

The background of the slide features a grayscale profile of a human head facing right. Overlaid on this profile are the carotid arteries, which are highlighted in a bright yellow-gold color. The arteries are shown in a 3D-like perspective, tracing their path from the neck up towards the brain. The overall aesthetic is medical and scientific.

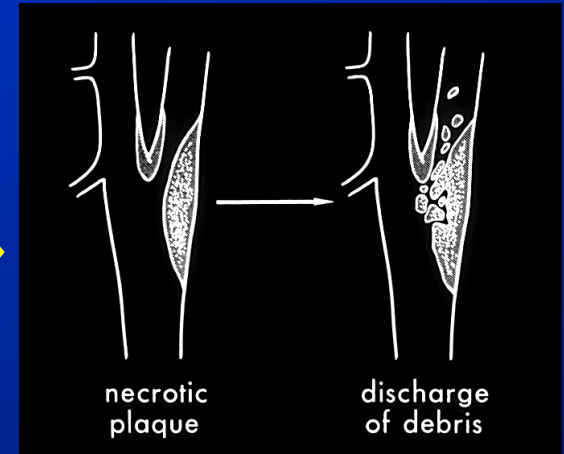
CEA vs. CAS-
*Which will be the Consensus in
Symptomatic Carotid Stenosis*

John R. Laird
Professor of Medicine
Medical Director of the Vascular Center
UC Davis Medical Center

Carotid Stenting

What a Crazy Idea!

- Pathogenesis of stroke



Does it make sense to think that expansion of luminal diameter with an uncovered stent will produce equivalent stroke prevention to removal of the plaque?

Key Questions

1. Can carotid stenting be performed with acceptably low procedural stroke and death rates for symptomatic patients?
2. Will the procedure protect against future stroke to the same degree as CEA?
3. Will the restenosis rates and need for reintervention be acceptably low?

Guidelines...

CEA: Acceptable morbidity and mortality *

Symptomatic



< 6%

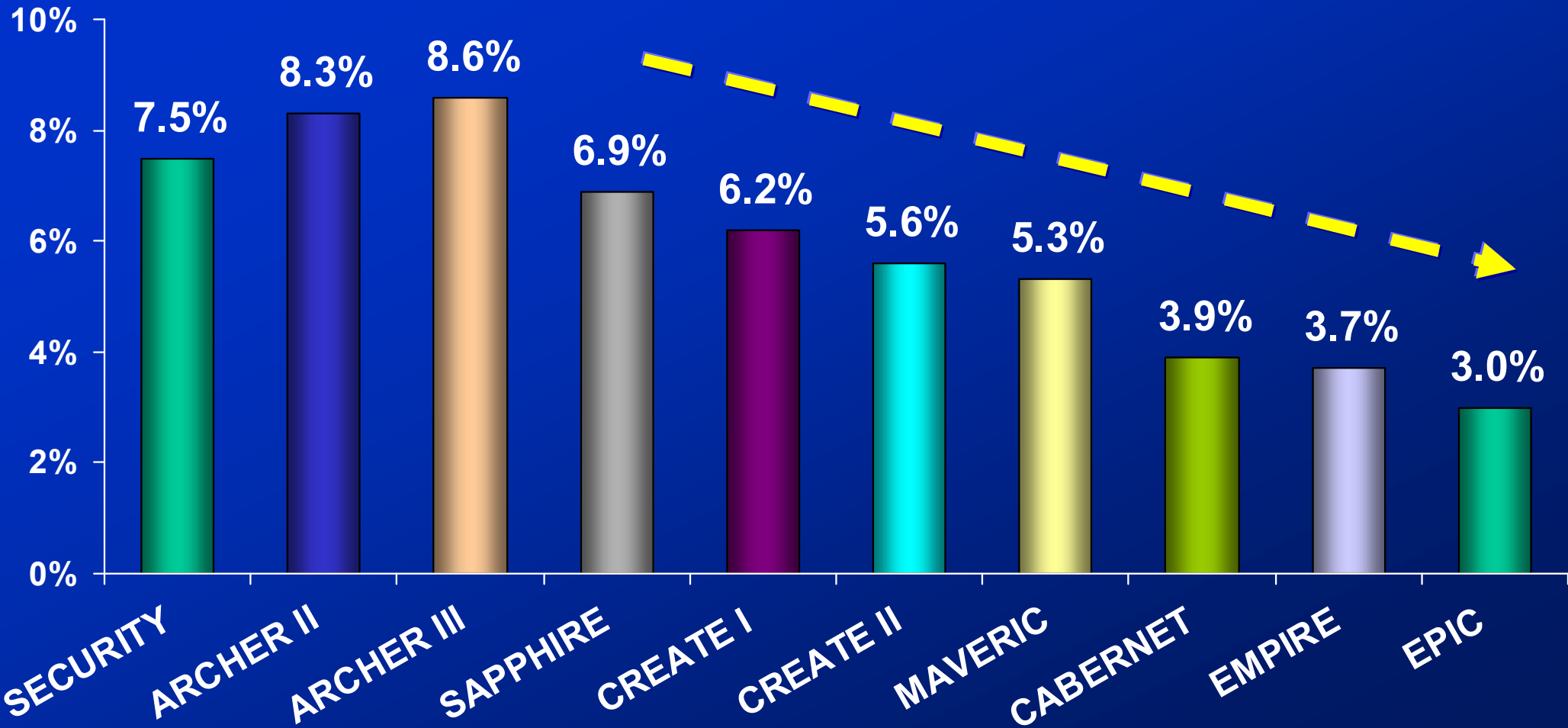
Asymptomatic

< 3%

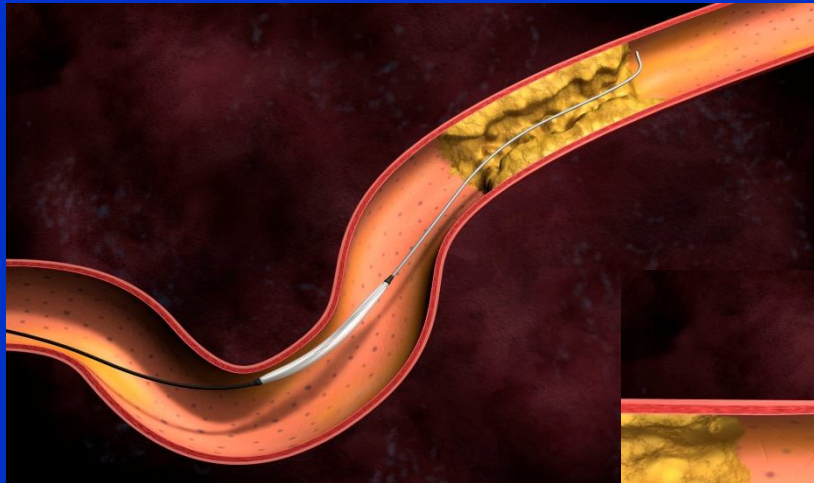
Ad Hoc Committee, AHA

30 Day Event Rates

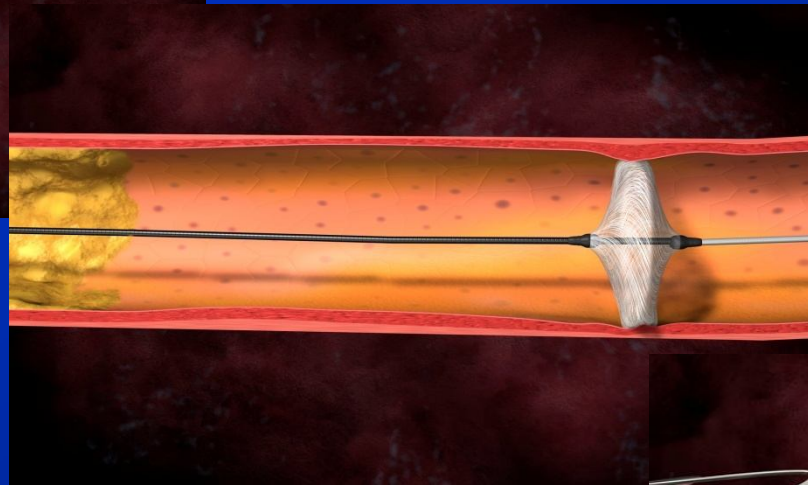
MACE (death, CVA, MI) Clinical Trials Comparison



