

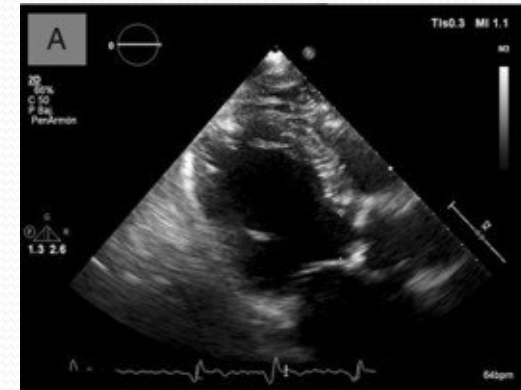
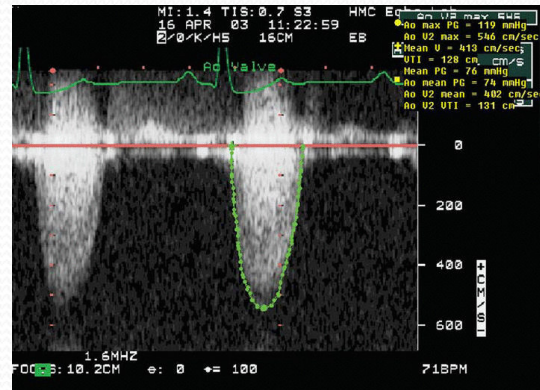
# Biofreedom Ultra prior to cardiac surgery.

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## ➤ Biofreedom Ultra prior to cardiac surgery.

### • Clinical case:

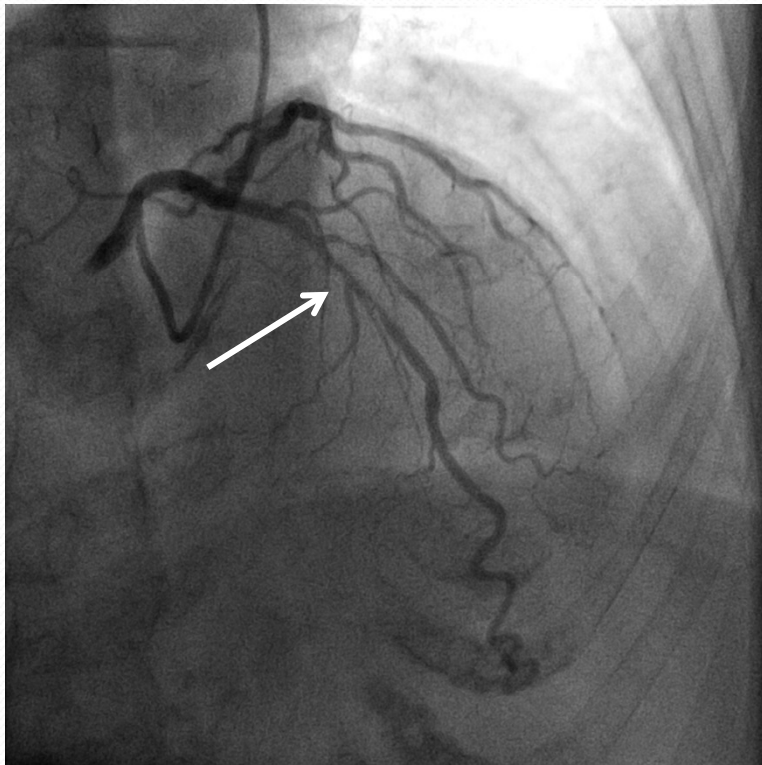
- 78 y.o. woman. 1,52 m; 78 kg.
- CVRF: Hypertension. Hypercholesterolemia
- Previous history of valvular disease:
  - Severe aortic stenosis with NYHA III dysnea.
  - Preserved LVEF. LV hypertrophy.



- Referred for coronariography prior to Heart Team evaluation:

## ➤ Biofreedom Ultra prior to cardiac surgery.

- **Coronariography:**
  - Right radial access 5F.



