MEET 2015
MULTIDISCIPLINARY EUROPEAN
ENDOVASCULAR THERAPY

New Carotid Stent Design: Will This Improve Results?

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MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

Disclosure

Peter A. Schneider

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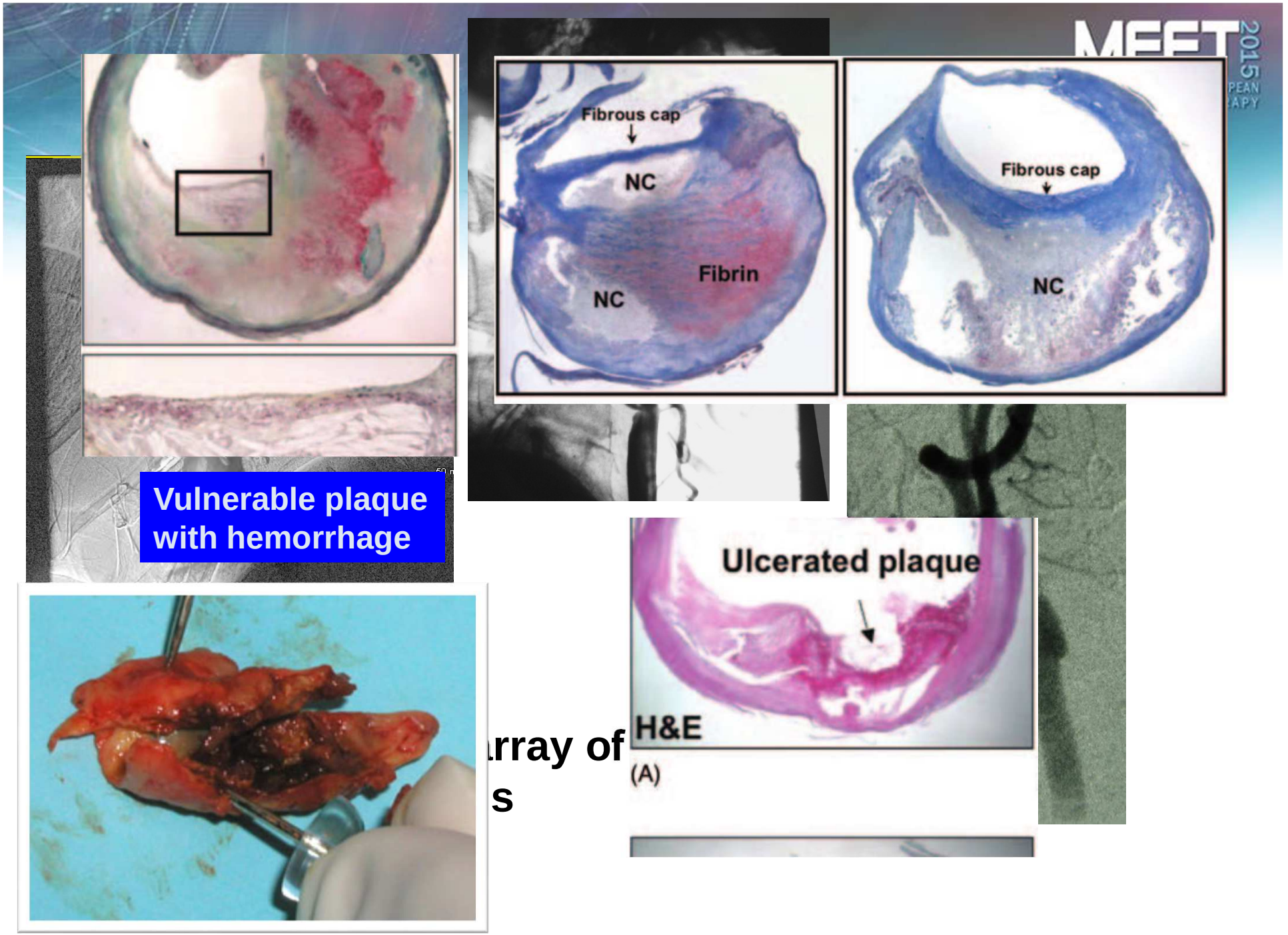
I have the following potential conflicts of interest to report:

Non-compensated participation in Scientific Advisory Board for Medtronic and Abbott

Shareholder in a healthcare company: Chief Medical Officer and shareholder, Intact Vascular and Cagent

Royalty for intellectual property: Cook (modest)


Fibrous cap
NC
Fibrin
NC
Fibrous cap
NC
Vulnerable plaque
with hemorrhage
Ulcerated plaque
H&E
(A)

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s

Carotid Stent Design

We are asking much of carotid stents.

- Scaffolding
- Lesion containment
- Conformability
- Fatigue resistance
- Minimal fish-scaling for ease of re-crossing
- Visibility
- Ease of use
- Low profile

Delayed Neurologic Events 1-30d

Especially with Open Cell Stents

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	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 neuro events were delayed (1-30d)

Failure of the stent!

