



## ANGIOPLASTY SUMMIT **TCTAP 2011**

TRANSCATHETER CARDIOVASCULAR THERAPEUTICS ASIA PACIFIC

The Convention Center of Sheraton Grande Walkerhill Hotel, Seoul, Korea



*Evaluation of Effectiveness and Safety of  
**BIOMATRIX (Biolimus A9<sup>®</sup>) StEnt** in  
Patients with **AcUTE** Coronary **SYndrome**;  
A Multicenter, PROSPECTIVE  
OBSERVATIONAL STUDY*

***BEAUTY Study***

**Young Joon Hong, MD**  
on behalf of **BEAUTY Investigators**

# Case I. 59Y/M UAP, HT(+), CAG

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

2011-02-17 오후 3:37:19  
R201102171537083  
2  
2  
1/51

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

2011-02-17 오후 3:37:19  
R201102171537083  
3  
3  
1/59

30.02 RAO  
15.05 CRA

44.97 LAO  
19.97 CRA

**RAO**

**LAO**

**Critical stenosis in from pmLAD to dLM (B2,85%,III) and dLCX (B2,85%,III)**

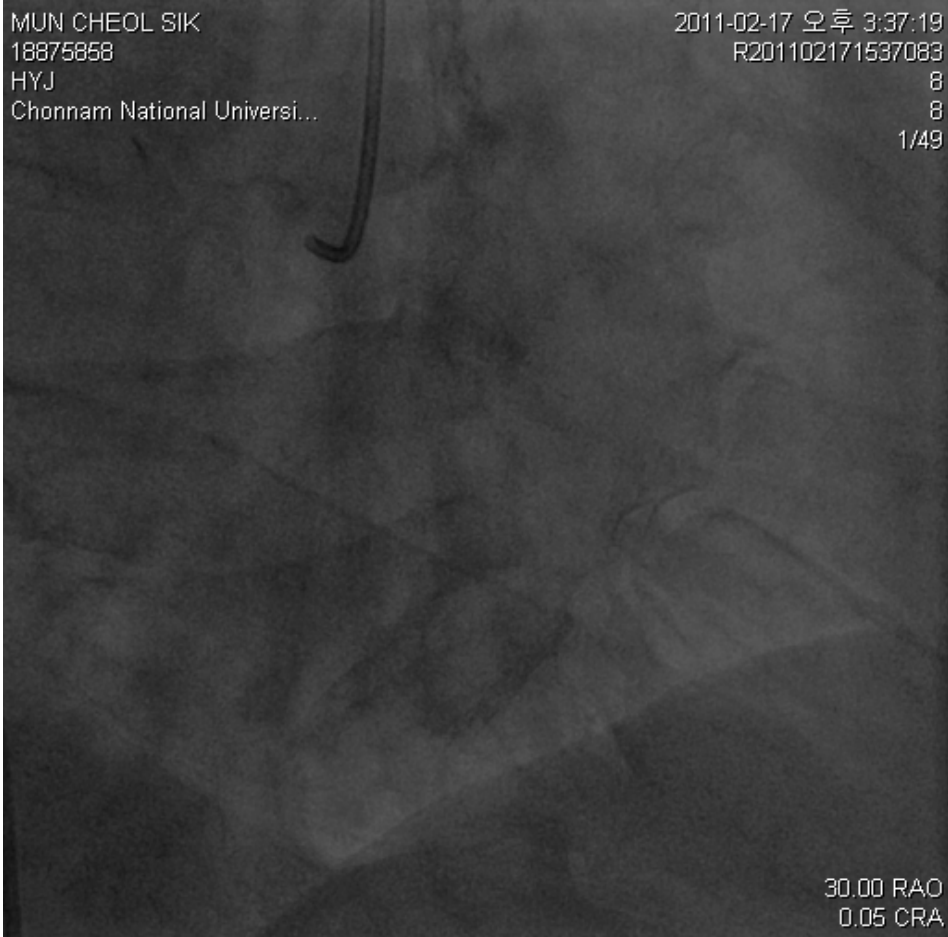
# CAG

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

2011-02-17 오후 3:37:19  
R201102171537083  
8  
8  
1/49

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

2011-02-17 오후 3:37:19  
R201102171537083  
7  
7  
1/62



30.00 RAO  
0.05 CRA



45.00 LAO  
0.03 CAU

**RAO**

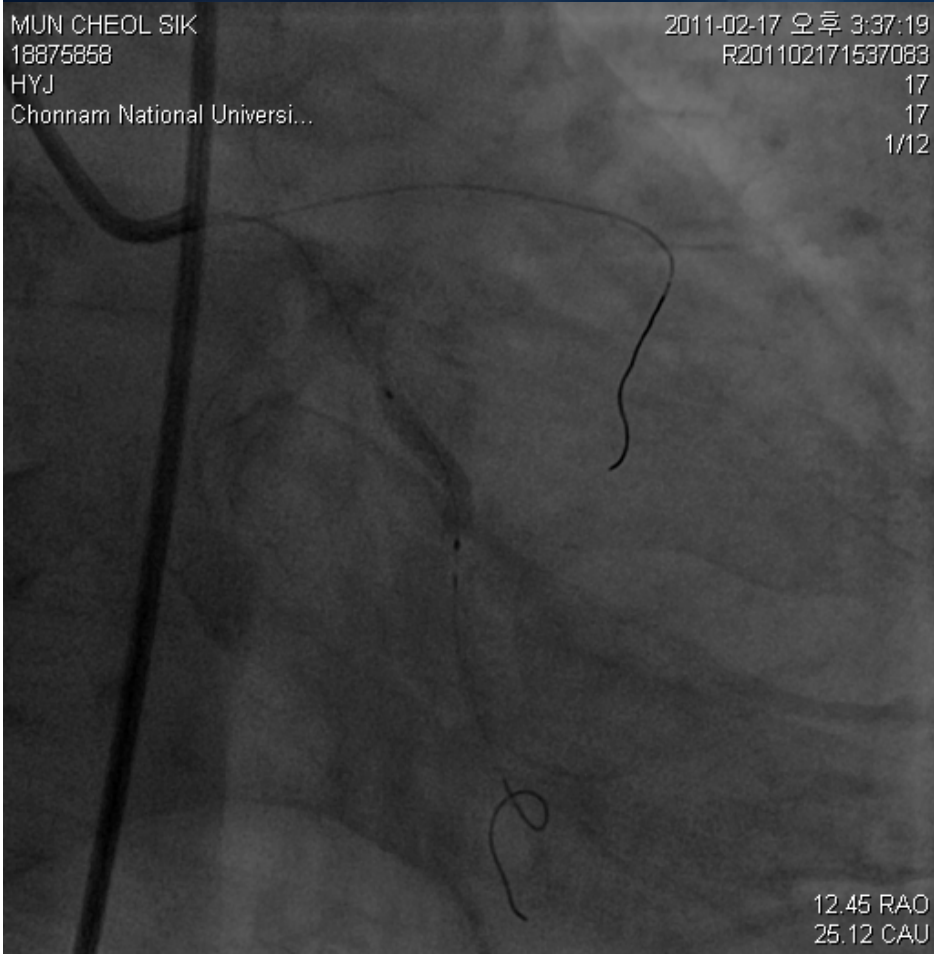
**LAO**

**No significant stenosis in RCA**

# PCI for dLCX

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

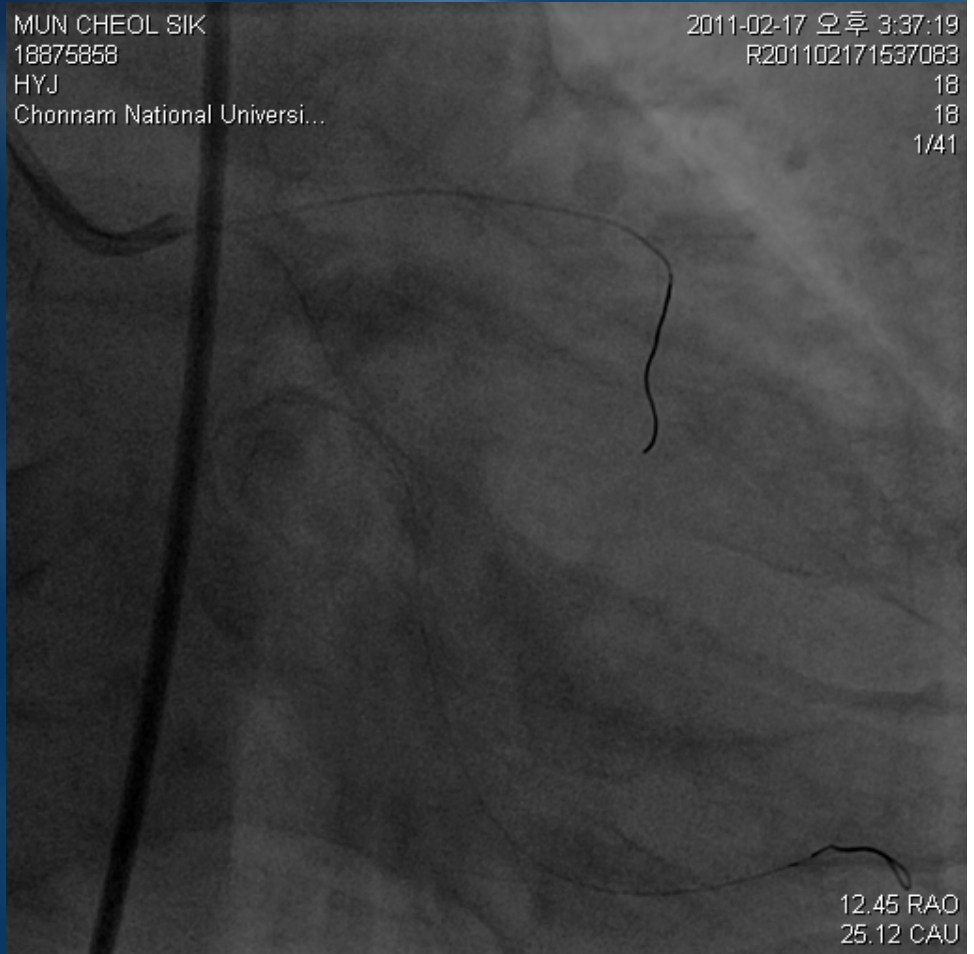
2011-02-17 오후 3:37:19  
R201102171537083  
17  
17  
1/12



