BUILDING ENDOVASCULAR SYNERGIES

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com

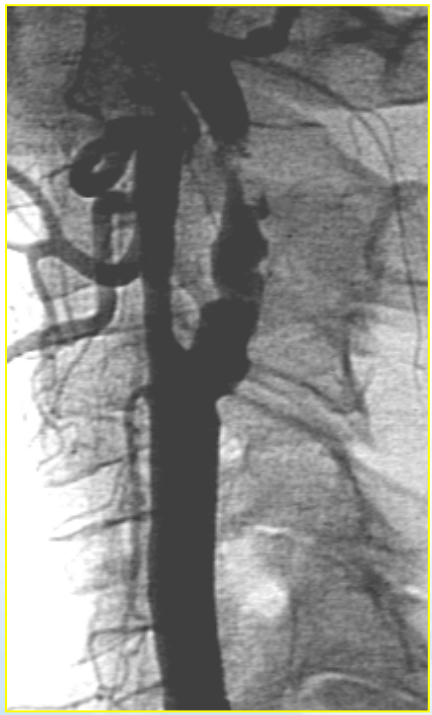
Why I'm afraid of occlusive devices

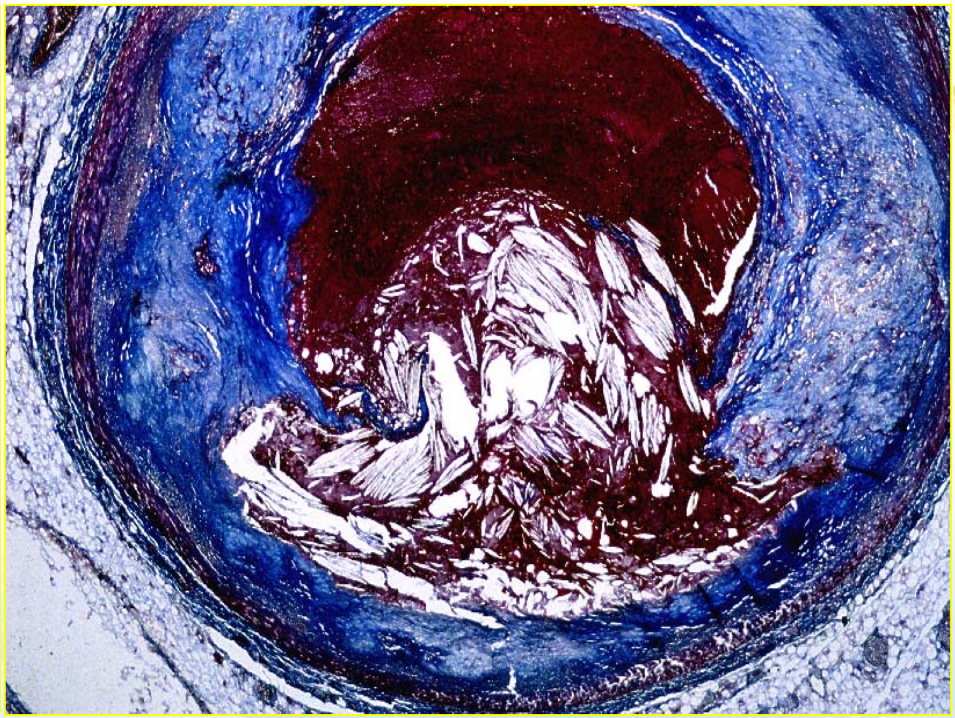
Carlo Cernetti
Cardiology Department
Mirano (Venice)

Cannes 28.06.2008

MEET 2008 CANNES

I HAVE NOT FINACIAL INTEREST/ARRANGEMENT OR AFFILIATION CONFLICT





BUILDING ENDOVASCULAR SYNERGIES

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com

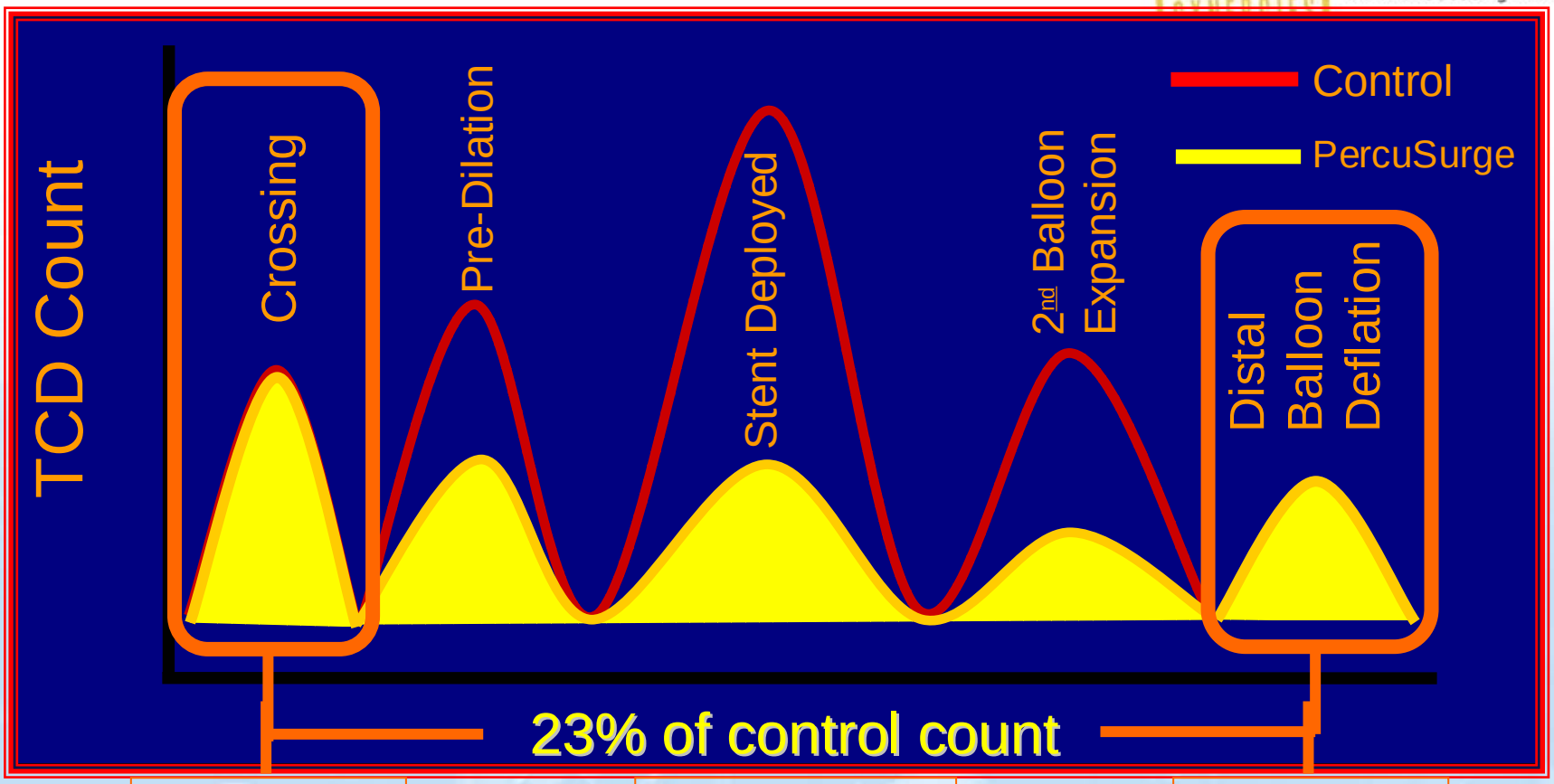
Obstructive carotid artery lesions are known to contain friable, ulcerated and thrombotic material that invariably embolize during the intervention as shown in transcranial Doppler, ex-vivo and in-vivo studies.

Imparato et al. Stroke 1979;10:238-245

Okhi et al. J Vas Surg 1999;30:1034-44

Angelini et al. Stroke 2002; 33:456-61

Trancranial Doppler during Carotid Stenting

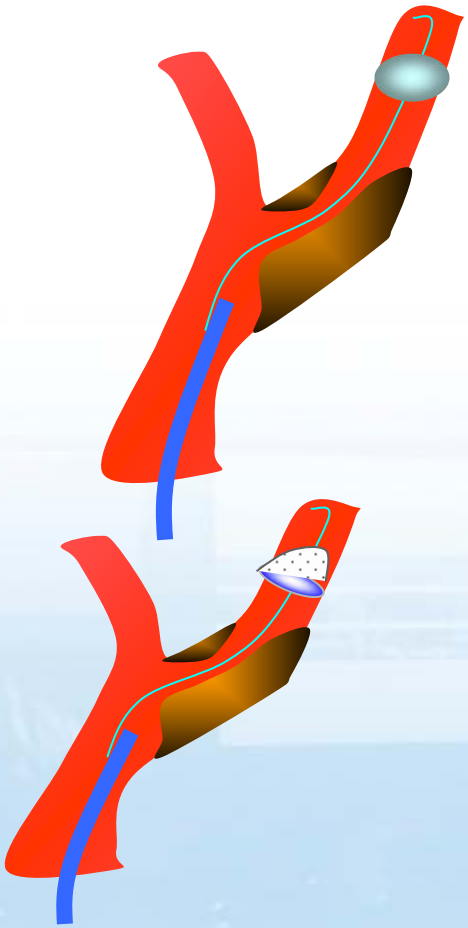


Protection device crossing

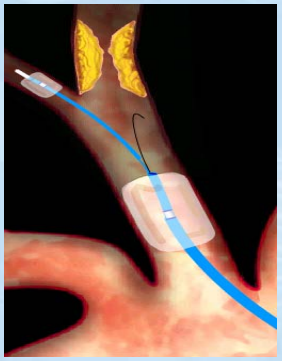
"Protected" stent procedure

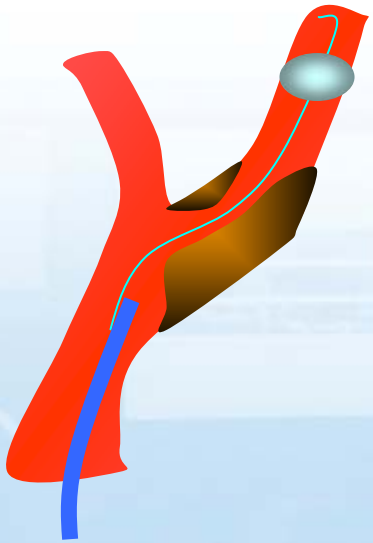
Protection device retrieval

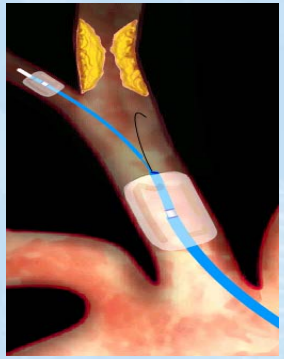
Al-Mubarak , AHA 2001



- Distal Occlusive Balloon
- Filters
- Proximal Occlusion Devices (MOMA:PARODI)

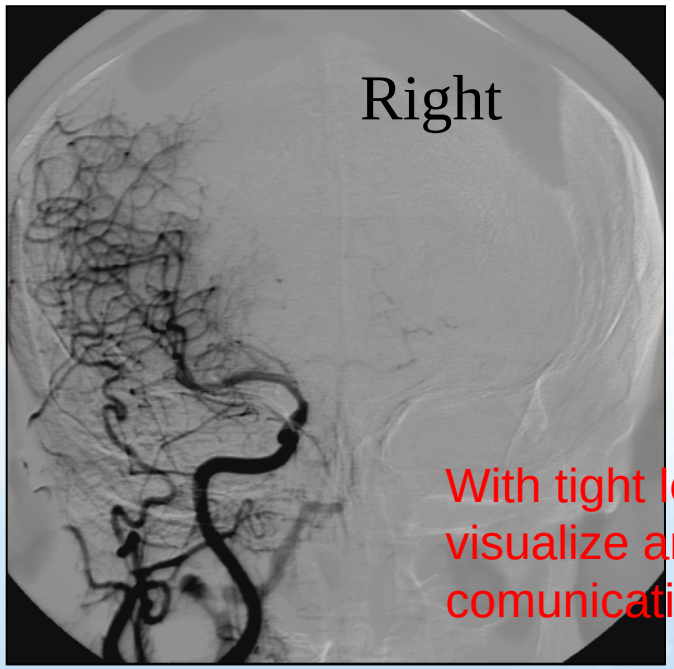


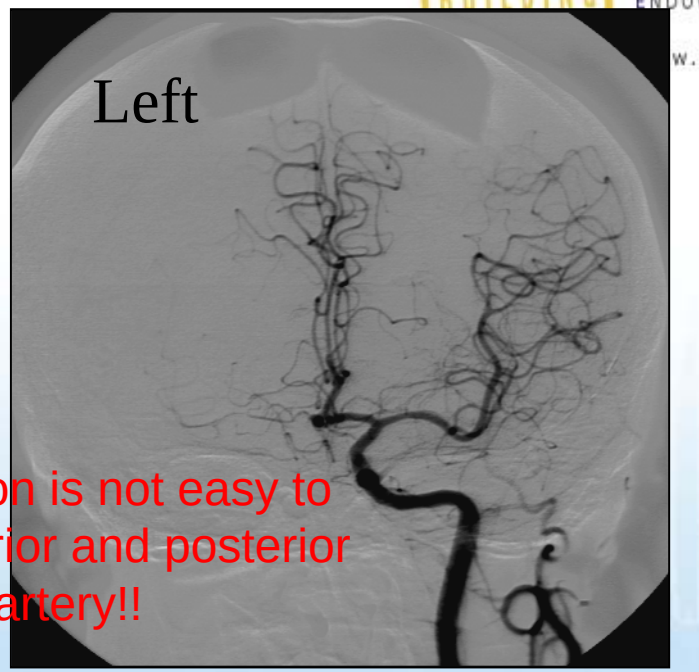




- Distal Occlusive Balloon
- Proximal Occlusion Devices (MOMA:PARODI)

