Angioplasty Summit 2005, Korea

Everolimus Drug-Eluting Stents I: Review of Guidant FUTURE I and II, and Status Update of FUTURE III and IV

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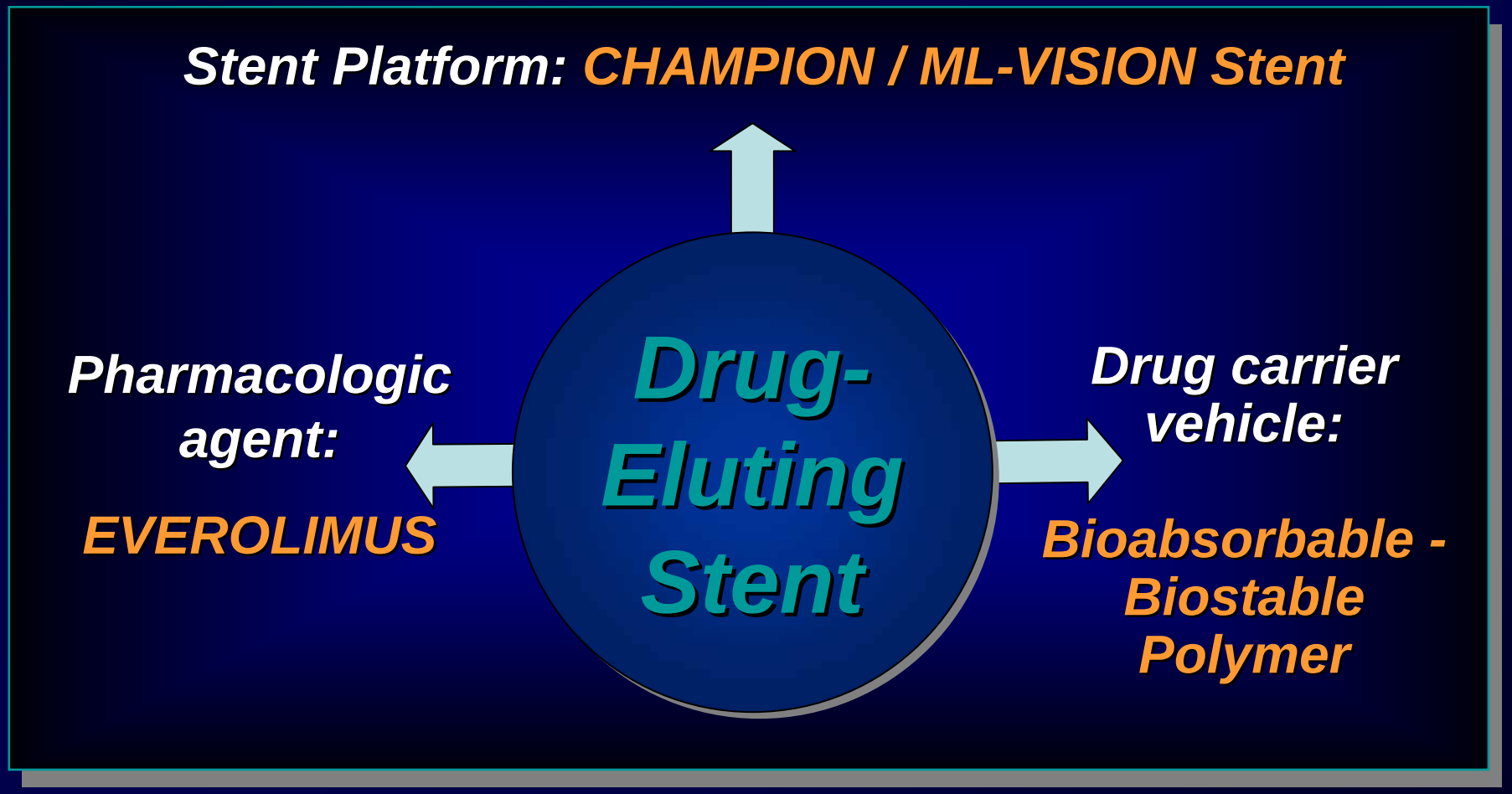
Everolimus Eluting Stent Program



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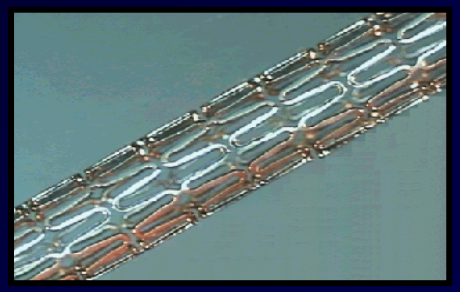
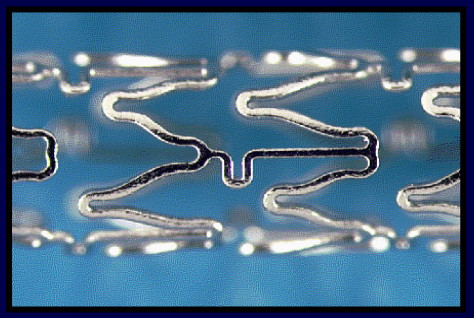
Guidant's EVEROLIMUS DES Program

CHAMPION™ Platform



Bioabsorbable Polymer Drug Carrier

Multi-Link VISION™ Platform



Bioabsorbable Polymer Drug Carrier

Durable Polymer Drug Carrier

FUTURE Clinical Trials

SPIRIT Clinical Trials

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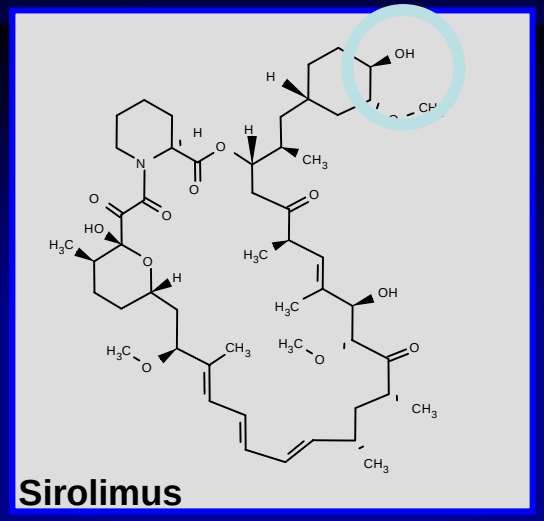
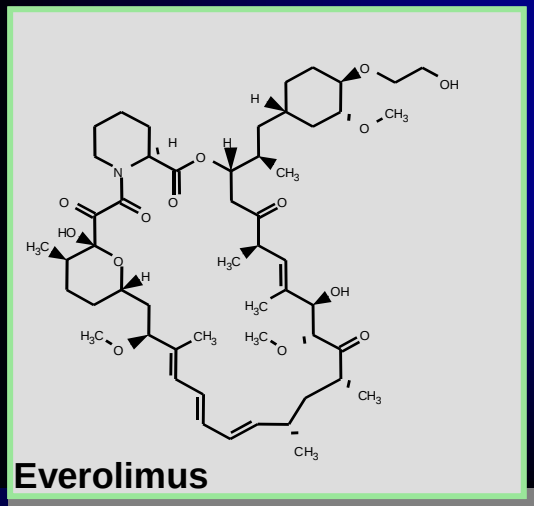
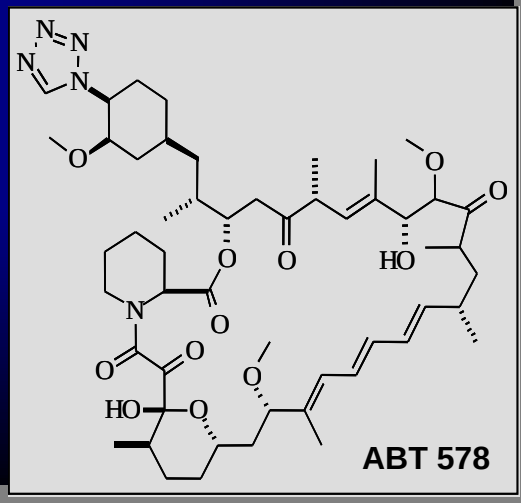
Limus Agents

