



Impact of Imaging- or Physiology-Guided Coronary Revascularization on Long Term Outcomes with Bioadaptor Implant **Insights from the INFINITY-SWEDEHEART Trial**

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on behalf of Stefan James, Uppsala University M.D., Ph.D. and
the INFINITY-SWEDEHEART investigators



2026

Potential conflicts of interest

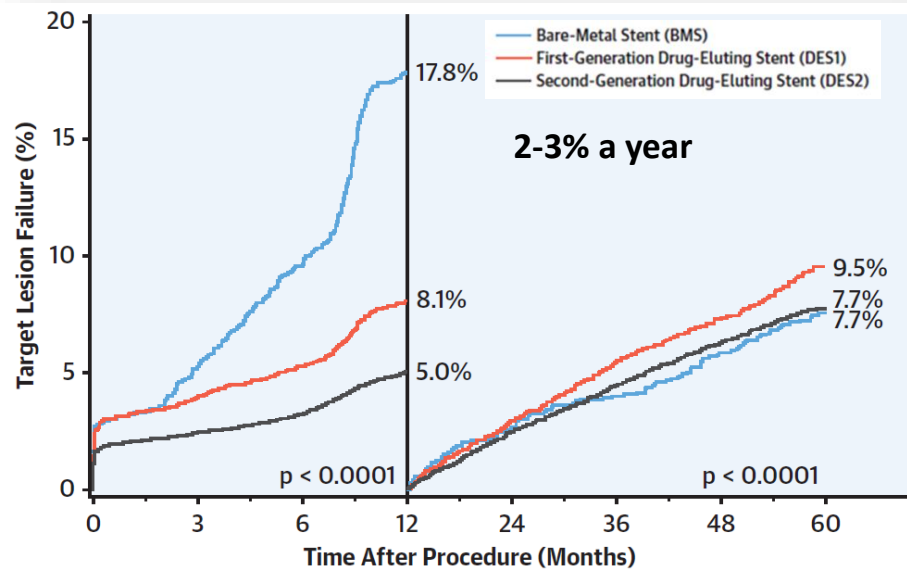
Speaker's name: ***David Erlinge, M.D., Ph.D.***

David Erlinge has received honorarium for advisory board/speaker fees from Amgen, AstraZeneca, Chiesi, Sanofi, NovoNordisk, InfraredX/Nipro and Kaminari Medical.

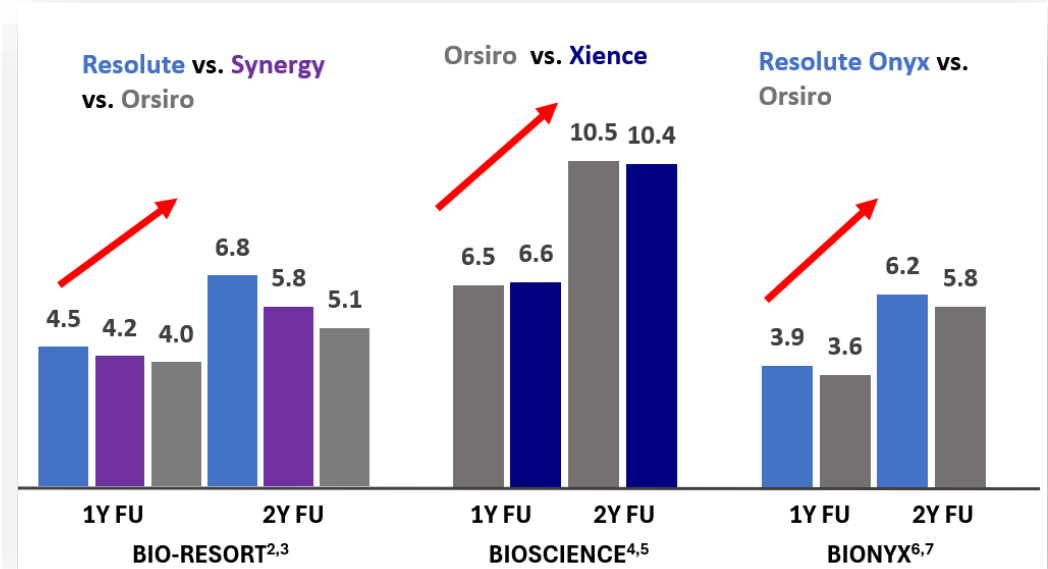
Stent Related Adverse Events Increase 2-3% Each Year After PCI