**LAD:** severe stenosis in middle segment. Severe calcification.



**RCA:** severe stenosis in middle segment. Moderate stenosis in distal segment. Severe calcification.

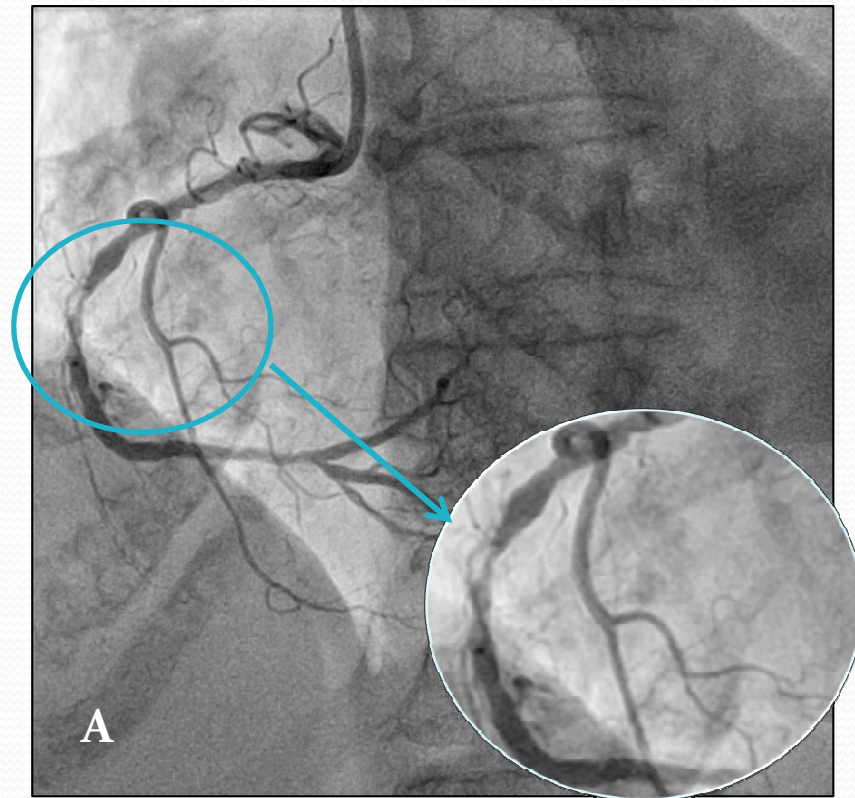
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- **Heart Team evaluation:**

- According to age, body index mass, and comorbidities, and after evaluation of the femoral accesses, cardiac surgery was the selected treatment (aortic valve prosthesis surgery).
- Coronary revascularization was rejected by surgeons due to extensive calcification of the vessels.
  - Prior to surgery, as the expected time to surgery procedure exceeded 3 months, coronary revascularization by percutaneous coronary intervention was scheduled.

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### ● Percutaneous Procedure:



- A) Severe stenosis in the middle segment of RCA.
- B) Predilatation with 2,5 x 10 mm non-compliant balloon.



### Material:

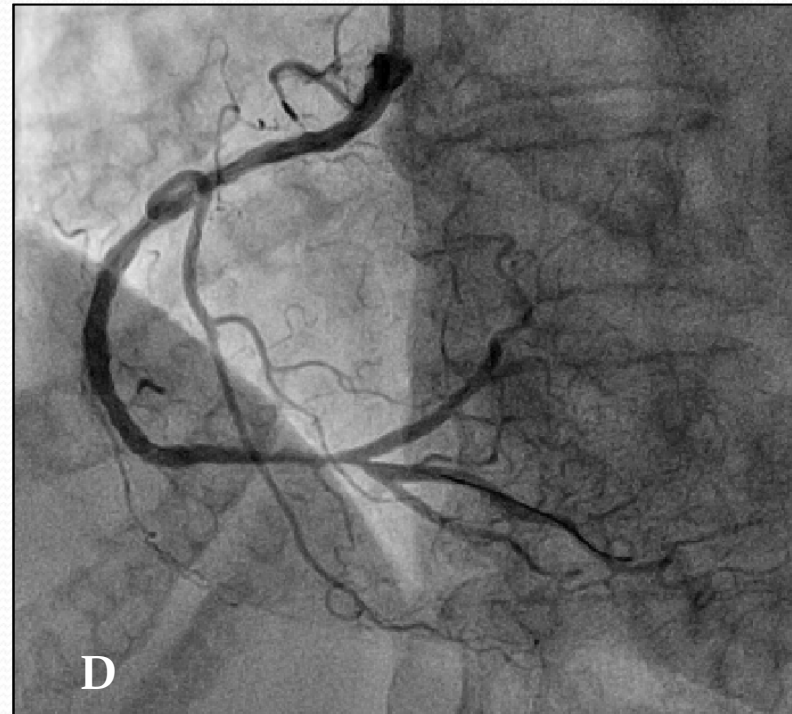
- Guiding catheter: AR2 6F
- Guidewire: Sion.

## ➤ Biofreedom Ultra prior to cardiac surgery.

### ● Percutaneous Procedure:



C) Implant of 3,5 x 19 mm Biomatrix Alpha stent.  
D) Final result.



