

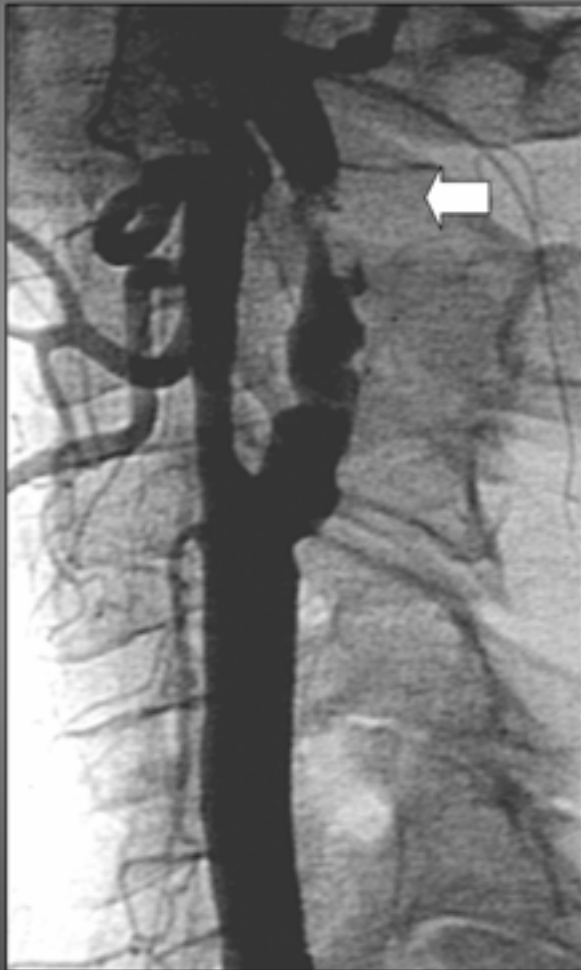
Update on Carotid Artery Stenting

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University of Leipzig – Heart Center & Park Hospital
Leipzig, Germany**

Carotid Artery Stenosis:

The dimension of the problem

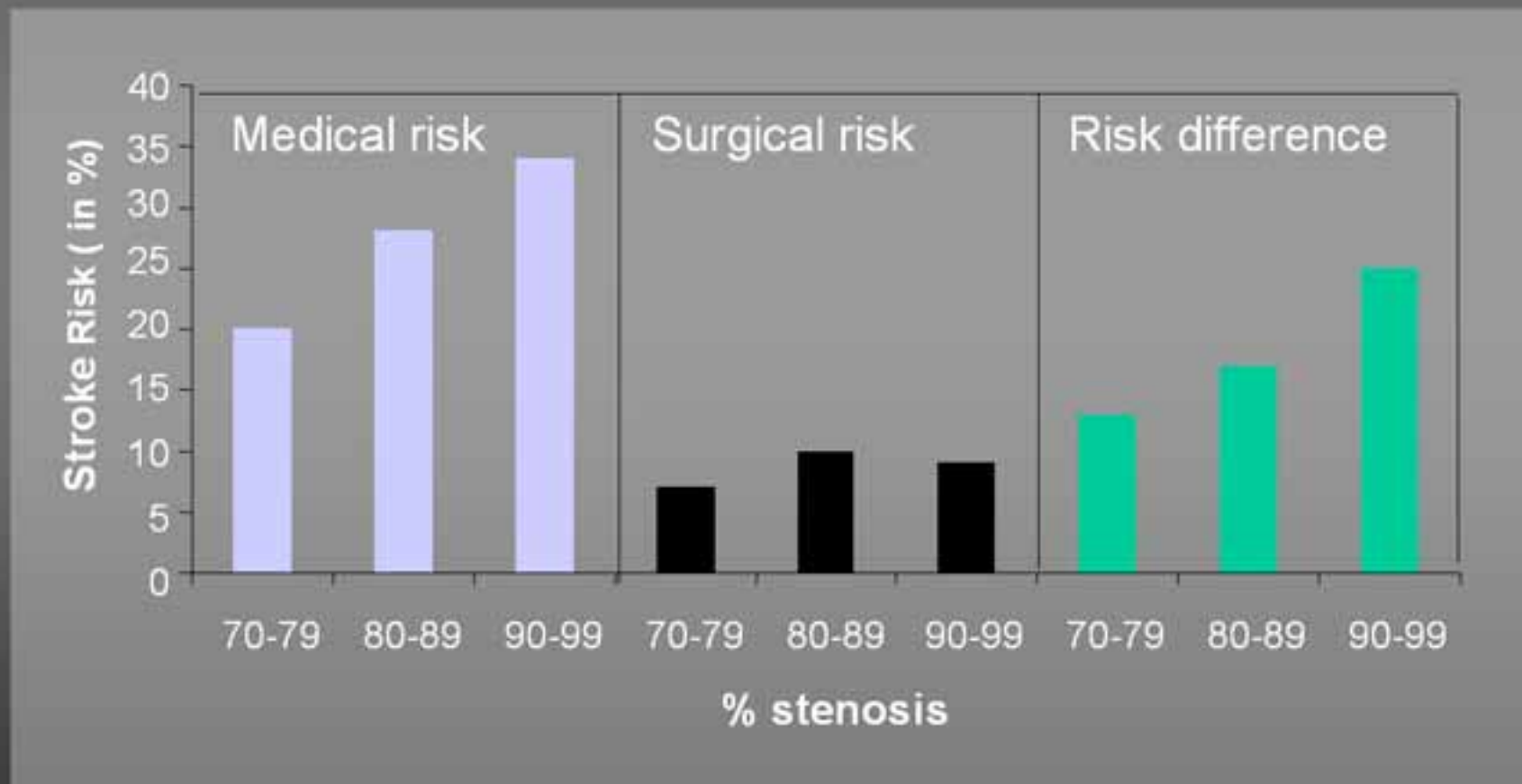


- 3rd leading cause of death in US following heart disease and cancer
- Stroke is the primary cause of long-term disability in the Western Europe and US
- 30-40% of these are related to carotid artery disease

Symptomatic patients

Medical vs Surgical treatment

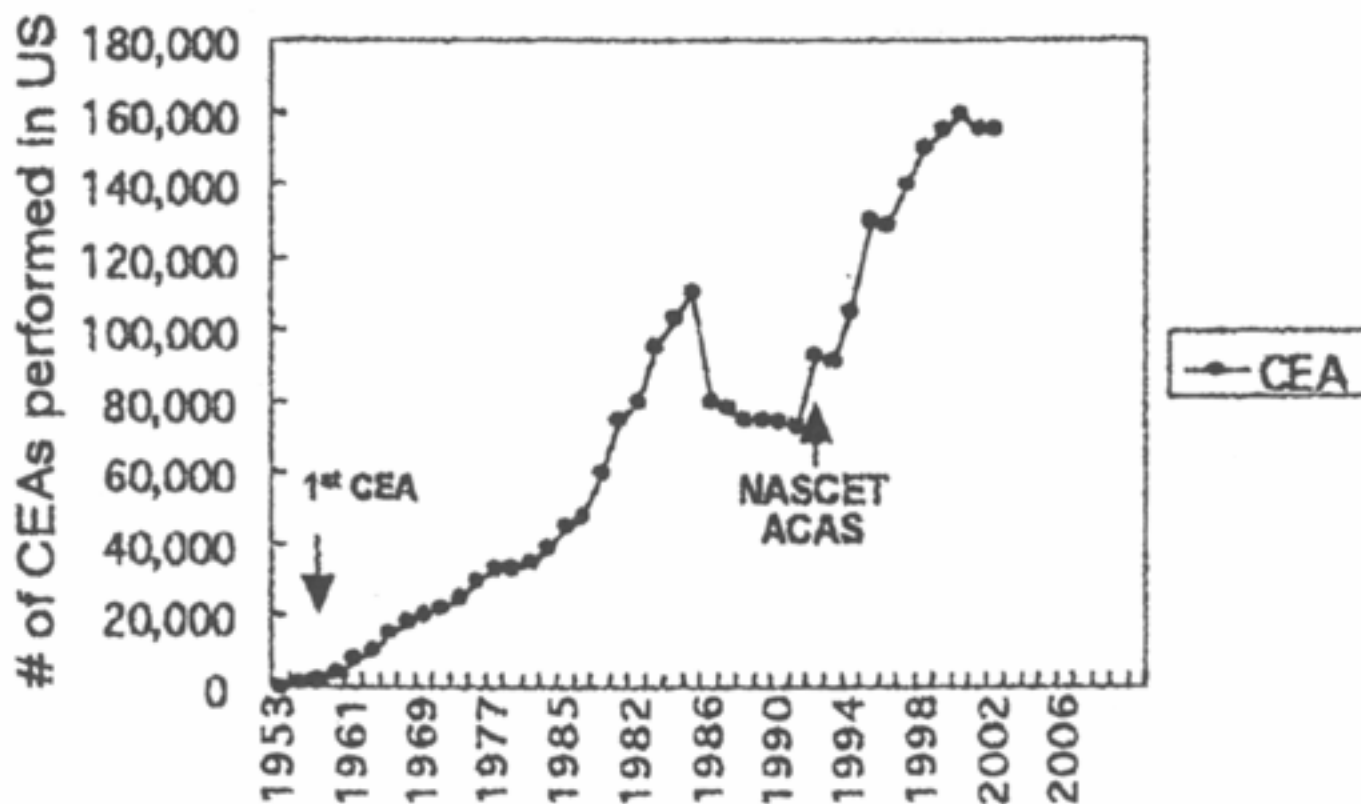
- **NASCET** (North-American Symptomatic Carotid Endarterectomy Trial)



