Current Status of Carotid Interventions



Role of CAS in 2018

Piotr Musialek



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Potential conflicts of interest

Speaker's name: Piotr Musialek

Advisory Board/Consulting Research Support

InspireMD, Medtronic Abbott

Concepts and Tools

- Concepts and Tools
- Outcomes

-2016 Update

Report From the American Heart Association

Heart Disease and Stroke Statistics-

PCR

Table 14-2. Modifiable Stroke Risk Factors

Factor	Prevalence, %	PAR, %*	RR
Cigarette smoking			
Overall	19.8	12-14†	1.9
Men	22.3		
Women	17.4		
Hypertension		‡	8
Ages 20-34 y			
Men	13.4	99	
Women	6.2	98	
Ages 35-44 y			
Men	23.2	99	
Women	16.5	106	
Ages 45-54 y			
Men	36.2	100	
Women	35.9	103	
Ages 55-64 y			
Men	53.7	100	
Women	55.8	102	
Ages 65-74 y			
Men	64.7	100	
Women	69.6	101	
Ages ≥75 y			
Men	64.1	100	
Women	76.4	101	
AF (nonvalvular)			
Overall age, y			
50-59	0.5	1.5	4.0
60-69	1.8	2.8	2.6
70–79	4.8	9.9	3.3
80-89	8.8	23.5	4.5
Asymptomatic carotid stenosis	2–8	2-7§	2.0

eart Disease and Stroke Statisti



Table 14-2.	Modifiable Stroke Risk Factors
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Factor	Prevalence, %	PAR, %*	RR
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Women	17.4		

Atherosclerotic Carotid Stenosis

Women 6.2 98
Ages 35–44 y

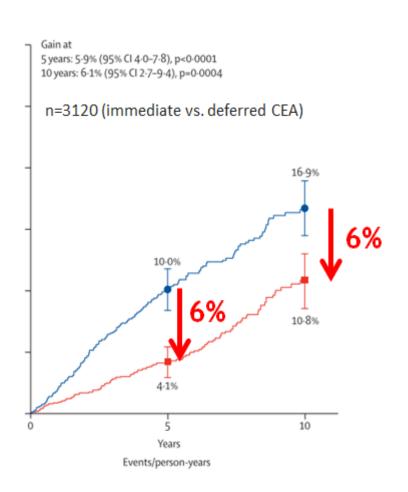
Men
Women
Ages 45–54 y
Men
Women
Women
Ages 55–64 y
Men
Men
Solution
Solution
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Sol

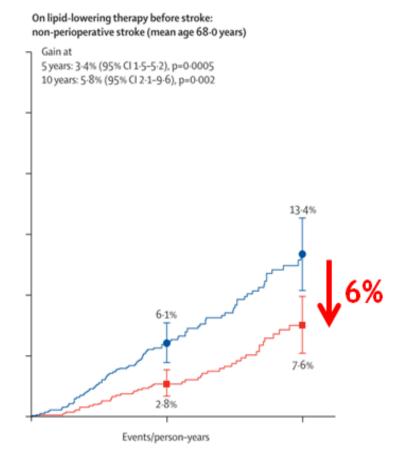
an important and modifiable!

DU-09	0.5	1.0	4.0
60-69	1.8	2.8	2.6
70-79	4.8	9.9	3.3
80-89	8.8	23.5	4.5
Asymptomatic carotid stenosis	2–8	2-7§	2.0



Stroke Reduction with Carotid Revascularization





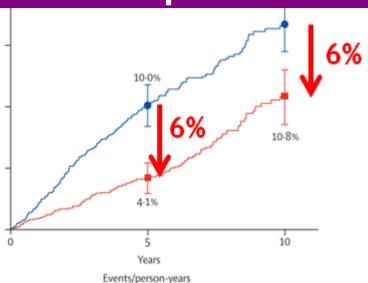


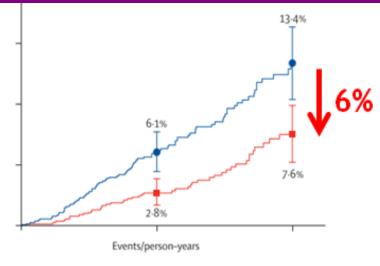
Stroke Reduction with Carotid Revascularization

Gain at 5 years: 5-9% (95% CI 4-0-7-8), p<0-0001 10 years: 6-1% (95% CI 2-7-9-4), p=0-0004 On lipid-lowering therapy before stroke: non-perioperative stroke (mean age 68-0 years)

Gain at 5 years: 3·4% (95% CI 1·5-5·2), p=0·0005 10 years: 5·8% (95% CI 2·1-9·6), p=0·002

The only way to recall Level-1 evidence would be to provide new evidence at similar level





PCR Carotid Revascularization 2018

Optimized Pharmacotherapy is <u>FUNDAMENTAL</u>

but

there is **ZERO!** evidence today to claim that pharmacotherapy ALONE protects sufficiently against stroke in atherosclerotic carotid disease

PCR Carotid Revascularization 2018

Optimized Current CAS studies...

there is **continue**nce today

to claim that

to receive patients who develop protects sufficiently against stroke

in atheroscleratic caratid disease



PCR CardioVascular Circular PCR are NOT "average" Carotid Stenosis Subjects



Cardiovascular Clinic Patients

are NOT "average" Carotid Stenosis Subjects

Fundamental Issue

"People" with Carotid Stenosis

Vascular Clinic Referral Patient



General Population Subject

annual ipsilateral stroke risk 2.5-3.0%

annual ipsilateral stroke risk ≈0.5%



PCR CAS indications 2018

 Focus on treating "symptomatic" patients is not the pride but rather failure of the system



PCR CAS indications 2018

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PCR CAS indications 2018

Focus on treating "symptomatic" patients is not the pride but rather failure of the system



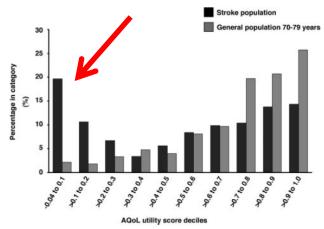


Figure 1. Distribution of AQoL utility scores among 5-year survivors and Australian general population aged 70-79 years.

Long-Term Outcome in the North East Melbourne Stroke **Incidence Study**

Predictors of Quality of Life at 5 Years After Stroke

Seana L. Paul, BSc (Hons); Jonathan W. Sturm, PhD; Helen M. Dewey, PhD; Geoffrey A. Donnan, MD; Richard A.L. Macdonell, MD; Amanda G. Thrift, PhD

Utility scores range from -0.04 (state worse than death) through 0.0 death-equivalent) to 1.0 (full health). The AQoL is valid and reliable in stroke patients.²⁷ Furthermore, it is reliable when completed by



CLINICAL RESEARCH



Novel PARADIGM in carotid revascularisation: Prospective evaluation of All-comer peRcutaneous cArotiD revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuardTM Micronet-covered embolic prevention stent system



Piotr Musialek^{1*}, MD, DPhil; Adam Mazurek¹, MD; Mariusz Trystula², MD, PhD; Anna Borratynska³, MD, PhD; Agata Lesniak-Sobelga¹, MD, PhD; Malgorzata Urbanczyk⁴, MD; R. Pawel Banys⁴, MSc; Andrzej Brzychczy², MD, PhD; Wojciech Zajdel⁵, MD, PhD; Lukasz Partyka⁶, MD, PhD; Krzysztof Zmudka⁵, MD, PhD; Piotr Podolec¹, MD, PhD

These people



Table 3. Evolution of neurological status in PARADIGM patients

umber # 5	NIHSS					
#5	minaa	Rankin	NIHSS	Rankin	NIHSS	Rankin
	6	1	6	1	6	1
#6	5	2	5	2	3	2
#7	1	1	1	1	1	1
#9	6	4	6	4	6	3
# 13	6	3	4	2	3	2
# 15	3	3	3	2	3	1
# 18	9	4	4	3	3	2
# 20	1	1	1	1	1	1
# 22	2	1	2	1	2	1
# 23	4	2	3	1	2	1
# 25	6	3	5	3	4	3
# 26	4	2	4	2	4	2
# 28	5	2	2	2	2	2
# 33	3	1	3	1	3	1
# 41	5	3	5	3	5	3
# 44	9	4	7	4	7	3
# 48	3	1	3	1	3	1
# 50	6	3	6	3	6	3
# 55	3	2	3	2	3	2
# 56	2	1	2	1	2	1
# 59	3	1	1	1	1	1
# 63	4	2	4	2	4	2
# 60	2	0	0	0	0	0
# 65	4	2	4	2	4	2
# 69	2	2	2	2	2	2
# 70	5	4	5	4	5	4
# 71	3	1	3	1	3	1
# 72	1	0	1	0	1	0
# 74	6	4	6	4	6	4
# 75	2	1	2	1	2	1
# 83	3	1	3	1	3	1
#86	2	2	2	2	2	2
#94	1	1	0	0	0	0
# 98	3	2	3	2	3	2
# 99	2	1	2	1	2	1
# 100	1	1	0	0	0	0
# 101	7	4	4	4	4	3



Every symptomatic Carotid Stenosis ...