Distal Occlusive Devices





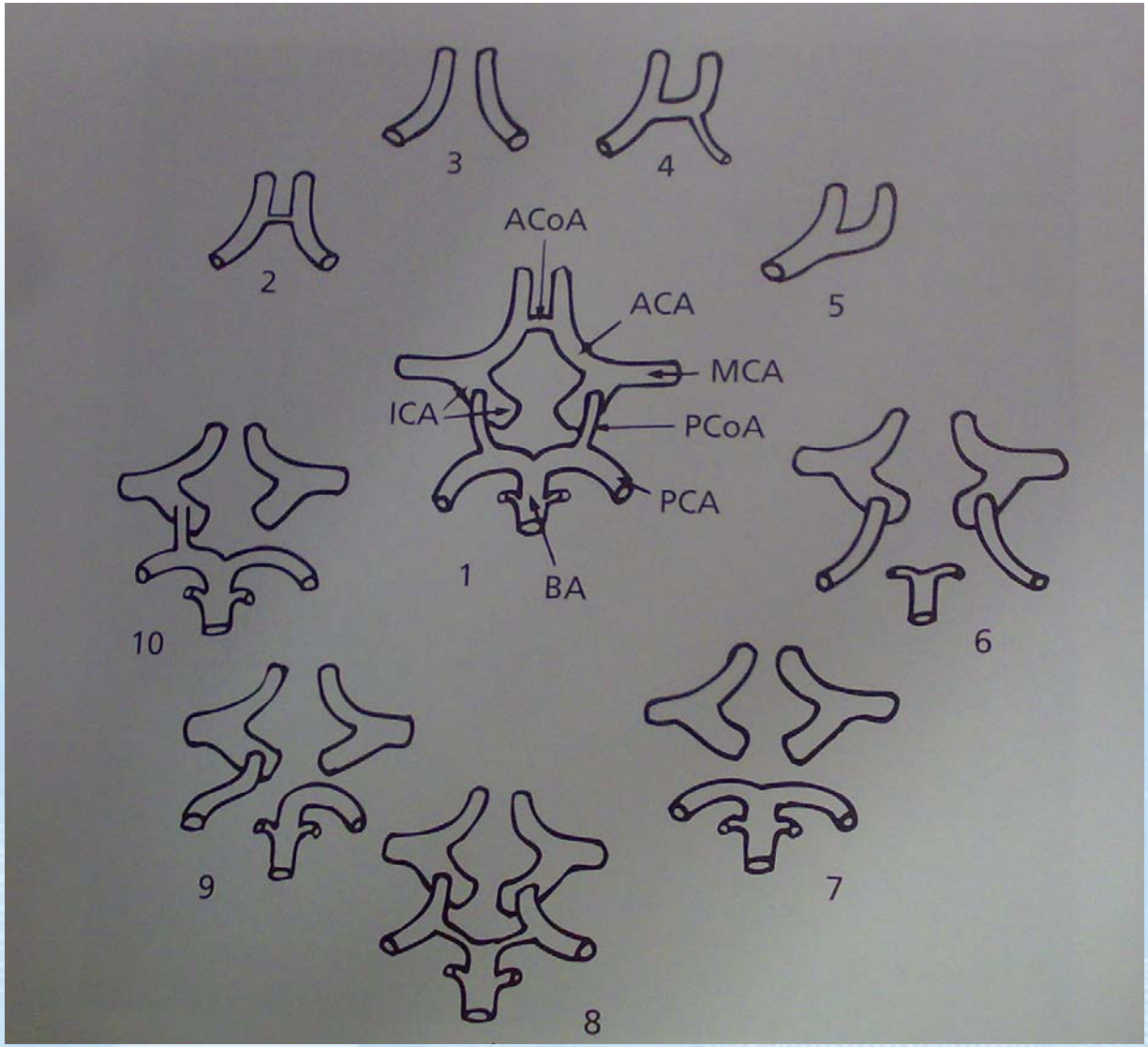
With tight lesion is not easy to visualize anterior and posterior comunicating artery!!

Did tolerate 15 min balloon inflation

Intolerance approx. 8-25% of cases

Did not tolerate Guardwire balloon inflation

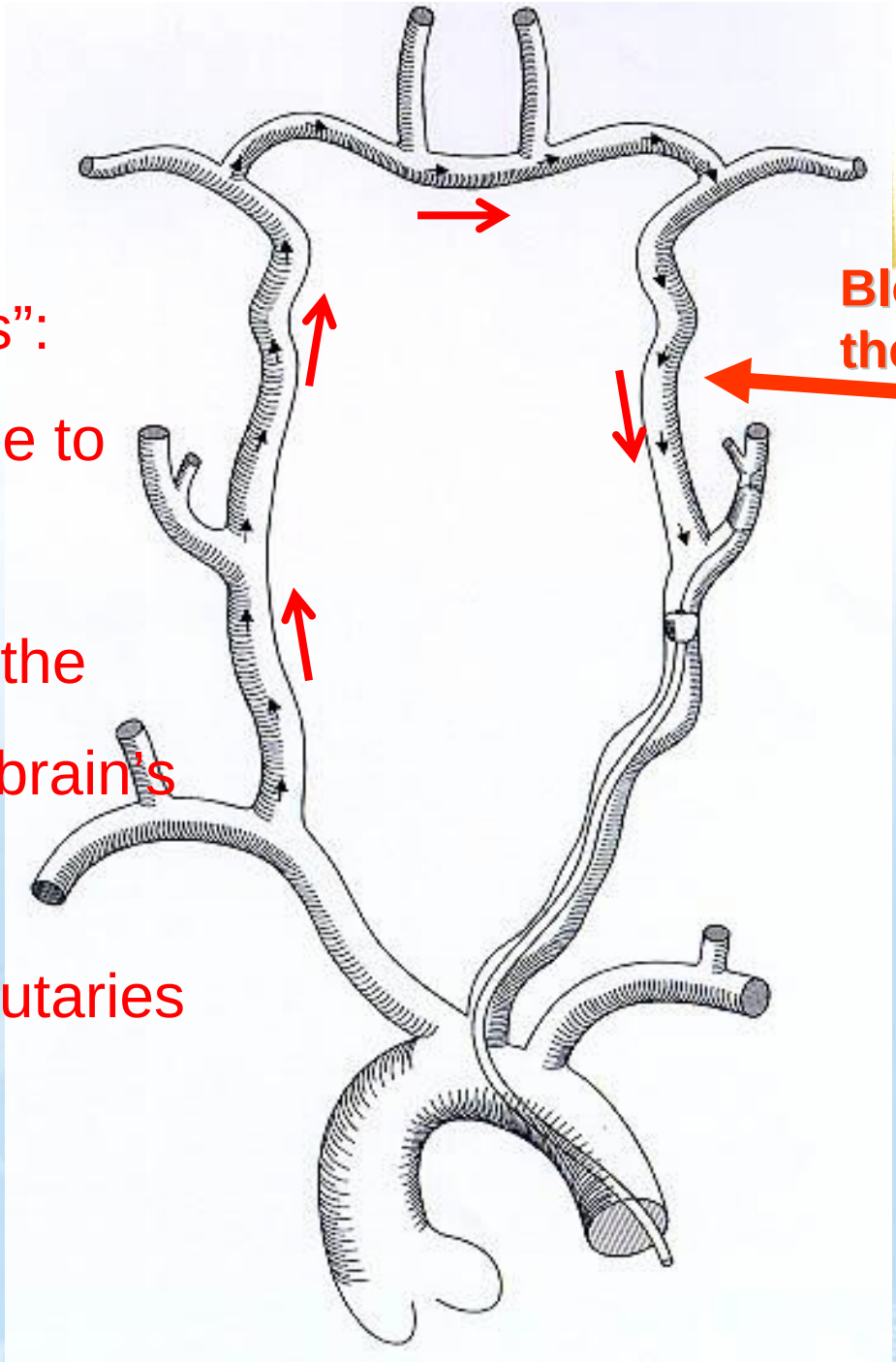
21 Possible anomalies of the circle of Willis!!!



Willis' Circle

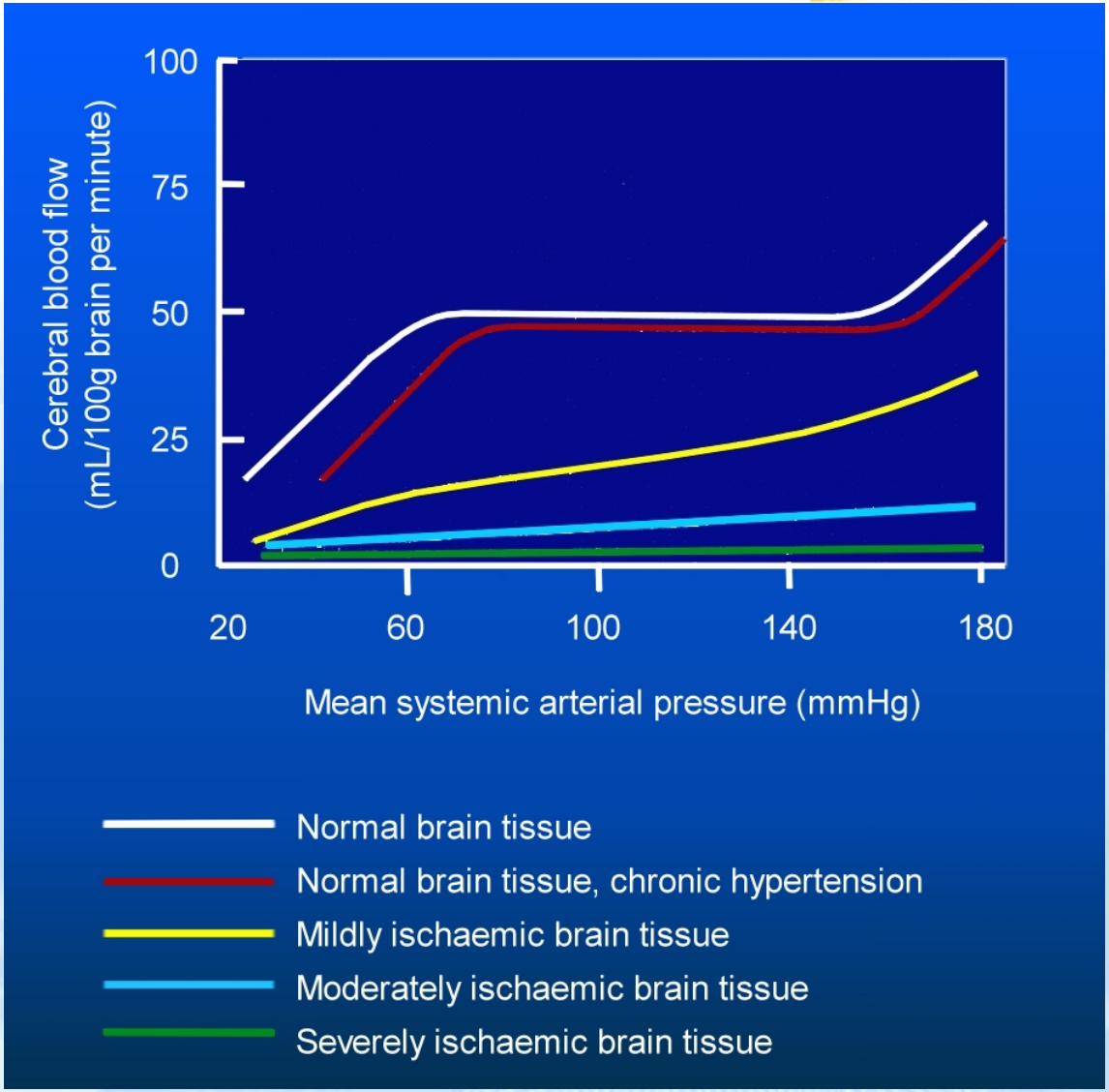
"WaterShed Zones":

