Differentiating Between Embolic Protection Choices in CAS

Max Amor, MD

Clinic Louis Pasteur

Essey les Nancy , France

max-amor@wanadoo.fr

Disclosure Statement of Financial Interest

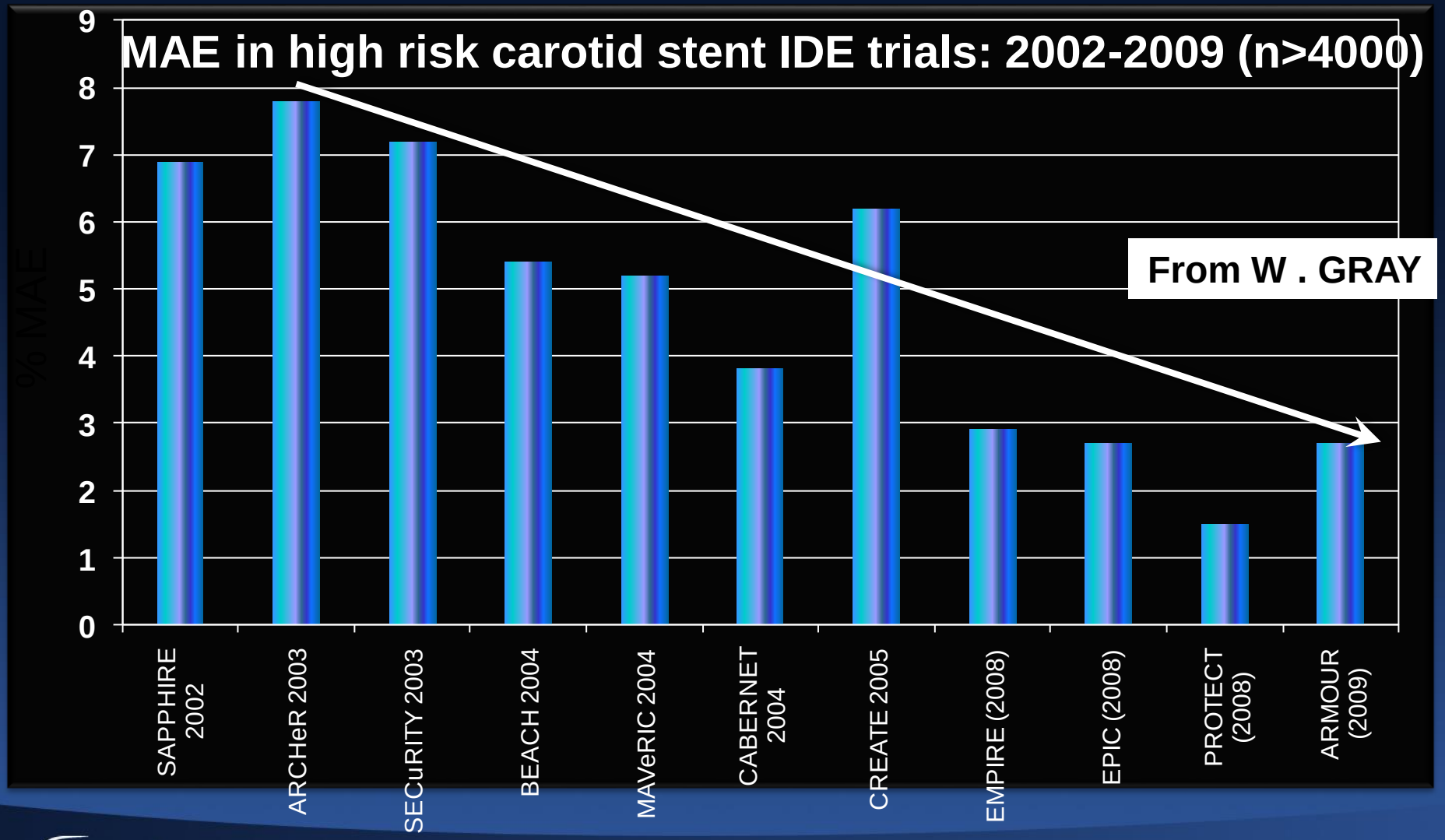
I, Max Amor M.D **DO NOT** have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.


Good indications
Good Learning
Meticulous Technique
Good selection of stent

11 Systems of protection

- 7 Filters:
  - Angioguard (J&J)
  - Accunet (Abbott)
  - Easy Filterwire(BSC)
  - Emboshield(Abbott)
  - Interceptor (Medtronic)
  - Spider Rx(EV3)
  - Fibernet(Lumen-Invatec)
- 2 Flow Reversal
  - Moma Device (Invatec)
  - Gore Neuro-protecting system (Gore)
- 2 Occlusive Balloon
  - Percusurge (Medtronic)
  - Mini-invasys Theron double balloon(Mini-Invasys)

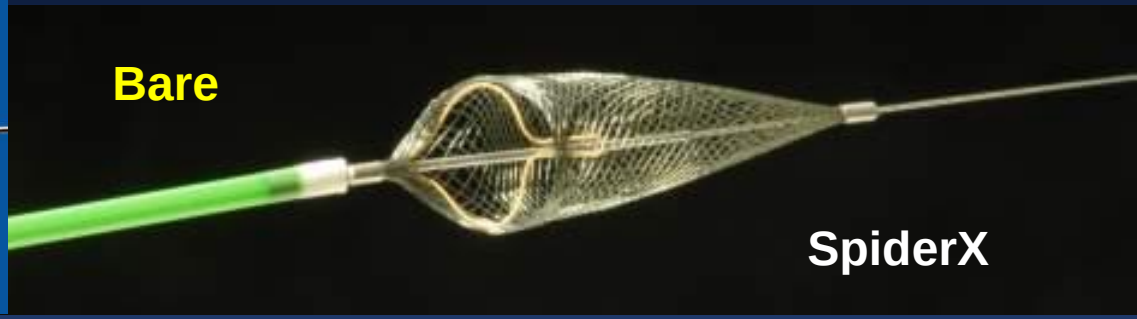
EMBOLIC P.D :Improvement of results over time
11 US FDA approval trials with improving outcomes (all approved as safe and effective) /Registries



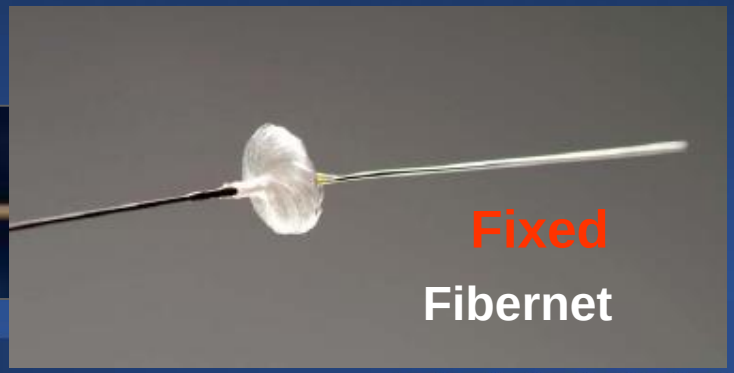
Columbia University Medical Center

Reported 30 day stroke rates. Study parameters and definition of stroke rate may vary per clinical trial.

Main filters in 2010



Medtronic
Interceptor



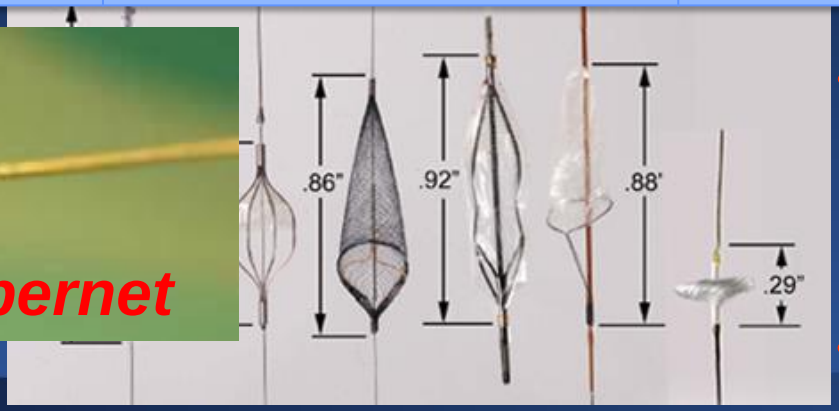
Advantages &Disadvantages of filters

- Advantages
  - Plethora of devices
  - Easiest to use: Fast & Simple
  - Cheapest EPD
  - Preservation of flow
  - Visualization all along the procedure
  - Usable if ipsilateral external carotid or contralateral internal carotid occluded

- Disadvantages
  - Incomplete & unsatisfactory protection
  - Stop flow complication difficult to understand and manage
  - Local complications: spasm, dissection

Filters Characteristics

DEVICE	Vessel Size (mm)	Crossing Profile (Inches/French)
FiberNet	3.5 mm – 7.0 mm	2.4 – 2.9 F
Angioguard XP	4.5 – 7.5 mm	3.2 - 3.9 F
FilterWire EZ	3.5 – 5.5 mm	3.2 F
Emboshield Pro	2.5 – 7.0 mm	2.8 – 3.2 F
RX AccuNet	3.25 – 5.0 mm	3.5 – 3.7 F
SpiderFX	3.0 – 7.0 mm	3.2 F
GuardWire	3.0 – 5.5 mm	2.8 F
Emboshield Nav 6	2.5 – 7.0 mm	3.2F



