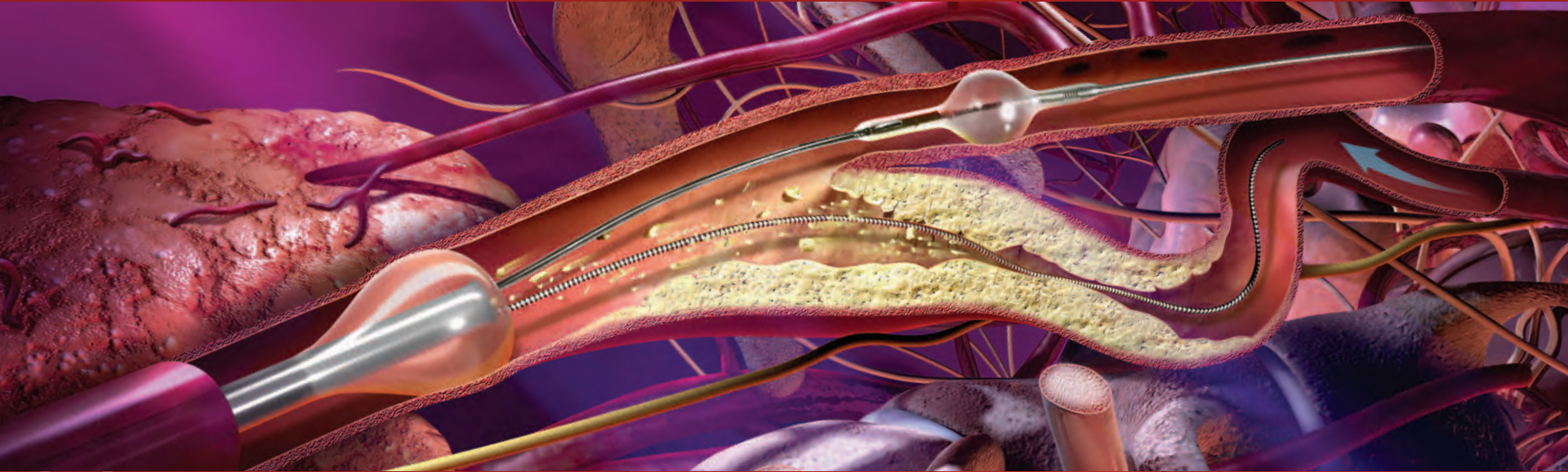


Gore EMPiRE Clinical Study Overview



PERFORMANCE by design

**The Gore EMPiRE Clinical Study
demonstrated the safety and
efficacy of the GORE® Flow Reversal
System for neuroprotection during
carotid artery stenting.**

Clair DG, Hopkins LN, Mehta M, *et al*; EMPiRE Clinical Study Investigators. Neuroprotection during carotid artery stenting using the GORE® Flow Reversal System: 30-Day outcomes in the EMPiRE clinical study. *Catheterization & Cardiovascular Interventions* 2011;77(3):420-429.



STUDY DESIGN

- **Design:** Prospective, multicenter, single-arm study against Objective Performance Criterion (OPC of 11.83%).
- **Primary Endpoint:** Proportion of subjects experiencing one or more Major Adverse Event (death, stroke, MI, TIA) through 30-day follow-up.
- **Subject Population:** Subjects diagnosed with carotid stenosis requiring revascularization and at high risk for adverse events from carotid endarterectomy.
- **Sample Size:** Minimum 240 pivotal subjects (after two training cases at each site).

INVESTIGATOR SITES

INVESTIGATOR SITE	CITY	STATE
St. Peter's Health Care Services	Albany	New York
Emory University Hospital	Atlanta	Georgia
Beth Israel Deaconess Medical Center	Boston	Massachusetts
Cleveland Clinic Foundation	Cleveland	Ohio
Medical University of South Carolina	Charleston	South Carolina
Dartmouth-Hitchcock Medical Center	Lebanon	New Hampshire
Harrisburg Hospital-Pinnacle Health	Harrisburg	Pennsylvania
Baptist Cardiac & Vascular Institute	Miami	Florida
Massachusetts General Hospital	Boston	Massachusetts
Northwestern Memorial Hospital	Chicago	Illinois
Riverside Methodist Hospital	Columbus	Ohio
Columbia University Medical Center	New York	New York
Millard Fillmore Gates Circle Hospital	Buffalo	New York
Arizona Heart Institute	Phoenix	Arizona
University of Alabama	Birmingham	Alabama
Hospital of the University of Pennsylvania	Philadelphia	Pennsylvania
University of Texas Southwestern Dallas VA Medical Center	Dallas	Texas
The Methodist Hospital System	Houston	Texas
Advanced Vascular Associates	Morristown	New Jersey
New York University Langone Medical Center	New York	New York
Ochsner Health Center	New Orleans	Louisiana
Aurora St. Luke's Medical Center	Milwaukee	Wisconsin
Barnes-Jewish Hospital	St. Louis	Missouri
Hoag Memorial Hospital Presbyterian	Newport Beach	California
Texas Heart Institute at St. Luke's Episcopal Hospital	Houston	Texas
University of Pittsburgh Medical Center	Pittsburgh	Pennsylvania
Vanderbilt University Medical Center	Nashville	Tennessee
Glendale Adventist Medical Center	Glendale	California
Greenville Memorial Hospital	Greenville	South Carolina
Lehigh Valley Hospital	Allentown	Pennsylvania
The Christ Hospital	Cincinnati	Ohio



