

Carotid Stenting Review

**Renan Uflacker, MD
Interventional Radiology
Medical University of South Carolina**

Carotid Stent



**IMPORTANCE
OF
CAROTID ARTERY
DISEASE
TREATMENT**

Carotid Stent

Stroke:

- 3rd cause of death in US
- 500,000 cases/year
- 2 milion/year handicaped people

HIGH SOCIAL / ECONOMIC COST

Carotid Stent

- 20 - 30% of VCA are related to carotid occlusive disease
- Increased incidence with age (33% < 45 yrs and 80% >50 yrs)

Carotid Stent

- **Stenoses > 75%**

risk of stroke in 1st yr = 2-5%

Roederer et al. Stroke, 1984

Hennereci et al. Brain, 1987

- **Ulceration = Imminent stroke**

risk of stroke = 7,5%

Autret et al. Lancet, 1987

Carotid Stent

- Carotid stenosis + TIA
- Risk of stroke in 1st yr = 12-13%
5th yr = 30-37%
Sundt et al., 1987
Dennis et al. Stroke, 1990
- CVA - risk in 1st yr = 59%
5th yr = 25-45%
Sacco et al. Stroke, 1982
Meissner et al. Stroke, 1988

Carotid Stent

- Heterogeneous and ulcerated lesions = Risk ↑ 2-4 x

Langsfeld *et al.* J Vasc Surg, 1989

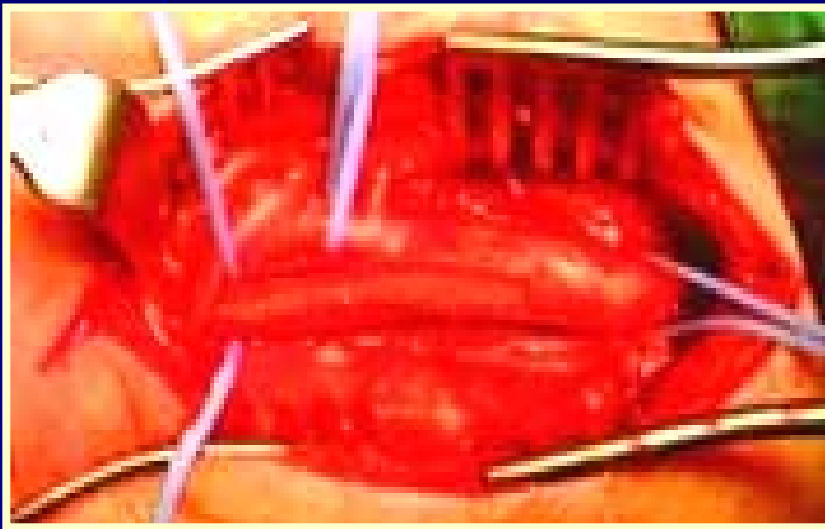
Sterpetti *et al.* Stroke, 1988

Carotid Stent

SURGICAL TREATMENT

Carotid Stent

ENDARTERECTOMY (1953)



- ↓ risk of stroke
- TIA = 1-2% / Yr
- CVA = 2-3% / Yr

Carotid Stent

- Clinical Trials such as NASCET/ACAS established the pattern of efficacy of surgical treatment in comparison to clinical treatment
- Demonstrated the superiority of the method with defined statistical criteria
- Surgery is the ‘gold standard’ for low risk patients

Carotid Stent

NASCET (North American Symptomatic Carotid Trial)

- 559 symptomatic patients / 2 anos
- Estenoses > 70%
- Risk of CVA

Clinical treatment = 13,1%

Surgical treatment = 2,5%

$P < 0,001$

N Engl J Med 1991;325:445

Carotid Stent

NASCET (North American Symptomatic Carotid Trial)

- Risk CVA/peri-operative death = 5,8%
- Benefits of surgery evident after 3 months
- Benefits for lesions > 50%

N Engl J Med 1991;325:445

Carotid Stent

ECST (European Carotid Surgery Trials)

- 778 symptomatic patients / 3 yrs
- stenoses > 70%
- Risk of CVA

Clinical treatment = 16,8%

Surgical treatment = 2,8%

$p < 0,001$

- Risk CVA/peri-operative deaths = 7,5%

Lancet 1991;337:1235

Carotid Stent

ACAS (Asymptomatic Carotid Atherosclerosis Study)

- 1662 asymptomatic patients / 5 yrs
- stenoses > 60%
- Risks of CVA

Clinical treatment = 10,6%

Surgical treatment = 4,8%

$P < 0,004$

- Risk CVA/peri-operative death = 2,3%

Carotid Stent



AHA Quality Standards Surgical Treatment CVA / Death

- Symptomatic Patients < 6%
- Asymptomatic Patients < 3%

Carotid Stent

NASCET (North American Syntomatic Carotid Trial)

- **Cranial Nerve Lesion : 7,6%**
- **Hematoma : 5,5%**

Extensive list of exclusion criteria !

N Engl J Med 1991;325:445

Carotid Stent

Exclusion Criteria - NASCET / ACAS

- age > 79 anos
- co-morbidity (cardiac/renal/hepatic/ca)
- valvulopathy / arrhythmias
- previous endarterectomy
- unstable angina / recent MI
- previous surgery (30 days)



Carotid Stent

Variation in carotid endarterectomy mortality in the Medicare population: trial hospitals, volume and patient characteristics

Wennberg DE, Lucas FL, Birkmeyer JD *et al.*

- Death incidence in patients treated with surgery followed by Medicare is higher in institutions participating in the NASCET/ACAS

NASCET	0,6%		1,4% MEDICARE
ACAS	0,1%		

JAMA 1998;279:1278

Carotid Stent

- Patients with high risk of stroke present also with high risk for surgical treatment

