Searching For The Best Protection

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Disclosures:

Consultancy:

CR Bard

COOK

Medtronic

Pyramed

Terumo

Chief Medical Officer:

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What Does The " Best In Class " Protection Look Like?

Protects at all hazardous *procedural* steps, prior to interaction:

- Catheterization of the arch & great vessel origins
- "Clamp" before lesion interaction
- "Back bleed" throughout
- No distal device which may cause injury beyond the " clamp zone "
- Protects throughout with superior capture efficiency (filters, DWMRI)

Protects against late events:

- Plaque scaffolding: stent design

" The Best Protection Device For The Brain Is A Clamp* "

***Jonanthan Beard, Charing Cross 2010**

ICSS Primary Analysis CEA Vs. CAS in 1713 symptomatic patients

ICSS Substudy: N = 231

New white lesions on DWI

62 of 124 (50%) **transfemoral CAS**

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

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

Lancet Neurol. 2010 Apr;9(4):353-62

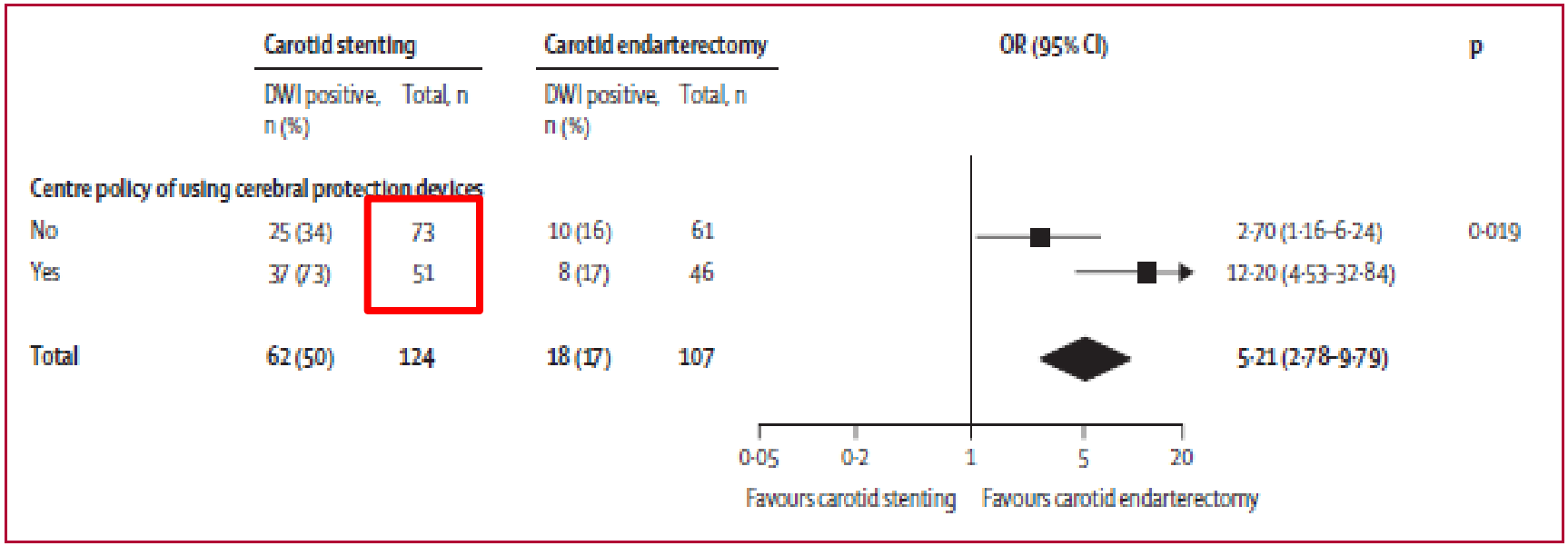
ICSS Substudy: N = 231

New white lesions on DWI

38 of 56 (68%) ***transfemoral filter-protected*** CAS

24 of 68 (35%) unprotected CAS

(OR 3.28, 1.50-7.20; p = 0.003)



	Carotid stenting		Carotid endarterectomy		OR (95% CI)	p
	DWI positive, n (%)	Total, n	DWI positive, n (%)	Total, n		
Centre policy of using cerebral protection devices						
No	25 (34)	73	10 (16)	61	2·70 (1·16–6·24)	0·019
Yes	37 (73)	51	8 (17)	46	12·20 (4·53–32·84)	
Total	62 (50)	124	18 (17)	107	5·21 (2·78–9·79)	

