

NexGen Polishexperience in ACS

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TCTAP

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Table 12 Recommendations for revascularization in non-ST-segment elevation acute coronary syndrome

Specification	Class ^a	Level ^b	Ref. ^c
An invasive strategy is indicated in patients with: <ul style="list-style-type: none"> • GRACE score >140 or at least one high-risk criterion. • recurrent symptoms. • inducible ischaemia at stress test. 	I	A	64, 68–70
An early invasive strategy (<24 h) is indicated in patients with GRACE score >140 or multiple other high-risk criteria.	I	A	63, 64, 66, 70–72
A late invasive strategy (within 72 h) is indicated in patients with GRACE score <140 or absence of multiple other high-risk criteria but with recurrent symptoms or stress-inducible ischaemia.	I	A	59, 66, 68
Patients at very high ischaemic risk (refractory angina, with associated heart failure, arrhythmias or haemodynamic instability) should be considered for emergent coronary angiography (<2 h).	IIa	C	—
An invasive strategy should not be performed in patients: <ul style="list-style-type: none"> • at low overall risk. • at a particular high-risk for invasive diagnosis or intervention. 	III	A	59, 68

^aClass of recommendation.

^bLevel of evidence.

^cReferences.

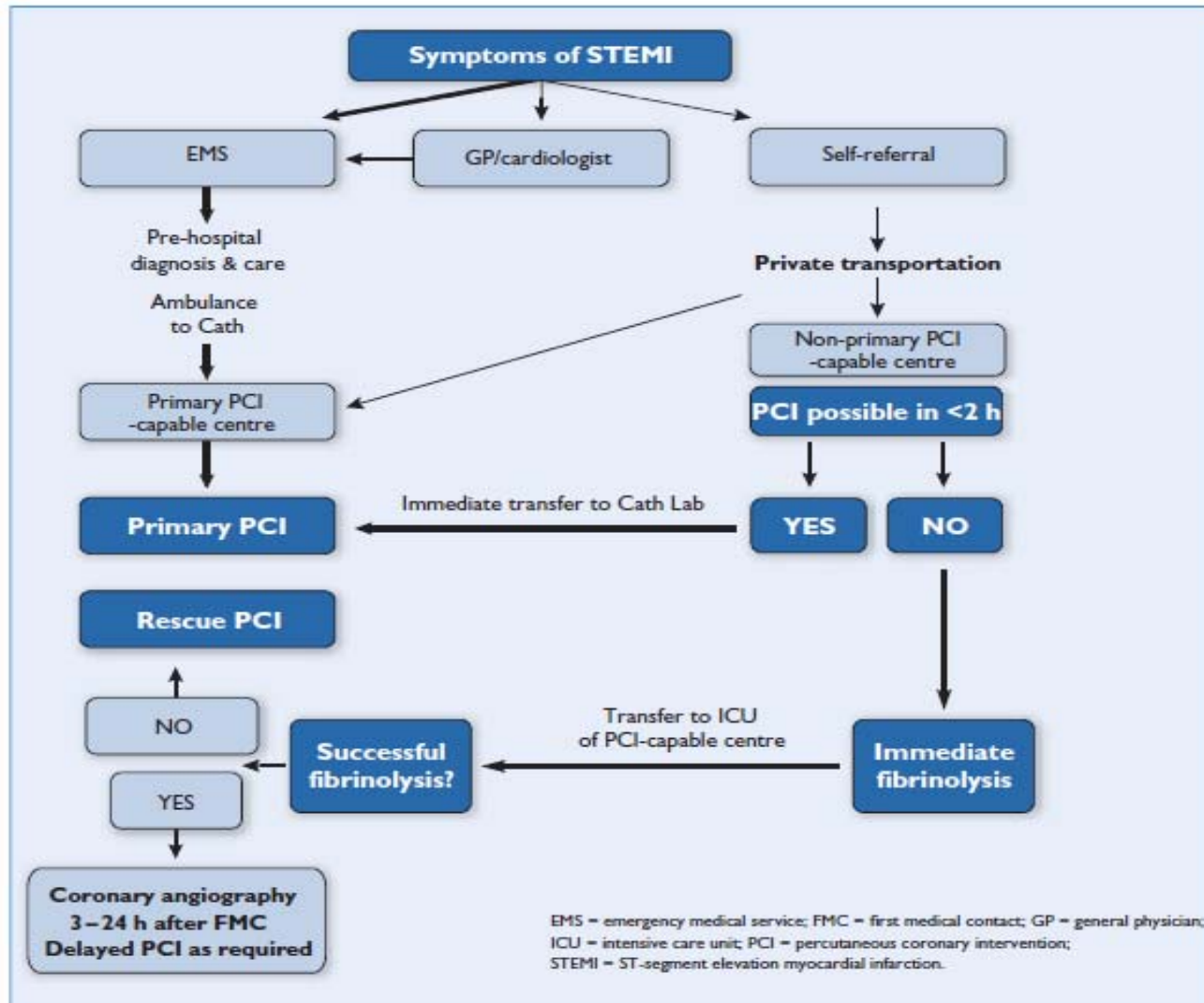
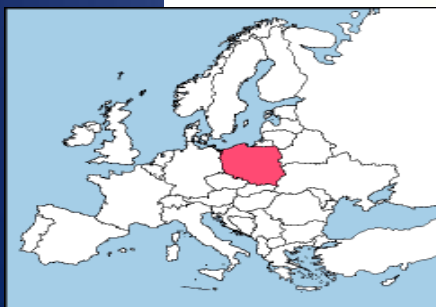
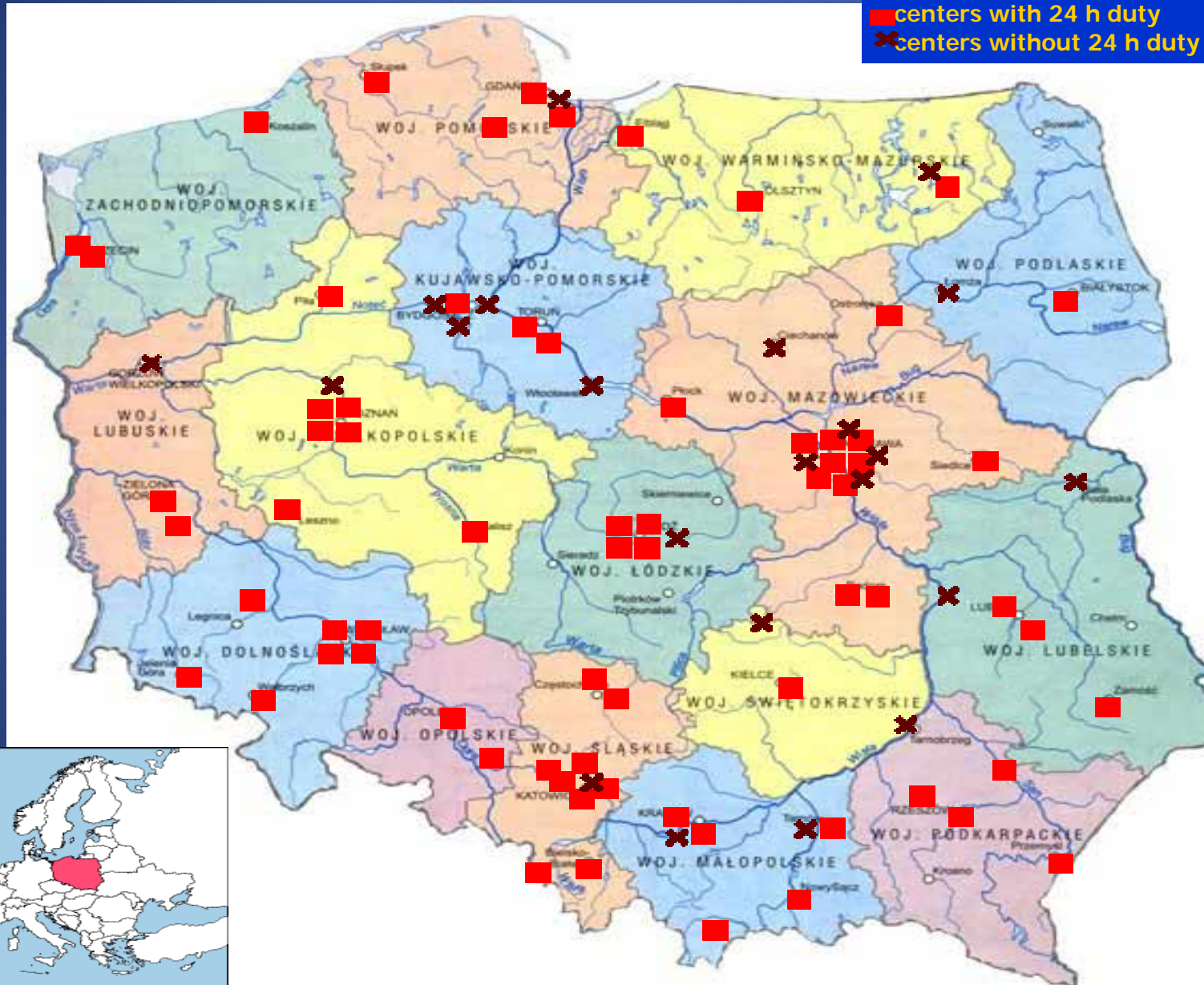


Figure 1 Organization of ST-segment elevation myocardial infarction patient pathway describing pre- and in-hospital management and reperfusion strategies within 12 h of first medical contact.

