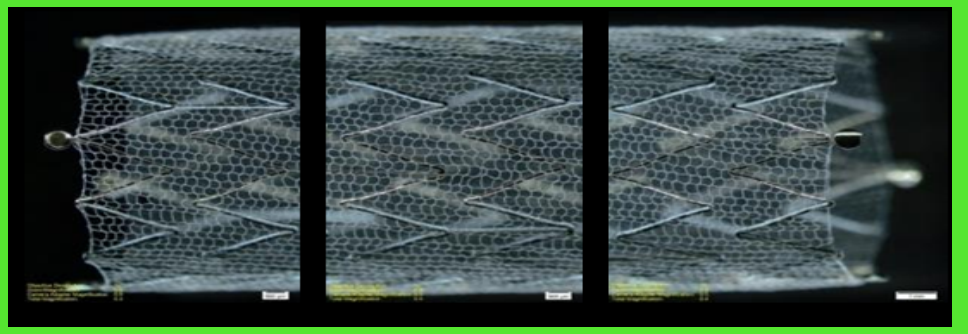
2015 VEITH

VASCULAR ENDOVASCULAR ISSUES TECHNIQUES HORIZONS



MicroNet Covered Embolic Prevention Carotid Stent System: From CARENET and PARADIGM Studies To Routine Clinical Practice

Piotr Musialek, MD DPhil

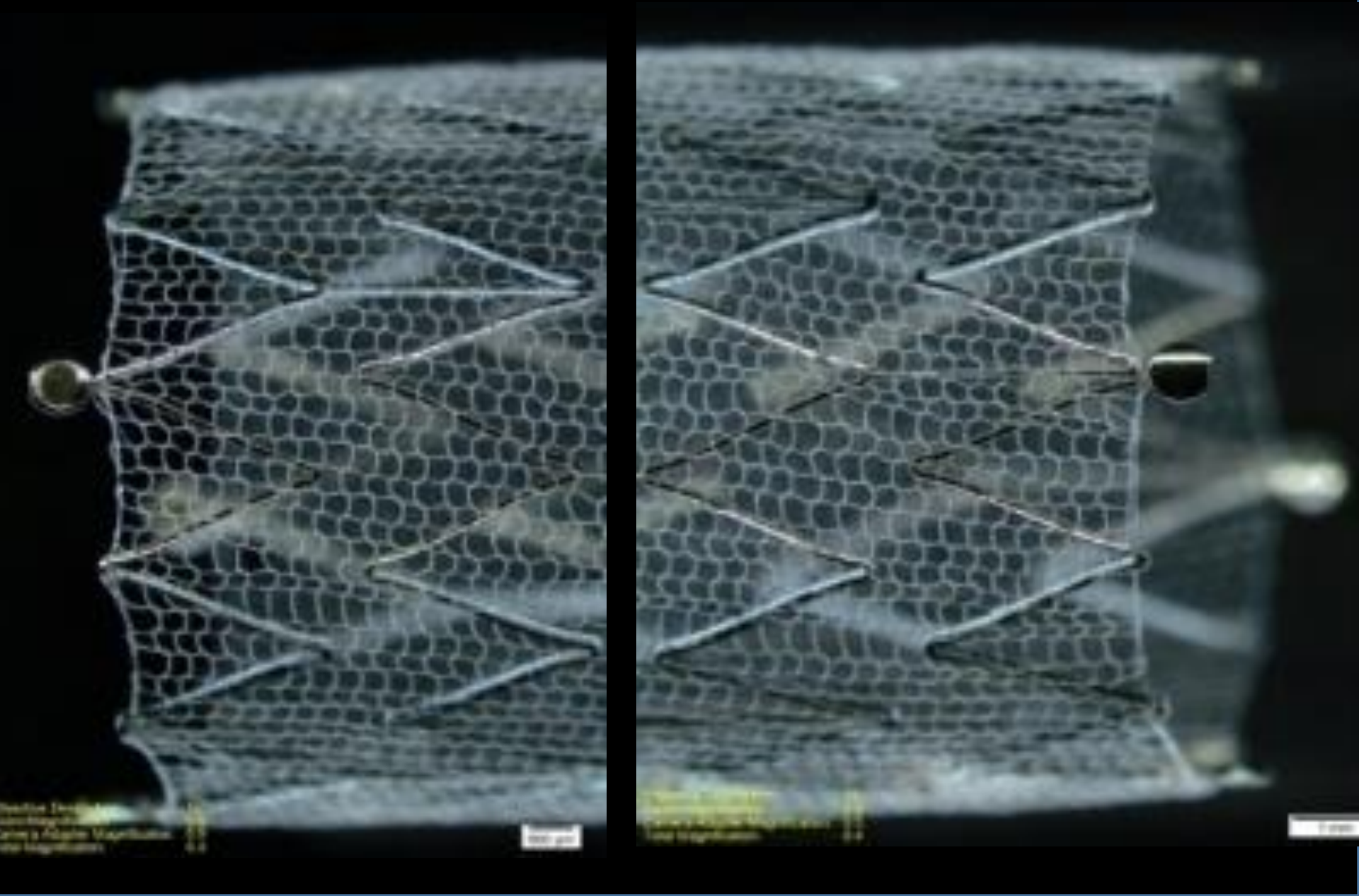
Jagiellonian University Dept. of Cardiac & Vascular Diseases
John Paul II Hospital, Krakow, Poland

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• ABBOTT
• Consulting Fees/Honoraria	• ABBOTT, Balton, InspireMD, Medtronic

CGuard ™ embolic prevention stent



J Am Coll Cardiol Intv 2015;8:1229–34

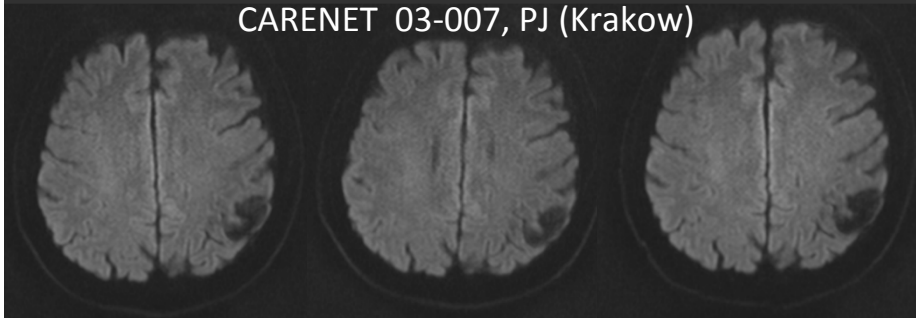
Mandatory DW-MRI

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

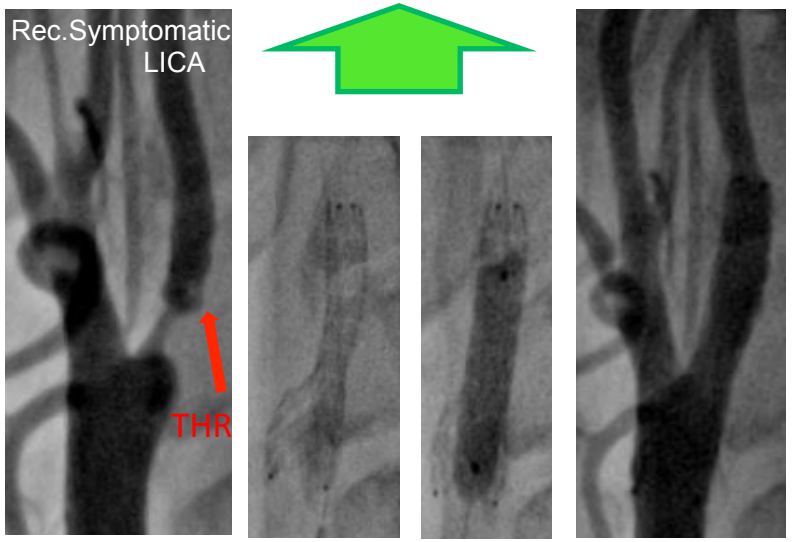
The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

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

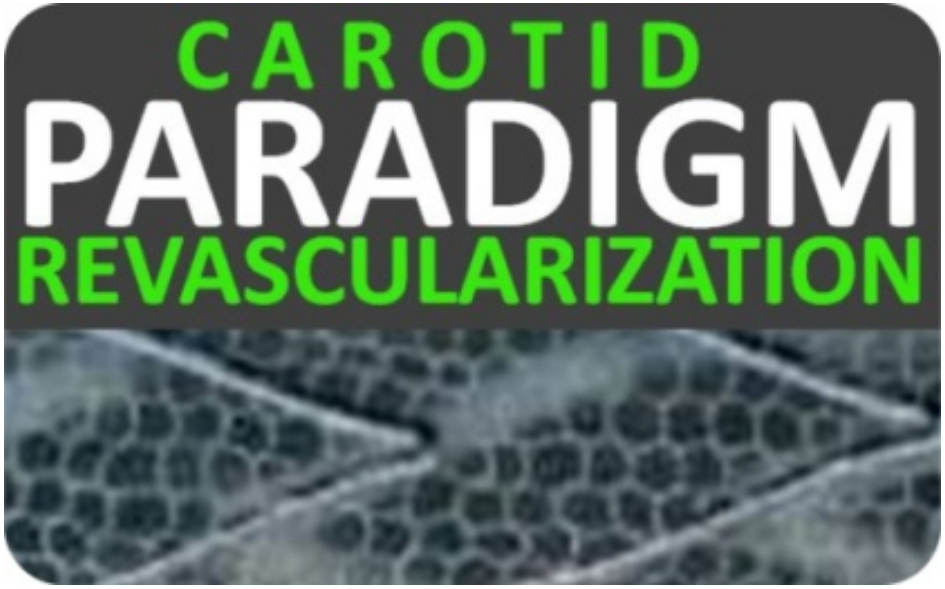
RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac 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.



