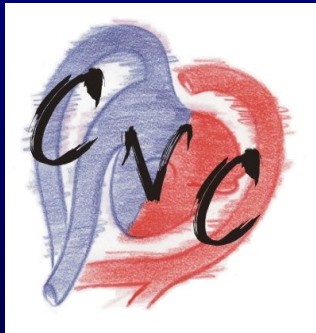


Flow Diversion For Embolic Stroke Prevention

Albrecht Römer, Marijke Skowasch, Horst Sievert



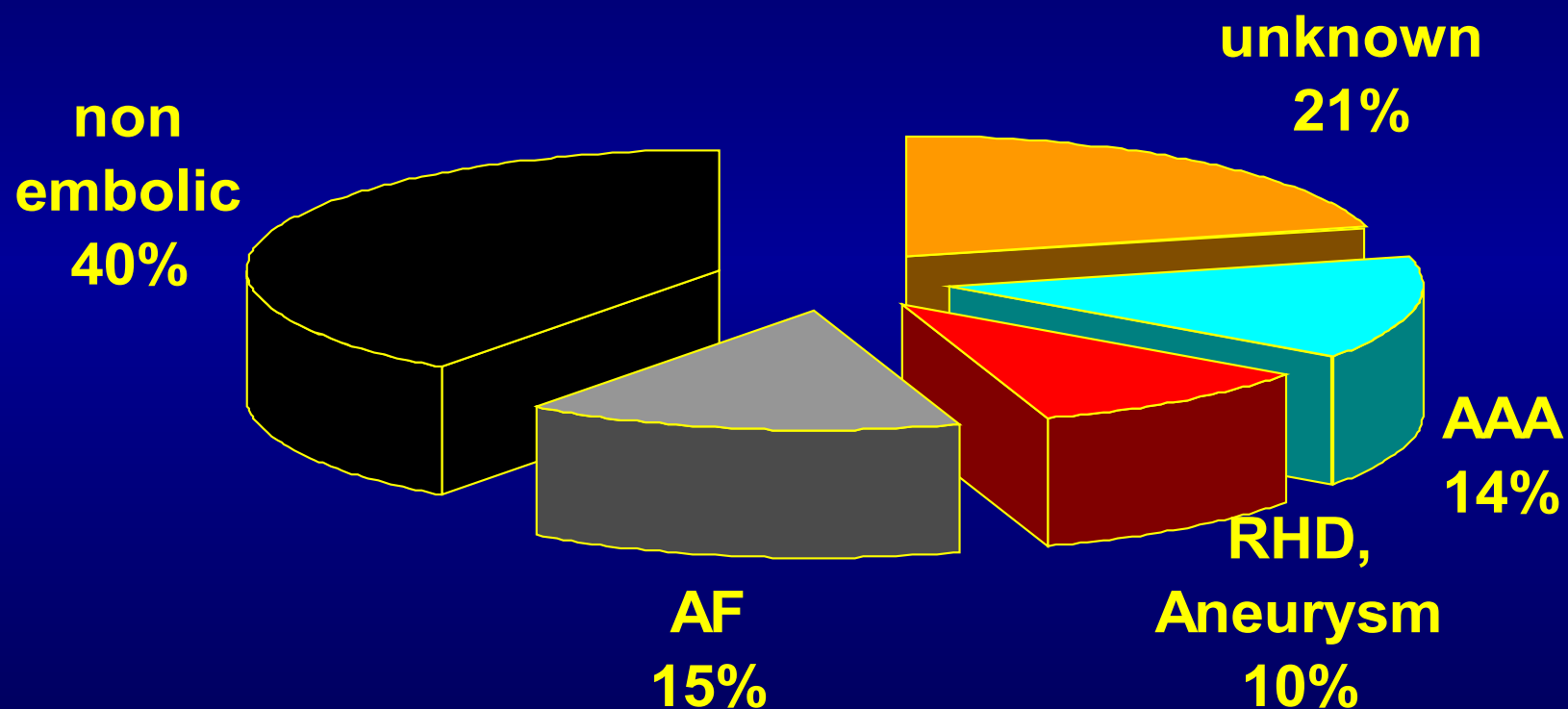
CardioVascular Center Frankfurt
Sankt Katharinen
Frankfurt, Germany





nothing to disclose

Causes of Stroke



Anticoagulation

- **effective in aortic arch atheroma ?**
- **risk of side effects**
- **contraindicated in many patients**

Anticoagulants in AF Patients

- in about 3.5 % not effective
- non-prescription or patient reluctance: 40-60%
- maintenance of therapeutic INR range: 40-50%

70 % - 80 %
of patients are
unprotected

Arch Intern Med 1996;156: 2311

Stroke 1997;28:2382-9.

Stroke 1997;28:72

Arch Intern Med 1997;157: 978

NEJM 2003 ;349:1019

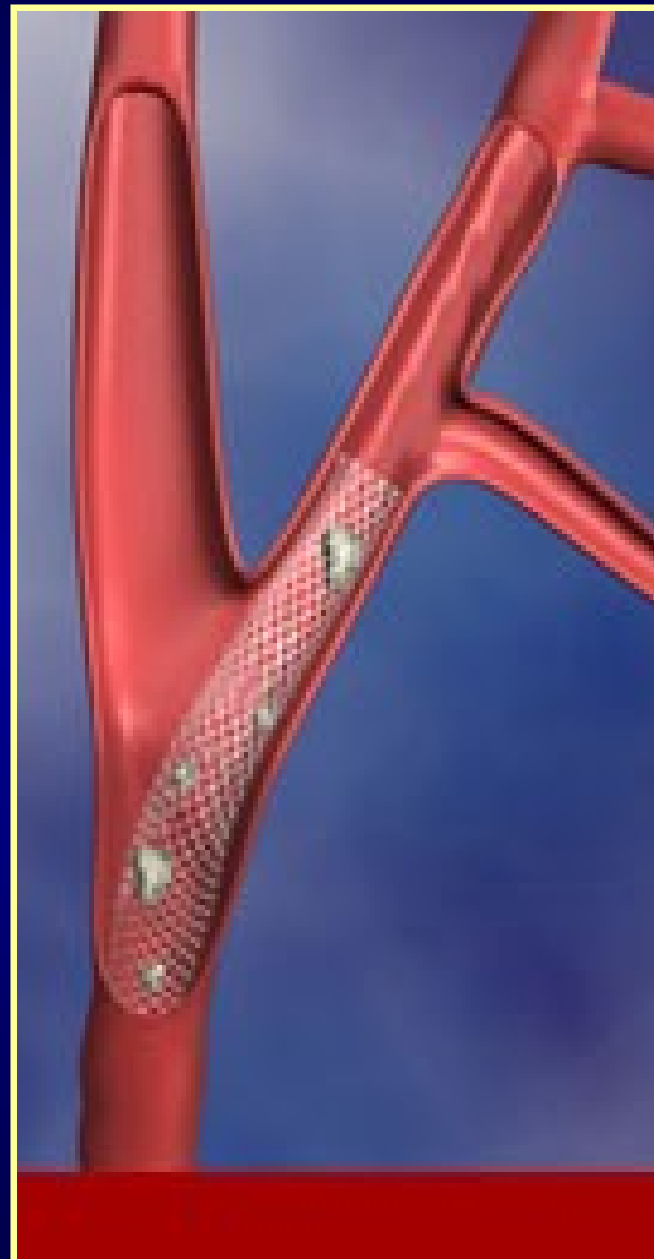
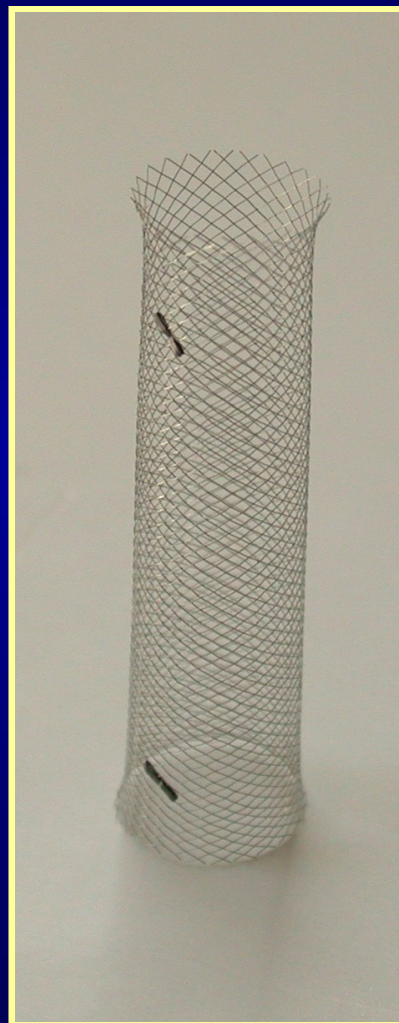
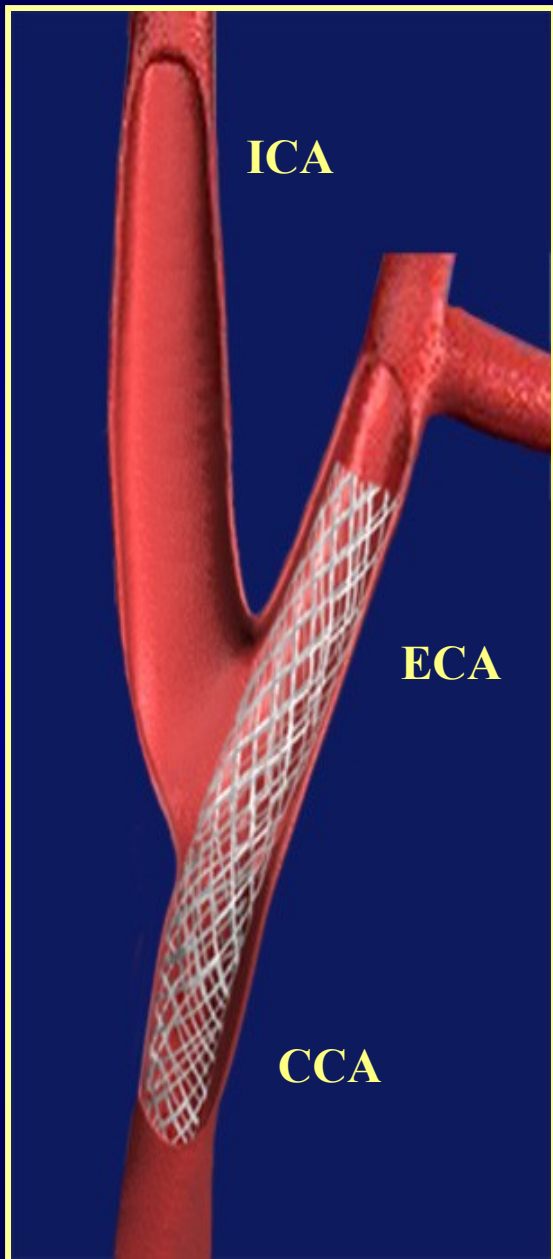
Idea

