TCT 2016 Featured Research

Innovation in Vascular Disease

Twelve-month Safety and Efficacy of CGuard™ MicroNet–covered Embolic Prevention Stent Routine Use to Perform Carotid Revascularization: PARADIGM *All-Comer Prospective Academic Study*

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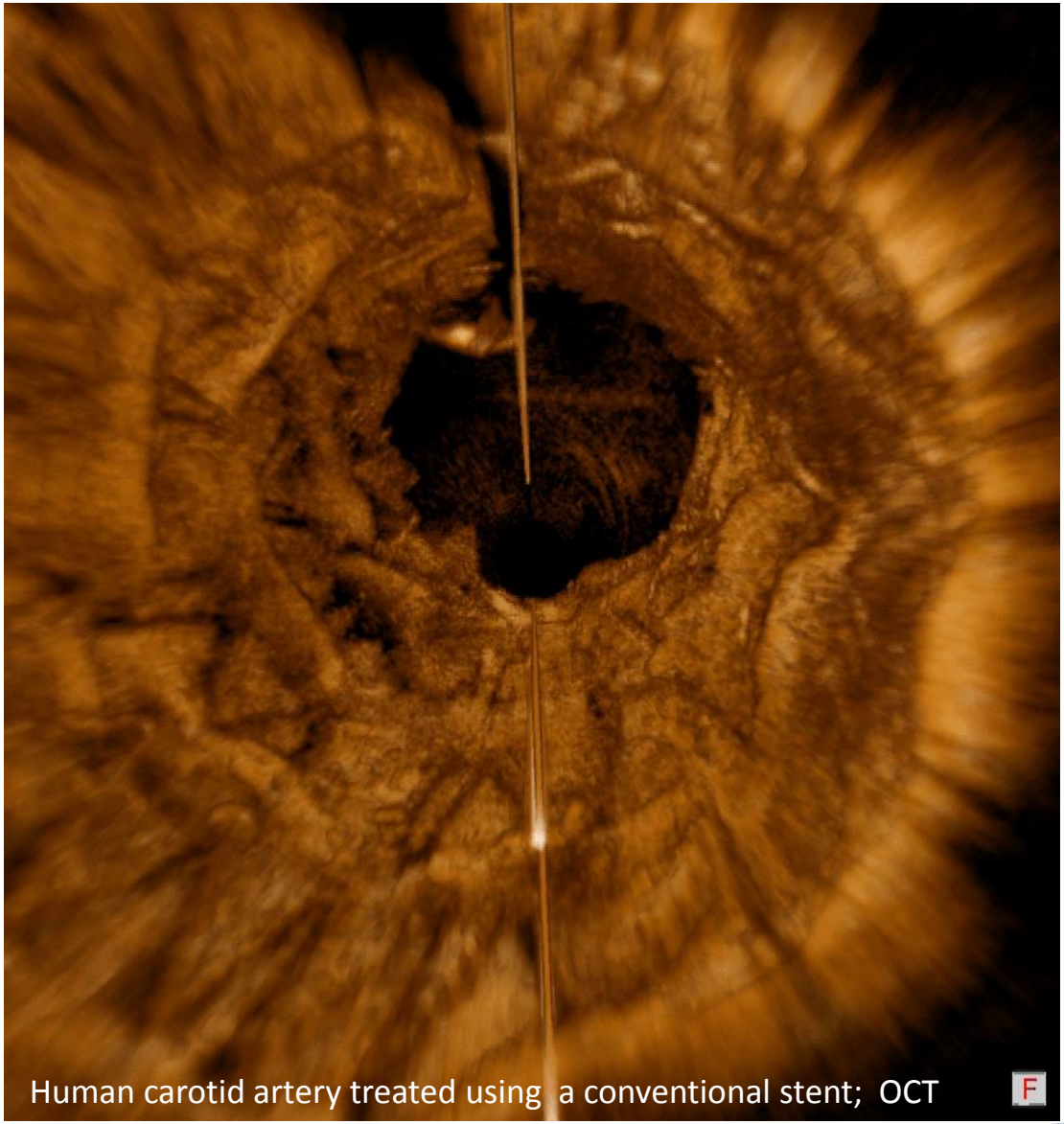
Disclosure Statement of Financial Interest

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
• Major Stock Shareholder/Equity	• no
• Royalty Income	• no
• Ownership/Founder	• no
• Intellectual Property Rights	• no
• Other Financial Benefit	• no

NB. **PARADIGM is an Investigator-Initiated, *Non-Industry Funded*, Academic study supported by the Jagiellonian University Medical College and 'For the Heart' Foundation in Krakow, Poland**

The Problem of Conventional Carotid Stents

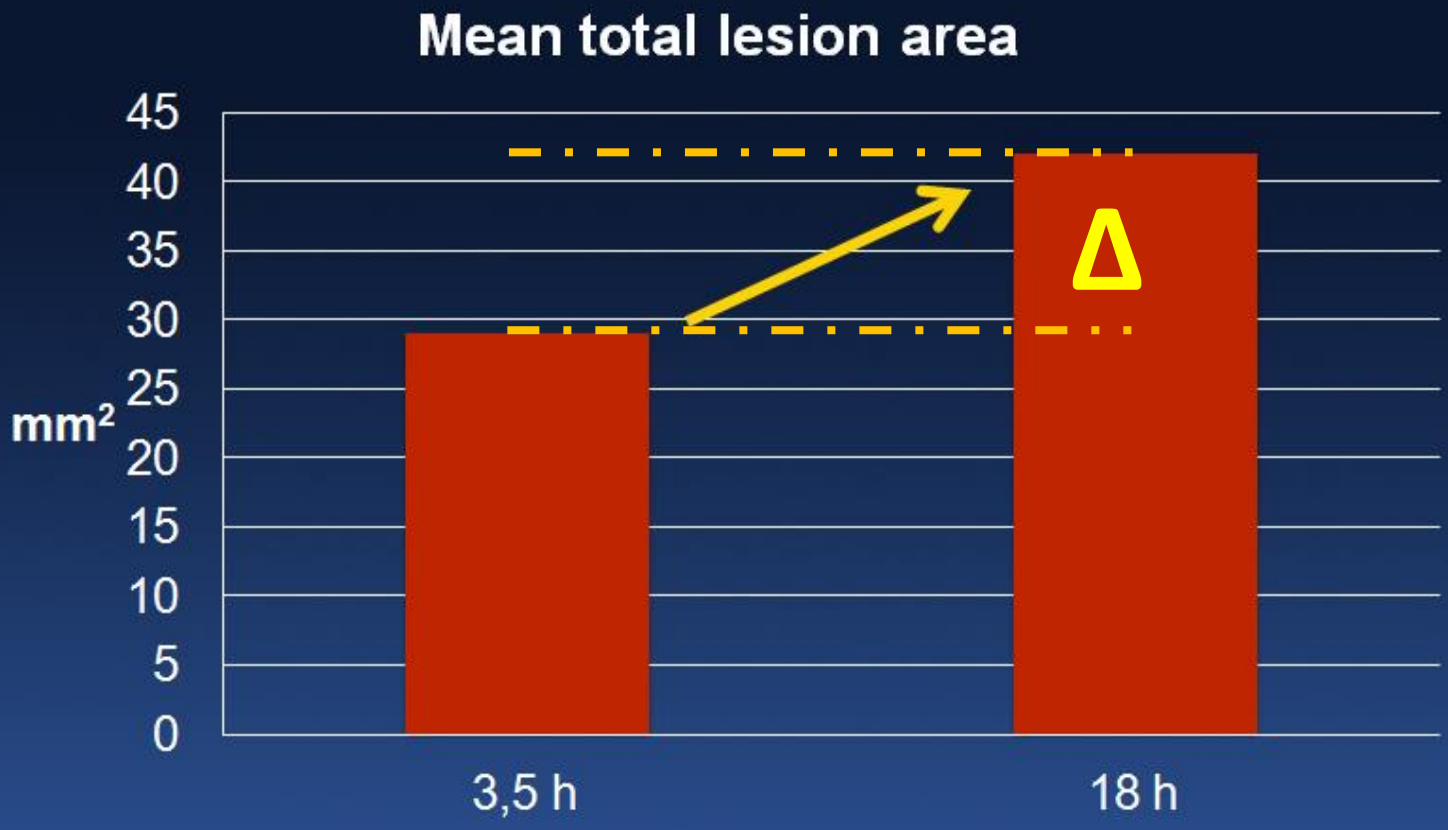


Human carotid artery treated using a conventional stent; OCT

Image courtesy Dr Joan Rigla, MD PhD
Perceptual Imaging Lab, Univerity of Barcelona

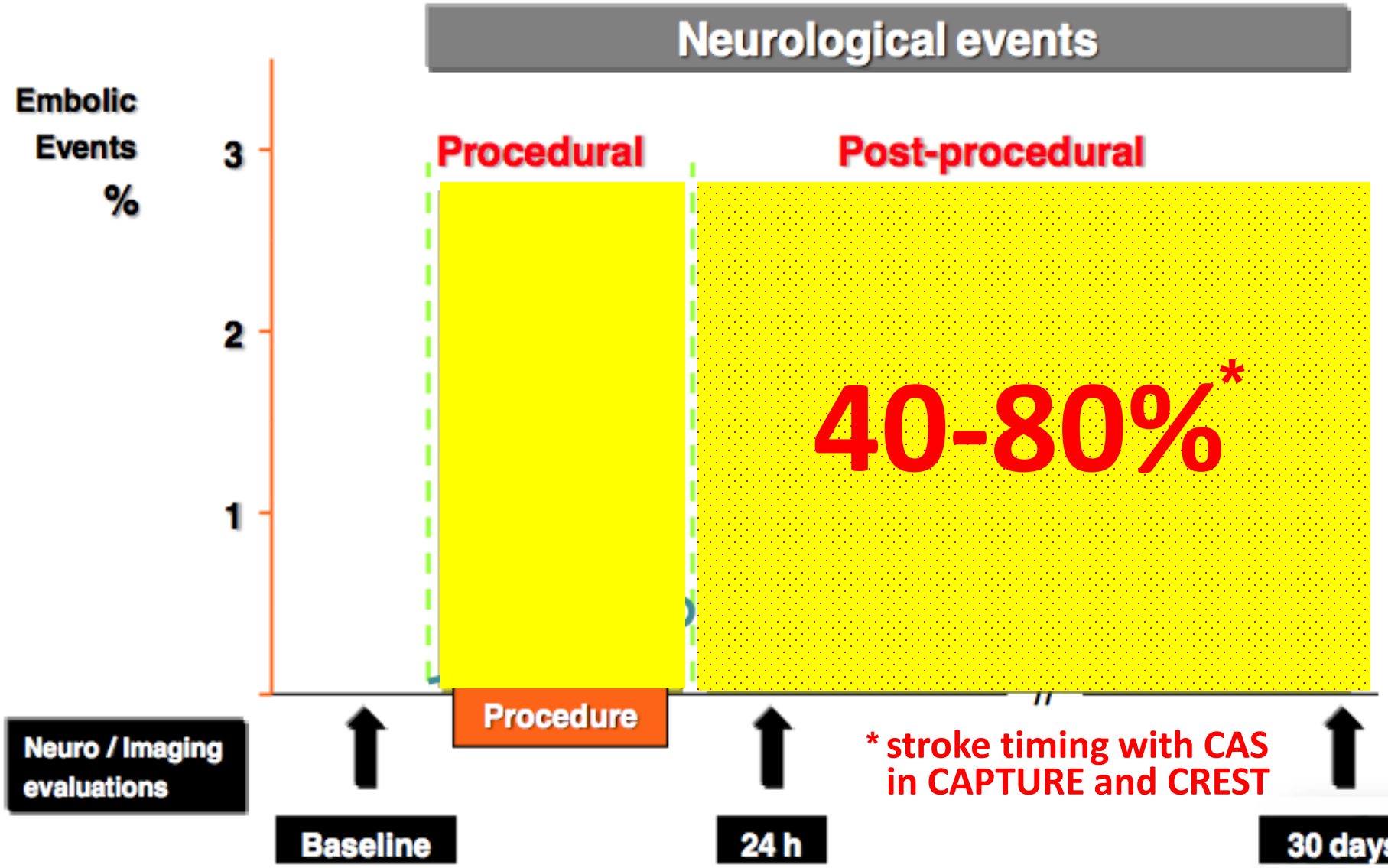
Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS



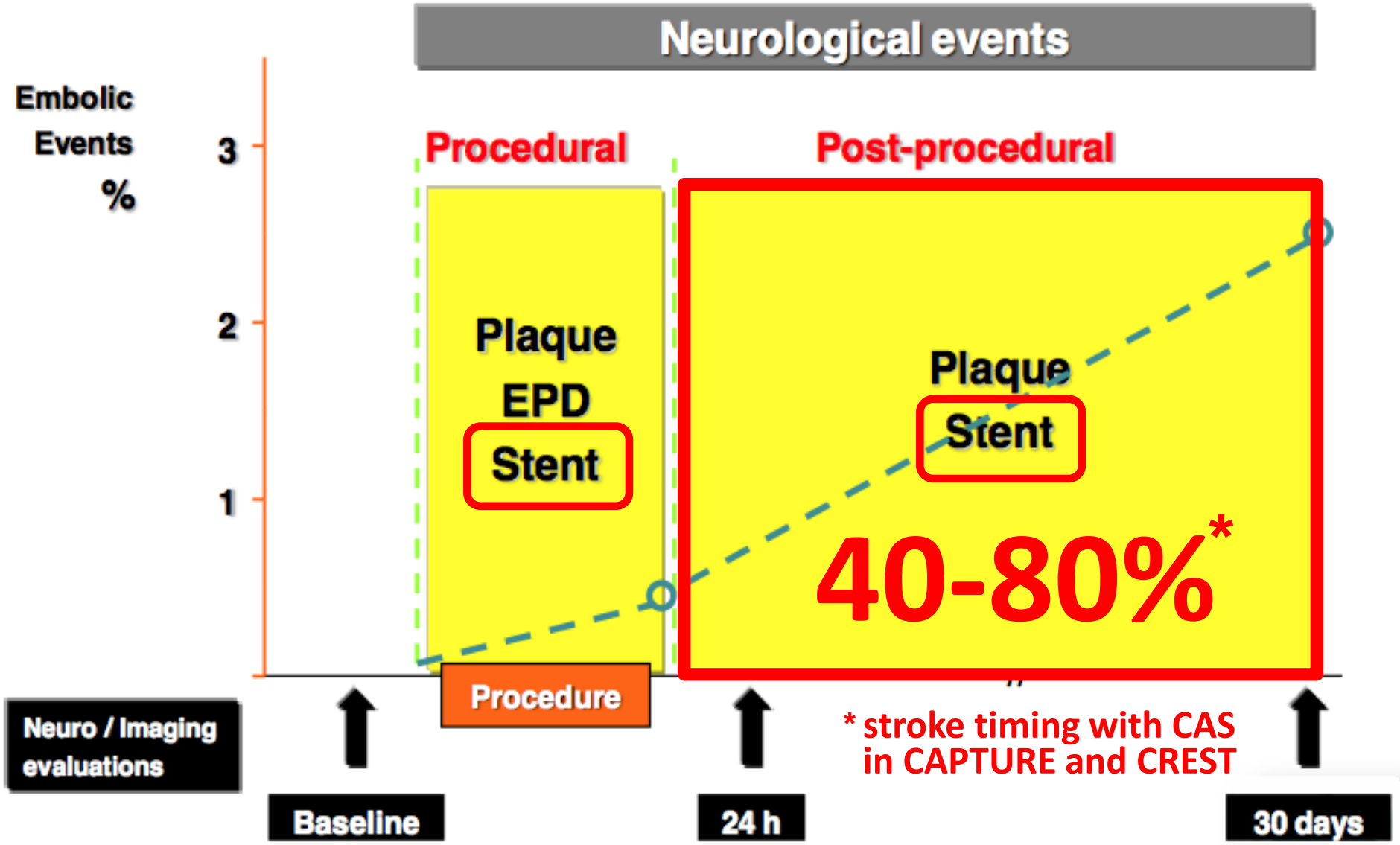
Schofer J et al, JACC Cardiovasc interv 2008

Timing of neuro-embolic events after CAS



D. McCormick TCT 2012, modified

Timing of neuro-embolic events after CAS



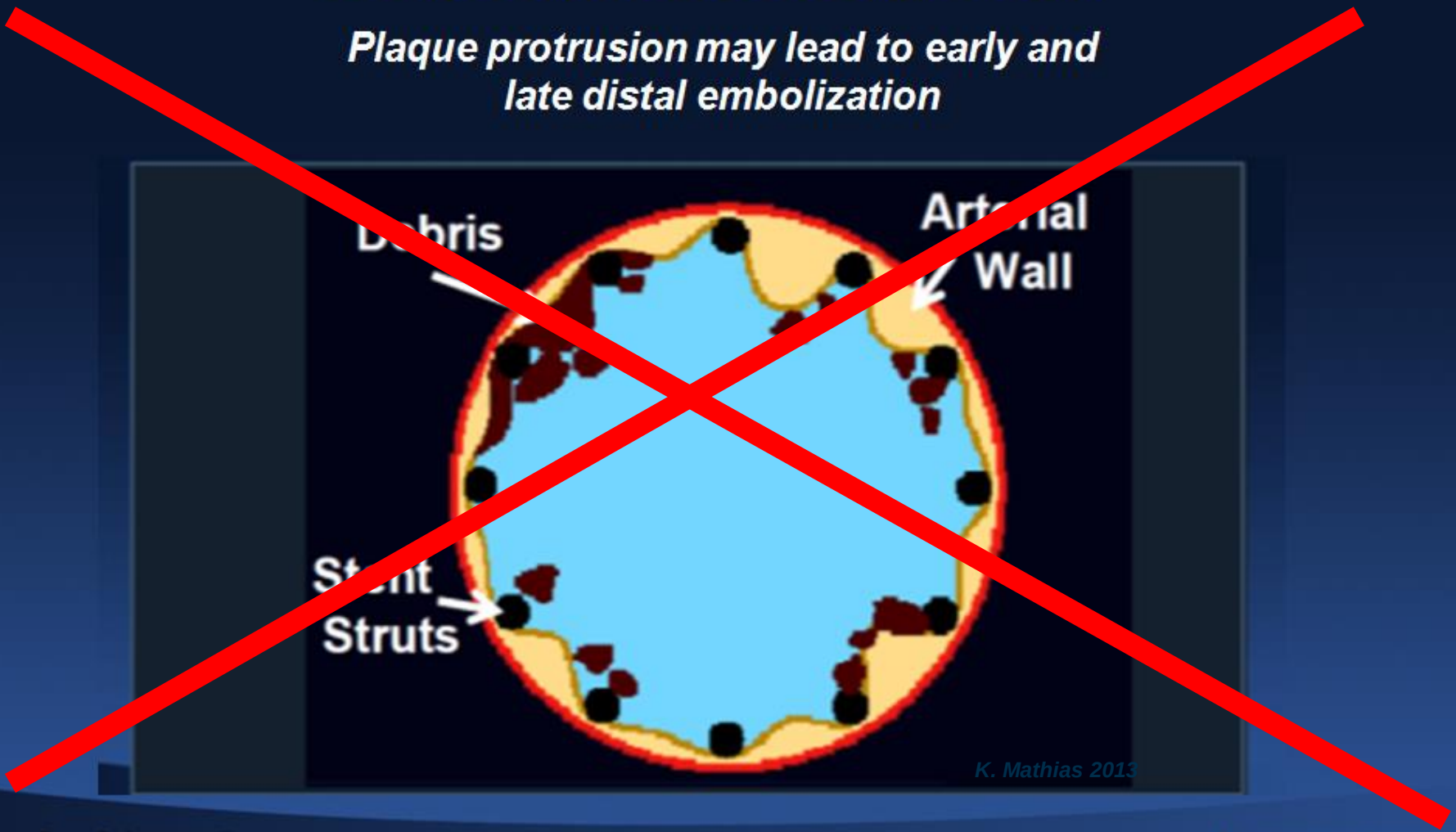
D. McCormick TCT 2012, modified

- CEA excludes the plaque

- CEA excludes the plaque
- In CAS, the stent should exclude the plaque too

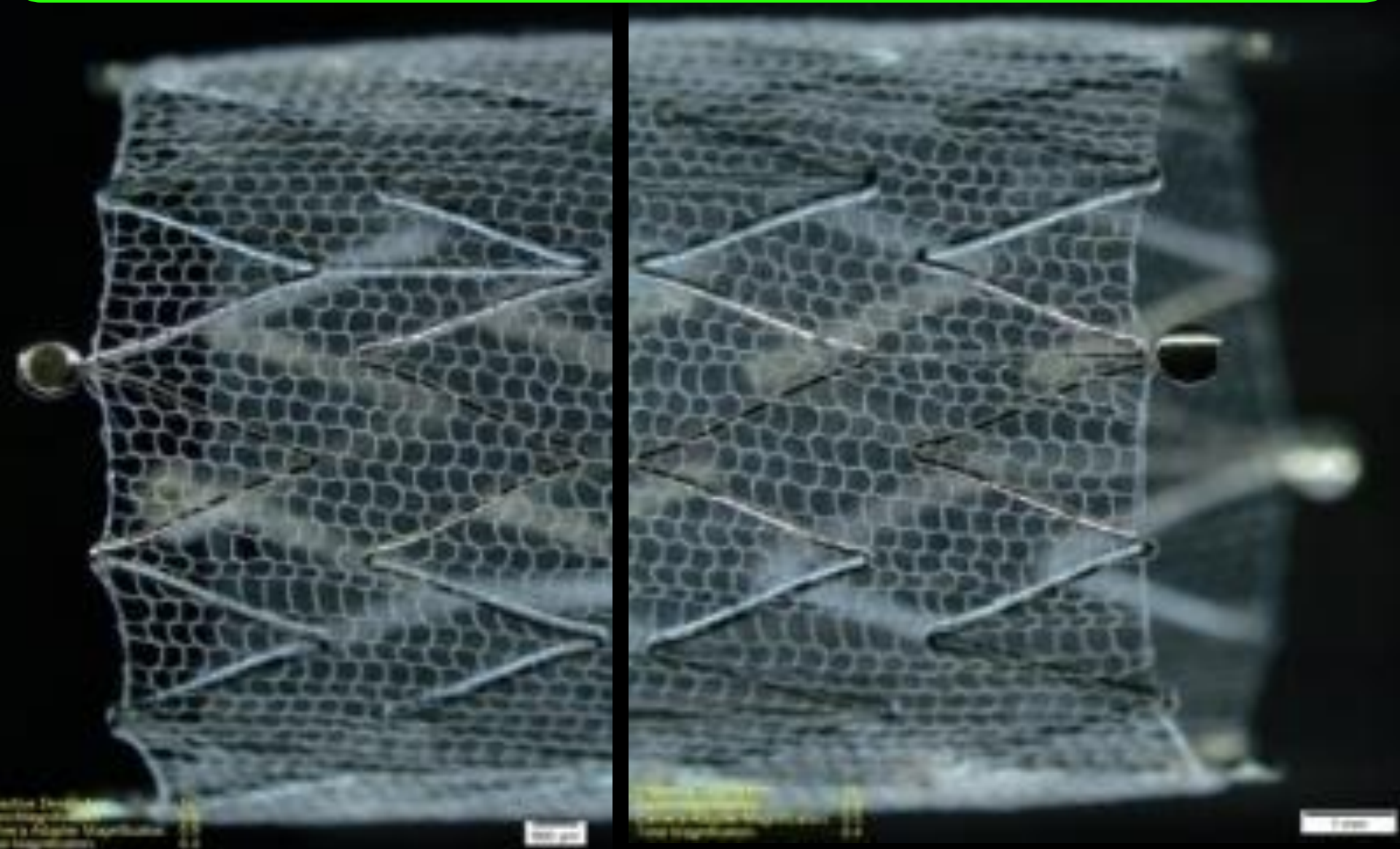
an unmet clinical need

Anti - Embolic Carotid Stent



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

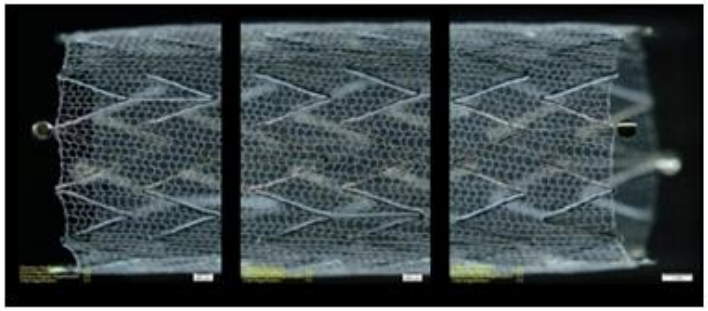
CGuard™ embolic prevention system



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 √

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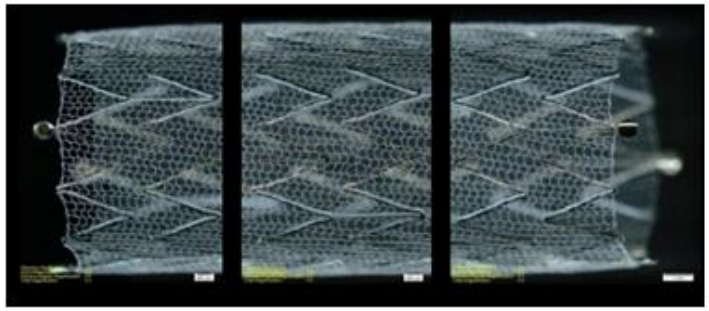

