FUNDACIÓN FAVALORO
HOSPITAL UNIVERSITARIO

How to select the Most Appropriate Device for CAS?

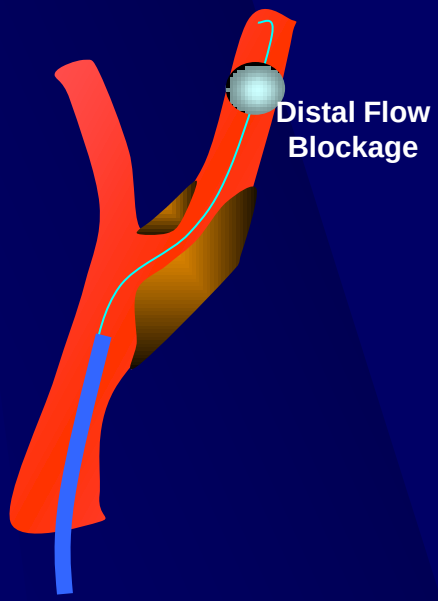
Oscar Mendiz. MD. FACC. FSCAI
Head Interventional Cardiology Department
Board of Directors Members
Hospital & Favaloro University

Cerebral Protection During CAS

- Multifactorial:
- **Operators** (training, experience, multidisciplinary team, etc.)
- **Patients selection** (Symptoms, age, DBT, plaque characteristics, aortic arch, bilateral disease, medications, previous lacunar defects, etc, etc).
- **Carotid Angioplasty Technique** (carotid engagement, wires, guiding, balloons, pre & post dilatation, post PTA care, radial approach, etc)
- **Cerebral Protection Devices. Which one for which lesion.**
- **Stent Design** (Closed vs. open cell ?)

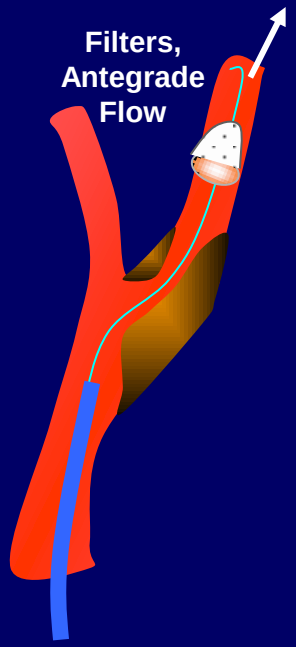
Cerebral Protection Strategies

Distal Flow Blockage by ICA Occlusion



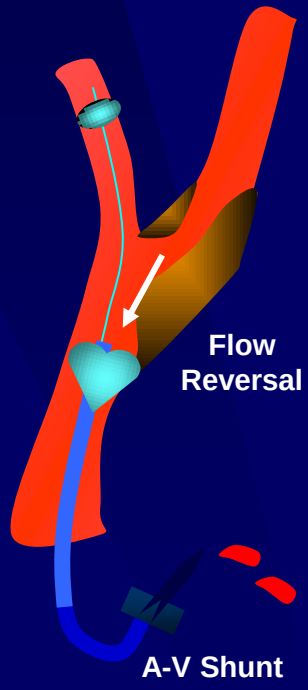
Guardwire Plus
Twin One

Distal ICA Filtering



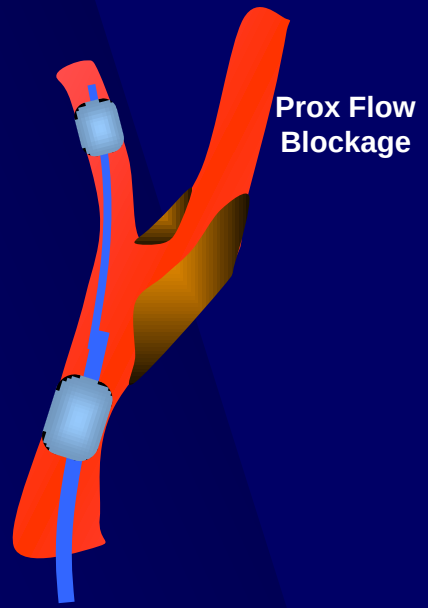
Filters

Flow Reversal by CCA and ECA Occlusion



Gore device

Proximal Flow Blockage by CCA and ECA Occlusion

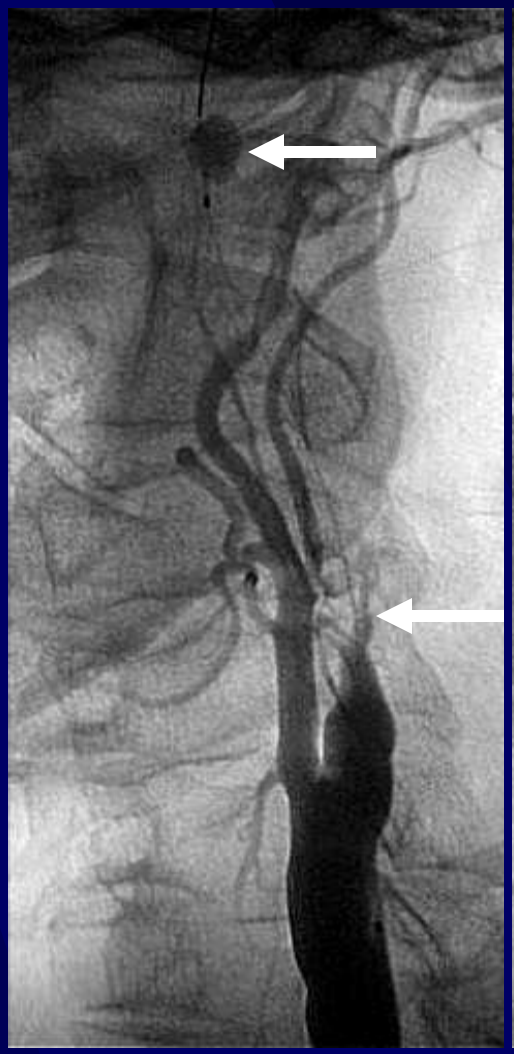


MOMA

Cerebral Protection Devices & Personal Experience

- **Distal Occlusive Balloon:**
  - Theron System.
  - GuardWire Plus. PercuSurge™. *Medtronic.*
  - Twin One. Mynvasis
- **Filters:**
  - Filter Wire EZ ™. *Boston Scientific.*
  - Angioguard ™. *Cordis J&J.*
  - Spider ™
  - Accunet ™. *Abboth*
  - EmboShield ™. *Abboth.*
  - Rubicon. *Boston Scientific.*
  - Others.
- **Reversal Flow and Flow Blockage:**
  - PAES ®. Parodi Anti-Embolism System. *Gore*
  - MOMA. *Medtronic.*

Distal Occlusive Balloons: GuardWire Plus



N=68

SOLACI

Fundación Favaloro

PercuSurge GuardWire System.

Fundación Favaloro Experience. *O Mendiz, et al.*

Distal Occlusive Balloons

- **Advantages:**

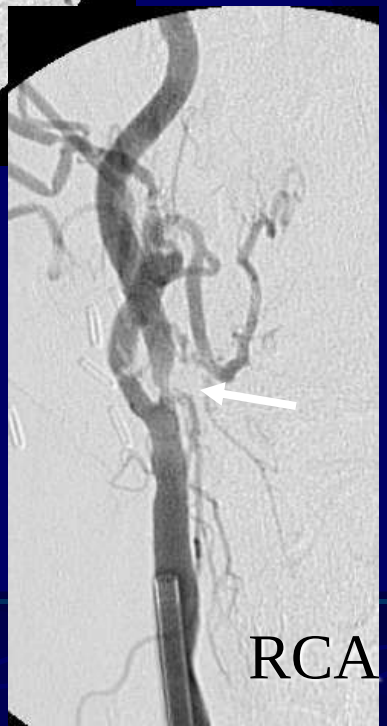
  Low profile.
  Block all possible particles embolization after crossing

- **Disadvantages:**

  Stop ICA flow while inflated (~ 4-5%
  Particles dislodgement
  Potential
  flush can embolize particles through the EC.
  Wire's lack of support (Guardwire plus).
  Not friendly to use (Guardwire plus)
  Stenting without protection (TwineOne)

If you are going to block the flow; Proximal is better

Distal Occlusive Balloons



Not Good Candidates:

- Contralateral occlusion or critical stenosis.
- Willis' Circle abnormalities.
- Subtotal obstructions

Tortuous ICA.

High or intracraneal lesions.

Beginners.

Filter Devices

- Over-the-wire Filters:

Advantage: easy to cross tight lesion and curves with bare wires.

Disadvantage: more steps for using.

- On-the-wire Filters:

Advantage: One step positioning

Disadvantage: Difficult to cross very tortuous vessel or tight lesions.

Filter Devices

- Concentric Filters:


Disadvantage: they need an straight landing zone. More rigid.

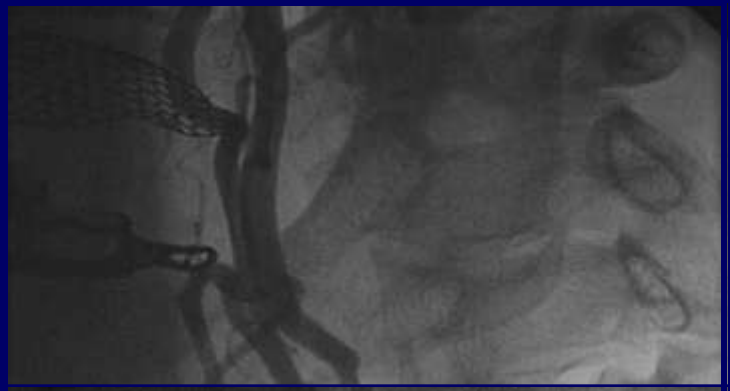
- Eccentric Filters:

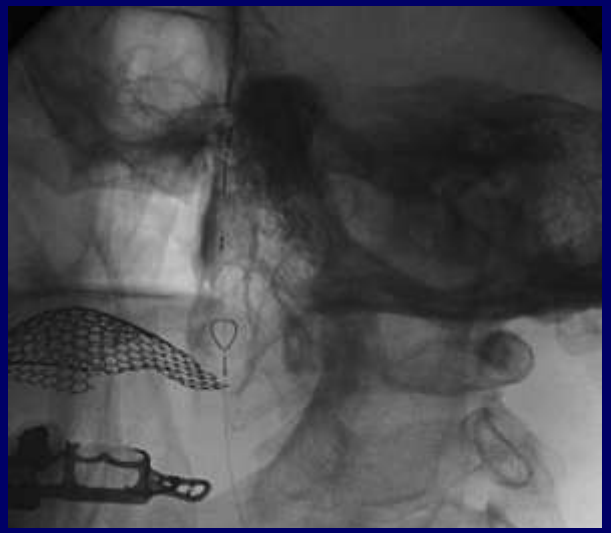
- Self Centering Filters:


Advantage: shorter straight landing zone. More flexible. Better artery wall appositioning.

