

What Are the Optimal Design Attributes for a Carotid Stent? Review of the Current and Future Options

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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

- Grant/Research Support
- Consulting Fees/Honoraria
- Royalty Income

Company

- Cordis, Abbott
- Abbott, Medtronic, Gore
- Cook

Carotid Stent Design

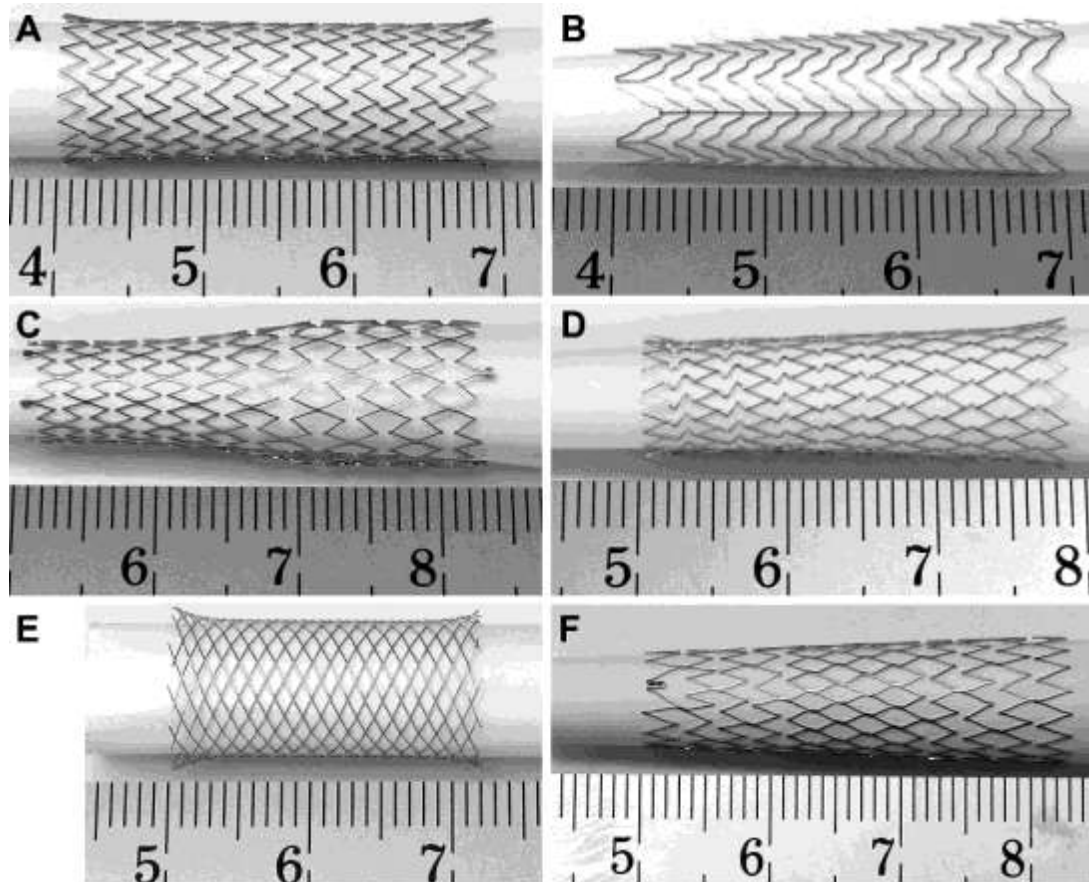


Figure 1 ♦ (A) Precise, (B) Acculink, (C) Protégé, (D) Xact, (E) Wallstent, and (F) Cristallo Ideale.

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

Carotid Disease is Different Than Other Pathologies We Treat

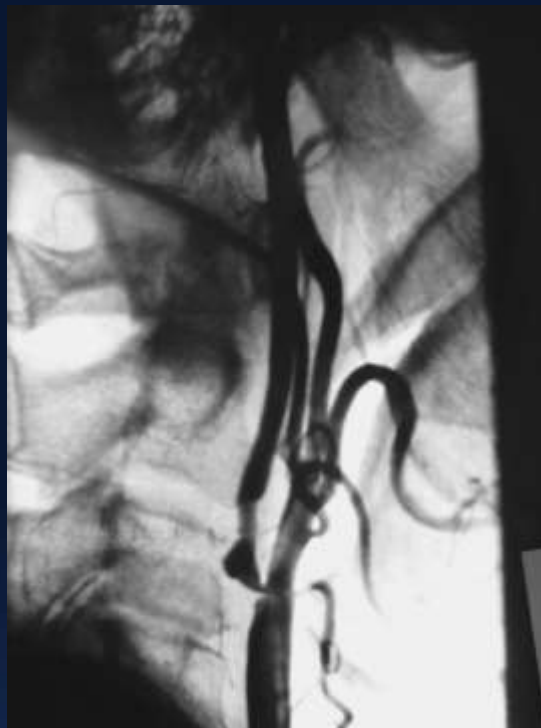
- Primarily an embolizing disease
- An artery connected to an embolus-sensitive organ
- Highly variable plaque morphology
- Carotid bifurcation is often tortuous
- Artery tapers
- Bifurcation has a branch



