LEIPZIG INTERVENTIONAL COURSE

LINC 2016

Carotid artery revascularization using CGuard™ MicroNet-Covered Embolic Prevention Stent System: A Change in the Game

Piotr Musialek, MD DPhil FESC

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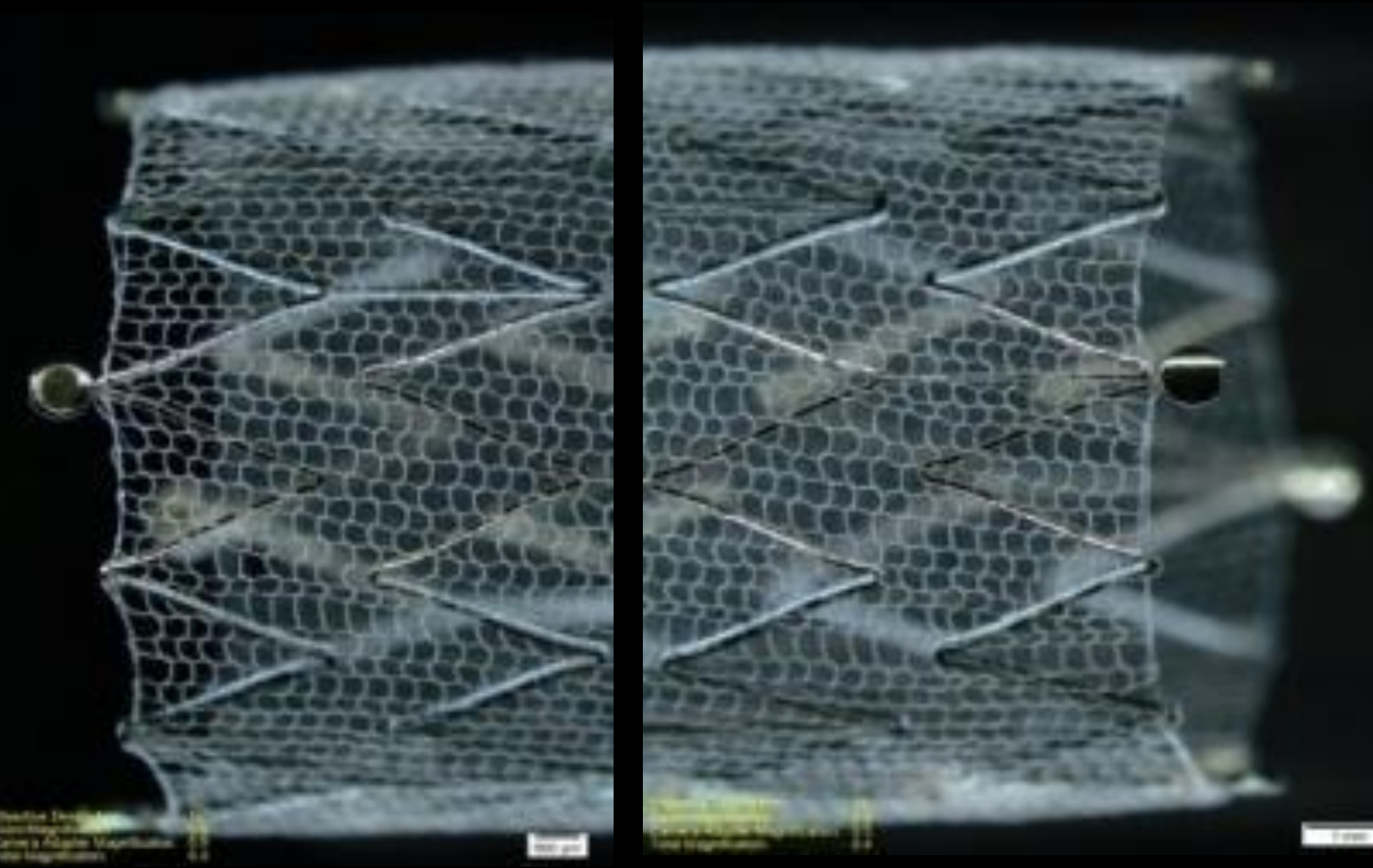
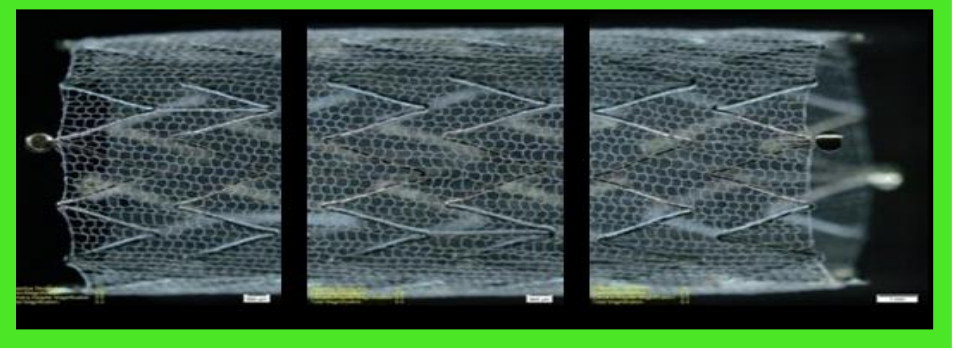
CGuard ™ embolic prevention stent





CARENET

J Am Coll Cardiol Intv 2015;8:1229–34

CAROTID PARADIGM REVASCULARIZATION

J Am Coll Cardiol 2015;66:B33

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Disclosure

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2016

Speaker name: Piotr Musialek

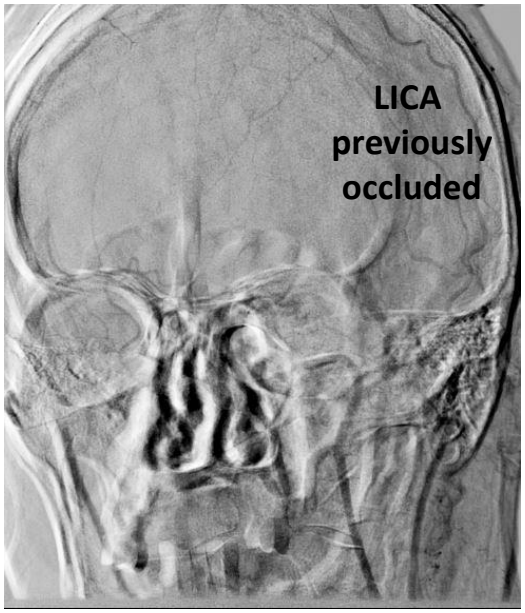
I have the following potential conflicts of interest to report:

- [√] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

NB. The **PARADIGM** study has been Invesigator-Initiated and Investigator-Executed **(no industry support)**

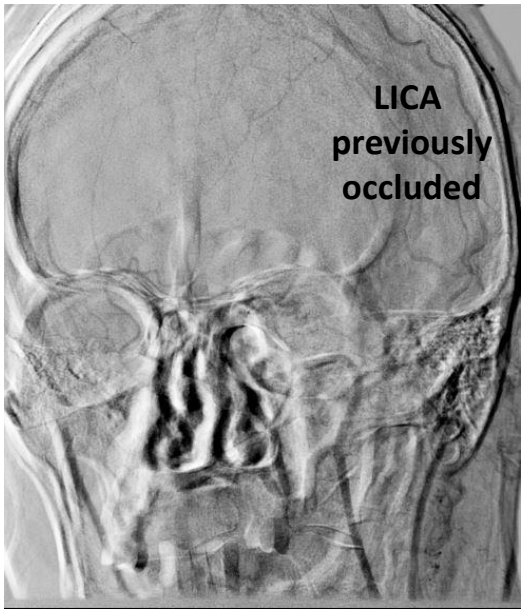
AC, man 63 yo



LICA chronic occlusion

Case # **018**
(Krakow)

AC, man 63 yo



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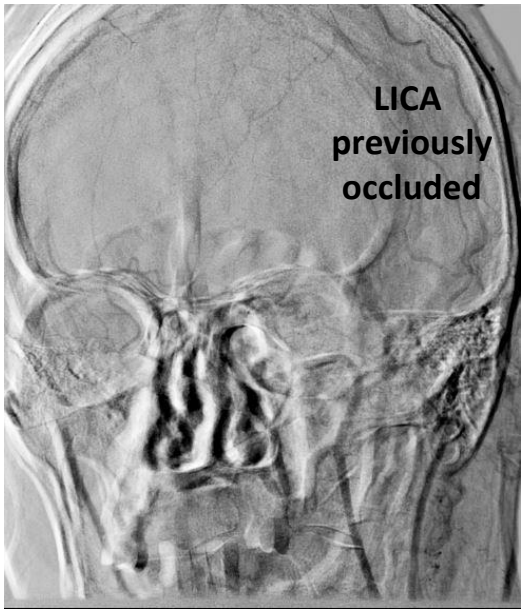

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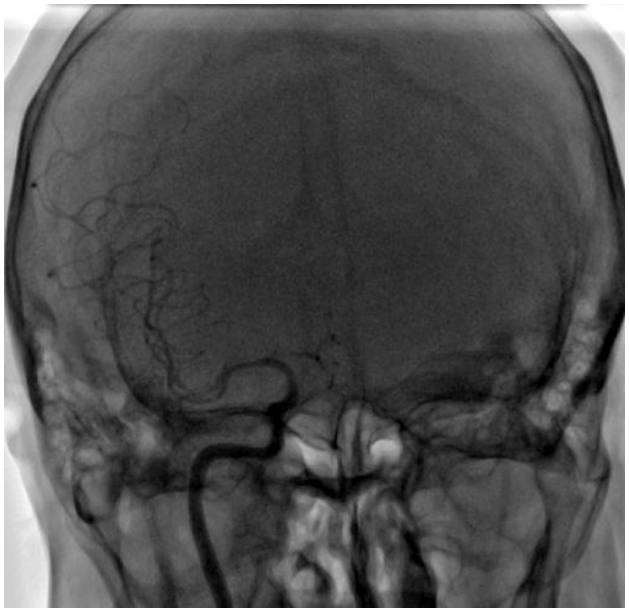
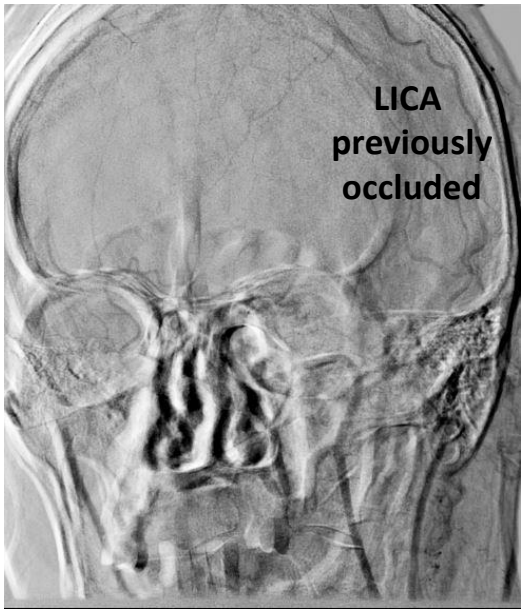


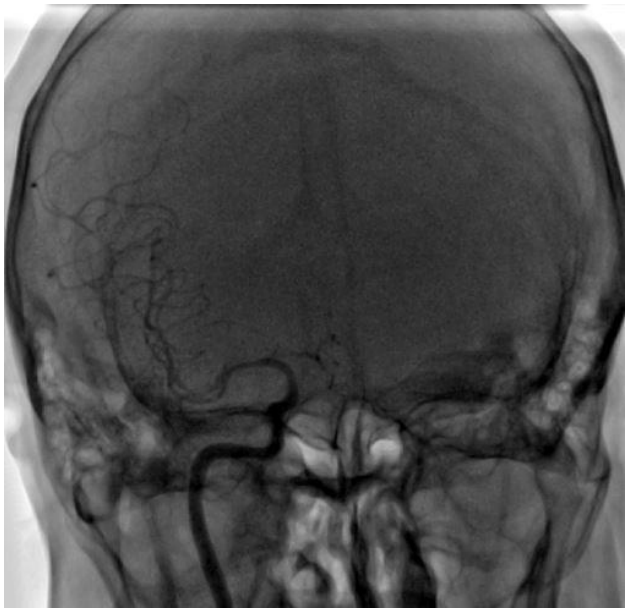
CAROTID PARADIGM REVASCULARIZATION

Case # **018**
(Krakow)

Thrombus-containing / acutely symptomatic
STROKE-in-evolution



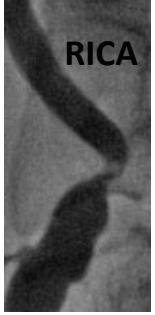
LICA chronic occlusion

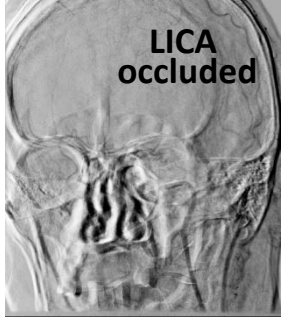


CAROTID PARADIGM REVASCULARIZATION

Case # **018**
(Krakow)

Thrombus-containing lesion
acutely symptomatic patient





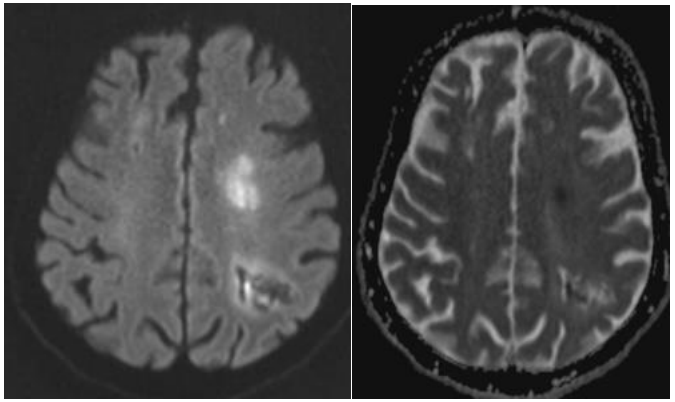
CAROTID PARADIGM REVASCULARIZATION

Case # **018**
(Krakow)

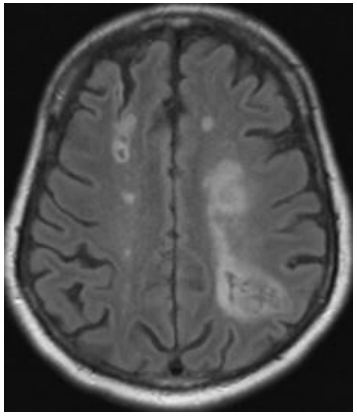
DW-MRI on admission

Fresh ischemic lesion in the L hemisphere
['haemodynamic' lesion, resulting from cross-flow ↓]
'old' ischemic lesion in te R hemisphere
(no diffusion limitation in the R)

DWI



Flair



ADC = proof of diffusion absence in the DWI focus

M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow

How would YOU treat?

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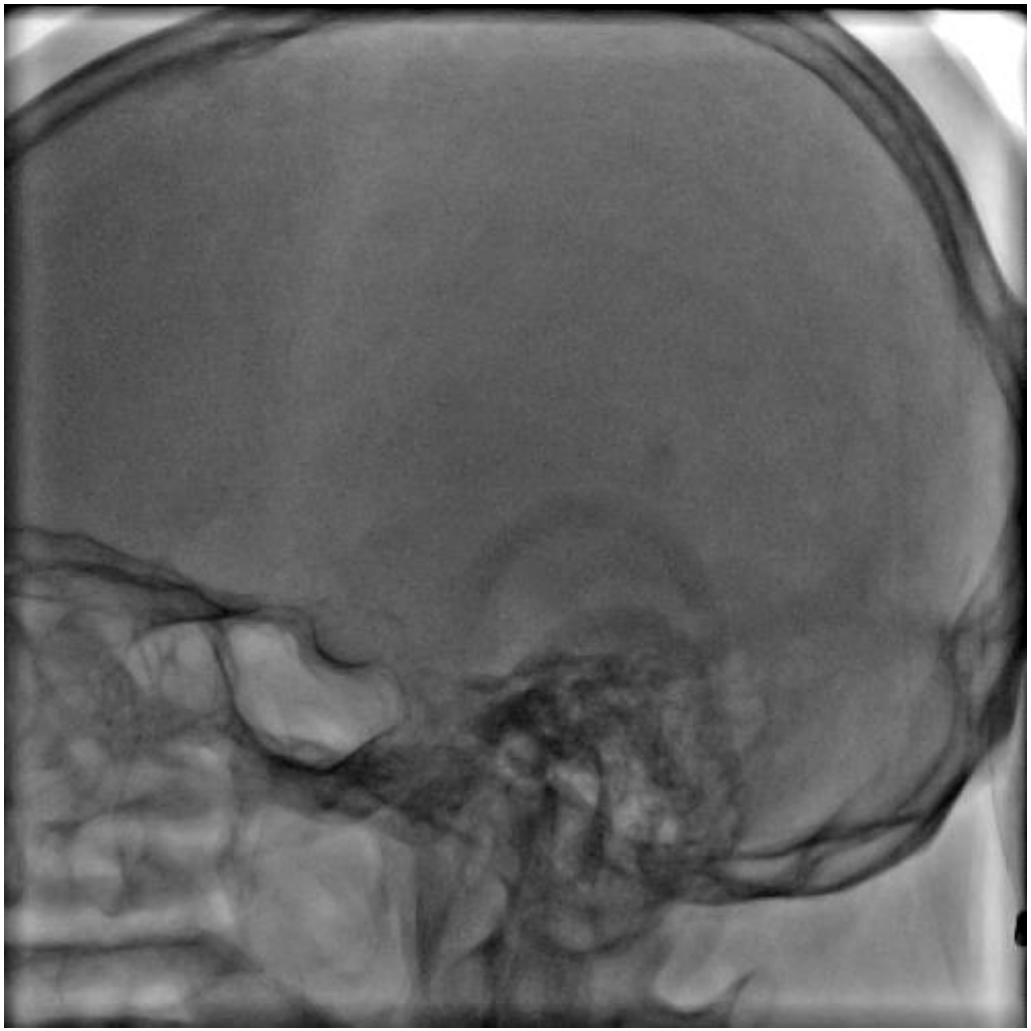
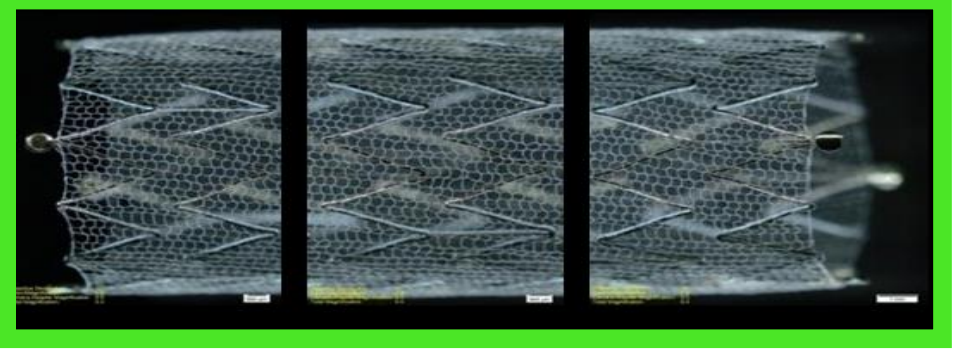


acutely symptomatic / thrombus-containing

CAROTID PARADIGM REVASCULARIZATION



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The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPHIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD‖

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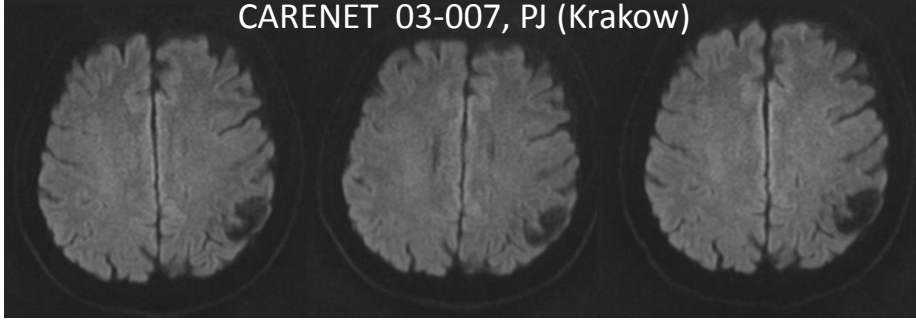

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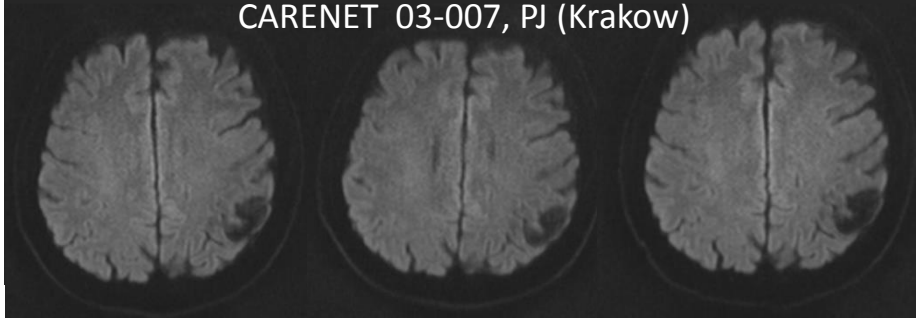

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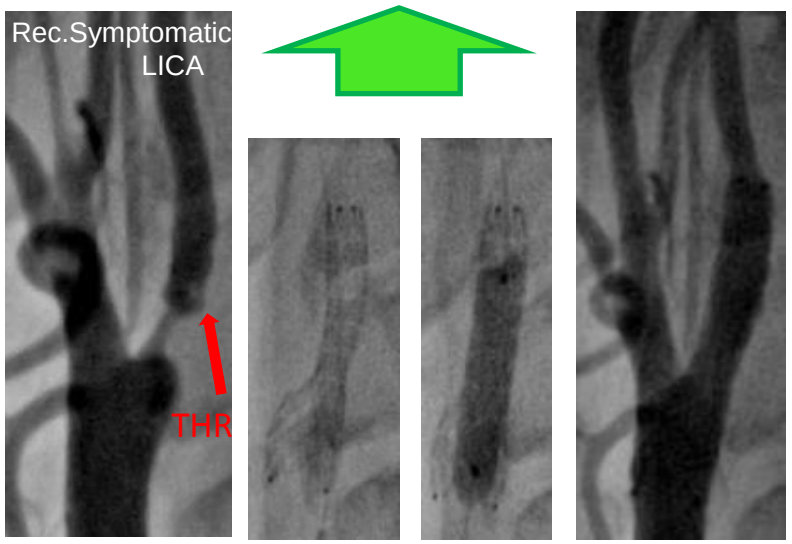

Note self-tapering

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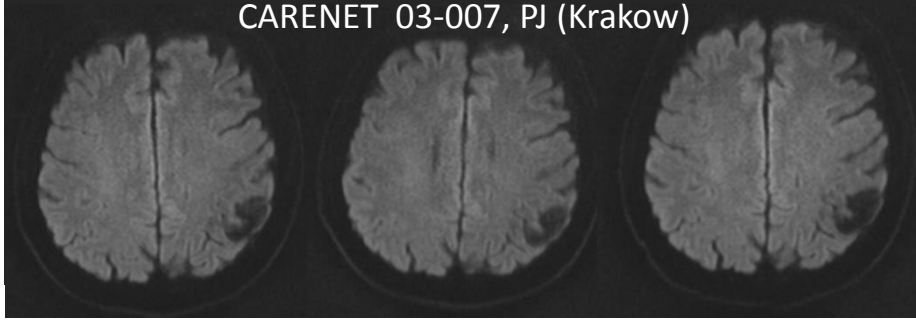
PARADIGM & PARADIGM-EXTEND STUDIES



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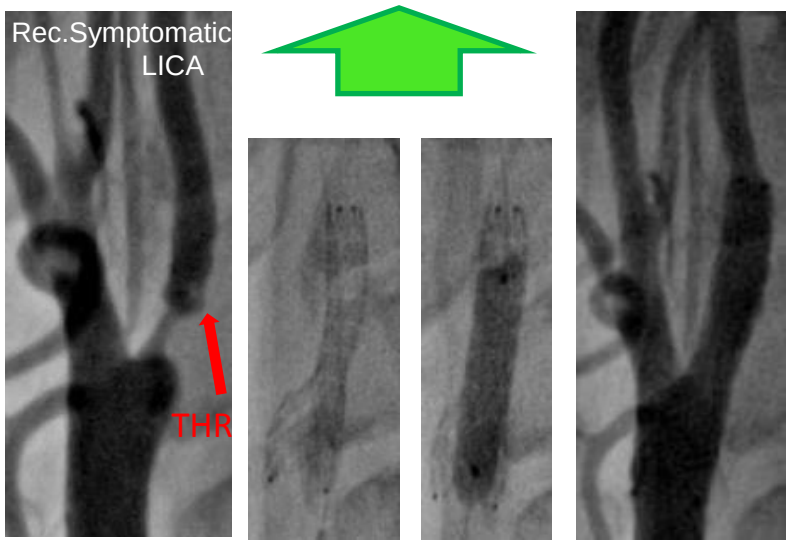

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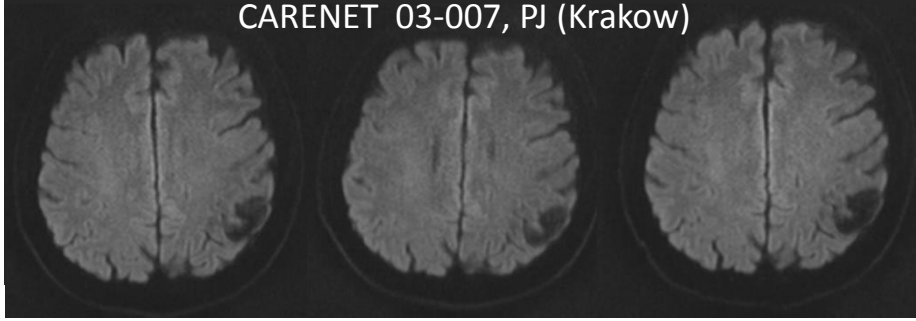

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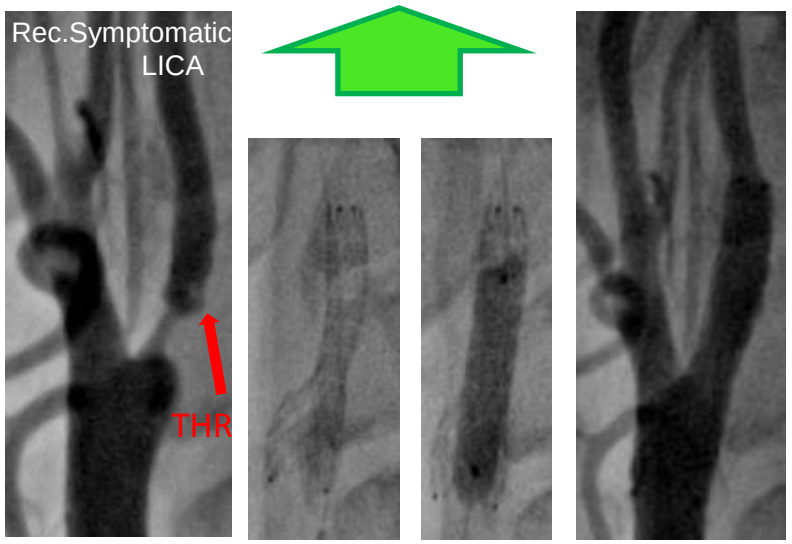

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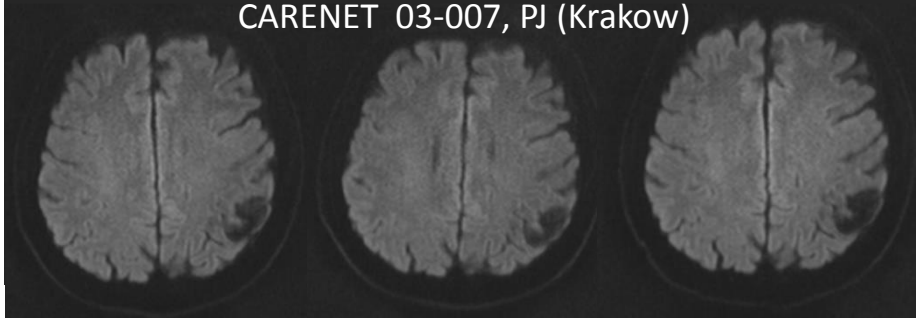

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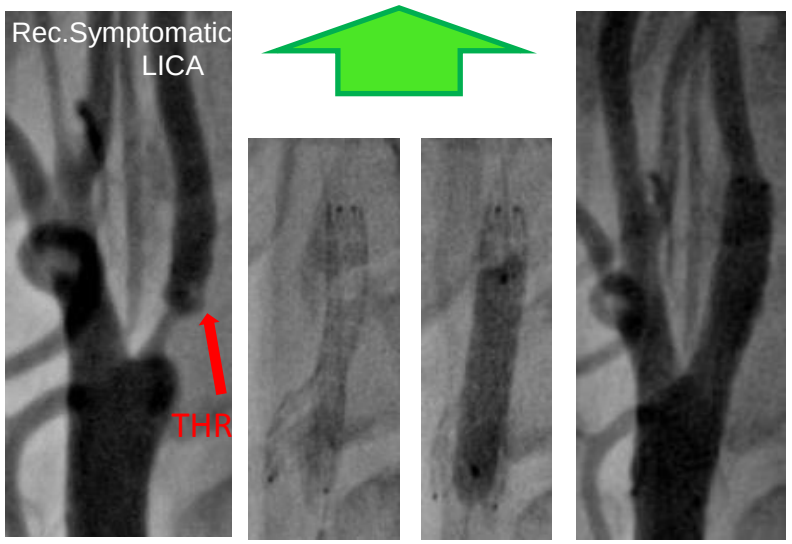

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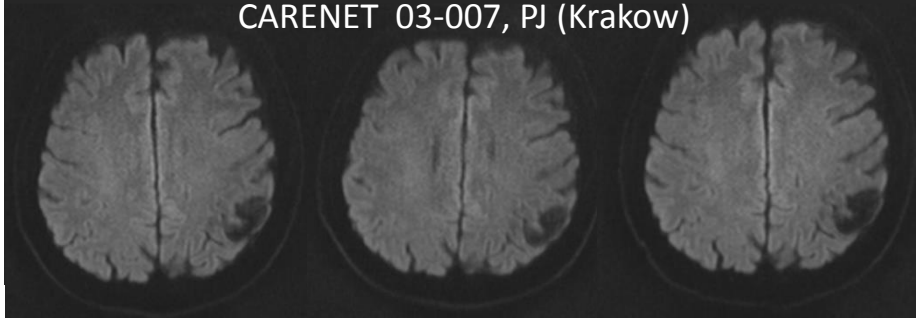

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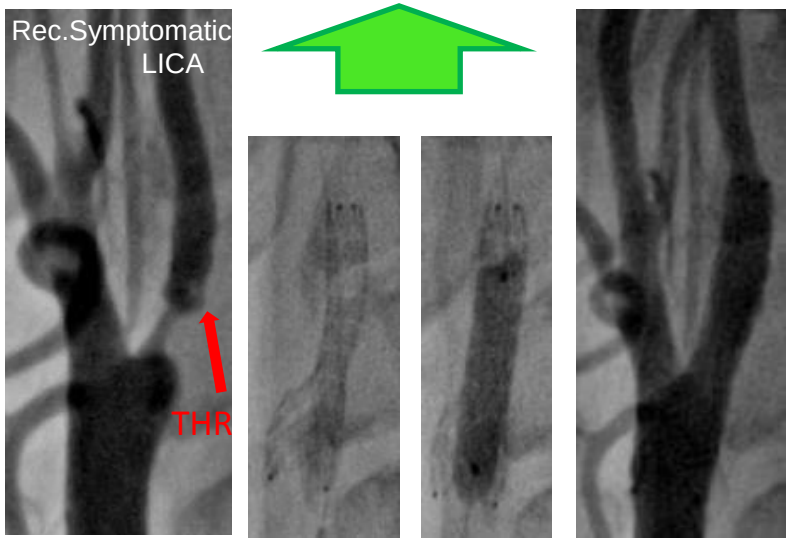

PARADIGM & PARADIGM-EXTEND

ROUTINE CLINICAL PRACTICE 2016+

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P. Musialek @ LINC 2016

LEIPZIG INTERVENTIONAL COURSE

LINC 2016

ROUTINE CLINICAL PRACTICE 2016+


P. Musiałek WCCI 2018

CAS (and CEA) are –and will remain– emboli-generating procedures

Effect of the Distal-Balloon Protection System on Microembolization During Carotid Stenting

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD

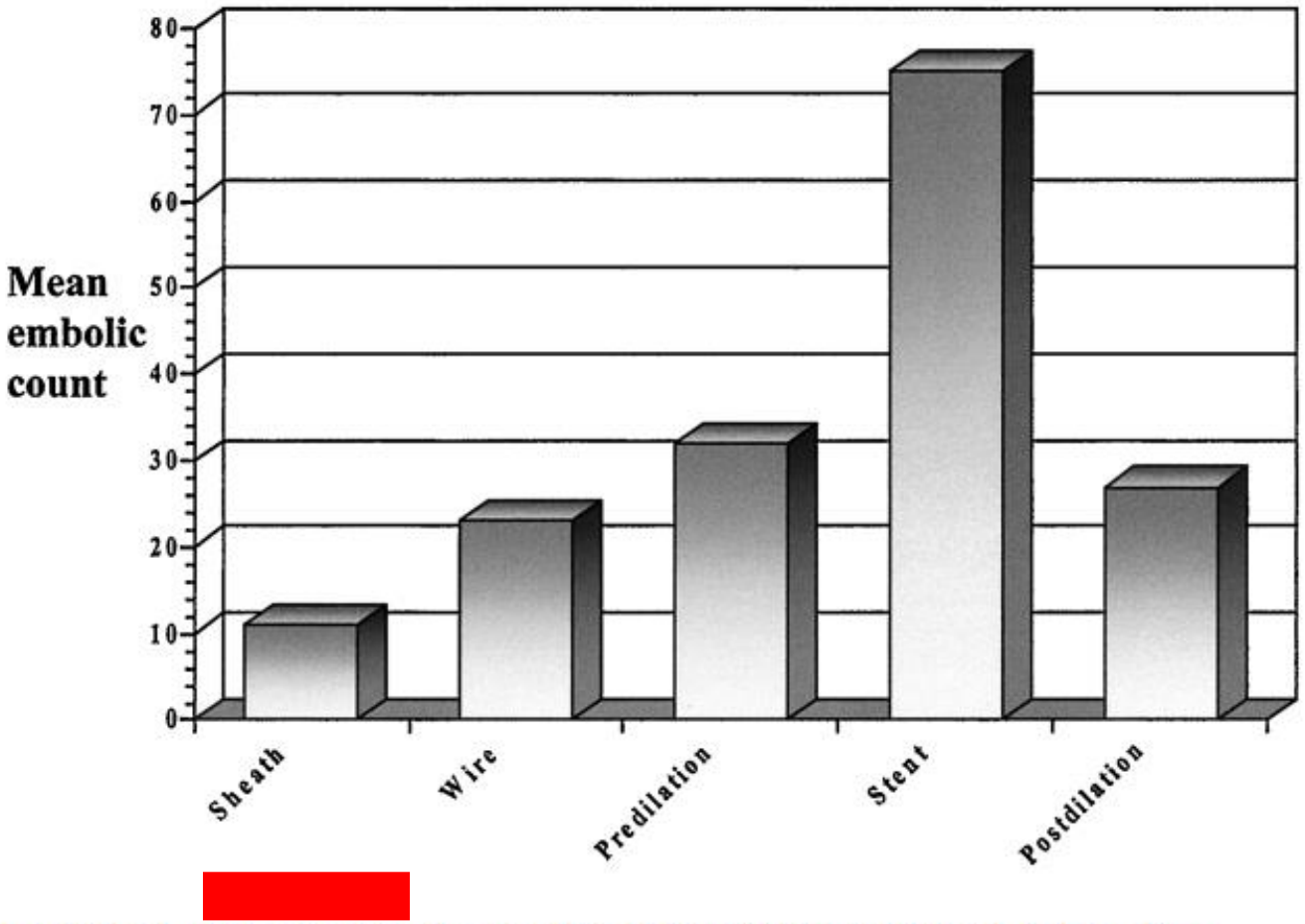

Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

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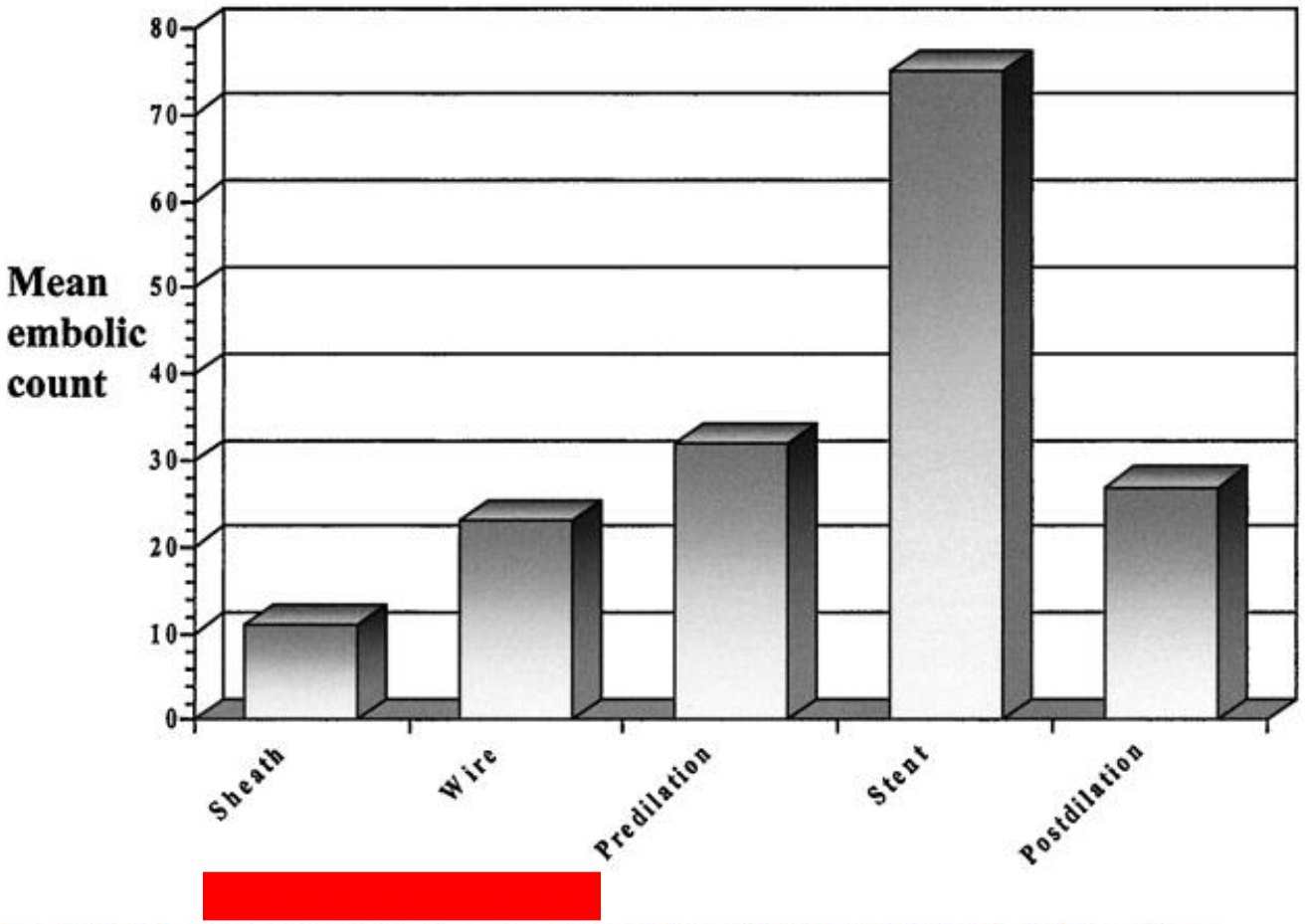

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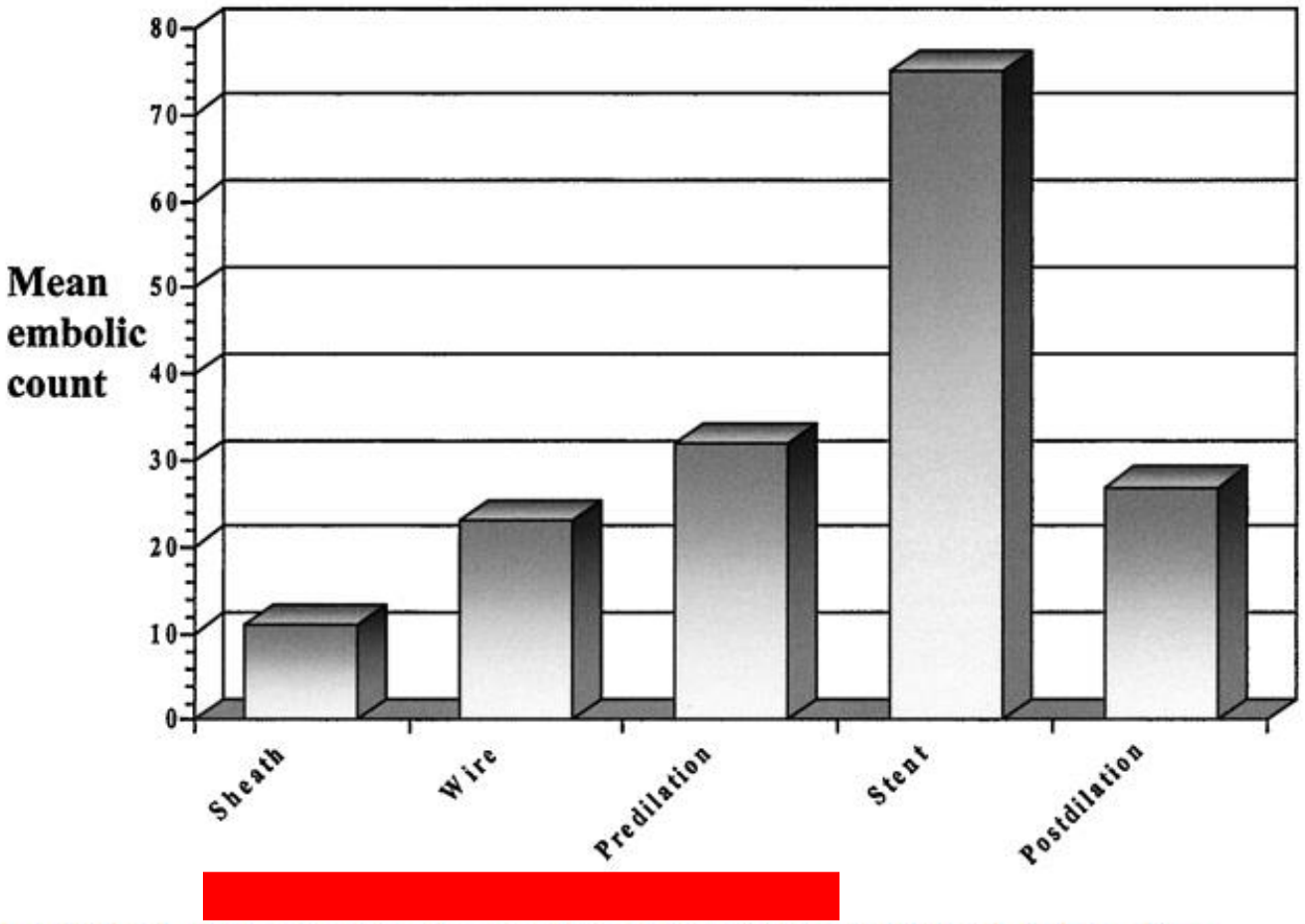

Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

CAS (and CEA) are –and will remain– emboli-generating procedures

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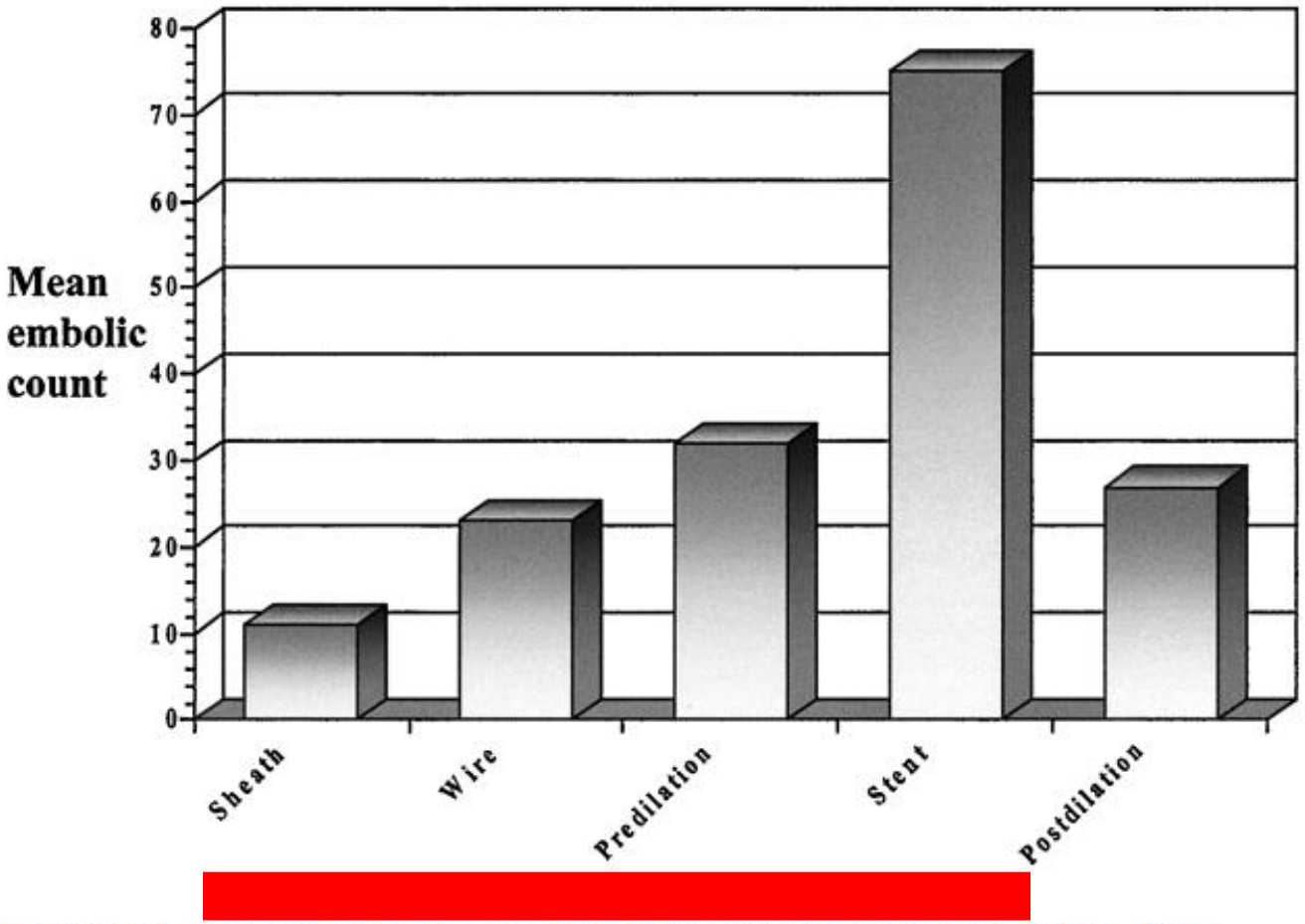

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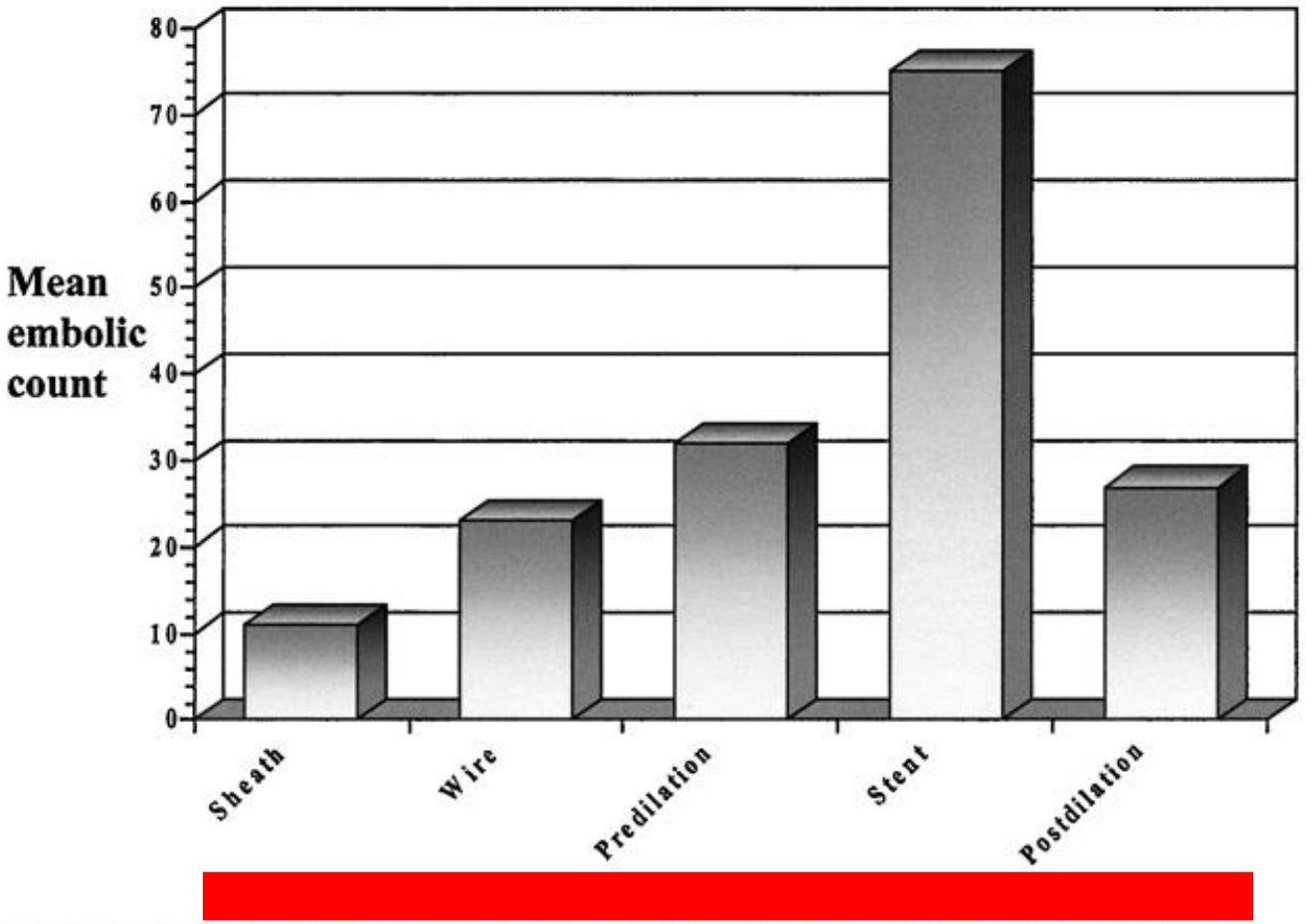

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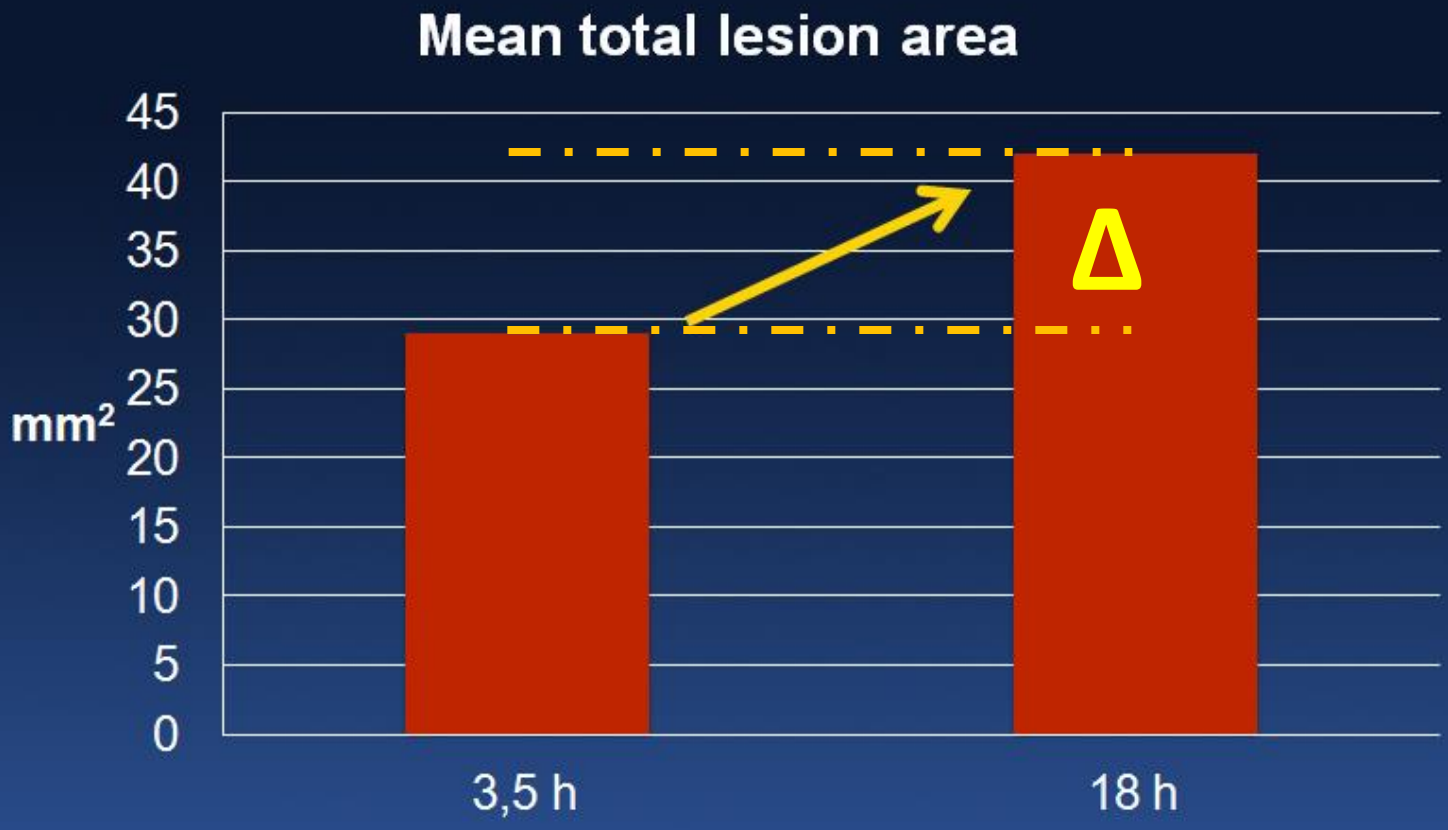
Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS



Schofer J et al, JACC Cardiovasc interv 2008

Does Free Cell Area Influence the Outcome in Carotid Artery Stenting?

M. Bosiers,[1*] G. de Donato,[2] K. Deloose,[1] J. Verbist,[3] P. Peeters,[3]
F. Castriota,[4] A. Cremonesi[4] and C. Setacci[4]

Overview of event rates related to the different stents n = 3179 consecutive CAS patients

	Total population			Symptomatic population			Asymptomatic population		
	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events
Stent name									
X-act		1.9%	1.9%		2.2%	2.2%		1.7%	1.7%
Nexstent		3.3%	3.3%		0.0%	0.0%		4.2%	4.2%
Wallstent		2.3%	1.2%		2.3%	1.2%		2.3%	1.2%
Precise		4.1%	3.1%		6.3%	4.9%		2.0%	1.3%
Protégé		3.0%	3.0%		6.7%	6.7%		1.4%	1.4%
Acculink		4.2%	3.7%		7.7%	7.1%		1.7%	1.2%
Exponent		11.8%	5.9%		9.1%	9.1%		13.0%	4.3%
Total	3179	2.83%	1.9%		3.6%	2.73%	1862	2.25%	1.3%

2/3

CAS neuro events (stroke, TIA) are POST-procedural

Eur J Vasc Endovasc Surg Vol 33, February 2007

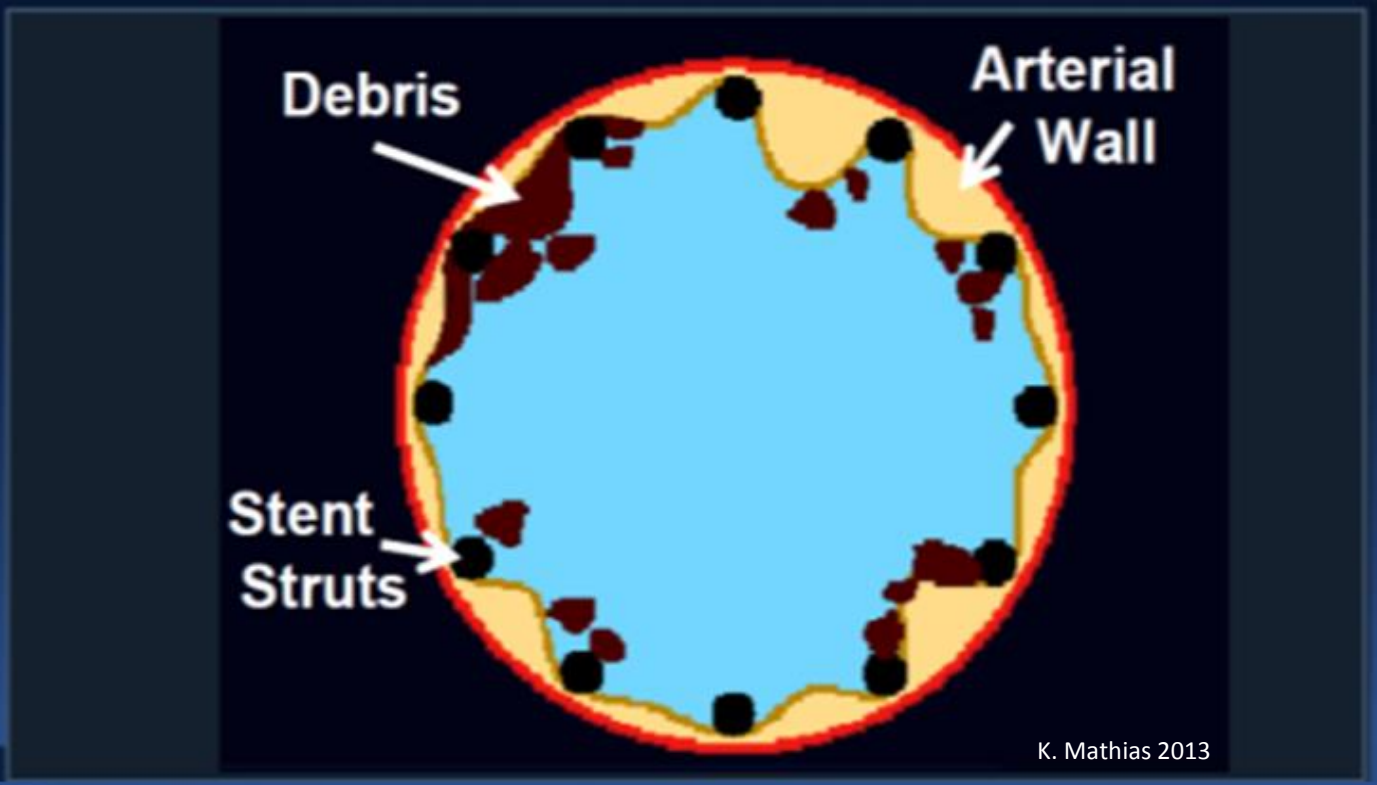
FREE CELL AREA drives CAS neurologic adverse events (and majority occur *post-procedure*)

Free cell area	Total population		Symptomatic population	
	All events	Post-procedural events	All events	Post-procedural events
<2.5 vs [2.5, 5]	1.00	1.00	1.00	1.00
<2.5 vs [5, 7.5]	0.054	0.072	0.048	0.024
<2.5 vs >7.5	0.27	0.006	0.0006	$2.8\ 10^{-6}$

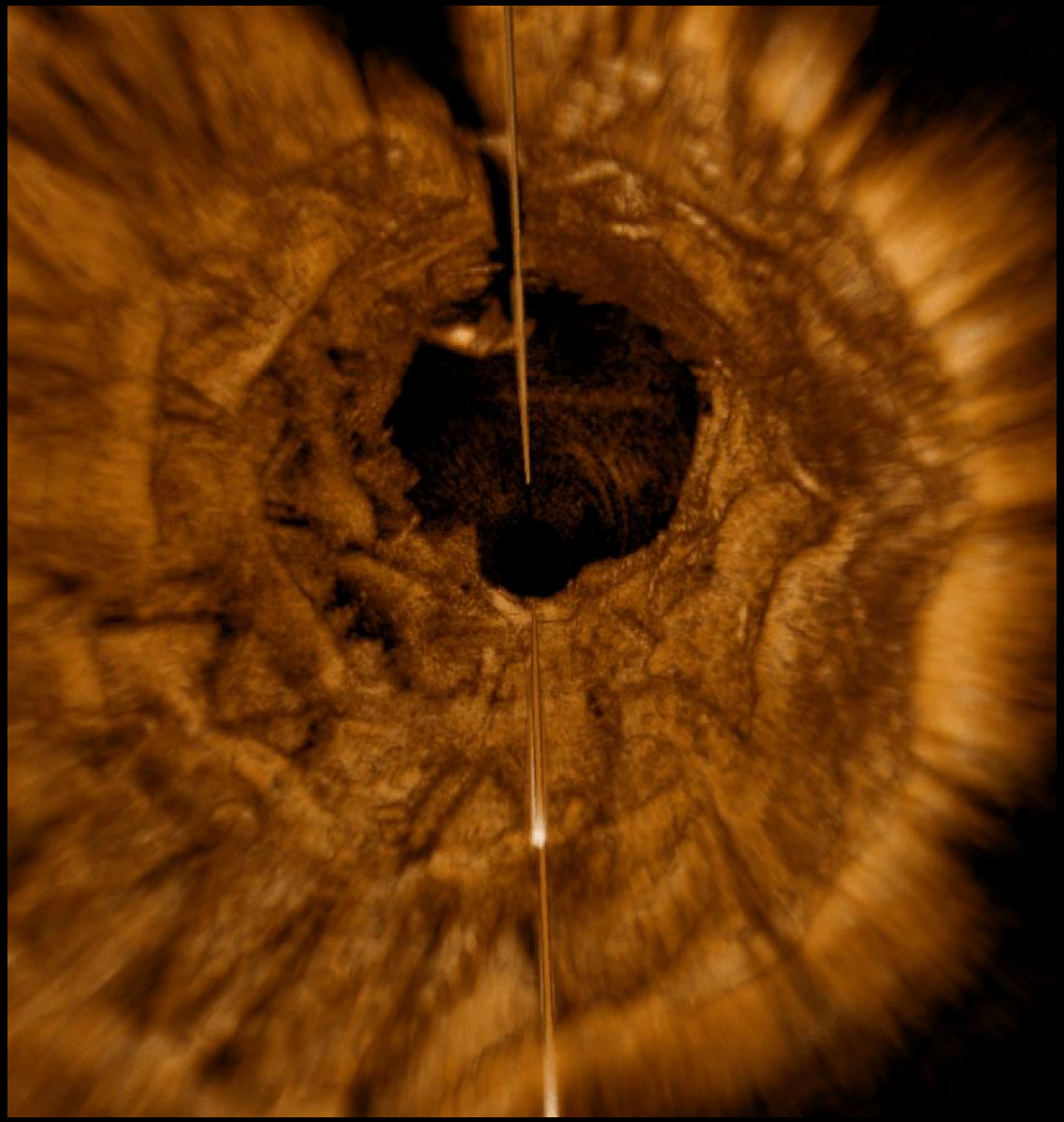
Eur J Vasc Endovasc Surg Vol 33, February 2007

Conventional Carotid Stent

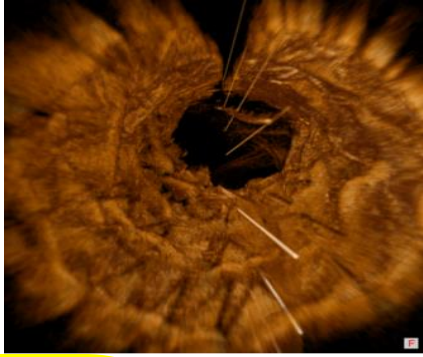
Plaque protrusion may lead to early and late distal embolization



Conventional Carotid Stent



Human Carotid OCT Image Courtesy Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, Univerity of Barcelona



ANY data

on the incidence of

PLAQUE PROLAPSE

in

conventional carotid stents ?

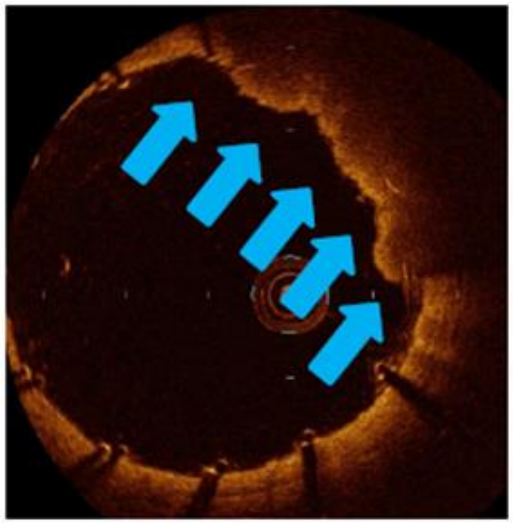
Post-procedural **PLAQUE PROLAPSE** through **conventional stent** struts

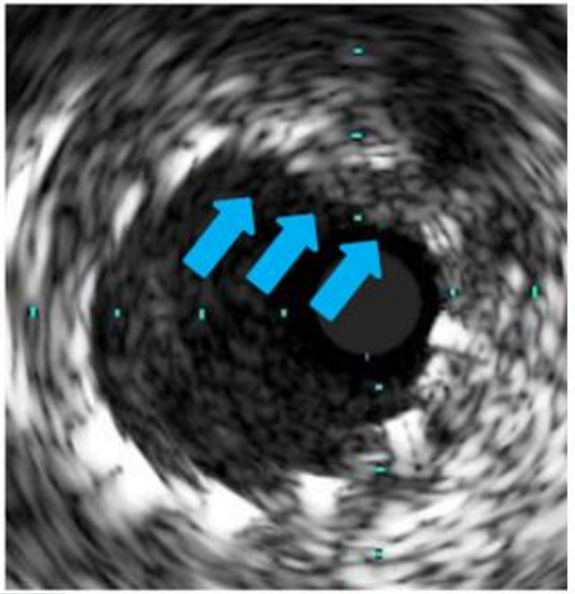
Suzuki M et al.
ESC 2014
Presentation
www.escardio.org

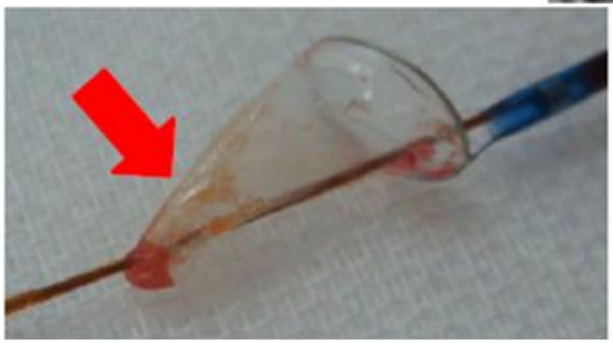
30.7%

1/3 stents = **Precise**
2/3 stents = **Carotid Wallstent**

81 y.o. Female, Symptomatic



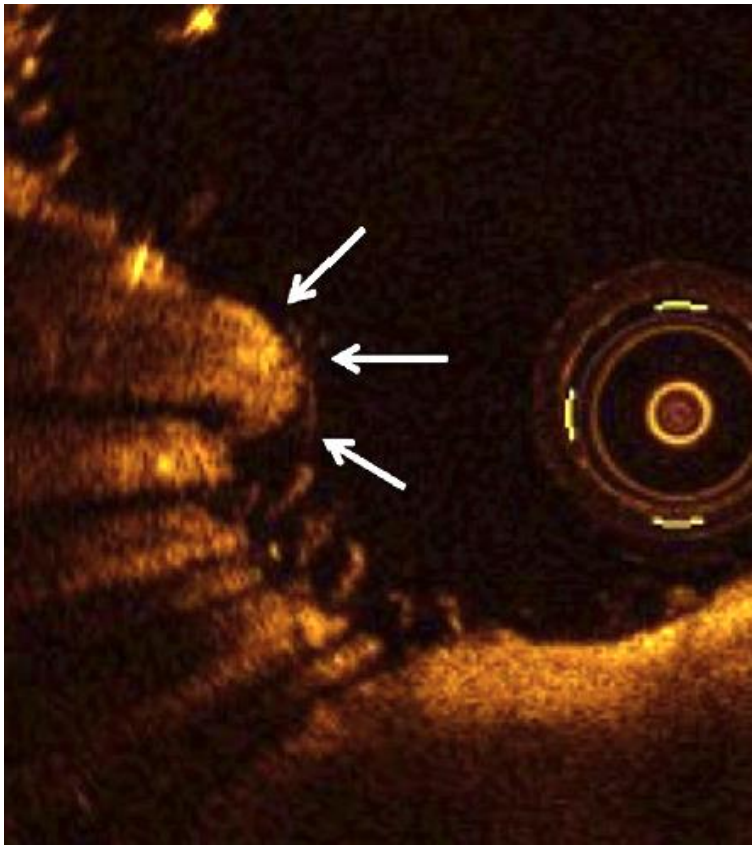




Images: Dr M. Suzuki
ESC 2014
www.escardio.org

Eur Heart J. 2014;35(Abstr Suppl):178

Post-procedural PLAQUE PROLAPSE through conventional stent struts

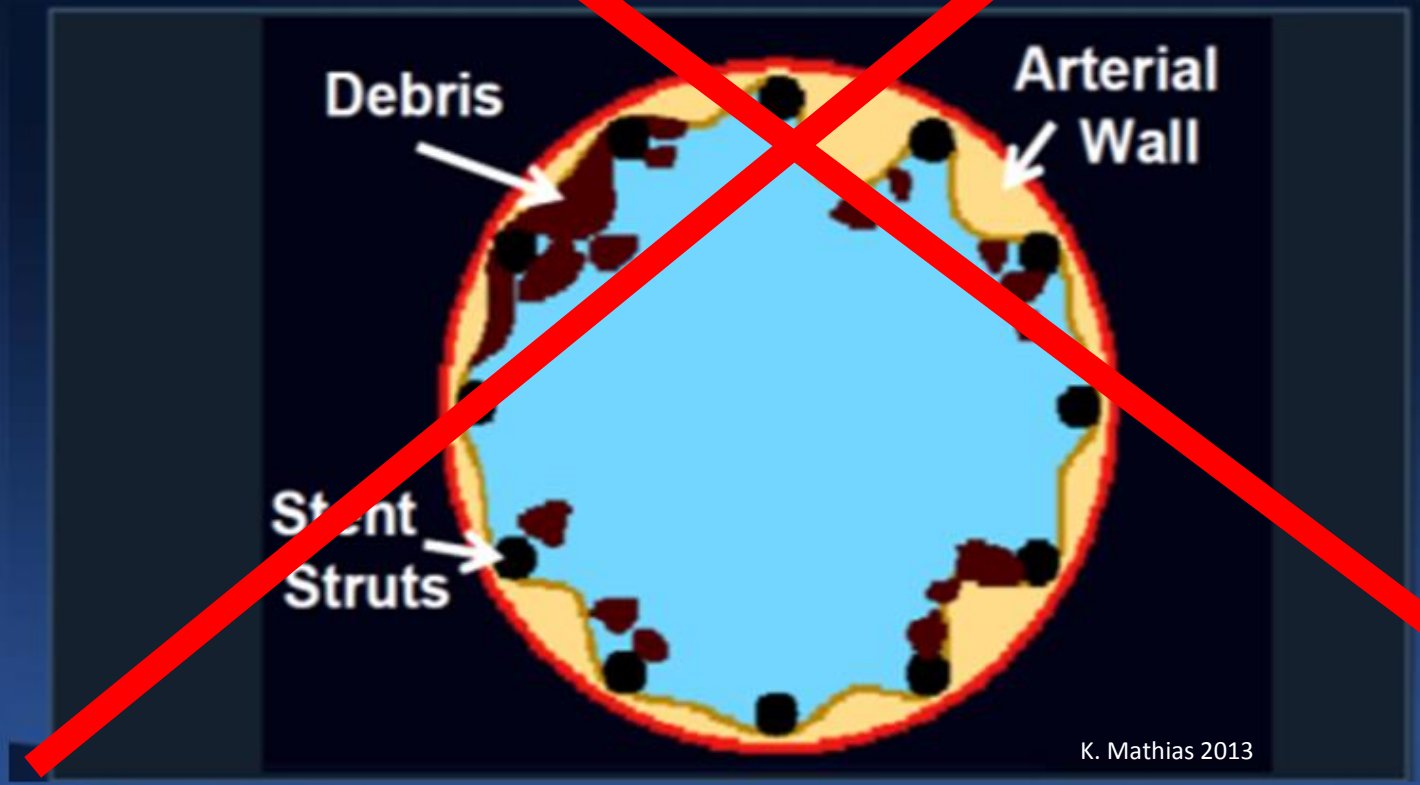


	Closed cell ($n = 17$)	Open cell ($n = 13$)	Hybrid cell ($n = 10$)
Plaque prolapse[b]	17.6%, (3)	61.5%, (8)	30%, (3)

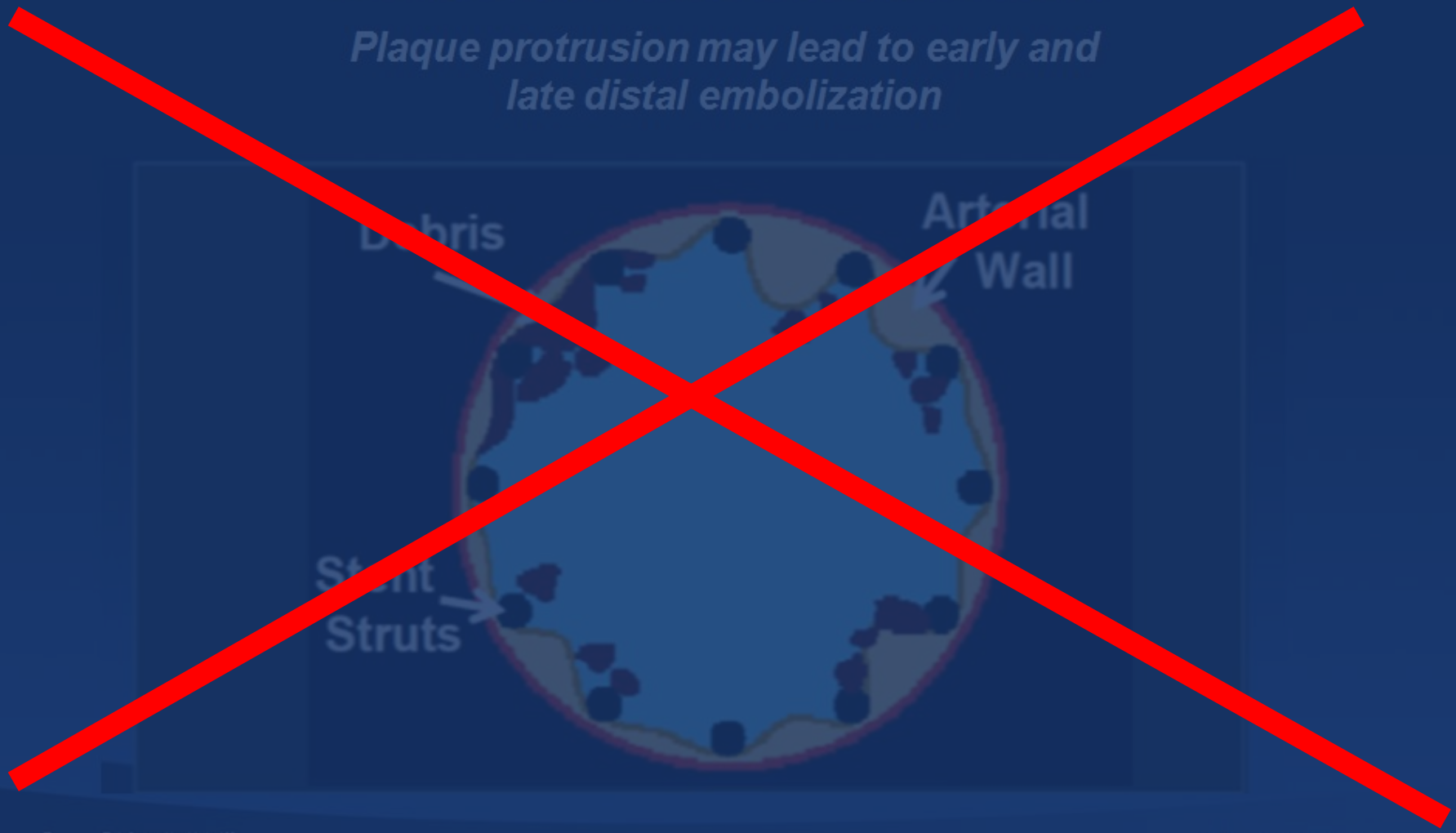
[b] At least 10 appreciable tissue prolapses between the stent struts per patient.

De Donato et al. Eur J Vasc Endovasc Surg 2013;45:579-587.

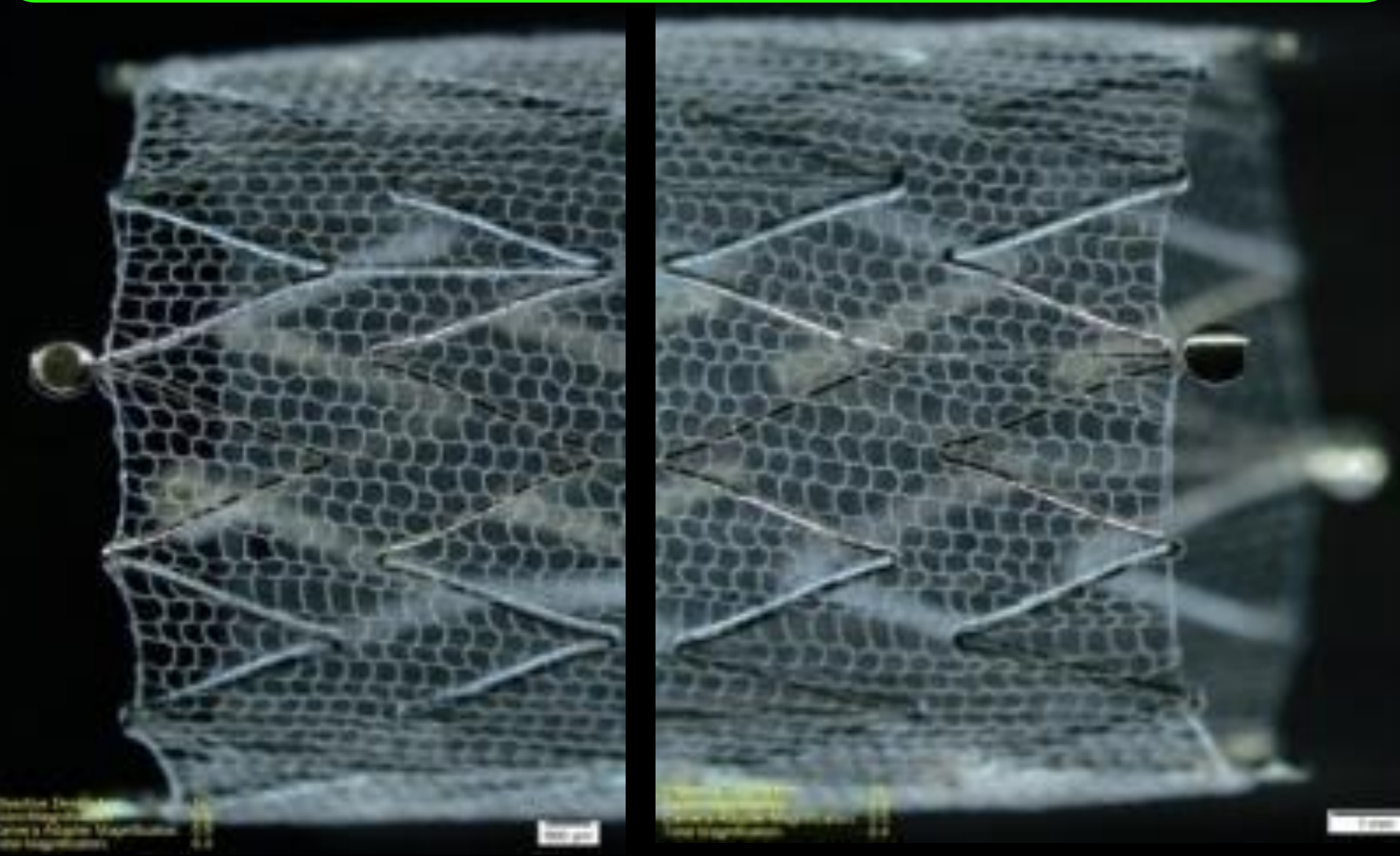
Conventional Carotid Stent



Anti - Embolic Carotid Stent



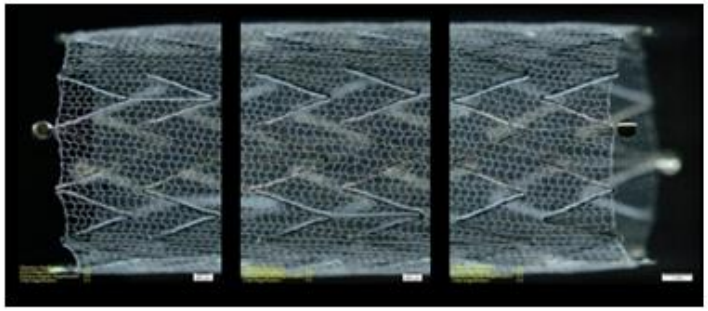
CGuard™ embolic prevention system



CGuard™– Carotid Embolic Prevention System

System specifications	
Stent type	Nitinol – self expanding
Micronet aperture size	150-180 µm
Guidewire	0.014”
Sizes - Diameter - Length	 6-10mm 20-60mm

CE Mark – March 2014



Specific, carotid-dedicated design √

NB. CGuard™ EPS is not yet available in the US

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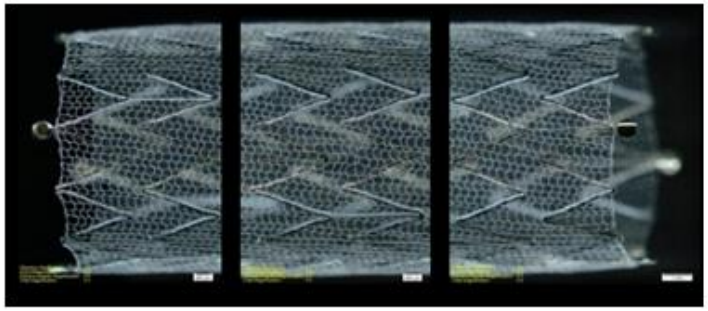

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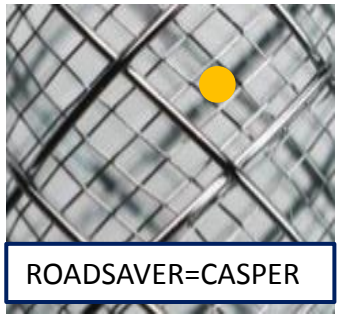
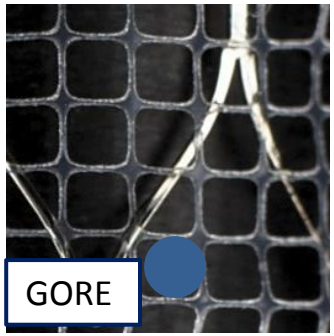
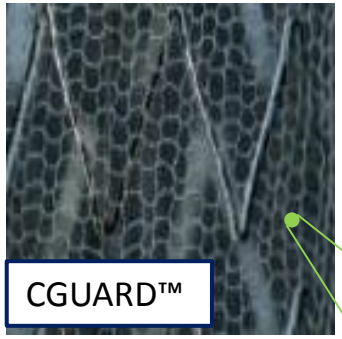
Pore Size



