

**NEUROPROTECTION AND CAROTID  
INTERVENTION  
CURRENT RECOMMENDATIONS**

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# **NEUROPROTECTION AND CAROTID INTERVENTION**

■ **AMERICAN REGISTRIES , RANDOMIZED STUDIES FOR HIGH RISK OR STANDARD RISK PATIENTS ( CREST.....) HAVE SHOWN THAT :**

**CAS IS NOT INFERIOR TO SURGERY AND GIVE GOOD IMMEDIATE AND LONG TERM RESULTS SIMILAR TO SURGERY**

■ **BUT BRAIN EMBOLIC EVENTS ,NEUROLOGICAL COMPLICATIONS REMAIN THE MAJOR DRAWBACK**

■ **WE HAVE TO REDUCE THE NEUROLOGICAL COMPLICATIONS WITH A BETTER NEUROPROTECTION HOW TO DO ?**

# **NEUROPROTECTION AND CAROTID INTERVENTION**

- **GOOD PT AND LESION SELECTION:  
MEDICAL / ANATOMICAL RISKS**
- **CORRECT TECHNIQUE : APPROACH WAYS / TECHNICAL  
POINTS**
- **EPDs : MANDATORY FOR ALL CAS**
- **STENTS**
- **PHARMALOGICAL NEUROPROTECTION**
- **TEAM EXPERIENCE**

# **NEUROPROTECTION AND CAROTID INTERVENTION**

- **GOOD PT AND LESION SELECTION**

**MEDICAL RISKS**

# CAS INDICATIONS

## PATIENTS TO AVOID OR TREAT W/ CAUTION

### ■ PTS WITH HIGH CARDIAC RISKS

CORONARY DISEASES

CARDIAC INSUFFICIENCY

UNCONTROLLED HYPERTENSION

**CAREFUL  
MONITORING**

### ■ PTS WITH NEUROLOGICAL RISKS

CRESCENDO T.I.A.

STROKE IN EVOLUTION

CONTRALATERAL ISCHEMIC SYMPTOMS

SYMPTOMATIC PTS

### ■ PTS WITH RENAL INSUFFICIENCY

### ■ DIABETICS □ 75 Y.

### ■ OCTOGENARIANS

### ■ PTS WITH POOR CEREBRAL RESERVE

# **NEUROPROTECTION AND CAROTID INTERVENTION**

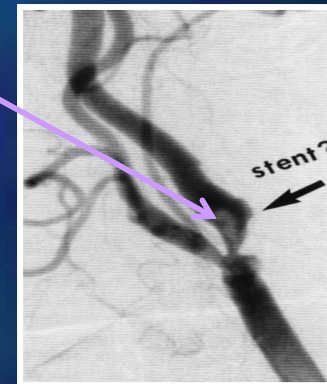
- **GOOD PT AND LESION SELECTION**

**ANATOMICAL RISKS**

# CAS INDICATIONS

## LESIONS TO AVOID OR TREAT W/ CAUTION

- HEAVY CIRCUMFERENTIAL CALCIUM
- MOBILE THROMBUS
- STRING SIGN



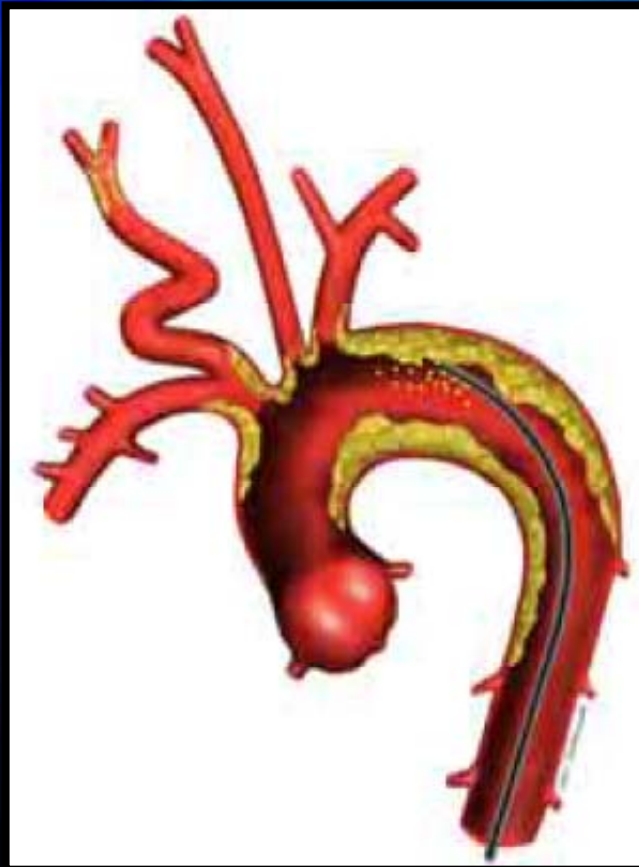
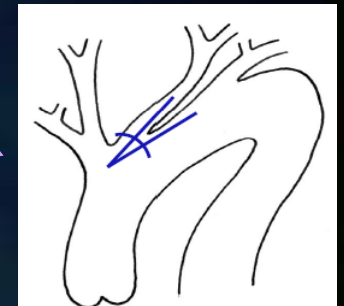
- TOTAL OCCLUSIONS
- LONG LESIONS
- SHARP « ENTRY » OR « EXIT » ANGLES

**C.A.S.**

## **HIGH RISK AORTIC ARCH**

### **HIGH RISK OF BRAIN EMBOLISM**

- . DIFFUSELY DISEASED ATHEROMATOUS AORTIC ARCH**
- . TYPE III AORTIC ARCH**
- . TORTUOSITIES**
- . SEVERE CALCIFICATIONS**



**AORTIC ARCH IS A SUBSTANTIAL SOURCE OF EMBOLI**

**AORTIC ARCH HAS ITS OWN SET OF EMBOLIC POTENTIAL**

**AVOID EXCESSIVE CATHETER MANIPULATION IN ARCH**

**BETTER TO QUIT**



# NEUROPROTECTION AND CAROTID INTERVENTION

- CORRECT TECHNIQUE

# NEUROPROTECTION AND CAROTID INTERVENTION

## ■ CORONARY TECHNIQUE

## ■ CHOOSE CAREFULLY

### ▶ GUIDE WIRES

0.014 , 0.018 , 0.035 AMPLATZ , HYDROPHYLIC

### ▶ CATHETERS

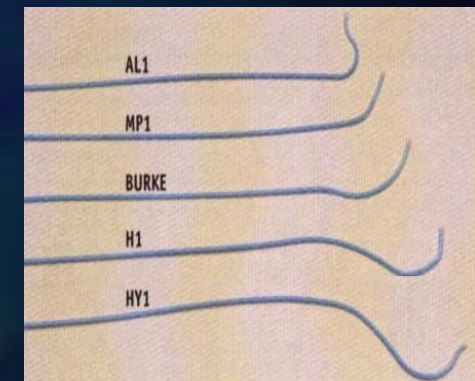
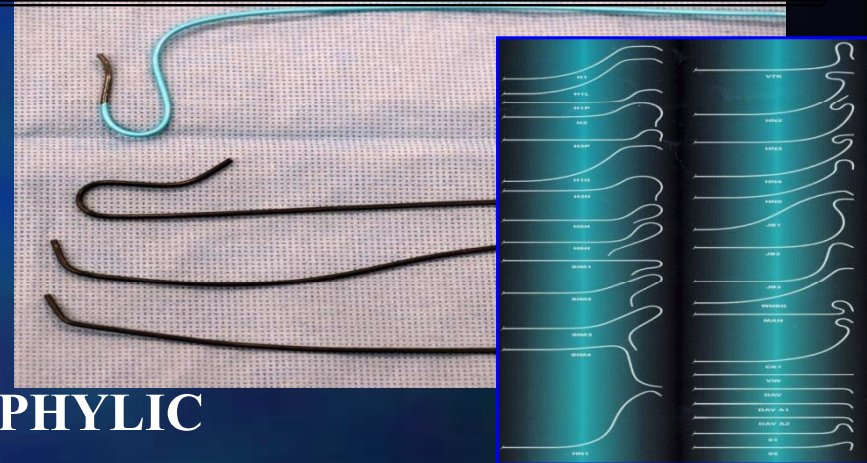
( VITEK, RIGHT JUDKINS, SIMMONS.....)

