

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:

- Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - 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

Table 1. Baseline and Lesion Characteristics for Patients With Intermittent Claudication (Rutherford Category 2,2) vs Critical Limb Ischemia (Rutherford Category 4,5)*

Variables	IC (1246 subjects, 1573 lesions)	CLI (156 subjects, 194 lesions)	P
Clinical characteristics^b			
Age, y	68.2 ± 10.0	71.8 ± 10.4	
Men	864 (69.3)	87 (55.8)	<0.001
Hypertension	1032 (83.2)	133 (85.3)	0.001
Hyperlipidemia	862 (71.3)	96 (62.3)	0.568
Diabetes mellitus	474 (38.2)	85 (54.5)	0.024
Cerebral artery disease	220 (20.4)	21 (17.8)	<0.001
Coronary heart disease	476 (46.1)	62 (44.0)	0.547
Current smoker	411 (33.0)	35 (22.4)	0.414
Renal insufficiency ^c	190 (16.0)	28 (20.1)	0.008
Obesity (BMI ≥ 30 kg/m ²)	254 (20.7)	38 (24.4)	<0.001
ABI	0.69 ± 0.11 [0.48 (0.00, 1.02)]	0.40 ± 0.26 [0.41 (0.00, 1.76)]	0.594
Bilateral treated	105 (8.7)	7 (4.5)	<0.001
Previous revascularization	647 (51.9)	87 (55.8)	0.08
Angiographic characteristics^d			
SFA	870 (69.8)	79 (50.6)	0.395
PA	89 (7.1)	12 (7.7)	
Both SFA and PA	287 (23.0)	45 (41.7)	<0.001
Lesion length, cm	11.56 ± 9.39	13.94 ± 10.55	0.744
Total occlusion	547 (34.8)	80 (41.3)	<0.001
Calcification	1064 (67.7)	149 (76.8)	0.009
Severe calcification^e			
Lesion type	159 (10.1)	22 (11.3)	0.080
De novo	1170 (74.4)	17 (8.8)	0.011
Restenotic	118 (7.5)	144 (74.2)	0.613
In-stent restenosis	285 (18.1)	33 (17.0)	0.962

Abbreviations: ABI, ankle-brachial index; BMI, body mass index; CLI, critical limb ischemia; IC, intermittent claudication; PA, popliteal artery; SFA, superficial femoral artery.
^aContinuous data are shown as mean ± standard deviation [median (min, max)]; categorical data are given as number (percentage).
^bClinical characteristics are subject based.
^cBaseline serum creatinine ≥ 1.1 mg/dL.
^dSegmental stenosis/occlusion ≥ 1.25 mm.
^eCalcification was defined as a segment with a maximum diameter stenosis of ≥ 50% and a length of ≥ 10 mm.

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 SFA¹, Biolux PI²)

Demographics Biolux PI

Most trials mixed ICL & CLI patients

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 Femorals

IN

Asian

Diabetic

Foot

Study Population (n = 64)