Specific, carotid-dedicated design

Nitinol frame open cell area ≈ 21 mm^2

MicroNet cell area ≈ 0.3mm^2

LARGEST √

SMALEST √

CGuard™ CAS:

CGuard™ CAS:

- **Intra-procedural cerebral embolization is minimized**

J. Schofer, P. Musialek, et al. *JACC Interv* 20152015;8:1229-1234

CGuard™ CAS:

- Intra-procedural cerebral embolization is minimized
- Post-procedural procedural cerebral embolization is nearly-eliminated

J. Schofer, P. Musialek, et al. *JACC Interv* 20152015;8:1229-1234

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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‖

Per-Protocol DW-MRI cerebral imaging at B/L, 24-48h after CAS, and at 30 days

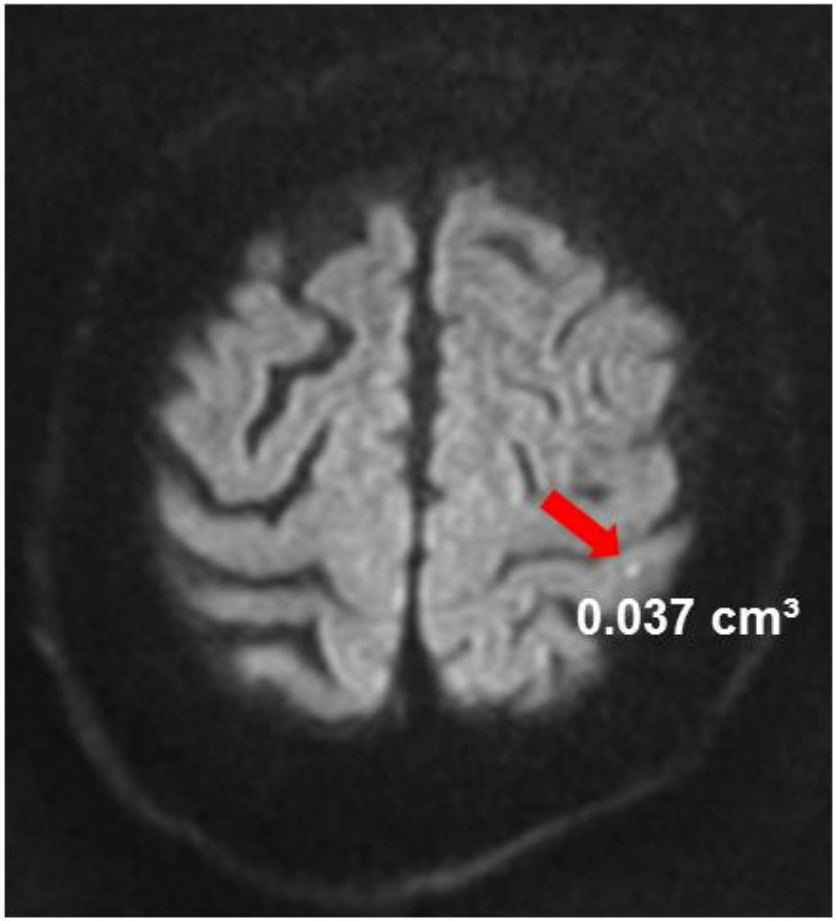
ABSTRACT

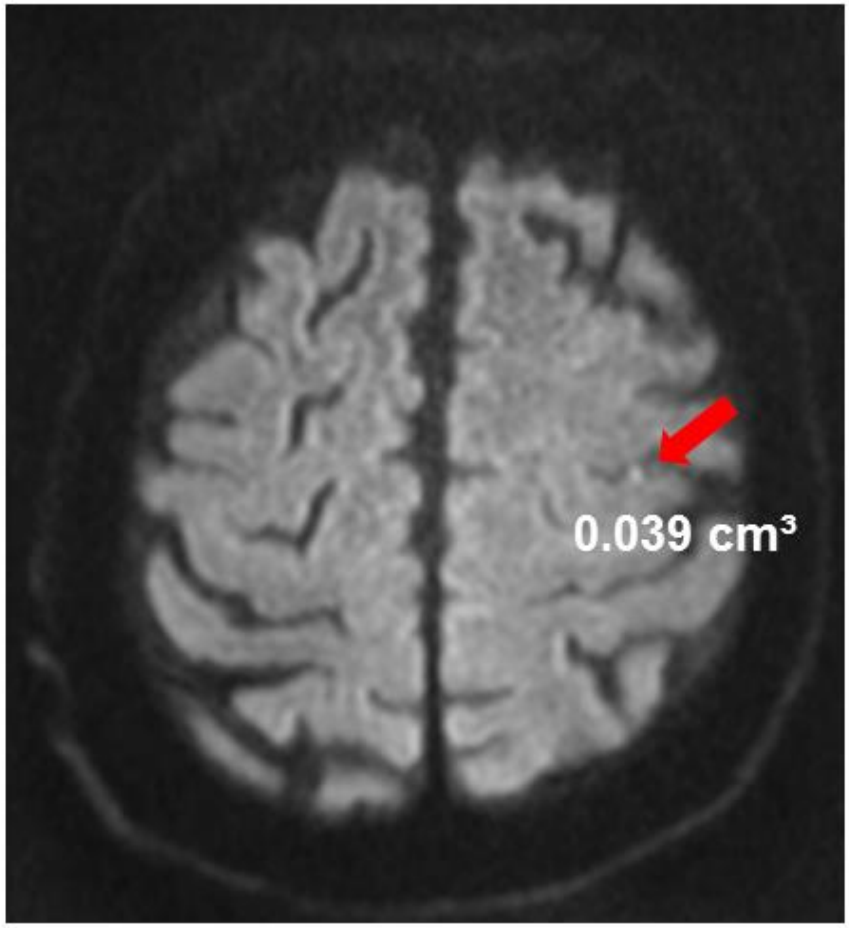
OBJECTIVES This study sought to evaluate the feasibility of the CGuard Carotid Embolic Protective Stent system—a novel thin strut nitinol stent combined with a polyethylene terephthalate mesh covering designed to prevent embolic events from the target lesion in the treatment of carotid artery lesions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

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

>10-fold reduction

in cerebral lesion **volume**

***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*

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

CARENET DW-MRI demonstrated CGuard™ EPD MicroNet

Embolic Prevention

E F F I C A C Y

CGuard EPS Image Courtesy Dr Joan Rigla, MD PhD
Perceptual Imaging Lab, Univerity of Barcelona

J. Schofer, P. Musialek, et al. *JACC Interv* 20152015;8:1229-1234

CARENET (n=30)

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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)

- *large* for routine DW-MRI at 3 time points in relation to CAS

CARENET (n=30)

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- *large* for routine DW-MRI at 3 time points in relation to CAS
- *uderpowered* for clinical endpoints or any potential device-related events

Prospective evaluation of All-comer perRcutaneous cArotiD revascularization In symptomatic and increased-stroke-risk asymptomatic carotid artery stenosis using the CGuard™ MicroNet – covered embolic prevention stent system:

The PARADIGM study

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)

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70 (PARADIGM design and 30-day outcome data)

The PARADIGM study

target

100 consecutive CAS pts / 12mo*

* determined by typical yearly volume

PARADIGM

Study questions:

(1) feasibility of routine use of CGuard MN-EPS in an all-comer carotid stenosis requiring revasc. ?

(2) CGuard EPS device/procedure acute success rate ?

(3) safety clinical efficacy @30-days and @12 months ?

(4) proportion of all-comer carotid stenosis patients that can be treated through the endovascular route ?

(5) feasibility of MN-EPS post-dilatation optimization (full endo reconstuction; "CEA-like" effect of CAS) ?

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70
(PARADIGM design and 30-day outcome data)

PARADIGM

Methods:

- academic cardio-vascular centre
- investigator-initiated study
- not industry-funded
- all-comer inclusion (target = 101 consecutive patients)
- **no exclusion critera**, all referrals tracked
- routine consultation and management pathways
- qualitative and quantitative lesion & stent evaluation
- ***investigator-independent*** **neurological and angiographic evaluation, and external study data verification**

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70
(PARADIGM design and 30-day outcome data)

PARADIGM

Methods (cont'd):

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

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

PARADIGM

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.

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70
(PARADIGM design and 30-day outcome data)

PARADIGM

PARADIGM: investigator – independent

- external source data verification

KCRI
Excellence in clinical research

- external angiographic analysis

Core Imaging Analysis
KCRI
Laboratory

- external statistical analysis

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70
(PARADIGM design and 30-day outcome data)

PARADIGM

Study endpoints:

- **PRIMARY** a composite of **death, stroke (major/minor) and MI** in the peri-procedural period, at 30 days, and up to 12 months

- **SECONDARY**

(1) **acute study device success** defined as ability to treat the index carotid lesion using the study device (CGuard MN-EPS) successfully delivered and deployed at the lesion site, obtaining residual diameter stenosis <30% by QA
(2) **procedural success** defined as device success in absence of any vascular complication that would require interventional management
(3) **in-stent velocities/patency** (Duplex) — **- 30 days**
(4) **long-term clinical efficacy**: stroke and stroke-related death — **- every 12 months up to 5y**

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70 (PARADIGM design and 30-day outcome data)

PARADIGM study: referrals flow chart

139 carotid stenosis patient referrals

CAROTID PARADIGM REVASCULARIZATION

Neuro Vascular Team

- Neurologist
- Interventional angiologist
- Vascular surgeon
- Cardiologist

for carotid revascularisation 108 patients

NOT for carotid revascularisation 31 patients

n=24: increased stroke risk and/or lesion severity criteria not met
n=2: ICA totally occluded on verification
n=2: ICA functional occluded + h/o prior ipsilateral large cerebral infarct with haemorrhagic transformation
n=1: major post-stroke disability, ICA functionally occluded
n=1: severe circulatory failure (ICA stenosis asympt.)
n=1: malignancy with limited life expectancy (ICA stenosis asympt.)

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70

PARADIGM study: revascularisation flow chart

108 patients for carotid revascularisation

(93%) → **CAS** in n=100 patients (bilateral in 5)

(1%) → **CAS+CEA** in n=1 patient (LICA-CEA and RICA-CAS) hybrid management

(6%) → **CEA** in n=7 patients

- n=1 eGRF 14 → no contrast
- n=2 hostile access
- n=1 major ICA kink/loop
- n=1 severe aortic valve disease +calcific LICA (AVR+CEA)
- n=1 floating thrombus in CCA
- n=1 ICA diameter <2.0 mm +contralateral ICA occlusion

106 ICAs treated endovascularly in 101 patients
using exclusively the MicroNet-covered embolic prevention stent system

P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70

Table 1. Clinical characteristics of the study patients (n=101).

Age, mean±SD (min-max)	69±7 (51-86)
Male, % (n)	70% (71)
Symptomatic, % (n)	55% (55)
Symptomatic ≤14 days, % (n)	22%* (12)
Acutely symptomatic (emergent CAS), % (n)	14%* (9)
Index lesion (CAS), % (n)	
RICA	51% (52)
LICA	49% (49)
RICA+LICA	5% (5)
CAD, % (n)	63% (64)
h/o MI, % (n)	32% (32)
CABG or PCI in the past, % (n)	40% (40)
PCI as bridge to CAS, % (n)	18% (18**)
AFib (h/o or chronic), % (n)	9% (9)
Diabetes, % (n)	41% (41)
h/o neck or chest radiotherapy, % (n)	6% (6)

*proportion of symptomatic patients; **simultaneous (one-stage) PCI+CAS in 4 patients; h/o: history of

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EuroIntervention 2016;12:e658-70

Table 2. Quantitative lesion characteristics (n=106), NPD type, CGuard MN-EPS in situ characteristics.