**RAO**

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

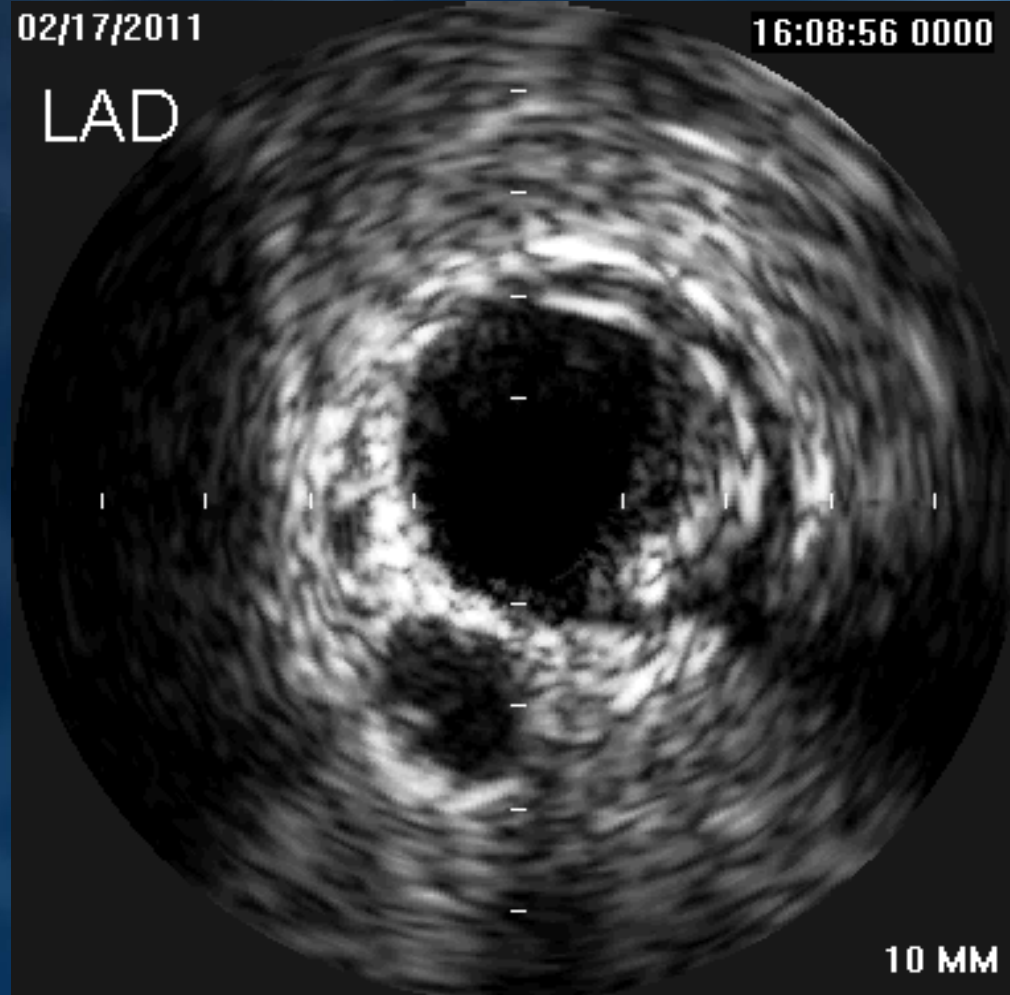
2011-02-17 오후 3:37:19  
R201102171537083  
18  
18  
1/41



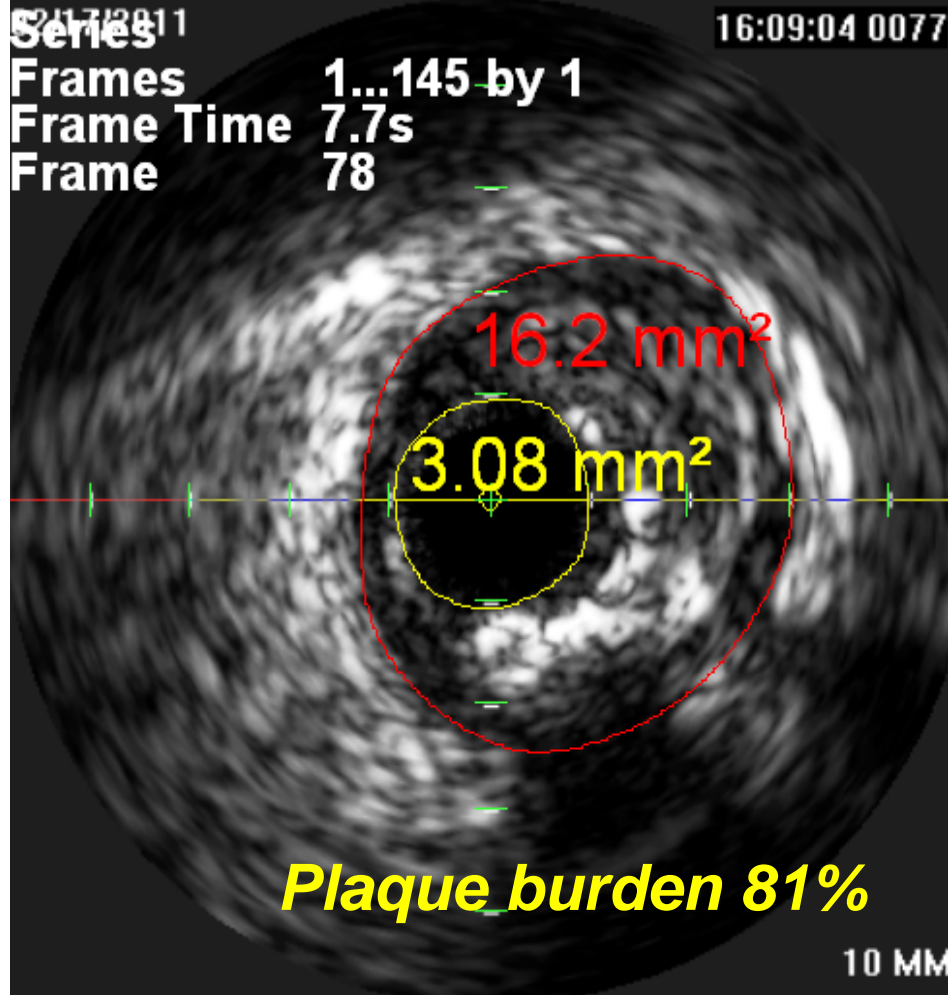
**RAO**

**3.0X18mm BIOMATRIX stent**

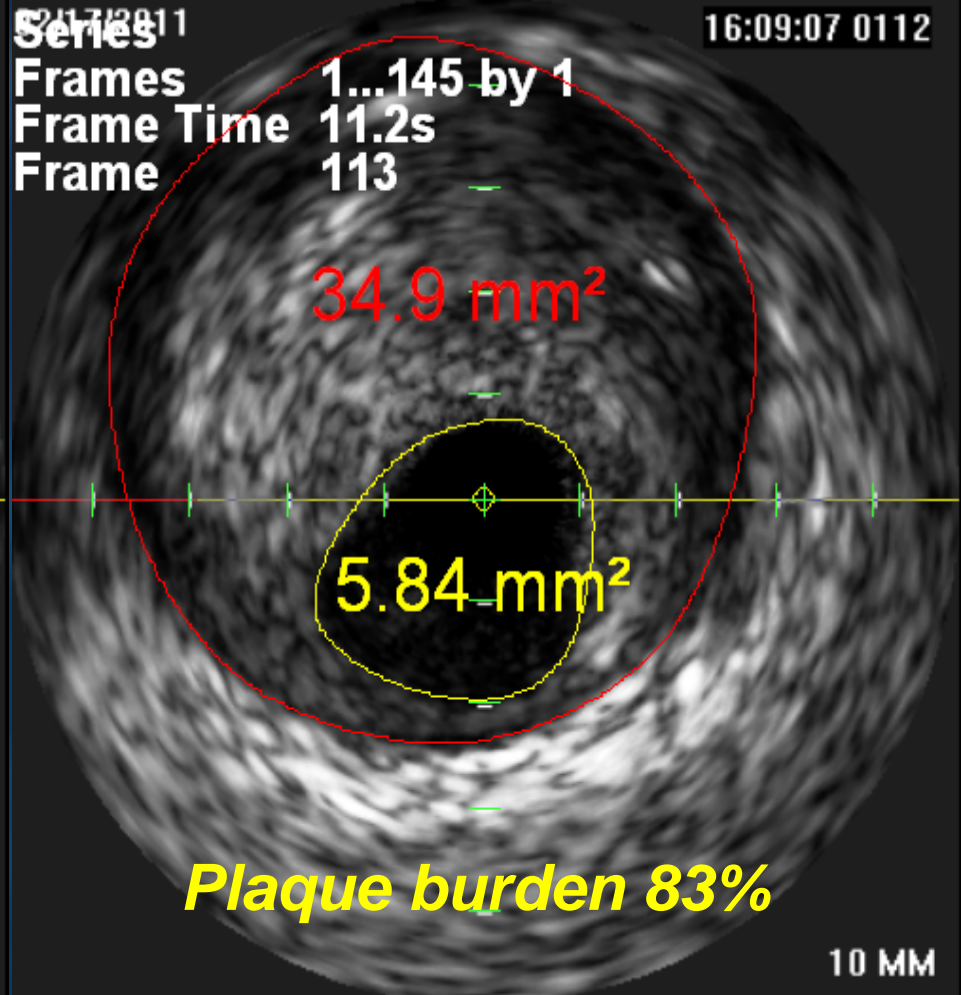
# Pre-PCI LAD, LM IVUS



# MLA Site



*LAD*



*LM*

# PCI for LM, LAD

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

2011-02-17 오후 3:37:19  
R201102171537083  
22  
22  
1/9

MUN CHEOL SIK  
18875858  
HYJ  
Chonnam National Universi...

