36-Month Outcomes for the BioMimics 3D Stent in Longer Lesions:

A subgroup Analysis of the MIMICS-3D European Registry

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Treatment challenges for long femoropopliteal lesions

- The DCB pivotal trials showed improved performance over simple angioplasty but in a well-defined set of lesions [1-5]
- The Global DCB Registries, however, show that the real world patient population is more complex than those recruited to the pivotal trials resulting in an average provisional stent rate of 28–35.5%, driven by lesion length and CTOs.[1-5]
- In IN.PACT Global, the provisional stent rate for lesions >25cm was 53%[1,2]

1. Tepe G. 12-Month Results from the IN.PACT SFA Randomized Trial. Circulation. 2014
2. Laird JRl. 24-Month Results of IN.PACT SFA. J Am Coll Cardiol. 2015;66:2329-2338.
3. Scheinert D. Twelve-month results from the BIOLUX P-I randomized trial. J Endovasc Ther. 2015;22:14-21.
4. Schroeder H. Two-year results from the ILLUMENATE first-in-human study. Catheter Cardiovasc Interv. 2015;86:278-286.
5. Rosenfield K, Jaff MR, White CJ et al. Trial of a Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. N Engl J Med. 2015;373:145-153.

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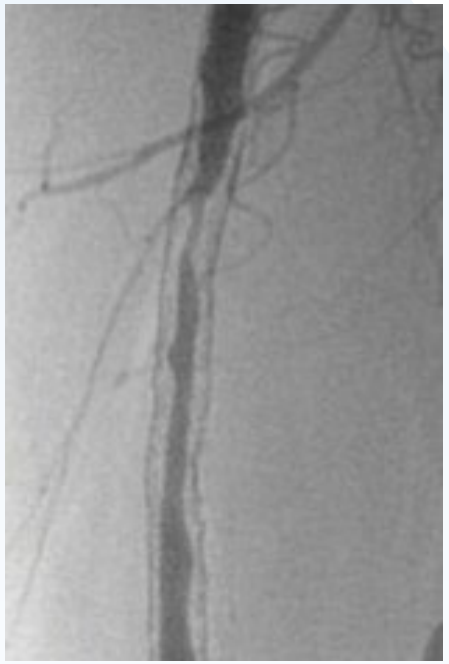
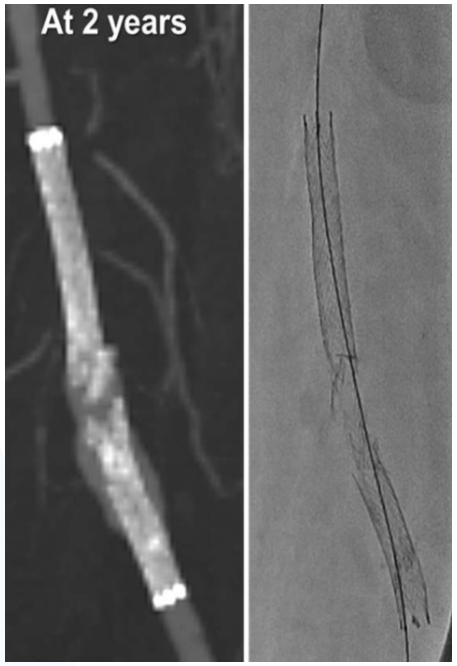
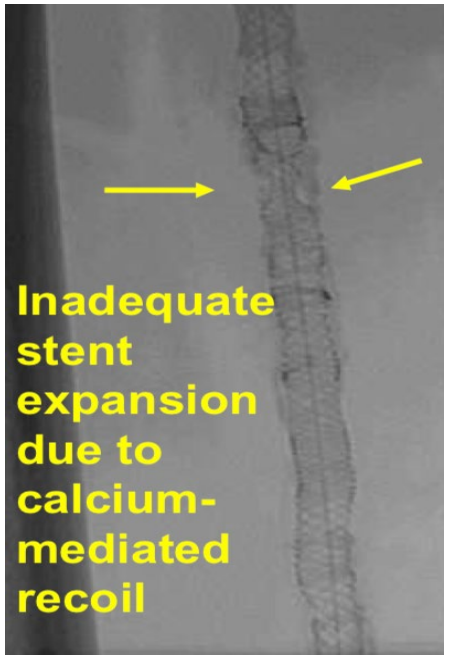
Persistent clinical issues when stenting long femoropopliteal lesions with straight stents



