

Differences in clinical outcomes of low COF stent vs high COF stent proven in clinical practice

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Speaker fees, travel support, research grant: Biotronik

Low vs High COF Stents Animal Study

COF Correlation to Neointimal Area, Results After 28 and 90 Days

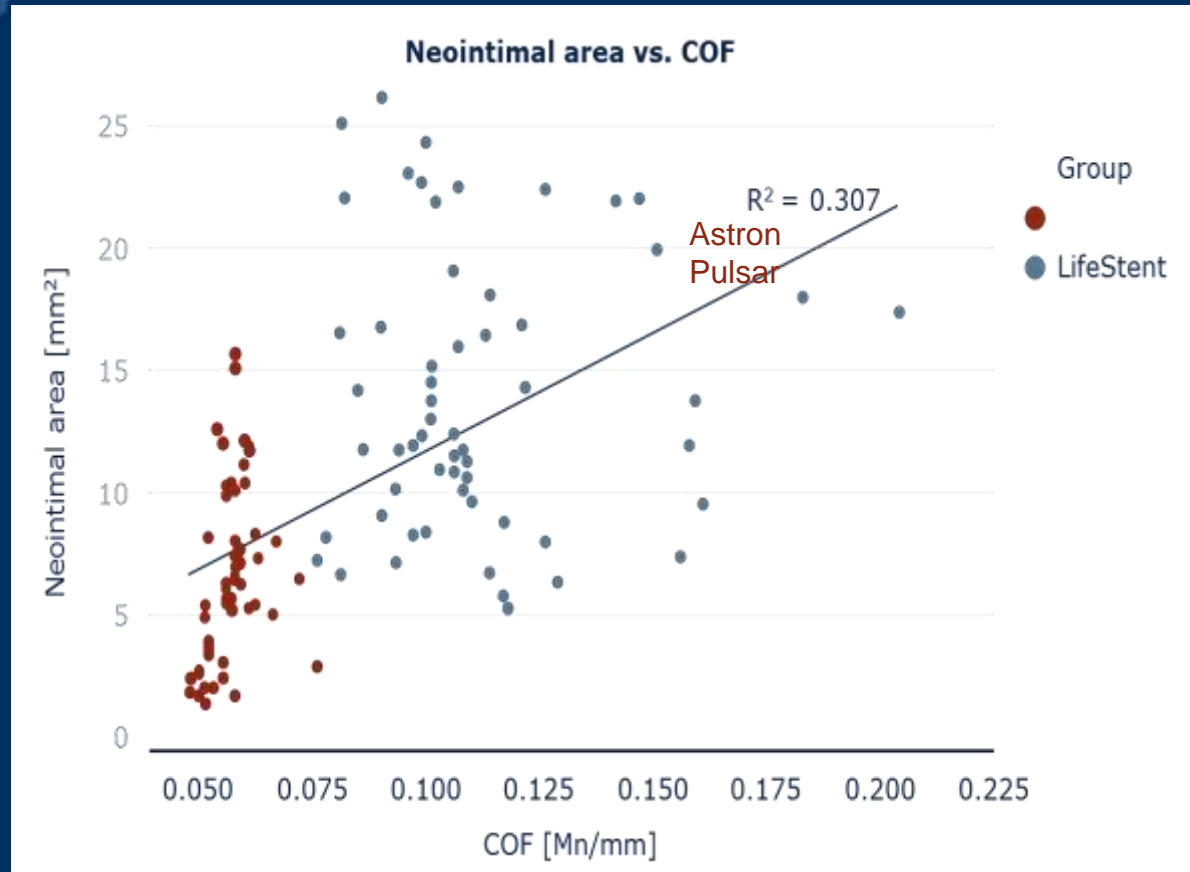
Low-COF vs High COF stent
in porcine iliac arteries

