

# TCT 2006

October 22-27, 2006

*Selecting the optimal  
carotid stent and  
protection system:  
Lesion and patient  
specific consideration*



***Bernhard Reimers, Mirano, Italy***

# Conflict of Interest Statement

**Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.**

## **Physician Name**

***Bernhard Reimers***

## **Company/Relationship**

**Gore: Training**

**Abbott: Training**

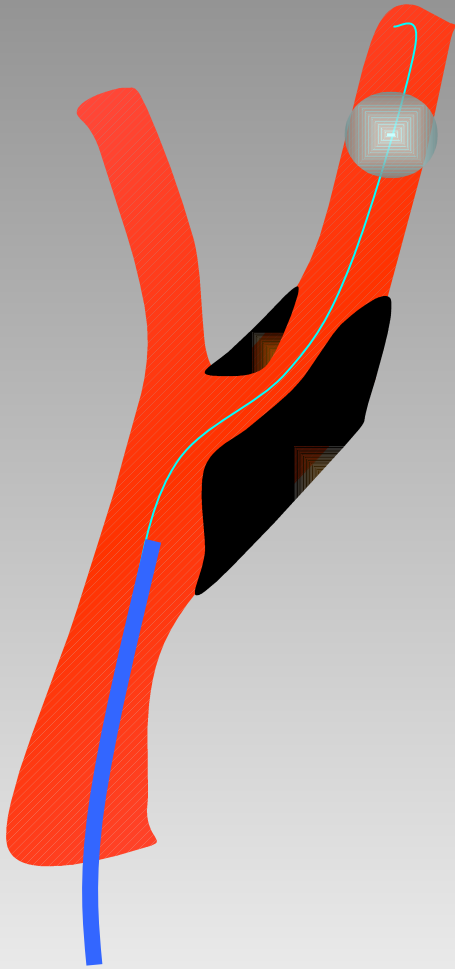
**Cordis: Training**

**Invatec: Training**

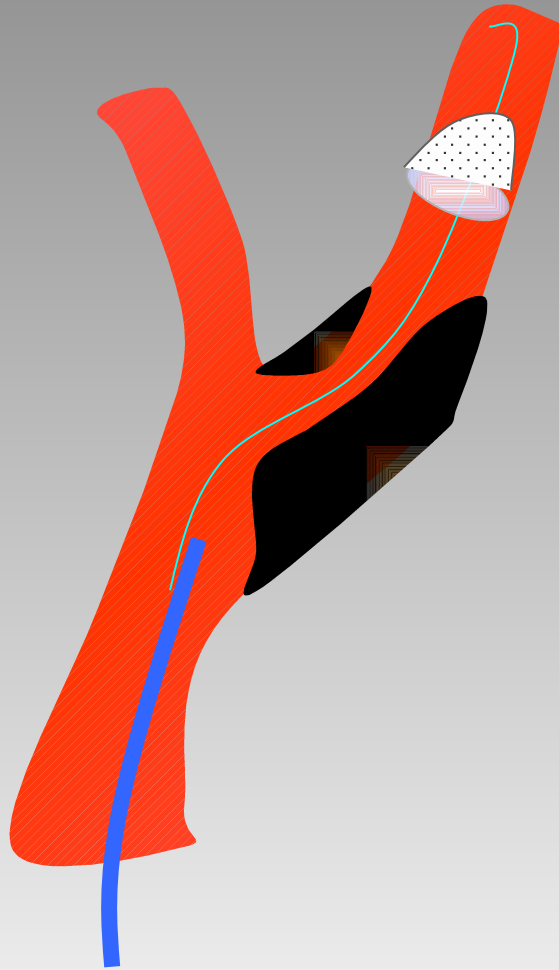
**Boston Sc.: Training**

- **EPD selection**
- **Stent selection**
- **Patient selection**

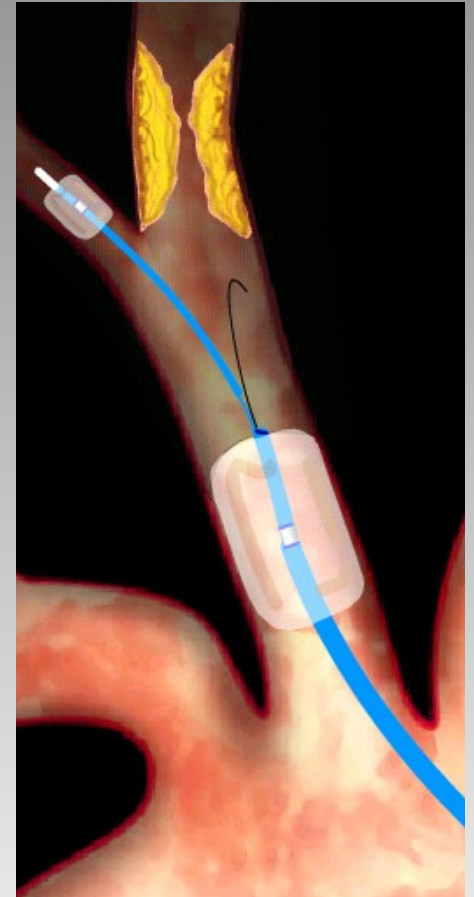
# 3 Different Systems of Cerebral Protection



Distal Balloon



Distal Filter



Proximal Balloon

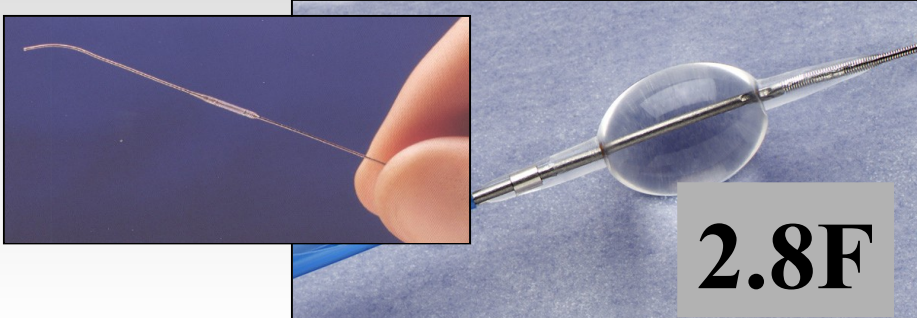
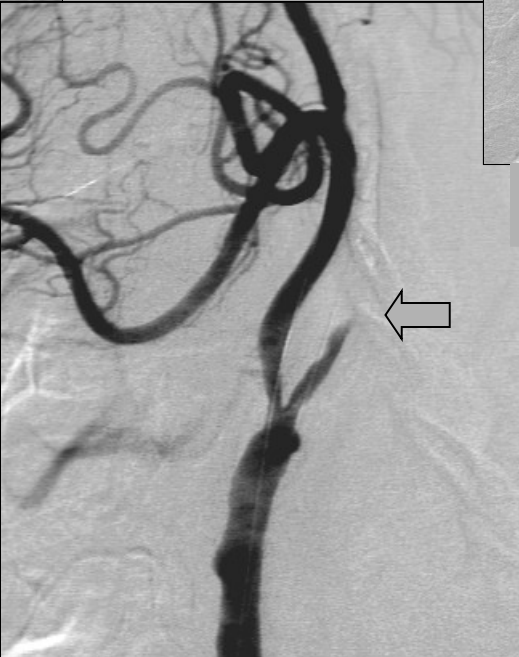
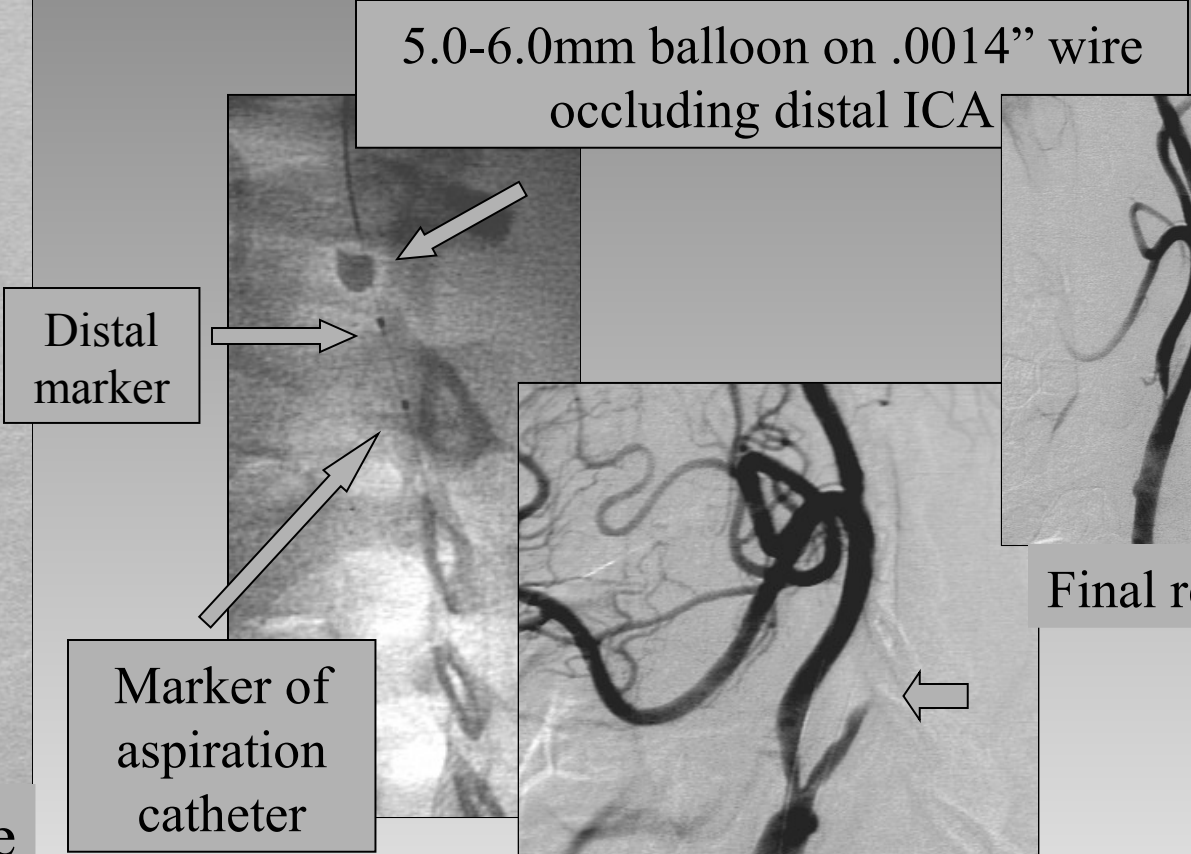


# PercuSurge GuardWire<sup>®</sup> System

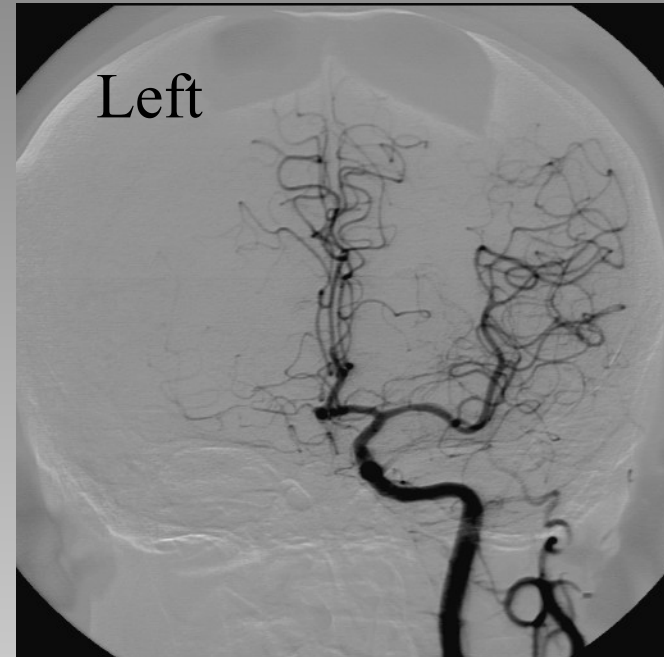
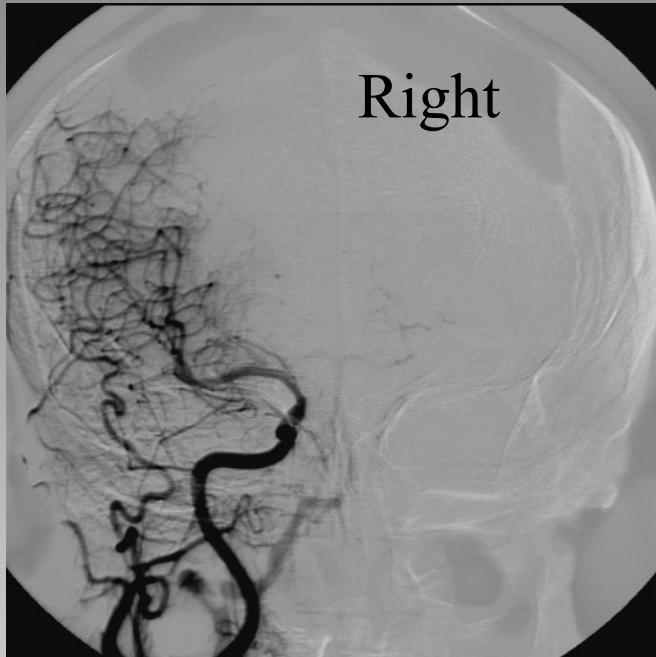
- Safe, effective, and cost-effective... but
  - Somewhat complex to use - 2 trained operators
  - Transient occlusion times 6.5 minutes (quartile 4.5 and 10.5 minutes)...*usually* well-tolerated



# The Percusurge Guardwire™ Protection system



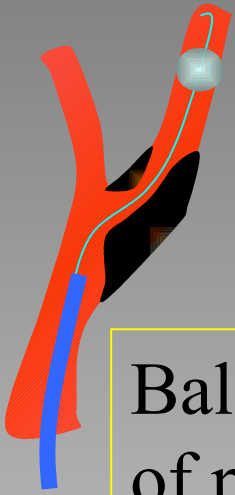
# The Percusurge Guardwire® Protection system



Did support 15 min  
Guardwire balloon  
inflation



Did not support  
Guardwire balloon  
inflation



# Wide clinical experience

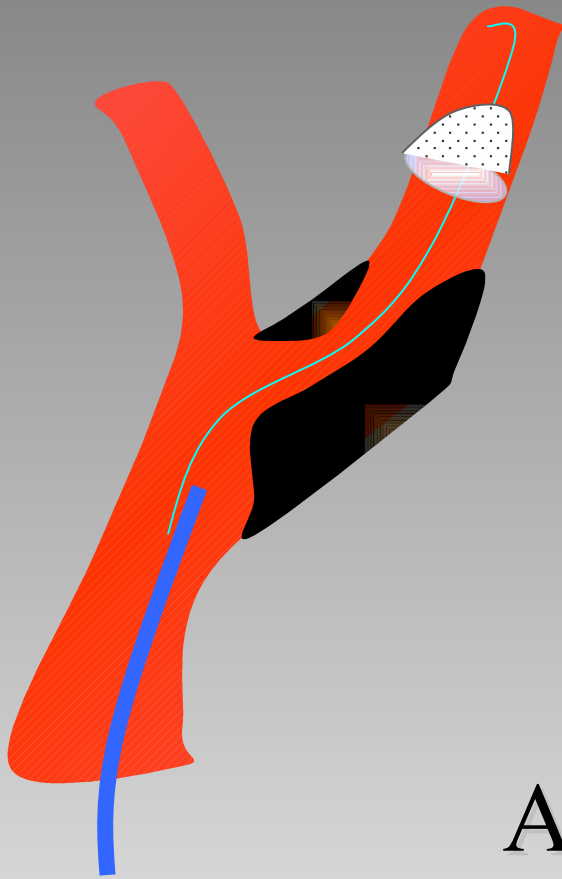
Balloon-protected carotid artery stenting: relationship of periprocedural neurological complications with the size of particulate debris.

Tuebler et al. *Circulation* 2001;104:2791.

Feasibility and efficacy of balloon-based neuroprotection during carotid artery stenting in a single center.

Schlueter et al. *JACC* 2002;40:890.