Every symptomatic Carotid Stenosis ...

... starts
as
asymptomatic

PCR Until (and if ever) Prospective Risk Scores are Developed...

PCR Until (and if ever) Prospective Risk Scores are Developed...

CHADS₂ Calculator for Atrial Fibrillation

Evaluates ischemic stroke risk in patients with atrial fibrillation

Criteria		Poss. Point
Congestive heart failure Signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction	Yes No	+1
Hypertension Resting BP > 140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment	Yes No	+1
Age 75 years or older	Yes No	+2
Diabetes mellitus Fasting glucose > 125 mg/dL or treatment with oral hypoglycemic agent and/or insulin	Yes No	+1
Stroke, TIA, or TE Includes any history of cerebral ischemia	Yes No	+2
Vascular disease Prior MI, peripheral arterial disease, or aortic plaque	Yes No	+1
Age 65 to 74 years	Yes No	+1
Sex Category (female) Female gender confers higher risk	Yes No	+1

Results:	
Total Criteria Point Count:	0
Reset Form	
Stroke Risk per 100 Person Y Interpretation	ears/Warfarin Rx
0 Points: 0.25 ON Rx; 0	.49 NO Rx
1 Point: 0.72 ON Rx; 1	.52 NO Rx
2 Points: 1.27 ON Rx; 2	.50 No Rx
3 Points: 2.20 ON Rx; 5	.27 NO Rx
4 Points: 2.35 ON Rx; 6	.02 NO Rx
5-6 Points: 4.60 ON Rx; 6	.88 NO Rx

PCR Until (and if ever) Prospective Risk Scores are Developed...

we have the duty to use published risk criteria

PCR Until (and if ever) Prospective PCR Risk Scores are Developed...

we have the duty to use published risk criteria



PARADIGM



Methods (cont'd):

- ASYMPTOMATIC patients treated interventionally only if at /stroke risk
- established lesion-level increased-risk crieria used:
 - thrombus-containing
 - documented progressive
 - irregular and/or ulcerated
 - contralateral ICA occlusion/stroke
 - asymptomatic ipsilateral brain infarct

AbuRahma A et al. *Ann Surg.* 2003;238:551-562. Ballotta E et al. *J Vasc Surg* 2007;45:516-522. Kakkos SK et al. (ACSRS) *J Vasc Surg.* 2009;49:902-909. Lovett JK et al. *Circulation* 2004;110:2190-97 Nicolaides AN et al. *J Vasc Surg* 2010;52:1486-96. Taussky P et al. *Neurosurg Focus* 2011;31:6-17.







How asymptomatic is "asymptomatic" carotid stenosis?

Resolving fundamental confusion(s)—and confusions yet to be resolved

Piotr Musiałek¹, Iris Q. Grunwald^{2,3}

- 1 Department of Cardiac and Vascular Diseases, Jagiellonian University Medical College, John Paul II Hospital, Kraków, Poland
- 2 Neuroscience and Vascular Simulation, Anglia Ruskin University, Chelmsford, United Kingdom
- 3 Southend University Hospital NHS Foundation Trust, Westcliff-on-Sea, United Kingdom

symptoms vs. sign(s) of cerebral ischemia

eg. "asymptomatic" infarct(s), retinal function, cognitive function, etc.

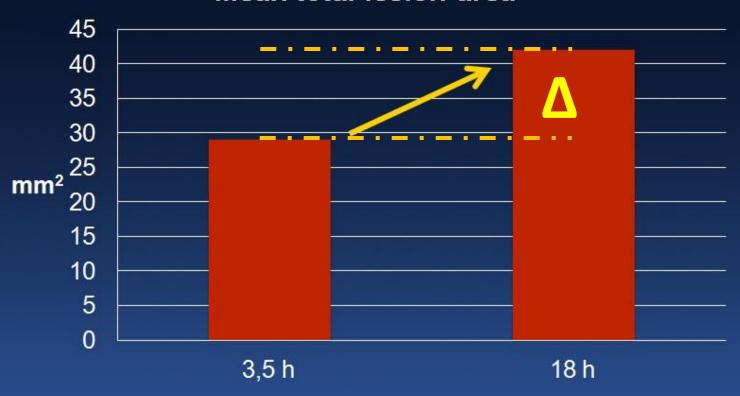
What is the meaning of "symptomatic" in relation to CS? The English language, in contrast to many others, differentiates between "symptoms" and "signs." A symptom is an indication of disease perceived by the patient and reported by the patient. Symptoms of CS-associated cerebral ischemia include ipsilateral TIA or clinical stroke. 2,10 A sign is an observable physical phenomenon indicative of the presence of a pathology or disease. Signs are detected by the physician through clinical examination and accessory investigations. A clinically-silent cerebral infarct ipsilateral to CS is a sign, not a symptom, and the patient is, strictly speaking, "asymptomatic." In such patients, however, there is evidence for an increased risk of further, clinically symptomatic, brain injury likely to occur in the absence of an intervention.^{2,8} While the definition of stroke includes an episode of clinically manifest neurological dysfunction, 10 according to the same guidelines, the term "stroke" may be also used for brain infarction in the absence of clinical symptoms. 10 According to some authors, patients with TIA or stroke become automatically "asymptomatic" from the point of 6 months after the event onwards. 3,9,11 Further confusions arise from the fact that different studies have used different time points to change the "symptomatic"/"asymptomatic" label, such as 1, 3, 4, or 12 months. 12 More accurate terms have been proposed, such as "recently symptomatic" and "remotely symptomatic."12 The above, and other, inconsistencies greatly confuse physicians, leading to different approaches to the same patient type by various specialties or in various medical centers or countries.

