DYNAMX
CORONARY BIOADAPTOR

TRANSFORMATION. UNLOCKED.

dynamxbioadaptor.com

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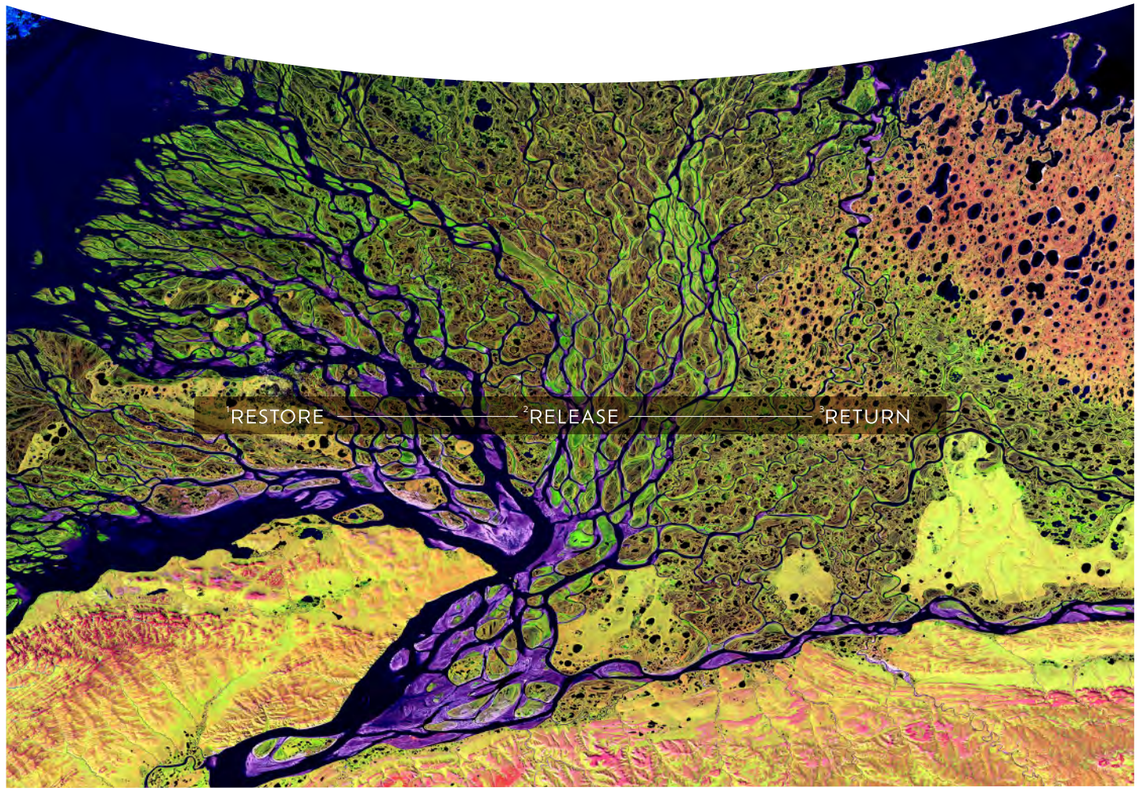
PMN 1626 Rev B

