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Outcome Of TCAR Combined With A Mesh-Covered Stent (CGuard From InspireMD): The Best Of All Worlds: What Is The Proof

Conflict of Interest: None

Outcomes from the VQI-TSP Database published in 2020\*

The VQI data point to the additional "non-stroke" related benefits of TCAR such as lower rates of Myocardial Infarction, Cranial Nerve Injury and reduced procedure time.

	TCAR (n=234)		CSA (n=234)
Stroke	1.4%	P=0.881	1.4%
Death	0.4%	P=0.662	0.3%
MI	0.9%	P=0.005	0.9%
Stroke/Death	1.6%	P=0.945	1.6%
Stroke/Death/MI	2.0%	P=0.172	2.4%
Isolated Stroke	1.2%	P=0.247	1.4%



Research on free-cell area presents conflicting evidence regarding benefits and associated risks, making the clinical relevance difficult to determine.

Are all Stents equal when using TCAR ?

Do we need dedicated stents for symptomatic patients depending on their symptoms ?

Do we need dedicated stents for patients with acute stroke

What is the role of open cell design stents versus closed cell design versus mesh coated ?

ROADSTER 2:  
Clinical Outcomes  
Patients Treated Per Protocol

Does the choice of stent truly have an impact?

	Patients with 30-day F/U		Patients with 30-day F/U		All Patients	
Stroke/Death/MI	6	3.0%	2	0.9%	2	0.8%
Stroke	1	0.5%	2	0.9%	2	0.8%
Death	2	1.0%	0	0.0%	0	0.0%
MI	3	1.5%	0	0.0%	0	0.0%
Stroke/Death	3	1.5%	2	0.9%	2	0.8%
CNI (permanent)	0	0.0%	0	0.0%	0	0.0%


ROADSTER 2 Stroke in Asymptomatic Patients = 0.5%  
ROADSTER 2 Stroke in Symptomatic Patients = 1.3%

Schneider P. LINC 2017

THE PROOF IS IN THE FILTER  
Macro & Micro emboli in ENROUTE® NPS FILTERS



### ICSS DWI sub study



- 73% of CAS patients with distal filter protection developed new ischemic infarcts by DWI-MRI
- 17% of Carotid Endarterectomy

*Distal filters produce > 4X higher incidence of cerebral embolization vs. CEA*

Bonaff LJ. Lancet Neurol. 2019; 9:353-62.

### Volume of subclinical embolic infarct correlates to long term cognitive changes after carotid revascularization

From the Society for Vascular Surgery

2018, Dima, MD<sup>1</sup>, Rodriguez D, Bagheri, MD, Kim, Eunyoung, MD<sup>2</sup>, Javed C, Lachy, PhD<sup>3</sup>, Elgendy, Mohamed, MD, Jinn, Shua, MD, and Khatami, Ramin, PhD<sup>4</sup>. Annals of Vascular Medicine and Biology

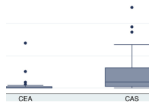
**81 %** new DWI lesions after CAS  
**36 %** after CEA

CAS is a predictor of infarction; cognitive function improved after CEA but significantly decreased after CAS.

#### Cognitive Changes

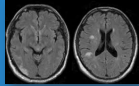
The larger the Micro Emboli on DWMRI

The more severe cognitive decline



### New DWI Lesions

T CAR Versus Mesh Covered Stents

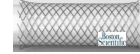


TCAR ( PROOF – Silkroad )	16.1 % (48 h)
Mesh Covered Stent ( CGuard Inspire MD )	37.0 % (48 h) *
( Transfemoral ) * 4% after 30 days	
A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent	
The CLOVER Carotid™ Trial	
The CLOVER Carotid™ Trial (Carotid Embolic Protection Using Microkats)	
CEA ( ICSS )	17 % (48 h)


Wang, Y. et al. J Neurointervent Radiol. 2019; 22(1): 1-10. doi:10.1177/1546954618800000. © 2019 American Society of Neuroradiology.

