Evolution of NexGen

Dr. Imad Sheiban

Director – Interventional Cardiology,
Div. of Cardiology, University of Turin, Italy

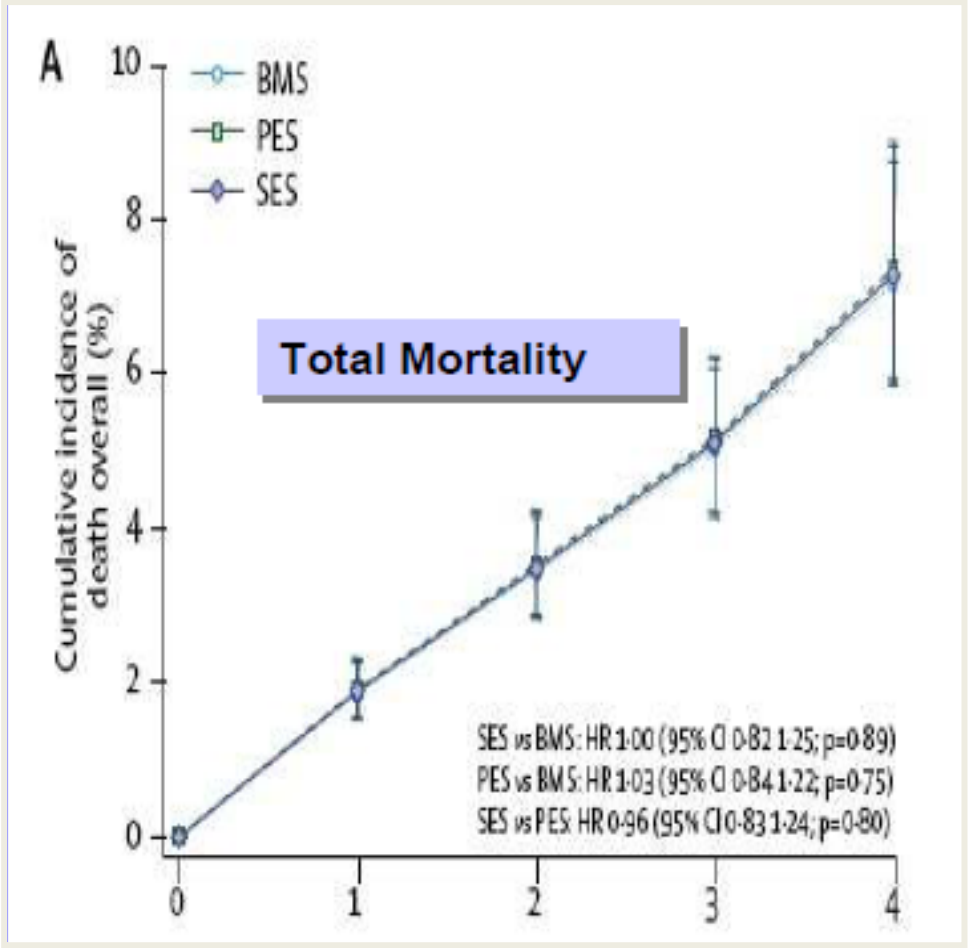
Still a room for BMS usage in 2010 ?

Usage pattern in Europe

- In Europe: is still used in almost 30-35% of treated lesions
- Mainly for Saftey issues & costs
- But also…efficacy in some subset of lesions. Large vessels (>3.0, focal leions, type A lesions , short lesions…)

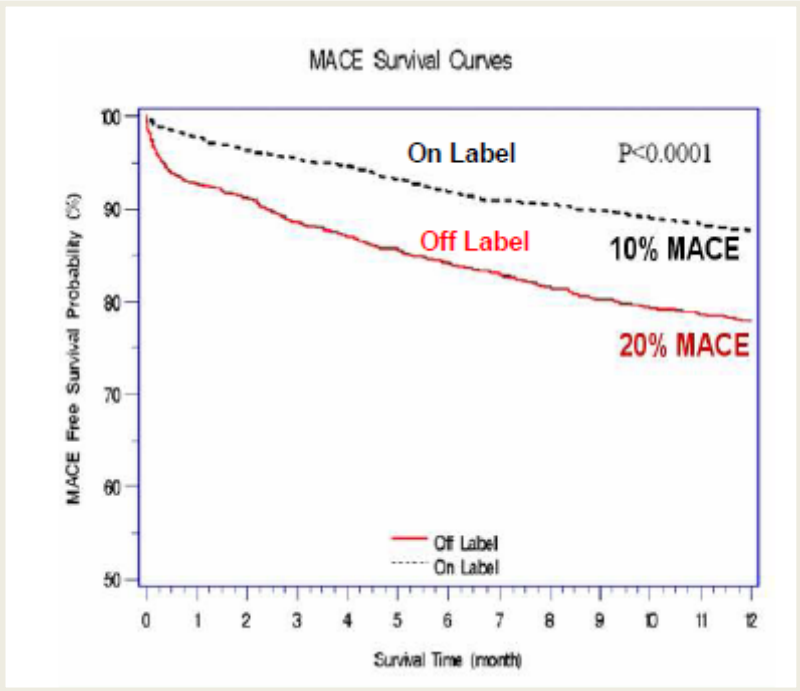
Death after DES or BMS

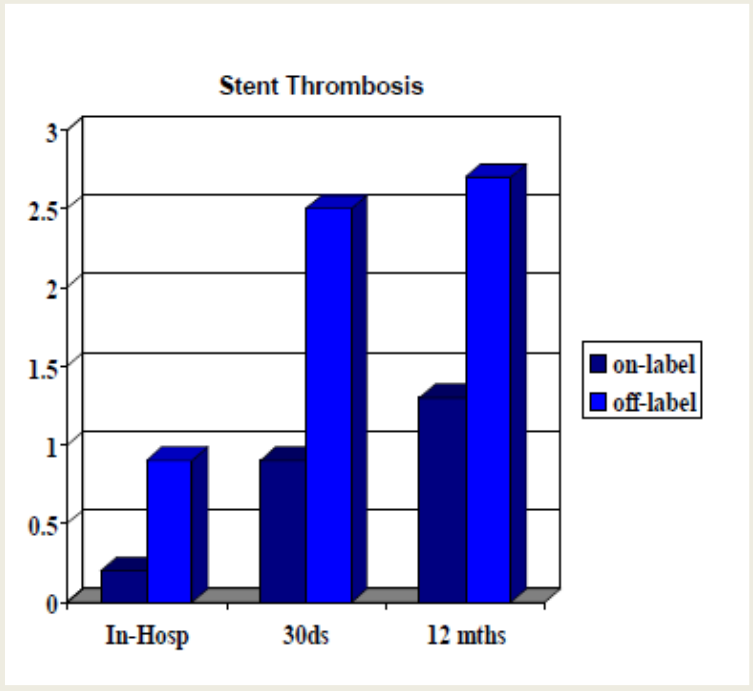
38 RCT , 18.023 patients



Sattler et al , Lancet 2007 , 370: 937-948

Off-Label Use of DES





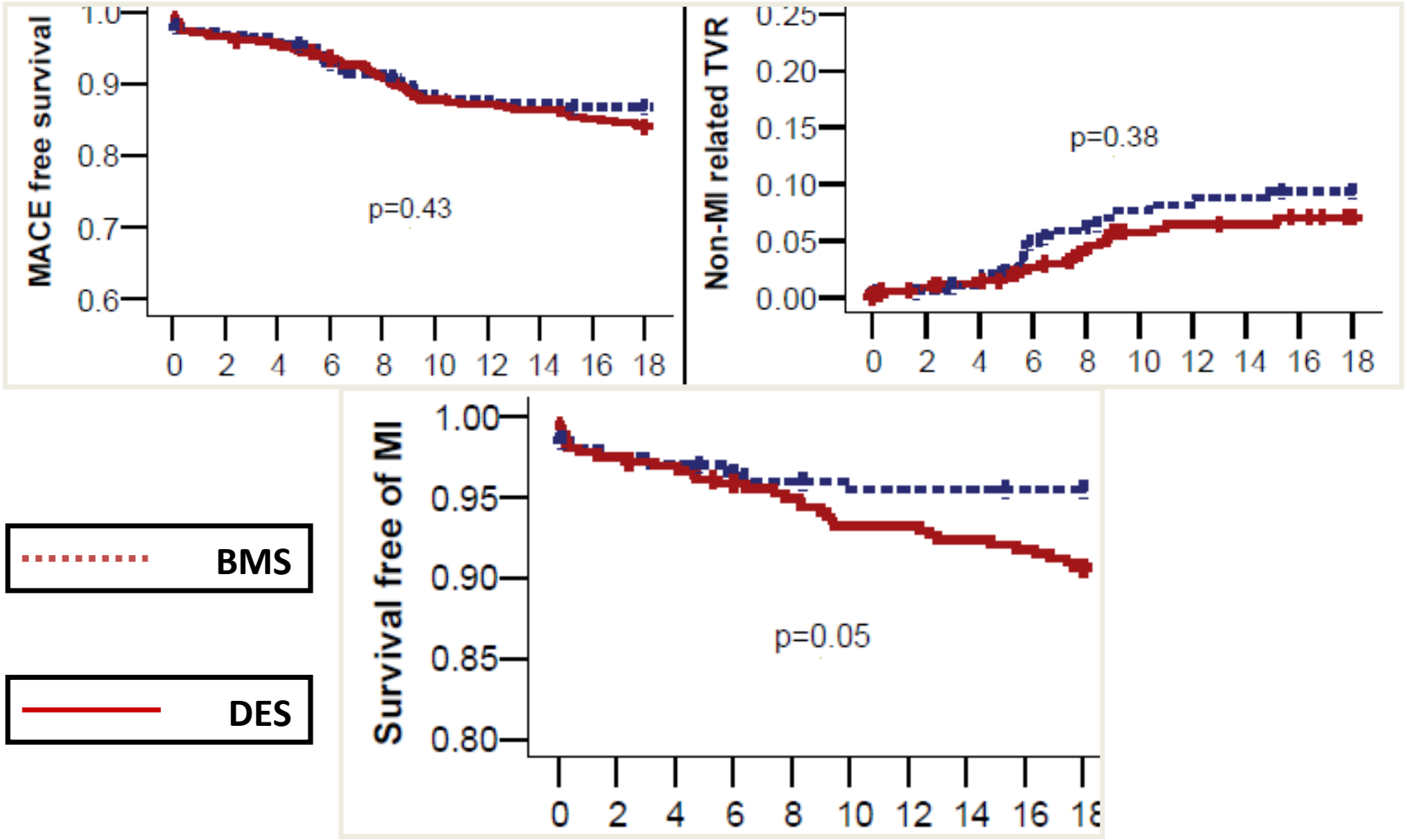
Roy et al. AJC 2008; 101: 293-299

Vessels > 3mm (no bypass grafts)

Randomized to Cypher, Taxus or Vision.

