

New DES Designs

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Disclosures

Research Grant Support

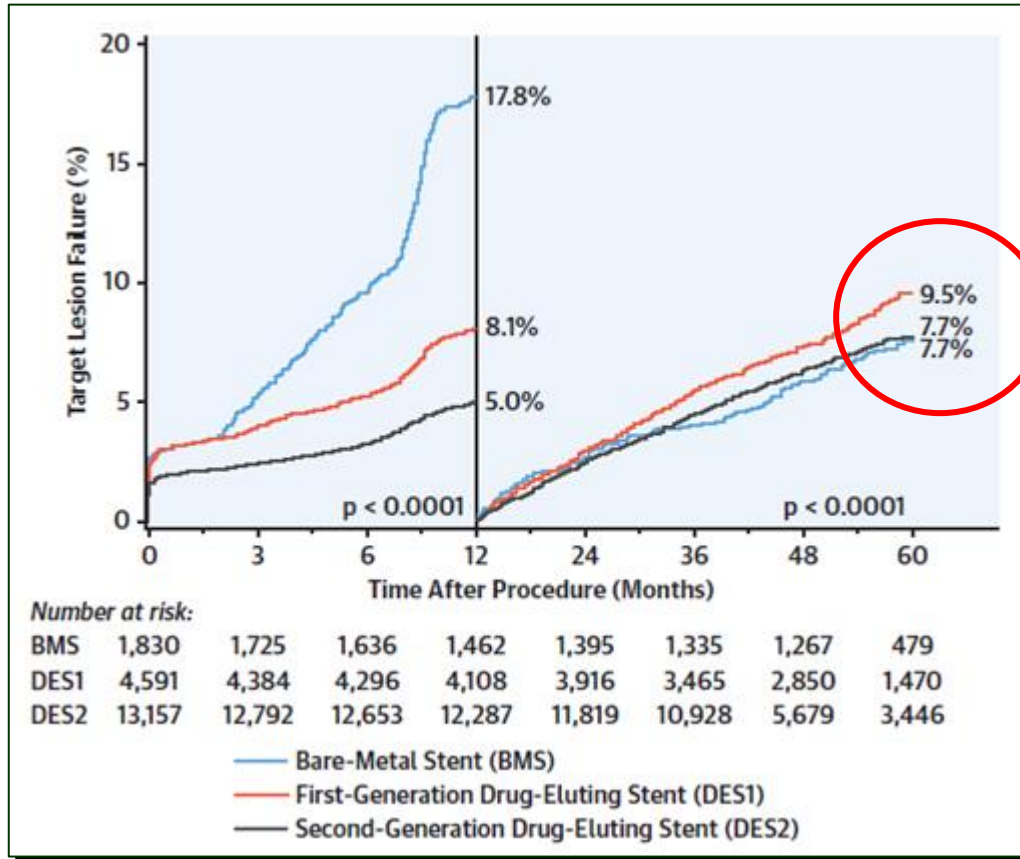
- Edwards Lifesciences
- Boston Scientific
- Corvia
- CathWorks
- Zoll/Therox
- JenaValve
- Abbott Vascular
- Medtronic
- Philips
- I-Rhythm
- JC Medical

Consulting/Advisory Boards

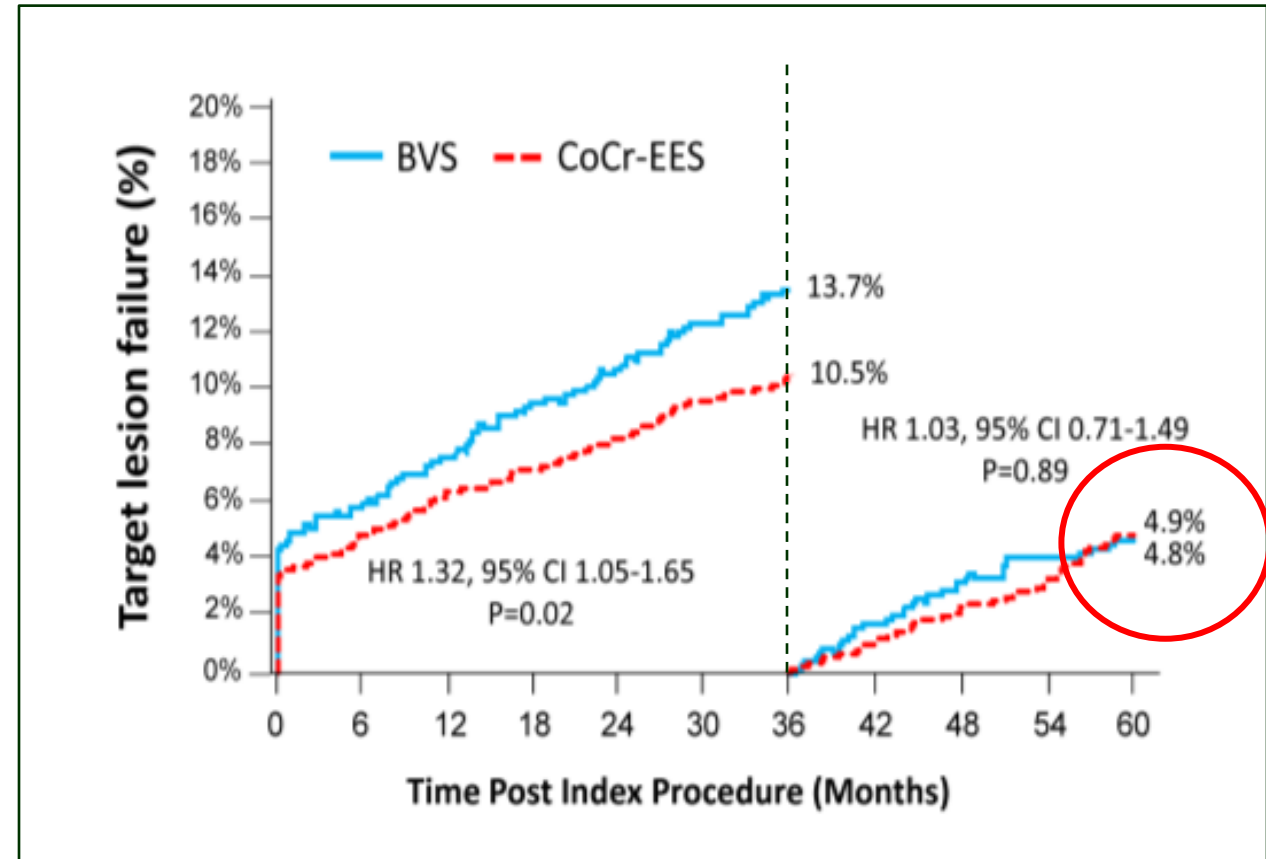
- Medtronic
- Boston Scientific
- HeartBeam
- Edwards Lifesciences
- Abbott Vascular