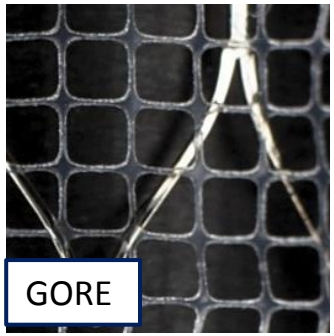


* 150–180µm



CGUARD™

ROADSAVER=CASPER



GORE

165µm*

375µm

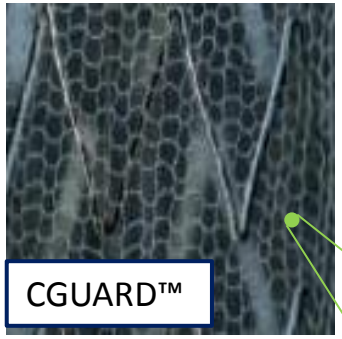
500 µm

1050µm
Closed cell stent

1900µm
Open cell stent

* 150–180µm

P. Musialek @ LINC 2016



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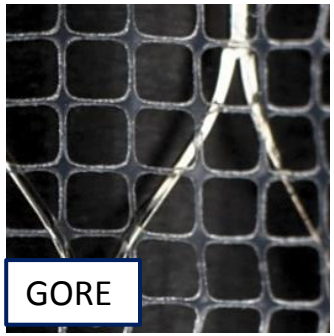

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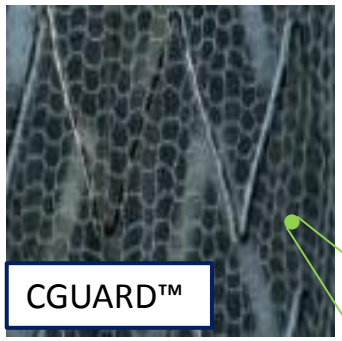

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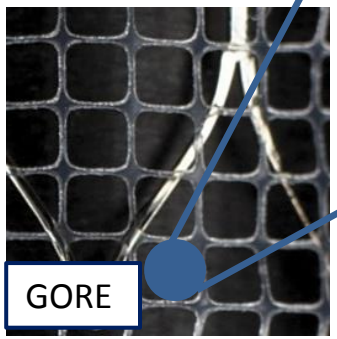

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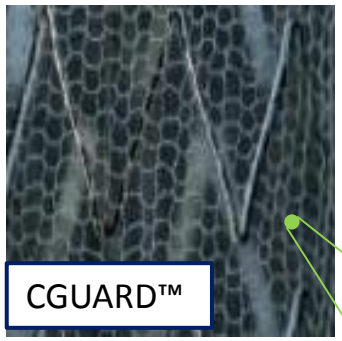

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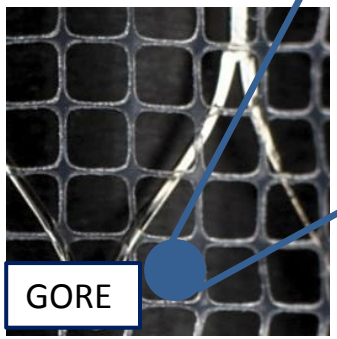

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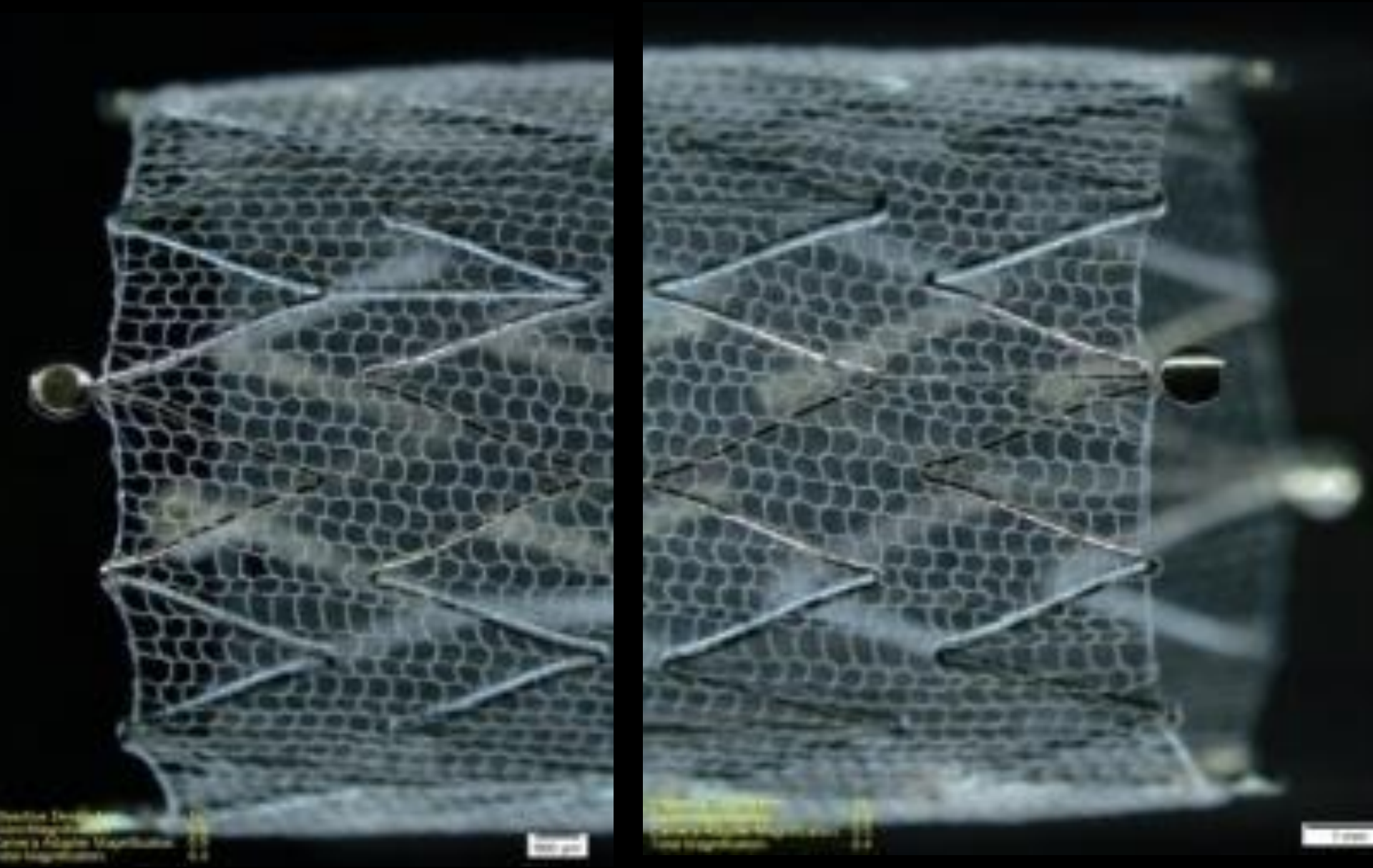
CGuard ™ embolic prevention stent



CARENET – Study Design

Prospective, multi-center, all-comer

Objectives:

To evaluate the periprocedural safety and efficacy of the CGuard stent in the treatment of carotid lesions in thirty consecutive patients with symptomatic and asymptomatic carotid artery stenosis, suitable for CAS

Sites:

- *Joachim Schofer (PI),* Hamburg University Cardiovascular Center
- *Piotr Musialek (Co-PI),* Jagiellonian University Medical College
- *Ralf Kolvenbach,* Augusta Hospital
- *Horst Sievert,* Cardiovascular Center Frankfurt

Endpoints:

- Acute /30-day **Cerebral Embolization by DWI** (incidence, volume)
- 30 day **MACCE** (death, stroke, MI)

J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34

Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease

The CARENET-Trial

(CARotid Embolic protection using microNET)

30 d data

Joachim Schofer (PI)
Piotr Musialek (Co-PI)
On behalf of the CARENET Investigators

Joachim Schofer, MD,PhD, Hamburg University CardiovascularCenter, Hamburg Germany
Piotr Musialek, MD, PhD, Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland,
Ralf Kolvenbach, MD, PhD, Augusta Hospital, Dusseldorf, Germany,
Horst Sievert, MD, PhD, Cardiovascular Center Frankfurt, Frankfurt, Germany

tct2014 In Partnership with the ACC

Columbia University Medical Center
NewYork-Presbyterian

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http://dx.doi.org/10.1016/j.jcin.2015.04.016

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPHIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD‖

ABSTRACT

OBJECTIVES This study sought to evaluate the feasibility of the CGuard Carotid Embolic Protective Stent system—a novel thin strut nitinol stent combined with a polyethylene terephthalate mesh covering designed to prevent embolic events from the target lesion in the treatment of carotid artery lesions in consecutive patients suitable for carotid artery stenting.

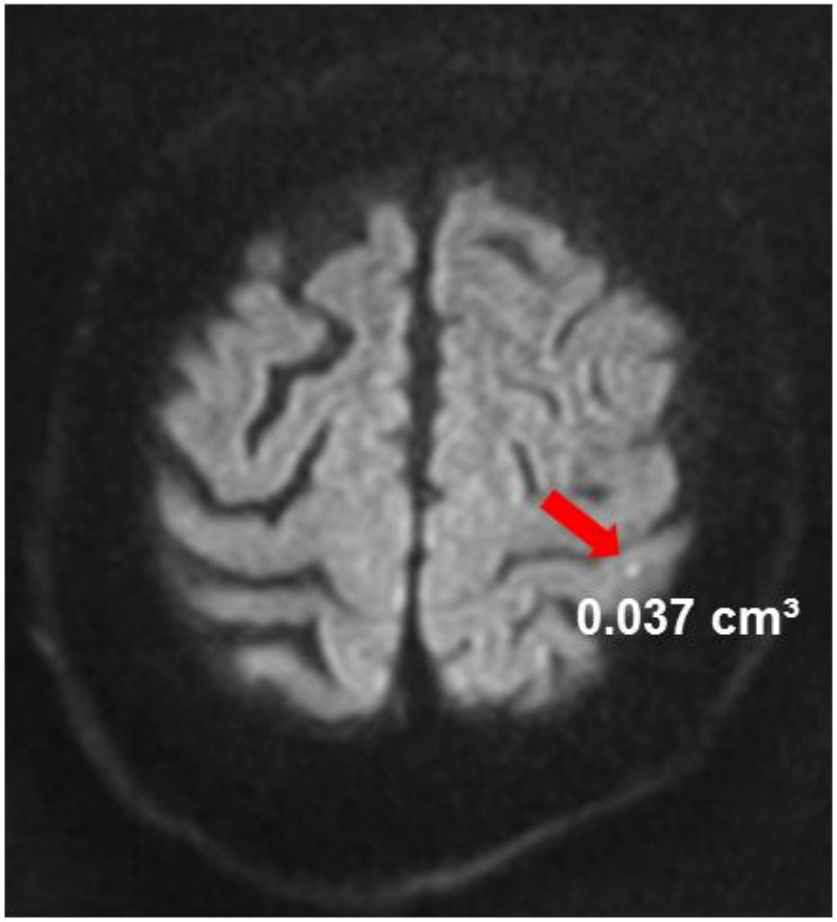
BACKGROUND The risk of cerebral embolization persists throughout the carotid artery stenting procedure and remains during the stent healing period.

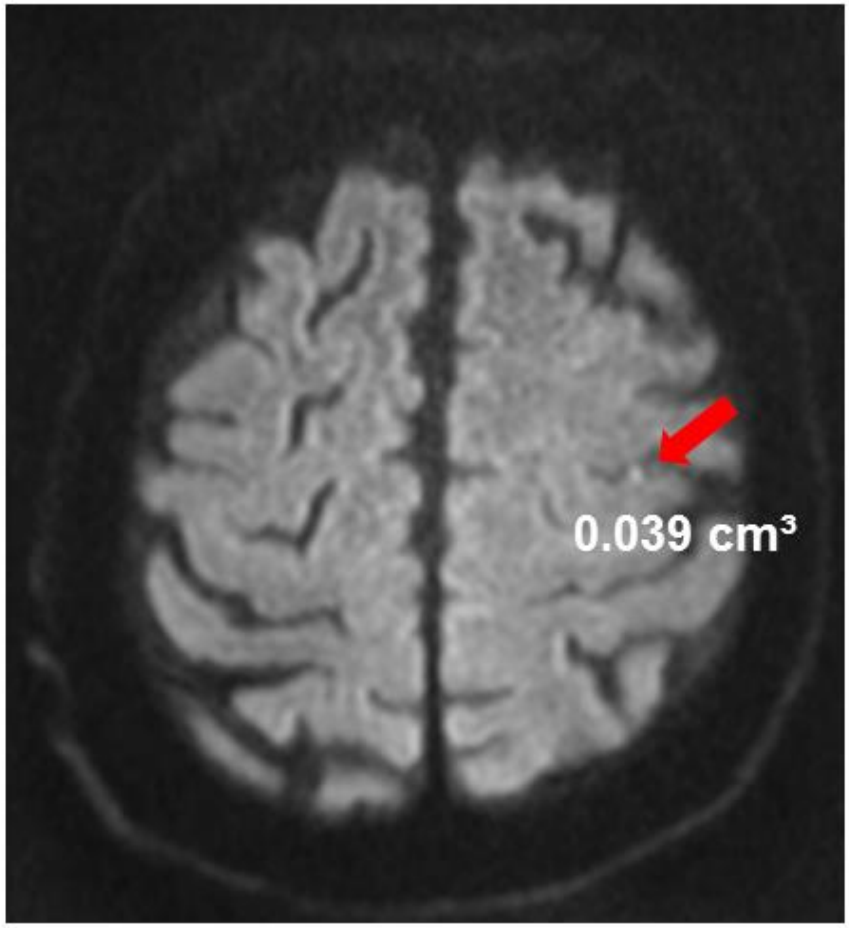
METHODS A total of 30 consecutive patients (age 71.6 ± 7.6 years, 63% male) meeting the conventional carotid artery stenting inclusion criteria were enrolled in 4 centers in Germany and Poland.

DW-MRI:

the unforgiving testimony of what you've done to the TARGET ORGAN...

The Power of DW-MRI...





48h after LICA-CAS

M. Urbanczyk, P. Banys, Dept. Radiology, JP2 Hospital, Krakow, Poland

CARENET DW-MRI analysis*

DW-MRI analysis @ 48 h	
	CARENET (n=27)
Incidence of new ipsilateral lesions	**37.0%**
Average lesion volume (cm^3)	0.039 ± 0.08
Maximum lesion volume (cm^3)	0.445

see patient fluxogram

***External Core Lab analysis (US)**

Bijuklic et al. *JACC*, 2012; Bonati et. al, *Lancet Neurol* 2010

† bilateral lesions

J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34

CARENET DW-MRI analysis*

DW-MRI analysis @ 48 hours			
	CARENET (n=27)	**PROFI (all)** (n=62)	**ICSS†** (n=56)
Incidence of new ipsilateral lesions	**37.0%**	**66.2%**	68.0%
Average lesion volume (cm^3)	0.039 ± 0.08	.375	-
Maximum lesion volume (cm^3)	0.445		

≈50% reduction

in new ipsilateral lesion **incidence**

see patient fluxogram

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† bilateral lesions

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Incidence of new ipsilateral lesions	37.0%	66.2%	68.0%
Average lesion volume (cm^3)	**0.039**	**0.375**	-
Maximum lesion volume (cm^3)	0.4[illegible]5		

>10-fold reduction

in cerebral lesion **volume**

see patient fluxogram

***External Core Lab analysis (US)**

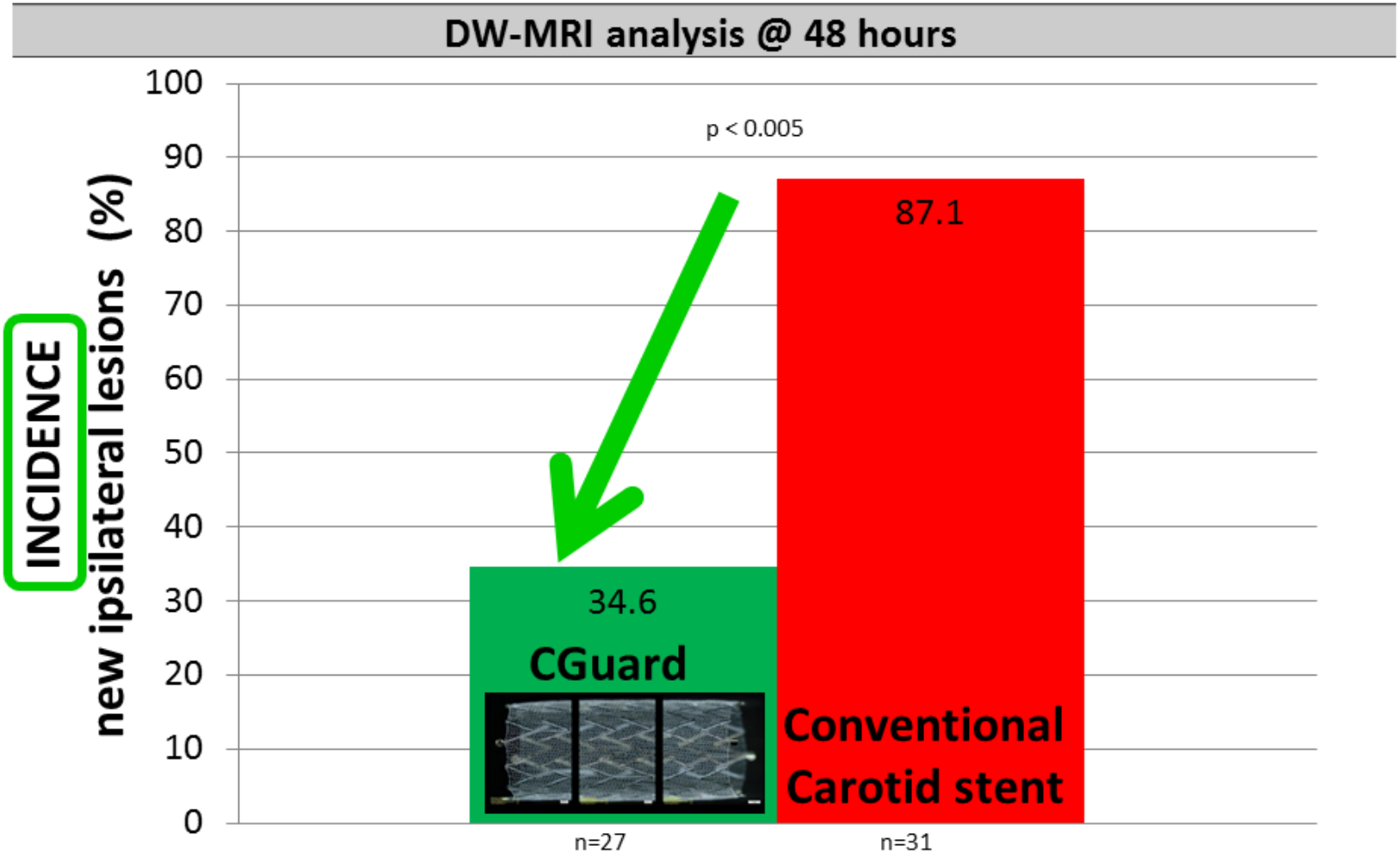
Bijuklic et al. *JACC*, 2012; Bonati et. al, *Lancet Neurol* 2010

† bilateral lesions

J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

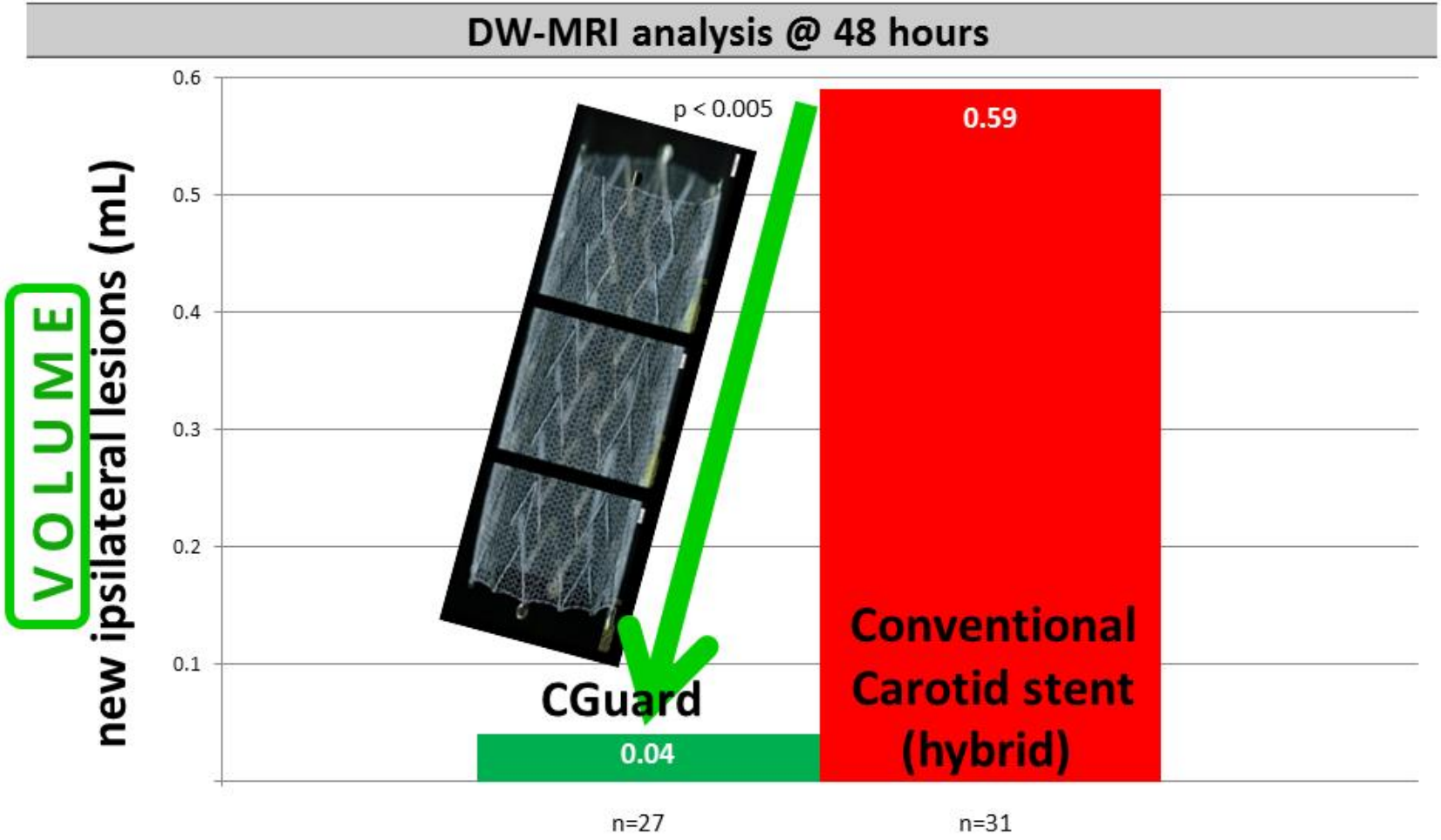


* see patient fluxogram
Bijuklic et al. *JACC*, 2012;59

J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34
Bijuklic et al. (manuscript in preparation)

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis



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J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34
Bijuklic et al. (manuscript in preparation)

CARENET DW-MRI analysis*

All but one peri-procedural ipsilateral lesions

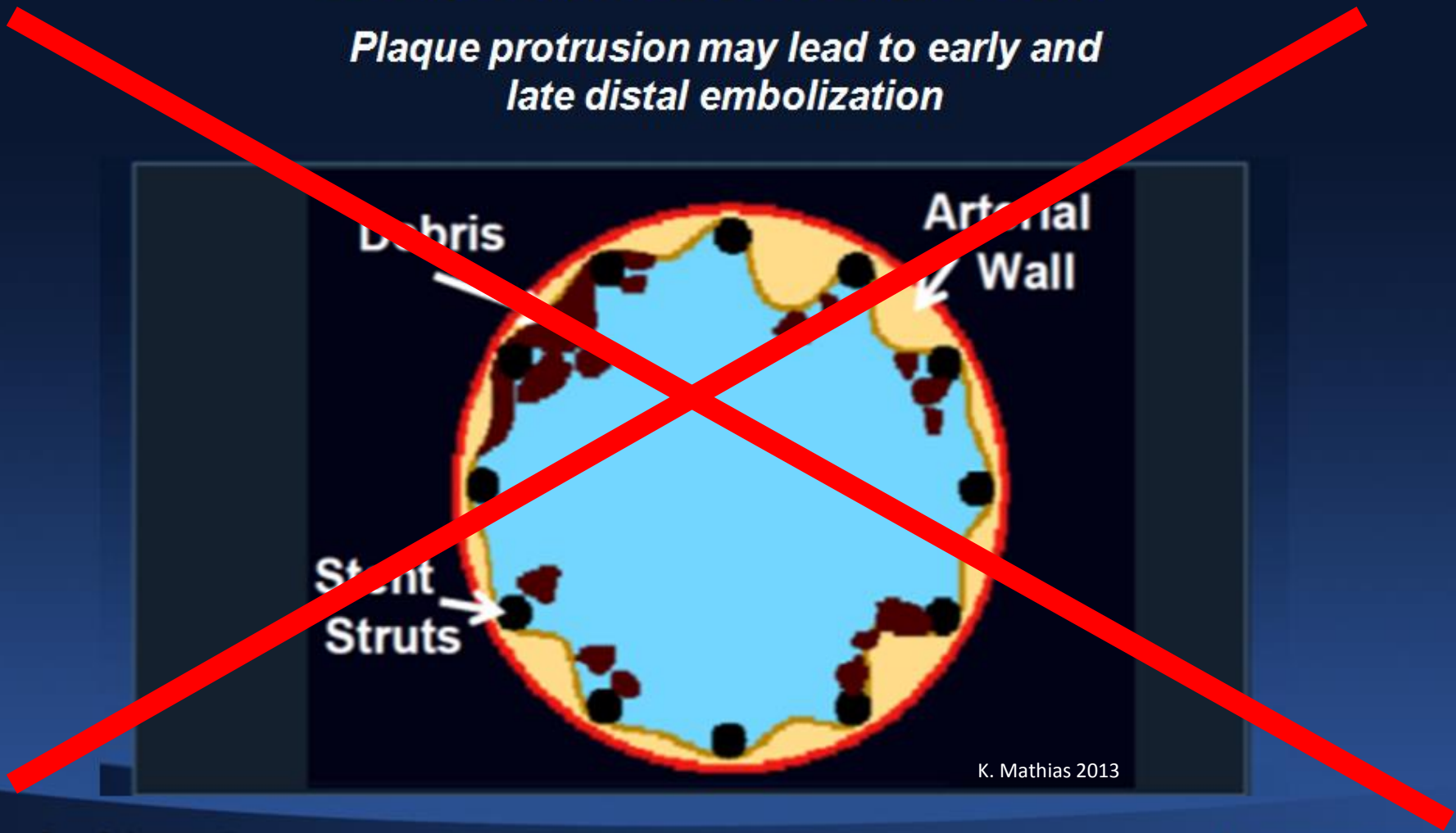
RESOLVED

DW-MRI analysis @ 30 days*	
Incidence of new ipsilateral lesions	1
Average lesion volume (cm^3)	0.08 ± 0.00
Permanent lesions at 30 days	1

***External Core Lab analysis (US)**

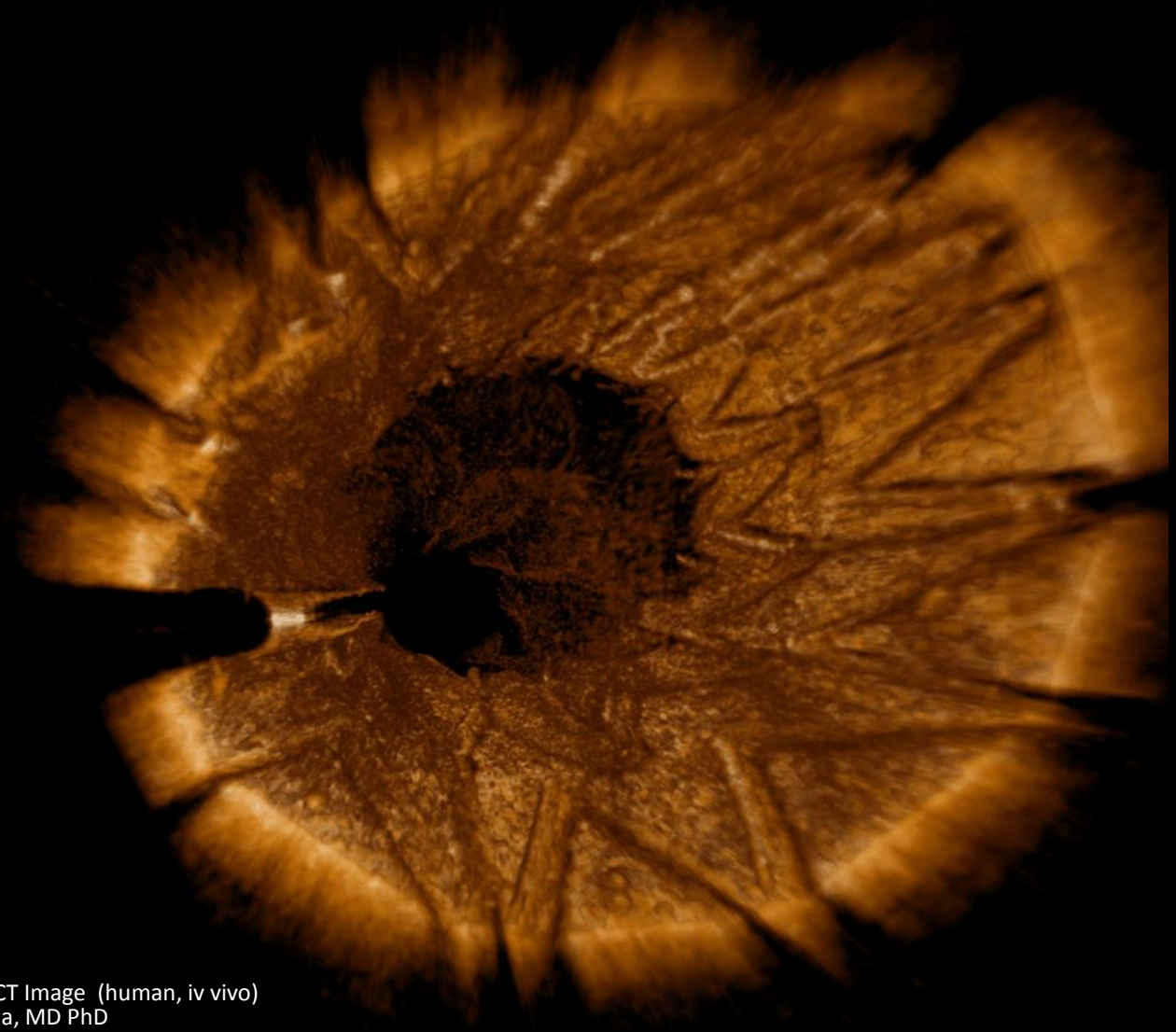
J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34

Anti - Embolic Carotid Stent



J. Schofer, P. Musialek et al. TCT 2014

Anti - Embolic Carotid Stent



CGuard Embolic-Prevention Stent OCT Image (human, iv vivo)
Courtesy Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, Univerity of Barcelona

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A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

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RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was 0.039 ± 0.08 cm^3. The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm^3) lesion in relation to the 48-h scan.

CONCLUSIONS The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period. (J Am Coll Cardiol Intv 2015;8:1229–34)

Prospective evaluation of All-comer peR-cutaneous cArotiD revascularization In sympto-matic and increased risk asymptomatic carotid artery stenosis using CGuard™ Micronet covered embolic prevention stent system:

The PARADIGM Study

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

CAROTID PARADIGM REVASCULARIZATION

Objective

- to evaluate feasibility and outcome of routine **anti-embolic stent system** use in unselected, consecutive patients referred for carotid revascularization ('all-comer' study)

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

Methods: The CAS Procedure

- **EPD** use mandatory; EPD selection according to the **'Tailored CAS' algorithm***
- **Liberal postdilatation** accepted in order to maximize potential for '**endovascular full reconstruction**' (minimizing residual stenosis)

NB. 1. DWI evidence of effective MicroNet prevention against cerebral embolization (CARENET/PROFI)
2. Residual stenosis after CAS as independent predictor of in-stent restenosis

Van Laanen J et al. *J Cardiovasc Surg* 2008
Cosottini M et al. *Stroke Res* 2010
Musialek P et al. *J Endovasc Ther* 2010
Wasser K et al. *J Neurol* 2012

* Pieniazek P, Musialek P et al. *J Endovasc Ther* 2008;15:249-62.
Cremonesi A et al. *EuroInervention* 2009;5:589-98.
Pieniazek P, Musialek P et al. *J Endovasc Ther* 2009;16:744-51.

PARADIGM

Endpoints:

- **feasibility of endovascular Tx in unselected referrals using the study device in otherwise routine practice**

- **device success** (able to deliver + implant + <30% DS)

- **procedure success** (device success w/o clinical compl.)
  (external neurologist, external non-invasive cardiologist)

- **clinical efficacy: MACNE** (death/stroke/MI) — **- 24-48h**
- **in-stent velocities** (Duplex) — **- 30 days**, **- 12 months**, **- up to 5y**

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

PARADIGM

- **ASYMPTOMATIC patients treated interventionally only if at ↗ stroke risk**
- **established lesion-level increased-risk crieria used:**
  - **thrombus-containing**
  - **tight, near-occlusive**
  - **documented progressive**
  - **irregular and/or ulcerated**
  - **contralteral 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.

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

Methods (cont'd)

PARADIGM: investigator – independent

- external study data verification
- external angiographic analysis
- external statistical analysis

KCRI
Krakow Cardiovascular Research Institute

Core Imaging Analysis Laboratory
KCRI
Krakow Cardiovascular Research Institute

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

Study Flow Chart (1)

97 carotid stenosis patient **referrals***

(external >> internal)

Neuro-Vascular Team

- Neurologist
- Interventional Angiologist
- Vascular Surgeon
- Cardiologist

for carotid revascularization
73 patients

NOT for carotid revascularization
24 patients

n=19: lesion increased risk and/or severity criteria not met
n=2: ICA totally occluded on verification
n=2: ICA functionally occlded + h/o prior ipsil. large infarct with hemorrhagic transformation
n=1: severe haemodynamic instability (ICA stenosis a sympt.)

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

Study Flow Chart (2)

73 Patients for carotid revascularization

(92%) → **CAS in n=67 Patients (bilateral in 3)**

(1%) → **CAS + CEA in n=1 Patient**

(LICA-CEA and RICA-CAS) hybrid management

(7%) → **CEA in n=5 Patients**

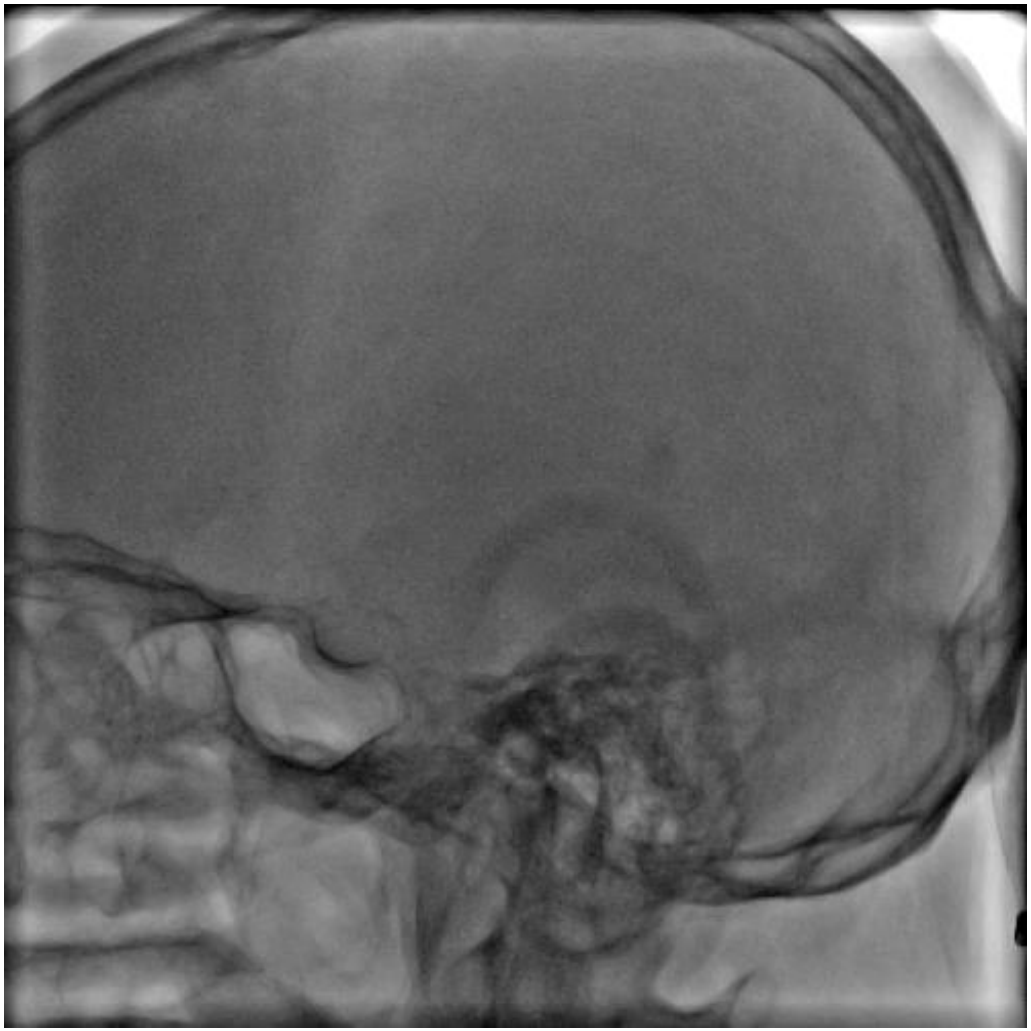
- n=1 eGRF 14 => no contrast
- n=1 extreme access tortuousity
- n=1 severe aortic valve disease + calcific LICA (AVR + CEA)
- n=1 floating thrombus in CCA
- n=1 ICA diameter <2.0 mm + contralat. occlusion

71 ICAs treated endovascularly in 68 patients

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

How would YOU treat?