2011-02-17 오후 3:37:19  
R201102171537083  
30  
30  
1/52

26.16 RAO  
24.04 CAU

12.75 RAO  
25.02 CAU

**RAO**

**RAO**

**3.5X23mm (LM), 3.0X18mm (LAD) BIOMATRIX stent**

# Post-PCI LAD, LM IVUS

02/17/2011

16:39:40 0042

LM STENT

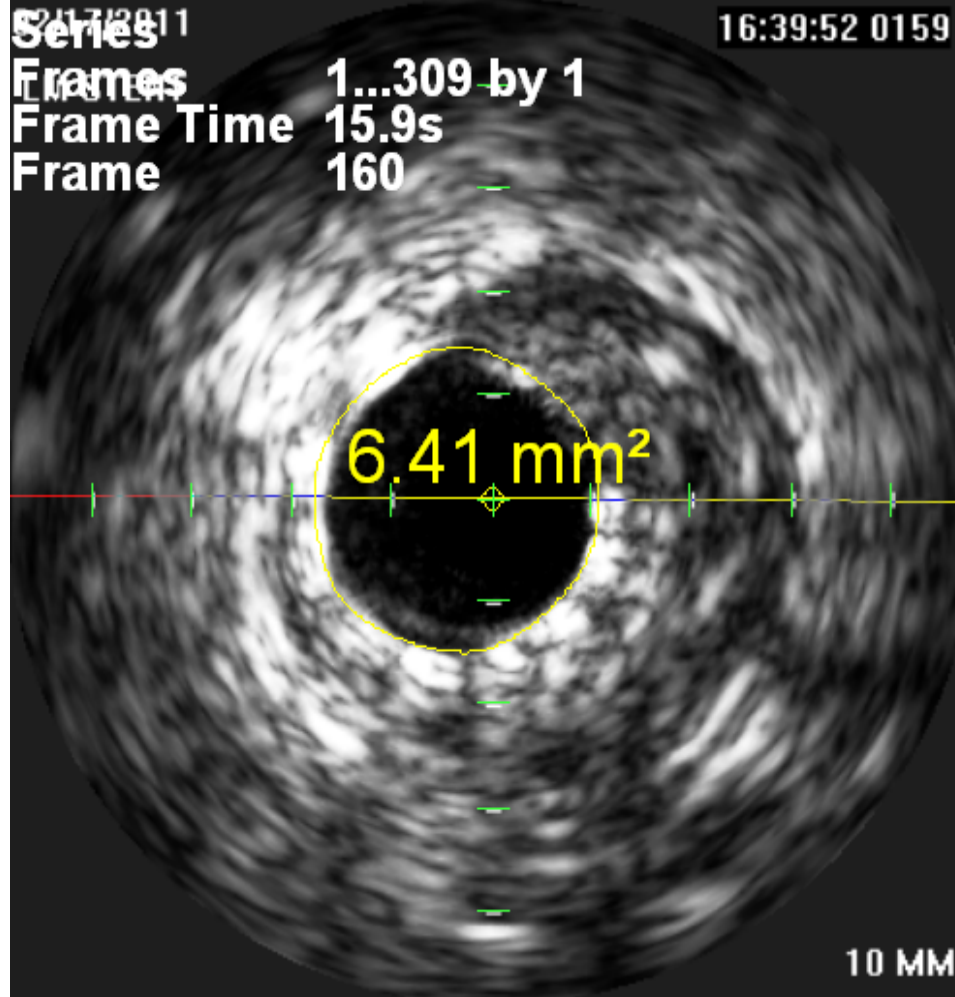


10 MM



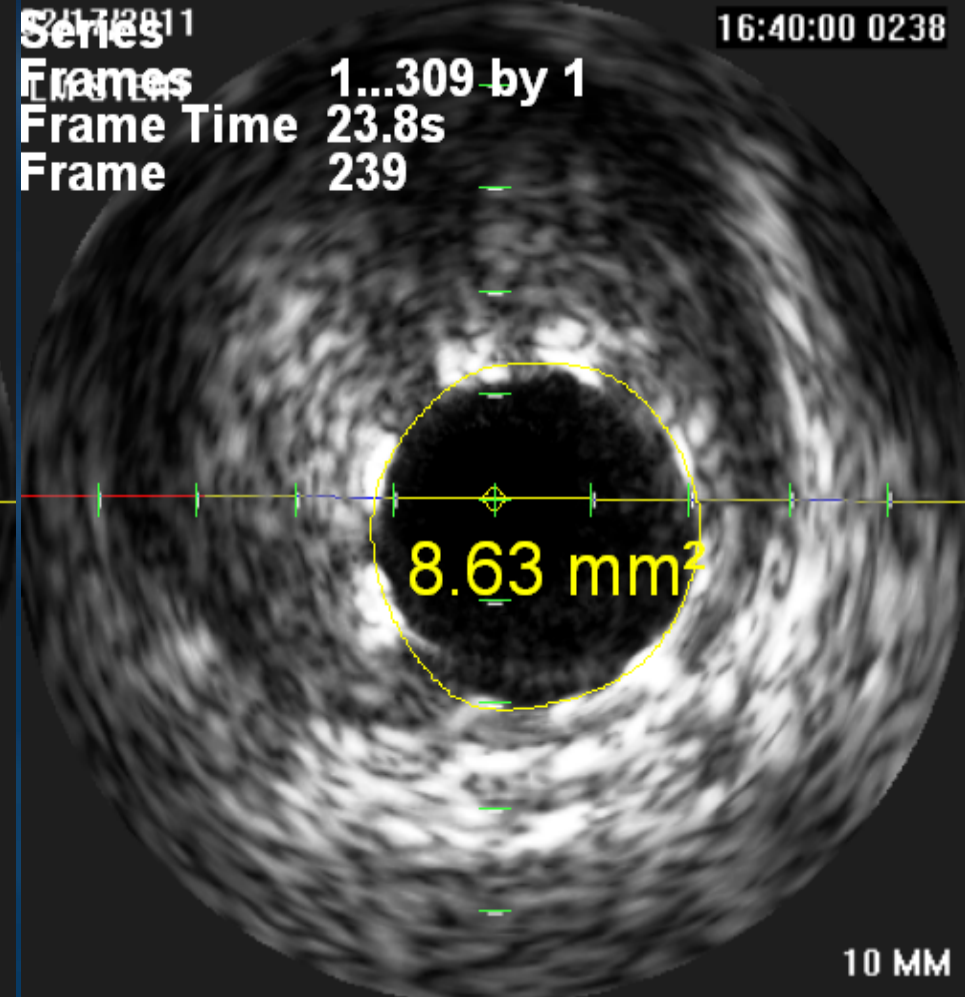
# Post-PCI MSA Site

Series 217/2811 16:39:52 0159  
Frames 1...309 by 1  
Frame Time 15.9s  
Frame 160



*LAD*

Series 217/2811 16:40:00 0238  
Frames 1...309 by 1  
Frame Time 23.8s  
Frame 239



*LM*



# BEAUTY-Study

Evaluation of Effectiveness and Safety of BIOMATRIX (Biolimus A9®) StEnt  
in Patients with AcUTE Coronary SYndrome



WELCOMING A MEMBER

ID

PASSWORD

Login

아이디 저장

Copyright 2009 T&W Software. All rights reserved. [ [Bookmark this site](#) ]

# BEAUTY-Study

Study Status

Home

New Case

Subject List

Statistics

## Study Status

그래프

Report

Status

작성도

Excel

| 번호  | 병원명      | Investigator | Week | Month | Total | Excluded | Last Date  |
|-----|----------|--------------|------|-------|-------|----------|------------|
| 01  | 전남대병원    | 정명호          | 4    | 9     | 18    | 0        | 2011-04-21 |
| 02  | 조선대병원    | 고영엽          | 0    | 0     | 0     | 0        |            |
| 03  | 해운대백병원   | 김두일          | 0    | 0     | 0     | 0        |            |
| 04  | 중앙대병원    | 김상욱          | 0    | 0     | 0     | 0        |            |
| 05  | 경희대병원    | 김원           | 0    | 0     | 0     | 0        |            |
| 06  | 고대구로병원   | 나승운          | 0    | 0     | 0     | 0        |            |
| 07  | 전주예수병원   | 류제영          | 0    | 0     | 0     | 0        |            |
| 08  | 영남대병원    | 박종선          | 0    | 0     | 0     | 0        |            |
| 09  | 경북대병원    | 박현식          | 0    | 0     | 0     | 0        |            |
| 10  | 건양대병원    | 배장호          | 0    | 0     | 0     | 0        |            |
| 11  | 충북대병원    | 배장환          | 0    | 0     | 0     | 0        |            |
| 12  | 원광대병원    | 오석규          | 0    | 0     | 0     | 0        |            |
| 13  | 일산백병원    | 이성운          | 0    | 0     | 0     | 0        |            |
| 14  | 광주기독병원   | 이승욱          | 0    | 0     | 0     | 0        |            |
| 15  | 홍남대병원    | 이재환          | 0    | 0     | 0     | 0        |            |
| 16  | 고대안산병원   | 임상엽          | 0    | 0     | 0     | 0        |            |
| 17  | 순천성가롤로병원 | 조장현          | 0    | 0     | 0     | 0        |            |
| 18  | 부산대병원    | 차광수          | 0    | 0     | 0     | 0        |            |
| 19  | 전북대병원    | 채제건          | 0    | 0     | 0     | 0        |            |
| 20  | 계명대병원    | 허승호          | 0    | 0     | 0     | 0        |            |
| 21  | 광주보훈병원   | 황선호          | 0    | 0     | 0     | 0        |            |
| 22  | 경상대병원    | 황진용          | 0    | 0     | 0     | 0        |            |
| 총 계 |          |              | 4    | 9     | 18    | 0        |            |

