

Carotid Artery Stenting

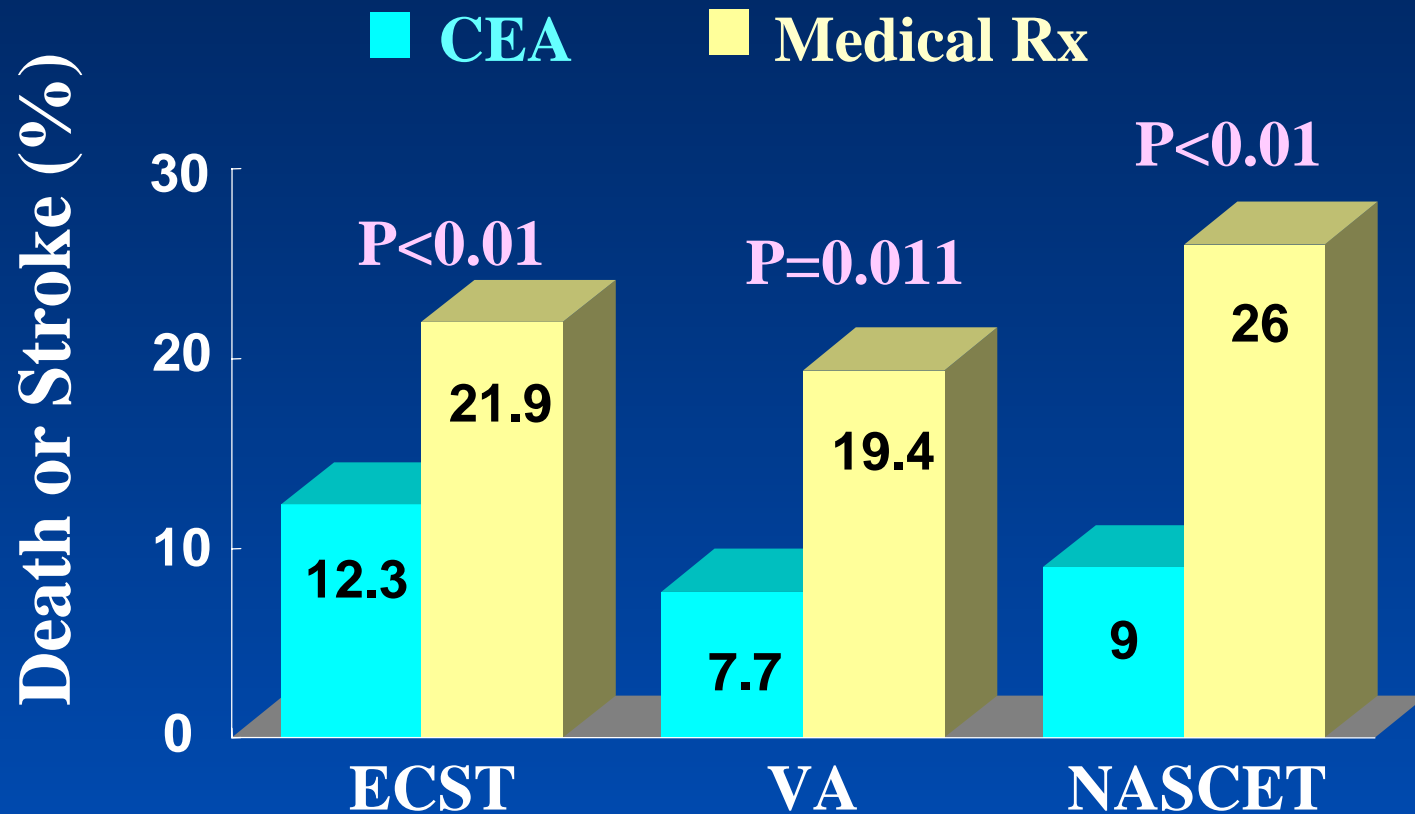
Natural history of the carotid stenosis ...

- Asymptomatic 80% carotid stenosis
 - 6% risk of stroke / year
- Symptomatic carotid stenosis have
 - 10% risk of CVA at one year and 40% at 5 years

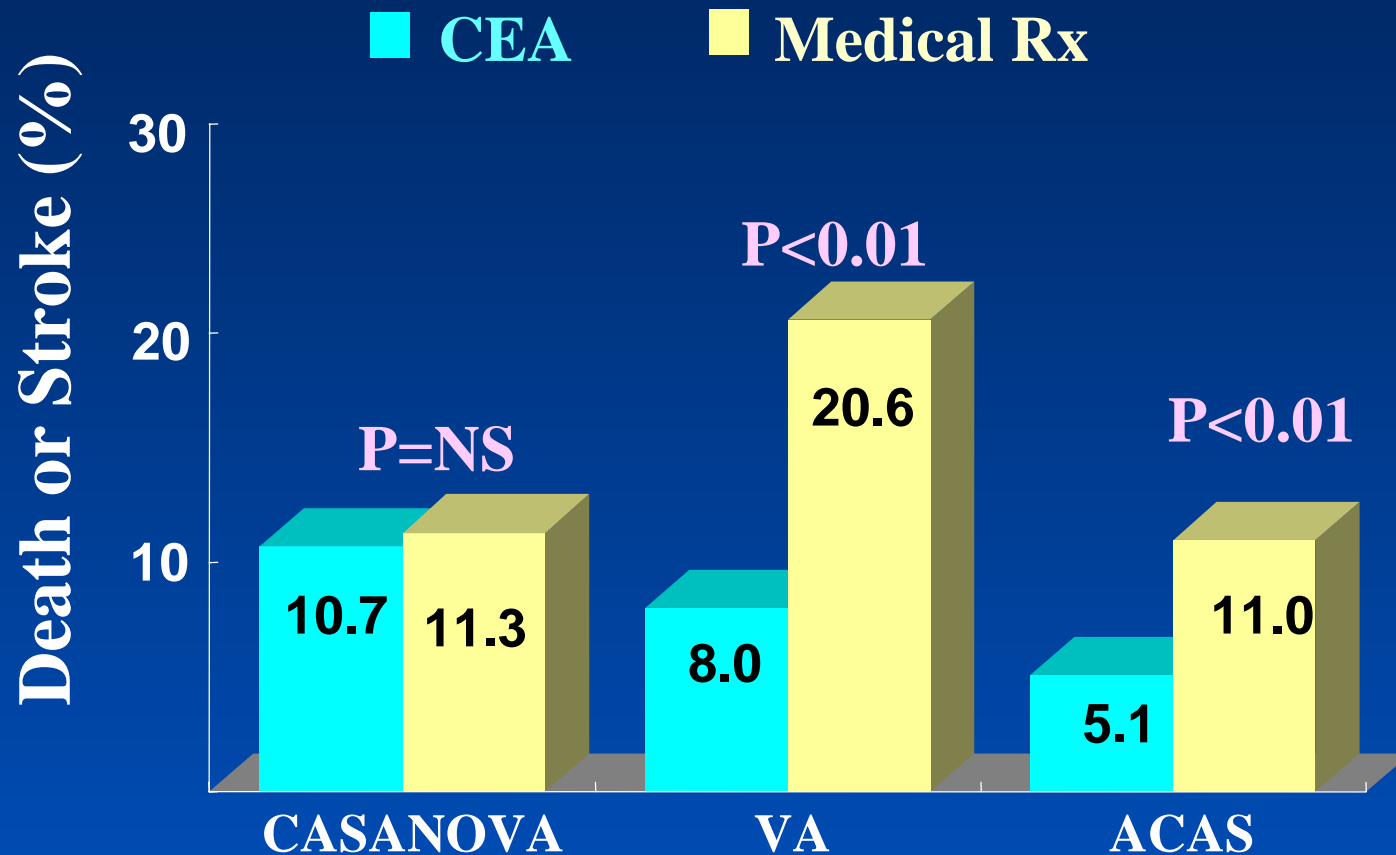
Do we drop CEA
as a treatment of
carotid artery stenosis ?

