International Symposium CHARING CROSS

Three-year results from the SIRONA randomized trial

Ulf Teichgräber, MD
Jena, Germany
on behalf of the SIRONA investigators

Disclosure

Speaker name: Ulf Teichgräber, MD

☒ I have the following potential conflicts of interest to report:

- ☒ Receipt of grants/research support (Concept Medical, Tampa, USA))
- ☐ Receipt of honoraria and travel support
- ☐ Participation in a company-sponsored speaker bureau
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company

☐ I do not have any potential conflict of interest

SIRONA Trial

Head-to-head comparison of sirolimus vs. paclitaxel DCB angioplasty in the femoropopliteal segment

- Investigator initiated
- 25 sites
- 482 participants
- 1:1 randomization
- Active, not recruiting

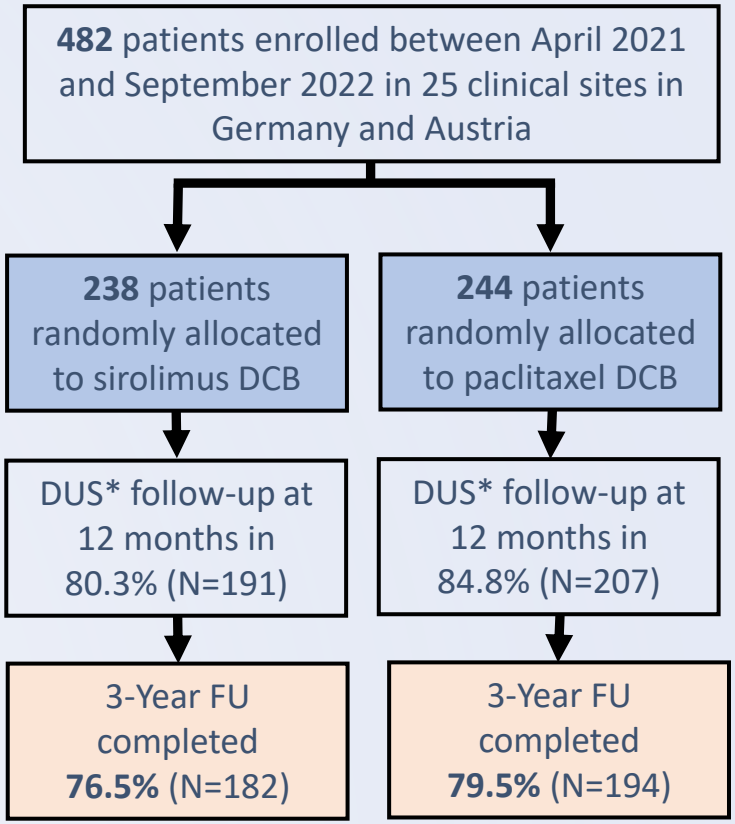
ClinicalTrials.gov NCT04475783

Teichgräber et al. Trials 2021, 22(1):665

SIRONA Trial

Head-to-head comparison of sirolimus vs. paclitaxel DCB angioplasty in the femoropopliteal segment

- Investigator initiated
- 25 sites
- 482 participants
- 1:1 randomization
- Active, not recruiting



*CoreLaboratory adjudicated

ClinicalTrials.gov NCT04475783

Teichgräber et al. Trials 2021, 22(1):665

Rationale

- Sirolimus is antiproliferative, cytostatic and immunosuppressive.
- The randomized **SirPAD** study showed superiority of Sirolimus DCB* to POBA at 12 months (major adverse limb events).
- The **SIRONA RCT** showed non-inferiority of Sirolimus DCB* to Paclitaxel DCB at 12 months (femoropopliteal primary patency).
- Do **long-term results** confirm the previous findings?

* **MagicTouch**® PTA Sirolimus Coated Balloon (Concept Medical Inc. Tampa, USA)

Study Device

- Sirolimus encapsulated in phospholipid drug carrier sub-micron particles
- Drug dosage 1.27 µg/mm^2

MagicTouch® PTA Sirolimus Coated Balloon (Concept Medical Inc. Tampa, USA)

Control

• Luminor 35™	83 (35%)
• Lutonix™	48 (20%)
• Ranger™	36 (15%)
• IN.PACT™	35 (14%)
• Other*	37 (16%)

* Stellarex™ (13), Orchid™ (9), SequentPlease™ (6), IN.Pact Pacific (1), ELUTAX (1), combined (4), unknown (3)

Study Participants

	SCB n = 238	PCB n = 244
Rutherford-Becker classification		
Category 2	24%	27%
Category 3	73%	69%
Category 4	2%	4%
Category 5	1%	0%

Teichgräber et al., JACC 2026, Online ahead of print.

