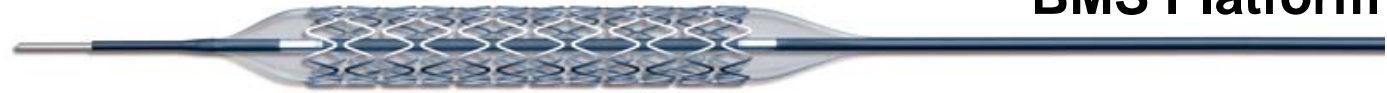
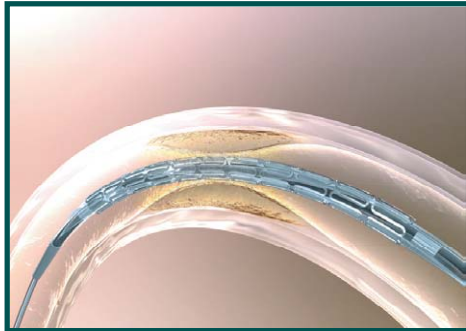


DES for Left Main & Bifurcation Lesions: Insights From The NOBORI 2 Study

G.B. Danzi, MD
Ospedale Maggiore Policlinico
Milan - Italy

I have no potential conflict of interest

Nobori DES Components

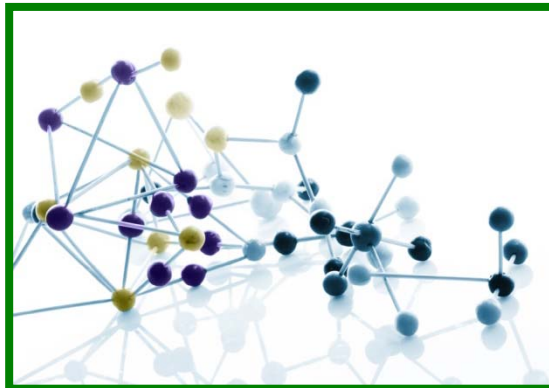
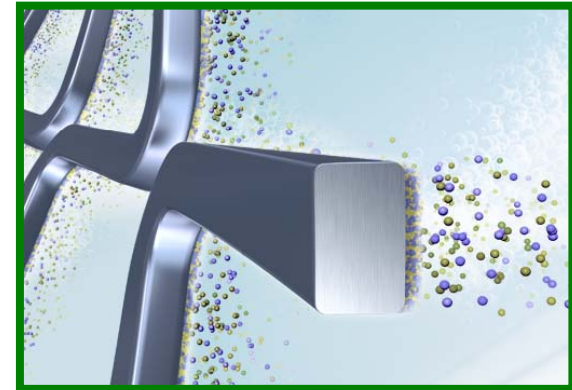


BMS Platform

Excellent Flexibility and Scaffolding
Optimal Side Branch Access
Innovative Delivery System with Hydrophilic M-coating

PLA Biodegradable Polymer

Abluminal Coating
Controlled Biodegradability
Precise Drug Release Kinetics
Simultaneous Polymer Degradation and Drug Release

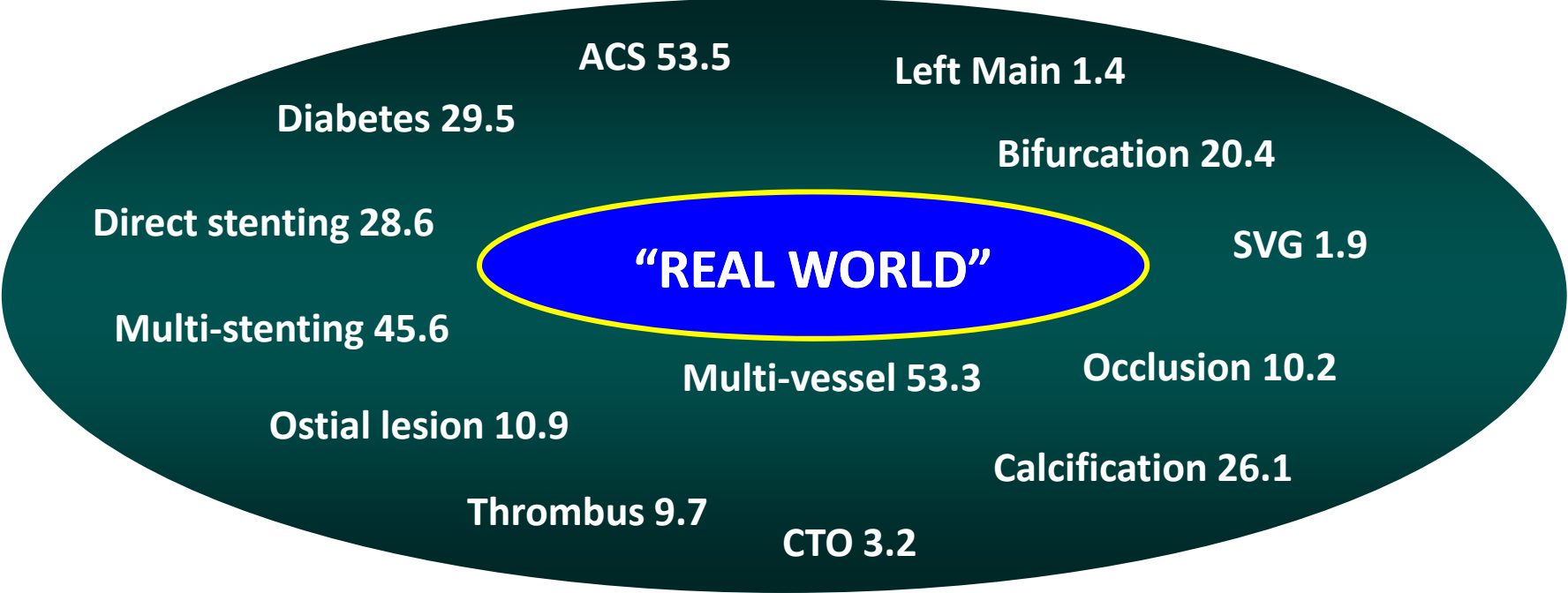


Biolimus A9™ (rapamycin derivative)

A Potent New “Limus” Designed for Stent Applications
Powerful Anti-proliferative and Anti-inflammatory properties
Prevents Smooth Muscle Cell Proliferation
Highly Lipophilic with Optimal Local Tissue Uptake

NOBORI 2 Trial

Patients suitable for treatment with DES; 125 sites (Europe, Asia, North-Africa)
N = 3067



Clinical Follow-Up up to 5 years

Primary Endpoint: Target Lesion Failure at 12 months
Composite of Cardiac Death, MI Target vessel related and TLR

