BIOADAPTOR RCT – 2-Year Outcomes

Randomized Controlled Trial of Sirolimus-Eluting Bioadaptor 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

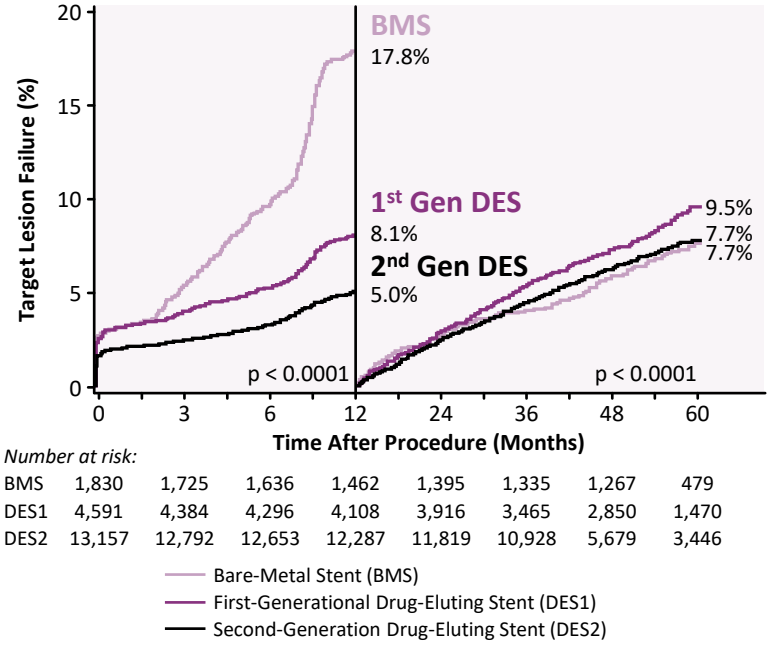
Disclosure

- Speaker's name: Shigeru Saito, MD
  - Consulting fees from Elixir Medical
  - Consulting fees from Medinol
  - Honorarium for proctorship from Abbott Medical

Background

- Stent related adverse events increase after the first year at a steady rate of 2-3% a year, reaching 20% at 5 years and 50% at 10 years[1,2]

- 12-month results from BIOADAPTOR RCT demonstrated the safety and efficacy of DynamX Bioadaptor[3] and established new benchmarks in restoring arterial viability
  - 1.8% vs. 2.8% TLF (p=0.001 for non-inferiority)
  - Superior %DS, LLL, and significantly different pulsatility, coronary flow volume
  - Novel plaque stabilization and regression



1. Madhavan MV et al. *J Am Coll Cardiol* 2020;75:590-604
2. Kufner et al. ISAR-TEST 4 Trial. Circulation, 2019
3. Saito S et al. *The Lancet eClinicalMedicine*. 2023;65:102304

Study Objective

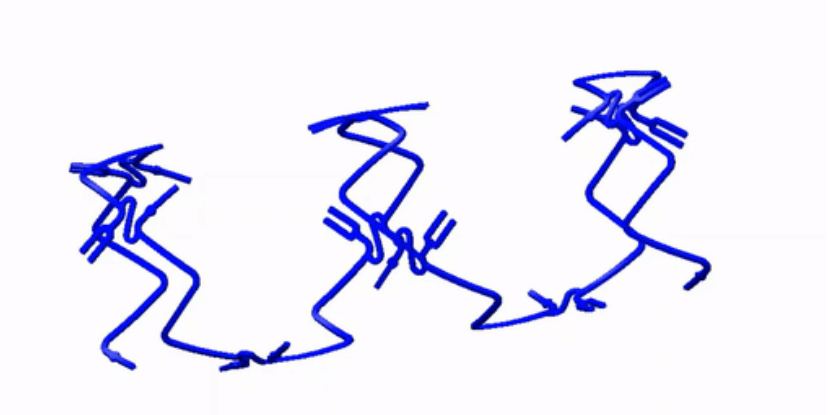
The objective of the present analysis is to report

