



JANUARY 19-21 2017

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

Debulking and CTO

The latest instruments

How do they work? Which indications for which results

Giovanni Torsello

Münster, Germany



Disclosure

Speaker name:

.....G.Torsello.....

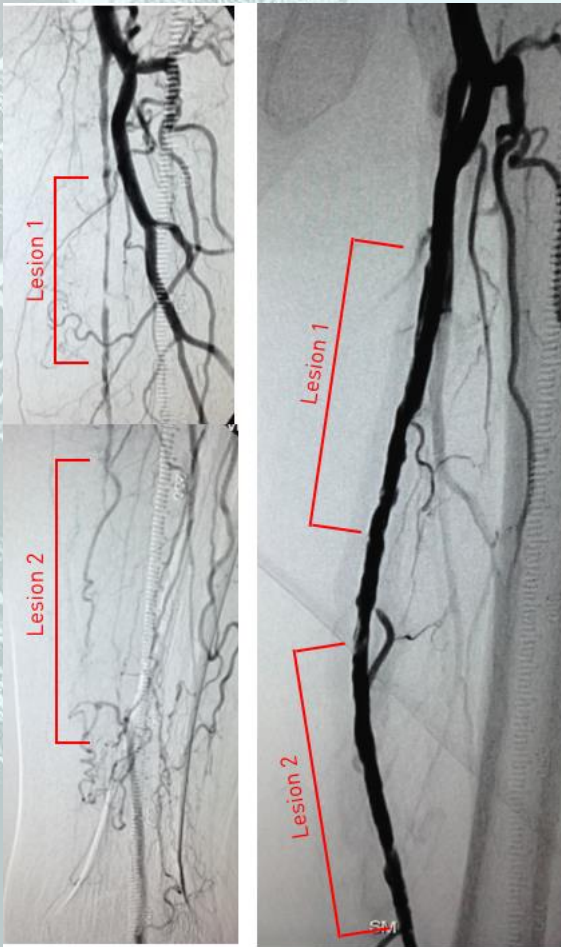
- I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

