

TCT Asia 2006

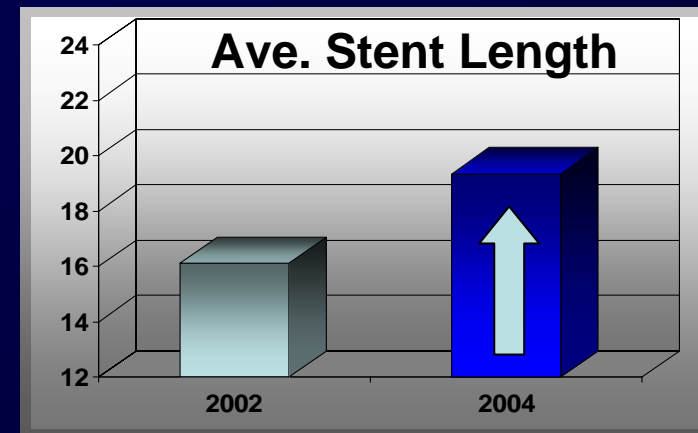
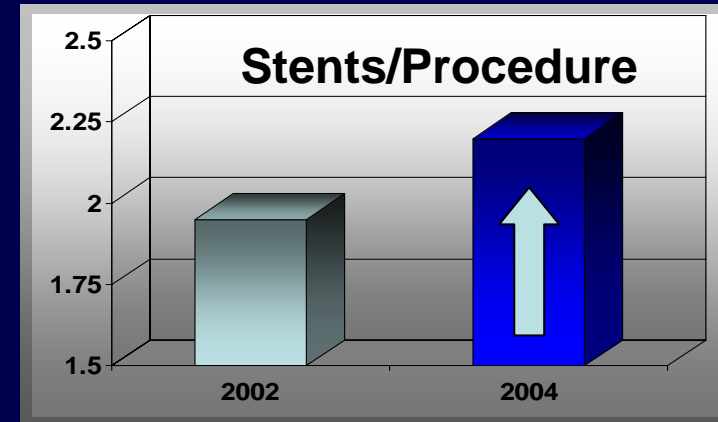
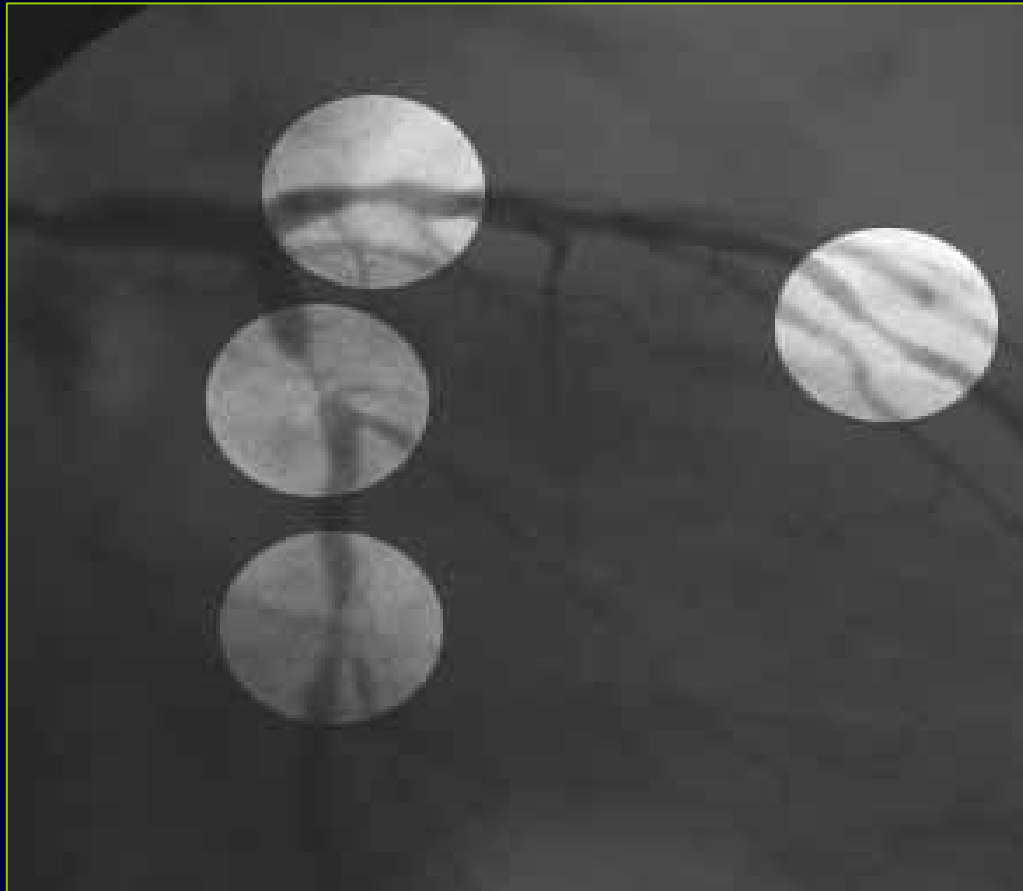
**The Xtent DES System: The Single
Solution for Multi-Lesion, Multi-
Vessel, and Long Lesion Treatment**

