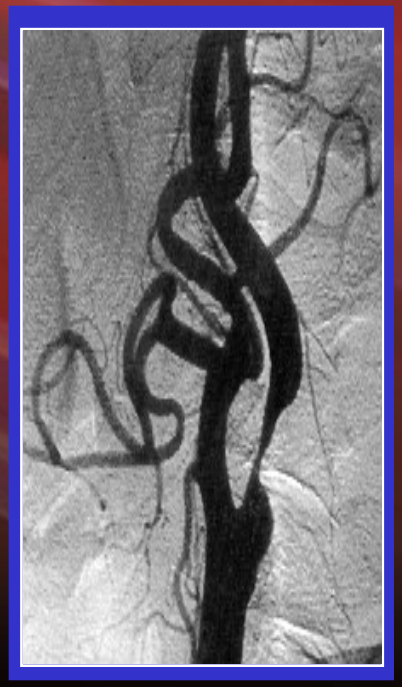
Carotid Stenting with the Fibernet Protection Device: A New Generation in EPD



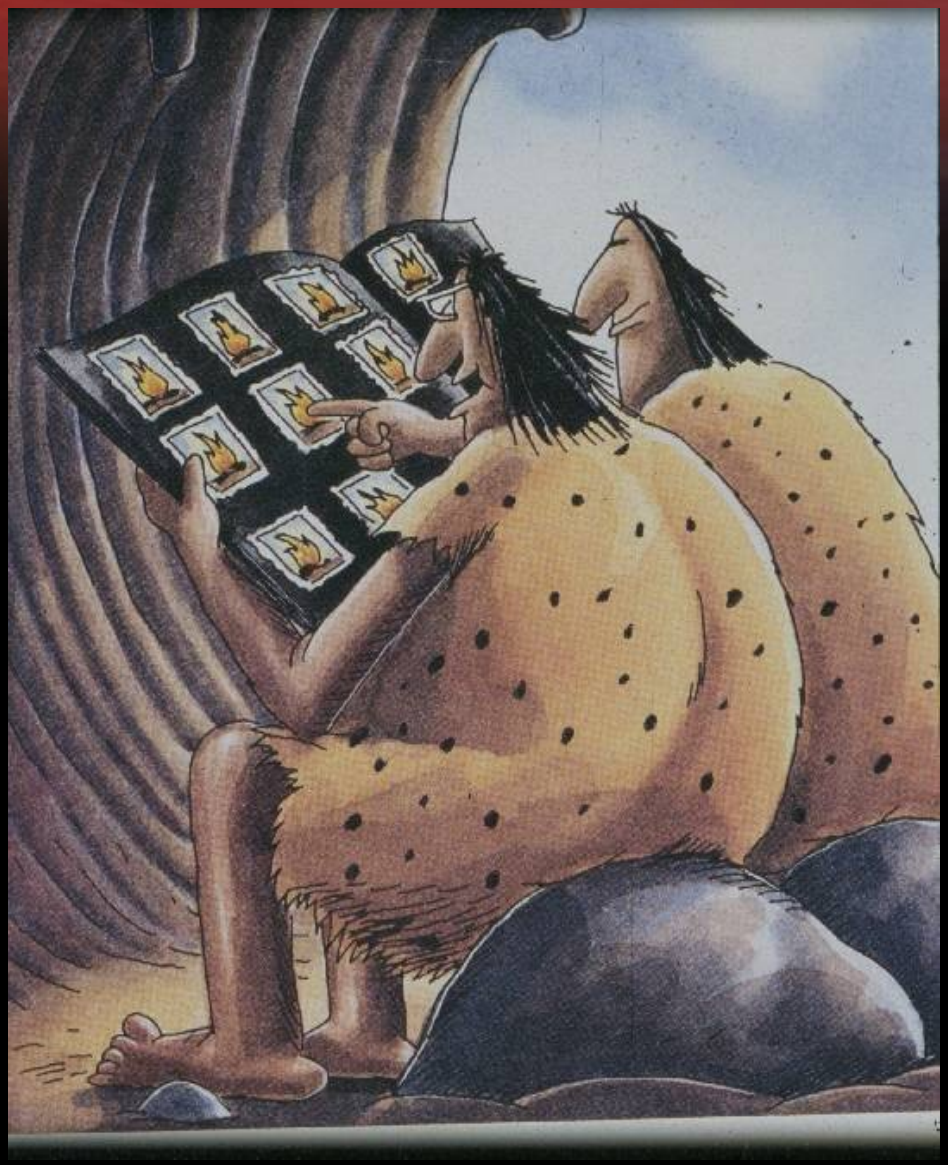
Gary M Ansel MD FACC
Clinical Director of Peripheral Vascular Intervention
MidOhio Cardiology and Vascular Consultants
Riverside Methodist Hospital
Columbus, Ohio

Non FDA approved:Investigational device

Relevant Disclosures

• Cordis JJ	• Advisory, education
• Bard	• Advisory
• Medtronic	• Advisory
• Abbott/Guidant	• Education, research
• Lumen biomedical	• Advisory
• Cook	• Royalties, advisory
• ev3	• Advisory

This Carotid Looks Like a Ripe One



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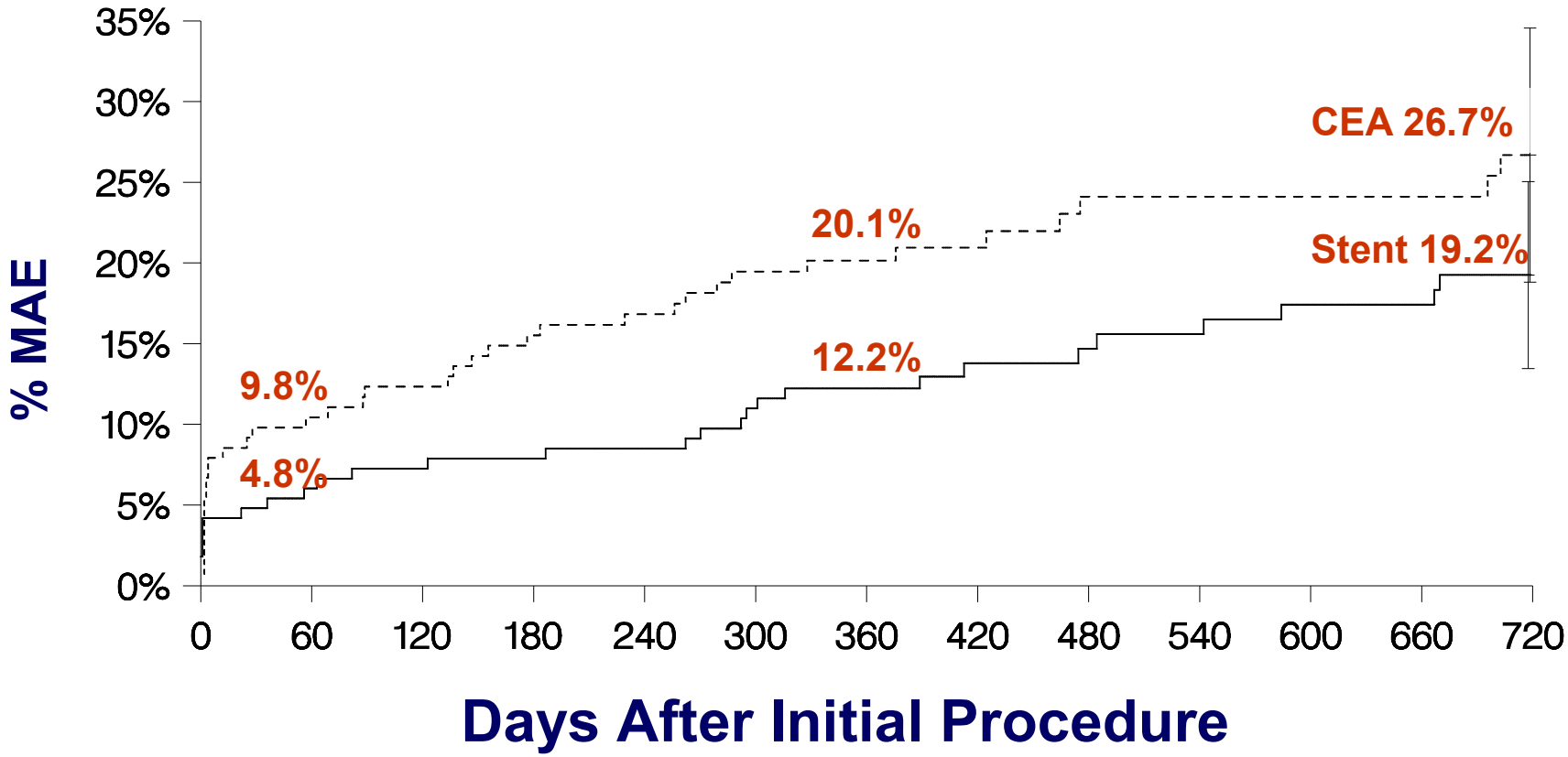
SAPPHIRE

