

Irregular Protrusion

Impact of Stent Platform

Yutaka Hikichi, M.D. Ph.D. Koichi Node, M.D. Ph.D.
Saga University School of Medicine
Saga, Japan

Kiyotaka Iwasaki, Ph.D
Waseda University, TWIns
Tokyo, Japan



Integrity



SYNERGY



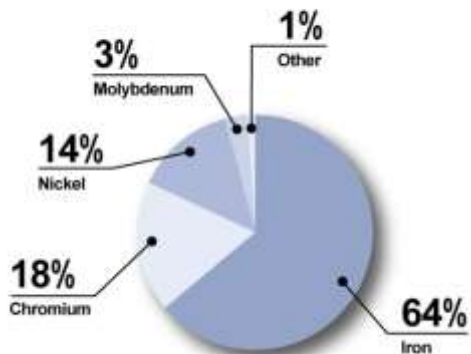
Xience



Ultimaster

Cypher[®]
Nobori[®] / BMX-J[®]

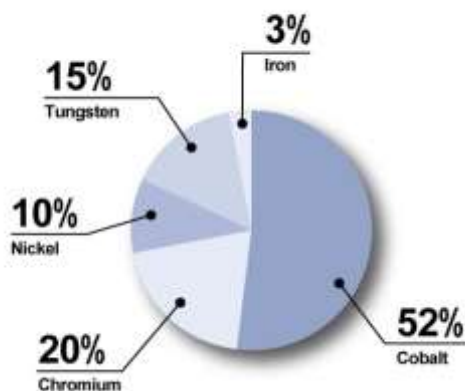
316L Stainless Steel



Stainless Steel

Xience[®]
Ultimaster[®]

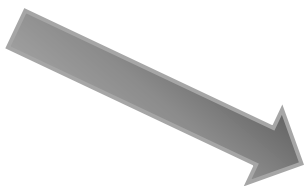
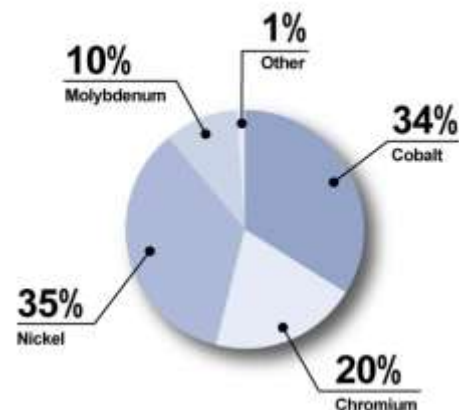
L605 Cobalt Chromium



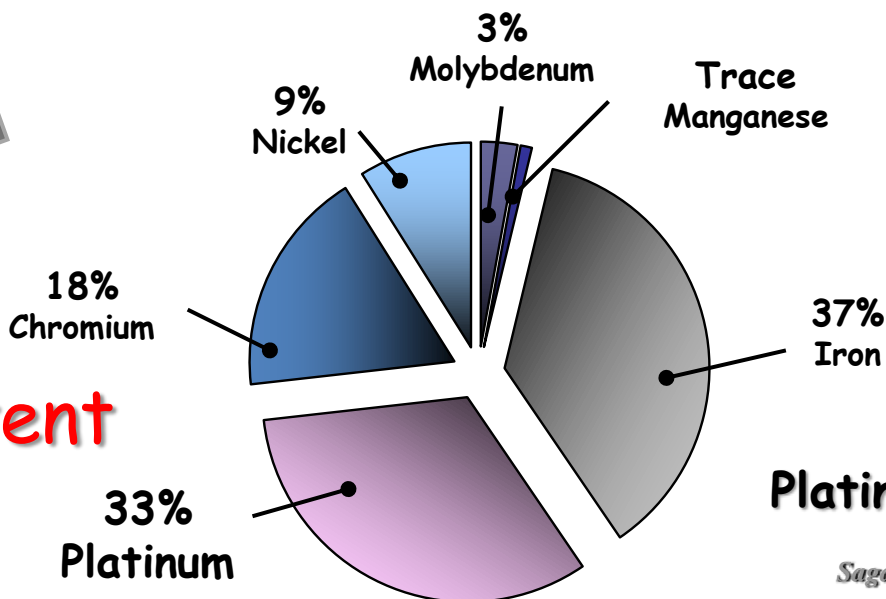
Cobalt Chromium

Integrity[®]

MP35N Cobalt Nickel



SYNERGY[®]

