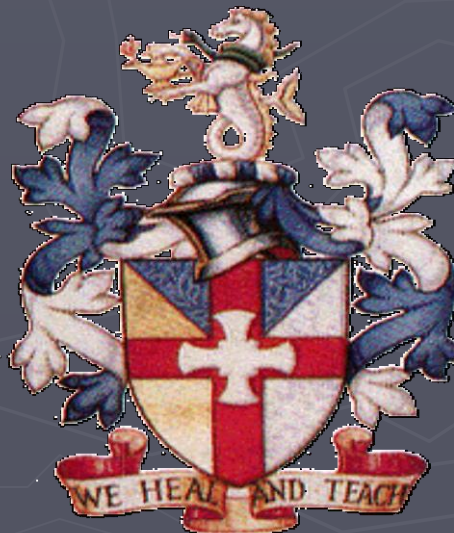


# New Devices & Techniques In Carotid Artery Stenting: *Clinically Meaningful ?*

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# Disclosures:

## Research / Educational Grants & / or consultancy:

Abbott Vascular

CR Bard

Biotronik

Bridgepoint / EPS vascular

Cordis (J & J)

COOK

Ev3/Covidien

Medtronic / Invatec

Merit Medical

**Silk Road Medical**

St Jude/AGA

Spectranetics

Tryton Medical

Pyramed

Terumo

Vascular Perspectives

Volcano

WL Gore

# Prevailing Limitations Of CAS:

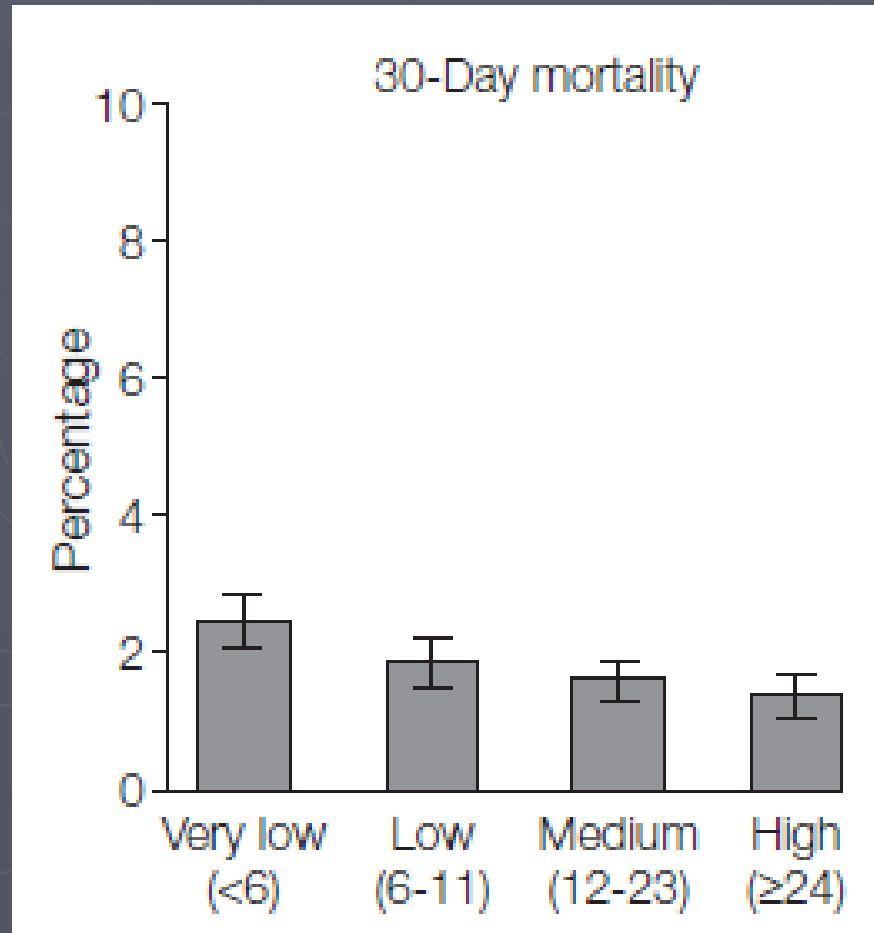
- **Real world outcomes**
- **Excess minor stroke** risk cf. CEA  
(may be age dependent)
- "**Day Zero**" Strokes for CAS cf. CEA
- "**Off table**" to **30-day strokes**
- **Excess DWMRI lesions** of brain cf. CEA  
(may be age dependent)
- **Anatomic constraints** (largely "access"  
related & ? influenced by operator experience)

# “ Real World ” CAS Outcomes:



# Operator Experience and Carotid Stenting Outcomes in Medicare Beneficiaries

N = 24,701

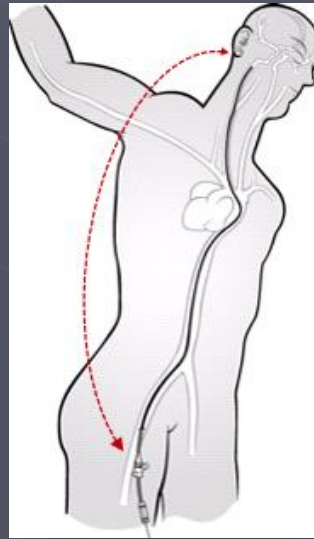


*Nallamothu BK et al JAMA 2011;28:1338-1343*

# Excess Minor Stroke:



# CREST: Transfemoral Filter-Protected CAS



Major Unmet Needs	CEA	CAS	p
CREST Peri-procedural Stroke <sup>1</sup>	2.3%	4.1%	0.01

# Short-term outcome after stenting versus endarterectomy for symptomatic carotid stenosis: a preplanned meta-analysis of individual patient data

## *Carotid Stenting Trialists' Collaboration*

	CAS (n=1725)	CEA (n=1708)	Risk ratio* (95% CI)	p value†	Risk difference* (95% CI)
Any stroke or death	153 (8.9%)	99 (5.8%)	1.53 (1.20 to 1.95)	0.0006	3.2 (1.4 to 4.9)
Disabling stroke or death	82 (4.8%)	64 (3.7%)	1.27 (0.92 to 1.74)	0.15	0.9 (-0.4 to 2.3)
All-cause death	32 (1.9%)	22 (1.3%)	1.44 (0.84 to 2.47)	0.18	0.7 (-0.2 to 1.5)
Any stroke	141 (8.2%)	84 (4.9%)	1.66 (1.28 to 2.15)	0.0001	3.3 (1.7 to 5.0)
Stroke severity‡					
Fatal	13 (0.8%)	6 (0.4%)	2.15 (0.82 to 5.65)	0.11	0.4 (-0.1 to 0.9)
Disabling	56 (3.2%)	43 (2.5%)	1.29 (0.87 to 1.90)	0.21	0.5 (-0.5 to 1.6)
Non-disabling	72 (4.2%)	36 (2.1%)	1.99 (1.34 to 2.95)	0.0004	2.0 (0.8 to 3.2)
Stroke type§					
Ischaemic	135 (7.8%)	71 (4.2%)	1.88 (1.42 to 2.48)	<0.0001	3.8 (2.2 to 5.4)
Haemorrhagic	6 (0.3%)	11 (0.6%)	0.54 (0.20 to 1.46)	0.21	-0.3 (-0.8 to 0.1)
Unknown	0	2 (0.1%)	..	..	..
Stroke region¶					
Ipsilateral carotid	126 (7.3%)	75 (4.4%)	1.66 (1.26 to 2.19)	0.0003	3.0 (1.4 to 4.5)
Contralateral carotid or vertebrobasilar	13 (0.8%)	9 (0.5%)	1.43 (0.61 to 3.34)	0.40	0.2 (-0.3 to 0.8)
Unknown	2 (0.1%)	0	..	..	..