High risk
patients

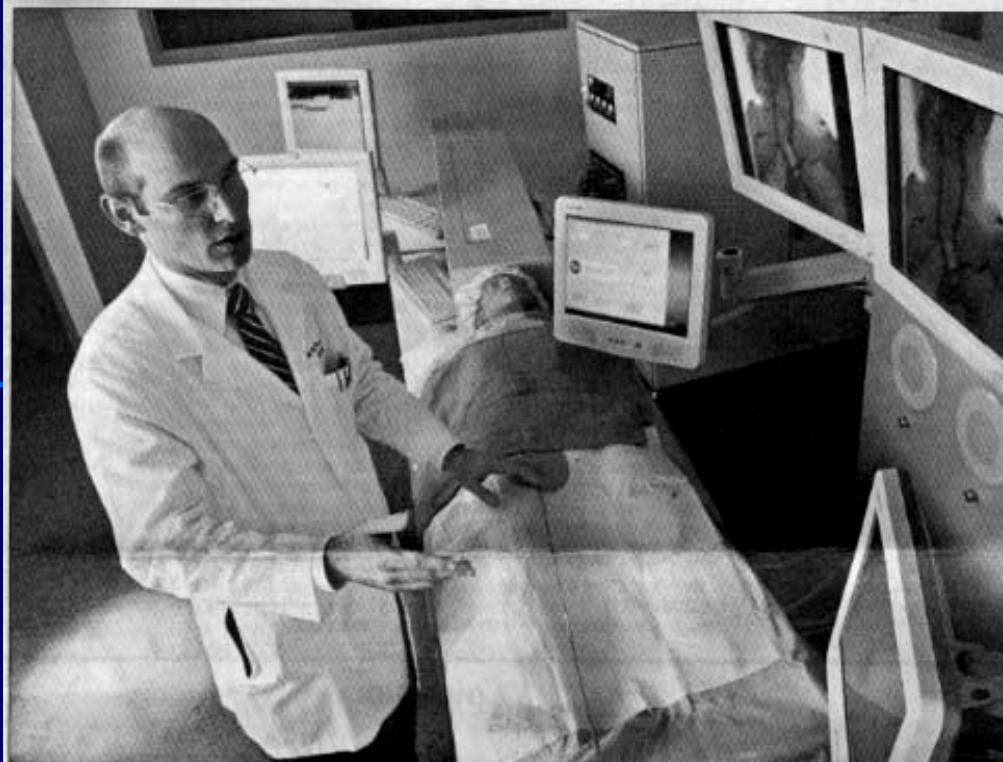


Endovascular
Treatment

Brown et al. J Vasc Surg, 2003; 37:32
Gasparis et al. J Vasc Surg 2003; 37:40

Carotid Stent

ENDOVASCULAR
TREATMENT



By Paul S. Howell for USA TODAY

Learning a new technique: James Wilson explains how the simulator Simantha works at St. Luke's in Houston.

Science clearing the way for shift in fighting stroke

But alternative to surgery has critics

By Steve Sternberg
USA TODAY

Lying in her glassed-in medical suite, Simantha looks almost human. And she has a very human problem.

Simantha's carotid arteries, the pipelines that supply precious blood to the brain, are clogged. If she were human, she'd be a classic candidate for a stroke.

She'd also be a candidate for an oper-

ation called carotid endarterectomy (car-ROT-id en-DAR-ter-ec-tomy), performed about 170,000 times in the USA each year. But there'll be no surgery for Simantha, a simulator designed to prepare doctors to use a controversial new technology for stroke prevention that may replace surgery for many patients.

The new approach is called carotid angioplasty and stenting. Using techniques now used routinely in the heart, doctors clear and prop open arteries that supply the brain. The advance reflects the latest shift from surgery to

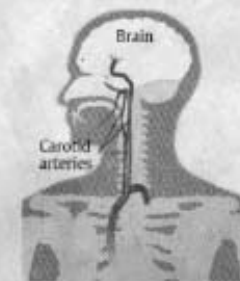
less invasive procedures. It also has divided the medical community.

Vascular surgeons, who do most of the carotid endarterectomies, have seen their dominance in blood vessel repair eroded by the shift from surgery. They fear that carotid stenting will shrink their livelihood. Interventional radiologists and others who work in the neck and head fear that they will be overrun by cardiologists who are eager to extend their reach almost into the brain.

Please see COVER STORY next page ►

Angioplasty for the brain

Angioplasty, which has begun to edge out bypass surgery as a way to treat clogged arteries near the heart, may soon reduce the need for an invasive procedure, carotid endarterectomy, now used to prevent stroke.



Step 1

Small incision is made in the femoral artery in the groin.

Step 2

Catheter is used to thread a guide wire to the narrowed section of artery.



Step 3

Guide wire is used to glide three items into place: a barrier that keeps stroke-promoting debris from flooding upstream to the brain, a narrow balloon and a stent.



Step 4

Balloon is inflated, clearing the artery. The stent slips into place. After the stent is installed, the debris is removed, along with all of the technology needed to put the stent in place. Procedure is complete.



Illustration: Jay Yafan, The Cleveland Clinic

By Nancy Pecker and Dave Mezzell, USA TODAY

Carotid Stent

- Carotid angioplasty is performed with incidence of CVA/death ranging **5,3-8,2%**.

Diethrich *et al.* J Endovasc Surg, 1996

Bergeron *et al.* Cardiovasc Surg, 1996

Yadav *et al.* Circulation, 1997

Henry *et al.* J Endovasc Surg, 1997

Carotid Stent

LEARNING CURVE:

CLINICAL EXPERIENCE: 89/99 10 years

N = 924 (independent neurologic evaluation)

#Angioplasties Complications

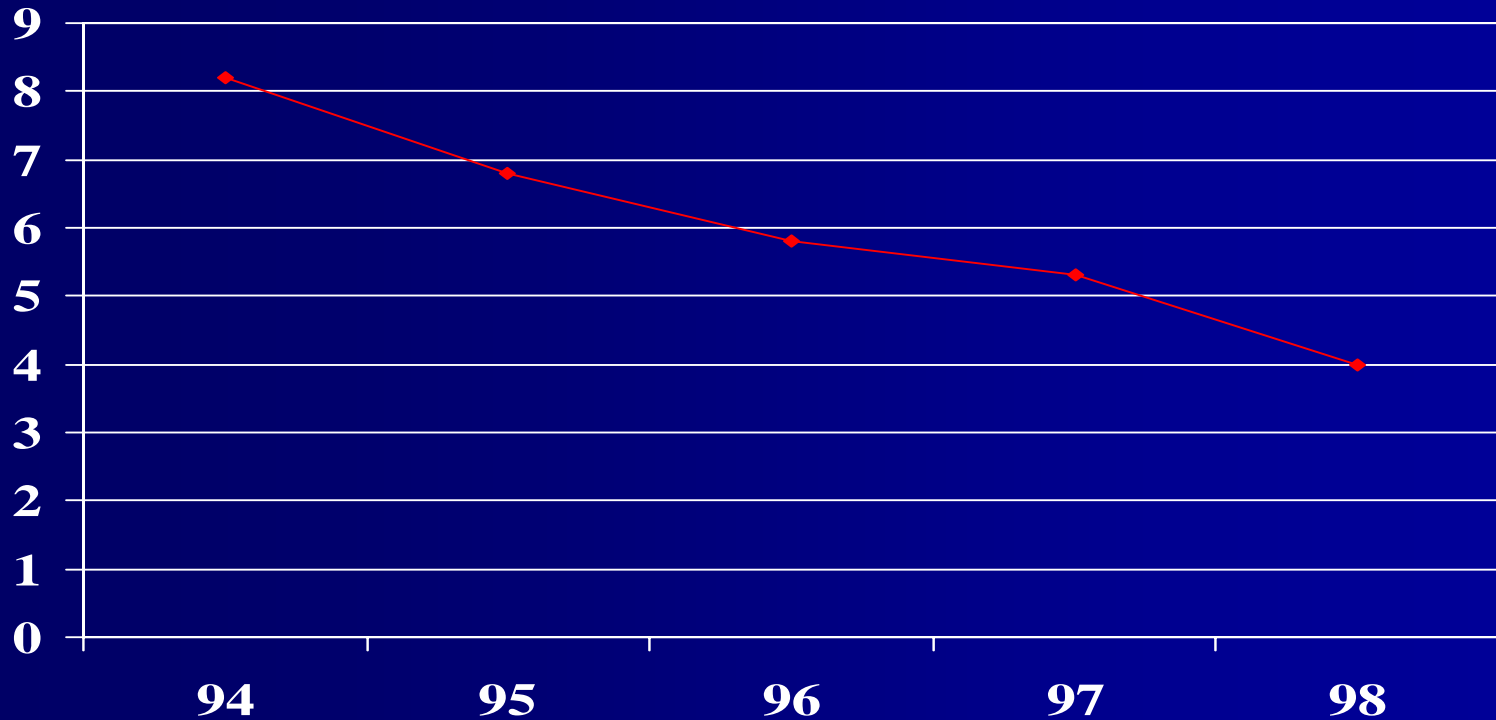
■ 89/91	111	8,8%
■ 92/94	196	4,8%
■ 95/99	617	2,0%

