A Novel Low Pressure Self Expanding Nitinol Coronary Stent (vProtect): Device Design and FIH Experience

Juan F. Granada, MD

Medical Director, Skirball Center for Cardiovascular Research

The Cardiovascular Research Foundation

Columbia University Medical Center

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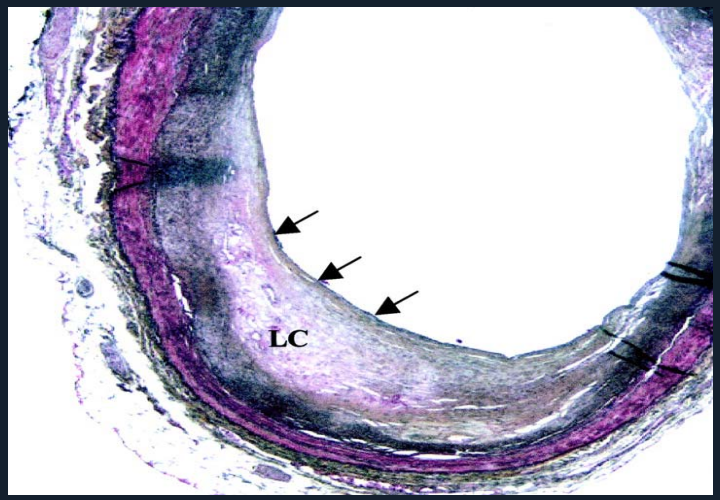
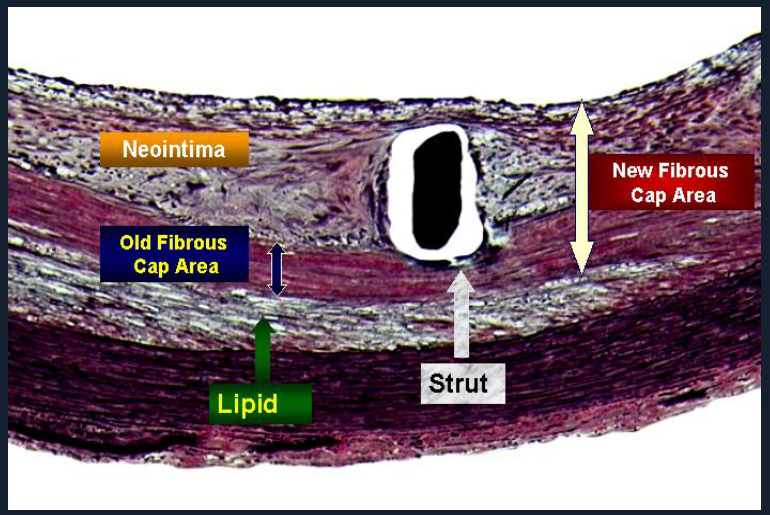
Mechanical Stabilization of TCFA

Mechanical Objectives



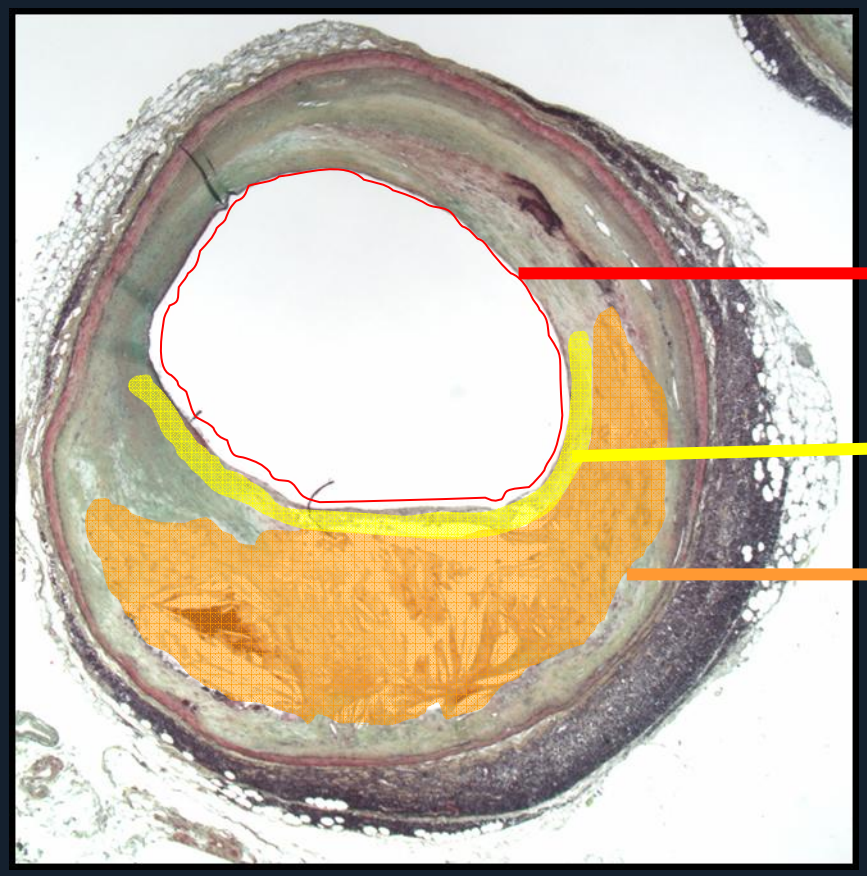


Plaque Features		Mechanical Stabilization
Soft Tissular Matrix	→	Mechanical Compression
Thin Fibrous Cap	→	“Neo-Cap” Formation
Prominent Lipidic Core	→	Minimal Lipidic Core
Thin Plaque Shoulders	→	Healthy Thin Neointima

Picture on the right acquired from Moreno PR.

Objectives of Focal VP Therapy

Biological Principle



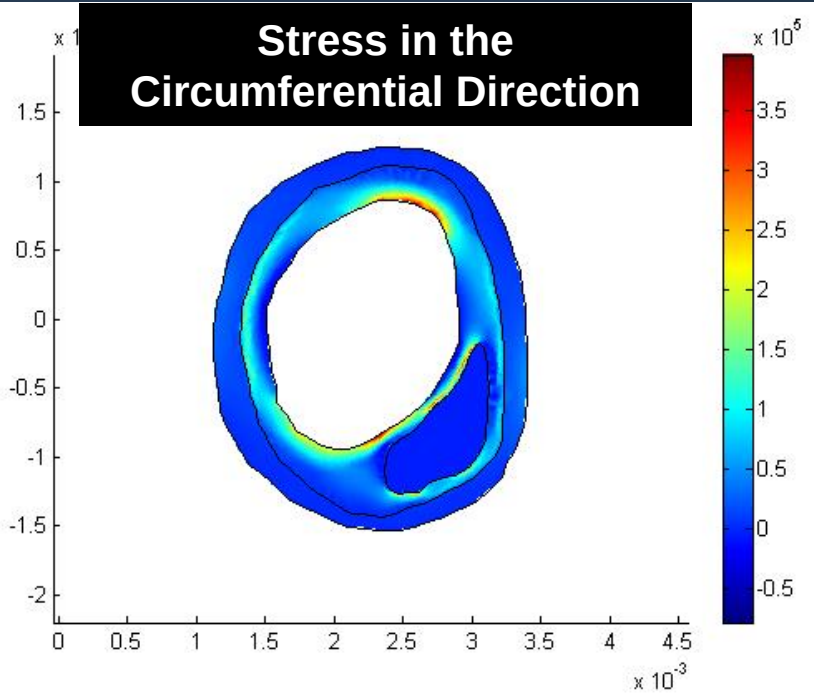
Mechanical Stabilization
Reinforcement of Fibrous Cap

Promotion of Vascular Healing

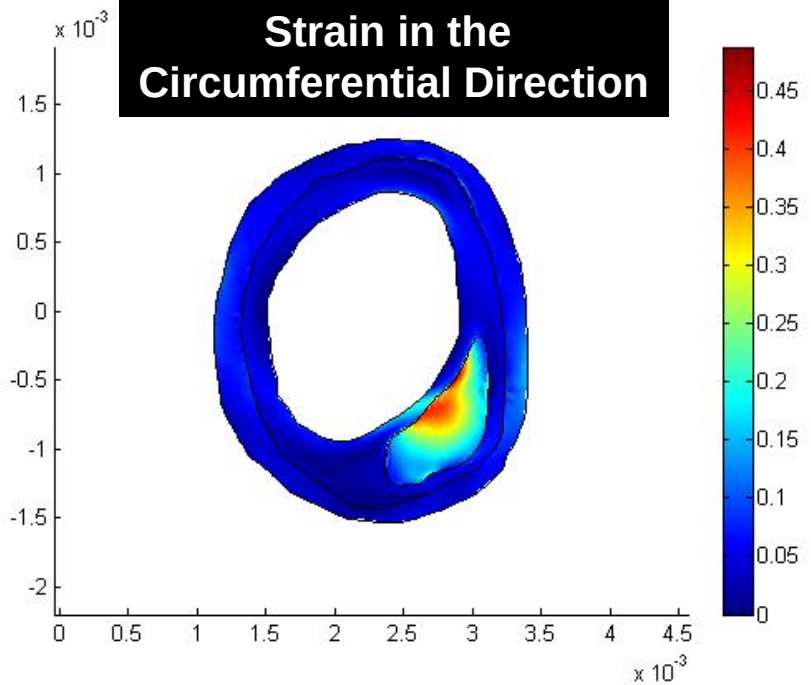
Regulation of Inflammation and Cell Growth