- **Endovascular device for prevention of embolic stroke from proximal sources**

Concept

- **Filter system to divert emboli to benign location**

Divarter*



*Investigational Device

The Challenge

- **efficient filtration of all harmful embolic particles**
- **no compromise of blood flow**
- **no thrombus formation**
- **no relevant proliferation**

Diverter in Vitro



Hemodynamics

Thick struts

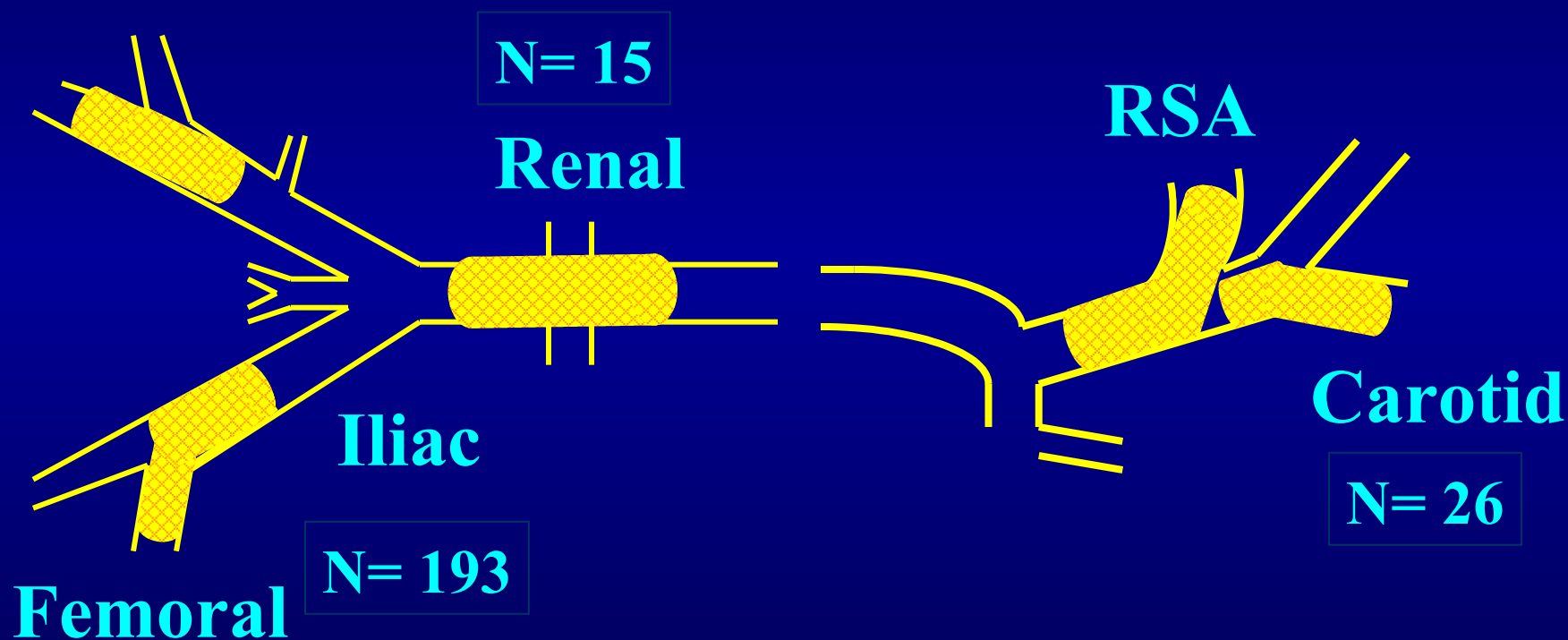
Thin struts



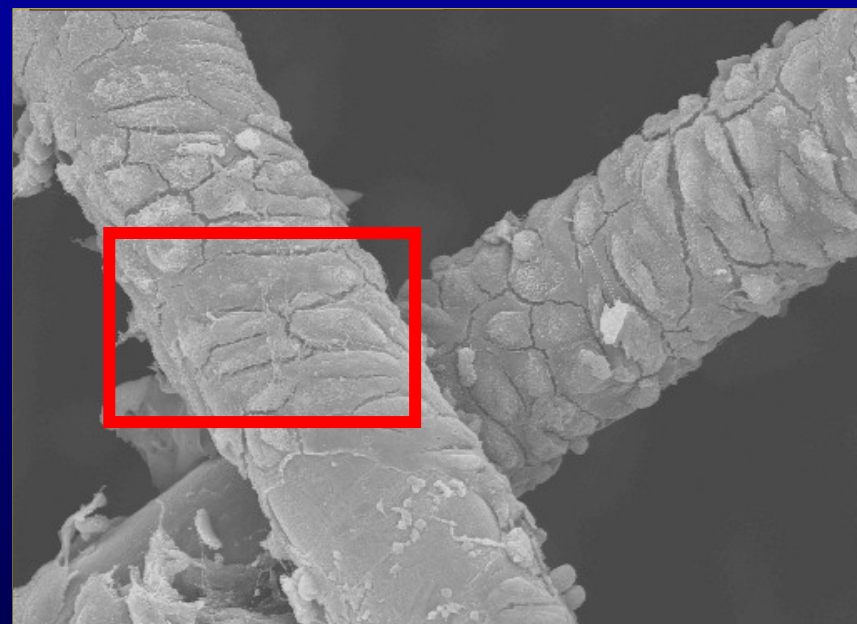
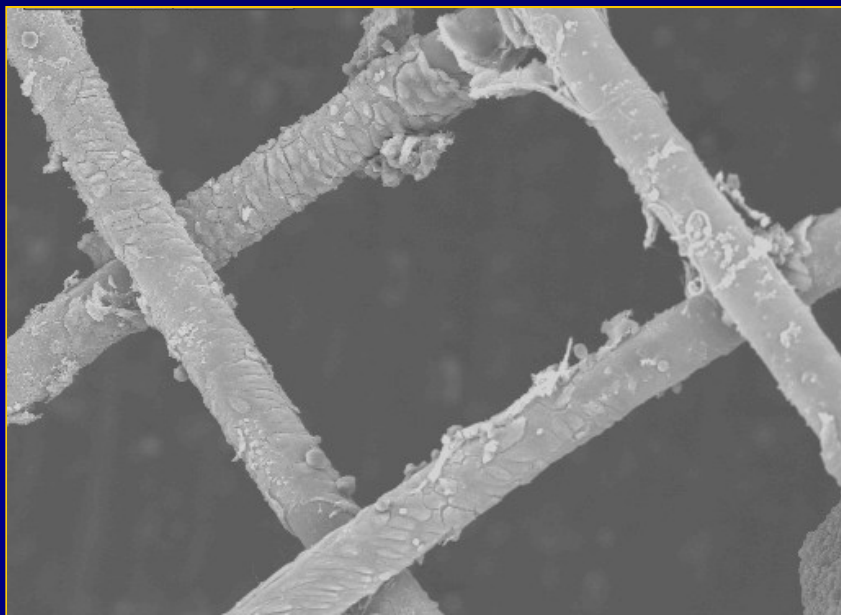
The Fine Wire Concept