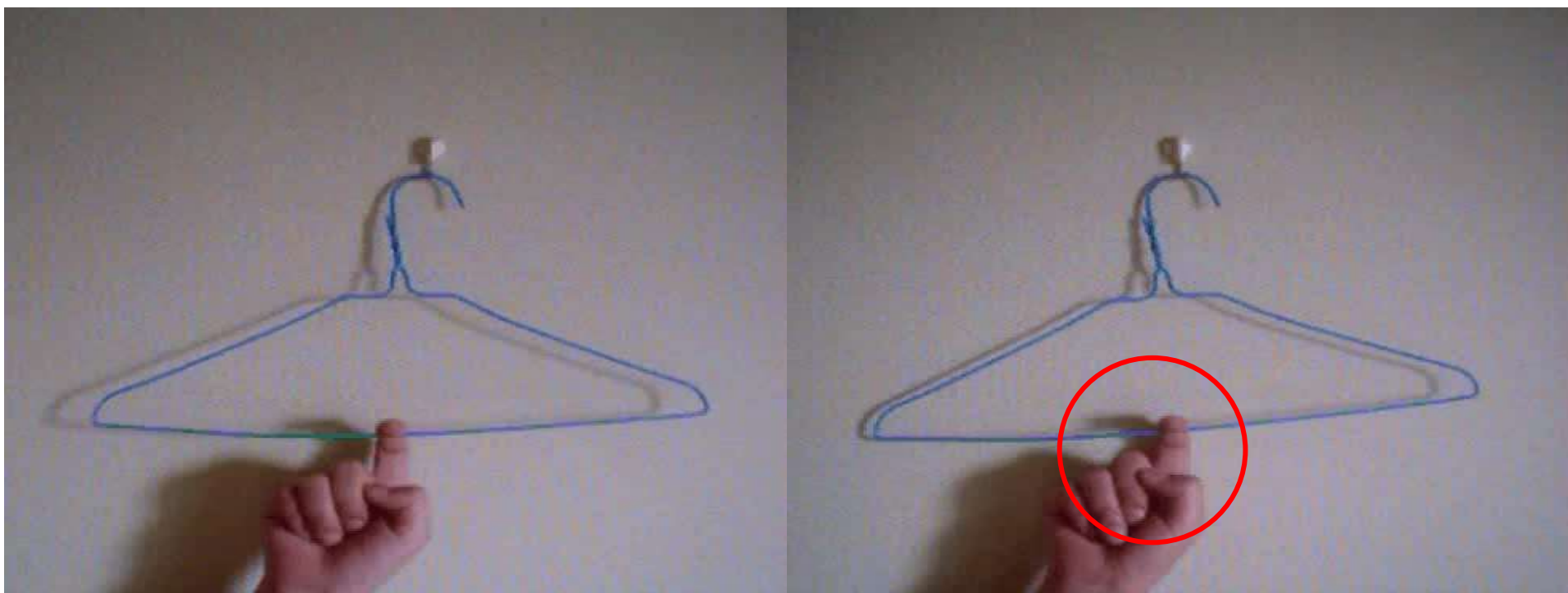


Platinum Chromium

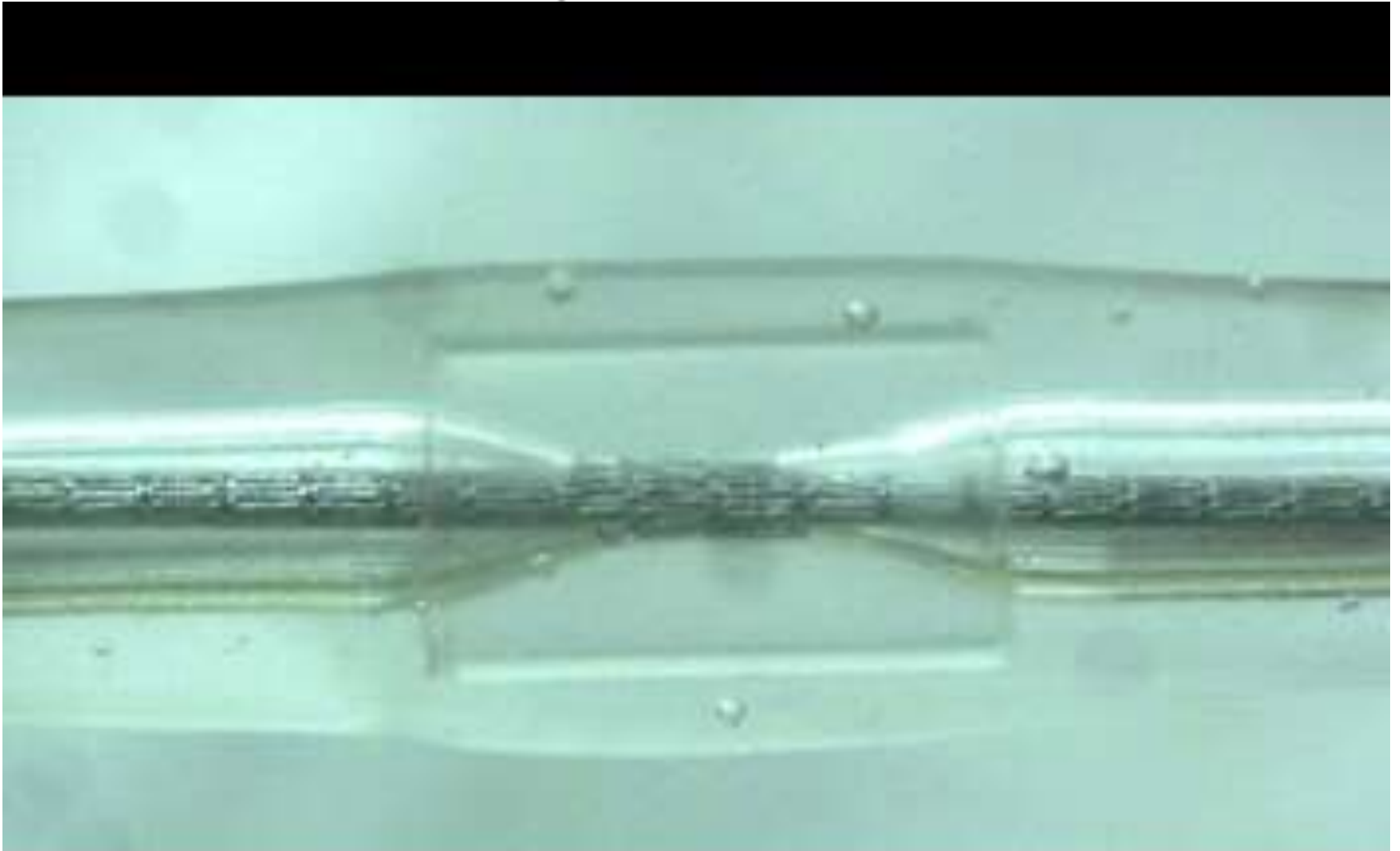
Components of Stent

Elastic deformation

Plastic deformation



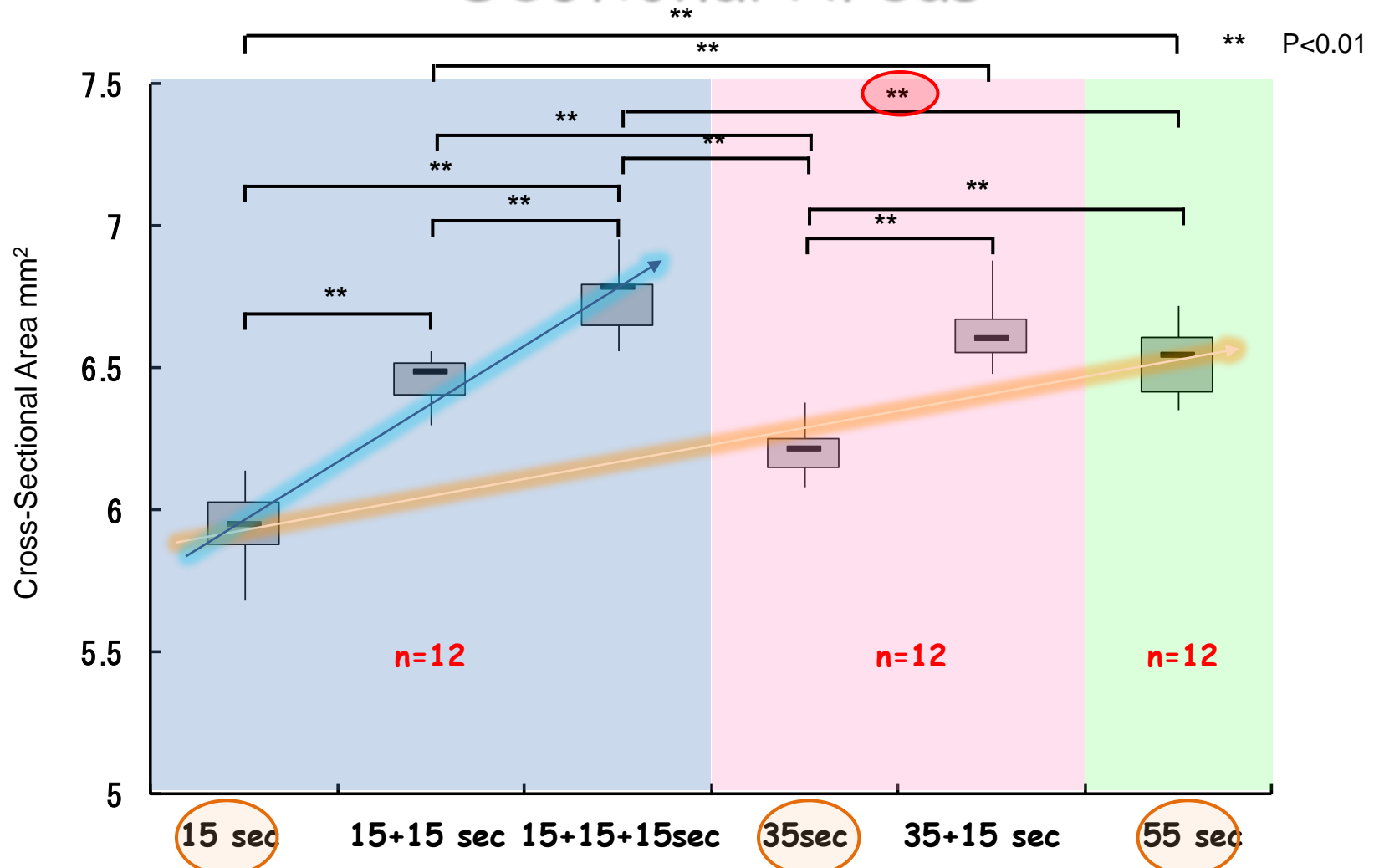
stent expansion and recoil



Courtesy of Dr.K. Iwasaki

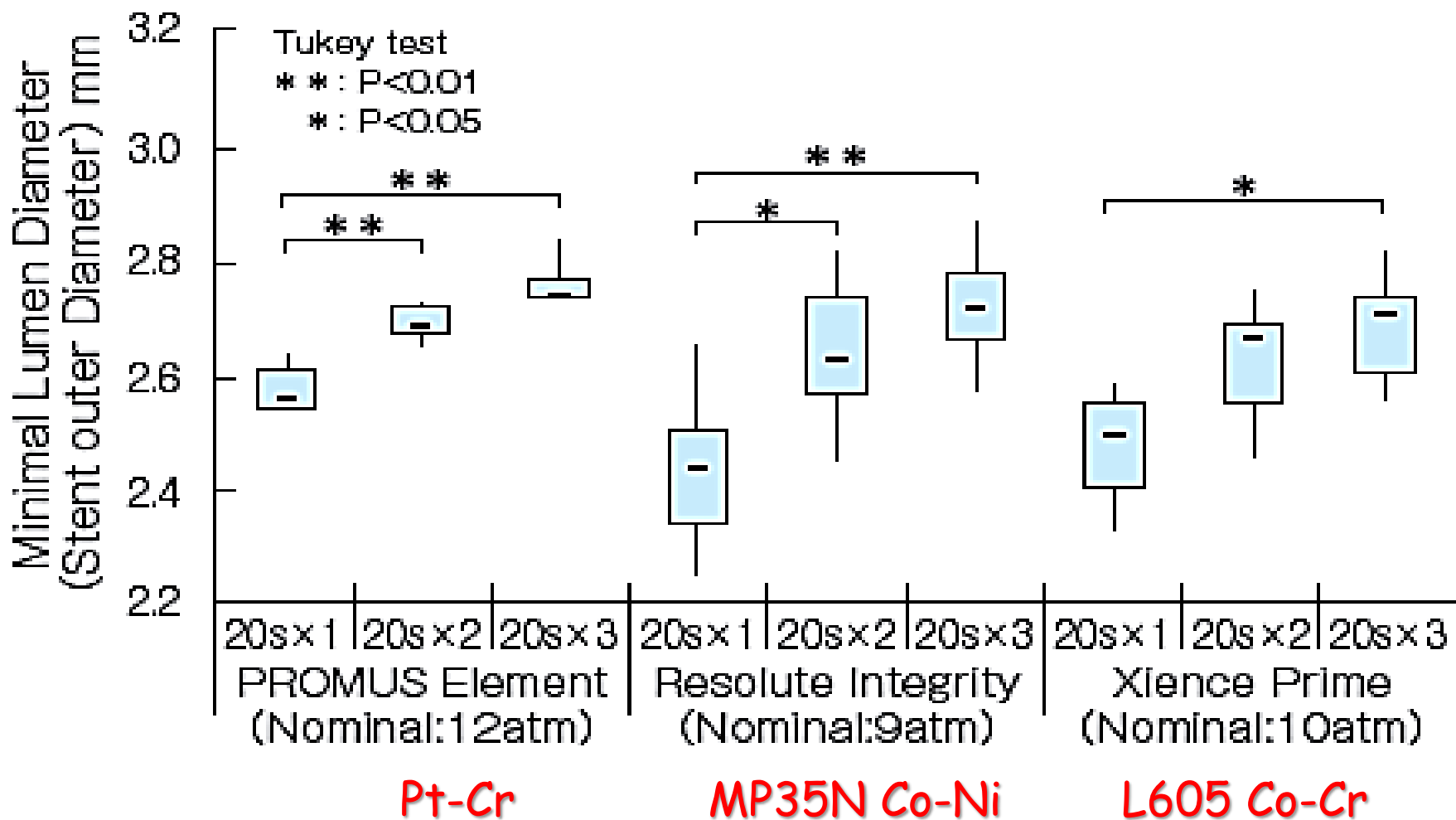
model: The center part is made more firmly than both sides.