28d Cohort: Hybrid Landrace-
Yorkshire

90d Cohort: Yucatan Mini
Swine

Neointimal area measured
at histologic cross-sections

Funovics et al: publication in progress

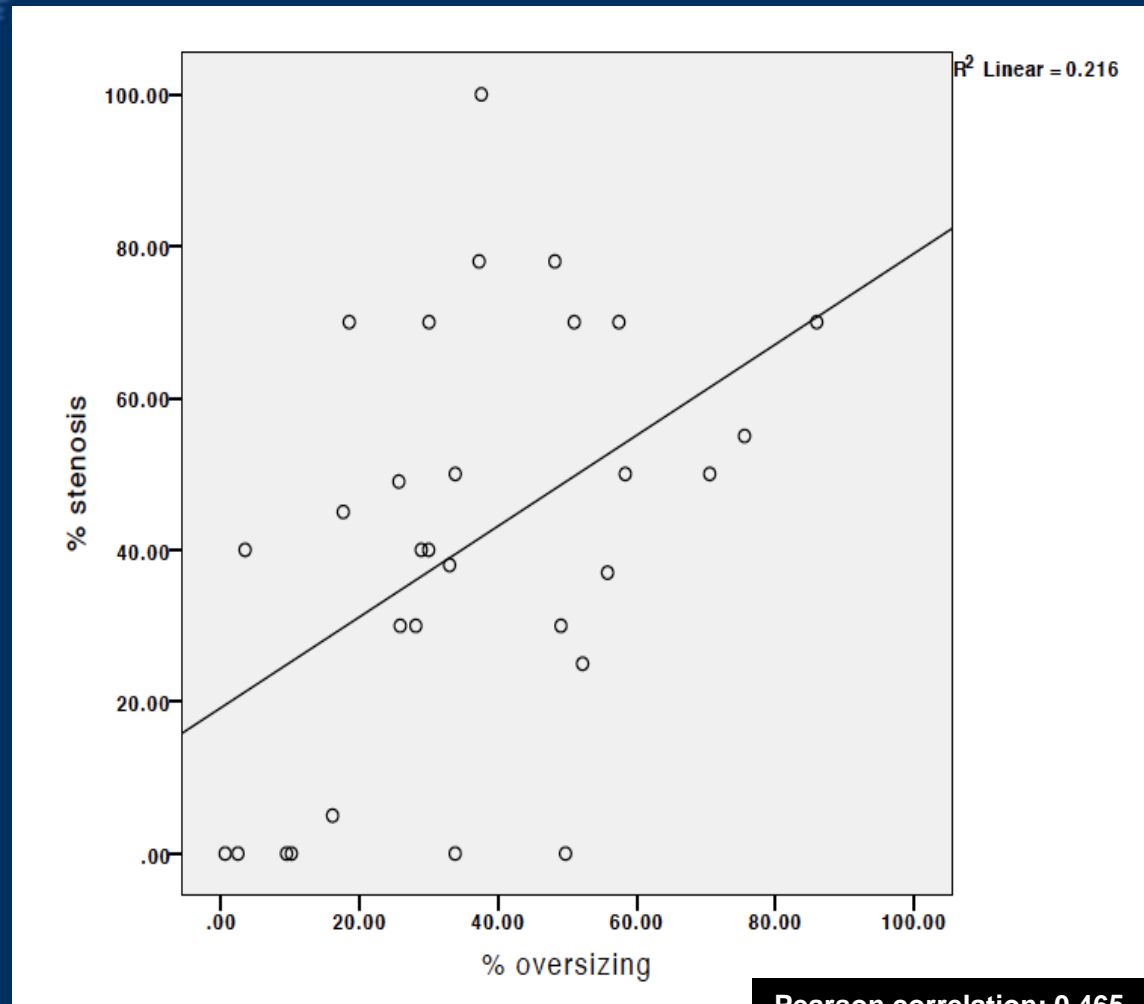


Low vs High COF Stents - clinical Study

30 Patients, retrospective analysis after de-novo SFA stenting with low-COF Stent

1yr – 2yr post implantation with CT or Angio available

Martin Funovics, unpublished data



Pearson correlation: 0.465,
 $p < 0.01$

Study Hypothesis:

Oversizing/stiffer stents →
high COF →
neointimal hyperplasia →
early restenosis

BIOFLEX-COF

(chronic outward force)

investigator initiated

blinded

prospective randomised (2 groups)