Carotid Stent Design

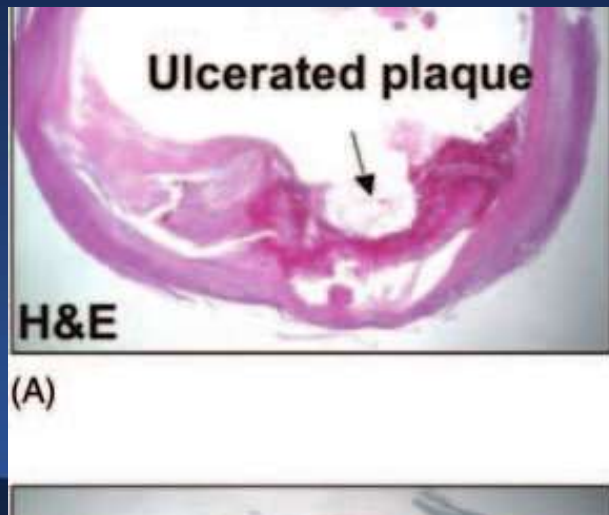
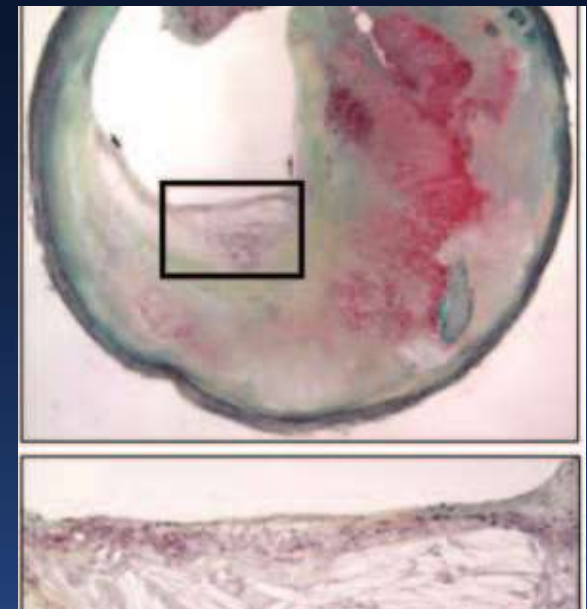
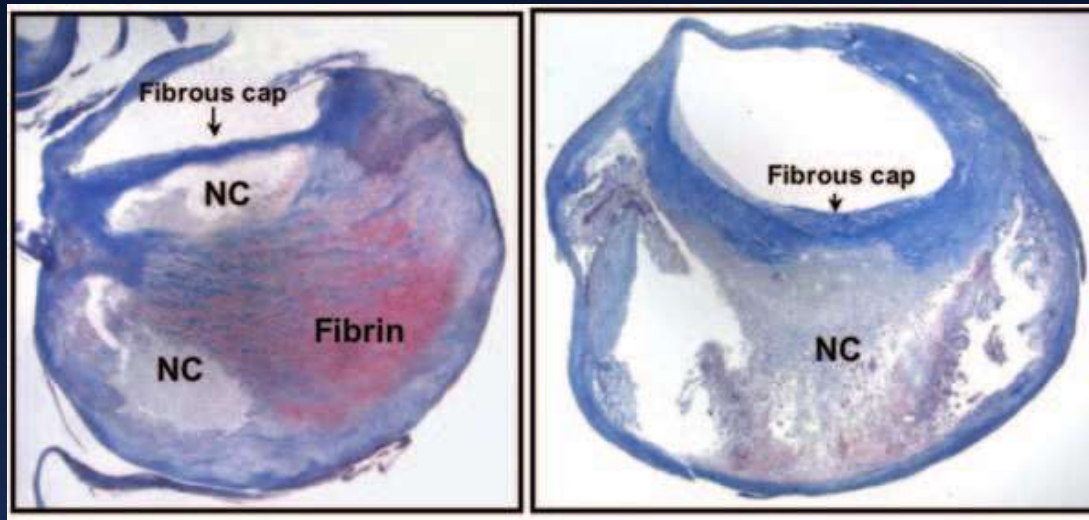
We are asking carotid stents to do many things at once.