	All (n=106 lesions)	Symptomatic n=55	Asymptomatic n=51	*p*-value
Before CAS				
PSV, m/s	3.7±1.2	3.7±1.1	3.7±1.2	0.964
EDV, m/s	1.2±0.5	1.1±0.5	1.2±0.5	0.268
Diameter stenosis % (QA)	83±9	80±9	86±9	0.002
CAS				
EPD type				
Proximal #	46% (49)	56% (31)	35% (18)	0.030
Distal *	54% (57)	44% (24)	65% (33)	

external Corelab

ICA reference diameter
4.99 ± 0.36mm (from 4.27 to 6.02 mm)

Lesion length
19.9 ± 5.8mm (from 8.19 to 30.25 mm)

* **Emboshield** (n=11); **FilterWire** (n=15); **Spider** (n=31)
\# **Gore FlowReversal** (n=6) or flow reversal with **MoMa** (n=43);
(mean flow reversal time was 6min 35s, from 3min 51s to 11min 2s)

Direct (primary) stenting in 9 (8.5%); predilatation in 97 (91.5%) lesions
Postdil. balloon: ø 4.5mm (n=9); ø 5.0mm (n=55); ø 5.5mm (n=37); ø 6.0mm (n

EuroIntervention 2016;12:e658-70

Table 2.*(cont'd)* CGuard MN-EPS in situ characteristics.

	All (n=106 lesions)	Symptomatic n=55	Asymptomatic n=51	*p*-value
After CAS				
Stent length (QA, CoreLab)[§]				N/A
Nominal 30 mm	29.82±0.68	29.83±0.76	29.80±0.59	
(min-max)	(27.83-32.62)	(27.83-32.62)	(28.83-31.89)	
Nominal 40 mm	39.89±0.59	39.80±0.70	39.97±0.51	
(min-max)	(38.88-41.43)	(38.88-41.43)	(39.14-41.01)	
Residual diameter stenosis	6.7±5%	6.1±5%	7.8±5%	0.262
In-stent PSV, m/s	0.68±0.29	0.64±0.26	0.72±0.31	0.121
in-stent EDV, m/s	0.18±0.08	0.16±0.07	0.19±0.08	0.087

[§]In three cases two overlapping stents were used to cover the whole lesion length; these are not included in the in situ stent length evaluation. N/A: not applicable

external Corelab analysis

⇒ ***no foreshortening, no elongation***
⇒ ***placement precision***

EuroIntervention 2016;12:e658-70

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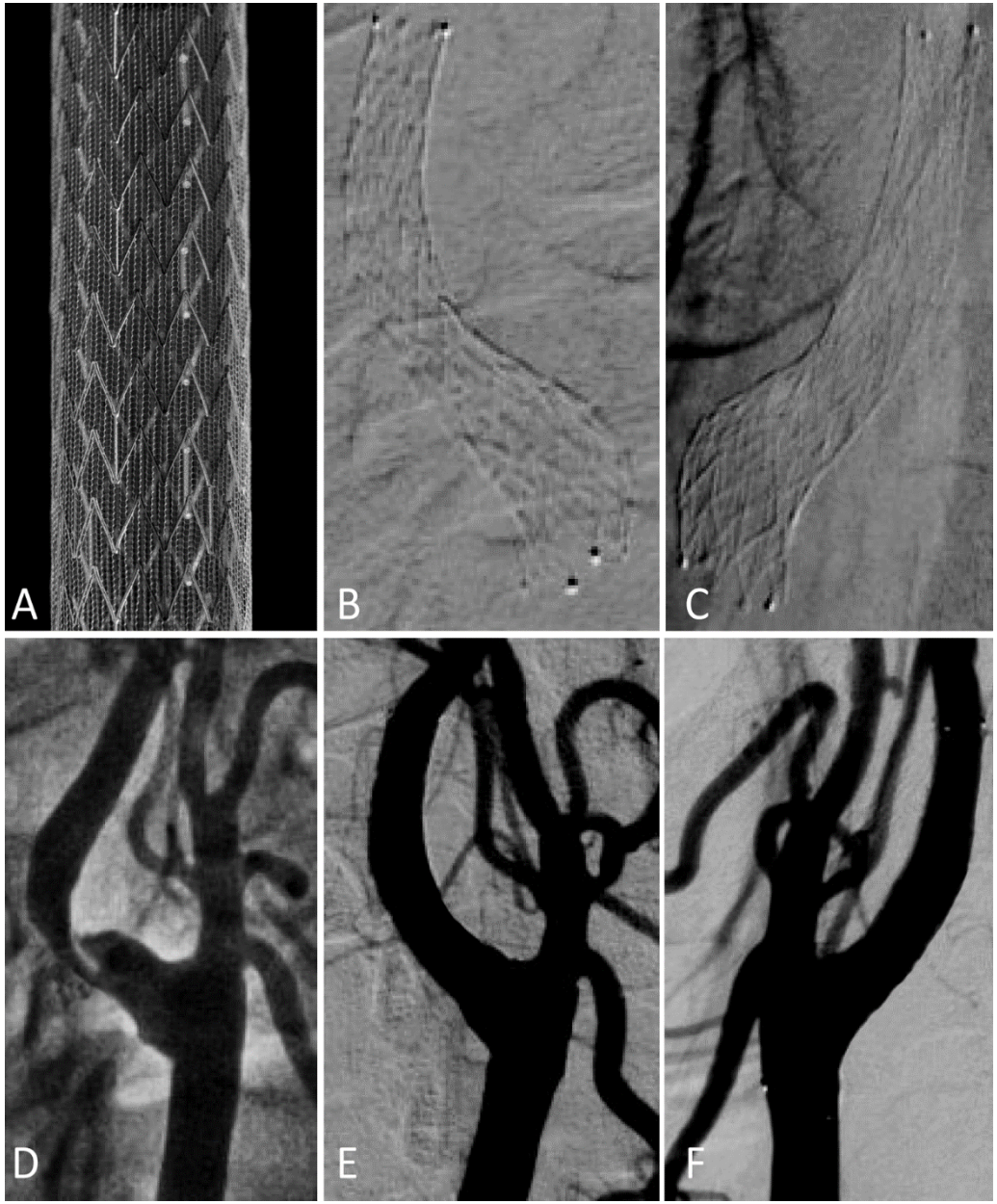
external Corelab analysis

⇒ **'CAE-like' effect of CAS**

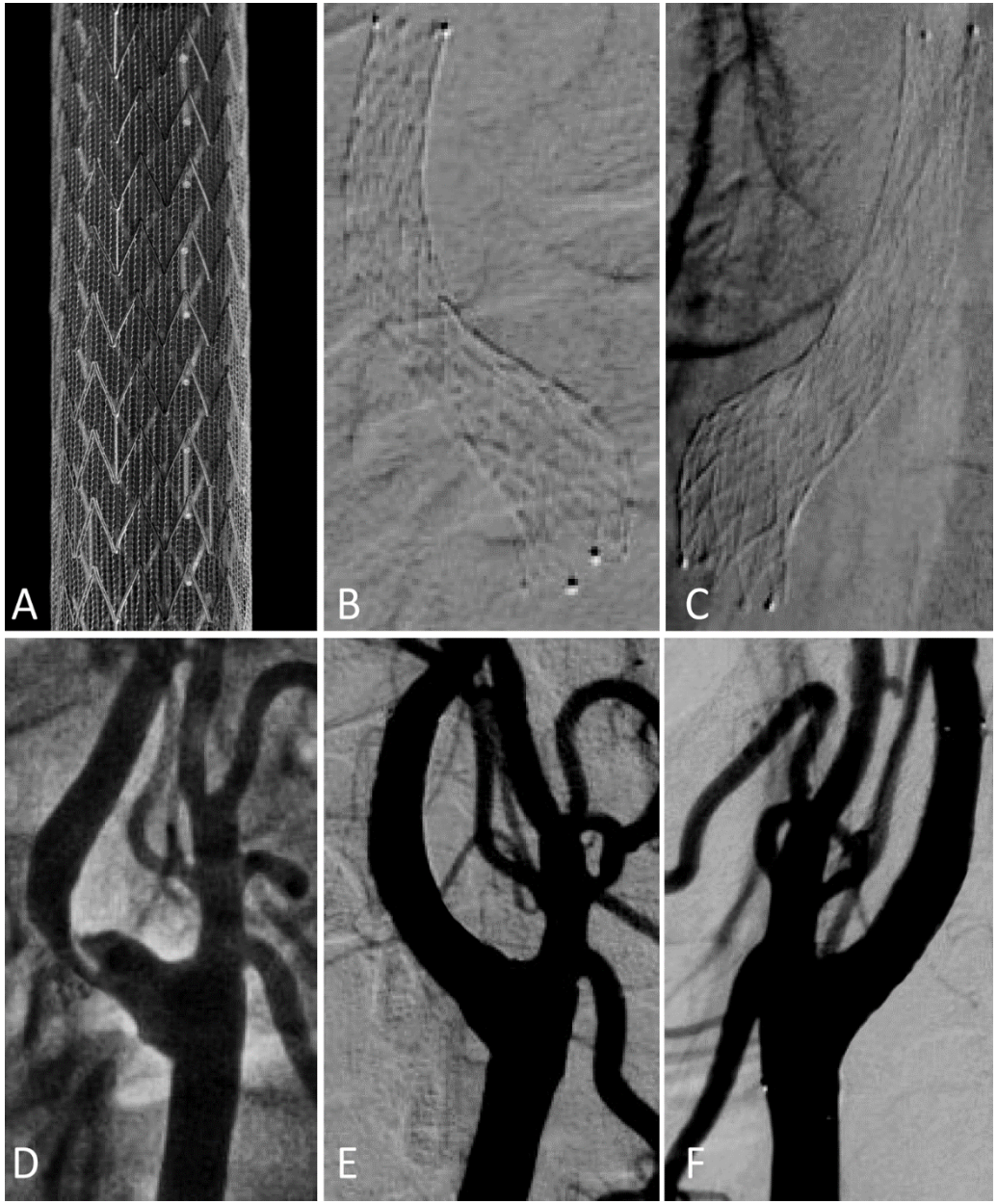
EuroIntervention 2016;12:e658-70



CAROTID PARADIGM REVASCULARIZATION

EuroIntervention 2016;12:e658-70

PARADIGM



CAROTID PARADIGM REVASCULARIZATION

systematic

CEA-like effect of CAS

EuroIntervention 2016;12:e658-70

PARADIGM

- **CAS feasibility using the study-tested MicroNet-covered embolic prevention stent system** **100% CAS** (n= 106)

(ie, no cross-over to other stents or other carotid stent use during the whole study period)

• **Device success**	**99.1%**	(n=105)*
• **Procedure success**	**99.1%**	(n=105)*
• **Transient dopamine infusion**	**15.1%**	(n = 16)
• **Debris in EPD**	**17.9%**	(n = 19)
• **Vascular plug closure**	**53.8%**	(n = 57)
• **Access site complications**	**0%**	(n = 0)

* in 1 case no stent post-dilatation was performed due to profound bradycardia-asystole, and 46% residual diameter stenosis was left (ie, above the Protocol-defined threshold <30% DS for "device success")

ECA patency data

6/106 (5.6%) ECAs were occluded on the index side prior to CAS
3/100 (3.0%), with severe stenosis prior to CAS, occluded at CAS
NO ECA occlusion occurred between CAS and 30 days

=> no concern

30-day neurological, duplex, and cardiologic follow up was executed in 100% patients (101) and arteries (106)

PARADIGM: 30 days

Clinical Results (MACNE)

- 0 peri-procedural death/major stroke/MI 0%
- 1 peri-procedural minor stroke* 0.9%
- 0 new clinical events by 30 days 0%

(100% follow-up, independent neuro evaluation)

* One patient, with symptomatic RICA stenosis (minor right-hemispheric stroke 2 months prior to CAS), had **hypotonia** and transient, fluctuating cognitive dysfunction at 24-48h after CAS. The patient had additional neurologic evaluation on discharge (day 7) that showed **no change in NIH-SS [=3] and no change in modified Rankin scale [=1] against 48h (and baseline) evaluation.** CT scan on day 2 showed no new cerebral lesions but day 6 CT indicated **an extension of the prior lesion in the right hemisphere.** The event, in **absence of right haemispheric symptoms and in absence of any clinical sequelae**, was CEC–adjudicated as 'minor stroke in relation to CAS'.

