

The High Surgical Risk
BEACH Trial:
Two-year Follow-up
after Carotid Stent Placement

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on behalf of the BEACH Investigators
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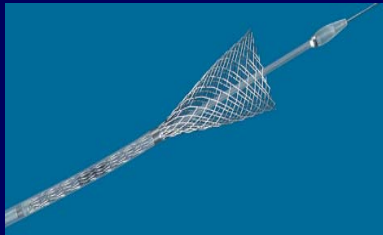
Conflict of Interest Disclosure

Michael R. Jaff, DO

- ❖ Consultant to Boston Scientific Corp.

BEACH Trial Design

- ◆ Prospective, single-arm trial (47 US sites)
- ◆ Pts at **high-risk for CEA** with stenosis in ICA, CCA, or bifurcation
- ◆ F/U (Clinical, Duplex, Neurologic): 30D; 6M; 1Yr; annually x 4
- ◆ **Roll-in Group, Pivotal Group, Bilateral Registry**



Carotid
WALLSTENT®

with



FilterWire
EX®/EZ™

Compared
to

FDA-agreed
calculated **Objective
Performance Criterion (OPC)**
based on literature review of
similar endpoints in patients
undergoing **Carotid
Endarterectomy (CEA)**

Objective: Demonstrate **non-inferiority** with composite 1° endpoint of
Non-Q MI (≤ 24 hrs); Q-MI, Death, Stroke (≤ 30 D);
Neurological Death & Ipsilateral Stroke (> 30 D-1yr).

BEACH Study Organization

Co-Principal Investigators

Christopher J. White, MD
Sriram S. Iyer, MD

Data Management and Analysis

Harvard Clinical Research
Institute (HCRI)

Site Monitoring and Compliance

J.Tyson and Associates,
Boston Scientific Corporation

Angiographic Core Lab

Brigham and Women's
Hospital, Boston MA

ECG Core Lab

Harvard Clinical Research
Institute (HCRI)

Vascular Core Lab

Vascular Ultrasound Core Lab.,
Boston MA

CT/MRI Core Lab

Perceptive Informatics, Inc.

BEACH Enrollment Criteria

Inclusion

- ◆Patients:
 - Symptomatic: Stenosis $\geq 50\%$ by angiography
 - Asymptomatic: Stenosis $\geq 80\%$ by angiography
- ◆Lesion: CCA, ICA, bifurcation
- ◆Segment reference diameter: $\geq 4.0\text{mm}$ and $\leq 9.0\text{mm}$
- ◆Vessel diameter distal to lesion: $\geq 3.5\text{mm}$ and $\leq 5.5\text{mm}$ as optimal FilterWire landing zone

Exclusion

- ◆Evolving, acute or recent stroke (21 days)
- ◆Known cardiac sources of emboli
- ◆Myocardial infarction < 72 hours
- ◆Surgery ≤ 30 days
- ◆Total occlusion of ipsilateral carotid artery
- ◆Pre-existing stent in ipsilateral carotid artery

BEACH Surgical High-risk Categories

Pivotal Group

Anatomic Risk*

- ◆ Restenosis post CEA (34.2%)
- ◆ Contralateral total occlusion (18.1%)
- ◆ Previous neck/head radiation therapy/surgery (10.8%)
- ◆ Surgically inaccessible lesions at or above C2 or below clavicle (9.2%)
- ◆ Spinal immobility of neck (7.3%)