- Stent related adverse events continue to accrue after the first year at a non-plateauing rate of 2-3%¹
- No device intervention to date has shown superiority vs. DES

Non-Plateauing Adverse Events Post 1-Year¹



1 and 2-year TLF Rates With Contemporary DES²⁻⁷



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. Pilgrim T, et al. The Lancet. 2014 Dec 13;384(9960):2111-22.

5. Zbinden R et al. JAMA 2016 Mar 15;315(11):1235-45.
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

Intravascular Imaging/Physiology Guideline Recommended for Complex PCI Yet Event Rates Continue to Rise Beyond 1 Year



European Society
of Cardiology

European Heart Journal (2024) 45, 3415–3537
<https://doi.org/10.1093/eurheartj/ehae177>

ESC GUIDELINES

2024 ESC Guidelines for the management of chronic coronary syndromes

Developed by the task force for the management of chronic coronary syndromes of the European Society of Cardiology (ESC)

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)

Intracoronary imaging guidance by IVUS or OCT is recommended when performing PCI on anatomically complex lesions in particular left main stem, true bifurcations and long lesions

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Intracoronary pressure measurement (FFR or iFR) or computation (QFR) is recommended to guide lesion selection for intervention in patients with multivessel disease

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Vrints et al. European Heart Journal (2024) 45, 3415–3537



The NEW ENGLAND
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ORIGINAL ARTICLE

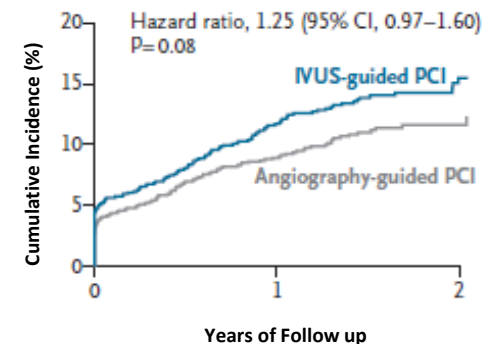


Intravascular Ultrasound–Guided or Angiography–Guided Complex High-Risk PCI

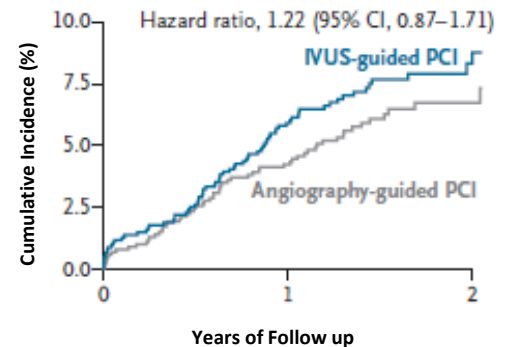
Authors: Roberto Diletti, M.D., Ph.D. , Joost Daemen, M.D., Ph.D., Benjamin Faurie, M.D., Marco Barbierato, M.D., Didier Tchétché, M.D., Thomas Hovasse, M.D., Koen Teeuwen, M.D., Ph.D., ⁺²¹, for the IVUS-CHIP Investigators* [Author Info & Affiliations](#)

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Target Vessel Failure (composite primary endpoint)



Clinically Indicated Target Vessel Revascularization



Diletti R et al. New England Journal of Medicine. 2026 Mar 30.

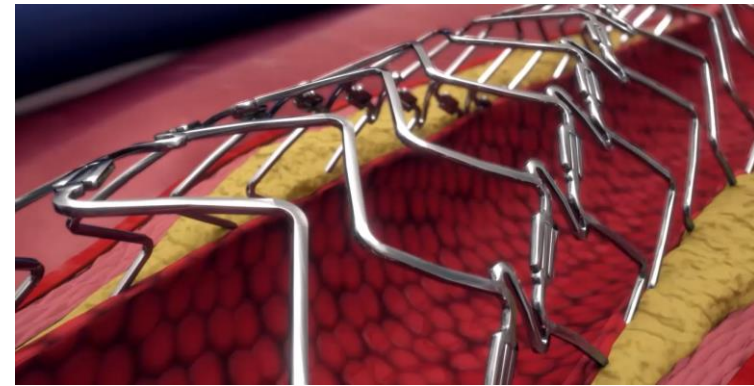
Bioadaptor Implant and Mechanism of Action

Bioadaptor coronary implant (DynamX®, Elixir Medical, California) is ***designed to adapt to vessel physiology to restore vessel function*** and address device related adverse events¹⁻³.