> 400 In vivo Implantations

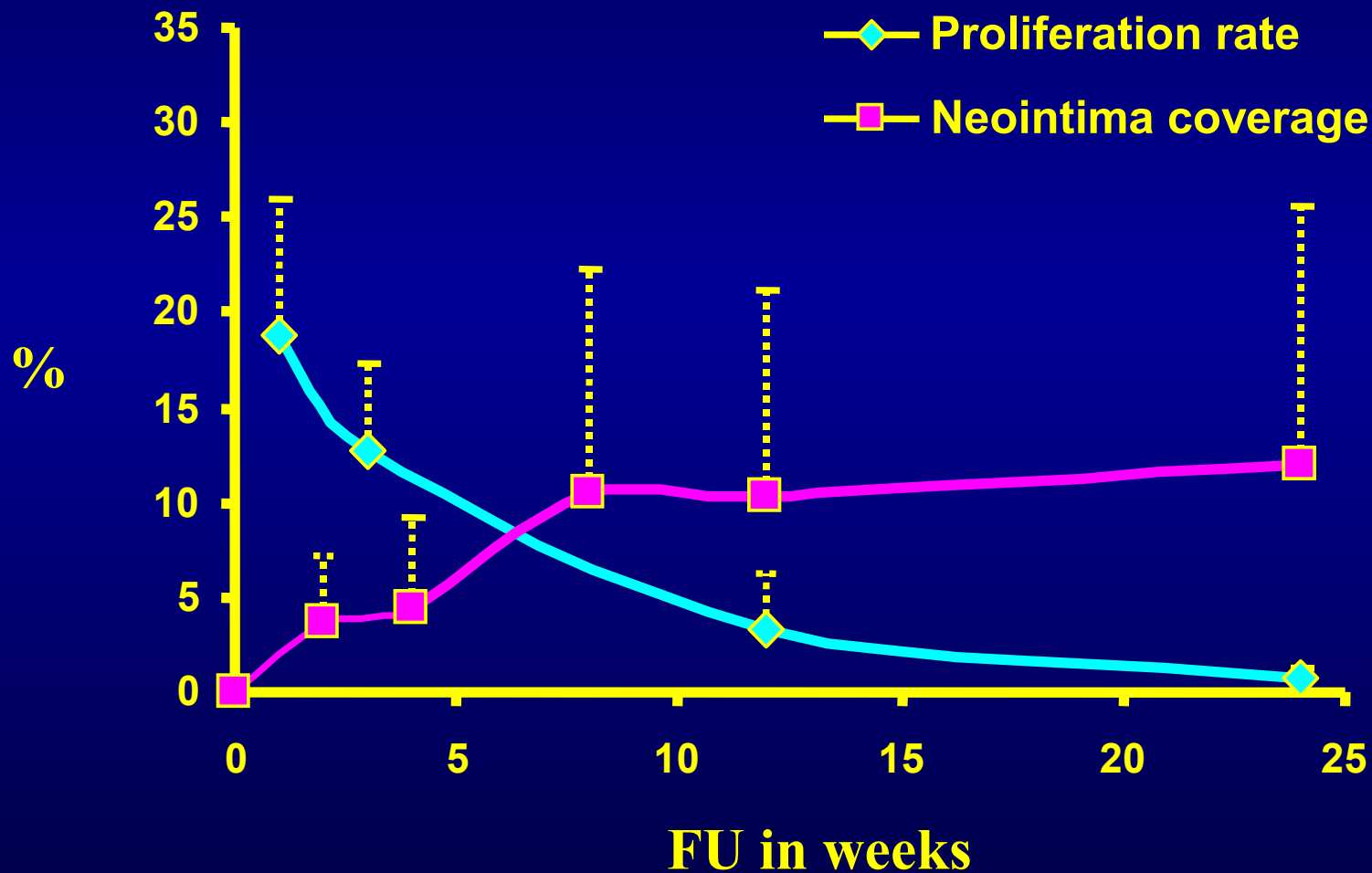


Endothelial Coverage





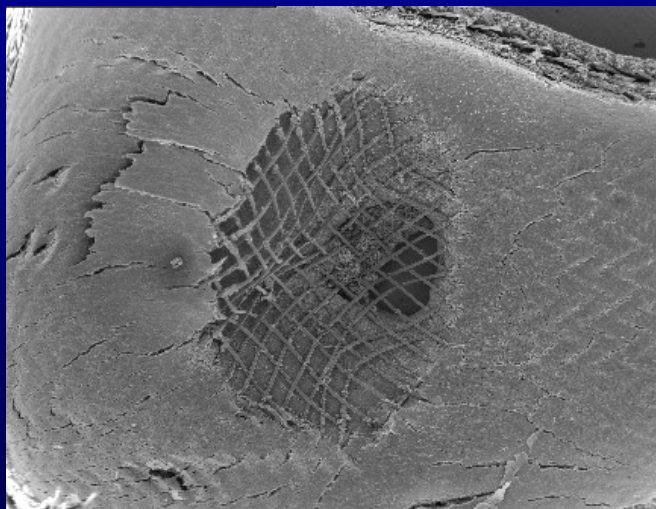
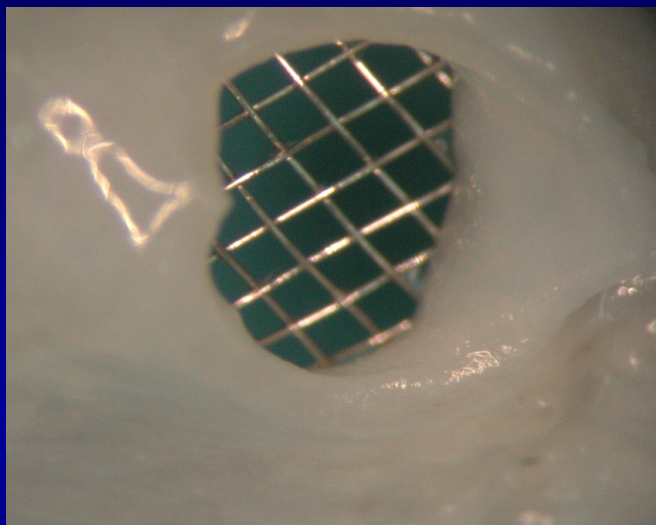
Proliferation and Neointima Coverage



The Diverter Patency

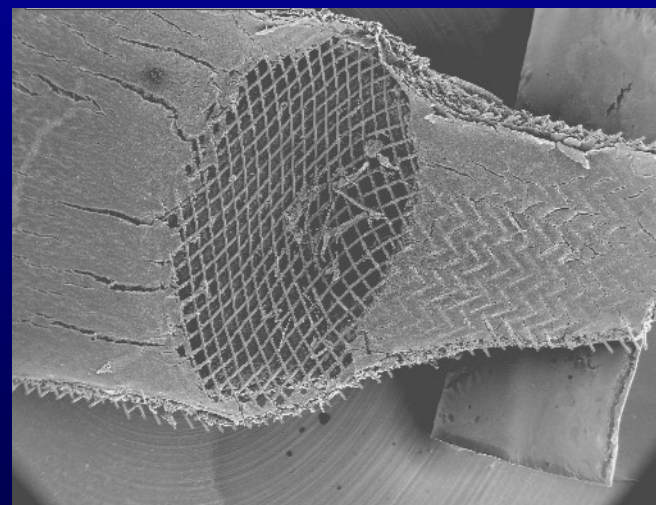
2

weeks



4

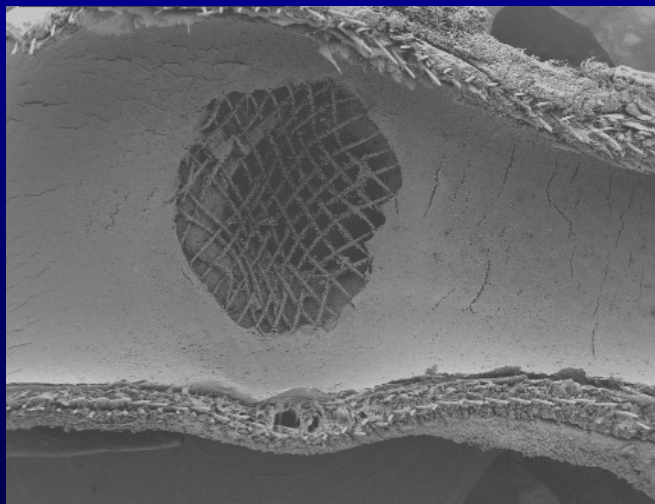
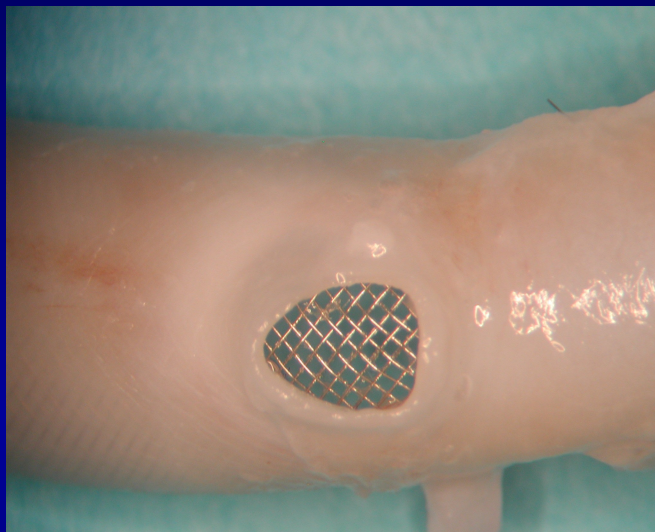
weeks



The Diverter Patency

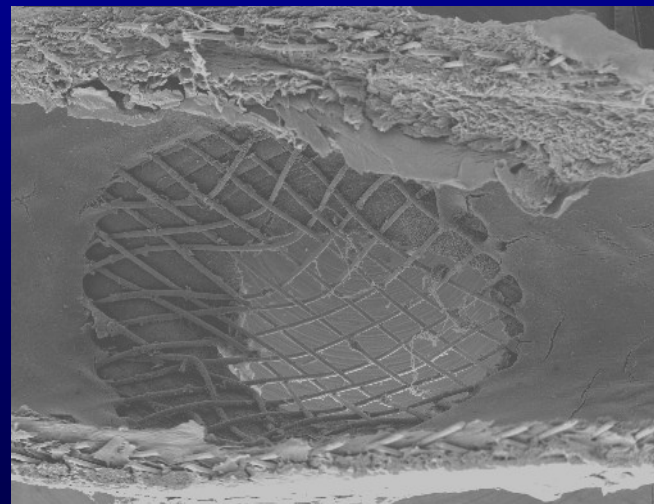
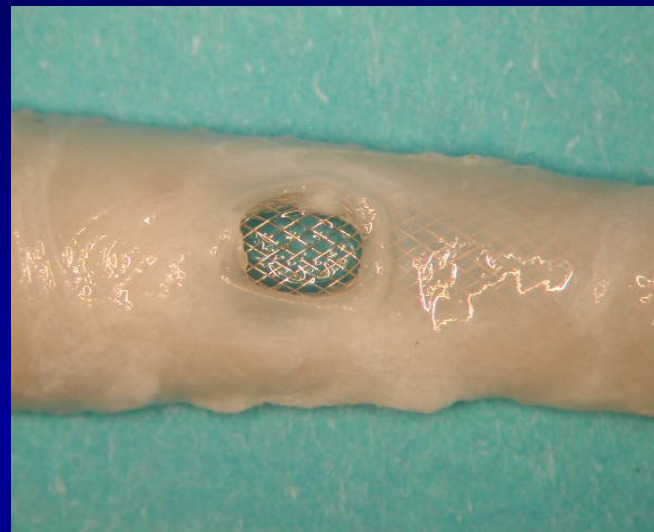
9