### ▶ 6-8 F SHEATH OR GUIDING CATHETER

## ■ MONORAIL SYSTEM

## ■ 0,014 " SYSTEM - STENT / EMBOLIC PROTECTION DEVICE

## ■ KEEP PROCEDURE TIME SHORT



# **NEUROPROTECTION AND CAROTID INTERVENTION**

## **■ CORRECT TECHNIQUE**

### **▶ APPROACH WAYS**

**40% OF ALL STOKES ARE RELATED TO ACCESS SITE**

**C.A.S.  
VASCULAR ACCESS**

**FEMORAL MOST OF THE TIME**

# NEUROPROTECTION AND CAROTID INTERVENTION

## DIFFICULT ANATOMY

### ■ SELECT OTHER APPROACH WAY

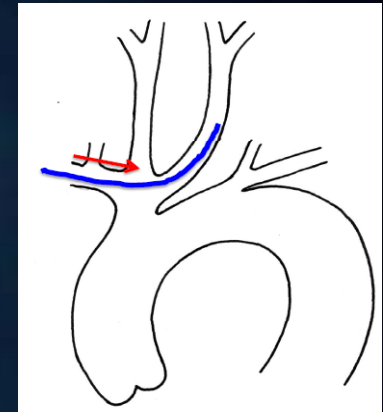
➤ BRACHIAL / RADIAL

➤ DIRECT PUNCTURE

. BOVINE ARCH

. TYPE III / HIGH RISK AORTIC ARCH (SEVERE  
ATHEROMATOUS LESIONS )

FOR FILTERS OR OCCLUSION BALLOON



### ■ DIRECT CAROTID ACCESS BY MINI SURGICAL INCISION IN HIGH RISK PTS FOR BOTH TRANSFEMORAL CAS AND CEA WITH CRITICAL LESIONS

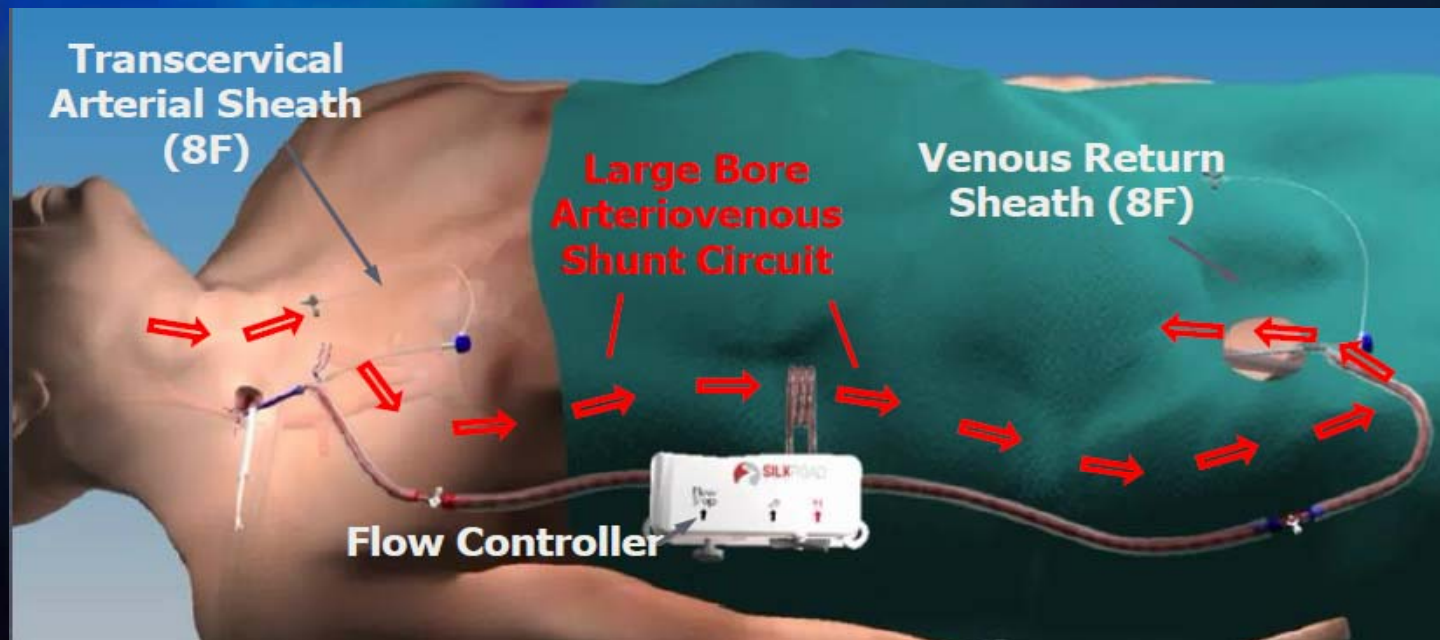
# NEUROPROTECTION AND CAROTID INTERVENTION

## DIFFICULT ANATOMY

### TRANSCAROTID STENTING

#### PROXIMAL EPD COMBINED WITH DIRECT CAR. ACCESS

- . MICHI NEUROPROTECTION SYSTEM
- . ENROUTE TRANSCAROTID NEUROPROTECTION SYSTEM



# NEUROPROTECTION AND CAROTID INTERVENTION

- **EPDs : MANDATORY FOR ALL CAS**

# C.A.S. UNDER PROTECTION PROTECTION DEVICES

## ■ OCCLUSION BALLOONS

- GUARDWIRE
- TRIACTIVE
- GUARDIAN
- THERON DEVICE

MEDTRONIC  
KENSEY NASH  
ABBOTT VASCULAR

## ■ FILTERS

- ACCU NET
- ANGIOGUARD
- FILTER WIRE EX
- INTERCEPTOR
- NEUROSHIELD / NAV6
- SPIDER
- FIBERNET
- GORE EMBOLIC FILTER

GUIDANT  
CORDIS  
BOSTON  
MEDTRONIC  
ABBOTT VASCULAR  
EV3  
MEDTRONIC  
GORE

## ■ PROXIMAL PROTECTION

- PAES
- MOMA

GORE  
INVATEC / MEDTRONIC



# C.A.S. UNDER E.P.D.

## ■ IS IT EFFICIENT ?

## ■ WHAT IS THE BEST PROTECTION ?

. IS PROXIMAL PROTECTION BETTER THAN FILTER?

. ARE NEW TECHNIQUES ( TRANSCAROTID ACCESS )  
PROMISING ?

## ■ SPECIFIC INDICATIONS ?

# C.A.S. UNDER E.P.D.

■ IS IT EFFICIENT ?