Prior to CAS **24h** after **30 d** after CAS



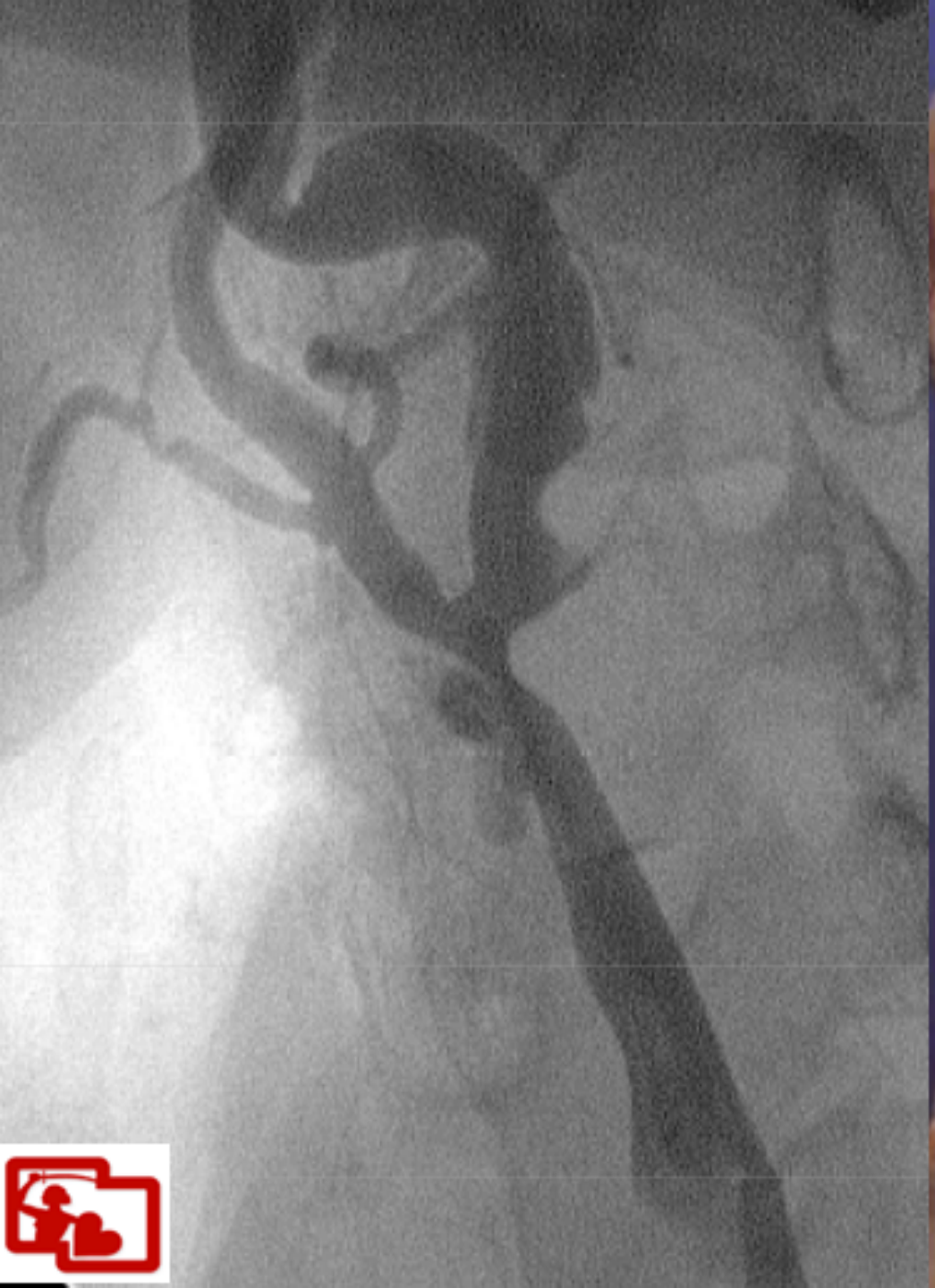
PARADIGM & PARADIGM-EXTEND

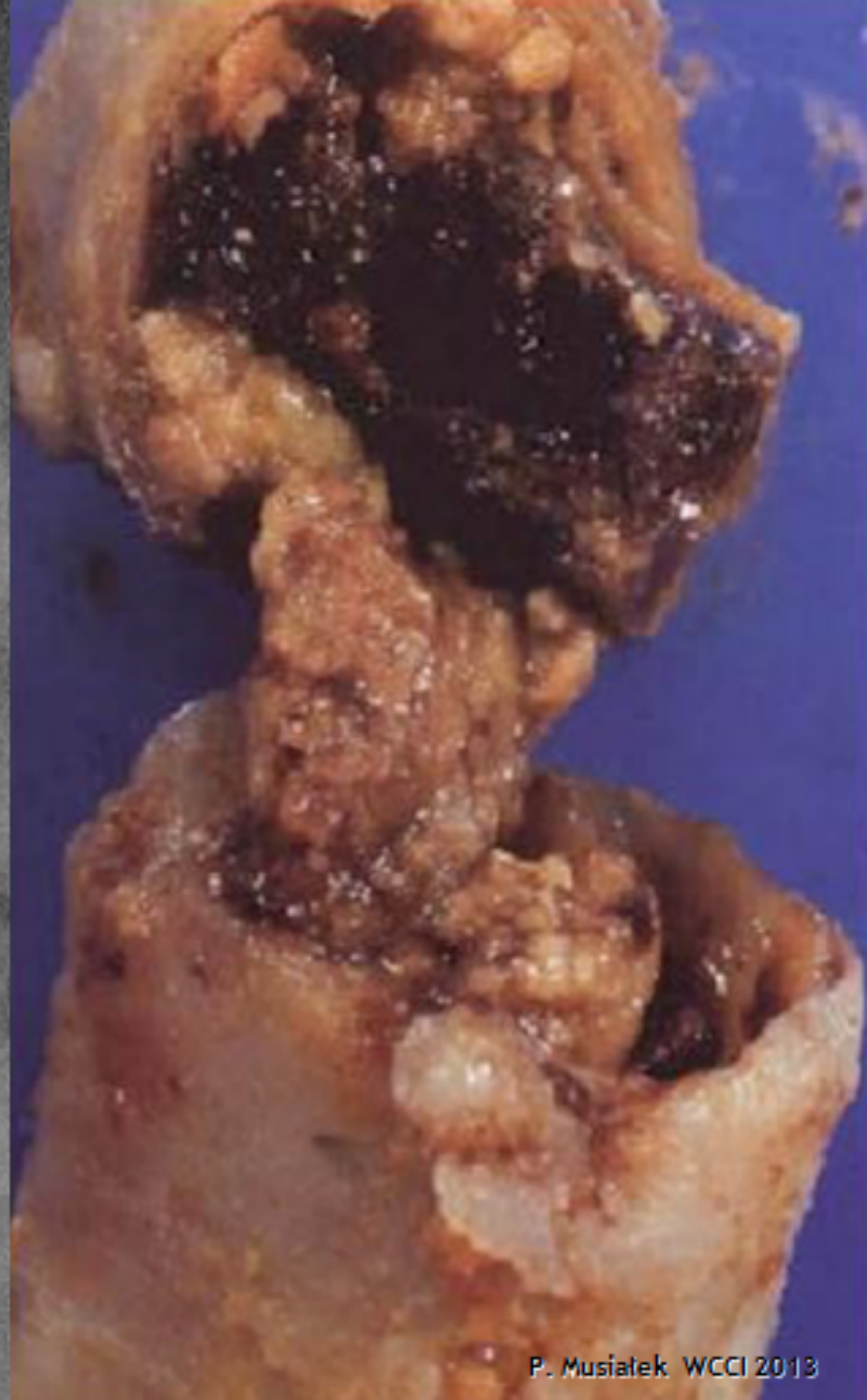


ROUTINE CLINICAL PRACTICE 2015+

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

P. Musialek @ VEITH 2015




P. Musiałek WCCI 2013

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

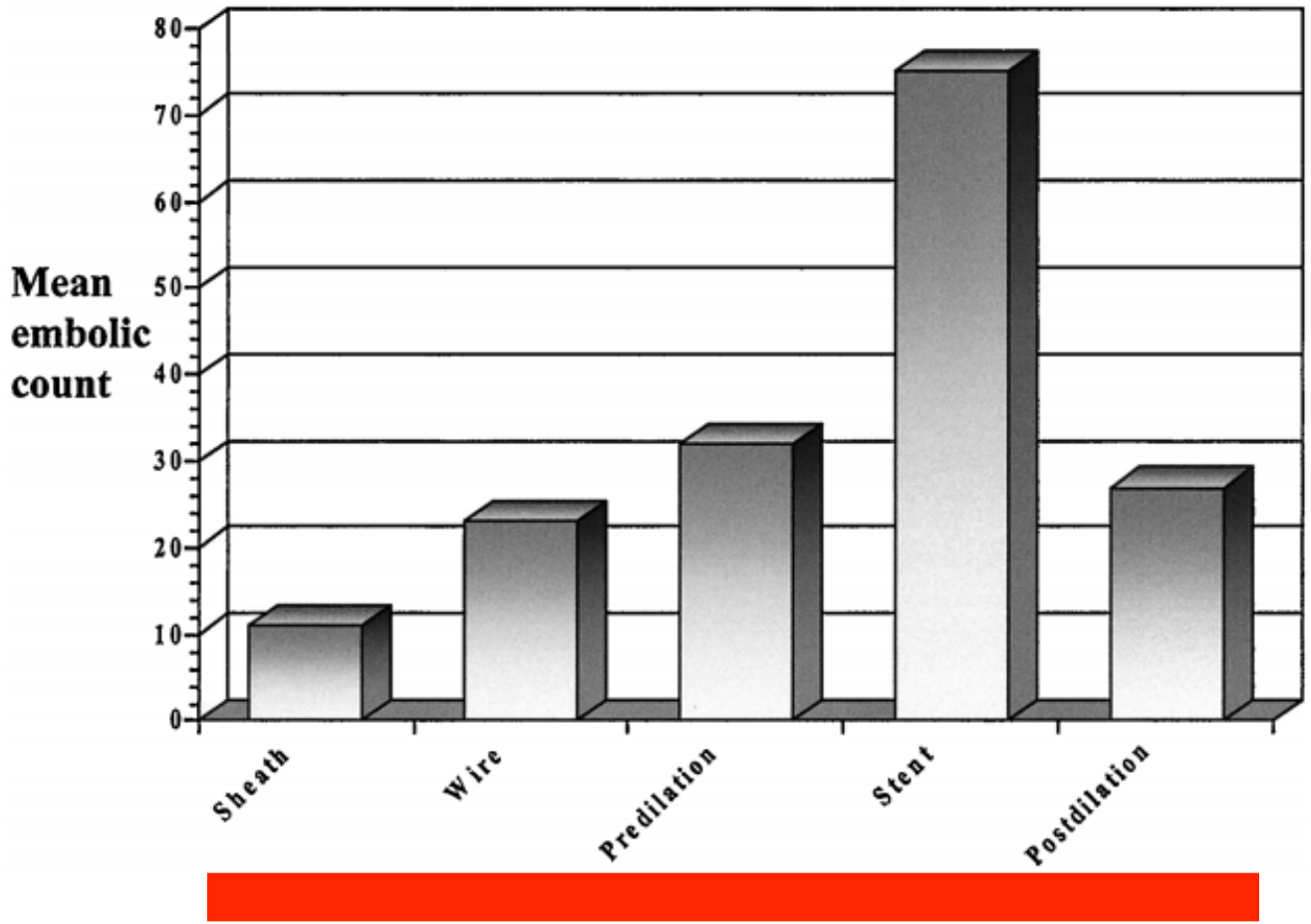
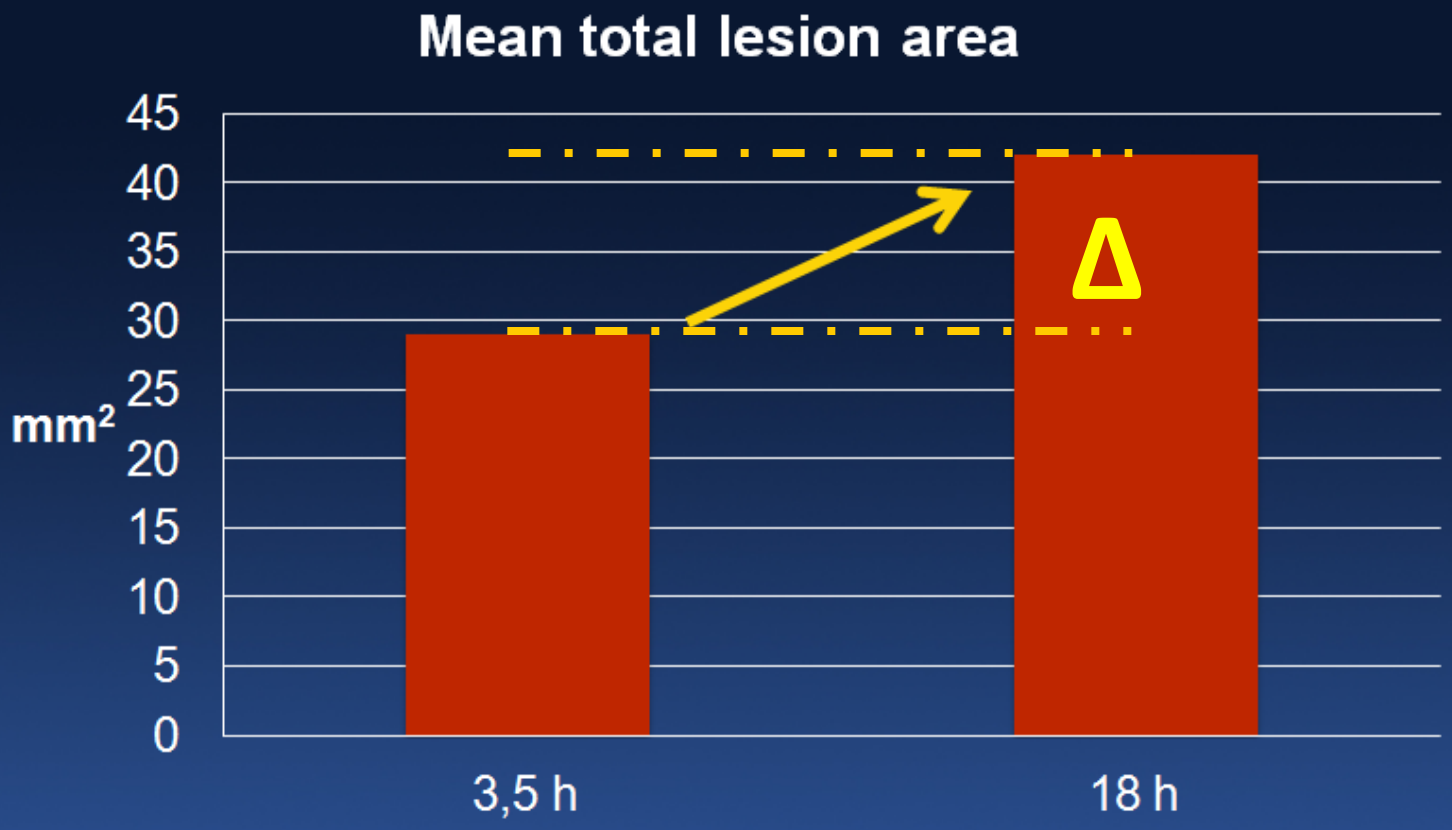


Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

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

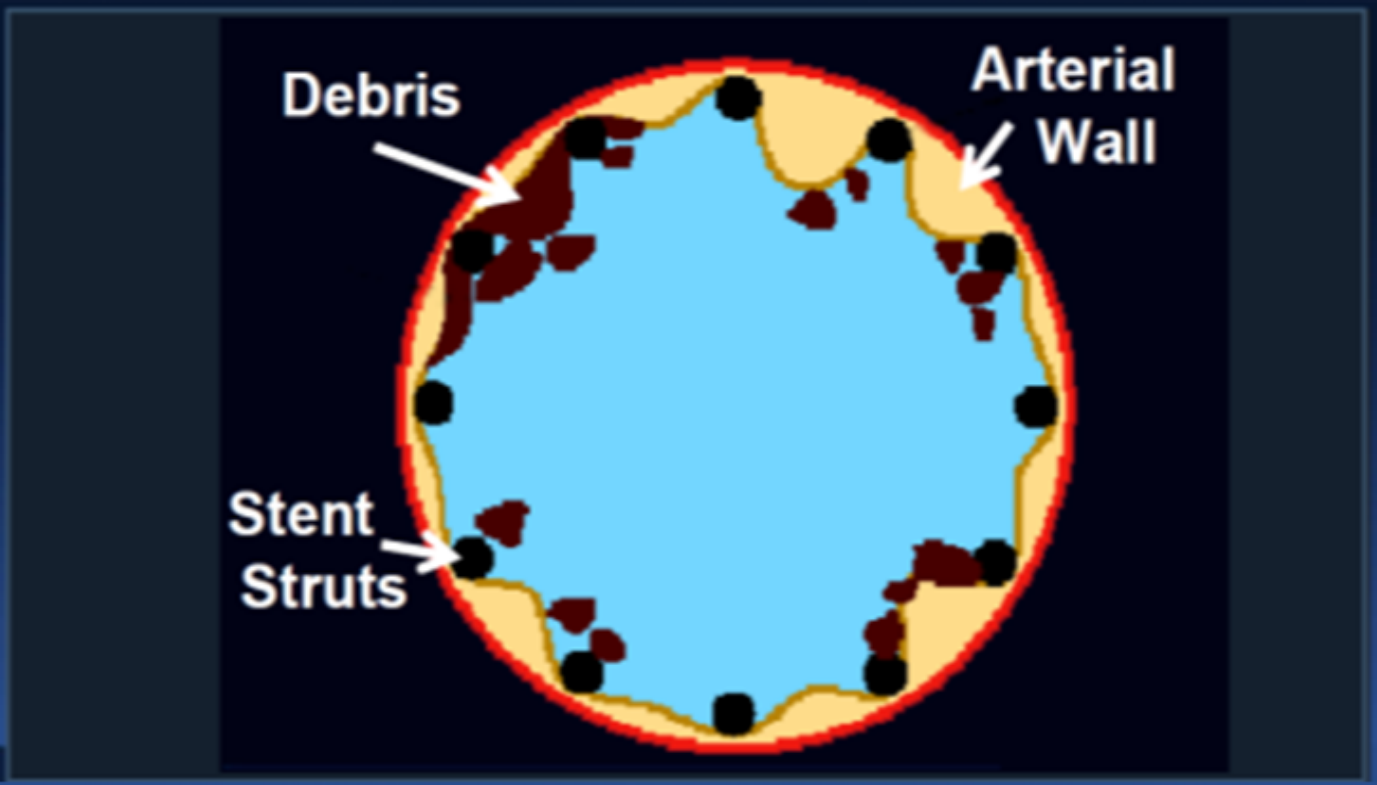
FREE CELL AREA drives CAS neurologic adverse events (and majority occur *post-procedure*)

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

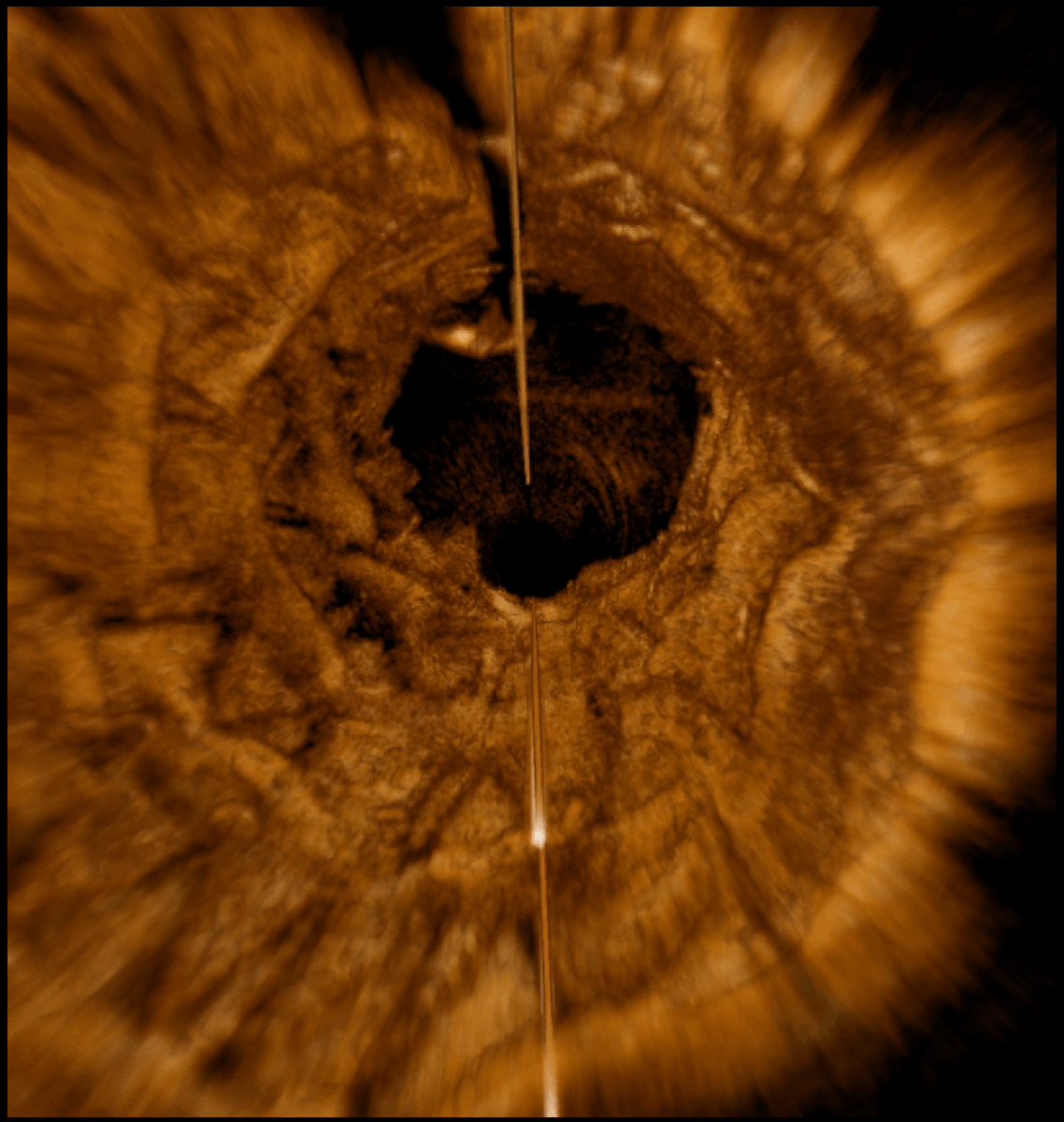
Conventional Carotid Stent

Plaque protrusion may lead to early and late distal embolization



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

Conventional Carotid Stent

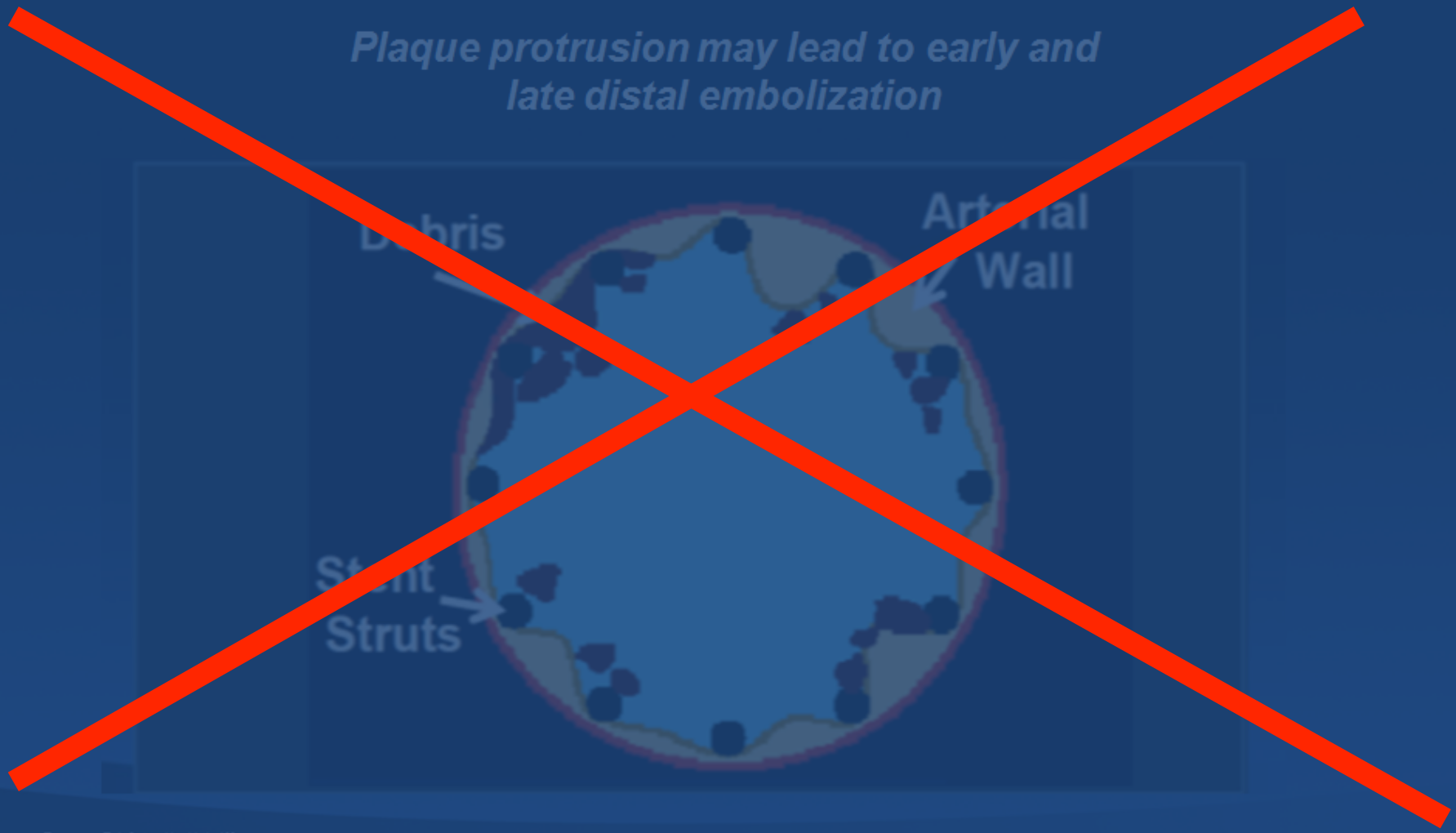


Human Carotid OCT Image Courtesy Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, Univerity of Barcelona

