Breakfast Program: Welcome to the Future of BRS Technologies

The Amaranth BRS Technology: Design, Advantages, Experimental Data and Future Directions

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Disclosure Statement of Financial Interest

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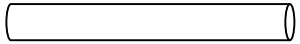
Grant/Research Support: Abbott Vascular, Amaranth Medical, Amber Medical, Amgen, Baylis, BIO2 Medical, Bristol-Myers, Boston Scientific, Cagent Vascular, Caliber Therapeutics, Cephea, Columbia Medical, Corindus Vascular, Celyad, Freudenberg Medical, Intact Vascular, JenaValve, Keystone Heart, LimFlow Medical, LoneStar Heart, Marvel Medical, Medtronic, Meril Life Sciences, MicroVention, Motus GI, Navigate Cardiac Structures, New York University, OrbusNeich Medical, SoundBite Medical, Spectranetics, Toray Industries, Vetex Medical, Volcano (Philips), Zimmer Biomet

Medical Advisor: Amarant Medical

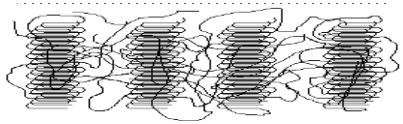
Description of Amaranth's Polymer Technology

Typical PLLA Resin

Tube Extrusion

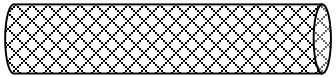


Bi-Axial Orientation
Leading To Crystallinity

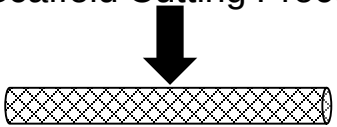


Mechanical
Strength Achieved

Highly-Crystalline Tube



Scaffold Cutting Process

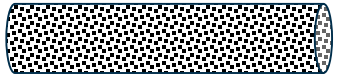


Final Scaffold Product

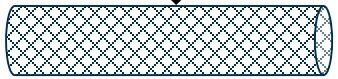
Ultra-High MW PLLA Resin

Solution Casting

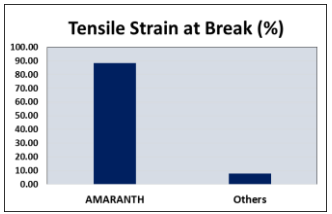
Mechanical
Strength Achieved



Highly Amorphous Tube

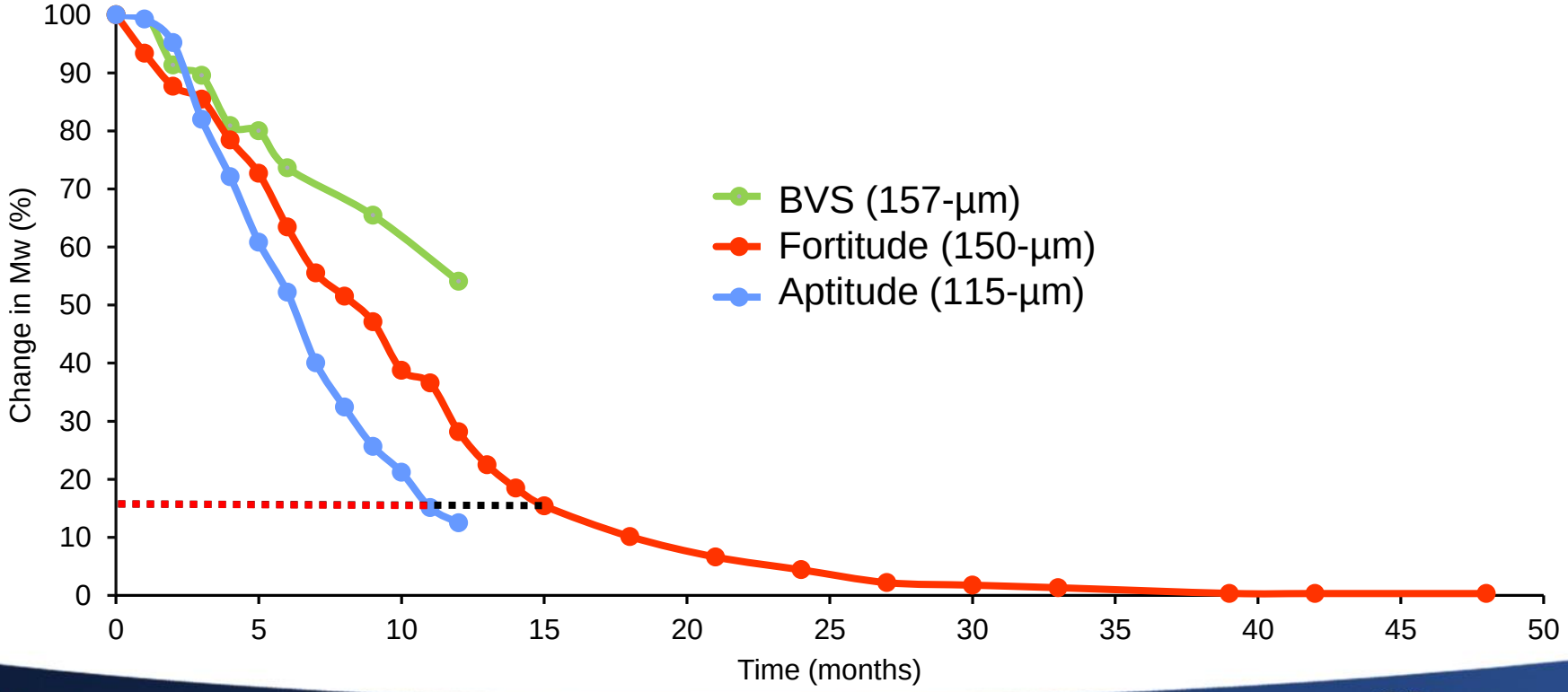


Scaffold Cutting Process

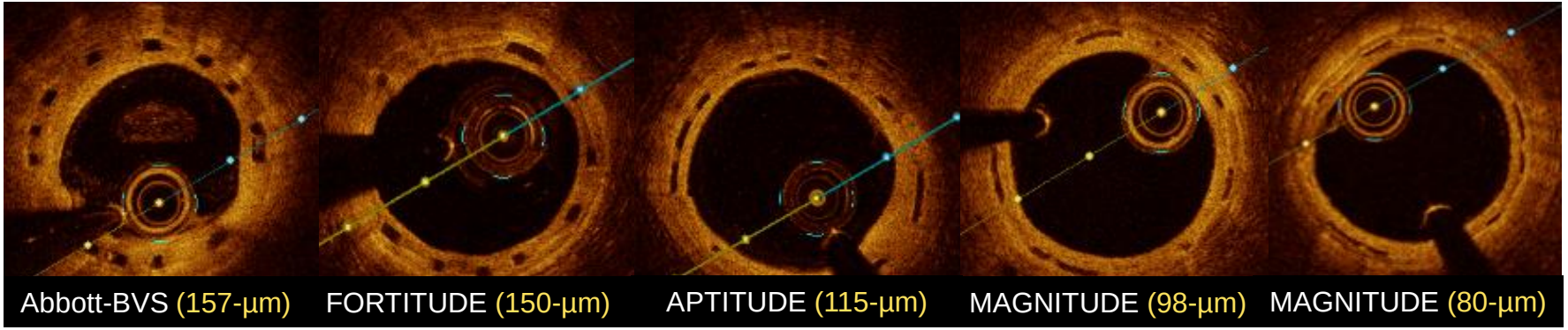


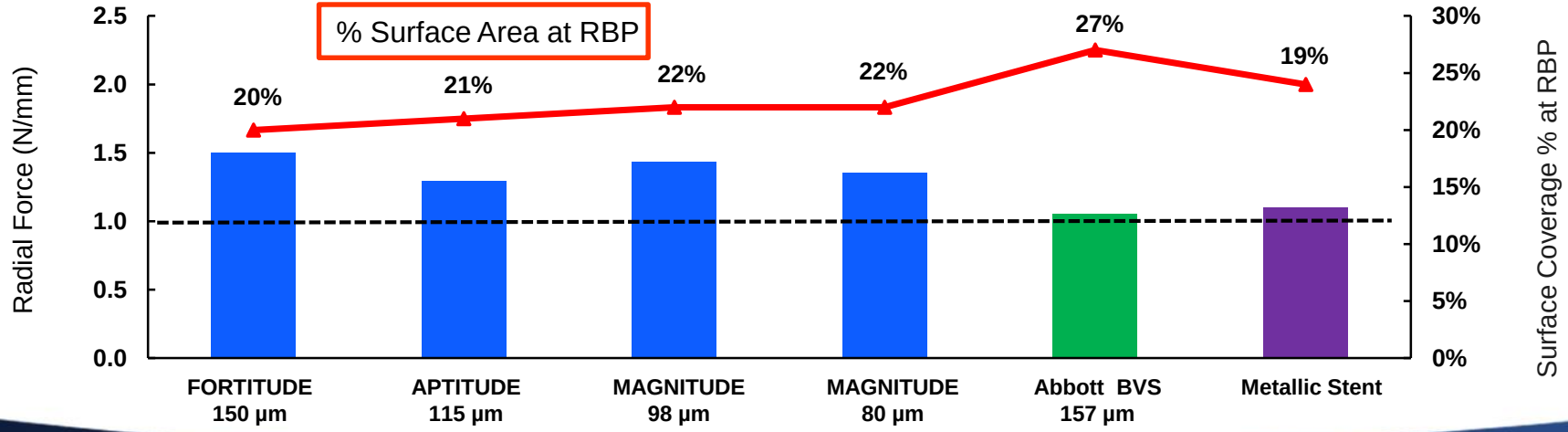
Final Scaffold Product

Impact of Strut Thickness on MW Loss and Polymer Resorption: In Vitro Polymer Degradation