de-novo SFA lesions

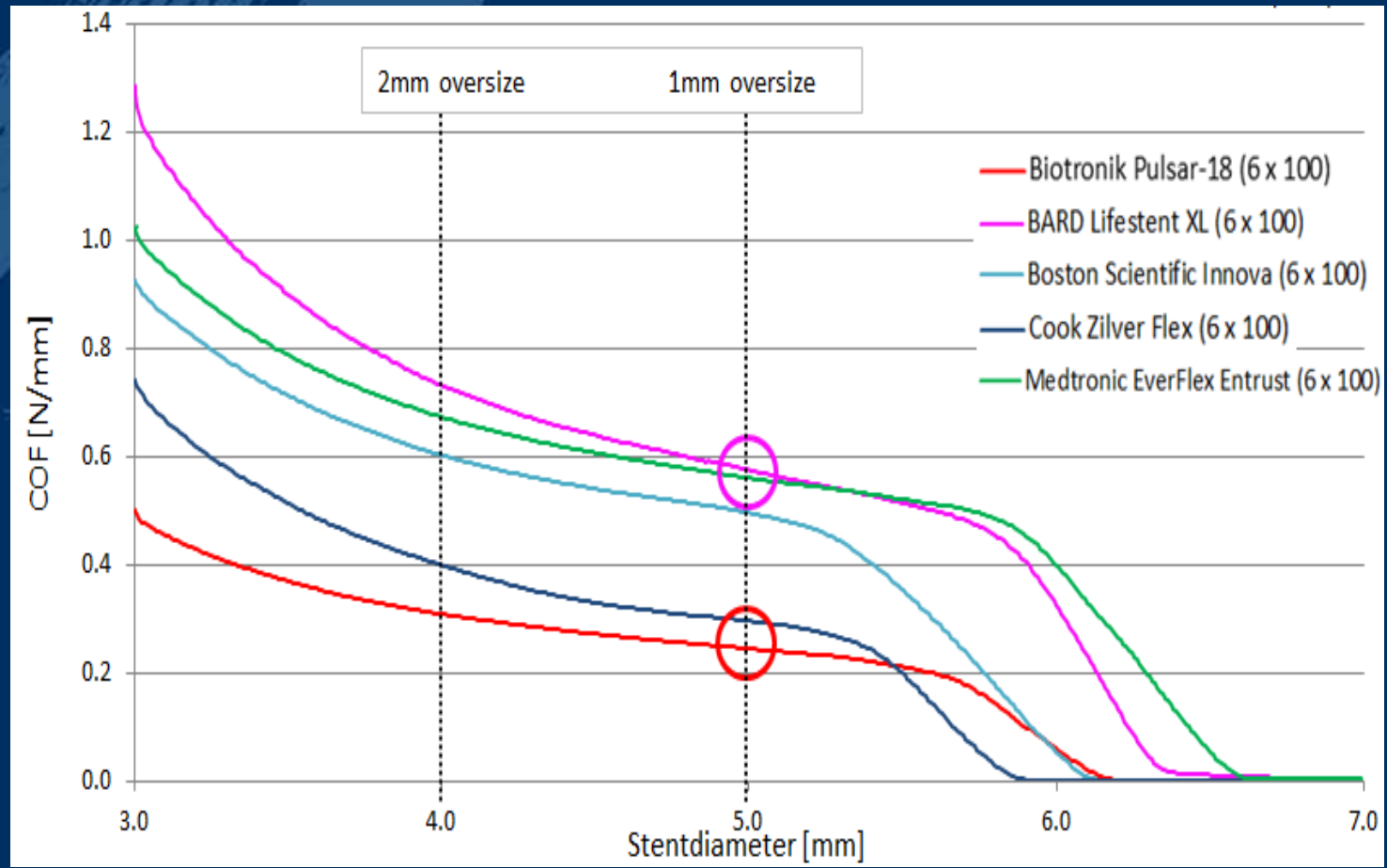
primary nitinol stenting

high vs. low COF

2 groups:

- Low-COF stent: Biotronic Pulsar
 - minimal oversizing, „soft“ expansion curve
- High-COF Stent: (Bard Life Stent)
 - 1-2mm oversizing, „stiff“ expansion curve

