

The Mindguard Carotid Mesh Diverter to Prevent Embolic Stroke

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Sankt Katharinen

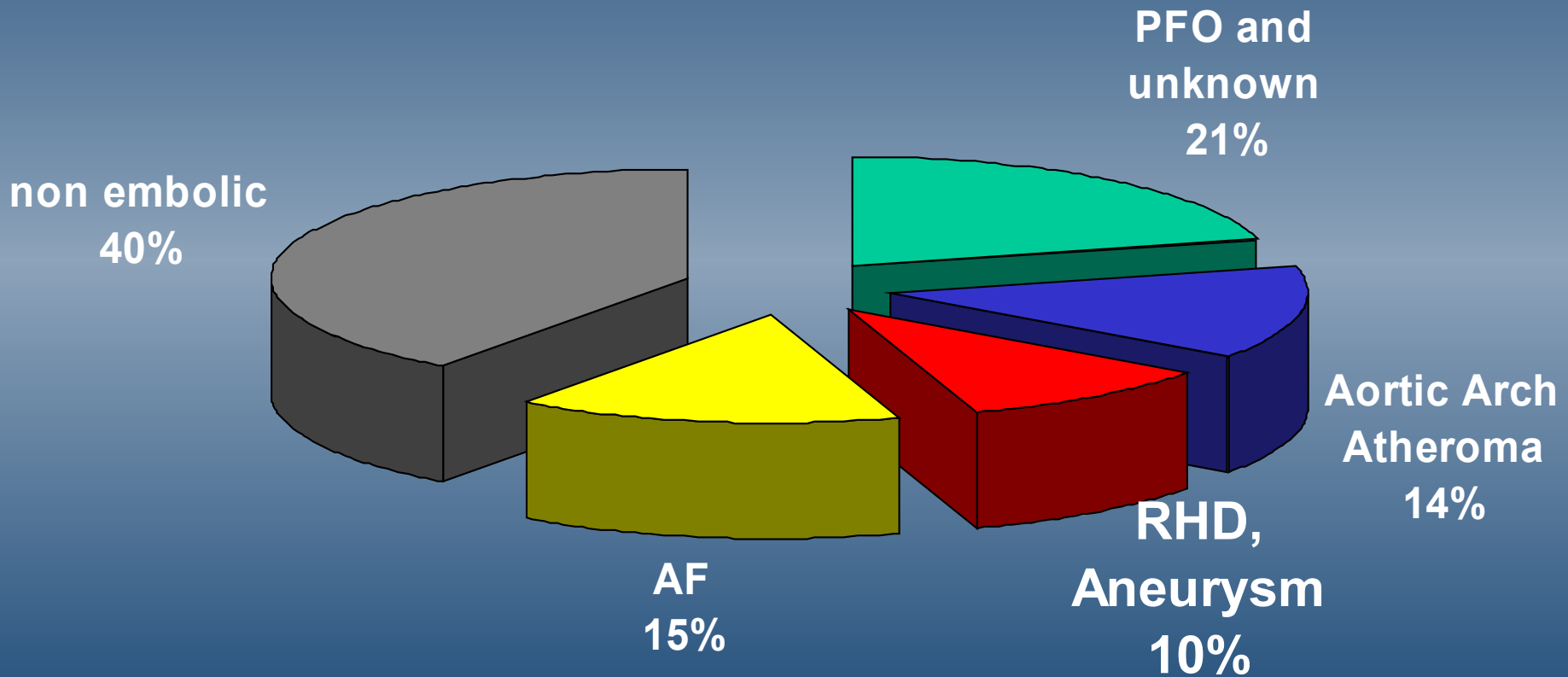
Frankfurt, Germany

PRESENTER DISCLOSURE INFORMATION

Name: Horst Sievert, M.D.