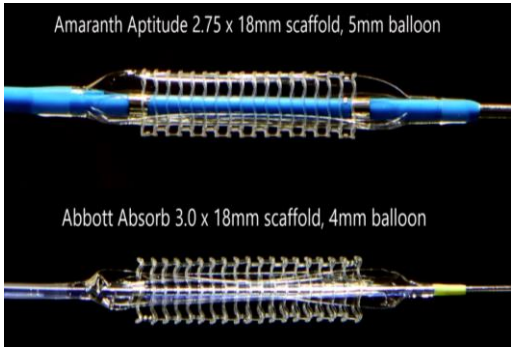
Step-Wise Reduction of Strut Thickness

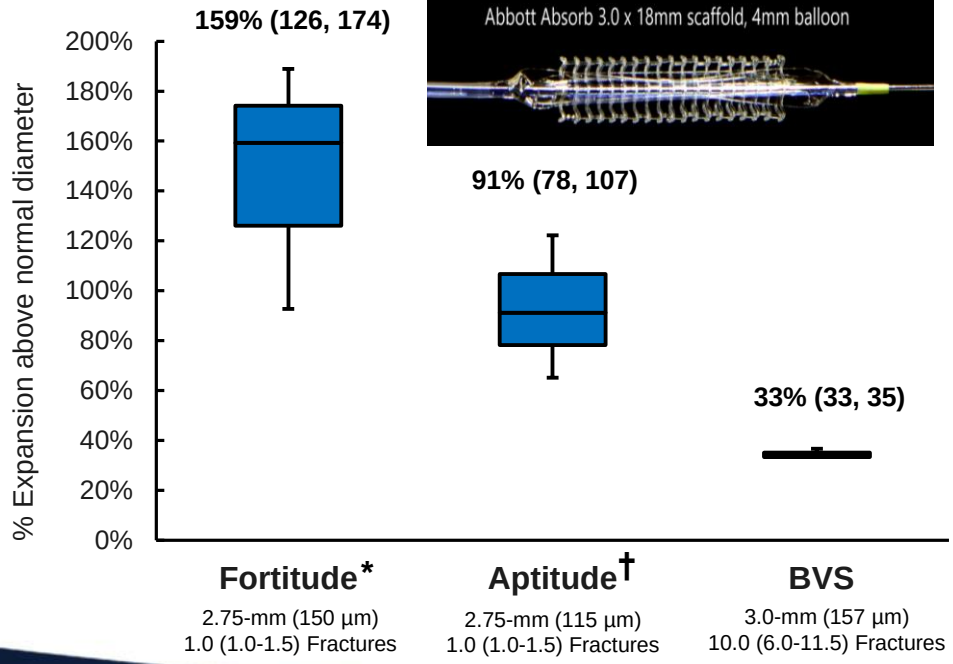


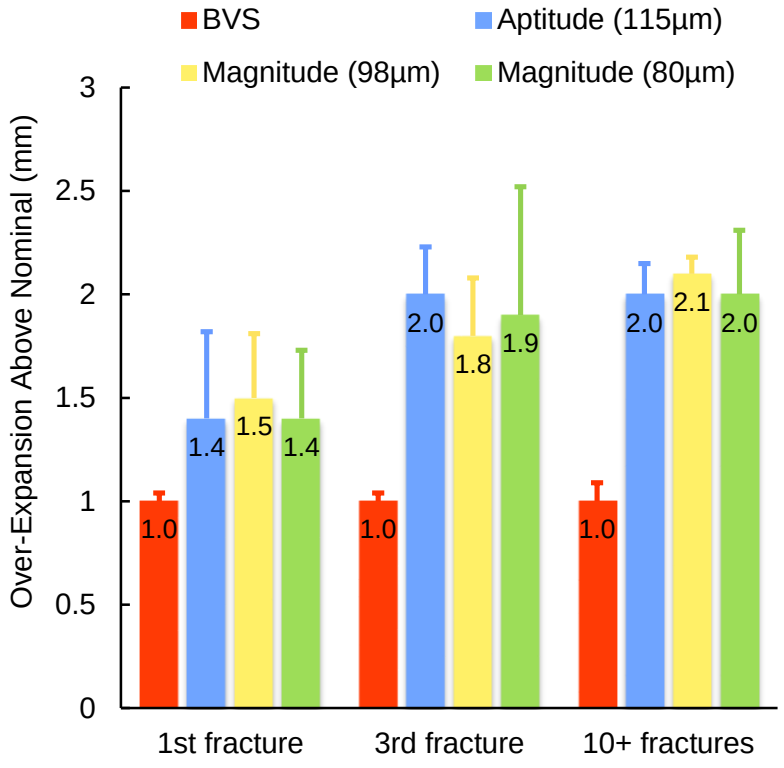


Data on file (Amaranth Medical)