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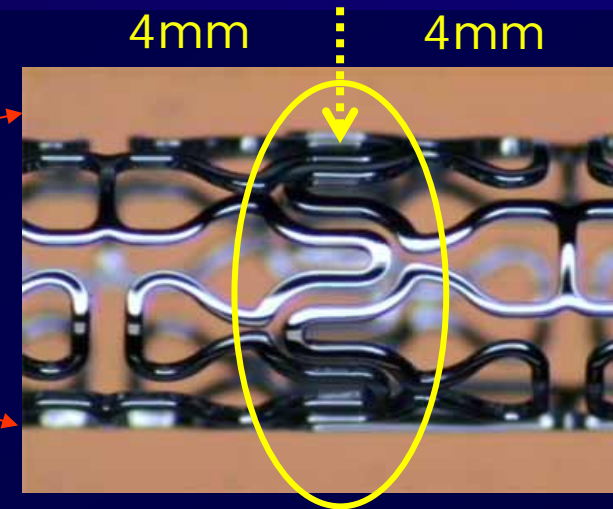
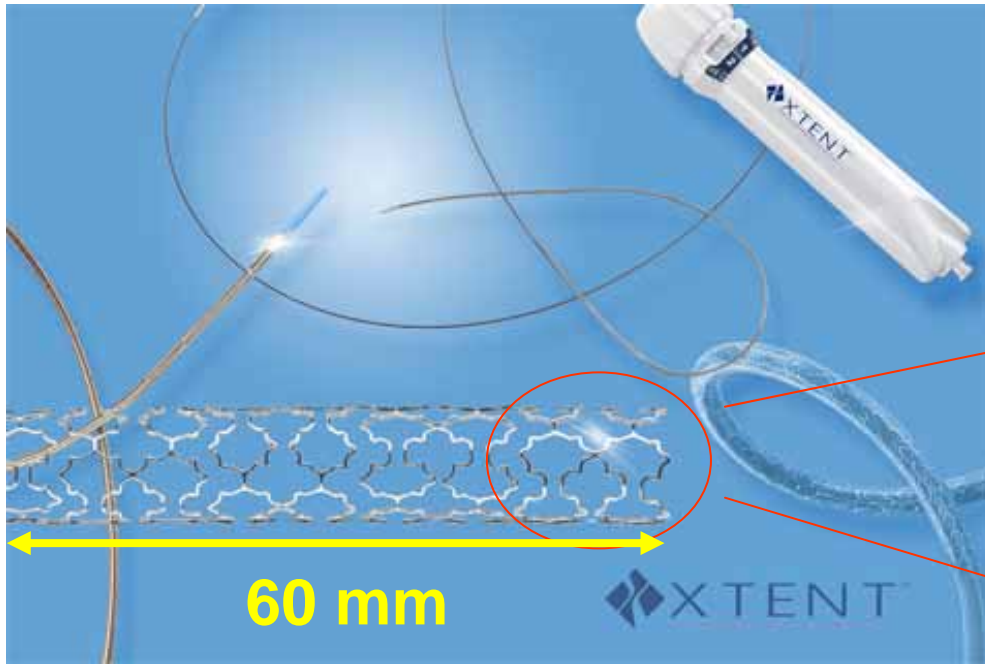
Current DES Environment (Background)

