Carotid Angioplasty Evolution – 2018

2018 euroPCR

Accumulating two-year clinical and duplex ultrasound evidence from the CGuard **PARADIGM-Extend** prospective academic trial: Durability of stroke prevention

P. Musiałek, A. Mazurek, M. Trystuła, A. Borratyńska, T. Tomaszewski, A. Lesniak-Sobelga, M. Brózda, P. Wilkołek, N. Dłużniewska, U. Gancarczyk, T. Drążkiewicz, A. Kozanecki, Ł. Partyka, P. Podolec

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

Potential conflicts of interest

Speaker's name: Piotr Musialek

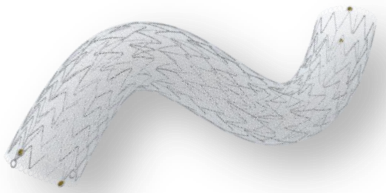
Advisory Board/Consulting	InspireMD, Medtronic
Research Support	Abbott

NB. PARADIGM and PARADIGM-Extend: *Non-Industry Funded,* Investigator-Initiated, Academic research project – supported by the Jagiellonian University Medical College and 'For the Heart' Foundation in Krakow, Poland

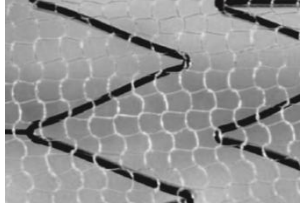
clinical

Evidence

10^{+} studies



CGuard Clinical Studies



- CARENET (MRI) *Multi-specialty*
- PARADIGM *Multi-specialty*
- Hamburg/Heide *INR*
- IRON-Guard *Vascular Surgery*
- TORINO (MRI) *INR*
- Milan (MRI substudy) *Vascular Surgery*
- **PARADIGM-Extend** *Multi-specialty*
- **CEA vs. TCAR-CGurad** *Vascular Surgery*
- **CGuard vs. Acculink RCT** (DW-MRI)

2018 IRON-Guard II (n=500, *Vascular Surgery*)

CGuard OPTIMAL (Sympt, IVUS, *Multi-specialty*)

CGuard PRO (n=500, *Vascular Surgery*)

CGuard Clinical Studies

- CARENET (MRI) *Multi-specialty*
- PARADIGM *Multi-specialty*
- Hamburg/Heide *INR*
- IRON-Guard *Vascular Surgery*
- TORINO (MRI) *INR*
- Milan (MRI substudy) *Vascular Surgery*
- **PARADIGM-Extend** *Multi-specialty*
- **CEA vs. TCAR-CGurad** *Vascular Surgery*
- **CGuard vs. Acculink RCT** (DW-MRI)

≈ 1000

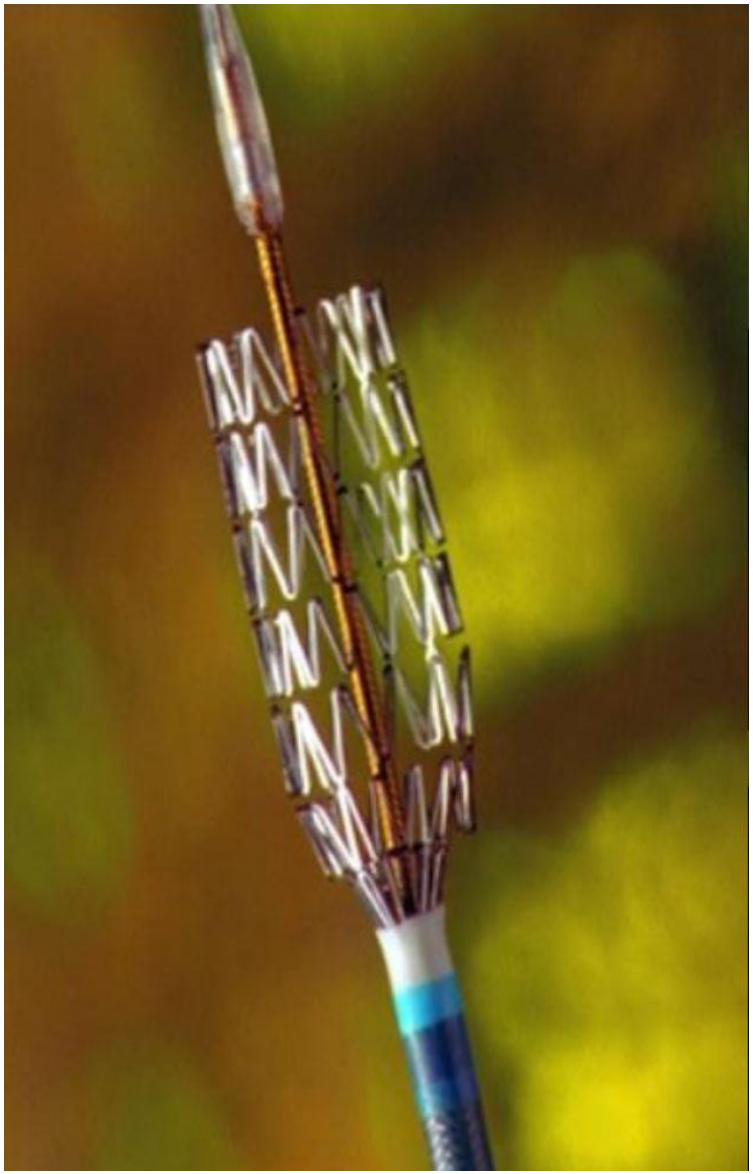
2018 IRON-Guard II (n=500, *Vascular Surgery*)