2 Year Clinical Outcomes from the BIOADAPTOR RCT

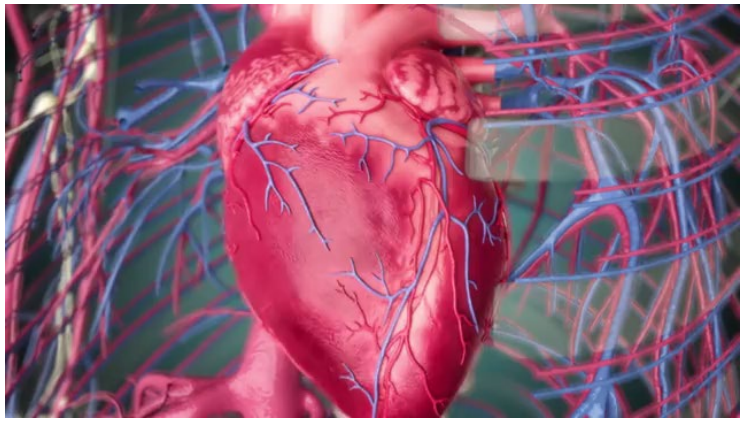
Clinical outcomes to confirm impact of significant 1-Year imaging outcomes demonstrating restoration of hemodynamic modulation

1. Saito S et al. 12-Months Outcomes BIODAPTOR-RCT. *The Lancet eClinicalMedicine*. 2023;65:102304.

DynamX Bioadaptor Novel Design and Unique Mechanism of Action



- Three helical sinusoidal strands (CoCr 71µm) are temporary locked and held by bioresorbable polymer
- They unlock after 6 months following polymer resorption

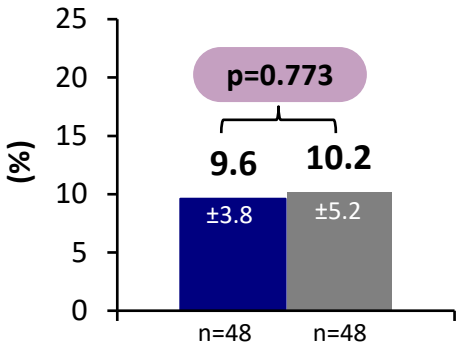


Mechanism of action and function:

- **Locked** to establish flow lumen
- **Unlock and separate** to maintain flow lumen
- **Dynamic adaptive support after unlocking and separating** to restore hemodynamic modulation

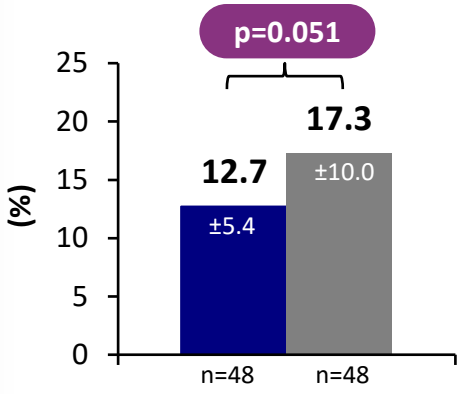
Significant QCA Imaging Outcomes Validate DynamX Mechanism of Action

Post Procedure QCA: Low %Diameter Stenosis



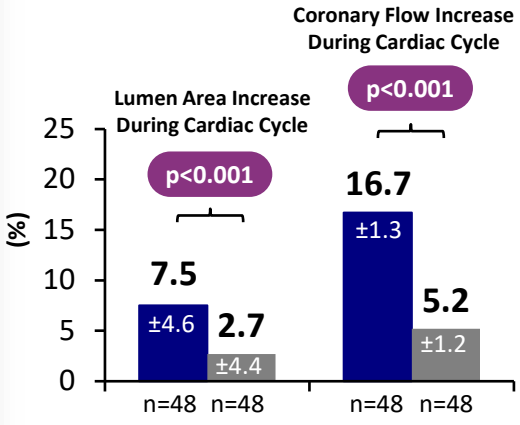
Establish Flow Lumen

1-Year QCA: Lower % Diameter Stenosis



Maintain Flow Lumen

1-Year IVUS: Restored Pulsatility and Adaptive Coronary Flow Volume



Restore Hemodynamic Modulation

DynamX Resolute Onyx

*Superior %DS reduction (p<0.05) in LAD, long lesions (≥ 23 mm) and small vessels (≤2.75mm)

**Vessel compliance restored at 1-Year in DynamX based on systole/diastole area changes in device segment matching (p<0.05) to distal and proximal vessel.