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

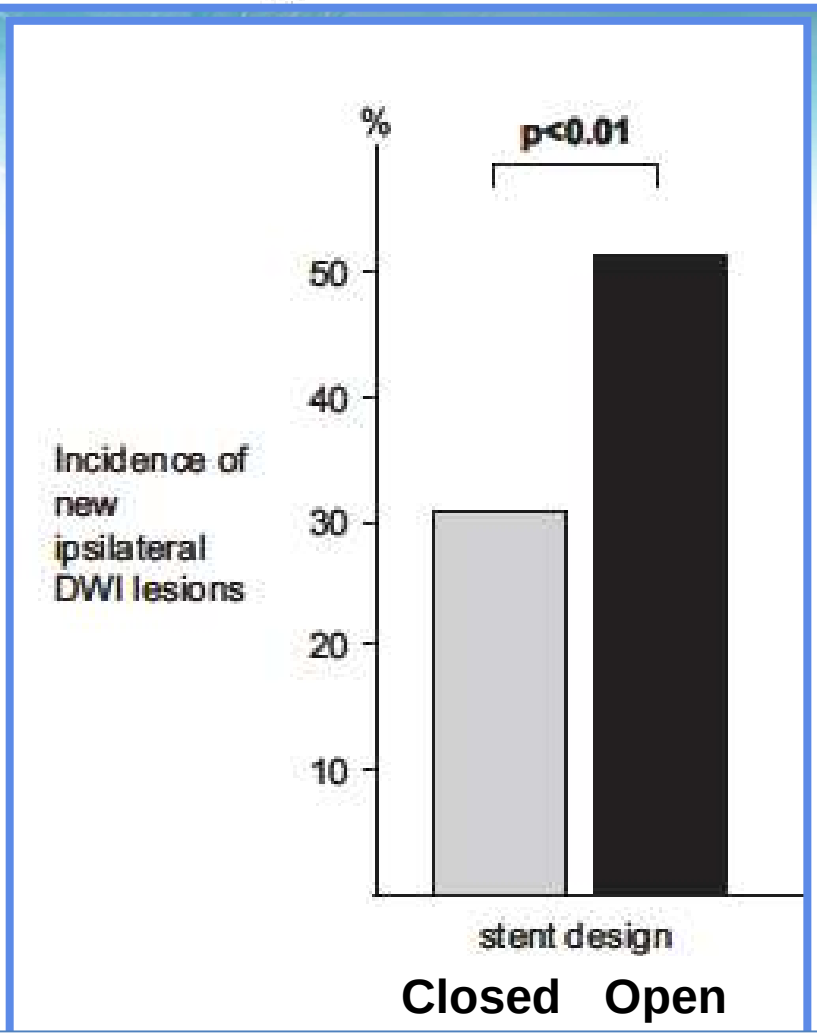
Stent	Wallstent	Acculink	Precise
No. of patients	436	92	35
Pat. with OE	24	9	5
OE rate (95% CI)	5.5% (3.6–8.1%)	9.8% (4.6–17.8%)	14.3% (4.8–30.3%)

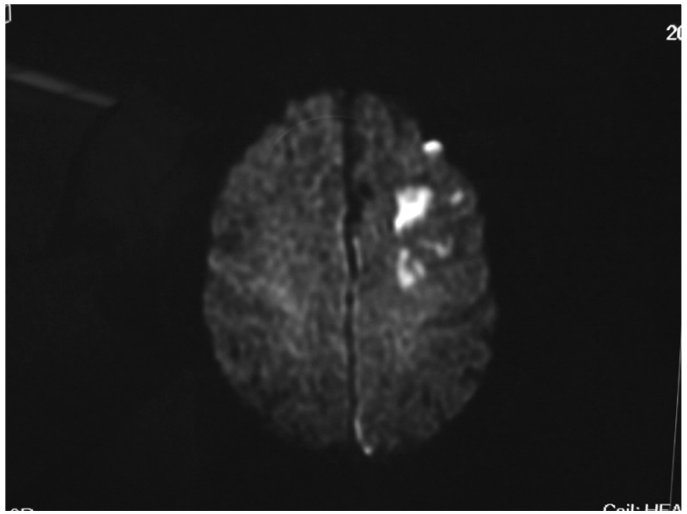
Closed → Open

Combined OE rate: 11.0% (6.2–17.8%)