EMPIRE

CLINICAL STUDY

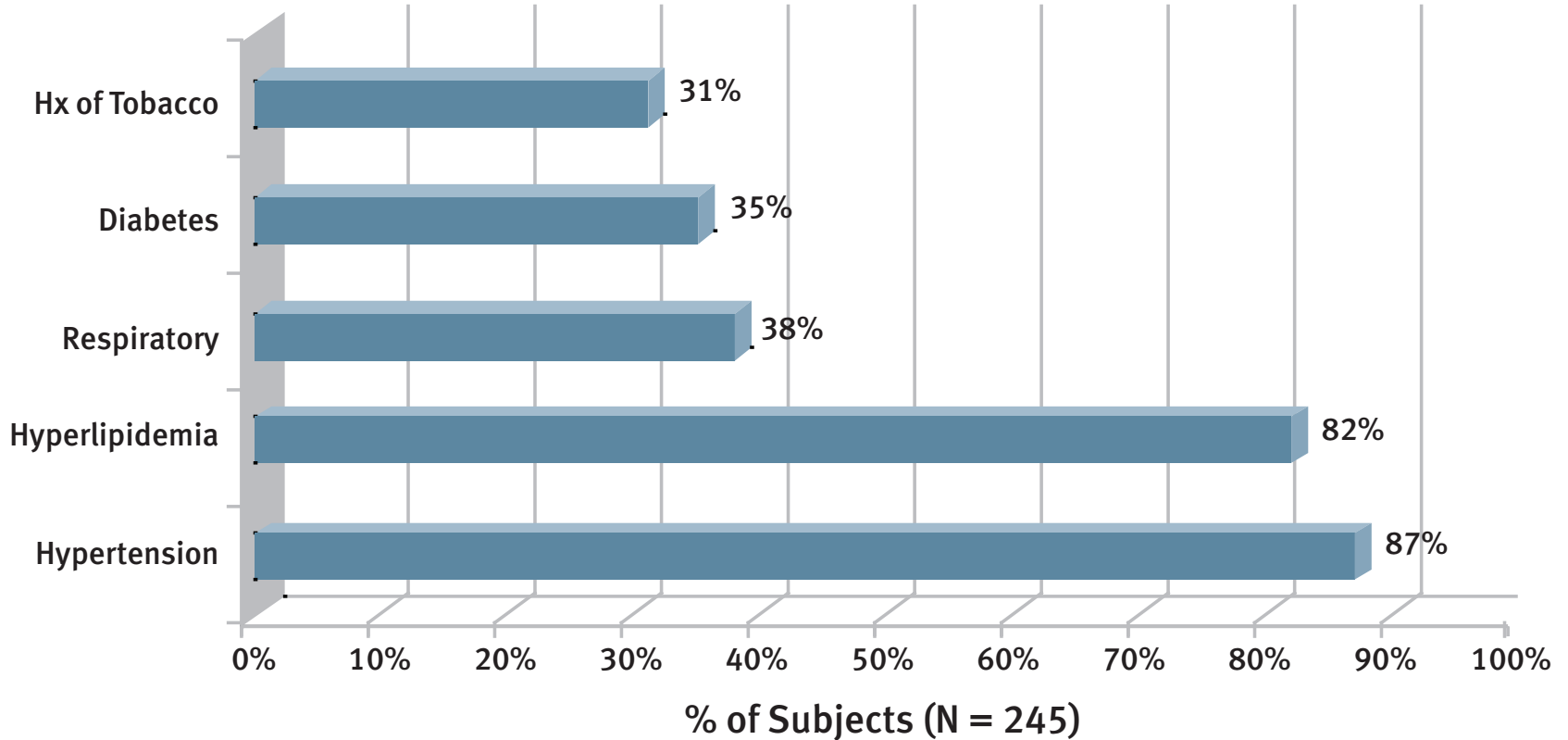
ENROLLMENT SUMMARY

- Enrollment: 301 subjects
 - Training Cases: 56 subjects
 - Pivotal: 245 subjects
- Number of Enrolling Sites: 29
- Enrollment Period: July 2006 – July 2008

PATIENT DEMOGRAPHICS

N = 245	n	MEAN / %	(MIN, MAX)
Age (years)		70	(46, 89)
Male	165	67%	
Symptomatic	78	32%	
Octogenarians (42% Symptomatic)	38	16%	