YES

## C.A.S.

# PROTECTED CAS VS UNPROTECTED CAS

### ■ METAANALYSIS 134 REPORTS

12263 PROTECTED CAS

11198 UNPROTECTED CAS

### ■ RELATIVE RISK ( RR ) FOR STROKE WAS 0,62

( 95% CI 0,54 TO 0,72 ) IN FAVOR OF PROTECTED CAS

### ■ SIGNIFICANT BENEFIT FOR PROTECTED CAS IN

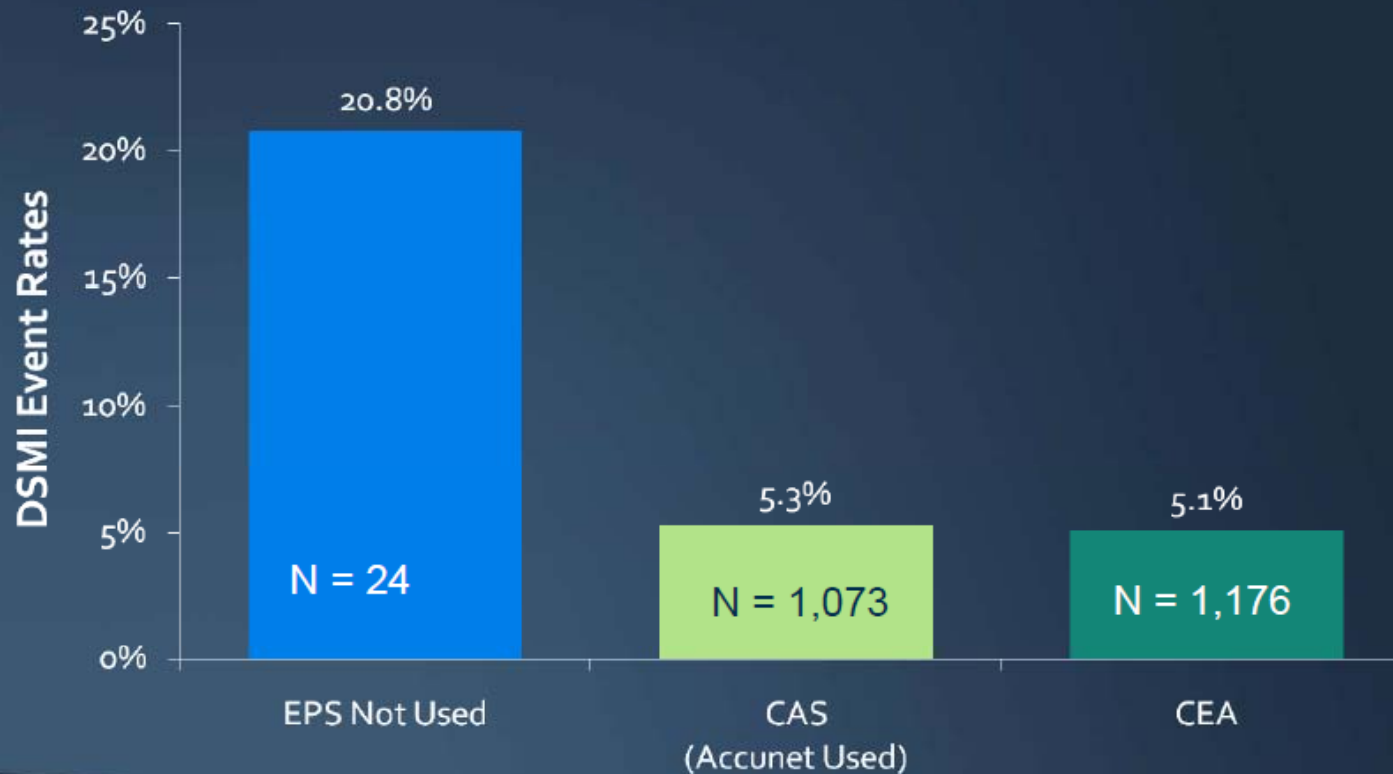
- SYMPTOMATIC PTS ( RR 0,67 ; 95% CI 0,52 TO 0,86 )  $p < 0,05$
- ASYMPTOMATIC PTS ( RR 0,61 ; 95% CI 0,41 TO 0,90 )

**EPD REDUCED THE RISK OF PERIOPERATIVE  
STROKE WITH CAS**

# CREST STUDY

## PROTECTED CAS VS UNPROTECTED CAS

Death, Stroke and MI within 30 Days  
by EPS Usage (PP)



# C.A.S. UNPROTECTED VS UNPROTECTED

## PERSONAL EXPERIENCE 1204 CAS 30 DAY OUTCOMES

	UNPROTECTED	PROTECTED
Nbr	188	1016
DEATH / STROKE / MI	4.3%	0.8%

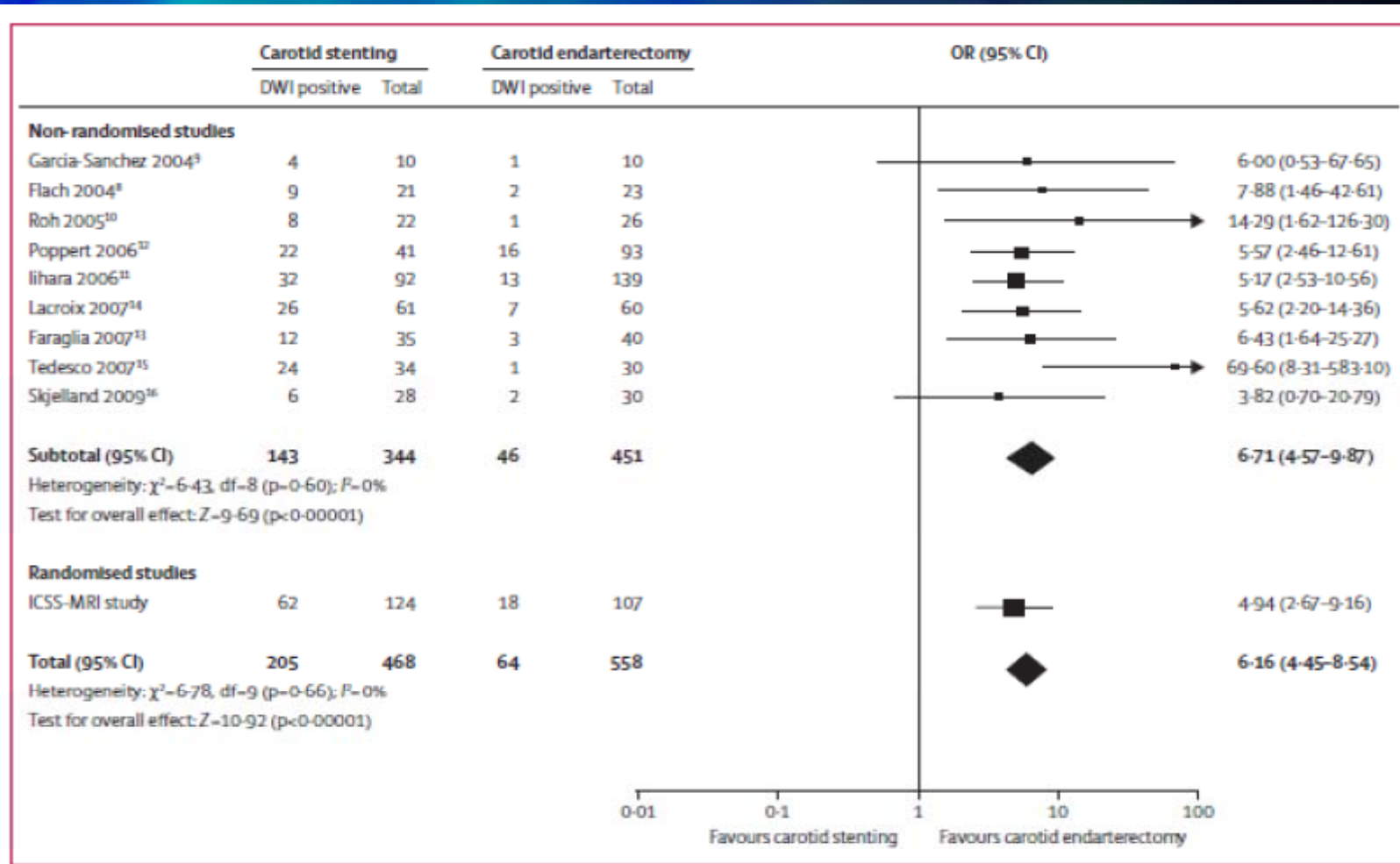
P: < 0,05

# C.A.S. UNDER CEREBRAL PROTECTION IS IT EFFICIENT?

- **E. P.D.** CAN NOT PREVENT ALL EMBOLIC EVENTS
- **2 TECHNIQUES TO DETECT BRAIN EMBOLISM**
  - ▶ **T.C.D.** CAN DETECT EMBOLISM ( H.I.T.S. , M.E.S. )
  - ▶ **DW – MRI** : A SENSITIVE TOOL TO IDENTIFY NEW CEREBRAL ISCHEMIC LESIONS



