

1-Year and Landmark 6-12 Month Clinical Outcomes from the INFINITY-SWEDEHEART Randomized Clinical Trial:

Bioadaptor Implant Compared to a Contemporary Drug-Eluting Stent Among Patients in Complex Lesion Subsets

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



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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I, *David Erlinge*, have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Consultant Fees/Honoraria

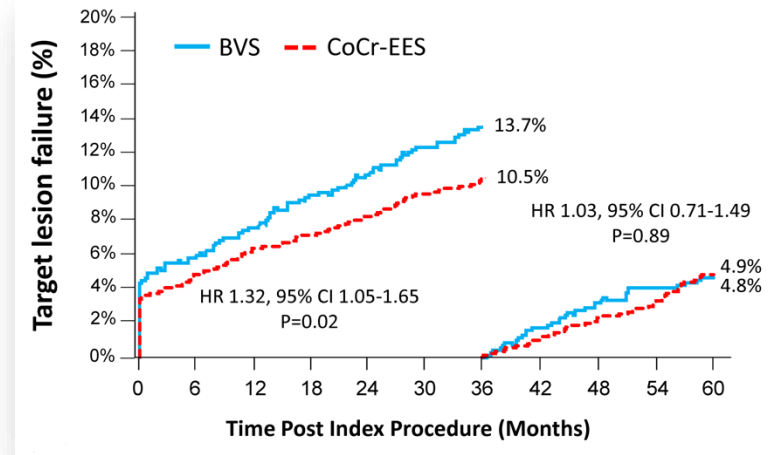
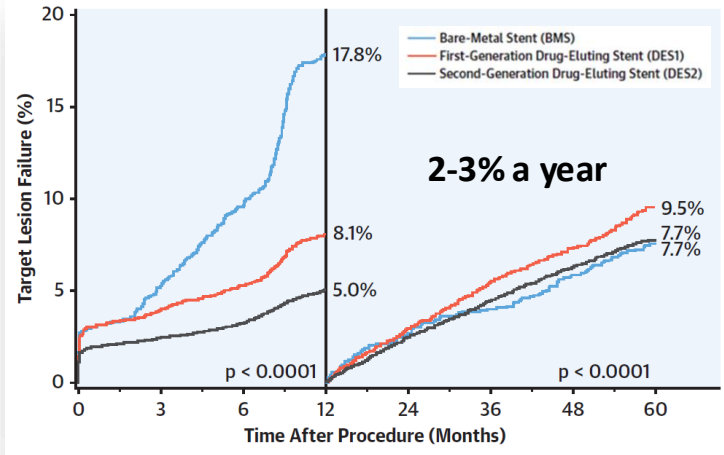
Ineligible Company

Amgen, AstraZeneca, Chiesi, Sanofi, NovoNordisk, InfraredX/Nipro and Kaminari 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 BMS¹.

- “Leave nothing behind” concept of Bioresorbable Scaffolds failed at improving short or long-term outcomes compared to DES, driven by poor acute performance and loss of long-term vessel dynamic support following scaffold resorption².



1. Madhavan MV et al. J Am Coll Cardiol 2020;75:590-604

2. Stone GW et al. Five-Year Clinical Outcomes After Coronary Bioresorbable Scaffolds and Drug-Eluting Stents: The ABSORB IV Randomized Trial. J Am Coll Cardiol 2023

Study Device: Bioadaptor Implant

Bioadaptor is a novel 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}.



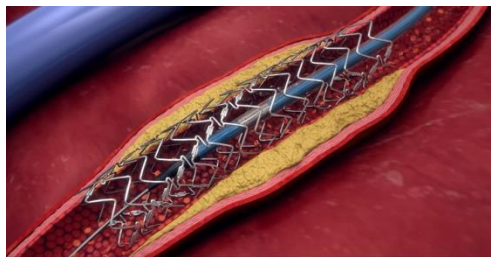
- *Three helical sinusoid strands (CoCr 71 μ m) are temporary connected by bioresorbable polymer coating eluting antiproliferative agent*
- *Following polymer resorption after 6 months, the helical strands unlock and separate*

Study Device: Bioadaptor Mechanism of Action

Bioadaptor (DynamX[®], Elixir Medical, CA) is a novel technology designed to *restore hemodynamic modulation of the vessel*.