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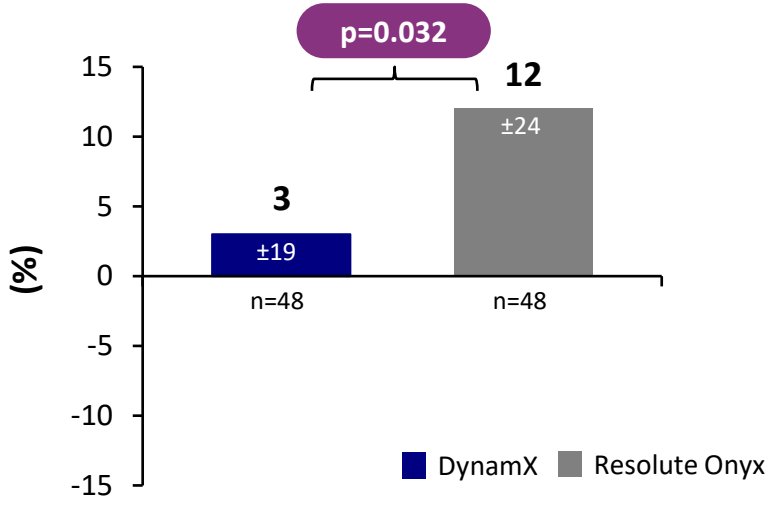
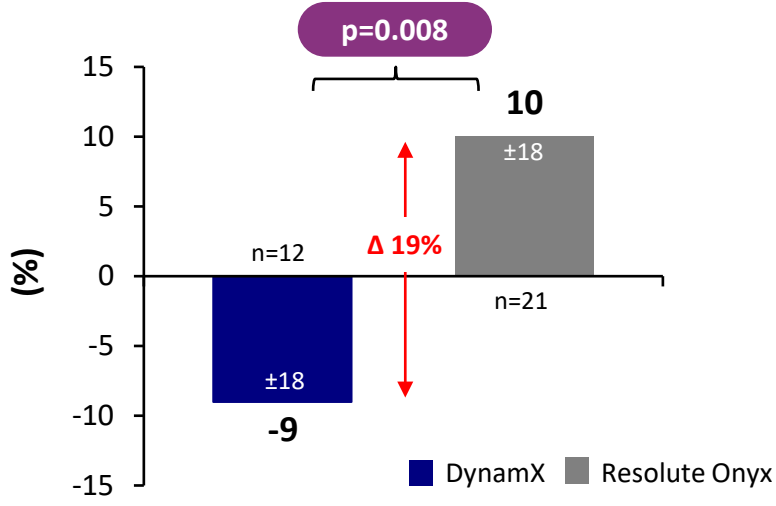
Significant Plaque Volume Regression with DynamX at 1 Year