# META ANALYSIS COMPARING DW – MRI LESIONS AFTER CAS &CEA



**GREATER NUMBER OF DW- MRI LESIONS AFTER CAS  
IN FAVOR OF C.E A.**

# C.A.S. UNDER E.P.D.

## ■ WHAT IS THE BEST PROTECTION ?

### ▶ 2 ISSUES :

- . NEW ISCHEMIC LESIONS
- . CLINICAL RESULTS



# CAROTID INTERVENTION DW-MRI STUDY

Study	Procedure	Embolic Protection	# subjects	% w/ New DWI Lesions
ICSS <sup>1</sup>	Transfemoral CAS	Distal filter (various)	51	73
ICSS <sup>1</sup>	CEA	Clamp, backbleed	107	17
PROFI <sup>2</sup>	Transfemoral CAS	Distal filter (Embosheid)	31	87
Leal <sup>5</sup>	Transfemoral	Distal Filter (FilterWire)	33	33
PROFI <sup>2</sup>	Transfemoral CAS	Proximal occlusion (MoMA)	31	45
DESERVE <sup>4</sup>	Transfemoral CAS	Proximal Occlusion (MoMa)	127	30
PROOF <sup>3</sup>	Transervical CAS	High flow rate flow reversal	48	16.7
Leal <sup>5</sup>	Transervical CAS	Flow Reversal	31	12.9

1. *Lancet Neurol.* 2010 Apr;9(4):353-62  
 2. *J Am Coll Cardiol.* 2012;59:1383-1389  
 3. *JVS* 2011;54:1317-1323

4. *Rubino P, EuroPCR* 2011  
 5. *JVS* 2012;56:1585-1590

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# C.A.S. UNDER CEREBRAL PROTECTION IS IT EFFICIENT?

## NEW ISCHEMIC LESIONS

- CEA AND TRANSCERVICAL ACCESS SEEM EQUIVALENT
- NEW ISCHEMIC LESIONS ARE MORE FREQUENTLY SEEN AFTER C.A.S. AND AFTER C.A.S. UNDER FILTERS IN THE MAJORITY OF REPORTED SERIES EXCEPT FOR :
  - ▶ DE CASTRO ALONSO et al ( CIRC. CARDIOVASC .2013 )  
FILTERS BETTER THAN REVERSAL FLOW: **47,6 vs 15,8 %**
  - ▶ GOODE SD et al ( JVIR 2013 )  
HIGHER NUMBER OF NEW CEREBRAL ISCHEMIC LESIONS WITH FILTERS BUT HIGHER NUMBER IN CONTRALATERAL SITE WITH REVERSAL FLOW

# **C.A.S. UNDER CEREBRAL PROTECTION IS IT EFFICIENT?**

- **WE DO NOT KNOW THE CLINICAL SIGNIFICANCE OF TCD DETECTED HITS AND NEW DW-MRI LESIONS**
- **THEY ARE USED AS AN ARGUMENT AGAINST CAS !!**
- **THE MAJORITY DOES NOT CAUSE NEUROLOGICAL DEFICIT**

# C.A.S. UNDER CEREBRAL PROTECTION DW- MRI STUDY

- 728 Pts UNDERGOING CAS UNDER EPD
- NEW ISCHEMIC LESIONS ON DW MRI FOUND IN 32,8% OF CAS
- AT A MEAN F.U. OF 766.8 DAYS

ASYMPTOMATIC CEREBRAL EMBOLIC EVENTS AFTER  
CAS HAVE NO PROGNOSTIC IMPACT

# **C.A.S. VS C.E.A. MICROEMBOLIZATION / DWI -MRI**

- **A SYSTEMATIC QUALITATIVE REVIEW OF THE LITERATURE COMPARING CAS & CEA DID NOT SHOW SIGNIFICANT DIFFERENCES IN OVERALL COGNITIVE FUNCTION**

( PARASKEVAS Eur J Endovasc Surg 2014 )



# C.A.S. VS C.E.A. MICROEMBOLIZATION / DWI -MRI

- **HOWEVER NEW ISCHEMIC LESIONS COULD BE A SIGNAL OF INCREASED RISK OF FUTURE STROKE OR TIA AT 5 YEARS**

**ICSS Substudy: N = 231**

**DWMRI +ve: 12/62**

**DWMRI -ve: 6/62**

22.8% vs. 8.8% (p=0.04)  
HR 2.85 (1.05-7.720)

**BUT 60% OF PTS TREATED WITHOUT EPD**

**MAY BE A MARKER OF UNSTABLE ATHEROSCLEROTIC PLAQUES ?  
MORE AGGRESSIVE AND PROLONGED ANTIPLATELET THERAPY?**

**BONATI L et al European Stroke Congress May 2013  
GENSICKE H et al JACC 2015 ,65 : 521-529**

# C.A.S. VS C.E.A. MICROEMBOLIZATION / DWI -MRI

## New Expanded AHA/ASA Consensus Definition of Stroke, May 2013

### AHA/ASA Expert Consensus Document

#### **An Updated Definition of Stroke for the 21st Century A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association**

*The American Academy of Neurology affirms the value of this statement as an educational tool for neurologists.*

*Endorsed by the American Association of Neurological Surgeons and Congress of Neurological Surgeons*

- “Silent brain infarcts increase the risk of clinical infarction by 2 to 4 times in population-based studies”
- “...silent infarcts are associated with risk of Alzheimer disease as well as of vascular dementia.”

Several studies have shown that patients with silent brain infarcts had a 5 times higher stroke incidence than those without.

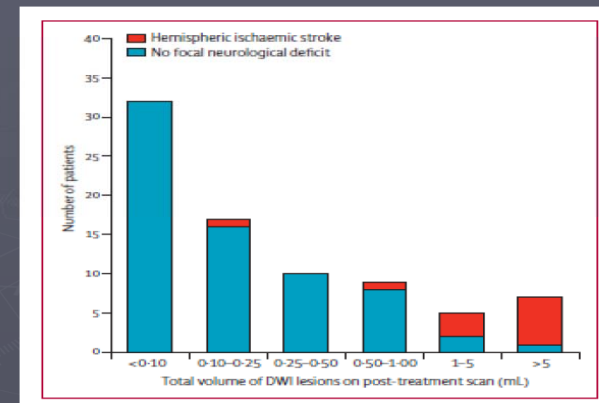
# C.A.S. VS C.E.A.

## MICROEMBOLIZATION / DWI -MRI

- **SIZE OF LESIONS AND NOT JUST LESION COUNT IS AN IMPORTANT CONSIDERATION.**
- **DATA FROM ICSS STUDY DEMONSTRATES :**
  - ▶ **AFTER CEA : FEWER , LARGER LESIONS**
  - ▶ **AFTER CAS : GREATER NUMBER BUT SMALLER LESIONS**
  - ▶ **SUCH THAT CAS AND CEA HAVE EQUAL VOLUME OF DWI ABNORMALITIES**