Randomized Patients: Kaplan Meier Analysis



Days:	30	360	720
N at Risk (CEA):	161	125	59
N at Risk (Stent):	163	147	88

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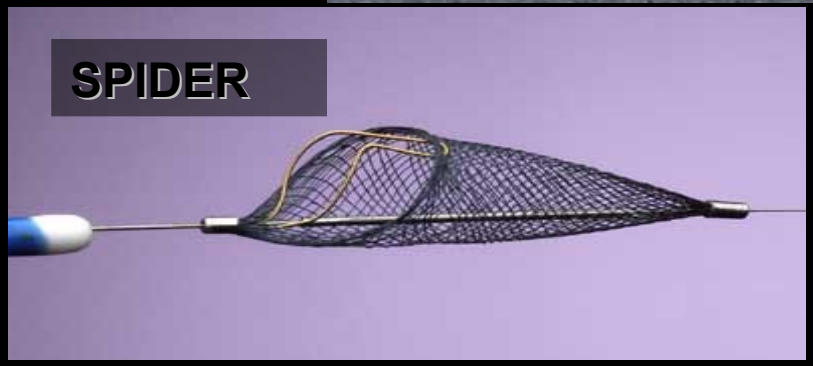
Filters: Newer Devices



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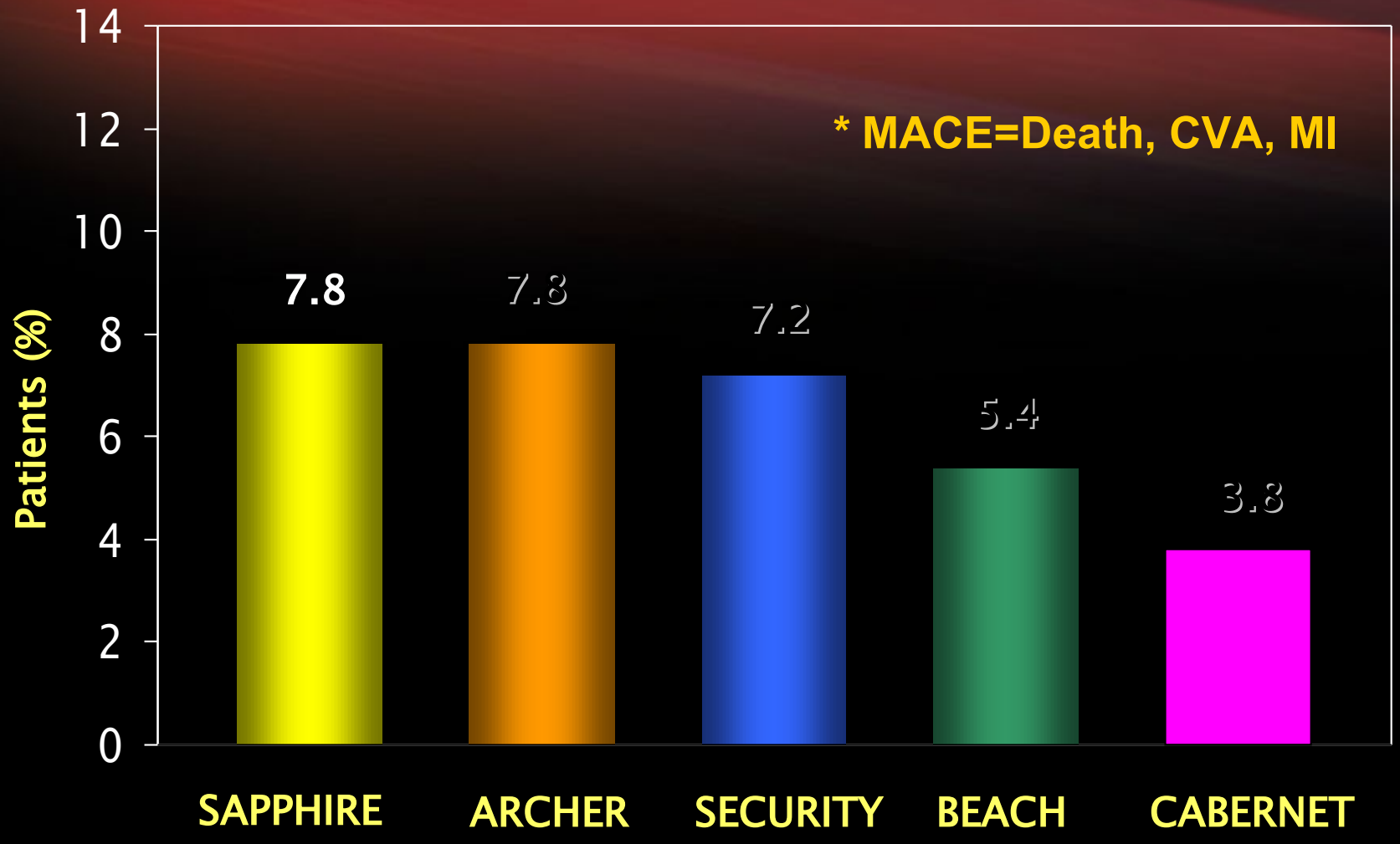
Carotid Stent Trials: 30-Day MACE*



