

A New Stent Design for the Treatment of True Bifurcation Lesions: H-Side Branch Stents

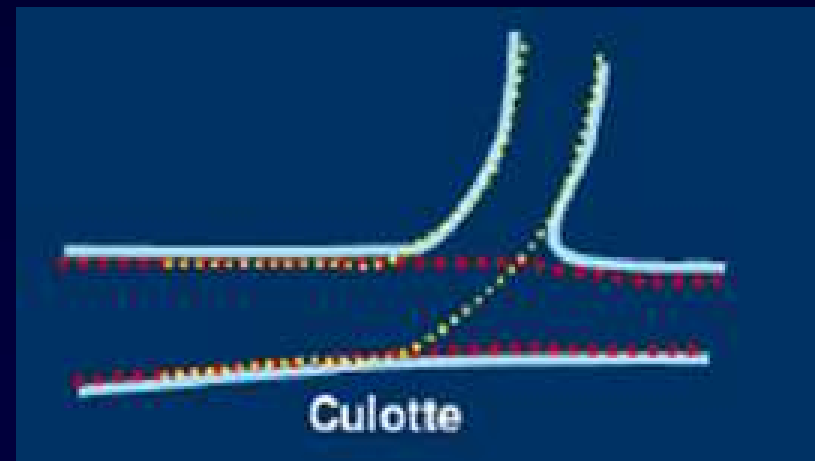
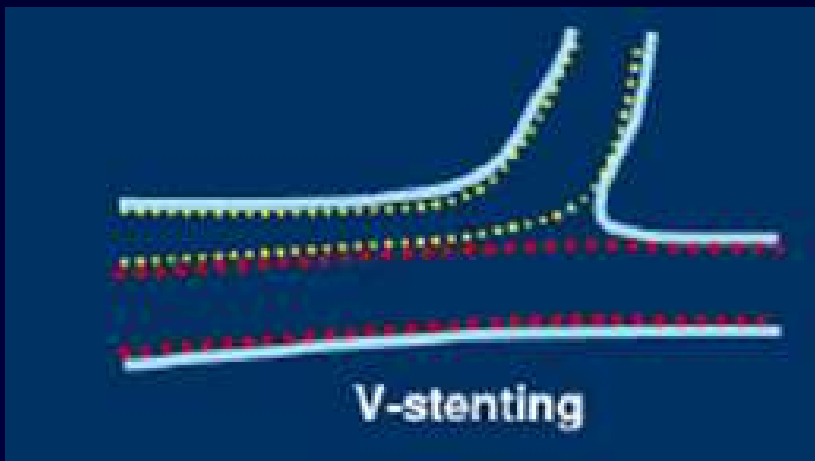
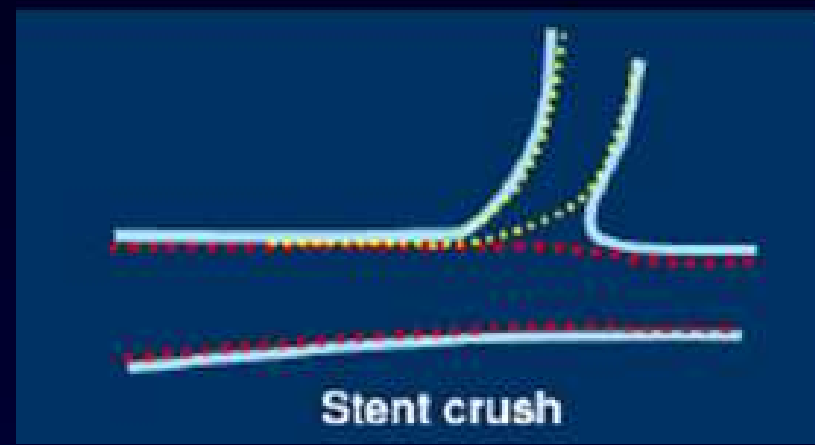
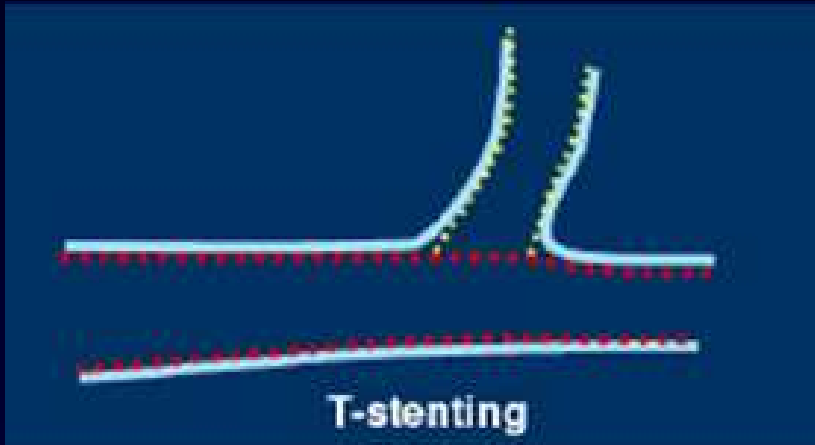
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J Interven Cardiol 2010;23:54-59

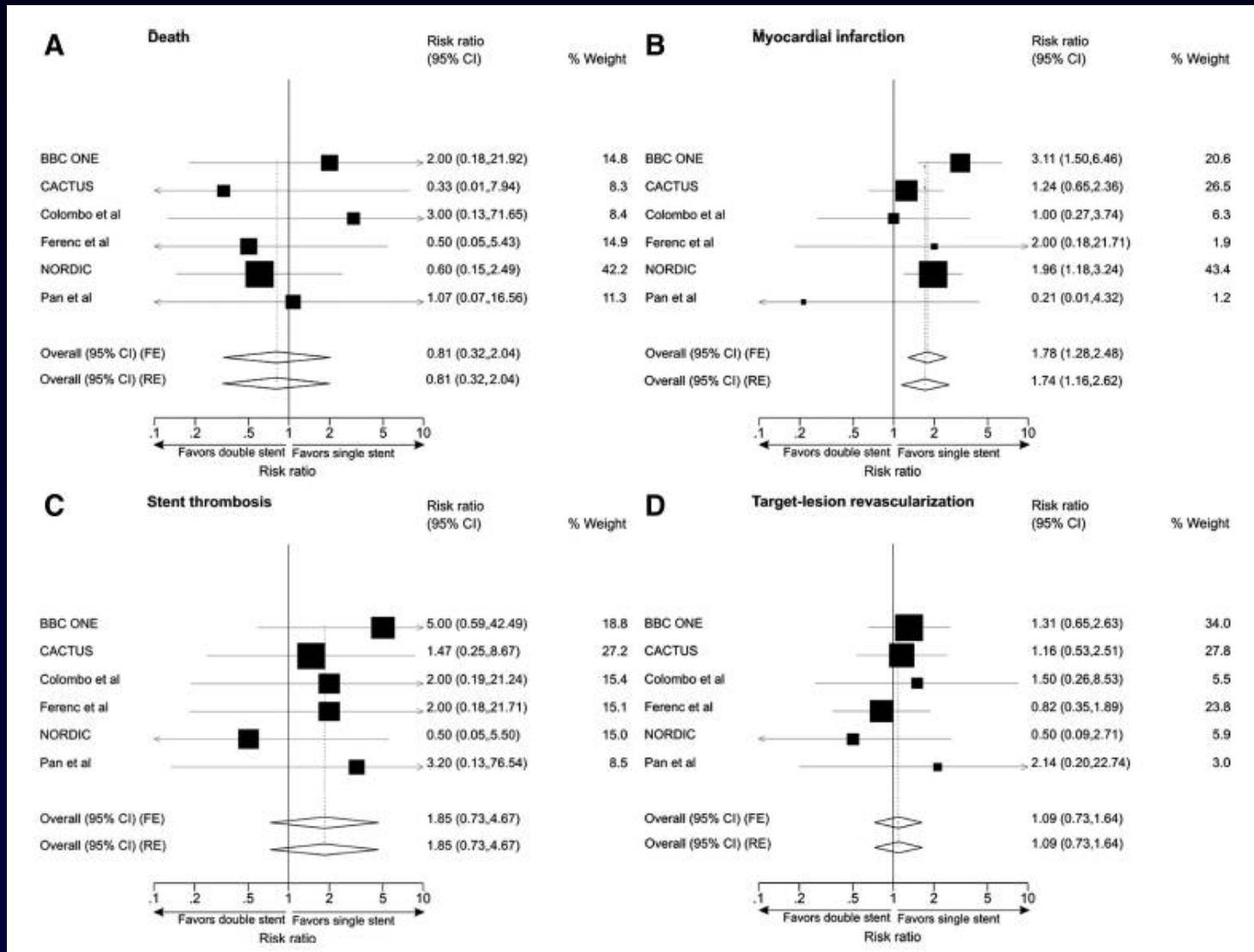
Several 2-stents techniques for bifurcation lesions in DES era



PCI for bifurcation Lesions

- Technically challenging and historically related with lower procedural success rates and worse clinical outcomes (Latib A, et al. *Heart* 2009; 95:495–504)
- No improvement in the restenosis rate in the side branch vessel despite a significant reduction of restenosis rate in the main vessel (Colombo A, et al. *Circulation*. 2009; 119:71–8. and Ferenc M, et al. *Eur Heart J*. 2008; 29:2859–67.)
 - the reported restenosis rate is still as high as 15-25% in the side branch vessel; predominantly ostium. (Hoyer A, et al. *J Am Coll Cardiol*. 2006; 47:1949–58. Moussa I, et al. *Am J Cardiol*. 2006; 97:1317–21).
- Additionally, regarded as an independent predictor for occurrence of **stent thrombosis** (Iakovou I, et al. *JAMA*. 2005; 293:2126–30 and Kuchulakanti PK, et al. *Circulation*. 2006; 113:1108–13).