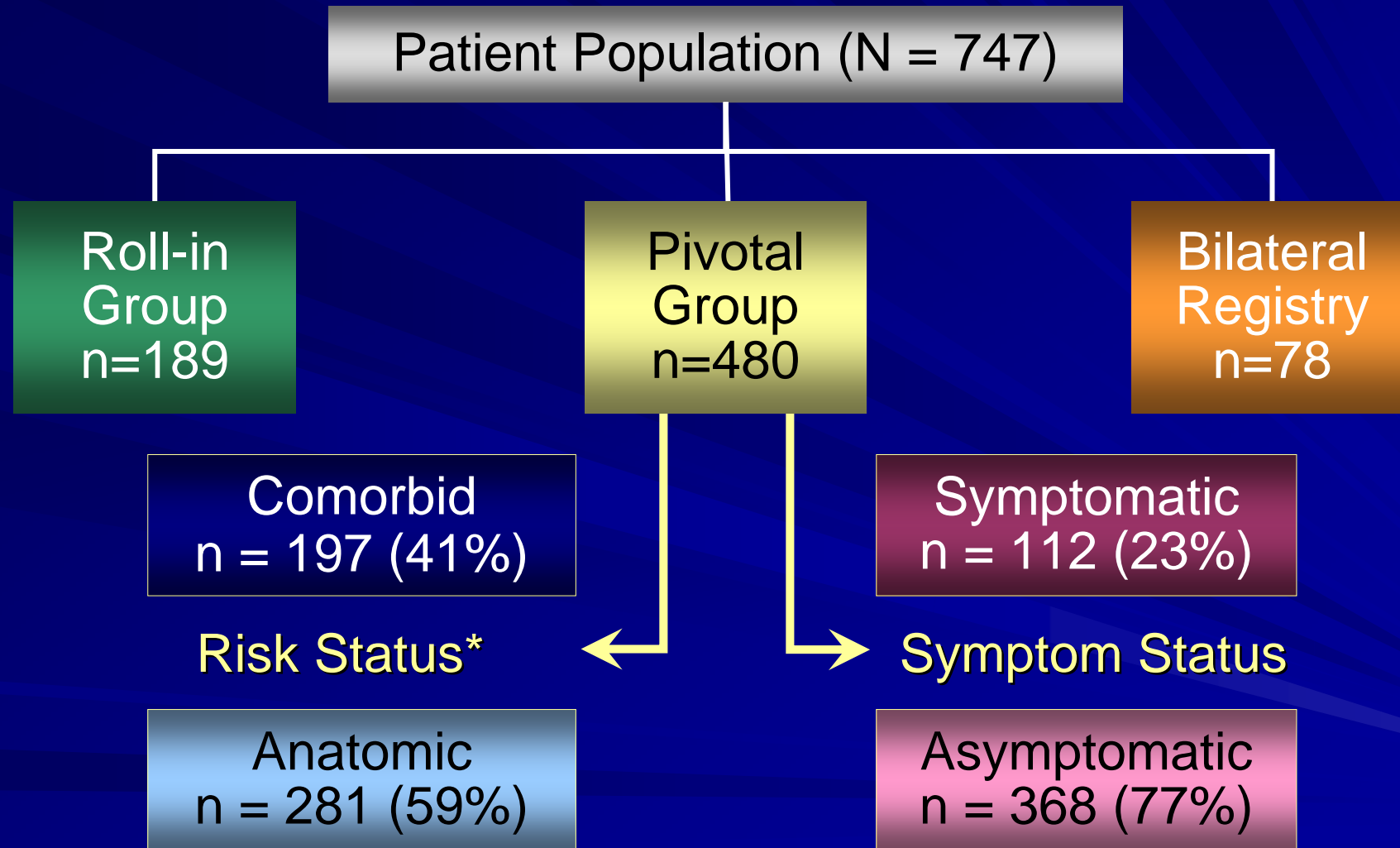
Co-Morbid Risk*

- ◆ Age ≥ 75 years[†] (39.0%)
- ◆ ≥ 2 major diseased coronary arteries with $\geq 70\%$ stenosis (21.7%)
- ◆ Unstable angina (12.5%)
- ◆ LVEF $\leq 30\%$ (12.1%)
- ◆ CHF: NYHA Class III/IV (11.7%)
- ◆ Planned valve replacement surgery /CABG post-CAS (6.5%)

* Categories above 5% in pivotal group are listed

[†] 2 criteria required

BEACH Enrollment



* 2 pts were neither

BEACH Pivotal Group

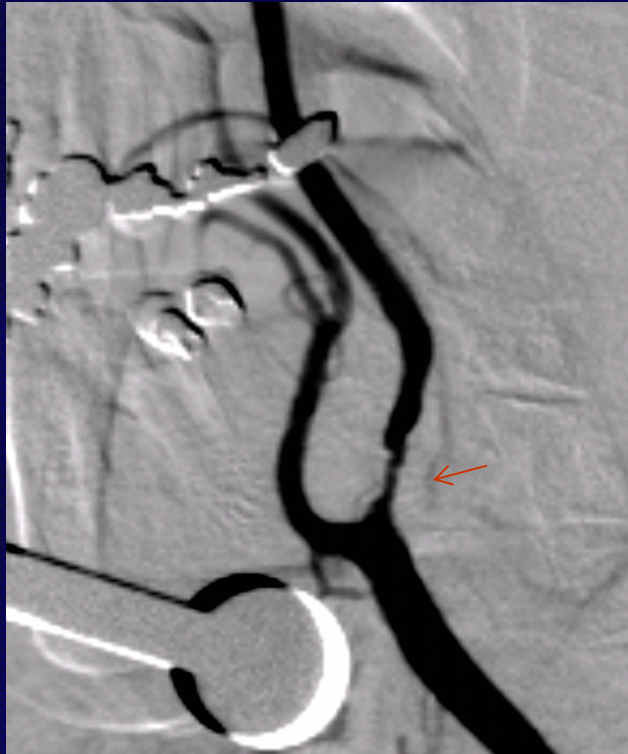
Key Demographics

N=480

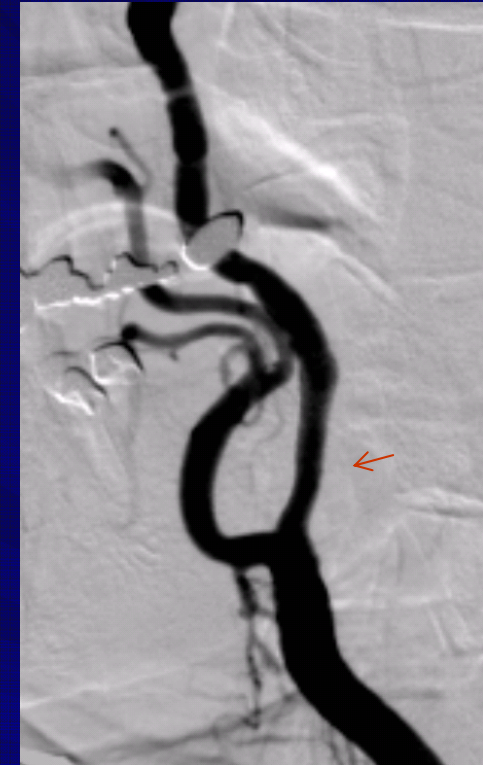
Patients	Age*	70.9±9.3
	Male gender (%)	65.2
	Previous CEA (%)	40.6
	Previous TIA (%)	30.4
	History of CVA (%)	28.1
Lesions	ICA (% pts)	88.3
	Lesion length (mm)*	15.13±7.25
	Diameter Stenosis (%)*	71.6±10.7