weeks



18

weeks





Clinical Safety and Performance

E-DIRECT Study

***Emboli **D**iversion and **R**erouting to the
External **C**arotid artery **T**echnique***

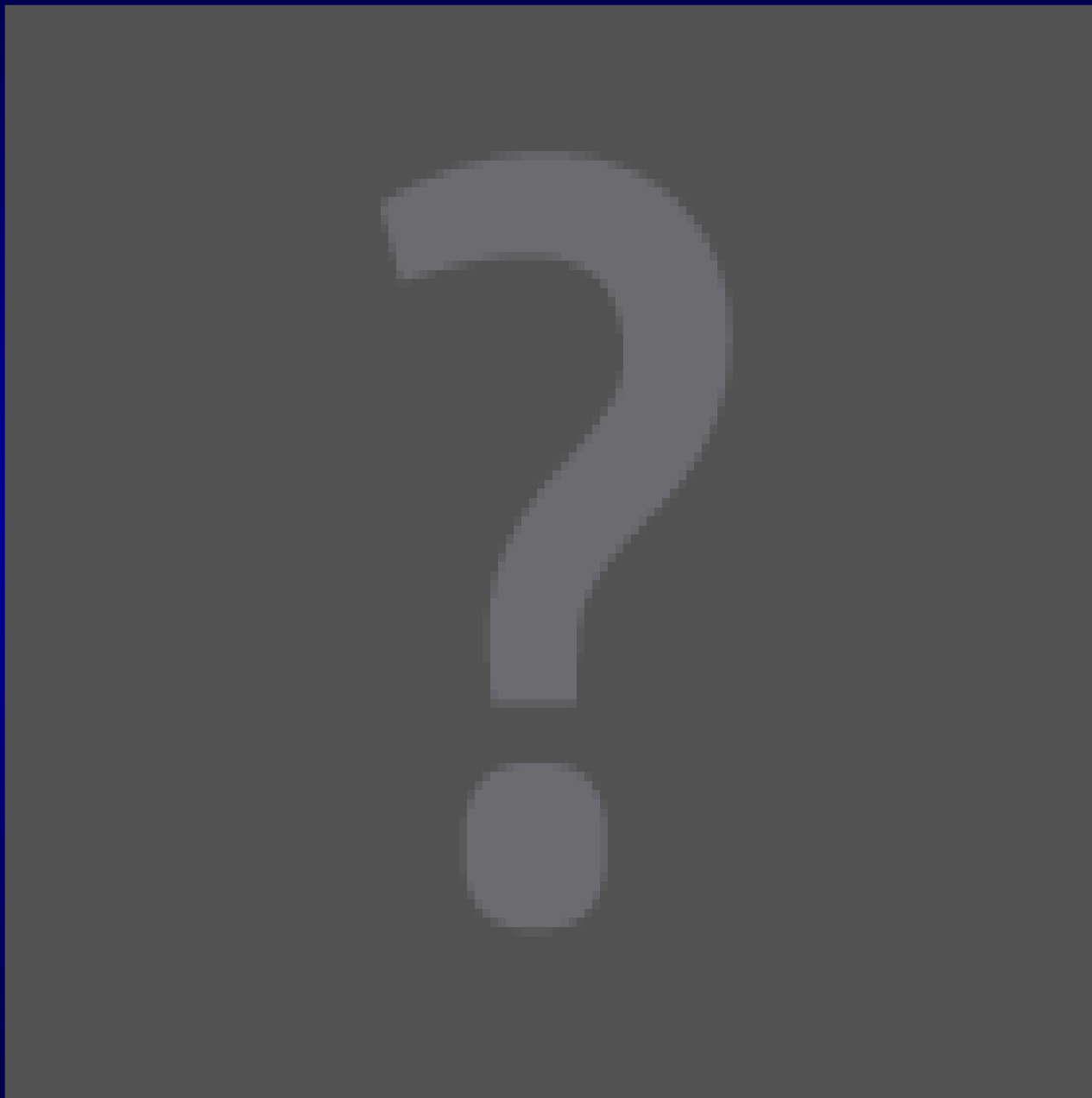
Patient Selection Criteria

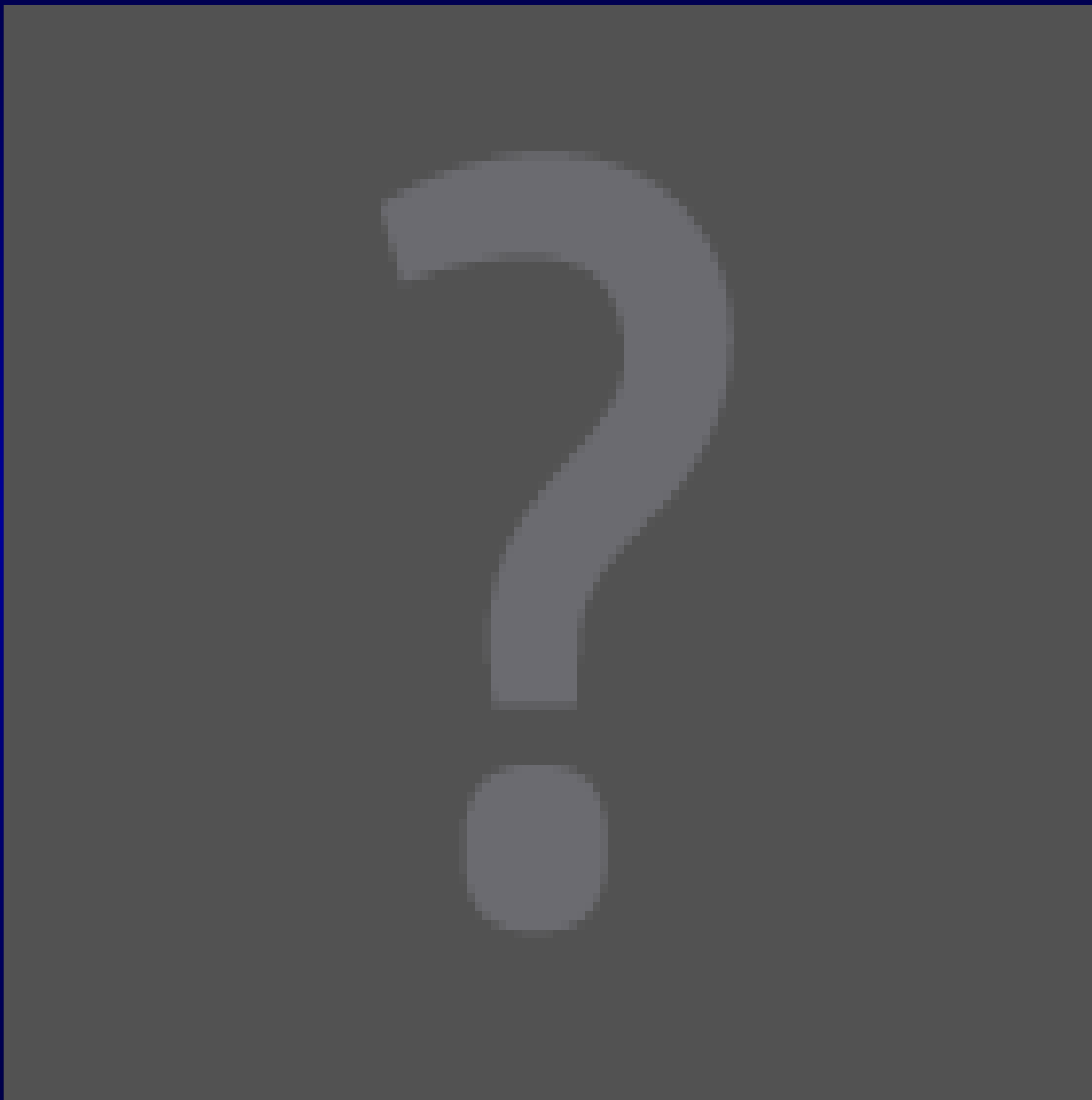
- **AF (chronic or paroxysmal)**
- **High risk for stroke**
- **Non-candidates for oral anticoagulants**
- **No carotid stenosis >30%**

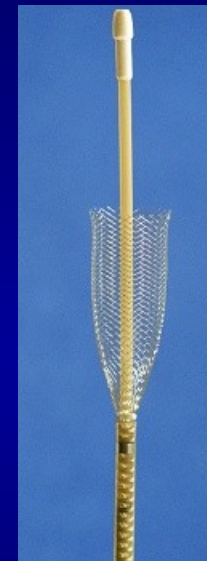
The First Divorter Implantation in Human