Diminished outcomes



Durability



Procedural complexity

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DES outcomes in long lesions

There have been promising 1-year clinical outcomes for Eluvia in real-world, long femoropopliteal lesions but the outcomes for Zilver PTX have been more controversial

Device	Study name / first author	n.	Mean lesion length (cm)	Primary patency	Freedom from TLR	Fracture rate
Eluvia[1]	Bisdas	62	20	87%	87%	0%
Eluvia[2]	Imperial LL sub-study	50	16	88%	93%	2.1%
Zilver PTX[1]	Zilver PTX single arm study	135	23	77.6%	85.4%	2.1%
Zilver PTX[1]	STELLA PTX registry	45	20	56.3%	63.6%	9%

- Study limitations: small cohorts and only 1-year follow up
- Study concerns:
  - Eluvia: fracture rate = 2%[2] & aneurysmal degeneration of the arterial wall = 8%[1]
  - Zilver PTX: high fracture rate = 2 – 9%

1. Bisdas T et al, JACC VOL. 11. NO.10 201
2. Gray WA, VIVA 2018 presentation

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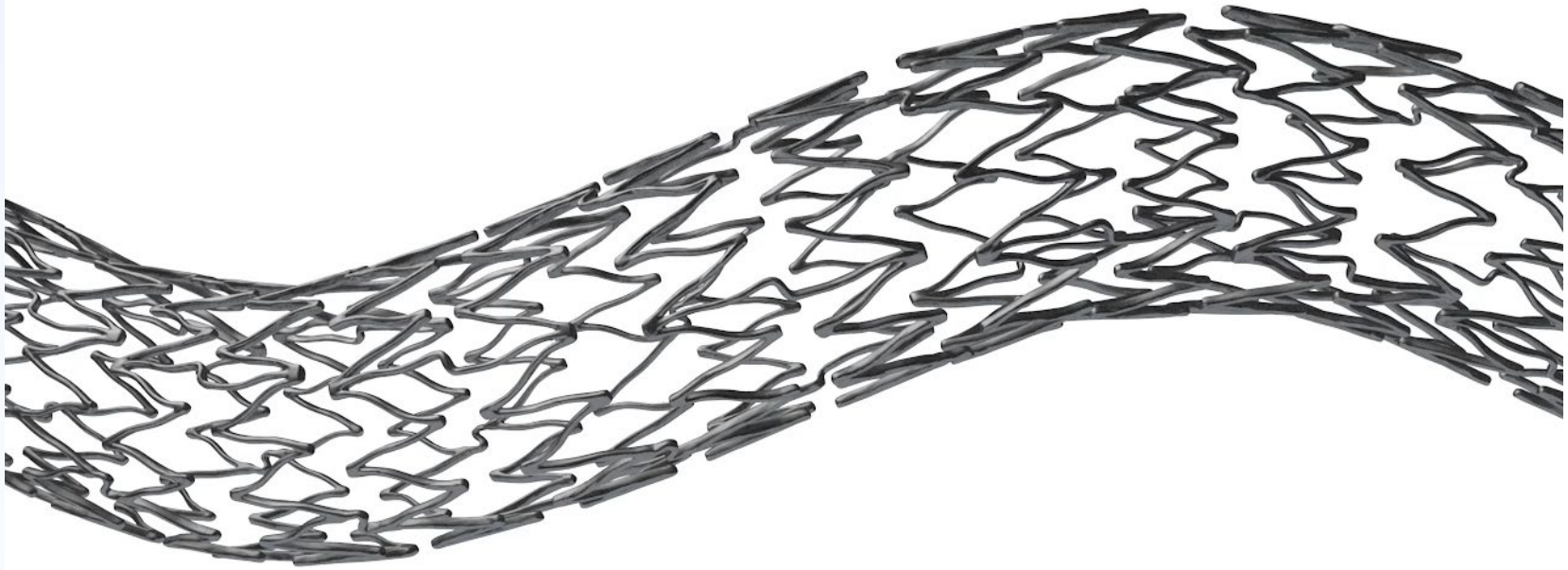
BioMimics 3D
Designed specifically for the Femoropopliteal Segment