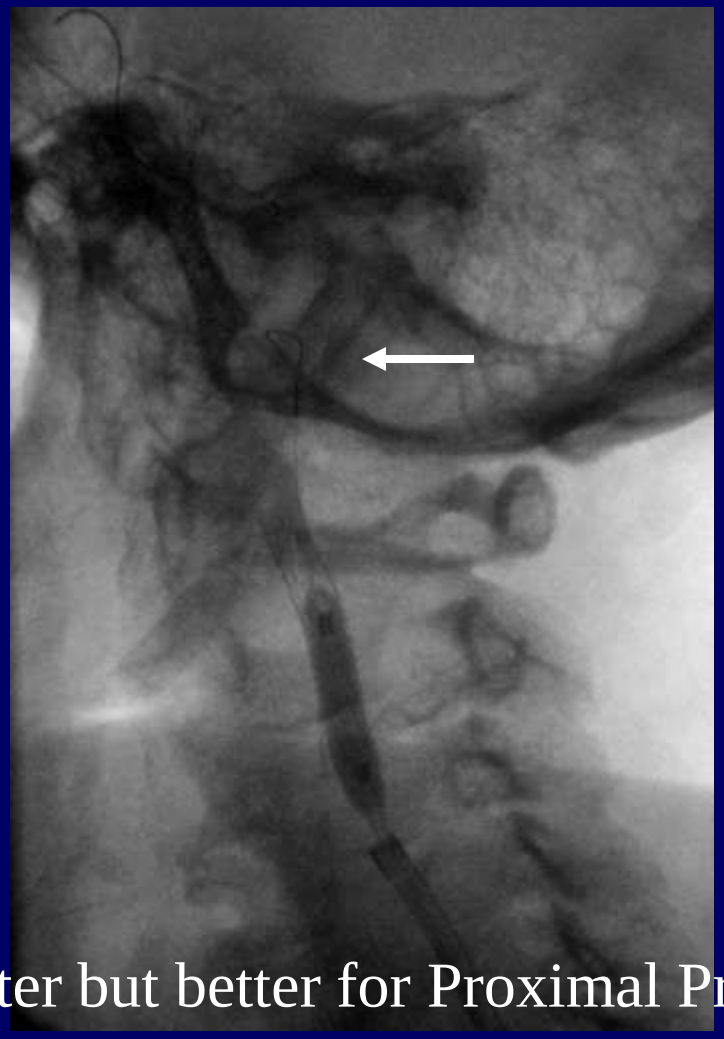
EPI Filter Wire

Long lesions at CCA & ICA





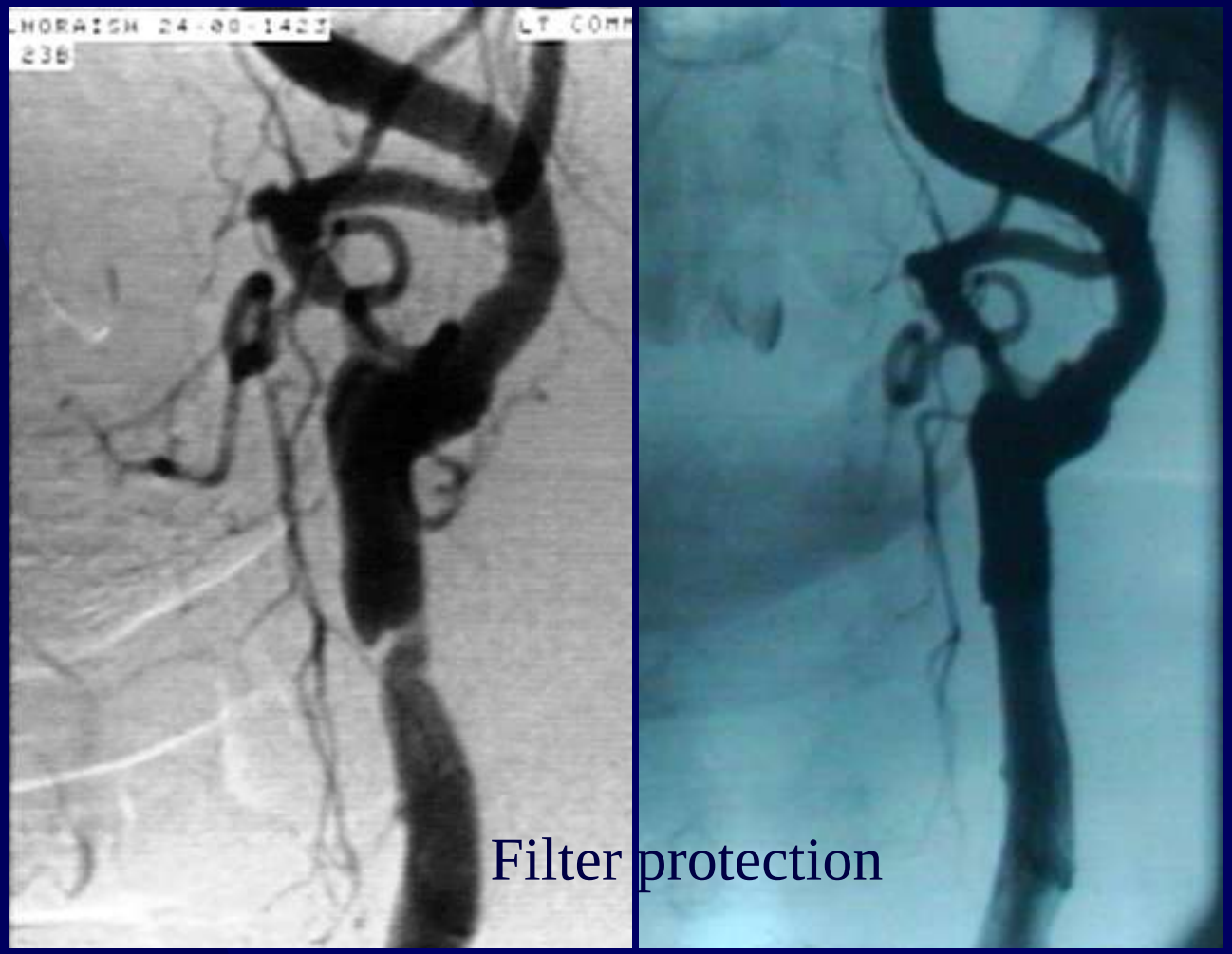
EPI Filter Wire



Done with filter but better for Proximal Protection Device

N=63

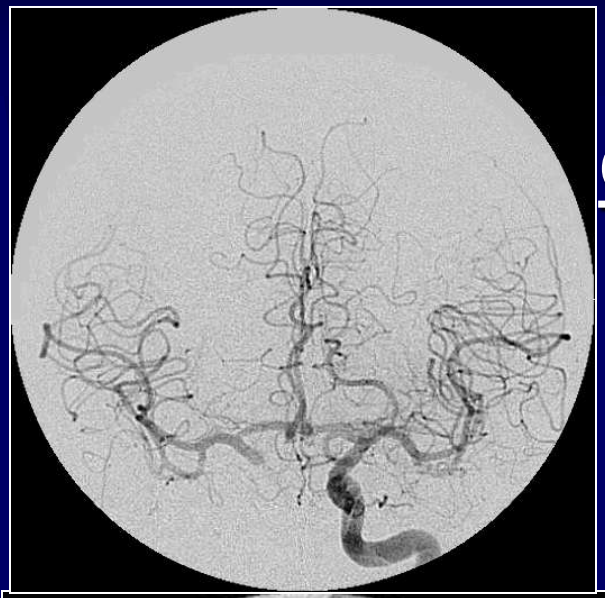
Second Surgical Restenosis post CEA:



Filter protection

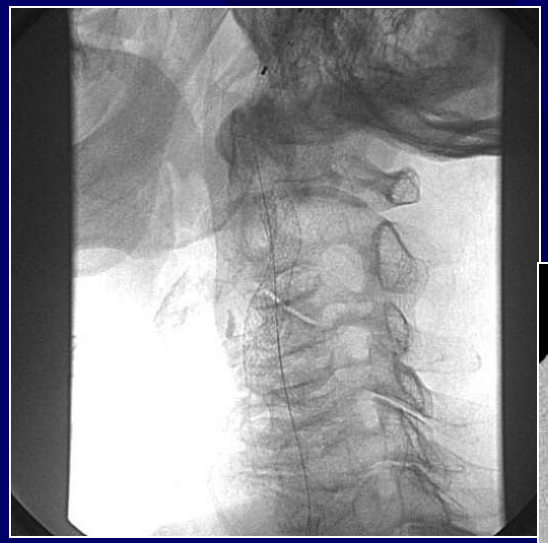
Straight Vessel, Concentric & Fibrotic Plaque; Ideal for Filter

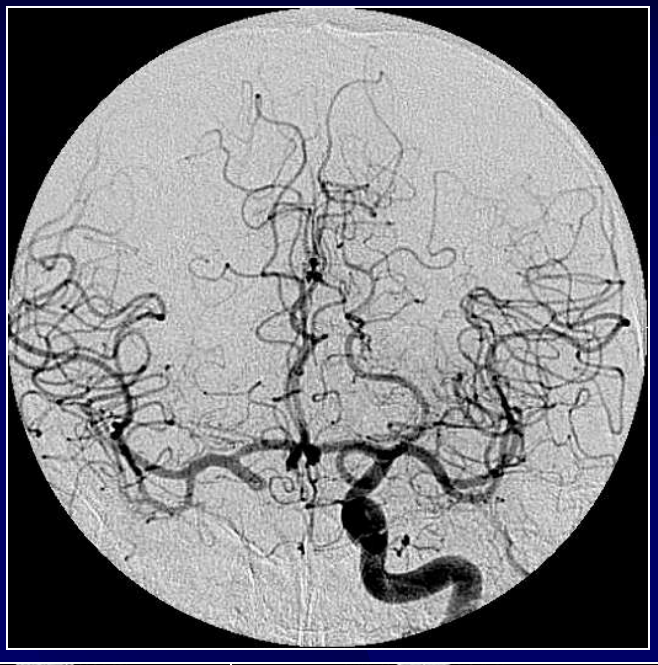
Angioguard + Precise
36174



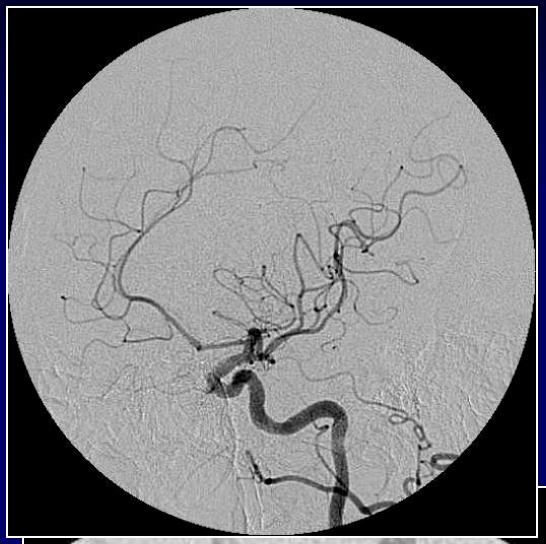
Ulcerated lesion but Contralateral Occlusion