NOBORI 2 – Left Main & Bifurcation Lesion

NOBORI 2

- Large multicentre study
- 125 centres (3 continents)
- Incorporates several in advance specified substudies

- Highest quality control standards (100% monitoring online & 30% monitoring on-site)
- Off-line baseline QCA analysis by independent Corelab
- Electronic CRF
- All events adjudicated by an independent CEC

Total N = 3067

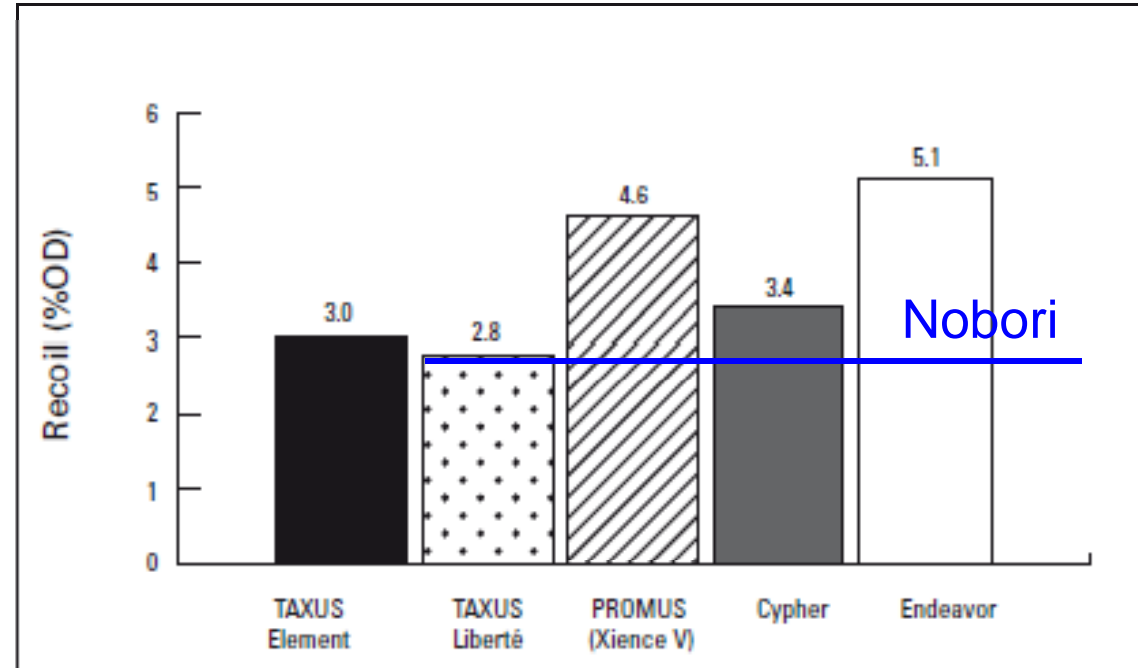
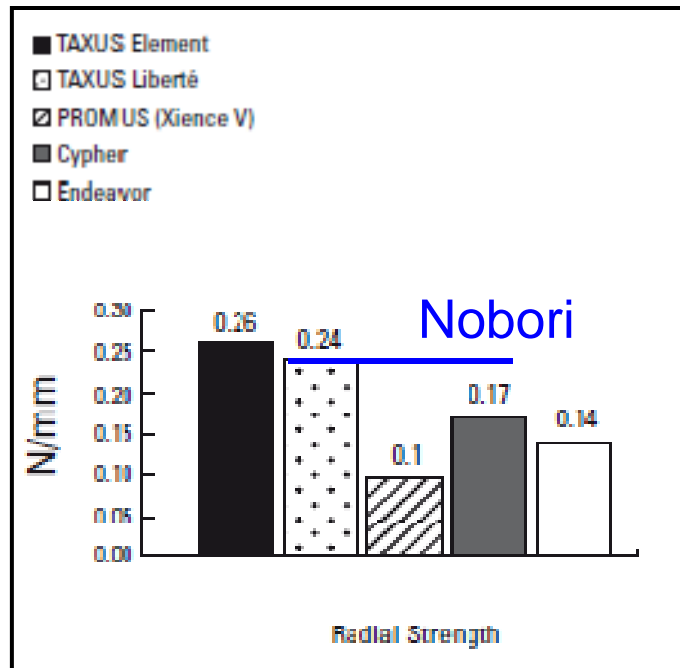
Left Main – N = 61

Bifurcation – N = 695

97% FUP rate at 12 months

95% FUP rate at 24 months

Nobori has a high level of radial force and less recoil rate, which keeps well apposition.



Boston Scientific Co.
Element stent. White paper

NOBORI 2 - Left Main Clinical Presentation

%	LM N = 61	No LM N = 2969	P-value
Age, years (mean \pm SD)	66.7 \pm 10.4*	64.3 \pm 11.1	0.1
Male gender (%)	80.3	76.2	0.8
Prior MI (%)	33.3	34.3	1
Prior PCI (%)	30.0	32.5	0.8
Prior CABG (%)	33.3	9.3	<.0001
Diabetes Mellitus (%)	31.2	29.9	0.8
Hyperlipidemia (%)	76.3	72.0	0.5
Hypertension (%)	65.0	69.3	0.5
Current smoker (%)	16.7	25.4	0.2

NOBORI 2 Study

Left Main Subset

N (Mean \pm SD)	LM N = 61	No LM N = 2969	P-value
N of diseased vessels	2.16 \pm 0.80	1.72 \pm 0.77	<.0001
N of treated vessels	1.89 \pm 0.86	1.24 \pm 0.47	<.0001
N of lesions	2.64 \pm 1.35	2.01 \pm 1.12	<.001
N of lesions treated	2.10 \pm 1.09	1.46 \pm 0.75	<.0001
N of implanted stents/patient	2.41 \pm 1.50	1.74 \pm 1.07	<.0001
N of implanted stents/lesion	1.15 \pm 0.52	1.19 \pm 0.57	0.30

NOBORI 2 - Left Main Lesion Characteristics

%	LM n=61
Left Main Isolated	15 (24.6%)
Left Main Two Vessels Disease	21 (34.4%)
Left Main Three Vessels Disease	25 (41.0%)
<hr/>	
Left Main Protected	23 (37.7%)

NOBORI 2- Left Main Clinical Outcomes At 2 Years

N, (%)	LM N = 61	No LM N = 2969	p-value
Cardiac Death	3 (4.9)	46 (1.6)	NS
MI	2 (3.3)	71 (2.4)	NS
TLR - CABG	0 (0.0)	15 (0.5)	NS
TLR - PCI	4 (6.6)	74 (1.9)	NS
TV non-TLR	2 (3.3)	43 (1.5)	NS
TLF	9 (14.8)	144 (4.9)	0.003
Stent Thrombosis	0 (0.0)	25 (0.8)	NS