Influence of Balloon Inflation Time and Step-by-step Inflation on Minimal Stent Cross-Sectional Areas



Courtesy of Dr. K. Iwasaki

Influence of balloon inflation time on Stent Minimal Lumen Diameter using Digital Microscope (stenotic lesion) (n=6 each)

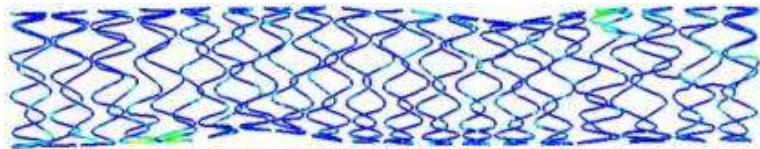


Stent Design and Stent Apposition

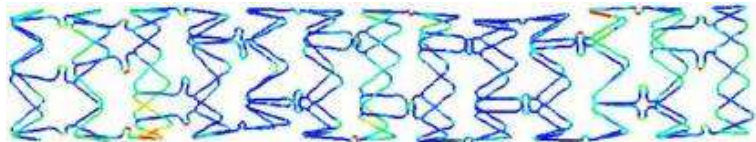
Computer simulation: Resolute Integrity had little incomplete apposition comparison with Xience Prime or Promus Element in the uneven vessel model.

the percentage of distance more than 0.01mm between stent and vessel wall

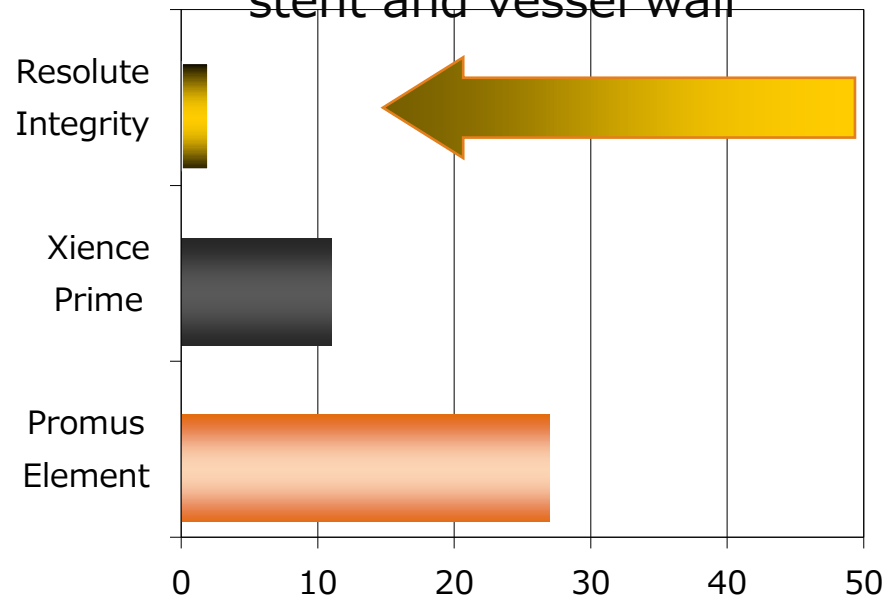
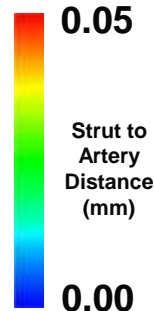
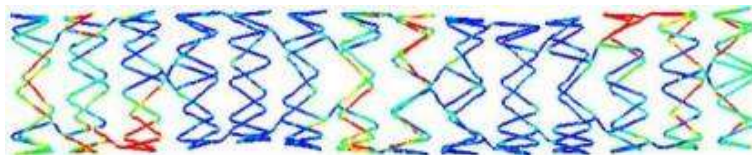
Resolute Integrity
Max distance=40 μ m



Xience Prime
Max distance=68 μ m



Promus Element
Max distance=152 μ m

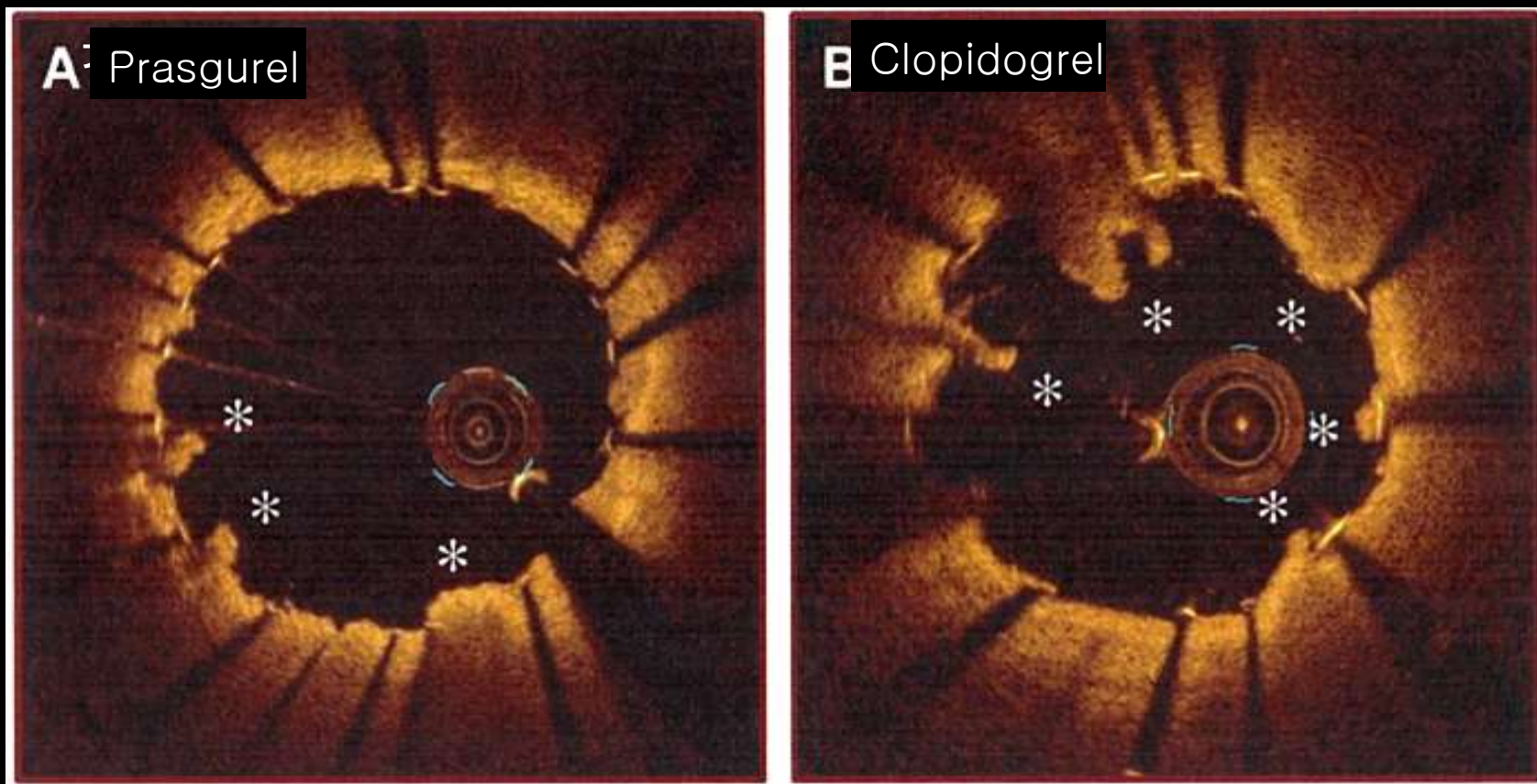


Various studies are accomplished to
reduce plaque protrusion after stenting

Reduction of in-stent thrombus immediately after percutaneous coronary intervention by pretreatment with **prasugrel compared with **clopidogrel**: An optical coherence tomography study**

Kubo T, et al. : J Cardiol 2016 ; doi:10.1016/j.jjcc.2016.04.005.

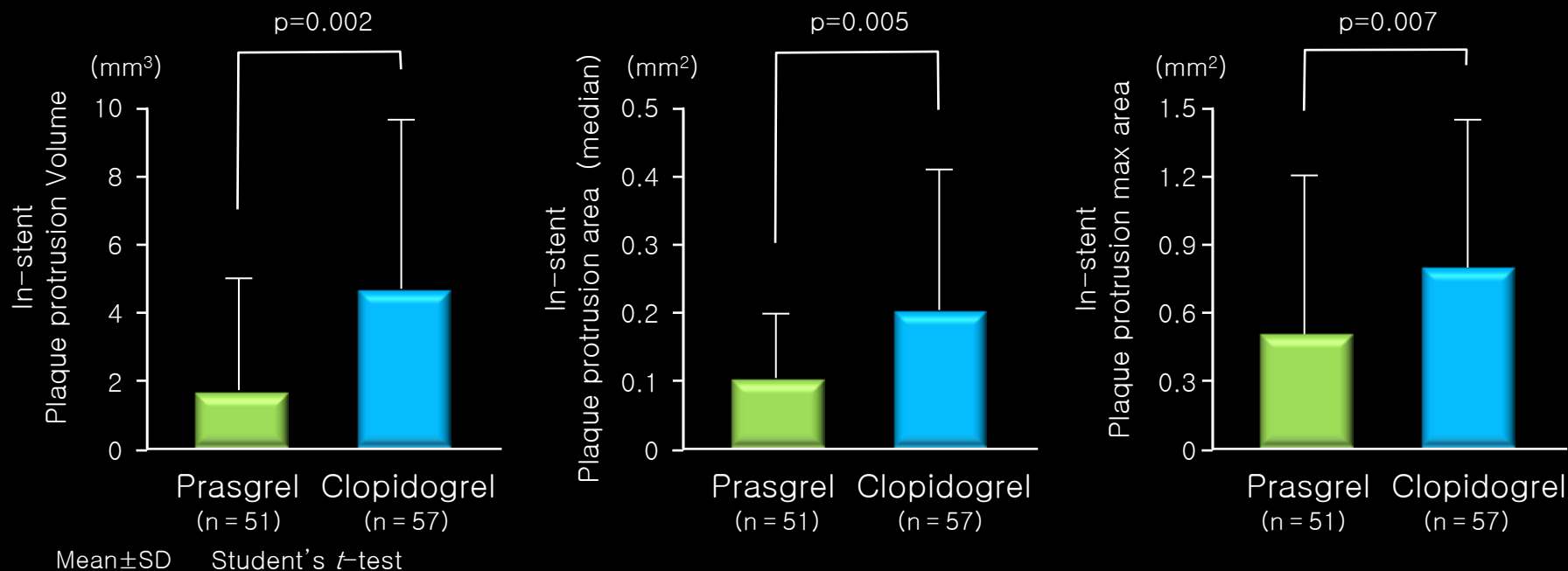
The OCT Image in-stent thrombus just after DES implantation for Acute Coronary Syndrome