Olav J et al. Stroke 2009;40:841

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



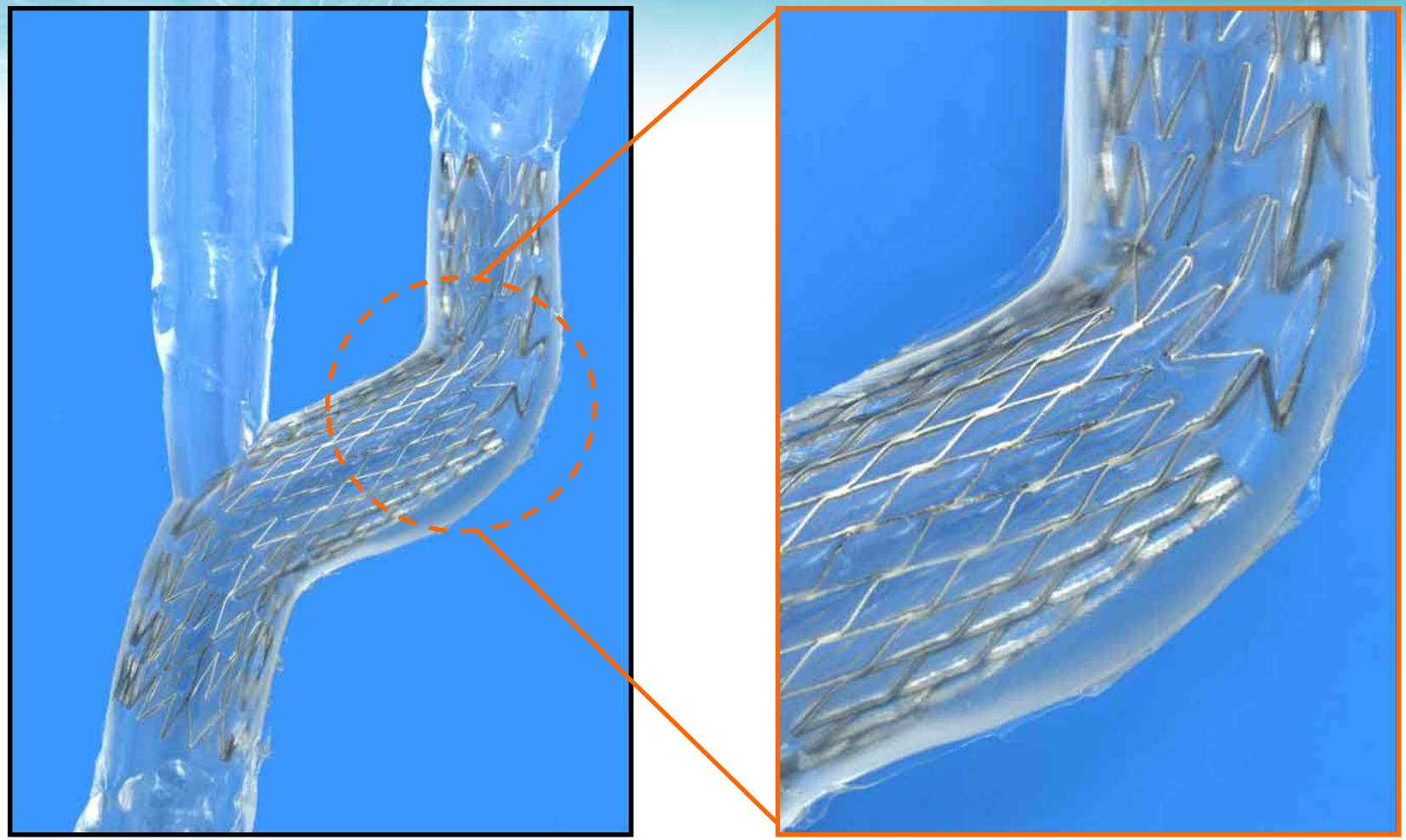


Increased DW-MRI Hits With Open Cell Stents

Schnaudigel et al. Stroke 2008;39:911

Carotid Stent Design

Open Cell In Tortuous Bifurcation



Wholey J Endovasc Ther 2009;16:178

Mesh-Covered Stents

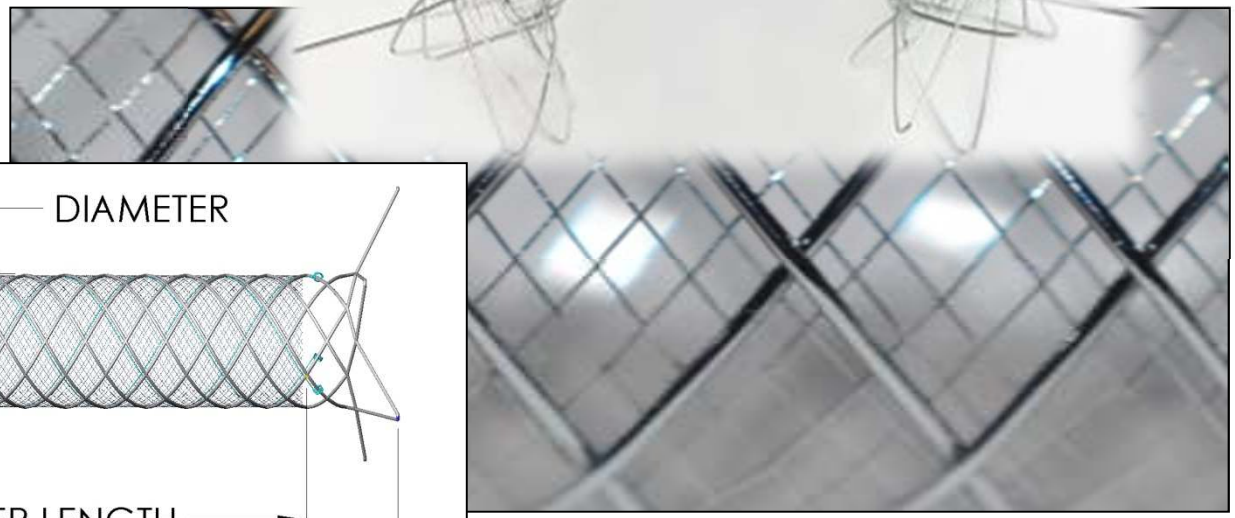
Roadsaver

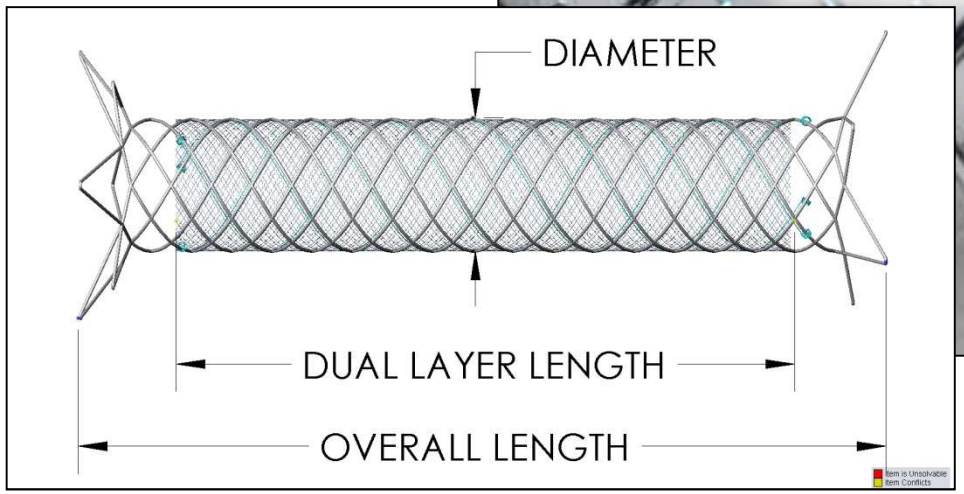
Mesh coverage for sustained embolic prevention

Retrievable and repositionable

5Fr delivery

Closed cell, woven st





Microvention/Terumo

Competitive Comparison

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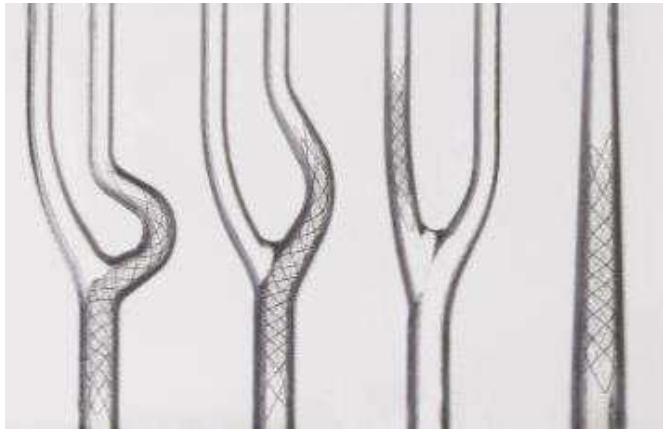
Stent/ Manufacturer	Design	Tapering	Guide Sheath Compatibility	Profile (mm)	Guidewire Compatibility (in)	Working Length (cm)	Diameters (mm)	Lengths (mm)	Free Cell Area (mm^2)[1,2]
Carotid Wallstent Boston Scientific	Braided weave closed-cell stainless steel	Self-tapering	5F: 6, 8 mm 6F: 10 mm	1.67 1.97	0.014	135	6, 8, 10	30, 40, 50	1.08
Precise Rx Cordis	Laser-cut open-cell nitinol tube with alternating bridges creating 2 mm independent segments	Self-tapering	5.5F: 5-8 mm 6F: 9-10 mm	1.85 2.0	0.014 or 0.018	135	5, 6, 7, 8, 9, 10	20, 30, 40	5.89