K. Matias ISES Jan 2000



Carotid Stent

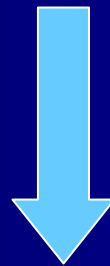
Incidence of complications:



Vitek et al. AJNR 2000

Carotid Stent

Antiplatelet therapy, before and after
the procedure



↓ **Acute thrombosis of the stent**
↓ **Embolism**

Vitek et al. AJNR 2000

Carotid Stent

WALLSTENT TRIAL

- 219 patients
- No protection
- No antiplatelet therapy

	Surgical	Endovascular
Risk CVA/death	4,5%	12,1%

Trial was interrupted

Carotid Stent



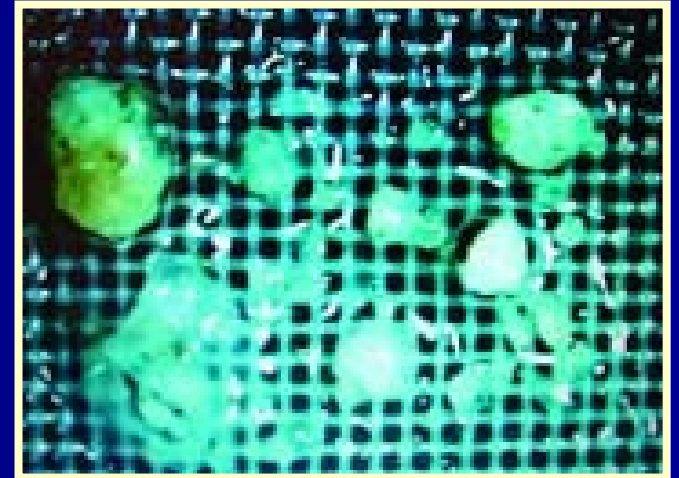
What to do with the plaque fragments

Carotid Stent

Cerebral Protection

Carotid Stent

There is considerable evidence of embolization during carotid angioplasty



DeMonte *et al.* J Neurosurg. 1989;70:138

Ohki, T *et al.* J Vasc Surg. 1998;27:463

Carotid Stent

Carotid artery stenting protected with an emboli containment system

Whitlow PL, Lylyk P, Londero H, *et al.*

Visible particles and debris from plaques, cholesterol and calcific fragments # 22 to 667 particles with average size of 200 microns (range 3.6 to 5262) captured with cerebral protection system (PercuSurge)

Stroke. 2002;33(5):1308-1314.

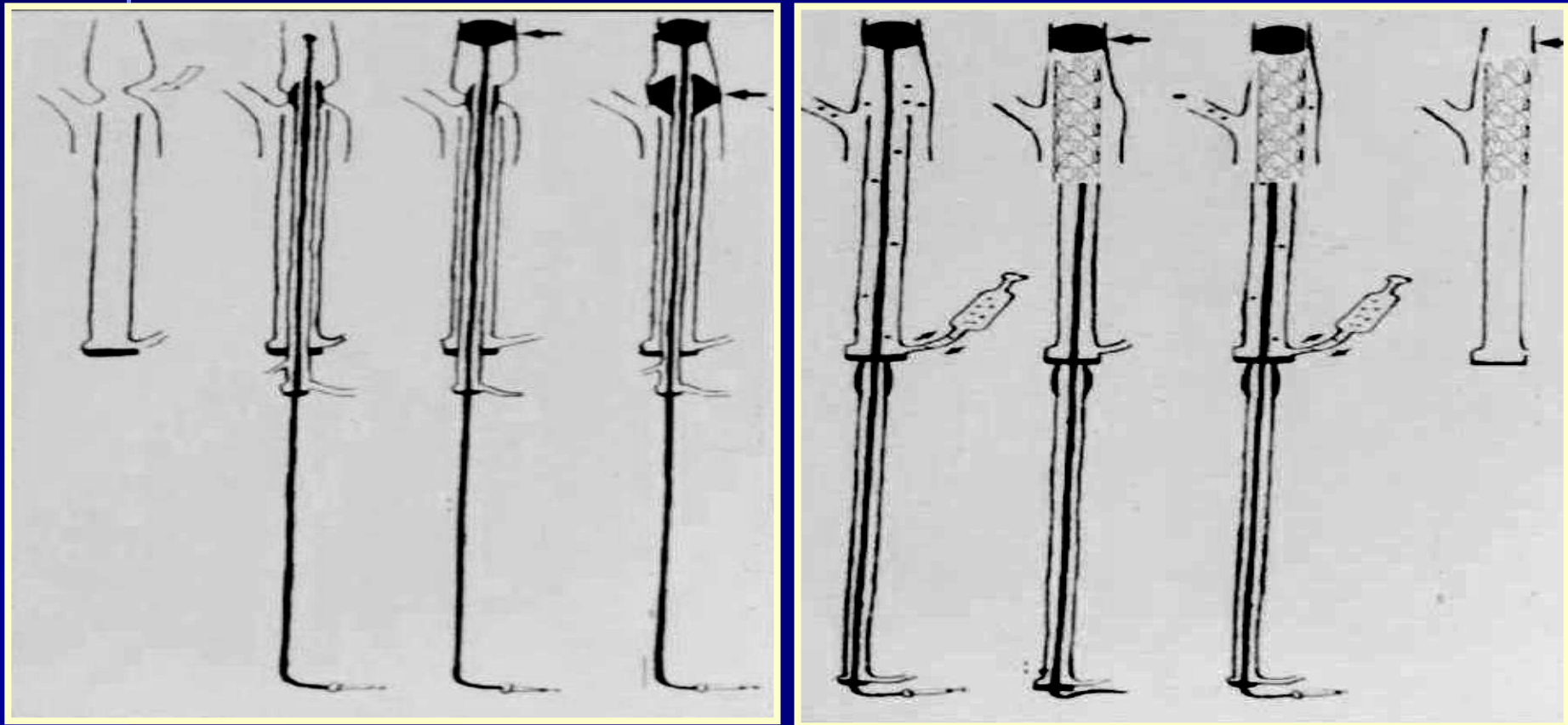
Carotid Stent

- Embolic event is related to:
 - Guidewire placement
 - Passage through the lesion
 - Dilation of the stenoses
 - Stent placement
 - Stent dilation (self or balloon expandable)