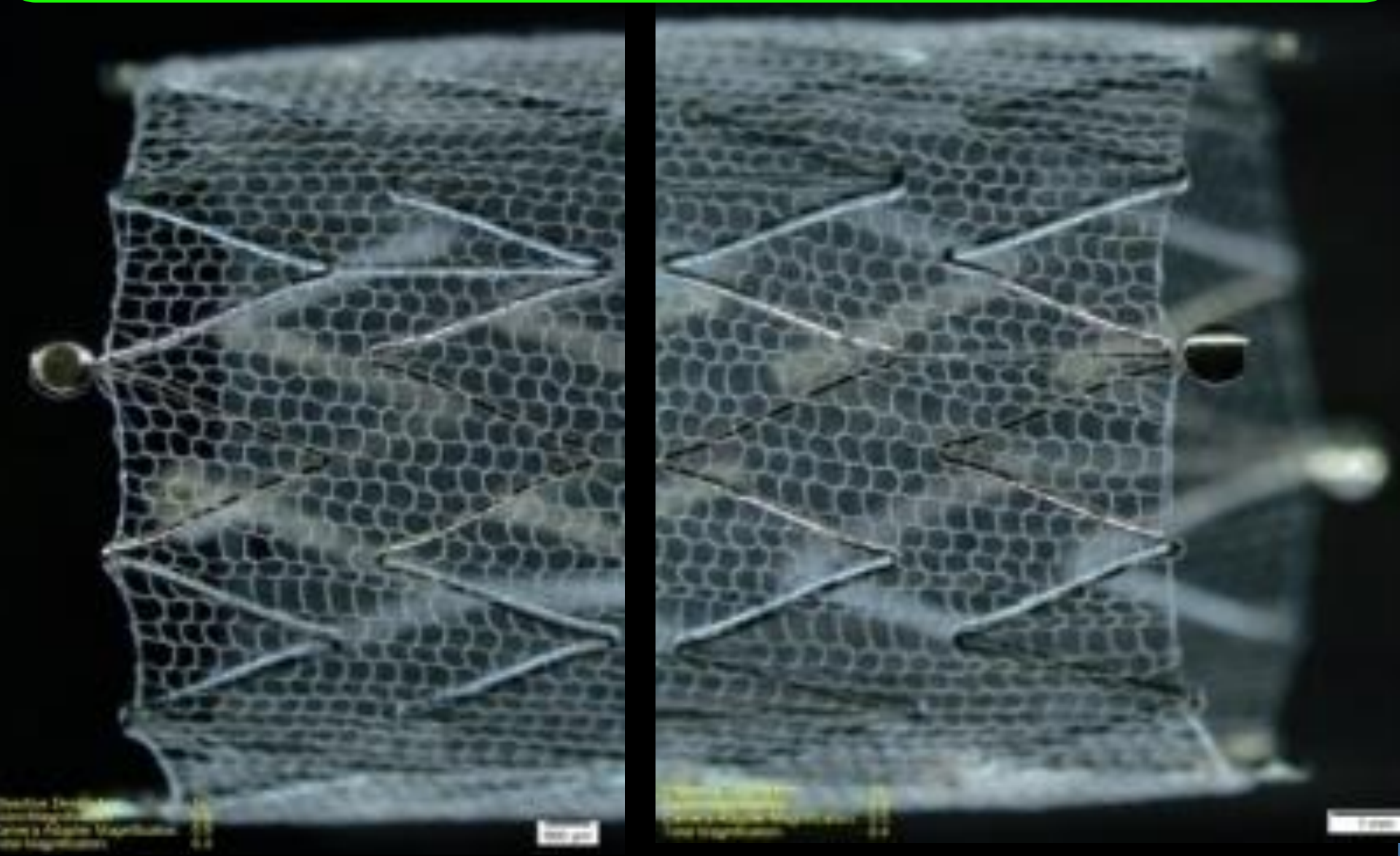
Conventional Carotid Stent

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

Anti - Embolic Carotid Stent

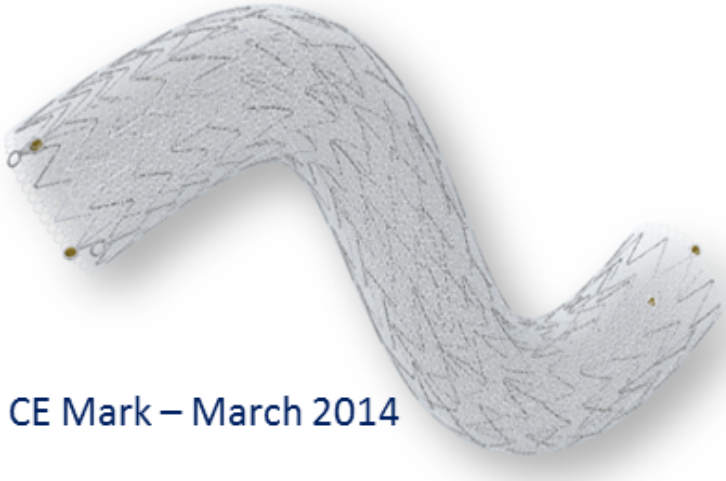


CGuard™ embolic prevention system

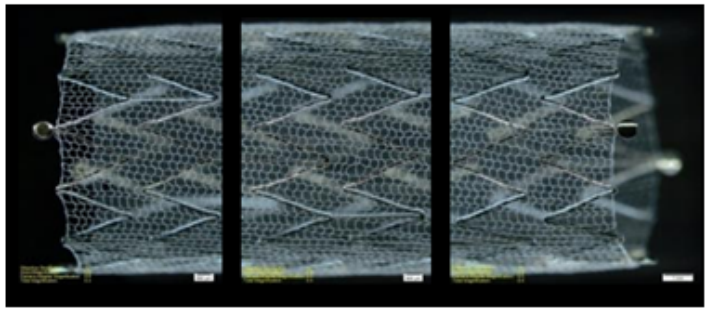


CGuard™– Carotid Embolic Prevention System

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

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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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.

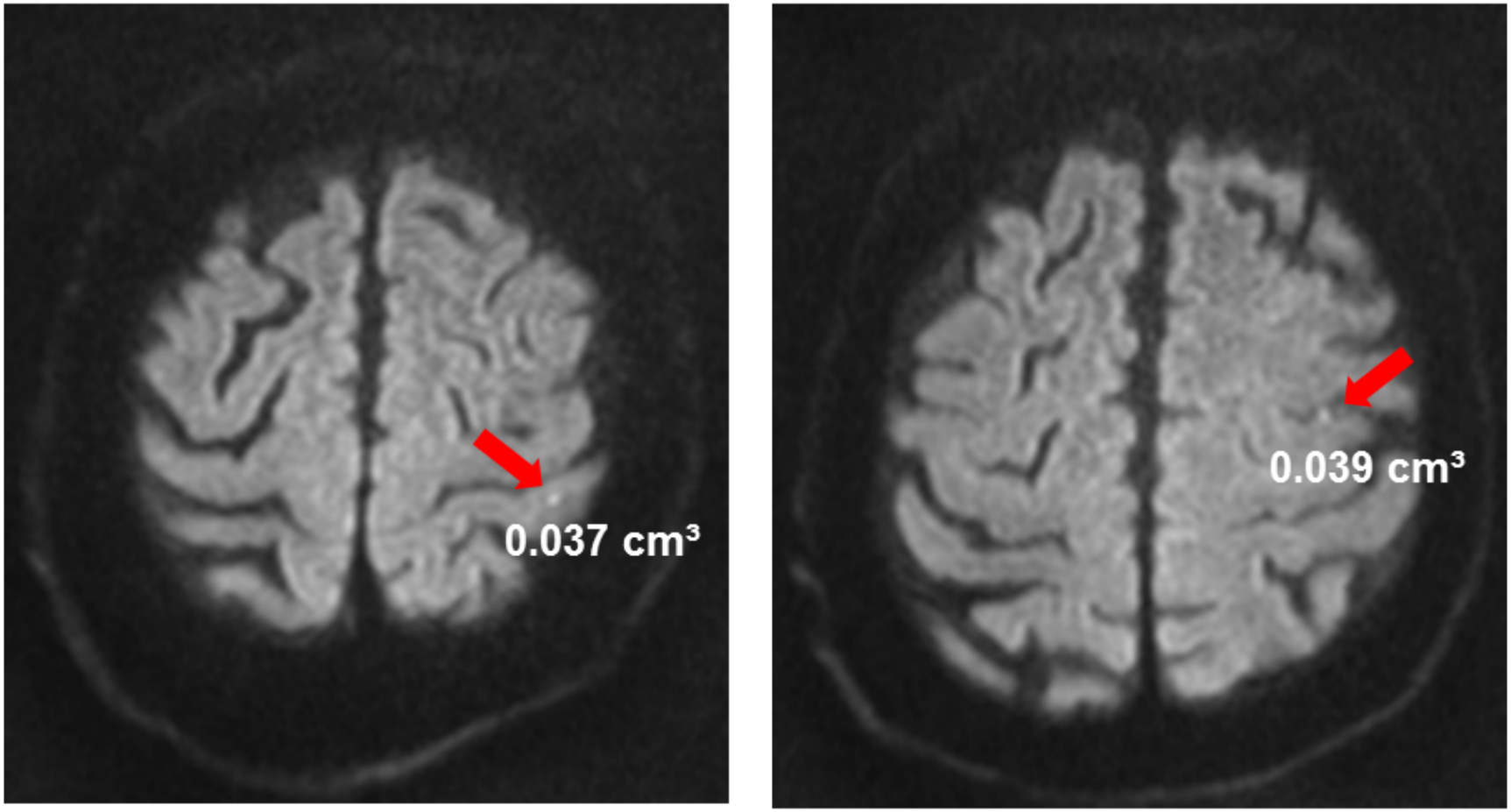
DW-MRI:

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 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

***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**	**0.375**	-
Maximum lesion volume (cm^3)	0.4[illegible]5		

>10-fold reduction

in cerebral lesion **volume**

see patient fluxogram

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

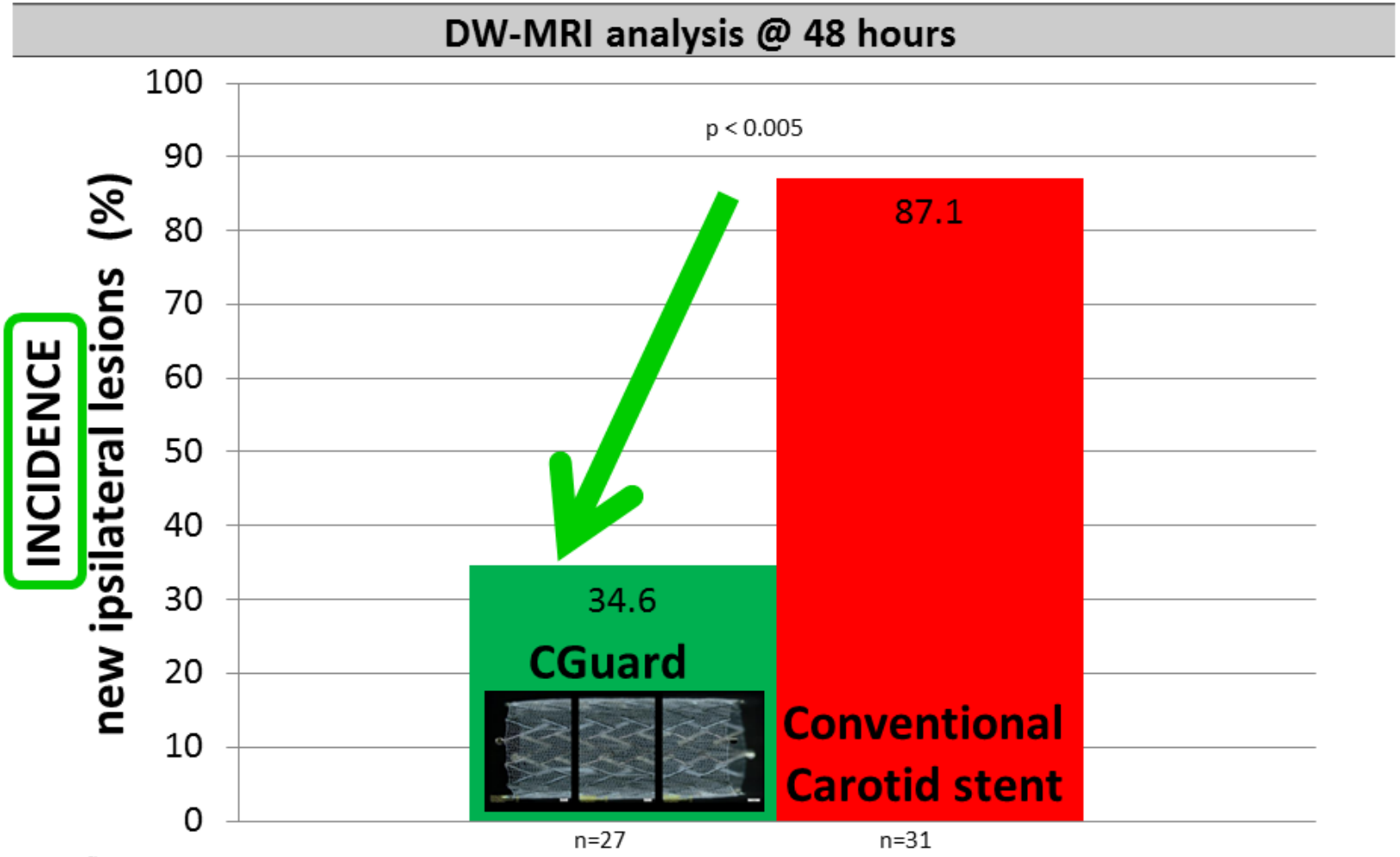
Bijuklic et al. *JACC*, 2012; Bonati et. al, *Lancet Neurol* 2010