**NEUROLOGICAL  
EVENTS RATE DEPENDS  
ON DWI- MRI LESION  
VOLUMES**

**Association of DWMRI Lesion Volumes  
& Neurological Events**



**CEA / CAS → SAME RISK OF NEUROLOGICAL EVENTS**

**C.A.S.  
UNDER E.P.D.**

**CLINICAL RESULTS**

# C.A.S. FILTERS

## CLINICAL RESULTS

- **FIBERNET ( LUMEN / INVATEC )**

30 DAY MAE : 3.0%

- **EMBOSHIELD ( ABBOTT )**

30 DAY MAE : 1.8 %

- **ANGIOGUARD WORLDWILDE REGISTRY**

30 DAY MAE : 4.4 %

- **CREST STUDY**

30 DAY MAE : 4.8 %

- **PERSONAL SERIES ( 1016 Pts )**

30 DAY MAE : 0.9%

# C.A.S.

## PROXIMAL PROTECTION

### CLINICAL RESULTS

- **METAANALYSIS :2937 PTS ( BERSIN RM 2012 )**

**D / S / MI : 2,25%**

- **ARMOUR TRIAL:257 PTS ( MOMA DEVICE )**

**D / S : 2,7 %**

- **EUROPEAN MOMA TRIAL**

**MAE : 3.0 %**

- **EMPIRE STUDY:245 PTS ( GORE DEVICE )**

**D / S : 2,9%**

**NO DIFFERENCE WITH FILTERS**

# C.A.S. UNDER E.P.D.

## ■ SPECIFIC INDICATIONS

SELECT EPD

# C.A.S.

## CEREBRAL PROTECTION TECHNIQUES

### ■ FILTERS

➤ MOST OFTEN USED

➤ SPECIFIC INDICATIONS

❖ Patients with contralateral stenosis or occlusion

❖ Poor collateral circulation

❖ Anastomosis between ICA, ECA, Vertebral territories



# C.A.S. UNDER CEREBRAL PROTECTION

## PROXIMAL PROTECTION

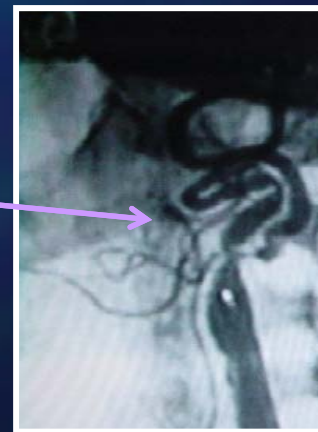
### INDICATIONS

#### ■ LESIONS WITH HIGHER RISK OF EMBOLIC COMPLICATIONS

- FRESH THROMBUS LESIONS
- ULCERATED LESIONS
- LONG SUBOCCLUSIVE LESIONS . STRING SIGN
- HIGHLY FRIABLE UNSTABLE PLAQUES
- ECHOLUCENT PLAQUES WITH G.S.M. LESS THAN 25
- VULNERABLE PLAQUES



#### ■ DIFFICULT ANATOMIES, VERY TORTUOUS I.C.A.



#### ■ INSUFFICIENT LANDING ZONE FOR FILTERS

# TRANS CAROTID C.A.S. WITH DYNAMIC FLOW REVERSAL

## ROADSTER IDE TRIAL

- ENROUTE NEUROPROTECTION SYSTEM (SILK ROAD MED.CA.)
- SHEATHS INSERTED IN COM. CAR. ART. AND FEM. VEIN CONNECTED THROUGH EXTERNAL TUBING
- 208 PTS ENROLLED
- RESULTS

STROKE RATE  
COMPARABLE TO  
CEA ARM OF  
CREST STUDY

Table 1. Pivotal Arm Outcomes at 30 Days

	Intention to Treat (n = 141)	Per Protocol (n = 136)
Stroke, Death, and MI	3.5%	2.9%
Major Stroke	0	0
Minor Stroke	1.4%	0.7%
Death	1.4%	1.5%
MI	0.7%	0.7%
Cranial Nerve Injury		
Overall	0.7%	0.7%
Unresolved at 6 Months	0	0

AN ALTERNATIVE IN PTS WITH UNFAVORABLE AORTOILIAC OR  
AORTIC ARCH ANATOMY AND HIGH RISK FOR CEA OR  
TRANSFEMORAL CAS

# NEUROPROTECTION AND CAROTID INTERVENTION

- **STENTS** : GOOD CHOISE AND CORRECT IMPLANTATION

# **C.A.S. NEUROPROTECTION**

**STENT DESIGN CAN PLAY AN IMPORTANT  
ROLE IN PREVENTING DISTAL EMBOLIZATION  
AND THUS REDUCING THE INCIDENCE OF  
PROCEDURE-RELATED STROKE**

# C.A.S. NEUROPROTECTION

## STENT DESIGN

Open Cell    Closed Cell



# C.A.S. NEUROPROTECTION

## ■ CLOSED CELL STENT DESIGN

————> LESS EMBOLIC EVENTS THAN OPEN CELL

### Delayed Stroke & Death At 1-30 Days Especially with Open Cell Stents

	Total population		
	Patients	All events	Post-procedural events
Open cell	937	39	32
Closed cell	2242	51	29
Total	3179	90	61
Cell type			
Open cell		4.2%	3.4%
Closed cell		2.3%	1.3%
Total	3179	2.83%	1.9%

2/3 of events delayed

Bosiers et al. Eur J Vasc Endovasc Surg 2007;33:135

### Increased Neurologic Events With Open Cell Stents SPACE Trial

Table 4. Influence of Different Stent Types on OE Rate

Stent	Wallstent	Acculink	Precise
No. of patients	436	92	35
Pat. with OE	24	9	5
OE rate (95% CI)	5.5% (3.6–8.1%)	9.8% (4.6–17.8%)	14.3% (4.8–30.3%)
Combined OE rate: 11.0% (6.2–17.8%)			

Jansen O et al. Stroke 2009;40:841-846

# C.A.S. NEUROPROTECTION

## ■ CLOSED CELL STENT DESIGN

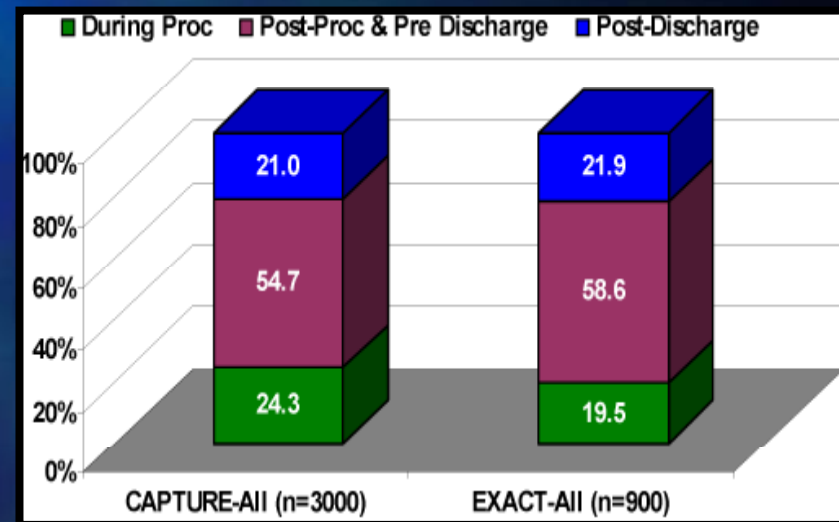
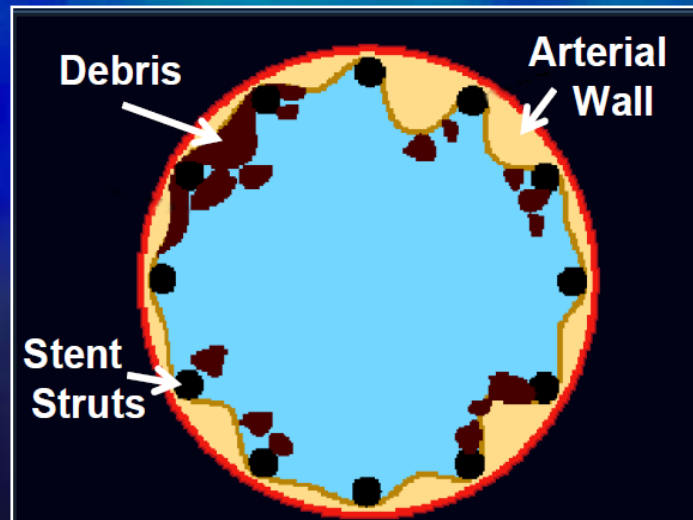
→ INDICATED FOR UNSTABLE PLAQUES  
HIGH RISK EMBOLIC LESIONS