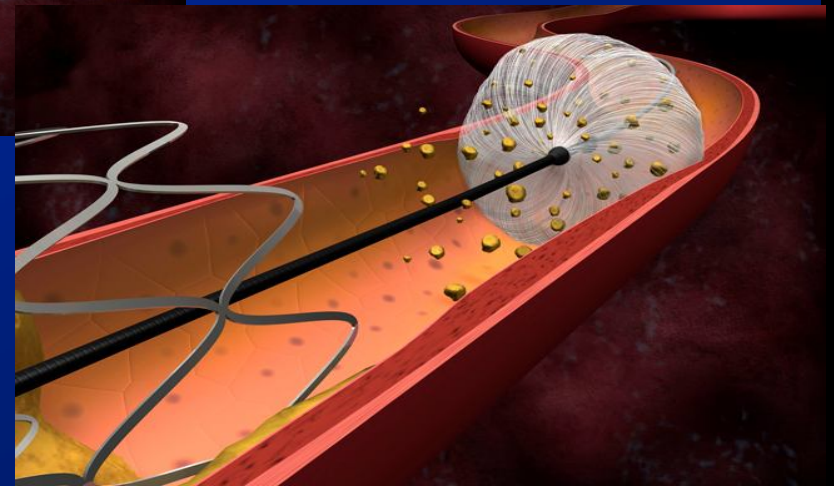
EPIC FiberNet[®] EPS



No delivery system required
with a crossing profile
1.7 to 2.9 F



Fiber-based filter conforms to
asymmetrical vessels



Particle entrapment as
small as 40 μm

EPIC Study High Risk Criteria

High Risk

N = 237

Clinical Criteria

59.6%

Anatomical Criteria

23.8%

Clinical and Anatomical Criteria

16.6%

EPIC Study

30 Day Event Rates

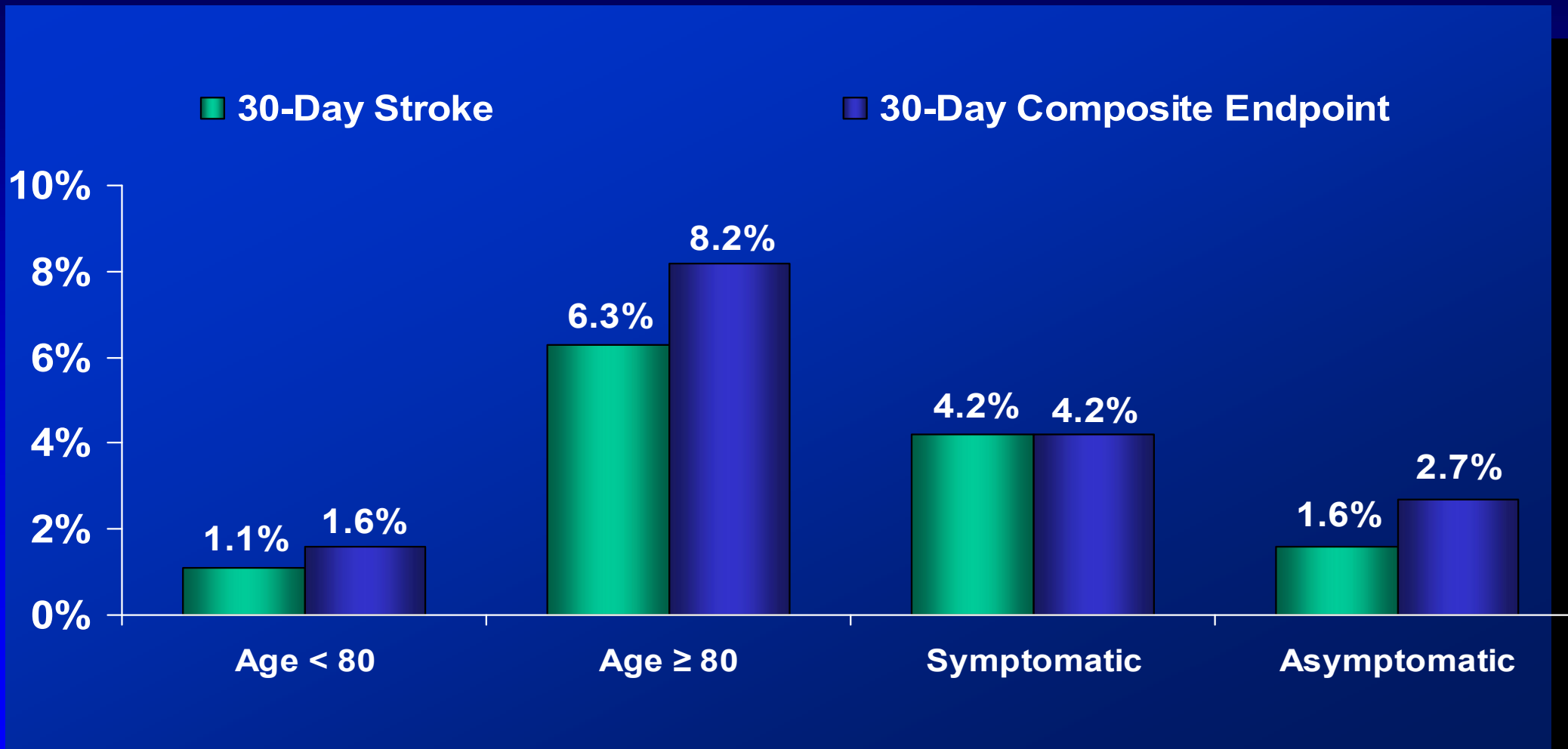
Endpoint

- All death = 0.4%
- All stroke = 2.1%
 - Major Stroke = 1.3%
 - Minor Stroke = 0.8%
- All MI = 0.9%