Polish Cardiac Society Working Group on Cardiovascular Interventions Interventional Cardiology in Poland 2009

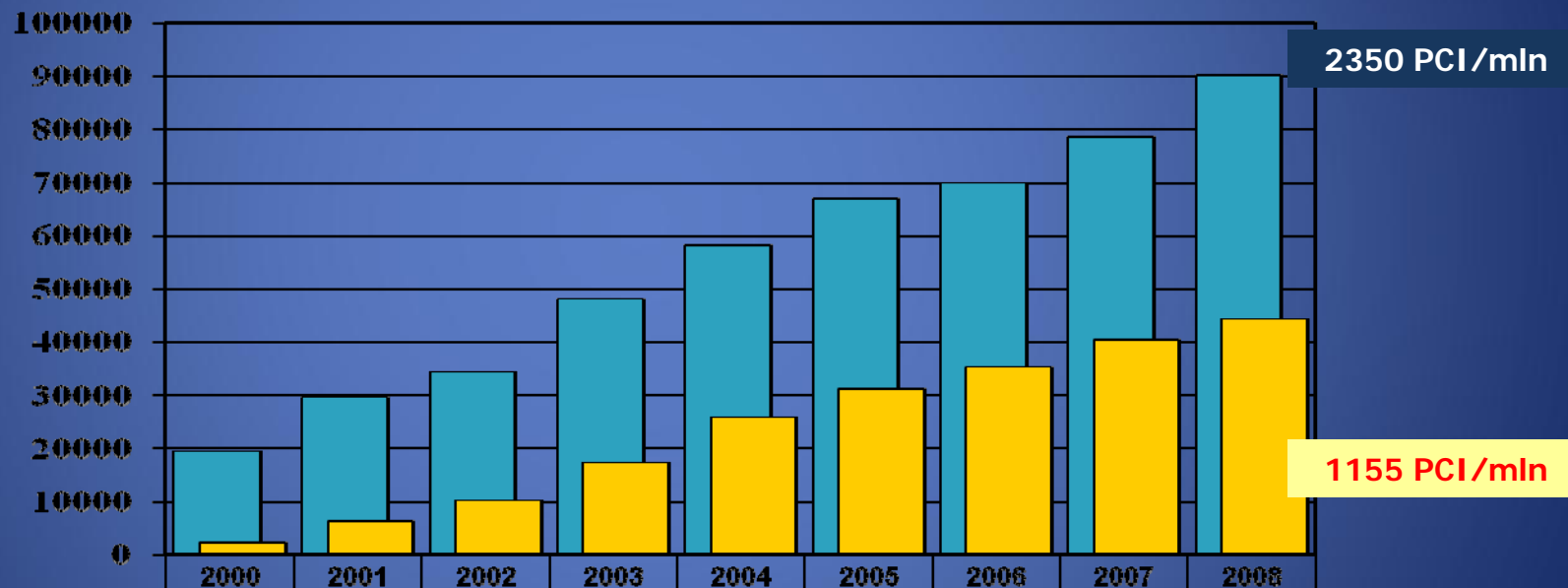
■ centers with 24 h duty
✕ centers without 24 h duty



PCI in Poland 2000-2008

Total PCI / PCI in AMI

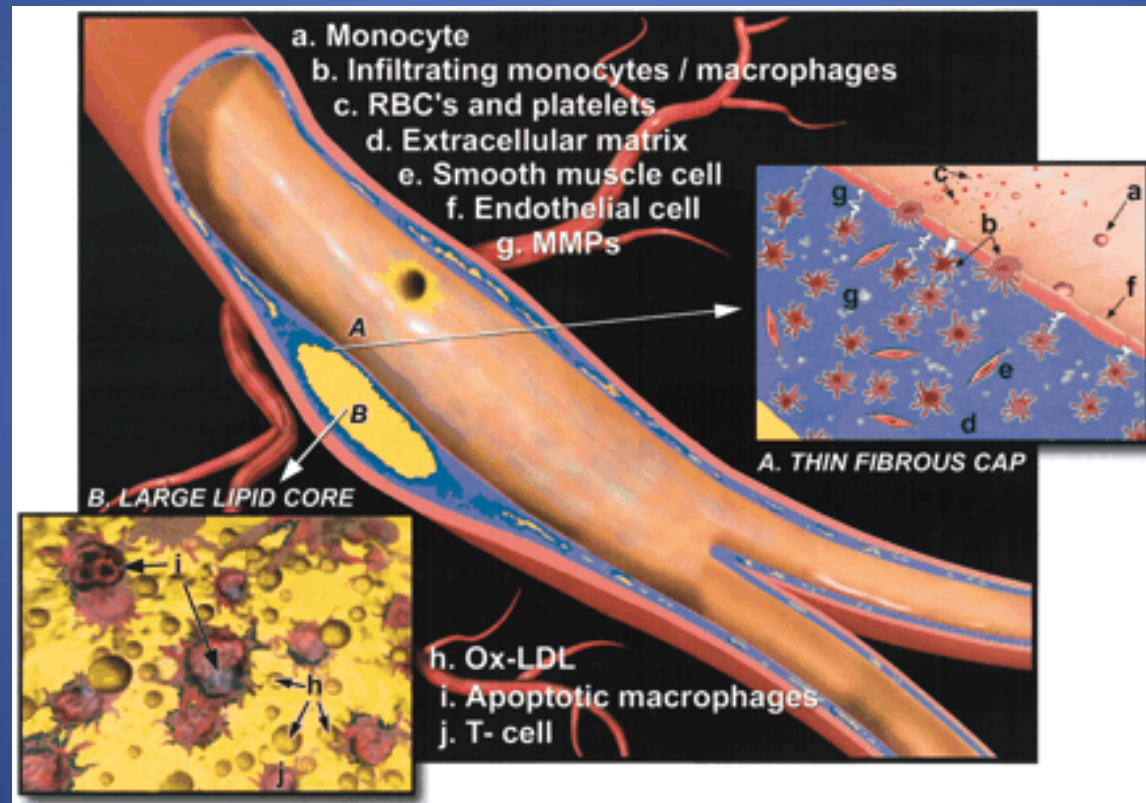
■ Total number of PCI ■ PCI in STEMI+NSTEMI



■ Total number of PCI	19355	29660	34500	48067	58105	66919	69820	78467	90238
■ PCI in STEMI+NSTEMI	2161	6335	10200	17211	25773	31236	35392	40329	44354

Vulnerable plaque

A subset of atherosclerotic plaques particularly prone to physical disruption, producing thrombosis that triggers acute coronary syndromes.



Goals for treatment of vulnerable plaque

- Improvement of the blood flow
- Expanding lumen and reducing percent diameter stenosis
- Mechanical stabilization of the plaque
- Elimination of thrombus/prevention of thrombus formation
- Promoting healing
- Decreasing of necrotic core size
- Minimizing neointima formation
- Decreasing inflammatory reaction

Potential consequences of plaque compression

Potential action:

Fibrous cap rupture

Media fracture

Lipid core compression/disruption

Thrombus disruption

Neointimal formation

Inflammatory reaction

Neovascularization

Less traumatic shape/structure of stents struts

Size of stent cells

Mesh covered stents

Balanced force of the balloon/stent system

(avoid plaque rupture, preserve morphology of the plaque)

