2023 euro PCR

BIOADAPTOR RCT

Randomized Controlled Trial of Sirolimus-Eluting Bioadaptor Scaffold Versus Zotarolimus-Eluting Drug-Eluting Stent

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On behalf of Stefan Verheye, MD, PhD; Holger M Nef, MD, PhD; Mark Webster, MD, and the BIOADAPTOR RCT investigators

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Disclosure

Speaker's name: Shigeru Saito, MD

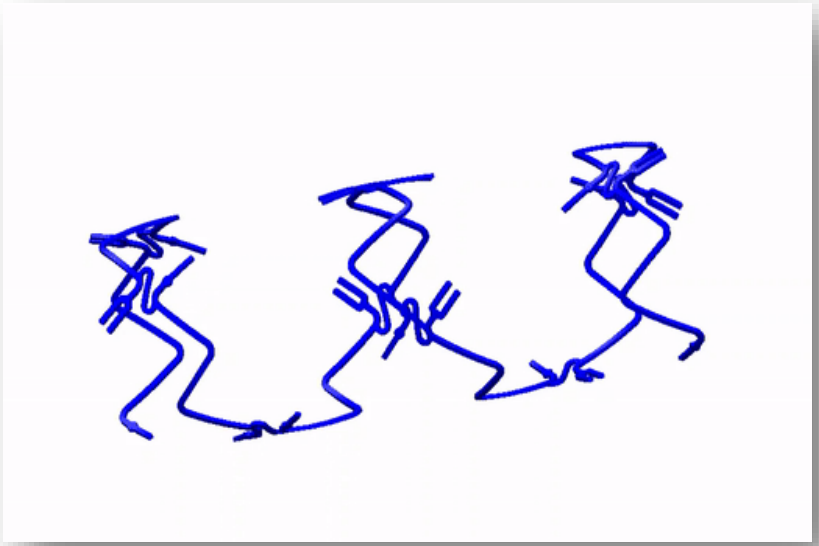
Consulting fees from Elixir Medical

Background

- Stent related adverse events continue to accrue after the first year at a non-plateauing rate of 2-3% a year, with no difference between 2nd generation DES, 1st generation DES and BMS.

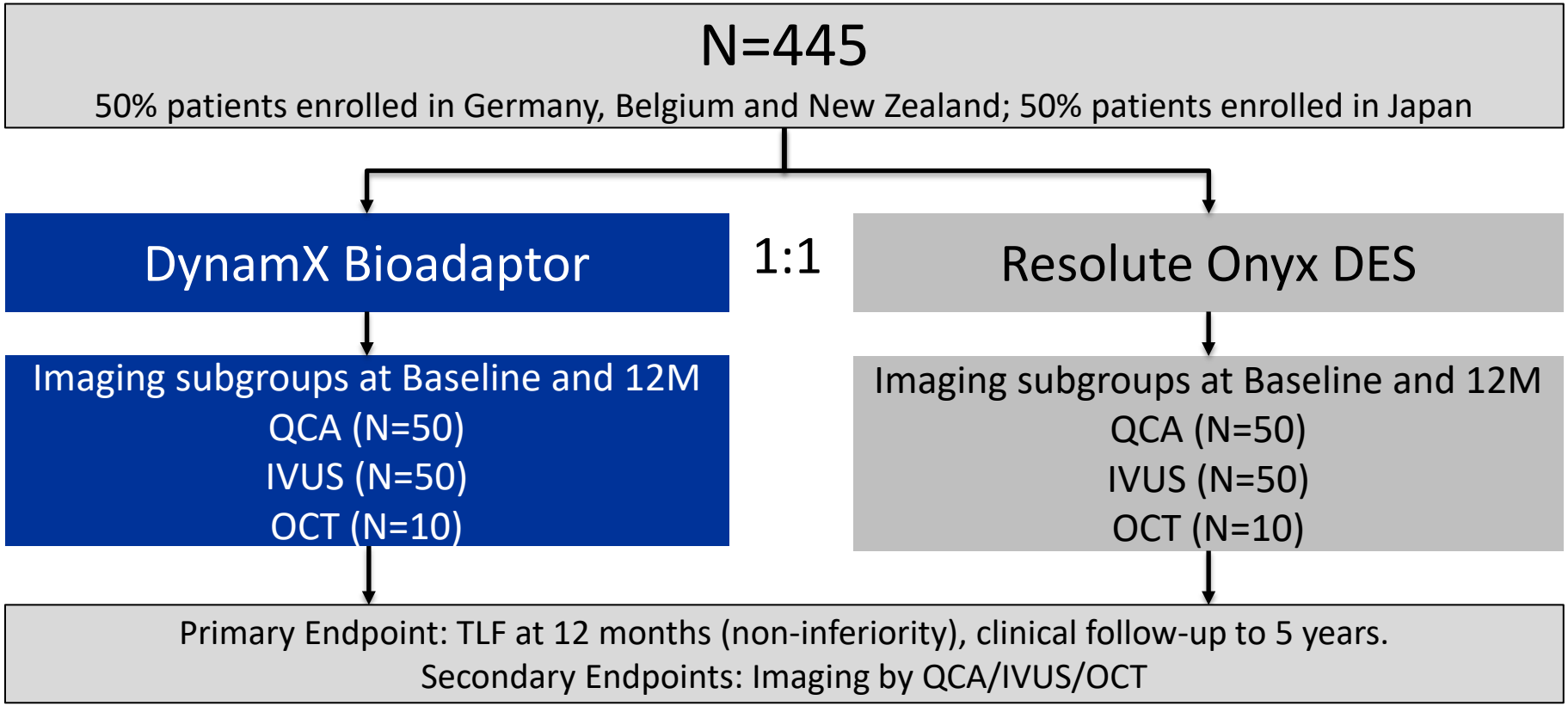
- Bioresorbable scaffolds had failed at improving short or long-term outcomes compared to DES, driven by poor acute performance and loss of long-term vessel dynamic support.