Long lesion & Multi-Lesion Treatment on the Rise



High Volume Hospital Survey

The Xtent System



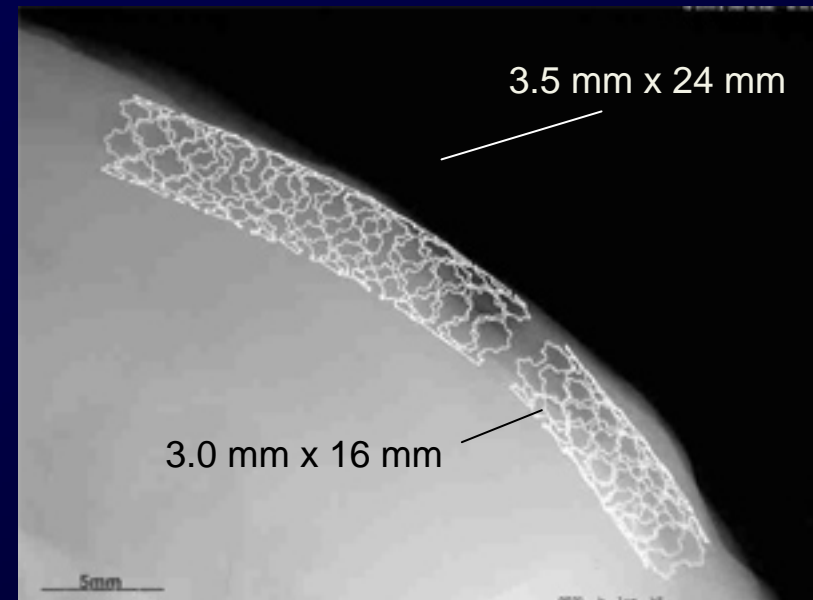
Interdigitated stent design

Stent: X tent (4 mm Segments
60 mm total length)

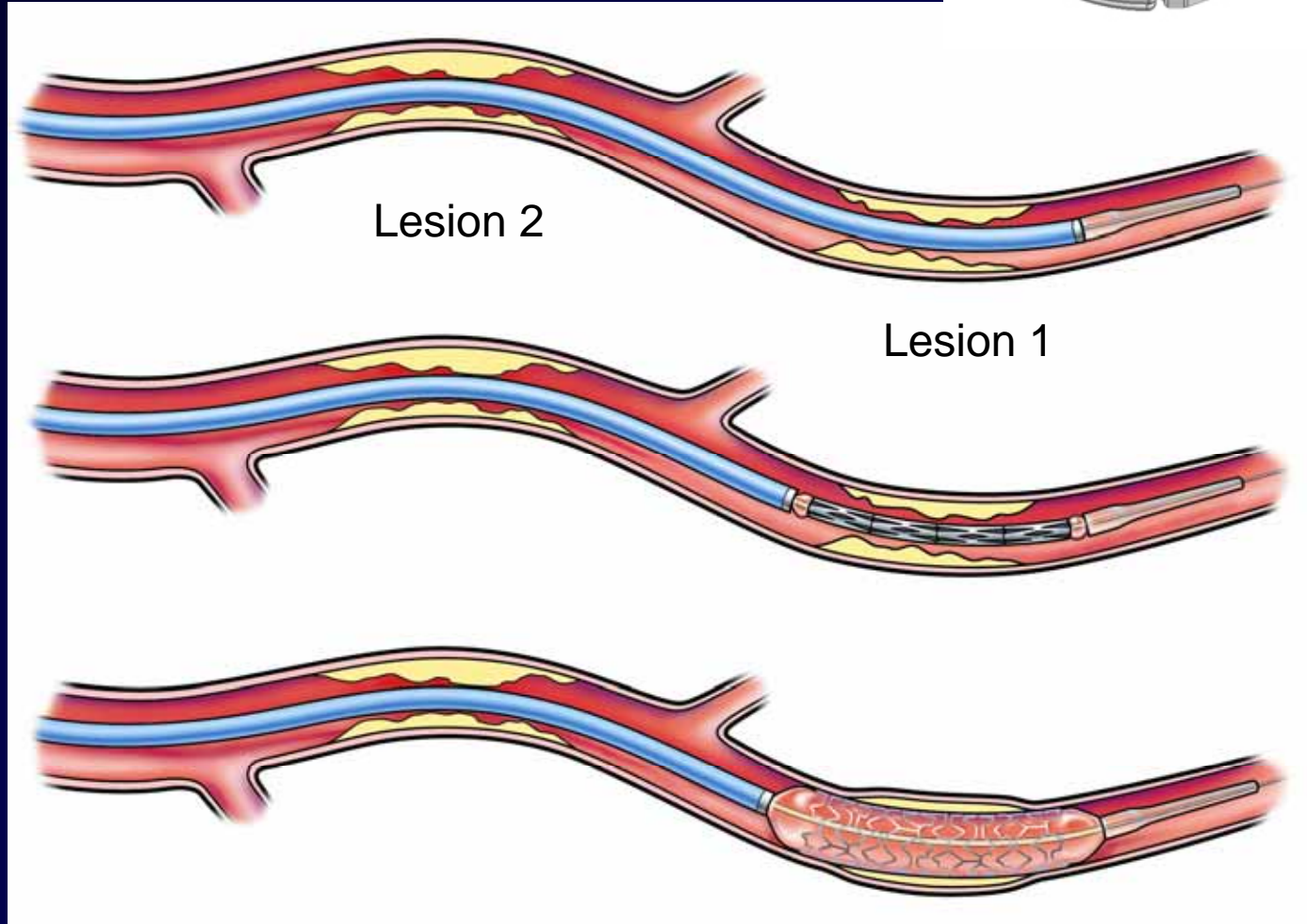
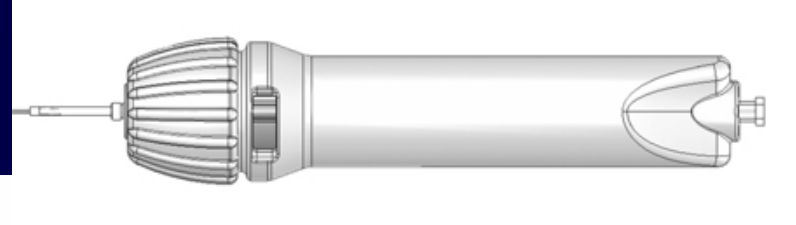
Delivery System: Sheath protected,
Balloon expandable