# C.A.S. NEUROPROTECTION

## ■ OPEN CELL STENT DESIGN

→ MORE PLAQUE PROTRUSION AND RISKS OF LATE EMBOLIC EVENTS



**THE MAJORITY OF STROKES OCCUR POST PROCEDURE AND BEFORE DISCHARGE**

**BUT MORE FLEXIBLE THAN CLOSED CELL**  
→ TORTUOUS ARTERIES

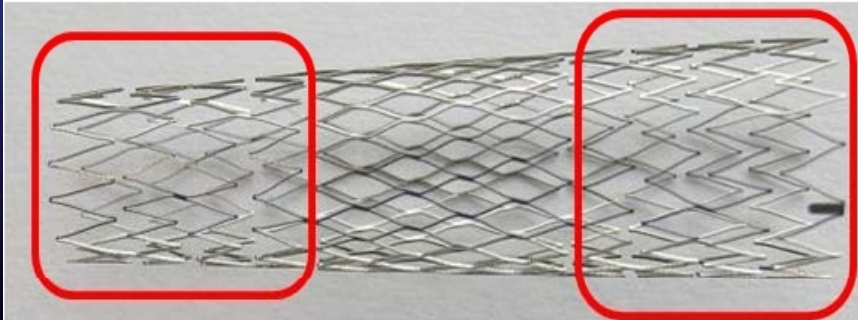


# C.A.S. NEUROPROTECTION

## ■ ROLE OF NEW STENTS DESIGN:

### HYBRID STENT : CRISTALLO STENT

Hybrid Stent  
Cristallo Ideale



Open cells proximally and distally

Hybrid Stent  
Cristallo Ideale



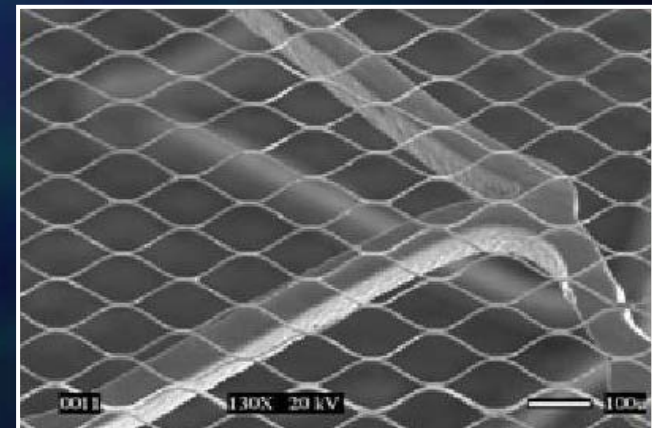
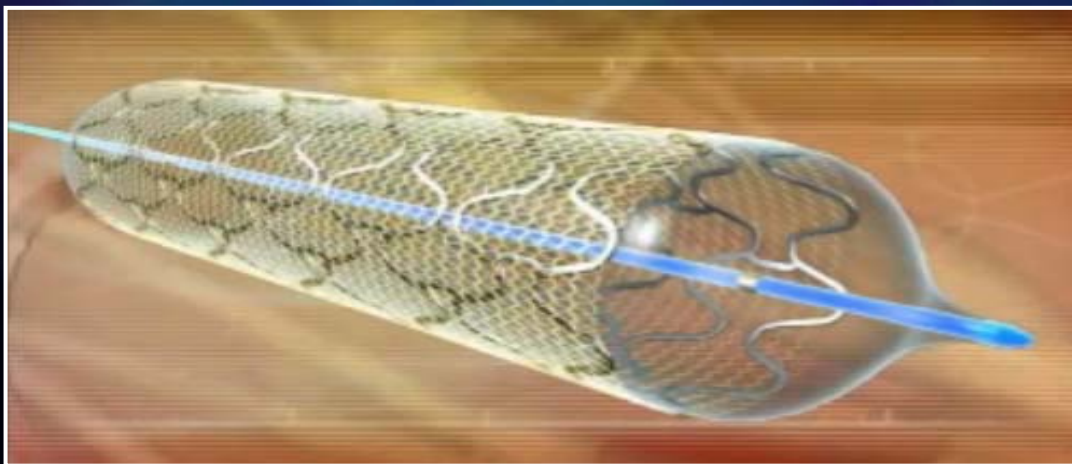
Closed cells in the center part

# C.A.S. NEUROPROTECTION

## ■ ROLE OF NEW STENT DESIGN:

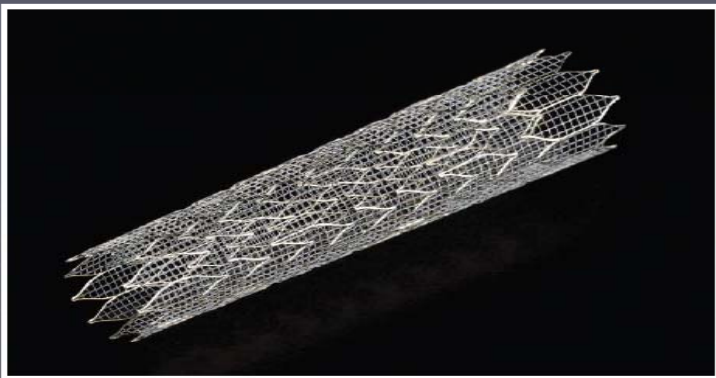
### MICROMESH STENT

NITINOL MEMBRANE COVERED STENT  
TO PREVENT PLAQUE PROLAPSE AND EMBOLIC EVENTS

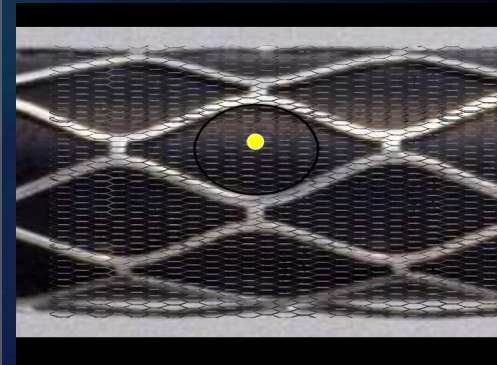


# C.A.S. MICROMESH STENT

## GORE® Carotid Stent The Next Generation



- Open cell nitinol frame
- Closed cell 500 μ lattice on outside of frame
- Permanently bound CBAS heparin on all device surfaces



NO DATA

### Roadsaver

#### Technical specifications

Stent platform  
 • Construction: double layer, braided mesh  
 • Material: Nitinol

Stent delivery system  
 • Outer sheath compressibility: 0.014" (0.36 mm)  
 • Intracatheter sheath compressibility: 0.014" (0.36 mm)  
 • Delivery system construction: rapid exchange, RX segment length 90 cm  
 • Unstable catheter length: 143 cm



#### Ordering information

Product code	Unexpanded dimensions (mm)			Expanded dimensions (mm)		
	Stent diameter	Micromesh layer depth	Deployment length	Stent diameter	Micromesh layer depth	Deployment length
R05-0520-4-C010	6	300	36	6	300	36
R05-0530-4-C010	6	300	37	6	300	37
R05-0540-4-C010	6	300	38	6	300	38
R05-0550-4-C010	6	300	39	6	300	39
R05-0560-4-C010	6	300	40	6	300	40
R05-0570-4-C010	6	300	41	6	300	41
R05-0580-4-C010	6	300	42	6	300	42
R05-0590-4-C010	6	300	43	6	300	43
R05-0600-4-C010	6	300	44	6	300	44
R05-0610-4-C010	6	300	45	6	300	45
R05-0620-4-C010	6	300	46	6	300	46
R05-0630-4-C010	6	300	47	6	300	47
R05-0640-4-C010	6	300	48	6	300	48
R05-0650-4-C010	6	300	49	6	300	49
R05-0660-4-C010	6	300	50	6	300	50
R05-0670-4-C010	6	300	51	6	300	51
R05-0680-4-C010	6	300	52	6	300	52
R05-0690-4-C010	6	300	53	6	300	53
R05-0700-4-C010	6	300	54	6	300	54
R05-0710-4-C010	6	300	55	6	300	55
R05-0720-4-C010	6	300	56	6	300	56
R05-0730-4-C010	6	300	57	6	300	57
R05-0740-4-C010	6	300	58	6	300	58
R05-0750-4-C010	6	300	59	6	300	59
R05-0760-4-C010	6	300	60	6	300	60
R05-0770-4-C010	6	300	61	6	300	61
R05-0780-4-C010	6	300	62	6	300	62
R05-0790-4-C010	6	300	63	6	300	63
R05-0800-4-C010	6	300	64	6	300	64
R05-0810-4-C010	6	300	65	6	300	65
R05-0820-4-C010	6	300	66	6	300	66
R05-0830-4-C010	6	300	67	6	300	67
R05-0840-4-C010	6	300	68	6	300	68
R05-0850-4-C010	6	300	69	6	300	69
R05-0860-4-C010	6	300	70	6	300	70
R05-0870-4-C010	6	300	71	6	300	71
R05-0880-4-C010	6	300	72	6	300	72
R05-0890-4-C010	6	300	73	6	300	73
R05-0900-4-C010	6	300	74	6	300	74
R05-0910-4-C010	6	300	75	6	300	75
R05-0920-4-C010	6	300	76	6	300	76
R05-0930-4-C010	6	300	77	6	300	77
R05-0940-4-C010	6	300	78	6	300	78
R05-0950-4-C010	6	300	79	6	300	79
R05-0960-4-C010	6	300	80	6	300	80
R05-0970-4-C010	6	300	81	6	300	81
R05-0980-4-C010	6	300	82	6	300	82
R05-0990-4-C010	6	300	83	6	300	83
R05-1000-4-C010	6	300	84	6	300	84
R05-1010-4-C010	6	300	85	6	300	85
R05-1020-4-C010	6	300	86	6	300	86
R05-1030-4-C010	6	300	87	6	300	87
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R05-1150-4-C010	6	300	99	6	300	99
R05-1160-4-C010	6	300	100	6	300	100