## Notice



사용자메뉴얼 추가되었습니다. 2011-04-18  
 작성도 조사표 신설안내입니다. 2011-03-14  
 Report Page 신설 안내입니다. 2011-03-14  
 스터디 등록을 시작합니다. 2011-03-14

1

|             | Week | Month | Total |
|-------------|------|-------|-------|
| Patient     | 4    | 9     | 18    |
| Clinical    | 3    | 8     | 17    |
| Procedure   | 4    | 9     | 18    |
| Lesion 1    | 4    | 9     | 18    |
| Lesion 2    | 2    | 2     | 7     |
| Lesion 3    | 0    | 0     | 0     |
| Lesion 4    | 0    | 0     | 0     |
| Lesion 5    | 0    | 0     | 0     |
| Lesion 6    | 0    | 0     | 0     |
| In Hospital | 4    | 8     | 17    |
| FollowUp 1M | 0    | 3     | 3     |
| FollowUp 6M | 0    | 0     | 0     |
| FollowUp 1Y | 0    | 0     | 0     |
| Death       | 0    | 0     | 0     |
| MI          | 0    | 0     | 0     |
| Revascular  | 0    | 0     | 0     |

## Free Board

Add

List

번호      제목      첨부파일      작성일      작성시간

# Purpose

To evaluate the effectiveness and safety after BioMatrix<sup>®</sup> (*Biolimus A9*<sup>®</sup>) stent deployment in patients with acute coronary syndrome



# Study Period

From March, 2011 to February, 2013



# Study Flow Sheet

ACS patients  
CAG DS > 50%  
Egligible for PCI

n=1,000

BioMatrix® stent

1 month clinical follow-up

6 month clinical follow-up

6-12 month follow-up CAG (optional)  
Not routine follow-up CAG

12 month clinical follow-up



# Patient Eligibility

## *Inclusion Criteria*

### ***Coronary artery disease***

- *Acute coronary syndrome including UA, NSTEMI and STEMI*

### ***At least one lesion with***

- *Diameter stenosis  $\geq$  50%*
- *RVD: 2.25-4.0 mm*
- *Number of lesions: no limitation*
- *Number of vessels: no limitation*
- *Lesion length: no limitation*

### ***Written informed consent***

## *Exclusion Criteria*

### ***Known allergy to***

- *aspirin, clopidogrel, heparin, stainless steel, biolimus, contrast material*

### ***Planned, elective surgery within 6 months of PCI unless dual APT could be maintained***

### ***Pregnancy***

### ***Participation in another trial***



# Primary Endpoint

Composite of cardiac death, non-fatal MI, TVR  
at 12 months after PCI



# Secondary Endpoint

- All cause death
- Cardiac death
- Non-fatal MI
- TVR
- TLR
- ARC-defined definite and probable ST

**23 patients were enrolled.**

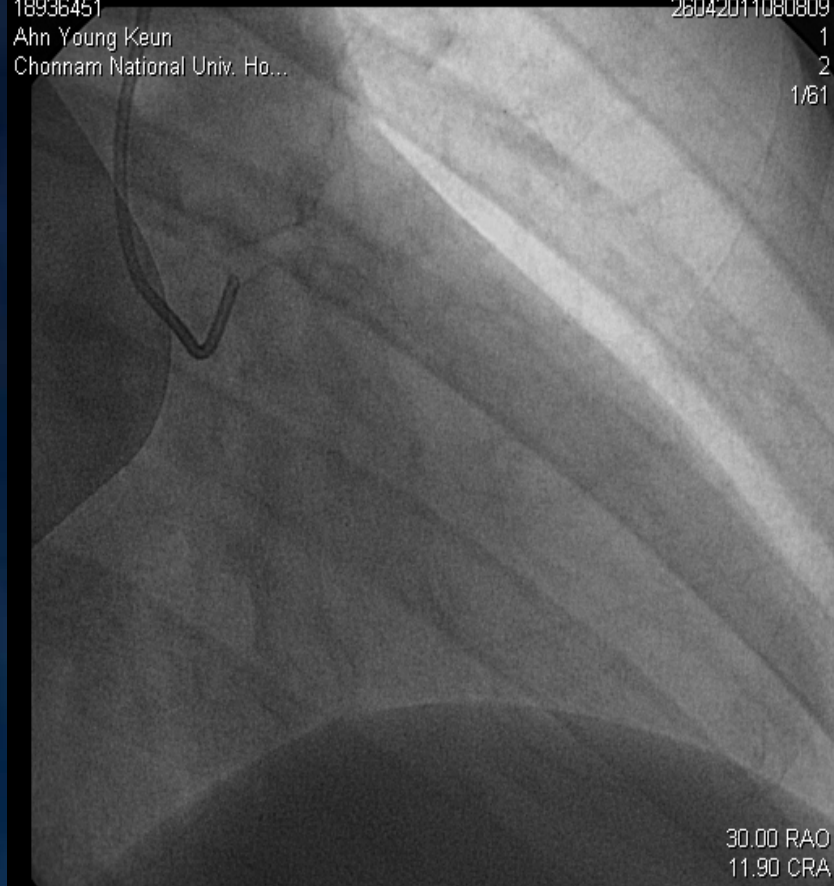
# Case II. 44Y/F, UAP, Current Smoker

HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...

BIPLANE A

2011-04-26 오전 8:08:09  
26042011080809

1  
2  
1/81



30.00 RAO  
11.90 CRA

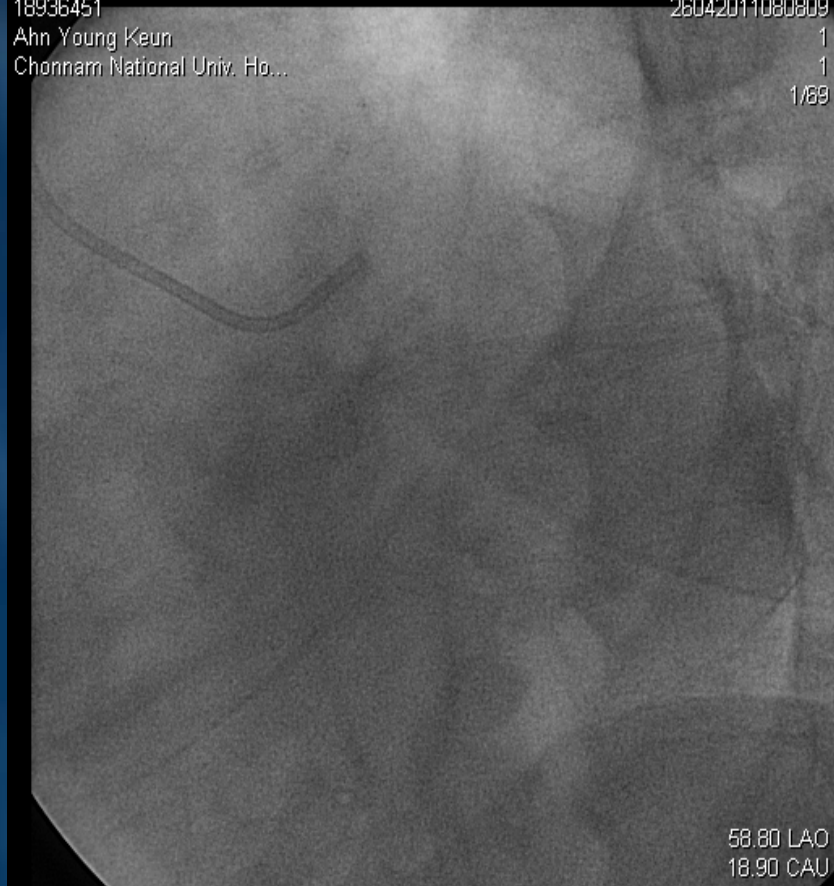
**RAO**

HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...