Coating: PLA bioabsorbable

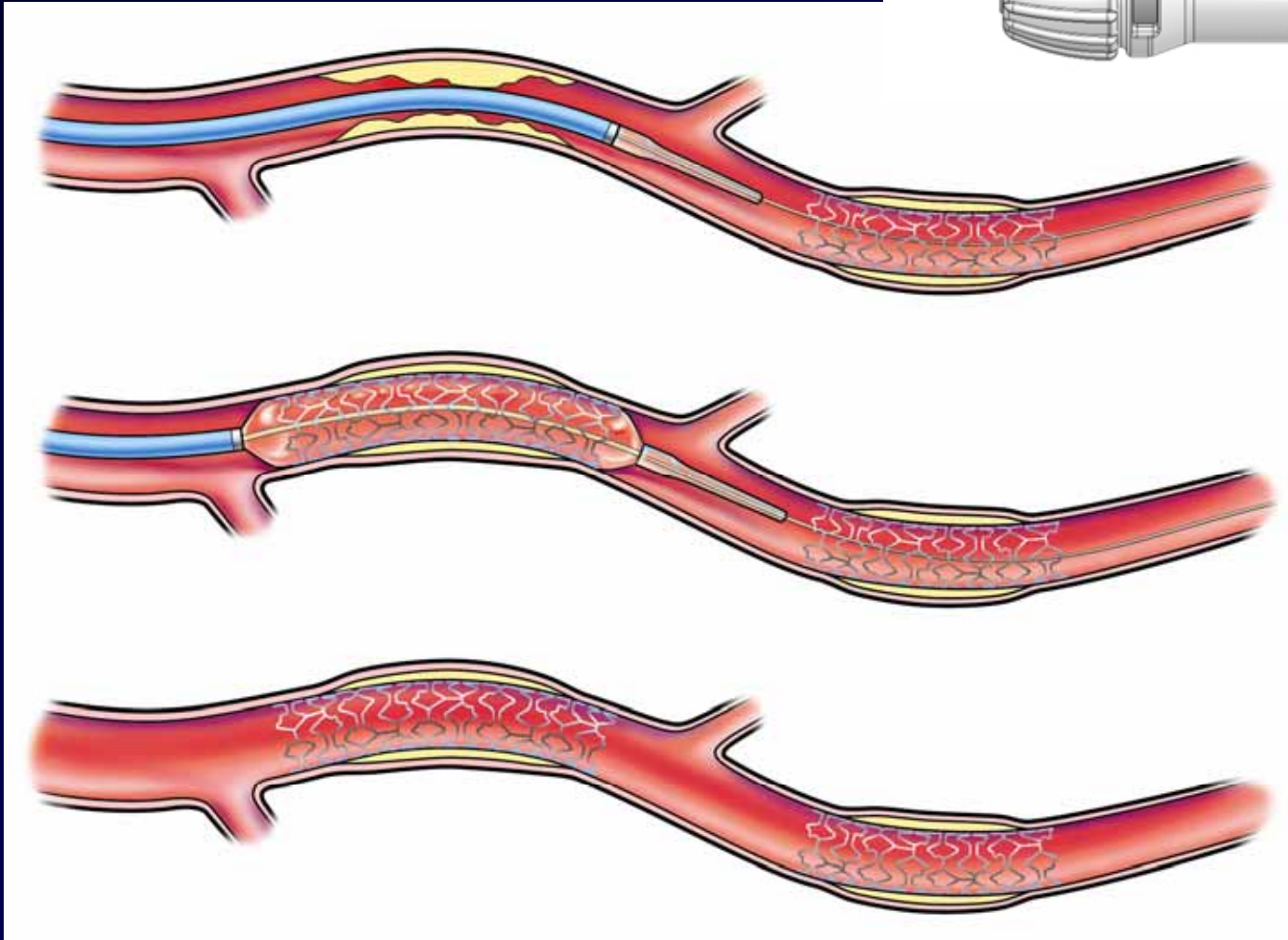
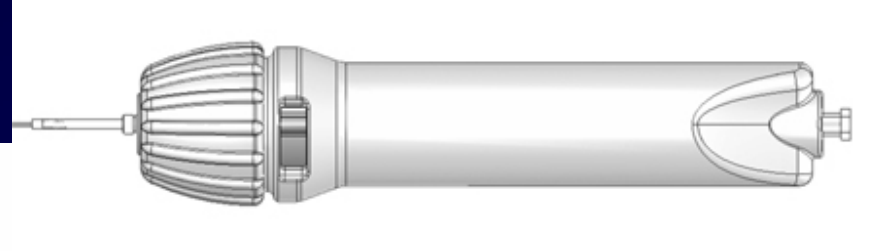
Drug: Biolimus A9



