Optimizing the SFA in CLI

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other(s)

- [ ] I do not have any potential conflict of interest

How to optimize the SFA in CLI?

Well, recanalize it and make it patent

But by what means?

What lesions do we face in CLI patients

More multilevel (SFA+POP)

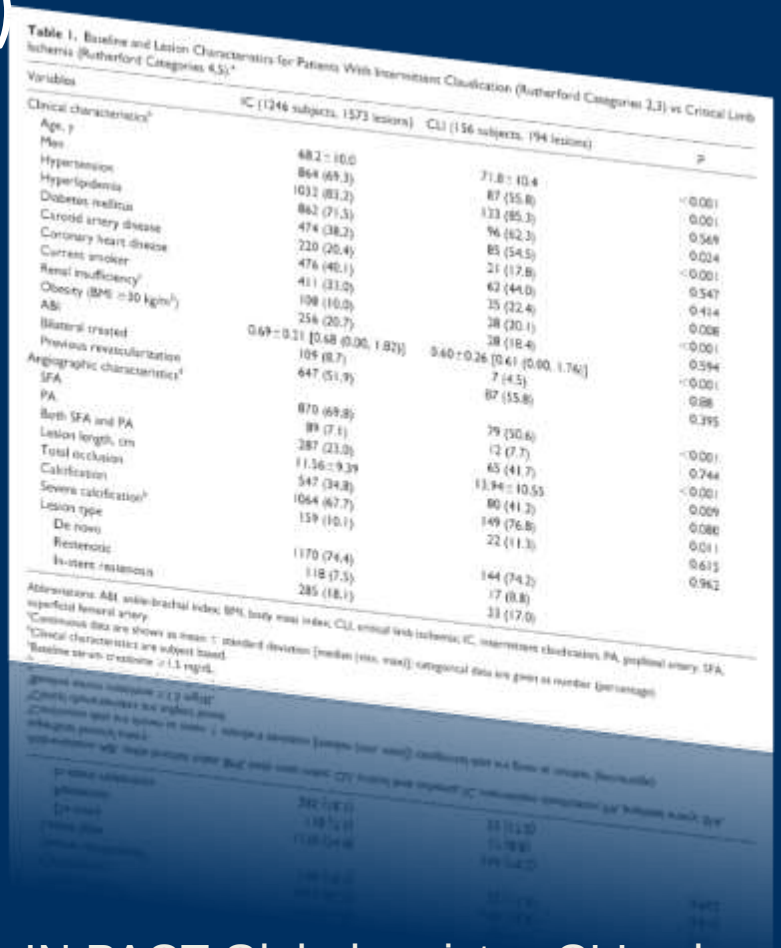
More renal insufficiency

More diabetes

Older

Longer lesions

- Compared to claudicants



IN.PACT Global registry, CLI subgroup

The Data Dilemma in SFA-Treatment concerning the CLI Population

Inclusion criteria for SFA-DCB RCDs excluded Rutherford 5/6 or CLI numbers were small (e.g. In.Pact SFA[1], Biolux PI[2])

Most trials mixed ICL & CLI patients

Demographics Biolux PI

Demographics	DRB n = 30 (n / %)	PTA n = 30 (n / %)
Age (Mean ± SD) yrs	70 ± 10	71 ± 10
Diabetes mellitus	11 / 37	9 / 30
Hypertension	23 / 77	21 / 70
Hyperlipidemia	18 / 60	19 / 63
Smoking	19 / 63	22 / 73
History of Peripheral Arterial Disease	18 / 60	20 / 67
History of previous PTA	17 / 57	18 / 60
Rutherford Classification		
Class 2 Moderate	7 / 23	9 / 30
Class 3 Severe	17 / 57	17 / 57
Class 4 Ischemic Rest Pain	4 / 13	2 / 7
Class 5 Minor Tissue Loss	2 / 7	2 / 7

Tepe, G, Laird, J, Schneider, P. Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal peripheral artery disease: 12-month results from the IN.PACT SFA randomized trial. Circulation. 2015;131:495–502.
J Endovasc Ther. 2015 Feb;22(1):14-21. doi: 10.1177/1526602814564383.
Paclitaxel-releasing balloon in femoropopliteal lesions using a BTHC excipient: twelve-month results from the BIOLUX P-I randomized trial.
Scheinert D1, Schulte KL2, Zeller T3, Lammer J4, Tepe G5.

