TCT 2005

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

A Lesion Specific Approach To Carotid Stenting

A. Cremonesi*, F. Castriota*

(*) Interventional Cardio-Angiology Unit
Villa Maria Cecilia Hospital
Cotignola (RA) - Italy

Potential conflicts of interest

Alberto Cremonesi, MD

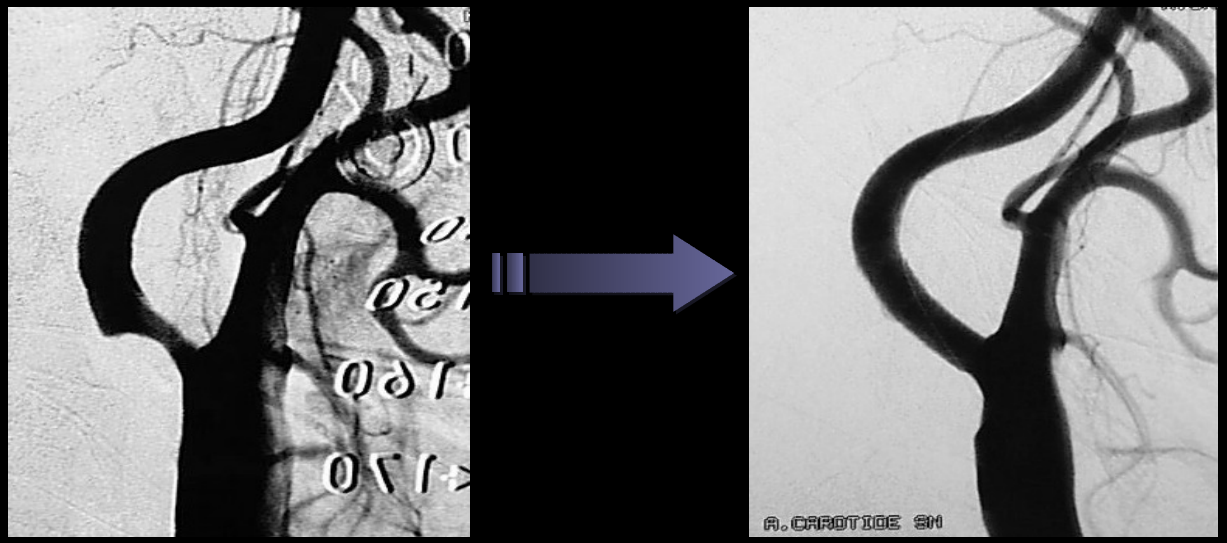
☑ **I have the following potential conflicts of interest to report:**

- ☑ Consulting: Boston Scientific
- ❑ Employment in industry
- ❑ Stockholder of a healthcare company
- ❑ Owner of a healthcare company
- ❑ Other(s).

❑ **I do not have any potential conflict of interest**

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

What is a carotid protected procedure?



Active protection

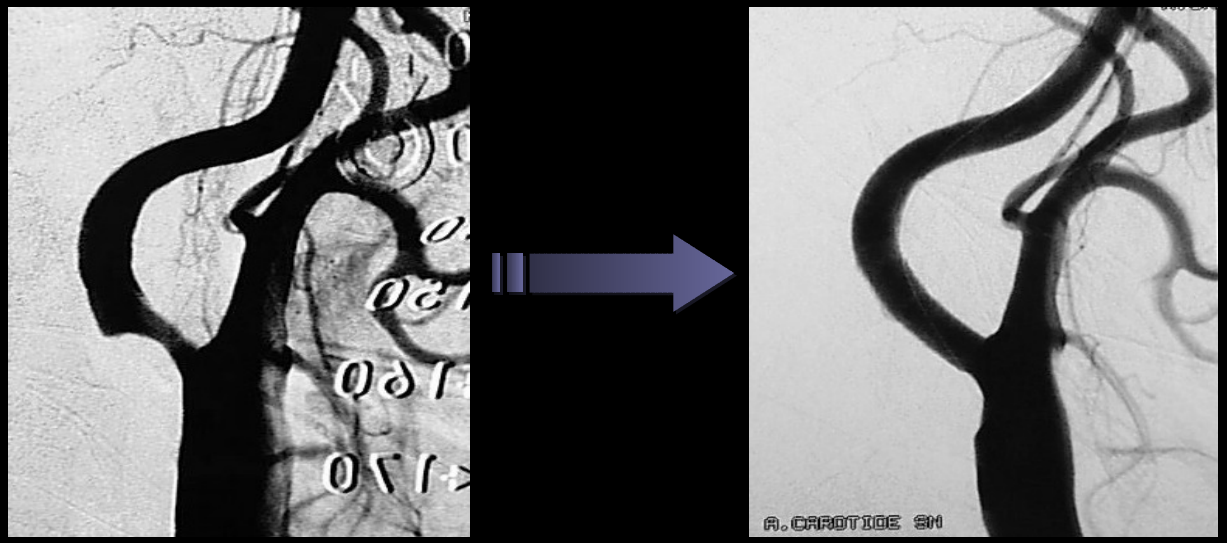
any method and/or work strategy to minimize the probability to generate big particles of embolic material during the endovascular procedure

Passive protection

devices which allow the operator to capture and remove embolic material generating during the procedure

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

What is a carotid protected procedure?



CC engagement

Stent selection & implantation

EPD selection & management

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Open question

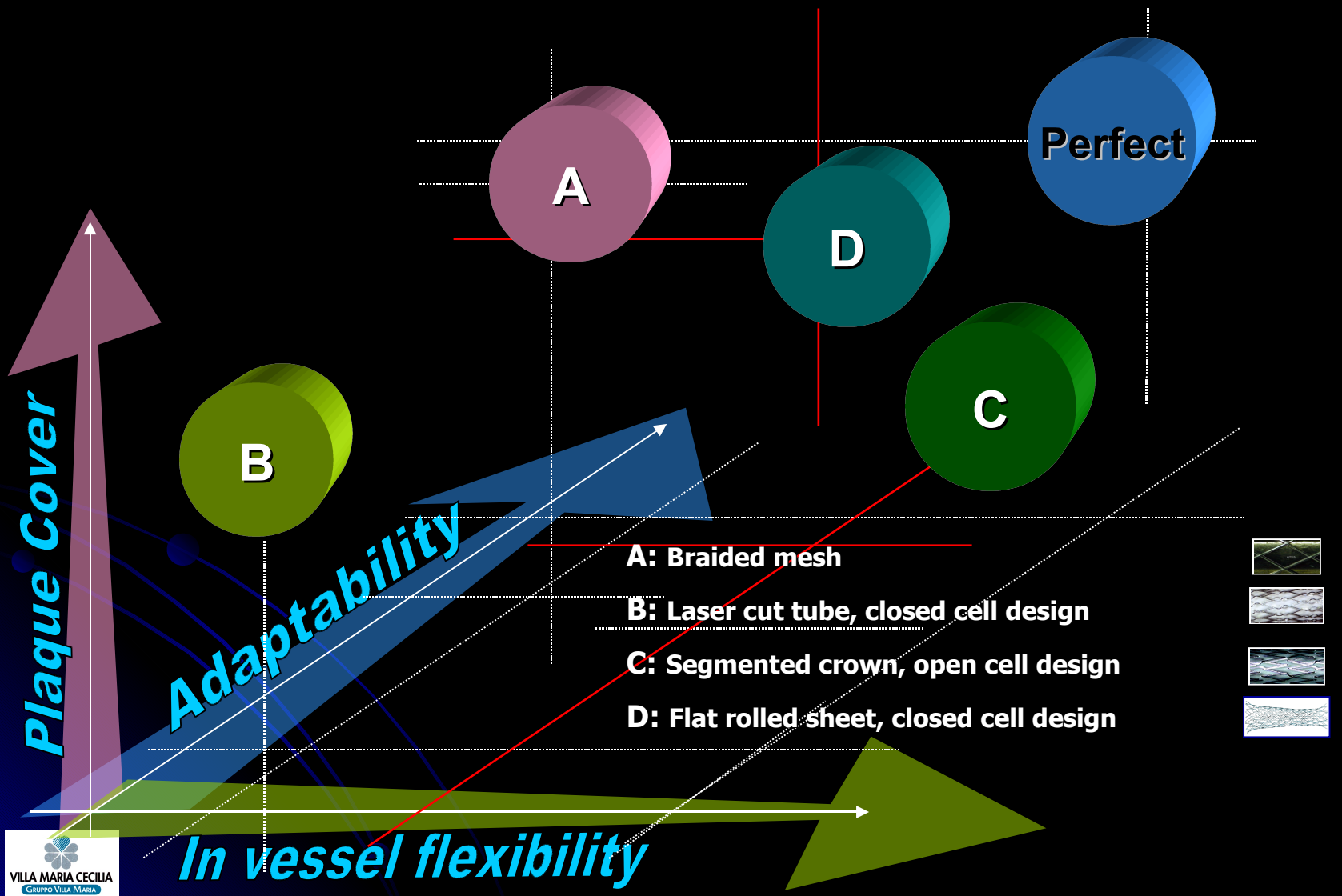
Ideal CAS devices? It's indeed true that …

- **Ideal carotid stent?**
  - A single stent applicable to all the carotid lesions and anatomies doesn't exist!
  - No technological stent frames put together adequate properties in term of plaque covering, in vessel flexibility, shape adaptability!
- **Ideal EPD?**
  - All the embolic protection devices failed in providing a full protected procedure!

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Open question

Carotid Stenting Strategies

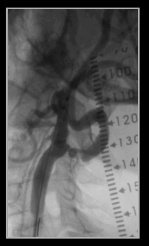


VILLA MARIA CECILIA
GRUPPO VILLA MARIA

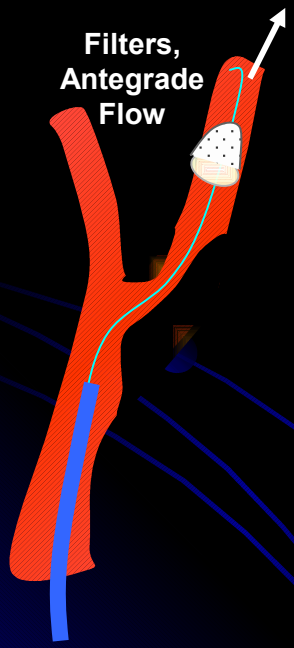
Int.C.V.Unit

Open question

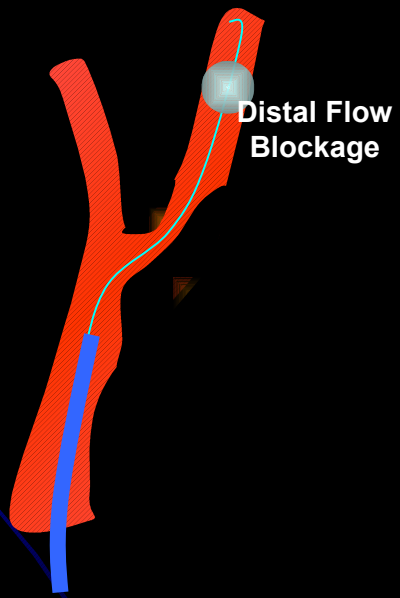
Cerebral Protection Strategies



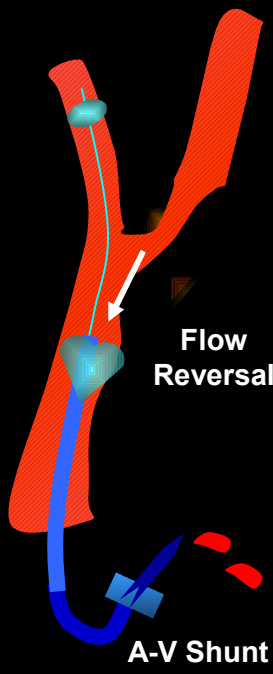
Distal ICA Filtering



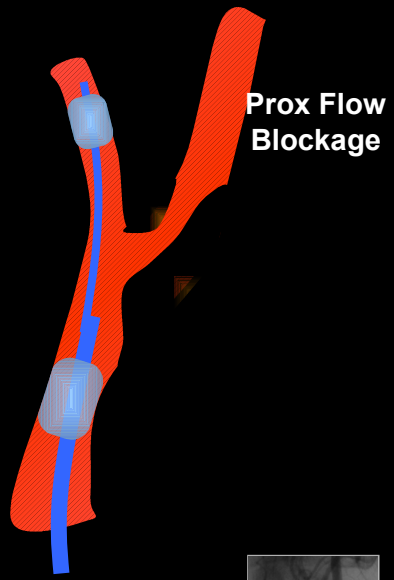
Distal Flow Blockage by ICA Occlusion



Flow Reversal by CCA and ECA Occlusion



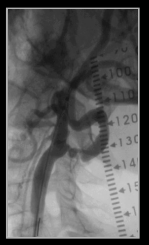
Proximal Flow Blockage by CCA and ECA Occlusion