† bilateral lesions

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

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

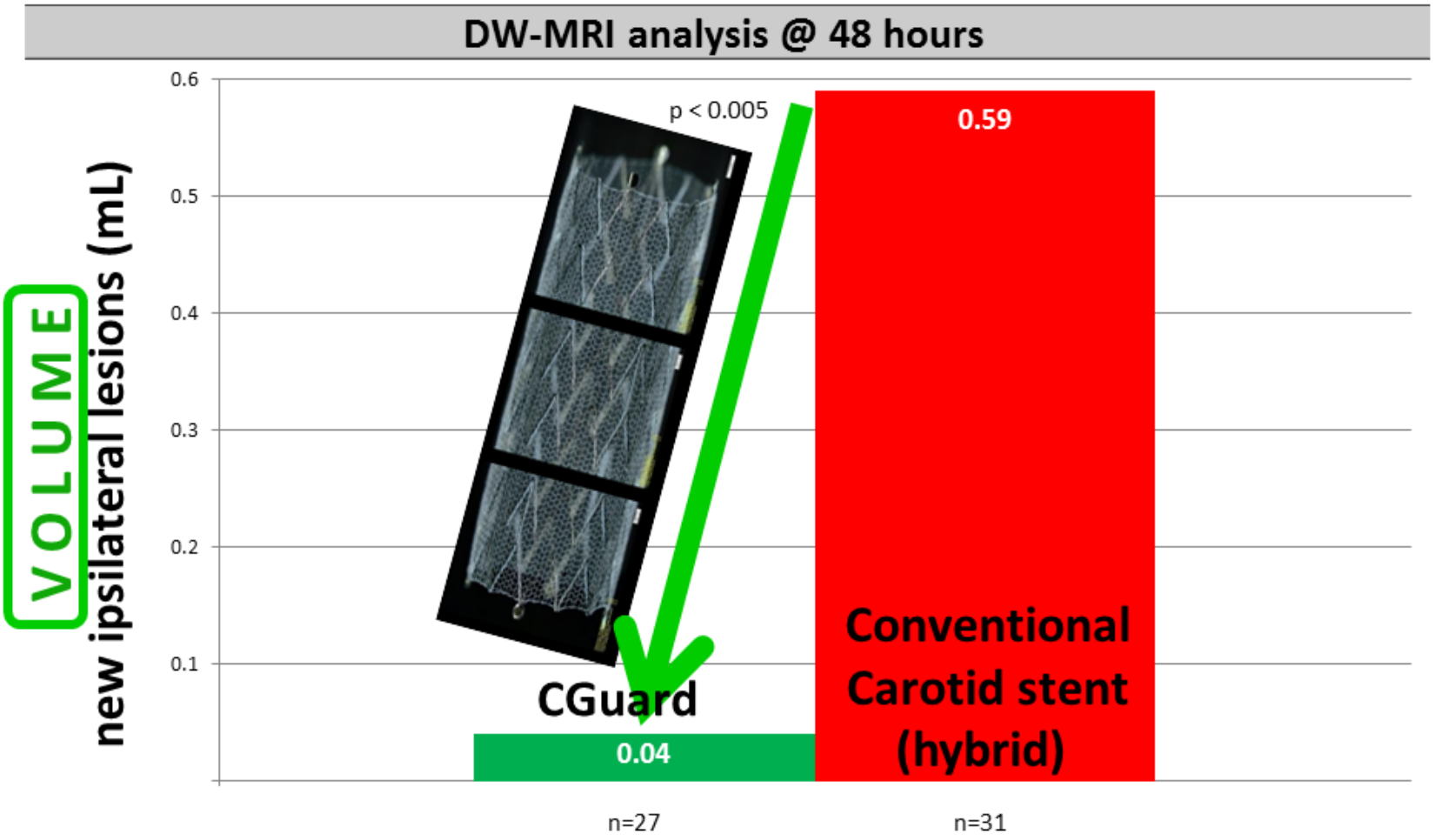


* see patient fluxogram
Bijuklic et al. *JACC*, 2012;59

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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Bijuklic et al. *JACC*, 2012;59

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)**

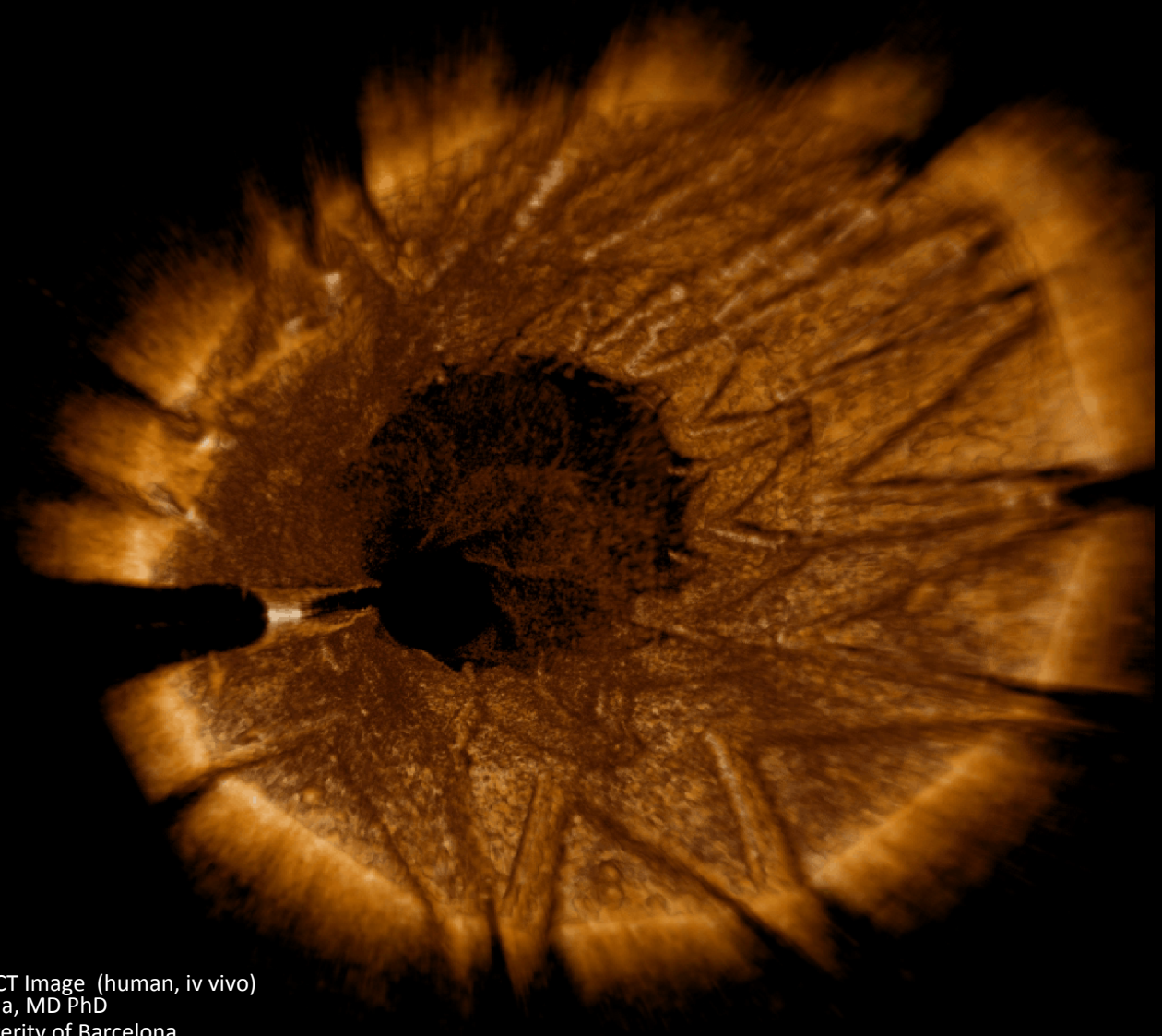
J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34

Anti - Embolic Carotid Stent

Plaque protrusion may lead to early and late distal embolization

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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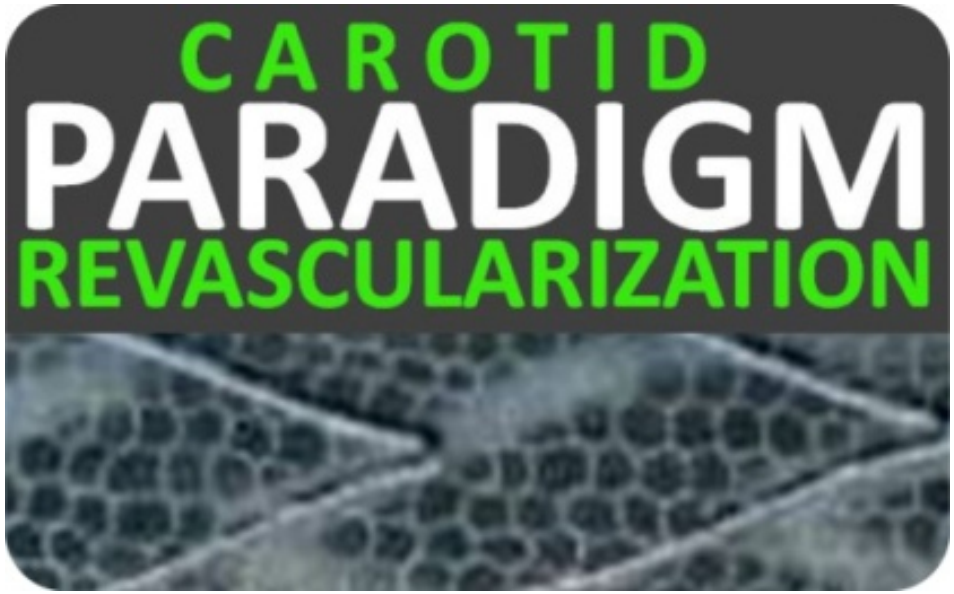
RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac 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)

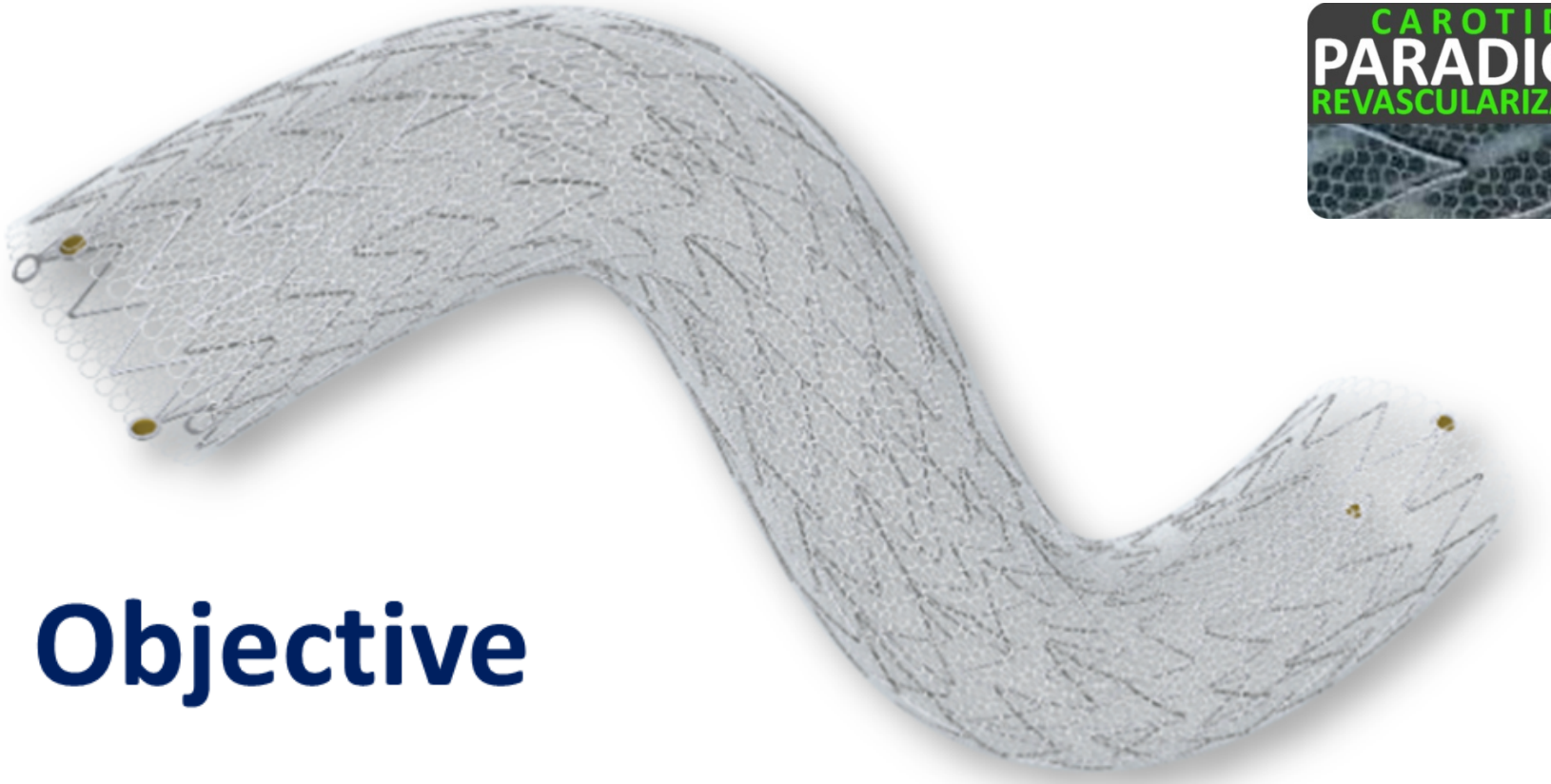
P. Musialek @ VEITH 2015

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



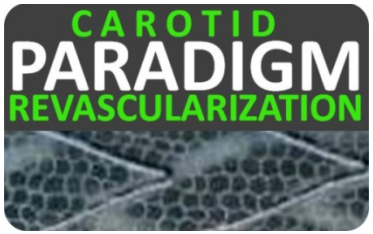
CAROTID PARADIGM REVASCULARIZATION

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)

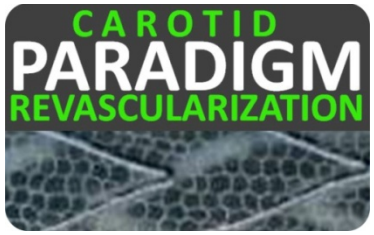
NB. 1. DWI evidence of effective MicroNet prevention against cerebral embolization (CARENET/PROFI)
2. Residual stenosis after CAS as independent predictor of in-stent restenosis

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.