X



Techniques for CTO

Guidewire and CTO support catheter
CTO crossing devices



Crossing Strategies

Mean lesion length= 134 ± 73 mm
Stent use= 70%

438 total CTO lesions

295 (67.4%) primary
wire-catheter

P<0.001

143 (32.6%) primary
CTO crossing device

83 (28.1%)
Switch to CTO
Crossing device

79 (26.7%)
Use of Re-entry
device

25 (17.5%)
Use of Re-entry
device

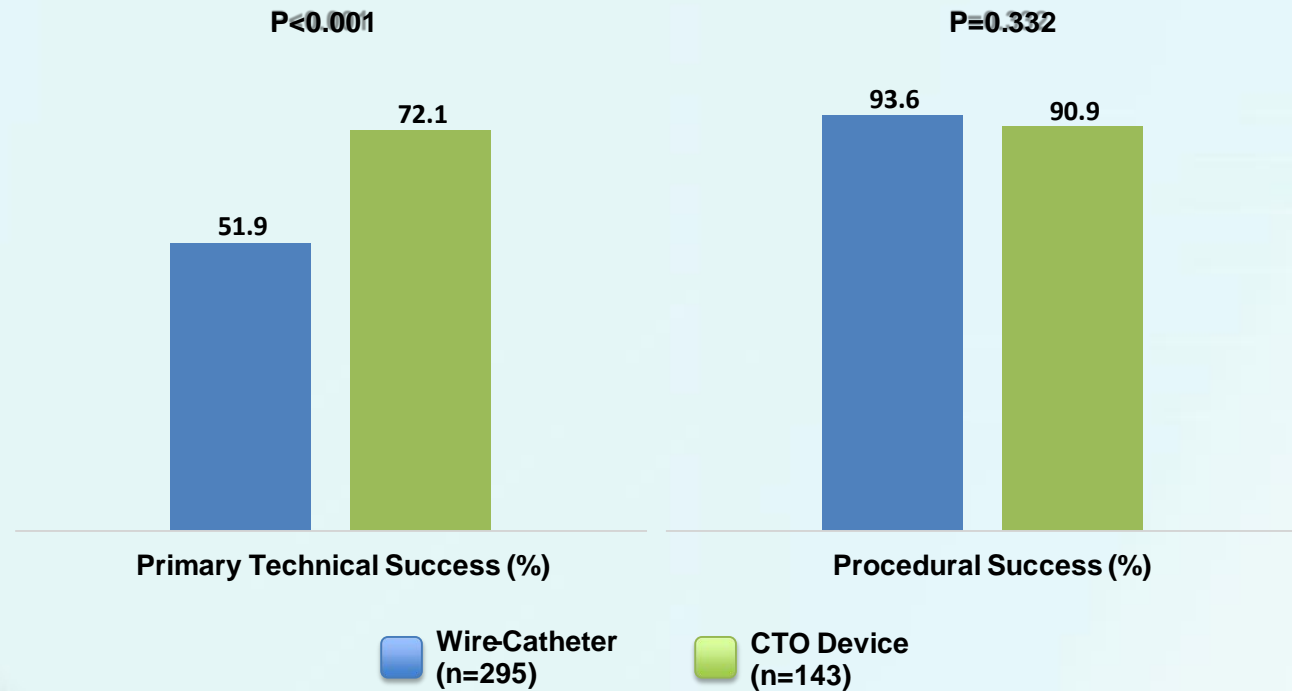
7 (4.9%)
Additional CTO
crossing device

P<0.001

P<0.001

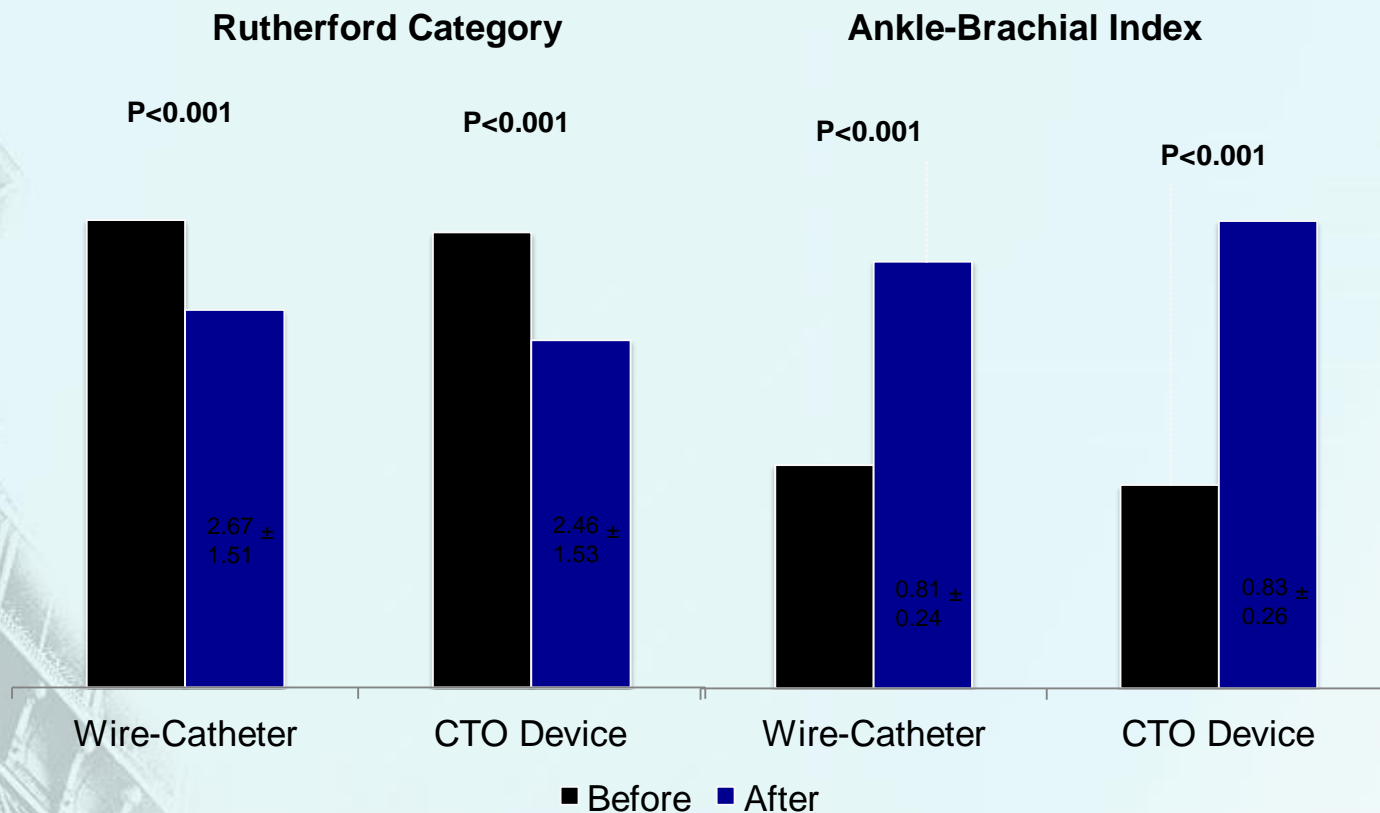


Technical and Procedural Success





Results: 12-month Clinical Outcomes





CTO support catheters

Quickcross

Trailblazer

Navicross

GlideCath

Rubicon

CXI



CTO crossing devices

Frontrunner

Truepath

Wildcat

Crosser

Viance

Laser



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Re-Entry catheters

Outback
Offroad
Pioneer
Enteer