THE FUTURE OF VASCULAR INTERVENTION WON'T JUST EVOLVE, *IT WILL ADAPT.*



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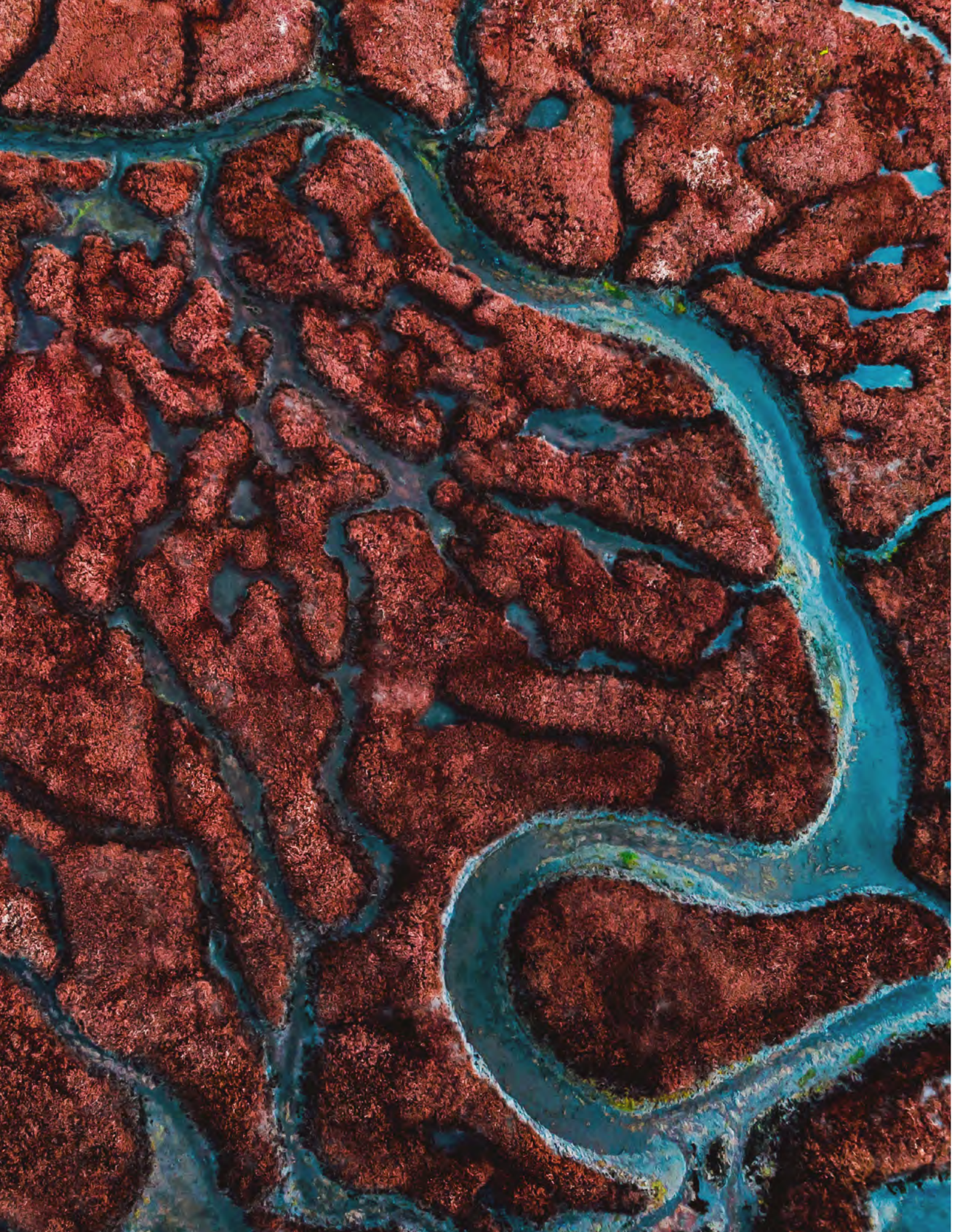


EVOLVING PCI BY FOLLOWING NATURE'S BLUEPRINT

LETTING VESSELS FUNCTION AS INTENDED

DYNAMX
CORONARY BIOADAPTOR

TRIPLE STAGE THERAPY

[1]RESTORE *FLOW*

First step in any intervention is restoring blood flow. And, with DynamX® you will achieve significant acute lumen gain without compromising the ability for the vessel to naturally heal.[1]

[2]RELEASE *VESSEL*

After 6 months the magic happens. DynamX unlocks itself, releasing the vessel to pulsate more freely, respond to every heartbeat, increasing vital blood flow.[1]