* : Plaque protrusion in the stent

In-stent thrombus/Plaque protrusion

Target : ACS 108cases (Prasgrel group 51case, Clopidogrel Group 57case
 Sep. 2013 ~ Aug. 2015 Loading dose: Prasgrel 20mg, Clopidogrel 300mg
 Maintenance dose : Prasgrel 3.75mg, Clopidogrel 75mg
 Aspirin: (LD) 200mg, (MD)100mg。



These results show that Prasgrel is effective in decreasing in-stent plaque protrusion than clopidogrel in the acute coronary syndrome.

Incidence and Clinical Significance of Poststent Optical Coherence Tomography Findings

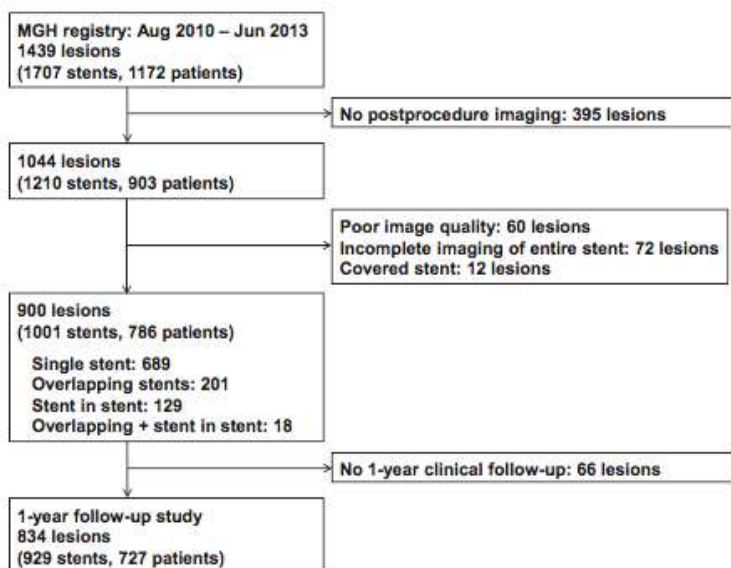
One-Year Follow-Up Study From a Multicenter Registry

Tsunenari Soeda, MD, PhD; Shiro Uemura, MD, PhD; Seung-Jung Park, MD, PhD;
Yangsoo Jang, MD, PhD; Stephen Lee, MD; Jin-Man Cho, MD, PhD;
Soo-Joong Kim, MD, PhD; Rocco Vergallo, MD; Yoshiyasu Minami, MD, PhD;
Daniel S. Ong, MD; Lei Gao, MD, PhD; Hang Lee, PhD; Shaosong Zhang, MD, PhD;
Bo Yu, MD, PhD; Yoshihiko Saito, MD, PhD; Ik-Kyung Jang, MD, PhD

A total of 900 lesions treated with 1001 stents in 786 patients who had postprocedure OCT imaging were analyzed to evaluate the incidence of post stent OCT findings and to identify the OCT predictors for device-oriented clinical end points, including cardiac death, target vessel-related myocardial infarction, target lesion revascularization, and stent thrombosis.

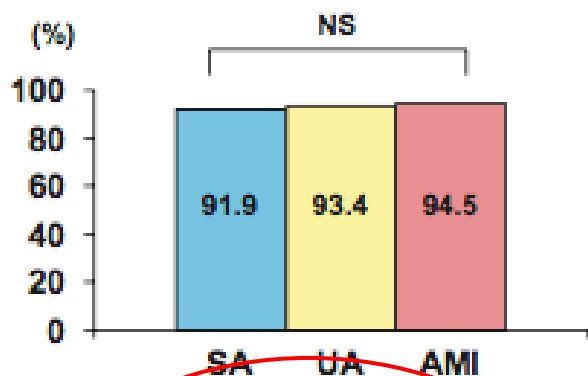
Patients were followed up to 1 year.

- Stent edge dissection was detected in 28.7% of lesions.
- Incomplete stent apposition was detected in 39.1% of lesions.

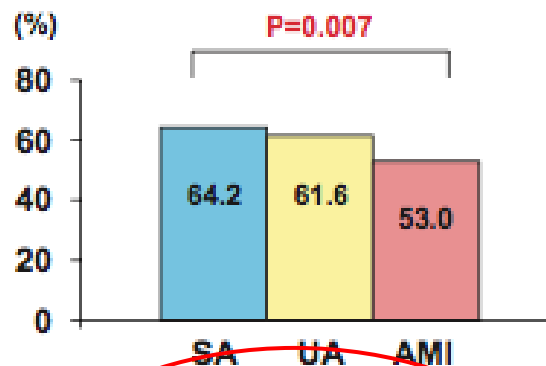


Acute results

A Smooth protrusion

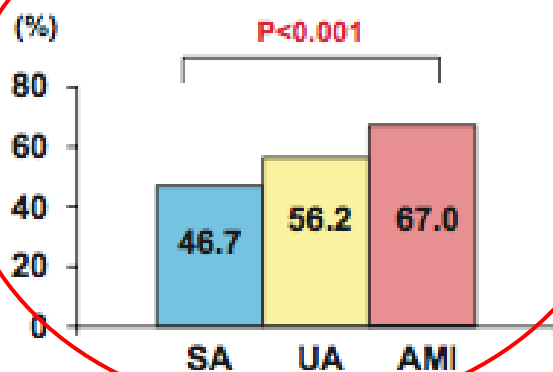


B Disrupted fibrous tissue protrusion

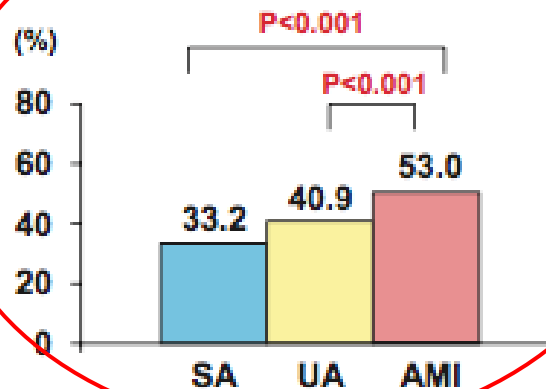


SA: Stable Angina
UA: Unstable Angina

C Irregular protrusion



D Thrombus



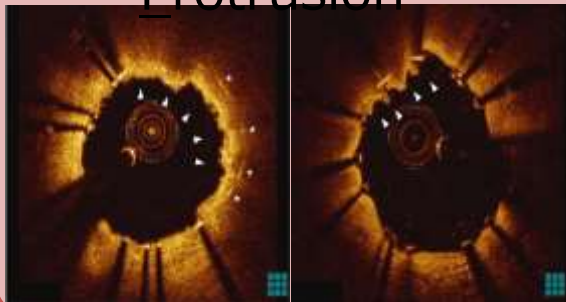
- The incidences of smooth protrusion, disrupted fibrous tissue protrusion, and irregular protrusion were 92.9%, 61.0%, and 53.8%, respectively.

Incidence and Clinical Significance of Poststent Optical Coherence Tomography Findings: One-Year Follow-Up Study From a Multicenter Registry

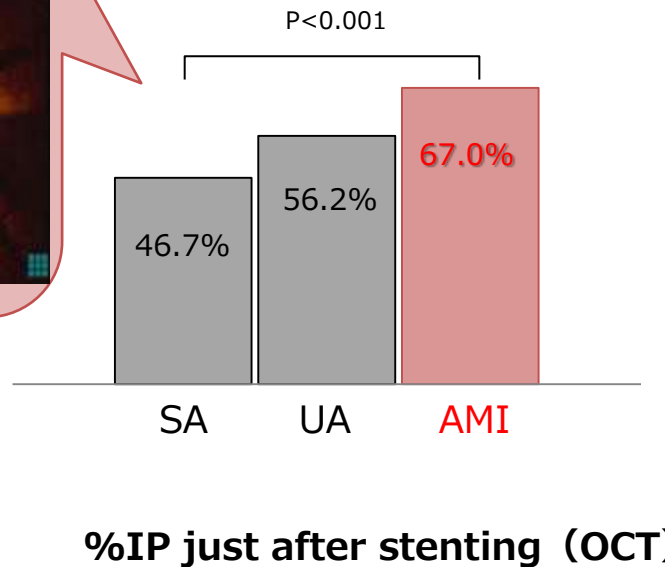
T Soeda, MD, PhD, et al. *Circulation*. 2015;132:1020-1029

786 patients, 900 lesions (1001 stents)