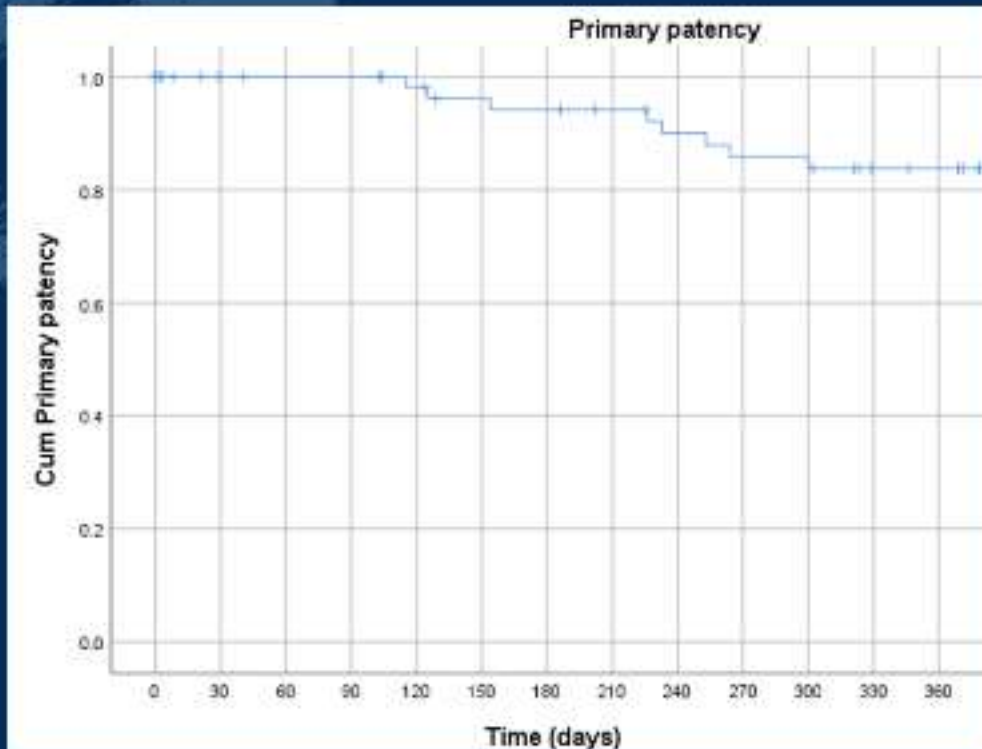
Age, mean±SD	70±12.5
Gender (male)	38(59)
Ischemic heart disease	26 (41)
Diabetes Mellitus	50 (78)
Hyperlipidemia	48 (75)
Hypertension	55 (86)
Dialysis dependent renal failure	11 (17)
Rutherford	
3	11 (16)
4	3 (5)
5	53 (79)
Runoff	
0	8 (12)
1	32 (48)
2	16 (24)
3	3 (11)