Frequency of Carotis-TEA

Number of CEAs and Major Milestones in carotid intervention

Ohki, Morgan Stanley estimates



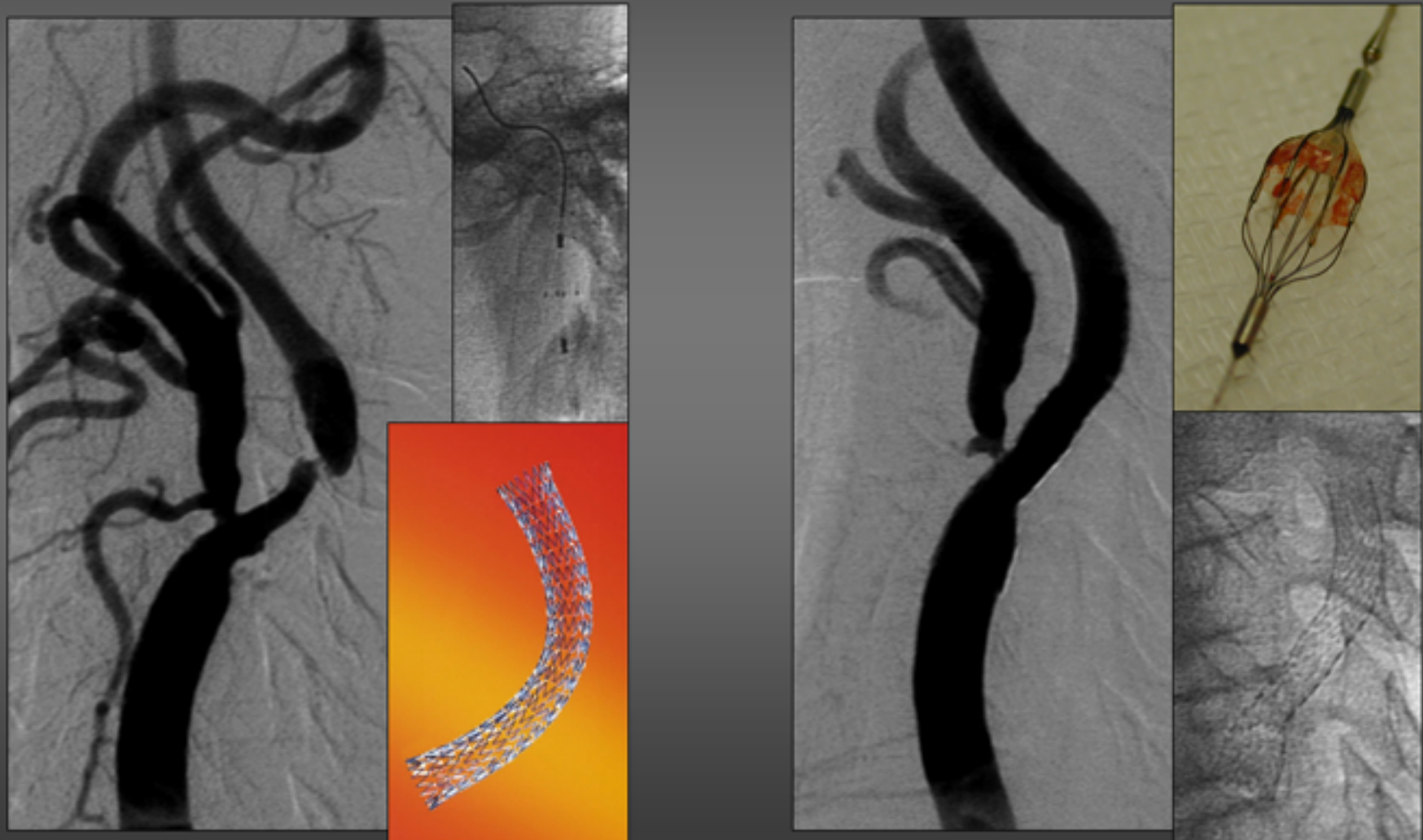
Indication for CEA

North American Symptomatic Carotid Endarterectomy Trial

- >60% Stenosis of the ACI in **Symptomatic** Patients
(peri-operative Complication Rate 5-10%)
- 70-99% Stenosis of the ACI in **Asymptomatic** Patients
(peri-operative Complication rate <3%)



Carotid artery stenting (CAS) has emerged as an alternative to surgical endarterectomy (CEA).

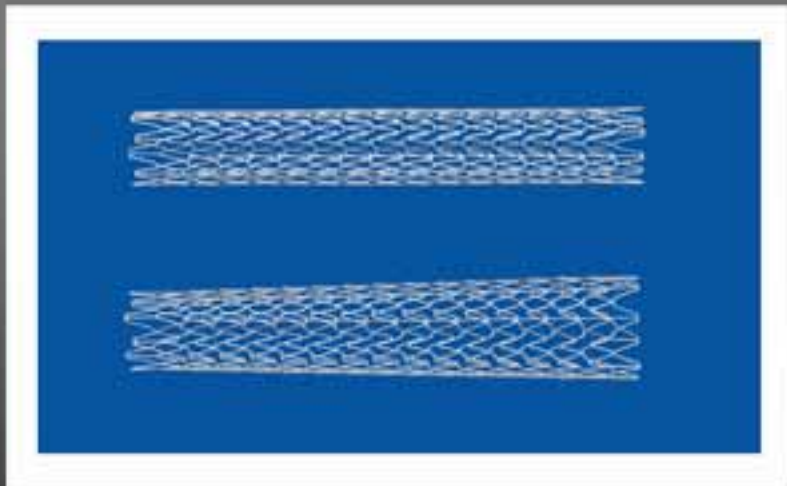


Rationale for Carotid Stenting

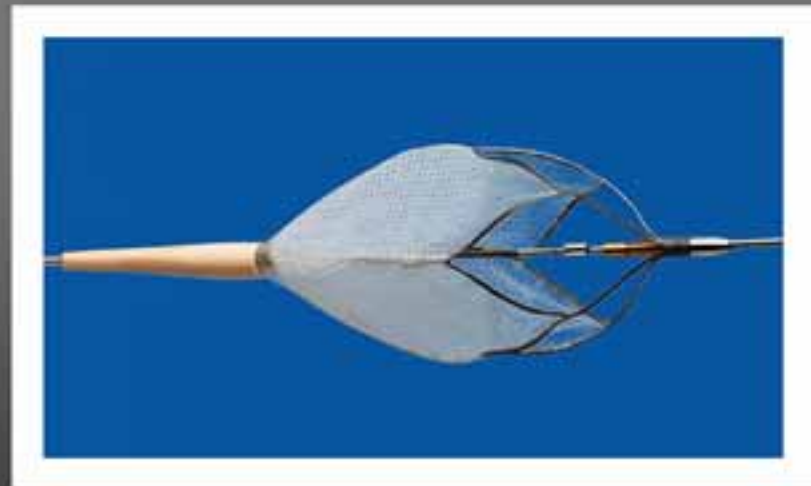
- Procedure is less invasive and safe
- In Hospital-stay is shorter
- CAS is cost – effective
- Patients are happier
- Mortality and Morbidity are lower (?)
- Restenosis - rate is lower (?)

Carotid Artery Stenting (CAS)

