CVT, Medtronic, Medalliance, Philips
Consultant Fees/Honoraria	BSC, Medtronic
Individual Stock(s)/Stock Options	
Royalties/Patent Beneficiary	
Executive Role/Ownership Interest	
Other Financial Benefit	

Limitation on the current data TASC C + D for endovascular intervention

- Most prospective randomized studies
  - IDE trials, TASC A and B
- Truly long lesions
  - Often retrospective or registries
  - No control group and dubious indirect comparisons
  - No standardized f/u, no core lab

No definitive data on primary strategy decision making

Current treatment possibilities for TASC C + D

- Endovascular
  - POBA
  - DCB (+ high rate bail out stent)
  - Stent (which one?)
  - DES
  - Covered Stentgraft
- Bypass Surgery

SPORTS

- DESIGN: Prospective, randomized, open-label, 3-arm, multi-center
- OBJECTIVE: To compare angiographic and clinical outcome of TASC C and D lesions in the SFA after treatment with PCB, PES or BNS
- PRIMARY ENDPOINT: Angiographic diameter stenosis at 12 month
- HYPOTHESES: 1) Superiority of PES over BNS
  2) Non-inferiority of PCB versus BNS
- PRINCIPAL INVESTIGATOR
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PCB: paclitaxel coated balloon (SeQuent Please OTW);
PES: paclitaxel eluting self-expanding nitinol vascular stent system);

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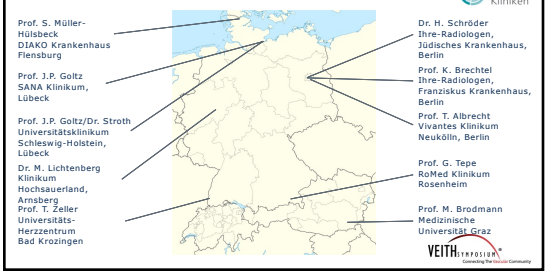
MAIN INCLUSION CRITERIA

- Rutherford classes 2 – 4
- Peripheral lesions in the SFA and / or A.pop. seg I
- Minimum diameter stenosis ≥70%
- Treatment length at least 15 cm (lesion length at least 13 cm)

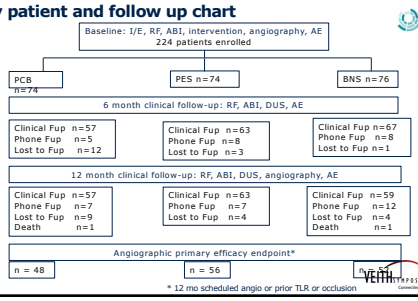
MAIN EXCLUSION CRITERIA

- ISR lesions
- A.pop. Seg II or below or within a bypass graft
- Acute thrombosis of the study lesion
- Strongly calcified lesions with circumferential presence of calcifications and a lesion calcification length >4 cm
- RVD <4 mm and >6 mm
- Lesions below the knee requiring treatment
- No patent distal run-off vessel

SPORTS



Study patient and follow up chart

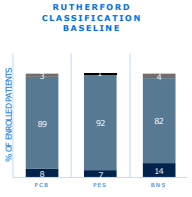


* 12 mo scheduled angio or prior TLR or occlusion

Patient baseline characteristics

	PCB n = 74	PES n = 74	BNS n = 76
Male (%)	66	60	72
Age (years, mean±SD)	70 ± 9	68 ± 8	67 ± 9
Weight (kg, mean±SD)	78 ± 19	79 ± 16	79 ± 16
Diabetes (%)	30	23	26
Hypertension (%)	88	80	78
Hyperlipidemia (%)	66	70	71
Obesity (%)	18	12	21
Renal disease (%)	12	8	3
Current smoker (%)	60	55	58
ABI study leg (mean±SD)*	0.6 ± 0.2 n = 60	0.6 ± 0.2 n = 64	0.6 ± 0.2 n = 61