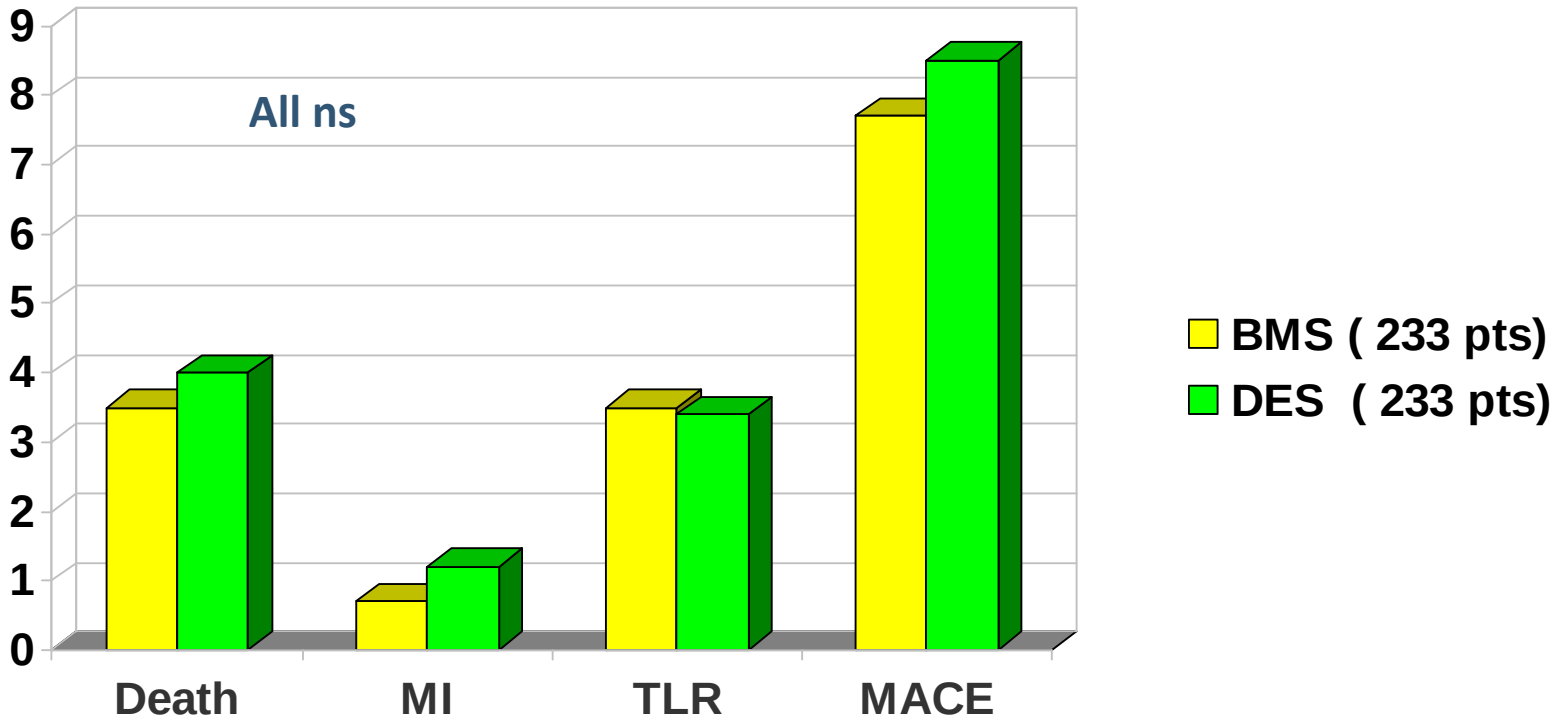
Kaiser et al., ESC 2006.

N=558 (68%), 18 months follow-up



BMS in Large vessels (> 3.5 mm)

MACE at 12-month Follow-up



Steinberg et al AJC 2007; 99:599-602

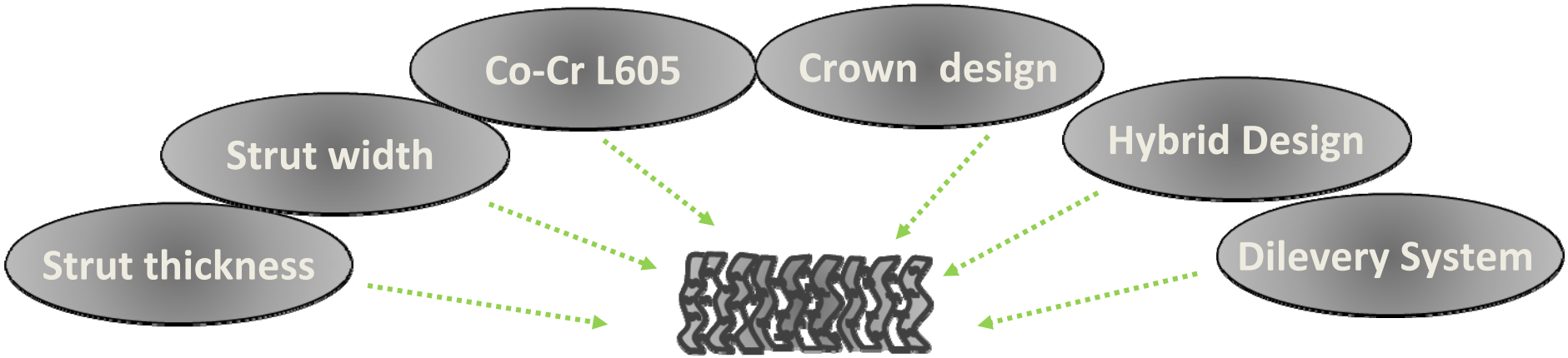
BMS still indicated in :

- Chronic oral anticoagulation
- Unable , unwilling to take medications as reccomended (old, age , uneducated , other..)
- Patients scheduled for non cardiac surgery
- Unable to pay for medications
- Emergency cases (without detailed informations on patient)
- Increased or untreatable risk of bleeding
- Intollerance or allergy to ASA / Clopidogrel
- Patient compliance to Double Antiplatelet Therapy
- Primary *PCI ? ..*

Which BMS ?

- Pushability
- Trackability
- Conformability
- Visibility
- Struts Thickness
- Stent design (open cell–closed cell)
- Stability on Delivery System
- Low profile and navigability in complex anatomy
- Availability of different sizes and lengths
- Costs

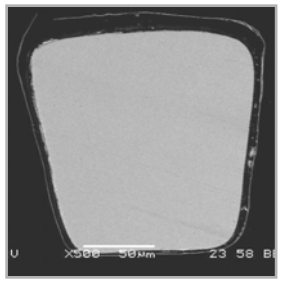
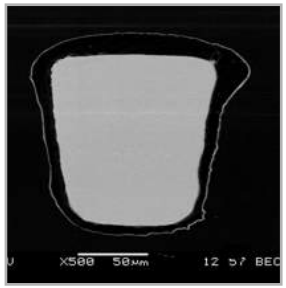
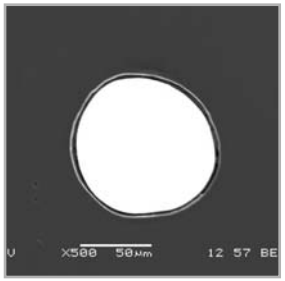
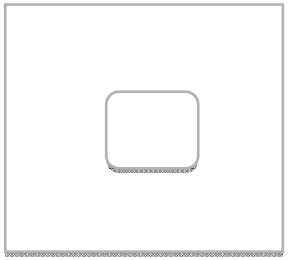
Key elements in Stent technology & Engineering



NEXGEN™
Cobalt Chromium Coronary Stent System

Stent Strut Thickness

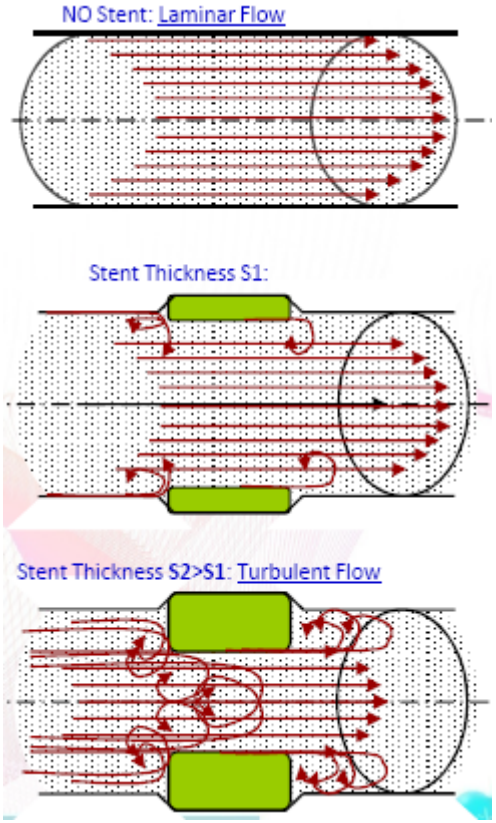
Minimising Vessel Injury

Bx Sonic	Liberte	Driver	Vision	NexGen
				
140 µm	132 µm	91 µm	81 µm	65 µm

3.0 mm diameter stents, 500X magnification

Thin Struts and Restenosis

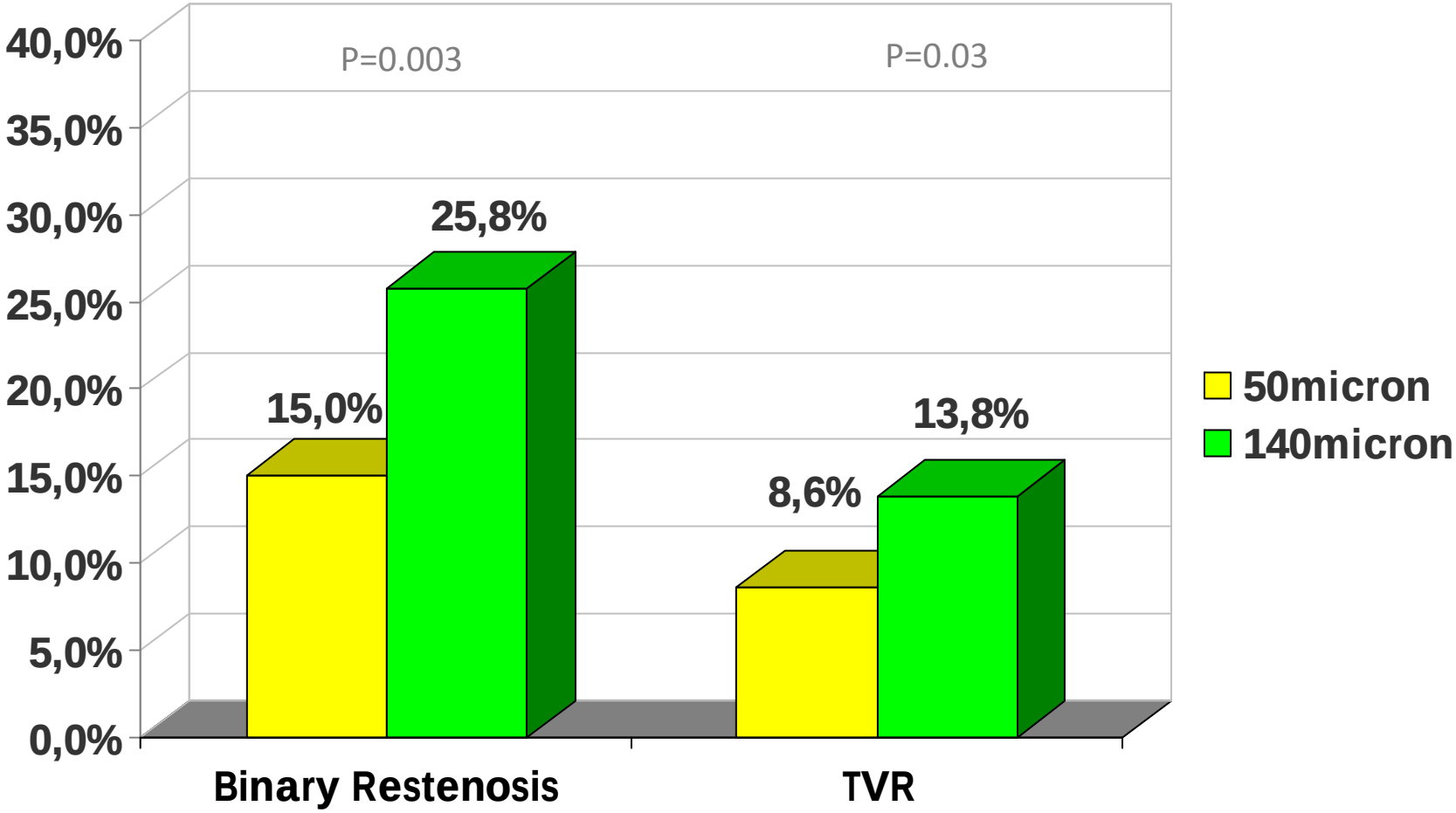
- Thin Struts as low as 65 μm(0.0026”)
  - Low blood flow perturbance
  - Easy struts nesting to the vessel wall
  - Added flexibility and conformability
- Improved clinical outcome*
- Improved, faster endothelialization **