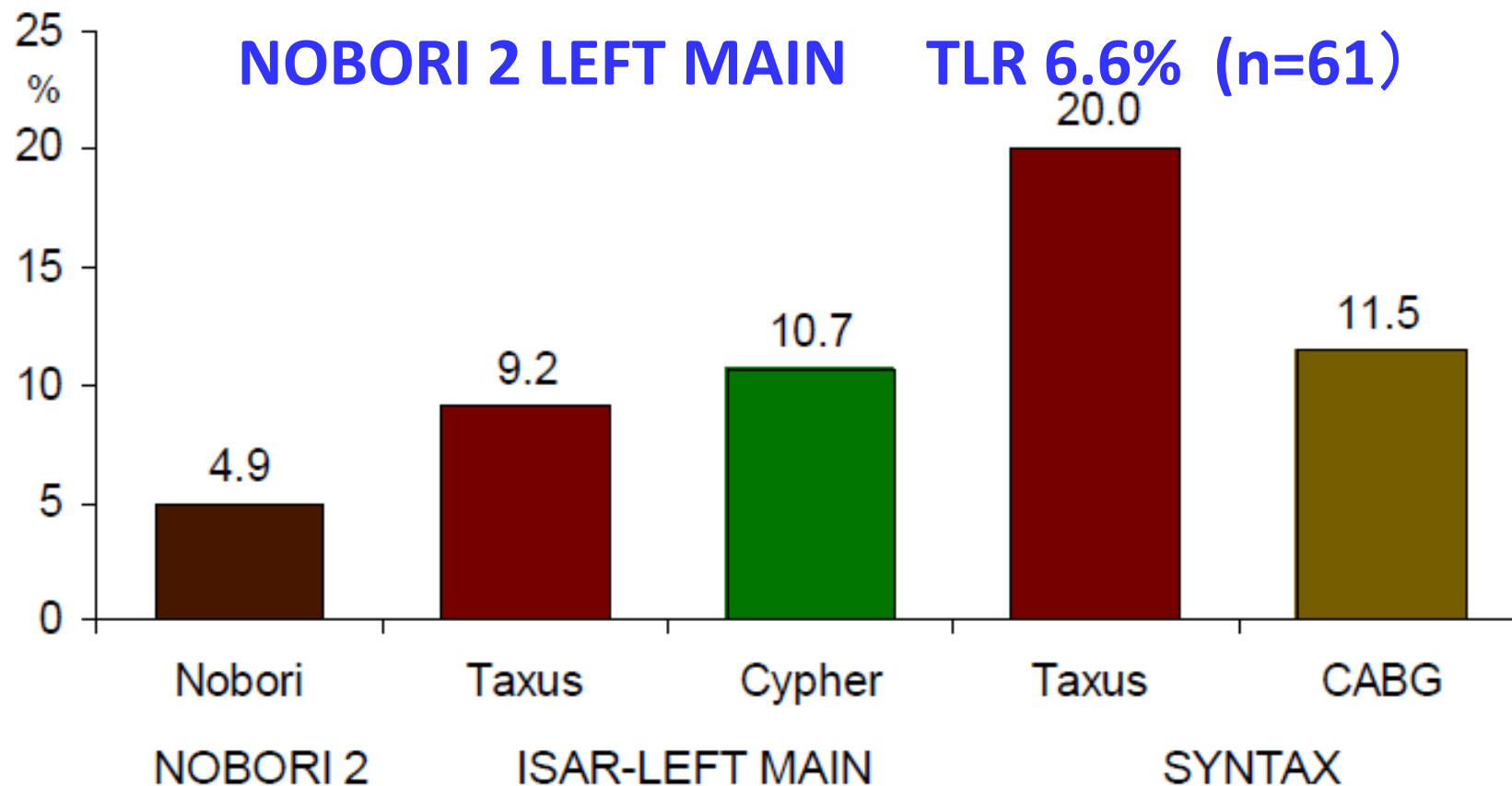
NOBORI 2 Registry Left Main



NOBORI 2 – SYNTAX – Left Main Subset
and ISAR LEFT MAIN Trial



TLR at 2 Years



ASIAN Registry*

Clinical Outcomes at 2 years

	# of patients	TLR (%)	Cardiac Death (%)	MI (%)	TVR (%)
Cypher	248	6.0	1.2	1.2	8.9
Taxus	172	8.7	1.2	1.2	11.7
Endeavor	104	11.5	1.9	1.0	14.4
ECS	42	16.7	0.0	0.0	19.0
Nobori	60	6.7	0.0	0.0	6.7
Xience V	50	8.0	2.0	2.0	8.0

*TCT 2009, Dr Nakamura; Asian registry enrolled 676 patients with unprotected Left Main disease using 6 different stents

