PCI for Saphenous Vein Graft Lesion With Embolic Protection

Higher In-hospital Mortality

In PCI for SVG

15,331 consecutive pts between 1994 and 1996

		In-hospital Mortality			
	% pts	Death	OR	CI (95%)	P value
Native	94.3	1.0 %	1.0		
SVG	5.7	3.0 %	3.0	2.0 – 4.7	< 0.001

O'Conor GT et al. JACC 1999;34:681

Distal Embolization in SVG Intervention

Vein graft atherosclerosis is diffuse and friable

- **Intervention may cause distal embolization**
- **Embolization compromises the distal microcirculation**
- **Manifestations of distal embolization**

No reflow	**8-10%**
CK elevation	**17-20%**
Mortality @ 30 days	
CK-MB > 3×normal	**14%**
CK-MB < 3 ×normal	**0.9%**

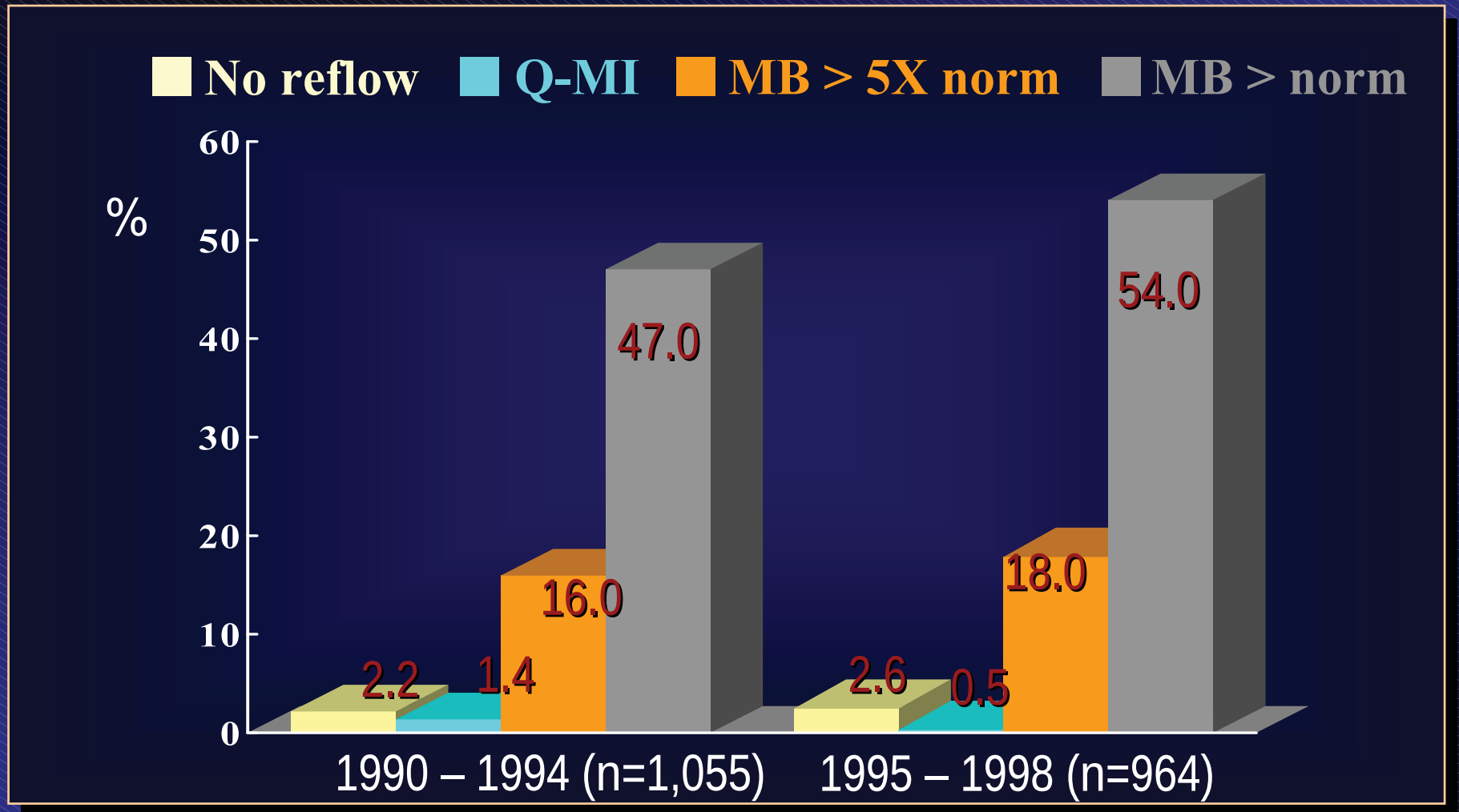
Diffuse Disease

PCI for SVG

Tough Lesions

Marked degeneration with ostial and shaft stenoses, In situ thrombosis, and large aneurysm formation

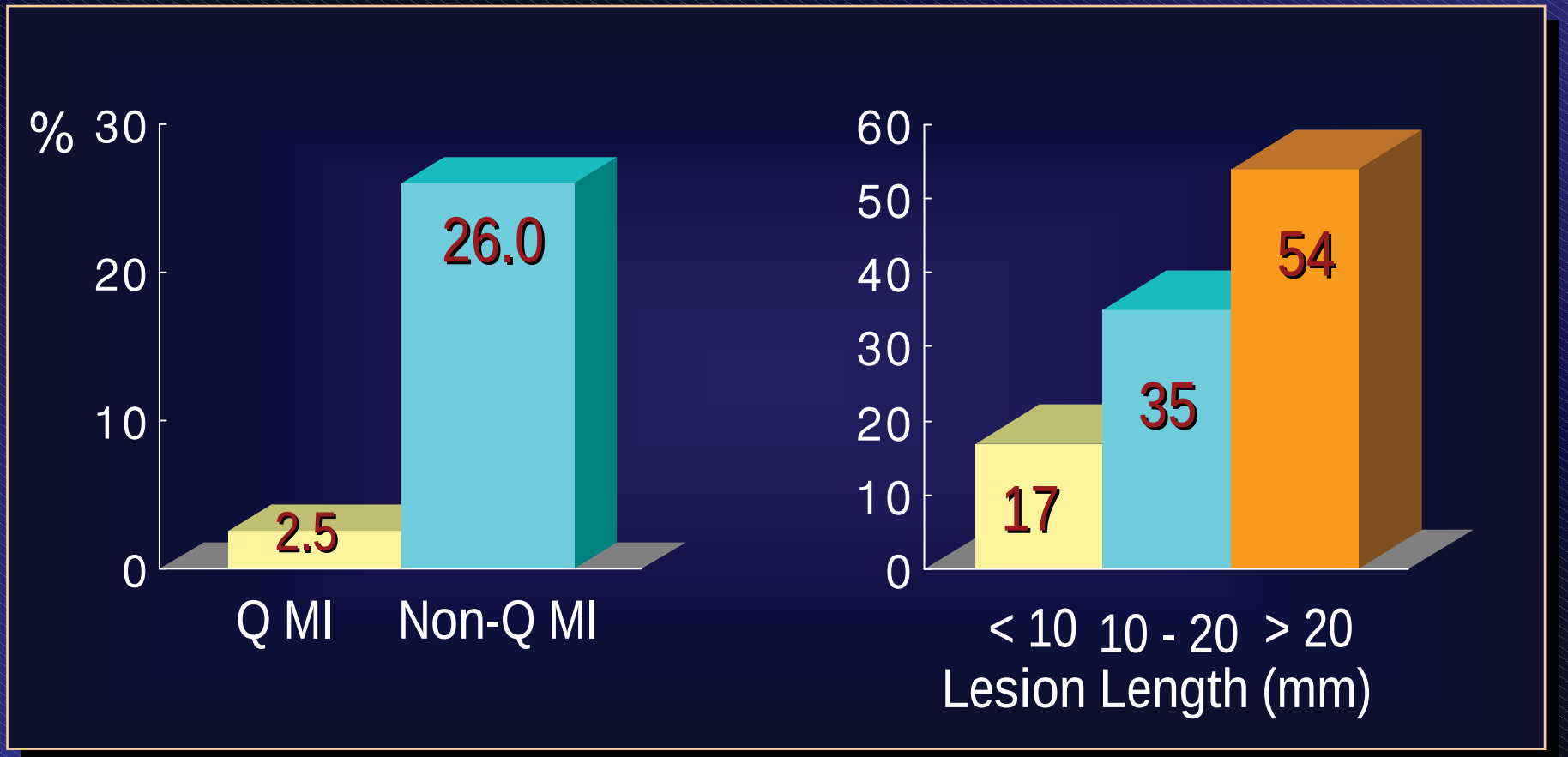
Myonecrosis after Intervention



Hon MK et al, Cir 1999 and JACC 2001

Myonecrosis after Intervention

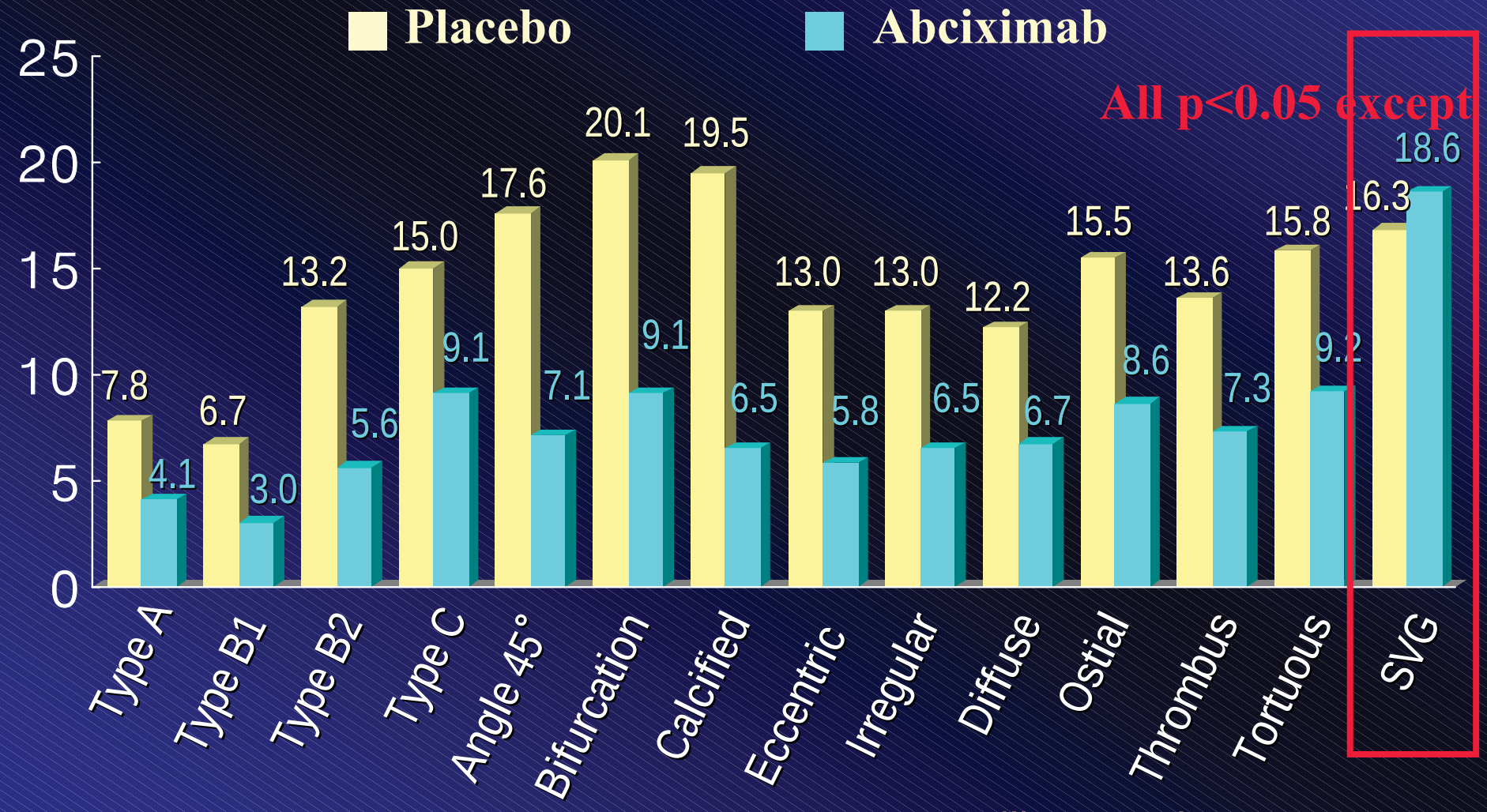
RAVES Trial : non-occluded graft with thrombi



Savage MP et al,JACC 1999;37A

30 Day Death/MI/UTVR

EPIC and EPILOG (n=4154)



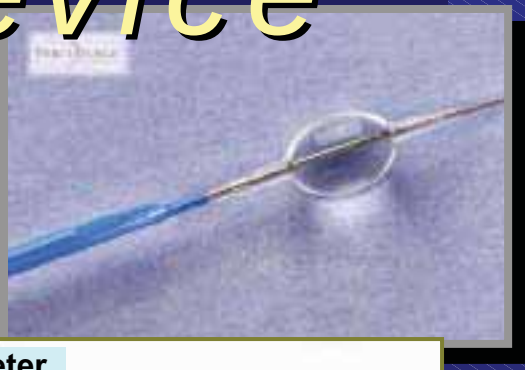
Ellis SG et al,JACC 1998;32:1619-23

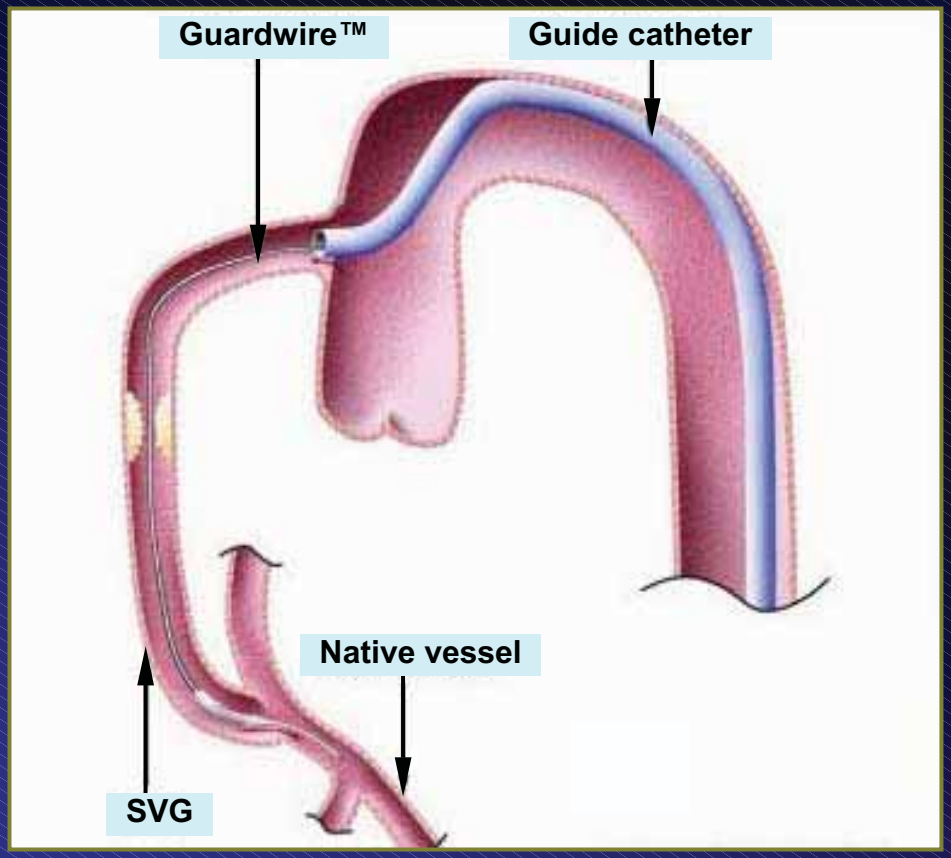
Distal Protection Devices

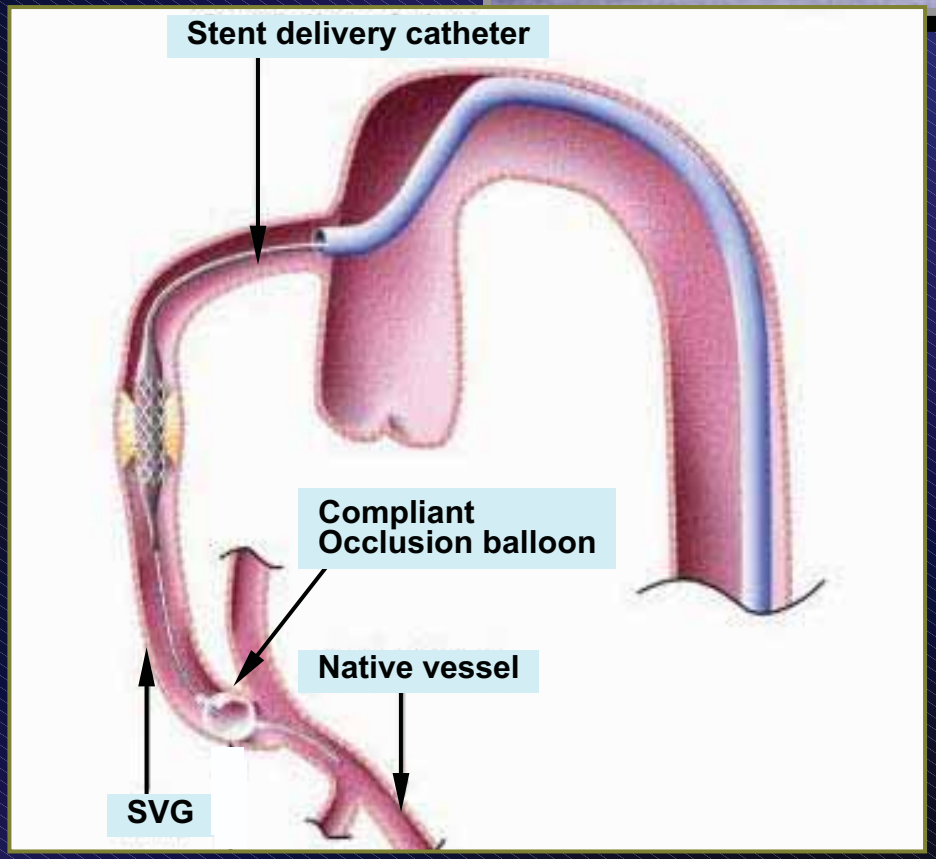
- Balloon occlusion and aspiration systems
  - The PercuSurge (MDT) GuardWire
  - The Kensey Nash TriActiv system
- Catheter-based filters
  - The EPI (BSC) FilterWire
  - The Microvena (EV3) Trap
  - The Cordis Angioguard
  - The Mednova CardioShield and NeuroShield
  - The Guidant Accunet and Net II
  - The Medtronic Filter

