BIOADAPTOR RCT Outcomes at 3-Year Follow Up

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

Shigeru Saito, MD

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

Potential conflicts of interest

Speaker's name: Shigeru Saito

☑ I have the following potential conflicts of interest to report

- Receipt of honoraria or consultation fees –Elixir Medical, Medinol

Study Organization

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Tsunekazu Kakuta	Tsuchiura Kyodo Hospital
Seiji Yamazaki	Sapporo Higashi Tokushukai Hospital
Yoshisato Shibata	Miyazaki Medical Association Hospital
Jyunji Yajima	Cardiovascular Institute
Yoshiaki Ito	Yokohama City Eastern Hospital
Tomohiro Kawasaki	Shinkoga Hospital
Kenji Ando	Kokura Memorial Hospital
Toshiyuki Matsumura	Kumamoto Rousai Hospital
Takashi Kajiya	Tenyokai Central Hospital
Ken Kozuma	Teikyo University Hospital
Takuo Nakagami	Oumi Hachiman City GMC

Clinical Research Organization Partners:

CERC Cardiovascular European Research Center

iC42 integrated solutions in systems biology clinical research & development

Europe:

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Mathias Vrolix	Ziekenhuis Oost-Limburg
Helge Möllmann	St. Johannes Hospital Dortmund
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Martin Landt	Segeberger Kliniken Bad Segeberg
Jürgen Bogoviku	Universitätsklinikum Jena
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Tommaso Gori	Universitätsmedizin Mainz
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Stephan Achenbach	Universitätsklinikum Erlangen
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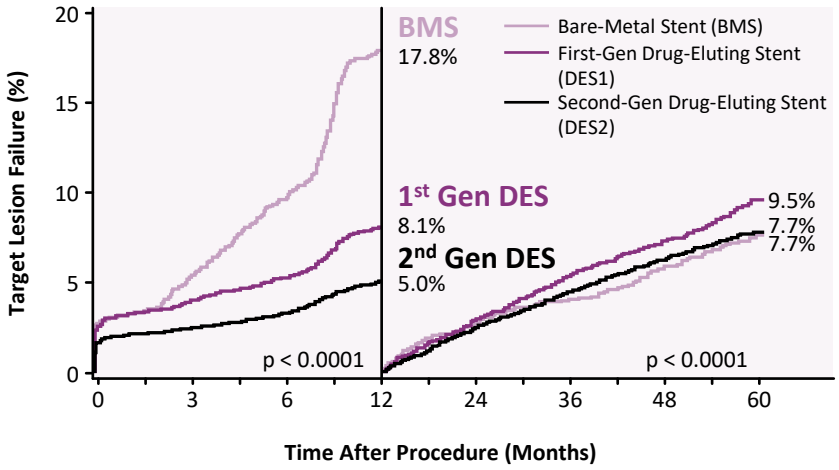
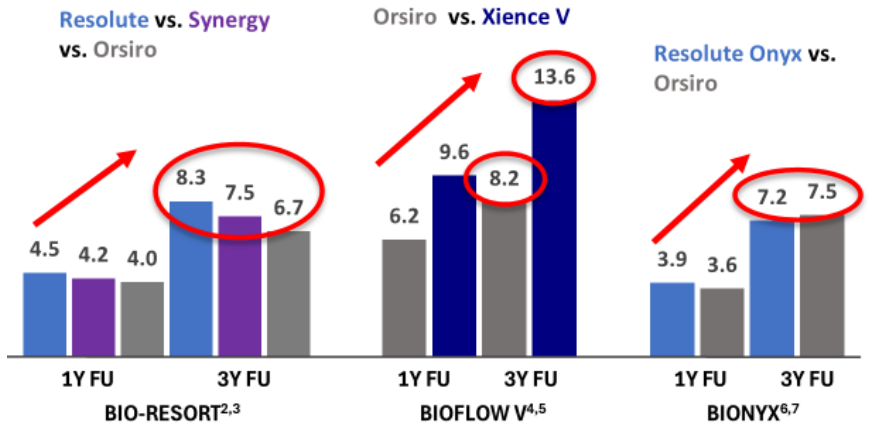
Seif El-Jack	North Shore Hospital Takapuna
Dougal McClean	Christchurch Hospital
Gerard Wilkins	Dunedin Hospital
Madhav Menon	Waikato Hospital
Douglas Scott	Middlemore Clinical Trials Trust