Diameter vs. COF



Outcome Variable

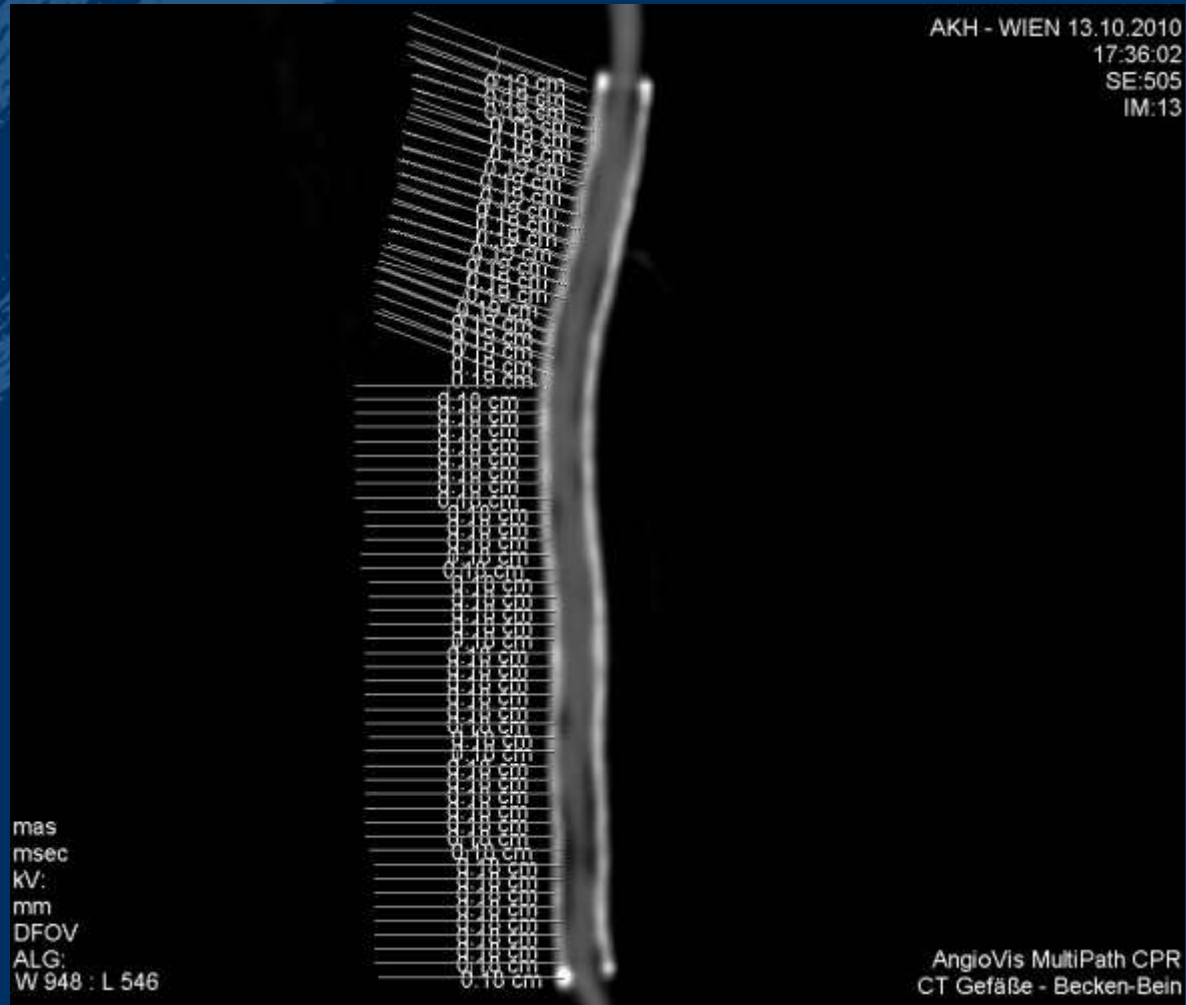
- % of restenosis measured at CT-Angiography
- NOT: binary restenosis (too insensitive)
- NOT: doppler US (operator-dependent)
- NOT: TLR (patient-dependent & insensitive)