Reduced arterial injury

Antiproliferative agents

Reduce injury

Antinflammatory agents

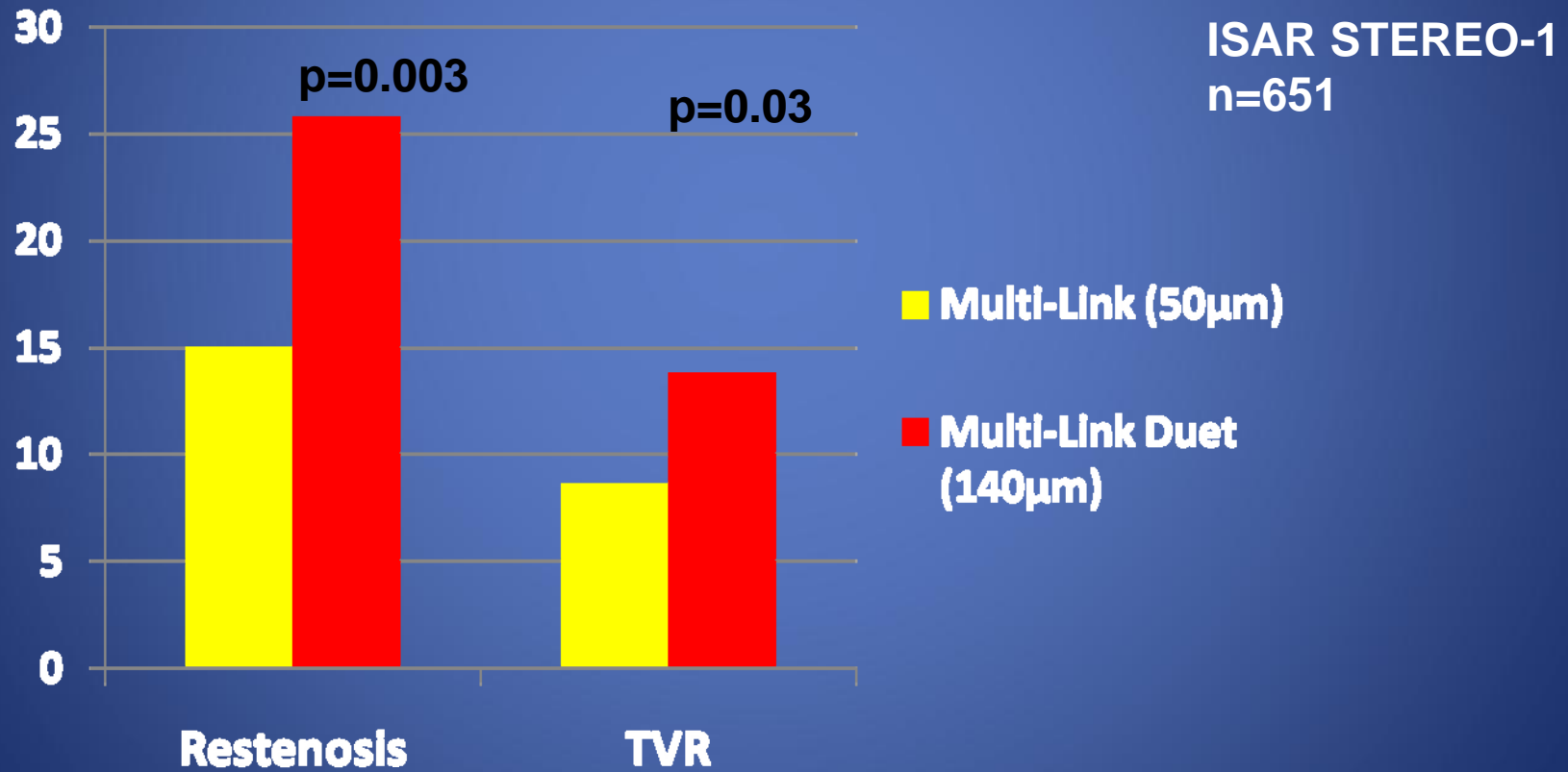
Characteristics of an ideal stent

- Low profile
- Good flexibility
- Low metal : vessel wall area
- Sufficient radial strength
- Adequate radio-opacity
- Inhibits restenosis
- Biocompatible

Cobaltchromiumstents

- Radial strength - cobalt alloy is about 40-50% stronger than stainless steel
- Enhanced visibility
- Allow low profile stents with good flexibility and curveconformity
- Impact on restenosis
- Biocompatibility and safety- cobalt-chromium alloy

Similar strut configuration Different strut thickness Same material



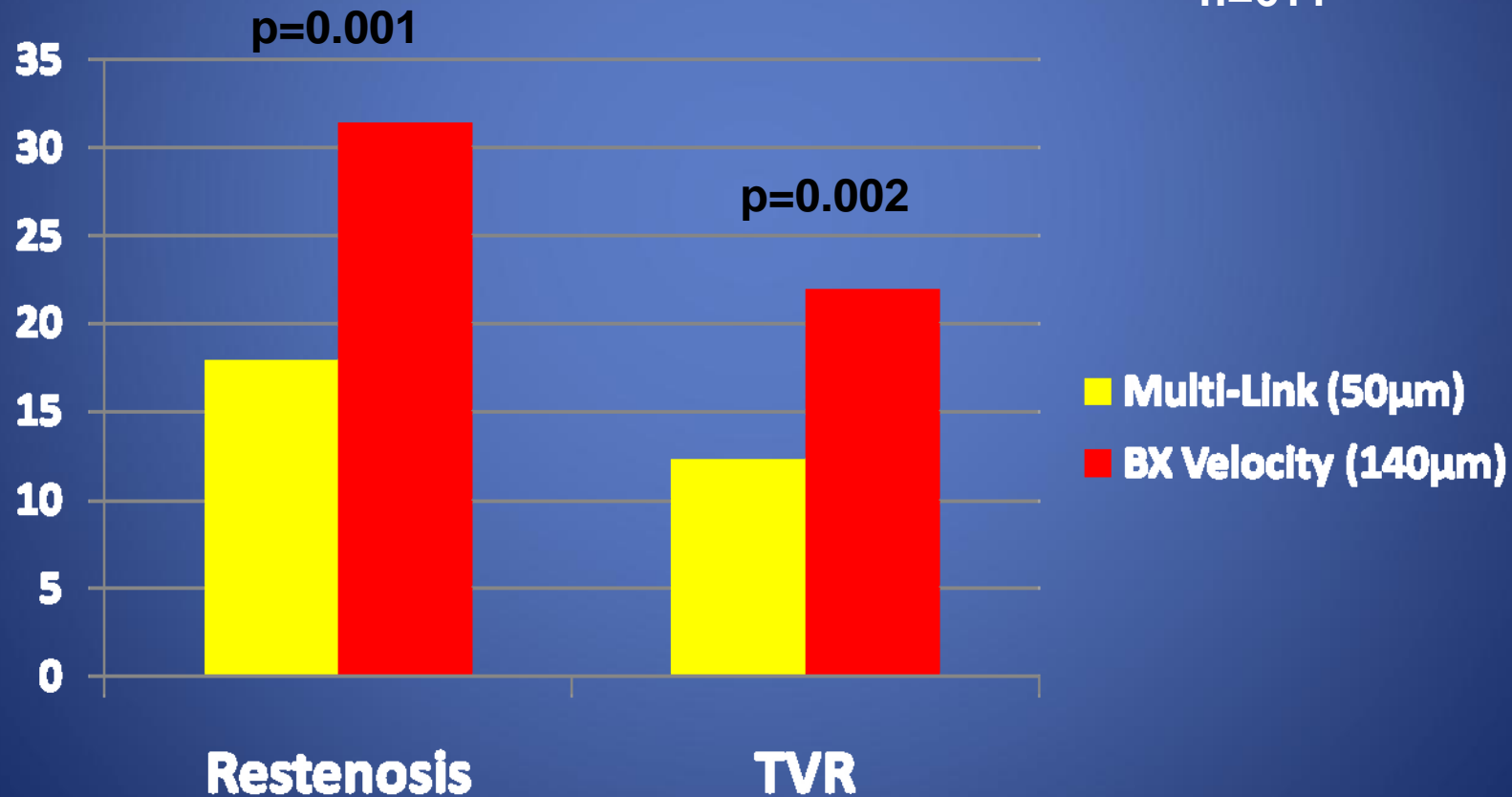
Kastrati et al., Circulation, 2001

Different strut configuration

Different strut thickness

Same material

ISAR STEREO-2
n=611



Pache et al., J Am Coll Cardiol, 2003

Optimal stent deployment

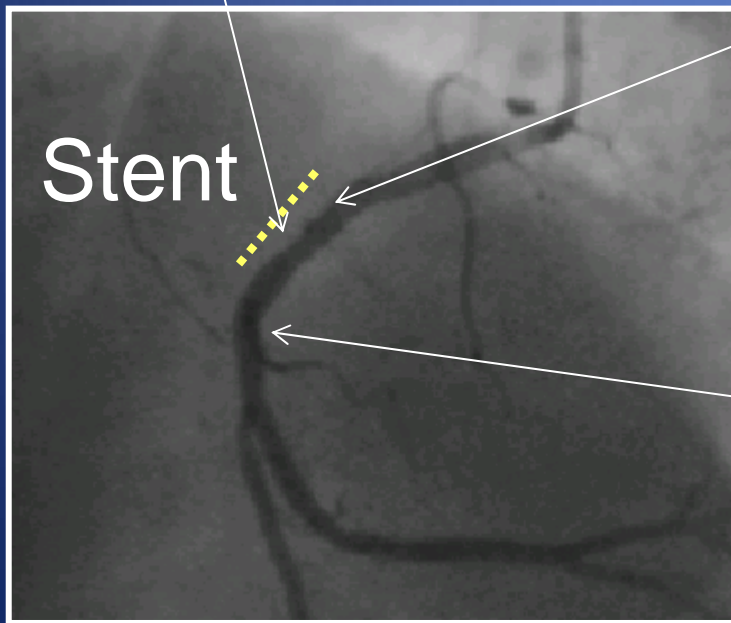
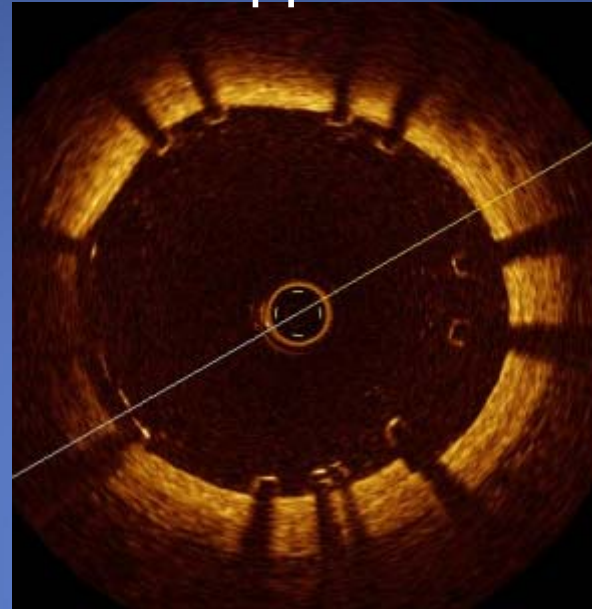
Risk of edge dissection