Easier with filter





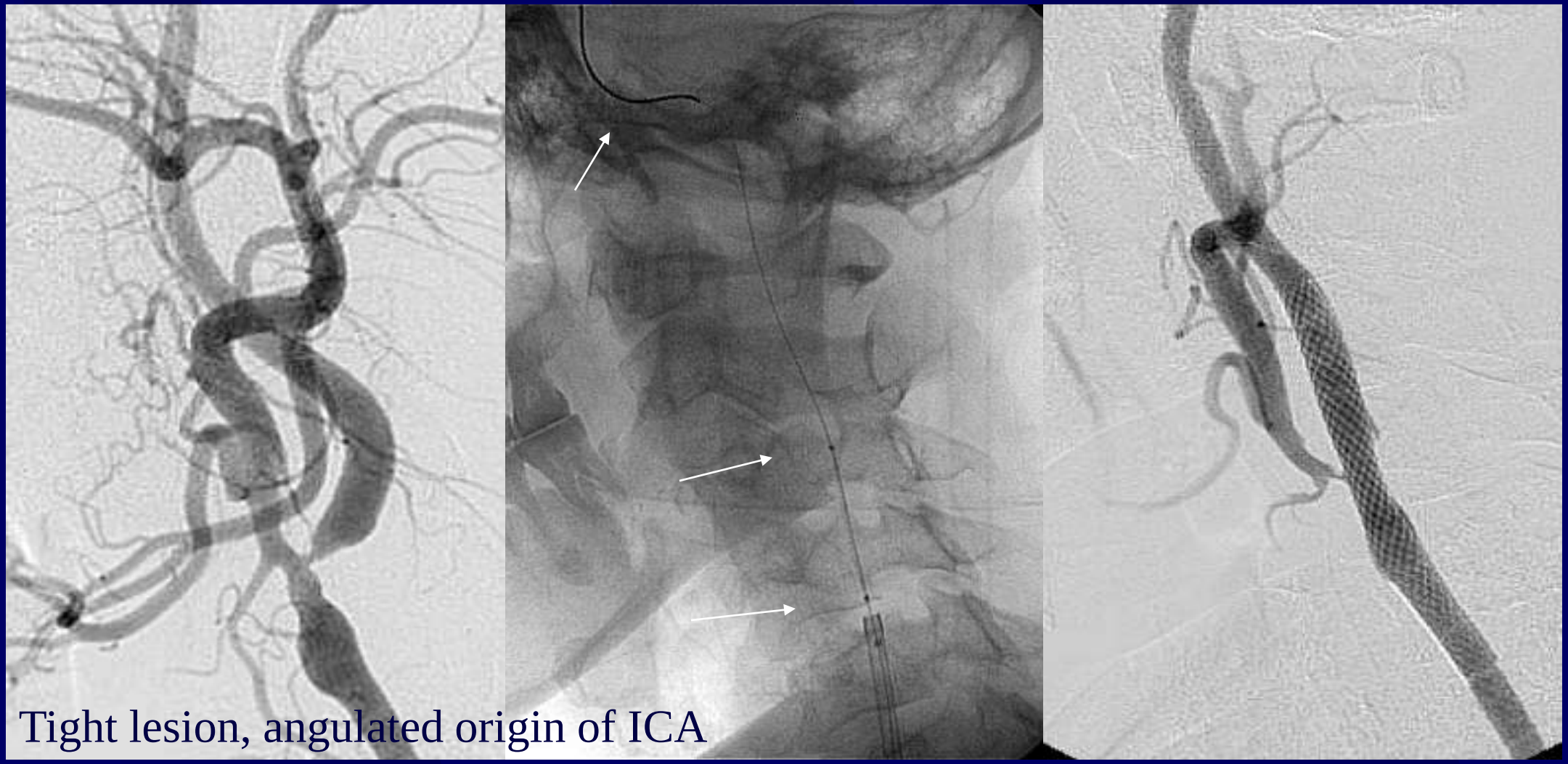
Filter (angioguard)
Close Cell or Microcel Stent



Soft, eccentric, ulcerated plaque at the bifurcation

Filter + Closed Cell Stent

Proximal Occlusion or Over the Wire Filters

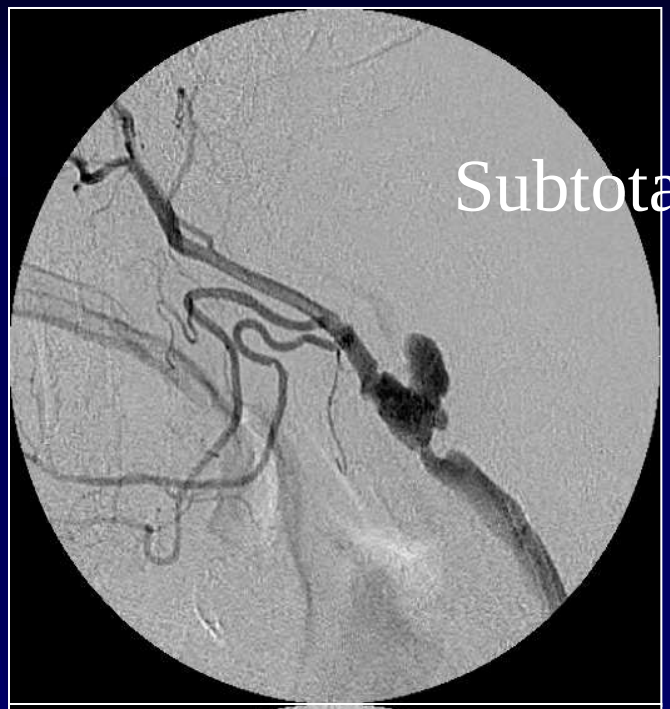


Tight lesion, angulated origin of ICA

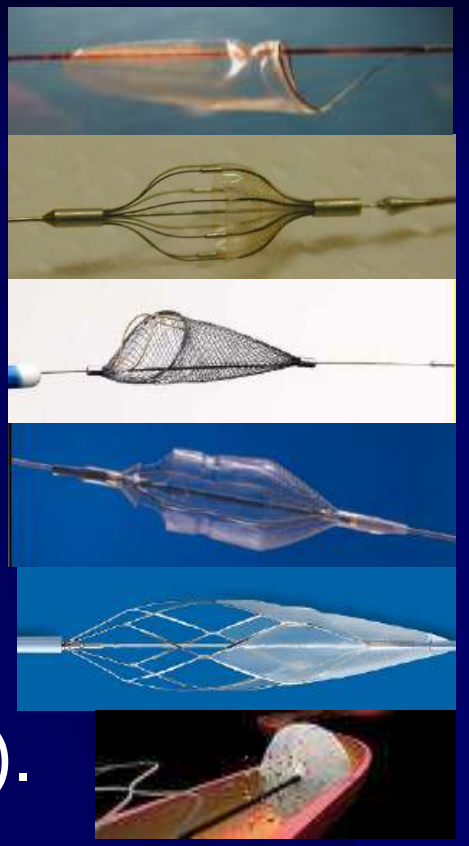
Better for over the wire filter (Emboshield-Spider)

Subtotal occlusion with plaque at the CCA

Filter ?? + Closed Cell St



Filter Devices



- **Advantages:**
  Maintain the ICA flow.
  Easy to use.
  Profile ?.

- **Disadvantages:**

  Allow small particles flow (±80-120 mμ).

  Particles dislodgement when crossing.

  Potential trauma at distal landing zone. *(dissection or spasm where the filter is deployed).*

  Profile ?.

  Flexibility ?

Crossing Failure: Epi Filter Wire

- Failure to cross the lesion:

Failure to cross the lesion: EpiFilter (BSC) & Roadrunner .018” (Cook)
It was crossed with a coronary guidewire (BMW .014”.Guidant)

Crossing Failure

"On the wire"

"Over the wire"

44845

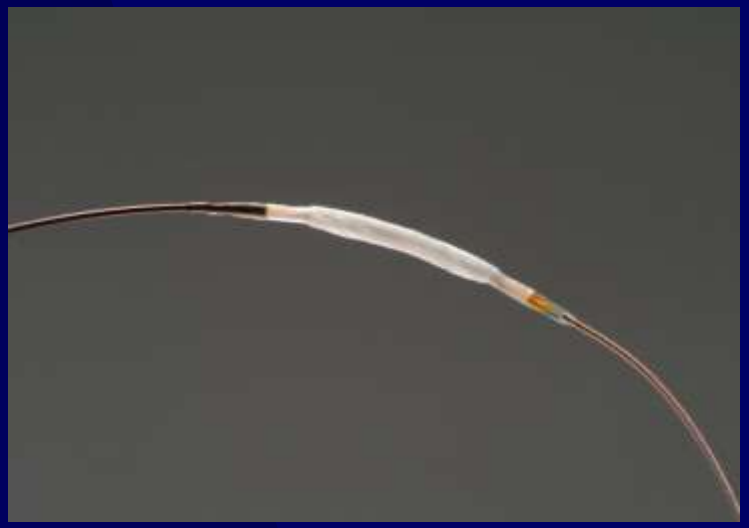
Ideal Case for Proximal Protection Device

Distal Protection Device Complication:

Distal nInternal Carotid Artery Dissection

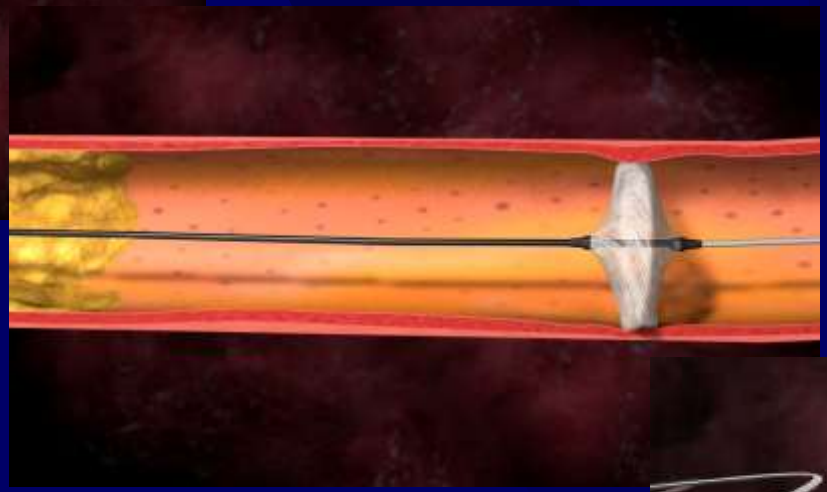
EPIC FiberNet Embolic Protection System

FiberNet® system is a novel EPD that incorporates the ability to allow flow during the procedure (filter), capability to capture small particles (occlusion balloon) and has deliverability of standard coronary guidewire.