Nothing to Disclose Related to this Presentation

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

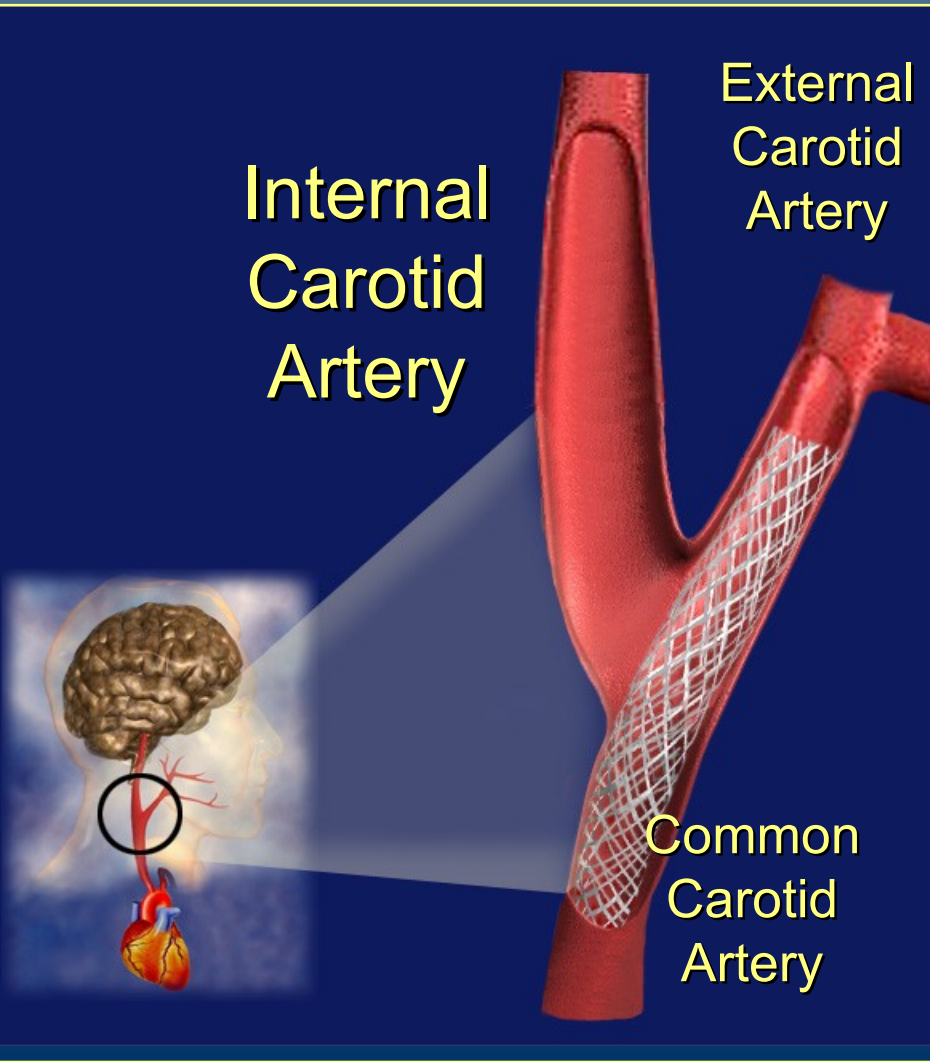
Framingham Study

Anticoagulation

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

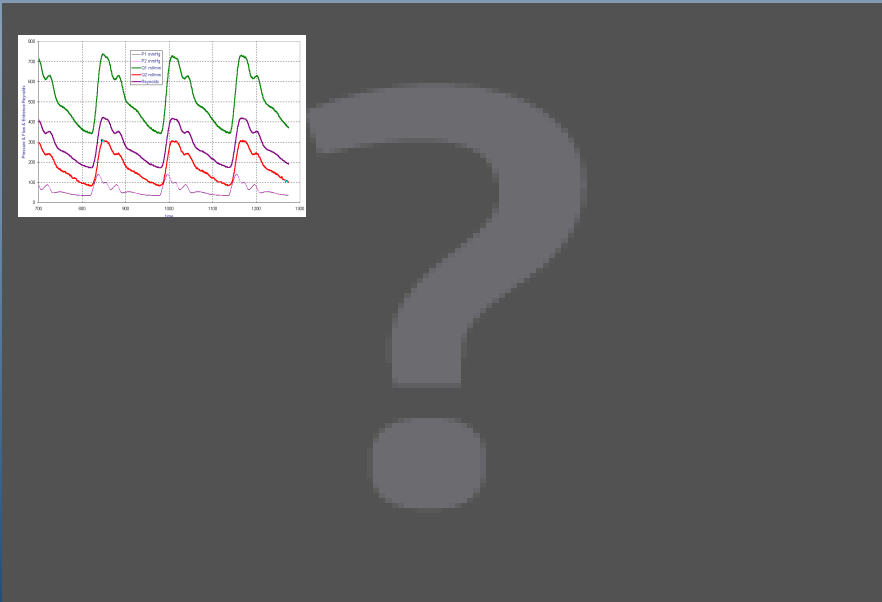
Mindguard Carotid Mesh Diverter

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



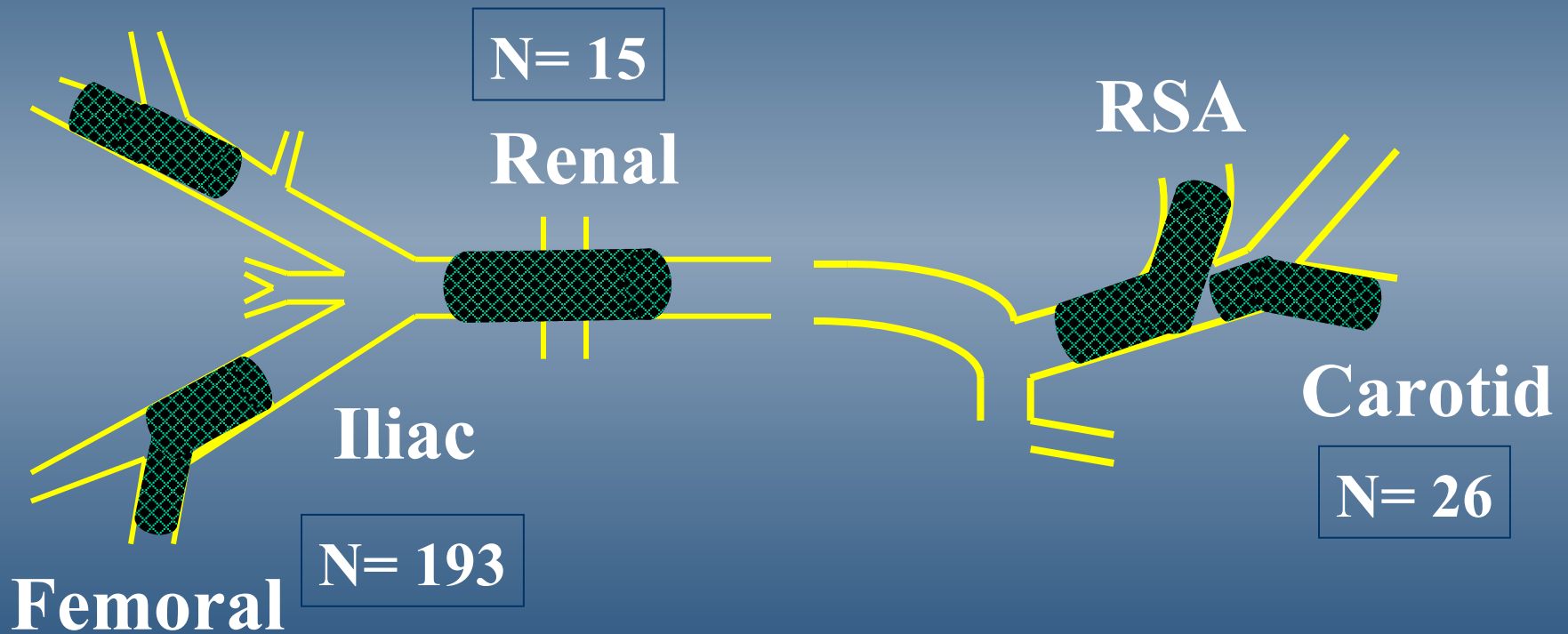
Turbulence,
(Steady)

The Fine Wire Concept



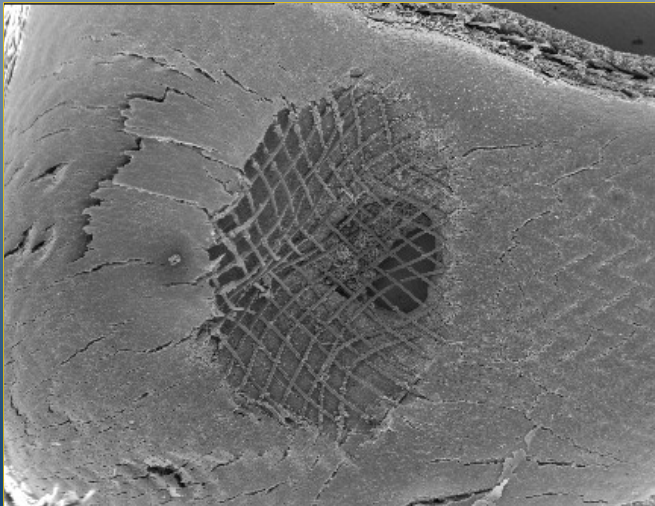
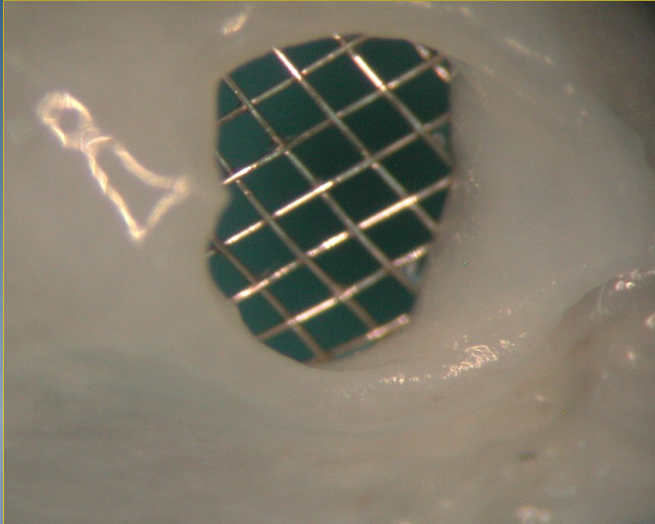
High porosity index

> 200 Implantations in Animals

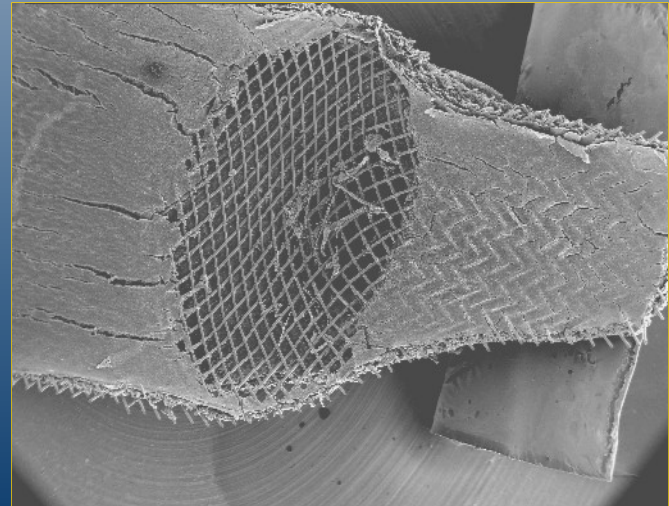
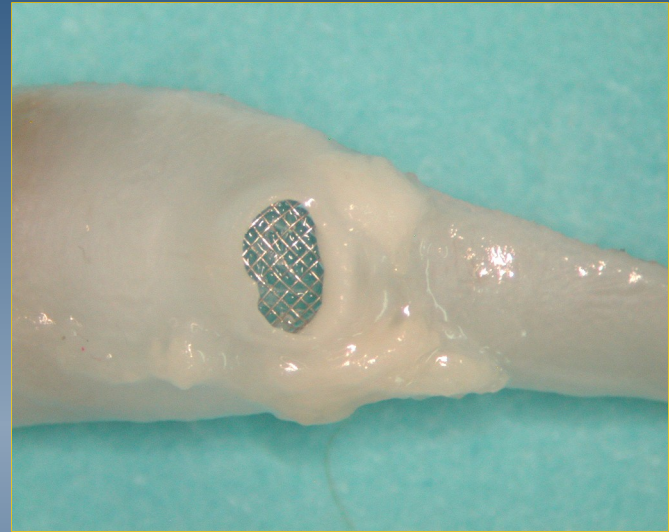