* Mean±SD

BEACH Pre- & Post Stenting



FilterWire &
8 × 30 mm
Carotid WALLSTENT



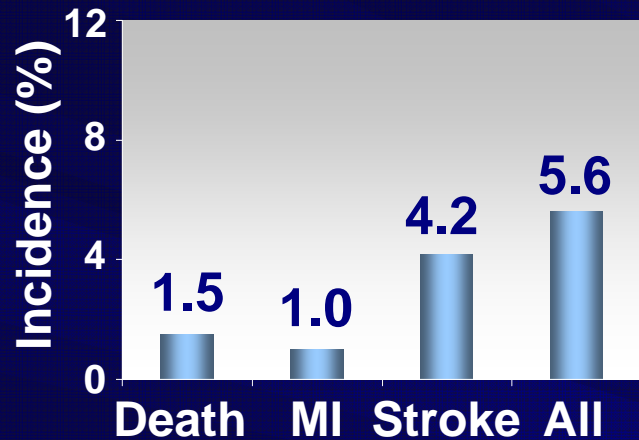
72 yr old man; TIA (amaurosis fugax); >70% Stenosis (Duplex) in RICA;
High surgical risk for prior neck surgery & radiation for laryngeal cancer;
Post procedure NIHSS = 0

Courtesy C. J. White, MD

BEACH Pivotal Group

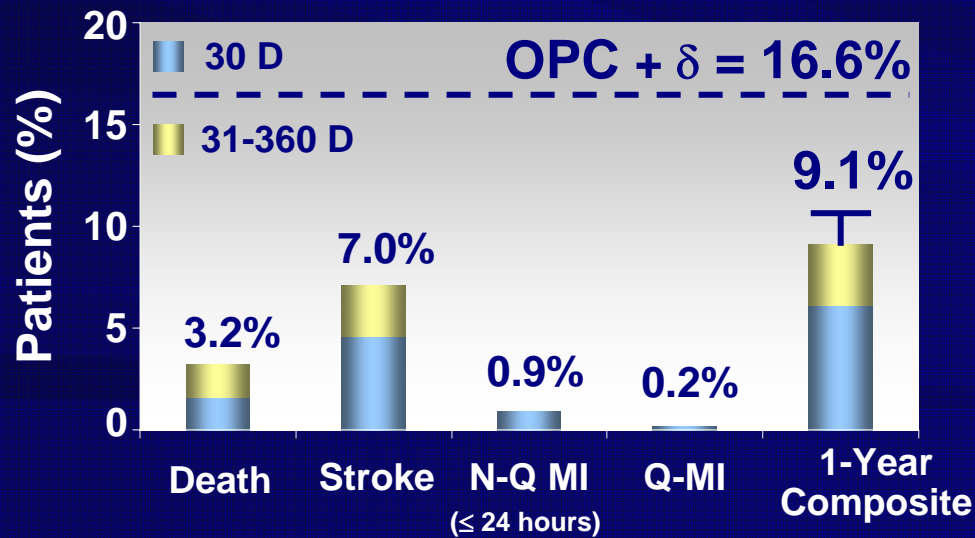
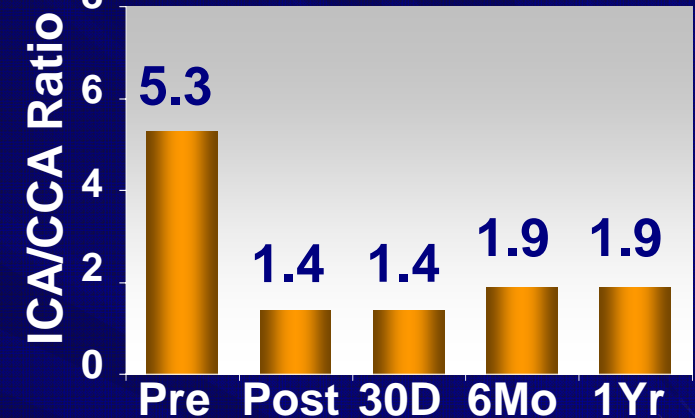
Non-inferiority established

