BIOADAPTOR RCT Outcomes at 4-Year Follow Up

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

Futoshi Yamanaka, MD

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

2026

Potential conflicts of interest

Speaker's name: ***Futoshi Yamanaka MD***

I have no potential conflicts of interest to report.

Study Organization: 34 Global Trial Sites

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Toshiyuki Matsumura	Kumamoto Rousai Hospital
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Clinical Research Organization Partners:

CERC Cardiovascular European Research Center

iC42 integrated solutions in systems biology clinical research & development

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Madhav Menon	Waikato Hospital
Douglas Scott	Middlemore Clinical Trials Trust

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BIOADAPTOR RCT

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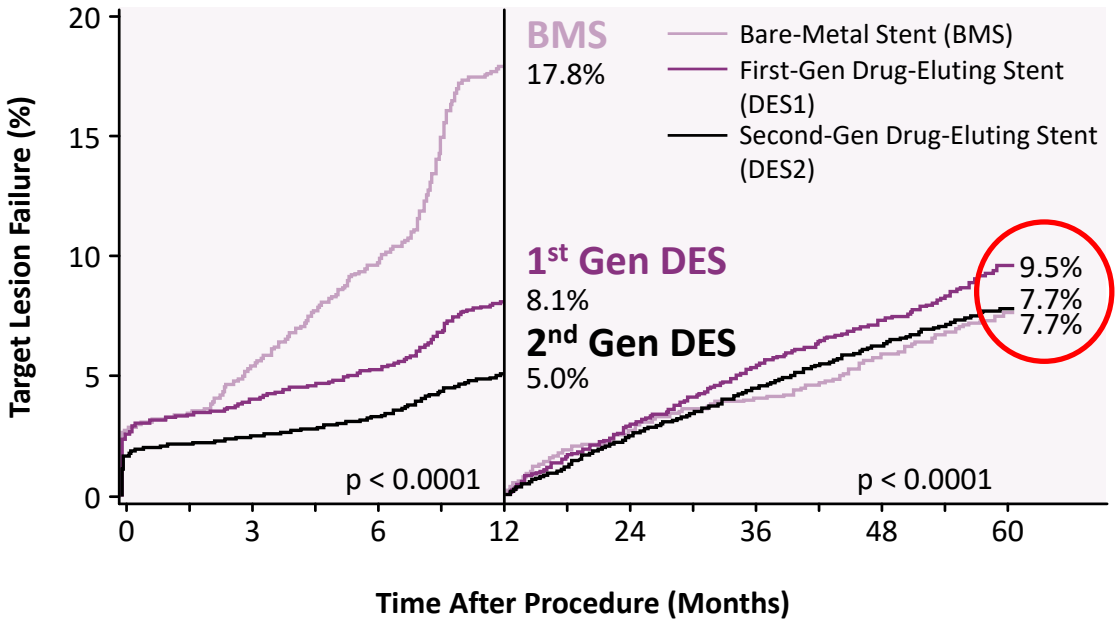
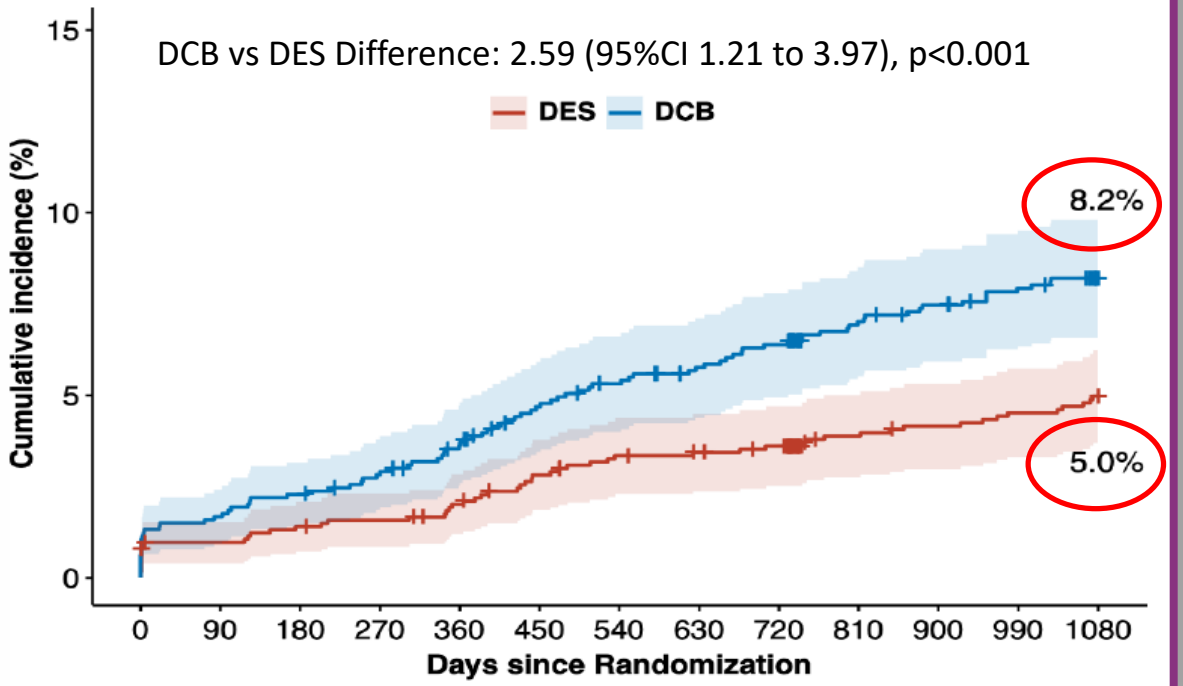
Long Term Durability of PCI Outcomes Remains A Challenge