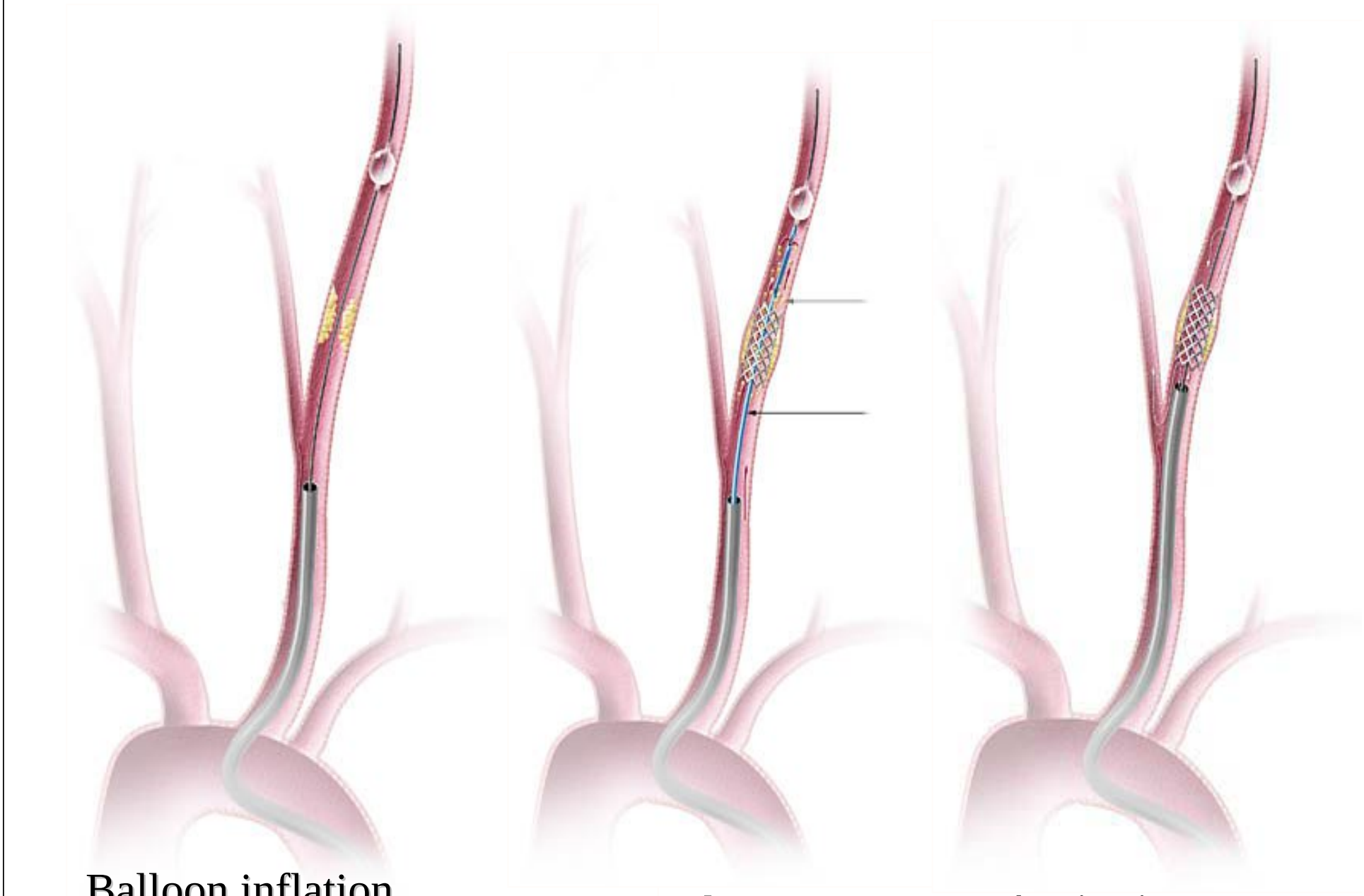
possible distress due to arterial hypotension during the clamping phase of the brain's areas at the border of two tributaries cerebral arteries



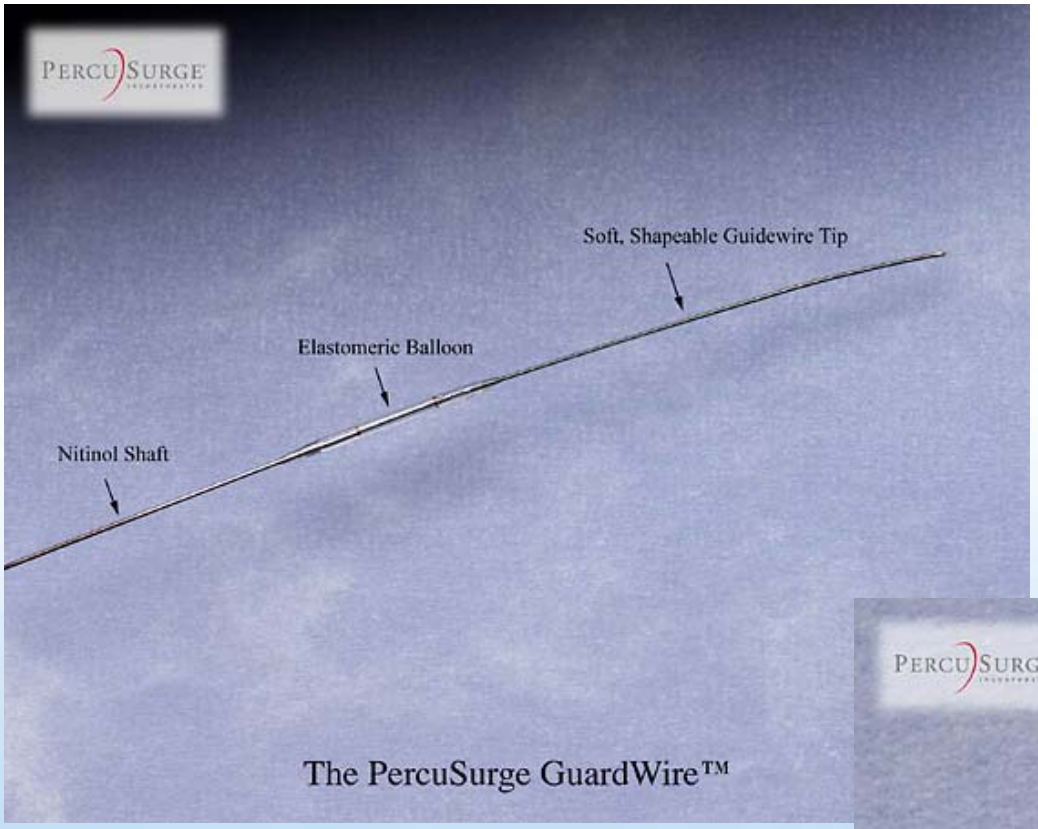
Autoregulatory Cerebral Flow and MAP

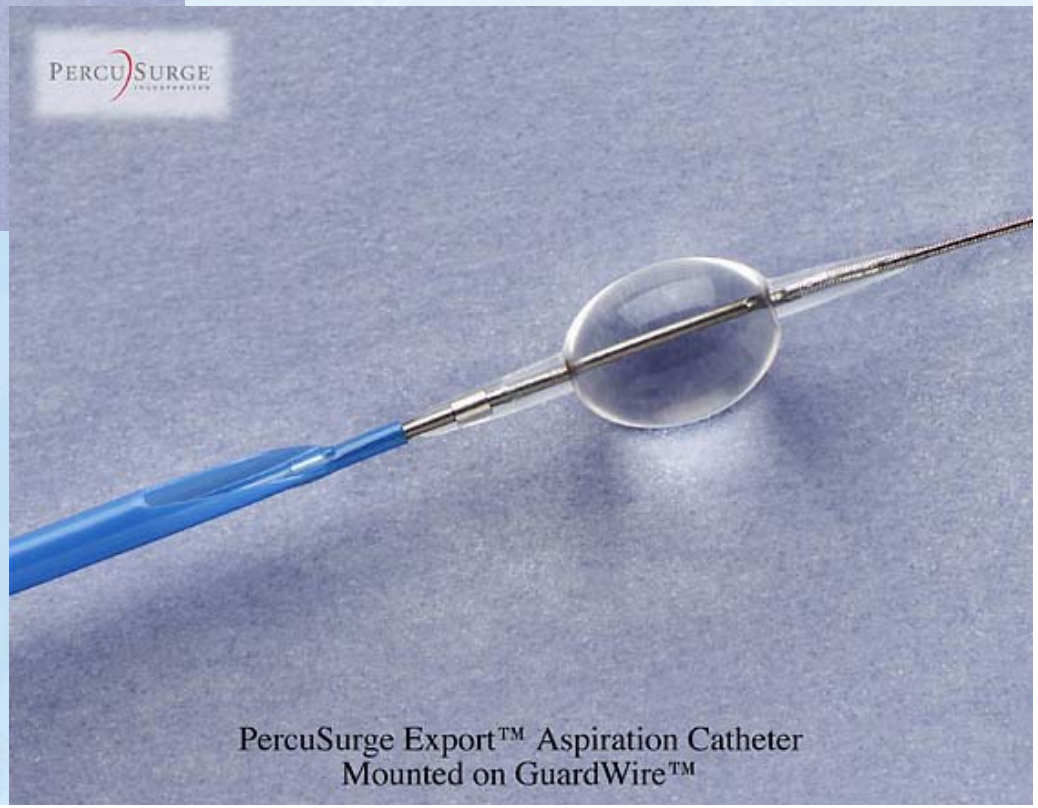
Median Artery Pressure=
2 x DBP + SBP
Total / 3




Balloon inflation
distal of the stenosis
Stent implantation
Aspiration

Percusurge/ Guardwire (Medtronic)





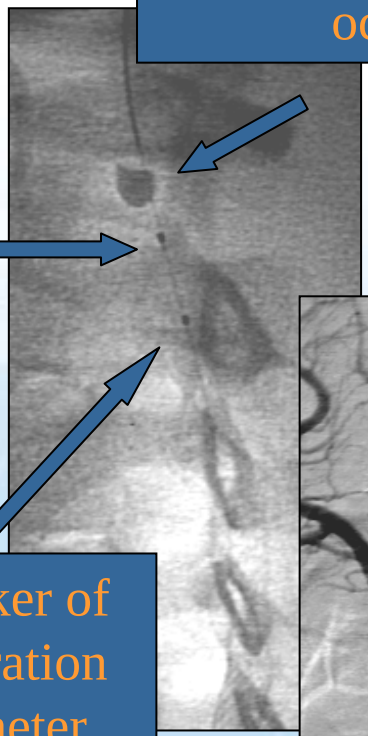
2.7 F
Retrieval-Catheter 5.4 F
Balloon ∅ (3-6) mm

The Percusurge Guardwire™ Protection

Baseline

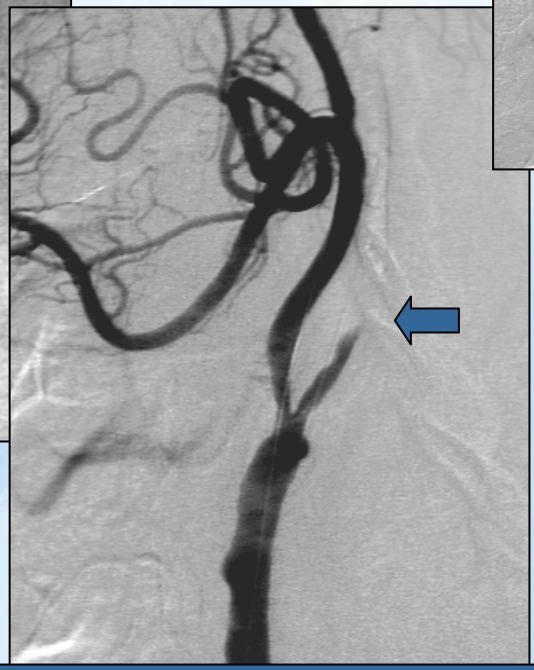
5.0-6.0mm balloon on .0014” wire occluding distal ICA

