TCT 131 - Impact of Vessel Prep Technology on Drug Uptake During Drug-coated Balloon Deployment- a Cadaver-based Study

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Background

Plaque modification devices are increasingly used during PTA procedures to improve vessel compliance and avoid large dissections prior to final treatment with drug coated balloons (DCBs). Anecdotal reports indicate that micro-incision devices increase the effectiveness of DCBs, but limited quantitative data is available.

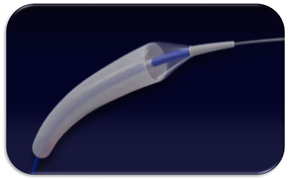
Material and Methods

Main study devices:

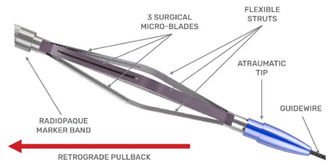
- **SELUTION SLR™ Sustained-Release Sirolimus-eluting Balloon* (DEB) manufactured by MedAlliance SA**

MicroReservoirs: to achieve sustained pharmaco-kinetic release up to 90 days.

Cell Adherent Technology (CAT™): amphipathic lipid technology which binds MicroReservoirs to the endolumenal surface and enhances drug retention.



- **FLEX Vessel Prep System (FLEX VP™ system)**
  - Manufactured by VentureMed



Protocol:
8 human cadaver vessels segments were treated with multiple passes with FLEX™ Vessel Prep followed by deployment of Selution SLR™ sirolimus-coated DEB. In two of the eight cases POBA balloons (Boston Scientific Sterling™ PTCA Catheter, 5 mm) were deployed after FLEX but prior to DEB. The Selution DEB was held at 6 atm for 180 seconds. Tissue samples were processed and analyzed for drug content according to validated test site laboratory methods.

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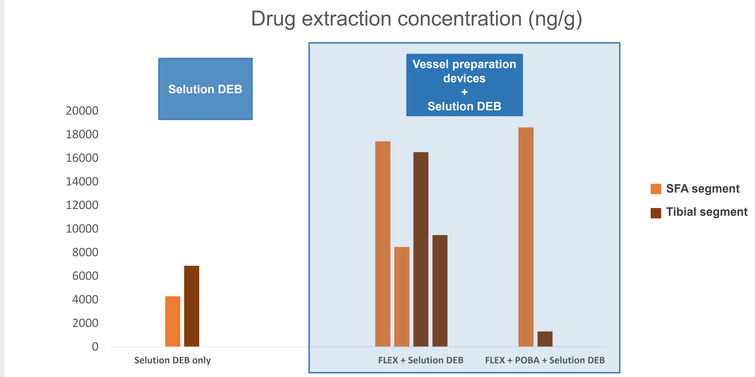
Patient Information	Cadaver Artery Treated	Treatment	Number of Pullbacks (FLEX)
81 years old, male	Proximal SFA	FLEX +Selution DEB	5
	Distal SFA	FLEX + POBA + Selution DEB	5
89 years old, male	Proximal Tibial	FLEX + Selution DEB	3
	Distal Tibial	FLEX + POBA + Selution DEB	3
64 years old, male	Proximal SFA	FLEX + Selution DEB	5
	Distal SFA	Selution DEB	-
	Proximal Tibial	FLEX + Selution DEB	3
	Distal Tibial	Selution DCB	-

Table 1. Baseline data

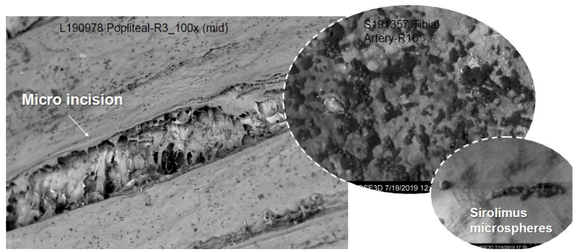
Conclusion

When Flex Vessel Prep device (Flex VP ⅄) is used to create micro-channels in the endolumenal wall prior to Selution SLR ⅄ DEB, the amount of drug retained in the vessel is enhanced, and SEM analysis provides evidence of drug microparticles deposited in the micro-incisions

Greater drug concentrations in artery treated with vessel preparation devices



Presence of Sirolimus in the created micro incisions



Impact on clinical practice

Physicians may choose using scoring devices prior to DEB treatment to enhance drug uptake

Study objective

To determine the influence of the FLEX Vessel Prep™ System™ on acute tissue adherence and distribution of drug microparticles and Sirolimus tissue concentrations following deployment of the SELUTION SLR™ DEB, in a human cadaver model

** SELUTION SLR DEB is an investigational device in the US and is not comercially available*

Results

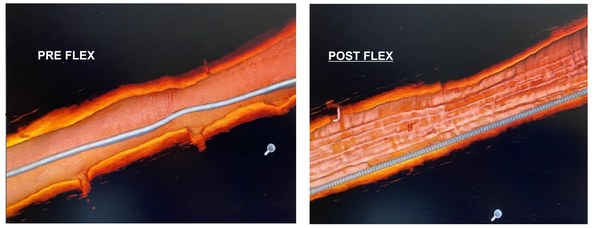


Figure 3. Example of Flex imicro-channel creation as shown by OCT in an animal ISR lesion-

Sample ID	Extraction Conc. (ng/g)	Total Sirolimus in Artery (µg/g)	Artery weight (g)	Total Sirolimus per Artery (µg)	Treatment matrix
Tibial Segment 1	16500	16.5	0.22	3.66	Proximal FLEX + Selution DEB
Tibial Segment 2	1300	1.30	0.25	0.33	Distal FLEX + POBA + Selution DEB
Tibial Segment 1	9470	9.47	0.43	4.09	Proximal FLEX + Selution DEB
Tibial Segment 2	6870	6.87	0.45	3.11	Distal Selution DEB

Table 2. Tibial lesions

Sample ID	Extraction Conc. (ng/g)	Total Sirolimus in Artery (µg/g)	Artery weight (g)	Total Sirolimus in Artery (µg)	Treatment matrix
SFA Segment 1	17400	17.4	1.55	27.0	Proximal FLEX + Selution DEB
SFA Segment 2	18600	18.6	1.91	35.5	Distal FLEX + POBA + Selution DEB
SFA Segment 1	8440	8.44	1.51	12.8	Proximal FLEX + Selution DEB
SFA Segment 2	4280	4.28	2.00	8.58	Distal Selution DEB

Table 3. SFA lesions

Limitations

Drug amounts found may underestimate actual drug delivery to living vessels since drug transport via the microcirculation in cadaveric samples is limited.. Test model may also underestimate drug transfer in a living vessels since Selution SLR™ DEB requires, at least in part, living cell membranes to fully attract the lipid coating membrane carrying the drug microparticles. The sample sizes in this preliminary study were small.

Disclosures:

- J Shulze is a paid consultant for Medalliance SA
- J Piggot MD holds a financial interest in Venturemed
- J Zeroni is a full time employee of Venturemed