Prevention of Thrombosis

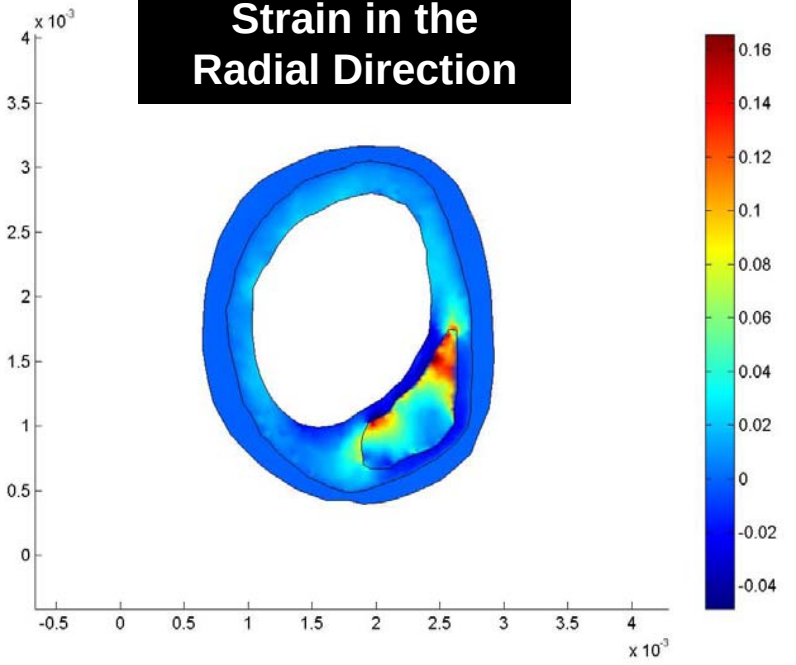
Stress in the Circumferential Direction



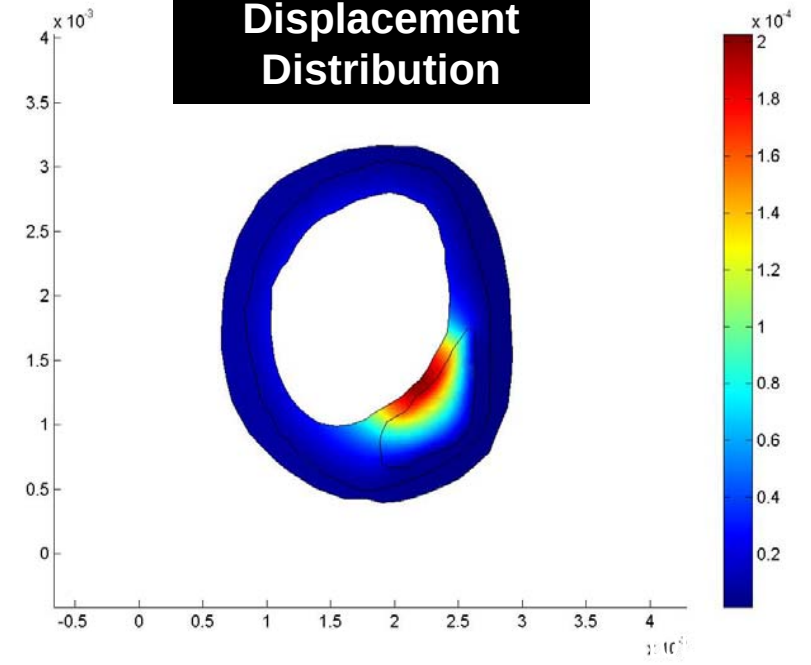
Strain in the Circumferential Direction



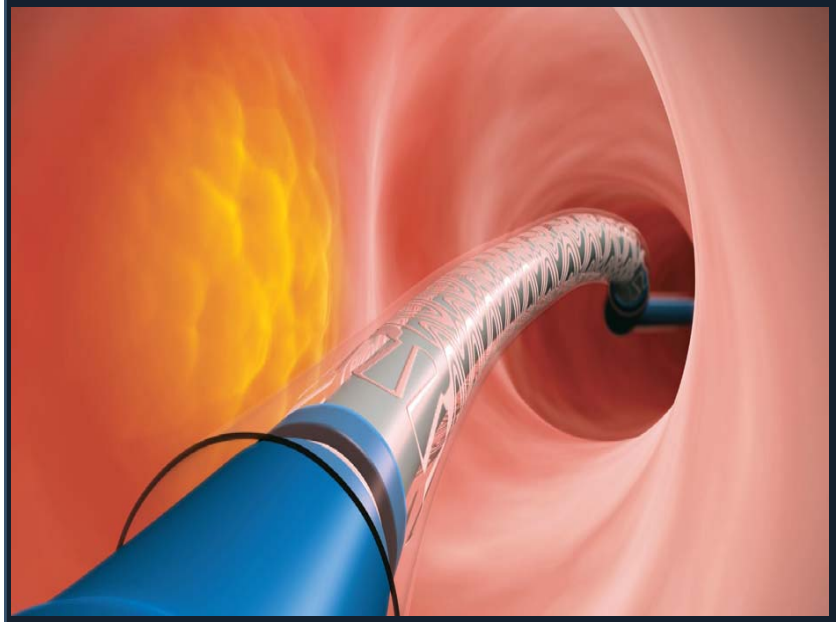
Strain in the Radial Direction

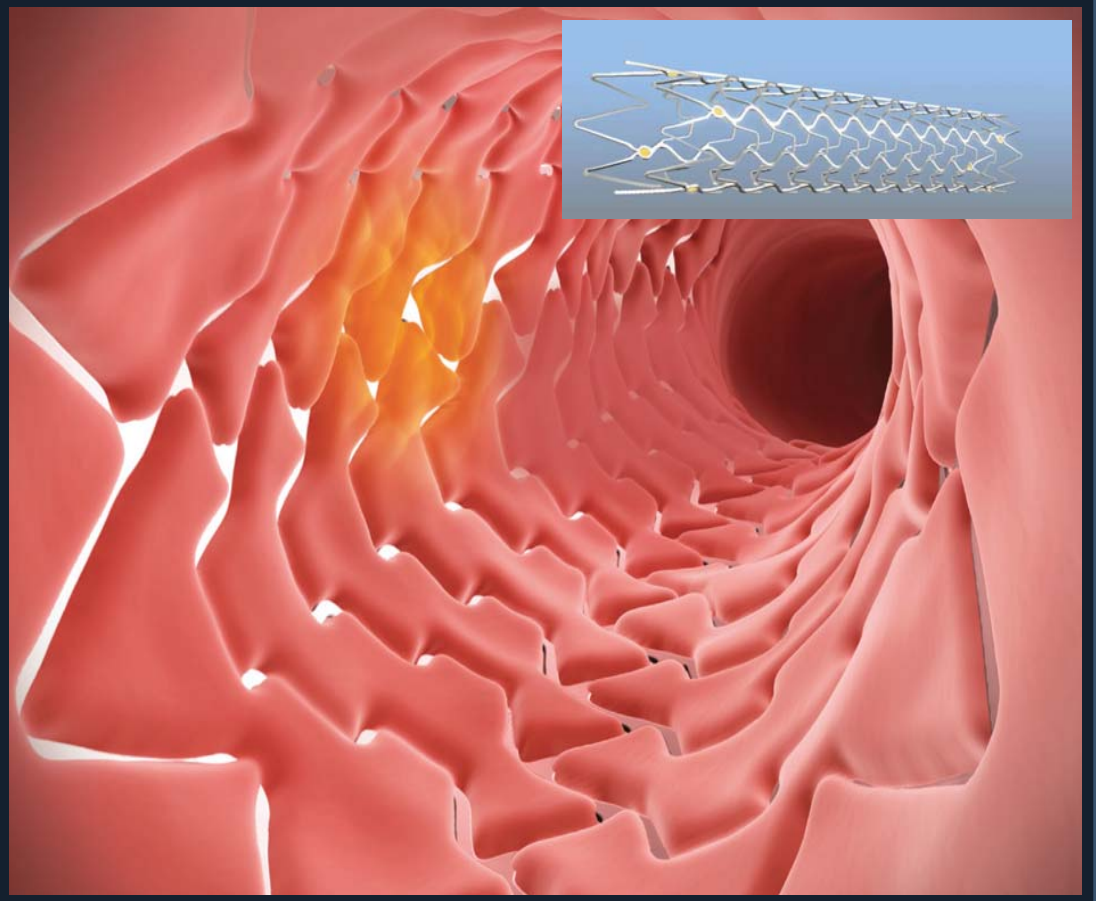


Displacement Distribution



Prescient vProtect Luminal Shield: Device Features





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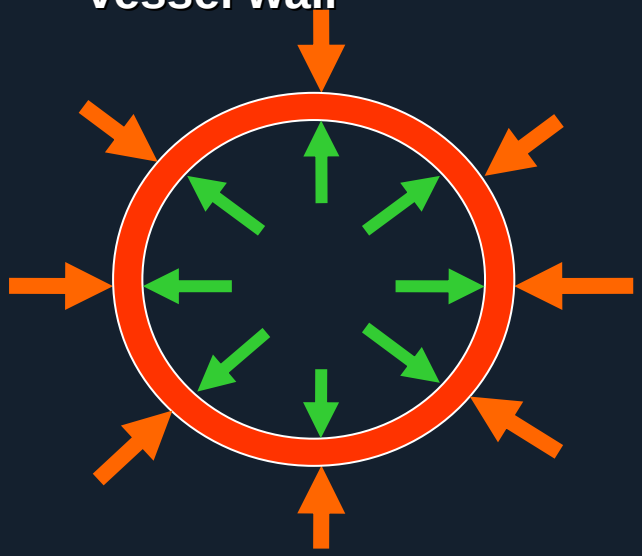
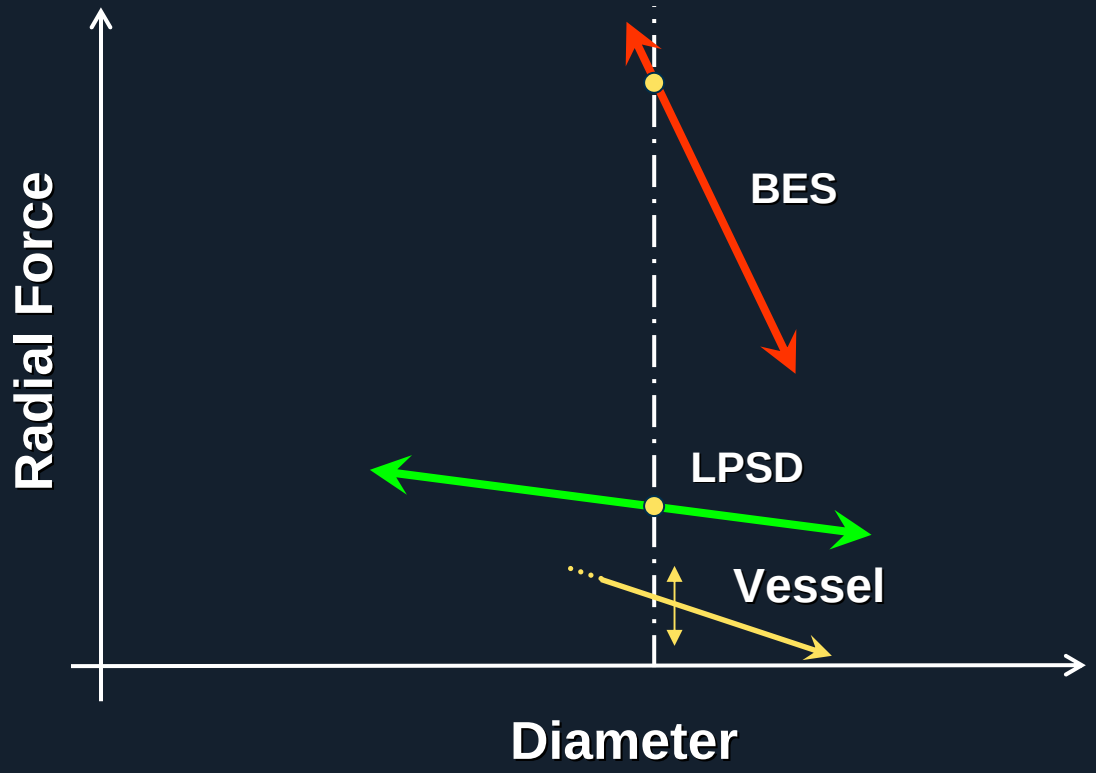
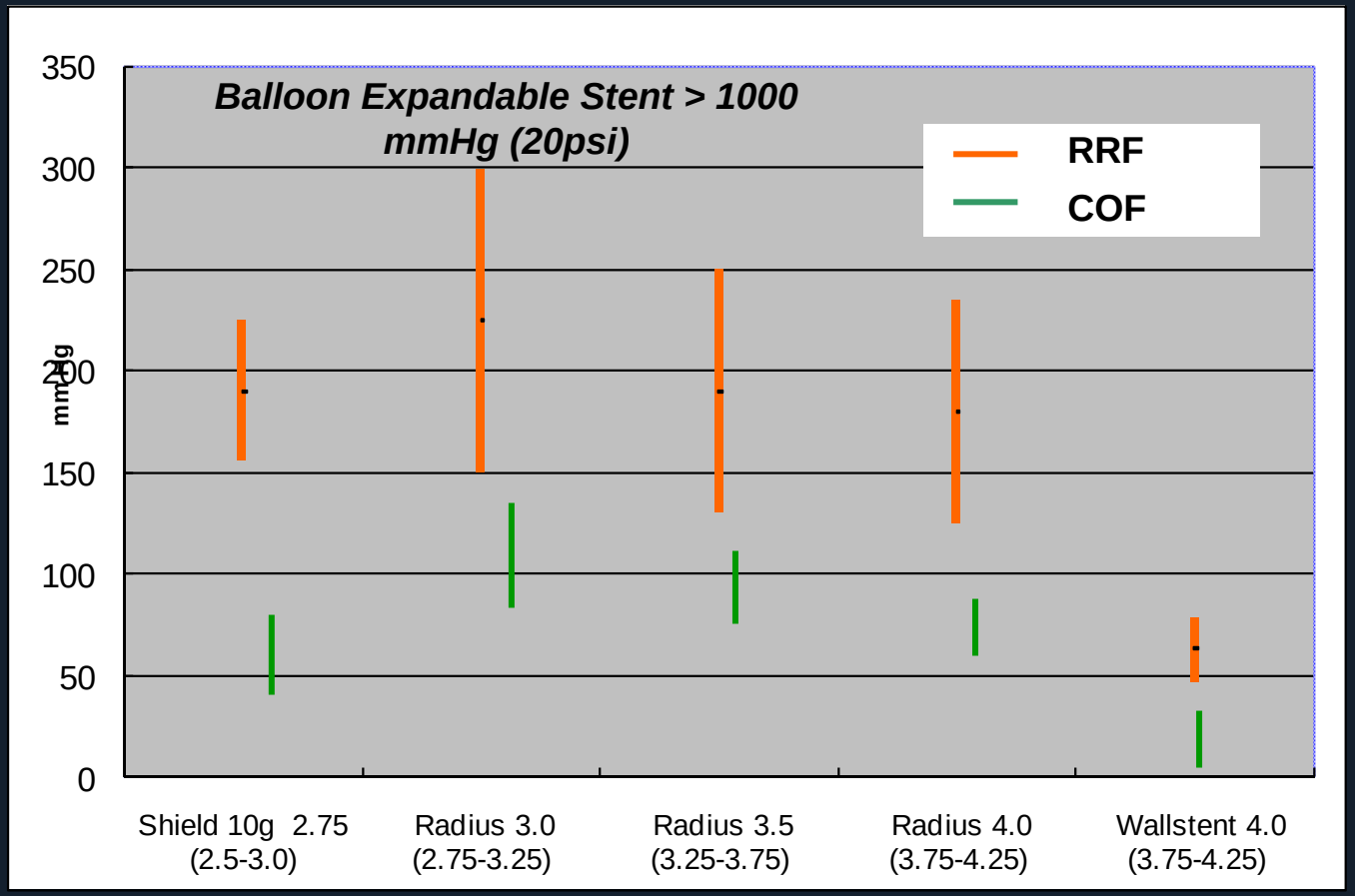
Mechanics of the vProtect Vascular Shield: RRF and COF