Acceptable 30-Day Safety



BEACH
at
1 Year

Significant Hemodynamic Improvement



Primary endpoint well below OPC

BEACH Trial at 2 Years

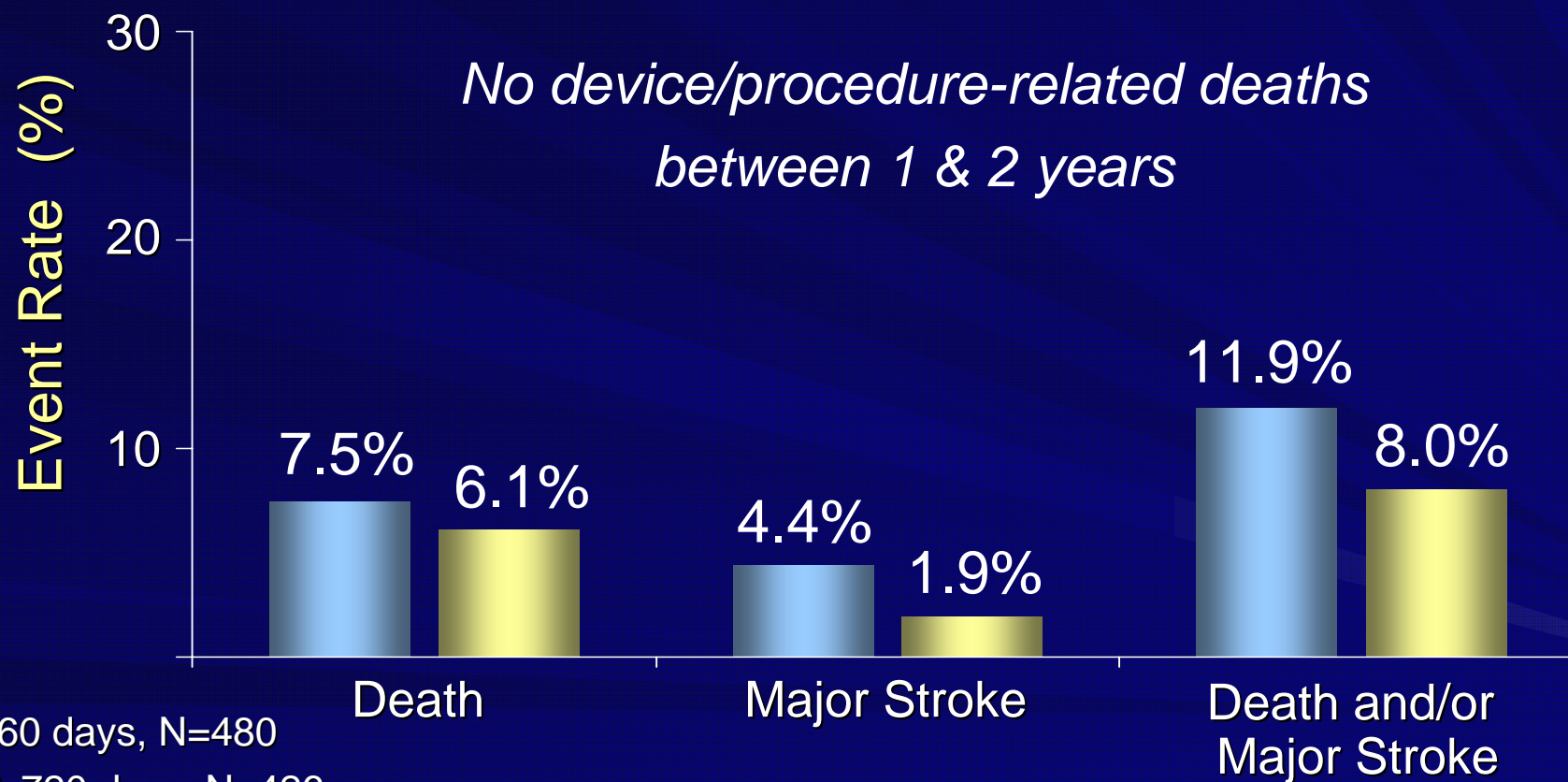
Are the benefits of the Carotid WALLSTENT
durable to 2 years without added
long-term safety risks?