30 Day Composite Primary Endpoint = 3.0%

EPIC Study 30 Day Event Rates

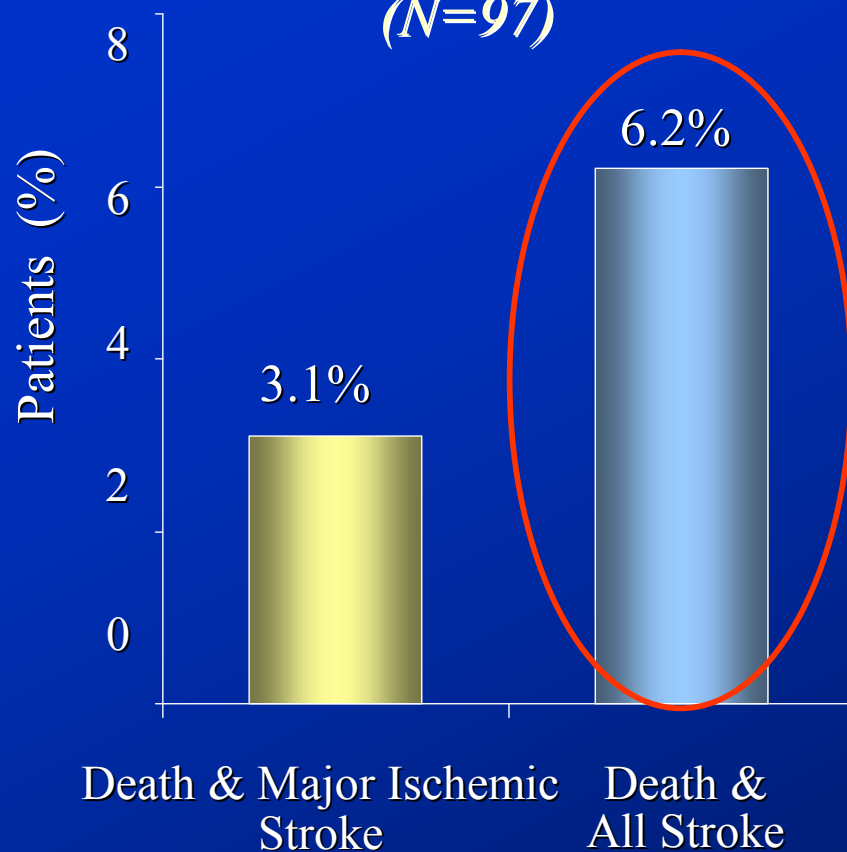
Primary Endpoint by Age and Symptom Status