CAFE studies

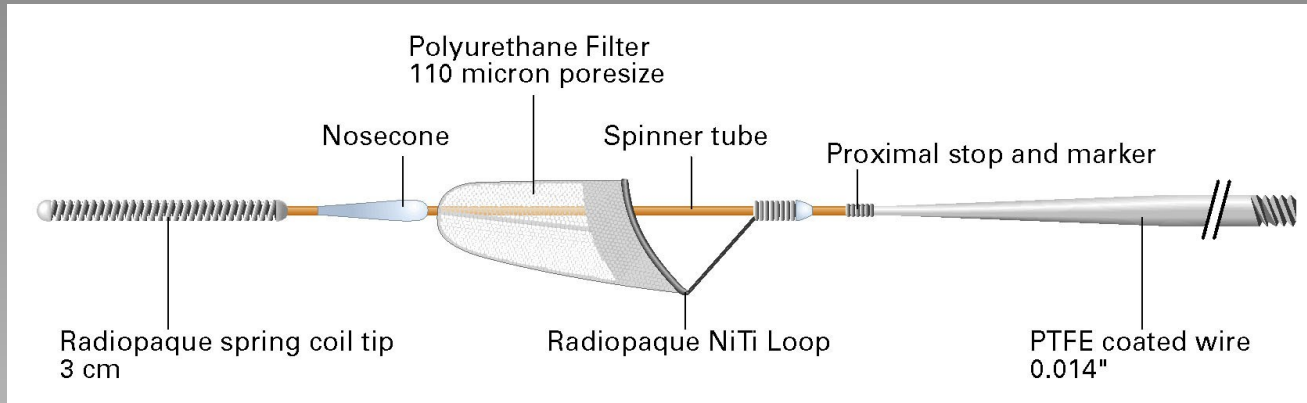


## Filter protection:

A filter positioned distal to the stenosis captures debris while maintaining antegrade flow



# The EZ™ Protection Wire

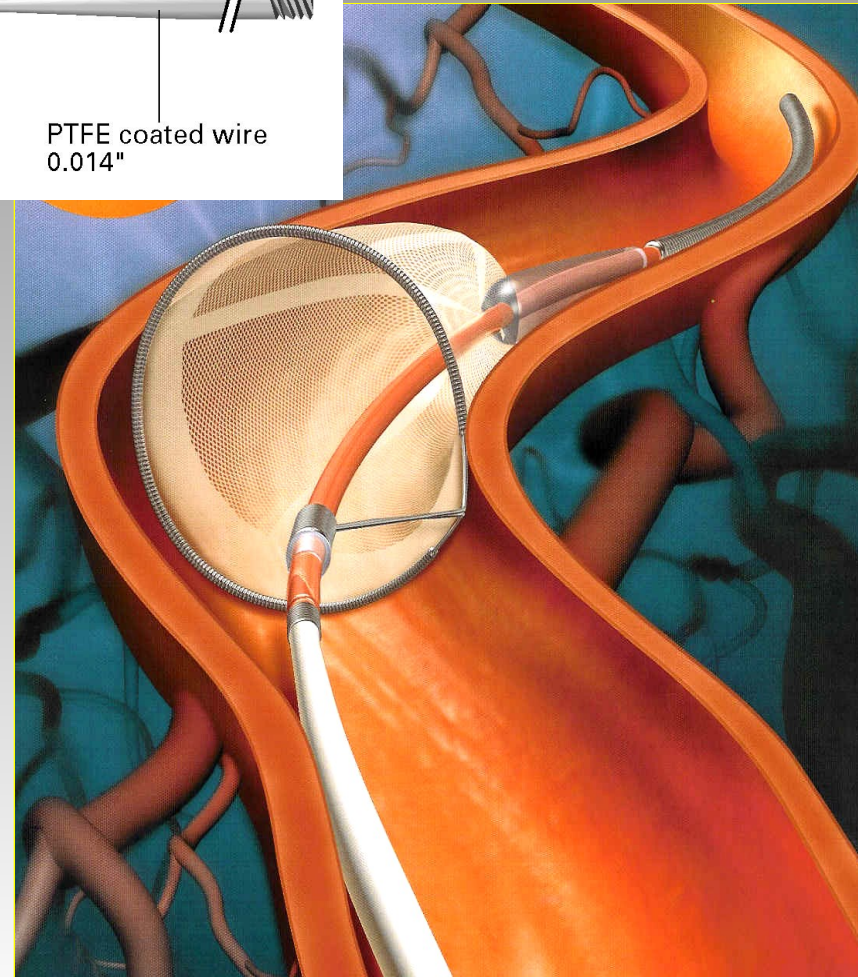


**3.2 French Crossing Profile**

**4.3 French Retrieval Catheter**

**3. – 5.5 mm Retrieval**

**110 µm Pore Size**



# Designed For Delivery Through Tight Turns

**Smooth Tip to  
Filter Transition**

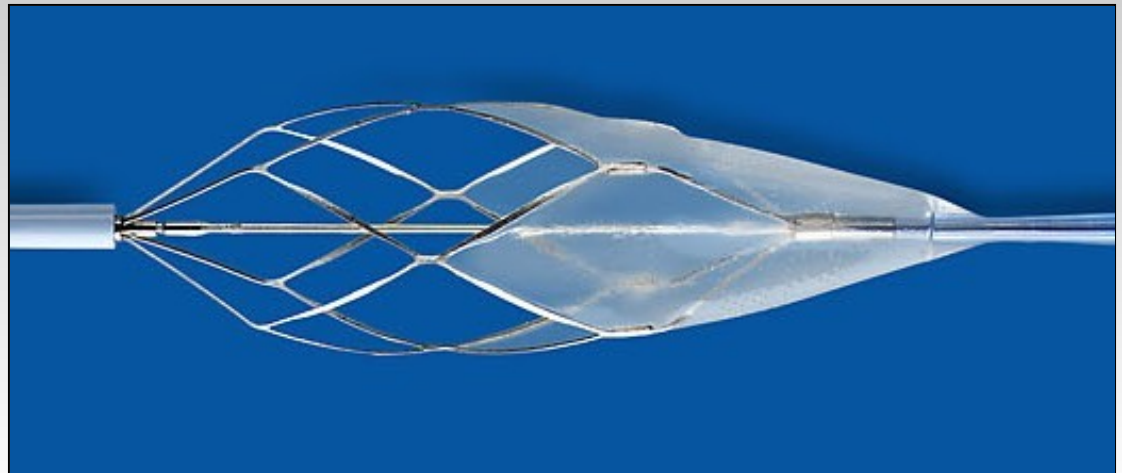
**Tip Coil**

**Obturator**

**Delivery  
Sheath Tip**



**Flexibility in the  
Basket & Obturator**

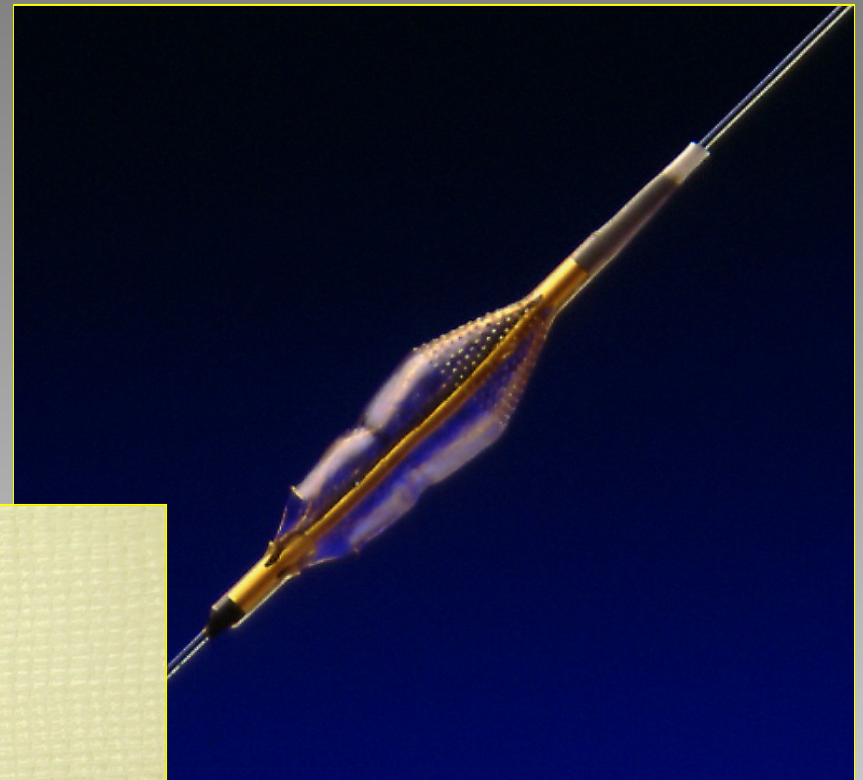
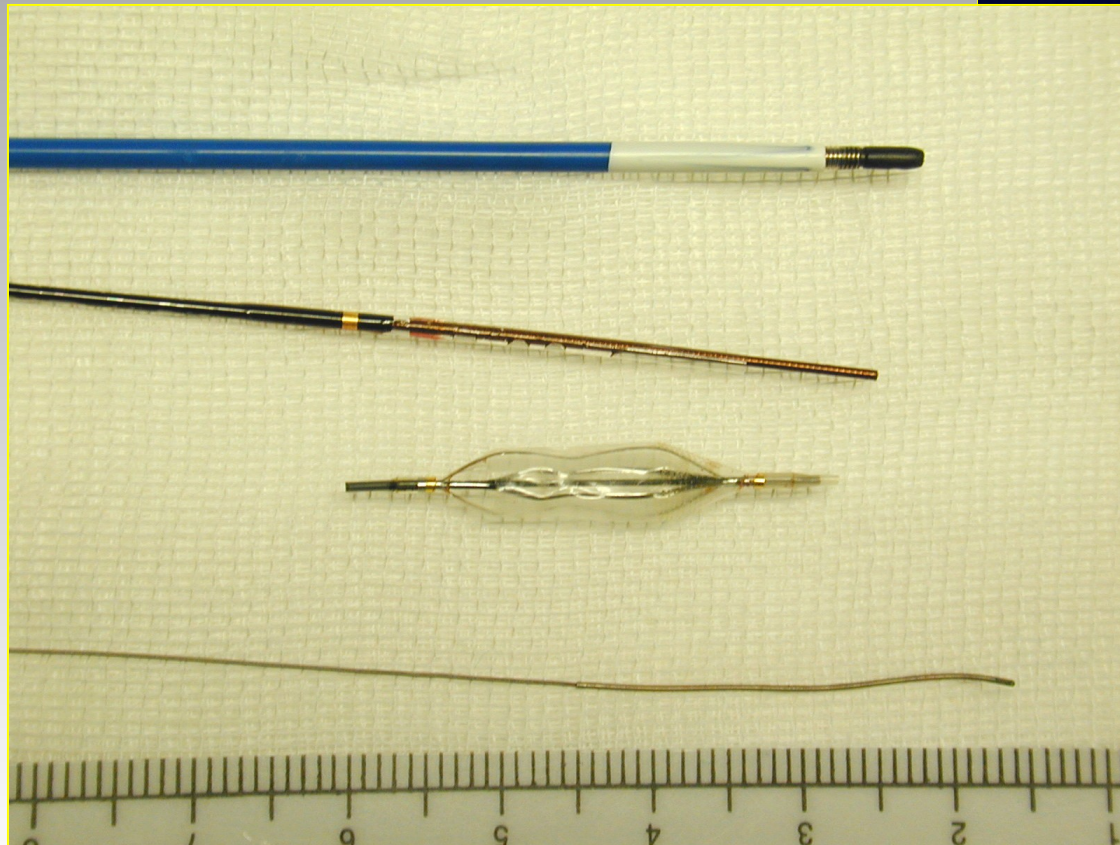


**Guidant AccUNET**

# Abbott

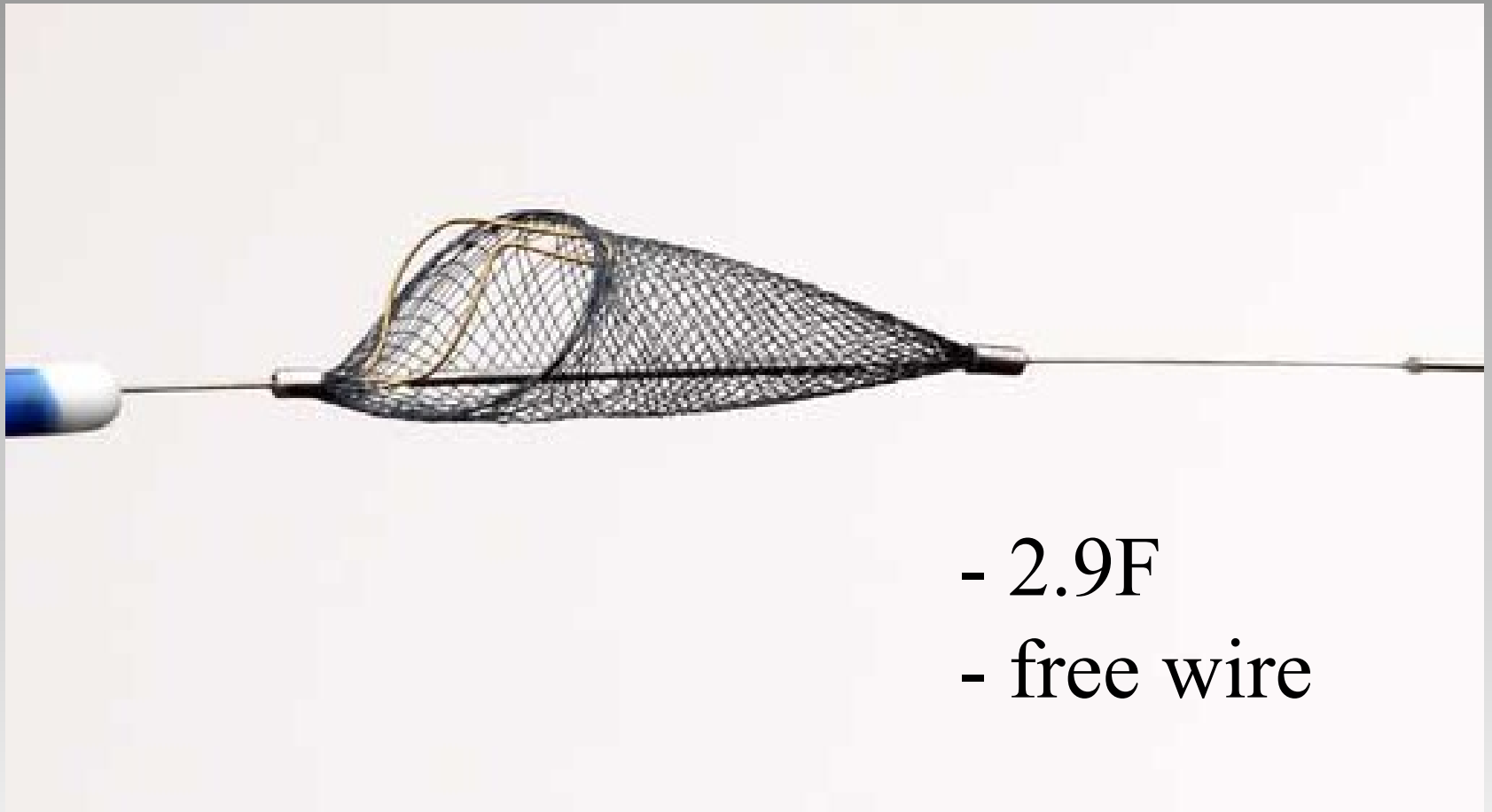
## EmboShield™

*Investigational devices only*





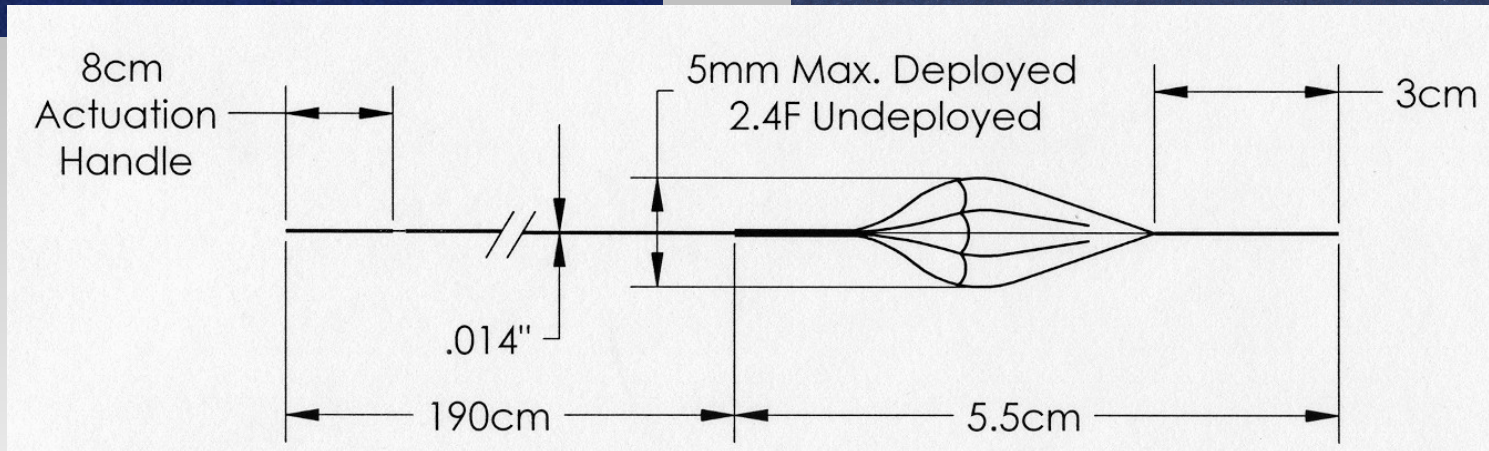
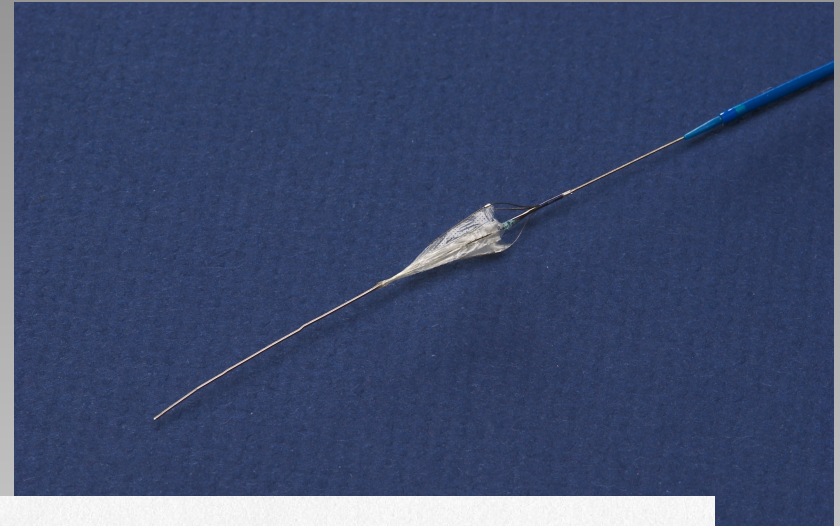
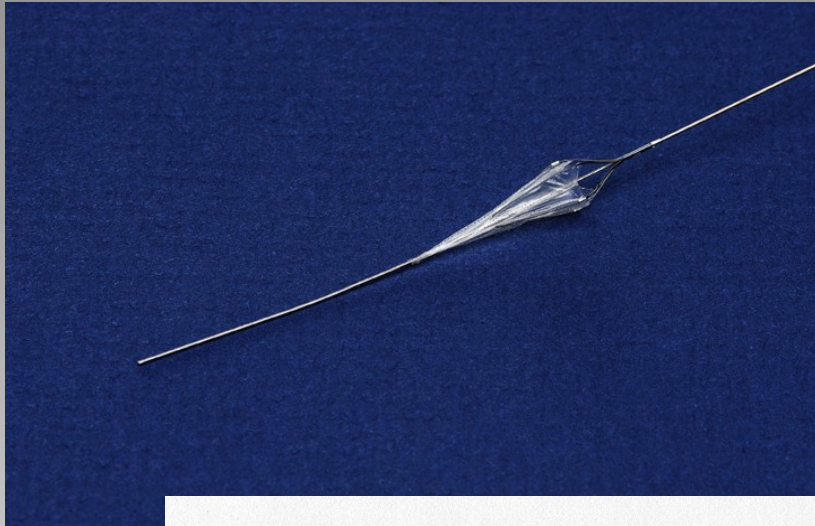
# Spider – Distal protection device



