

The logo for LINC (Lifestyle in Network) is located in the top left corner. It features the letters 'LINC' in a white, sans-serif font. To the right of the text is a stylized graphic consisting of two overlapping, curved lines in red and orange, set against a dark blue background.

LINC

Interim Report of the BIOFLEX-COF RCT

-

comparing high vs low chronic outward force
of nitinol stents in the SFA

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Disclosure

Speaker name:

Martin Funovics

I have the following potential conflicts of interest to report:

Travel support, Speakers Bureau, Consulting:

Cook, Biotronik, Bolton Medical

Background – what is COF?

COF is:

Force exerted by a nitinol stent on the vessel wall

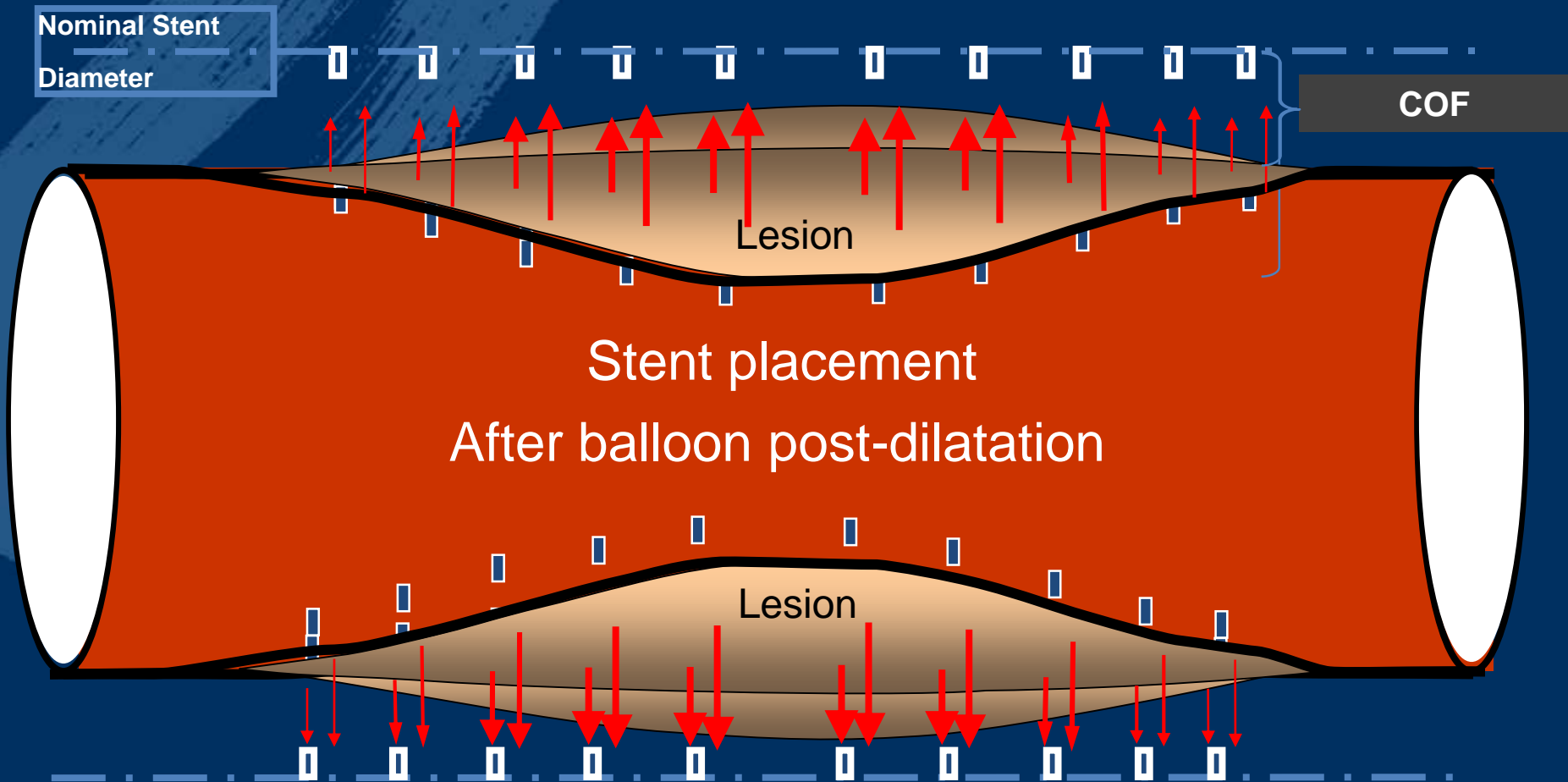
Chronic: after pre- and postdilatation

Background – how big is COF?