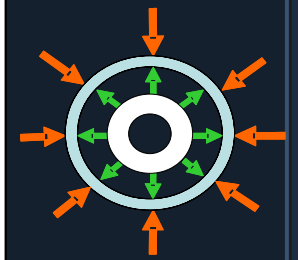
- **Radial Resistive Force (RRF): Force the Shield resists the recoil of the plaque and vessel wall**
- **Chronic Outward Force (COF): Force the Shield exerts on the plaque and vessel wall**





Mechanics of the vProtect Vascular Shield Compared to Other SE Stents





Maximum to Minimum Indicated Diameter.
High crush resistance / chronic outward force ratio

Testing performed on MSI tester May 2007

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Experimental Data: 28 Days

- Porcine normal coronary model (11 animals).
- 30 coronary arteries were randomized to receive:
  - Vascular shields (3.5 x 16.8 mm, n=10)
  - VisionTM stents (Abbott, 3.0 x 18mm, n=10)
  - XienceTM stents (Abbott, 3.0 x 18 mm, n=10)

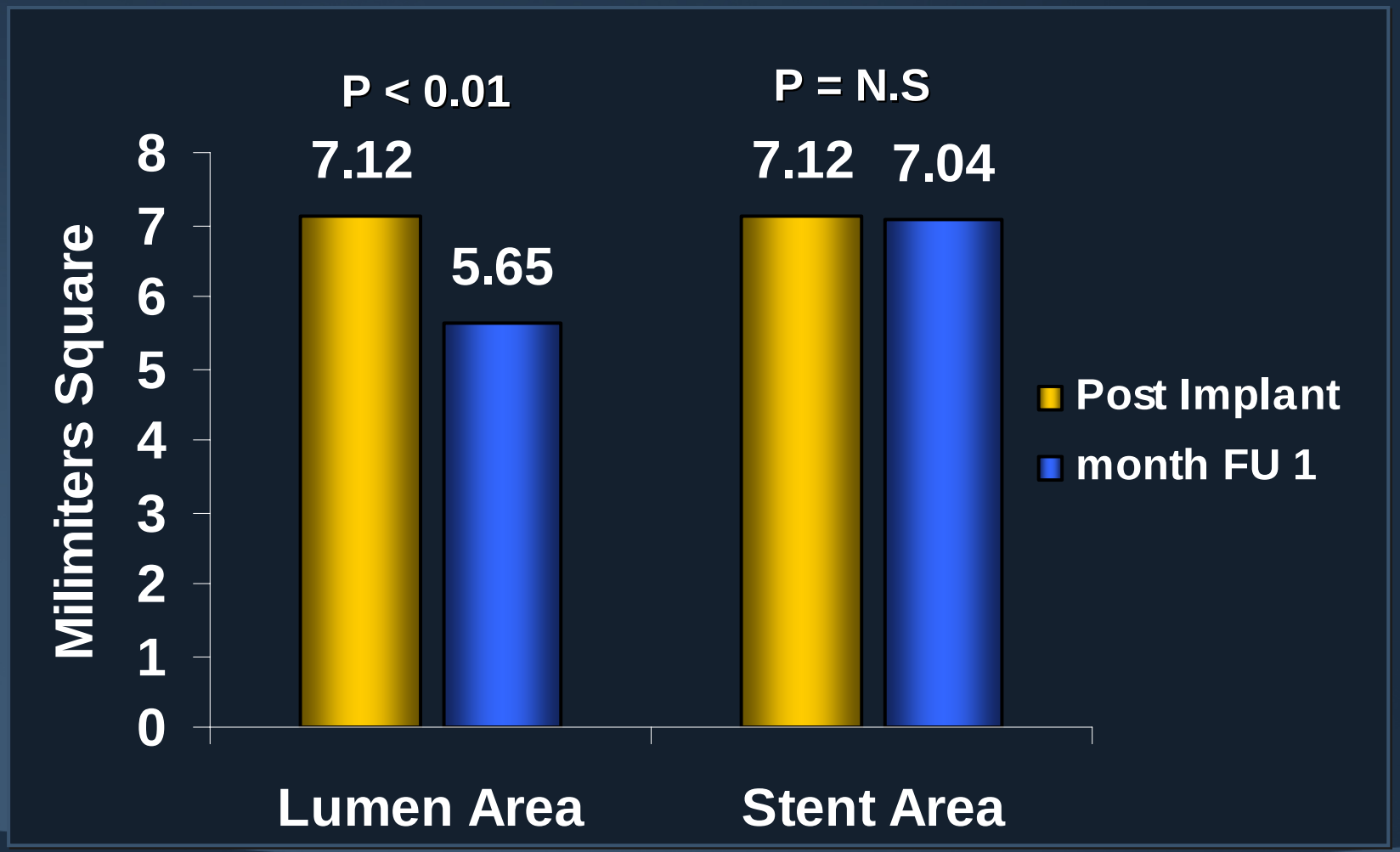
- Devices deployed at 110% of pre-intervention RVD.

- Stented arteries were imaged with angiography and IVUS at baseline, post-implant and after 1 month.

- Optical Coherence Tomography (OCT) at 1 month.

- Pathology analysis at CVPath.

Lumen / Shield Areas at 1-Month: IVUS Overexpansion Analysis



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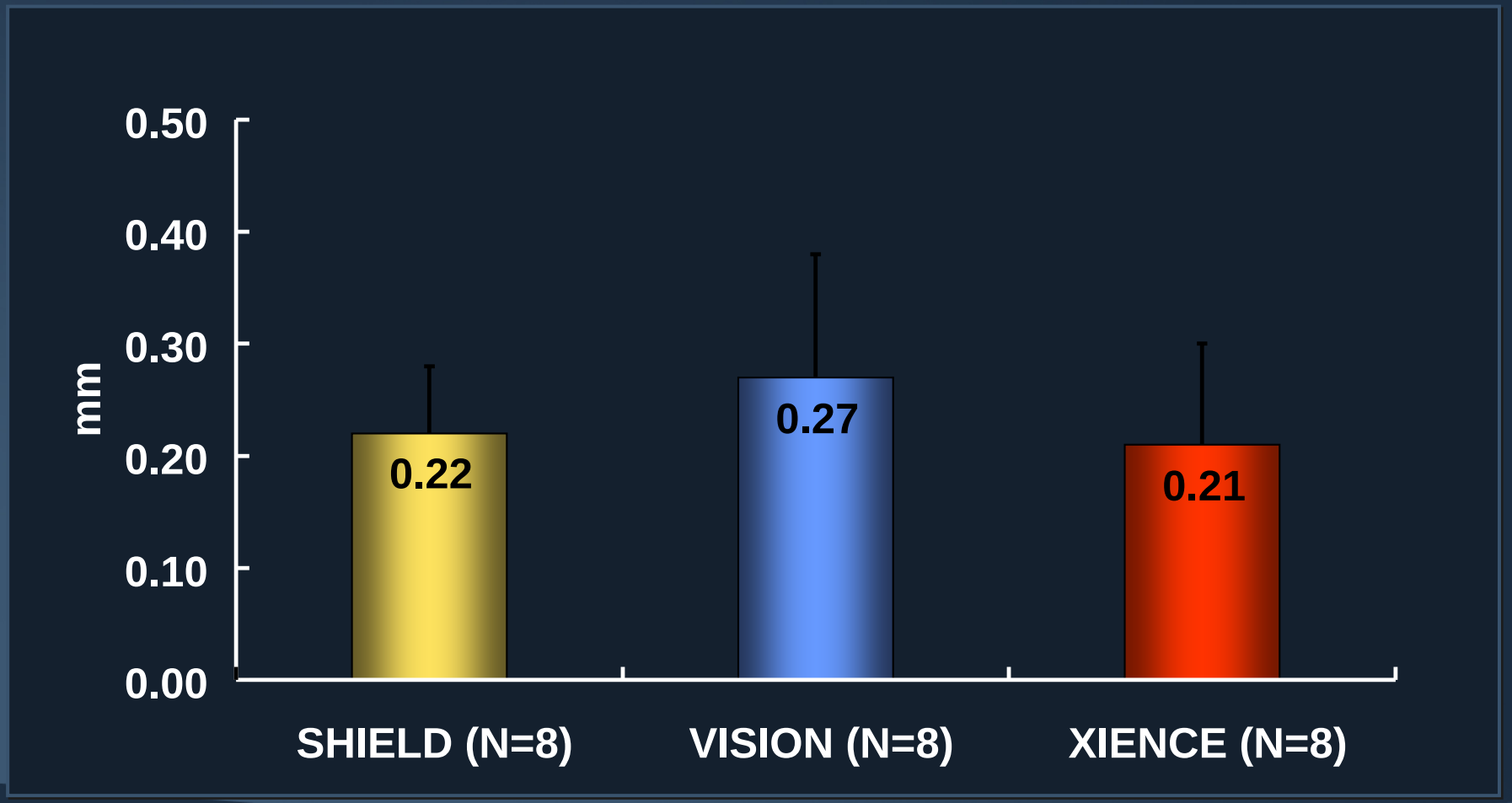
Average Calculated Neointimal Thickness at 1 month by IVUS