Fracture Resistance Following Over-Expansion

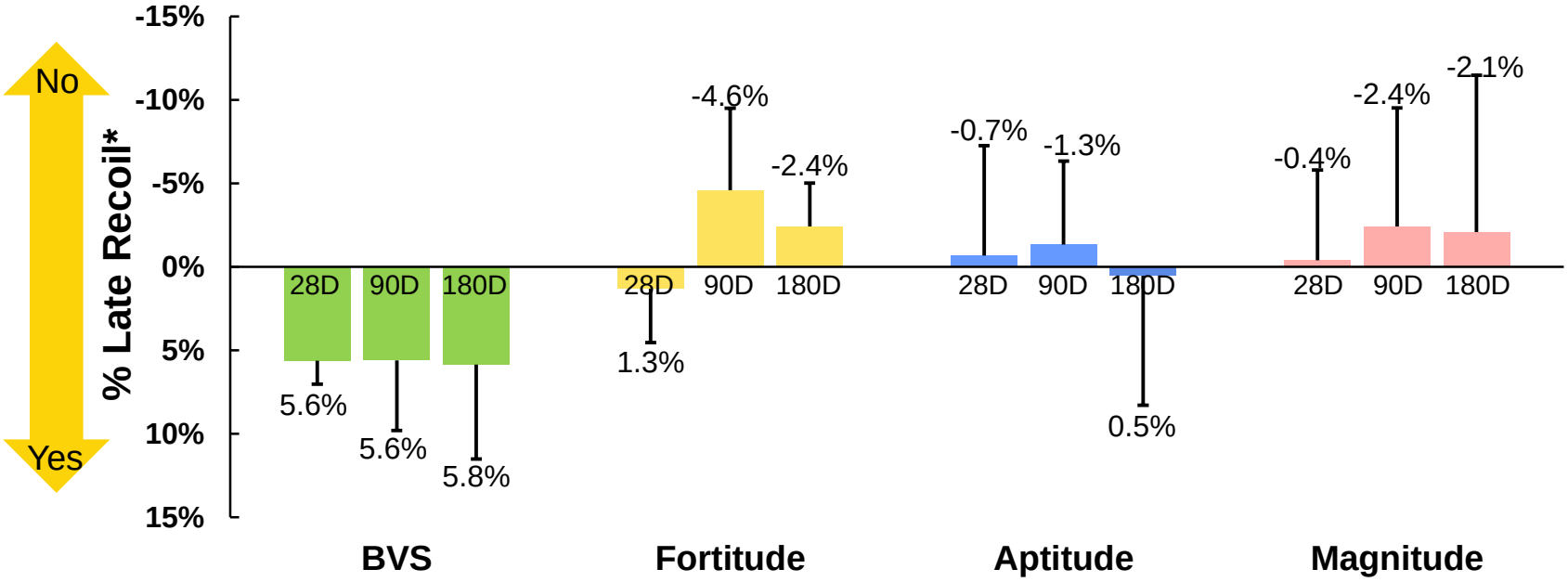






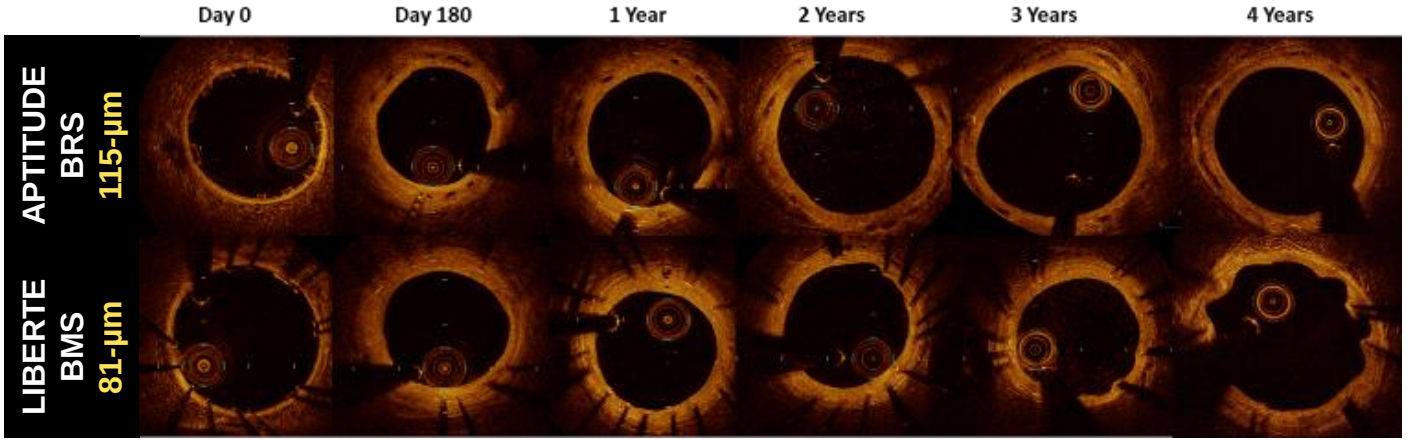
* Cheng Y. Circ Cardiovasc Interv. 2016 Oct;9(10). †Cheng Y. Circ Cardiovasc Interv. 2017 Jul;10(7)

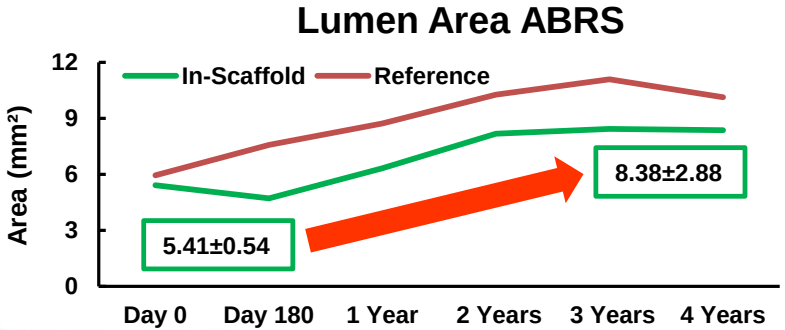
Percentage of Late In-Vivo Recoil in Swine Arteries: OCT Analysis of BVS vs. Amaranth up to 180-Days

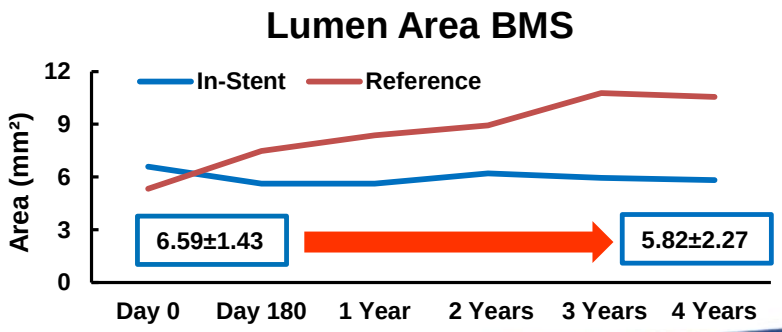


**Percentage late recoil was calculated as [(Post-implant mean scaffold area - mean scaffold area at follow-up)/post-implant mean scaffold area]×100*

Vessel Healing and Remodeling at 4 Years by OCT BRS APTITUDE (115-µm) in Normal Swine Arteries