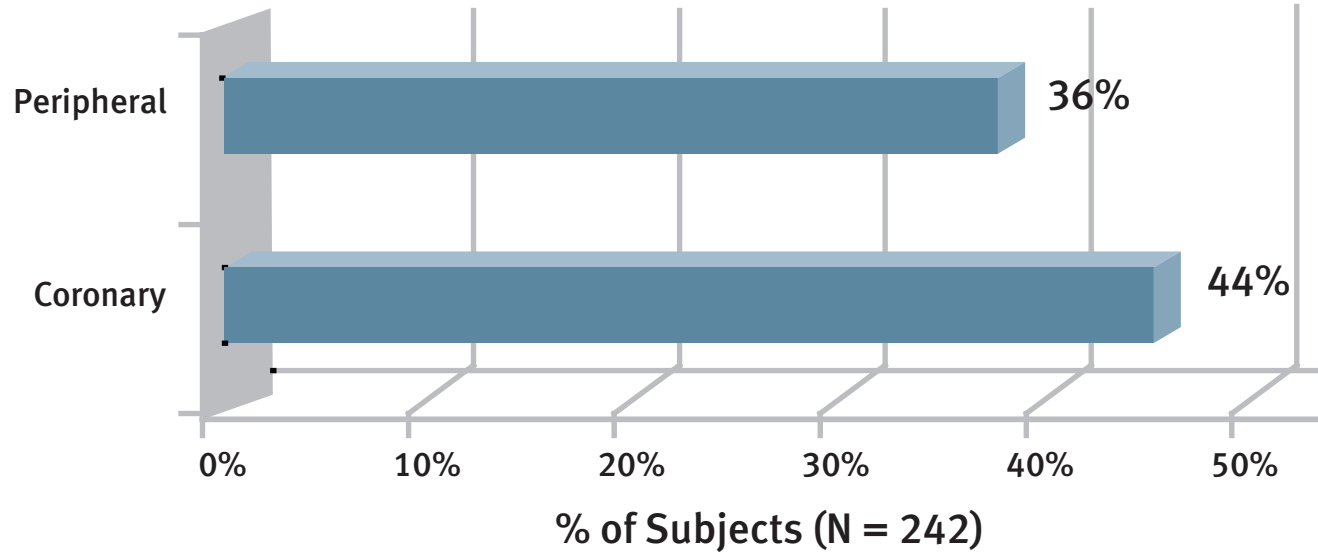
GENERAL MEDICAL HISTORY



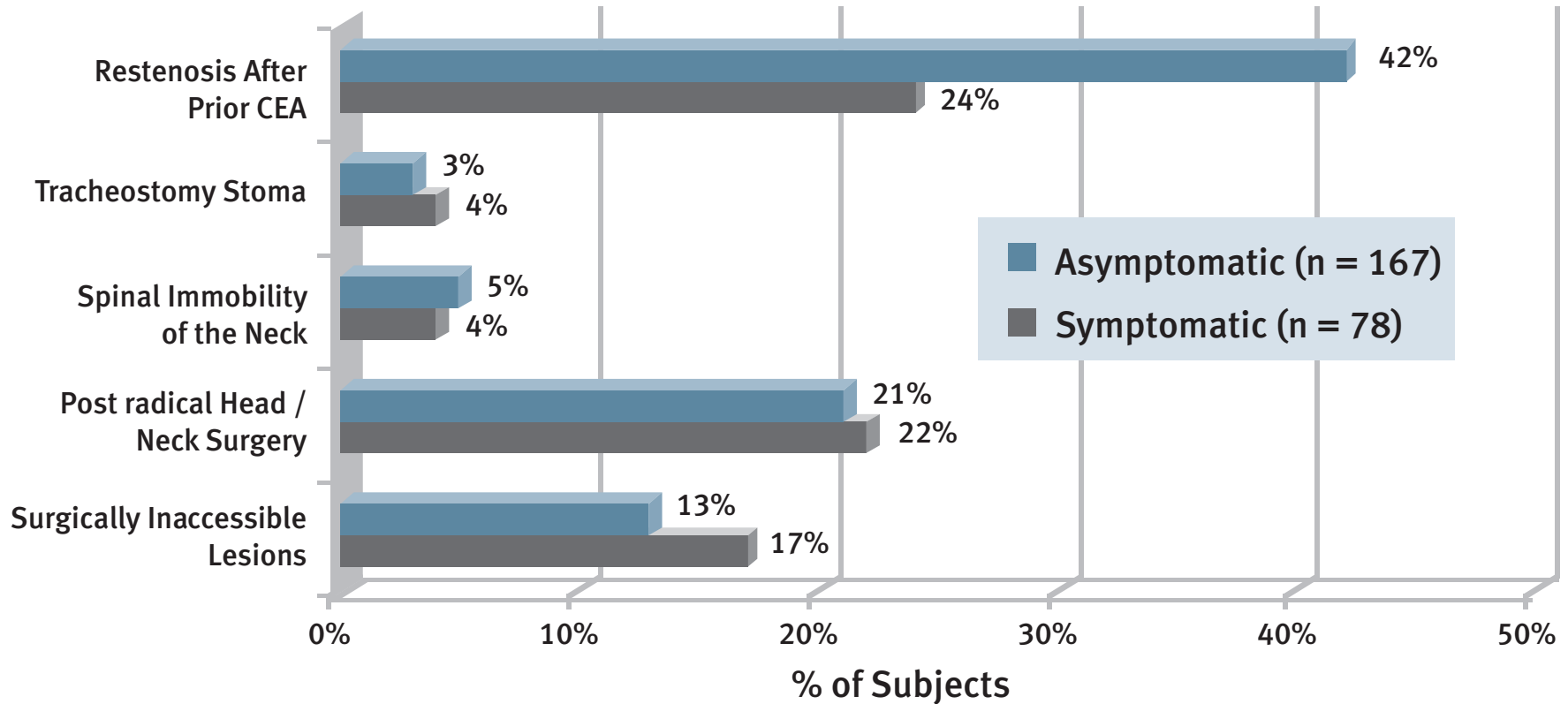
EMPIRE

CLINICAL STUDY

HISTORY OF NON-CAROTID VASCULAR DISEASE



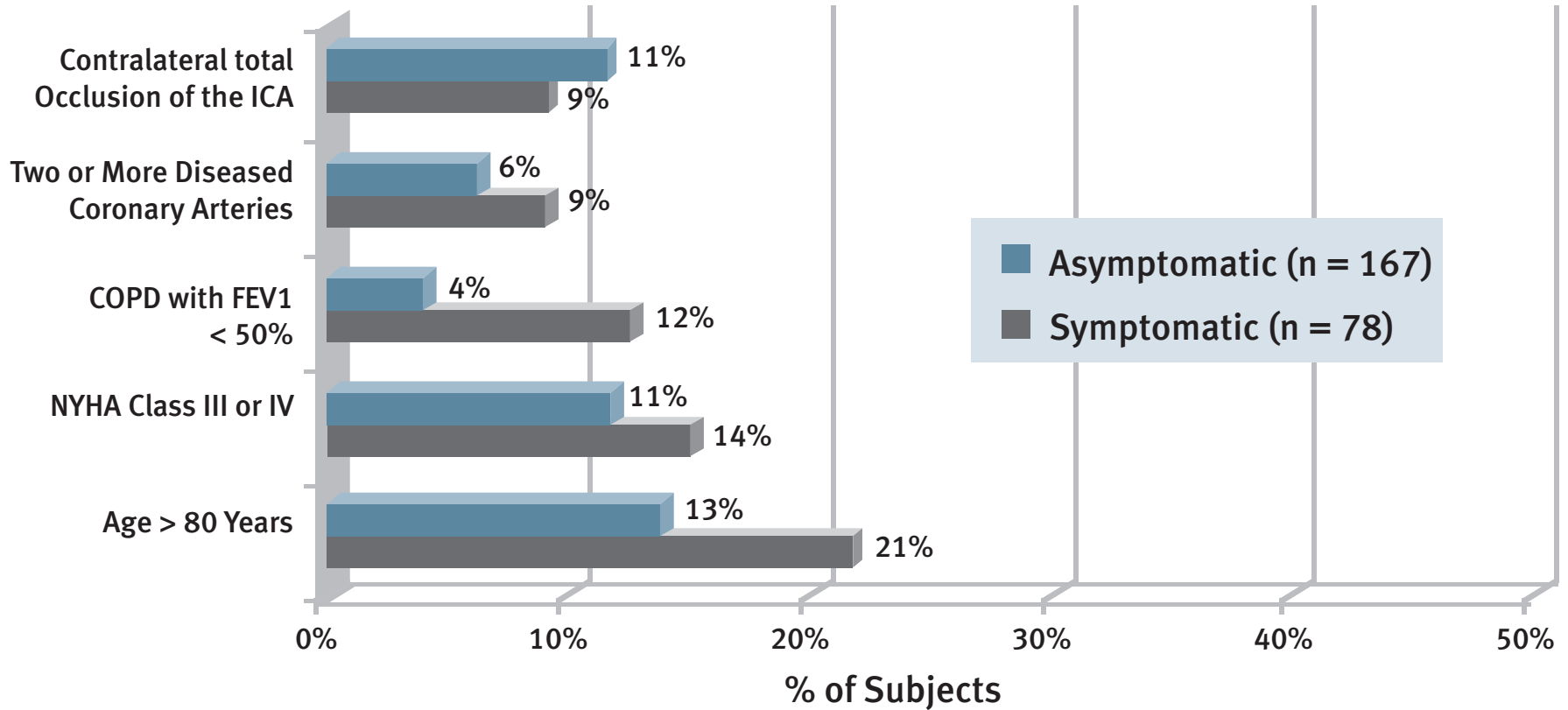
ANATOMIC HIGH RISK FACTORS



EMPIRE

CLINICAL STUDY

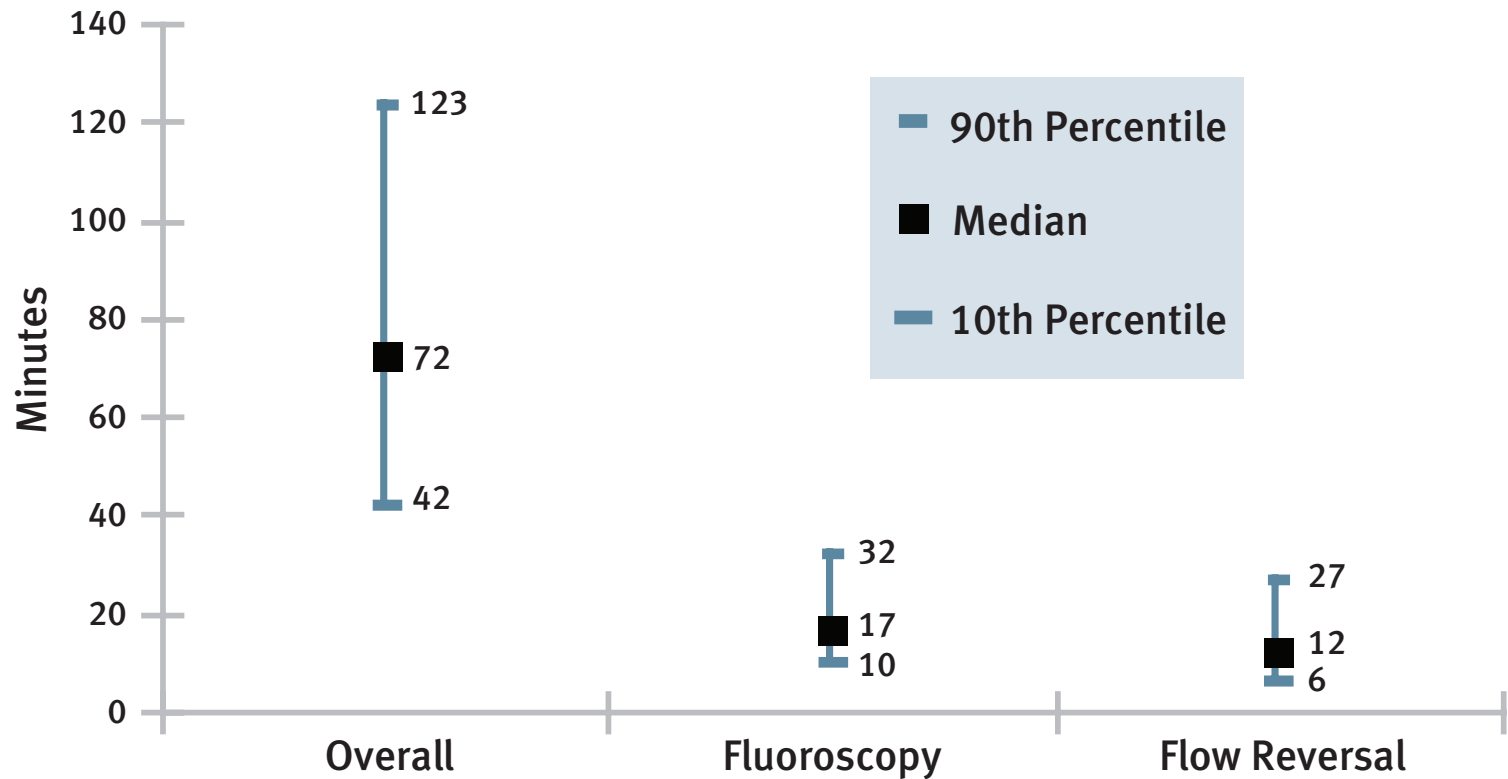
CO-MORBID HIGH RISK FACTORS



EMPIRE

CLINICAL STUDY

PROCEDURE TIMES



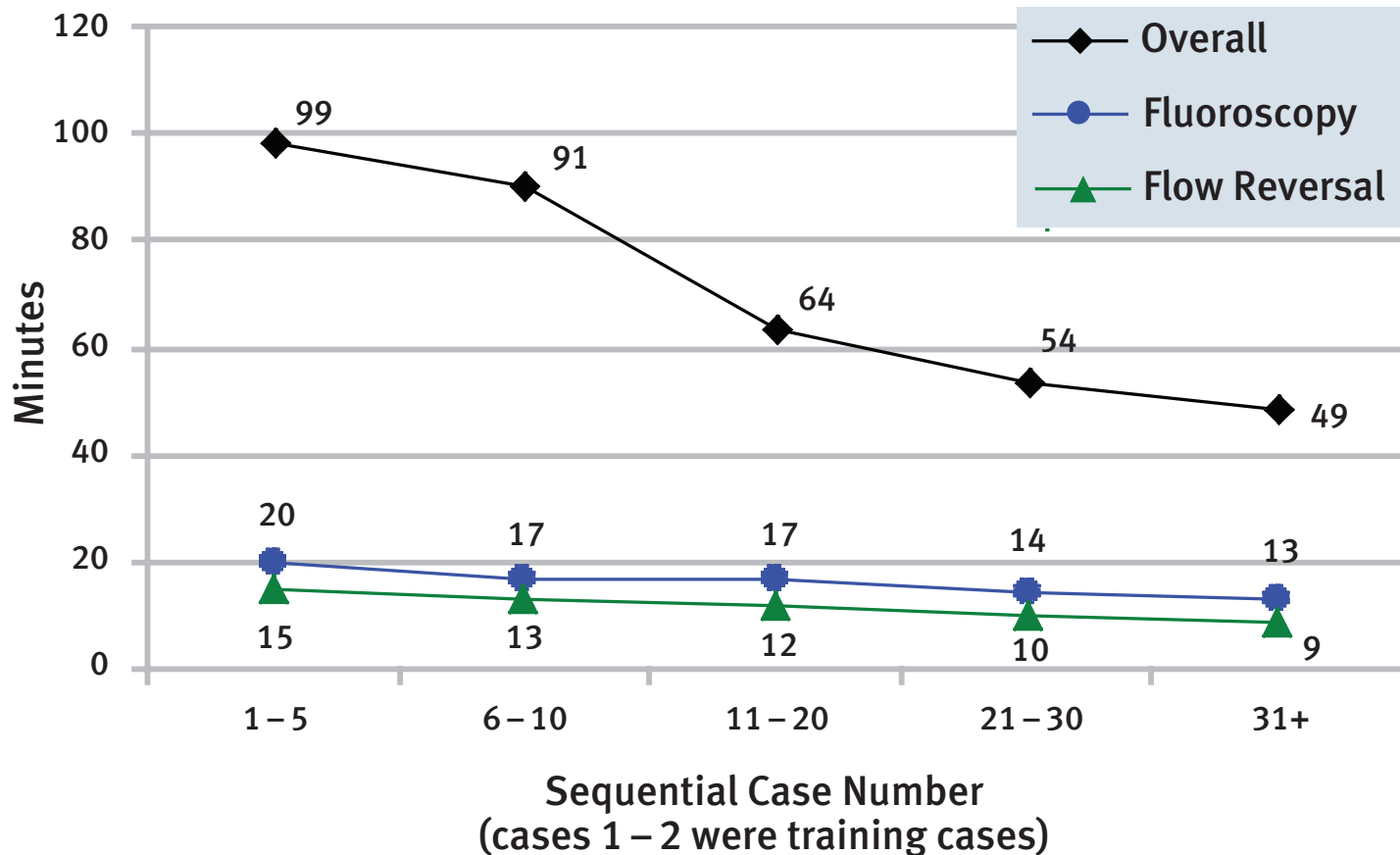
- This information below will be in the “Notes” section in the final PPT for the previous slide entitled “Procedure Times”

Procedure times

(N = 245)	MEDIA	ST DEV	90%
Overall (min)	80	38	123
Fluoroscopy (min)	20	14	32
Flow reversal (min)	15	9	27

LEARNING CURVE

Median Procedure Time by Site Case Number



PROCEDURE TECHNICAL RESULTS

- 96.3% GORE® Flow Reversal System Technical Success (n = 236)
- 3.7% GORE® Flow Reversal System Technical Failure (n = 9)
