



# Clinical impact of Eluvia

**Michel J. Bosiers, MD**

Consultant Vascular and Endovascular Surgery

St. Franziskus-Hospital Münster

Director: PD Dr. Austermann



# Disclosure

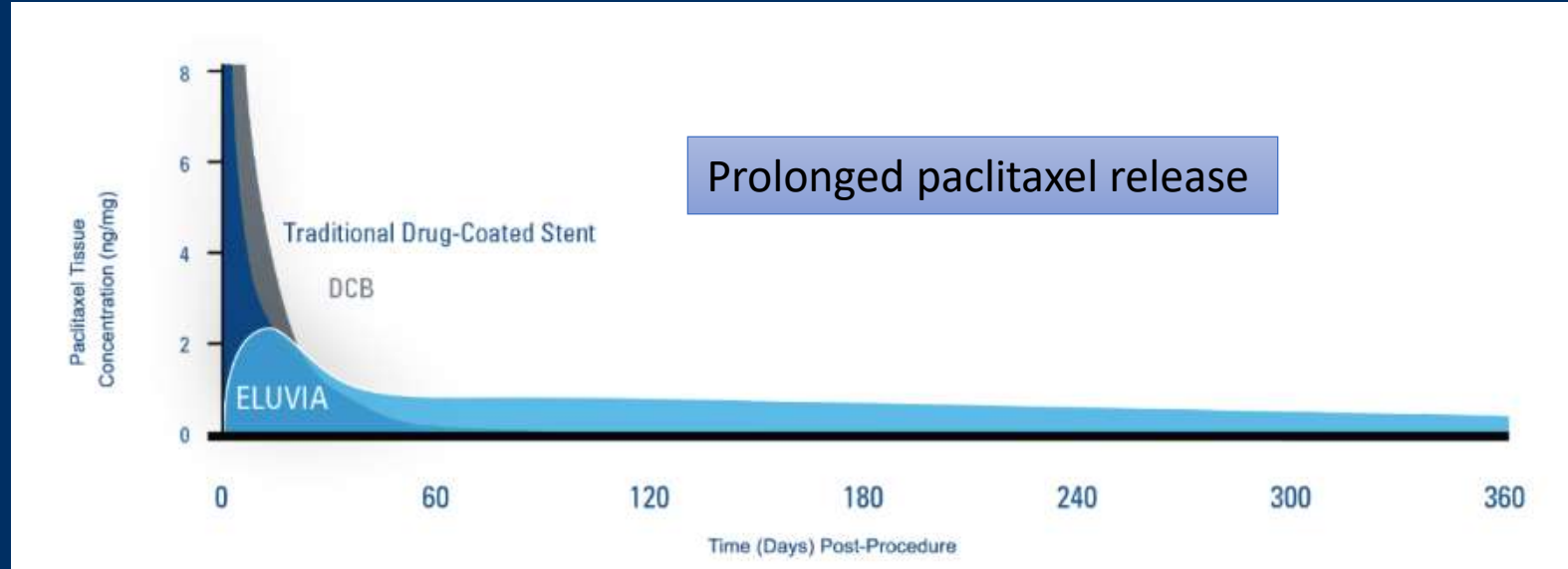
Speaker name: Michel Bosiers

I have the following potential conflicts of interest to report:

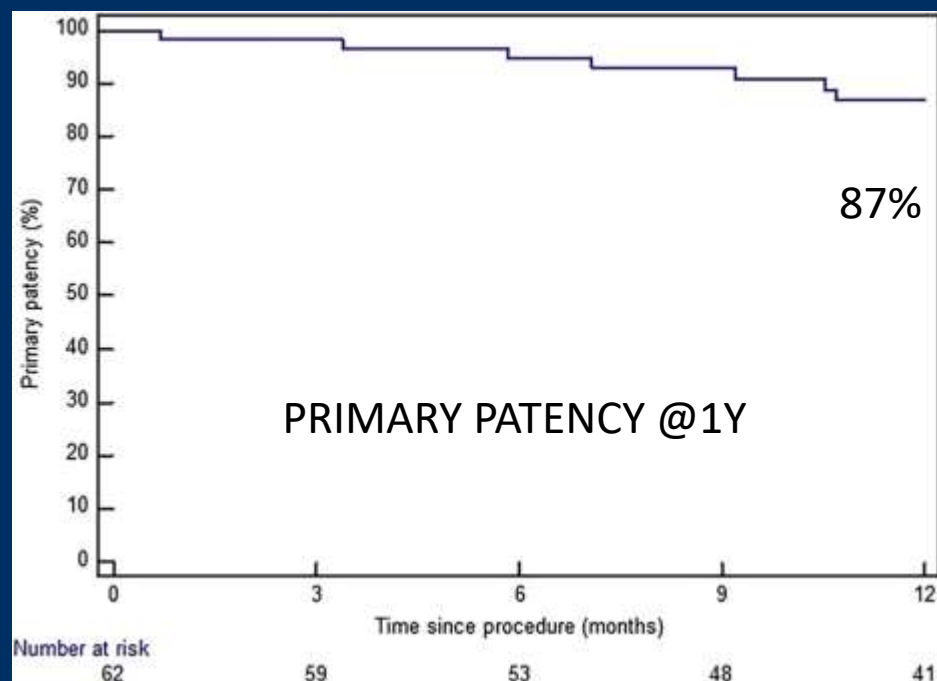
- Consulting: Cook
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Eluvia