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## TERUMO Roadsaver®

A novel carotid stent for sustained embolic protection



# C.A.S. MICROMESH STENT

## CGuard™ Carotid Embolic Prevention System Specifications

### Device Features

Stent type	Nitinol Self-Expanding
MicroNet Aperture Size	150-180μ
Guidewire	0.014"
Foreshortening	<10%
Sizes	Diameter( 6mm-10mm) x Length (20mm – 60mm)
Delivery System (OD)	6F (2.1mm)



**INSPIRE MD**

# C.A.S. MICROMESH STENT

***CGuard™ CARENET (CARotid Embolic protection using microNET) Trial Design***

## Clinical Outcomes

**30 PTS**

	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

# C.A.S. MICROMESH STENT

***CGuard™ CARENET (CARotid Embolic protection using microNET) Trial Design***

## **CARENET Comparison DW-MRI @ 24-48 hrs**

	CARENET (Filter group) N=26	PROFI <sup>1</sup> (Filter group) N=31	ICSS <sup>2</sup> (Filter group) N=37
Incidence of New Lesions	48%	87%	73%
Avg Lesion Volume	0.06 cm <sup>3</sup>	0.59 cm <sup>3</sup>	NA

<sup>1</sup> JACC, April 2012

<sup>2</sup> Lancet, March 2010

# C.A.S. NEUROPROTECTION

- **METICULOUS CLEANING OF THE DILATED AREA**
  - ▶ **WITH ASPIRATION CATHETER OR GUIDING CATH.**  
**TO AVOID PROCEDURAL AND DELAYED EMBOLIC EVENTS**

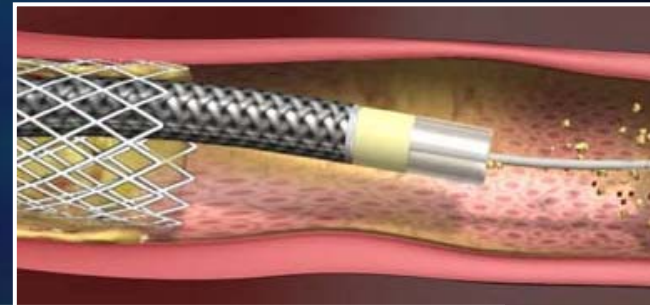
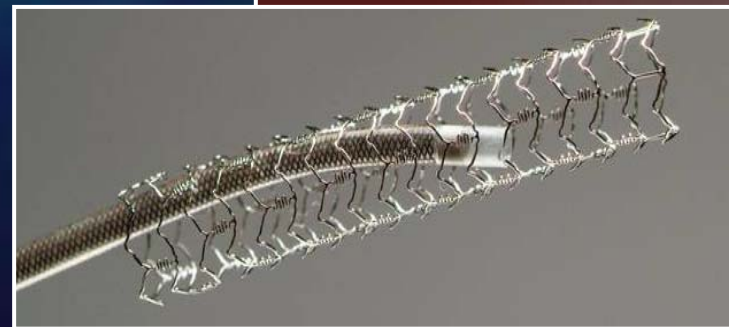
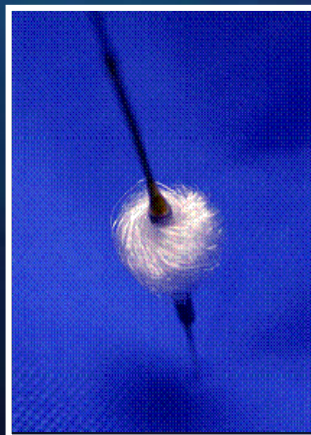
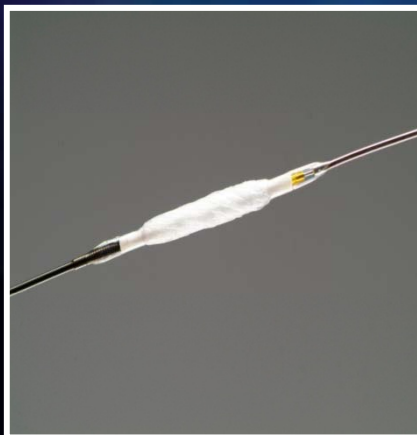