- Optimization of stent deployment during PCI is a key element to obtain most favorable immediate and long-term results'
- Suboptimal or incomplete stent expansion is associated with increased restenosis and target vessel revascularization rate
- High-pressure balloon dilation is still necessary to improve the PCI result

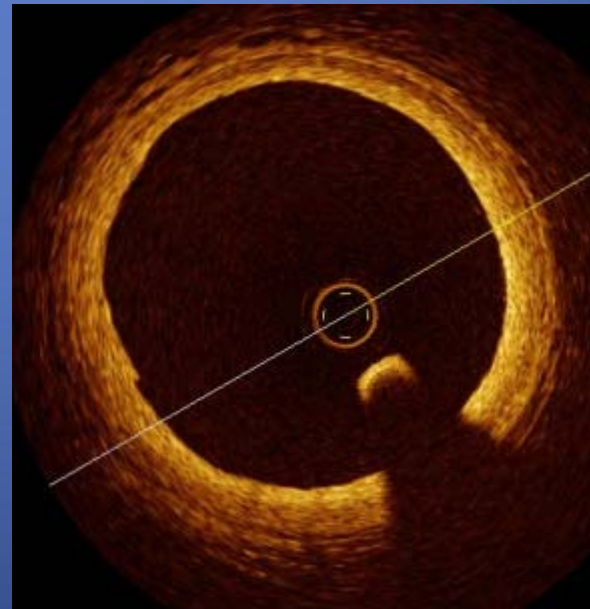
Plaque prolapse



Underexpansion
Malapposition

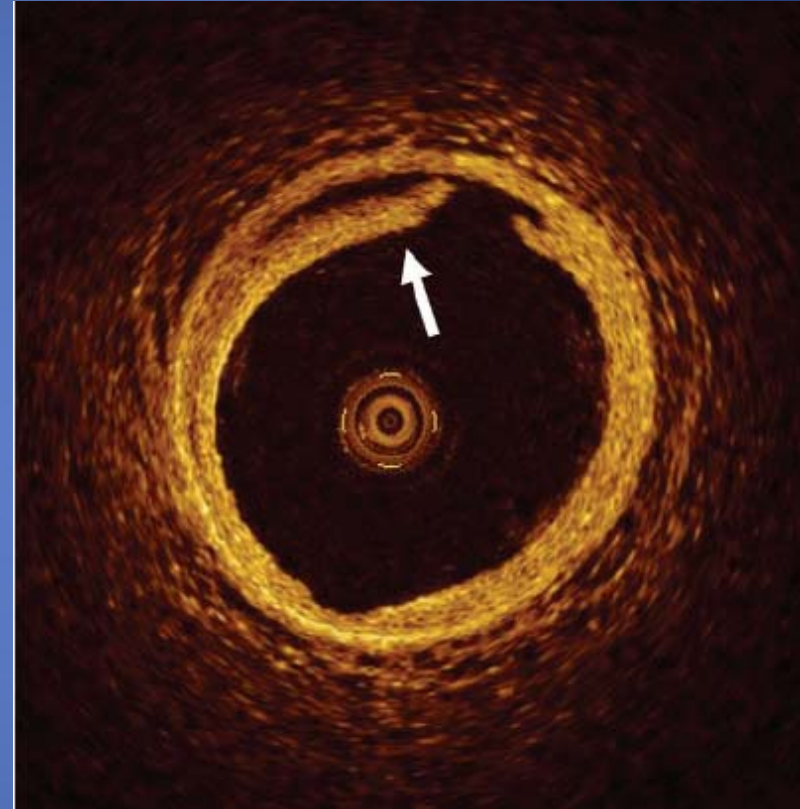
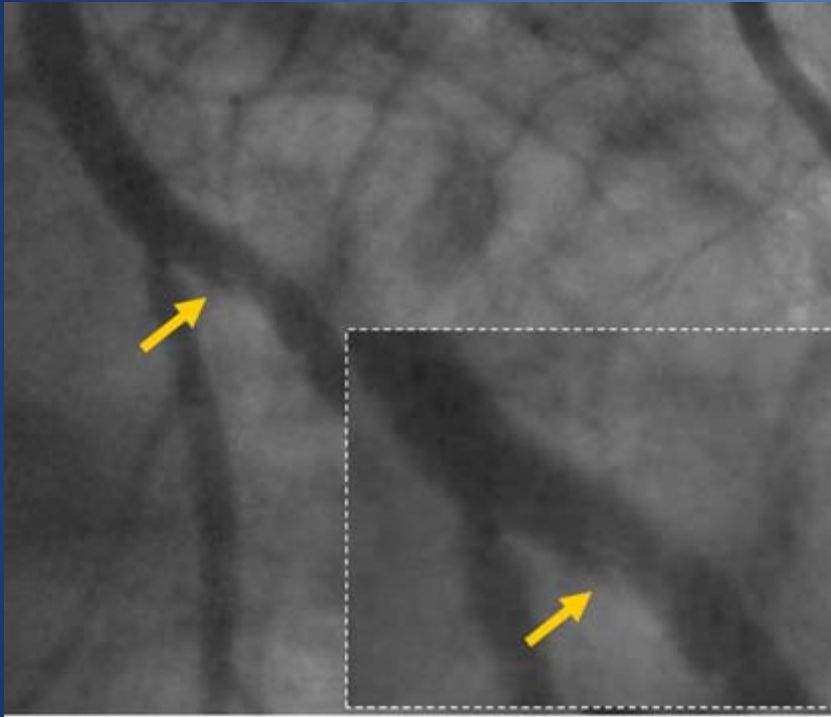


Reference



Edge dissection in OCT

Relation to plaque type



	Fibrous	Fibrocalcific	Fibroatheroma	TCFA	Total
Proximal edge	14 (31.1%)	15 (33.3%)	13 (28.9%)	3 (6.7%)	45
Distal edge	40 (55.6%)	16 (22.2%)	11 (15.3%)	5 (6.9%)	72
Total	54	31	24	8	117

Edge dissection in OCT

Intra-stent dissection

Intra-stent dissection visible, n (%)	70 (87.5)
<i>Intra-stent dissection flap</i>	
Intra-stent dissection flap visible, n (%)	69 (86.3)
Number intra-stent dissection flaps, median (IQR)	3 (1.25–6)
Number intra-stent dissection flaps per mm, median (IQR)	0.10 (0.05–0.22)
Intra-stent dissection flap average length (μm), mean (SD)	300 (130)
Intra-stent dissection flap maximum length (μm), mean (SD)	450 (220)
<i>Intra-stent dissection cavity</i>	
Intra-stent dissection cavity visible, n (%)	55 (68.8)
Number cavities, median (IQR)	2 (0–4.75)
Number cavities per mm, median (IQR)	0.07 (0–0.16)
Maximum depth cavity (μm), mean (SD)	340 (170)
Edge dissection	
Edge dissection visible, n (%)	20/76 (26.3)
Length edge dissection flap, mean (SD)	744 (439)