### Material:

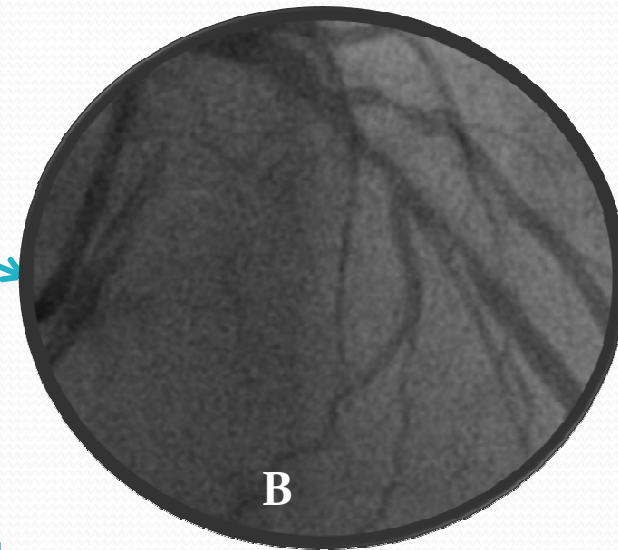
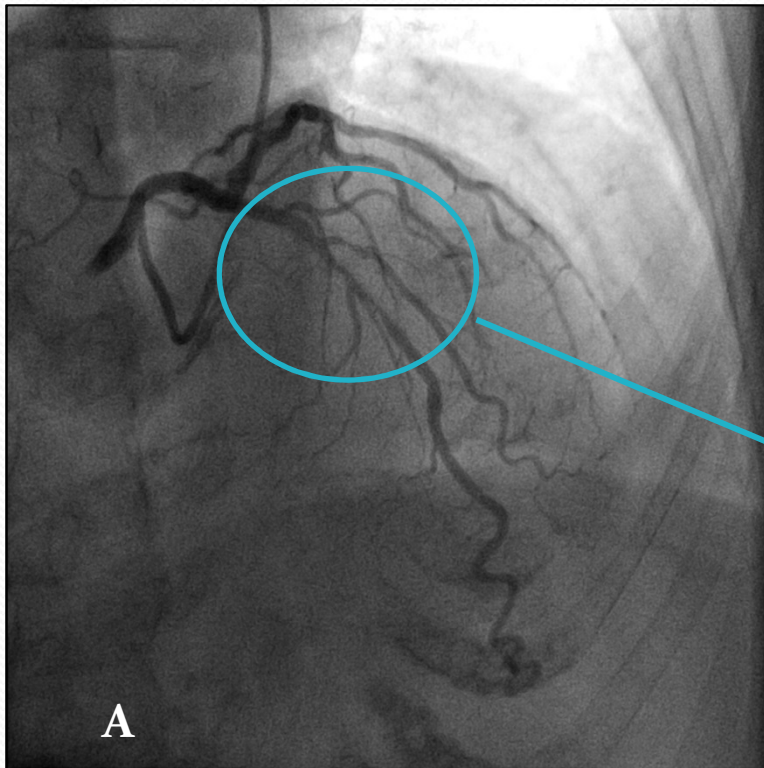
- Guiding catheter: AR2 6F
- Guidewire: Sion.
- Balloon: 2,5 x 10 mm non-compliant balloon.
- Stent: 3,5 x 19 mm Biofreedom Ultra.

## ➤ Biofreedom Ultra prior to cardiac surgery.

### ● Percutaneous Procedure:

#### Material:

- Guiding catheter: EBU 3,5 6F
- Guidewire: Sion, BHW (buddy wire).



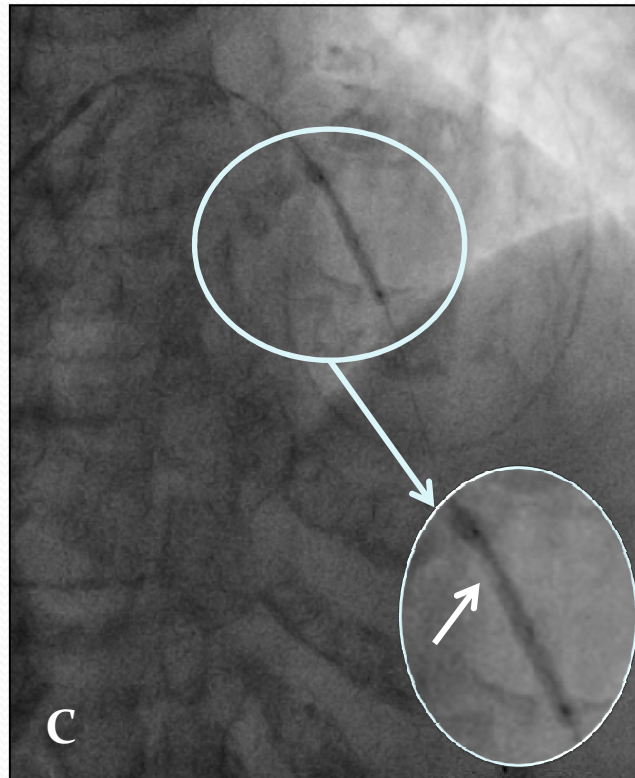
- A) Severe stenosis in middle segment of LAD.  
B) Detail of the lesion.