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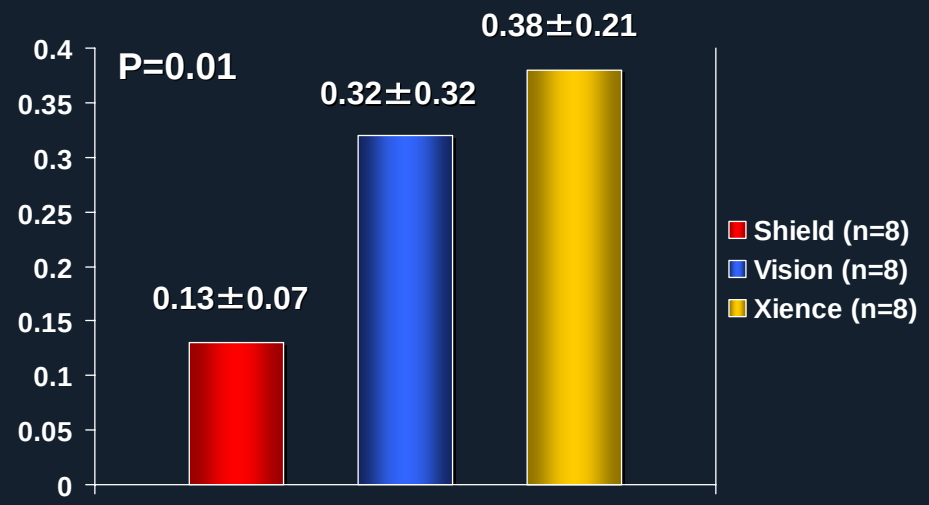
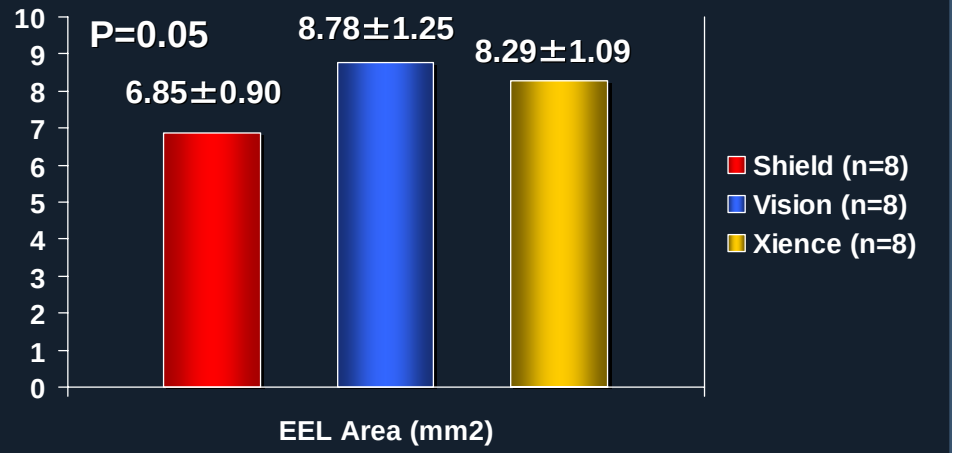
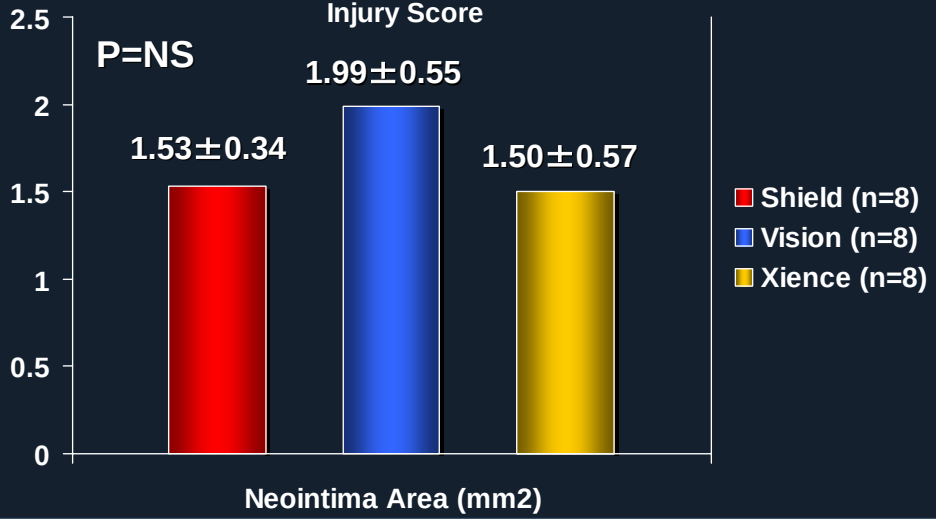
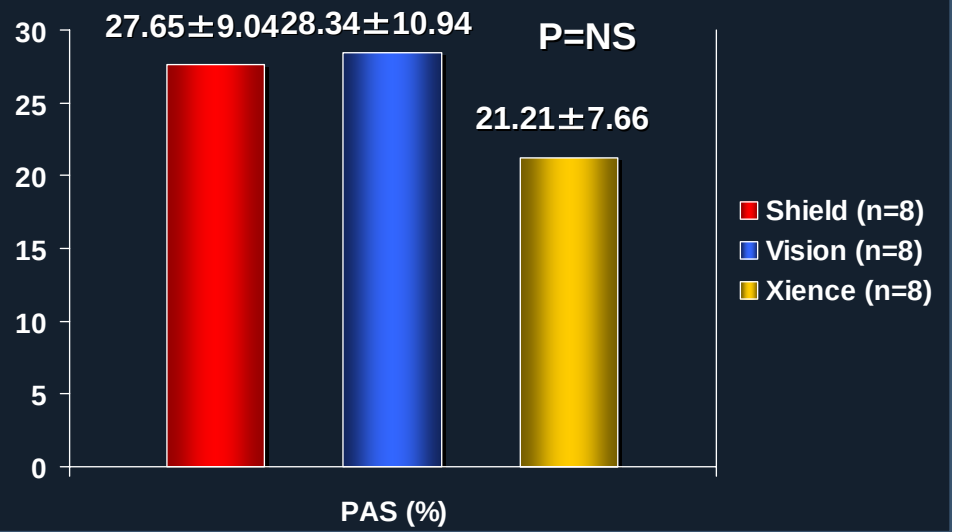
Histological Data at 28 Days









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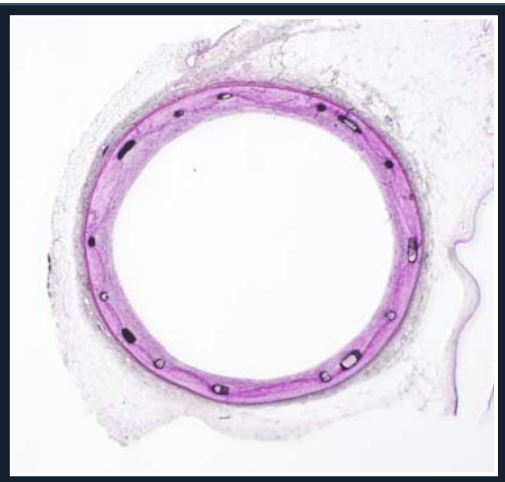
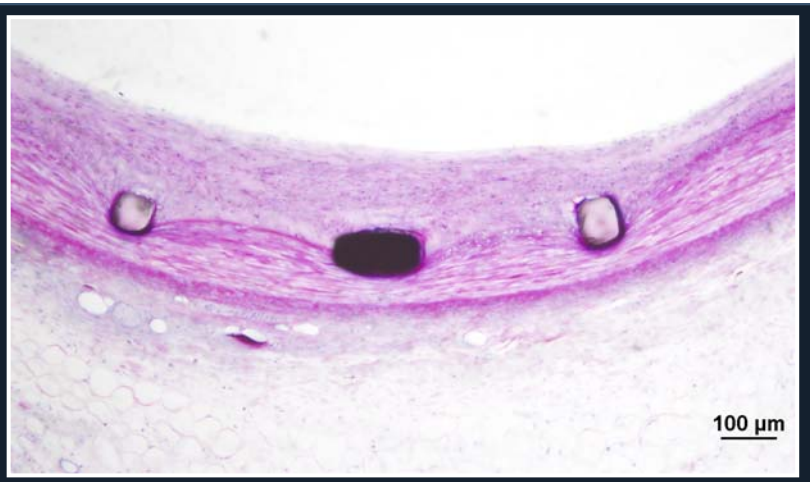
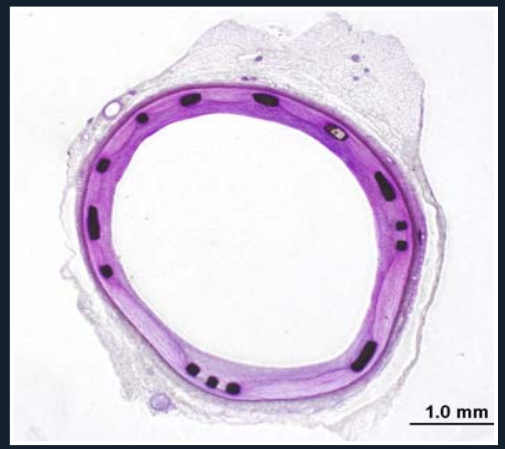
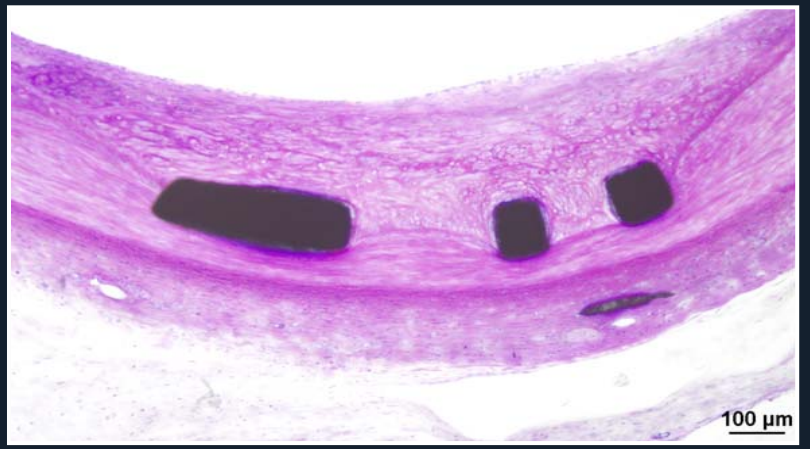
CV18925 107
RCA mid
Shield