- Self expandable stent
- coated with polymer
- Paclitaxel-eluting: dose density of 0.167  $\mu\text{g}$  paclitaxel per mm stent surface area



# Eluvia Münster Registry: 1Y



- Aneurysmal degeneration in 5 patients (8%) (mean diameter 14mm)

events in 59 (19%) patients in the Eluvia group and 27 (17%) patients in the Zilver PTX group. No aneurysmal degeneration of stented lesions was reported during the 12 months of follow-up; however, after some cases observed in a registry in Germany were reported,<sup>18</sup> personnel at the core laboratory reviewed all available and suitable 1-year duplex ultrasound images and found six cases (all in the Eluvia group). Five of those patients had chronic occlusions at baseline. All six patients were patent at 1 year and none had experienced target lesion revascularisation or stent thrombosis.

IMPERIAL-Trial

- Bisdas et al. 1-Year All-Comers Analysis of the Eluvia Drug-Eluting Stent for Long Femoropopliteal Lesions After Suboptimal Angioplasty. JACC Cardiovasc Interv. 2018;11(10):957-966
- Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018;392(10157):1541-1551.

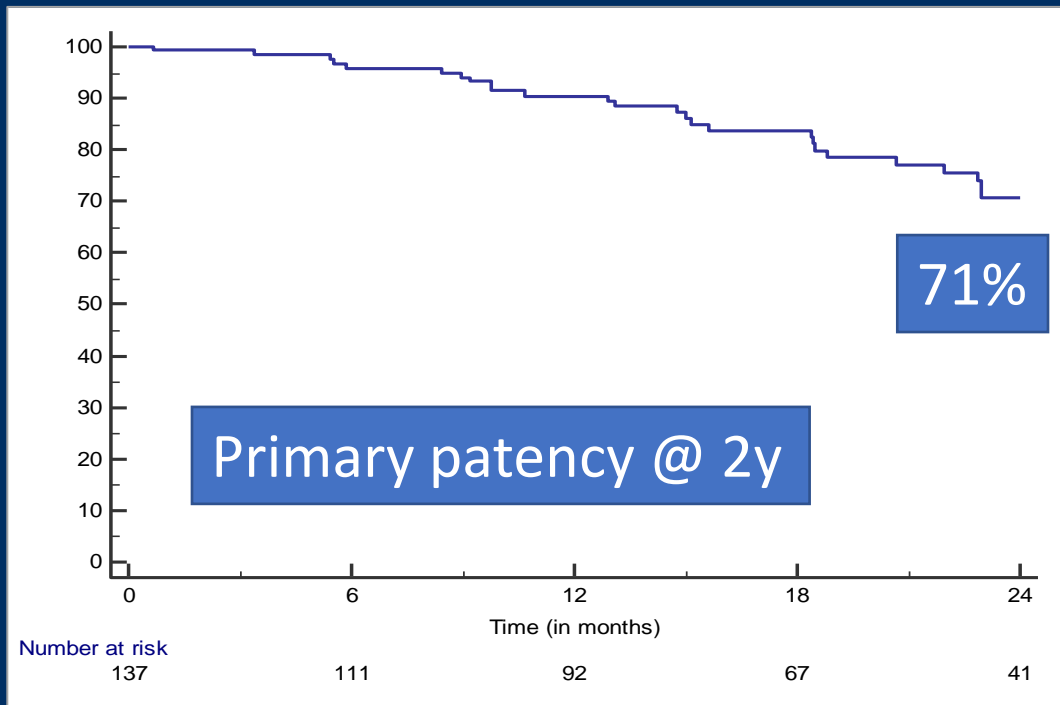
# Eluvia Münster Registry: 24 months

- March 2016- December 2018
- 137 lesions in 130 patients
- mean lesion length: 194±108 mm
- 40% >250 mm
- 74% CTO
- 72% calcified (moderate-severe 48%)