## ➤ Biofreedom Ultra prior to cardiac surgery.

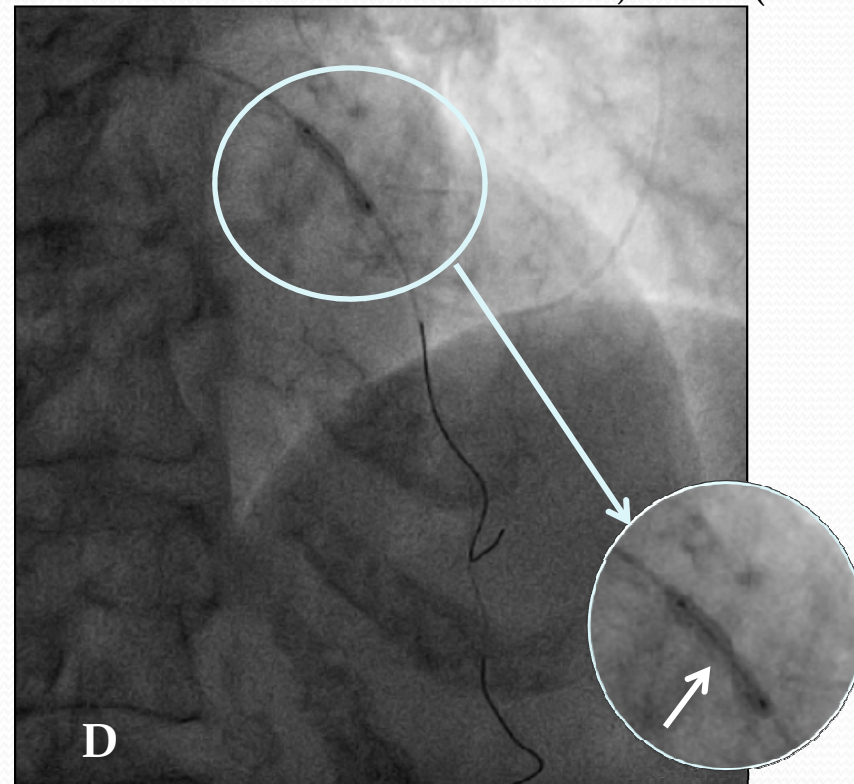
### ● Percutaneous Procedure:

#### Material:

- Guiding catheter: EBU 3,5 6F
- Guidewire: Sion, BHW (buddy wire).



C) Predilatation with 2,0 x 20 mm semi-compliant balloon. Incomplete expansion of the balloon in the middle portion



D) Predilatation with 3,0 x 10 mm non-compliant balloon. Incomplete expansion of the balloon in the middle portion.