Stent Related Adverse Events Continue to Increase Post 1-Year[1]



Event Rates Continue to Increase Post 1-Year with Drug Coated Ballons[2-3]



- **Increase in adverse events attributed to constraining the vessel and loss of vessel function[4]**

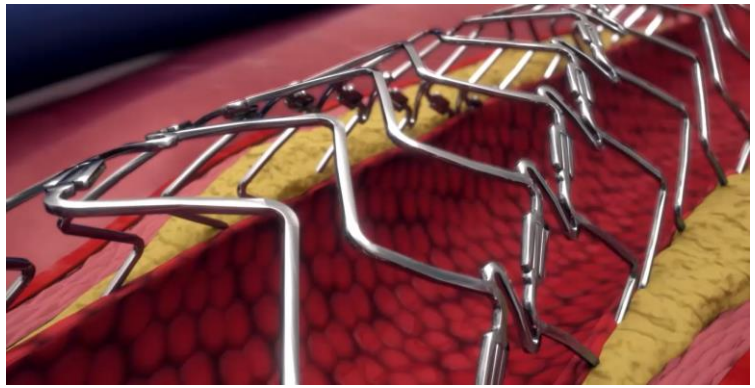
1. Madhavan MV et al., JACC 2020, Stent-related adverse events >1 year after PCI,
2. Tao L et al., JACC 2025, Drug-coated balloon angioplasty versus upfront stenting for de novo CAD: 3-year follow-up of REC-CAGEFREE I
3. Jeger RV et al., The Lancet. 2020: Paclitaxel-coated DCB vs. Xience stent (72% of cases) or Taxus Element stent (28% of cases)
4. Stone et al., JAMA Cardio. 2019, Time-varying outcomes with the absorb bioresorbable vascular scaffold

Bioadaptor Implant and Mechanism of Action

Bioadaptor coronary implant (DynamX®, Elixir Medical, California) is ***designed to adapt to vessel physiology to restore vessel function*** and address device related adverse events[1-3].

Novel Implant Design

Three independent helical sinusoid strands *(CoCr 71µm) are temporarily connected by bioresorbable polymer coating eluting antiproliferative agent*

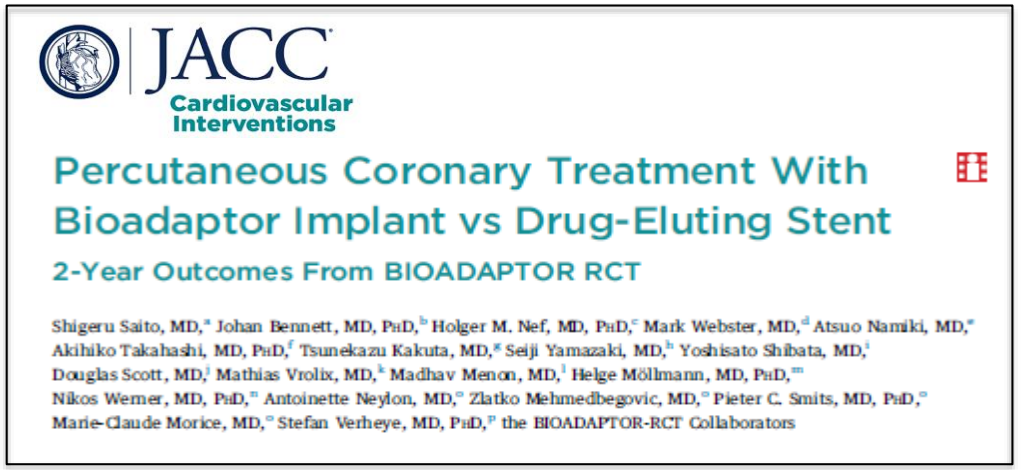


Dynamic Support After 6 Months:
Restore Hemodynamic Modulation

Following polymer resorption ***after 6 months, the helical strands unlock, separate*** *and* ***provide dynamic support to the diseased vessel enabling*** **arterial pulsatility and compliance, adaptive remodeling (Glagov)**[1,2]