Protégé EVS	Laser-cut open-cell nitinol tube	Straight	6F	1.98	0.014	135	6, 7, 8, 9, 10	20, 30, 40, 60	10.71
		Tapered (shoulder)	6F				6-8, 7-10	30, 40	
Rx Acculink Abbott	Laser-cut open-cell nitinol tube with longitudinal spines	Straight	6F	1.98	0.014	126	5, 6, 7, 8, 9, 10	20, 30, 40	11.48
		Tapered (conical)	6F				6-8, 7-10	30, 40	
XACT Abbott	Laser-cut closed-cell nitinol tube	Straight	6F	1.9	0.014	136	7, 8, 9, 10	20, 30	2.74
		Tapered (conical)	6F				6-8, 7-9, 8-10	30, 40	
Zilver 518 Cook	Laser-cut open-cell nitinol tube with z-shaped cells and horizontal connectors	Straight	5F	1.67	0.014 or 0.018	125	6, 7, 8, 9, 10	20, 30, 40, 60, 80	12.76
Roadsaver			**5F**		**0.014**				**~0.3**

Mesh-Covered Stents

Roadsaver

- Product Line Breadth
  - 5-10 mm stents
  - 16-40 mm unconstrained lengths
  - Self tapering stents: max taper of 3.5 mm
  - Delivery System: 5F, 143 cm length, Rx, .014” wire
  - Repositionable Low Profile Delivery: Up to 50% deployment fully re-sheathable and repositionable
  - Clear Road Trial
  - 100 patients, multicenter



