Next-Generation Carotid Artery Stents:

Are Mesh/Membrane Stents Game Changers?

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Research Study Sponsorship	• Medtronic, Gore, Cordis (non-compensated)
• Royalty Income (modest)	• Cook Medical
• Ownership/Founder	• Intact Vascular

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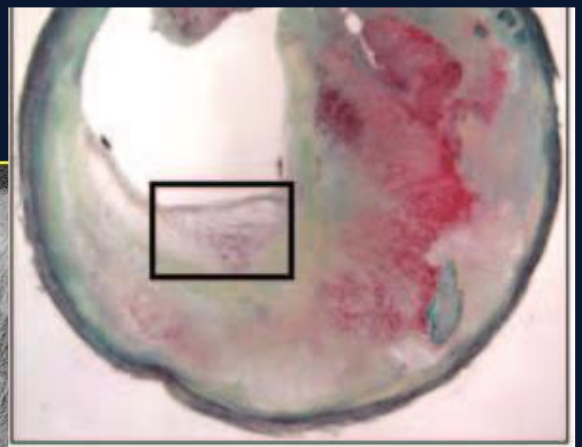
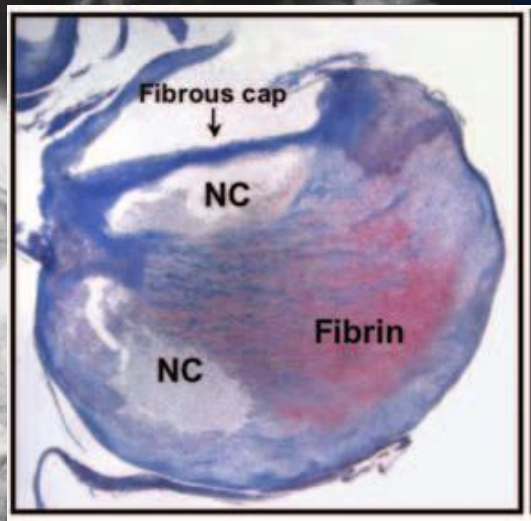
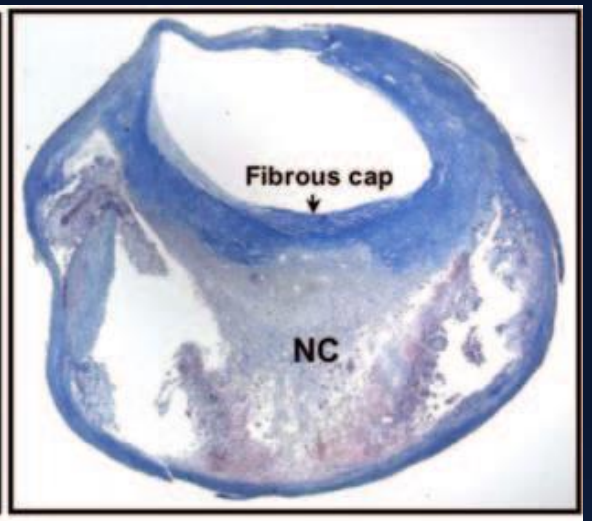
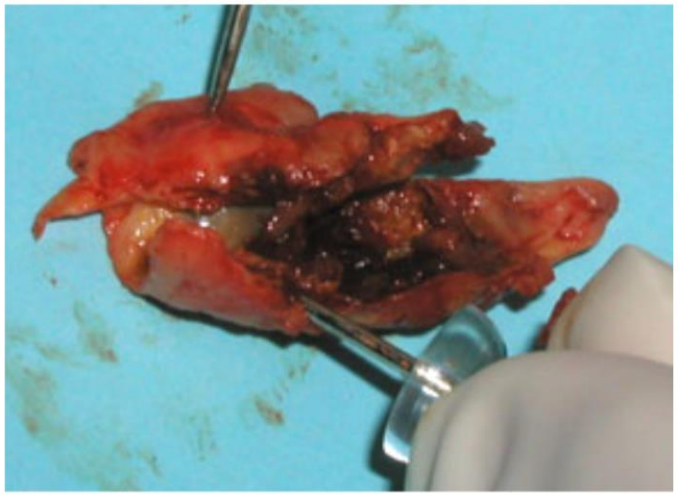
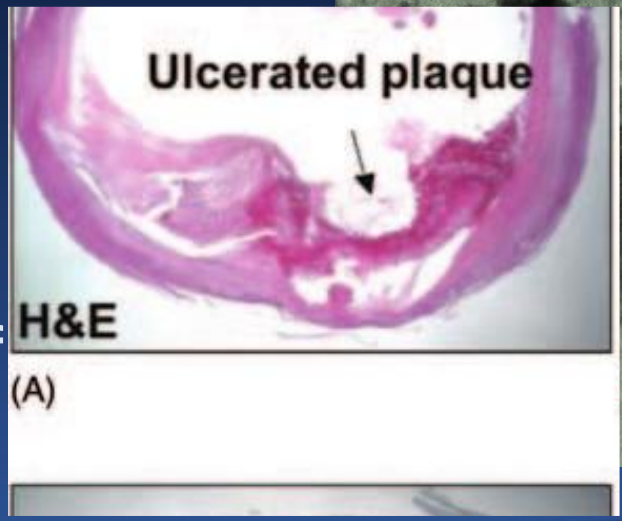