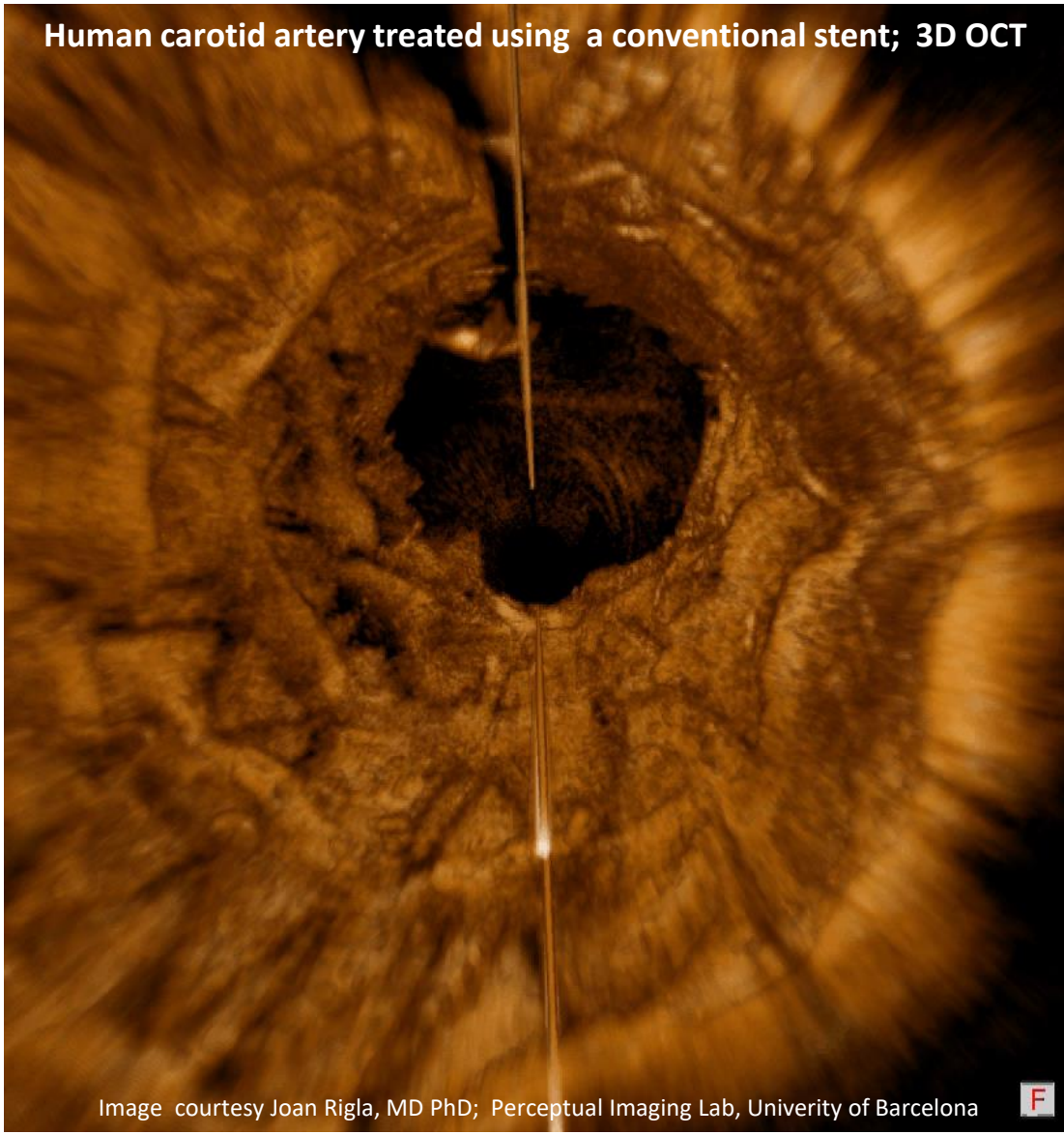
CGuard OPTIMAL (Symbiot, IVUS, *Multi-specialty*)

CGuard PRO (n=500, *Vascular Surgery*)