Determine the Landing zone

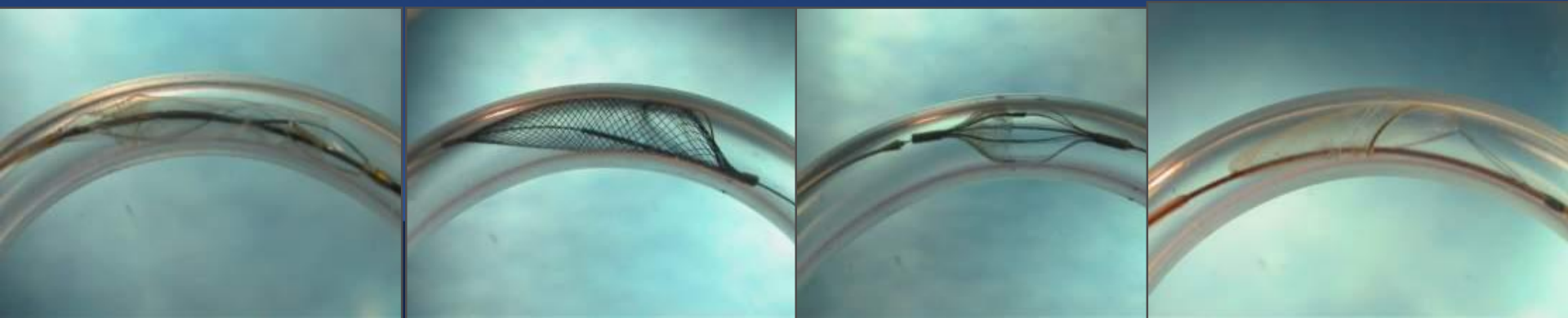
Acc Ang Spi Emb EZ Fiber

Product Attribute Differences

Features	Emboshield NAV6	FilterWire EZ	Accunet 3:1
Crossing Profile	2.8/3.2 F	3.2 F	3.5-3.7F
Radiopacity	Circumferential	Circumferential	4 Radiopaque Markers
Pore Size	120 µM	110 µM	115 µM average
Filter length	19/22.5 mm	34 mm	44 mm
Vessel Size Range	2.5-4.8 mm/4.0-7.0 mm	3.5-5.5 mm	3.25-7.0mm
Filter Sizes Offered	2	1	4
Filtration membrane design & materials	Nylon	Polyurethane	Polyurethane
Non-thrombogenic Coating	Yes	No	Yes
Capture Efficiency	Equivalent	Equivalent	Equivalent
Wire type	3 BareWires to choose anatomy specific	Coronary Wire?	Balanced Heavy Weight
BareWire or Fixed Wire	BareWire	Fixed Wire	Fixed Wire

Filters: main differentiating points

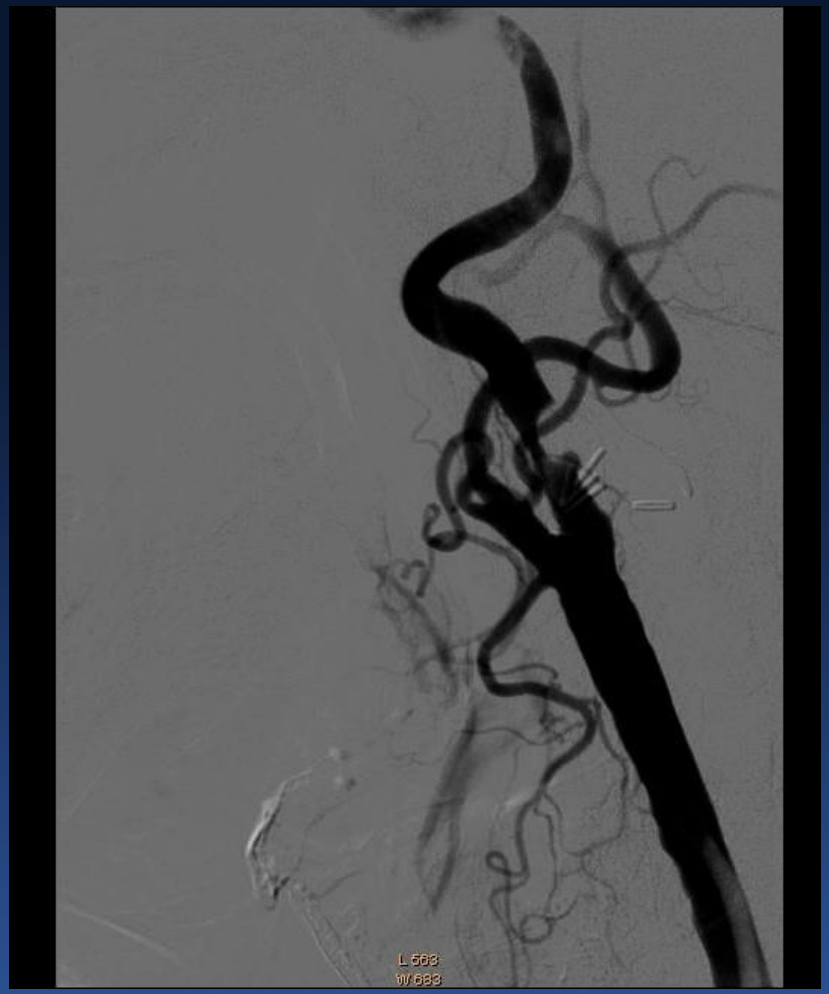
- Crossing profile & length of the landing zone
- Bare or Fixed wires► maneuverability
- One or multiple size ►vessel size range
- Capture efficiency in straight and curved segments
- Retrieval catheter (size ,aspiration, shapeable…)
- Stent Snagging

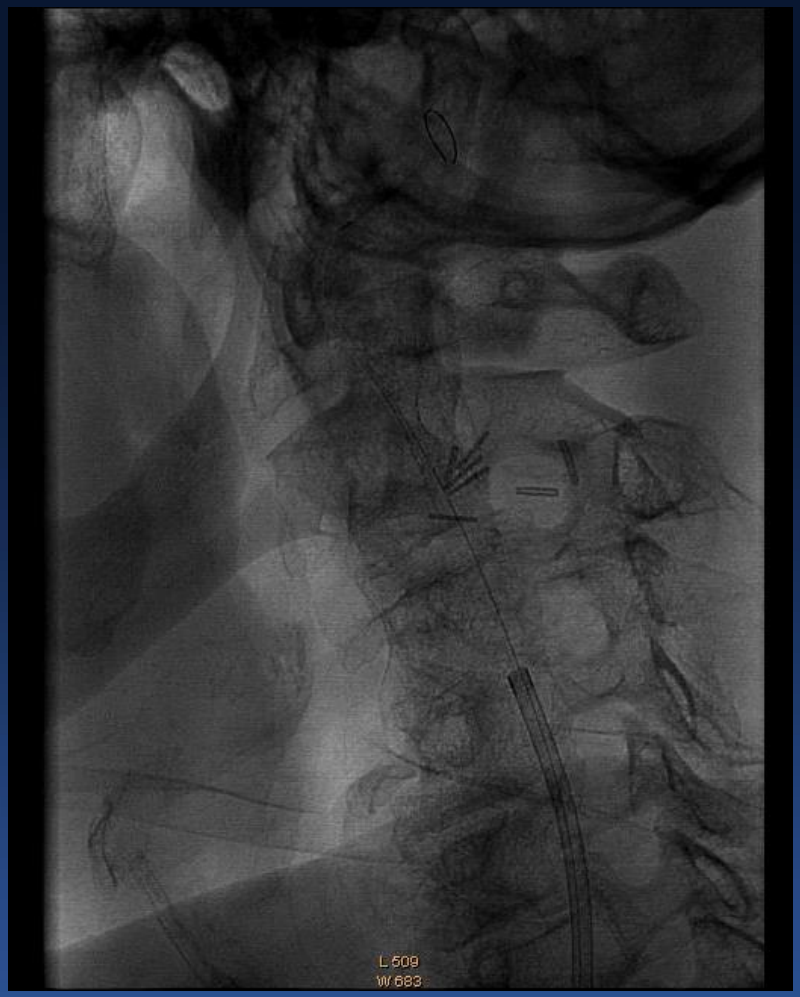


Geometric Factors for selecting filters

	EZ	Accunet	Nav 6	SPIDER	Fibernet
ø≥ 6mm	no	yes	yes	yes	yes
Tight stenosis	++	++	+++	++±	+
Small landing zone	+	+	++	+	+++
Angulations	++	++	++±	+++	+
Curved landing	+	++	++	+	+++
Complex crossing	+	+	++	+++	+

