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DynamX Bioadaptor: a novel "uncaging" platform for coronary artery revascularization 12-month clinical and imaging results

Stefan Verheye, MD

On behalf of the co-investigators

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Potential conflicts of interest

Stefan Verheye, MD, PhD

Speaker's name : Stefan Verheye

☑ I have the following potential conflicts of interest to declare:

Receipt of honoraria or consultation fees: Biotronik, Elixir Medical, Neovasc

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Why this study?

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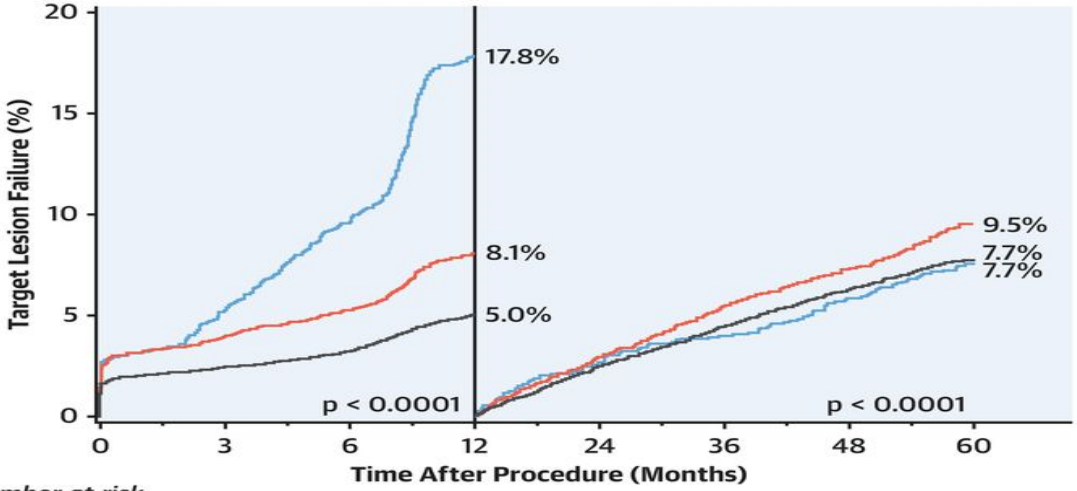
DES long-term event rates are high with, accruing at a rate of 2% - 3% per year without plateau

TLF in Meta-Analysis of 19 Trials (N=25,032)



Number at risk:

BMS	1,830	1,725	1,636	1,462	1,395	1,335	1,267	479
DES1	4,591	4,384	4,296	4,108	3,916	3,465	2,850	1,470
DES2	13,157	12,792	12,653	12,287	11,819	10,928	5,679	3,446

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What did we study?

DynamX Bioadaptor represents a significant innovation beyond drug-eluting stent technology

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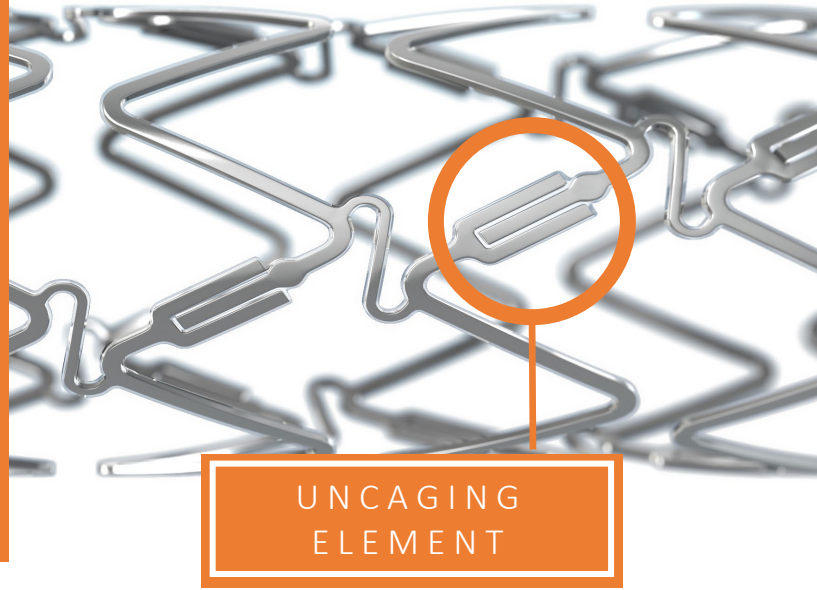
Potential to reduce adverse events by adapting to vessel physiology