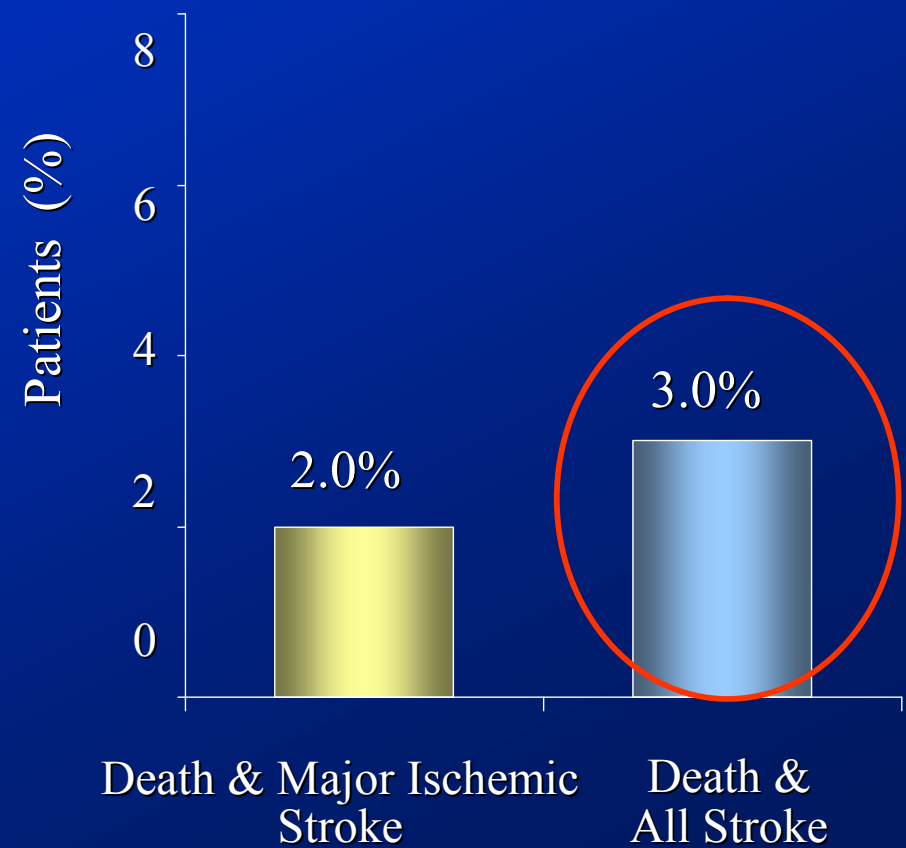
BEACH Age & Symptomatic Status

30-Day Outcomes: Death & Stroke

*Symptomatic Patients
<80 Yrs
(N=97)*

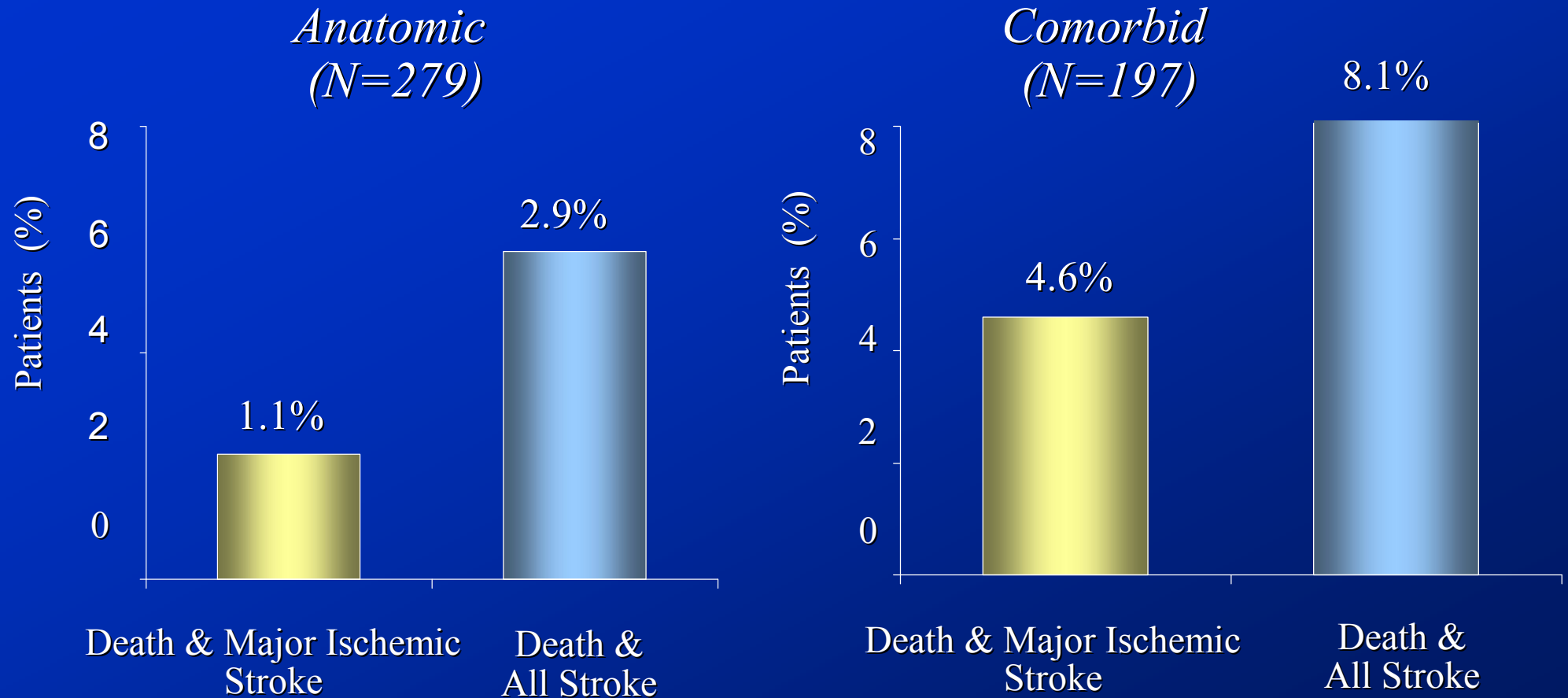


*Asymptomatic Patients <80 Yrs
(N=297)*



BEACH High Risk Groups

30-Day Outcomes

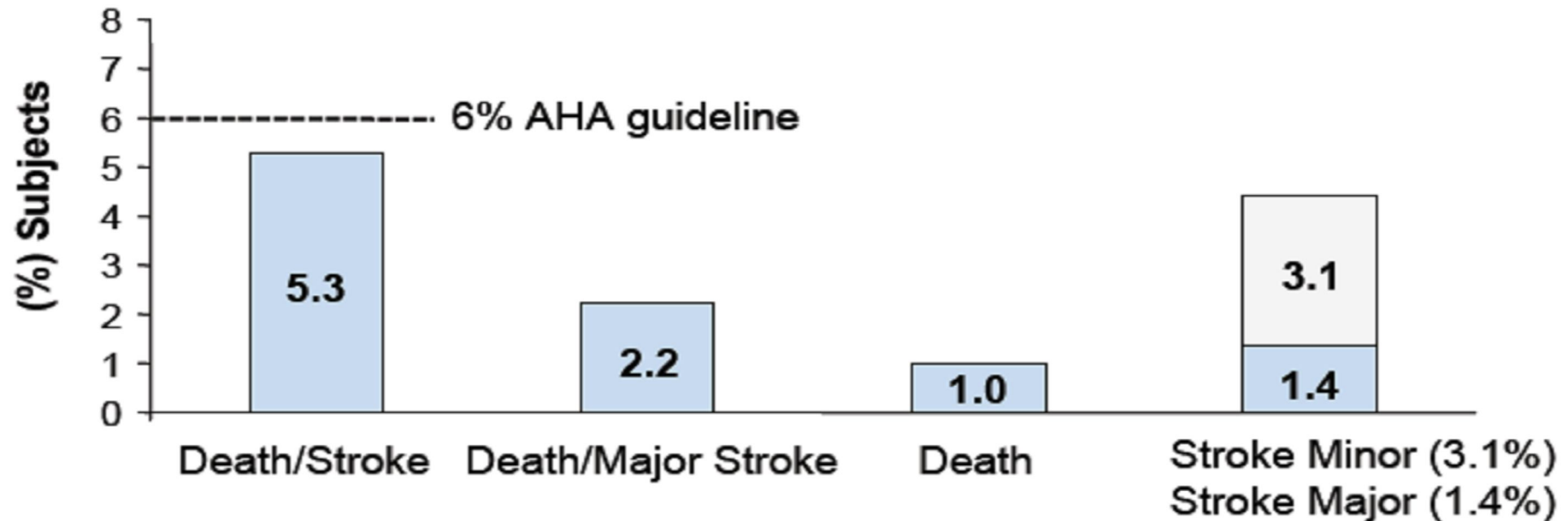


Intent to Treat Analysis

30-Day Outcomes from XACT and Capture 2 (N=6320)—All High Risk Patients