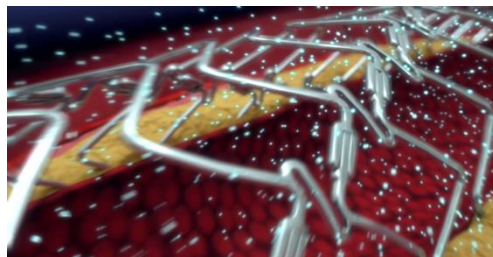
0 – 6 months

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}

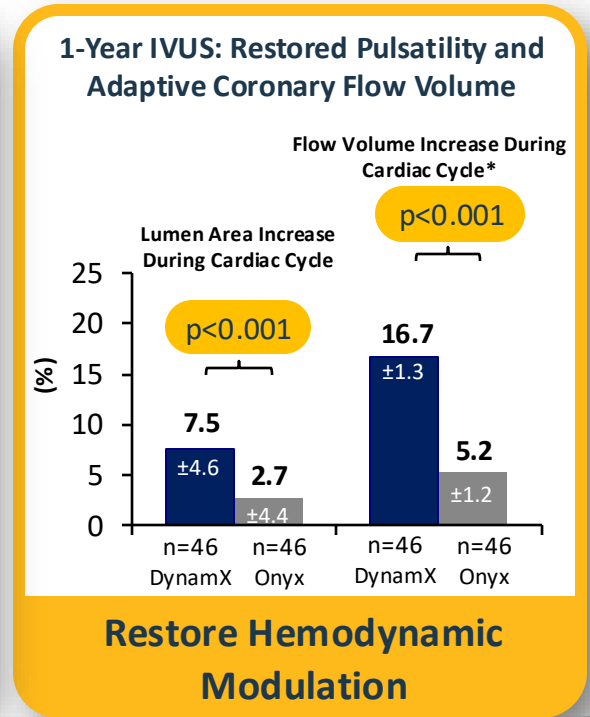
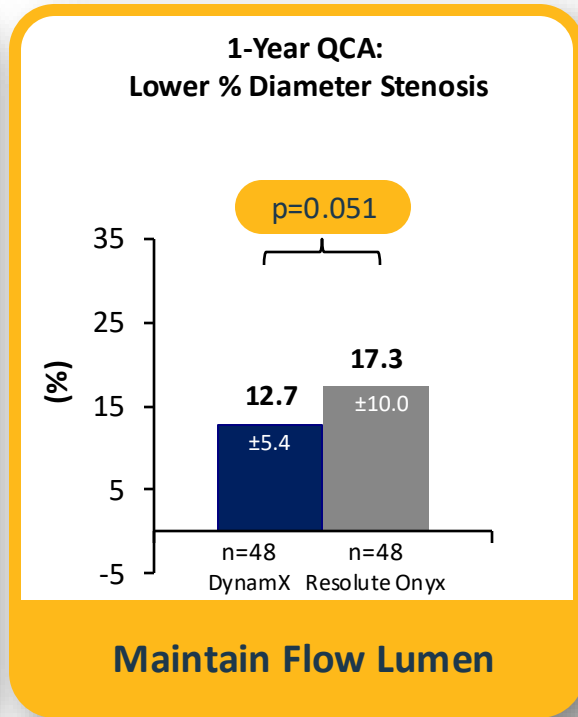
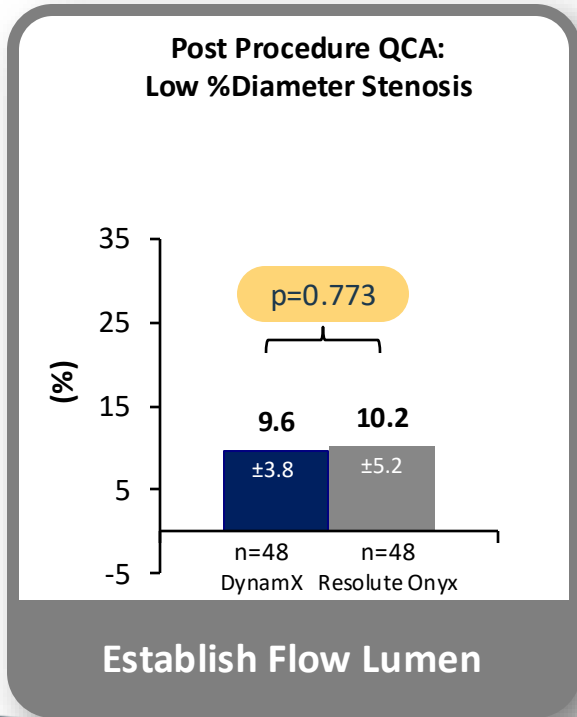


3. Dynamic Support:
Restore Hemodynamic Modulation

Restore pulsatility, compliance, adaptive coronary flow¹⁻³

Study Device: Bioadaptor Mechanism of Action

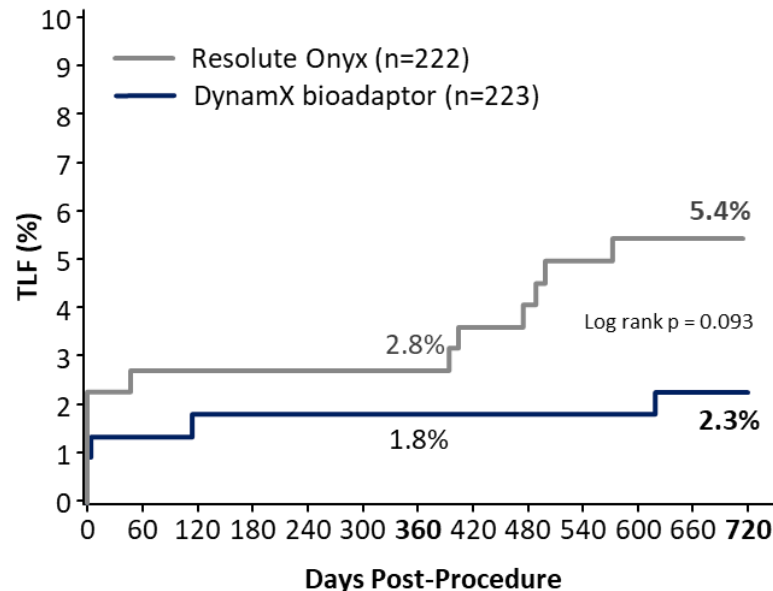
Results from the BIOADAPTOR-RCT¹ imaging cohort