1. Saito S et al. 12-Months Outcomes BIODAPTOR-RCT. The Lancet eClinicalMedicine. 2023;65:102304.
2. Verheye S et al. Twelve-month clinical and imaging outcomes of the uncaging coronary DynamX bioadaptor system, EuroIntervention 2020, 16(12);E974
3. Kwak BR et al. Biomechanical factors in atherosclerosis: mechanisms and clinical implications. European heart journal. 2014 Nov 14;35(43):3013-20.

Reduction of Events After 6 Months Reported in Two RCTs[1,2]

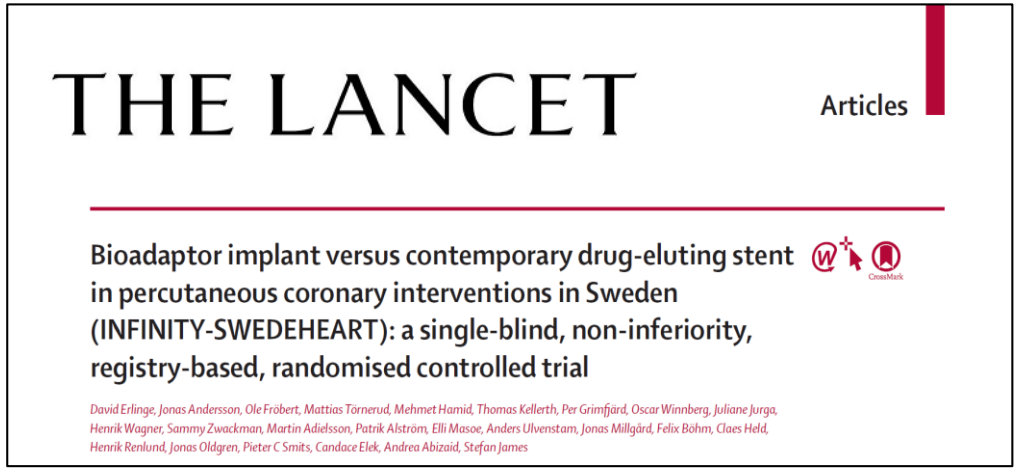


JACC Cardiovascular Interventions

Percutaneous Coronary Treatment With Bioadaptor Implant vs Drug-Eluting Stent

2-Year Outcomes From BIOADAPTOR RCT

Shigeru Saito, MD,[a] Johan Bennett, MD, PhD,[b] Holger M. Nef, MD, PhD,[c] Mark Webster, MD,[d] Atsuo Namiki, MD,[e] Akihiko Takahashi, MD, PhD,[f] Tsunekazu Kakuta, MD,[g] Seiji Yamazaki, MD,[h] Yoshisato Shibata, MD,[i] Douglas Scott, MD,[j] Mathias Vrolix, MD,[k] Madhav Menon, MD,[l] Helge Möllmann, MD, PhD,[m] Nikos Werner, MD, PhD,[n] Antoinette Neylon, MD,[o] Zlatko Mehmedbegovic, MD,[o] Pieter C. Smits, MD, PhD,[o] Marie-Claude Morice, MD,[o] Stefan Verheye, MD, PhD,[p] the BIOADAPTOR-RCT Collaborators