*only ABI values ±1.3 included



Lesion baseline characteristics

	PCB n = 74	PES n = 74	BNS n = 76	P value
Lesion length, mm, mean ± SD	221 ± 87 n=73	235 ± 78 n=73	227 ± 78 n=75	0.57
Occlusion, n (%)	52 (70)	63 (85)	56 (74)	0.08
Occlusion length, mm, mean ± SD	175 ± 91 n=51	179 ± 89 n=62	151 ± 81 n=54	0.18
RVD, mm, mean ± SD	5.0 ± 0.6	5.3 ± 0.7	5.2 ± 0.7 n=75	**0.01**
MLD in lesion, mm, mean ± SD	0.4 ± 0.7	0.2 ± 0.6	0.3 ± 0.7	0.18
Diameter stenosis in lesion, %, mean ± SD	92.6 ± 13.2	96.8 ± 9.7	94.2 ± 11.7	0.10

Lesion baseline characteristics

	PCB n = 74	PES n = 74	BNS n = 76	P value
Calcification (PACCS), n (%) - Corelab				0.36
0	3 (4.1)	2 (2.7)	5 (6.6)	
1	15 (20.3)	28 (37.8)	18 (23.7)	
2	1 (1.4)	0	0	
3	38 (51.4)	29 (39.2)	31 (40.8)	
4	15 (20.3)	14 (18.9)	20 (26.3)	
NA	2 (2.7)	1 (1.4)	2 (2.6)	

Procedural data

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	PCB n = 74	PES n = 74	BNS n = 76	P value
Pre-dilation (%)[1]	91	95	90	0.50
Bail out stenting (%)[1]	58	NA	NA	NA
Treated length, mm (mean±SD)[2]	269 ± 82 n=73	273 ± 80 n=73	257 ± 68 n=74	0.42
Post-procedural MLD in lesion, mm (mean±SD)[2]	3.5 ± 0.7 n=73	4.2 ± 0.7	4.1 ± 0.7 n=74	<0.0001
Post-procedural diameter stenosis, % (mean±SD)[2]	30 ± 12 n=73	20 ± 15	20 ± 14 n=74	<0.0001

[1] CRF data; [2] Corelab analysis; NA = not applicable

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Efficacy and safety endpoints

RoMed Kliniken

12 month Corelab data, ITT

	PCB n = 48	PES n = 56	BNS n = 52	P value
Diameter stenosis in lesion, %, mean ± SD	53.7 ± 33.9	25.3 ± 32.4	60.0 ± 29.8	
LLL in lesion, mm, mean ± SD	1.1 ± 1.8	0.4 ± 1.7	2.0 ± 1.5 n=50	<0.0001
MLD in lesion, mm, mean ± SD	2.3 ± 1.7	3.9 ± 1.7	2.1 ± 1.6	<0.0001

Hypothesis testing for primary endpoint (in-lesion diameter stenosis)

Hypothesis 1: Superiority DES vs. BNS ✓ p<0.0001 (-34.7 [CI 97.5%: -47.7; -20.2])*

Hypothesis 2: Non-inferiority PCB vs. BNS ✓ p=0.0010 (-6.3 [CI 97.5%: -22.3; 7.6])*

*estimates and p-values based on a mixed model with baseline as covariate

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Efficacy and safety endpoints

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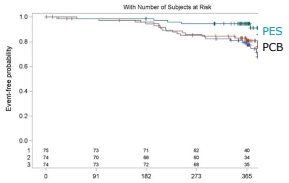
Freedom from CD-TLR



	PCB	PES	BNS	p value
6 month (180 days)	95.8%	98.7%	96.0%	0.015
12 month (365 days)	80.7%	94.5%	77.4%	

Efficacy and safety endpoints

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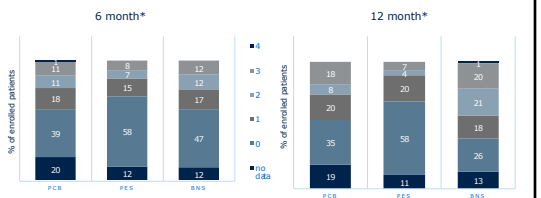
Rutherford Classification



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* pre-TLR data in case of previous TLR

Summary and Conclusion

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- PES showed significantly better angiographic results 12 months after treatment compared to treatment with BNS
- Non-inferiority of PCB treatment compared to BNS shown for angiographic stenosis degree
- PCB treatment in long, complex lesions required high bailout stenting rate, mainly due to dissections
- TLR rates favor PES over PCB and BNS treatment
- Long-term data necessary
- Subgroup analyses planned

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