BIOADAPTOR-RCT Demonstrated Events Plateau After 6 Months



- 12- and 24-month results from BIOADAPTOR RCT (n=445) demonstrated safety and efficacy of DynamX bioadaptor and established benchmarks in restoring vessel function
 - TLF primary endpoint at 12 months was met ($p < 0.001$ for non-inferiority)¹
 - Reduction and plateauing in TLF, TVF through 2 years²
 - Statistically significantly lower %DS and LLL versus DES, and uniquely demonstrated pulsatility in intravascular imaging endpoints¹
 - Novel finding of plaque stabilization and regression¹



INFINITY-SWEDEHEART RCT

Objectives and Powered Endpoints:



Objectives

- To evaluate the safety and efficacy of the bioadaptor implant compared to the DES in a large multi-center RCT
- To evaluate potential superior clinical benefit after 6 months on reducing non-plateauing event rates compared with a contemporary DES in a representative patient population, including:
 - High risk patients with Acute Coronary Syndrome (ACS) and complex lesion subsets

Powered Endpoints

Primary endpoint (non-inferiority):

Target lesions failure (TLF) at 1 year

Powered Secondary endpoints (superiority):

Landmark analysis of:

1. TLF from 6 months to End of Follow-up
2. TVF from 6 months to End of Follow-up
3. TLF in ACS from 6 months to End of Follow-up

Study Management and Site Enrollment



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

- Imaging Core Lab

PI	Hospital Name	# Enrolled
Jonas Andersson, MD, PhD	Umeå University Hospital	316
Stefan James, MD, PhD	Uppsala University Hospital	275
David Erlinge, MD, PhD	Skåne University Hospital, Lund	221
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
Sammy Zwackman, MD	Linköping University Hospital	81
Juliane Jurga, MD, PhD	Karolinska University Hospital, Huddinge	76
Martin Adielsson, MD	Halland Hospital, Halmstad	69
Patrik Alström, MD	Södersjukhuset, Stockholm	67
Elli Masoe, MD	Sundsvall Hospital	57
Juliane Jurga, MD, PhD	Karolinska University Hospital, Solna	49
Anders Ulvenstam, MD, PhD	Östersund Hospital	48
Jonas Millgård, MD, PhD	Sunderby Hospital, Luleå	43
Maria Tafesse, MD	Blekinge Hospital, Karlskrona	29
Mats Birgander, MD, PhD	Skåne University Hospital, Malmö	15

