Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Nothing to disclose

All TCT 2017 faculty disclosures are listed online and on the app.

Amaranth's BRS: Summary of Clinical Program

Status Update (n = 206)

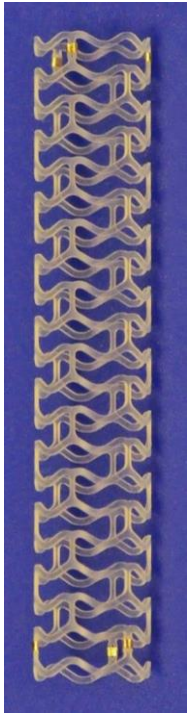
STUDY NAME	DEVICE TYPE	ENROLLMENT STATUS	# PATIENTS ENROLLED	ANGIO-OCT FOLLOW UP	LATEST FOLLOW UP
MEND I	FORTITUDE 150-µm BARE	Completed	13	2-Years Completed	4-Years Completed
FORTITUDE (Colombia)	FORTITUDE 150-µm SES	Completed	42	2-Years Completed	>2-Year Ongoing
FORTITUDE (Italy)	FORTITUDE 150-µm SES	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

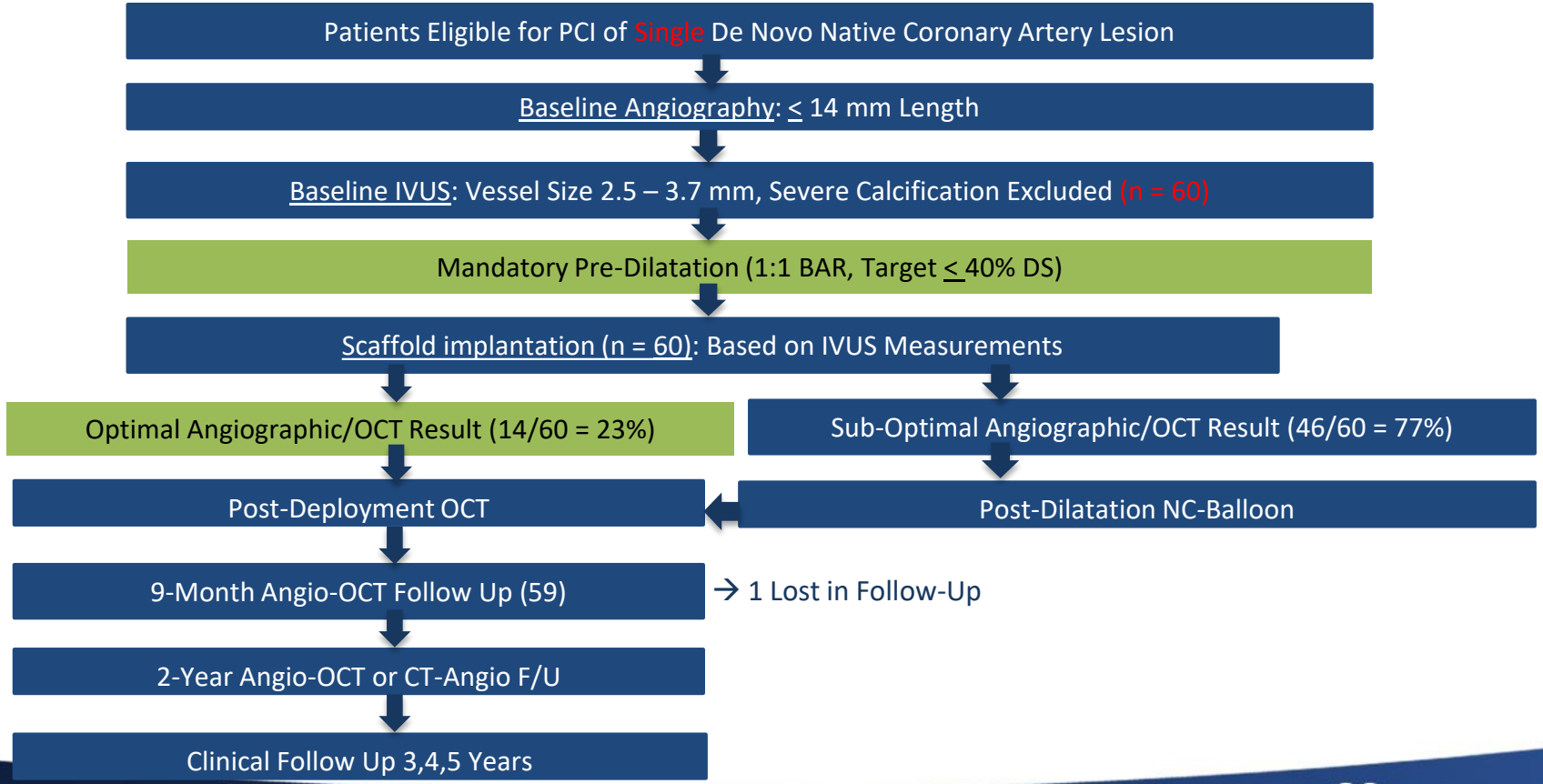
Amaranth Medical BRS Characteristics

Design Feature	APTITUDE® 115 µm BRS	MAGNITUDE® 98 µm BRS
Polymer	Ultra High MW-Poly-L-Lactide (PLLA)	
Diameters	2.5, 2.75, 3.25, and 3.5 mm	2.5, 3.0, and 3.5 mm
Lengths	13 and 18 mm	
Wall Thickness	115 µm All Scaffold Sizes	98 µm All Scaffold Sizes
Surface Coverage Area (at RBP)	22%	22%
Drug Coating	1:1 Poly D L-lactide:Sirolimus	
Drug Content	95 to 160 µg*	97 to 141 µg*
Drug Density	96 µg/cm^2	
Inflation Pressures	Nominal: 8 to 10 ATM RBP: 13 to 16 ATM	Nominal: 6 to 9 ATM RBP: 16 ATM
Guide Catheter Size	6 French Compatible	



*Depending on scaffold size

RENASCENT II Study Design (APTITUDE® BRS)



Enrollment in Italy and Colombia: Investigators (Number of Patients)

San Raffaele (12)
Antonio Colombo (PI)
Alaide Chieffo
Azeem Latib

Fatebenefratelli (7)
Bernardo Cortese
Roberto Adriano Latini
Orrego Pedro Silva

San Donato (4)
Francesco Bedogni
Federico De Marco
Francesco La Rosa

Milano

Policlinico Universitario (3)
Giuseppe Tarantini

Padova

Torino

A.O. Ordine Mauriziano Umberto I (4)
Emanuele Meliga
Tiziana C. Aranzulla

A.O.U. Federico II (7)
Eugenio Stabile
Giovanni Esposito

Napoli

Juan Granada (Colombia PI)

EMMSA Clinica Especializada (13)
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Instituto del Corazon (5)
Boris Vesga
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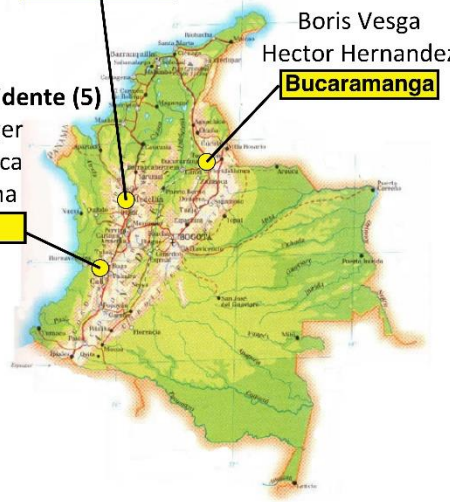
Cali