Study Device: DynamX Bioadaptor Scaffold



- Three thin (71µm) Co-Cr helical sinusoid strands
- PLGA bioresorbable topcoat contains Sirolimus designed to elute over 3 months
- PLLA bioresorbable polymer basecoat resorbs over 6 months to UNLOCK the scaffold circumferentially along the 3 uncaging elements in each ring
- Following neointimal formation and healing, unlocked helical strands continue to provide dynamic scaffolding support

BIOADAPTOR RCT Trial Design



Patient Baseline Characteristics

	DynamX (N=223)	Resolute Onyx (N=222)
Age, years	67.1 ± 10.3	66.2 ± 10.1
Female	49 (22.0%)	49 (22.1%)
Hypertension	161 (73.2%)	156 (70.9%)
Dyslipidemia	178 (80.9%)	177 (80.5%)
Diabetes Mellitus	59 (26.5%)	75 (33.8%)
Prior MI	42 (19.1%)	48 (21.8%)
Prior PCI	88 (40.0%)	83 (37.7%)
Prior CABG	2 (0.9%)	1 (0.5%)
Current smoking	52 (23.6%)	48 (21.8%)

	DynamX (N=223)	Resolute Onyx (N=222)
Clinical Presentation		
Stable Angina	64.6%	67.6%
Unstable Angina	16 (7.2%)	9 (4.1%)
NSTEMI	15 (6.7%)	10 (4.5%)
Silent Ischemia	18 (8.1%)	18 (8.1%)
Asymptomatic post MI	6 (2.7%)	15 (6.8%)
Other	24 (10.8%)	20 (9.0%)

Angiographic Characteristics

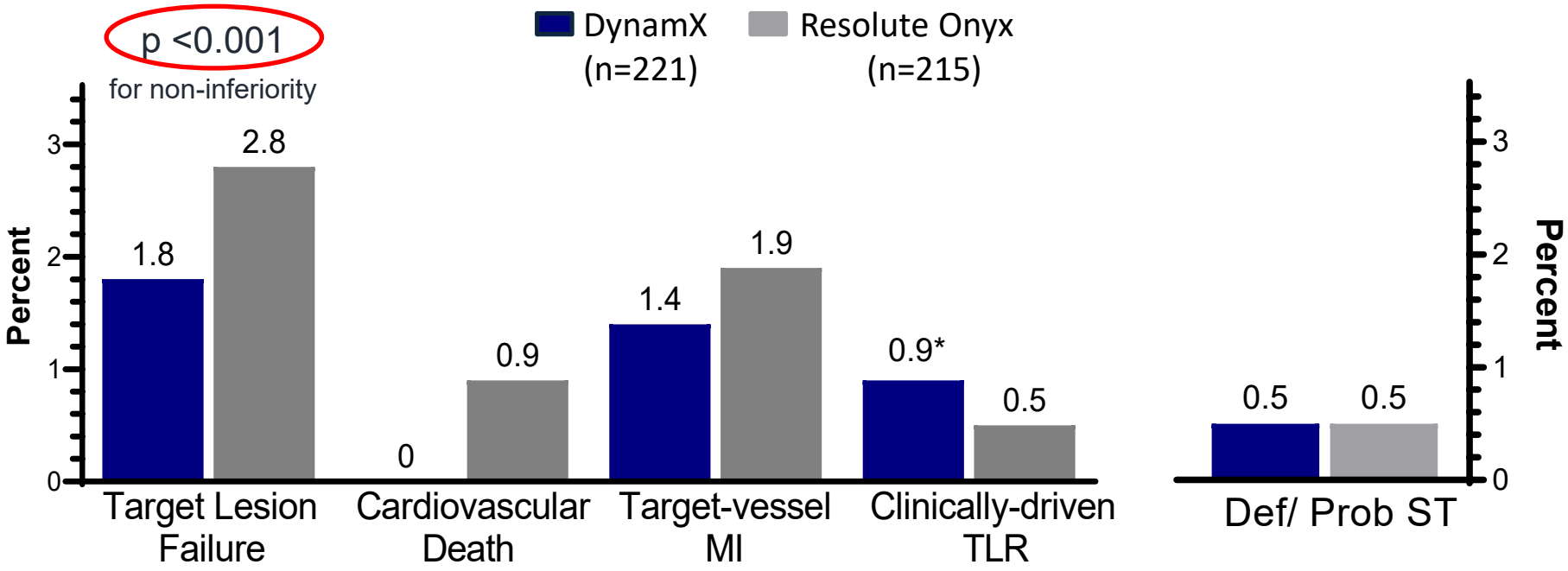
Angiographic Characteristics	DynamX (N=223, L=226)	Resolute Onyx (N=222, L=230)
Target lesion vessel		
LAD	114 (50.4%)	104 (45.2%)
LCX	35 (15.5%)	66 (28.7%)
RCA	77 (34.1%)	60 (26.1%)
Ostial lesion	13 (5.8%)	8 (3.5%)
Bifurcation lesion	50 (22.1%)	55 (23.9%)
Moderate/severe calcification	43 (19.0%)	47 (20.4%)
Moderate/severe tortuosity	53 (23.5%)	46 (20.0%)
ACC/AHA lesion class B2/C	51 (22.6%)	49 (21.3%)
Reference vessel diameter, mm	3.1 ± 0.4	3.0 ± 0.4
Target lesion length, mm	15.8 ± 6.0	16.2 ± 6.0

BIOADAPTOR RCT – Procedural Outcomes

Acute Success Rate	DynamX	Resolute Onyx
Device Success*	224/225 (99.6%)	228/229 (99.6%)
Lesion Success**	225/226 (99.6%)	229/230 (99.6%)
Procedure Success***	220/223 (98.7%)	216/222 (97.3%)

*Device success (% diameter stenosis after implantation of allocated study device <30%)
**Lesion success (% diameter stenosis after treatment of target lesion with percutaneous coronary intervention, PCI, < 30%)
***Procedure success (lesion success without major adverse cardiac events during index hospitalization)