Pronto V3™



Quick Cat™

- ▶ **OR FIBERNET FILTER**



# CAS UNDER CEREBRAL PROTECTION

## CHOICE REGISTRY

CAS WITH OR WITHOUT ASPIRATION (20cc BLOOD )  
PRIOR RETRIEVAL EPD

### ■ 52 Pts WITHOUT ASPIRATION

→ 4 MINOR NEUROLOGICAL DEFICITS THAT  
OCCURRED AT 24 H. AND RESOLVED AT 30 DAYS

### ■ 42 Pts WITH ASPIRATION

→ NO NEUROLOGICAL DEFICIT



# NEUROPROTECTION AND CAROTID INTERVENTION

## ■ PHARMACOLOGICAL NEUROPROTECTION

# C.A.S. NEUROPROTECTION

## ARMYDA – 9 CAROTID STUDY

### ■ CONCLUSIONS

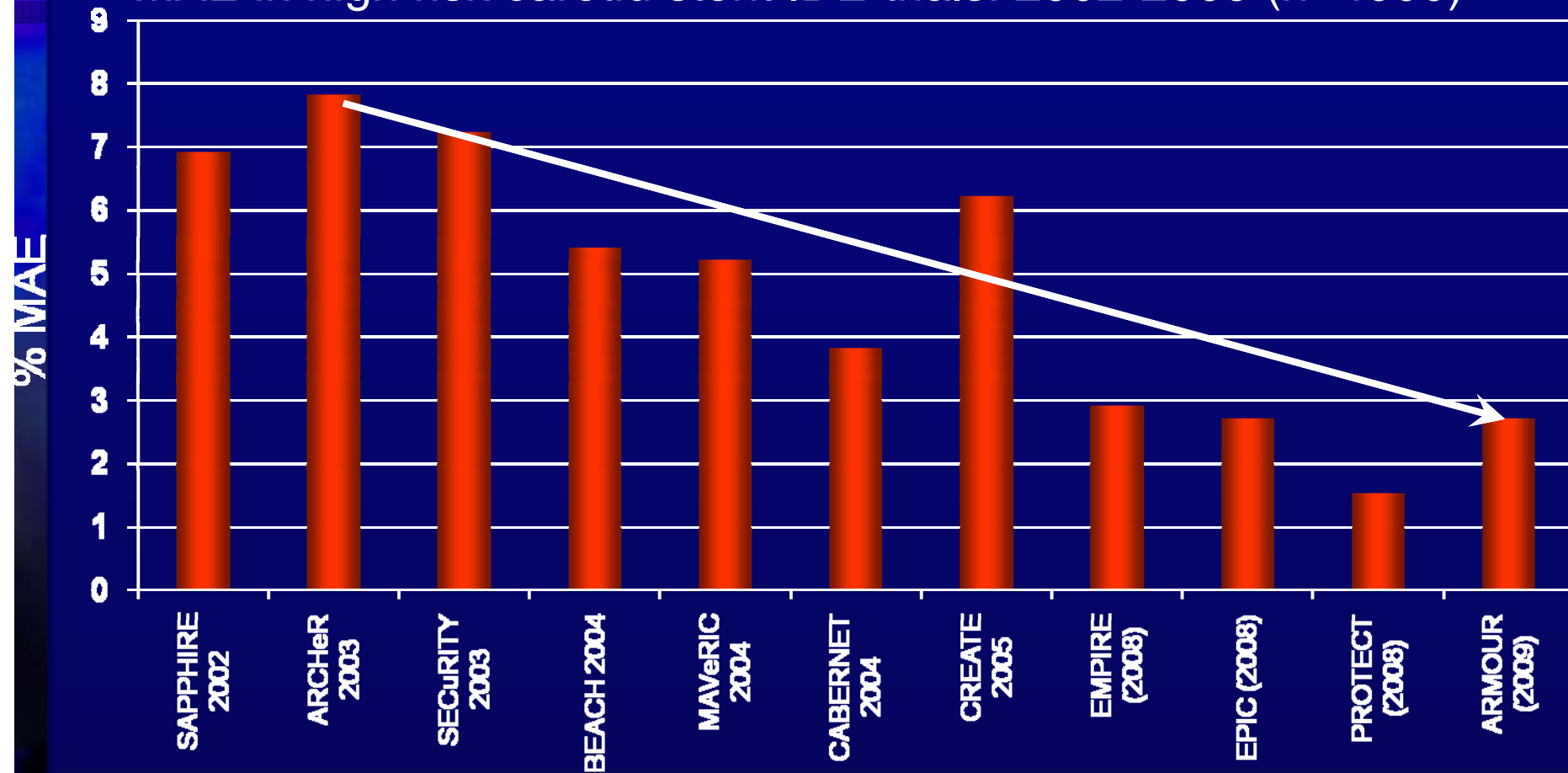
- STRATEGY USING BOTH A 600 mg CLOPIDOGREL LOAD AND A SHORT TERM RELOAD WITH HIGH DOSE ATORVASTATIN ( 80mg ) REDUCES PERIPROCEDURAL ISCHEMIC CEREBRAL EVENTS AND TIA / STROKE RATES AT 30 DAYS ( 0 % vs 9 % ; P =0.02 )

# **NEUROPROTECTION AND CAROTID INTERVENTION**

- **TEAM EXPERIENCE / LEARNING CURVE**

# C.A.S. AMERICAN STUDIES

MAE in high risk carotid stent IDE trials: 2002-2009 (n>4000)



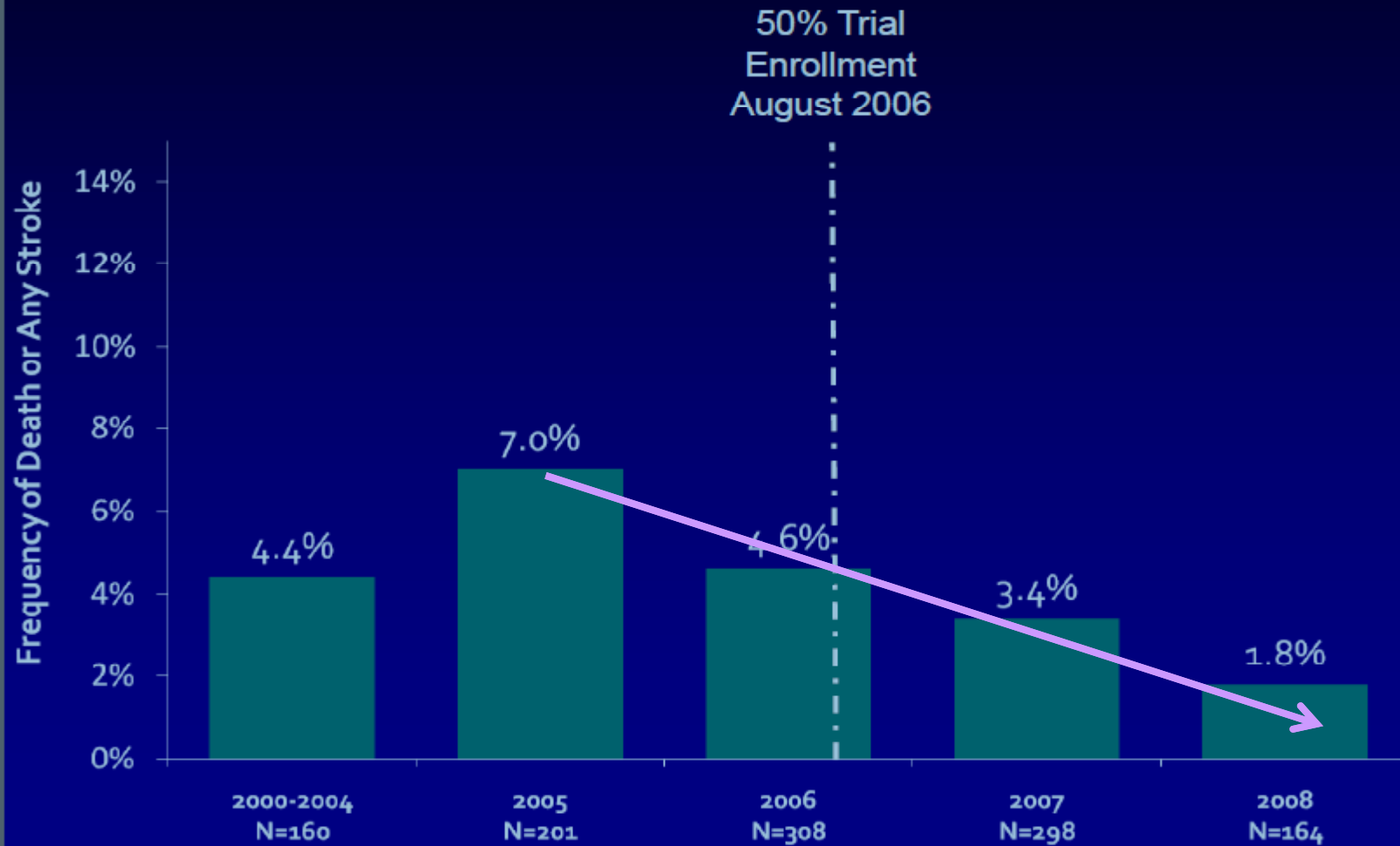
**11 US FDA DEVICE APPROVAL TRIALS  
IMPROVING RESULTS OVERTIME**

# CREST STUDY

## OUTCOMES OVERTIME

Does CAS Improve with Experience ?

Death or Any Stroke Rates Decrease for CAS 2000-2008



# NEUROPROTECTION AND CAROTID INTERVENTION

## CONCLUSIONS

■ **WITH ALL AMERICAN REGISTRIES AND RANDOMIZED STUDIES LIKE CREST STUDY WE HAVE ENOUGH REPORTED DATA TO SAY THAT C.A.S. UNDER PROTECTION IS A SAFE AND EFFICIENT PROCEDURE AND EQUIVALENT TO C.E.A.**

■ **BUT WE NEED**

- ▶ **GOOD INDICATIONS**
- ▶ **EXPERIENCED OPERATORS ( AT LEAST 50 CAS? )**
- ▶ **GOOD NEUROPROTECTION**
- ▶ **GOOD DEVICE SELECTION AND EPD**
- ▶ **ROLE OF NEW STENT DESIGN ( MICROMESH )**