However, CEA is still better than Medical treatment in symptomatic patients with > 70% stenosis

CEA vs. Medical Symptomatic Patients



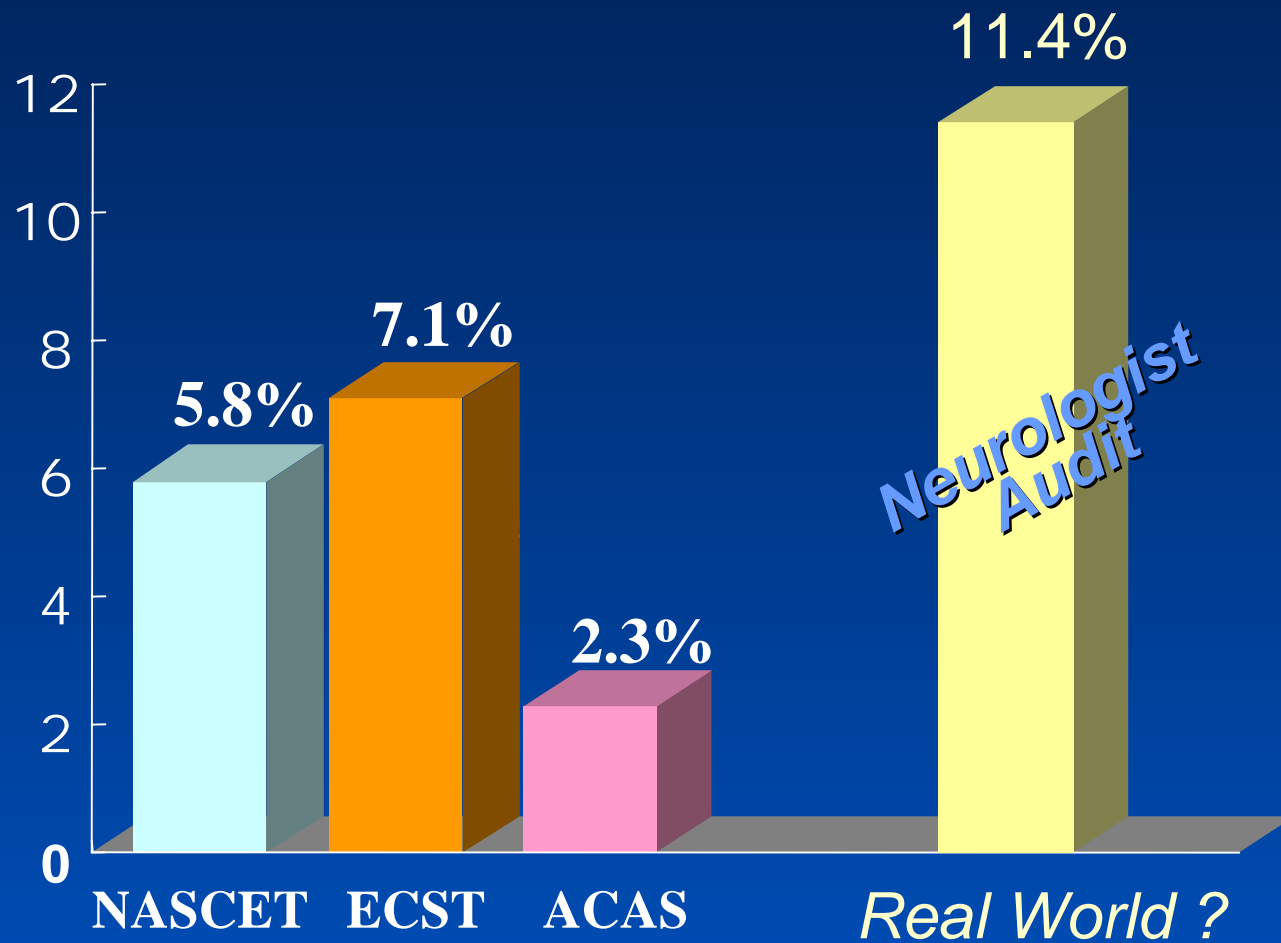
CEA vs. Medical Asymptomatic Patients



Limitations of CEA

- Average risk of perioperative stroke for low risk patient is ~6%
- Anatomic considerations
- Cranial nerve palsies (7~27%)
- Restenosis ~15%
- > 50% have severe coronary artery disease

Death or Stroke after CEA



Chaturverdi, Neurology 2001 Sep

Who is good candidate for the
CEA ?

Only Low risk patients ?

Why not stenting ?

General High Risk Surgical Criteria

Anatomic high risk

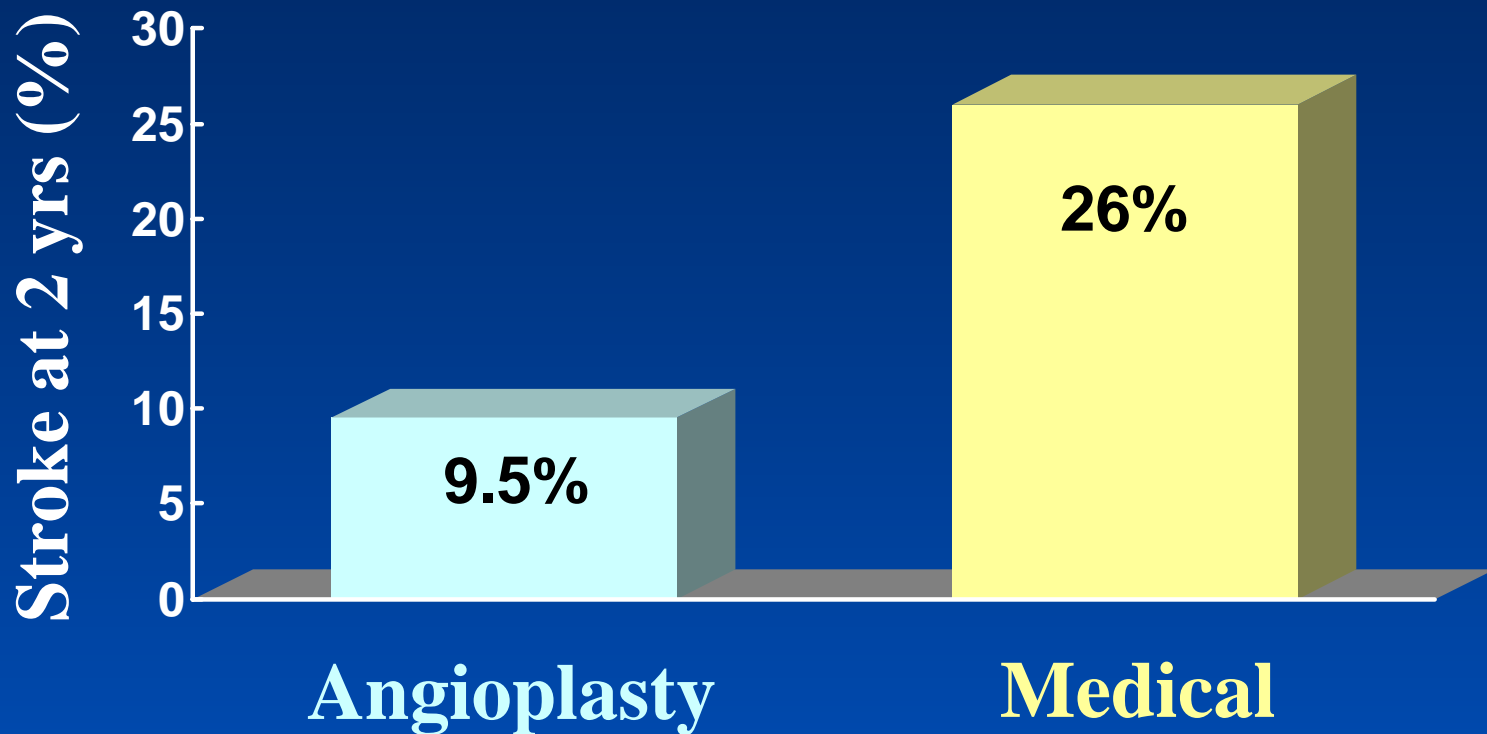
- High(C2) carotid bifurcation
- Prior neck irradiation or radical neck dissection
- Restenosis following prior CEA
- Contralateral occlusion
- Ostial common carotid lesion
- Spine immobility