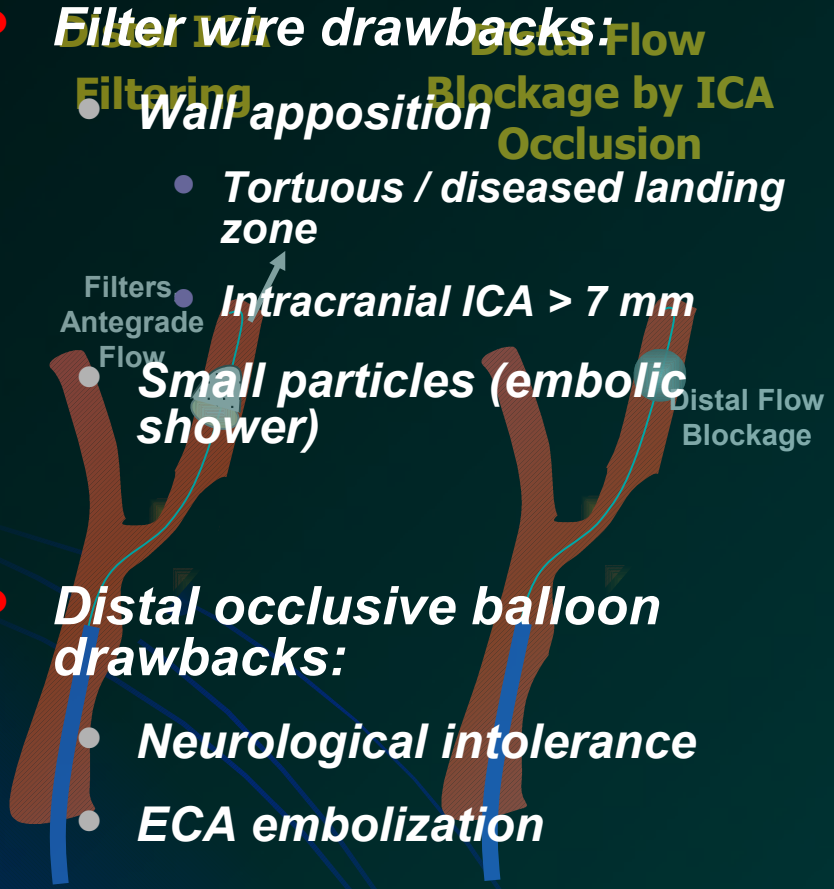
VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Open question

Cerebral Protection Strategies

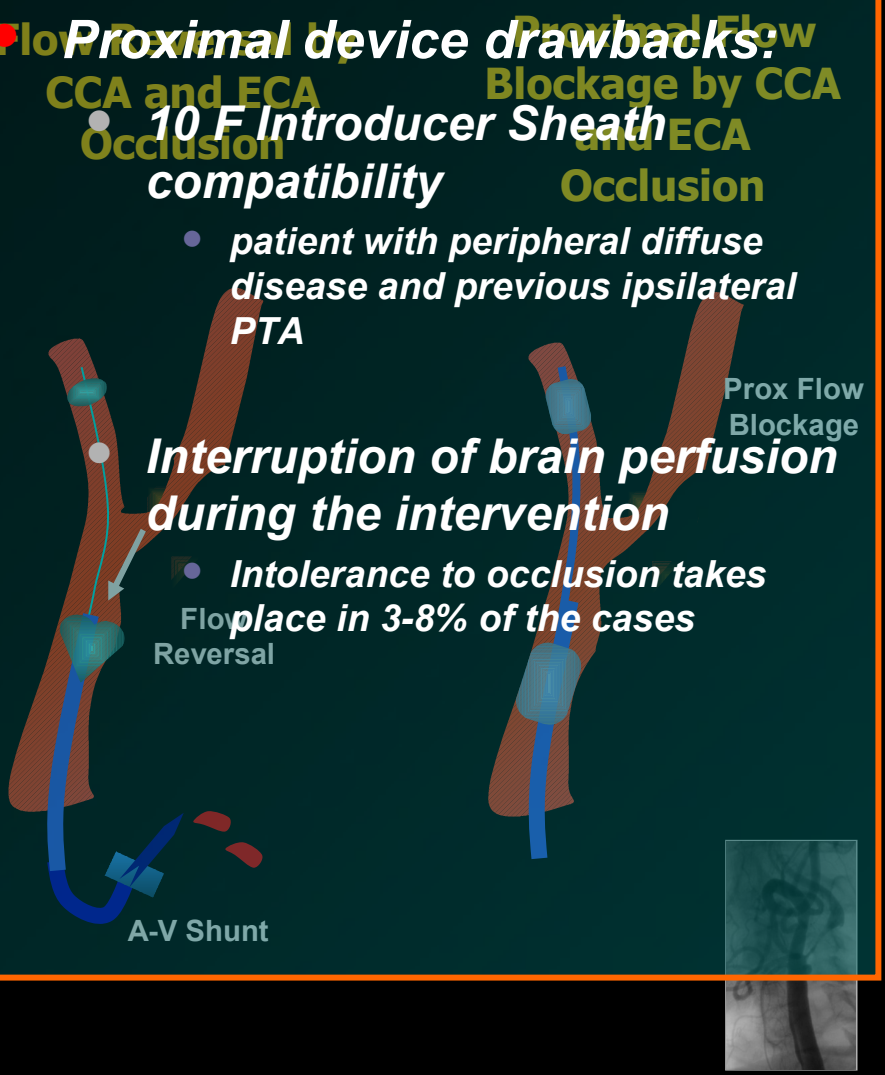


- *Filter wire drawbacks:*
  - *Wall apposition*
    - *Tortuous / diseased landing zone*
    - *Intracranial ICA > 7 mm*
  - *Small particles (embolic shower)*



- *Distal occlusive balloon drawbacks:*
  - *Neurological intolerance*
  - *ECA embolization*

- *Proximal device drawbacks:*
  - *10 F Introducer Sheath compatibility*
    - *patient with peripheral diffuse disease and previous ipsilateral PTA*
  - *Interruption of brain perfusion during the intervention*
    - *Intolerance to occlusion takes place in 3-8% of the cases*