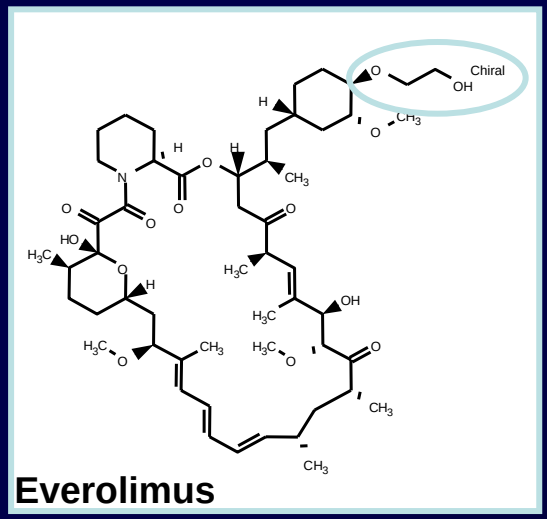


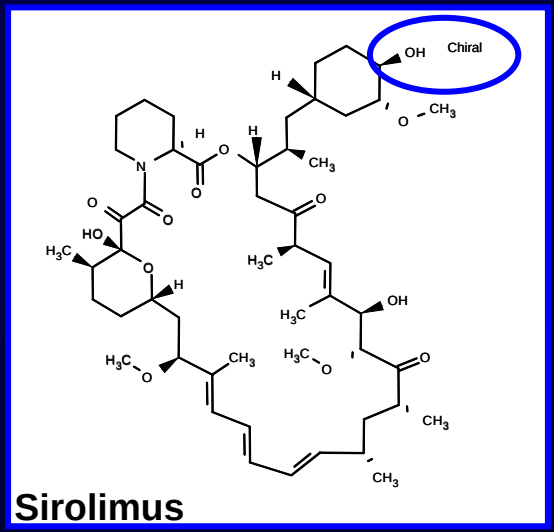




Everolimus

- Potential Advantages
- - Everolimus designed to have improved pharmacokinetics versus sirolimus for treating organ transplant patients
- - Increased lipophilicity and rapid tissue absorption[1]
  - –Longer cellular residence time and activity[2]
  - –Improved chemical stability[3]
- - Reduced intimal thickening in cardiac graft vessels[4] in randomized clinical trial



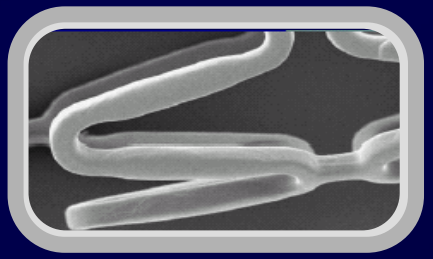


[1] Crowe and Lemaire. Pharmaceutical Research 1998, 15:11 (1666-1672)
[2] Jacobsen et al. Transplantation Proceedings 2001, 33 (514-515)
[3] Novartis Pharma
[4] Eisen H.J., NEJM, August 28, 2003, 349;9, 847-858

CHAMPION™ Drug Eluting Stent Objectives

Minimize Vessel Injury

- Narrower strut width at crest allows for lower deployment pressures to minimize vessel injury

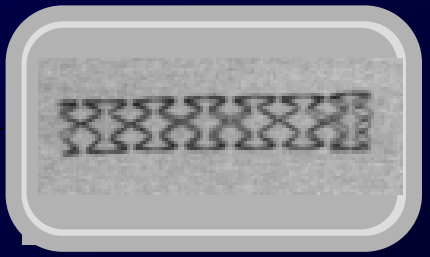


Uniform Strut to Wall Apposition

- Promotes uniform drug delivery in vessel

Precision Placement

- Excellent radiopacity for accuracy of stent placement



Deliverability

- Incorporates same delivery system as ML VISION™ for enhanced deliverability

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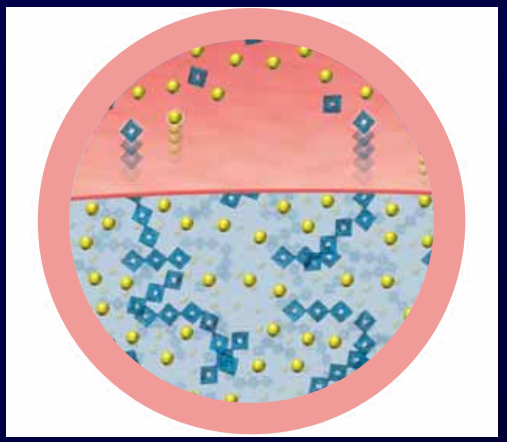
CHAMPION™ Bioabsorbable Polymer

- Thin–film Poly Lactic Acid (PLA)
- Safely used in numerous medical applications since the 1980's
  - Vascular, orthopedic, dental
- Breaks down to lactic acid, a natural metabolite
- High drug loading capability
  - High drug to polymer ratio—ability to load >50% drug
- As drug release matrix is absorbed, no residual drug is encapsulated in polymer