Surgical high risk

- Severe CAD
 - Not revascularized or awaiting CABG
- Class III or IV CHF
- Severe COPD
- Age > 80

Angioplasty vs. Medical In Poor Surgical Candidates

NASCET



Fox DJ, Stroke 2002;33:2877

Carotid Artery Stenting in High-risk Patients

: AMC experience

High Risk Patients

N=19

- **NASCET ineligible criteria**
 - Unstable angina 9 (47%)
 - Severe LV dysfunction 1 (5%)
 - ESRD 2 (11%)
 - Severe intracranial atherosclerosis 2 (11%)
 - Unstable neurological examination 3 (16%)
 - Stable angina with LM or 3 vessel disease 5 (26%)

Baseline characteristics

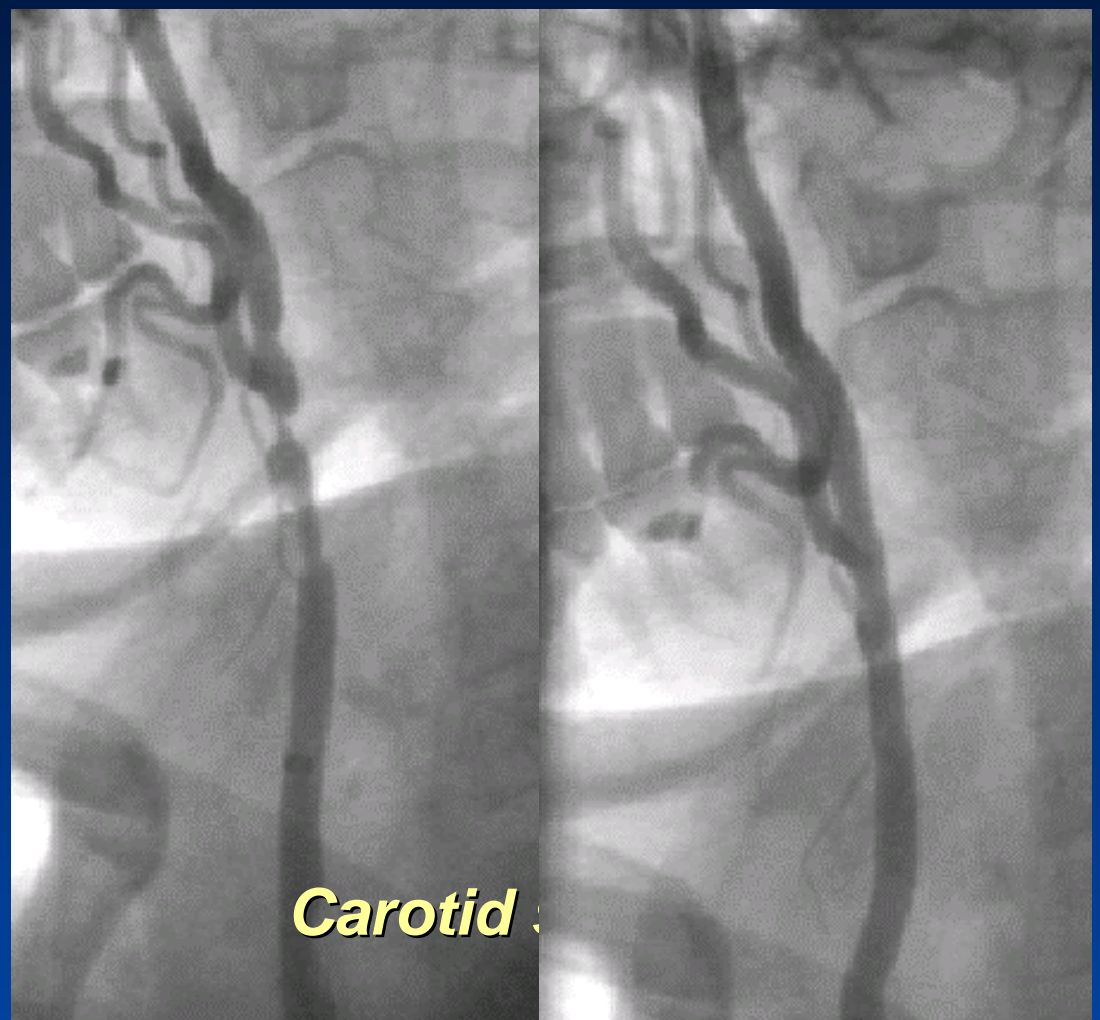
Men	15 (79%)
Age	65±7 years
Diabetes	6 (32%)
Hypertension	17 (90%)
Smoking	10 (53%)
Hypercholesterolemia	8 (42%)
Stroke	13 (68%)
TIA	0 (0%)

Angiographic results

Stenosis pre CAS	90±6%
Stenosis post CAS	8±5%
Contralateral stenosis >50%	8 (42%)
Contralateral occlusion	3(16%)
Distal protection device (PercuSurge)	4 patients



Left main stenting



Carotid

- 60YO woman with stable angina
- Stenting of left main coronary and carotid artery in a single procedure

Results

- **Technical success** *100%*
- **Periprocedural strokes**
 - Major stroke** **1**
 - TIA** **1**
- **1 Year follow up**
 - Fatal ICH 3.5 months after CAS in 1 case**

Carotid Stenting

Potential Benefits

- Reduced complication rates
- Less invasive
- Can reach essentially all blockages
- Very low restenosis rate
- Rapid return to daily life

Why Cardiologist ?