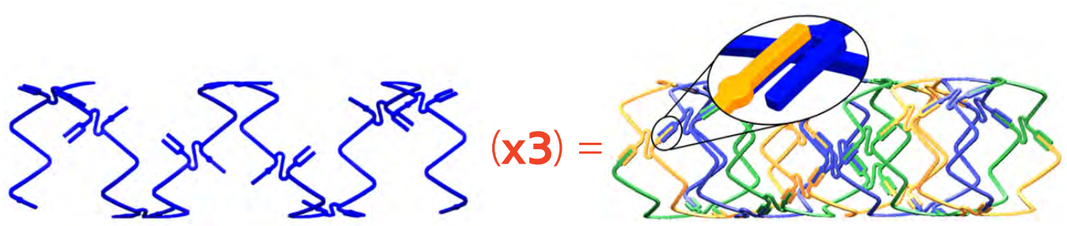
[3]RETURN *FUNCTION*

Finally, the vessel returns back to its natural physiology, motion and function. It's free to adapt and maintain optimal lumen size while DynamX continues to provide dynamic support.[1]

1. Saito, MD, Presented at EuroPCR 2023.

THE DYNAMX BIOADAPTOR:
BIOADAPTIVE BY DESIGN

Uniquely integrated elements designed to deliver
Triple Stage Therapy



[1]RESTORE

Interlocked CoCr helical strands, fused by PLLA basecoat provide radial strength

Low 71 micron strut profile minimizes injury and enables faster healing

[2]RELEASE

3-month resorption of polymer top coat and release of 'limus drug enables optimal healing and thin neointima formation

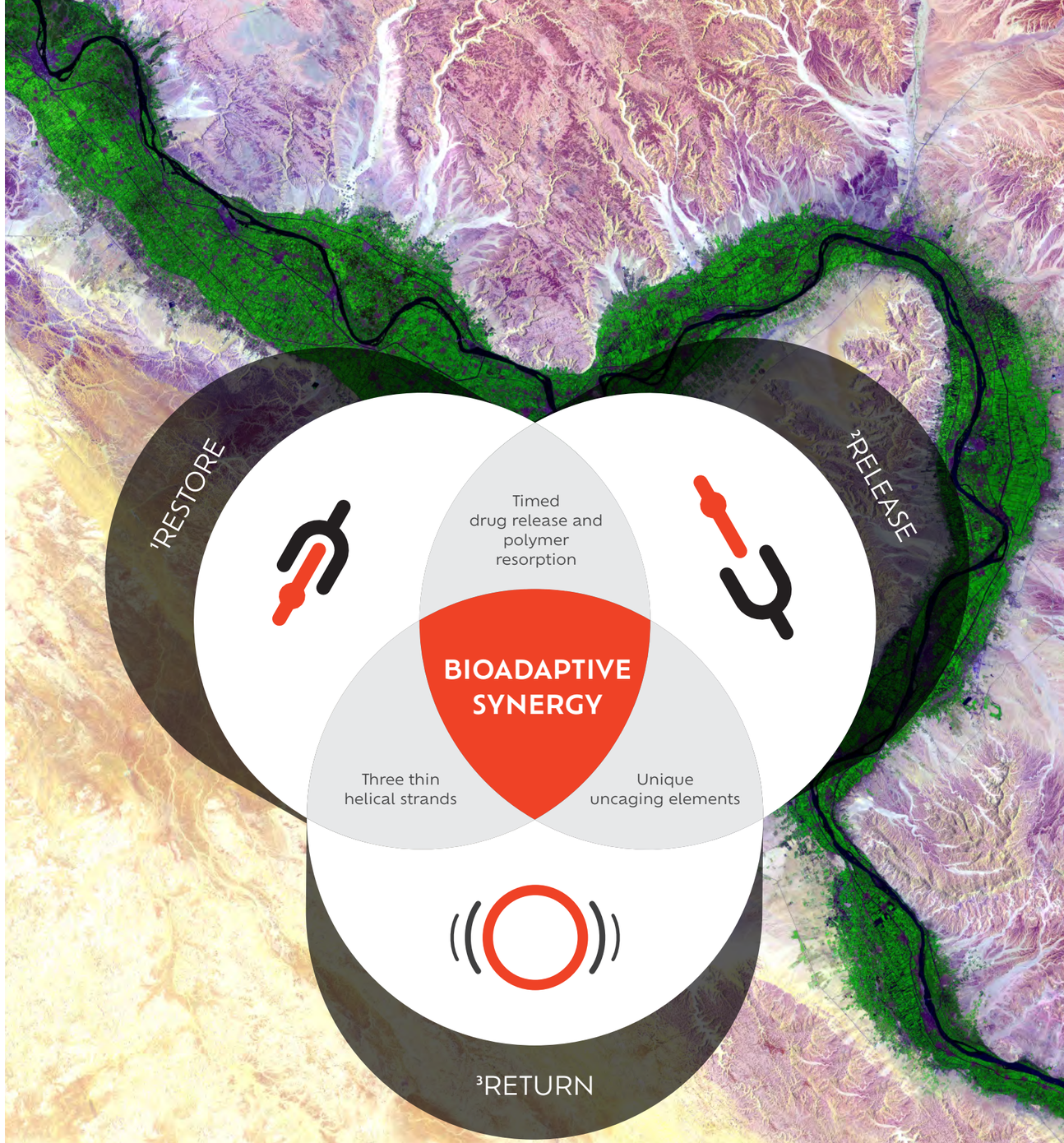
Controlled resorption of basecoat polymer over 6 months enables designed separation of the helical strands and growth of functional muscle cells around the struts