BEACH Mortality & Major Stroke

Lower event rates between 1 & 2 years

Pivotal Group

0-1 Yr* 1-2 Yrs†



*0-360 days, N=480

†361-720 days, N=426

BEACH Stroke Breakdown

Decline in overall stroke risk over time

Per Patient

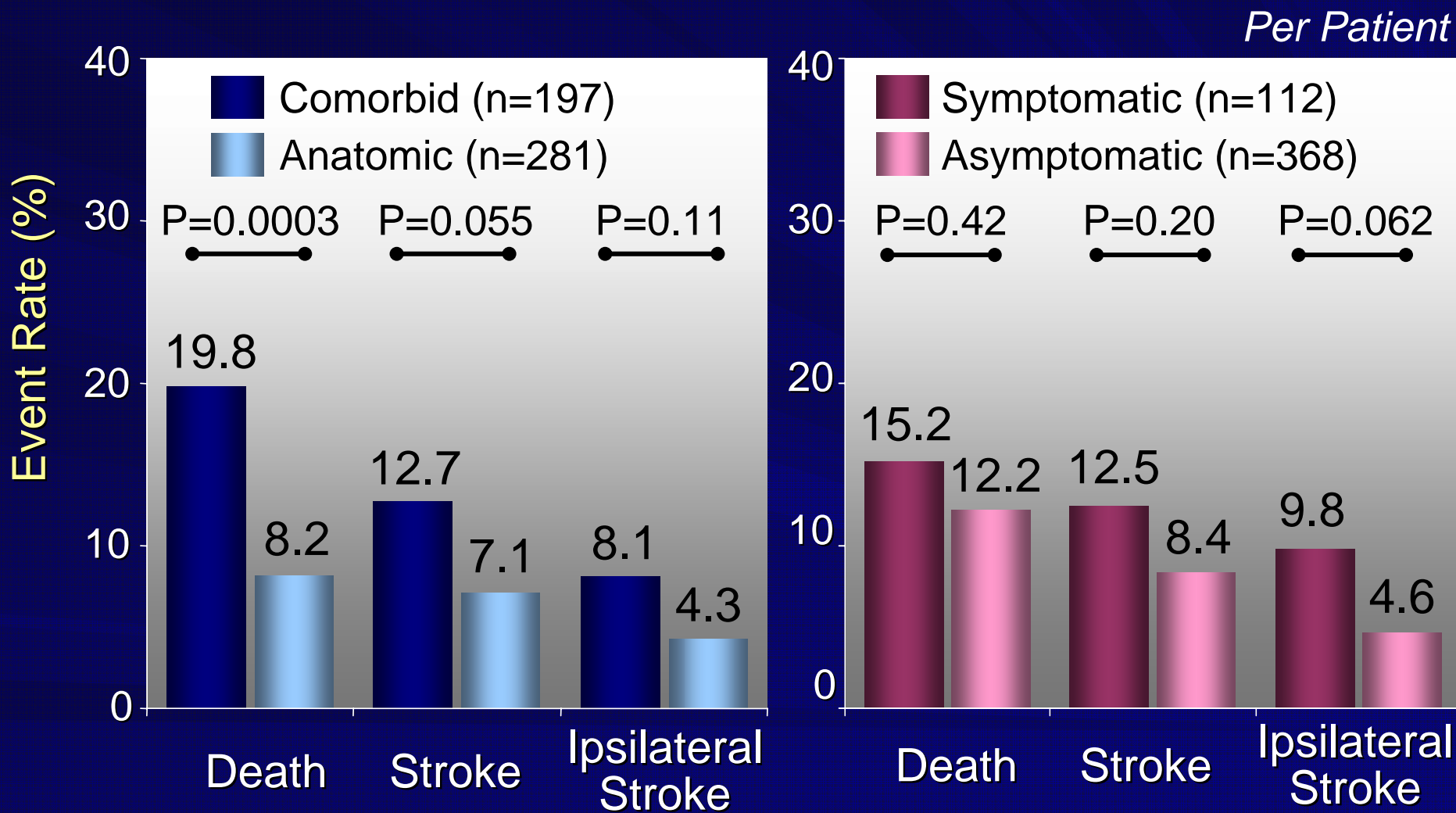
Pivotal Group

	Ipsilateral	Contralateral	Total
0-30 Days*	3.1%	1.0%	4.2%
31 D-1 Yr [†]	2.3%	1.7%	4.0%
>1 Yr-2 Yrs [§]	0.94%	1.4%	2.3%