**First FDA Approval
Sept. 10th 2004**



Guidant ACCULINK™ Stent



Guidant ACCUNET™ Filter

Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy

(The **SAPPHIRE** Study)
NEJM, 2004;351:1493

Sapphire

>50% stenosis SX

>80% stenosis Asx

One or More Comorbidity Criteria

Physician Team: Neurologist, Surgeon, Interventionalist

CONSENSUS

Surgical Refusal



**Stent
Registry
409**



RANDOMIZED
307
Stenting = 156
CEA = 151

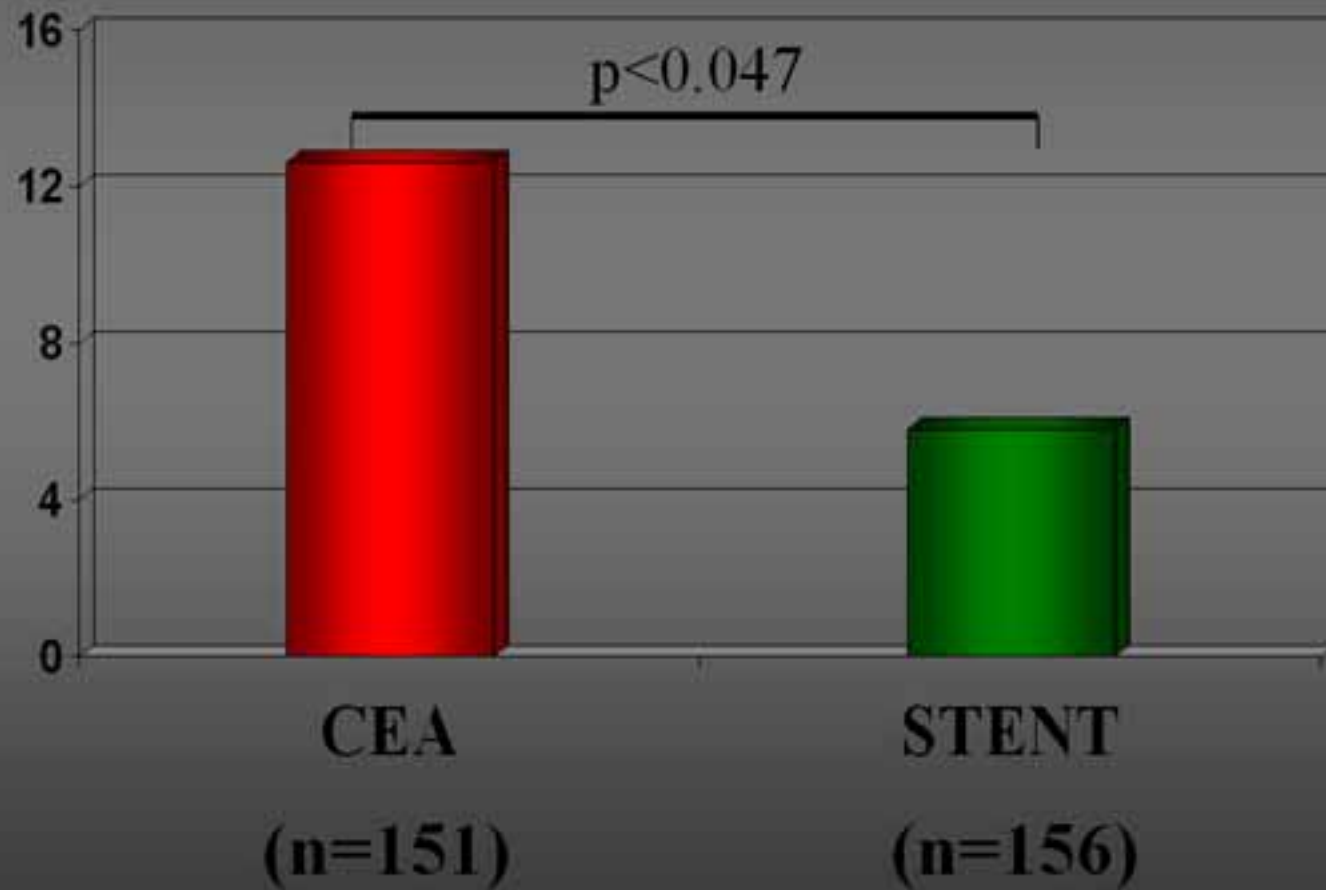
**Interventional
Refusal**



**Surgical
Registry
7**

Sapphire - Study

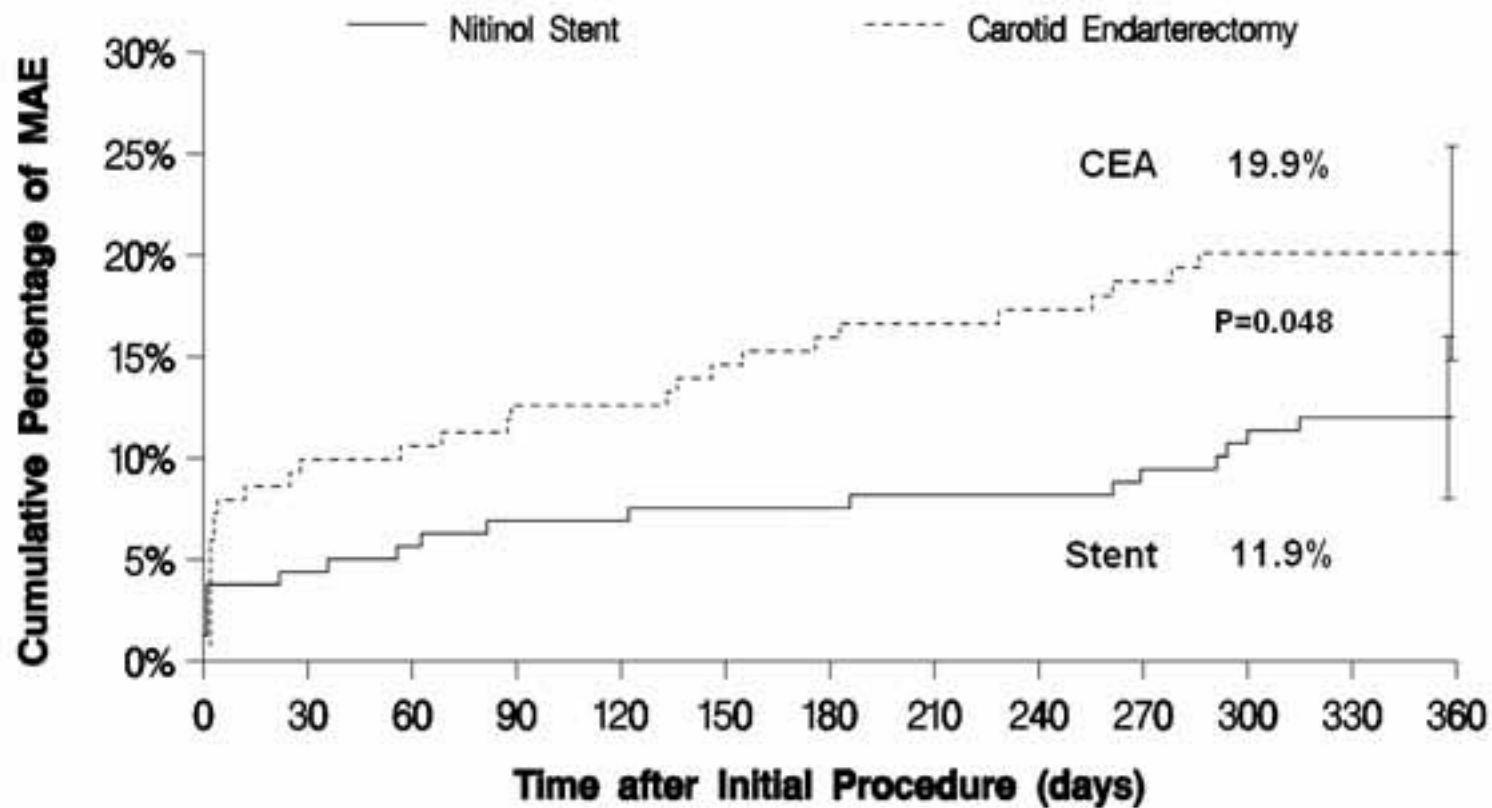
Death, MI, Stroke at 30 Days



Sapphire Study – 30 day Results

	Stenting	TEA	<i>P</i>
Death	0,6%	2,0%	0,29
Stroke	3,1%	3,3%	0,94
MI	1,9%	6,6%	0,04
Nerve lesions	0	4,9%	0,004
Hospital stay	1,84	2,85	0,002

SAPPHIRE randomized: 1 year data



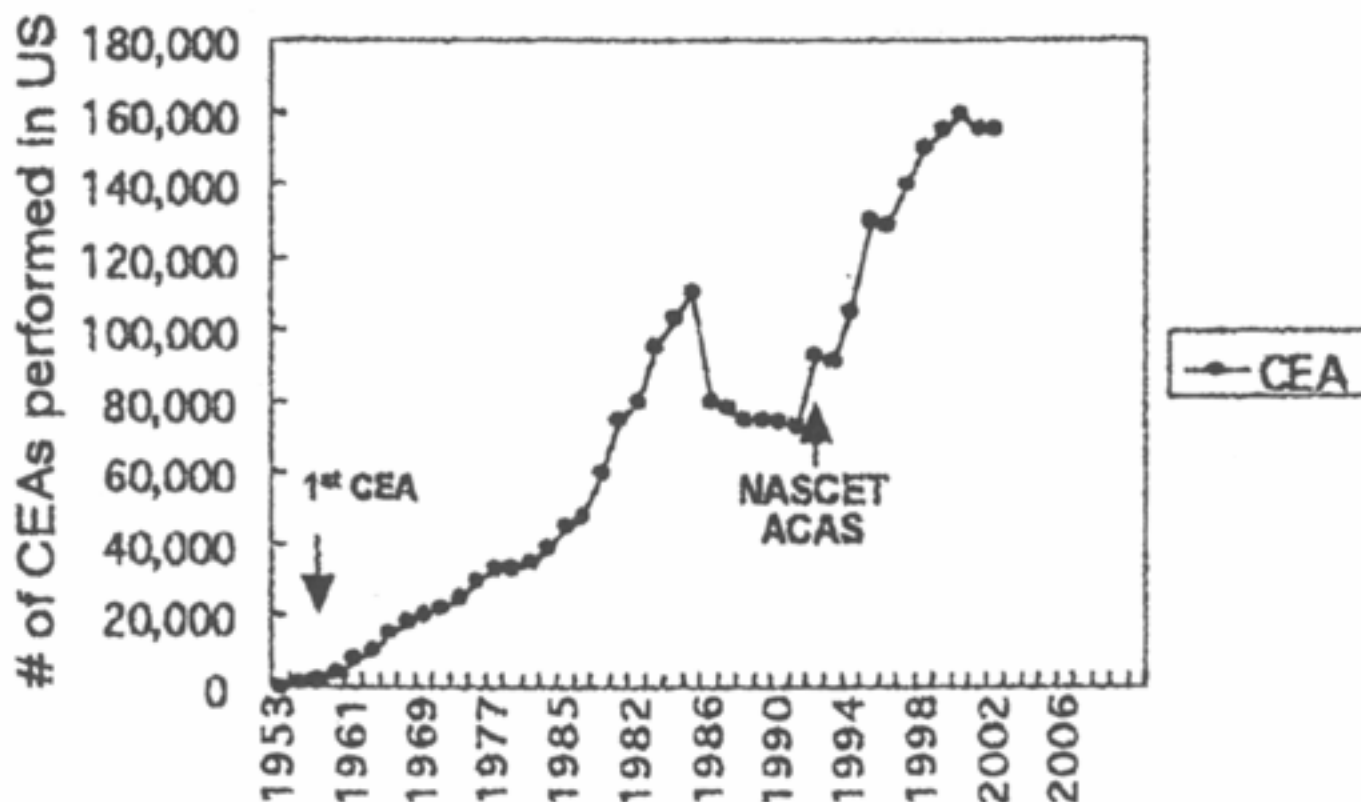
Sapphire Study – 1 year Results

	Stenting	TEA	<i>P</i>
Death	7,0%	12,9%	0,08
Stroke	5,8%	7,7%	0,52
Major ipsilateral	0	3,5%	0,02
Repeat revascularization	0,7%	4,6%	0,04
Primary endpoint	12,0%	20,1%	0,048