Balloon Occlusion Device

PercuSurge Guardwire

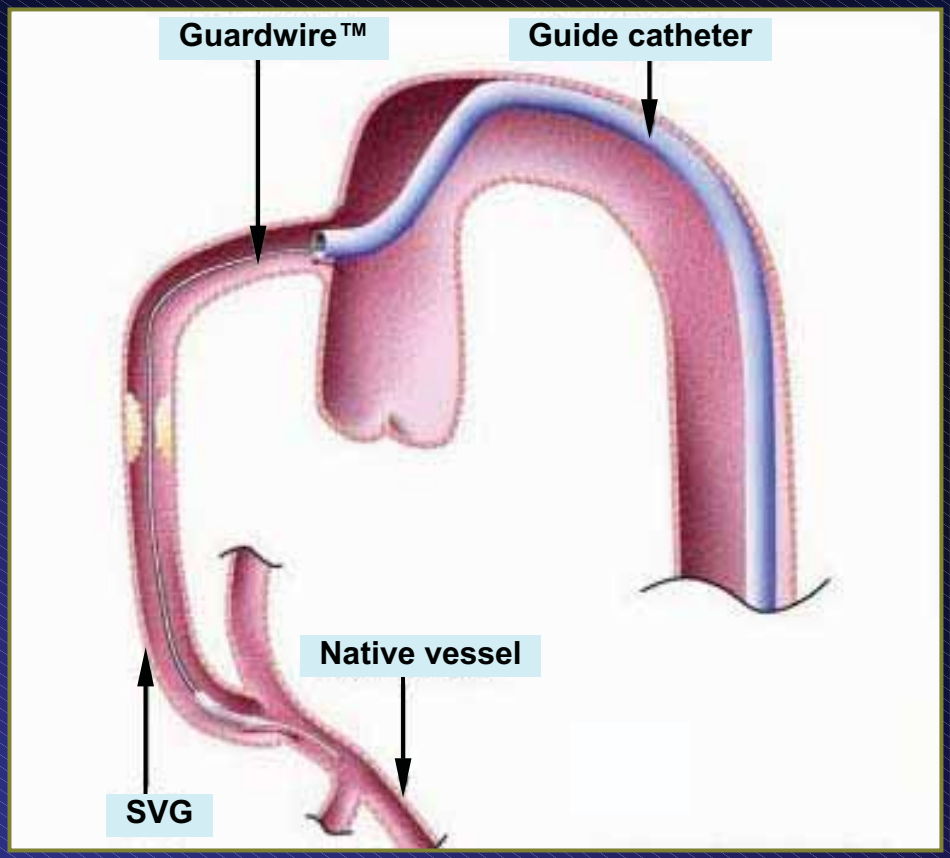


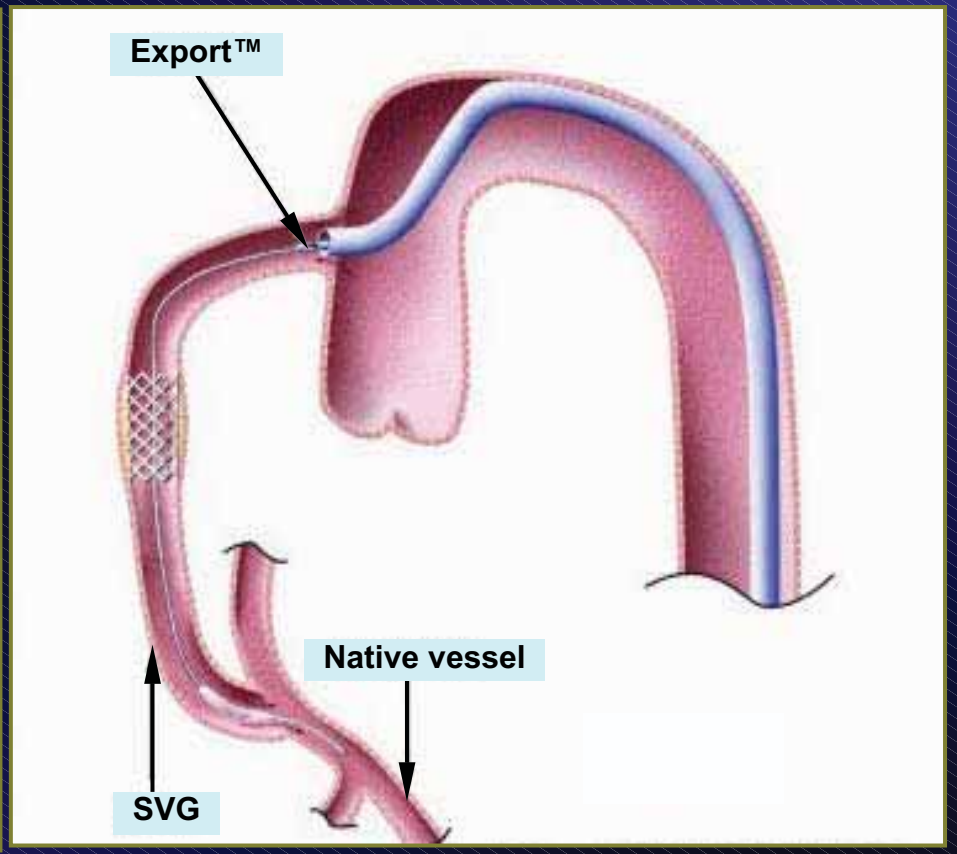




Balloon Occlusion Device

PercuSurge Guardwire

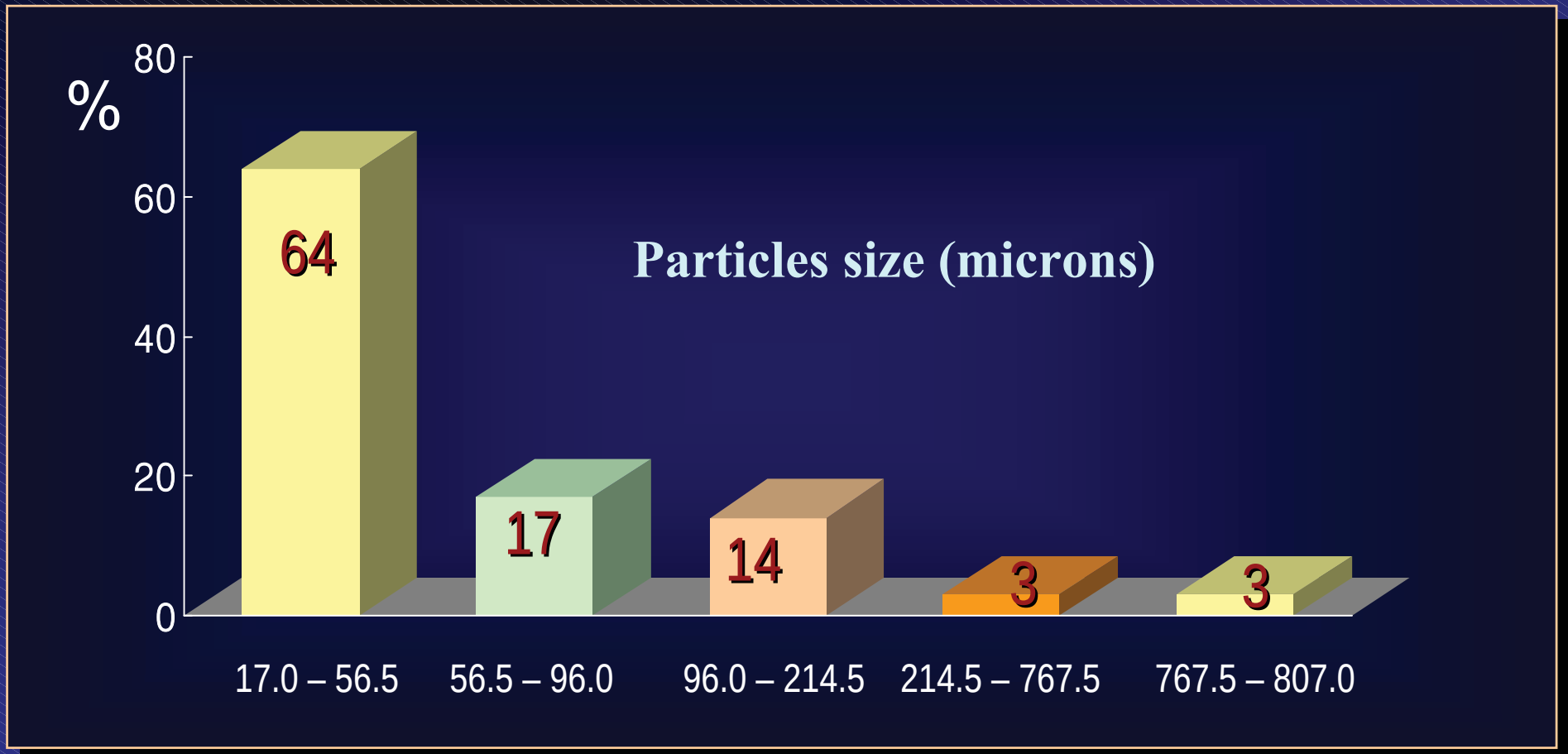




Retrieved Particles

SAFE study

Particles were retrieved in 91% of 103 pts



Grube et al, AJC 2002;89:941-5

SAFER trial

PercuSurge vs. Standard

801 pts (406 PercuSurge, 395 standard)

Primary end point : 30 day MACE

Mean graft age : 10.7 (7.1 ~ 13.5) yrs

Lesion length 16 mm

Thrombus 39 %

Baim DS et al, Cir 2002;105:1285-90

SAFER

Procedural Data

	GuardWire	Control	p
Technical success *	90.1 %	—	NS
Procedural success	90.5 %	82.0 %	< 0.05
Inflation time (min)	6.5 (4.5 ~ 10.5)	—	—
Intolerance	2 %	—	—
N of stents	1.38	1.35	NS

** Failure: inability to deliver (5.4%); inability to achieve/sustain occlusion (3.2%);Inability to aspirate >20mL before deflation (1.2%)*

Baim DS et al, Cir 2002;105:1285-90

SAFER

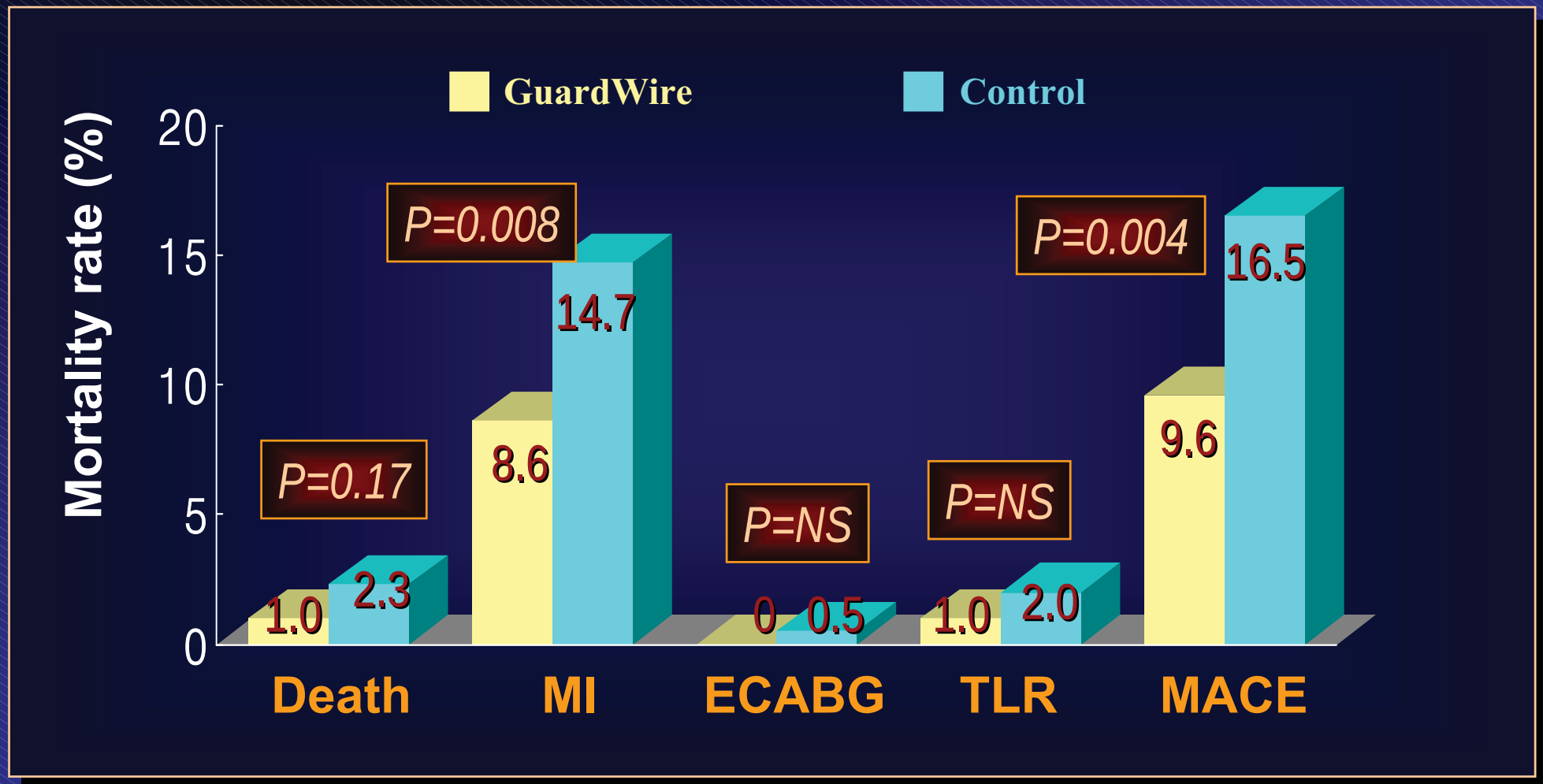
Cath Lab Outcomes

	GuardWire	Control	p
N of pts	395	406	
Final TIMI-3 flow	97.8 %	95.1 %	0.04
No reflow	3.2 %	8.3 %	0.001
Distal emboli	2.2 %	3.2 %	0.40
Perforation	0.2 %	1.5 %	0.05
Subacute closure	1.7 %	0.5 %	0.18
Dissection	4 %	1 %	0.12

Baim DS et al, Cir 2002;105:1285-90

SAFER

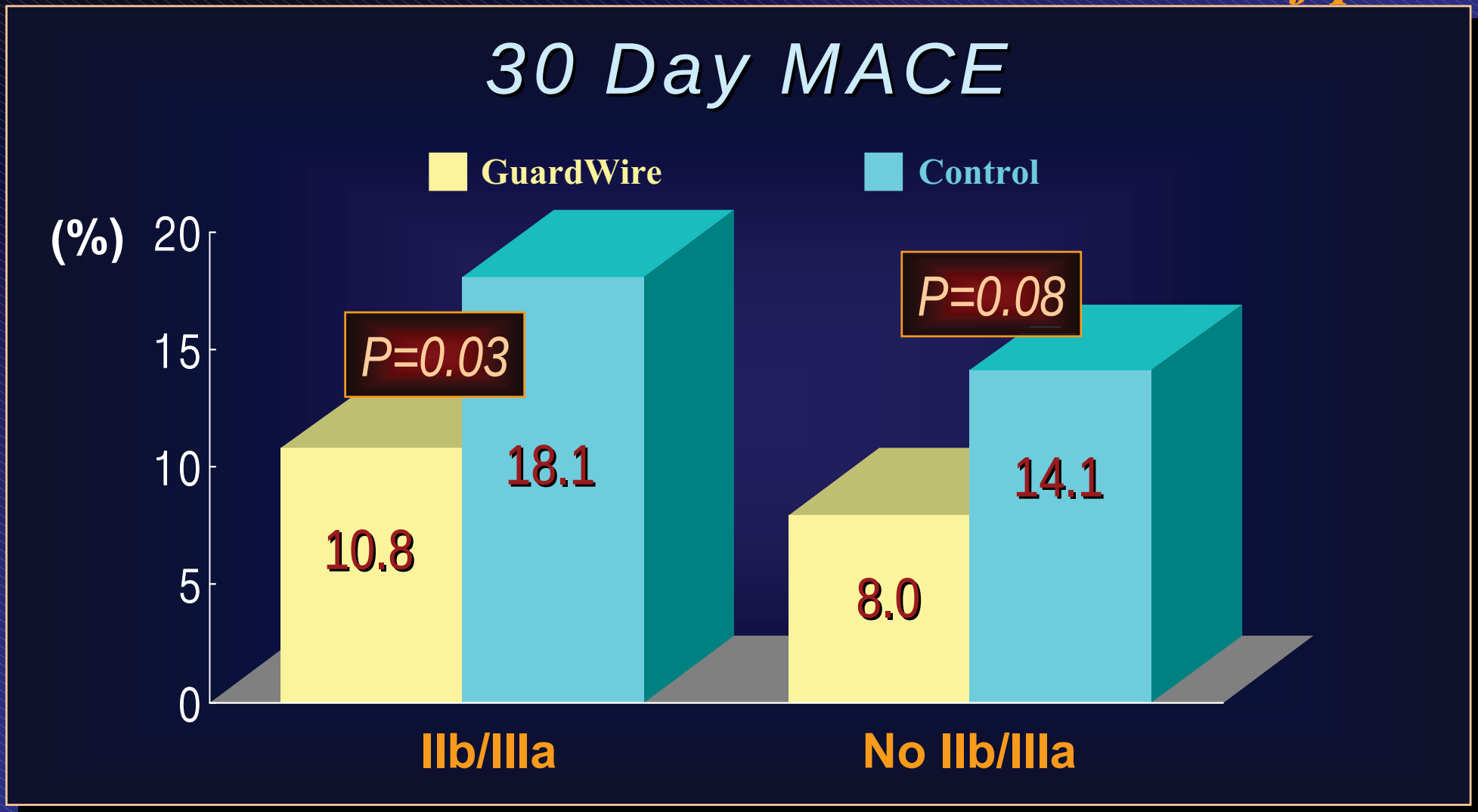
30 Day MACE (n=801)