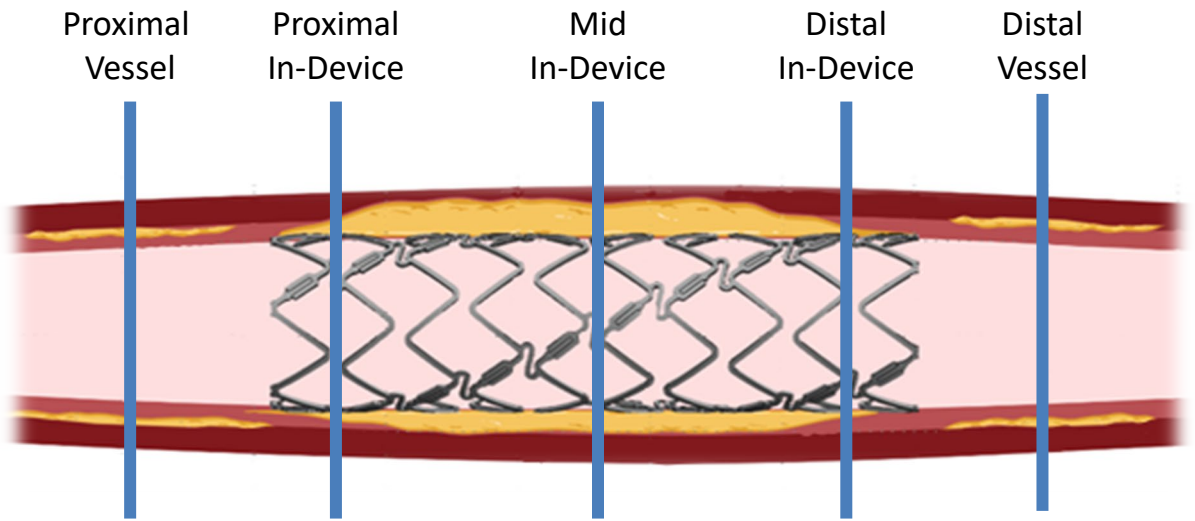
The Primary Endpoint of TLF Non-Inferiority Was Met



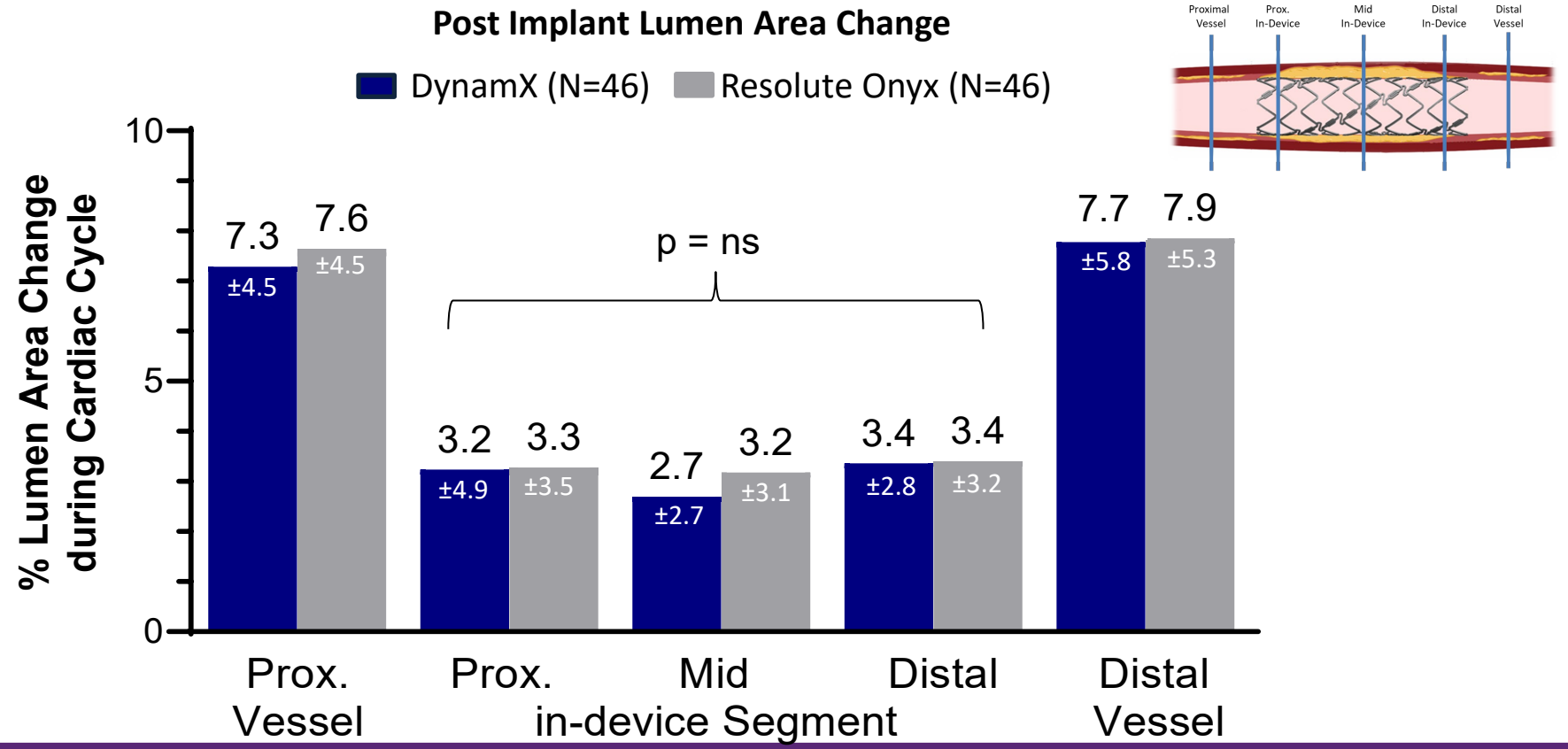
Note: *One TLR patient violated the exclusion criteria of in-stent restenosis (Bioadaptor was implanted in a lesion previously treated with a bioresorbable scaffold); the second TLR patient violated the exclusion criterion of severely calcified lesions (the lesion required 4 balloon predilatations).

Secondary Endpoint: Stationary IVUS Pulsatility Paired Analysis (N=100)