Lesion Characteristics*

	SCB n = 238	PCB n = 244
Lesion length	84 ± 62 mm	84 ± 60 mm
Long lesions (≥ 15 cm)	15%	18%
Chronic total occlusion	34%	32%
Calcification PACSS 3	45%	47%
Calcification PACSS 4	29%	28%
Diameter stenosis	83% ± 16%	82% ± 18%
No patent runoff vessels**	13%	16%

*Reported by the core laboratory, ** Patent: < 50% stenosis

Teichgräber et al., JACC 2026, Online ahead of print.

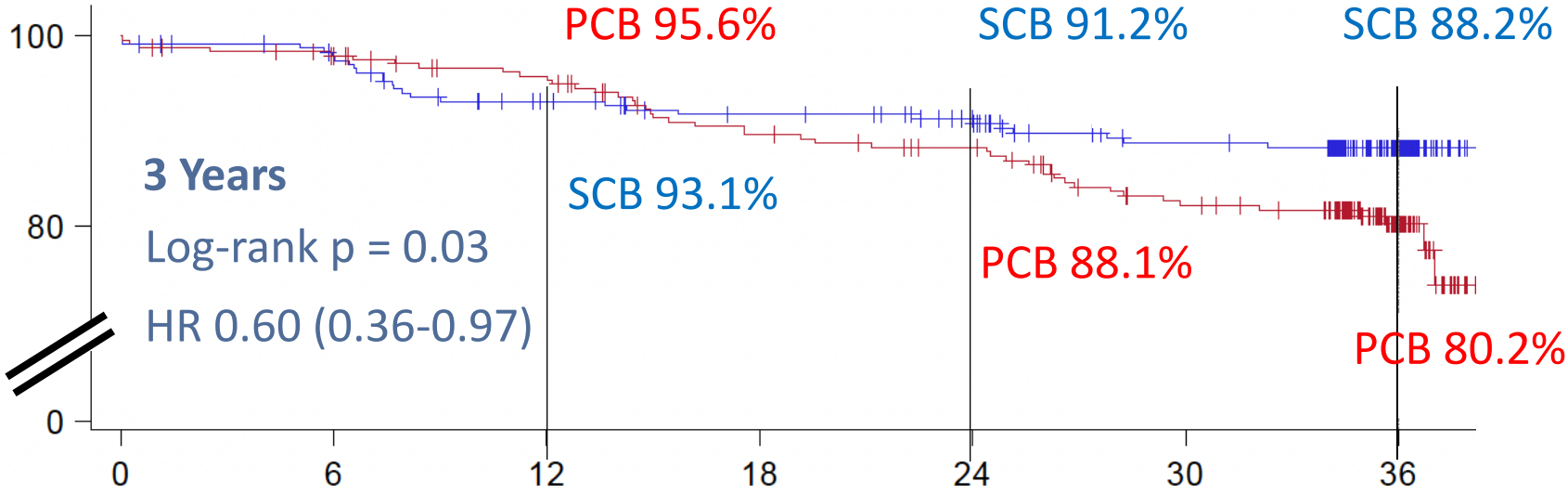
Procedure Characteristics*

	SCB n = 238	PCB n = 244
Predilation	100%	100%
> 1 DCB	26%	27%
Dissection ≥ NHLBI type D*	43%	36%
Postdilation	32%	34%
Bailout stent	24%	21%
Residual diameter stenosis*	25%	28%

*Reported by the core laboratory

Teichgräber et al., JACC 2026, Online ahead of print.