The BioMimics 3D Vascular Stent System has FDA, PMDA and CE Mark approval.
CAUTION: Federal law restricts this device to sale by or on the order of a physician

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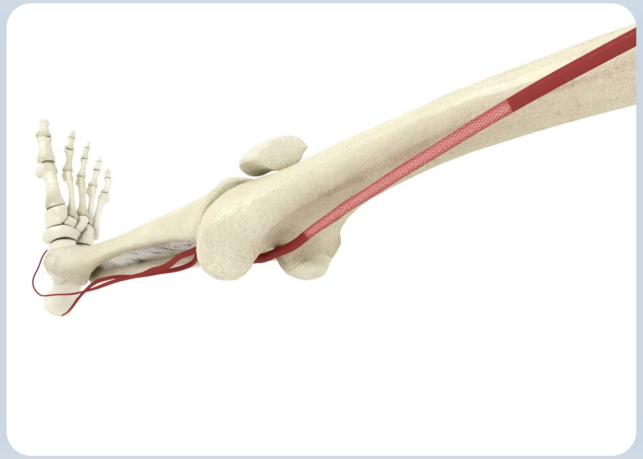
BioMimics 3D
Designed specifically for the Femoropopliteal Segment

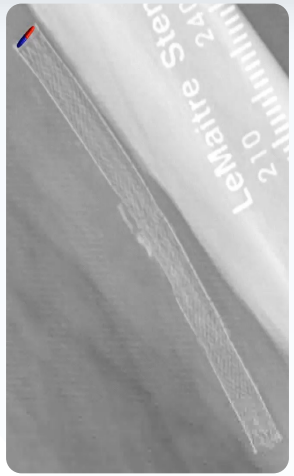
BIOMIMETIC DESIGN[1]

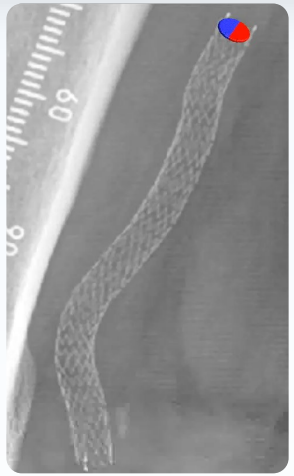
Mimics natural movement of the femoropopliteal segment

Aids in reducing localized trauma

Helps reduce risk of stent fracture in dynamic artery







ELEVATED WALL SHEAR STRESS[2]