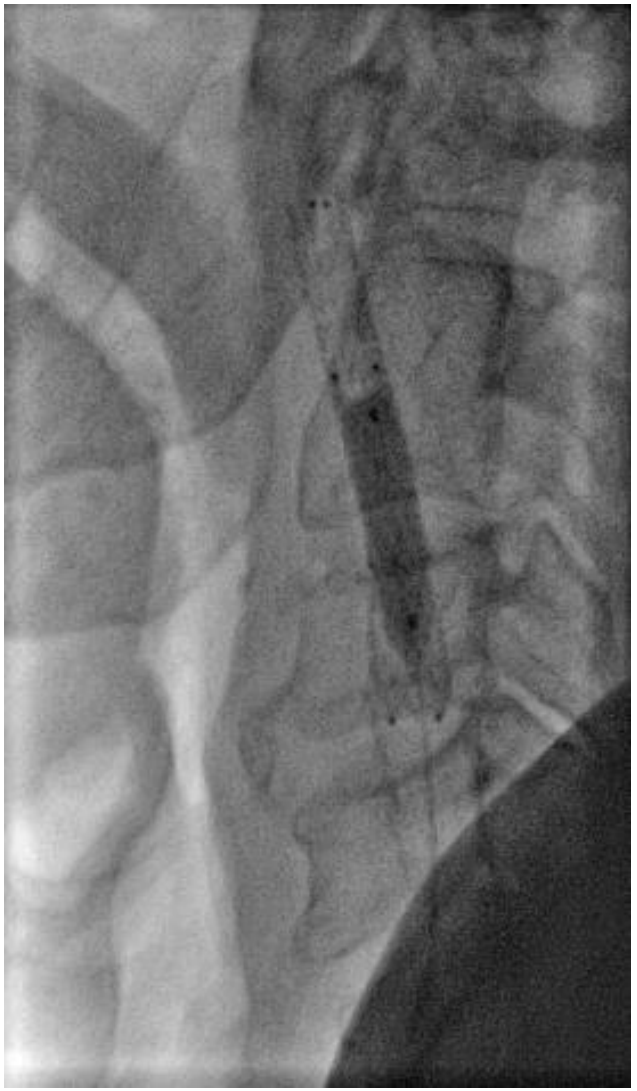
LEIPZIG INTERVENTIONAL COURSE
LINC 2016



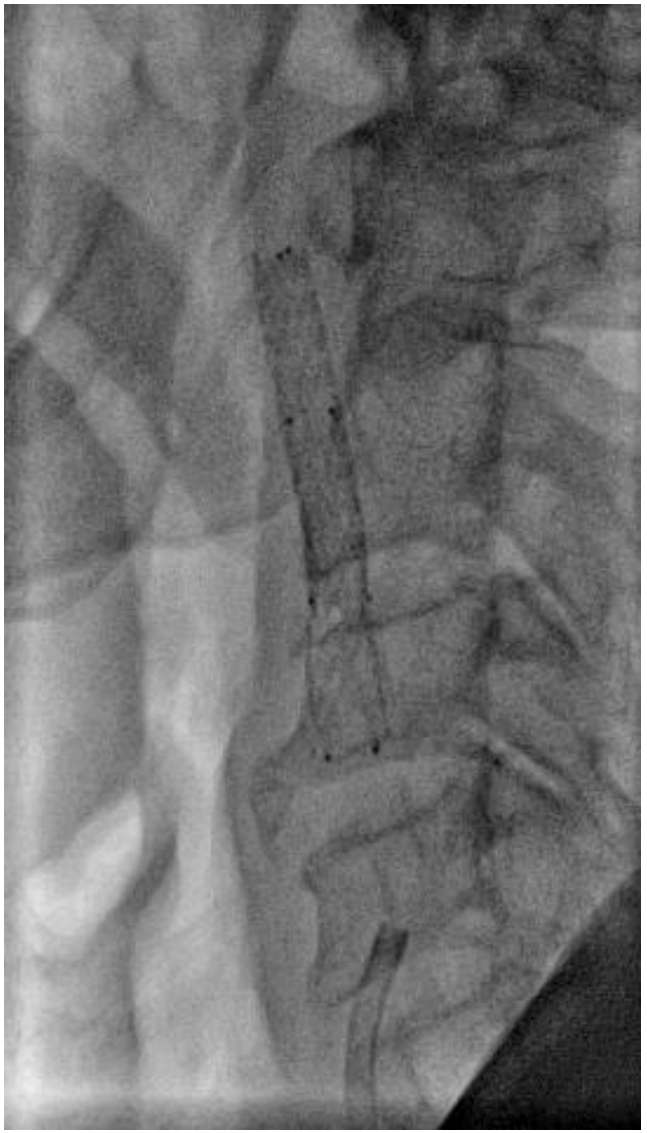
acutely symptomatic / thrombus-containing

CAROTID PARADIGM REVASCULARIZATION

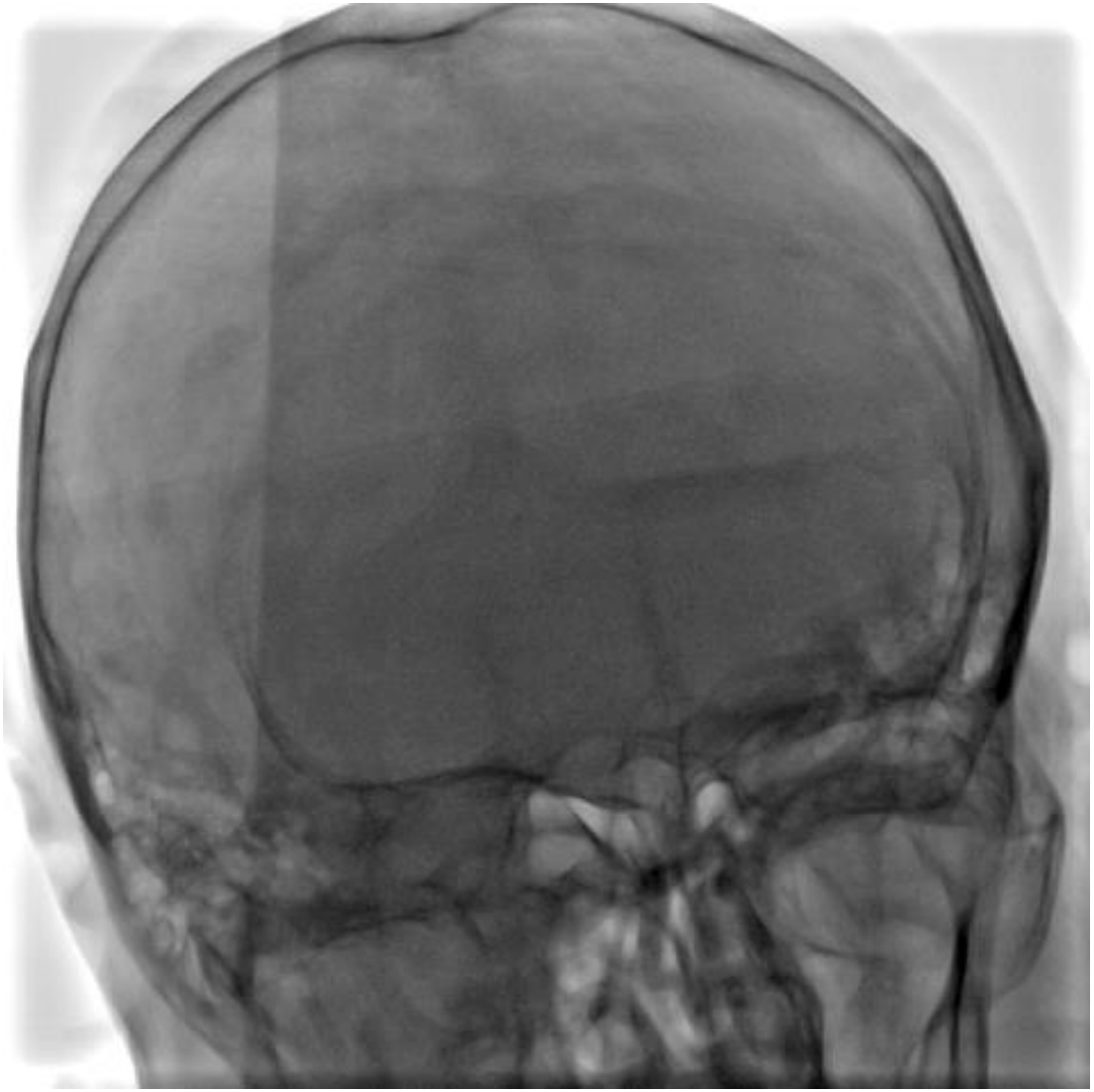
Thrombus-containing / acutely symptomatic



Thrombus-containing / acutely symptomatic



Thrombus-containing / acutely symptomatic

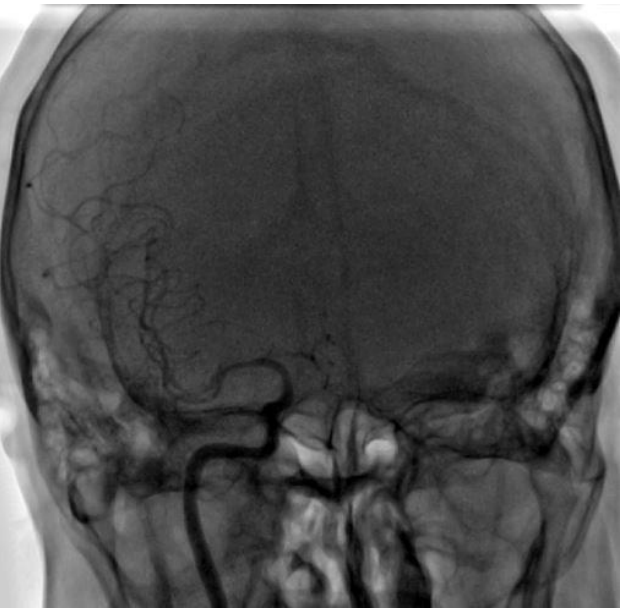


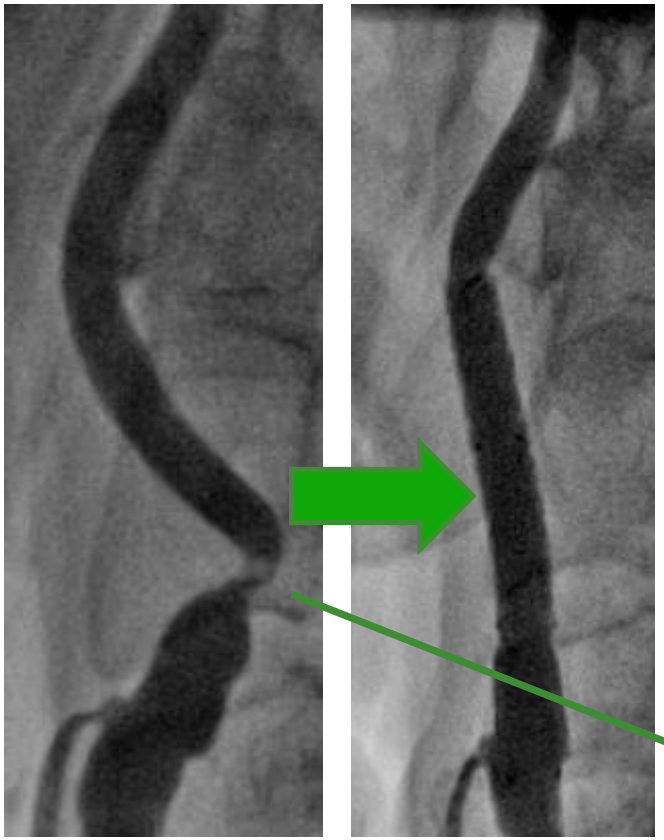
Case # **018**
(Krakow)

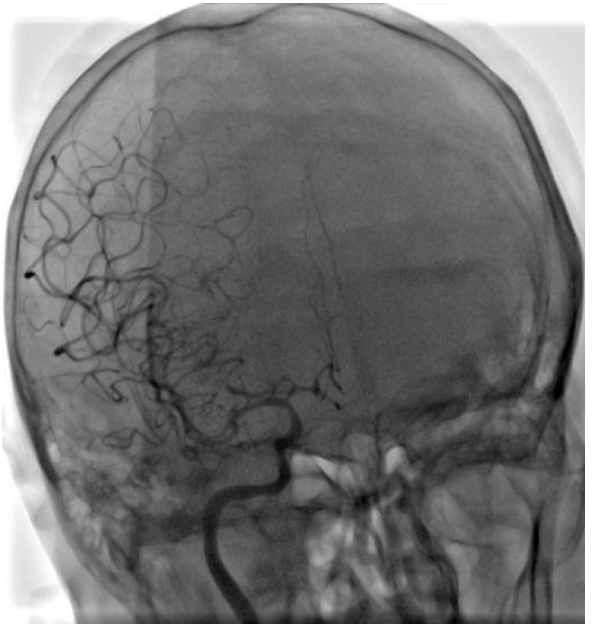
CAROTID PARADIGM REVASCULARIZATION

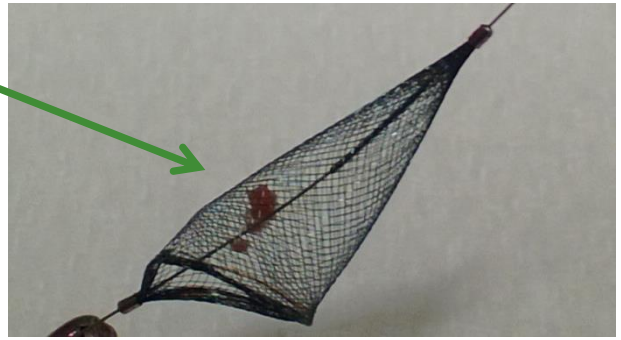
Thrombus-containing
Acutely symptomatic

NIH-SS
immediate
4-point improvement



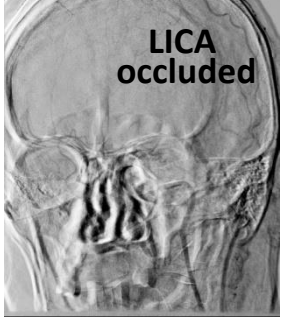






CAROTID
PARADIGM
REVASCULARIZATION

Thrombus-containing lesion
acutely symptomatic patient



Case # **018**
(Krakow)

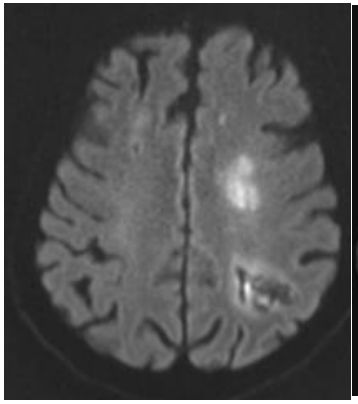
DW-MRI on admission

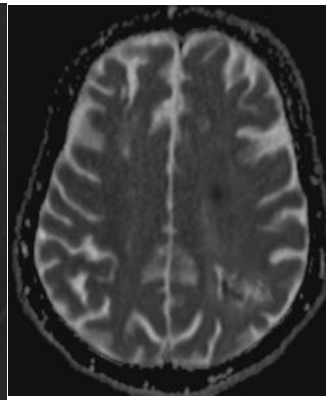
Fresh ischemic lesion in the L hemisphere
['haemodynamic' lesion, resulting from cross-flow]
'old' ischemic lesion in te R hemisphere
(no diffusion limitation in the R)

no new lesions
24h after CAS

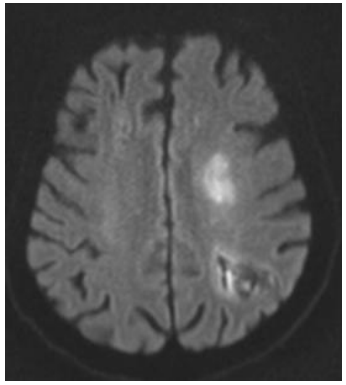
no new lesions
30 days after CAS

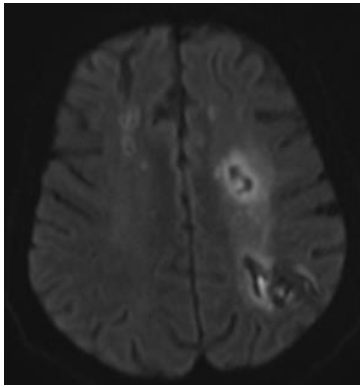
DWI



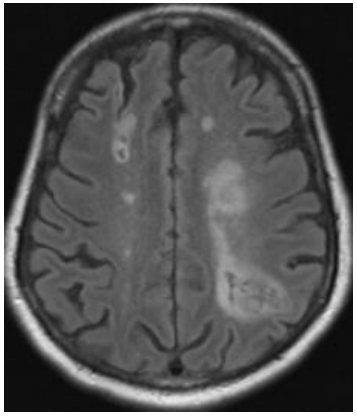


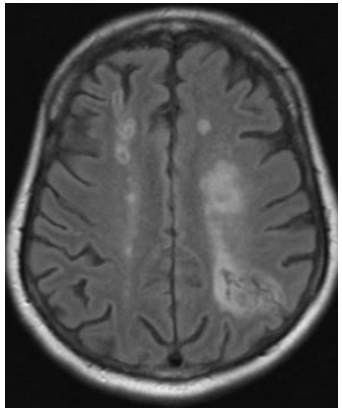
ADC = proof of diffusion absence in the DWI focus

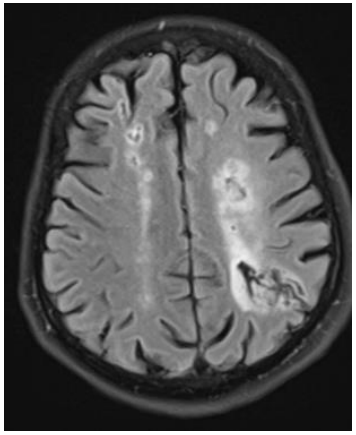




Flair







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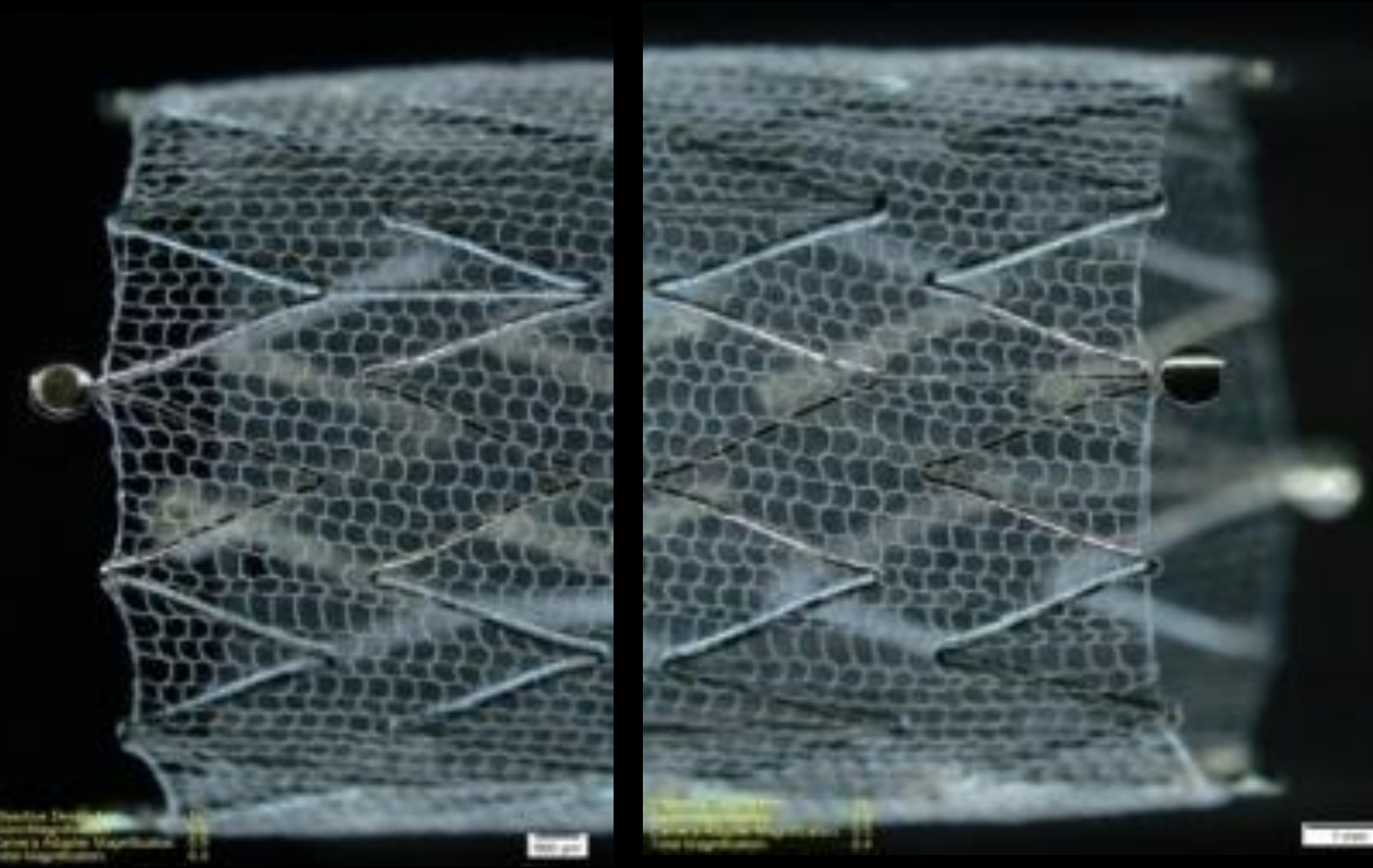
NIH-SS
4-point improvement

NIH-SS
further 2-point improvement

CGuard ™ embolic prevention stent



Clinical characteristics of study patients (n=68)

age, mean±SD (min–max)	69 ±7 (55–83)
male, % (n)	66% (45)
symptomatic, % (n)	53% (36)
symptomatic ≤ 14 days, % (n)	28% (19)
acutely symptomatic (emergent CAS) , % (n)	9% (6)
index lesion (CAS) , % (n)	
RICA	52% (35)
LICA	44% (30)
RICA+LICA	4% (3)
CAD, % (n)	65% (44)
h/of MI, % (n)	27% (18)
CABG or PCI in the past, % (n)	38% (26)
PCI as bridge to CAS, % (n)	16% (11)
AFib (h/o or chronic), % (n)	6% (4)
diabetes, % (n)	35% (24)
h/o neck or chest radiotherapy, % (n)	4% (3)

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

PARADIGM: Results (1)

- **Percutaneous treatment 100% using the intended MicroNet-covered embolic prevention stent system CGuard**
  (ie, no other stents used during the study period)

- **Device success** — **100%**
- **Procedure success** — **100%**
- **Transient Dopamine infusion** — **19%** (n=14)
- **Debris in EPD** — **18%** (n=13)
- **Access site complications** — **0%** (n=0)
- **Vascular plug closure** — **45%** (n=32)

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PARADIGM: Results (2)

Index lesion qualitative characteristics (n=71 lesions)

	All (n=71)	Symptomatic (n=37)	Asymptomatic (n=34)	p
thrombus, % (n)	15% (11)	24% (9)	6% (2)	0.025
near occl./string, % (n)	21% (15)	30% (11)	12% (4)	0.084
proggressive*, % (n)	27% (19)	11% (4)	44% (15)	0.003
ulcerated, % (n)	41% (29)	46% (17)	35% (12)	0.470
irregular, % (n)	72% (51)	65% (24)	79% (27)	0.197
contralateral occl., % (n)	17% (12)	22% (8)	35% (12)	0.291
highly calcific, % (n)	23% (16)	14% (5)	35% (12)	0.050
asymptomatic ipsilat. brain embolization/infarct	N/A	N/A	32% (11)	N/A

* verified on imaging

CoreLab-Quantified

- **ICA reference diameter** **4.99 ± 0.36mm** (from 4.27 to 6.02mm)
- **Lesion length** **19.9 ± 5.8mm** (from 8.19 to 30.25mm)

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PARADIGM: Results (3)

Index lesion quantitative characteristics (n=71 lesions)

	All (n=71 lesions)	Symptomatic n=37	Asymptomatic n=34	p
Before CAS				
PSV, m/s	3.8 ± 1.3	3.7 ± 1.1	3.8 ± 1.5	0.862
EDV, m/s	1.3 ± 0.7	1.4 ± 0.6	1.3 ± 0.8	0.687
Diameter stenosis % (QA)	82 ± 9	79 ± 9	84 ± 9	0.021
CAS				
EPD type				0.092
Proximal*	35% (25)	44% (16)	26% (9)	
Distal**	65% (46)	56% (21)	74% (25)	
post-dilat balloon# peak pressure, mmHg	18.4 ± 3.4	17.5 ± 3.6	19.2 ± 2.9	0.037
After CAS				
Stent length (QA)§				NA
Nominal 30 mm	29.66 ± 0.30	29.66 ± 0.28	29.65 ± 0.32	
(min-max)	(28.73-30.07)	(29.02-30.07)	(28.73-30.02)	
Nominal 40 mm	39.73 ± 0.34	39.69 ± 0.41	39.77 ± 0.28	
(min-max)	(38.88-40.22)	(38.88-40.22)	(39.14-40.04)	
Residual diam. stenosis	7 ± 4%	5 ± 4%	7 ± 5%	0.257
in-stent PSV, m/s	0.70 ± 0.28	0.66 ± 0.29	0.74 ± 0.27	0.266
in-stent EDV, m/s	0.17 ± 0.07	0.17 ± 0.07	0.18 ± 0.07	0.457

* Emboshield (n=7); FilterWire (n=14); Spider (n=25)
** Gore FlowReversal (n=4) or flow reversal with MoMa (n=21)

(NB. mean flow reversal time was 6min 48s, from 5min 18s to 11min 2s)
ø 4.5mm (n=5); ø 5.0mm (n=36); ø 5.5mm (n=29); ø 6.0mm (n=1);
§ 30mm in 51 lesions; 40mm in 18 lesions (2 other lesions required two stents each)

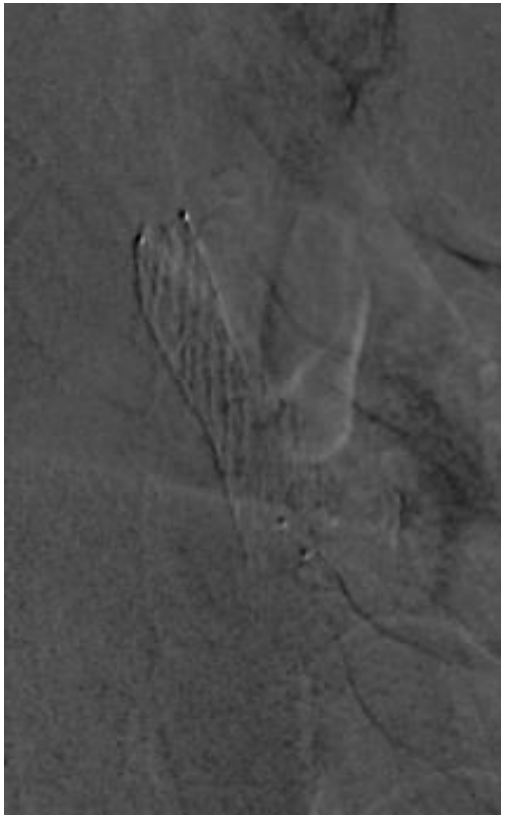
PARADIGM: Results (4)

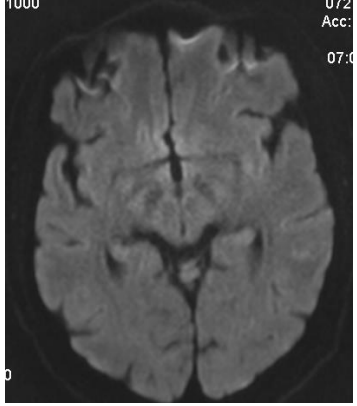
- Death/stroke/MI @ 48h 0%
- Death/stroke/MI @ 30d 0%

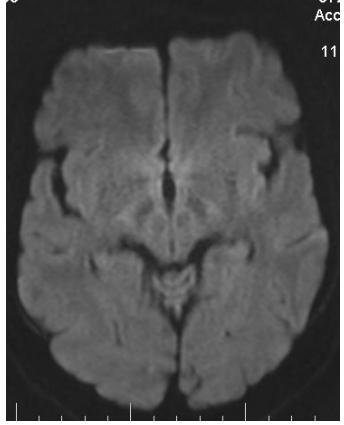
Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66:B33

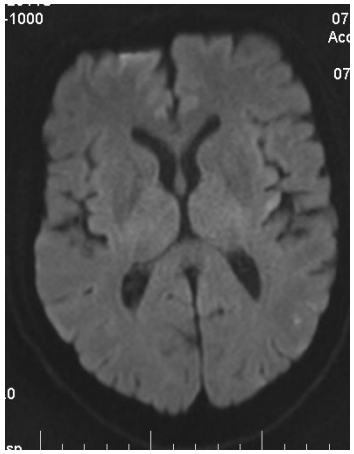
Evolving L Haemisph stroke

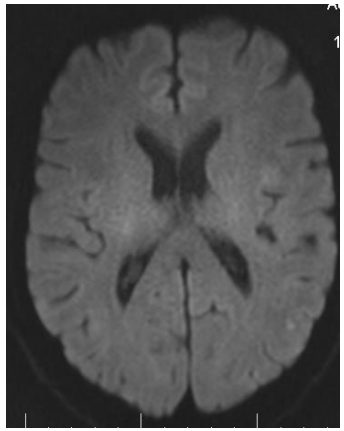
Case # 063
(Krakow)

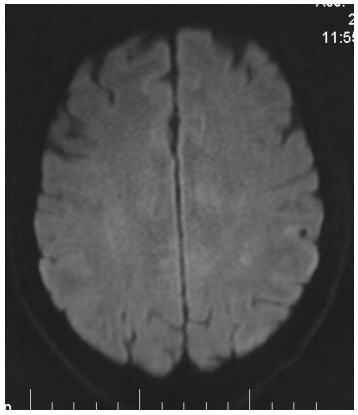


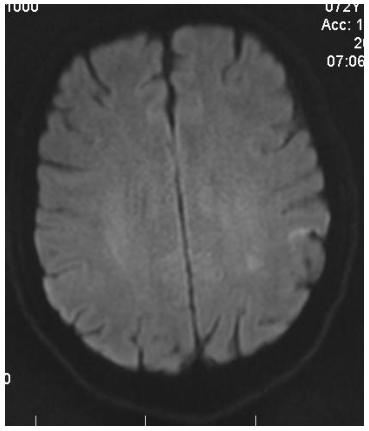












CAROTID PARADIGM REVASCULARIZATION

Case # 063 (Krakow)

NO new brain lesions

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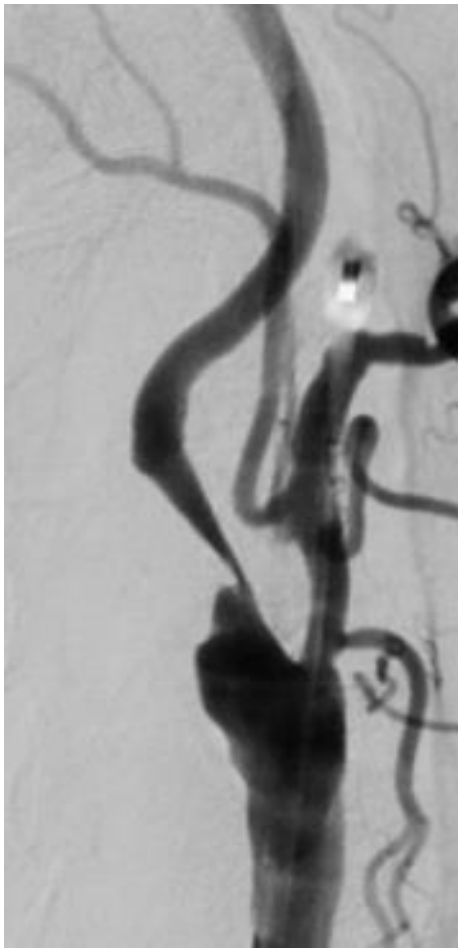
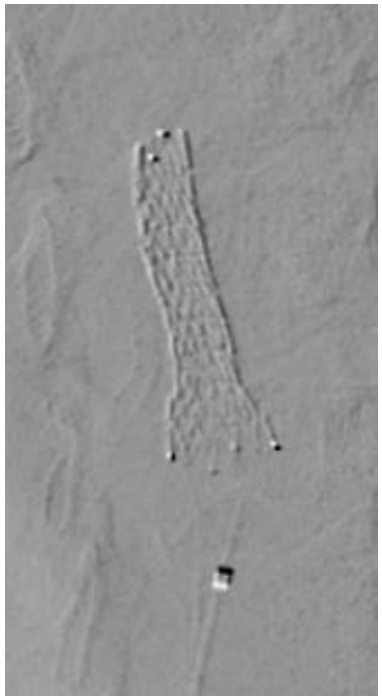
R Haemisph minor stroke 4 d before, now recurrent TIAs

CAROTID PARADIGM REVASCULARIZATION

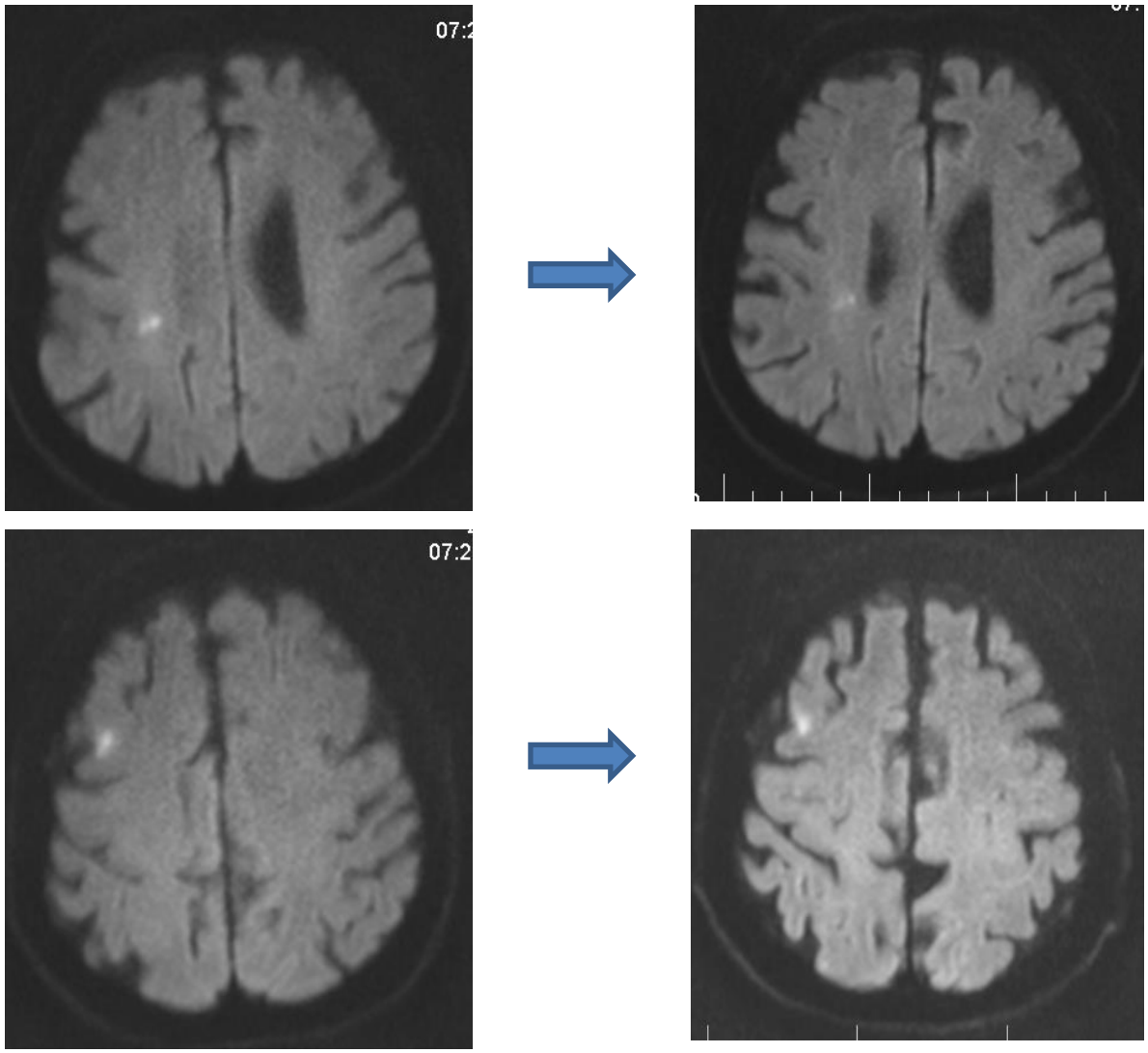
Case # 067 (Krakow)



Note self-tapering



R Haemisph minor stroke 4 d before, now recurrent TIAs



Case # 067
(Krakow)

NO
new
brain lesions

NO
new
brain lesions

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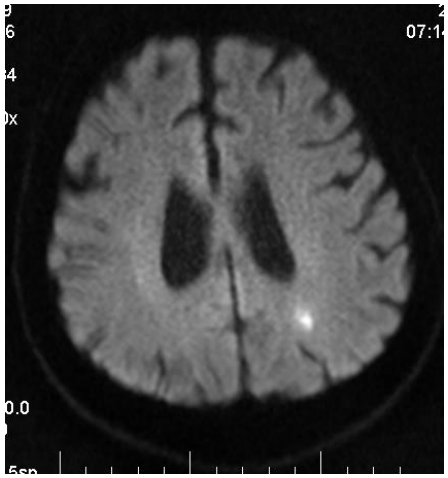
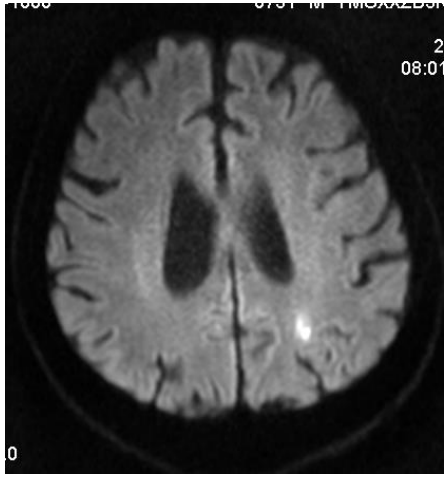
L Haemisph minor stroke 5 d before

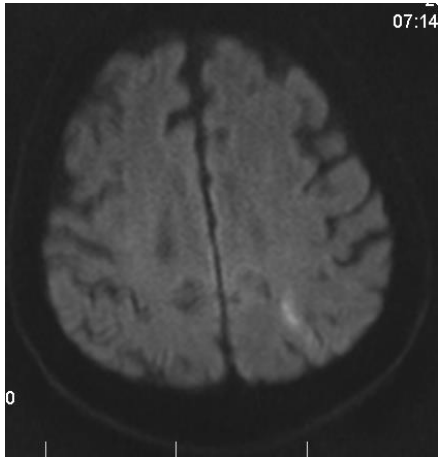
Case # 068
(Krakow)

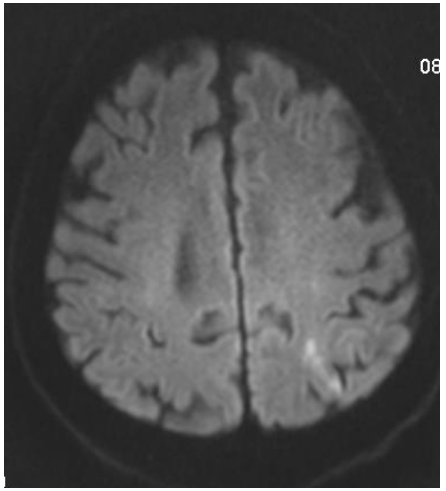
L Haemisph minor stroke 5 d before





NO new brain lesions



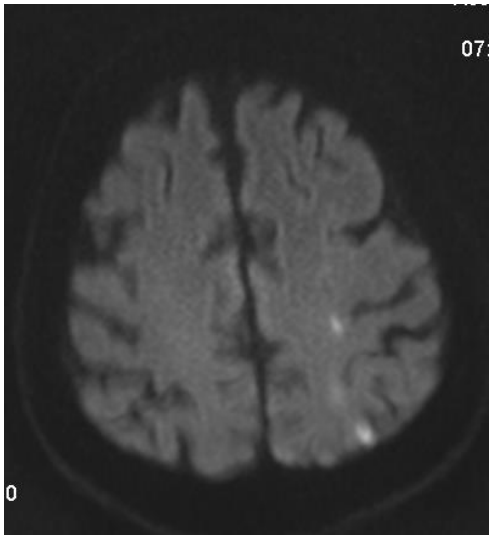


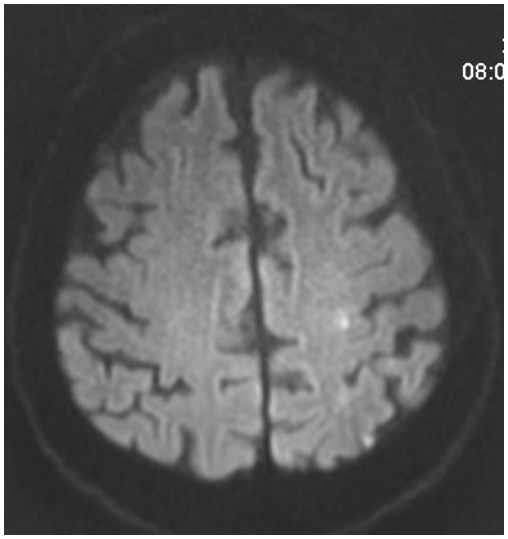
NO new brain lesions

Case # 068 (Krakow)

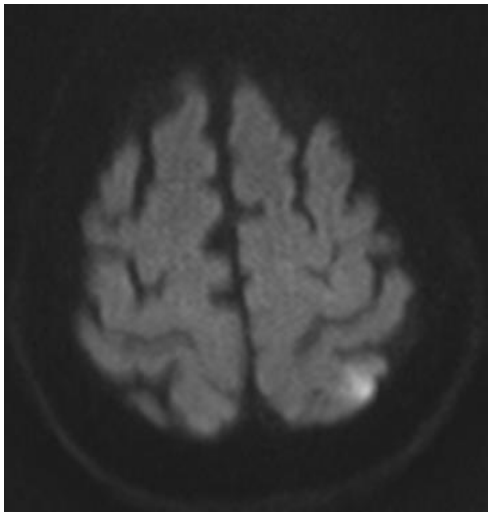
M. Urbanczyk, P. Banys, Dept. Radiology, JP2 Hospital, Krakow, Poland

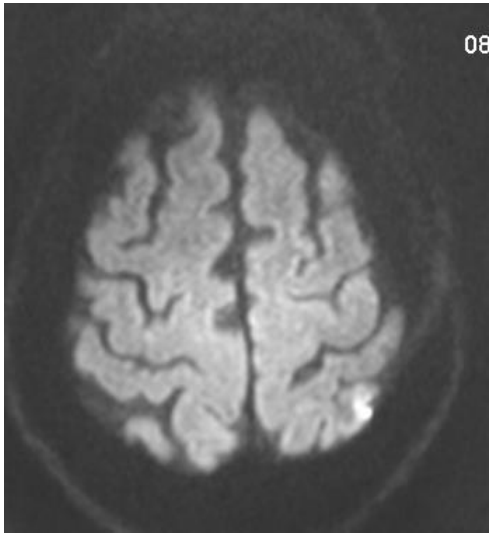
L Haemisph minor stroke 5 d before





NO new brain lesions



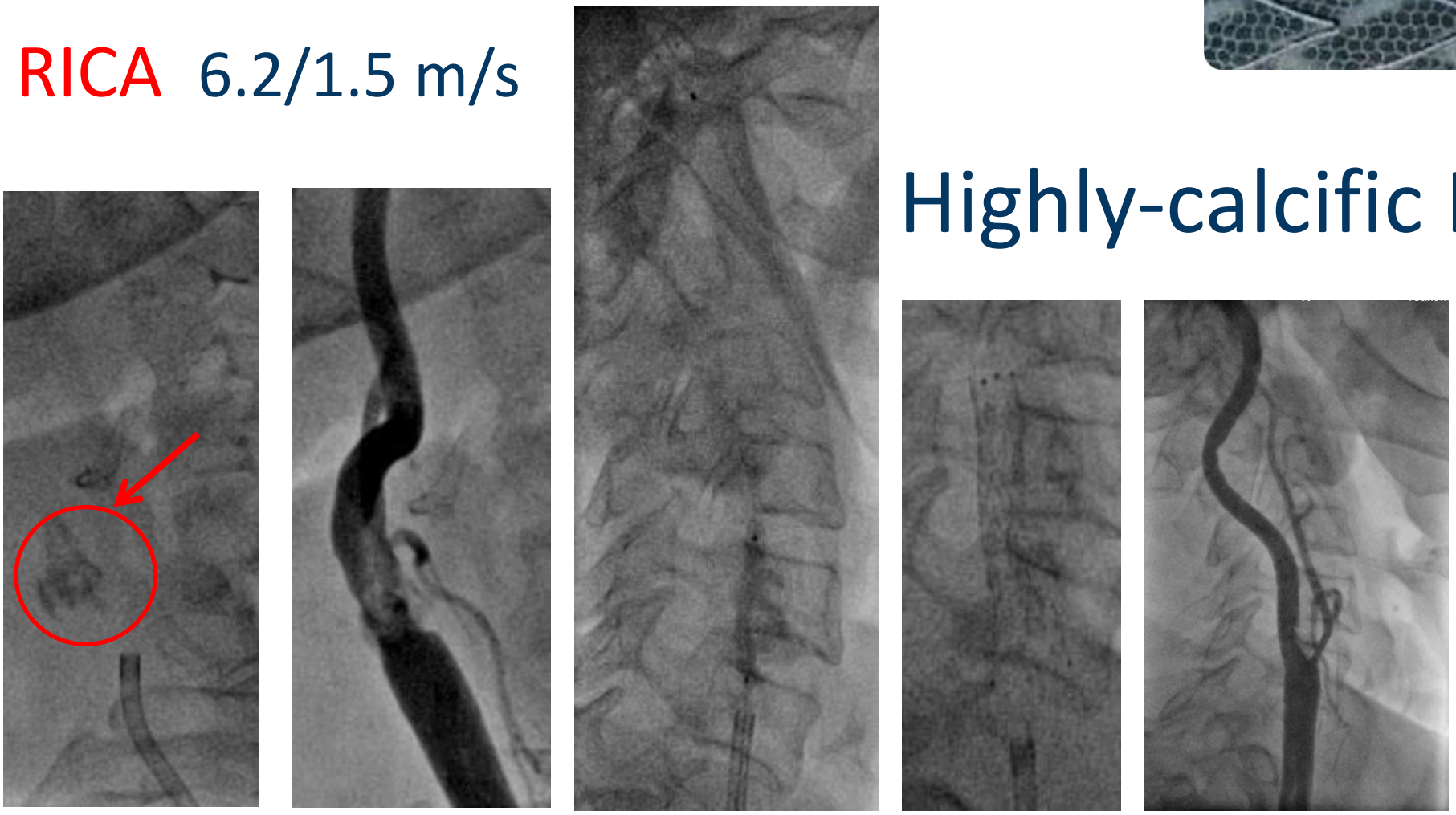


NO new brain lesions

Case # 068 (Krakow)