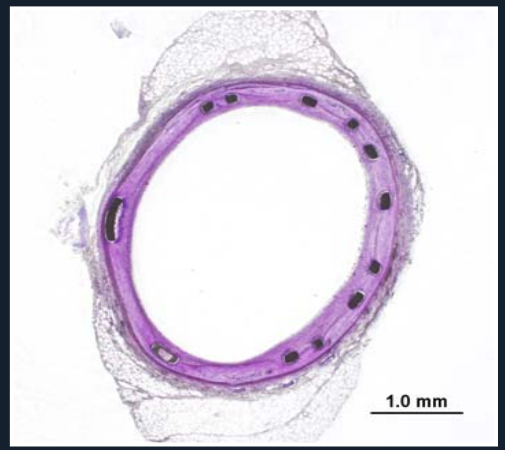


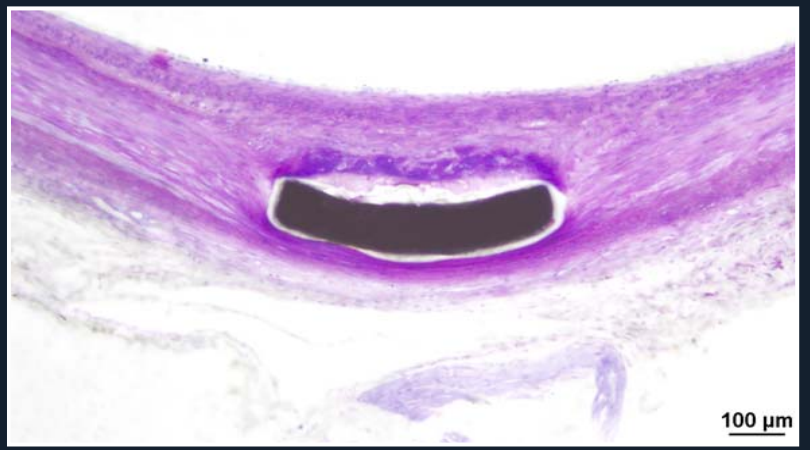
CV18932 114
LAD mid
Vision





CV18928 110
RCA mid
Xience





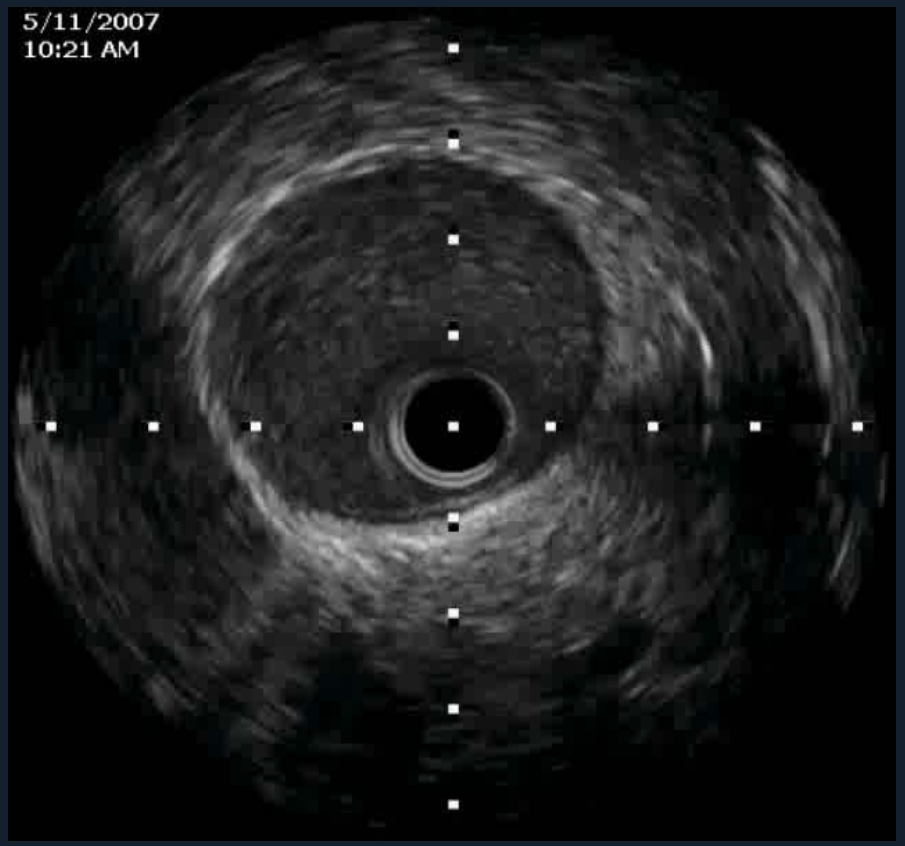
Long Term Porcine Data

90-Day GLP – QCA Data

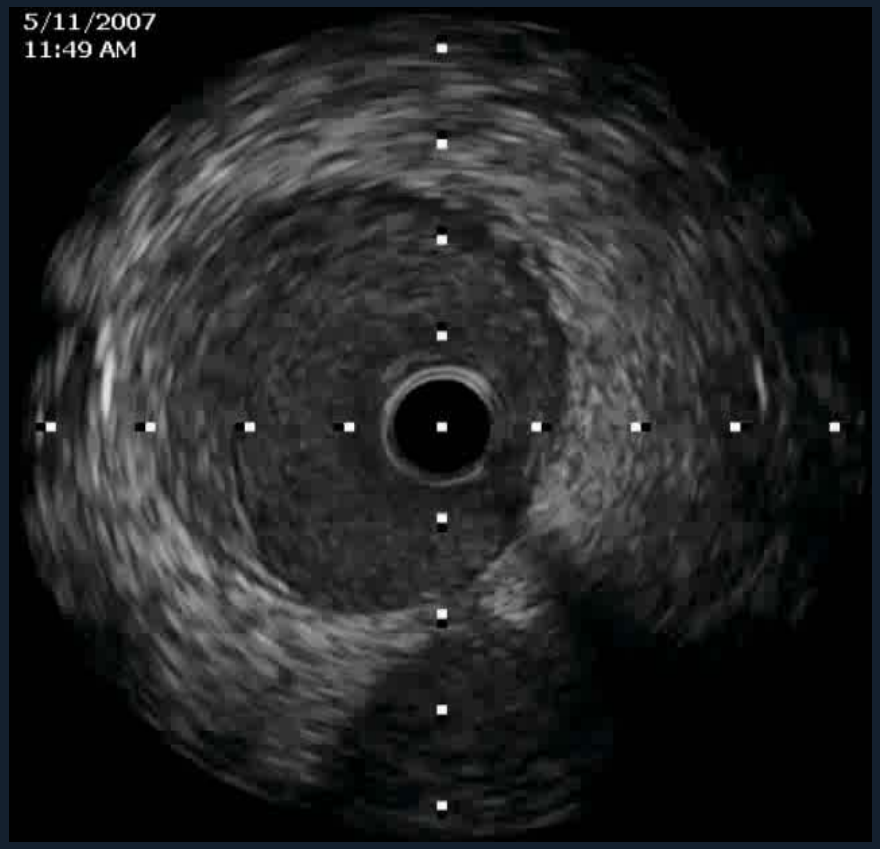
	Post-Implant				90 Day Follow-up		
	Reference Vessel Diameter (mm)	Minimum Lumen Diameter (mm)	Over –stretch (%)		Minimum Lumen Diameter in segment (mm)	% Diameter Stenosis	Late Loss (mm)
Shield **n=11**	**2.69 ± 0.23**	**2.54±0.30**	**1.09± 0.10**		**2.27± 0.22**	**15.48± 7.89**	**0.44± 0.32**
Vision **N=11**	**2.64± 0.19**	**2.45±0.18**	**1.14± 0.06**		**2.26± 0.33**	**15.94± 11.03**	**0.47± 0.34**

Evaluation of the vProtect Vascular Shield Mechanics on the LDLr(-) Swine

Baseline



Post-Shield



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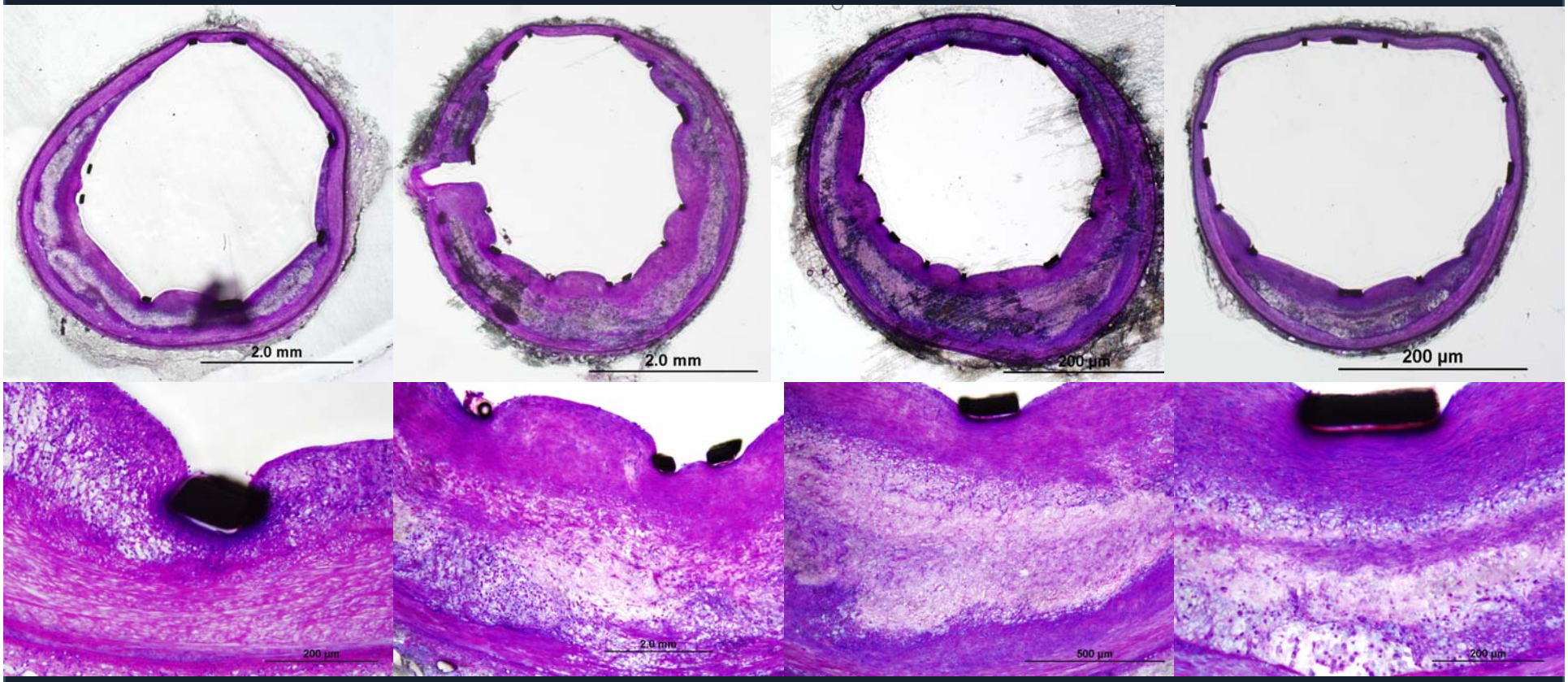
Evaluation of the vProtect Vascular Shield Mechanics on the LDLr(-) Swine



Granada JF, Kaluza GL, Kolodgie F, Virmani R

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vProtect Luminal Shield: Study Design

Non-randomized 30 patients study
Consecutive enrollment
2 OUS centers
10 to 20 patients/center

General inclusion criteria
- Symptomatic CAD undergoing PCI

Angiographic Inclusion Criteria
- Single *de novo* lesion: ≥50% DS by QCA
- IVUS: minimal calcification
- RVD 2.75 – 3.5 mm, LL ≤ 20 mm

Exclusion Criteria
- Known allergy or sensitivity to Nitinol
- Contraindication to anticoagulants
- Major surgery within 30 days
- Severe calcification by IVUS
- Anatomical exclusion criteria

PRIMARY ENPOINT
- Post-procedural DS ≤30%
- IVUS MLA ≥ 4 mm^2
- In-hospital through 30 days MACE*

SECONDARY ENDPOINT
- 9 month angiographic restenosis
- 9 month TLR, TVR, TVF
- 9 month MACE*

*MACE: Death, MI, stent thrombosis, TLR.