Concepts and Tools

Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS

Mean total lesion area

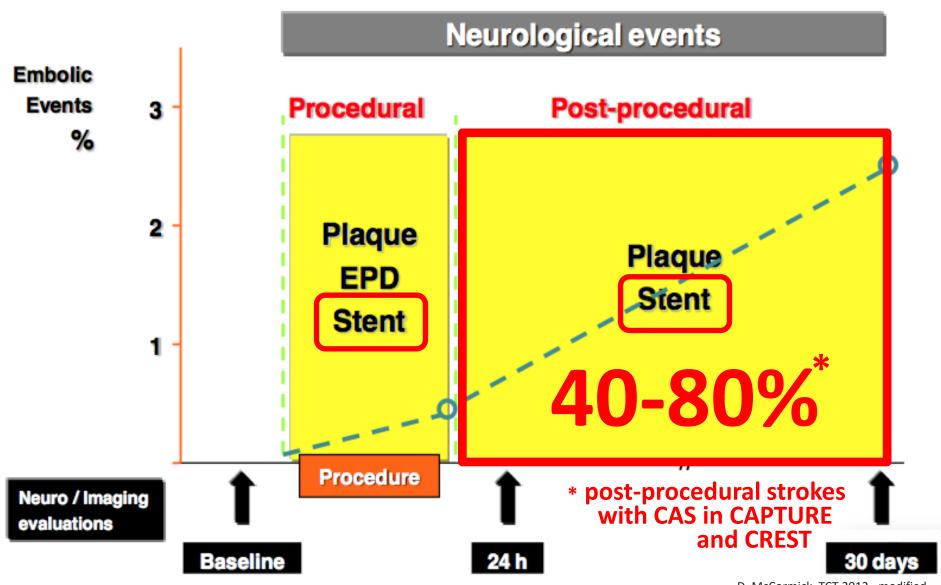


Schofer J et al, JACC Cardiovasc interv 2008



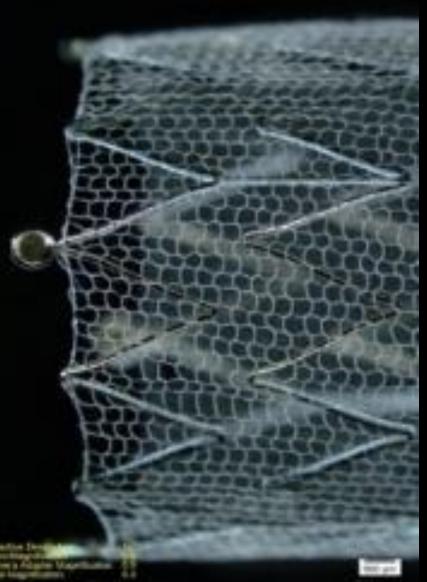


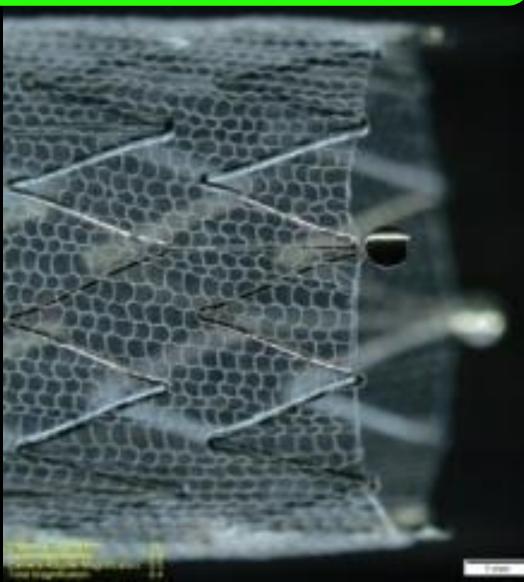
Timing of neuro-embolic events after CAS

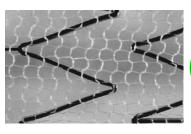


- CEA excludes the plaque
- •In CAS, the <u>stent should</u> exclude the plaque too

CGuard™ embolic prevention system

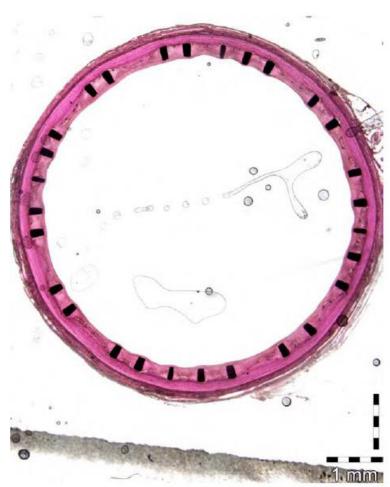




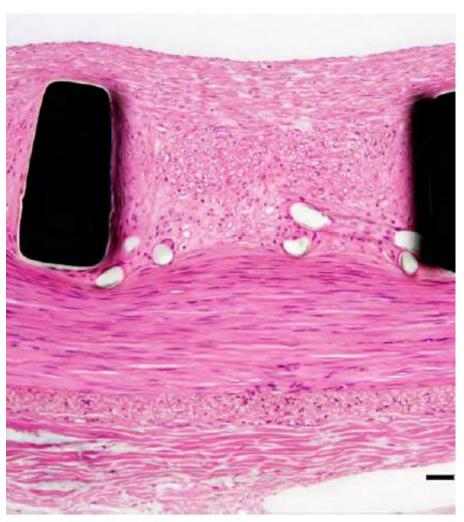


CGuard EPS 90 days/pig





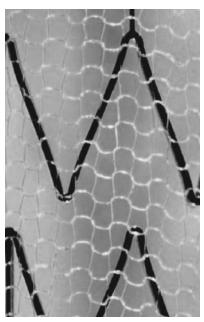
12-105 LCCA-S 3 13-1689-3 1.25x H&E.tif

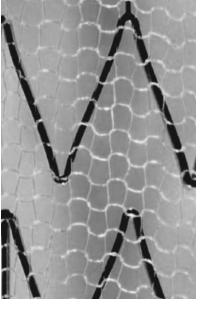


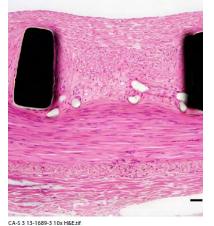
CA-S 3 13-1689-3 10x H&E,tif

CGuard EPS 30 & 90 days / pig









Mean ± SD Standard Histomorphology Parameters (2 of 2) 4.0 3.5 3.0 2.5 2.0 1.5 1.0 0.5 0.0 BMS **CGuard** BMS **CGuard** (n=3)(n=9)(n=3)(n=9)Day 30 Day 90 ■Neointimal Maturation (0-3) ■ Endothelialization (0-4)

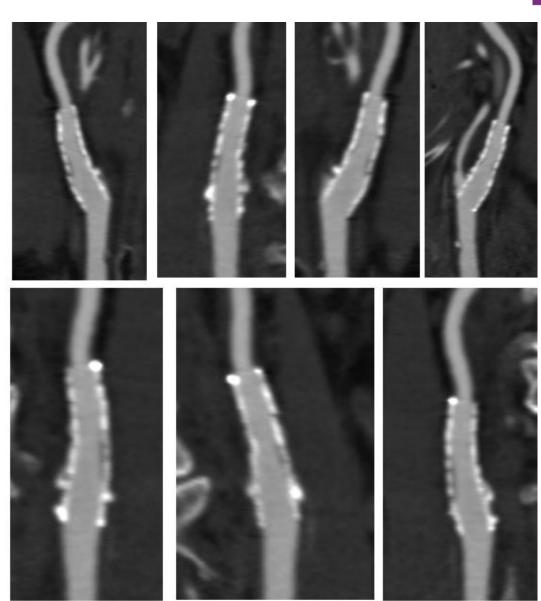
Mean ± SD and Median Standard Histomorphology Parameters								
Parameter	Day 30			Day 90				
	BMS (n=	=3) CGuard (n=9)		=9)	BMS (n=3)		CGuard (n=9)	
Injury (0-3)	0.00 ± 0.01	0.00	0.00 ± 0.01	0.00	0.01 ± 0.02	0.00	0.00 ± 0.01	0.00
Inflammation (0-3)	0.43 ± 0.23	0.51	0.41 ± 0.22	0.36	0.17 ± 0.16	0.11	0.09 ± 0.08	0.07
Neointimal Fibrin (0-3)	1.13 ± 0.23	1.00	0.82 ± 0.37	1.00	0.00 ± 0.00	0.00	0.00 ± 0.00	0.00
Adventitial Fibrosis (0-3)	0.00 ± 0.00	0.00	0.02 ± 0.07	0.00	0.00 ± 0.00	0.00	0.00 ± 0.00	0.00
Neointimal Maturation (0-3)	3.00 ± 0.00	3.00	3.00 ± 0.00	3.00	3.00 ± 0.00	3.00	3.00 ± 0.00	3.00
Endothelialization (0-4)	3.67 ± 0.42	3.80	3.62 ± 0.35	3.80	4.00 ± 0.00	4.00	4.00 ± 0.00	4.00