Vulnerable plaque with hemorrhage





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Why Do We Need Mesh-covered Stents?
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

	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

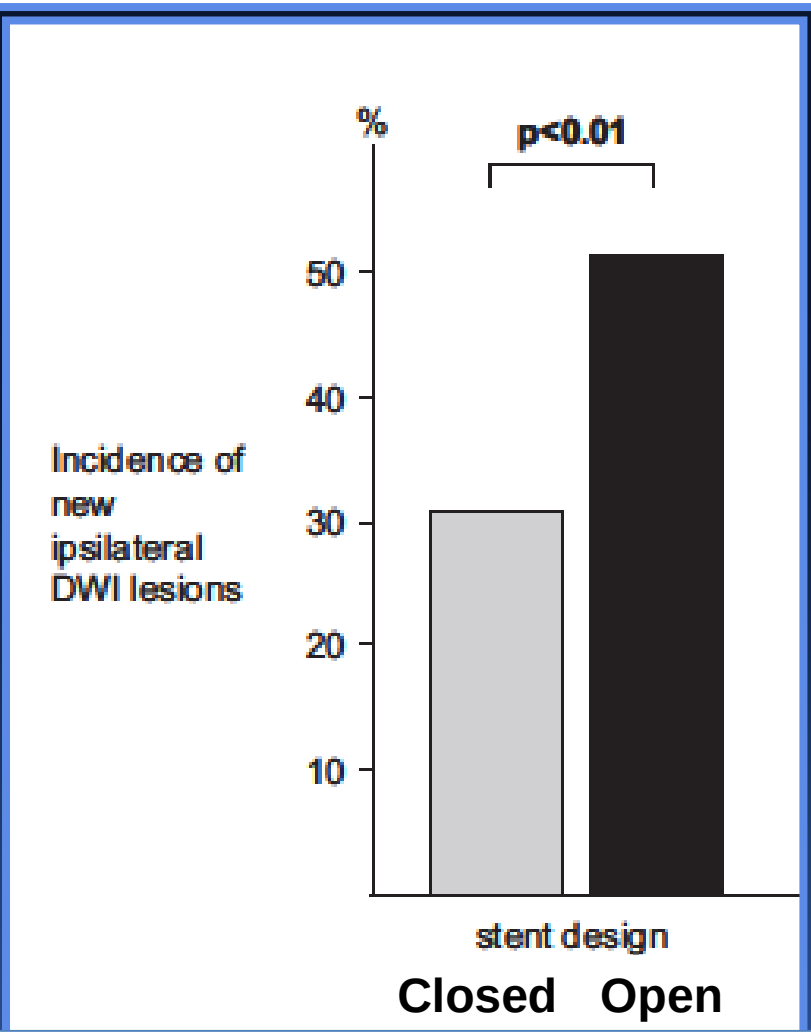
Stent	Wallstent	Acculink	Precise
No. of patients	436	92	35
Pat. with OE	24	9	5
OE rate (95% CI)	5.5% (3.6–8.1%)	9.8% (4.6–17.8%)	14.3% (4.8–30.3%)