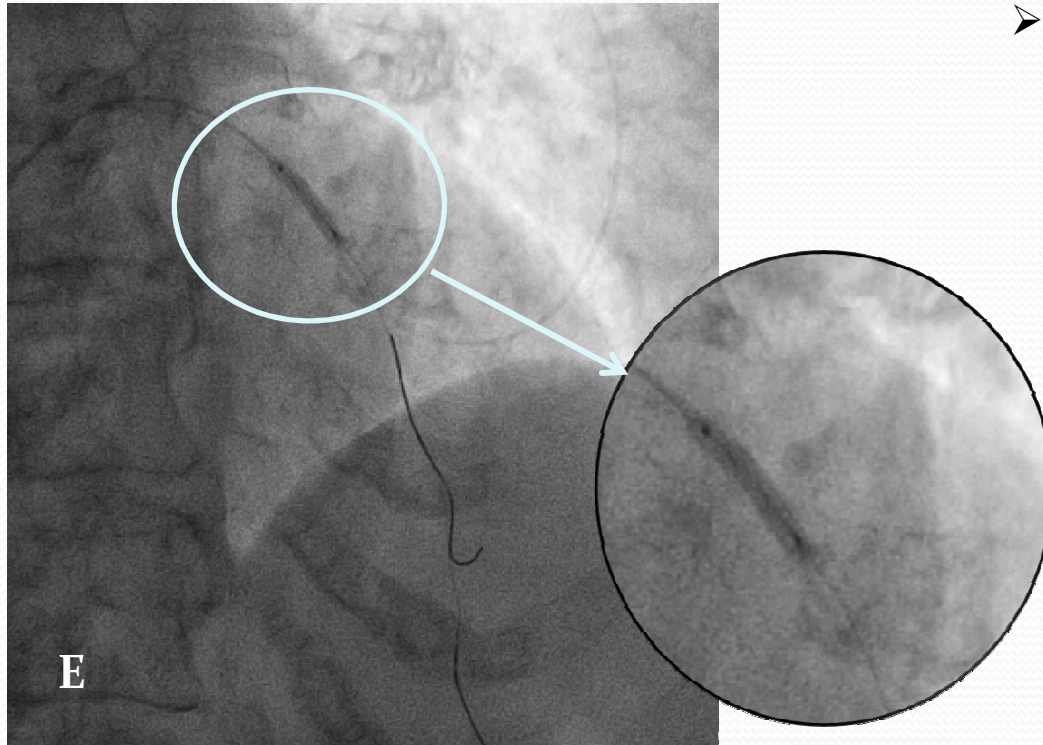


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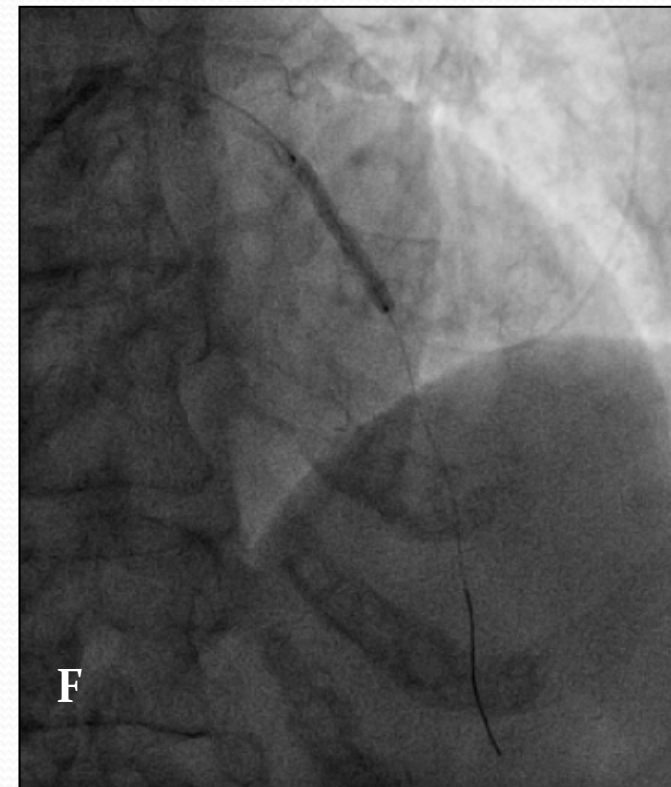
- **Percutaneous Procedure:**

**Material:**

- Guiding catheter: EBU 3,5 6F
- Guidewire: Sion, BHW (buddy wire).



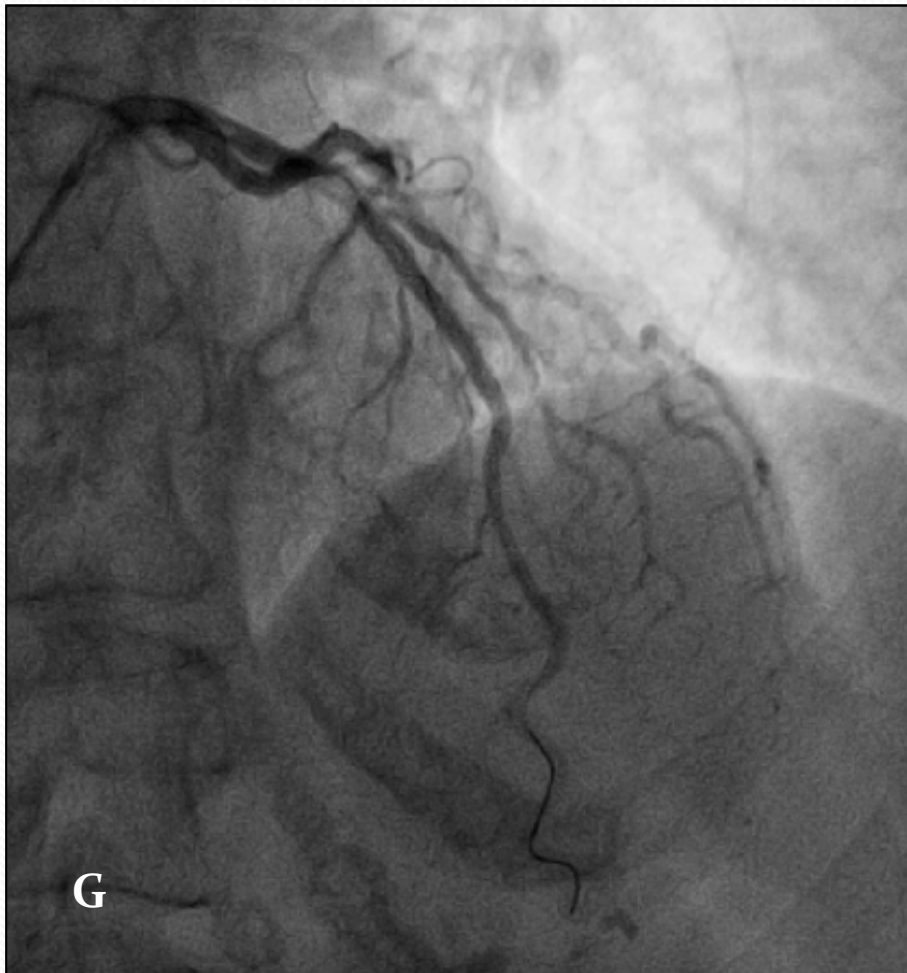
E) Final expansion of the plaque is achieved after Wolverine 3.0 x 10 mm balloon.



F) Implant of 3,0 x 24 mm Biofreedom Ultra.