Mesh-Covered Stents

GORE Carotid Stent

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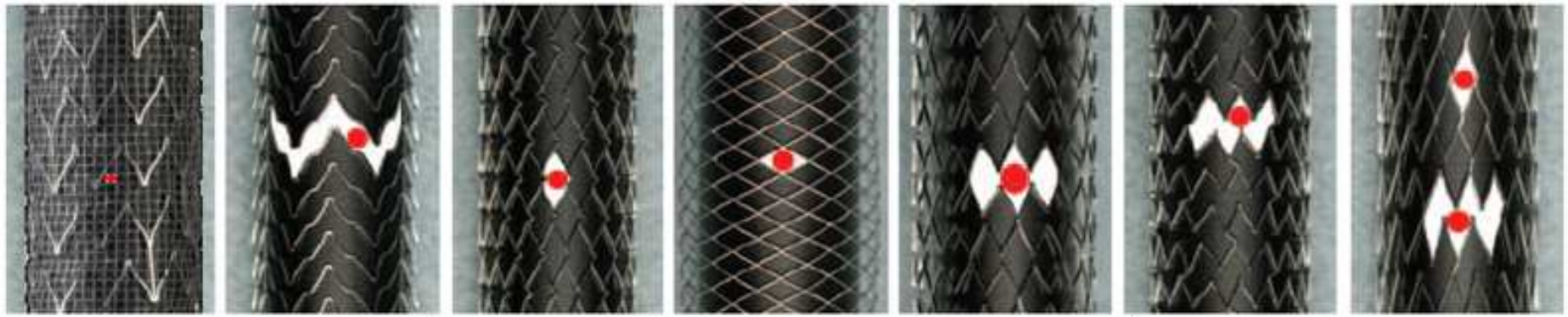
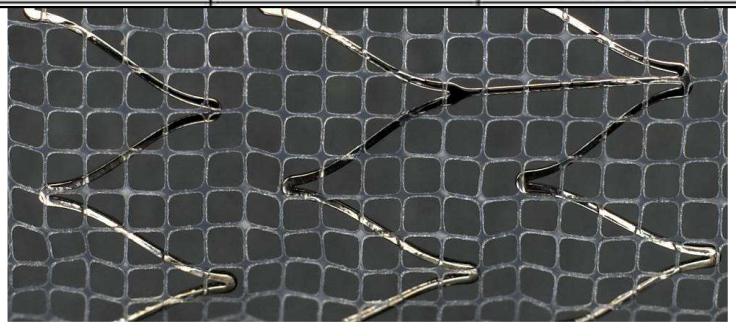
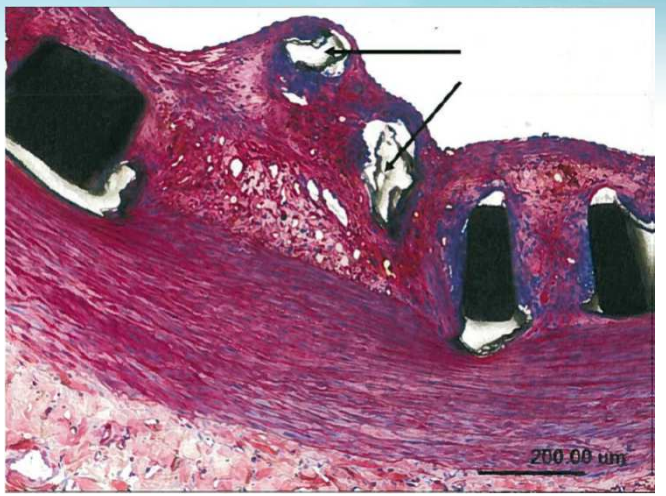


W.L. Gore and Associates*	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
GORE® Carotid Stent	ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE

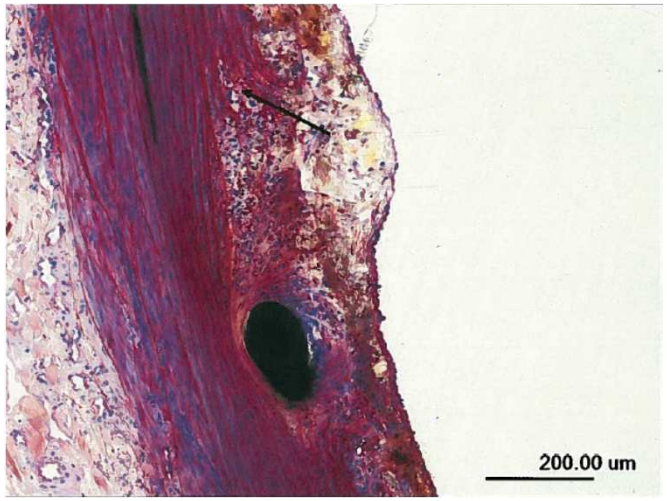


GORE Carotid Stent Preclinical Studies

- Canine artery model
- Biologically acceptable tissue response
  - All sidebranches and devices patent through 56 days
  - Full device endothelialization at 30 days
  - Comparatively less medial compression



GORE® Stent



Carotid WALLSTENT ™

Mesh-Covered Stents

SCAFFOLD Trial

- Design-Prospective study comparing the GORE® Carotid Stent to a performance goal developed from carotid endarterectomy outcomes
- 50 sites, 312 subjects.
- Co-PIs-Bill Gray and Peter Schneider
- Objective-Evaluate safety and efficacy of GORE® Carotid Stent in patients at increased risk for adverse events from carotid endarterectomy.
- Primary endpoint-Death, stroke, or myocardial infarction through 30 days plus ipsilateral stroke between 31 days and 1 year.