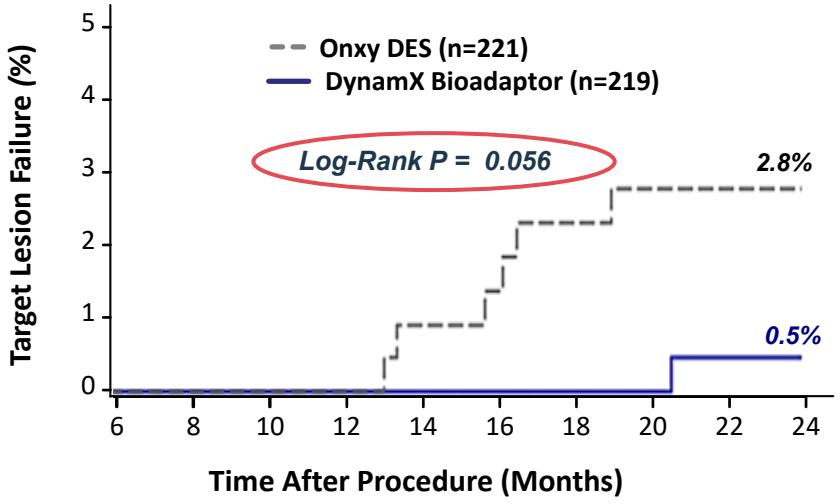
THE LANCET

Articles

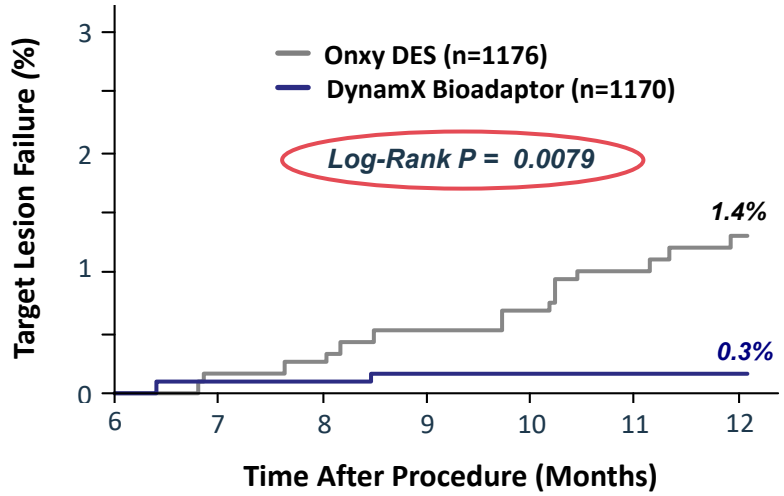
Bioadaptor implant versus contemporary drug-eluting stent in percutaneous coronary interventions in Sweden (INFINITY-SWEDEHEART): a single-blind, non-inferiority, registry-based, randomised controlled trial

David Erlinge, Jonas Andersson, Ole Fröbert, Mattias Törnerud, Mehmet Hamid, Thomas Kellerth, Per Grimfjärd, Oscar Winnberg, Juliane Jurga, Henrik Wagner, Sammy Zwackman, Martin Adielsson, Patrik Alström, Elli Masoe, Anders Ulvenstam, Jonas Millgård, Felix Böhm, Claes Held, Henrik Renlund, Jonas Oldgren, Pieter C Smits, Candace Elek, Andrea Abizaid, Stefan James

BIOADAPTOR RCT:
Plateauing of TLF after 6-Months to 24 Months[1]



INFINITY-SWEDEHEART RCT:
Plateauing of TLF after 6-Months to 12 Months[2]



1. Saito S et al. 24-month Outcomes BIOADAPTOR-RCT. JACC Interv 2025 Apr 28;18(8):988-97.
2. Erlinge D et al. 12-Month Outcomes INFINITY-SWEDEHEART-RCT The Lancet. 2024 Nov 2;404(10464):1750-9.

BIOADAPTOR RCT - Trial Design

N=445 in 34 centers

50% patients enrolled in Germany, Belgium and New Zealand; 50% patients enrolled in Japan

DynamX Bioadaptor (n=223)

1:1

Resolute Onyx DES (n=222)

Imaging subgroups at Baseline and 12M:
QCA (N=50), IVUS (N=50), OCT (N=10)

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QCA (N=50), IVUS (N=50), OCT (N=10)

1-Year Primary Endpoint (ITT): TLF (non-inferiority), clinical follow-up to 5 years;
Secondary Endpoints: %DS, pulsatility by QCA/IVUS/OCT, TVF; **Subgroup Analysis:** LAD, LL (≥23mm), SV (≤2.75mm)

4-Year Clinical Follow-up (Per Protocol Population)

Follow-up Completion: 98% (432/440)

Per Protocol (PP) Population Analysis at 4 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 follow-up through 4 years:

- 8 subject withdrawals

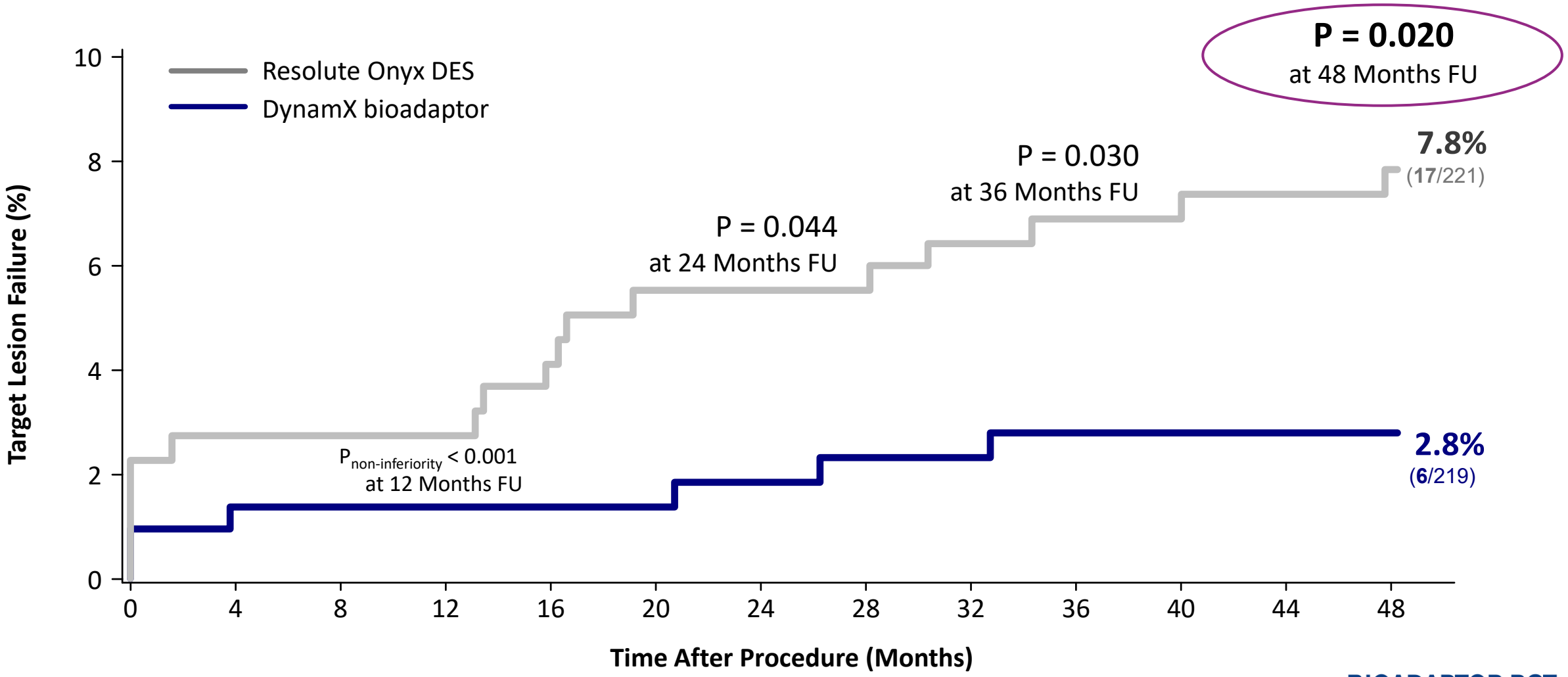
Patient Baseline Characteristics

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%)

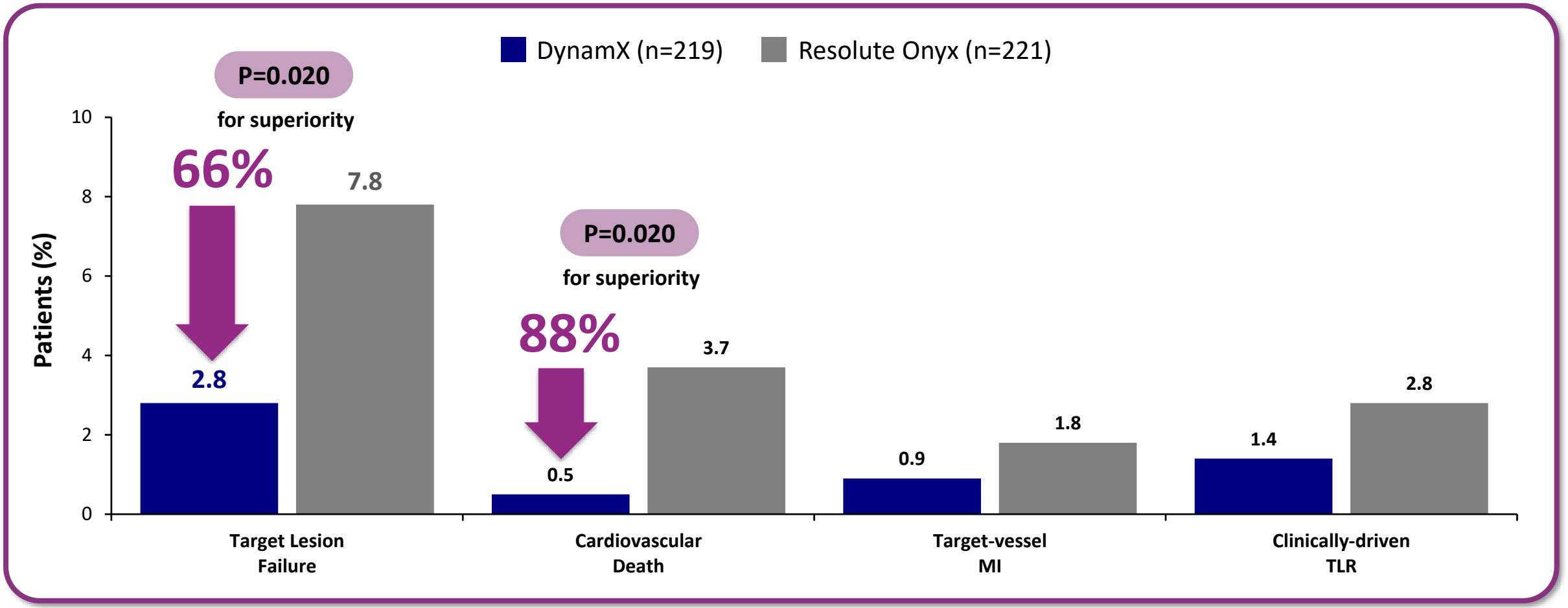
Anatomical Characteristics	DynamX (N=223)	Resolute Onyx (N=222)
Target lesion vessel		
LAD	**114 (50.4%)**	**104 (45.2%)**
LCX	35 (15.5%)	66 (28.7%)
RCA	77 (34.1%)	60 (26.1%)
Ostial lesion	**13 (5.8%)**	**8 (3.5%)**
Bifurcation lesion	**50 (22.1%)**	**55 (23.9%)**
Moderate/severe calcification	**43 (19.0%)**	**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