DES in CLI

DESAFINADO Registry

DES
for
Arteria **F**emoralis
IN
Asian
Diabetic
F**O**ot

Study Population (n = 64)

Age, mean±SD	70±12.5
Gender (male)	38(59)
Ischemic heart disease	26 (41)
Diabetes Mellitus	50 (78)
Hyperlipidemia	48 (75)
Hypertension	55 (86)
Dialysis dependent renal failure	11 (17)
Rutherford	
3	11 (16)
4	3 (5)
5	53 (79)
Runoff	
0	8 (12)
1	32 (48)
2	16 (24)
3	3 (11)

78% DM

84 % CLTI

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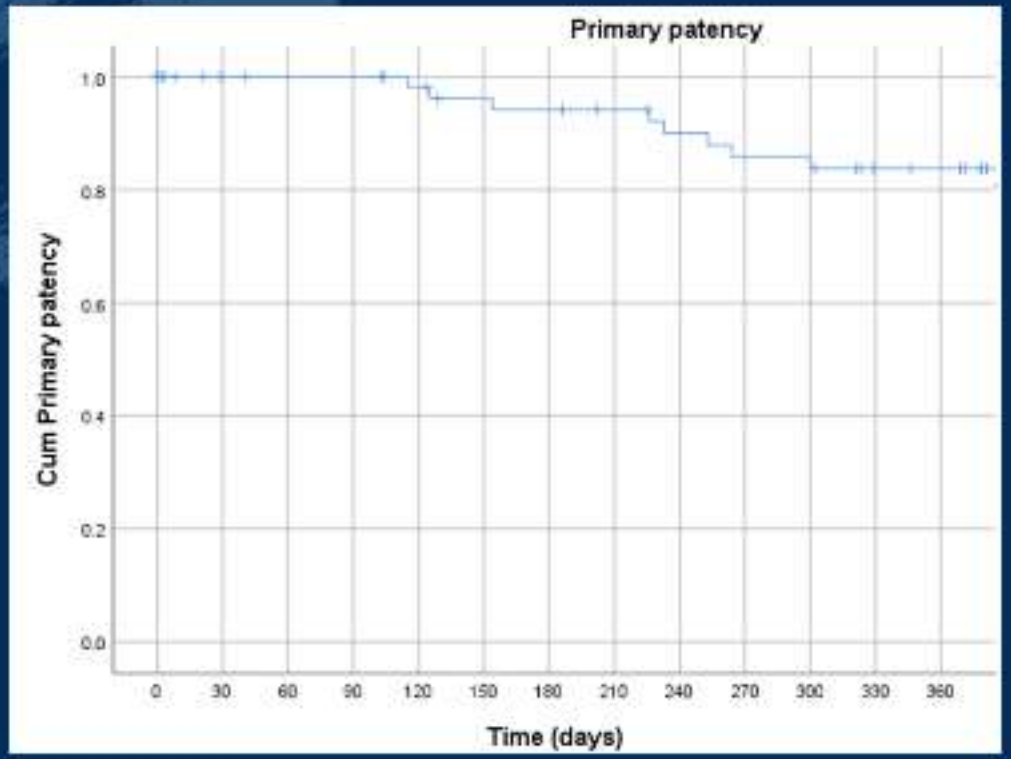
12 Month Primary Patency – Total Cohort