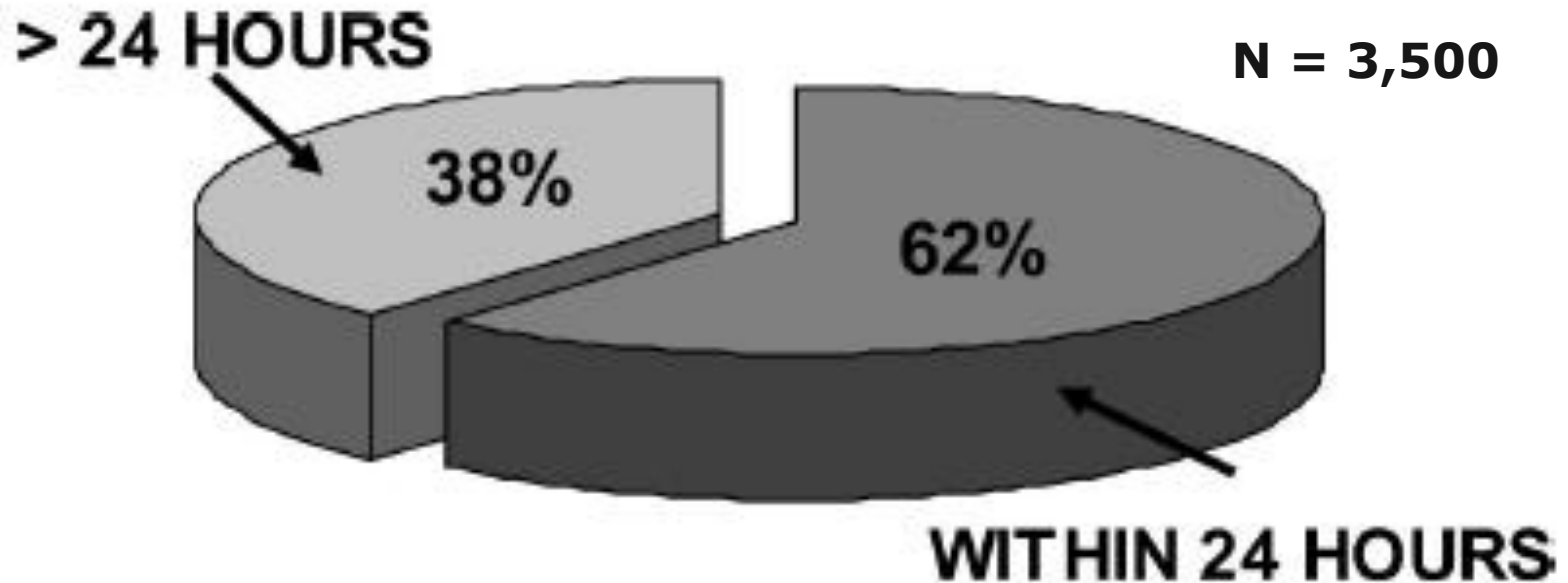
# **The Timing of Strokes & Their Proposed Aetiology:**

## **Day Zero Strokes:**



## The CAPTURE Registry

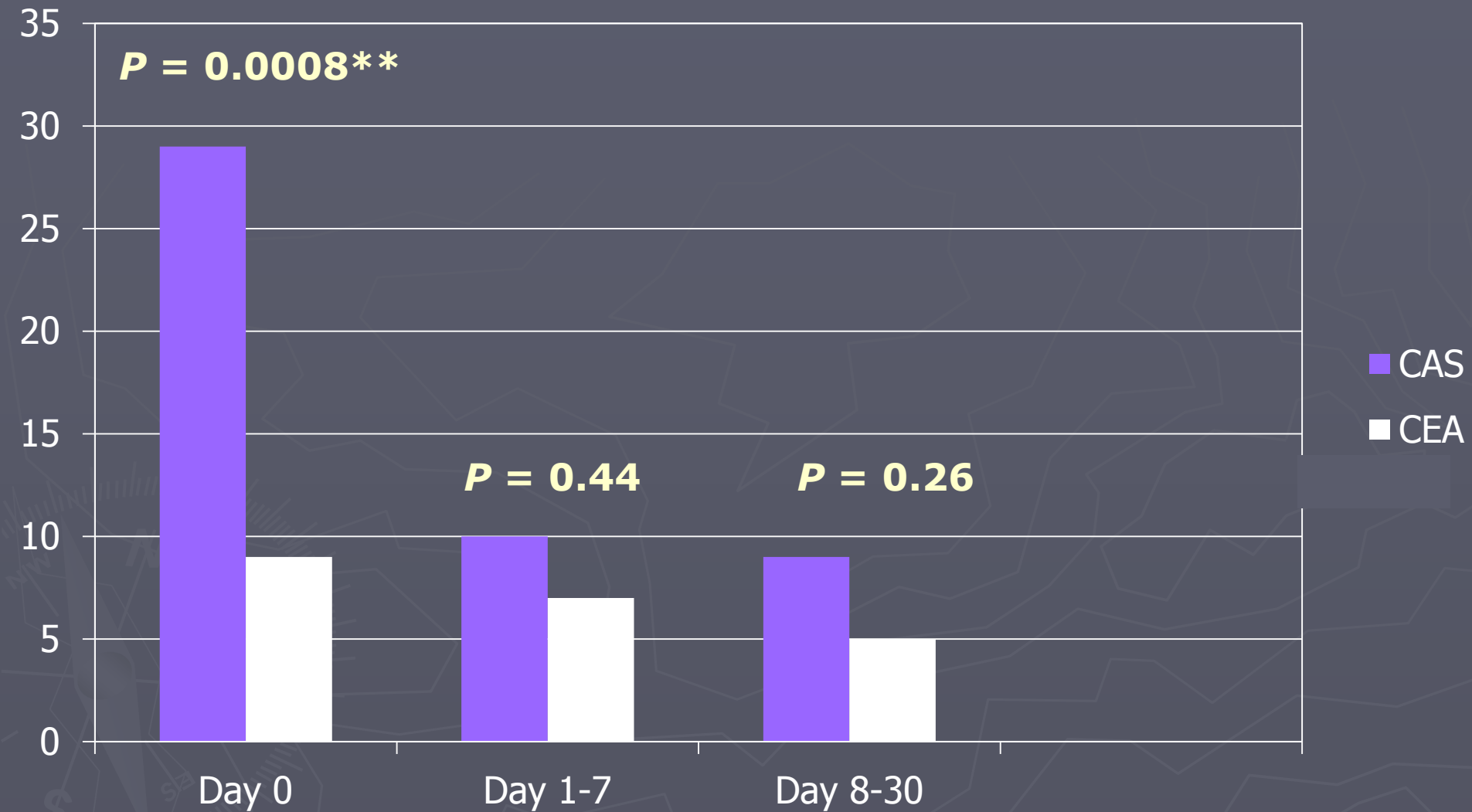
*Analysis of Strokes Resulting From Carotid Artery Stenting in the Post Approval Setting: Timing, Location, Severity, and Type*