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**

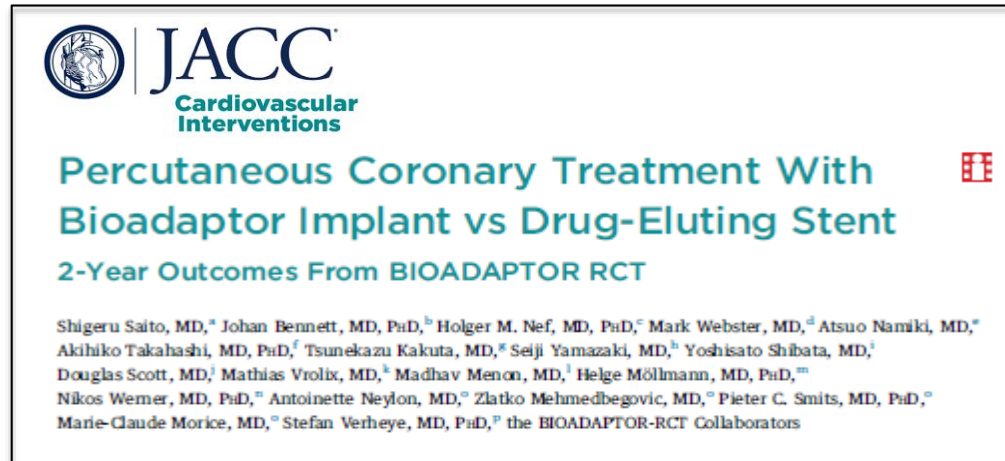
Following polymer resorption after 6 months, the helical strands unlock, separate and provide dynamic support to the diseased vessel enabling arterial pulsatility and compliance, adaptive remodeling (Glagov)^{1,2}

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.

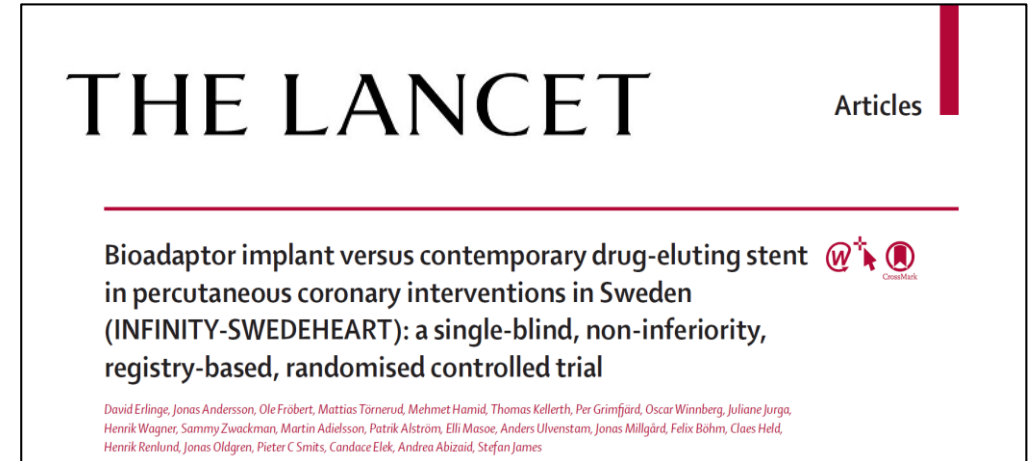
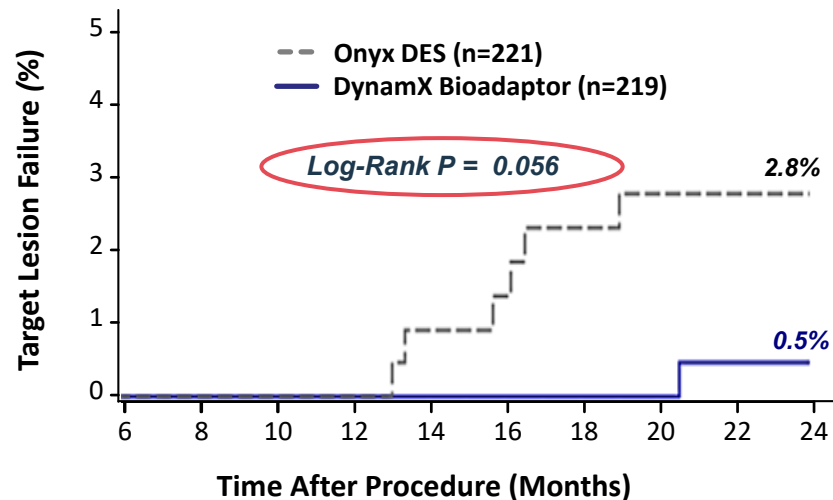
The DynamX Coronary Bioadaptor System is CE Mark approved.