EuroIntervention 2016;12:e658-70

Novel PARADIGM in Carotid Revascularization:

12month data

Clinical & Duplex US Outcome Data

@ 12 months

TCT 2016

CGuard™ EPS Carotid **PARADIGM** Study

12mo Clinical Outcome Data

12month data

- 106 index arteries / 101 study subjects
- no patient withdrawals by 12 months
- 100% - clinical
  - neurological
  - Duplex US

} 12 month follow up

CGuard™ EPS Carotid **PARADIGM** Study
12mo Clinical Outcome Data

12month data

- 106 index arteries / 101 study subjects
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} 12 month follow up

Z E R O Stroke Deaths
Z E R O Strokes @ 12mo
Per-Protocol independent neurological evaluation

CGuard™ EPS Carotid **PARADIGM** Study
12mo Clinical Outcome Data

12month data

- **106 index arteries / 101 study subjects**
- **no patient withdrawals by 12 months**
- **100%** **- clinical**
  - neurological } **12 month follow up**
  - Duplex US

Z E R O Stroke Deaths
Z E R O Strokes 30d–12mo
Per-Protocol independent neurological evaluation

- **1 cardiac death @ 11mo** (man 68y, heart failure death)
- **3 non-cardiac deaths @ 3mo, 5mo, 11mo**
  - urosepsis (woman 73y)
  - pulmonary embolism (woman 67y)
  - microcellular pulmonary cancer (man 71y)

CGuard™ EPS Carotid **PARADIGM** Study
12mo Clinical Outcome Data

12month data

- **0% stroke**
- **0% TIA**
- **0% MI**

between 30 days and 12 months

in n=101 ↑ stroke-risk patients

(55% symptomatic)

CGUARD™
Carotid Embolic Prevention System

CAROTID PARADIGM REVASCULARIZATION

12month data

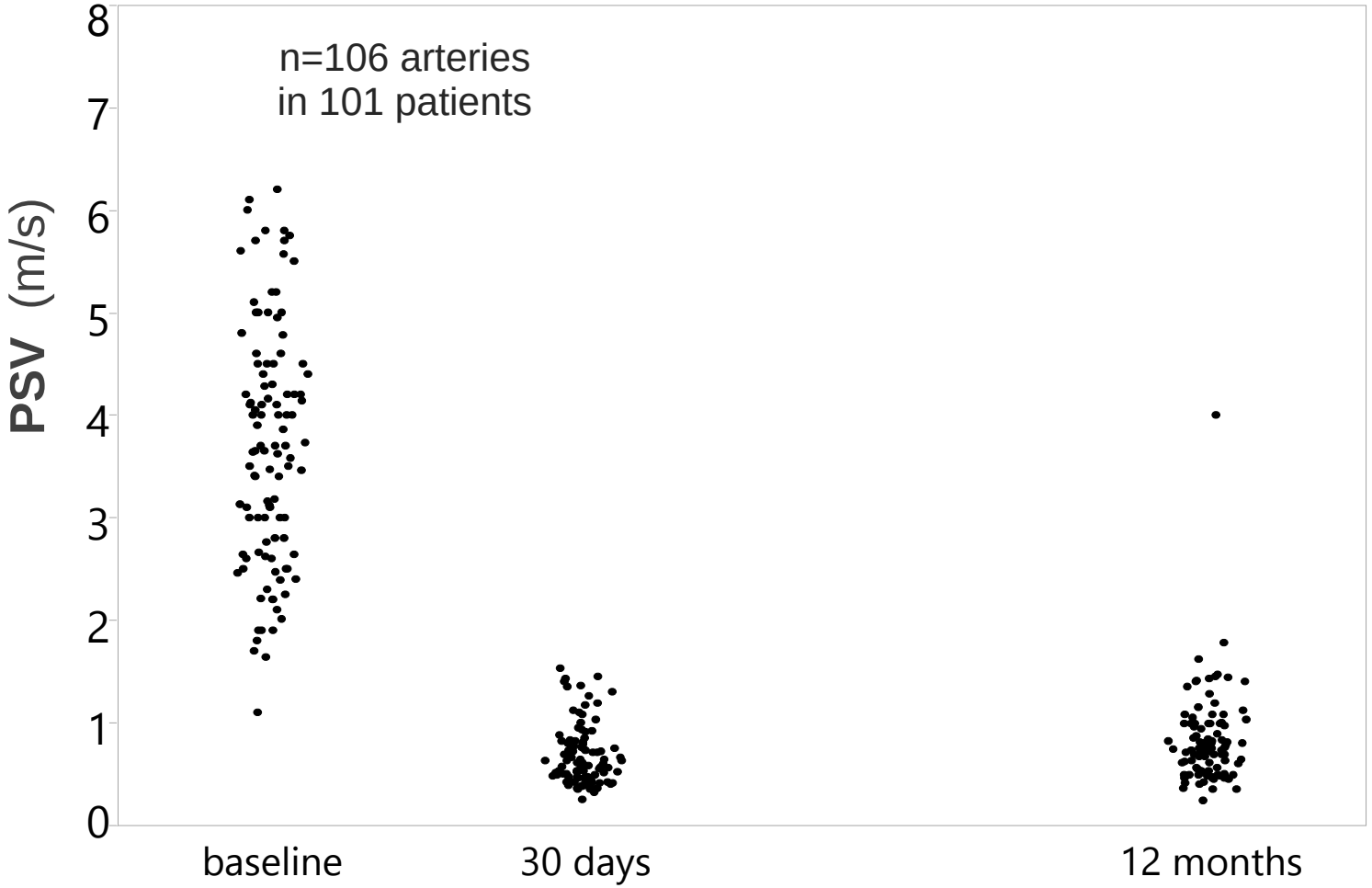
PARADIGM

12 months

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

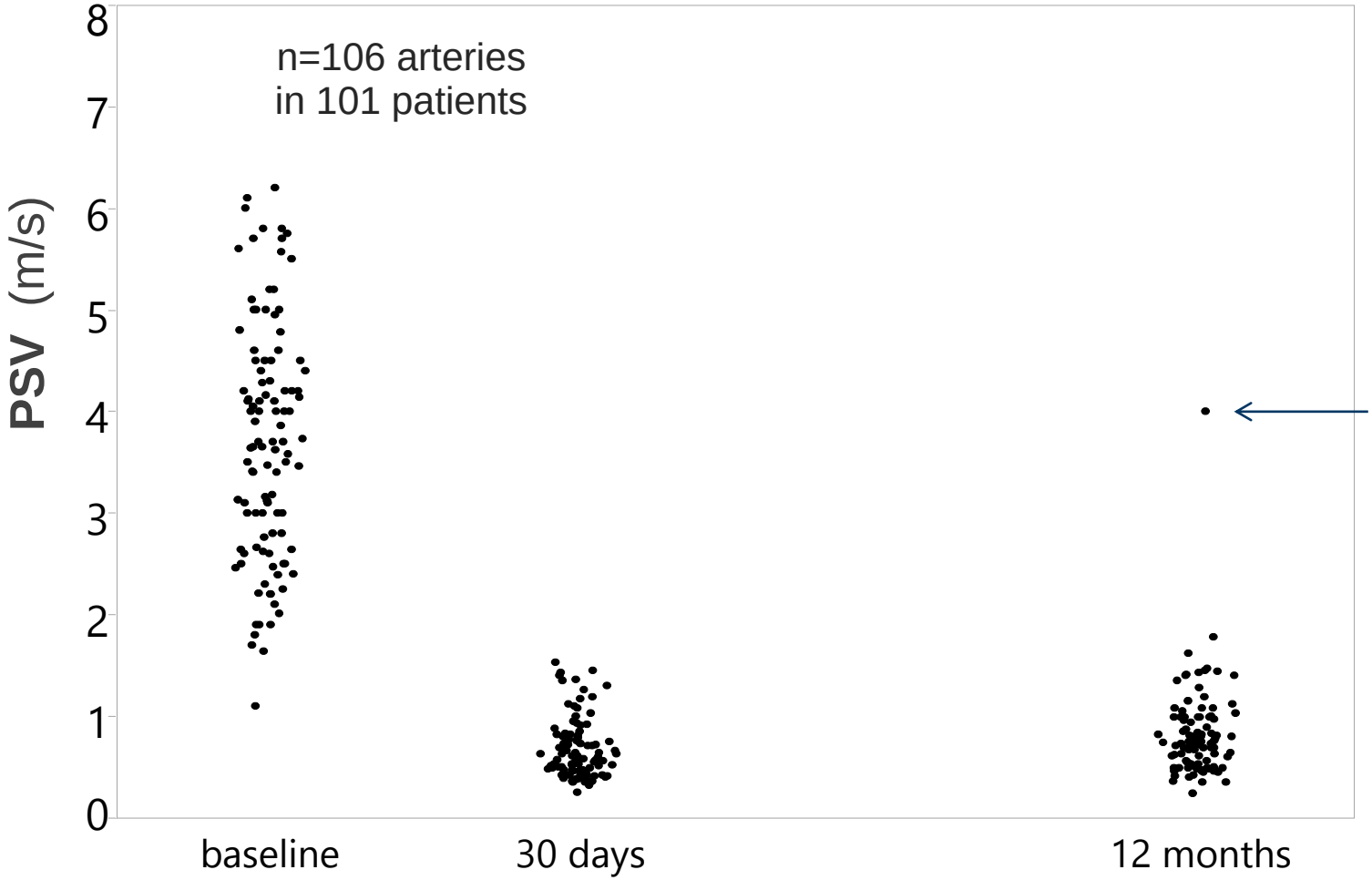
CGuard™ EPS Carotid **PARADIGM** Study
12mo Duplex Ultrasound Data