Recanalisation rates with established devices

■ Crosser CTO Recanalization System (Flowcardia Inc, Sunnyvale, CA now Bard)	70%
■ TruePath CTO device (Boston Scientific, Natick, MA)	80%
■ Frontrunner XP (Cordis Corp, Miami, FL)	65% - 90%
■ Wildcat/Ocelot (Avinger, Redwood City, CA)	90% - 100%
■ Outback (Cordis Corp, Miami, FL)	86% - 100%
■ Pioneer	86% - 100%



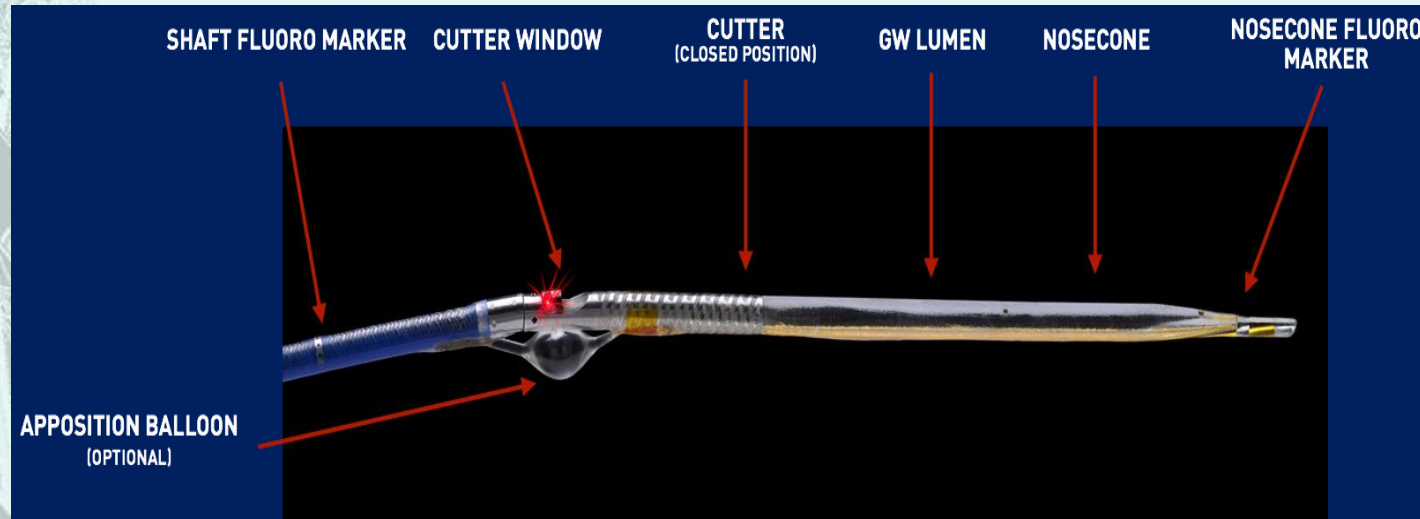
The latest instruments

Pantheris Catheter (Avinger, Redwood City, CA)

OCT guided CTO crossing
+
OCT guided atherectomy



Pantheris Catheter (Avinger)



- 8Fr/7Fr
- 130/110 cm working length
- .014 guidewire compatible
- Cutter rotation = 1000rpm
- OCT - frequency



Step 1.

Recanalization of total occlusion

- Crossed using the Ocelot Catheter
- Real time confirmation of true lumen crossing
- Reduced fluoroscopy using OCT for crossing



Step 2.