Developement of Carotis-TEA

Number of CEAs and Major Milestones in carotid intervention

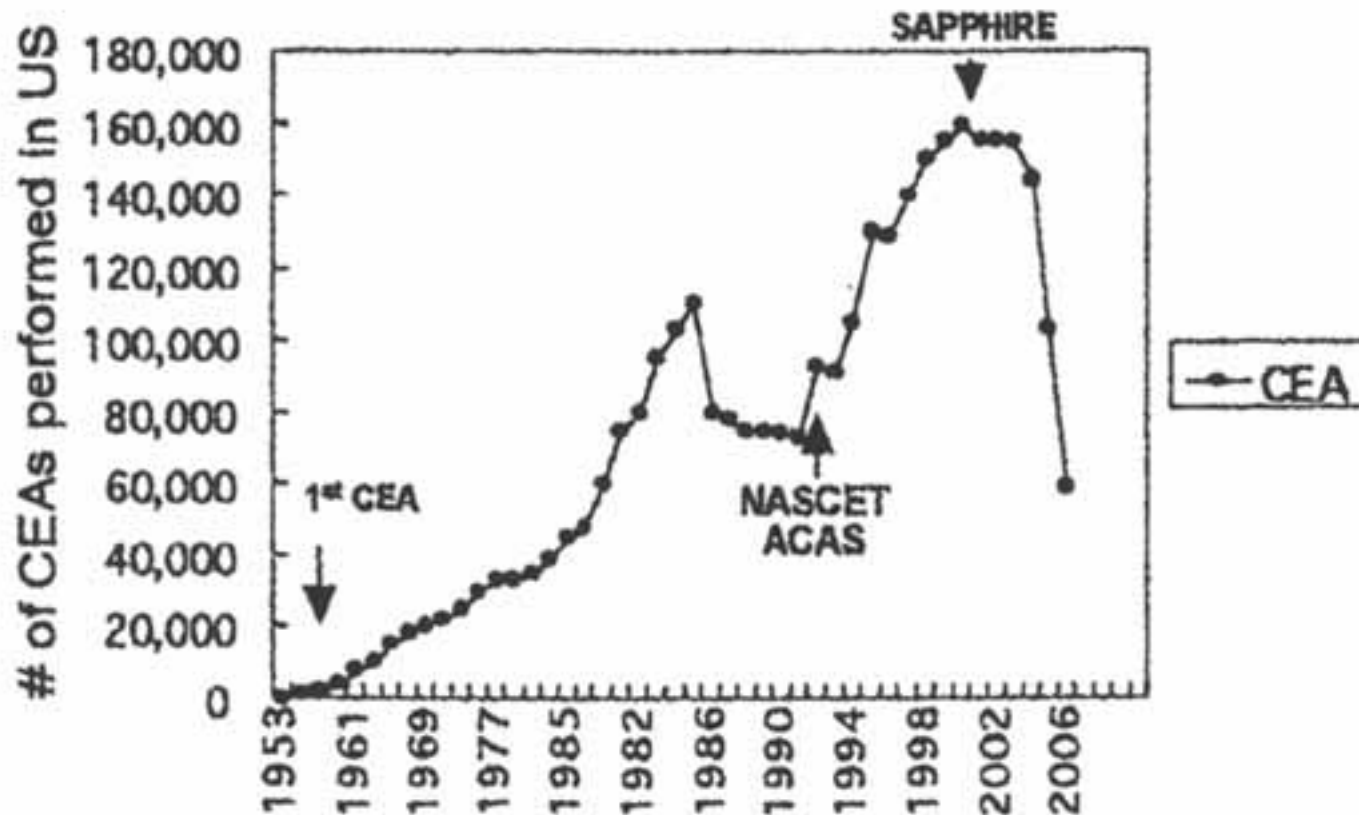
Ohki, Morgan Stanley estimates



Development of Carotis-TEA

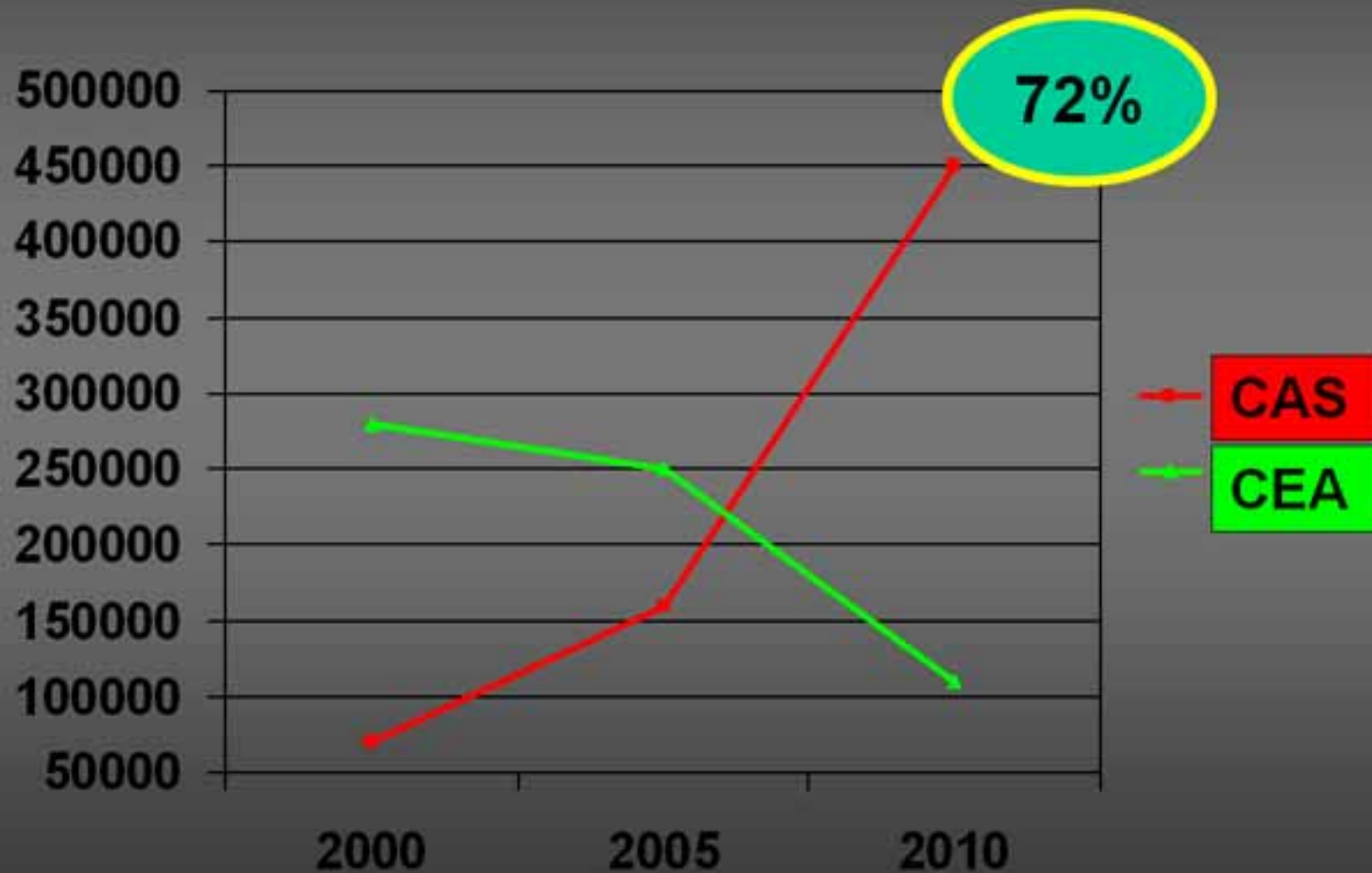
Number of CEAs and Major Milestones in carotid intervention