- 2.9F
- free wire

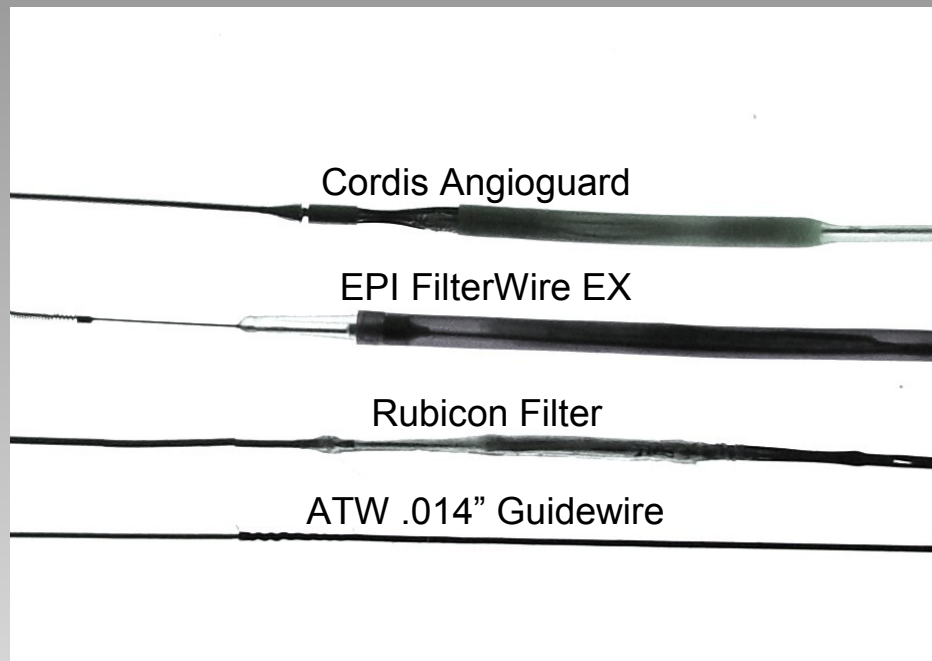
ev-3

# The Rubicon™ Filter



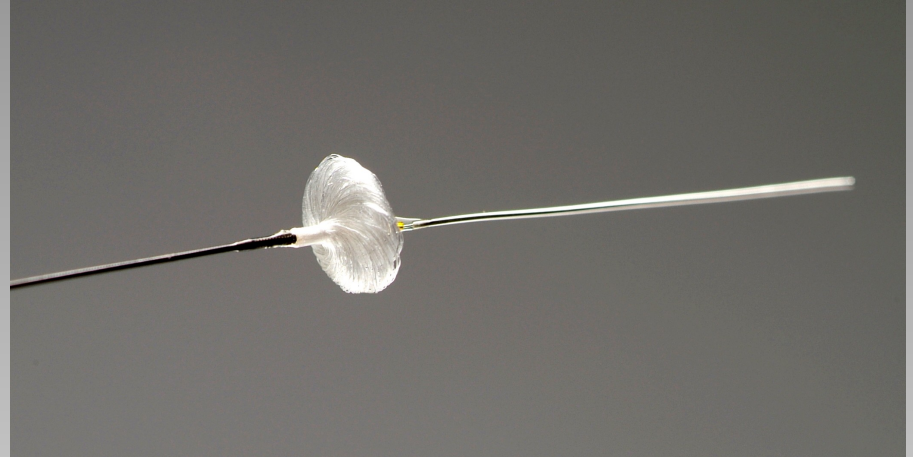
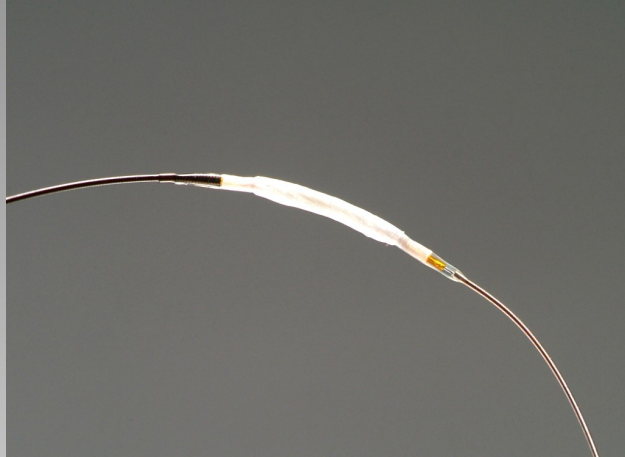
- Standard 0.014" guidewire, Crossing profile 2.4F,
- No delivery catheter, 100 micron pore size

# The Rubicon™ Filter



Comparison of Crossing Profiles

# FiberNet<sup>®</sup> Embolic Protection System



# In vitro carotid flow model

	<b>Capture Efficiency, %</b>
<b>AngioGuard</b>	<b>91.4</b>
<b>FilterWire</b>	<b>91.7</b>
<b>EmboShield</b>	<b>95.9</b>
<b>Trap</b>	<b>91.3</b>
<b>Percusurge</b>	<b>85.4</b>

Mueller-Huelsbeck et al.

Joint annual meeting

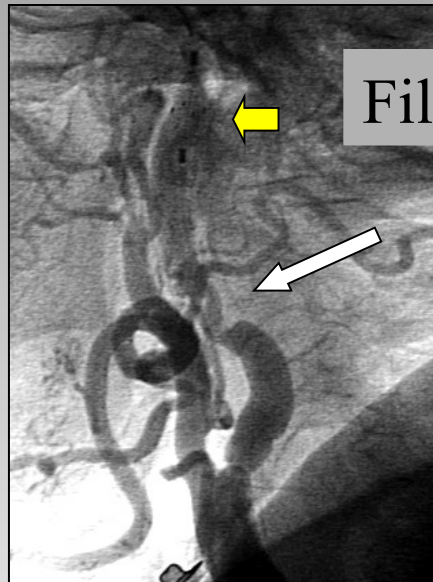
Deutsch-Oesteriechische Roentgengesellschaft, May 2002



# Distal Protection: Possible Difficulties



Baseline



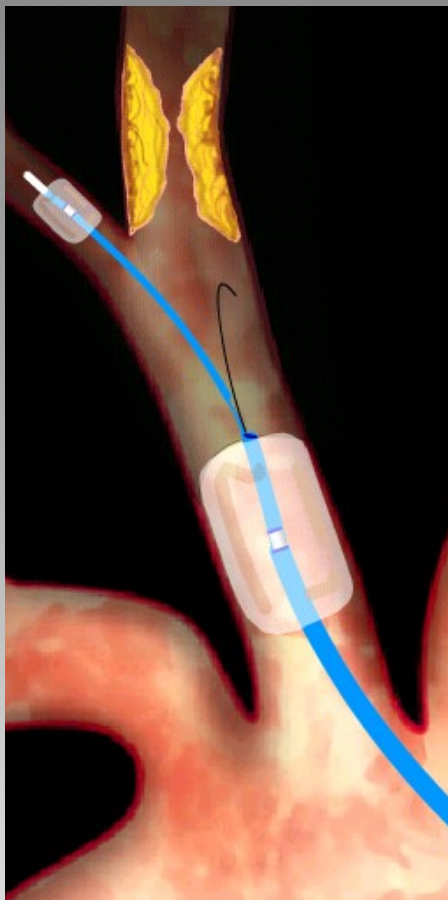
Spasm



Slow Flow

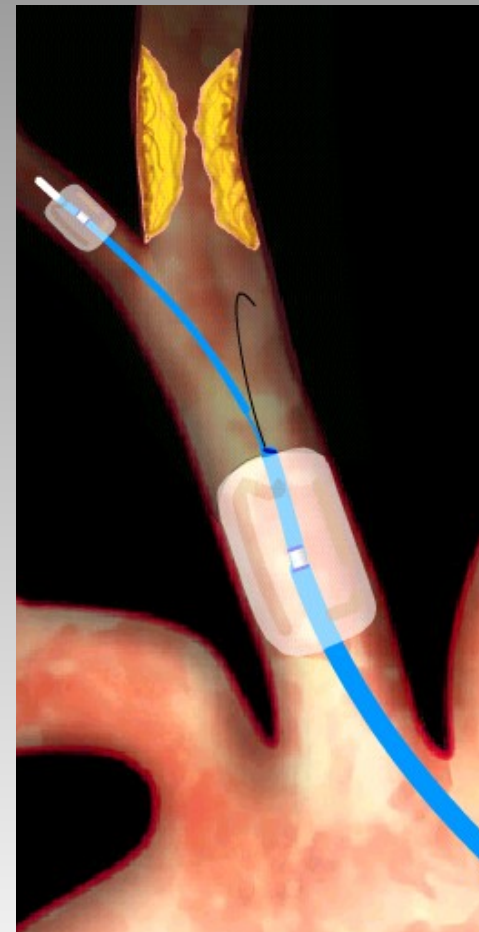
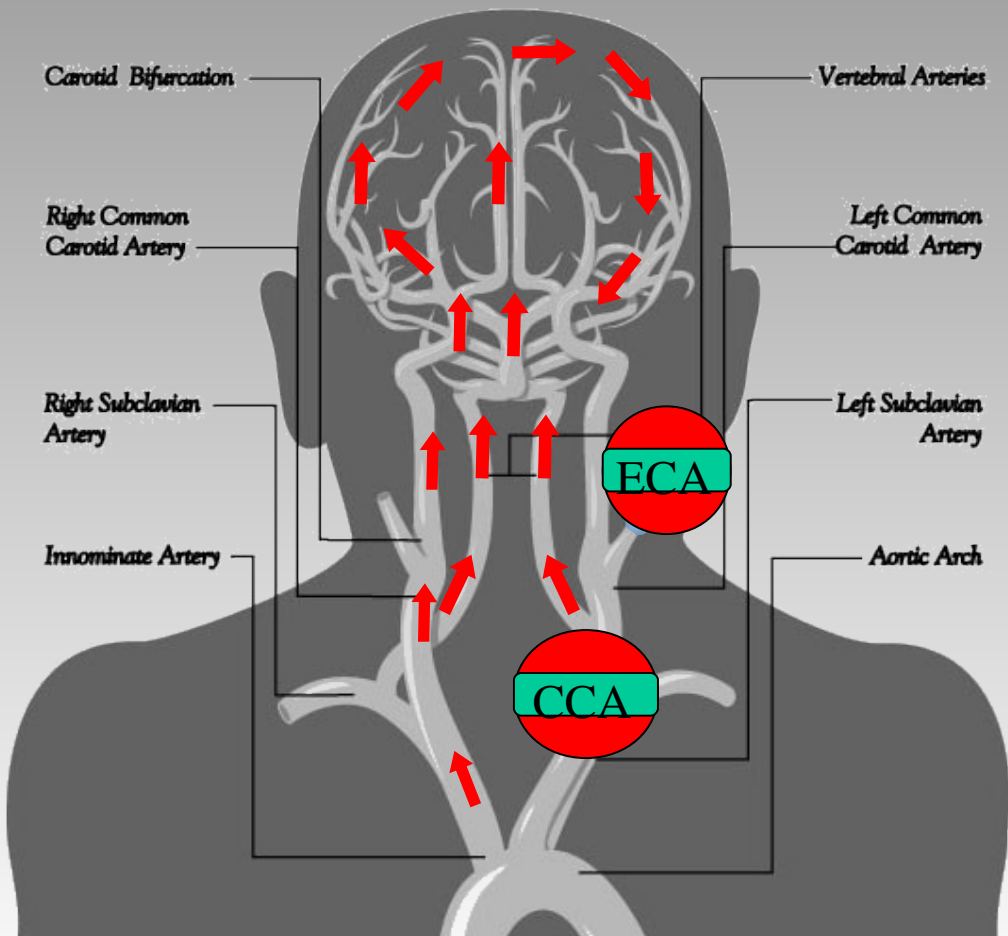