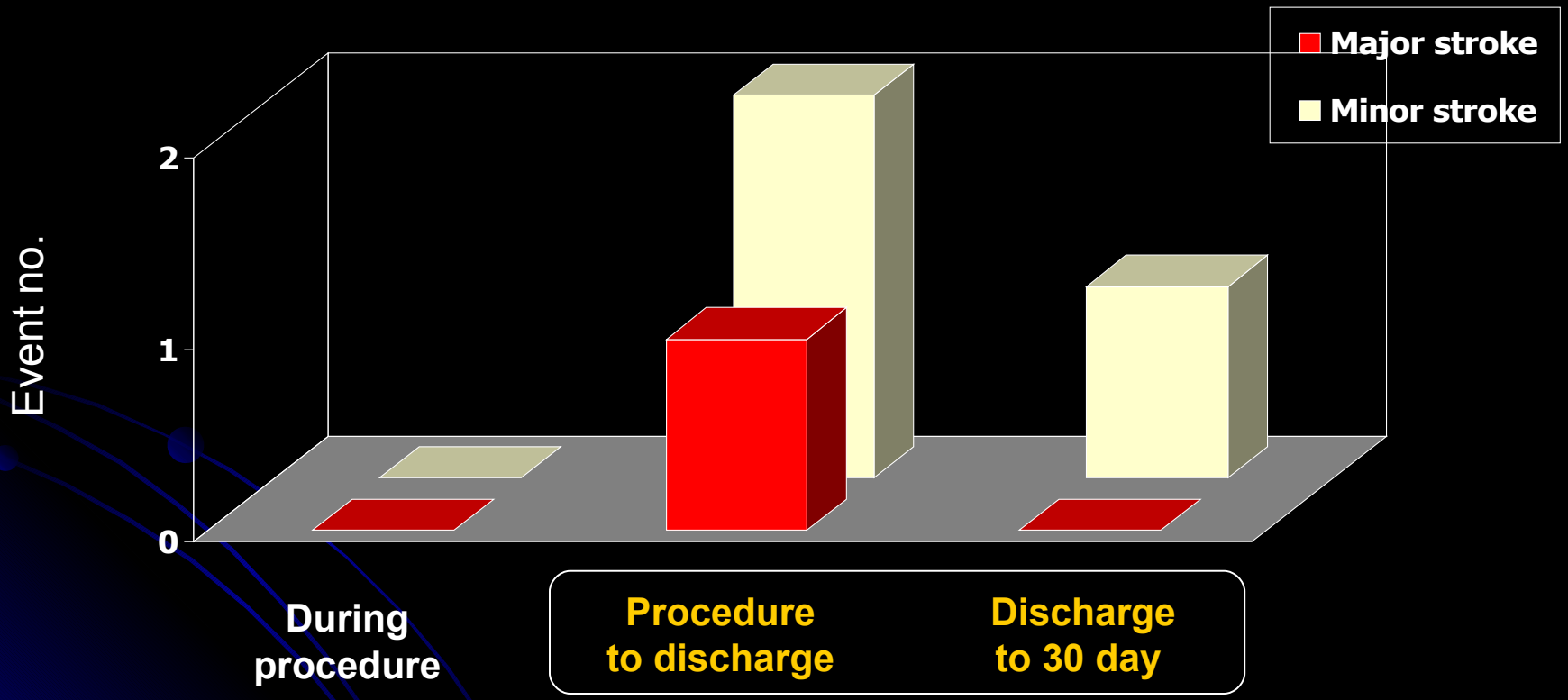


VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Open question

Temporal distribution of complications

Data from 734 “tailored” CAS



VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Open question

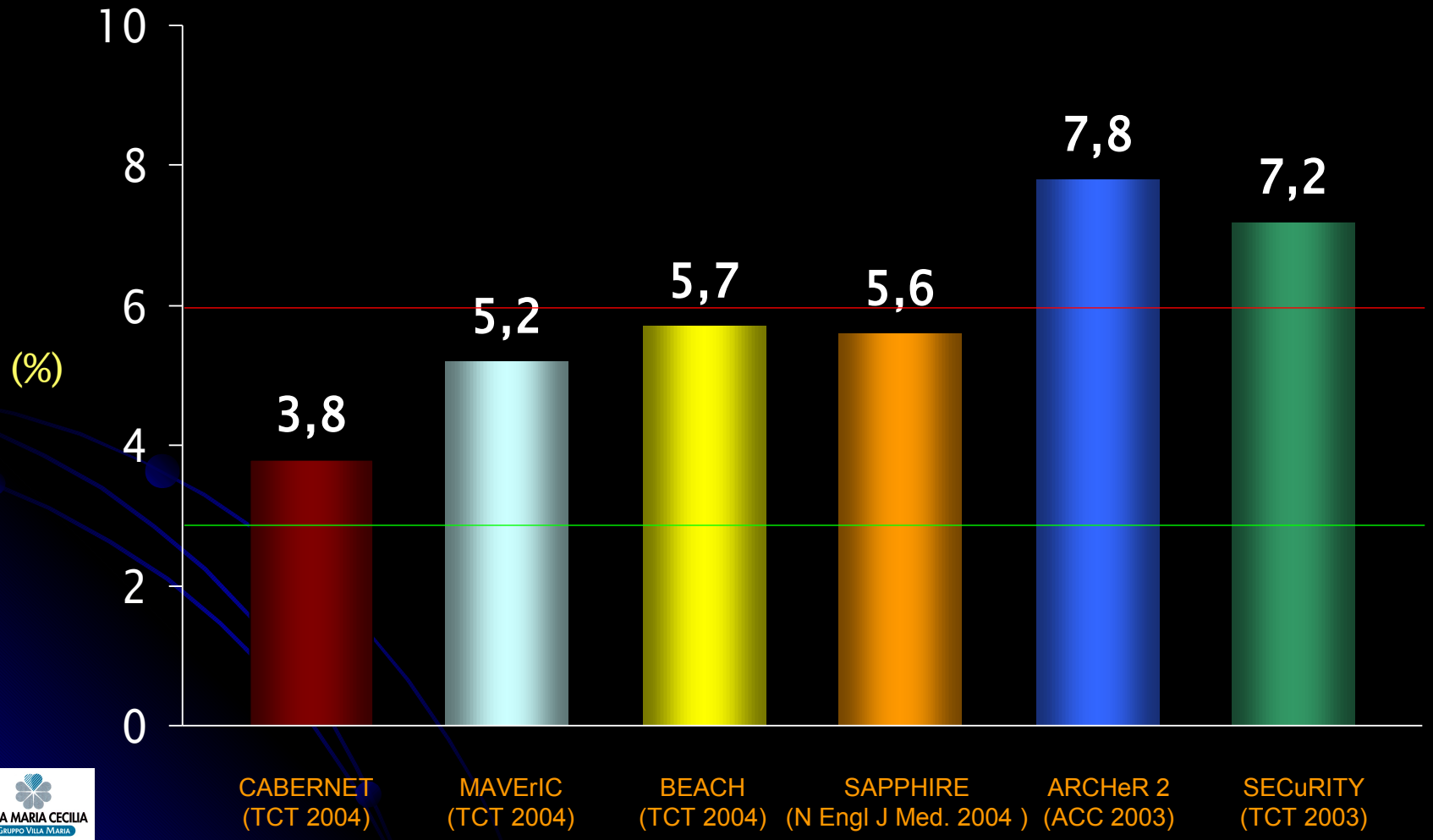
Temporal distribution of complications

Data from 734 "tailored" CAS

- Late embolic events occur in the post-procedure period, between stent implantation and its complete re-endotelization (3-4 weeks).
- Late symptomatic embolic events depend mostly on prolapsed soft tissue as well as platelet micro-aggregates / thrombi detached from the stent metallic frame

Open question

30-Day Composite Endpoint Carotid Stenting Registries/RCT



VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

Open question

30-Day Composite Endpoint Carotid Stenting Registries/RCT

In all these studies,
the "<u>one device fits all" bias</u>:

all the lesions and anatomies were addressed and treated with a single pre-assigned stent and EPD

…. Trouble is my business

VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

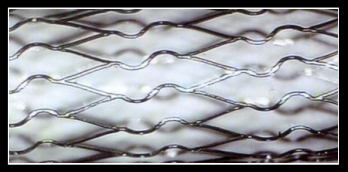
…. Trouble is my business

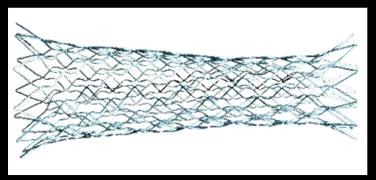
VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

Can one device fit all?

- **Self-expanding stent technical features**
  - *Foreshortening*
  - *Conformability or flexibility*
  - *Vessel wall adaptability*
  - *Scaffolding & wall coverage*
  - *Radial strength*
  - *Radial stiffness*

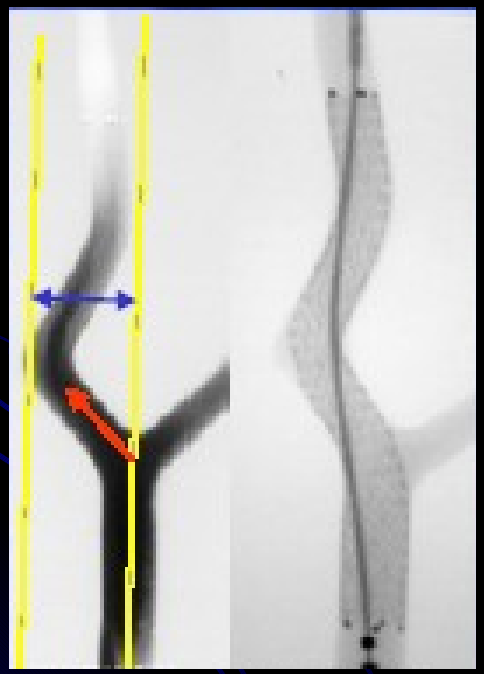




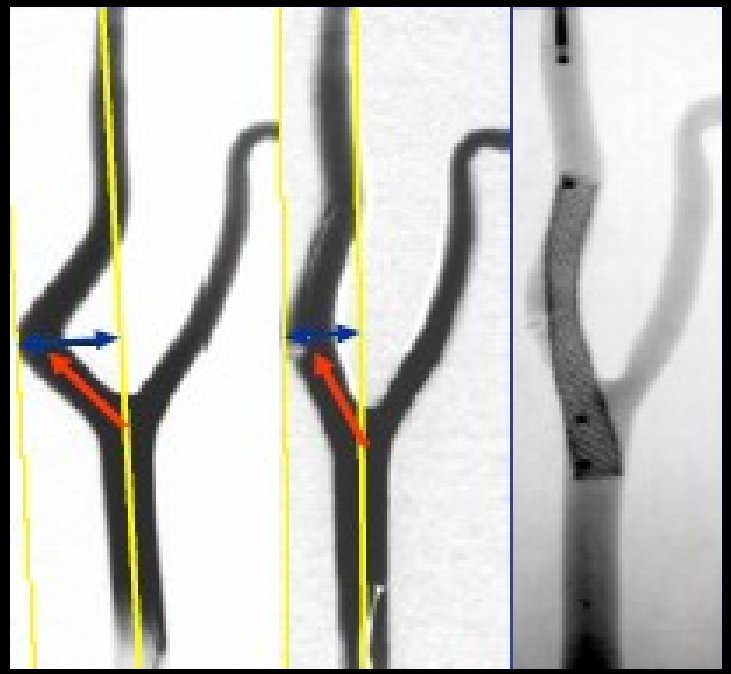
VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Conformability
Flexibility

Ability to conform to vessel tortuosity during deployment



Good

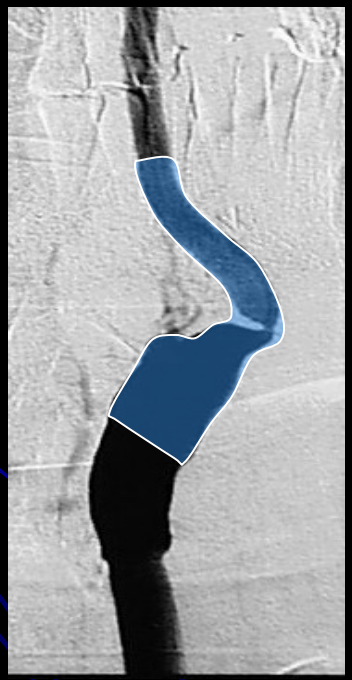


Poor

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Vessel wall adaptability

Ability of stent to adjust to the anatomy of the carotid bifurcation



VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Scaffolding and wall coverage

- **Scaffolding:**
  - amount of support a stent gives to the vessel wall at the lesion site
- **Wall coverage:**
  - ratio between quantity of stent material in comparison to amount of vessel tissue