> 1000

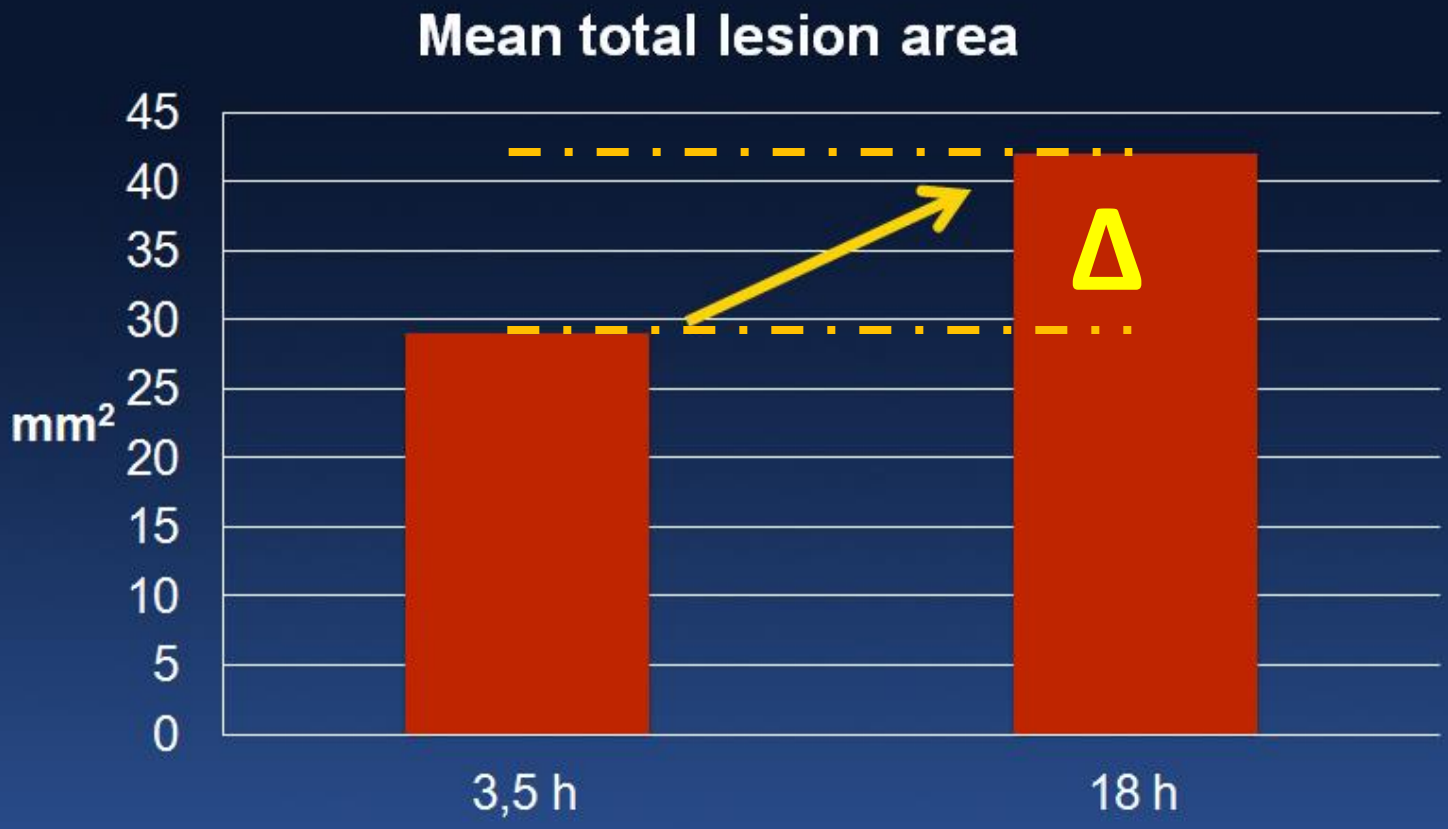
The Problem of Conventional Carotid Stents