\* n= 168 patients; 2 patients each had two strokes

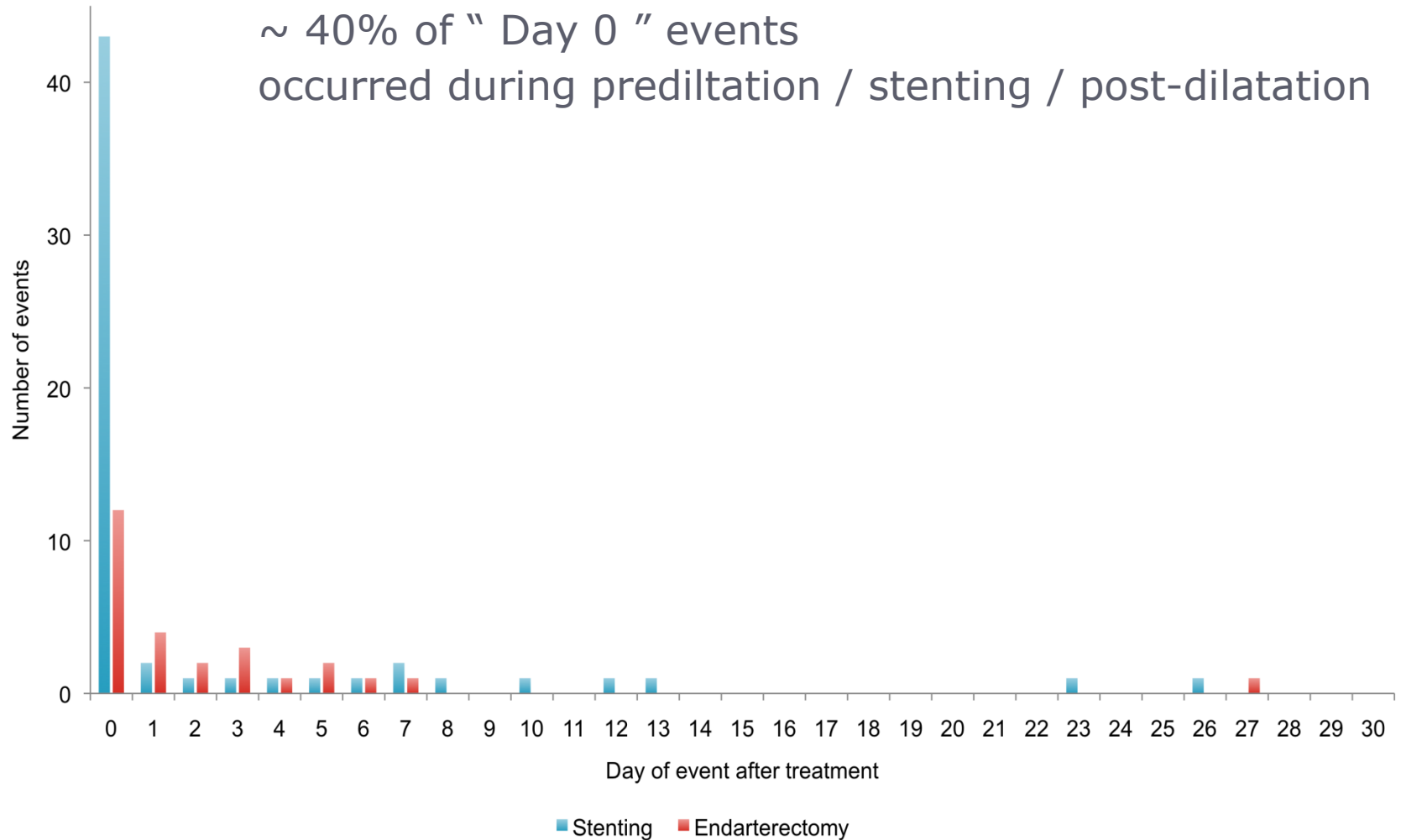
Stroke timing.

# "Day Zero" Strokes In CREST:



\*\* p value for CREST only

# ICSS: Timing of first stroke after allocated procedure

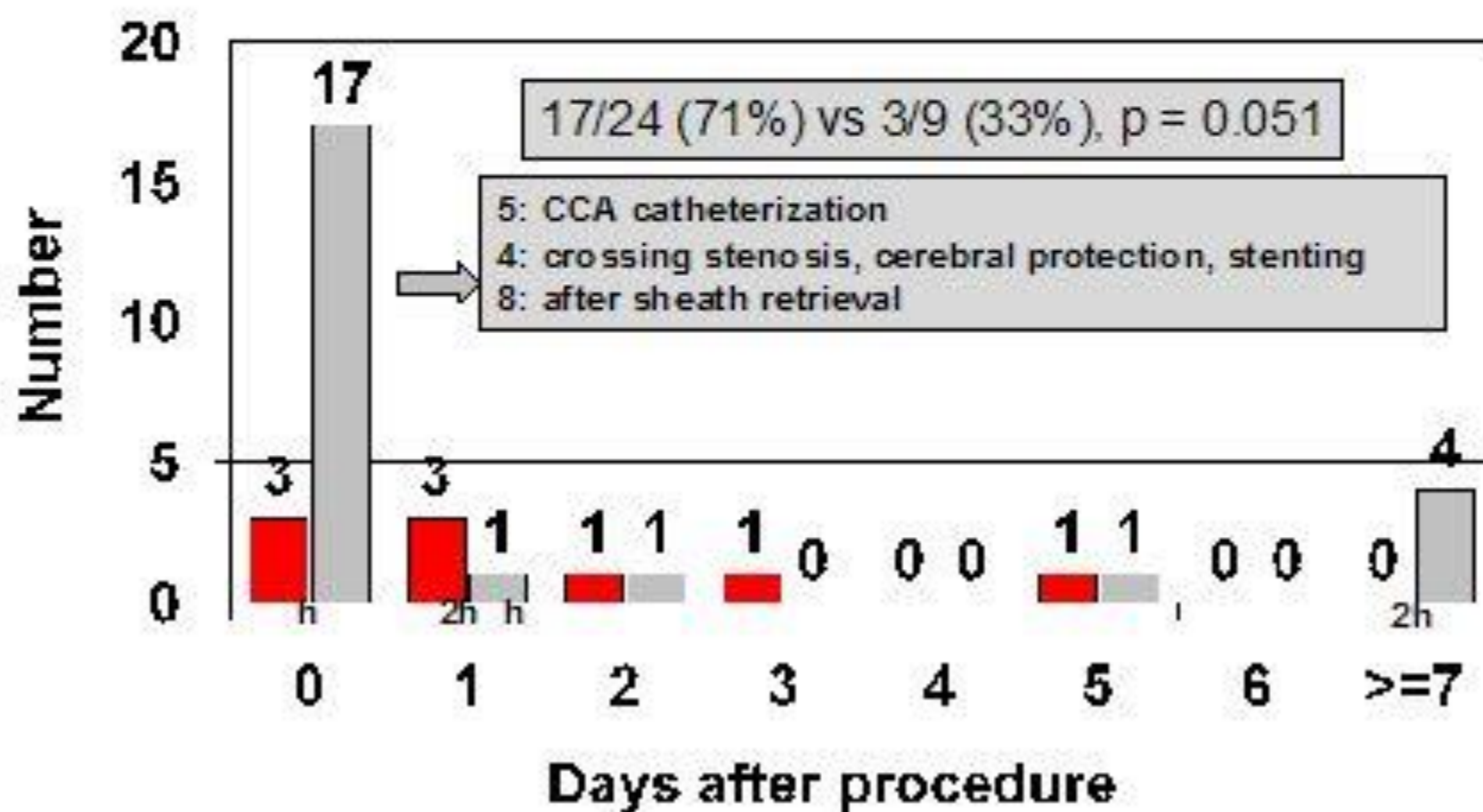




# EVA-3S : timing of procedural stroke

■ CEA

■ CAS



# The Arch Is A Hostile Territory:

The incidence of microemboli to the brain is less with endarterectomy than with percutaneous revascularization with distal filters or flow reversal