Baseline Clinical Characteristics

Baseline Characteristics	APTITUDE® BRS (n = 60) Mean ± SD or % (n)
Male	78.3% (47)
Age (Years)	65.2 ± 8.0
History of Smoking	60.0% (36)
Medically Treated Diabetes • Insulin Requiring • Non-Insulin Requiring	18.3% (11) 27.3% (3) 72.7% (8)
Medically Treated Hypertension	73.3% (44)
History of Renal Disease	1.7% (1)
Clinical Presentation • Stable Angina • Acute Coronary Syndrome • Silent Ischemia	 50.0% (30) 33.3% (20) 16.7% (10)
Previous MI	51.7% (31)
History of PCI	63.3% (38)
History of CABG	0%
LVEF	54.9% ± 8.1%

Angiographic Lesion Characteristics

Baseline Characteristics	APTITUDE® BRS (n = 60) Mean ± SD or % (n)
Target Artery • LAD • LCX • RCA	 40.0% (24) 30.0% (18) 30.0% (18)
Proximal-Mid Lesion Location	81.7% (49)
Reference Vessel Diameter (mm)	2.8 ± 0.4
RVD < 2.5 mm by QCA	21.7% (13)
QCA Diameter Stenosis	63.2% ± 10.8%
QCA Length (mm)	12.4 ± 3.6
ACC/AHA Lesion Class Type B1-C	83.3% (50)
Any Bifurcation/Side Branch	5.0% (3)
Moderate-Severe Calcification	10.0% (6)
Pre-Procedure TIMI 3 Flow	100% (60)

Device Implantation: Procedural Endpoints

Index Procedure Characteristics (QCA)	APTITUDE® BRS (n = 60) Mean ± SD or % (n)
Pre-Procedure Diameter Stenosis	63.2% ± 10.8%
Pre-Dilatation Prior to Implant	100% (60)
Post-Dilatation using NC Balloon	76.7% (46)
Max. Scaffold Deployment Inflation Pressure (ATM)	11.8 ± 2.4
Final In-Segment Diameter Stenosis	7.1% ± 6.8%
Failure to Cross Due to Severe Calcification/Tortuosity	0%
Distal Dissection Treated with DES	0%
Clinical Device Success[1]	98.3% (59)
Clinical Procedure Success[2]	100% (60)

[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.

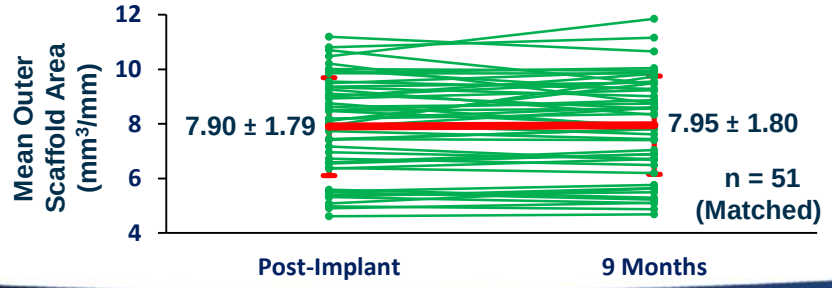
[2] Defined as clinical device success with any adjunctive device without the occurrence of major adverse clinical events related to ischemia up to day of discharge.

9-Month Angiographic Analysis

QCA Measurements Mean ± SD	Baseline Procedure (n = 60)	Post-BRS Implantation (n = 60)	9-Month Follow-Up (n = 59)	p-Value
In-Segment Analysis				
Interpolated RVD (mm)	2.8 ± 0.4	2.9 ± 0.4	2.8 ± 0.4	<.0001
MLD (mm)	1.0 ± 0.3	2.5 ± 0.4	2.3 ± 0.4	<.0001
Late Lumen Loss (mm)	---	---	0.19 ± 0.26	
Diameter Stenosis (%)	63.2 ± 10.8	13.7 ± 6.2	17.7 ± 9.2	<.0001
In-Scaffold Analysis				
Interpolated RVD (mm)	---	3.1 ± 0.4	2.9 ± 0.4	<.0001
MLD (mm)	---	2.8 ± 0.4	2.5 ± 0.4	<.0001
Acute Gain (mm)	---	1.8 ± 0.4	---	
Late Lumen Loss (mm)	---	---	0.33 ± 0.36	
Diameter Stenosis (%)	---	7.1 ± 6.8	13.4 ± 9.4	<.0001
Binary Restenosis (%)	---	---	0%	

9-Month In-Scaffold OCT Measurements

OCT Measurements Mean ± SD or %	Post-BRS Implantation (n = 53)	9-Month Follow-Up (n = 58)	Difference (Post vs. 9-Month)
Mean Lumen Area (mm^3/mm)	7.016 ± 1.690	5.983 ± 1.696	-1.033 (-14.7%)
Mean Outer Scaffold Area (mm^3/mm)	7.815 ± 1.807	7.839 ± 1.790	0.024 (0.3%)
Percent NIH Volume (%)	---	13.3 ± 6.1	---
Post-Implantation Strut Fracture (%)	0%	---	---
OCT Volumetric Measurements Mean ± SD or %	**Percent Covered Struts (At 9 Months)**	**Percent Uncovered Struts (At 9 Months)**	**Total**
Percent Apposed per Patient (%)	96.522 ± 5.017	2.971 ± 4.757	99.5%
Percent "Malapposed " of Total Struts (%)	0.037 ± 0.160	0.000 ± 0.000	0.0%
Percent "Orifice of Branch" of Total Struts (%)	0.438 ± 0.844	0.032 ± 0.139	0.5%
Total	97.0%	3.0%	100%