Characteristics	N (%)
<b>Total number of patients</b>	<b>130</b>
Men	82 (63%)
Age (±SD), in years	71±8
Arterial hypertension	120 (92%)
Diabetes mellitus	46 (35%)
Dyslipidemia	70 (53%)
Statins on admission	82 (63%)
Coronary heart disease	46 (35%)
Obesity	41 (31%)
COPD	23 (18%)
Cerebrovascular disease	41 (31%)
Chronic kidney disease	25 (19%)
End-stage renal disease	6 (5%)
Tobacco use	39 (29%)
<b>Rutherford Classification</b>	
<i>Class 3</i>	90 (69%)
<i>Class 4</i>	13 (10%)
<i>Class 5</i>	21 (16%)
<i>Class 6</i>	7 (5%)



# Eluvia Münster Registry: 24 months



Vessel wall degeneration 20% (27 lesions)



Only in 2 lesions perfusion of the degenerated segment

- Secondary patency and freedom from TLR: 80%



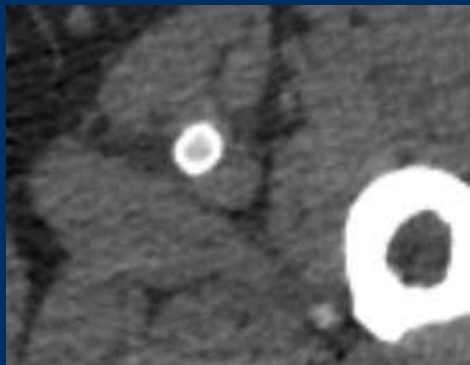
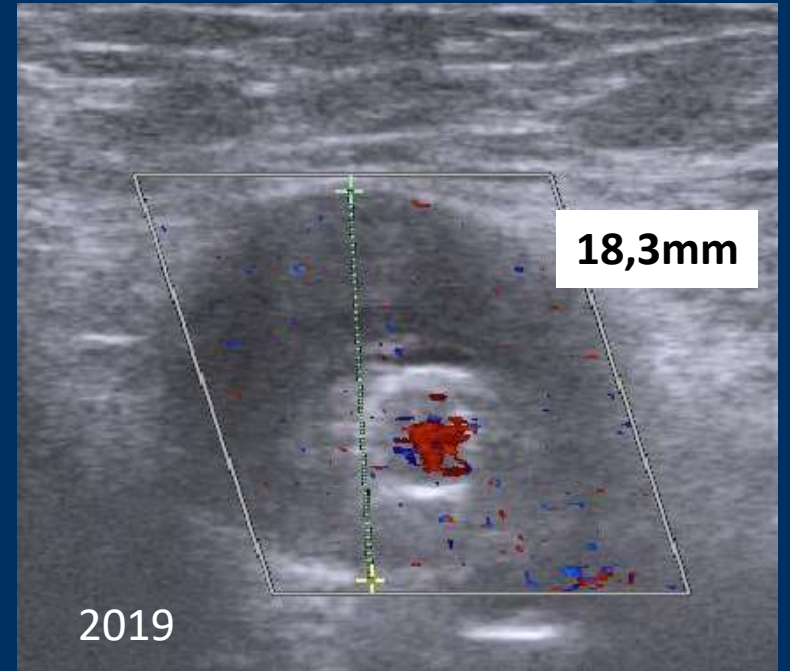
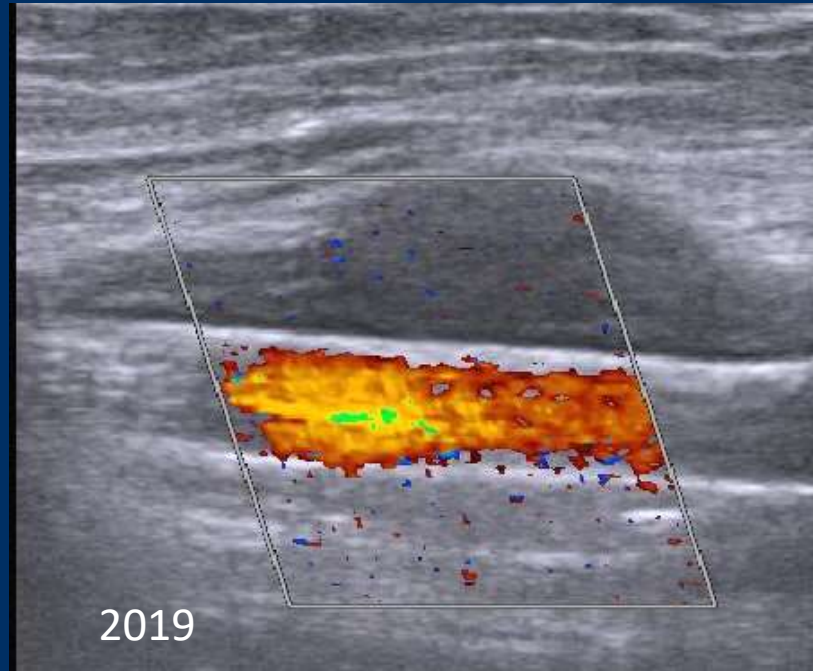
# Eluvia Münster Registry: 24 months