Total Cohort

PP = 84 %

PSVR < 2.4

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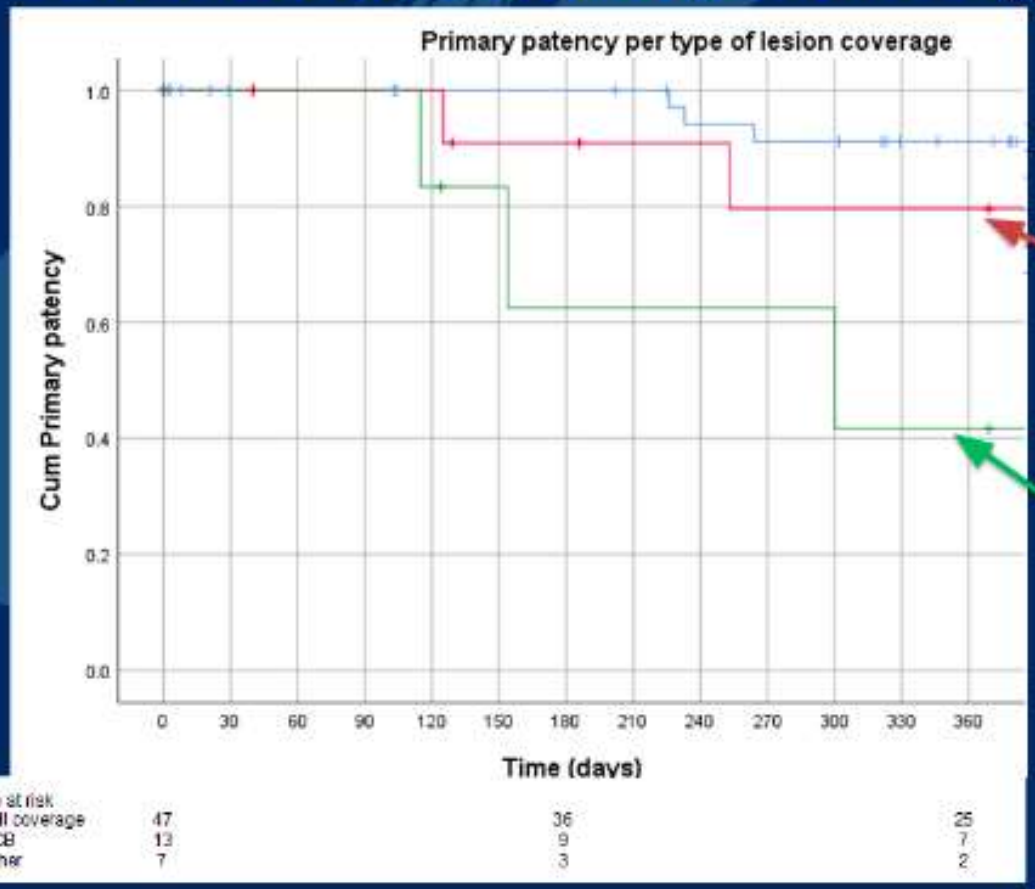
If DES are used full lesion coverage works best