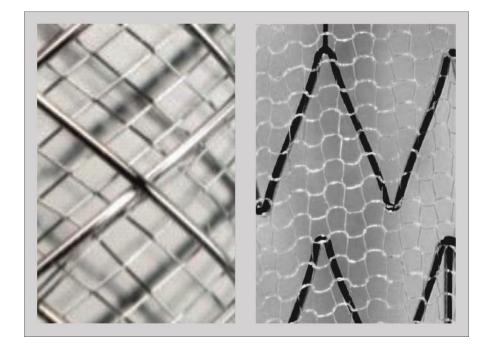


Normal Long-Term Healing







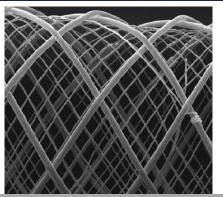


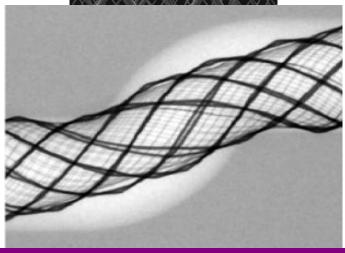


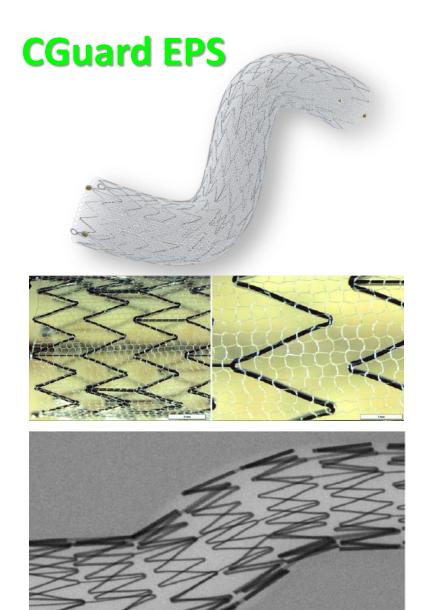
mechanical Properties

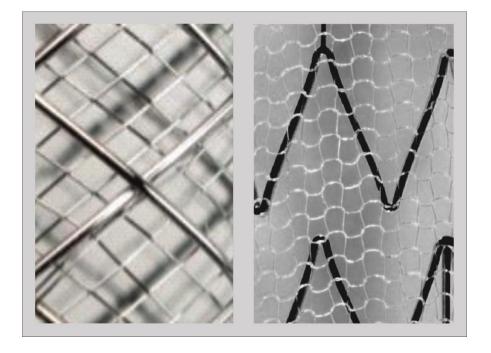
RoadSaver / Casper



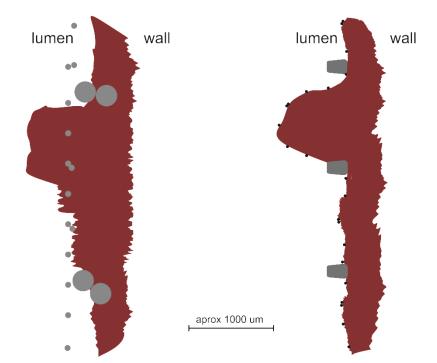






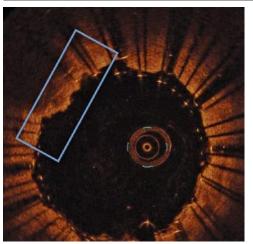


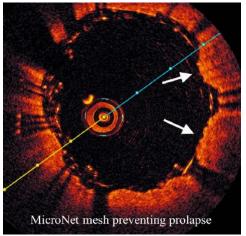














Nerla et al. EuroIntervention 2017 Musialek & Stabile EuroIntervention 2017 Umemoto et al. EuroIntervention 2017

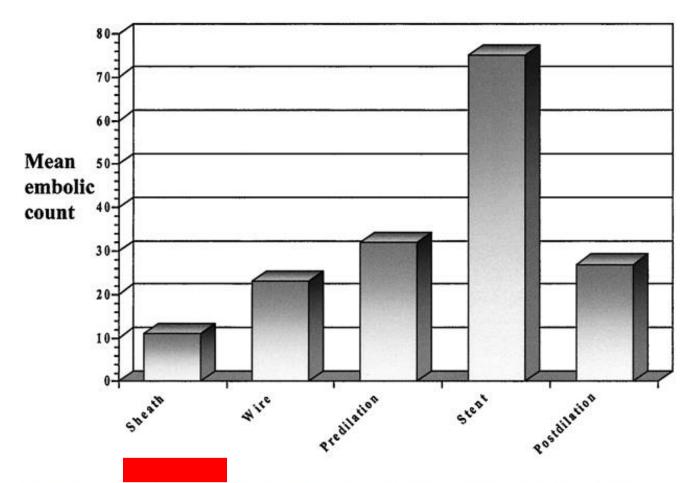


Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

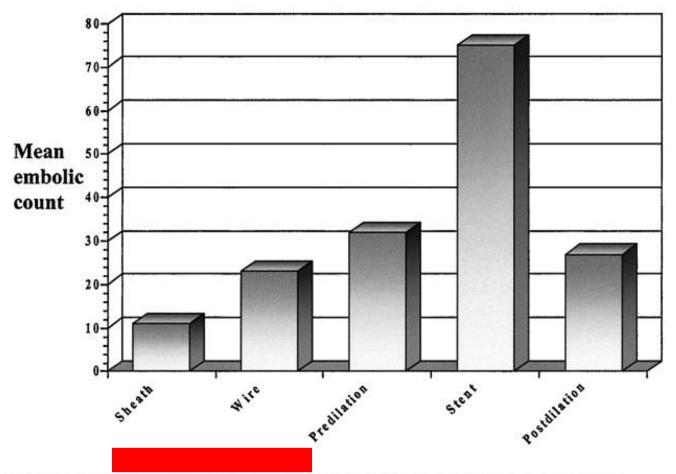


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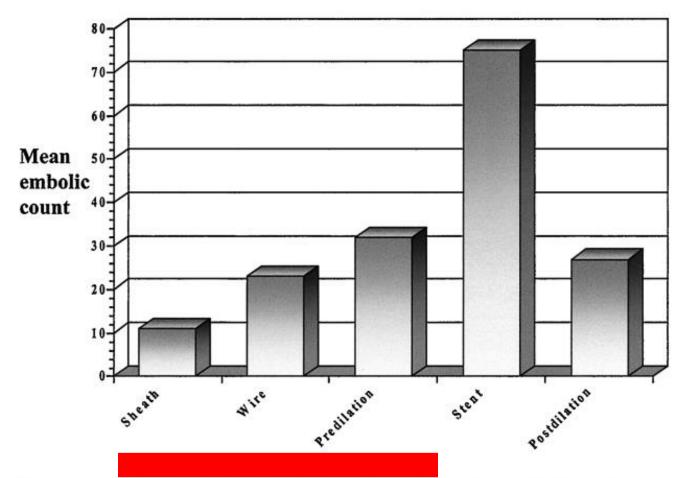


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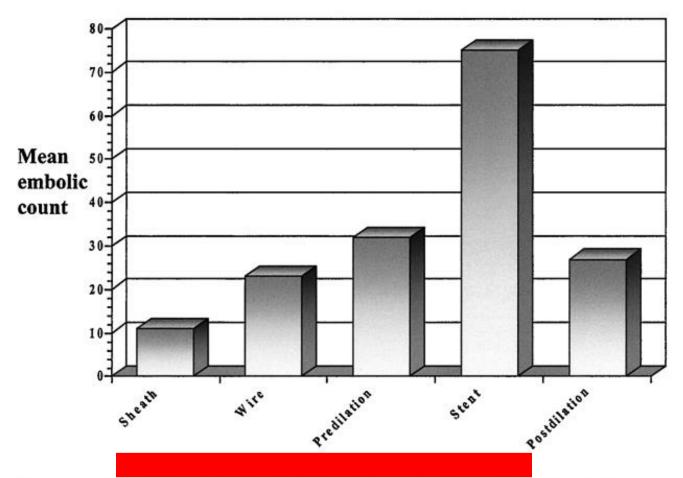


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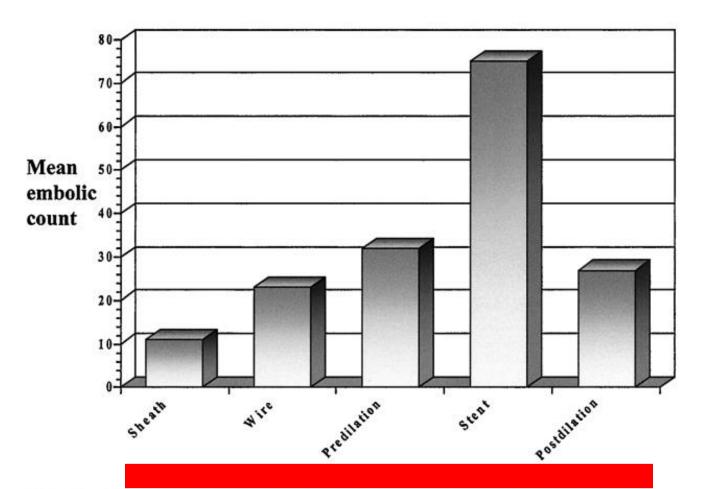
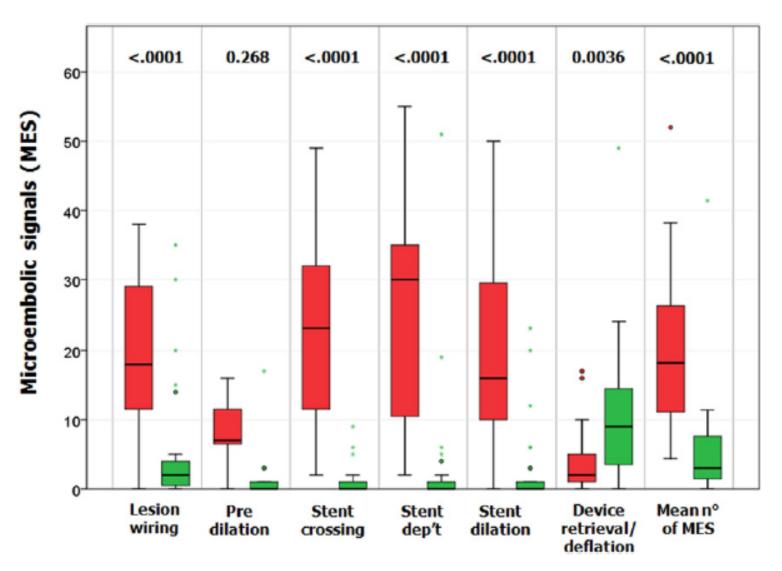