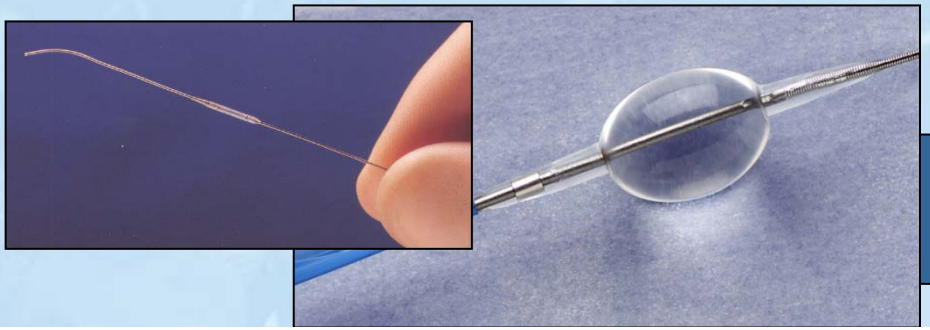
Distal marker



Marker of aspiration catheter

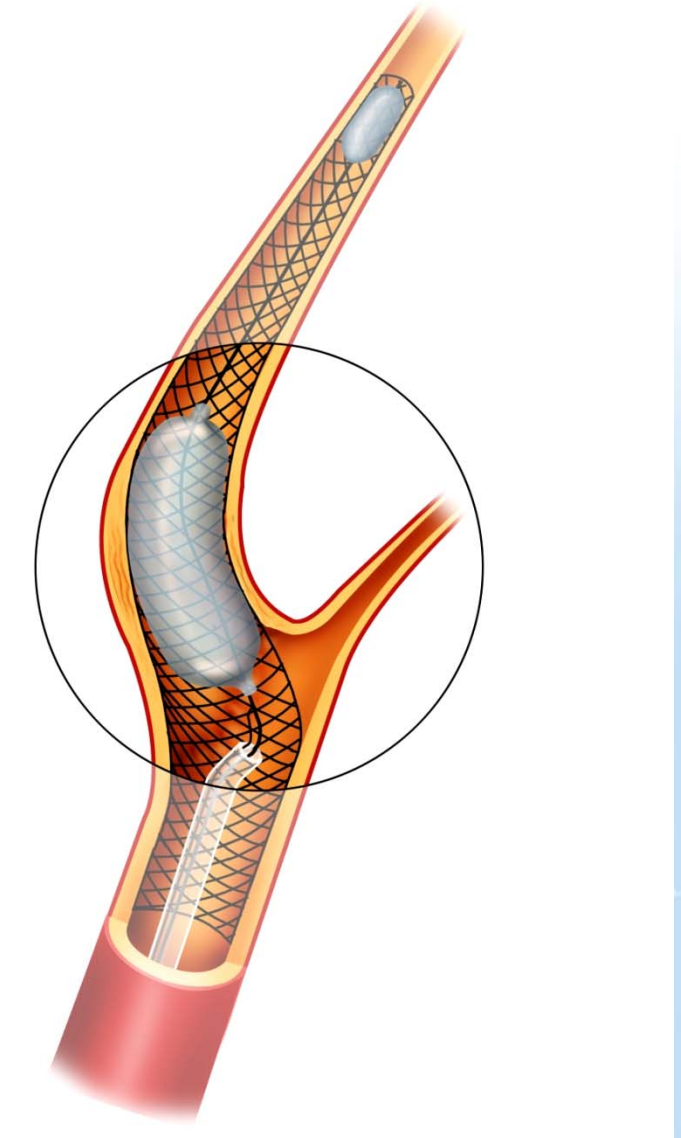
Final result





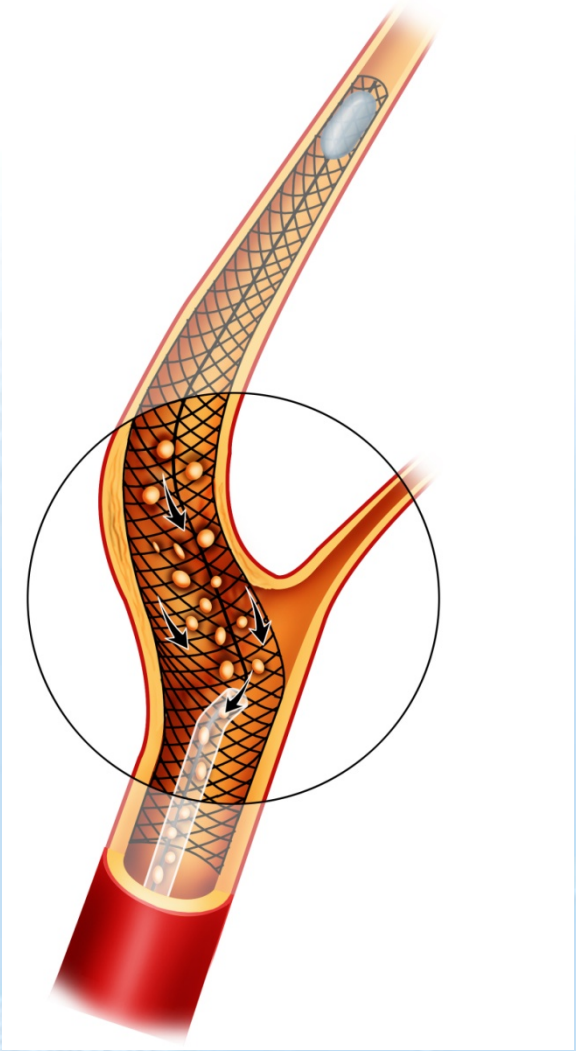
Injection with inflated balloon confirms absence of flow in the ICA

Twin One (Minvasys)



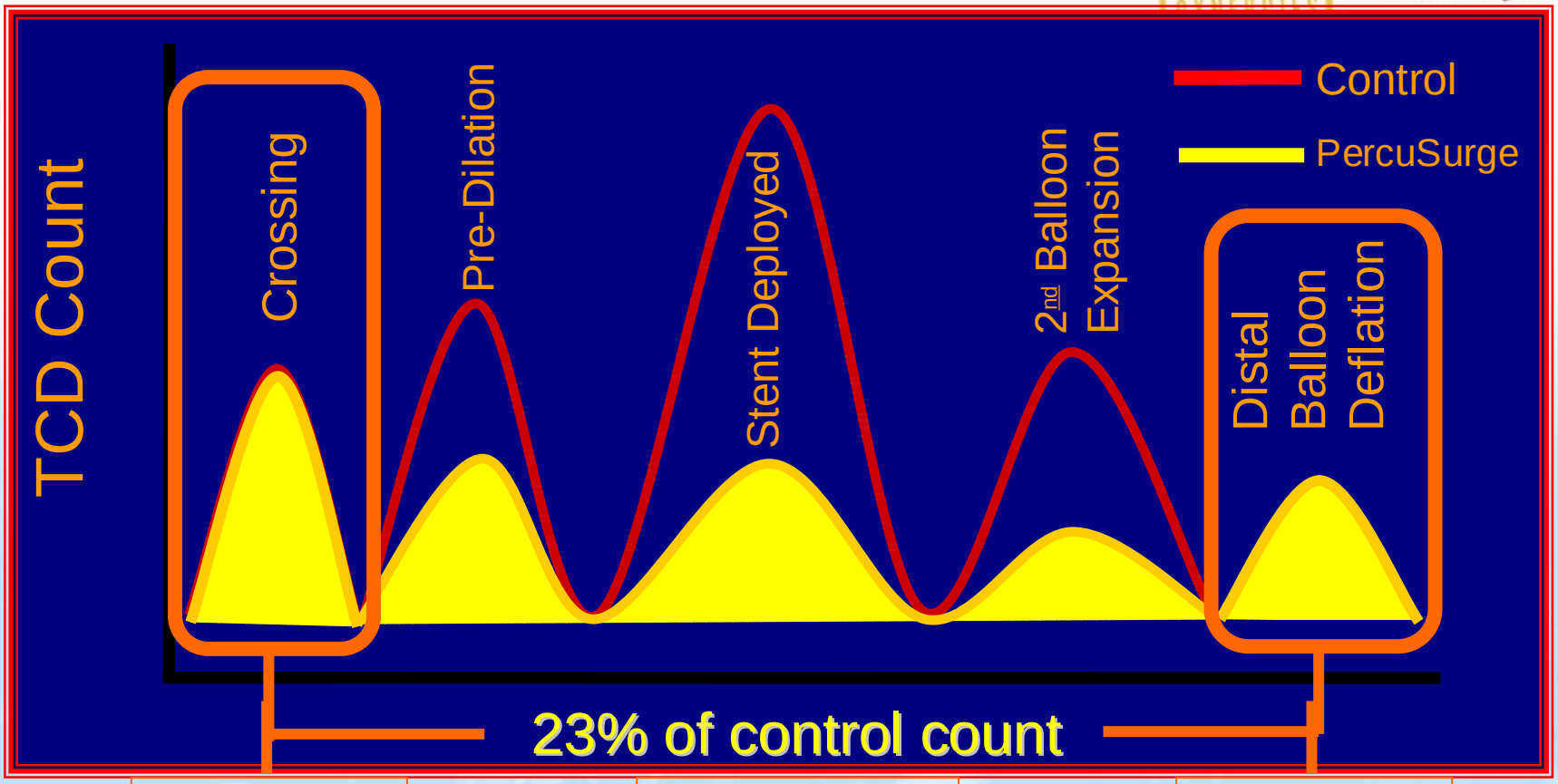
Distal protection (only) during post-dilatation

Twin One (Minvasys)



Debris is aspirated via the guiding catheter

Trancranial Doppler during Carotid Stenting



Protection device crossing

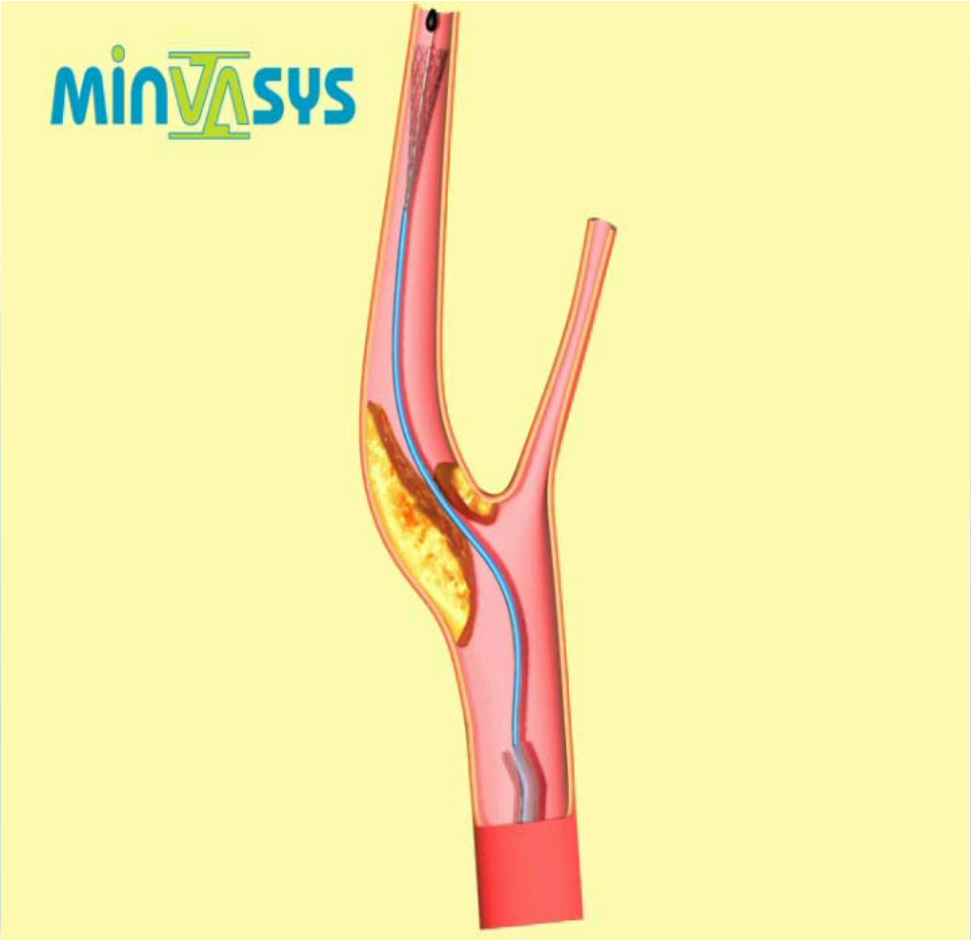
"Protected" stent procedure

Protection device retrieval

Al-Mubarak , AHA 2001

Twin One (Minvasys)

- Implantation of a Wallstent (without protection)
- Advance the guide
- Remove the wire
- Introduce the TwinOne catheter
- Inflation of the distal occlusion balloon
- Balloon angioplasty
- Aspiration of debris via the guiding catheter
- Deflation of the distal occlusion balloon



Twin One Multicenter Trial

Patient demographics

- N 210
- Male 69.4%
- Age 71.5 (SD 7.9)
- > 80 16%
- Symptomatic 32.5%

J Theron, ICCA 2007

Twin One Trial

Procedure

Occlusion time

- Mean 3.9 min
- Min 1.25 min
- Max 13.0 min

Procedure time

- Mean 51±25 min

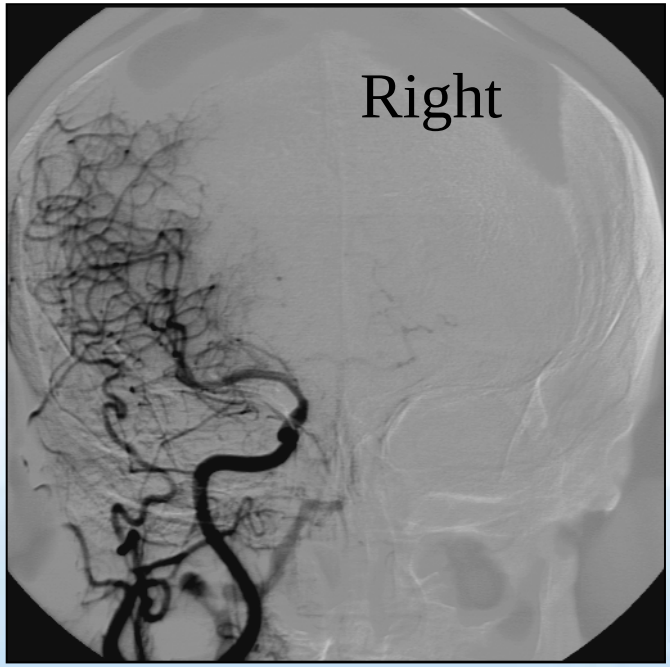
30 day stroke/death 2.9%

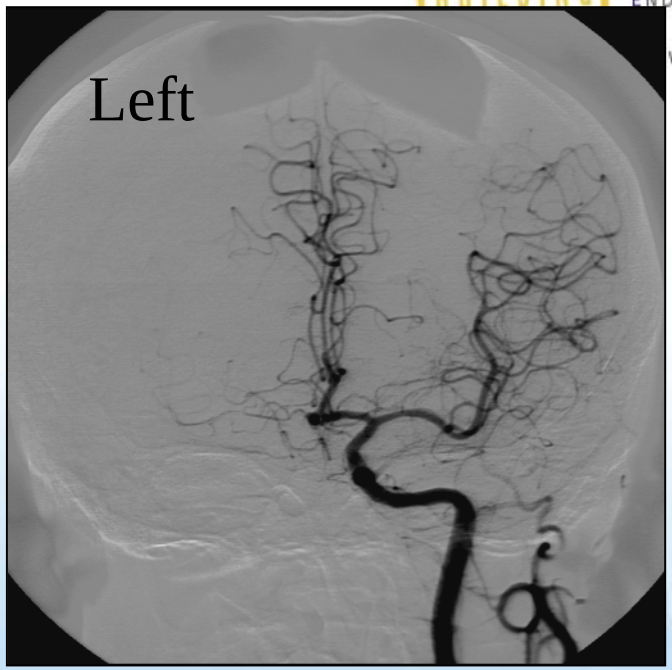
J Theron, ICCA 2007

Distal Occlusions Balloons

- Advantages
  - Low profile
  - Small particles are kept back
- Disadvantages
  - More experience required (VS filter)
  - No wire of your choice
  - No protection during crossing (+pred+stent dep)
  - Distal landing zone required
  - Distal spasm, dissections
  - Occasionally problems during aspiration
  - No angiography during balloon occlusion
  - Intolerance may occur 8-25%
  - "All or nothing"