- * Kastrati A, Schömig A, DirschingerJ, et al. Strut Thickness Effect on Restenosis Outcome (ISAR STEREO Trial). Circulation 2001; 103:2816-2821
- ** Simon C, Palmaz JC, Sprague EA. Influence of topography on endothelialization of stents: clues for new designes. J Lon Term Eff Med Implants. 2000;10:143-151

Why Thinner Struts?

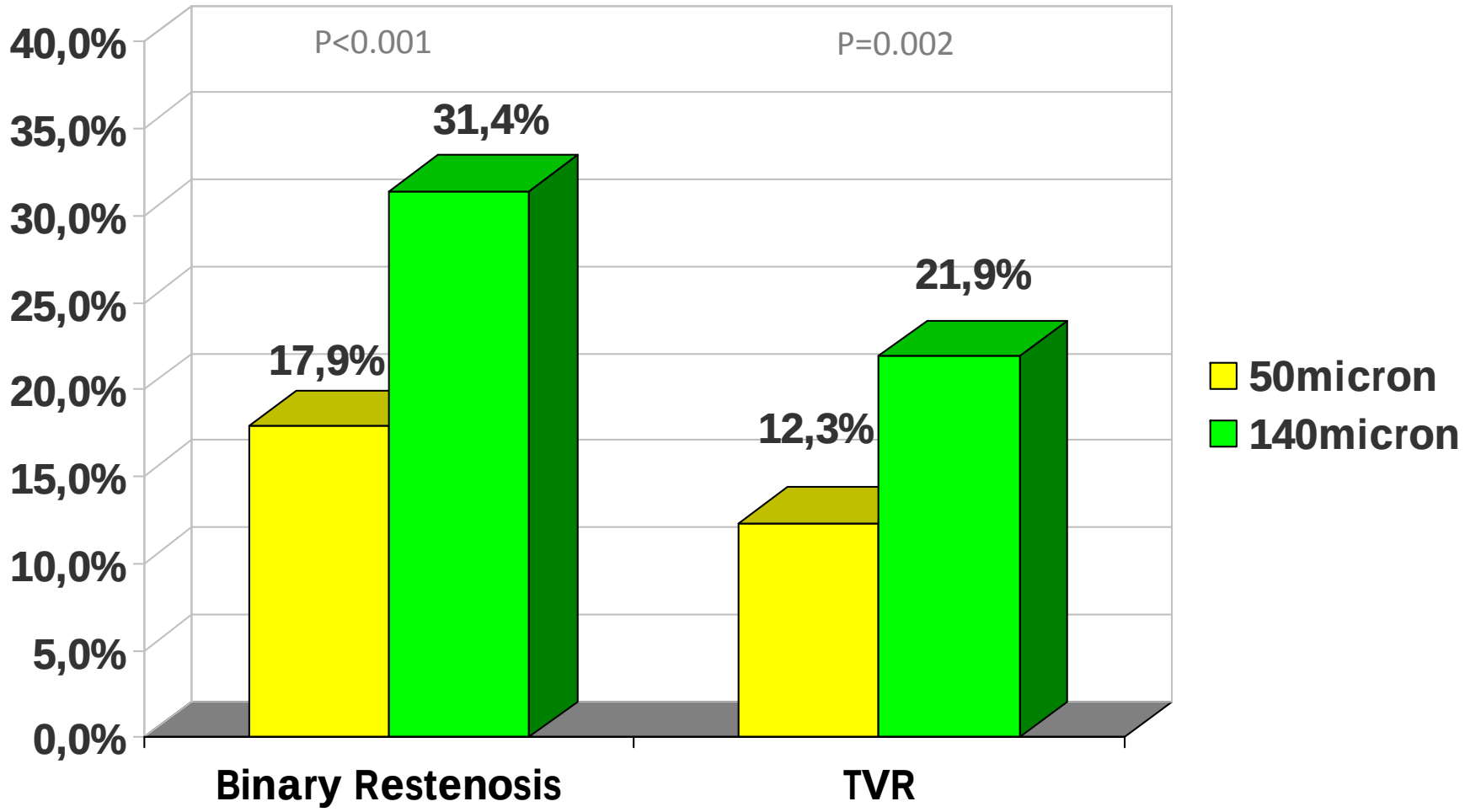
ISAR-STEREO 1



. Kastrati et al. Circulation 2001; 103:2816-2821

Why Thinner Struts?

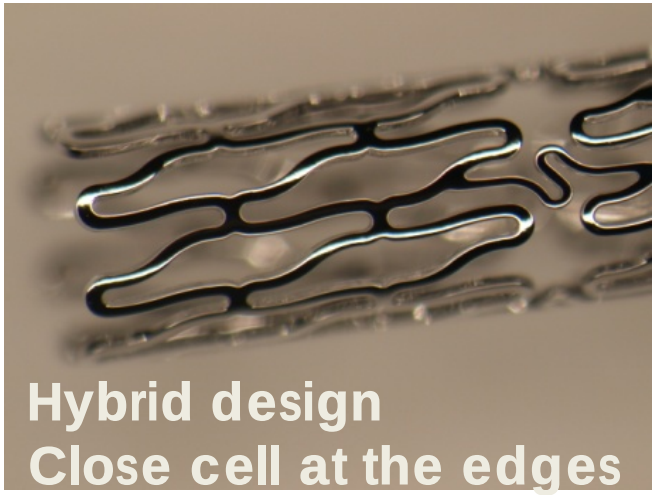
ISAR-STEREO 2

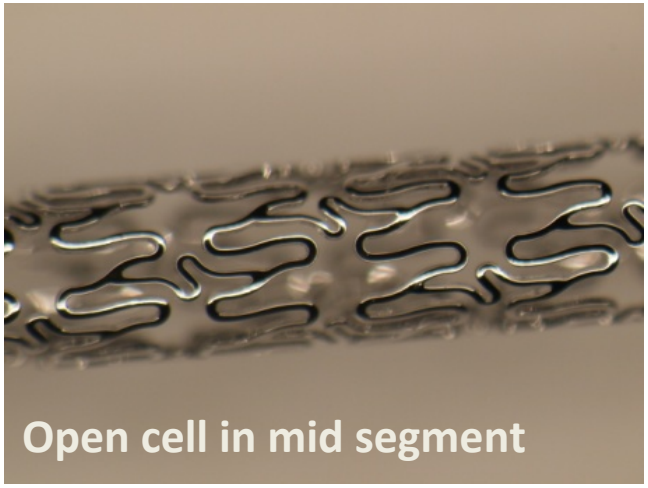


ISAR-STEREO 2. Kastrati et al. JACC 2003; 41:1283-8

Unique Design Features

- Conventional edge-flaring stent designs allow the stent to dog-bone during deployment.
- This dog-boning coupled with balloon overhang may cause edge injury.
- NexGen stent is made up of unique hybrid cell design comprising of an intelligent mix of open and close cell designs resulting in a structure which provide excellent radial strength with a high degree of flexibility