All Lesions

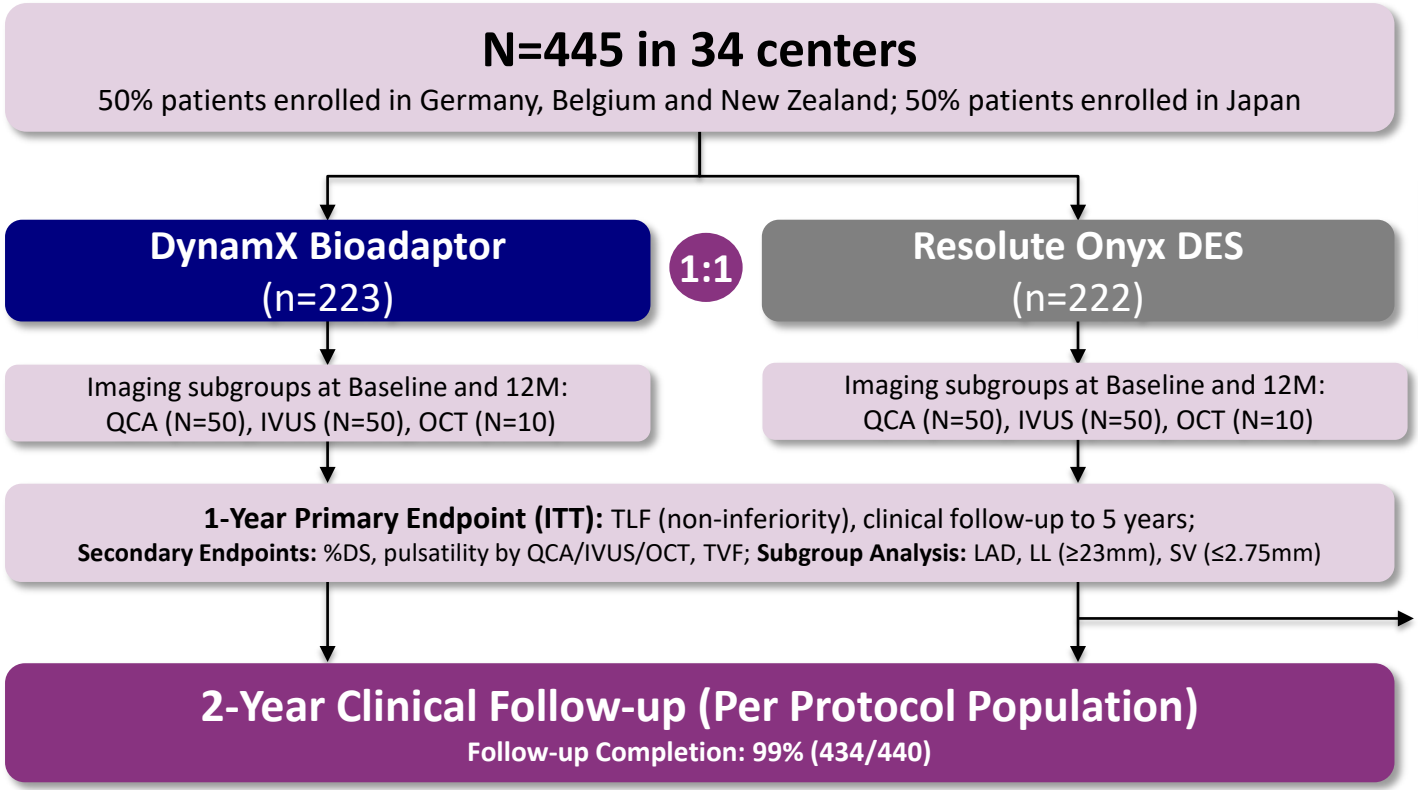


Lipid Containing Lesions

1. Saito S et al. 12-Months Outcomes BIODAPTOR-RCT. *The Lancet eClinicalMedicine*. 2023;65:102304.

***Plaque volume assessed by IVUS**

BIOADAPTOR RCT - Trial Design



Per Protocol (PP) Population Analysis at 2 Years:

- 3 subjects excluded due to non-de novo lesion (ISR in prior BVS implant)
- 2 subjects excluded due to cross-over randomization error

Subjects who did not complete 2-year follow-up:

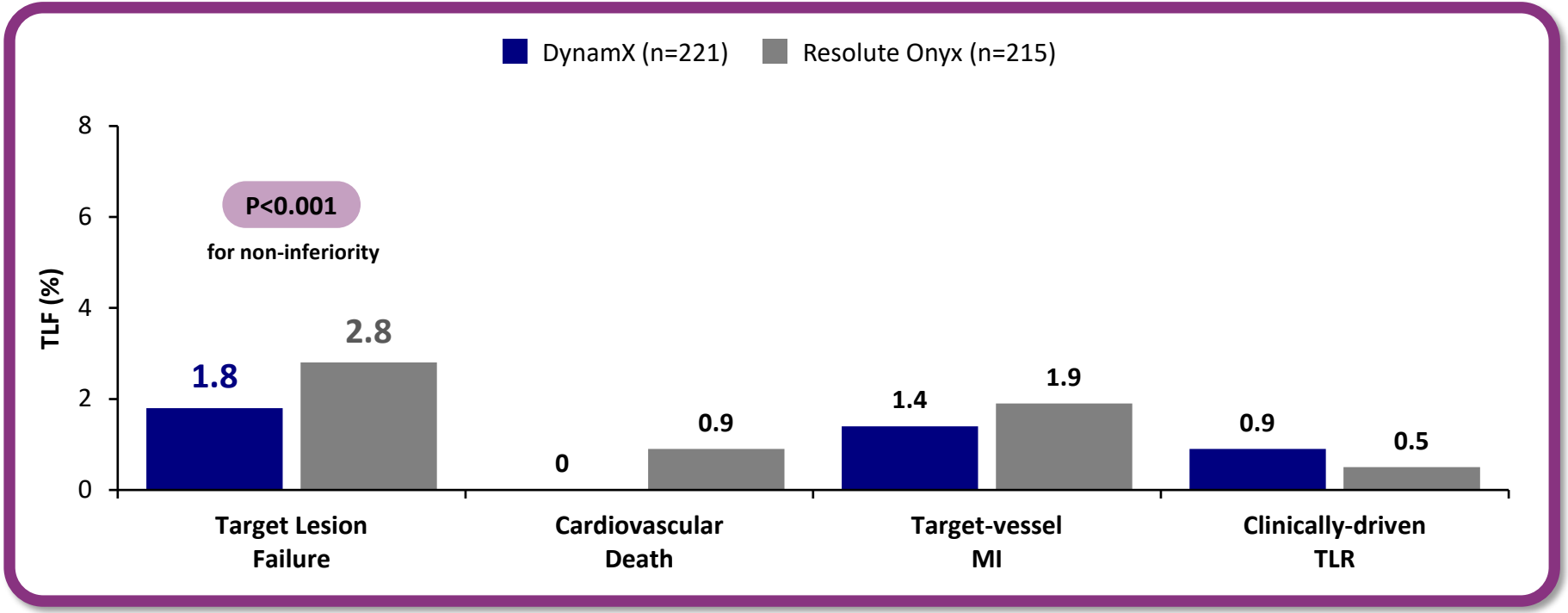
- 2 subject withdrawals
- 4 subjects missed 2-Year visits

Patient Baseline Characteristics

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/CABG	90 (40.9%)	84 (38.2%)
Stable Angina	144 (64.6%)	150 (67.6%)
ACS	79 (35.4%)	72 (32.4%)

Anatomical Characteristics	DynamX (N=223)	Resolute Onyx (N=222)
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 B2/C	51 (22.6%)	49 (21.3%)
Target lesion length, mm	15.8 ± 6.0	16.2 ± 6.0

Primary Endpoint is Met: TLF at 1 Year (ITT Population)