Aren't Current DES "Good Enough"?

TLF: BMS, 1st, 2nd Generation DES



TLF: CoCr EES, BVS



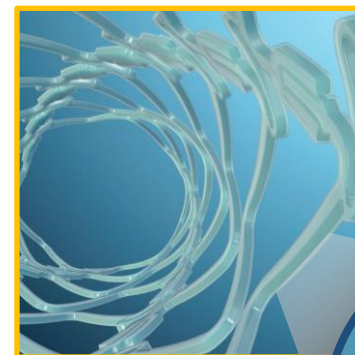
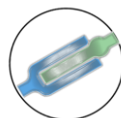
New Stent Concept #1

Stent-Polymer Hybrid Systems

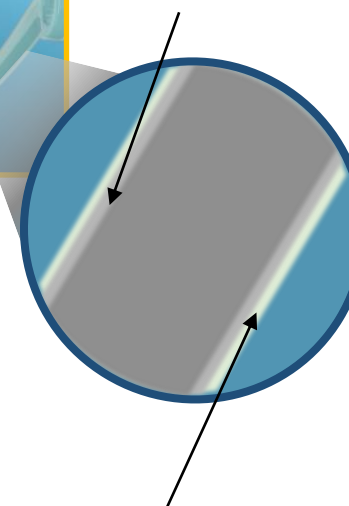
DynamX Coronary Bioadaptor System Design



- Three thin (71 μ m) Co-Cr helical sinusoid strands
- Axially connected for longitudinal continuity
- “Uncaging elements” create temporary circumferential links



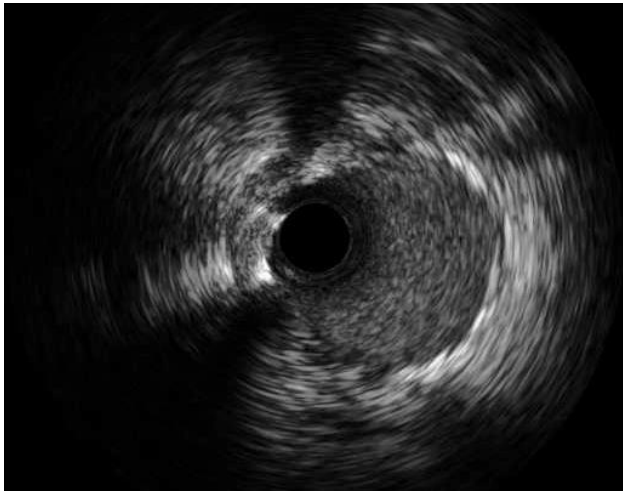
- PLLA bioresorbable polymer BASECOAT holds the scaffold together and is designed to resorb over 6 months



- PLGA bioresorbable TOPCOAT contains sirolimus designed to elute over 3 months

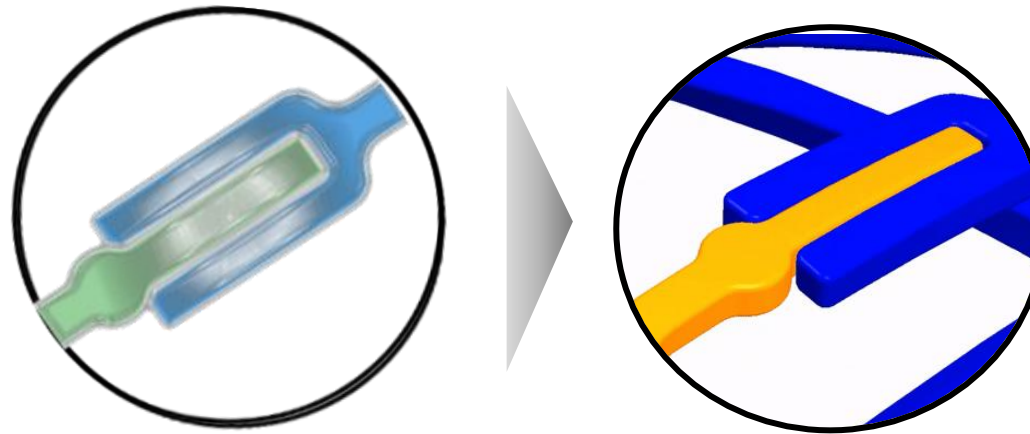
DynamX Coronary Bioadapter – Restoration of Function