M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow

RICA 6.2/1.5 m/s



Highly-calcific I

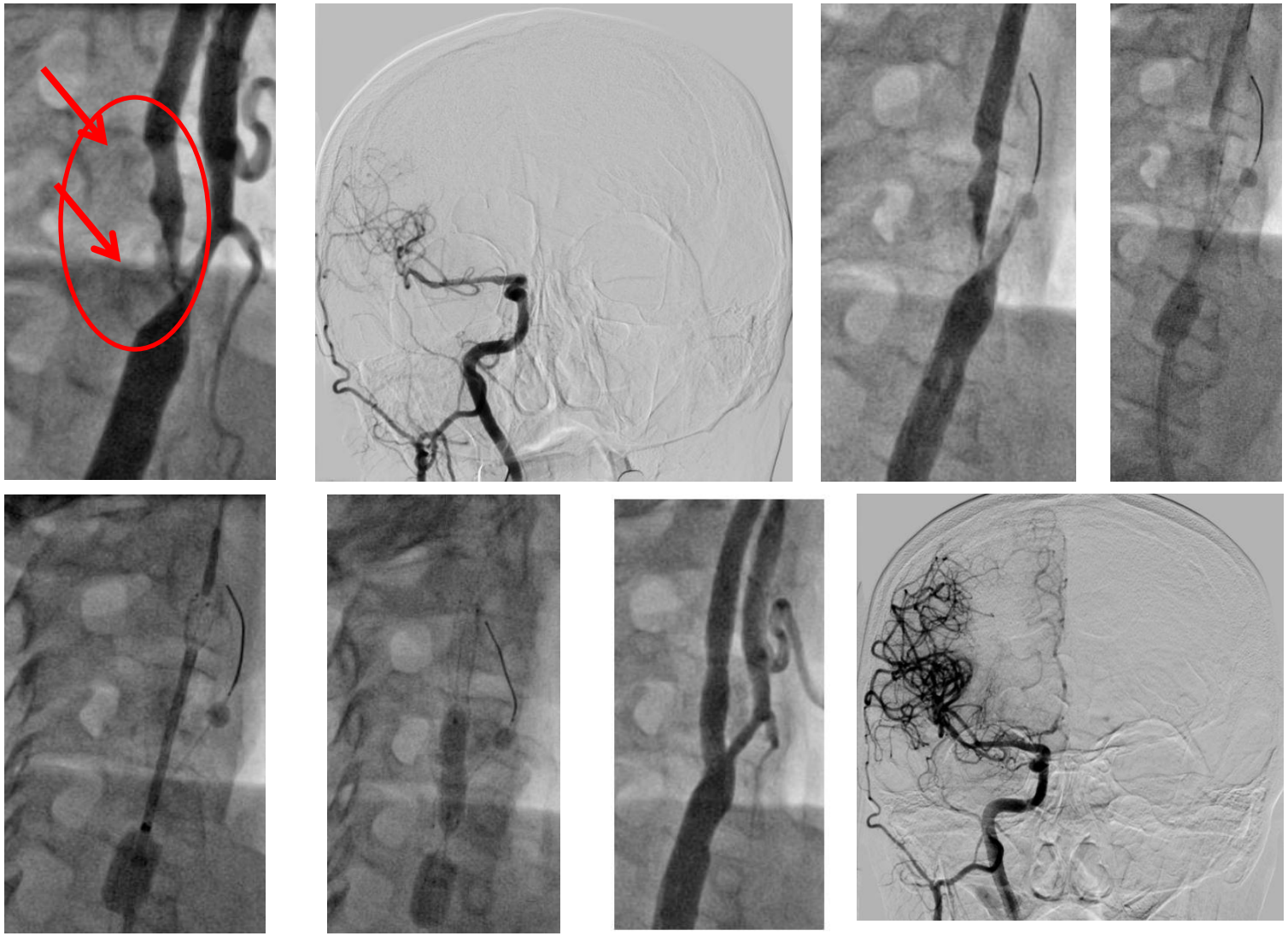
Predilatation 3.0x20mm followed by NC 4.5x15/20atm

CGuard™ 9.0x30mm, postdilated ø5.5x20mm/16atm

A. Mazurek, P. Musialek ePCR2015: CGuard Micro-Net covered embolic prevention stent in endovascular management of highly calcific lesions

Highly-calcific II

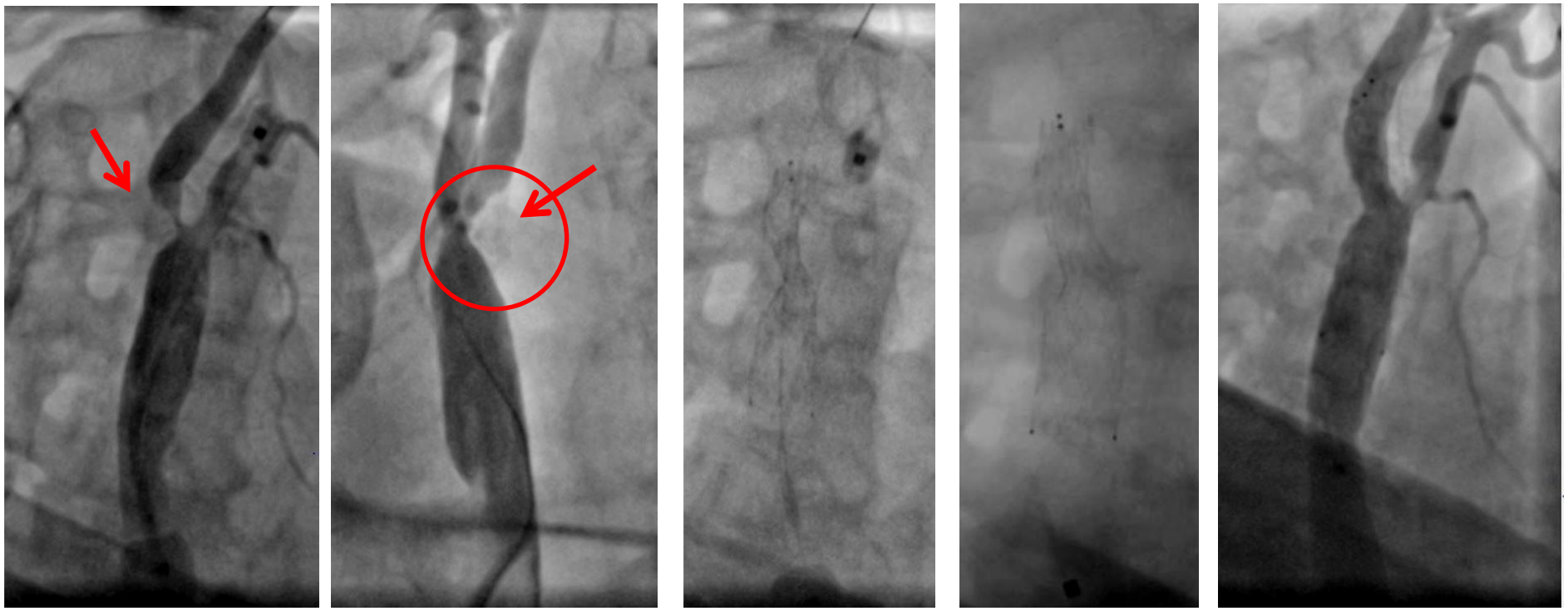
NO brain lesions with CAS



Predilatation 2.0x20 followed by NC 4.0x15, CGuard™ 8.0x40mm, postdilated ø 5.0mm/16 atm

A. Mazurek, P. Musialek ePCR2015: CGuard Micro-Net covered embolic prevention stent in endovascular management of highly calcific lesions

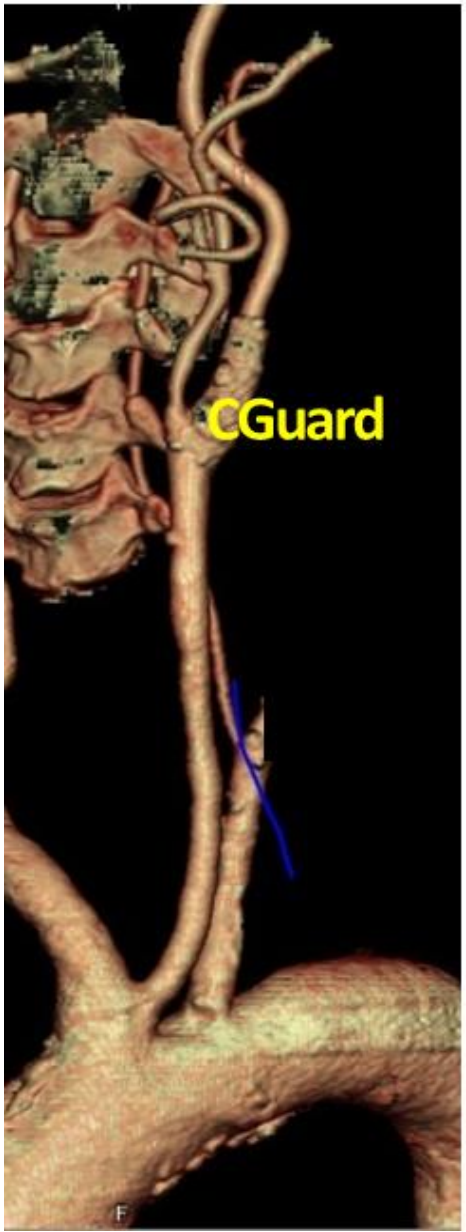
Highly-calcific III

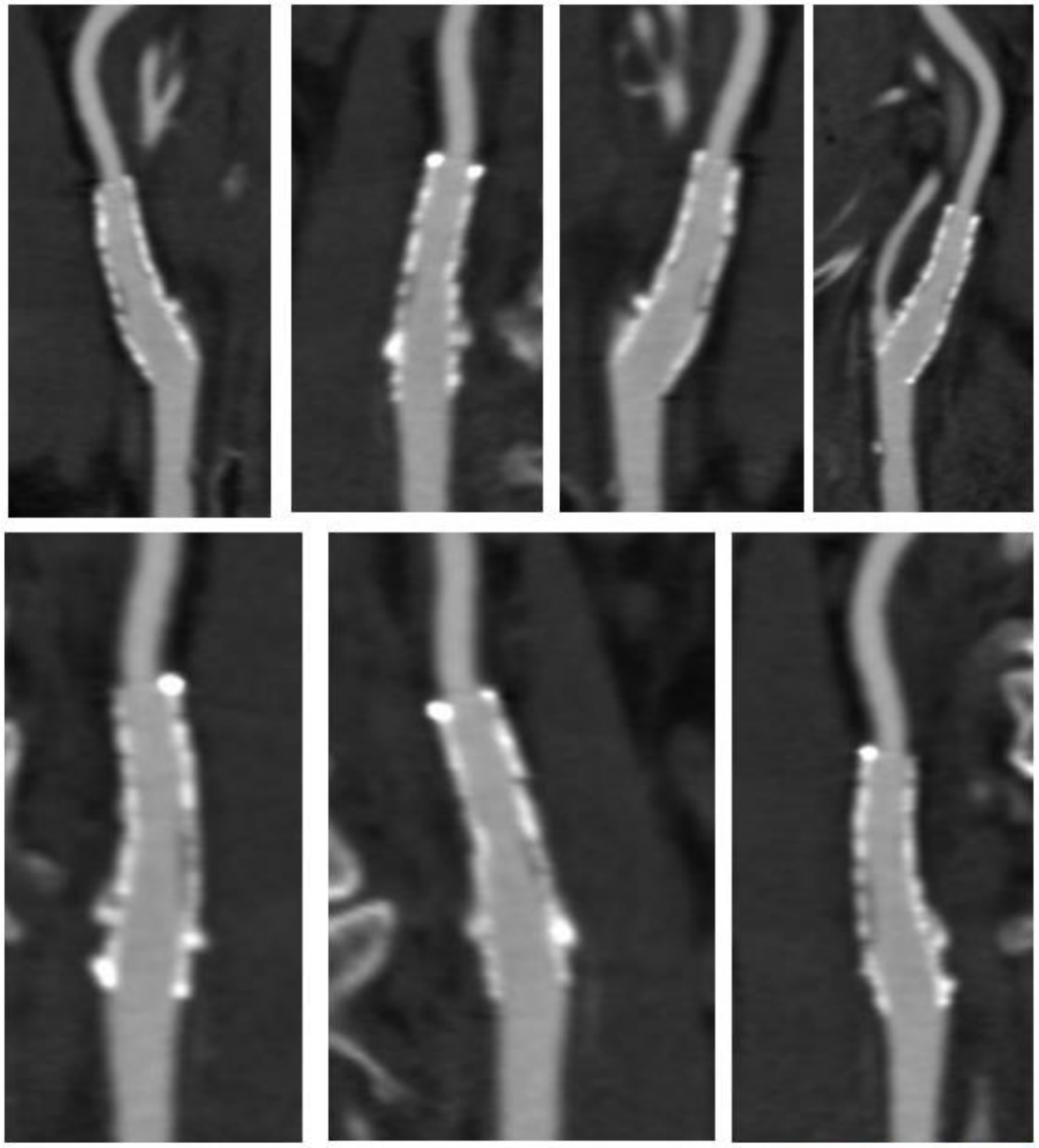


Predilatation 2.5x15mm followed by 4.0x15,
CGuard™ 9.0x30mm, postdilated ø5.0mmx20/24atm

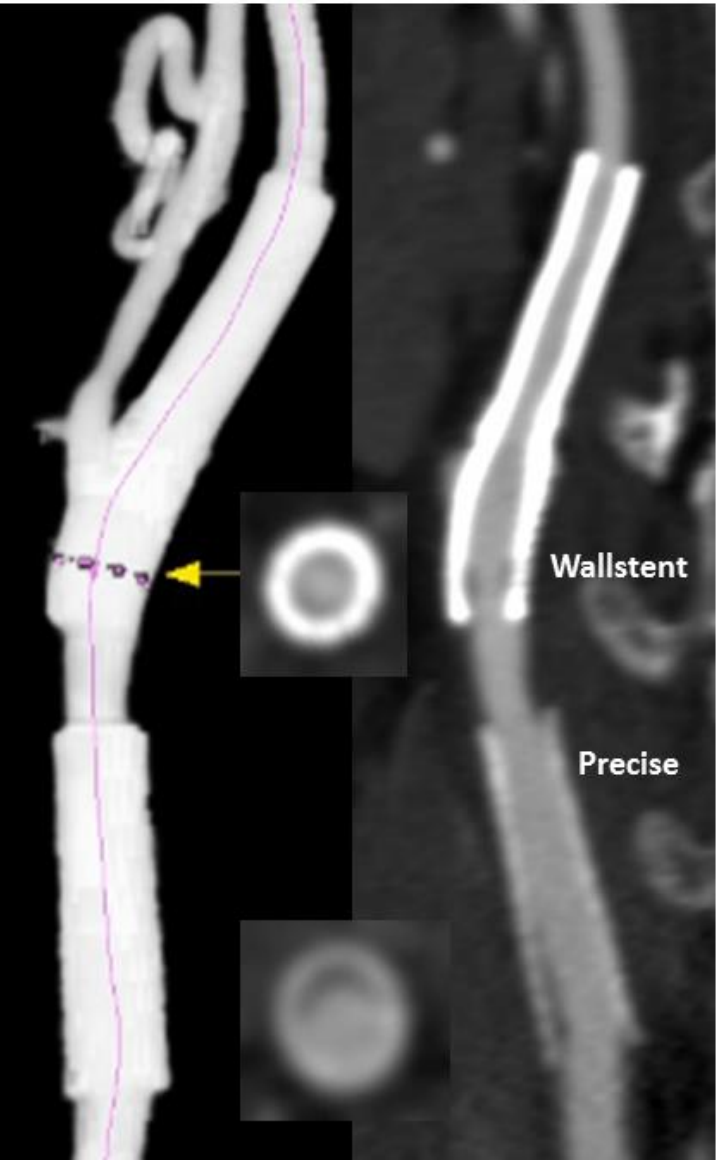
A. Mazurek, P. Musialek ePCR2015: CGuard Micro-Net covered embolic prevention stent in endovascular management of highly calcific lesions

CGuard 5 months follow-up



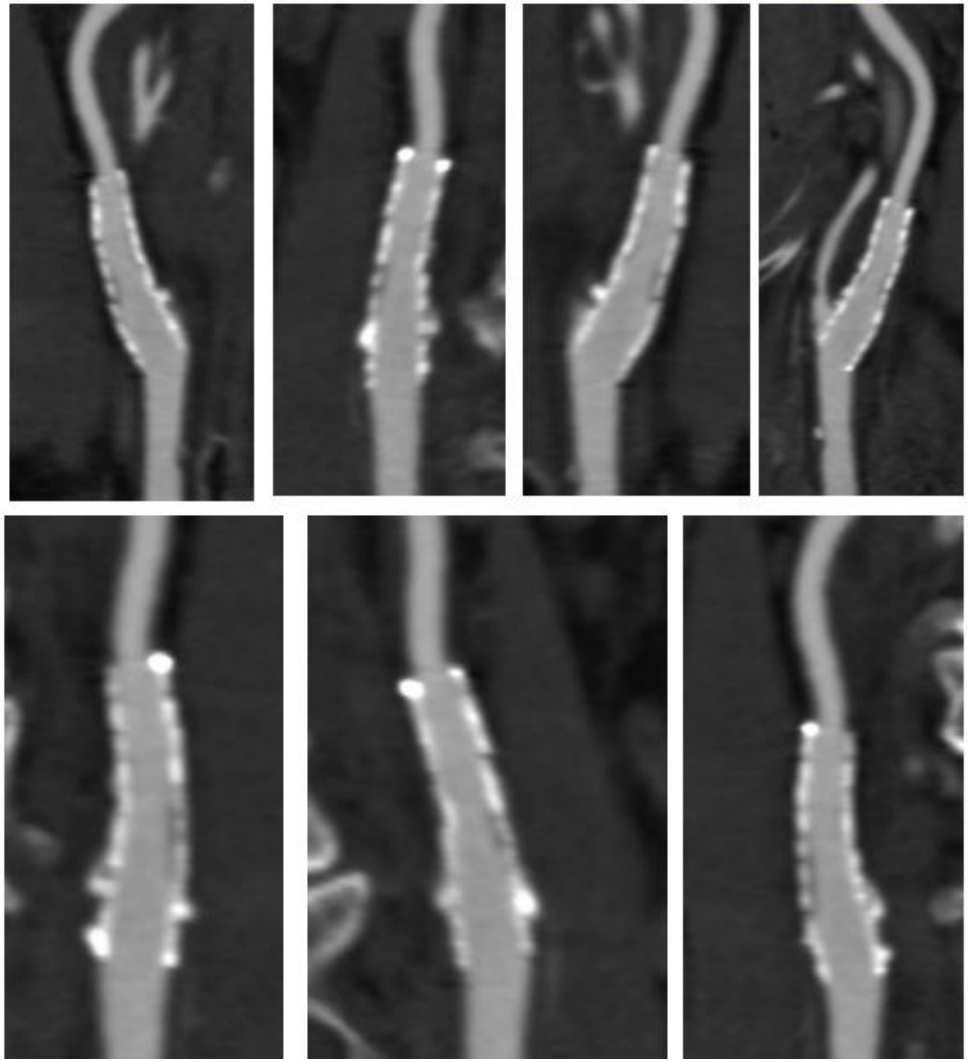


RCCA & RICA



LICA CGuard

5 months follow-up



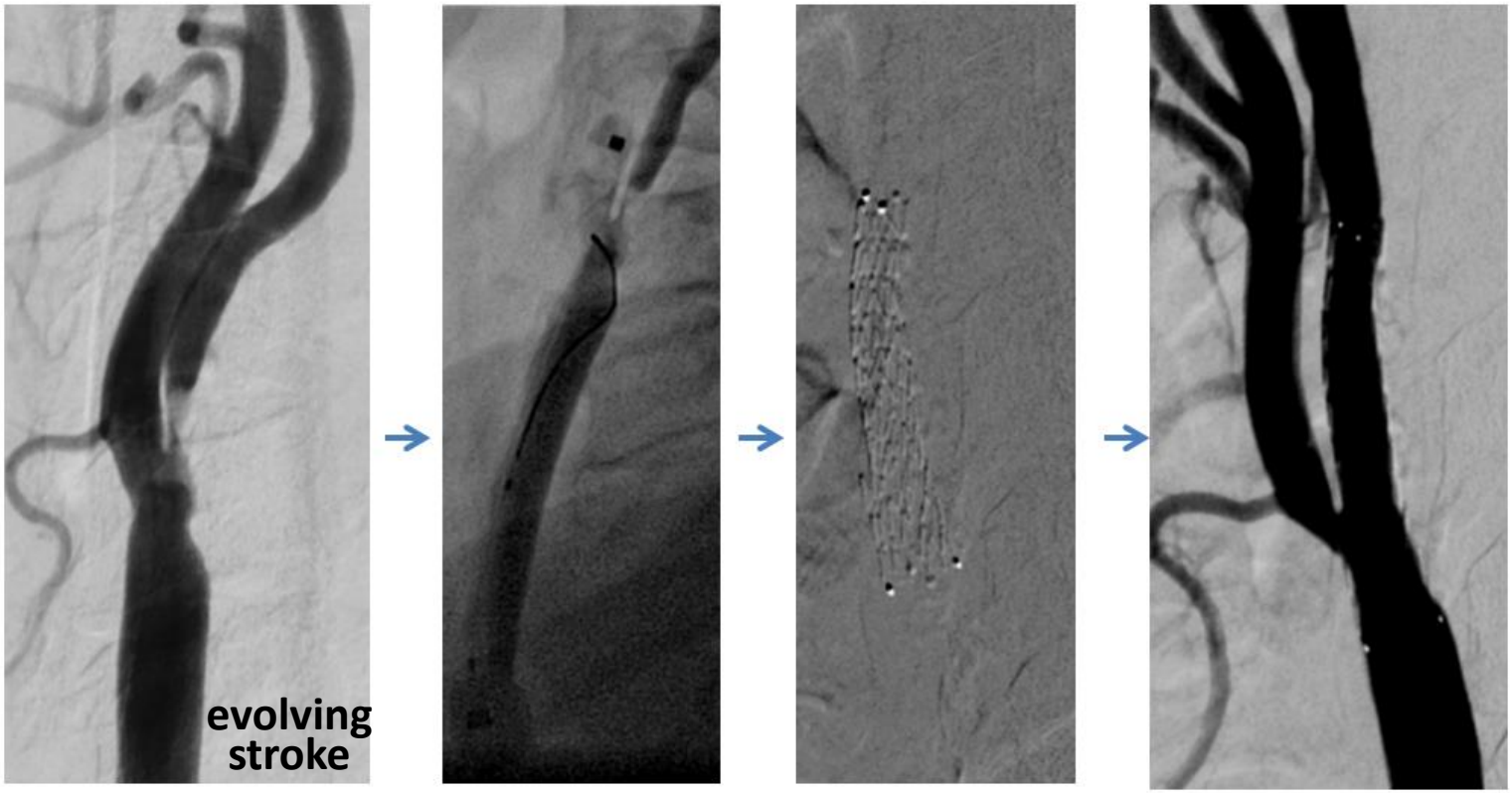
PARADIGM – EXTEND

Cardiovascular and Interventional Radiological Society of Europe

Lisbon, Portugal
September 26-30
CIRSE 2015

24.09.2015

PARADIGM – 101 **recruitment completed**



√

Patient #101 in 'PARADIGM-EXTEND' (*a.k.a.* 'PARADIGM 101')

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPHIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD‖

30d data

ZERO Stroke/ MI/death √

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12mo data

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- 2 asymptomatic self-withdrawals @ 30 days

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ZERO Stroke/ MI/death √

- 2 asymptomatic self-withdrawals @ 30 days
- **100% follow up** of the remaining patients √

12mo data

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30d data

ZERO Stroke/ MI/death √

- 2 asymptomatic self-withdrawals @ 30 days
- **100% follow up** of the remaining patients

12mo data

ZERO Stroke Deaths
ZERO Strokes
@ 12mo

Per-Protocol independent neurological assessment

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

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30d data

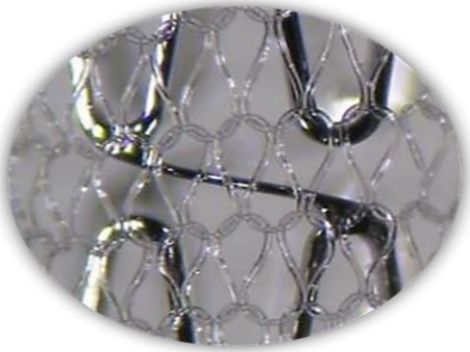
ZERO Stroke/ MI/death √

- 2 asymptomatic self-withdrawals @ 30 days
- **100% follow up** of the remaining patients

ZERO Stroke Deaths
ZERO Strokes **@ 12mo**

Per-Protocol independent neurological assessment

- 1 pulmonary embolism death @ 5 mo
- 1 respiratory failure death @ 8 mo
- 1 malignant tumor death @ 9 mo



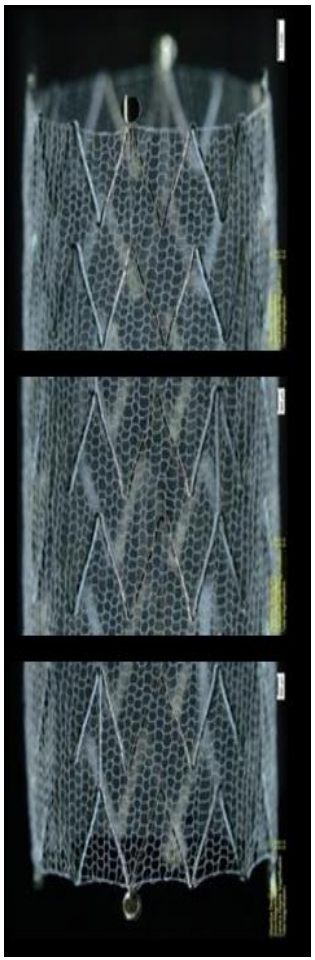
InspireMD

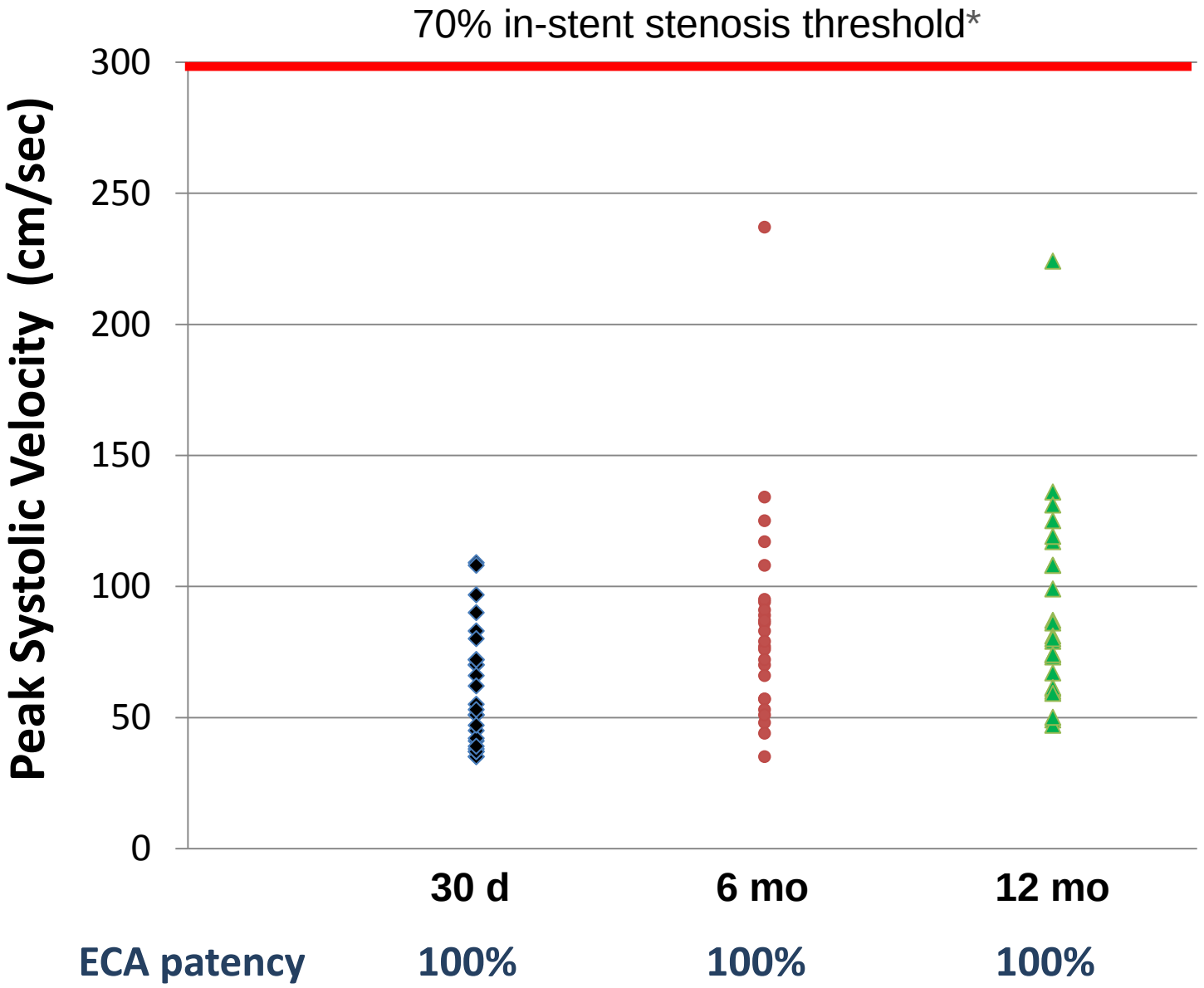
CGUARD™
Carotid Embolic Prevention System

- NO device-related adverse events
- NO procedure-related events

CARENET Multicenter Trial **12 mo data**

CARENET in-stent Peak Systolic Velocities

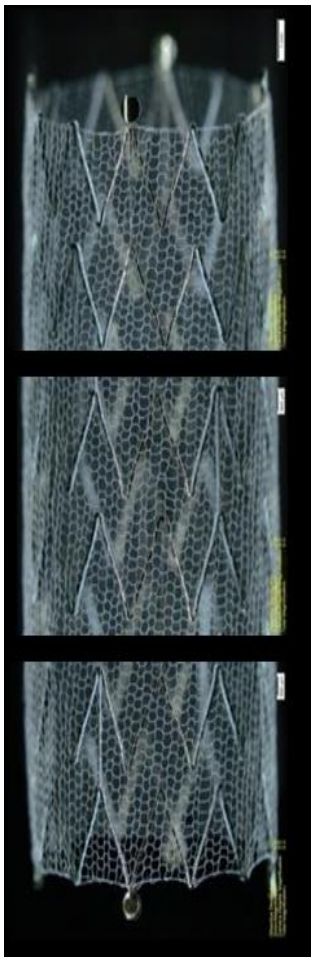




	30 d	6 mo	12 mo
ECA patency	100%	100%	100%

* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke* 2008

CARENET in-stent Peak Systolic Velocities



70% in-stent stenosis threshold*

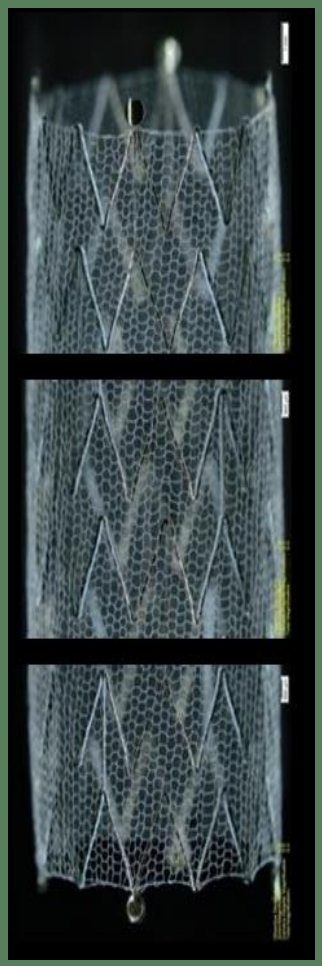
Peak Systolic Velocity (cm/sec)

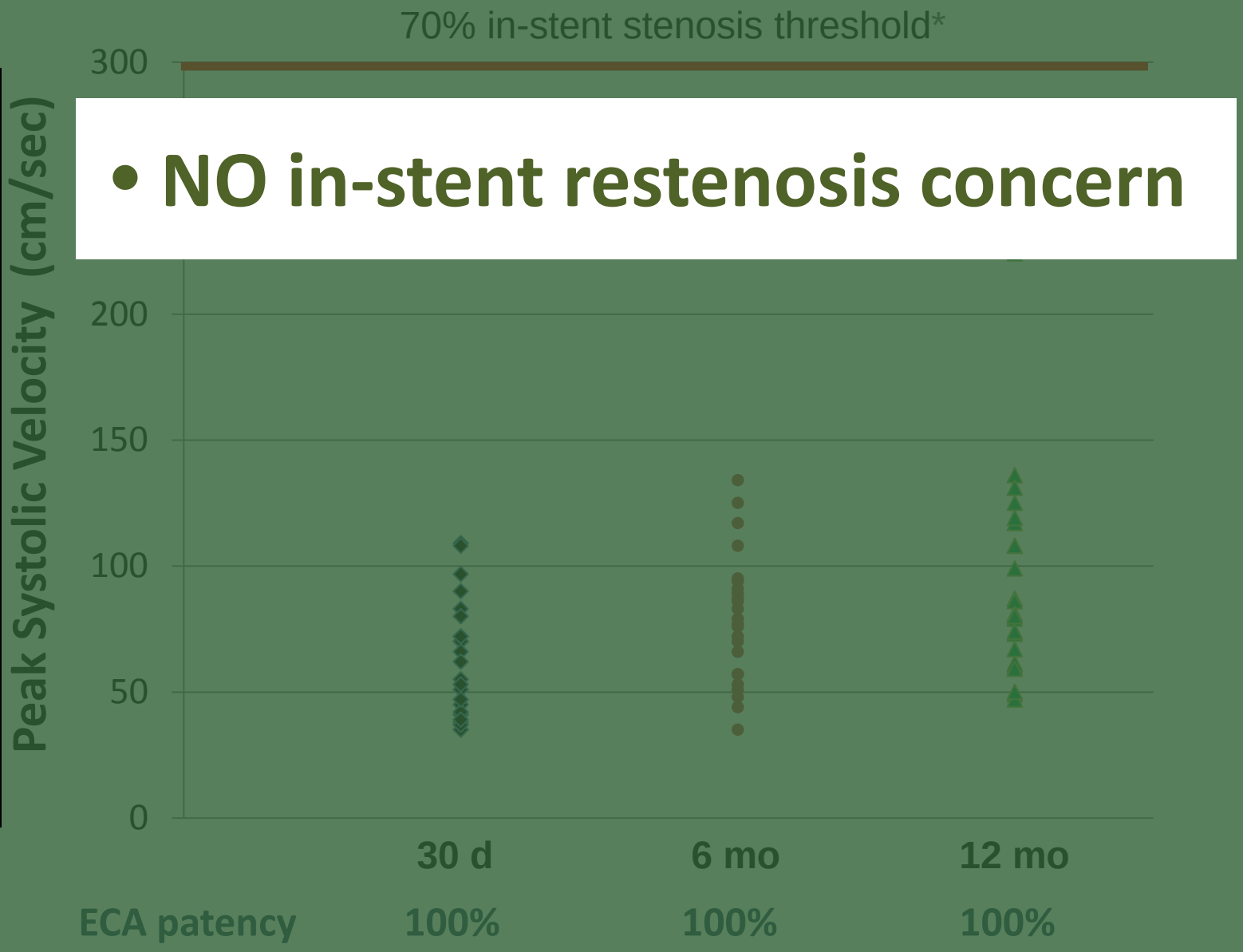
300
250
200
150
100
50
0

	30 d	6 mo	12 mo
ECA patency	100%	100%	100%

* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke* 2008

CARENET in-stent Peak Systolic Velocities

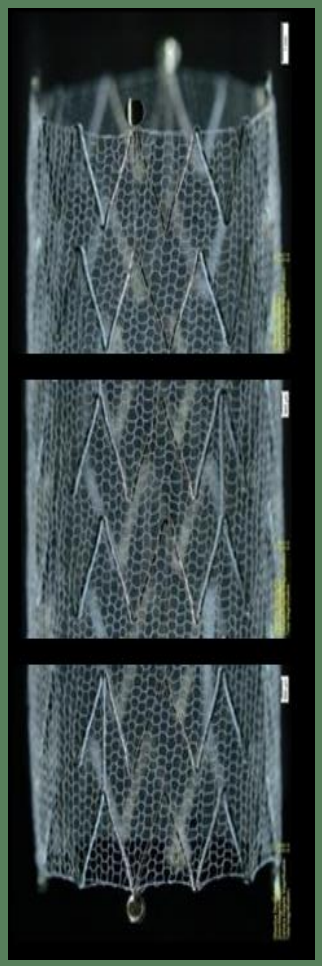


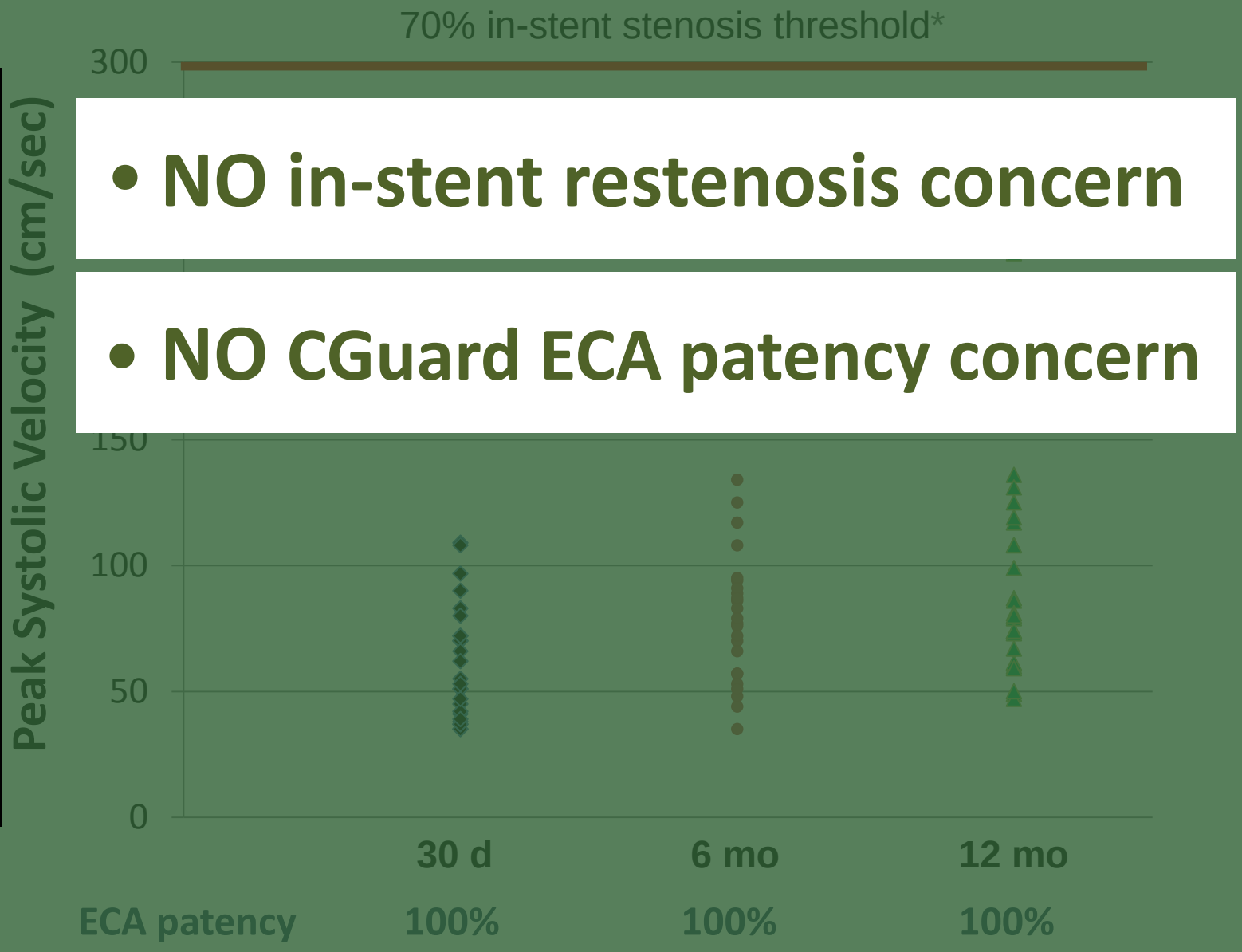


- **NO in-stent restenosis concern**

* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke* 2008

CARENET in-stent Peak Systolic Velocities





- **NO in-stent restenosis concern**
- **NO CGuard ECA patency concern**

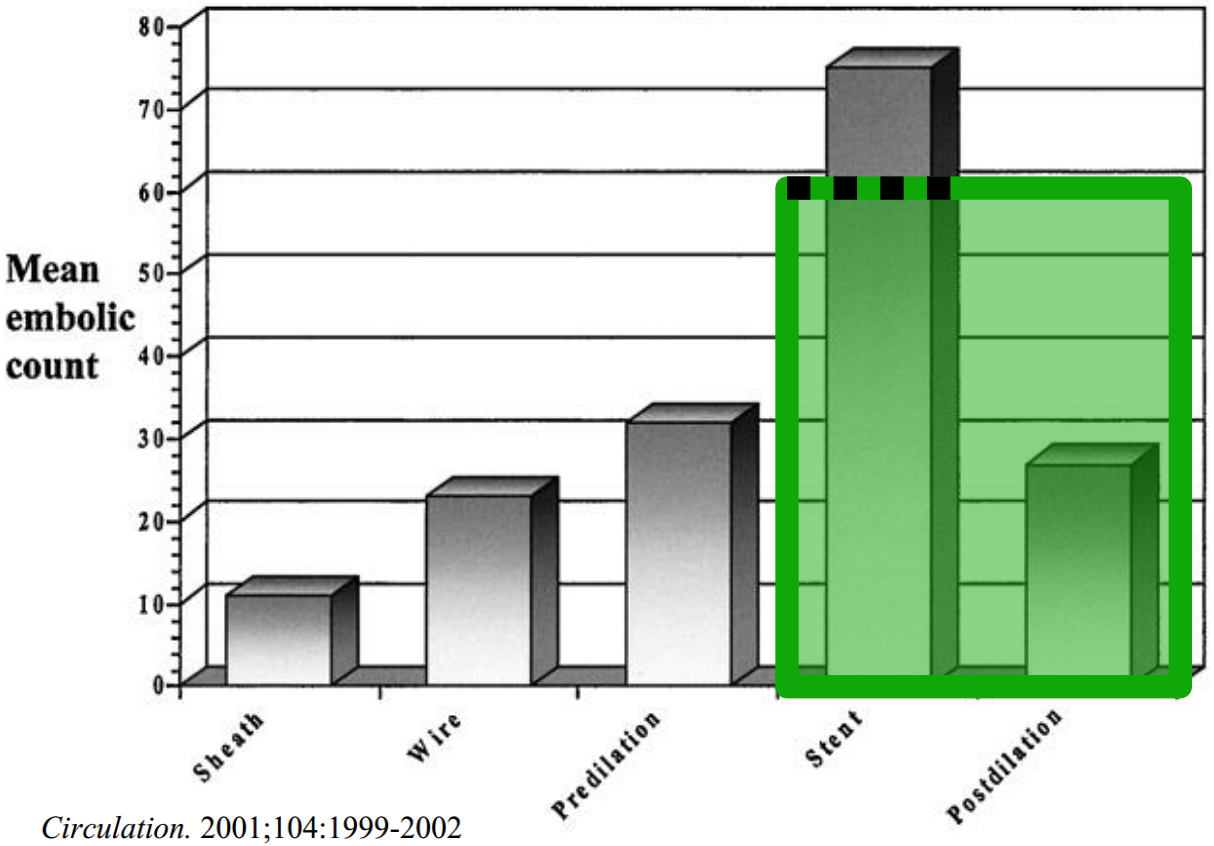
* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke* 2008