BIPLANE B

2011-04-26 오전 8:08:09  
26042011080809

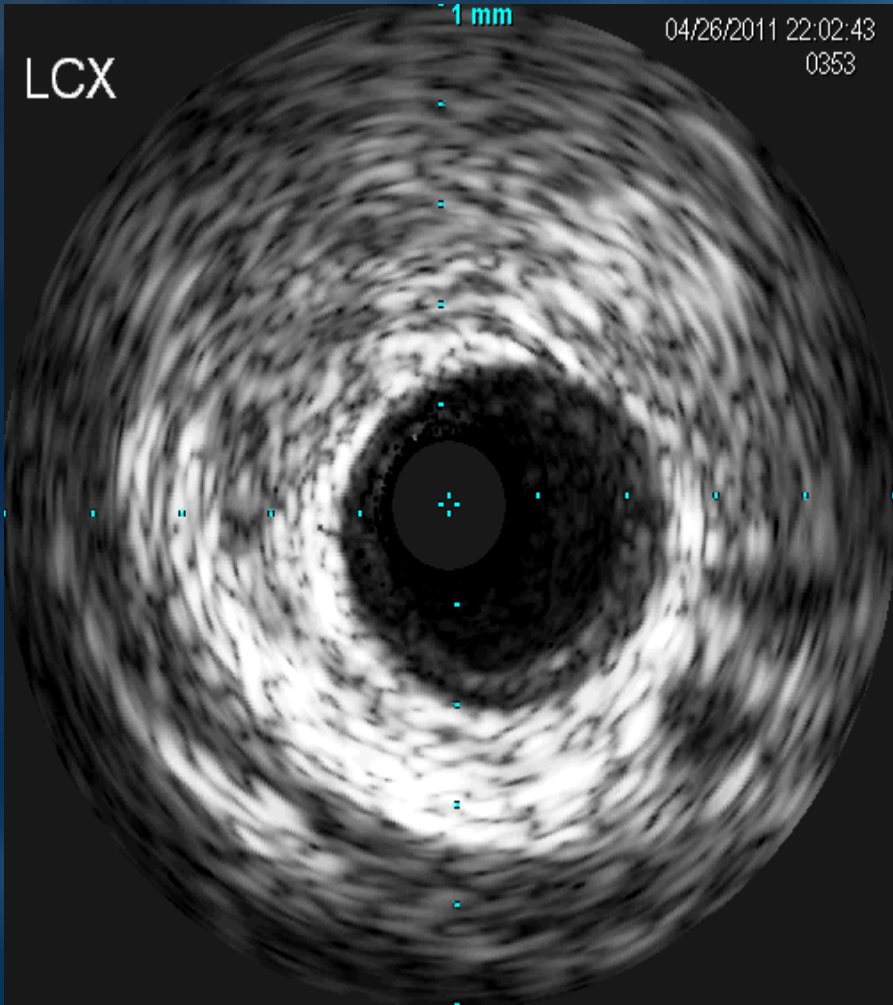
1  
1  
1/89



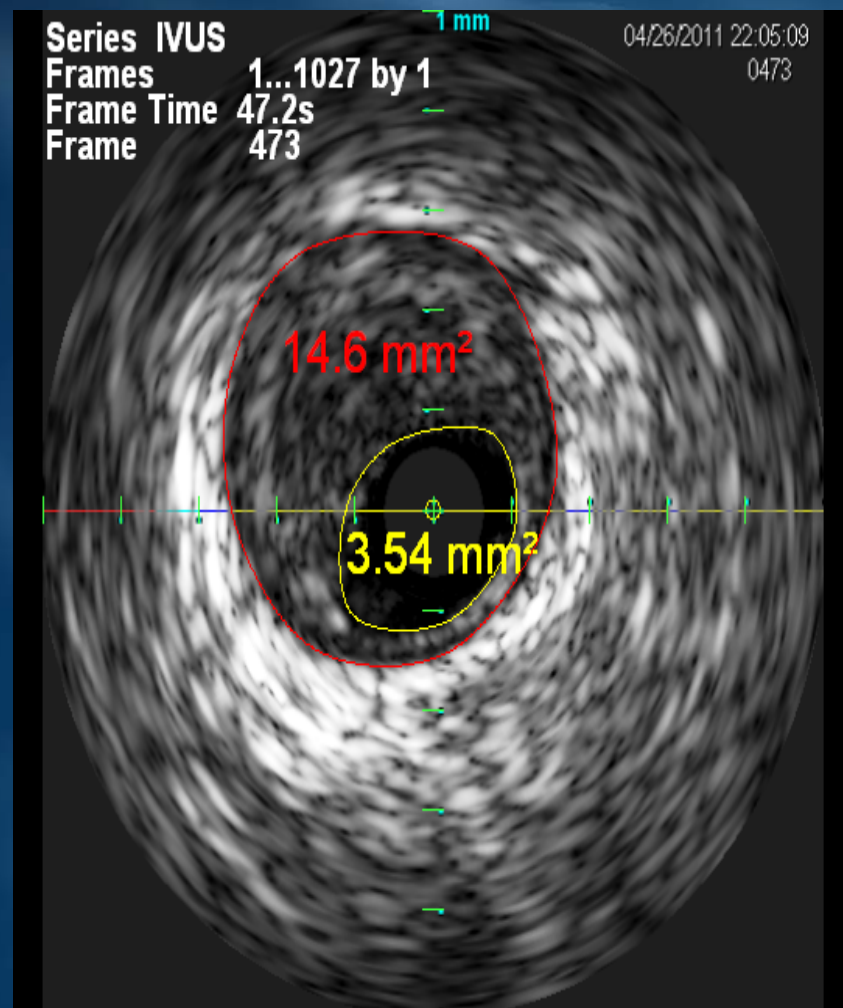
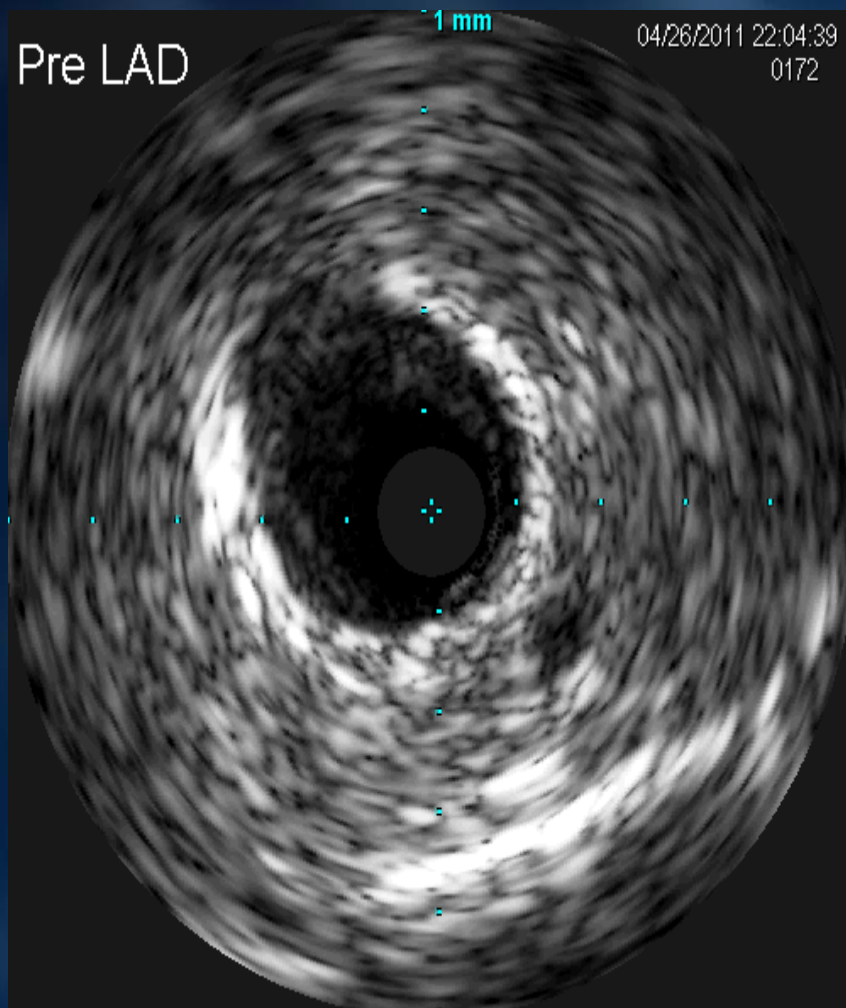
58.80 LAO  
18.90 CAU

**LAO**

# LCX IVUS

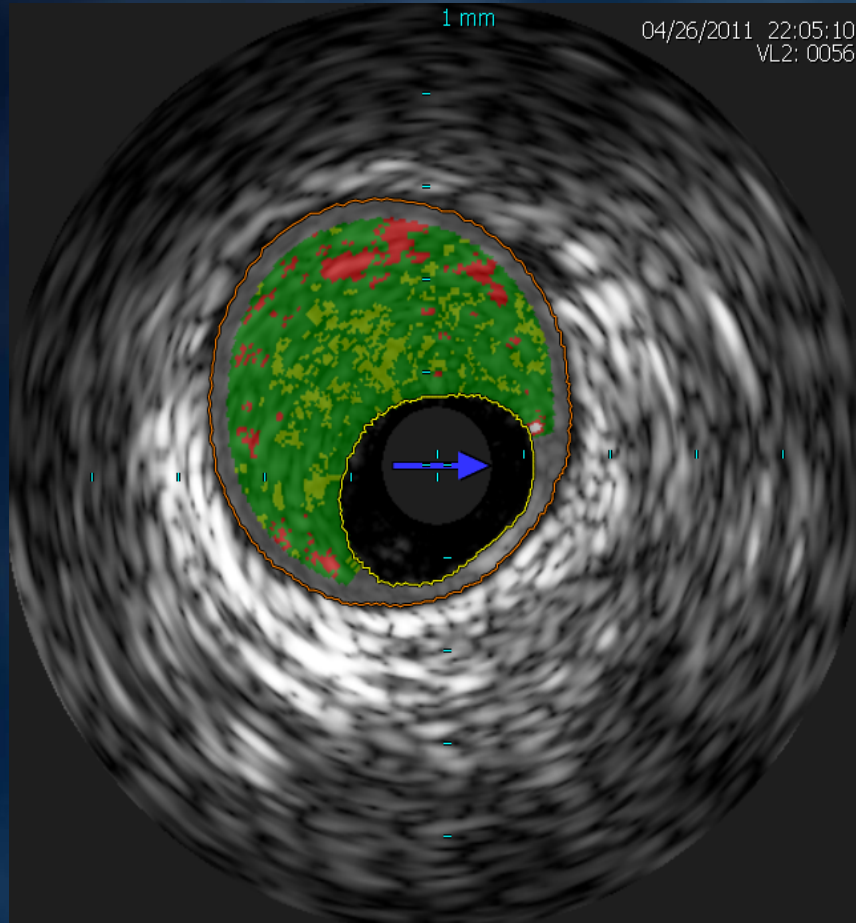


# LAD IVUS



Plaque burden 76%

# LAD MLA VH-IVUS



## Frame Statistics

### LUMEN

Area: 3.5 mm<sup>2</sup>

Min Dia: 1.8 mm

Max Dia: 2.4 mm

### VESSEL

Area: 14.6 mm<sup>2</sup>

Min Dia: 4.1 mm

Max Dia: 4.4 mm

PLAQUE Burden: 75.7 %

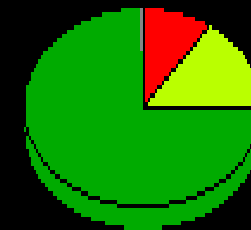
### COMPOSITION

■ FI: 6.0 mm<sup>2</sup> (74.4%)