Double vs. Single stenting (meta-analysis)



Katritsis DG et al. Circ Cardiovasc Intervent 2009;2:409-415

Double vs. Single stenting (meta-analysis)

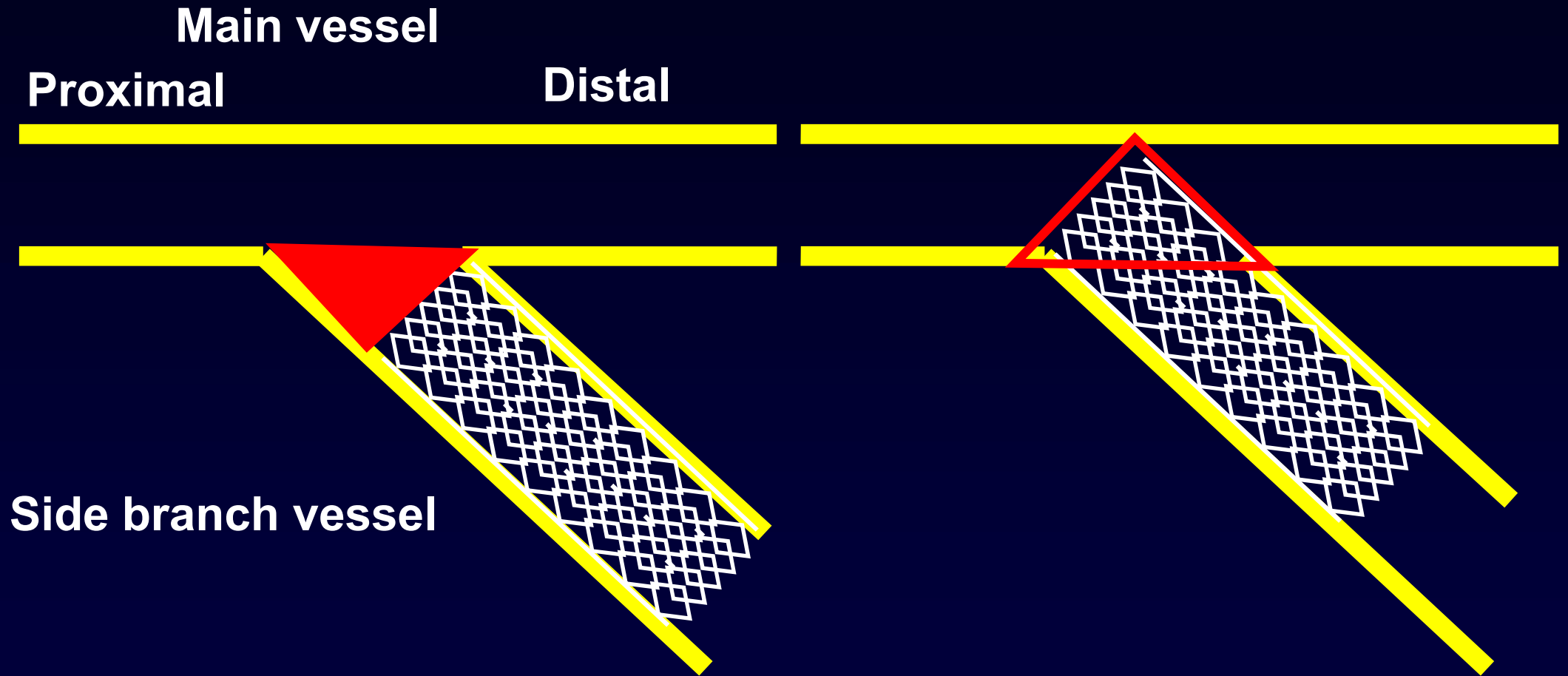
Study	No. Pts (simple vs. complex)	True bifurcation	Cross-over to complex strategy	Post-IVUS
CACTUS	350 (173:177)	94%	54 (31%)	2-4%
Colombo et al	86 (43:43)	ND	22 (51%)	All
Ferenc et al	202 (101: 101)	68%	19 (19%)	ND
Nordic	413 (207: 206)	ND	9 (4%)	ND
Pan et al	91 (47: 44)	86%	1 (2%)	ND

Objective

Hypothesis: Because the improvement of clinical outcomes may not be expected with tubular shape of the current stent platform, special stent platforms for the treatment of the ostium of the side branch vessel are required.

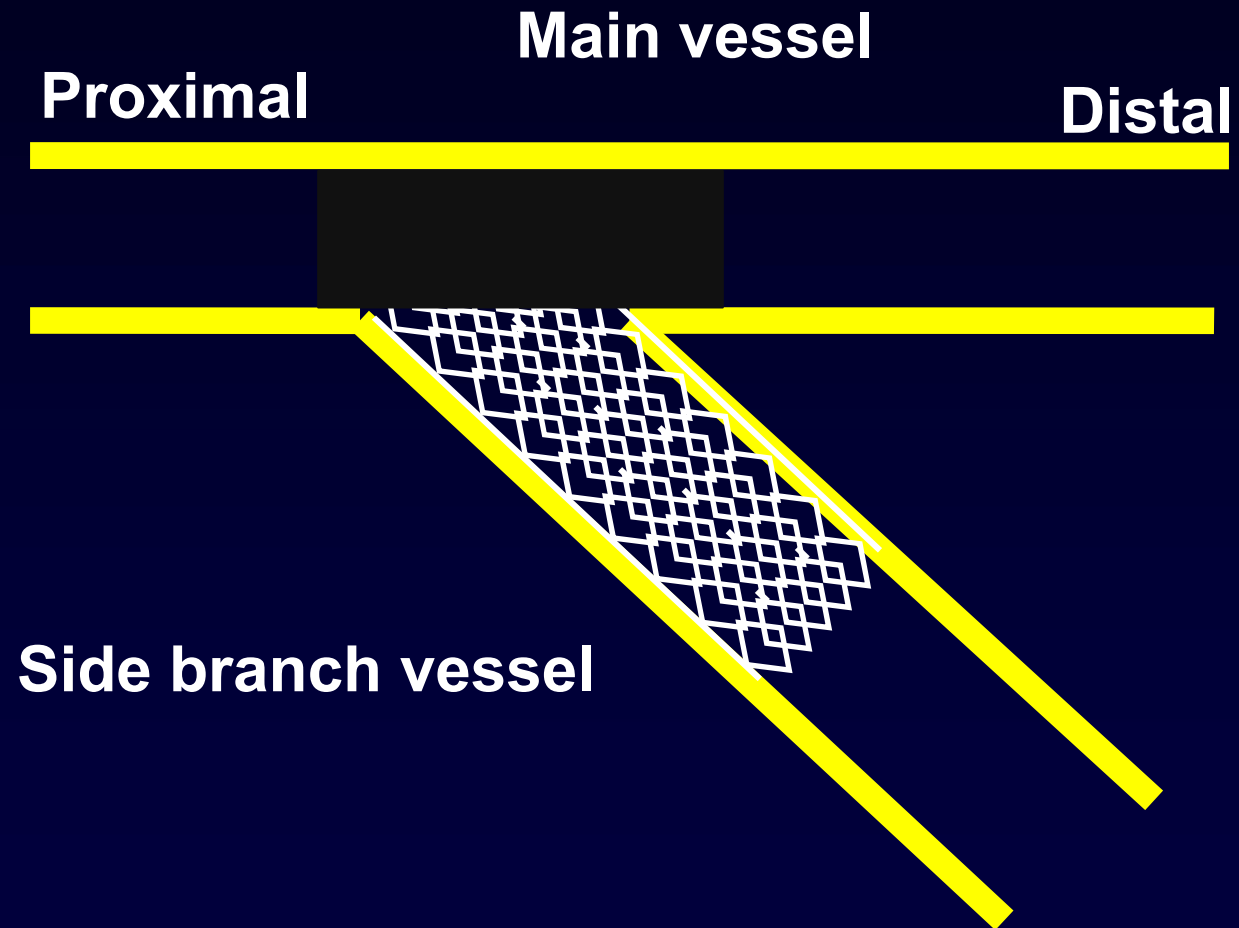
Objectives: Special stent platform for the treatment of the side branch vessel in true bifurcation lesions is introduced and its immediate results are tested in this study.