Reduces restenosis by reducing thrombus formation and inflammation

Reduces Smooth Muscle Cell proliferation

Reduces neointimal hyperplasia

1.Data on file at Veryan Medical

2. Murphy EA, Cardiovascular Engineering and Technology 2012

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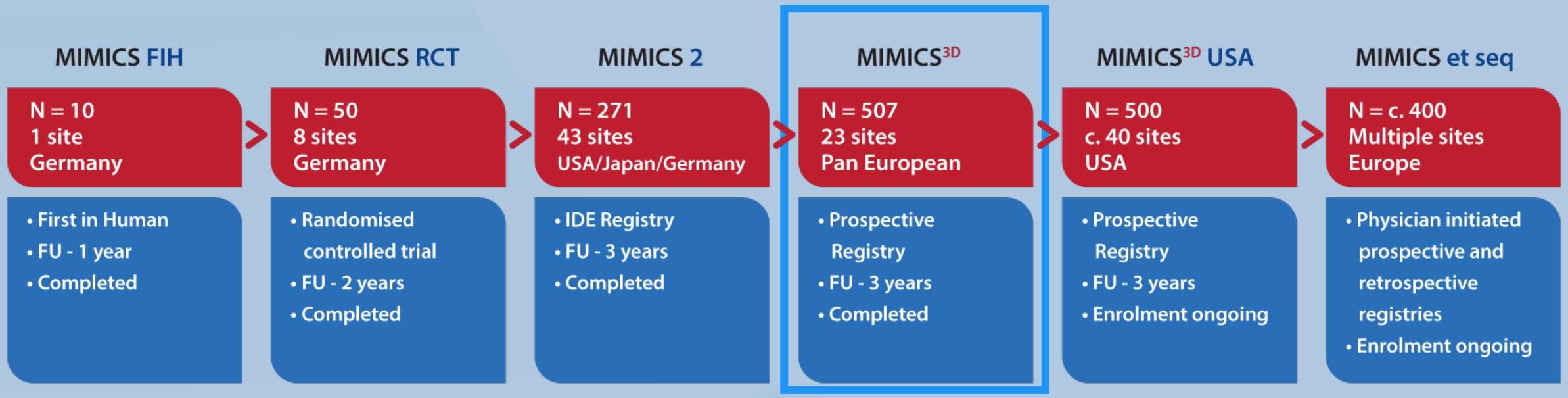
MIMICS Clinical Programme



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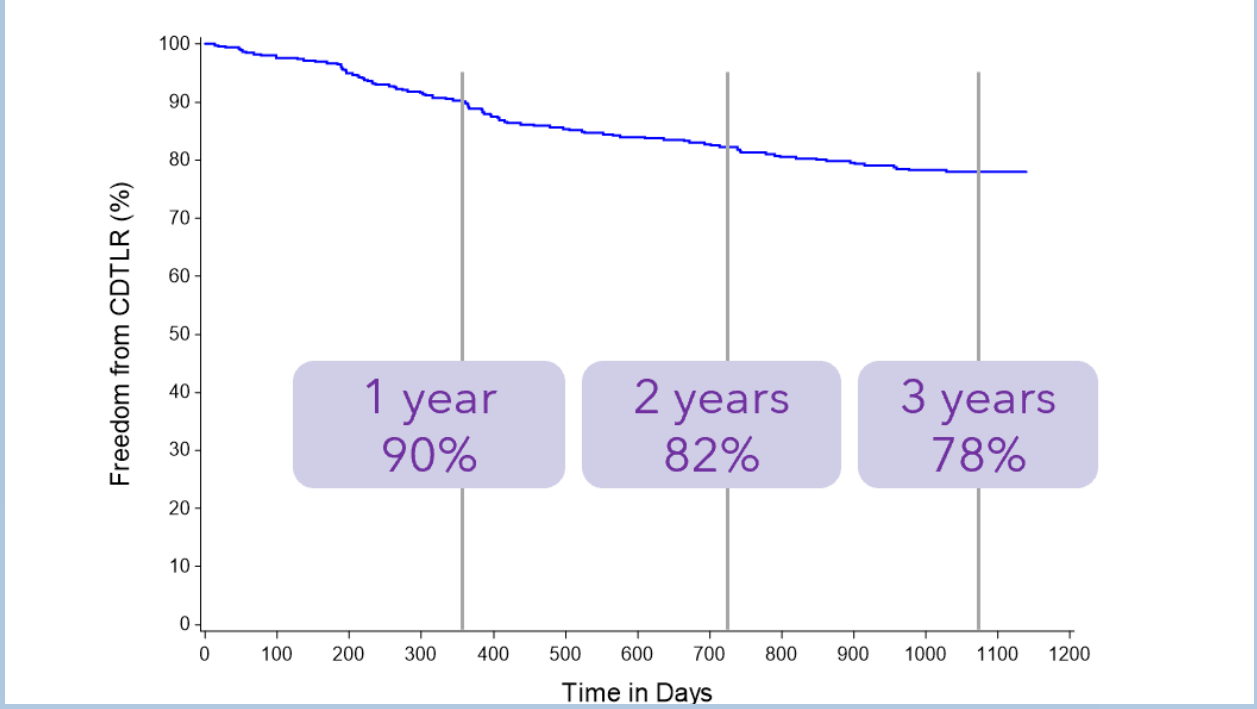
MIMICS^{3D} European Registry: 3-Year Summary