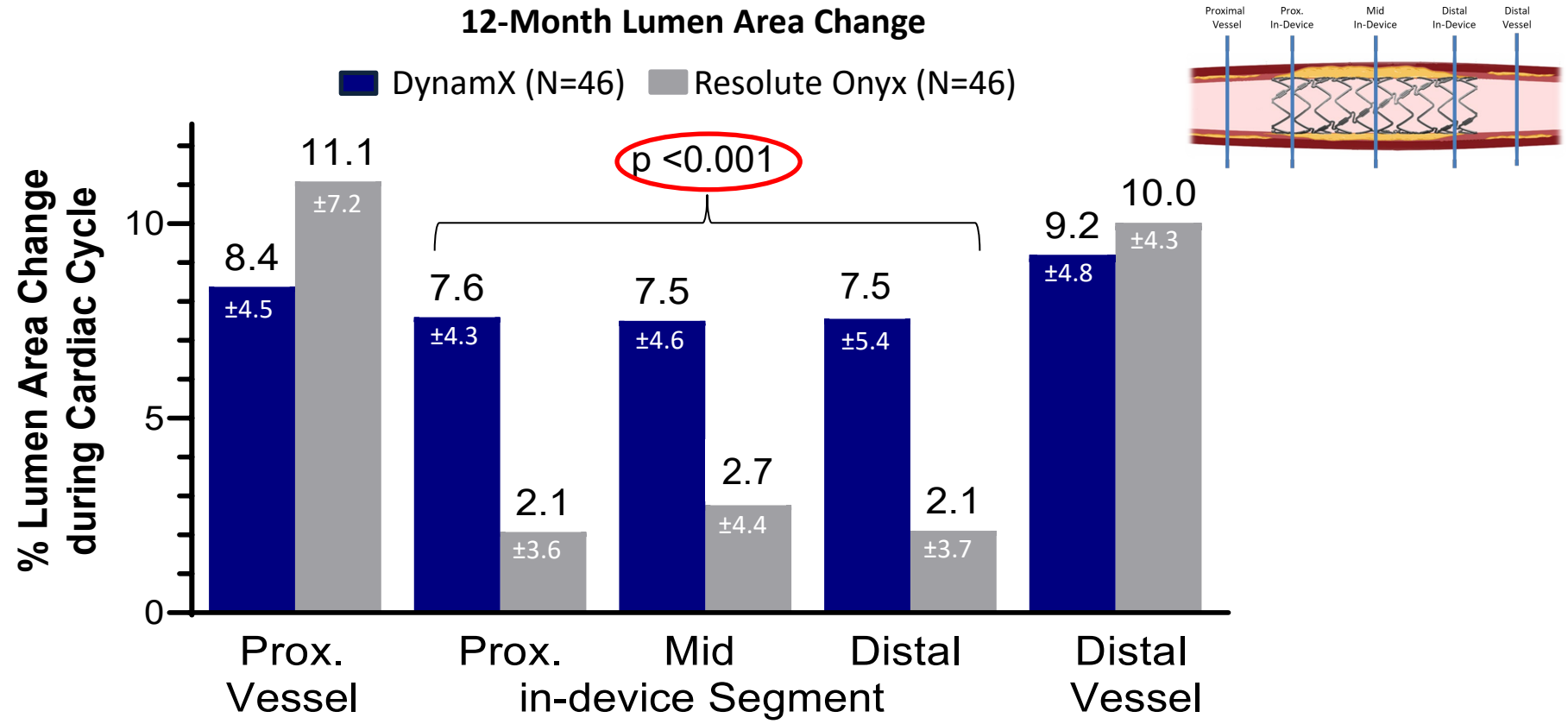
- % Change in Lumen Area between systole and diastole cycles
- Recorded using the same frames at Post-Implant and 12-month follow-up
- Measured across at least three cardiac cycles



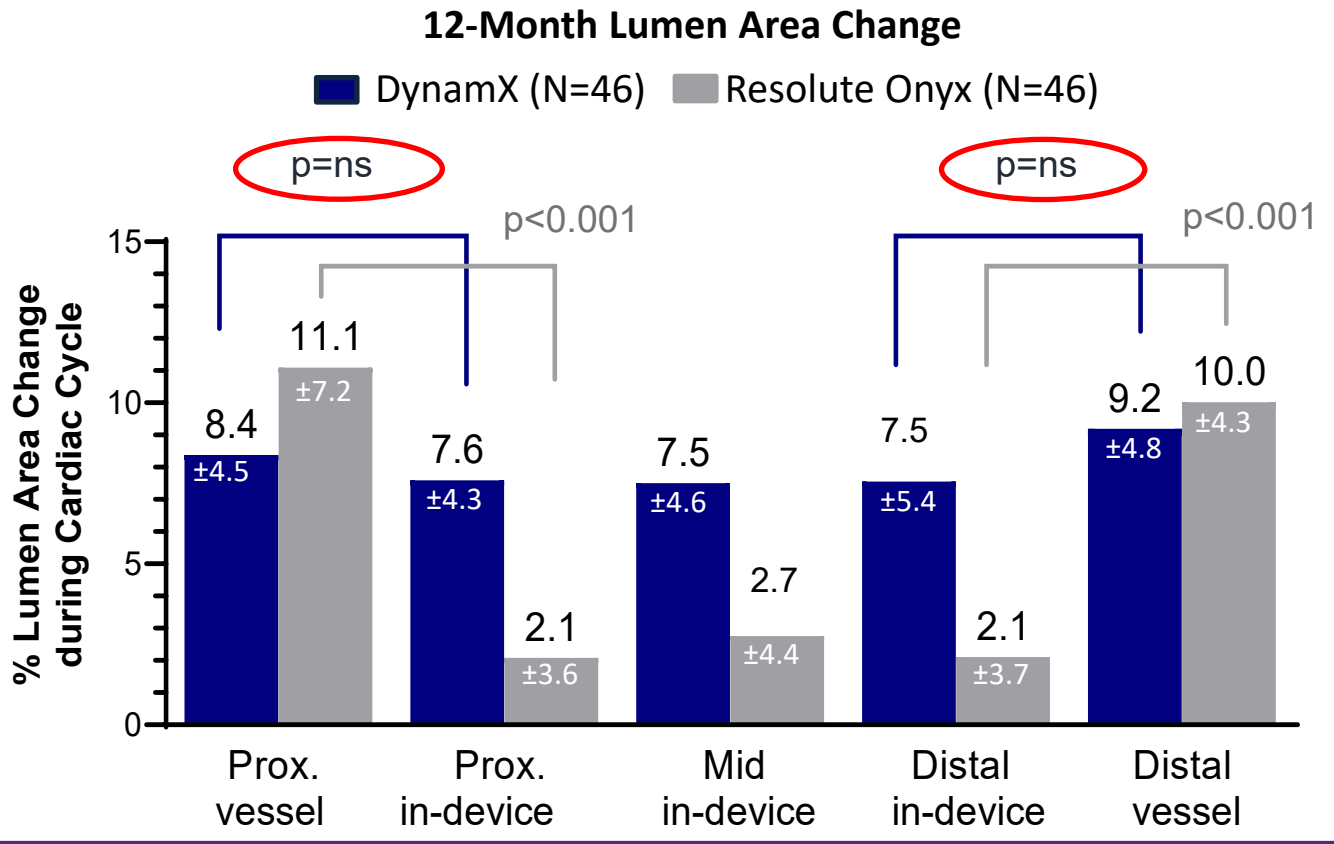
Post Implant Pulsatility Was Constrained in Both Arms