## ➤ Biofreedom Ultra prior to cardiac surgery.

### ● Percutaneous Procedure:



### Material:

- Guiding catheter: EBU 3,5 6F
- Guidewire: Sion, BHW (buddy wire).
- Balloons: semicompliant 2,0 x 20 mm; non-compliant 3,0 x 10 mm; Wolverine 3,0 x 10 mm.
- Stent: Biofreedom Ultra 3,0 x 24 mm

G) Final result after stent implant.

## ➤ Biofreedom Ultra prior to cardiac surgery.

- **Clinical management:**

- **In-hospital evolution.**

- No complications following interventional procedure. Discharge after 24 hours.

- **Discharge Treatment:**

- AAS 100 (chronic)
    - Clopidogrel 75 mg (1 month)

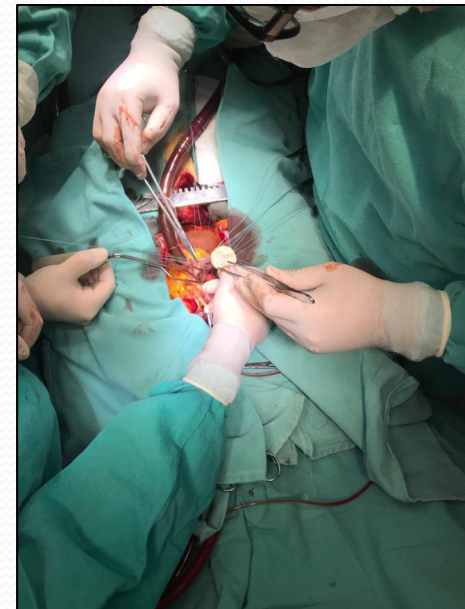


## ➤ Biofreedom Ultra prior to cardiac surgery.

- **Clinical management:**

- **Follow-up.**

- Valvular surgery scheduled 3 months after PCI.
- **Surgery under treatment with ASA alone.**
- **Successful implant of a biological aortic prosthesis (Hancock II, Medtronic).**
  - No complication during hospitalization stay.
  - Discharge on the 7th day.
  - Treatment: AAS 100 mg+ clopidogrel 75 mg



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- **Discussion:**

- Aggressive antiplatelet treatment (dual platelet therapy) may increase the risk of bleeding complications in surgery (both cardiac and non-cardiac).
- The implant of a polymer-free stent (Biofreedom) in patients who need percutaneous treatment of coronary stenosis, may reduce the time of dual platelet therapy.
- Several studies (Leaders<sup>1</sup>; Leaders Free<sup>2</sup>, Onyx-One<sup>3</sup>) have demonstrated an excellent behaviour of the Biofreedom stent in patients with coronary angioplasty and short DAPT duration.

1) EuroIntervention 2010;6:233-239

2) N Engl J Med. 2015 Nov 19;373(21):2038-47

3) N Engl J Med. 2020 Mar 26;382(13):1208-1218

# ➤ Biofreedom Ultra prior to cardiac surgery.

## • Discussion:

- Some studies have studied the outcome of patients with coronary revascularization with Biofreedom prior to non-cardiac surgery.



Original Article

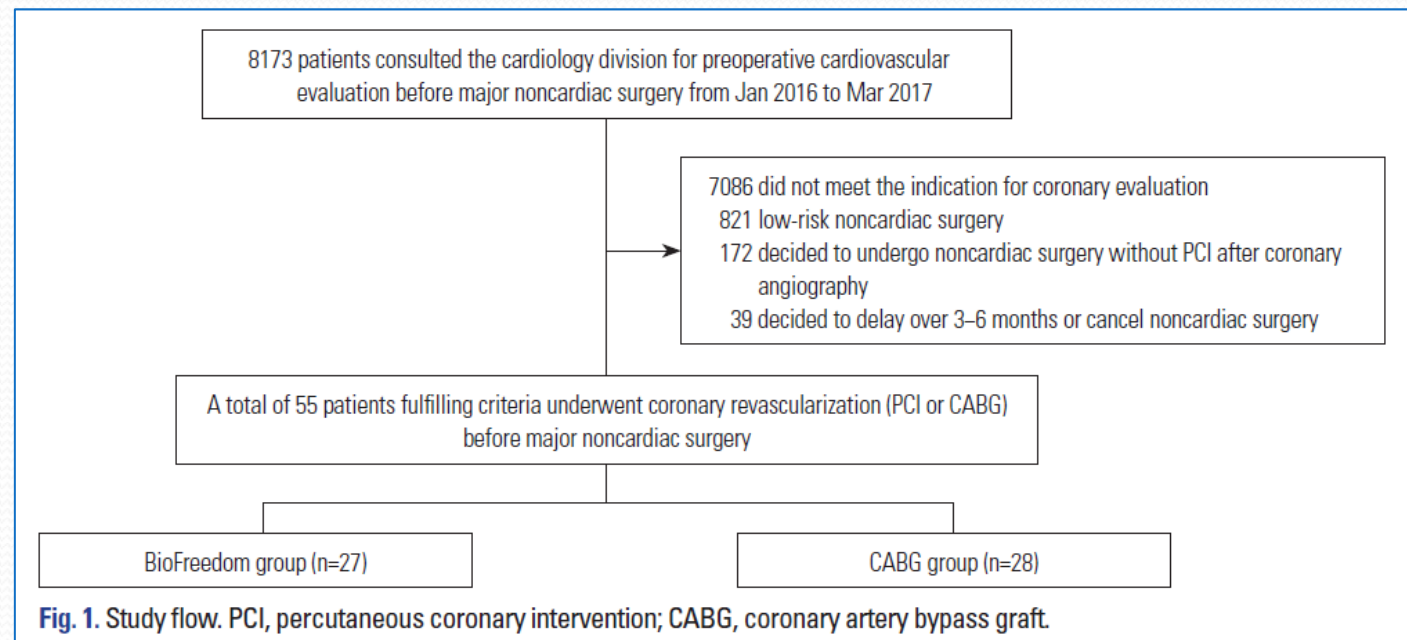
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## ● Discussion:



Original Article

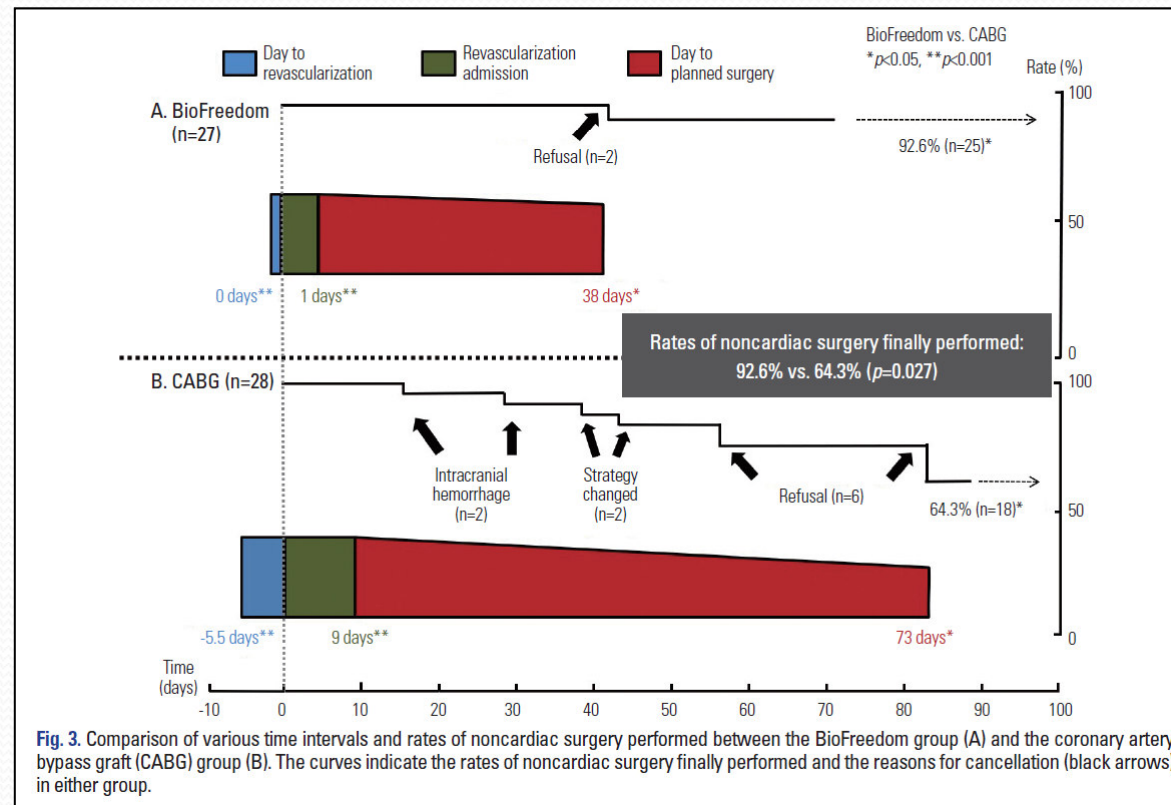
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**Fig. 3.** Comparison of various time intervals and rates of noncardiac surgery performed between the BioFreedom group (A) and the coronary artery bypass graft (CABG) group (B). The curves indicate the rates of noncardiac surgery finally performed and the reasons for cancellation (black arrows) in either group.

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## • Discussion:

### • Hospitalization for revascularization:

- During the hospitalization for revascularization period, the occurrence of primary outcomes did not differ between the groups.
- BioFreedom group showed a shorter hospitalization period and lower total treatment cost than the CABG group.