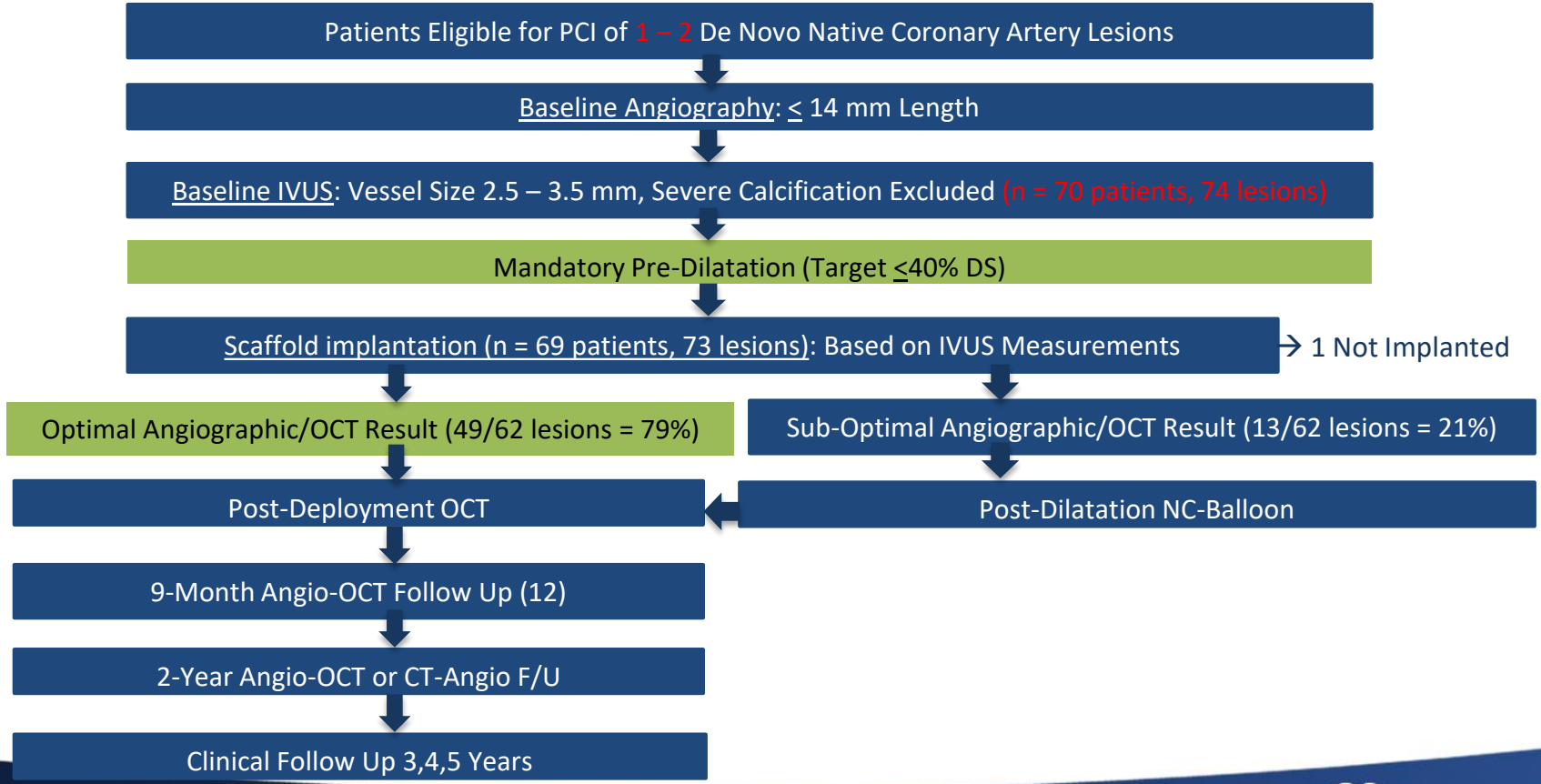
Safety End-Points Through 9 Months

Safety Endpoints % (n)	In Hospital (n = 60)	Discharge to 30 Days (n = 60)	9 Months (n = 59)
Target Vessel Failure **(Cardiac Death, TV-MI, or ID-TLR)**	0%	0%	3.4% (2)
All Death	0%	0%	0%
Cardiac Death	**0%**	**0%**	**0%**
Non-Cardiac Death	0%	0%	0%
Target Vessel MI	**0%**	**0%**	**3.4% (2)**
Q-wave MI	0%	0%	0%
Non-Q-wave MI	0%	0%	3.4% (2)
Ischemia Driven TLR	**0%**	**0%**	**0%**
PCI	0%	0%	0%
CABG	0%	0%	0%
ARC Stent Thrombosis			
Definite or Probable	0%	0%	0%
Possible	0%	0%	0%

RENASCENT II Study: Conclusions

- **The international, multi-center study of the thin walled 115 µm Amaranth APTITUDE® BRS showed:**
  - ✓ **High clinical device success rate (98.3%)**
  - ✓ **Low MACE rate (3.4%; both non-Q wave MIs related to non-TLR)**
  - ✓ **No angiographic binary restenosis or scaffold thrombosis**
  - ✓ **Scaffold stability assessed by OCT lumen area maintained at 9 months**
  - ✓ **High level of strut coverage (97.0%) and low rate of malapposition (0.037%, all covered) by OCT at 9-months**
- **The proprietary ultra-high molecular weight PLLA and unique polymer processing technology has led to a further thinning of the BRS wall. The 98-µm MAGNITUDE® BRS is currently being evaluated in the RENASCENT III study.**

RENASCENT III Study Design (MAGNITUDE® BRS)



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Jaime Fonseca
Camilo Arana

Cali

Juan Granada (Colombia PI)

Baseline Clinical Characteristics

Baseline Characteristics	MAGNITUDE® BRS (n = 57 Patients) Mean ± SD or % (n)
Male	64.9% (37)
Age (Years)	64.1 ± 10.0
History of Smoking	54.4% (31)
Medically Treated Diabetes • Insulin Requiring • Non-Insulin Requiring	14.0% (8) 12.5% (1) 87.5% (7)
Medically Treated Hypertension	56.1% (32)
History of Renal Disease	1.8% (1)
Clinical Presentation • Stable Angina • Unstable Angina • Silent Ischemia • Other Evidence of Ischemia	 18.2% (10/55) 49.1% (27/55) 16.4% (9/55) 16.4% (9/55)
Previous MI	58.2% (32/55)
History of PCI	63.6% (35/55)
History of CABG	0%
LVEF	53.2% ± 8.2% (52)

Angiographic Lesion Characteristics

Baseline Characteristics	MAGNITUDE® BRS (n = 59 Lesions) Mean ± SD or % (n)
Target Artery • LAD • LCX • RCA	 47.5% (28) 28.8% (17) 23.7% (14)
Lesion Location • Proximal-Mid	 79.7% (47)
Reference Vessel Diameter (mm)	2.8 ± 0.3
QCA Diameter Stenosis	59.7% ± 8.6%
QCA Length (mm)	11.7 ± 3.4
ACC/AHA Lesion Class • Type B1-C	 79.7% (47)
Any Bifurcation/Side Branch	42.4% (25)
Calcification • Moderate-Severe	 25.4% (15)
Pre-Procedure TIMI 3 Flow	100%

Device Implantation: Procedural Endpoints

Index Procedure Characteristics (QCA)	MAGNITUDE® BRS (n = 59 Lesions) Mean ± SD or % (n)
Pre-Procedure Diameter Stenosis	59.7% ± 8.6%
Pre-Dilatation Prior to Implant	100% (58)
Post-Dilatation using NC Balloon	22.4% (13/58)
Max. Scaffold Deployment Inflation Pressure (ATM)	13.5 ± 2.5
Final In-Segment Diameter Stenosis	13.8% ± 6.7%
Failure to Cross Due to Severe Calcification/Tortuosity	1.7% (1/60)
Distal Dissection Treated with DES	0%
Clinical Device Success[1]	96.7% (59/61 Lesions)
Clinical Procedure Success[2]	94.8% (55/58 Patients)[3]

[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.

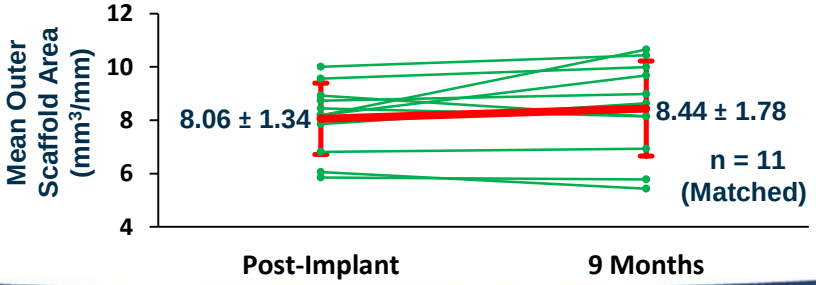
[3] Two cases of peri-procedural asymptomatic cardiac enzyme elevation and one case of peri-procedural OCT-related air embolization.