1. Connected bioadapter provides acute radial strength



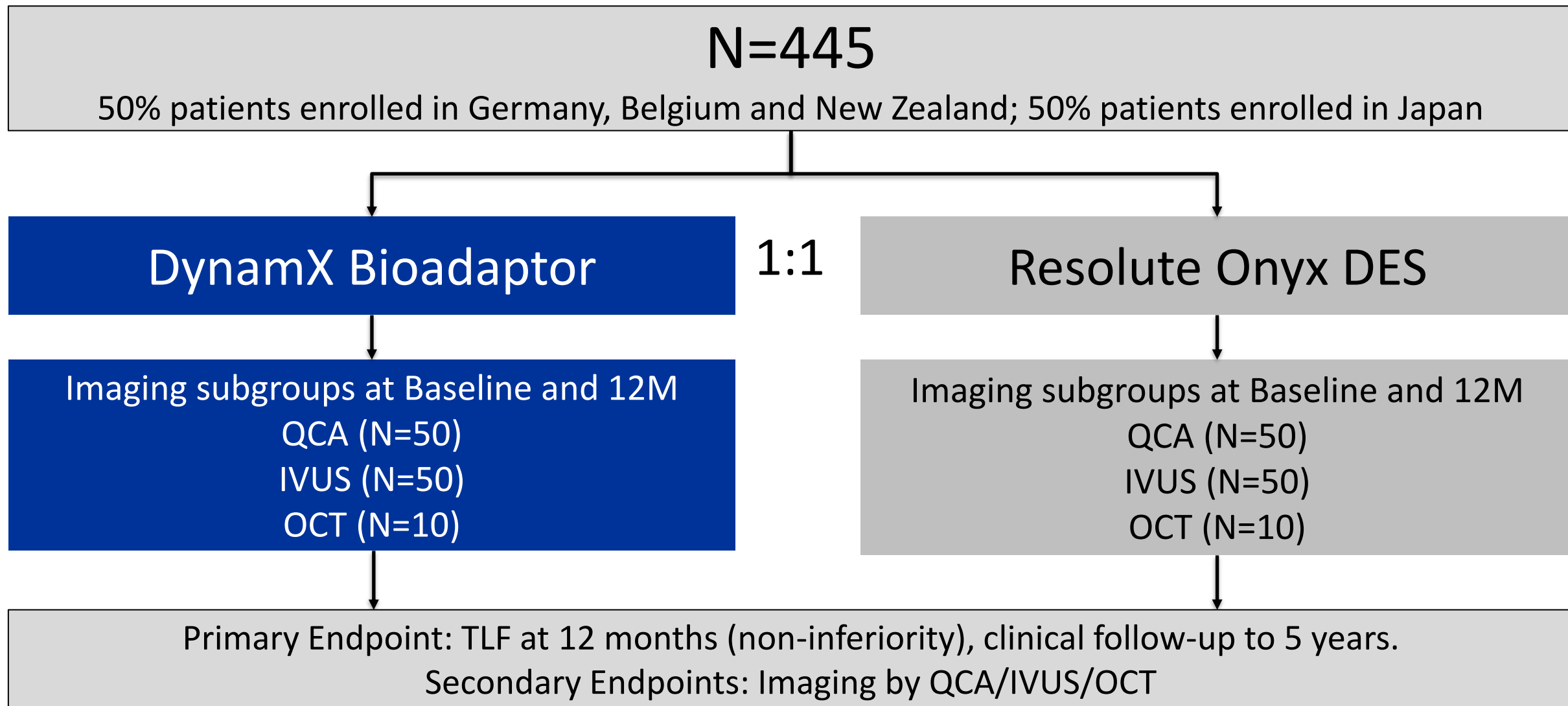
Patient image from Mechanistic study

2. By 6 months, bioadapter uncaging elements release to uncage the vessel

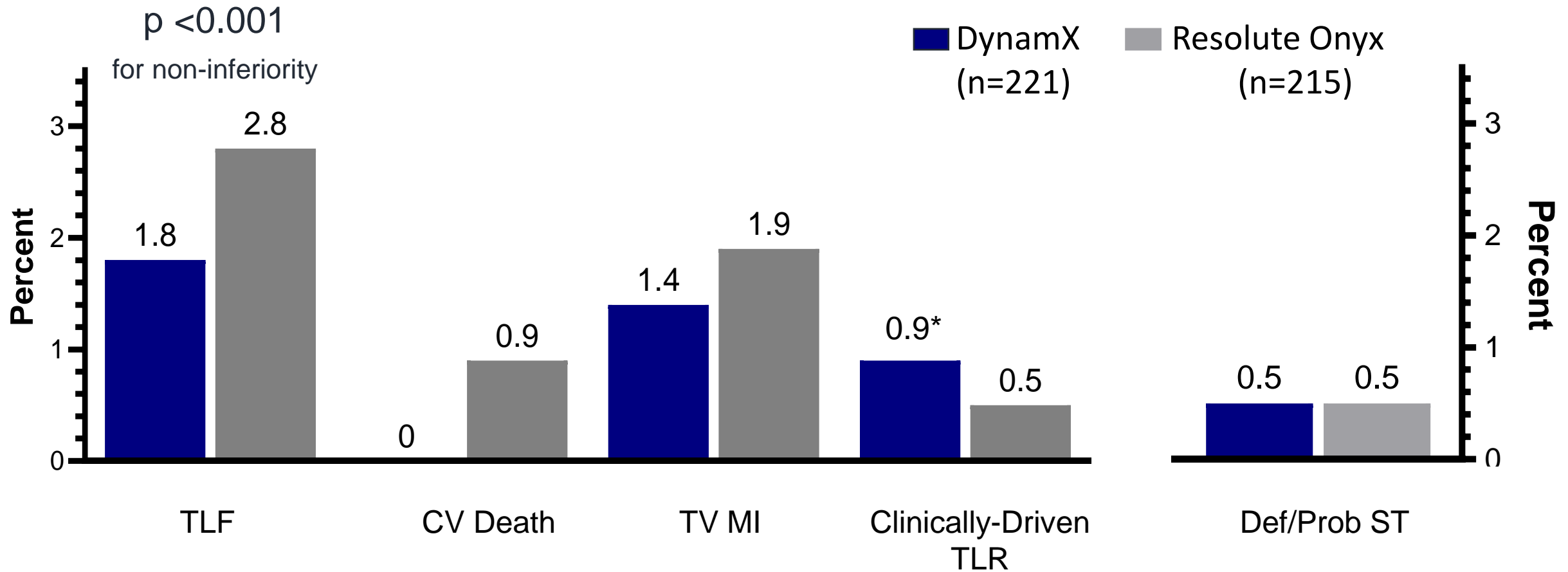


After vessel is uncaged, sinusoidal elements continue to provide vascular support while allowing for restoration of vessel flexibility and pulsatility