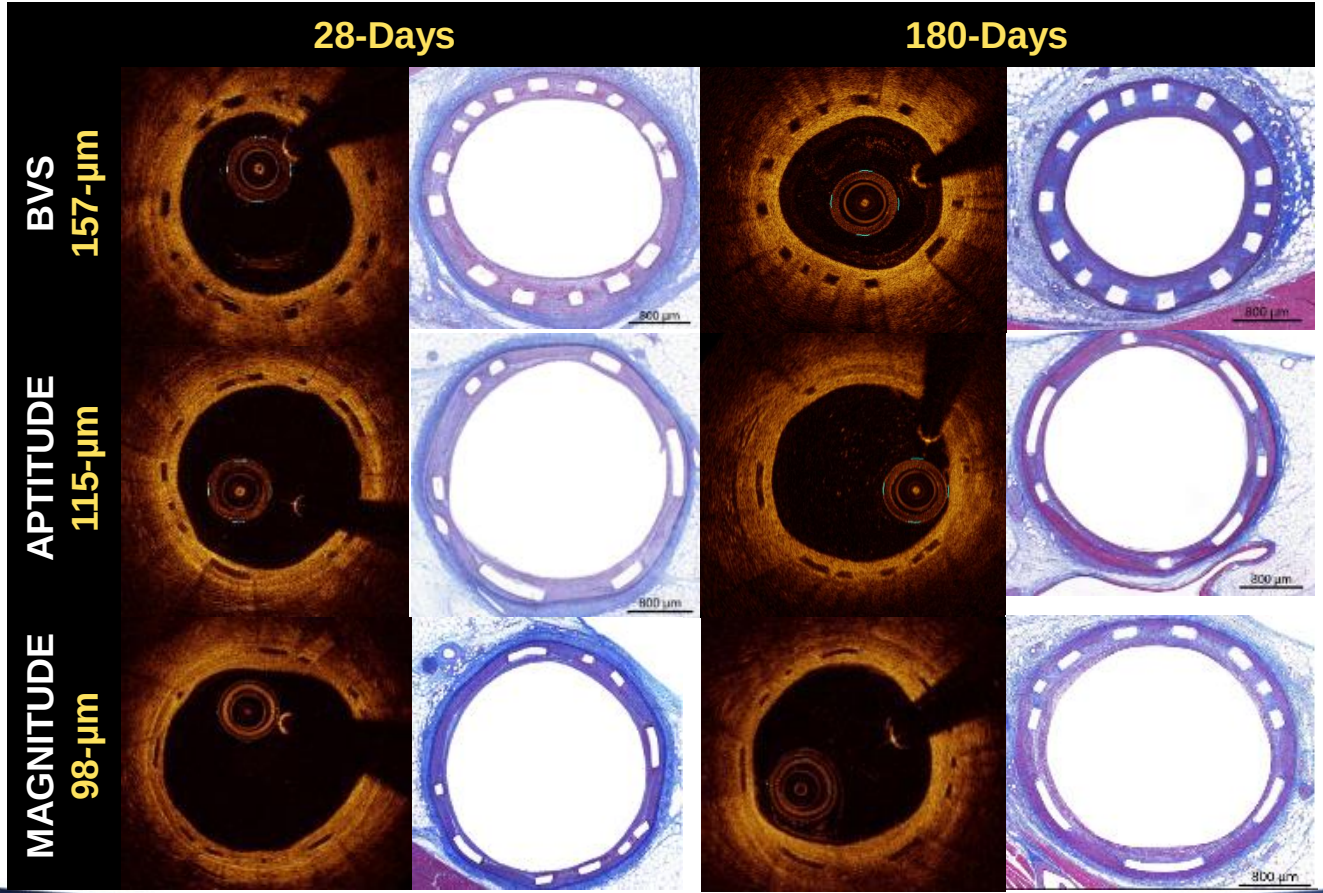






Slide Courtesy of Cheng YP. Skirball Center for Innovation

Vessel Healing at 180-Days Sirolimus Eluting Amaranth BRS



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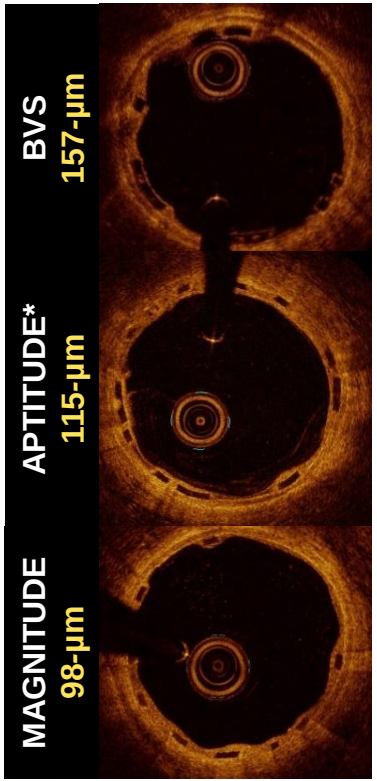
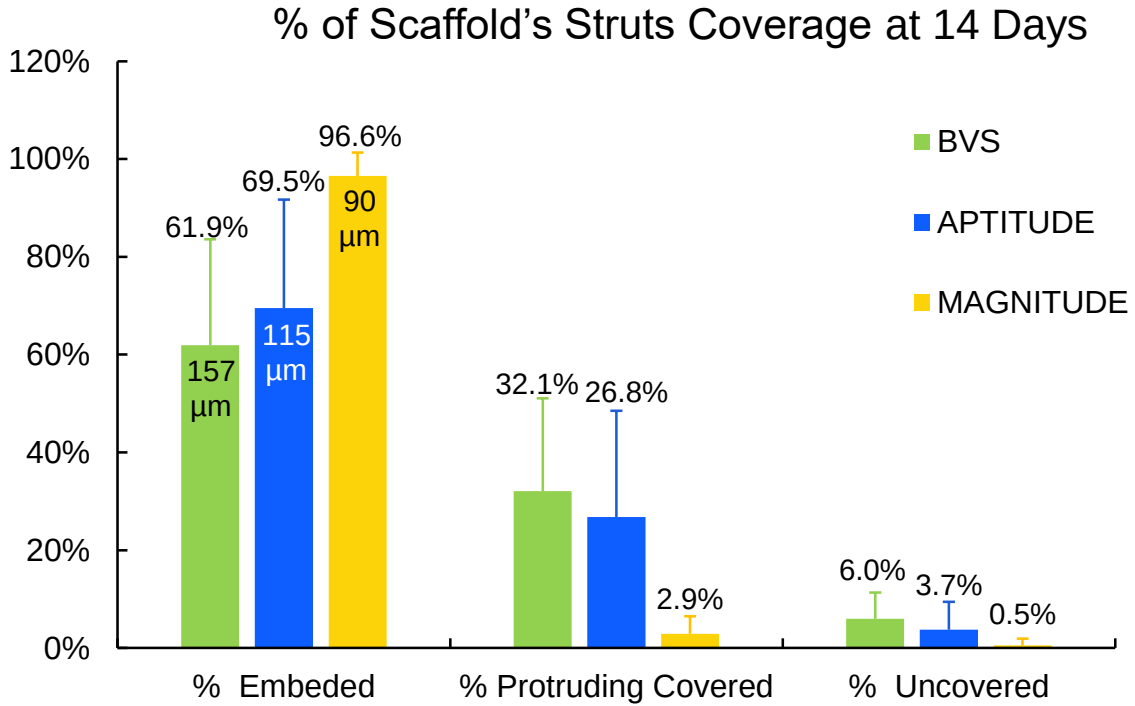
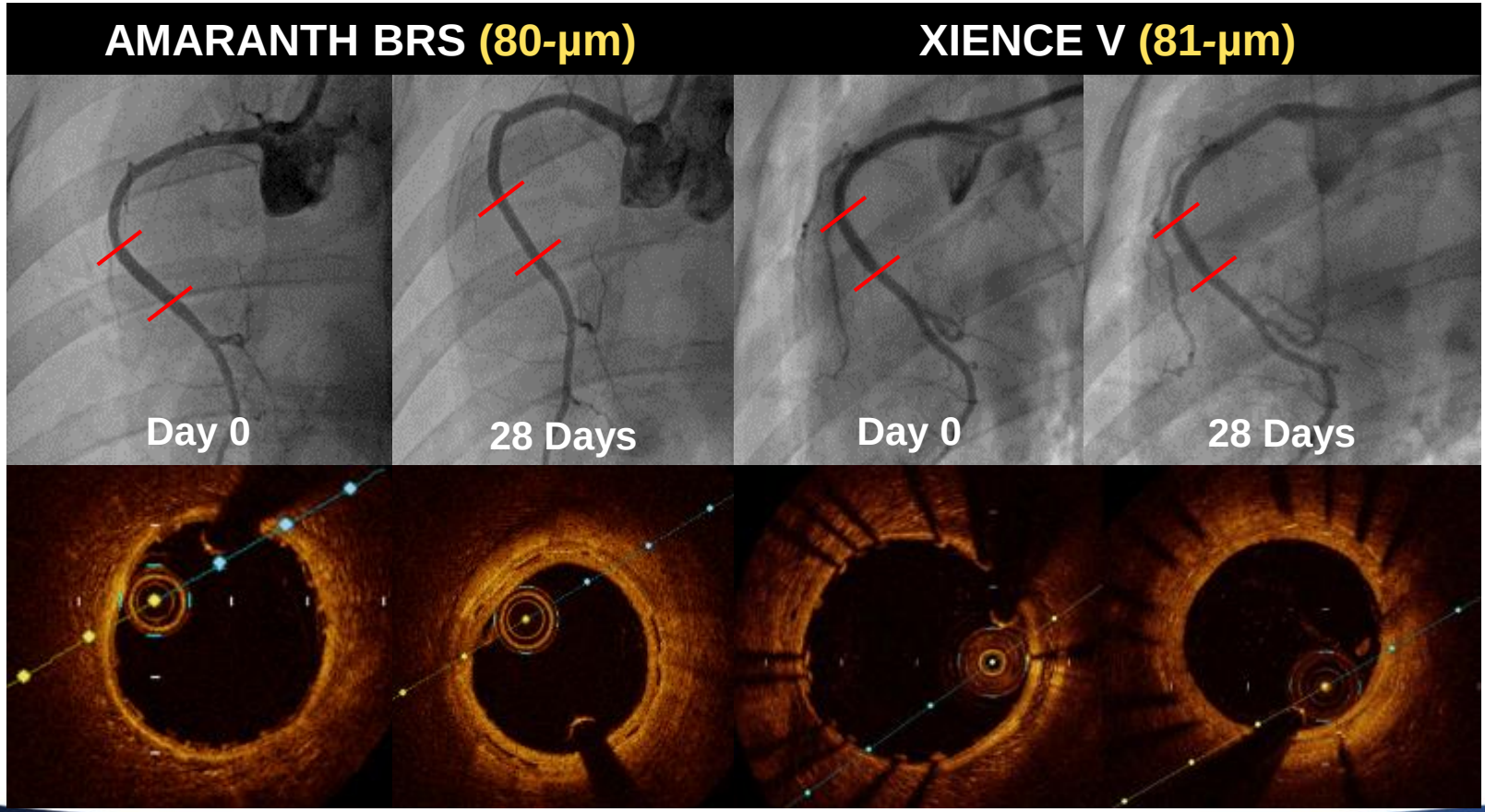
Impact of Strut Thickness on Strut Coverage 14-Day OCT Analysis In Normal Swine Arteries





* Cheng Y. Circ Cardiovasc Interv. 2017 Jul;10(7)

Next Generation Amaranth BRS (80-µm)



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Amaranth's BRS: Summary of Clinical Program

Status Update (n = 206)