Mesh-Covered Stents

SCAFFOLD Trial

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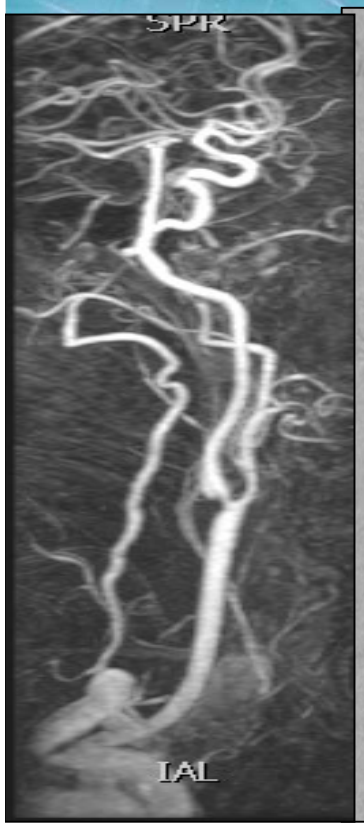
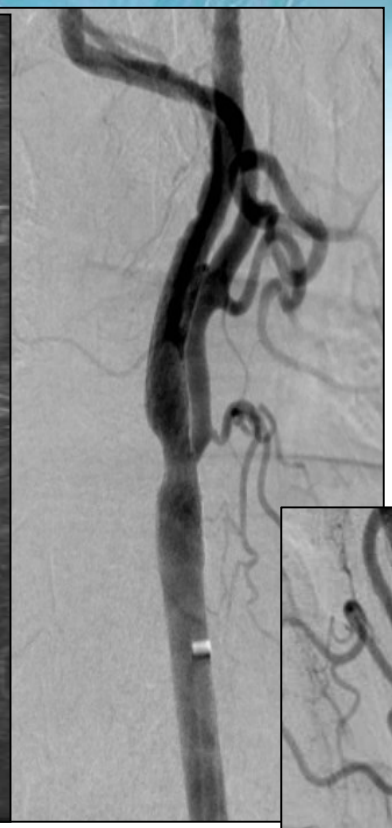
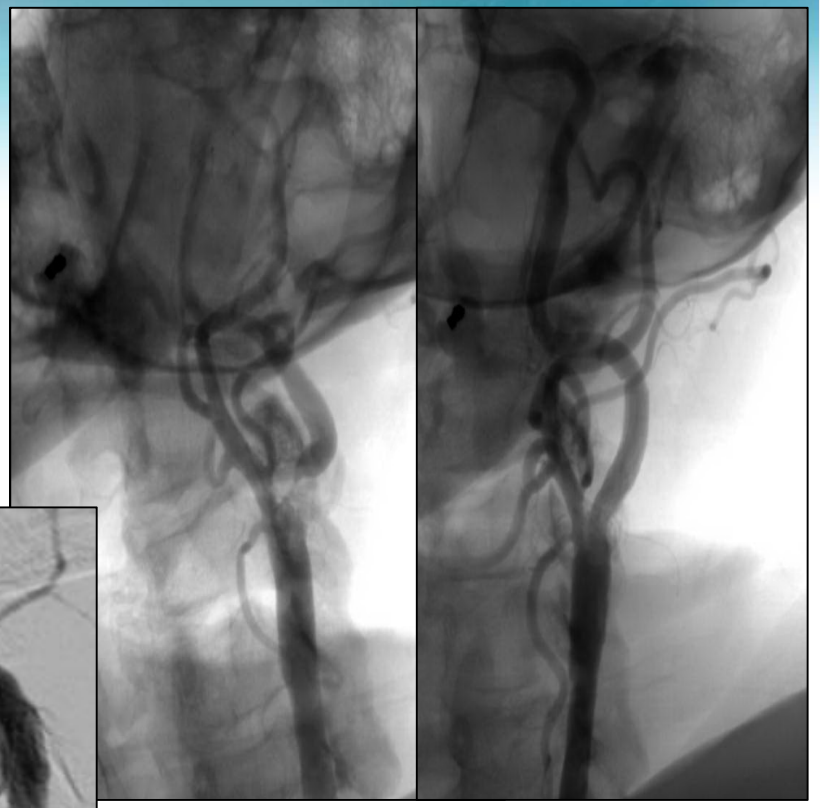
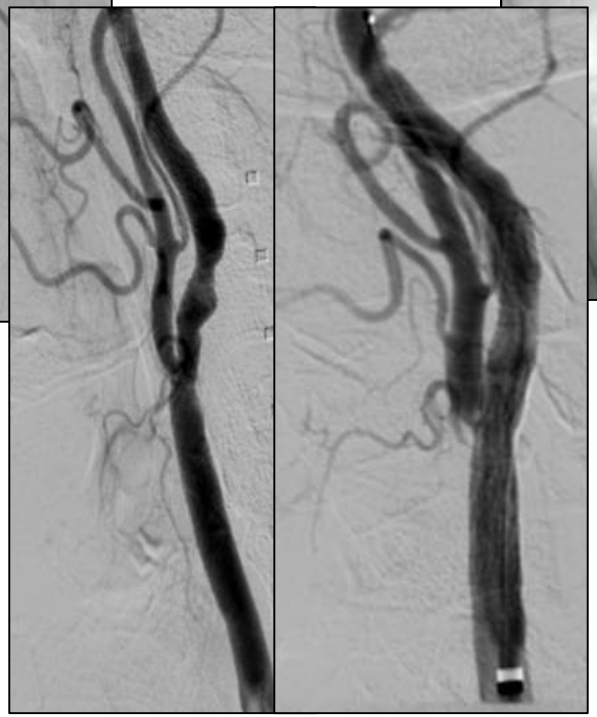