Ohki, Morgan Stanley estimates



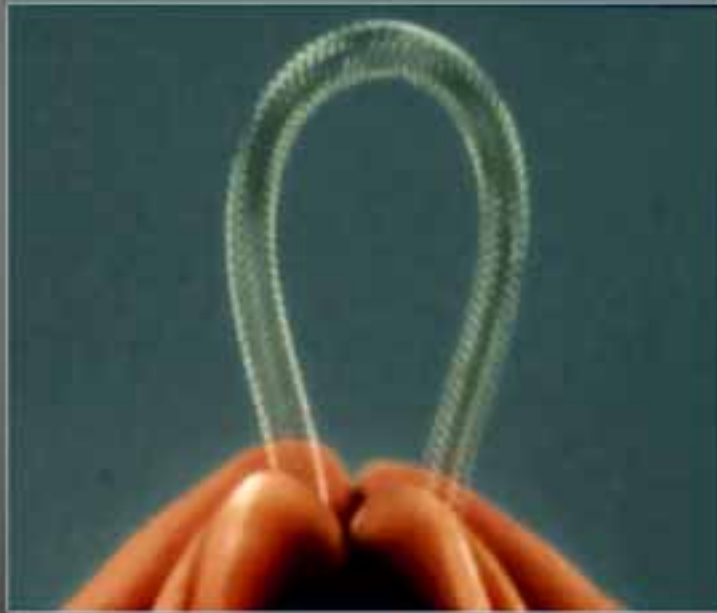
World Wide Carotid Procedures

Morgan Stanley, BSC, estimates

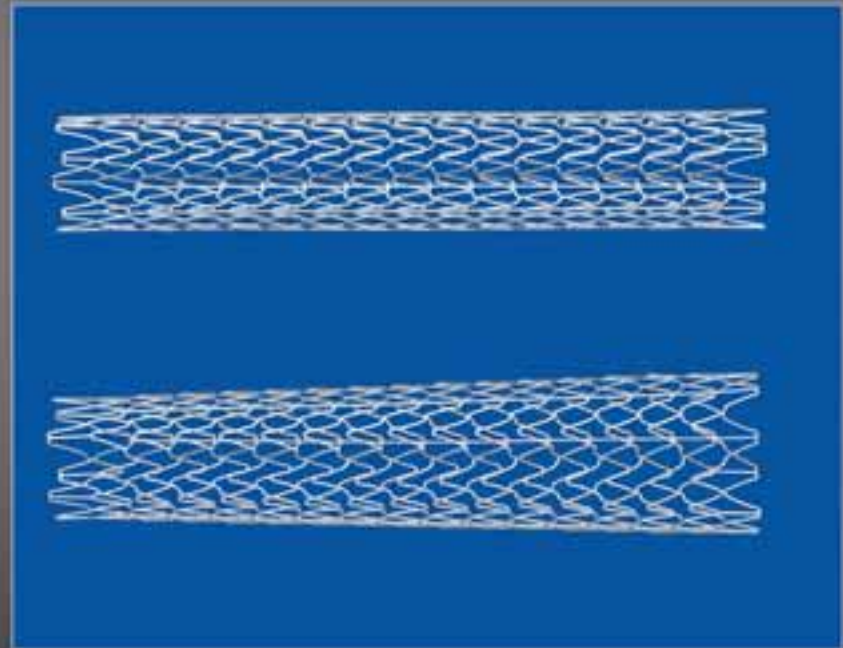


Selfexpanding Stents for CAS

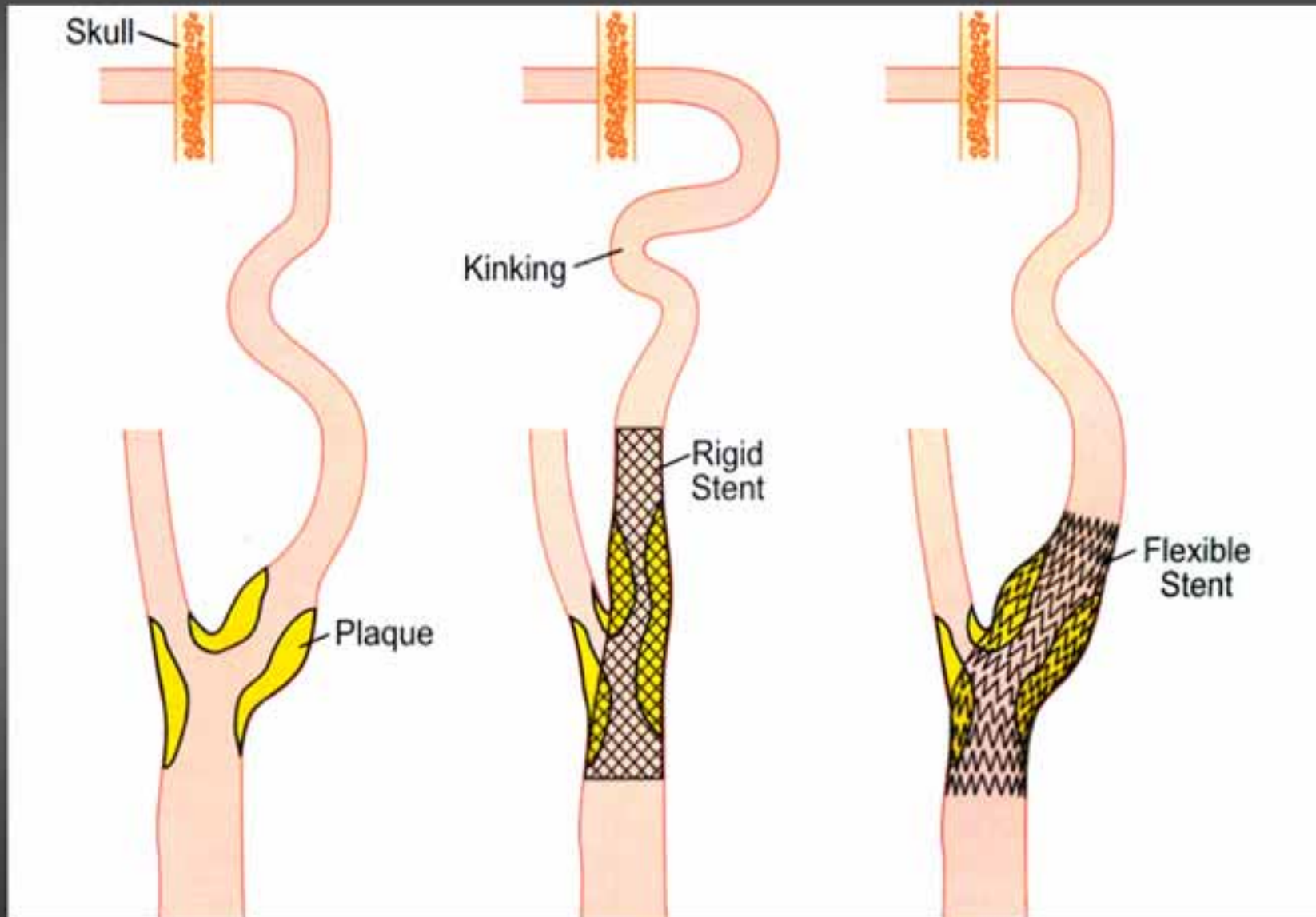
Carotid-Wallstent
Stainless-steel



Nitinol-Stents
Nickel / Titanium - alloy

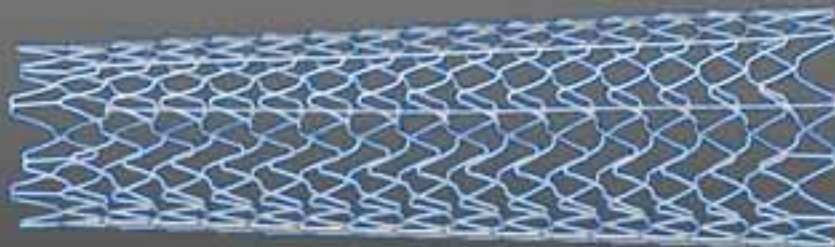
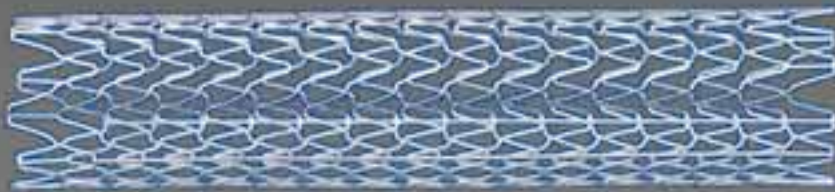


Selection of the Stent



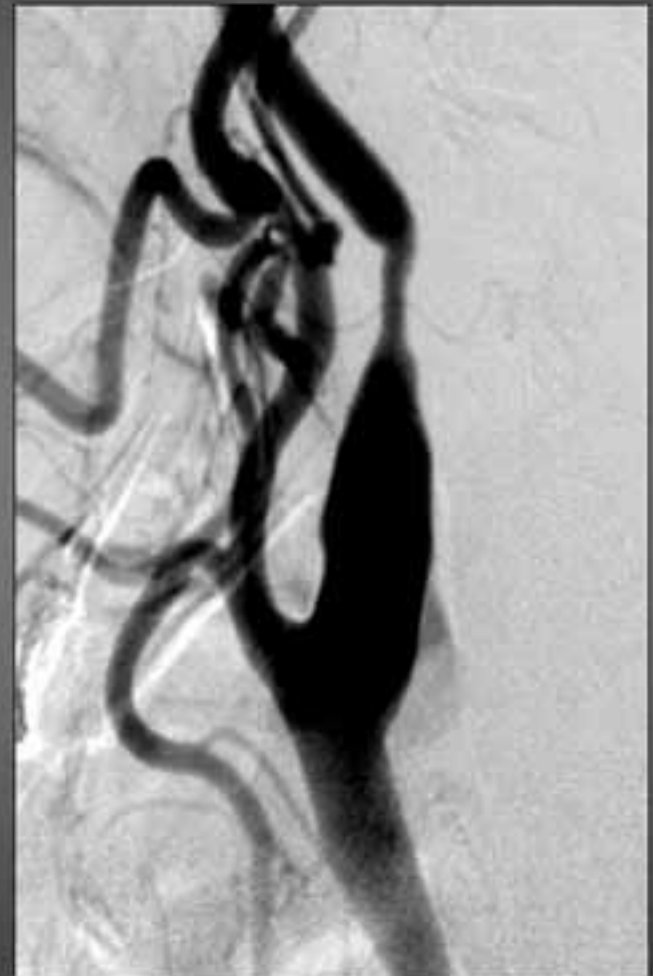
Vessel-Wall Alignment of Stents

Acculink (Guidant)



6 → 8mm

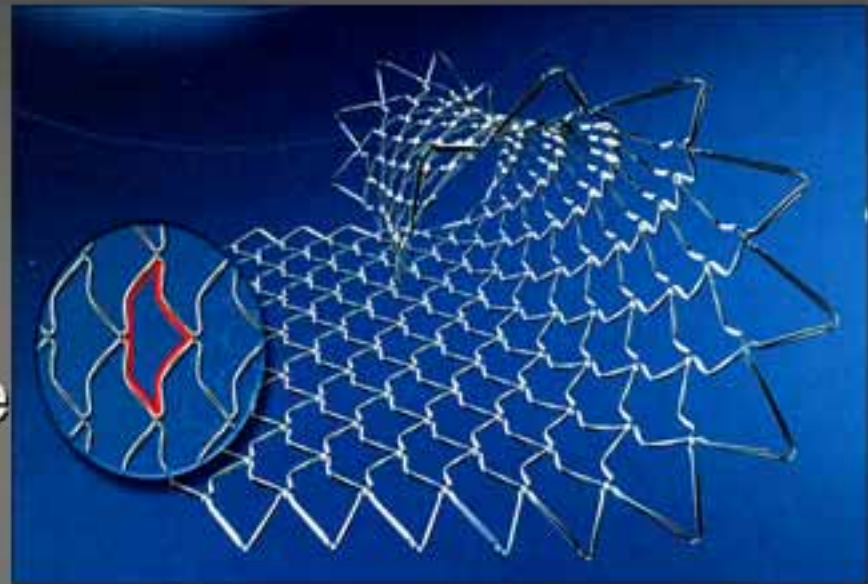
7 → 10mm



NexStent™ Monorail™ (B.S.)

- Nitinol-stent
- Closed-cell design
- 5F system
- 1 stent for vessel-diameter

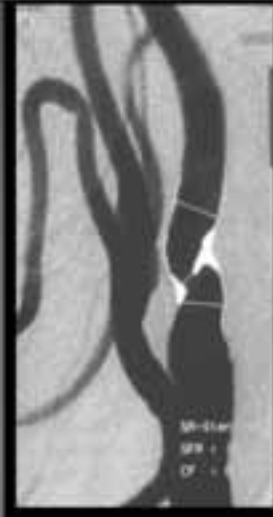
4 – 9 mm



- CABERNET NexStent clinical trial
 - 488 patients
 - 30-MAE: 3,8 % (stroke, MI, death)
 - After 1 year no restenosis

Neurological complication during carotid angioplasty

Baseline



Baseline



Critical 80%,
irregular stenosis
of LICA in
asymptomatic
patient.

After Stent

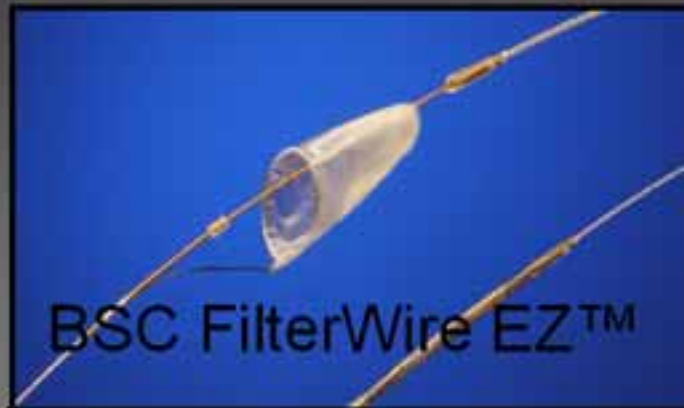


After Stent

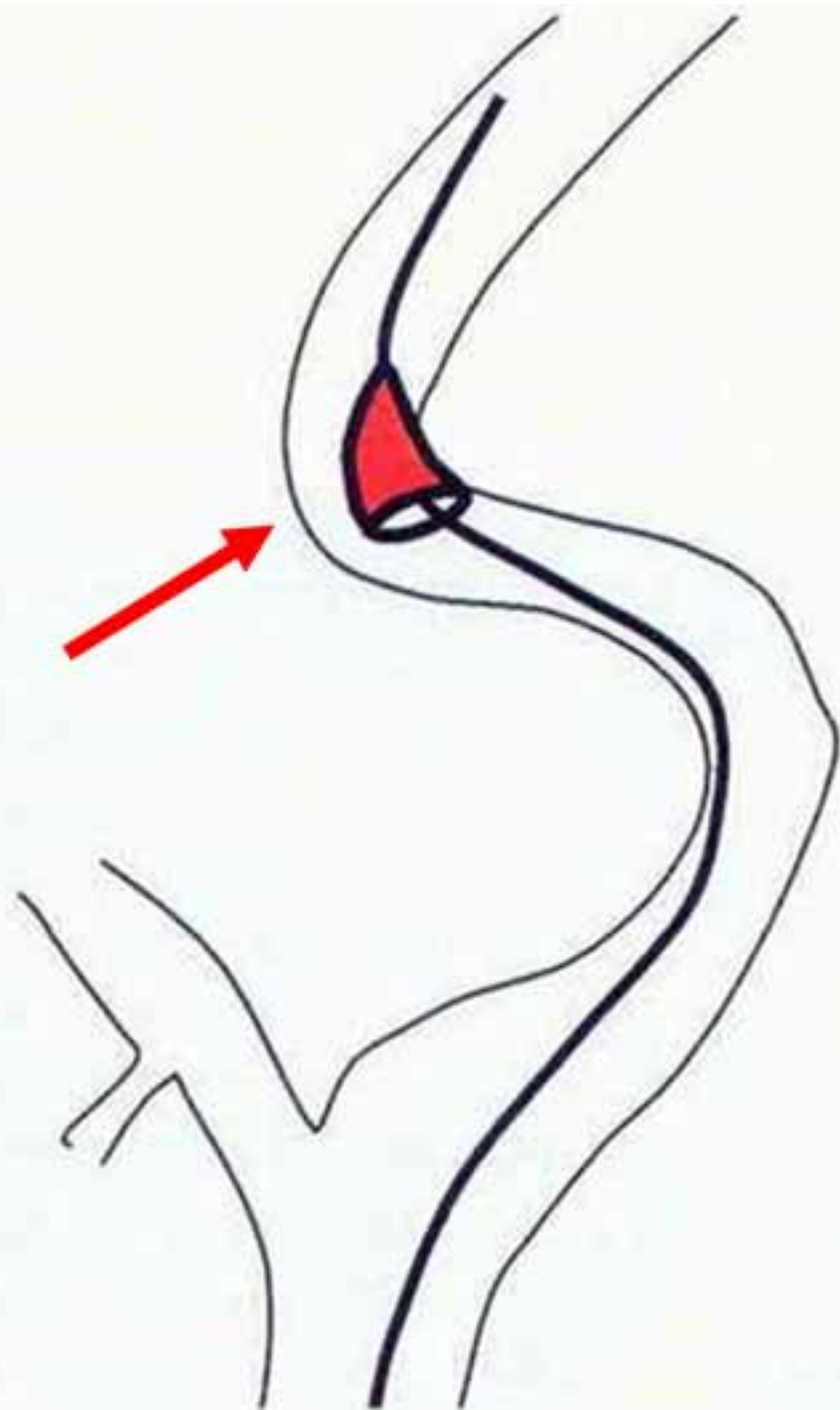


Thrombotic
occlusion of side
branch of median
artery.
Transient
hemianopsia,
persistent aphasia