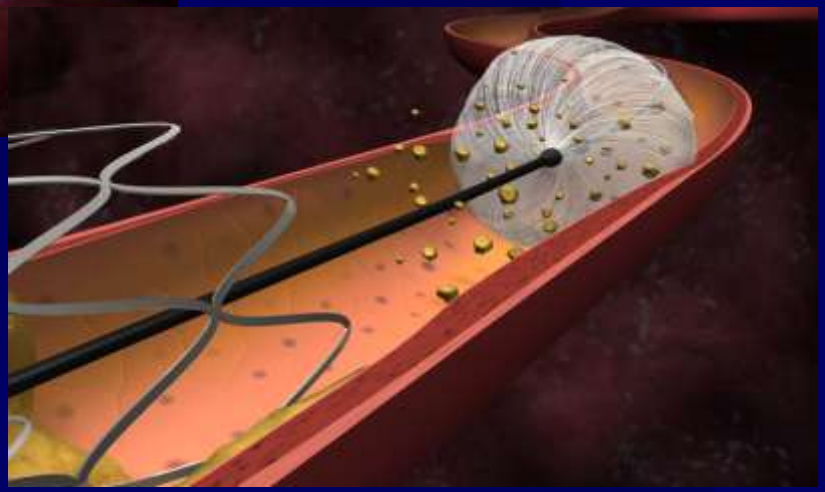


EPIC FiberNet® EPS

No delivery system required
with a crossing profile
1.7 to 2.9 F

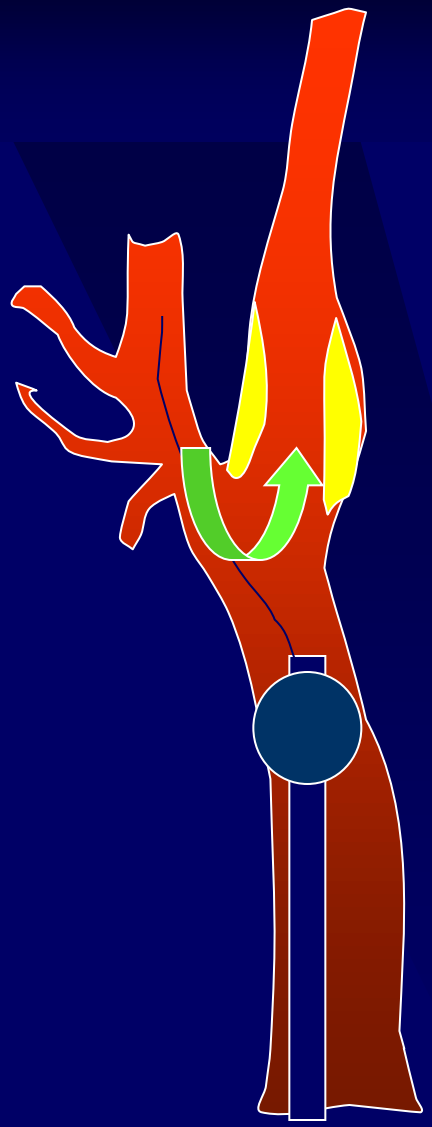


Fiber-based filter conforms to
asymmetrical vessels

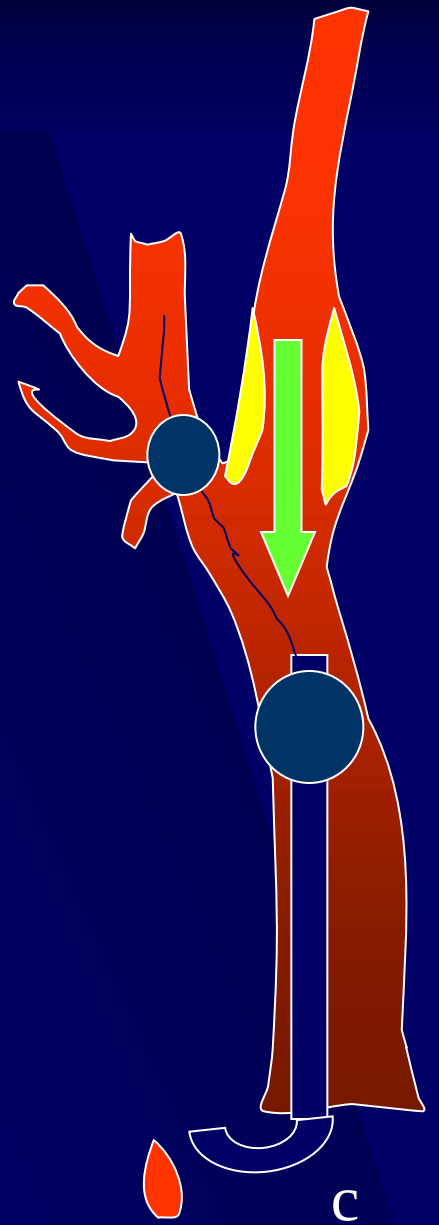


Particle entrapment as
small as 40 µm

a



b



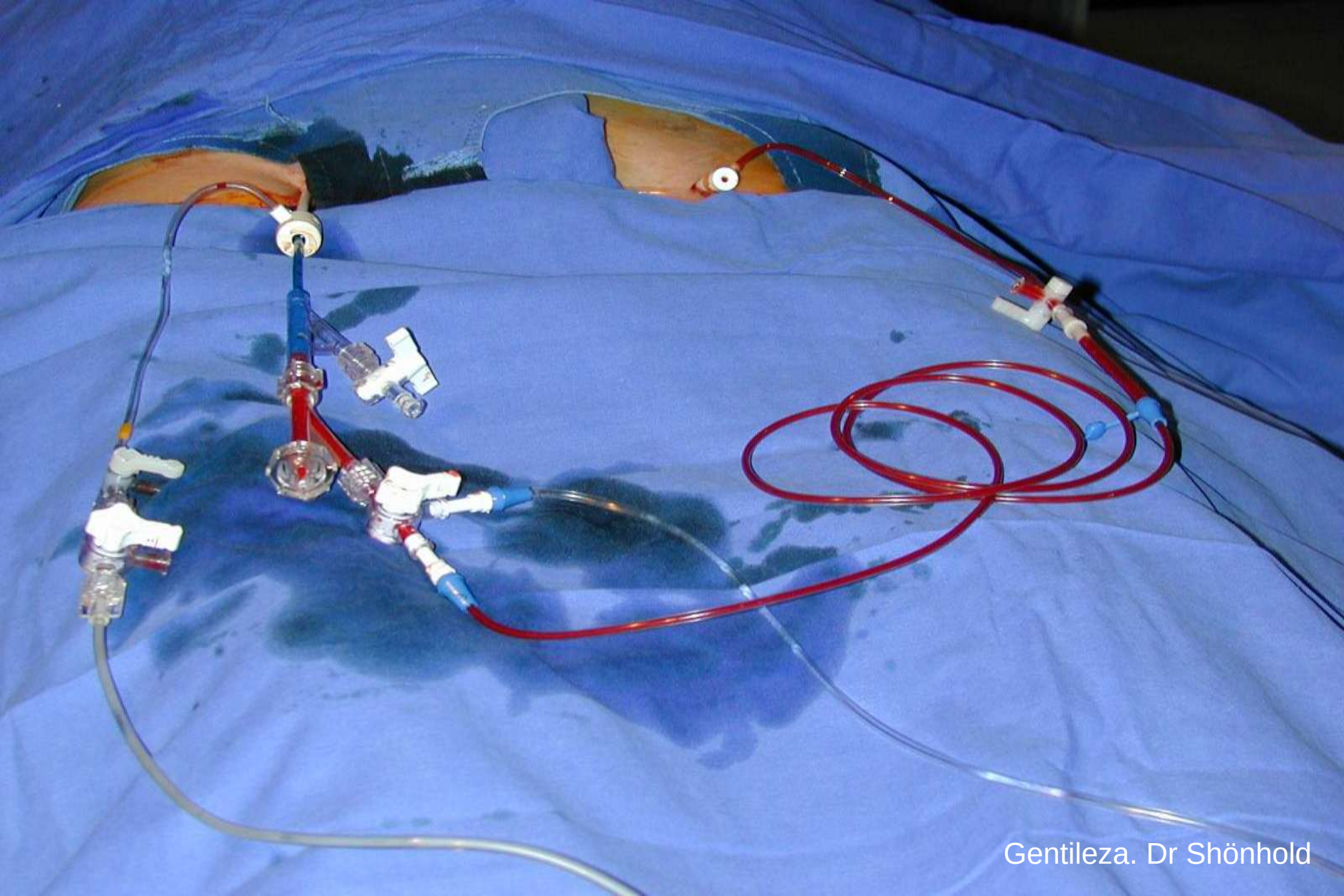
c

Retrograde flow from the external to internal carotid artery

Gentileza Dr. Parodi

SOLACI

Fundación Favaloro

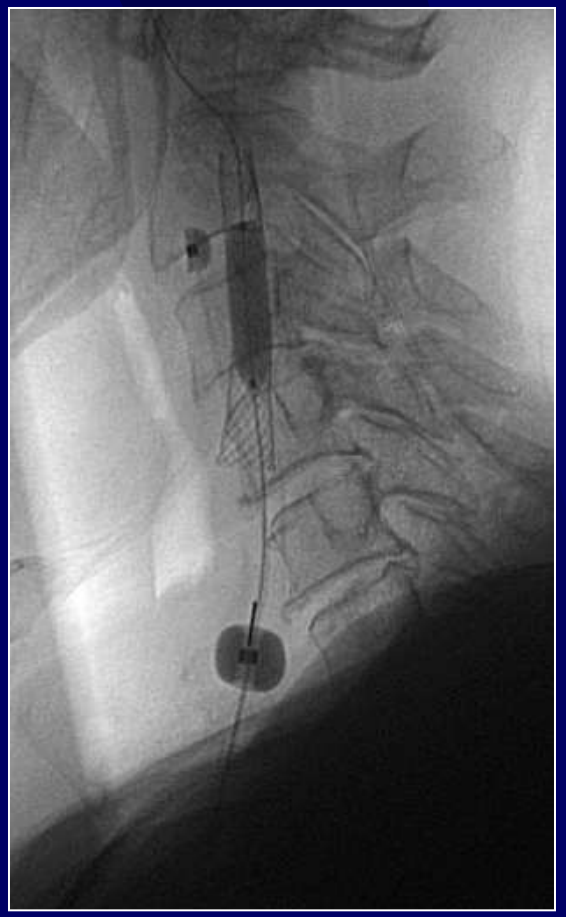

Gentileza. Dr Shönhold

Rationale for Proximal Protection Devices

- Pass lesions unprotected (balloon-filters)
- Unreliable wall apposition (filters)
- Emboli passing through the filter
- Need for suitable landing zone (balloon-filter)
- Potential trauma to the landing zone (balloon-filter).
- Difficult to negotiate tortuous anatomies, tight lesions.