Pulsatility at 12 Months Restored in DynamX

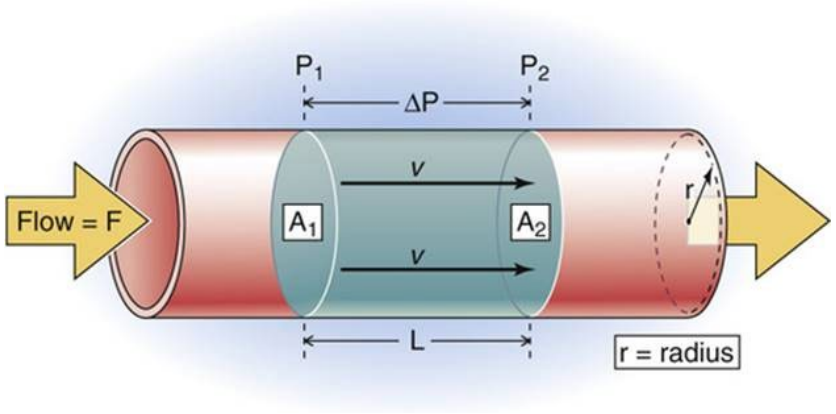


Return of Compliance Only in DynamX Arm

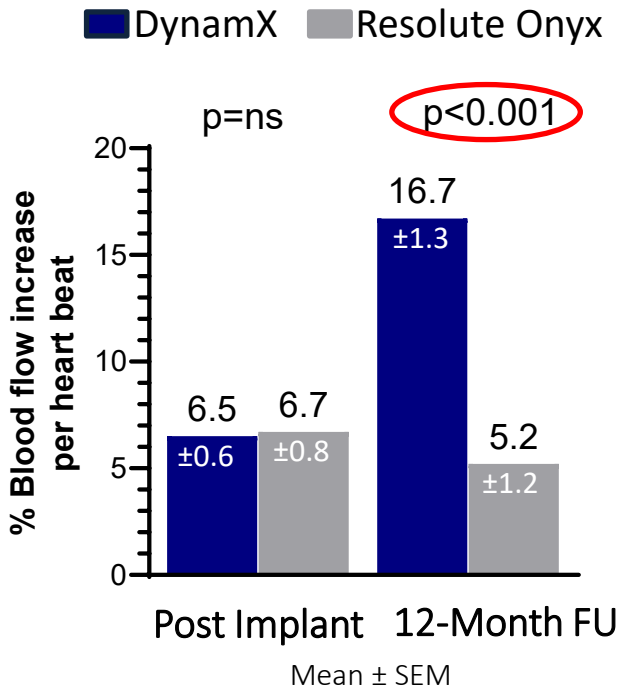


Significant Increase in Blood Flow With DynamX

Blood flow change estimated by Hagen Poiseuille flow equation (Pontiga and Gaytan 2005)