Problems of current stent platform in bifurcation

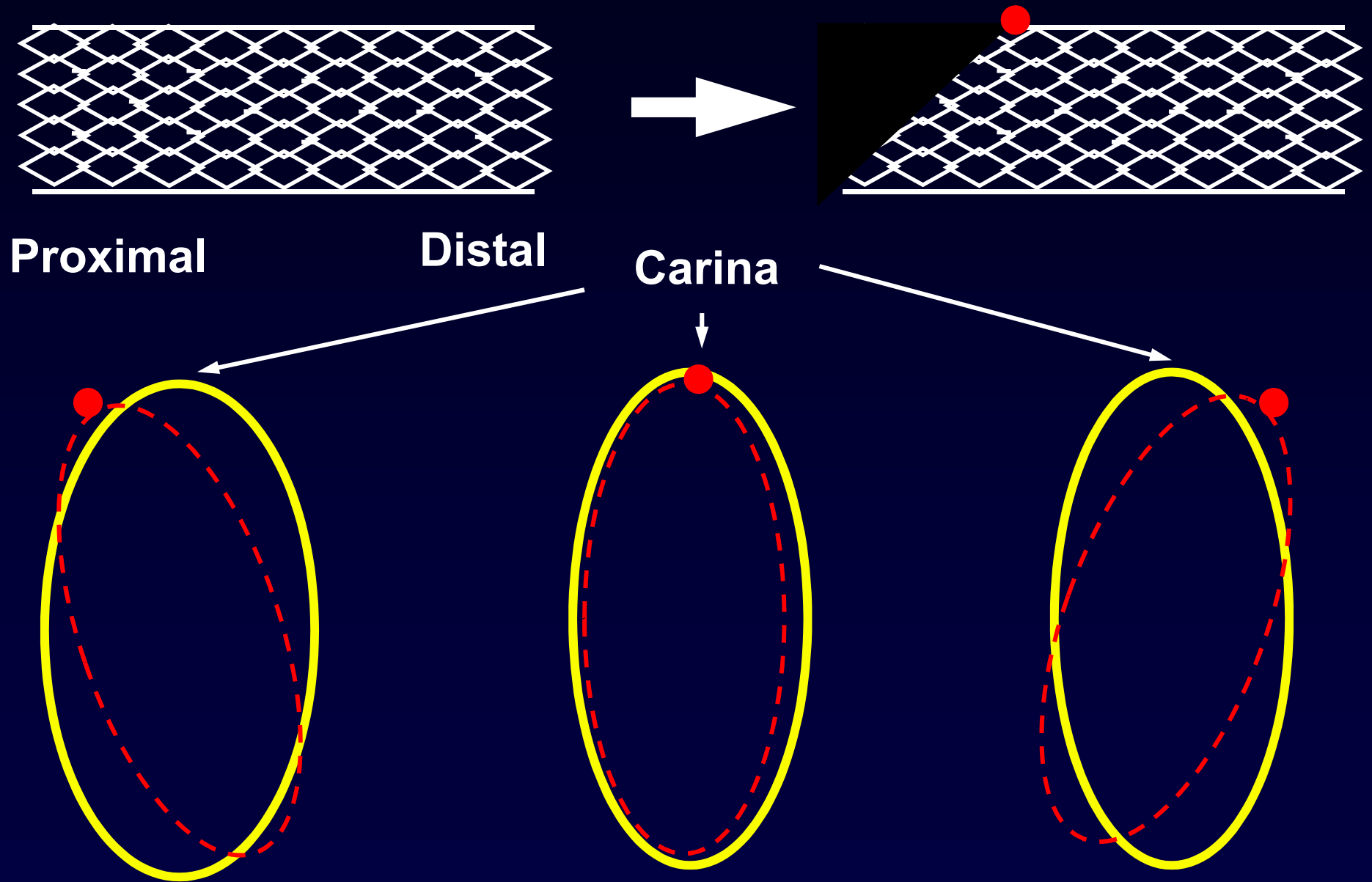


For coverage of side branch ostium

Ideal side-branch stent platform

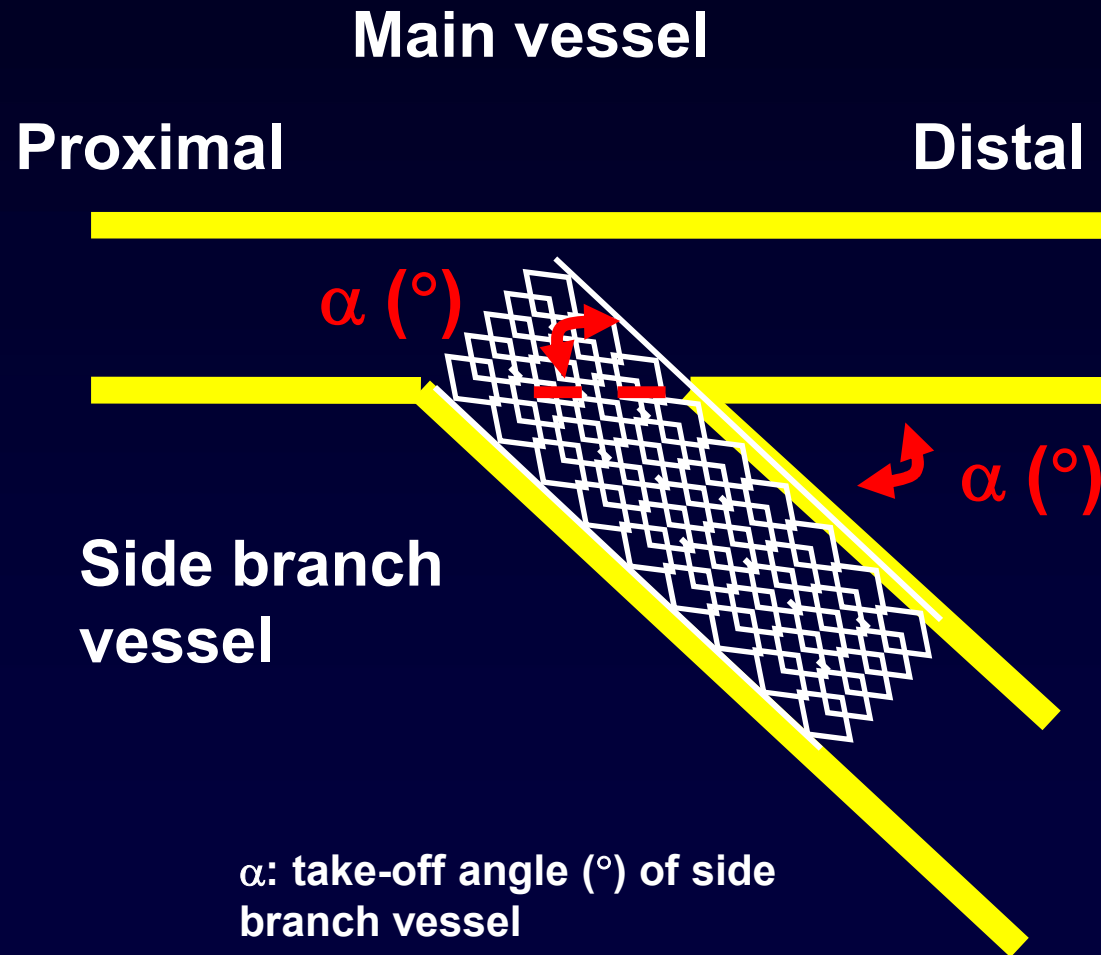


Tests in phantom model

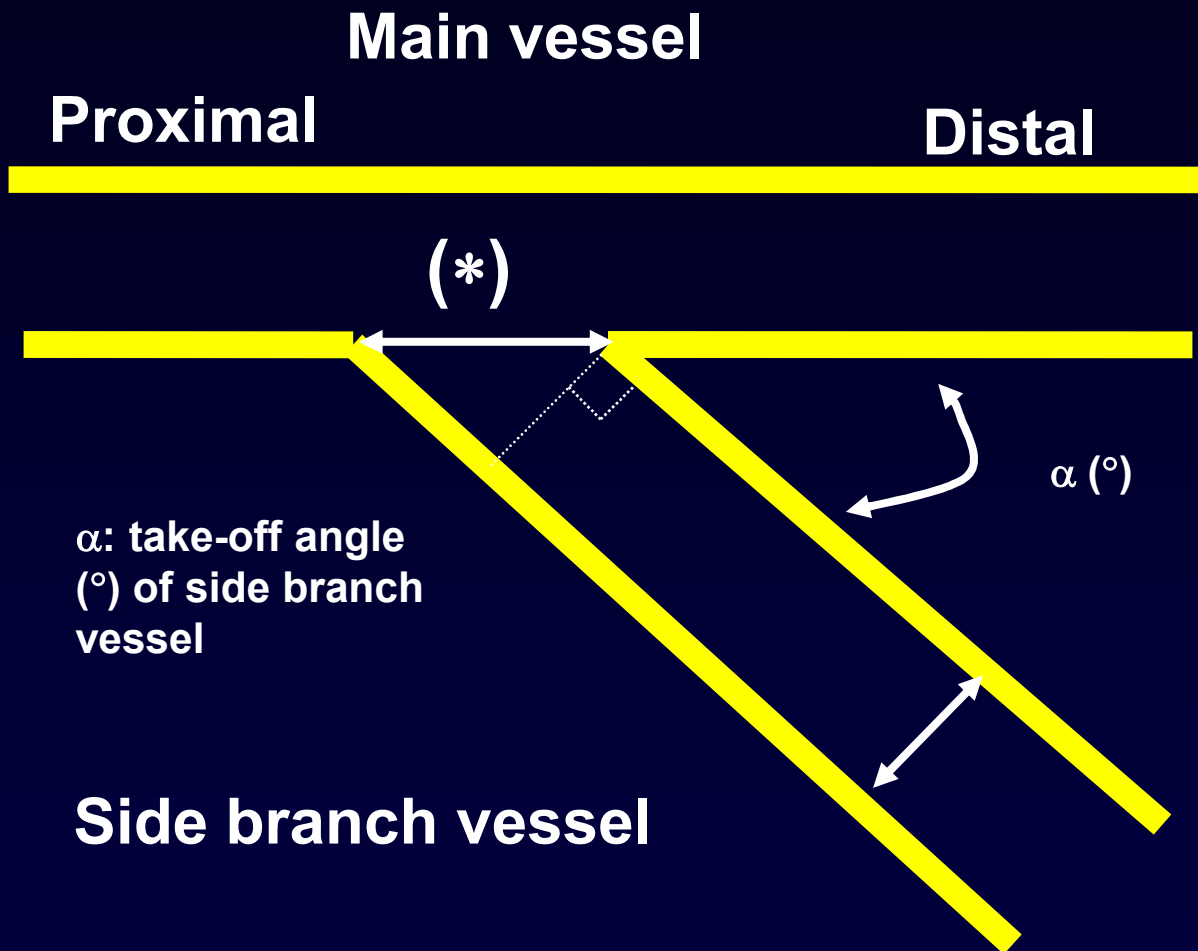


Coverage for side branch ostium

The take-off angle (α) is same as the slope-side margin by an indentation in the distal part.



