ABSORB EXTEND – Lesion Characteristics (ITT)

	EXTEND (L = 502)	Cohort B (L=102)
Lesion Characteristics (%)		
Angulation (≥ 45°)	3	4
Calcification (Moderate/Severe)	12	15
Eccentric	96	99
Thrombus	2	3
ACC/AHA Lesion Classification (%)		
A	2	1
B1	59	55
B2	35	40
C	4	4
Lesion Length (mm)		
Mean	11.61	9.91
Range (min, max)	(3.13, 33.78)	(2.92, 22.93)

Note: L is the total number of target lesions.

Procedural Parameters
(ITT)

	EXTEND (N=469) (S=540)	Cohort B (N=101) (S=102)
Number of Target Lesions (%)		
1 lesion subjects	93.0	99.0
2 lesion subjects	7.0	1.0
Planned Overlapping (%) – per subject	7.7	NA
Bailout (%) – per subject	4.1	4.0
with BVS	1.5	0.0
with metallic EES	2.3	4.0
with other stent	0.4	0.0
Device Usage (%) – per scaffold		
3.0 x 18 mm BVS	80.4	100
3.0 x 28 mm BVS	12.6	NA
2.5 x 18 mm BVS	7.0	NA

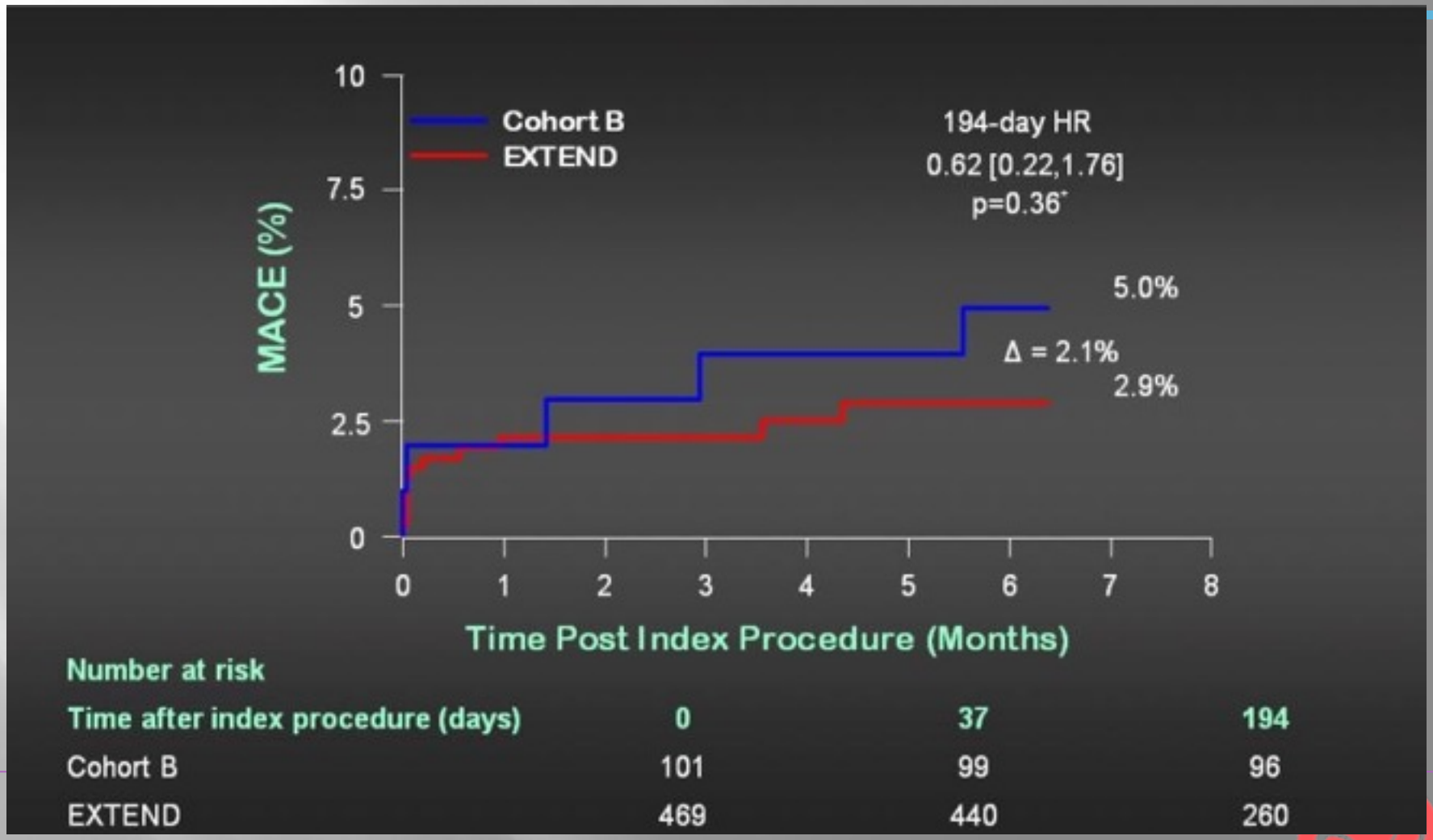
Note: S is the total number of study scaffolds.