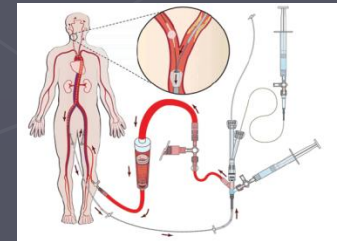
Procedure	N	Incidence MES	Procedural Stage
CEA	15	15.3 (+/- 22)	Post procedure
Filter protected CAS	20	319.3 (+/- 110.3)	During protection
Flow reversal CAS	7	184.2 (+/- 110.5)	Pre protection

*CEA vs filter  $p = 0.001$*

*CEA vs flow reversal  $p = 0.007$*

*Flow reversal vs filter  $p = 0.053$*

**N = 42**



# Assessment of Reverse Flow as a Means of Cerebral Protection during Carotid Artery Stent Placement with Diffusion-weighted and Transcranial Doppler Imaging

Finding	Reverse Flow (n = 15)	Filter-protected (n = 15)
DWI scans in 24 h	29	24
Positive DWI scans (%)	17.2	29.0
Lesions on DWI	6	14
Total lesions (%)		
Ipsilateral ACA/MCA distal to stent	4/6 (67)	12/14 (86)
Ipsilateral PCA and contralateral ACA/MCA or PCA territories	2/6 (33)	2/14 (14)

**Non-target territory embolization implies embolic burden of the arch & great vessel origins from a transfemoral approach with a 9F sheath**

Stephen D. Goode, MRCS, FRCR, PhD, Nigel Hoggard, MD, MRCP, FRCR, Sumaira Macdonald, FRCR, PhD, David H. Evans, PhD, DSc, Trevor J. Cleveland, FRCS, FRCR, and Peter A. Gaines, FRCP, FRCR

# Anatomic Constraints:





# Complex CAS Anatomy: Dictated By Arch Type:

**Green**



Left ICA score < 4.9

**Amber**



Left ICA score 5.0-5.9

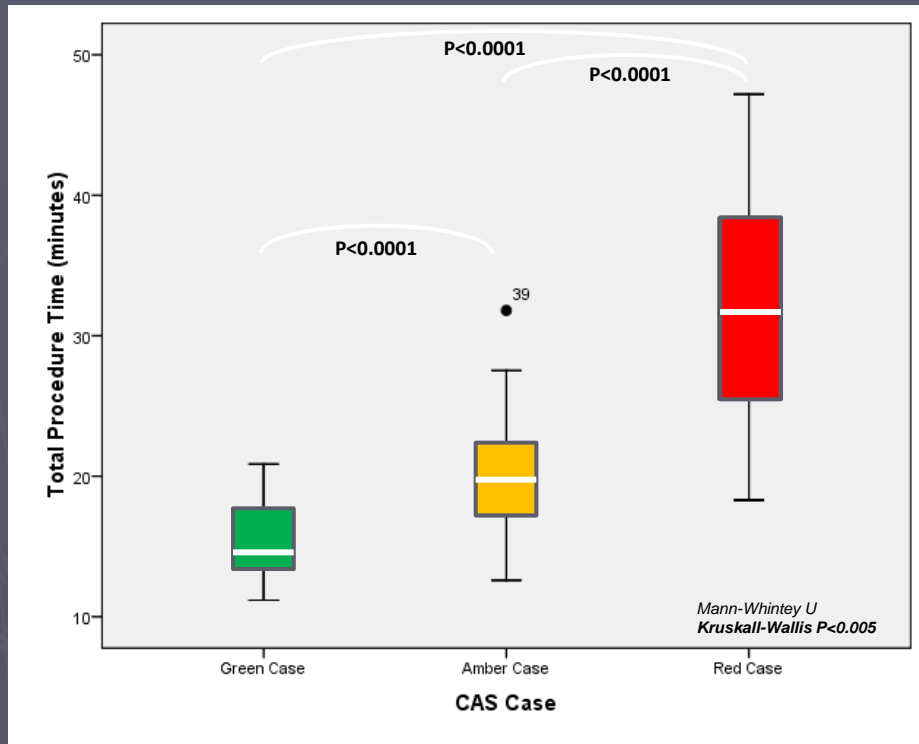
**Red**



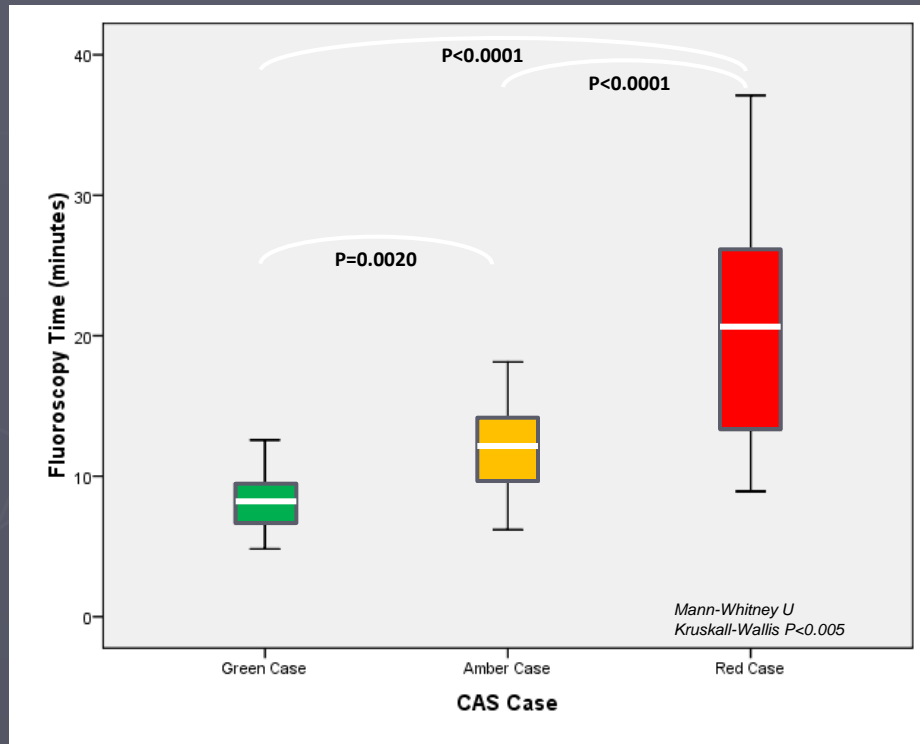
Right ICA score > 7.0

	Normal aortic		B.C.A. position		Abnormal C.C.A.			Normal aortic		B.C.A. position		Abnormal C.C.A.		
	Normal target vessel	Abnormal distal B.C.A.	Normal target vessel	Abnormal distal B.C.A.	Normal target vessel	Abnormal distal B.C.A.		Normal target vessel	Abnormal distal B.C.A.	Normal target vessel	Abnormal distal B.C.A.	Normal target vessel	Abnormal distal B.C.A.	
Head/neck	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Stroke	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pickhale	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Stroke	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Head/neck	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Stroke	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pickhale	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Stroke	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Head/neck	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Stroke	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pickhale	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Stroke	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