 - Intolerance (n = 3)
 - Balloon sheath balloon rupture (n = 2)
 - Tortuous anatomy (n = 2)
 - Unable to position device (n = 2)
- 99.2% Carotid Stent Technical Success (n = 243)

- This information below will be in the “Notes” section in the final PPT for the previous slide entitled “Procedure Technical Results”

Technical Failures (N = 9; 3.7%)

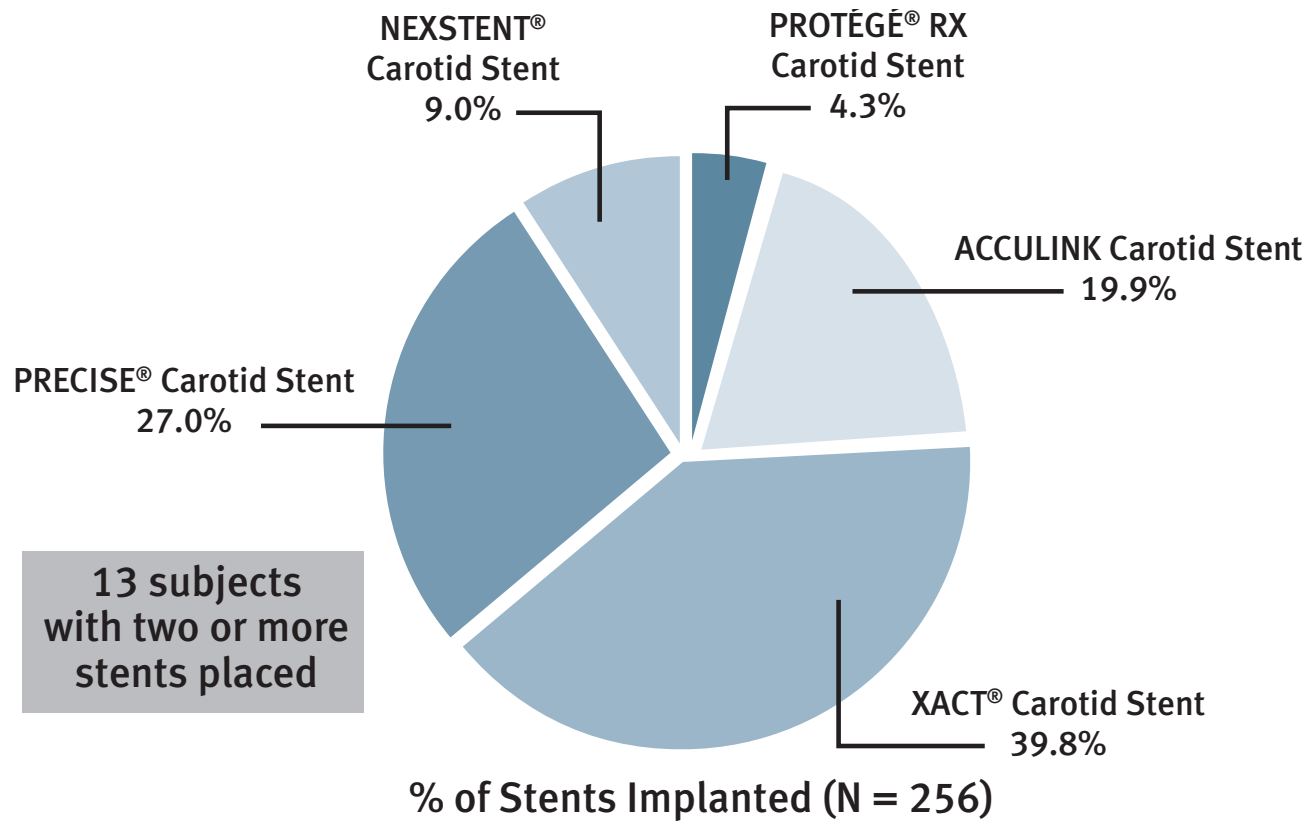
REASON FOR FAILURE	DESCRIPTION	ALTERNATIVE EPD USED	STENT BRAND IMPLANTED
Intolerance	Patient did not tolerate more than 3 minutes of flow reversal	RX ACCUNET® EMBOLIC PROTECTION DEVICE	XACT® CAROTID STENT
Intolerance	Patient unable to tolerate reverse flow – decrease in neurological function	RX ACCUNET® EMBOLIC PROTECTION DEVICE	PRECISE® CAROTID STENT
Intolerance	Patient did not tolerate reverse flow	FILTERWIRE EZ EMBOLIC PROTECTION SYSTEM	XACT® CAROTID STENT
Balloon sheath balloon rupture	Balloon sheath balloon ruptured	RX ACCUNET® EMBOLIC PROTECTION DEVICE	ACCULINK CAROTID STENT
Balloon sheath balloon rupture	Balloon rupture noted	EMBOSHIELD® PRO EMBOLIC PROTECTION SYSTEM	XACT® CAROTID STENT
Tortuous anatomy	Tortuous ECA	RX ACCUNET® EMBOLIC PROTECTION DEVICE	ACCULINK CAROTID STENT
Tortuous anatomy	Tortuous anatomy	RX ACCUNET® EMBOLIC PROTECTION DEVICE	ACCULINK CAROTID STENT
Unable to properly position balloons	Unable to properly position balloon	FILTERWIRE EZ EMBOLIC PROTECTION SYSTEM	XACT® CAROTID STENT
Unable to properly position balloons	Unable to pass wire into the ext. carotid artery due to the presence of a large calcific plaque at the right internal artery /bifurcation causing a severe high grade stenosis	Referred for CEA after failed attempts with distal filter protection	