Stent Related Adverse Events Increase 2-3% Each Year After PCI

Non-Plateauing Adverse Events Post 1-Year[1]



1 and 3-year TLF Rates With Contemporary DES[2-7]

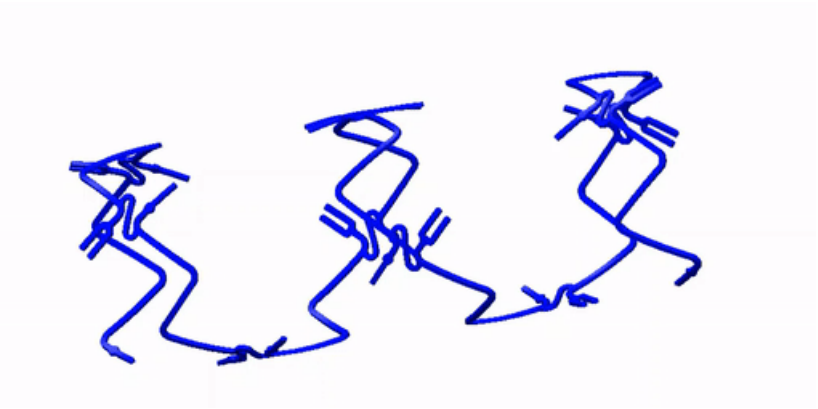


- **Increase in adverse events attributed to constraining the vessel and loss of vessel function[5]**

1. Madhavan MV et al. *J Am Coll Cardiol* 2020;75:590-604
2. von Birgelen C et al The Lancet. 2016 Nov 26;388(10060):2607-17.
3. Buiten A et al JACC: Cardiovasc Interv., 2019. Vol. 12, No. 17.
4. Kandzari DE et al. The Lancet. 2017 Oct 21;390(10105):1843-52
5. Kandzari DE, et al. J Am Coll Cardiol Intv. 2020 Jun, 13(11) 1343-1353
6. von Birgelen C et al. The Lancet. 2018 Oct 6;392(10154):1235-45.
7. Ploumen EH et al. Circ J. 2021 Oct 25; 85(11):1983-1990

Novel Bioadaptor Implant

Bioadaptor is a coronary implant (DynamX®, Elixir Medical, California) that is ***designed to adapt to vessel physiology to restore vessel function*** and address device related adverse events[1,2].



- ***Three independent helical sinusoid strands*** *(CoCr 71µm) are temporarily connected by bioresorbable polymer coating eluting antiproliferative agent*
- *Following polymer resorption* ***after 6 months, the helical strands unlock, separate*** *and provide dynamic support*

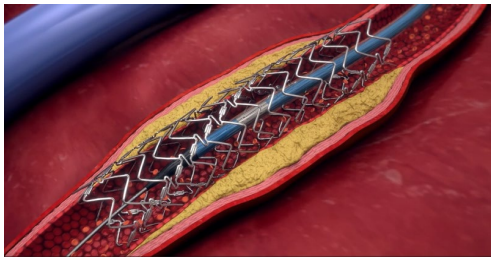
*The DynamX Sirolimus Eluting Coronary Bioadaptor System is an investigational device. Limited by Federal (or United States) law to investigational use.

1 Verheye, et al. 12-Month Clinical and Imaging Outcomes of DynamX Bioadaptor System. EuroIntervention 2020;16:e974-e981
2. Saito S et al. 12-Month Outcomes BIOADAPTOR-RCT. The Lancet eClinicalMedicine. 2023;65:102304.

Study Device: Bioadaptor Mechanism of Action

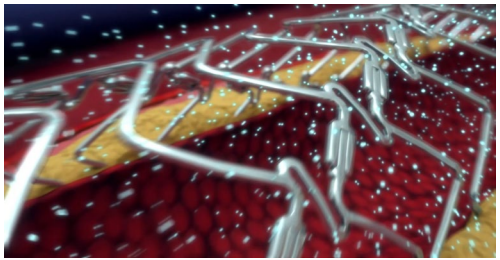
Bioadaptor (DynamX®, Elixir Medical, CA) is a novel technology designed to *restore hemodynamic modulation of the vessel* and address device related adverse events.