# Total Procedure Time (mins)



# Fluoroscopy Time (mins)



**Red case: 10/20 > 15 minutes to cannulate CCA**  
**Amber case: 2/20**  
**Green case: 0/20**

# **The Timing of Strokes & Their Proposed Aetiology:**

## **≤ 30-Day Strokes:**



# Delayed Stroke & Death At 1-30 Days Especially with Open Cell Stents

	Total population		
	Patients	All events	Post-procedural events
Open cell	937	39	32
Closed cell	2242	51	29
Total	3179	90	61
Cell type			
Open cell		4.2%	3.4%
Closed cell		2.3%	1.3%
Total	3179	2.83%	1.9%

2/3 of events delayed

# Increased Neurologic Events With Open Cell Stents

## SPACE Trial

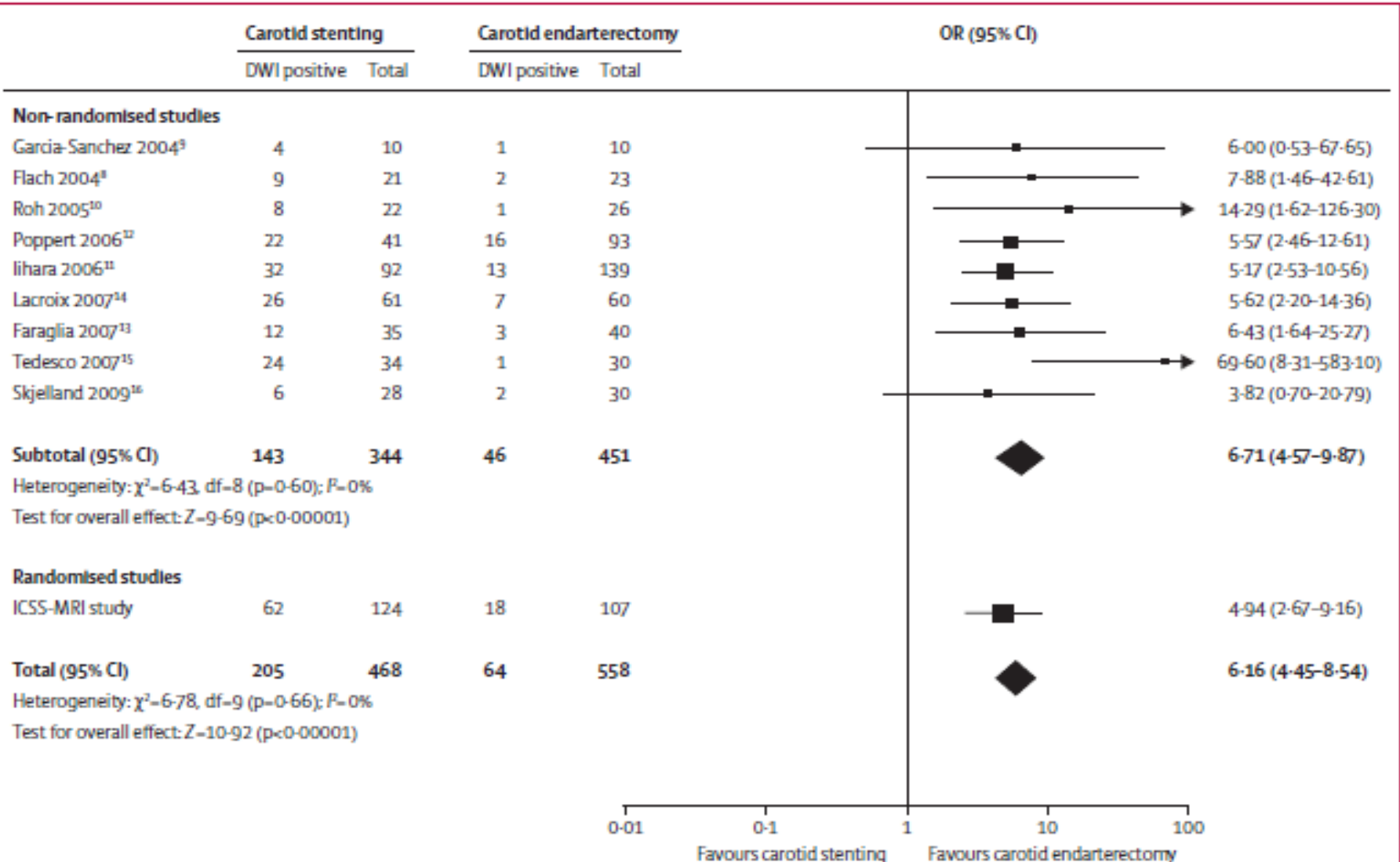
**Table 4. Influence of Different Stent Types on OE Rate**

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%)			

# Excess DWMRI Lesions:



# Meta-Analysis Comparing DWMRI Lesions After CEA & CAS



# ICSS Primary Analysis CEA Vs. CAS in 1713 symptomatic patients

**ICSS Substudy: N = 231**

## New white lesions on DWI

62 of 124 (50%) transfemoral distal filter CAS

18 of 107 (17%) **CEA**

(OR 5.21, 2.78-9.79;  $p < 0.0001$ )



# ICSS Substudy: N = 231

## Recurrent stroke OR TIA (5 year cumulative)

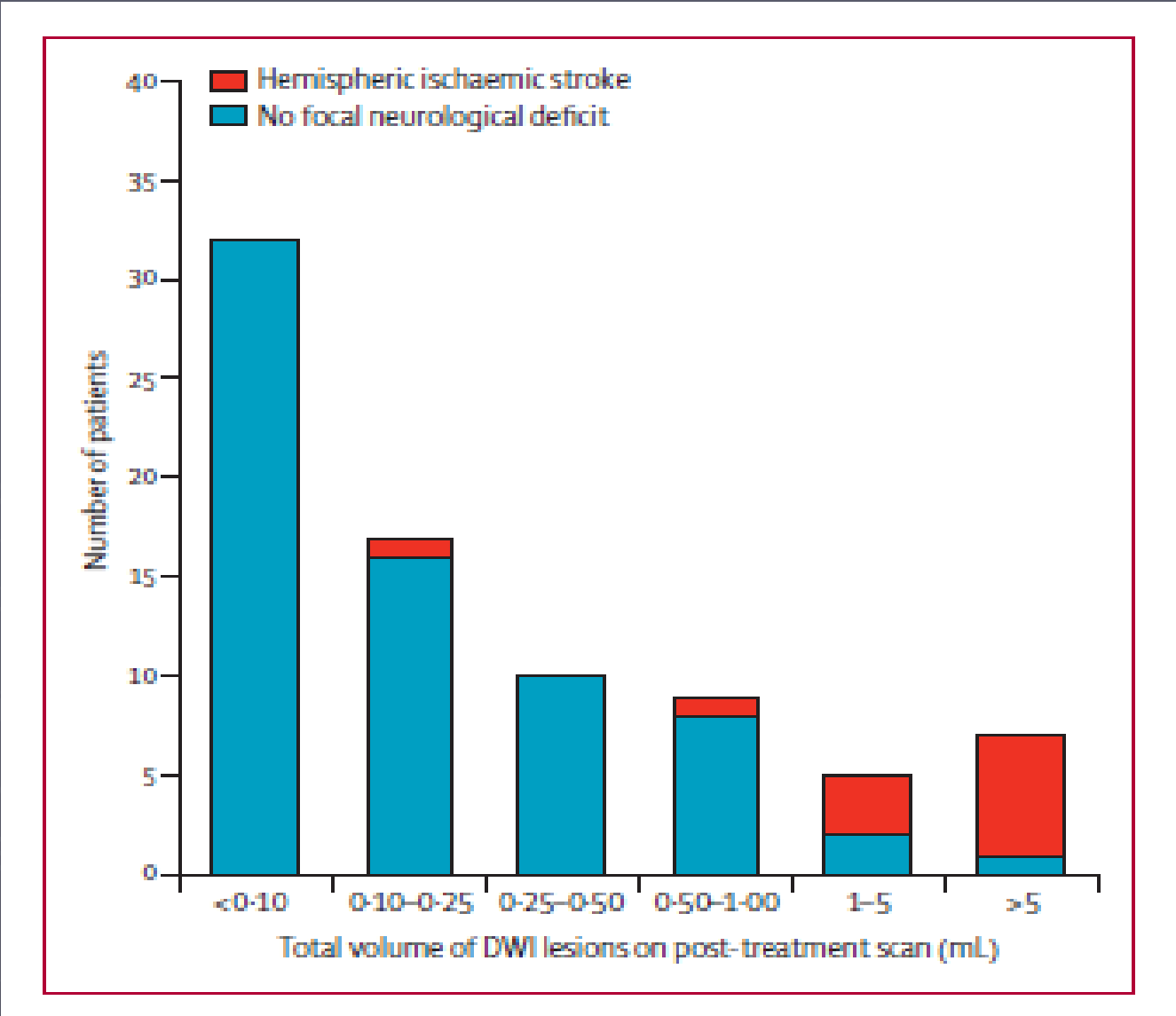
### CAS:

DWMRI +ve: 12/62

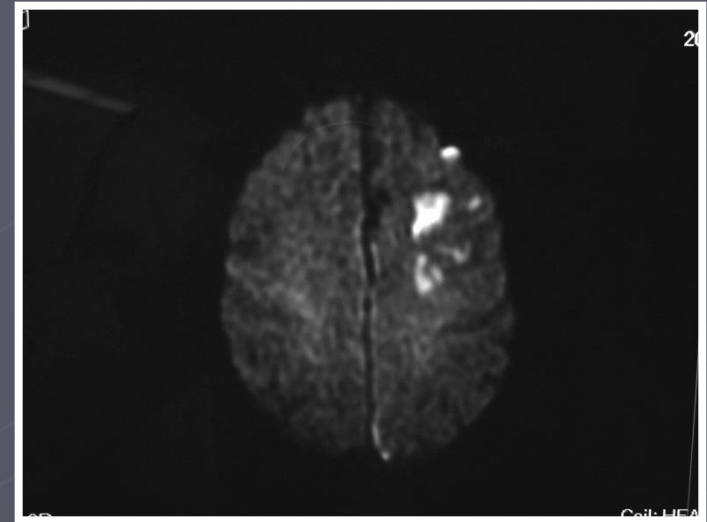
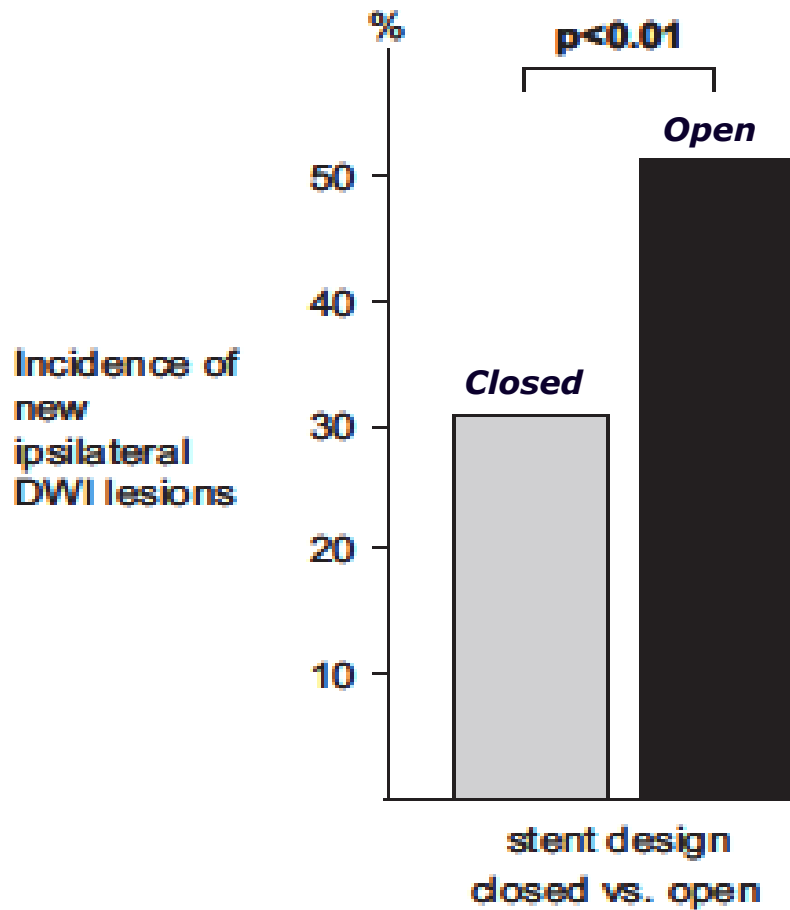
DWMRI -ve: 6/62

} 22.8% vs. 8.8% (p=0.04)  
HR 2.85 (1.05-7.720)

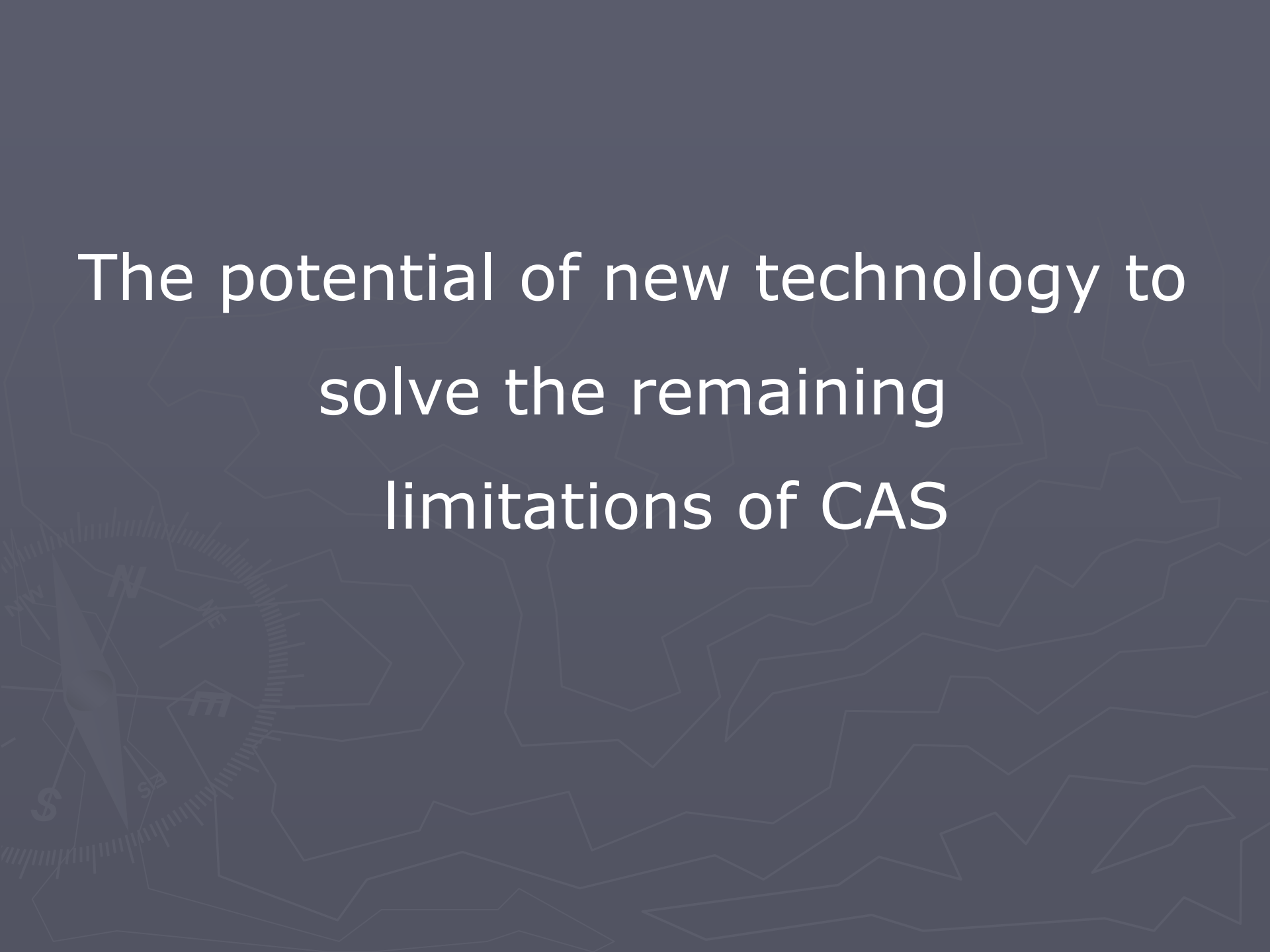
# Association of DWMRI Lesion Volumes & Neurological Events