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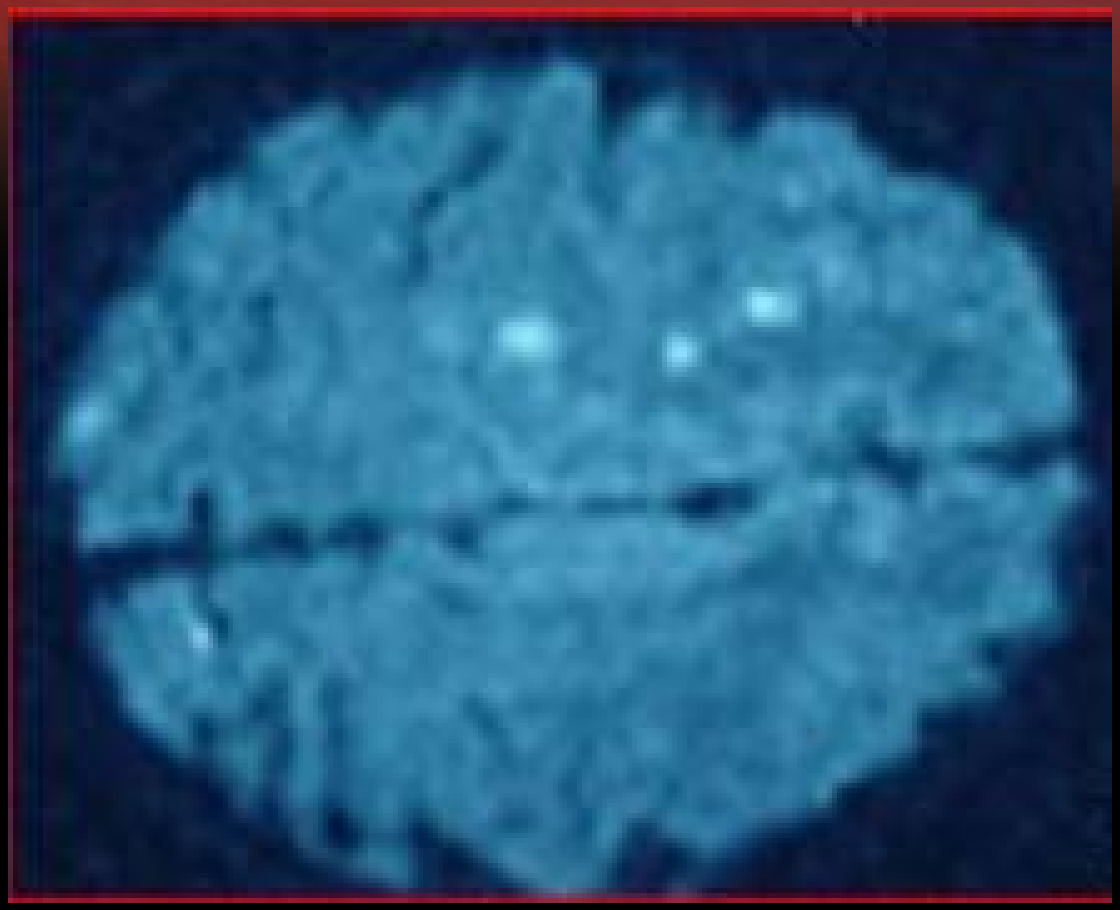

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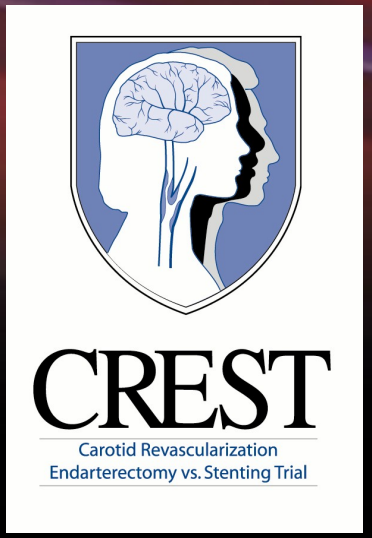
Population



The 30 day clinical outcomes in a pop. of patients recruited in to the LEAD-IN Phase of the CREST study.

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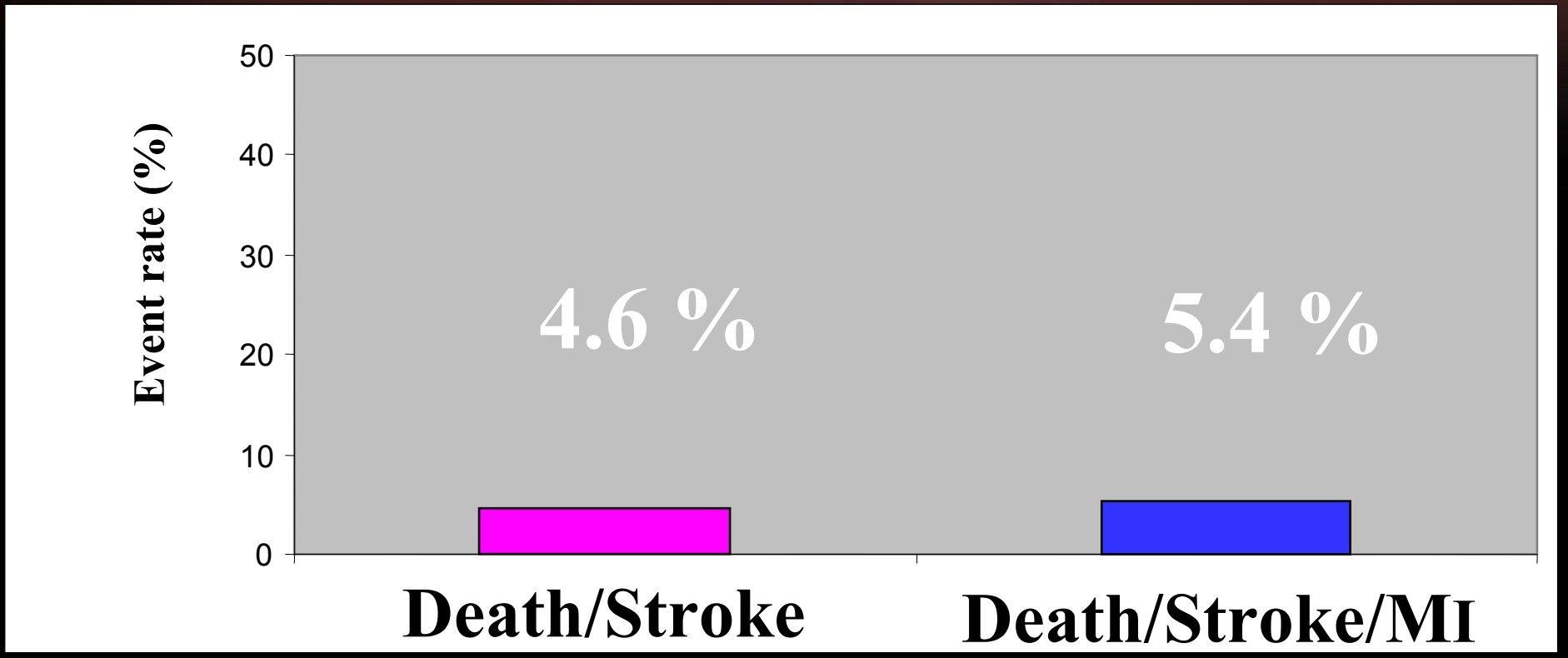
Patient Population

- **Inclusion Criteria**
  - Symptomatic - >50% diameter stenosis
  - Asymptomatic - >70% diameter stenosis
  - High and Standard Risk CEA Pts.
  - Initially no age exclusions. Later recruitment only < 80 yrs.