- PTCA skills are easily transferable
- Provide continuing care to the patients
- Willing and able to manage complications

Carotid Stenting

Indications

- Symptomatic stenosis $\geq 50\%$
- Asymptomatic stenosis $\geq 60\%$

Carotid Stenting

Contraindications

- Severely tortuous, calcified and atheromatous aortic arch vessels
- Pedunculated thrombus at the lesion site
- Severe renal impairment
- Recent stroke (3 weeks)
;should be placed on anticoagulants and antiplatelets for 1 month
- Unable to tolerate antiplatelet agents

Carotid Stenting

Success & Complications

Study	Setting	N	Success	Stroke & TIA*	Death
Roubin (1996)	High risk	146	99%	6.2%	0.7%
Shawl (2000)	High risk	170	99%	2.9%	0%
Wholey (2000)	registry	5129	98.4%	4.2%	0.8%
Roubin (2001)	High risk	428	99%	4.6%	0.2%

* Major stroke < 1%

Carotid Stenting

Complication Rate

N=4757 pts, 36 major carotid centers, 1988-1997

TIAs 2.82 %

Minor Stroke 2.72 %

Major stroke 1.49 %

Deaths 0.86 %

Total stroke & death 6.29 %

6-mo ISR = 1.99%

12-mo ISR = 3.46%

Wholey MH, et al. CCI 2000;50:160-7

Is Carotid Stenting Durable?

Long-term Follow-up

6% Restenosis Rate

CEA vs Stenting

Which is better ?

Which one will be final winner ?

CAVATAS

Multicenter Randomized Trials: *CEA vs. Angioplasty*

	Angioplasty N=251	CEA N=253
30-day death & stroke	6.4%	5.9 %
Cranial neuropathy	0 %	8.7 %
1-year restenosis *	14 %	4 %

* *Stenting = only in 26%*

Lancet 2001;357:1729-37

Carotid Artery Stenting

The Most Serious Complication Is

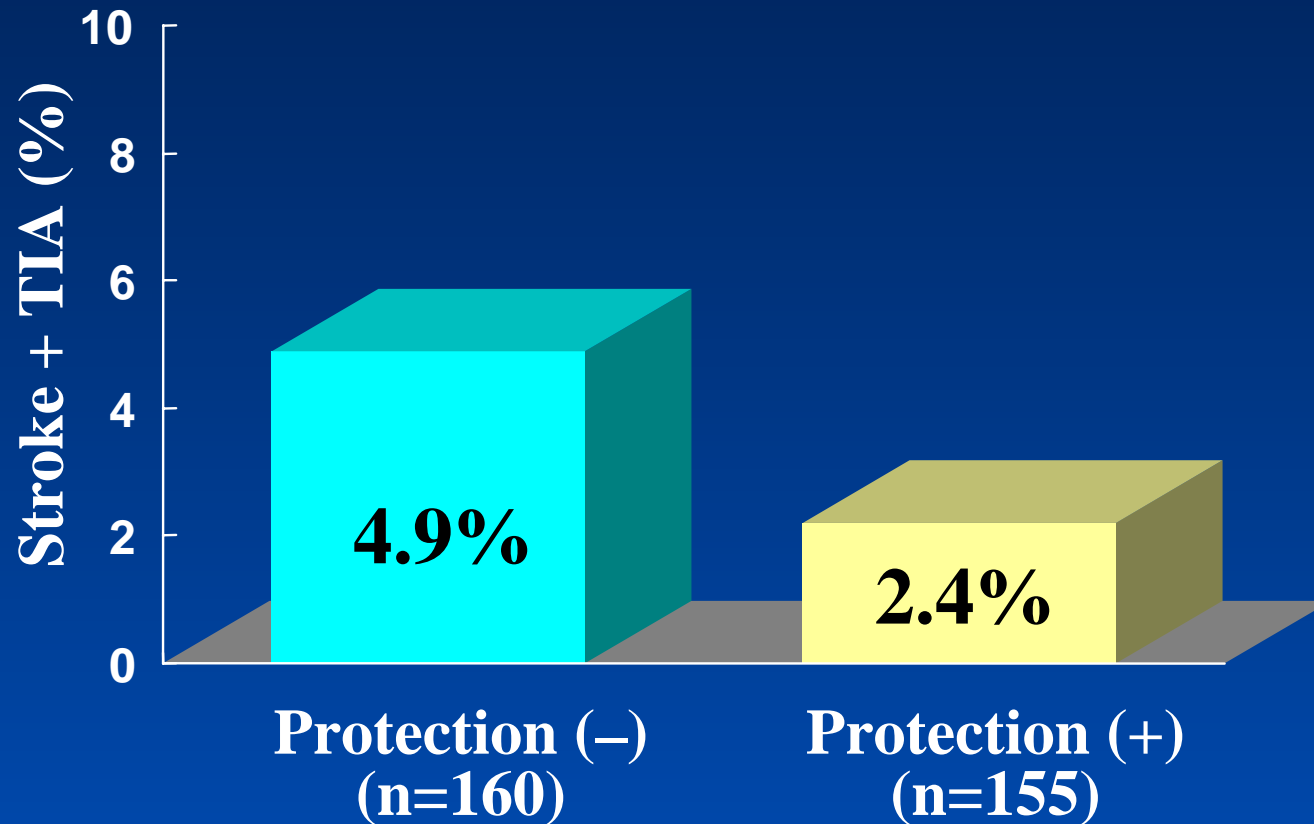
Cerebral
Embolization !!

Distal Protection Devices

Will be mandatory for
all carotid stentings ?

Effect of Protection Device

* Protection devices: Angioguard & PercuSurge



Henry M et al, Tex Heart Inst J 2000;27:150-8

Embolization during CAS

	<i>Cerebral Protection</i>	
	<i>No</i> <i>(n=102)</i>	<i>Yes</i> <i>(n=142)</i>
<i>TCD-HITS</i>	<i>100%</i>	<i>100%</i>
<i>DW-MRI</i>	<i>29%</i>	<i>7.1%</i>
<i>TIA</i>	<i>8%</i>	<i>2.7%</i>
<i>Stroke</i>	<i>3%</i>	<i>1.3%</i>
<i>TIA + Stroke</i>	<i>11%</i>	<i>4%</i>

** Protection devices: Angioguard, PercuSurge & EPI*

K. Mathias et al, AJNR 2001

Cerebral Embolization

Highest Risk

- Unstable plaque
break down of fibrous cap
- Soft plaque
- Long stenosis string sign
contains thrombus

Avoiding Distal Embolization

- Use cerebral protection device
- No pre-dilatation with a peripheral balloon
- No oversizing of balloon
- Never use high pressures
- Never try to dilate the stent to obliterate contrast filled ulcerated area external to the stent