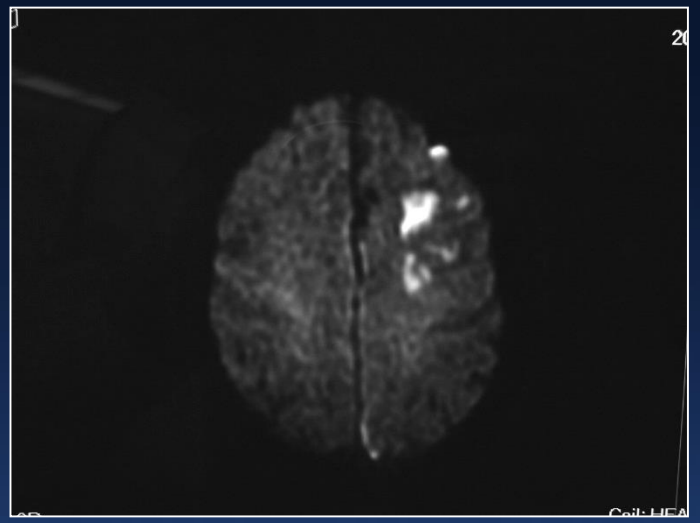
Closed → Open

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

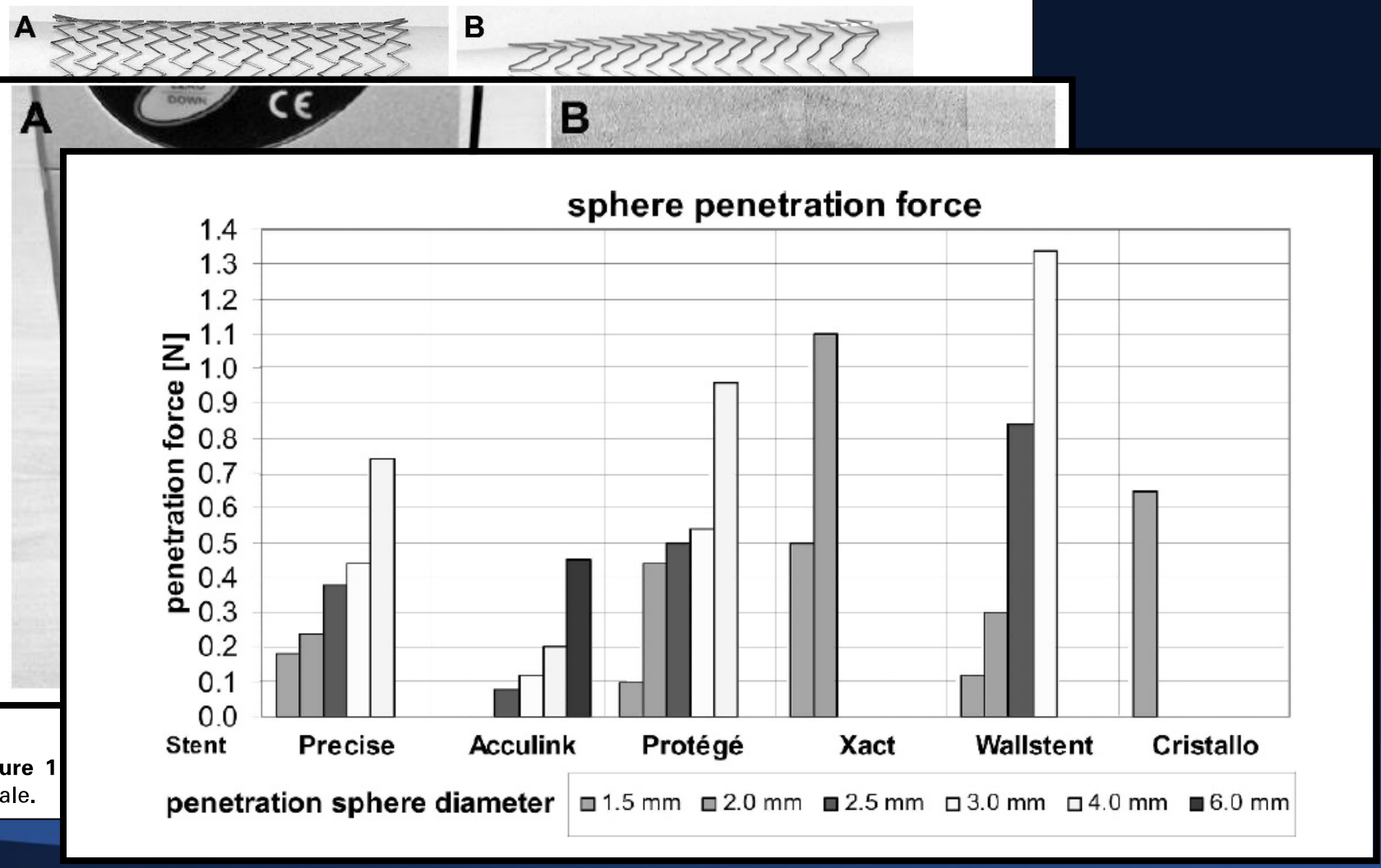
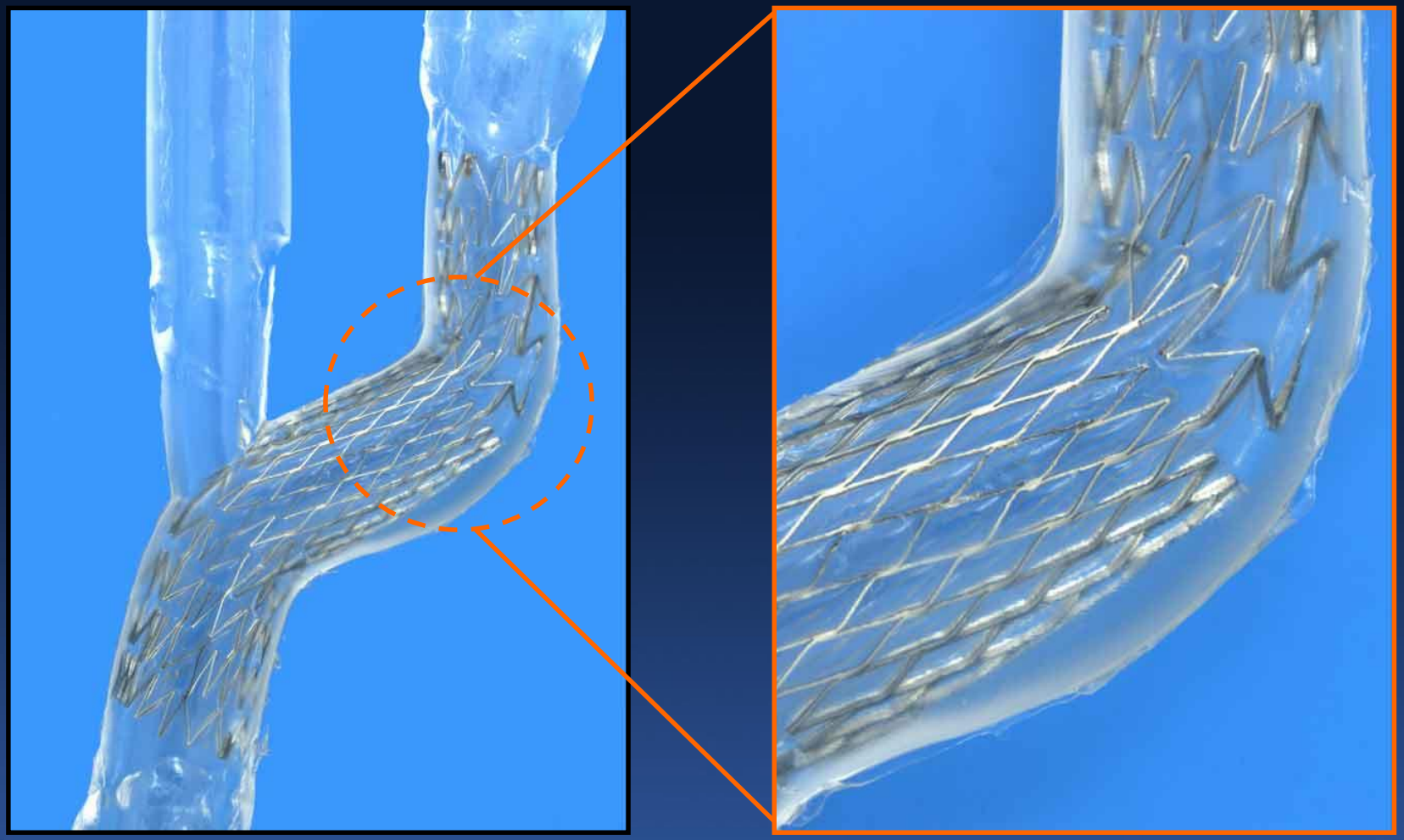