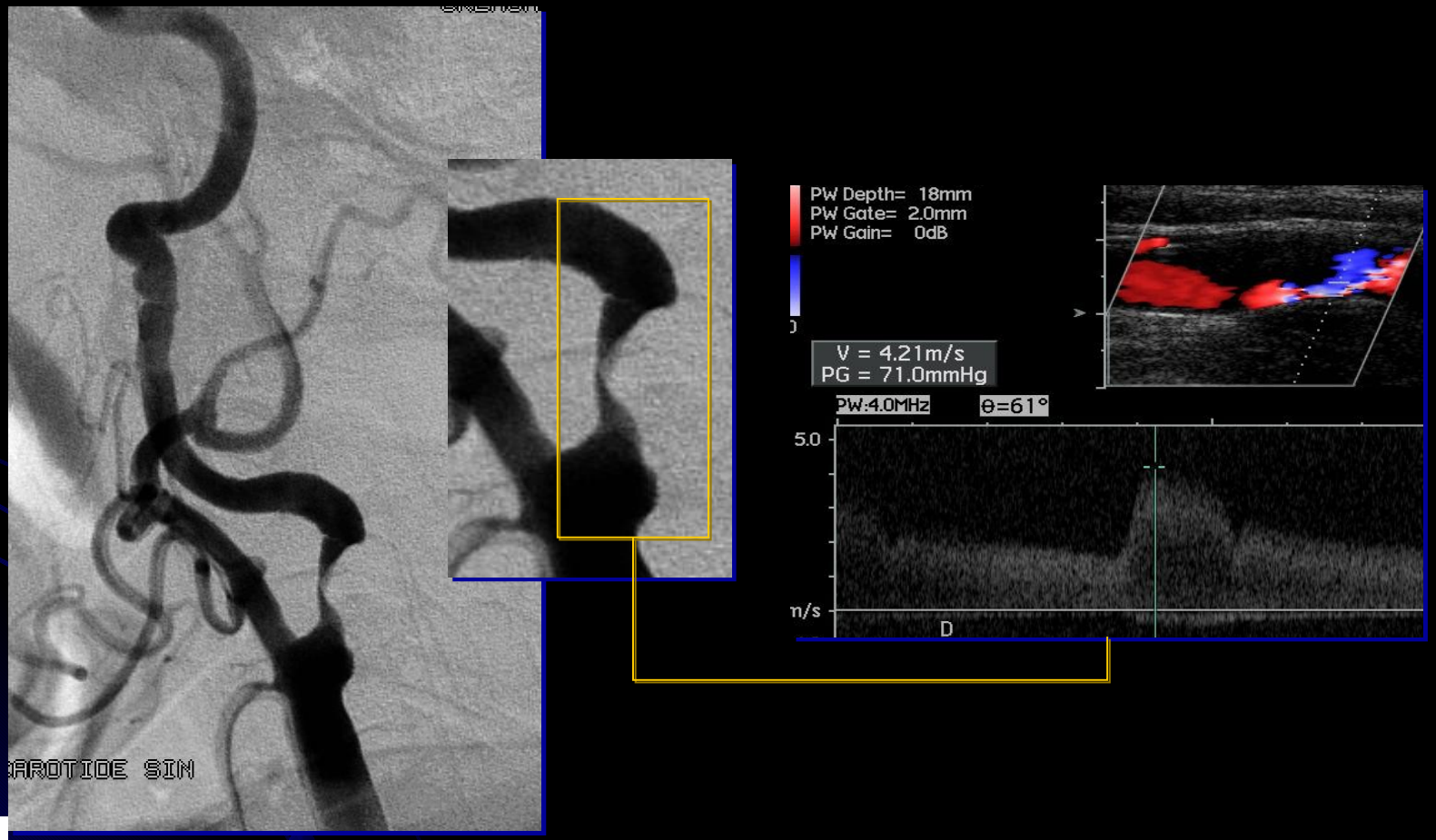
More scaffolding

More wall coverage

Less plaque prolapse

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

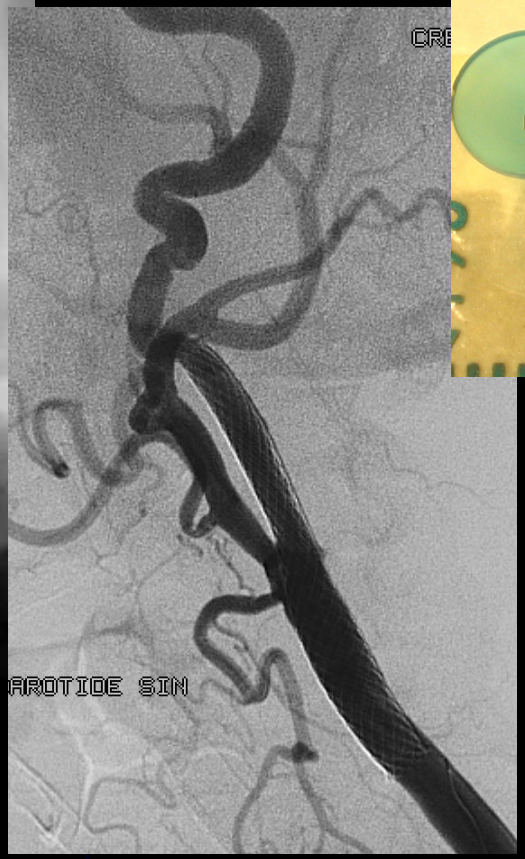
Soft plaque

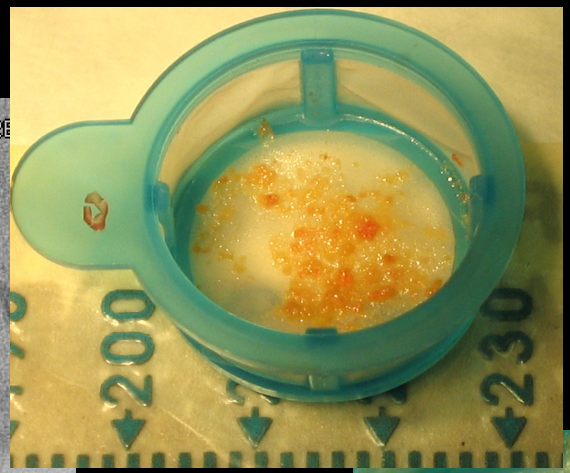


VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

Soft plaque

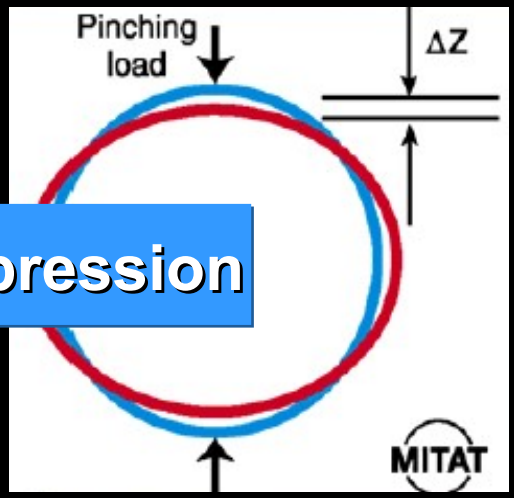




Radial force

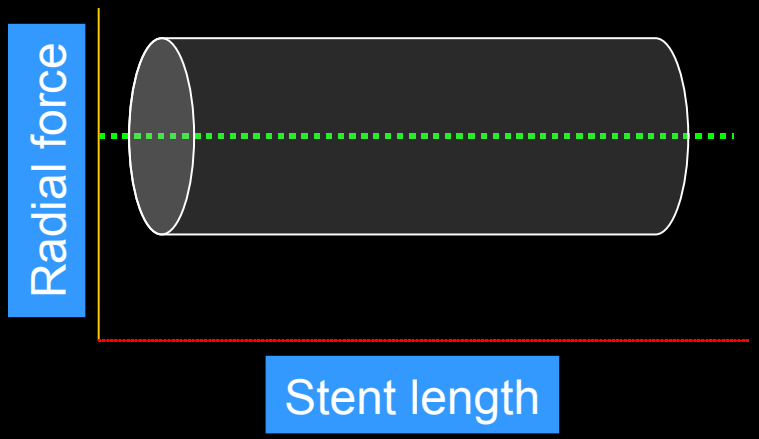
- **Outward radial force**
  - Amount of external pressure a stent can withstand without resulting in a permanent reduction of the vessel lumen
- **Inward radial force**
  - Ability of a stent to maintain its diameter when an aexternal force is applied

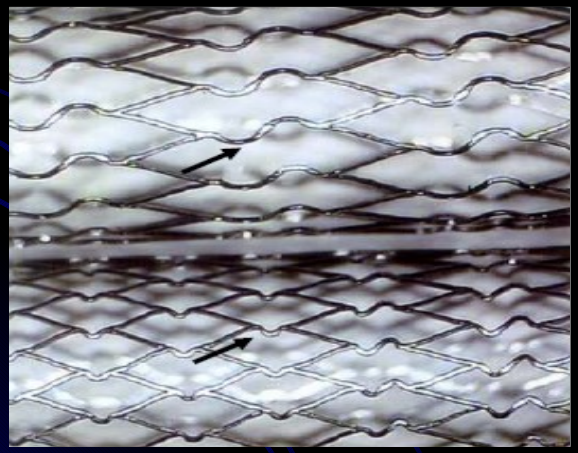
Resistance to compression

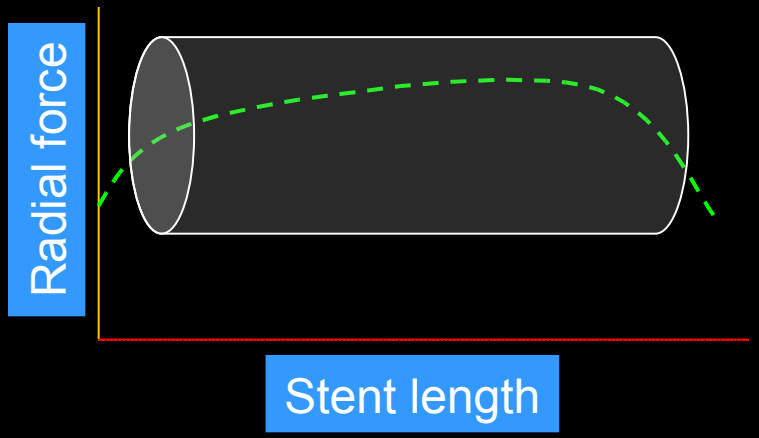


VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

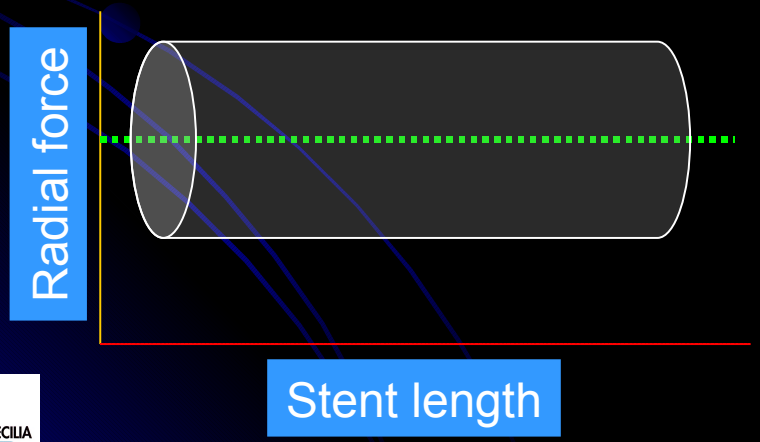
Fixed vs variable geometry

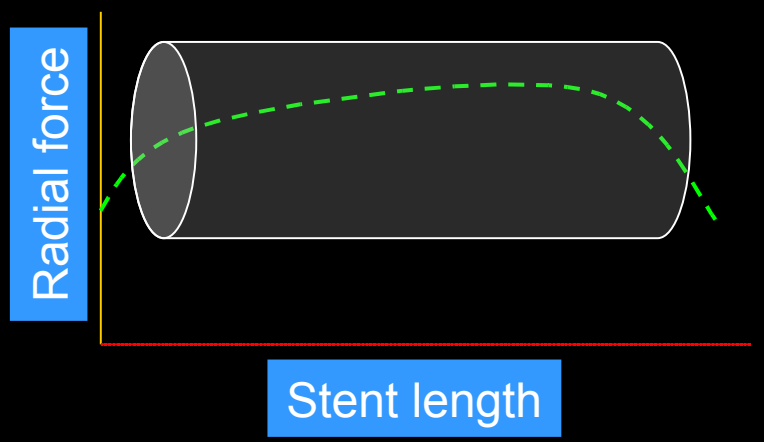






Highly calcified / resistant lesions

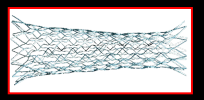




VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Carotid stenting
Lesion specific approach



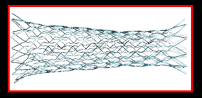



Lesion/Anatomy characteristics	Braided mesh	Segmented crown, open cell design	Laser cut tube, closed cell design	Flat rolled sheet, closed cell design
Long, soft, dishomogeneous lesion	+++	-	++	++
Short, calcified lesion	+	++	+++	++
Straighten vessel	++	-	+	+
Maintain original anatomy	-	++	-	+
Follow complex lesion contour	-	++	-	-
Prevent plaque prolapse	+++	+	-	++
Focal ICA / CCA lesions	Straight			
Carotid bifurcation / Ø mismatch	Tapered – Self & dynamic tapering			

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Carotid stenting
Lesion specific approach



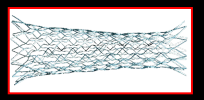



Lesion/Anatomy characteristics	Braided mesh	Segmented crown, open cell design	Laser cut tube, closed cell design	Flat rolled sheet, closed cell design
Long, soft, dishomogeneous lesion	+++	-	++	++
Short, calcified lesion	+	++	+++	++
Straighten vessel	++	-	+	+
Maintain original anatomy	-	++	-	+
Follow complex lesion contour	-	++	-	-
Prevent plaque prolapse	+++	+	-	++
Focal ICA / CCA lesions	Straight			
Carotid bifurcation / Ø mismatch	Tapered – Self & dynamic tapering			

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Carotid stenting
Lesion specific approach



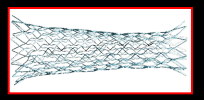



Lesion/Anatomy characteristics	Braided mesh	Segmented crown, open cell design	Laser cut tube, closed cell design	Flat rolled sheet, closed cell design
Long, soft, dishomogeneous lesion	+++	-	++	++
Short, calcified lesion	+	++	+++	++
Straighten vessel	++	-	+	+
Maintain original anatomy	-	++	-	+
Follow complex lesion contour	-	++	-	-
Prevent plaque prolapse	+++	+	-	++
Focal ICA / CCA lesions	Straight			
Carotid bifurcation / Ø mismatch	Tapered – Self & dynamic tapering			