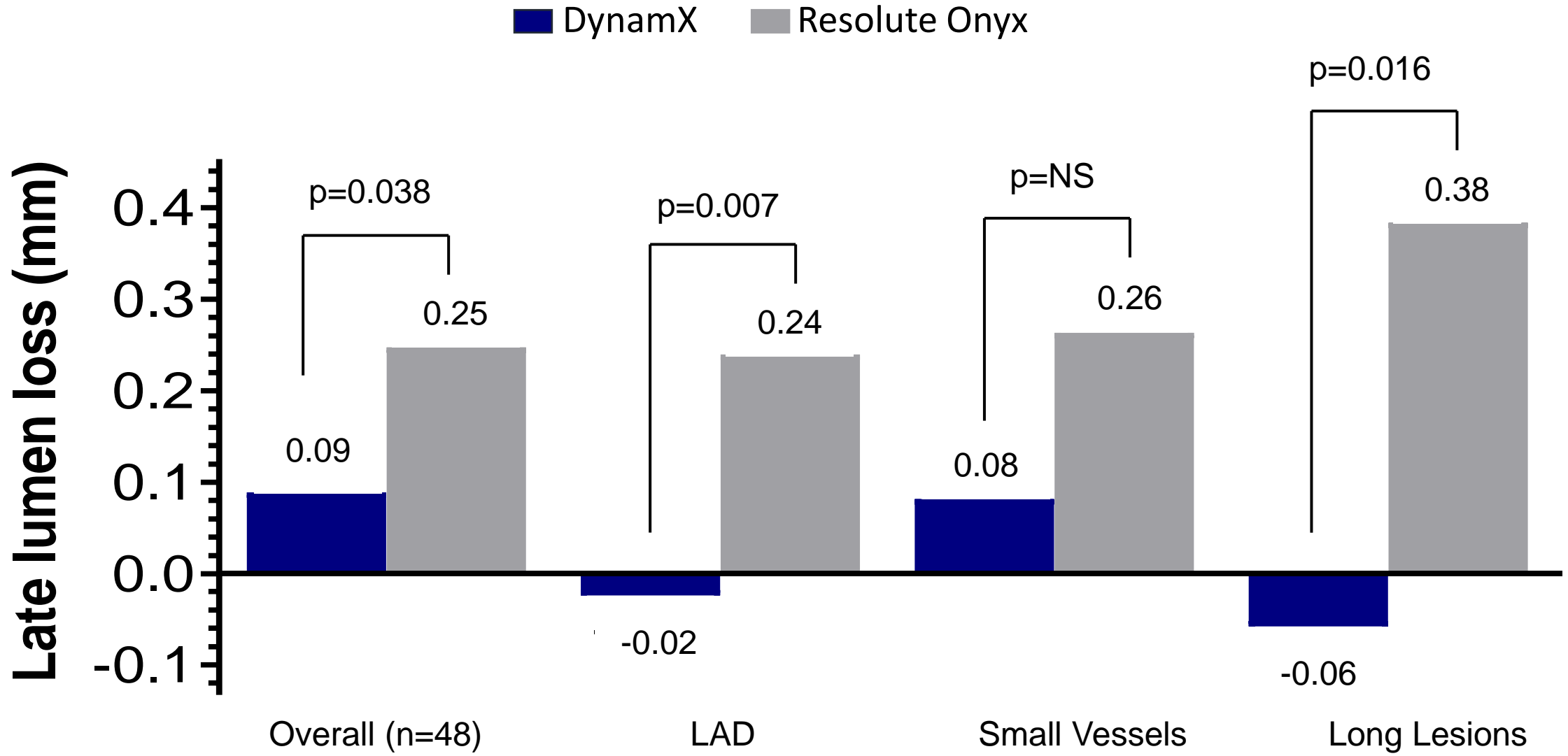
BIOADAPTOR RCT Trial Design



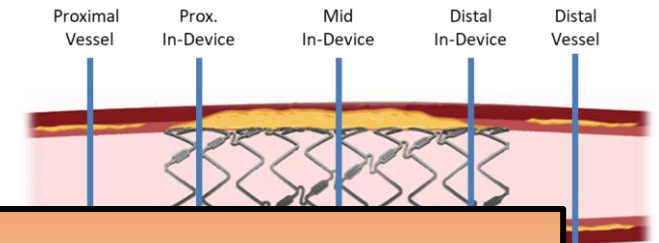