12 Month Primary Patency – Coverage subtype



Total Lesion Coverage with DES
(mean LL = 201 ± 136)
PP = 91 %

"Hybrid" lesion coverage with DES/DCB
(mean LL = 153 ± 86)
PP = 80 %

BMS/POBA + DES
(mean LL = 211 ± 143)
PP = 42 %

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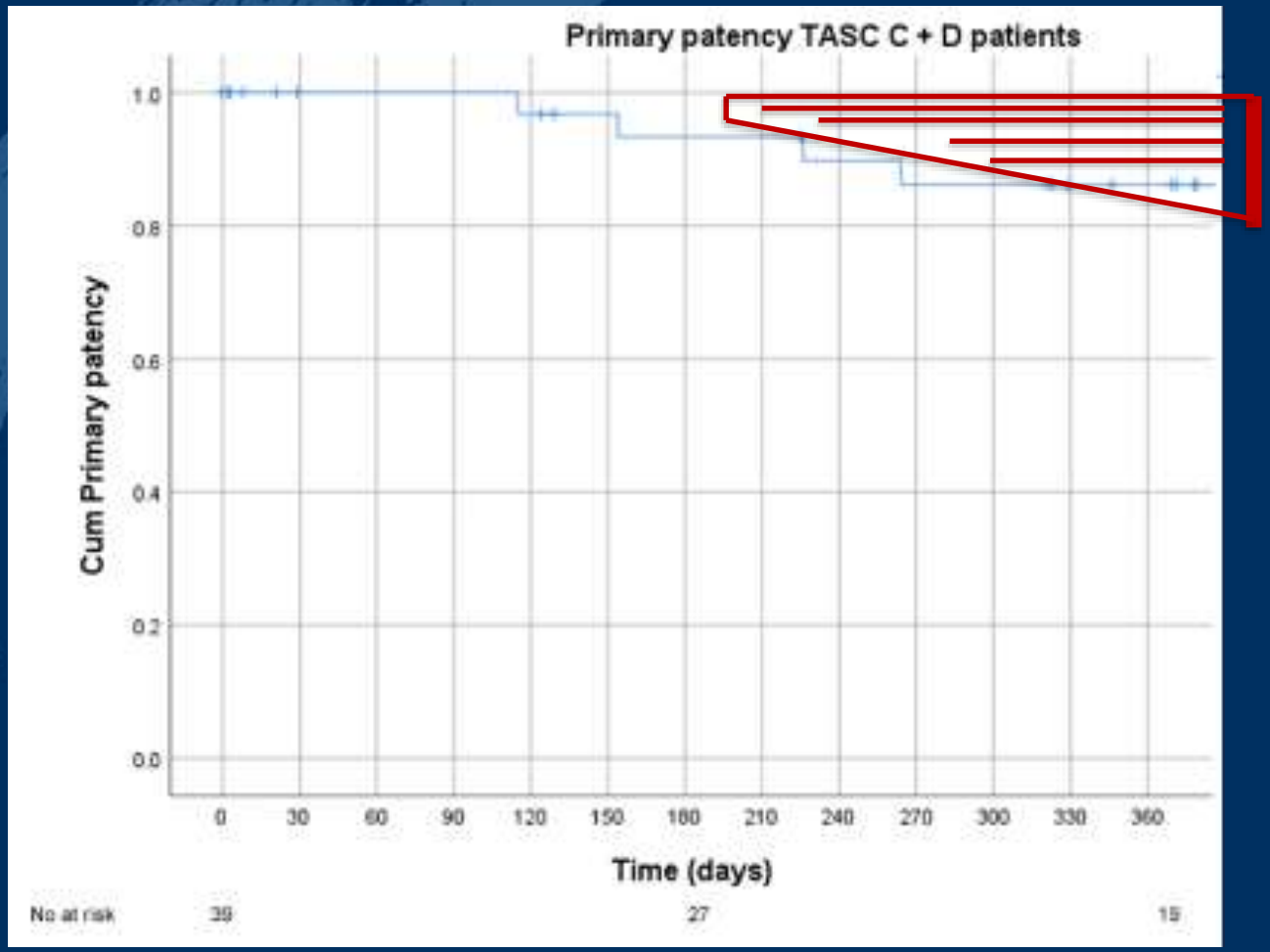
Options for the patients above the patency curve



CASE STUDY SFA/POP CLI

Case Details

- 65 year old female
- Right leg Rutherford IV, ABI 0,3
- Contralateral approach
- Multiple treatment locations
- Proximal SFA: ISR TOSAKA III/ 140mm
- Popliteal artery: Denovo CTO / 40mm based on an ideopathic dissection from PII down to TP-trunc
- AT: Denovo High Grade Stenosis / 10mm