The Diverter Patency

weeks 2

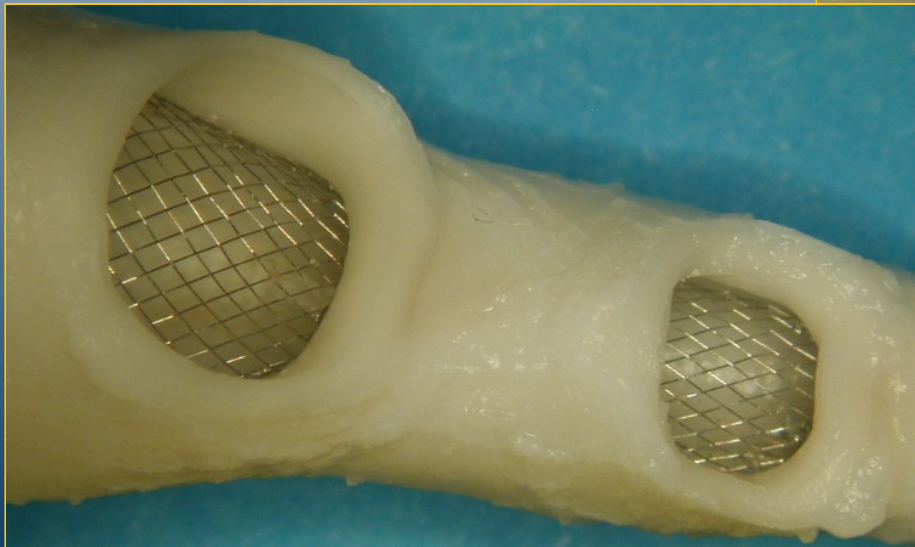
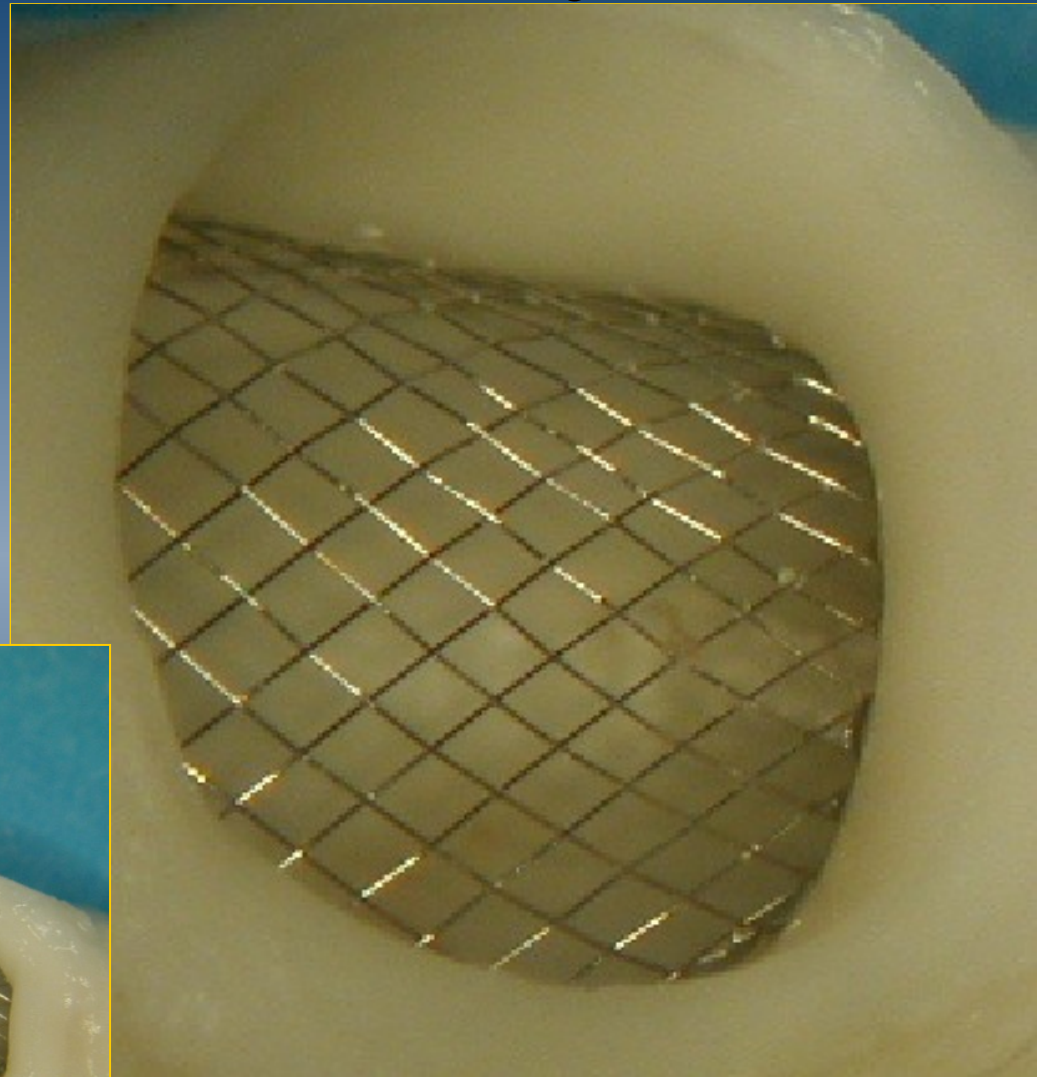


weeks 4



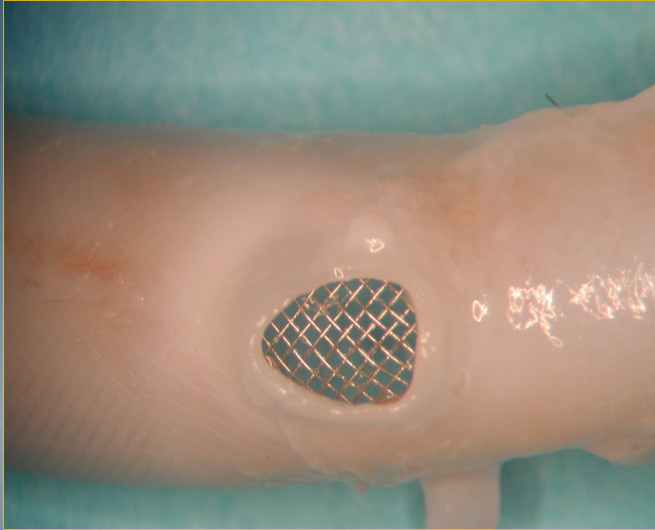
The Diverter Patency

weeks 5

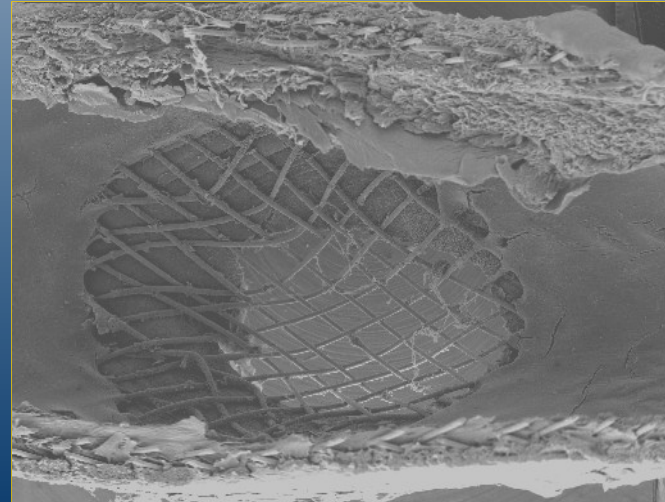
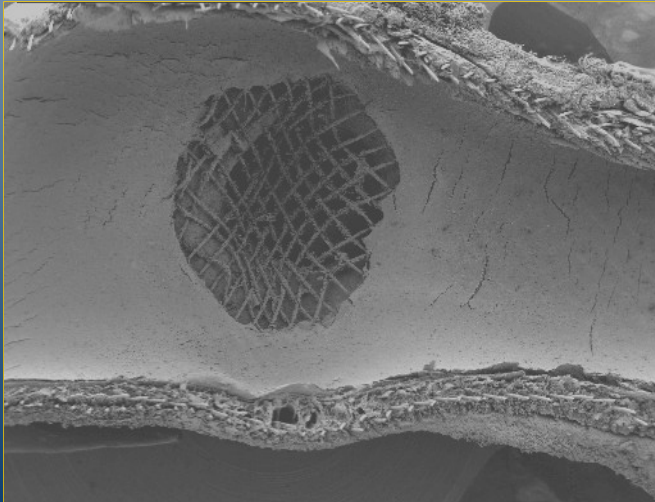
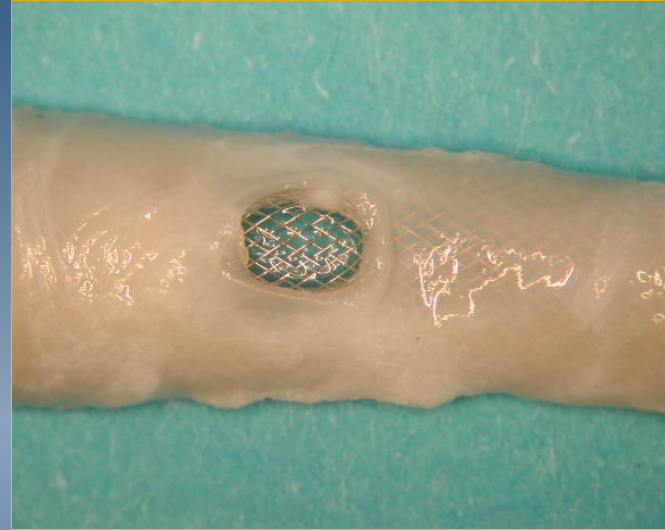