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

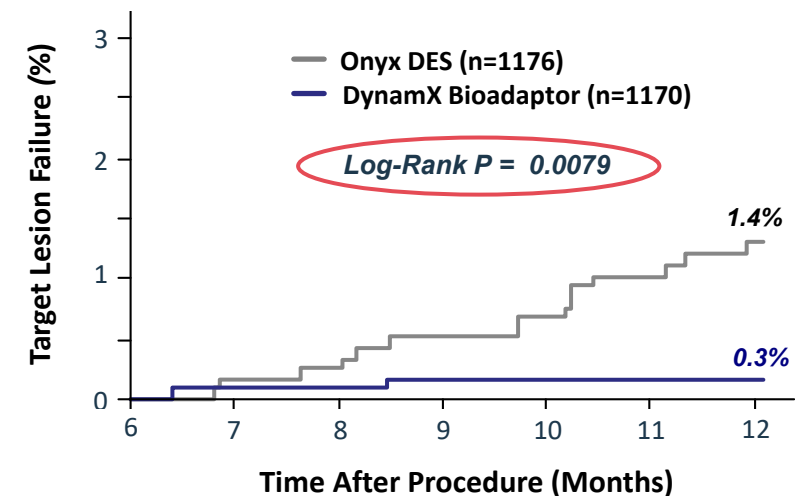
Reduction of Events with Bioadaptor After 6 Months in Two RCTs^{1,2}