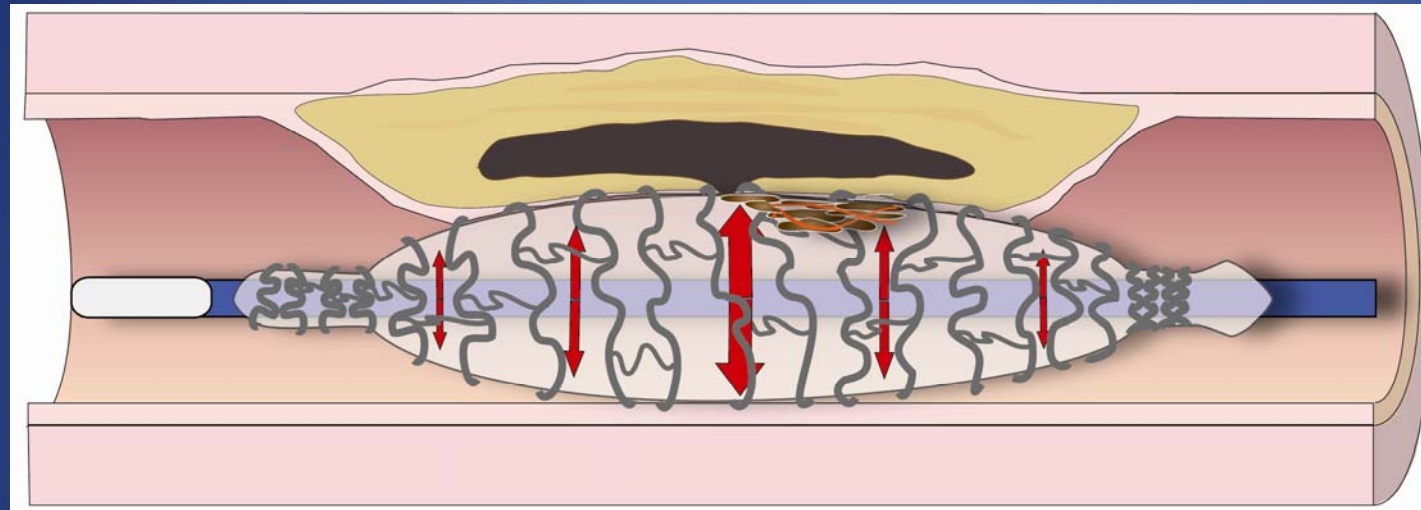
Edge dissection in OCT

Stable vs. unstable patients

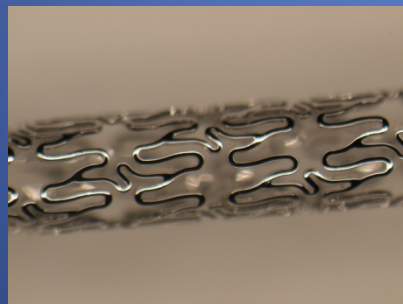
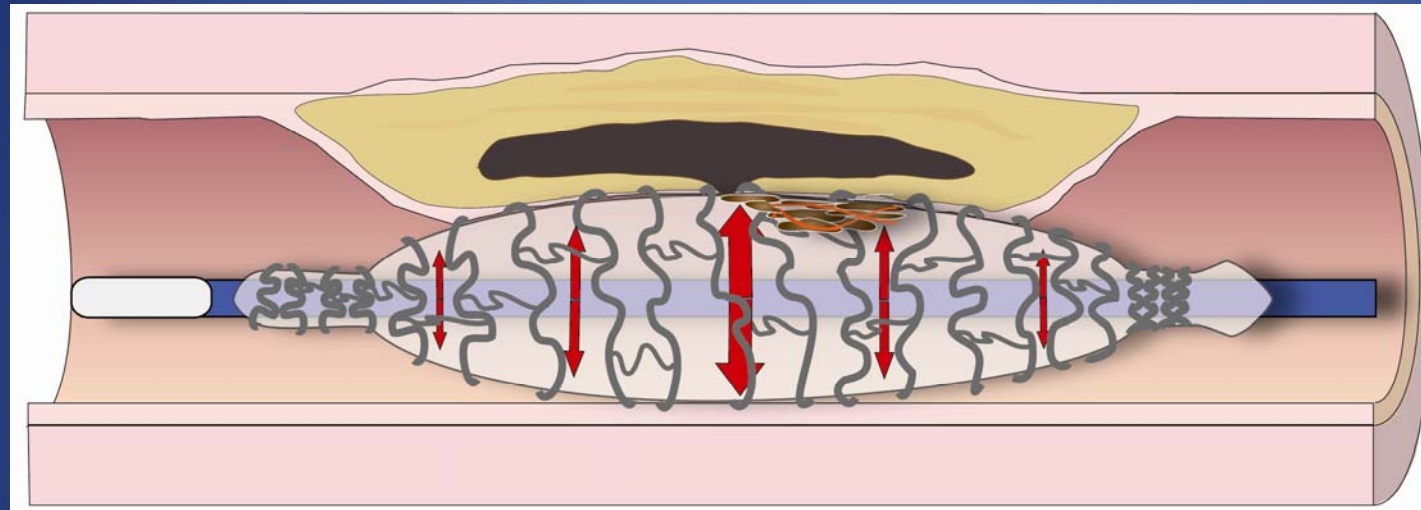
Intra-stent dissection			
Intra-stent dissection visible, n (%)	41/45 (91.1)	29/35 (82.9)	0.3
<i>Intra-stent dissection flap</i>			
Intra-stent dissection flap visible, n (%)	39/45 (86.7)	30/35 (85.7)	0.9
Number of intra-stent dissection flaps, median (IQR)	3 (2–7)	3 (1–4)	0.3
Number of intra-stent dissection flaps per mm, median (IQR)	0.12 (0.05–0.25)	0.12 (0.04–0.18)	0.3
Intra-stent dissection flap average length (μm), mean (SD)	297 (134)	289 (120)	0.8
Intra-stent dissection flap maximum length (μm), mean (SD)	488 (238)	419 (197)	0.1
<i>Intra-stent dissection cavity</i>			
Intra-stent dissection cavity visible, n (%)	32/45 (71.1)	23/35 (65.7)	0.6
Number cavities, median (IQR)	2 (0–4.5)	1 (0–5)	0.6
Number cavities per mm, median (IQR)	0.07 (0–0.15)	0.04 (0–0.17)	0.8
Maximum depth cavity (μm), mean (SD)	336 (183)	357 (150)	0.6
Edge dissection			
Edge dissection visible, n (%)	9/42 (21.4)	11/34 (32.3)	0.3
Edge dissection length (μm), mean (SD)	860 (579)	650 (277)	0.3

Prevention of edgedissection

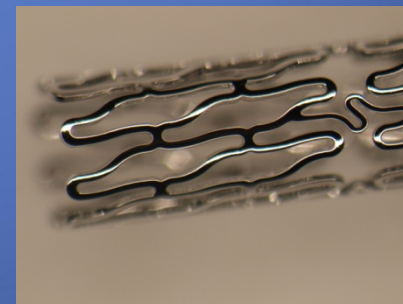
Stagedexpansion



Prevention of edgedissection Stagedexpansion (NexGen)