} 78% DM

} 84% CLTI



12 Month Primary Patency – Total Cohort



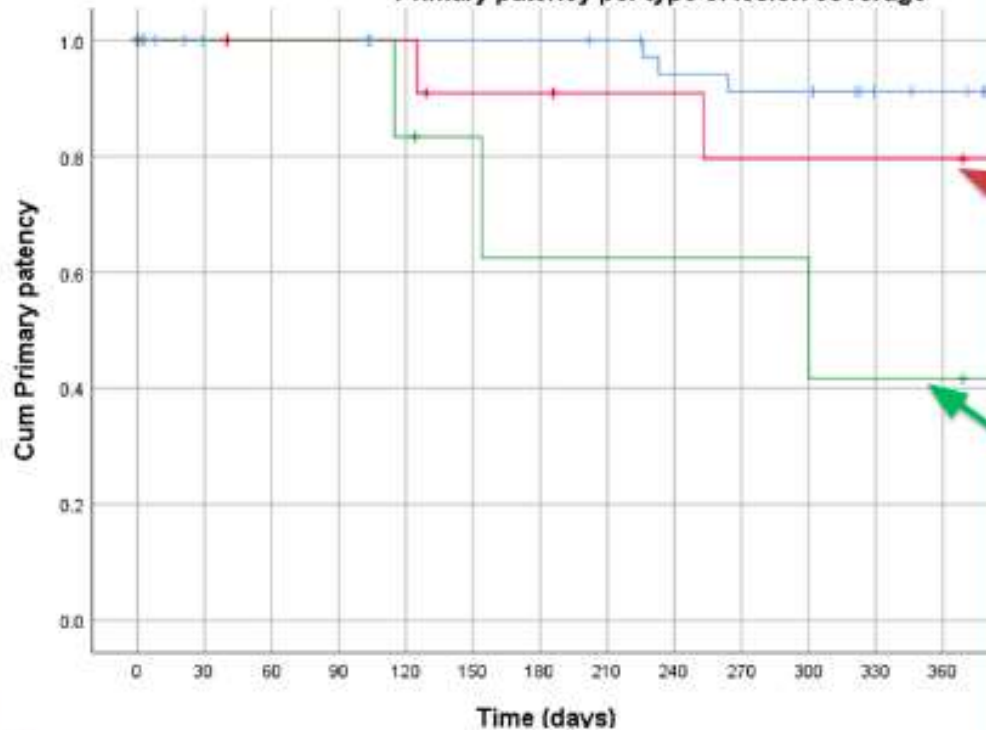
Total Cohort
PP = 84 %

PSVR < 2.4

If DES are used full lesion coverage works best

12 Month Primary Patency – Coverage subtype

Primary patency per type of lesion coverage



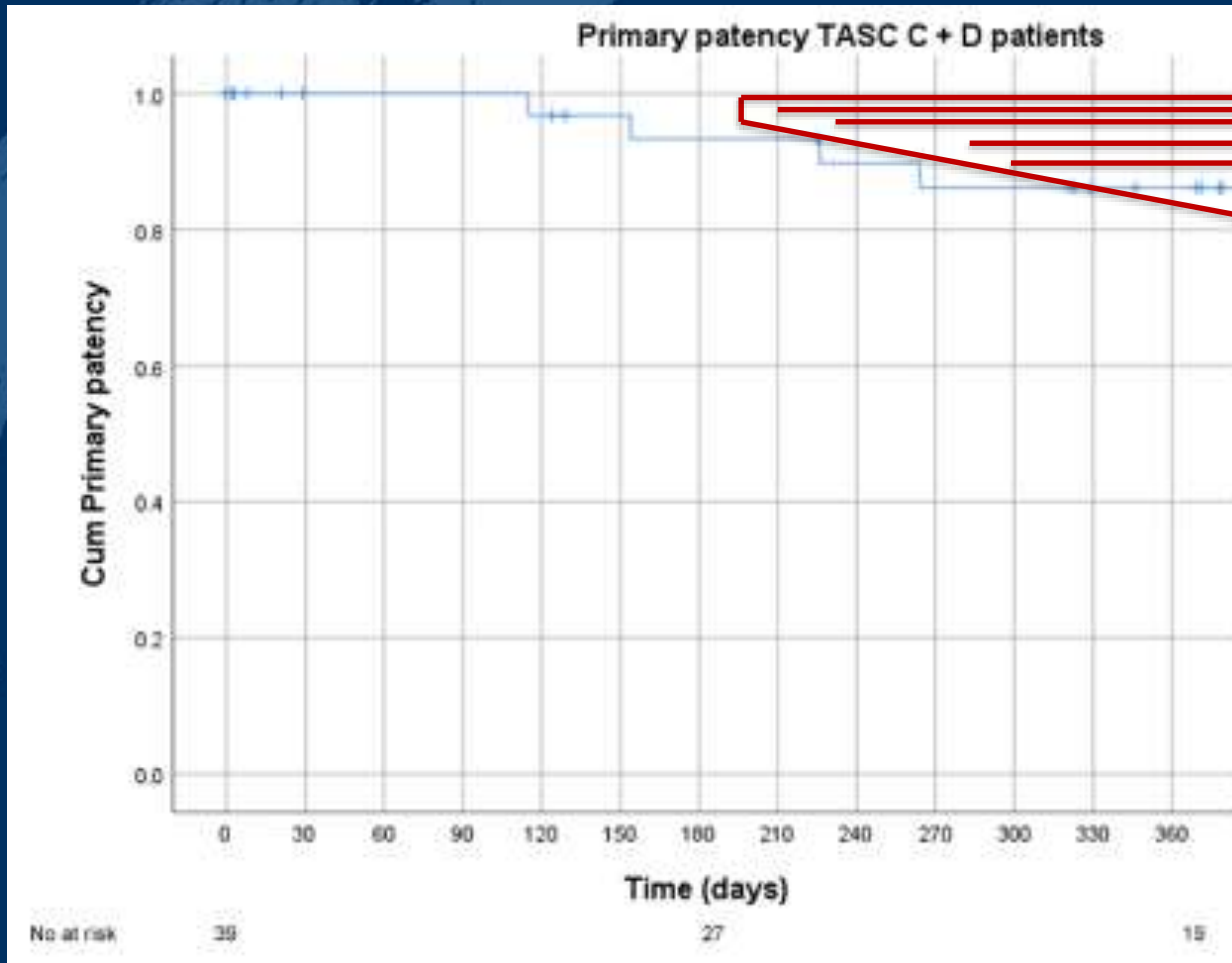
Total Lesion Coverage with DES
(mean LL = 201 ± 136)
PP = 91 %