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



Endpoints:

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

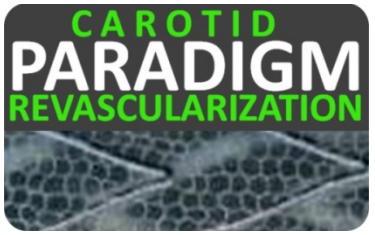
- **device success** (able to deliver + implant + <30% DS)

- **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

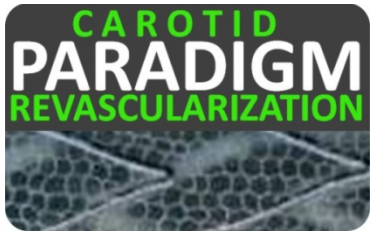


- **ASYMPTOMATIC patients treated interventionally only if at ↗ stroke risk**
- **established lesion-level increased-risk crieria used:**
  - **thrombus-containing**
  - **tight, near-occlusive**
  - **documented progressive**
  - **irregular and/or ulcerated**
  - **contralteral ICA occlusion/stroke**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

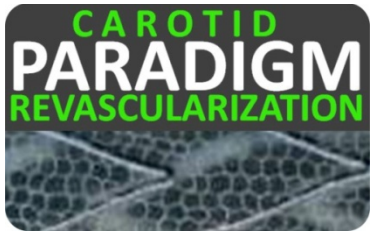
Krakow Cardiovascular Research Institute

Core Imaging Analysis Laboratory

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

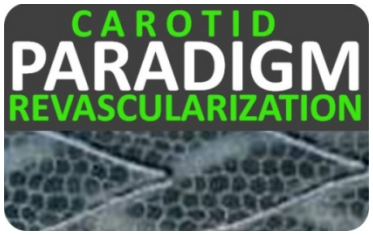
for carotid revascularization
73 patients

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

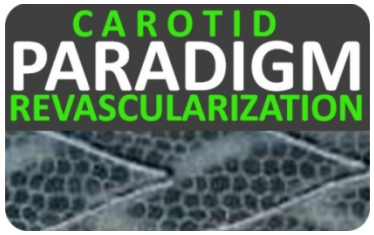
(7%) → **CEA in n=5 Patients**

- 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

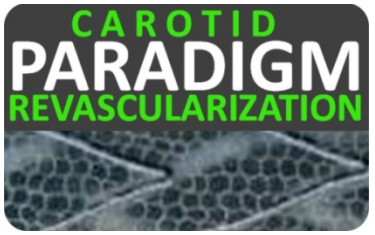
Clinical characteristics of study patients (n=68)



age, mean±SD (min–max)	69 ±7 (55–83)
male, % (n)	66% (45)
symptomatic, % (n) symptomatic ≤ 14 days, % (n) acutely symptomatic (emergent CAS) , % (n)	53% (36) 28% (19) 9% (6)
index lesion (CAS) , % (n) RICA LICA RICA+LICA	 52% (35) 44% (30) 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)

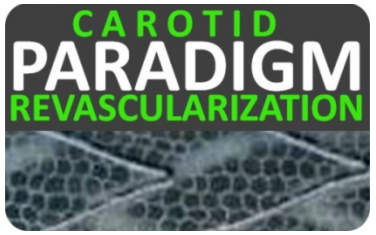


- **Percutaneous treatment 100% using the intended MicroNet-covered embolic prevention stent system CGuard**
  (ie, no other stents used during the study period)

- **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)

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 (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

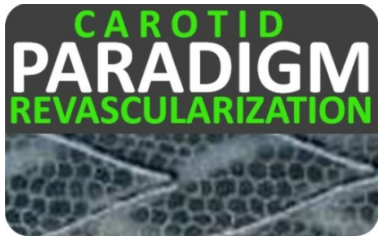
* verified on imaging

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)

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 (3)



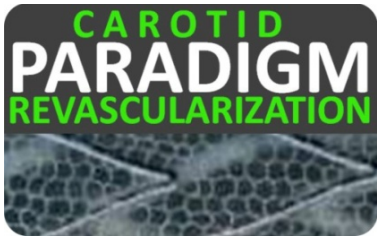
Index lesion quantitative characteristics (n=71 lesions)

	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)

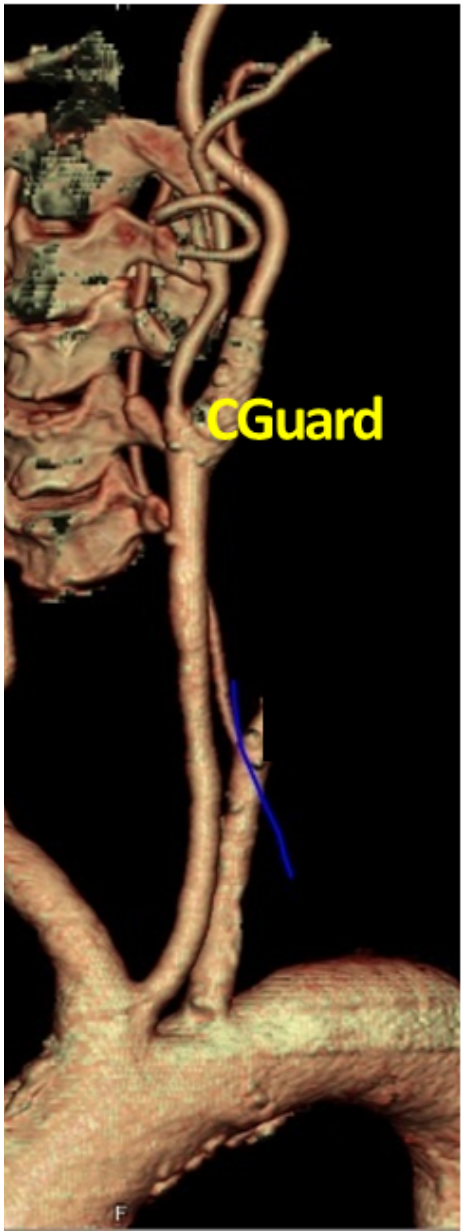
PARADIGM: Results (4)