Open cell in mid segment

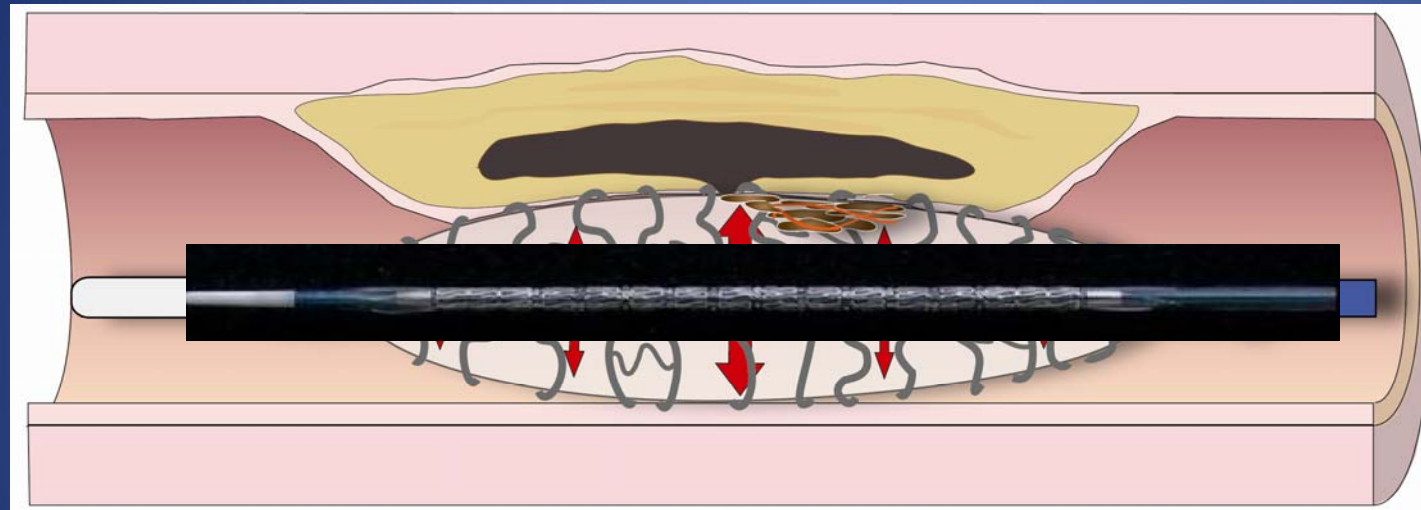


Close cell at edges

Hybrid design

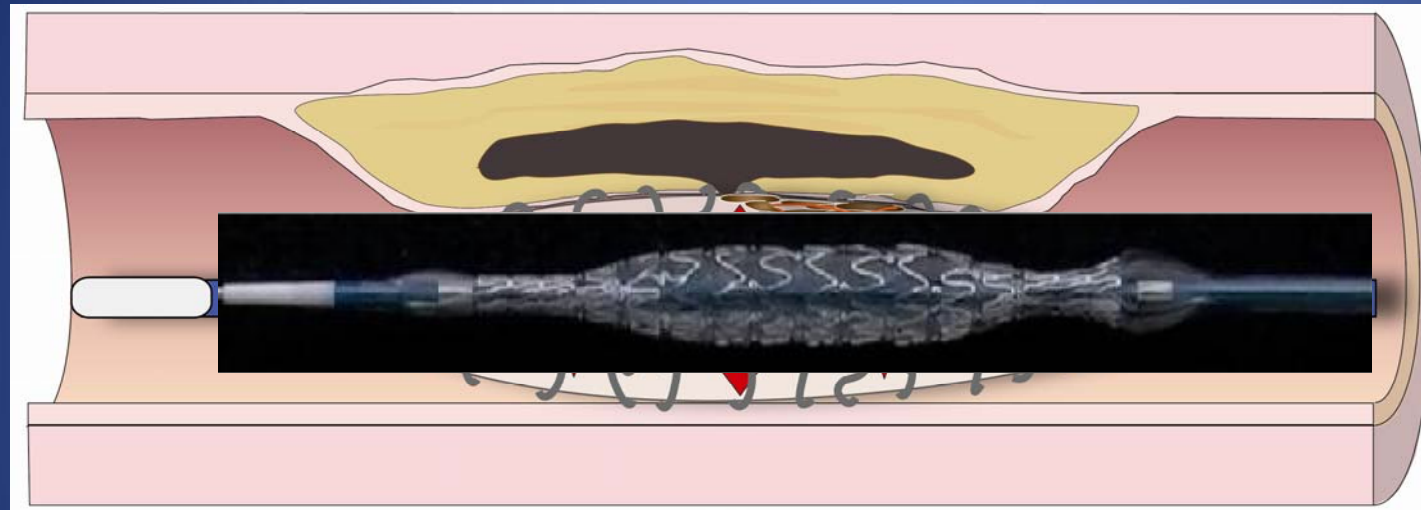
Prevention of edgedissection

Stagedexpansion



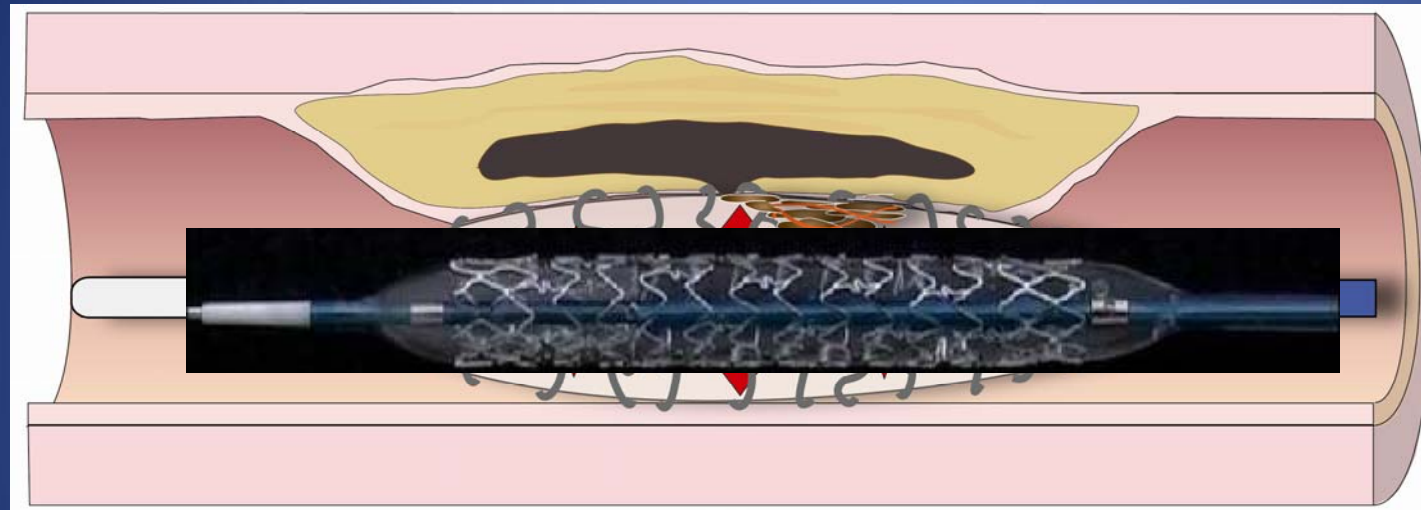
Prevention of edgedissection

Stagedexpansion



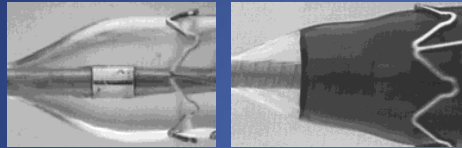
Prevention of edgedissection

Stagedexpansion

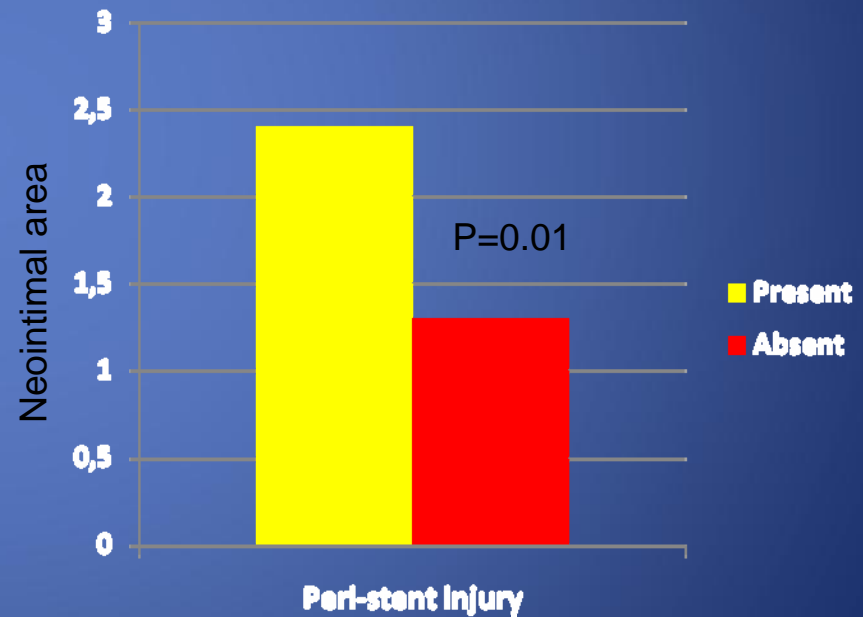
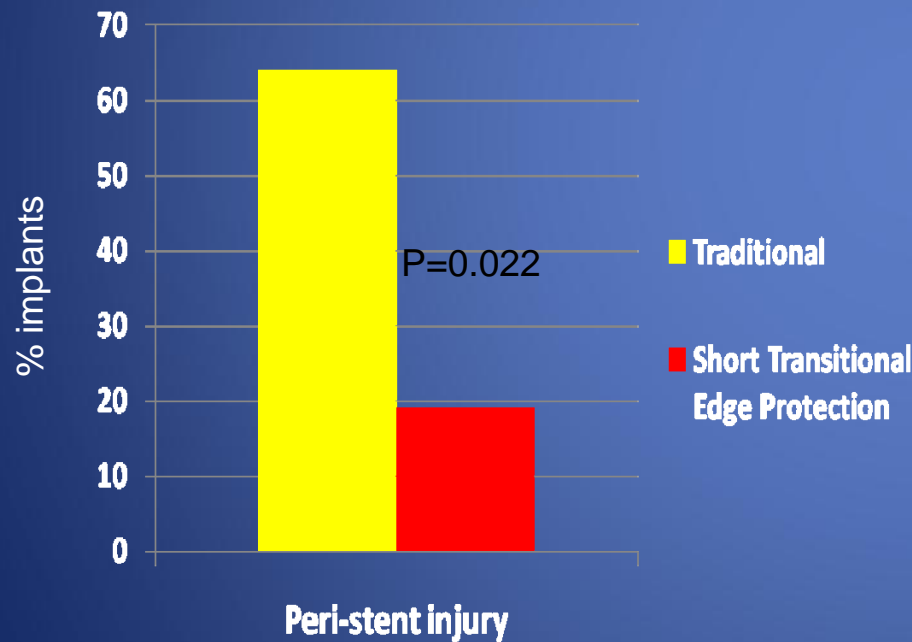


Balloon – related vessel injury

Relation to neointima growth



In-stent vessel injury scores
 1.0 ± 0.3 vs. 1.0 ± 0.03 , $P=0.73$

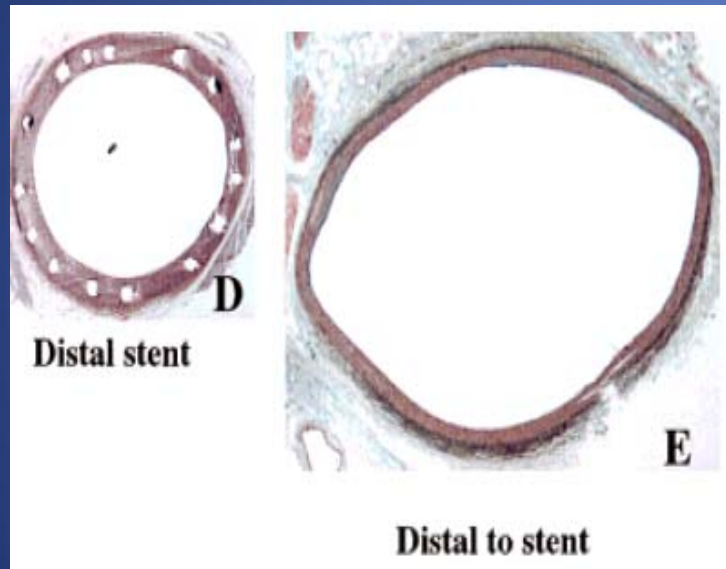


In-stent neointimal hyperplasia and % stenosis
vs. severity of peri-stent injury ($r=0.47$, $P=0.04$)