0 – 6 months → **after 6 months**



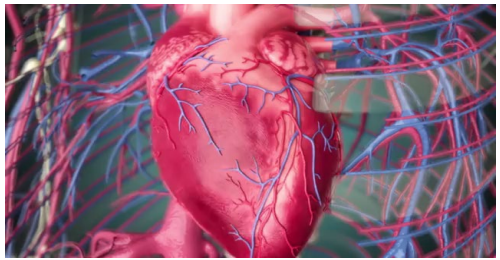
1. Locked:
Establish Flow Lumen

Restore flow and achieve high acute gain and low residual %DS[1,2]



2. Unlocked:
Maintain Flow Lumen

Restore adaptive remodeling and maintain low %DS[1,2]

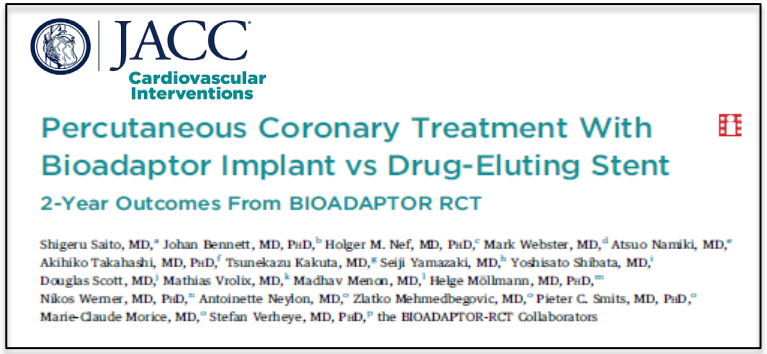


3. Dynamic Support:
Restore Hemodynamic Modulation

Restore pulsatility, compliance, adaptive coronary flow[1-3]

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.

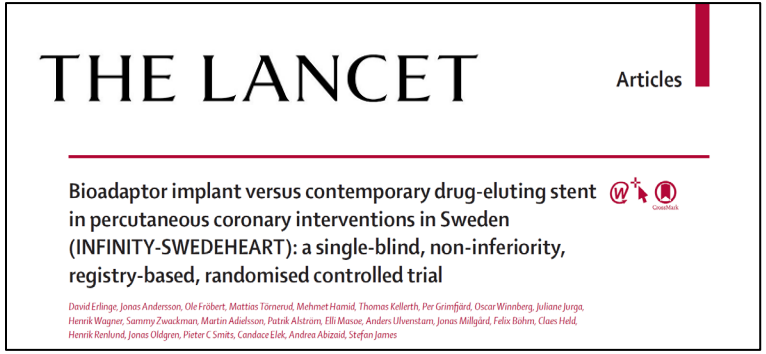
Plateauing of Events After 6 Months in Two RCTs[1,2]


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

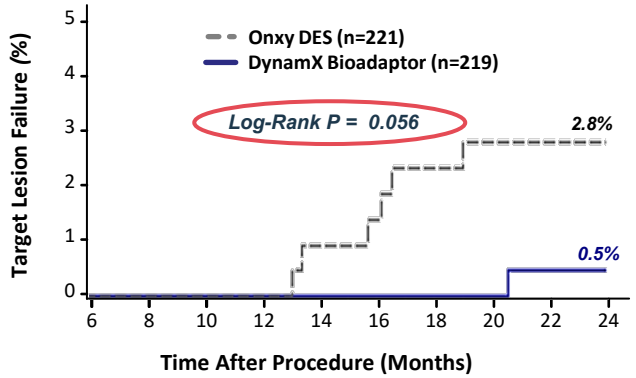

THE LANCET

Articles

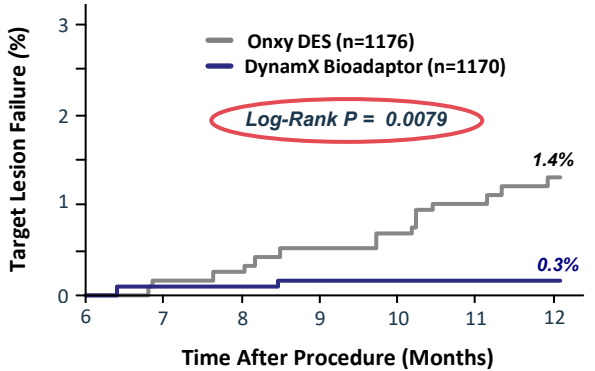
Bioadaptor implant versus contemporary drug-eluting stent in percutaneous coronary interventions in Sweden (INFINITY-SWEDEHEART): a single-blind, non-inferiority, registry-based, randomised controlled trial