ABSORB Extend--Clinical Results

Non-Hierarchical	30 Days* n = 451	6 Months* n = 269
Cardiac Death n (%)	0 (0.0)	1 (0.4)**
Myocardial Infarction n (%)	10 (2.2)	7 (2.6)
Q-wave MI	3 (0.7)	3 (1.1)
Non Q-wave MI	7 (1.6)	4 (1.5)
Ischemia Driven TLR n (%)	1 (0.2)	1 (0.4)
PCI	1 (0.2)	1 (0.4)
CABG	0	0
Hierarchical MACE n (%)	10 (2.2)	8 (3.0)

Abizaid, A. ACC 2012.

MACE through 6 months

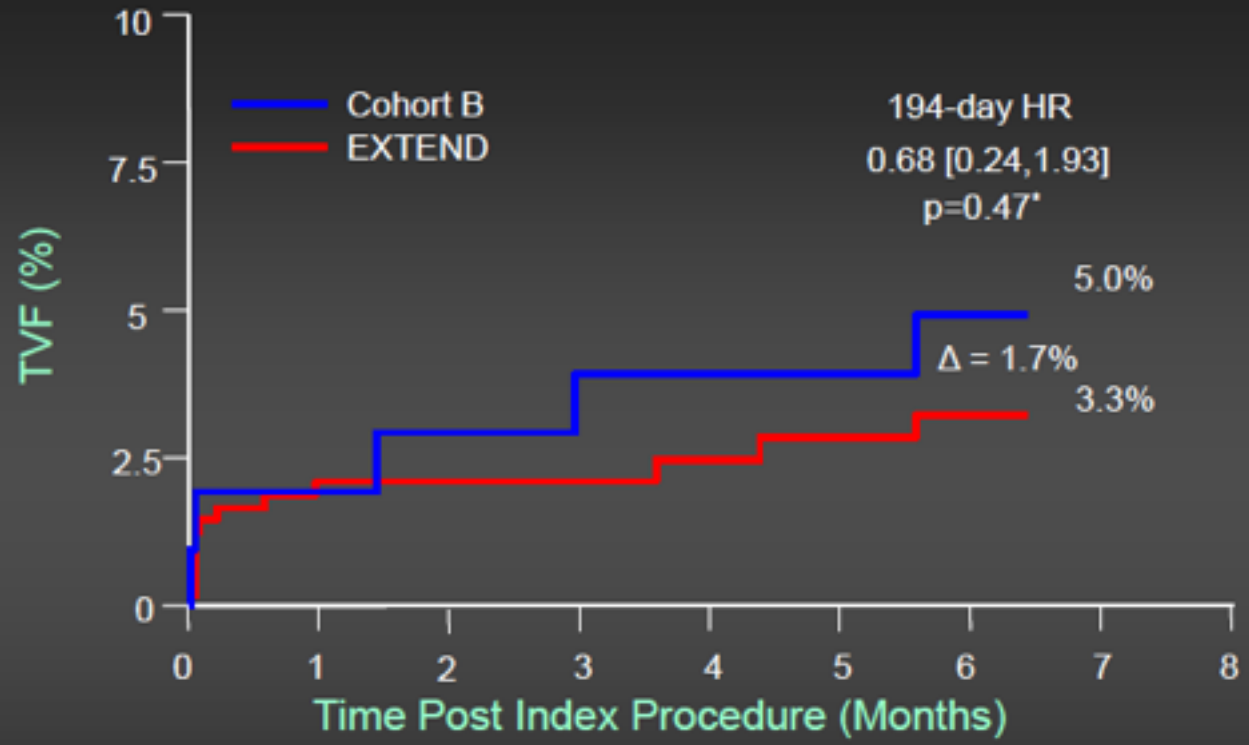


Number at risk

Time after index procedure (days)	0	37	194
Cohort B	101	99	96
EXTEND	469	440	260

Van Genus RJ. PCR 2012

TVF through 6 months



Number at risk

Time after index procedure (days)	0	37	194
Cohort B	101	99	96
EXTEND	469	440	259

Note: TVF is defined as the composite of cardiac death, MI, ischemia-driven TLR, and ischemia-driven TVR, non-TL

* P-value is not from formal hypothesis testing and is displayed for descriptive purpose only.

Van Genus RJ. PCR 2012

Protocols & Technique (Suggestion by Abbott)

Choice of BVS diameter & length

Diameter

- QCA analysis

  maximal vessel lumen diameter (D max) in proximal and distal reference segments

- IVUS/OCT

  in case of doubts regarding reference diameter / atherosclerotic plaque /calcifications

D max is a real value of maximal vessel diameter at sites of the target location of the scaffold margins.

Table 1. Ranges of target artery diameters and the ABSORB™ system diameters used for implantation

Proximal and distal diameter of the target artery [mm]	Diameter of the ABSORB BVS™ system [mm]
≥ 2.0 and ≤ 3.0	2.5