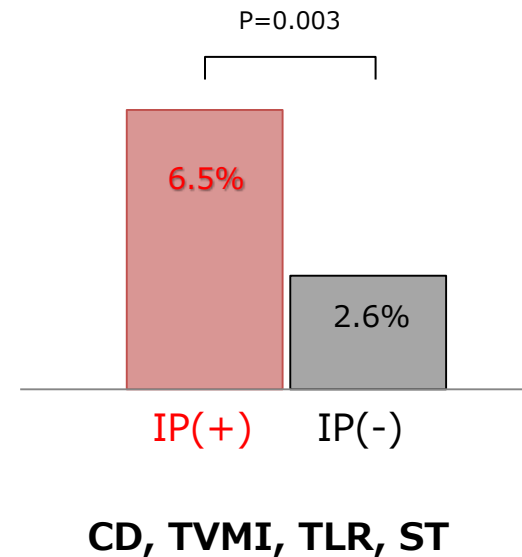
Irregular Protrusion



material of irregular shape is observed protruding between stent struts



臨床転帰 @ 1年



Irregular protrusion was independent predictors of 1-year device-oriented clinical end points, Cardiac Death, Target vessel MI, in-stent thrombosis

Stent design and Plaque Protrusion

investigation of prolapse volume inside cell of stent platform

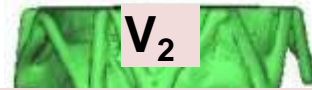
- We made the precise stenosis model which worked as plaque prolapse after stenting.
- After stenting in the 75% stenotic phantom model, we calculated prolapse volume inside cell of stent platform using micro CT.
- Resolute Integrity, Xience Xpedition, Ultimaster, Synergy (n=6)

Calculating V_0 : Volume prolapsed inside stent cell

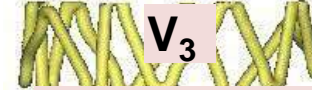
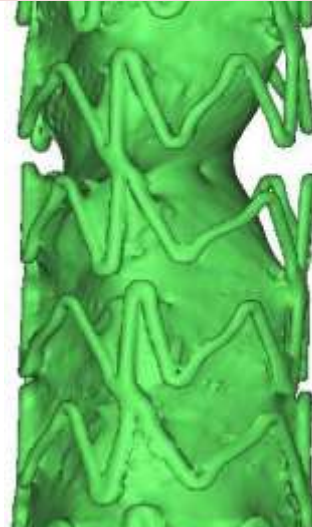
$$V_0 = V_1 - (V_2 - V_3)$$