ICSS Substudy: N = 231

Lesion Volumes:

Individual lesion volume significantly smaller for CAS vs. CEA ($p < 0.001$)

Total lesion volume: Not significantly different ($p = 0.18$)

Hensicke G et al Stroke 2013;44: 80 -86

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)

Bonati L et al. European Stroke Congress May 2013

A Comparison of Protection Strategies

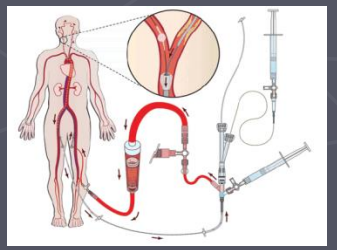
The Arch Is A Hostile Territory:

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

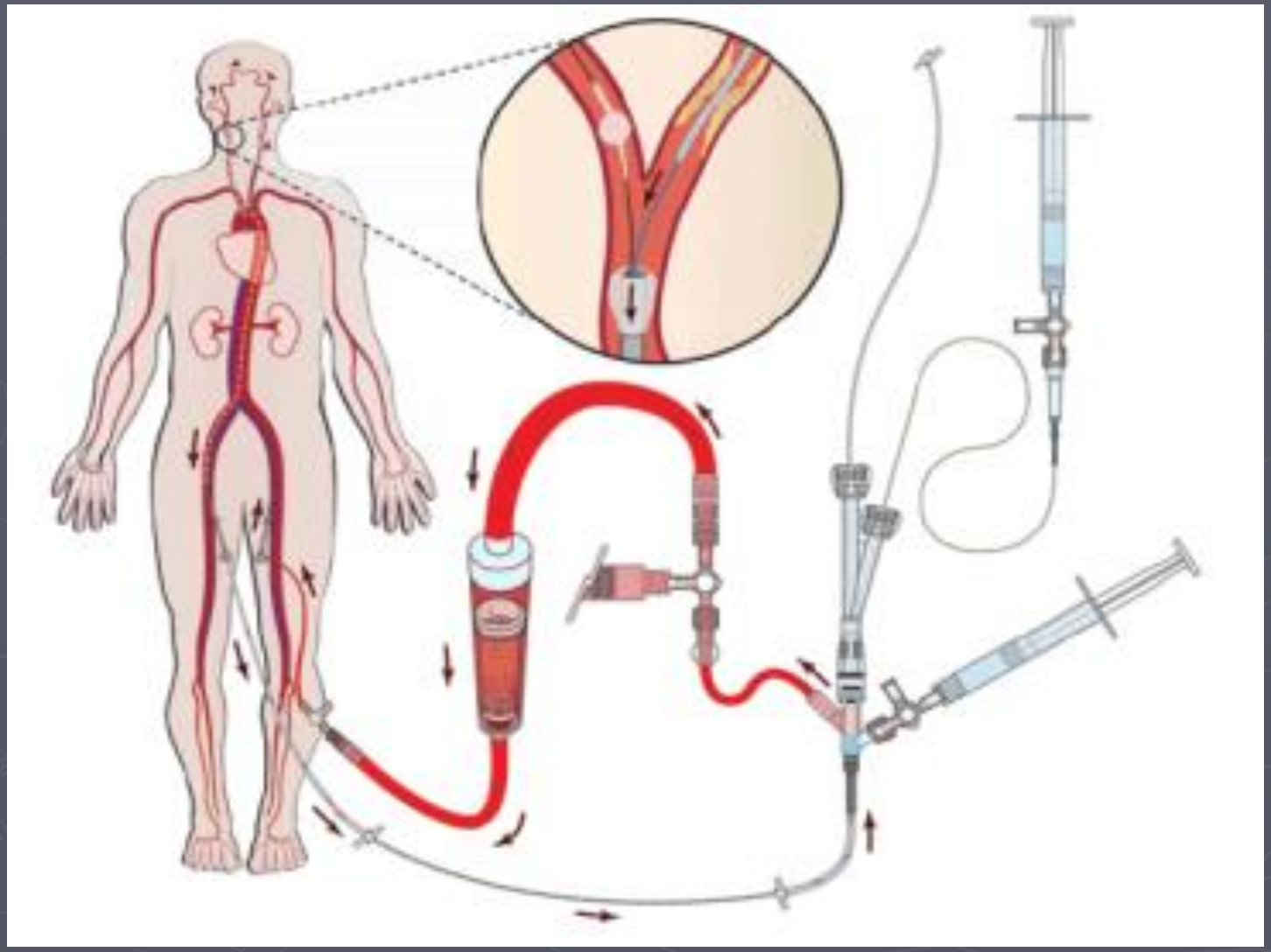
N = 42



Gupta N et al. JVS. 2011;53:316-322

Alternative Protection Strategies Based on " Clamping "