Final Result



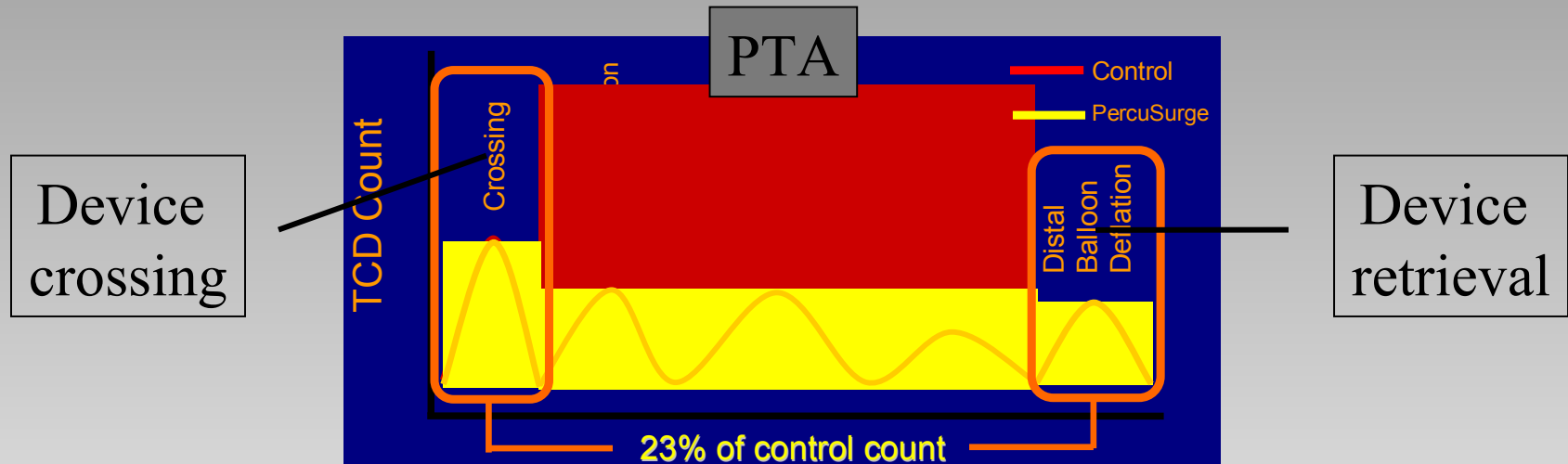
Proximal Protection

# The Concept of Endovascular Flow Blockage

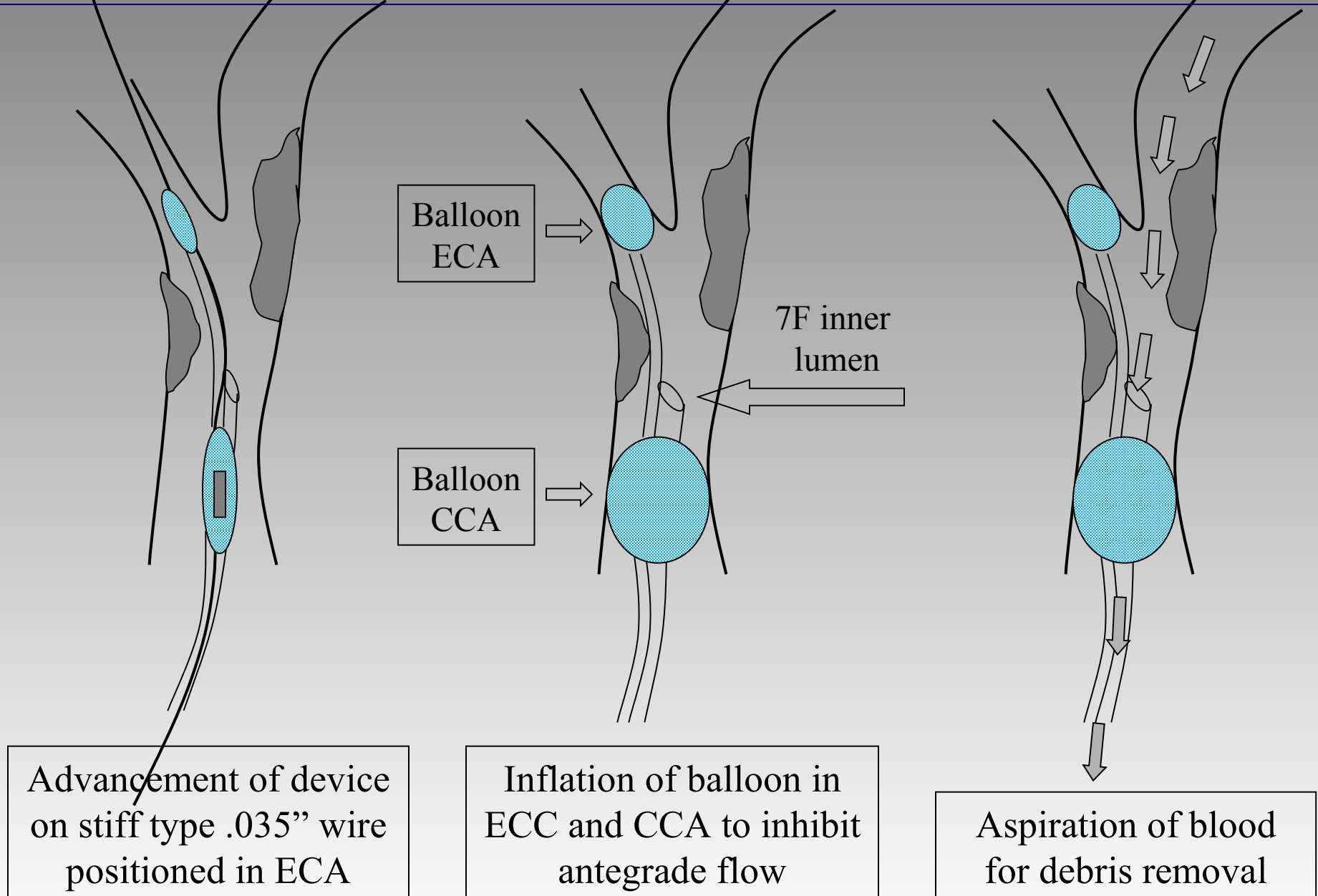




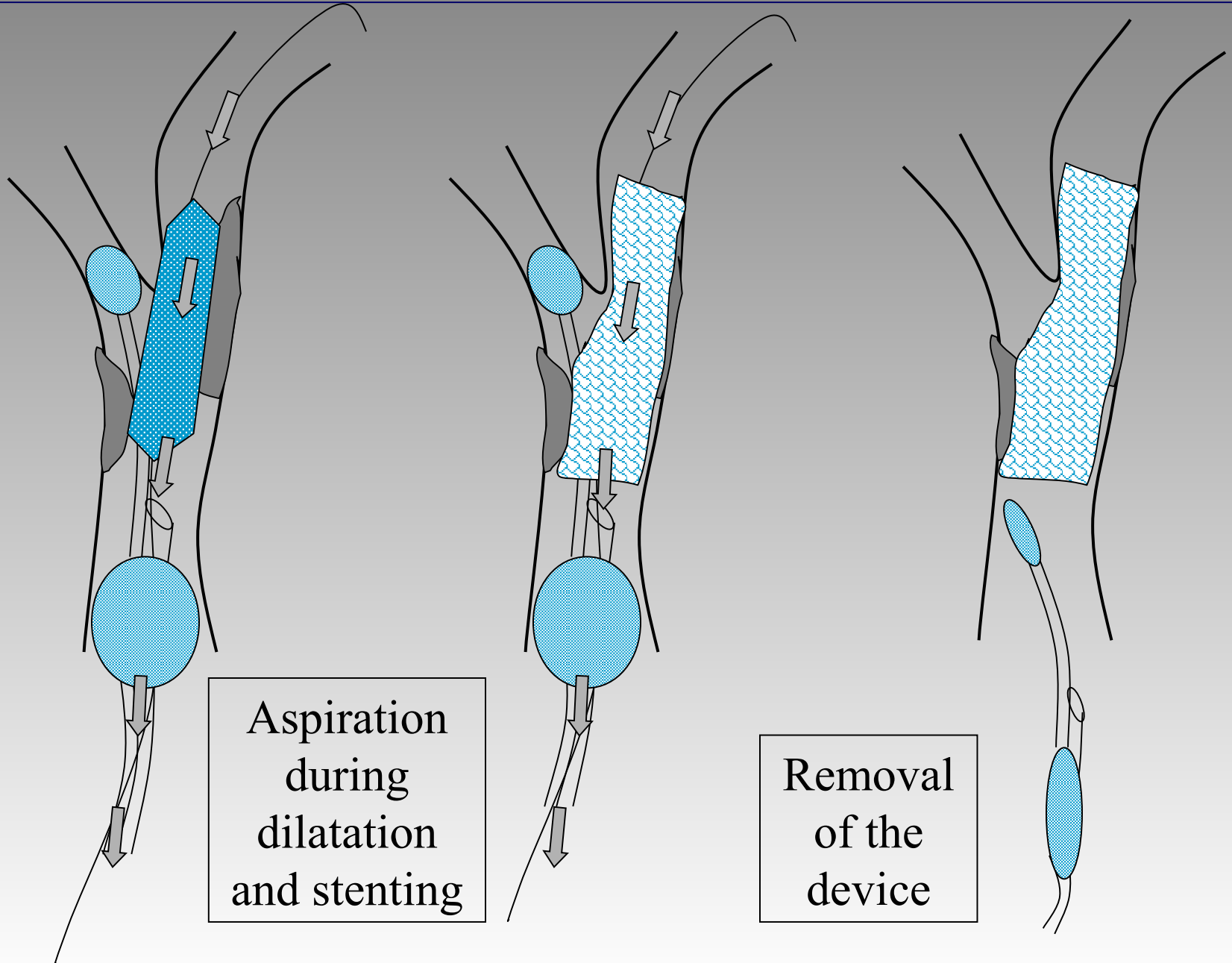
# Why pursuing a new concept of cerebral protection?



# Proximal protection with endoluminal clamping of ECA and CCA

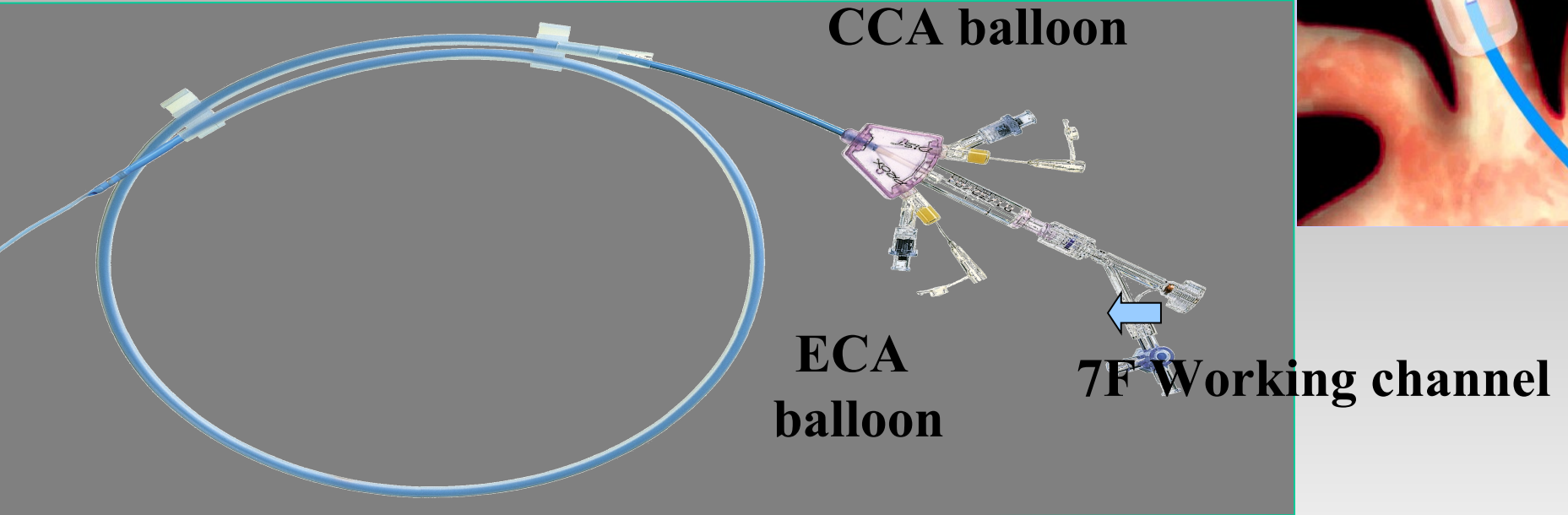


# Proximal protection with endoluminal clamping of ECA and CCA



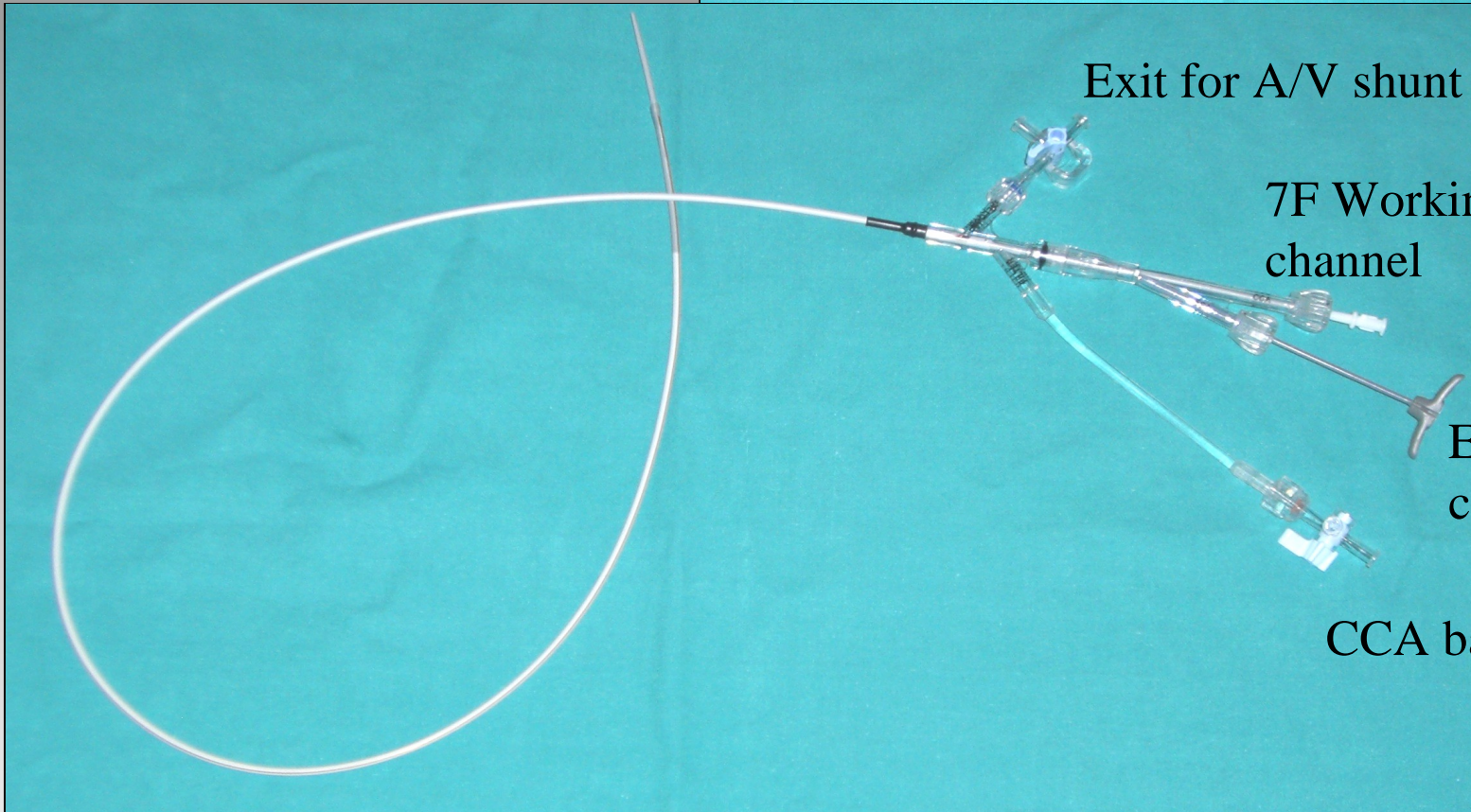
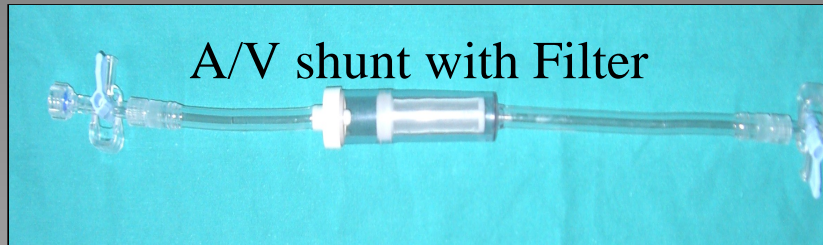
*MOMA*

**Single Device consisting of  
long 90 cm sheath and 2  
occlusion balloons**



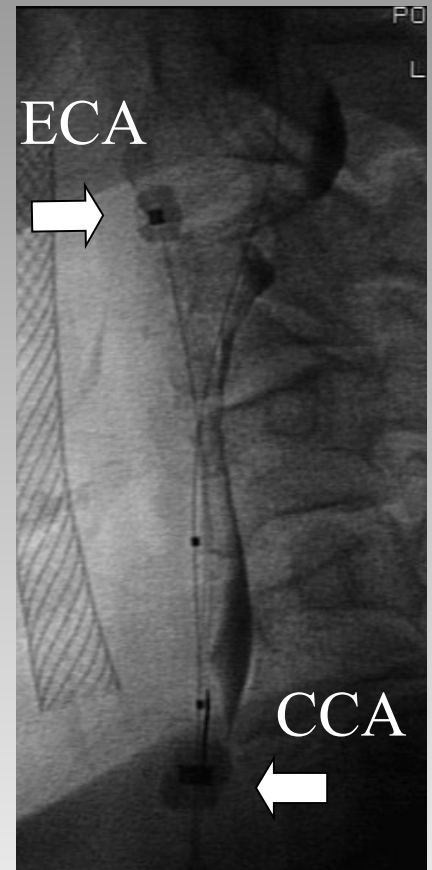
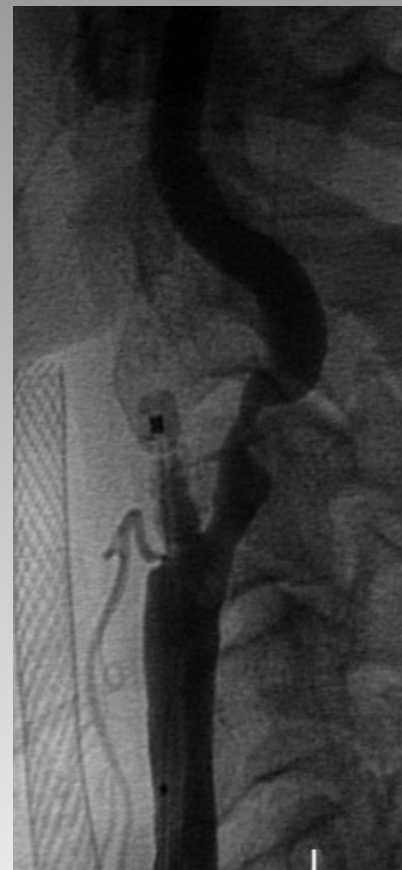
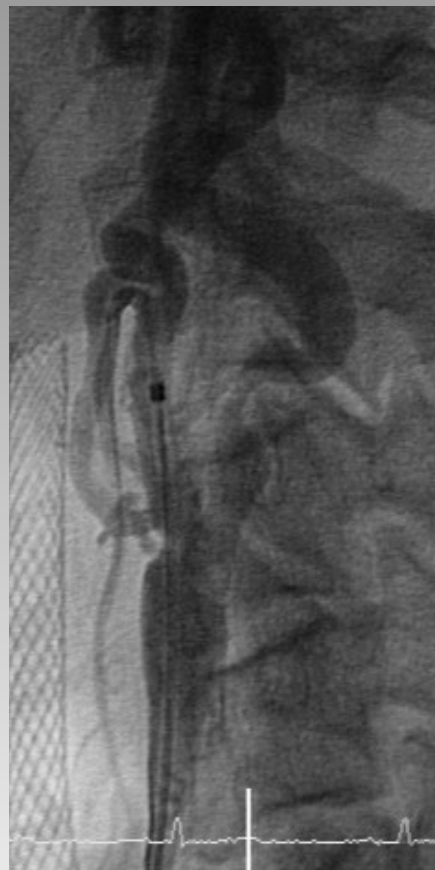
**9F device available**