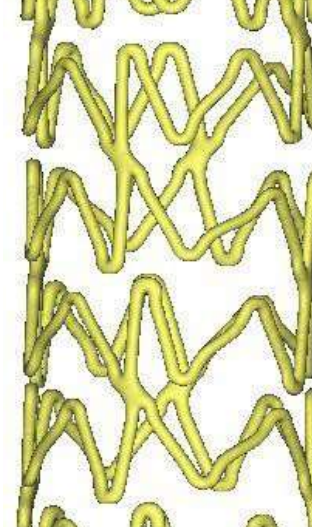
Total Volume of Phantom



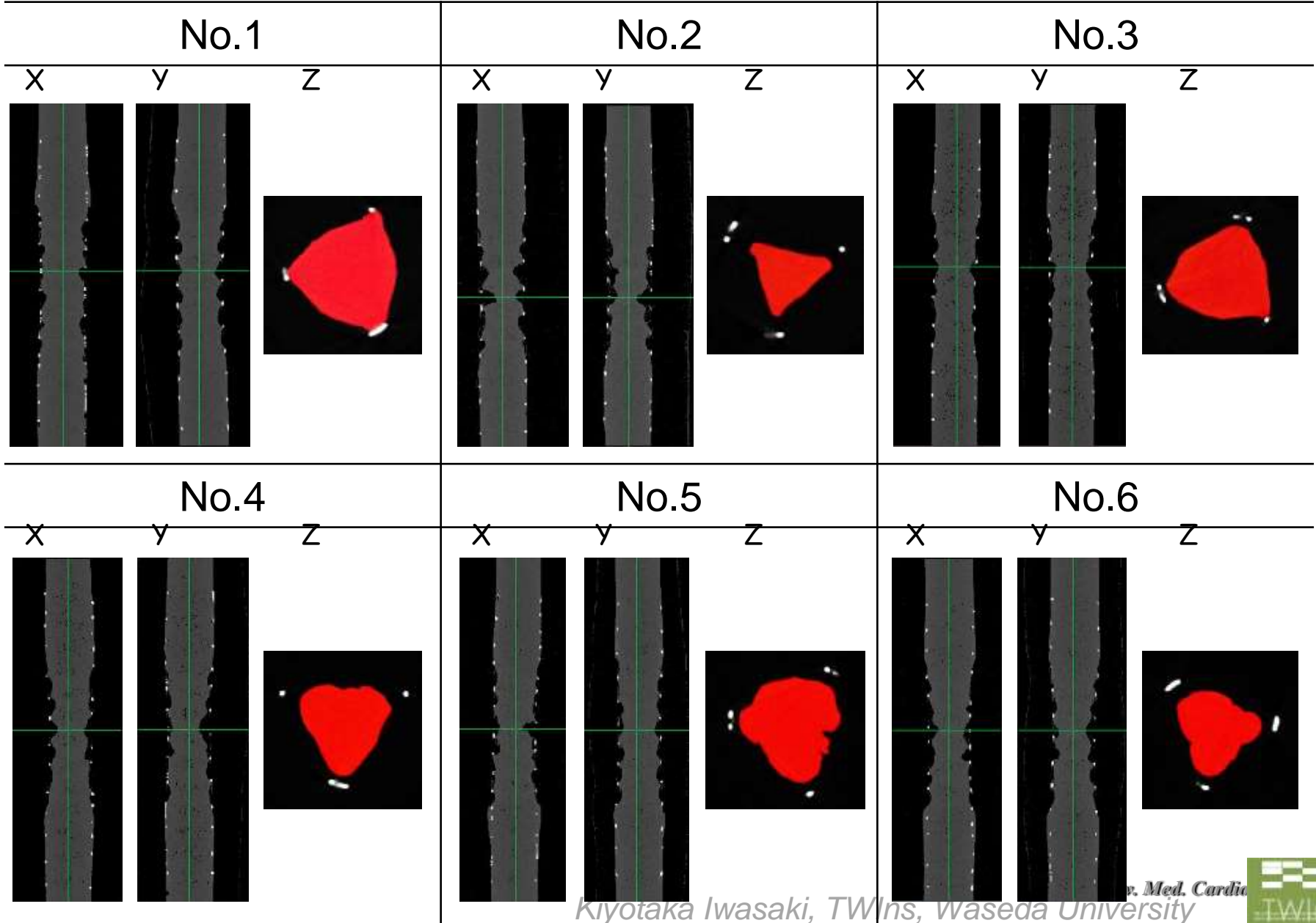
volume of contrast + stent



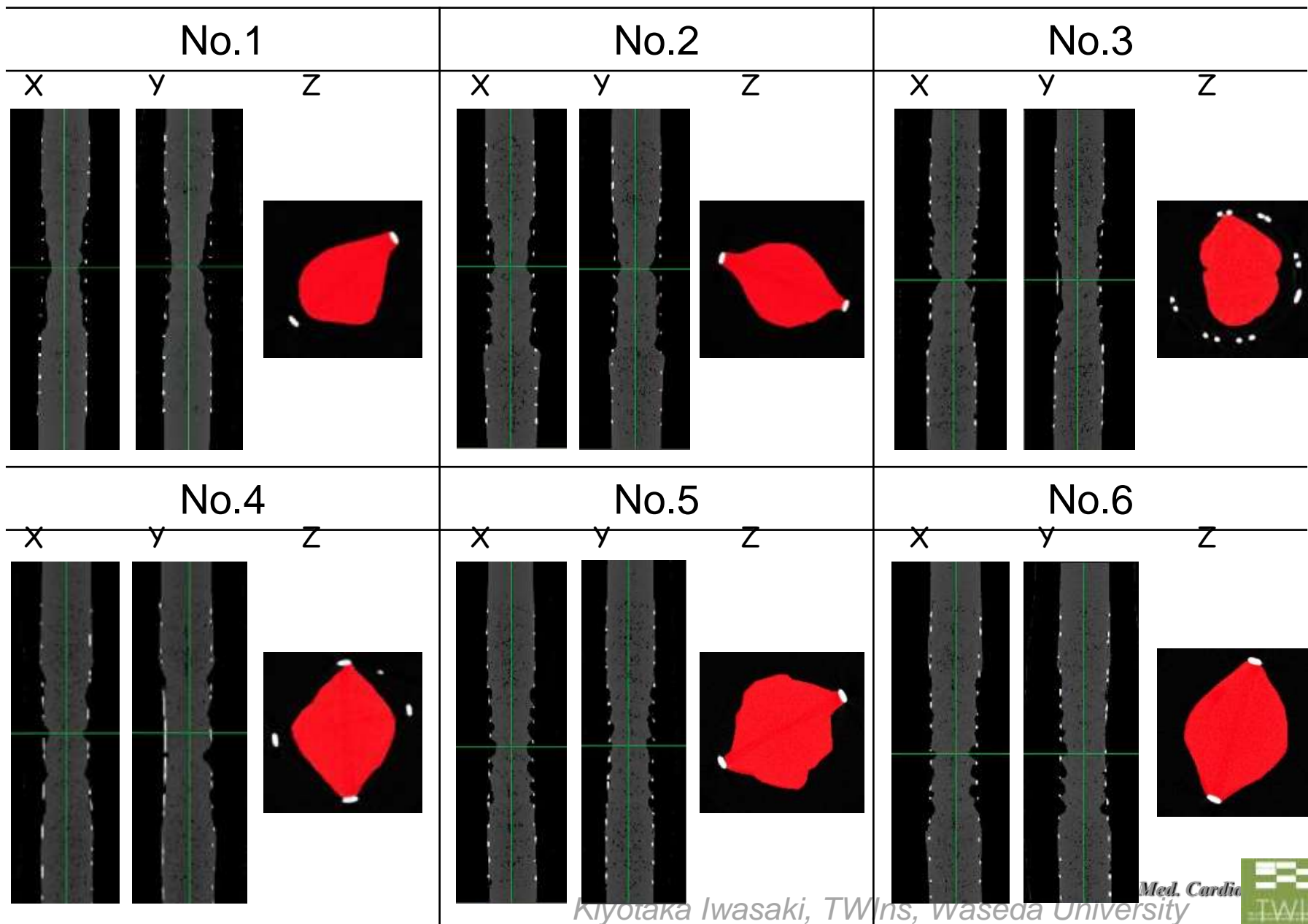
volume of stent



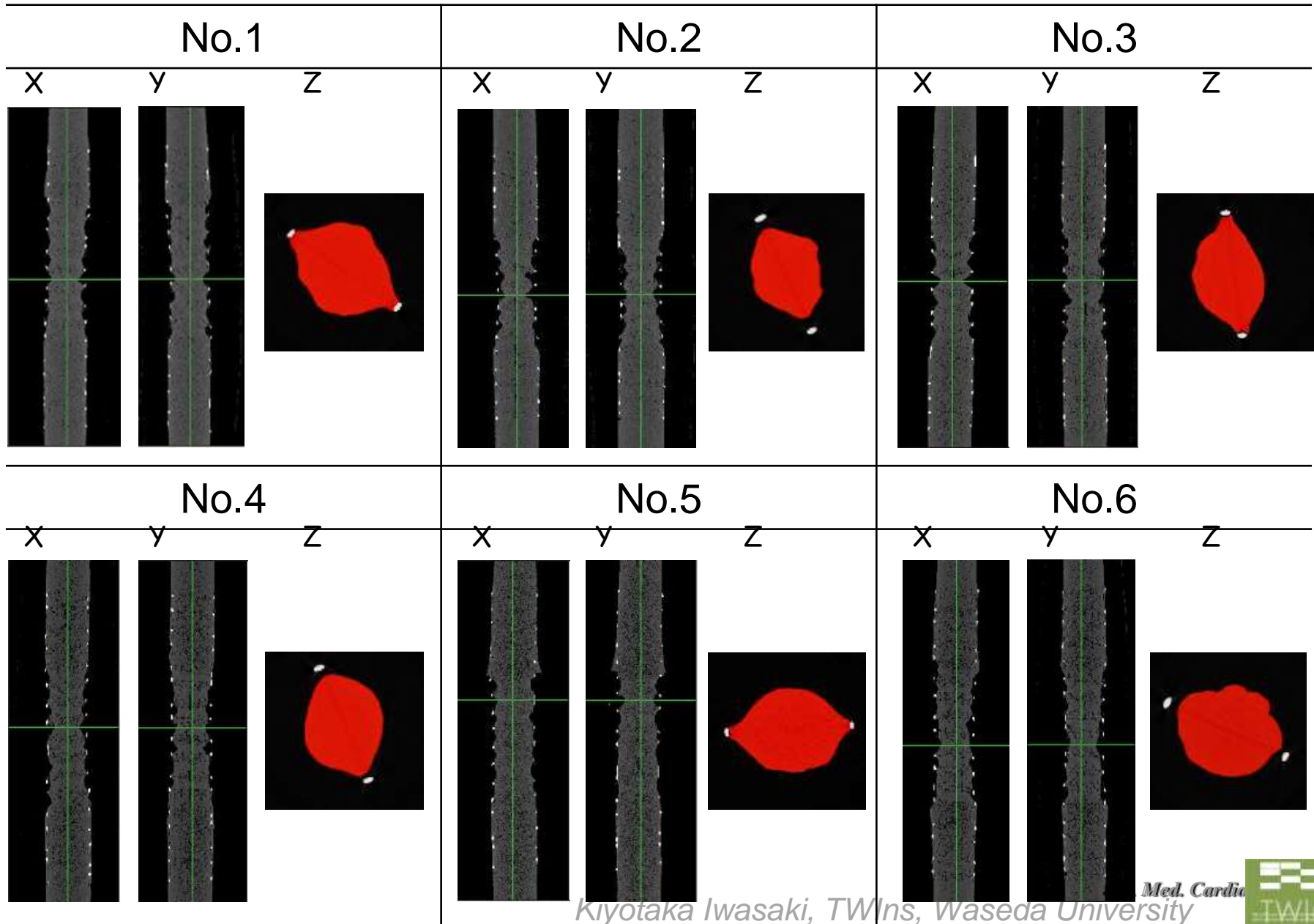
The Minimal Cross-Sectional Area: *Xience Xpedition*



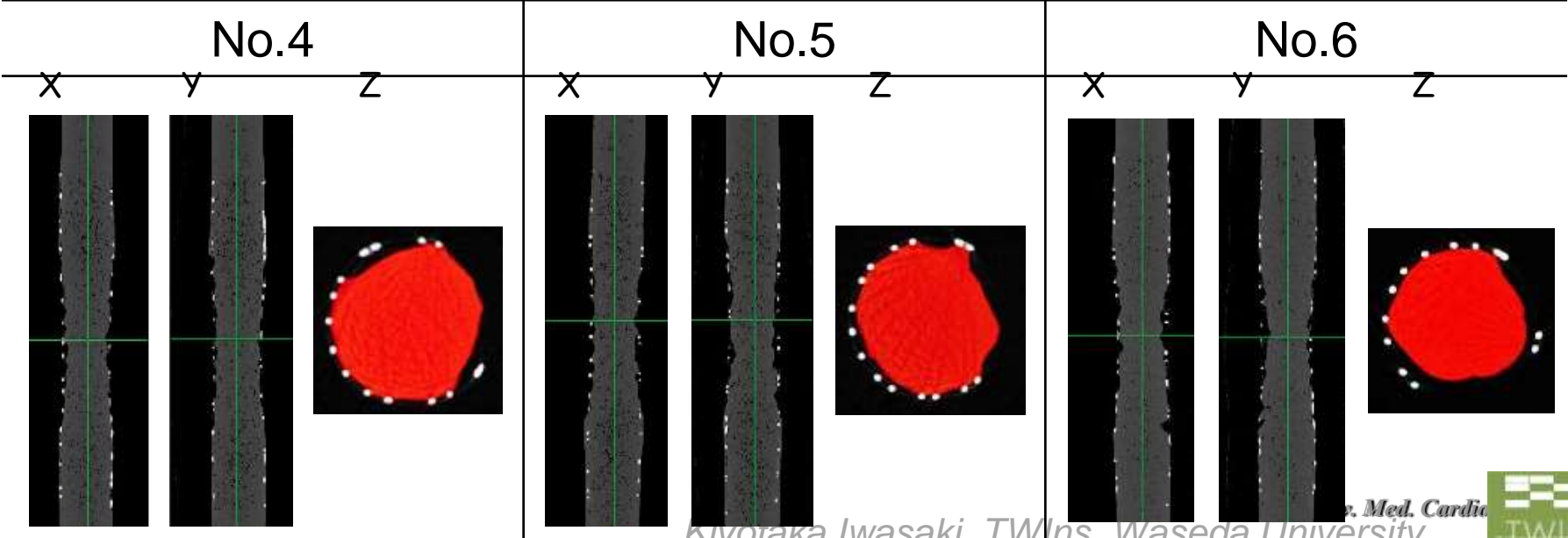
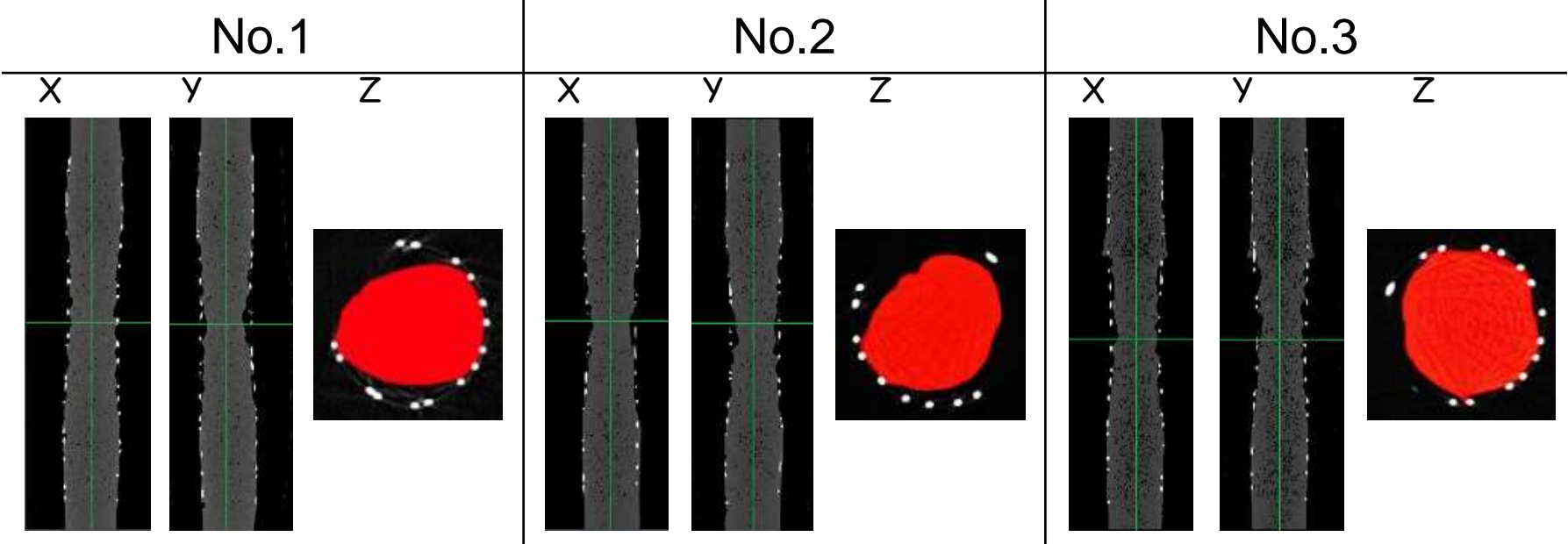
The Minimal Cross-Sectional Area: **Ultimaster**