The *Diverter* Patency

weeks 9

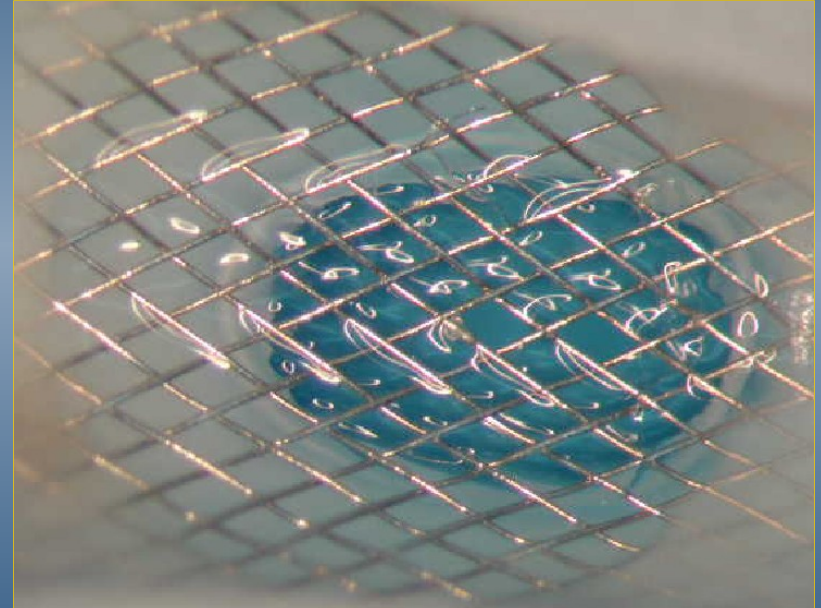
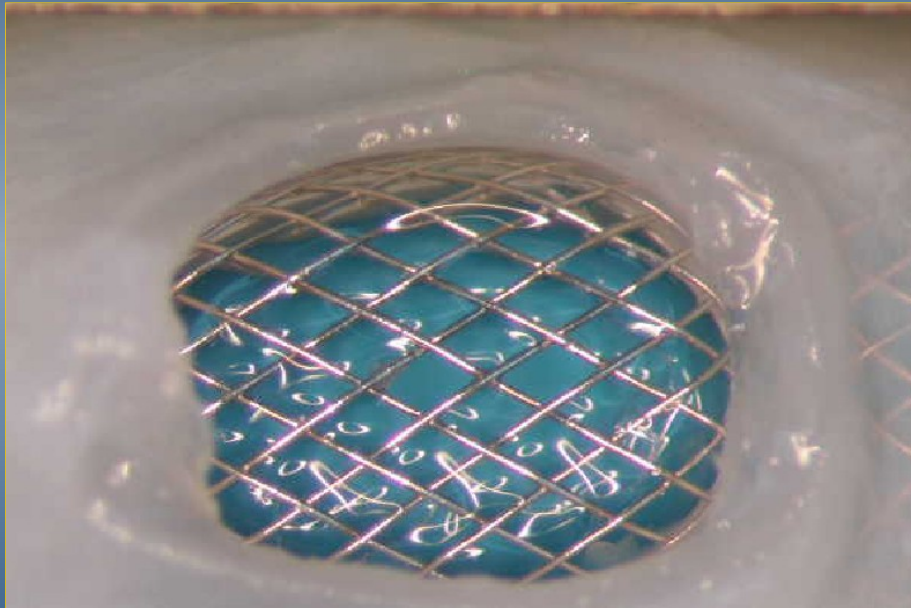


weeks 18

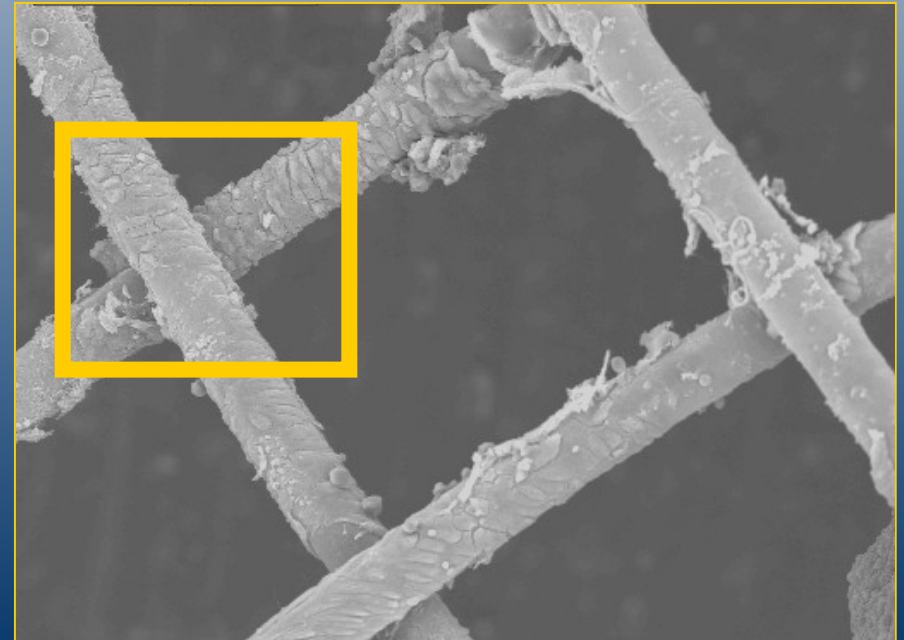
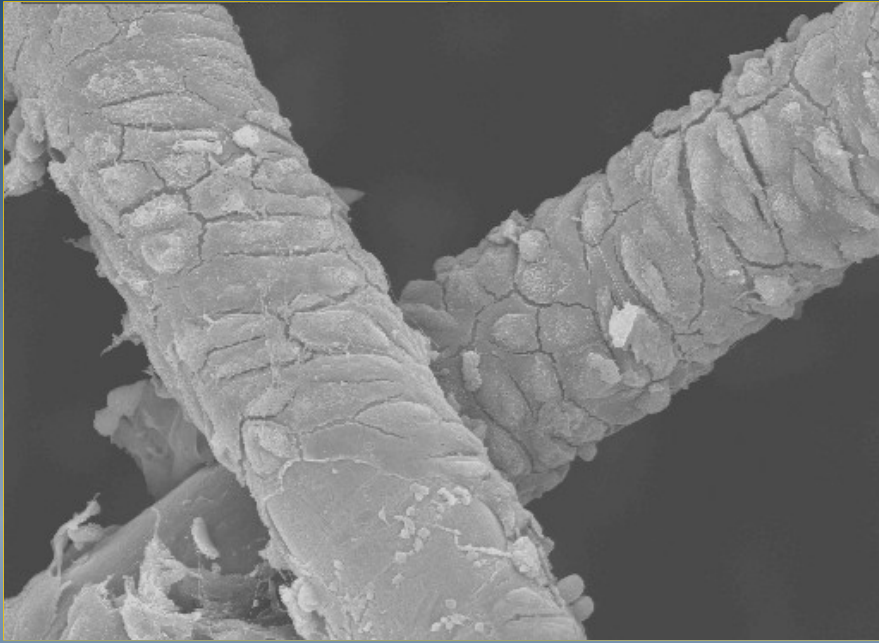