12month data



CGuard™ EPS Carotid **PARADIGM** Study
12mo Duplex Ultrasound Data

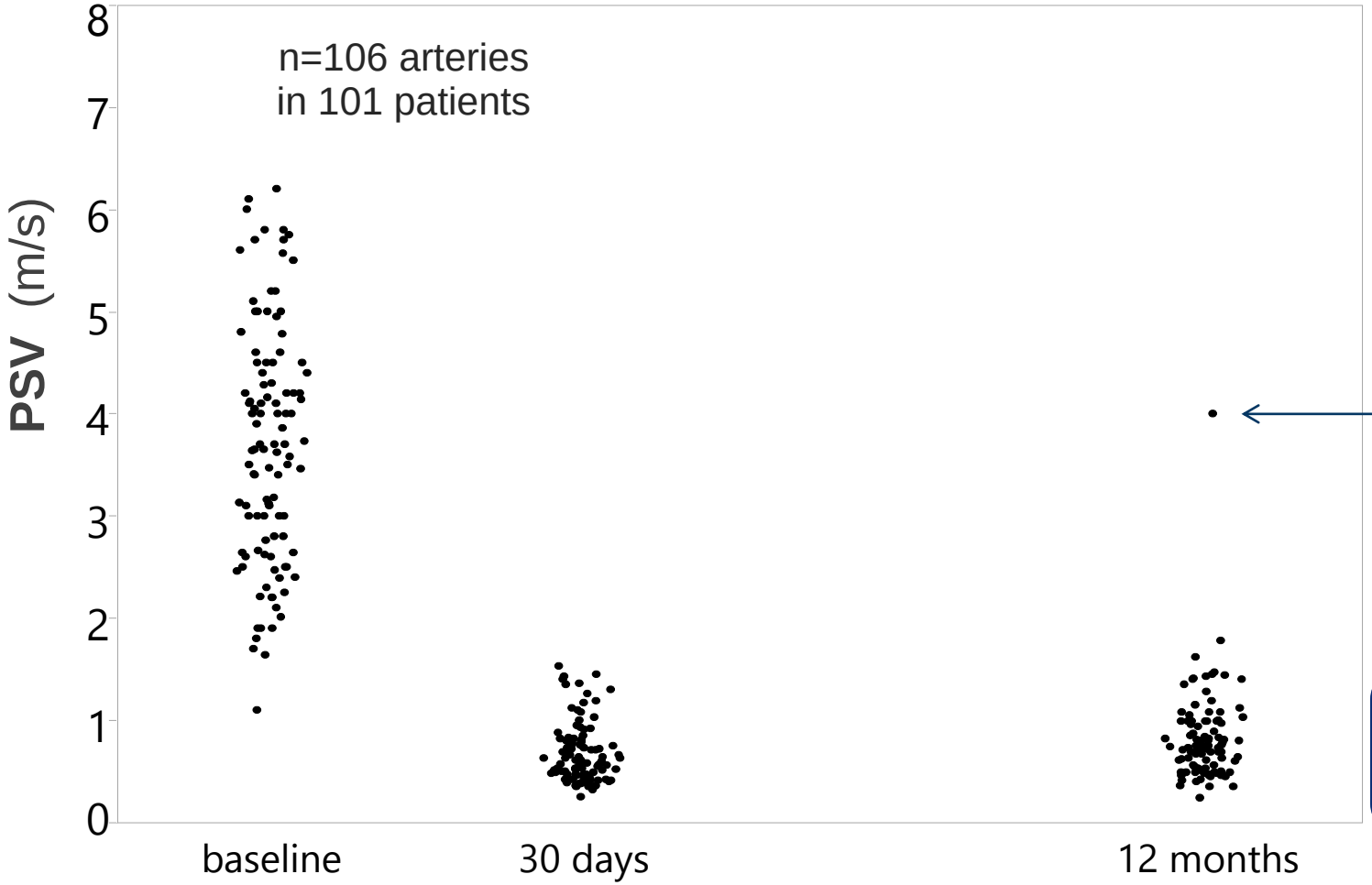
12month data



CGuard™ EPS Carotid **PARADIGM** Study
12mo Duplex Ultrasound Data

CAROTID PARADIGM REVASCULARIZATION

12month data



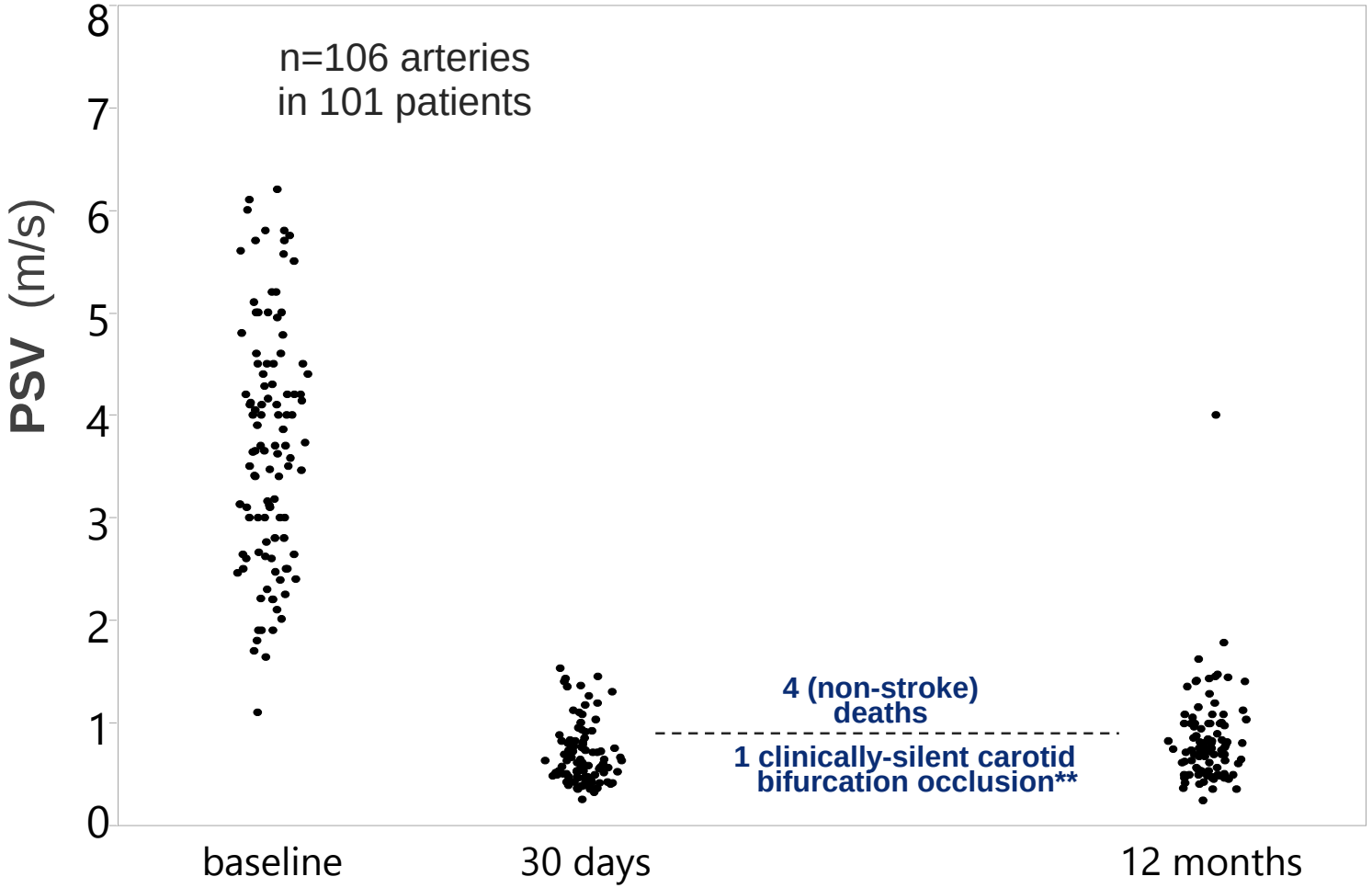
1 asymptomatic **ISR**
(treated with PTA+DEB)

NB. **CEA 'arm'**
- **1** critical **restenosis** –> CGuard CAS
- **1** silent **occlusion**

CGuard™ EPS Carotid **PARADIGM** Study
12mo Duplex Ultrasound Data

CAROTID PARADIGM REVASCULARIZATION

12month data



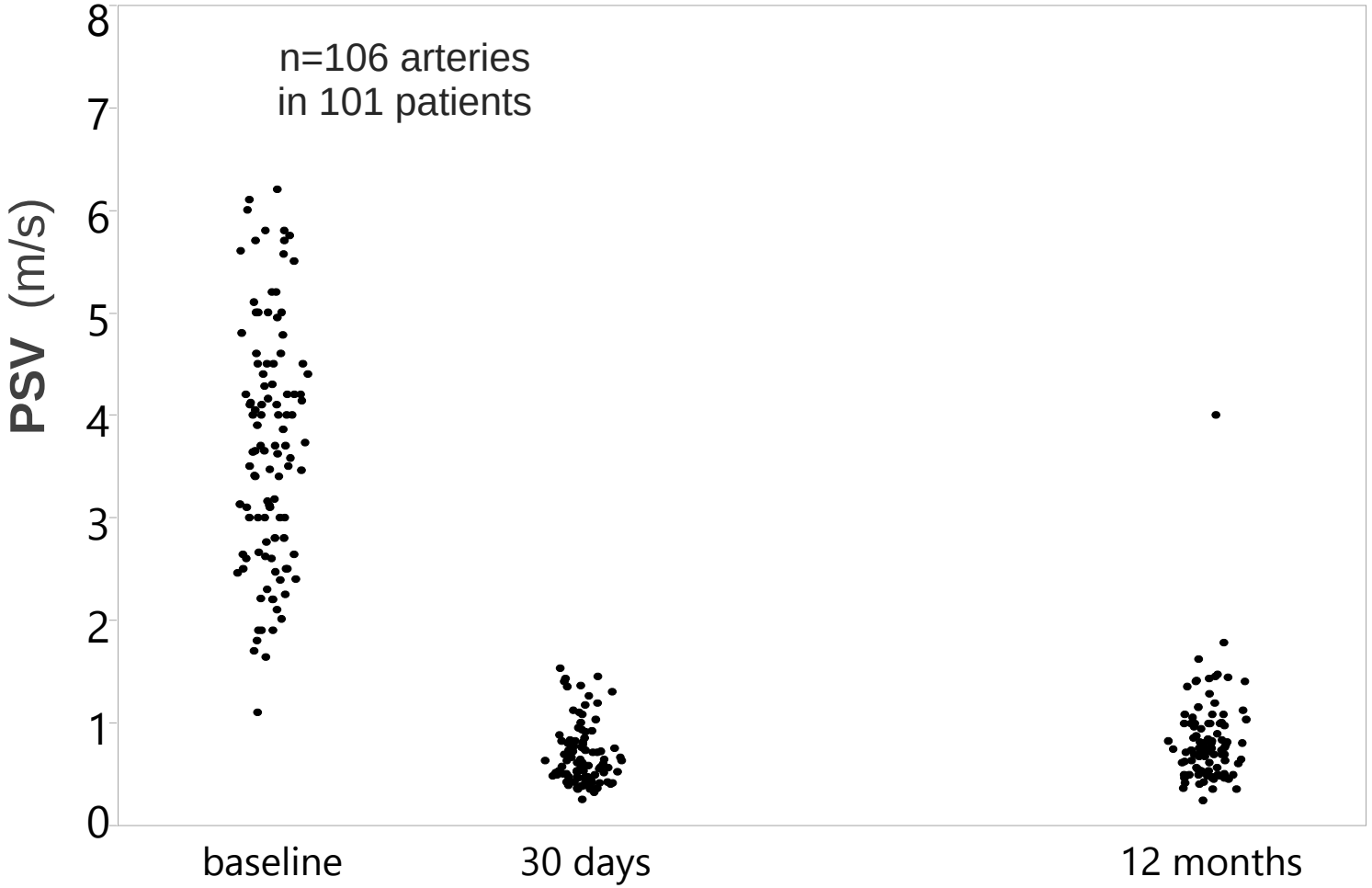
**laryngeal cancer relaps
5-session **radioTx course**
3 months after CAS

CGuard™ EPS Carotid **PARADIGM** Study
12mo Duplex Ultrasound Data

CAROTID PARADIGM REVASCULARIZATION

12month data

ECA* patency



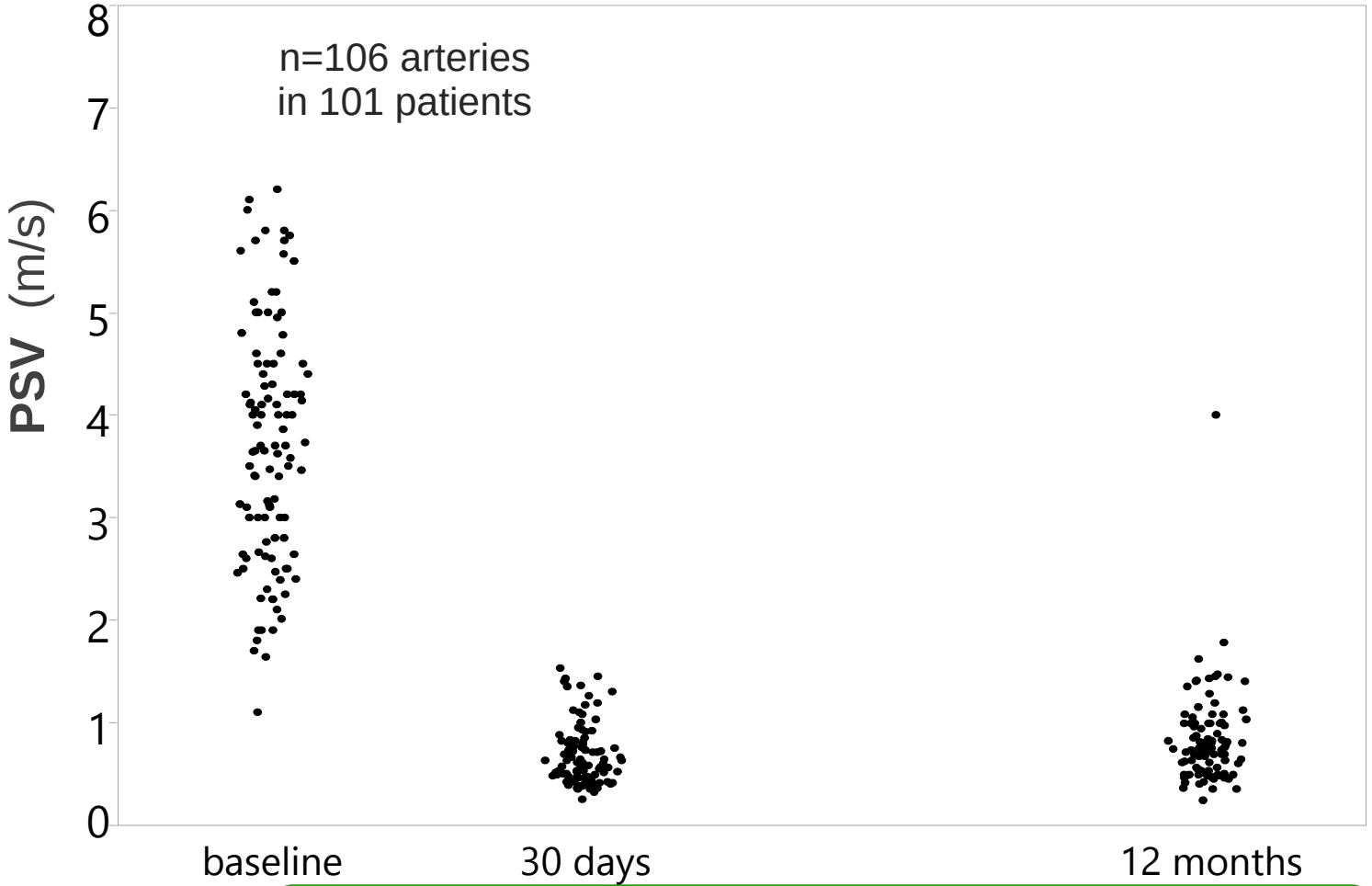
* patient alive, target CCA and ICA patent