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]

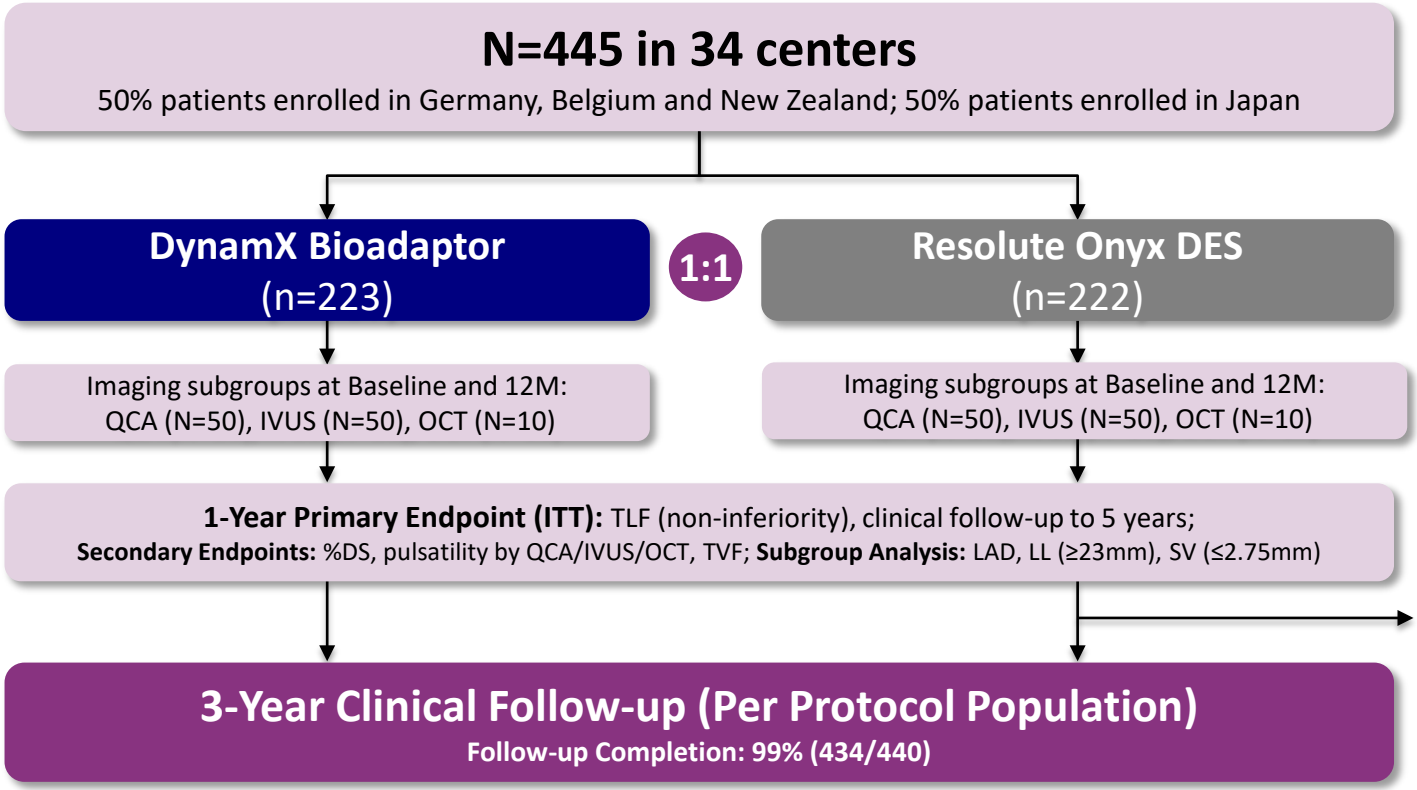


INFINITY-SWEDEHEART RCT:
Plateauing of TLF after 6-Months to 12 Months[2]



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



Per Protocol (PP) Population Analysis at 3 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 3 years:

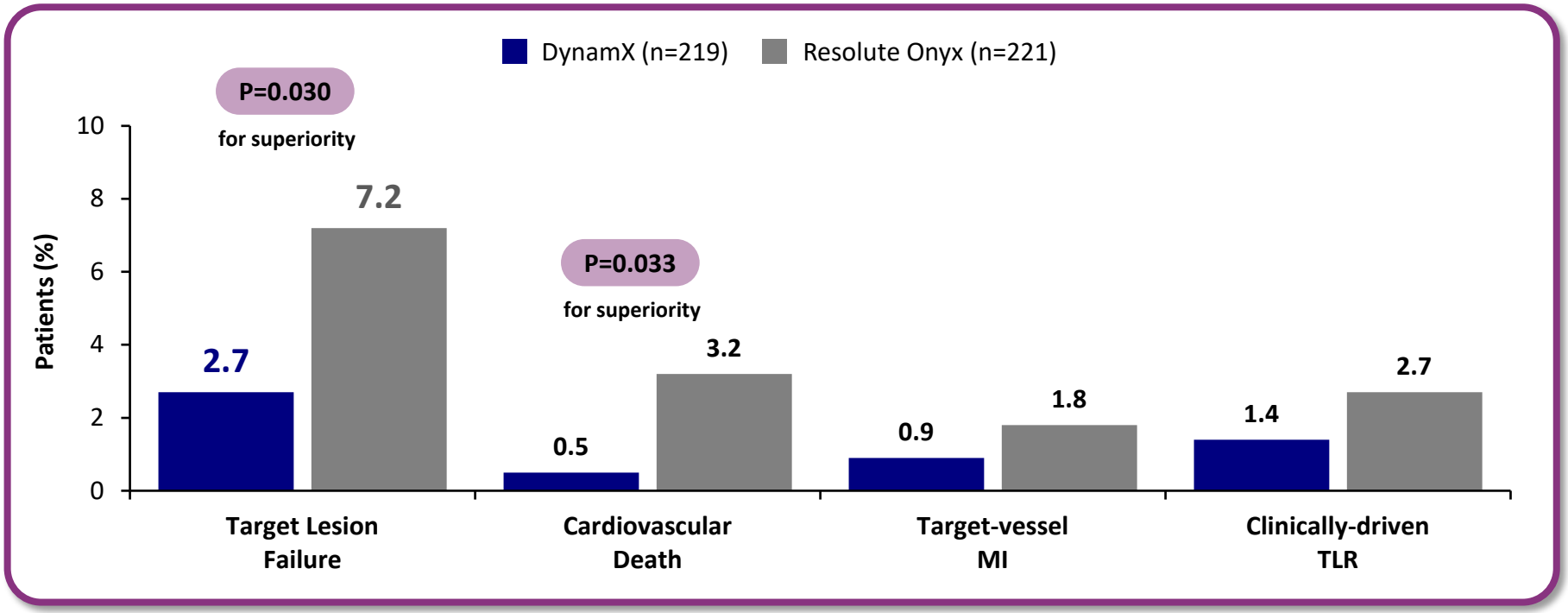
- 5 subject withdrawals
- 1 subjects missed 3-Year visit

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%)