- Scaffolding
- Conformability
- Fatigue resistance
- Minimal fish-scaling for deployed stent
- Visible
- Easy to use



An amazing array of configurations

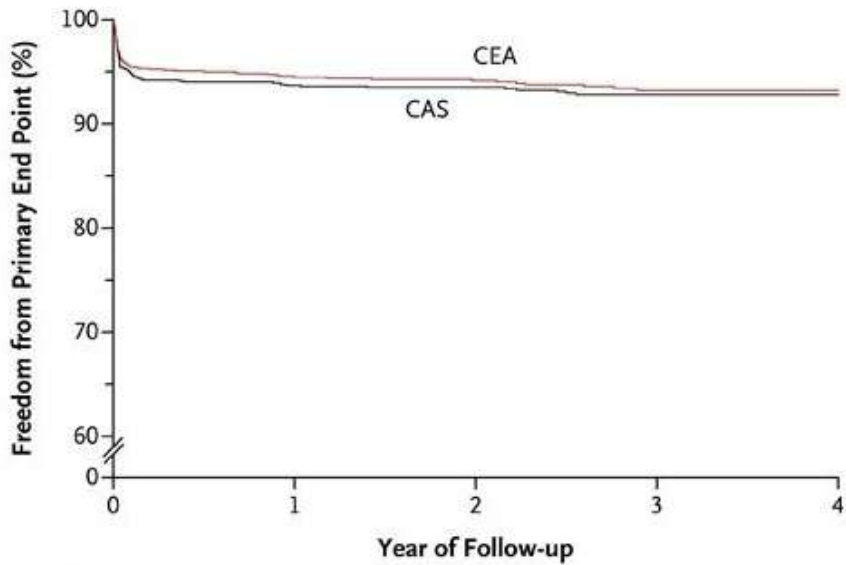
We are asking carotid stents to manage the plaque for us.



Vulnerable plaque with hemorrhage

And yet: Long-term results are as good with stenting as with plaque removal

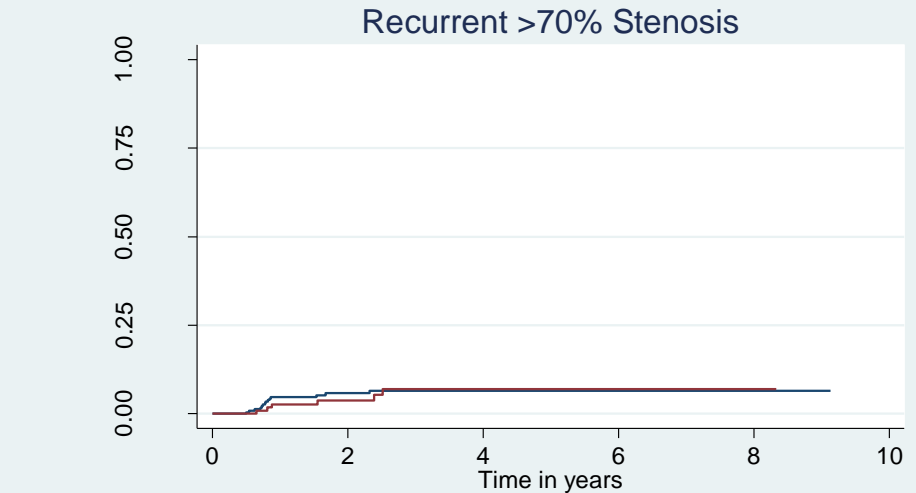
Long-term stroke prevention



No. at Risk						
CAS	1262	1100	787	460	162	
CEA	1240	1099	770	430	145	

CREST N Engl J Med 2010

Restenosis



Number at risk							
CEA	281	161	94	35	8	0	
CAS	148	75	42	15	2	0	

Caps et al. Western Vascular Society, 2011

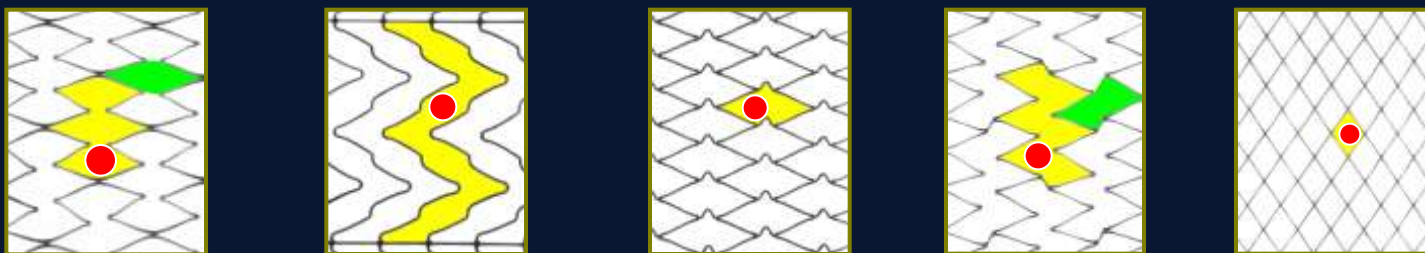
Carotid Stent Design

We need to make the first 30 days safer

- **CAS related neurologic events are multifactorial**
 - Arch and great vessel anatomy
 - Lesion morphology
 - Operator experience
 - Quality of embolic protection
 - Carotid stent attributes