COF depends on:

- Oversizing (stent size vs.vessel size)
 - (operator dependent, every mm)
- Stent Material
 - „stiffness“ of the stent (a.k.a. „spring constant)
- Irregularities in the lesion
 - After pre and postdilatation

COF differs in lesions



Study Hypothesis:

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

Swine data

28 days FUP

Astron Pulsar – 8.78



Lifestent – 17.02

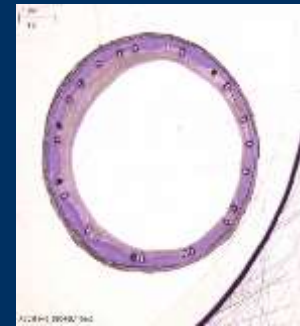


Soft (Pulsar-18)

Stiff (LifeStent)

90 days FUP

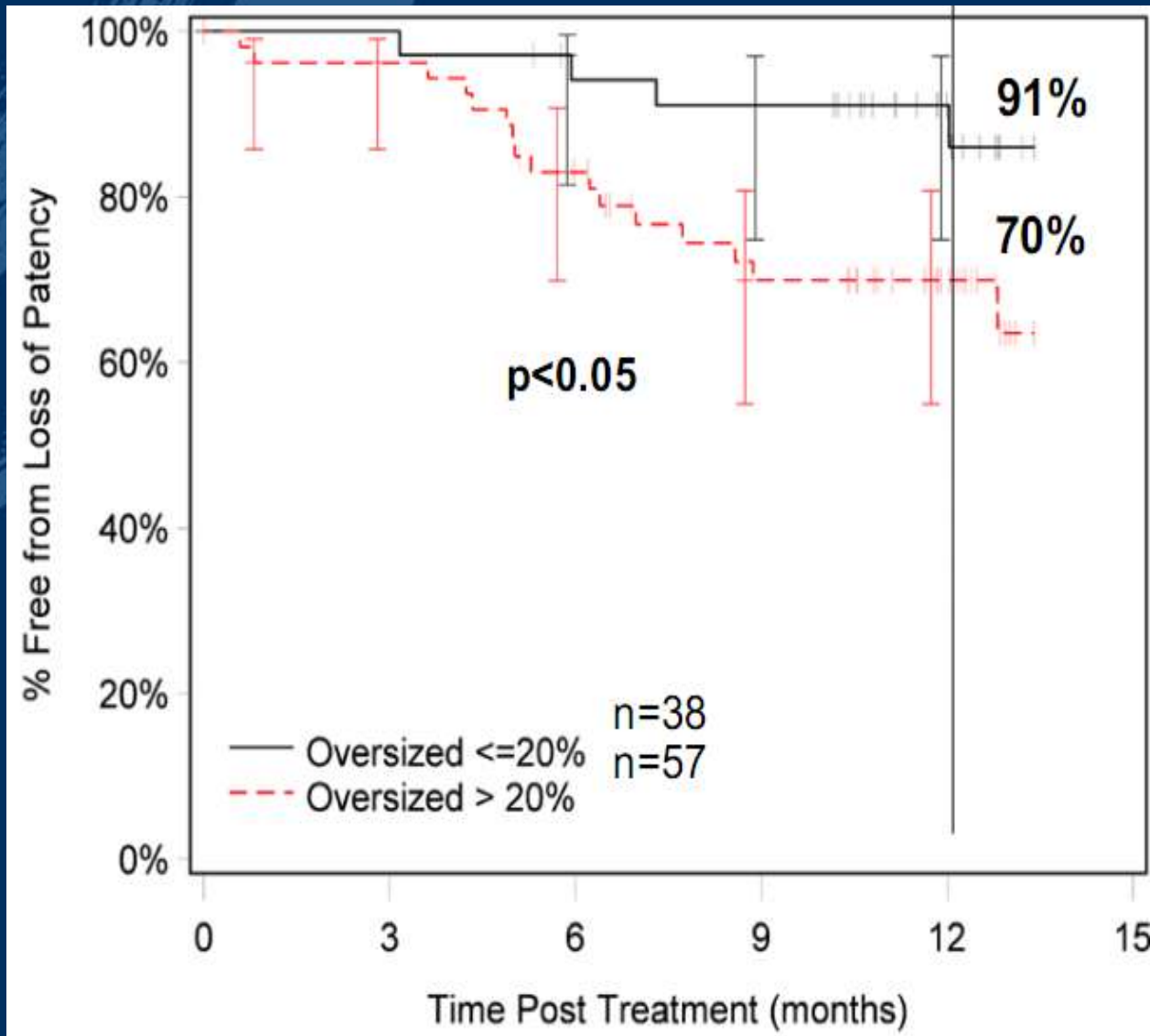
Astron Pulsar – 6.9



Lifestent – 19.32



VIPER – lessons learned



Patients & Lesions

High COF

- 40 Patients
- 63% male
- 68yrs
- 55% smokers
- 108mm lesion
- 30% occl
- AFS 5,08mm
- BTK 10/40
- ABI 0,63

Low COF

- 40 Patients
- 68% male
- 69yrs
- 43% smokers
- 148mm lesion
- 43% occl
- 5,16mm
- BTK 9/40
- ABI 0,64