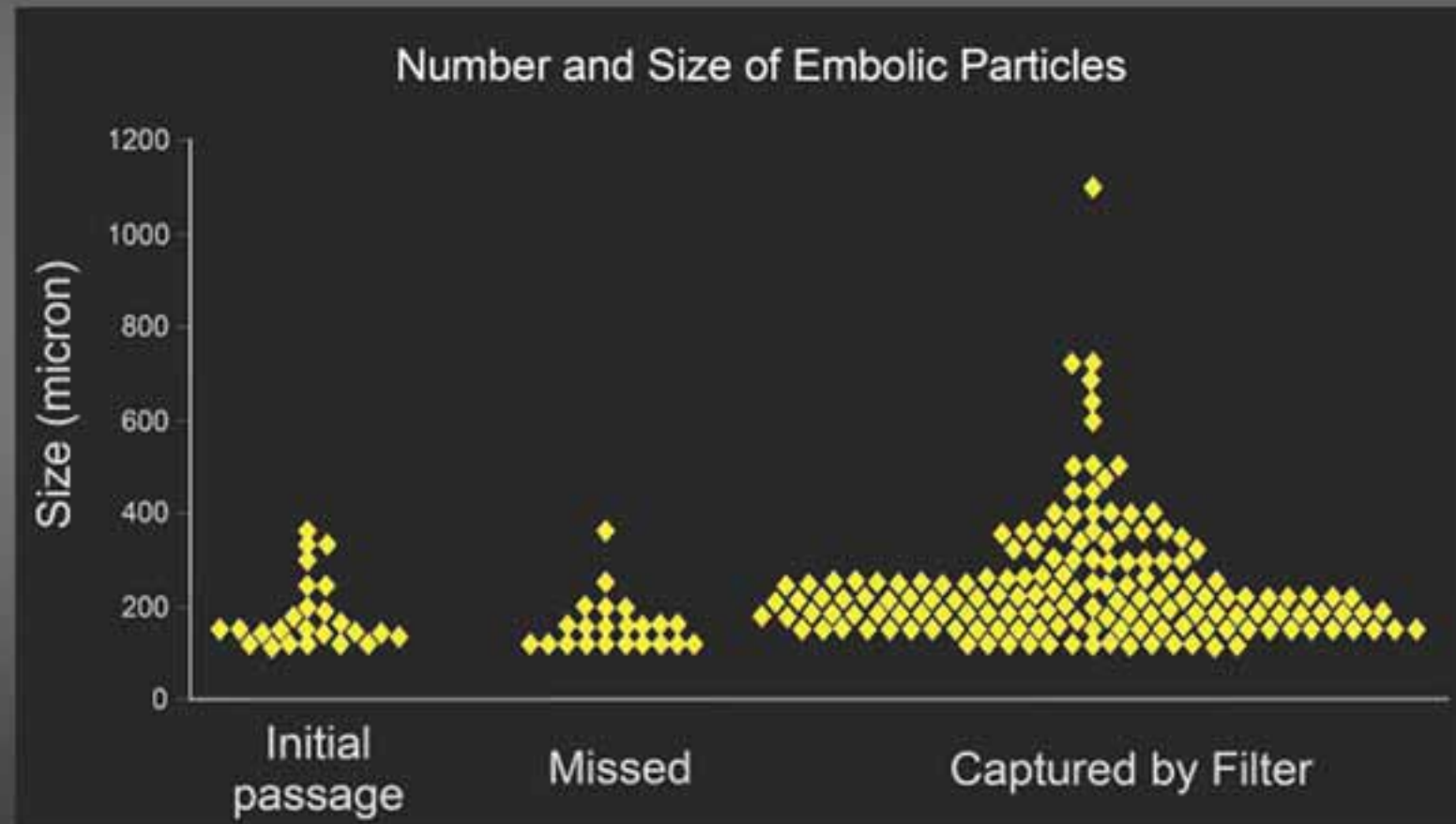
Filter - Protection Systems



- Maintained antegrade flow during intervention
- Passage of the stenosis before neuroprotection



Filter Protection



Ohki T et al. - J Vasc Surg - 1999;30:1034-44

Cerebral Protection with MoMa



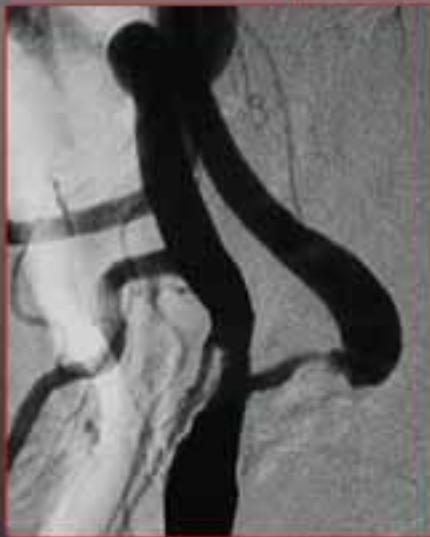
Proximal Flow Blockage

Indications

- **1st Choice 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)

Proximal Flow Blockage

Indications



Proximal Flow Blockage

Indications

- Recommended Choice in *Severe Anatomical Complexity*
 - Difficult to access ICAs due to very angulated ICA-CCA take-off and tortuous ICAs
 - Lack of a suitable ICA's landing zone for distal protection

Proximal Flow Blockage

Indications



PRIAMUS Registry – Patient Demographics

“PROximal Endovascular Flow Blockage for Cerebral Protection
During CARotid Stenting: Results from a MULTIcenter Italian
RegiSTRy”*

Patients	416
Symptomatic Patients %D.S. > 50%	264 (63,5%)
Asymptomatic Patients %D.S. > 70%	152 (36.5%)
Mean %D.S. diameter stenosis	80.03% ± 9.8
Mean age (300 men/ 116 women)	71.6y ± 9
Lesion characteristics/ morphologies	
Lesion length > 1.5 mm	297 (71.4%)
De novo lesions	401 (96.0%)
Ostial lesions	273 (65.6%)
Heterogeneous soft	211 (50.7%)
Restenotic, calcified	15 (3.6%)

*Coppi, G. et al., JCardiovasc Surg 2005; 46: 219-27

PRIAMUS Registry – Procedural Data

"PRoximal Endovascular Flow Blockage for Cerebral Protection
During CArotid Stenting: Results from a MUlticenter Italian
RegiStry"*

Protection successfully established	414 (99.5%)
Intolerance to Flow Blockage	24 (5.7%)
Resolved by intermittent balloon deflation	7
Using different protection device	5
Mean flow blockage time	4.91 min. \pm 1.1
Mean back pressure	50.8 mmHg \pm 7.5
Evidence of macroscopic debris	245 (58.9%)
Stent placement and postdilation	416 (100%)

*Coppi, G. et al., JCardiovasc Surg 2005; 46: 219-27

PRIAMUS Registry - outcome/complication

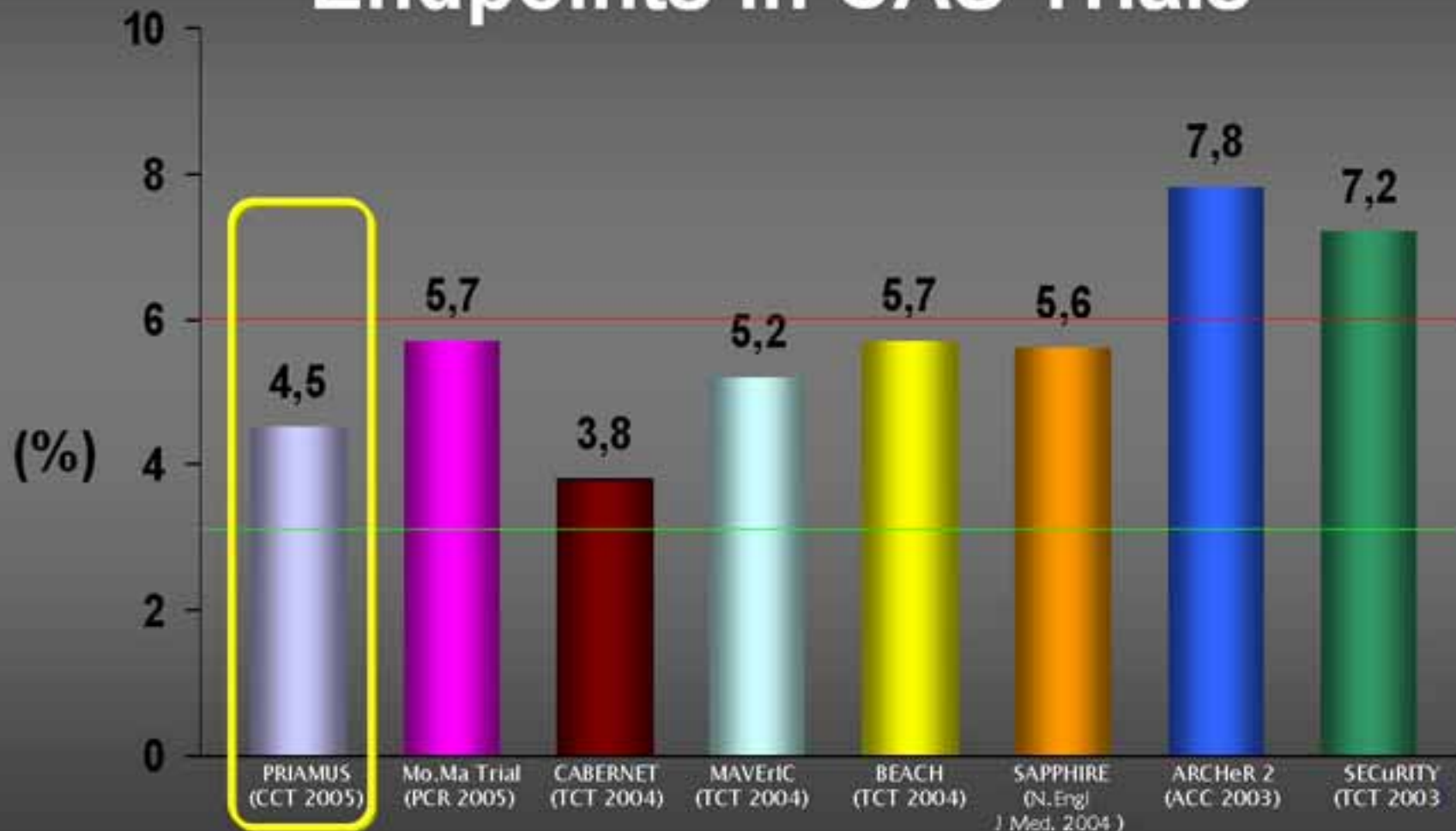
"PRoximal Endovascular Flow Blockage for Cerebral Protection
During CARotid Stenting: Results from a MUlticenter Italian
RegiStry"*