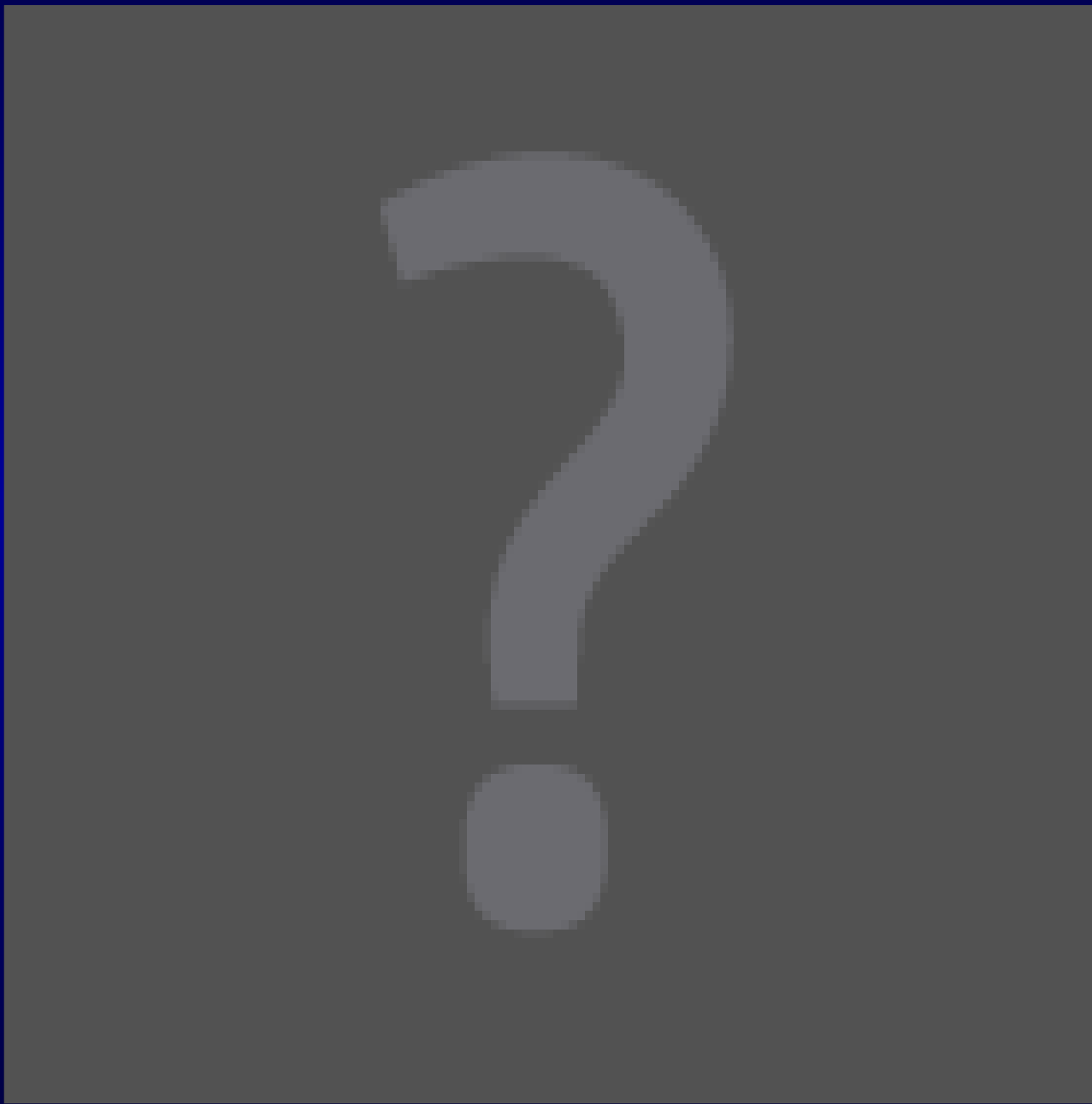
- **80 year old woman**
- **chronic atrial fibrillation**
- **no anticoagulation:**
 - **recurrent falls**
 - **patient reluctance**

