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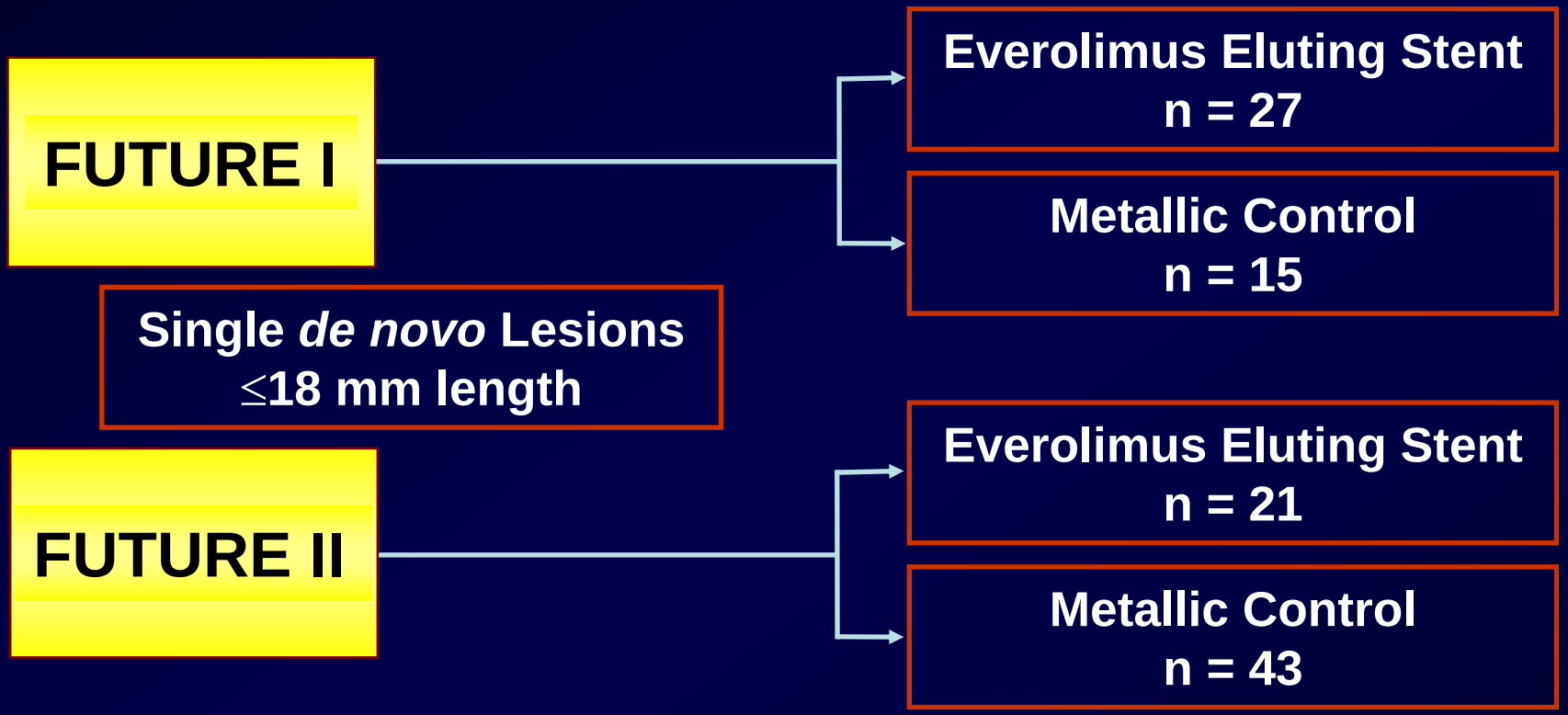
Everolimus Eluting Stent Program
FUTURE I and II



- Stent sizes: 2.5 – 4.0 mm diameter, 14 and 18 mm lengths
- Prospective, randomized
- **Key Endpoints:** Angiographic and IVUS results at 6 months, clinical endpoints at 1, 6 and 12 months

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FUTURE I & II
Clinical and Angiographic FU Summary

	FUTURE I 6-mo n=26 Angio 96% FU	FUTURE II 6-mo n=21/22** Angio 95% FU
Ref Diameter (mm)	3.07	2.91
Lesion Length (mm)	9.17	11.07
Diabetics (%)	4%	23.8%
MACE (%)	7.7% *(2/26)	4.8% (1/21)
TLR (%)	3.8% (1/26)	4.8% (1/21)
% DS at follow-up	2.63	2.94
Late Loss (mm) in-stent	0.11	0.12
Late Loss (mm) in-segment	0.19	0.16
Restenosis (%) in-stent	0.0% (0/25)	0.0% (0/21)
Restenosis (%) in-segment	4.0% (1/25)	4.8% (1/21)

*One Death was non-cardiac due to underlying COPD
**One EES patient had two lestions treeated

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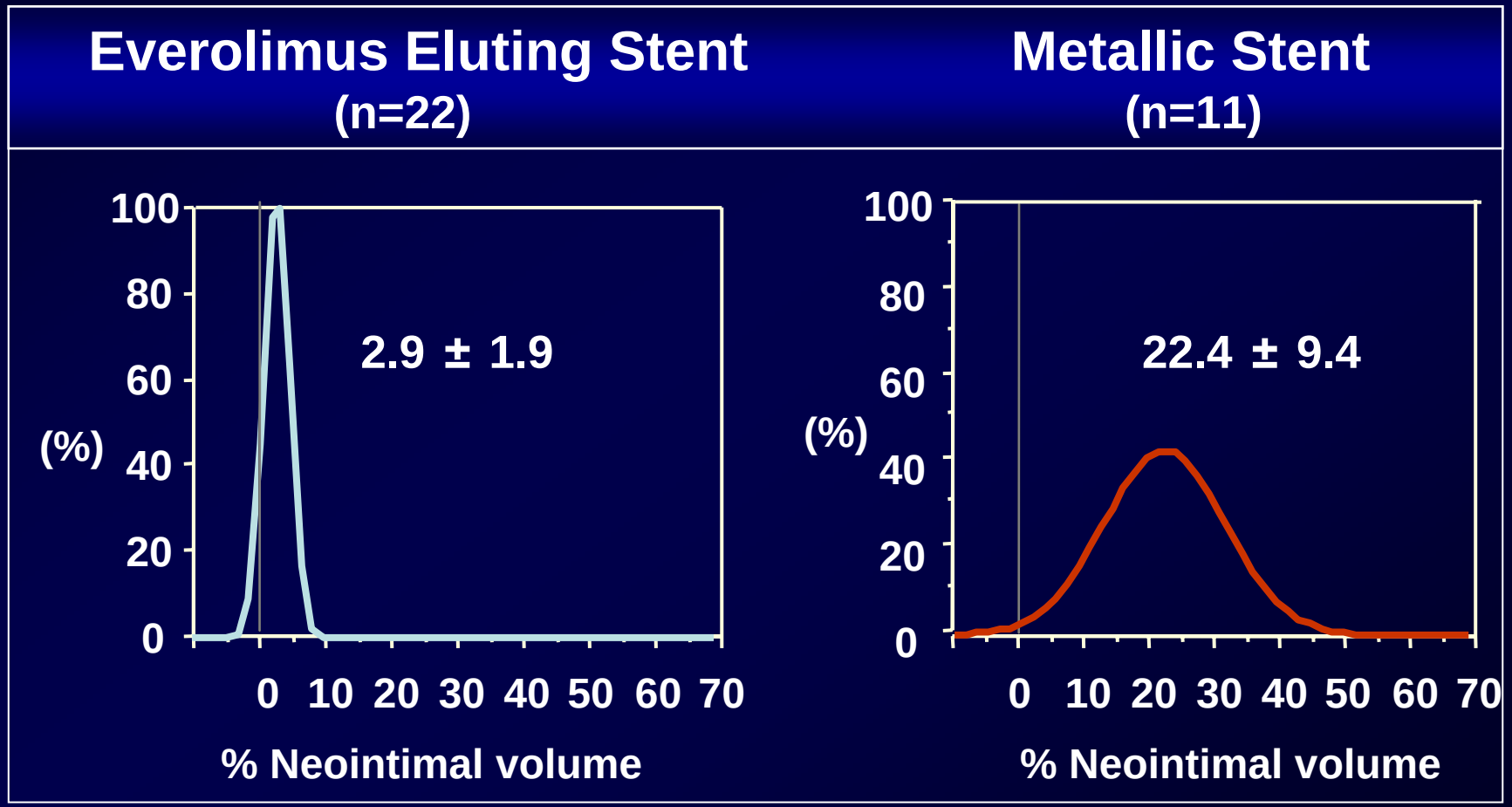
FUTURE I
IVUS 6 Month Follow-Up