Figure 1
Ideale.

Muller-Hulsbeck et al. J Endovasc Ther 2009;16:168

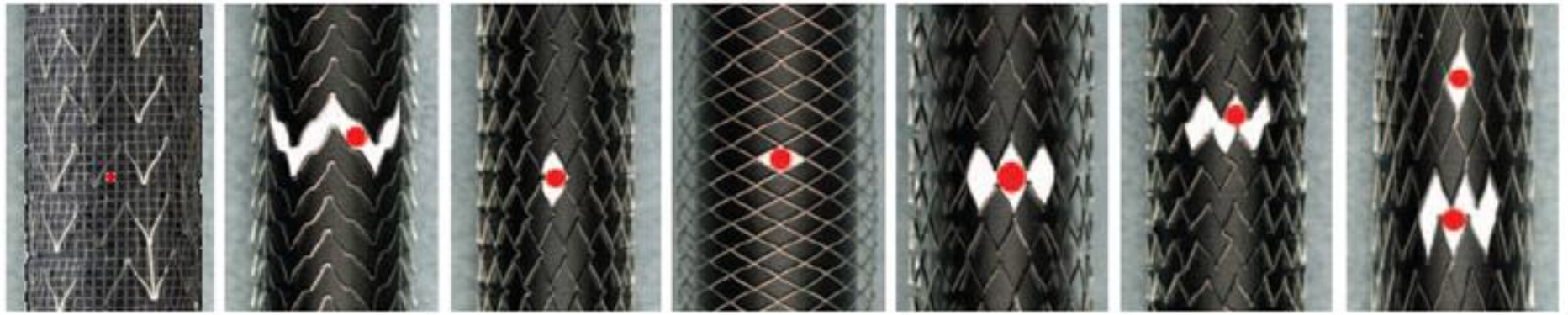
Carotid Stent Design

Open Cell In Tortuous Bifurcation

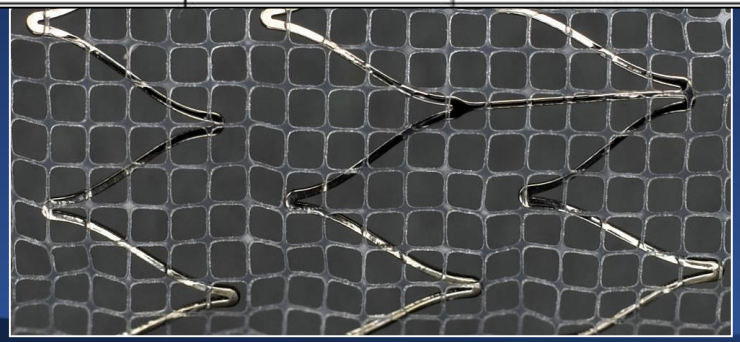


Wholey J Endovasc Ther 2009;16:178

Mesh-Covered Stents
GORE Carotid Stent



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



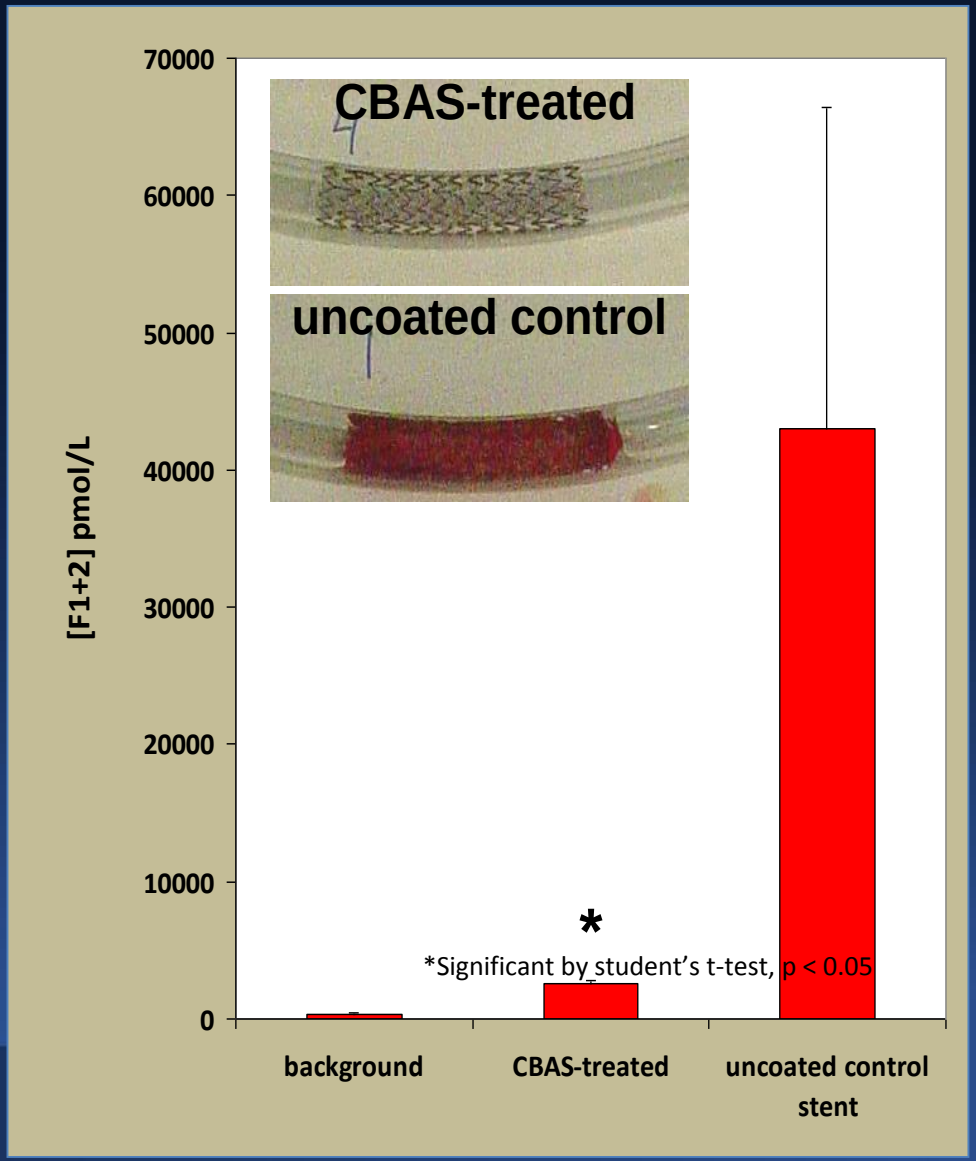
CAUTION: Investigational Device.

Limited by United States Law to Investigational Use only. Not available in US. Not approved by FDA.

Mesh-Covered Stents

CBAS®-Heparin Evaluation

- Modified Chandler Loop - recirculating blood model
  - CBAS®-treated devices thrombus-free after a one hour exposure to human blood,
  - Untreated control device contained adherent thrombus.
- Coagulation biomarker prothrombin fragment 1 and 2 (F1+2) revealed significantly lower levels associated with CBAS®-treated GCS compared to uncoated control devices