Proximal Occlusive Devices



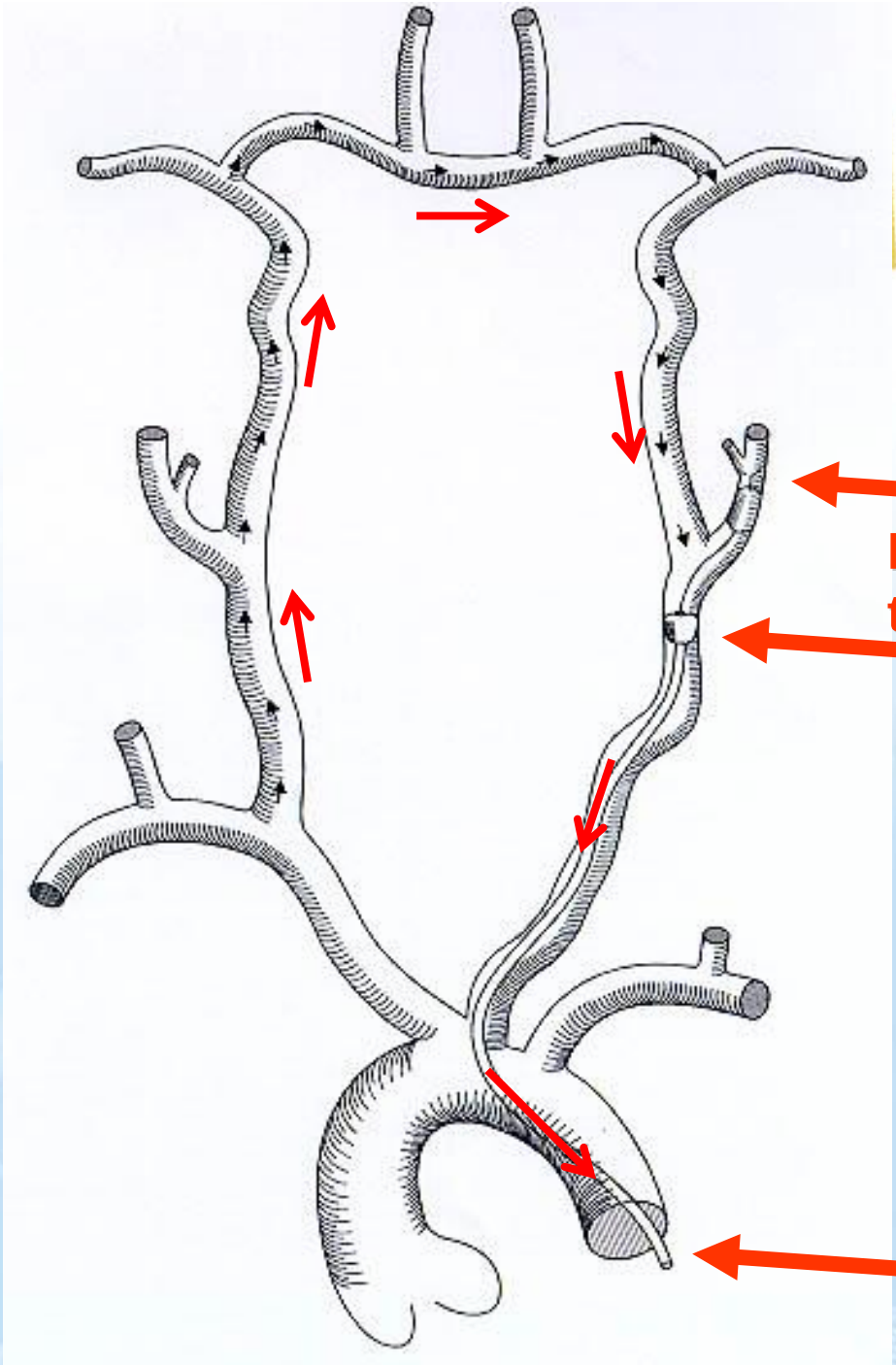


Did tolerate 15 min occlusion inflation

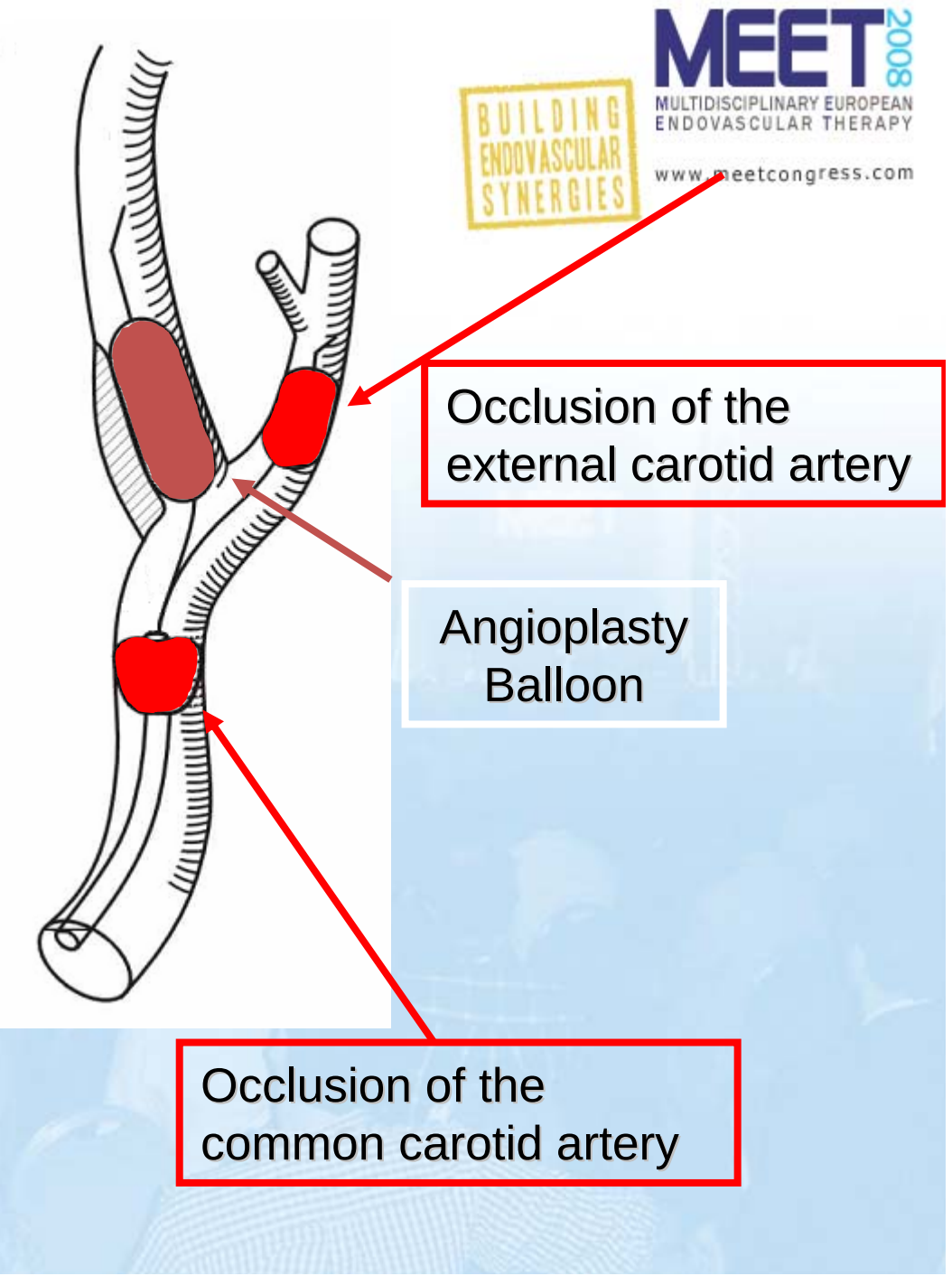
Intolerance approx. 8-25% of cases

Did not tolerate balloon inflation

Willis' Circle



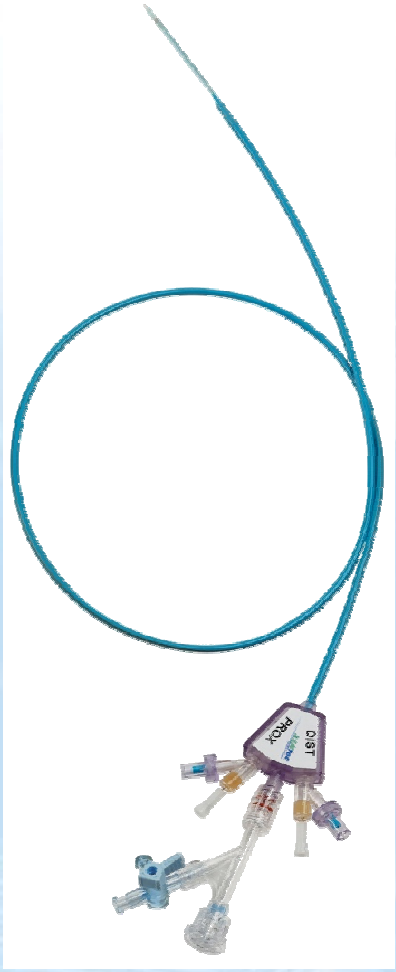
The external carotid artery also has to be occluded to avoid backflow



Disadvantages of Proximal Occlusion Devices

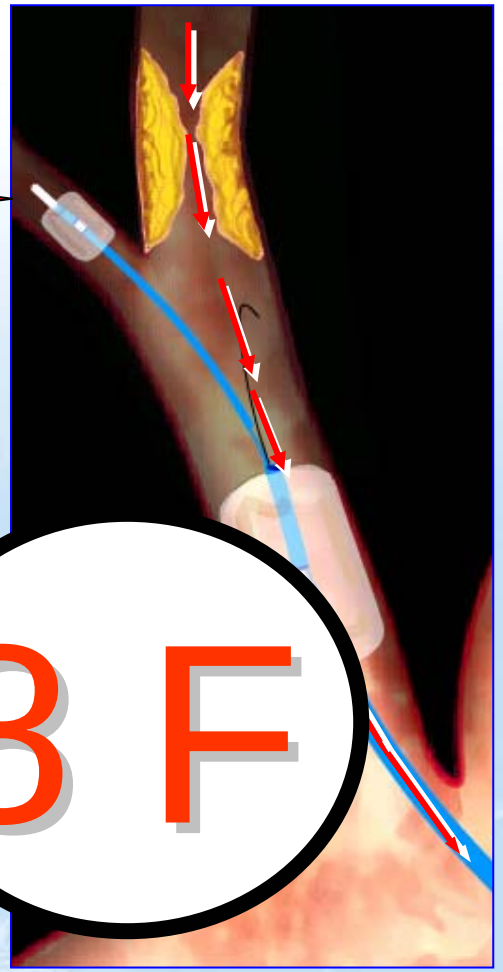
- More experience required (VS filter)
- Intolerance in 8-25%
- Not indicated in contralateral occlusions
- "All or nothing"
- If the balloon does not seal
  → all debris goes to the brain
- No protection in case of retrograde flow from large proximal side branches of the external carotid artery