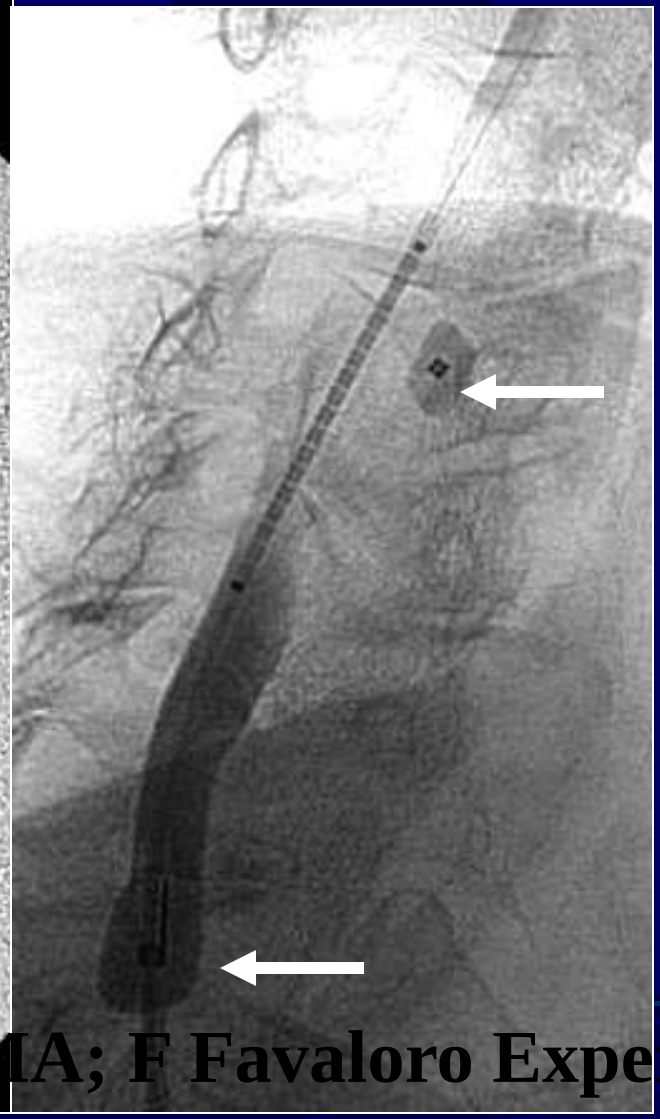
Main Indication:

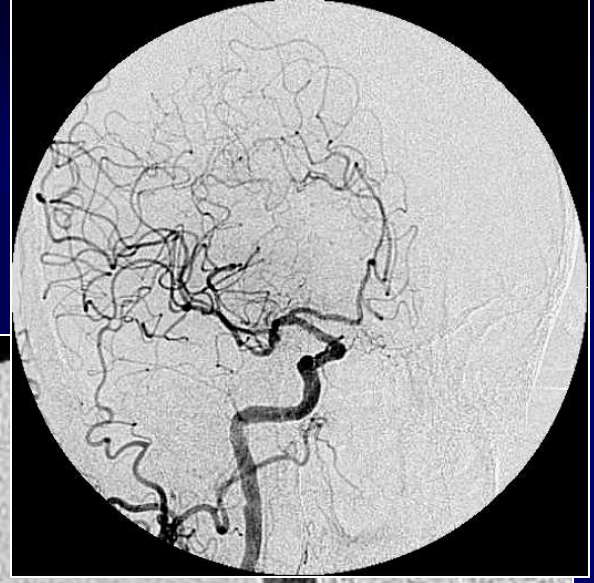
Soft, tight, eccentric plaque without bifurcation compromise and good contralateral circulation



3
9
1
0
2

Soft, tight, eccentric plaque without bifurcation compromise and good contralateral circulation





MOMA; F Favaloro Experience

Spontaneous ICA Disection

Proximal Flow Blockage

Proximal Protection Devices

- First choice for:
  - Soft ulcerated plaque ?
  - High lesions
  - Critical stenosis
  - Intracraneal associated lesions
  - Lack of distal landing zone for DPD (tortuosity, lesion, high plaque, etc).

Protection Devices Differences

- **Reversal Flow / Flow Blockage Systems :**
- **Advantages:**

  Lesions are crossed under protection.

  No particles embolization through ECA.
- **Disadvantages:**

  Can not be well tolerated *(contralateral disease, Willis circle abnormalities)*

  Difficult to use at bifurcational lesions.

  Potential dissection, spasm or trauma where the balloon is inflated.

  Look unfriendly to use.

Which Protection Device is Better?

- Lack of appropriate level of evidence.
  - Not adequate randomized trial.
  - Most of the information provided by single center, small, industry sponsored or based on operators experience.
- However, different patients and lesions seem to be better approached by an specific device based on operators experience and device .

Finol et al. J Endovasc Ther 2008;15:177-185.
El-Koussy et al. J Endovasc Ther 2007;14:293-303
Iyer V, et al. J Vasc Surg 2007;48:251-258

◆ CLINICAL INVESTIGATION — J ENDOVASC THER 2008;15:249–262

Carotid Artery Stenting With Patient- and Lesion-Tailored Selection of the Neuroprotection System and Stent Type: Early and 5-Year Results From a Prospective Academic Registry of 535 Consecutive Procedures (TARGET-CAS)

Piotr Pieniazek, MD, PhD[1]; Piotr Musialek, MD, PhD[1]; Anna Kablak-Ziembicka, MD, PhD[1]; Lukasz Tekieli, MD[1]; Rafal Motyl, MD, PhD[2]; Tadeusz Przewlocki, MD, PhD[1]; Zbigniew Moczulski, MD[3]; Mieczyslaw Pasowicz, MD, PhD[3]; Andrzej Sokolowski, MD, PhD[4]; Agata Lesniak-Sobelga, MD, PhD[1]; Krzysztof Zmudka, MD, PhD[5]; and Wieslawa Tracz, MD, PhD[1]

What Practical Factors Guide the Choice of Stent and Protection Device during Carotid Angioplasty?*

M. Bosiers,[1*] K. Deloose,[1] J. Verbist[2] and P. Peeters[2]

Eur J Vasc Endovasc Surg 35, 637–643 (2008)

The importance of angioplasty and stenting in the treatment of carotid artery disease cannot be underestimated. Successful carotid stenting does not only depend of the operator's skills and experience, but also an adequate selection of cerebral protection devices and carotid stents can help avoiding neurological complications. A broad spectrum of carotid devices is cur-

Safety, efficacy and long-term durability of endovascular therapy for carotid artery disease: the tailored-Carotid Artery Stenting Experience of a single high-volume centre (tailored-CASE Registry)

EuroIntervention 2009;5:589-598

Alberto Cremonesi[1]*, MD; Shane Gieowarsingh[2], MBBS; Barbara Spagnolo[3], PhD; Raffaella Manetti[1], MD; Armando Liso[1], MD; Alessandro Furgieri[1], MD; Maria Cristina Barattoni[3], MSc; Luca Ghetti[3], MSc; Luigi Tavazzi[4], MD; Fausto Castriota[1], MD

Tailored CAS: Protocol for Patient- and Lesion-Specific Selection of the Neuroprotection System and Stent Type

General direct stenting strategy	Predilate only if very tight or highly calcified lesion according to duplex ultrasound, CTA, and angiography.
Soft/thrombus-containing plaque or a severe string-sign lesion in a symptomatic patient (Fig. 1A1, 1B, 1E)	(1) Use a proximal NPD [flow reversal if (non-critical) ECA stenosis or severe angulation that precludes the use of a (one-piece) proximal flow blockade system]; if no ECA stenosis/tortuosity, either of the 2 proximal systems can be used. (2) Use a closed-cell stent (cobalt-alloy braided in a straight segment; nitinol if tortuous).
Soft/thrombus-containing plaque or a severe string-sign lesion in a symptomatic patient with access vessel (severe iliofemoral atherosclerosis) or target vessel anatomy precluding the use of proximal NPD (e.g., severe ECA stenosis or diffuse CCA disease or severe CCA stenosis at the bifurcation)	Use an independent-wire filter with 1.25- to 1.5-mm balloon dilation prior to filter delivery or a 6-F–compatible distal occlusion system.
Severe ICA angulation/tortuosity at bifurcation or severe calcifications (Fig. 1D)	Use an open-cell stent.
Soft/symptomatic lesion coexisting with a severe ICA angulation/tortuosity	Consider a hybrid (open-cell/closed-cell/open-cell) stent.*
Severe calcifications on CT angiography	Consider cutting balloon predilation; avoid aggressive postdilation.
Non-severe echogenic or fibrotic/partly calcified asymptomatic lesion	(1) Use a distal NPD (Fig. 1A2). (2) Use open- or closed-cell stent (depending on the target segment tortuosity).
Bilateral ICA stenosis (Fig. 1A)	(1) Consider treating the less severe lesion with distal NPD first. (2) If the contralateral lesion is tight/soft/symptomatic, treat it under proximal NPD (within a few days).
Severe ICA/CCA diameter mismatch	Consider using a tapered (nitinol) stent.
Lack of optimal landing zone for a filter (Fig. 1B, 1D)	Use a proximal NPD; if not applicable (no femoral access, diffuse iliofemoral atherosclerotic disease, or severely angulated arch), use a distal occlusion system.
Lack of femoral access	Use a transradial or brachial approach with a 6-F–compatible filter or distal occlusion system.
Critical stenosis (particularly if symptomatic) + contralateral ICA/CCA occlusion (Fig. 1C)	(1) Consider proximal NPD (document collateral supply via the basilar and posterior communicating artery(-ies) on TCD). (2) If proximal NPD excluded, use an independent-wire filter with 1.25 to 1.5-mm balloon predilation prior to filter delivery (Fig. 1C). (3) Use a closed-cell stent.

J ENDOVASC THER
2009; Dec, 16/6/744
P Pieniazek, et al.

J ENDOVASC THER
2008;15:249–262
TAILORED CAROTID ARTERY STENTING
Pieniazek et al.

Kraków experience: Tailored CAS, Pieniazek & multidyscyplinarny team

1717 CAS procedures (01.2001 - 11.2012)
1549 pts; (50.1%) symptomatic

675 high risk lesion - 39.3%

PROXIMAL EPD in 618 CAS (35.9%)
In 2012 53% !