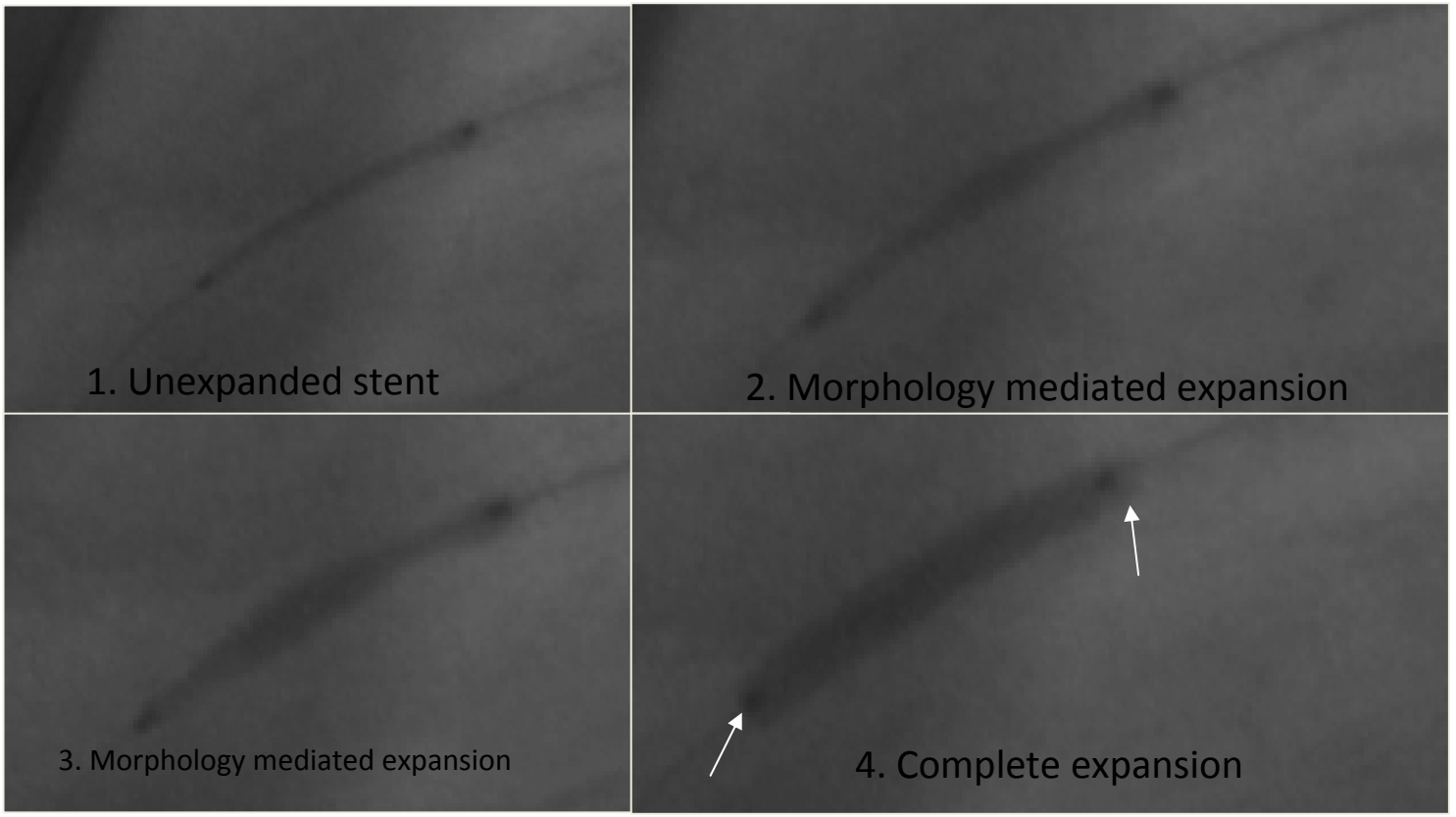
Delightful expansion

Crimped Stent

Morphology Mediated Expansion ™

Fully Expanded Stent

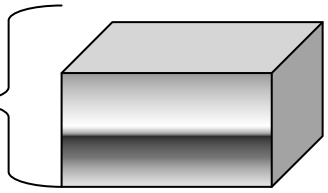
Delightful expansion



4. Note the narrow balloon shoulders which assist in minimizing balloon related vessel injury

65µm Strut Thickness

Strut
Thickness
65µm

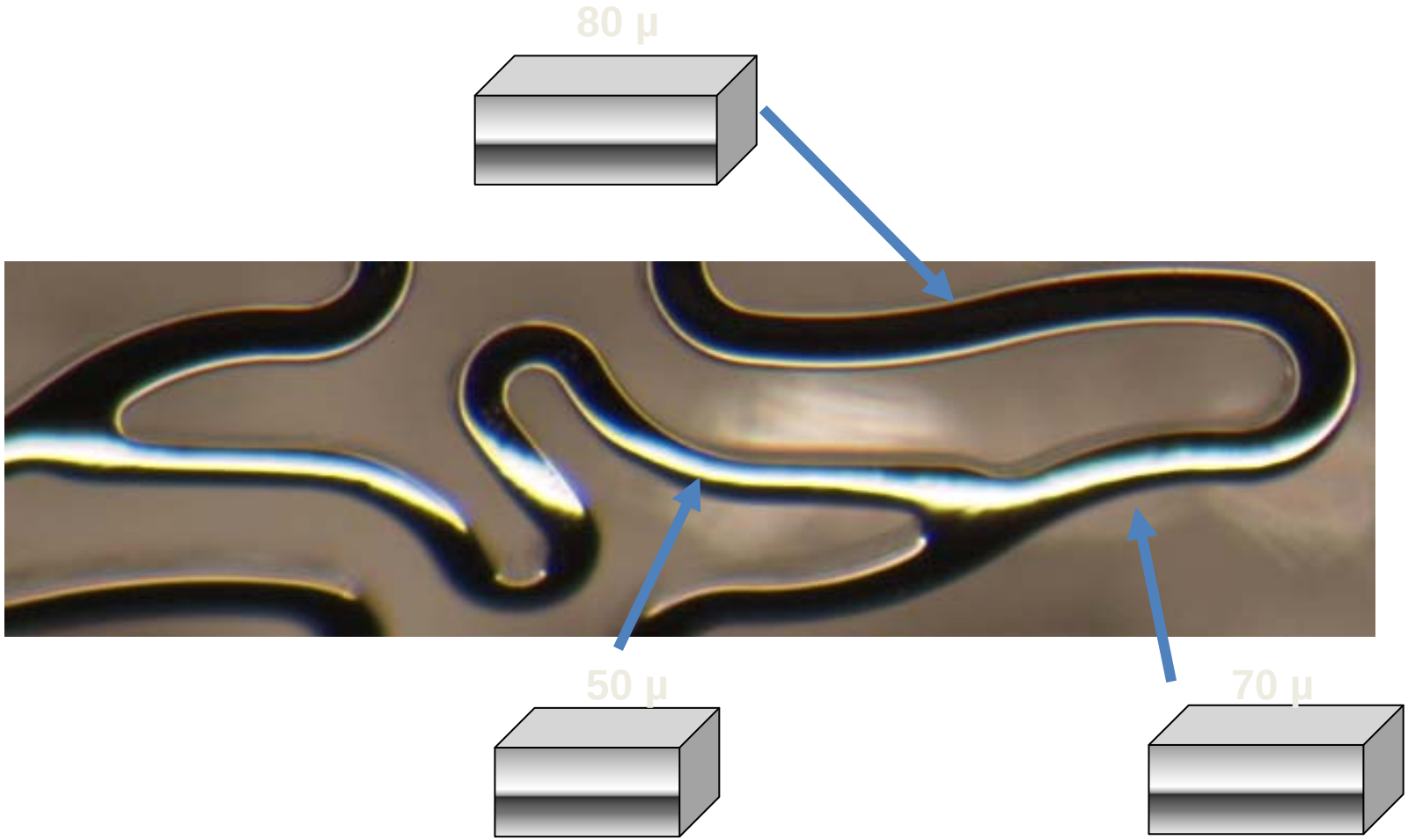


Mid Stent

Proximal / Distal Stent

Uniform Strut Thickness for all sizes from diameter 2.50mm to 4.50mm. No loss in radial strength

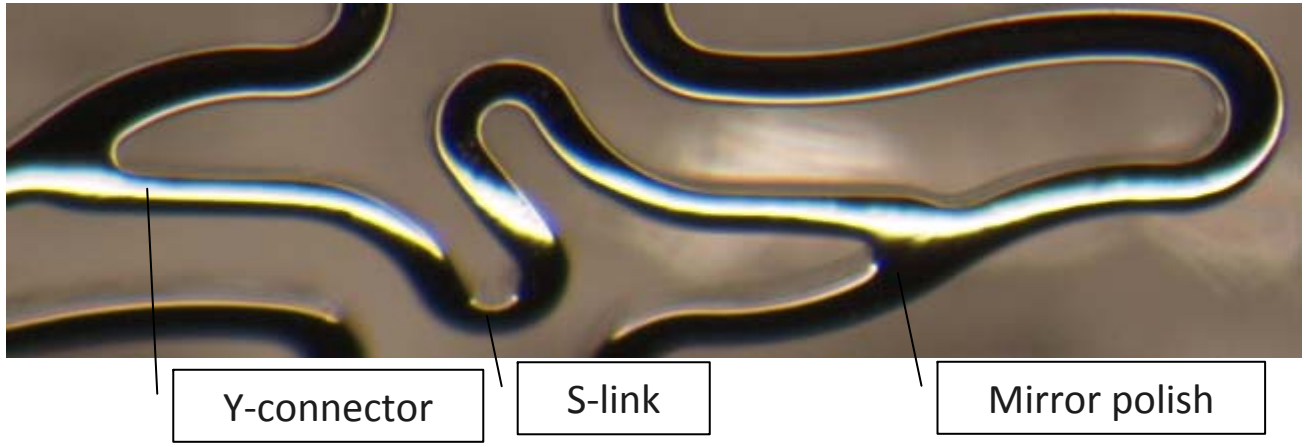
Variable Strut Width



Morphology mediated expansion & Better conformability

No Recoil & Zero Foreshortening

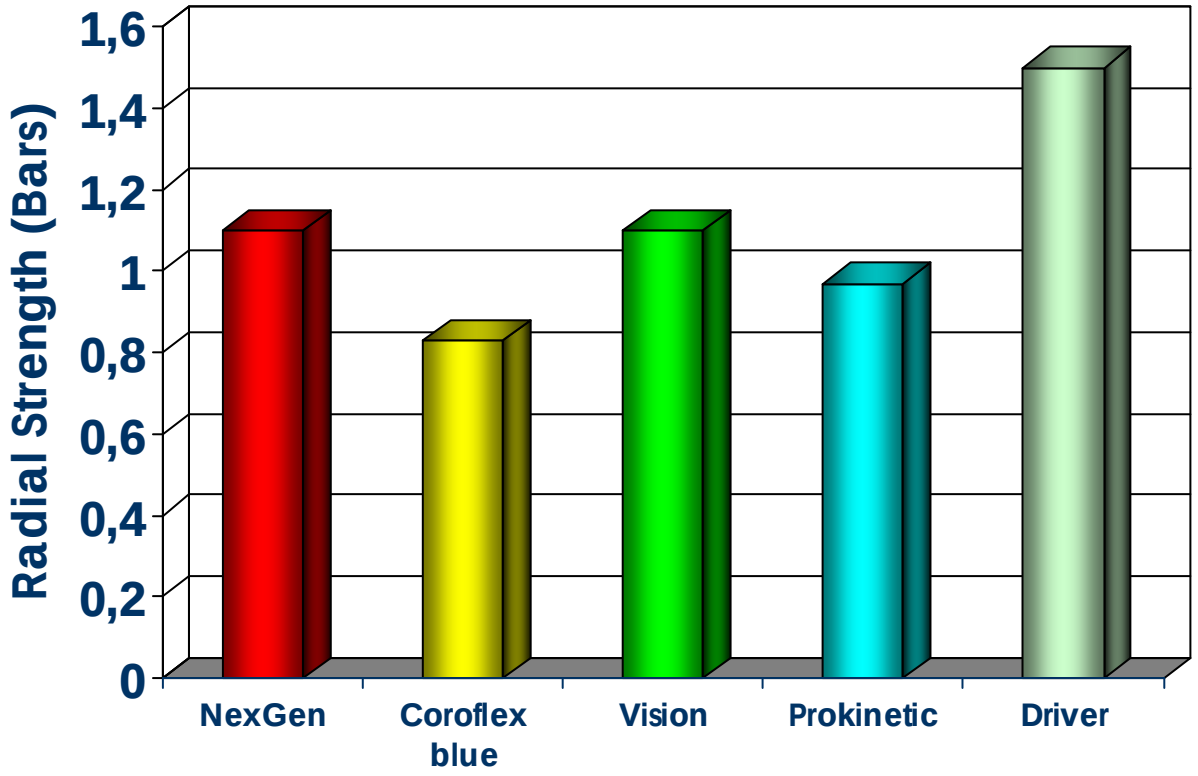
- NexGen's S-links and Y-connectors have demonstrated during bench testing that there is <3% recoil and 0.29% foreshortening
- Meril's proprietary Electro-polishing technique, renders the surface with ultra-high mirror finish and no residual surface metal oxides