Length of side branch ostium using the Pythagoras' law



Using the Pythagoras' law in 3 different types of take-off angle (30° , 45° and 60°), the diameter (*) of side branch ostium can be mathematically calculated with the diameter and take-off angle of side branch vessel.

Length of side branch ostium

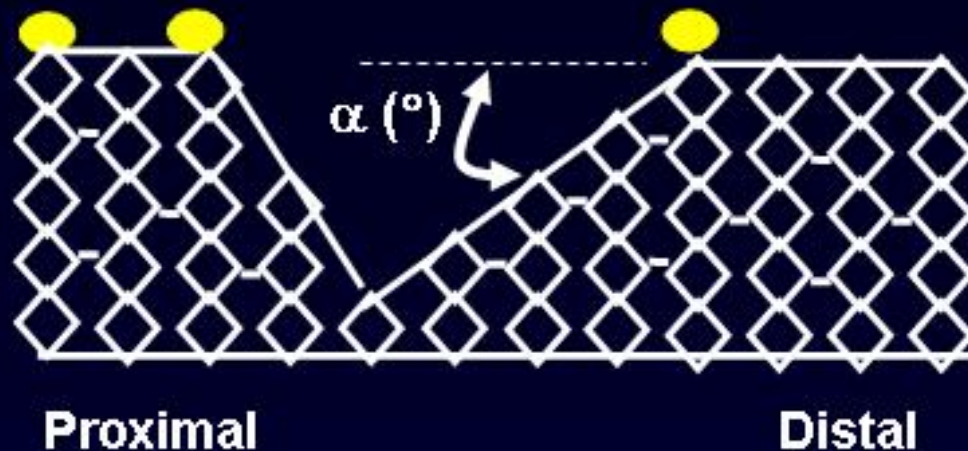
- Determination of the length of slope-sided margin in side branch stent is important in clinical practice for complete scaffolding of side branch ostium. However, the diameter of side branch ostium is always variable. Therefore, adequate selection for precise length of slope-sided margin in side branch stent to cover the ostium completely is very difficult in every bifurcation lesions in daily clinical practice.
- To simplify the bifurcation lesions, they may be divided into 3 types according to take-off angle (α) of side branch vessel from main vessel; $\alpha=30^\circ$, 45° and 60° .
- For examples, in treatment of bifurcation lesions with take-off angle of 32° and 56° will be adequately treated with side branch stent which is suitable for 30° and 60° take-off angle, respectively.

Length of side branch ostium using the Pythagoras' law

Calculated diameter (mm) of side branch ostium according to diameter and take-off angle of side branch

Diameter of side branch (mm)	Take-off angle of side branch (α°)		
	$\alpha=30^\circ$	$\alpha=45^\circ$	$\alpha=60^\circ$
2.5	5.0	3.535	2.887
3.0	6.0	4.242	3.464
3.5	7.0	4.949	4.042
4.0	8.0	5.656	4.619

Stent design (nominated as H-side branch stent)

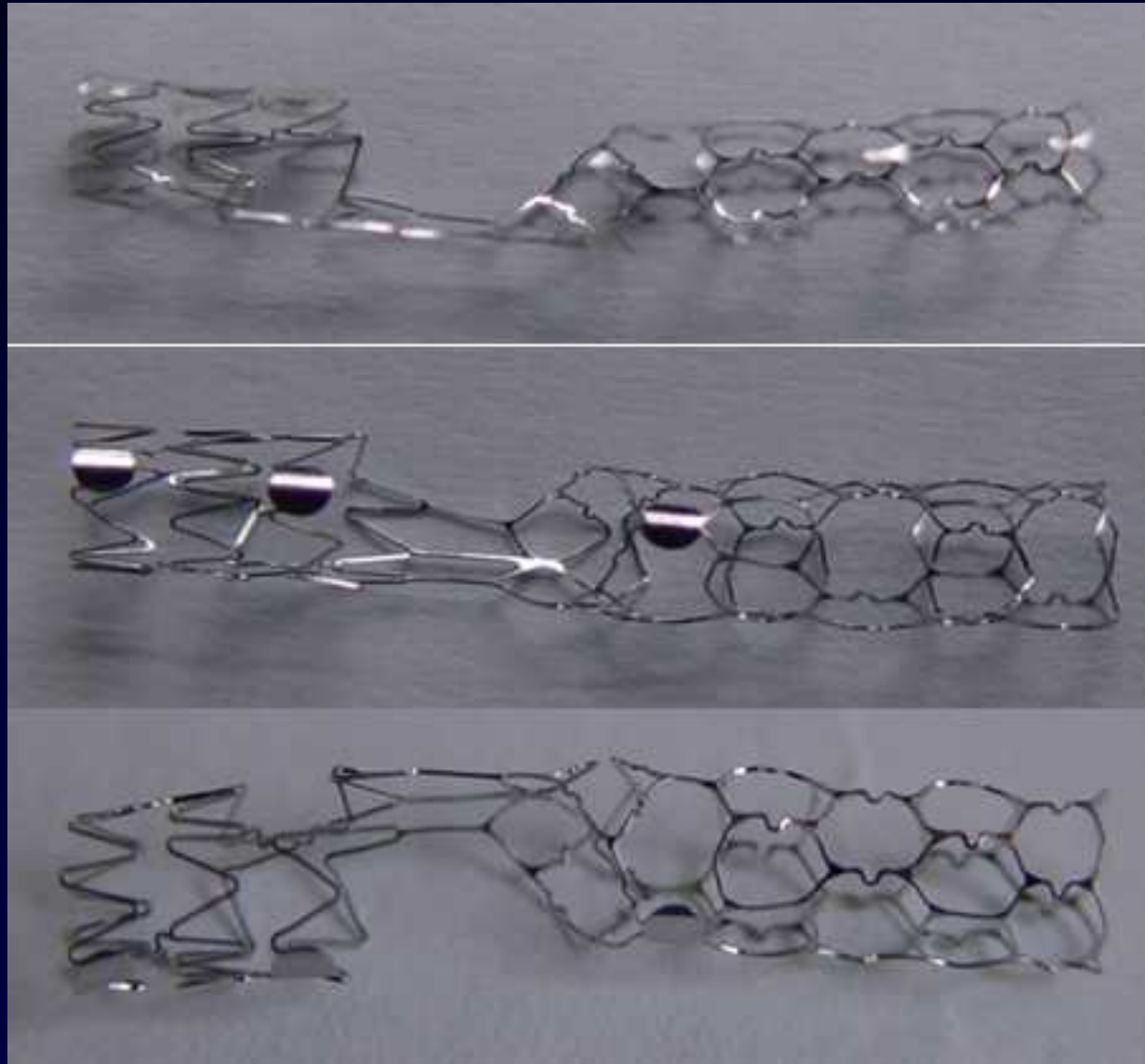


α : take-off angle (°) of side branch vessel

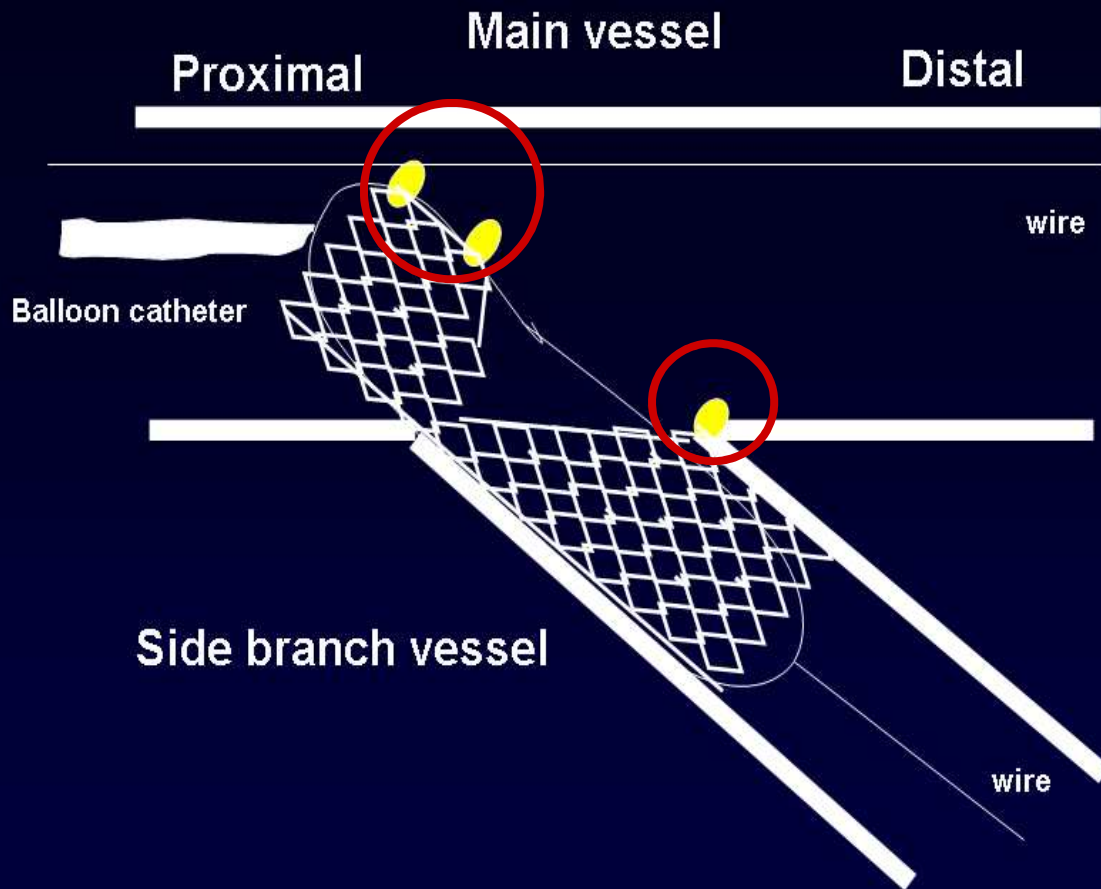
- The proximal part operates for the safe delivery and useful guidance for a more precise placement of the distal part of the stent on the side branch ostium.