Kraków experience: Tailored CAS, Pieniazek & multidyscyplinarny team

1717 CAS procedures (01.2001 - 11.2012)
1549 pts; (50.1%) symptomatic

	Proximal NPS (618 CAS)	distal NPS (1099 CAS)	p
High-risk lesion	**92.1%**	**9.7%**	p<0,001
Direct stenting	**29.8%**	**63.7%**	p<0.001
Closed-cell-design stents	**83.8%**	**68.1%**	p<0.001
Residual stenosis by QCA	11 ± 9% (0-40)	10 ± 8 (0-30)	NS
Restenosis >50% (US, CT)	1.7%	2.1%	NS

Kraków experience: Tailored CAS, Pieniazek & multidyscyplinarny team

1717 CAS procedures (01. 2001 - 11. 2012)
1549 pts (50.1%) symptomatic

RESULTS 30-days	Proximal protection	Distal protection	
No. of CAS	618	1099	
death	0.48% (3/618)	1.0% (11/1099)	p=0,254
major/disabling stroke	0.3% (2/618)	0%	p=0,059
any stroke	1.29% (8/618)	1.36% (15/1099)	p=0,903
death/disabling stroke	0.8% (5/618)	1.0% (11/1099)	p=0,691
death/any stroke	1.78% (11/618)	2.37% (26/1099)	p=0,422
Long-term (4.6 +/-2.8 y) follow-up ipsilateral stroke	2.7% (16/618)	4.0% (43/1099)	p=0,148
Long-term (4.6 +/-2.8 y) follow-up death	5.4% (33/618)	9,0% (99/1099)	p=0,062

Journal of the American College of Cardiology
© 2012 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 59, No. 15, 2012
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.11.035

FOCUS ISSUE: TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

The PROFI Study (Prevention of Cerebral Embolization by Proximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting)

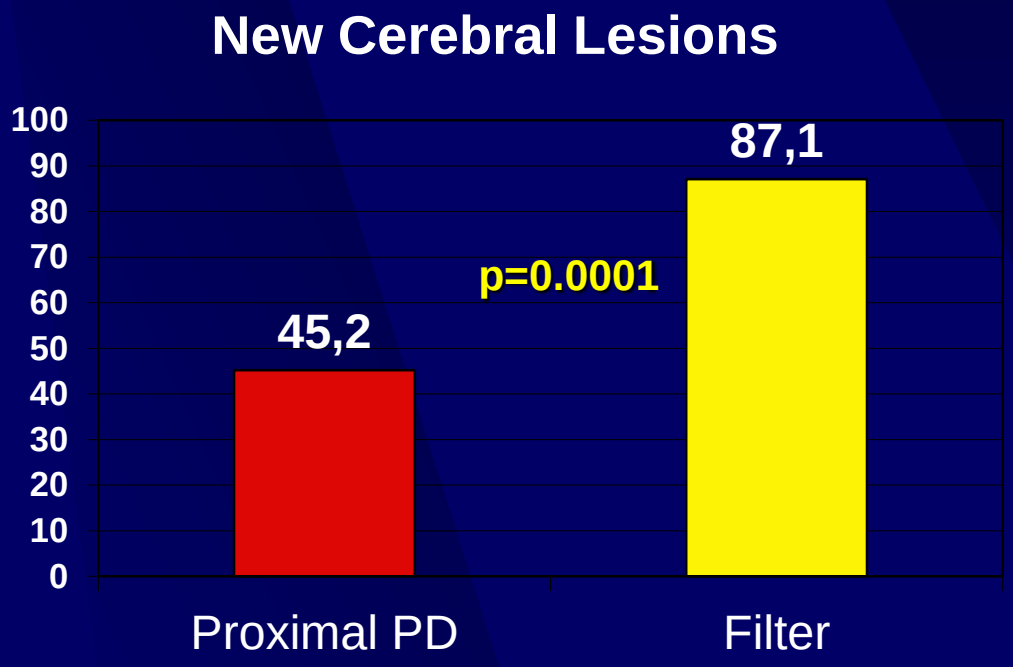
A Prospective Randomized Trial

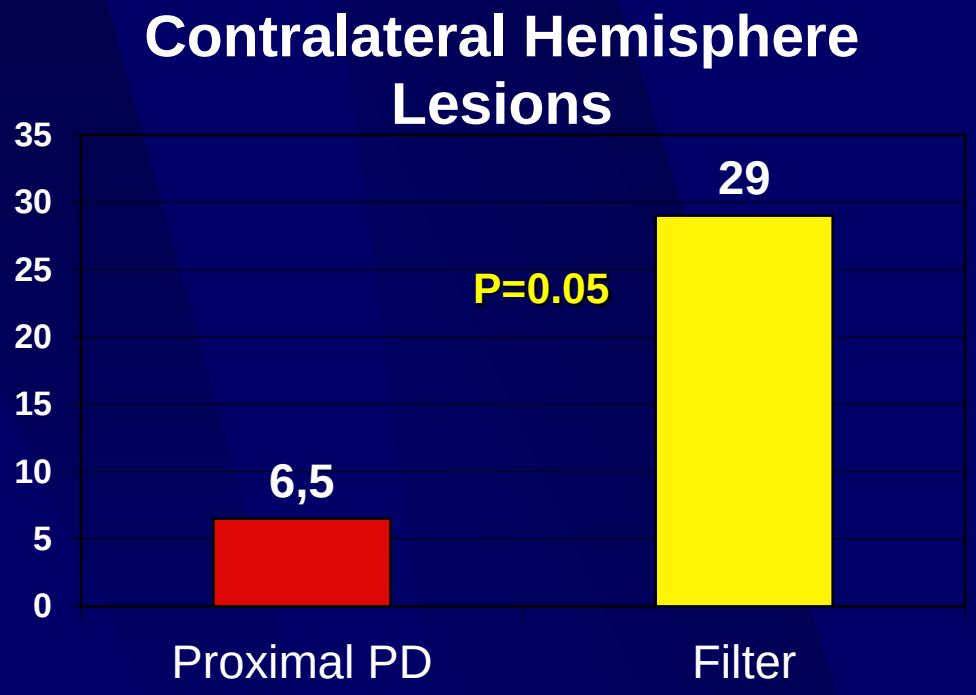
Klaudija Bijuklic, MD, Andreas Wandler, MD, Fadia Hazizi, MD, Joachim Schofer, MD, PHD

Hamburg, Germany

Proximal Protection vs. Filter: The PROFI Trial

Diffusion-weighted MRI evaluation
CAS Ptes randomized to PPD (31) vs. Filter D (31)





PPD vs. Filter:

The number (median [range]: 0 [0 to 4] vs. 2 [0 to 13]), p=0.0001

The volumen (0 [0 to 0.84] cm^3 vs. 0.47 [0 to 2.4] cm^3), p=0.0001

Proximal Protection vs. Filter: The PROFI Trial

Diffusion-weighted MRI evaluation
CAS Ptes randomized to PPD (31) vs. Filter D (31)

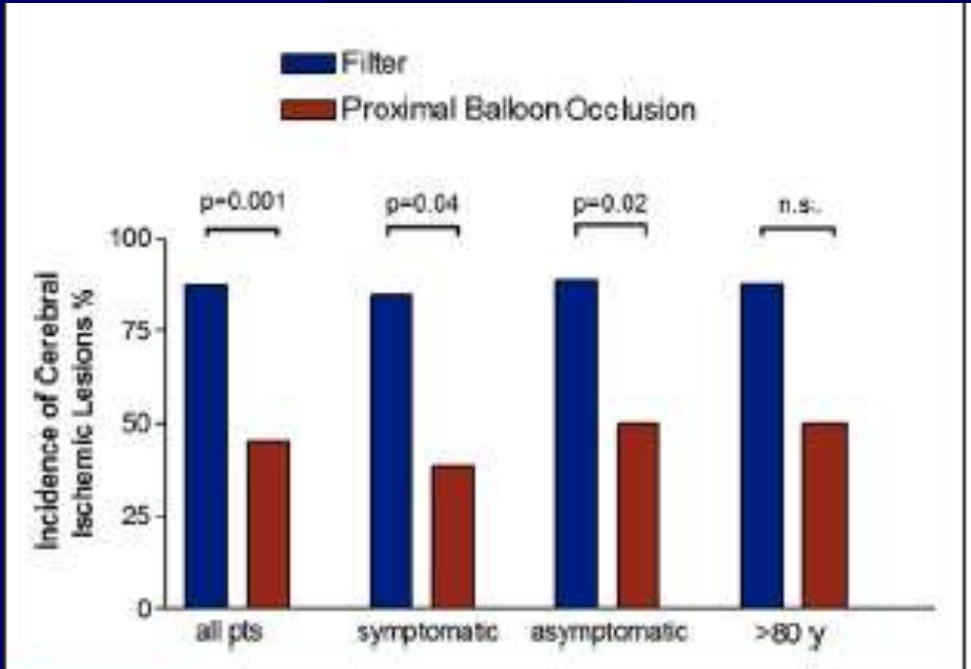


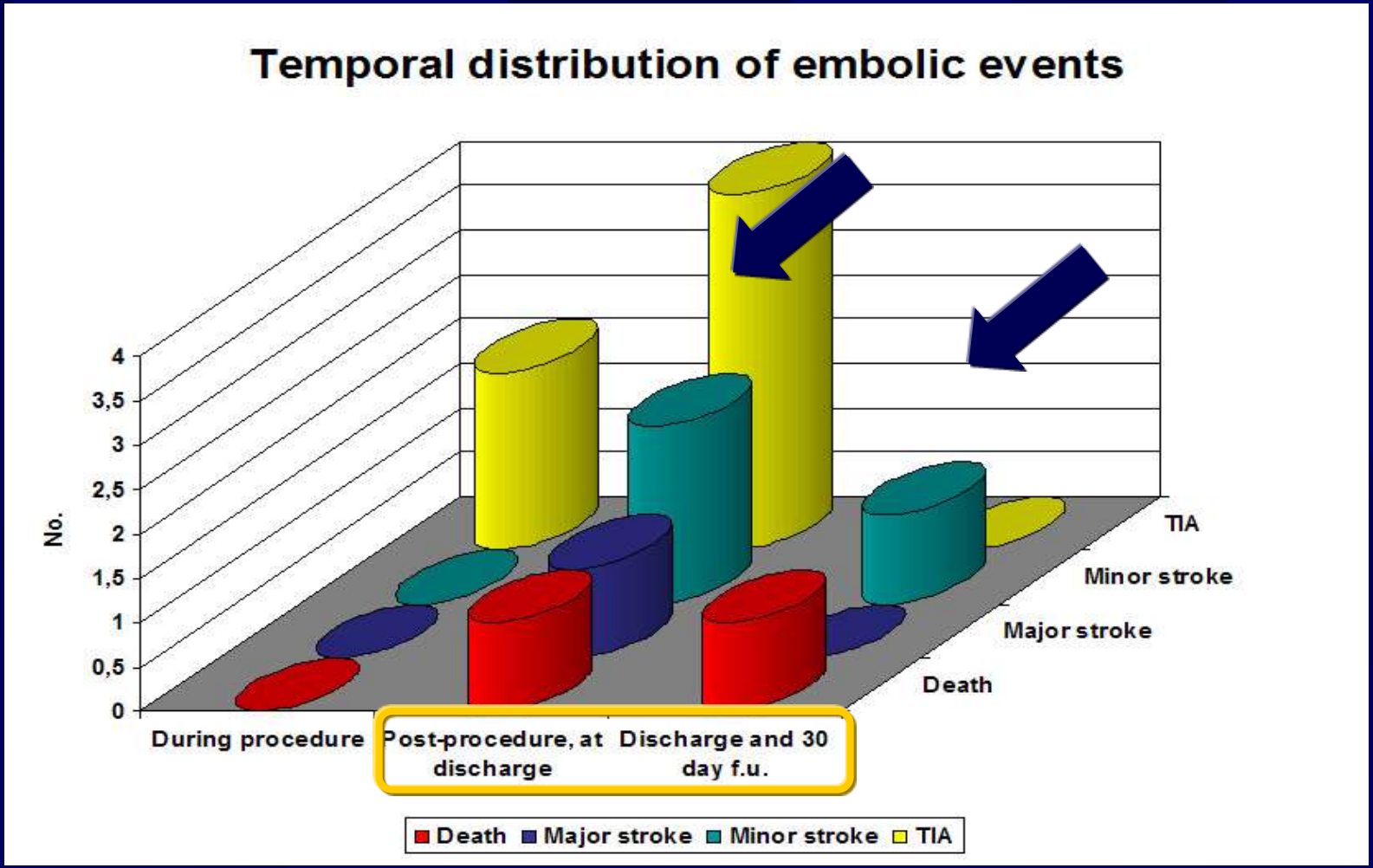
Figure 2 **Incidence of New Ischemic Lesions in Patients With Filter Protection Versus Proximal Balloon Occlusion**