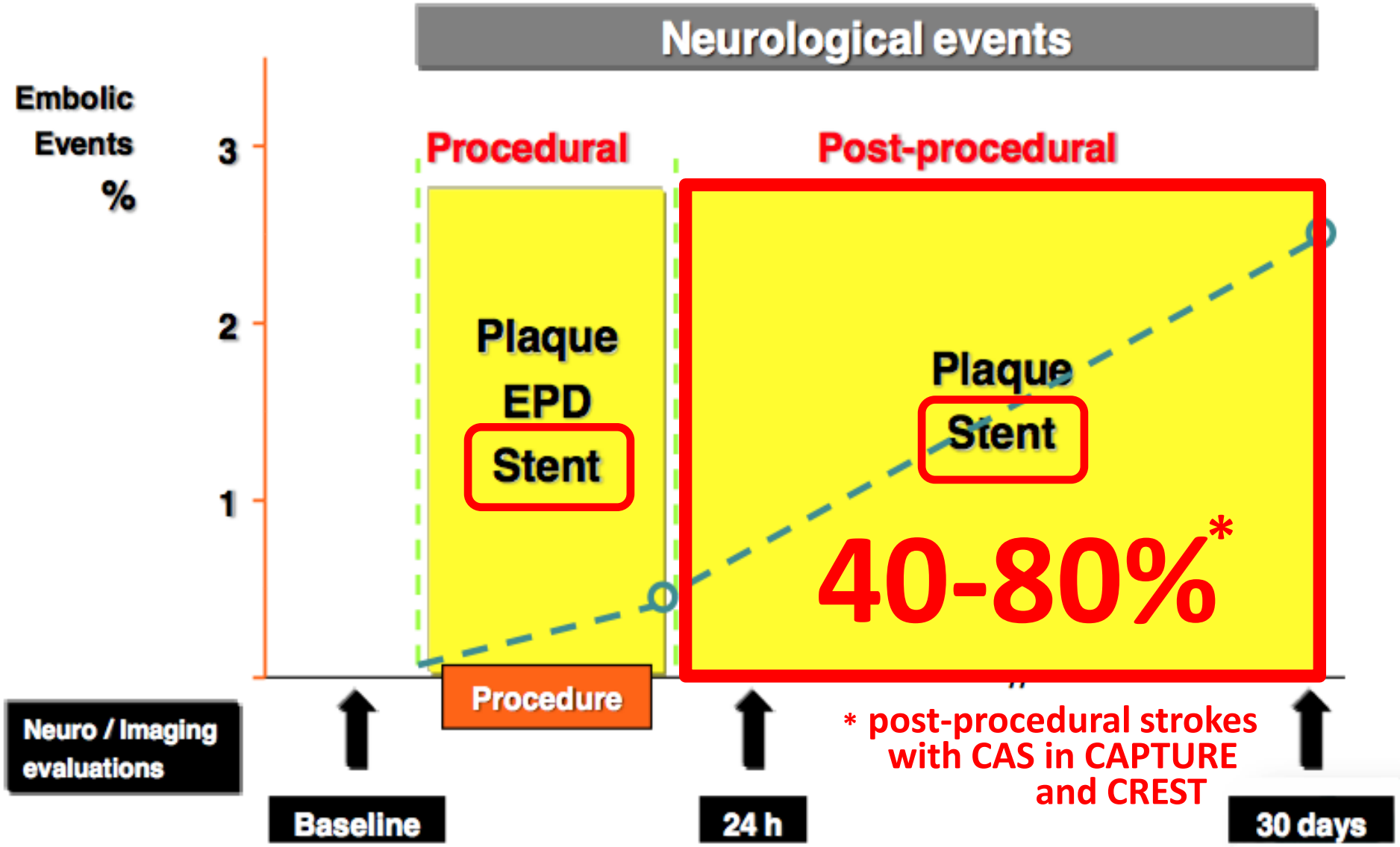
Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS



Schofer J et al, JACC Cardiovasc interv 2008

Timing of neuro-embolic events after CAS

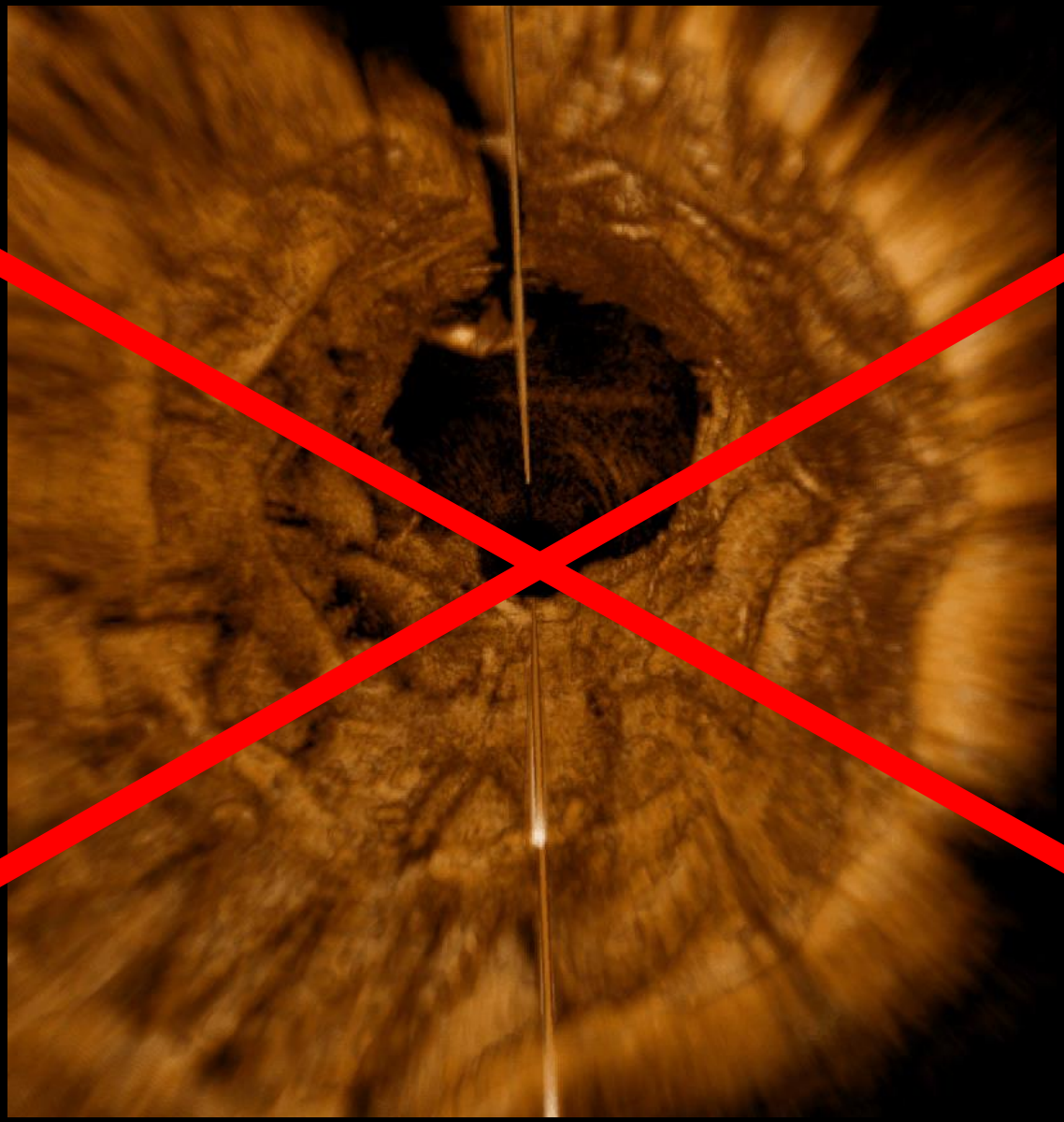


D. McCormick TCT 2012, modified

Role of CAS in 2018

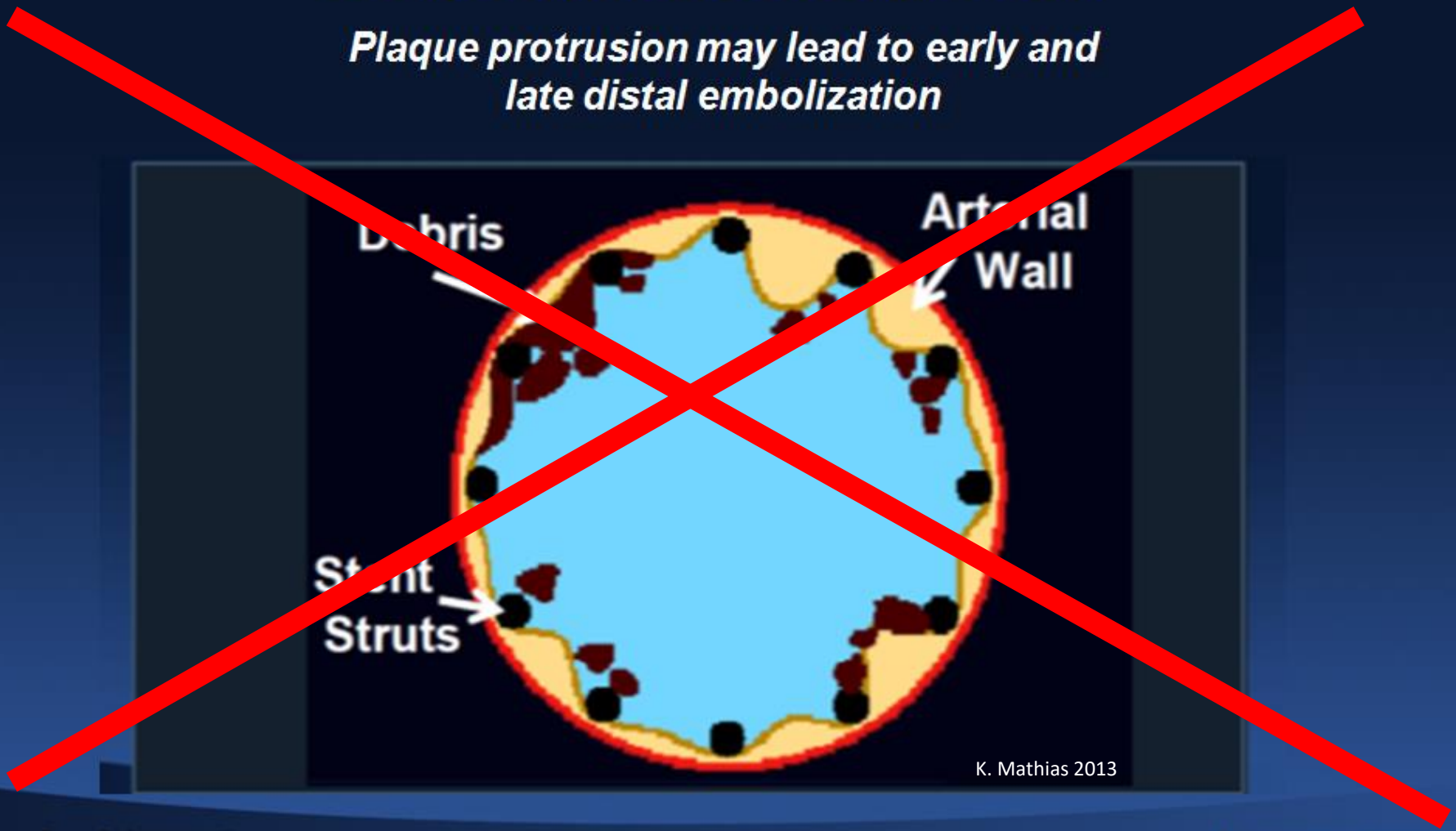
- CEA excludes the plaque
- In CAS, the stent should exclude the plaque too