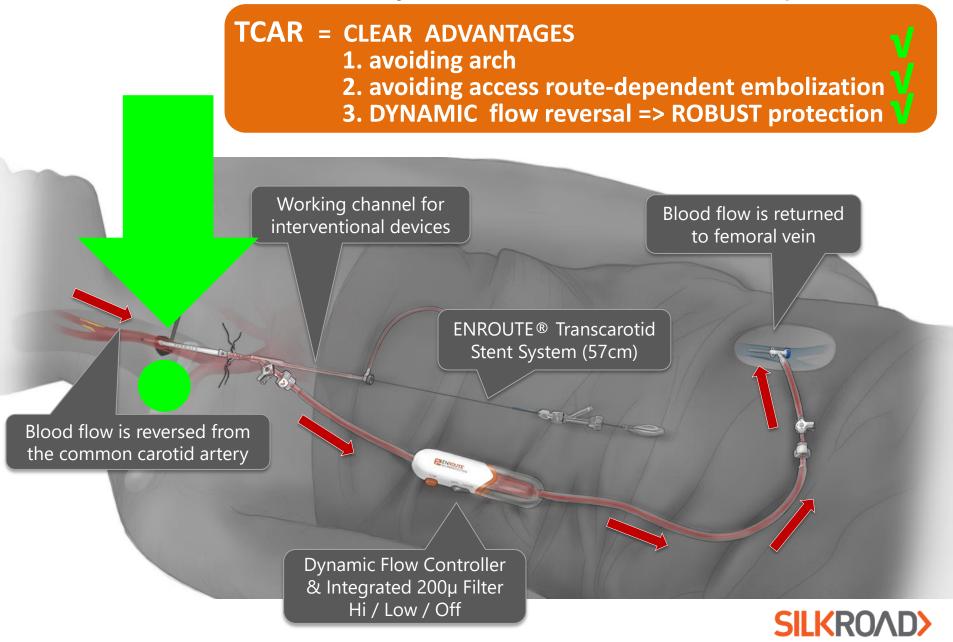
Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

Microembolization During Carotid Artery Stenting

A Randomized Trial of Proximal Versus Distal Cerebral Protection

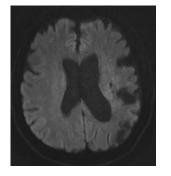


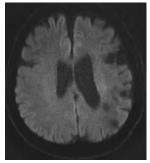
TransCarotid Artery Revascularization (TCAR)



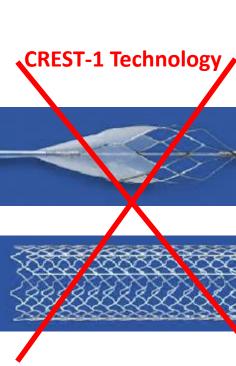
T.W., man 69 yo critical LICA stenosis

L haemisph stroke **5mo**



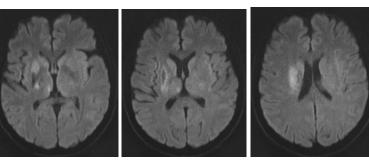


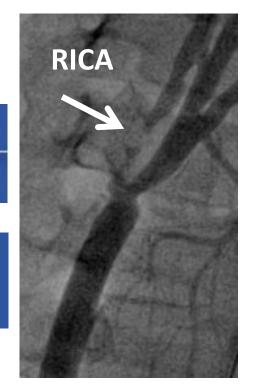
LICA

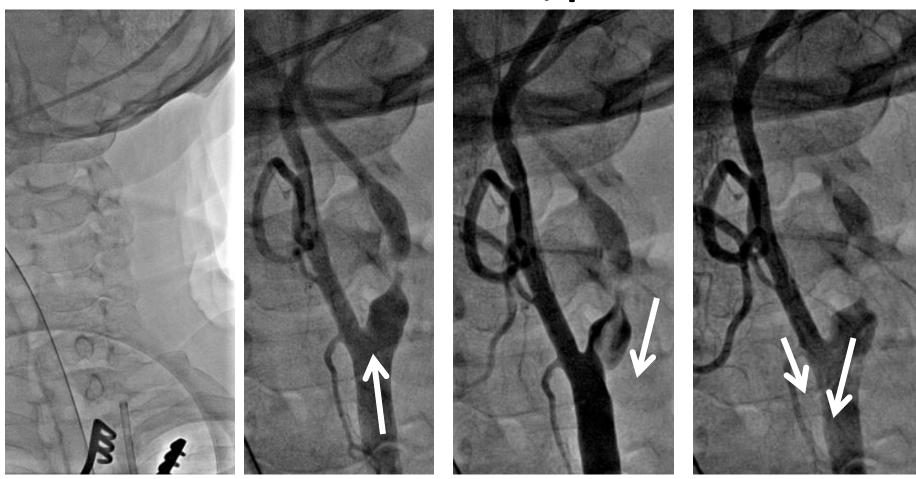


E.W., woman, 58 y,
TWO recent (20d and 5d)
R haemispheric
minor strokes despite OMT!





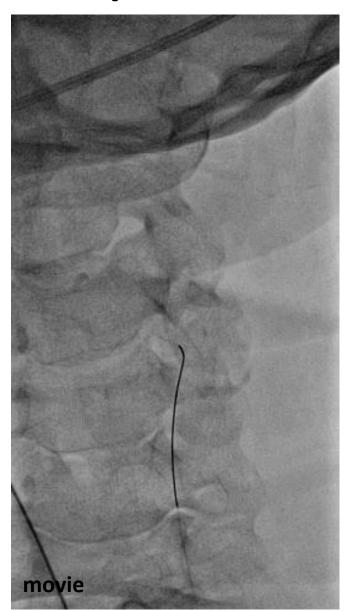


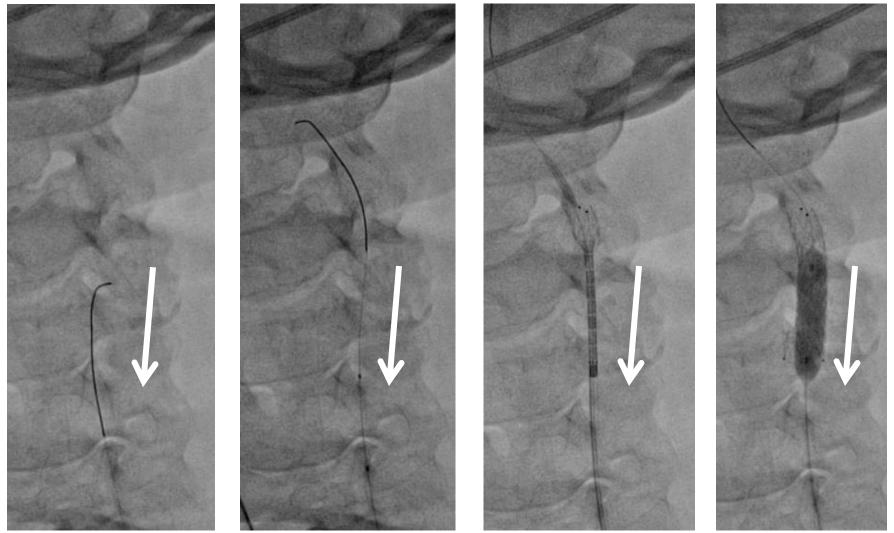


Surgical Team: M. Trystula, M. Kazubudzki, J. Krzywoń, A. Brzychczy; L. Pinter Endo: P. Musialek & A. Mazurek