### Conventional Carotid Stents

**Closed cell**




BSC Wallstent




Abbott Xact


**Open Cell**



Abbott Acculink



Cordis Precise

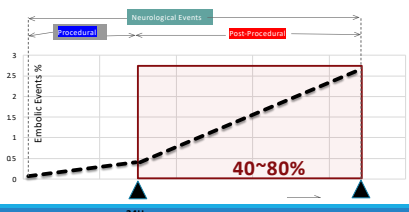


Medtronic (EV3) Protege

### Conventional Stents Post-Procedure

CREST timing of stroke after CAS


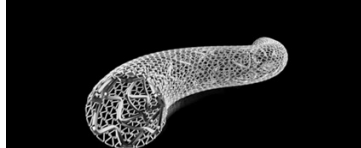
**40~80% of embolic events are post-procedural**



### MicroNet™ – Designed to Prevent Distal Embolization

Ultrathin PET™ mesh made of a single 20 micron fiber from a biocompatible polymer – widely used in other medical implants

MicroNet™ acts as a “safety net” by offering greater vessel area coverage to prevent large plaque protrusion through the scaffold into the vessel lumen

From the Society for Vascular Surgery

### Outcomes after transcatheter artery revascularization stratified by preprocedural symptom status

**ARTICLE HIGHLIGHTS**

- Type of Research: Retrospective cohort study of prospectively collected data from the Vascular Quality Initiative registry
- Key Findings: After transcatheter artery revascularization (TCAR) in symptomatic patients, increasing preprocedural neurologic injury (prior ocular transient ischemic attack vs prior hemiparesis, transient ischemic attack vs prior stroke) was associated with higher in-hospital stroke/death rates. Furthermore, patients who experienced neurologic symptoms more than 180 days before TCAR had higher in-hospital stroke/death rates compared with asymptomatic patients.
- Take Home Message: To improve preoperative risk assessment for patients undergoing TCAR, and to increase accuracy in future TCAR studies, patients should be stratified by their specific preprocedural symptom status. Additionally, patients with symptoms more than 180 days before TCAR should be distinguished from asymptomatic patients.

**Additional stratification by stent type**

From the Society for Vascular Surgery

### Outcomes of early transcatheter artery revascularization versus carotid endarterectomy after acute neurologic events

**Take Home Message:**

TCAR performed within 14 days of a neurological event leads to higher rates of postoperative strokes on the ipsilateral side when compared to CEA, particularly if done within 48 hours of a stroke.

**Is there a role for mesh-covered stents in this situation?**

**RESEARCH CORRESPONDENCE**

### 5-Year Clinical and Ultrasound Outcomes in CARENET Prospective Multicenter Trial of C-CARD MicroNET Covered Carotid Stent

**30 patients age 55 to 86 years**  
**63.4% men**  
**33% symptomatic**

**Transfem. CAS**

New ipsilateral diffusion-weighted lesions at 48 hours occurred in 37.0% of patients; these were small (average volume: 0.039 cm<sup>3</sup>)

Thirty-day MRI showed a complete resolution of all but 1

The MicroNET-covered stent reduced the total permanent cerebral lesion volume by 92.3% (P < 0.001)

Is it possible that there are only 30 patients?

### The PROOF Study

#### Micro-Emboli Measurement

DW-MRI Studies - Silk Road's CEA-Like Outcomes

Study	Procedure	Embolic Protection	Patients	% w/ New DWI Lesions
ICSS <sup>2</sup>	CEA	Clamp, backbleed	107	17%
PROOF <sup>2</sup>	Silk Road	Transcatheter Access, w/ Flow Reversal	56	16.1%
PROFI <sup>1</sup>	Transfemoral CAS	Proximal occlusion (MoMA)	31	45%
ICSS <sup>2</sup>	Transfemoral CAS	Distal filter (various)	51	73%
PROFI <sup>1</sup>	Transfemoral CAS	Distal filter (Embolshield)	31	87%

44 patients TCAR Hemispheric symptomatic  
 Mean Age 74 (51 - 84)

21 patients Carotid Wallstent Boston Sci

4 patients with transient neurological symptoms TIA

19%

23 patients C - Guard Inspire  
 1 patient with TIA

4.3%

How to get optimal protection without perioperative stroke, late emboli and plaque protrusion?

Transcervical proximal flow reversal (TCAR)!

Mesh covered Stent? **To be continued**

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