Conventional Carotid Stent

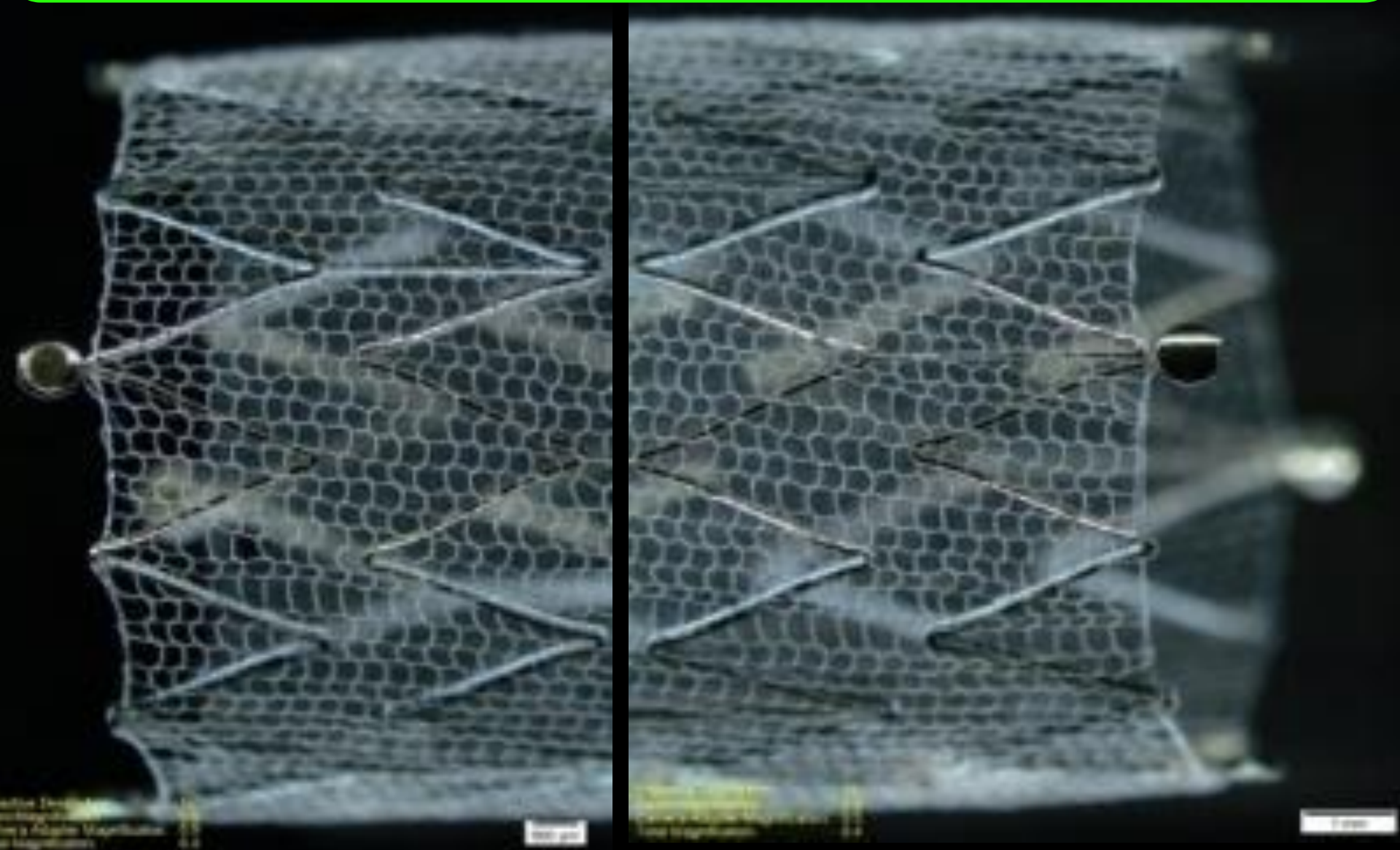


Anti - Embolic Carotid Stent

Anti - Embolic Carotid Stent



CGuard™ embolic prevention system

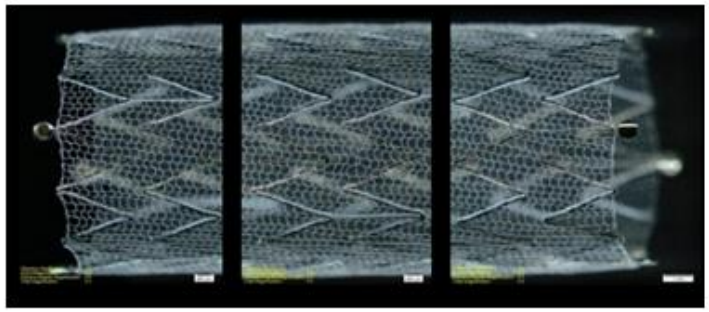


CGuard™– Carotid Embolic Prevention System

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