9-Month Matched Angiographic Analysis

QCA Measurements Mean ± SD	Baseline Procedure (n = 10)	Post-BRS Implantation (n = 12)	9-Month Follow-Up (n = 12)
In-Segment Analysis			
Interpolated RVD (mm)	2.8 ± 0.3	3.0 ± 0.3	2.9 ± 0.3
MLD (mm)	1.1 ± 0.3	2.5 ± 0.2	2.4 ± 0.2
Late Lumen Loss (mm)	---	---	0.14 ± 0.15
Diameter Stenosis (%)	59.8 ± 10.9	14.4 ± 6.4	17.0 ± 6.0
In-Scaffold Analysis			
Interpolated RVD (mm)	---	3.1 ± 0.3	3.0 ± 0.3
MLD (mm)	---	2.8 ± 0.3	2.6 ± 0.3
Acute Gain (mm)	---	1.67 ± 0.44	---
Late Lumen Loss (mm)	---	---	0.19 ± 0.16
Diameter Stenosis (%)	---	8.5 ± 7.4	12.1 ± 8.3
Binary Restenosis (%)	---	---	0%

9-Month Matched In-Scaffold OCT

OCT Measurements Mean ± SD or %	Post-BRS Implantation (n = 11)	9-Month Follow-Up (n = 11)	Difference (Post vs. 9-Month)
Mean Lumen Area (mm^3/mm)	7.372 ± 1.267	6.858 ± 1.799	-0.514 (-7.0%)
Mean Outer Scaffold Area (mm^3/mm)	8.058 ± 1.338	8.437 ± 1.780	0.379 (4.7%)
Percent NIH Volume (%)	---	10.3 ± 5.5	---
Post-Implantation Strut Fracture (%)	0%	---	---
OCT Volumetric Measurements Mean ± SD or %	**Percent Covered Struts (At 9 Months)**	**Percent Uncovered Struts (At 9 Months)**	**Total**
Percent Apposed per Patient (%)	96.369 ± 6.201	2.923 ± 4.977	99.3%
Percent "Malapposed " of Total Struts (%)	0.335 ± 0.812	0.051 ± 0.169	0.4%
Percent "Orifice of Branch" of Total Struts (%)	0.244 ± 0.585	0.078 ± 0.258	0.3%
Total	96.9%	3.1%	100%



30-Day Safety End-Points

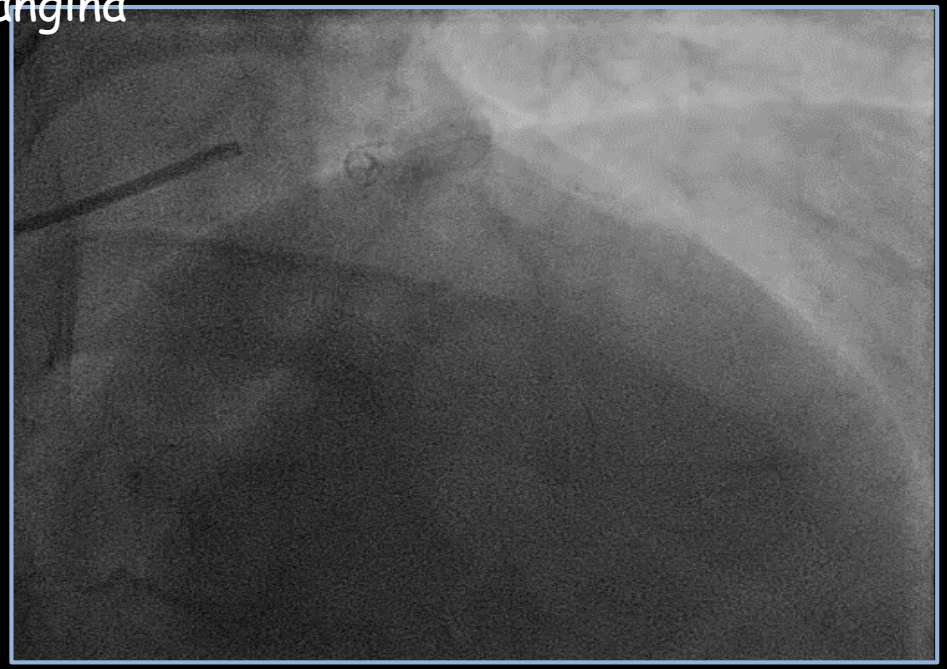
Safety Endpoints % (n)	In Hospital (n = 70)	Discharge to 30 Days (n = 70)
Target Vessel Failure **(Cardiac Death, TV-MI, or ID-TLR)**	4.3% (3*)	0%
All Death	0%	0%
Cardiac Death	**0%**	**0%**
Non-Cardiac Death	0%	0%
Target Vessel MI	**4.3% (3*)**	**0%**
Q-wave MI	0%	0%
Non-Q-wave MI	4.3% (3*)	0%
Ischemia Driven TLR	**0%**	**0%**
PCI	0%	0%
CABG	0%	0%
ARC Stent Thrombosis		
Definite or Probable	0%	0%
Possible	0%	0%

No additional events reported > 30 days in the 12 patients with completed 9-month follow-up

* Two cases of peri-procedural asymptomatic cardiac enzyme elevation and one case of peri-procedural OCT-related air embolization.

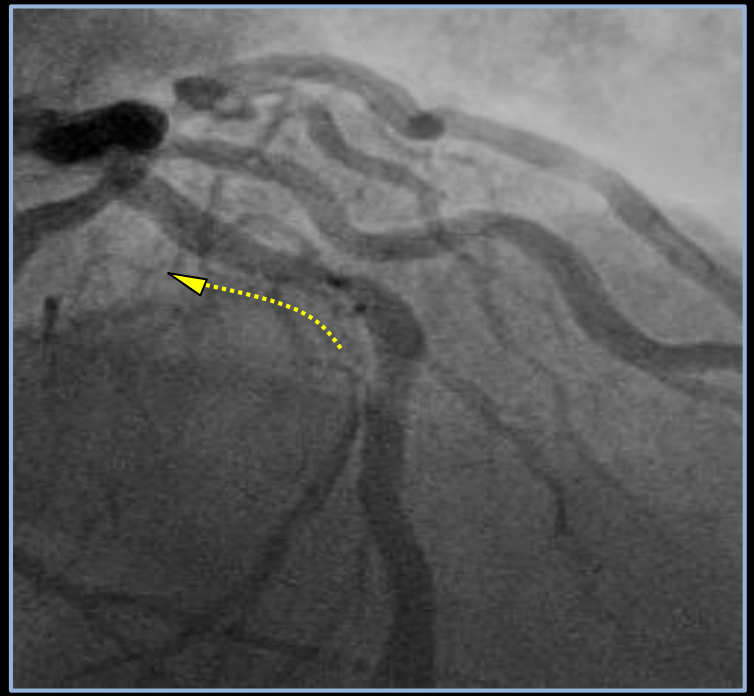
The 1st RENASCENT III patient: mid LAD lesion