Customize Stent Length to Lesion #1



Customize Stent Length to Lesion #2



CUSTOM I Study Design

Prospective, multi-center Registry

n = 30

Up to two *de novo* Lesions / pt
Customized stent treatment up to 36 mm

- PI: Eberhard Grube MD
- Stent Size: 3.0 x up to 36 mm of customizable length
- Vessel size: 2.8 – 3.2 mm
- Clinical follow-up: 1, 4, 8 months then annually for 5 years
- Angiographic and IVUS follow-up at 4 months (n=10) and 8 months (n=20)
- Clopidogrel 3 months plus Aspirin

ACC/i2 = 4 months follow up results

n = 30

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Study Coordination

Investigational Centers

- Herzzentrum Siegburg, Prof. Grube Siegburg, Germany
- Barmherzige Brueder, Dr. Hauptmann, Trier, Germany
- Sankt Katharinen, Prof. Sievert Frankfurt, Germany

Core labs

- University of Florida Core Imaging Laboratories
Marco Costa M.D., PhD, Jacksonville FL USA
- Cardiovascular Core Analysis Lab
Peter Fitzgerald MD, PhD Stanford CA, USA

Monitoring

- CardioNow System, Heartlab-Agfa-Gevaert USA
- KRAUTH-Group, Hamburg, Germany

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Endpoints

Primary Endpoint

- MACE at 8 months

Secondary Clinical Endpoints

- MACE at 30 days, 120 days, 1,2,3,4 and 5 years
- Rate of acute or sub-acute thrombosis

Secondary Endpoints (QCA and IVUS)

- In-stent and in-segment
 - binary restenosis rate
 - late loss
 - % diameter stenosis
- In-stent % volume obstruction

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Patient Demographics (n=30)

Age (yrs) (mean \pm SD)	67.3 \pm 7.9
Male Gender	19
Female Gender	11
Previous MI	16.7%
Previous Intervention	26.7%
Diabetes mellitus	30.0%
Hyperlipidemia	80.0%
Hypertension	76.7%
History of smoking	23.3%
Family history CAD	10.0%

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Baseline - Lesion Characteristics

Location of lesion

LAD	40.0%
RCA	33.3%
LCX	26.7%

Lesion classification

Type A	0%
Type B1	40.0%
Type B2	56.7%
Type C	3.2%

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In-Stent Baseline QCA

Pre-Procedure

Lesion length (mm)	16.67 ± 9.3
RVD (mm)	2.62 ± 0.35
MLD (mm)	0.98 ± 0.4
DS (%)	62.8 ± 14.11

Post- Procedure

MLD (mm)	2.45 ± 0.32
DS (%)	14.48 ± 7.56
Acute gain (mm)	1.48 ± 0.39

Stent length (mm)