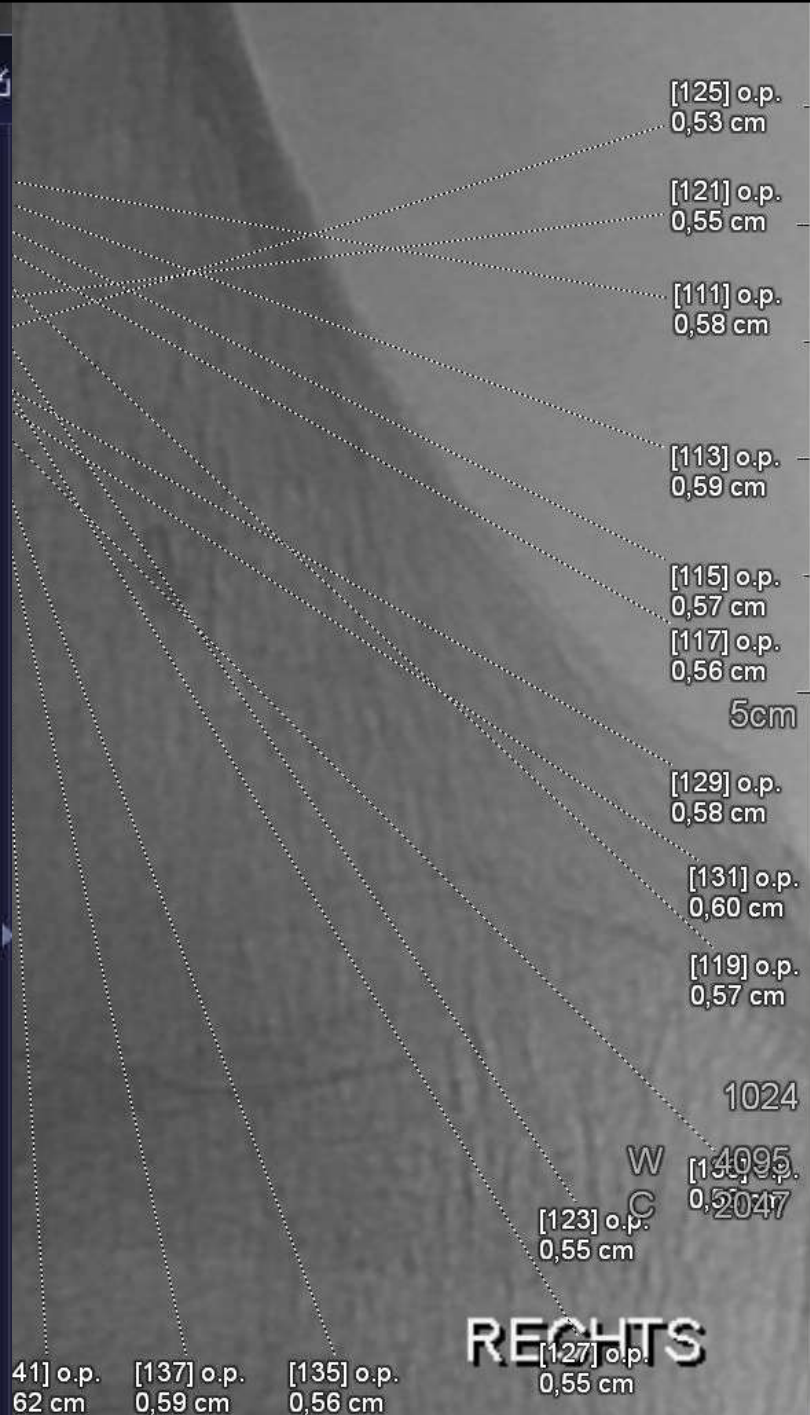
Findings

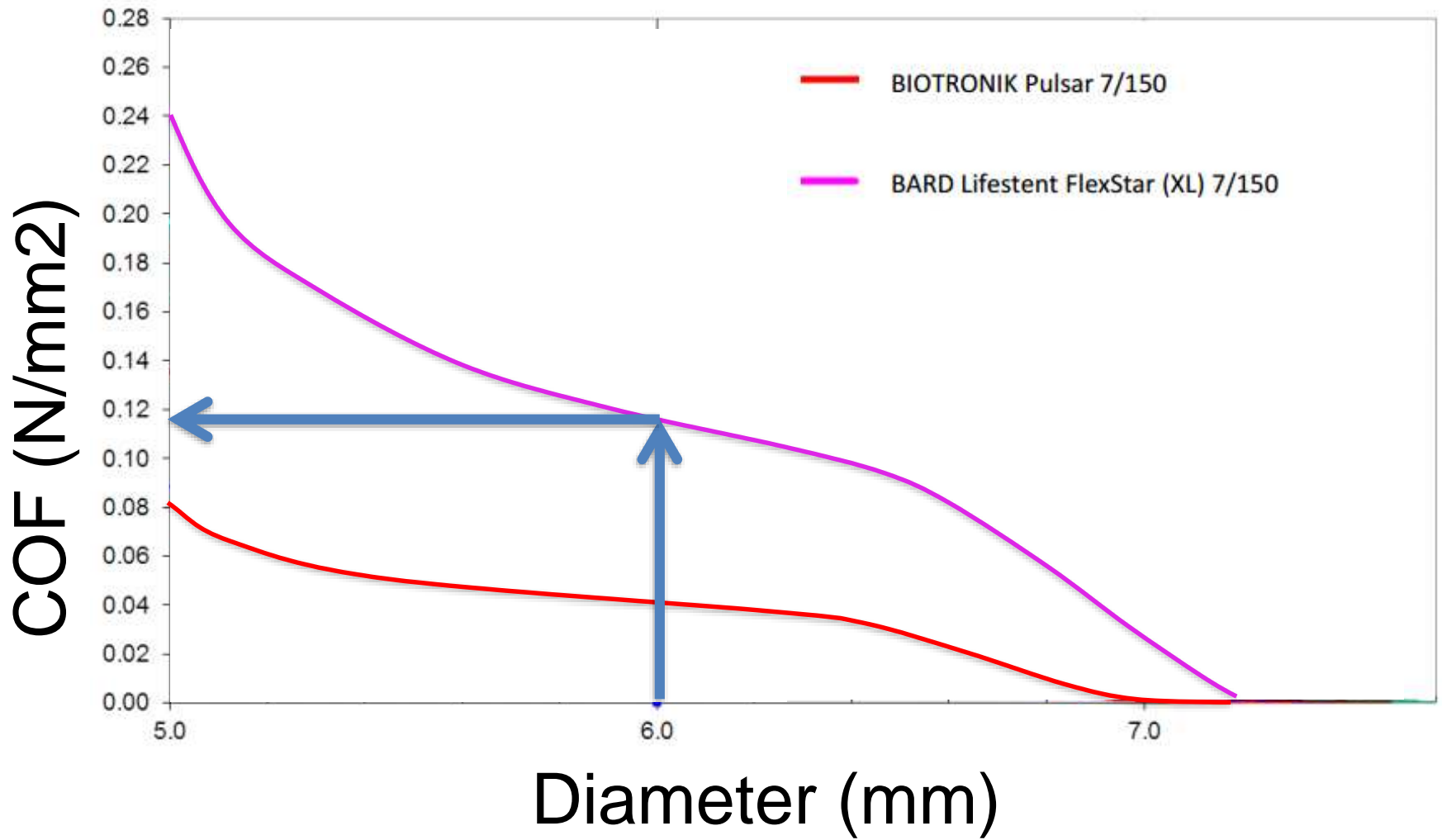
Finding 9

[111] Distance Line	0,58 cm	
[113] Distance Line	0,59 cm	
[115] Distance Line	0,57 cm	
[117] Distance Line	0,56 cm	
[119] Distance Line	0,57 cm	
[121] Distance Line	0,55 cm	
[123] Distance Line	0,55 cm	
[125] Distance Line	0,53 cm	
[127] Distance Line	0,55 cm	
[129] Distance Line	0,58 cm	
[131] Distance Line	0,60 cm	