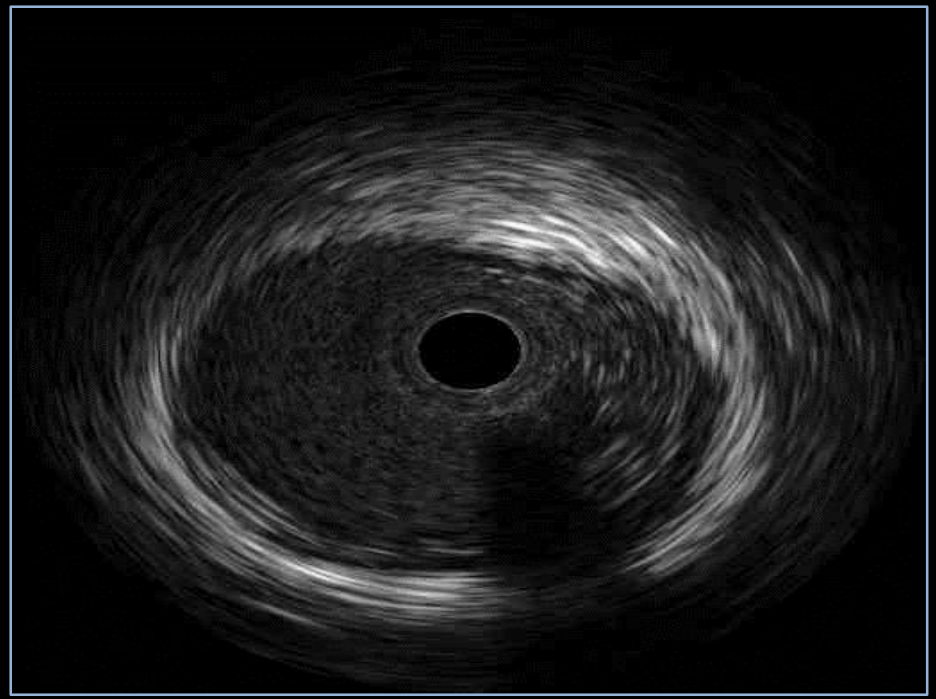
46 year-old, male
Coronary risk factor: hypertension, dyslipidemia, ex-smoking
Stable angina



Mid LAD: simple stenotic lesion

Baseline IVUS evaluation

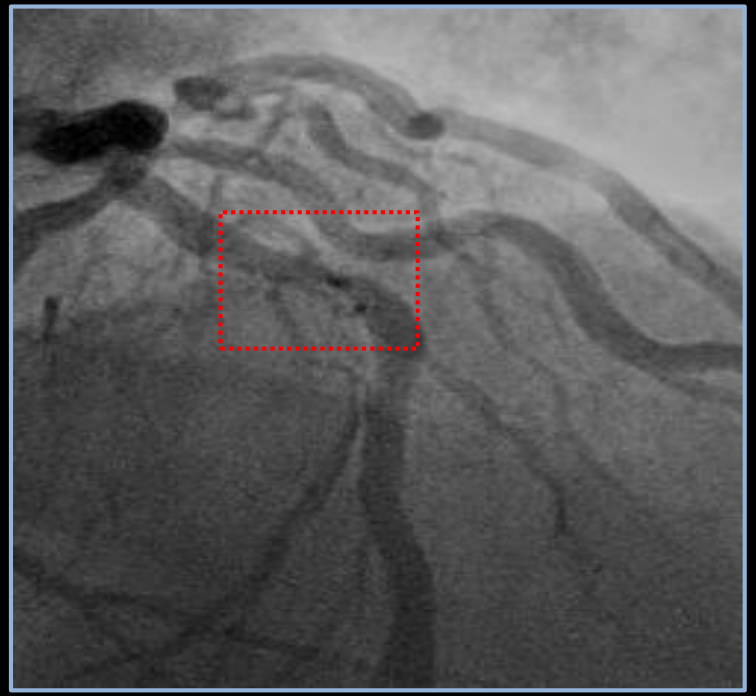


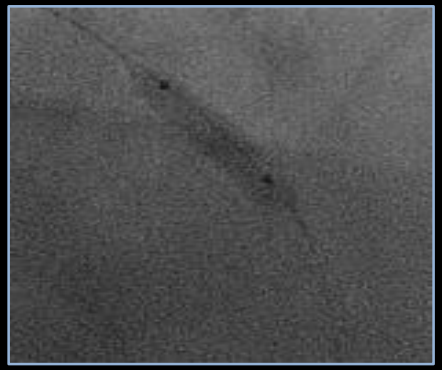


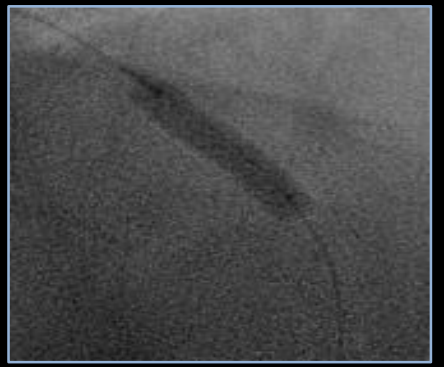
Dist. reference LD: 3.48/3.60 mm
VD: 4.27/4.76 mm
Prox. reference LD: 3.24/3.82 mm
VD: 4.16/4.35 mm