Outcomes at 4 Year Follow Up

Sustained Significant Reduction in TLF with Bioadaptor compared to DES

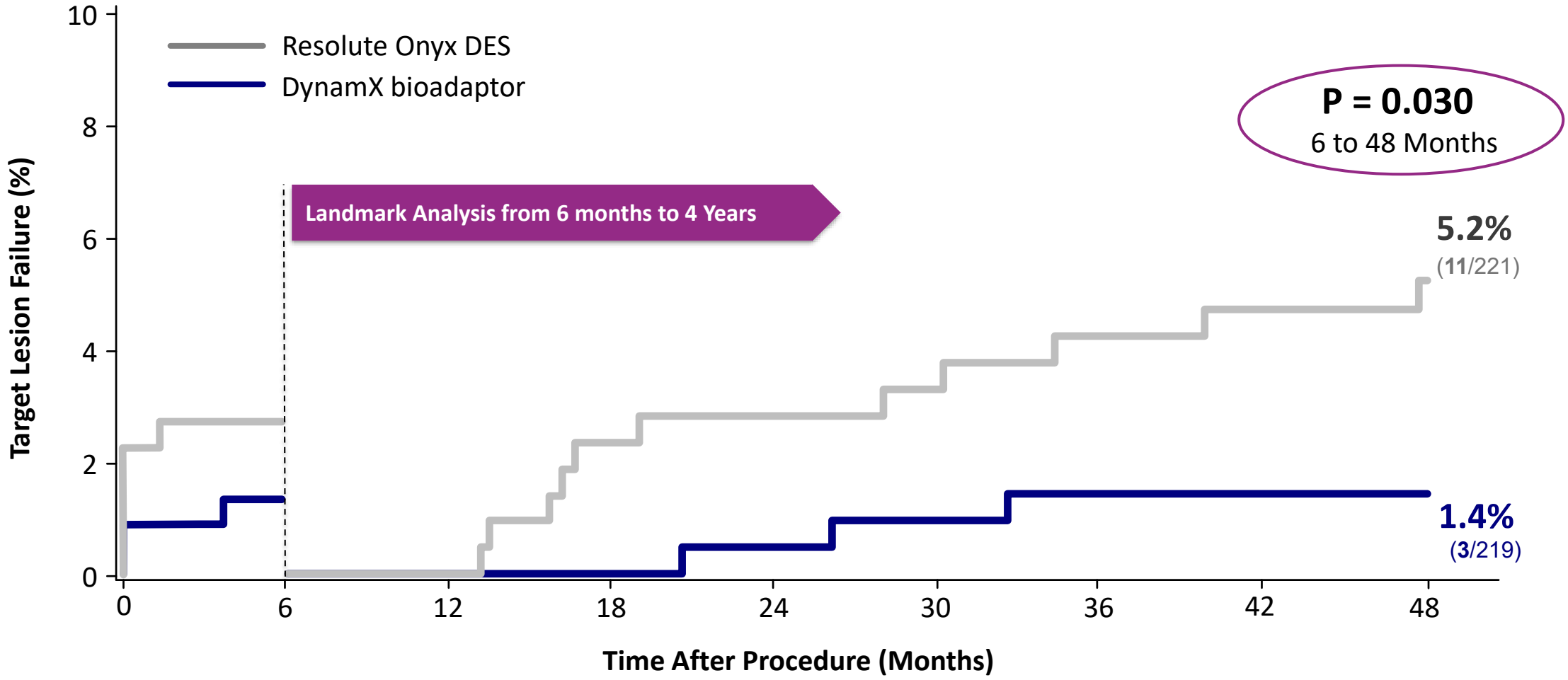


Reduction in TLF at Year 4 with Bioadaptor Driven by All Components
With Reduced CV Death Compared to DES