≥ 2.5 and ≤ 3.3	3.0
≥ 3.0 and ≤ 3.8	3.5

Length

- At least 2 mm of the “healthy” vessel before and after the stenosis should be covered

- 2 scaffolds into one lesion should include an overlap of 1-4mm

Predilation

Predilation balloon

- 0.5mm smaller in diameter of scaffold

- Equal to the diameter of scaffold with non-compliant high pressure balloon

  if no effect of the first predilation /persistent residual stenosis > 40%

Introduction to Target Lesion

- 6 F or larger catheters with minimal internal diameter of 0.070″ (1.8 mm)
- Collinear position of guiding catheter
- Guided by platinum markers (struts are invisible to X-ray)
- Tortuous segments/significant visible calcifications should not be treated

Implantation of BVS

- Progressive inflation by 2 atm every 5 s – minimal total time of inflation is 30 s, RBP should not be exceeded.

- In case of vessel dissection ,use a second scaffold with adequate diameter or everolimus-eluting metallic stent.

Postdilation

- The vessel diameter at the site of the implanted scaffold may appear smaller on control angiography
- Postdilation should be used only in cases of evident residual stenosis or scaffold deflection

Postdilation should be performed using high pressure low compliant balloon catheters

Diameter of BVS (mm)	Diameter of Postdilation Balloon (mm)
2.5	2.75-3.0
3.0	3.25-3.5
3.5	3.75-4.0

Drug therapy

Dual antiplatelet treatment is recommended for **a minimum of 6 months or longer** depending on clinical indications.