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Carotid stenting
Lesion specific approach



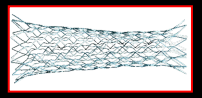



Lesion/Anatomy characteristics	Braided mesh	Segmented crown, open cell design	Laser cut tube, closed cell design	Flat rolled sheet, closed cell design
Long, soft, dishomogeneous lesion	+++	-	++	++
Short, calcified lesion	+	++	+++	++
Straighten vessel	++	-	+	+
Maintain original anatomy	-	++	-	+
Follow complex lesion contour	-	++	-	-
Prevent plaque prolapse	+++	-	+	++
Focal ICA / CCA lesions	Straight			
Carotid bifurcation / Ø mismatch	Tapered – Self & dynamic tapering			

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Carotid stenting
Lesion specific approach



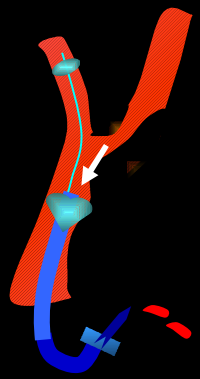
Lesion/Anatomy characteristics	Braided mesh	Segmented crown, open cell design	Laser cut tube, closed cell design	Flat rolled sheet, closed cell design
Long, soft, dishomogeneous lesion	+++	-	++	++
Short, calcified lesion	+	++	+++	++
Straighten vessel	++	-	+	+
Maintain original anatomy	-	++	-	+
Follow complex lesion contour	-	++	-	-
Prevent plaque prolapse	+++	+	-	++
Focal ICA / CCA lesions	Straight			
Carotid bifurcation / Ø mismatch	Tapered – Self & dynamic tapering			

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

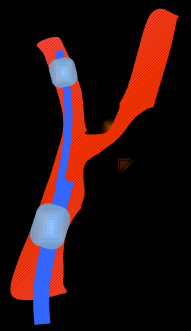
Proximal cerebral protection? Establish the need

1. In some complex cases it's impossible (predilatation is needed) or not advisable (floating thrombus, "string sign" lesions) to cross the lesion with a distal protection device
2. In presence of post-lesion extreme tortuosity the proper management of distal EPDs may result either impossible or dangerous

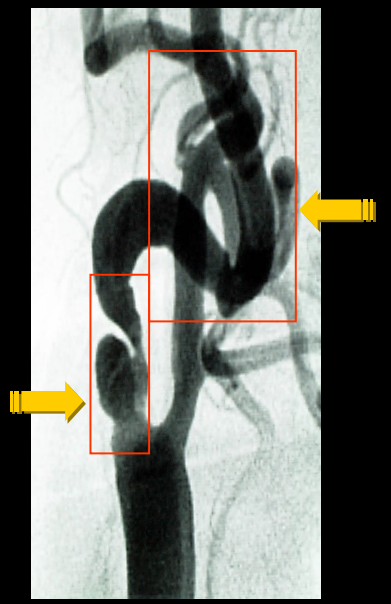
VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit



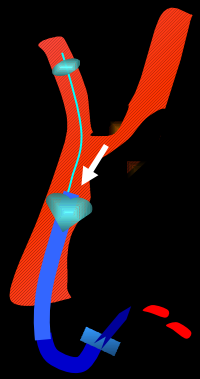
Proximal EV clamping
Advantages



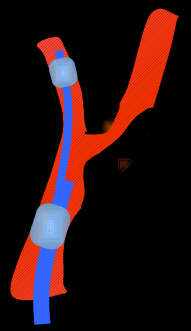
- ***Full-Time***, **complete protection - lesion crossed only while under protection**
- **Easy lesion crossing and high tech success in difficult anatomies**
- **Reduced incidence of ICA spasms and dissections due to device fixation outside the target (diseased) vessel**
- **Effective debris removal of any <u>type</u> and <u>size</u> through large, fully usable ≠2 mm working channel**



VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

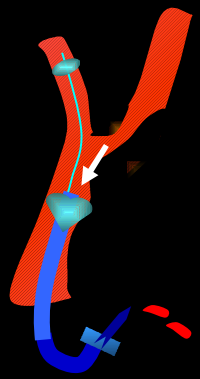


Proximal EV clamping
Advantages

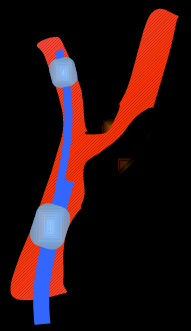


- **1st Choice Device in High Embolic Risk Lesions**
  - *Fresh thrombus lesions*
  - *Soft ulcerated plaques*
  - *Long, sub-occlusive lesions*
  - *Diffuse diseased ICAs*
  - *Friable, unstable plaque by*
    - *Echo Doppler and angiographic findings*
    - *Recent, recurrent symptoms (i.e. patients with "stuttering" TIAs)*

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit



Proximal EV clamping
Advantages

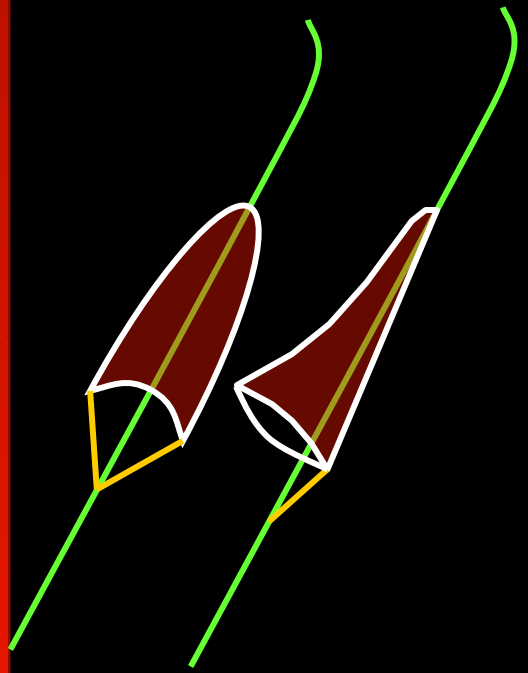


- **Mandatory Choice in Severe Anatomical Complexity**
  - *Difficult to access ICAs*
    - *Tortuous ICAs*
    - *Very angulated ICA-CCA take-off*
  - *Lack of a suitable ICA's landing zone for distal protection*

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

EPDs: Filter wires

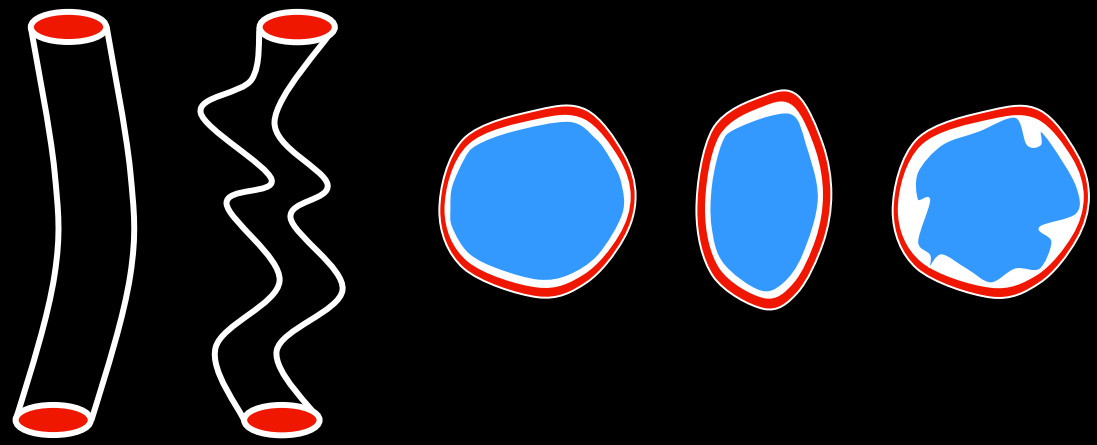
- **Filter-wire performances**
  - ✓ ***Flexibility***
  - ✓ ***Trackability***
  - ✓ ***Crossing profile***
  - ✓ ***Conformability***
  - ✓ ***Capturing capabilities***
    - **Pore size and distribution**
    - **Capturing volume**
    - **Vessel lumen form fitting (diameter, contour, asymmetry, bends, tortuousity, etc.)**



Filter conformability & capturing performances

- **The capacity of filter to fit the vessel shape at the landing zone is obtained:**
  - ✓ ***Concentric filter***
    - **Nitinol cage**
    - **Self centering property: relationship between nitinol cage / poliurethane umbrella and landing zone**
  - ✓ ***Eccentric filter***
    - **Nitinol loop**
    - **Self centering property: relationship between nitinol loop and landing zone**

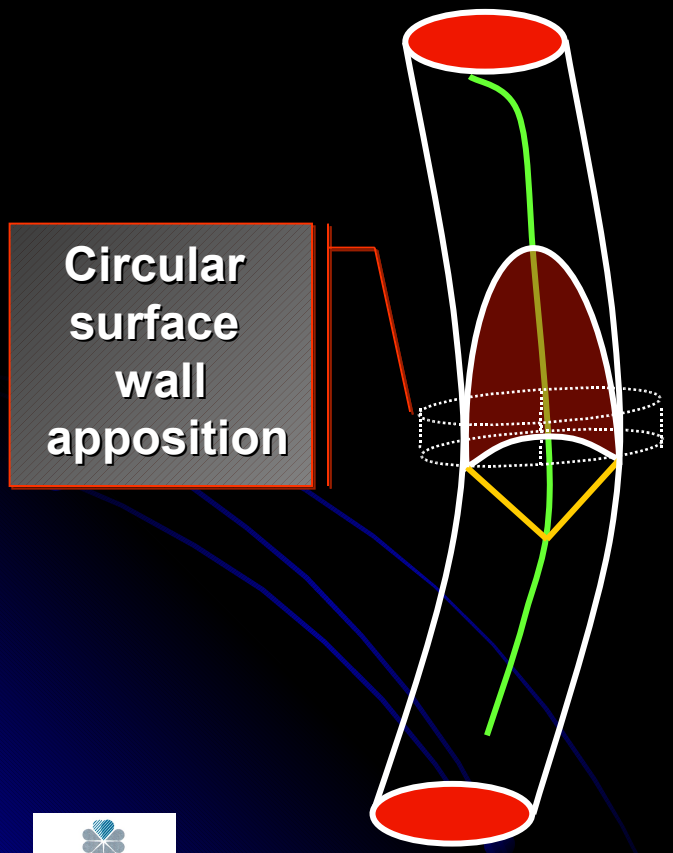
Landing zone



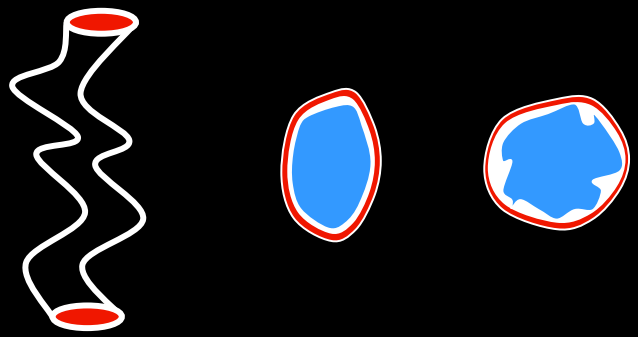
VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Carotid stenting
Lesion specific approach