The *Diverter* Patency

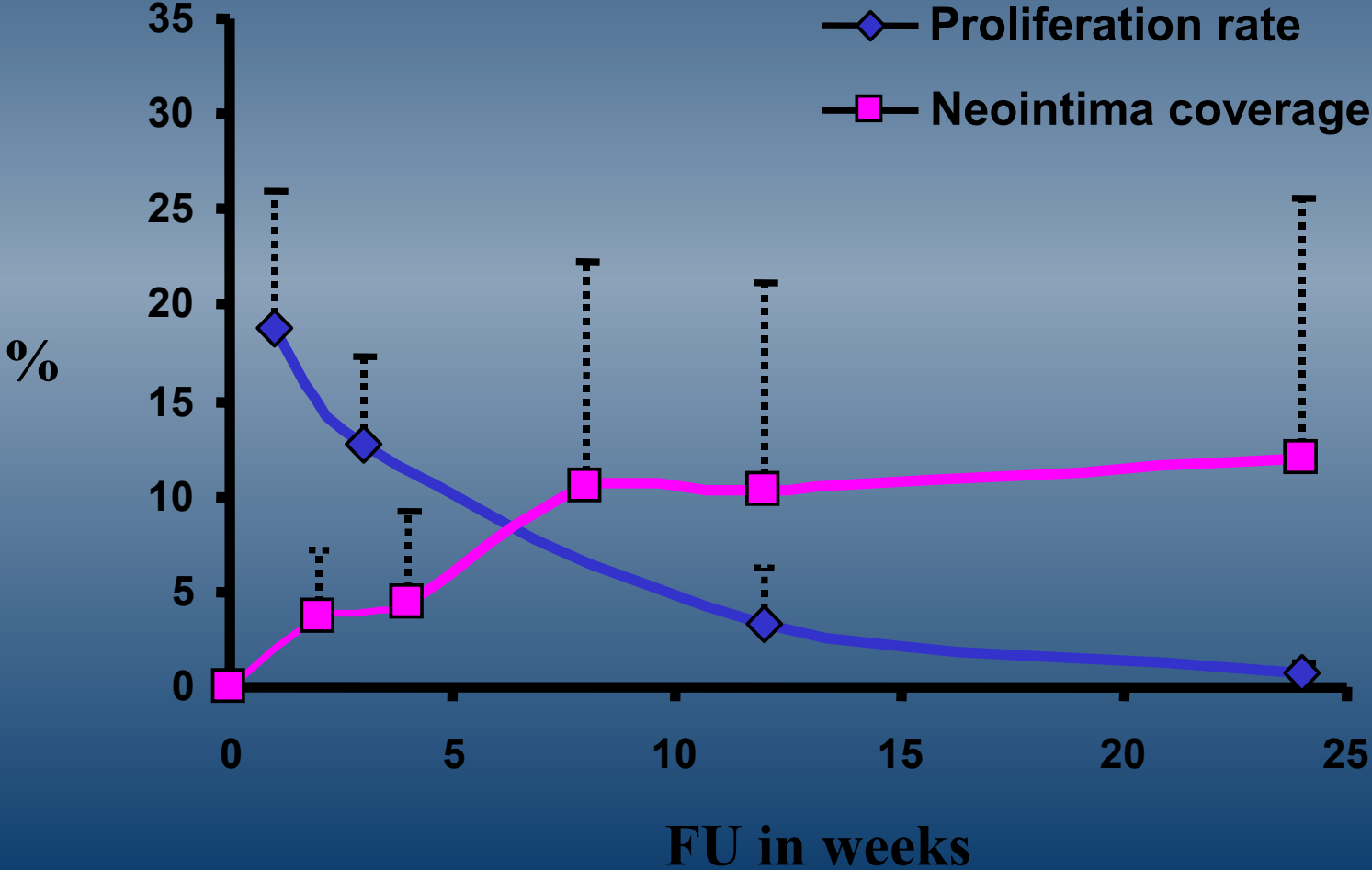
weeks 18



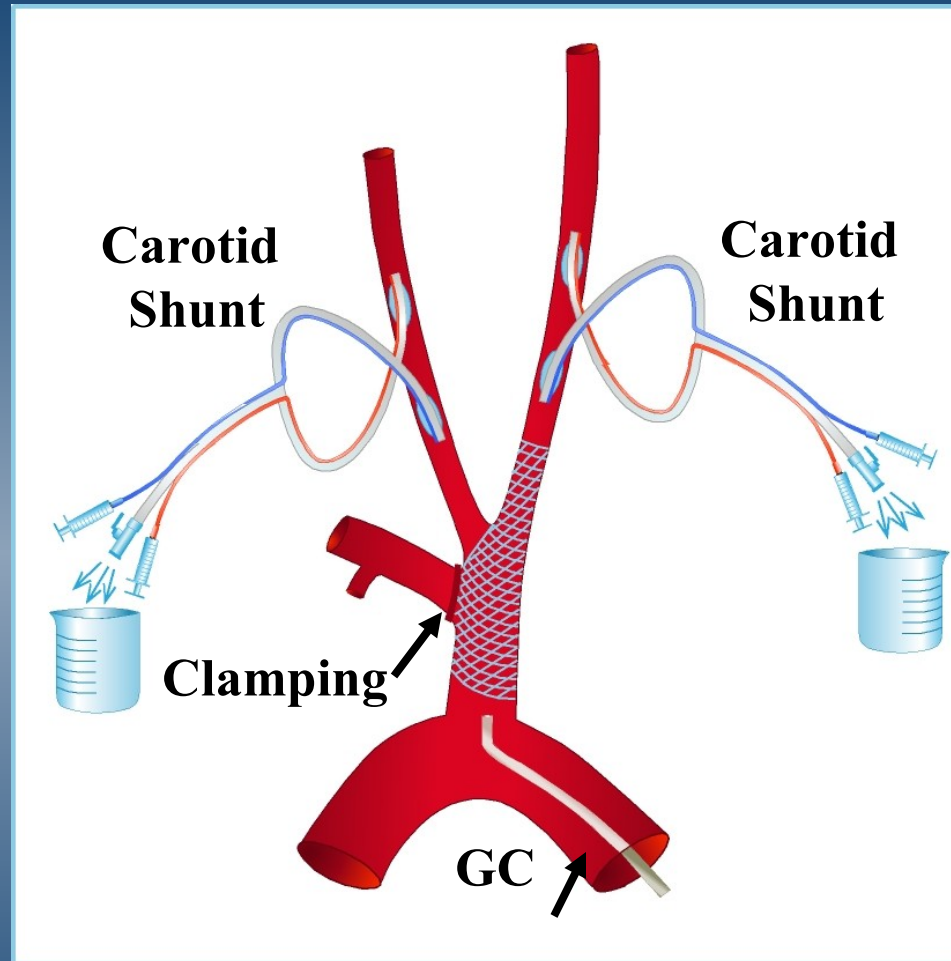
The *Diverter* Patency



Proliferation and Neointima Coverage



METHODS



**Schematic description of the procedure,
post deployment and shunt insertion**

So we thought

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

- Let's go for a clinical trial

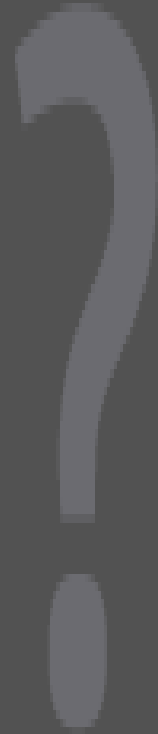
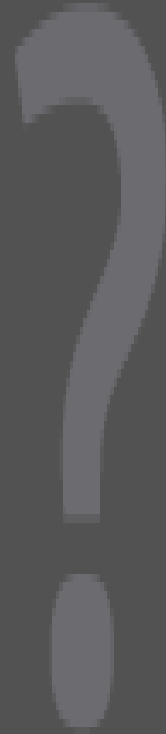
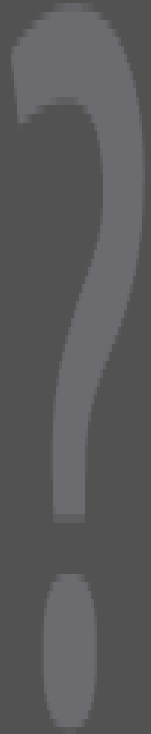
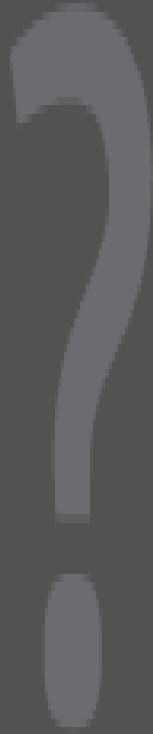
E-DIRECT Study

*E*mboli *D*iversion and *R*erouting to
the *E*xternal *C*arotid artery
*T*echnique