A Prospective, Multicentre Observational Study to Evaluate BioMimics 3D Stent in PAD in the Real World

Kaplan Meier survival estimates of Freedom from Clinically-Driven TLR at 3 Years



36-Month KM Freedom from loss of Primary Patency**	71%
36-Month KM Freedom from CDTLR	78%
Stent fracture (site reported)	0.6% (4/676)
Stent fracture (confirmed by investigation)	0.4% (3/676)

*1 patient did not have a final diameter stenosis recorded

**ITT population. PSVR >2.4

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Post-hoc Subgroup Analysis of the MIMICS-3D European Registry

- Three groups:
- Moderate Lesions (L): length <140mm (N=342)
- Long lesions (LL): length between 140mm to ≤ 190mm (N=46)
- Very long lesions (VLL): length >190mm (N=119).

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Baseline Patient Demographics

		Moderate Lesions <140mm (N=342)	Long lesions 140mm to ≤ 190mm (N=46)	Very long lesions >190mm (N=119)
Age	Mean years ± SD	70.1 ± 9.9	70.4 ± 9.6	69.8 ± 10.3
Gender	% Male	66% (227/342)	57% (26/46)	66% (79/119)
Risk Factors	Diabetes Mellitus	37% (125/342)	33% (15/46)	40% (47/119)
	Smoker Current	36% (124/342)	37% (17/46)	42% (50/119)
Rutherford Category	Mean ± SD (n)	3.2 ± 1.1 (339)	3.2 ± 0.9 (46)	3.3 ± 0.9 (119)
Ankle Brachial Index	Mean ± SD (N)	0.62 ± 0.27 (270)	0.61 ± 0.23 (42)	0.54 ± 0.22 (105)

CLTI present in 24% of enrolled subjects

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Baseline Lesion Characteristics

		Moderate Lesions <140mm (N=342)	Long lesions 140mm to ≤ 190mm (N=46)	Very long lesions >190mm (N=119)
Reference Vessel Diameter (mm)	Mean ± SD	5.4 ± 0.7	5.5 ± 0.7	5.5 ± 0.7
Diameter Stenosis (%)	Mean ± SD	93.0 ± 8.7	94 ± 8.0	99 ± 2.4
Occlusions	Total	45%	58%	92%
Lesion Length (mm)	Mean ± SD	72.2 ± 29.4	160.2 ± 22.6	269 ± 61
Calcification	Severe bilateral wall calcification	26%	25%	38%

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3-Year Results

	Moderate Lesions <140mm	Long lesions 140mm to ≤ 190mm	Very long lesions >190mm
Acute technical success	99% (339/341)	100% (46/46)	98% (116/119)
Primary Effectiveness Endpoint – 12-month KM Freedom from CDTLR	93%	85%	82%
KM freedom from Major Amputation at 3 years	99%	98%	98%
Fracture rate* at 3 years	0.5%	0%	0.8%