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

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

At risk	47	36	25
Full coverage	13	9	7
Other	7	3	2

Options for the patients above the patency curve



CASE STUDY SFA/POP CLI

Case Details

Pre Intervention

- 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



SFA ISR & CTO



DISTAL SFA CTO



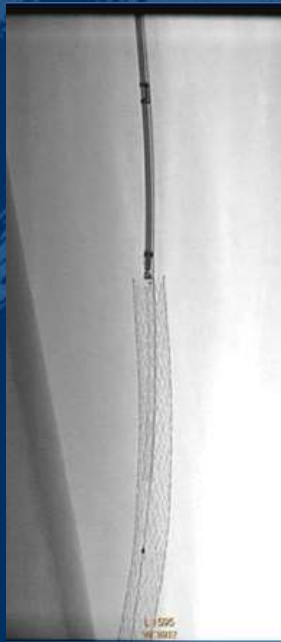
AT

PROXIMAL SFA: ISR & CTO

Fluoro Series



Post CTO Crossing

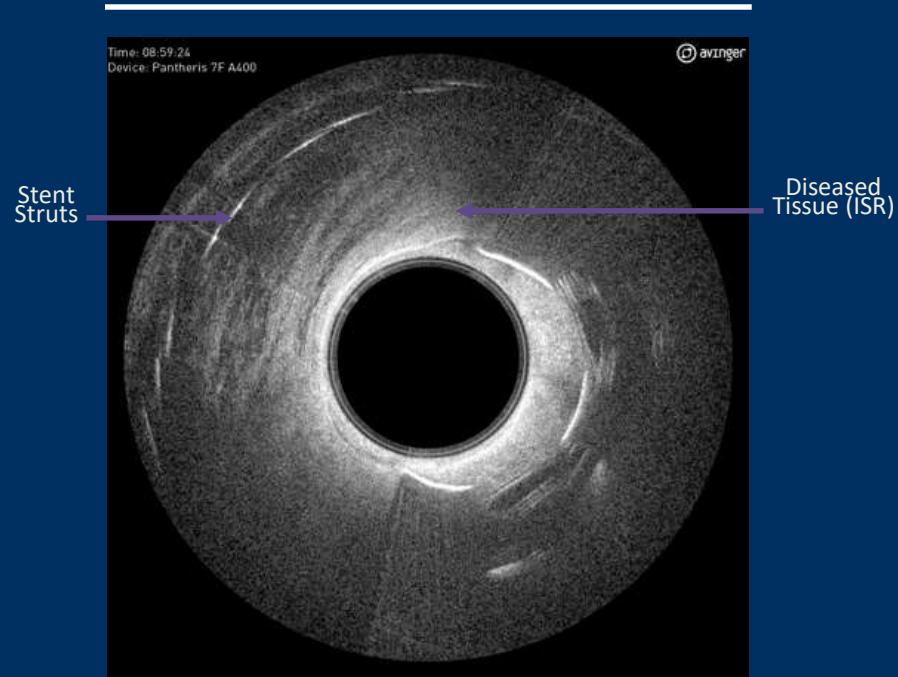


Treating Proximal Lesion



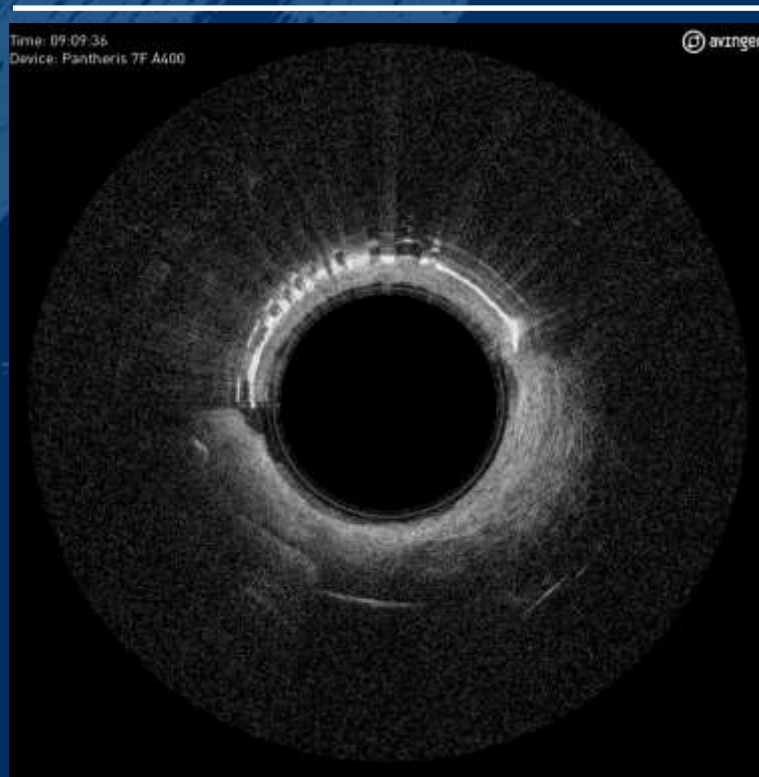