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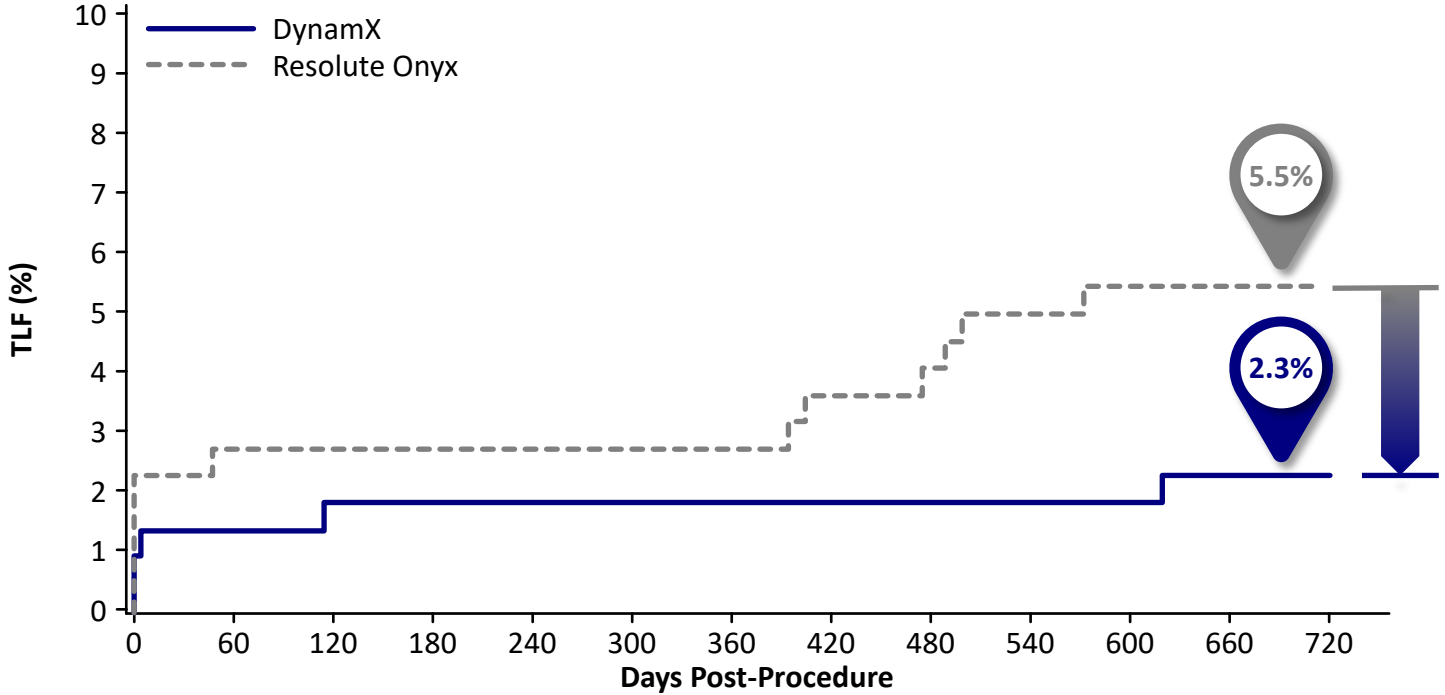
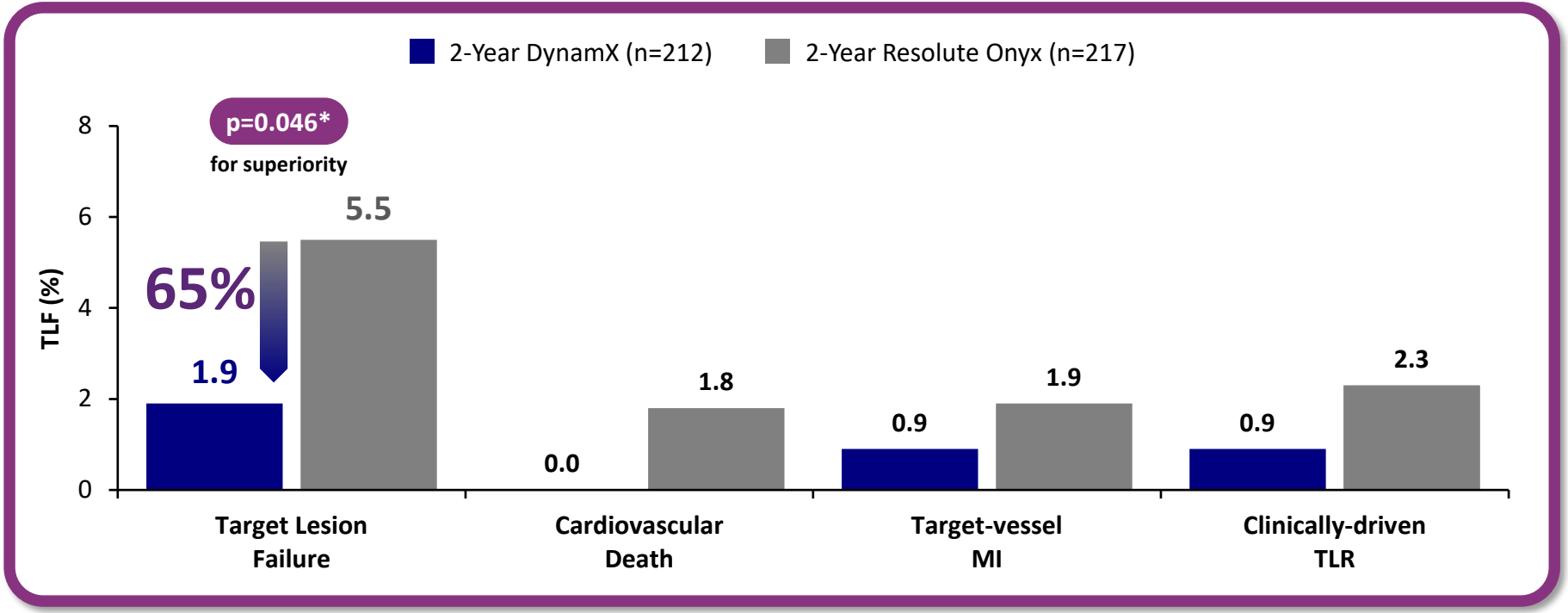
TLF Reduction With DynamX at 2 Years (ITT Population) Showing Further Separation of the KM Curves