➡ Amaranth 3.5/ 13 mm

Amaranth implantation







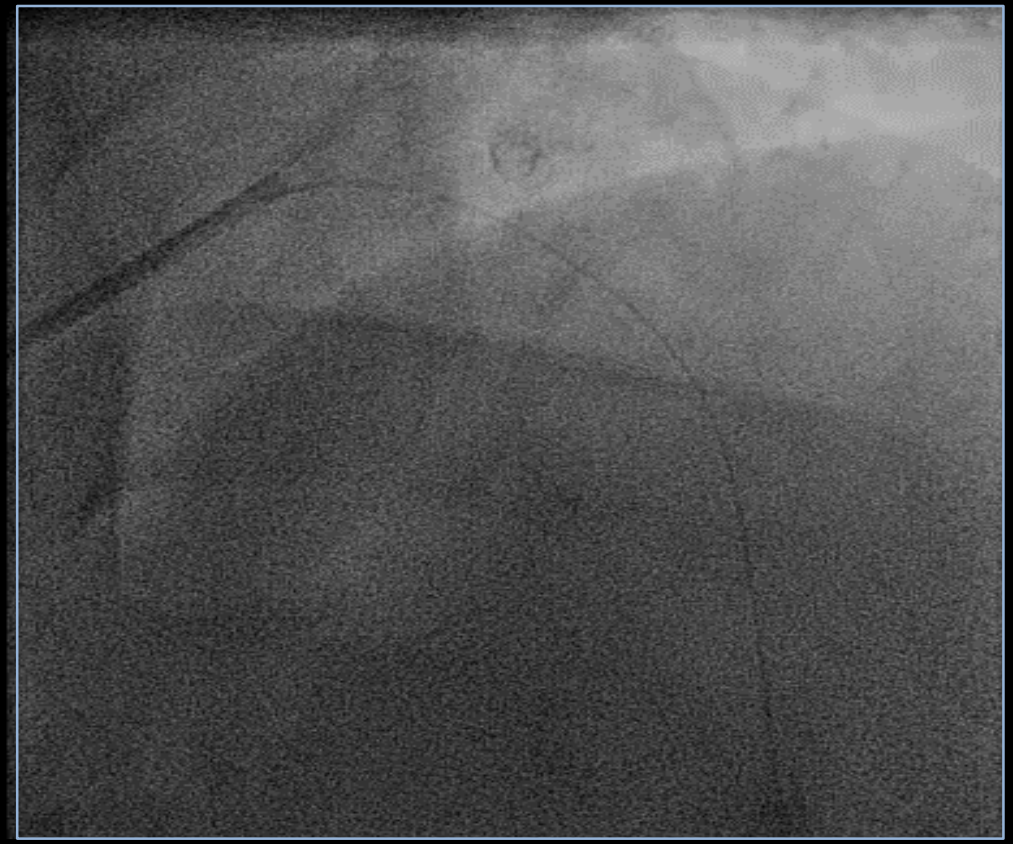
Predilatation:
3.5mm (NC) 18atm

Amaranth:
3.5/13mm

According to the IVUS evaluation
✓ Predilatation: 3.5mm NC

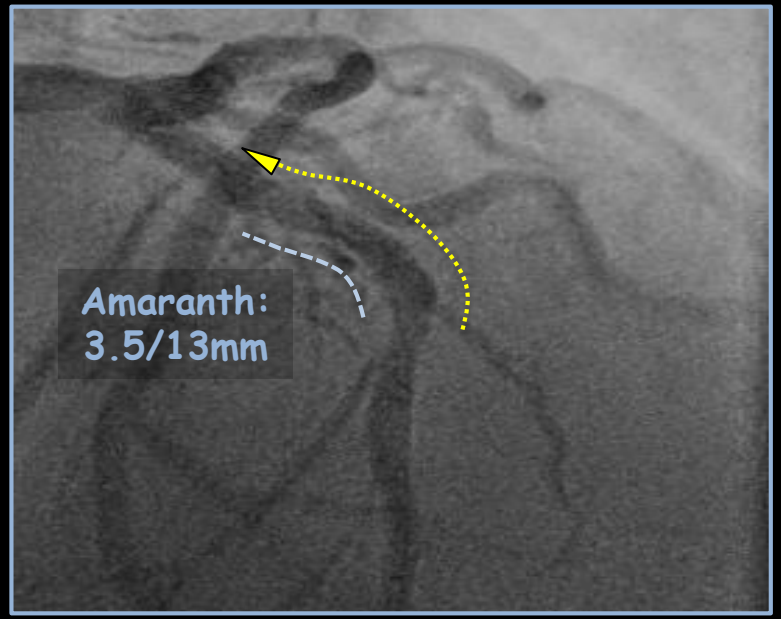
➡ Appropriate balloon expansion

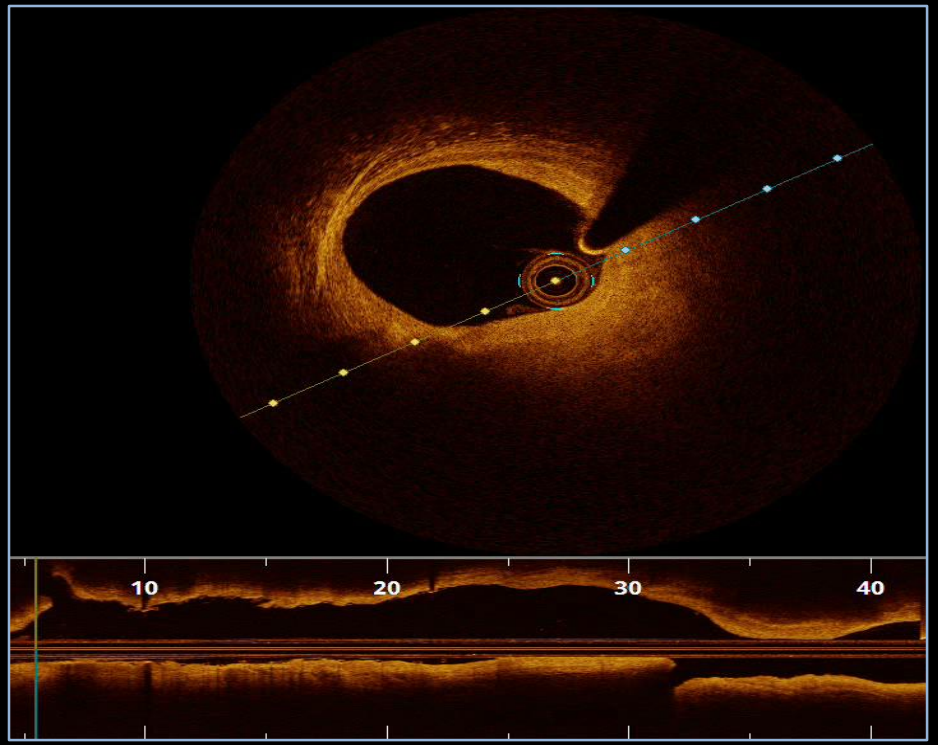
After Amaranth implantation



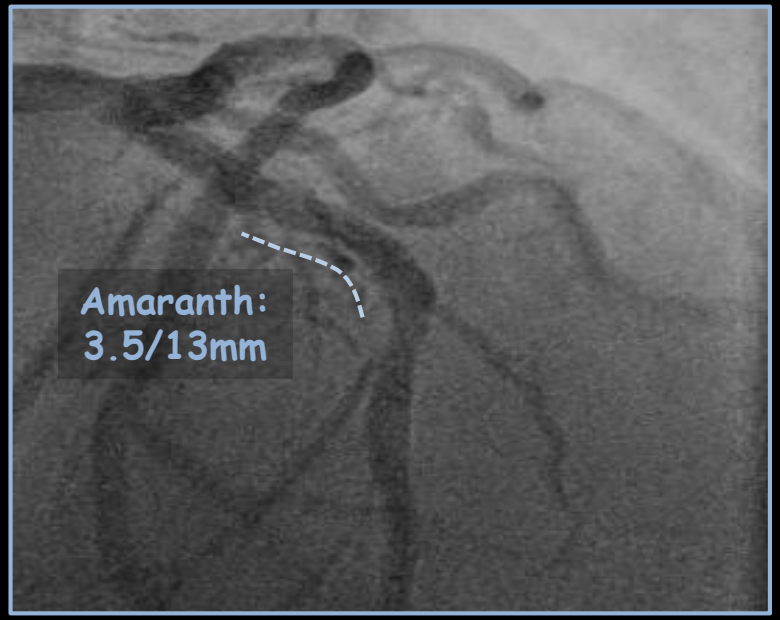
After Amaranth implantation

OCT pullback after Amaranth implantation



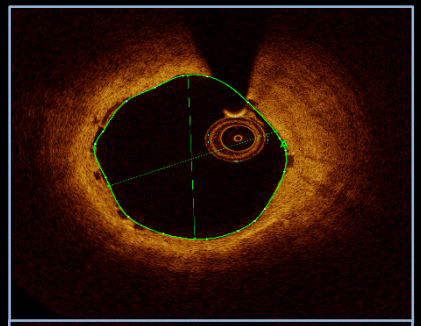


OCT findings after Amaranth implantation



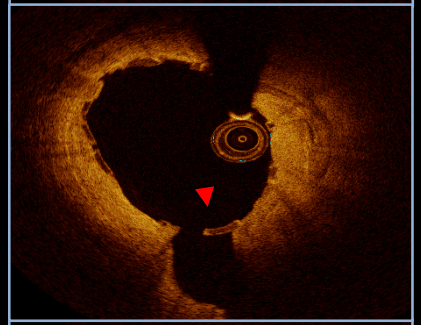
Excellent results

➡ No post-dilatation



MSA

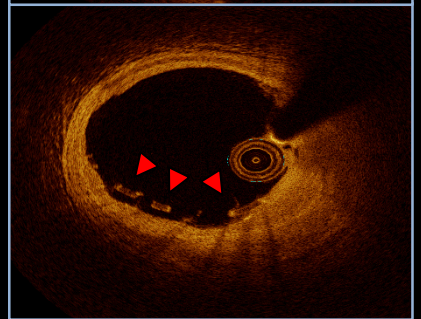
7.25mm² (3.02/3.34)