- **Size discrepancy between main and side-branch vessel:** closed cell structure in the distal and connecting part, and open cell structure in the proximal part.

H-side branch stent

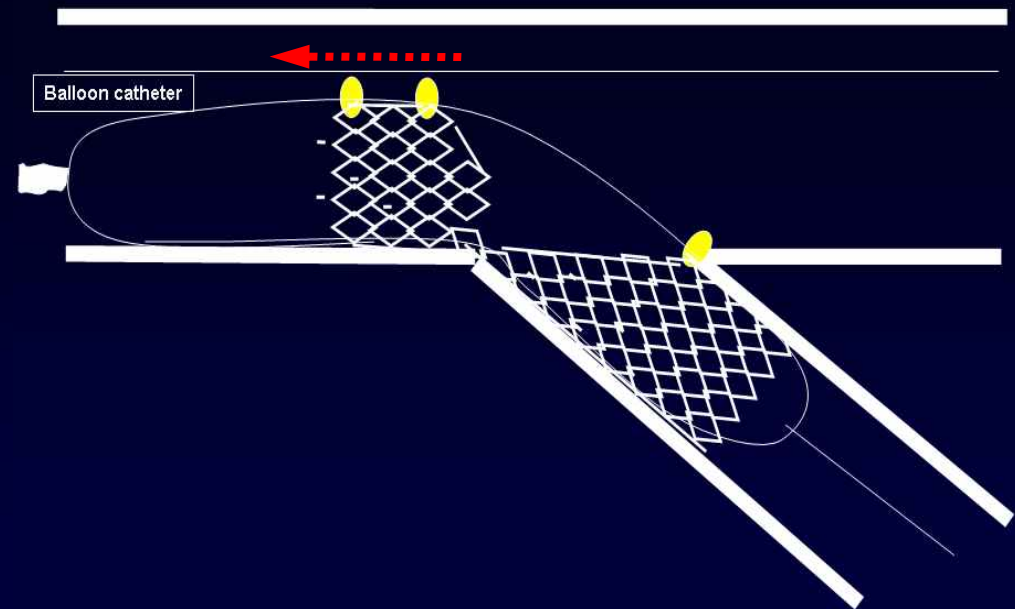
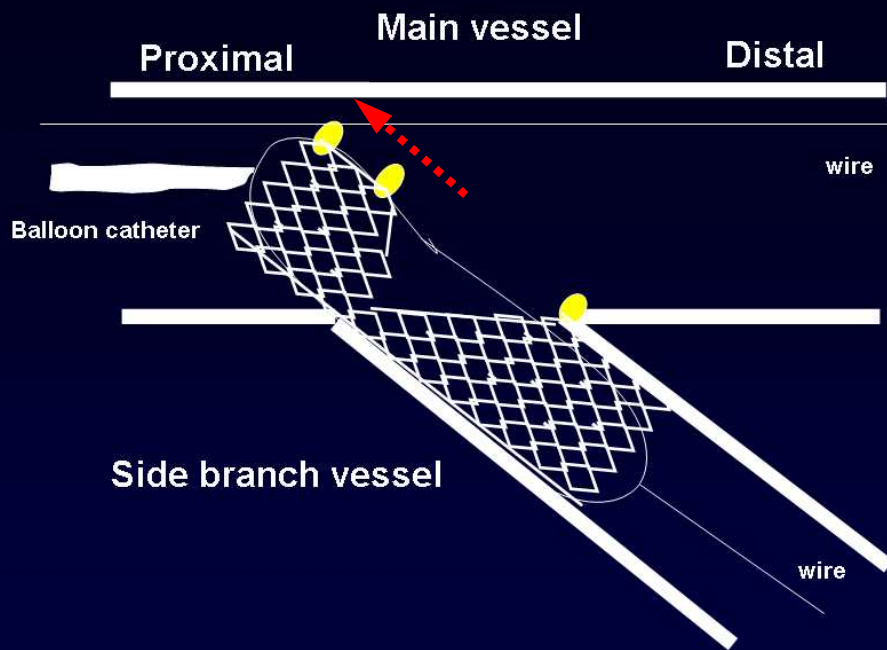


Radio-opaque markers in H-side branch stent



One radio-opaque marker in the distal part of the side branch stent is useful in targeting the carina of the side branch ostium for complete coverage with stent struts under the unexpanded condition of stents.

Two radio-opaque markers in the proximal part of the stent are useful to guide the accurate placement of one radio-opaque marker in the distal part of the stent to the carina of the bifurcation lesions in a 3-dimensional position of the coronary arteries.



When the usual length of stent delivery balloon is used for this stent, the proximal part of the stent could be somewhat vertically aligned with the main vessel, especially in the bifurcation lesions with greater take-off angles.

When balloons that are slightly longer than the actual length of this stent are used (especially longer balloon length proximal to the proximal stent margin), they facilitate a smooth parallel transition of the proximal part of the stent toward the main vessel.

In-vitro test and micro-computed tomography

-In-vitro tests were performed in the acrylic resin-made phantom model with a 45° angle between the main and side branch vessel.

-The results of in-vitro tests were scanned and reconstructed into a 3-dimensional structure with micro-CT (SkyScan 1076, SkyScan, Antwerpen, Belgium).

-The reconstructed data set was then segmented by an automated thresholding algorithm. *Waarsing JH, et al. J Bone Miner Res. 2004; 19:1640–50.*

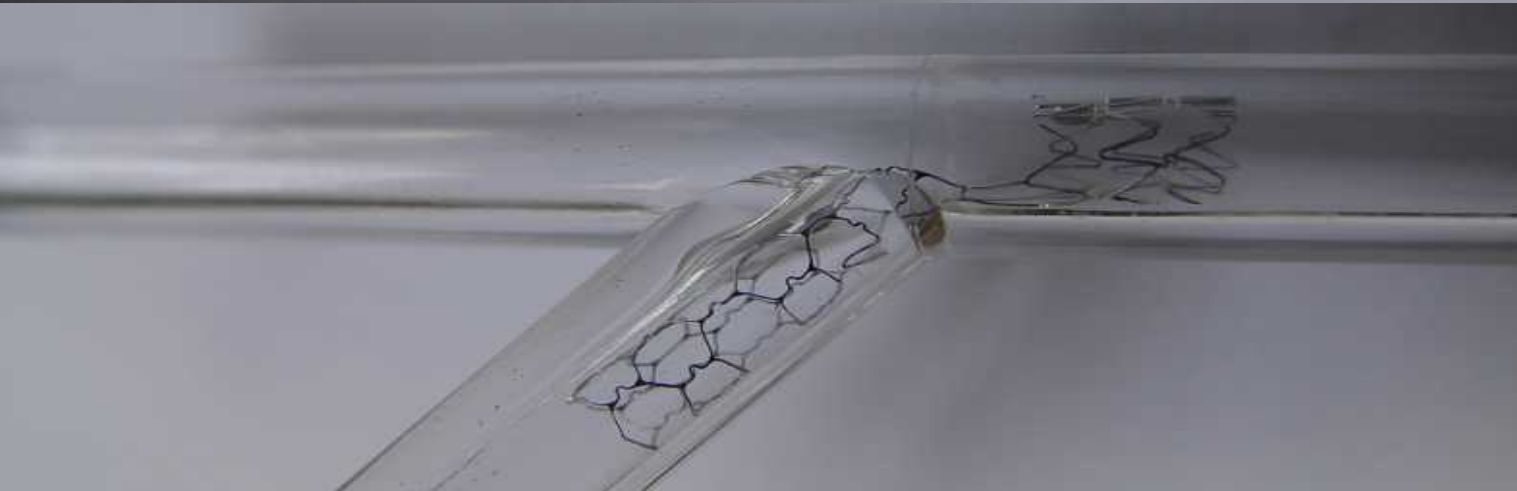
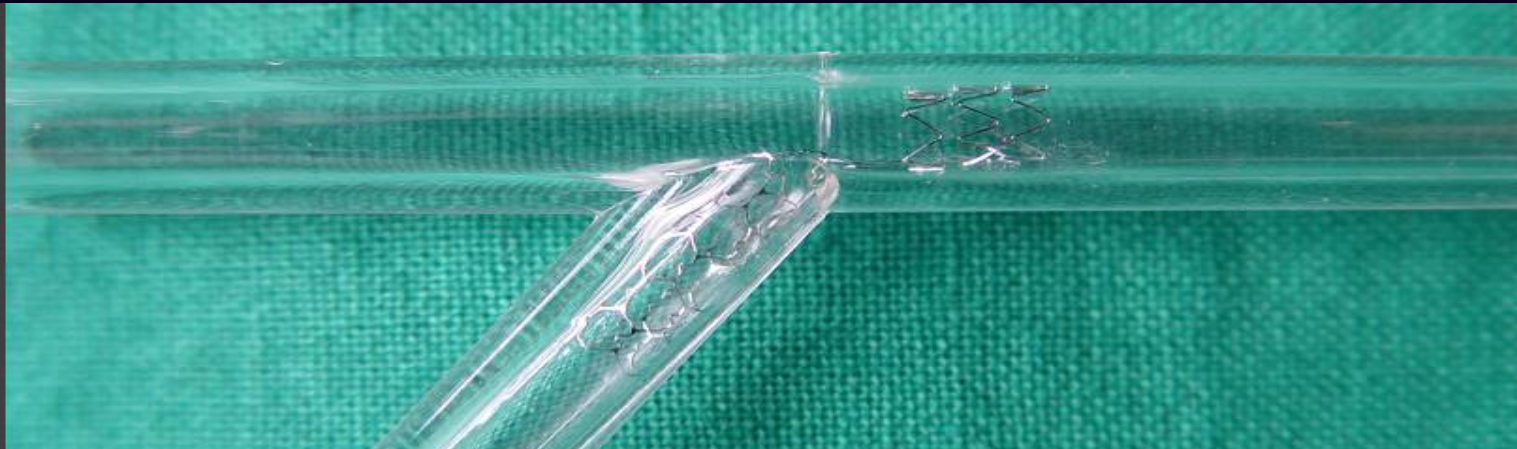
- The projection images were reconstructed into 3-dimensional images using NRECON software (version 1.5.1) and CT-Analyzer™ (version 1.7), both from SkyScan.