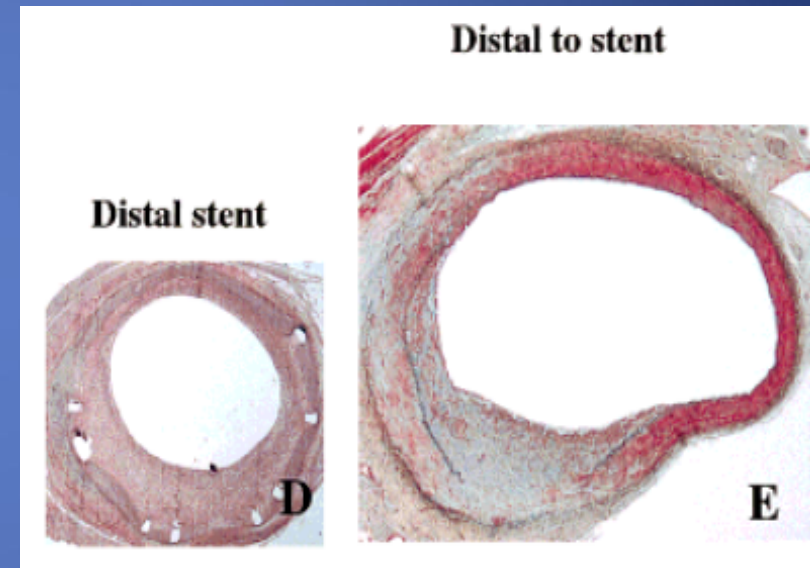
Balloon – related vessel injury

Relation to neointima growth

short transitional
edge protection balloon

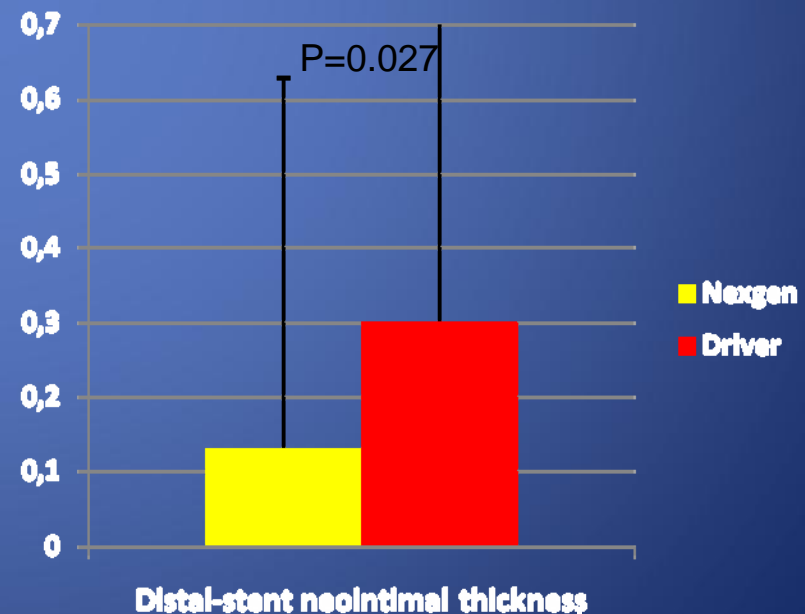
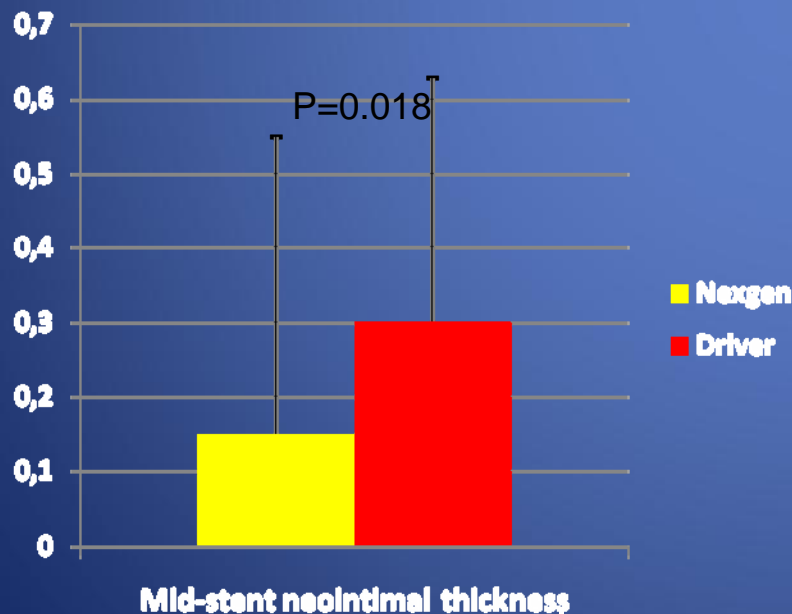
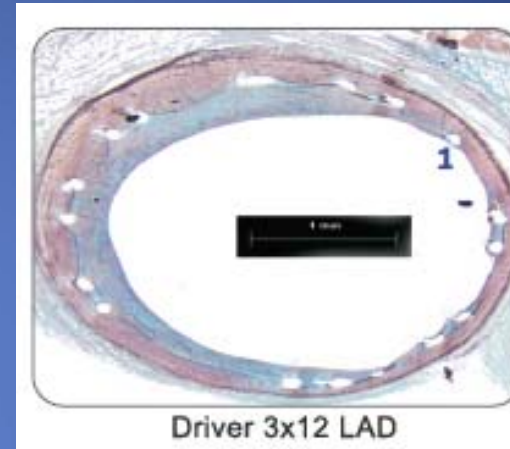
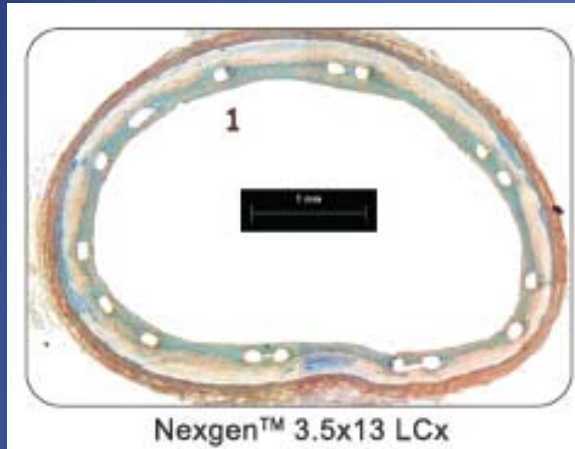


conventional
balloon



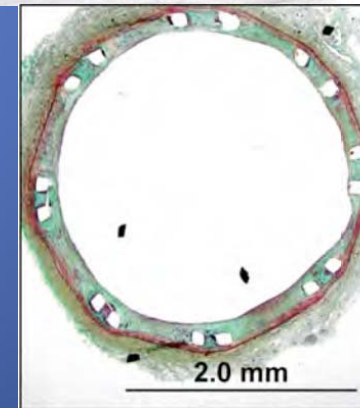
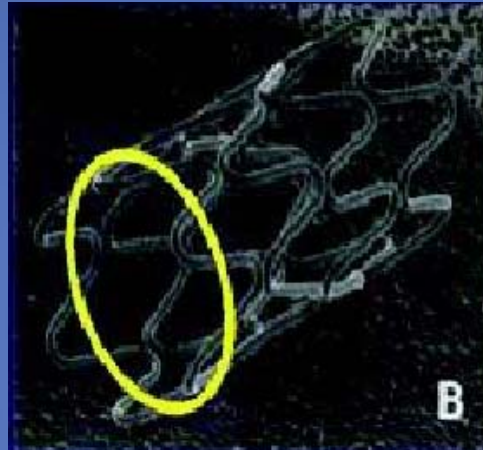
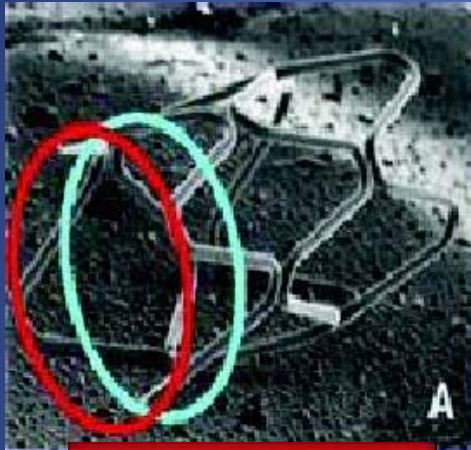
NexGenvs. Driver in porcine coronary arteries