STUDY NAME	DEVICE TYPE	ENROLLMENT STATUS	# PATIENTS ENROLLED	ANGIO-OCT FOLLOW UP	LATEST FOLLOW UP
MEND I	FORTITUDE 150-µm BARE	Completed	13	2-Years Completed	4-Years Completed
FORTITUDE (Colombia)	FORTITUDE 150-µm SES	Completed	42	2-Years Completed	>2-Year Ongoing
FORTITUDE (Italy)	FORTITUDE 150-µm SES	Completed	21	2-Years Completed	>2-Year Ongoing
RENASCENT II[#]	APTITUDE 115-µm SES	Completed	60	9-Months Completed	2-Year Ongoing
RENASCENT III Up to 2 Lesions	MAGNITUDE 98-µm SES	Completed	70	9-Months Ongoing	>9-Months Ongoing

* Colombo A. First Report Investigation, TCT 2016

[#] Colombo A. Late Breaking Clinical Trial, PCR 2017

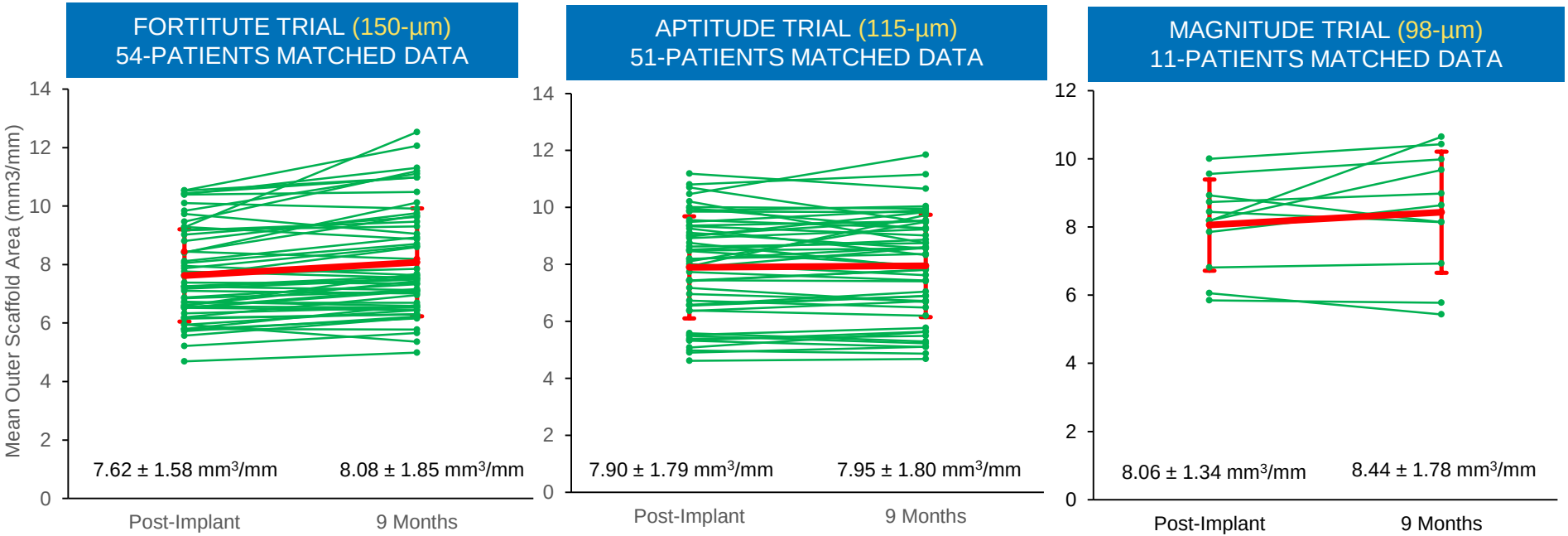
Summary of Clinical Program: Procedural Features

Index Procedure Characteristics (QCA)	FORTITUDE® 150-µm Mean ± SD or % (n) (n= 63)	APTITUDE® 115-µm Mean ± SD or % (n) (n= 60)	MAGNITUDE® 98-µm Mean ± SD or % (n) (n= 57)
Reference Vessel Diameter (mm)	2.9 ± 0.5	2.8 ± 0.4	2.8 ± 0.3
QCA Diameter Stenosis (%)	60.1 ± 10.1	63.2 ± 10.8	59.7 ± 8.6
QCA Length (mm)	12.5 ± 3.0	12.4 ± 3.6	11.7 ± 3.4
ACC/AHA Lesion Class Type B1-C	56 (88.9%)	50 (83.3%)	47 (79.7%)
Pre-Dilatation Prior to Implant	63 (100%)	60 (100%)	57 (100%)
Post-Dilatation using NC Balloon	22 (35%)	46 (76.7%)	13/58 (22%)
Clinical Device Success[1]	62 (98.4%)	59 (98.3%)	(59/61 Lesions) 96.7%
Clinical Procedure Success[2]	61 (96.8%)	60 (100%)	(55/58 Patients) 94.8%

[1] Defined as successful delivery and deployment of the scaffold at the intended target lesion with final residual stenosis of <50% of the target lesion by QCA after the index procedure

[2] Defined as clinical device success with any adjunctive device without the occurrence of major adverse clinical events related to ischemia up to day of discharge