Logistic regression analysis for vessel wall degeneration

Variable	Odds ratio	95% CI	P-value
CTO	2.9577	0.7962 to 10.9867	0.105
PACSS 3 or 4	0.4852	0.1591 to 1.4792	0.203
Calcification	0.5581	0.2030 to 1.5342	0.258
CLTI	0.2677	0.0735 to 0.9757	0.046

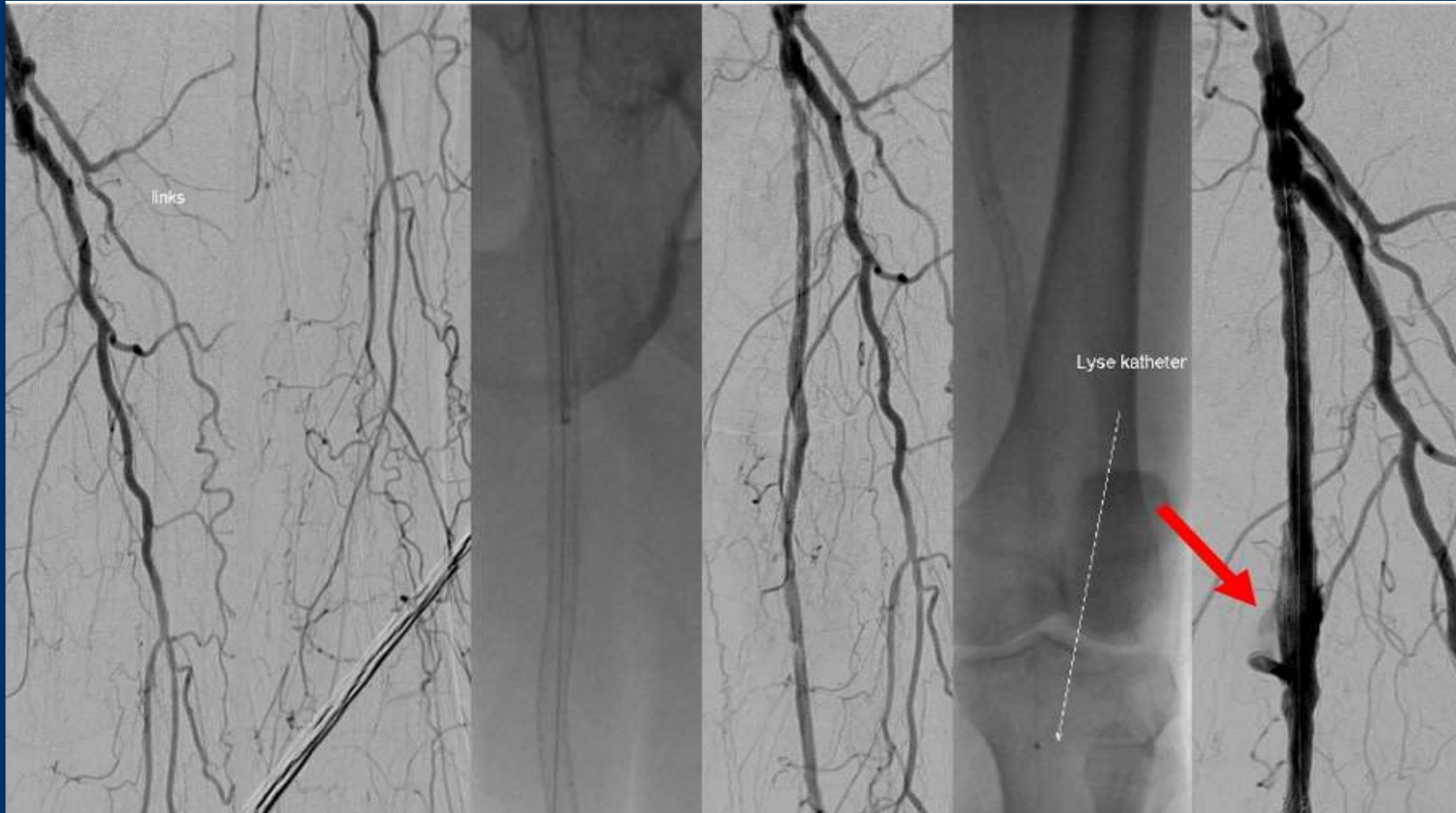
- Protective role of CLTI compared to IC in multivariate analysis