1 st stent (mean ± SD)	25.7 ± 6.6
2 nd stent (mean ± SD) (n=4)	17.3.0 ± 4.6

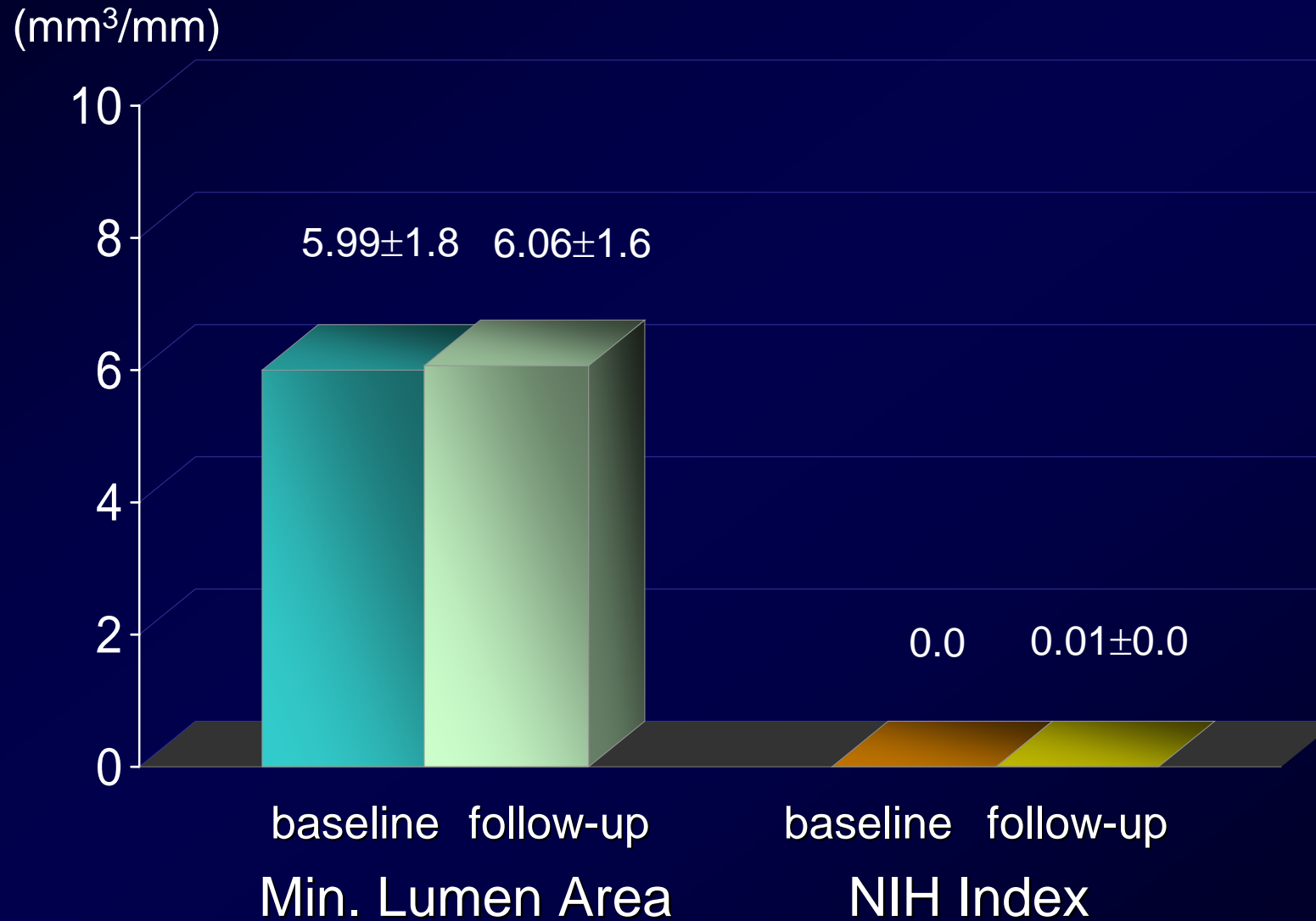
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QCA Analysis at 120-day follow-up – in-stent

	Post procedure n=10	120 days n=10
MLD (mm)	2.45 +/- 0.32	2.25 +/- 0.36
Diameter Stenosis (%)	14.5 +/- 7.6	15.8 +/- 8.2
Late loss (mm)	-	0.28 +/- 0.29
Late loss index	-	0.19
Binary restenosis rate (%)	-	0

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IVUS - Serial MLA & NIH Index – in-stent