	In hospital	Discharge to 30d FU.
TIA	3 (0.74%)	4 (1.68%)
Non fatal strokes		
Minor Stroke	16 (3.84%)	0
Major Stroke	1 (0.24%)	0
Death	2 (0.48%)	0
All Stroke and Death Rate	19 (4.56%)	0

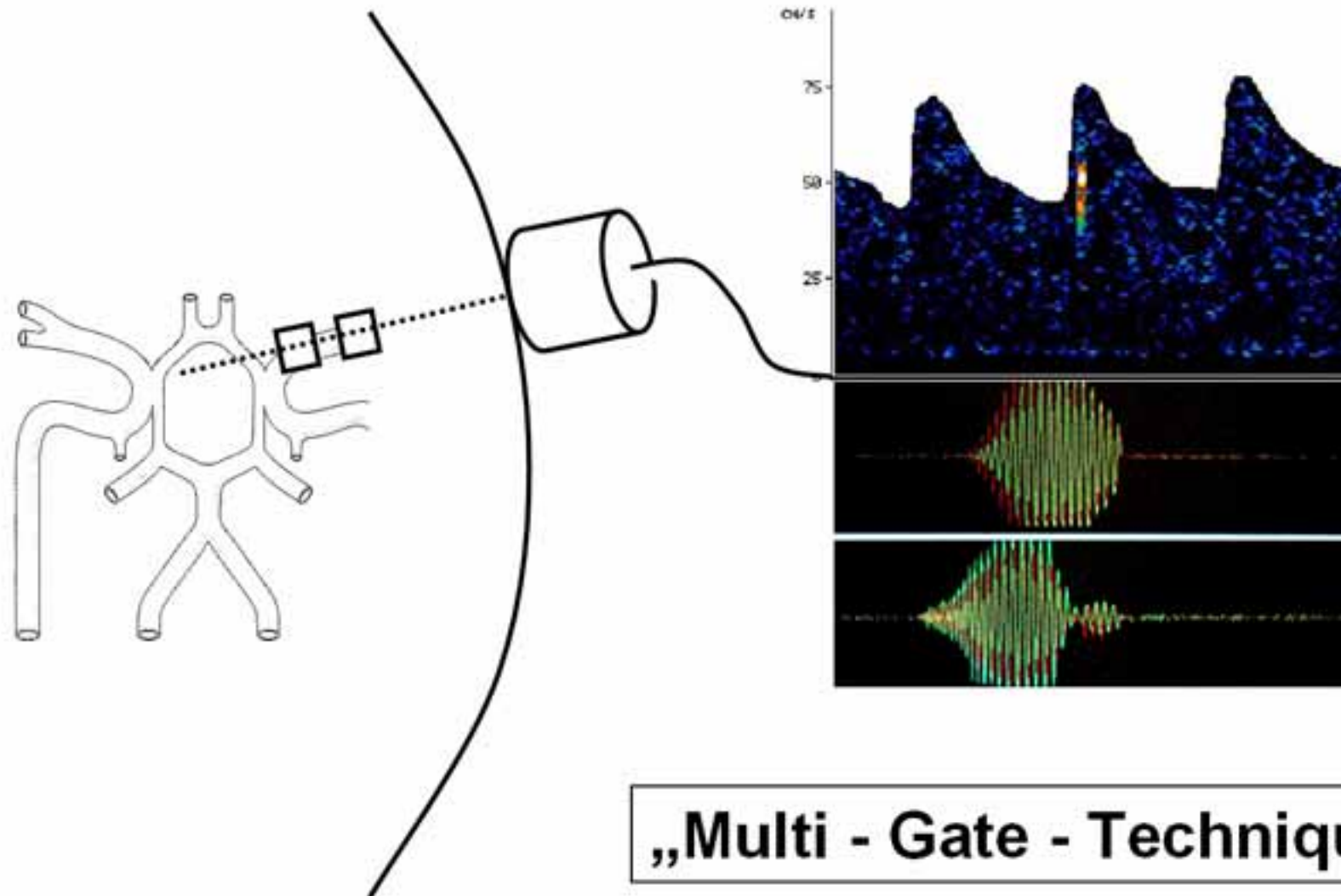
No Fatal Stroke and no Myocardial Infarction was recorded.