BIODAPTORT RCT:
Plateauing of TLF after 6-Months to 24 Months¹



INFINITY-SWEDEHEART RCT:
Plateauing of TLF after 6-Months to 12 Months²



1. Saito S et al. 24-month Outcomes BIODAPTORT-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.

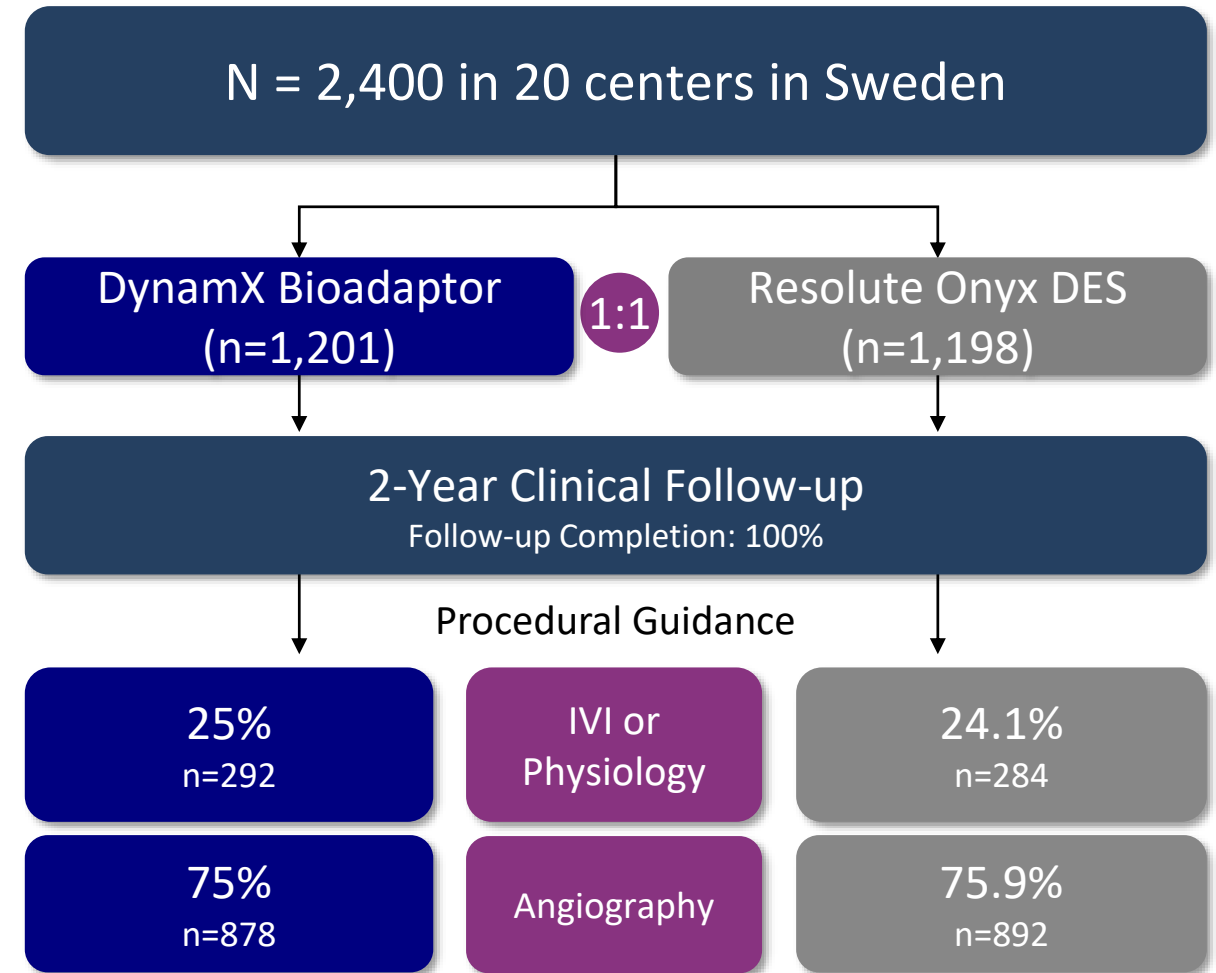
Objective and Methods of the Current Analysis

Objective:

To assess the impact of procedural guidance strategy, intravascular imaging (IVI) or physiology compared to angiography alone, on the long-term clinical outcomes of bioadaptor, compared to DES, from the large INFINITY-SWEDEHEART RCT trial

Methods:

- Prespecified landmark analyses of target lesion failure (TLF) from 6 to 24 months for superiority
- Outcomes stratified by procedural guidance:
 - IVI (IVUS/OCT) or Physiology (FFR/iFR) guided
 - Angiography guided
- Multivariable Cox proportional hazards adjustment to account for baseline and procedural confounders



Study Management and Site Enrollment



Study/Site Management, Data Mgmt., Statistics, CEC, DSMB



Imaging Core Lab

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Ole Fröbert, MD, PhD	Örebro University Hospital	215
Mattias Törnerud, MD	Danderyd Hospital, Stockholm	198
Mehmet Hamid, MD	Mälarsjukhuset, Eskilstuna	170
Thomas Kellerth, MD	Central Hospital, Karlstad	146
Per Grimfjärd, MD, PhD	Västerås hospital,	133
Daniel Ohm, MD	Capio St Göran Hospital, Stockholm	107
Carl-David Dolata, MD	Helsingborg Hospital	84

PI	Hospital Name	# Enrolled
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Juliane Jurga, MD, PhD	Karolinska University Hospital, Solna	49
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Mats Birgander, MD, PhD	Skåne University Hospital, Malmö	15