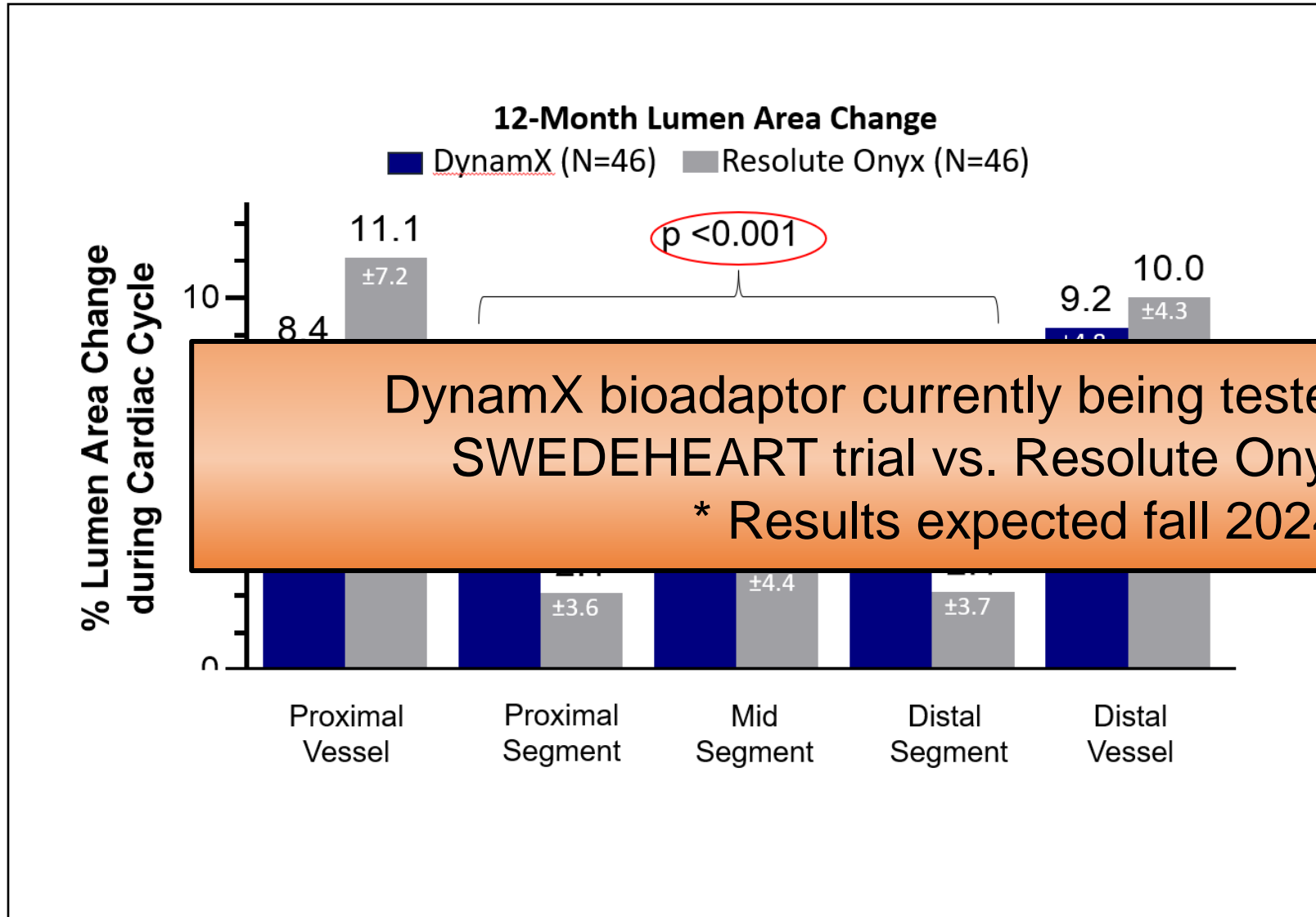
12 Month Outcomes



Angiographic Late Lumen Loss



Pulsatility Assessment (IVUS)