Symptomatic Patients <80

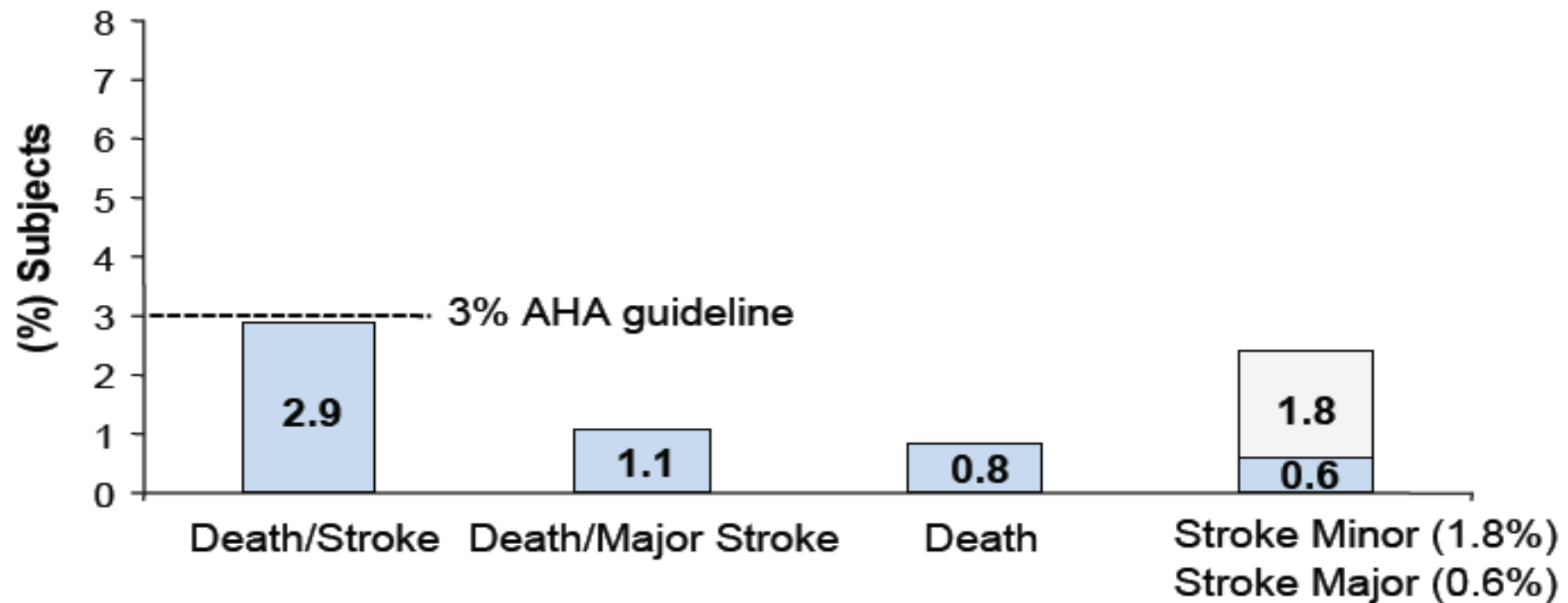
N=589



30-Day Outcomes from XACT and Capture 2 (N=6320)—All High Risk Patients

Asymptomatic Patients <80

N=4282



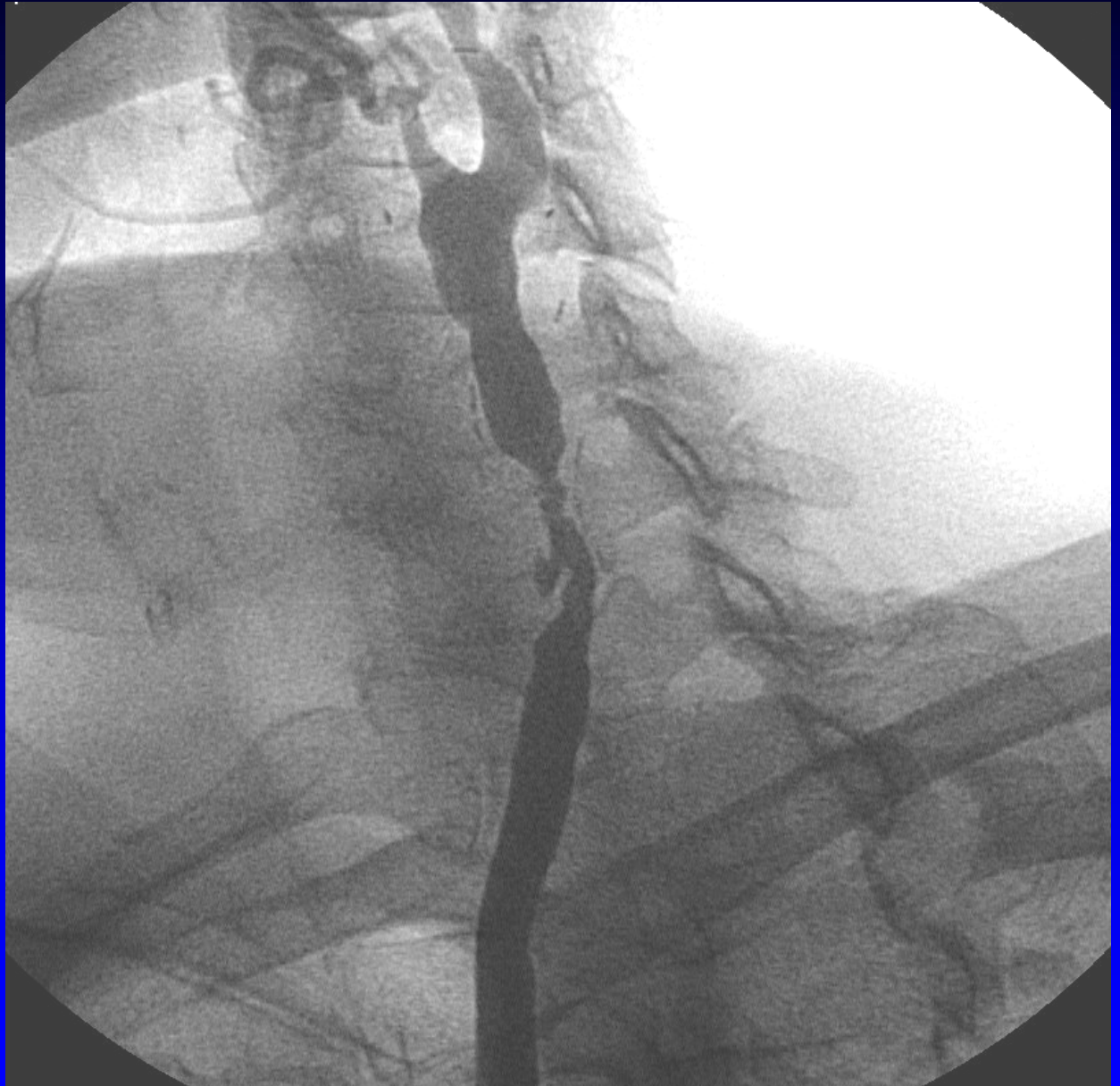
Anatomic “High Risk”

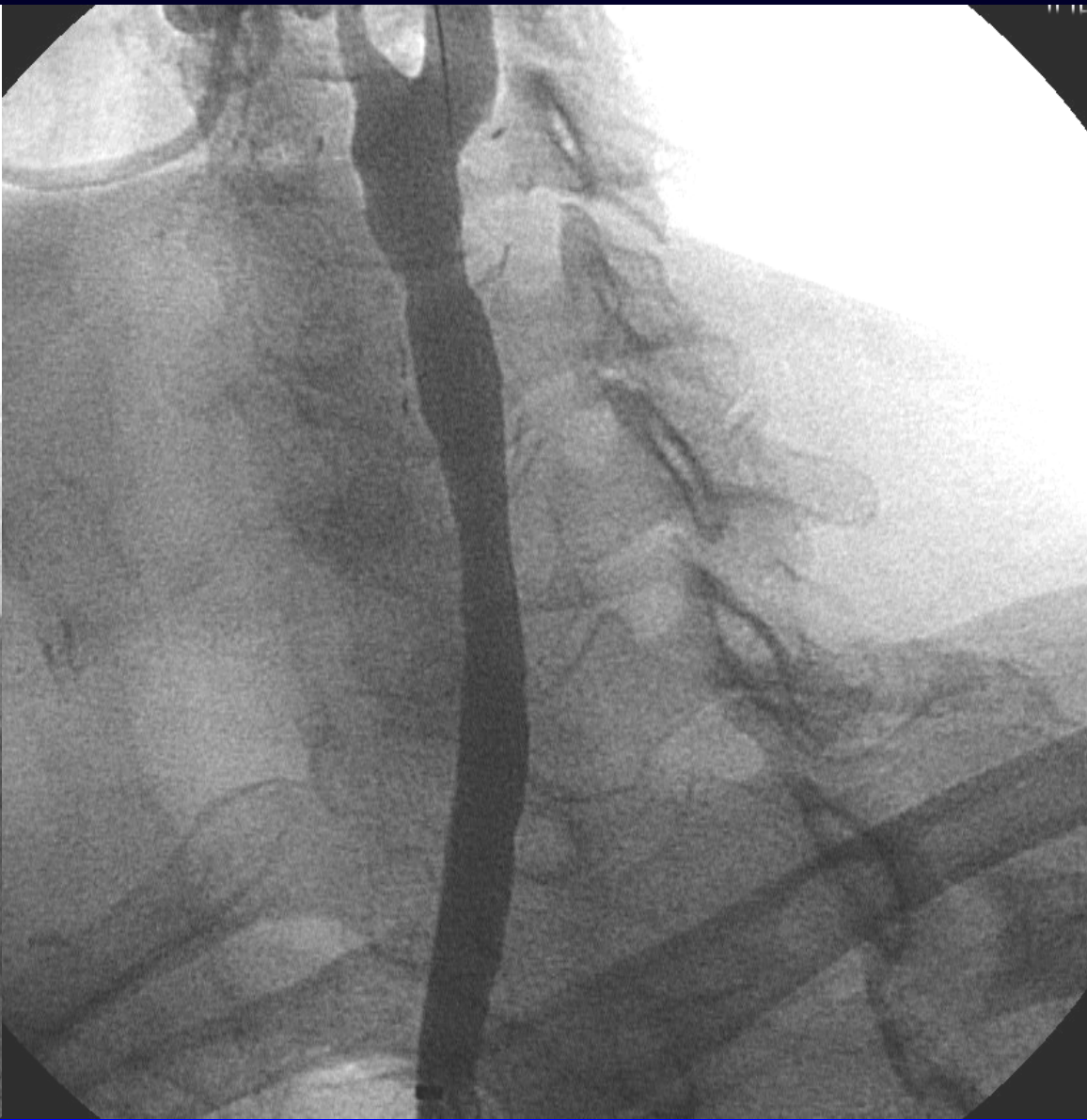
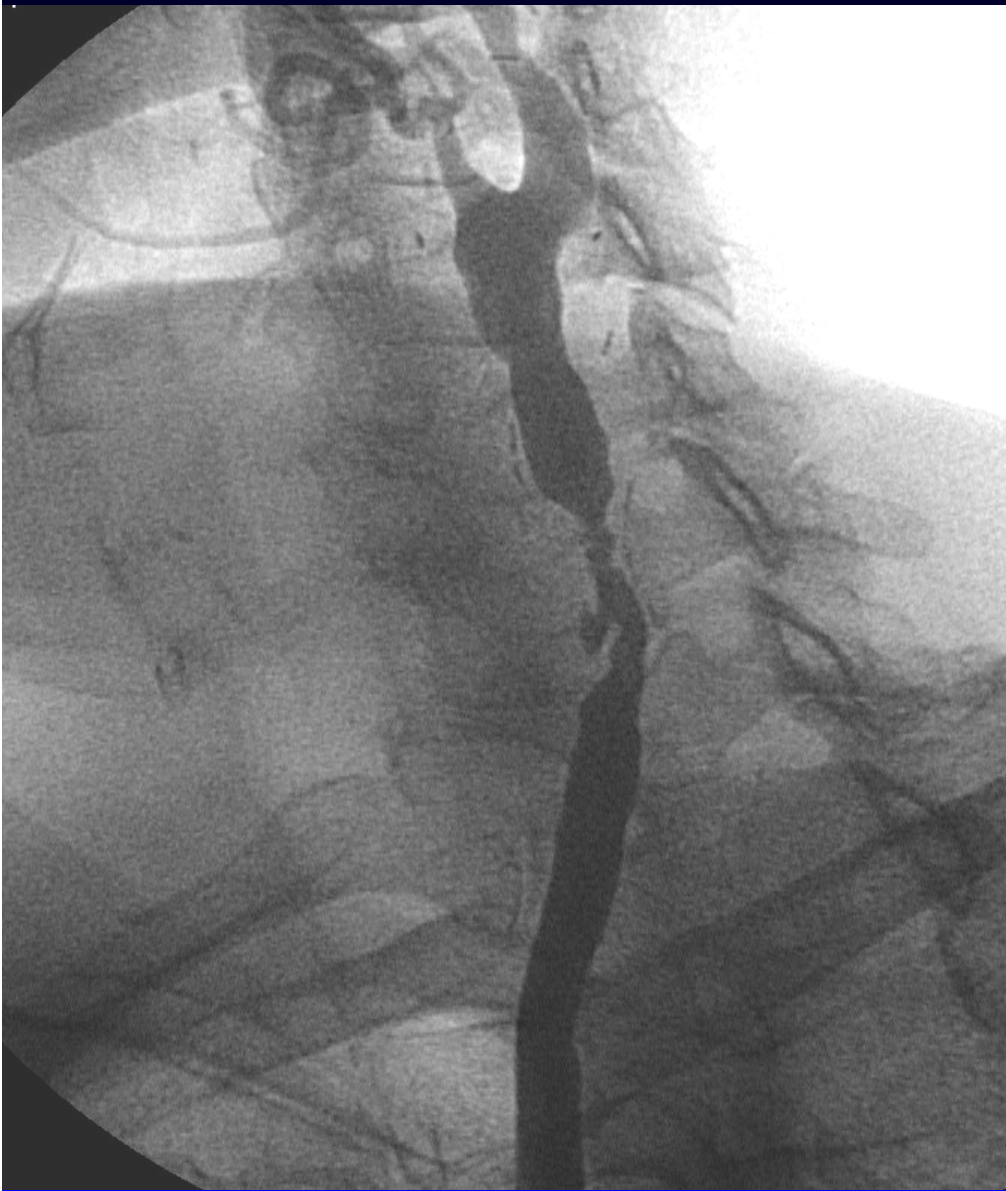
“Hostile Neck”