Total Population data at 30 days

N=1303



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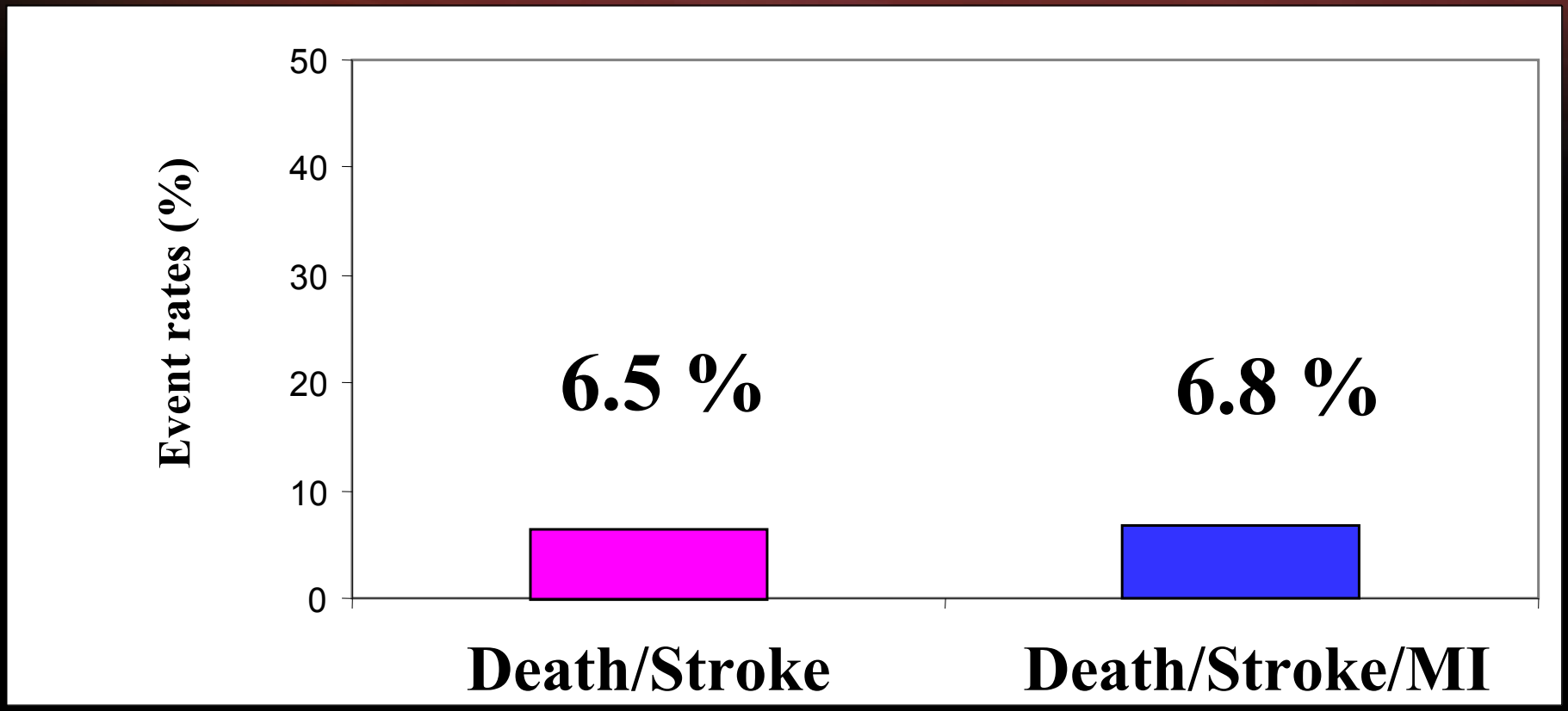
Symptomatic population at 30 days

N = 343



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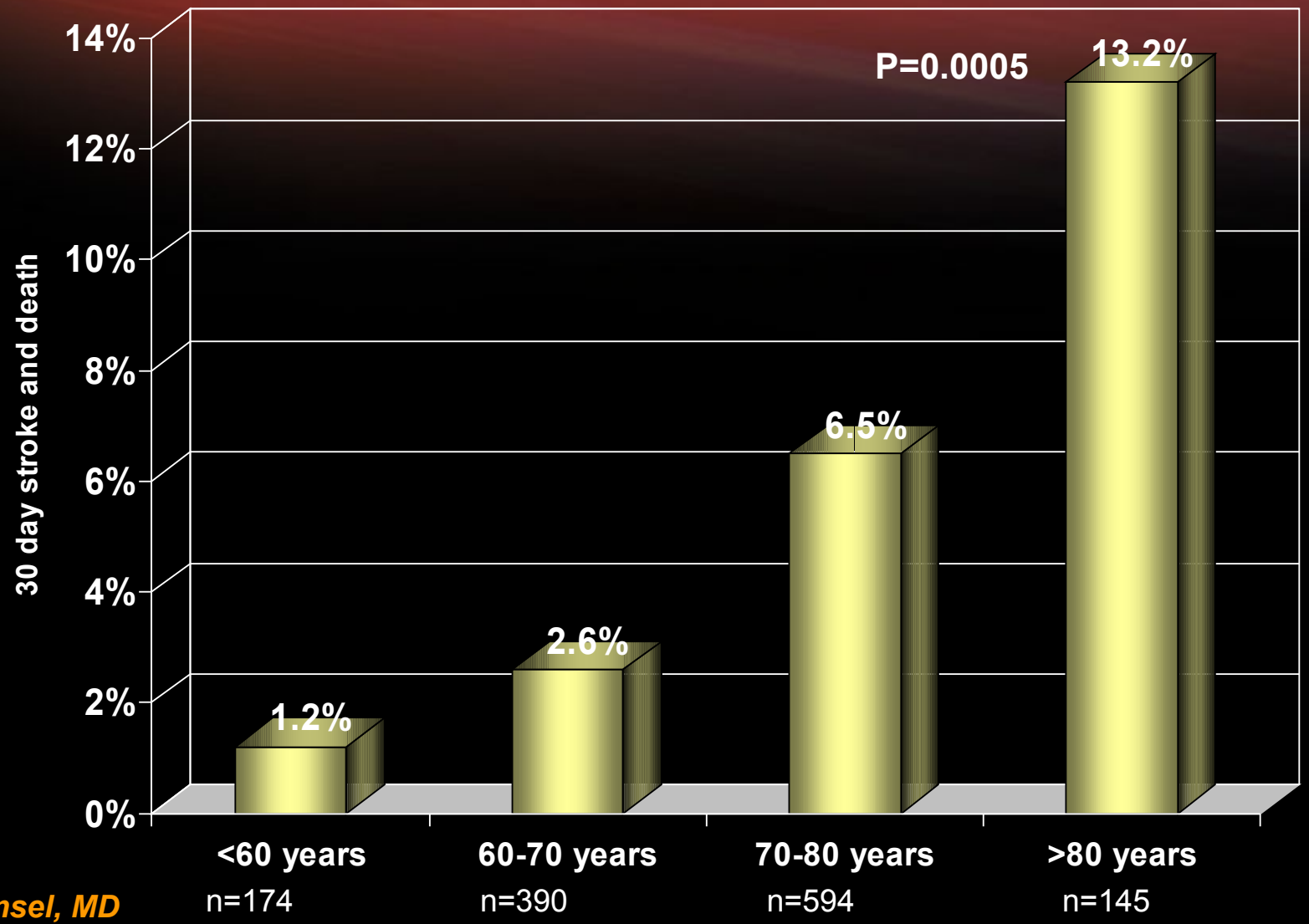
CREST:
30 day death/stroke rate by age group

n=1303



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Primary Events <30 days:

CAPTURE 2500 vs ARCHeR

EVENT	CAPTURE (N=2500)	ARCHeR (n= 581)	DIFFERENCE 95% CI
Death, Stroke and MI* §	5.7%	8.3%	-2.54% [-4.96%, -0.13%]
Death	1.6%	2.1%	-0.47% [-1.72%, 0.79%]
Stroke-Related Death	0.8%	0.5%	0.24% [-0.43%, 0.92%]
All Stroke	4.2%	5.5%	-1.27% [-3.28%, 0.75%]
Major Stroke	1.7%	1.5%	0.13% [-0.99%, 1.25%]
Minor Stroke	2.6%	4.0%	-1.32% [-3.02%, 0.39%]
MI§	0.9%	2.4%	-1.49% [-2.79%, -0.19%]
All Stroke and Death*	5.1%	6.9%	-1.80% [-4.04%, 0.43%]
Major Stroke and Death*	2.5%	2.9%	-0.41% [-1.91%, 1.10%]

*Hierarchical- Includes only the most serious event for each patient and includes only each patient first occurrence of each event.