- **Distribution of % Neointimal Volume**



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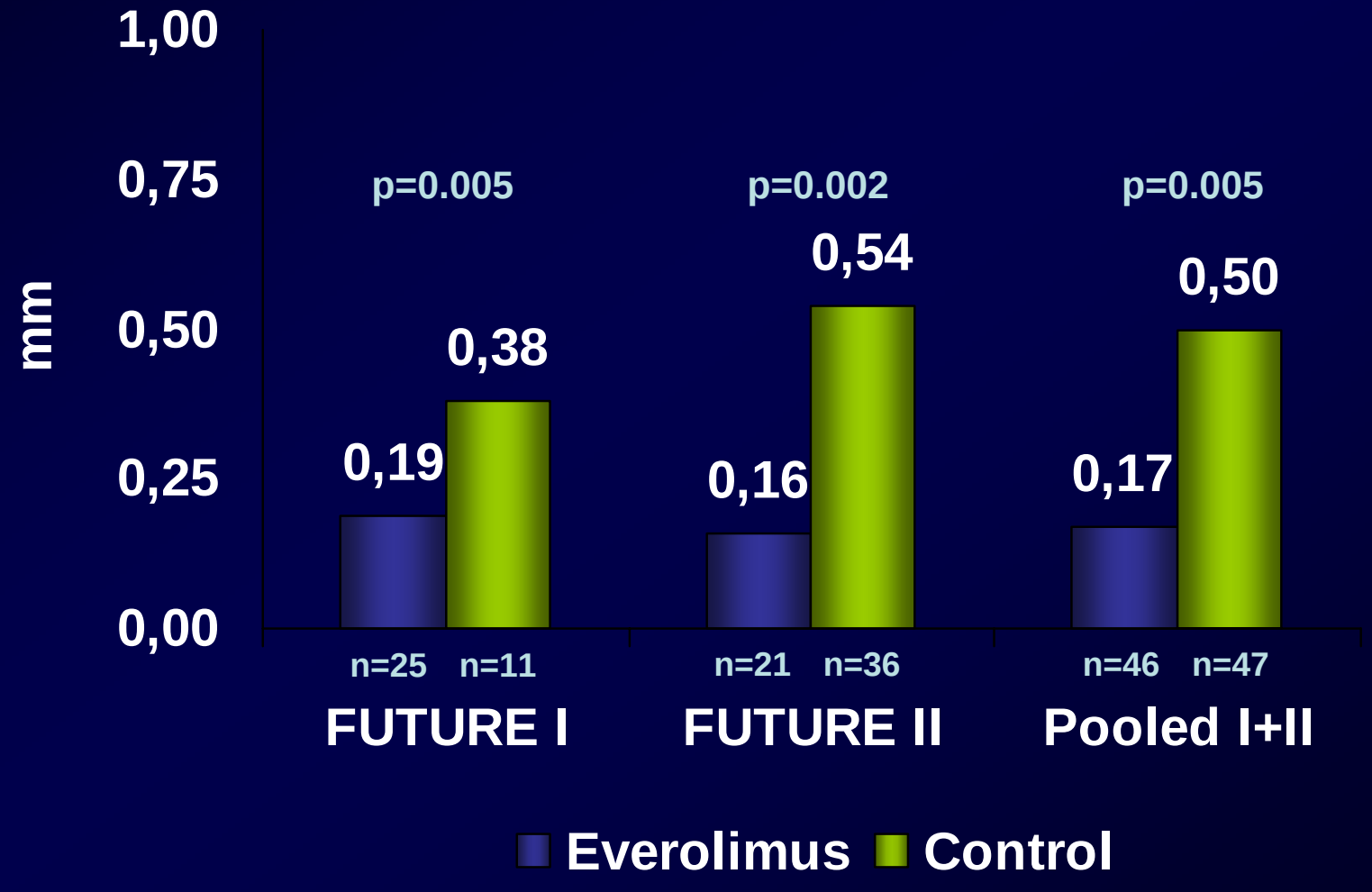
FUTURE I and FUTURE II
In-segment Late Loss at 6MFU