- Positive adaptive vessel remodeling
- Restoration of pulsatility and physiologic cyclic strain
- Return of vessel angulation

Similar acute performance to DES (deliverability, implantation, radial strength)



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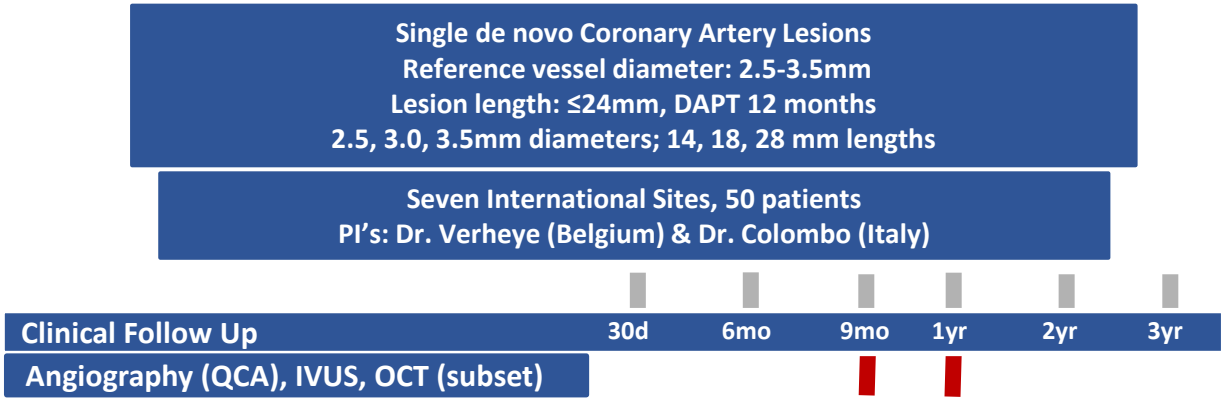
How was the study executed?



Study Purpose: Evaluate the safety and performance of the DynamX in de novo native coronary arteries

Study Design: Non-randomized, consecutive enrolment: 9 & 12 month imaging follow-up cohorts

Principal Endpoints:

- **Clinical:** Target Lesion Failure (cardiac death, target vessel MI, and clinically-indicated TLR); bioadaptor thrombosis at 9/12 months (additional follow-up at 30 days, and 1–3 yrs)
- **QCA:** Late lumen loss, MLD, % DS at baseline and follow-up
- **IVUS:** Change in mean and minimum lumen, bioadaptor and vessel areas from post-procedure to 9/12 month follow-up; pulsatility/vasomotion assessment at 9/12 month follow-up; malapposition at baseline and follow-up
- **OCT:** NIH Volume, Bioadaptor Strut apposition and coverage

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What are the essential results?

No Target Vessel Revascularization (TVR) through 12 months

	30 Day (n = 50)	6 Months (n = 49) [3]	9 Months (n = 49)	12 Months (n = 48) [4]
TLF	0	0	2	2
All Death	0	0	2	2
Cardiac Death [1,2]	0	0	2	2
Non-Cardiac Death	0	0	0	0
Target Vessel MI	0	0	0	0
Clinically Indicated-TLR	0	0	0	0
Non-Clinically Indicated TLR	0	0	0	0
Definite/Probable Thrombosis	0	0	0	0

1 – Unwitnessed death (Day 255), Hx of Korsakoff's Syndrome, No autopsy performed; Adjudicated per ARC-2 as Cardiac Death due to unwitnessed death.
2 – Multi-organ failure following Heart Failure Hospitalization (Day 267); Adjudicated per ARC-2 as Cardiac Death due to Heart Failure hospitalization.
3 - LTFU after 81 Days
4 - LTFU after 304 Days

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What are the essential results?

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Excellent Acute Performance and Low Late Lumen Loss by QCA

QCA Parameter	Paired QCA Results	
	Post-Procedure (n=45)	9 + 12 Month Follow-up (n=45)
In-Bioadaptor		
RVD Interp (mm)	2.95 ± 0.36	2.92 ± 0.36
MLD (mm)	2.74 ± 0.30	2.64 ± 0.36
%DS	6.69 ± 6.8	9.3 ± 10.2
Acute gain (mm) (Mean ± SD)	1.63 ± 0.34	--
Late Lumen Loss (mm) (Mean ± SD)	--	0.12 ± 0.18
Late Lumen Loss (mm) (Median, IQR)	--	0.05 (0.02, 0.17)