§ Denotes statistically significant difference at the 0.05 level

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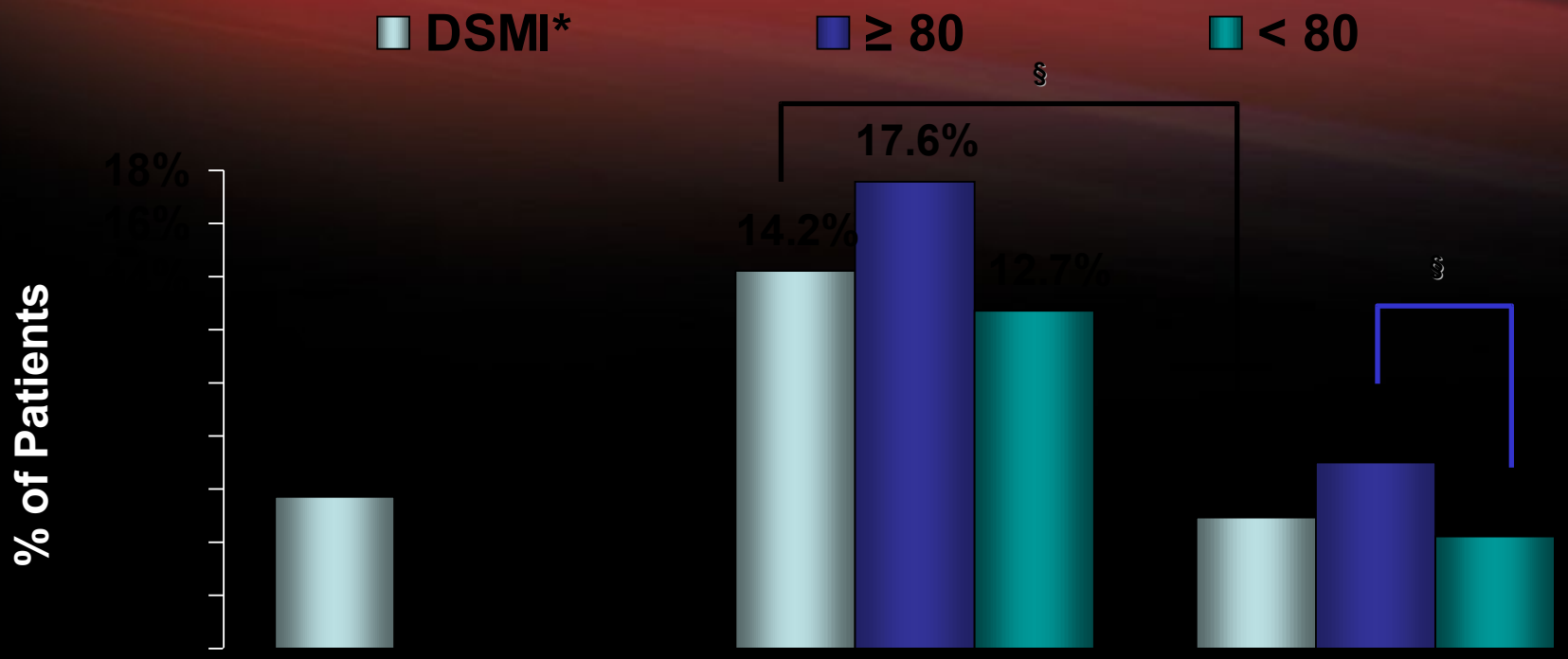
CAPTURE 2500: DSMI by Combined Octogenarian/Symptomatic Status



Asymptomatic patients <80 year:
Stroke and death: 3.6% (63/1741) [2.8%, 4.6%]

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Controversial Studies

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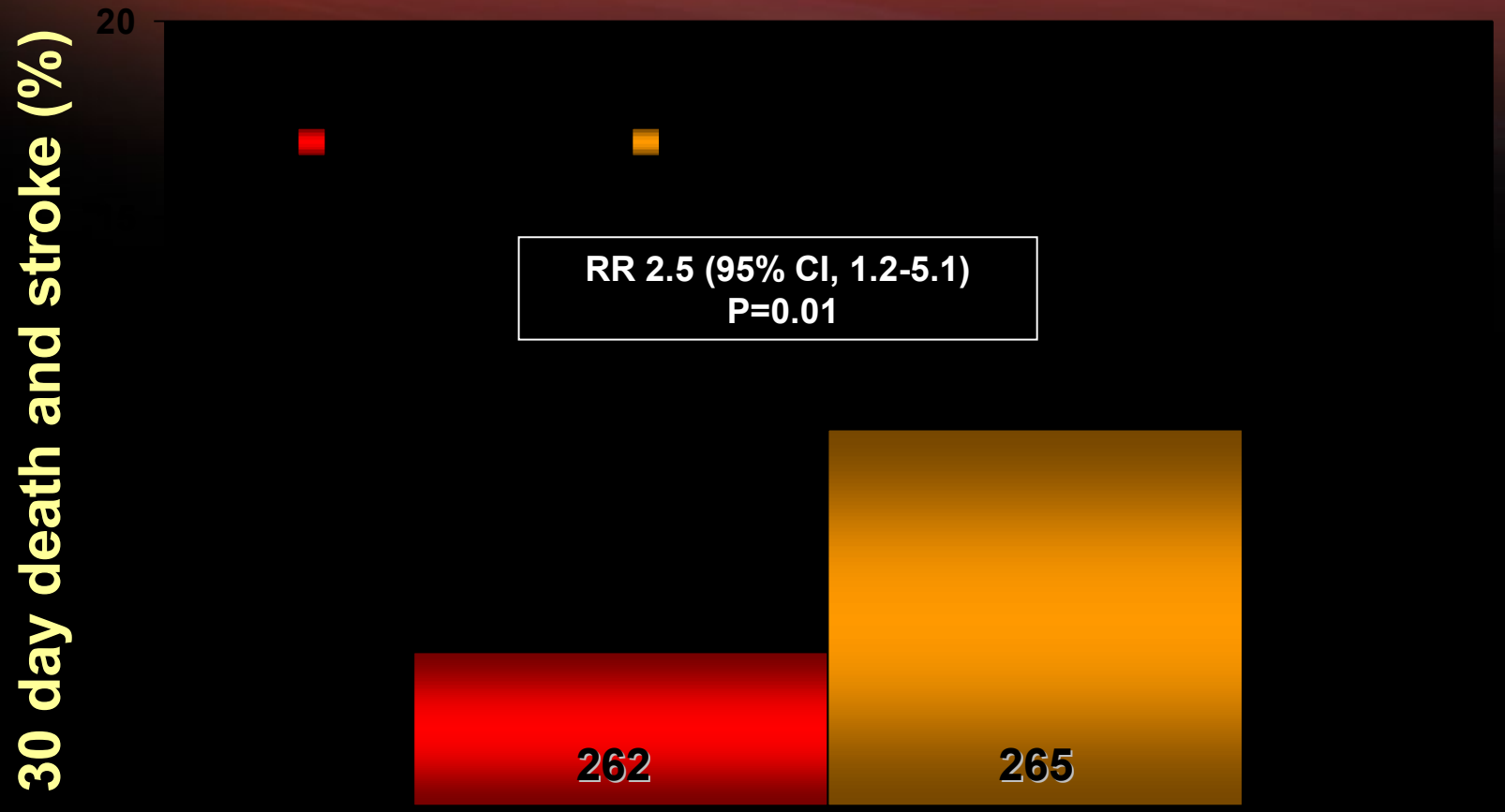
EVA-3S: Randomized CEA vs. CAS



Mas JL et al. New Engl J Med 2006;355:1661-71

EVA-3S critique

- Slow enrollment resulted in limited investigator experience
  - 1.7 CAS patients/year/site