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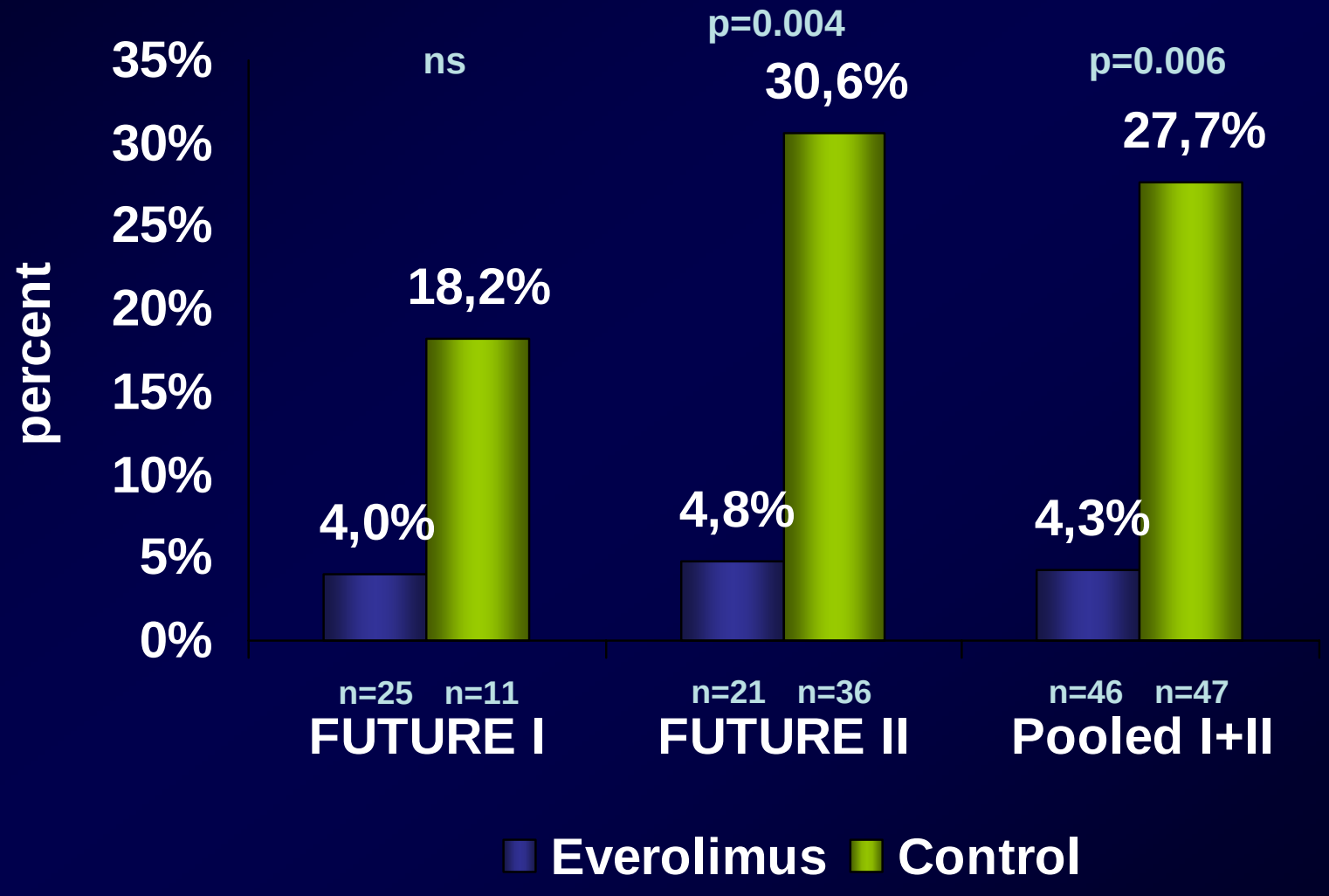
FUTURE I & FUTURE II
In-segment Binary Restenosis at 6MFU



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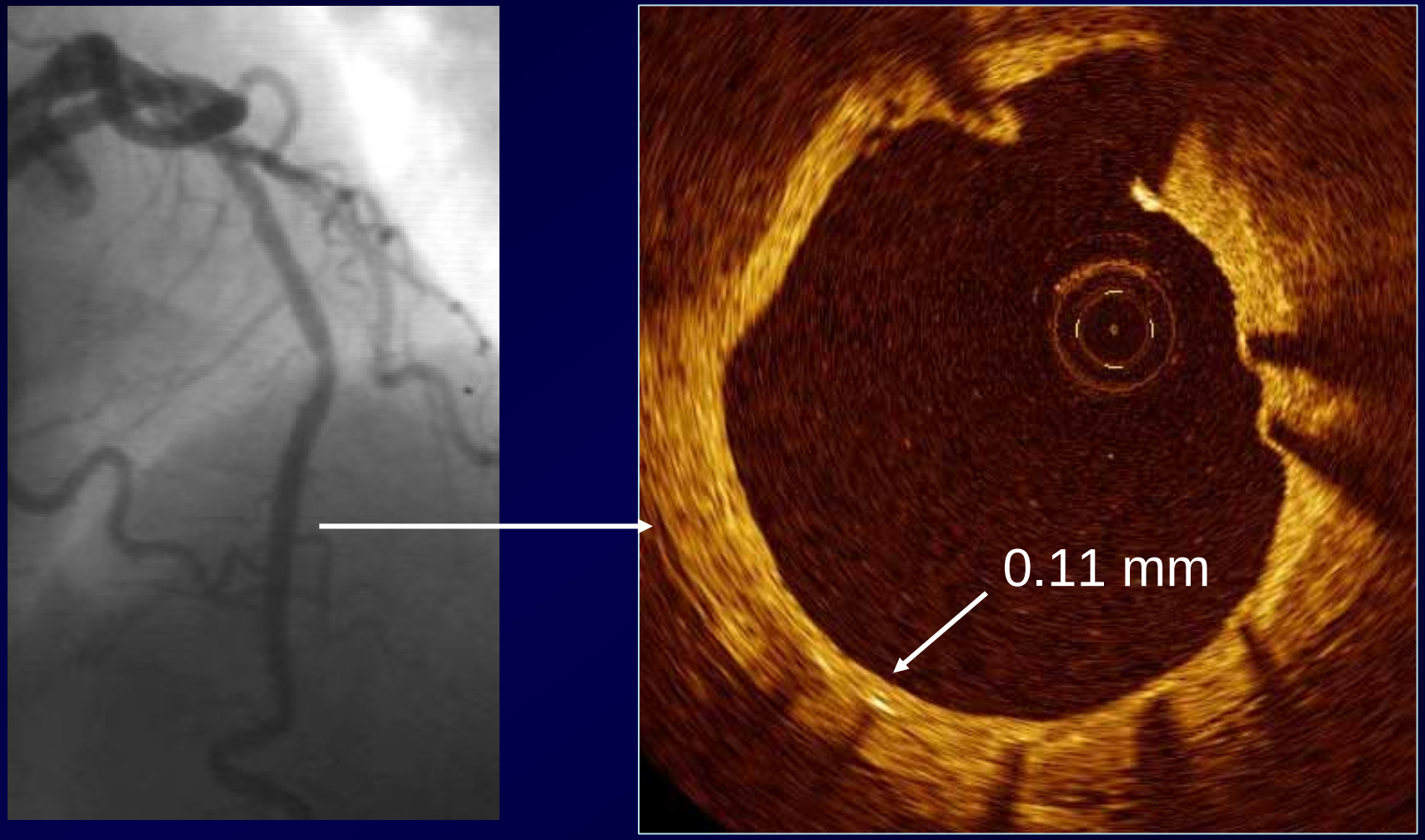
Everolimus-eluting stent