Positive Adaptive Remodeling to Maintain Lumen Area (IVUS)

IVUS Parameter	Paired IVUS Results			
	Post-Procedure	9 + 12 Month FU (n=38)	Change from Post-Procedure	p=
Mean Vessel Area (mm^2)	14.10 ± 2.99	14.54 ± 3.12	3%	0.0170
Mean Bioadaptor Area (mm^2)	7.39 ± 1.20	7.74 ± 1.46	5%	0.0005
Mean Lumen Area (mm^2)	7.39 ± 1.20	7.36 ± 1.31	0%	0.5940

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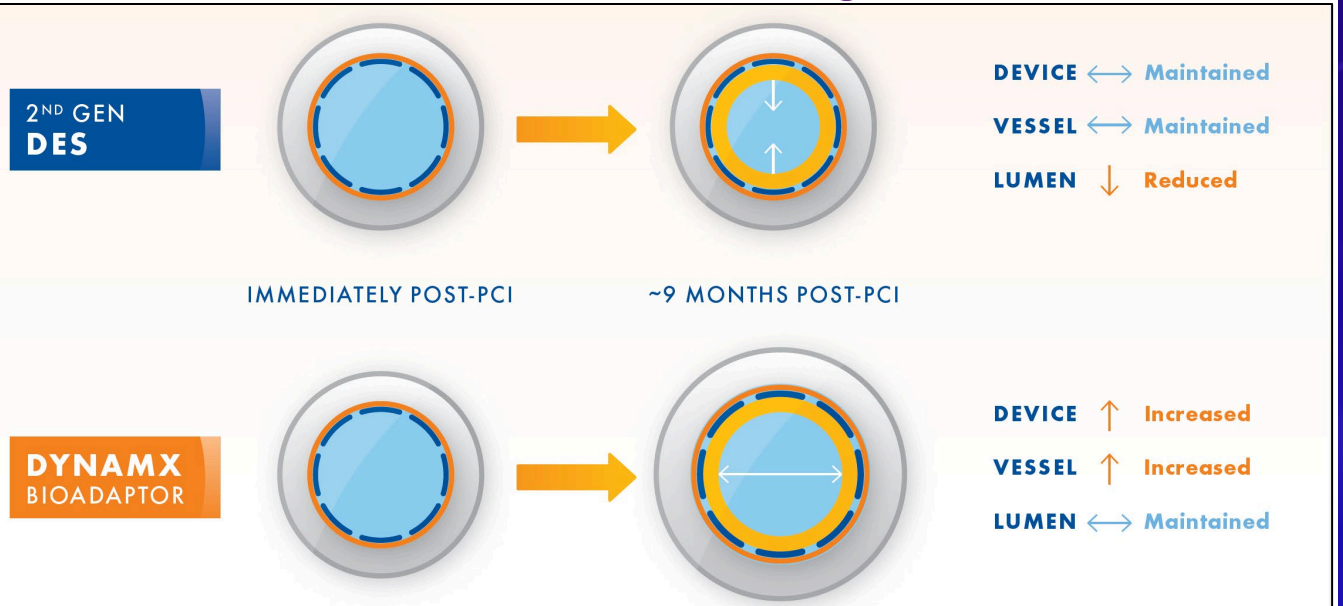
Why is this important?

DynamX Bioadaptor Preserves Positive Adaptive (Glagov) Vessel Remodeling



Vessel and device increase in area, allowing the vessel to maintain lumen diameter and preserve good blood flow over time

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The essentials to remember

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- **Why?** DES event rates beyond year one remain high accumulating at a rate of 2-3% per year without plateau
- **What?** The DynamX Bioadaptor performs similar to 2nd gen DES - implantation technique, deliverability, conformability and radial strength during the healing phase, later uncaging the vessel to preserve positive adaptive remodeling, maintain vessel lumen
- **How?** This multi-center clinical study in 50 patients included clinical follow-up through 12 months; and QCA/IVUS and 9/12 months
- **What are the results?** The DynamX Bioadaptor demonstrated excellent safety through 12 month follow-up and excellent efficacy as demonstrated preserved positive adapative remodeling and maintained the vessel lumen as demonstrated by IVUS data and low LLL by QCA at 9/12 months
- **Why is this important?** A fundamental innovation in device design that allows the bioadaptor to match current DES in acute performance while showing the promise of mitigating the 2-3% annualized event rates beyond year 1. Longer term follow-up in comparative studies will show the reduction in these device-oriented events that have been observed with current DES.

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