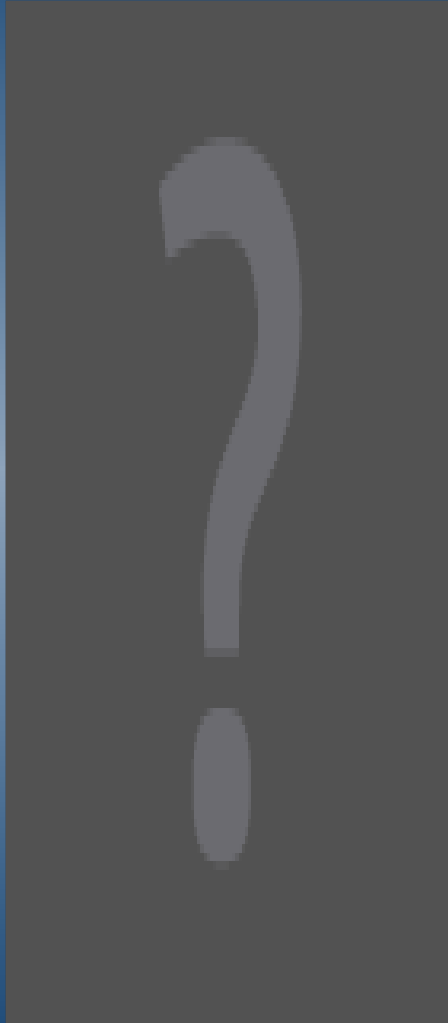
Patient Selection Criteria

- 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



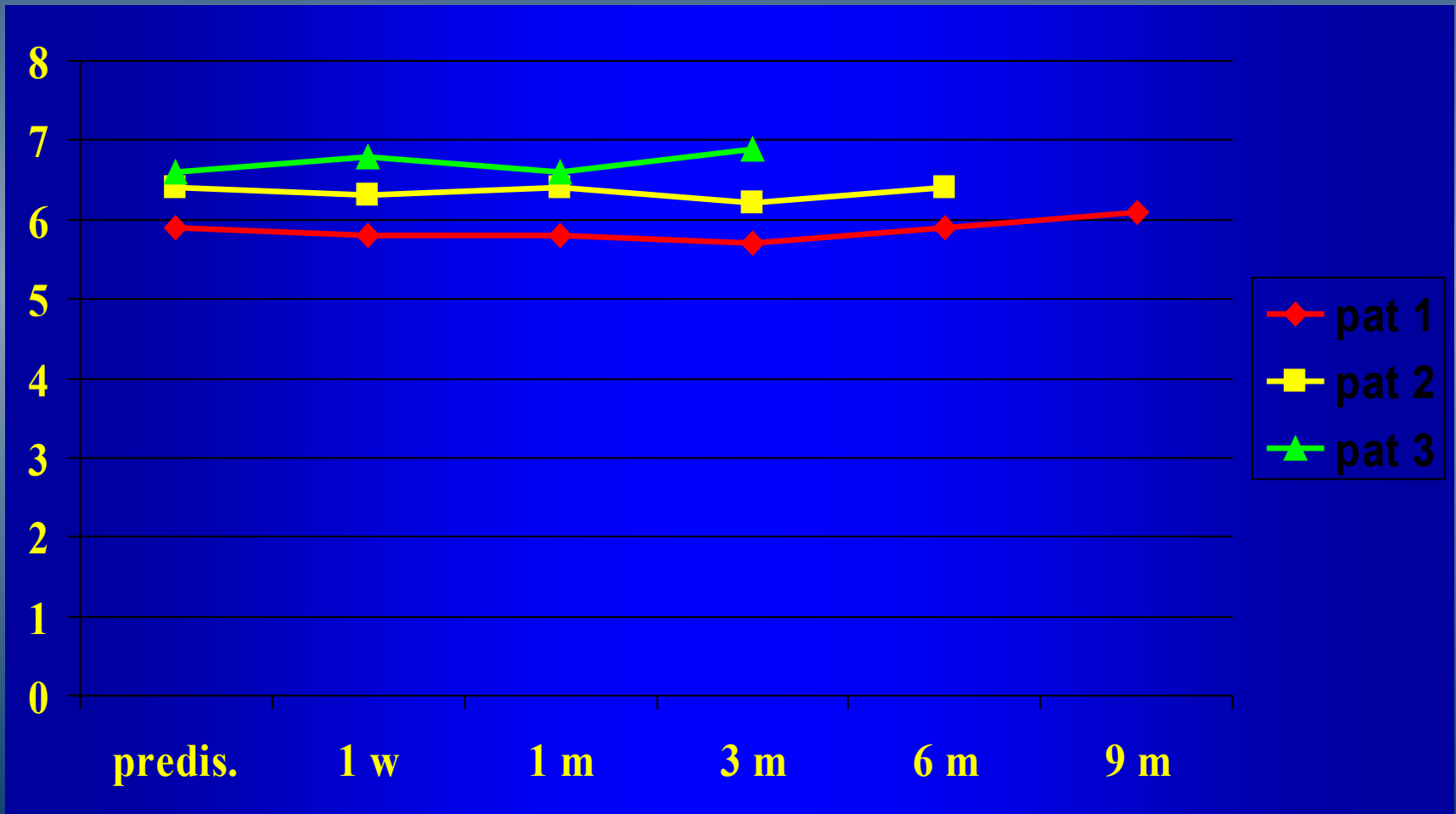
FU 6 mo Duplex



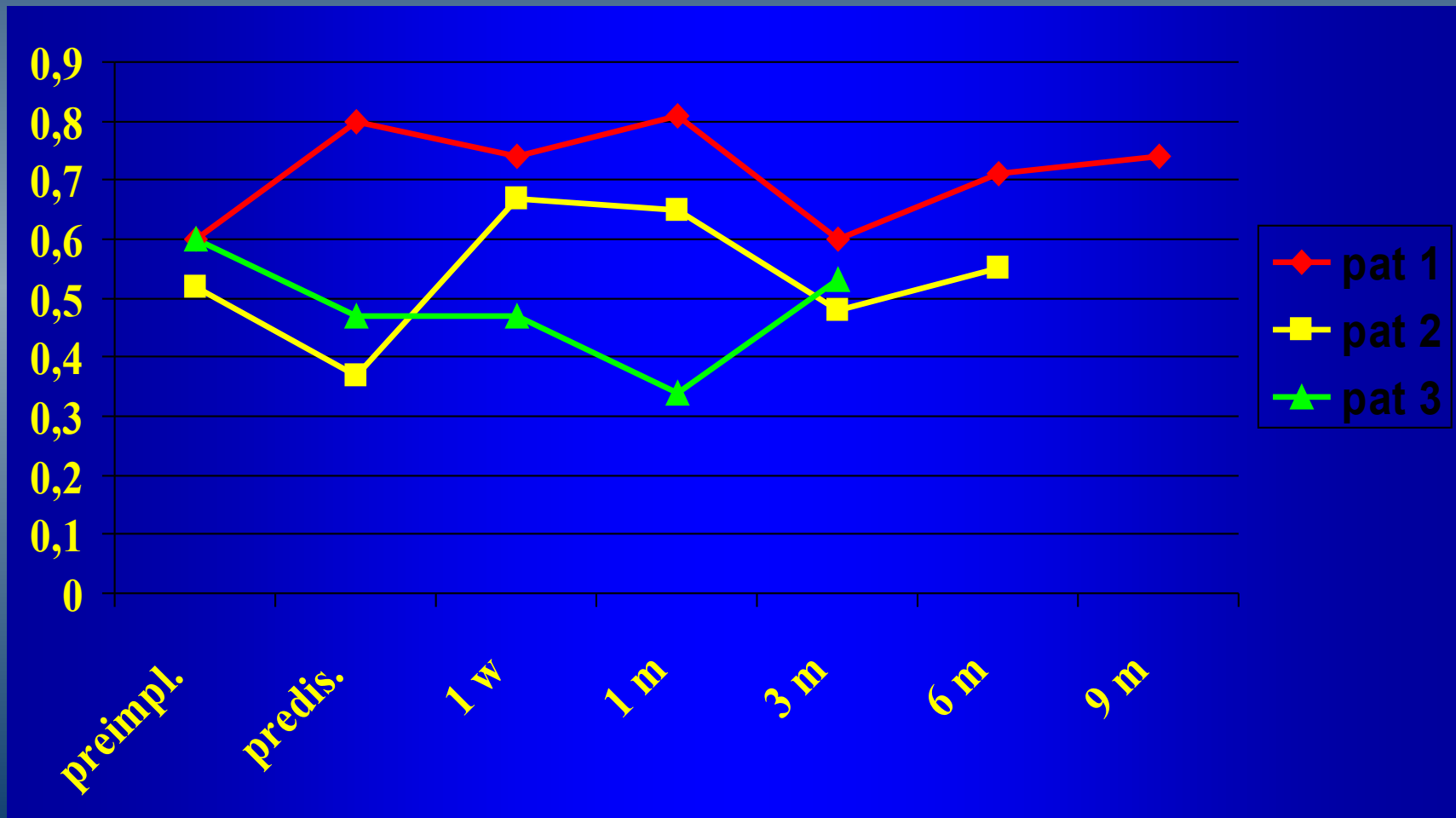
FU 9 mo Duplex



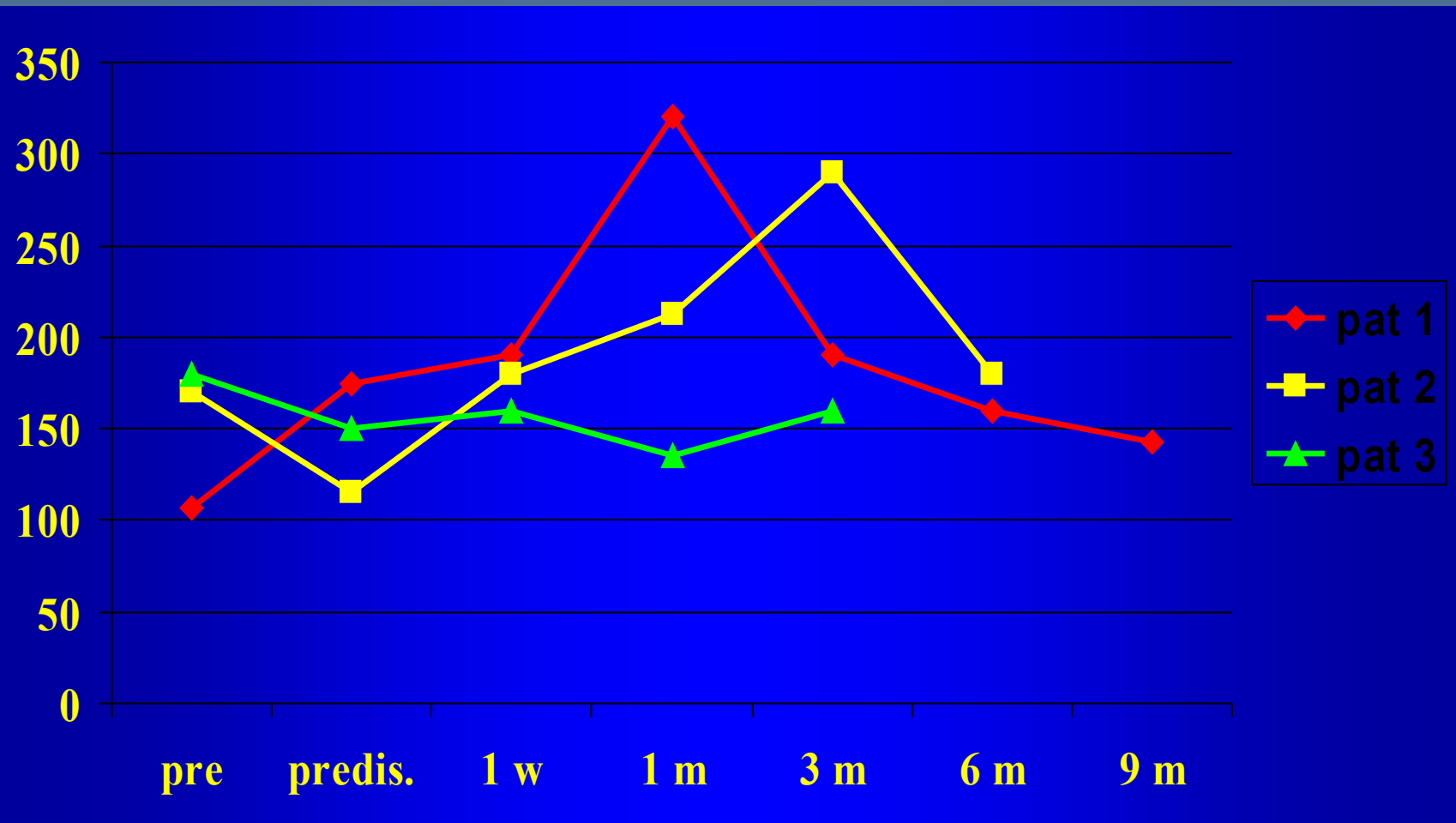
CCA Diverter Diameter (mm)