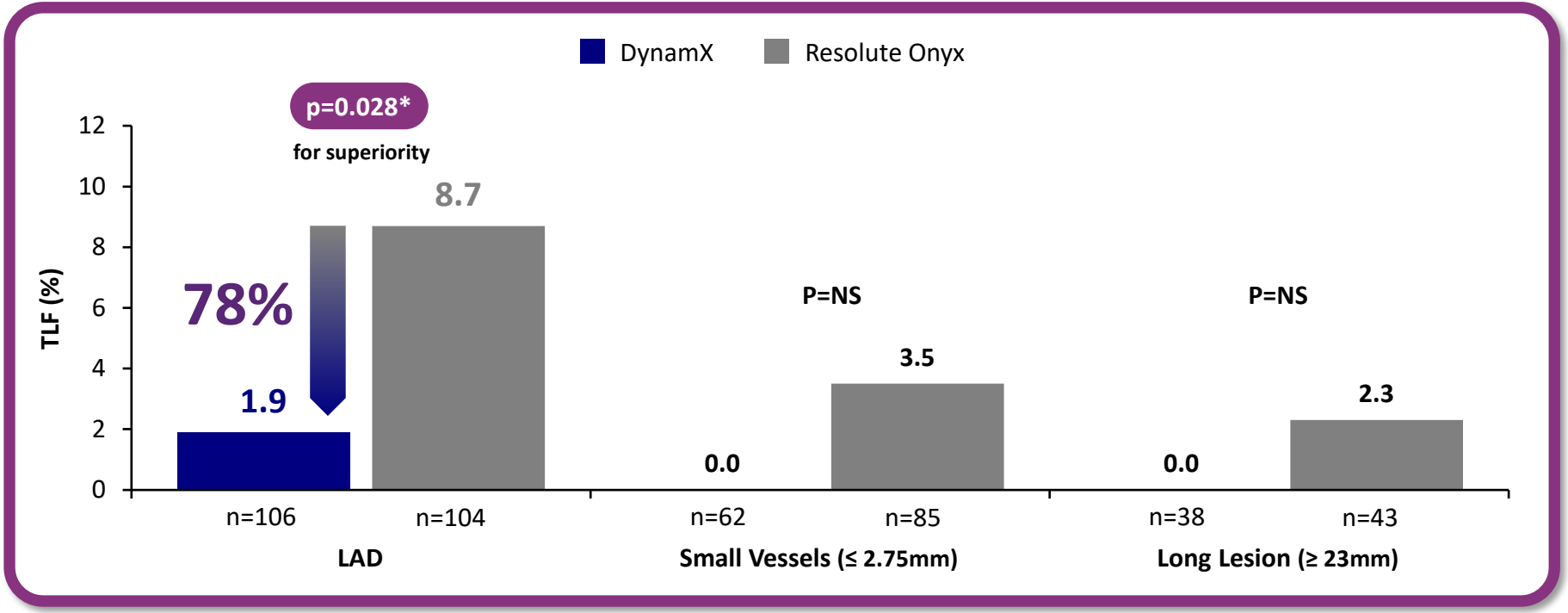
Randomization	Day 0	Day 30	Day 180	Day 360	Day 720
DynamX	223	220	219	217	212
Resolute Onyx	222	217	214	214	208