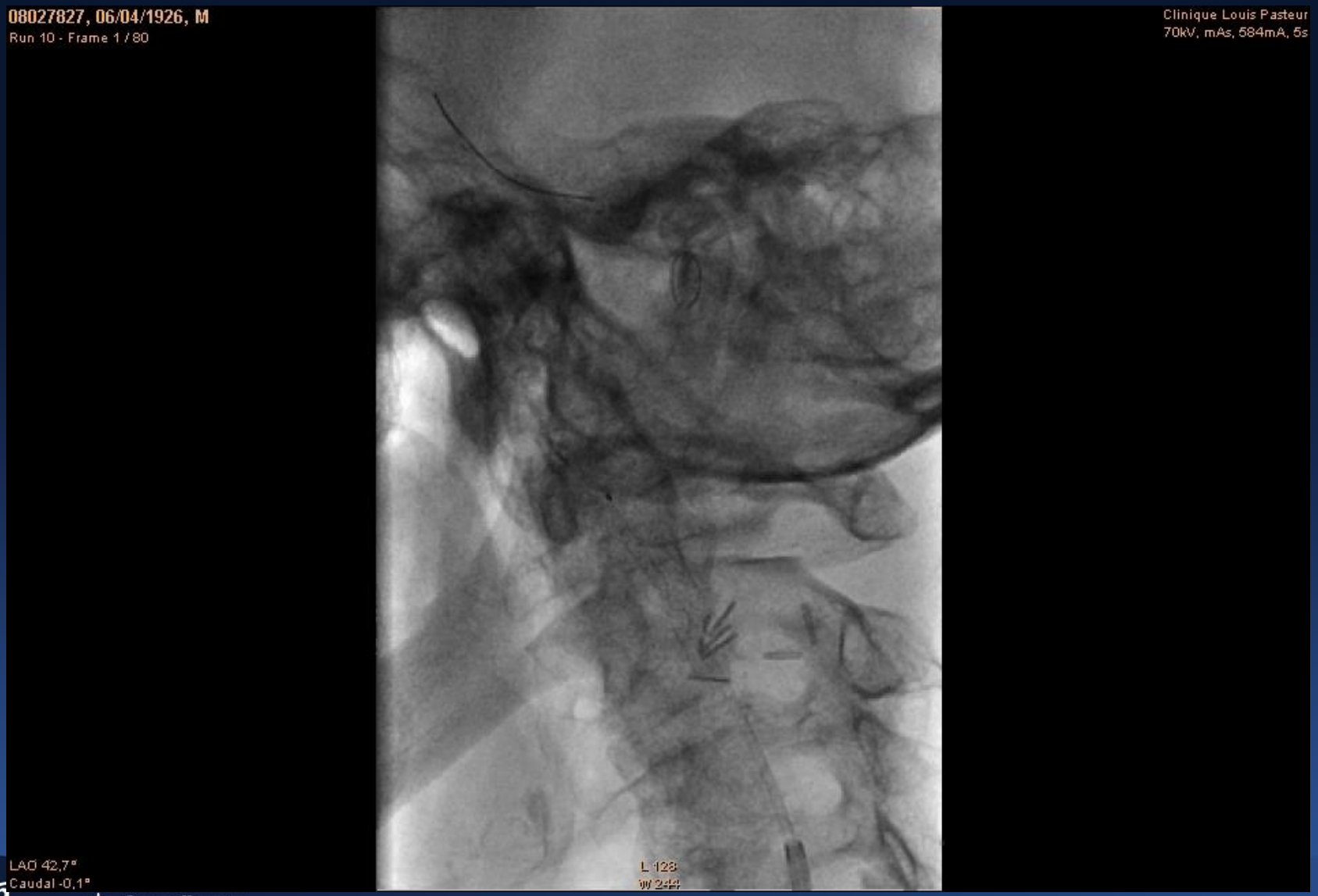
Complications of filters



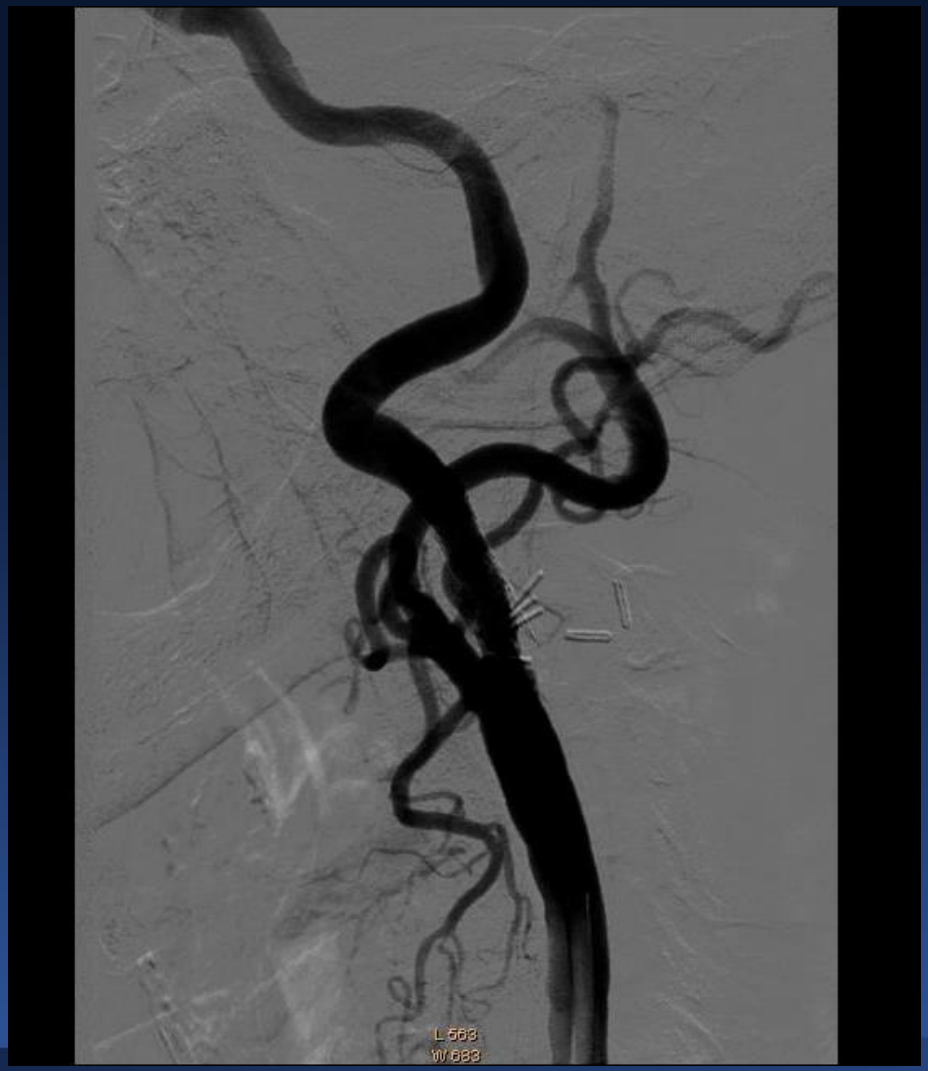


Stop Flow after post dilatation

Export™ catheter for aspiration



Successful retrieval of EPD
Uneventful 30 day period



Access selection for CAS

Femoral access → Direct Puncture

Possible

Impossible

Common Femoral

Radial Art.

Brachial Art.

Normal

Pathologic

6FShuttle

6F Shuttle
Guiding 7F

Guiding 8 or 7 F if filter

6F Shuttle

8F Introducer if flow Reversal

9F Introducer if flow reversal

Closing
Angioseal 8F
Perclose

Manual
Compression

Starclose
For Closing

Clinique Louis Pasteur

Institut Lorrain du Coeur et des Vaisseaux ILCV

Selection according to the presence of symptoms or high risk factors for CAS (Hypo-echogenic, Ulceration)

Asymptomatic Low Risk

Filter

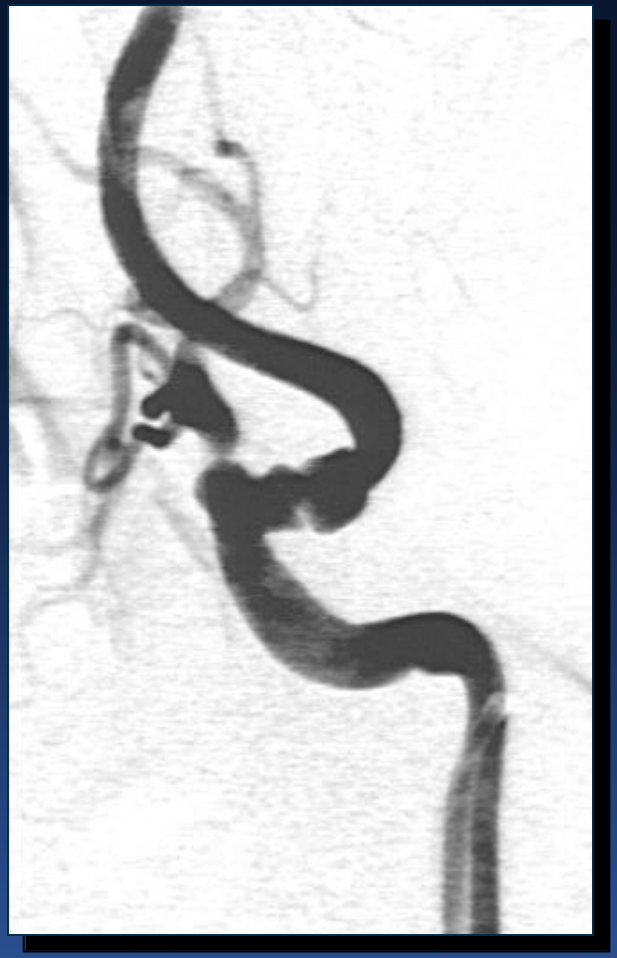
- Distal IC
  - ≤5mm : Easy Boston, Spider Rx EV3
  - >5mm: Emboshield, Accunet ,Angioguard
- Crossing
  - Easy : Easy Boston
  - Difficult: Emboshield Abbott
  - Very Difficult: Spider RX
  - Failure : Surgery or ►