Key Inclusion and Exclusion Criteria



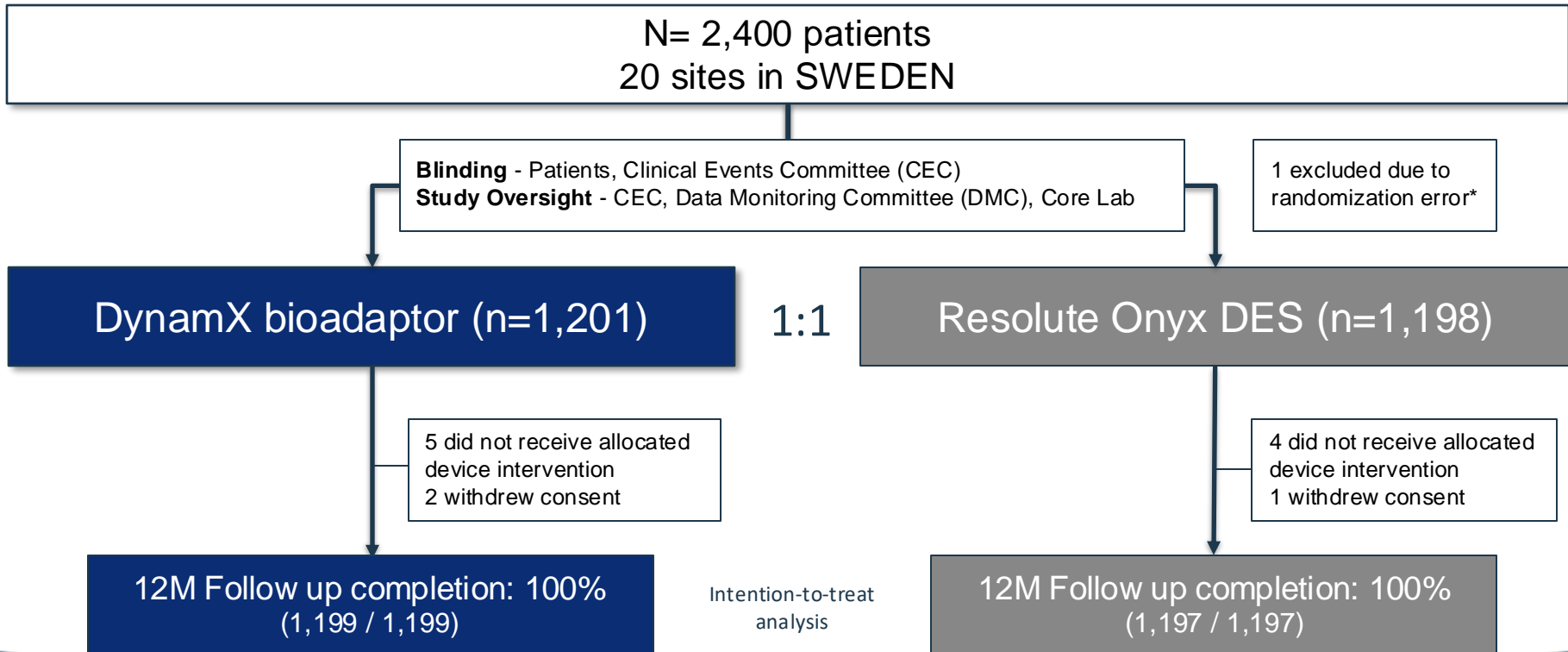
KEY INCLUSION

- Patient age ≥ 18 and ≤ 85 years
- **Patients with CCS or ACS indicated for PCI with stent implantation**
- Successful pre-dilation of at least 1 Target Lesion
- **Maximum of 3 Lesions may be treated**
 - Up to 3 Target Lesions, or
 - Up to 2 Target Lesions and 1 Non-Target Lesion, which must be without complications prior to randomization
- Target Lesion vessel diameter and lesion length suitable for implantation with either study device

KEY EXCLUSION

- Life expectancy < 2 years
- Prior PCI in the target vessel within 12M
- AMI with Killip class III/IV
- Chronic heart failure with LVEF $< 30\%$
- On renal dialysis or with known eGFR < 30 ml/min
- **Lesions in the Left Main artery**
- **Venous or arterial bypass grafts**
- **In-stent restenosis**
- **Chronic total occlusion**
- **Lesions < 3 mm from ostium**

12-M Follow up completion: 100%



Patient Baseline Characteristics



Baseline Characteristics	DynamX (N=1,201)	Onyx (N=1,198)
Age, years	68.2 ± 9.7	68.1 ± 9.6
Female	290 (24.1%)	285 (23.8%)
Hypertension	722 (60.5%)	710 (59.9%)
Hyperlipidemia	544 (45.6%)	492 (41.5%)
Diabetes Mellitus	231 (19.3%)	198 (16.6%)
Prior MI	144 (12.1%)	141 (11.9%)
Prior PCI	176 (14.7%)	165 (13.9%)
Prior CABG	12 (1.0%)	8 (0.7%)
Current Smoking	164 (14.2%)	187 (16.1%)

Clinical Presentation	DynamX (N=1,201)	Onyx (N=1,198)
Acute Coronary Syndrome (ACS)	925 (77.0%)	913 (76.2%)
STEMI	282 (23.5%)	317 (26.5%)
NSTEMI	458 (38.1%)	437 (36.5%)
Unstable Angina	185 (15.4%)	159 (13.3%)
Chronic Coronary Syndrome (CCS)	276 (23.0%)	285 (23.8%)