FUTURE-1 29 mths follow-up

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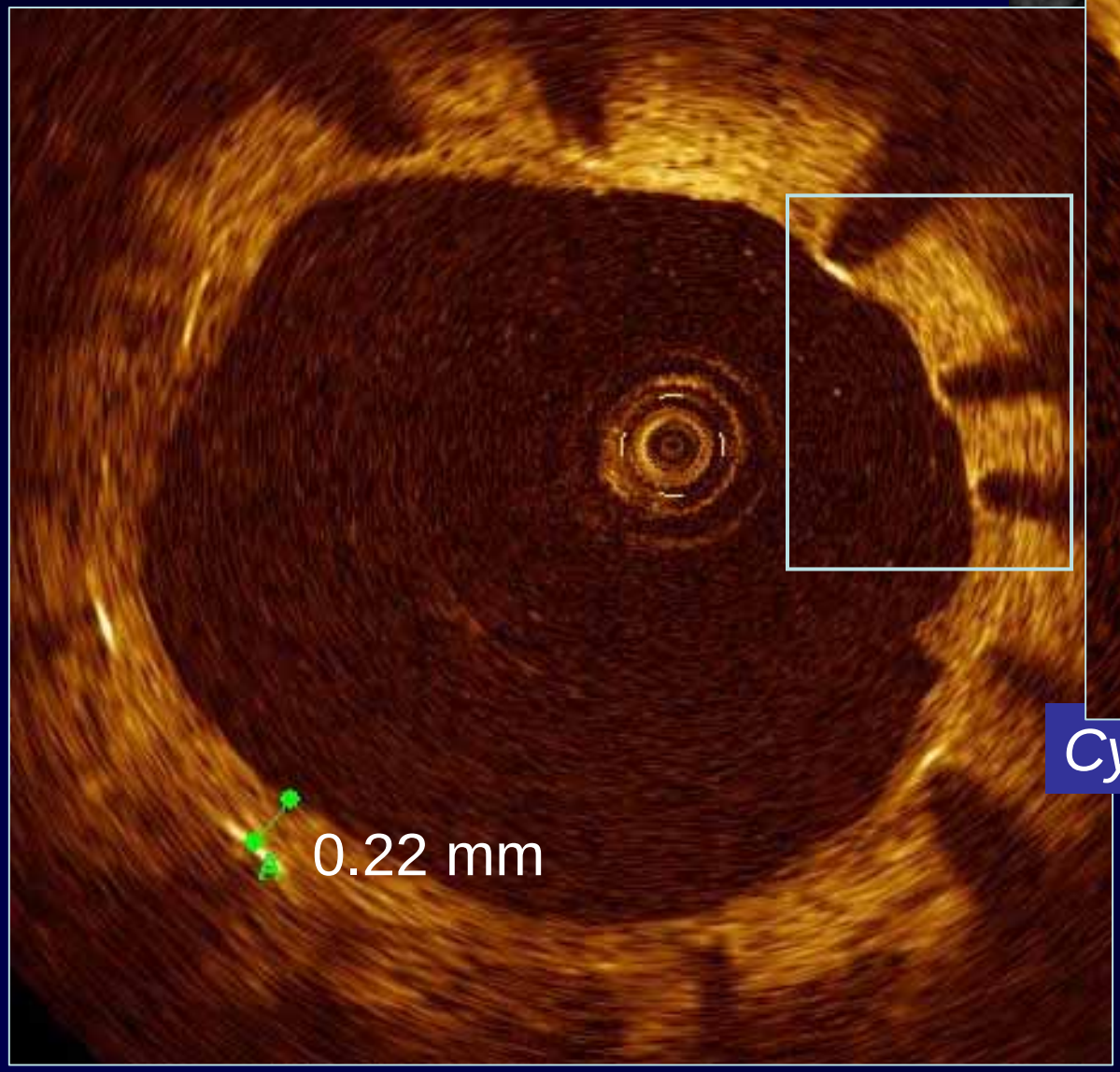
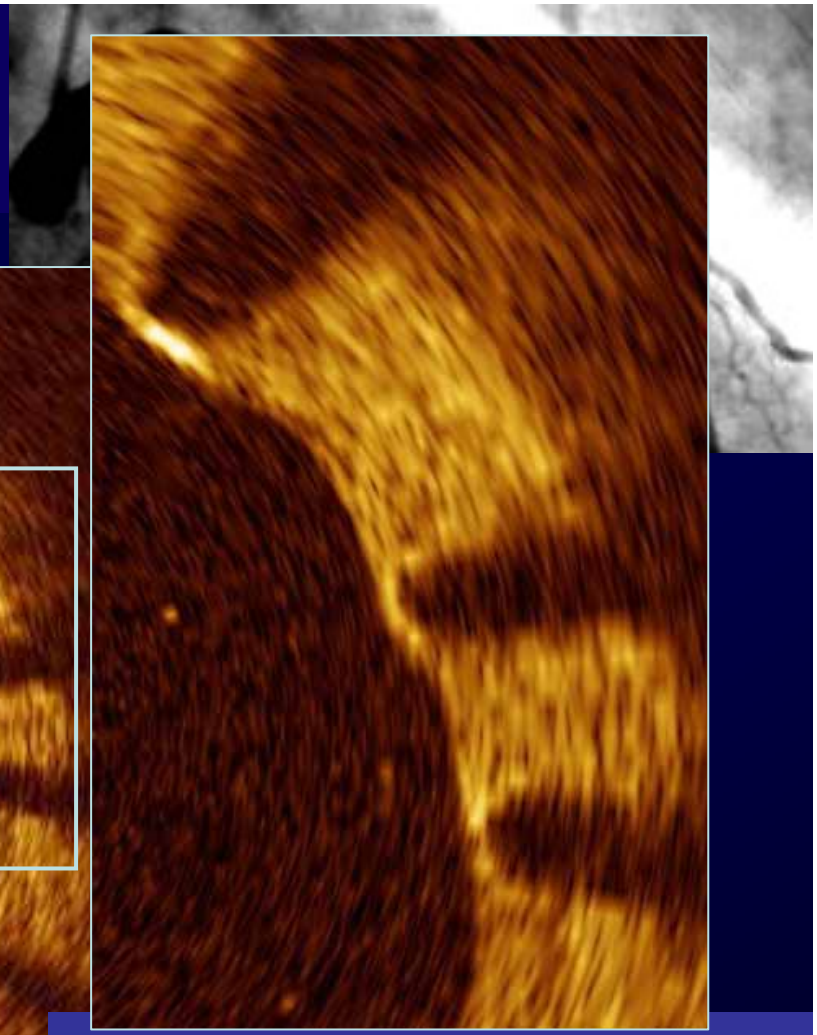
Cypher DES