INTOLERANCE

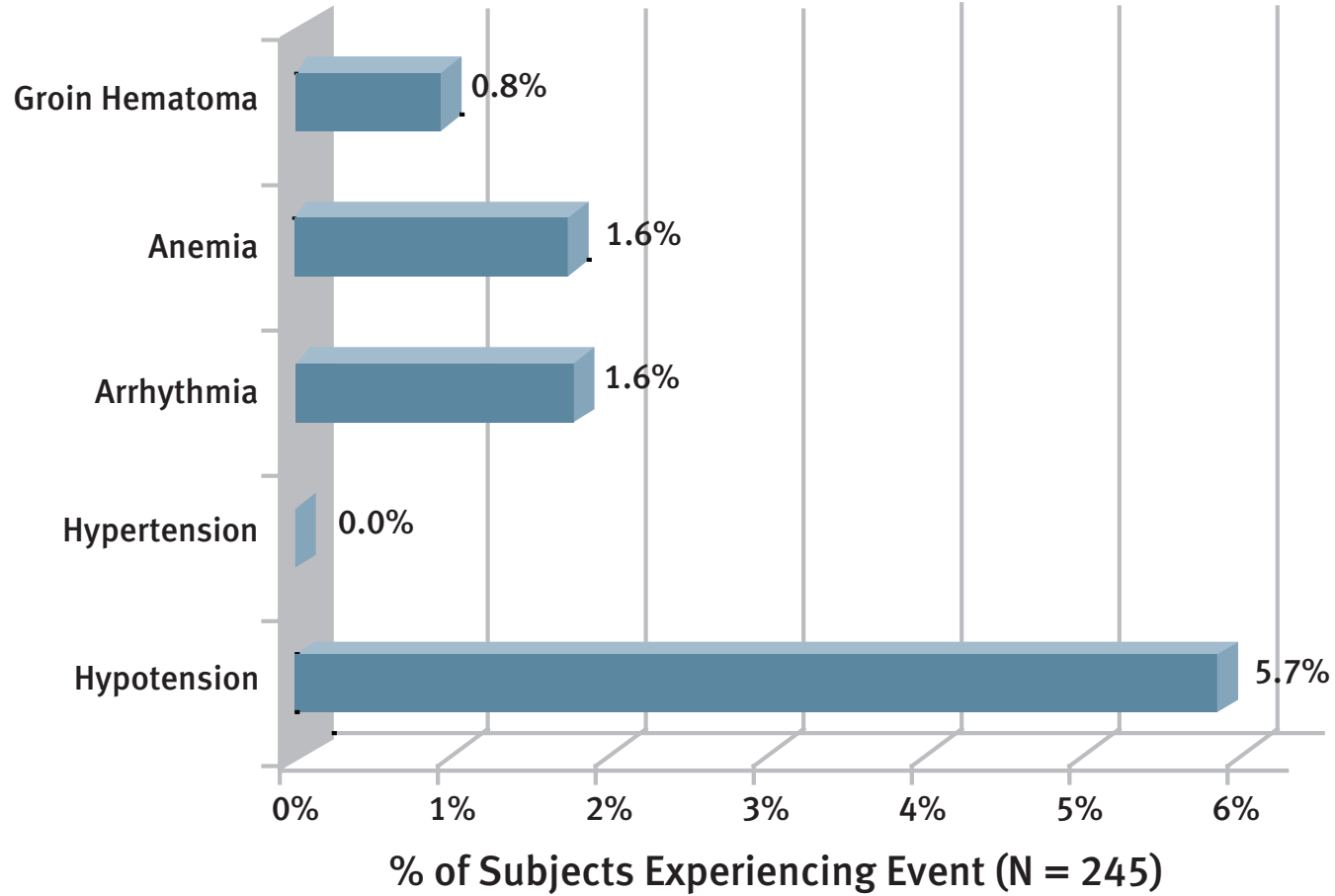
- Intolerance reported in six (2.4%) subjects.
 - Flow Reversal successfully used in 3 / 6.
 - Flow Reversal discontinued in 3 / 6.
- No permanent neurological deficits — intolerance resolved when balloons deflated.