*0-30 days, N=480; [†]31-360 days, N=470; [§]361-720 days, N=426

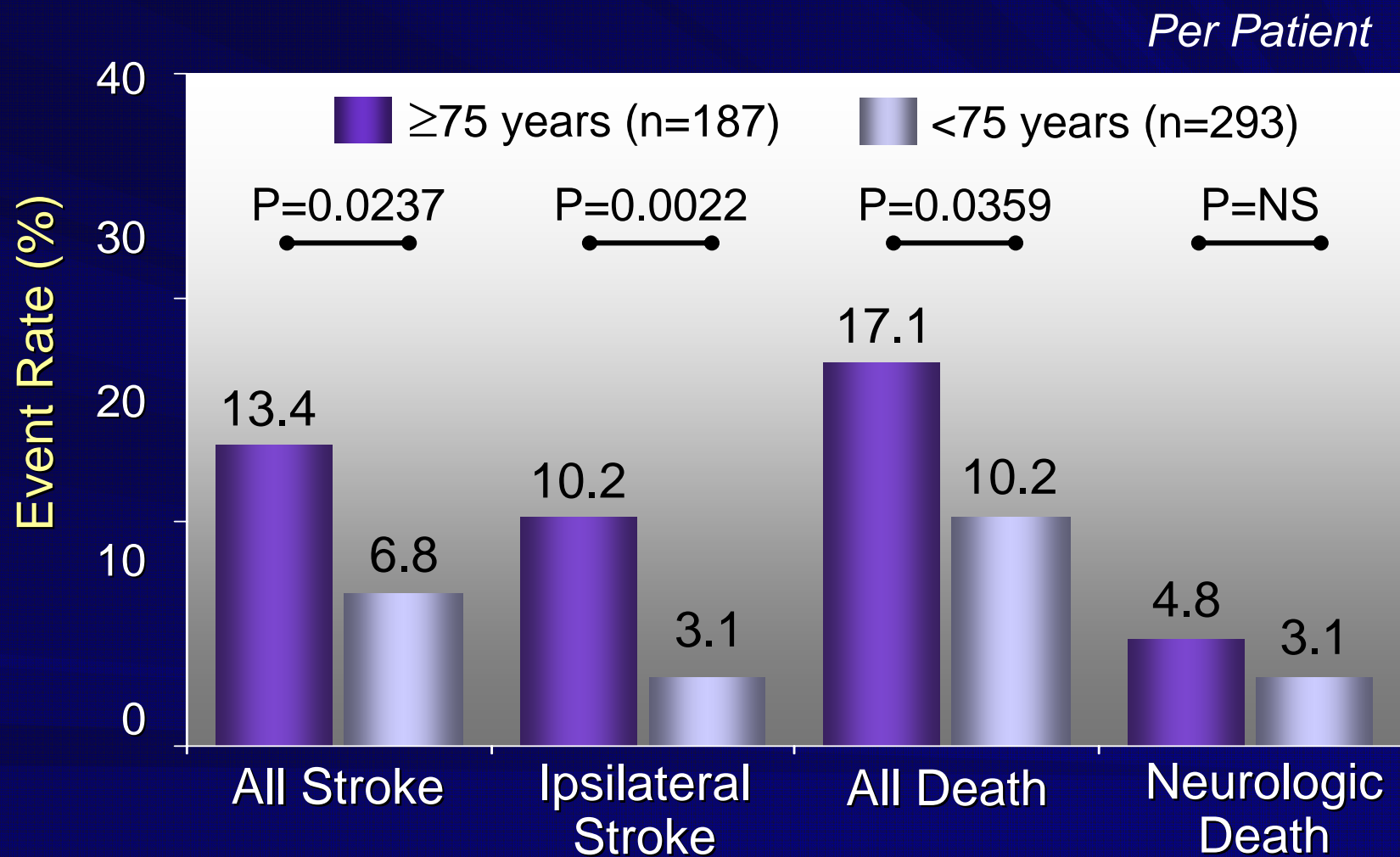
BEACH Pivotal Group at 2 Years

Higher event rates in comorbid & symptomatic patients

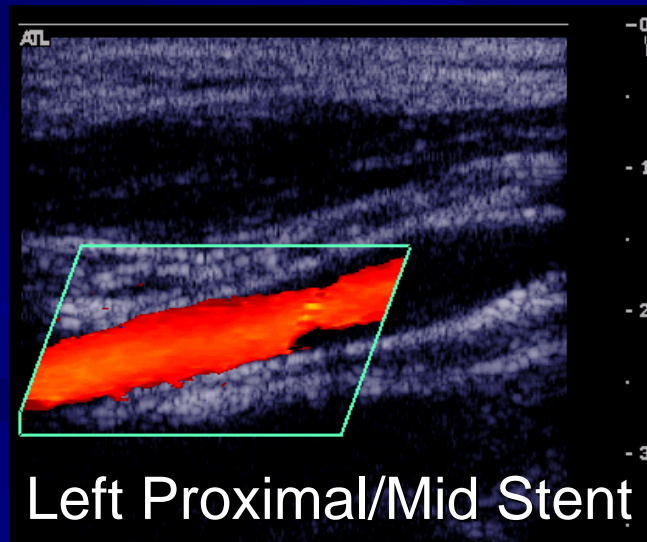
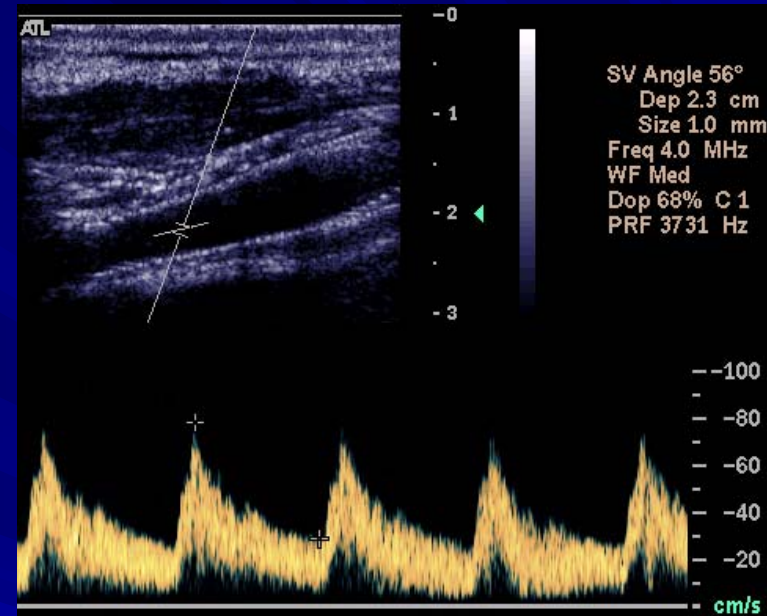