Concentric filter-wire

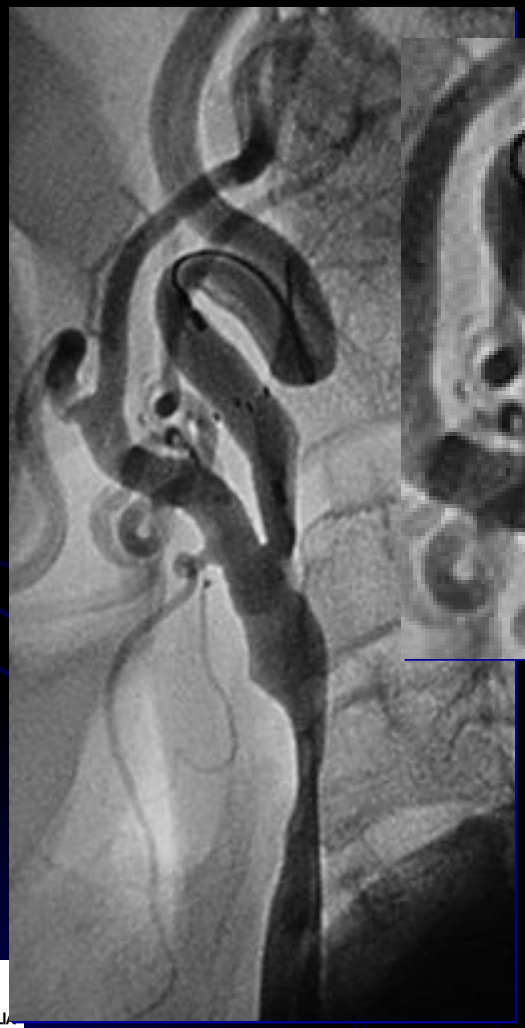


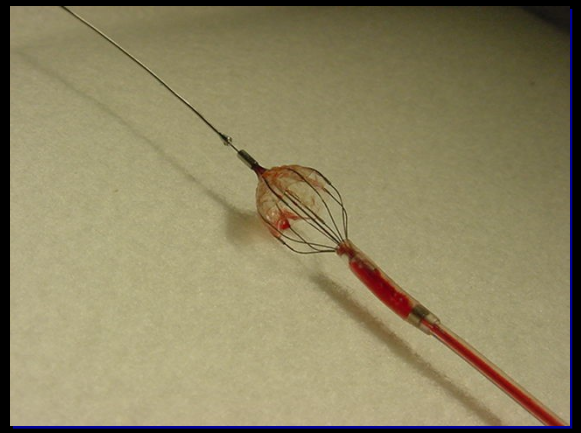
- **A larger area of filter wall apposition at the landing zone can determine:**
  1. ***Better performances in "regular" anatomy***
  2. ***Worse performances in "complex" anatomy***

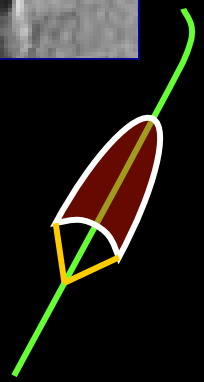


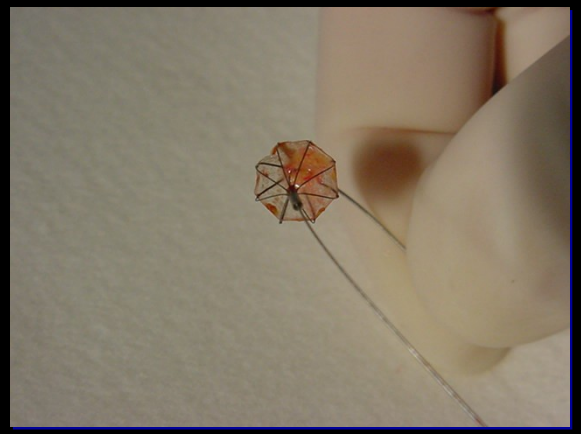
VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Concentric filter-wire: practice



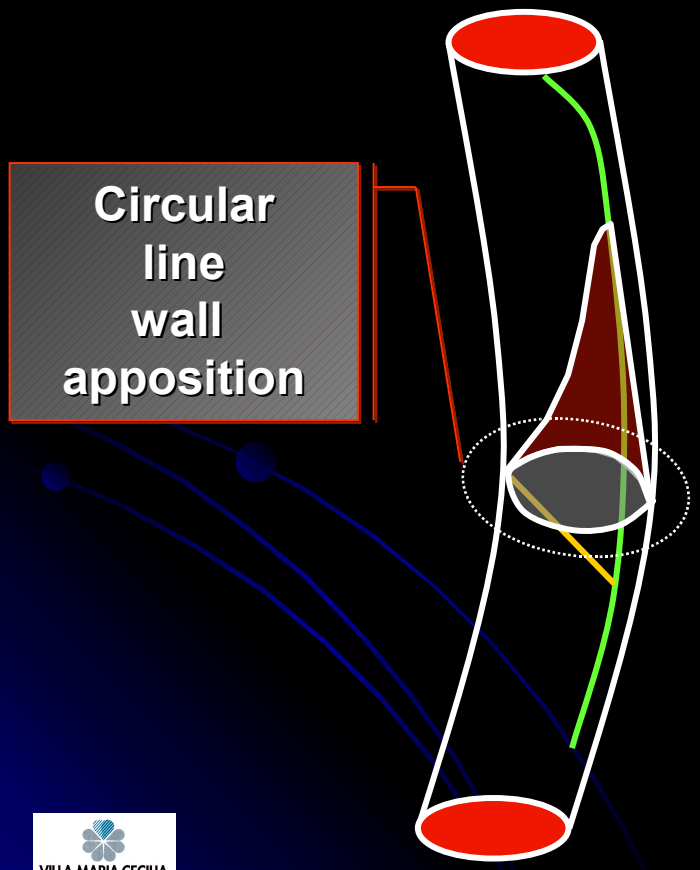




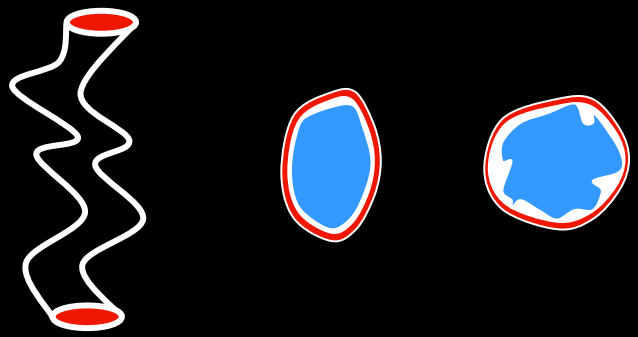


Carotid stenting
Lesion specific approach

Eccentric filter-wire



- **A linear wall apposition of filter at the landing zone can determine:**
  1. ***Good performances in "regular" anatomy***
  2. ***Better performances in "complex" anatomy***



VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Eccentric filter-wire: practice

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Case 1:
Angled soft ulcerated plaque associated to anatomic complexity

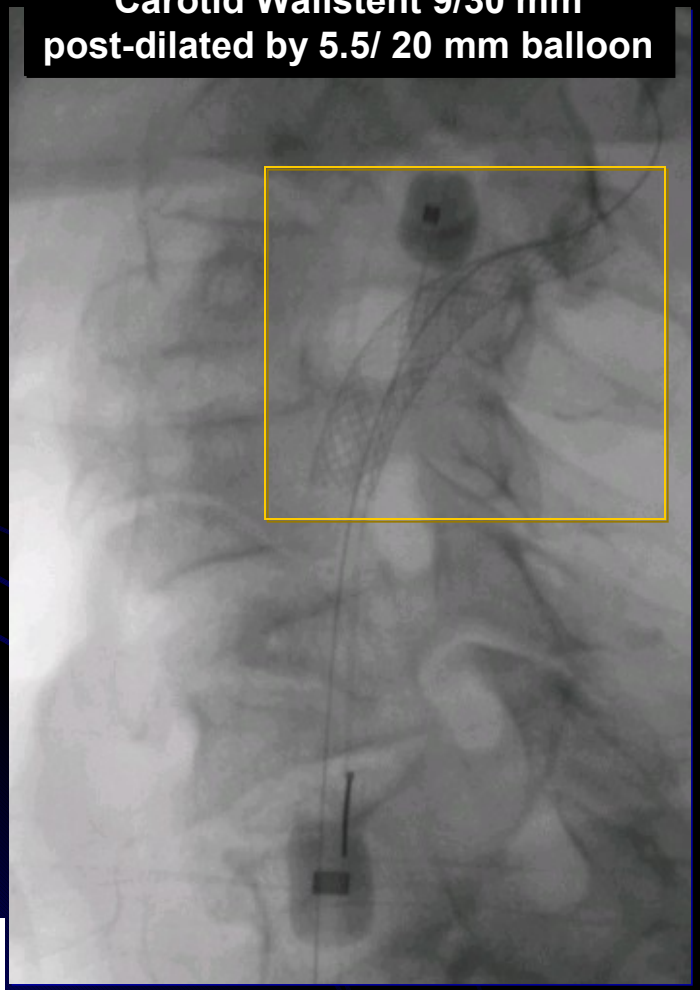
Strategy endpoints
1. Prevention of massive distal embolization
2. Respect of original anatomy
3. Prevention of plaque prolapse (late events)

Type of EPD	Proximal occlusion
Type of carotid stent	Braided mesh

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Case 1:
Angled soft ulcerated plaque associated to anatomic complexity

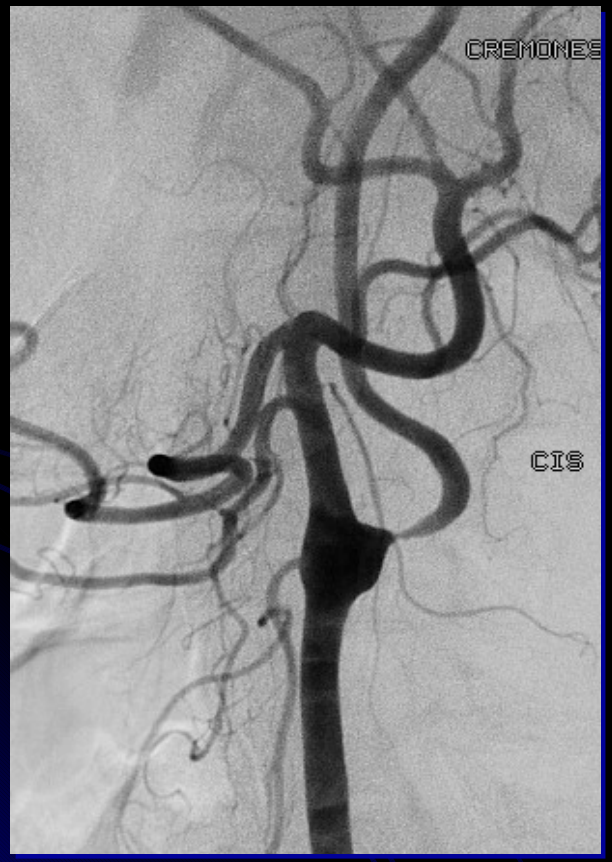
Carotid Wallstent 9/30 mm post-dilated by 5.5/ 20 mm balloon



Final result and plaque debris collected by aspiration of 60 cc of blood

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Case 2:
Angled, high grade lesion



Strategy endpoints
1. Respect of original anatomy (angled lesion, mismatch diam. CCA/ICA)
2. Spot stenting

Type of EPD	Proximal occlusion
Type of carotid stent	Nitinol, open cell, tapered

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Case 2:
Angled, high grade lesion

Final result

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Case 3:
Highly calcified plaque + bend

Strategy endpoints
1. Plaque remodeling: CBA
2. Long acting high radial force stent
3. Respect of original anatomy