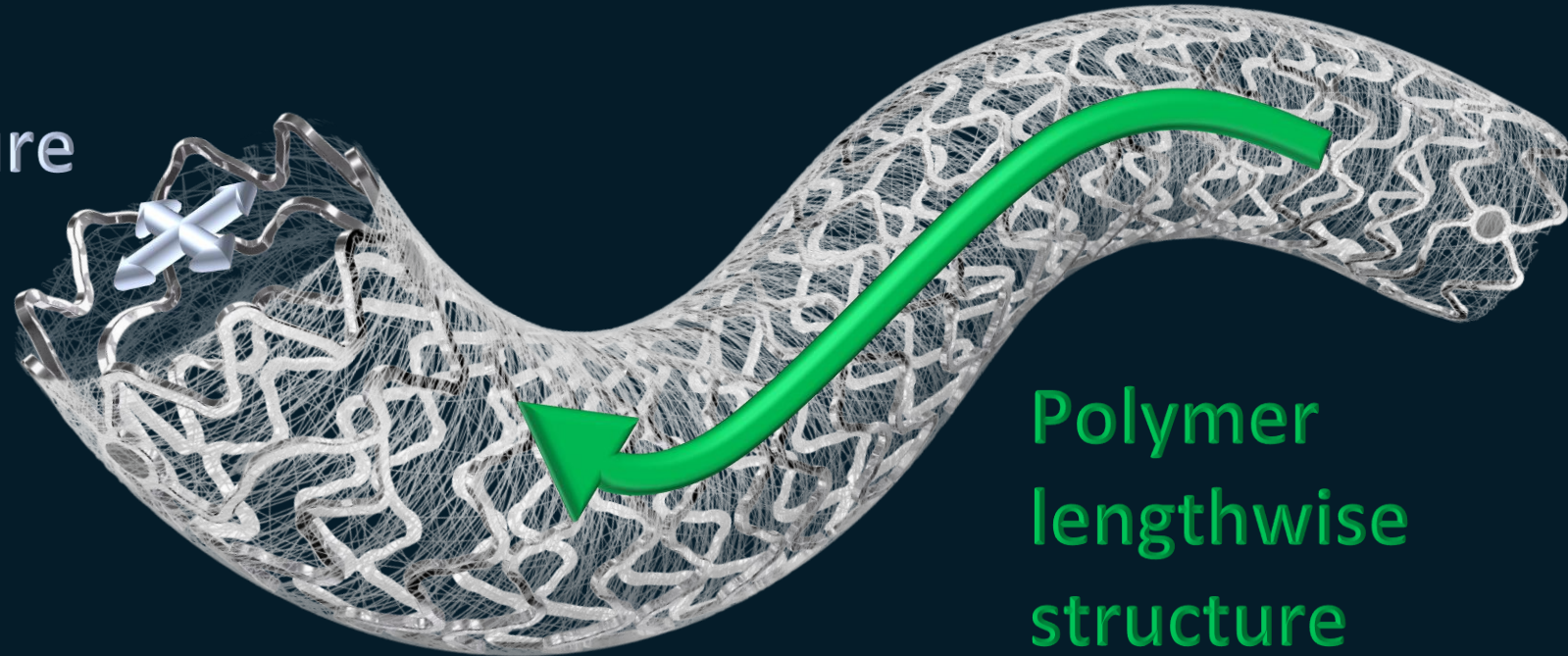


DynamX bioadaptor currently being tested in INFINITY SWEDEHEART trial vs. Resolute Onyx (n=2400)
* Results expected fall 2024

IoNIR hybrid coronary stent

A radically new concept in coronary devices

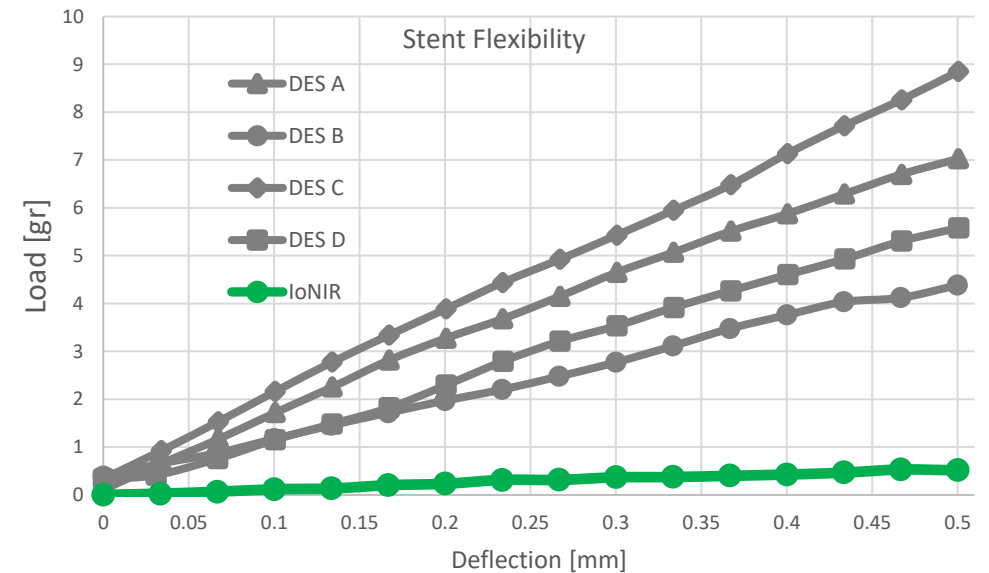
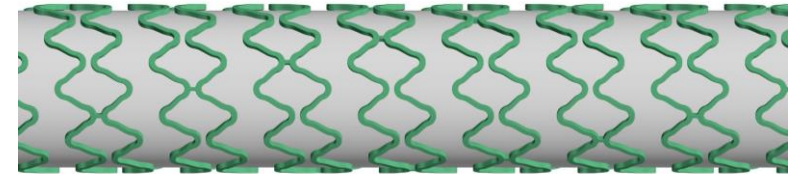
Metal
radial
structure



Polymer
lengthwise
structure

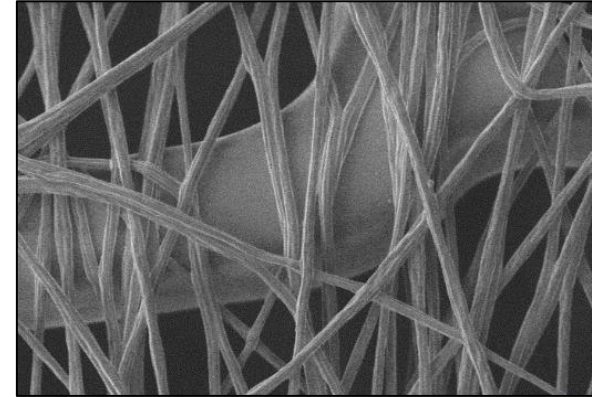
IoNIR: Scaffold Design

- Spiral design with high radial strength
 - Optimal support for vessel
- No lengthwise connections
 - Supreme flexibility
 - Allows vasomotion
- Ultra-low footprint
 - Promote vessel healing



IoNIR: Polymer Mesh

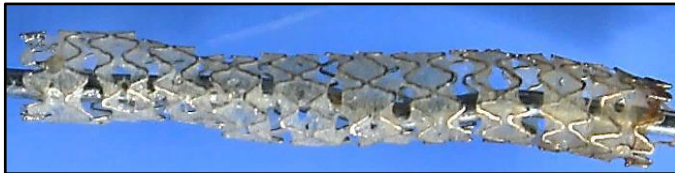
- Thin fibers (3-5 μm)
 - Provides short-term longitudinal support
 - Allows passage of RBCs into side branches
 - Bio-degradation w/o inflammation