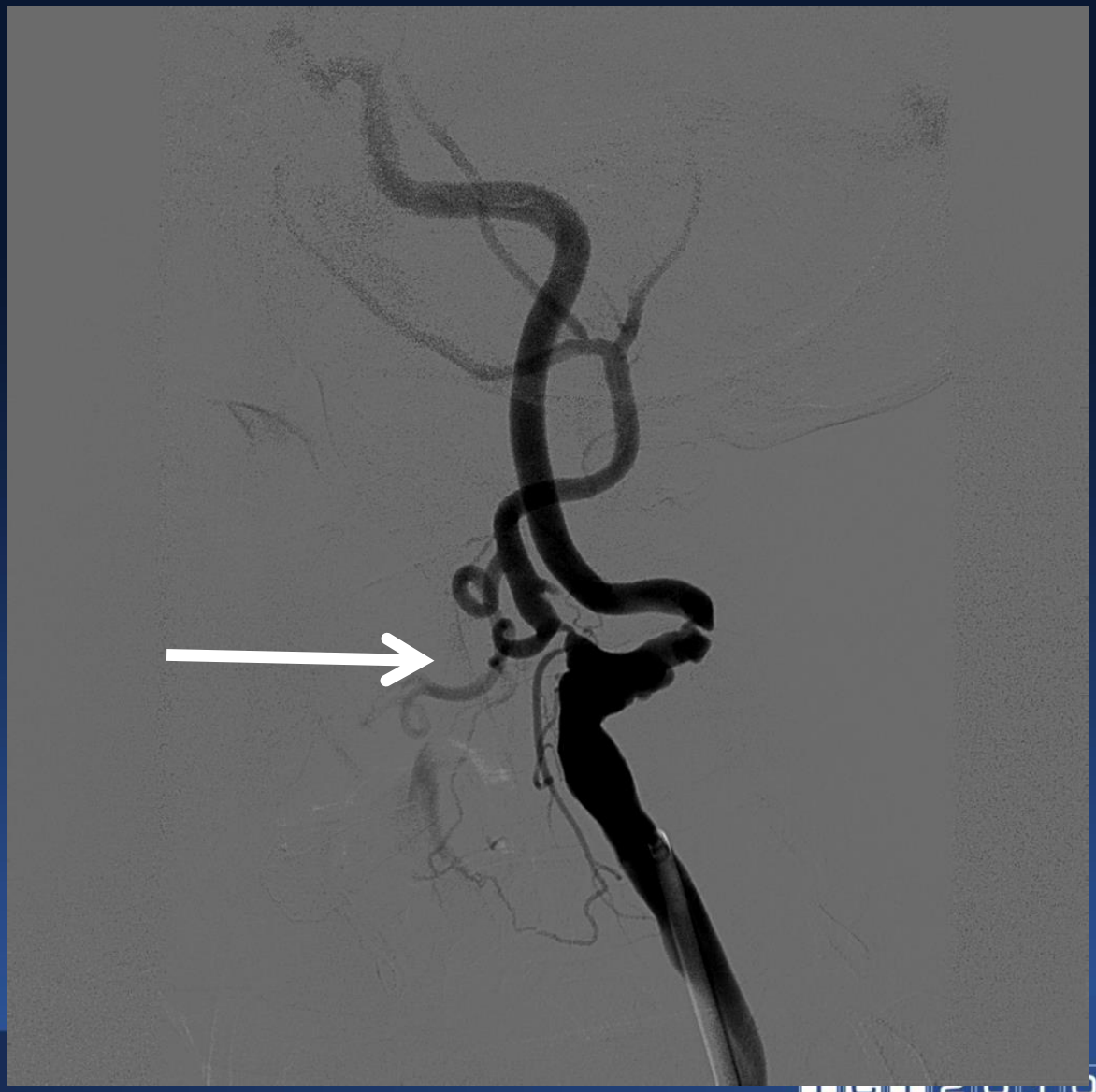
Symptomatic High Risk Octogenarians ?

Flow Reversal

Filter Fibernet Invatec

TORTUOSITIES: 2 exemples of impossible filter placement

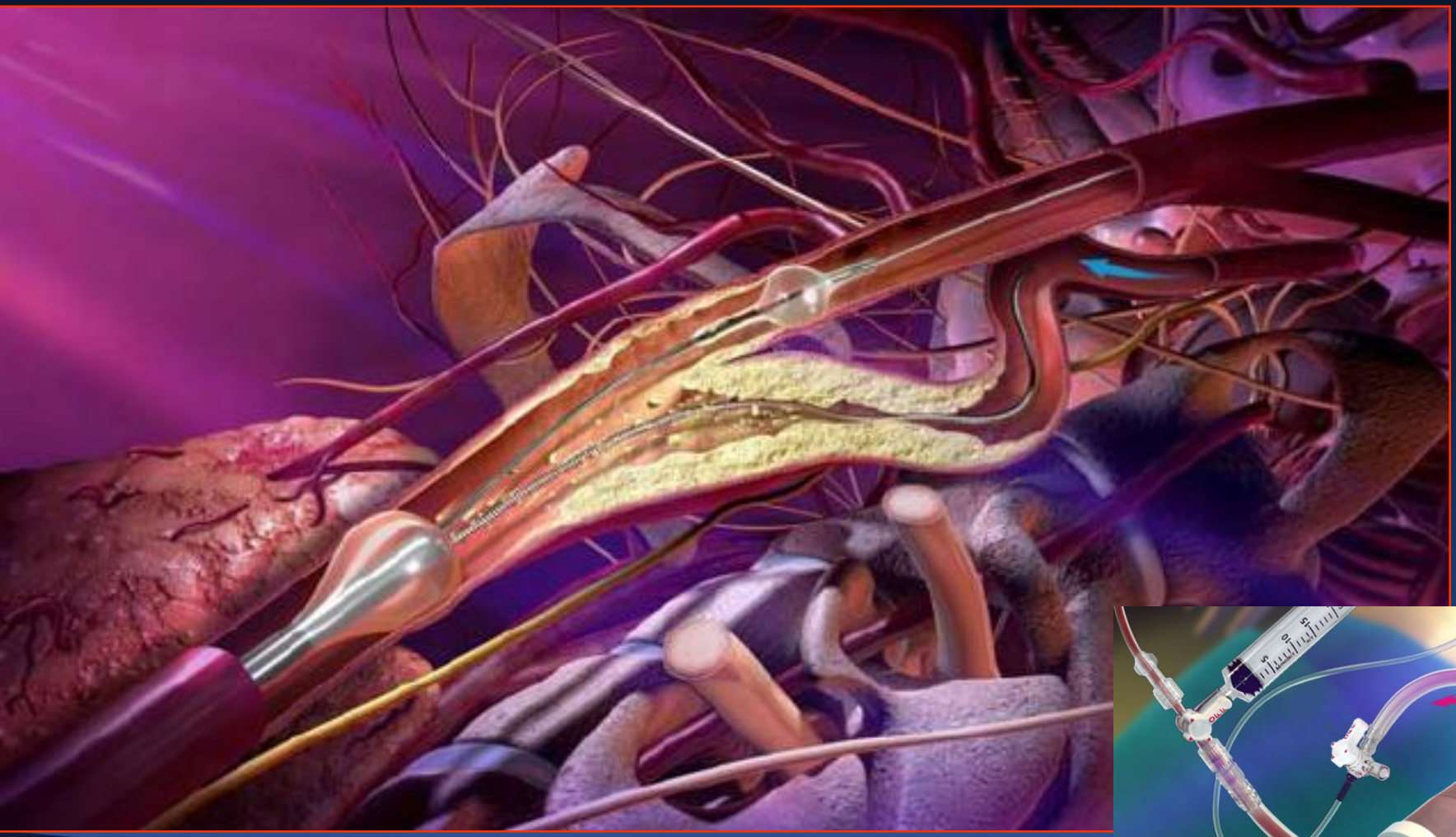


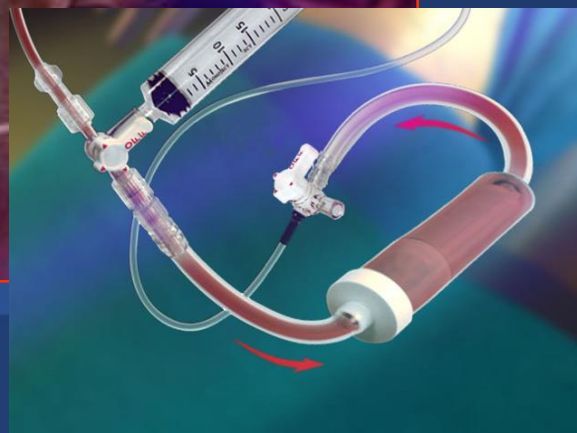


Systems of protection

- **Numerous Filters:**
  - **Angioguard (J&J)**
  - **Accunet (Abbott)**
  - **Easy Filterwire(BSC)**
  - **Emboshield(Abbott)**
  - **Spider Rx(EV3)**
  - **Fibernet(Lumen-Invatec)**
- **Flow Reversal**
  - **Moma Device (Invatec)**
  - **Gore Neuro-protecting system (Gore)**
- **Occlusive Balloon**
  - **Percusurge (Medtronic)**
  - **Mini-invasys Theron double balloon(Mini-Invasys)**

GORE Neuro-Protection System





CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian
The University Hospital of Columbia and Cornell