Distal Protection Devices

- **Distal occlusion**

Theron balloon

PercuSurge Guardwire

- **Filter**

MedNova NeuroShield

EPI filter

Angioguard filter

Medtronic filter

BSC Captura

Bate's Floating Filter

Accu-Filter

E-Trap

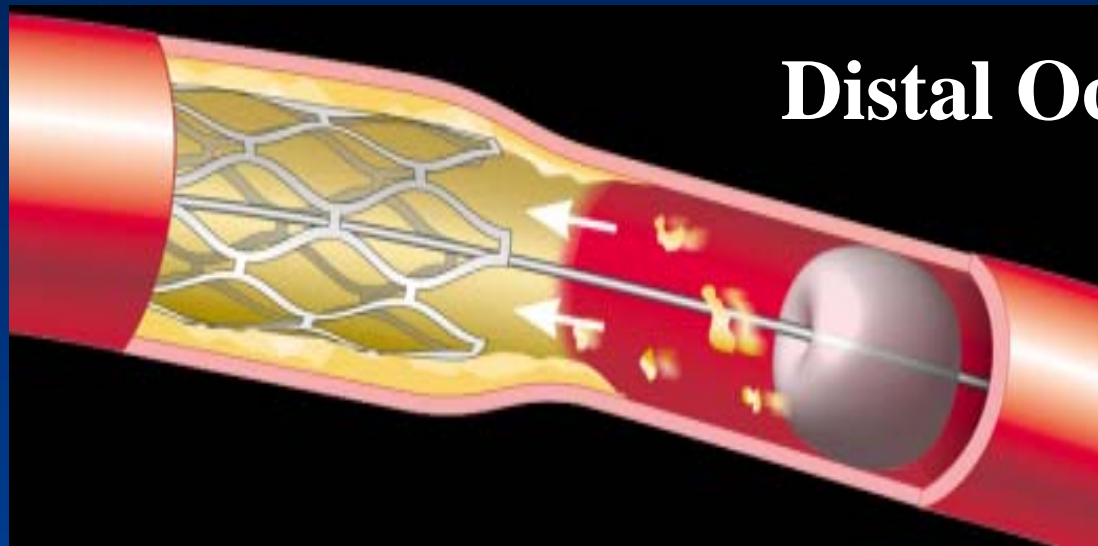
Microvena Trap

- **Proximal occlusion**

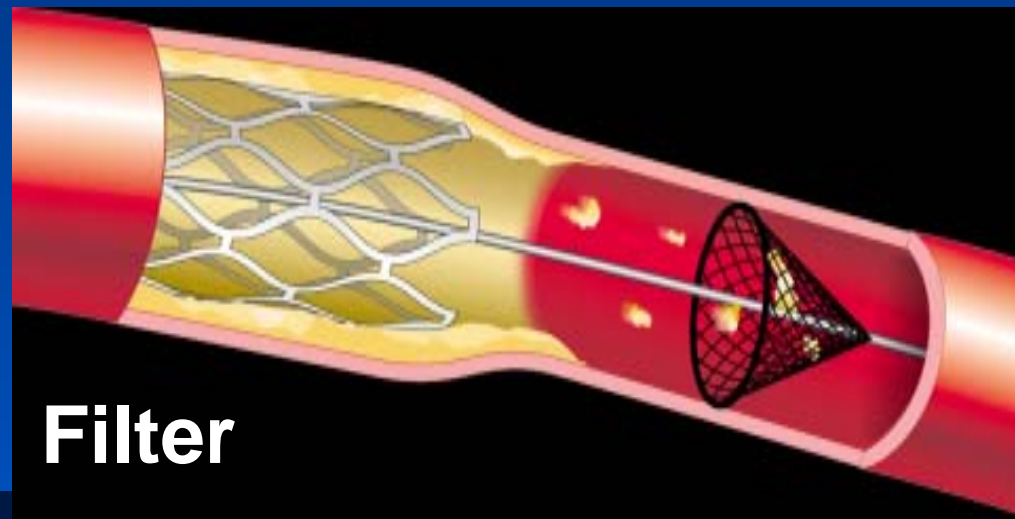
Kachel balloon

ArteriA Parodi Catheter

Distal Protection Devices - *Concepts*

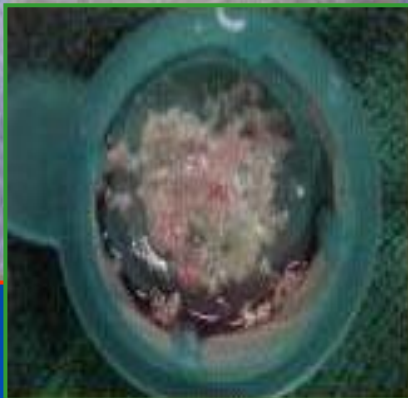
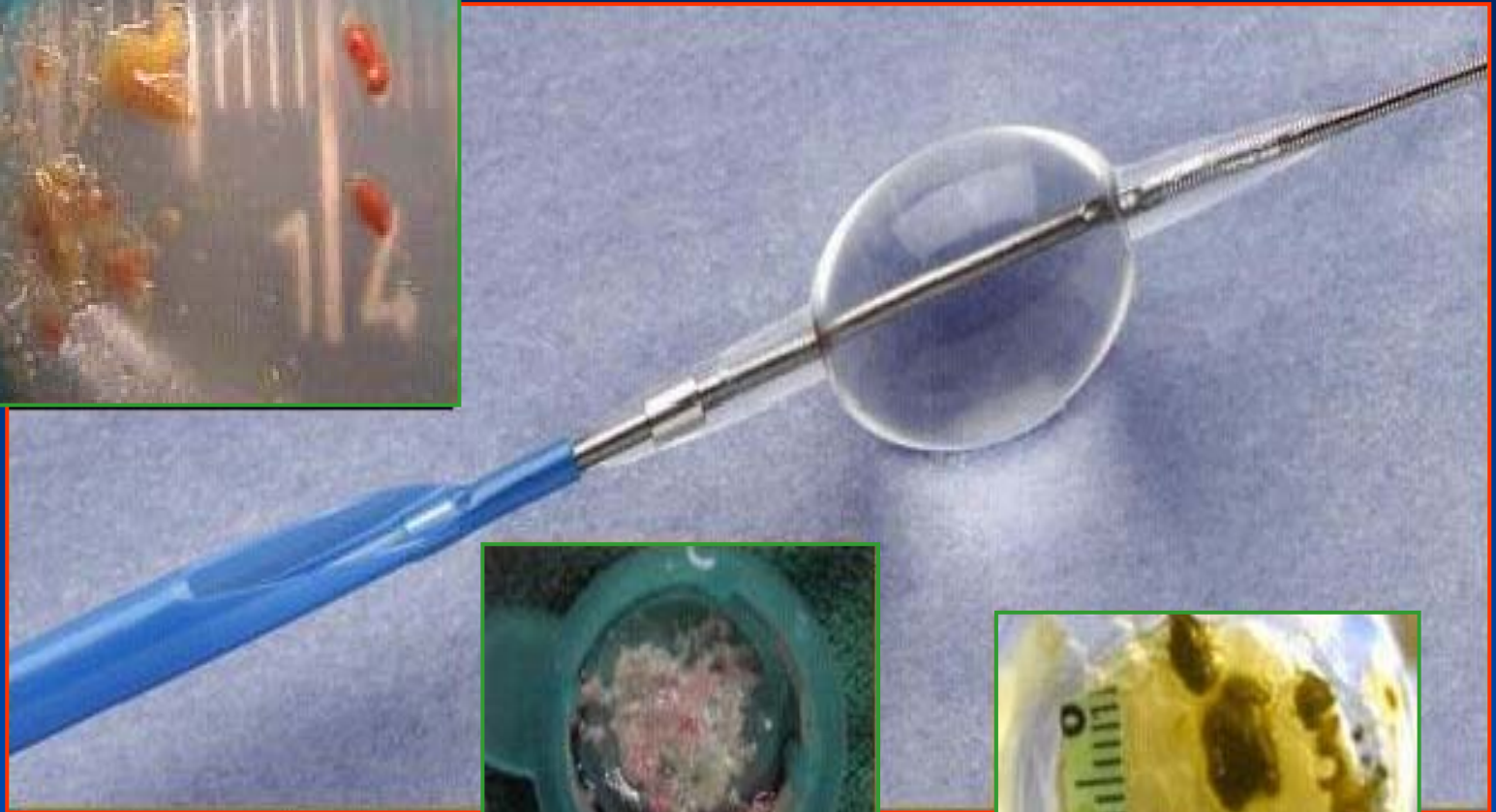