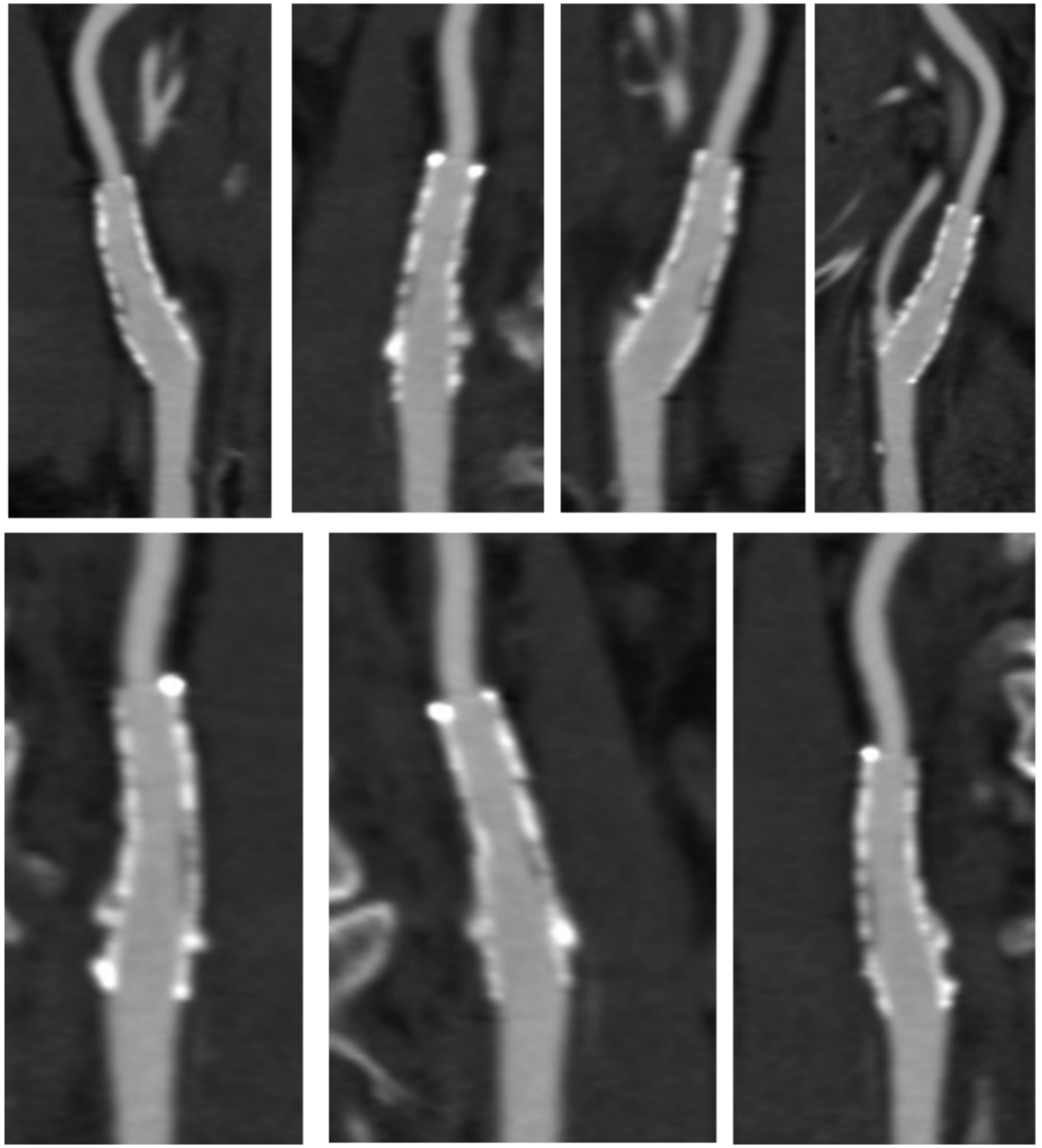


- **Death/stroke/MI @ 48h** **0%**
- **Death/stroke/MI @ 30d** **0%**

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(suppl):B33

CGuard 5 months follow-up





PARADIGM – EXTEND

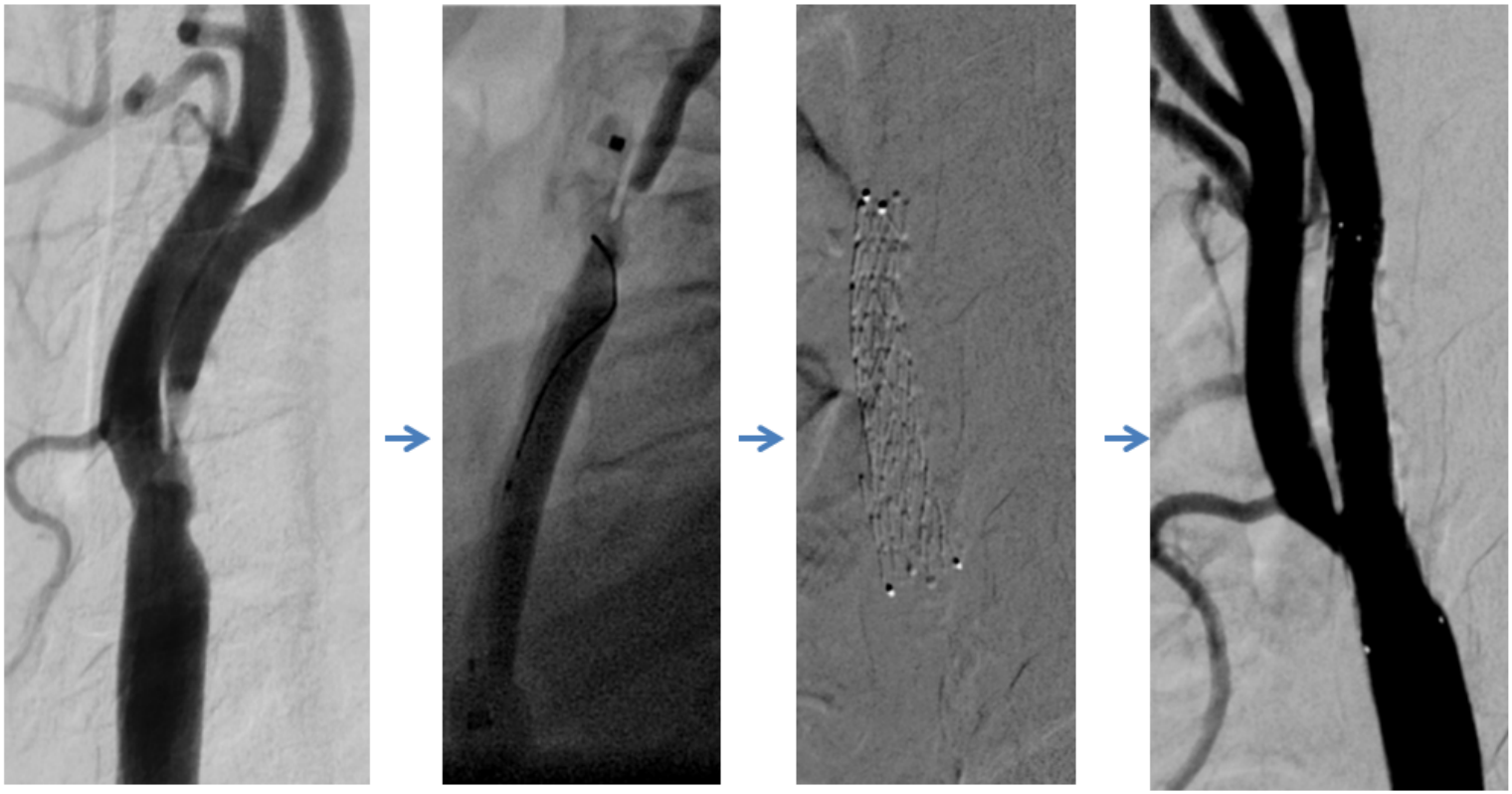
CAROTID PARADIGM REVASCULARIZATION

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')

P. Musialek @ VEITH 2015

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

12mo data

NEW

CARENET

1 yr Follow Up Data

November 20, 2015

VEITH Vascular Endovascular Issues Techniques Horizons

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

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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

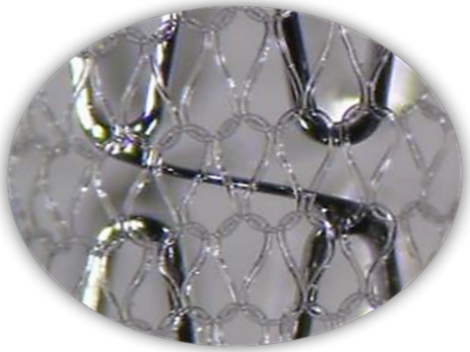
- 1 pulmonary embolism death @ 5 mo
- 1 respiratory failure death @ 8 mo
- 1 malignant tumor death @ 9 mo

VEITH
VASCULAR ENDOVASCULAR ISSUES TECHNIQUES HORIZONS

November 20, 2015

2015 VEITH

VASCULAR ENDOVASCULAR ISSUES TECHNIQUES HORIZONS



InspireMD

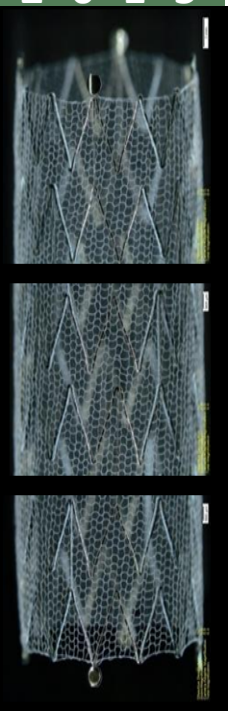
CGUARD™

Carotid Embolic Prevention System

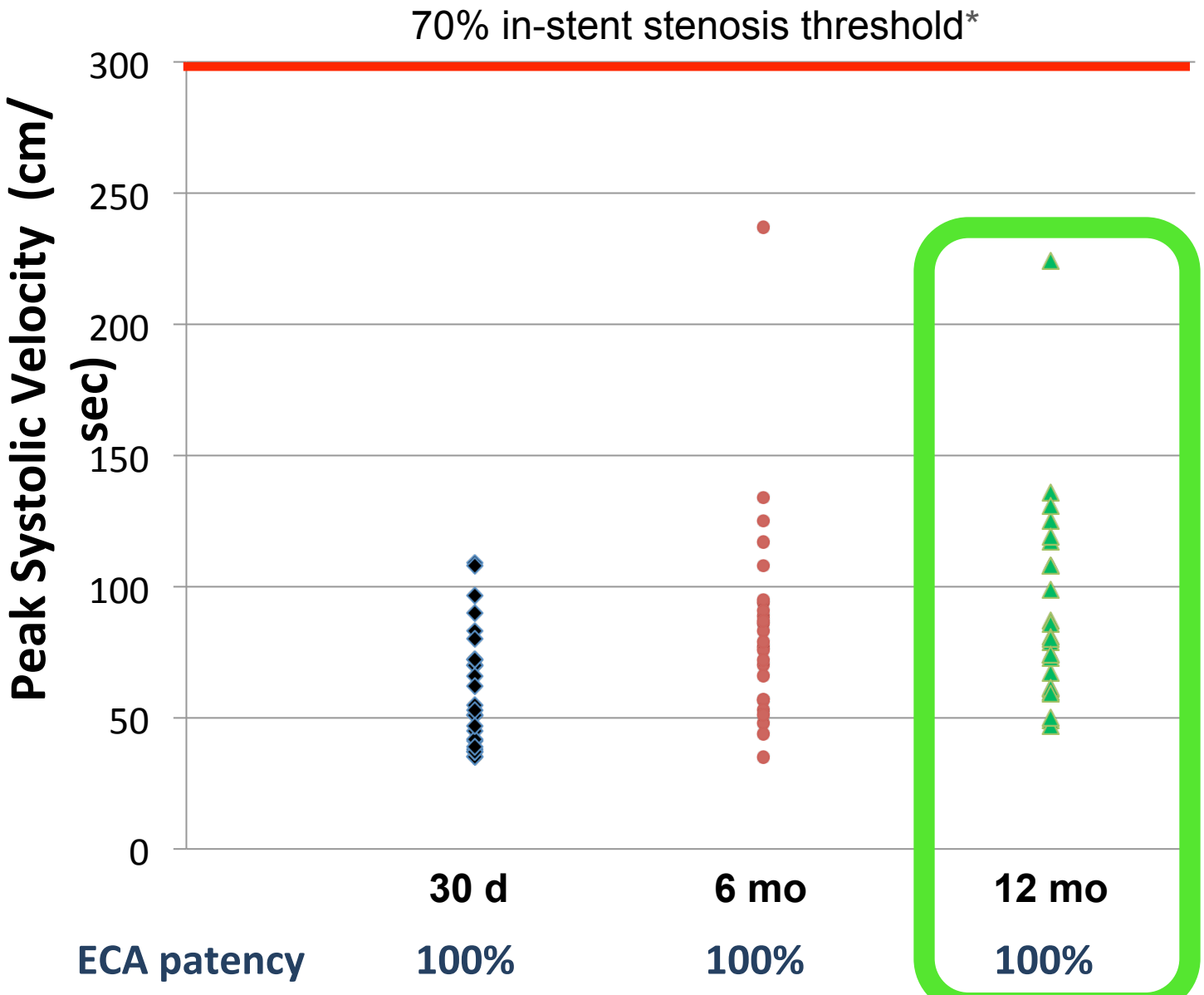
- NO device-related adverse events
- NO procedure-related events

CARENET Multicenter Trial **12 mo data**

New York, November 20, 2015

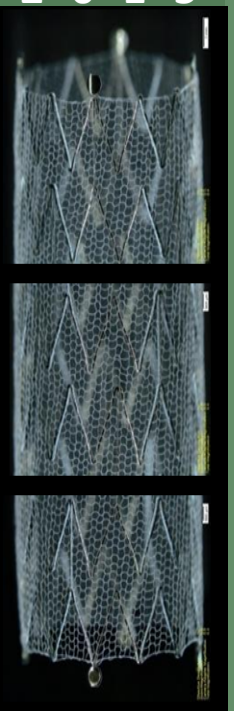


CARENET in-stent Peak Systolic Velocities



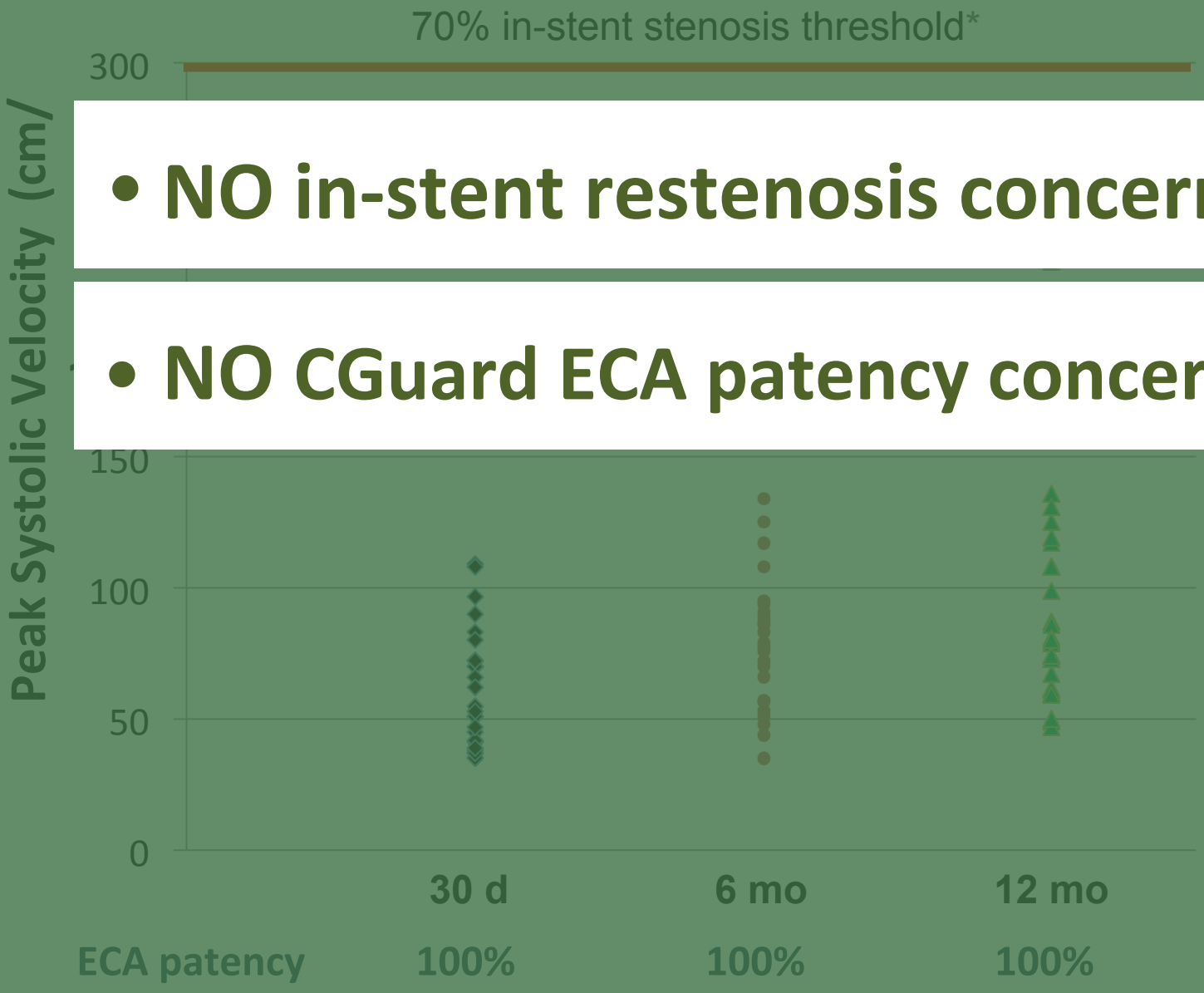
* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke* 2008