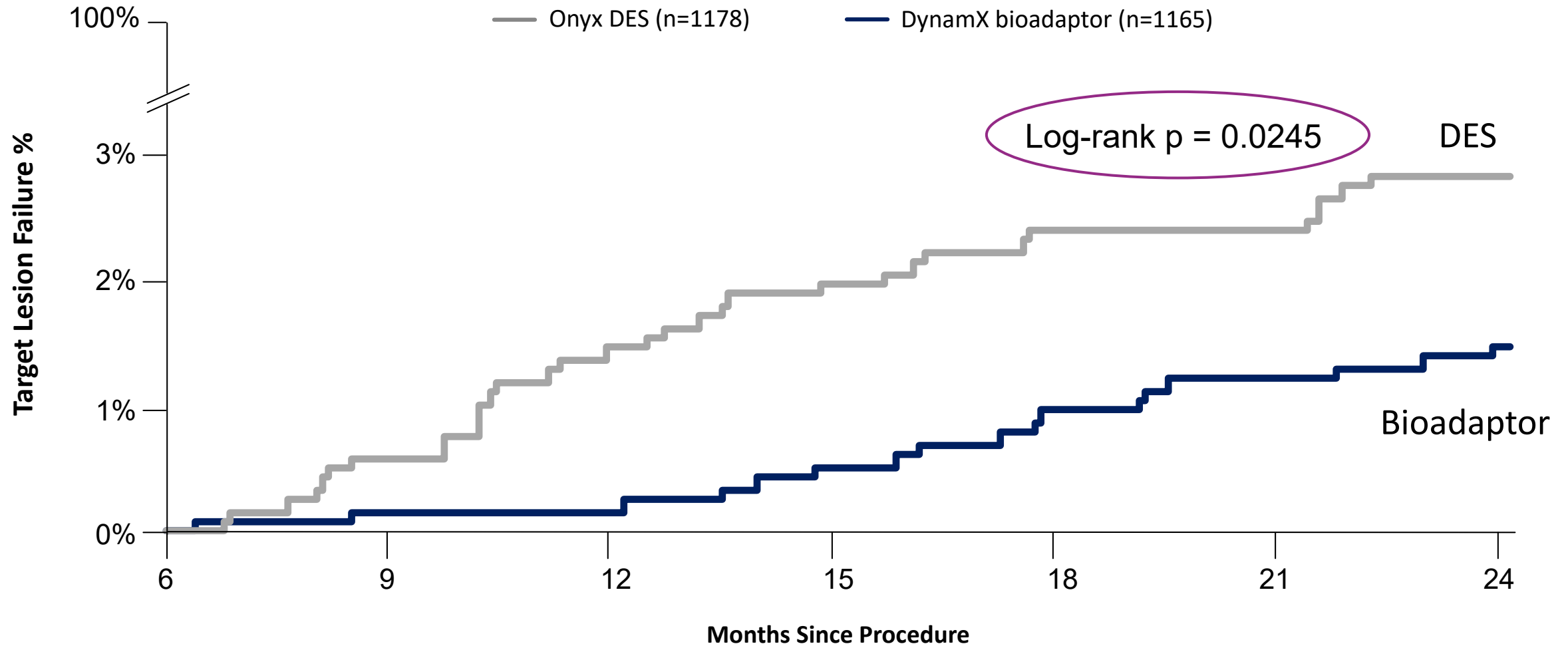
Patient Baseline Characteristics

Baseline Characteristics	IVI or Physiology (N=576)		Angiography (N=1,770)	
	DynamX (n=292)	Onyx (n=284)	DynamX (n=878)	Onyx (n=892)
Age, years	67.7 ± 9.80	67.4 ± 9.10	68.2 ± 9.69	68.3 ± 9.75
Female	73 (25.0%)	68 (23.9%)	208 (23.7%)	213 (23.9%)
Hypertension	187 (64.0%)	176 (62.2%)	514 (58.9%)	520 (58.9%)
Hyperlipidemia	153 (52.4%)	144 (50.7%)	374 (42.9%)	341 (38.7%)
Diabetes Mellitus	57 (19.5%)	42 (14.8%)	163 (18.6%)	153 (17.2%)
Prior MI	39 (13.4%)	44 (15.5%)	98 (11.2%)	95 (10.7%)
Prior PCI	46 (15.8%)	53 (18.7%)	122 (13.9%)	110 (12.4%)