CAS (and CEA) are –and ***will*** remain– **emboli-generating** procedures

LEIPZIG INTERVENTIONAL COURSE
LINC 2016

Effect of the Distal-Balloon Protection System on Microembolization During Carotid Stenting

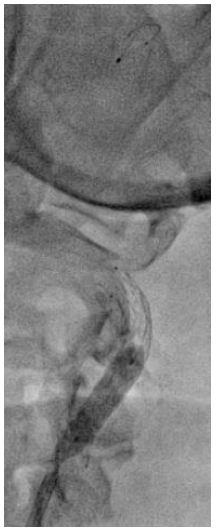
Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD

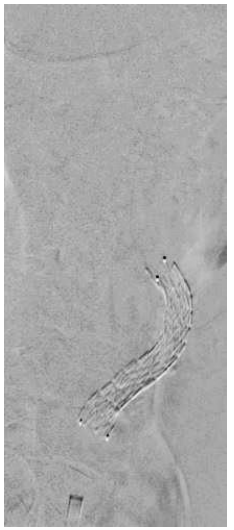


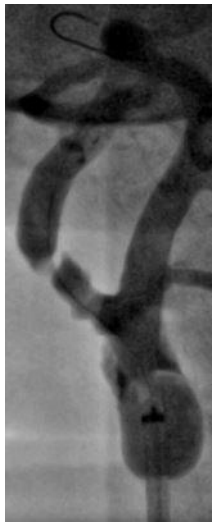
Circulation. 2001;104:1999-2002

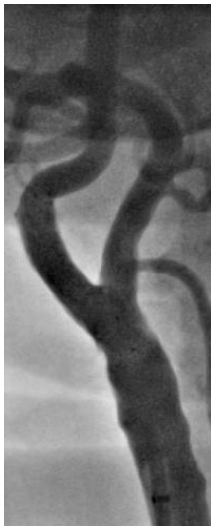
amenable to elimination with MicroNet

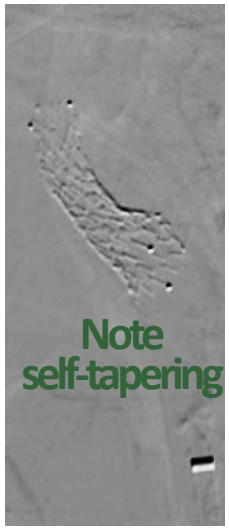
Endovascular Solution for All-Comers











Endovascular Reconstruction of the Carotid Bifurcation

Prevention of embolism, Optimal radial force, Excellent conformability…

CGuard embolic prevention stent system

- **Full respect of the carotid bifurcation anatomy**
  -> 'endovascular anatomic reconstruction' √

- **Optimal performance across all lesion subsets (including high calcium/thrombus/string)** √

'The most OPEN of open-cell stent designs'
and
'The most CLOSED of the closed-cell designs'

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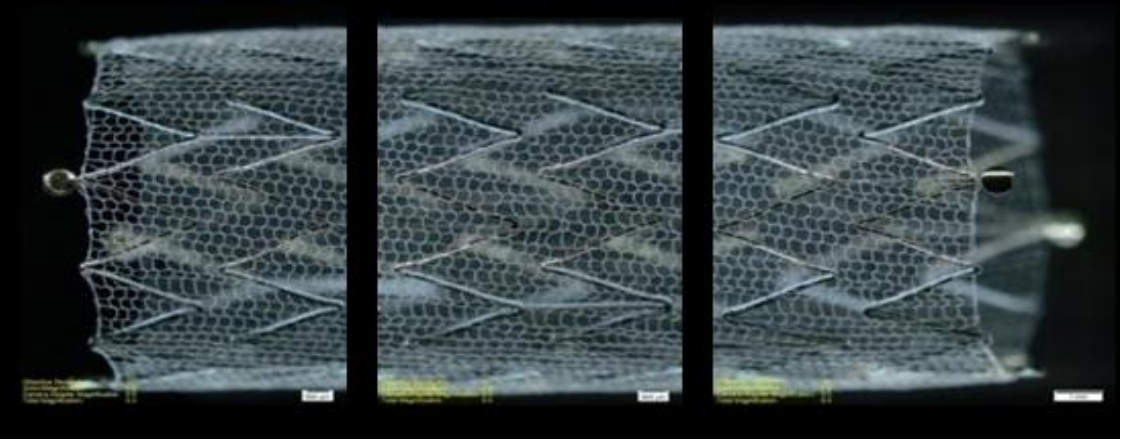
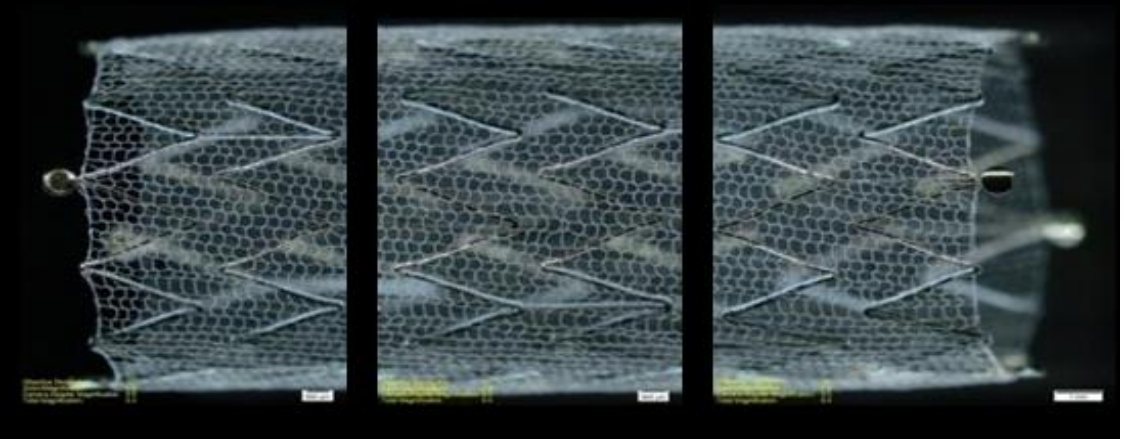
DW-MRI Evidence (CARENET)

+ Clinical Evidence (CARENET, PARADIGM, PARADIGM-EXTEND)

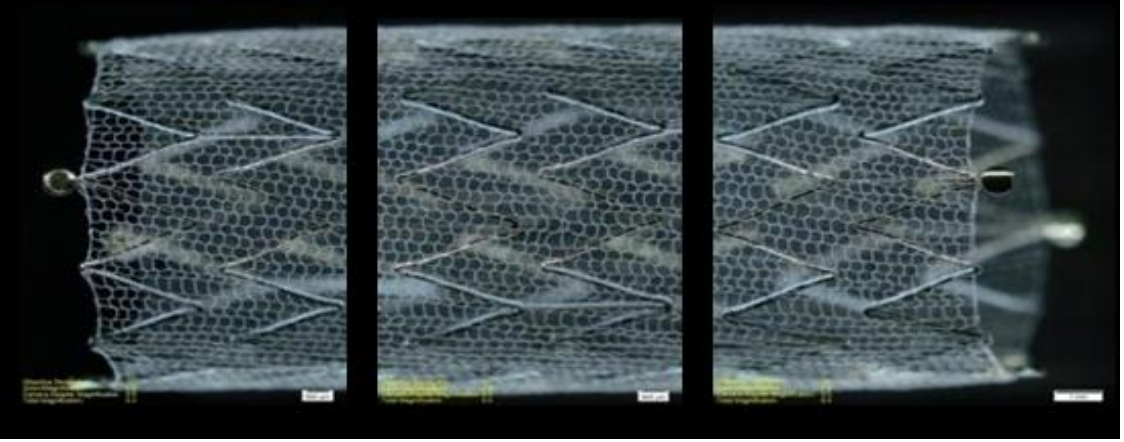


This concept has been desired.



This concept has been desired.

And it works.



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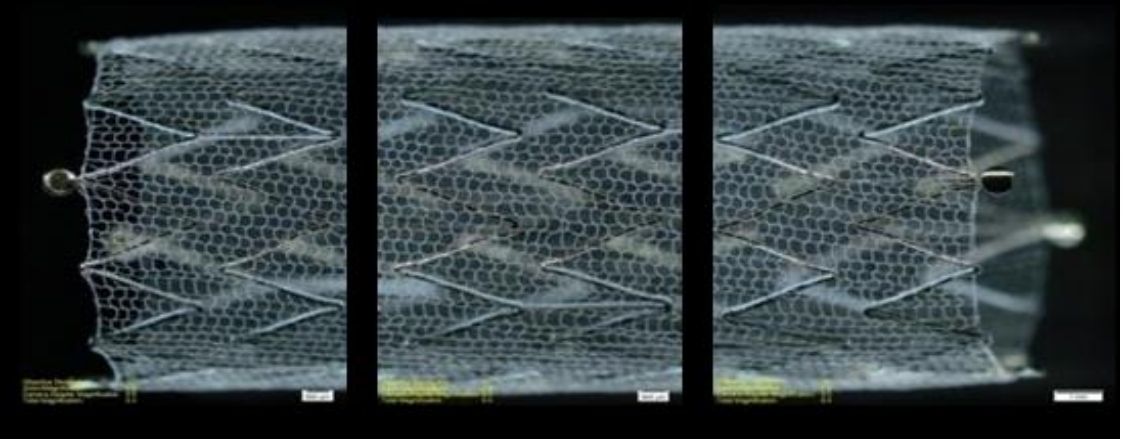
This is the future

of Carotid Artery Stenting



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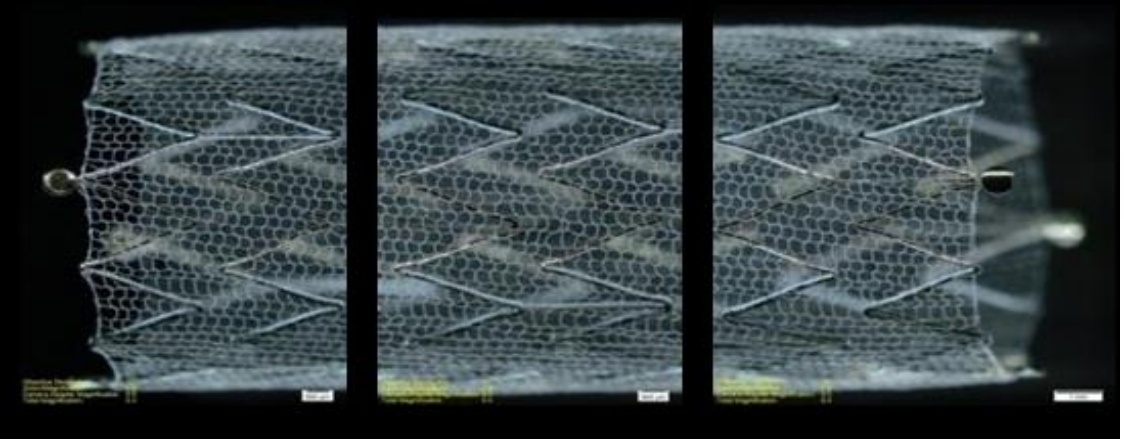

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And it works.

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of Carotid Artery St[illegible]

revascularization ?

CGuard Embolic-Prevention Stent Image Courtesy Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, Univerity of Barcelona

Study Flow Chart (2)

73 Patients for carotid revascularization

(92%) → **CAS in n=67 Patients (bilateral in 3)**

(1%) → **CAS + CEA in n=1 Patient**

(LICA-CEA and RICA-CAS) hybrid management

(7%) → **CEA in n=5 Patients**

- n=1 eGRF 14 => no contrast
- n=1 extreme access tortuousity
- n=1 severe aortic valve disease + calcific LICA (AVR + CEA)
- n=1 floating thrombus in CCA
- n=1 ICA diameter <2.0 mm + contralat. occlusion

71 ICAs treated endovascularly in 68 patients

Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

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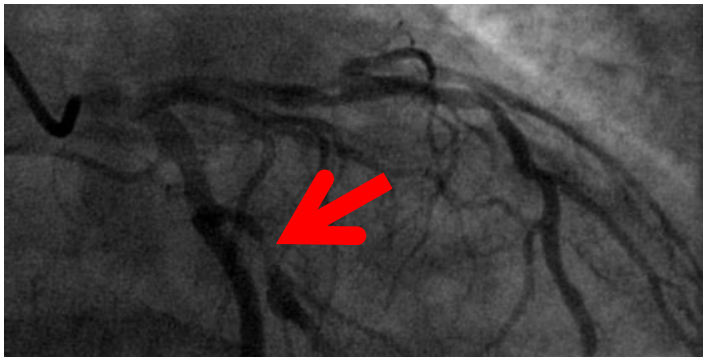

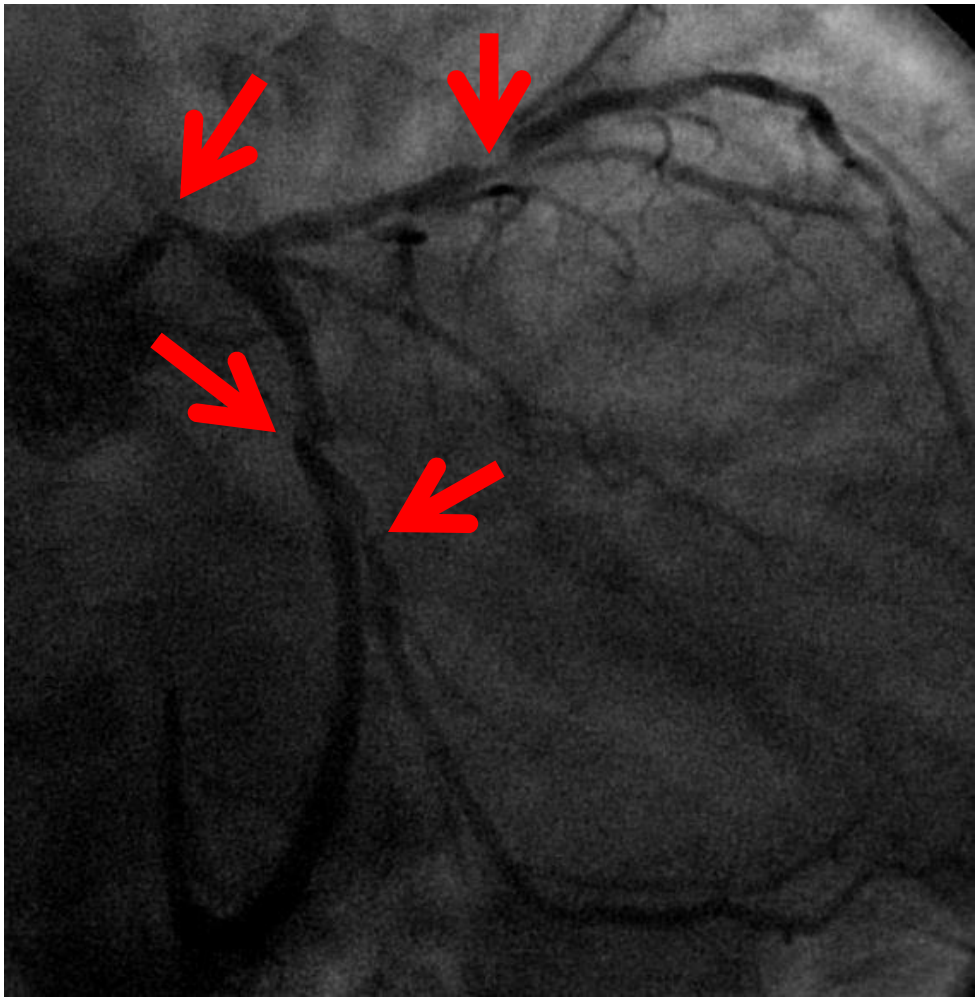

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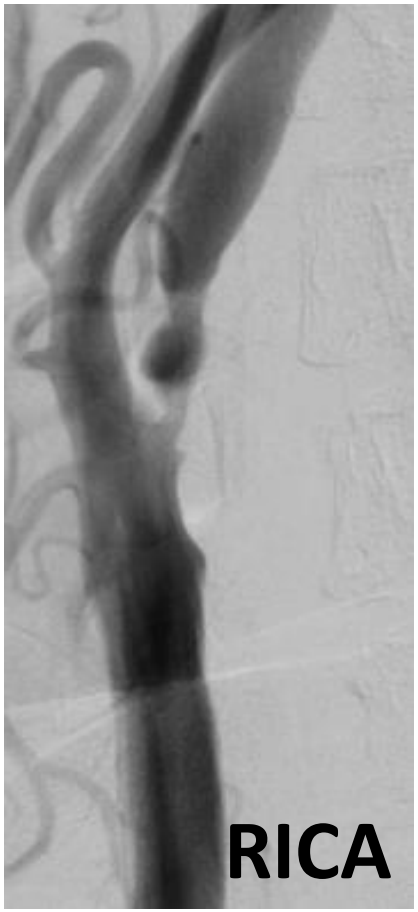

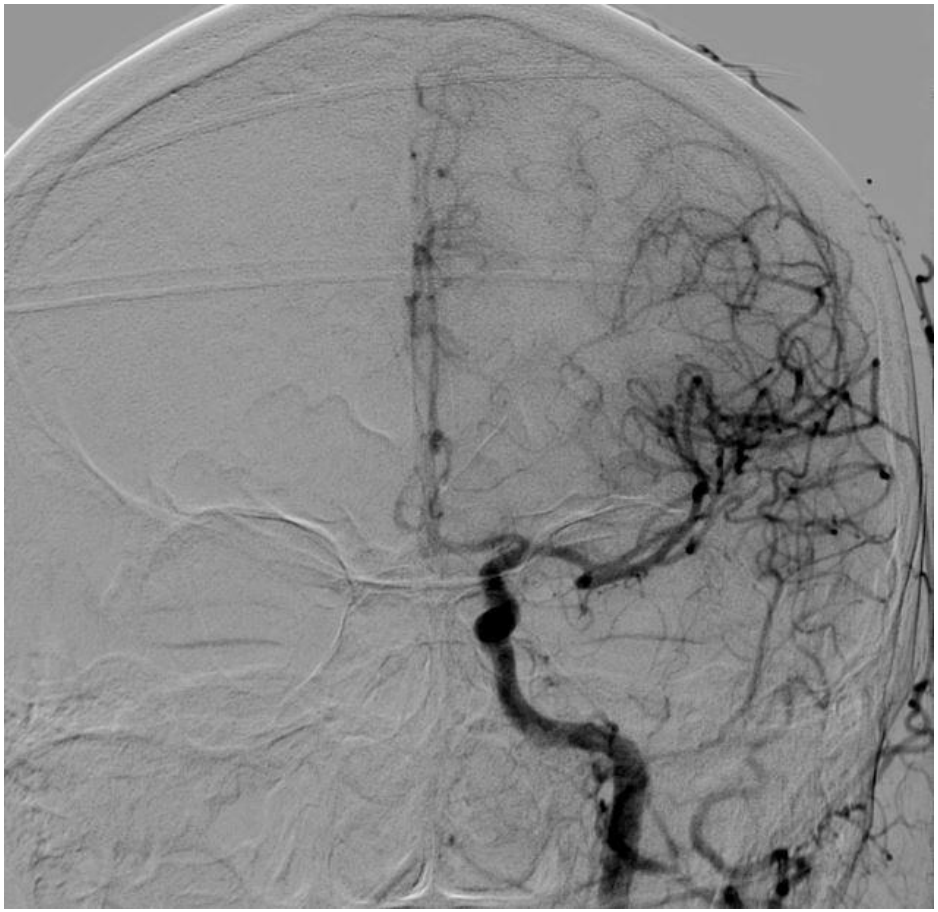

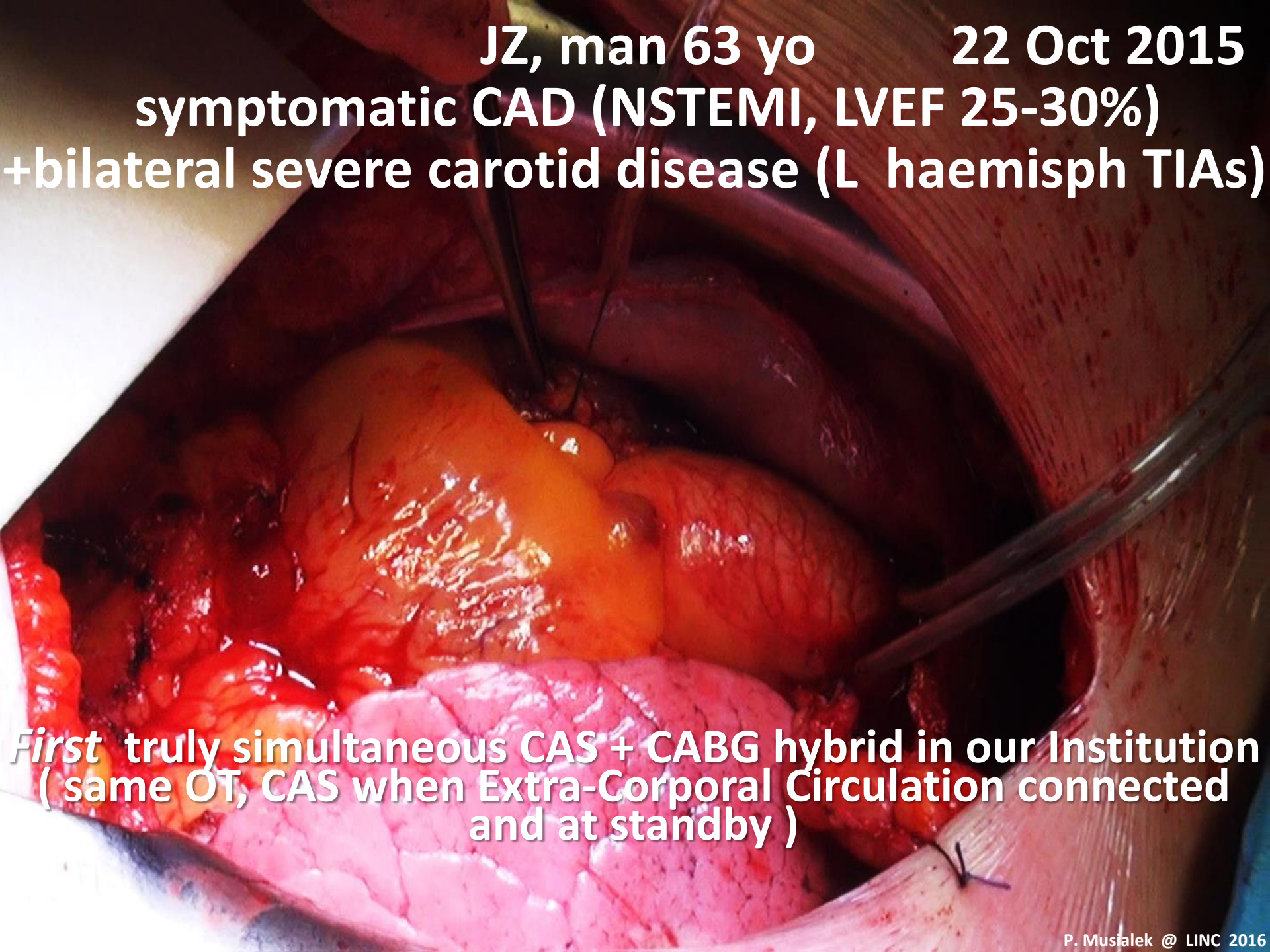
JZ, man 63 yo 22 Oct 2015
symptomatic CAD (NSTEMI, LVEF 25-30%)
+bilateral severe carotid disease (L haemisph TIAs)
First truly simultaneous CAS + CABG hybrid in our Institution
(same OT, CAS when Extra-Corporal Circulation connected
and at standby)
P. Musialek @ LINC 2016

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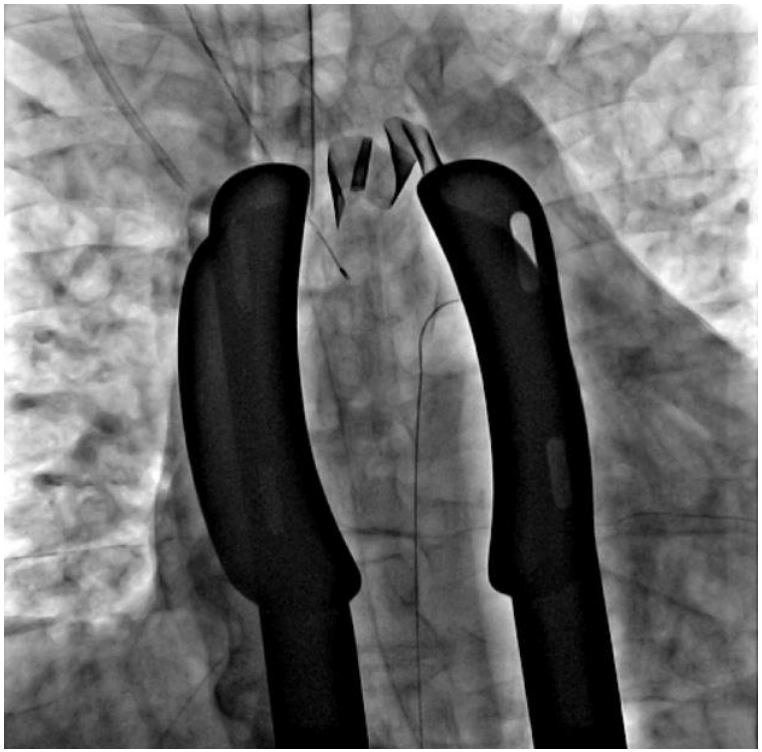

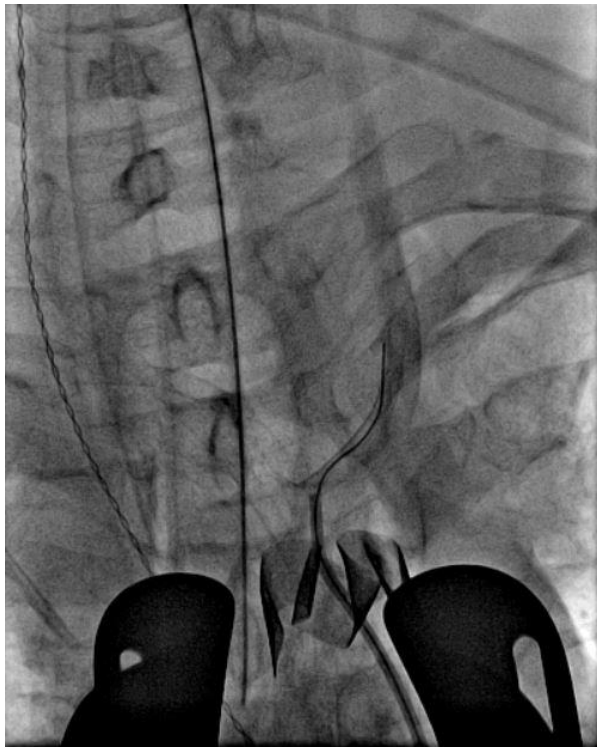

Open-chest patient

Spider-protected CAS

First **truly simultaneous CAS + CABG hybrid in our Institution**
(same OT, CAS when ECC hooked up and at standby)

JZ, man 63 yo 22 Oct 2015
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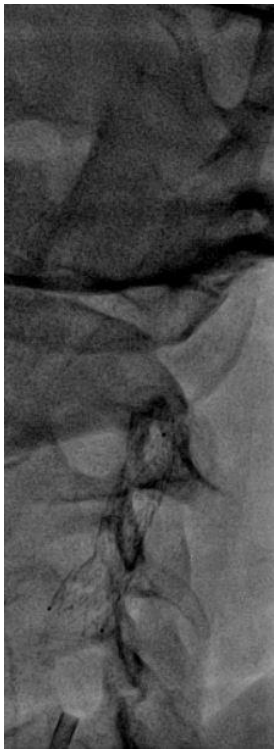

Spider-protected CAS

CGuard 8.0 x 30mm
full endovascular reconstruction

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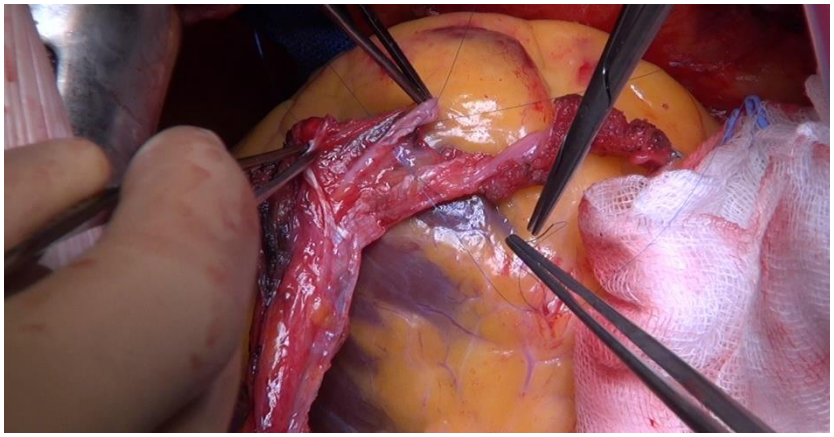
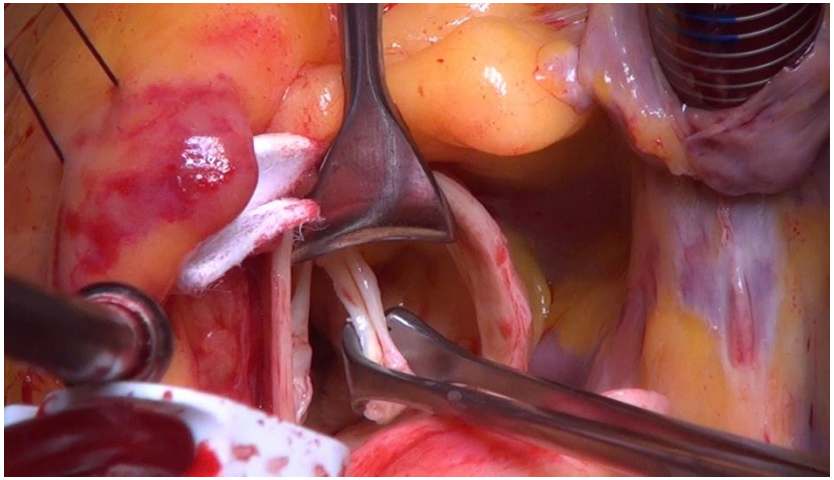




CABG

(3 grafts)

Dr Jacek Piątek
Dr Piotr Mazur

First **truly simultaneous CAS + CABG hybrid in our Institution**
(same OT, CAS when ECC hooked up and at standby)

JZ, man 63 yo 22 Oct 2015
symptomatic CAD (NSTEMI, LVEF 25-30%)
+bilateral severe carotid disease (L haemisph TIAs)

On day 5 the patient – asymptomatic and w/o any deficit – discharged to a rehab centre, 30 day follow-up uneventful; now scheduled for RICA - CAS

First **truly simultaneous CAS + CABG hybrid in our Institution (same OT, CAS when ECC hooked up and at standby)**

Study Flow Chart (2)

73 Patients for carotid revascularization

(92%) → **CAS in n=67 Patients (bilateral in 3)**

(1%) → **CAS + CEA in n=1 Patient**

(LICA-CEA and RICA-CAS) hybrid management

(7%) → **CEA in n=5 Patients**

- n=1 eGRF 14 => no contrast
- n=1 extreme access tortuousity
- n=1 severe aortic valve disease + calcific LICA (AVR+CEA)
- n=1 floating thrombus in CCA
- n=1 ICA diameter <2.0 mm +contralat. occlusion

71 ICAs treated endovascularly in 68 patients

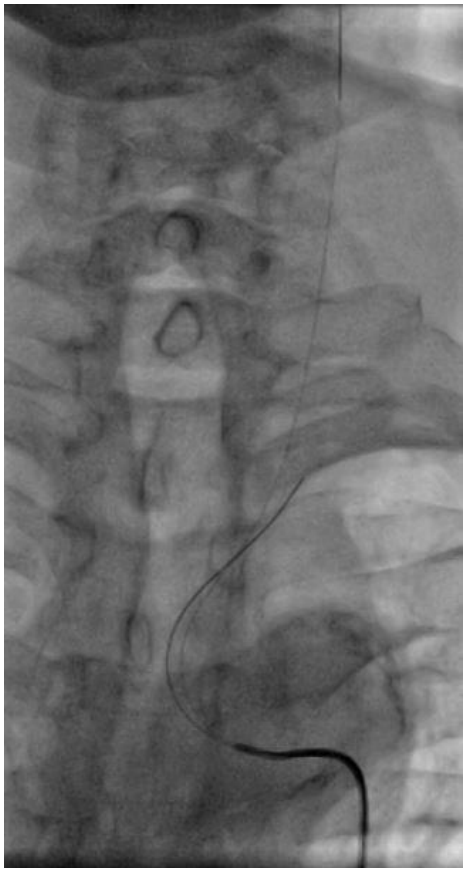
Musialek P et al. Impact of routine micronet-covered embolic prevention stent system use on contemporary carotid revascularization: All-comer PARADIGM Study. ***JACC*** 2015;66(suppl):B33

Hostile access

TW, man 69 yo

9 Dec 2015

critical LICA stenosis post stroke



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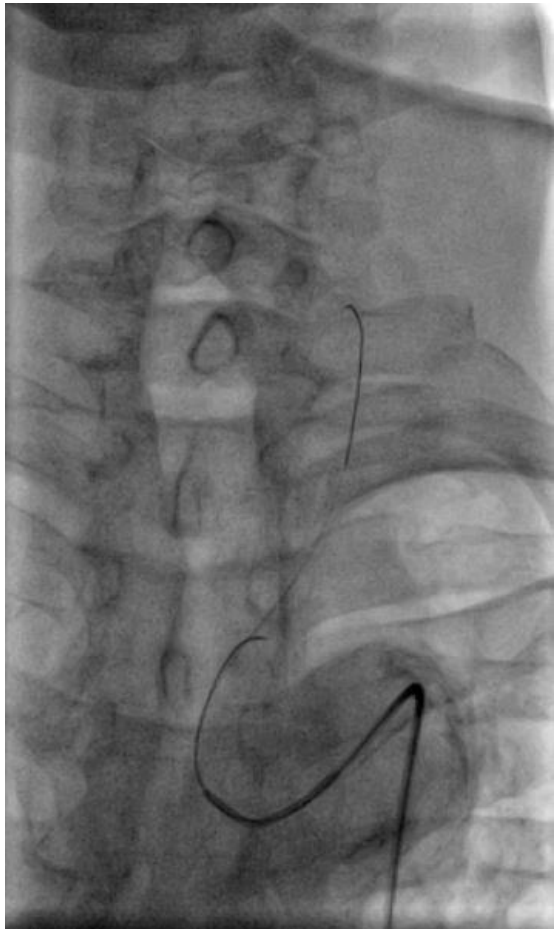