Carotid Stent Design

Proximal



	PROTÉGÉ® RX (Tapered, 8-6mm)	RX ACCULINK™ (Tapered, 8-6 mm)	Xact® (Tapered, 8-6mm)	PRECISE® (Straight, 8 mm)	WALLSTENT® (Straight, 8 mm)
Pore Diam. (mm) ■	1.12	1.10	1.00	1.12	0.92
Pore Size (mm ²) □	2.65	12.50	3.46	2.43	0.948
Cell Area (mm ²) ▲	7.19	12.50	3.46	7.39	0.948

Distal



	PROTÉGÉ® RX (Tapered, 8-6 mm)	RX ACCULINK™ (Tapered, 8-6mm)	Tapered, 8-6mm Xact	PRECISE® (Straight, 8 mm)	WALLSTENT® (Straight, 8 mm)
Pore Diam. (mm) ■	1.08	1.06	0.96	1.12	0.92
Pore Size (mm ²) ■	1.80	10.78	2.23	2.43	0.948
Cell Area (mm ²)	4.48	10.78	2.23	7.39	0.948

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%)			

Increase in Delayed Neurologic Events With Open Cell Stents 1-30 days

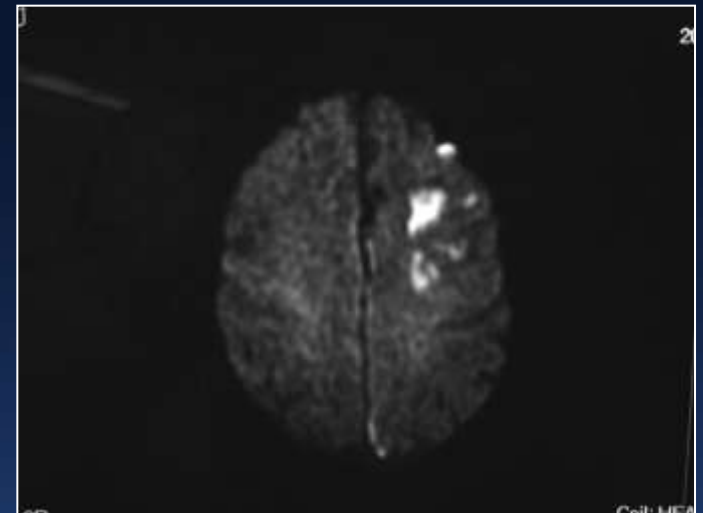
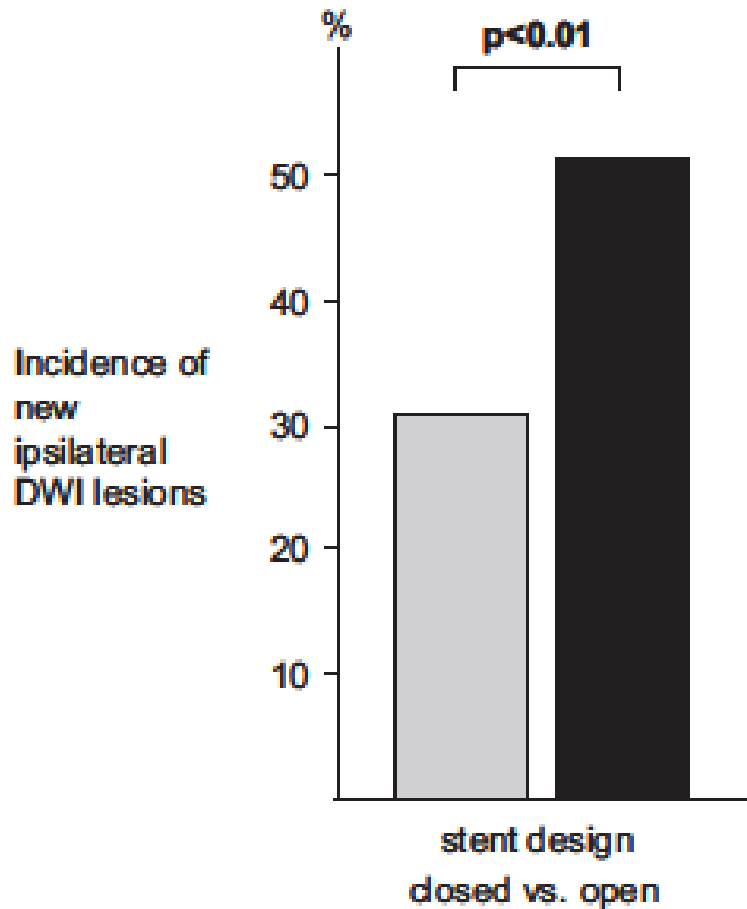
	Total population		
	Patients	All events	Post-procedural events
Open cell	937	39	32
Closed cell	2242	51	29
Total	3179	90	61
Cell type			
Open cell		4.2%	3.4%
Closed cell		2.3%	1.3%
Total	3179	2.83%	1.9%

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	<i>p</i> -value
<i>Total</i>	All events	0.018
	Post-procedural events	0.002
<i>Symptomatic</i>	All events	0.006
	Post-procedural events	<0.0001
<i>Asymptomatic</i>	All events	0.248
	Post-procedural events	0.790