Type of EPD	**Distal filter**
Type of carotid stent	**Nitinol high conformability, tapered, 30 mm**

Case 3:
Highly calcified plaque + bend

Final result

VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

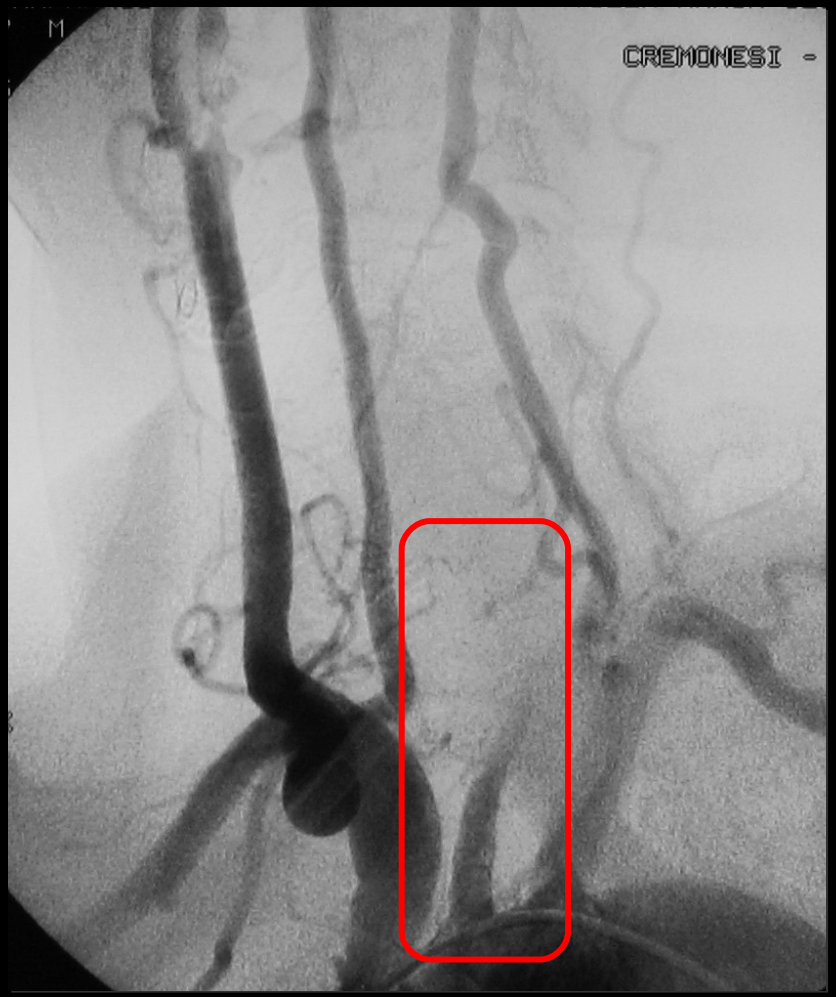
Case 4:
High grade soft ulcerated lesion
- Type I/II aortic arch, RCCA occluded -

Strategy endpoints
1. Prevention of massive distal embolization
2. Prevention of plaque prolapse (late events)

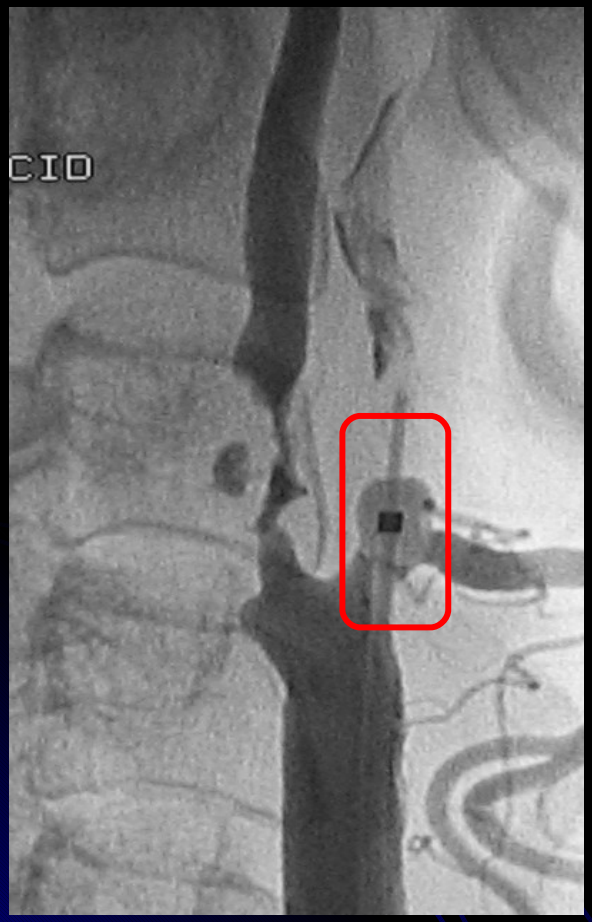
Type of EPD	**Filter wire + proximal occlusion**
Type of carotid stent	**Braided mesh**

VILLA MARIA
GRUPPO VILLA MARIA
Int.C.V.Unit

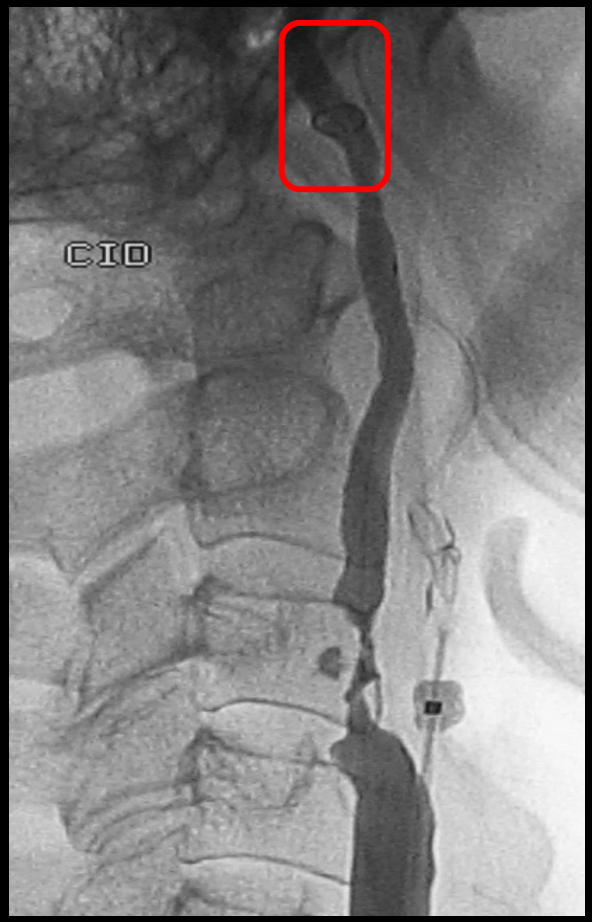
Case 5:
High grade soft ulcerated lesion
- Type I/II aortic arch, RCCA occluded -



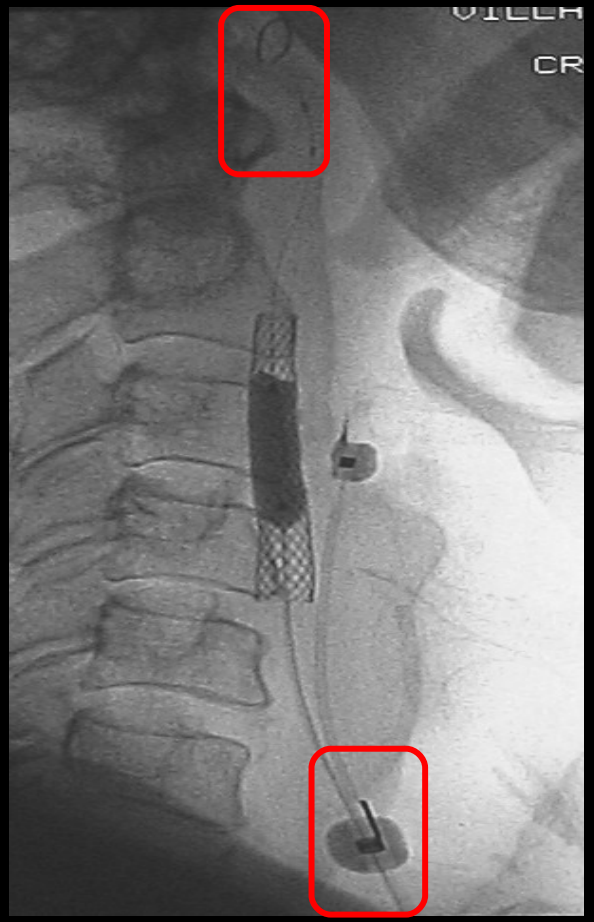
Case 5:
High grade soft ulcerated lesion
- Type I/II aortic arch, RCCA occluded -



MO.MA:
• ECA stop flow blockage

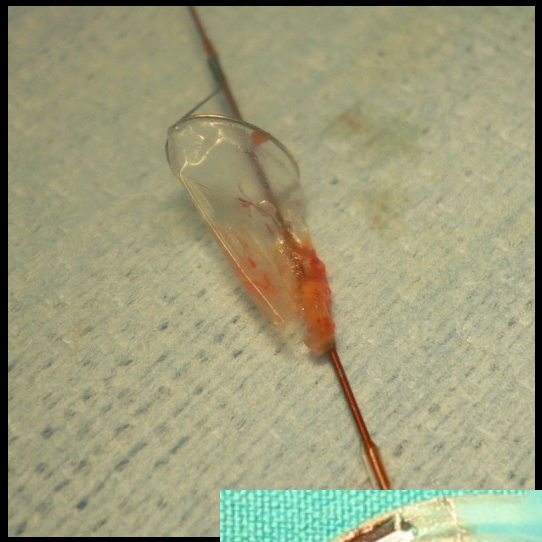


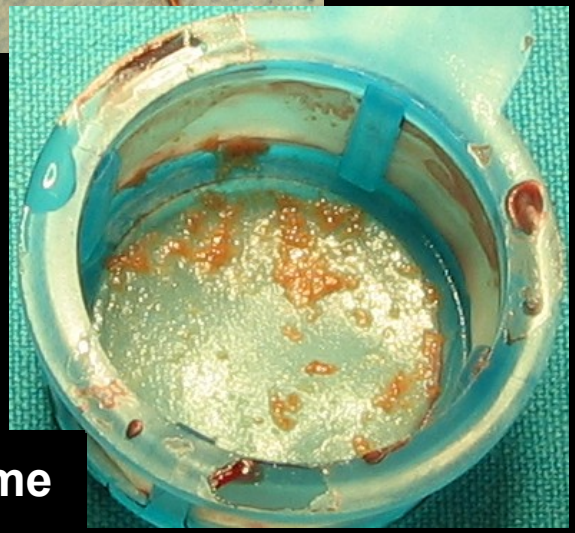
•ECA stop flow blockage
•EPI EZ filter-wire in ICA



•CCA+ECA stop flow blockage
•EPI EZ filter-wire in ICA
•Carotid Wallstent 9/30 mm

Case 5:
High grade soft ulcerated lesion
- Type I/II aortic arch, RCCA occluded -





Total occlusion time
72 seconds

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

EuroPCR 2005

Carotid angioplasty and stenting: lesion related treatment strategies

Alberto Crem Castriota,
et al

Submitted to EuroIntervention

Stenting strategies to prevent peri-procedural complications

Carotid lesion / bifurcation issue	Type of stent
1. medium to long lesions (15 to >25 mm) 2. soft-dishomogeneous lesions 3. straight carotid bifurcation	Cobalt-alloy braided thread stent
1. carotid bifurcation lesions with ICA/ CCA diameter mismatching 2. angled carotid bifurcation	Nitinol open cell stents
1. short lesions (<15 mm) 2. highly calcified lesions 3. straight carotid bifurcation	Nitinol closed cell stents