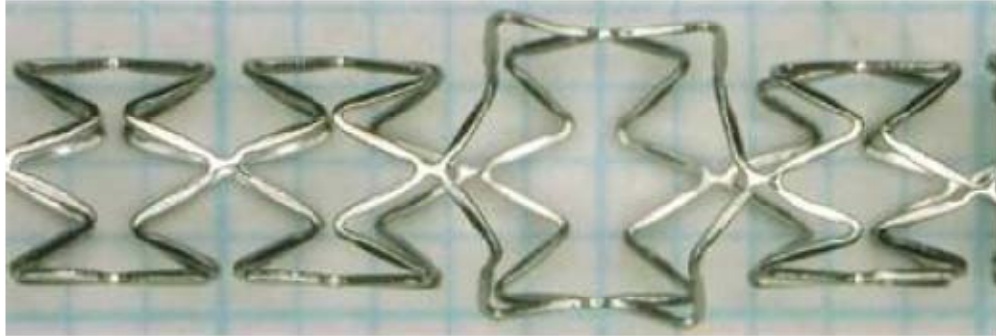
DES for Left Main

Conclusion

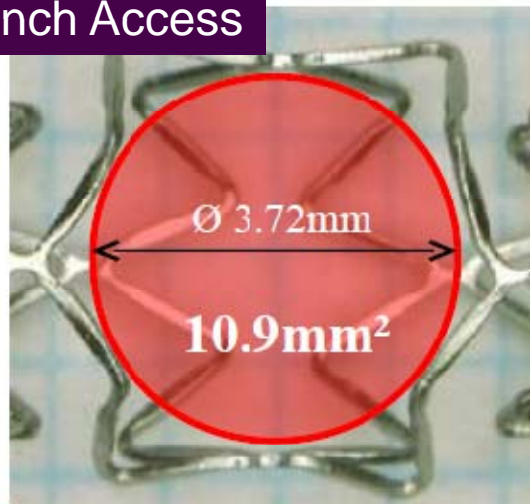
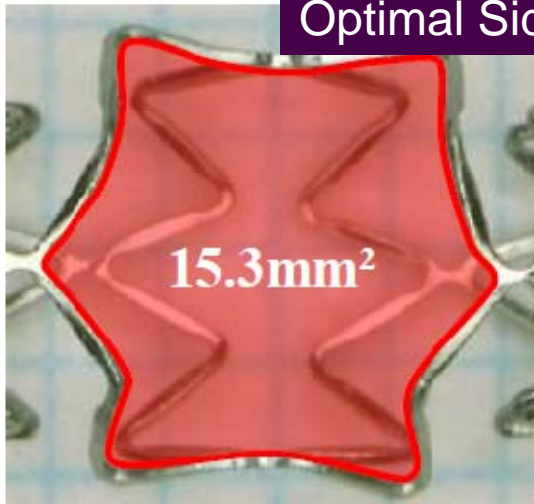
- **Nobori stent shows good results in LM & could be considered as treatment of choice when surgery is not indicated**
- **Nobori stent with good scaffolding, low recoil & easy access to side branch is particularly attractive for this type of lesions**
- **Very low rate of stent thrombosis in Nobori stent with biodegradable polymers might be a safer alternative to treat this lesion subset**

Nobori 2: Bifurcation

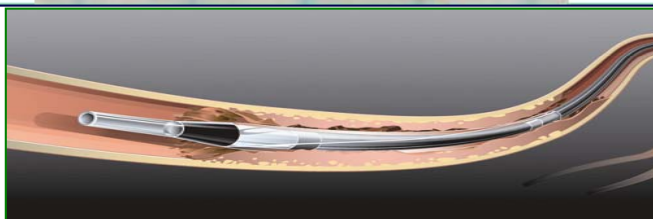
Nobori DES 3.5mm dilated with 4mm balloon



Optimal Side Branch Access

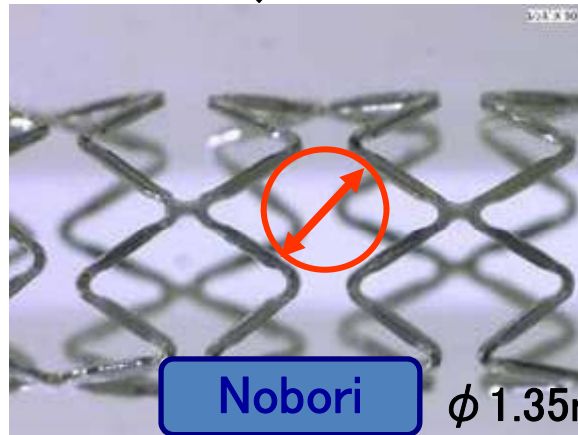


24 Months FUP
95%

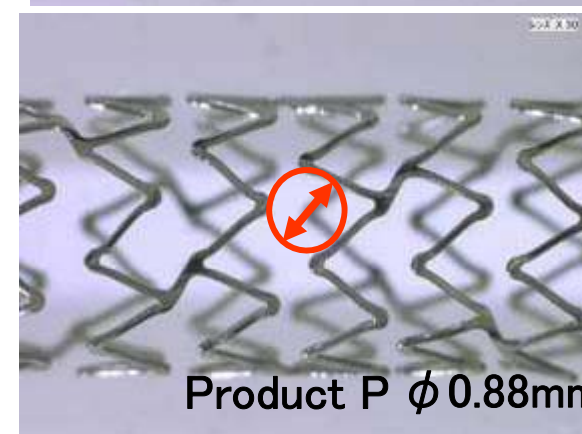
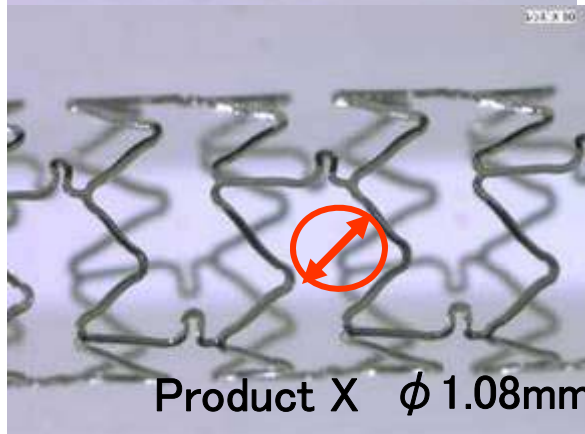
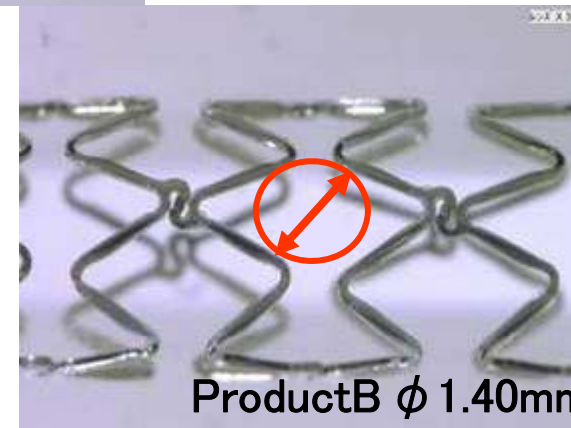
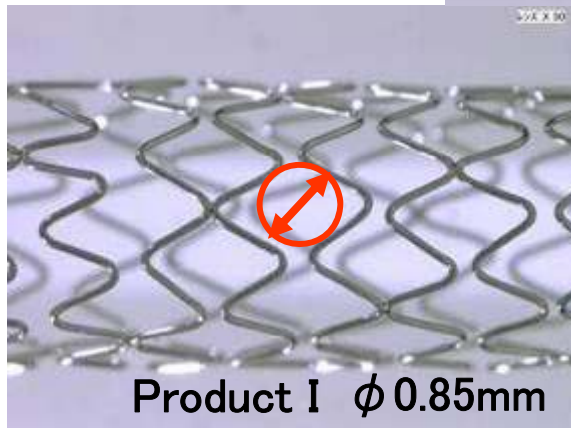


Enhanced deliverability
thanks to hydrophilic
coating

Cell design (3.0mm NBP)



open cell design
would be better
for side branch
access!