Endovascular Clamping
MO.MA



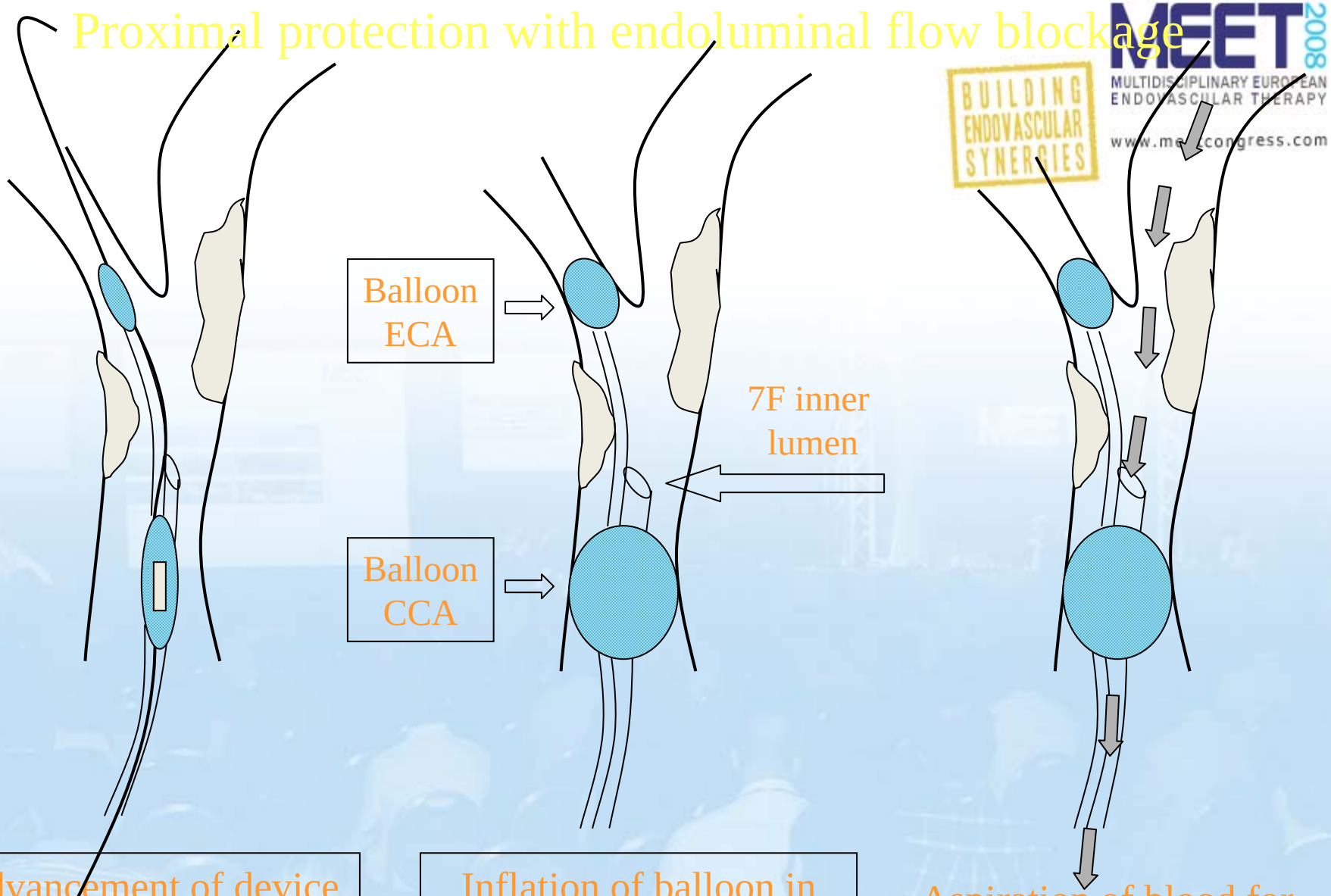
External carotid balloon

Common carotid balloon



Aspiration of Debris with Syringe

Proximal protection with endoluminal flow blockage

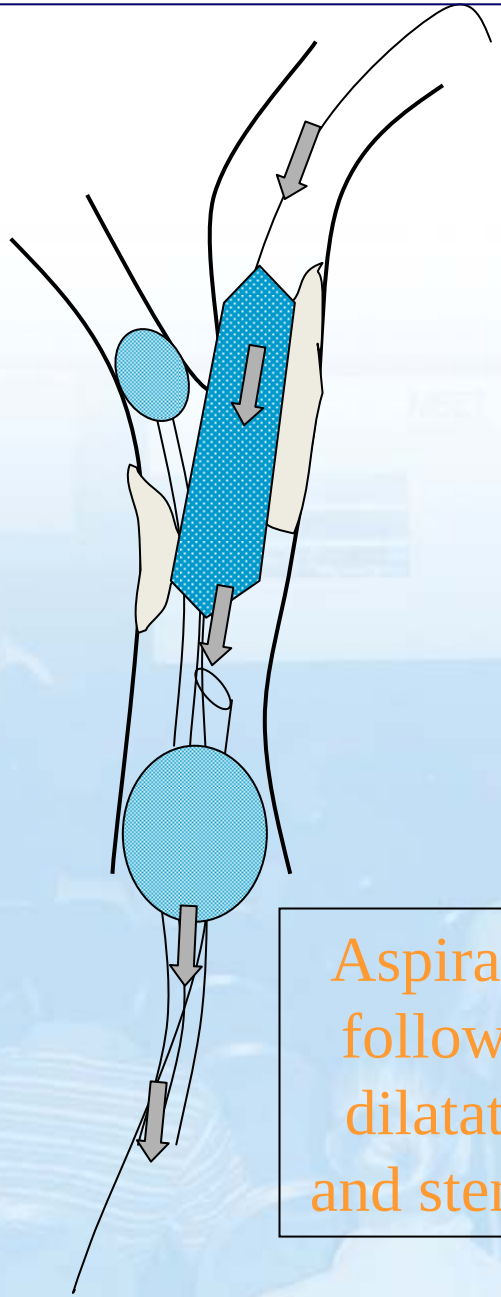


Advancement of device on stiff type .035” wire positioned in ECA

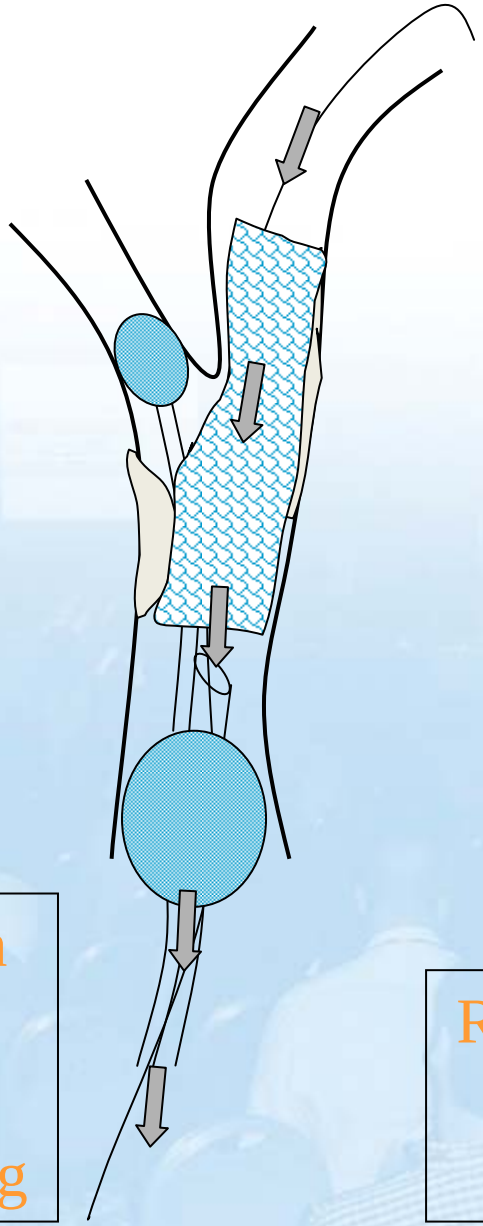
Inflation of balloon in ECC and CCA to inhibit antegrade flow

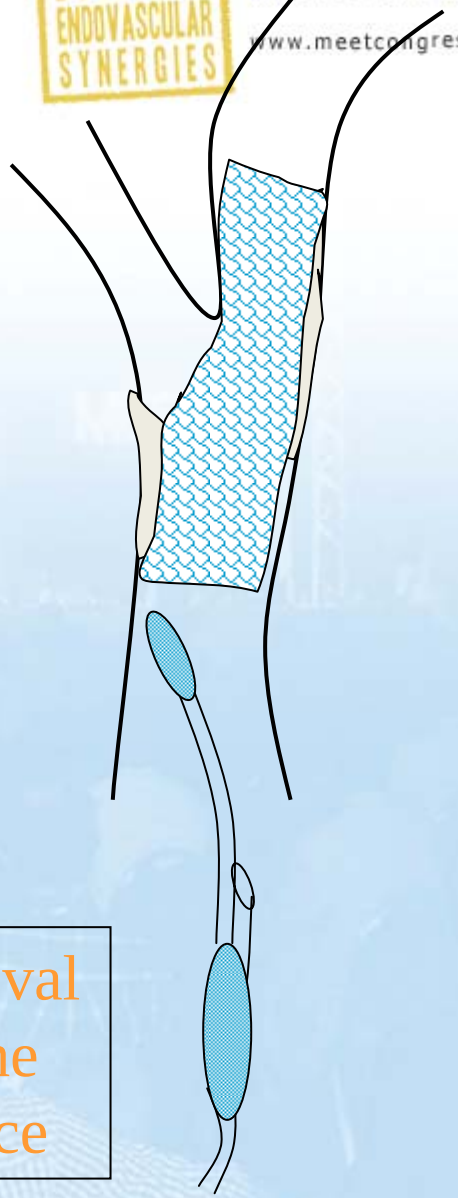
Aspiration of blood for debris removal

Proximal protection with endoluminal clamping of ECA and CCA



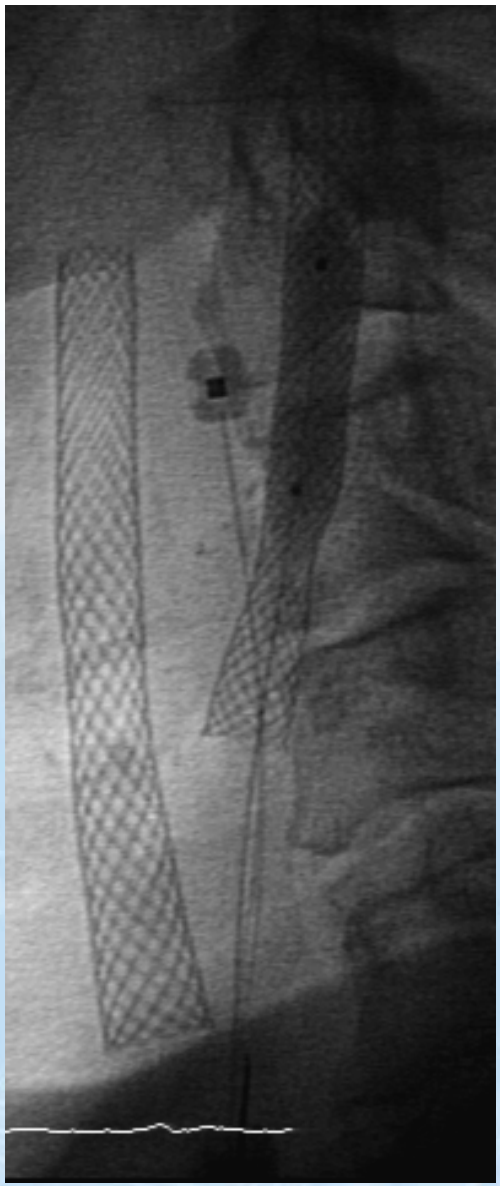
Aspiration following dilatation and stenting





Removal of the device


ECA
CCA

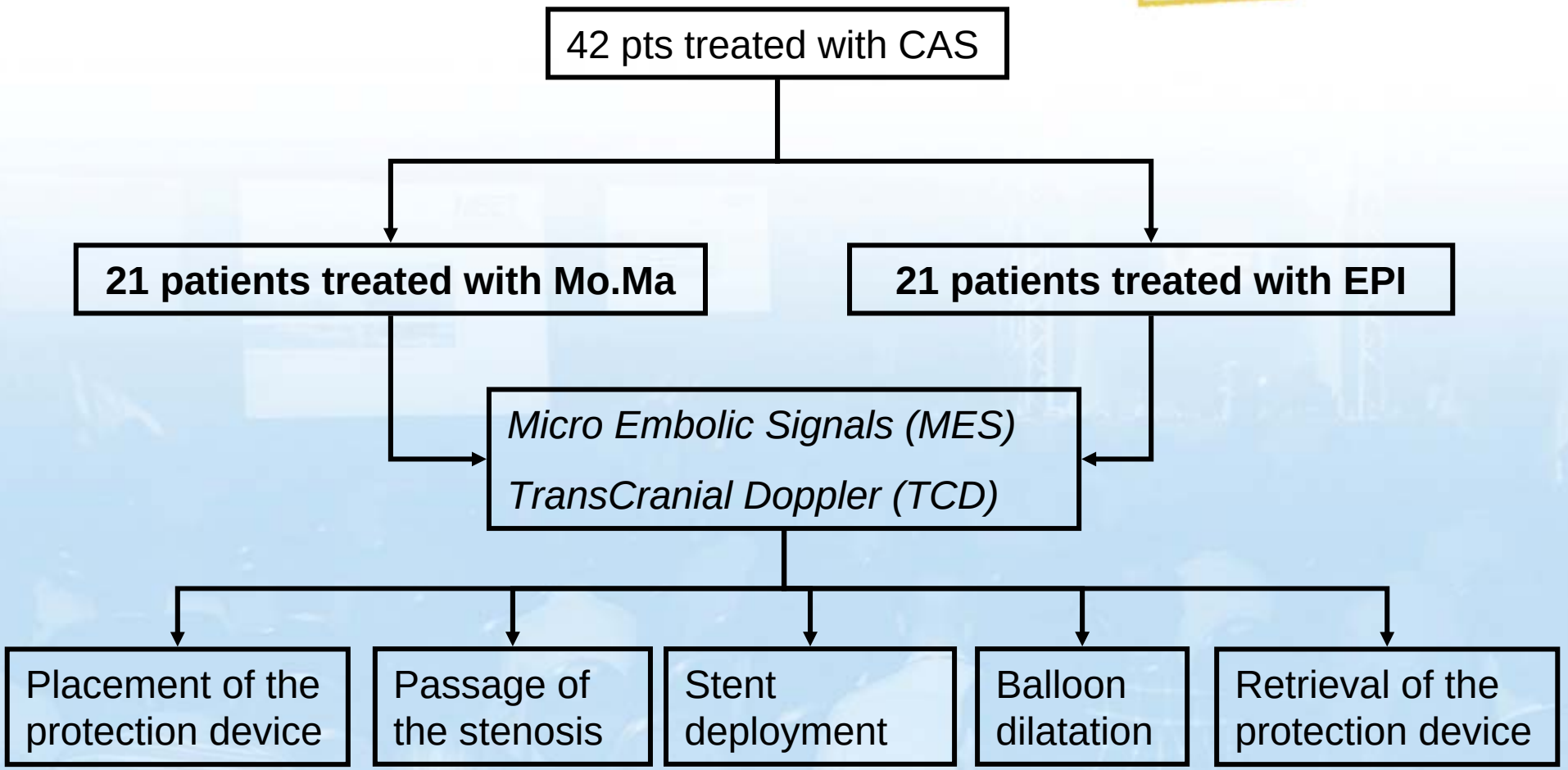


BUILDING ENDOVASCULAR SYNERGIES

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

www.meetcongress.com

Mo.Ma vs. EPI Filter Wire



Schmidt A et al. J Am Coll Cardiol 2004;44:1966-1969

Mo.Ma vs. EPI Filter Wire

MEET 2008 MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY www.meetcongress.com

