



# CAS Revival is now

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# BACKGROUND

**EVA3S** (France 2004), **SPACE** (Germany 2006), **ICSS** (international 2009)

Controversies but favor surgery for **SYMPTOMATIC** patients

**CREST** (USA 2010): **SYMPTOMATIC & ASYMPTOMATIC** patients

**Major Stroke/death rate equivalent** (7,2% VS 6,8%)

More MI with **CEA** (2,3% VS 1,1%) p: 0.03

More TIA with **CAS** (4,1% VS 2,3%) p: 0,01

**ACST2** (mainly Europe 2008): ongoing trial

**ASYMPTOMATIC patients 986 pts**

Stroke death MI (1%)

➔ FDA approval for low risk patients 05/06/2011  
(previous FDA approval for HRP 01/26/2004)

# RCT trials conclusion (CEA VS CAS)

**RCT's:** favor **CEA** rather **CAS**  
less **TIA**, even more **MI**

> **CEA remains the gold standard**

**CREST** Concluded equivalency in **Stroke Death Rate**  
**Higher risk for symptomatic and elderly**

BUT STILL RESIDUAL CONTESTATIONS  
about TIA's > 4%

# Current recommendations and guidelines according to benefit

Thomas G. Brott & all – Stroke 2011

- **Class I : Benefit >>> risk** (recommended)  
**Symptomatic patients** (>6M) with **Stenosis  $\geq$  50%** should underwent **CEA** or **CAS**  
(level B proof ) anticipated risk of stroke or death <6%
- **Class IIa : Benefit >> risk** (reasonable)  
**Asymptomatic patients  $\geq$ 70%**
  - low risk Patients** "stroke-death-MI" is low select **CEA** (level A proof)
  - elderly** with unfavorable anatomy select **CEA** (level B)\*
  - hostile neck** select **CAS** (level B)

# Recommendations and LOE according to CEA or CAS

	Symptomatic Patients		Asymptomatic Patients
	50% to 69% Stenosis	70% to 99% Stenosis*	70% to 99% Stenosis*
Endarterectomy	Class I LOE: B	Class I LOE: A	Class IIa LOE: A
Stenting	Class I LOE: B	Class I LOE: B	Class IIb LOE: B

—————> Level of recommendation is **SIMILAR**



# Limitations

- Many subgroups of patients were not submitted to comparison and may be recommended for CAS.
- CEA is not evolving / CAS is evolving with a reduced TIA rate from new technology  
**This can make a difference**
- Obsolete CAS technology (Arch navigation, Filter protection, Bare stents ) must be reviewed

# Progress in CAS

- **Objective :**

To reduce TIA's per (22%) and post (58%) procedure:

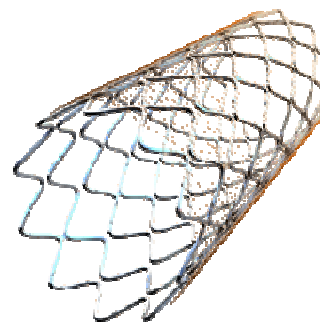
(The CAPTURE Registry : Ann Surg 2007)

- **Means :**

**New stents** (mesh covered stents)

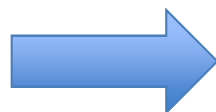
-> smaller stent struts

-> smaller debris migration



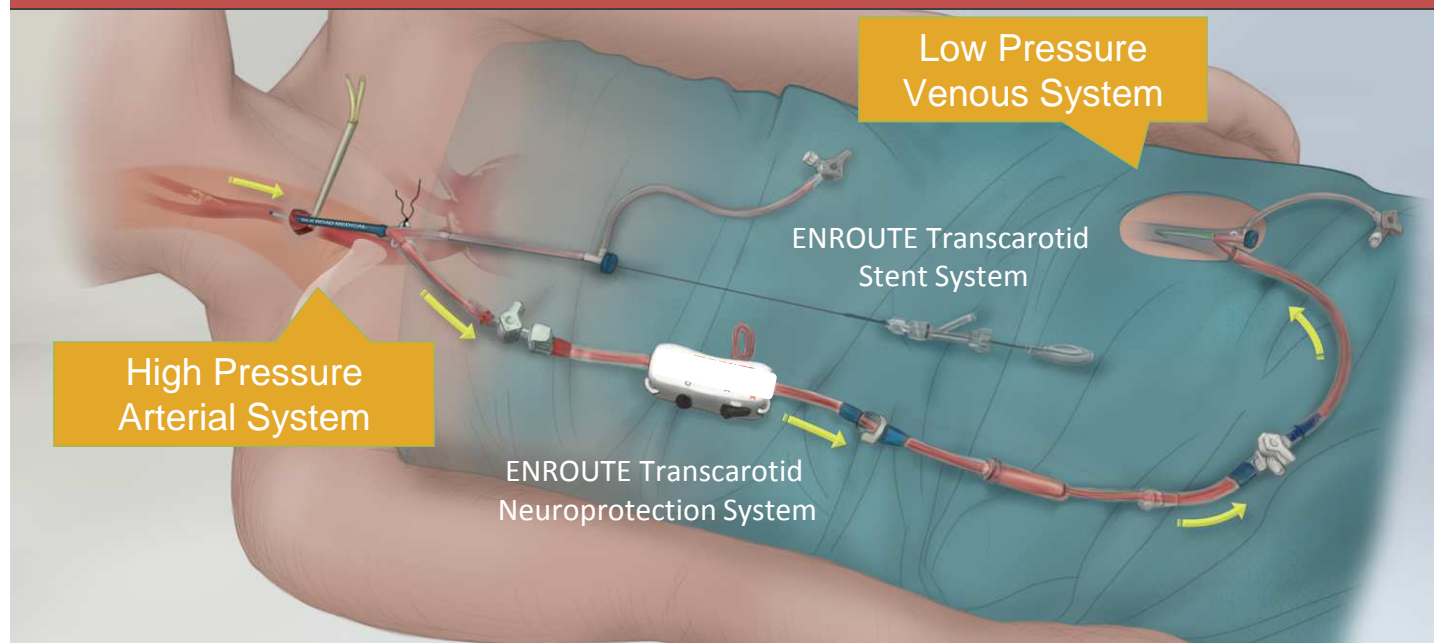
**New accesses** avoid arch navigation and debris dislodgement