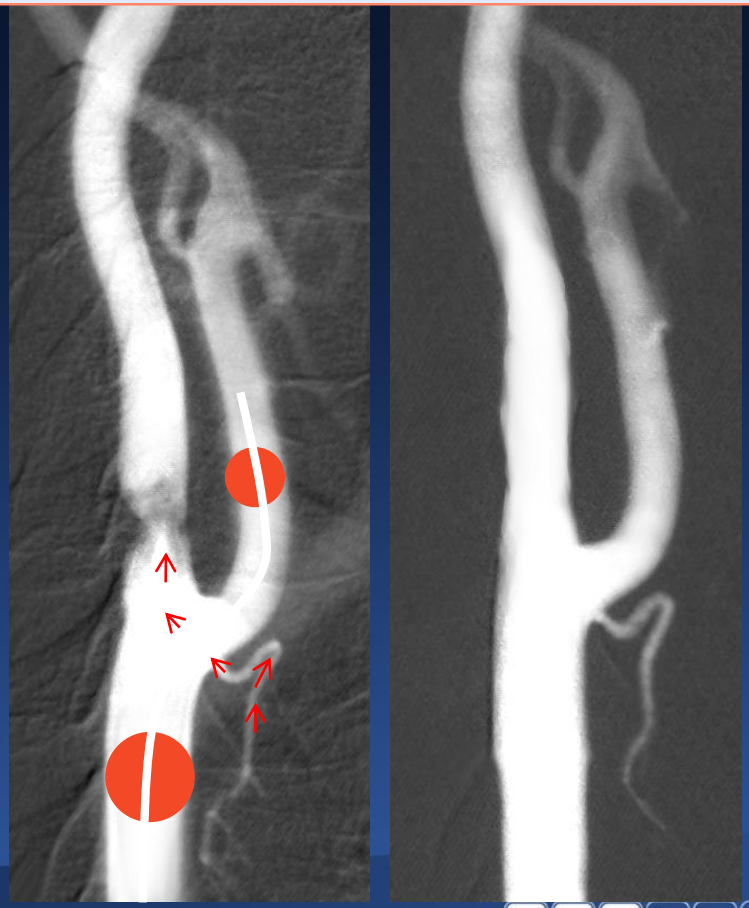
Advantages &Disadvantages of Flow reversal

- Advantages
  - Protection before crossing
  - Any Coronary Wire to cross the lesion
  - No parking space required
  - No local complication: spasm, dissection
  - Angiography possible during occlusion
  - All particles are stopped
- Disadvantages
  - Unusable if ipsilateral external carotid or contralateral internal carotid occluded
  - Unusable if diseased or difficult aortic arch

When do we *NOT* use proximal balloon protection?

arteries arising at the bifurcation

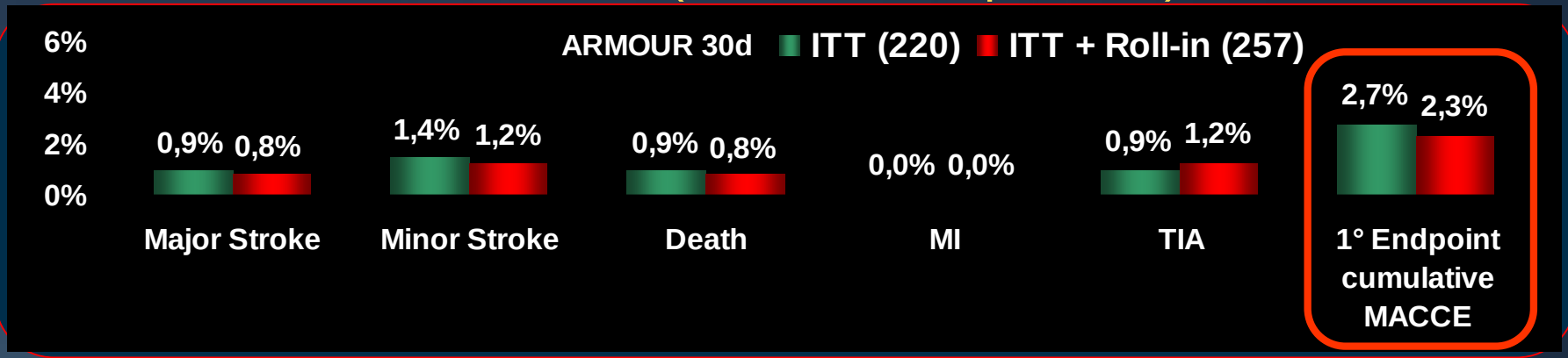
- reversed flow in the superior thyroid artery
- orthograde flow in the ICA



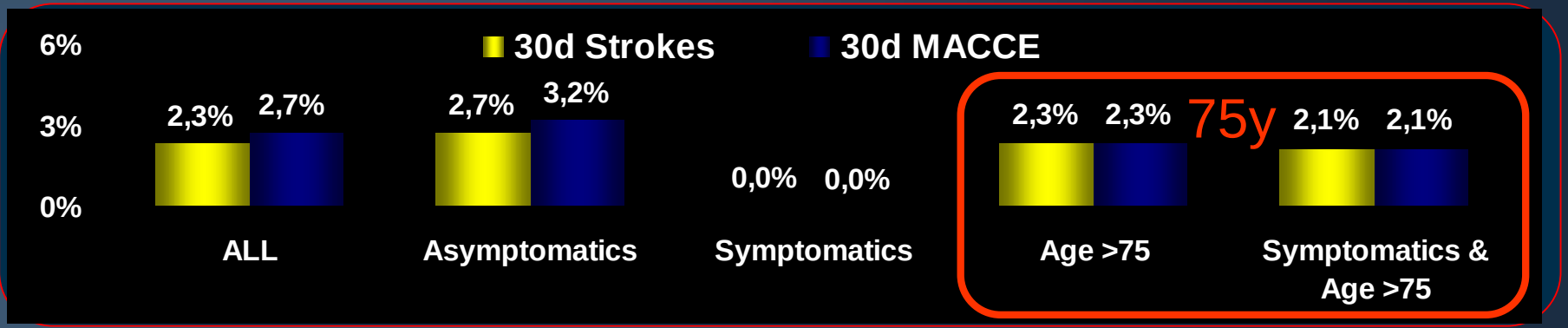
From Klaus Mathias (Meet 2010)

ARMOUR (MO.MA) results (225 Pts)

30d Results (ITT & Full Population)



30d Results by Symptoms and Age (ITT)



From W. GRAY MEET 2010

CARDIOVASCULAR RESEARCH FOUNDATION

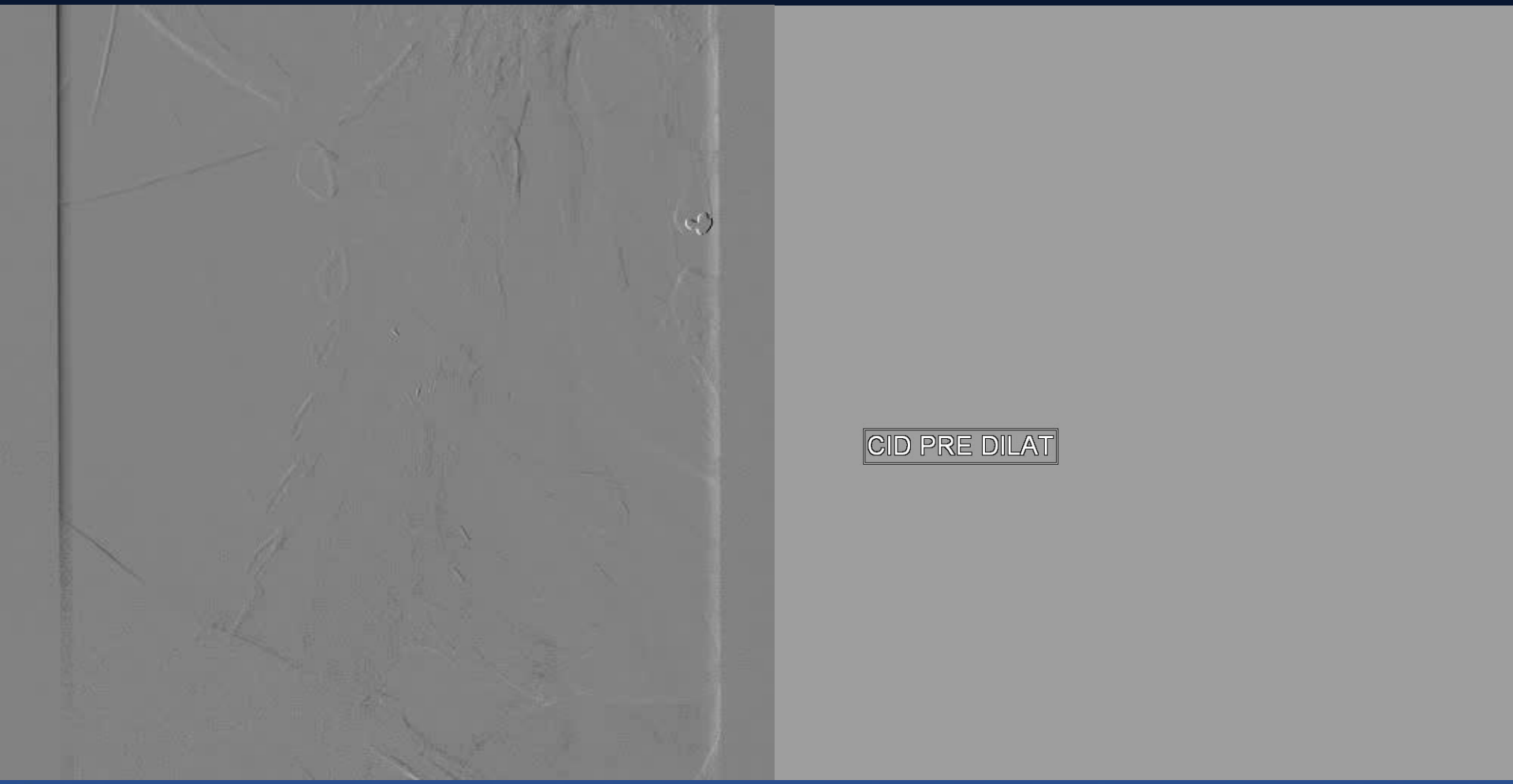
COLUMBIA UNIVERSITY MEDICAL CENTER

Carotid artery stenting in octogenarians using a proximal endovascular occlusion cerebral protection device: a multicenter registry