CGuard™ EPS Carotid **PARADIGM** Study
12mo Duplex Ultrasound Data

CAROTID PARADIGM REVASCULARIZATION

12month data

ECA* patency

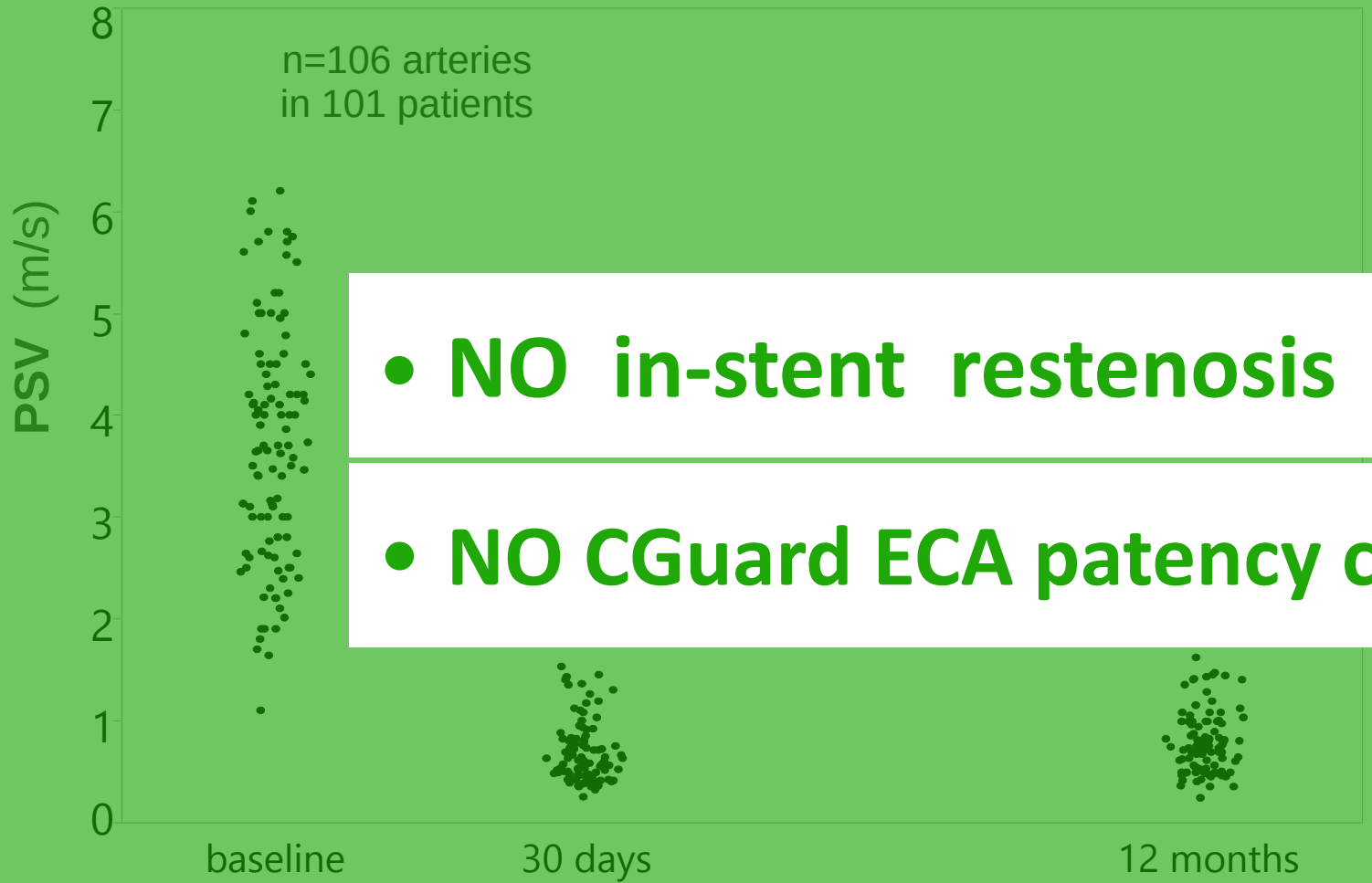


ECA

100/106 ECAs were patent prior to CAS

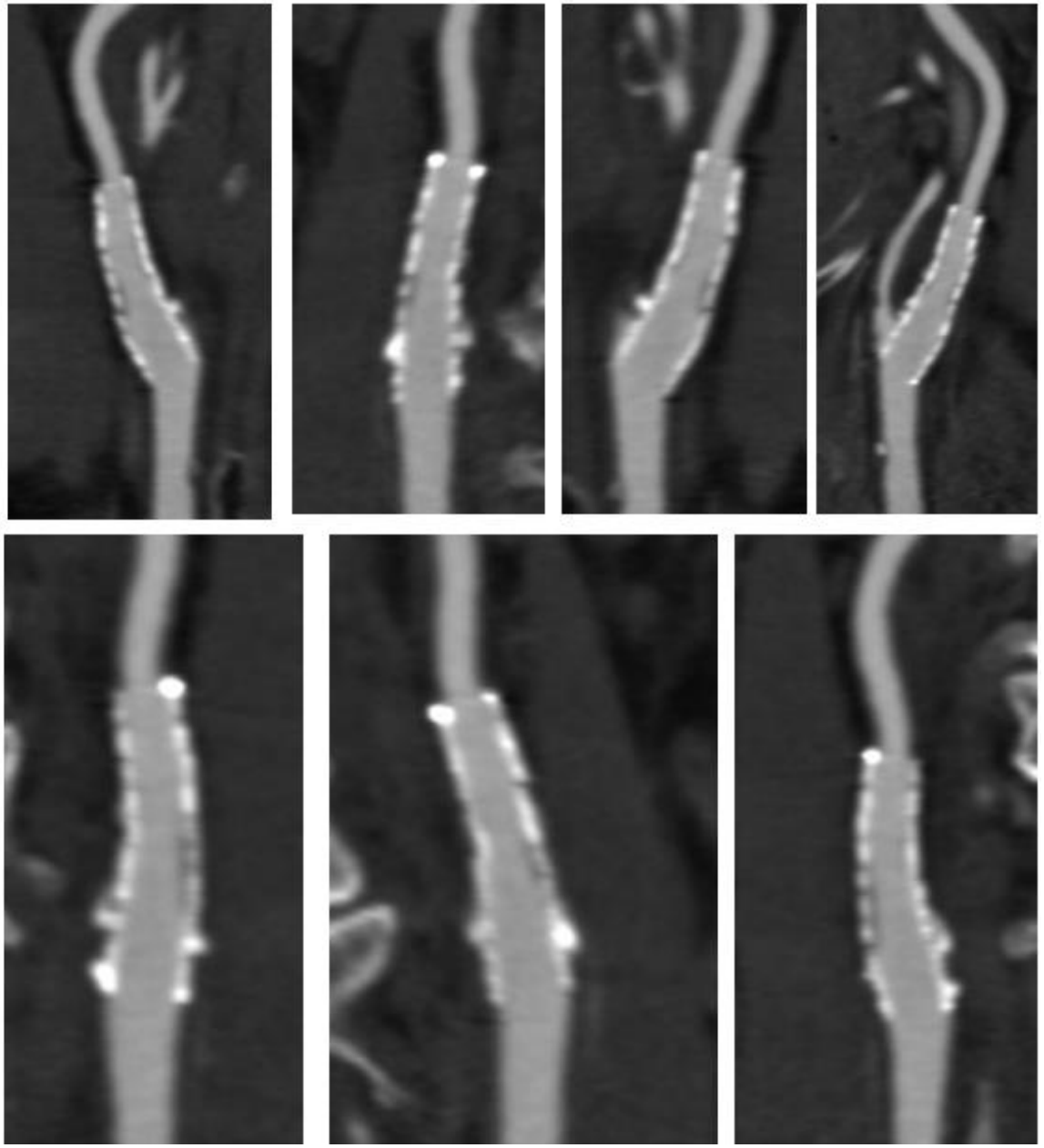
baseline	30 days	12 months
97.0% 3 ECAs occluded at CAS	**97.0%** 97/100 ECAs patent	**96.9%** 93/96 ECAs patent

CGuard™ EPS Carotid **PARADIGM** Study
12mo Duplex Ultrasound Data



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


CGuard



tct2016

CGuard™ image courtesy C. Wissgott and colleagues.
J Endovasc Ther. 2016 Oct 12 [epub ahead of print]

TCT 2016 Featured Research

CGuard™ EPS Carotid **PARADIGM** Study
12-month Data

Conclusions

CGuard™ EPS Carotid **PARADIGM** Study
12-month Data

Conclusions

- **In the increased-stroke-risk population, including >50% symptomatic patients, CGuard™ EPS demonstrated effective and durable protection against stroke**

CGuard™ EPS Carotid **PARADIGM** Study
12-month Data

Conclusions

- **In the increased-stroke-risk population, including >50% symptomatic patients, CGuard™ EPS demonstrated effective and durable protection against stroke in absence of any device-related adverse events by 12 months**

CGuard™ EPS Carotid **PARADIGM** Study
12-month Data

Conclusions

- **In the increased-stroke-risk population, including >50% symptomatic patients, CGuard™ EPS demonstrated effective and durable protection against stroke in absence of any device-related adverse events by 12 months**

- **12-month Duplex Ultrasound data indicate normal device healing and ECA patency**

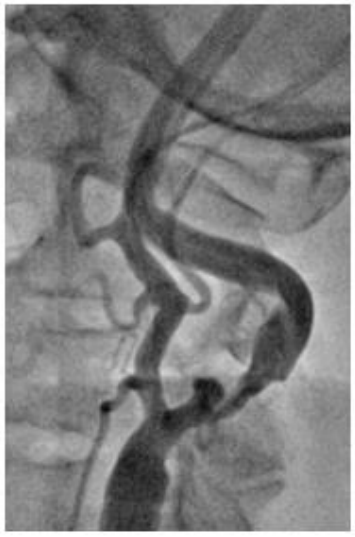
Impact on clinical practice

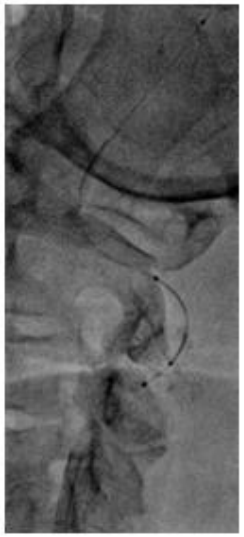
***With this novel technology*,**

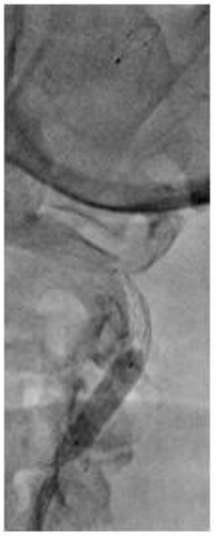
The ENDOVASCULAR route of carotid stenosis management in PRIMARY and SECONDARY Stroke Prevention is

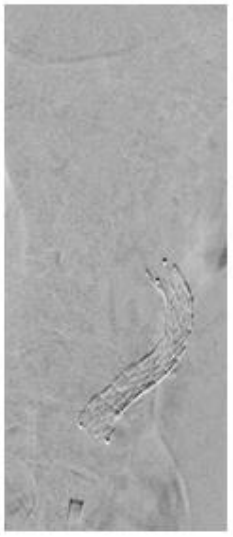
- **Viable √**
- **Safe and effective √**
- **Applicable to routine practice of CAS √**
- **Applicable to >90% of all-comer patients √**
- **Durable in absence of device-related issues √**