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



Schnaudigel et al.
Stroke 2008;39:911

Closed Open

Sphere penetration force

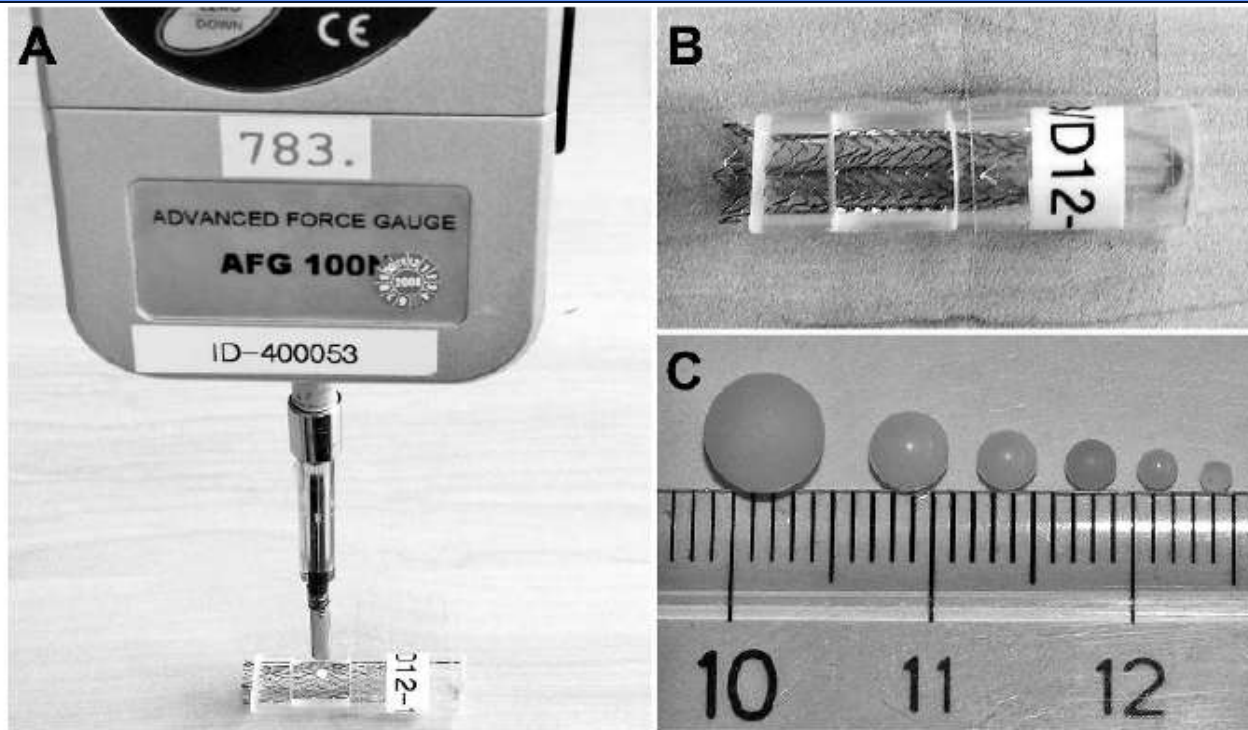
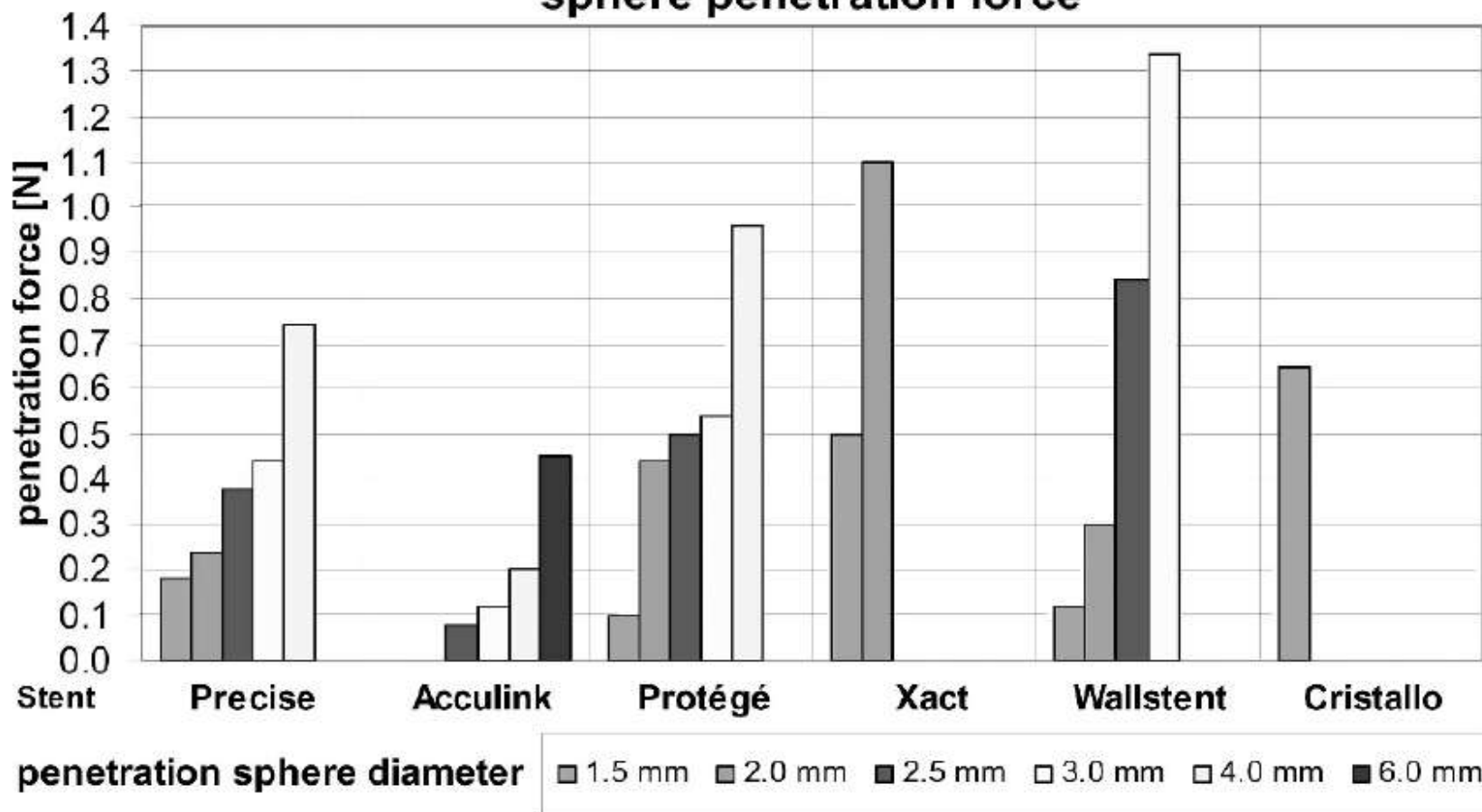
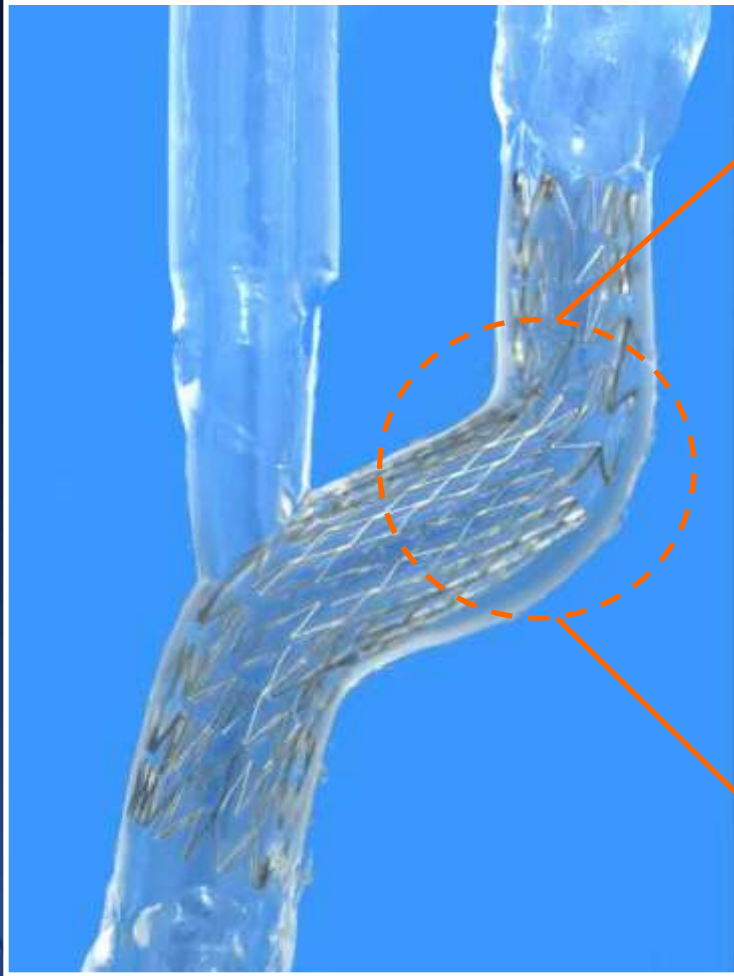