J Vasc Surg 2004;40:254-261

Radiation Induced Carotid Stenosis





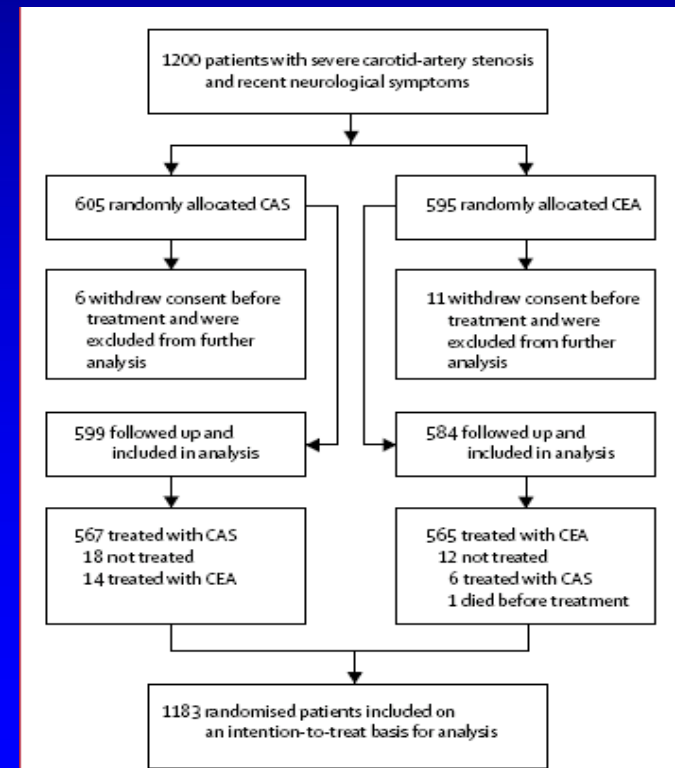
SPACE

30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial

The SPACE Collaborative Group*



1° Endpoint: 30-Day ipsilateral stroke or death (all cause) by ITT



SPACE



Study Population

randomized	1,200	
	CAS	CEA
Consent withdrawn	6	11
ITT-pop	599	584
Not treated	1	1
Switched tx	13	6
PP-pop	585	577
Protect-device	172	413
	Yes	No

SPACE



Study population

Randomised

1,200

CAS

CEA

ITT-pop

599

584

AE

41

37

6.84%

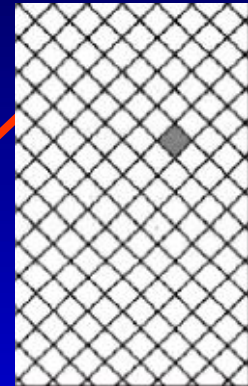
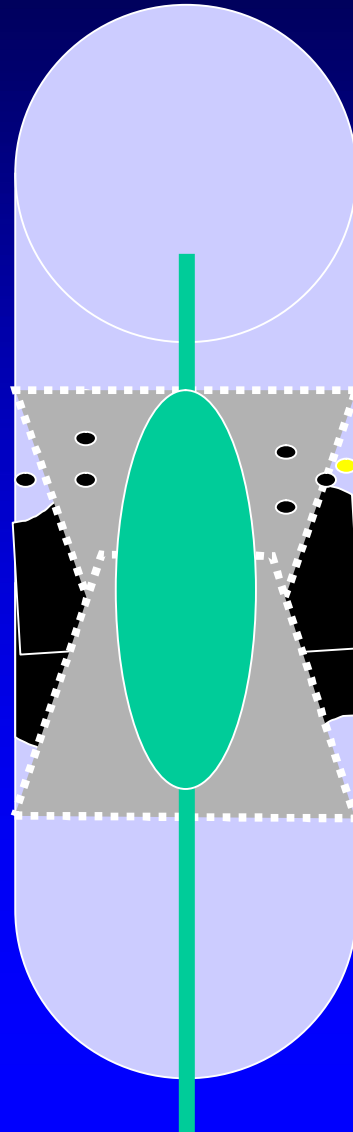
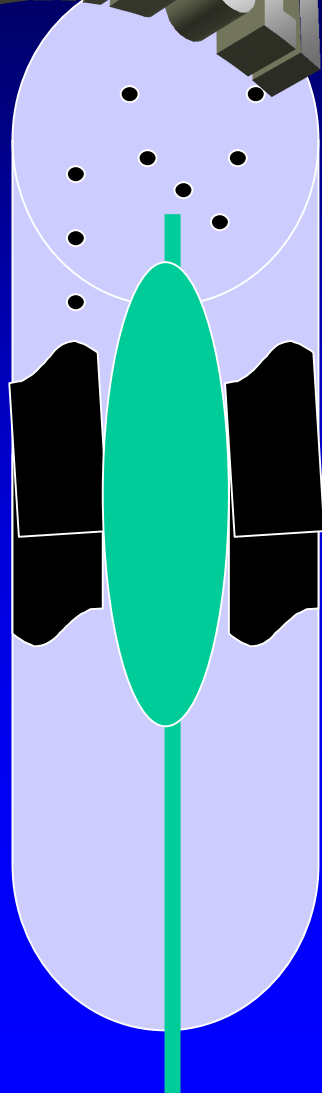
6.34%

Diff. 0.51 %

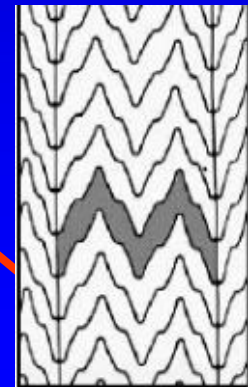
P=0.09 not significant

Does the Stent Design Influence Clinical Outcomes?