■ FF: 1.3 mm<sup>2</sup> (16.1%)

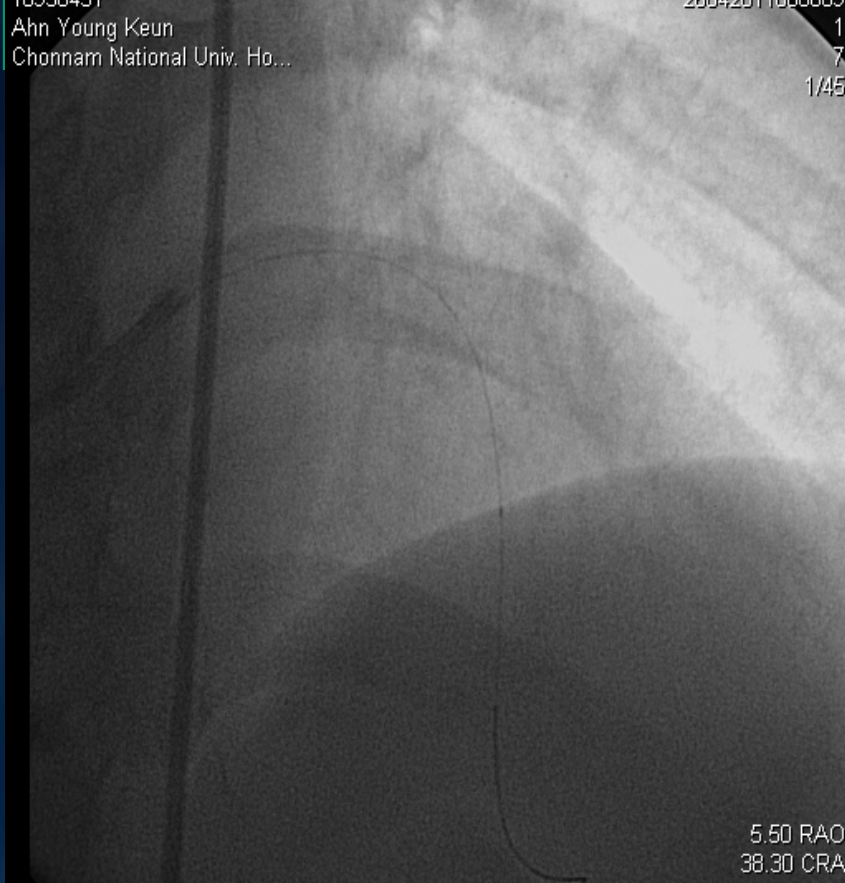
■ NC: 0.8 mm<sup>2</sup> (9.3%)

■ DC: 0.0 mm<sup>2</sup> (0.2%)



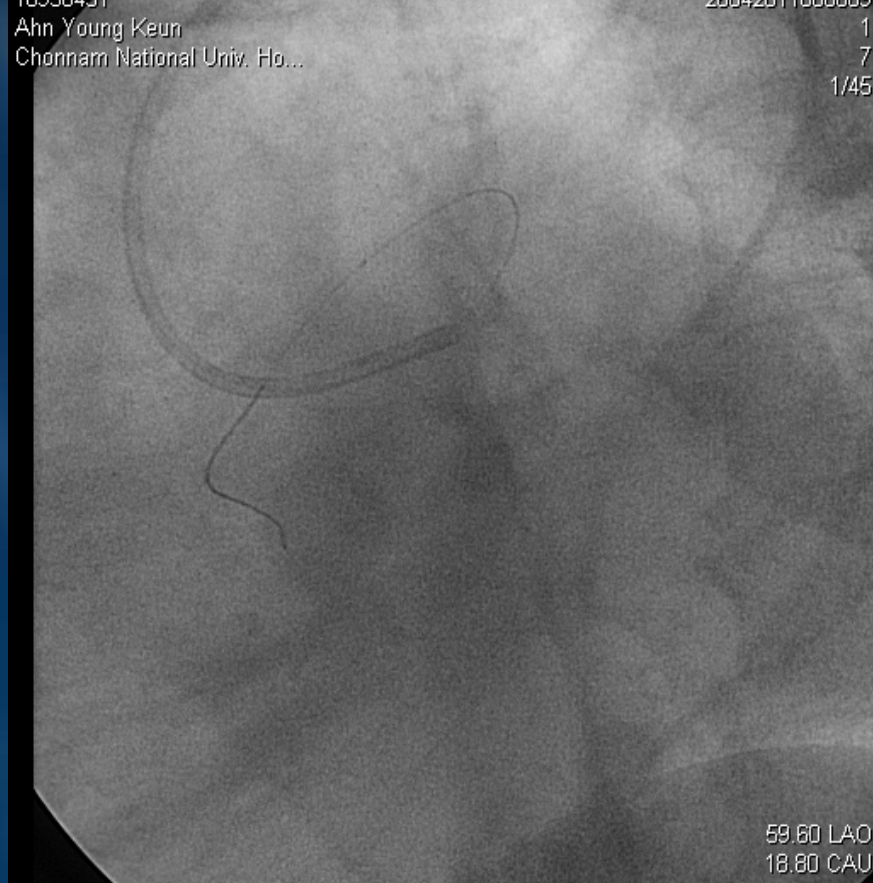
# Post-IVUS CAG

HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...  
2011-04-26 오전 8:08:09  
26042011080809  
1  
7  
1/45



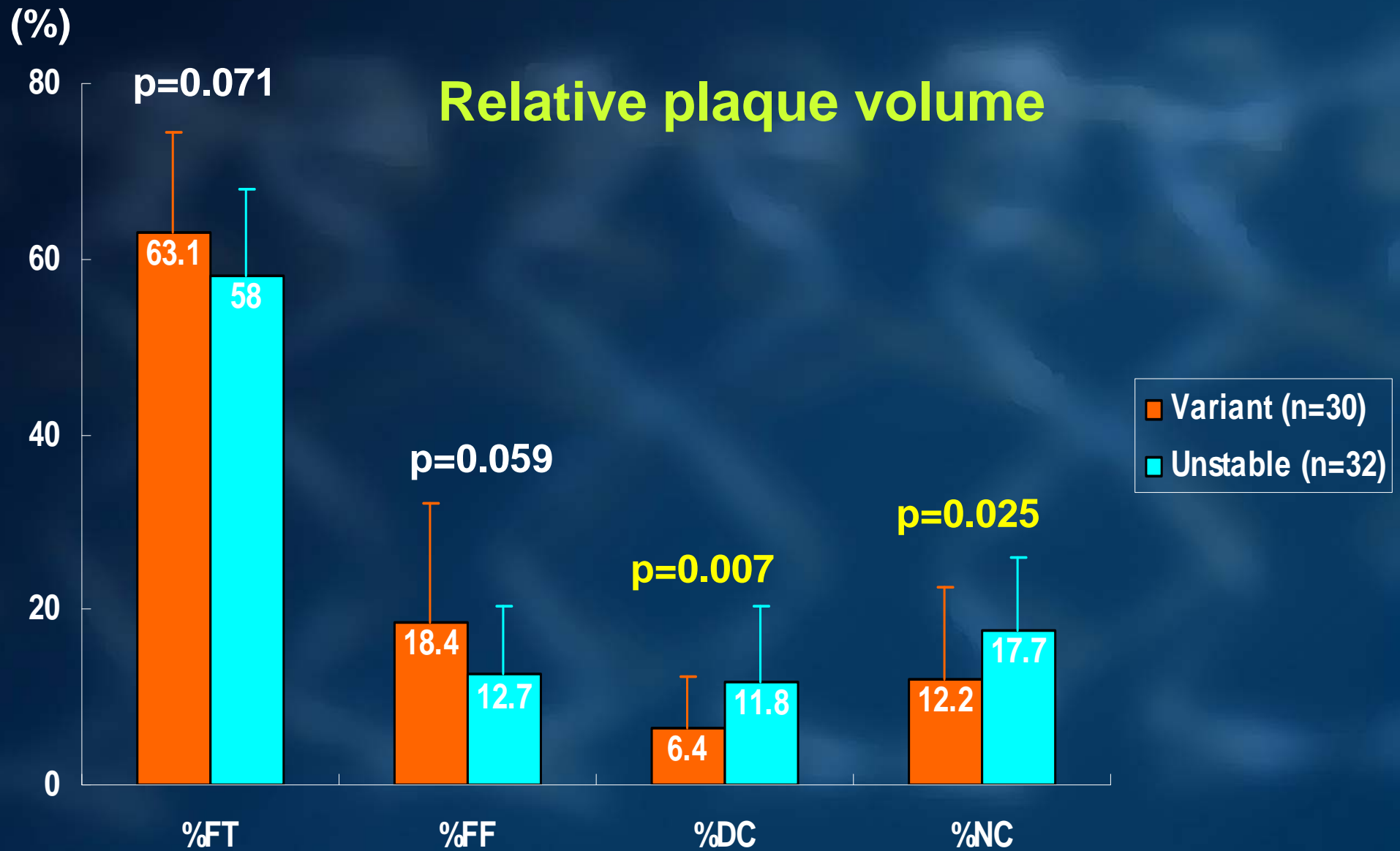
**RAO**

HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...  
2011-04-26 오전 8:08:09  
26042011080809  
1  
7  
1/45