### • Hospitalization for non-cardiac surgery:

- Time from revascularization to non-cardiac surgery was significantly shorter in the BioFreedom group (38.0 days) than in the CABG group (73.0 days;  $p=0.042$ ).
- The rate of major non-cardiac surgery was significantly higher in the BioFreedom group (92.6%) than in the CABG group (64.3%;  $p=0.027$ ).
- During the hospital stay for non-cardiac surgery, the occurrence of composite outcome was not significantly different between groups (4% vs. 0%;  $p>0.999$ ): stroke occurred in only 1 case, and there were no cases of death or stent thrombosis in the BioFreedom group.

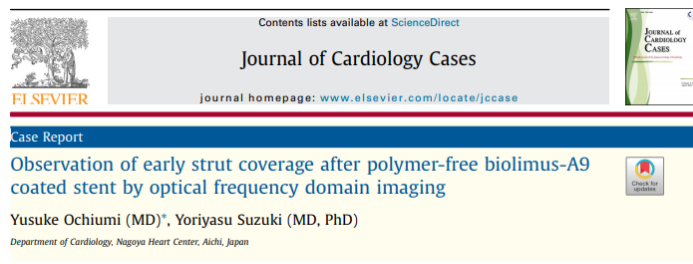
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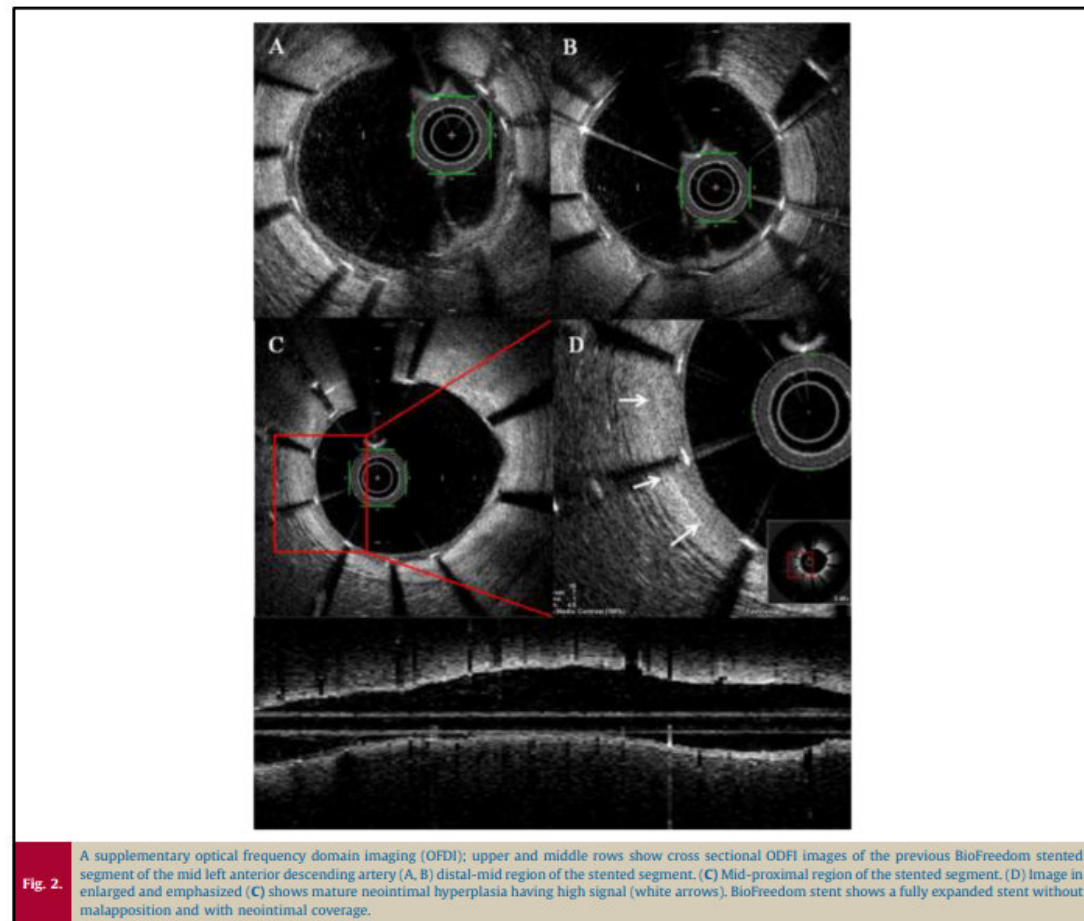


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## ● Discussion:



- 30 days OCT of a Biofreedom stent:
  - Full coverage of the stent with neointima hyperplasia.



## ➤ Biofreedom Ultra prior to cardiac surgery.

- **Conclusion:**

- The Biofreedom-Ultra (the new platform of the Biofreedom stent) seems to be a safe option for revascularization of patients prior to cardiac surgery, due to:
  - 1) the short duration of the DAPT required.
  - 2) the quick endothelization of the struts.
- 3) the good safety profile demonstrated by Biofreedom in previous randomized controlled studies.