Results

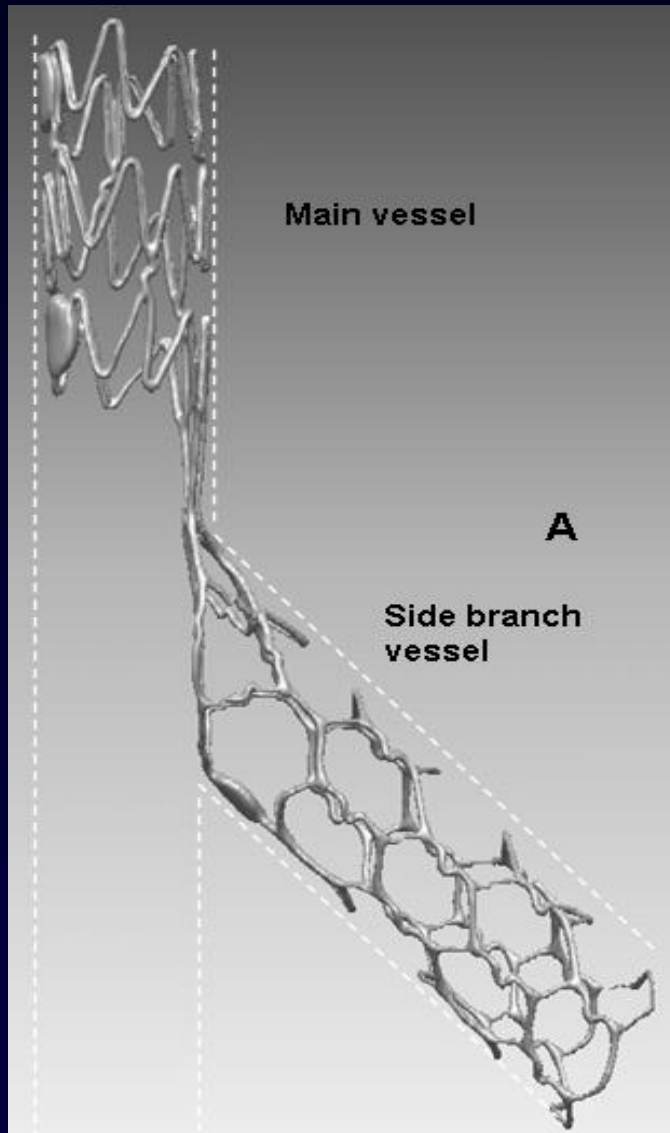


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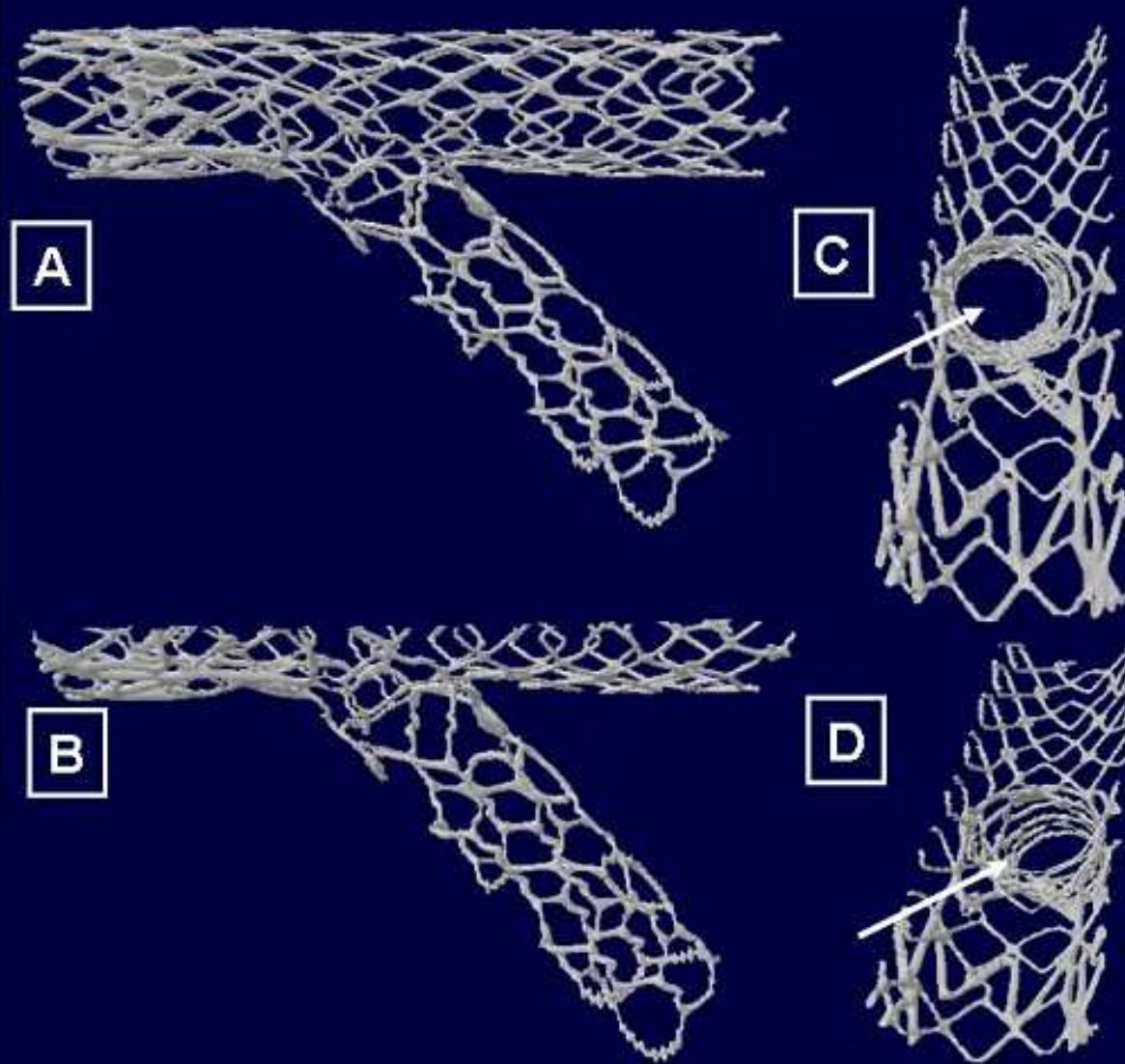
- Successfully deployed in the phantom model
- The circumference of the side branch ostium is completely covered by the slope-sided margin in the distal part of the stent without any missing between the stent strut and the ostium in the side branch vessel, and with little to no protrusion of the stent strut into the main vessel.



Micro-CT evaluation of in-vitro tests



Micro-CT: 2-stents after kissing balloon



In-vivo experiments

- **Five domestic crossbred juvenile pigs (20-30 kg)**
- **One day prior to the procedure, loading dose of 200 mg aspirin and 300 mg clopidogrel**
- **After sedation, an intravenous line was established, and the animals were intubated and mechanically ventilated with oxygen (2 L/min) and isoflurane (1.5–3.0%).**
- **Continuous hemodynamic and surface electrocardiographic monitoring throughout the procedure**
- **Arterial access via a right carotid arteriotomy using a cut-down approach**
- **A 7F introducer sheath was placed, and each pig received a single dose of heparin (150 U/kg).**

In-vivo experiments (cont.)