Predischarge Duplex Scan Long Axis



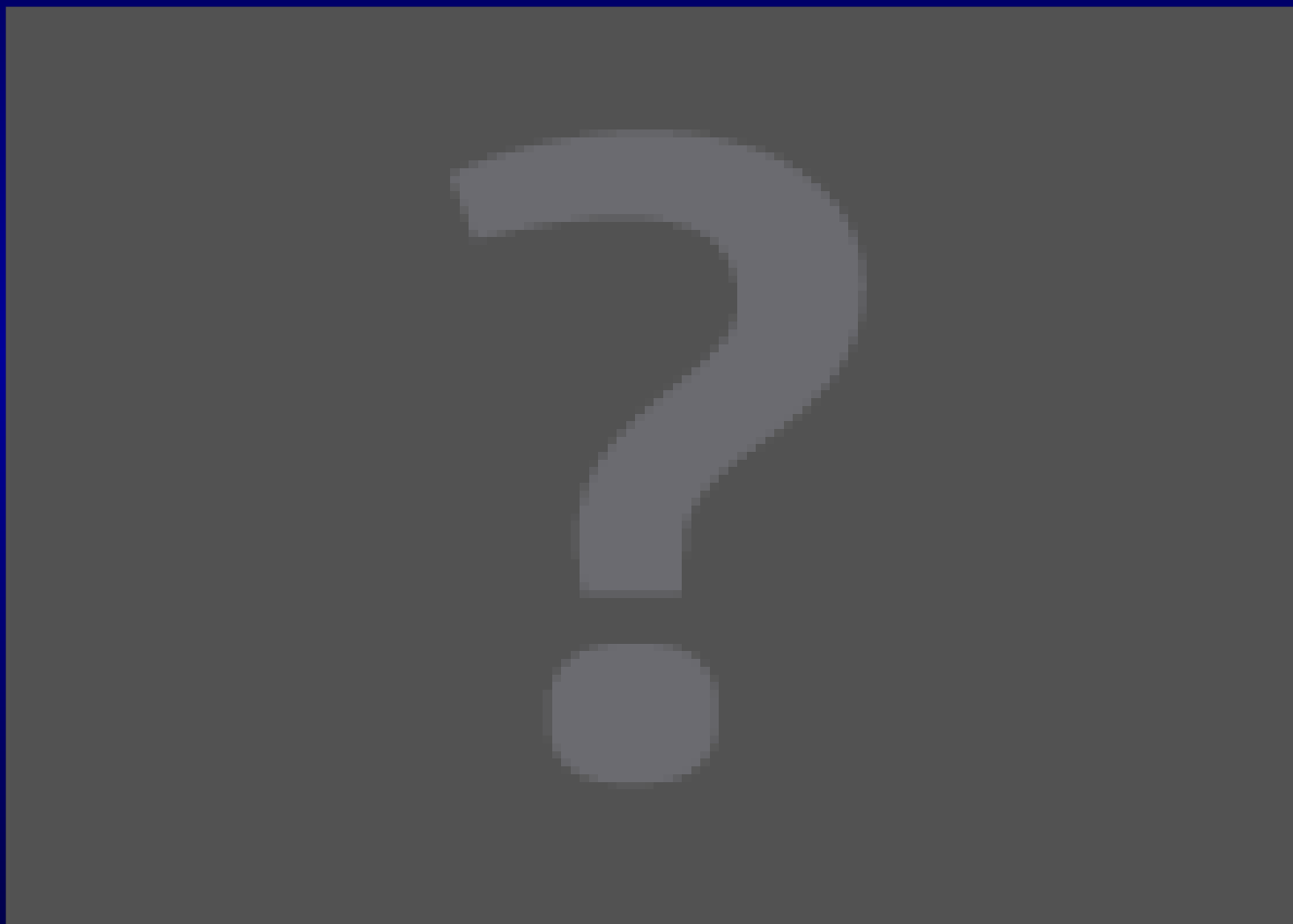
Predischarge CD-Duplex Scan



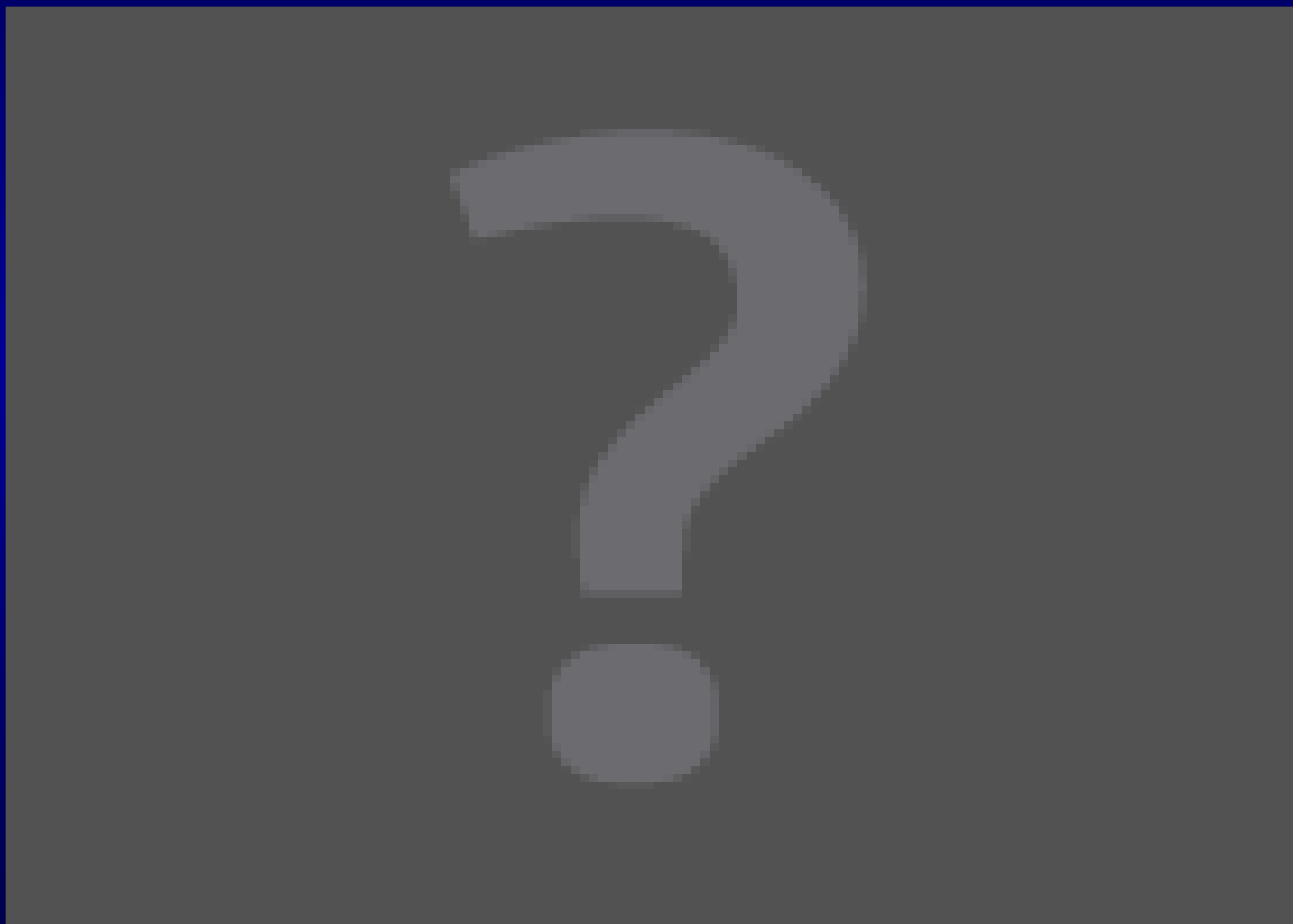
FU 1 mo CD-Duplex Scan



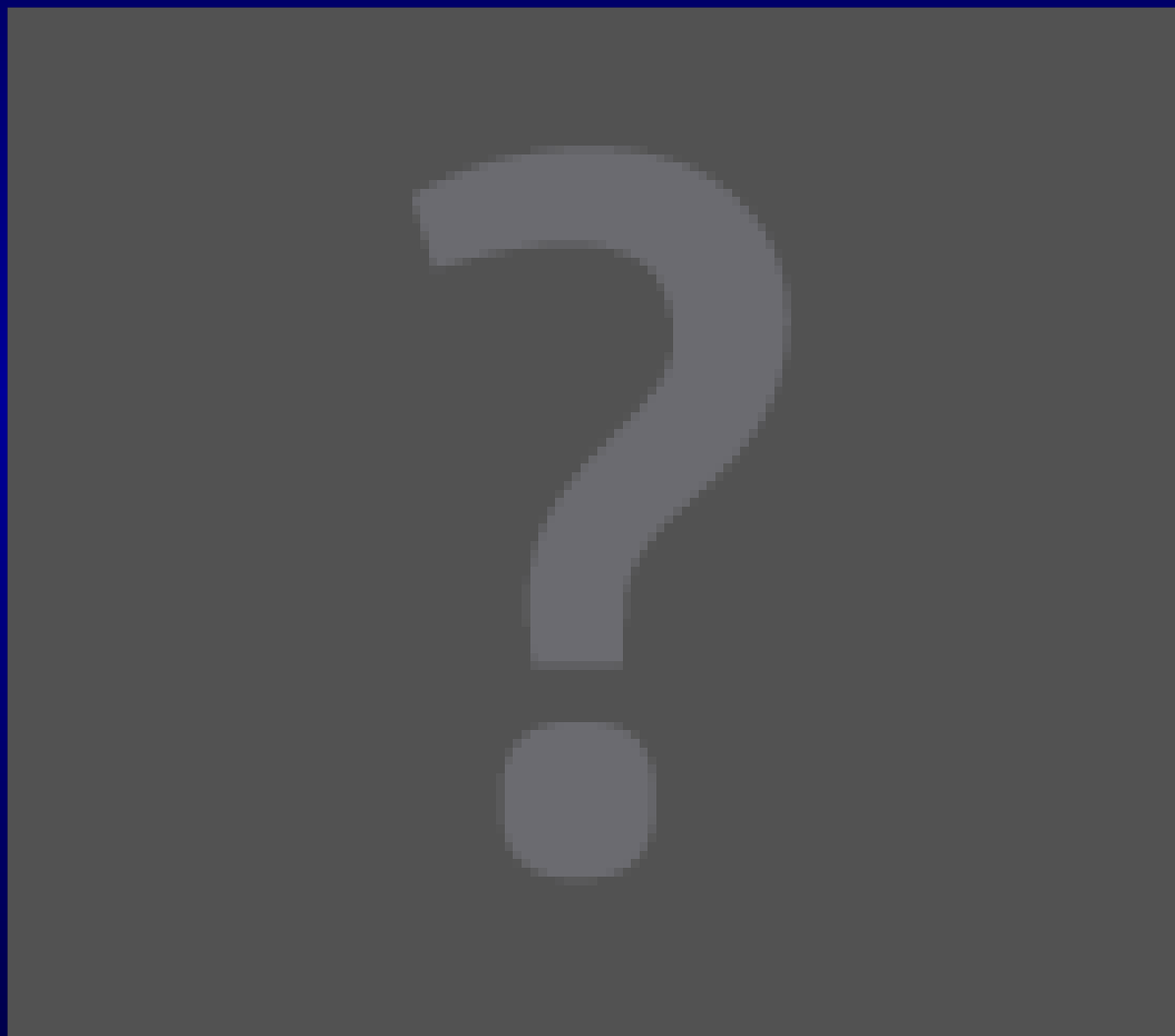