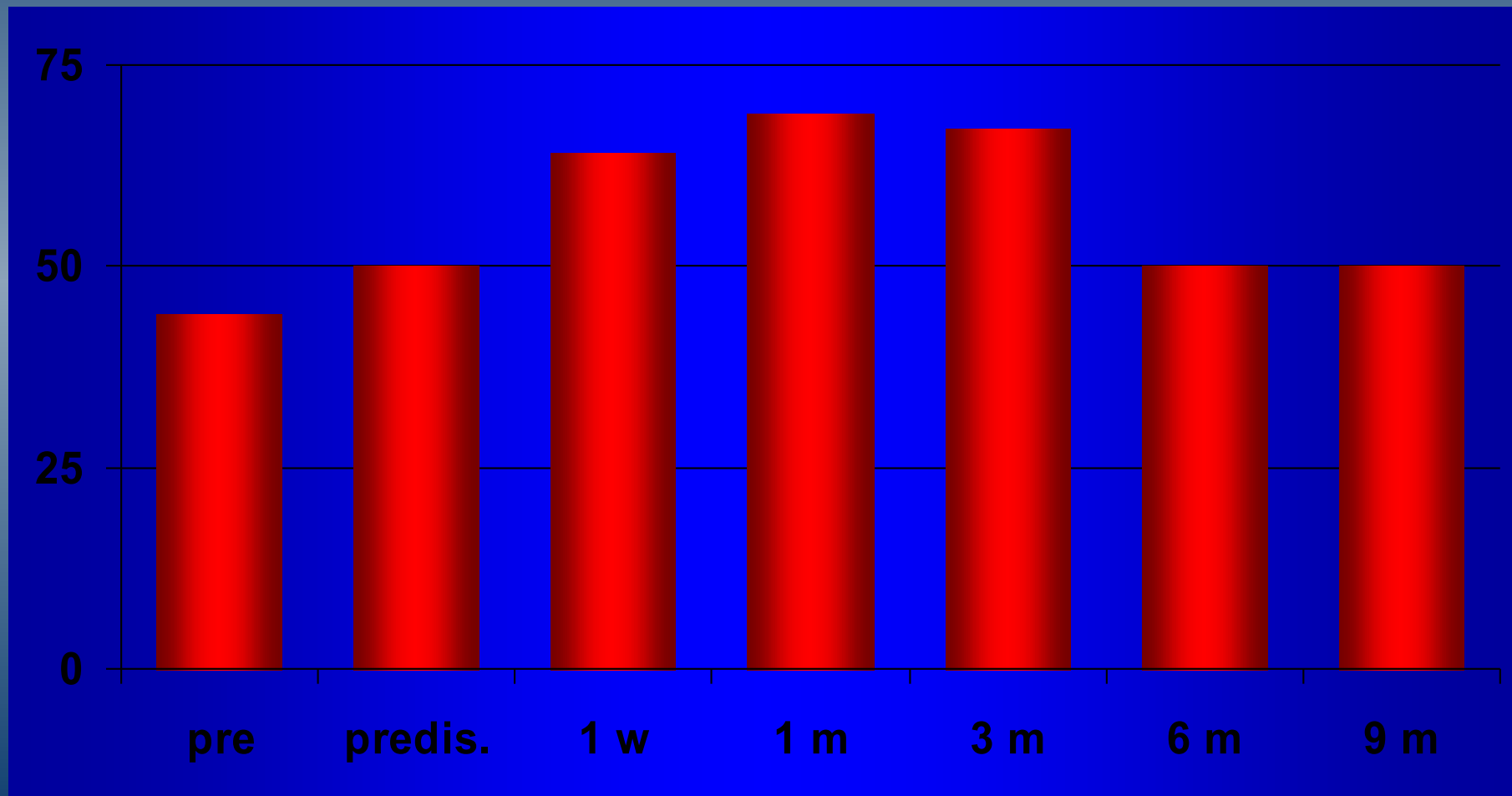
Syst. Peak Vel. ICA (m/sec)



Volume Flow (ml/min) ICA



% Volume Flow ICA / CCA



Patient #3

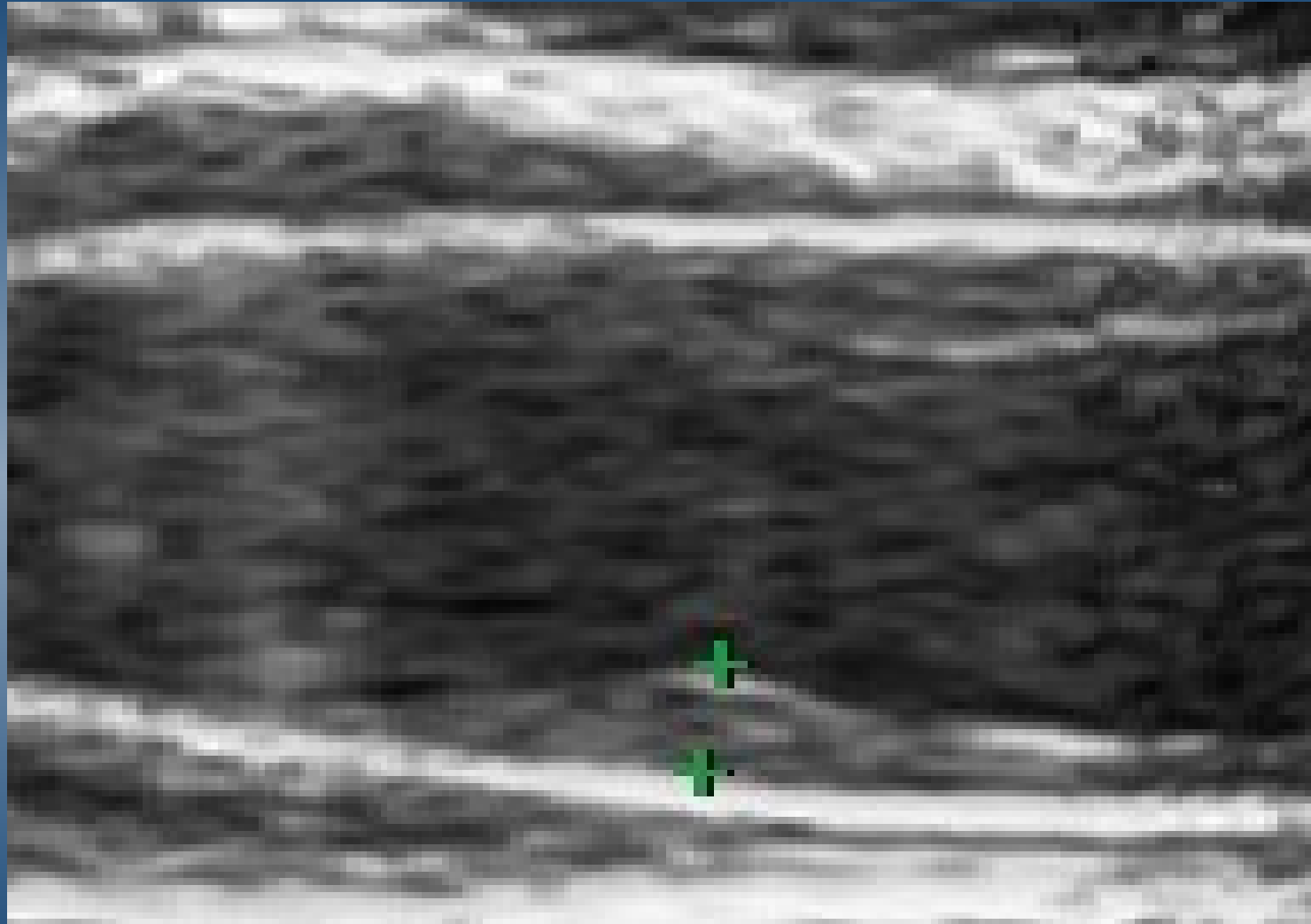
- 57 year old man
 - Chronic atrial fibrillation
 - Surgical ASD occlusion 1971
 - Congestive heart failure (EF 20 %)
 - LV Thrombus
 - Liver cirrhosis
-
- 3 month FU normal
 - 6 month FU postponed
 - 7 month → symptom-free but ...