Off-lable Use of BVS in Complicated Coronary Diseases

Small Vessels

Journal of the American College of Cardiology
© 2011 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 58, No. 3, 2011
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.02.052

CLINICAL RESEARCH **Interventional Cardiology**

6-Month Clinical Outcomes Following Implantation of the Bioresorbable Everolimus-Eluting Vascular Scaffold in Vessels Smaller or Larger Than 2.5 mm

Study Objective	BVS in small coronary vessels(<2.5mm)
Endpoints	Typical PCI clinical endpoints
Treatment	**2 groups [group I (n =41) with RVD<2.5 mm and group II (n=60) with RVD ⩾2.5 mm] treated by 3.0-mm BVS**
Device Sizes	Scaffold diameters: 3.0 mm Scaffold lengths: 18, 28 mm

Diletti R, et al. JACC.2011,58:258-264

Table 4 QCA Analysis at Baseline and 6-Month Follow-Up

	Small Vessels (<2.5 mm; n = 20)	Large Vessels (≥2.5 mm; n = 25)	Difference (95% CI)	p Value
Baseline QCA analysis				
Before procedure				
RVD, mm	2.24 ± 0.17 (20)	2.96 ± 0.33 (25)	−0.72 (−0.88 to −0.57)	<0.0001
MLD to mm	0.93 ± 0.22 (19)	1.15 ± 0.35 (25)	−0.22 (−0.40 to −0.04)	0.0154
Percent diameter stenosis, %	58.0 ± 11.1 (19)	60.8 ± 11.9 (25)	−2.8 (−9.9 to 4.2)	0.4216
After procedure				
In-scaffold acute gain, mm	1.23 ± 0.37 (19)	1.29 ± 0.35 (25)	−0.05 (−0.28 to 0.17)	0.6269
6-month QCA analysis				
In-scaffold late loss, mm	0.16 ± 0.18 (19)	0.21 ± 0.17 (23)	−0.05 (−0.16 to 0.06)	0.3525
In-scaffold percent diameter stenosis, %	18.1 ± 7.2 (19)	20.2 ± 8.0 (23)	−2.1 (−6.8 to 2.6)	0.3736
In-scaffold binary restenosis	0.0% (0/19)	0.0% (0/23)	0.0% (assumption not met)	NA

Values are mean ± SD (n).

Abbreviations as in Tables 2 and 3.

Table 3 Adverse Events at 6-Month Follow-Up

	Small Vessels (<2.5 mm; n = 41)	Large Vessels (≥2.5 mm; n = 60)	p Value
ID-MACE*	3/41 (7.3)	2/60 (3.3)	0.3933
Cardiac death	0/41 (0.0)	0/60 (0.0)	NA
MI	2/41 (4.9)	1/60 (1.7)	0.5645
QMI	0/41 (0.0)	0/60 (0.0)	NA
NQMI	2/41 (4.9)	1/60 (1.7)	0.5645
ID-TLR	1/41 (2.4)	1/60 (1.7)	1.0000
CABG	0/41 (0.0)	0/60 (0.0)	NA
PCI	1/41 (2.4)	1/60 (1.7)	1.0000
Non–ID-TLR	0/41 (0.0)	0/60 (0.0)	NA
CABG	0/41 (0.0)	0/60 (0.0)	NA
PCI	0/41 (0.0)	1/60 (1.7)	1.0000

