Lessons Learned from Carotid Flow Diversion for Stroke Prevention: the Mindguard Experience

Sievert S, Skowasch M, Römer A

CardioVascular Center Frankfurt
Sankt Katharinen
Frankfurt, Germany

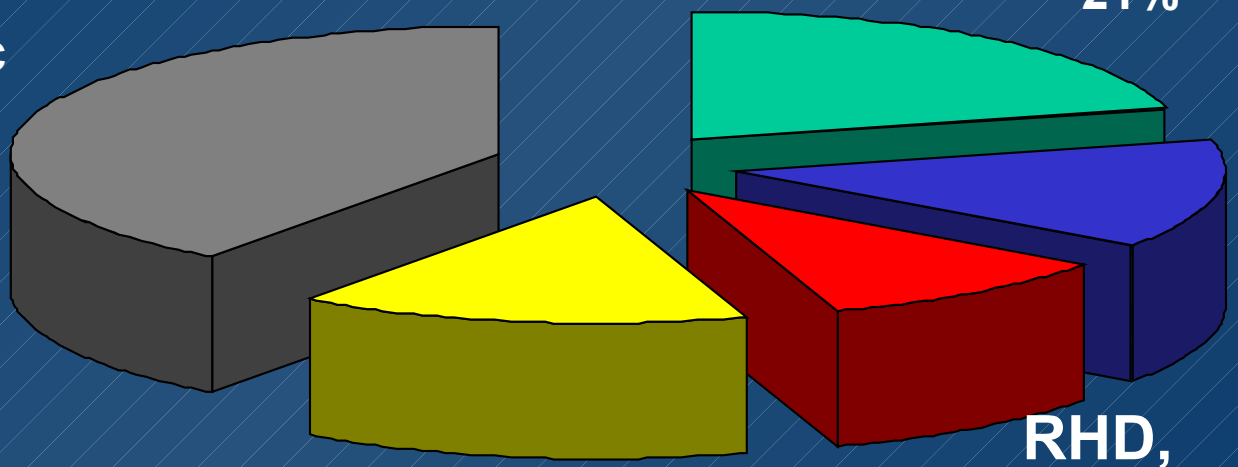
Presenter Disclosure Information

Name: Horst Sievert

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

Company Name:	Relationship:
•Terumo	Consultant
•Cierra	Consultant
•Velocimed	Consultant
•Cordis	Consultant
•Abbott	Consultant
•Bard	Consultant

Emboli are the Major Cause of Ischemic Stroke



Stroke 1988;19:547 *Data from NINCDS Stroke Data Bank*
Stroke 1999: 30:2513 *Minnesota population based study*
NEJM 2000;342:1743 *Framingham Study*

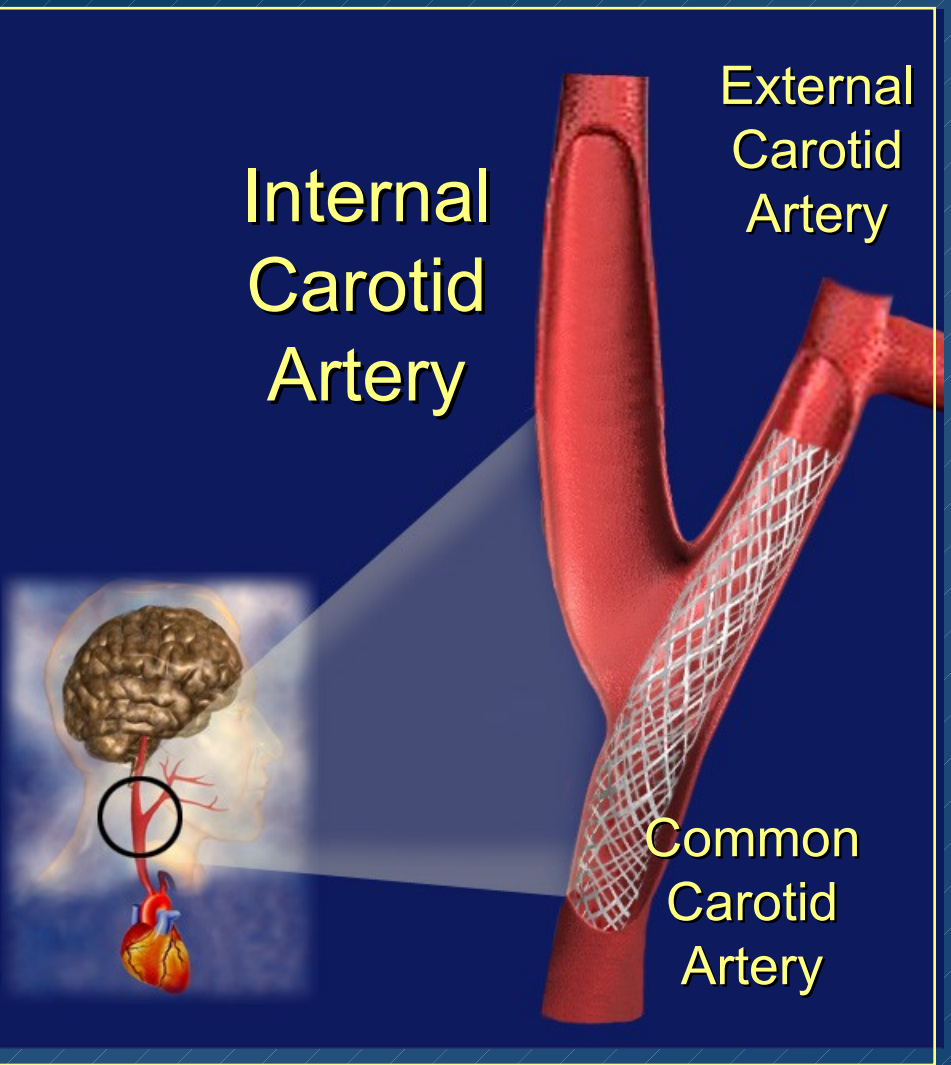
Anticoagulation

- Is the current gold standard, but…

- Difficult to manage in clinical practice
- Risk of side effects
- Contraindicated in many patients
- Probably not effective in aortic arch atheroma

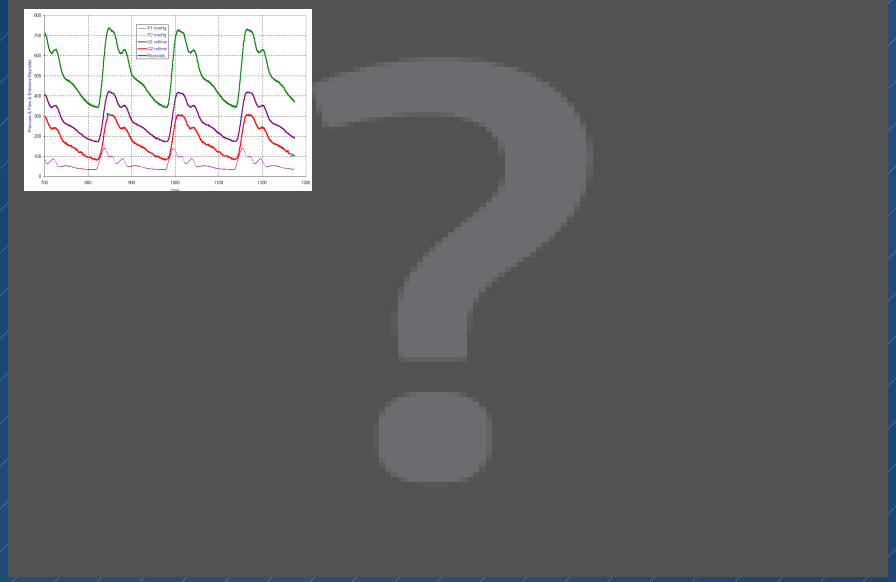
Mindguard Carotid Mesh Diverter

Concept: To divert emboli to a benign location



The In-vitro Model

Flow studies (CDPIV) were carried out to test global and local aspects of bifurcation filtration