Blood Flow Changes During Cardiac Cycle

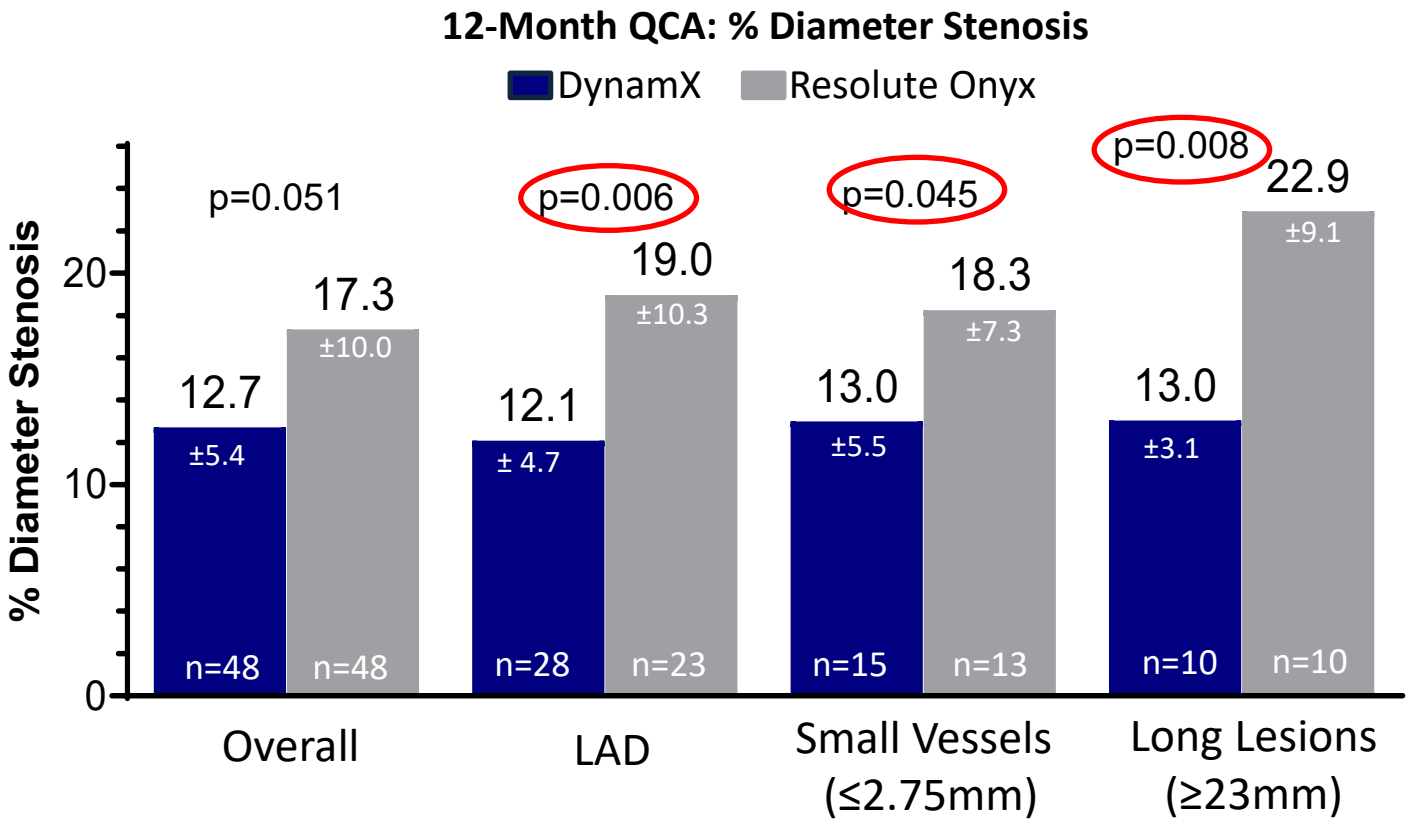


Mean ± SEM

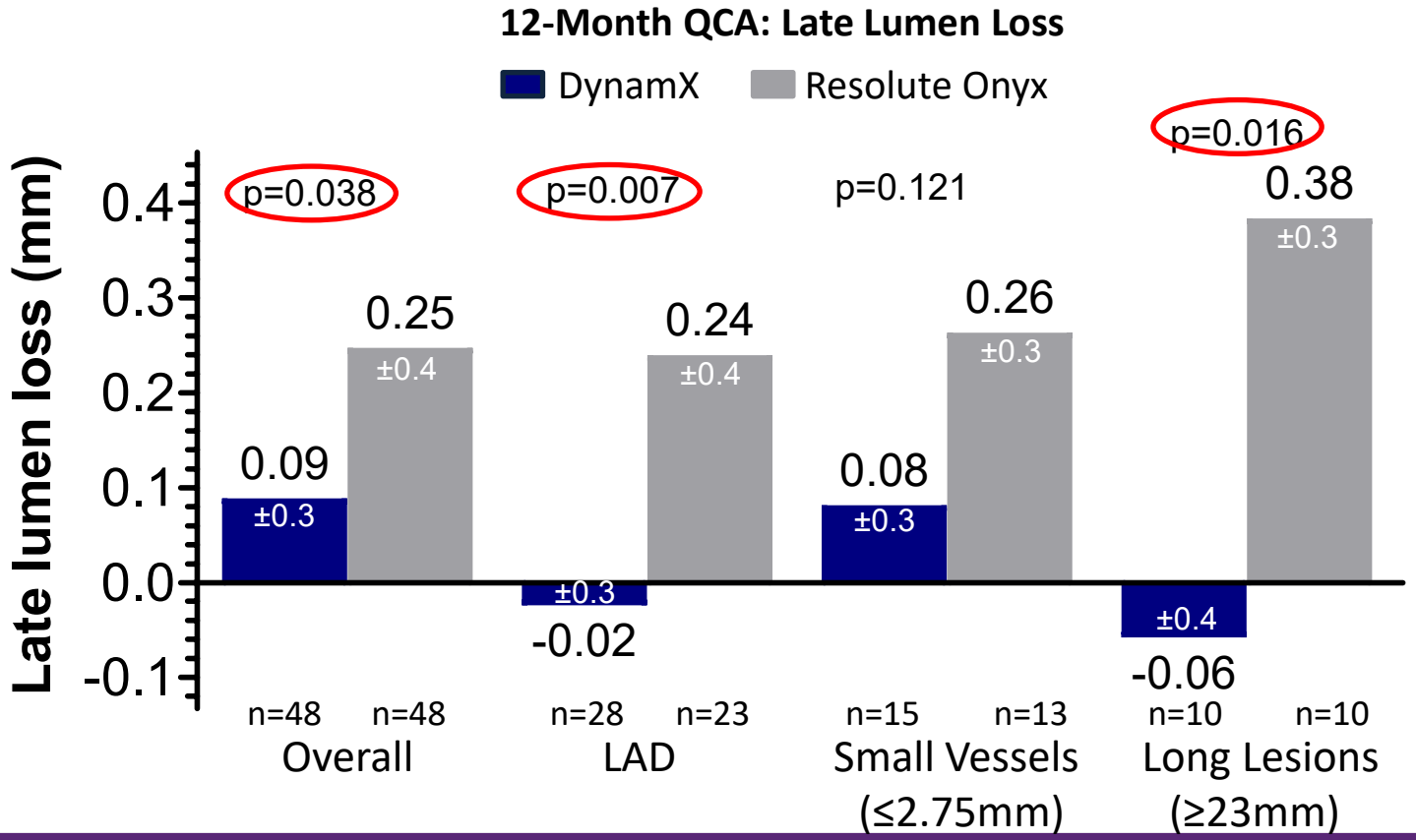
QCA Analysis: Acute Performance

In-device	DynamX (N=48)	Resolute Onyx (N=48)	P-value
Reference Diameter (mm)	2.64 ± 0.48	2.72 ± 0.55	0.482
%DS Stenosis Pre-Procedure	64.39 ± 11.04	64.40 ± 13.29	0.996
Residual %DS Post Implant	9.56 ± 3.77	10.24 ± 5.22	0.773
Acute gain, mm	1.66 ± 0.45	1.75 ± 0.52	0.408

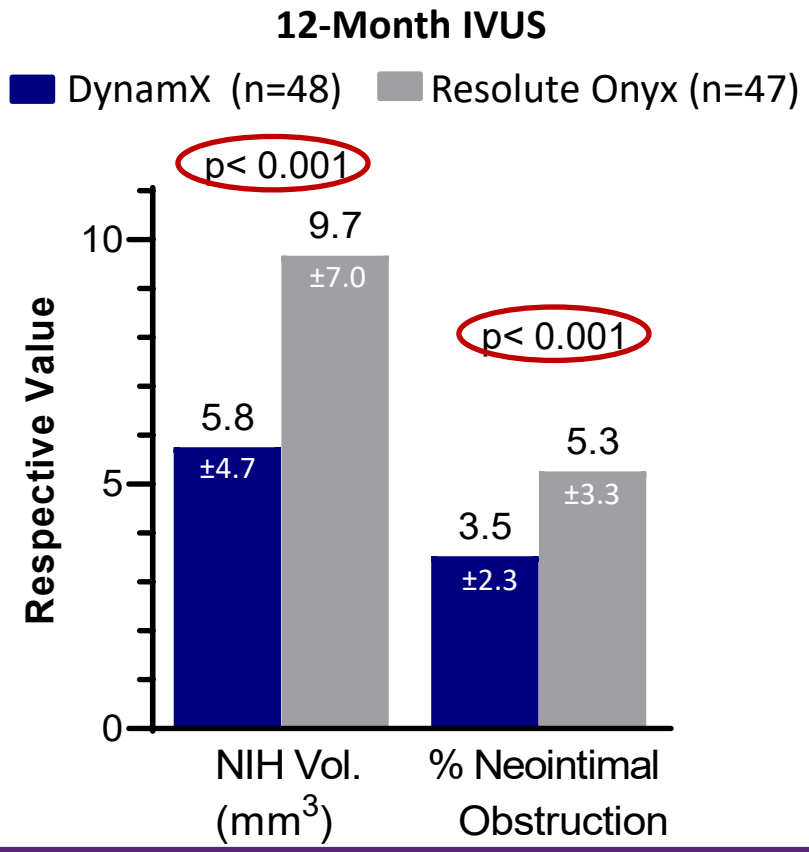
Bioadaptor: Lower %DS in Overall Cohort and Subgroups