- Early and/or non-standard technique resulted in unnecessary morbidity
  - Use of EPD not widespread or familiar
    - Lack of use in the early phase of the trial likely responsible for 4-5 excess strokes (~20% of all strokes in the CAS arm)
  - *5%* stent procedure failure requiring emergency surgery in this trial resulting in 2 strokes in the CAS group
    - Major pivotal trials in this country (e.g., SAPPHIRE, ARCHeR) have not reported *any* emergent surgical conversions
  - No pre-dilation in >80% of procedures (standard in US)
  - Significant (beyond local) anesthesia was employed in ~30% of procedures (estimated <5% in US)

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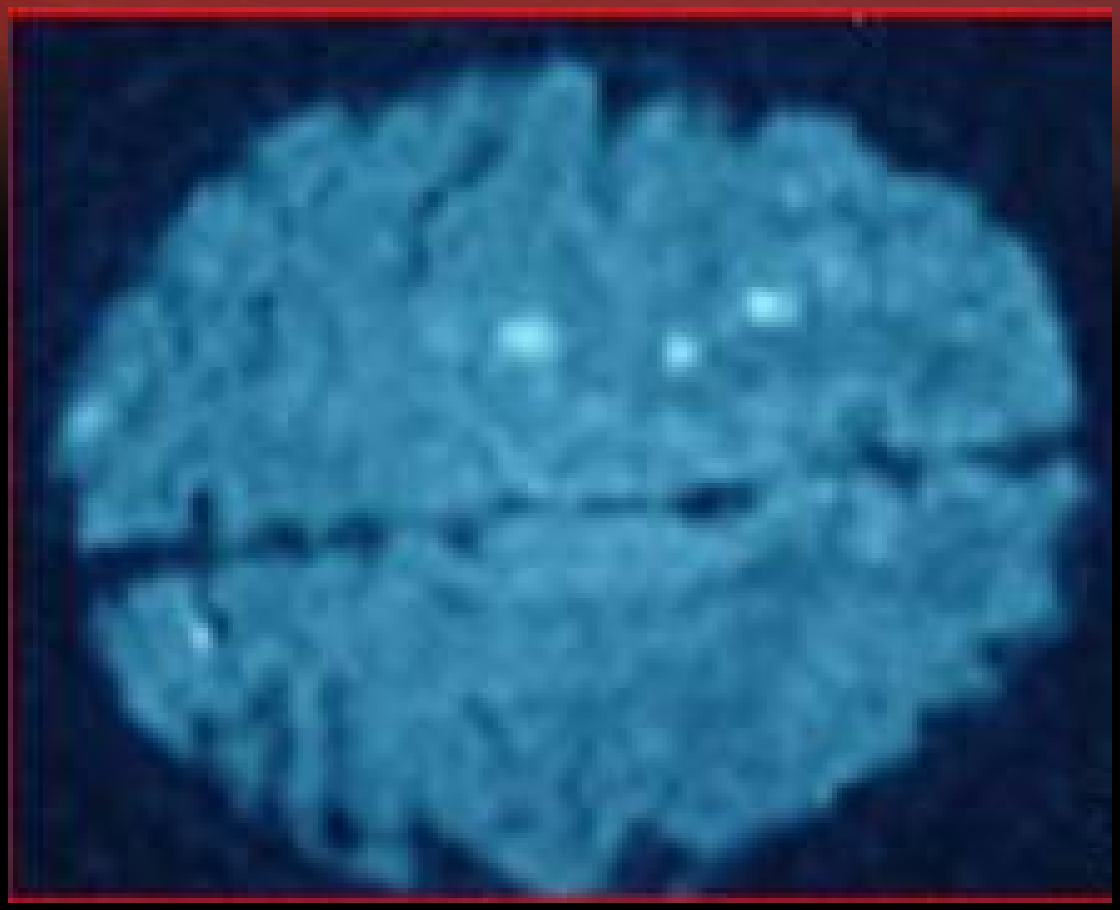
William Gray

EVA-3S critique

- Limited investigator experience and number of trained sites/operators
  - Experienced operators defined by 12 *lifetime* CAS procedures or 5 CAS procedure if 35 supra-aortic procedure
    - These operators were deemed experienced and allowed to tutor the non-experienced
  - No centralized training qualification process (local proctors pronounced the operators qualified)
  - Approximately 2/3 of sites were under tutelage at the beginning of their *randomized* participation.



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"Silent" Cerebral Embolization

Animal Data

- **Microspheres 15 microns no effect**
- **Microspheres 50 microns neuro effect**

Heistaded DD et al

Measurement of cerebral blood flown in animals

Williams and Wilkins;1980:202-11

"Silent" Cerebral Embolization

MRI data

- **N = 20**
- **DW MRI**
- **Carotid Stent placement**
- **Protection successful in 16**
- **Abnormal study in 3/20 (15%)**
  - No permanent deficits

Jaeger et al. Cardiovasc Intervent Radiol 2001:24:249-56

"Silent" Cerebral Embolization

MRI data

- N = 42
- DW MRI
- Carotid Stent placement
- Protection in all (multiple types)
- Abnormal study in 10/42 (22.7%)
  - 1 major stroke
  - 9 no deficit

Jaeger et al. Cardiovasc Intervent Radiol 2001:24:249-56

"Silent" Cerebral Embolization

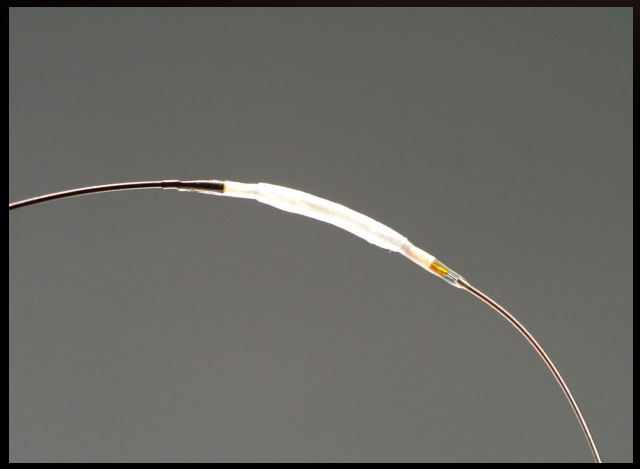
MRI data

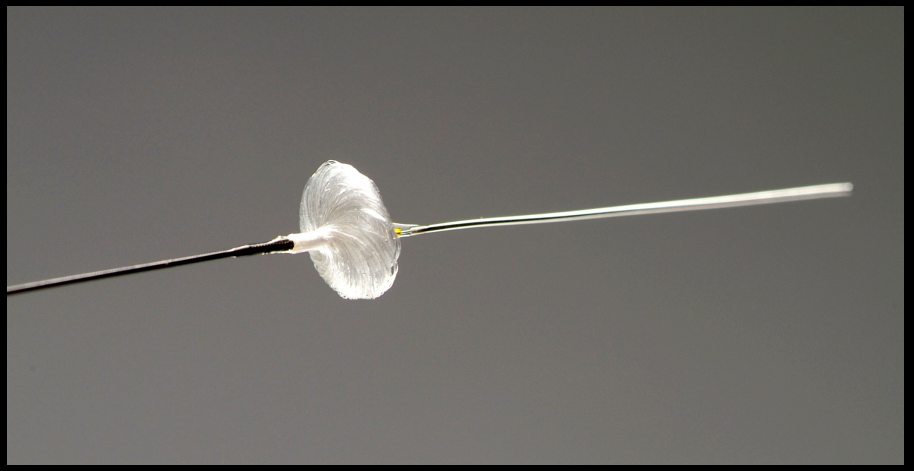
- N = 88
- DW MRI
- Carotid Surgery
- Abnormal study in 17/88 (17%)
  - 2 major stroke

Eur J Vasc Endovasc Surg 2004;27:167-71

Possible Technology answers?