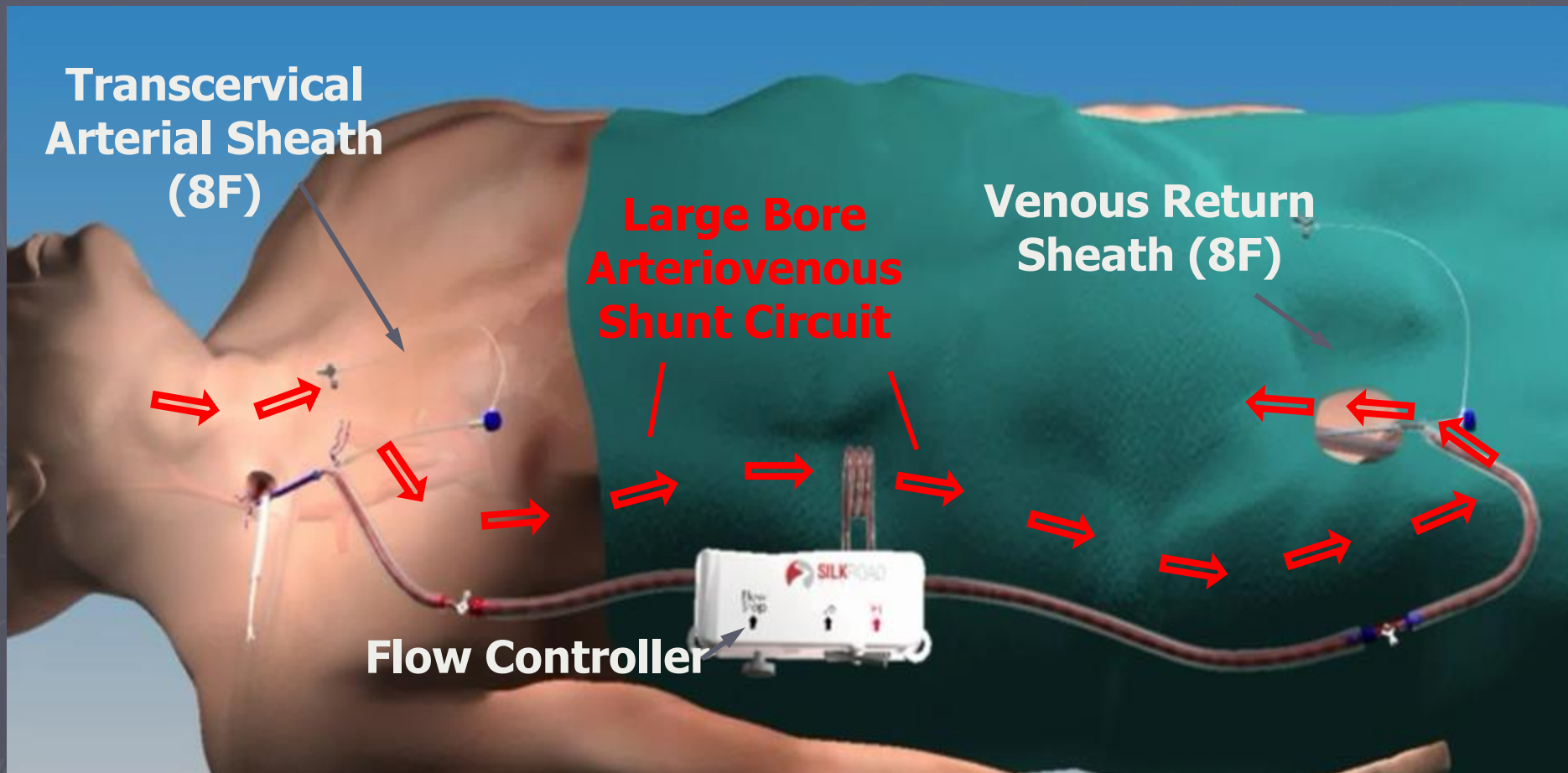
# New Brain Lesions After Carotid Stenting Versus Carotid Endarterectomy: A Systematic Review of the Literature



The potential of new technology to  
solve the remaining  
limitations of CAS

The background of the slide is a dark blue-grey color. On the left side, there is a faint, light-colored graphic of a compass rose with a needle pointing towards the top-left. The compass rose is overlaid on a topographic map, which consists of several concentric, irregular lines representing contour lines or terrain elevation. The overall aesthetic is technical and modern.

# MICHI™ Neuroprotection System



# PROOF: FIRST IN MAN

## DWI SUBSTUDY

- Baseline scan within 72 hours
- Post-procedure scan within 12-48 hours
- Submitted to core laboratory for blinded evaluation by two independent neuroradiologists

Parameter	Value (n=56)
Subjects with new DW-MRI lesion(s)	11 (19.6%)

# **Prospective DWMRI outcomes for various carotid interventional regimes:**



<b>Study</b>	<b>Procedure</b>	<b>Embolic Protection</b>	<b># subjects</b>	<b>% w/ New DWI Lesions</b>
ICSS <sup>1</sup>	Transfemoral CAS	Distal filter (various)	51	73
ICSS <sup>1</sup>	CEA	Clamp, backbleed	107	17
PROFI <sup>2</sup>	Transfemoral CAS	Distal filter (Embosheid)	31	87
Leal <sup>5</sup>	Transfemoral	Distal Filter (FilterWire)	33	33
PROFI <sup>2</sup>	Transfemoral CAS	Proximal occlusion (MoMA)	31	45
DESERVE <sup>4</sup>	Transfemoral CAS	Proximal Occlusion (MoMa)	127	30
PROOF <sup>3</sup>	Transervical CAS	High flow rate flow reversal	48	16.7
Leal <sup>5</sup>	Transervical CAS	Flow Reversal	31	12.9