*Investigator reported

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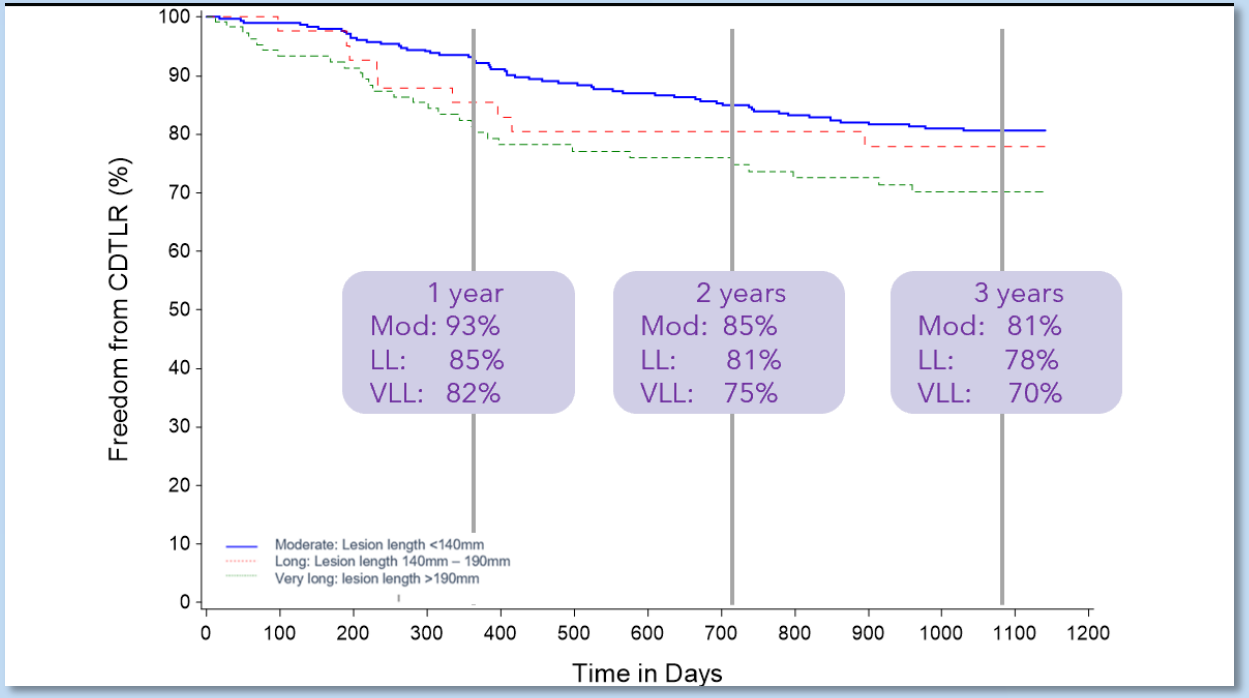
3-Year Kaplan-Meier Freedom from CDTLR



Lesion Length	CDTLR
<140mm	81%
140mm–190mm	78%
>190mm	70%

No significant difference between moderate and long lesion groups

As expected, there is an observable difference between the moderate and very long lesion groups however, the CDTLR and durability of the very long lesion group is impressive given the lesion length and morphology