Therapy by atherectomy

- OCT guided atherectomy using the Pantheris Catheter
- Real time directional cutting targeting plaque
- Reduced fluoroscopy using OCT for atherectomy
- Post atherectomy DEB



LUMIVASCULAR CASE STUDY

- 52 yo female
- Claudication both legs, popliteal and foot pulses missing, ABl right 0,4 left 0,5
- pain free WD 100m
- nicotine use until 2010 40 pck yrs, hyperlipidemia, chemo and surgery for breast cancer 2010
- lesion: bilateral TASC D SFA CTO





Clinical outcome

- complete pulses right leg
- ABI 1,2
- **after treatment of left leg
(Pantheris + DEB) WD
exceeds 8000m**





6 week angiographic and Duplex FU

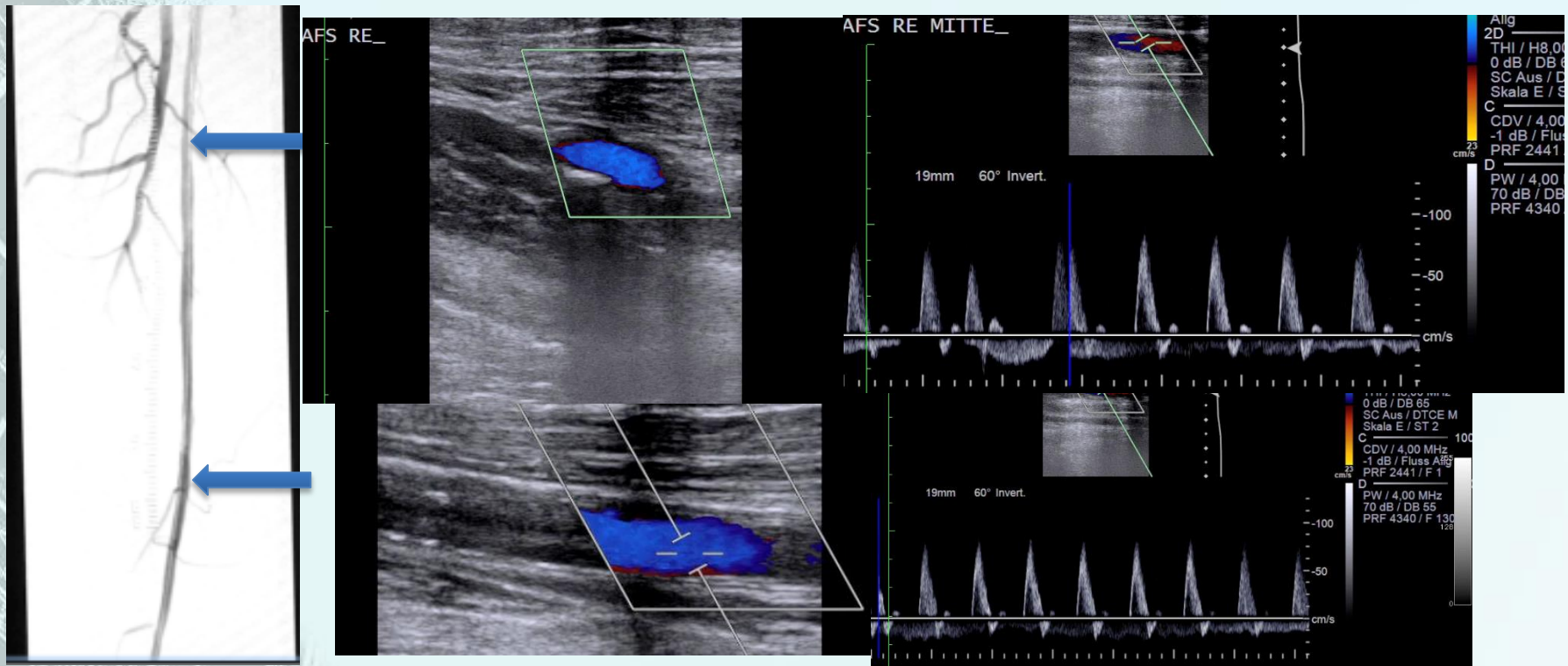


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12 month Duplex FU,- ABI: 1,2



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VISION IDE trial

VISION Trial for Optical Coherence Tomography (OCT) Guided Atherectomy Using the Pantheris Catheter

*6 Month Safety and Efficacy Endpoints
Correlated with OCT Imaging and Histologic
Tissue Analysis*