[3]RETURN

Separated helical strands maintain flexibility while providing radial support

Thin struts and low metal volume make it possible for new smooth muscle cells to contract and achieve pulsatility and vasomotion

CoCr=cobalt-chromium
2.25mm - 3.0mm are 71µm thick.



THE UNCOMFORTABLE TRUTH OF LIFE-LONG STENTING

PERMANENT CAGING OF VESSELS LEAVES PATIENTS AT RISK OF LATE EVENTS[1]

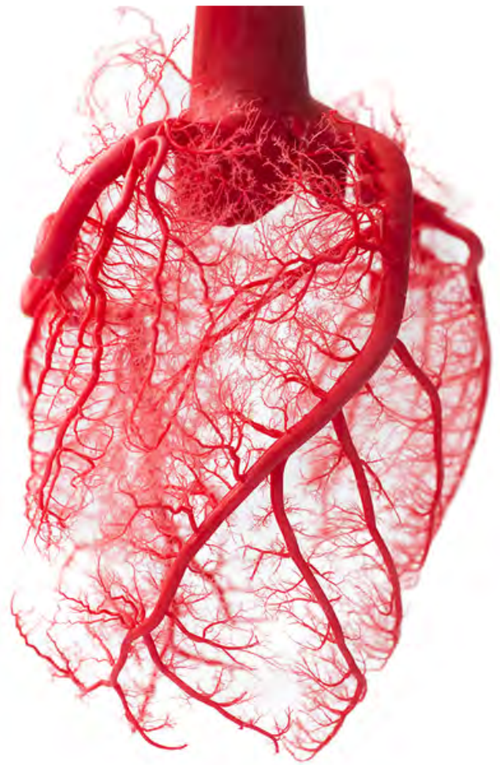
Drug-eluting stents have shown

>50%

lifetime risk of stent-related Major Adverse Cardiac Events[1]

Reinforced by findings showing ongoing risk of about 2% a year at least through 5-year follow-up with no sign of plateau, irrespective of stent type[2]

Caging natural vascular motion and physiology can contribute to stent fractures, restenosis, myocardial infarctions, and cardiac death[3]



The heart is a dynamic, pulsating, living organ, arteries are no different. They do what they need to adapt to the heart's changing demands and sustain life.