Courtesy: C. Schonholtz



Courtesy of R. Dave



Courtesy of
C. Metzger

Mesh-Covered Stents

CGuard Prime EPS

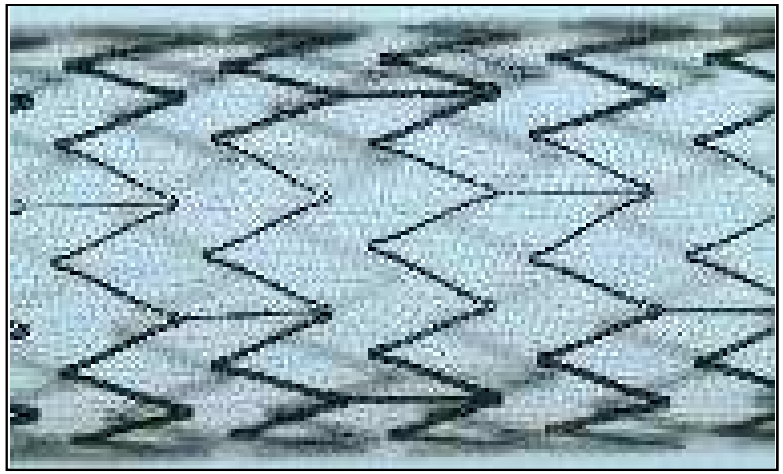
Polyethylene Terephthalate (PET) 20µ wide fiber micronet on a nitinol stent