CAROTID STENTS IMPLANTED

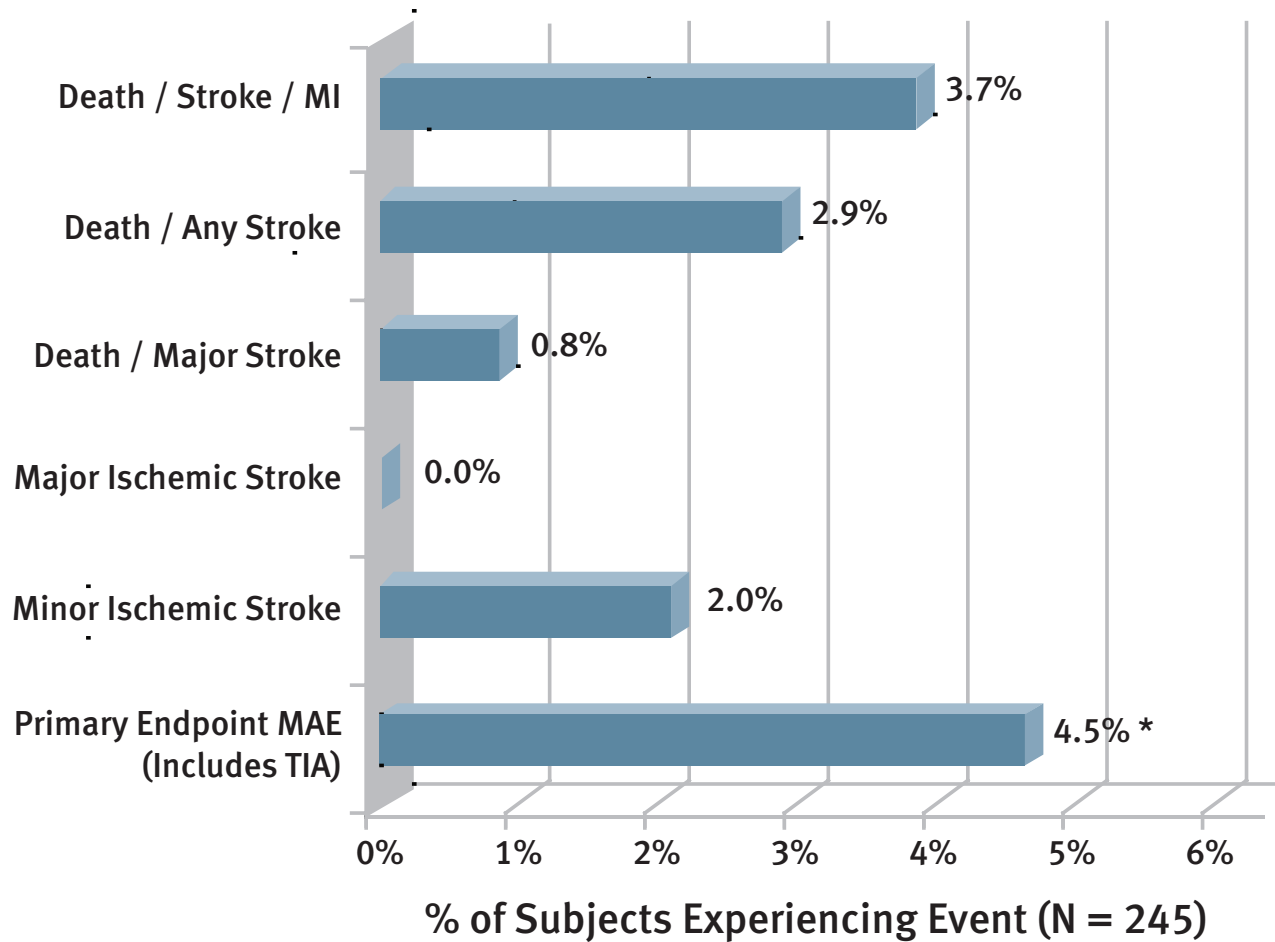
Successful use of available FDA-approved carotid stents



SERIOUS ADVERSE EVENTS



MAJOR ADVERSE EVENTS



* < OPC of 11.83% (p = 0.002)

PRIMARY ENDPOINT: MAJOR ADVERSE EVENTS

NUMBER OF SUBJECTS BY TYPE OF EVENT (HIERARCHICAL)	
ALL ENROLLED SUBJECTS (N = 245)	N (%)
Death and Major Hemorrhagic Stroke	2 (0.8%)
Ipsilateral	1 (0.4%)
Non-Ipsilateral	1 (0.4%)
Minor Ischemic Stroke	5 (2.0%)
Ipsilateral	5 (2.0%)
Myocardial Infarction	2 (0.8%)
Non Q-wave	2 (0.8%)
TIA	2 (0.8%)
Ipsilateral	2 (0.8%)
Non-Ipsilateral	0 (0.0%)
SUBJECTS WITH ONE OR MORE MAE	11 (4.5%)