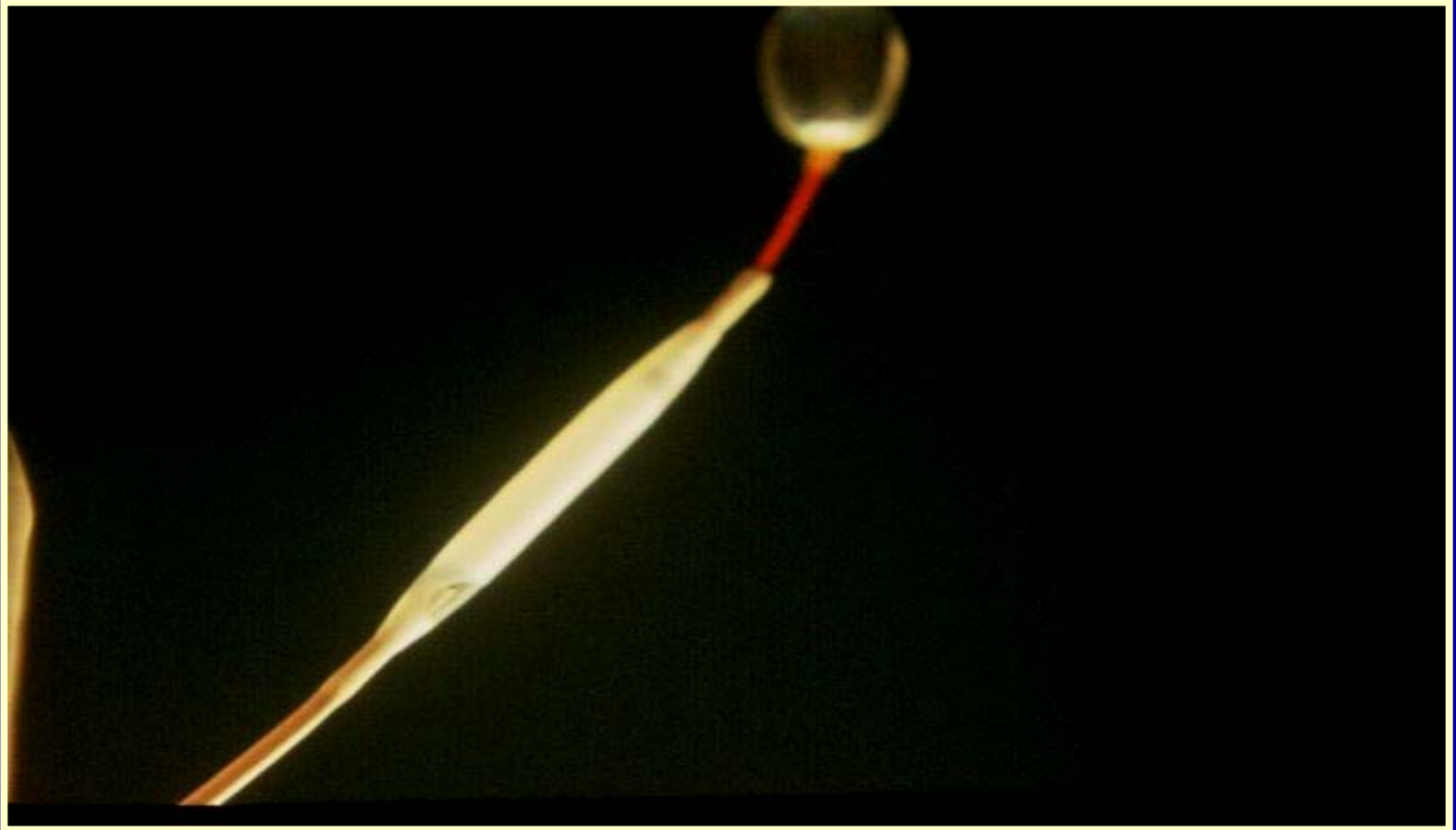
Carotid Stent

J. Theron's Technique



Theron *et al.* AJNR, 1990

Carotid Stent



Carotid Stent

Company	Embollic Protection Devices		
	Name	Type	Position
Abbott Vascular	EmboShield	Filter	Distal
ArteriA	PAES	Continuous flow reversal	Proximal
Boston Scientific	Filterwire EZ	Filter	Distal
	Filterwire EX	Filter	Distal
Cordis	AngioGuard XP	Filter	Distal
Cordis	AngioGuard RX	Filter	Distal
EndoTex	FilterWire EX	Filter	Distal
ev3	Spider	Filter	Distal
Guidant	RX AccUNET	Filter	Distal
Medtronic	Interceptor	Filter	Distal
	GuardWire	Occlusion	Distal

PERCUSURGE
LABORATORIES

The PercuSurge GuardWire™ System is not approved for use in the U.S. in the coronary, cerebral or carotid vasculature.



PercuSurge Export™ Aspiration Catheter
Mounted on GuardWire™

PERCUSURGE
LABORATORIES

The PercuSurge GuardWire™ System is not approved for use in the U.S. in the coronary, cerebral or carotid vasculature.



The PercuSurge Export™ Aspiration Catheter

PERCUSURGE
LABORATORIES

The PercuSurge GuardWire™ System is not approved for use in the U.S. in the coronary, cerebral or carotid vasculature.



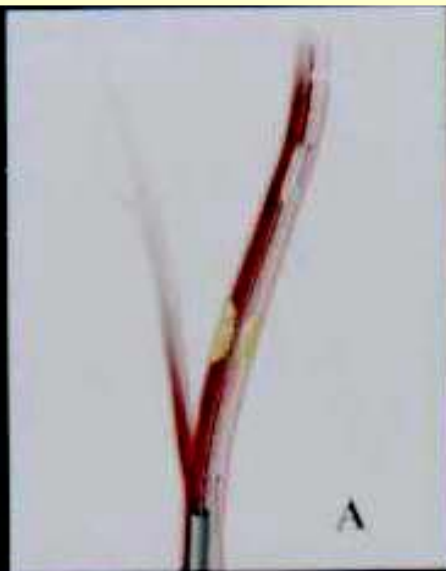
The PercuSurge GuardWire™ System

The PercuSurge GuardWire™ System is not approved for use in the U.S. in the coronary, cerebral or carotid vasculature.