VISION IDE trial

MAJOR INCLUSION CRITERIA

- Patient is ≥ 18 years old
- Patient is candidate for percutaneous intervention for PAD
- Rutherford Classification 2-5
- RVD ≥ 3.0 mm and ≤ 7.0 mm by visual estimation
- De novo target lesion(s) with stenosis $\geq 70\%$. No more than 2 lesions may be treated.
- Target lesion length ≤ 15 cm (may be two tandem lesions that do not exceed 15 cm in length)
- At least one patent tibial run-off

MAJOR EXCLUSION CRITERIA

- Moderate to severe calcification
- Target lesion stenosis $< 70\%$
- Target lesion within graft or target lesion in the iliac artery
- In-stent restenosis within the target lesion
- Acute ischemia and/or acute thrombosis
- Significant ($\geq 70\%$) lesions proximal to the TL not successfully treated during the index procedure (i.e., iliac lesion treated prior to target lesion treatment on same day)
- Lesion in the contralateral limb requiring intervention during the index procedure or within 30 days from index procedure



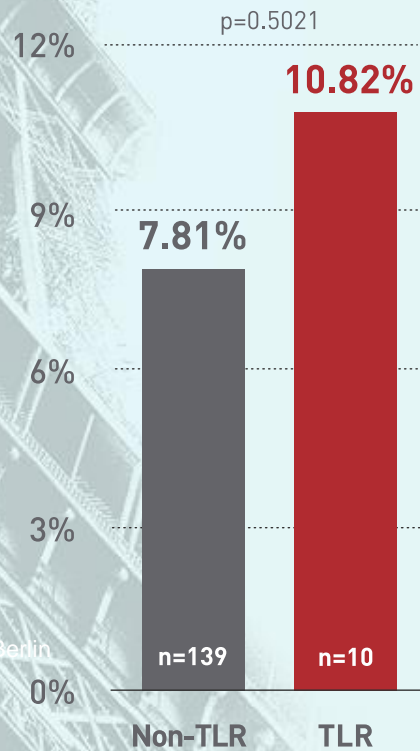
Major Adverse Events through 6 months

6 Month Major Adverse Events	Subjects (n=151)*
Cardiovascular related death	2.6% (4 / 151)
Unplanned, major index limb amputation	0% (0 / 151)
Target lesion revascularization (TLR)	7.9% (12 / 151)
Myocardial infarction	2.0% (3 / 151)
Device related events	4% (6 / 151) [†]

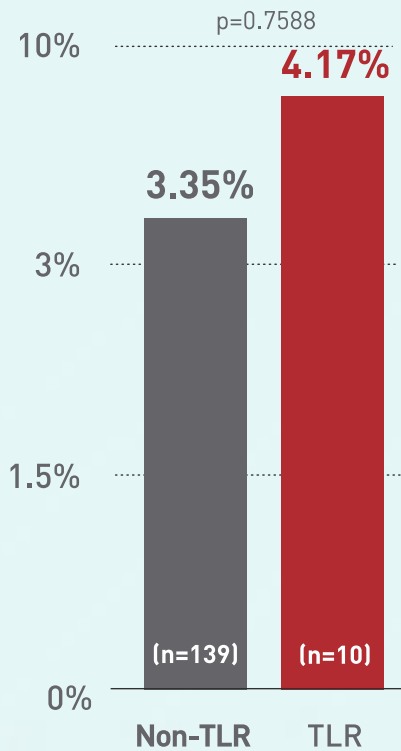


Histologic Analysis: Non-TLR vs. TLR

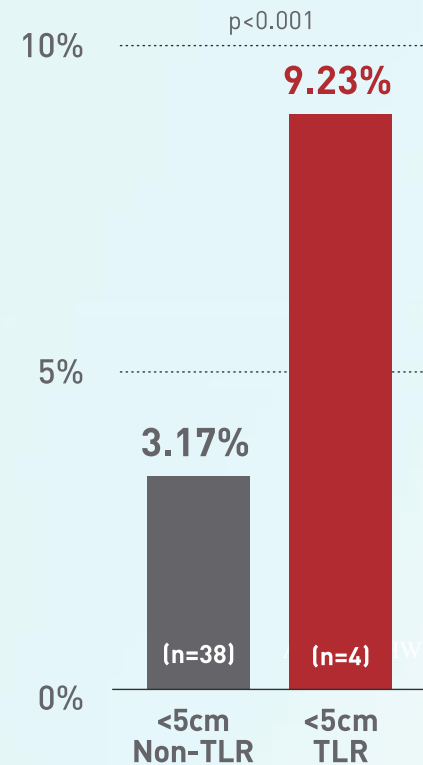
Thrombus Burden (%)