Pre Intervention

SFA ISR & CTO

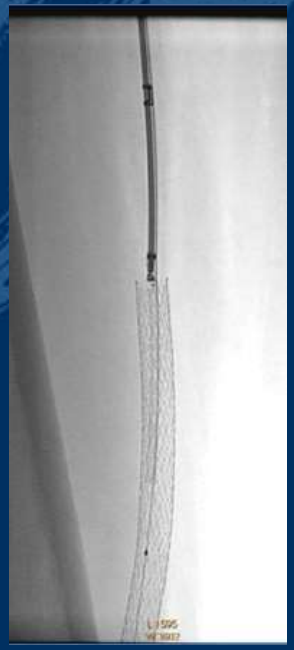
DISTAL SFA CTO

AT

PROXIMAL SFA: ISR & CTO

Fluoro Series

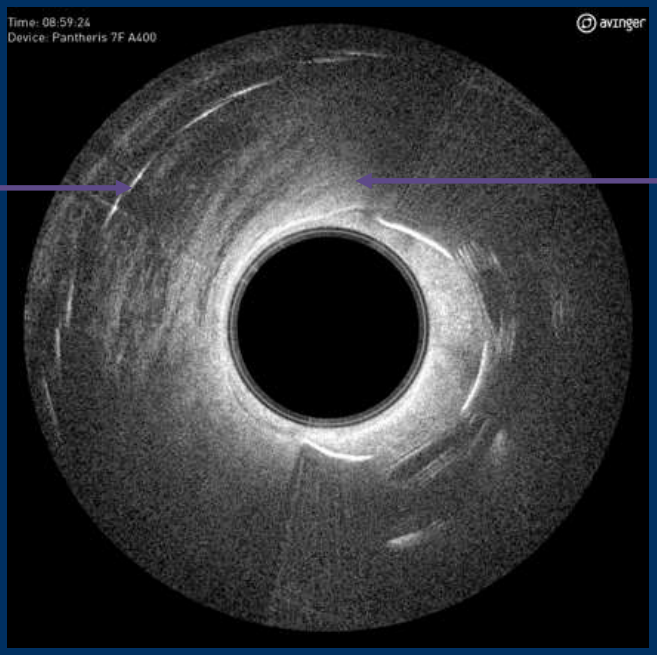
Post CTO Crossing



Treating Proximal Lesion

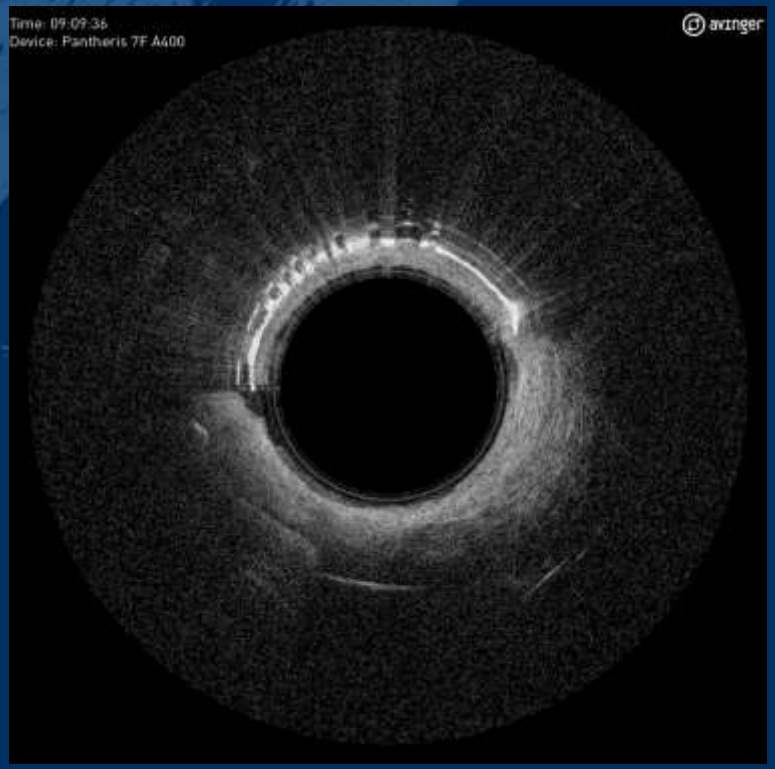
Post Pantheris

OCT Image



PROXIMAL SFA: VIDEO OF ISR TREATMENT

OCT Loop

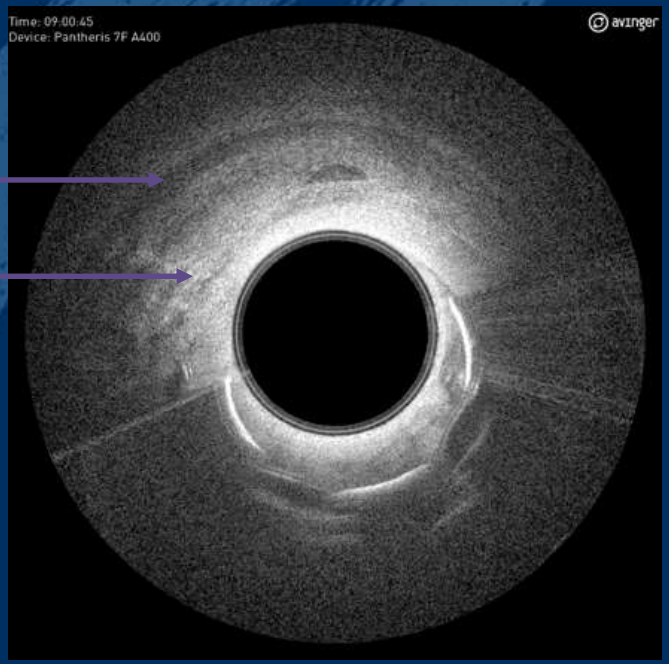


What to Look For

- Clear visualization of stent struts
- Real-time information allowing physician to cut up to stent struts