Three-dimensional vasomotion
To meet the demands of every heartbeat

Pulsatility
To help maintain blood flow and pressure[4]

Positive adaptive remodeling
To mitigate against disease progression[5]

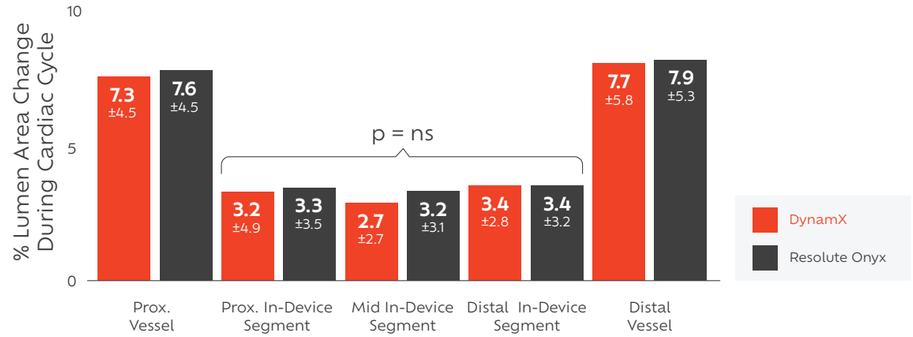
1. Kufner S, Joner M, Thannheimer A, et al.
Ten-Year Clinical Outcomes From a Trial of Three Limus-Eluting Stents With Different Polymer Coatings in Patients With Coronary Artery Disease – Results From the ISAR-TEST 4 Randomized Trial. Circulation. 2019;139:325–333
2. Madhavan MV, Kirtane AJ, Redfors B, et al. Stent-Related Adverse Events >1 Year After Percutaneous Coronary Intervention. J Am Coll Cardiol 2020; 75:590–604.
3: Borovac JA, D'Amario D, Niccoli G. Neoatherosclerosis and Late Thrombosis After Percutaneous Coronary Intervention: Translational Cardiology and Comparative Medicine from Bench to Bedside. Yale J Biol Med 2017;90:463–70.
4. Kim HL, Weber T. Pulsatile Hemodynamics and Artery Disease. Korean Circ J. 2021
5. Glagov S, et al. Compensatory Enlargement of Human Atherosclerotic Coronary Arteries. N Engl J Med 1987; 316:1371-1375

LIFE DOESN'T STAND STILL. AND NOR SHOULD VESSELS.

ONLY DYNAMX RESTORES PULSATILITY

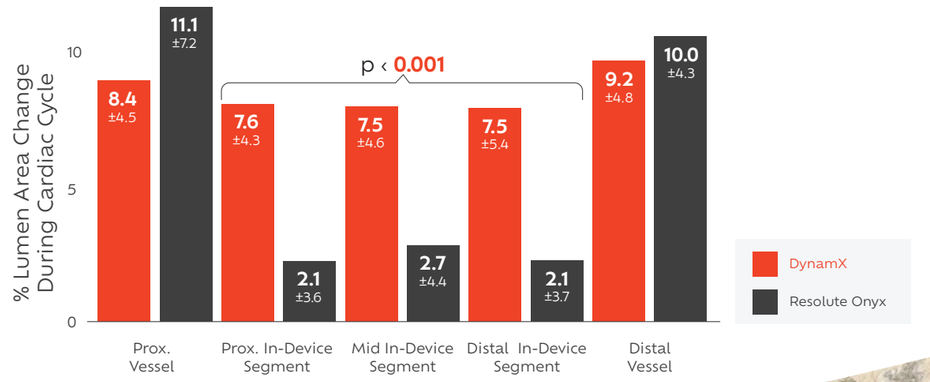
Immediately post-procedure:

Pulsatility is constrained in both DynamX bioadaptor and DES (p=ns)[1]



At 12-months:

DynamX bioadaptor has uniquely uncaged to deliver superior pulsatility and lumen area changes with every heartbeat vs DES[1]



Findings from paired imaging analysis. Lumen area changes measured by stationary IVUS across at least 3 cardiac cycles (n=46 DynamX; n=46 DES). DES=drug-eluting stents. IVUS=intravascular ultrasound. ns=not significant.