Cypher 10 mths follow-up

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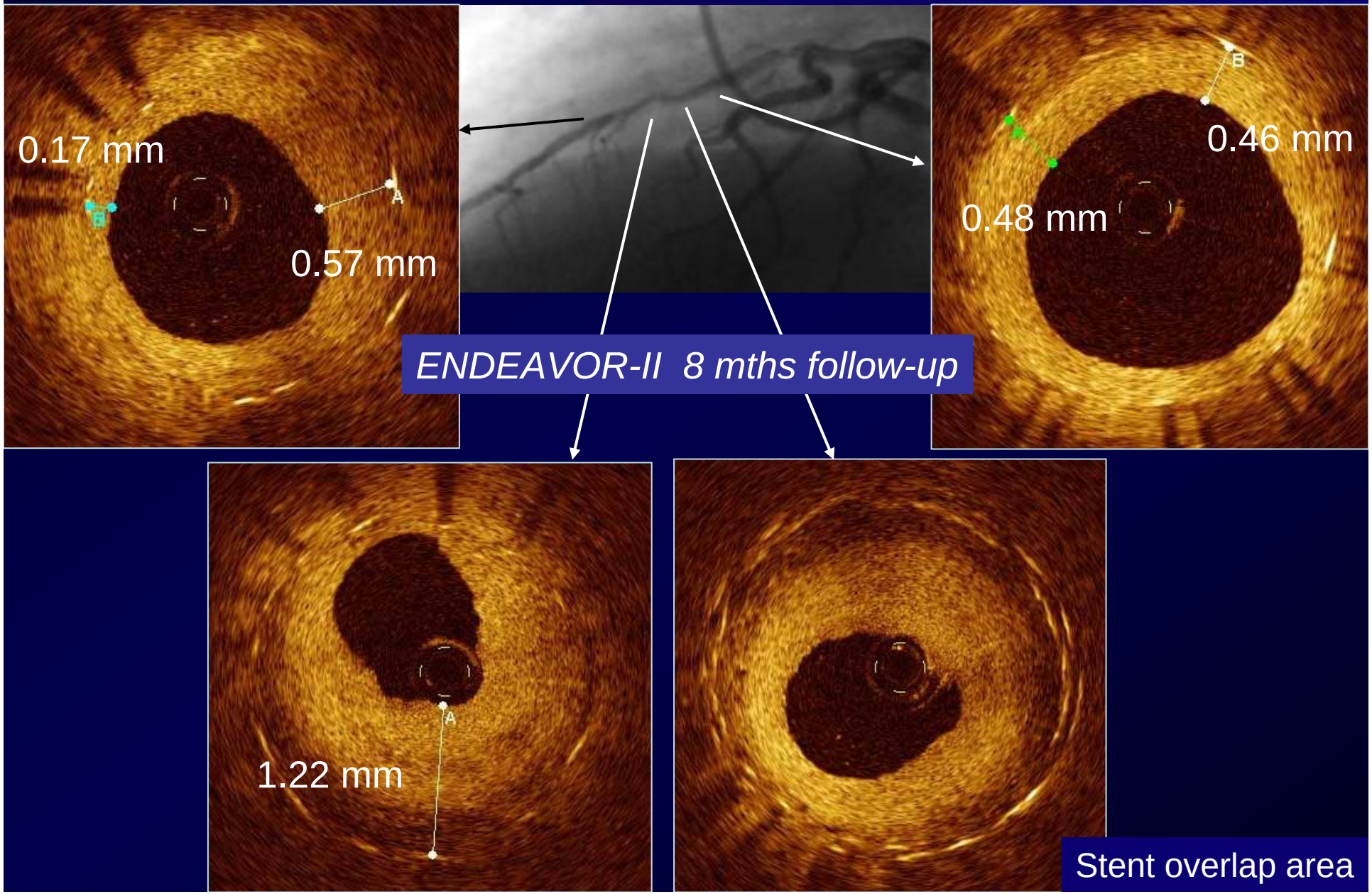
ABT-578-eluting stent



CHAMPION™ Clinical Trials

FUTURE I	FUTURE II	FUTURE III	FUTURE IV
Safety and performance	Safety and performance	Clinical support for OUS launch	Pivotal U.S.: Support PMA approval
Europe	Europe	International	U.S.A.
n = 42	n = 64	n = 800	n = 975 PI: C. Rogers

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CHAMPION™ Clinical Trials

FUTURE I	FUTURE II	FUTURE III	FUTURE IV
Safety and performance	Safety and performance	Clinical support for OUS launch	
Europe	Europe	International	
n = 42	n = 64	n = 800 PI: E. Grube	

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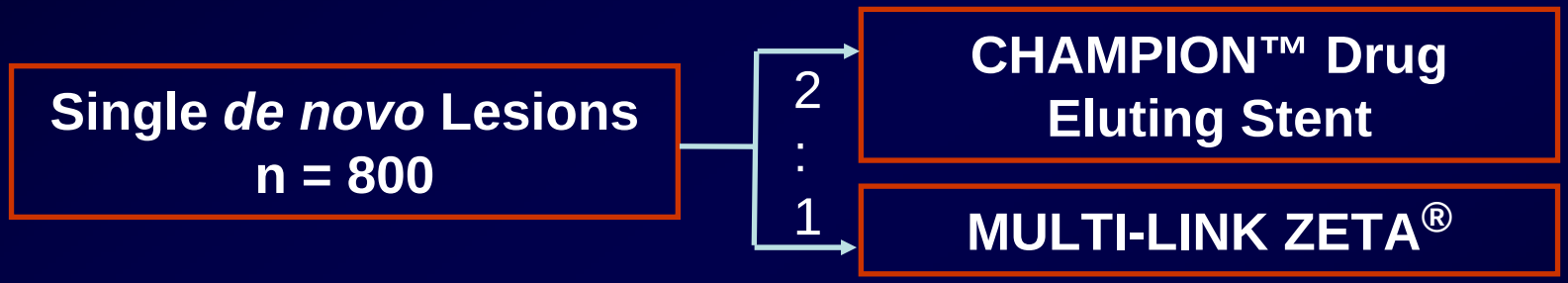
FUTURE III Study Design

FUTURE III



- Prospective, randomized 2:1, multi-center, single-blind, superiority trial
- International: up to 80 study sites
- Stent sizes: 2.5 – 4.0 mm diameter, 8 - 28 mm lengths
- Primary endpoint: In-stent late loss at 4/6 months
- Clinical follow-up at 1, 4, 6, 9, 12 months, 2 and 3 years
- Angiographic and IVUS follow up subsets at 4 & 12 and 6 & 12 months

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CHAMPION™ Clinical Trials

FUTURE I	FUTURE II	FUTURE III	FUTURE IV
Safety and performance	Safety and performance	Clinical support for OUS launch	**Pivotal U.S.: Support FDA approval**
Europe	Europe	International	**U.S.A.**
n = 42	n = 64	n = 800	**n = 975** **PI: C. Rogers**

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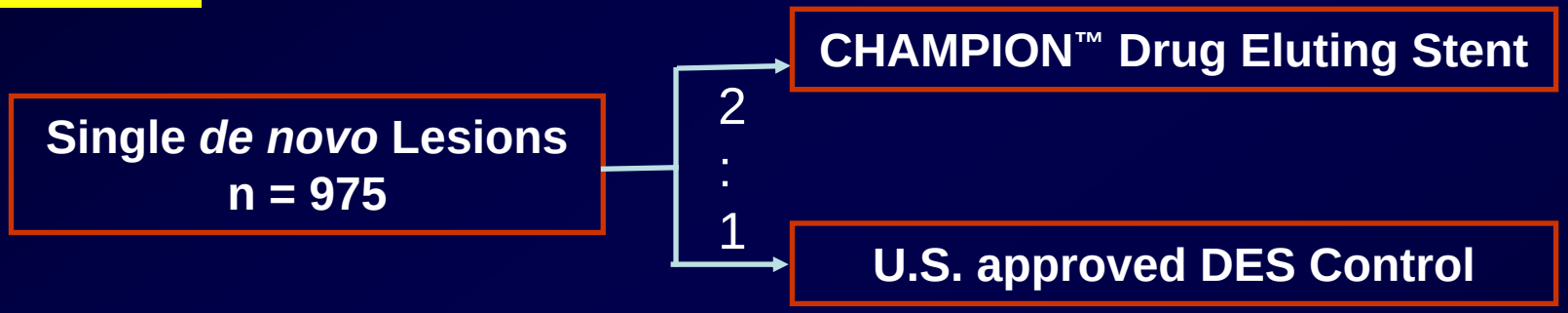
FUTURE IV Study Design