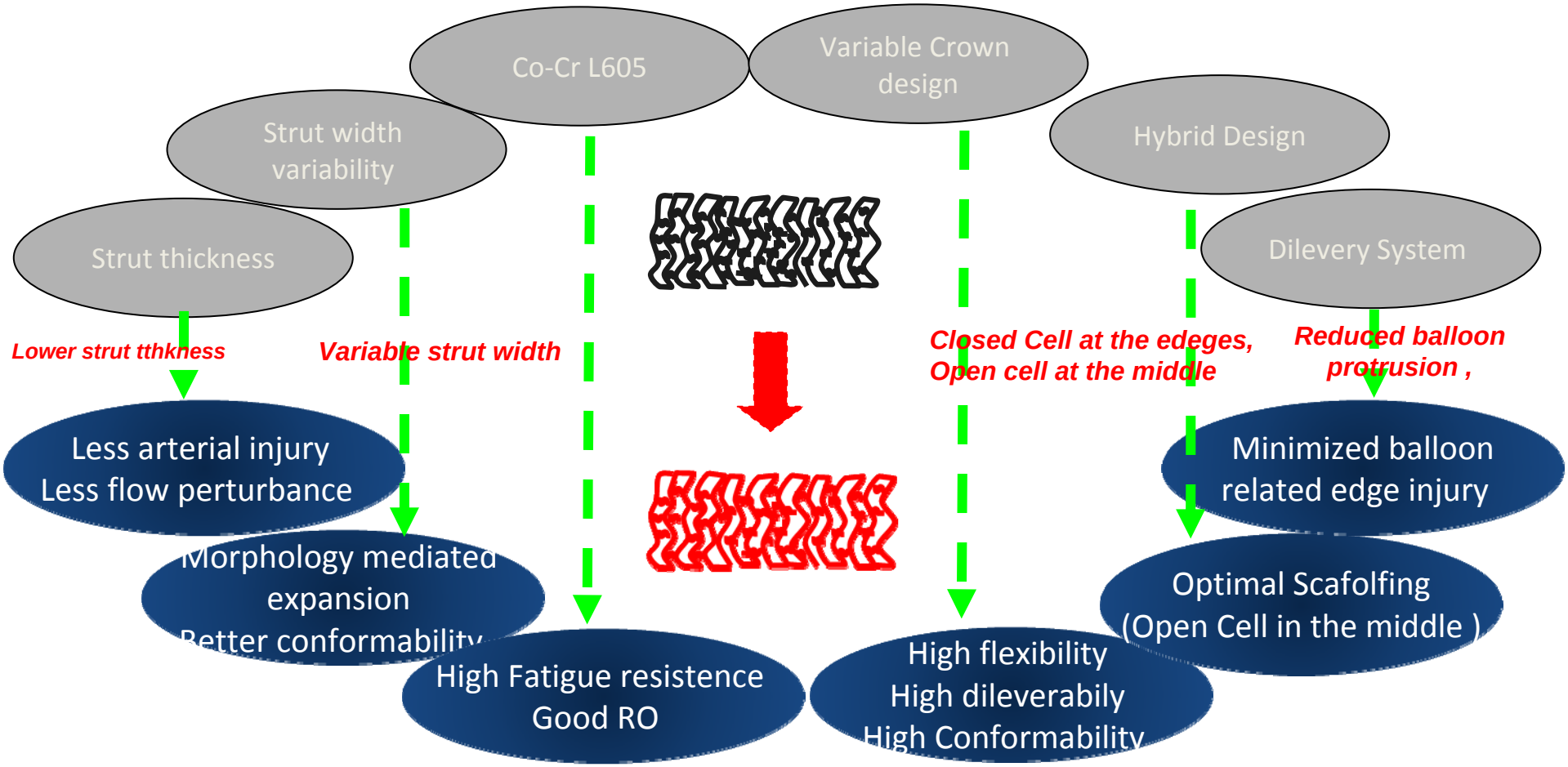
Data on file

Comparative Radial Strength

- Competitive radial strength combined with high flexibility with ultra-low strut thickness



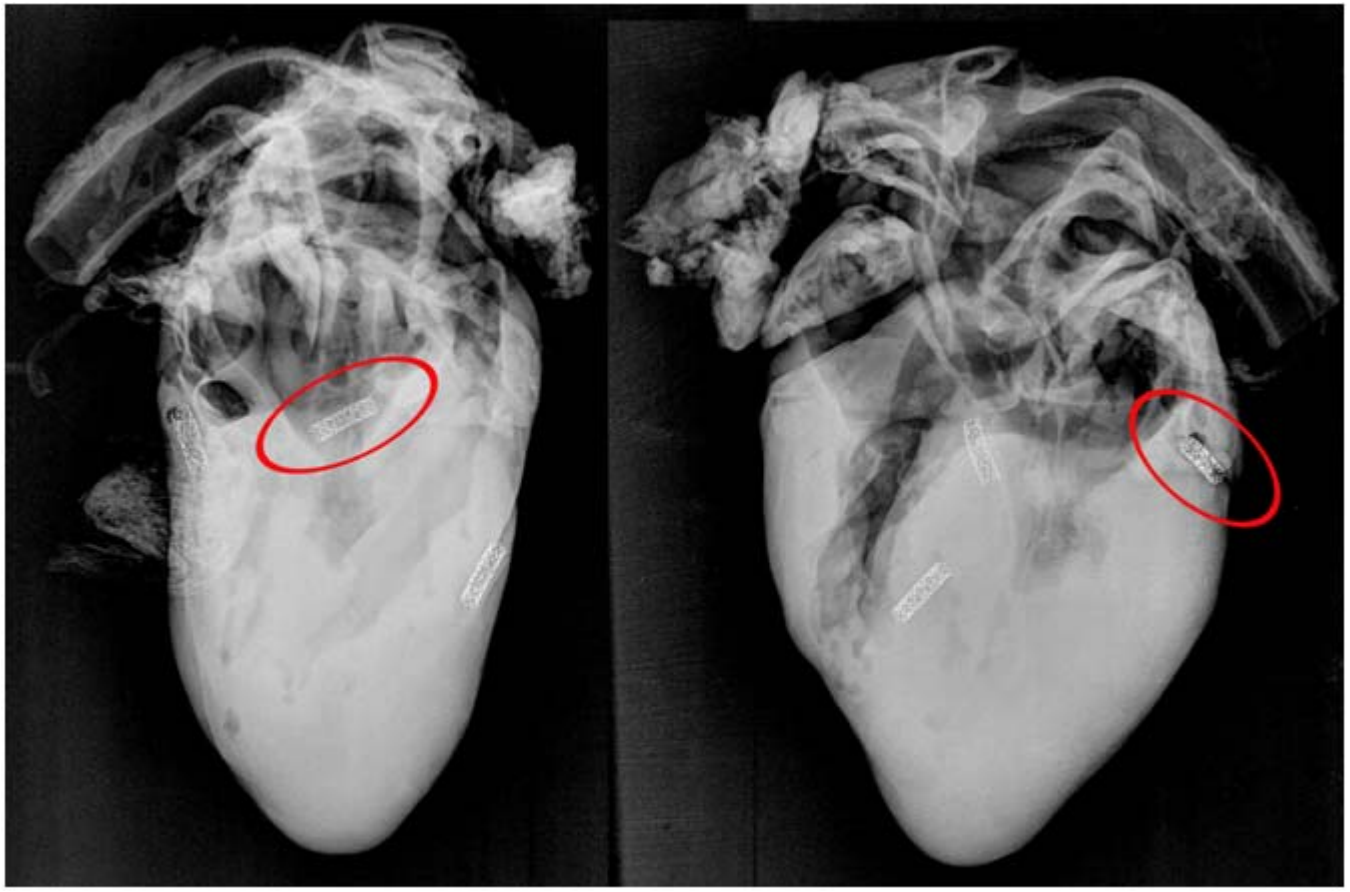
Key elements in Stent technology & Engineering



Propensity for early endothelization ,reduced flow perturbance , reduced binary restenosis & TLR- Ease stent recrossing

Increased safety and clinical efficacy

NexGen - RO



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Pre-clinical study

The goal of the study was to evaluate coronary stents for in vivo tissue compatibility and biofunctionality in a porcine coronary artery model. Biofunctional/tissue compatibility evaluation involved implantation in the pig coronary artery .

15 pig

45 arteries

45 stents

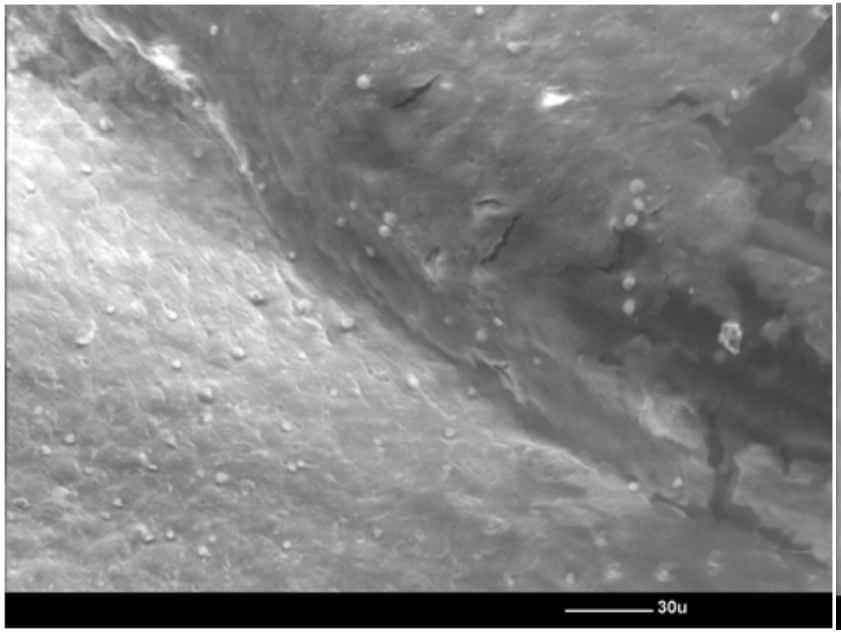
Study Summary

Duration of study	7 days	28 days	90 days	Total
Number of animals tested at various time periods	5*	6	4	15
Segments treated	15	18	12	45
Stents overall	15	18	12	45
Study bare-metal cobalt chromium stents with transitioning design (NexGen)	3	4	3	10
Study bare-metal cobalt chromium stents with non-transitioning design (Osum)	3	2	3	8
Study bare-metal stainless steel stents (Crypton)	3	6	2	11
Commercially available bare-metal cobal chromium stents (Driver©)	3	4	1	8
Commercially available bare-metal stainless steel stents (Duraflex©)	3	4	1	8

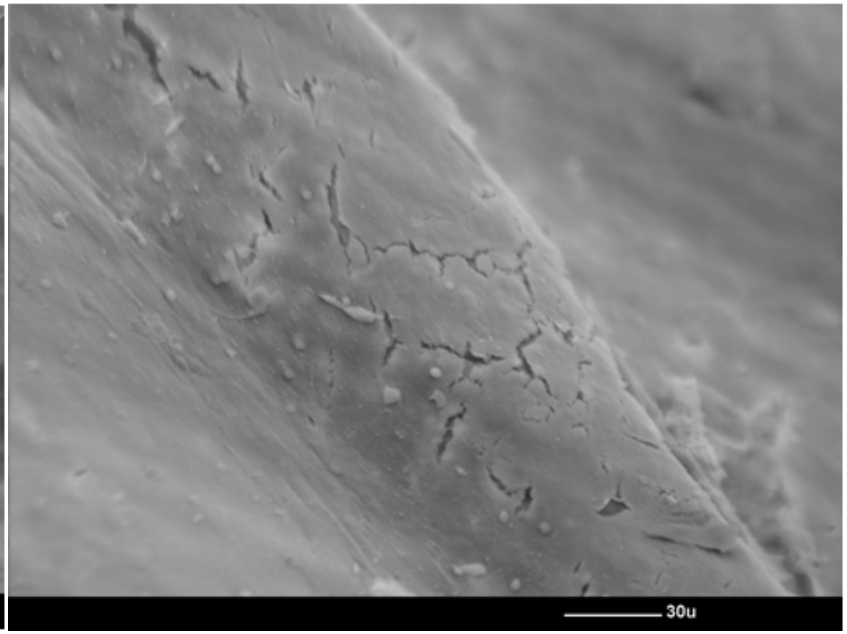
Preclinical Study : 7 days

No differences in stent endothelization, injury score , inflammatory score and intimal thickness