% Adventitia Resection



% Adventitia Resection in <5cm Lesions



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PT35 – no adventitia

Elastica van Gieson staining

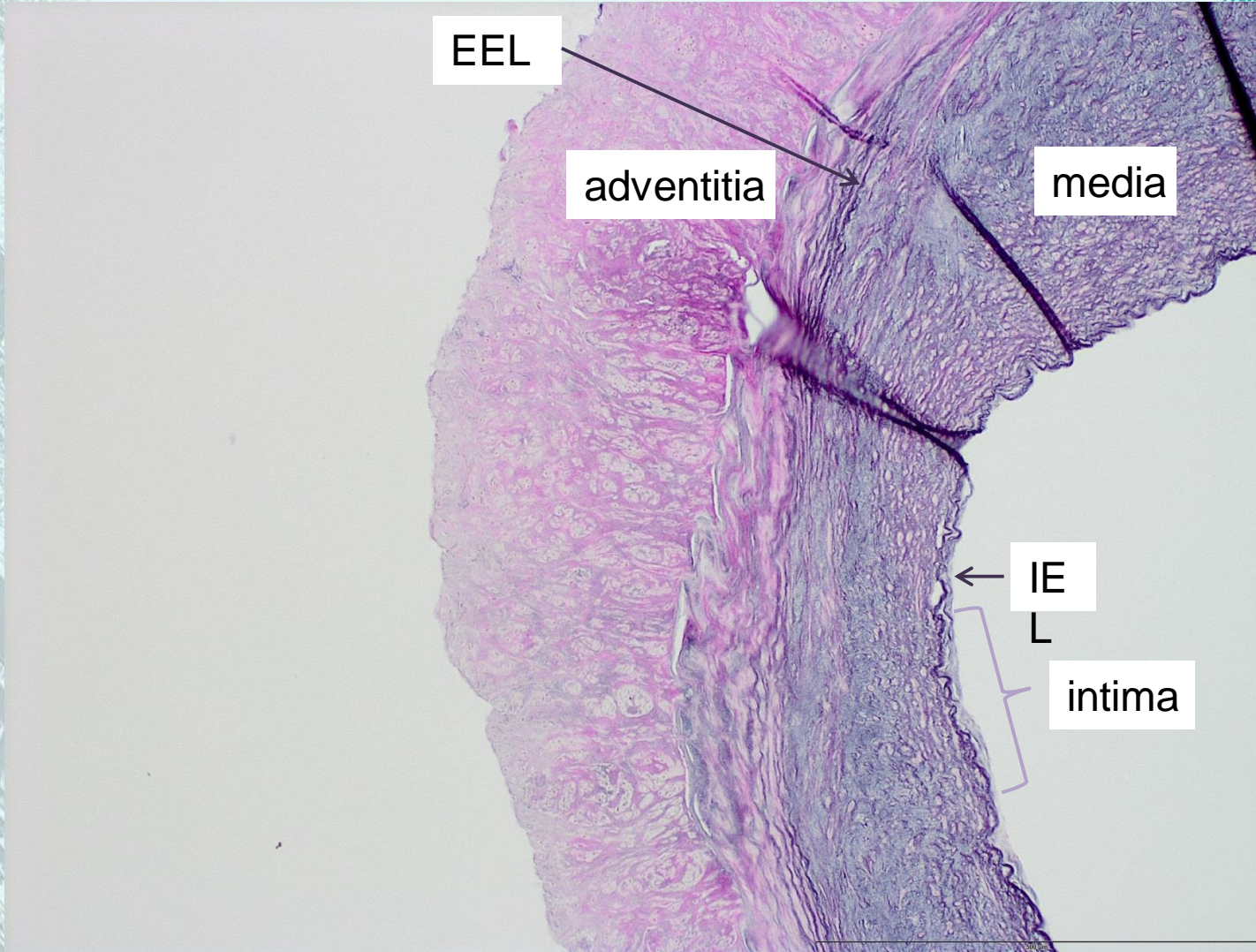


Masson Goldner staining





PT11





Conclusions

Several strategies have been introduced for CTO-recanalization

The Ocelot Catheter is a high-quality image catheter facilitating visualization of the vascular wall

Proofed intraluminal crossing is the first step to safely apply debulking strategies like directional atherectomy in femoro-popliteal CTOs

Prospective randomized studies or head to head evaluations are required



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homepage: www.gefaesschirurgie-muenster.de

Thank you!



Universitätsklinik Münster



St. Franziskushospital Münster