global **local**

Local Hemodynamics

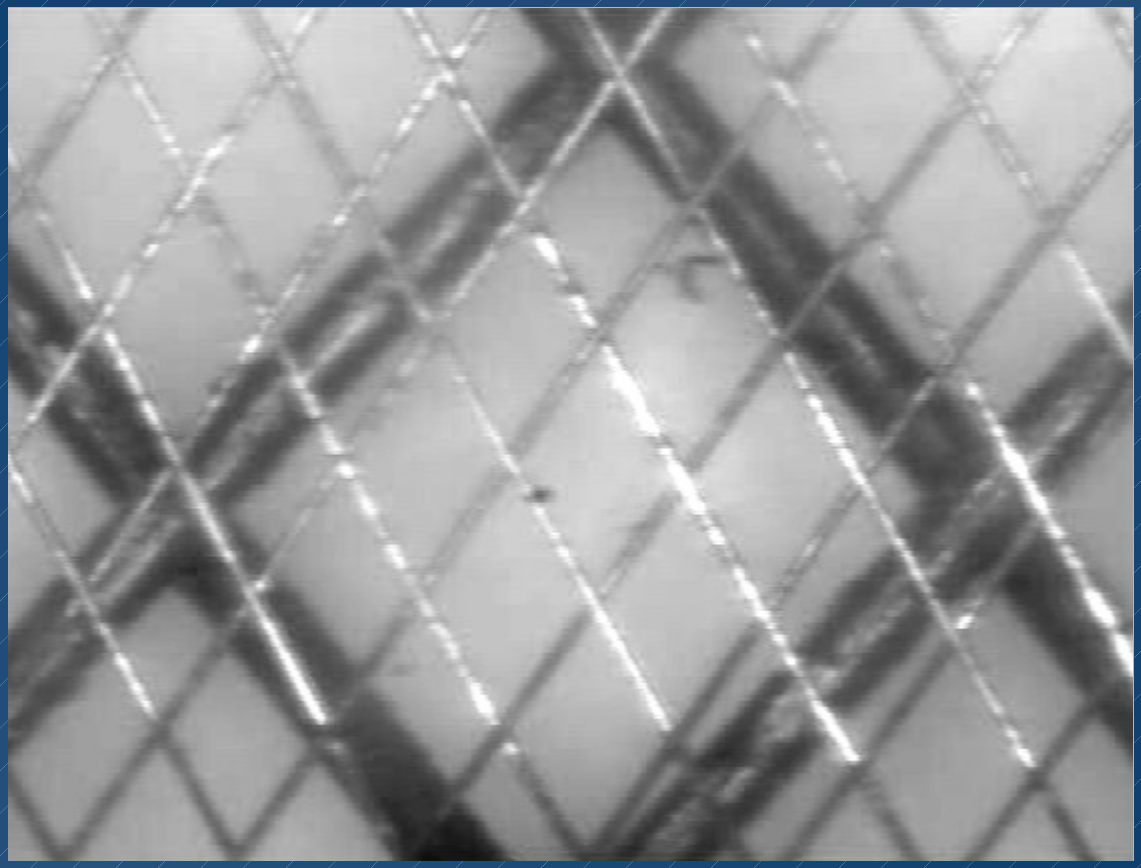
Thin struts

Pulsatile, laminar

Thick struts

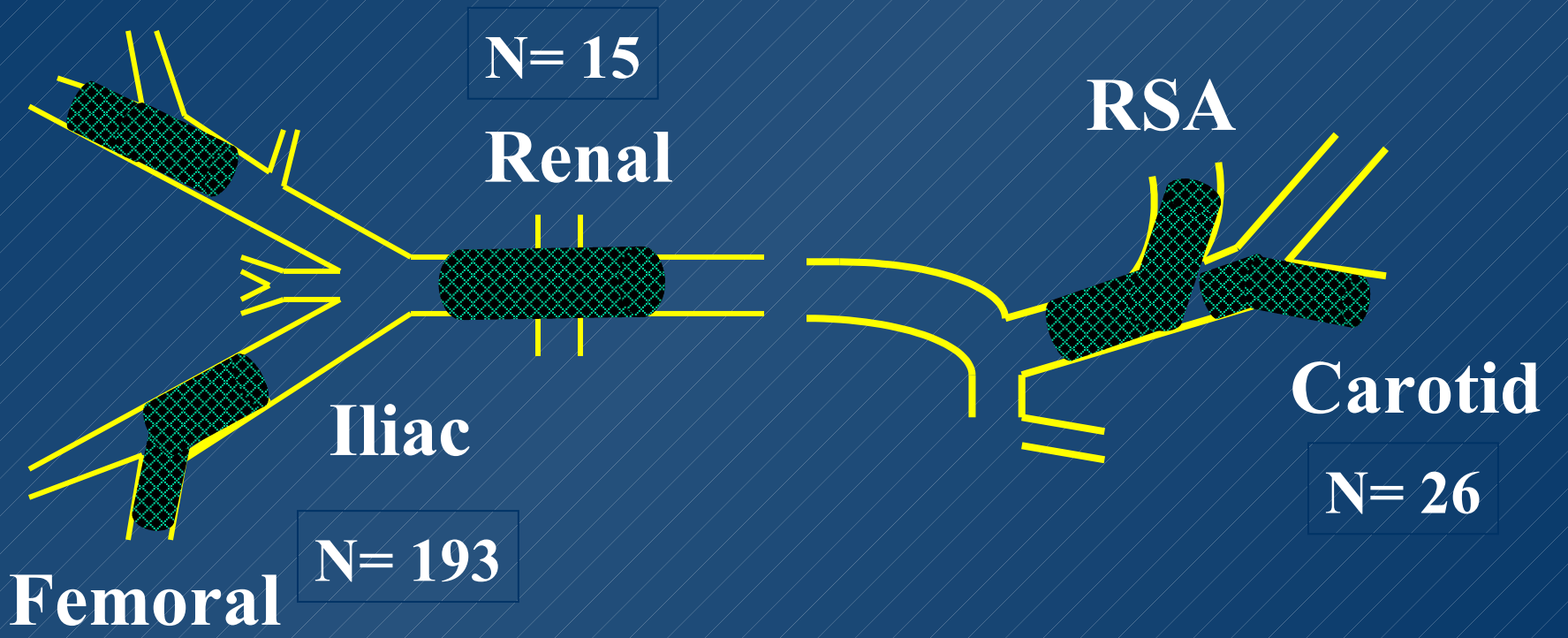
Turbulence, (Steady)

The Fine Wire Concept



High porosity index

> 200 Implantations in Animals



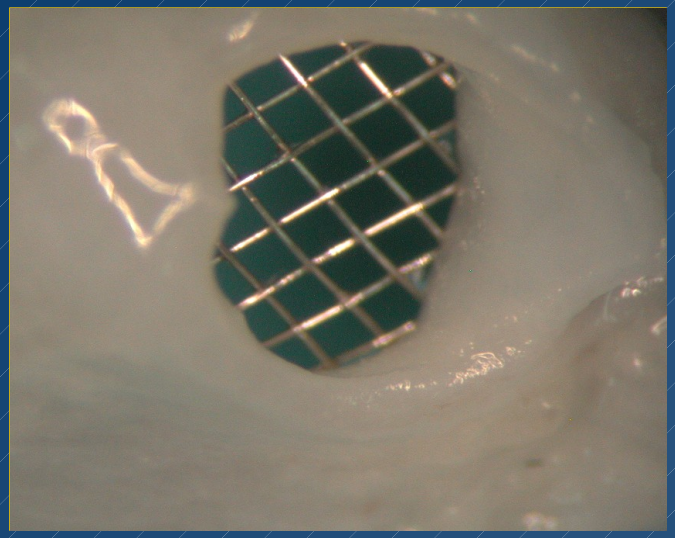
Pigs are the ideal model:

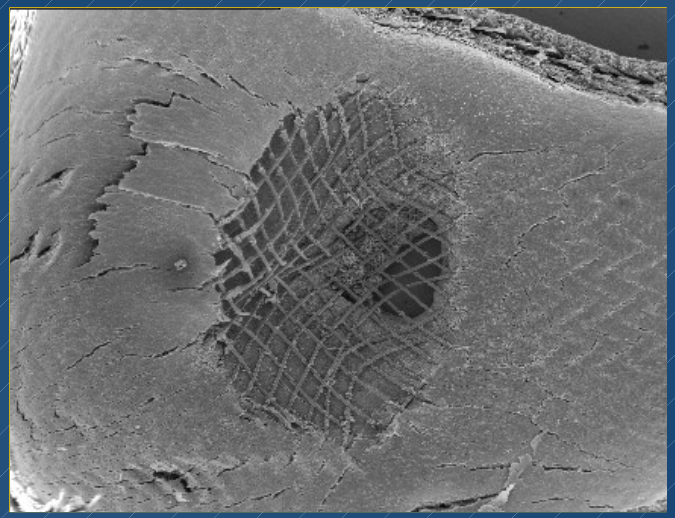
→ Like to proliferate

→ Like to thrombose

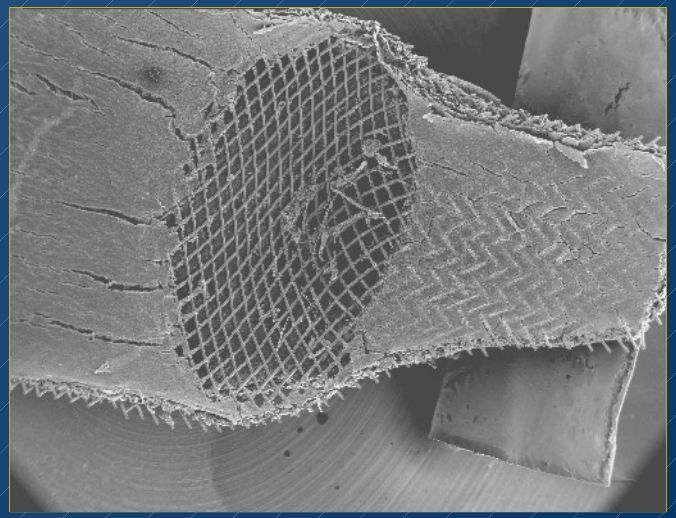
The Diverter Patency

weeks 2





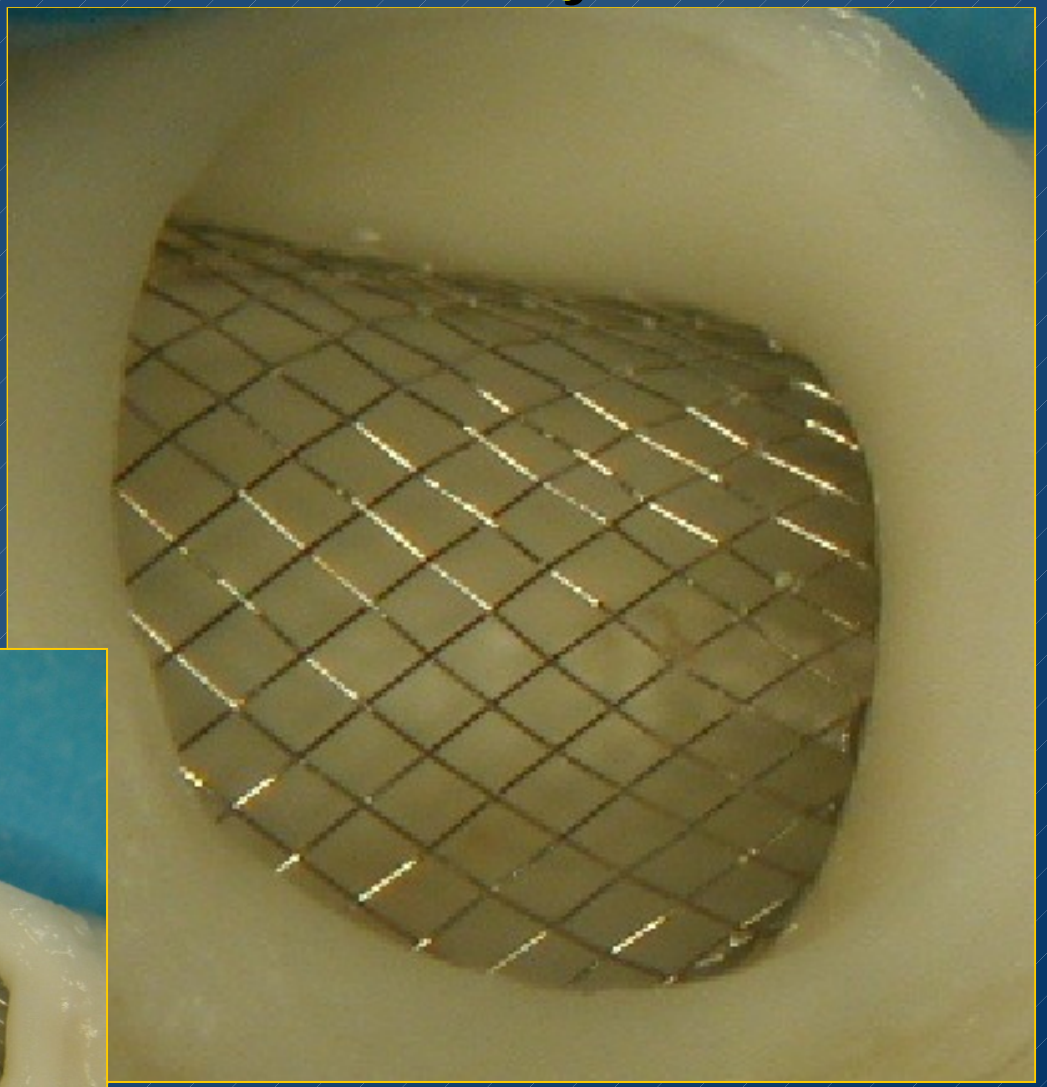
weeks 4

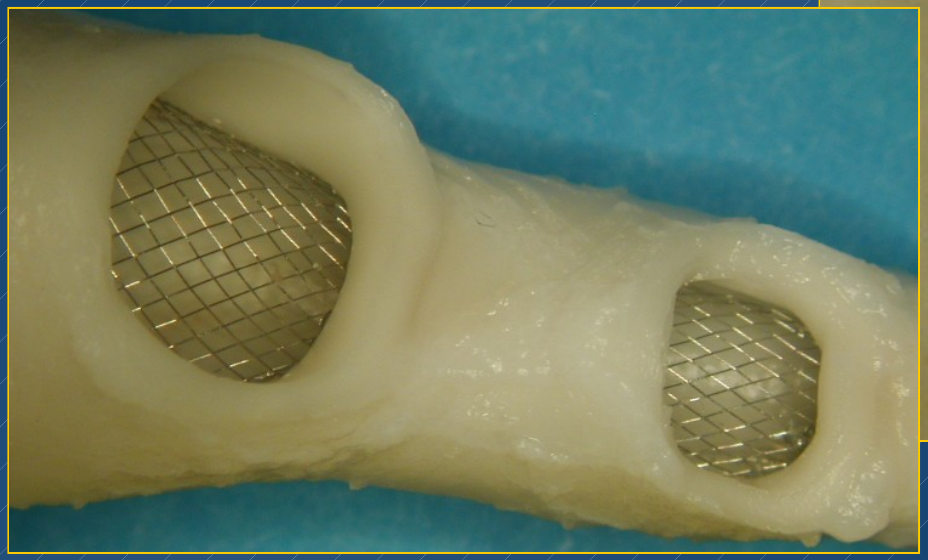


CardioVascular Center Frankfurt, Sankt Katharinen

The Diverter Patency

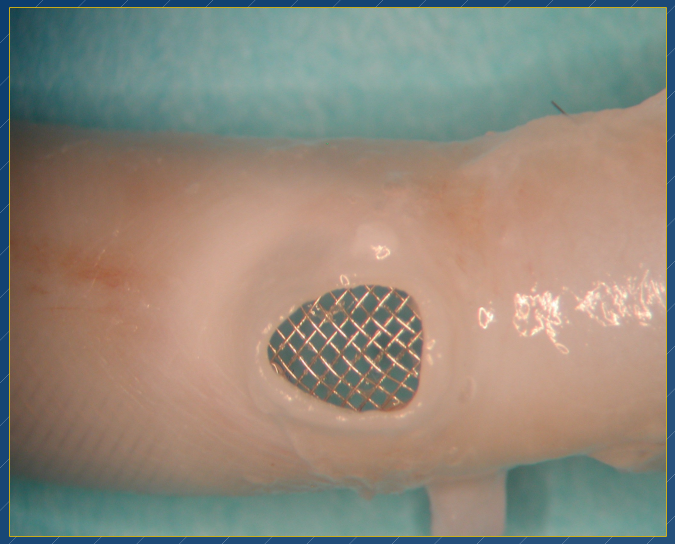
weeks 5

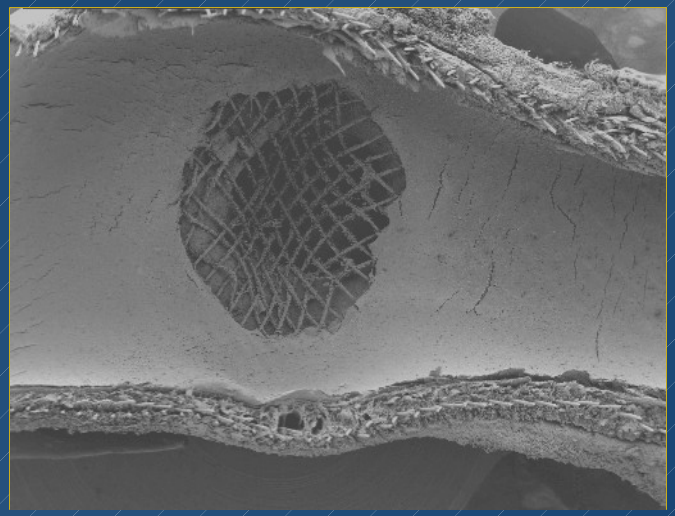




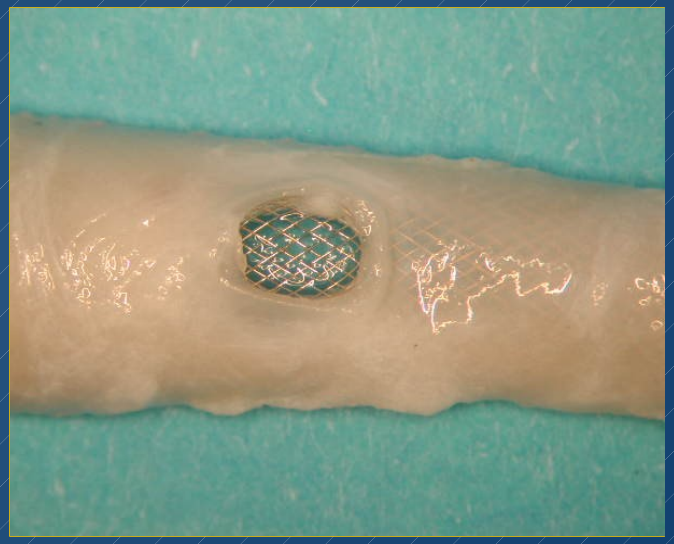
The *Diverter* Patency