Significant TLF Reduction Driven by Lower CVD, TVMI, TLR



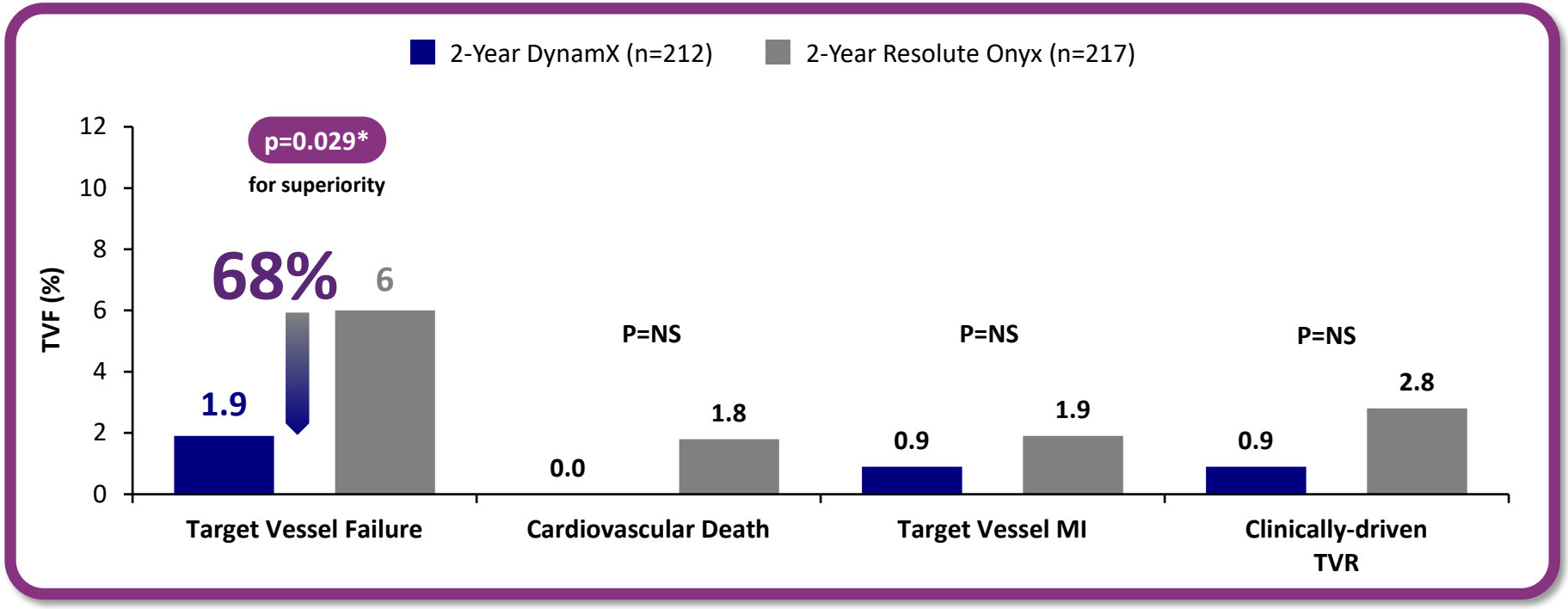
*Chi-square test. Per Protocol Population

Significant Reduction in TLF Rate in LAD Lesions at 2 Years



*Chi-square test. Per Protocol Population

Significant Reduction in TVF at 2 Years



*Chi-square test. Per Protocol Population

Conclusions

- Significant clinical outcomes at 2-Year follow-up from the BIOADAPTOR RCT:
  - 65% reduction in TLF (1.9% versus 5.5%, p=0.046) with further separation of KM curves
  - TLF event rate flattens after 1 Year compared with non-plateauing events increase for DES
  - 68% reduction in TVF (1.9% versus 6.0%, p=0.029)

- For lesions at higher risk of restenosis DynamX demonstrated:
  - LAD: significant reduction in TLF (1.9% versus 8.7%, p=0.028)
  - Small vessels and long lesions: lower event rates (0% versus 3.6% and 0% versus 2.3%), confirming 1-Year QCA outcomes

- **DynamX Bioadaptor is the first technology with a novel design and mechanism of action that restores hemodynamic modulation to the artery and delivers sustained significant clinical benefit, establishing a new therapy and potentially a new standard of treatment for patients with CAD.**

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