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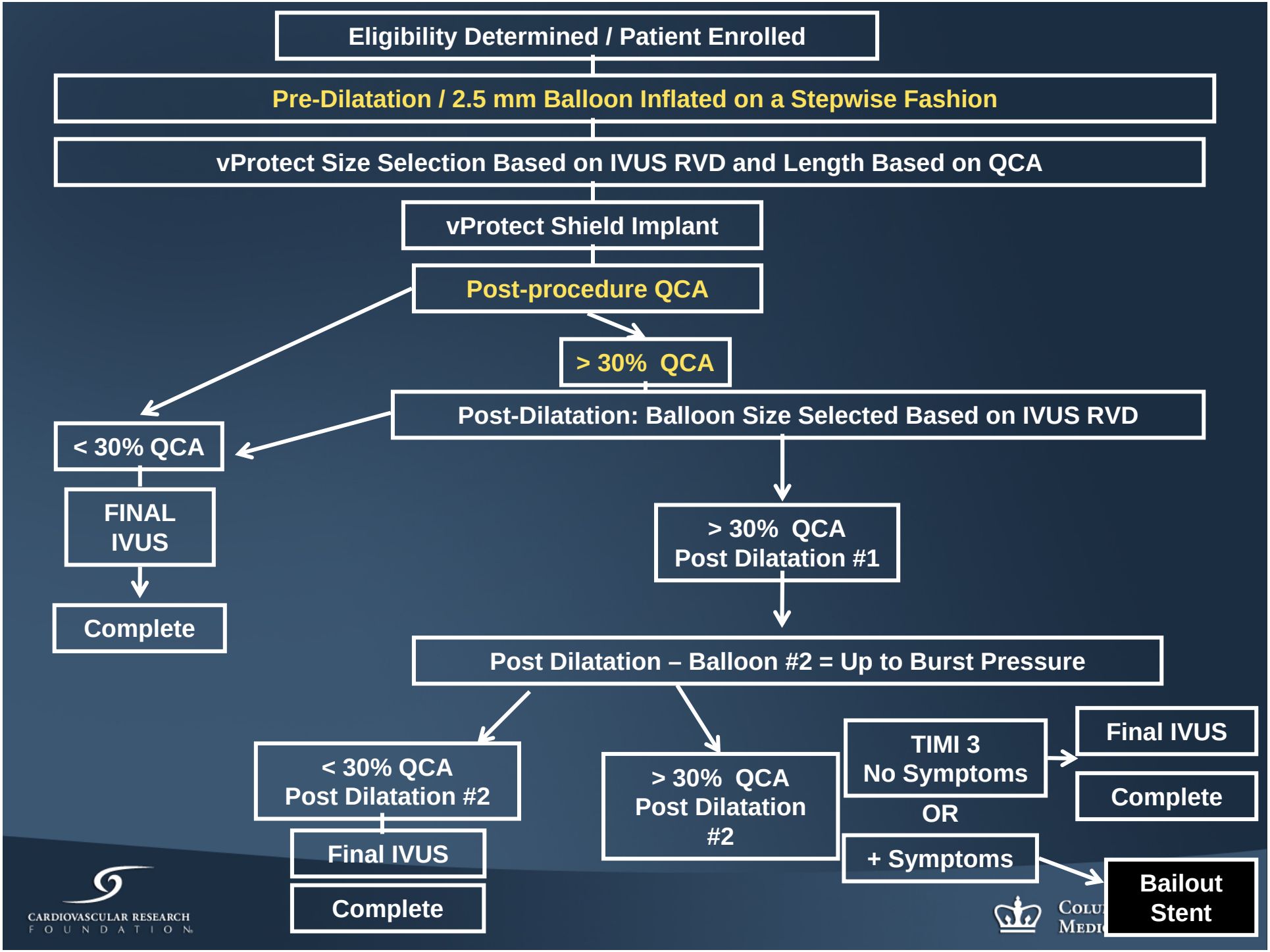
Eligibility Determined / Patient Enrolled
Pre-Dilatation / 2.5 mm Balloon Inflated on a Stepwise Fashion
vProtect Size Selection Based on IVUS RVD and Length Based on QCA
vProtect Shield Implant
Post-procedure QCA
> 30% QCA
Post-Dilatation: Balloon Size Selected Based on IVUS RVD
< 30% QCA
FINAL IVUS
Complete
> 30% QCA Post Dilatation #1
Post Dilatation – Balloon #2 = Up to Burst Pressure
< 30% QCA Post Dilatation #2
Final IVUS
Complete
> 30% QCA Post Dilatation #2
TIMI 3 No Symptoms
OR
+ Symptoms
Final IVUS
Complete
Bailout Stent
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j2

First in Human Study: Study Design of the vProtect Luminal Shield

Characteristic	All Patients N=30
Age (mean yrs.)	59.0 ± 7.7
Gender	Male: 17 (57%) Female: 13 (43%)
Diabetes Mellitus (%)	37%
Hypertension (%)	70%
Previous MI (%)	33%
Coronary Artery Disease	1-Vessel 11/30 (37%) 2-Vessel 14/30 (47%) 3-Vessel 5/30 (17%)

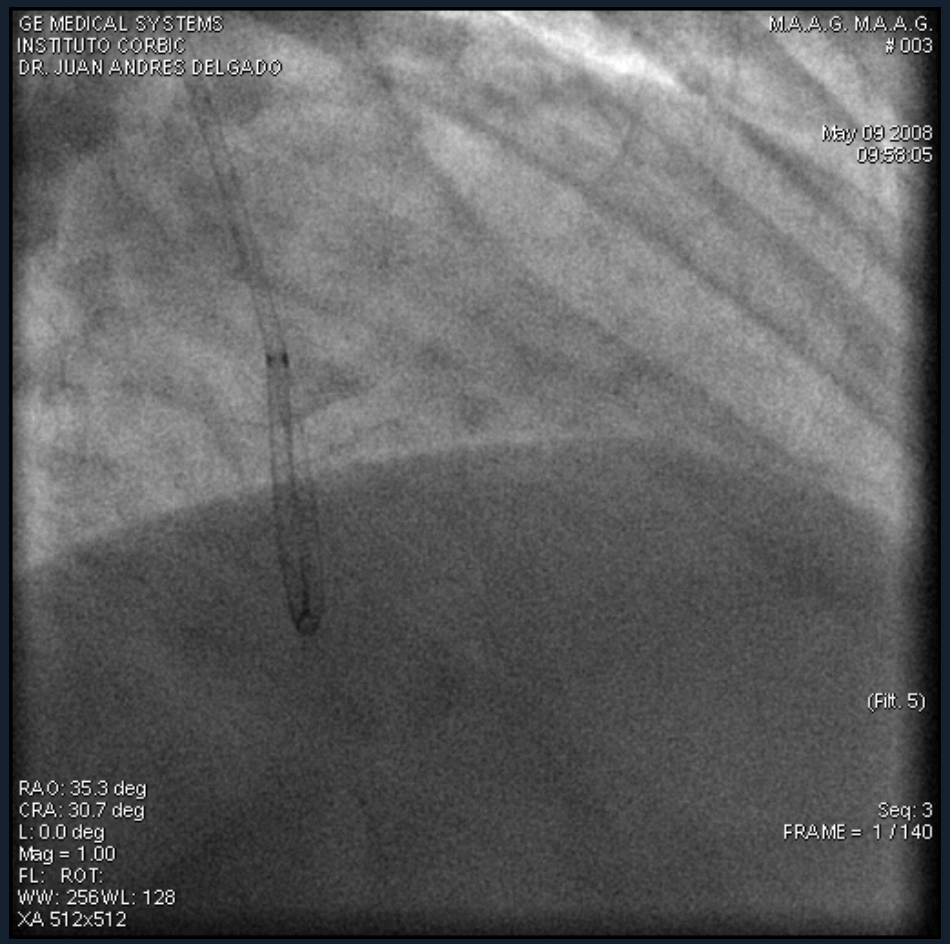
j2 Can we add more data, like treated vessel (culprit), timi flow, etc...I would like to make this table to look more robust.
jgranada, 2009-03-17

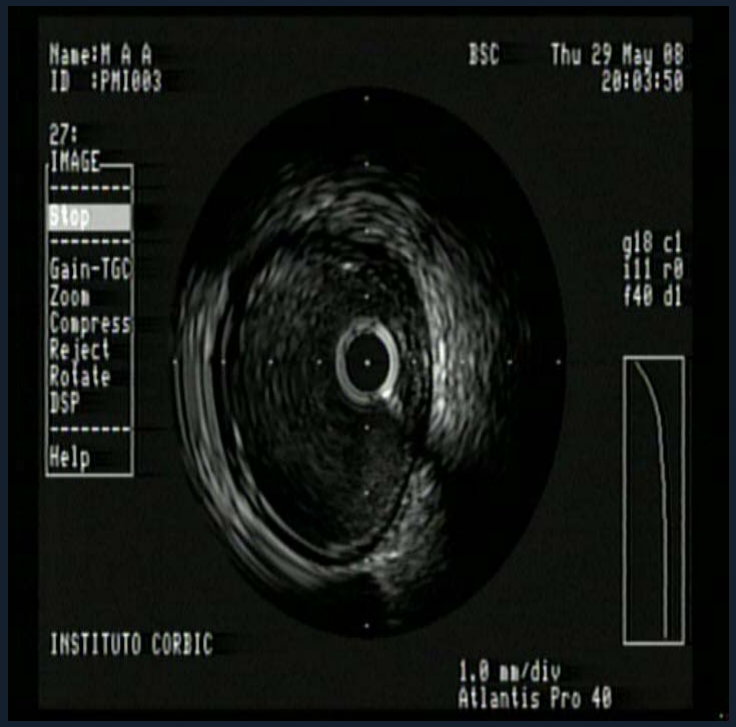
First in Human Study: Study Design of the vProtect Luminal Shield

Variable	All Patients (N=28)
Reference Vessel Diameter	3.05 ± 0.22mm
Diameter Stenosis QCA (mean)	Baseline TV DS: 59.4 ± 9.2% Post-Shield DS: 35.9 ± 8.2% *Post-Dilatation DS: 9.23% ± 5.54*
#Pts w/ DS<20% (on-line QCA)	2 (7.14%)
#Pts w/ Single Procedure Dilatation Resulting in DS<30%	28 (100%)
Dilatation Pressure (mean)	Pre: 7.8±2.7ATM (6-16) Post: 9.46±3.56 ATM (3-18)
Mean Luminal Area (IVUS)	Pre: 2.4±0.64mm^2 Post: 4.7±0.98mm^2
Pts. Requiring Bailout Procedure	0