Baim DS et al, Cir 2002;105:1285-90

Effect of GP IIb/IIIa

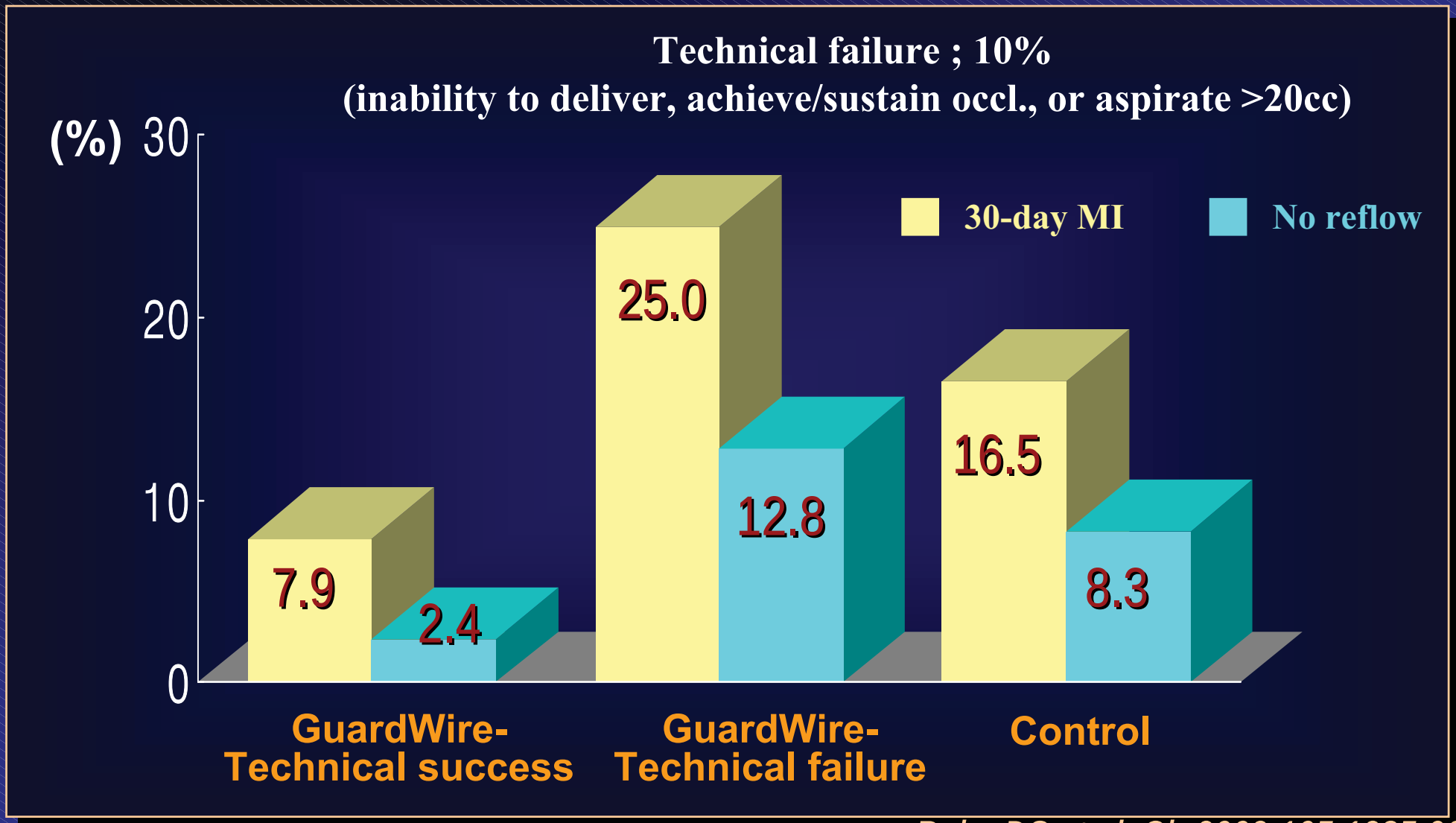
SAFER
~60% of pts



Baim DS et al, Cir 2002;105:1285-90

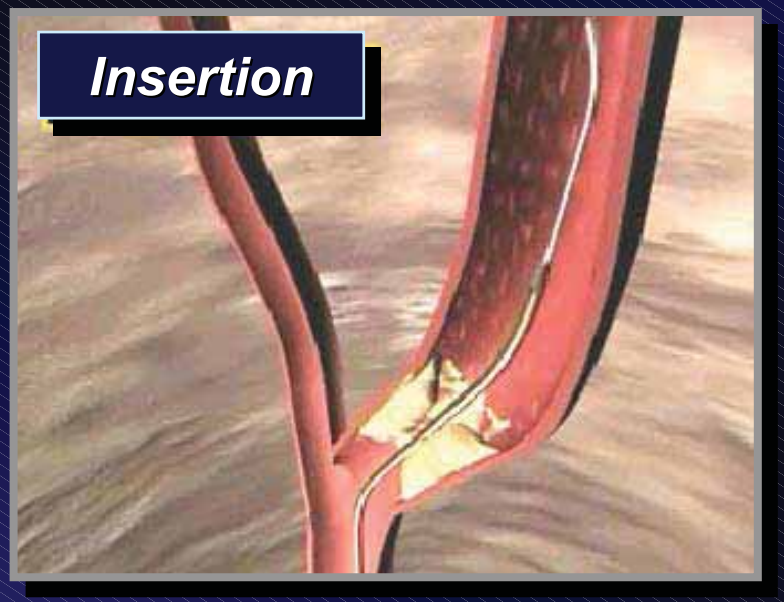
Effect of Compliance

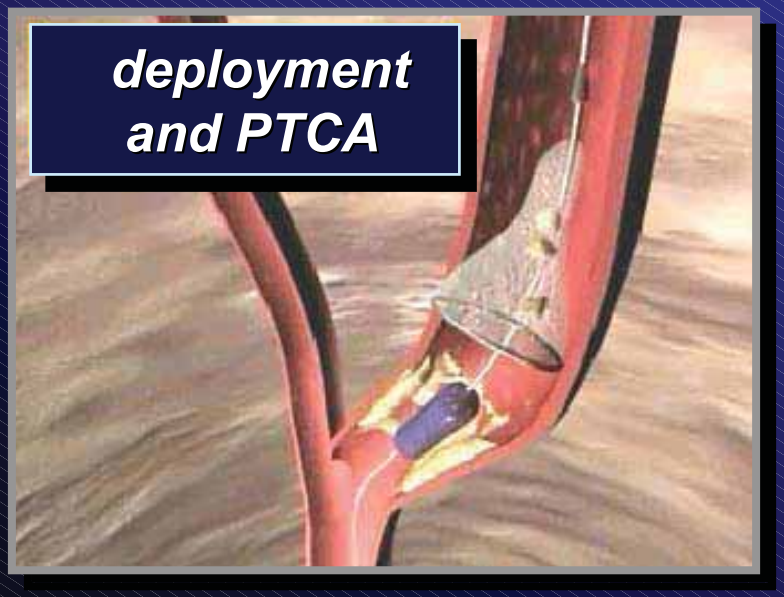
SAFER

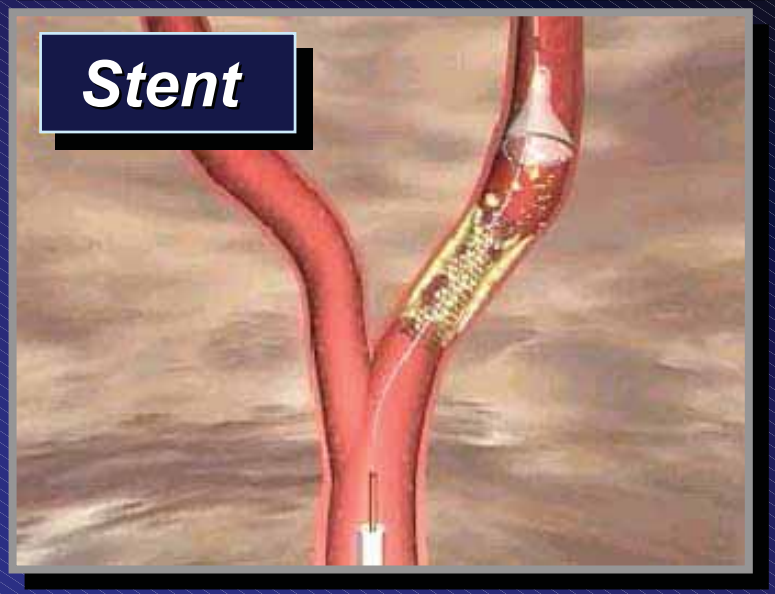


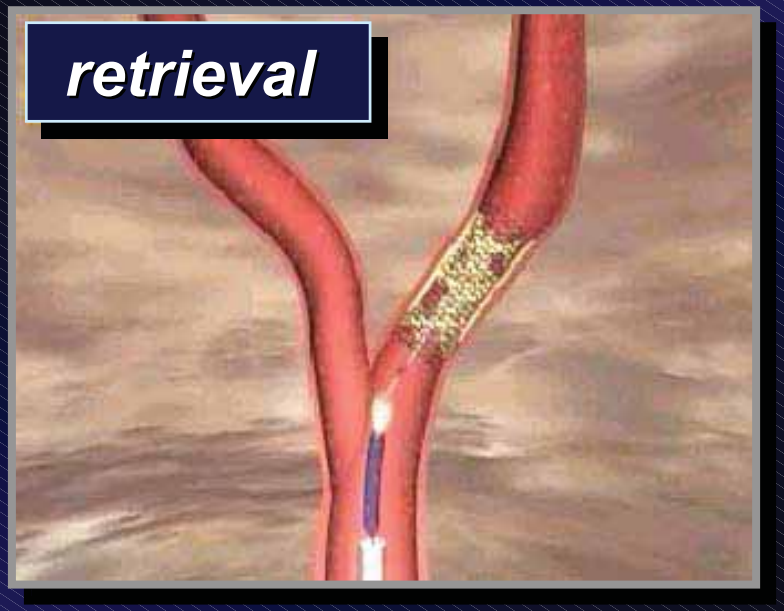
Baim DS et al, Cir 2002;105:1285-90

Filter Based Distal Protection

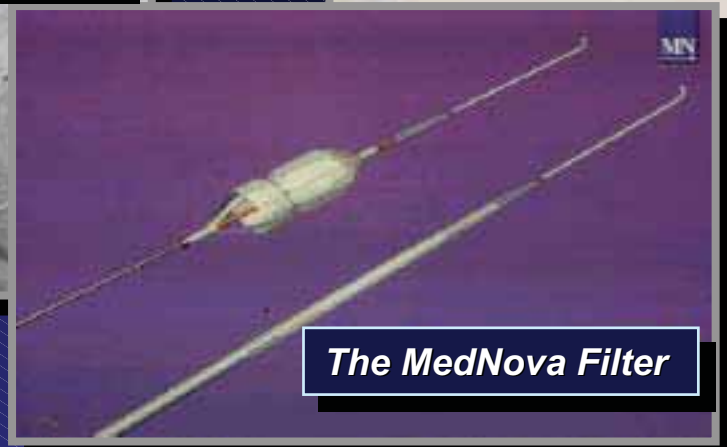


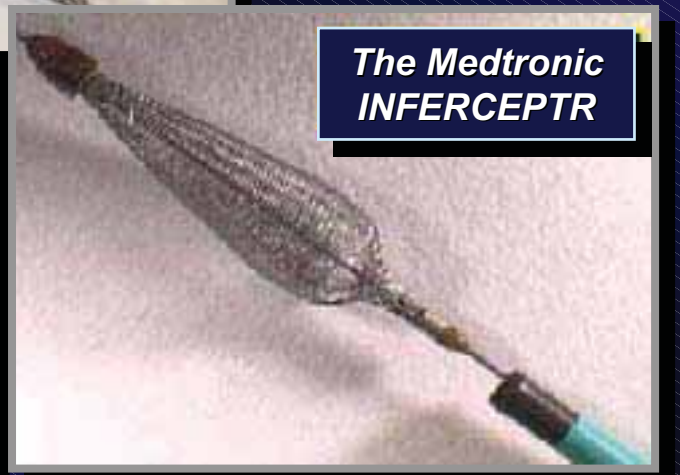






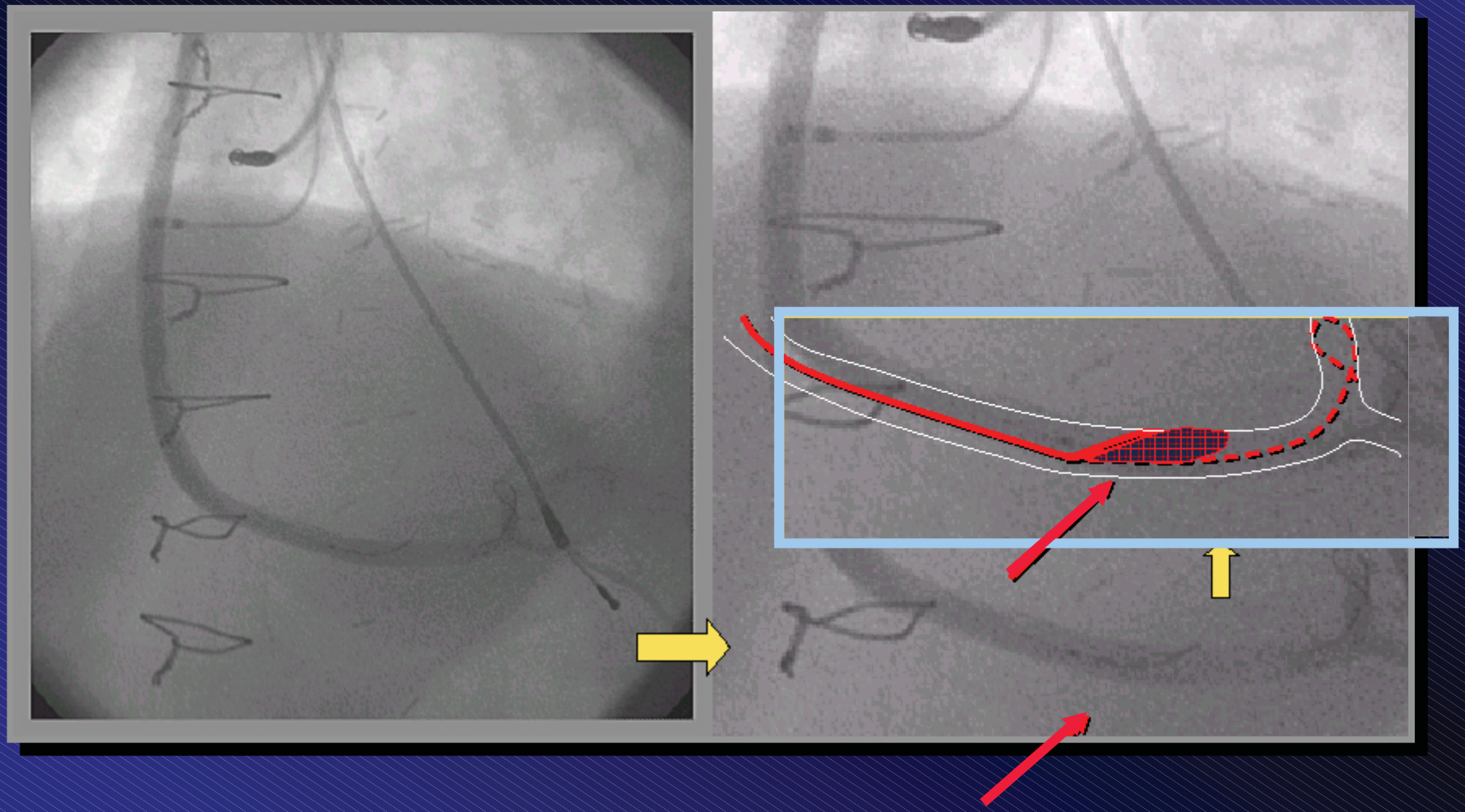
Filter Based Distal Protection





Problems of FilterWire

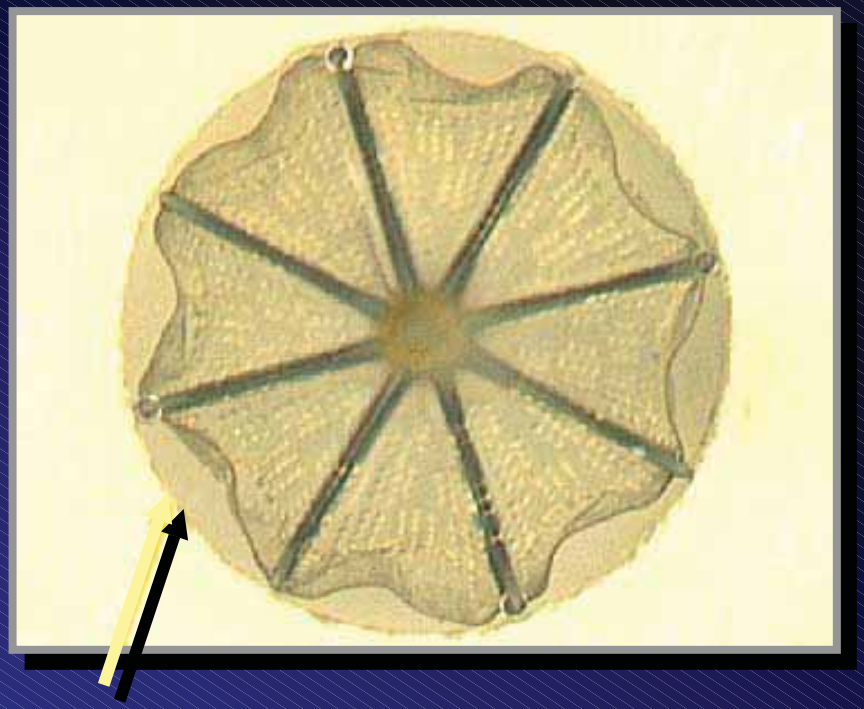
Poor Apposition



Problems of FilterWire

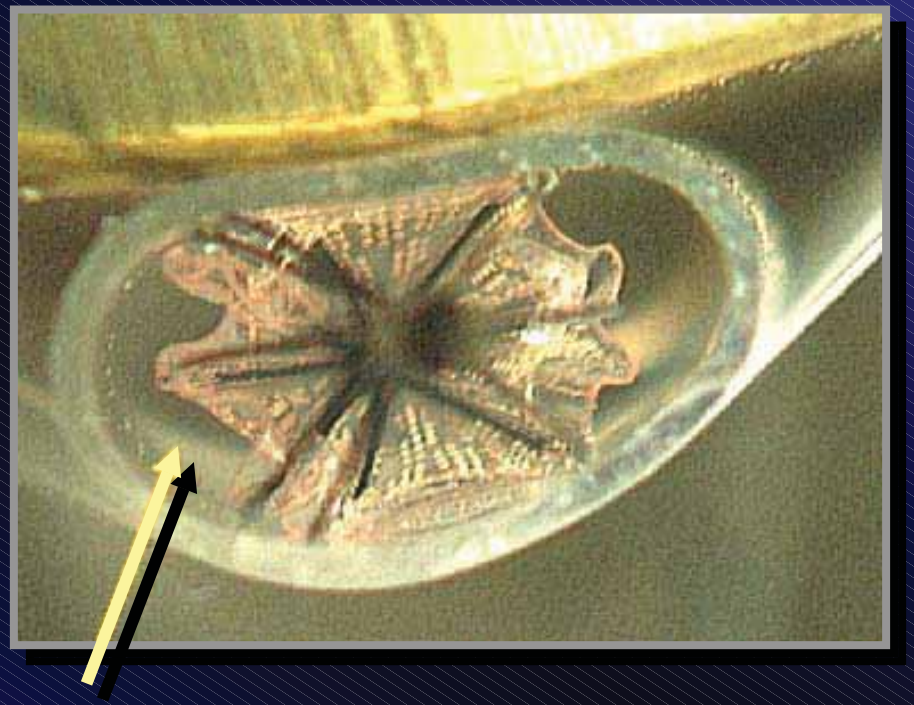
Lack of Apposition

6.0 mm Angioguard
in 5.5 mm round tube



Lack of circumferential wall apposition between struts

6.0 mm Angioguard in a
5.0 mm asymmetrical tube

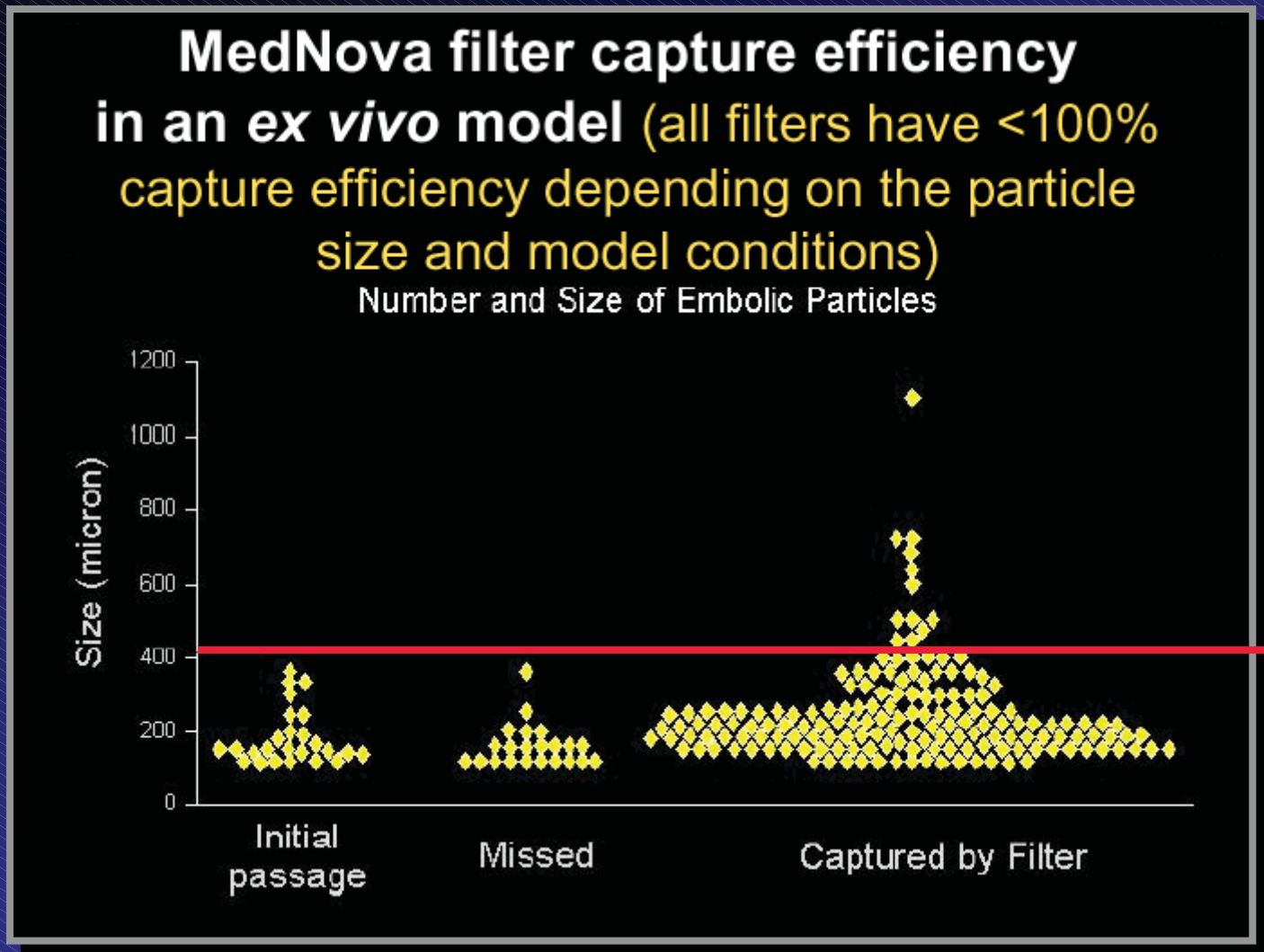


The asymmetrical shape causes struts to pull farther away from wall

Problems of FilterWire

Capture Efficacy

MedNova filter capture efficiency in an *ex vivo* model (all filters have <100% capture efficiency depending on the particle size and model conditions)



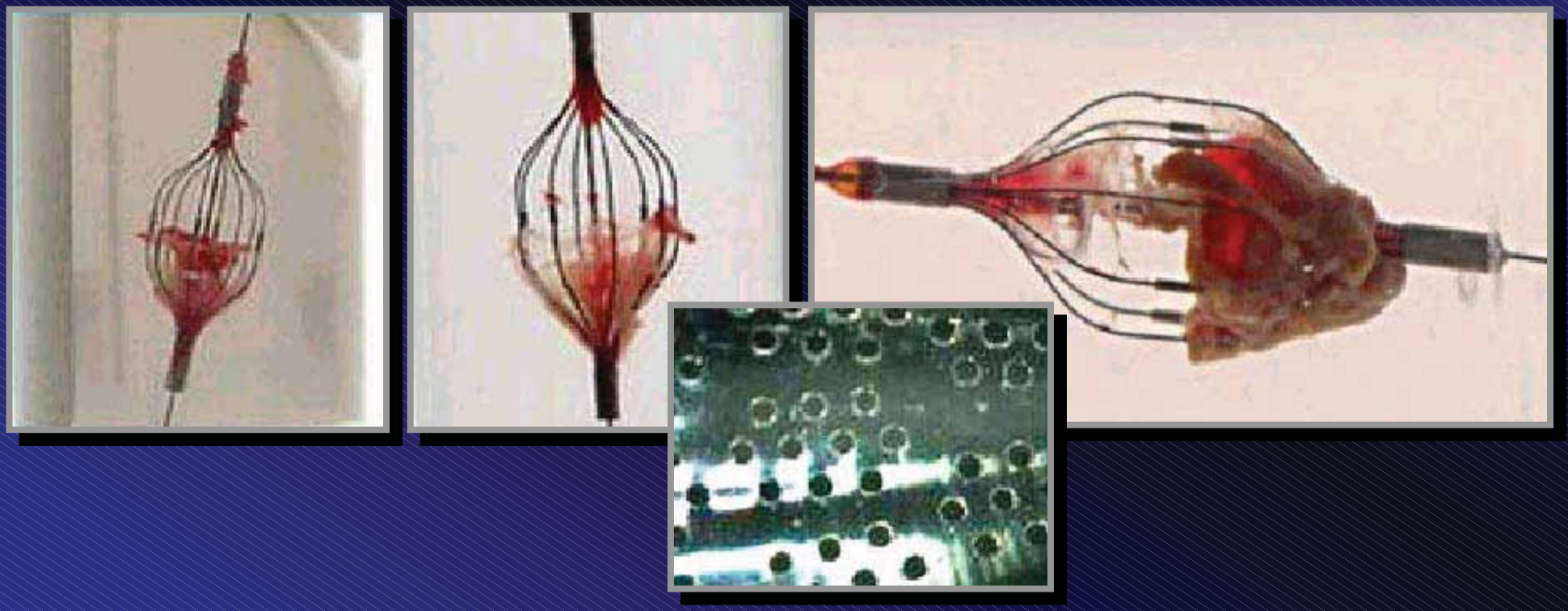
Ohki T et al. J Vasc Surg 1999;30:1034-44

Problems of FilterWire