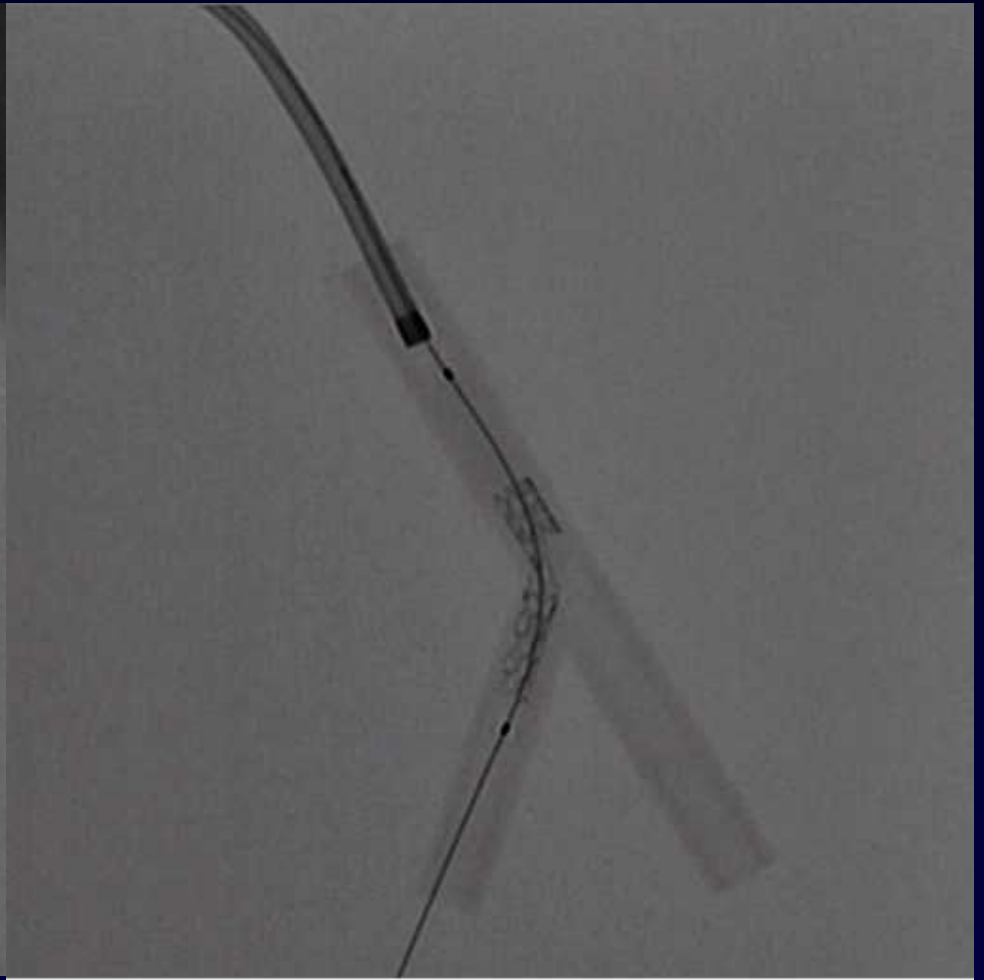
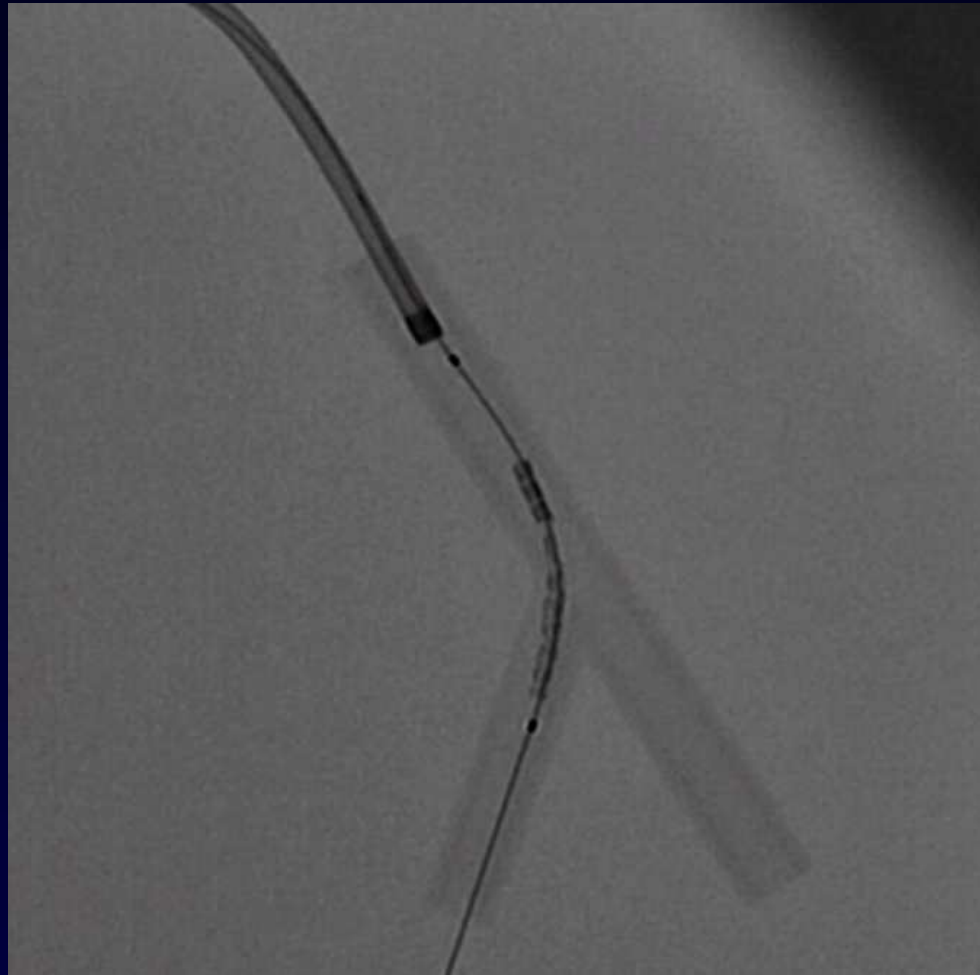
A guiding catheter was positioned in the left coronary artery ostium under fluoroscopic guidance and control angiography of the left coronary artery was performed using a nonionic contrast agent in two orthogonal views.

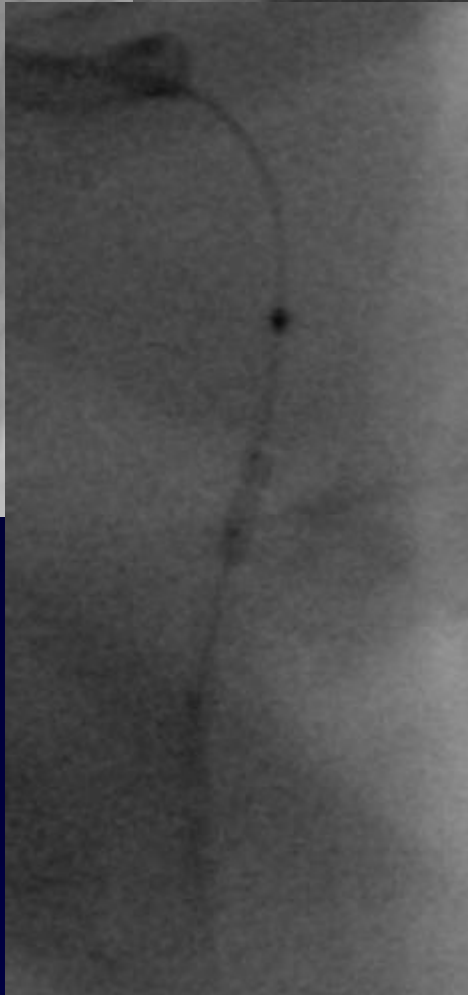
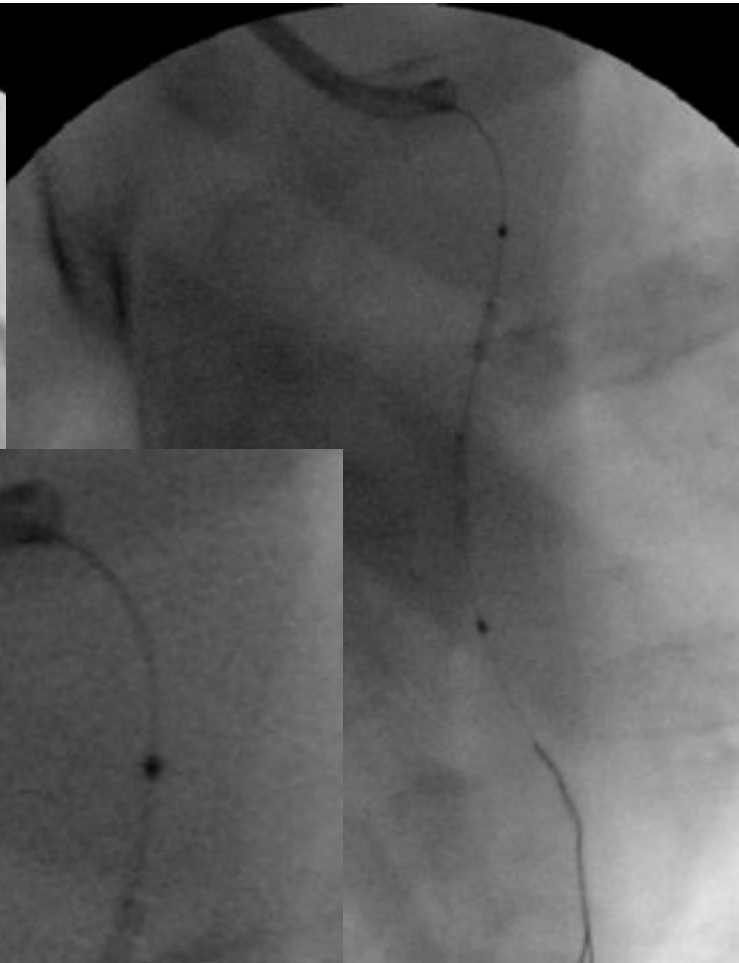
→ These stents were advanced over an angioplasty guide-wire into the bifurcation segments of the left anterior descending artery-diagonal branch and inflated at a pressure of 12-16 atm for 20 seconds.