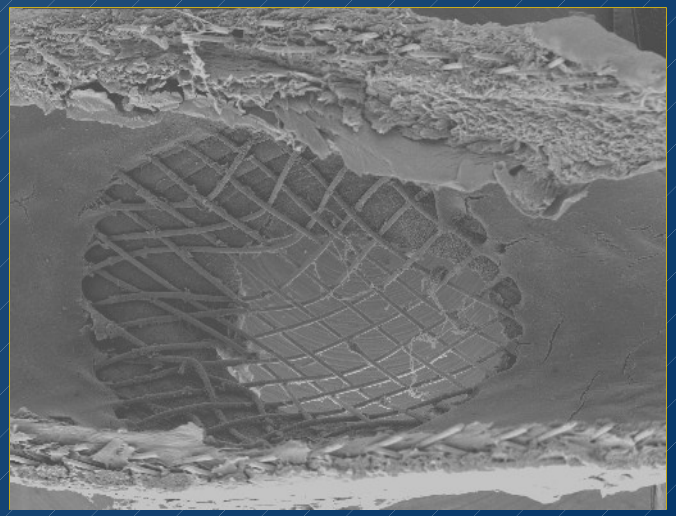
weeks 9





weeks 18

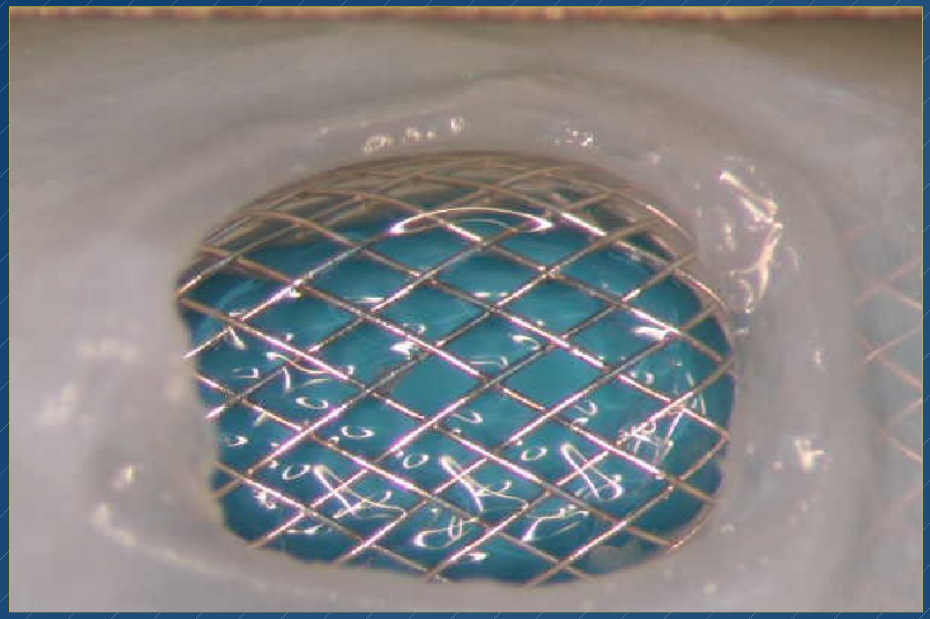


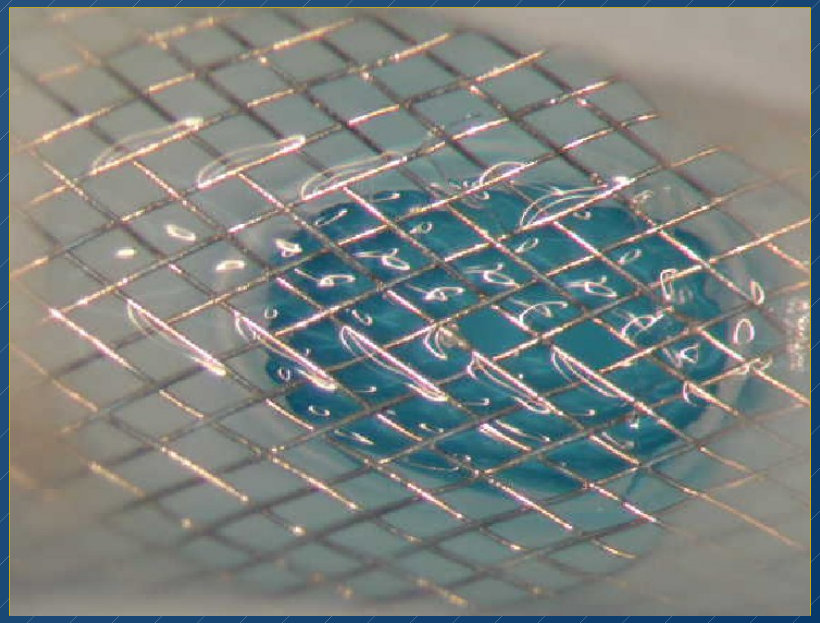


CardioVascular Center Frankfurt, Sankt Katharinen

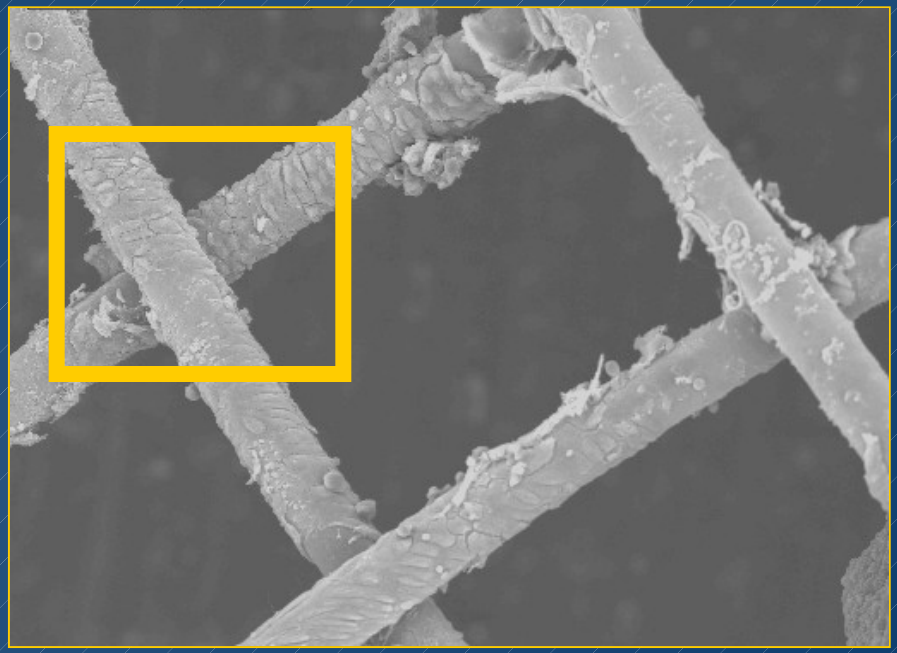
The *Diverter* Patency

weeks 18

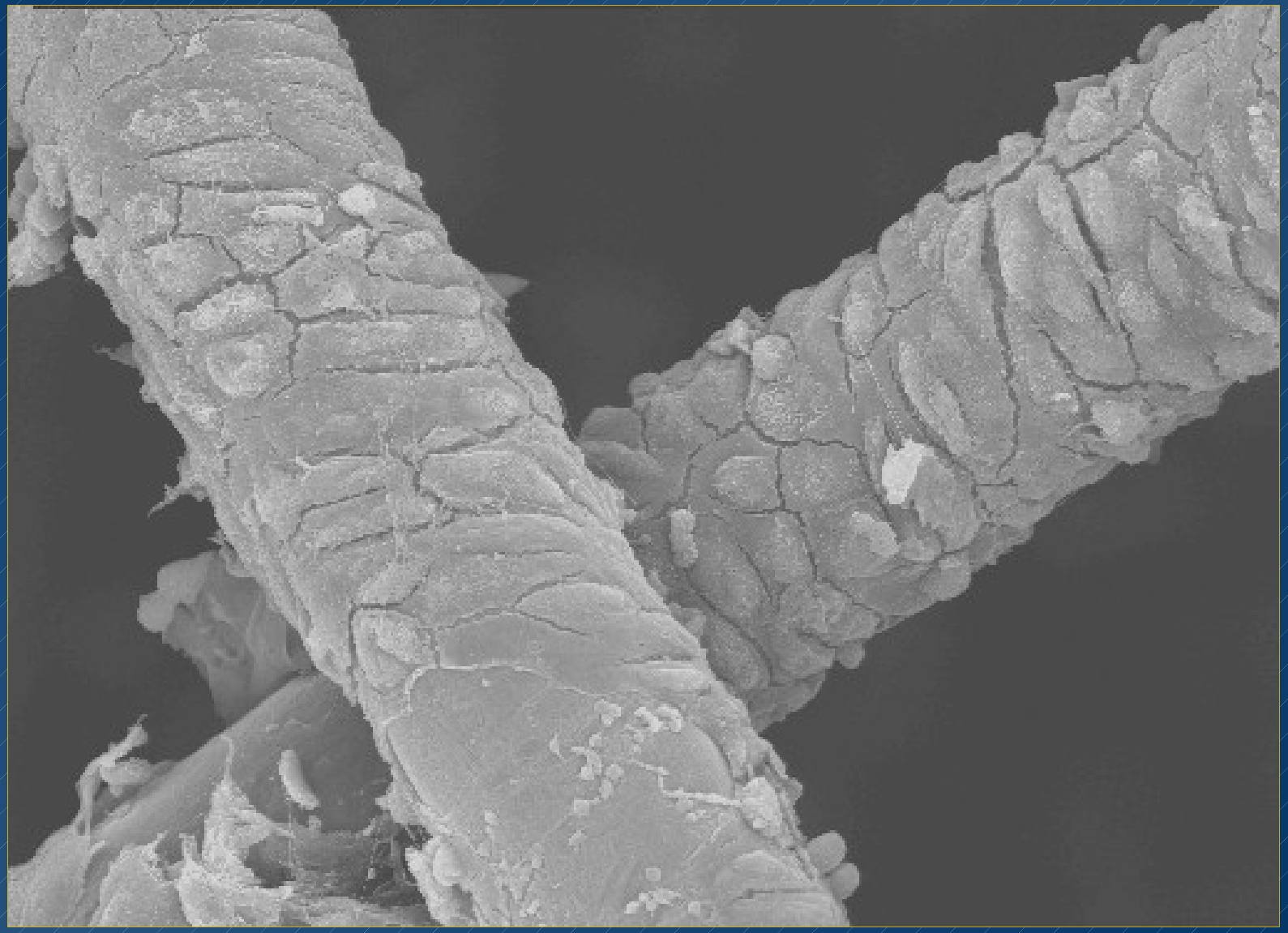




The *Diverter* Patency

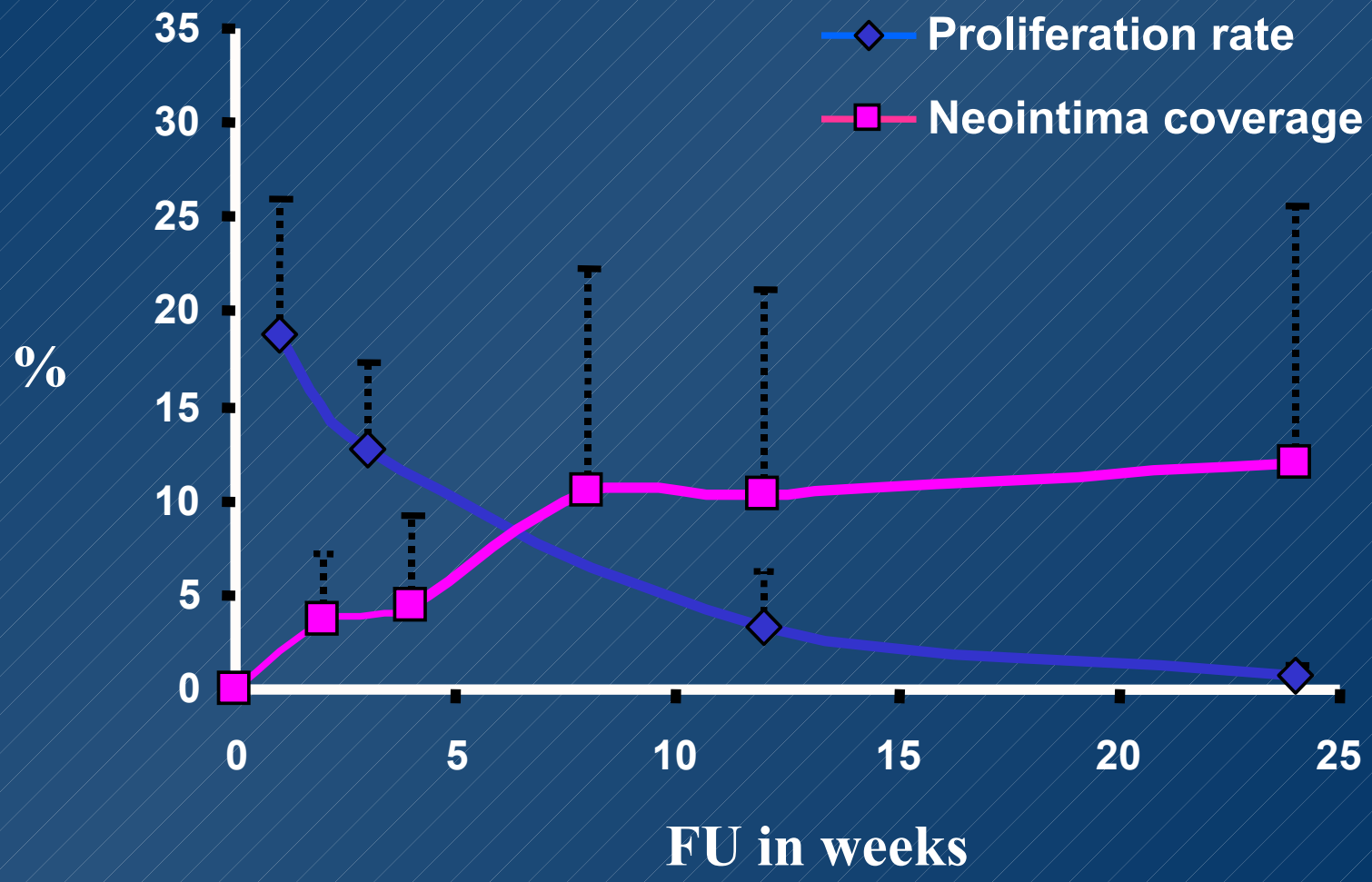


The *Diverter* Patency

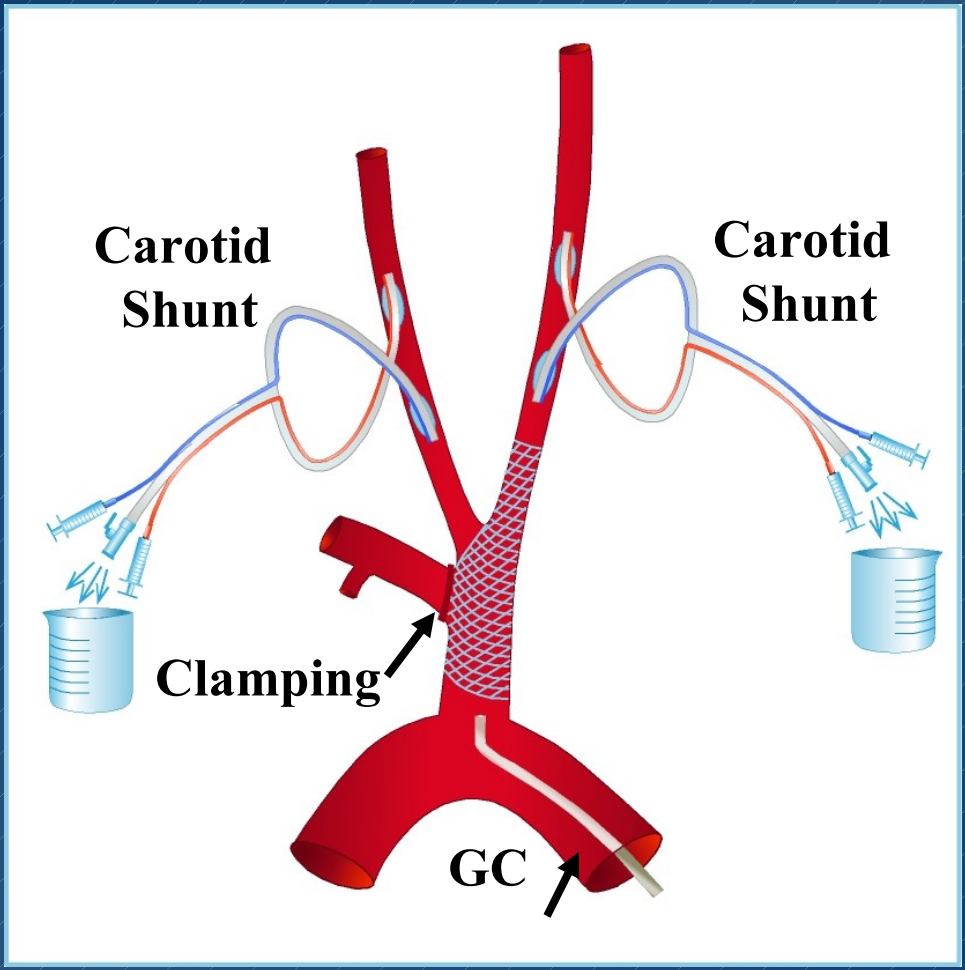


CardioVascular Center Frankfurt, Sankt Katharinen