Post Pantheris

OCT Image



PROXIMAL SFA: VIDEO OF ISR TREATMENT

OCT Loop



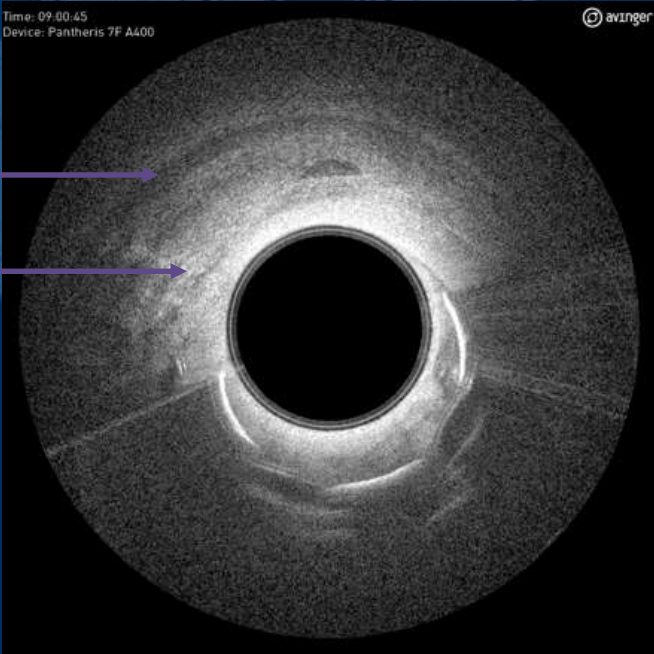
What to Look For

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

DISTAL SFA: DENOVO CTO

OCT Image

Fluoro Series



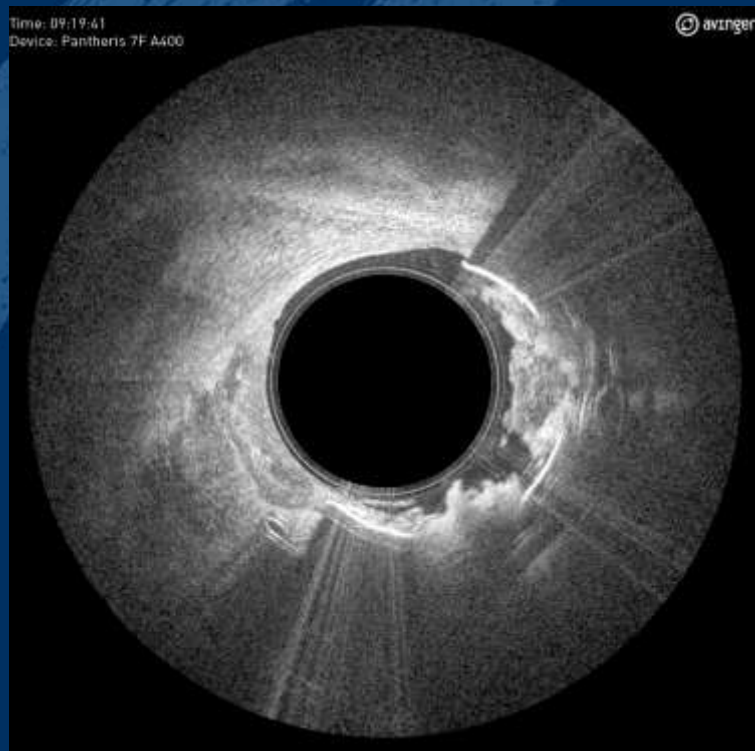
Treating non-stented segment

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

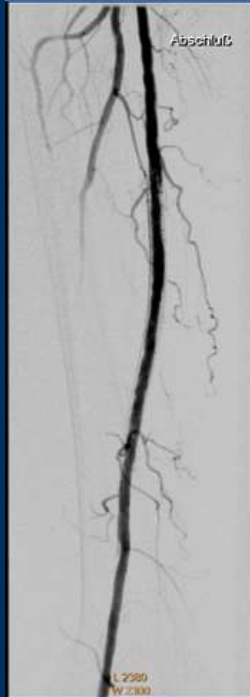
PROXIMAL SFA



PRE



PRE - DISTAL SFA



POST

DISTAL SFA / AT



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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