carotid-dedicated design

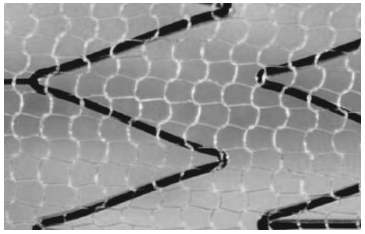


Nitinol frame open-cell area ≈ 21 mm^2

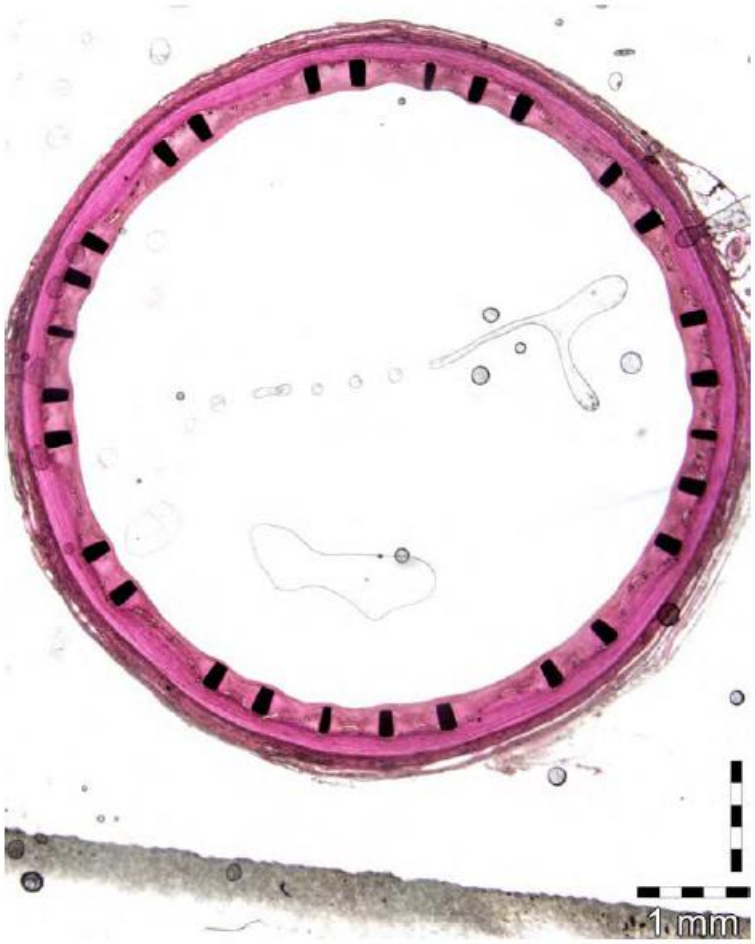
MicroNet closed-cell area ≈ 0.3mm^2

LARGEST √

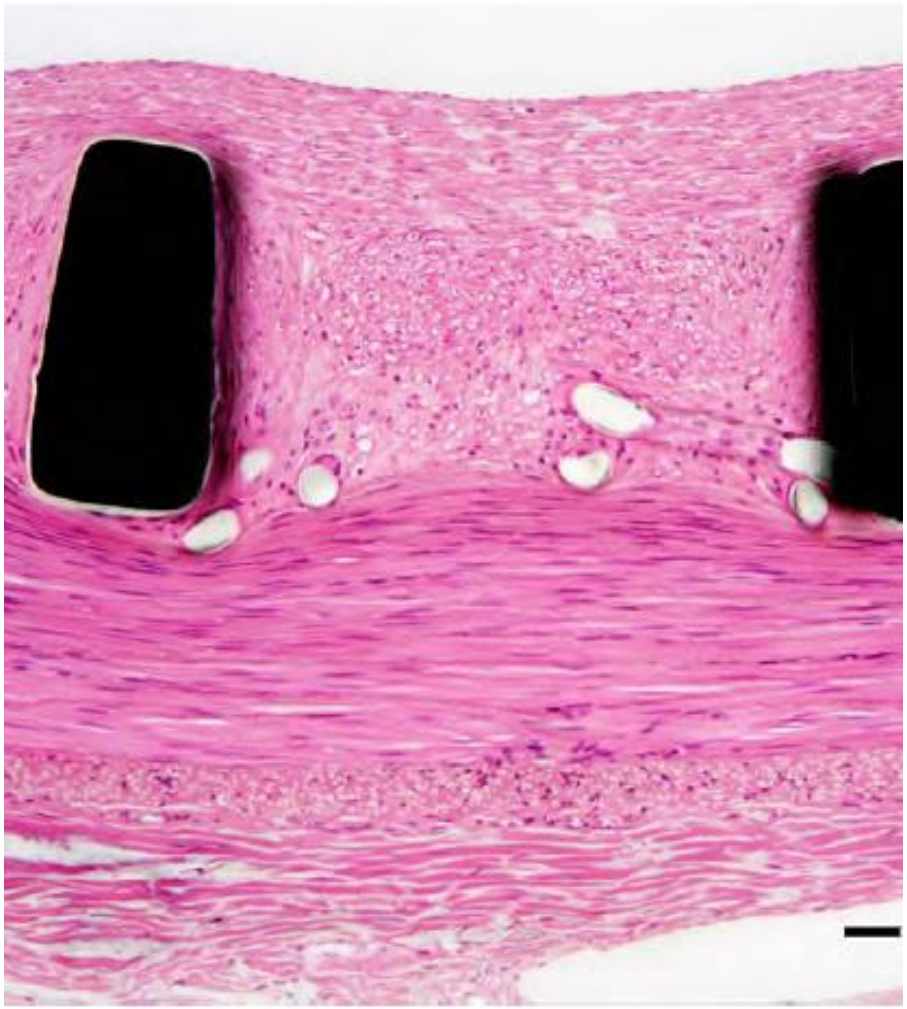
SMALEST √