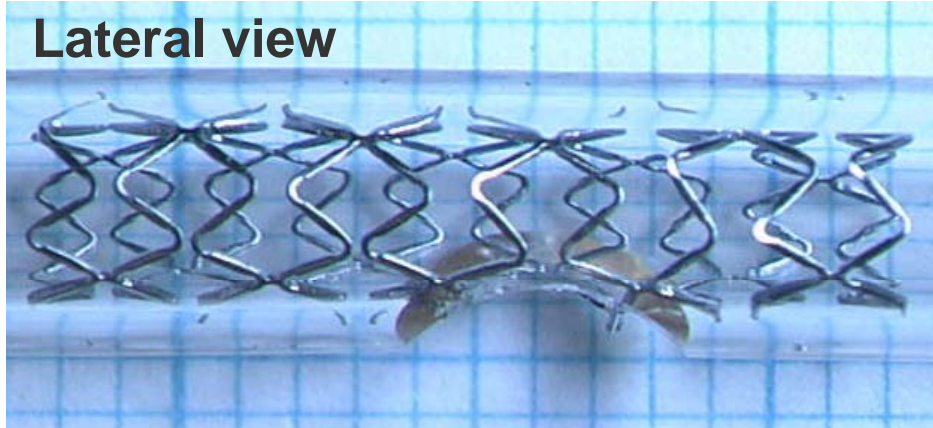


■ Balloon re-wrapping (ϕ 3.0mm, after 16atm inflated)



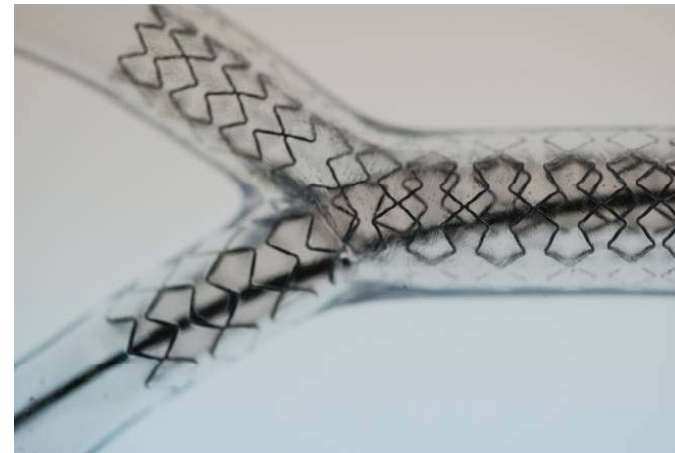
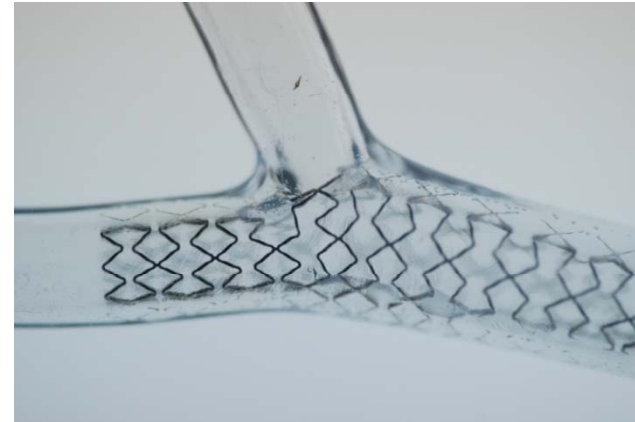
Nobori 2: Bifurcation

Lateral view



Cell is fitting to the side branch ostium

**Conformability To Side Branch
No Gap & No Distortion!**



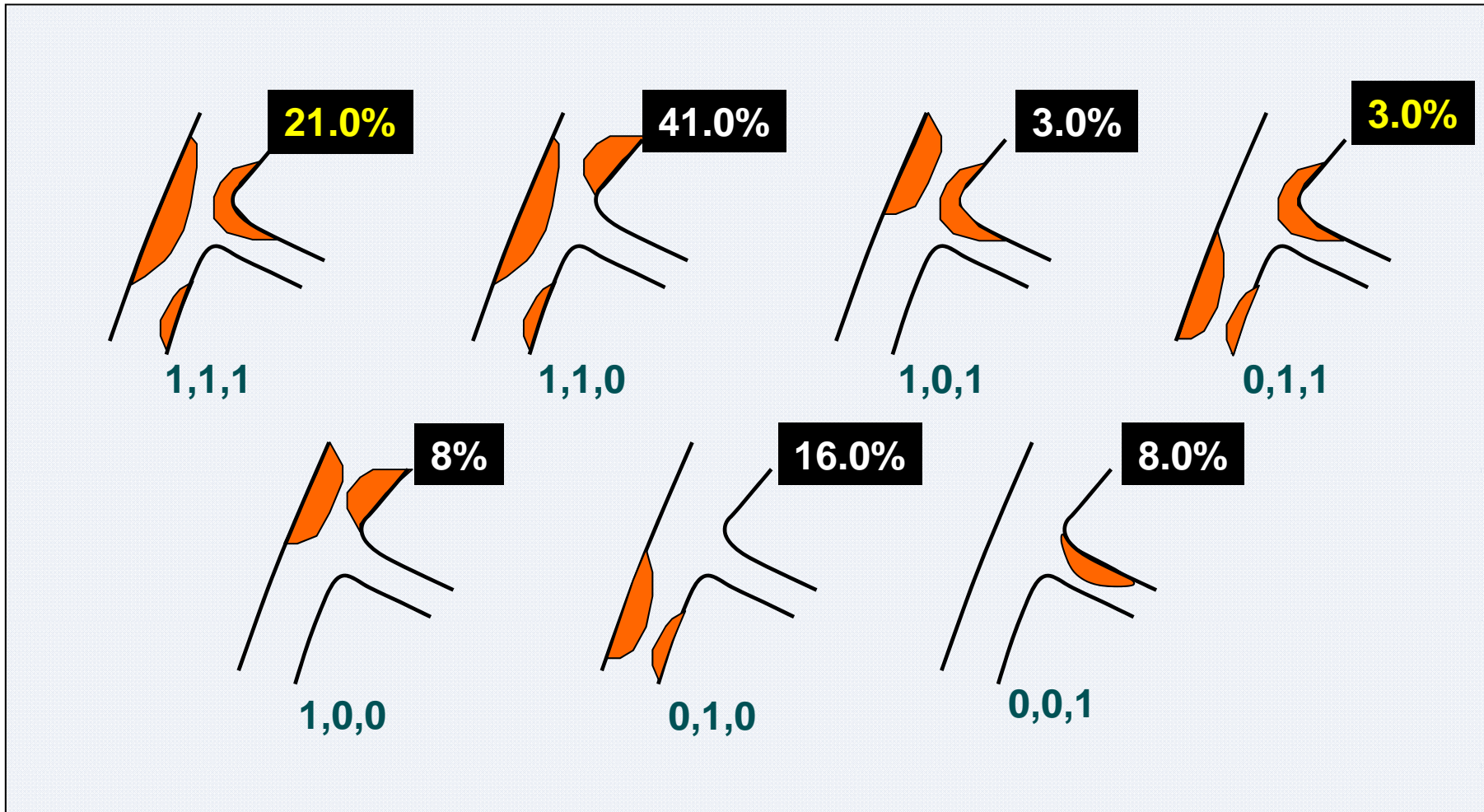
**2x (1 Nobori 3.5 x 24 mm)
Proximal vessel 4.5 mm, distal 3.5 mm
2nd stent deployment for culotte technique**