Attached to proximal and distal crowns of the stent

CARANET Study-30 patient trial

No stroke or death at 30 days

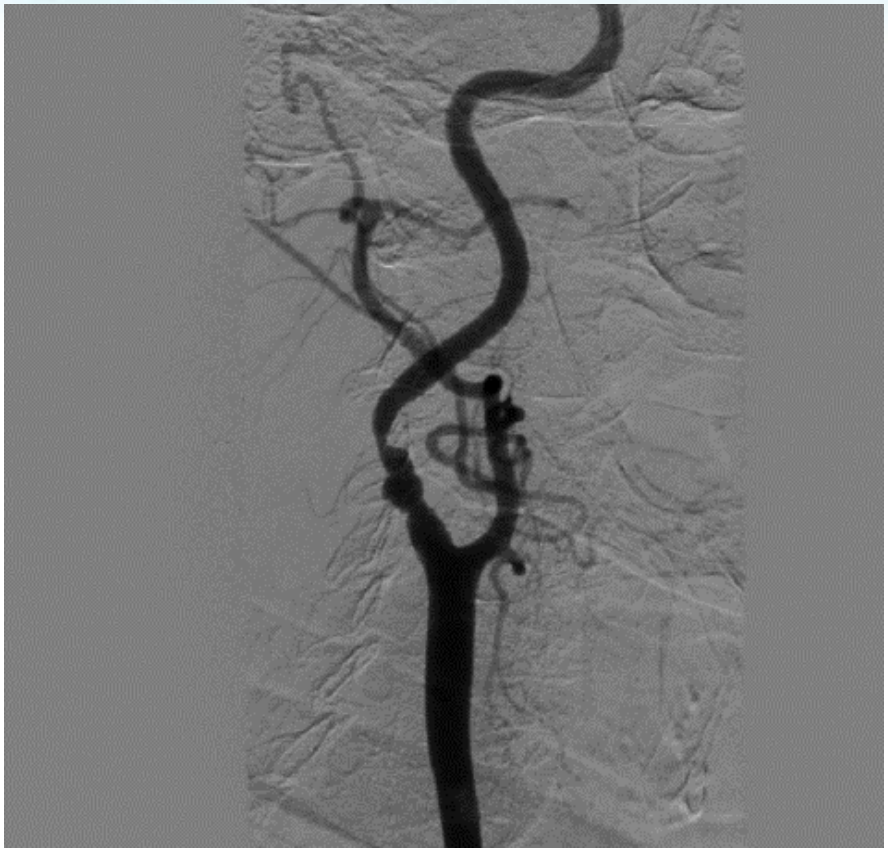
50% reduction in DW-MRI lesions

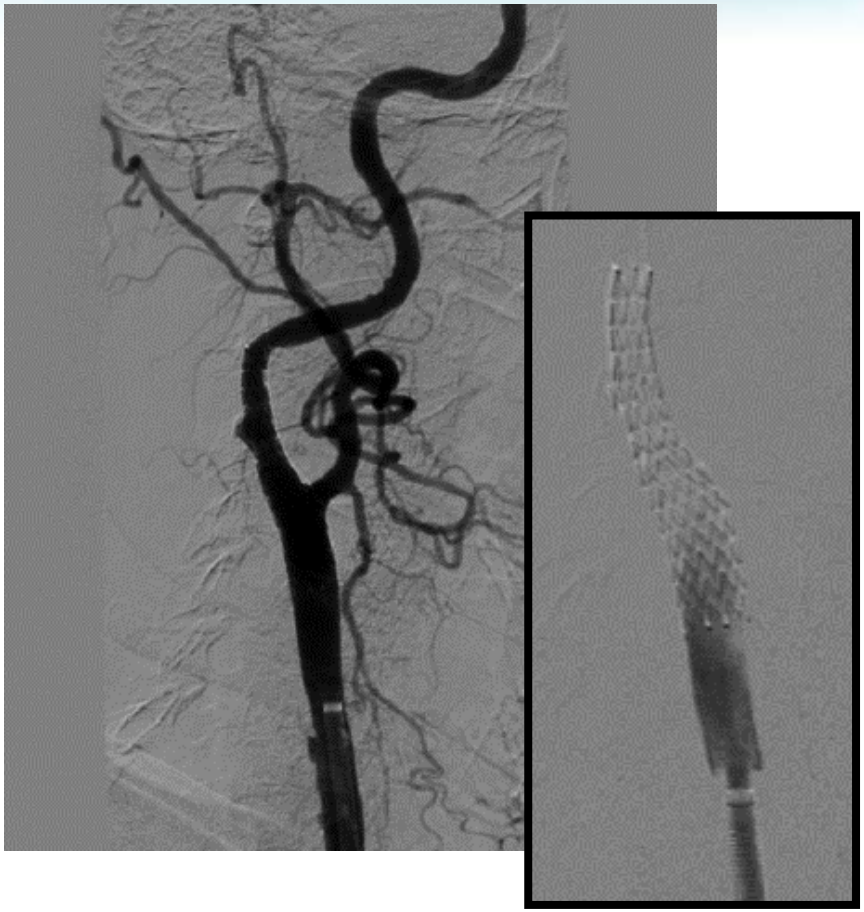


InspireMD

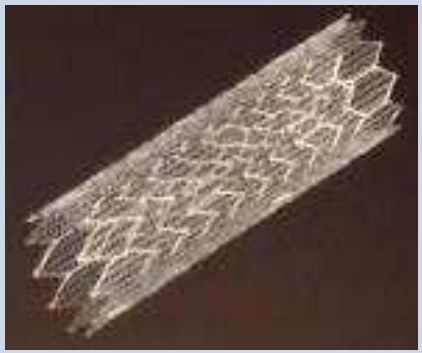
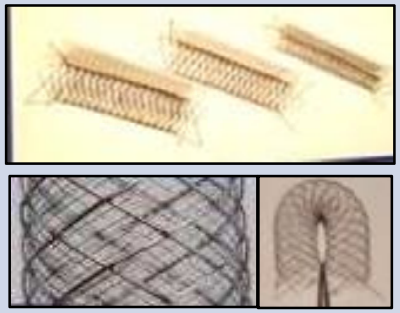
Mesh-Covered Stents

CGuard Prime EPS





Mesh Covered Stent Designs

	Gore	Terumo Roadsaver	InspireMD CGuard™
Design			
Aperture Size	500µ	300µ	180µ
Materials	PTFE mesh (Heparin coated) on nitinol stent	nitinol on nitinol	PET MicroNet™ on nitinol stent
CE Mark	No	Yes	Yes

Increase in Neurologic Events With Open Cell Stents Symptomatic Patients

Table 5. *P*-values for the test that event rates differ between stents

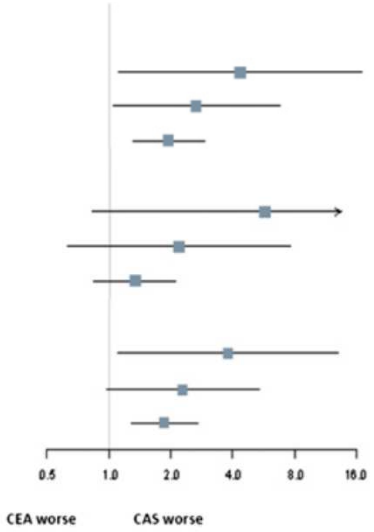
Population	Outcome	*p*-value
Total	All events	0.018
	Post-procedural events	0.002
Symptomatic	All events	0.006
	Post-procedural events	<0.0001
Asymptomatic	All events	0.248
	Post-procedural events	0.790

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

The risk of carotid artery stenting compared with carotid endarterectomy is greatest in patients treated within 7 days of symptoms

Table II. Risks for different end points depending on the timing of treatment (0-7 days, 8-14 days, and thereafter) and treatment modality

	CEA, No. (%)	*CAS, No. (%)*	*Crude RR (95% CI)*	P *value*
Stroke or death				
0-7 days	3 (2.8%)	13 (9.4%)	3.79 (1.1-13.1)	.03
8-14 days	7 (3.4%)	19 (8.1%)	2.42 (1.0-5.7)	.04
>14 days	44 (4.0%)	78 (7.3%)	1.82 (1.3-2.6)	.001
Disabling stroke or death				
0-7 days	1 (0.9%)	7 (5.1%)	6.40 (0.8-51.0)	.08
8-14 days	3 (1.4%)	7 (3.0%)	2.28 (0.6-8.7)	.23
>14 days	28 (2.6%)	34 (3.5%)	1.35 (0.8-2.2)	.22
Any stroke				
0-7 days	3 (2.8%)	13 (9.4%)	3.79 (1.1-13.1)	.03
8-14 days	7 (3.4%)	18 (7.7%)	2.27 (1.0-5.4)	.06
>14 days	41 (3.8%)	74 (7.0%)	1.86 (1.3-2.7)	.001



Rantner et al. J Vasc Surg 2013;57:619.

Mesh-Covered Carotid Stents
Conclusion

- Goal: decrease neurologic events, especially delayed embolization through the cells of the stent.
- Future: clinically useful stent design will likely include mesh coverage.
- Balance between material type, positioning, and cell size.