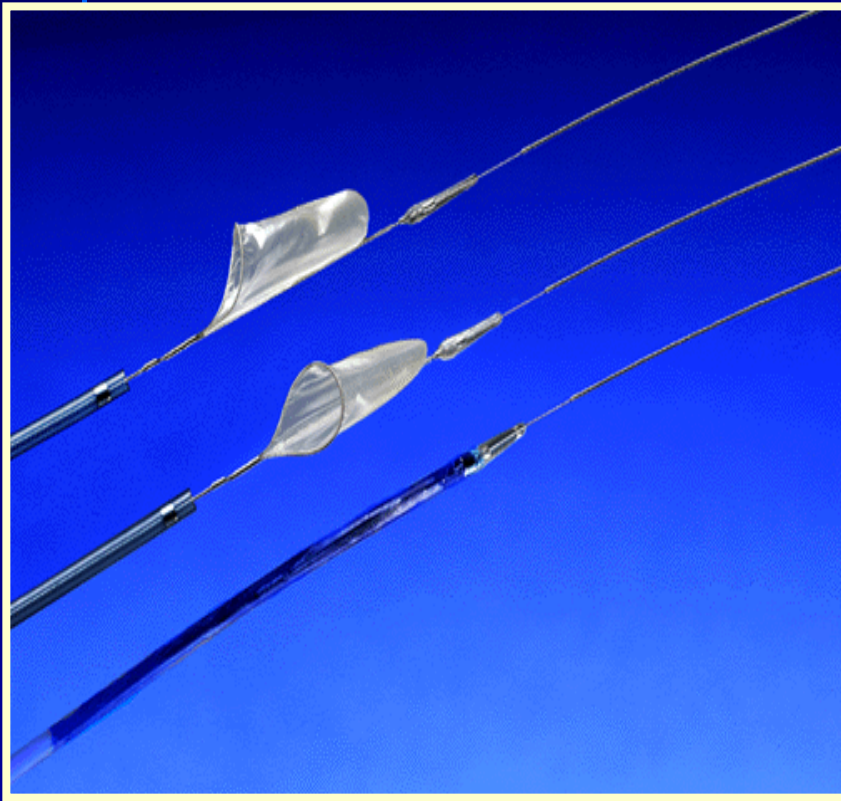


The PercuSurge GuardWire™ System

Carotid Stent



Carotid Stent

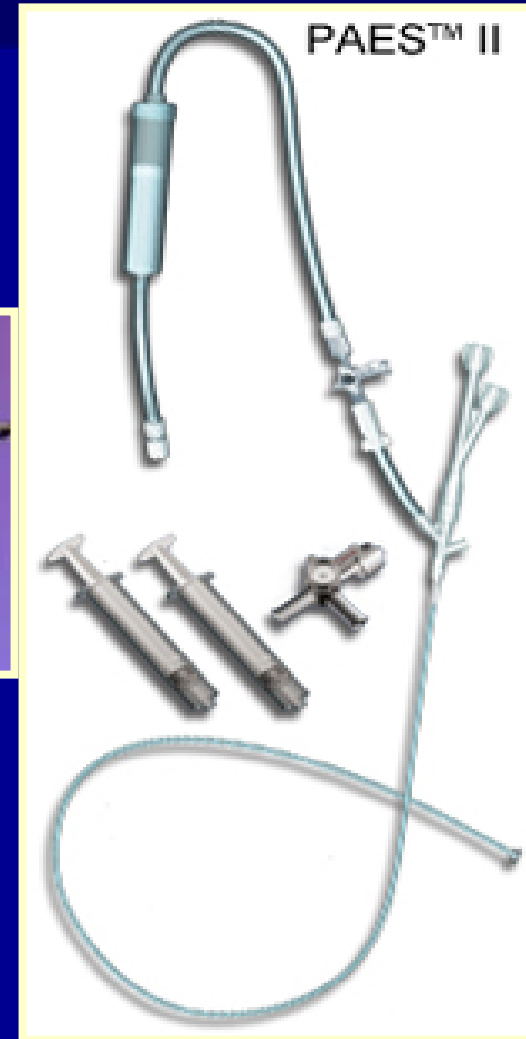
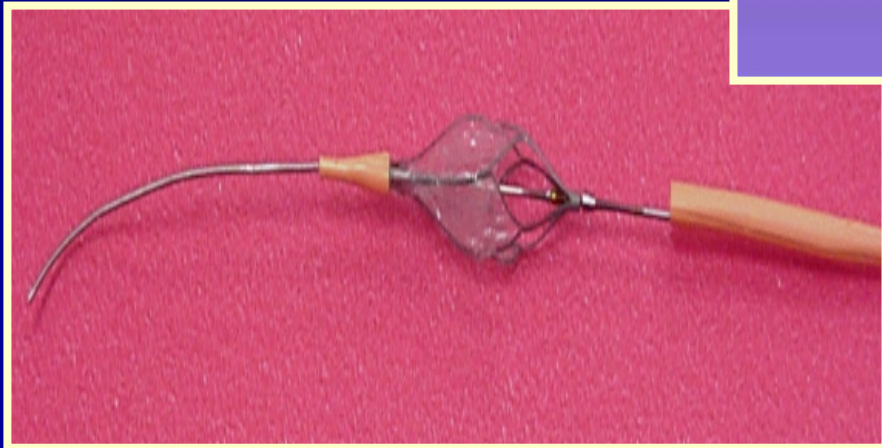
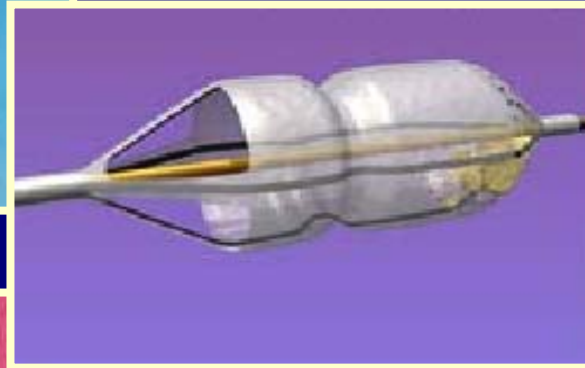
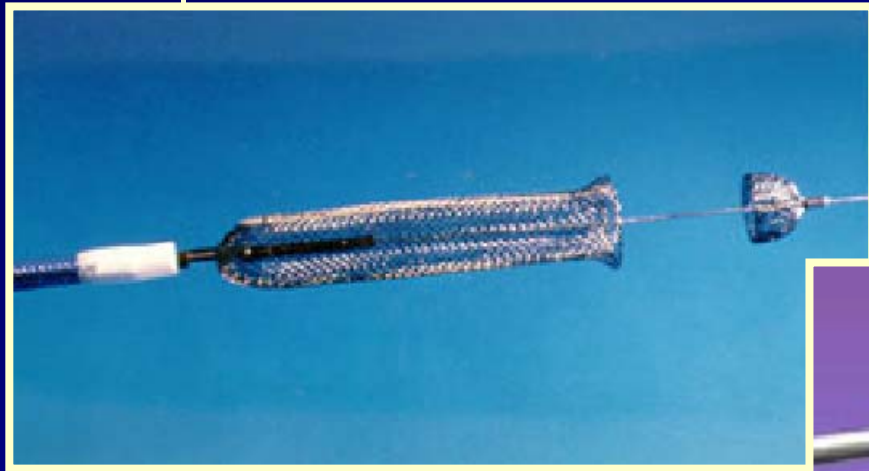


E.P.I.