NOBORI 2 - Bifurcation

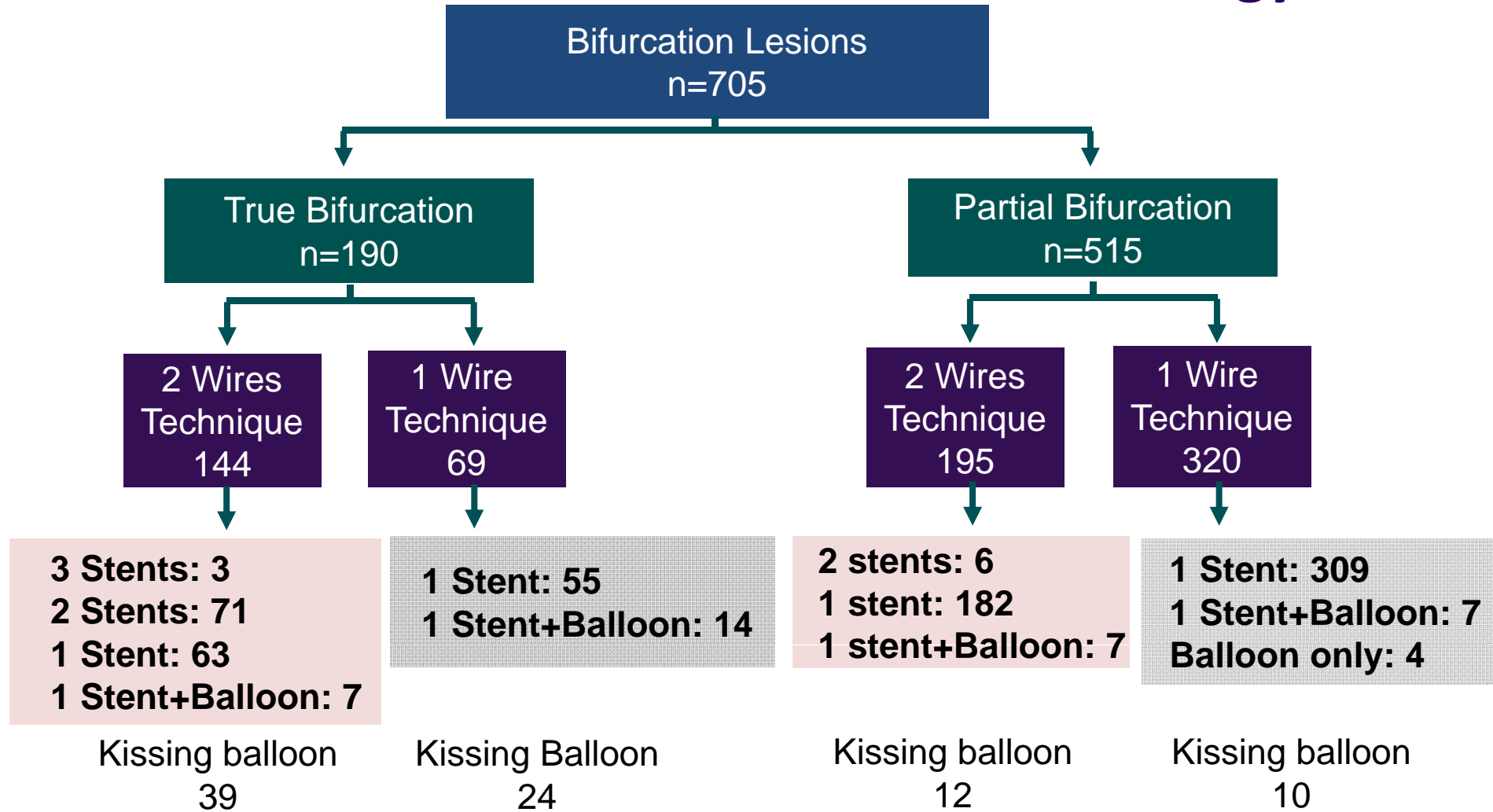
Baseline demographics

	Bifurcation n=695	No-bifurcation n=2130	p-value
Age, years±SD	64.5 ± 10.81	64.3 ± 11.05	NS
Male (%)	82.7	76.2	<0.001
Prior MI (%)	31.8	34.3	NS
Prior PCI (%)	30.4	32.5	NS
Prior CABG (%)	6.4	9.3	0.019
Diabetes Mellitus (%)	27.1	29.9	NS
Hyperlipidemia (%)	69.7	72.0	NS
Hypertension (%)	68.3	69.3	NS
Current smoker (%)	24.1	25.4	NS
Charlson Comorbidity Index (mean ± SD)	1.17 ± 1.18	1.27 ± 1.29	0.043

NOBORI 2 - Bifurcation Medina Classification



NOBORI 2 - Bifurcation Treatment Strategy



True bifurcation = Medina 1.1.1 + 0.1.1. + 1.0.1
 Partial bifurcation = Medina 1.1.0 + 0.1.0 + 1.0.0 + 0.0.1

NOBORI 2 - Bifurcation

Baseline QCA data

Mean±SD	Bifurcation	No bifurcation	p-value
Lesion length (mm)	16.09±10.10	15.38±9.36	NS
RVD –pre (mm)	2.62 ±0.59	2.61±0.58	NS
MLD – pre (mm)	0.86±0.47	0.82±0.51	0.022
Diameter stenosis – pre (%)	67.1±16.35	68.6±17.91	0.027
RVD –post (mm)	2.87 ±0.51	2.89±0.50	NS
MLD – post (mm)	2.47±0.47	2.52±0.47	0.002
Diameter stenosis – post (%)	13.8±7.53	12.8±6.79	<0.001
Acute gain in-stent (mm)	1.61±0.55	1.70±0.59	<0.001

NOBORI 2- Bifurcation Procedure Characteristics

Mean±SD	Bifurcation n=695	No-bifurcation n=2130	p-value
Diseased vessels per patient	1.83 ± 0.76	1.70 ± 0.77	
Lesions per patient	2.22 ± 1.16	1.96 ± 1.11	<0.001
Lesions treated per patient	1.61 ± 0.81	1.33 ± 0.62	
Stents per patient	2.00 ± 1.25	1.66 ± 1.00	