NexGen – 7-day SEM



NexGen 3x13. LCx



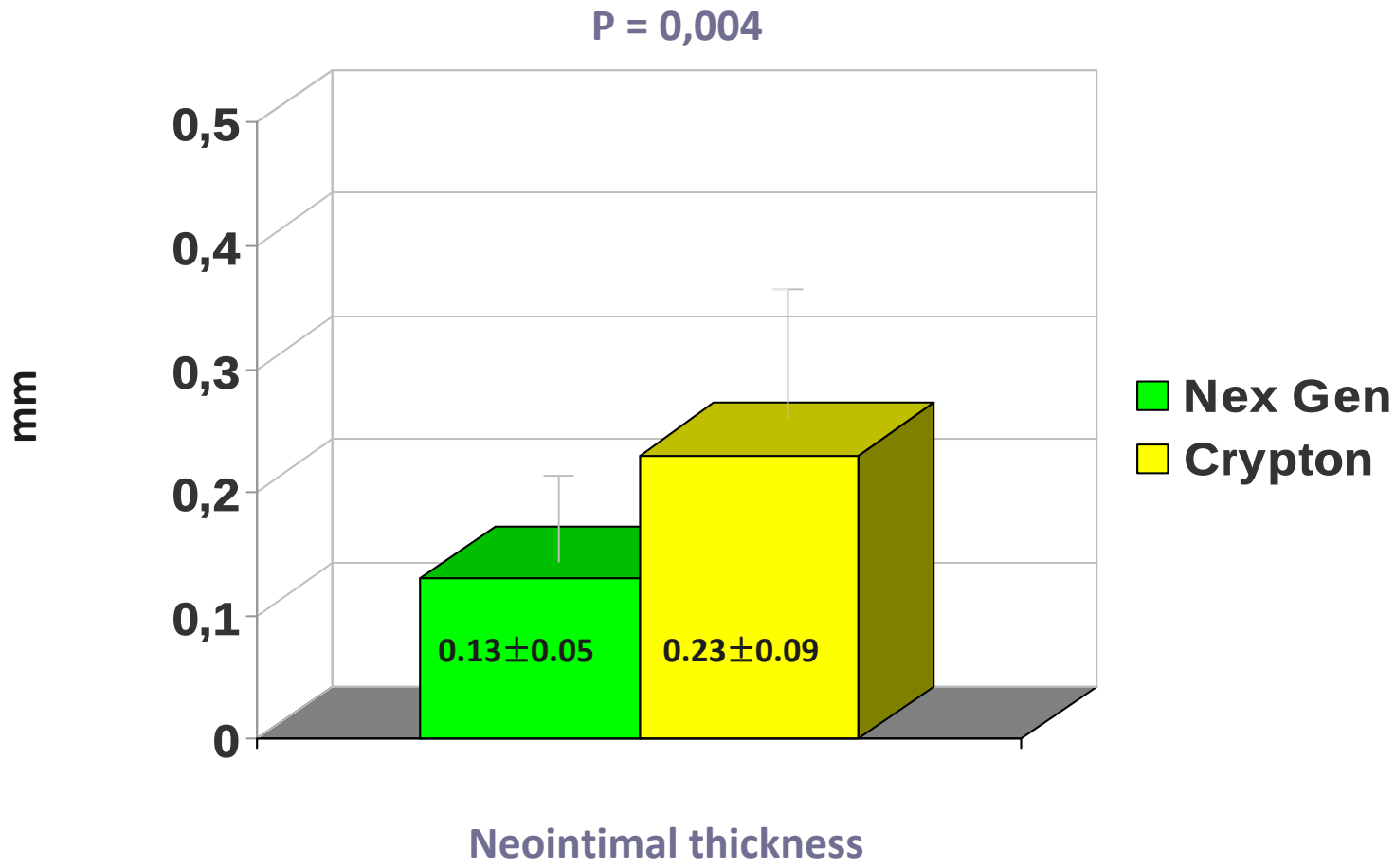
SEM pictures : Complete endothelization of stent struts at 7 days

Data on file

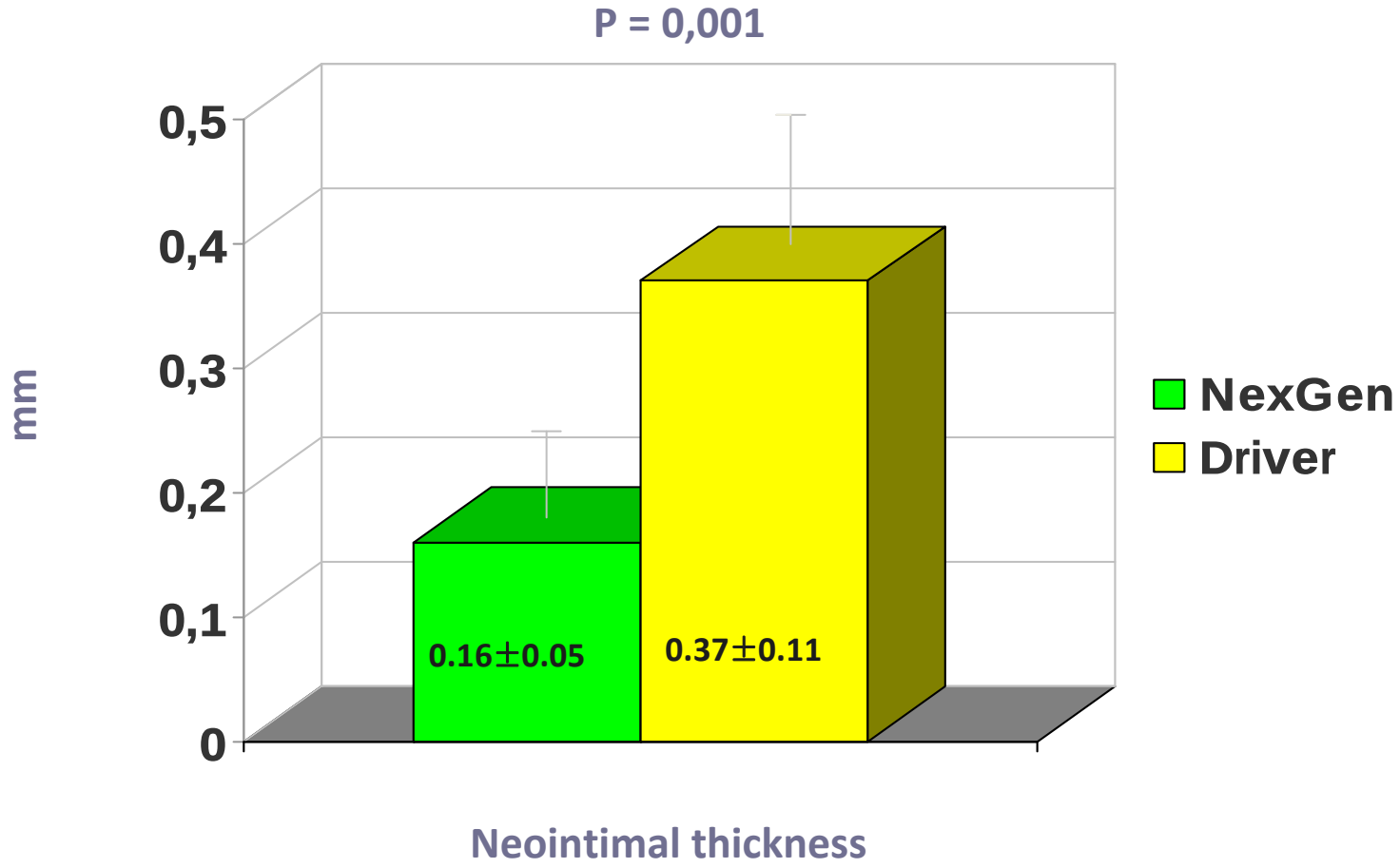
Preclinical Study : 28 days

No differences in stent endothelization , Injury score & inflammatory score

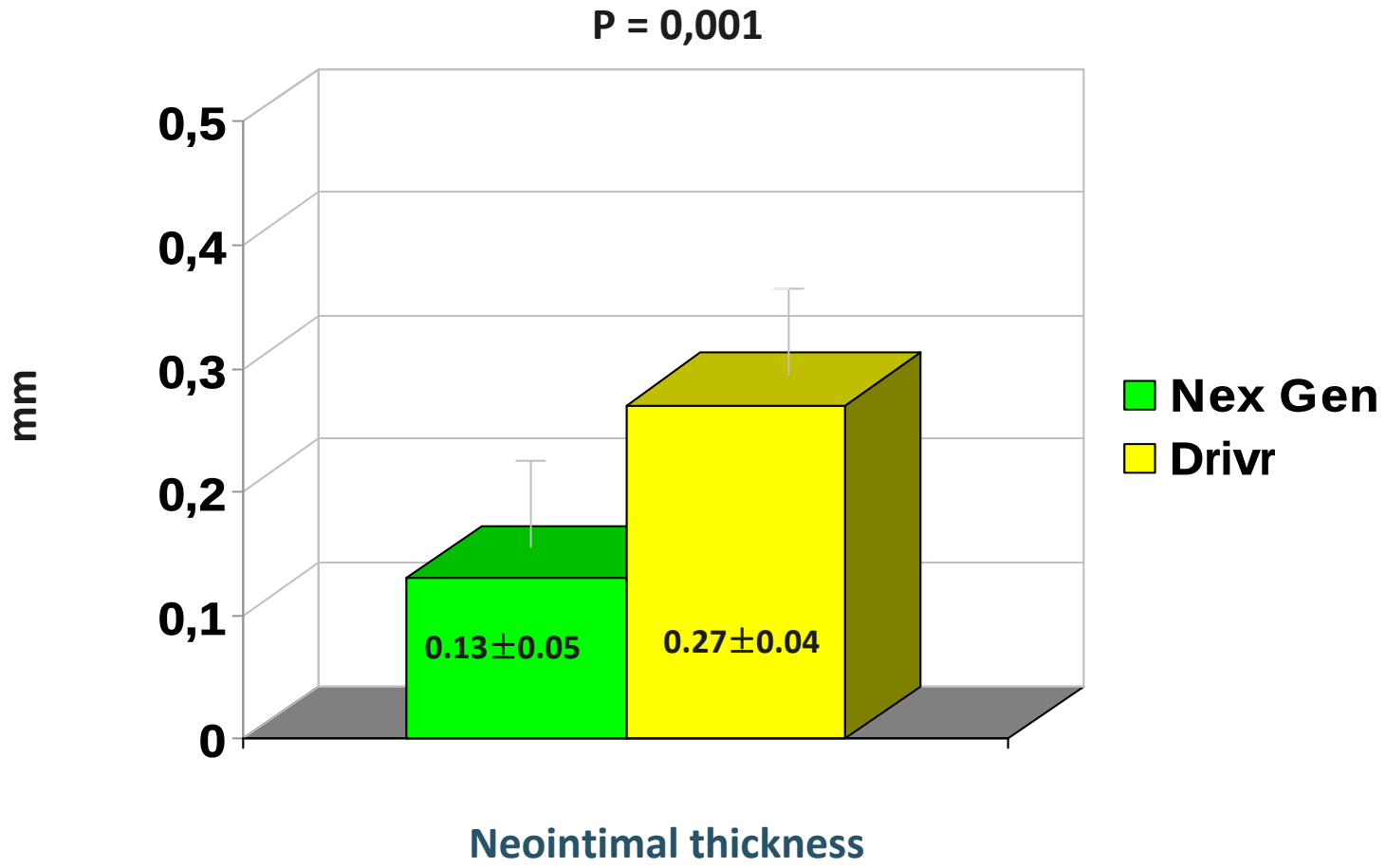
Cobalt Chromium (NexGen) vs Stainless Steel (Crypton)