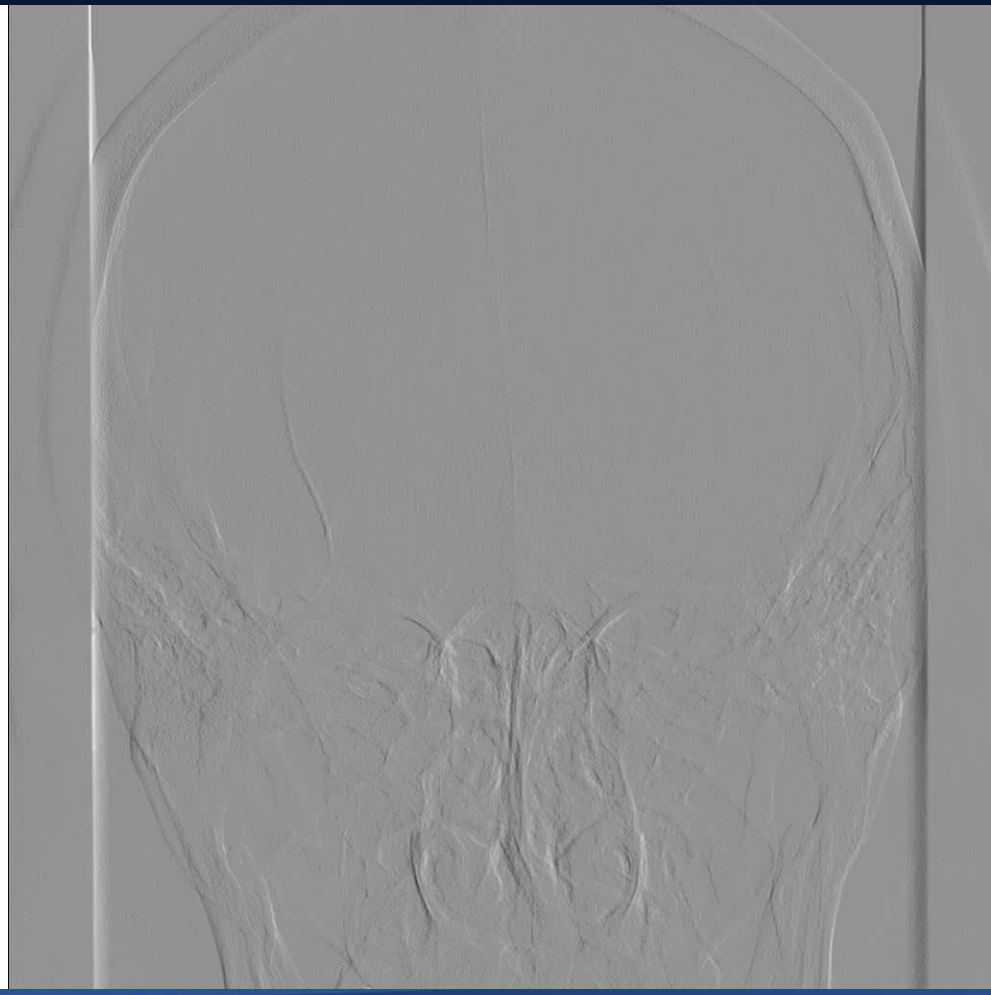
Micari A& all Catheter Cardiovasc Interv. 2010 Jul 1;76(1):9-15.

- From July 2005 to May 2009, a total of 198 octogenarians patients, in three different institutions, were included in this registry. All patients underwent CAS using proximal endovascular occlusion device (MoMa. device Invatec, Roncadelle, Italy).
- 198 octogenarians (135 men; mean age: 83.2 years) were included in the registry. 39.4% of the patients were symptomatic
- Procedural success was 100%. In-hospital complications: Two minor and two major strokes (2.02%) occurred. No device-related complications and no serious access site complication were noted .Between discharge and 30-day follow-up, one patient died due to a cardiac arrest.
- The overall 30-day combined stroke/death rate was 2.52%, resulting in 1.61% event incidence in asymptomatic and 3.9% in symptomatic patients (P = ns). Logistic regression did not identify independent predictor of neurological events, except in the female gender.
-

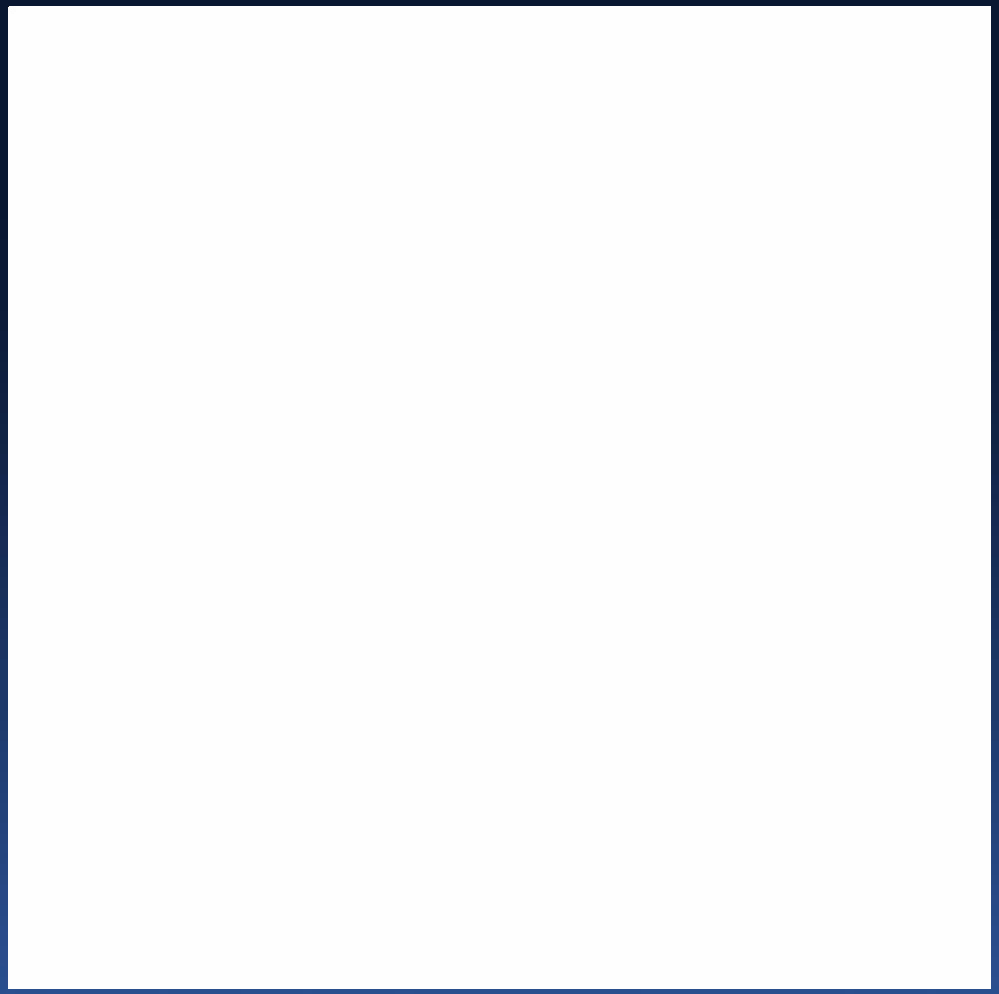
RICA restenosis before & after MOMA placement



Intra-cerebral circulation
Right & Left injection



Post Balloon 3 x20mm



Careful contrast medium injection

After placement of BSC ADAPT Stent L 21mm ø 4-9mm

IVUS before & after placement

Complications of proximal occlusion

- Due to flow reversal
  - Cerebral consciousness
  - Seizures

5 to 15%

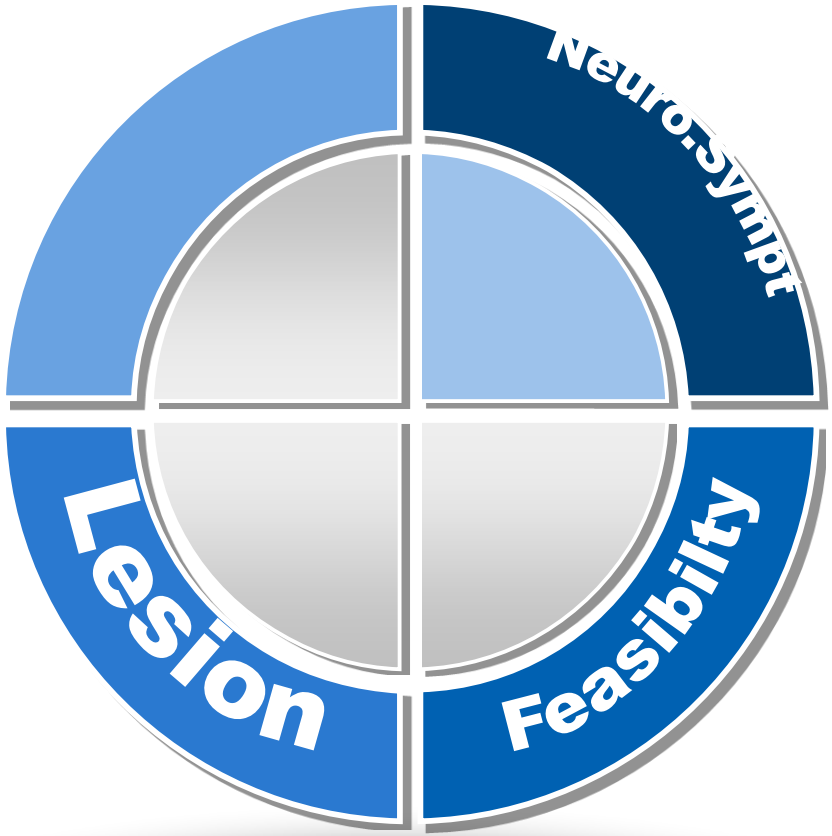
- Due to common carotid balloon
  - Dissection, flap
- Due to external carotid balloon
  - Occlusion , dissection

4 chapters to consider for each individual.