N=9

Siegburg / Stanford

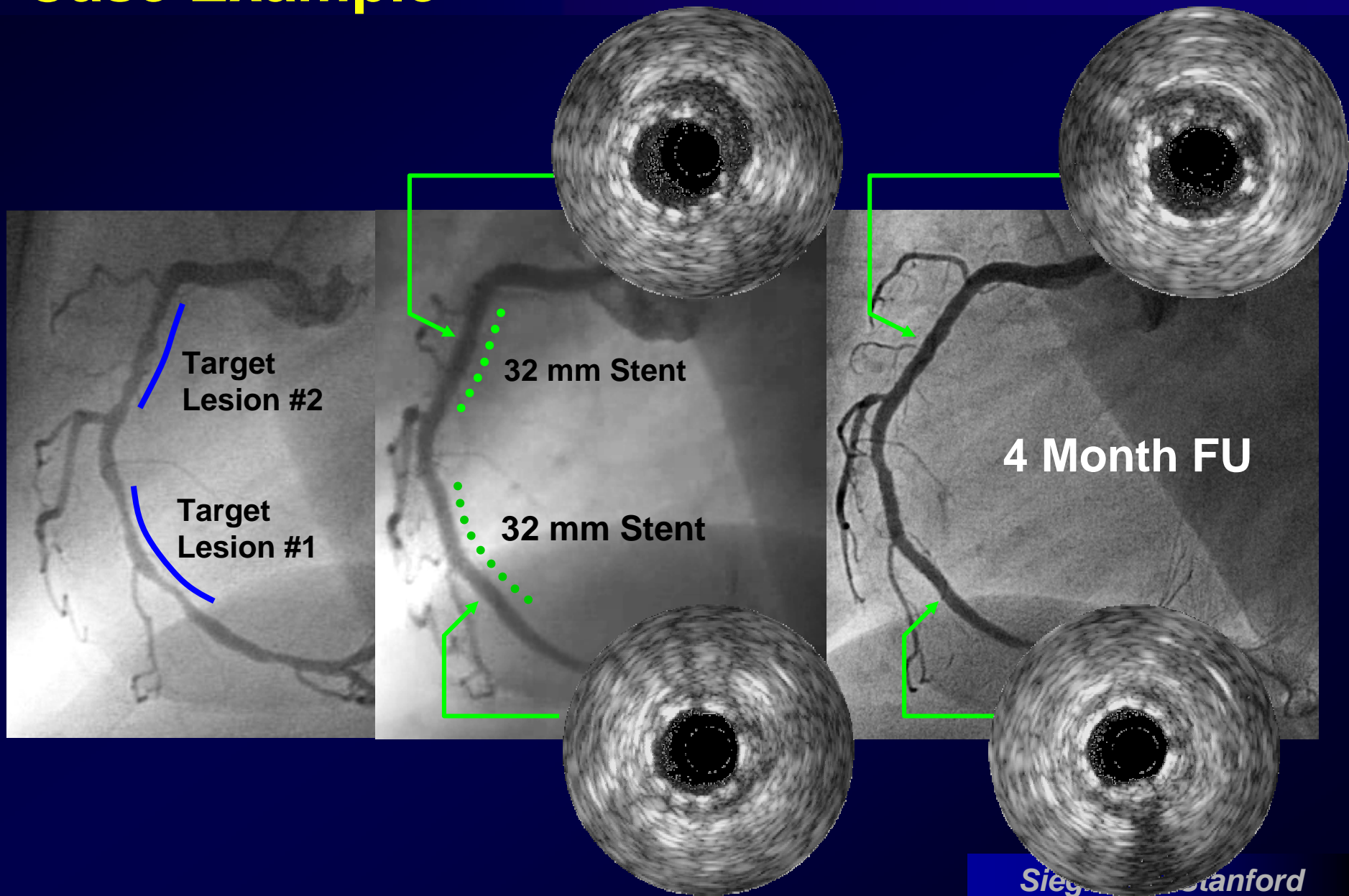
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Clinical Outcome - MACE

	0-30 Days n=30	30- 120 Days n=30
Cardiac death (n)	0	0
MI (n) Q-wave	0	0
Non Q-wave*	2	0
Clinically driven		
TLR-CABG (n)	0	0
TLR-PCI (n)	0	0
Total MACE (n)	2	0