NexGen vs Driver : proximal segment

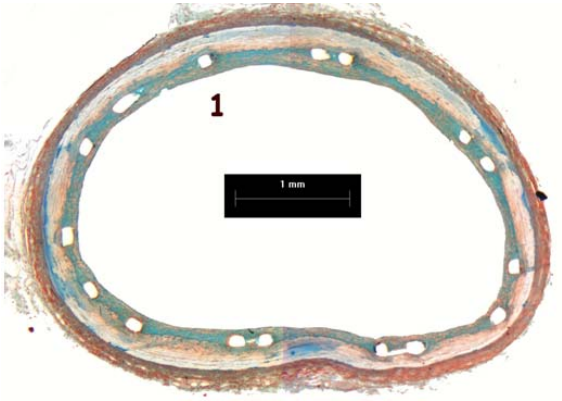


NexGen vs Driver : Med segment

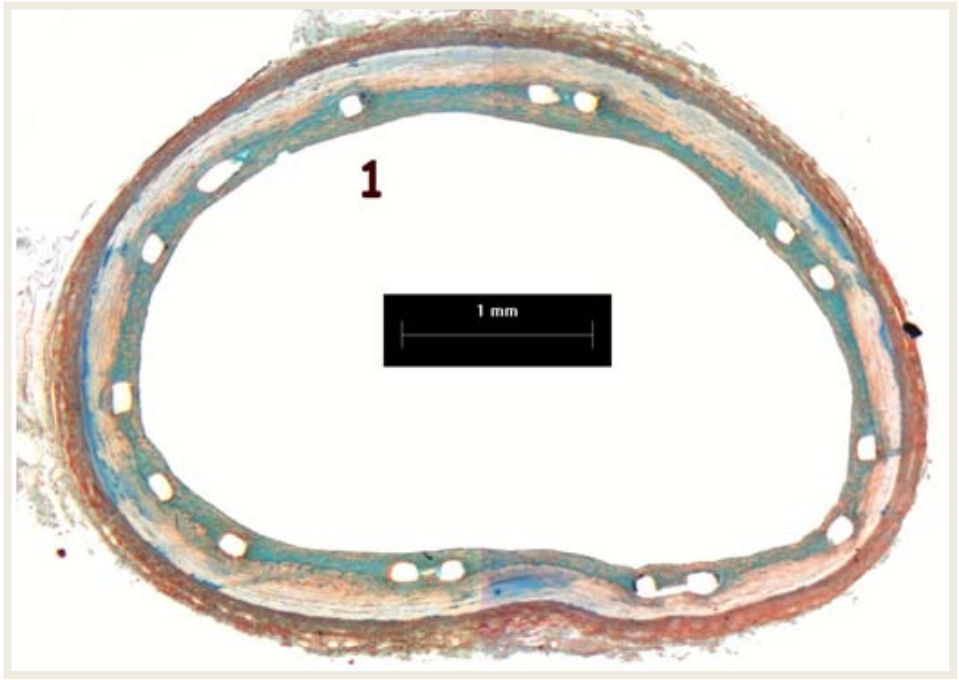


28 Days – NexGen 3.5x13 LCx

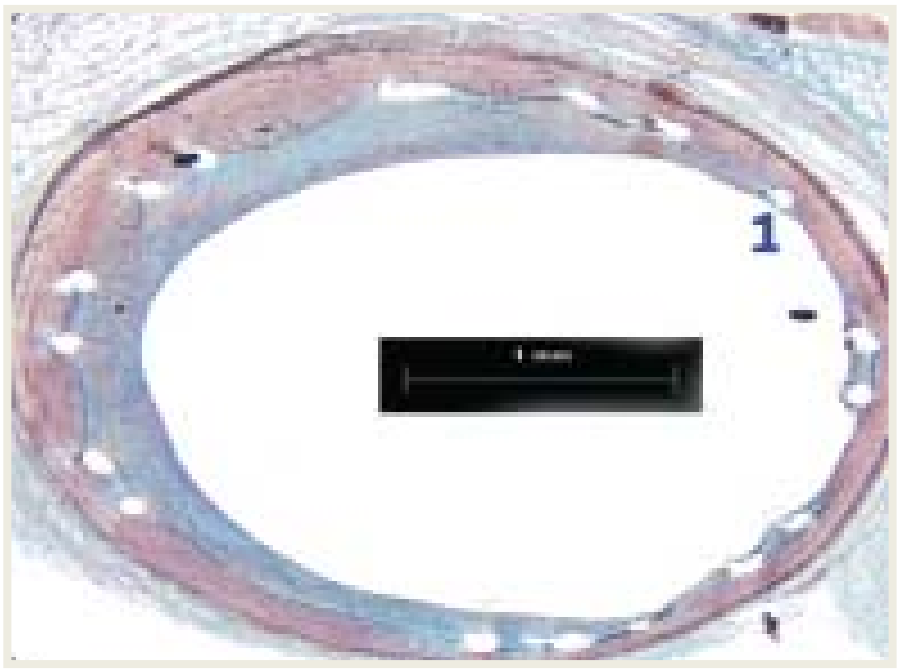
- Histopathology of NexGen 3.5x13 in porcine LCx demonstrating complete wall apposition of struts, mild neo-intima, normal media & adventitia