Baseline Lesion Characteristics

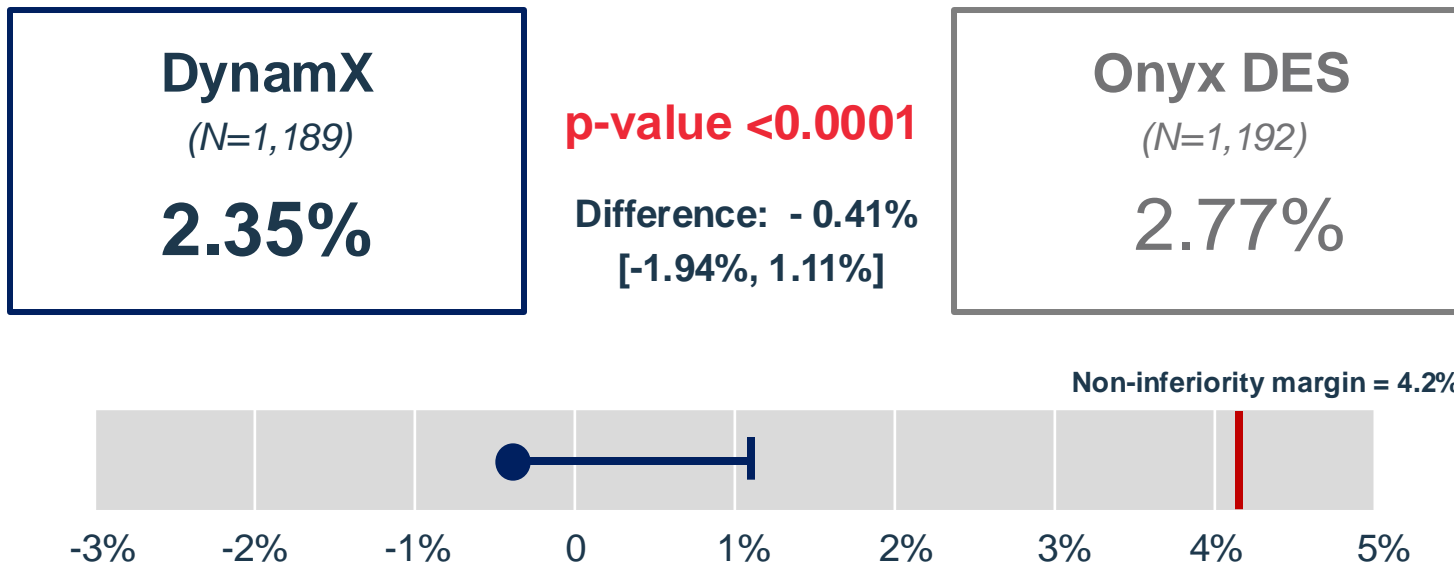


Baseline Characteristics	DynamX (N=1,201) (L=1,419)	Onyx (N=1,198) (L=1,431)
Target Lesion Location		
LAD	726 (51.2%)	728 (50.9%)
RCA	365 (25.7%)	384 (26.8%)
LCx	327 (23.0%)	318 (22.2%)
Lesion Classification		
A	160 (11.4%)	170 (11.9%)
B1	639 (45.4%)	666 (46.7%)
B2/C	609 (43.3%)	590 (41.4%)
Bifurcation	165 (11.8%)	161 (11.3%)
Calcified lesion*	239 (16.9%)	204 (14.3%)
Tortuous lesion*	109 (7.7%)	105 (7.3%)

Baseline Characteristics	DynamX (L=1,419)	Onyx (L=1,431)
Number of target lesions per subject, n (%)		
1	1009 (84.1%)	987 (82.6%)
≥2	191 (15.9%)	208 (17.4%)
RVD, mm	3.2 ± 0.5	3.2 ± 0.5
Lesion Length, mm	24.4 ± 9.1	24.7 ± 9.4
%DS, pre-procedure	87.0 ± 12.1	87.3 ± 11.7
%DS, post-procedure	1.0 ± 5.4	0.6 ± 3.5
Successful pre-dilation	1413 (99.7%)	1429 (99.9%)
Post-dilation	819 (58.5%)	754 (52.9%)