Extruded Debris

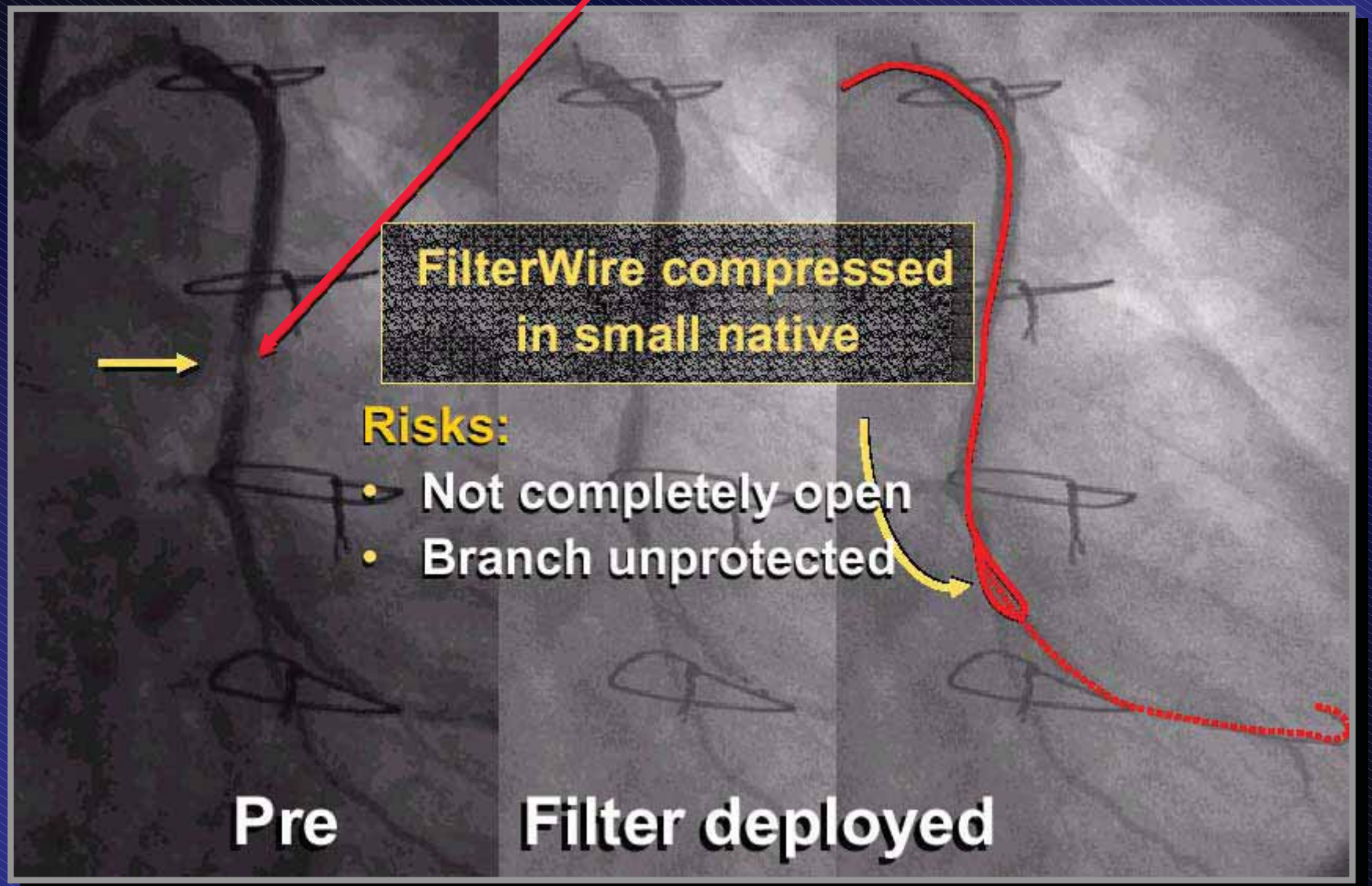
Cordis AngioGuard Cases

(But can happen with all filters depending on pore size and retrieval mechanism)



Problems of FilterWire

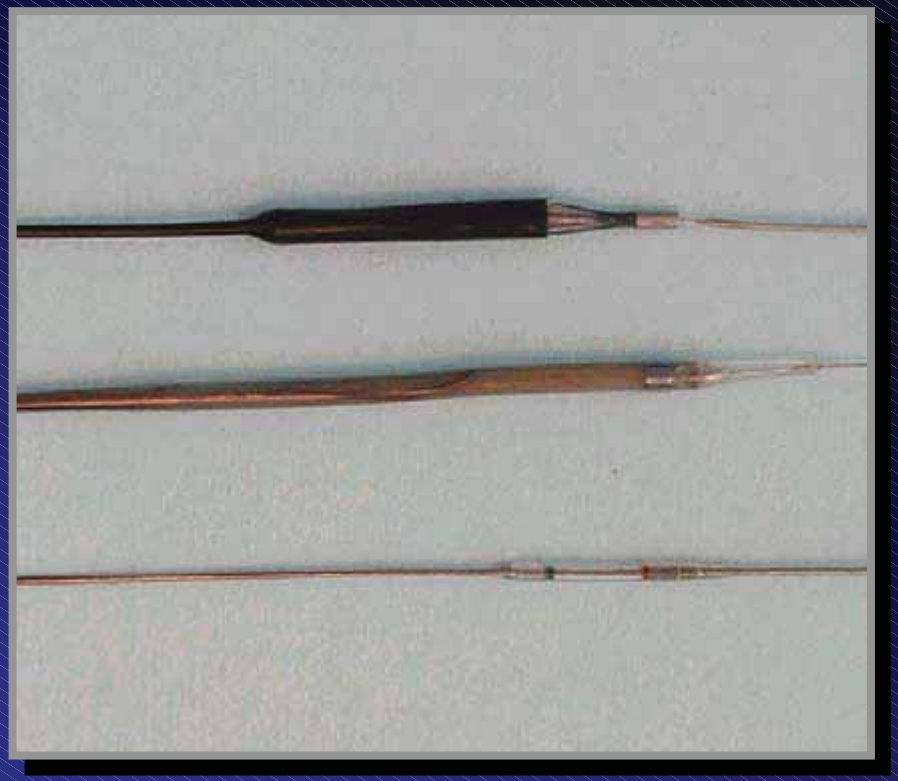
Too Distal Lesion



Problems of FilterWire

Device Profile

Can inhibit lesion crossing, or result in embolization during passage



Angioguard 4.7 F

EPI FilterWire EX 3.9 F

GuardWire 2.7 F

SVG PCI with FilterWire

Multicenter Prospective

Phase 1

48 lesions
Lesion length < 40mm
Reference 3.5 ~ 5.5 mm
DS < 100%
TIMI ≥ 2
Straight portion of
distal to lesion ≥ 2cm
Exclusion of AMI or
LVEF < 30%

More tough lesions, Multicenter

Procedural technique change after failure analysis

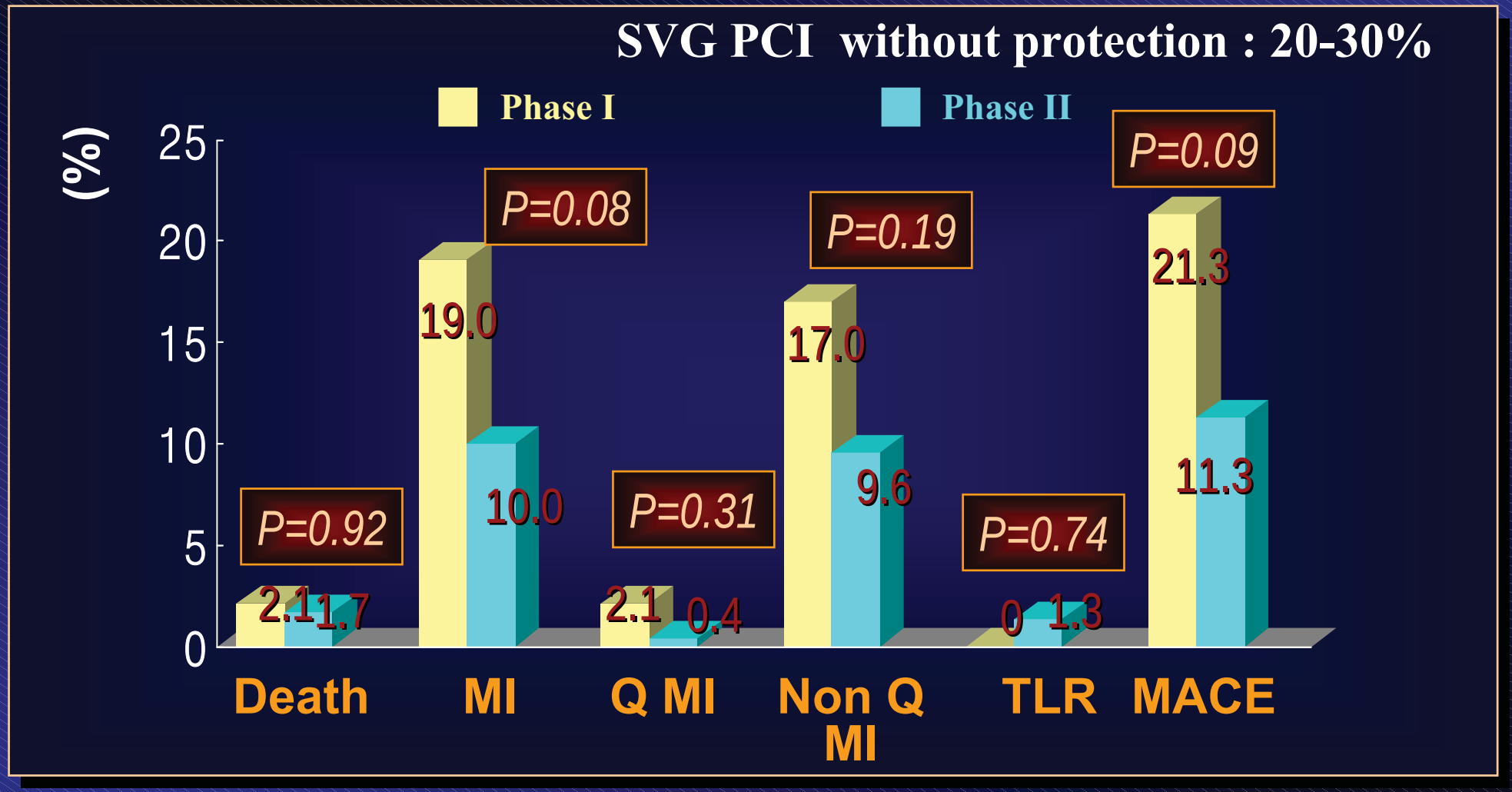
Phase 2

65 centers
230 lesions
Lesion ; any length
Reference 3.5 ~ 5.5 mm
DS < 100%
TIMI ≥ 1
Straight portion of
distal to lesion ≥ 2cm
Exclusion of AMI or
LVEF < 30%

Stone GW et al, JACC 2002;10:1882-8

Higher incidence of 30 Day MACE

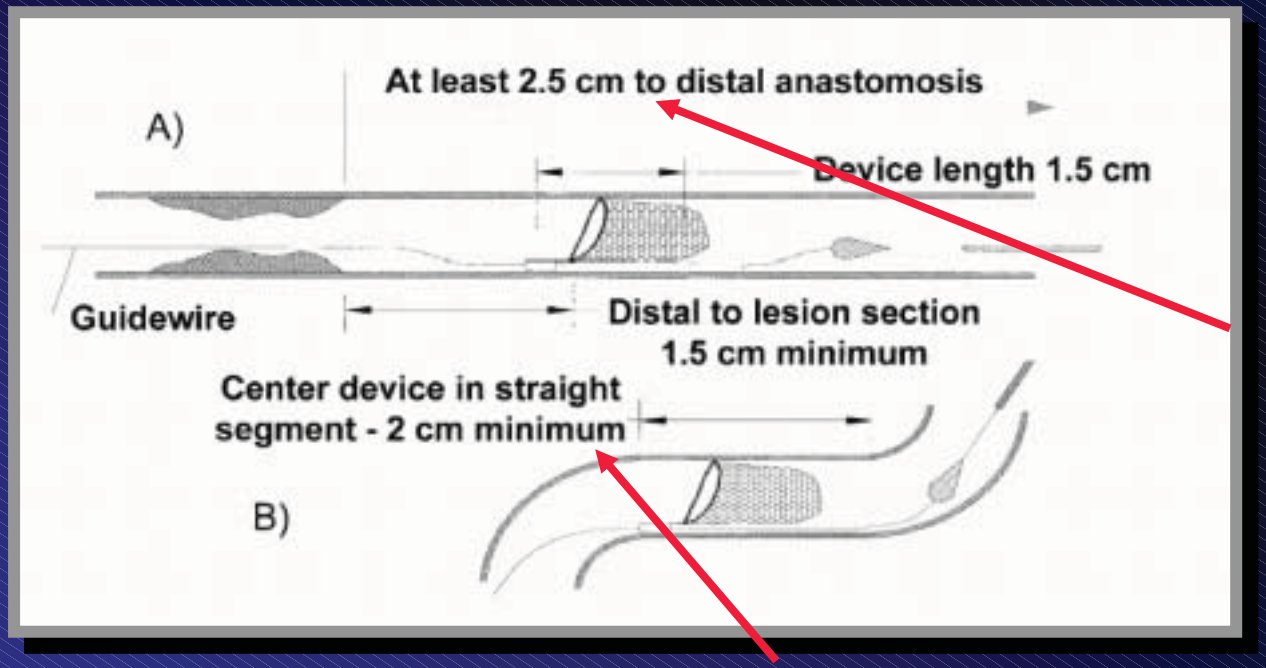
In Phase I than Phase II



Stone GW et al, JACC 2002;10:1882-8

Procedural Change after Phase I

- Orthogonal view to detect filter loop malapposition
- Retract the filter into the retrieval sheath enough to close the nitinol loop
- Enough distal protection during all phase of procedure