BEACH Pivotal Group at 2 Years

Higher incidence of stroke & death in the elderly



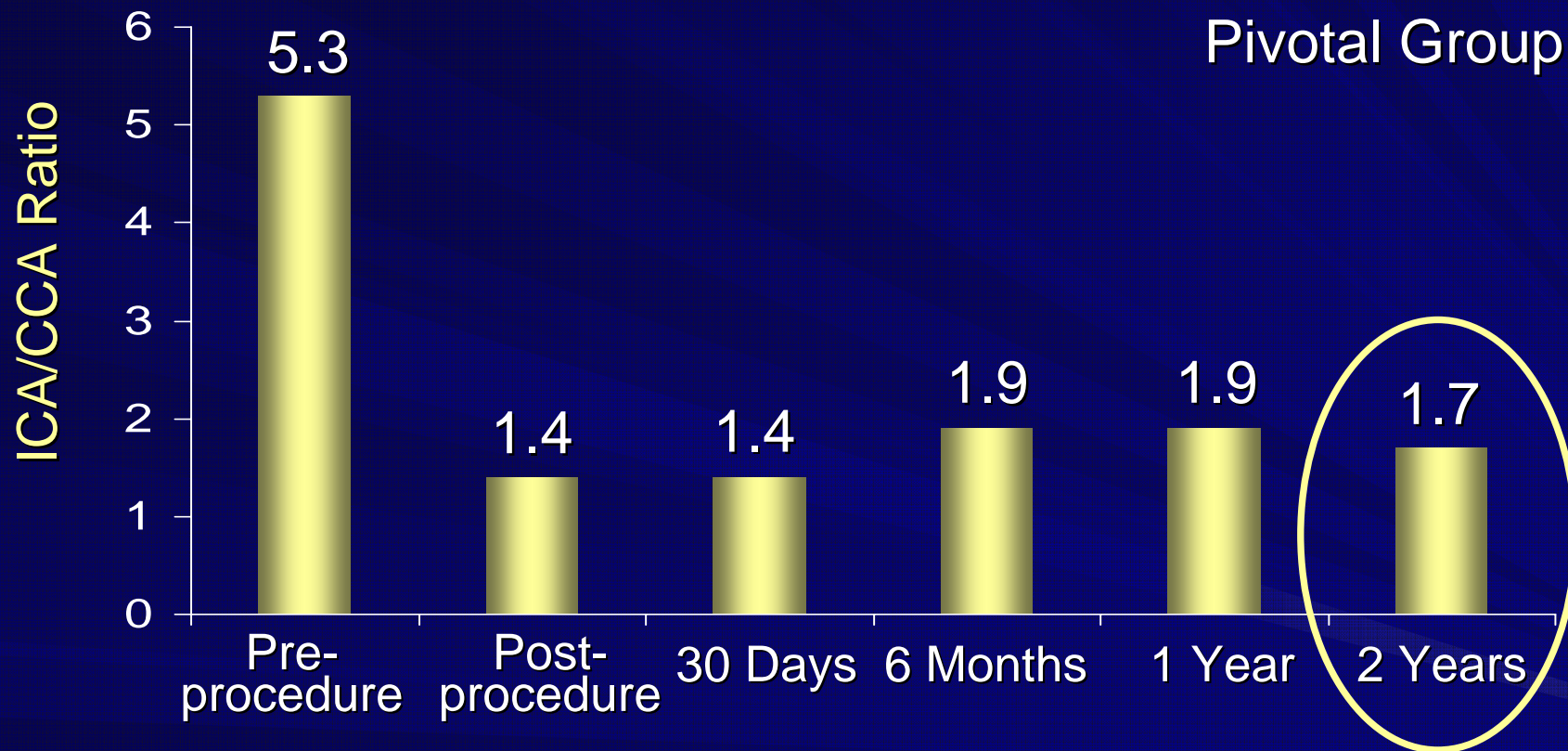
BEACH Carotid Duplex Ultrasound Studies



Sustained Patency >1 Year

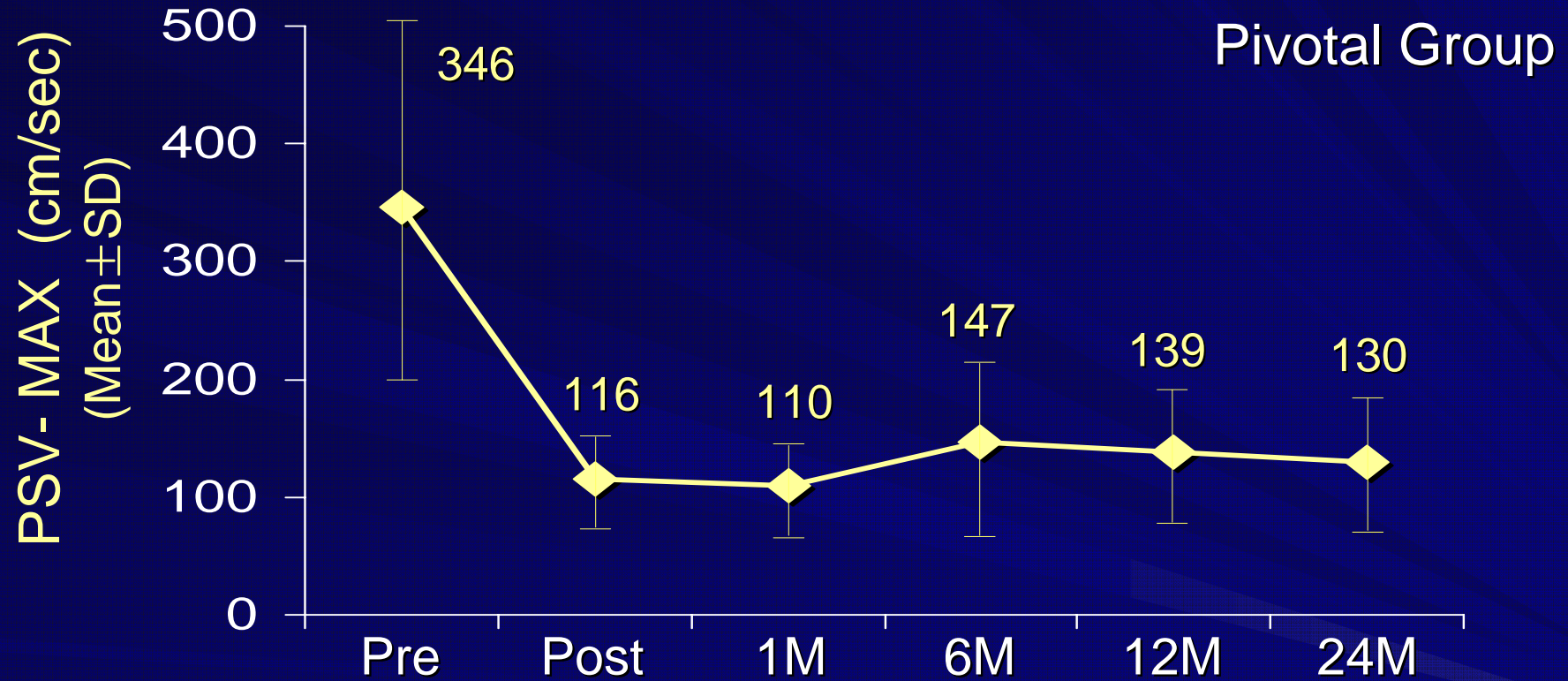
BEACH ICA/CCA Ratio by Ultrasound

Sustained hemodynamic improvement



BEACH ICA Maximum Peak Systolic Velocity

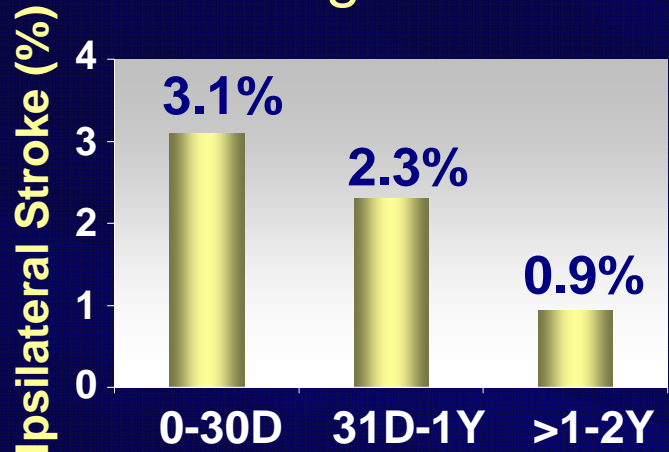
No progressive restenosis from 6 months to 2 years



Progressive reduction in velocity ratios from 6M to 24M (P=0.0012)

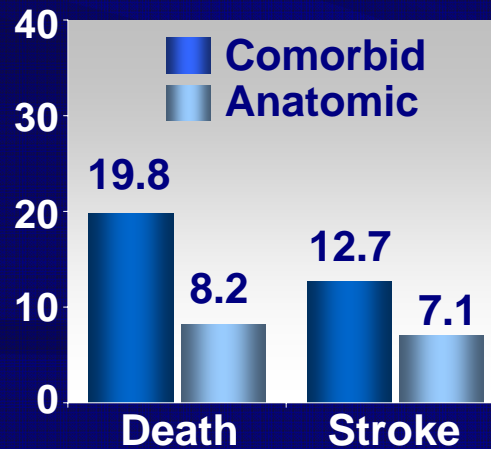
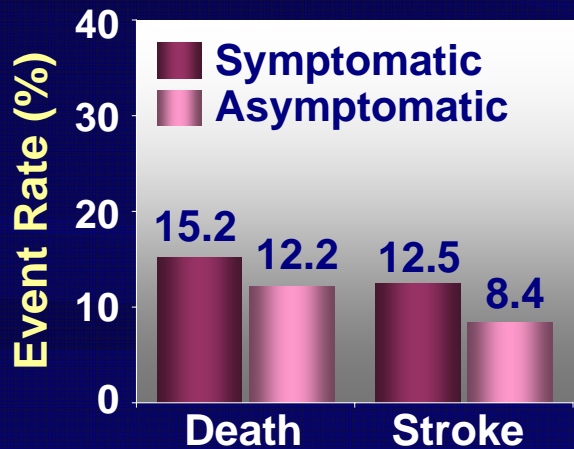