NOBORI 2 : Bifurcation

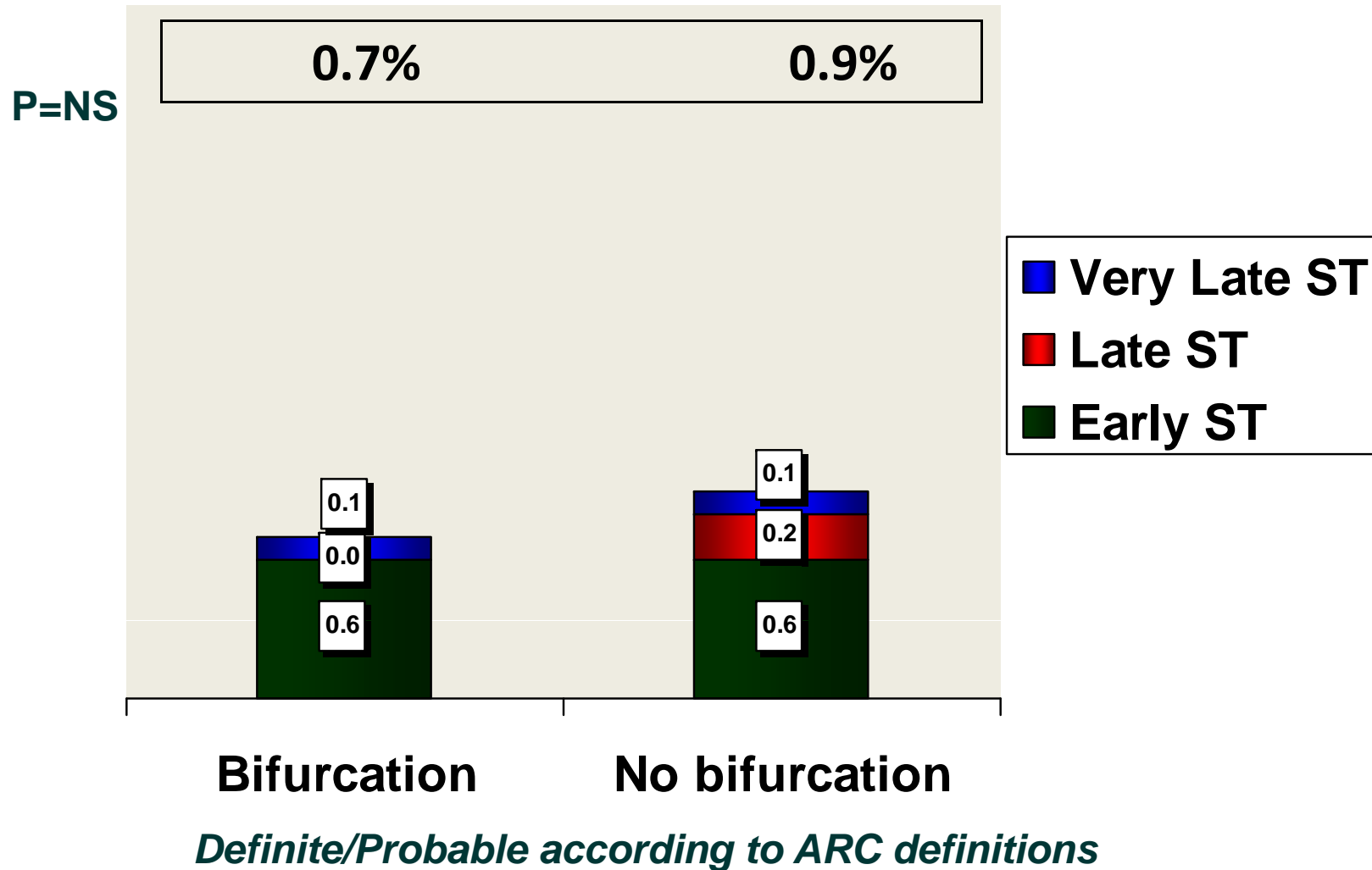
Clinical Outcomes At 2 years

All events (%)	Bifurcation n=695	No-bifurcation n=2130	p-value
Cardiac Death	0.7	1.9	0.026
MI	3.2	2.1	NS
TL-CABG	0.7	0.5	NS
TL-Re-PCI	2.5	1.7	NS
TV-non TL revasc.	1.4	1.5	NS
TLF	5.9	4.8	NS
MACE	7.3	6.6	NS

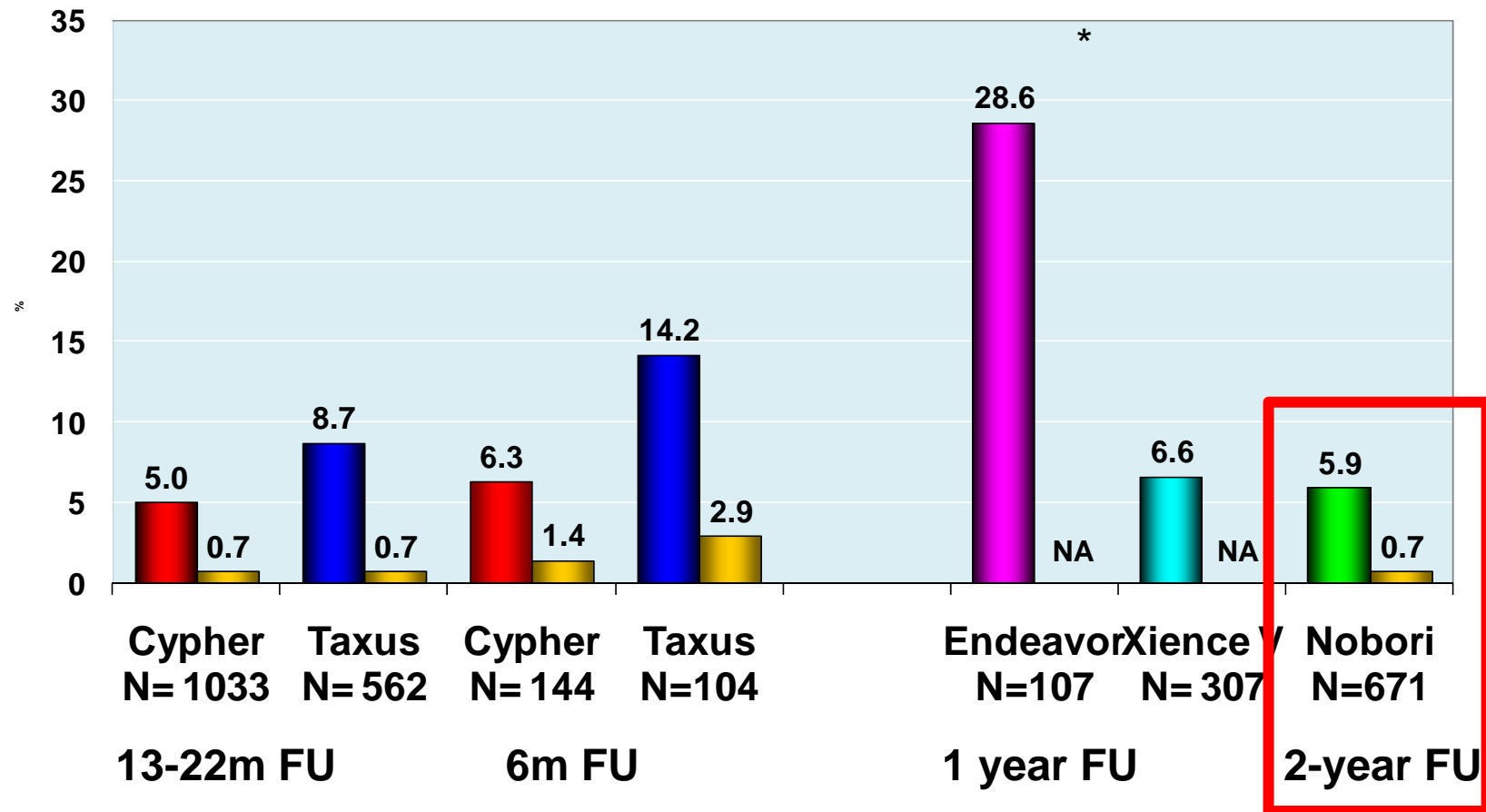
TLF = Cardiac death, MI (TV related), TLR