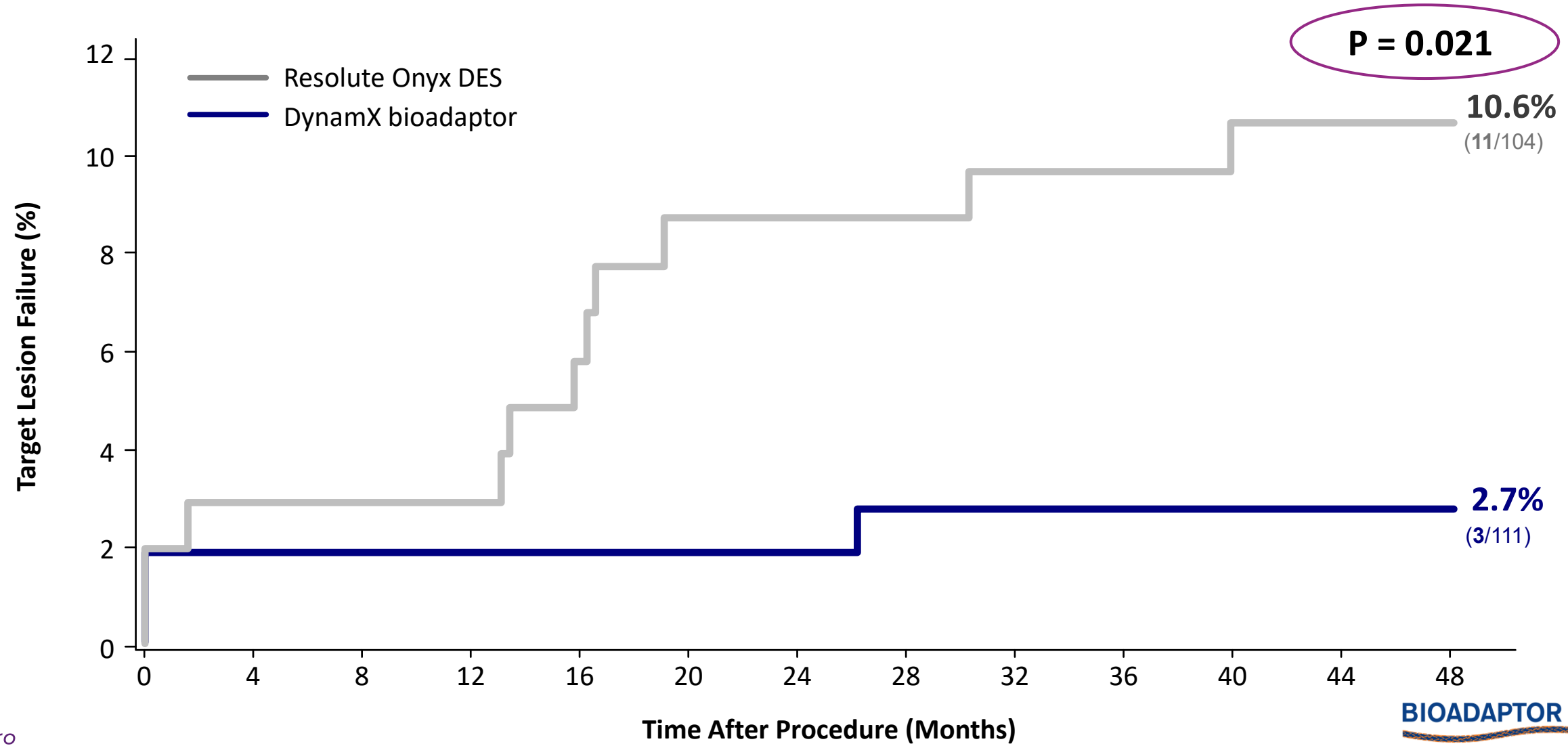


Kaplan Meier (KM) event rates. KM log rank test for p values. Per protocol analysis. Target lesion failure hazard ratio (HR): 0.34 [0.13, 0.87]; cardiovascular death HR: 0.12 [0.02, 0.98]