Target Lesion Failure at 12 Months

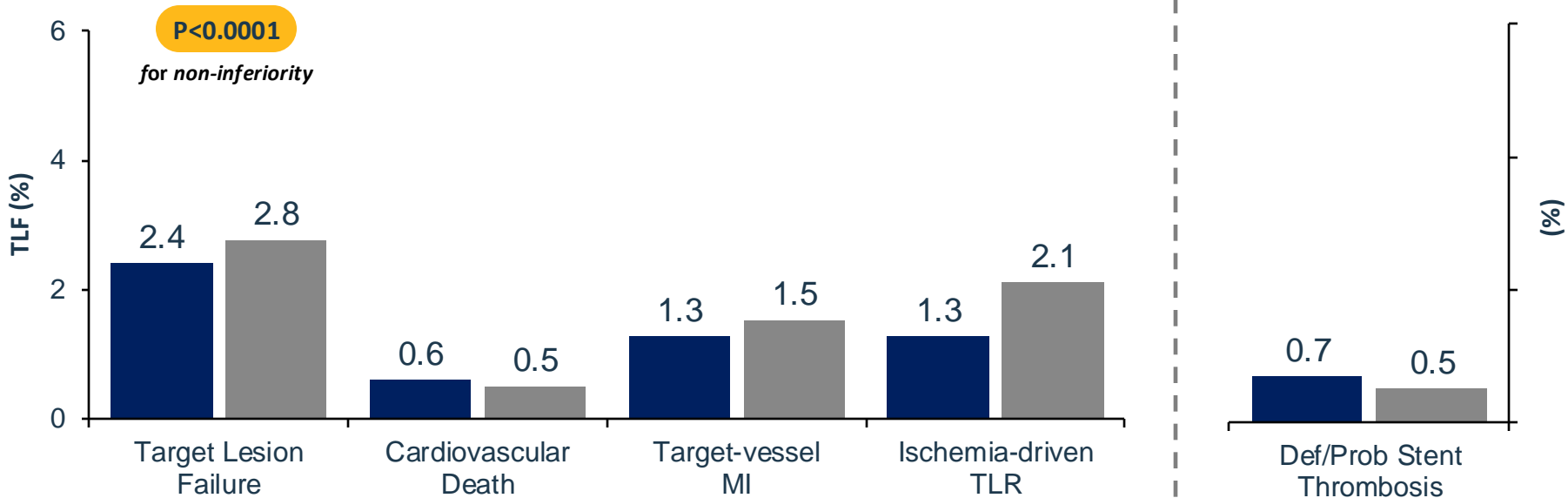
Primary Non-Inferiority Endpoint Met



TLF and Components, Stent Thrombosis at 12 Mos



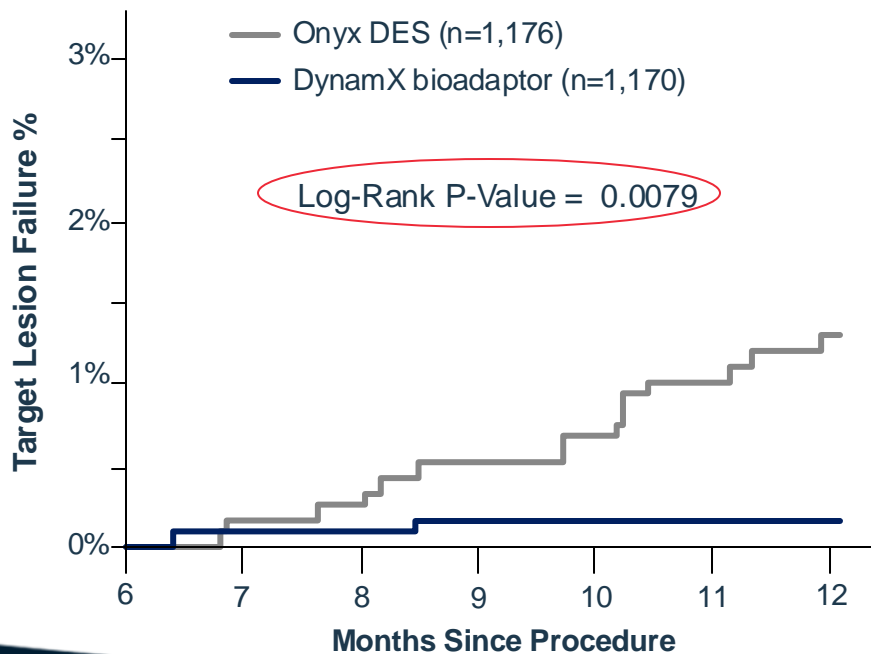
■ DynamX bioadaptor (n=1,189) ■ Onyx DES (n=1,192)