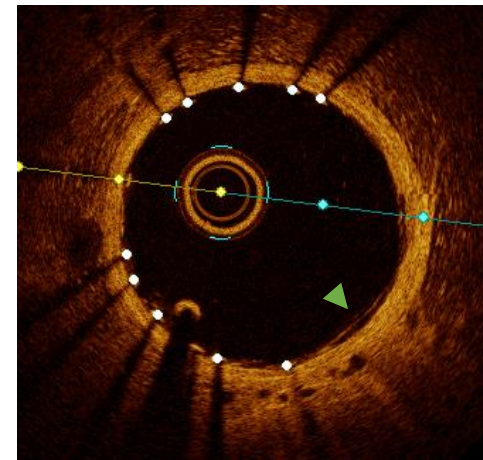
Day 7 in-vivo



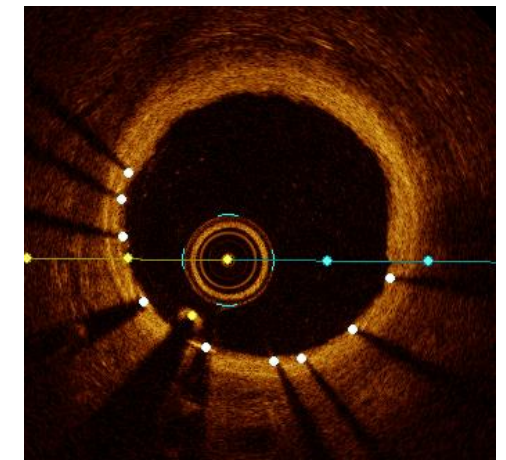
Day 30 in-vivo



Day 90 in-vivo



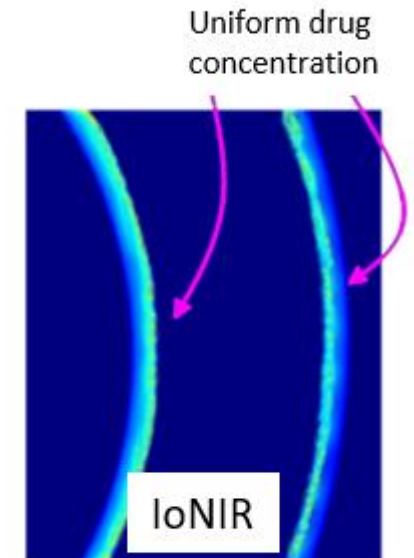
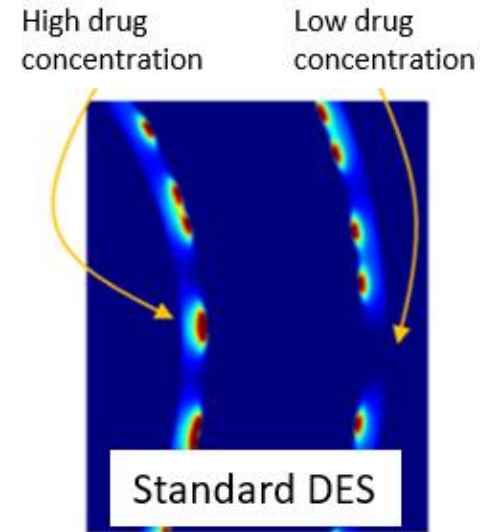
Day 0



Day 7

IoNIR: Drug Elution from Fibers

- Elution from entire stent envelope
 - Provides uniform dosing of entire vessel wall
 - Minimizes “hot spots” of drug toxicity
- Short diffusion distance
 - Allows for similar antiproliferative activity with 1/4 the drug dose



IONMAN - First In Human Study



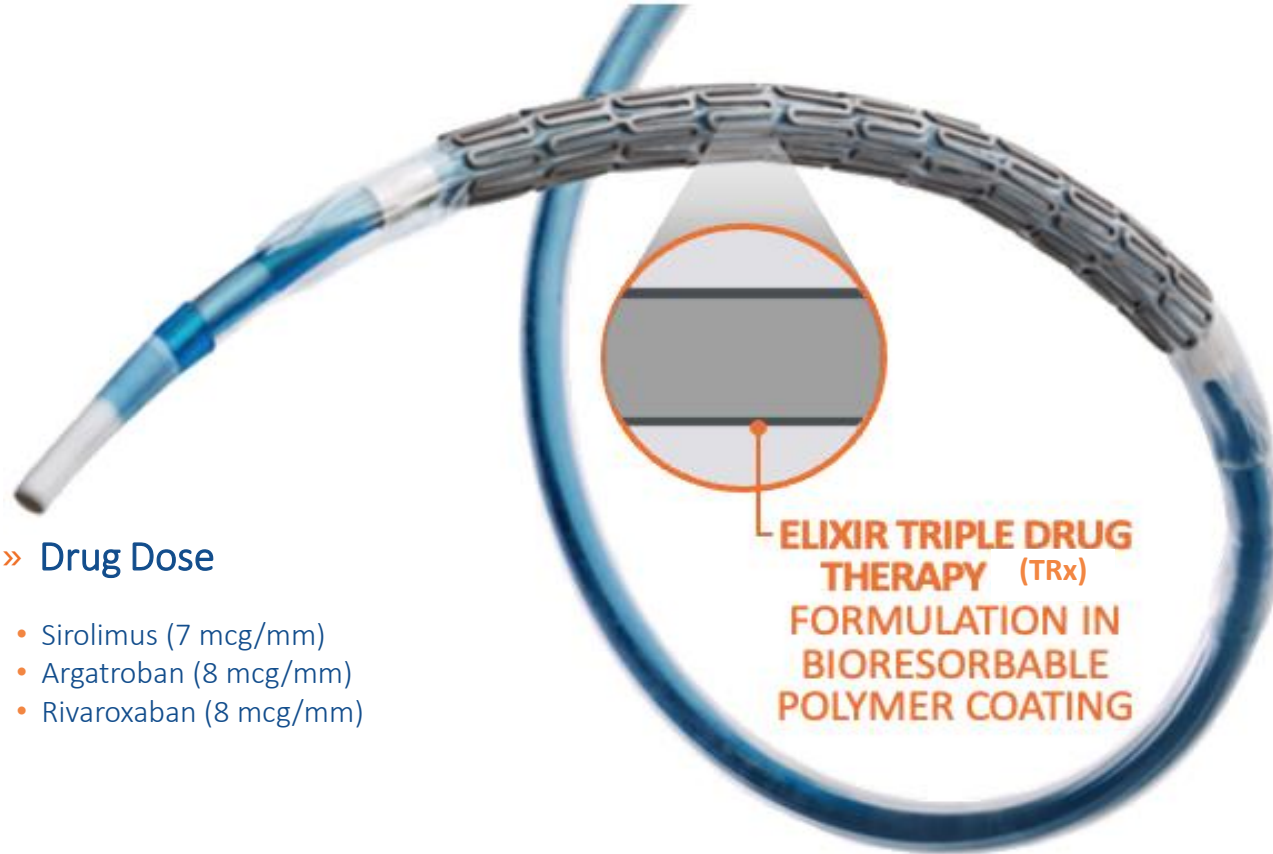
- Goal: FIM study of IoNIR device → Assess initial safety/efficacy with emphasis on stent healing
 - 60 patients
 - 5 Centers in Israel & Brazil
 - 1^o Endpoint: 1yr TLF
 - Secondary Endpoints: Angio & OCT at baseline, 30 days, 1yr
-