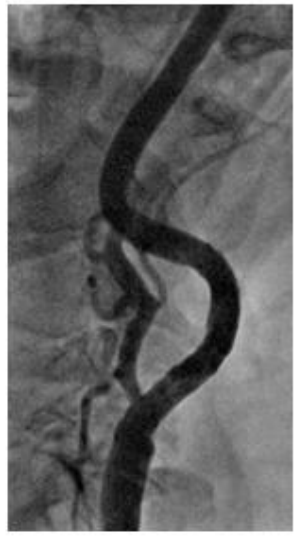
Endovascular Solution for All-Comers

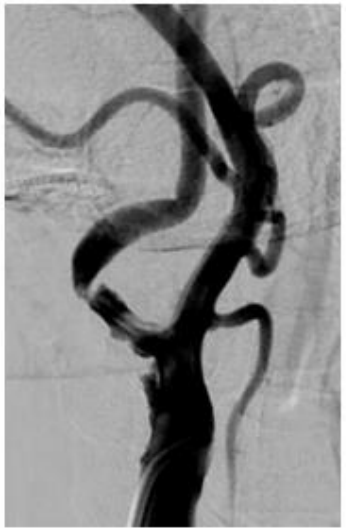


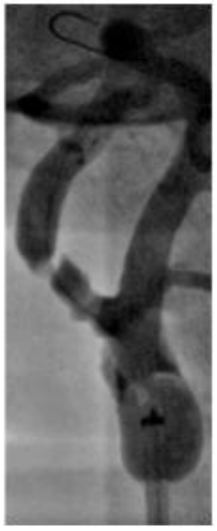


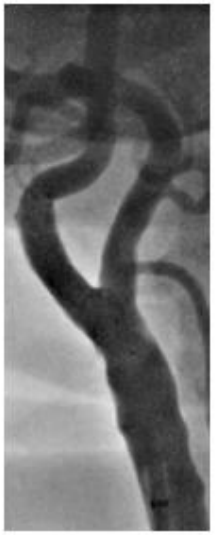


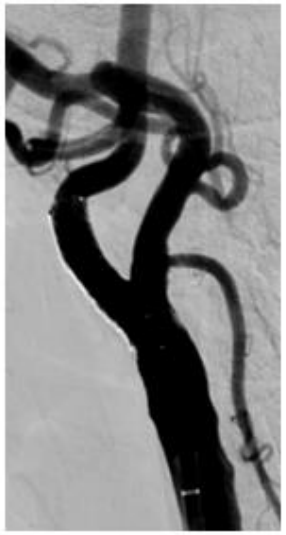












Endovascular Reconstruction of the Carotid Bifurcation

Prevention of embolism, Optimal radial force, Conformability

Endovascular Solution for All-Comers

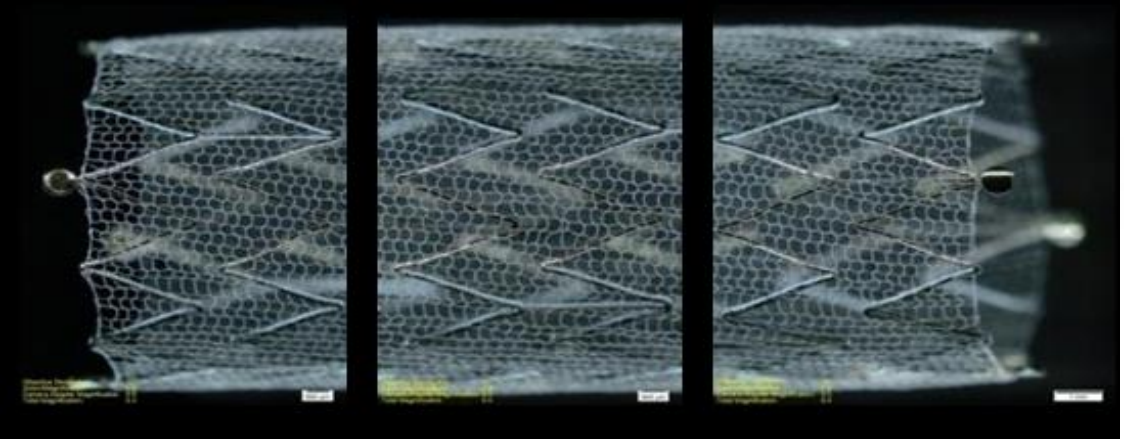
routine

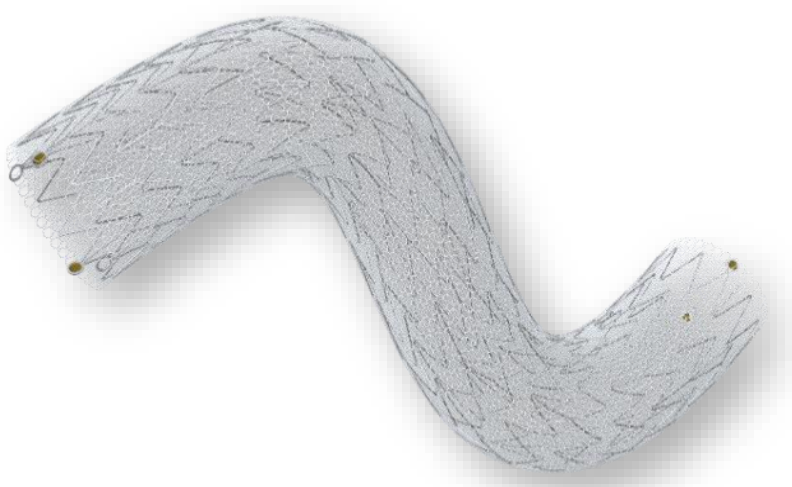
CEA-like effect of C A S

Note self-tapering

Endovascular Reconstruction of the Carotid Bifurcation

Prevention of embolism, Optimal radial force, Conformability

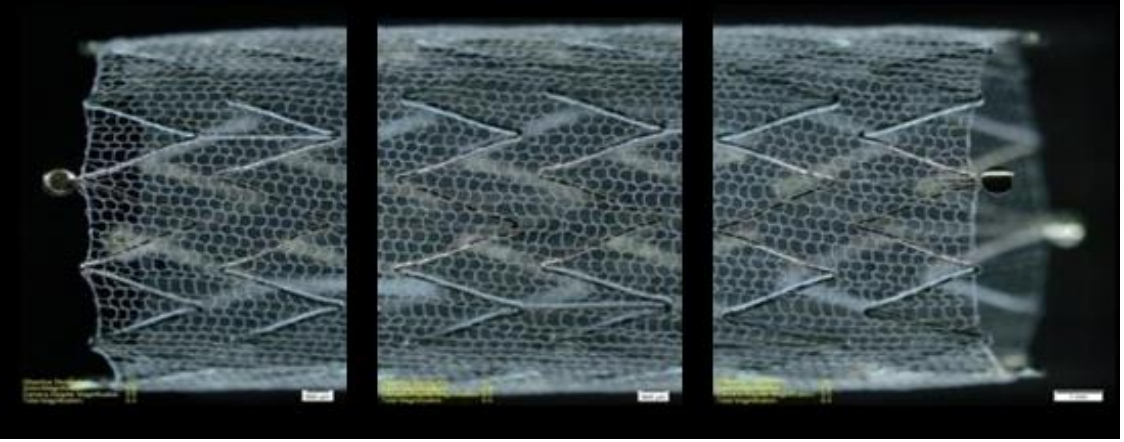


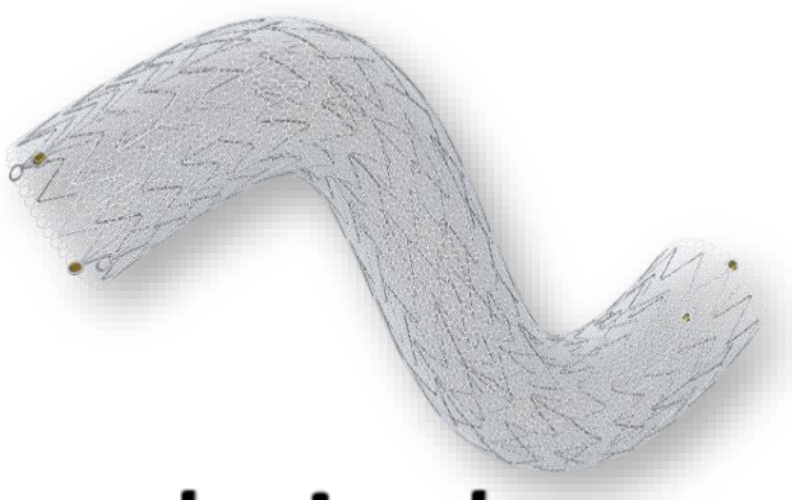


This concept has been desired.

And it works.

This is the future of Carotid Artery Stenting √





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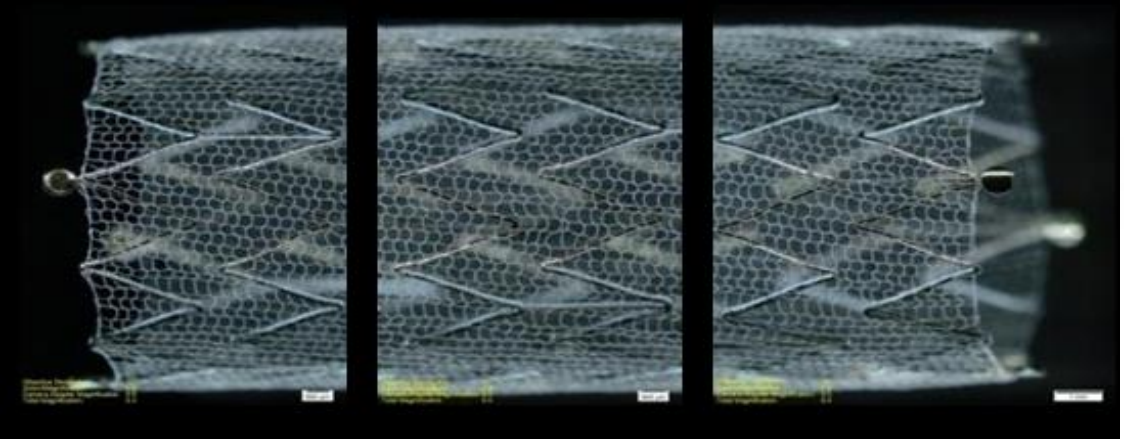

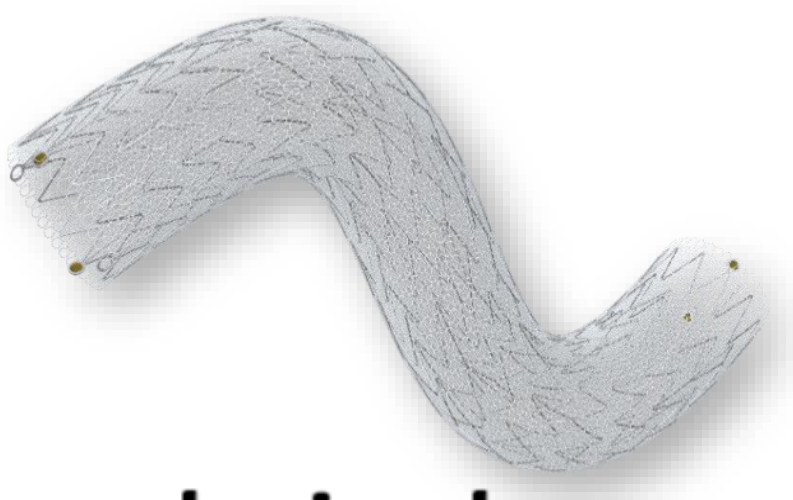

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revascularization ?

2016

Carotid Artery Revascularization for Stroke Prevention: A New Era

Journal of Endovascular Therapy
1–11

DOI: 10.1177/1526602816671263
www.jevt.org
SAGE

Piotr Musialek, MD, DPhil[1], and Silke Hopf-Jensen, MD[2]

Keywords
atherosclerosis, carotid artery stenosis, carotid artery stent, double-layered stent, embolic prevention stent, MicroNet-covered stent, mesh-covered stent, stroke

Carotid Artery Stenosis

"Significant" atherosclerotic carotid artery disease [usually, though not always rightly[1] understood as ≥50% diameter reduction at the carotid bifurcation and/or in the proximal internal carotid artery (ICA)] is present in 2% to 8% of the general population, making it a relatively common pathology.[2] Its prevalence is similar to that of nonvalvular atrial fibrillation (AF), and similar to AF, it increases with age.[2,3] Carotid stenosis (CS) is notably more prevalent in patients with diabetes, coronary artery disease, and peripheral artery disease.[4,5]

Atherosclerotic carotid artery disease is associated with stroke risk through plaque rupture or erosion and consequent thrombus formation, and the stroke mechanism is predomi-

proportion of these patients are already on antiplatelet and maximized statin treatment prior to the CS-associated stroke events,[11,14,15] consistent with the fact that medical therapy reduces but does not abolish the CS stroke risk.

CS and Stroke Risk

Recently, a series of influential communications have been addressed to the medical community with the message of a currently "low" (<1.0%[10,16] or ~0.5%[17]) yearly incidence of stroke in relation to asymptomatic CS on medical management.[10,16,17] This is in contrast to contemporary data from vascular clinics that show a yearly stroke rate of ~2.0% to 2.5% in real-life cohorts including OMT patients.[15,18] This