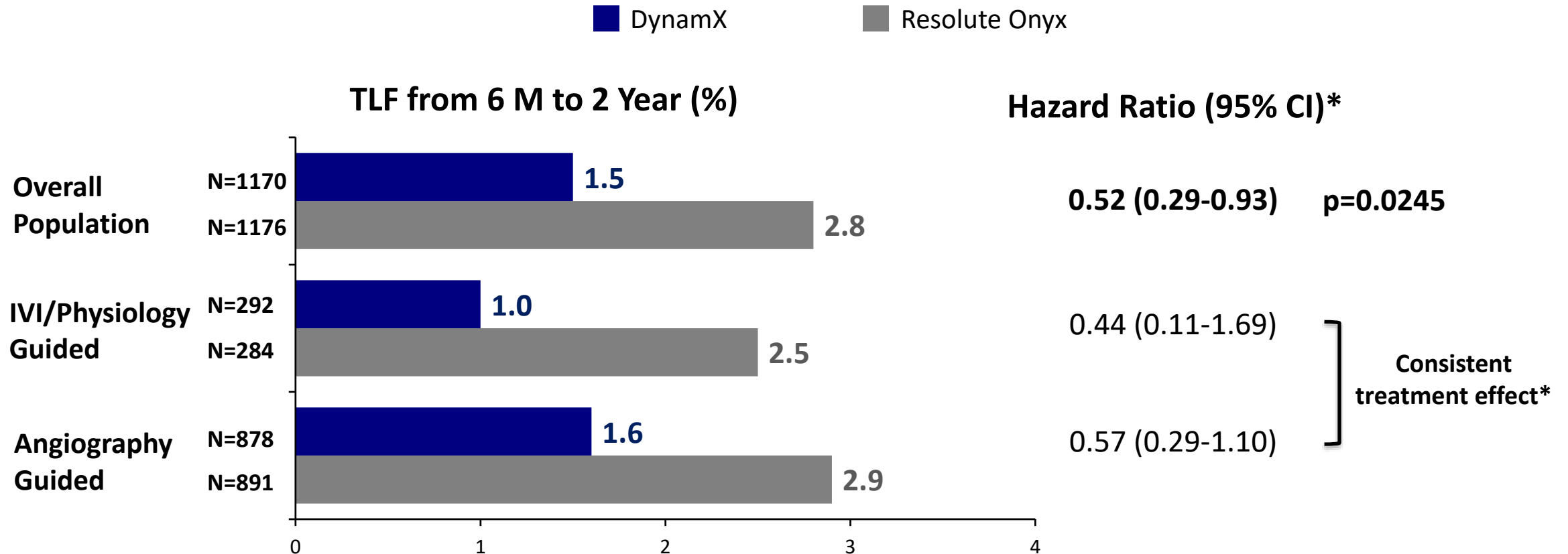
Baseline Characteristics	IVI or Physiology (N=576)		Angiography (N=1,770)	
	DynamX (n=292)	Onyx (n=284)	DynamX (n=878)	Onyx (n=892)
Acute Coronary Syndrome (ACS)	186 (63.7%)	161 (56.7%)	720 (82.0%)	734 (82.3%)
Chronic Coronary Syndrome (CCS)	106 (36.3%)	123 (43.3%)	158 (18.0%)	158 (17.7%)
Complex Lesion (B2/C)	116 (39.7%)	110 (38.7%)	405 (46.2%)	411 (46.2%)
LAD Lesion	189 (64.7%)	172 (60.6%)	484 (55.2%)	498 (56.0%)
Bifurcation Lesion	43 (14.9%)	48 (17.0%)	110 (12.7%)	106 (12.0%)
Long lesions (>20 mm)	207 (71.4%)	203 (72.0%)	513 (59.4%)	543 (61.4%)
≥ 2 lesions	48 (16.4%)	50 (17.6%)	137 (15.6%)	152 (17.1%)
Multivessel	35 (12.0%)	36 (12.7%)	90 (10.3%)	106 (11.9%)