Figure 4 ♦ Measurement setup: (A) sphere penetration force, (B) stent positioned in a stiff plastic tube, and (C) test specimens: Ø 1.5 to 6.0 mm.

sphere penetration force

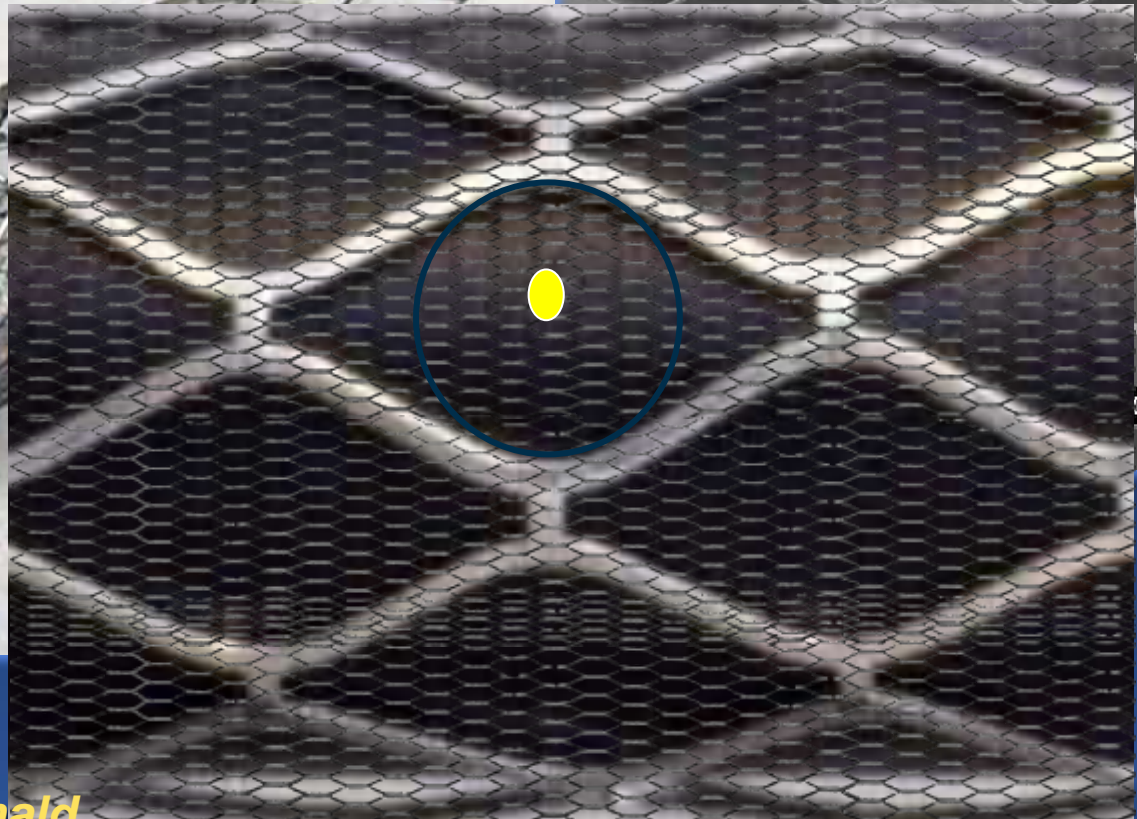
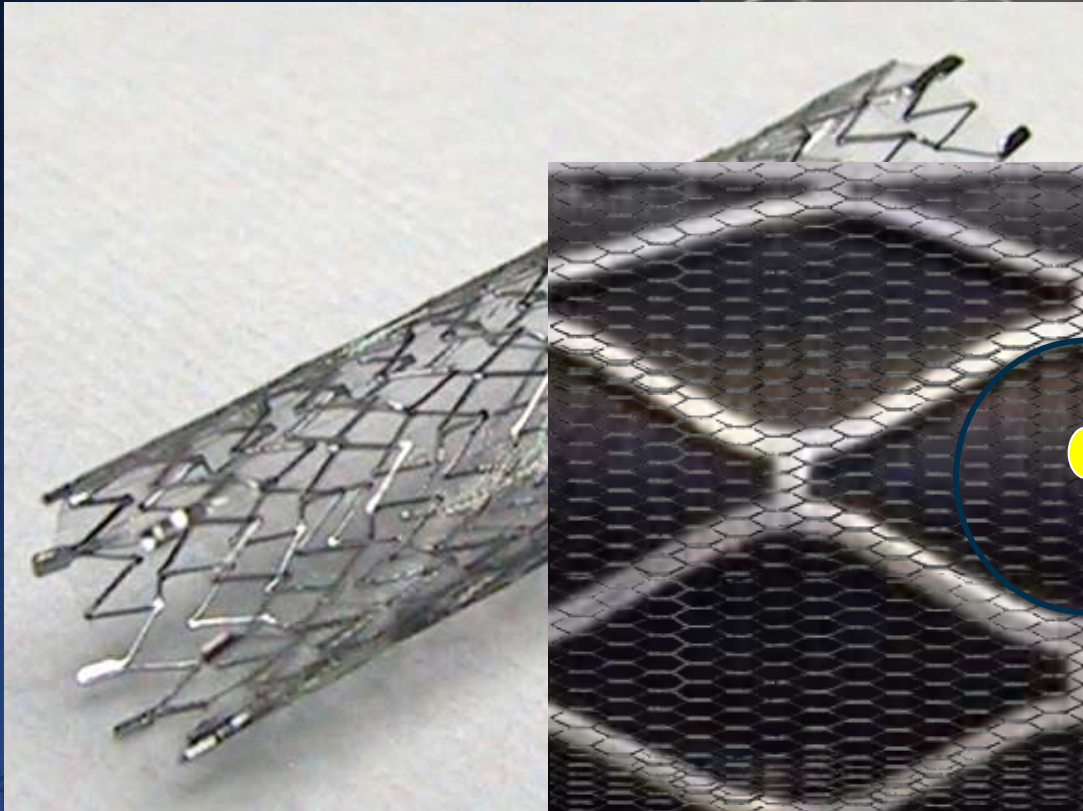