Proliferation and Neointima Coverage



METHODS



Schematic description of the procedure, post deployment and shunt insertion

So we thaught

- The concept is good
- The device is good
- We are good

- Let's go for a clinical trial

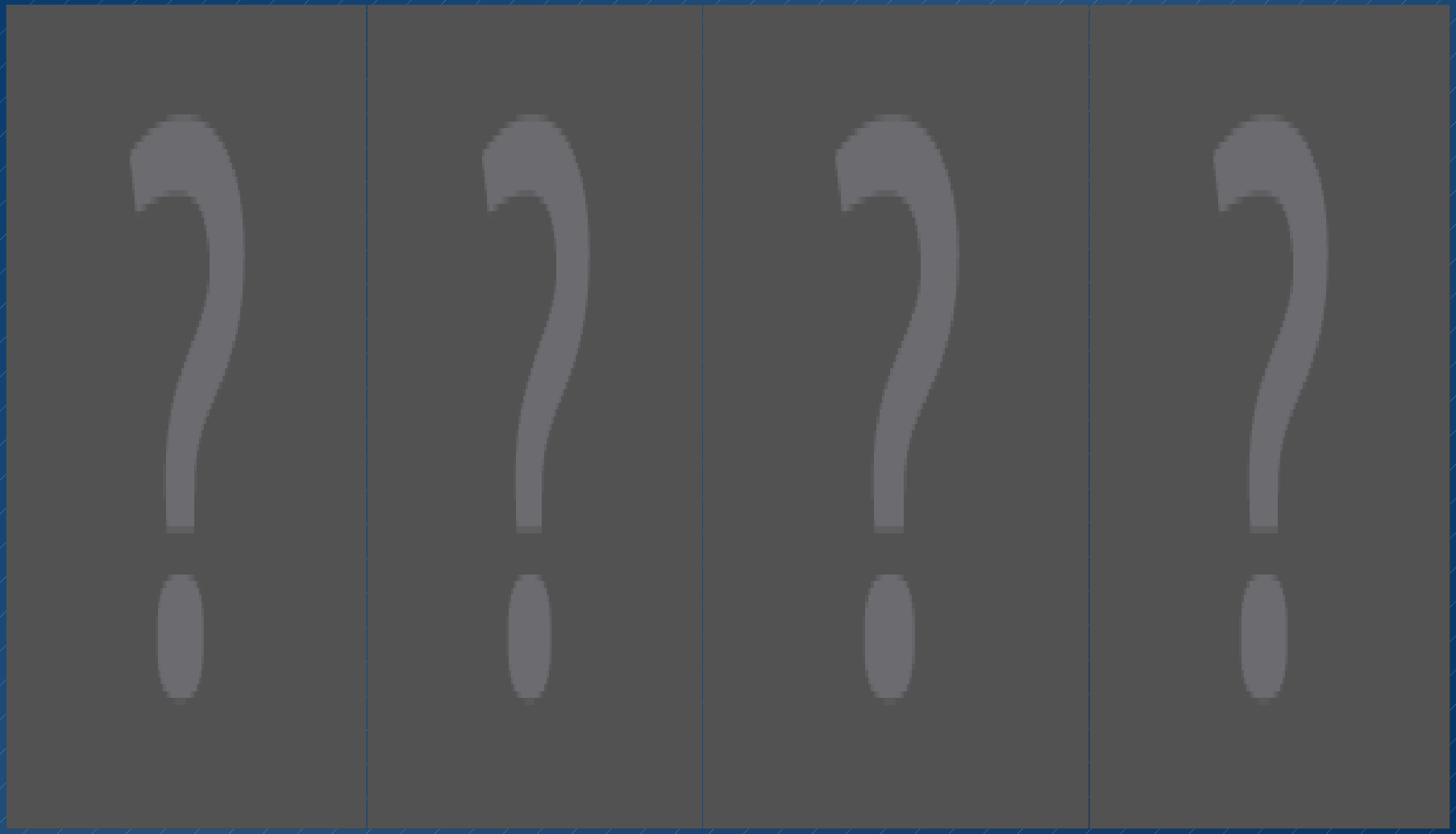
E-DIRECT Study

*E*mboli *DI*version and *R*erouting to the *E*xternal *C*arotid artery *T*echnique

Patient Selection Criteria

- Atrial fibrillation
- High risk for stroke
- Non-candidates for oral anticoagulants