**9F device**



**Parodi EPD system (Gore)**

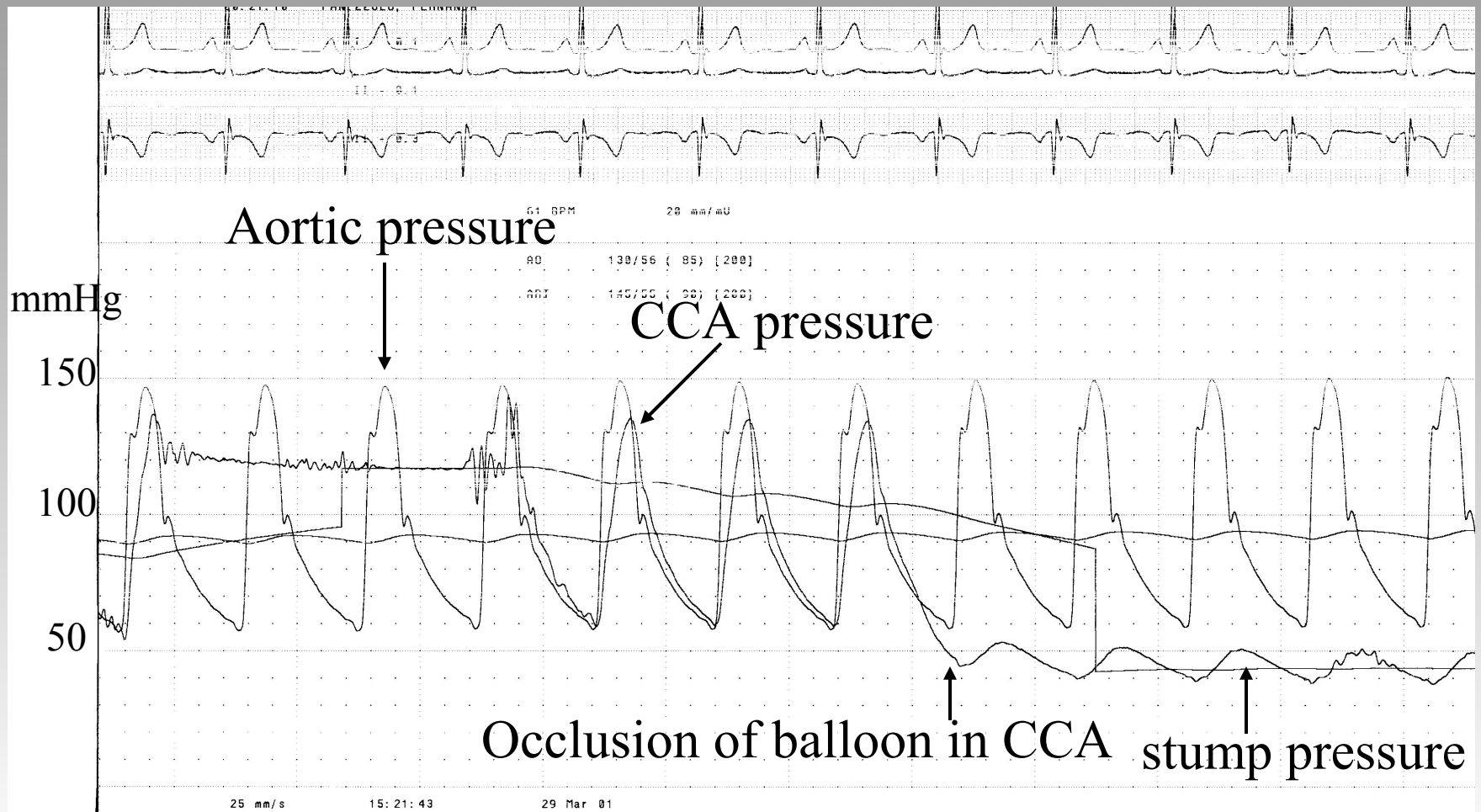
# Proximal protection

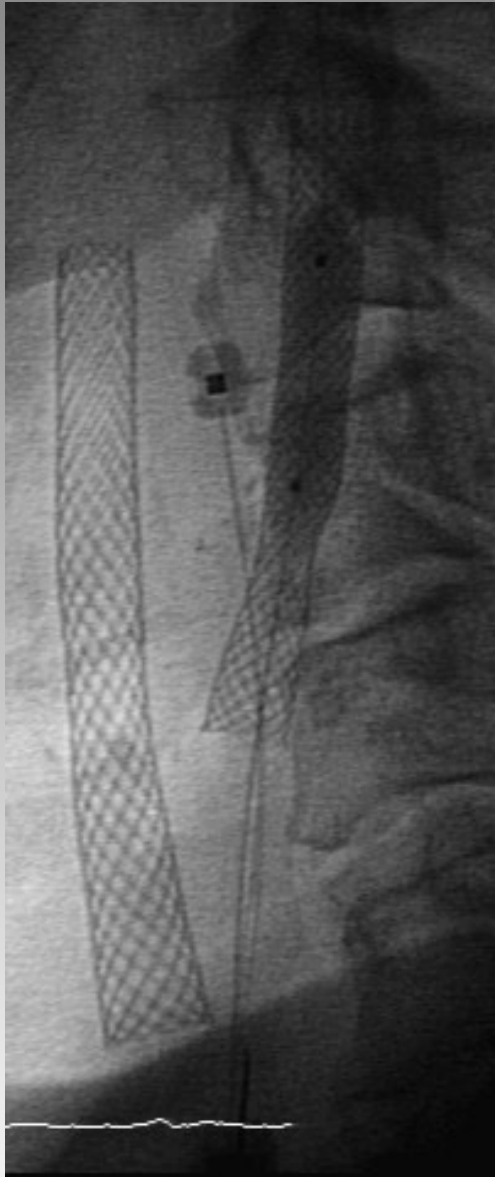




# Emboli protection during carotid artery stenting

## Pressure tracing after balloon occlusion in CCA



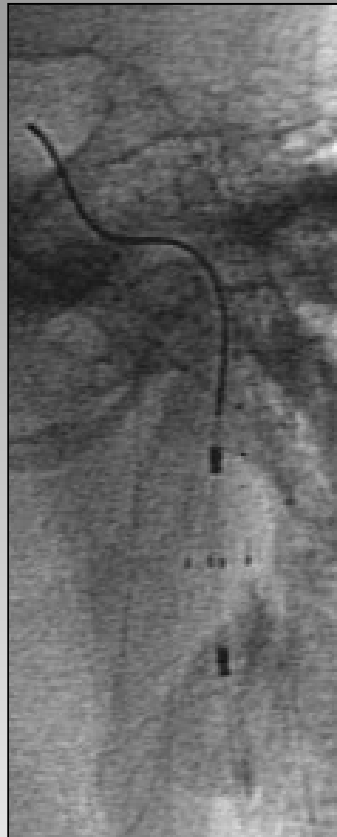




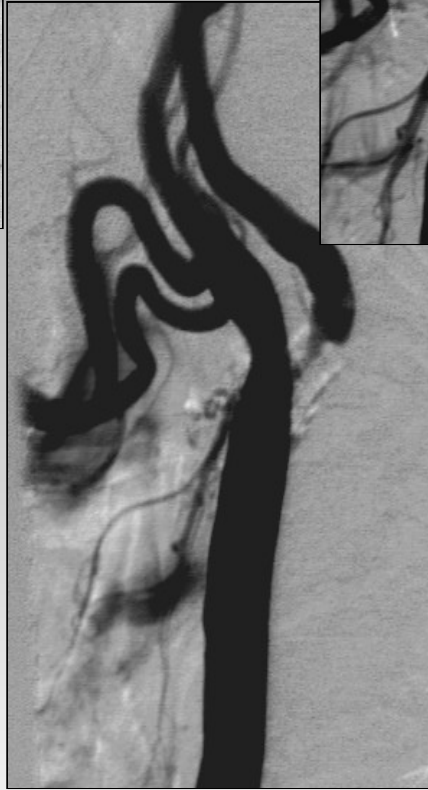
Some case examples

## Decide strategy before you start:

**Tight lesion, some calcium, moderate tortuosity ICA**



# Filter Devices : Profile matters?



**Did Cross**

**Did Cross**

**Did **Not** Cross**

# Filter Protection during CAS

## Predilatation for Filter Crossing



Baseline,  
filter does not cross



2.0mm coronary  
balloon  
predilatation

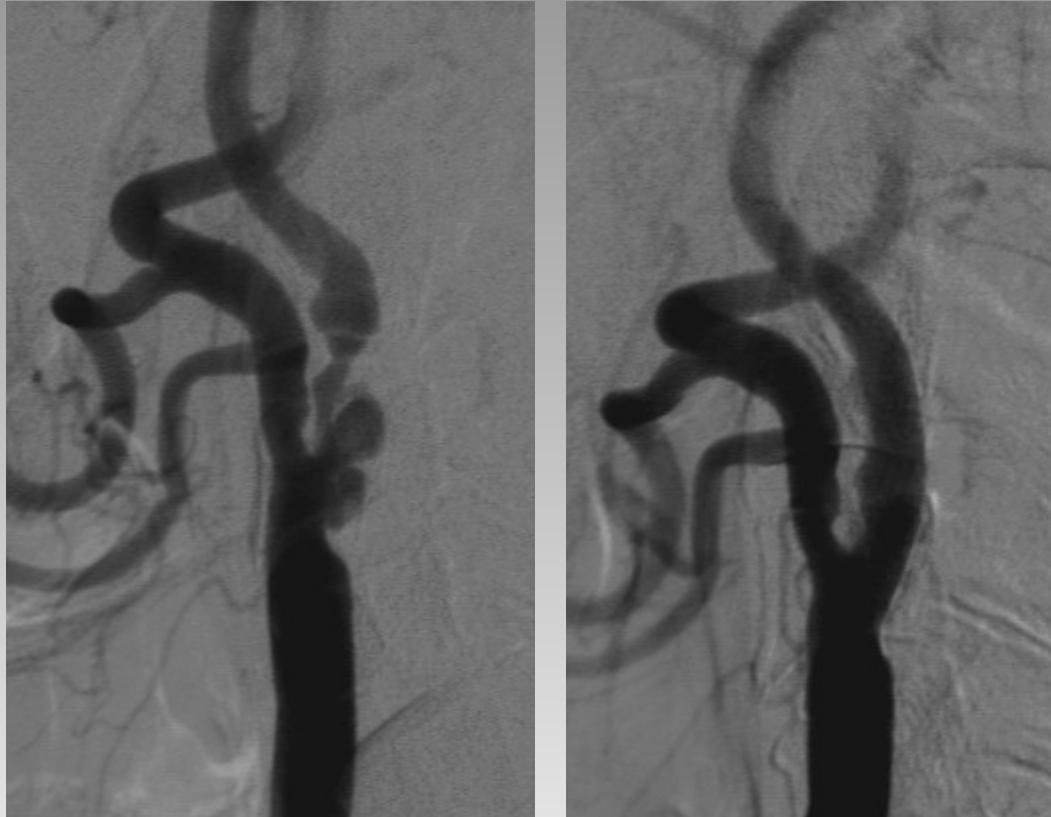


Crossing of  
6.0mm filter



After Wallstent

# Irregular Lesion, TIA 2 months earlier



If distal protection: Extremely careful navigation, proximal protection valid alternative

# String sign with thrombus and distal slow flow in patient with fully recovered minor stroke



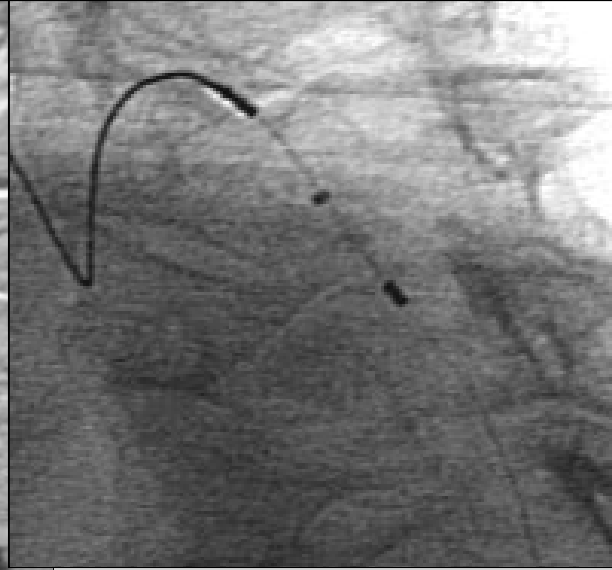
**Or don't do or proximal protection**

# Distal Vessel Tortuosity

Filter  
did not advance



Baseline



Final result



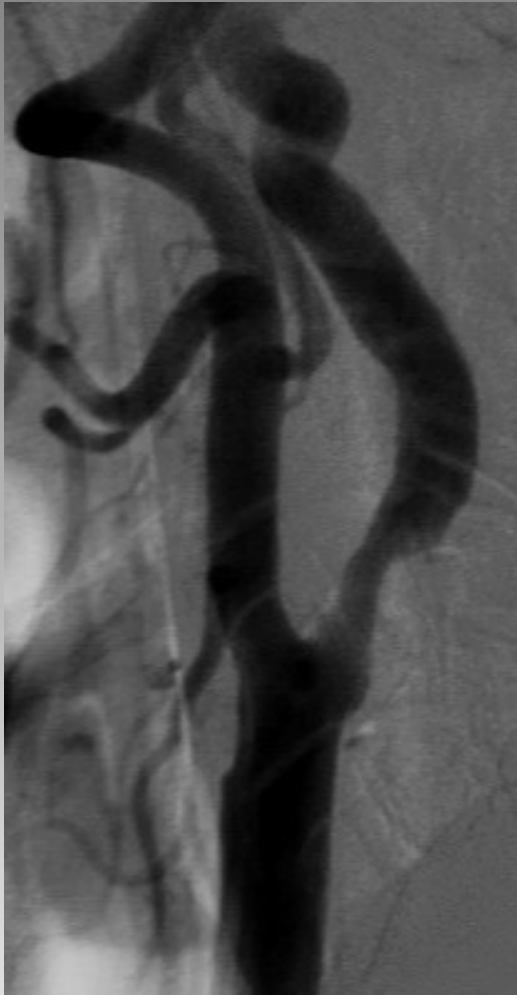
# Distal Tortuosity



Good support from sheath. Angioguard and Filterwire did not cross despite buddy-wire; Spider delivery catheter crossed but filter could not be advanced

041573





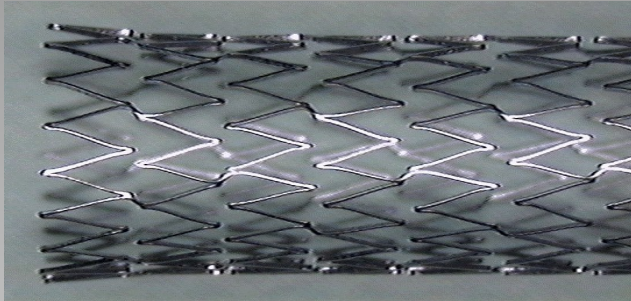
No complication **but** 3 filters and 1 Mo.Ma device used.  
Increased risk because of increased procedural time  
'working' in the carotid artery.

## How to cover such a lesion?

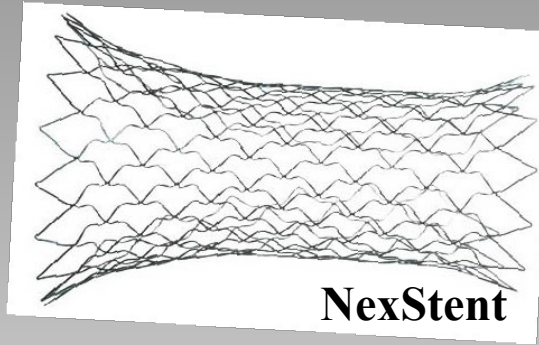


Lesions with fresh (floating) thrombus and highly symptomatic lesions (crescendo TIA's)

# Carotid stents



**Precise**



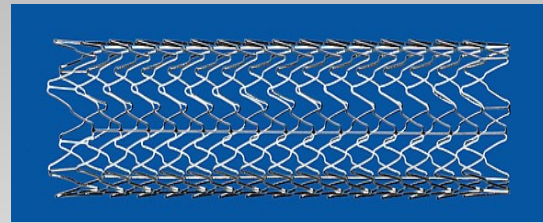
**NexStent**



**Exponent RX**



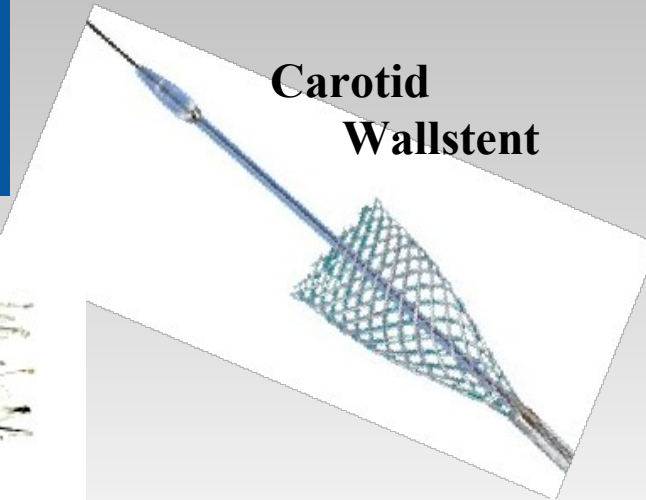
**Xact Carotid Stent**



**RX Acculink**



**ProtégéRX**



**Carotid Wallstent**

# Stent Design: What we know

Actually we have 2  
different stent  
“philosophies”

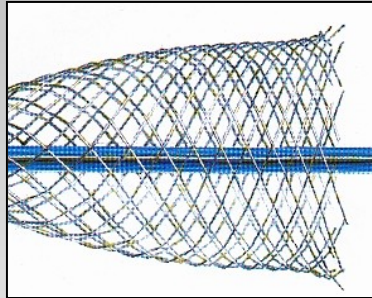


# Carotid artery stents

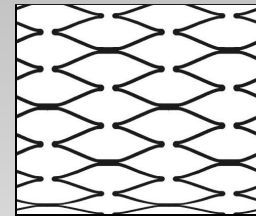
~~Balloon expandable~~

Self expandable

Braided mesh wire  
(Cobald Alloy)



Nitinol  
(Nickel-Titanium)