The Minimal Cross-Sectional Area: SYNERGY

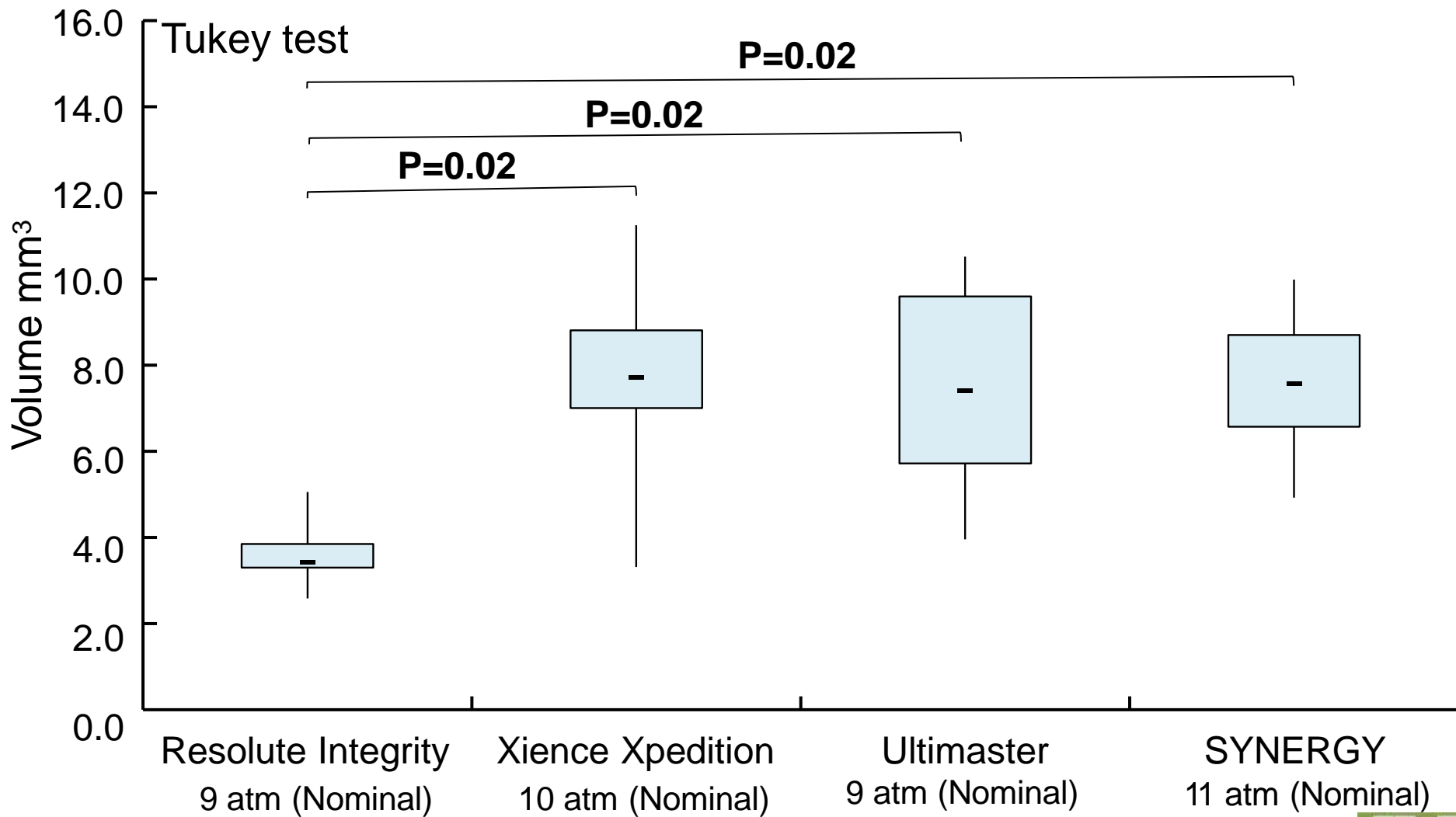


The Minimal Cross-Sectional Area: *Resolute Integrity*



Prolapse volume inside cell of stent platform

Prolapse volume of Resolute was significantly low than other DES. It was suggested that Resolute dense cell design controlled prolapse



The comparison of tissue prolapse just after implantation DES in Acute coronary syndrome

Nakamura T, Okamura T 2013.9 J Cardiol 8[Suppl I] : 603

Everolimus-eluting stent(EES) 6case
Biolimus-eluting stent(BES) 6case
Zotarolimus-eluting stent(ZES) 6case

◆ Lesion & procedural characteristics

	EES	BES	ZES	P value
Treated artery LAD	5	5	1	
LCx RCA	1	0	1	
	0	1	4	
Number of stents used	1	1	1.2±0.4	0.391
Stent length(mm)	20.8±3.49	19.3±3.93	20.2±5.31	0.835
Stent diameter(mm)	2.71±0.25	3.04±0.40	2.83±0.38	0.275
MBP(atm)	19.7±2.0	18.7±3.5	18.8±5.2	0.889
QCA				
Reference diameter	3.27±0.47	3.35±0.30	3.13±0.51	0.681
MLD	0.73±0.7	0.75±0.12	0.94±0.44	0.360
Final MLD	2.34±0.23	2.67±0.41	2.40±0.39	0.251
%DS	77.4±3.3	77.3±4.9	71.1±8.3	0.142
Final %DS	27.1±13.8	20.6±6.7	22.7±10.8	0.575



Measurement



Lumen area(LA)
Stent area(SA)
Tissue prolapse area(TPA)
Prolapse height(PH)

◆ OCT data

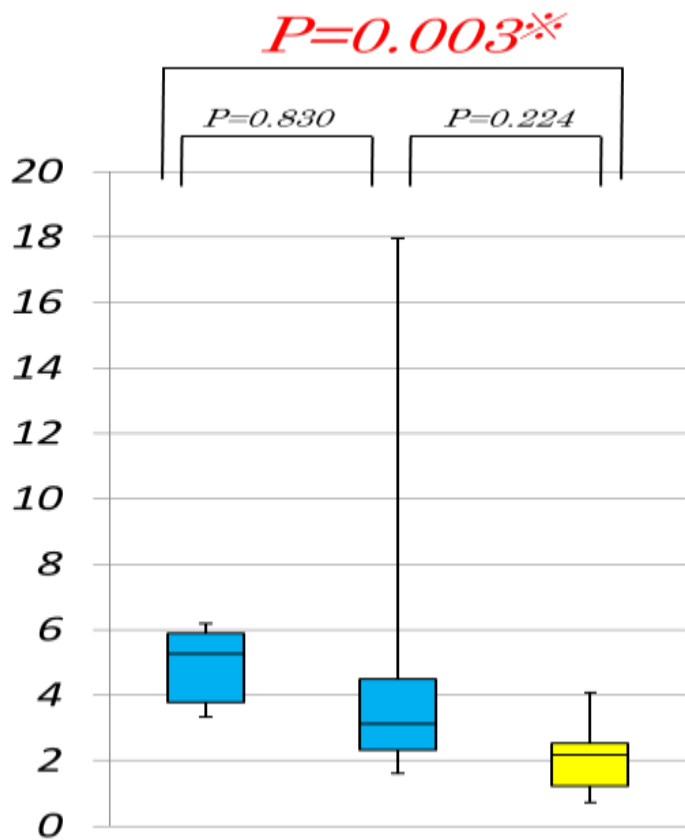
	EES	BES	ZES	P value
N(frame)	113	120	125	
LA(mm ²)	5.91±1.80	7.48±1.47	6.69±2.18	0.000
SA(mm ²)	6.24±1.87	7.79±1.39	6.77±2.17	0.000
TP(frame)	99(87.6%)	108(90%)	86(68.8%)	0.000

MBP:Maximum balloon pressure
MLD:minimum lumen diameter
%DS: percent diameter stenosis

The comparison of tissue prolapse just after implantation DES in Acute coronary syndrome

★ **TPV:** tissue prolapse volume

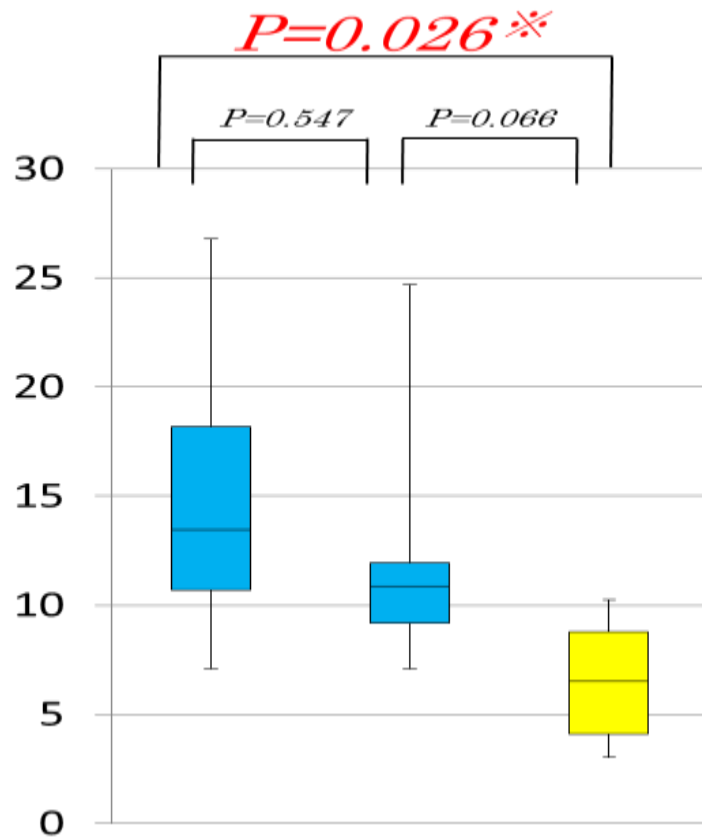
★★ **MTPA:** maximum tissue prolapse area