Case #1



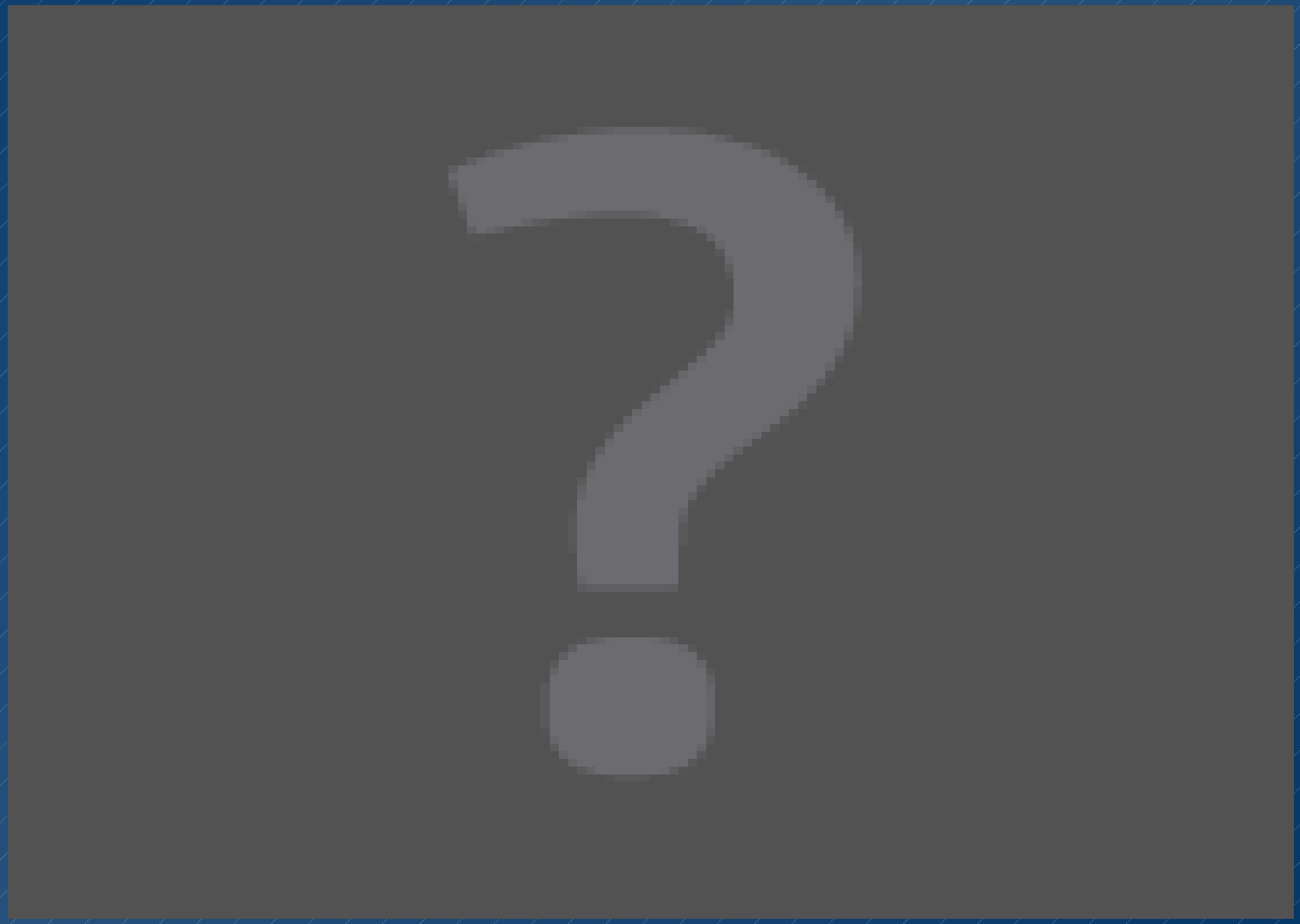
Case #1

Before

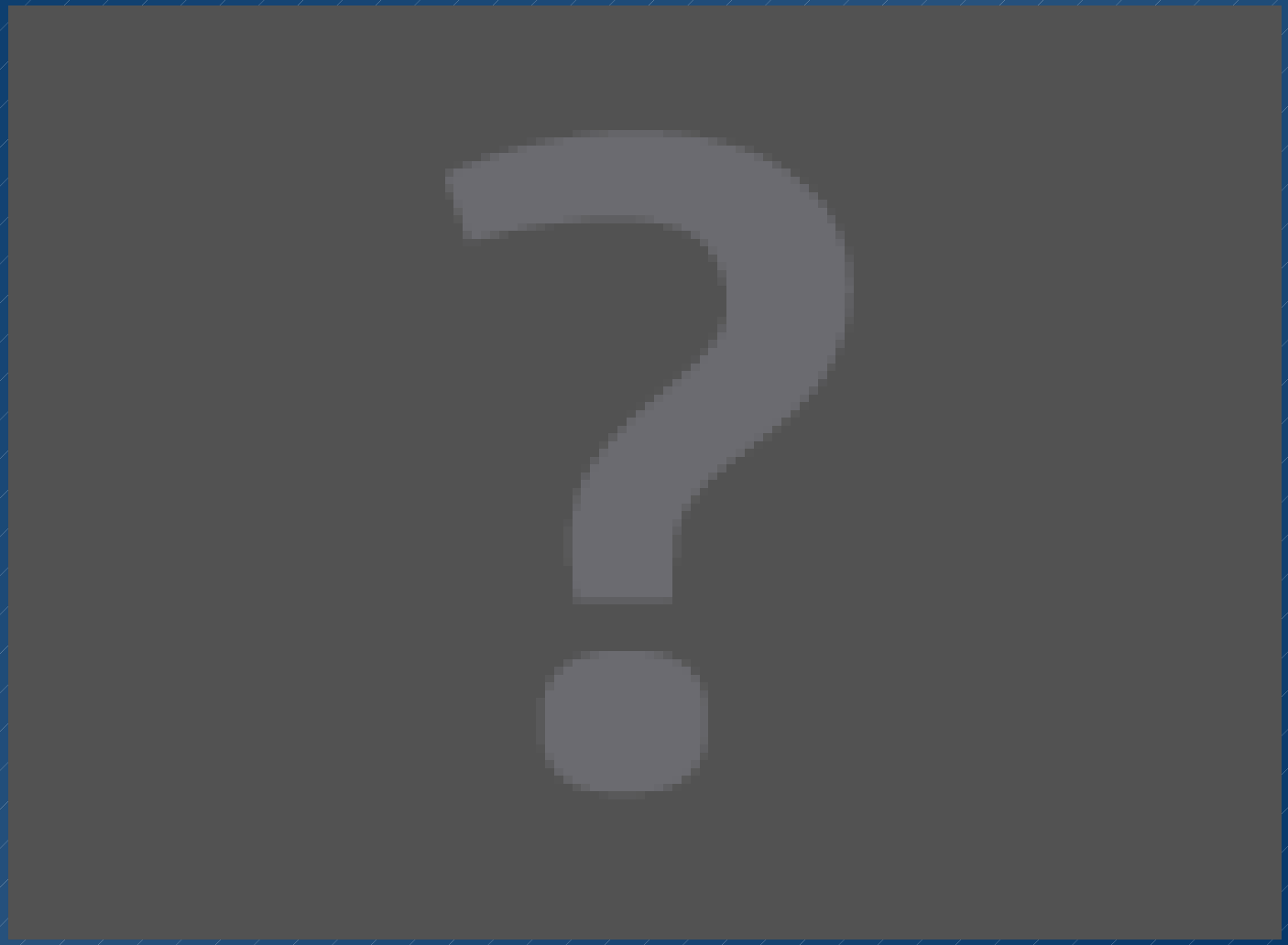
After

FU 1 mo Duplex

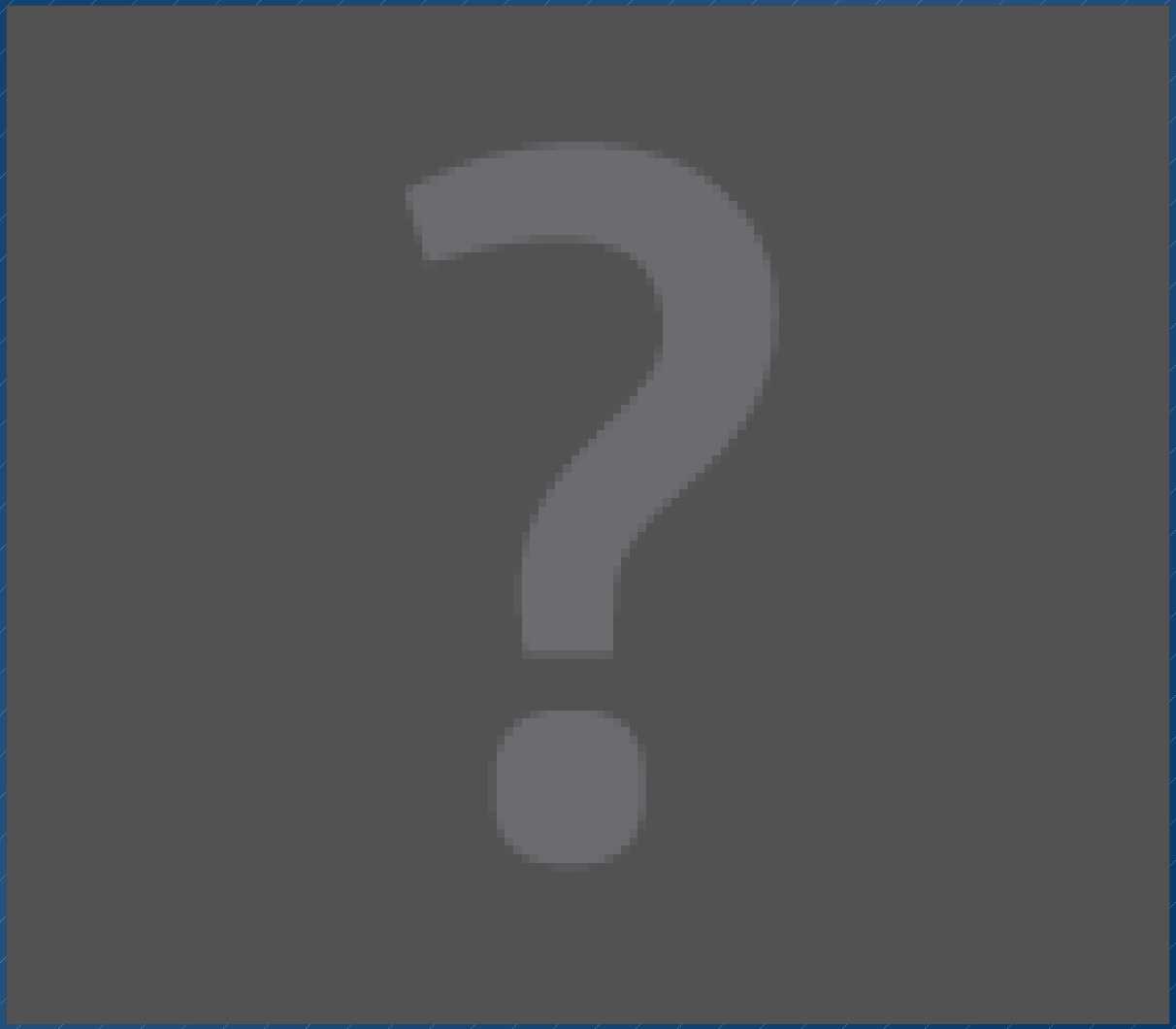
FU 3 mo Duplex



FU 6 mo Duplex



FU 9 mo Duplex

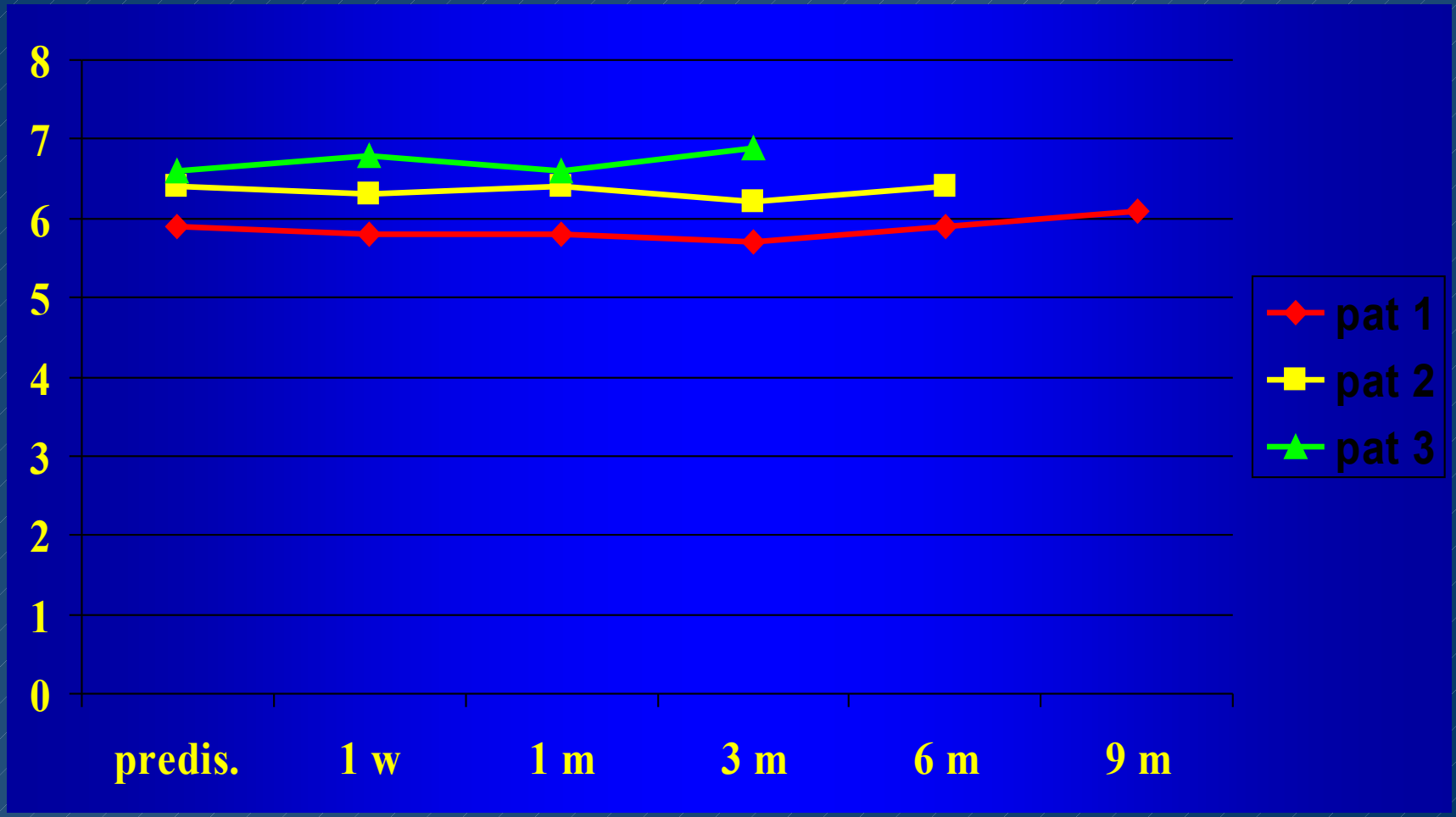


after the first case

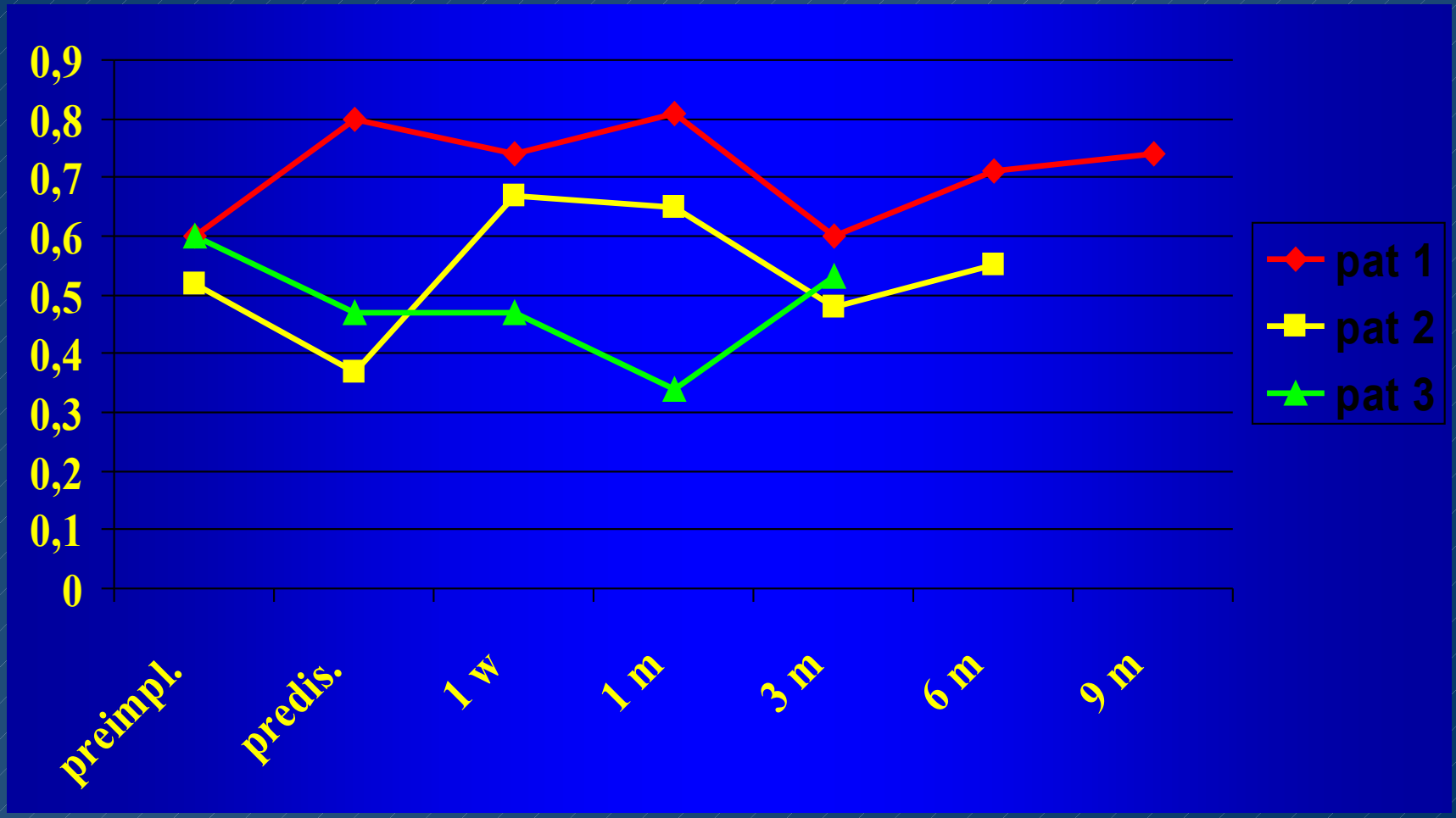
- 2 more patients were enrolled

- Huge interest of the media
- Many referrals
- A lot of pressure from the investors