Discrete variable, 15-100 values per patient

Measurement of stent diameter



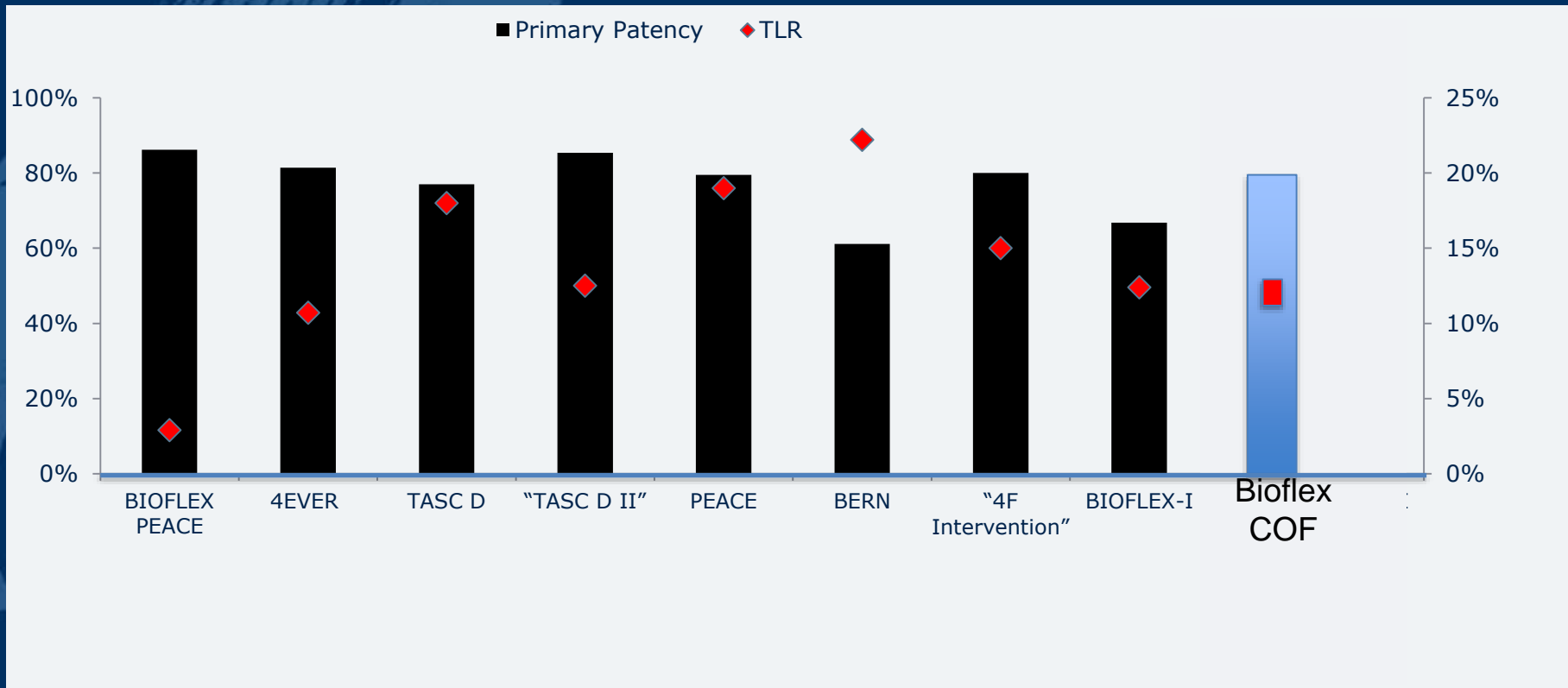
Measurement of lumen diameter





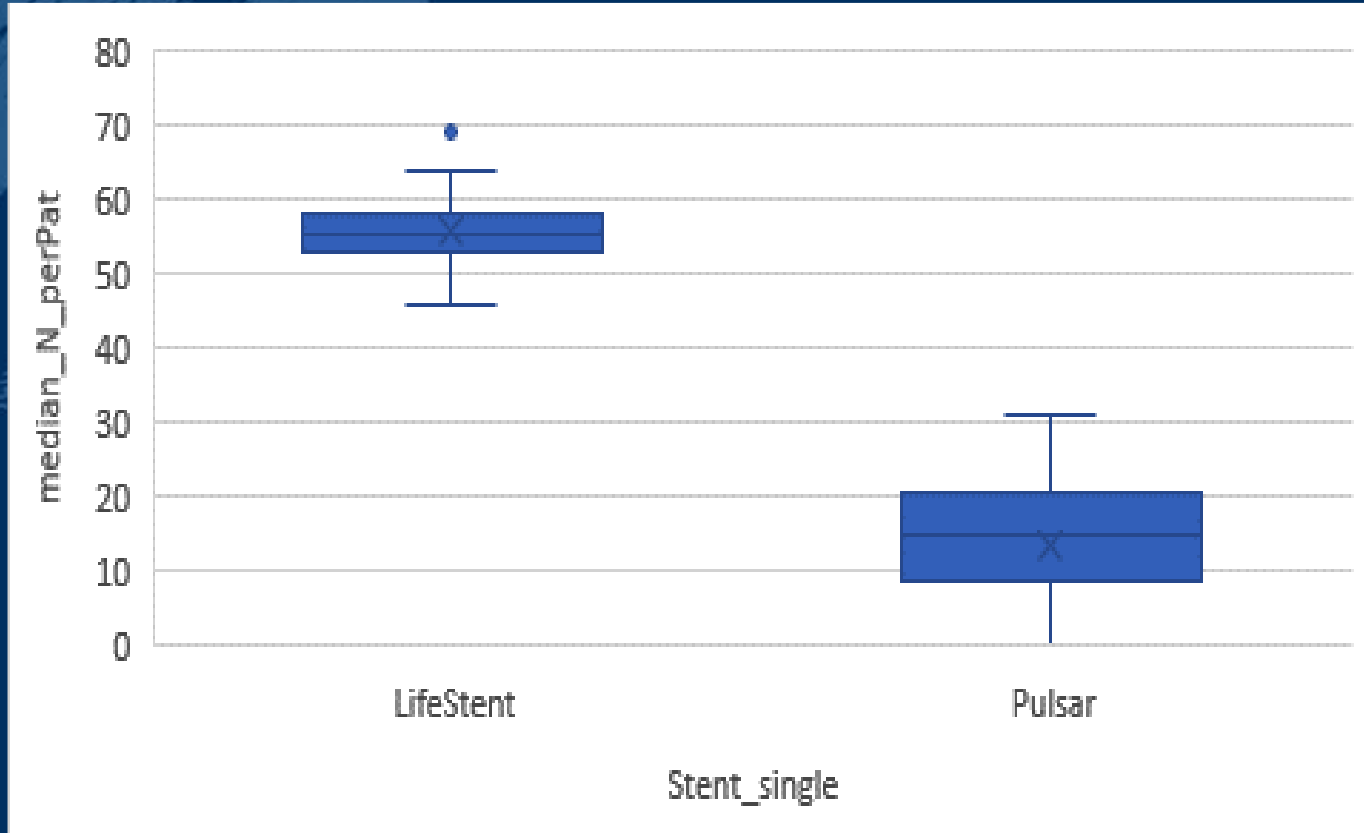
Results at 1 yr:

Pulsar clinical results



Source: BIOFLEX PEACE (interim). Lichtenberg M. Presented at CIRSE 2017. 4EVER Bosiers M. JEVT 2013;20:746-756; PEACE Lichtenberg M. JEVT, 2014, 21:373-380; BERN registry Baumann F. JCS 2012;52:475-80; TASC D registry Lichtenberg M. JCS 2013: 54; 433-9; "TASC D II" registry Lichtenberg M. Clin Med Insights 2014; 8; 37-42; 4F intervention" Sarkadi H, Eur J Vasc Endovasc Surg (2015) 49, 199-204. US Food and Drug Administration, Center for Devices and Radiological Health. FDA Summary of Safety and Effectiveness Data – Astron Pulsar and Pulsar-18 Stent, P160025. www.fda.gov (accessed, May 5, 2017). Trial comparison is for illustration only.