Septal branch

✓ Jailing

✓ Patent

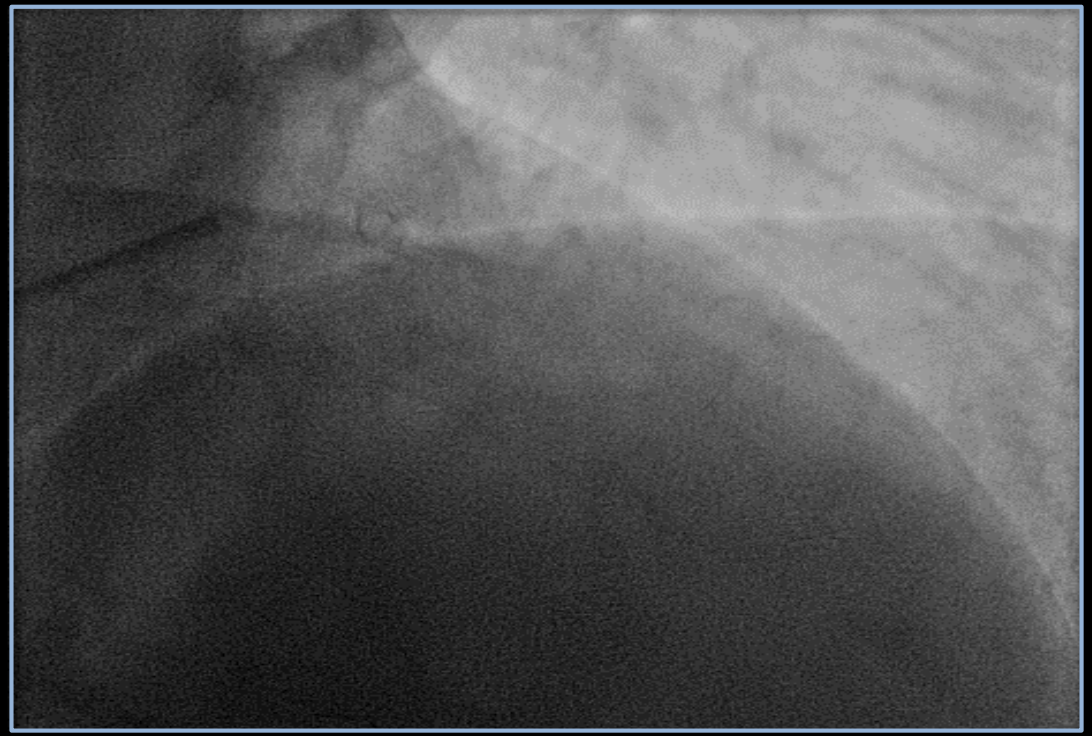


Distal edge

✓ Minor malapposition

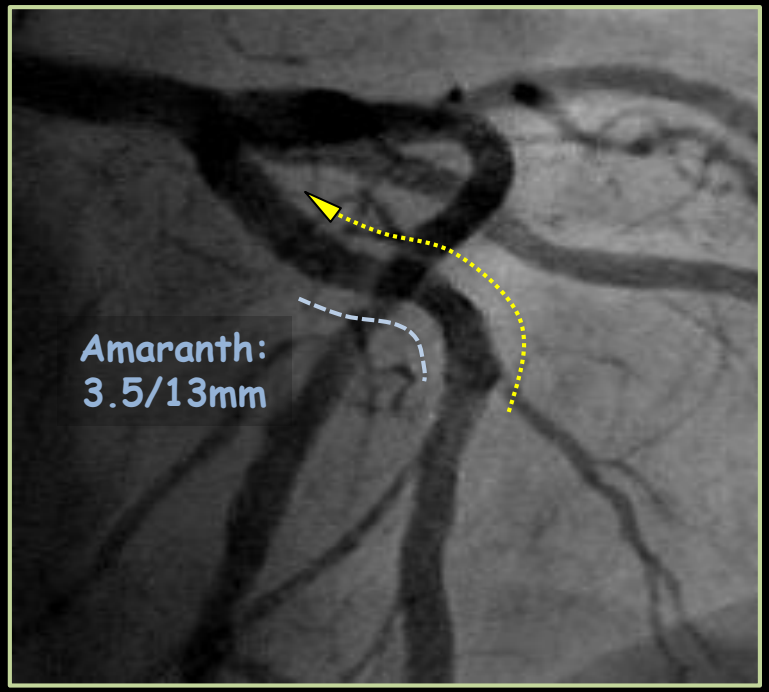
✓ No dissection

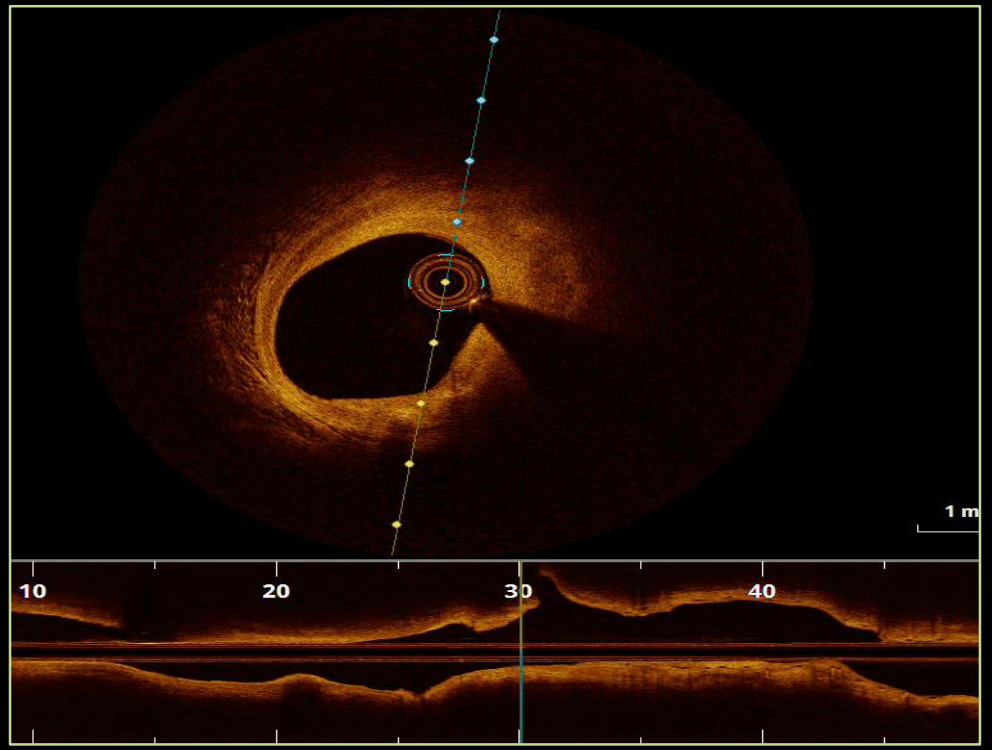
9-month follow-up



9-month follow-up CAG

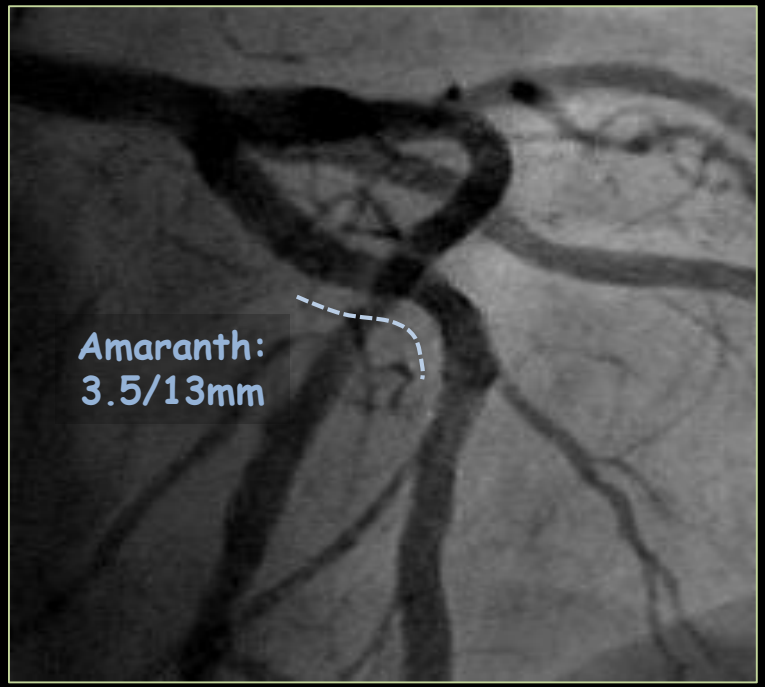
OCT pullback after Amaranth implantation