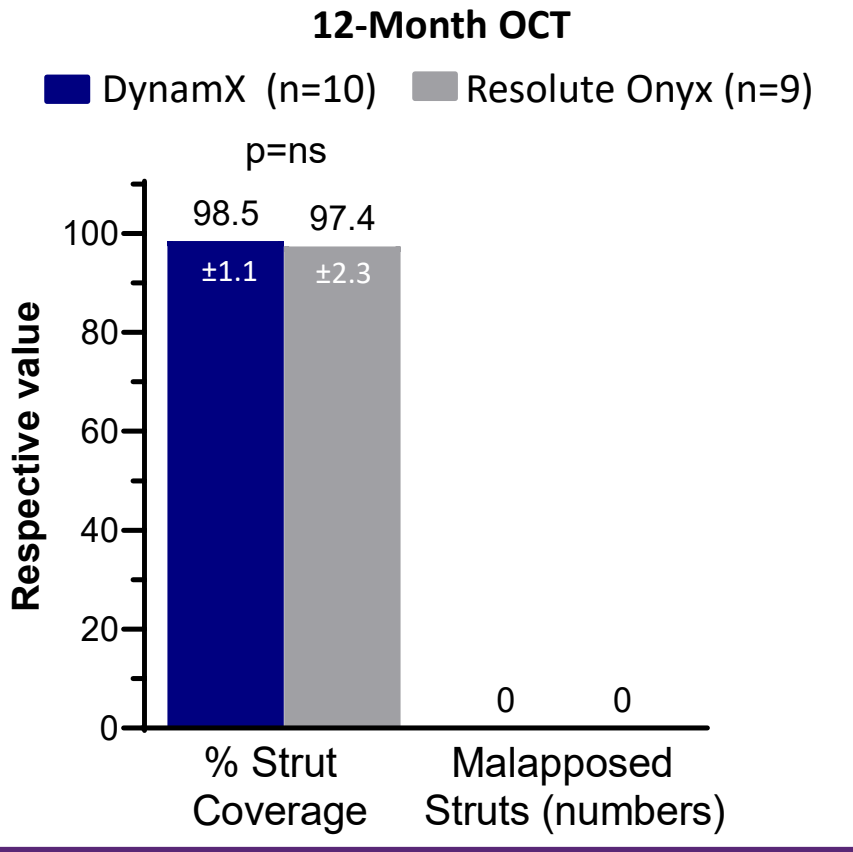


Bioadaptor: Lower LLL in Overall Cohort and Subgroups



Bioadaptor: Lower NIH Volume, Complete Strut Coverage

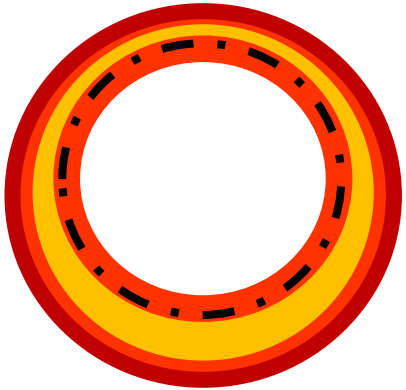


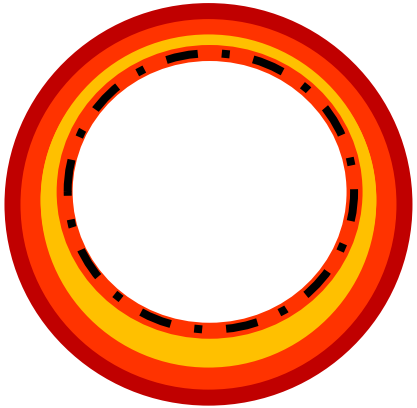


Key Endpoint Results

- Primary Endpoint of TLF Non-inferiority Was Met
  - 1.8% vs 2.8% at 12-Months, DynamX Bioadaptor vs. Resolute Onyx ($p<0.001$)
- Acute Procedure Performance Was Similar to DES
- DynamX Biodaptor Demonstrated Superiority Across Key Secondary Imaging Endpoints at 12 Months
  - Restoration of In-Device Pulsatility with DynamX
  - Significantly Lower LLL and %DS
  - Significantly Lower NIH Volume and %Neointimal Obstruction

Novel Finding: Plaque Volume Change (mm^3) at 12 Months





Plaque volume change behind the device from post-procedure to 12-month follow-up (mm^3)

Resolute Onyx (N=47)		
Post procedure (mm^3)	Δ (mm^3)	**Δ (%)**
148.57 ± 74.08	18.22 ± 35.42	**12 ± 24**
p = 0.378	p = 0.024	p = 0.032

DynamX (N=48)		
Post procedure (mm^3)	Δ (mm^3)	**Δ (%)**
136.37 ± 58.14	3.89 ± 23.20	**3 ± 19**

Plaque Changes Were Similar Outside Device-Treated Area

Lipid-lowering medication use	Screening/Baseline	Discharge	1 Month	6 Months	12 Months
DynamX	88%	90%	92%	92%	92%
Resolute Onyx	90%	94%	94%	94%	94%