FU 3 mo CD-Duplex Scan



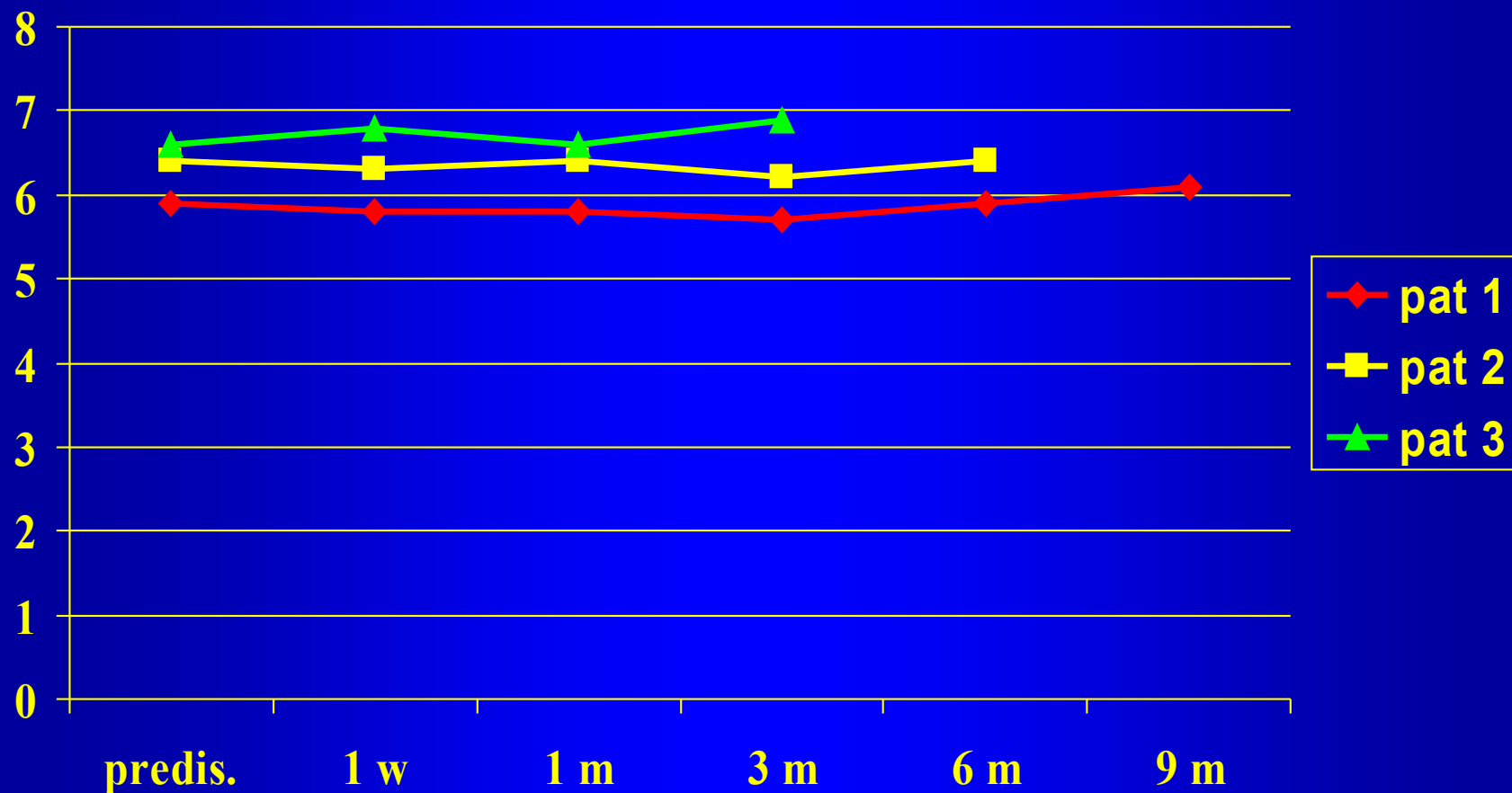
FU 6 mo CD-Duplex Scan



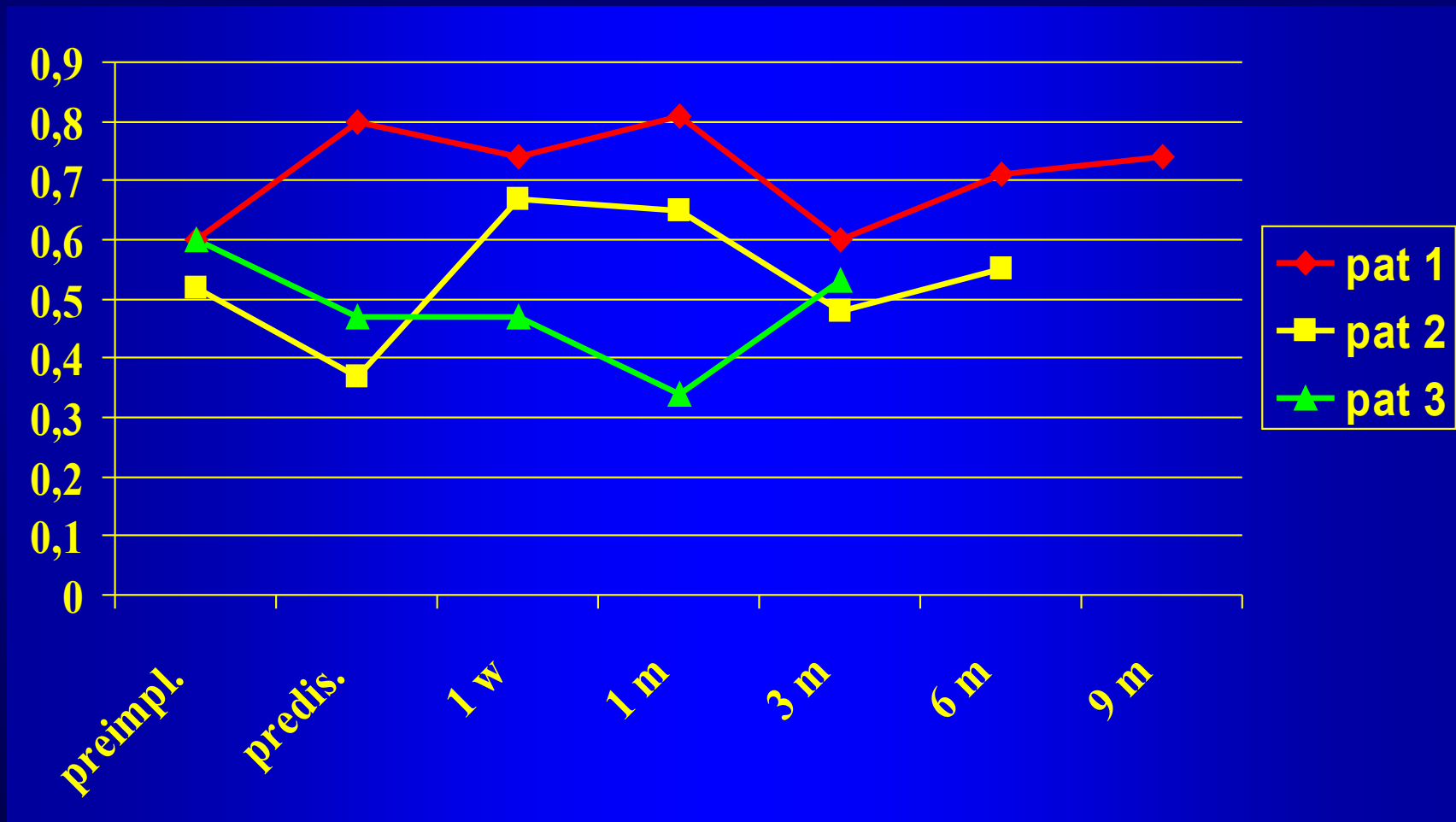
FU 9 mo CD-Duplex Scan



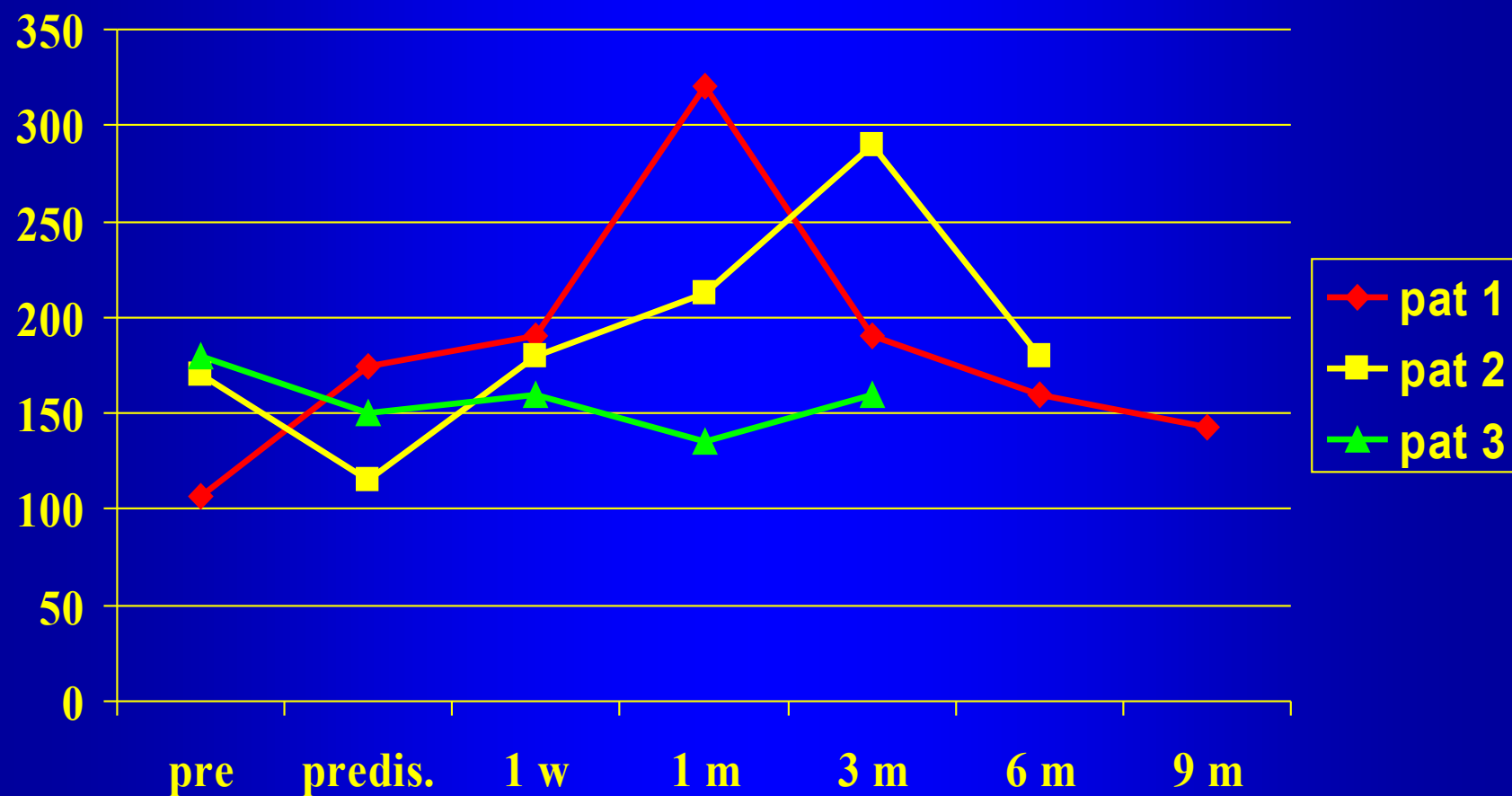
CCA Diverter Diameter (mm)