**LAO**

# Plaque components in VAP vs. UAP



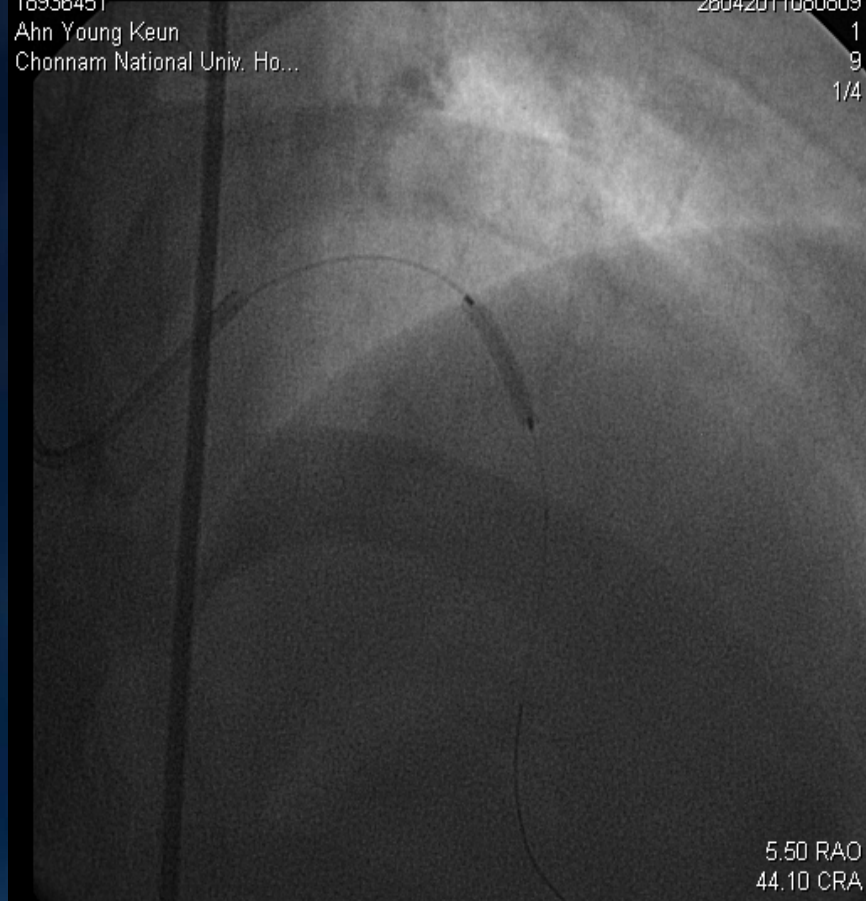
# Post-balloon, post-NTG CAG

HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...

BIPLANE A

2011-04-26 오전 8:08:09  
26042011080809

1  
9  
1/4



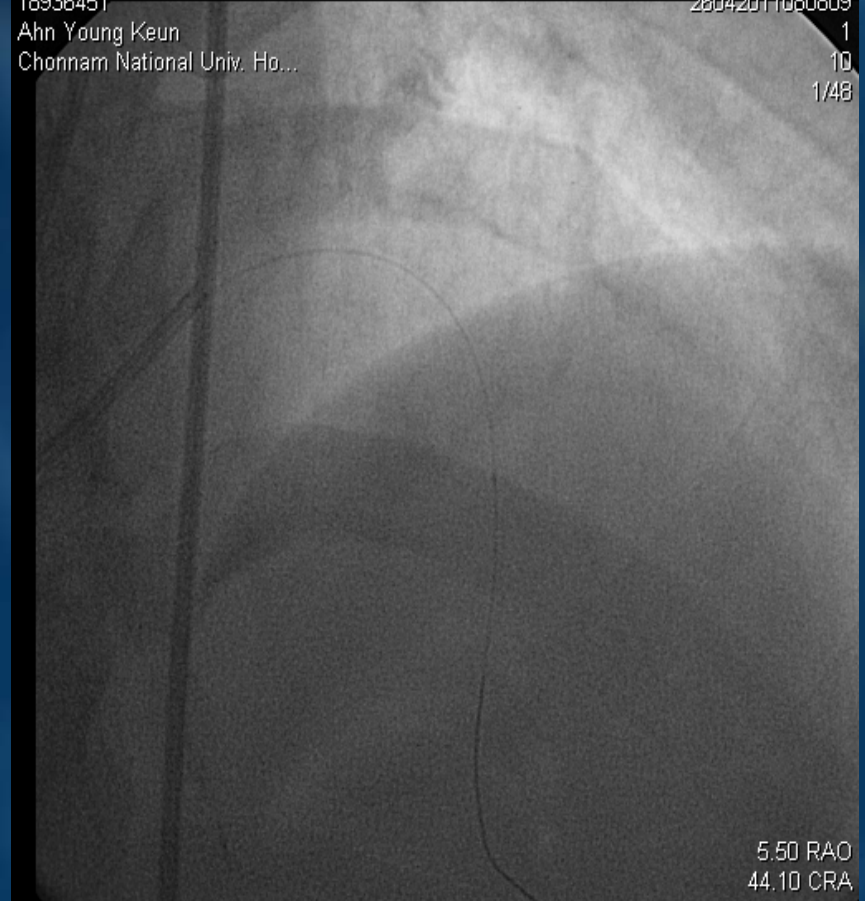
**RAO**

HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...

BIPLANE A

2011-04-26 오전 8:08:09  
26042011080809

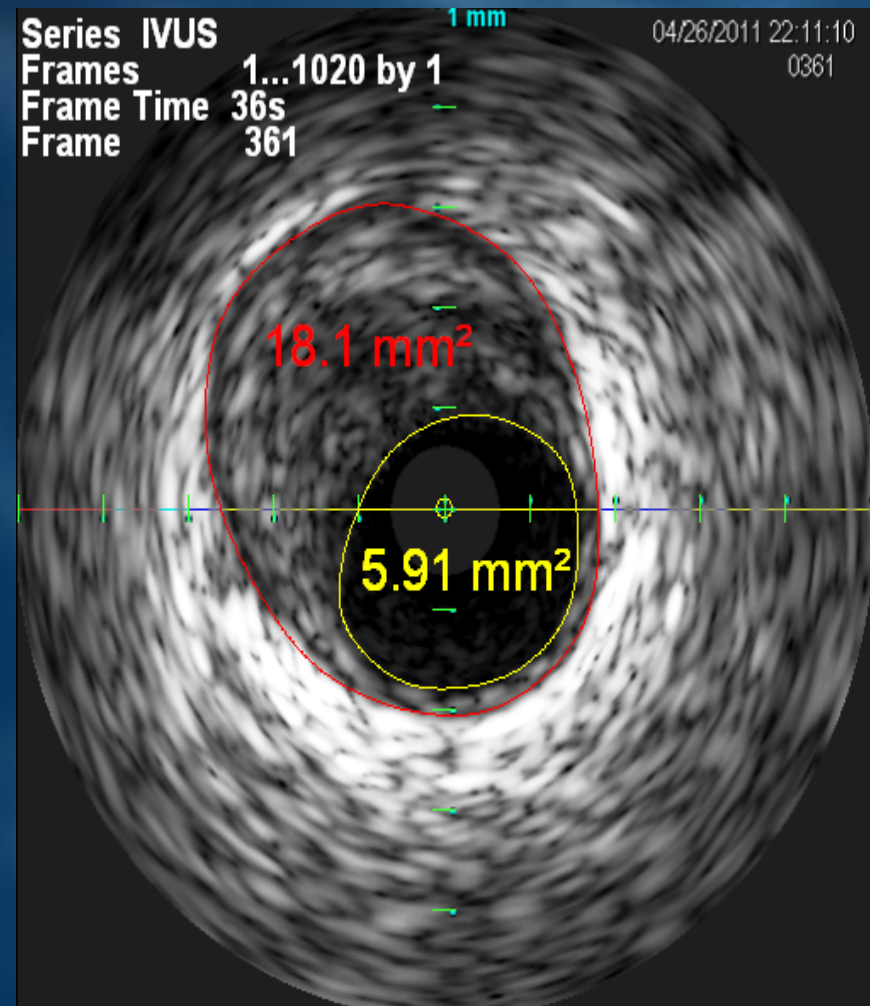
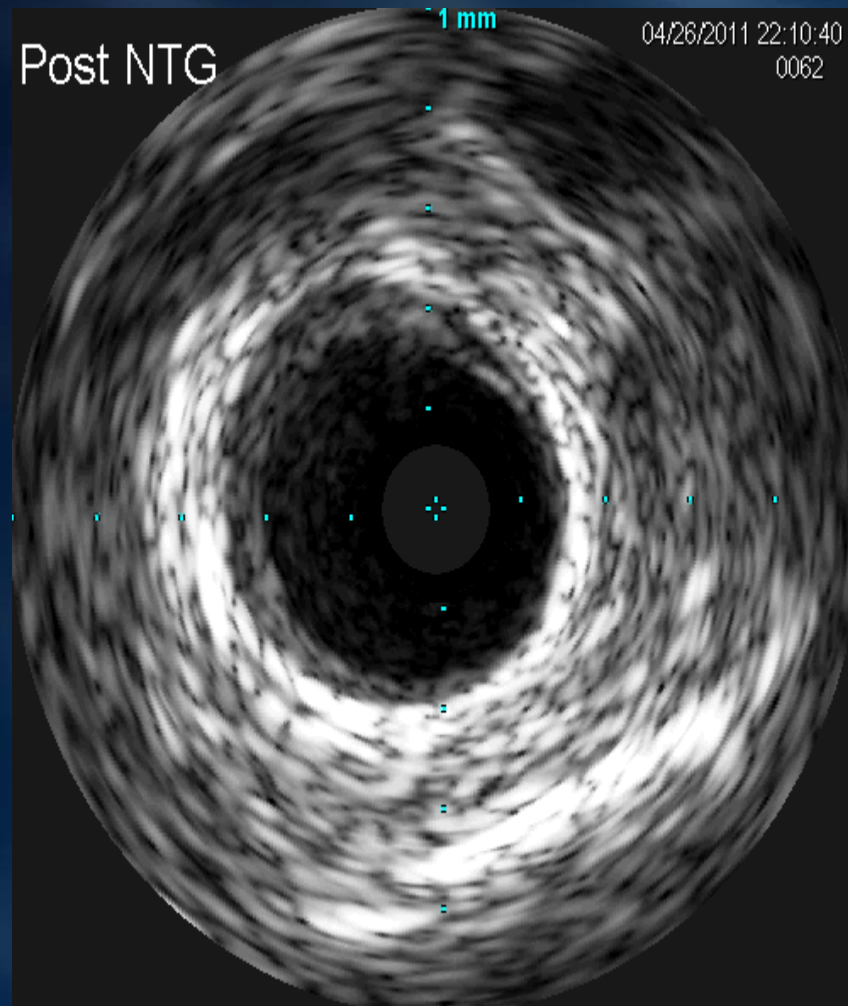
1  
10  
1/48