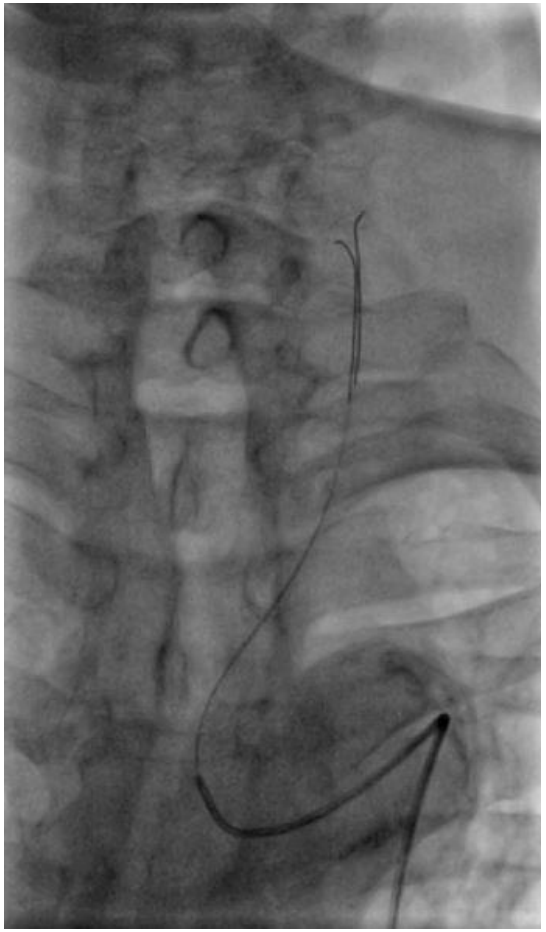

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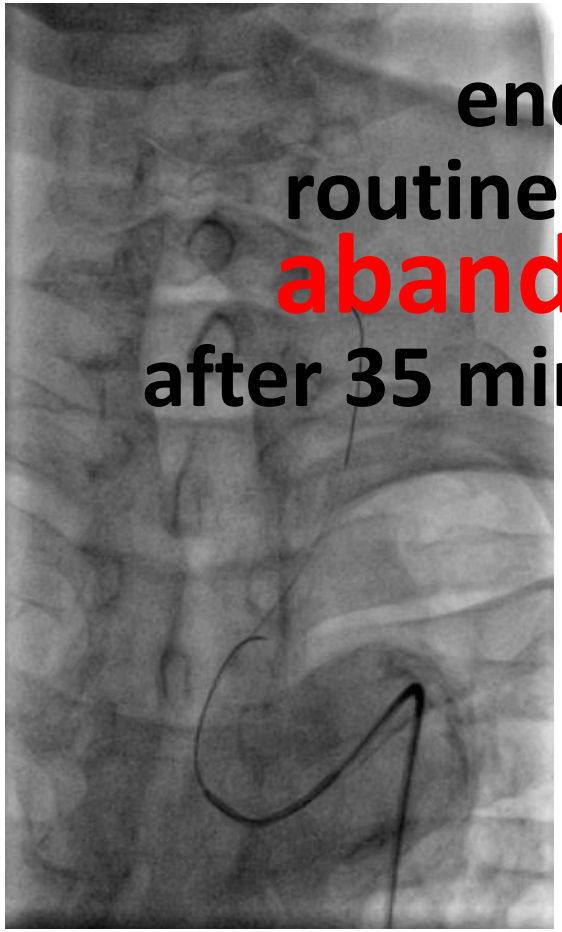
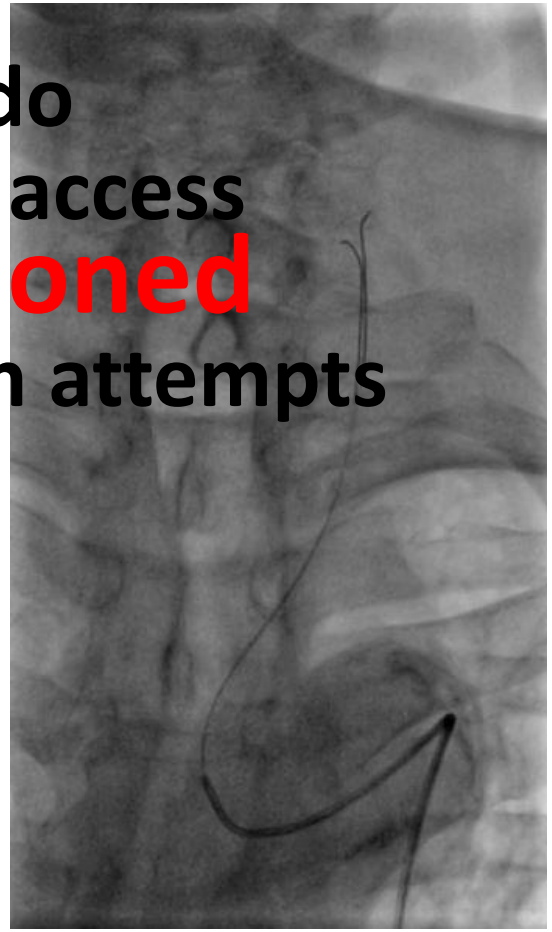
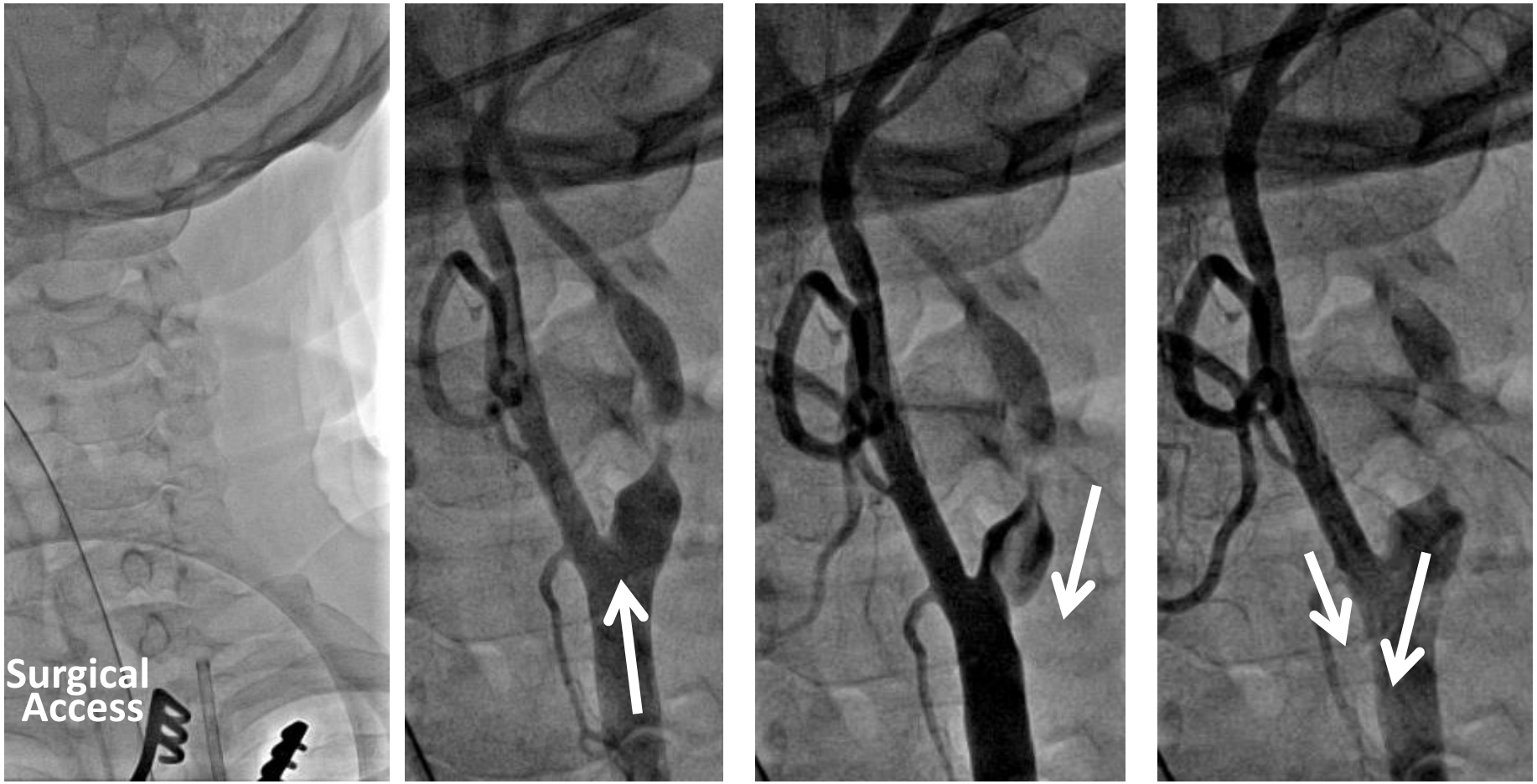


endo
routine access
abandoned
after 35 min attempts



TW, man 69 yo
critical LICA stenosis, post-stroke

12 Jan 2016



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

First-in-Poland **direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal**

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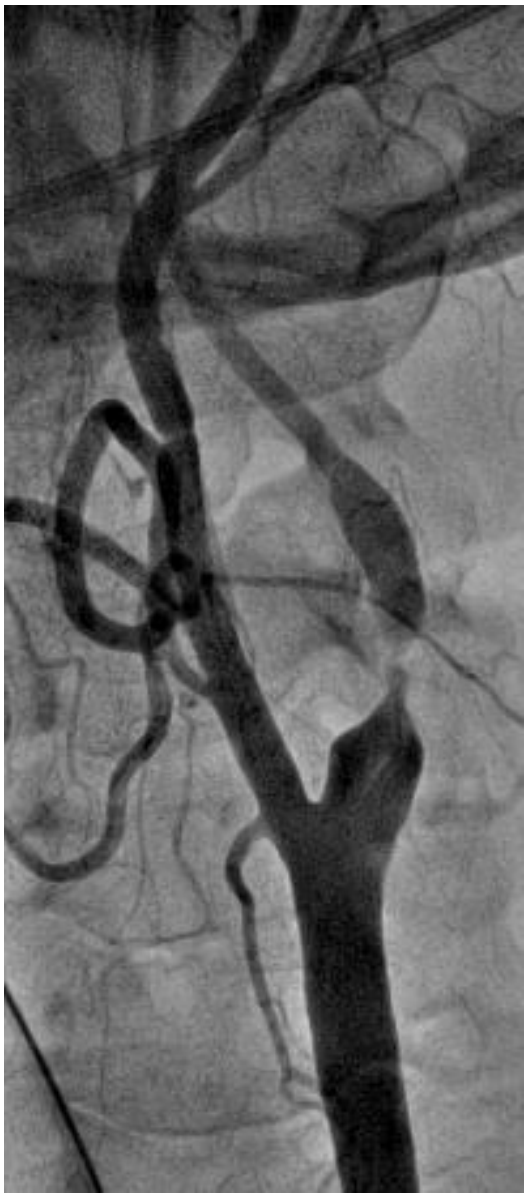
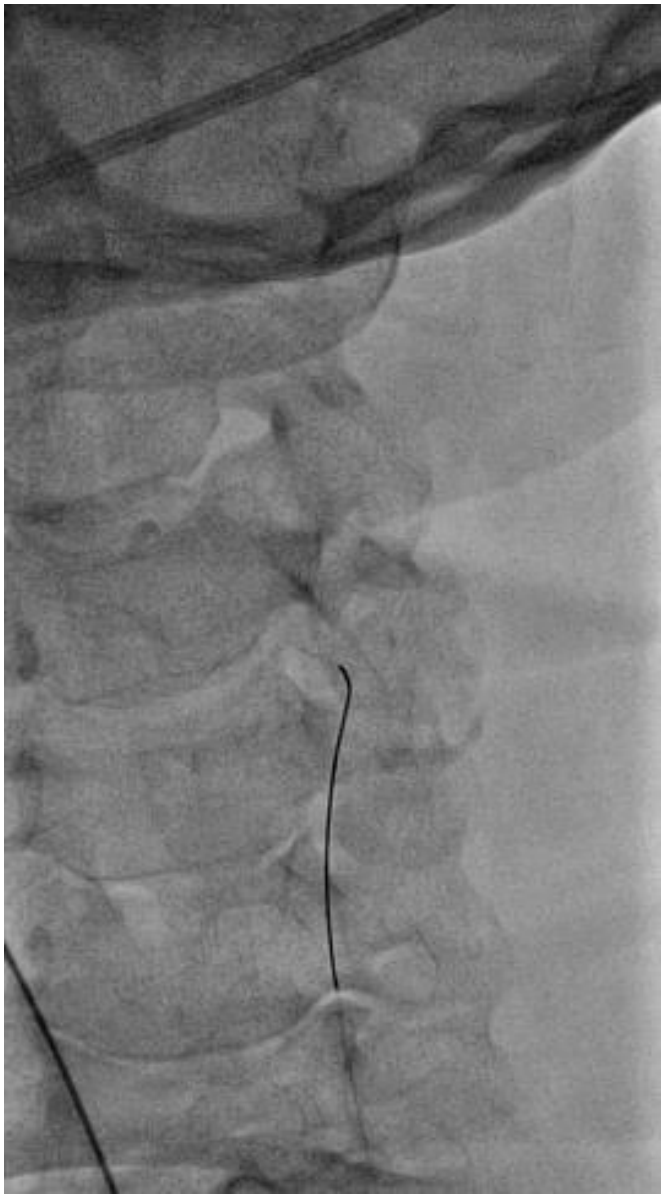
12 Jan 2016





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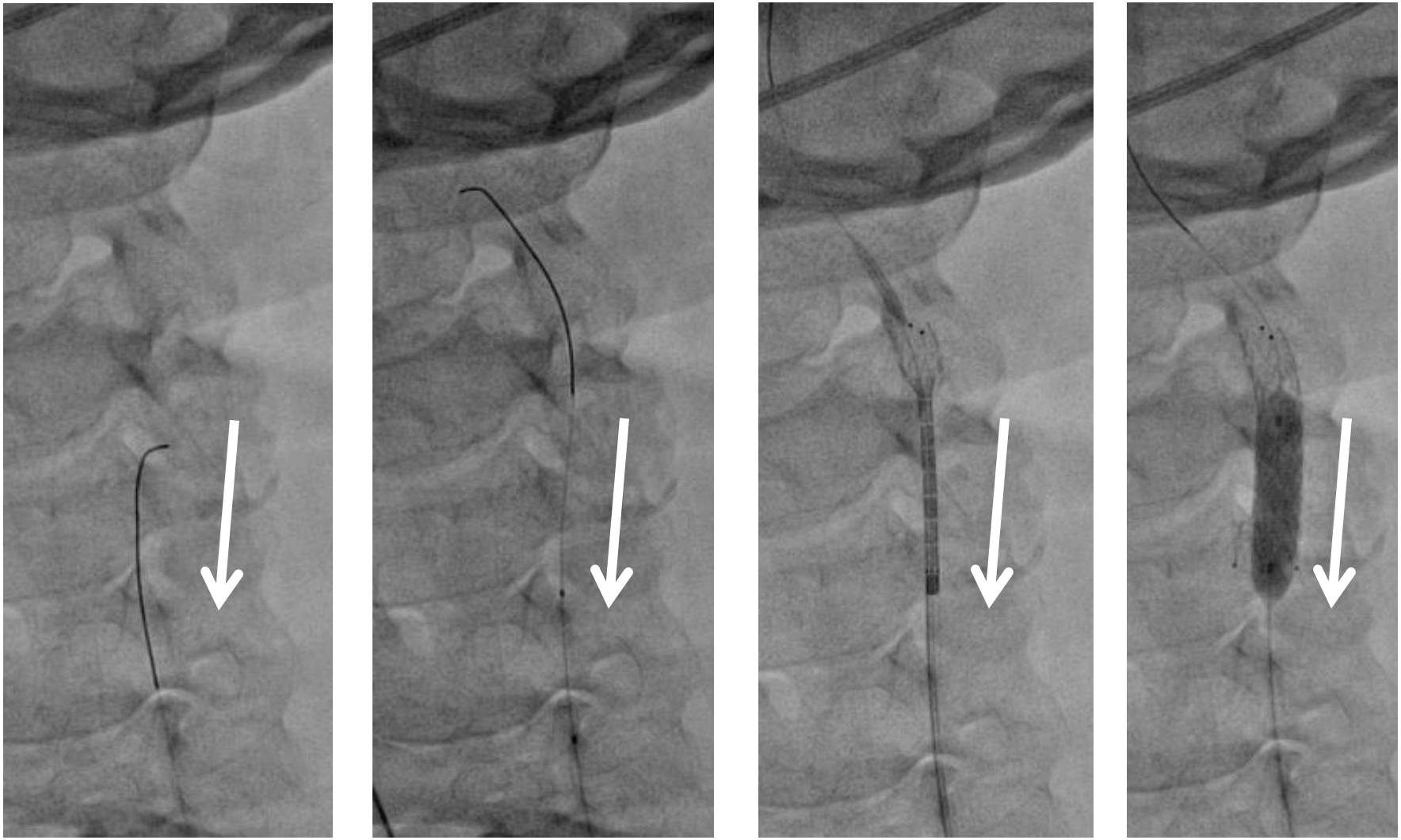

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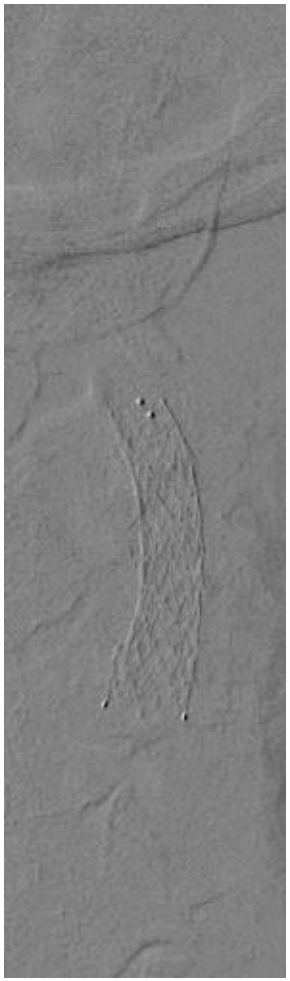

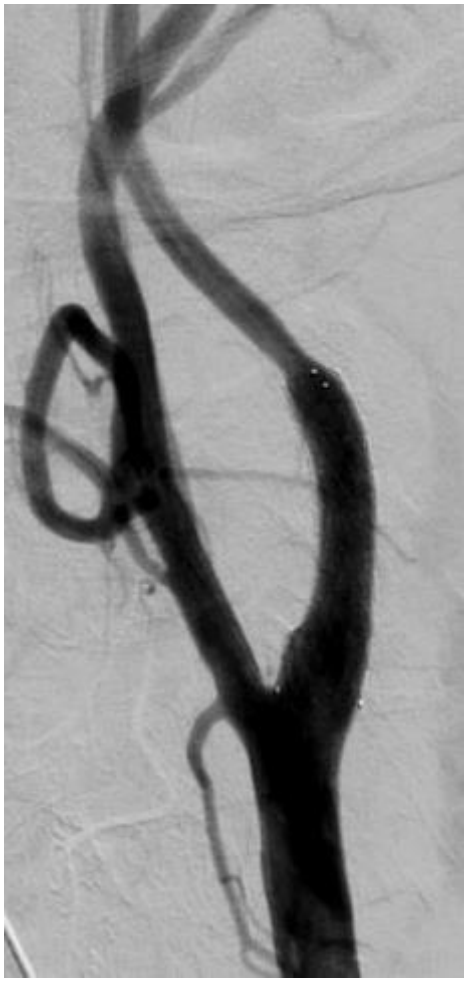

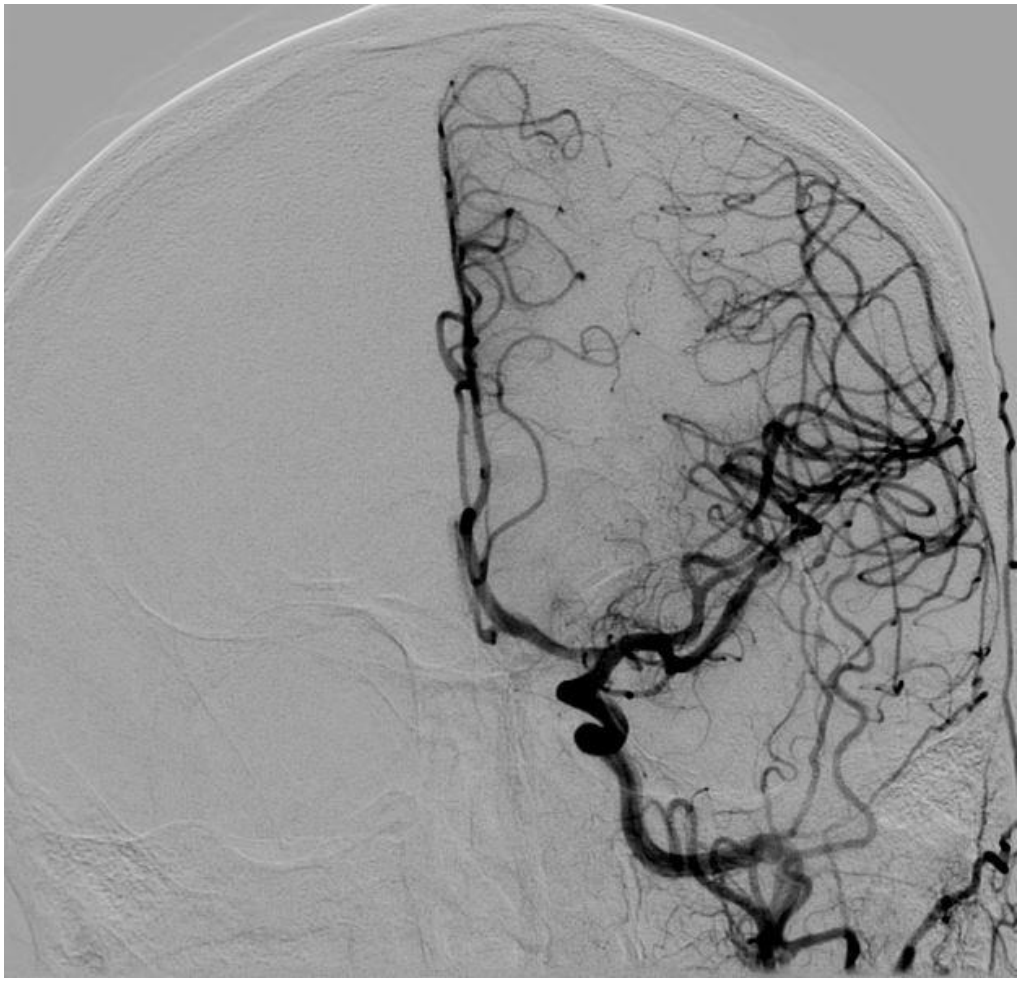

CGuard 7.0 x 30mm full endovascular reconstruction

First-in-Poland direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal

P. Musialek @ LINC 2016

TW, man 69 yo
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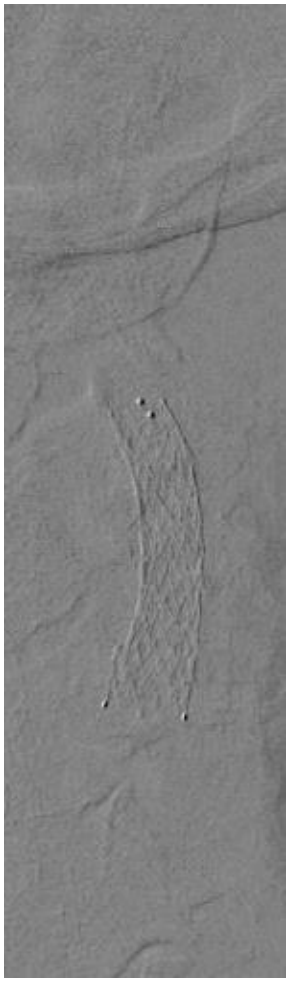
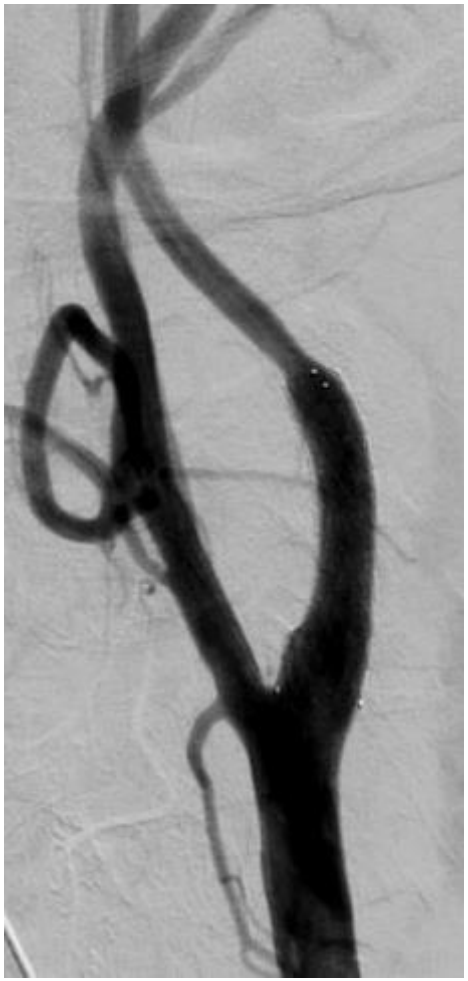
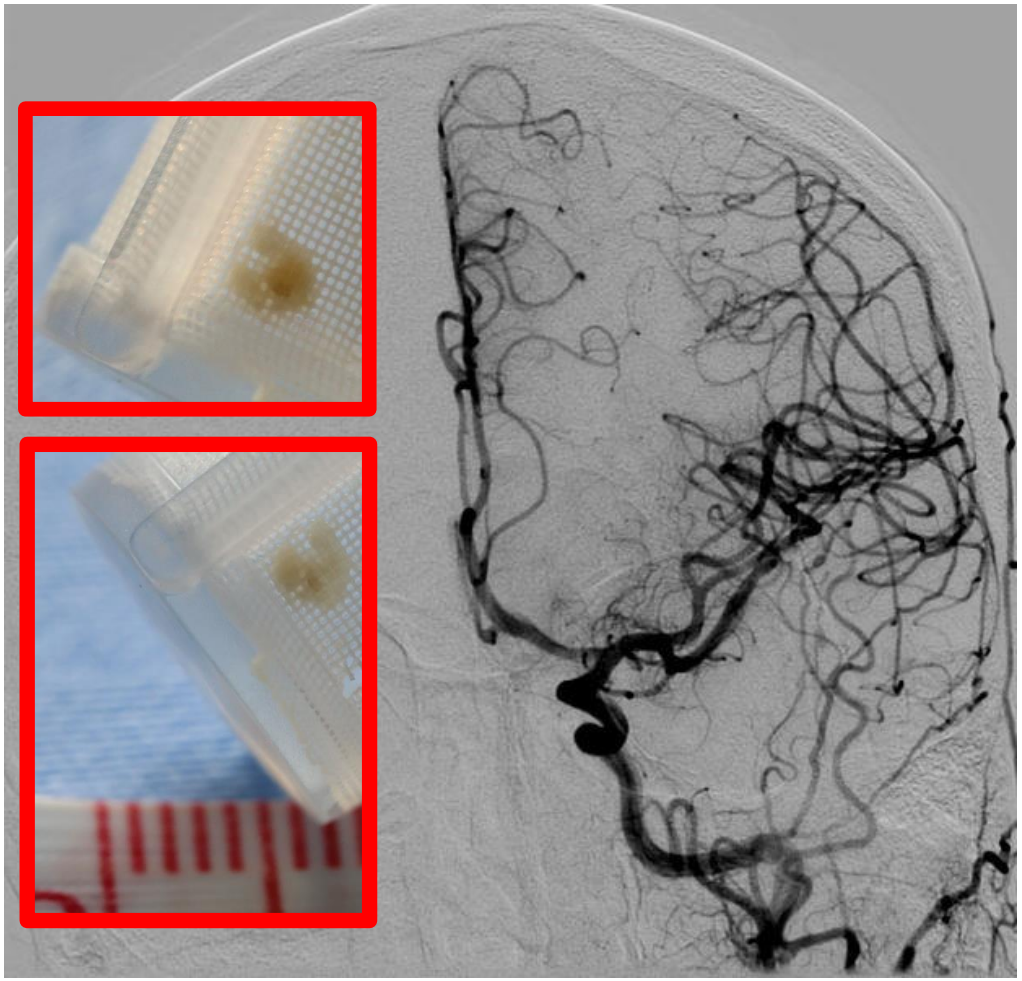
12 Jan 2016







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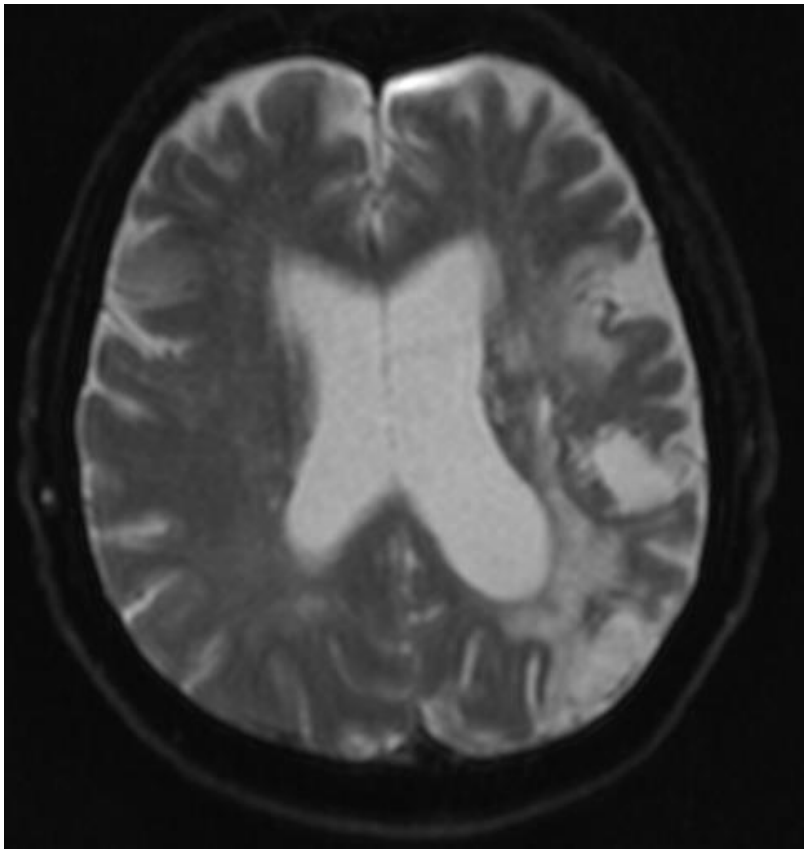
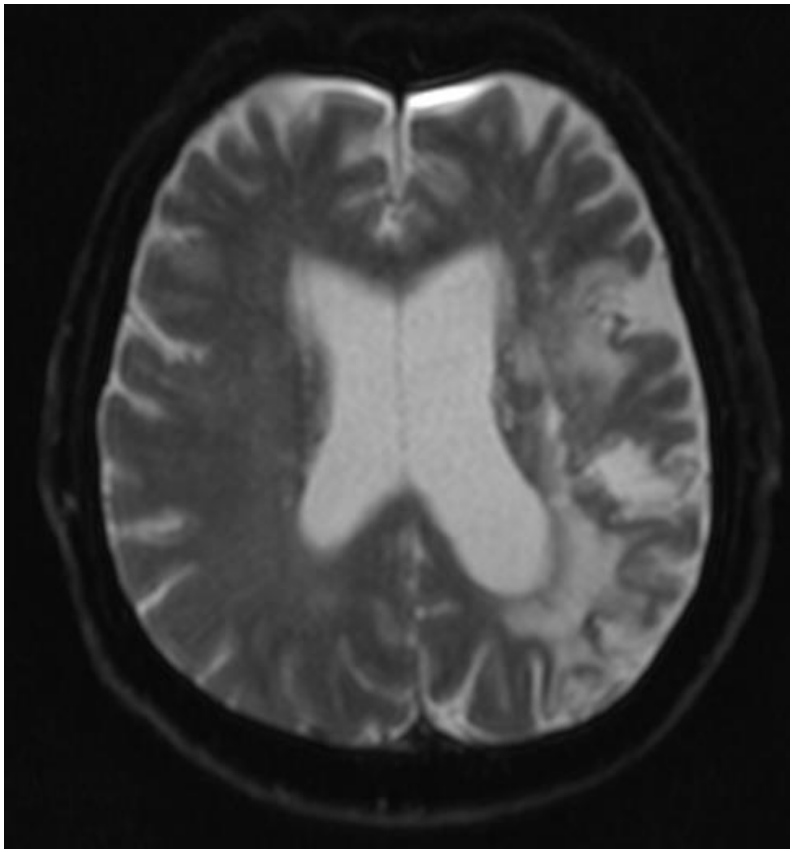
Z E R O new DWI lesions



24h prior to CAS



48h after CAS

First-in-Poland direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal + CGuard MicroNet Stent

Brain Imaging: M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow

P. Musialek @ LINC 2016

TW, man 69 yo
critical LICA stenosis, post-stroke

12 Jan 2016

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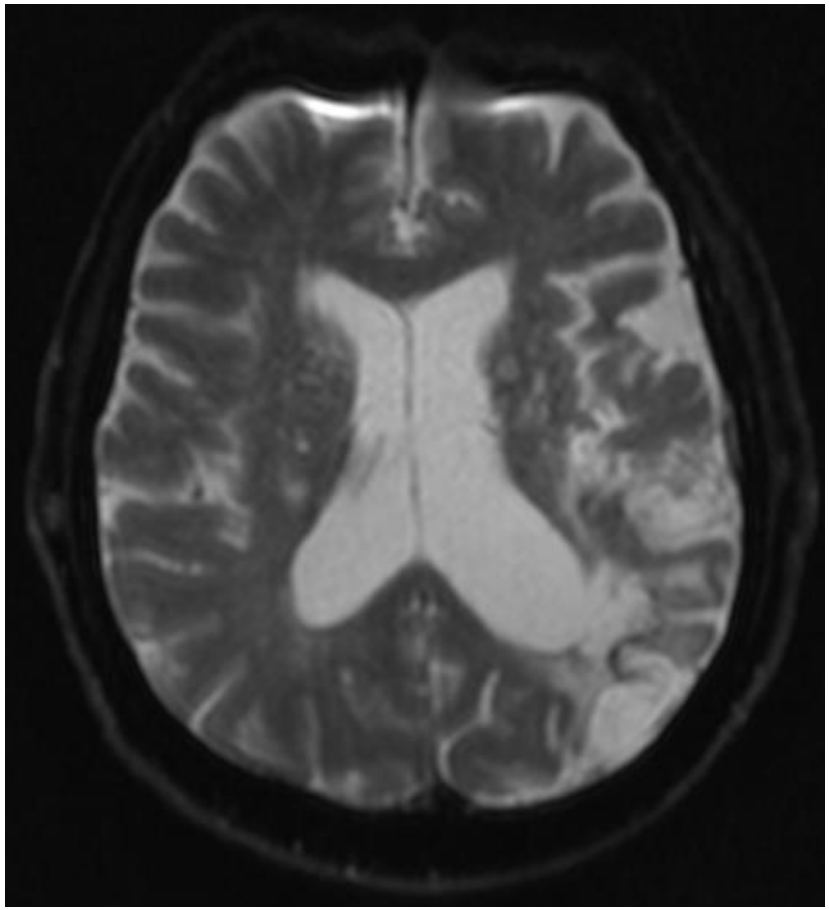

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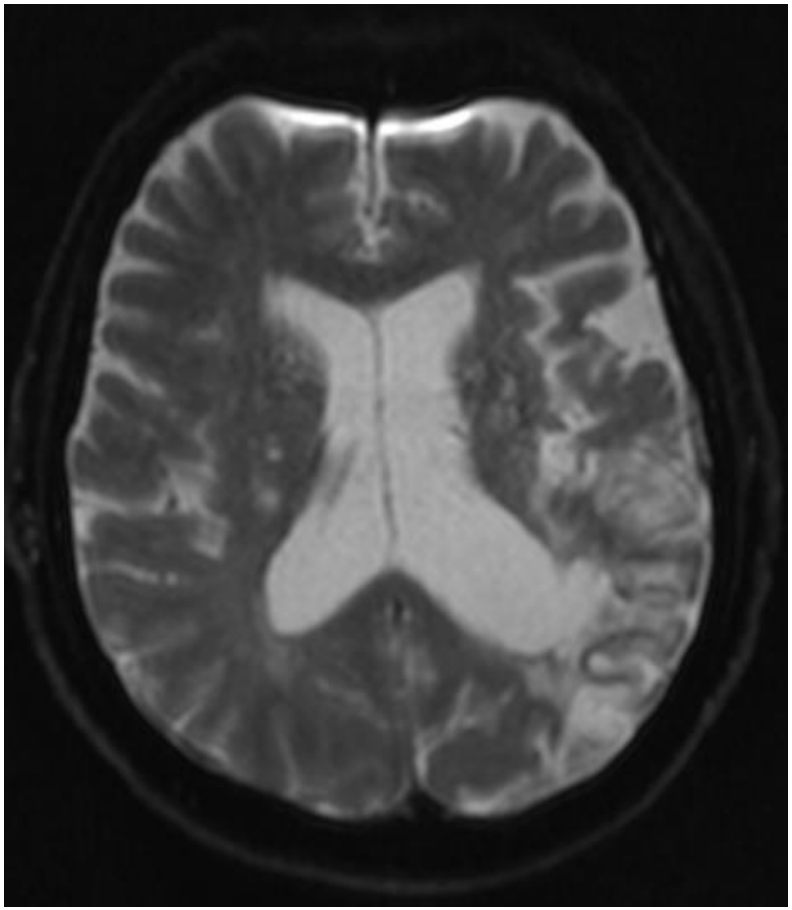

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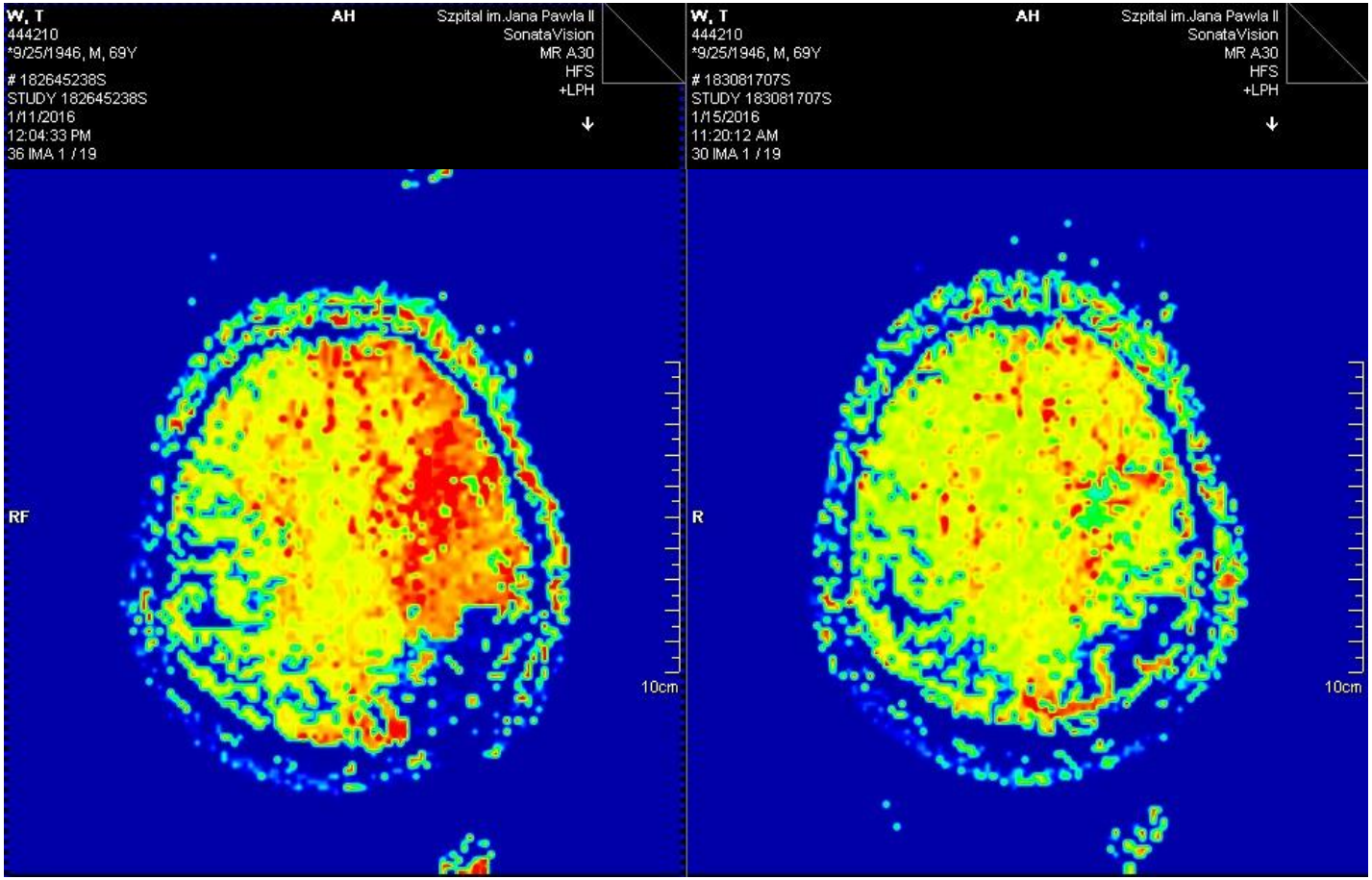
TW, 69 y, L haemispheric stroke with haemorragic transformation Feb 2015

En Route plus **CGuard** (Krakow, 12 January 2016)

Profound improvement of L hemipheric viable tissue perfusion



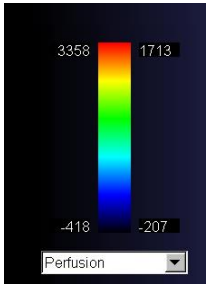
24h prior to CAS **48h after CAS**

TTP

Time-To-Peak Flow

red is prolongued

yellow shows fast



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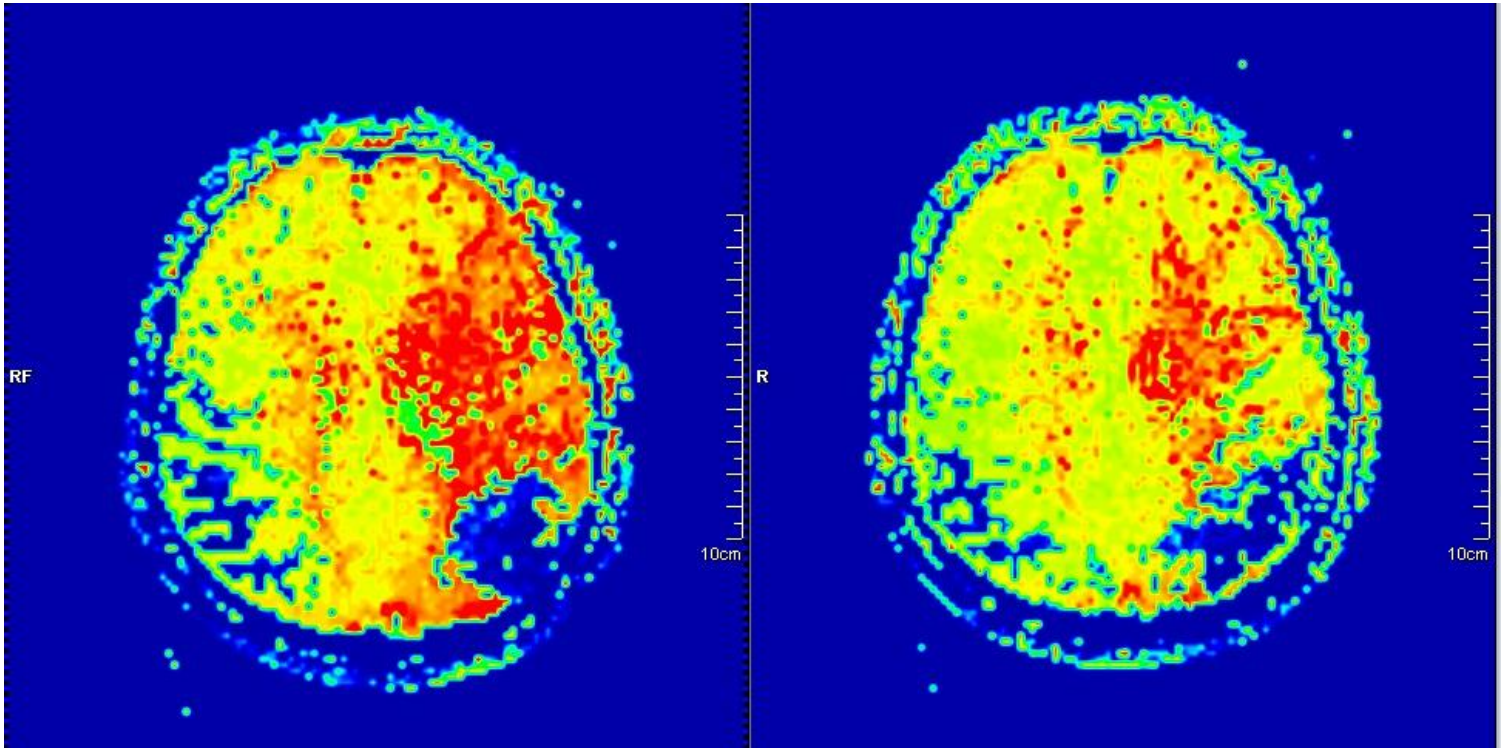

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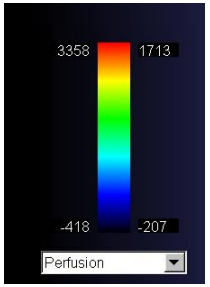

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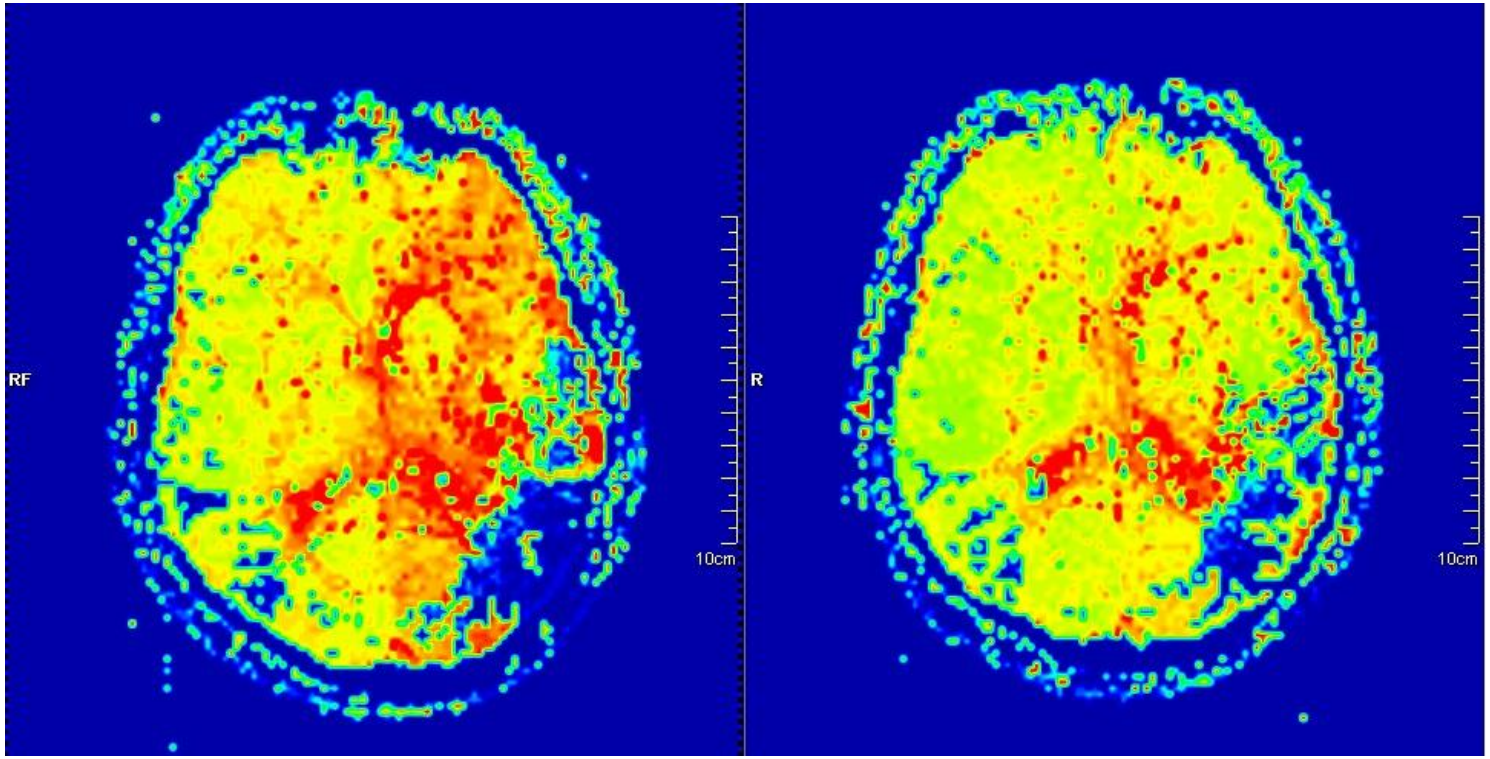