To protect release of debris to native vessel

Straight portion to protect malapposition

Stone GW et al, JACC 2002;10:1882-8

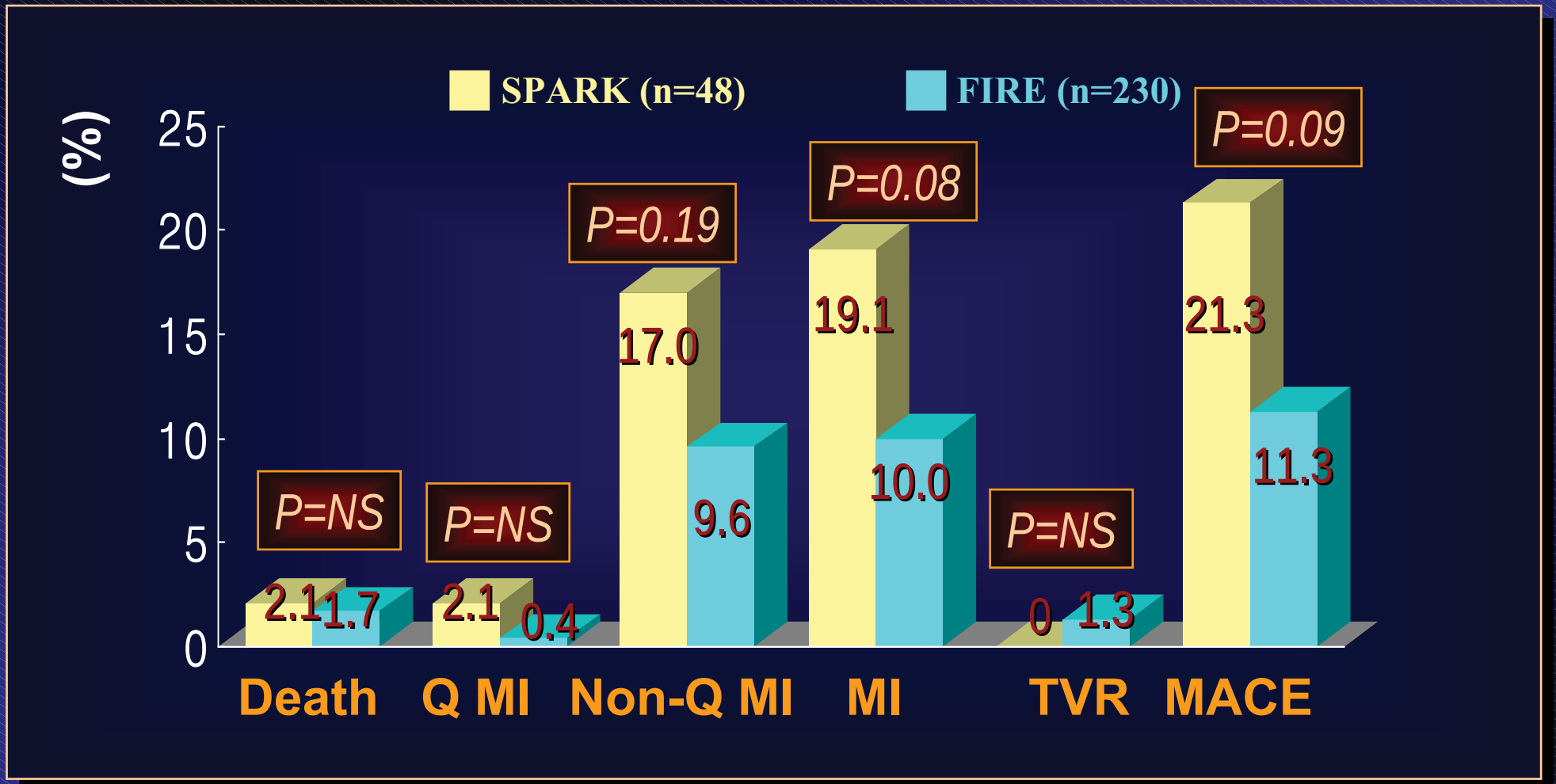
SVG Protection

Planned Randomized Trials

	FIRE	GUARD	TRAP	CAPTIVE
Device	BSC/EPI FilterWire	Cordis AngioGuard	Microvena TRAP 1	MedNova CardioShield
N of pts	800	800	785	800
Centers	60	35	20	50
Trial design	Hybrid	Hybrid	Superiority	Hybrid
Status	Enrolled	Enrolling	Enrolling	Enrolling
PI	GW Stone	SG Ellis	WW O'Neill	D Holmes
1° Endpoint	30d MACE	30d MACE	30d MACE	30d MACE

Effect of Protection Device

30 MACE in SPARK vs. Roll ins



Effect of Protection Device

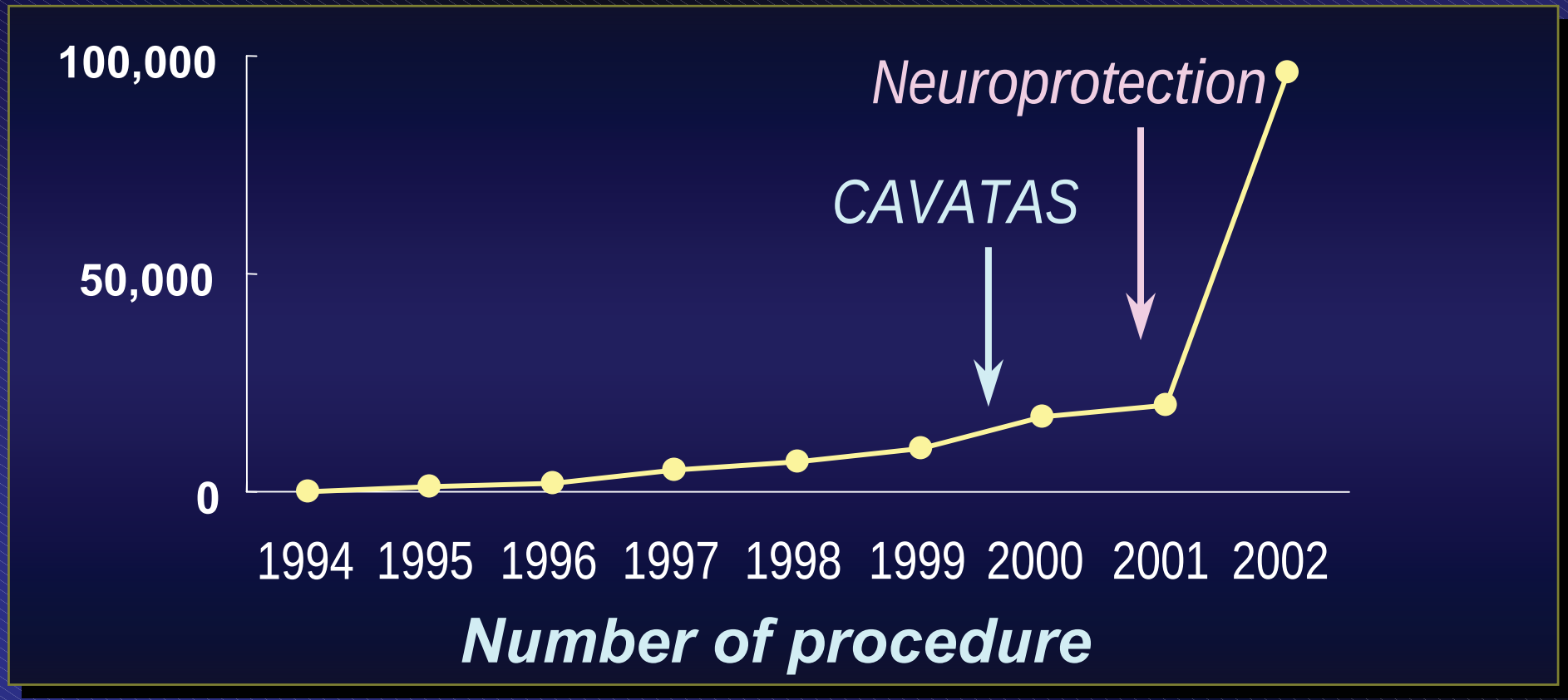
QCA in SPARK vs. Roll ins

N of pts and lesion	SPARK (n=48, 60)	FIRE (230, 248)	P value
RVD (mm)	3.6 ± 0.6	3.5 ± 0.7	NS
Lesion MLD (mm)	3.1 ± 0.7	3.0 ± 0.7	NS
Diameter sten (%)	15 ± 11	13 ± 12	NS
TIMI-3 (%)	94.9	94.5	NS
No reflow (%)	12.3	5.0	0.07
Distal emboli (%)	10.5	3.0	0.03

Carotid Stenting with Embolic Protection

Growth of Carotid Stenting

- No reimbursement
- No FDA devices
- No professional societal support



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%	4.21%	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

Carotid Artery Stenting

The Main Cause of Complications Is

Cerebral Embolization !!

Distal Protection Devices

- **Will be mandatory for all carotid trials ?**

- **Will it be an additional stroke risk factor?**

Cerebral Embolization

Highest Risk

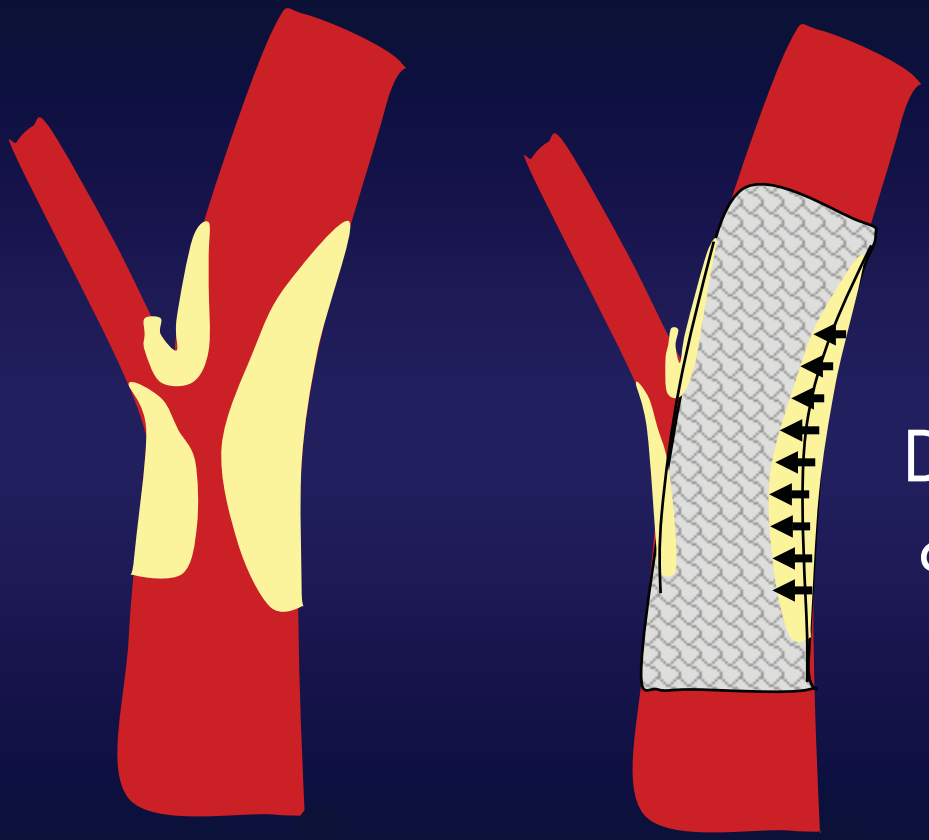
- **Unstable plaque**
  break down of fibrous cap
- **Soft plaque**
- **Long stenosis string sign**
  contains thrombus

Cerebral Embolization

Mechanisms

- **Dislodging of thrombus**
  any step of the procedure
- **Plaque cracking**
  balloon dilatation
- **Material cut-off**
  stent placement