FiberNet® Embolic Protection System





Lumen Biomedical, Inc.

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FiberNet EPS Device Description

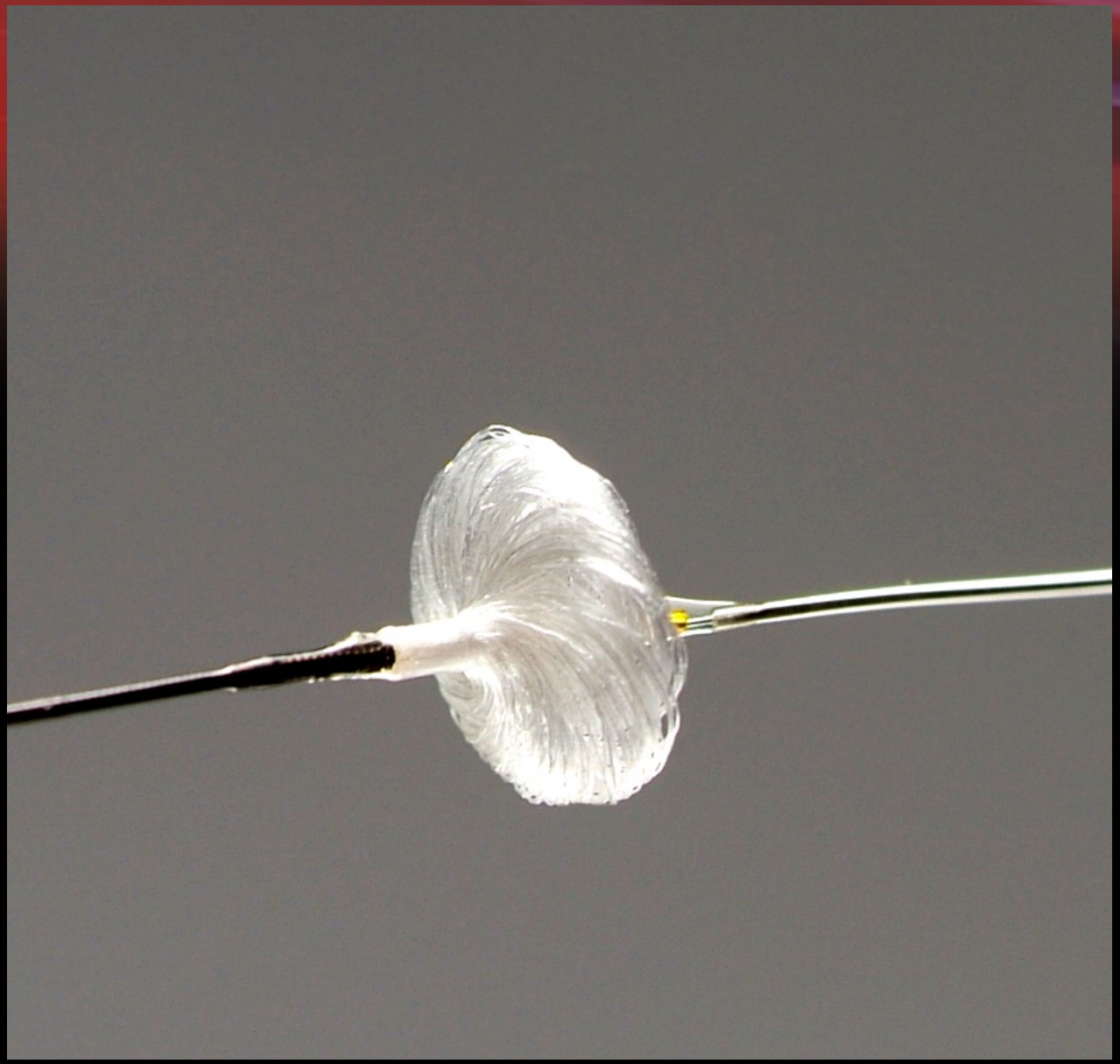
The FiberNet® system consists of

- Expandable filter mounted on a high performance 0.014" guidewire
- RX focal-suction retrieval catheter.

The filter

- numerous strands of polymer fibers.
- seek the vessel wall, forming a 3-D depth filter.

Focal-suction catheter



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FiberNet EPS Features

Effective Particulate Capture/Retrieval:

- completely fills (even eccentric) vessels
- 3-D depth filter efficiently traps particles ≥40 microns

Greater Access:

- flexible 0.014" high performance wire; low crossing profile; no delivery catheter
- very small landing zone requirement

Maintains blood flow during the intervention:

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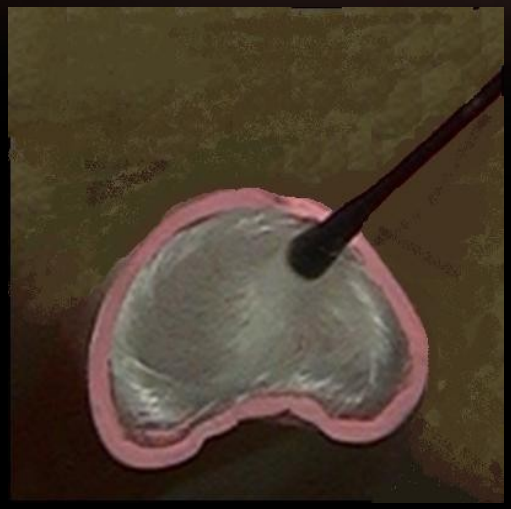
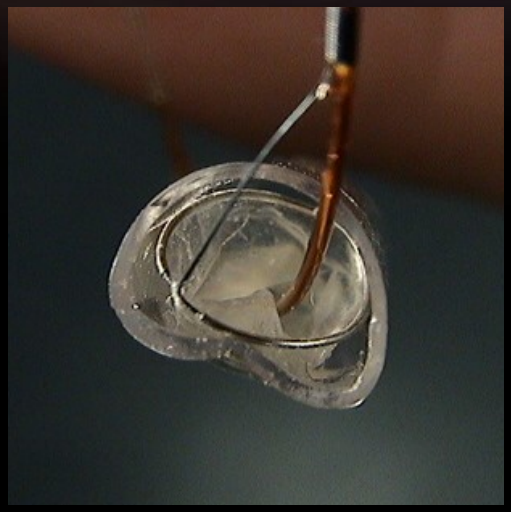
FiberNet: Fills (even eccentric) Vessels



FiberNet



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FiberNet: Efficient 3D Depth Filter

Bench Tests Confirm Filtration Efficacy:

99% particulate ≥ 100 µm

93% particulate ≥ 40 µm

data on file at Lumen Biomedical

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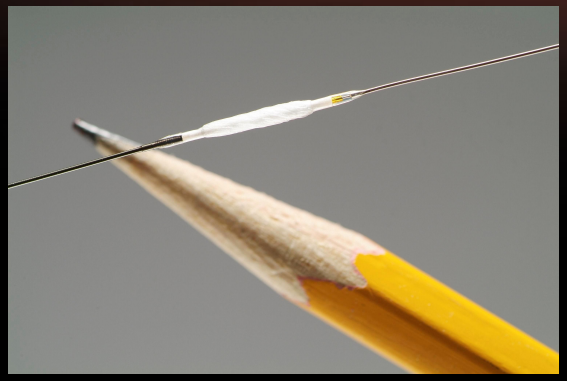
FiberNet: Low Crossing Profile