FUTURE IV



- **Prospective, randomized 2:1, multi-center, single blind, non-inferiority, 975 patients**
  - Stent Sizes: 2.5 – 3.5 mm diameter, 8 – 28 mm lengths
- **4.0 mm non-randomized arm: 105 patients**
  - Stent Sizes: 8 – 28 mm length
- **Up to 70 study sites**
- **Primary endpoint: Angiographic in-segment late loss at 8 months**
- **Secondary endpoint: Clinically-driven target vessel failure at 9 months**
- **Clinical follow-up at 1, 8, 9, 12 months and 2, 3, 4, 5 years**
- **Angiographic and IVUS subsets at 8 months**

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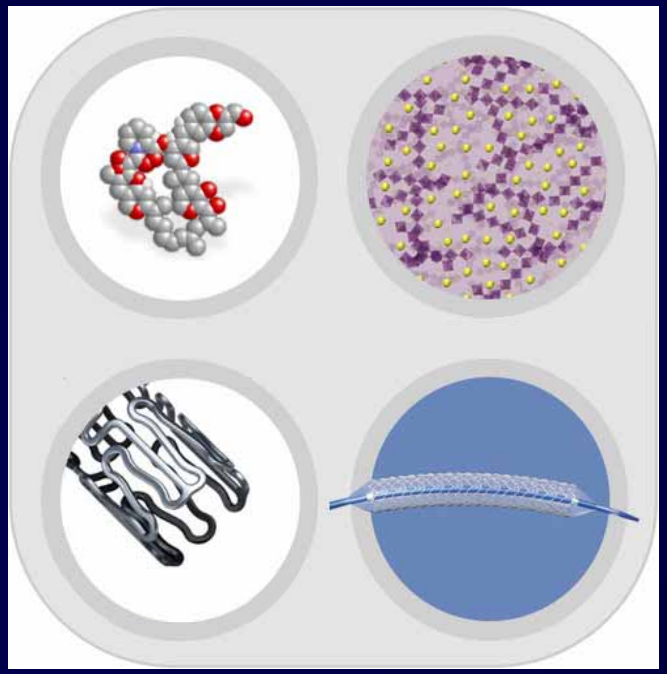
ML VISION® DES

Everolimus Eluting Coronary Stent System

Everolimus

ML VISION®
Platform



Durable Polymer

ML VISION®
Stent Delivery
System

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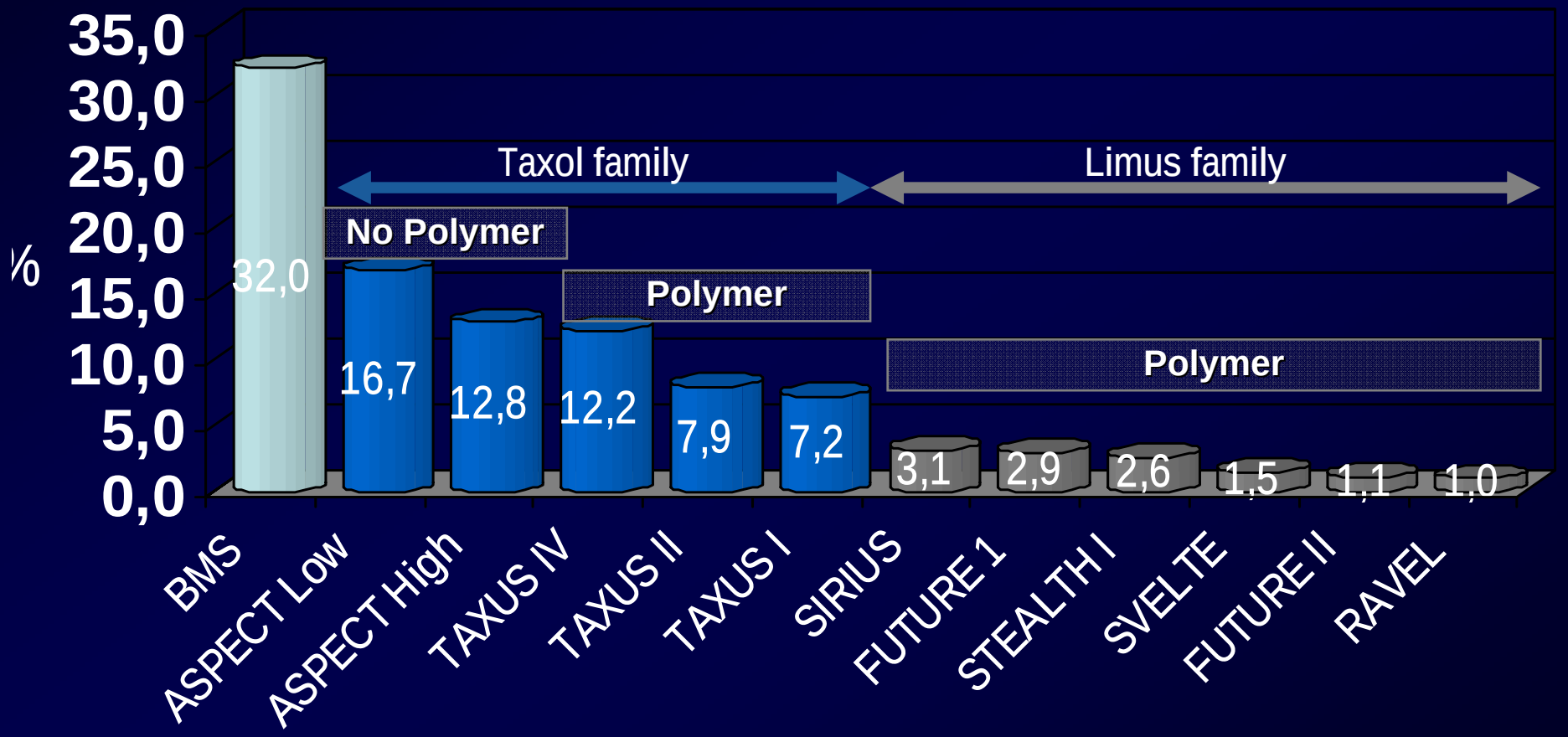
STEALTH
Comparison of Neointimal Volume



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Conclusions

- Studies on everolimus eluting stent systems demonstrate safety and efficacy of these stent concepts
- Larger randomized trials are ongoing for stent approval