Patient # 3 - 7 mo Duplex



Internal carotid artery occluded

Patient # 3 - 7 mo Duplex



Massive proliferation

Patient # 3 - 7 mo Duplex

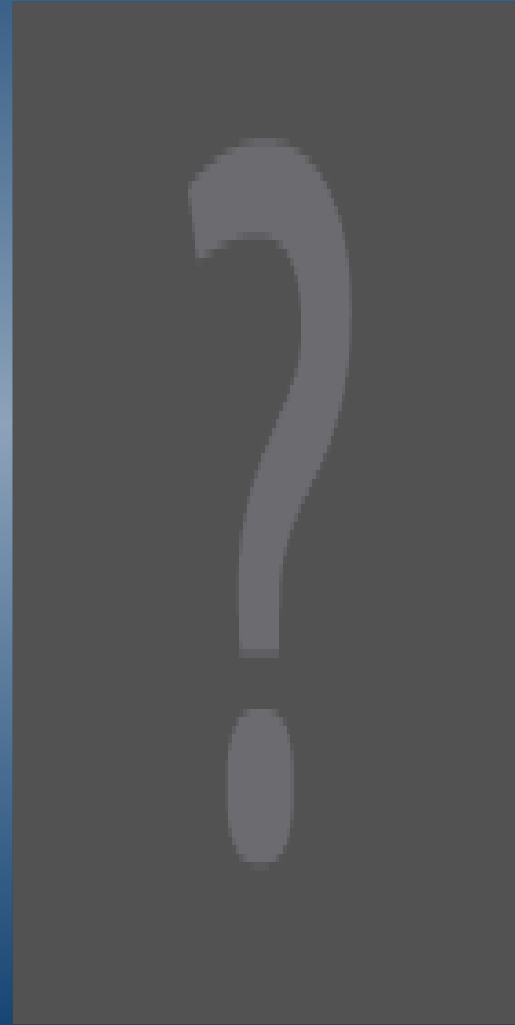


Massive proliferation, stenosis at distal end of Diverter

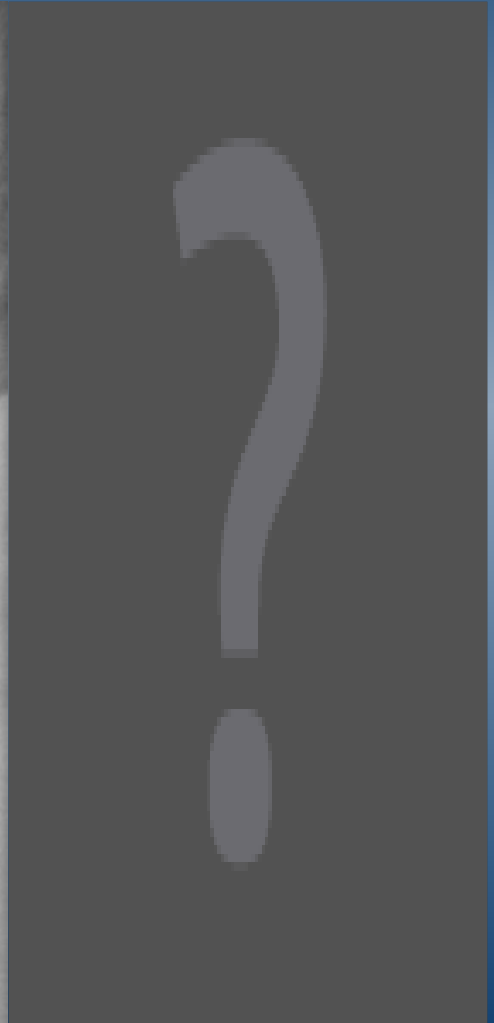
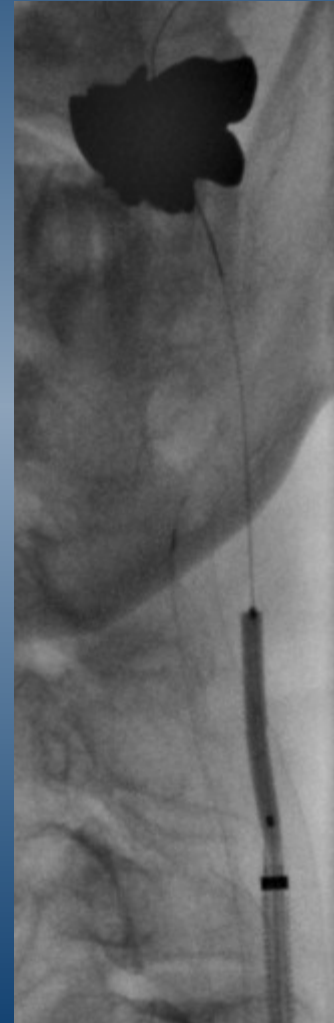
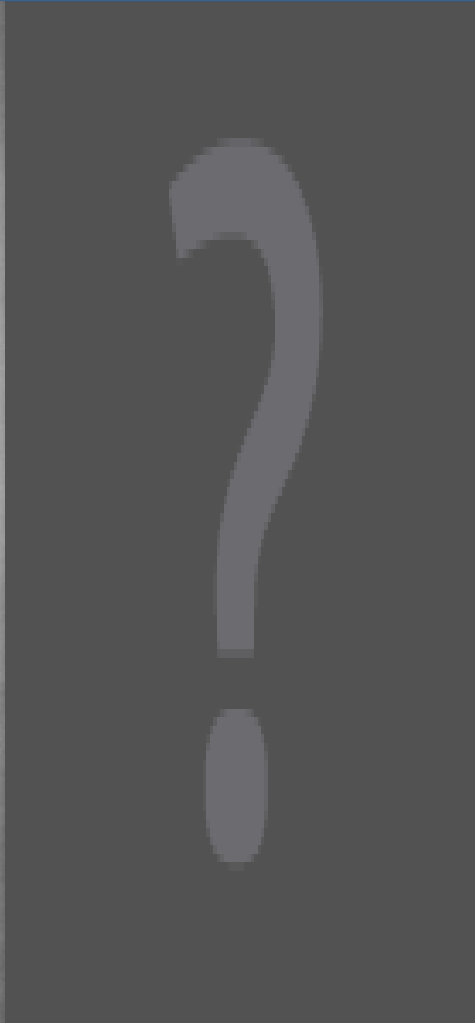
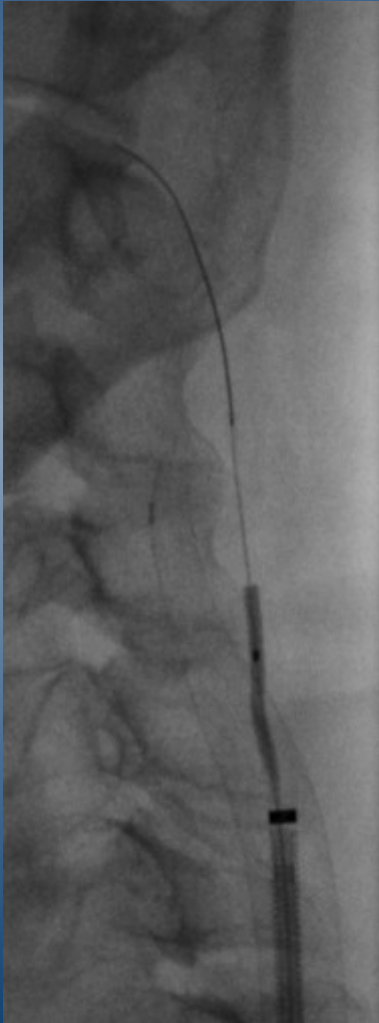
Patient 3 - 7 mo Angiogram



*What to
do now?*



Patient 3 - 7 mo



1.5 mm balloon

2 mm balloon

Patient 3 - 7 mo



4 mm



6 mm



ECA



Take Home Messages

- The Diverter concept has been safe and effective in animal experiments
- We can do this in humans
 - but
- Excessive intima proliferation may occur
- This was independent from flow and from pore size of the Diverter
- Occlusion of the diverter can be treated by catheter techniques
- We need to learn more