




How should we move forward with Limus coated Devices after FDA has cleared PTX coated Devices:
Are there promising results currently with Limus coated DCBs?

Marianne Brodmann
 Division of Vascular Medicine, Medical University
 Graz, Austria



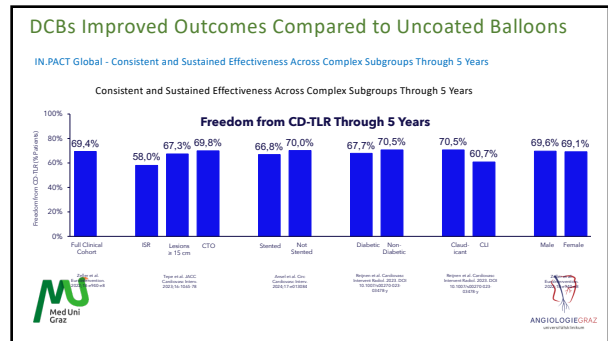
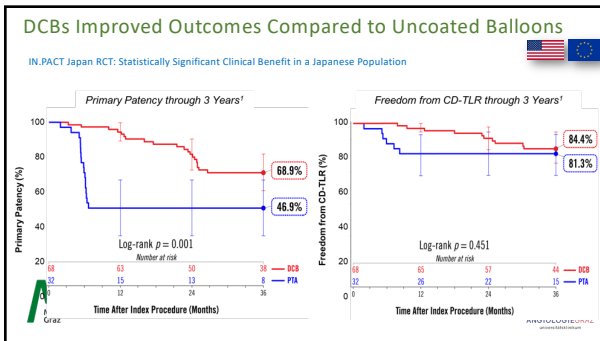
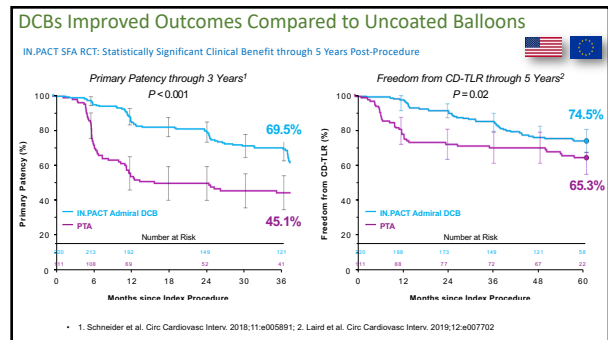



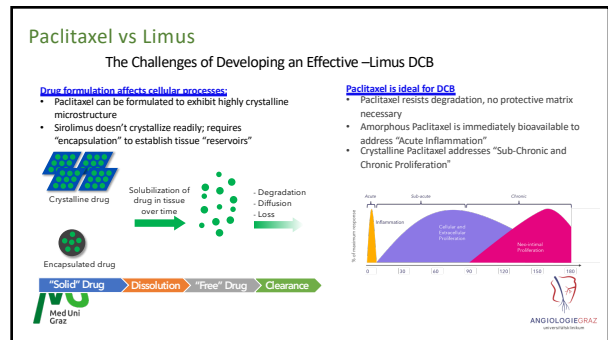
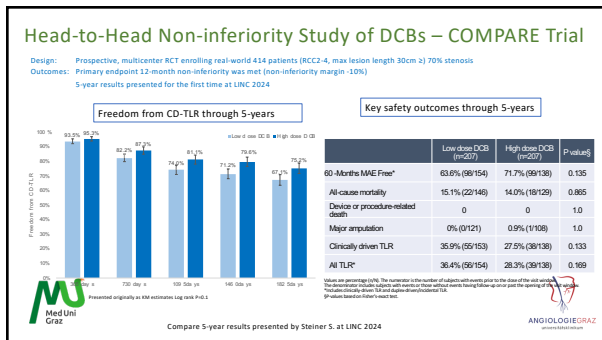
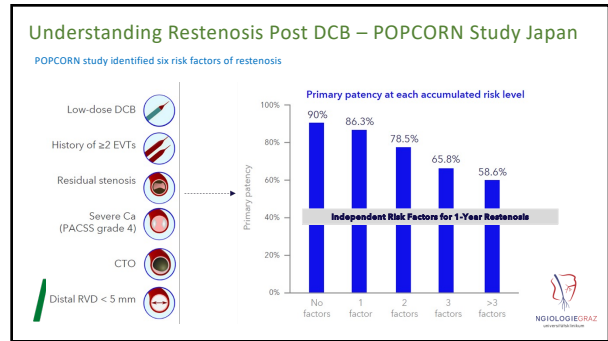
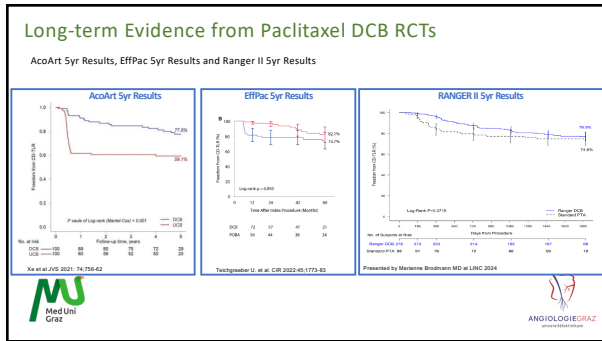
No Disclosures