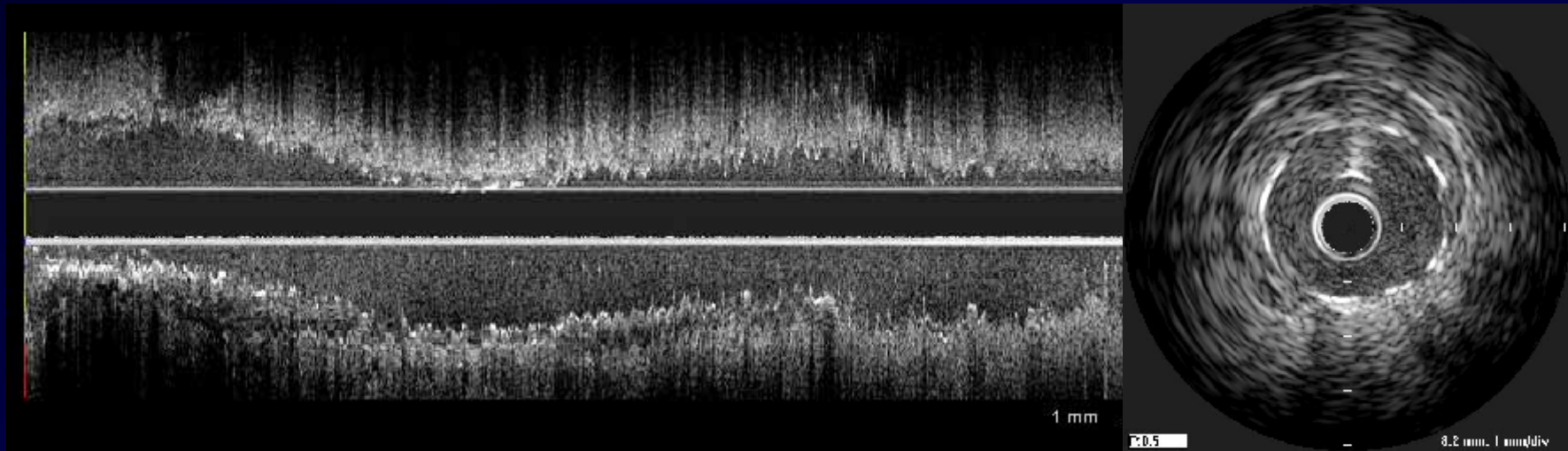
* Asymptomatic at FU

CUSTOM I Case Example

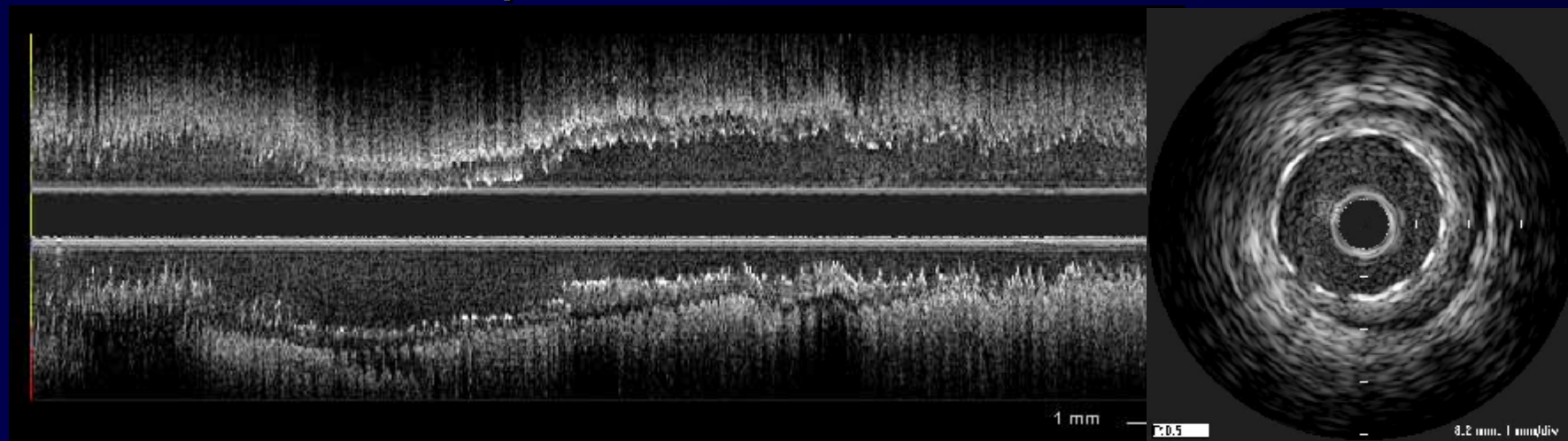


CUSTOM I IVUS Example

Baseline



4-month follow up (%NIV=0%, Max %CSN=0%)



CUSTOM I Mid-term Results

Conclusion

CUSTOM I establishes in-situ customization of stent length with the Xtent DES System

- No difference in MACE 30 days vs. 4months
- No stent thrombosis

CUSTOM I 4-month follow-up QCA data is promising

- In-stent binary restenosis 0% at 4 months
- Low late lumen loss comparable to other “limus” drugs
- No change in % stenosis between post implant and 4 month

CUSTOM I 8 month results will be presented at

Euro PCR 2006