28-Day comparison



NexGen 3.5 x 16 mm in LAD

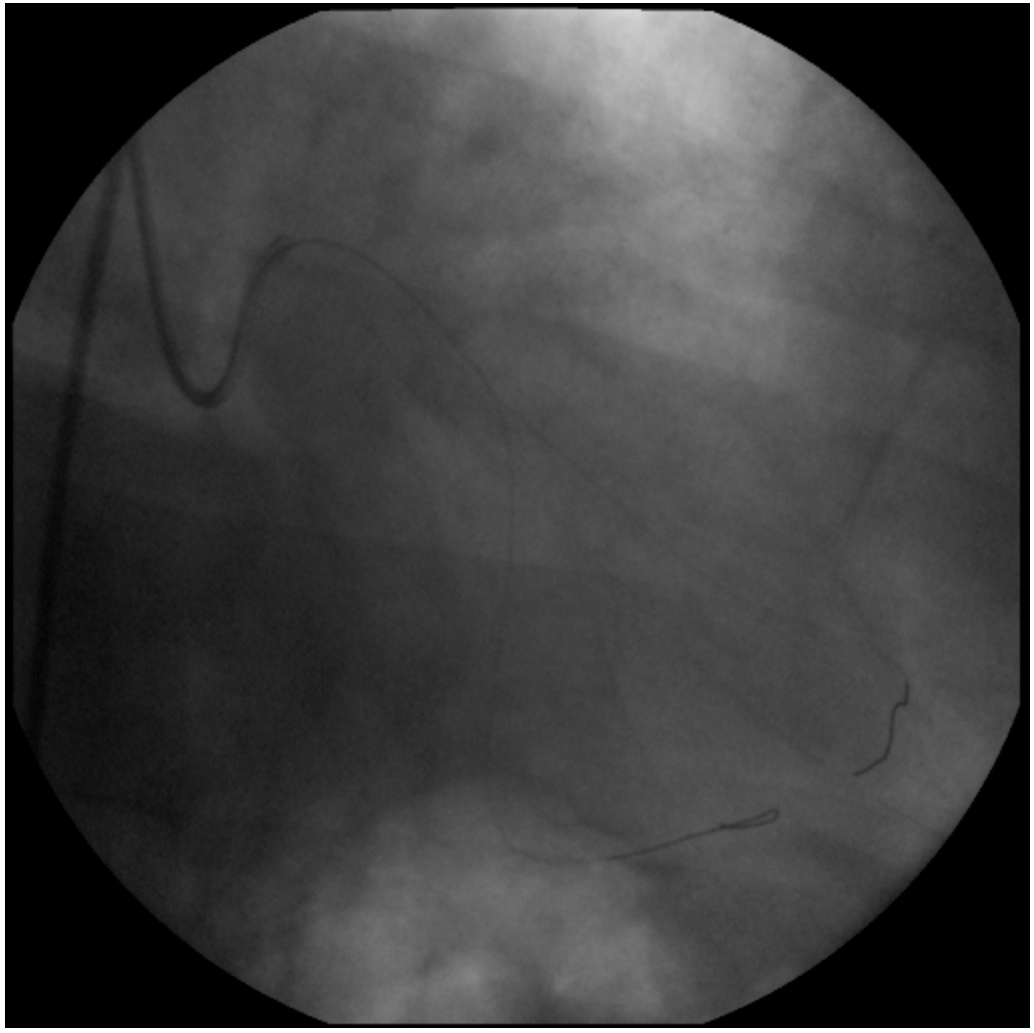


Driver 3.5 x 15 mm in LAD

First Clinical Experience

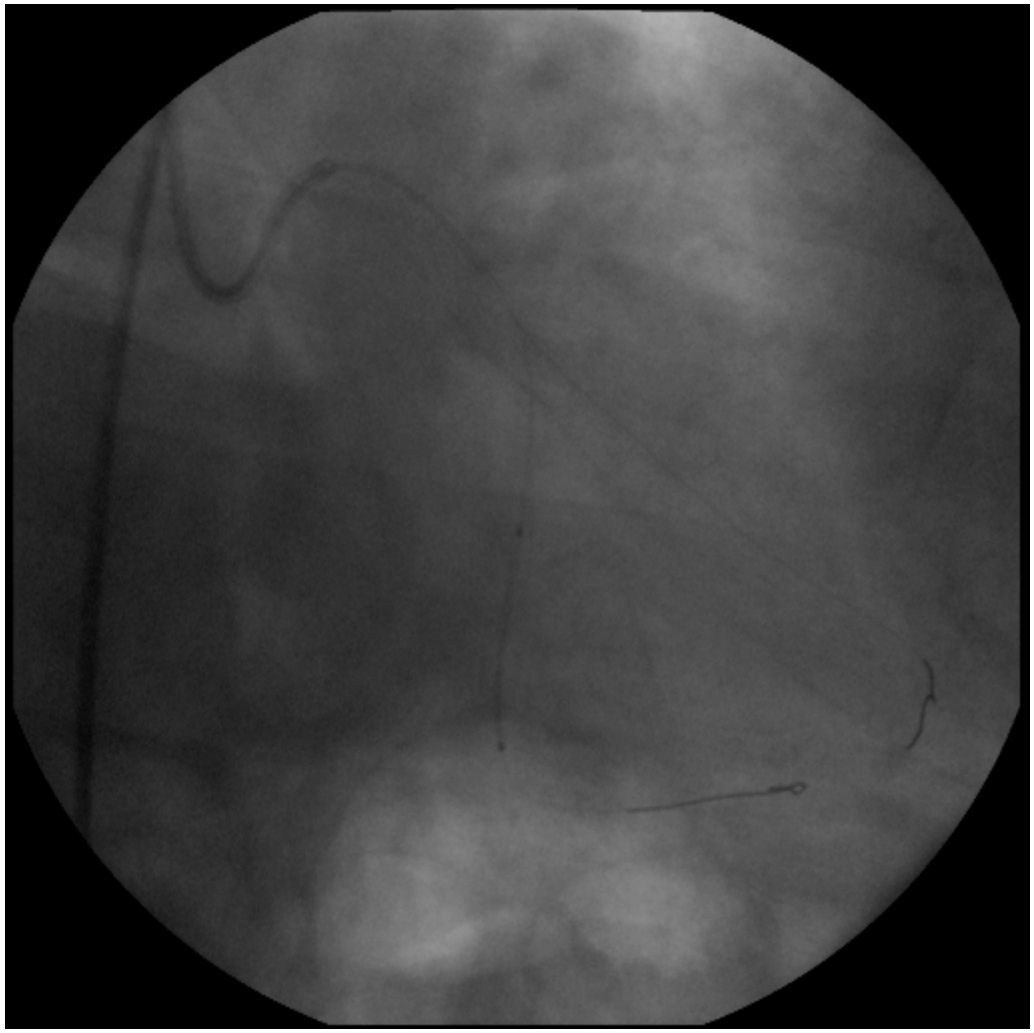
- 20 patients, 20 NexGen stents
- Procedural Success : 20 (100%)
- 6 – months Clinical F-U : 1 TLR

M.L. , 55yrs Male.



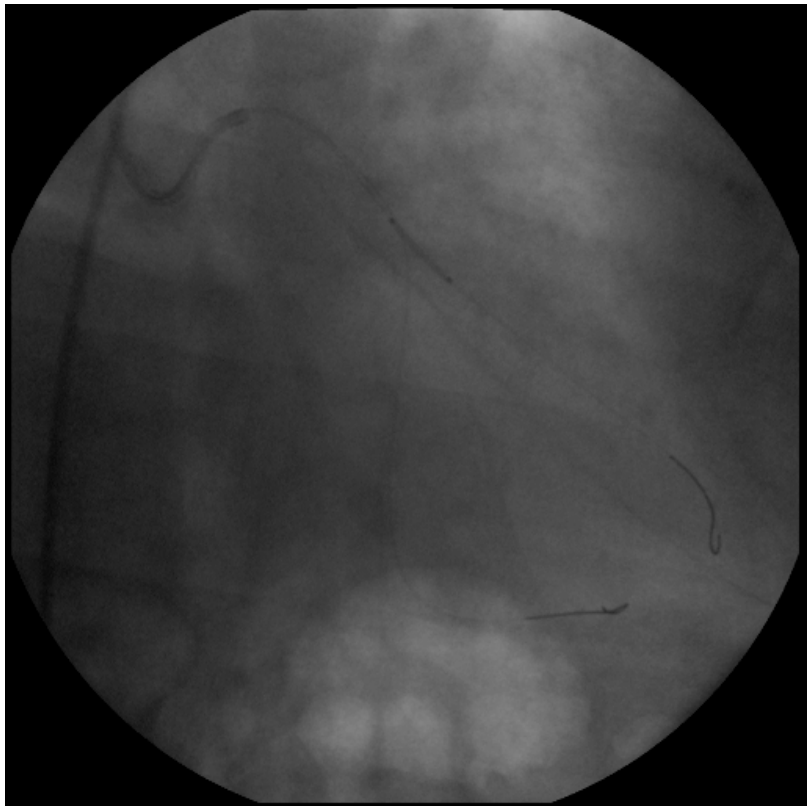
LCX –MO bifurcation Lesion : Medina 1,0,0

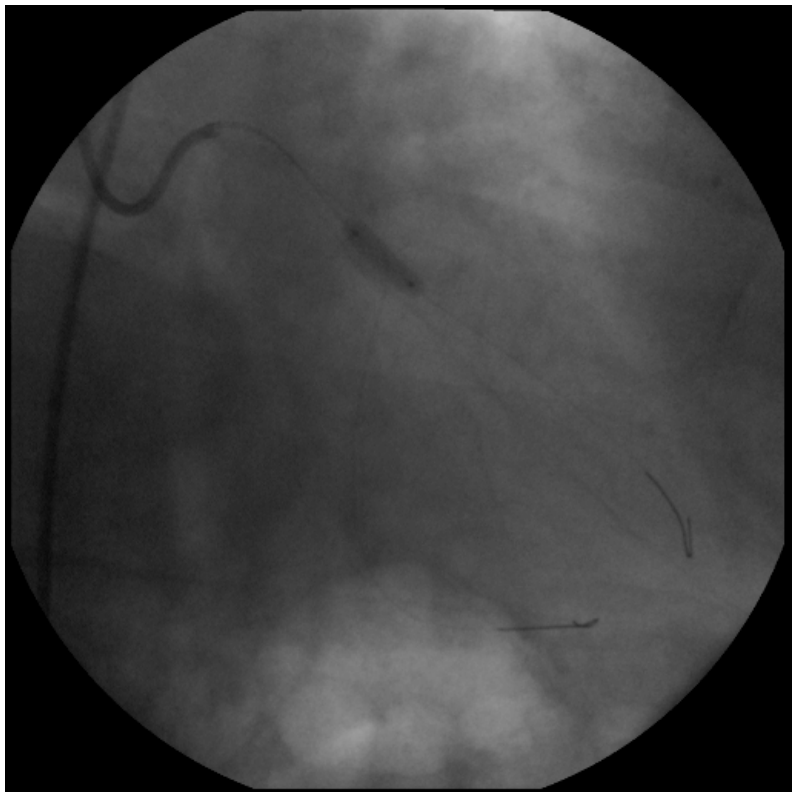
M.L. , 55yrs Male.



Distal LCX lesion treated with Xience V 2.5x 23 mm stent

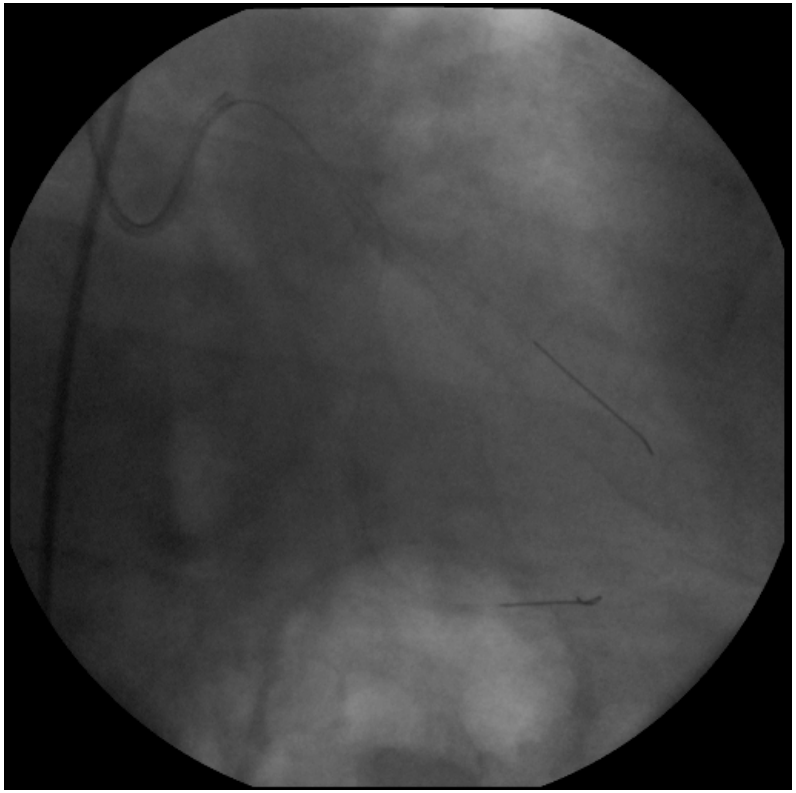
M.L. , 55yrs Male.



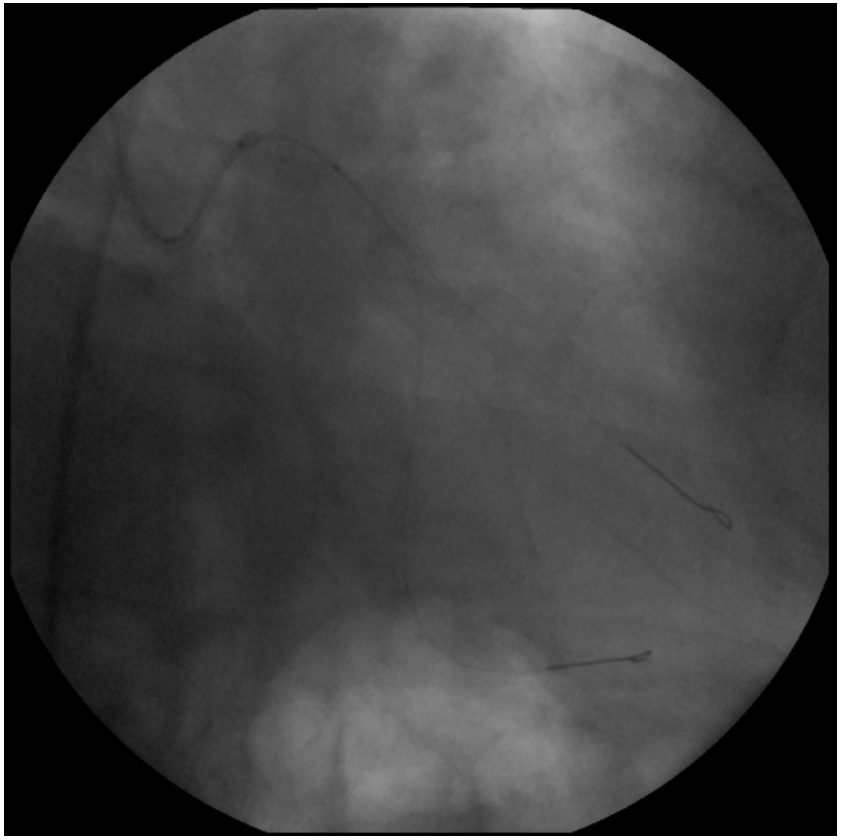


NexGen 3.5 x16 mm positioning and Deployment at LCX –OM Bifurcation

M.L. , 55yrs Male.



Following stent deploymet at 18 atm



Exchanging wires , used dilevery balloon easily crossing the stent struts

Final Remarks

- BMS is here to stay : are used in nearly 30% of treated lesions.
- Characteristics of the stent could impact the clinical outcome (strut thickness & design)
- NexGen Stent showed very promising histoligical and clinical data likely due to the new technology in stent enjeneering
- The new challenge : would it be possible a further reduction of strut thikness - without compromising the stent radial strength - for a further improvement in clinical outcome (better endothelization , lesser perturbance and likely lesser restenosis) ?