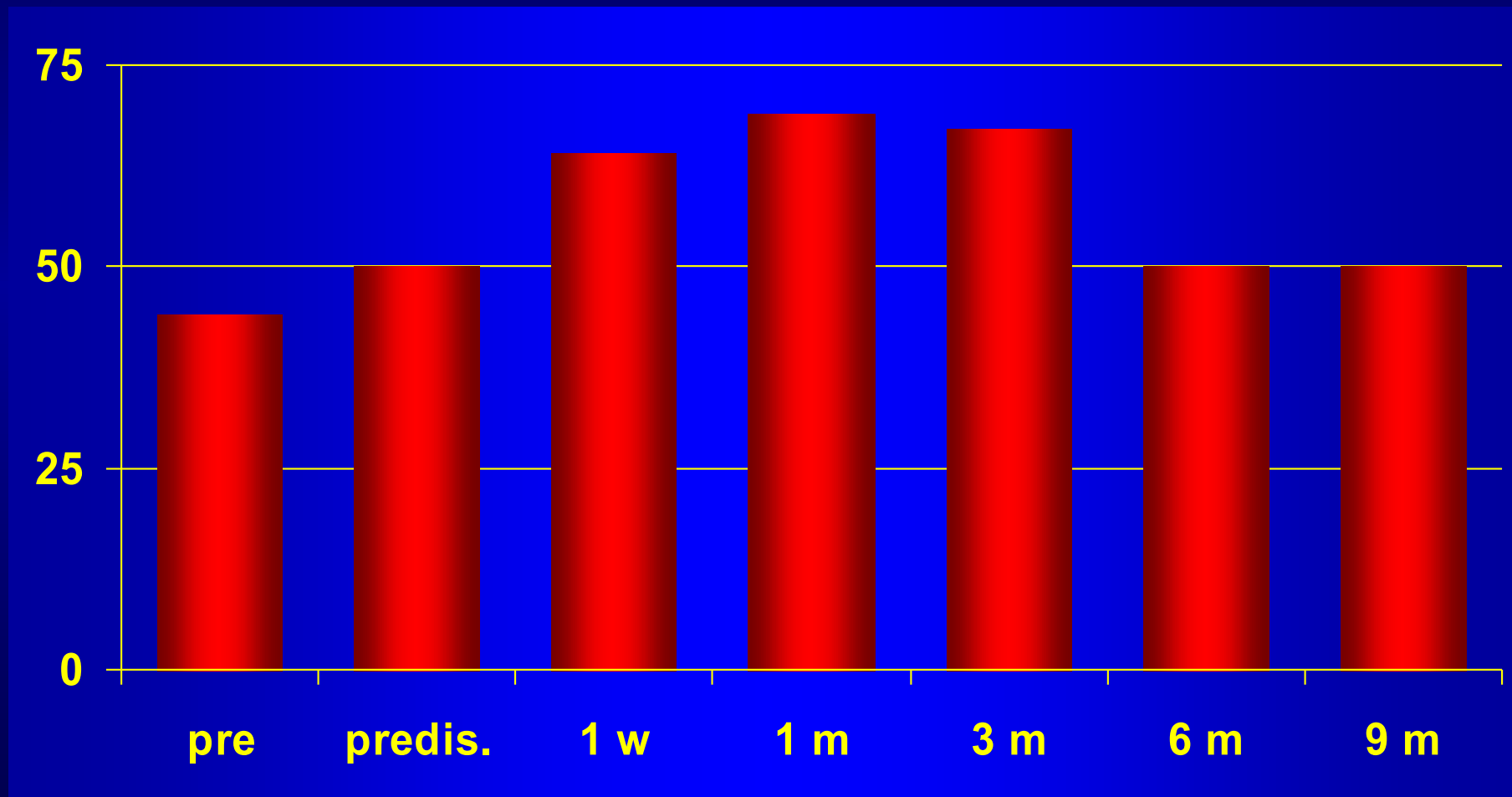
Syst. Peak Vel. (m/sec) ICA



Volume Flow (ml/min) ICA



% Volume Flow ICA / CCA



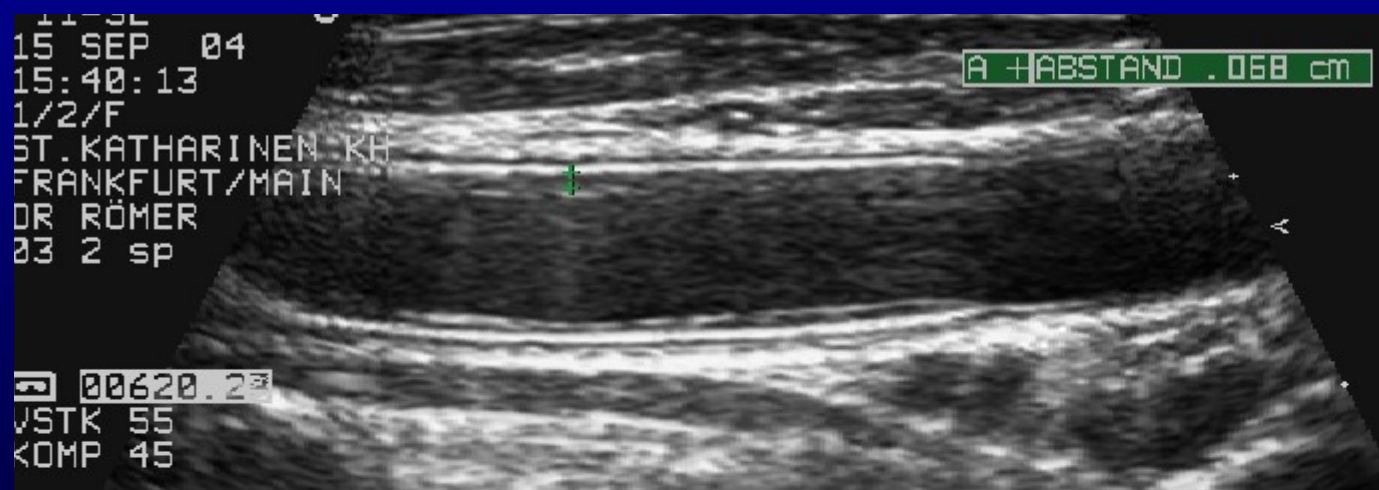
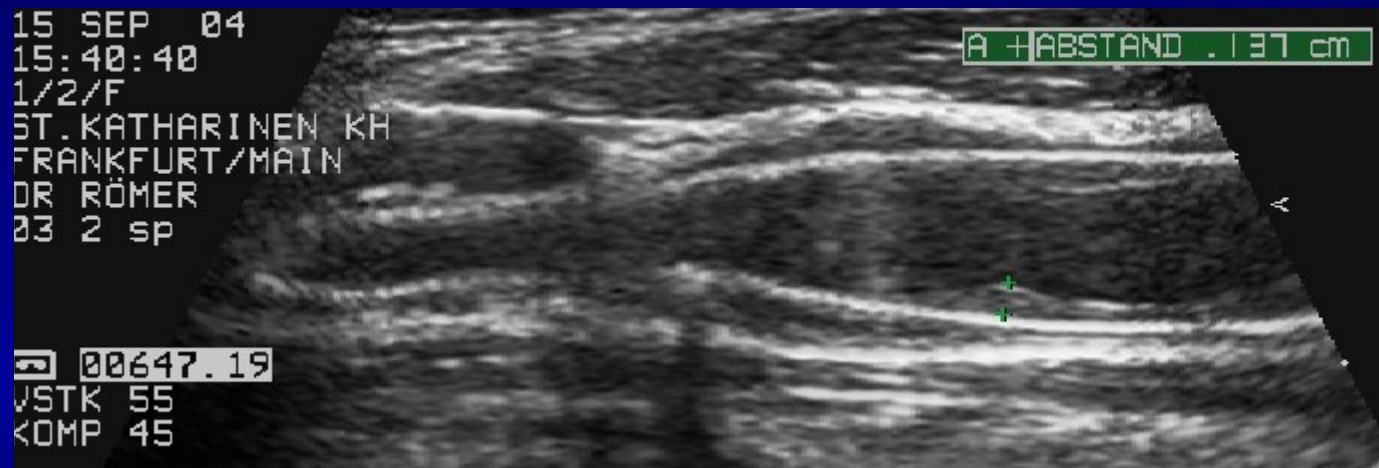
Third Patient

- **57 year old gentleman**
- **Chronic AF**
- **Surgical ASD occlusion 1971**
- **Dil. cardiomyopathy (EF 20 %)**
- **Thrombus in left ventricle 2003**
- **Alcoholic steatohepatitis**
- **Clopidogrel / ASS compliance ?**

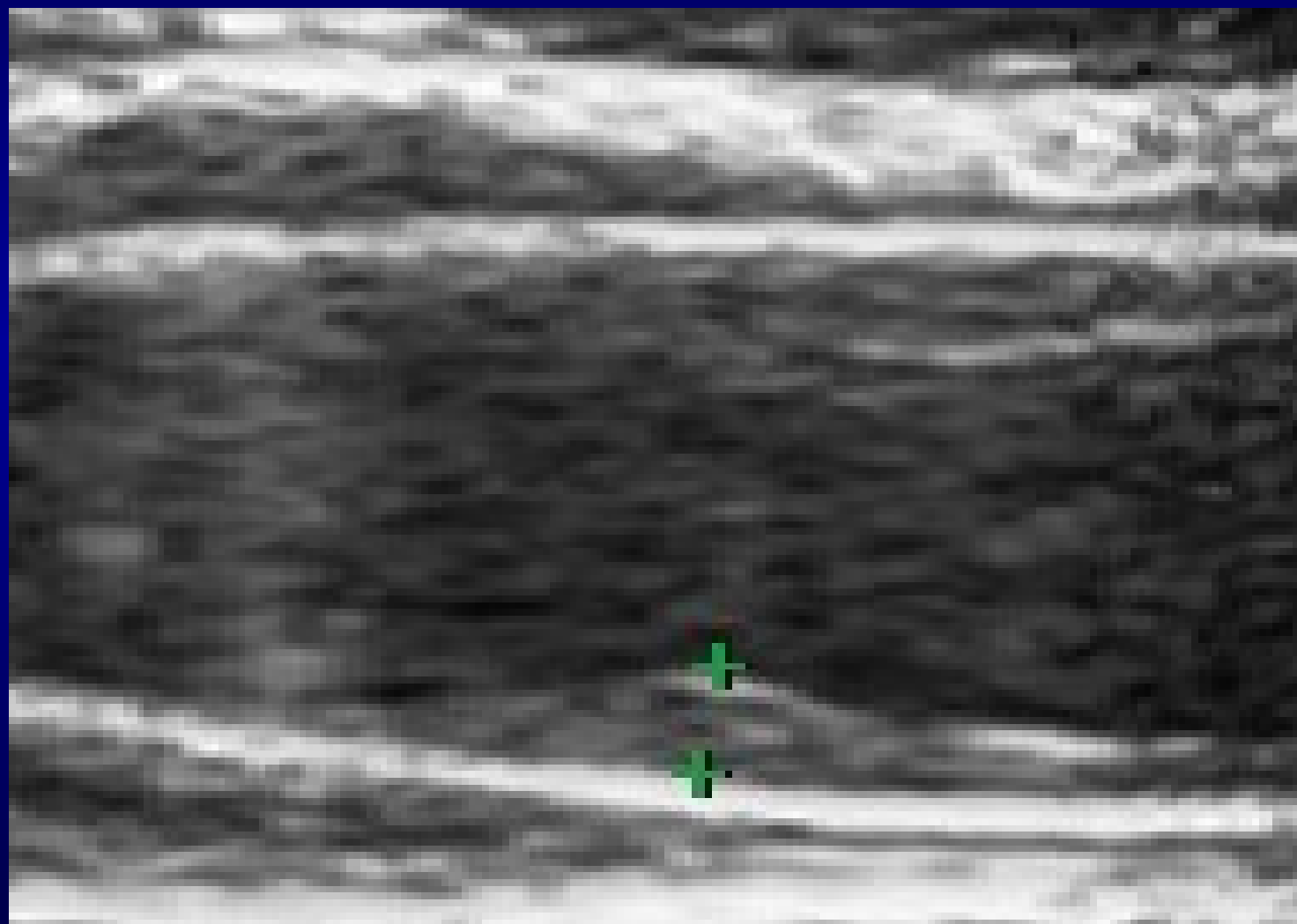
Patient 3 - FU 7 Mo Duplex



Patient 3 - FU 7 Mo Duplex



Patient 3 - FU 7 Mo Duplex



Patient 3 - FU 7 Mo Duplex



Patient 3 - FU 7 Mo Angiogram



Dilatation of Filter Mesh



Final Result



Conclusion

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