1. Saito, MD, Presented at EuroPCR 2023.

THE DYNAMX FLOW EFFECT

CHANGE IN BLOOD FLOW WITH EVERY HEARTBEAT

Pulsatility

7.5%

increase in lumen area with every heartbeat

In-device % increase in lumen area:
2.7% (±2.7) post-procedure and 7.5% (±4.6) at 12 months for DynamX[1]

→

Blood Flow

16.7%

increase in blood flow with every heartbeat

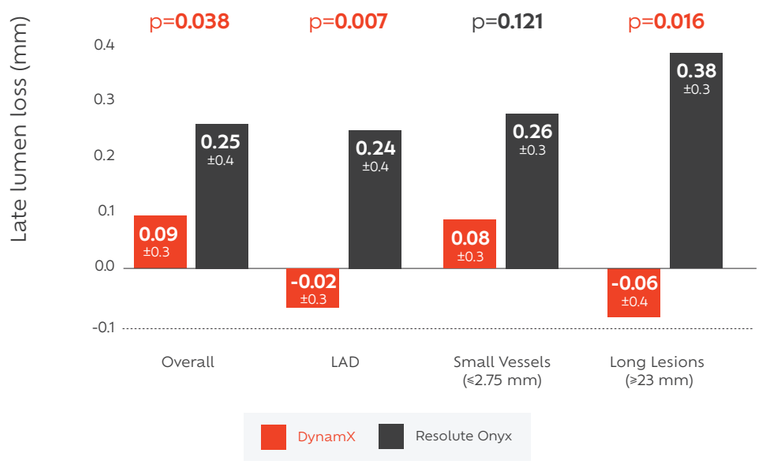
Blood flow increase per heartbeat:
6.5% (±0.6) post-procedure and 16.7% (±1.3) at 12 months for DynamX[1]

Findings from a preplanned imaging subgroup analysis. Lumen area changes and blood flow increase measured by IVUS (n=48 DynamX; n=47 DES). IVUS=intravascular ultrasound.
1. Saito, MD, Presented at EuroPCR 2023

RESTORED VASOMOTION AND POSITIVE ADAPTIVE REMODELING

ACHIEVING LOWER LUMEN LOSS

Significantly lower late lumen loss, especially in vessels and lesions at high risk of restenosis.[1]