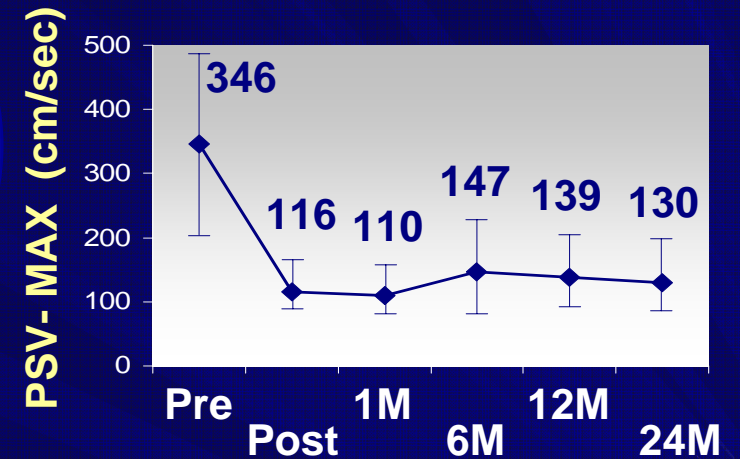
BEACH Summary at 2 Years

Declining Stroke Rate



Durability & Safety Maintained

Continued Stent Patency



Acceptable 2-year stroke & mortality rates across symptomatic & high-risk groups

BEACH Conclusions

Extended follow-up after stenting with the Carotid WALLSTENT together with the FilterWire EX[®]/EZ[™] in a high-risk surgical population demonstrates:

- ❖ Long-term safety, with declining stroke & mortality rates at 2 years
- ❖ Long-term efficacy, with excellent stent patency and stability of the treated lesions