**New brain protection:** ineffective filters and  
encephalopathy risk



**TCAR (Trans Carotid Artery Revascularisation)**  
(PMA from FDA on May,19,2015)

# Direct Carotid Access with High Rate Flow Reversal



- Avoid the arch
- “CEA-like” neuroprotection
- Less manipulation
- Predictable, efficient

**Silk Road Medical, Inc.**

CAUTION: Investigational device. Limited by federal (USA) law to investigational use.  
The ENROUTE™ Transcarotid Stent and Neuroprotection Systems bear the CE mark of conformity.



# Proof Study (Lazlo Pintes JVS 2011)

## *Protection system First in man study:*

- Controlled blood flow reversal cervical access
- FAST-CAS (flow alterned slow transcervical CAS)
- DW- MRI studies
- 44 patients (9% symptomatic) L.A.
- **No stroke, no TIA**
- **5 (16%)** new asymptomatic ischemic brain lesion  
(comparable to ICSS endarterectomy group 17%)
- **10%** Transient intolerance (11% with controlateral occlusion)

# ROADSTER Patient Population

## Physiologic HSR Inclusion

- Severe cardiac disease; severe COPD; chronic renal insufficiency
- Permanent contralateral CNI
- **Age  $\geq 75$**

## Anatomic HSR Inclusion

- Contralateral occlusion; bilateral or high or tandem stenoses
- Restenosis post CEA
- Hostile neck
  - Irradiation
  - Radical neck dissection
  - Cervical spine immobility

## Exclusion: Common to CAS

- Afib; recent valve or MI; bleeding
- Evolving stroke; neuro disorders
- Occlusion; ostial CCA or intracranial stenosis; string sign; previous stent

## Exclusion: Transcarotid

- CCA disease at entry site
- $< 5\text{cm}$  clavicle to bifurcation

# ROADSTER Baseline Characteristics

High Surgical Risk	Pivotal Group (n=141)
Age	72.9 ± 9 (40, 90)
Age ≥ 75	47%
Age ≥ 80	28%
Female	35%
Symptomatic	26%
Physiologic Risk Factors	56%
Anatomic Risk Factors	69%
- Hostile Neck	16%
- Restenosis post CEA	21%
Physiologic & Anatomic Risk Factors	40%

# ROADSTER Outcomes

## intention to Treat, Per protocol

High Surgical Risk	Pivotal Group, ITT (n=141)		Pivotal Group, PP (n=136)	
S/D/MI*	5	3.5%	4	2.9%
Major Stroke	0	0%	0	0%
Minor Stroke	2	1.4%	1	0.7%
Death	2	1.4%	2	1.5%
MI	1	0.7%	1	0.7%
Stroke & Death	4	2.8%	3	2.2%
Cranial Nerve Injury (CNI)	1	0.7%	1	0.7%
CNI Unresolved at 6 Mos	0	0%	0	0%

\*Hierarchical

Per Protocol excludes major protocol deviations

All FDA-approved carotid stent systems were used per site preference  
(Acculink, Xact, Precise, Protégé, Wallstent)

Courtesy of C. Kwolek

# ROADSTER Subgroup Outcomes

High Surgical Risk Pivotal Intention to Treat	Age $\geq 75$	Symptomatic
n	n=66 (47%)	n=36 (26%)
S/D/MI	3 (4.5%)	1 (2.8%)
Major Stroke	0%	0%
Minor Stroke	0%	0%
Death	3.0%	2.8%
MI	1.5%	0%
Stroke & Death	3.0%	2.8%



# CONCLUSION

- **Conventional CAS is exceeded:** forgot arch navigation, filters and previous stents
- New CAS technology will **reduce TIA's** and make CAS equal or superior to CEA
- RCT of **TCAR Vs New CAS** are needed
- **Cervical Percutaneous** access of reversal flow is under development