New Stent Concept #2

Combination Therapy DES

DESyne BDS Plus Stent (Elixir Medical)

DESyne BDS Plus Coronary DES System



» Drug Dose

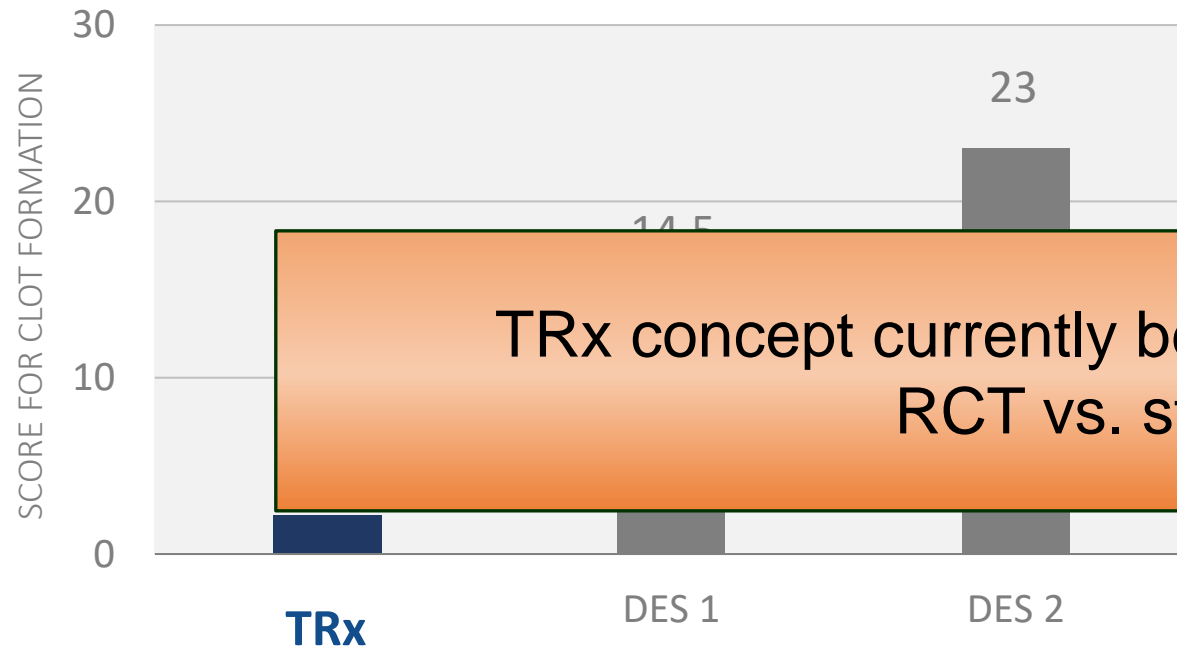
- Sirolimus (7 mcg/mm)
- Argatroban (8 mcg/mm)
- Rivaroxaban (8 mcg/mm)

Triple Drug Therapy (TRx)

- Sirolimus-- antiproliferative
- Argatroban– direct thrombin inhibitor
- Rivaroxaban- prothrombin (factor IIa) inhibitor
- Drug-elution controlled by bioresorbable polymer

TRx Resistance to Clot Formation

AV Shunt Model



TRx shows 6.5 – 10x more resistance to clot formation compared to two second-generation DES controls

Potential Applications for TRx

- High risk for stent thrombosis (AMI, complex lesion)
- PCI with high bleeding risk– potential for

tricuspid)

- LAAO without need for short-term OAC or DAPT
- Intervention for hemorrhagic stroke

Summary

- Although current DES results are generally excellent, there is still room for improvement with respect to complex lesions and late stent-related events
- Major theme is composite designs that provide temporary scaffolding with rapid restoration of vasomotion and flexibility
- Ongoing clinical trials (including long-term follow-up) are essential to demonstrate whether these new devices offer meaningful advantages over current DES platforms