*Coppi, G. et al., JCardiovasc Surg 2005; 46: 219-27

Overview on 30-Day Composite Endpoints in CAS Trials

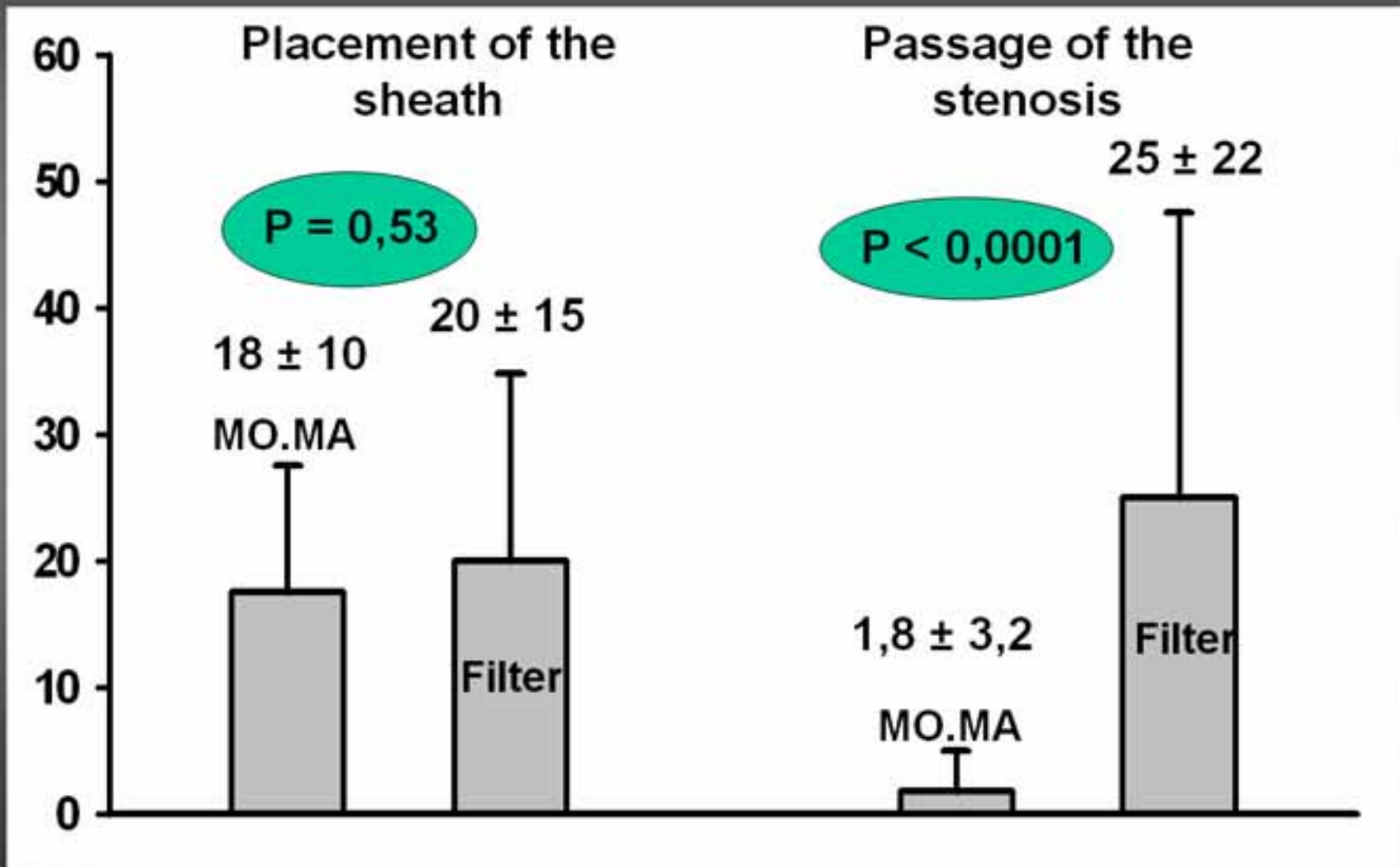


Detection of Microembolic Signals

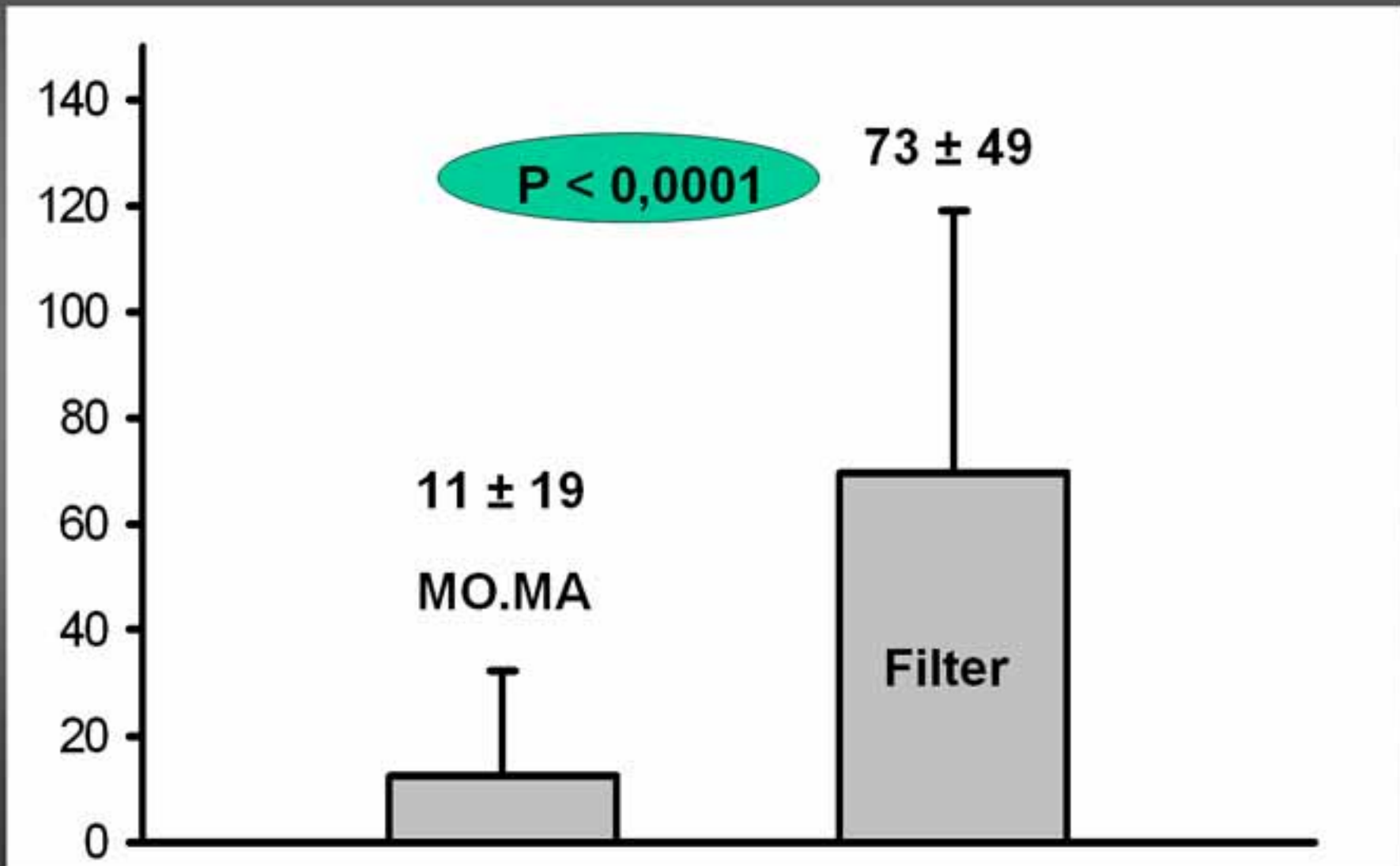


MO.MA versus Filter-Protection

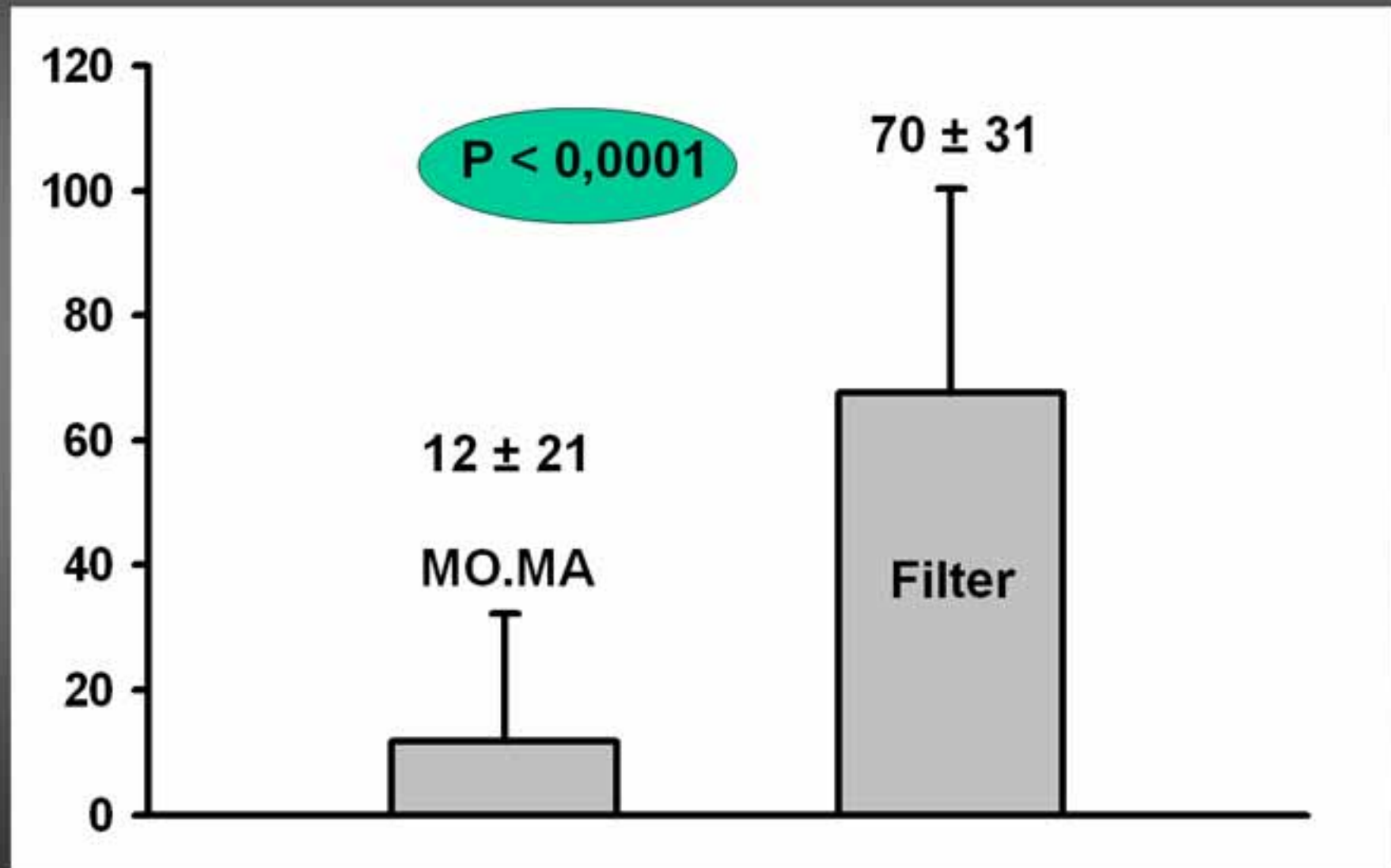
Mean MES - Count



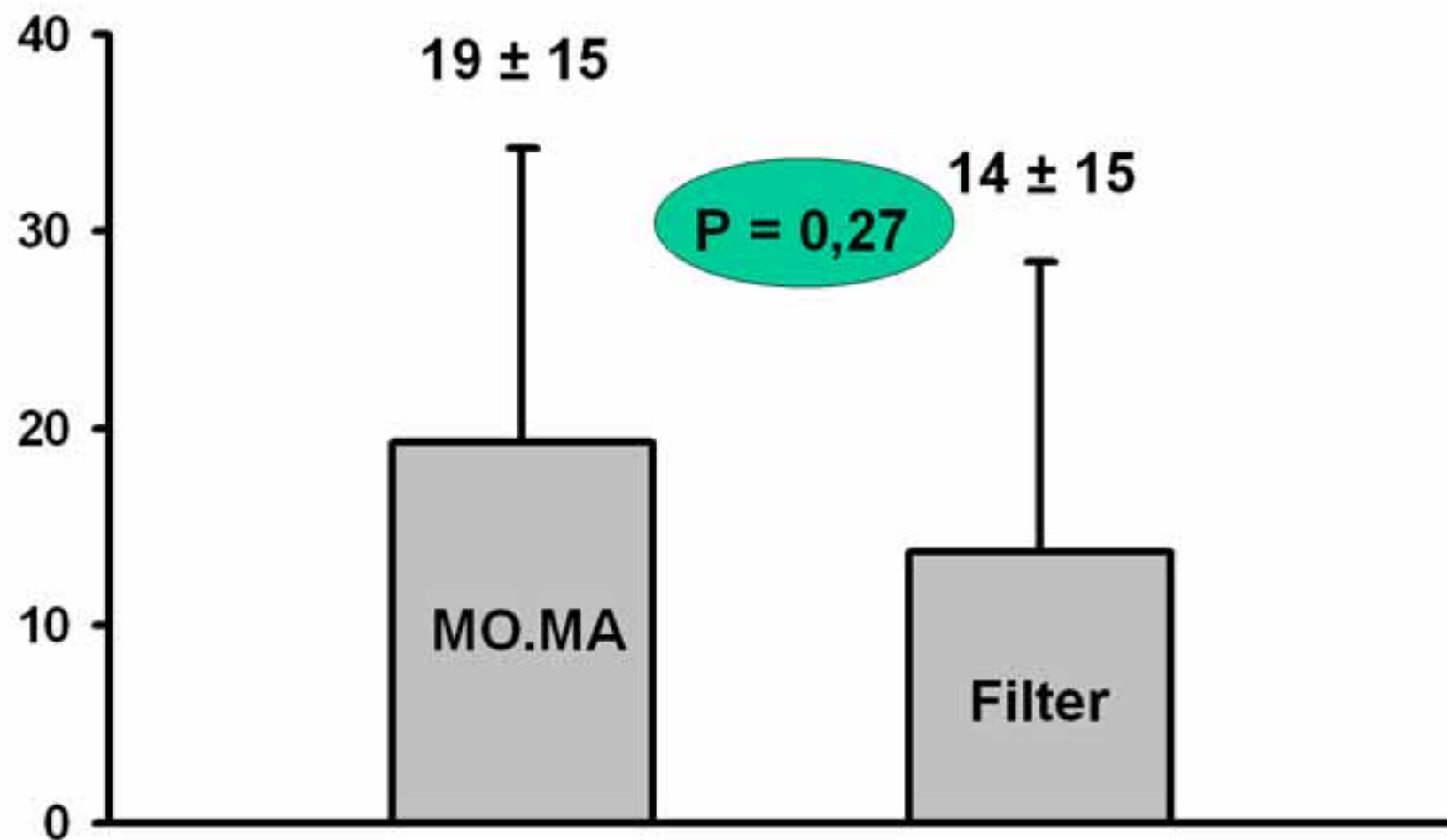
MO.MA- versus Filter-Protection MES - Count during Stent-Deployment



MO.MA- versus Filter-Protection MES - Count during Balloon-Dilatation



Removal of the Protection-System and MES - Count



CONCLUSIONS

- Neuroprotection mandatory for CAS ?

YES

- Proximal Flow Blockage with Endovascular Clamping is not a must, but.....

the best solution in more than 85 %

Best Way to Successful CAS

- Experience -