Distal Occlusion



Filter

PercuSurge GUARDWIRE™



PercuSurge GUARDWIRE™

GuardWire™	PERCUSURGE, Inc
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System	0.014
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Crossing Profile	0.036”(3-6mm), 0.028”(2-5mm)
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The Export® Aspiration Catheter	PERCUSURGE, Inc
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Total Length	137 cm
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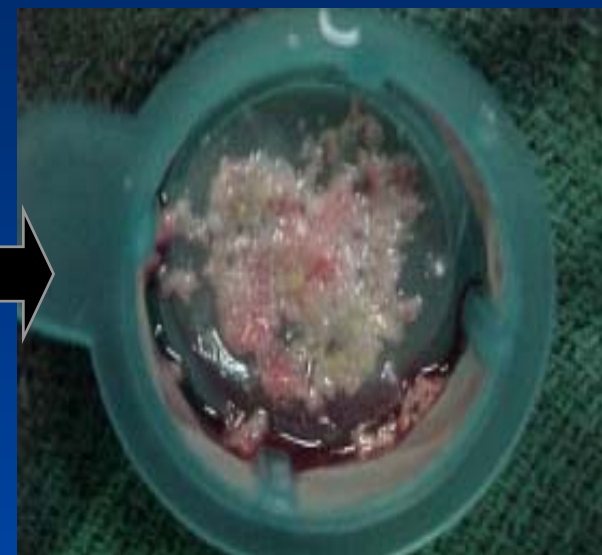
RX shaft design	3.5 x 4.5F distal OD
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Aspiration system	20cc locking syringe
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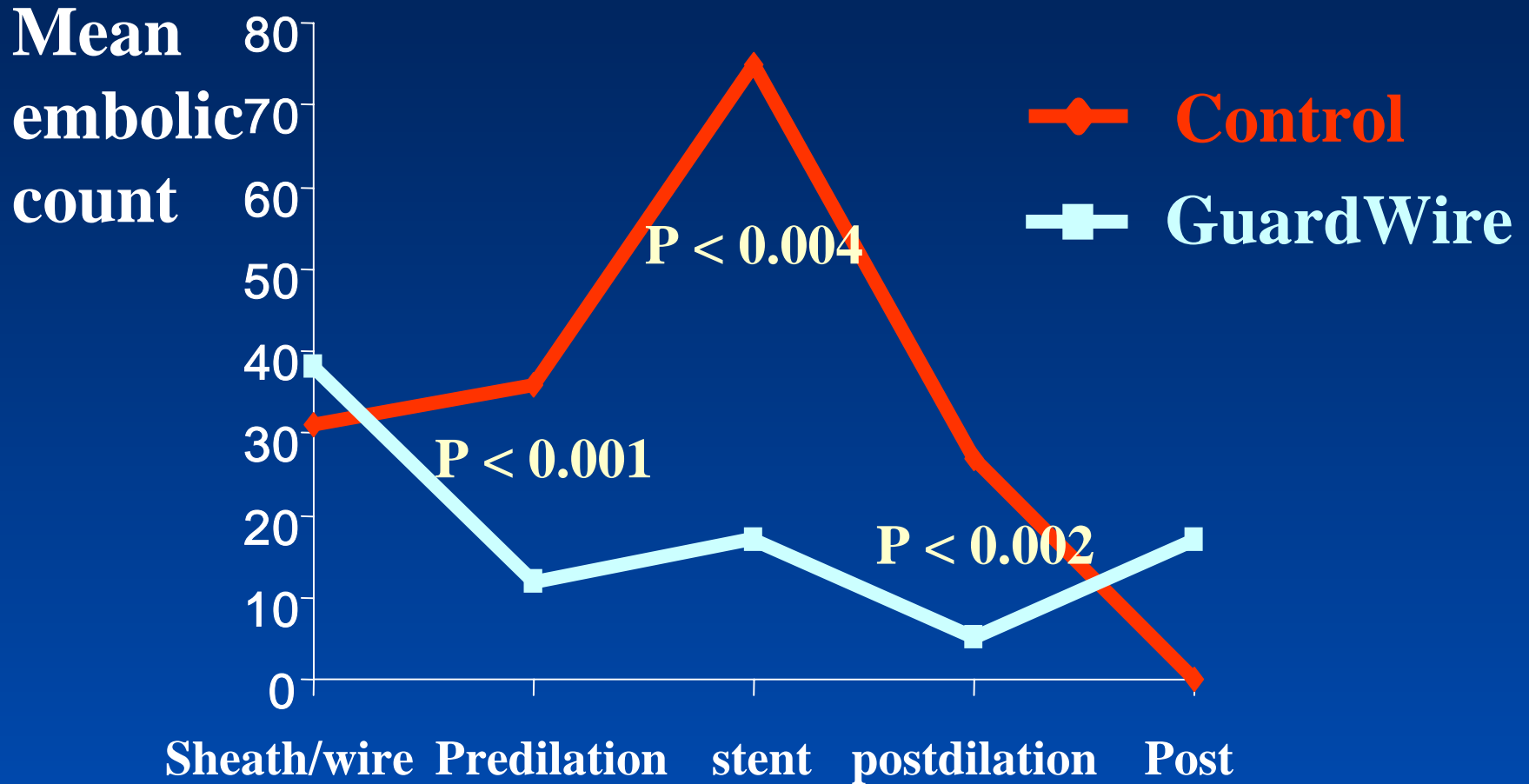
PercuSurge GUARDWIRE™



PercuSurge GUARDWIRE™



PercuSurge GUARDWIRE™



Al-Mubarak et al, Circulation, 2001

CAFE USA

Carotid Angioplasty Free of Emboli

- 125 High risk patients with PercuSurge
- 97.6% Technical Success
- 91% Cases Using Continuous Occlusion Technique;
Overall mean balloon protection time = 12.8 min
- 30 days outcome
 - Minor Stroke 0.8 % (1)
 - Major Stroke 1.6 % (2)
 - Death 0.8 % (1)

Distal Occlusion balloon

Strength

- **Mimics standard guidewire more than any filters**
- **Ability to cross lesion**
- **Particles of all sizes can be blocked (ICA)**