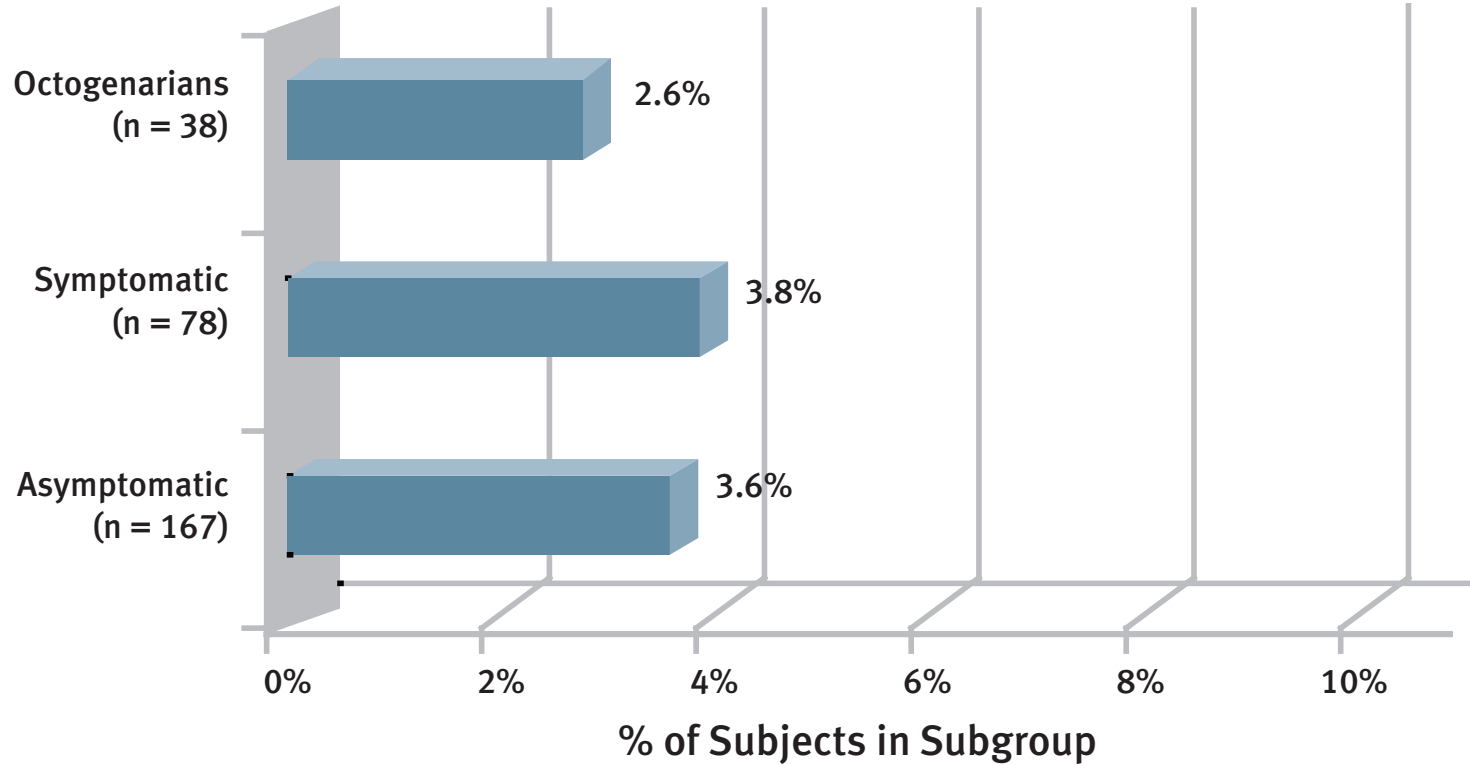
EMPIRE

CLINICAL STUDY

MAJOR ADVERSE EVENTS BY TIMING AND TYPE

ONSET	DESCRIPTION OF MAJOR ADVERSE EVENT
Day 0 (all events reported as post procedure)	Stroke — Hemorrhagic, major ipsilateral (Death on day 1) Stroke — Ischemic, minor ipsilateral Stroke — Ischemic, minor ipsilateral Stroke — Ischemic, minor ipsilateral TIA — Ipsilateral
Day 1	Non Q-wave MI
Day 2	Stroke — Ischemic, minor ipsilateral
Day 4	TIA — Non-ipsilateral (ipsilateral TIA day 12 and 13)
Day 7	Non Q-wave MI
Day 11	Stroke — Ischemic, minor ipsilateral
Day 16	Stroke — Hemorrhagic, major non-ipsilateral (Death on day 21)

STROKE, DEATH, MI RATES BY SUBGROUP



COMPARISON TO AHA GUIDELINES

	GUIDELINES FOR CAROTID ENDARTERECTOMY DEATH / STROKE RATES*	GORE EMPIRE CLINICAL STUDY DEATH / STROKE RATES
Symptomatics	6%	2.6%
Asymptomatics	3%	3.0%

* Moore WS, Barnett HJM, Beebe HG, *et al.* Guidelines for Carotid Endarterectomy: A Multidisciplinary Consensus Statement From the Ad Hoc Committee, American Heart Association *Circulation* 1995; 91:566-579.

Gore EMPIRE Clinical Study met
death / stroke rates in AHA Guidelines

TRAINING CASES COMPARED TO PIVOTAL CASES

	TRAINING (N = 56)	PIVOTAL (N = 245)
Symptomatic	30%	32%
Octogenarians	25%	16%
Technical Success	91.1%	96.3%
Procedure Time (median)	110 min	72 min
Flow Reversal Time (median)	15 min	12 min
Death / Stroke / MI Rate	1.8%	3.7%



EMPIRE

CLINICAL STUDY

RESULTS SUMMARY

- Met Study Primary Endpoint
 - Low death rate of 0.8%
 - Low death / stroke rate of 2.9%
 - Low MAE rate of 3.7% (4.5% with TIA)
- Low Death, Stroke, MI Rates for Challenging Subgroups
 - 2.6% for Octogenarians
 - 3.8% for Symptomatic Subjects
- Technical Success Rate of 96.3%
- Low Intolerance Rate of 2.4%
- Low Access Site Complication Rate of 0.8%

INDICATIONS FOR USE: The GORE Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for patients diagnosed with carotid artery stenosis and who have appropriate anatomy as described in the *Instructions for Use*. Refer to the *Instructions for Use* for contraindications, warnings and precautions.^{Rx Only}

Products listed may not be available in all markets.

GORE® and designs are trademarks of W. L. Gore & Associates.

ACCULINK, EMBOSHIELD PRO, RX ACCUNET®, and XACT® are trademarks of Abbott Laboratories.

FILTERWIRE EZ and NEXSTENT® are trademarks of Boston Scientific.

PRECISE® is a trademark of Cordis Corporation.

PROTÉGÉ® RX is a trademark of ev3 Inc.

© 2009, 2011 W. L. Gore & Associates, Inc. AN0082-EN2 APRIL 2011



EMPIRE

CLINICAL STUDY