VEITH Vascular Endovascular Issues Techniques Horizons 2015



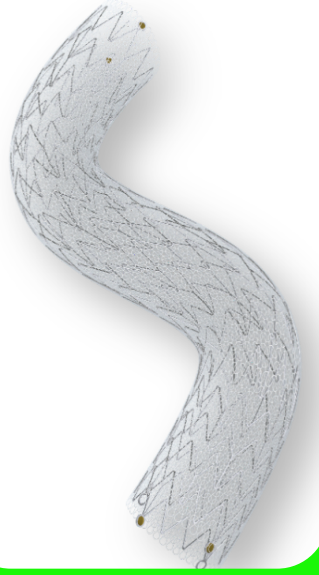
CARENET in-stent Peak Systolic Velocities

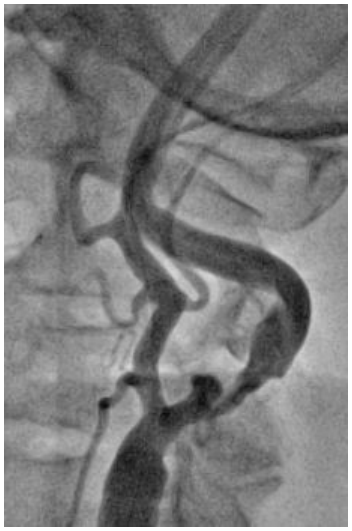
- NO in-stent restenosis concern
- NO CGuard ECA patency concern

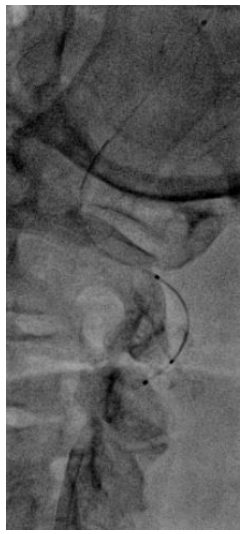


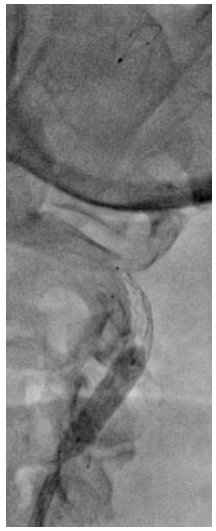
* Setacci et. Al.. Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke* 2008

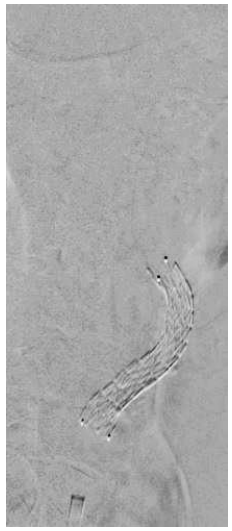
Endovascular Solution for All-Comers

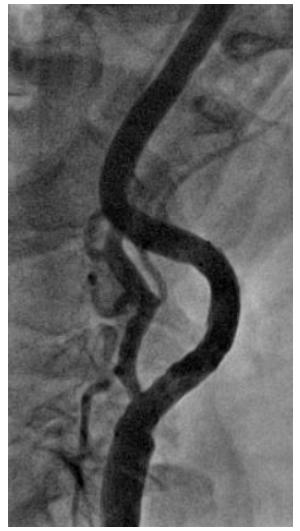


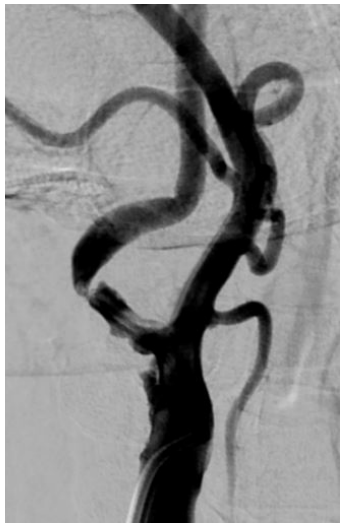


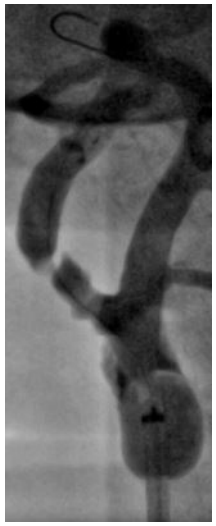


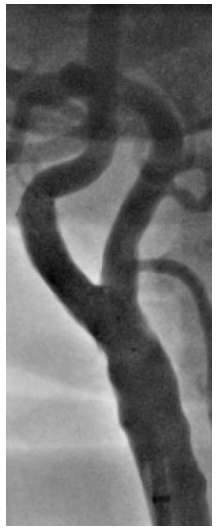


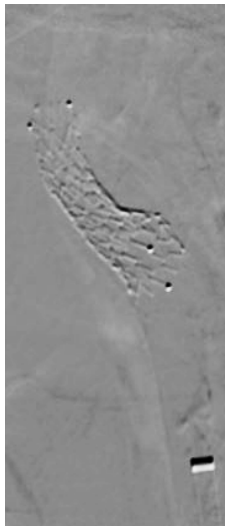


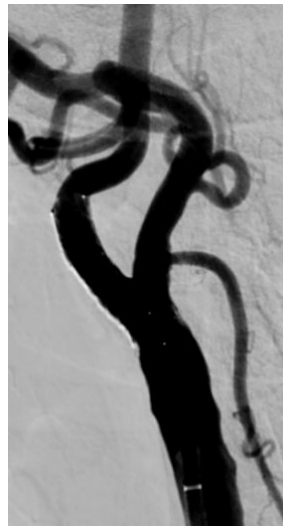












Endovascular Reconstruction of the Carotid Bifurcation

P. Musialek @ VEITH 2015

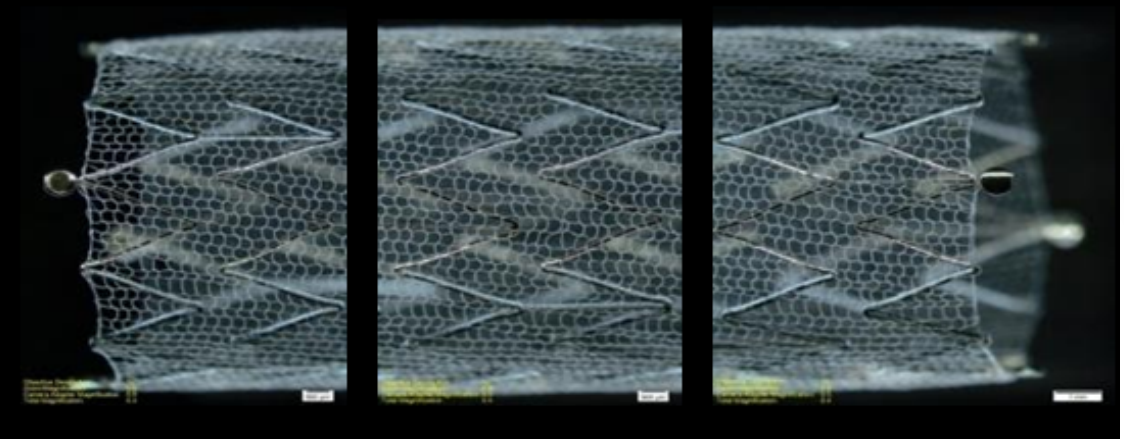
CGuard embolic prevention stent system

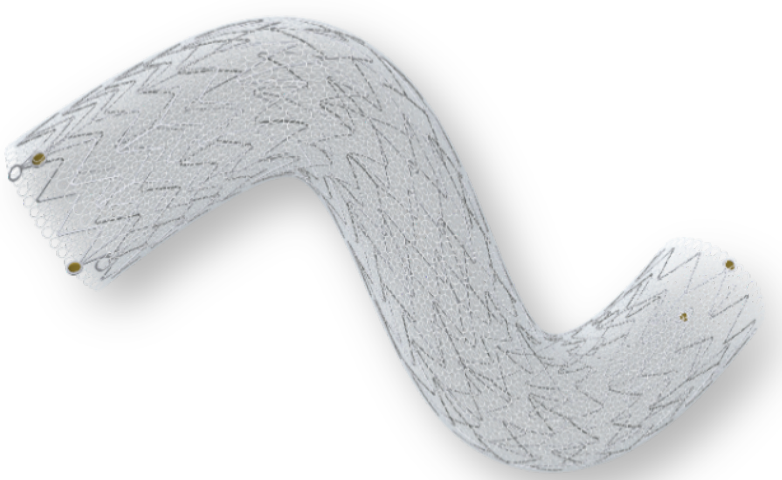
- **Full respect of the carotid bifurcation anatomy**
  -> 'endovascular anatomic reconstruction' √

- **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'

DW-MRI Evidence (CARENET) **2015**
+ Clinical Evidence (CARENET, PARADIGM, PARADIGM-EXTEND)





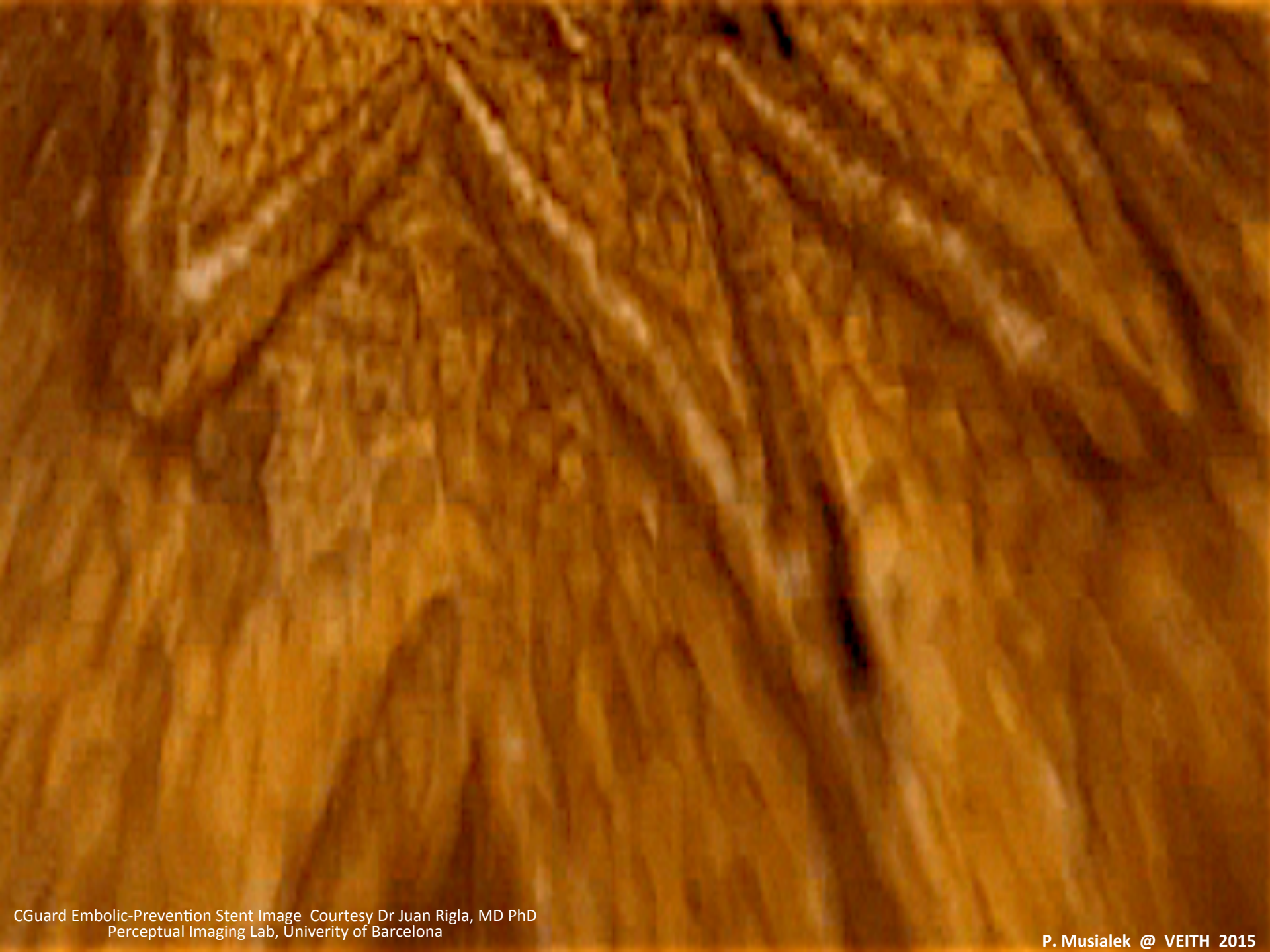
This concept has been desired.

And it works.

This is the future

of Carotid Artery St[illegible]

revascularization ?



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

Carotid Revascularization 2015+ REALITY

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