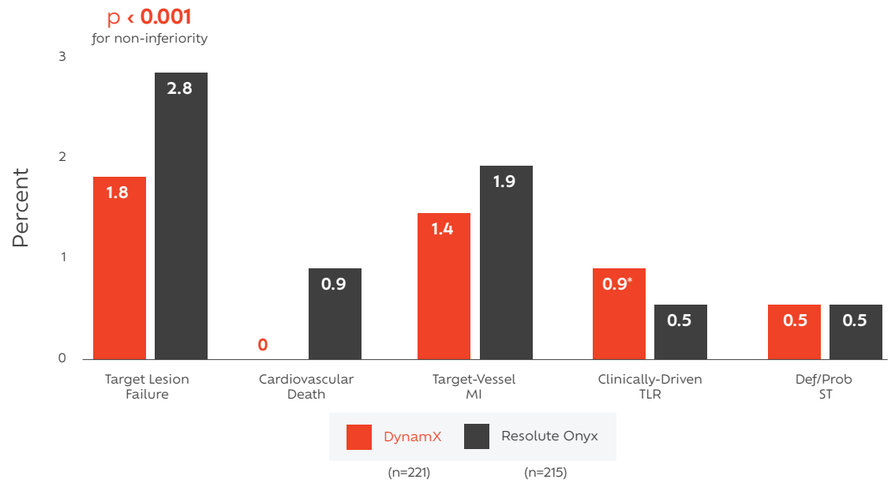


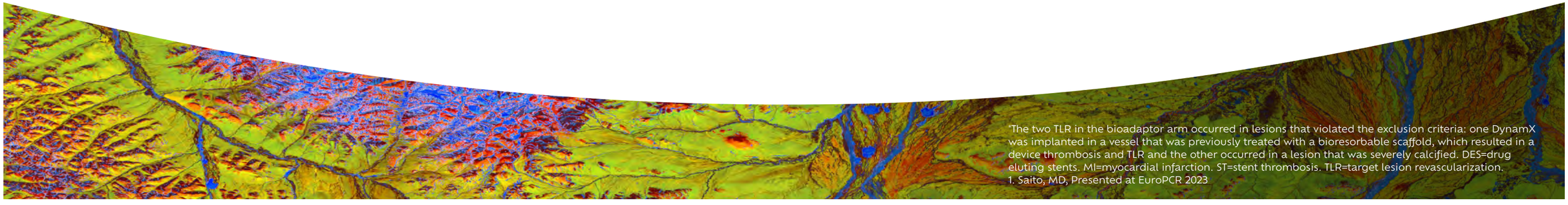
Bioadaptor: LLL in overall cohort and subgroups

1.8%

Primary endpoint: Target Lesion Failure at 12 months vs. 2.8% for Resolute Onyx™[1]

(p for non-inferiority < 0.001)





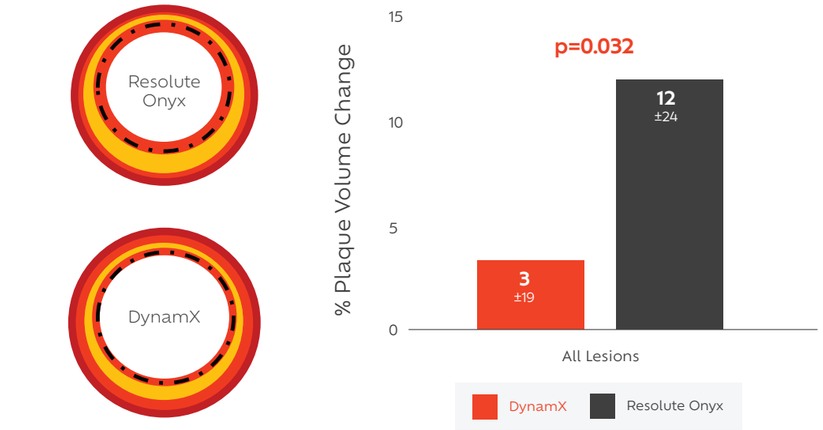
*The two TLR in the bioadaptor arm occurred in lesions that violated the exclusion criteria: one DynamX was implanted in a vessel that was previously treated with a bioresorbable scaffold, which resulted in a device thrombosis and TLR and the other occurred in a lesion that was severely calcified. DES=drug eluting stents. MI=myocardial infarction. ST=stent thrombosis. TLR=target lesion revascularization.

1. Saito, MD, Presented at EuroPCR 2023

WITH SUPPORT, THE VESSEL RETURNS TO ITS NATURAL STATE

THEN SOMETHING EXTRAORDIANRY HAPPENS

Plaque volume behind the stent increased by 12% in Resolute Onyx arm, while staying stable in DynamX arm[1]



% plaque volume change at 12 months (IVUS)

↓9%

Plaque volume regression in lipid rich lesions with DynamX vs. an increase with DES[1]

An exploratory finding that points to a hypothesis of a synergistic effect between restoration of vessel motion and function and systemic use of lipid-lowering medications[1]

Findings from a post-hoc imaging subgroup analysis (all lesions). % change in plaque volume measured by IVUS (all lesions: n=48 DynamX; n=47 DES) DES=drug-eluting stents. IVUS=intravascular ultrasound.
1. Saito, MD, Presented at EuroPCR 2023

Findings from a post-hoc imaging subgroup analysis (lipid-containing lesions). % change in plaque volume measured by IVUS (lipid-containing lesions: n=12 DynamX and n=21 DES. DES=drug-eluting stents. IVUS=intravascular ultrasound.