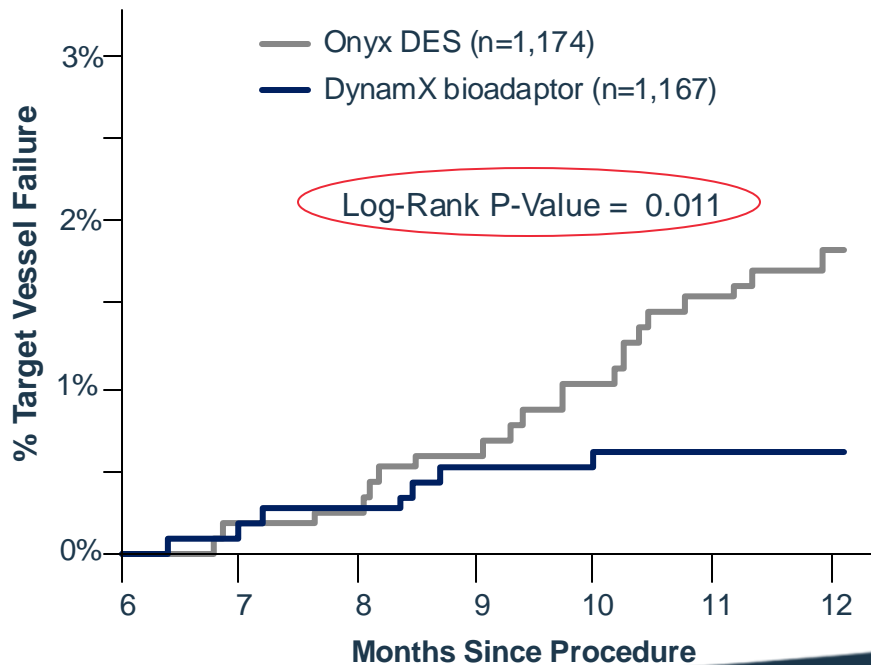
Powered Secondary Endpoints, 6-12 Mos

Significant Reduction and Plateau in TLF and TVF After 6 Mos

#1: TLF, Landmarked at 6 Months



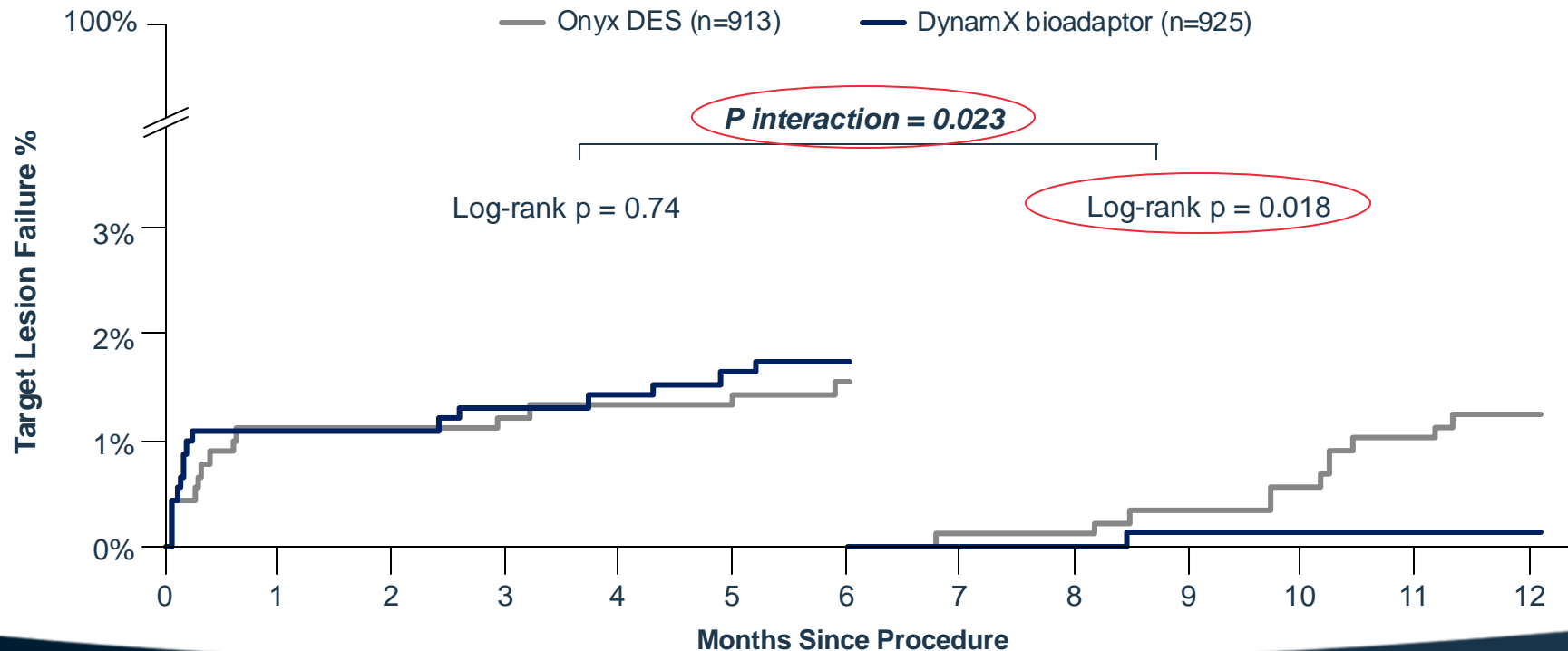
#2: TVF, Landmarked at 6 Months



Powered Secondary Endpoint: TLF in ACS, 6-12 Mos

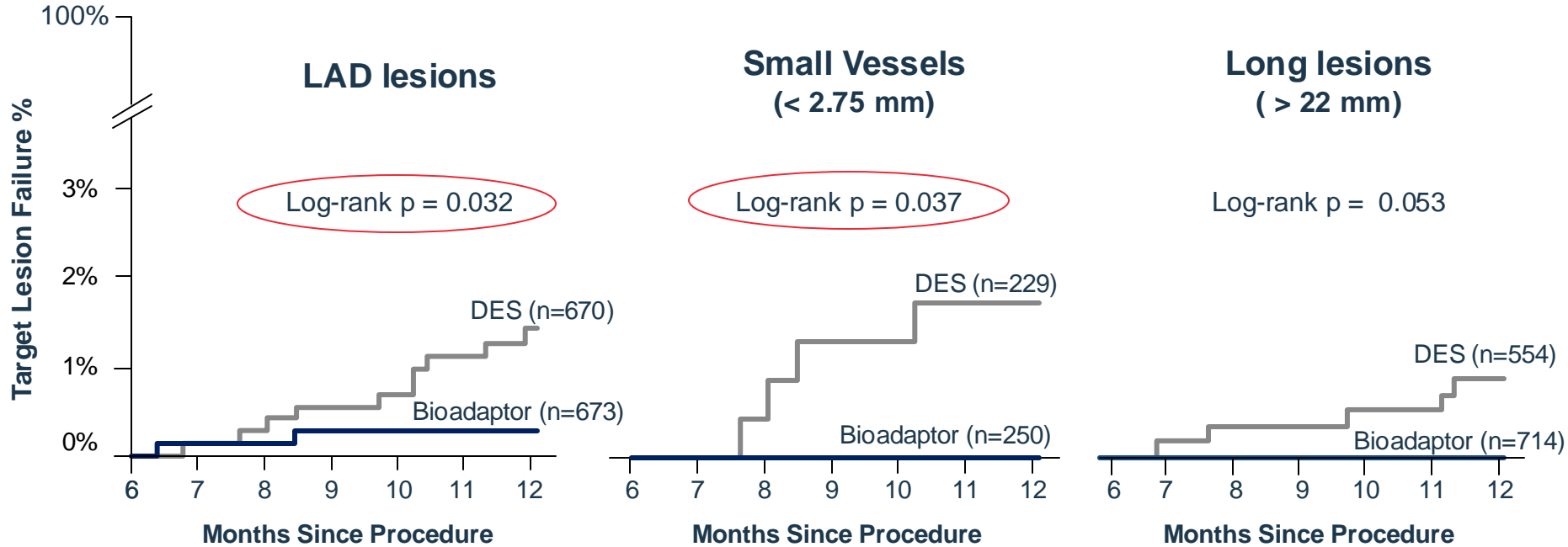


Significant Reduction and Plateau in TLF After 6 Months

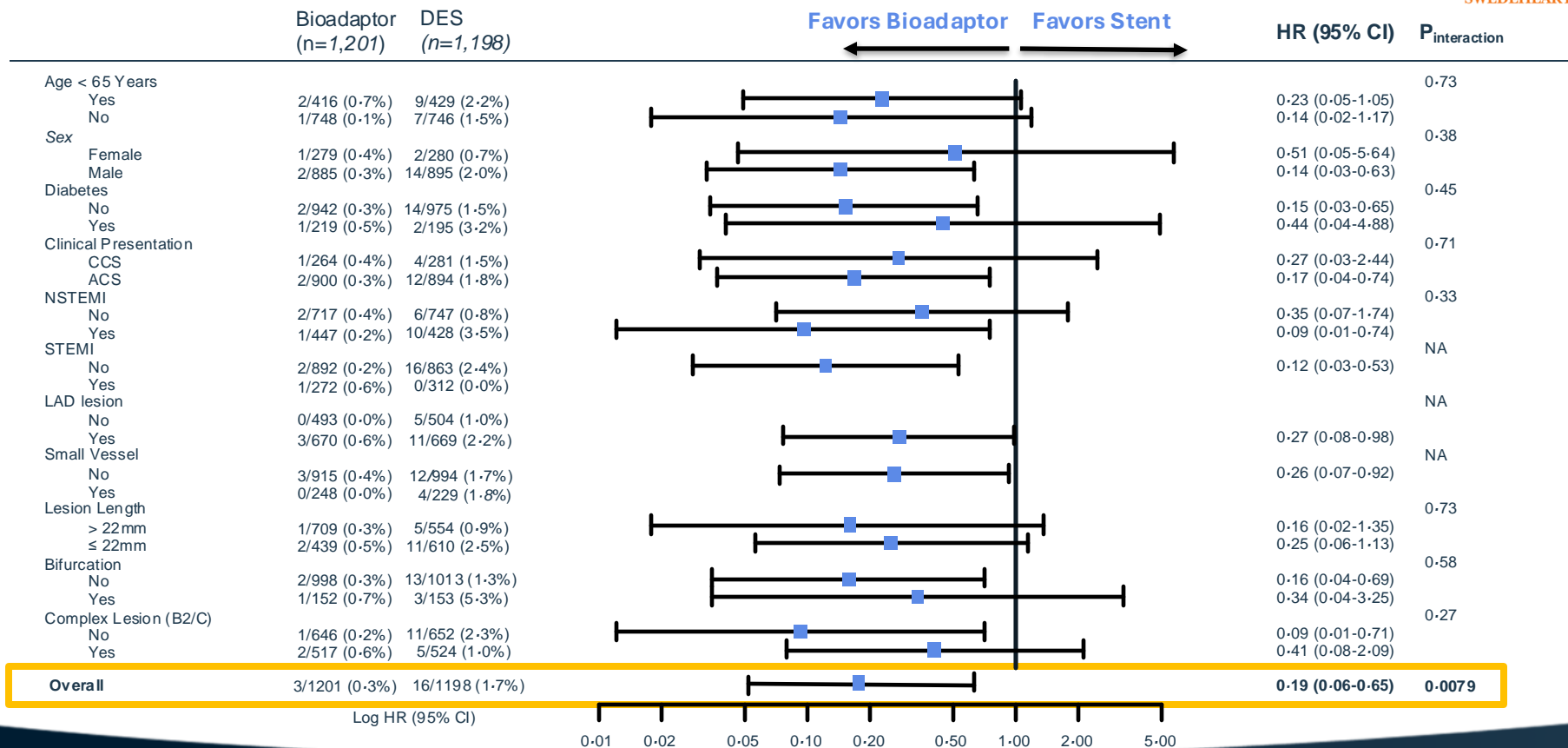


TLF in High-Risk Lesions, 6-12 Mos

Significant Reduction and Sustained Treatment Effect



Consistency of 6-12M Outcomes Across Subgroups



Log HR (95% CI)

0.01 0.02 0.05 0.10 0.20 0.50 1.00 2.00 5.00



Stratified Analysis of TLF from 6 to 12 month Across Subgroups

*NA: Not available/evaluable due to limited number of events

Conclusions



- The INFINITY-SWEDEHEART is a large-scale, multicenter RCT comparing bioadaptor implant versus DES in a representative, clinically complex ischemic patient population.
 - **Low and non-inferior TLF rates at 12 months** (2.4% versus 2.8%, $p < 0.0001$)
 - **Significant reduction in TLF ($p = 0.008$) and TVF ($p = 0.011$) and flattening of event curves after 6 months in favor of bioadaptor**, in prespecified landmark analyses
 - **Substantial clinical benefit for the high-risk subgroups including ACS ($p = 0.018$)** after 6 months in prespecified landmark analysis and **consistent effect across prespecified subgroups** including LAD, small vessels, long lesions.
- Evidence from the large-scale INFINITY-SWEDEHEART RCT confirms the results from the BIOADAPTOR-RCT trial and suggests **bioadaptor may represent the long-awaited solution to flatten the event curve following PCI**, marking a significant advancement in coronary interventions

INFINITY-SWEDEHEART Primary Outcomes Simultaneous Publication in 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