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

Stenting strategies to prevent peri-procedural complications

Carotid lesion / bifurcation issue	Type of stent
Plaque covering Long acting plaque prolapse prevention	Cobalt-alloy braided thread stent
In vessel flexibility Wall/plaque conformability	Nitinol open cell stents
Outward radial force Resistance to compression	Nitinol closed cell stents

EPD strategies to prevent peri-procedural complications

Carotid lesion / vascular anatomy issue	Type of EPD
1. predominantly echogenic fibrous plaques 2. calcified plaques 3. contralateral carotid severe stenosis / occlusion	Distal filters
1. anechoic soft plaques at high risk for distal embolization 2. ICA lesions followed by extreme post-stenosis tortuosity 3. sub-occlusive / string sign lesions	Proximal endovascular clamping devices

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

EPD strategies to prevent peri-procedural complications

Carotid lesion / vascular anatomy issue	Type of EPD
Standard anatomies Low to medium risk of embolization	Distal filters
Complex anatomies High risk of embolization	Proximal endovascular clamping devices

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

“Tailored CAS” in an unselected population

A. Cremonesi et. al, 2005 – In press

Patients	377
Symptomatic Patients	64,72 %
Risky plaques	
Uniformly echolucent	20,69 %
Severe calcifications	13,79 %
Erosion / Ulcer	35,54 %
All stroke and death rate @ 30 days	1,33 %

Neurological events defined by independent neurological team

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

ISES 2005
February 14, 2005

Carotid soft plaque endovascular treatment: single centre experience

Alberto Cremonesi, Faust
Raffaell

Int vascular Unit
ia - Cotignola (RA) Italy

Submitted to JEVT

EPD strategy related to the specific carotid lesions

Carotid lesion issue	Type of EPD
1. anechoic soft plaques at high risk for distal embolization 2. sub-occlusive / string sign lesions	Proximal endovascular clamping devices

EPD strategy related to the specific carotid lesions

Carotid lesion issue	Type of EPD
High risk of significant embolization	Proximal endovascular clamping devices

“Tailored CAS” in a selected population at high risk for procedural embolization

A. Cremonesi et. al, 2005

Patients	78
Symptomatic Patients	85,90 %
Risky plaques Uniformly echolucent < 25 GSM	100,00 %
All stroke and death rate @ 30 days	1,28 %
Neurological events defined by independent neurological team	

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

GISE 2005

Carotid highly calcified plaque endovascular treatment: the role of plaque remodelling induced by CBA

Alberto Cremonesi, [illegible]niota, Ca[illegible] et al

Work in progress

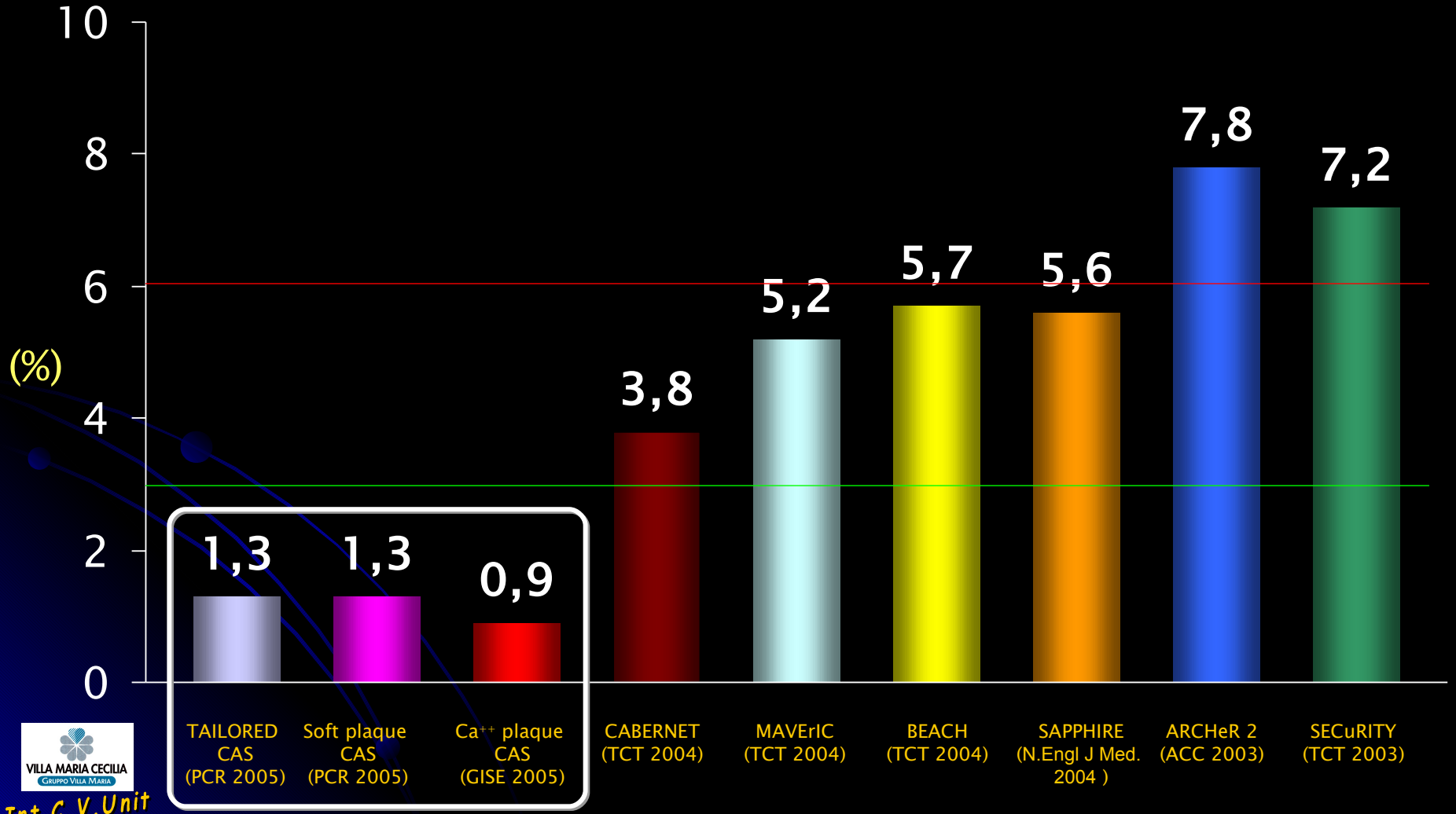
Carotid highly calcified plaque endovascular treatment: the role of plaque remodelling induced by CBA

A. Cremonesi et. al, 2005

Patients	107
Symptomatic Patients	49 %
Risky plaques Severely calcified	100,00 %
All stroke and death rate @ 30 days	0,93 %
Neurological events defined by independent neurological team	

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

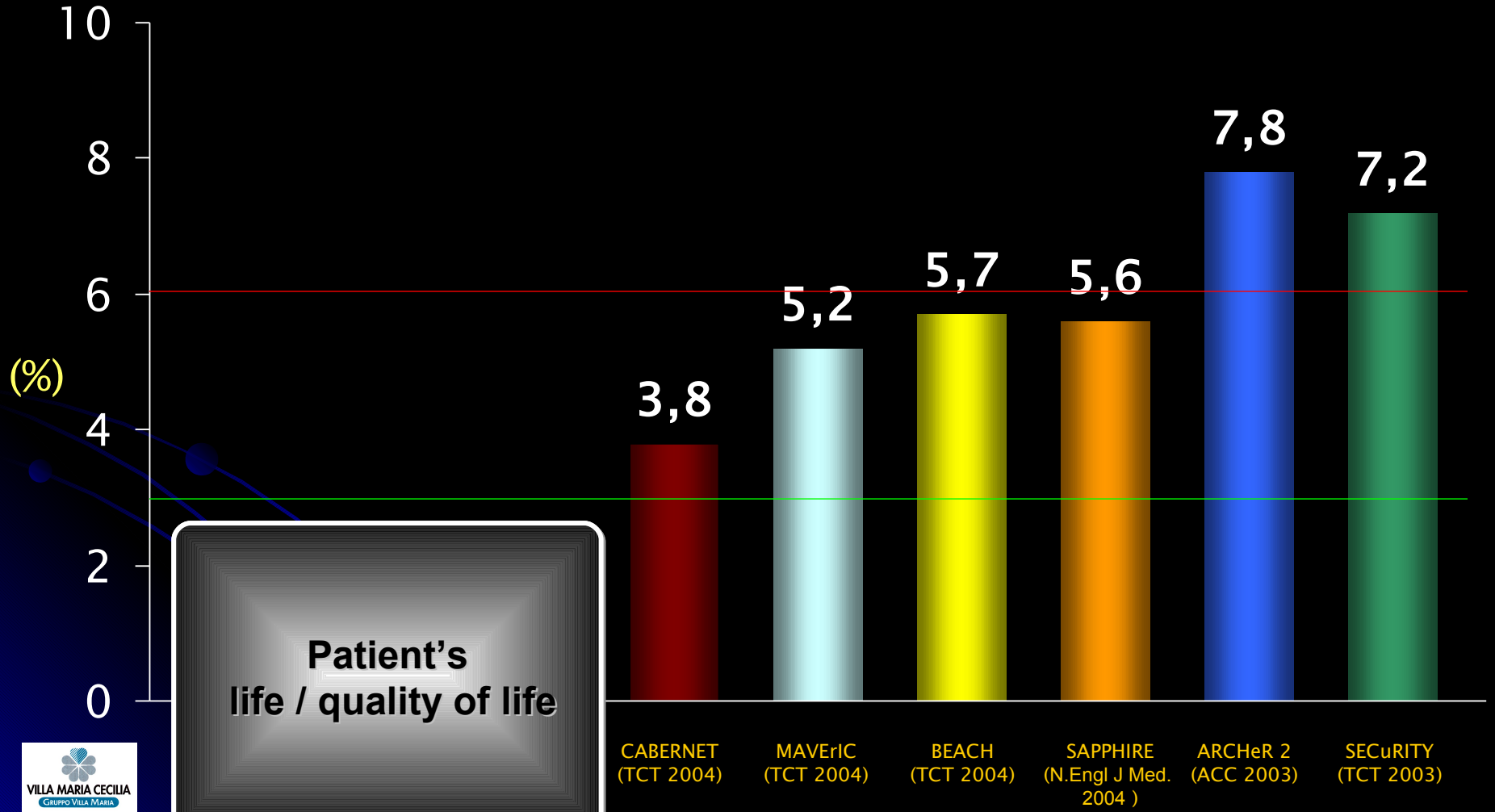
30-Day Composite Endpoint Carotid Stenting Registries/CRT vs "Tailored CAS"



VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

30-Day Composite Endpoint Carotid Stenting Registries/CRT vs "Tailored CAS"



Patient's life / quality of life

VILLA MARIA CECILIA
GRUPPO VILLA MARIA

Int.C.V.Unit

A lesion specific approach to carotid stenting
Conclusion

- Neither the ideal stent nor the ideal neuro-protection device does exist at the moment!

- The individual treatment strategy remains by now the only logical answer for treating standard as well as complex carotid lesions and anatomies

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit

A lesion specific approach to carotid stenting

Conclusion

- **Neither the ideal stent nor the ideal neuro-protection device does exist at the moment!**

Brain & Hands Approach

VILLA MARIA CECILIA
GRUPPO VILLA MARIA
Int.C.V.Unit