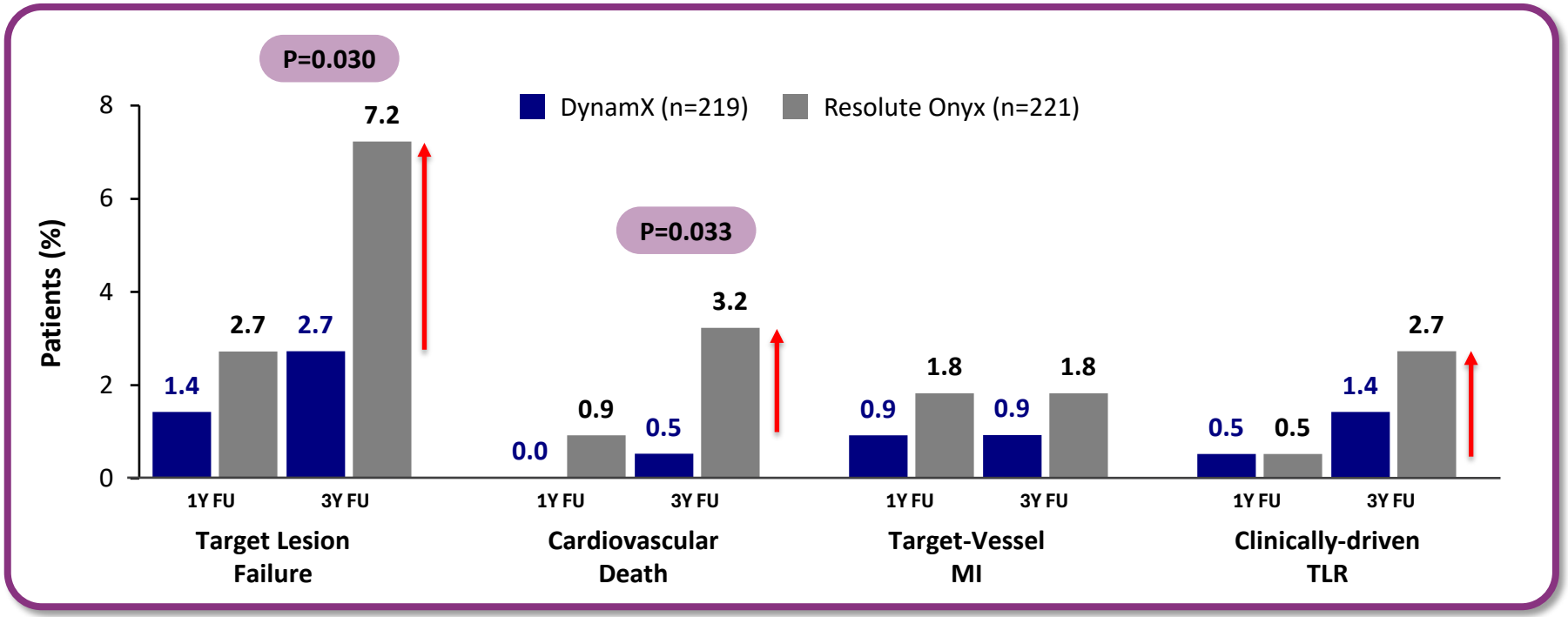
Anatomical Characteristics	DynamX (N=223)	Resolute Onyx (N=222)
Target lesion vessel		
LAD	**114 (50.4%)**	**104 (45.2%)**
LCX	35 (15.5%)	66 (28.7%)
RCA	77 (34.1%)	60 (26.1%)
Ostial lesion	**13 (5.8%)**	**8 (3.5%)**
Bifurcation lesion	**50 (22.1%)**	**55 (23.9%)**
Moderate/severe calcification	**43 (19.0%)**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

Significant Reduction in TLF with Bioadaptor at 3 Year Follow-up Compared to DES



*Chi-square test for p values. Per protocol analysis. Events adjudicated per the ARC-2 Criteria. Percentages indicate patients who had an event through the 1095±100 days follow up window.

Low TLF with Bioadaptor Sustained at 3Y Follow-up, while a Non-plateauing Increase in TLF, CVD and ID-TLR with DES