**1. Lancet Neurol. 2010 Apr;9(4):353-62**  
**2. J Am Coll Cardiol. 2012;59:1383-1389**  
**3. JVS 2011;54:1317-1323**

**4. Rubino P, EuroPCR 2011**  
**5. JVS 2012;56:1585-1590**

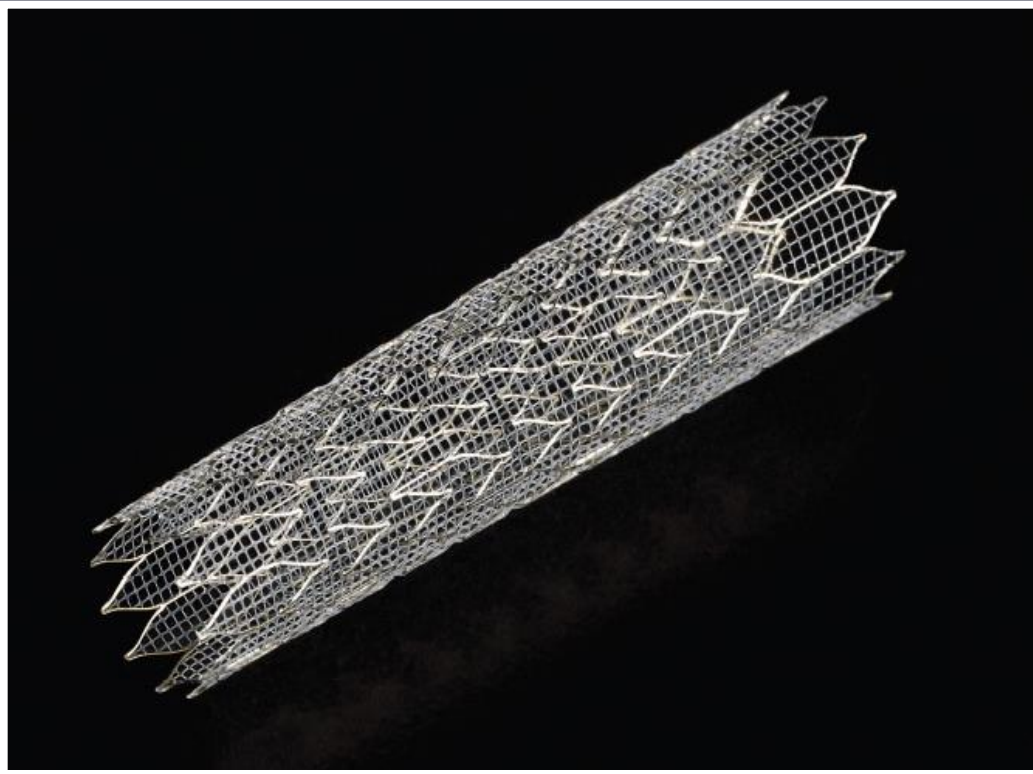


# Prevailing Limitations Of CAS:

- **Real world outcomes**
- **Excess minor stroke** risk cf. CEA  
(may be age dependent)
- "**Day Zero**" Strokes for CAS cf. CEA
- "**Off table**" to **30-day strokes**
- **Excess DWMRI lesions** of brain cf. CEA  
(may be age dependent)
- **Anatomic constraints** (largely "access"  
related & ? influenced by operator experience)

# GORE<sup>®</sup> Carotid Stent

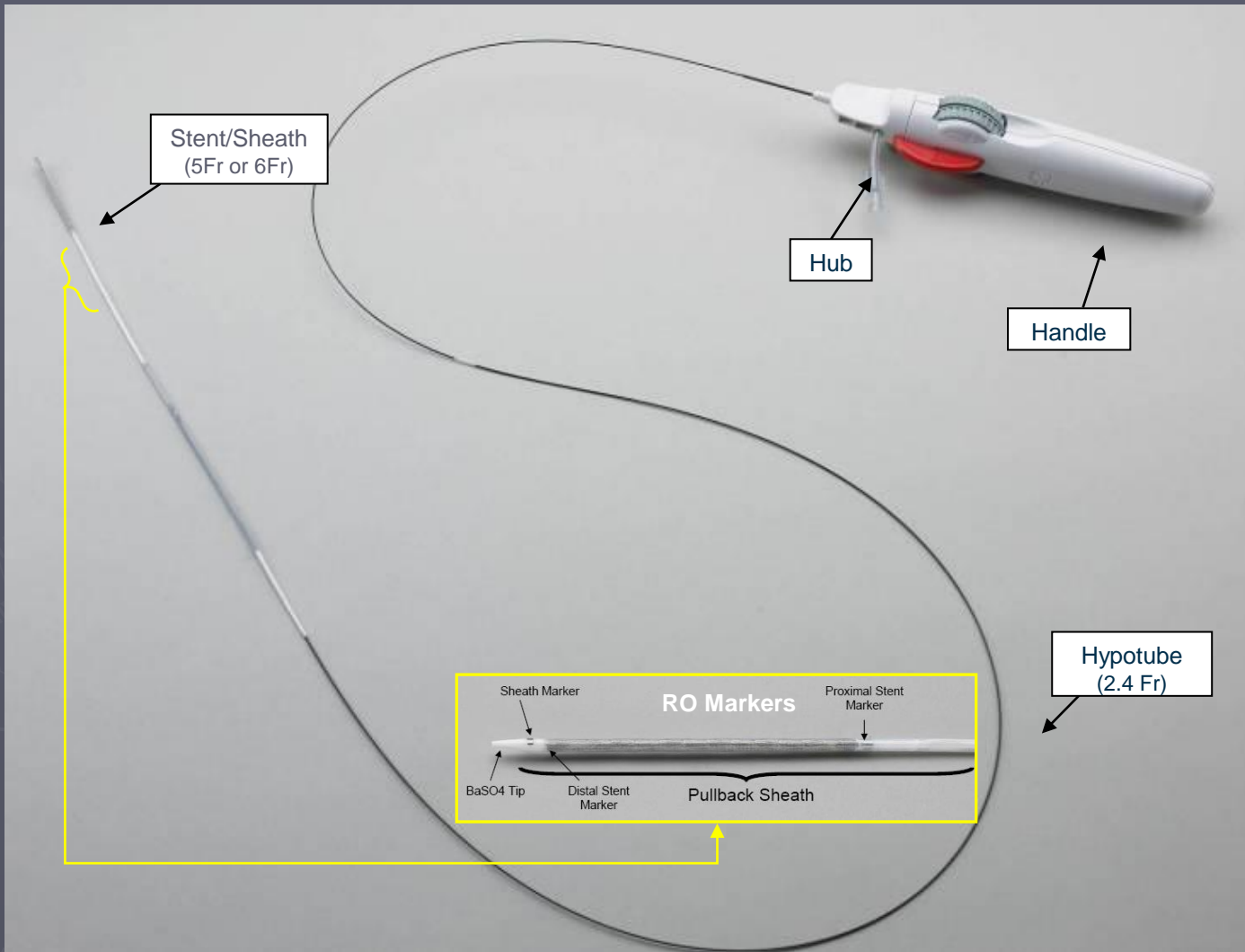
## The Next Generation



- Open cell nitinol frame
- Closed cell 500  $\mu$  lattice on outside of frame
- Permanently bound CBAS heparin on all device surfaces

**\*CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

# Carotid Stent Delivery System



## Attributes

- Single handed delivery
- 5Fr Introducer Sheath Compatible (White Tip)
- 6Fr Introducer Sheath Compatible (Gray Tip)
- Hypotube Design
  - Allows for complete closure of hemostatic valve
- 135 cm Working Length
- 30 cm Rx

**\*CAUTION: Investigational Device. Limited by United States Law to Investigational use only.**

# Prevailing Limitations Of CAS:

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