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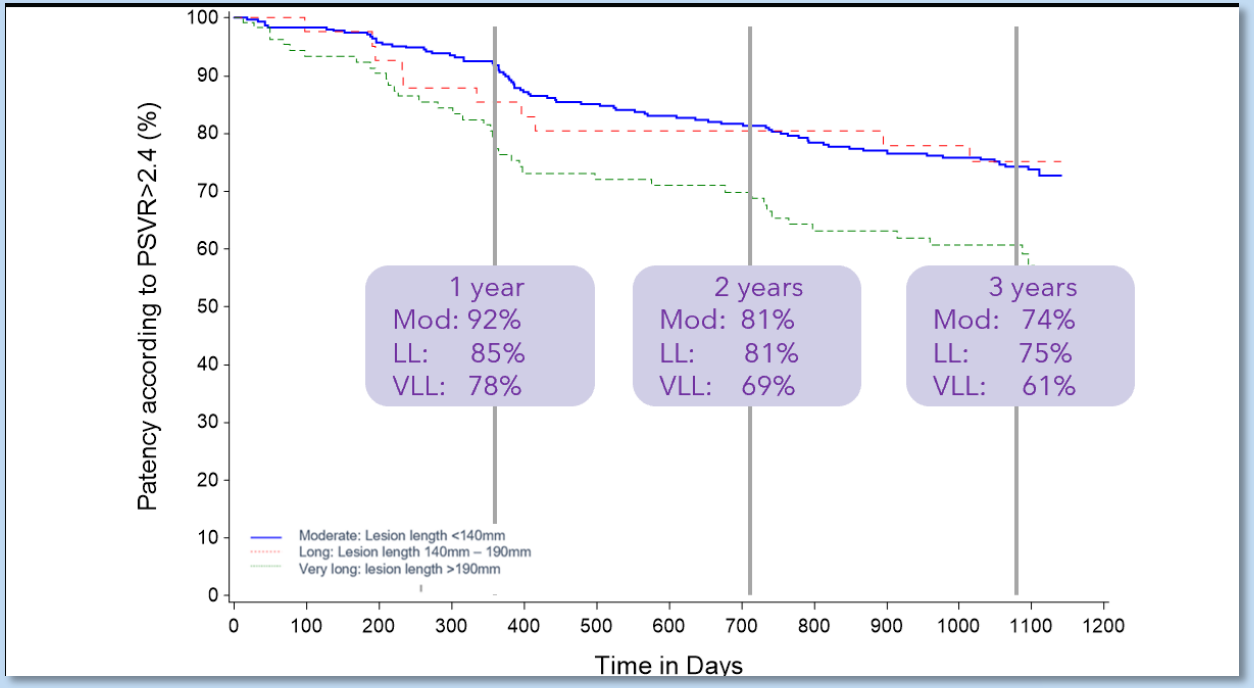
3-Year Kaplan-Meier Estimate of Primary Patency



Lesion Length	PSVR 2.4
<140mm	74%
140mm–190mm	75%
>190mm	61%

No significant difference between moderate and long lesion groups

As expected, there is an observable difference between the moderate and very long lesion groups however, the patency and durability of the very long lesion group is impressive given the lesion length and morphology