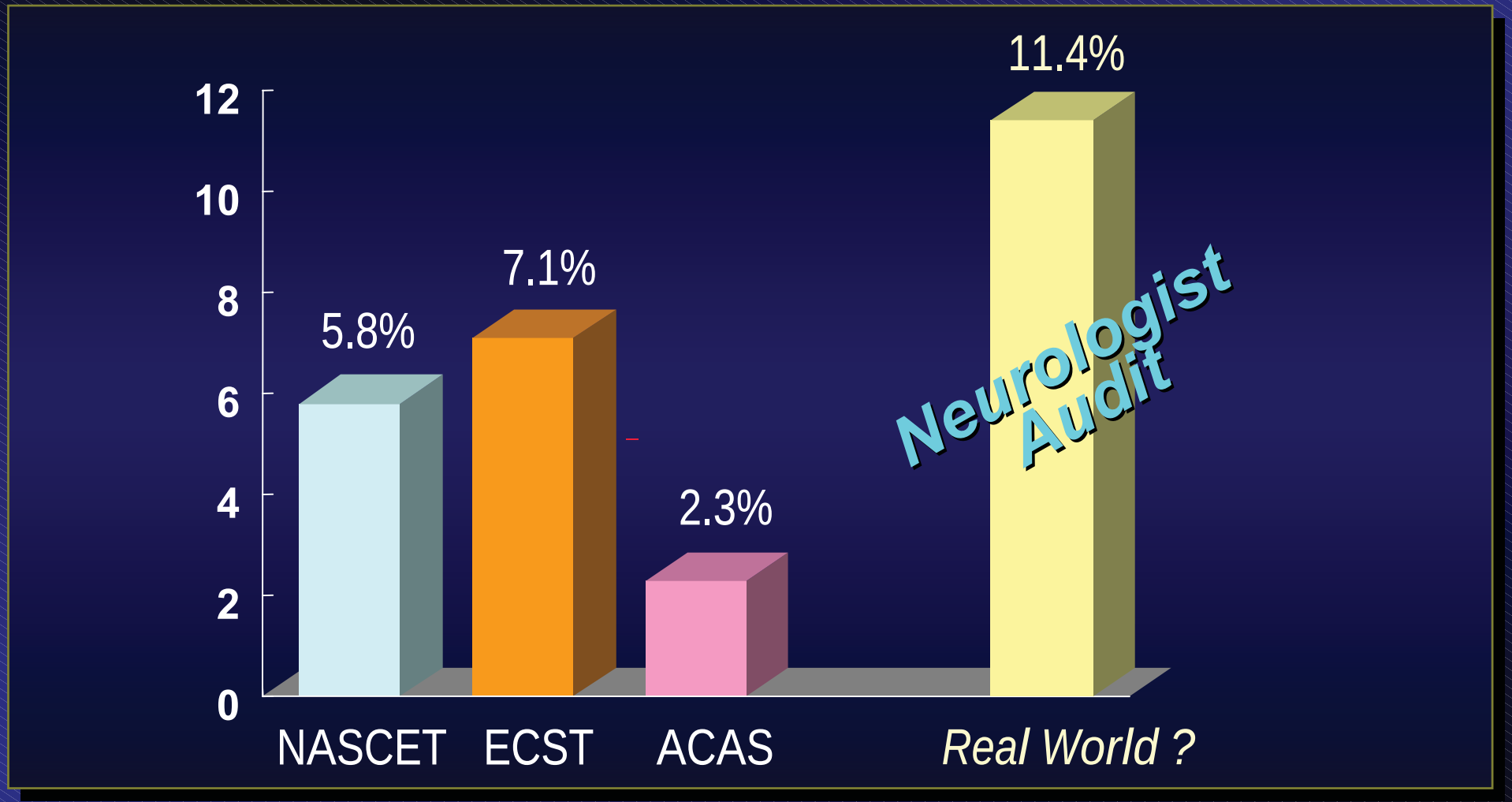
Soft Plaque



Depends on mesh size
& radial force of stent

Plaque material protrudes through stent meshes

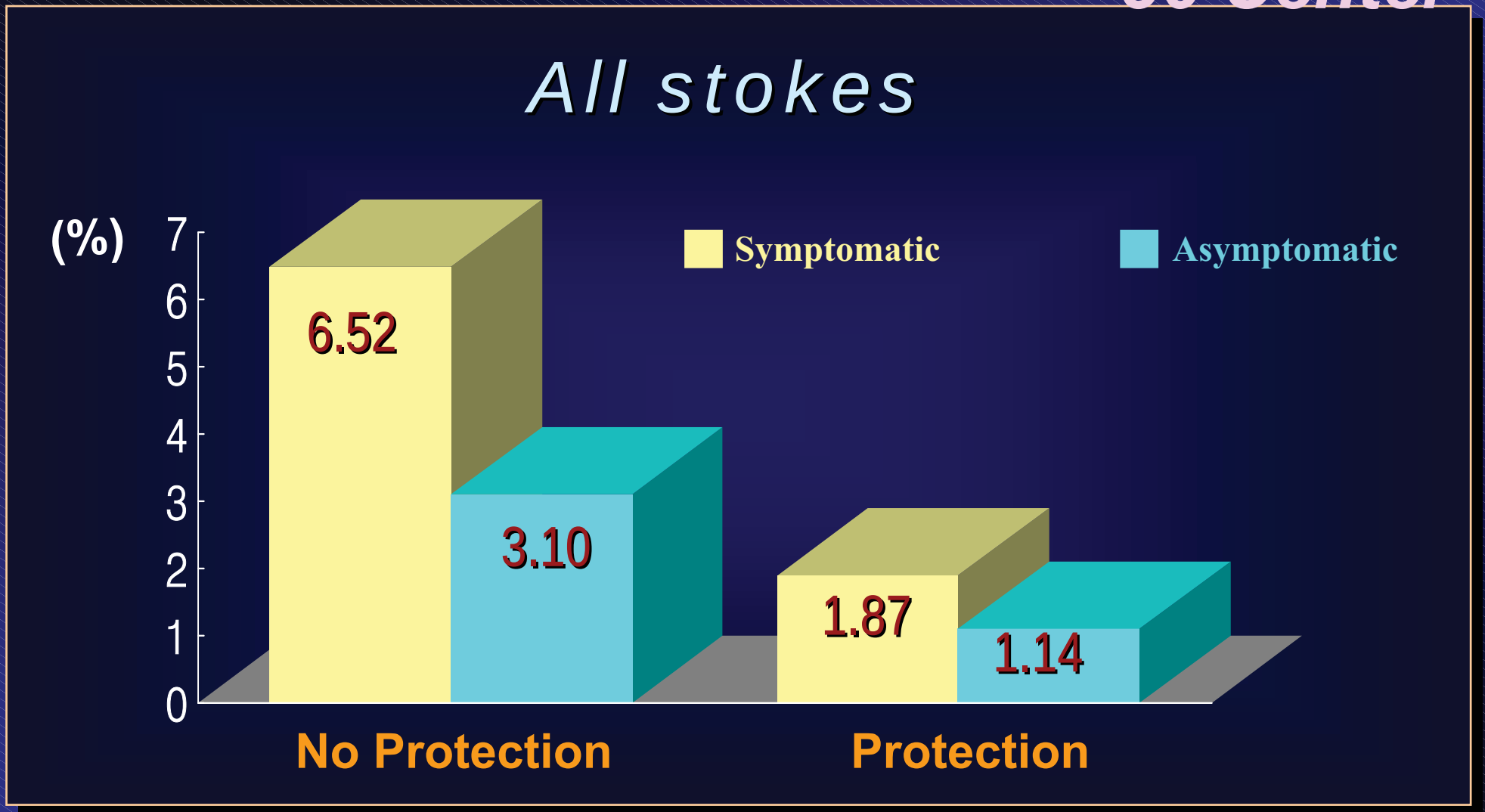
Death or Stroke after CEA



Chaturverdi, Neurology 2001 Sep

Benefit of Cerebral Protection

36 Center



Wholey et al, Cath Cardiovasc Intervent 2000;50:160

Approaches to Brain Protection

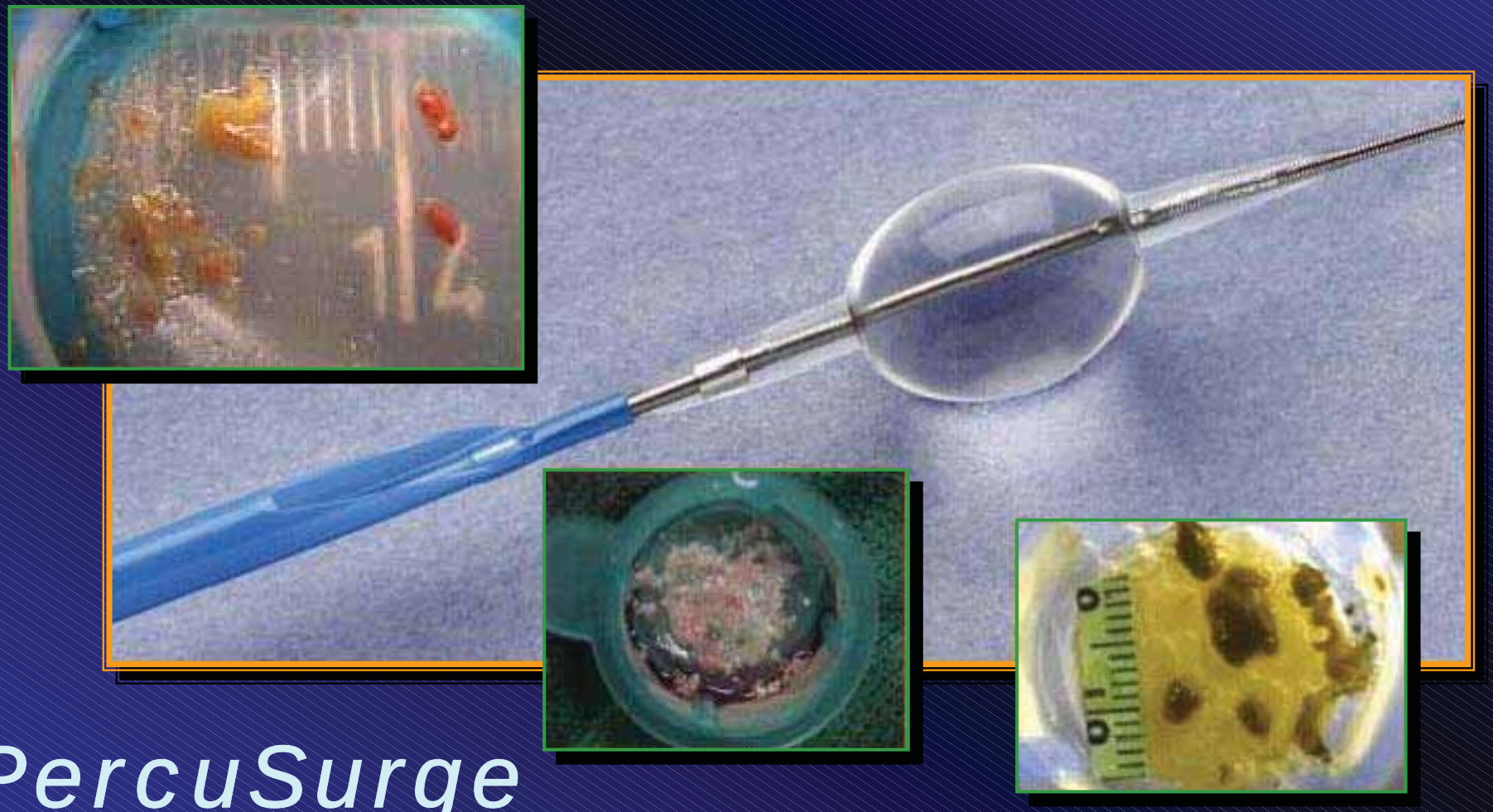
- Distal occlusion
  - Theron balloon
  - PercuSurge Guardwire
- Filter
  - MedNova NeuroShield
  - EPI filter
  - Angioguard filter
  - Medtronic filter
  - BSC Captura
  - Bate's Floating Filter
  - Accu-Filter
  - E-Trap
  - Microvena Trap
- Proximal occlusion
  - Kachel balloon
  - ArteriA Parodi Catheter

The Ideal Protection System

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

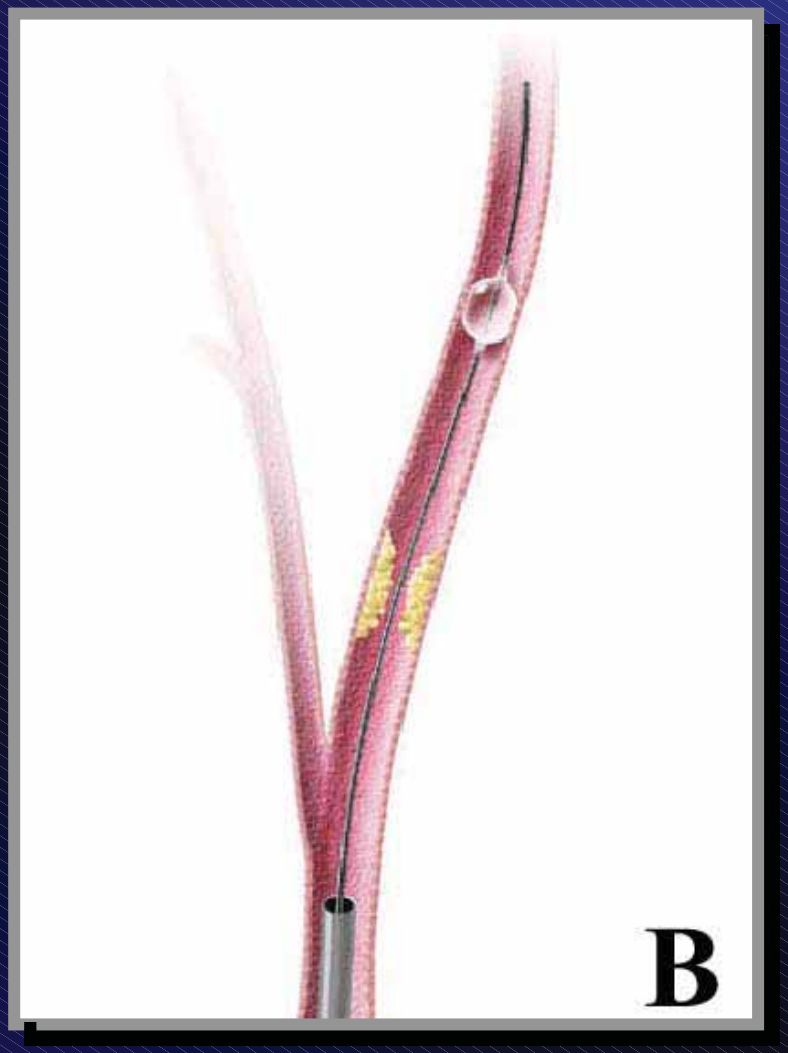
Distal Occlusion Device

Guardwire®



PercuSurge

GuardWire



GuardWire

Strength and Weakness

Distal Occlusion balloon

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

Carotid Stenting with Distal Occlusion Device

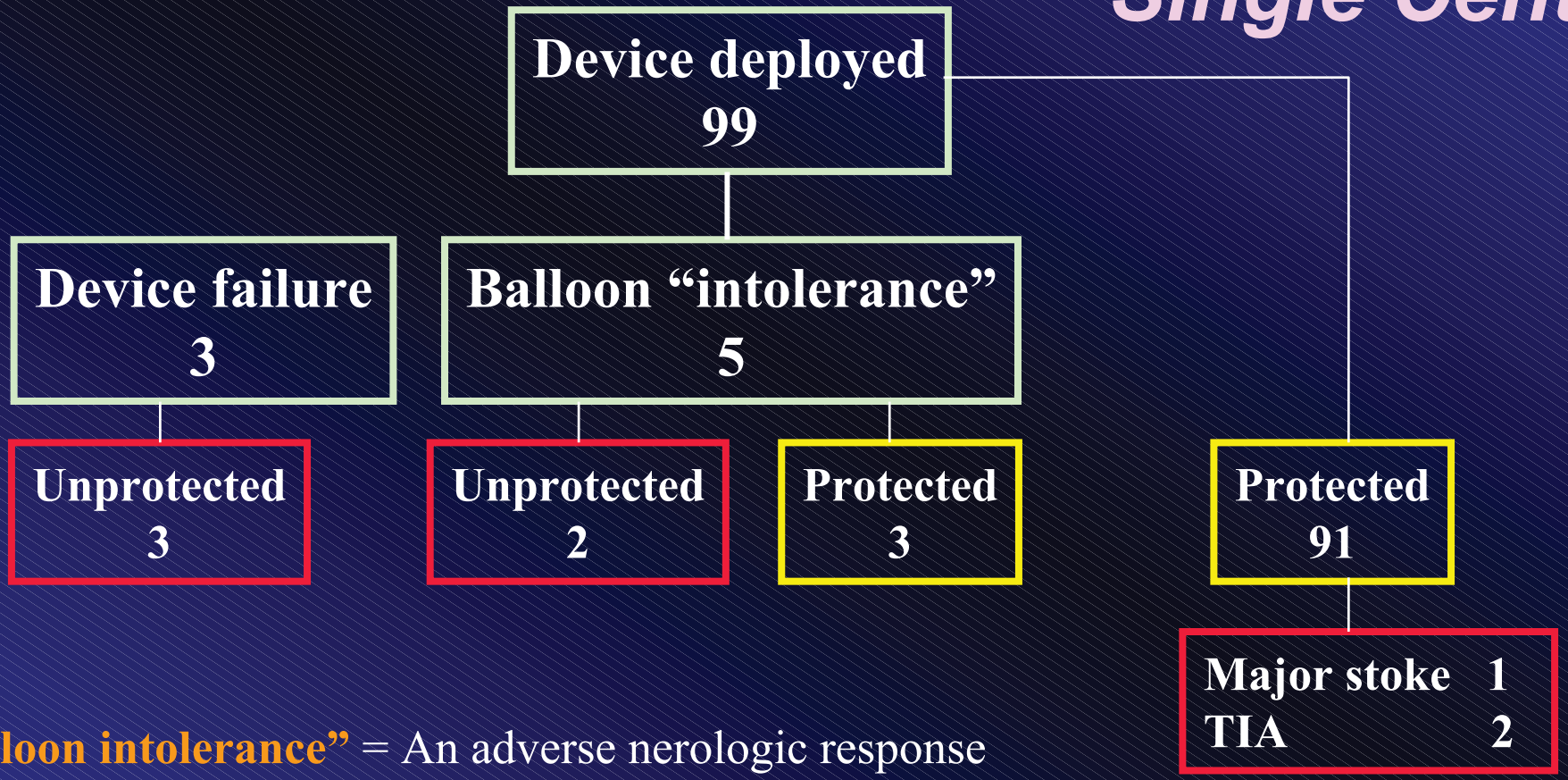
Single Center

- Carotid stenting with GuardWire
- Number = 96 pts, 102 lesions
- Angiographic success = 162 (99%) lesions
- Successful GuardWire deployment = 99 (97%) proc
- Neurologic complications = 5 (5.2%) pts
  (3 Strokes, 2 TIA)

Schluter M et al, JACC 2002;40:890-5

Carotid Stenting with Distal Occlusion Device

Single Center

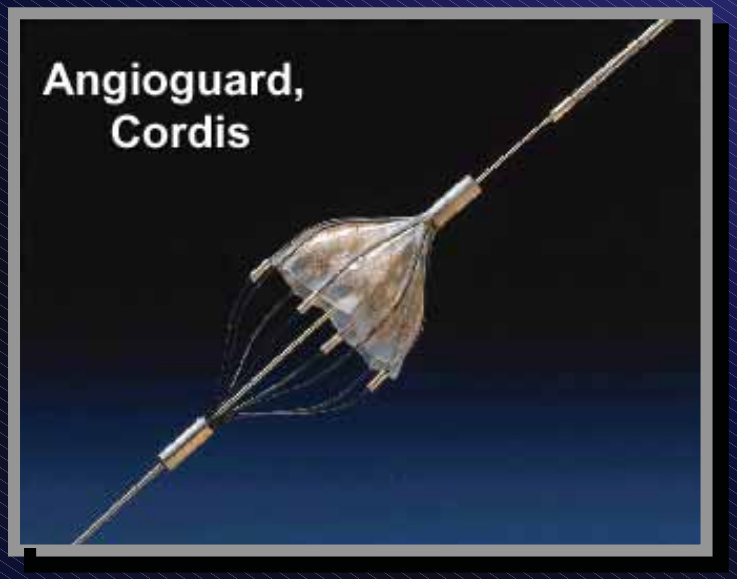


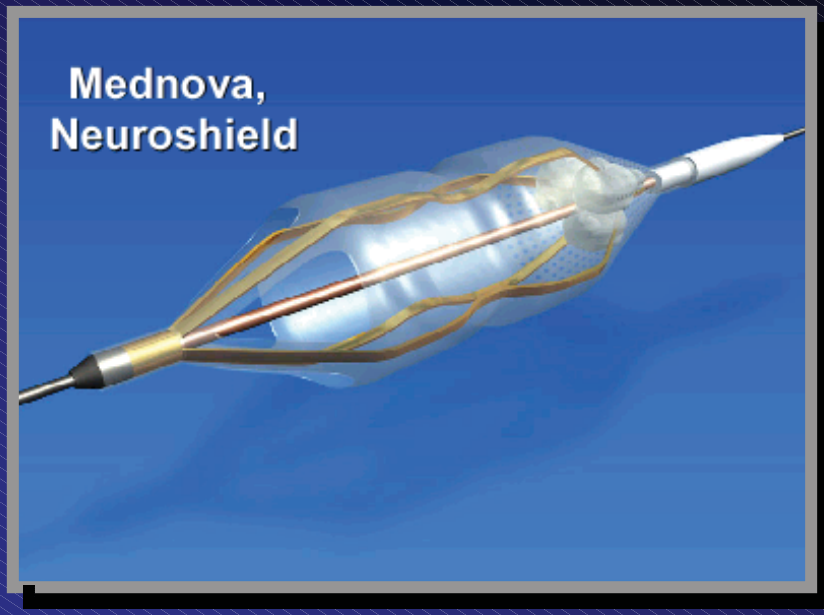
"Balloon intolerance" = An adverse nerologic response to occlusion of GuardWire device that promptly resolved after balloon deflation