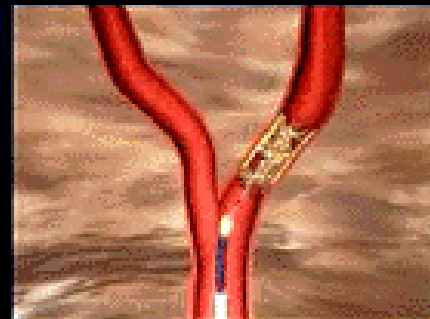
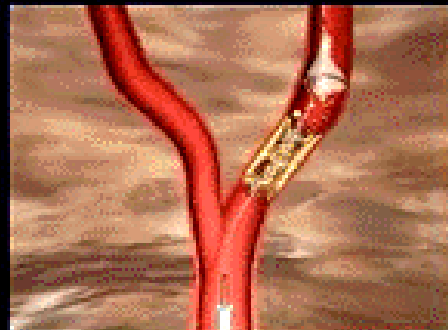
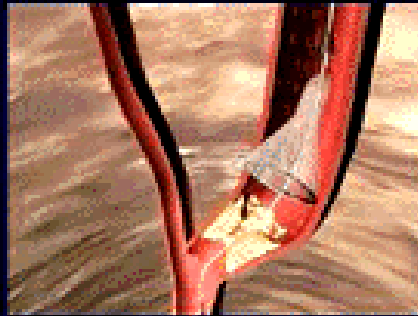
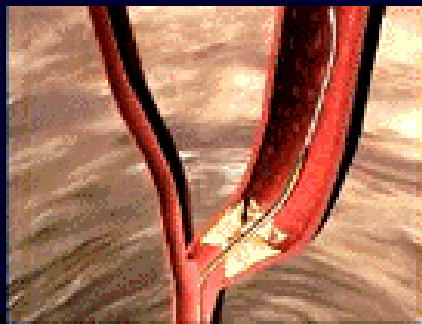
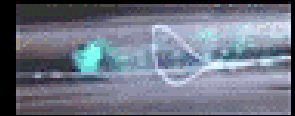
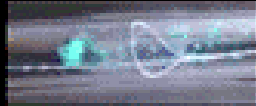


Angioguard

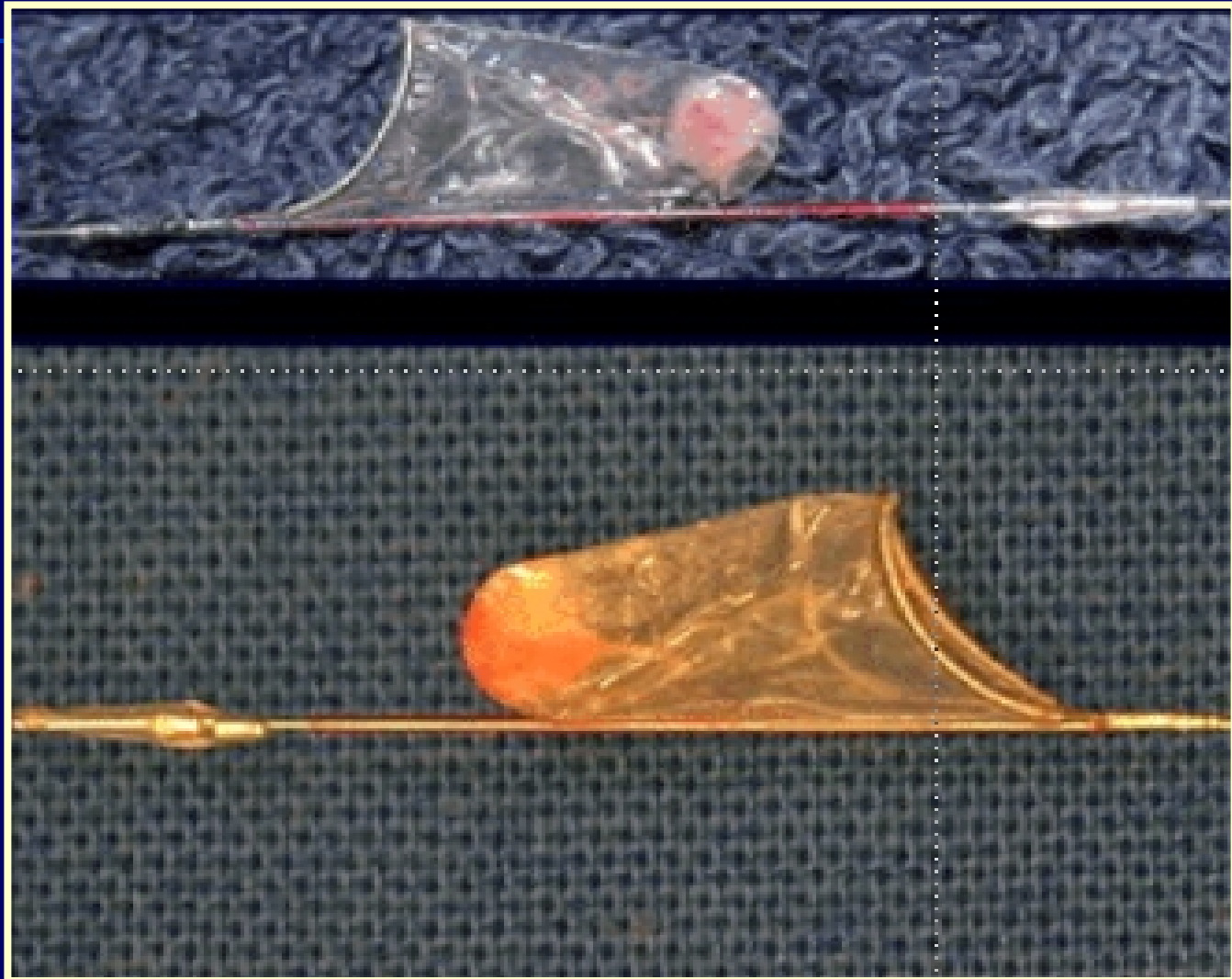
Carotid Stent



Carotid Stent



Carotid Stent



Carotid Stent

- Risk factors for embolism:
 - Old age (> 80 anos)
 - Arterial Hypertension
 - Recent stroke

Carotid Stent

- Non contributing factors:
 - Gender
 - Neurologic symptoms
 - Coronary disease
 - Diabetes, ↑ cholesterol, tabaco use
 - Bilateral lesion
 - Contralateral occlusion

Matur *et al.* Circulation, 1998

Carotid Stent

Clinical experience:

- Jacques Theron **CVA/death = 2%**
Theron J. *et al*/AJNR 1990;11:869
- 75 patients **CVA/death = 0**
Whintlow P. CAFE study 2000
- 167 patients **CVA/death = 2,7%**
Henry M. *et al*/J Endovasc T 2002;9:1

Carotid Stent

Global experience in cervical carotid artery stent placement.

Wholey M H, Mathias K, *et al.*

CVA/death

PTA/Stent NO/ cerebral protection (n=1596) 4,2%

PTA/Stent WITH/ cerebral protection (n=771) 1,7%

Cathet Cardiovasc Intervent. 2000;50(2):160

Carotid Stent

Early outcome of carotid angioplasty and stenting with and without cerebral protection devices. Review of literature

Kastrup A, Groschel K, Kraft H *et al.*

	PTA NO/ PROTECTION	PTA WITH/ PROTECTION	
GLOBAL	5,5%	1,8%	<i>P < 0.001</i>
<i>cva minor</i>	3,7%	0,5%	<i>P < 0.001</i>
<i>cva major</i>	1,1%	0,3%	<i>P < 0.05</i>
<i>death</i>	0,8%	0,8%	<i>P = 0.6</i>

Stroke 2003;34:813

Carotid Stent

CAVATAS

- Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): A randomized trial.