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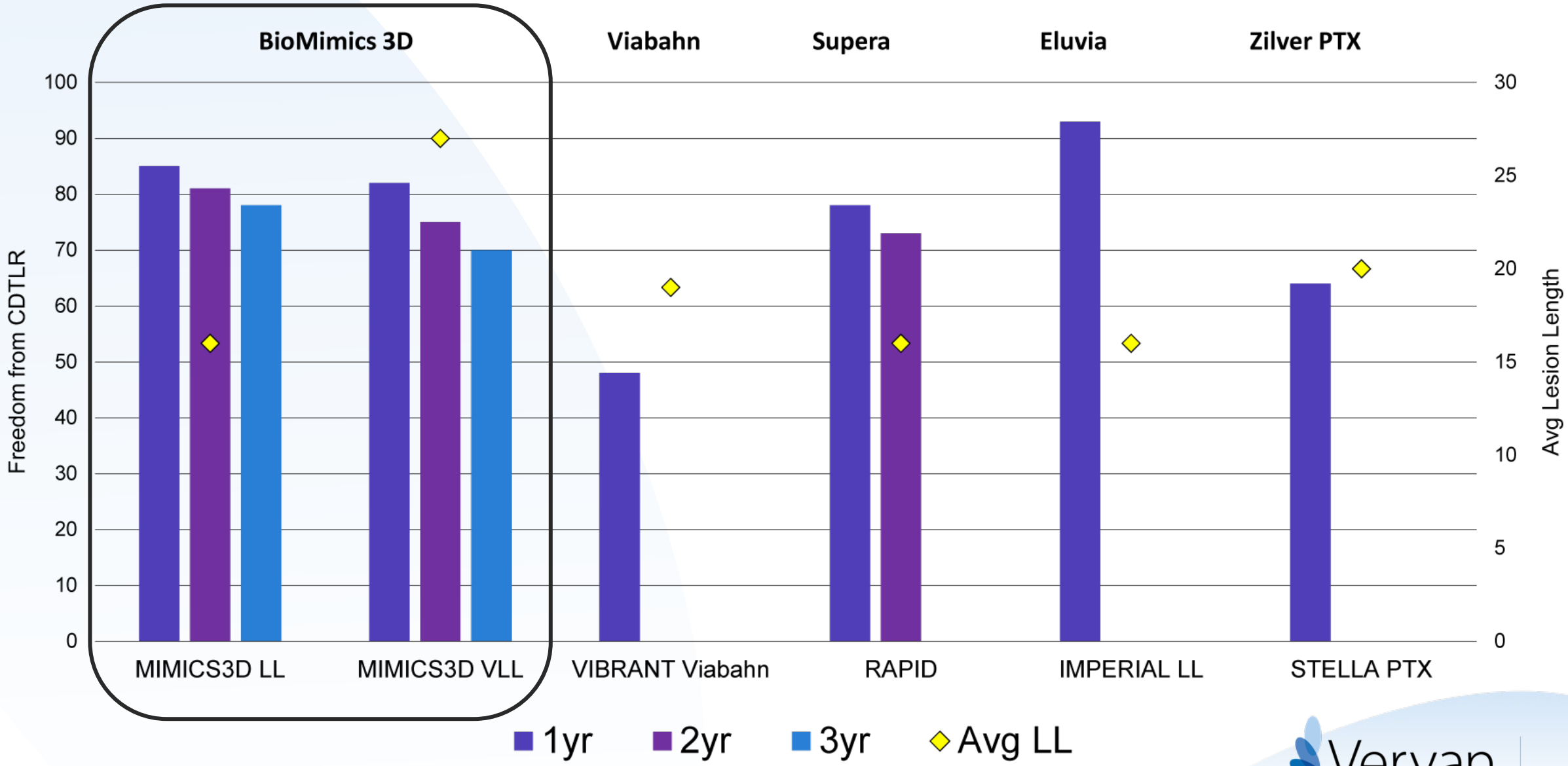
Industry Study Comparisons-Freedom from CDTLR



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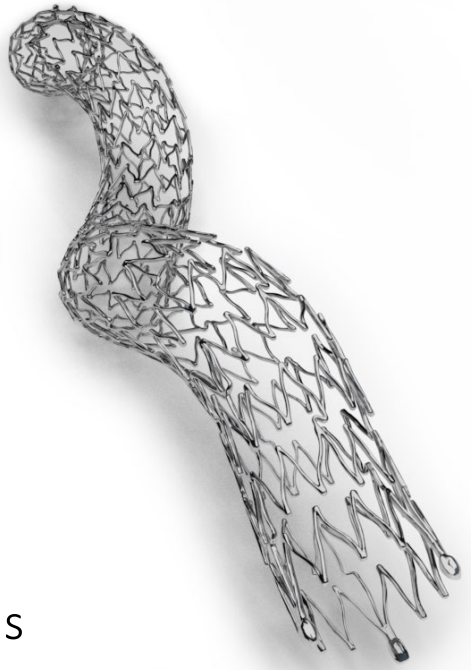
Conclusions

Longer follow up (3 years) than reported in other long lesion studies

More challenging population than typically enrolled in registry studies, including longer, more complex lesions:

- 9% long lesions (140mm to ≤ 190mm)
- 24% very long lesions >190mm
- 24% CLTI
- 53% moderate to severe calcification
- 57% CTO



Excellent 3-year results including those for long lesions and very long lesions

Very low fracture rate at 3 years: 0% in long lesions and 0.8% in very long lesions

Comparable outcomes to DES and Supera despite more challenging, longer lesions

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