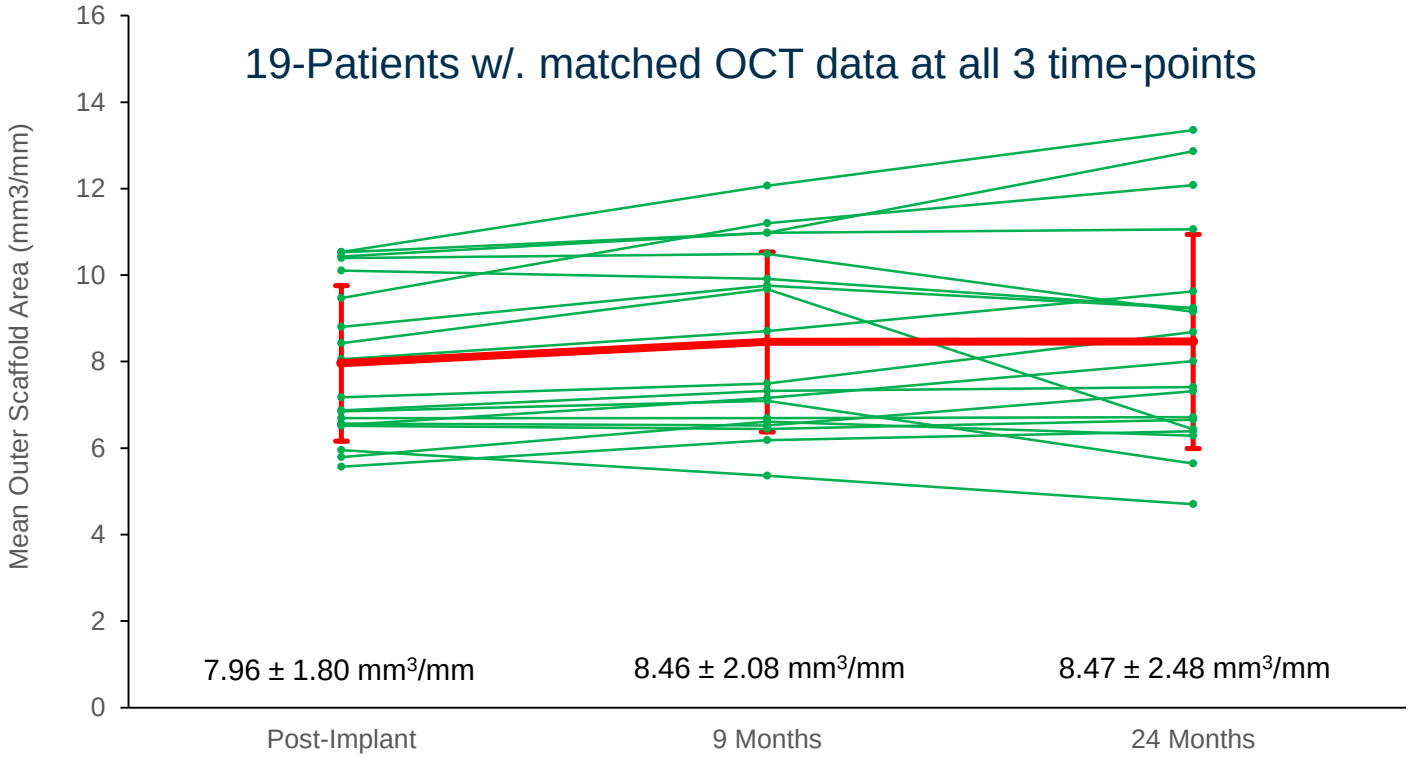
Scaffold Integrity at 9-Months: Mean Outer Scaffold Area By OCT in All Amaranth Trials



Summary of Clinical Program: 9-Month OCT Analysis

	FORTITUDE TRIAL 150-µm Mean ± SD		APTITUDE TRIAL 115-µm Mean ± SD		MAGNITUDE TRIAL 98-µm Mean ± SD	
OCT Measurements Mean ± SD (n)	Post-BRS Implantation (n = 55)	9-Month Follow-Up (n = 61)	Post-BRS Implantation (n = 53)	9-Month Follow-Up (n = 58)	Post-BRS Implantation (n= 11)	9-Month Follow-Up (n= 11)
Mean Lumen Area (mm^3/mm)	7.0 ± 1.6	6.3 ± 1.9	7.0 ± 1.6	5.9 ± 1.6	7.3 ± 1.2	6.8 ± 1.7
Mean Outer Scaffold Area (mm^3/mm)	7.6 ± 1.5	8.0 ± 1.8	7.8 ± 1.8	7.8 ± 1.7	8.0 ± 1.3	8.4 ± 1.7
Percent NIH Volume (%)	N/A	9.1 ± 7.1	N/A	13.3 ± 6.1	N/A	10.3 ± 5.5
Post-Implantation Strut Fracture (%)	0%	N/A	0%	N/A	0%	N/A
OCT Volumetric Measurements Mean ± SD (n)	% Covered Struts (At 9 Months)	% Uncovered Struts (At 9 Months)	% Covered Struts (At 9 Months)	% Uncovered Struts (At 9 Months)	Percent Covered Struts (At 9 Months)	Percent Uncovered Struts (At 9 Months)
% Apposed per Patient	94.2 ± 7.0	4.0 ± 5.6	96.5 ± 5.0	2.9 ± 4.7	96.3 ± 6.2	2.9 ± 4.9
% "Malapposed" of Total Struts	0.5 ± 1.7	0.1 ± 0.7	0.03 ± 0.1	0.0 ± 0.0	0.3 ± 0.8	0.05 ± 0.1
% "Orifice of Branch" of Total Struts	0.7 ± 1.4	0.1 ± 0.2	1.5 ± 2.0	0.4 ± 0.8	0.2 ± 0.5	0.078 ± 0.2

2-Year Matched Mean In-Scaffold Outer Area by OCT Measurements FORTITUDE 150-µm Trial



Conclusions

- The clinical success of the BRS field depends on the development of <100-micron scaffolds displaying DES-like performance
- The Amaranth BRS technology has progressively miniaturized its BRS platform to ~80-microns without compromising biomechanical performance
- Experimental data has already validated the biocompatibility, mechanical behavior and healing response down to the 98-micron range
- A careful step-by-step (150 to 80-microns) clinical program is undergoing to investigate the impact of strut thickness in clinical performance
- Experimental and early human imaging data suggests that the <100-micron BRS exhibits DES-like performance in regards to angiographic restenosis and strut healing response