# Wall degeneration:





# Wall degeneration:



# Wall degeneration or „Halo“



ELUVIA

ZILVER PTX

Arterial wall degeneration:  
Not only in ELUVIA

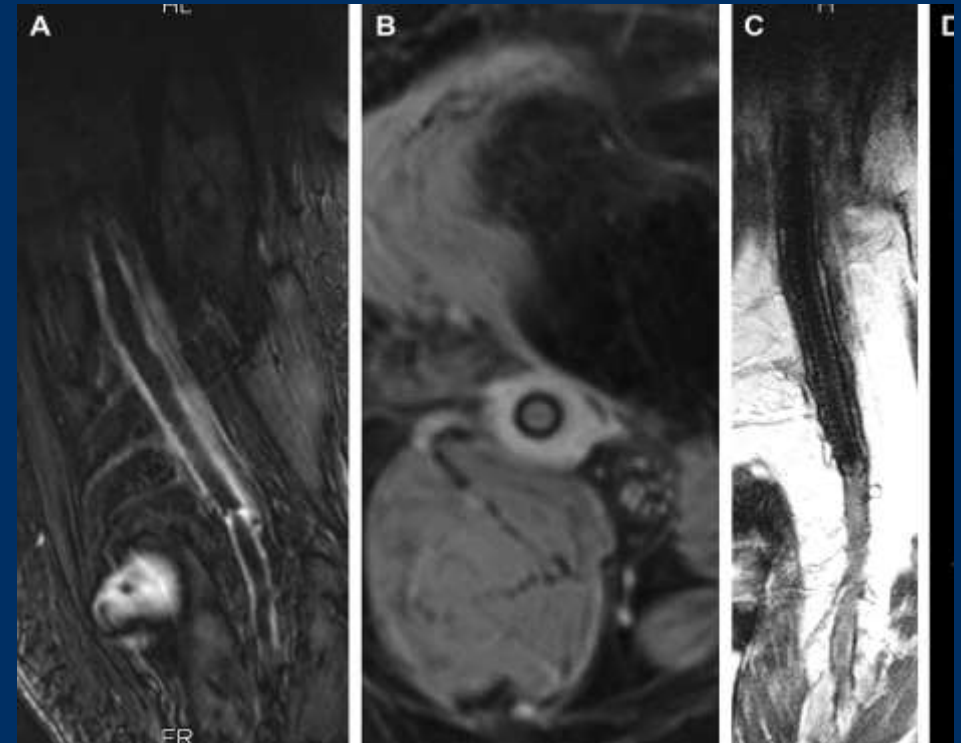
RCT. The prevalence rates of hypoechogenic halo did not differ significantly between Eluvia (33.7% [29/86], 95%CI 23.9%, 44.7%) and Zilver PTX (21.4% [9/42], 95%CI 10.3%, 36.8%) study arms ( $P = 0.1529$ ). The Eluvia rate