**RAO**

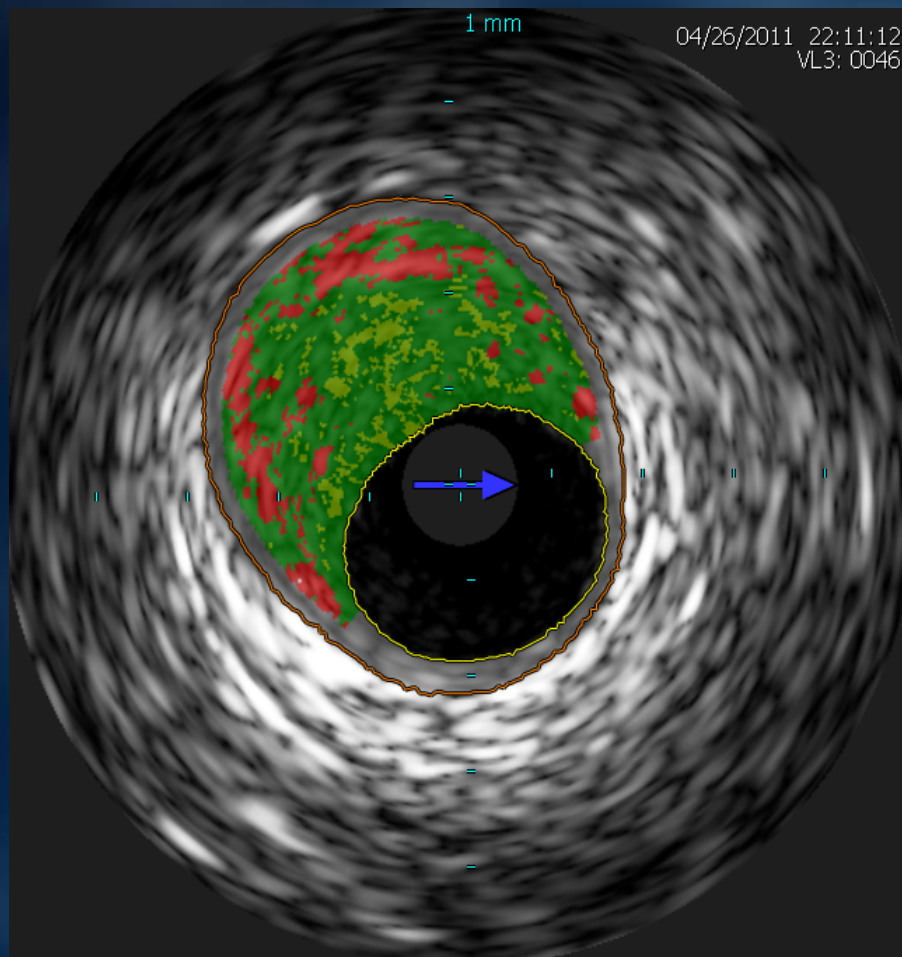


# Post-balloon, Post-NTG IVUS



Plaque burden 68%

# Post-balloon, Post-NTG VH-IVUS



## Frame Statistics

### LUMEN

Area: 5.9 mm<sup>2</sup>

Min Dia: 2.5 mm

Max Dia: 3.0 mm

### VESSEL

Area: 18.4 mm<sup>2</sup>

Min Dia: 4.3 mm

Max Dia: 5.3 mm

PLAQUE Burden: 67.7 %

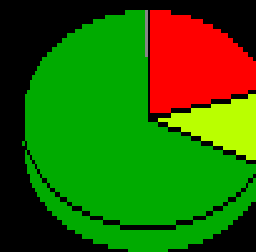
### COMPOSITION

■ FI: 6.0 mm<sup>2</sup> (67.8%)

■ FF: 1.0 mm<sup>2</sup> (11.6%)

■ NC: 1.8 mm<sup>2</sup> (20.6%)

■ DC: 0.0 mm<sup>2</sup> (0.0%)



*Do We Have To  
Treat This Patient?*

# Stenting for LAD

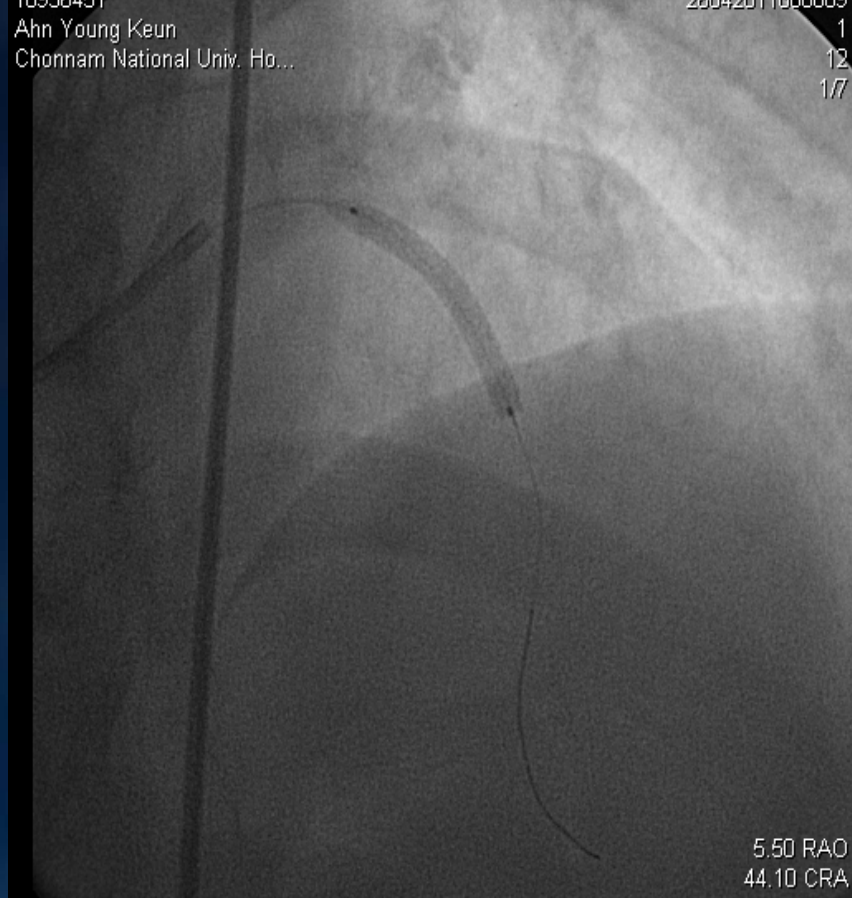
HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...

BIPLANE A

2011-04-26 오전 8:08:09

26042011080809

1  
12  
1/7



5.50 RAO  
44.10 CRA

**RAO**

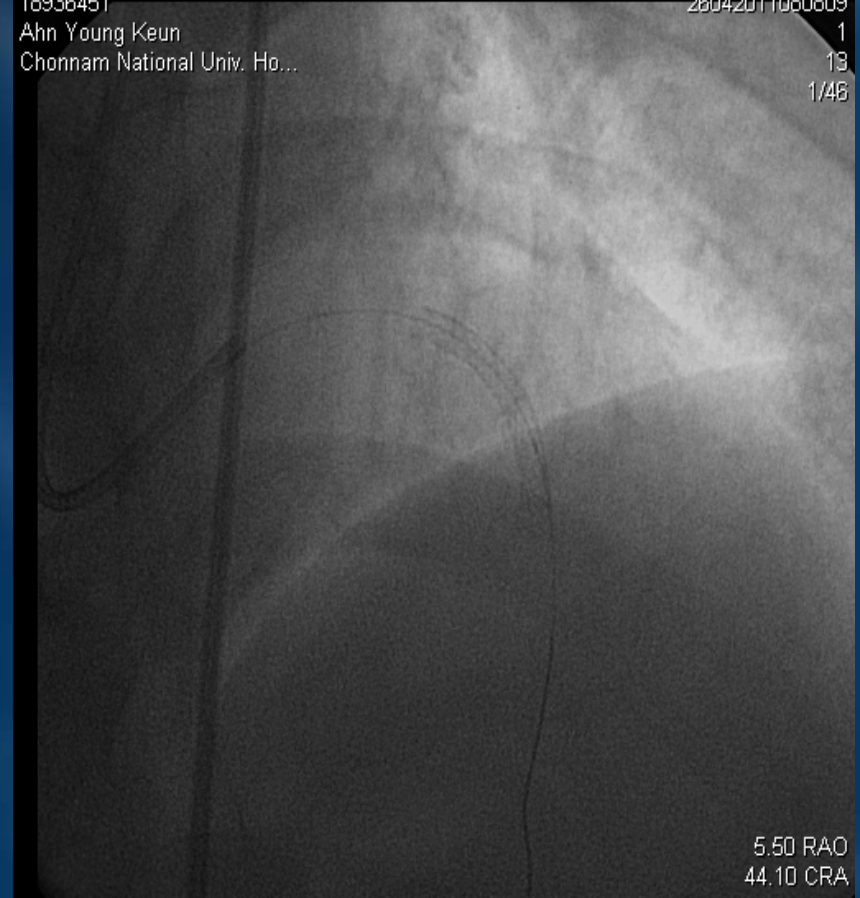
HEO HYE JIN  
18936451  
Ahn Young Keun  
Chonnam National Univ. Ho...

BIPLANE A

2011-04-26 오전 8:08:09

26042011080809

1  
13  
1/48



5.50 RAO  
44.10 CRA

**RAO**

**3.5X28mm BIOMATRIX stent**

# Post-PCI LAD IVUS