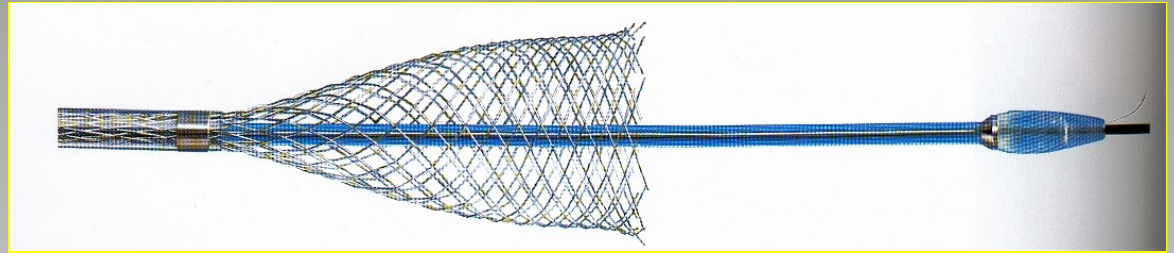


Open cell design

~~Closed cell design~~

## Braided mesh wire (Cobald Alloy)

Mesh-Wire  
stent

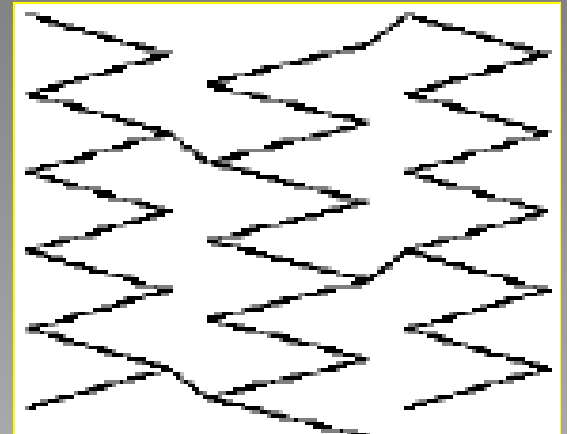


- Super-alloy wires braided to a tubular mesh
- Braided to different diameters
- Spring like expansion
- “Closed cell” like

e.g. Carotid Wallstent Boston Scientific



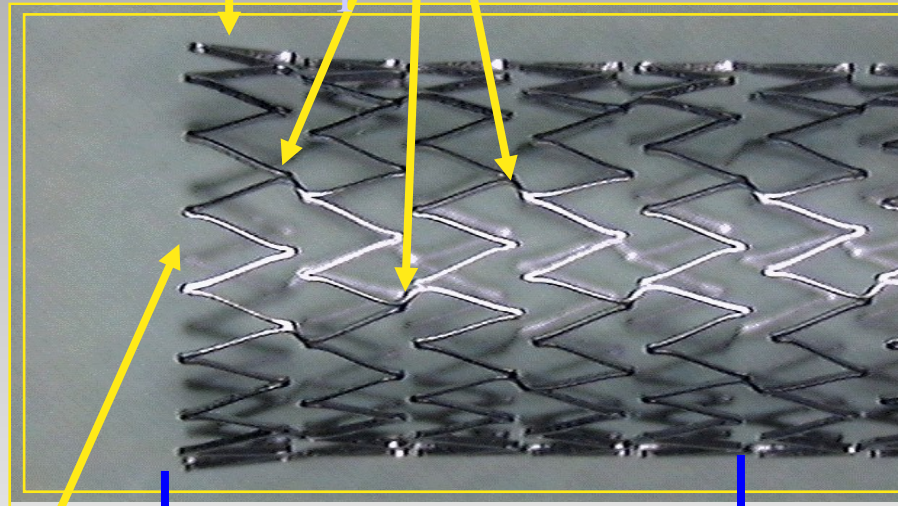
Nitinol Stents  
(Nickel Titanium  
Naval Ordnance Laboratory)



**Segment**

**Bridges**

Diapositiva 96



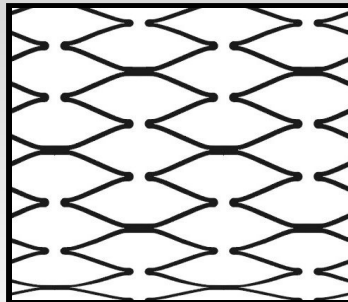
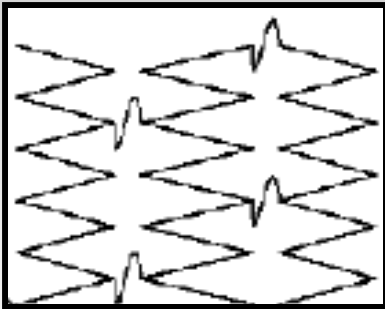
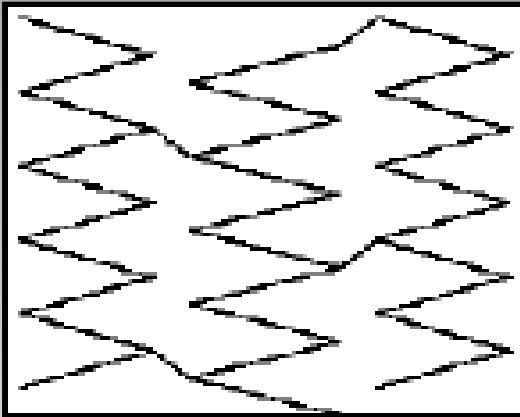
**“Crown”  
pattern**

**1cm**

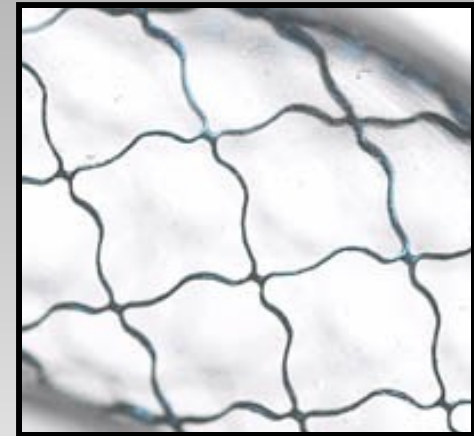
**5 segments**

# Nitinol Stents

Open cell design



Closed cell design



**Stent design:  
What we know, don't know, and assume**

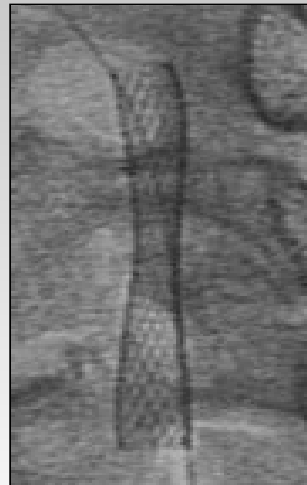
**What we know**

# Stent Design: Vessel Adaptability

**Nitinol**



**Mesh Wire**



**Open cell  
Nitinol** has a  
better vessel  
adaptability

# Vessel tortuosity



.018" Smart  
7.0 x 30 mm

**Better conformability  
of open cell **Nitinol** stents**

# Mesh Wire Stent



Distal  
kinking



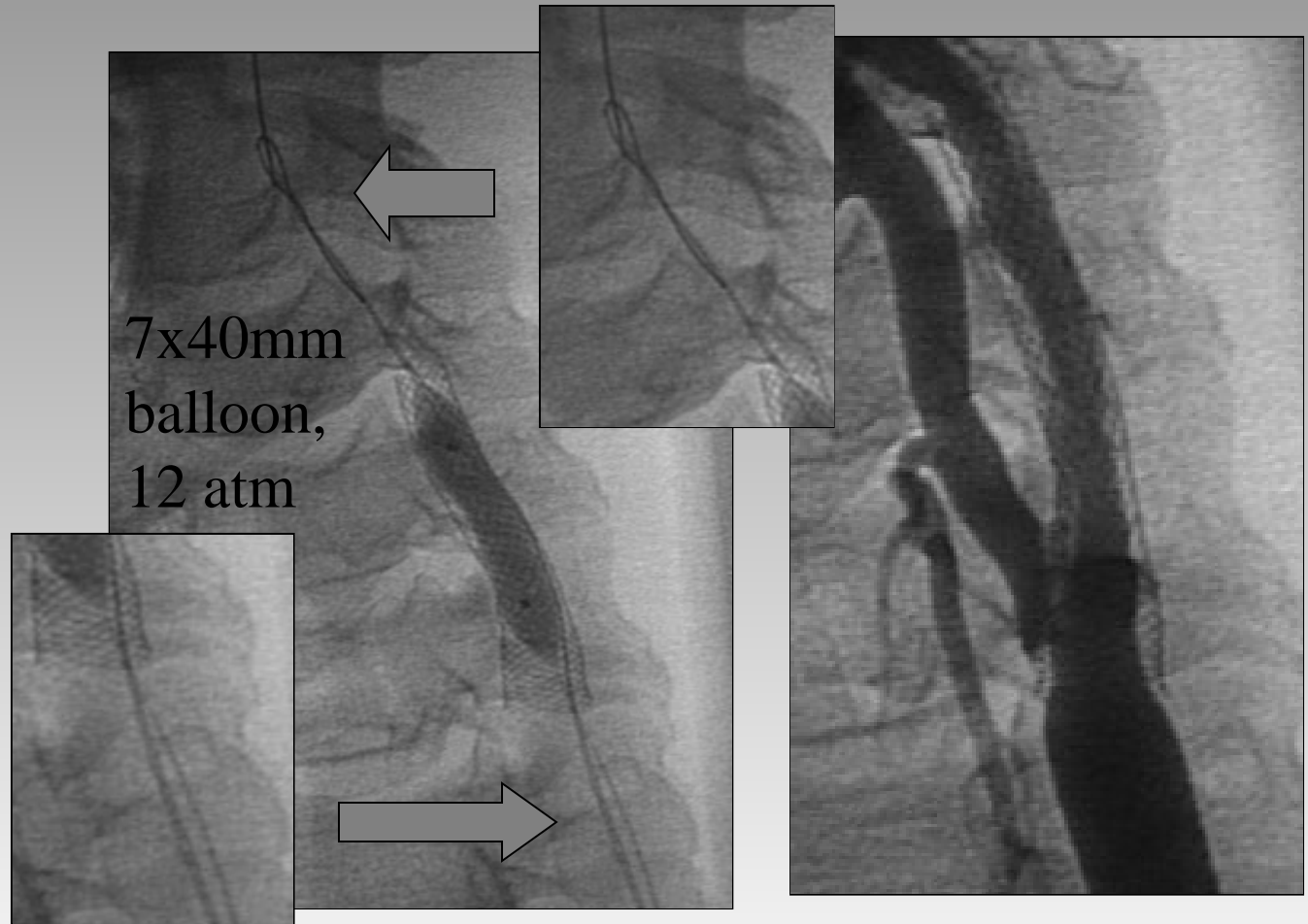
**Clinical impact of  
different vessel  
adaptability ??**

# CAS - Restenosis is low

## The carotid artery is very forgiving



Baseline



.014" filter wire and two .014" coronary wires

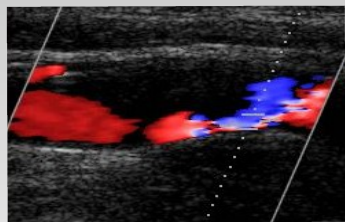
Final Result

# What we assume

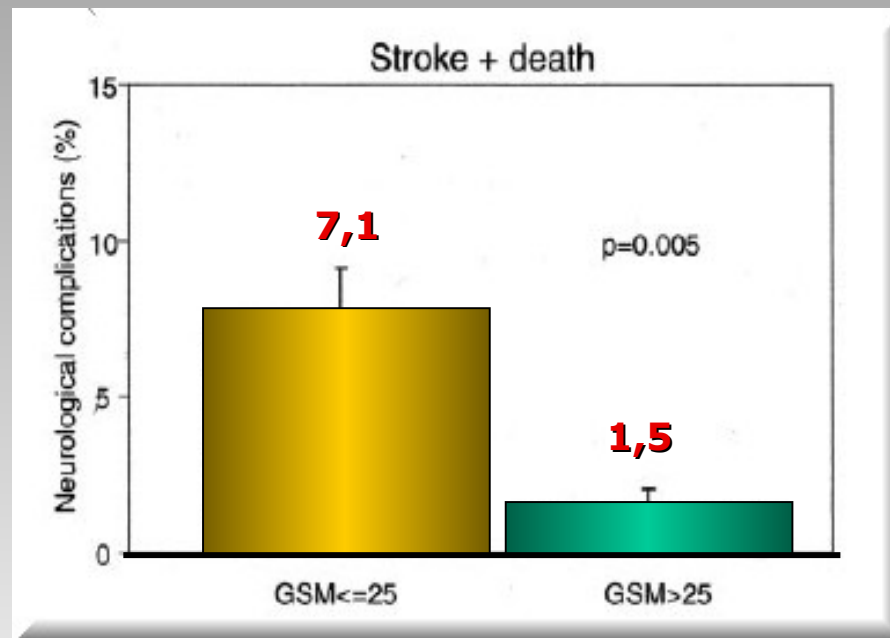
- **Lesion coverage may matter**
- **Plaque prolaps may be harmful**
- **Some stents may be more suitable for 'dangerous' lesions**

# Carotid Plaque Echolucency Increases the Risk of Stroke in Carotid Stenting

- Multivariate analysis revealed that **GSM** (OR, 7.11;  $P=0.002$ ) and **rate of stenosis** (OR, 5.76;  $P=0.010$ ) are independent predictors of stroke.

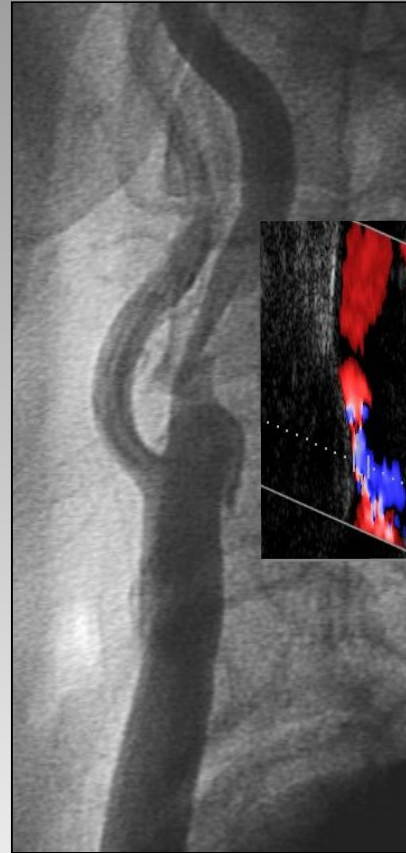


## The Imaging in Carotid Angioplasty and Risk of Stroke (ICAROS) Study



**418 cases of CAS collected from 11 international centers.**

# Lesion Coverage & Scaffolding



Mesh Wire

Nitinol

# Lesion coverage / Plaque prolapse

(Patient with minor stroke 12 hrs after procedure)