2y IMPERIAL-Data

• Müller-Hüsbeck et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent

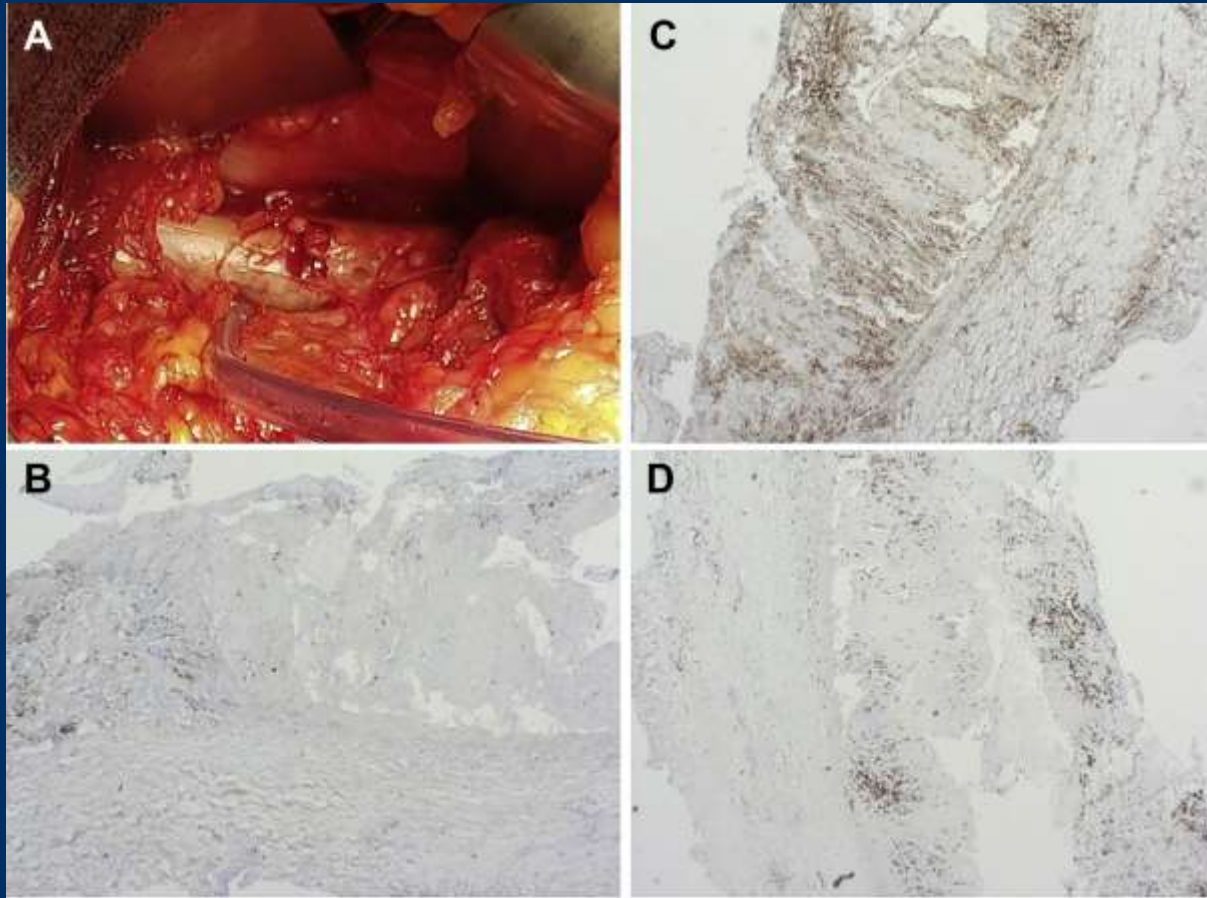
# Eluvia Münster Registry

- immunohistological assay and MRI revealed an excessive inflammation of the vessel wall: **vasculitis?**
- spontaneous regression in 1 patient: **localized inflammation?**
- Also in 1 patient treated by Zilver PTX: complication of all PTX based treatment strategies?



- Stavroulakis K, Torsello G, Bosiers MJ et al. 2 years outcomes of the Eluvia polymer-based drug eluting stent for the treatment of long femoropopliteal lesions. Accepted JACC Cardiovasc Interv
- Bisdas et al. 1-Year All-Comers Analysis of the Eluvia Drug-Eluting Stent for Long Femoropopliteal Lesions After Suboptimal Angioplasty. JACC Cardiovasc Interv. 2018;11(10):957-966

# Immunohistological analysis



(B) thin infiltration with **CD20<sup>+</sup>** B cells,  
(C) overexpression of **CD3<sup>+</sup>** T cells, and  
(D) increased expression of **CD56<sup>+</sup>** T cells.



Inflammation

# Conclusion

- pathophysiology and nature of this observation seems to be multifactorial and its long-term impact has to be further evaluated
- Also observed in the coronary arteries: combination of vessel injury (stent implantation) and paclitaxel-associated impaired vascular healing contribute to vessel wall degeneration
- So far no clinical impact in the SFA
- Appears more often with Polymer-based DES