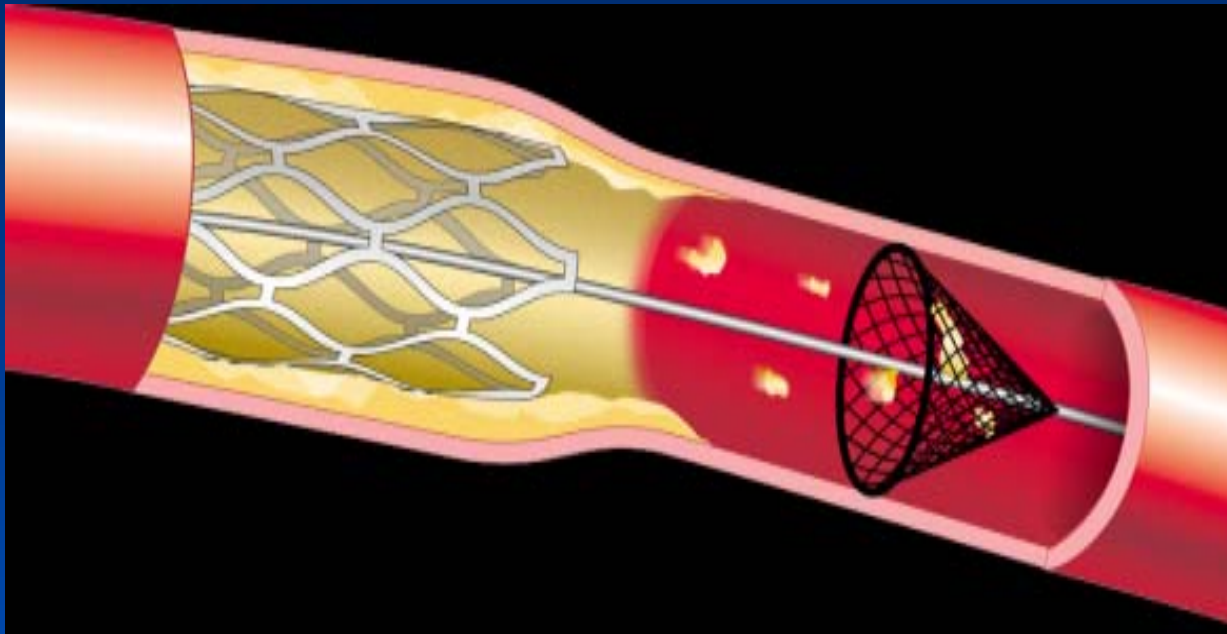
Distal Occlusion balloon

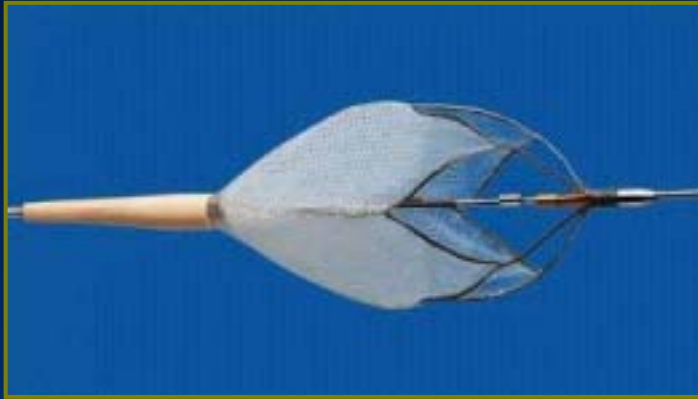
Weakness

- Unprotected
 - 1) During passage,
 - 2) ECA
 - 3) Incomplete suction
- Does not preserve ICA flow (can't be angio)
- May cause spasm/dissection in distal ICA
- Cumbersome procedure (cannot move wire during exchange, several added steps, aspiration)

Distal Protection Devices

Filter





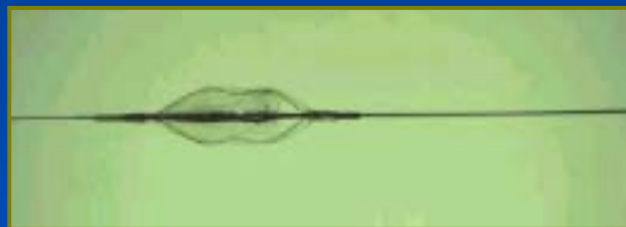
Guidant - ACCUNET



BSC - EPI

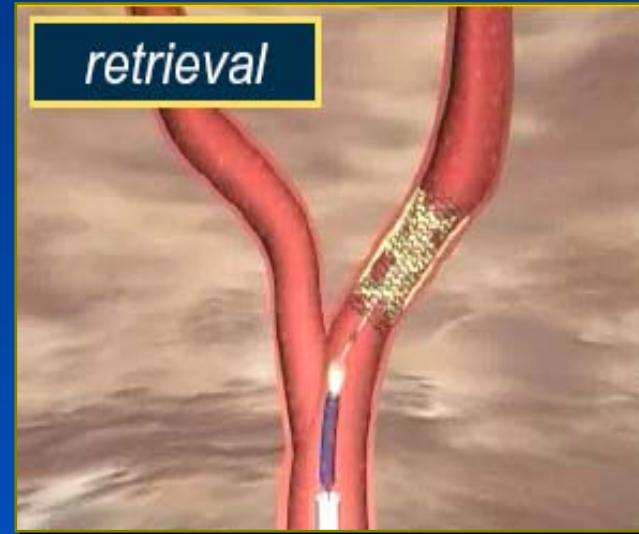
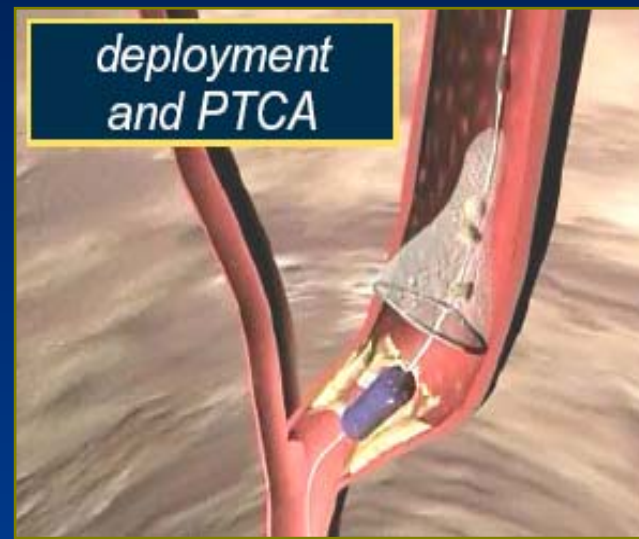
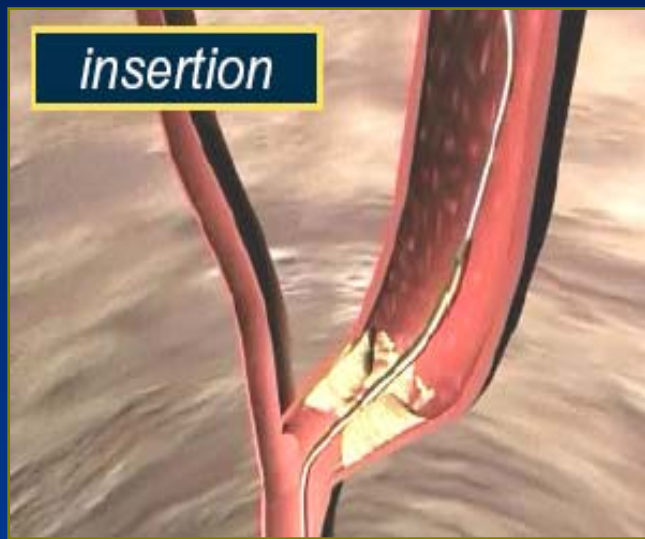