MACE = Cardiac death, any MI, TVR

NOBORI 2 - Bifurcation Stent Thrombosis At 2 Years



Clinical Outcome at 6-22m TLF & Stent Thrombosis Different DES



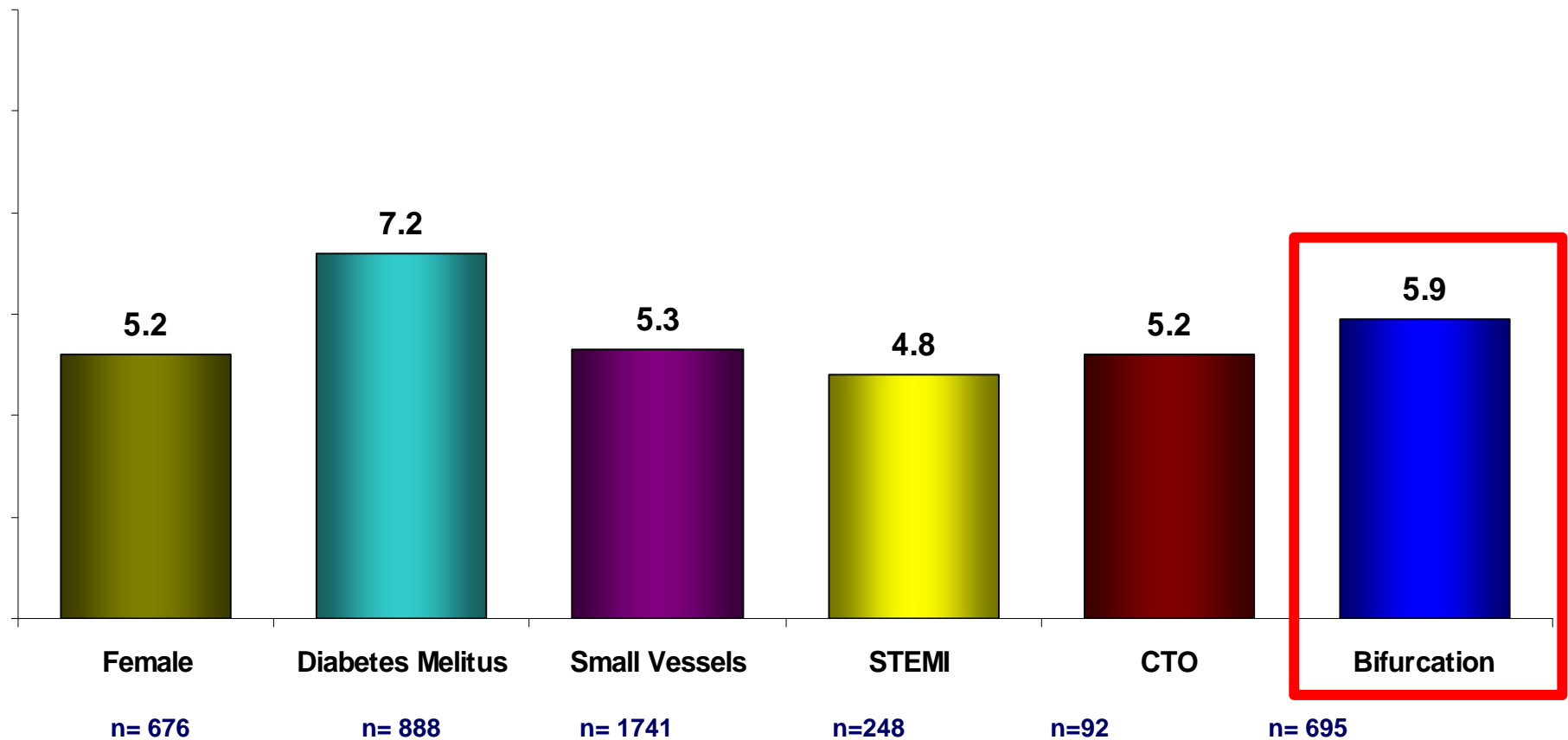
*Angiographic FU NA= Not Available

Soung YB, JACC, 2010;55:1743-50, Hoyo A. et al. EuroIntervention 2005;1; Fernandez-Guerrero J.C et al. JIC, 2010; 23:2, Kaul U et al. ACC 2010, Serra A. et al. PCR 2010

NOBORI 2 Registry

TLF at 2 years 5.1%

High risk patient / Lesion subset



TLF = Target Lesion Failure (Cardiac death, MI Target vessel related, TLR)

NOBORI 2 : Bifurcation Conclusions

- **Contemporary therapy of bifurcated lesions utilises Drug-Eluting Stents**
- **Restenosis & stent thrombosis are significant problems in bifurcation stenting: DESs with higher efficacy to prevent neointimal hyperplasia are recommended**
- **DES with open cell & larger side branch access (such as NOBORI stent) makes the procedure safer & more successful**
- **NOBORI stent with biodegradable polymer shows promising results in this complex lesion subset with low revascularization & stent thrombosis rates**