Overview – What is the latest?

- What is the latest in long-term evidence for DCBs?
- What have the latest European and Japanese comparative studies told us?
- What is the latest on limus DCBs?

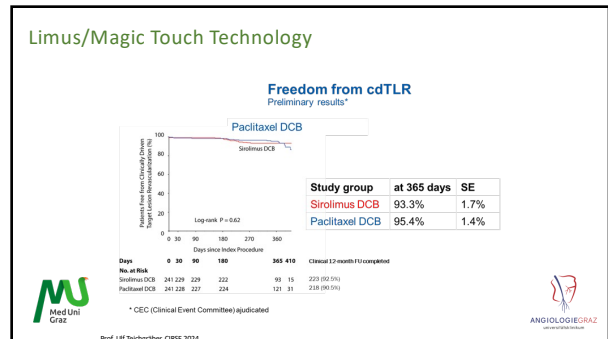






Limus Studies in the Femoropopliteal Artery?

SIRONA is the only Limus DCB RCT to compare against Paclitaxel DCBs in the SFA

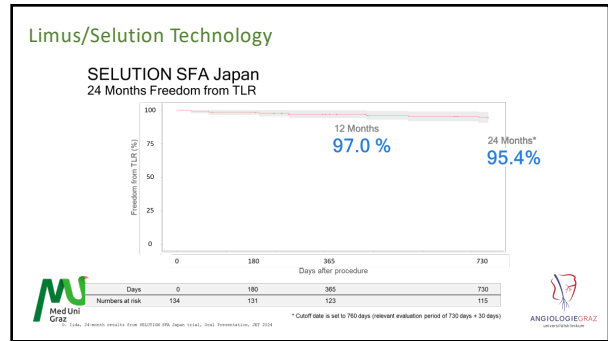
Study Name	Device	Patients included	Design	Geography	Sponsor	Status
PREVISION [®]	BD sirolimus DCB	34 (FH)	Single Arm	ANZ/Singapore	BD Bard	Enrolling
Future SFA Asia [†]	Magic Touch	279	RCT vs POBA	Asia	Concept Medical	Ongoing
SirPAD [‡]	Magic Touch	1132 (ATK and BTK)	RCT vs POBA	Switzerland	Investigator Initiated	Ongoing
SIRONA [§]	Magic Touch	478	RCT vs PTX DCB	Germany/Austria	Investigator Initiated	Ongoing
SOLUTION FIM [¶]	Solution SLR DCB	50 (FH)	Single Arm	Germany	Med Alliance	Completed
SUCCESS ^{**}	Solution SLR DCB	723 (ATK and BTK)	Single Arm	Asia/Europe/Latin America	Med Alliance	Completed
3rd FIM MSFA ^{††}	Solution SLR DCB	300	RCT vs POBA	US/Europe/Asia	Med Alliance	Ongoing
3rd FIM SFA ^{‡‡}	Solution SLR DCB	134	Single Arm	Japan	Med Alliance	Completed



Limus/Selution Technology

SELUTION SLR™ DEB in PAD – Clinical Program Overview

Extensive clinical evidence program consisting of 9 Studies and more than 1,800 patients



Overview – What is the latest?

- What is the latest on paclitaxel safety?**
The totality of evidence now clearly shows there is no paclitaxel mortality safety risk.
- What is the latest in long-term evidence for DCBs?**
Multiple devices now have evidence out to 5 years. Some showing sustained benefit.
- What have the latest European and Japanese comparative studies told us?**
Popcorn has identified risk factors associated with restenosis, COMPARE has shown non-inferiority at 12 months between high and low dose DCBs and reported 5yr outcomes at UINC 2024. PROSPECT Monster has shown similar outcomes between DCBs at 2 years in a non-randomized study.
- What is the latest on -limus DCBs?**
-We eagerly anticipate more evidence on the safety and effectiveness of -limus DCBs from randomized trials.

Thank you for your attention