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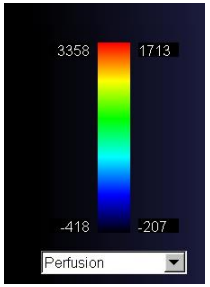

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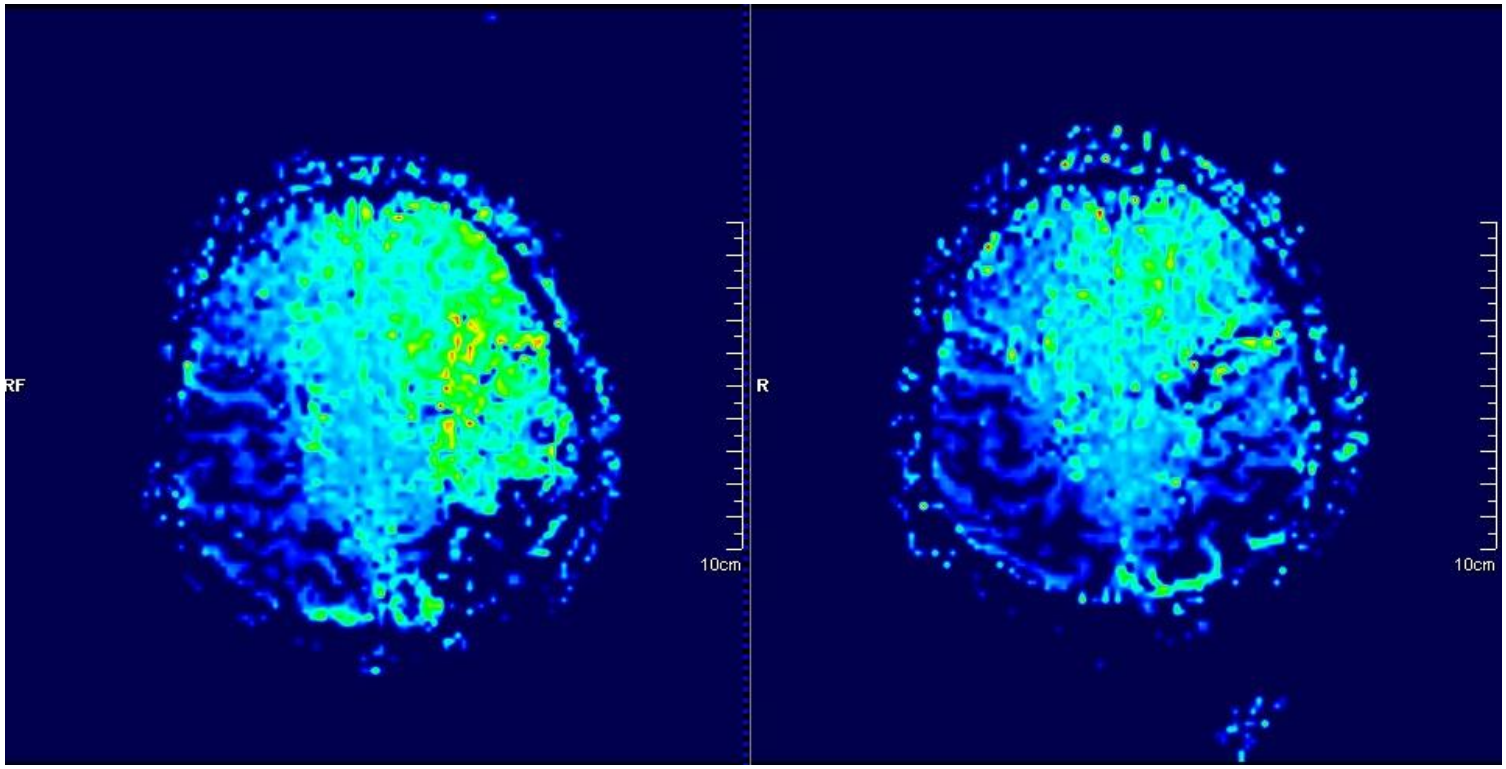
MTT

Mean Transit Time



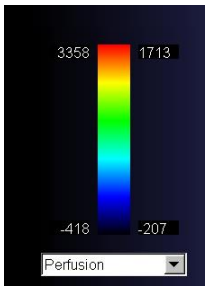
yellow

green

is prolongued

blue

shows fast



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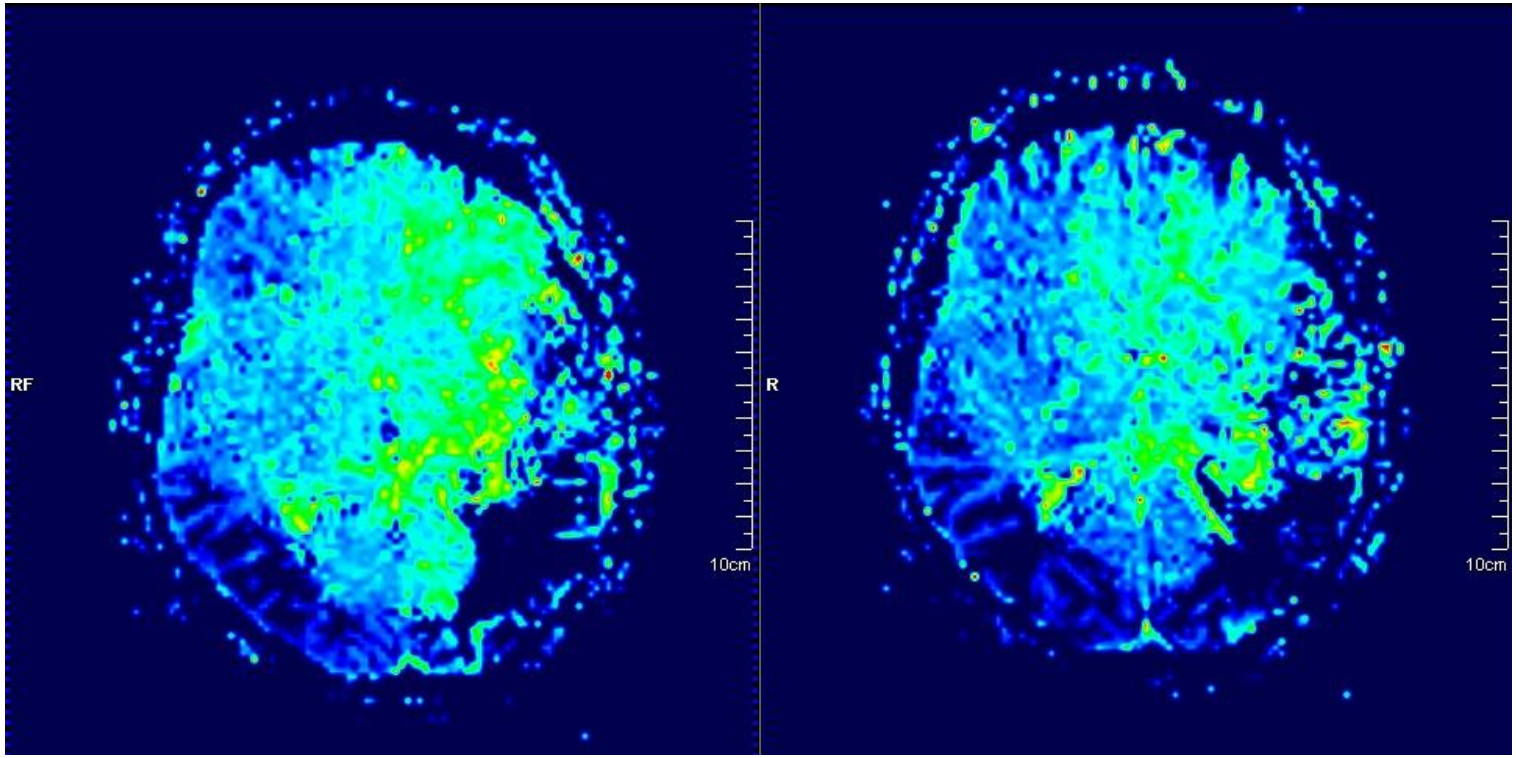
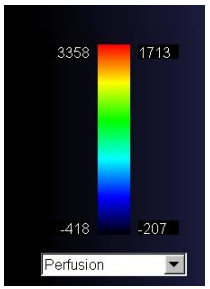


24h prior to CAS **48h after CAS**

yellow
green
is prolongued

blue
shows fast



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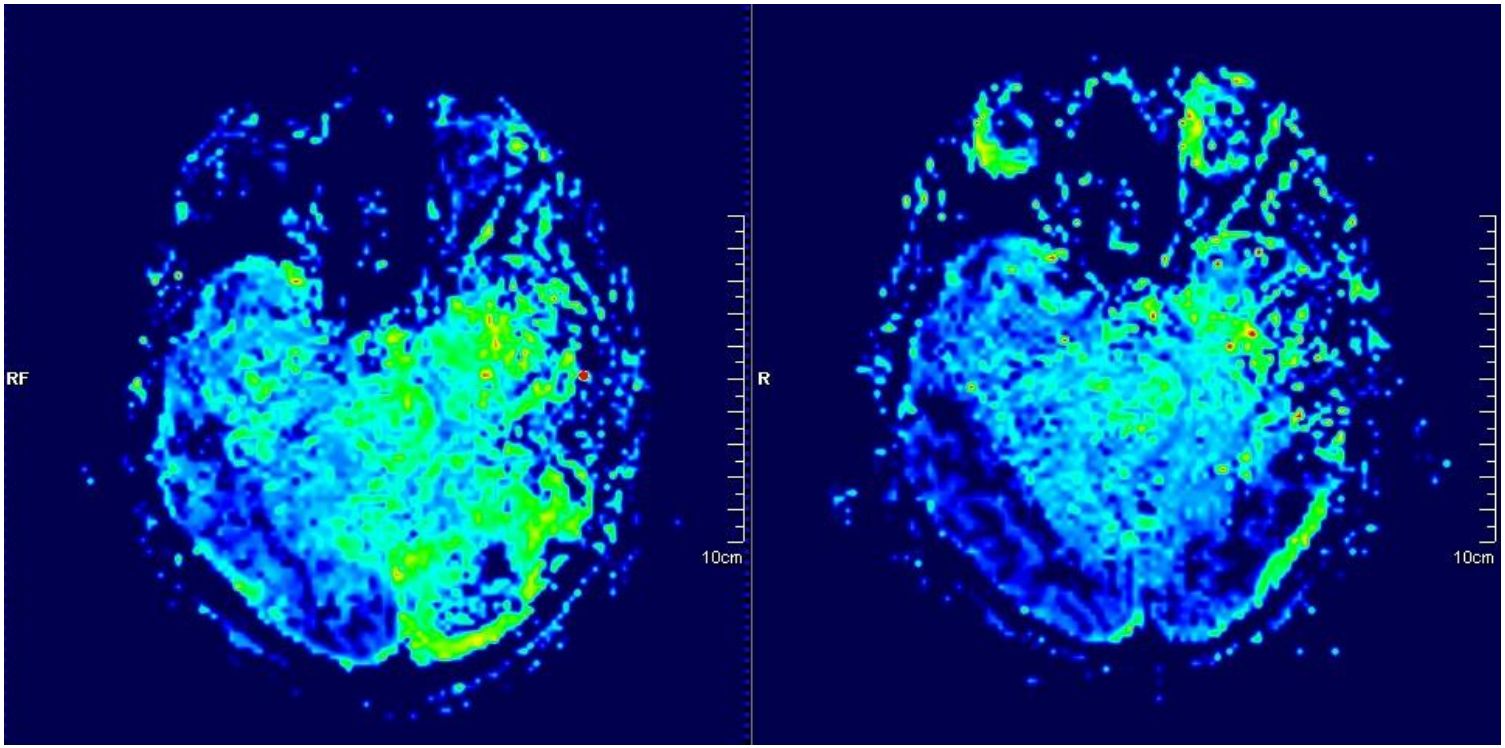

yellow
green
is prolongued

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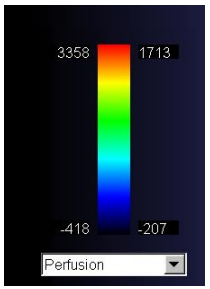
shows fast



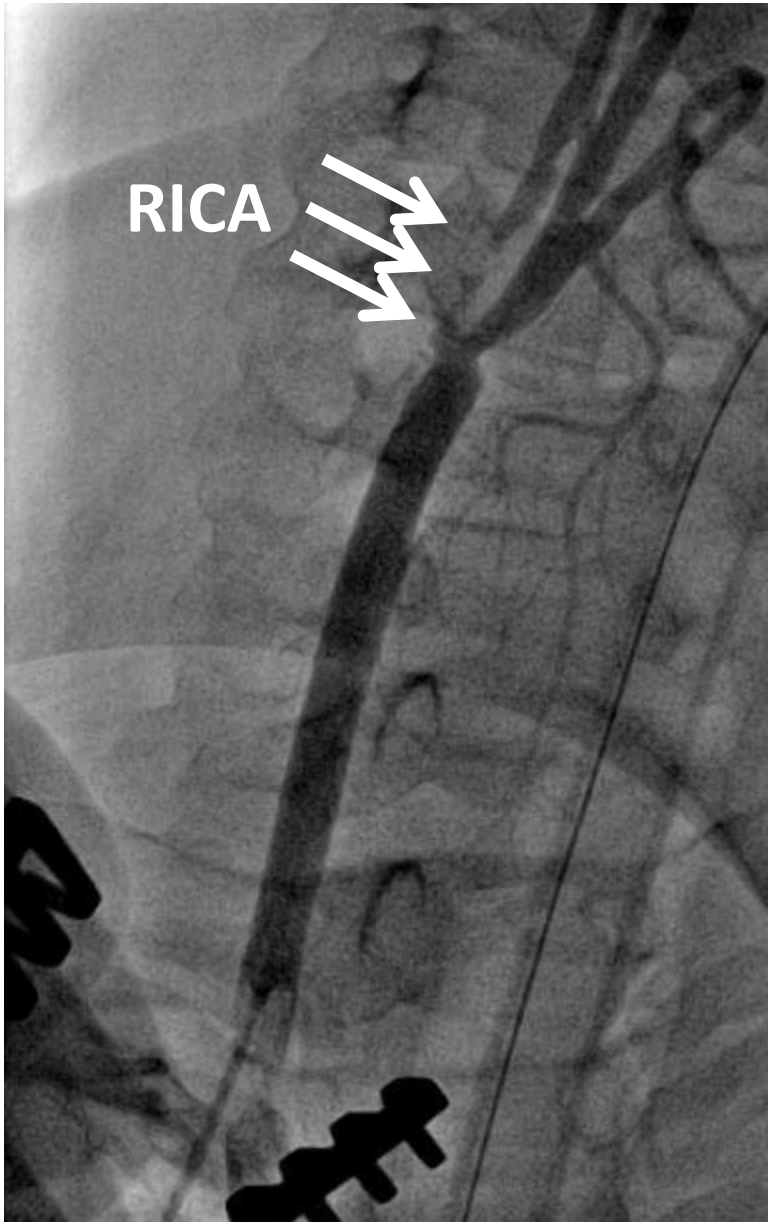
24h prior to CAS **48h after CAS**

Images: M. Urbanczyk & RP. Banys, Dept. of Radiology, John Paul II Hospital, Krakow

WE, woman, 58 y, **R** haemispheric minor stroke on 22 Dec and 30 Dec 2015

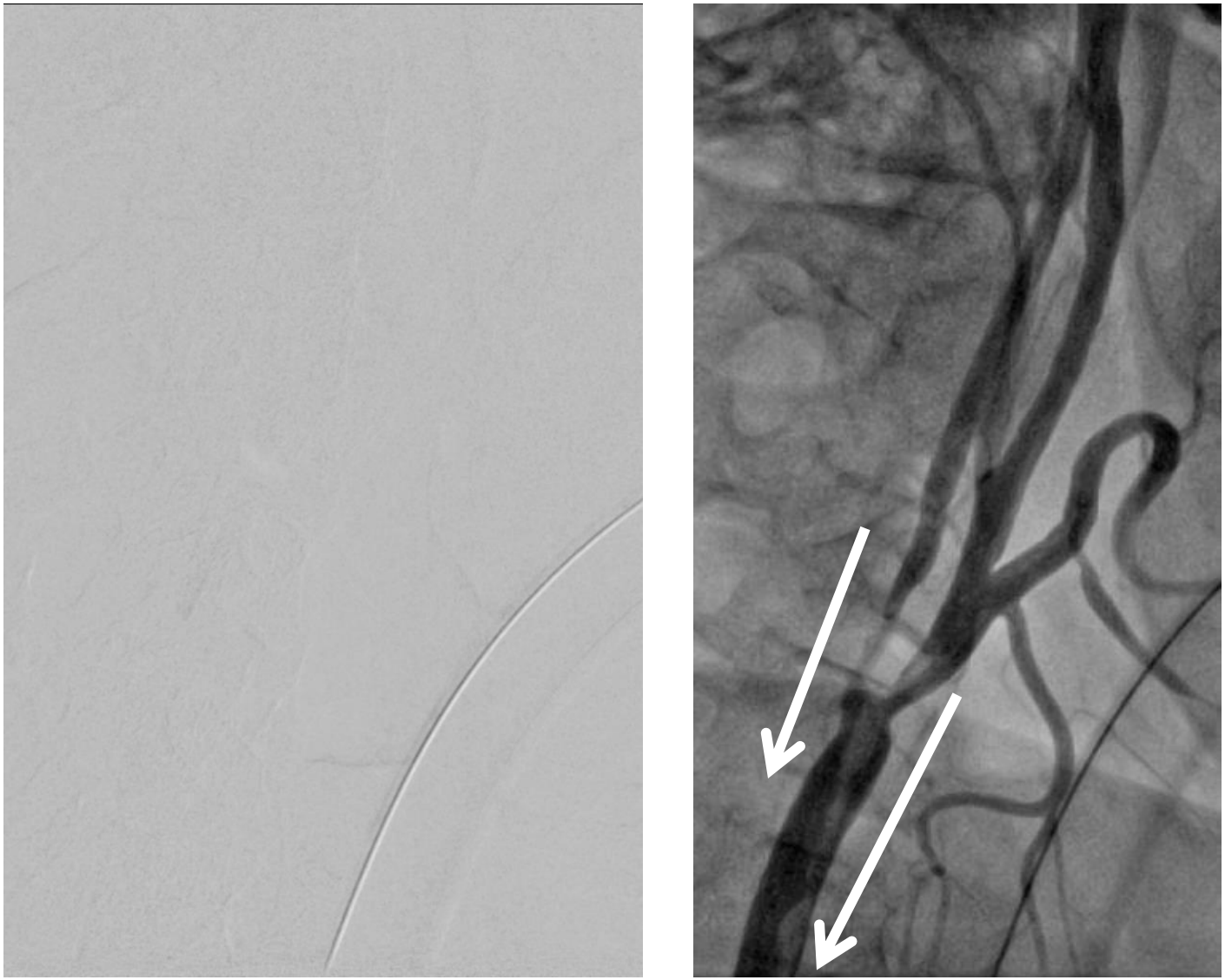
WE, woman, 58 y, **R** haemispheric minor stroke 22 Dec and 30 Dec 2015

En Route plus **CGuard** (Krakow, 12 January 2016)



WE, woman, 58 y, **R** haemispheric minor stroke 22 Dec and 30 Dec 2015

En Route plus **CGuard** (Krakow, 12 January 2016)



En Route (SilkRoad Medical) Flow Reversal

WE, woman, 58 y, **R** haemispheric minor stroke 22 Dec and 30 Dec 2015

En Route plus **CGuard** (Krakow, 12 January 2016)

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

WE, woman, 58 y, **R** haemispheric minor stroke 22 Dec and 30 Dec 2015

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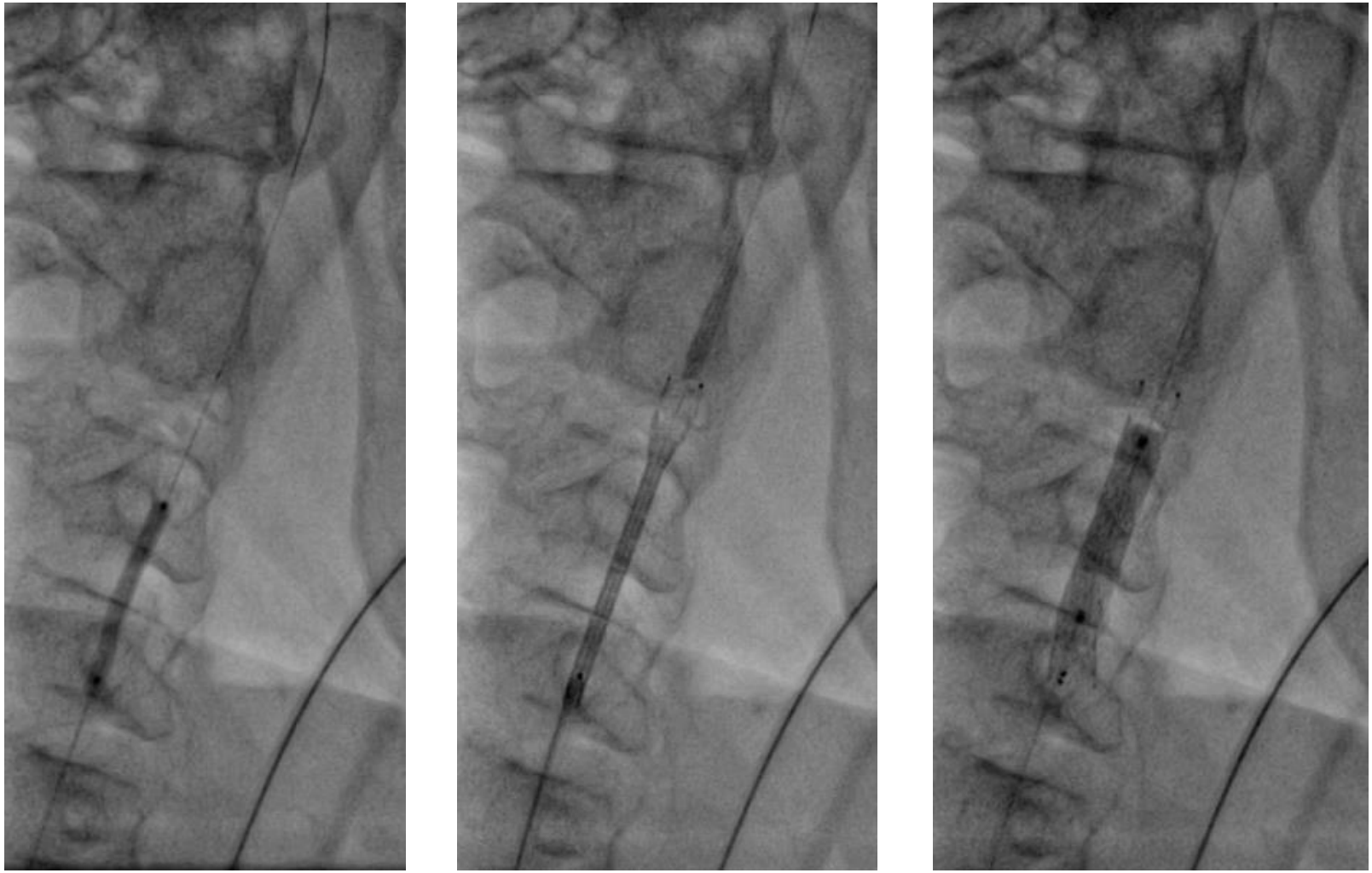

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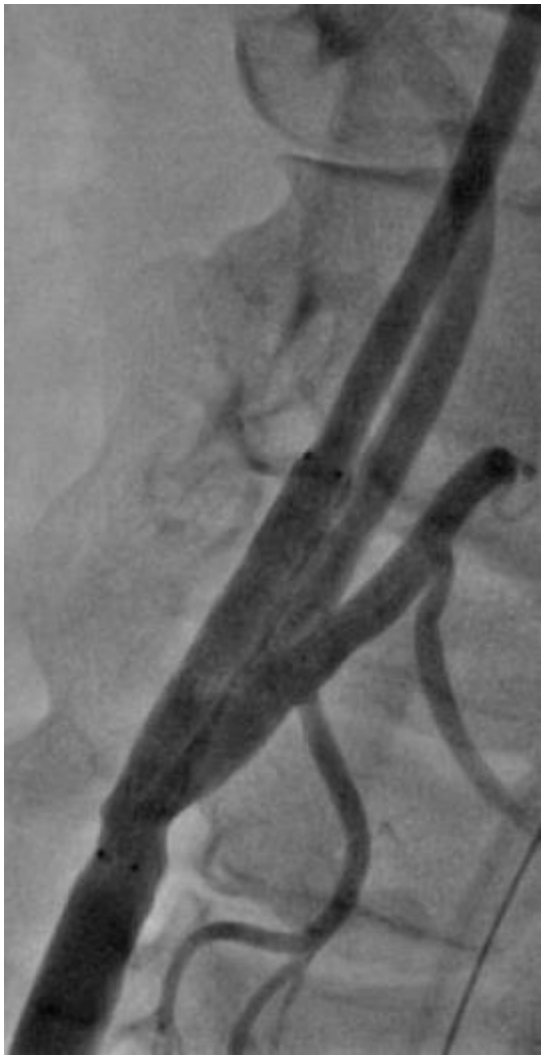
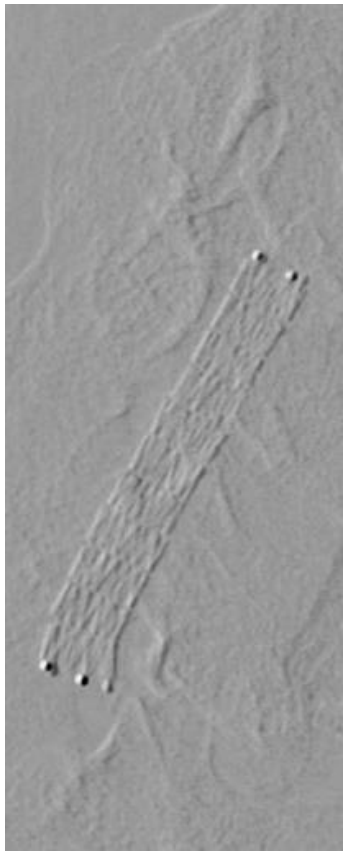
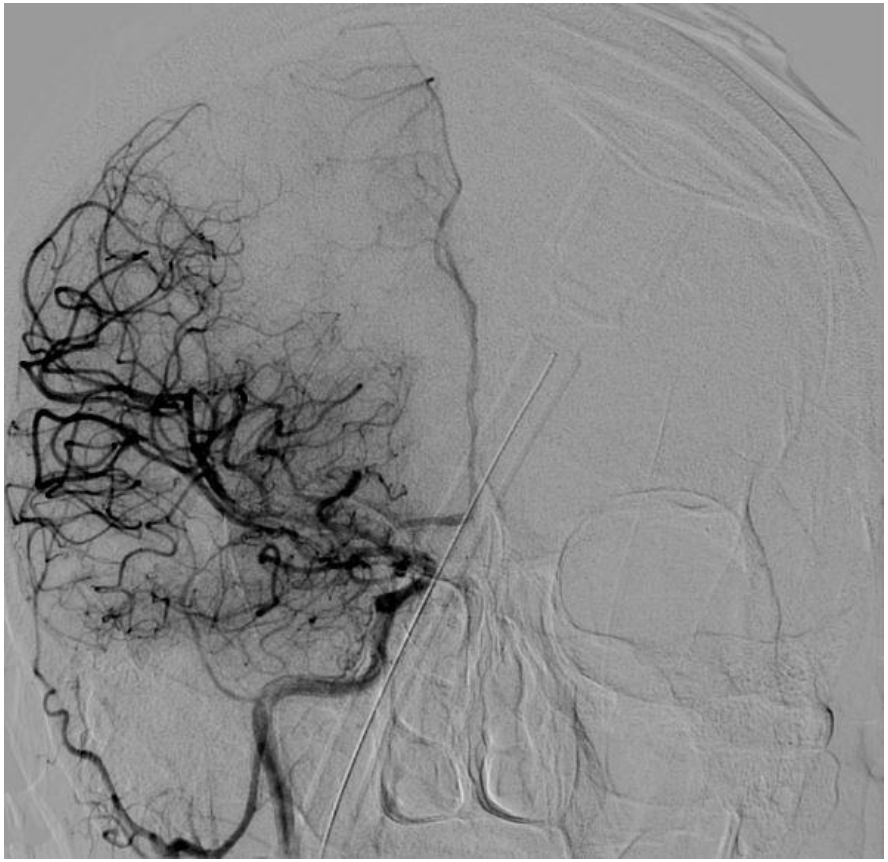


Final Result





CGuard 7.0x30 mm **full endovascular reconstruction**

plus NO new lesions on DW-MRI !

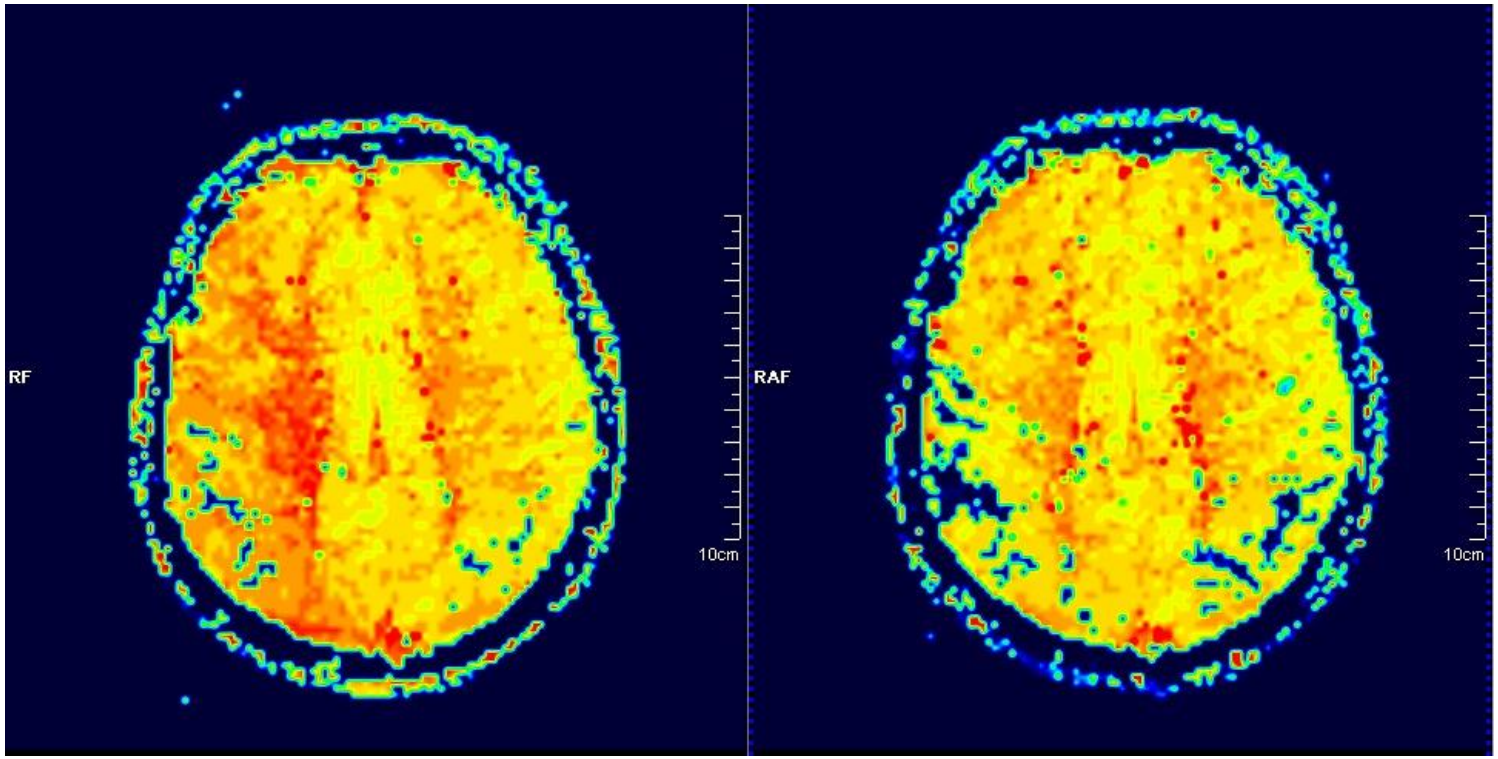
WE, woman, 58 y, **R** haemispheric minor stroke 22 Dec and 30 Dec 2015

En Route plus **CGuard** (Krakow, 12 January 2016)

TTP

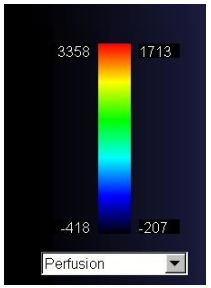
Time-To-Peak Flow

Profound improvement in R hemipheric perfusion



red is prolongued

yellow shows fast



24h prior to CAS **48h after CAS**

Images: M. Urbanczyk & RP. Banys, Dept. of Radiology, John Paul II Hospital, Krakow

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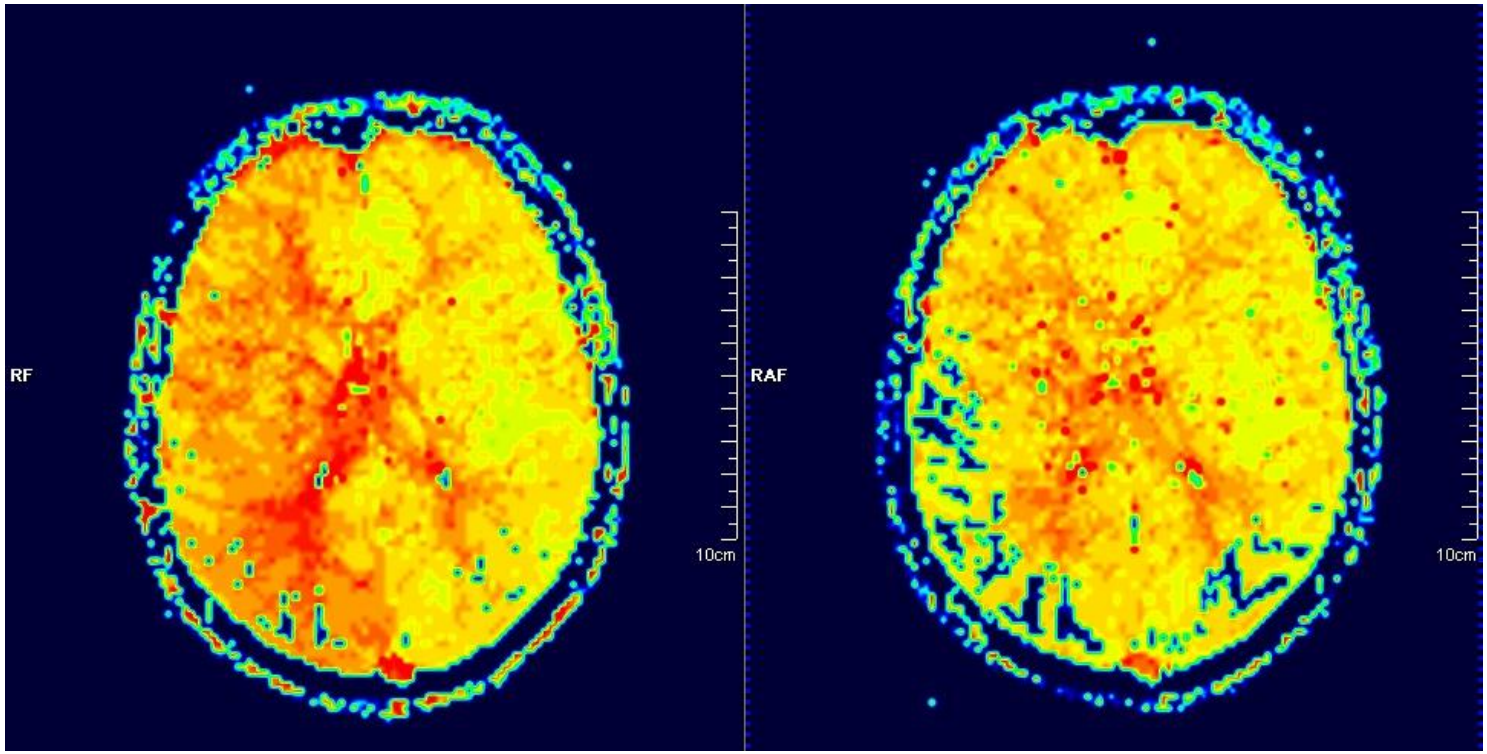

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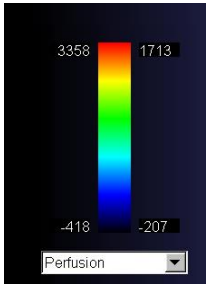

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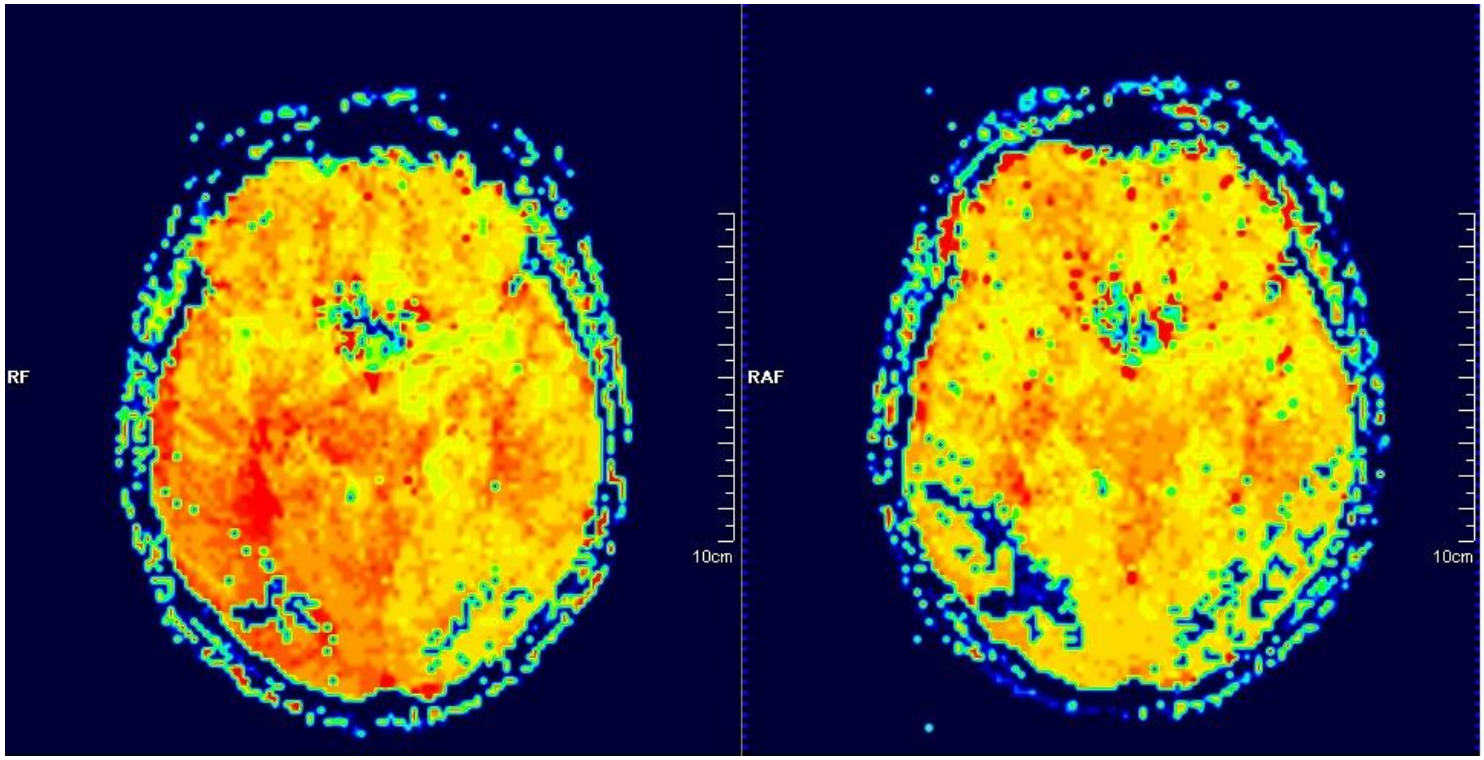

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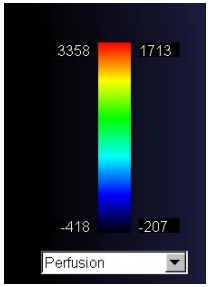

Images: M. Urbanczyk & RP. Banys, Dept. of Radiology, John Paul II Hospital, Krakow

CAS 2010 VISION

Kosmas I. Paraskevas, MD,[a] Dimitri P. Mikhailidis, MD, FFPM, FRCPath, FRCP,[b] and
Frank J. Veith, MD, FACS,[c,d] *Athens, Greece; London, United Kingdom; Cleveland, Ohio; and New York, NY*

Improved technology for CAS — better EPDs (flow reversal and proximal occlusion) and better stents (membrane-covered, ultra-closed cell, and biodegragable). Several issues may improve CAS outcomes, such as the introduction of new and better stents. An ex vivo study showed that use of a polyurethane membrane-covered stent resulted in lower cerebral embolization rates.[69]

JOURNAL OF VASCULAR SURGERY
November 2010

CGuard Embolic-Prevention Stent Image Courtesy Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, Univerity of Barcelona

Carotid Revascularization 2016+ REALITY

CAS 2010 VISION

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Perceptual Imaging Lab, Univerity of Barcelona

LEIPZIG INTERVENTIONAL COURSE

LINC 2016

Carotid artery revascularization using CGuard™ MicroNet-Covered Embolic Prevention Stent System: A Change in the Game

Piotr Musialek, MD DPhil FESC

Jagiellonian University Dept. of Cardiac & Vascular Diseases
John Paul II Hospital, Krakow, Poland