Randomi-zed control-led trials for ISR

Clinical evidence SeQuent® SCB
Preclinical work and randomized controlled trials

B|BRAUN
SHARING EXPERTISE

Combined analysis of two parallel randomized trials of sirolimus-coated and paclitaxel-coated balloons in coronary in-stent restenosis lesions

First in Man Trials in Malaysia, Germany & Switzerland

Scheller B et al. Circ Cardiovasc Interv. 2022 Sep;15(9):e012305.

Description

Design: Randomized | Prospective | Multicenter | Non-inferiority

Indication: DES-ISR

Control: SeQuent® Please NEO

Primary endpoints: LLL @ 6-month follow-up

Secondary endpoints:

- Procedural success

- MACE (TLR, cardiac death, TL-MI) @ 12-month follow-up
- Thrombosis rate @ 12-month follow-up
- Binary restenosis rate

101 patients (DES-ISR)

1:1 randomization

51 patients	**50 patients**
SeQuent® Please NEO	SeQuent® SCB

Follow-up:

1 month	**6 months**	**12 months**
Clinical	Angiographic	Clinical

Results

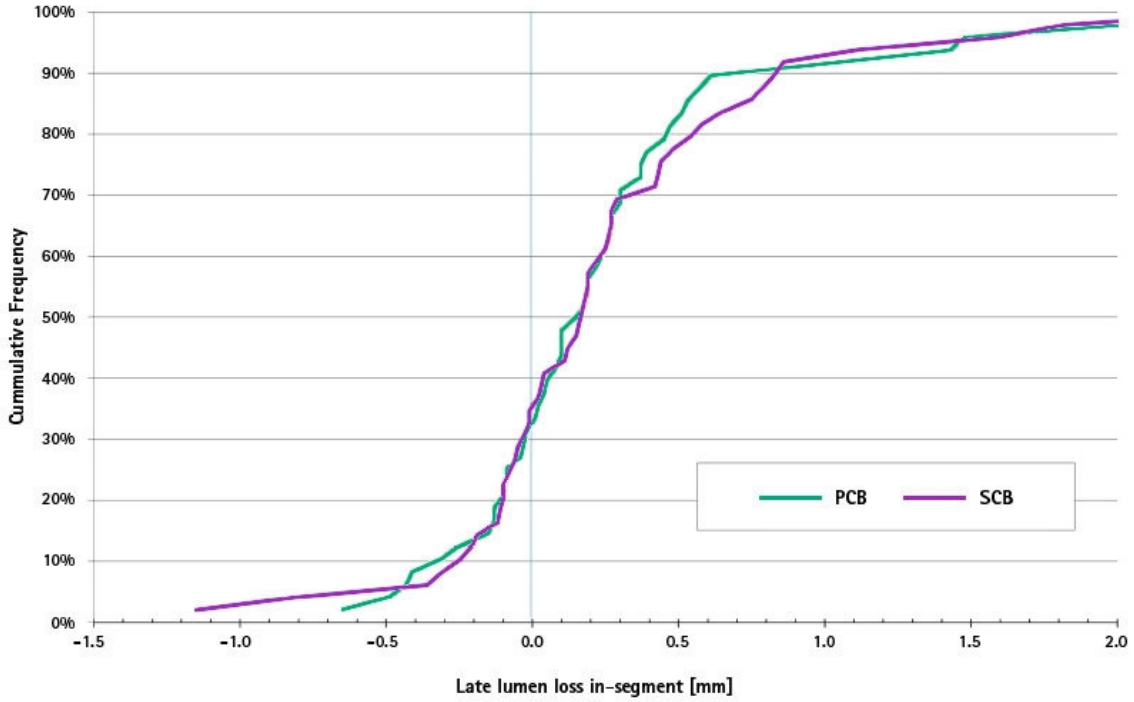
Quantitative coronary angiography revealed no differences in baseline parameters.

After 6 months, in-segment late lumen loss was:

- 0.25±0.57 mm in PCB group
- 0.26±0.60 mm in SCB group

Mean difference between SCB and PCB was 0.01 (95% CI, -0.23 to 0.24).

Non-inferiority at a predefined margin of 0.35 was shown.



Angiographic patency: cumulative frequency distribution of in-segment late lumen loss determined by quantitative coronary angiography. Paclitaxel-coated balloon (PCB) versus sirolimus-coated balloon (SCB).

Clinical follow-up at 1 year

	SCB Total	PCB Total	P value SCB vs. PCB
Number of patients (n [%])	50 (100)	51 (100)	
TLR (n [%])	8 (16)	5 (10)	0.389
Stent thrombosis (n [%])	0	1 (2)	1.000
Death (n [%])	1 (2)	1 (2)	1.000
MI (n [%])	0	1 (2)	1.000
MACE (n [%])	9 (18)	7 (14)	0.596

Clinical events up to 12 months did not differ between the groups.

Conclusion

This **first-in man comparison of a novel SCB** with a crystalline coating showed **similar angiographic and clinical outcomes** in the treatment of coronary drug-eluting stent **in-stent restenosis compared with PCB**.

AESCULAP® – a B. Braun brand | Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany Phone +49 7461 95-0 | Fax +49 7461 95-2600 | www.aesculap.com