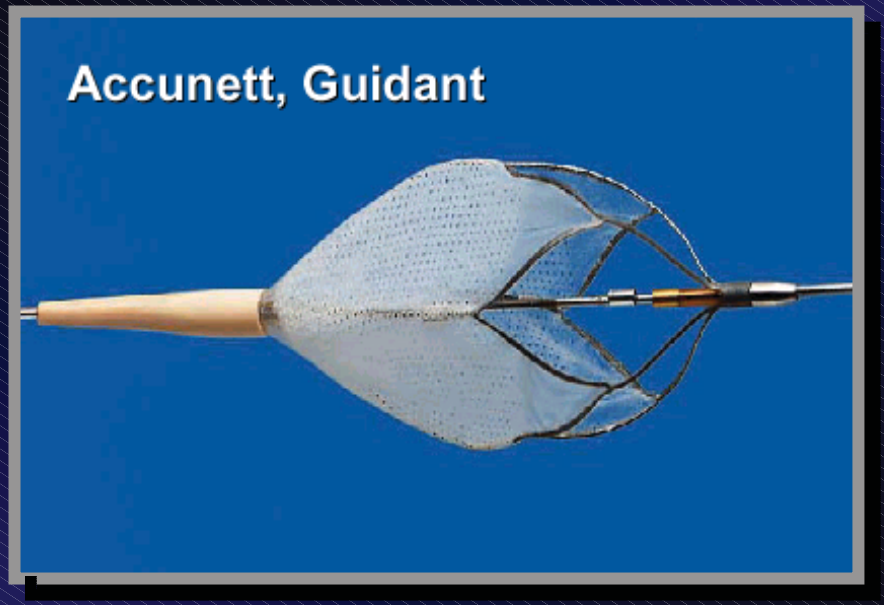
Schluter M et al, JACC 2002;40:890-5

Distal Filter Device

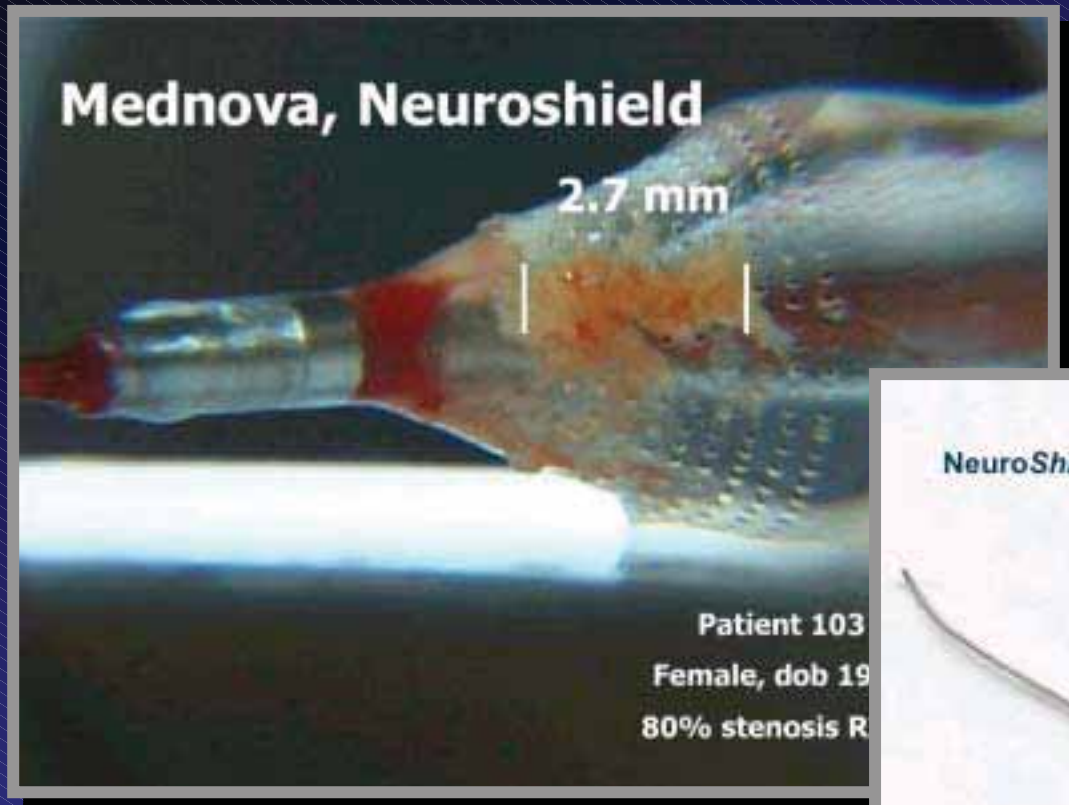
Different Types of Filters

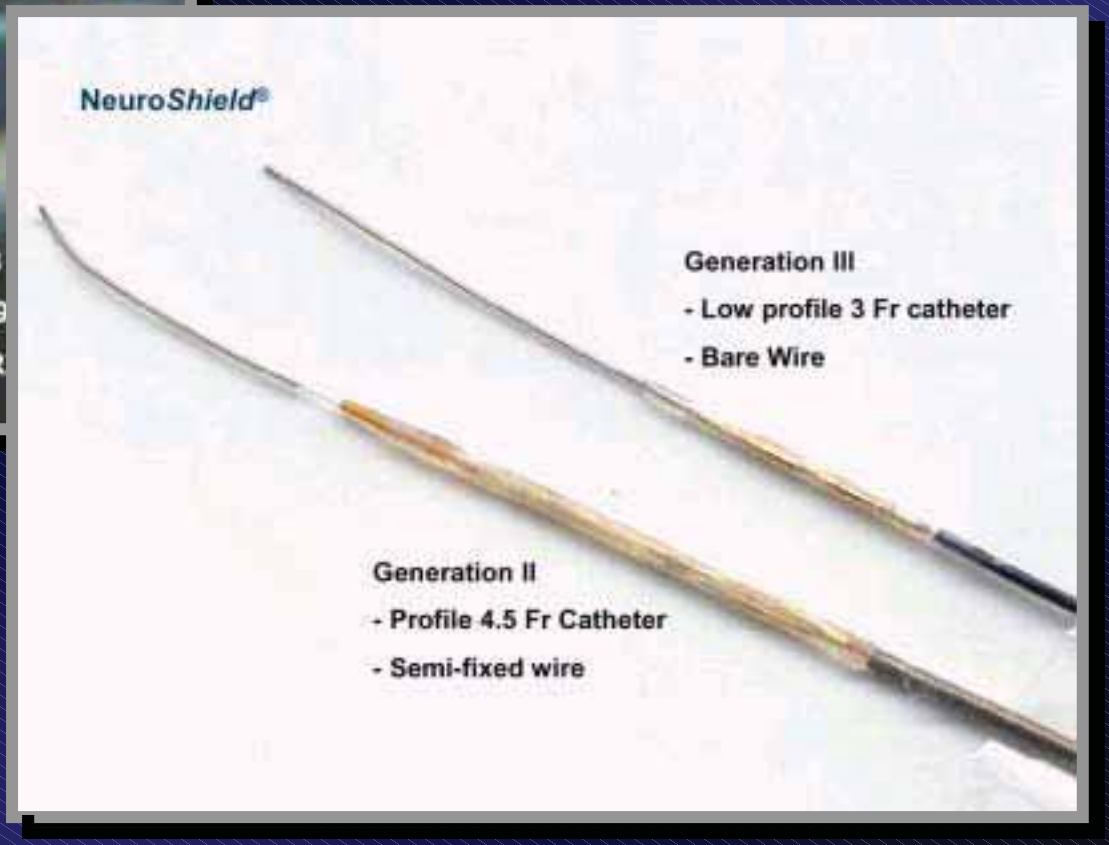




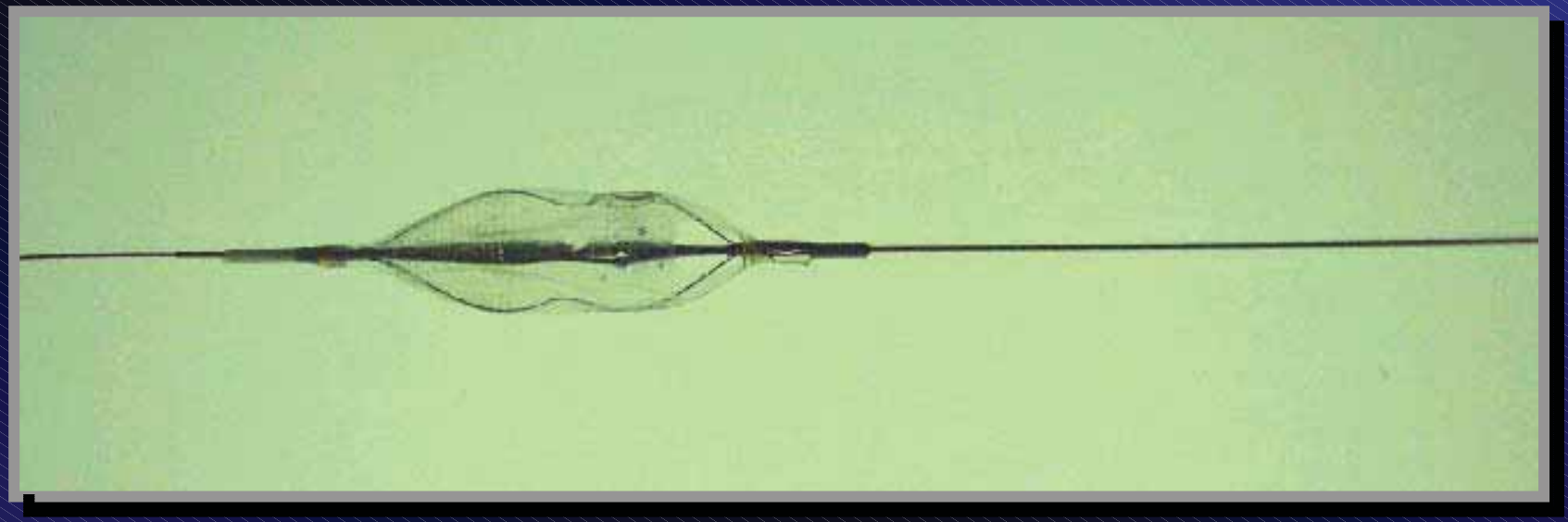


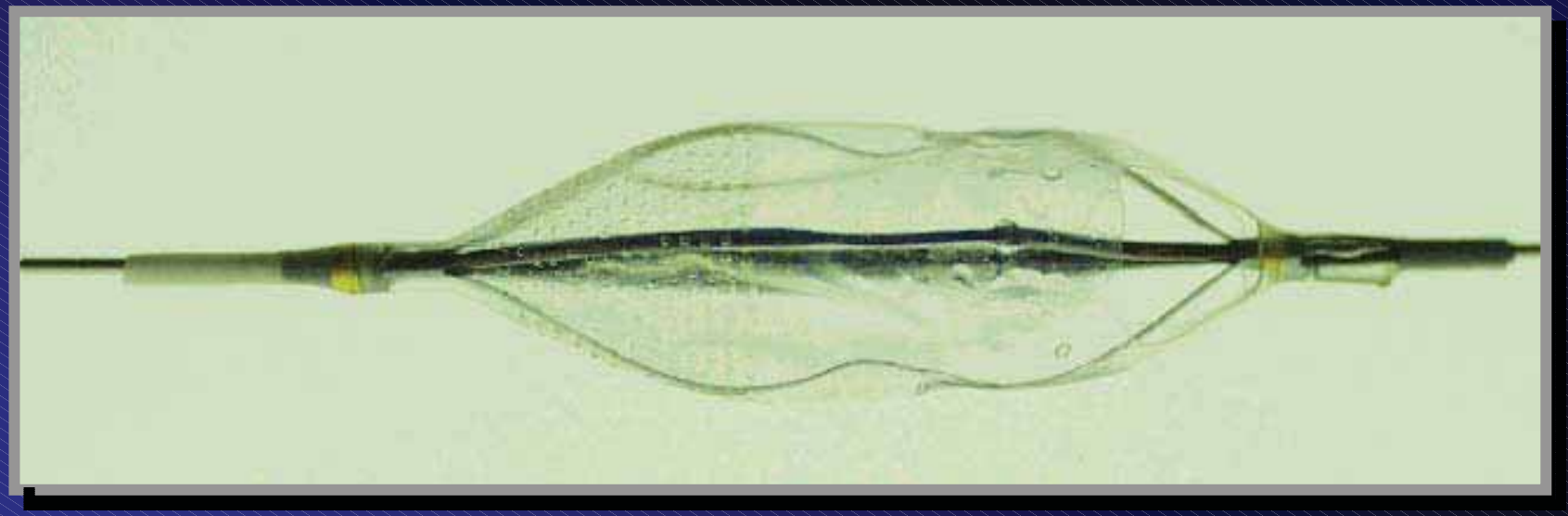
NeuroShield



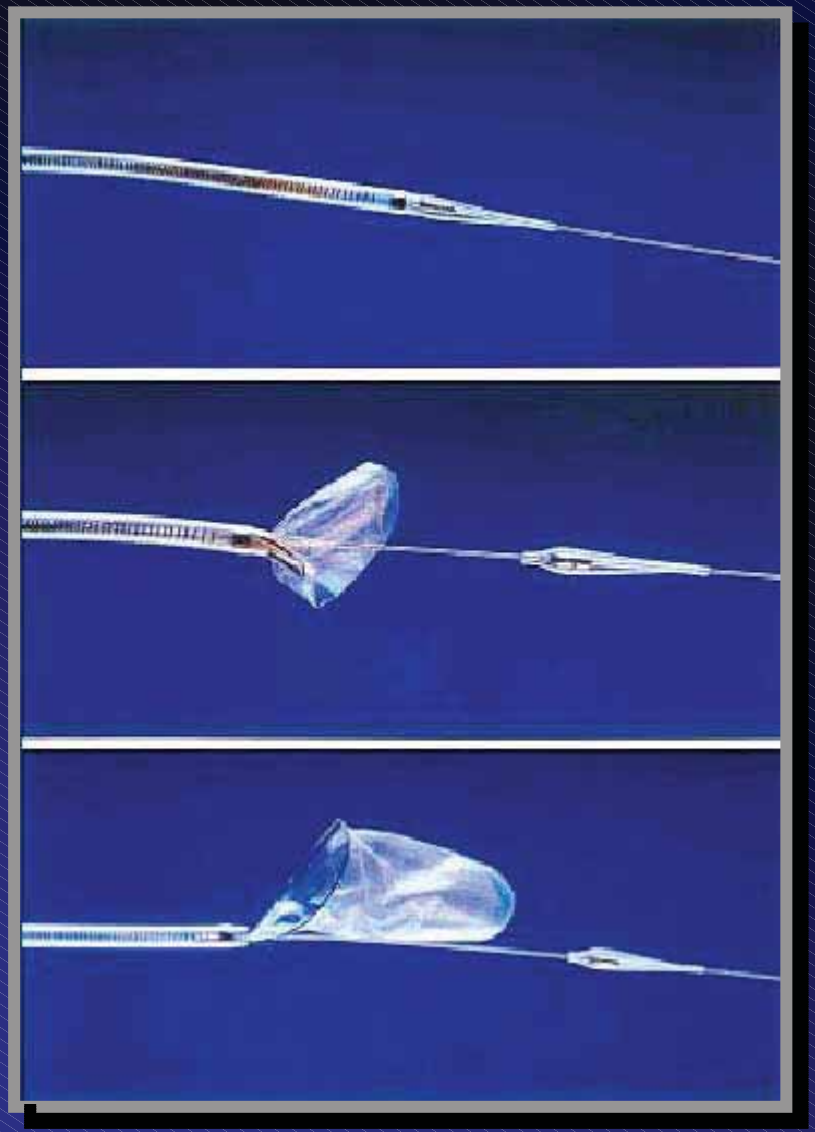


MEDNOVA Gen III Carotid Filter





EPI Filter Wire



1. Closed

2. Partially Deployed

3. Fully Deployed

Strength and Weakness
Distal Filter

- ***Strength***
  - Intuitive
  - Preserves ICA flow
- ***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)

Filter Protection

"The Pore size dilemma"

- ***Small pores***
  - ↑ Risk of fibrin deposition and thrombosis
  - ↓ Flow
- ***Large pores***
  - ↑ Risk of embolization

Definition of Stroke

Minor Stroke

an sudden onset nondisabled arterio-occlusive brain infarction, persist ≥ 24 h

Major stroke

an sudden onset arterio-occlusive brain infarction, NIHSS ≥ 9 and persist ≥ 30 days

Carotid Stenting with Filter Wire

Multicenter Prospective

- Carotid stenting with Neuroshield Filter
- Number = 162 pts, 164 hemispheres
- Angiographic success = 162 (99%) lesions
- Successful filter retrieval = 154 (94%) proc
- No device failure after deployment
- 30 day stroke and death rate = 2.5%
- Major stroke = 0%
- Minor stroke = 1%
- 30 day mortality = 1.5% (1 bleed, 1 arrhythmia)

Al-Mubarak et al, JACC 2002;39:841-6

Carotid Stenting with Filter Wire

Multicenter Prospective

- Carotid stenting with 3 filters (Angioguard, NeuroShiled, and FilterWire)
- Number = 84, 88 hemispheres
- Angiographic success = 86 (97.7%) lesions
- Crossing failure = 3 (3.5%) lesions
- Successful filter retrieval = 92.6% proc
- No device failure after deployment
- Major stroke = 0%
- Minor stroke = 1 (1.2%) patient

Reimer B et al, Circ 2001;104:12-5

Fundamental Issues Related to Distal Protection
(Balloon and Filters)

- Unprotected during initial passage
- Need to re-cross PTA site,
  if predilation is needed
- Distal end of the wire attached to the ICA
- Not as flexible and low profile as a standard wire

Problems Encountered with Cerebral Protection Devices
(Balloon and Filters)

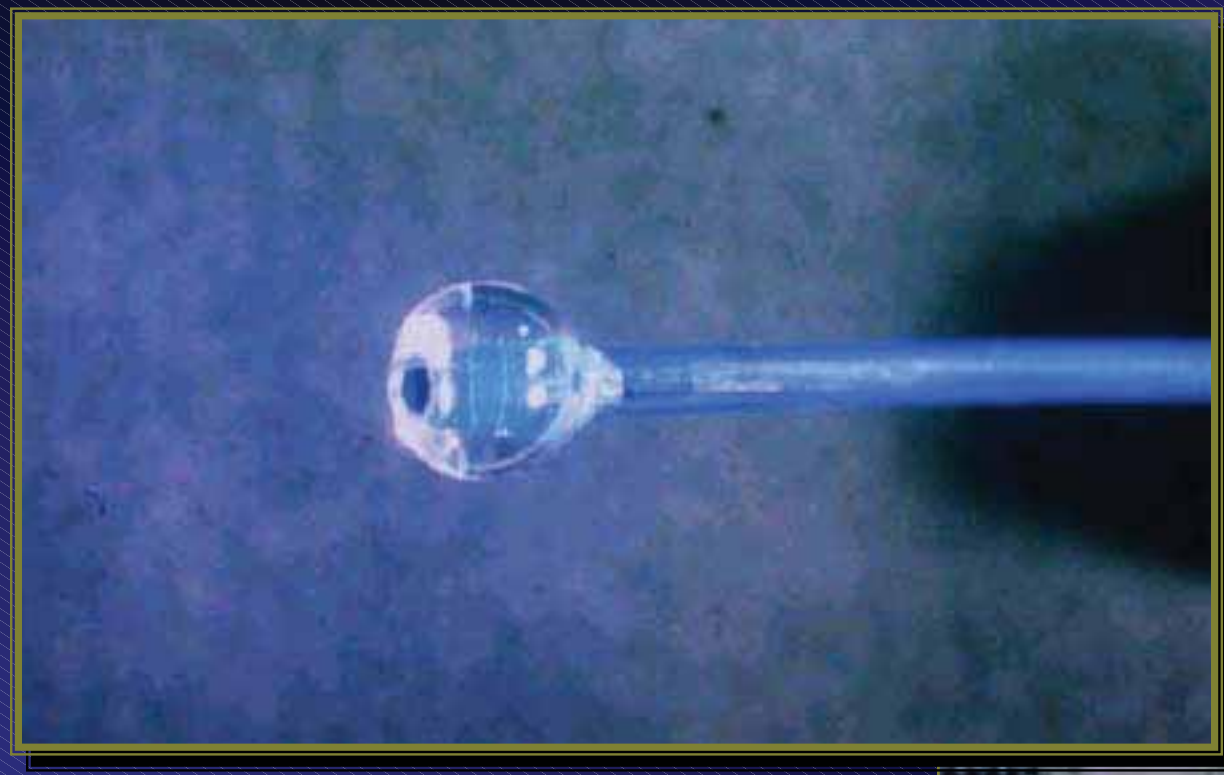
- 128 CAS under cerebral protection
- PercuSurge, AngioGuard, EPI, MedNova

- Uncomplicated filter deployment	73%
- Need for predilatation	27%
- Problems with retrieval	7%
- New ischemic lesions (DW-MRI)	7%