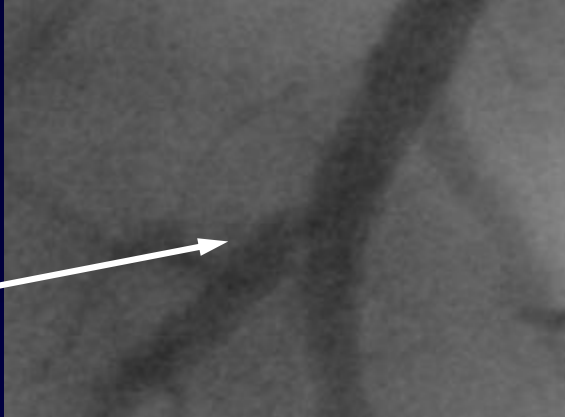
→ Coronary angiography was repeated and recorded in orthogonal view.

→ After the procedure, the hearts were removed immediately and fixed.

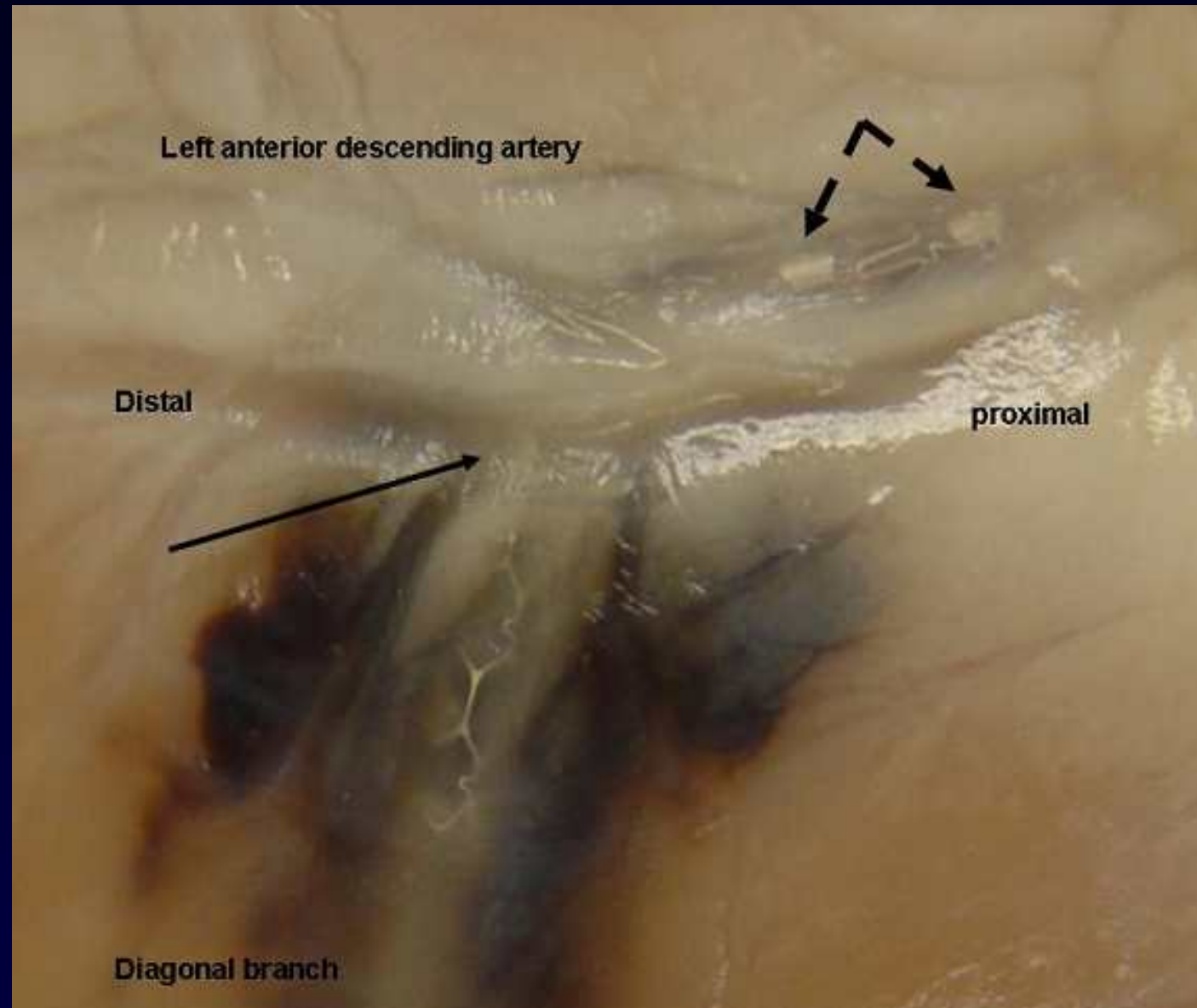
→ The status of stented coronary segments was evaluated after a part of the mid-portion of the left anterior descending artery was removed.



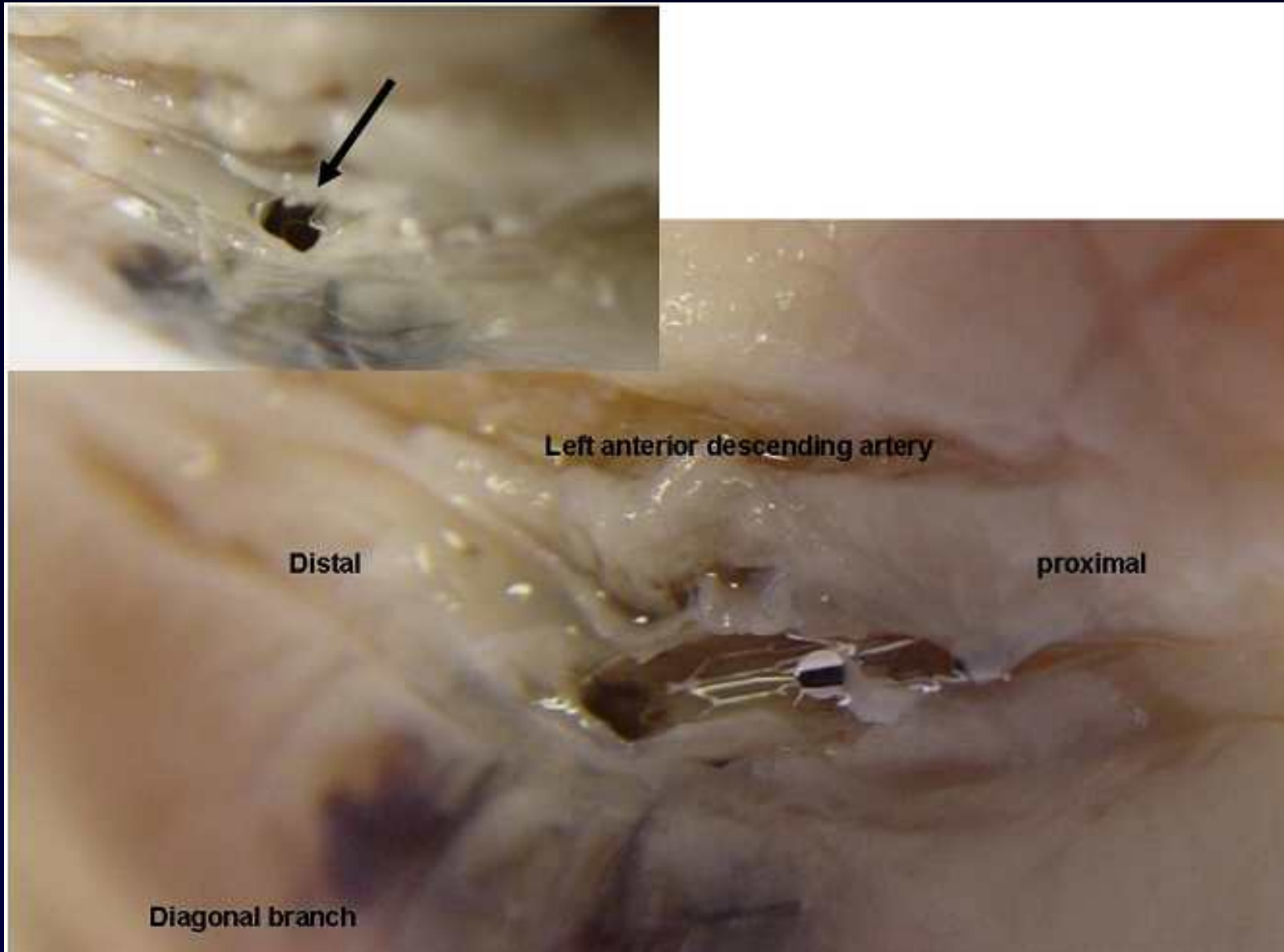




< In-vivo experiments >



< In-vivo experiments >



Ideal stent platform

First requirement is complete scaffolding or coverage of side branch ostium with DES strut.

Second requirement is absence of significant influence on coronary blood flow by extended stent struts in the main vessel.

Third requirement is the condition that the stent struts just above or near the side branch ostium should be minimal or absent.

Summary

Clinical implications ;

- Not necessary special apparatus and accompanying devices or catheters
- Quite similar technique to the usual conventional procedure
- Simple and familiar to the operators when the H-side branch stent is used for treating coronary bifurcation lesions

Limitations ;

- Immediate results for adequacy in stent design
- No data regarding restenosis and stent thrombosis

Conclusions

The phantom model test with micro-CT evaluation and animal experiments showed that use of the H-side branch stent may be a promising and effective strategy for the treatment of true coronary bifurcation lesions.