EMBOLI



Closed cell



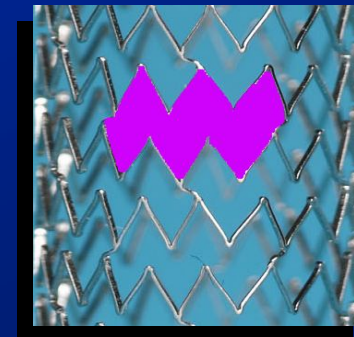
Open cell

Stent Design: Closed and Open

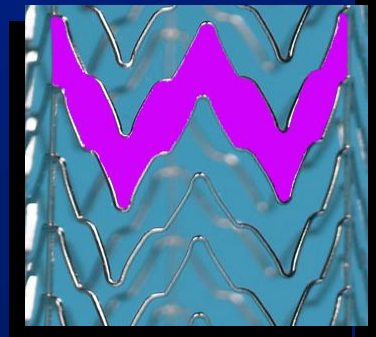
- Closed cell stent design
 - A stent with overlapping or fully connecting struts
 - Examples
 - Carotid WALLSTENT® Endoprosthesis
 - Xact® Carotid Stent
- Open cell stent design
 - A stent with connecting and non-connecting struts
 - Examples
 - Precise® PRO Rx Nitinol Stent System
 - RX Acculink® Carotid Stent



Carotid WALLSTENT
Endoprosthesis



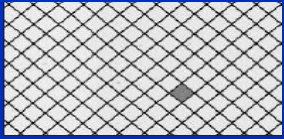

Precise PRO Rx
Nitinol Stent System



RX Acculink
Carotid Stent

SPACE

Influence of Stent Cell Design on Adverse Events

Cell design	Total Population	Without protection	With protection
Closed Cell 	5.9% (26/437)	5.8% (21/362)	6.7% (5/75)
Open Cell 	11% (14/127)	12.3% (7/57)	10% (7/70)

(1214 pat.)

P = 0.075
Fischer Test

P = 0.084
Fischer Test

P = 0.55
Fischer Test

Carotid Stent Design and Outcomes

Closed Cell vs. Open Cell

“Stent design” based analysis

ALL EVENTS	Total population		Symptomatic		Asymptomatic	
	n/N	%	n/N	%	n/N	%
Closed	51/2242	2.3%	21/934	2.2%	30/1308	2.3%
Open	39/937	4.2%	27/383	7.0%	12/554	2.2%
TOTAL	90/3179	2.8%	48/1317	3.6%	42/1862	2.3%

$p=0.005$

$p<0.0001$

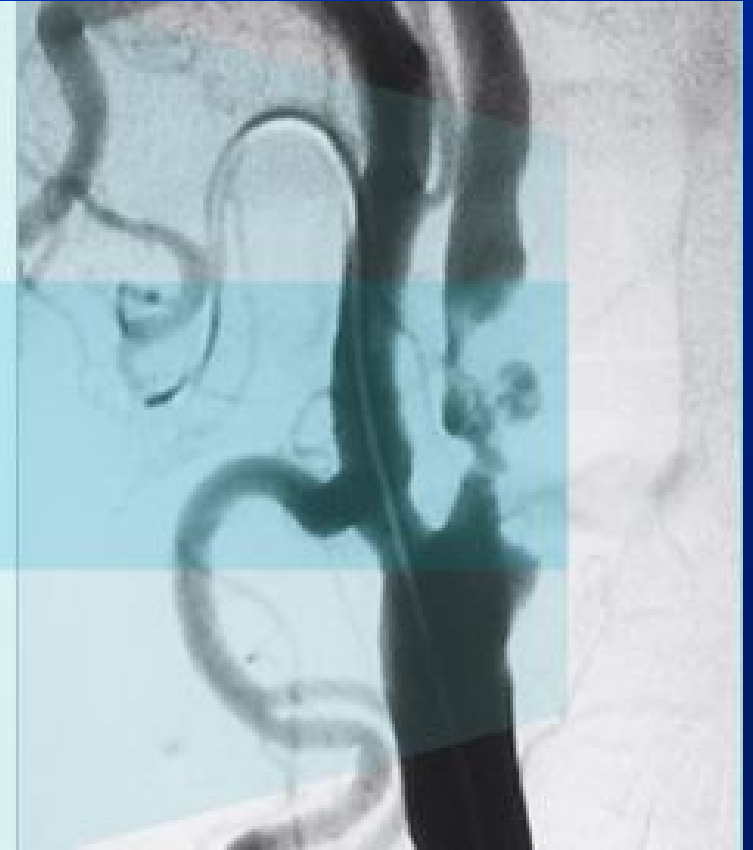
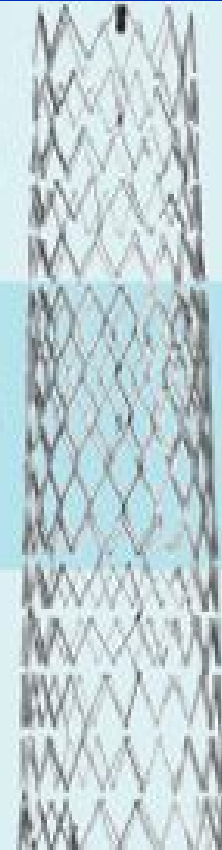
$p=1.00$

Evolution of Closed Cell and Hybrid Carotid Stent Designs



Open cell design in the distal and proximal sections enhance conformability and reduce radial force in healthy vessel segments

Closed cell design in the central part secures the appropriate scaffolding and prevents plaque prolapse



Long-Term Results of CAS vs. CEA

- EVA-3S 4 Year Follow-up (Lancet Neurology 2008;10:885-92)
 - “After the peri-procedural period, the risk of ipsilateral stroke was similar in both groups”
- SPACE 2 Year Follow-up (Lancet Neurology 2008;10:893-902)
 - At 2 years, “ipsilateral stroke and peri-procedural stroke and death do not differ between carotid stenting and CEA groups.”