Age

General conditions

Patient Preference



Asymptomatic

Symptomatic

Time & Delay .

Bifurcation

Calcification

Irregular,Ulceration

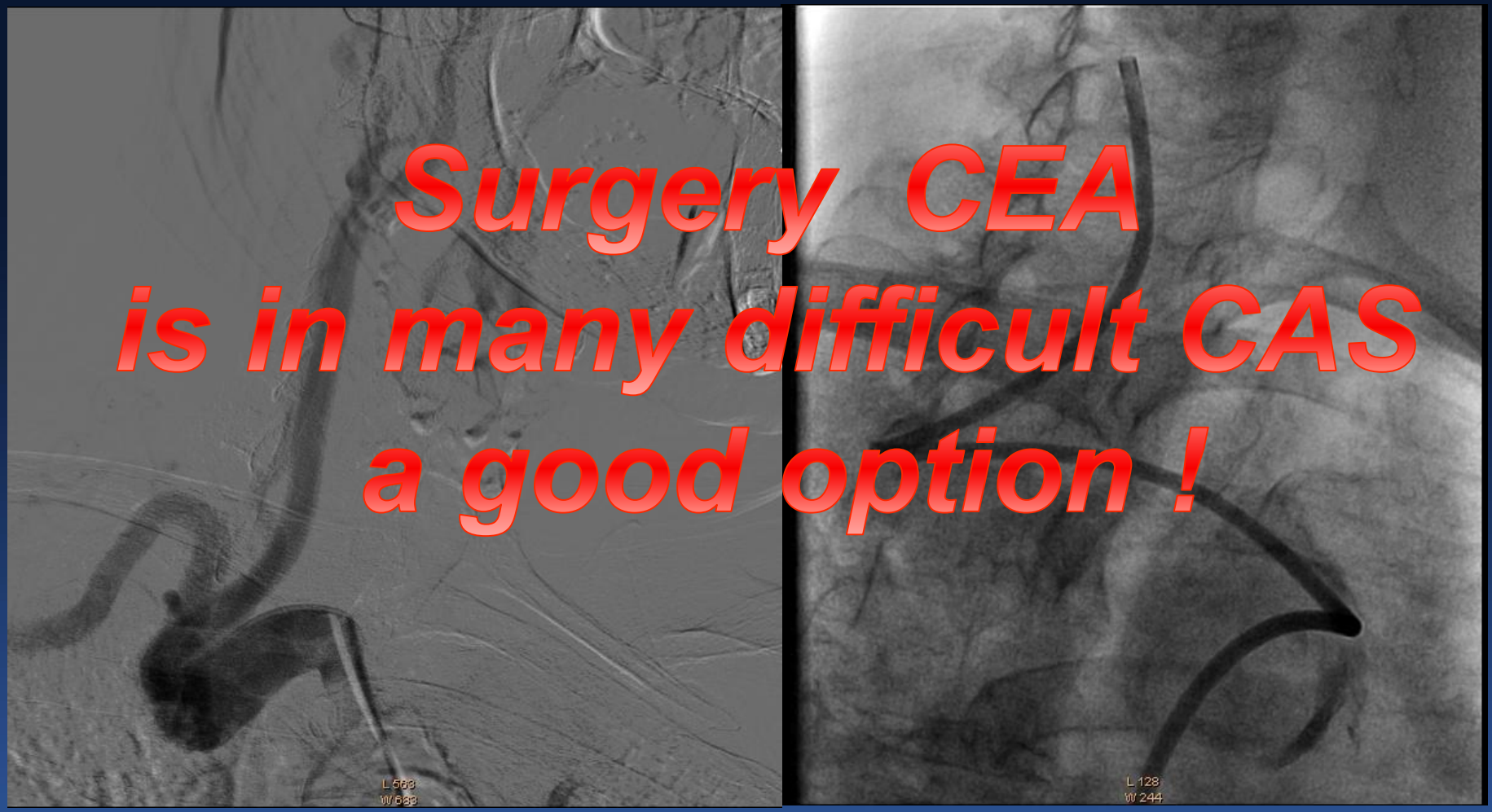
Length …

Access

Protection

Stenting

Extreme tortuosities : Protection impossible



Conclusion

- Carotid protection is indispensable in all patients and is possible in more than 97 % of CAS procedures
- Filter are the easiest device : have a favorite fixed wire and a favorite bare wire
- Reversal of flow with proximal balloons is complex but could become prevalent in high risk patients or lesions

9th anniversary of the pioneer of the multidisciplinary congresses

Save the date MEET 2011

BUILDING ENDOVASCULAR SYNERGIES

MEET 2011
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

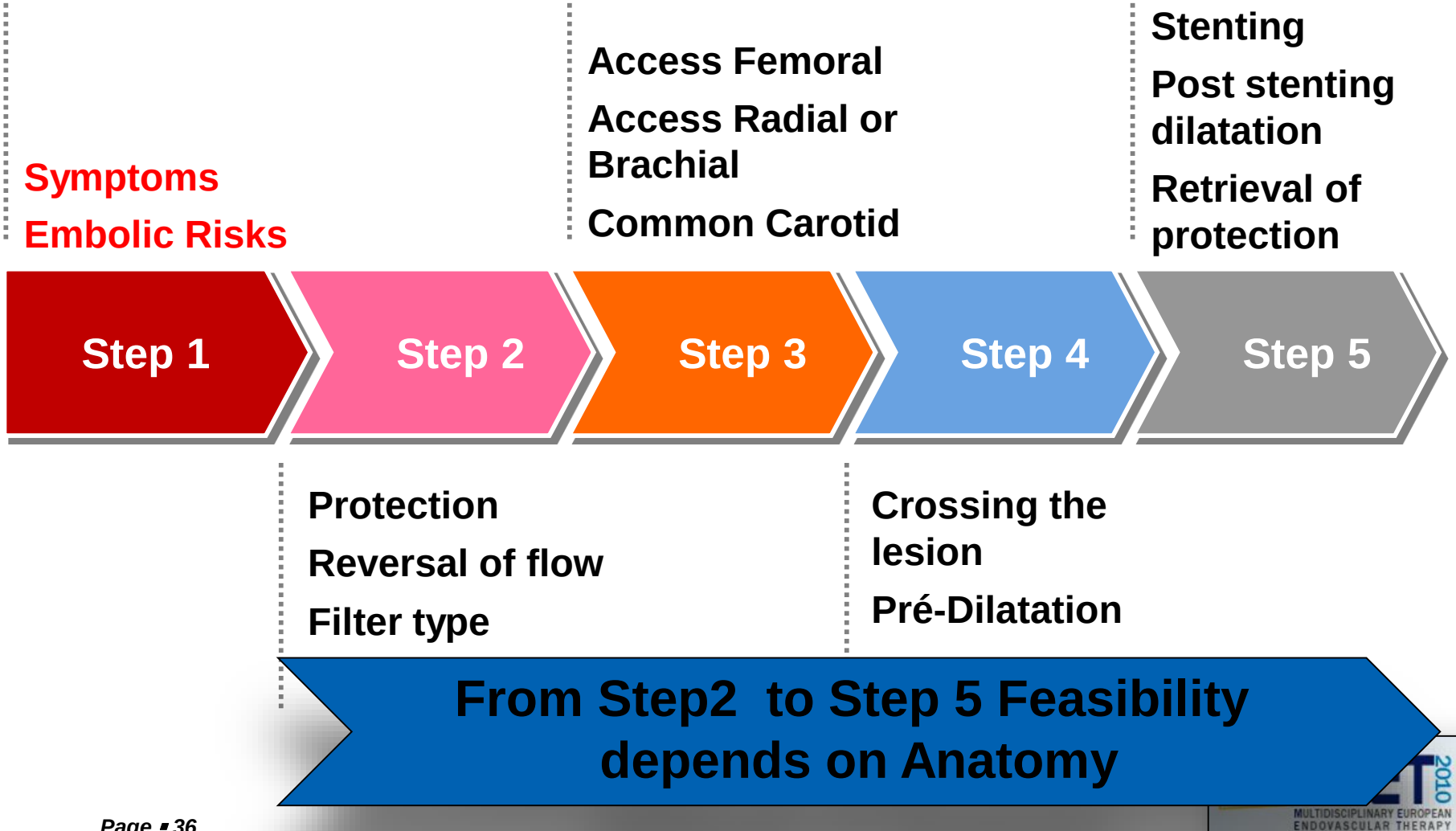
New dates & location!

Crowne Plaza St Peter's Hotel

Rome, Italy

October 27-29

5 Steps to consider for feasibility



CAPTURE 2 risk-adjusted stroke outcome benchmarks for carotid artery stenting with distal embolic protection.

Matsumura JS J Vasc Surg. 2010 Sep;52(3):576-583.e2.