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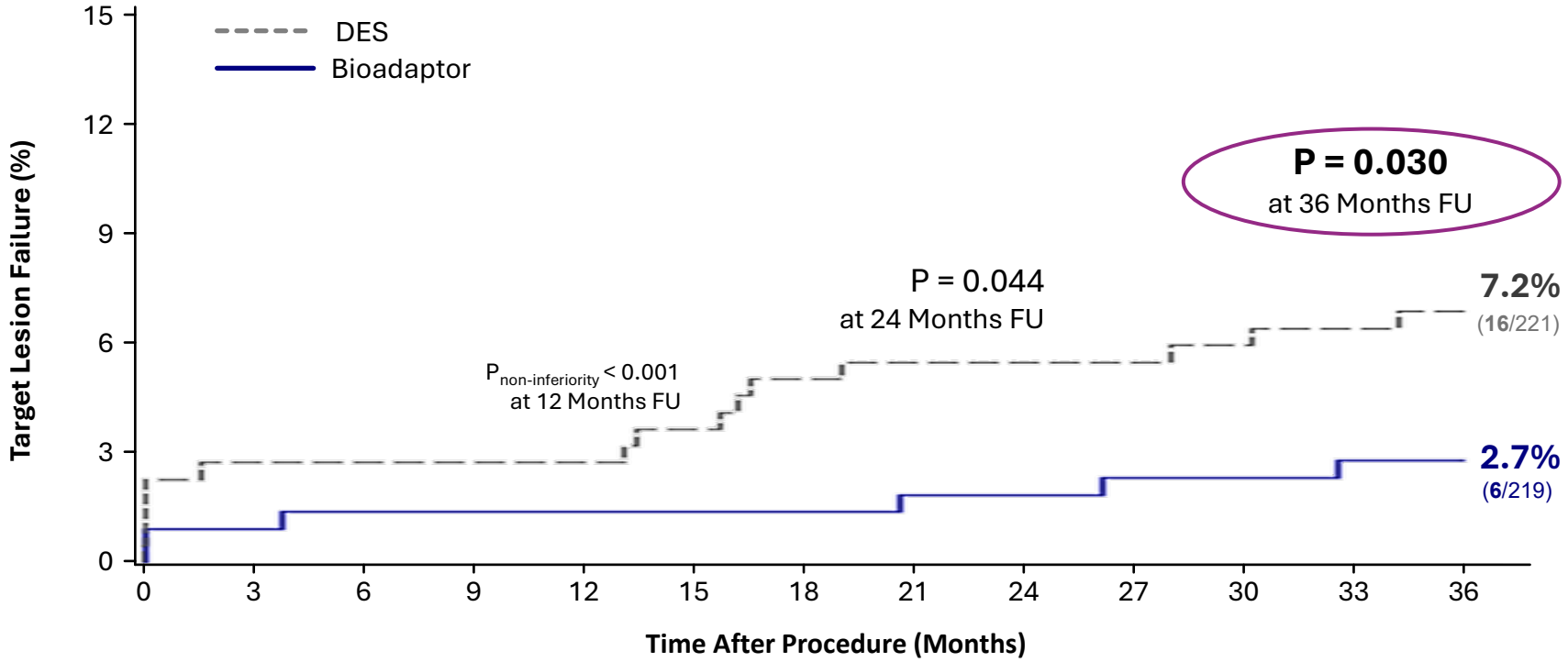
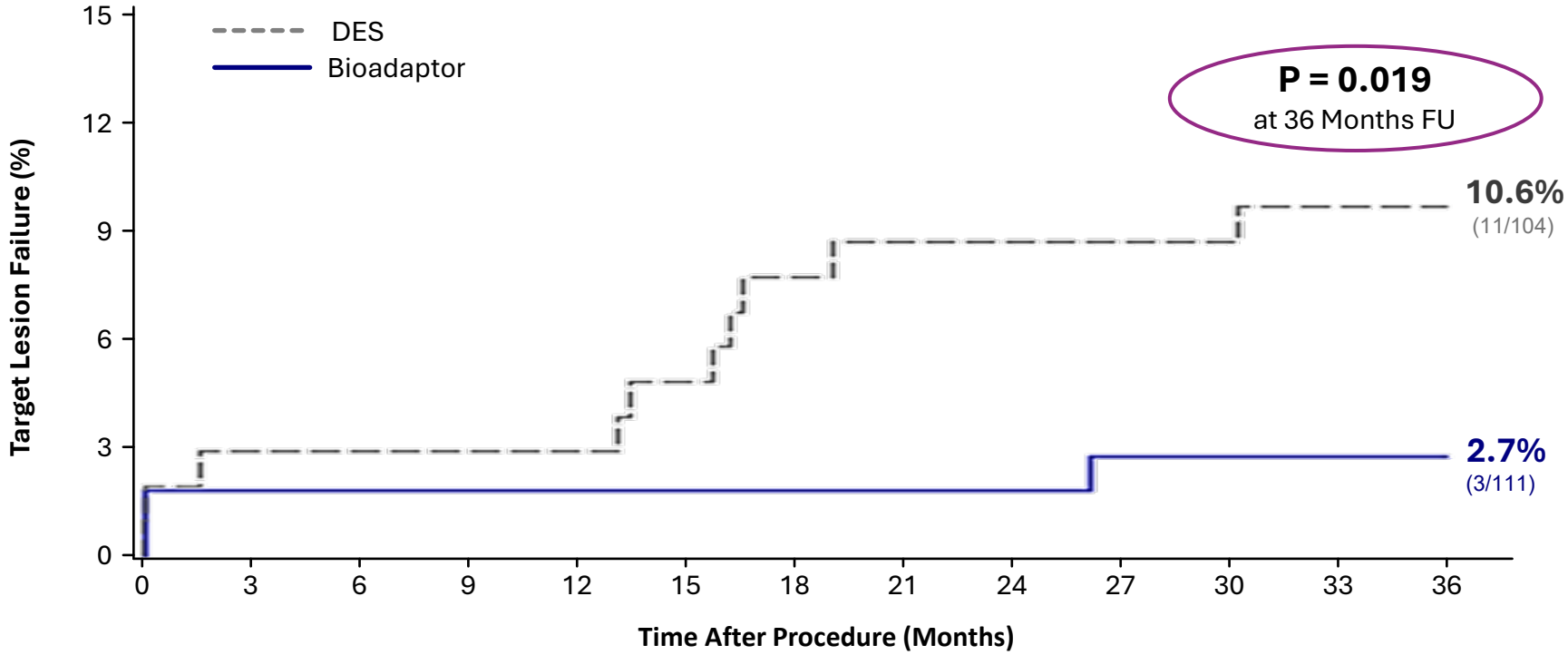
Saito S et al. 12-Months Outcomes BIODAPTOR-RCT. The Lancet eClinicalMedicine. 2023;65:102304.