Chronic outward force



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Restenosis

Runoff r



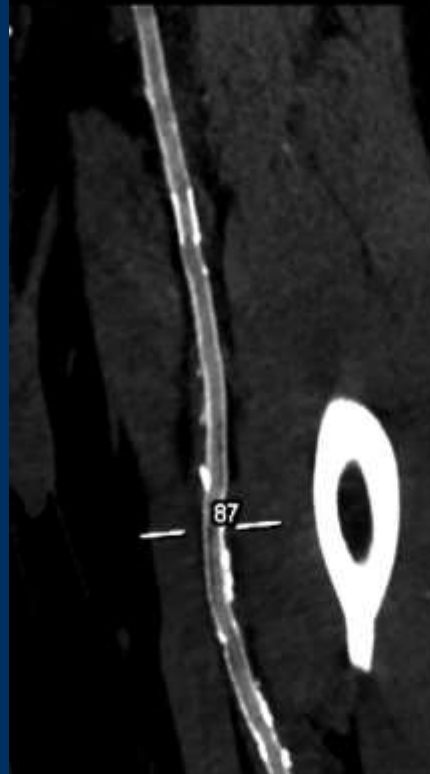
ROI
A = 9,4 mm2 (1173 pix2)
U = 11,1 mm
avg = 353 HU
sd = 13 HU
max = 392 HU
min = 324 HU

measure on left side of the imagel

SeqNr: 1021
BildNr: 32
W/L: 172,52/595,83

Siemens Healthineers syngo via VB30A

Runoff l



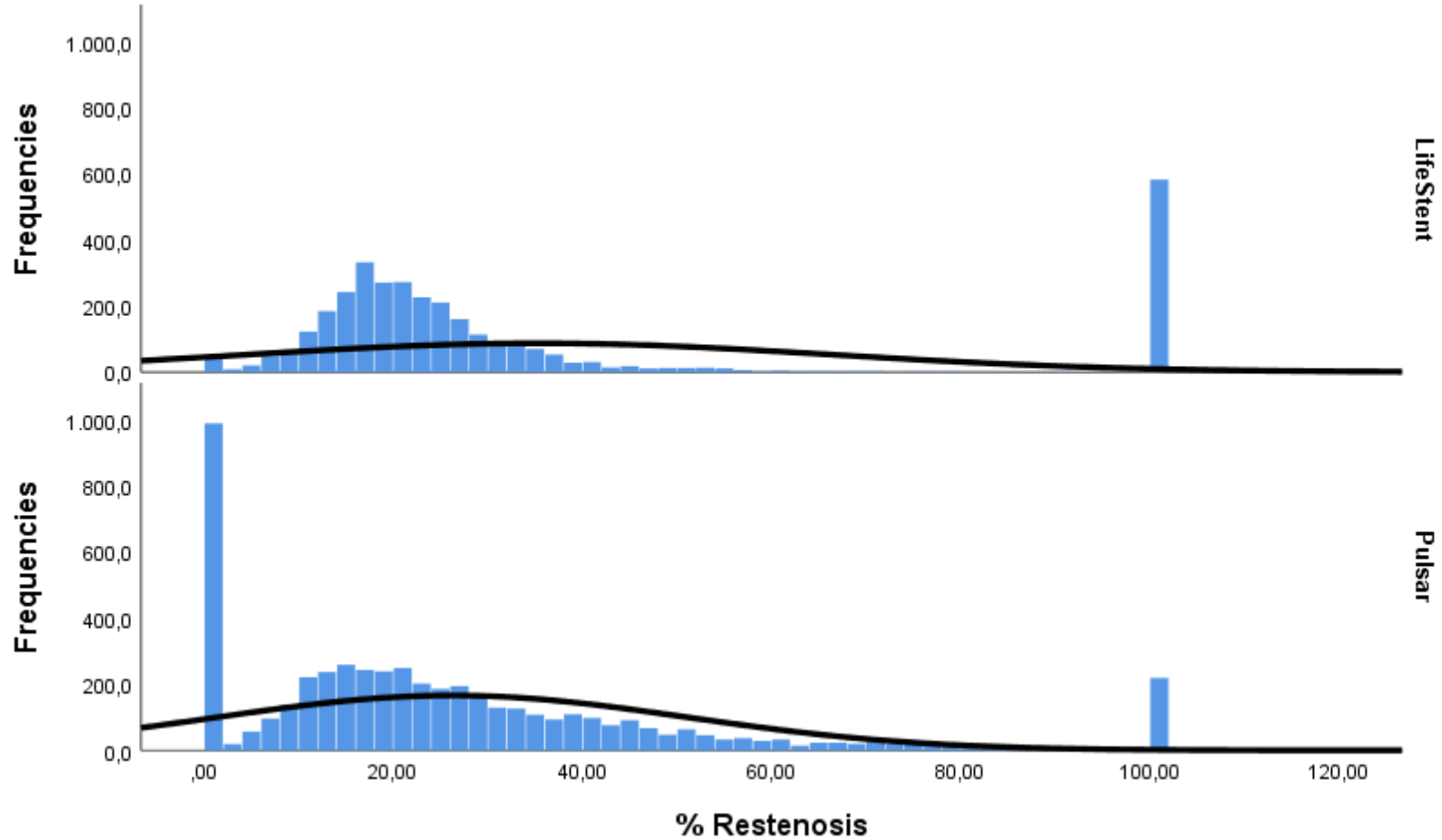
Do not measure on left side of the imagel