Powered Superiority Endpoint: TLF from 6M to 2 Years

Significant Reduction in TLF and Sustained Treatment Benefit After 6 Months



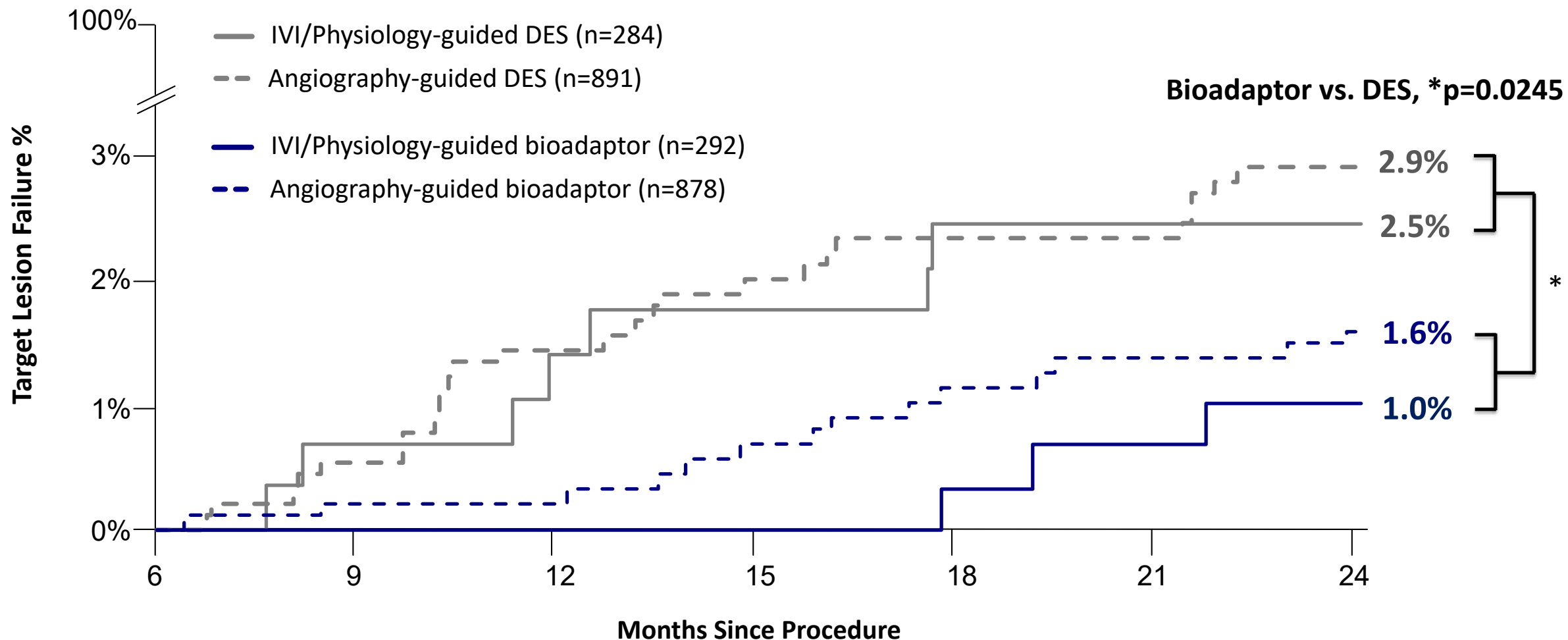
Bioadaptor Demonstrates Consistent Treatment Effect Independent of Use of IVI/Physiology-Guidance from 6 to 2 years



*Hazard ratios are derived from cox proportional hazards models, subgroups adjusted for baseline imbalances. P interaction = 0.73

Low TLF Events from 6 to 24 Months with Bioadaptor

Independent of Use of IVI/Physiology-Guidance



Conclusions

- The INFINITY-SWEDEHEART is a large-scale, multicenter RCT comparing bioadaptor implant versus DES in a representative, clinically complex ischemic patient population.
- This analysis demonstrates:
 - Long term outcomes with bioadaptor implantation are superior to DES, independent of the use of IVI/physiology guidance.
 - 6-24 Month TLF trended lower with intravascular imaging/physiology guidance, consistent with EU guidelines.
- These findings support the use of bioadaptor implant and imaging/physiology guidance to achieve optimal PCI outcomes with lower adverse events, compared to PCI with DES.



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