TLF Landmark Analysis from 6 Months to 4 Years:
Significant Reduction Consistent with Bioadaptor Mechanism of Action



TLF Outcomes in LAD Lesions:
Substantial Benefit with Bioadaptor compared to DES Through 4 Years



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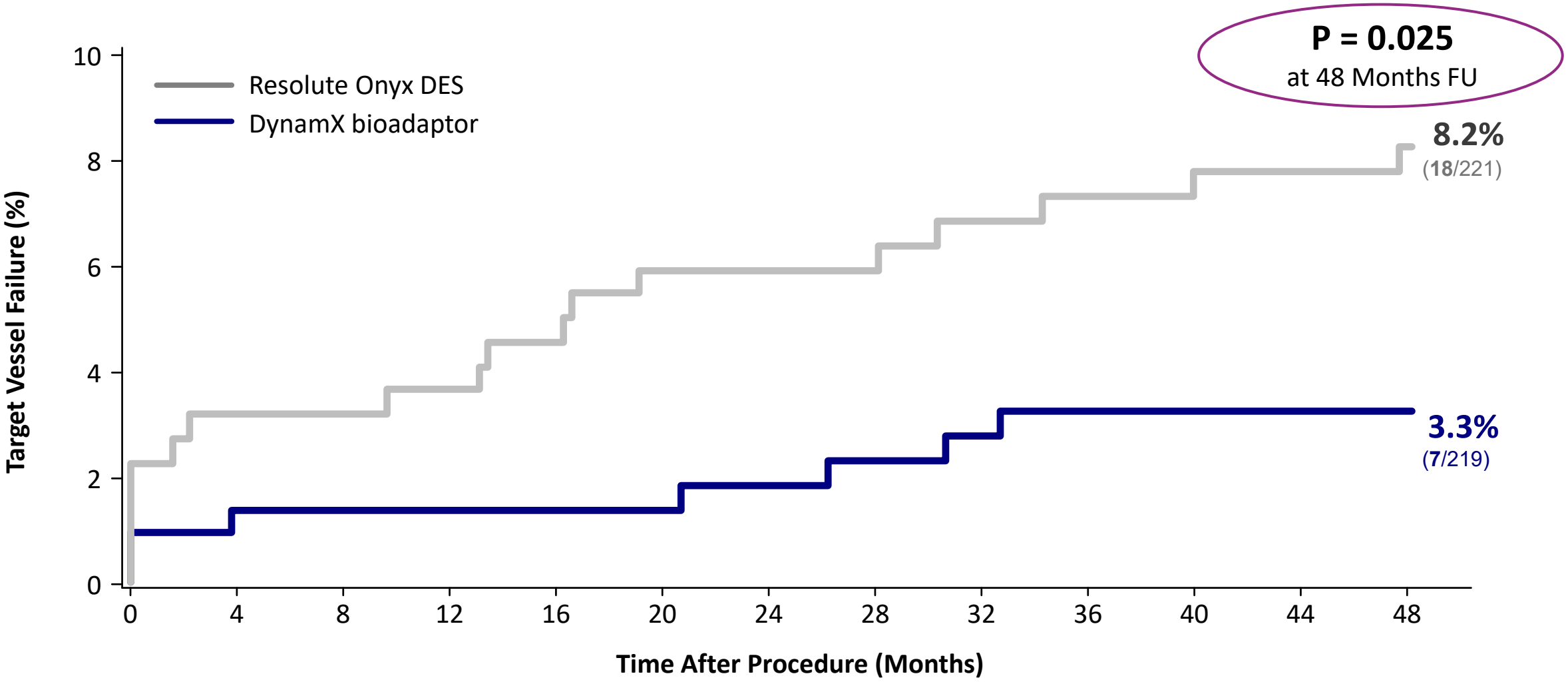
Significant Reduction in Target Vessel Failure with Bioadaptor Through 4 Years Compared to DES



Conclusions

- Four-year clinical follow up results from the BIOADAPTOR-RCT demonstrate:
  - **Significantly lower TLF rates (2.8% versus 7.8%, p = 0.020)** with bioadaptor compared to DES driven by all components of composite endpoint
  - **Significant reduction in Cardiac Death (0.5% versus 3.7%, p = 0.020)**
  - **Substantial clinical benefit with bioadaptor in LAD lesions (TLF: 2.7% versus 10.6%, p = 0.021)**

- Long-term results demonstrate **significant reduction of device-related events with bioadaptor compared to DES and a strong benefit in CV Death**, confirming durable treatment benefit of restoring hemodynamic modulation with DynamX bioadaptor.

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