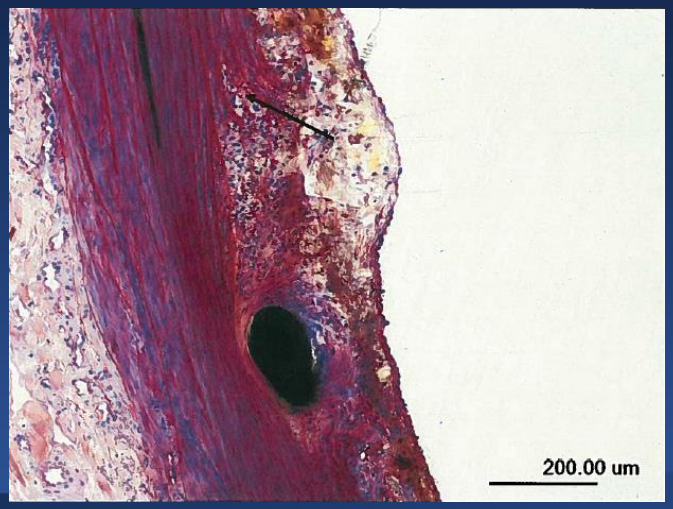


Mesh-Covered Stents

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.

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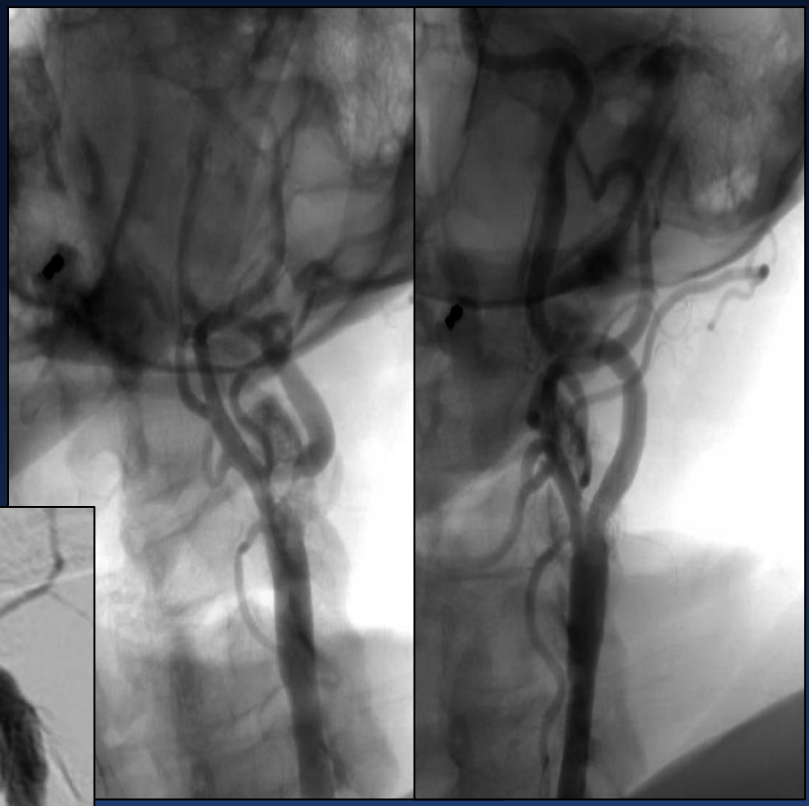
Mesh-Covered Stents