ACS – Anterior Wall Ischemia

LAD at Bifurcation Point





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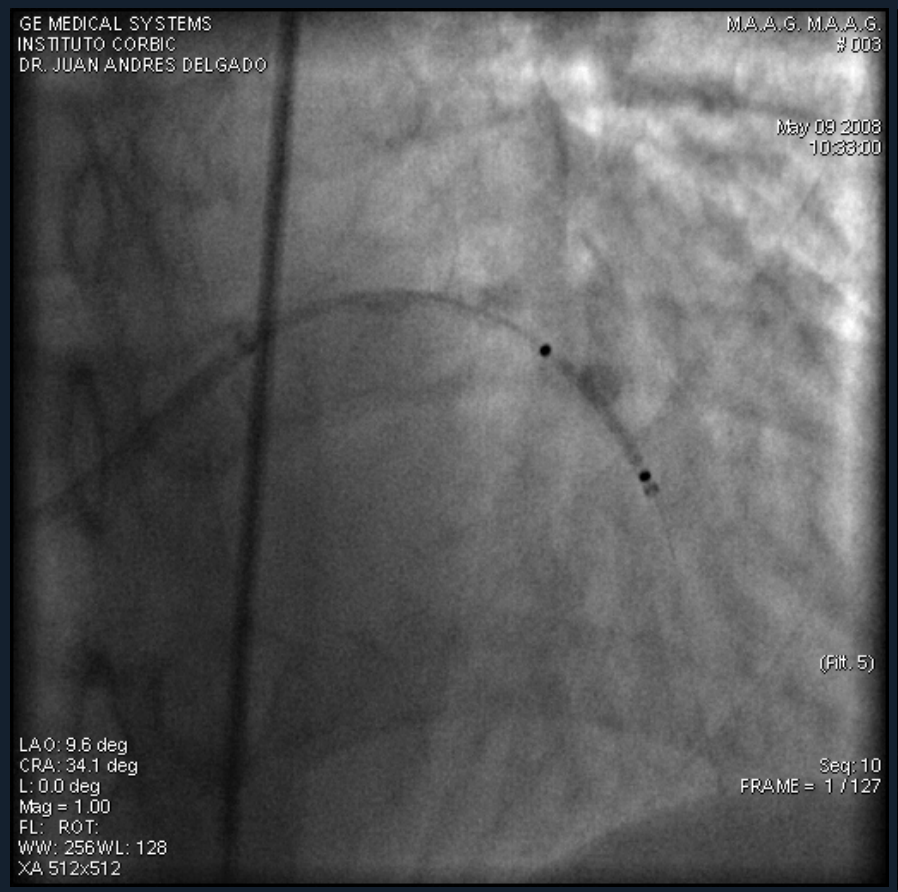
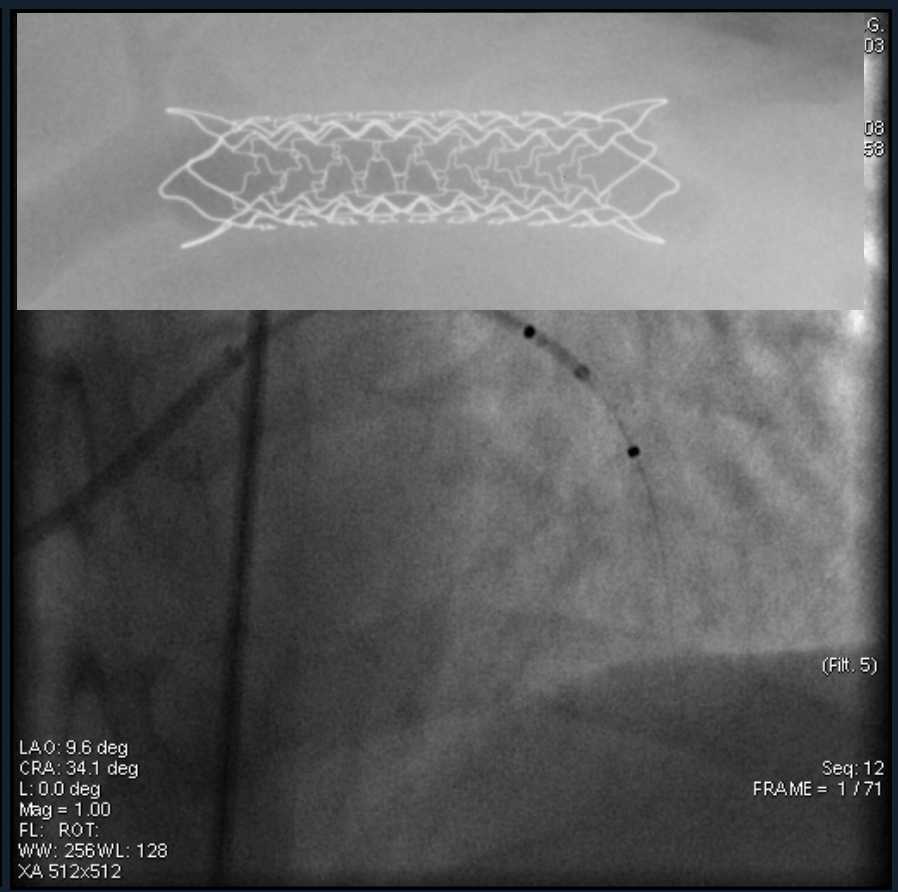
ACS – Anterior Wall Ischemia

LAD – Pre-Dilatation and Positioning





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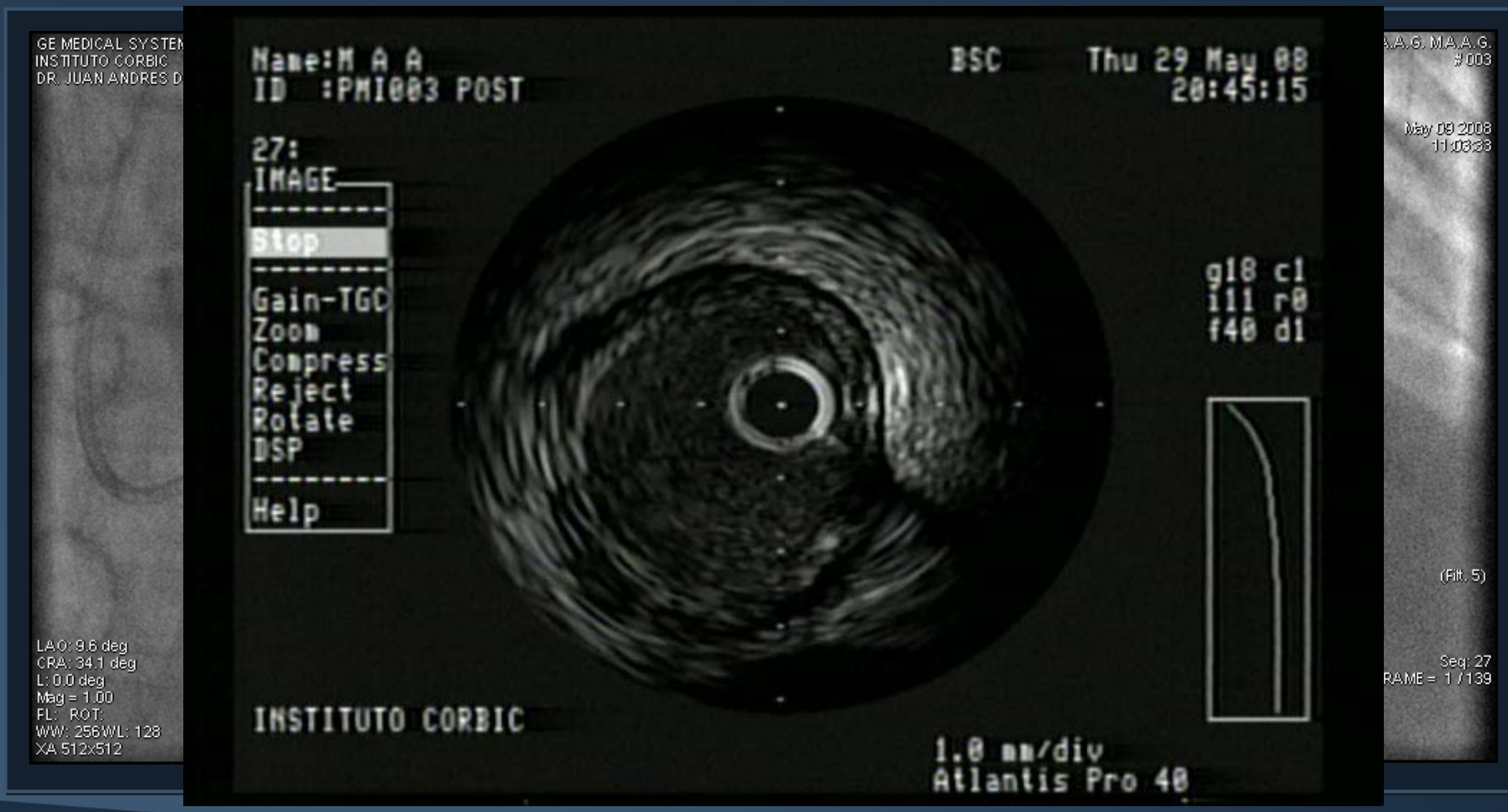
ACS – Anterior Wall Ischemia
Following Deployment and Post Balloon



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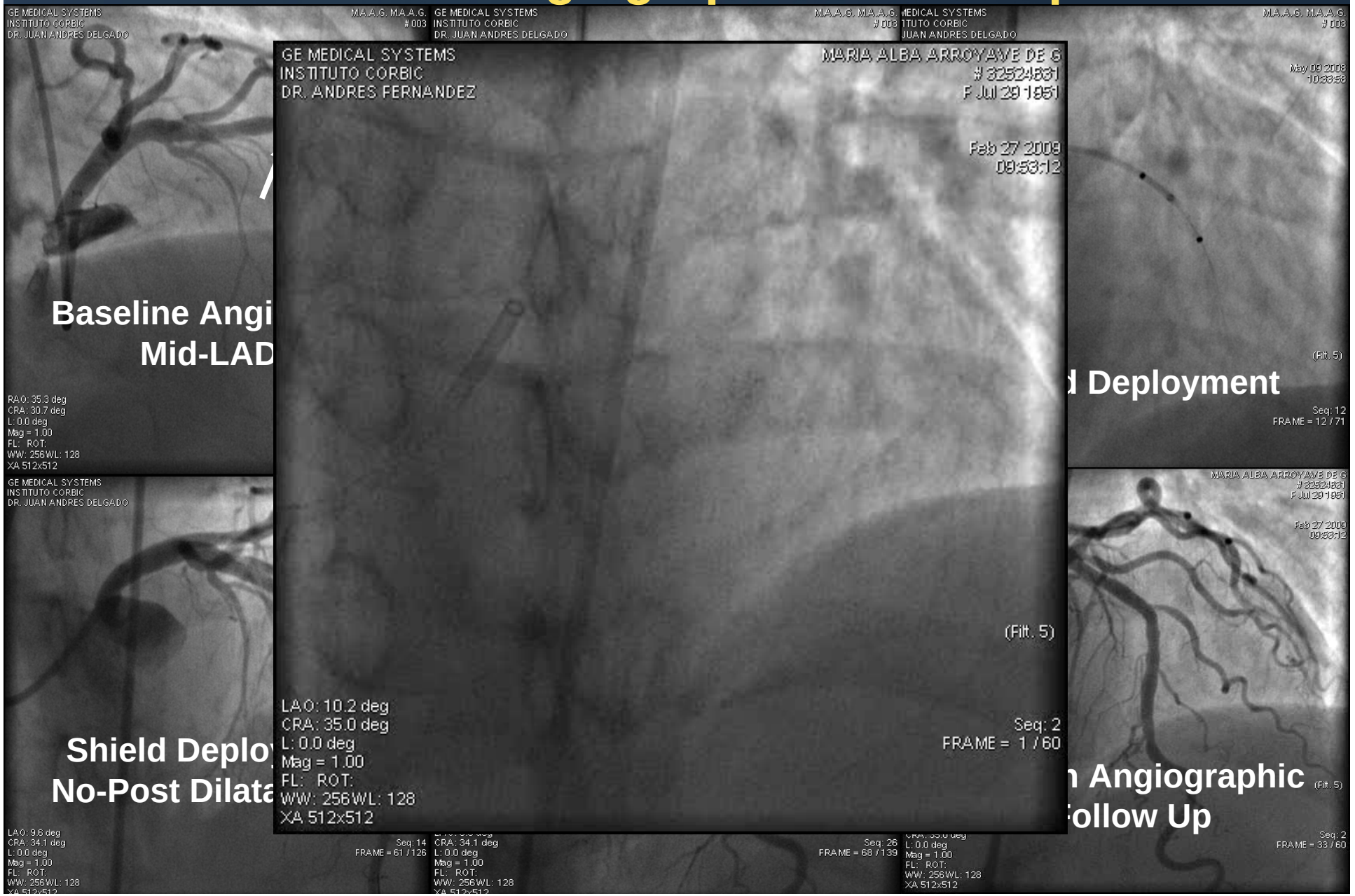
ACS Patient: Shield in mid-LAD. Post-Implantation & 9 Month Angiographic Follow-Up.