Direct carotid access CAS (TCAR)
Under En Route (SilkRoad Medical) Flow Reversal





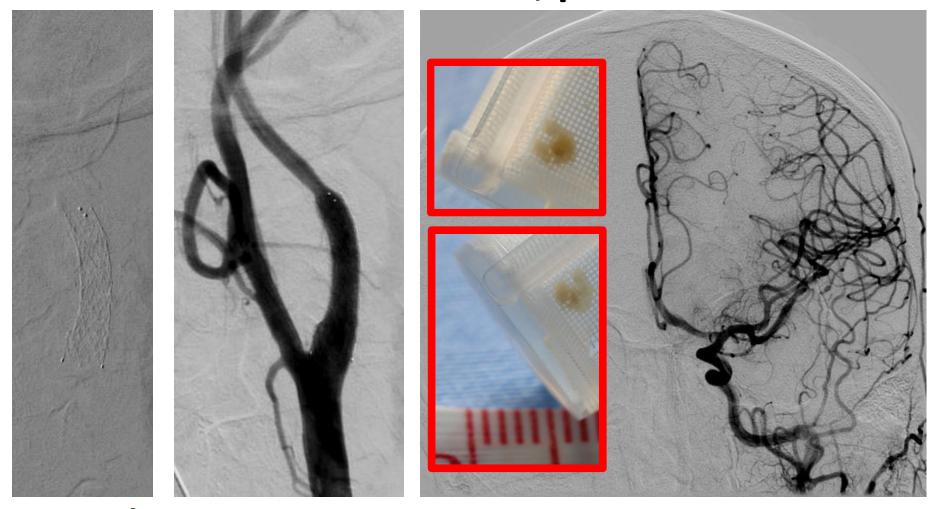


lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal

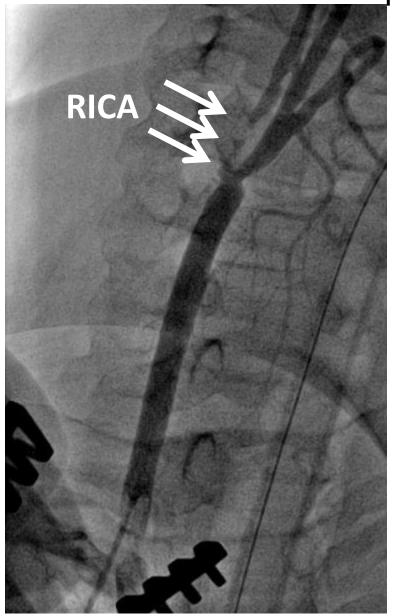


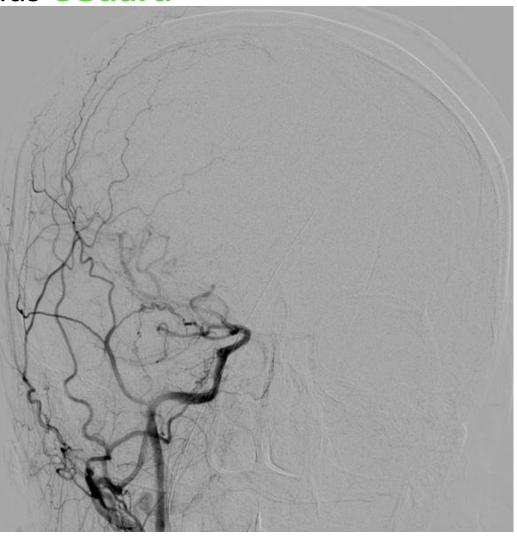
CGuard 7.0 x 30mm full endovascular reconstruction

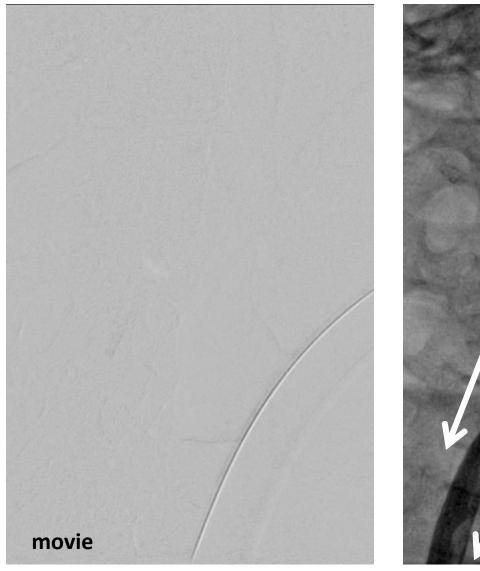
Direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal



CGuard 7.0x30mm full endovascular reconstruction direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal

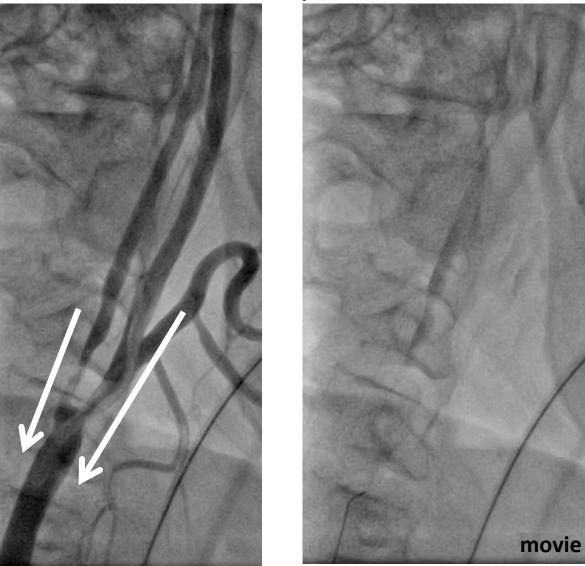






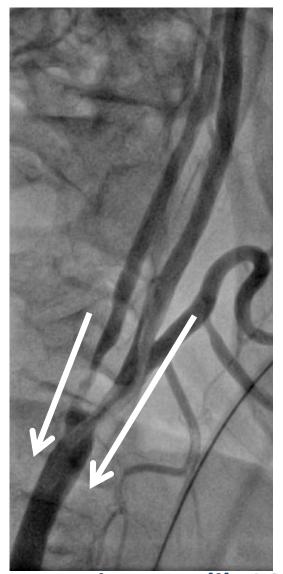


En Route (SilkRoad Medical) Dynamic Flow Reversal



lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal

TCAR plus CGuard







Debris captured in the A-V shunt filter



in this procedure

lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal

P Musialek @ ePCR 2018





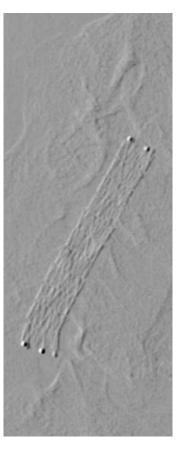


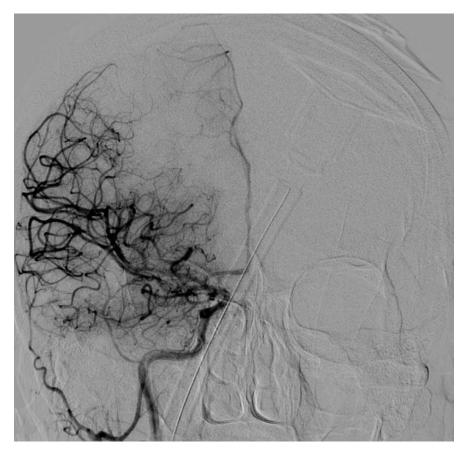
lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal

TCAR plus CGuard

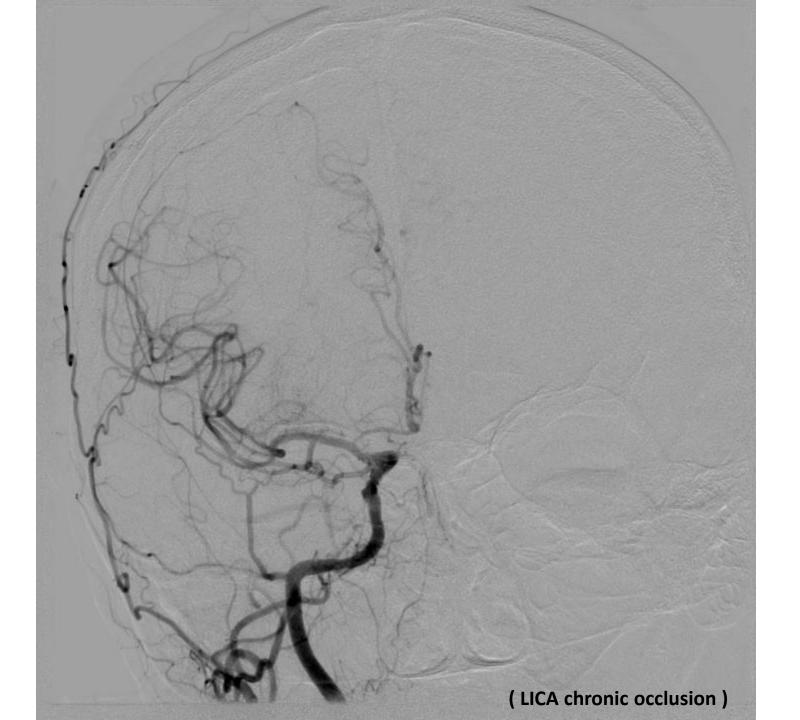


Final Result

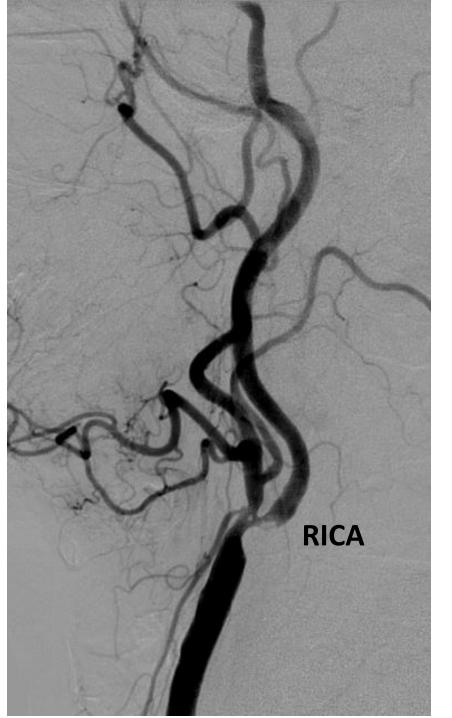




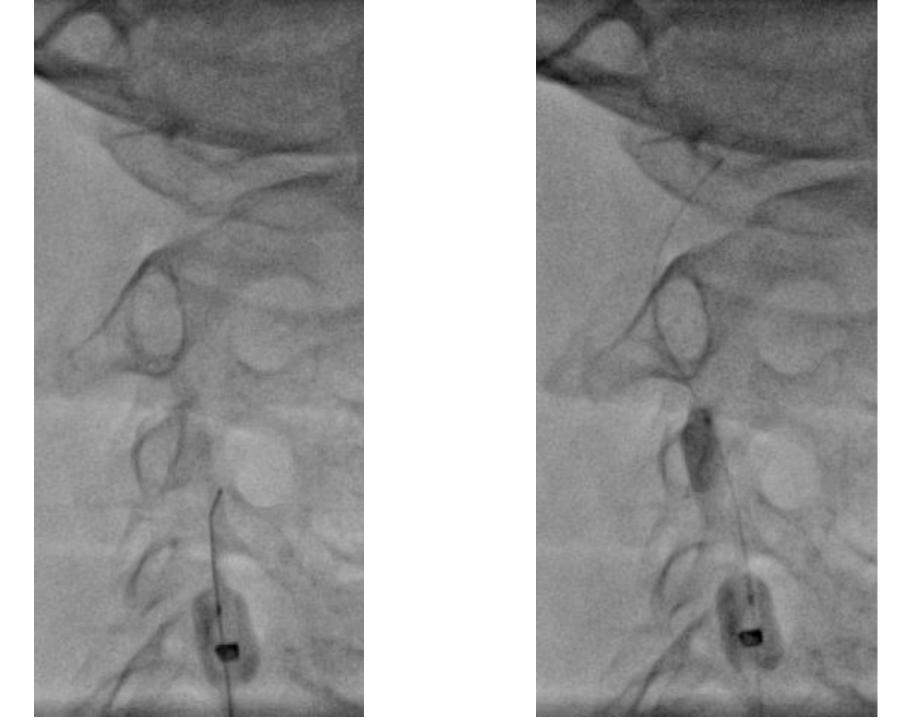
CGuard 7.0x30 mm full endovascular reconstruction plus NO new lesions on DW-MRI!

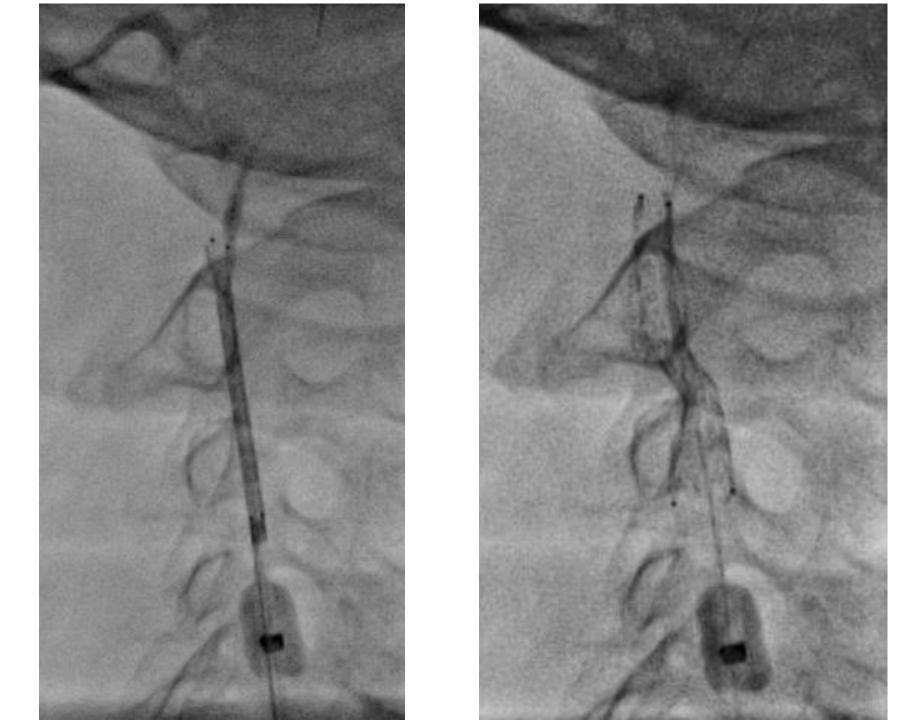






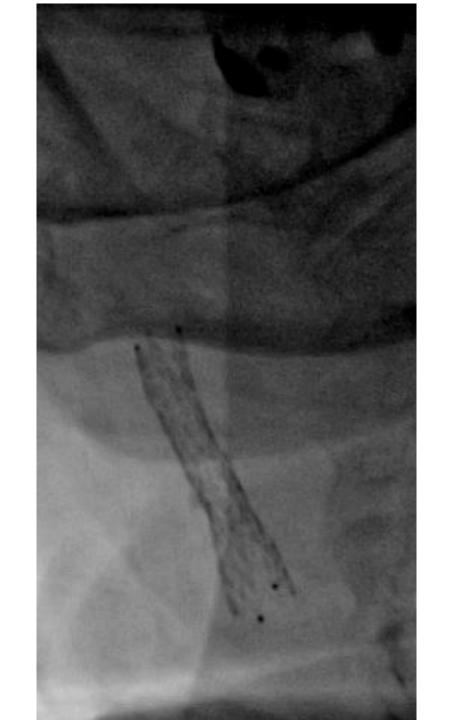




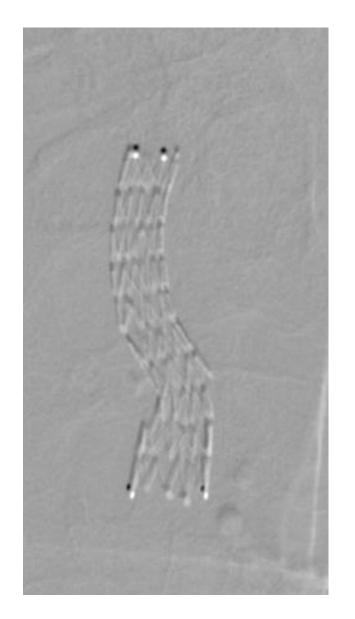


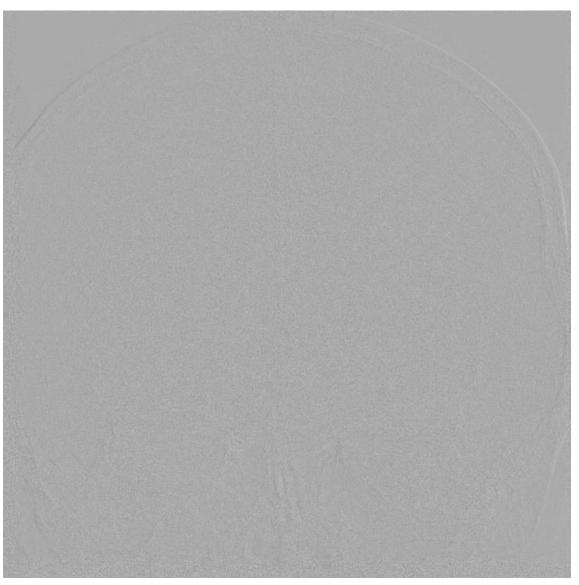


Flow reversal time 7min 10sec Intolerance in the last 80sec (active aspiration still !! performed)