Xience

Nobori

Resolute



Xience

Nobori

Resolute

Early Phase Arterial Reaction Following Drug-Eluting and Bare-Metal Stent Implantation in Patients With ST-Segment Elevation Myocardial Infarction Optical Coherence Tomography Assessment at 2 Weeks

Ryo NISHIO,¹ MD, Toshiro SHINKE,¹ MD, Yoshihiro MORINO,² MD, Kengo TANABE,³ MD, Jungo FURUYA,⁴ MD, Kaname TAKIZAWA,⁵ MD, Junya AKO,⁶ MD, Ken KOZUMA,⁷ MD, Kiyoshi HIBI,⁸ MD, Hideki ISHII,⁹ MD, Atsushi HIROHATA,¹⁰ MD, Yoritaka OTSUKA,¹¹ MD, Hiromasa OTAKE,¹ MD, Tomofumi TAKAYA,¹ MD, and Ken-ichi HIRATA,¹ MD

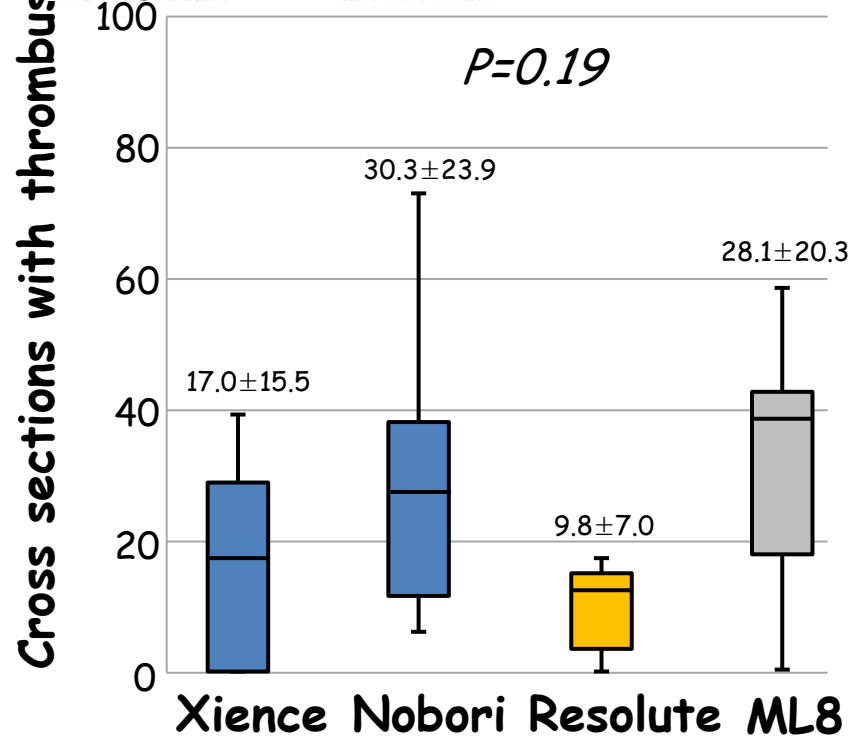
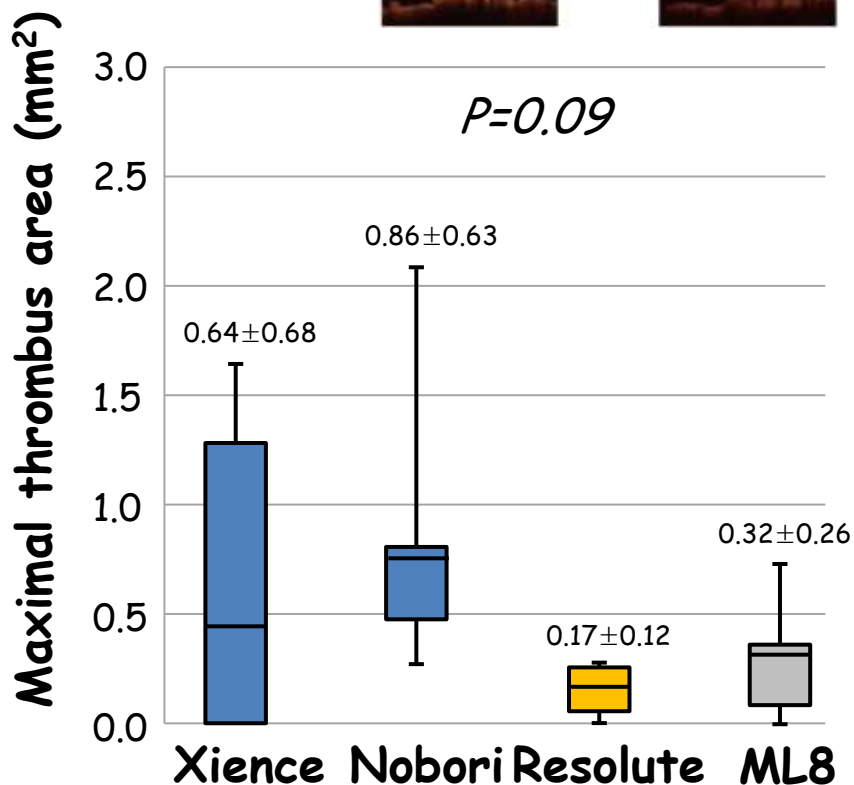
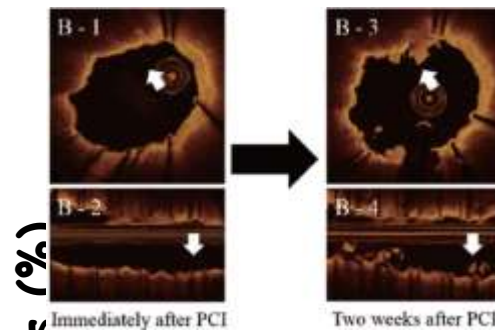
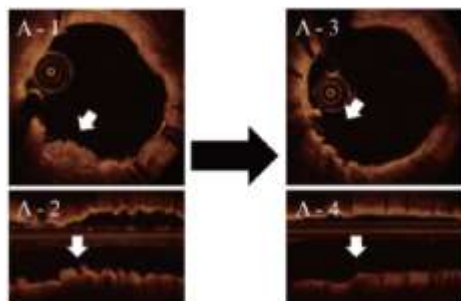
The MECHANISM pilot study is a multi-center prospective registry that enrolled 24 STEMI patients (from 11 centers) who had undergone implantation of everolimus-eluting (n = 6), biolimus A9-eluting (n = 6) or zotarolimus-eluting stents (n = 6), or BMS (n = 6). Scheduled optical coherence tomography (OCT) was performed 2 weeks after implantation.

More than 90% of struts were already covered 2 weeks after the index procedure, regardless of the stent type. There were no differences in stent diameter, minimal lumen diameter, minimal lumen area, neointimal thickness, or the frequencies of malapposed and uncovered struts among the 4 groups.

The quantity of intra-stent thrombus also did not differ among the 4 groups.

Early Phase Arterial Reaction Following Drug-Eluting and Bare-Metal Stent Implantation in Patients With ST-Segment Elevation Myocardial Infarction Optical Coherence Tomography Assessment at 2 Weeks

Ryo Nishio MD, Toshiro Shinke MD et al. *Int Heart J* 2015; 56: 389-394



Resolute dense cell and helical design will reduce plaque protrusion

Resolute Integrity



0.9mm²

Xience



5.4mm²

Ultimaster



7.8mm²

Promus/Synergy



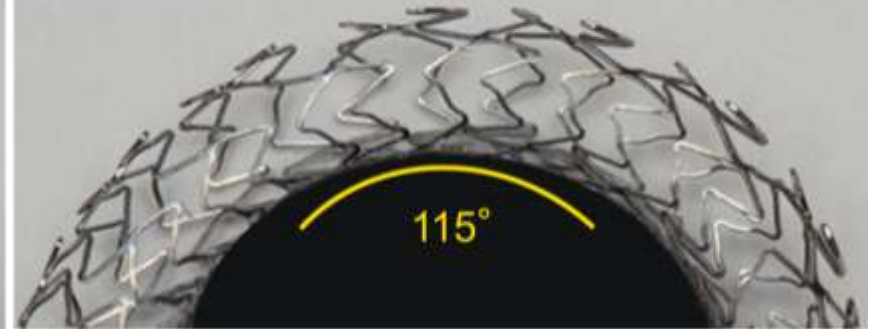
6.7mm²

Resolute Integrity



115°

Ultimaster



115°

Bench test data of 3.5 mm stents on file at Medtronic.

Conclusion

- All stents are formed by different materials and different designs. Each stents has each suitable expansion methods.
- Three times stent inflation method is effective to take big minimal stent area, and to reduced stent recoil.
- Irregular protrusion inside cell of stent platform was independent predictors of 1-year device-oriented clinical end points, Cardiac Death, Target vessel MI, in-stent thrombosis.
- Resolute reduces the irregular protrusion in the Acute Coronary Syndrome.