Table 1. Patient Characteristics

	Filter Group	MO.MA Group	p Value
Age (yrs)	69 ± 9	70 ± 6	NS
Male gender, n (%)	16 (76)	18 (86)	NS
Hypertension, n (%)	19 (90)	19 (90)	NS
Diabetes, n (%)	9 (43)	9 (43)	NS
Hyperlipidemia, n (%)	10 (48)	10 (48)	NS
Coronary artery disease, n (%)	15 (71)	16 (76)	NS
Symptomatic stenosis, n (%)	6 (29)	7 (33)	NS

Table 2. Lesion Characteristics and Procedural Data

	Filter Group	MO.MA Group	p Value
Grade of stenosis (%)	85 ± 8	86 ± 9	NS
Lesion length (mm)	11 ± 5	13 ± 4	NS
Calcification, n (%)	15 (71)	16 (76)	NS
Eccentricity, n (%)	11 (52)	12 (57)	NS
Ulceration, n (%)	7 (33)	6 (29)	NS
Contralateral stenosis ≥70%, n (%)	6 (29)	0 (0)	0.008
Contralateral occlusion, n (%)	2 (10)	0 (0)	NS
Macroscopic evidence of debris, n (%)	14 (67)	18 (86)	NS

No difference in pts and lesions' characteristics

Schmidt A et al. J Am Coll Cardiol 2004;44:1966-1969

Mo.Ma vs. EPI Filter Wire

Table 3. Number of Patients (%) with Detectable MES During the Different Phases of CAS

	Filter Group	MO.MA Group	p Value
Sheath placement-protection device placement	21 (100%)	21 (100%)	NS
Wiring of the stenosis	20 (95%)	6 (29%)	< 0.0001
Stent deployment	21 (100%)	11 (52%)	0.0003
Balloon dilation	21 (100%)	15 (71%)	0.008
Retrieval of the protection device	21 (100%)	21 (100%)	NS

Data are mean values ± SD or n (%).
CAS = carotid artery stenting; MES = microembolic signals; NS = not significant.

Schmidt A et al. J Am Coll Cardiol 2004;44:1966-1969

Mo.Ma vs. EPI Filter Wire

Table 4. MES Counts During the Different Phases of CAS

	Filter Group	MO.MA Group	p Value
Sheath placement-protection device placement	20 ± 15	18 ± 10	NS
Wiring of the stenosis	25 ± 22	2 ± 3	< 0.0001
Stent deployment	73 ± 49	11 ± 19	< 0.0001
Balloon dilation	70 ± 31	12 ± 21	< 0.0001
Retrieval of the protection device	14 ± 15	19 ± 15	NS
Total	196 ± 84	57 ± 41	< 0.0001

Data are mean values ± SD or n (%).
Abbreviations as in Table 3.

Schmidt A et al. J Am Coll Cardiol 2004;44:1966-1969

Mo.Ma vs. EPI Filter Wire

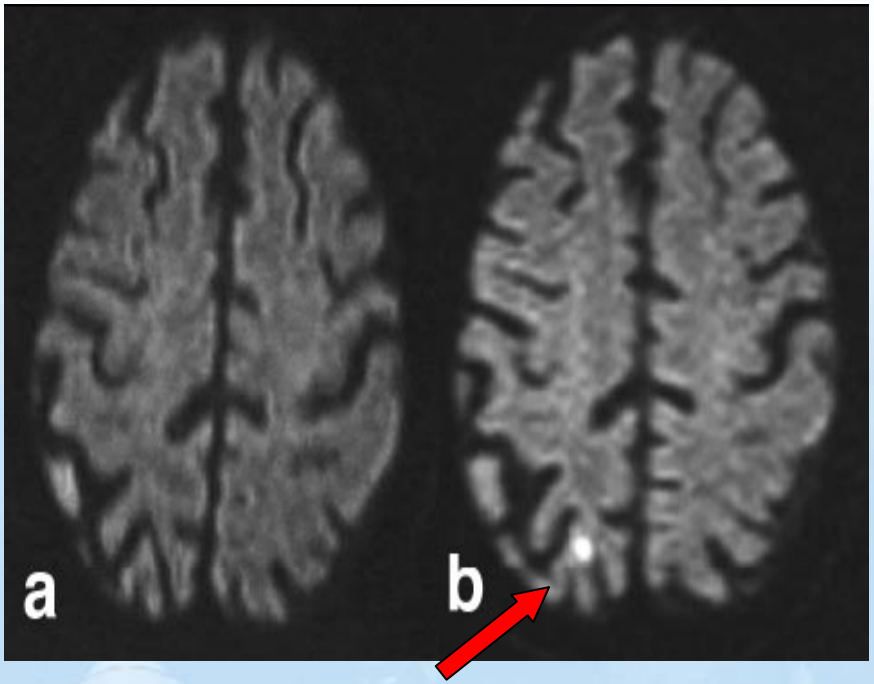
MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com

Limit of the study:

There were no significant differences in clinical or angiographic outcomes between the two groups.

Therefore……

Missed DWI MRI that could give an instrumental meaning to the reduced MES in the MOMA Group !!!



Silent cerebral embolism is appreciable at the corticalsubcortical

Schmidt A et al. J Am Coll Cardiol 2004;44:1966-1969

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com
BUILDING ENDOVASCULAR SYNERGIES

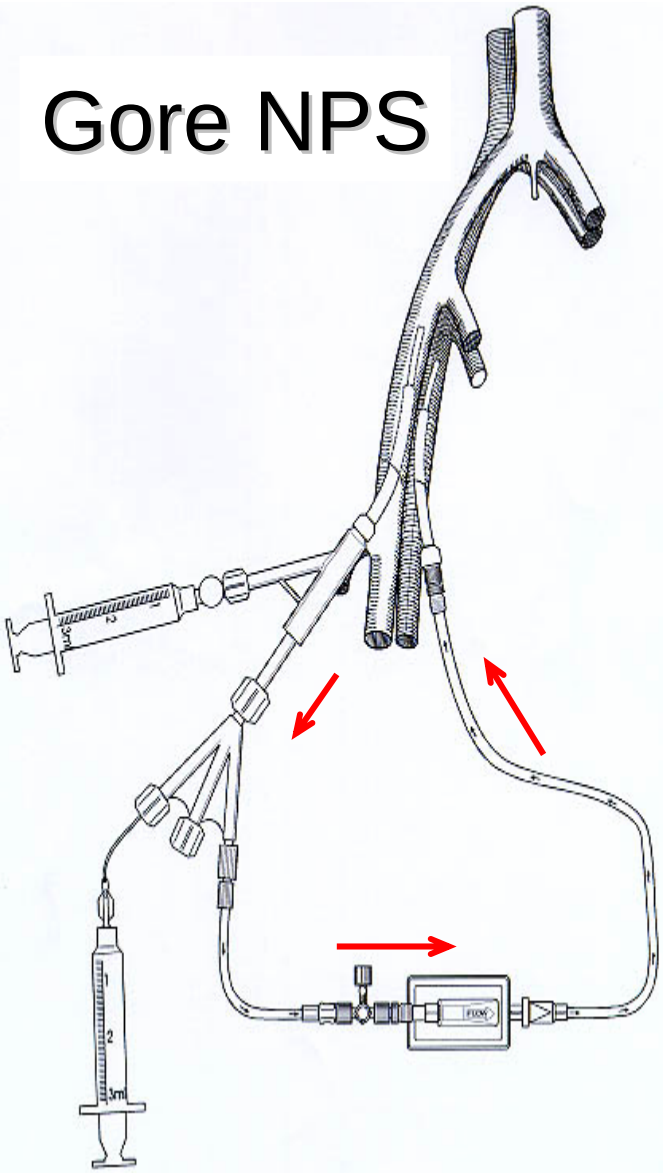
Diffusion Weighted-MRI based evaluation of the effectiveness of endovascular clamping during Carotid Artery Stenting with the Mo.Ma device.

- A prospective, multicenter study
- The DESERVE Study
- The detection of new ischemic lesions after carotid artery stenting by diffusion weighted magnetic resonance imaging (DW-MRI), using the endovascular proximal flow blockage (Mo.Ma device) for cerebral protection

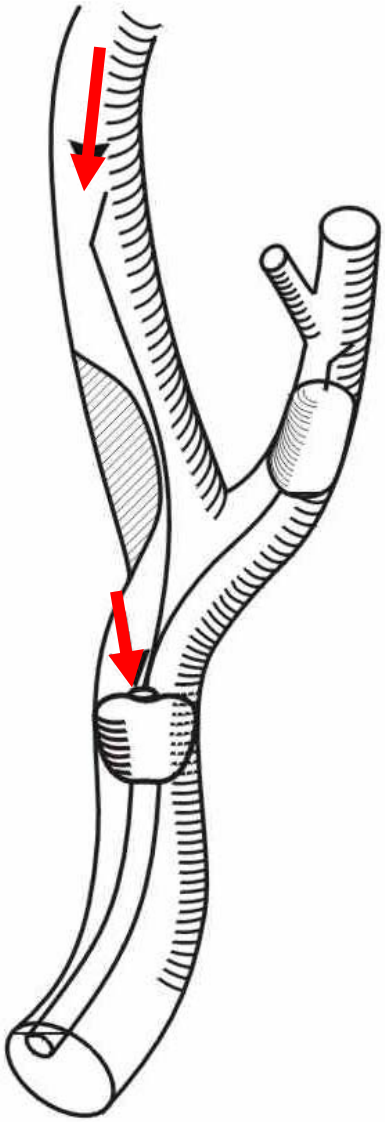
Gore NPS

- Occlusion balloon for the ECA comes separate from the guiding catheter
  - Distance between the occlusion balloons can be adjusted
- Guiding catheter is connected to a venous sheath (with filter in between)
  - Continous retrograde flow in the ICA