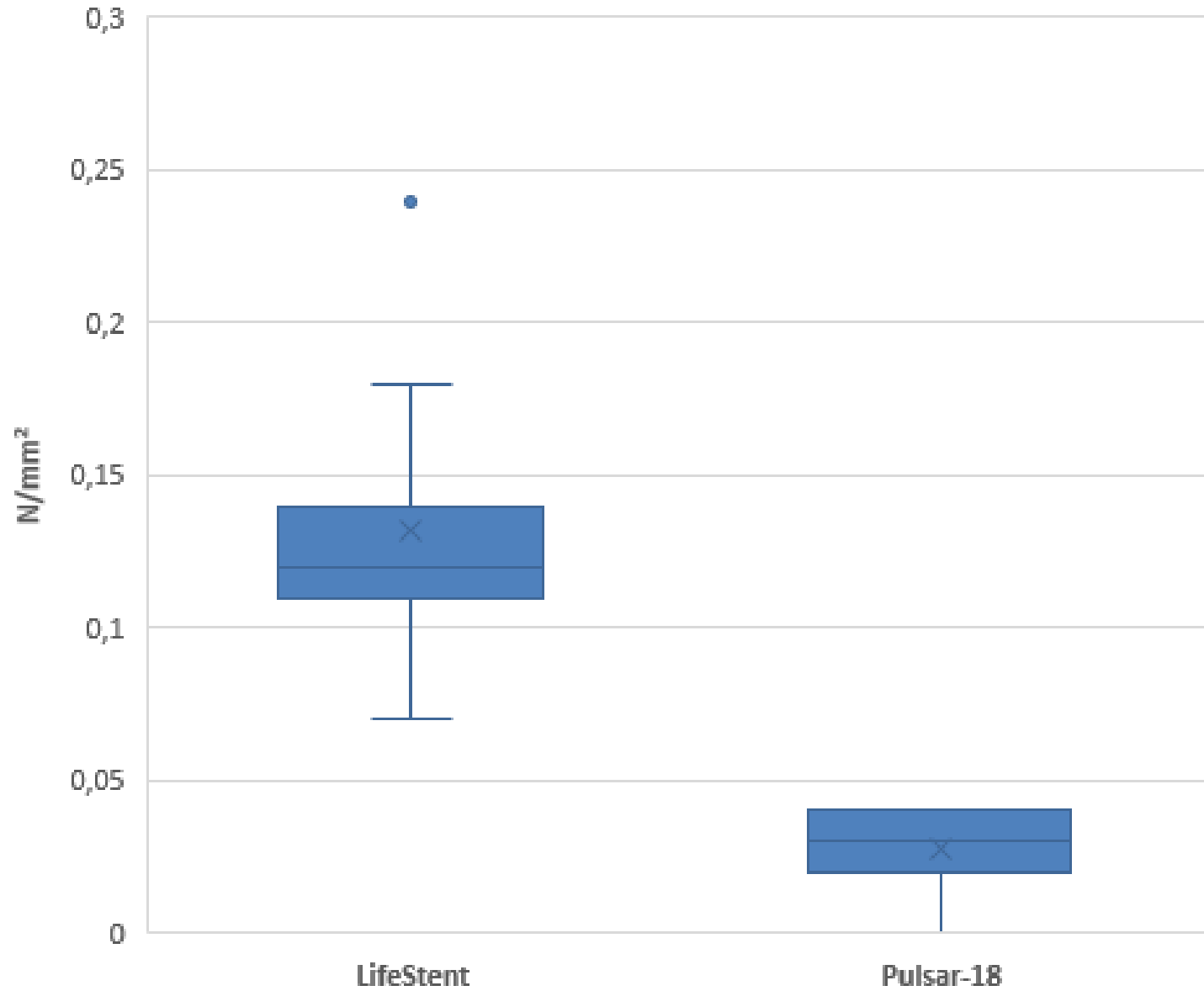
Finding 10

[133] Distance Line	0,58 cm	
[135] Distance Line	0,56 cm	
[137] Distance Line	0,59 cm	
[139] Distance Line	0,59 cm	
[141] Distance Line	0,62 cm	
[142] Distance Line	0,61 cm	





COF (partial sample)



Outcome parameter

Lumen diameter at CT-Angio
measured at every mm



Conclusion

- 1st RCT to assess COF in nitinol stents
- Implantation successful
- COF difference between groups approx 3x
- Recruitment completed

- 1yr data hopefully available @ LINC 2019.