Sustained Treatment Benefit with Bioadaptor From 6 Months to 3 Years



Substantial Treatment Benefit Demonstrated in LAD Lesions at 3 Years



Conclusions

- Three-year clinical follow up results from the BIOADAPTOR-RCT shows:
  - **Sustained significantly lower TLF rates (2.7% versus 7.2%, p=0.030)** with bioadaptor compared to DES
  - **Significantly lower rate of Cardiac Death (0.5% versus 3.2%, p=0.033) compared to DES, and lower rate of clinically driven revascularizations**
  - **Substantial clinical benefit with bioadaptor in LAD lesions (TLF: 2.7% versus 10.6%, p=0.019),** consistent with bioadaptor mechanism of action of restoring vessel function
- Evidence from the BIOADAPTOR-RCT demonstrate **sustained significant reduction of device-related events with bioadaptor compared to DES**, confirming the durability of treatment benefit from 6 months and through long-term follow-up

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Supplemental Material

30 Months Imaging Follow up From BIOADAPTOR-RCT

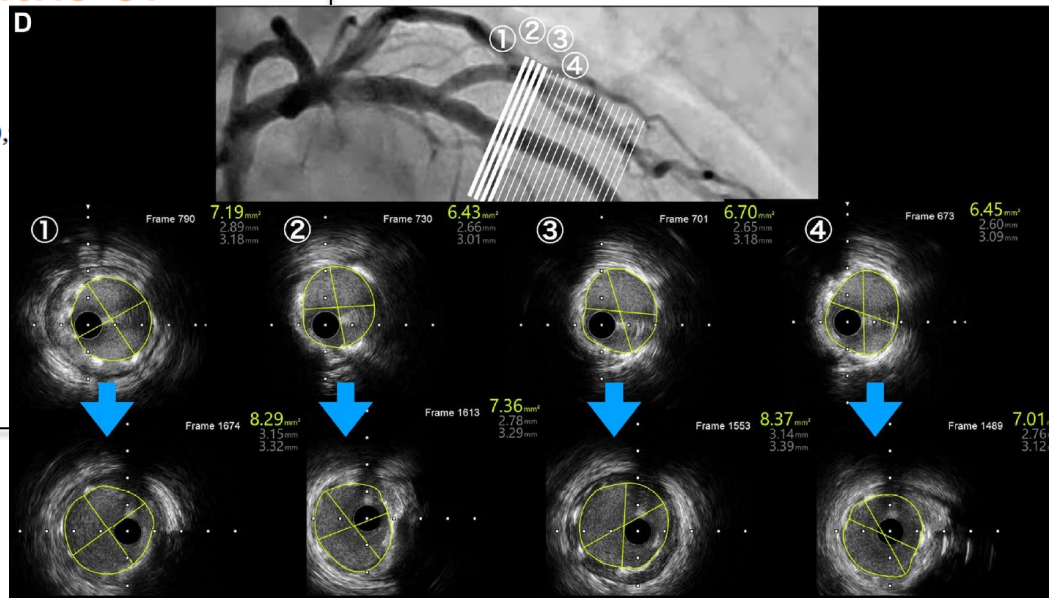
CORONARY, PERIPHERAL, AND STRUCTURAL INTERVENTIONS

CLINICAL CASE SERIES

Physiological Scaffold Remodeling in the Coronary Artery After 30 Months of Bioadaptor Implantation

Shiori Kawakami, MD,[a] Akihiko Takahashi, MD,[a,b] Norimasa Taniguchi, MD, Tetsuya Hata, MD,[a] Shunsuke Nakajima, MD,[a] Shigeru Saito, MD[c]

JACC: CASE REPORTS



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Sustained Plateau in TVF at 3-Year Follow up