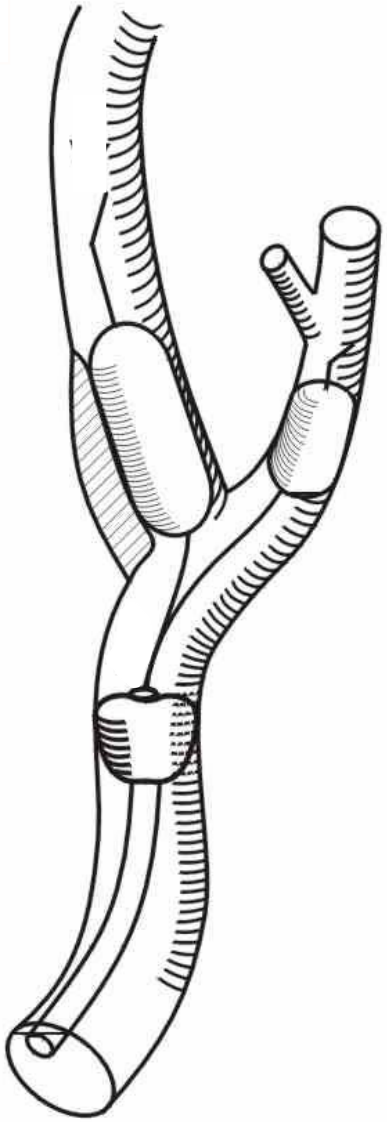
Gore NPS



Retrograde Flow via the guiding catheter

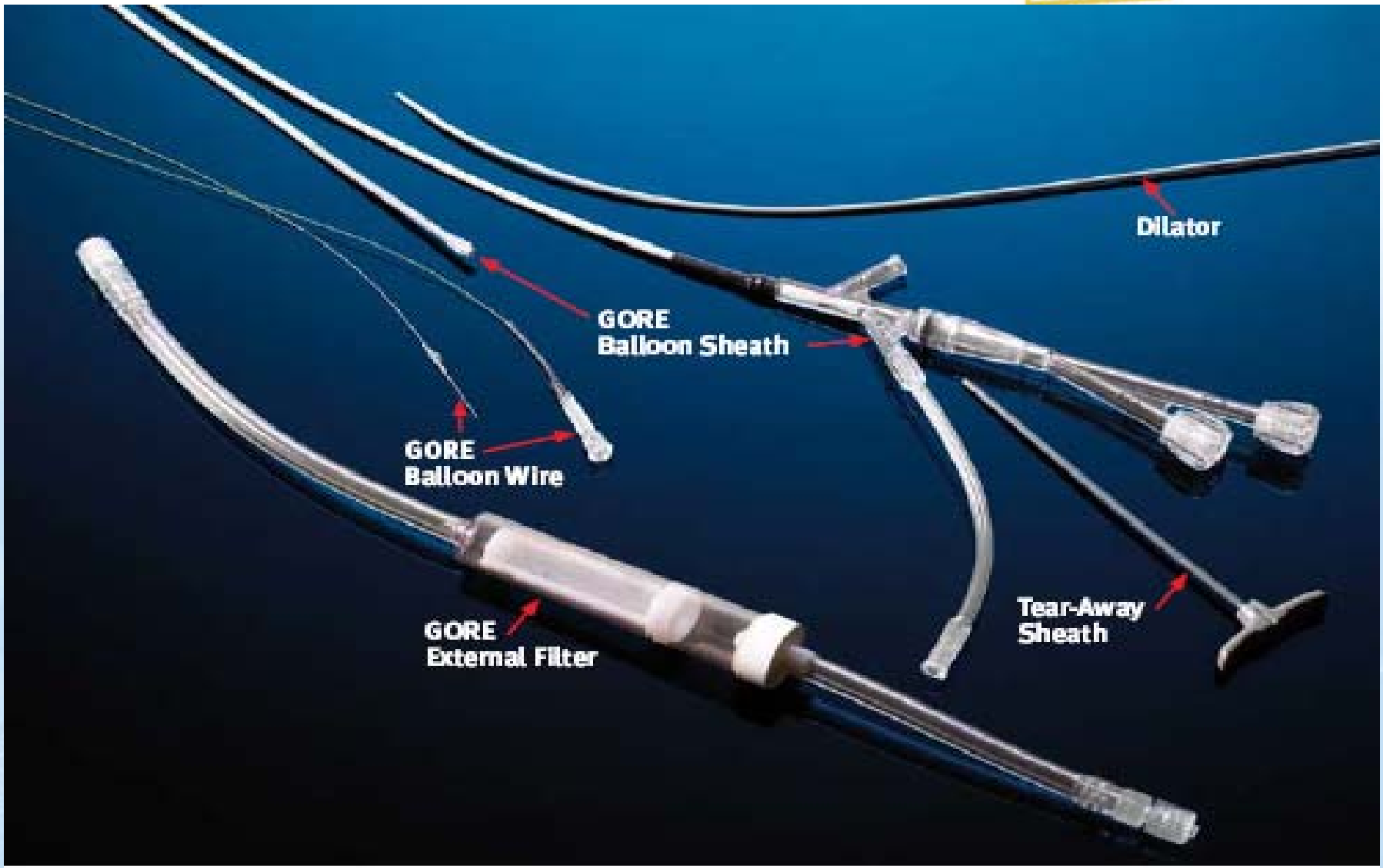


Lesion crossed



Balloon angioplasty

PARODI Neuro Protection System



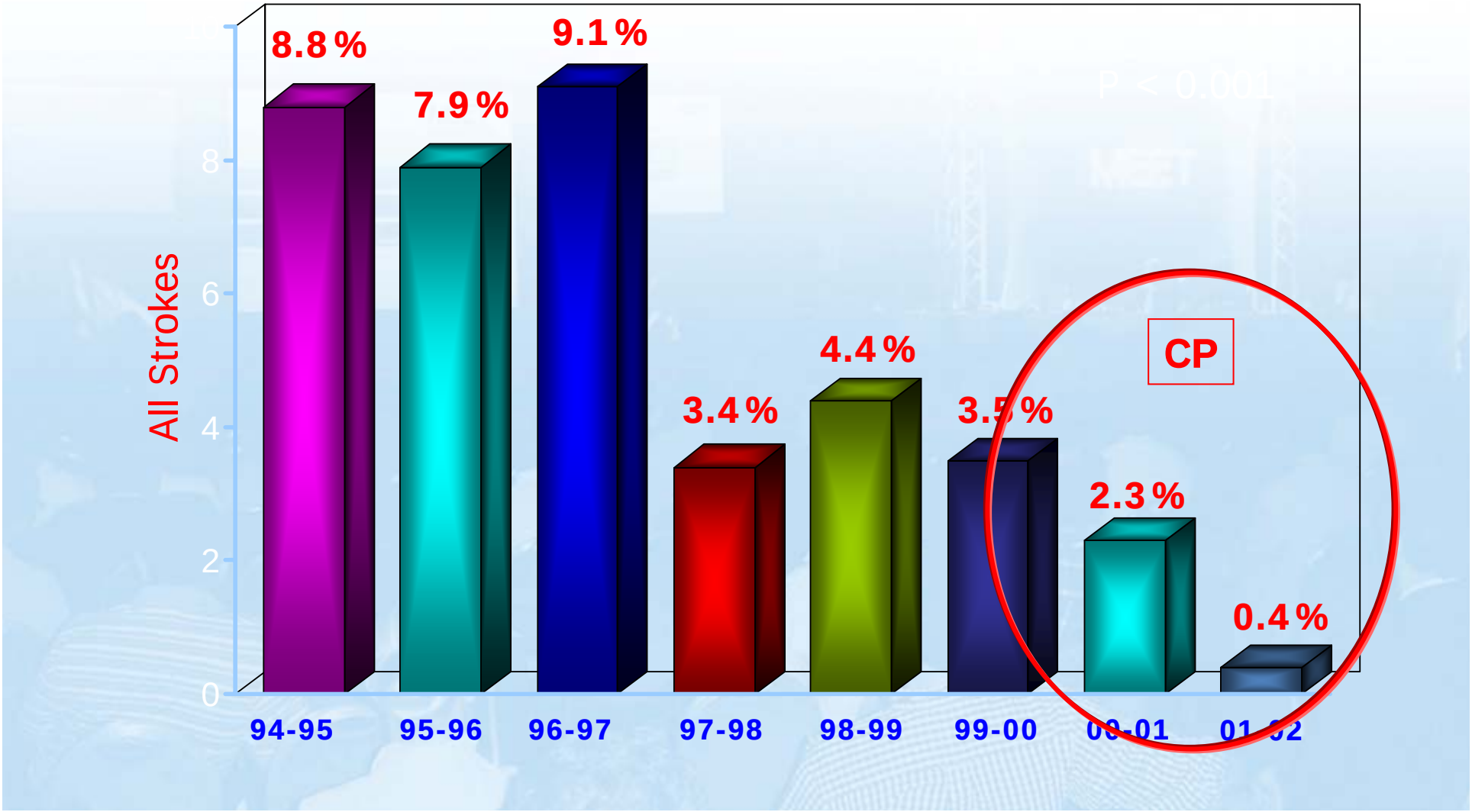
Advantages of Proximal Occlusion Devices

- Protection before crossing
- Wire of your choice
- No distal landing zone required
- No distal spasm, dissection
- Angiography possible during occlusion
- Small particles are kept back

Lennox Hill NY - Learning Curve: All Strokes

BUILDING ENDOVASCULAR SYNERGIES

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com



BUILDING ENDOVASCULAR SYNERGIES

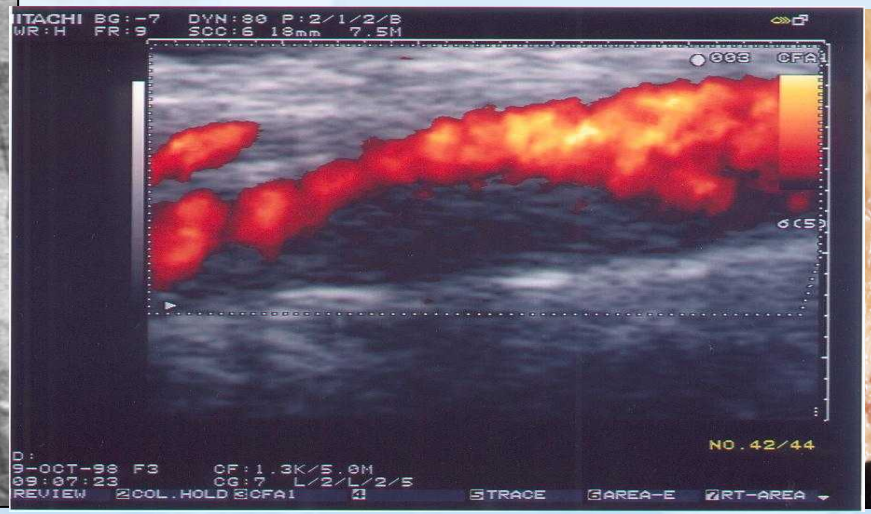
MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com

Why I'm afraid of occlusive devices

Carlo Cernetti
Cardiology Department
Mirano (Venice)

Cannes 28.06.2008

I’m afraid of Cerebral Embolazation!!



Conclusions 1

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com
BUILDING ENDOVASCULAR SYNERGIES

1)I'm afraid of embolazation!!!!!!!!!
This can change PERMANENTLY working and relation life of PTS

2)Clinical and Angiographical Echo and MRI characteristic are the best "guide" in choosing the appropriate EPD for "That Patient " ….

3)Training is fundamental to low complication rate

Conclusions 2

BUILDING ENDOVASCULAR SYNERGIES

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com

4)Selection of the device depends on anatomic features and on the operators experience with the single device

5)Device related complications are low but can be severe in unskilled hands

Don’t forget Cerebral Protection is Important!!!

BUILDING ENDOVASCULAR SYNERGIES

MEET 2008
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY
www.meetcongress.com

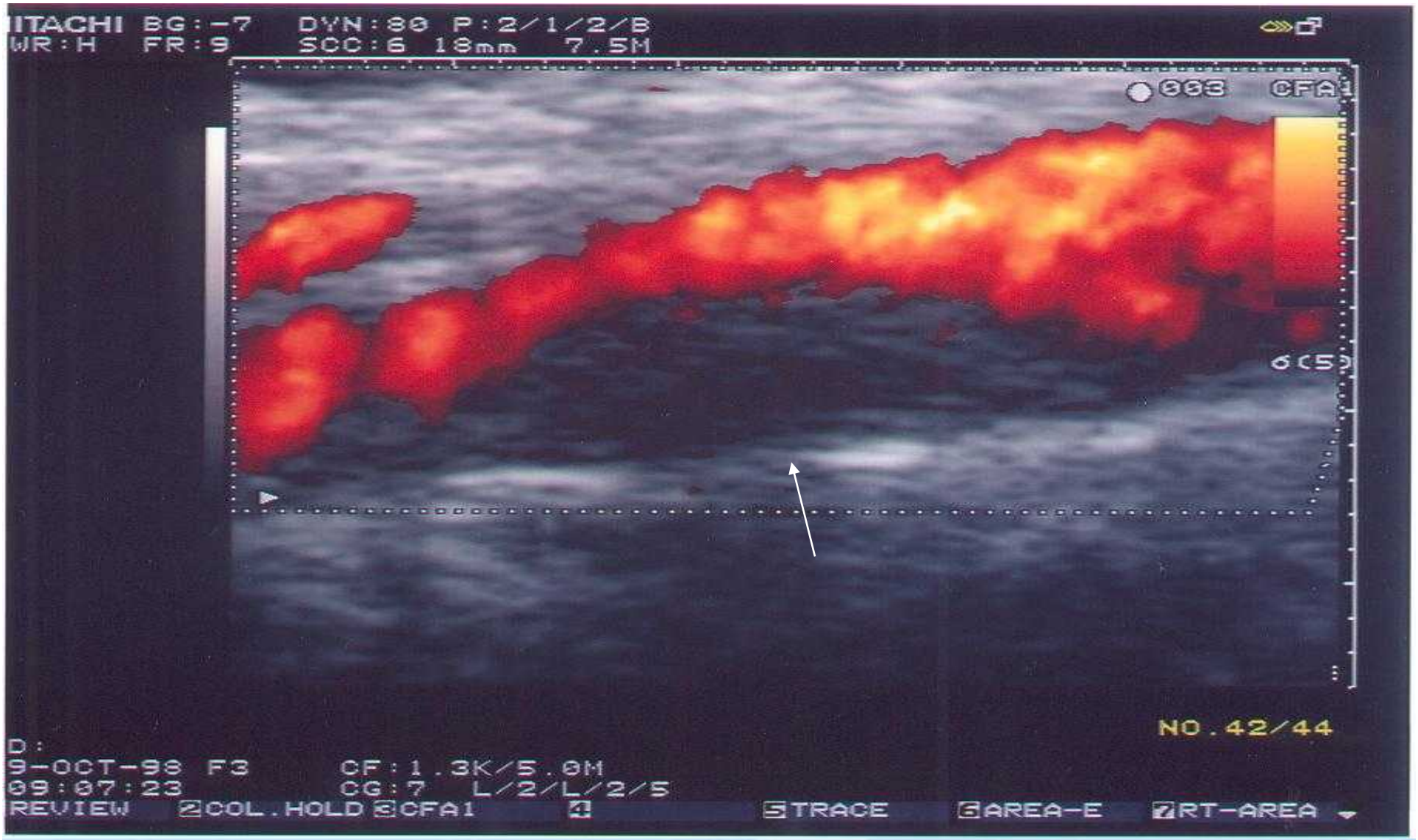
Thanks a lot for your Attention

BUILDING ENDOVASCULAR SYNERGIES

MEET 2008

MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

www.meetcongress.com



Echo-plaque complexity:hypoechogenic