Baseline



Open cell  
Nitinol Stent



First Projection

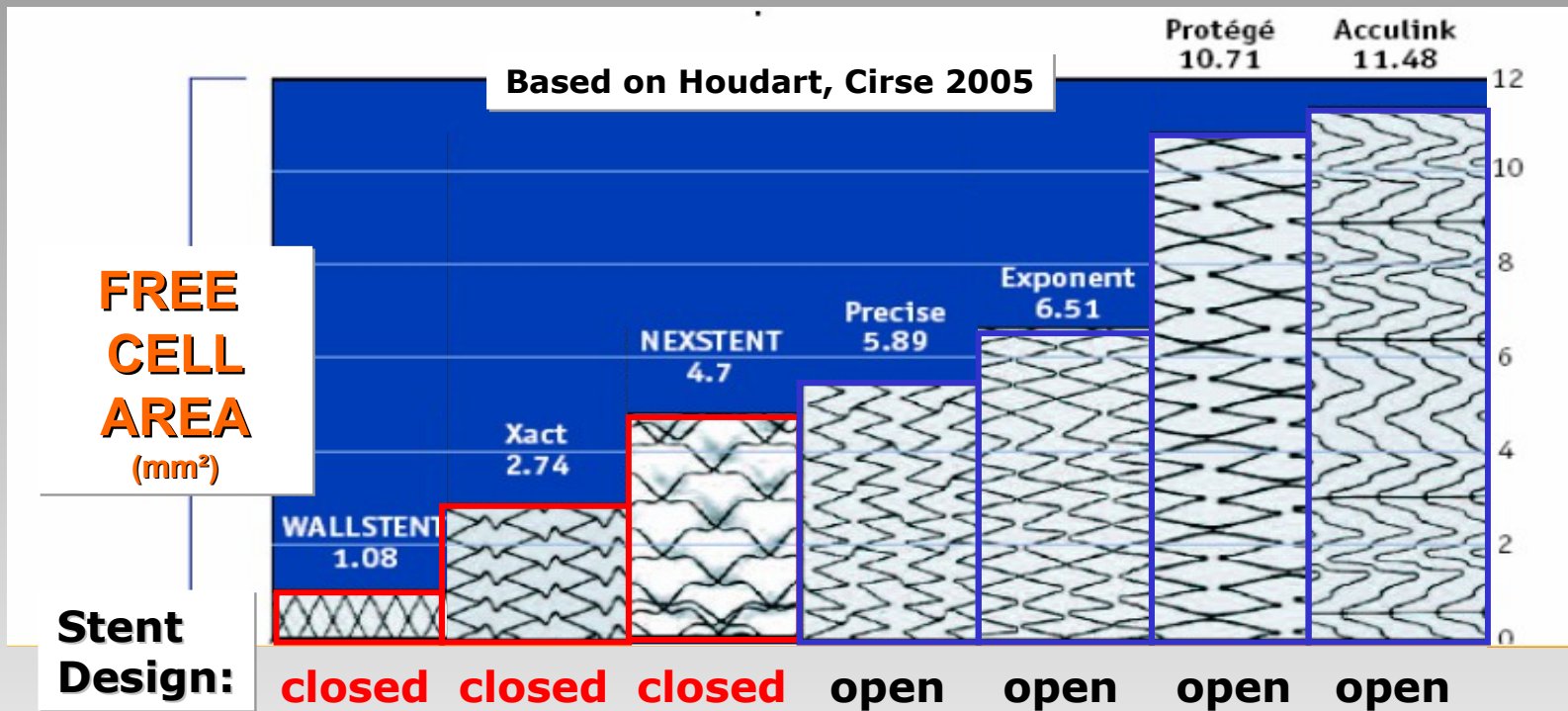


Second Projection

Up to 50% of events out of cath-lab  
And up to 30% between day 1 and day 30



# “Stent” based analysis



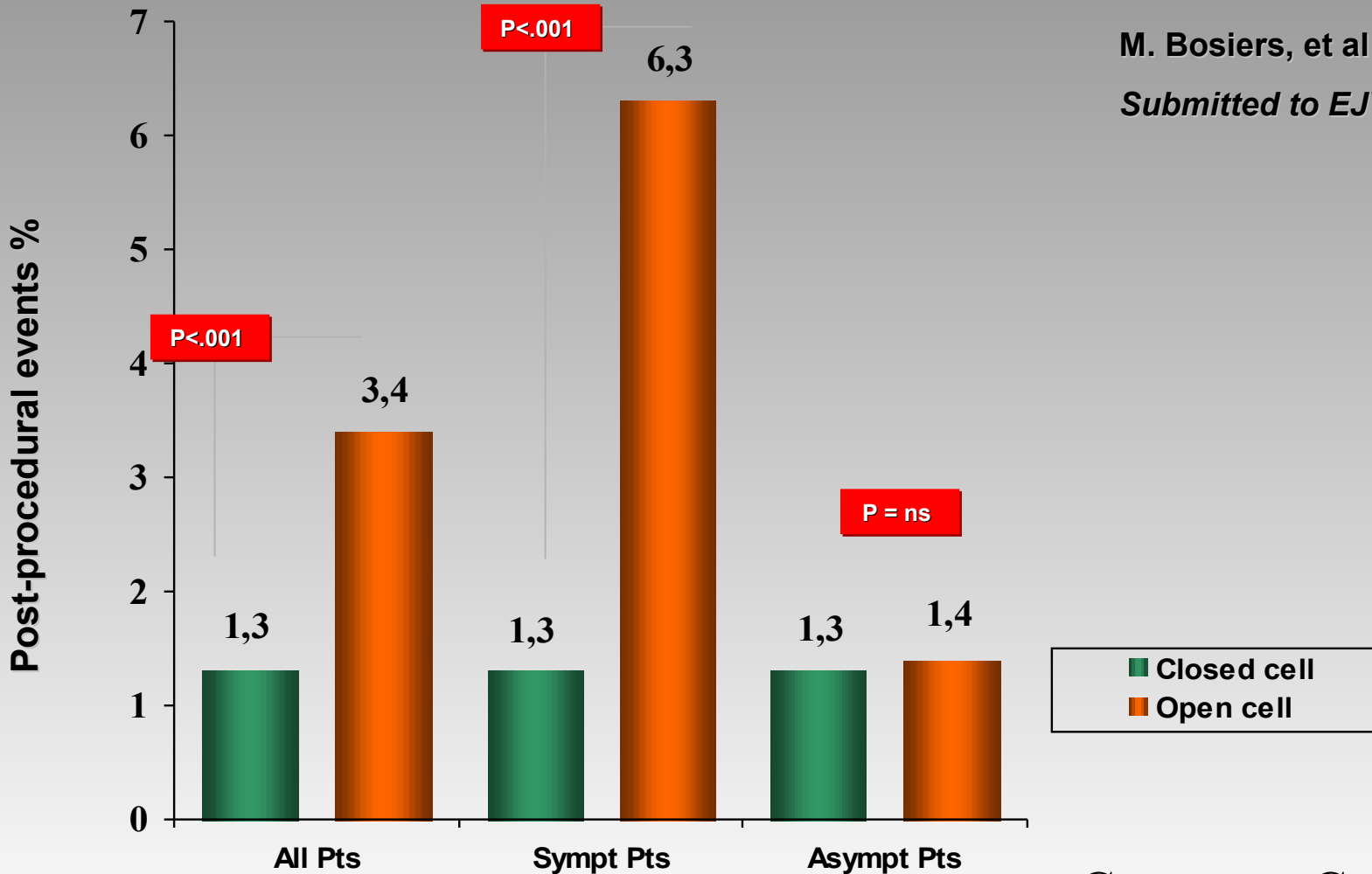
**Clinical impact of  
different stent  
designs ?**

# Comparison of post-procedural event rates by cell types

- Sample 3179 Pts -

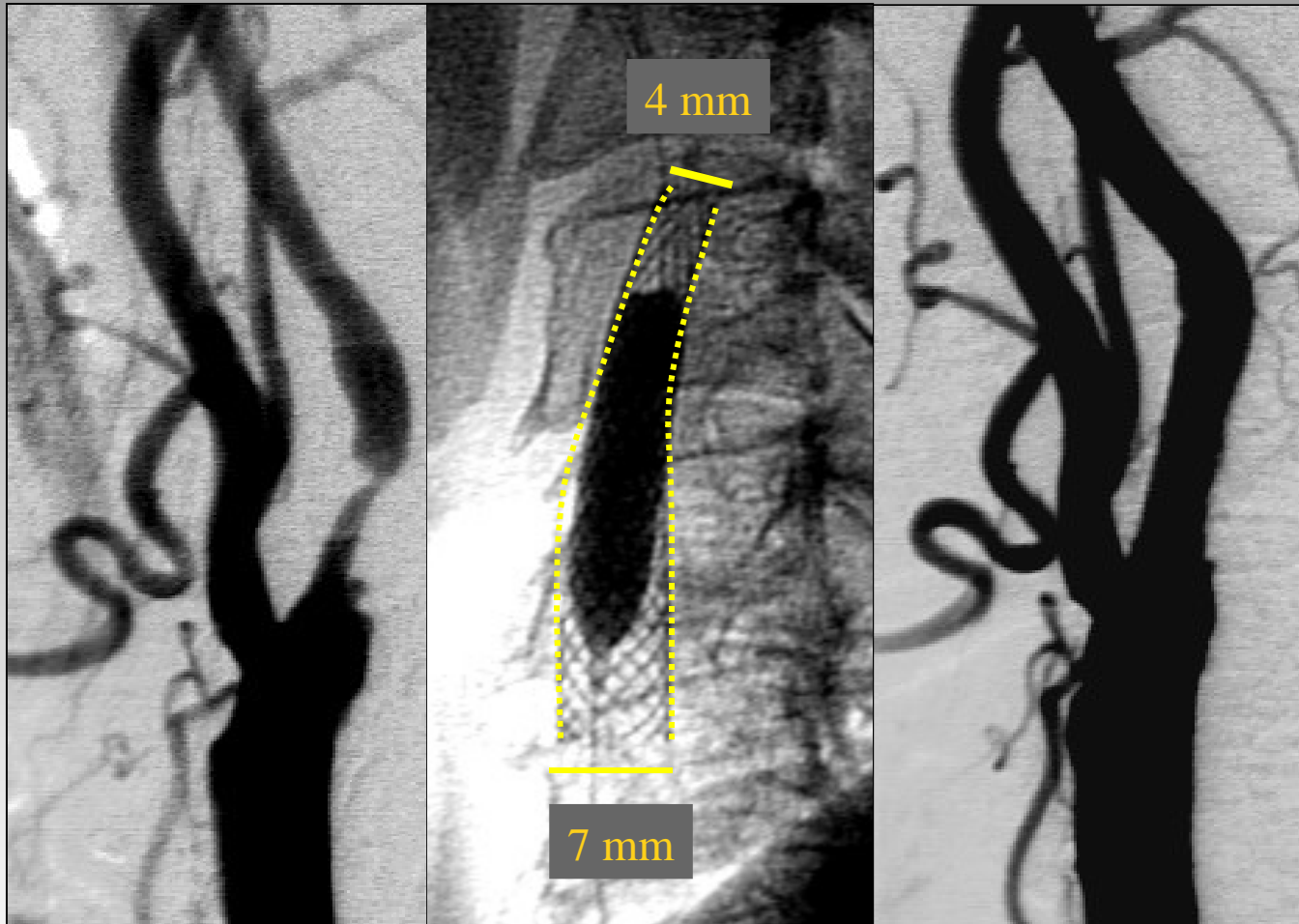
M. Bosiers, et al

Submitted to *EJVES* 2006



Courtesy: Cremonesi

# Different vessel diameters: CCA - ICA



# Conformability to different vessel diameters

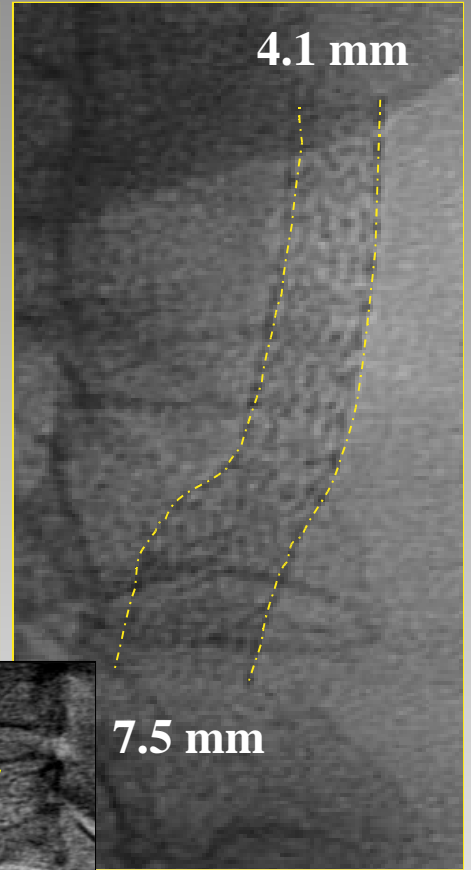
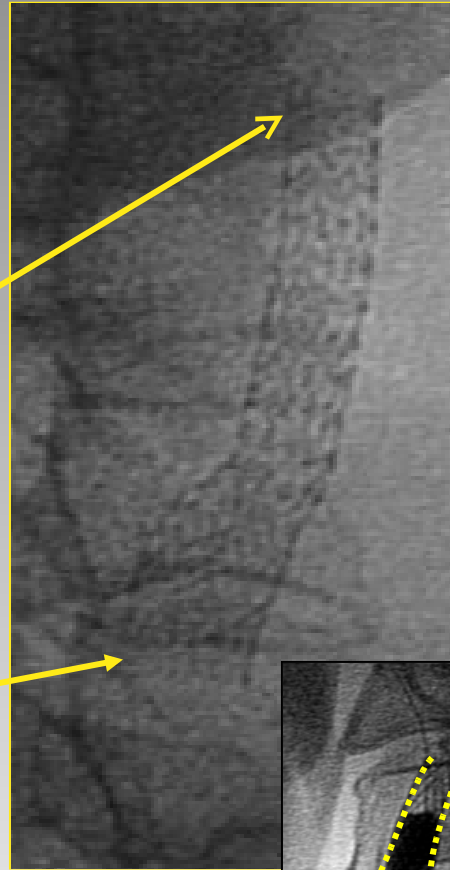


Baseline



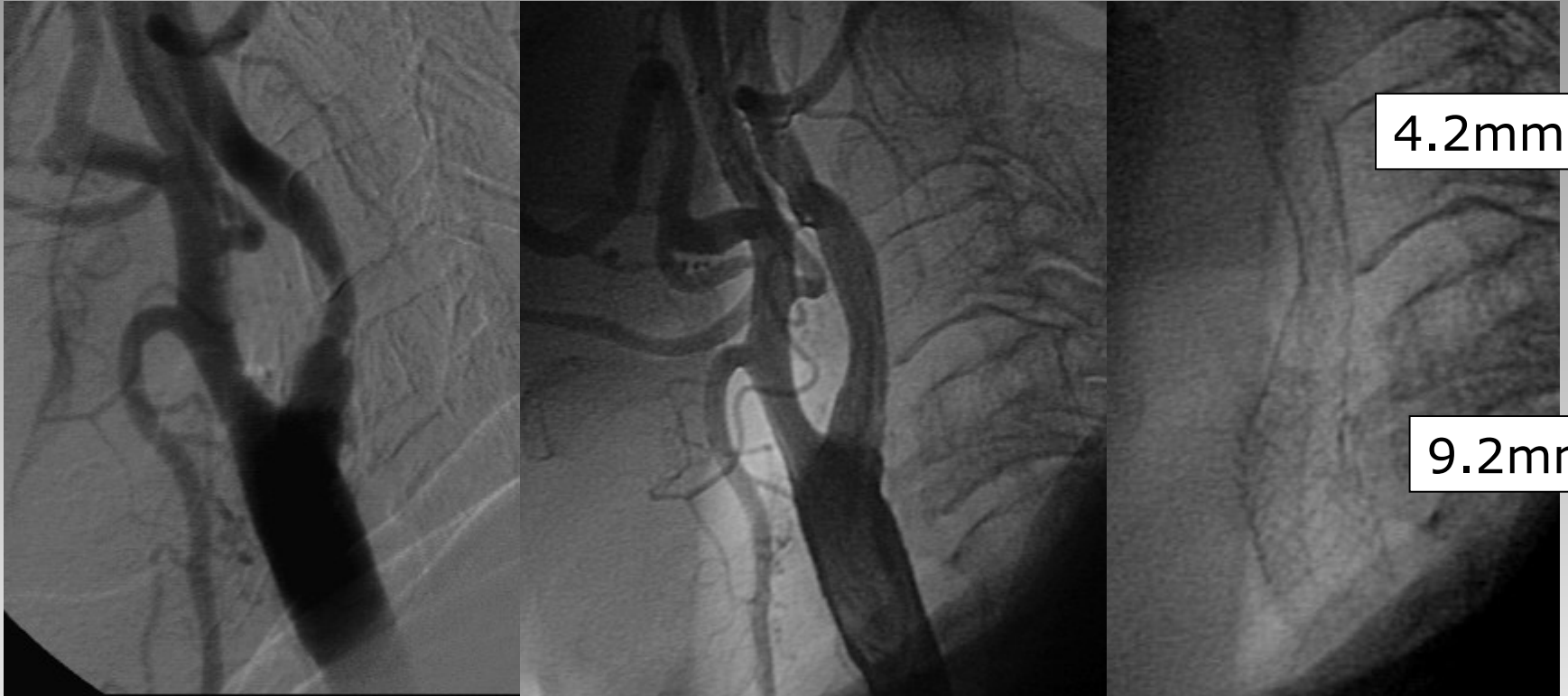
After 7.0x30mm

**Precise**



'Safe up to 50% difference in diameter'

# Tapered 7-10 x 30mm Stent





# **Available Stent Length**

# Long lesions



baseline



Carotid wallstent 7.0x40 mm  
(would approx. correspond to  
60mm long Nitinol stent)



Final Result

# Profile

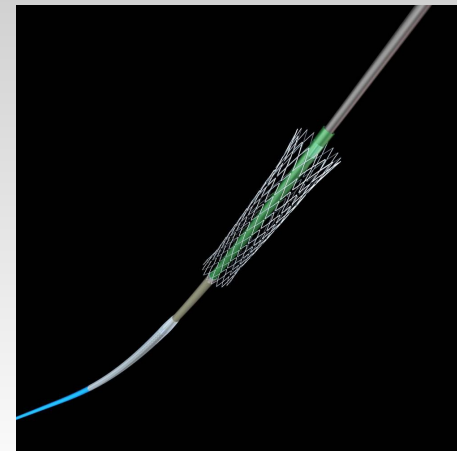
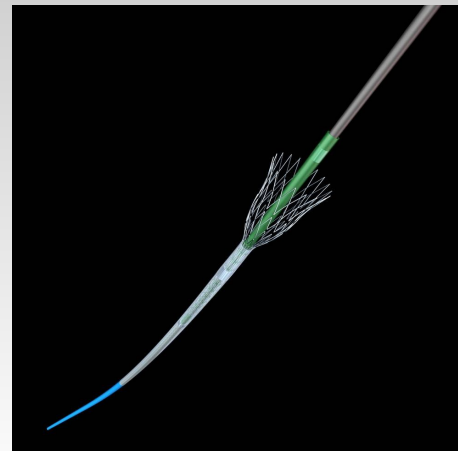
# High Grade Stenotic lesions



1. Crossing depends on:
  - stent profile and tip design
  - Lesion characteristics
2. If filter crosses, normally stent also crosses.
3. Predilation only necessary to deploy distal protection or to avoid vessel occlusion due to unexpanded stent

**FEATURE:**

**„Tipless“ inner  
catheter**



# **Patient selection**

# Patient selection:

## clinical presentation

- asymptomatic
- symptomatic/highly symptomatic/stroke
- co-morbidities

## anatomical presentation

- arch/CCA anatomy (access)
- lesion anatomy (device crossing)
- lesion morphology (ultrasound/angiography)