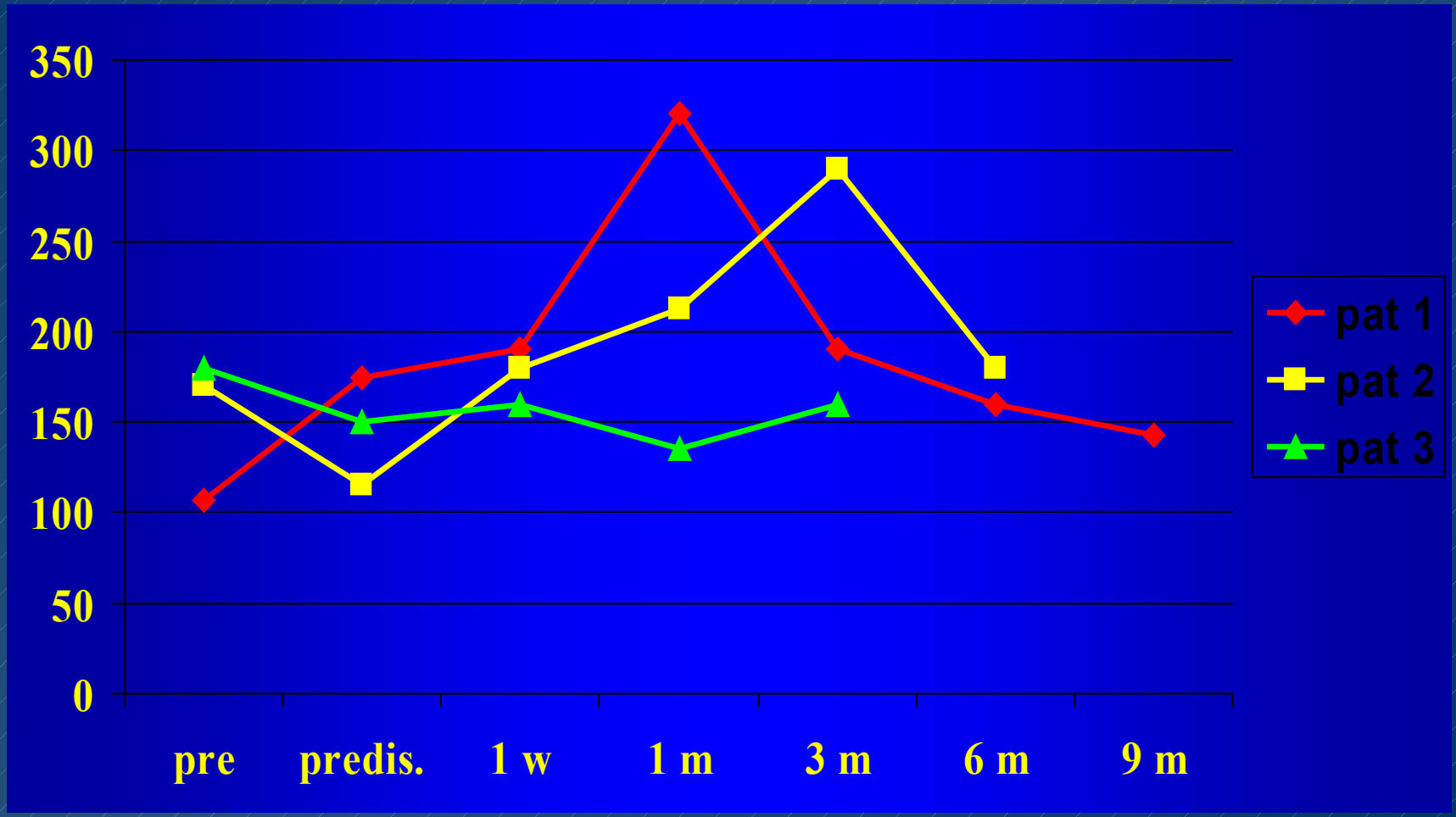
CCA Diverter Diameter (mm)



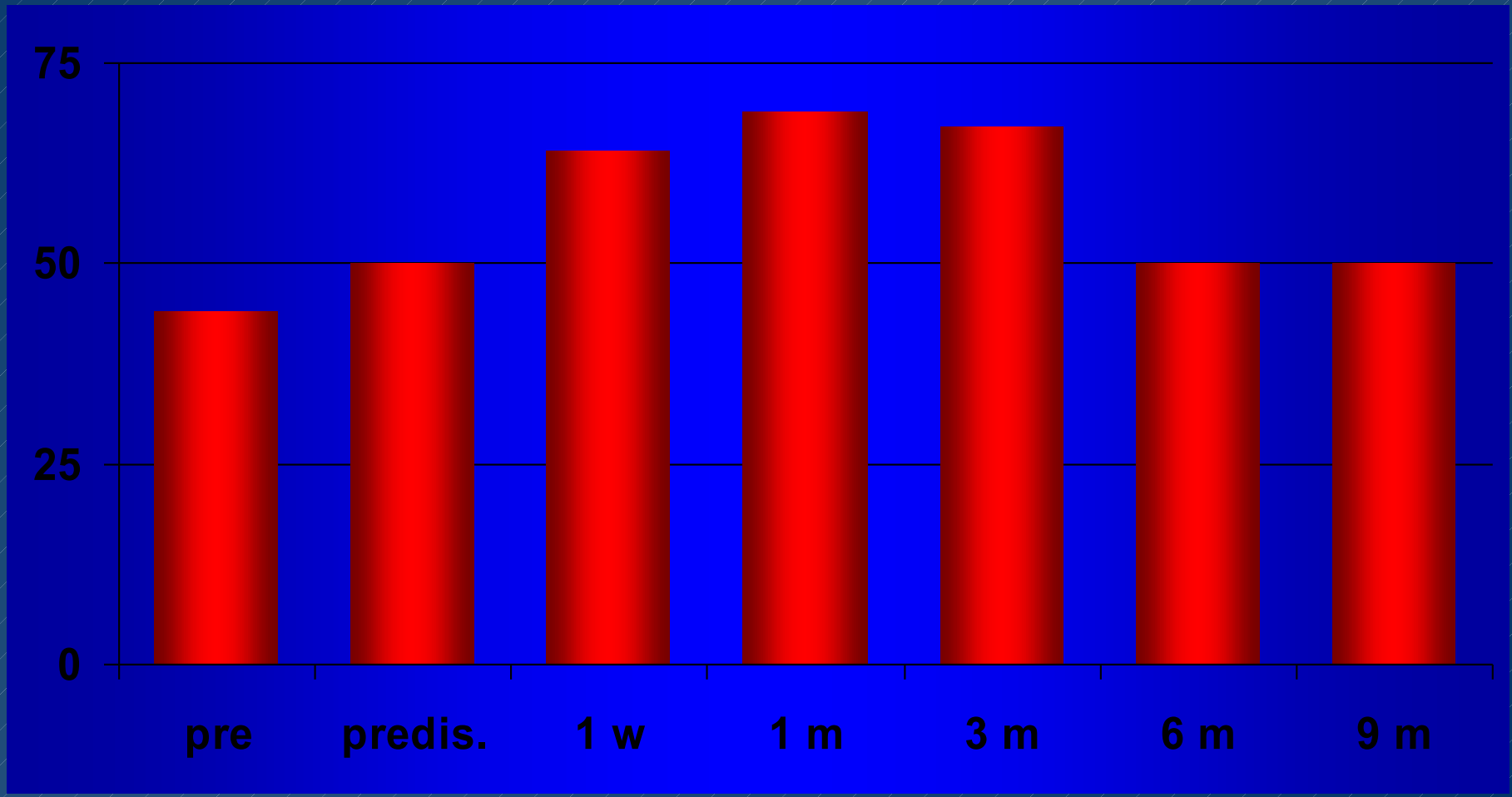
Syst. Peak Vel. ICA
(m/sec)



Volume Flow (ml/min) ICA



% Volume Flow ICA / CCA



Patient #3

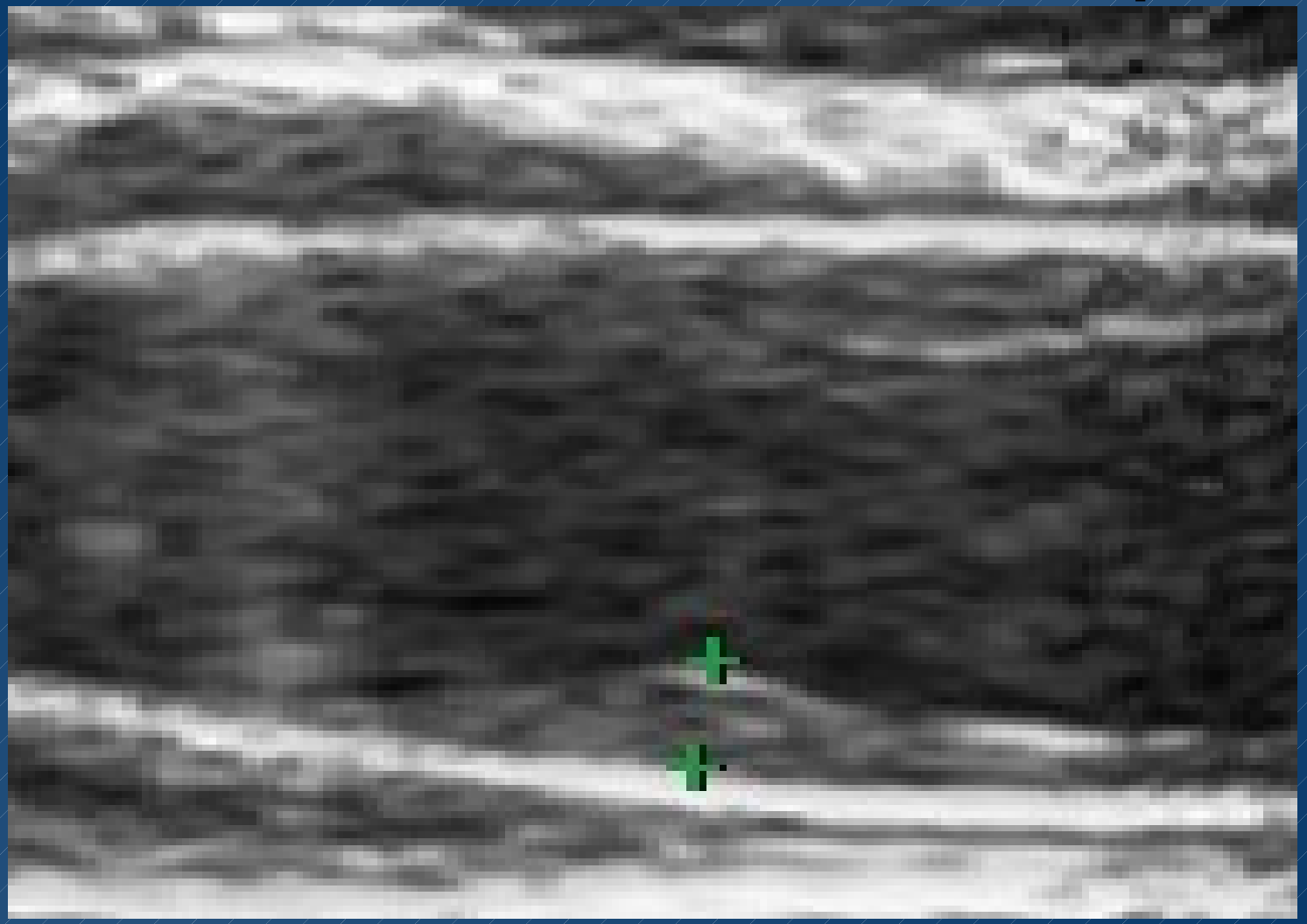
- 57 year old man
- Chronic atrial fibrillation
- Surgical ASD occlusion 1971
- Congestive heart failure (EF 20 %)
- LV Thrombus
- Liver cirrhosis

- 3 month FU normal
- 6 month FU postponed
- 7 month → symptom-free but ...