Proximal EPD 1:
GORE Flow Reversal



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

TCD Finding	Reverse Flow (n = 11)	Filter-protected (n = 7)
Total MES	192 ± 201	469 ± 181
P Value*		.01
Embologenic MES‡	46 ± 42	169 ± 110
P Value*	–	.004
* During protection device deployment†	87 ±102	220 ± 71
P Value*	–	.009

From transfemoral access to establishment of protection

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

JVIR; 2013;24:528-533

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

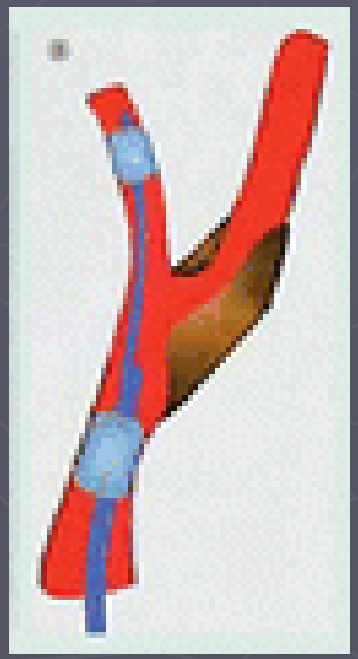
Proximal EPD 2:

DESERVE: DWI study of Mo.Ma transfemoral proximal protection

DESERVE: N = 127

New white lesions on DWI

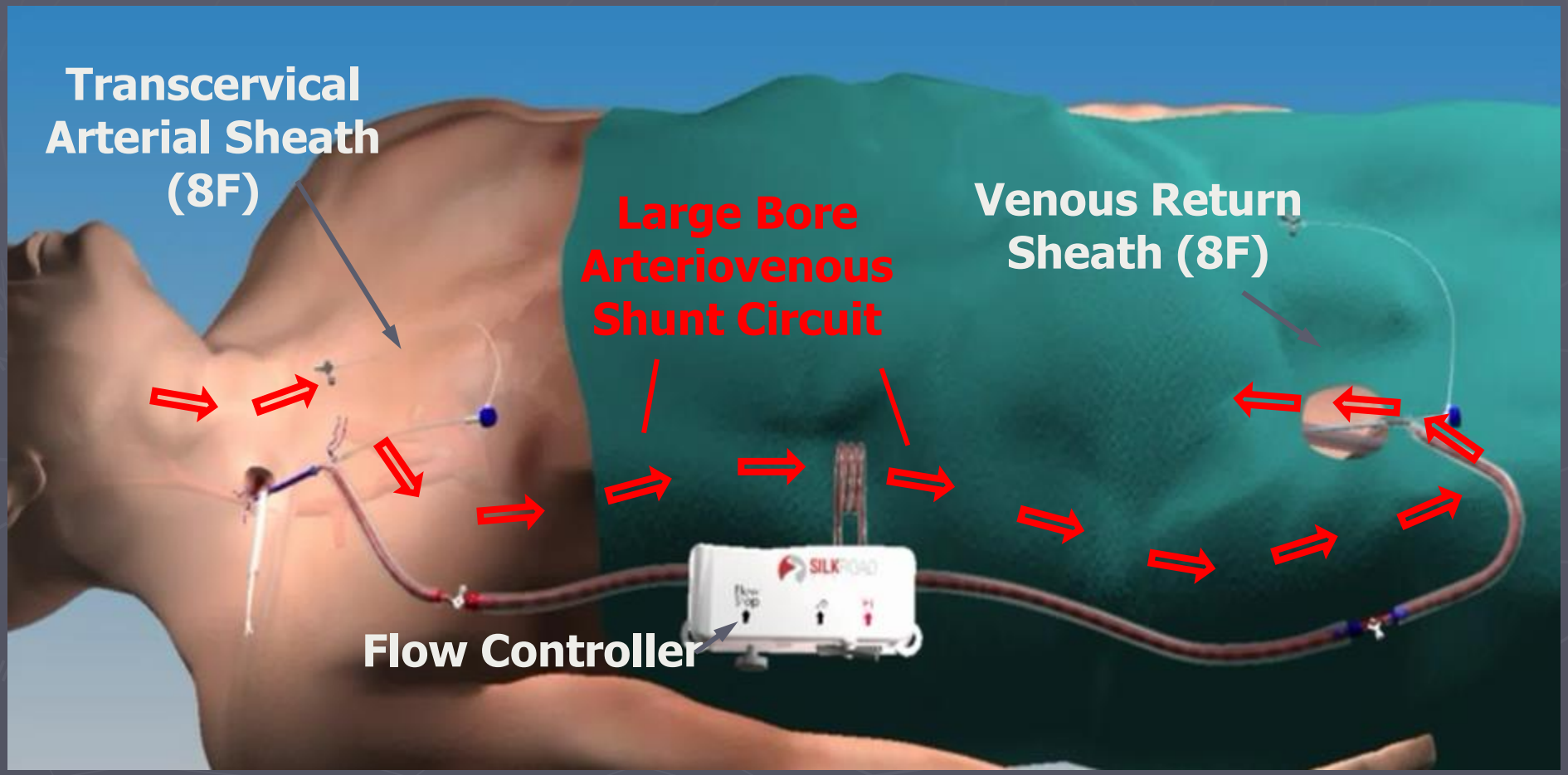
38 of 127 **(30%)**



P Rubino, EuroPCR 2011

Proximal EPD 3:

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:

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

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

Bosiers et al. Eur J Vasc Endovasc Surg 2007;33:135

Increased Neurologic Events With Open Cell Stents

SPACE Trial

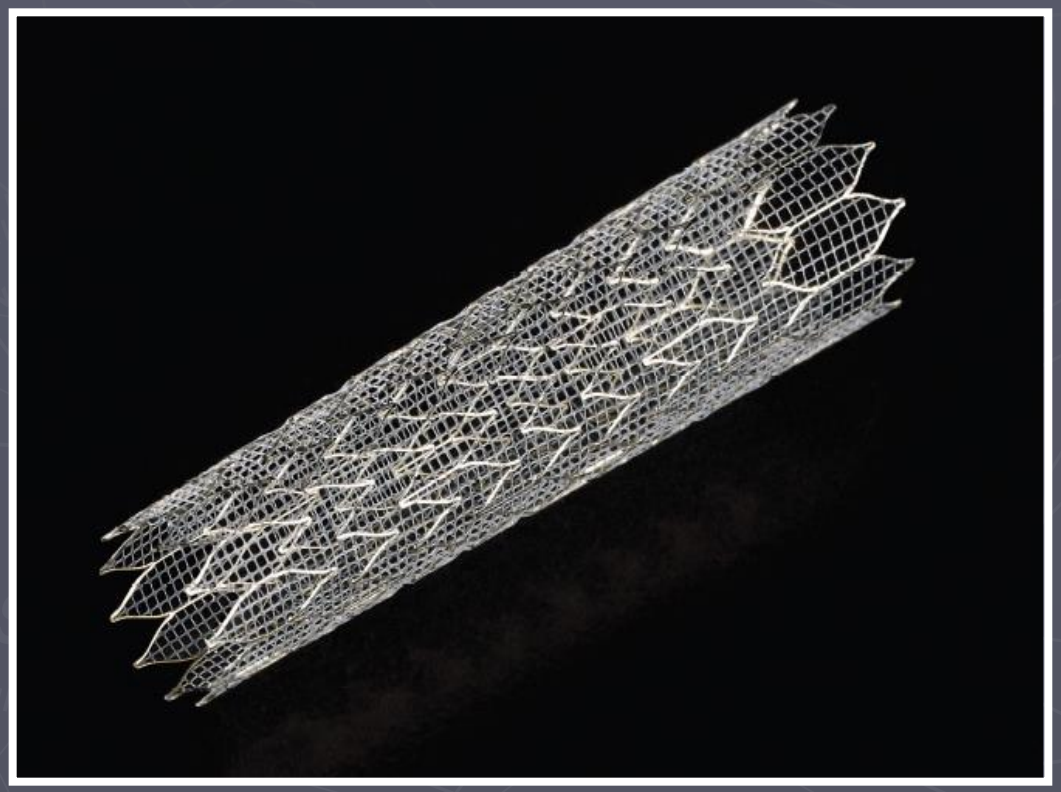
Table 4. Influence of Different Stent Types on OE Rate

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%)	

Jansen O et al. Stroke 2009;40:841-846

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

GORE® Carotid Stent
The Next Generation



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

What Does The " Best In Class " Protection Look Like?

Direct carotid access, flow reversal & membrane mesh stent technology

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