28-Day comparison



Prevention of edgedissection Vesselwall support at the stented edge

More Cells per Diameter



Data on file

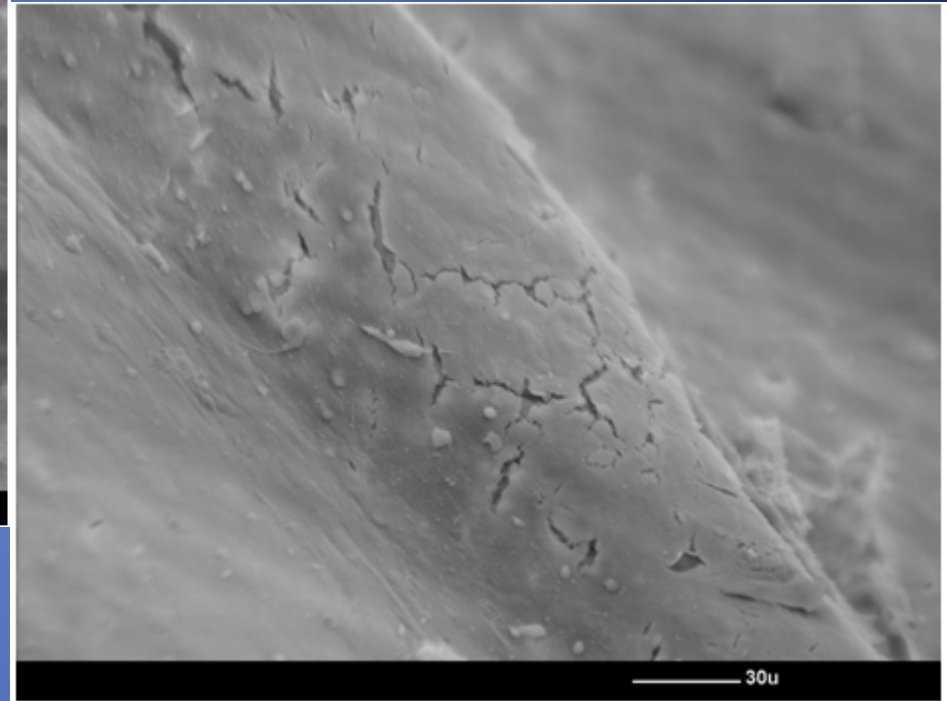
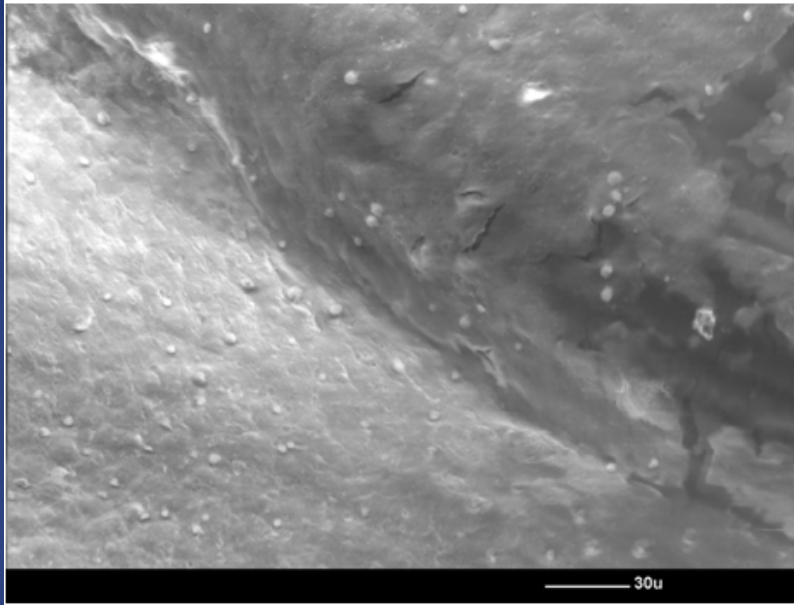
Impaired endothelialization

Most common location of uncovered stent struts:

- Middle section
- Stent overlap
- Penetration into the necrotic core of plaques
- Malapposition,
- Bifurcations
- Hypersensitivity reactions

Endothelialization of NexGen

7-day SEM



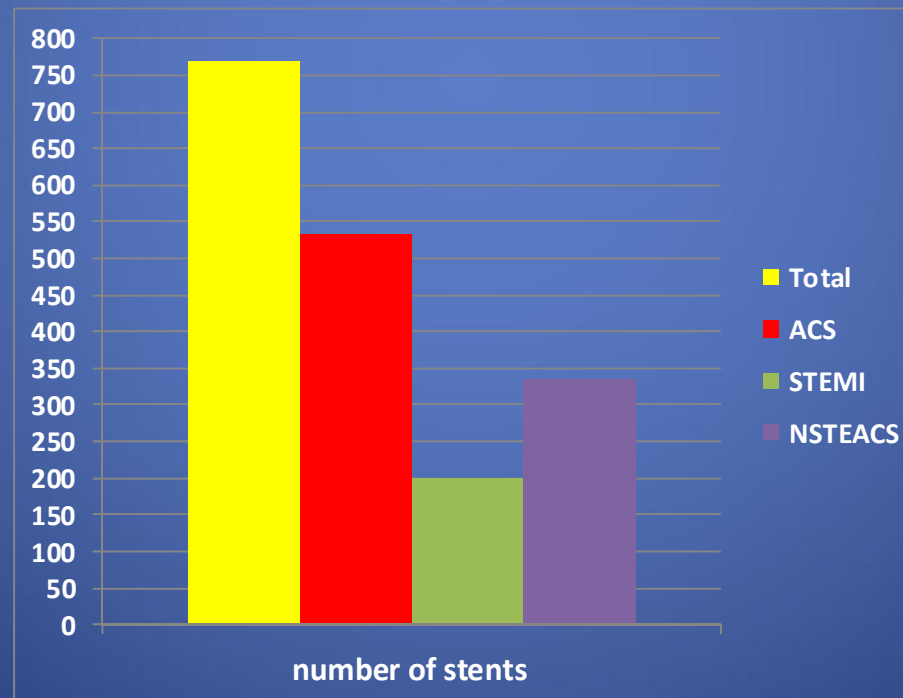
NexGen 3x13. LCx

Data on file

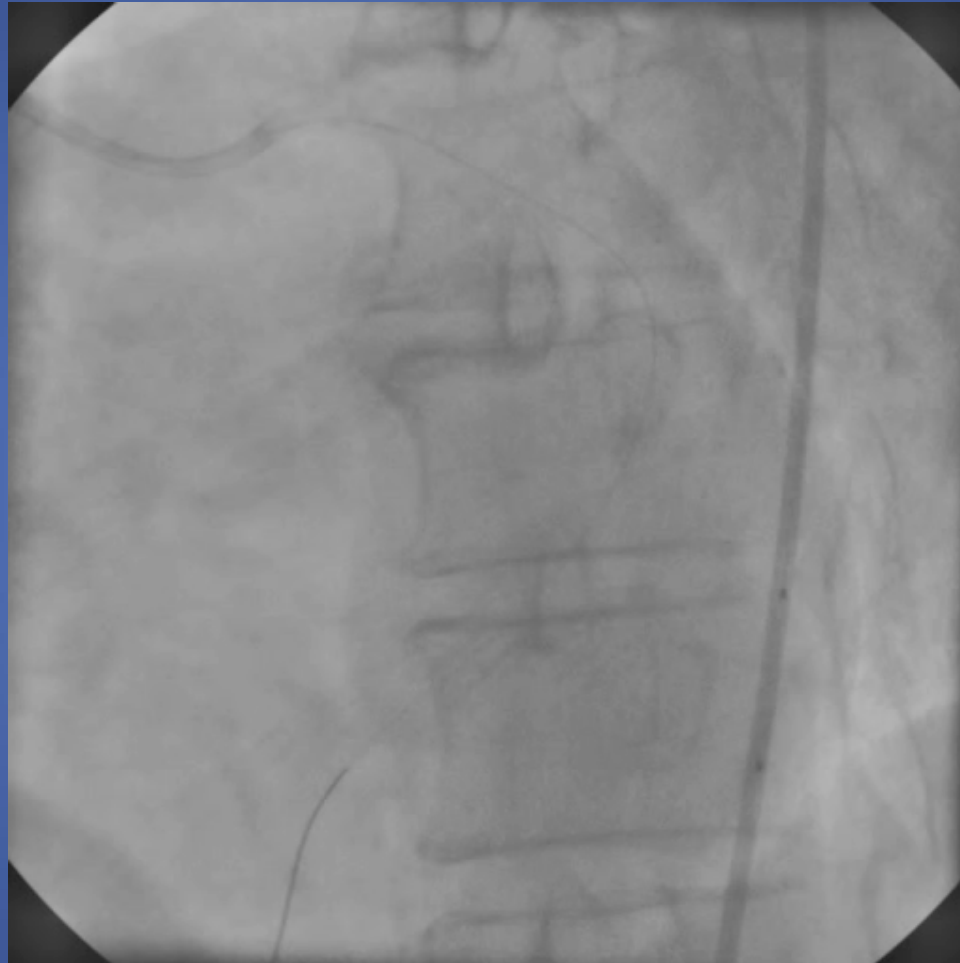
NexgenPolishexperience

American Heart of Poland, 10 cathlabs

- Total 770 NexGenstents
- 535 pts with ACS (201 STEMI, 334 NSTEMI-ACS)
- 100% procedural success, no in-hospital death
- No cases of stentthrombosisuptp 6 months
- Prospective registry of NexGen in progress



Final angio



- After thrombectomy and stenting:
LAO/Caudal

NexGen

Experiencemainlyinacute coronary syndromes

- Good deliverability
- No dissections
- No stent thrombosis