Lancet. 2001;357:1729-1737.

Carotid Stent

CAVATAS

- 506 patients
- 22 centers / 3 years
- Intervencionalists with small experience in carotid PTA.
- Irregular use of stents
- No cerebralprotection

Lancet. 2001;357:1729-1737.

Carotid Stent

CAVATAS - RESULTS

	PTA	Surgical
■ CVA/death (30 days)	6,4%	5,9%
■ CVA/death (> 7 days)	10%	9,9%
■ Cranial nerve	0	8,7%
■ Restenosis (1yr)	14%	4%
■ No statistical differences in stroke risk between the two groups after 3 years.		

Lancet. 2001;357:1729-1737.

Carotid Stent

SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy)

- 334 patients symptomatic or not with high risk (excluded from NASCET criteria)
- Randomized
- Degree stenoses
 - Symptomatic > 50%
 - Asymptomatic > 85%
- 413 patients not randomized (registry)
- Sponsored by Cordis - angioguard + precise

Carotid Stent

SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy)

PTA/Stent technical success 95,6%

Death, stroke, MI cumulative within 30 days or between 31 days and 1 year:

PTA/Stent = 12.2%

CEA = 20.1%

Randomized group

$P = 0.047$

Carotid Stent

SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy)

Stroke, death, MI < 30 days:

PTA/Stent 4.8%

CEA 9.8 %

Stroke, death, MI Symptomatic at 1 yr

PTA/Stent 16.8 %

CEA 16.5 %

Carotid Stent

ARChER TRIAL:

- Technical Success = 95.9% - 99.3%
- Particles in the filter (debrís) = 57%
- CVA/Death = 6,6%
- CVA/Death/MI = 7,8%
- Degree of stenoses
 - Symptomatic > 50%
 - Asymptomatic > 80%

Carotid Stent

ARChER Trial – 581 combined patients

- **ARChER 1 – Carotid Stent**
 - 158 patients
- **ARChER 2 – Stent + Embolic Protection**
 - 278 patients
- **ARChER 3 – Newer version Rapid exchange system + Embolic Protection**
 - 145 patients

Sponsored by Guidant: Accunet + Acculink

ARChER Trial – 581 combined patients

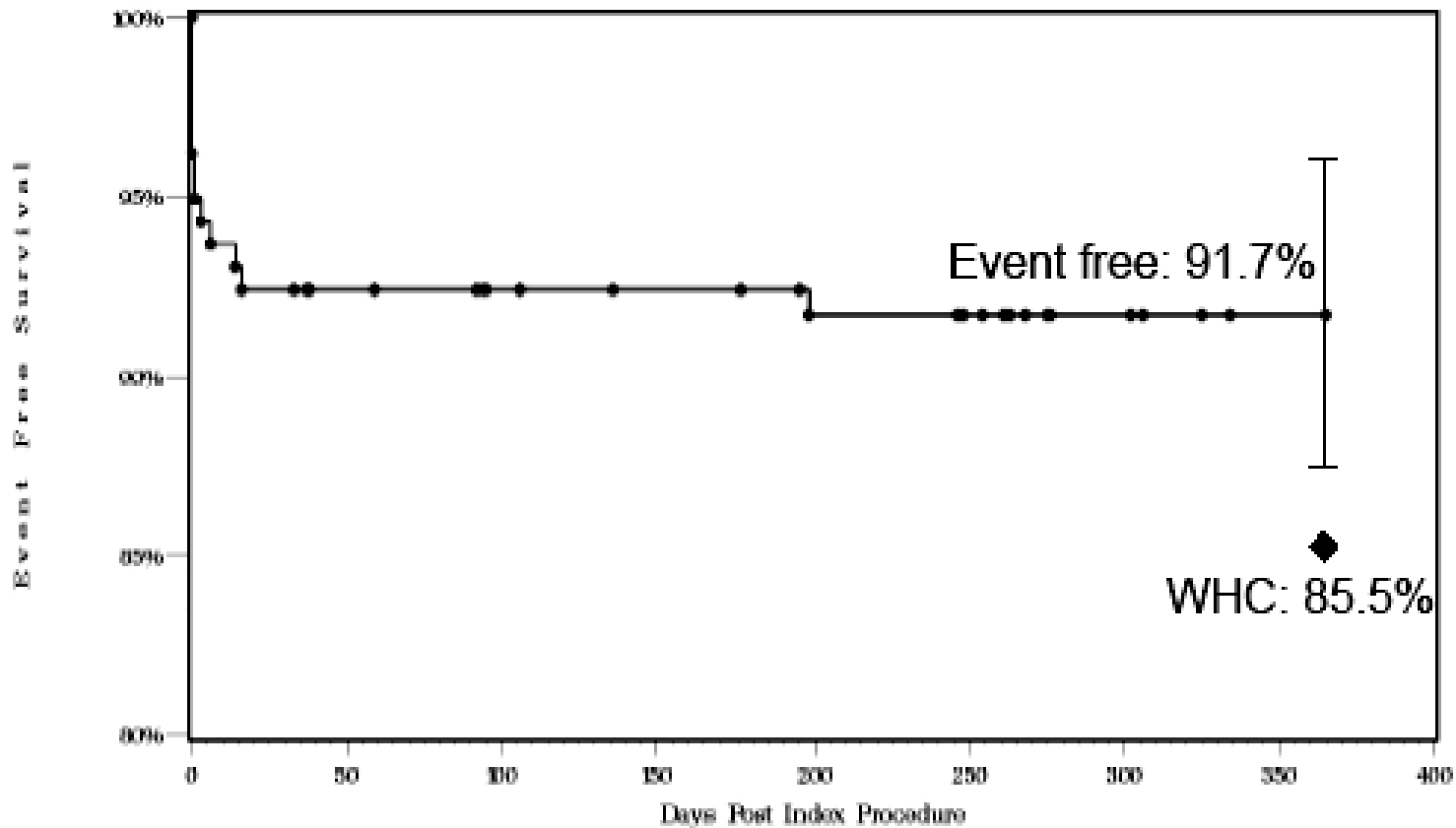
30 days combined end points

<i>*Non-hierarchical</i> <i>**Hierarchical</i>	ARChER 1 N = 158	ARChER 2 N = 278	ARChER 3 N = 145
Death*	2.5%	2.2%	1.4%
Stroke related	0.6%	0.7%	0.0%
Non-stroke related	1.9%	1.4%	1.4%
Stroke*	4.4%	5.8%	6.2%
Major	1.9%	1.4%	1.4%
Minor	2.5%	4.3%	4.8%
MI*	2.5%	2.9%	0.7%
Q-wave	1.3%	1.1%	0.0%
Non-Q wave	1.3%	1.8%	0.7%
Death/Stroke**	6.3%	6.8%	7.6%
Death/Stroke/MI**	7.6%	8.6%	8.3%
Major + Fatal strokes**	1.9%	1.4%	1.4%