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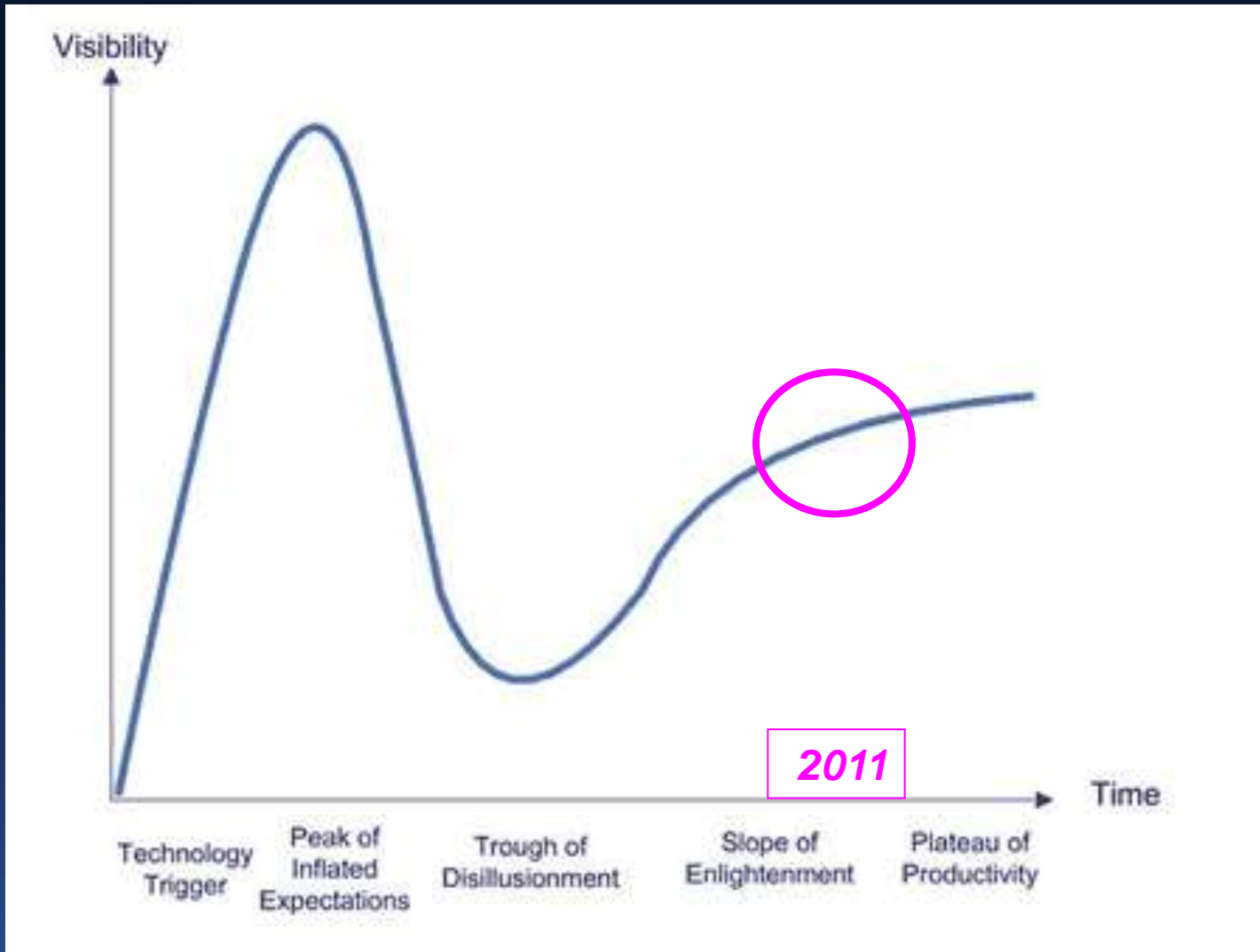


Wholey J Endovasc Ther 2009;16:178

Covered Stent Systems



*RM Bersin TCT 2008
Wholey TCT 2009
Courtesy of S. Macdonald*



Carotid Stenting

Carotid Stent Design Conclusion

- **Make the first 30 days safer**
- **Cell size matters**
 - **More events**
 - **More delayed events**
- **Future stent design may include some type of coverage**
 - **Maintain conformability**