MedNova - Neuroshield



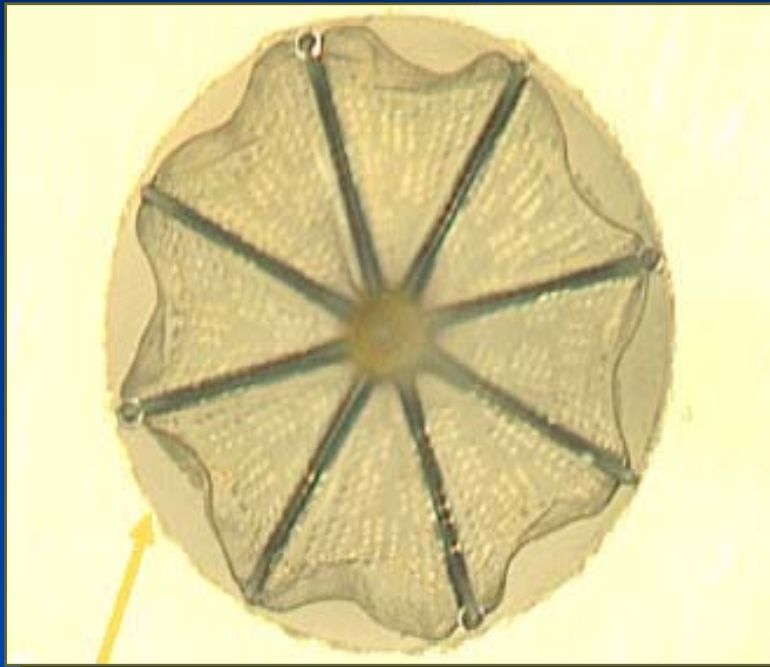
MedNova – Gen III

Filter Based Distal Protection; *Concepts*

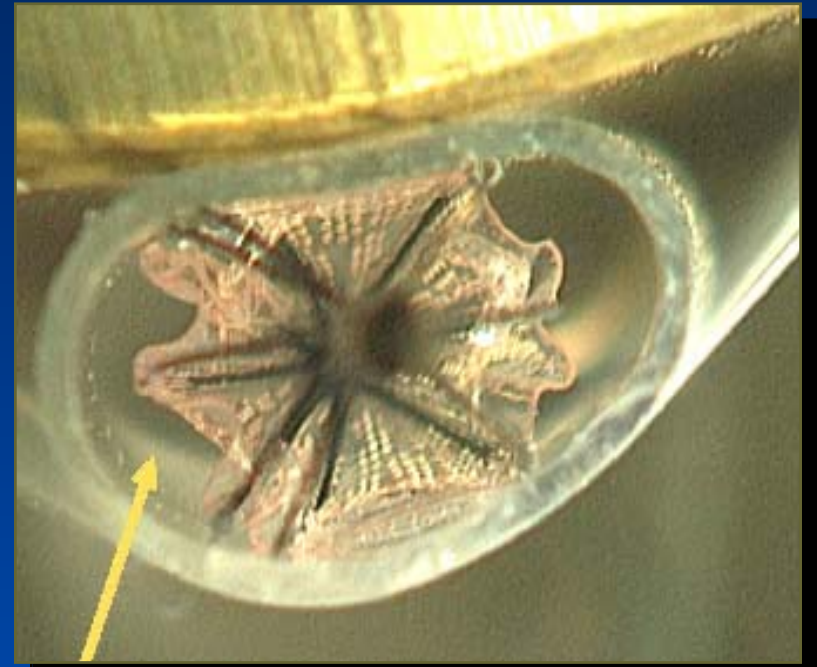


Embolization in Filter Device

Lack of Apposition



**6.0mm Angioguard
in a 5.5mm round tube**



**6.0mm Angioguard in a
5.0mm asymmetrical tube**

Filter Device

Strength

- Intuitive
- Preserves ICA flow

Filter Device

Weakness

- Not same as standard guidewire
- Larger profile, less flexible
- Frequent need to predilate (recross PTA site)
- Unprotected
 - 1) during passage
 - 2) small particles
 - 3) flow around filter
 - 4) during filter retrieval
- May thrombose
- May cause spasm/dissection in distal ICA
- Cumbersome procedure (cannot move wire during exchange, several added steps)

The SAPPHIRE Study

In high risk subsets for CEA

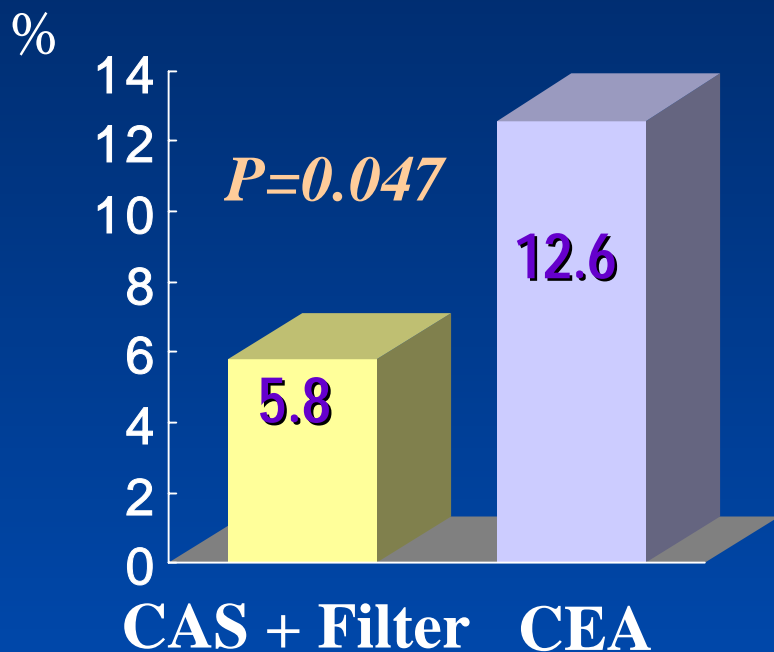
Stenting with filter device

vs. CEA

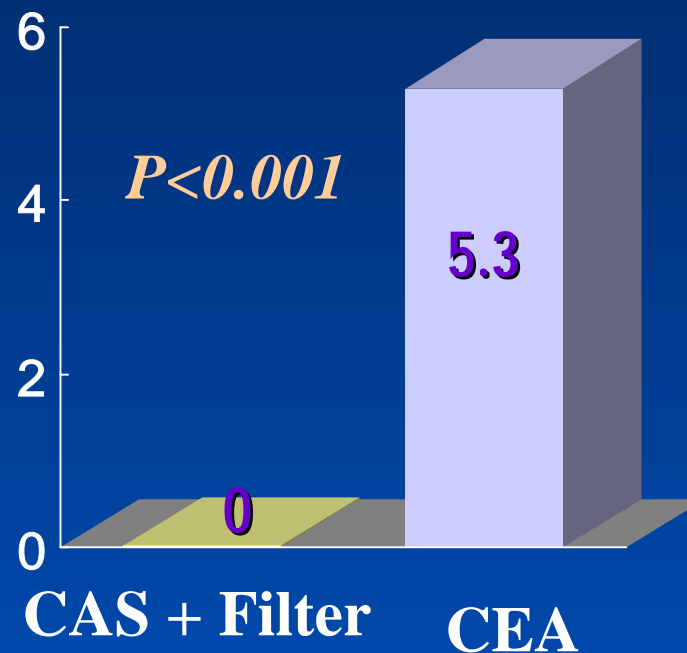
SAPPHIRE

30-Day Events

Death/MI/Stroke



Cranial n. palsy



The Ideal Protection System

- Does not cause harm
 - *Complete protection*
 - *Capture efficiency*
- Protection at all time for all particles
- Wide applicability
- User friendly

CAS in 2003....

Carotid artery stenting with embolic protection is a viable option for the treatment of patients with significant carotid stenosis.

Growth of Carotid Stenting

In current Practice