ARChER 1

1-Year Composite Primary Endpoint

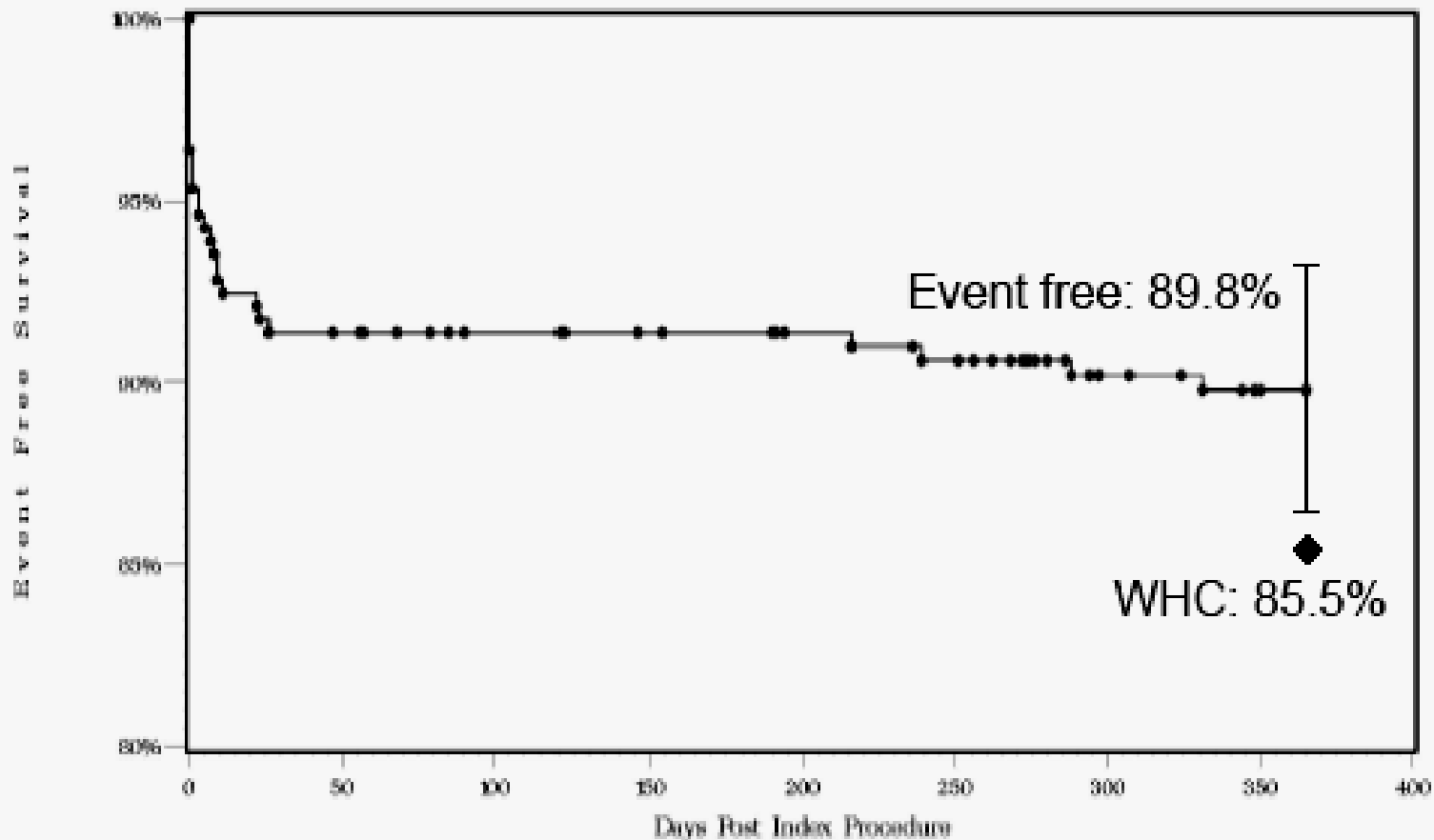
Composite Endpoint: 8.3%



ARCHeR 2

1-Year Composite Primary Endpoint

Composite Endpoint: 10.2%



Carotid Stent

TRIALS E REGISTERS

Study	Sponsor	Sample Size	Stent	Embolio Protection Device
ARCHeR	Guidant	n=437	OTW Acculink	OTW Accunet
ARCHeR RX	Guidant	n=145	RX Acculink	RX Accunet
BEACH	Boston Scientific	n=480 (400 evaluable)	Carotid Wallstent Monorail endoprosthesis	Filterwire EX and EZ
CABERNET	EndoTex	n=380	NexStent	FilterWire EX
CREATE	ev3	n=400	Protégé	SPIDER
CREST	NIH and Guidant	n=2,500	OTW Acculink	OTW Accunet
MAVERIC Int1	Medtronic	n=51	Exponent	Interceptor
MAVERIC II	Medtronic	n=99 (Phase I) n=399 (Phase II)	Exponent	GuardWire
PASCAL	Medtronic	n=115	Exponent	Any CE Mark-approved device
SAPPHIRE	Cordis	n=724*	Precise	AngioGuard-XP
SECURITY	Abbott Vascular Devices	n=320	MedNova Xact	MedNova NeuroShield/EmboShield

Carotid Stent

■ CREST

- 2.500 Symptomatic patients with low risk / 5 years
- Randomized; 60 centers
- Cerebral Protection
- Sponsored by NIH / Guidant

Carotid Stent

- **CARESS** (Carotid Revascularization Using Endarterectomy or Stenting Systems)
 - 439 patients
 - 90% with >75% stenosis
 - 68% asymptomatic
 - 30-day mortality and stroke
 - CEA 2%
 - CSS 2% (with protection)
 - 30-day all-cause mortality, stroke, MI
 - CEA 3%
 - CSS 2% (with protection)

Carotid Stent

- **Surgical treatment is still the “gold standard” for low risk patients**
- **More recent studies with cerebral protection devices are rapidly changing this concept.**

Carotid Stent

- In 2002 only 4% of carotid stenosis were treated by PTA and stents
- Projections for year 2006 anticipate it will be 75% of all cases of carotid stenosis due to approval of the procedure/devices by the FDA in light of the clinical studies

Morgan & Stanley 2003

Carotid Stent

**Timing and frequency of complications
after carotid artery stenting:**

What is the optimal period of observation?

Tan KT, Cleveland TJ, Berczi V, *et al.*

- **Safety criteria for same day discharge of patients**
 - **204 patients Incidence of complications = 5,4%**
 - **52,6%** **6 hs**
 - **5,3%** **6-12 hs**
 - **7,9%** **12-24 hs**

Carotid Stent

Outpatient Carotid Stenting

Mr. F. A.

Admit 7:00 am

Stent 9:00 am

Discharge 5:00 pm