K. Mathias et al, presented at ESVS 2001

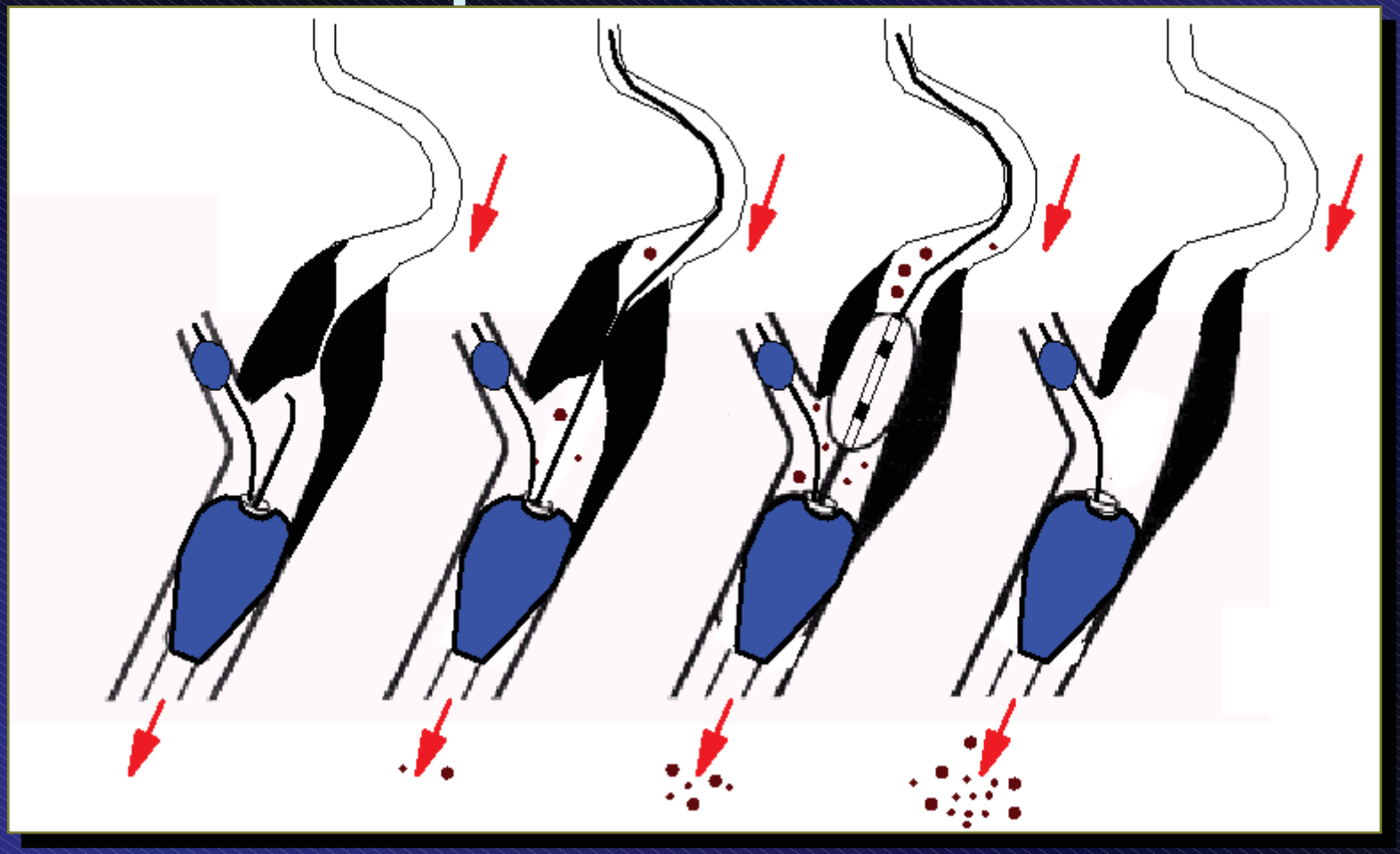
Proximal Occlusion

ArteriA Parodi Anti-embolization System



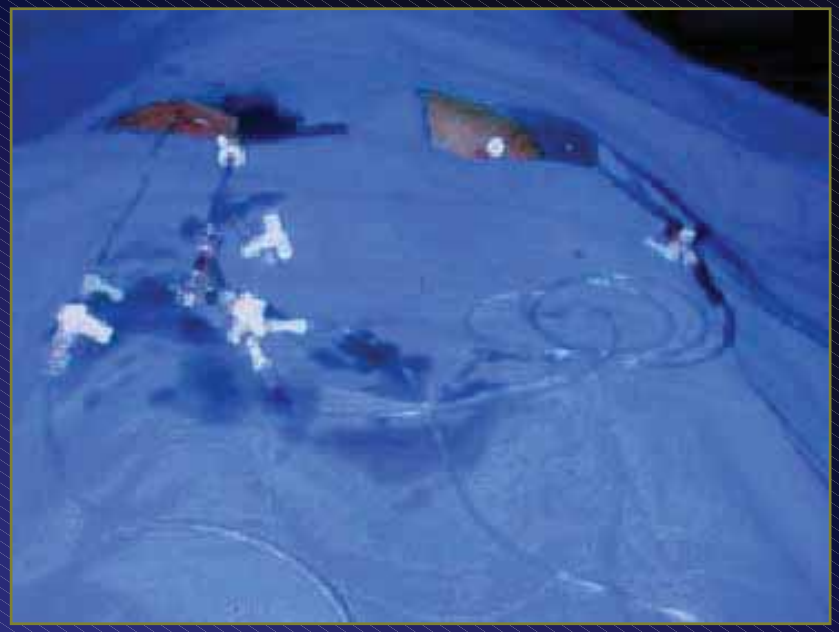
ArteriA Parodi Anti-embolization System

Complete Protection

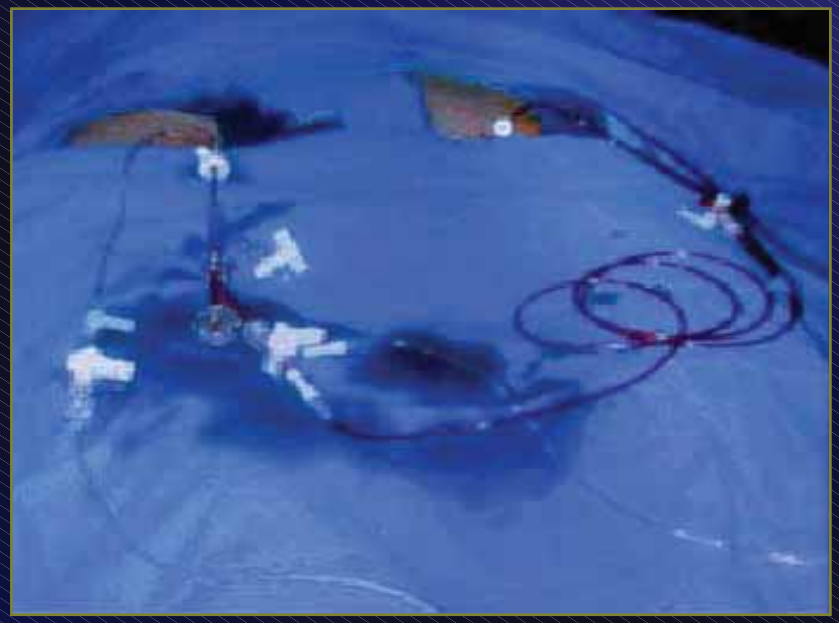


PAEC Reversal of Flow

Femoral Artery-Venous Shunt



Shunt closed



Shunt open

Strength and Weakness

Proximal occlusion + Reversal of flow

- ***Strength***
  - Complete protection (chronologically, size)
  - Able to use guidewire of choice
  - Advantageous in tight, tortuous lesions
  - Can be combined with filters
- ***Weakness***
  - Does not preserve ICA & ECA flow
  - Larger puncture site hole (10 Fr)
  - May cause spasm/dissection in CCA
  - Counter-intuitive

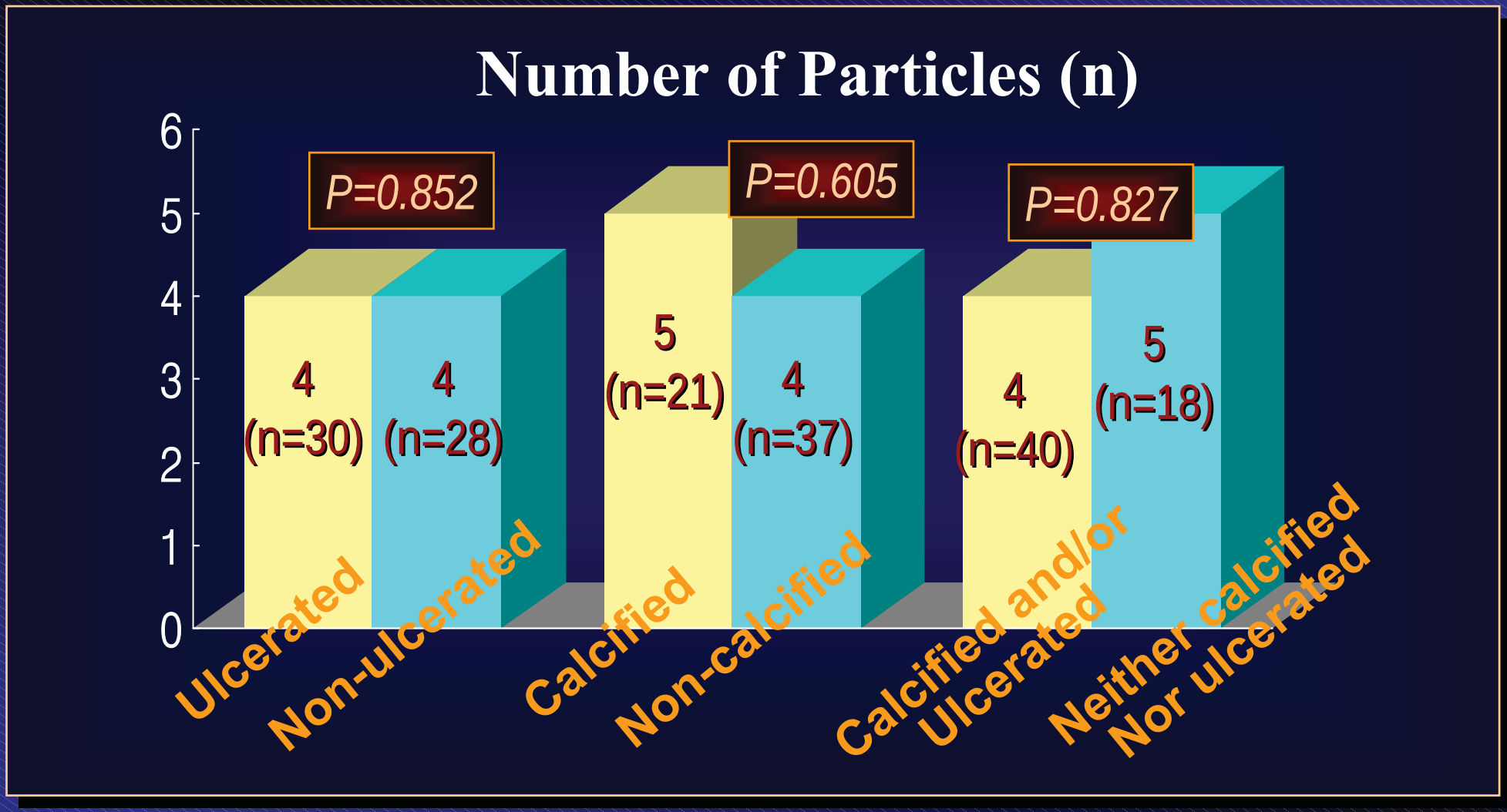
Embolic Protection Trials

30-day outcomes	N	Minor Stroke	Major Stroke	Overall Stroke	Stroke Death	Overall Death	Total
Theron, 1996	93	?	?	2 (2%)	0 (0%)	0 (0%)	2 (2%)
Jaeger, 2001	20	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0(0%)	0(0%)
Tubular, 2001	58	1 (2%)	1 (2%)	2 (4%)	0 (0%)	0 (0%)	2 (4%)
Al-Mubarak, 2002	164	2 (1%)	0 (0%)	2 (1%)	1 (0.6%)	2 (1%)	4 (2%)
Reimers, 2001	86	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Guimaraens, 2002	194	?	?	2 (1%)	?	3 (2%)	5 (3%)
Angelini, 2002	38	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.8%)	1 (2.8%)

Characteristics of Retrieved Particles

Using PercuSurge

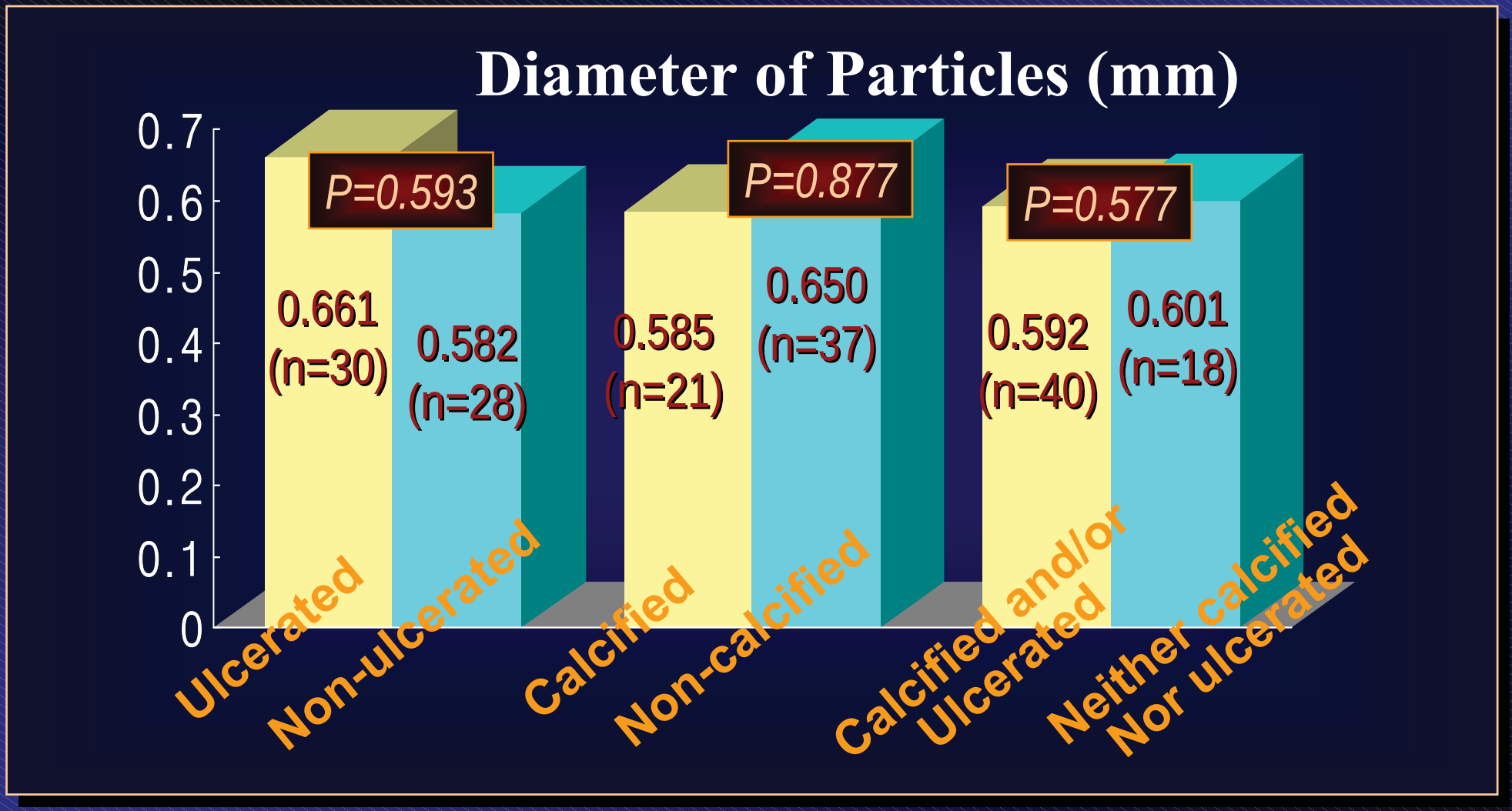
Particle Character by Lesion Chracter



Tubler T et al, Cir 2001;104:2791-6

Using PercuSurge

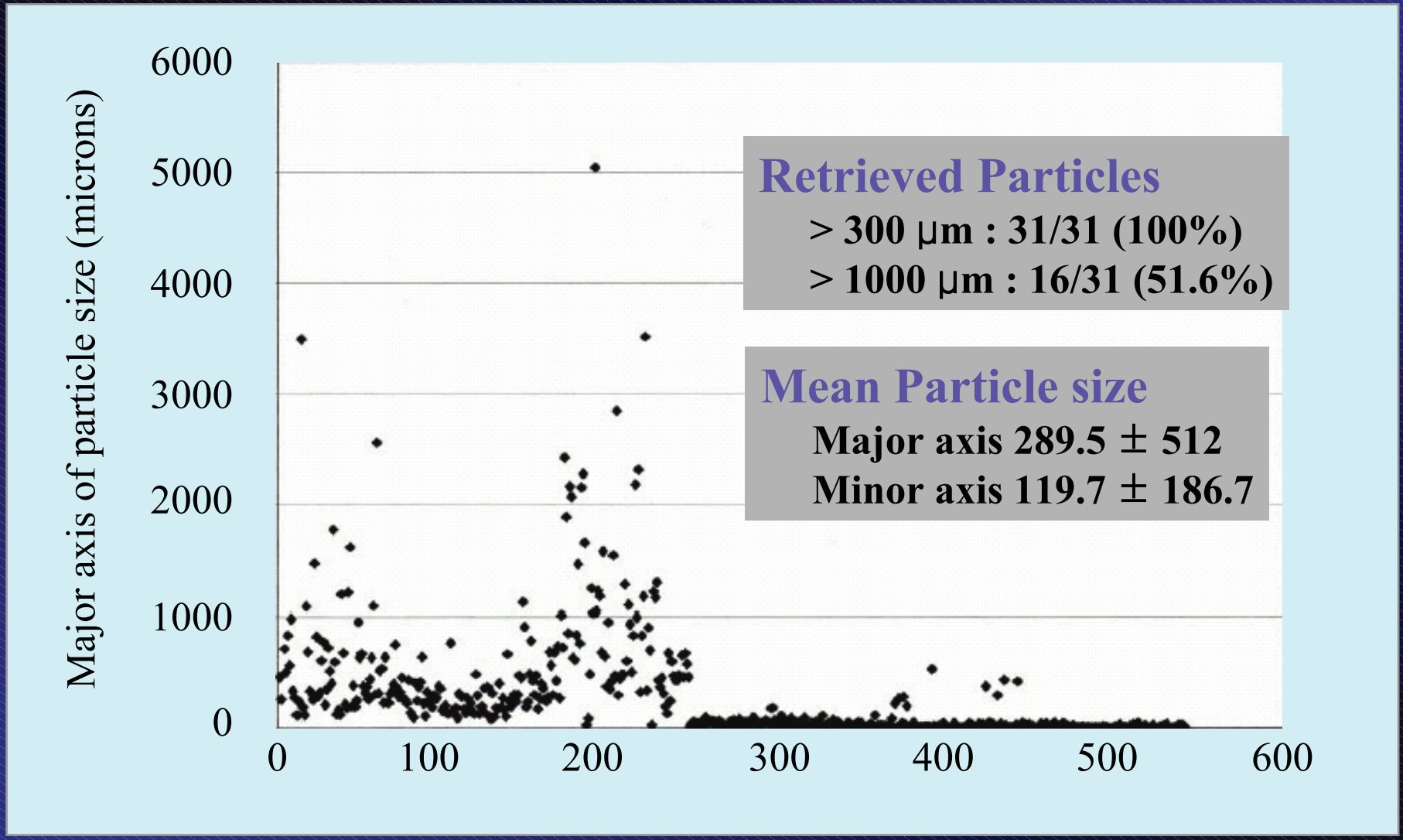
Particle Character by Lesion Chracter



Tubler T et al, Cir 2001;104:2791-6

Using filter device

Number and Size of Particles



Angelini A et al, Cir 2002;33:456-61