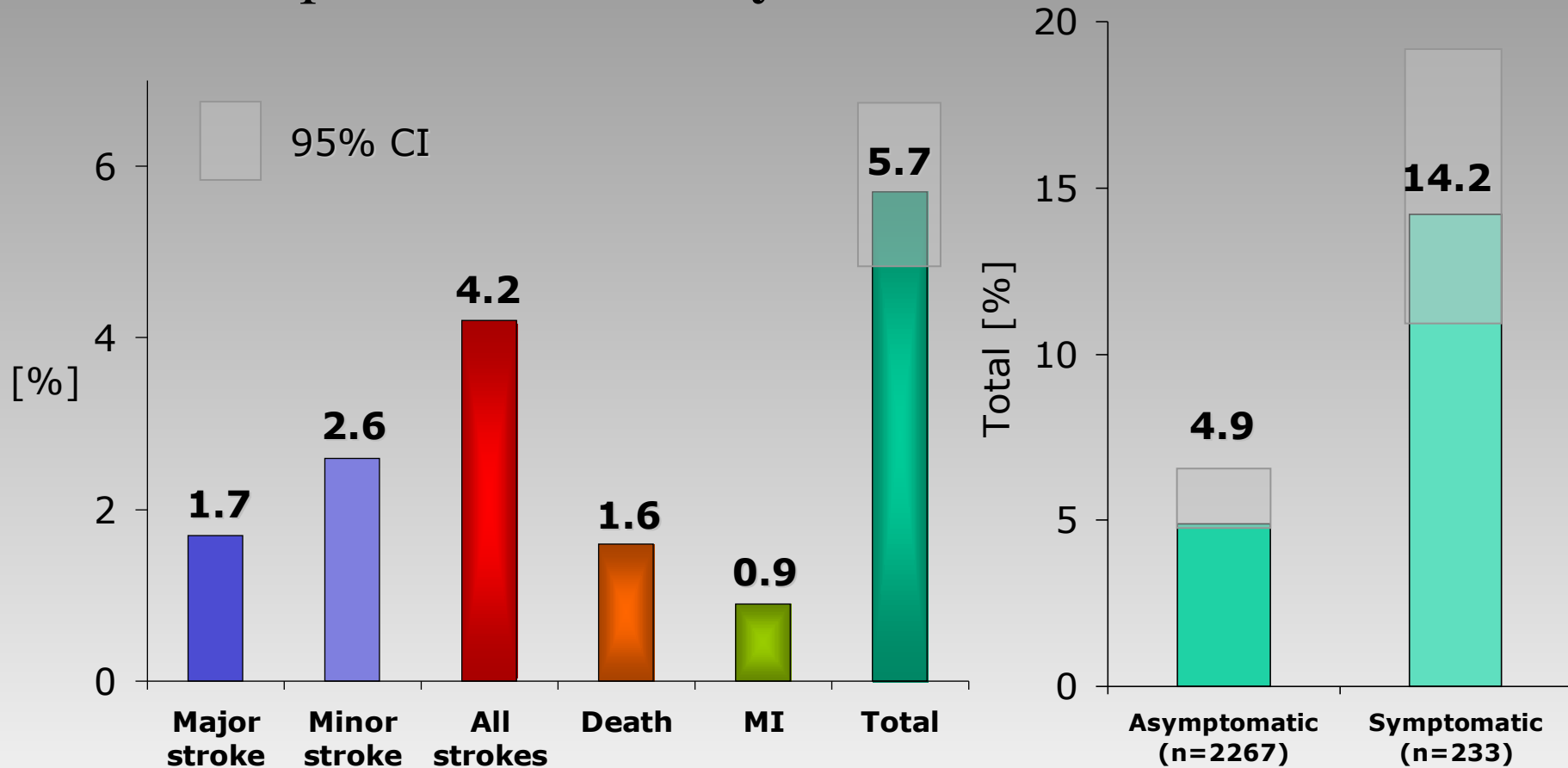
# **CAS - Registries**

## **Risk - Stratification**

# CAS Registries

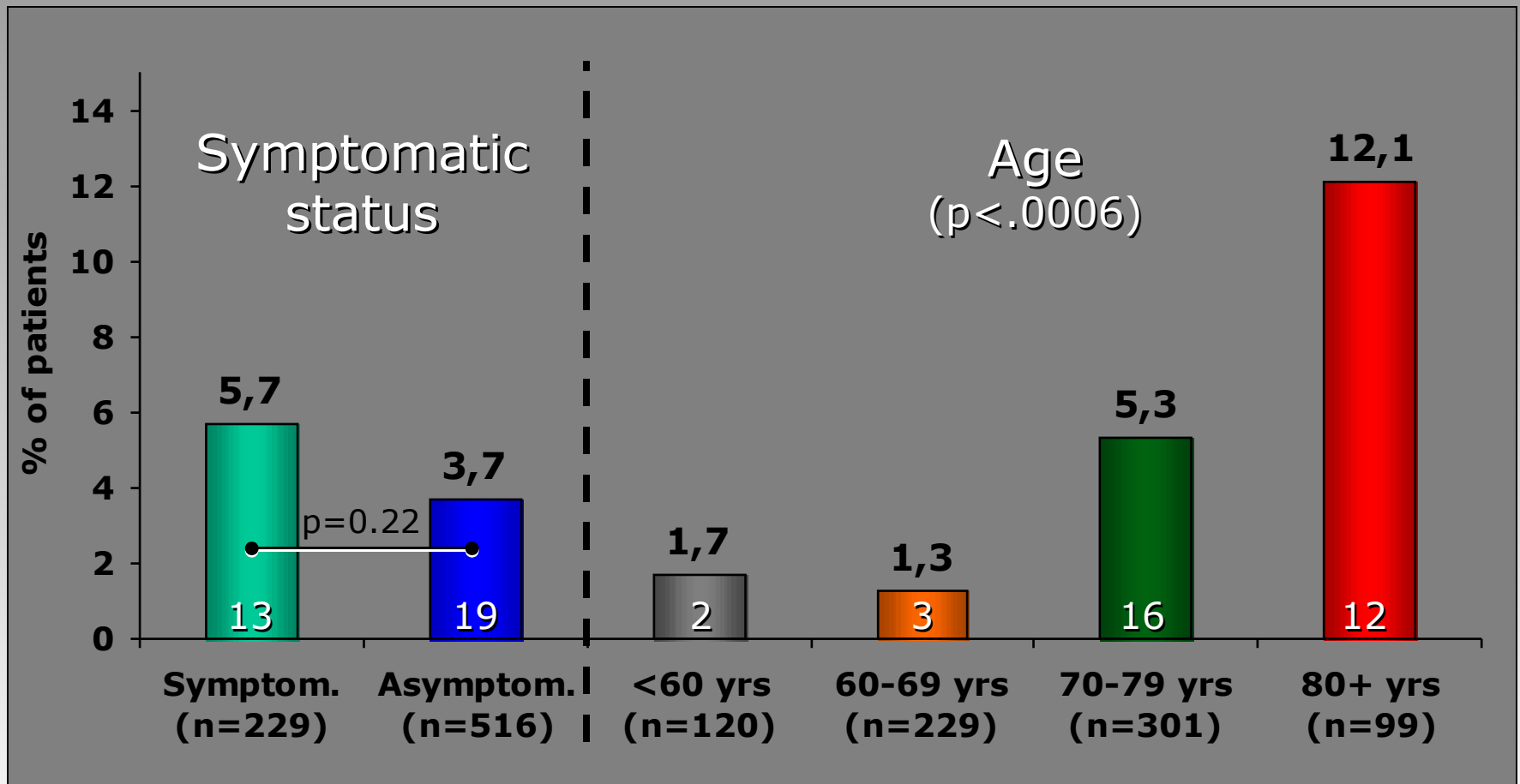
## CAPTURE (n=2500)

- Complications  $\leq 30$  days



# CREST Lead-In

- 30-day death/stroke rates of CAS stratified by symptomatic status and age

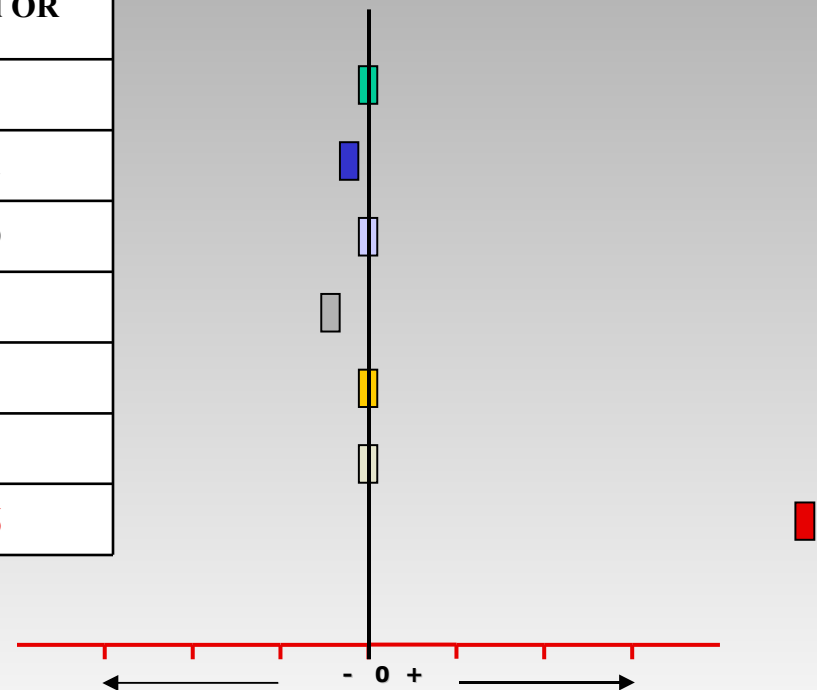


# Correlation of demographics and clinical characteristics with post-procedural events (VMCH database: 803 patients)

## 30 Day All Stroke+Death Symptomatic Pts

Clinical variables	All Stroke + Death (1,7%)		
	N°	Stroke & Death	Adjusted OR
Age < 70	331(41,3%)	1,2%	1
Age 71-80	378(47,2%)	1,9%	0,72
Age > 81	92(11,5%)	1,1%	0,99
Female	244(30,4%)	1,2%	0,51
Male	559(69,6%)	1,6%	1
PAOD	308(53,1%)	1,4%	1
CABG	191(23,8%)	2,6%	5,66

Adjusted Odds Ratio  
95% CI

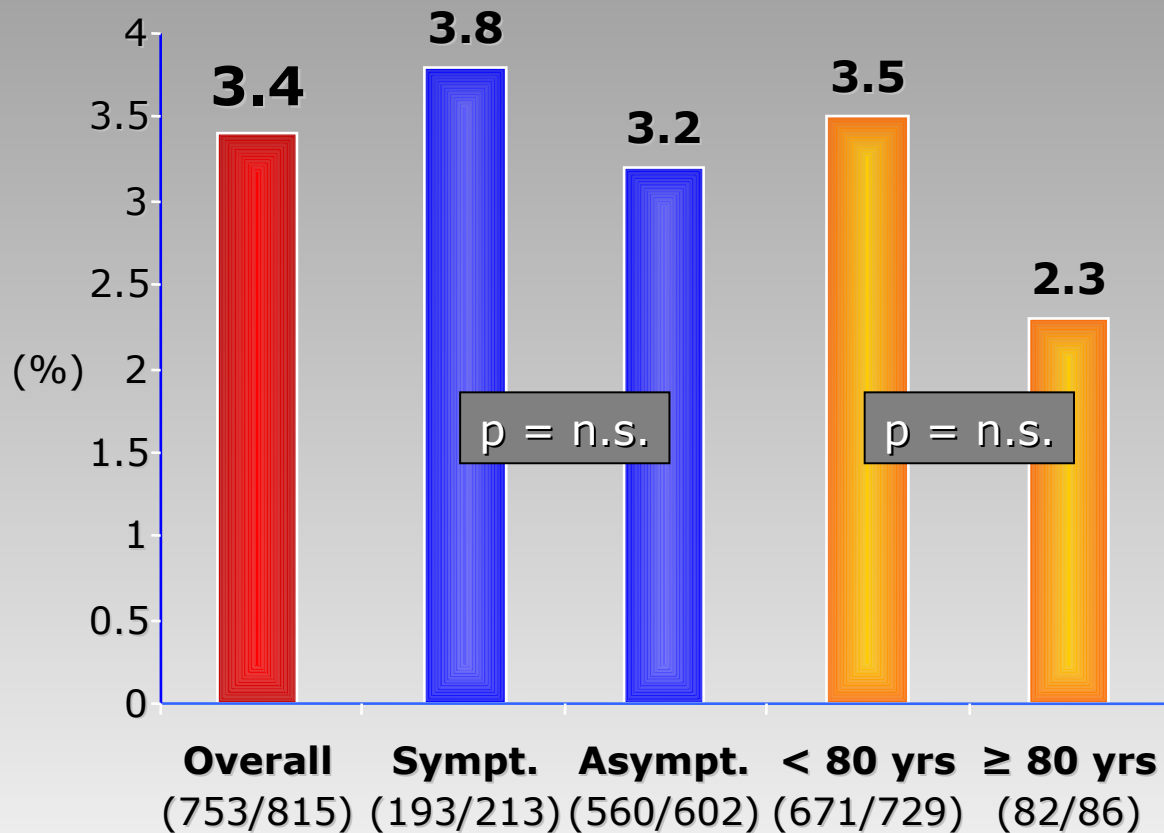


Courtesy of Alberto Cremonesi, 2006

R.Manetti, A. Berardo - VMCH EV database, 2006

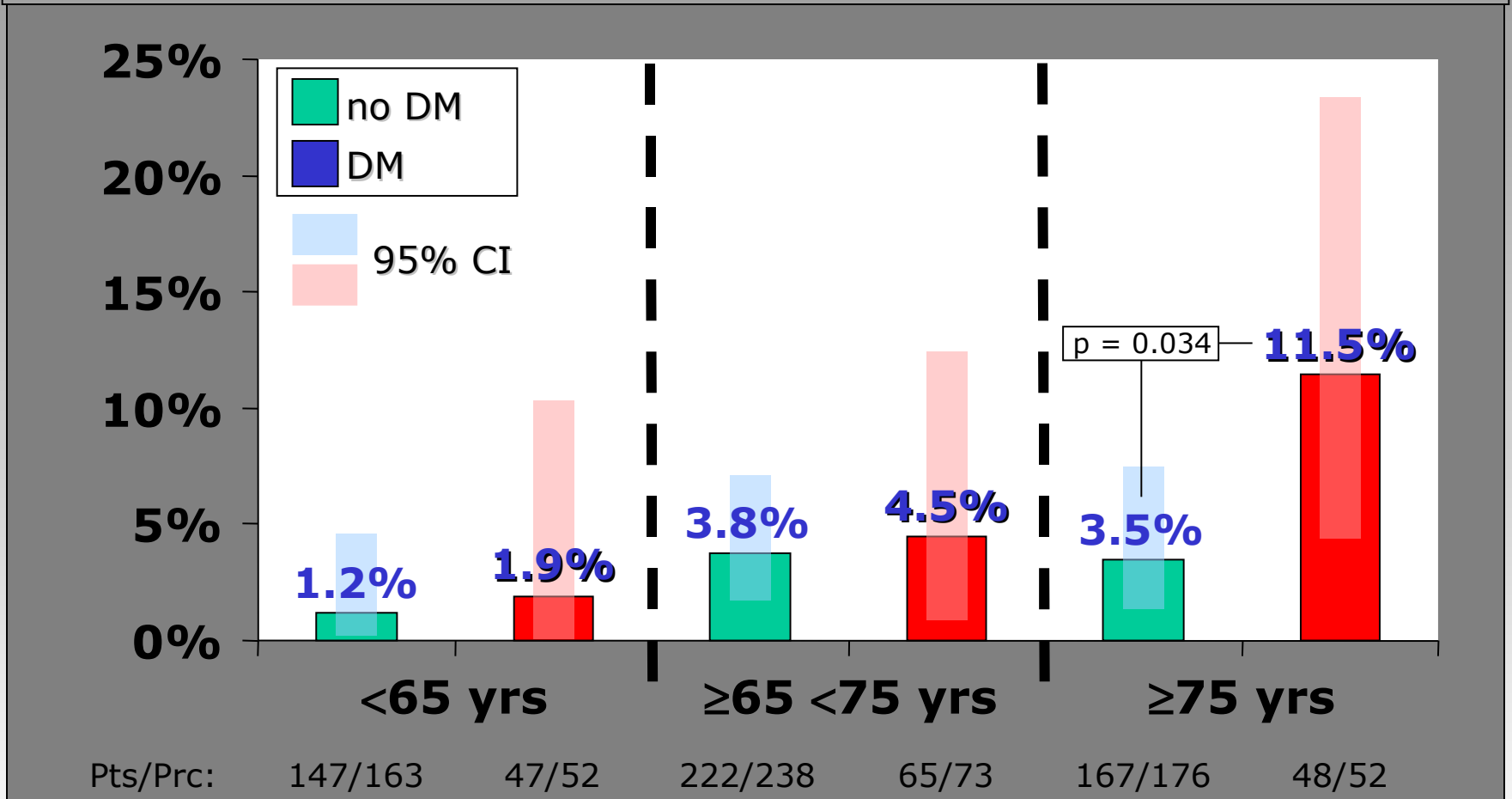
# Routine use of cerebral protection during carotid artery stenting: results of a multicenter registry of 753 patients.

- All strokes and all deaths at 30 days



# CAS in Diabetics

- Italian-German registry for neuroprotected carotid artery stenting:
  - 30-Day Stroke/Death Rates: **Impact of Age**





# Conclusions

- **Patients should be selected according to individual risk stratification based on clinical & anatomical criteria**
- **EPD & stent selection should be 'tailored' according to above criteria**

October  
19th, 2006

# **EVA 3S Trial**

**NEnglJM 2006;355:1660-71**

**CEA vs CAS**

**symptomatic patients**

**872pts planned - 527pts enrolled**

**30-day death-stroke rate**

**CEA 3.9%**

**CAS 9.6%**

**92% with protection**

**Required Interventions: 12 CAS or 30 subclavians + 5 CAS**

**Required Operatons: 25 during last year**

**Or we get better or we have to stop**

# How to get better?

- **Training**
- **Experience**
- **Patient selection**
- **Device selection**