Summary of Clinical Outcomes

Variable	All Patients (n=30)
Intra-Procedural Follow Up	30/30 (100%)
#Pts achieved <30% DS post shield implant w/ or w/out post dilatation	30/30 (100%)
Peri-procedural complications	0%
MACE Rate	0%
30 Days Clinical Follow Up	30/30 (100%)
MACE Rate	0%
90 Days Clinical Follow Up*	30/30 (100%)
180 Days Clinical Follow Up*	17/28 (60%)
9-Month Angiographic Follow Up*	5/28 (18%)

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**** By second week of May***

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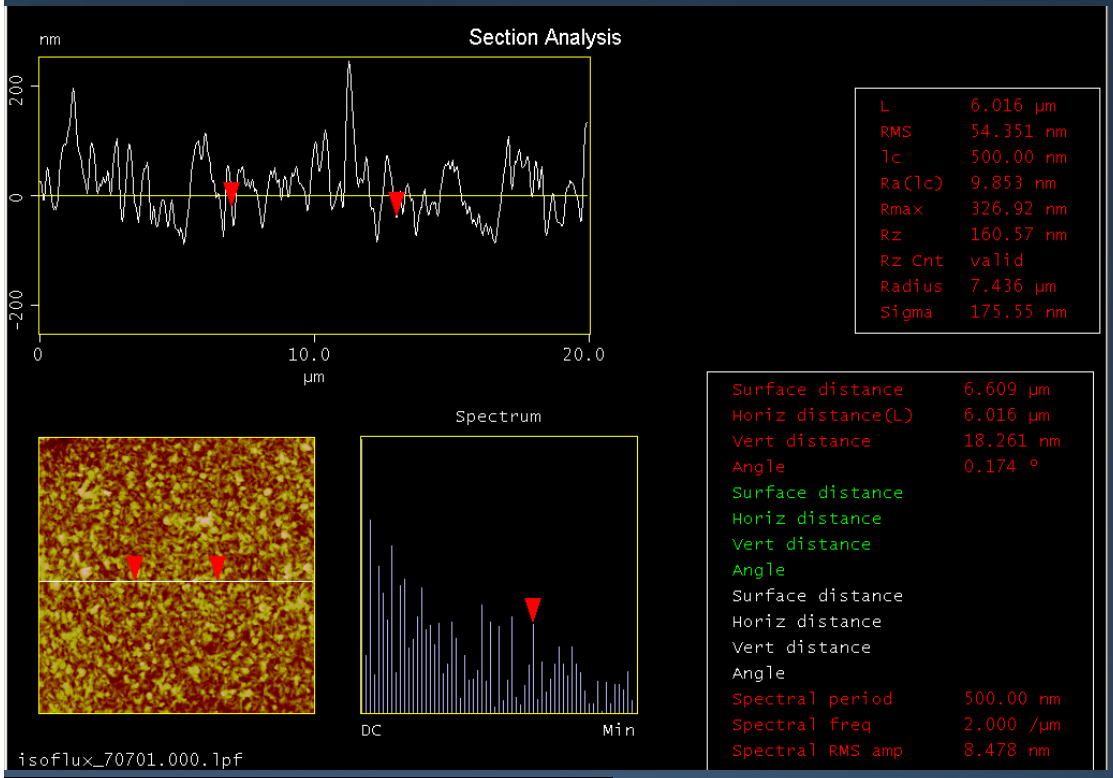
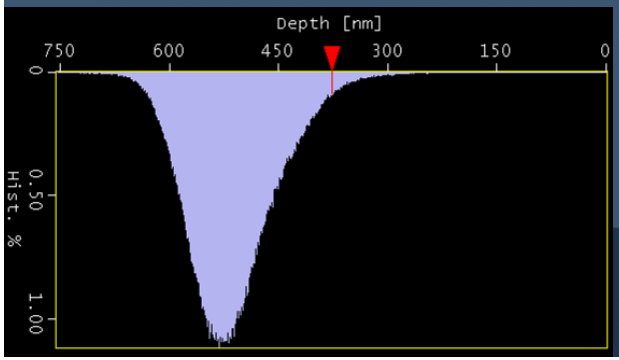
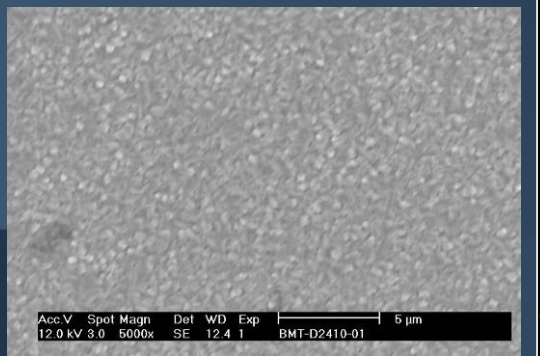
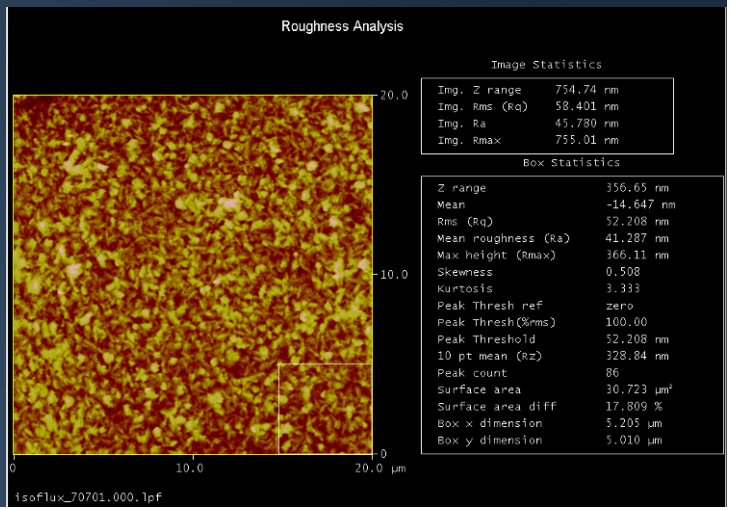
Second Generation vProtect: Nanotextured Surfaces

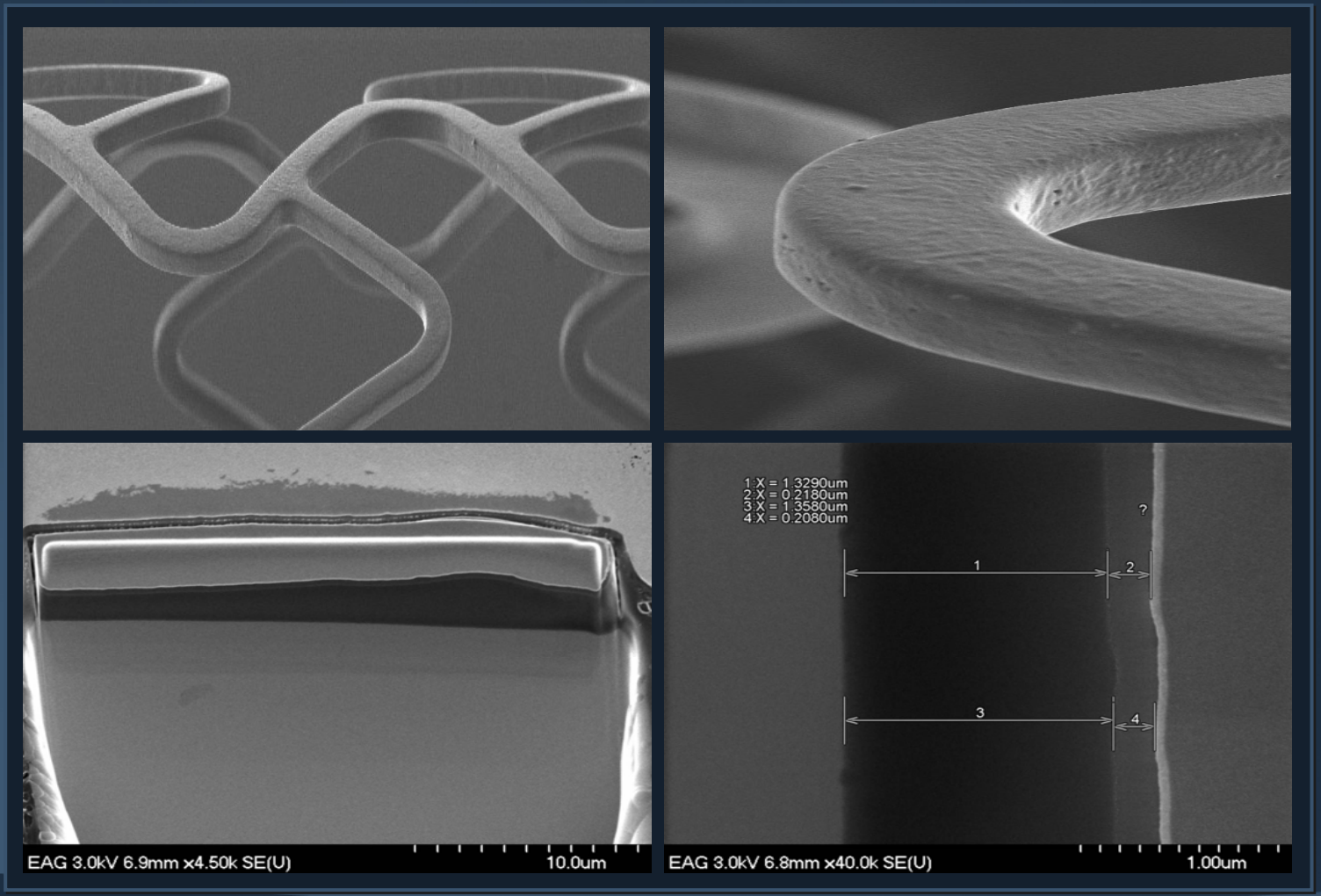








Second Generation vProtect: Biological Coating



CARDIOVASCULAR RESEARCH FOUNDATION

COLUMBIA UNIVERSITY MEDICAL CENTER

Conclusions (1)

- A self-expandable “vascular shield” has been successfully developed aiming to match the mechanical forces needed to “compress” the necrotic core avoiding fibrous cap rupture.
- Preliminary animal experience suggest that this device achieves smaller lumen areas, significantly less degree of vascular injury and comparable degree of neointimal formation compared with state of the art vascular devices.
- In animals vascular shields have demonstrated favorable biocompatibility with no marked difference to control stents in the qualitative or quantitative indices of healing of the arterial injury, foreign body reaction and endothelialization.
- Diseased animal models suggest that the vascular shield could compress and remodel the necrotic core, maintaining acceptable luminal gain and not causing additional vascular injury.

Conclusions (2)

- The implantation of a low pressure self-expandable scaffolding (vPredict™ Luminal Shield) is feasible and safe in patients with obstructive CAD achieving an adequate luminal gain and complete apposition after implantation.
- Complete device apposition is the rule, however, smaller lumen areas are consistently found.
- The primary safety endpoint was achieved. Thirty days clinical follow up demonstrated that the early safety profile is maintained.
- Due to its intrinsic mechanical properties, this device may improve the outcomes of PCI by inducing less injury at the time of implantation. Thus, this device could be indicated in specific patient subsets such as acute coronary syndromes.