DISTAL SFA: DENOVO CTO

OCT Image



Treating non-stented segment

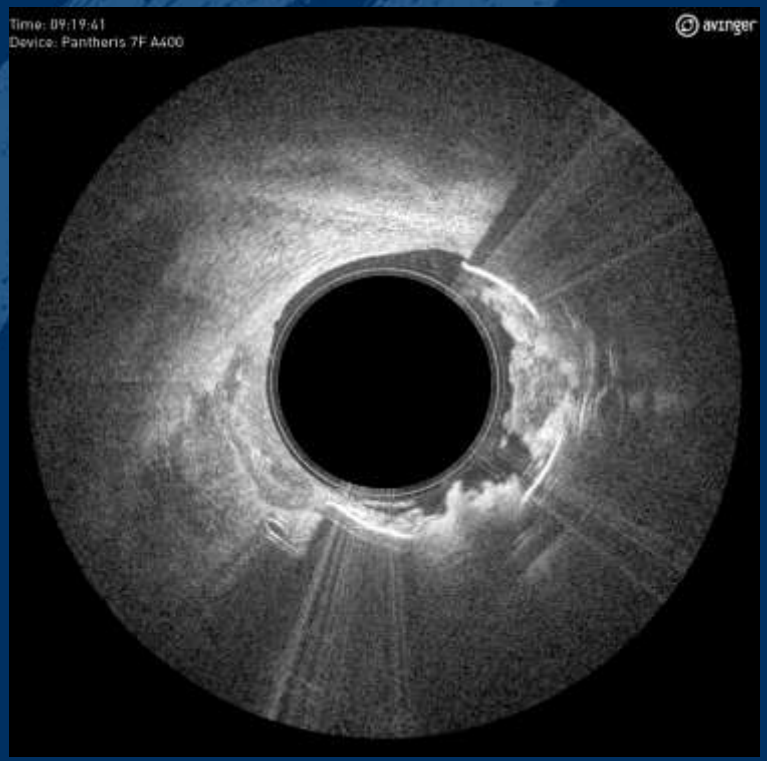
Fluoro Series

Pre Treatment

Post Pantheris

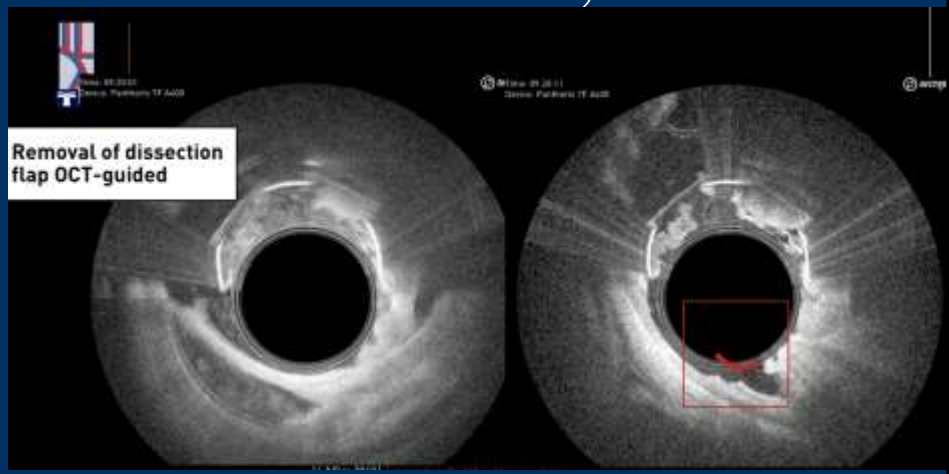
DISTAL SFA: DENOVO CTO

OCT Loop



What to Look For

- Visualization allows reliable removal of disease while leaving arterial structures intact
- Directional cutting in combination with onboard imaging allows for precise targeting of problem areas
- Dissection flap, which may cause acute and long-term issues if left behind, can be removed effectively



AT: HIGH GRADE STENOSIS

Fluoro Series

Pre Treatment

Pantheris Treatment AT

PT Touch Up

FINAL RESULT

PROXIMAL SFA

DISTAL SFA / AT

PRE

PRE - DISTAL SFA

POST

PRE - AT

POST

ABI post procedure 1,2, Rutherford 0

Conclusion

- The best treatment option for SFA-disease in CLI-patients is still to be defined since head-to-head comparisons are rare
- Paclitaxel based SFA devices show clear superiority in TLR reduction in CLI patients
- If stented there is more evidence for full lesion coverage than spot stenting
- INSIGHT Trial (multicenter, multinational, single arm)evaluates the role of image-guided atherectomy + DCB in ISR, results are expected for end 2020

Thank you for listening

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