ROI
A = 9,1 mm2 (1370 pix2)
U = 11,3 mm
avg = 176 HU
sd = 63,8 HU
max = 323 HU
min = 39 HU

ROI
A = 6,1 mm2 (857 pix2)
U = 9,2 mm
avg = 212 HU
sd = 39,5 HU
max = 334 HU
min = 120 HU

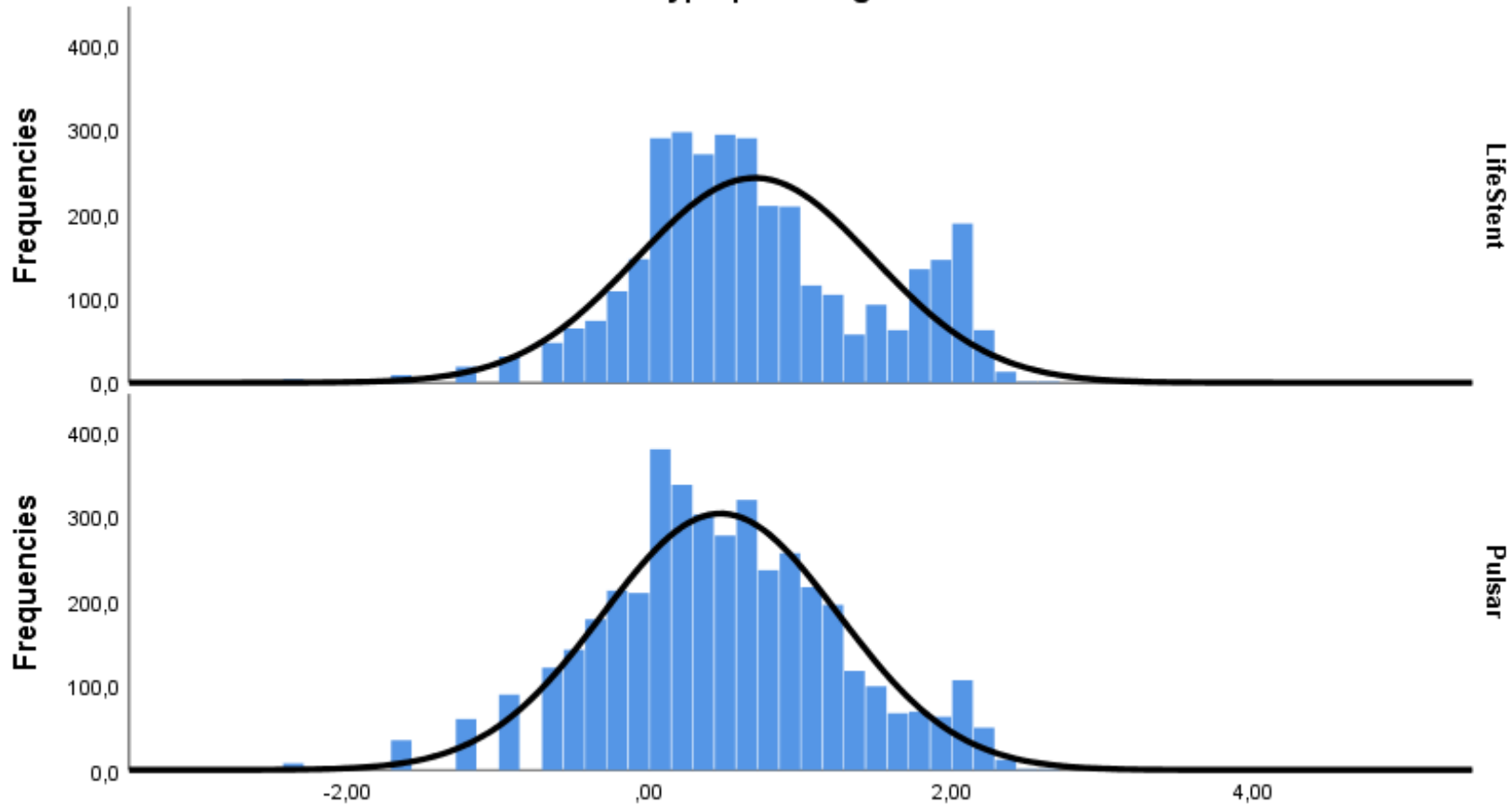
Restenosis in %

Percent Restenosis



Log (restenosis) in mm²

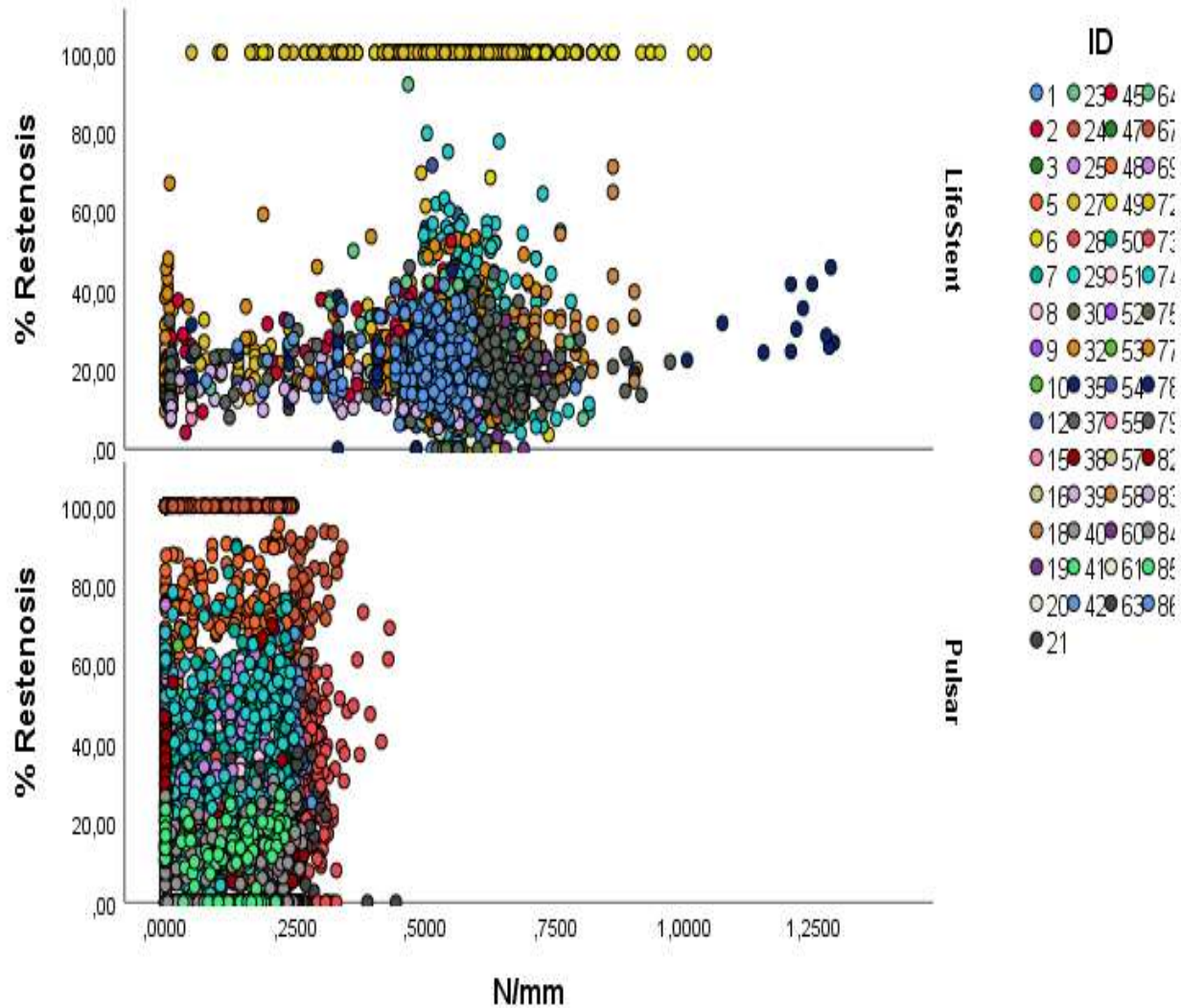
Intima hyperplasia logarithmized



Mean & absolute Restenosis in %

	High COF	Low COF	P-Value
Mean Restenosis (%)	35.43±30.91	26.21±24.71	<0.001 t-test & Mann–Whitney U test
Absolute Restenosis (mm²)	2.73±2.70	1.75±1.90	<0.001 t-test & Mann–Whitney U test

Subgroups & correlations



Conclusion

- BIOFLEX-COF :
 - 1st RCT to assess COF
 - Generous inclusion criteria, “real-world data”
 - 4x difference in COF between groups
 - Sig. lower restenosis in low COF group
 - Clinically relevant amount (26% vs 35%) at 1 year

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