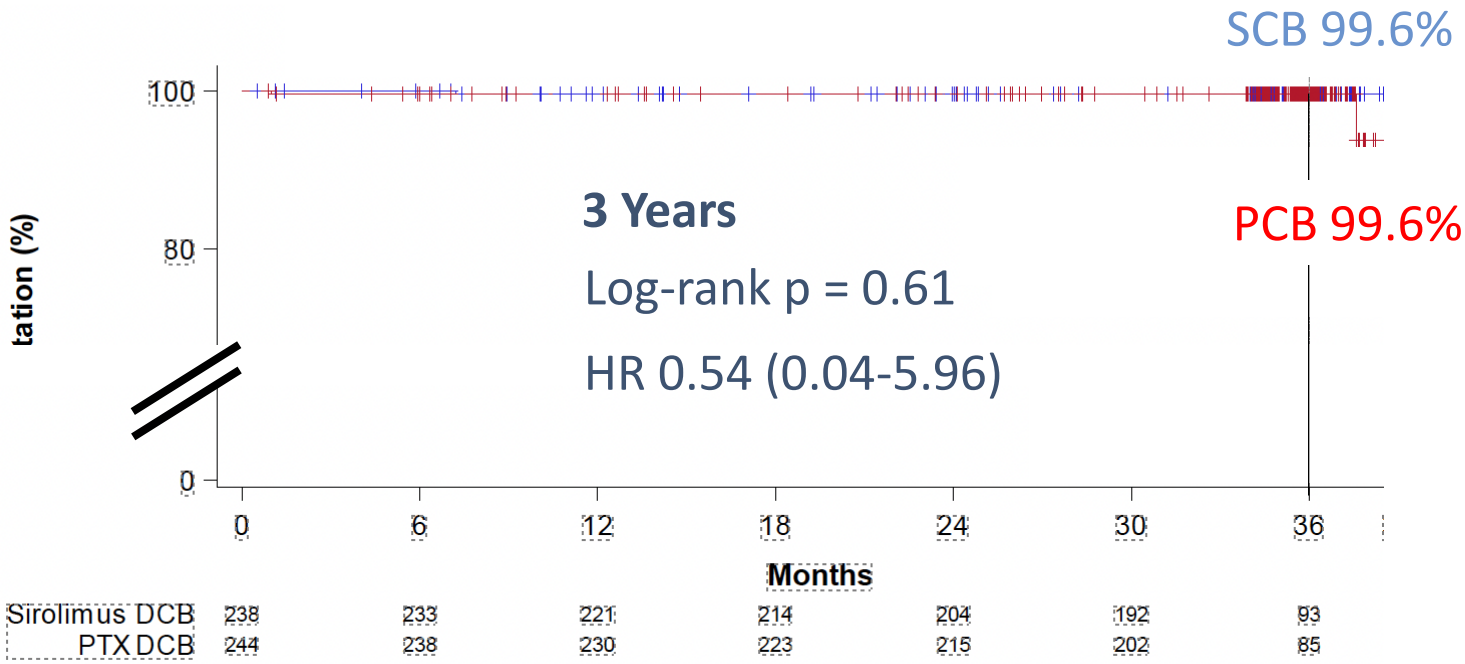
Freedom from cdTLR



Sirolimus	238	228	208	198	187	169	76
Paclitaxel	244	234	222	202	193	171	68

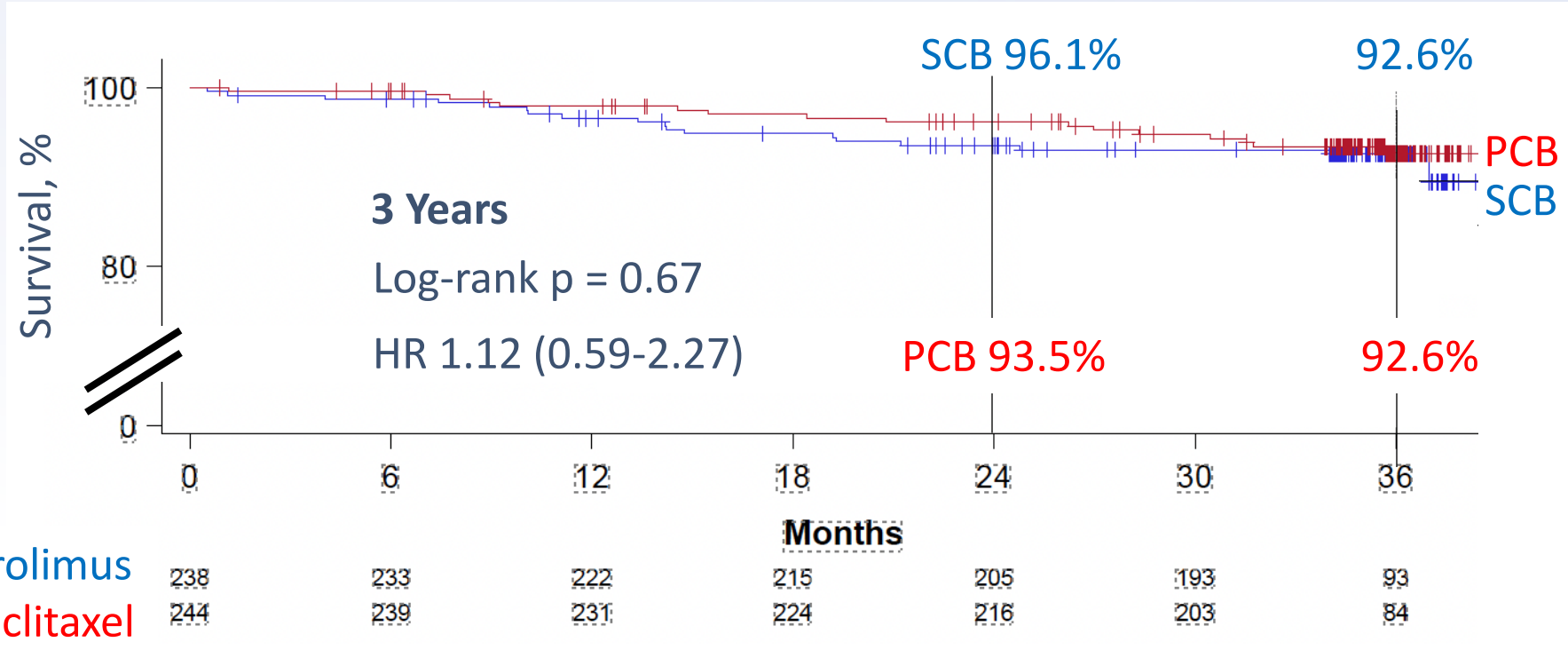
Preliminary before CEC adjudication

Freedom from major amputation



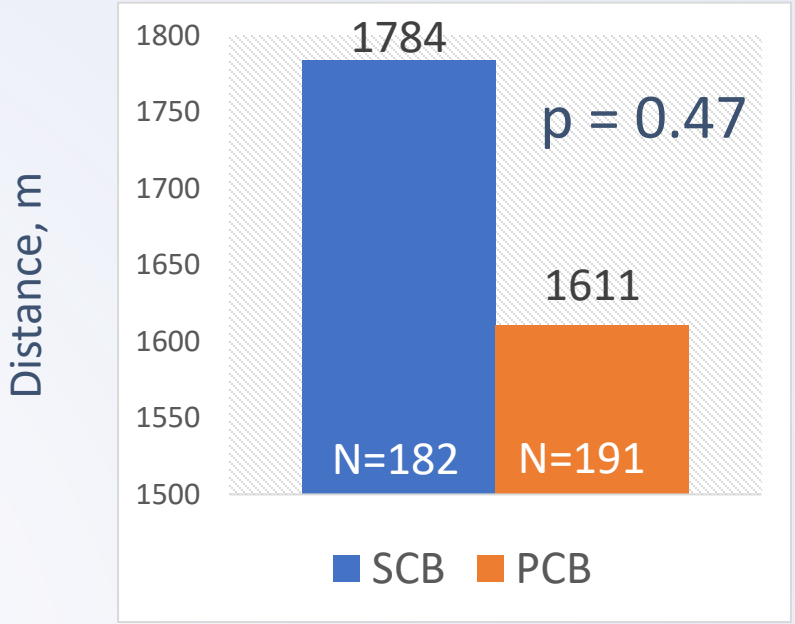
Preliminary before CEC adjudication

Freedom from all-cause mortality



Preliminary before CEC adjudication

Pain free walking distance (self assessment)



Conclusion

At 3 years, SCB was **superior** to PCB regarding

- Freedom from clinically driven TLR

At 3 years, SCB **did not differ** from PCB regarding

- Freedom from major amputation
- Freedom from all-cause death
- Walking distance