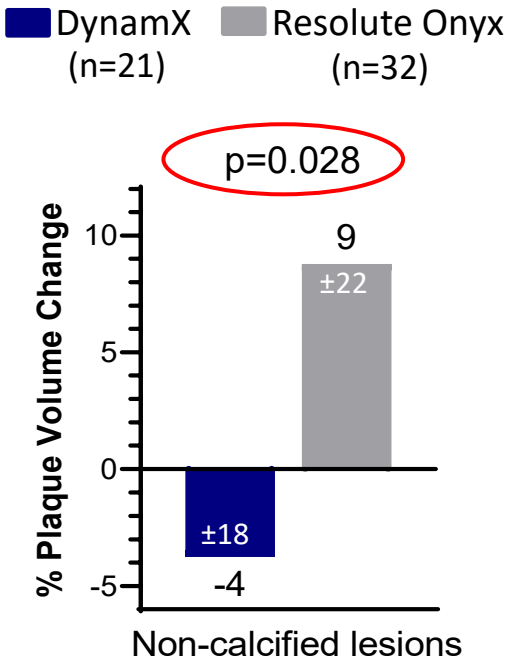
Proximal

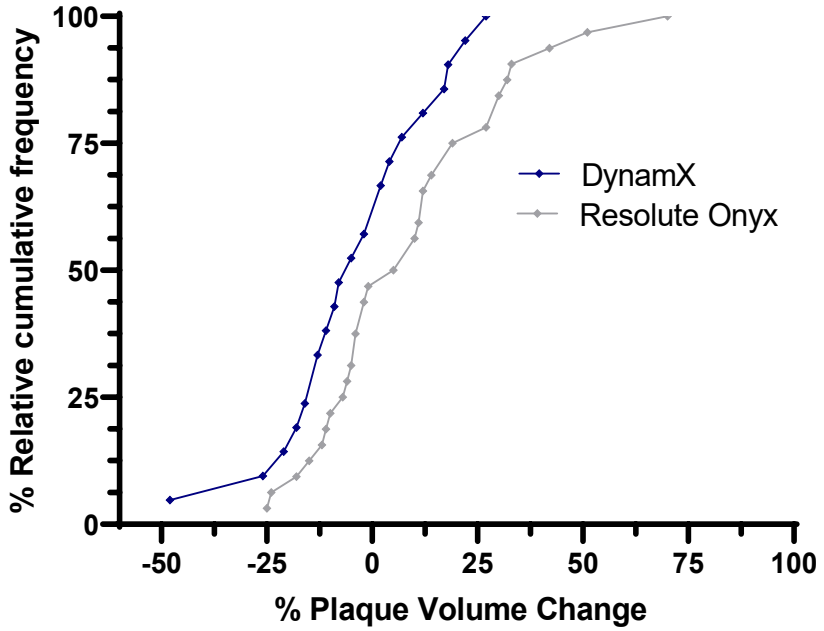
Absolute change in plaque volume normalized per length from baseline to 12M FU (mm3)		
DynamX (N=42)	**Resolute Onyx (N=42)**	p-value
0.67 ± 1.45	0.42 ± 1.73	0.991

Distal

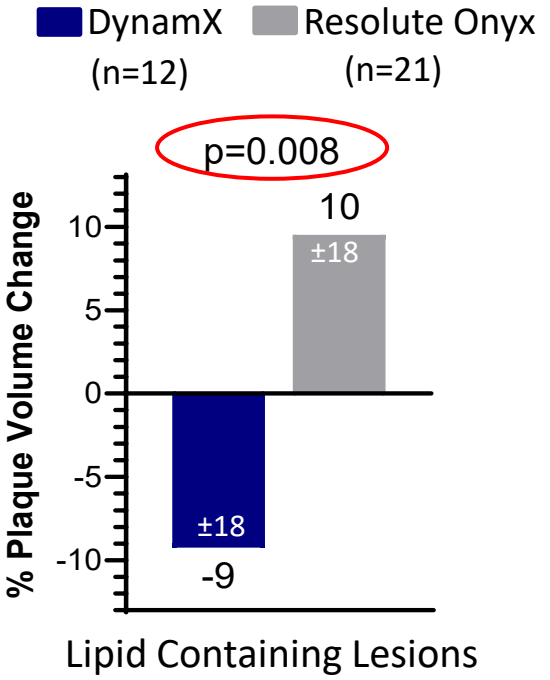
Absolute change in plaque volume normalized per length from baseline to 12M FU (mm3)		
DynamX (N=41)	**Resolute Onyx (N=42)**	p-value
0.50 ± 1.34	0.41 ± 1.30	0.503

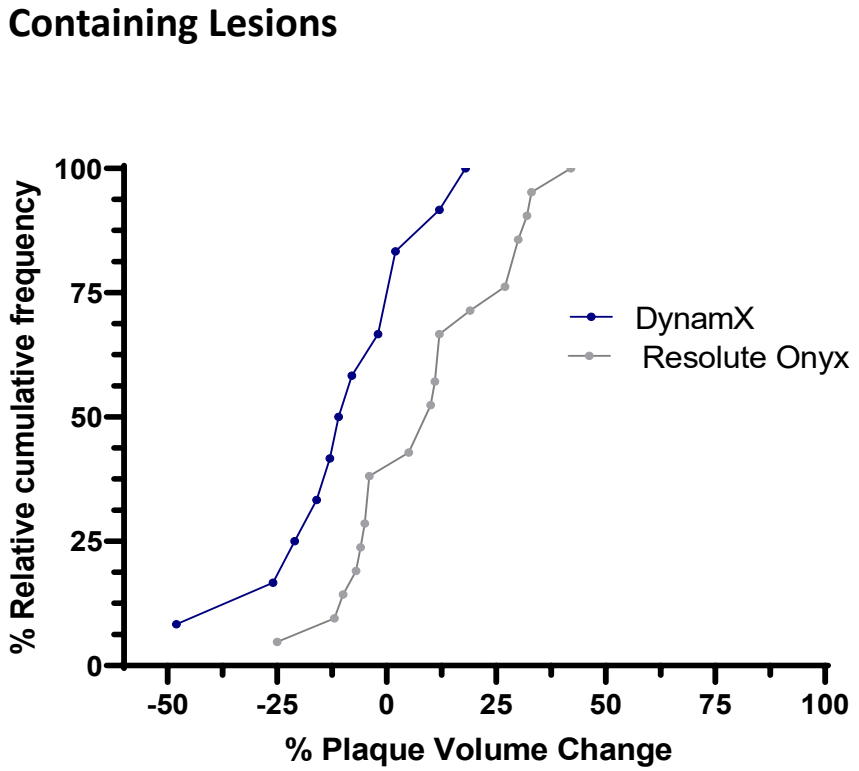
Plaque Volume Change Behind the Device in Non-Calcified Lesions





Plaque Volume Change Behind the Device in Lipid Containing Lesions





Conclusions

- DynamX is non-inferior to DES in TLF with favorably low event rate
- DynamX demonstrated superior restoration of vessel motion and function
  - Restoration of In-Device Pulsatility with DynamX
  - Significantly Lower LLL and %DS
  - Thin and Uniform Neointimal Coverage
- Plaque stabilization and regression in DynamX Bioadaptor compared to plaque volume increase in DES may point to synergistic effect between lipid lowering medication and restored vessel motion and function

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