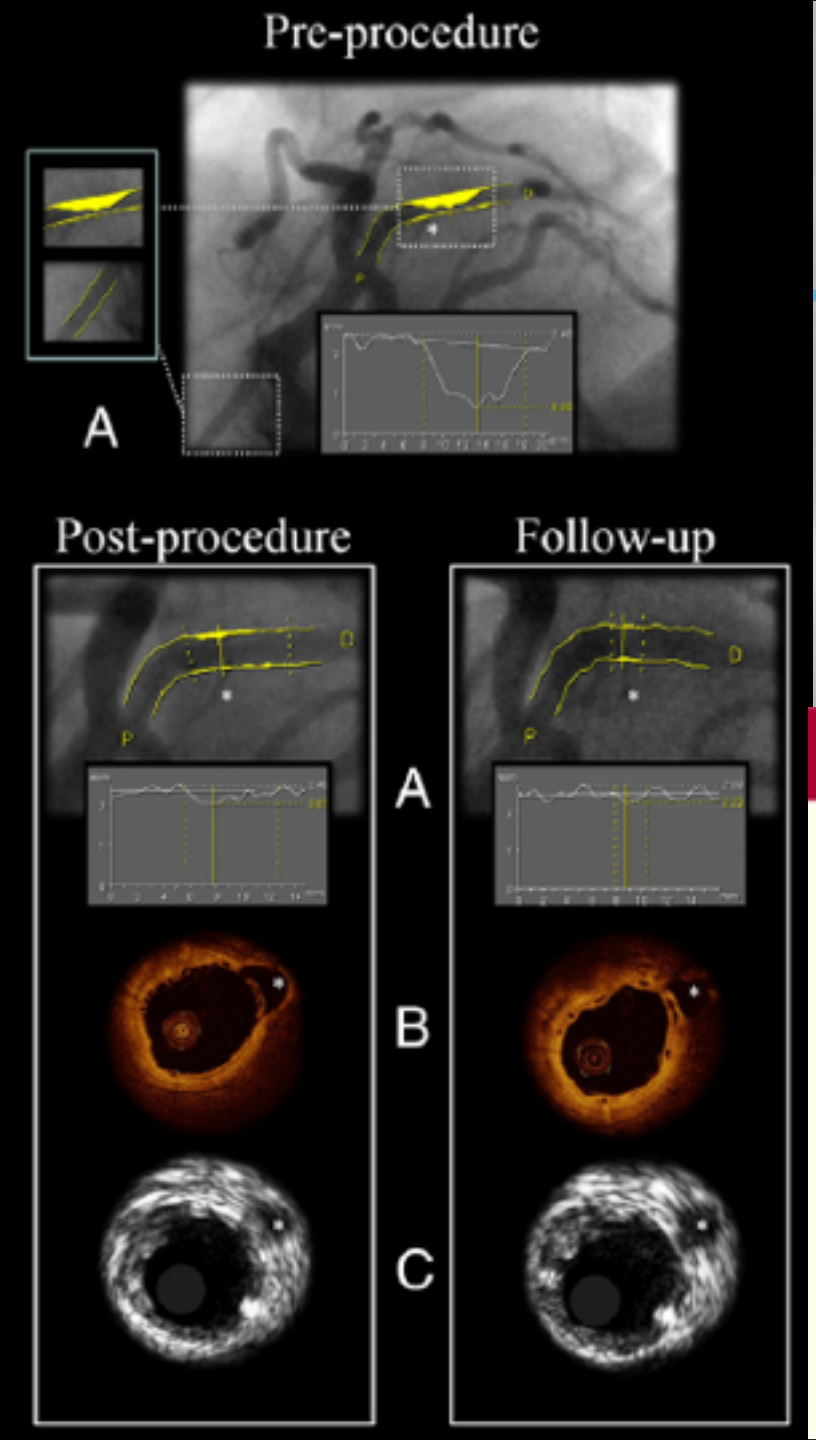


Figure 2 **Small Vessel Treated With Implantation of BVS**

Angiographic, optical coherence tomography (OCT), and intravascular ultrasound (IVUS) images before procedure, after procedure, and at 6-month follow-up are shown. The images show an example of a small vessel treated with a bioresorbable drug-eluting vascular scaffold (BVS) (pre-RVD 2.24 mm). **(A)** A visual comparison between the vessel-treated segment and a 6-Fr catheter (1.98 mm) is highlighted. Pre-procedural angiography and quantitative coronary angiography (QCA) analysis revealed a minimal lumen diameter (MLD) of 0.65 mm. Post-procedural angiography **(left panel)** and QCA analysis demonstrated an MLD of 2.01 mm. At the 6-month follow-up **(right panel)**, the MLD was 2.23 mm. For illustrative purposes, the OCT **(B)** and IVUS **(C)** images are presented. These are corresponding frames taken from the MLD. A small side branch **(*)** located at the post-procedural MLD was used as a landmark for accurate matching of the images among different imaging modalities (angiography, OCT, and IVUS) and between the 2 time points. Abbreviations as in Figure 1.