The NEW ENGLAND JOURNAL of MEDICINE

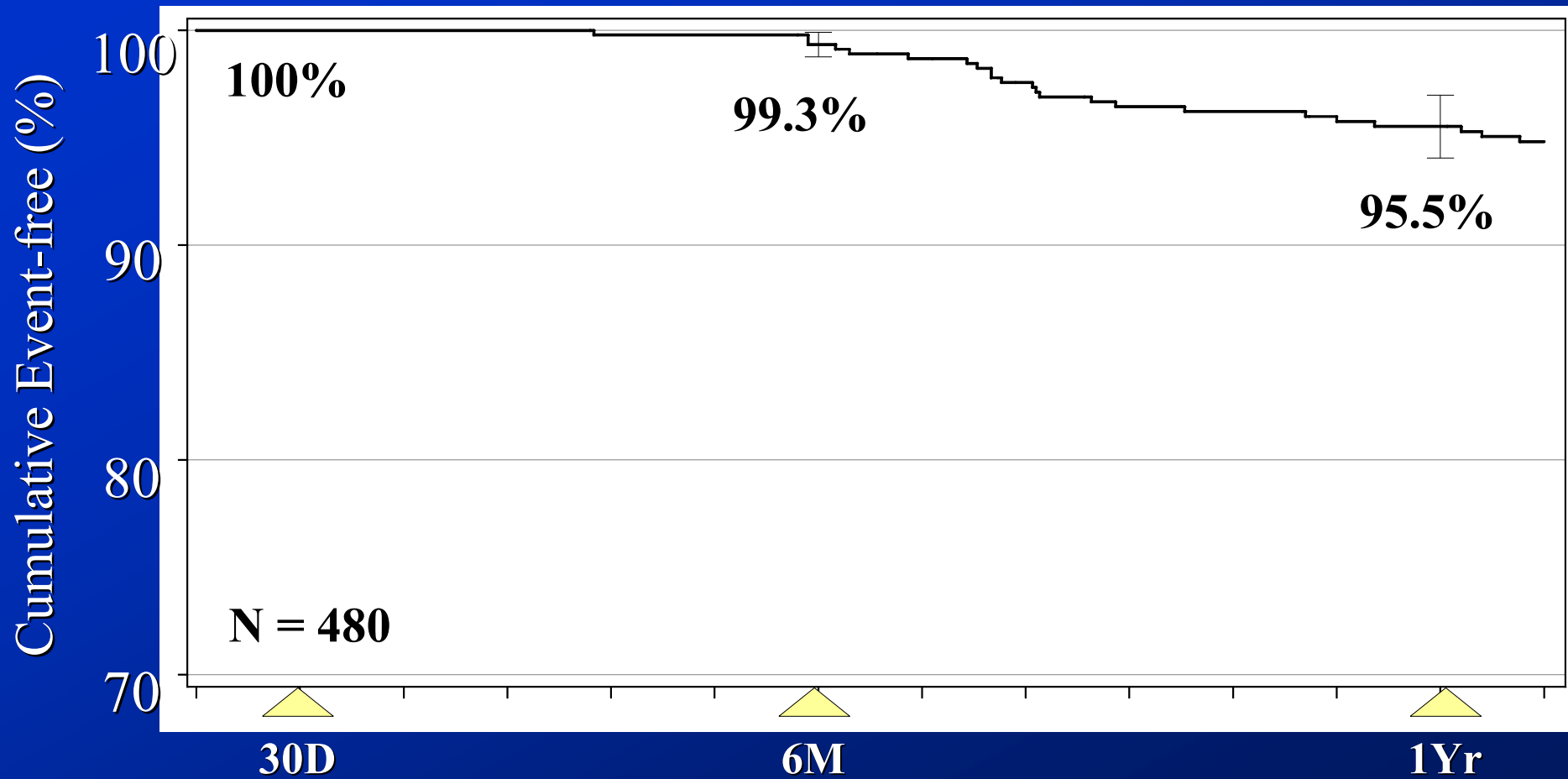
ORIGINAL ARTICLE

CONCLUSIONS

In our trial of patients with severe carotid artery stenosis and increased surgical risk, no significant difference could be shown in long-term outcomes between patients who underwent carotid artery stenting with an emboli-protection device and those who underwent endarterectomy. (ClinicalTrials.gov number, NCT00231270.)

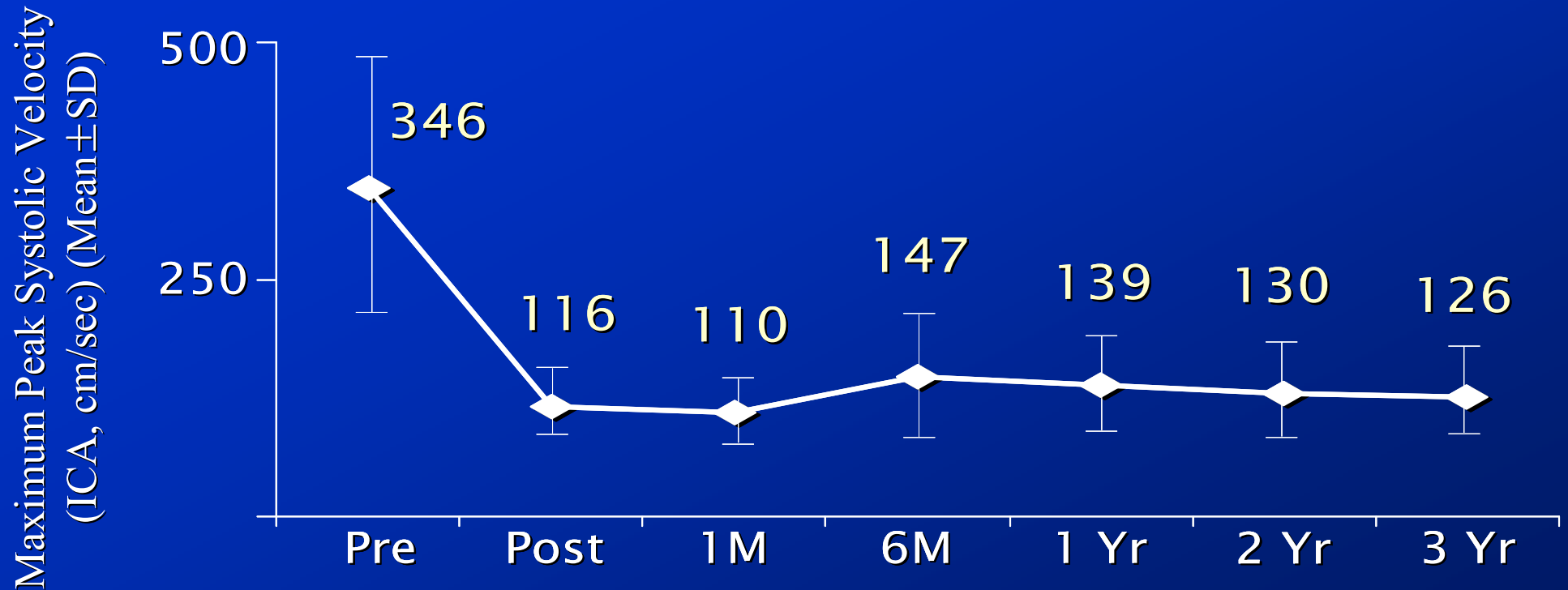
Gary Ansel, M.D., Neil E. Strickman, M.D., Hong Wang, M.D., M.P.H.,
Sidney A. Cohen, M.D., Ph.D., Joseph M. Massaro, Ph.D.,
and Donald E. Cutlip, M.D., for the SAPPHIRE Investigators*

BEACH Freedom from Target Vessel Revascularization Results through 1 yr



BEACH Ultrasound: Continued Stent Patency

No progressive restenosis from 6 mos to 3 yr



Pre-procedure, N=436; Post procedure, N=452; 1M, N=440; 6M, N=406; 1 Y, N=370

Summary

- Peri-procedural results with carotid stenting continue to improve with improving techniques, better equipment, and increasing operator experience
- Carotid stenting and CEA offer similar long-term protection against stroke
- Restenosis and the need for reintervention following carotid stenting are very low

Summary

- Carotid stenting is the preferred technique for symptomatic patients with anatomic high risk for CEA
- Procedure should still be performed with caution in symptomatic patients > 80 years of age
- Equipment/technique may make a difference:
 - Closed cell design
 - Proximal protection

Carotid Revascularization Endarterectomy vs Stenting Trial



CREST

Carotid Revascularization
Endarterectomy vs. Stenting Trial

Grant Number: 2 R01 NS038384-07

Thomas G. Brott, MD, PI
Robert Hobson, II, MD, PI 1999-2007