FiberNet Model	Vessel Size	Crossing Profile
2500	1.75-2.5 mm	1.7F
3500	2.5-3.5 mm	2.1F
5000	3.5-5.0 mm	2.4F
6000	5.0-6.0 mm	2.7F
7000	6.0-7.0 mm	3.2F

Other Device Specifications

Device	Vessel Size	Crossing Profile
EmboShield	3.0-6.0 mm	3.7-3.9F
AccuNet RX	3.5-5.0 mm	3.5-3.7F
FilterWire EZ	3.5-5.5 mm	3.2F
SpideRX	3.0-7.0 mm	3.2F
GuardWire	3.0-5.0 mm	2.7F

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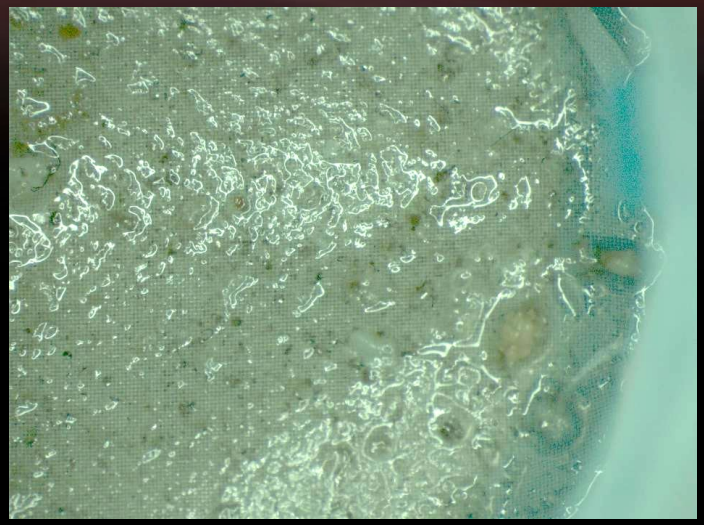
High Capture Efficiency:
Clinical Cases – Greece, Germany, US

Visible debris has been removed in **100%** of the cases to date.



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Clinical Studies

Epic US Carotid Study:

- **High surgical risk, multicenter, single arm registry, 30 day follow-up**
- **Symptomatic with ≥ 50% stenosis, Asymptomatic with ≥ 70% stenosis**
- **Enrollment Ongoing**

Epic European Carotid Study:

- **Multicenter, single arm registry, 30 day follow-up**
- **Symptomatic with ≥ 50% stenosis, Asymptomatic with ≥ 70% stenosis**
- **Enrollment Ongoing**

Retrieve European Saphenous Vein Graft Study:

- **Multicenter, single arm registry, 30 day follow-up**
- **Enrollment Pending**

Evaluating the Use of the FiberNet® Emboli Protection Device in Carotid Artery Stenting:

The EPIC US Feasibility Study

"CAUTION – Not commercially available: INVESTIGATIONAL DEVICE"
90-1003,B

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EPIC Study Objective

Multicenter, prospective, feasibility study designed to demonstrate the performance and safety of the Lumen Biomedical, Inc. FiberNet® Embolic Protection System as an adjunctive device during carotid artery percutaneous intervention in high risk patients.

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EPIC Study Design, Scope, and Duration

- High Surgical Risk Patient Carotid Registry study.
- Up to 10 US Centers enrolling up to 30 subjects.
- All subjects who meet criteria will be treated with the FiberNet device and Acculink stent. Patients will be followed through 30 days.
- Pivotal study to support commercial clearance to begin first quarter 2007
- Principle Investigator: Michael Bacharach MD

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EPIC Study Endpoints

Primary Endpoint: **the rate of all death, stroke, and MI within 30 days of the procedure.**

Secondary Endpoints:

- **All death and stroke rates**
- **Non-stroke neurological event rates**
- **Technical success rates**
- **Procedural success rates**
- **Access site complication rates**

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FiberNet Procedures Done in Greece with Dr. Henry and Dr. Polydorou

"CAUTION – Not commercially available: INVESTIGATIONAL DEVICE"
90-1003,B

Non FDA approved:Investigational device

Greece Baseline Characteristics

N = 46 Carotid Patients and 4 Renal Patients

Mean Age at Procedure	**69 years**
Percent Male	**68%**
Mean Percent Stenosis	**84.6%**

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Greece FiberNet Results

Patients N = 50 subjects (51 lesions)

Procedure Success **96%**

% Cases Visible Debris Caught **100%**

Two Instances of TIMI 1 flow and one instance of TIMI 0 flow. TIMI 3 flow restored after suction in all cases.

Three vessel spasm treated with nitro (not at the location of distal protection device)

No Changes noted in 30 day follow-up CT/MRI

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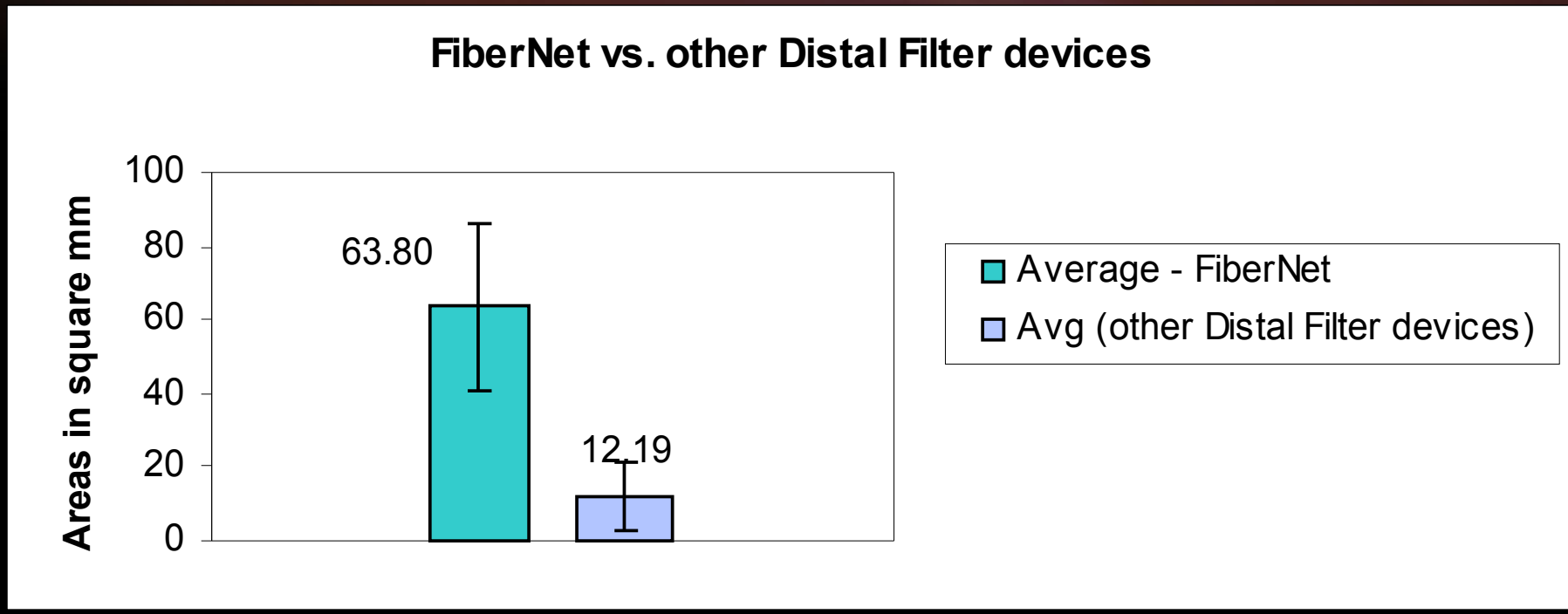
Debris Analysis
Area of Debris Captured (mm^2)



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