In addition, symptomatic patients, asymptomatic patients, and patients >80 years of age are displayed.

Bijuklic K. Et al. J Am Coll Cardiol 2012;59:1383-9

- CAS complications:
  - Is it all about Protection Devices?
  - Which is the Importance of Stent Design?

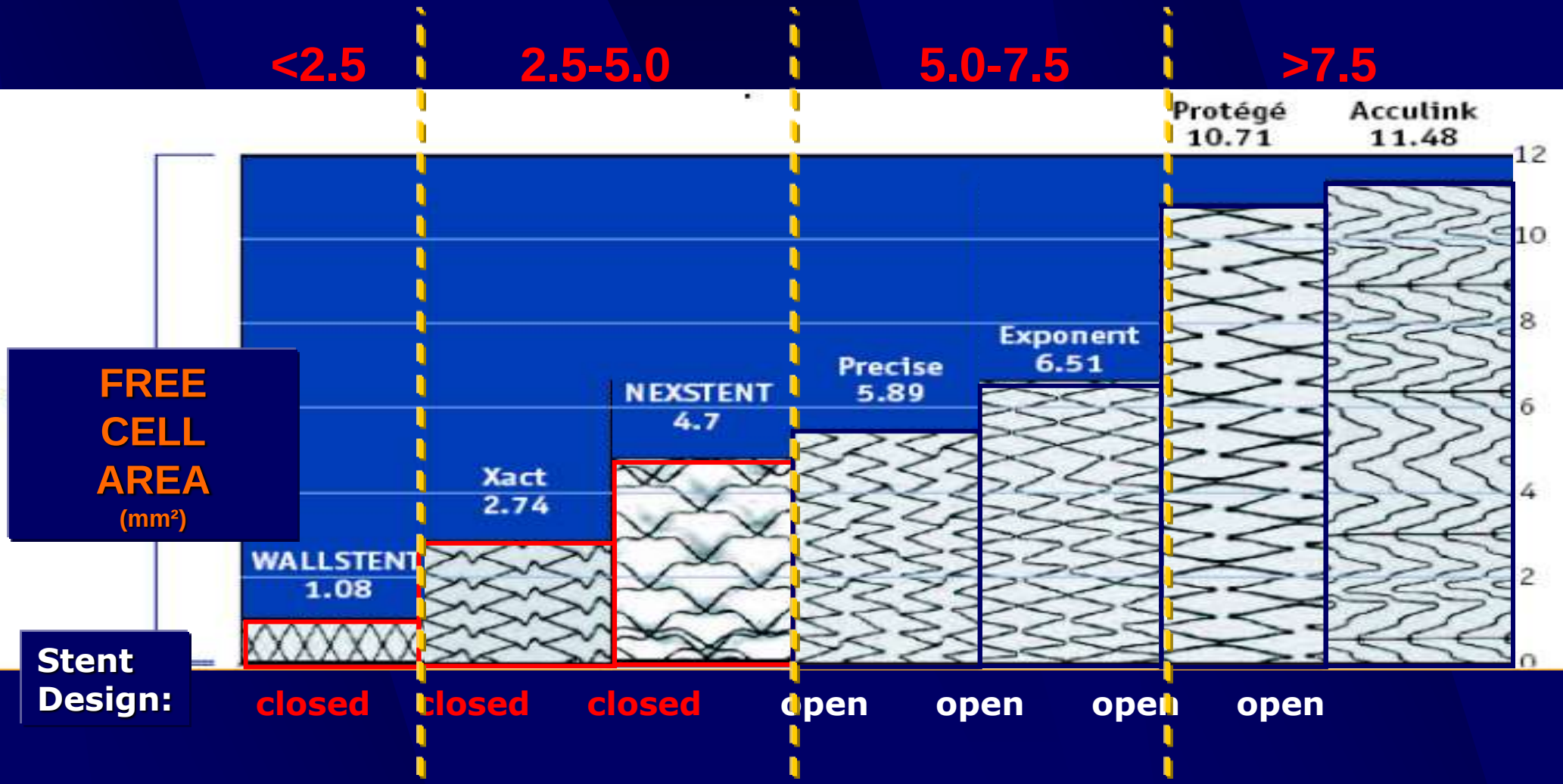
Post-procedural phase: the dark side of stents



Modified from, A. Cremonesi et al. – EuroIntervention, December 2005

Fundación Favaloro

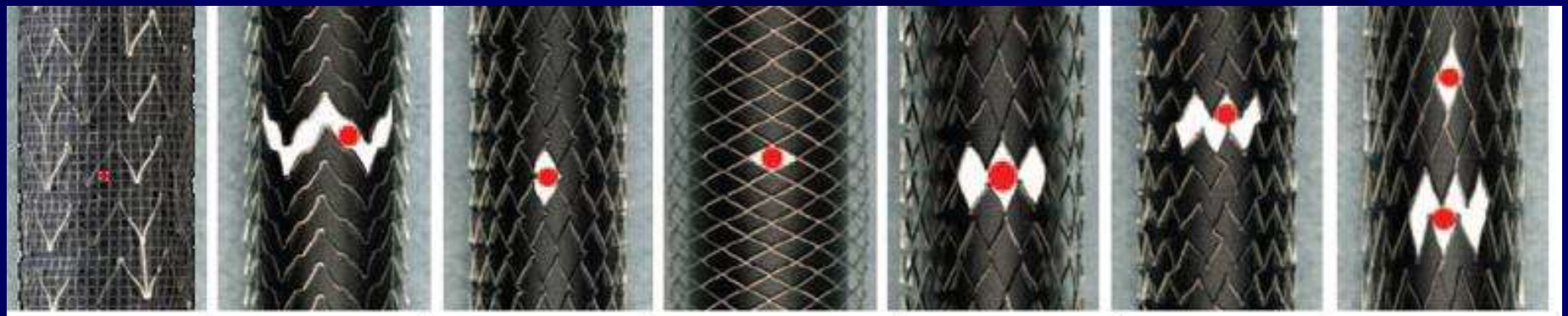
“Free cell area” based analysis



Based on Houdart, Cirse 2005 and Cremonesis, SOLACI 2007

Fundación Favaloro

Carotid Stent Design:
Cell size comparison



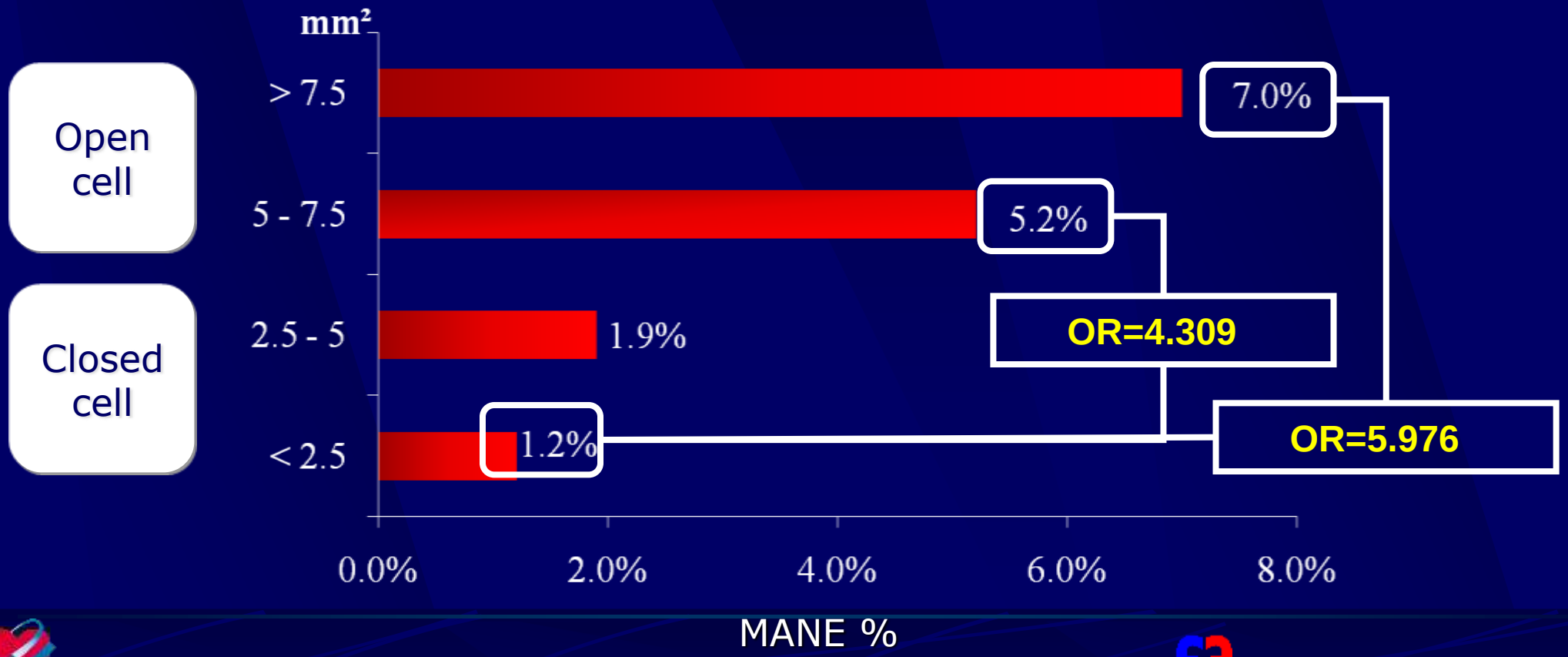
W.L. Gore and Associates*	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
GORE® Carotid Stent	ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE

Modified from J Laird, Linc 2014

“Free cell area” based analysis

Post-procedural neuro events:

Symptomatic population



M. Bosiers, et al. *EJVES 2007*

Fundación Favaloro

SPACE TRIAL:

Higher Neurologic Events with Open Cell Design

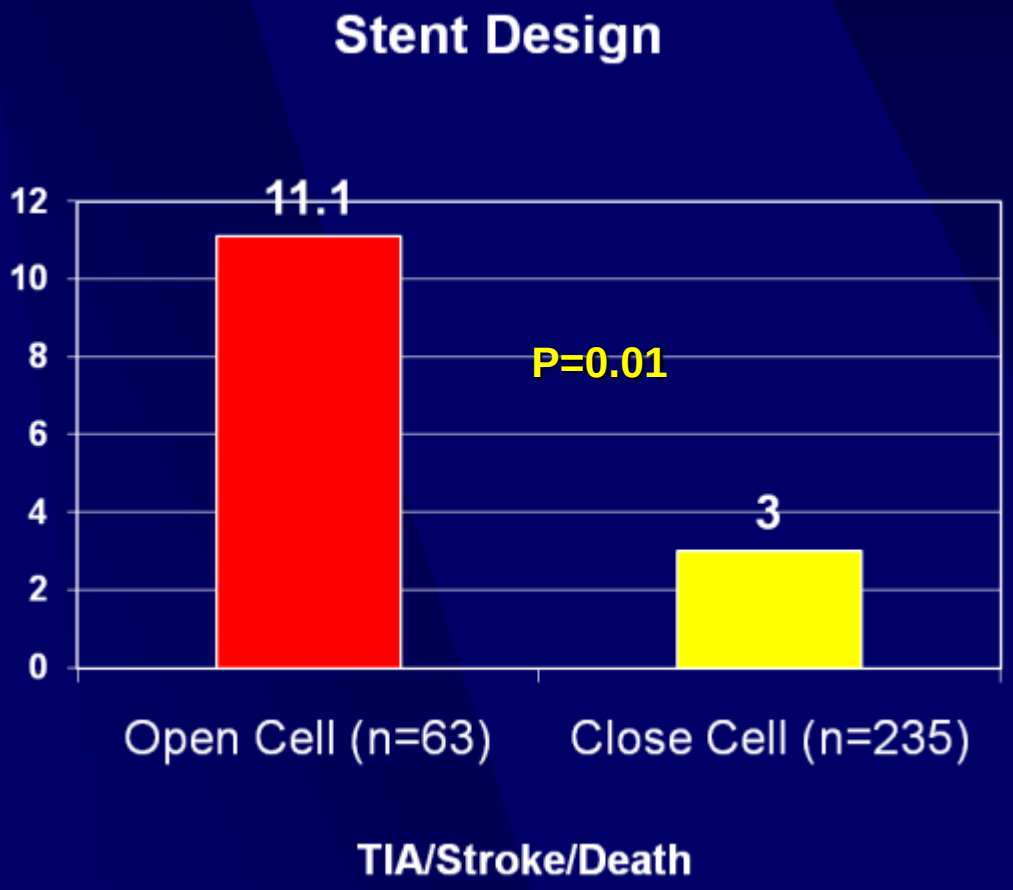
Table 4. Influence of Different Stent Types on OE Rate

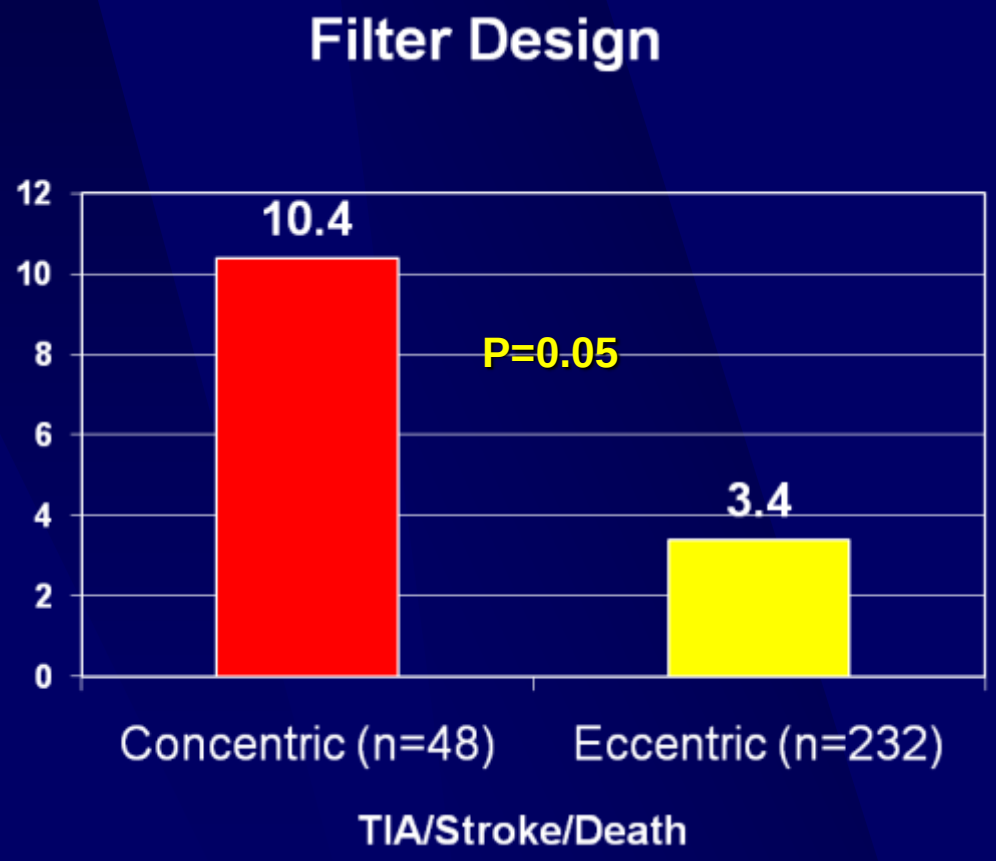
Stent	Wallstent	Acculink	Precise
No. of patients	436	92	35
Pat. with OE	24	9	5
OE rate (95% CI)	5.5% (3.6–8.1%)	9.8% (4.6–17.8%)	14.3% (4.8–30.3%)
		Combined OE rate: 11.0% (6.2–17.8%)	

Jansen, et al. Stroke 2009;40:841

Do device characteristic impact outcome in carotid stenting?

Adverse events at 30 days in symptomatic

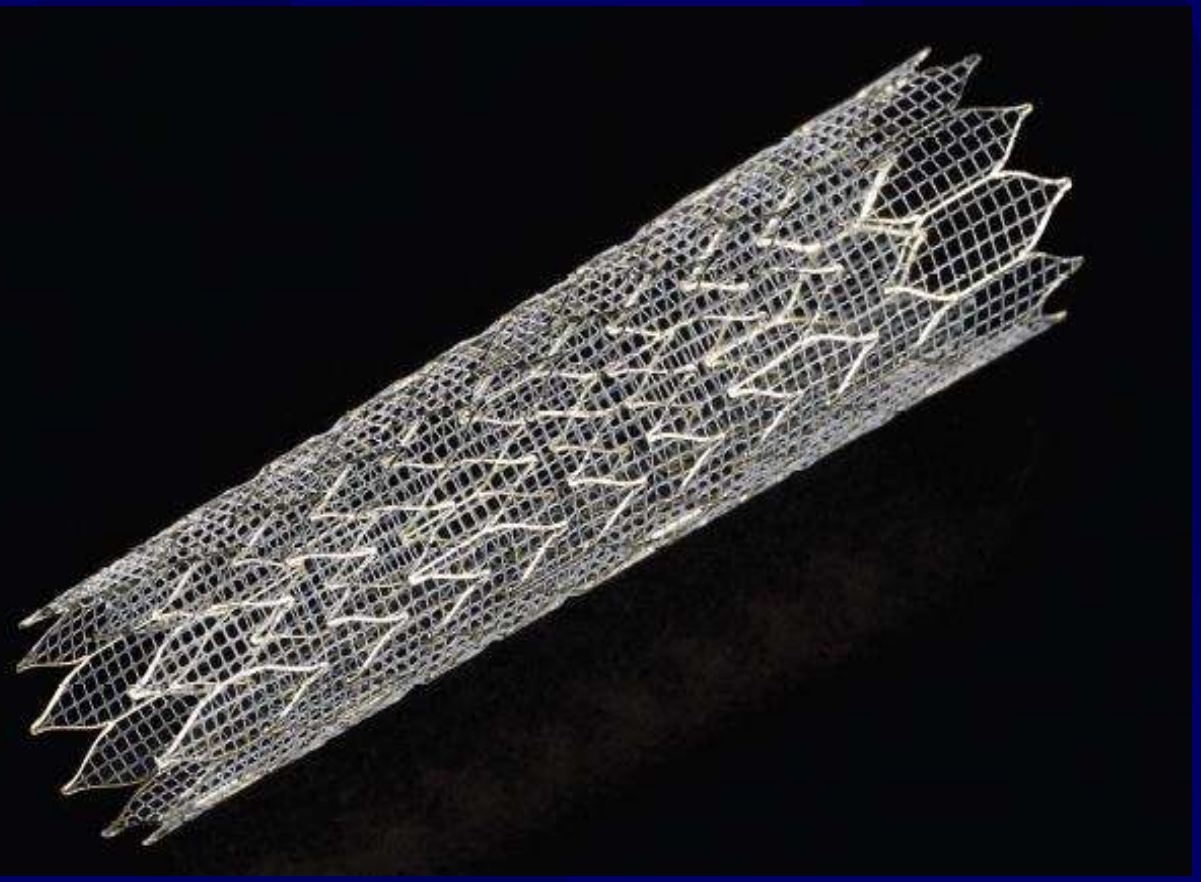




Hart JP. Et al. J Vasc Surg 2006;44:725-30

Fundación Favaloro

GORE® Carotid Stent:



- Open Cell Nitinol Frame
- Closed Cell 500 μ lattice on outside of Frame
- Permanently Bound CBAS Heparin on all device Surfaces

SCAFFOLD Trial is ongoing

Modified from J Laird, Linc 2014

Which is the Best Strategy for CAS?

- Although there are not good randomized trials: Tailored CAS using different Protection Devices and Stent Design has been shown as a good strategy to treat more complex patients without increasing the complication rate

- New approaches (radial), Proximal Protection Devices and new stent design may improve CAS outcomes.

Thank you for your attention

omendiz@ffavaloro.org