- The second phase of carotid ACCULINK/ACCUNET post approval trial to uncover rare events (CAPTURE 2)is an ongoing prospective, multicenter, clinical trial conducted to assess CAS outcomes in the general practice setting after device approval for high surgical risk patients (symptomatic with >50% stenosis or asymptomatic with >80%stenosis).
- Five thousand two hundred ninety-seven consecutive patients (5297) had CAS performed by 459 physicians at186 sites before the data cutoff of January 10, 2009.
- The 30-day rate of stroke was 2.7% (95% confidence interval [CI], 2.3-3.2) Multivariable predictors of periprocedural stroke included age, symptomatic status, and dwell time of embolic protection device.
- A parsimonious model P(i) = 1/(1+e (-(-3.83 + 0.51 x(symptomatic) + 0.31 x (age >/=80) + 0.62 x (age >/=80 x symptomatic))),including symptomatic and octogenarian status and the term of the interaction of the two, was established based on consideration of clinical predictors, clinical interaction, and practicability

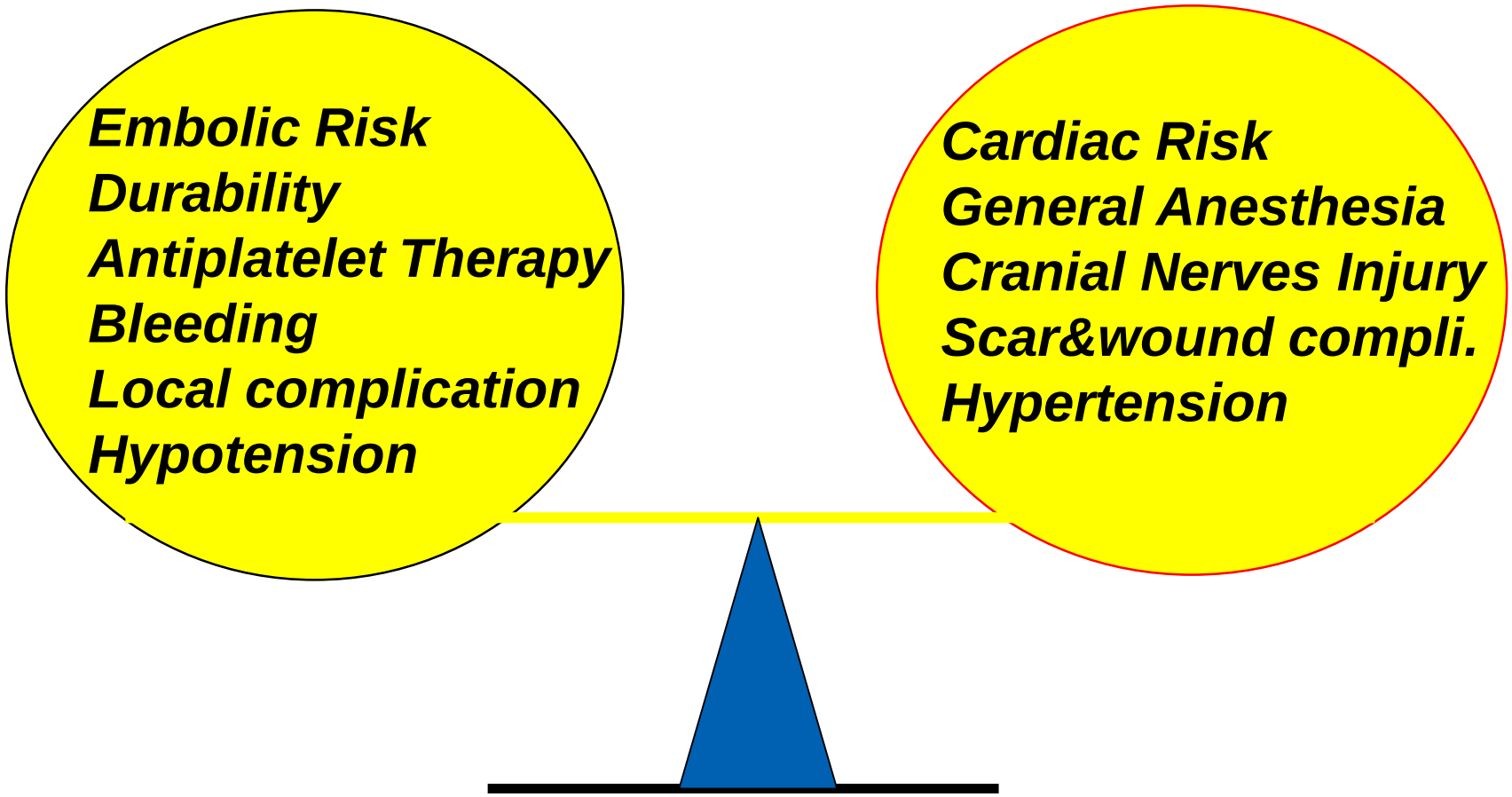
Safety and effectiveness of the INVATEC MO.MA proximal cerebral protection device during carotid artery stenting: results from the ARMOUR pivotal trial.

Ansell GM&all Catheter Cardiovasc Interv. 2010 Jul 1;76(1):1-8.

- This prospective registry enrolled 262 subjects,37 roll-in and 225 pivotal subjects evaluated with intention to treat (ITT) from September 2007 to February 2009. Subjects underwent CAS using the MO.MA device.
- The primary endpoint, myocardial infarction, stroke, or death through 30 days (30-day major adverse cardiac and cerebrovascular events [MACCE]) was compared to a performance goal of 13% derived from trials utilizing distal EPD
- Symptomatic patients comprised 15.1% and 28.9% were octogenarians. Device success was 98.2% and procedural success was 93.2%. The 30-day MACCE rate was 2.7% [95% CI (1.0-5.8%)] with a 30-day major stroke rate of 0.9%. No symptomatic patient suffered a stroke during this trial
- The absence of stroke in symptomatic patients is the lowest rate reported in any independently adjudicated prospective multicenter registry trial to date.

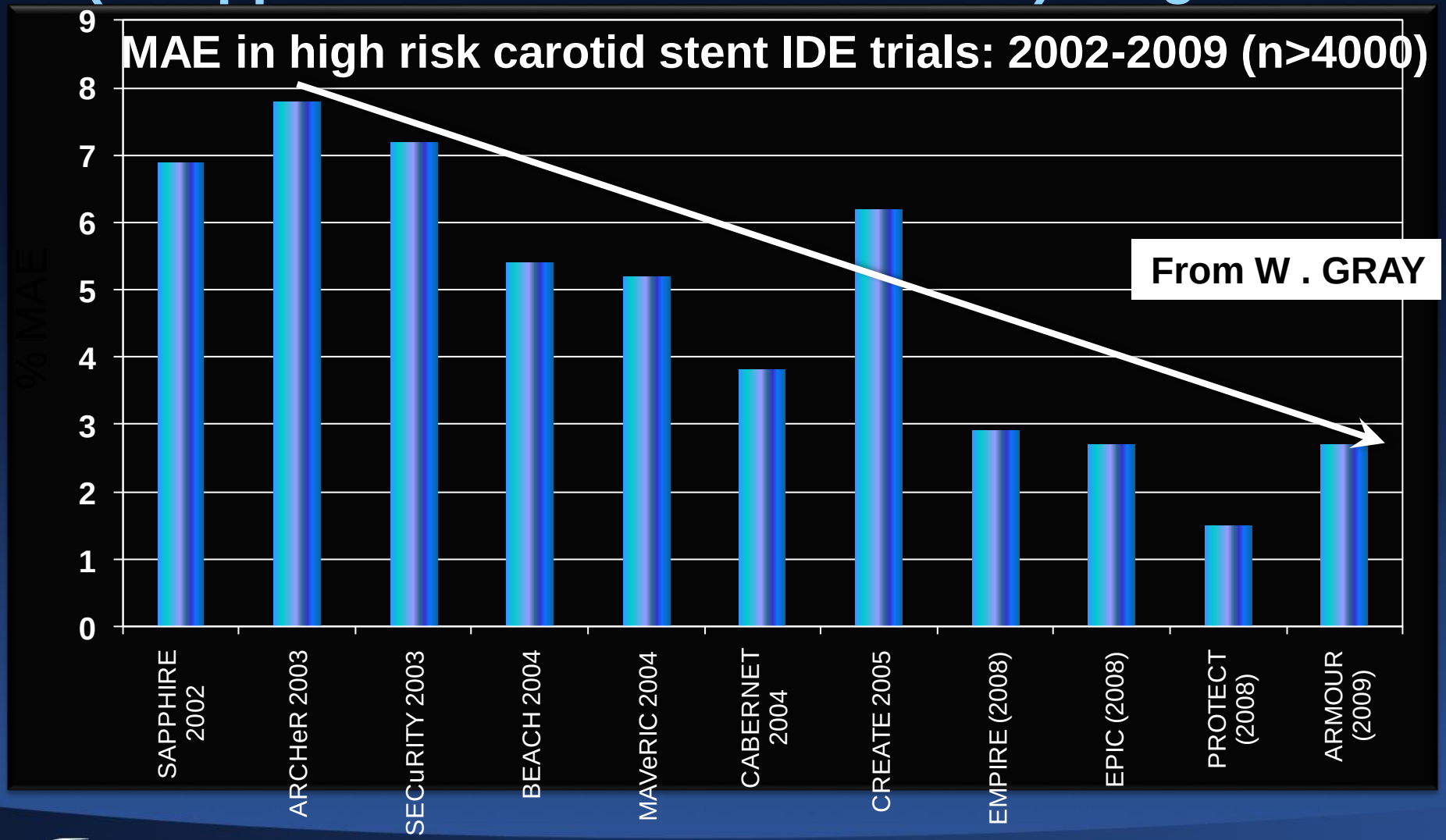
STENTING SURGERY

RISKS



Natural History
under Medical therapy

Improvement of results over time
11 US FDA approval trials with improving outcomes (all approved as safe and effective) /Registries



Reported 30 day stroke rates. Study parameters and definition of stroke rate may vary per clinical trial.

Right intra-cerebral circulation