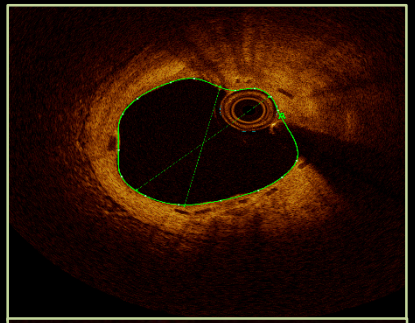


➡ Good neointimal coverage of the whole scaffolds

OCT findings after Amaranth implantation

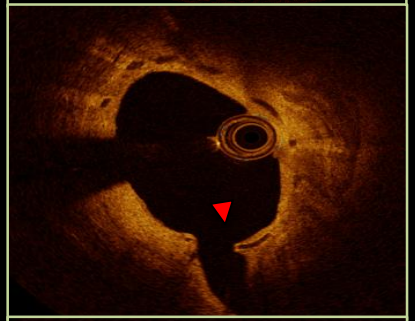


Excellent follow-up results

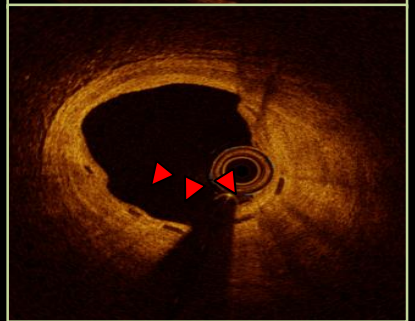


MLA of the lesion

6.36mm^2 (2.77/2.94)

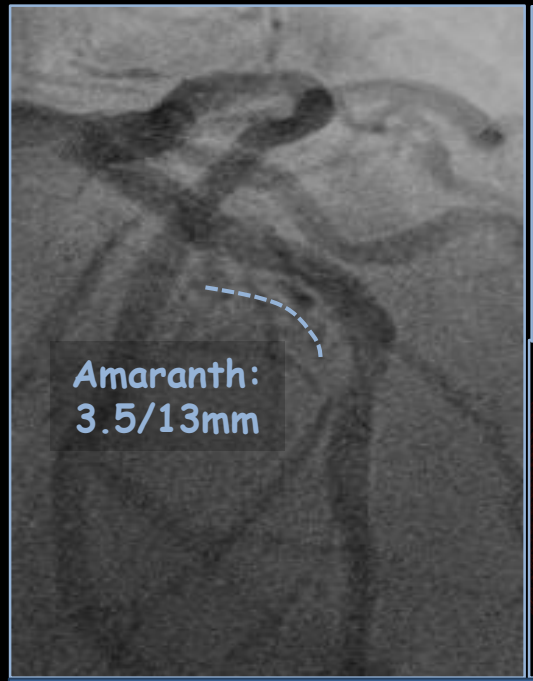


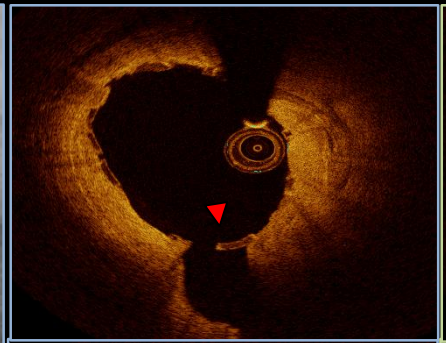
Septal branch
- ✓ Patent
- ✓ No tissue bridging

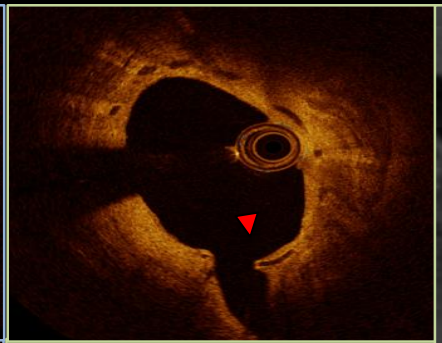


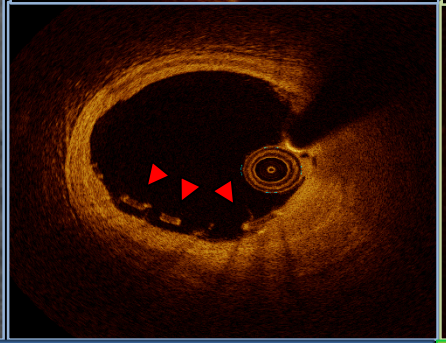
Distal edge
- ✓ Resolved malapposition
- ✓ Neointimal coverage

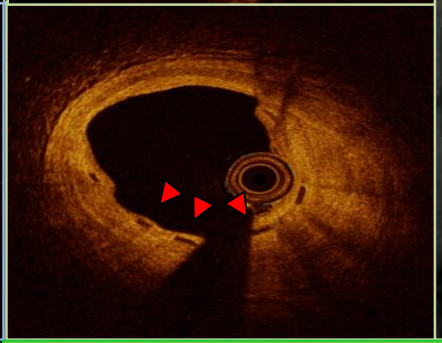
Comparison of OCT findings

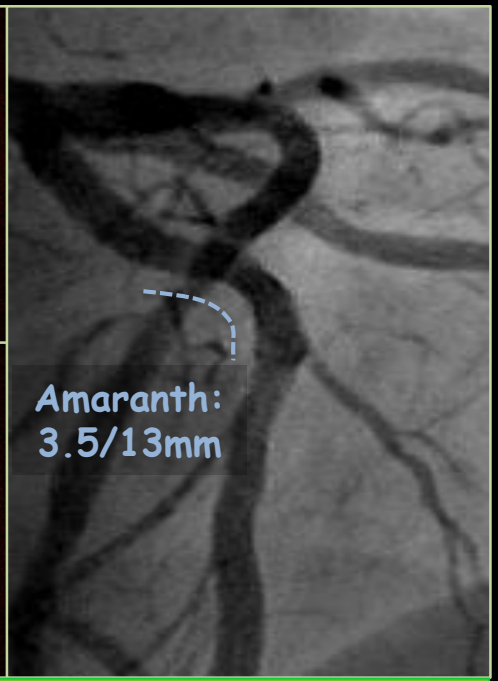












The index PCI

9-month follow-up

RENASCENT III Study: Conclusions

- The RENASCENT III trial is the first trial testing the clinical performance of a BRS with a wall thickness below 100 microns
- The interim results of this international, multi-center trial of the 98-µm MAGNITUDE® BRS:
  - ✓ High clinical device success rate (97%)
  - ✓ Low peri-procedural MACE rates (4.3%; all three were non-Q wave MIs not related to target lesion)
  - ✓ DES-like scaffold areas after implantation
- 9-Month angiographic (12 patients) and OCT (11 patients) evaluation:
  - ✓ No angiographic binary restenosis or scaffold thrombosis
  - ✓ DES-like angiographic late loss
  - ✓ Scaffold stability as assessed by OCT lumen area maintained
  - ✓ High level of strut coverage (97.0%) and low rate of malapposition (0.037%, all covered) by OCT
- The MAGNITUDE® BRS is the first BRS to display DES-like outcomes in a clinical trial