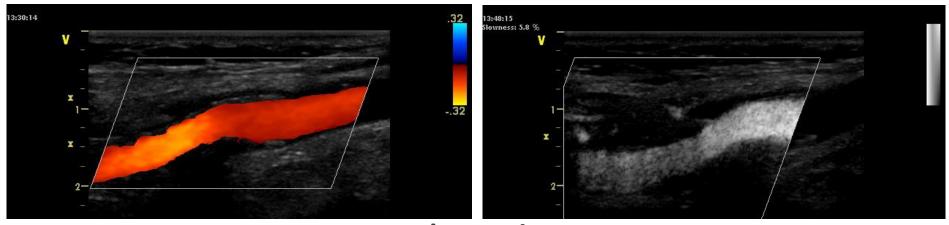


Final Result

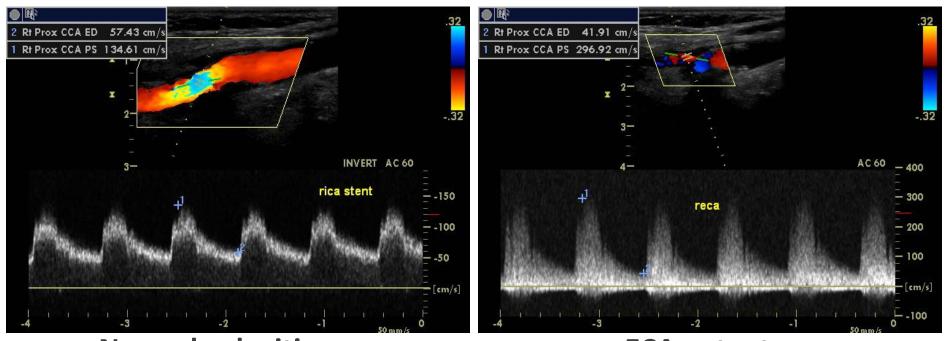




November 13, 2017 – patient A/S, discharged home



Normal stent image



Normal velocities

ECA patent



Double layered stents for carotid angioplasty: A meta-analysis of available clinical data

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Anna Sannino, MD^{1,2*} | Giuseppe Giugliano, MD, PhD^{1,2*} | Evelina Toscano, MD^{1,2} | Gabriele G. Schiattarella, MD^{1,2} | Anna Franzone, MD, PhD^{1,2} | Tullio Tesorio, MD^3 | Bruno Trimarco, MD^{1,2} | Giovanni Esposito, MD, PhD^{1,2} | Eugenio Stabile, MD, PhD^{1,2} ^{\circ}
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	Event Rate	95% CI	N	
Mazzaccaro et al. 2010	80.0	0.01 / 0.62	5	
Musialek et al. 2010	0.00	0.00 / 0.07	101	
Shofer et al. 2015	5 0.02	0.00 / 0.21	30	
Speziale et al. 2017	7 0.03	0.01 / 0.06	200	-
CGuard	0.02	0.01 / 0.05	336	*
Bosiers et al. 2010	6 0.02	0.01 / 0.08	100	
Castagno et al. 2010	6 0.10	0.01 / 0.67	4	
Kedev et al. 2019	5 0.05	0.00 / 0.45	10	
Nerla et al. 2010	0.00	0.00 / 0.05	150	
Ruffino et al. 2010	6 0.02	0.00 / 0.26	23	
Wissgott et al. 2010	0.04	0.00 / 0.40	12	
Roadsave	r 0.02	0.01 / 0.06	299	-

FIGURE 2 30-day mortality and stroke rate. Random effects event rate and 95% confidence interval for 30-day mortality and stroke (A) and relative subgroup analysis (B)

(evaluate stroke risk & SIGNS of ischaemia)

PHARMACOTHERAPY + INERVENTIION

ISOLATED PHARMACOTHERAPY



PHARMACOTHERAPY + INERVENTIION

ISOLATED PHARMACOTHERAPY

procedure risk

PHARMACOTHERAPY + INERVENTIION

ISOLATED PHARMACOTHERAPY

procedure risk

OPTIMIZED
PHARMACOTHERAPY
+ INERVENTION

ISOLATED PHARMACOTHERAPY



Double-layered stents ///

Stenting replaces CEAs

 Minimal invasiveness / incl. TransRadial Double-layered stents ///

eg. CGuard growth by > 130% (Q1 2017/Q1 2018)

Stenting replaces CEAs!

eg. TCAR growth (coming predominantly from CEA) by > **350**% (2016/2017) CMS (US) reimbursement, both in symptomatics and HR asymptomatics already > 500 patients in ROADSTER-2 + Vascular Quality Initiative

Minimal invasiveness numbers Incl. TransRadial

One swallow does not a summer make but many swallows do: accumulating clinical evidence for nearly-eliminated peri-procedural and 30-day complications with mesh-covered stents transforms the carotid revascularisation field

Piotr Musiałek¹, L. Nelson Hopkins², Adnan H. Siddiqui²

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Adv Interv Cardiol 2017; 13, 2 (48): 95–106 DOI: https://doi.org/10.5114/pwki.2017.69012

Abstract

Atherosclerotic carotid artery stenosis (CS) continues to be a common cause of acute ischaemic stroke. Optimised medical therapy (OMT), the first-line treatment modality in CS, may reduce or delay – but it does not abolish – CS-related strokes. As per current AHA/ASA and ESC/ESVS/ESO guidelines, carotid artery stenting (CAS) is a less-invasive alternative to carotid endarterectomy (CEA) for CS revascularisation in primary and secondary stroke prevention.

Ten-year follow-up from the CREST trial in patients with symptomatic and asymptomatic CS confirmed equipoise of CAS and CEA in the primary endpoint. Nevertheless CAS – using a widely open-cell, first-generation stent and first-generation (distal/filter) neuroprotection – has been criticised for its relative excess of (mostly minor) strokes by 30 days, a significant proportion of which were post-procedural.

Atherosclerotic plaque protrusion through conventional carotid stent struts, confirmed on intravascular imaging, has been implicated as a leading mechanism of the relative excess of strokes with CAS vs. CEA, including delayed strokes with CAS. Different designs of mesh-covered carotid stents have been developed to prevent plaque prolapse. Several multi-centre/multi-specialty clinical studies with CGurad MicroNet-Covered Embolic Prevention Stent System (EPS) and RoadSaver/Casper were recently published and included routine DW-MRI cerebral imaging peri-procedurally and at 30 days (CGuard EPS).

Data from more than 550 patients in mesh-covered carotid stent clinical studies to-date show an overall 30-day complication rate of $\sim 1\%$ with near-elimination of post-procedural events. While more (and long-term) evidence is still anticipated, these results – taken together with optimised intra-procedural neuroprotection in CAS (increased use of proximal systems including trans-carotid dynamic flow reversal) and the positive 12-month mesh-covered stent data reports in 2017 – are transforming the carotid revascularisation field today.

Establishing effective algorithms to identify the asymptomatic subjects at stroke risk despite OMT, and large-scale studies with mesh-covered stents including long-term clinical and duplex ultrasound outcomes, are the next major goals.

Key words: carotid artery stenting, mesh, stroke, endarterectomy, neuroprotection.

Thursday 24 May - Morning

10:30 - 12:00

J. Martins

Carotid angioplasty evolution for 2018

ROOM 343 Level 3

Chairperson: L.N. Hopkins

10:30	Accumulating two-year clinical and duplex ultrasound evidence from the CGuard PARADIGM-Extend prospective academic trial: durability of stroke prevention P. Musialek	11:22 11:30	 What we learned after first 122 CAS procedures using dual-layer micromesh Roadsaver stents P. Odrowaz-Pieniazek Discussion and audience interaction 	
10:38	 Discussion and audience interaction 	11:35	Novel angiographic algorithm to grade calcification severity of carotid stenosis: development and performance in the CGuard PARADIGM trial involving highly-calcific lesions management	
10:43	 Predictors of the long-term antihypertensive effect of carotid artery stenting F. Shukurov 			
10:51	 Discussion and audience interaction 		A. Mazurek	
10:56	 Total wrist access for carotid artery stenting B. Zafirovska 	11:43 11:48	 Discussion and audience interaction Results of hybrid repair multilevel lesions of the brachiocephalic arteries 	
11:04	 Discussion and audience interaction 		M. Chernyavskiy	
11:09	Synchronous vs. staged carotid artery stenting and open heart surgery? a	11:56	The Charly devotage	
	propensity score matched comparison		Discussion and audience interaction	

One swallow does not a summer make but many swallows do: accumulating clinical evidence for nearly-eliminated peri-procedural and 30-day complications with mesh-covered stents transforms the carotid revascularisation field

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