Patient # 3 - 7 mo Duplex

Internal carotid artery occluded

Patient # 3 - 7 mo Duplex



Massive proliferation

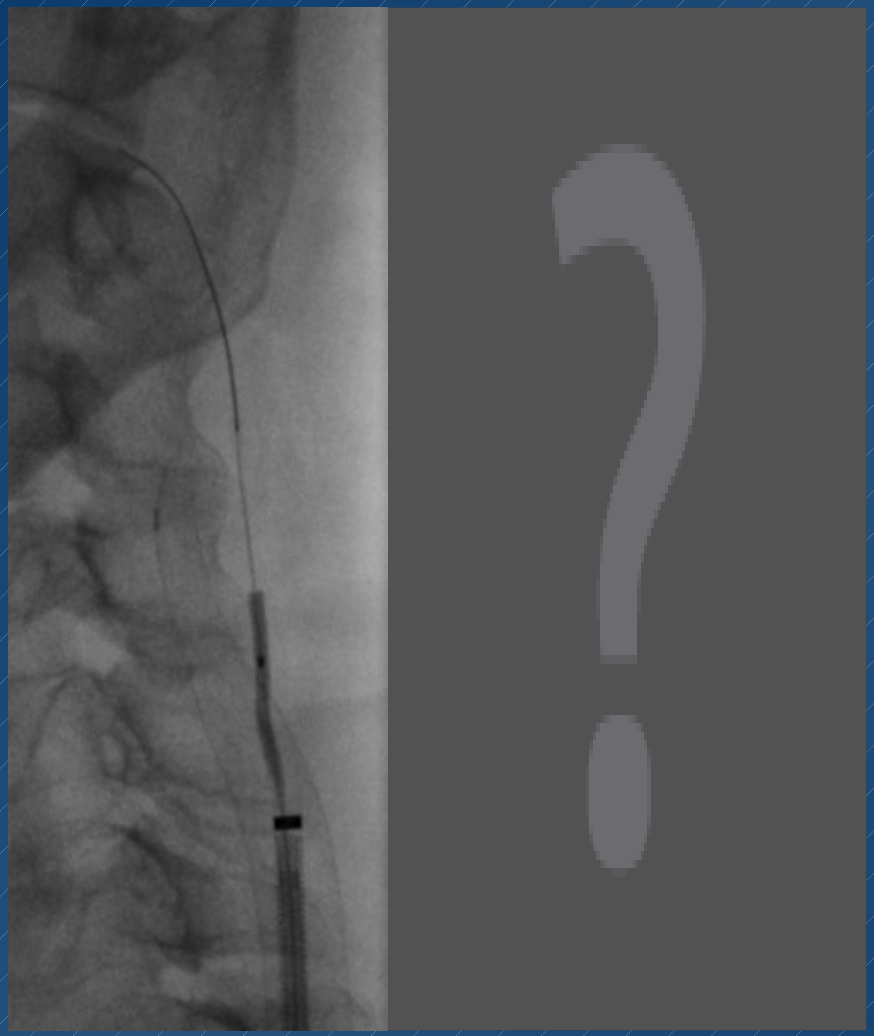
Patient # 3 - 7 mo Duplex

Massive proliferation, stenosis at distal end of Diverter

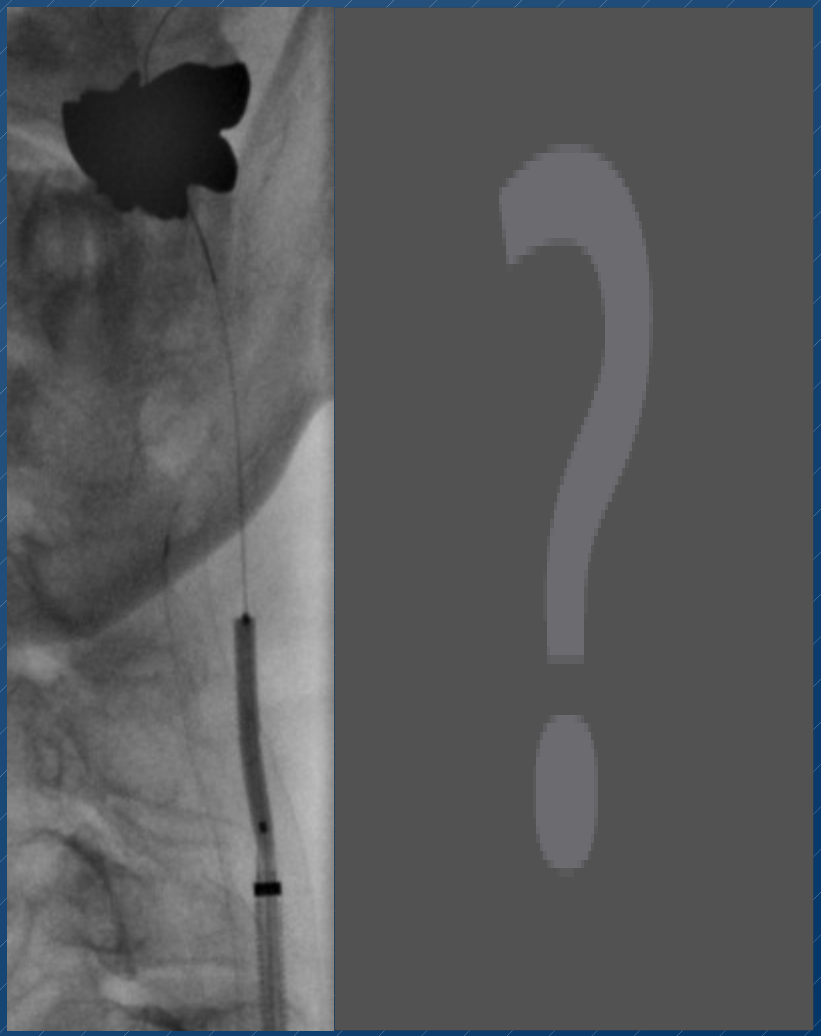
Patient 3 - 7 mo Angiogram

What to do now?

Patient 3 - 7 mo

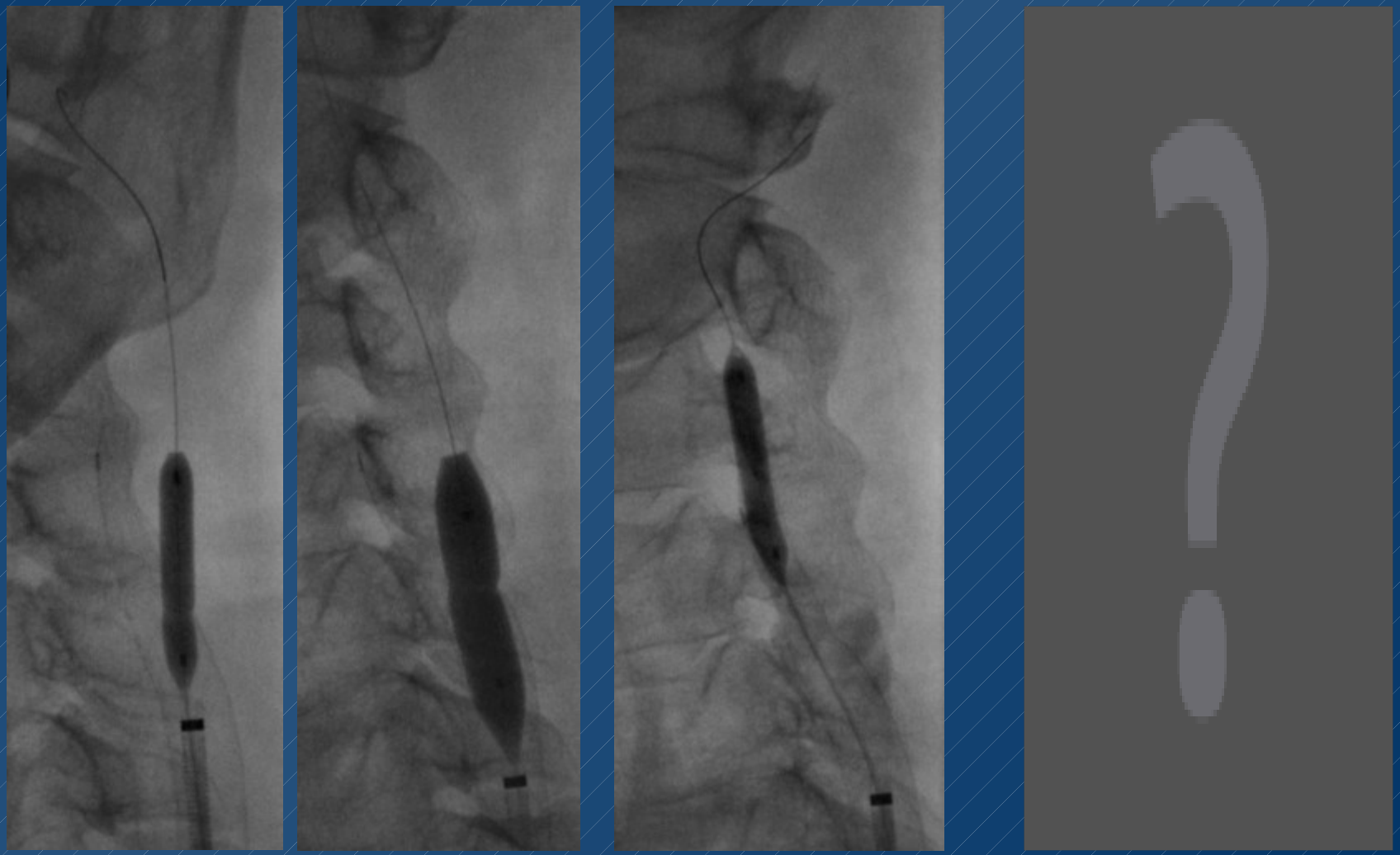


1.5 mm balloon



2 mm balloon

Patient 3 - 7 mo



4 mm 6 mm ECA

And the other patients?

- Patient #1
  - Massive proliferation (angiographically) after 15 months
    - Balloon angioplasty
- Patient #2
  - Doing fine
  - Became angry
    - about frequent FU
    - and because he received only 1 device

And the Company?

Lessons Learned

- Animal experiments are necessary and provide solutions for many problems
- Unfortunately sometimes the results are completely misleading
- In humans new technologies should be used carefully and stepwise