SCAFFOLD Trial

Courtesy: C. Schonholtz

Courtesy of C. Metzger



Courtesy of R. Dave

Mesh-Covered Stents

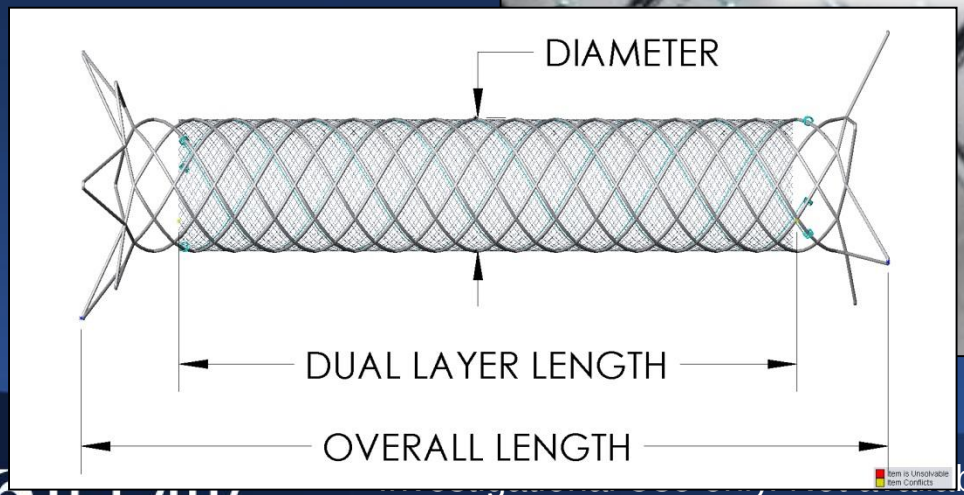
Casper

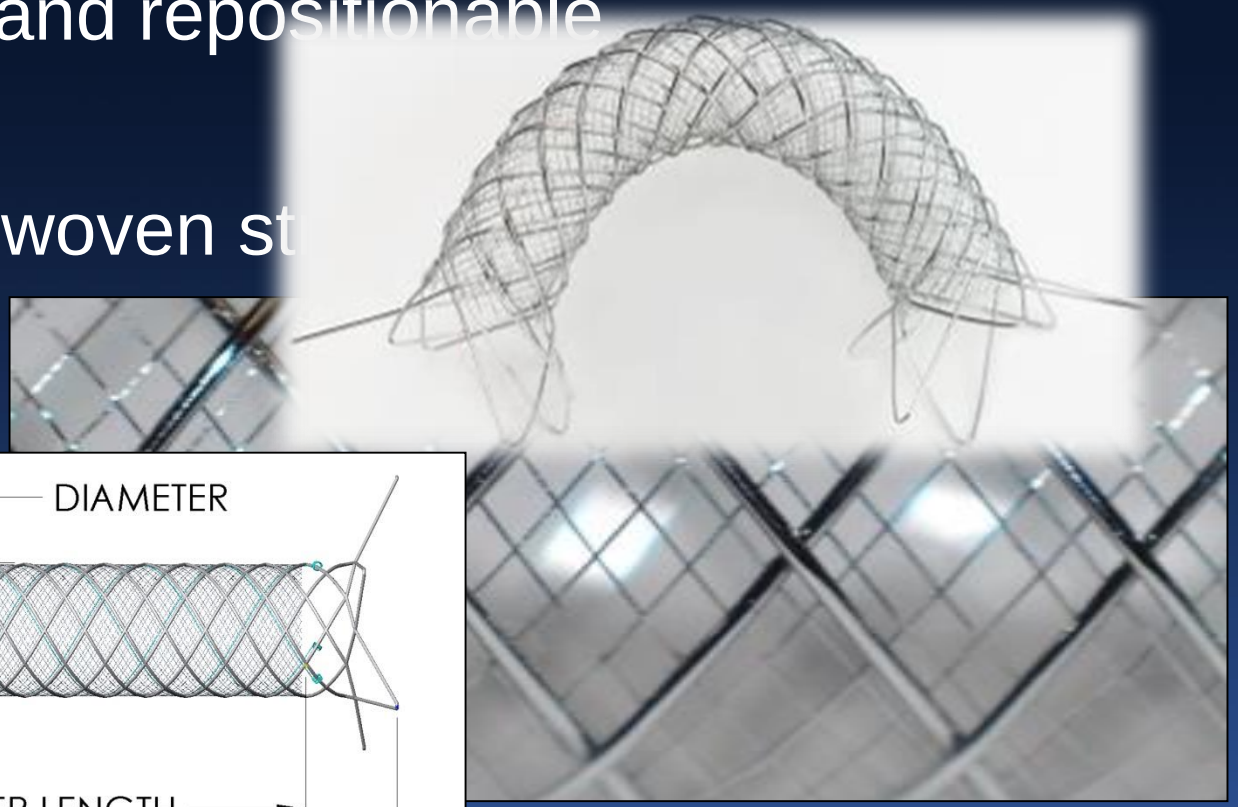
Mesh coverage for sustained embolic prevention

Retrievable and repositionable

5Fr delivery

Closed cell, woven st





Microvention/Terumo

ble in US. Not approved by FDA.

Mesh-Covered Stents

CGuard Prime EPS

Polyethylene Terephthalate (PET) 20µ wide fiber

InspireMD

CAUTION: Investigational Device. Limited by United States Law to Investigational Use only. Not available in US. Not approved by FDA.

Mesh-Covered Stents

CGuard Prime EPS

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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.