CGuard EPS 90 days/pig



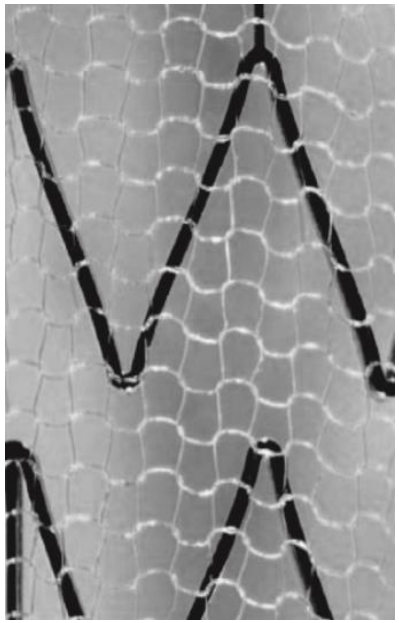
12-105 LCCA-S 3 13-1689-3 1.25x H&E.tif

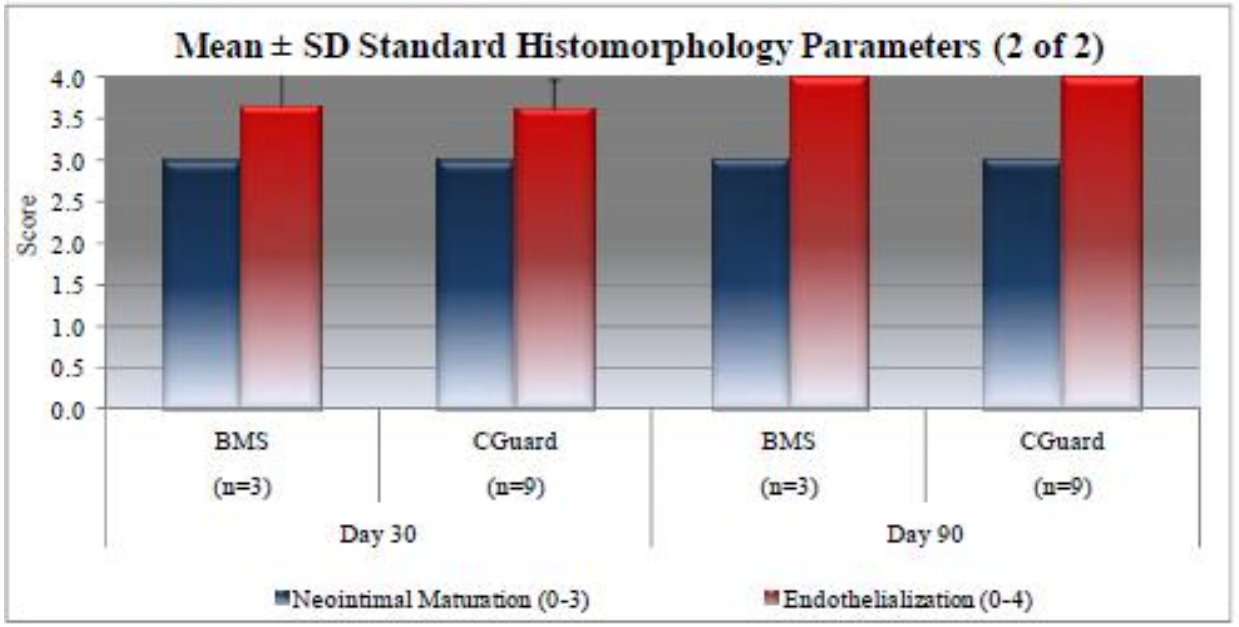


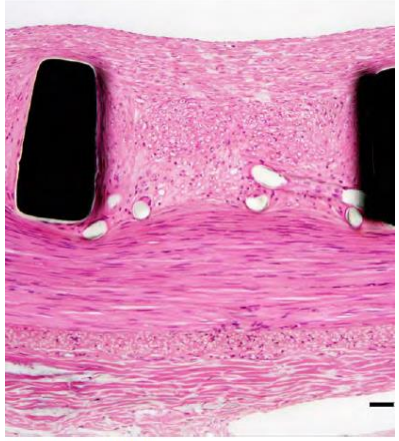
CA-S 3 13-1689-3 10x H&E.tif

InspireMD data / by permission

CGuard EPS 30 & 90 days / pig





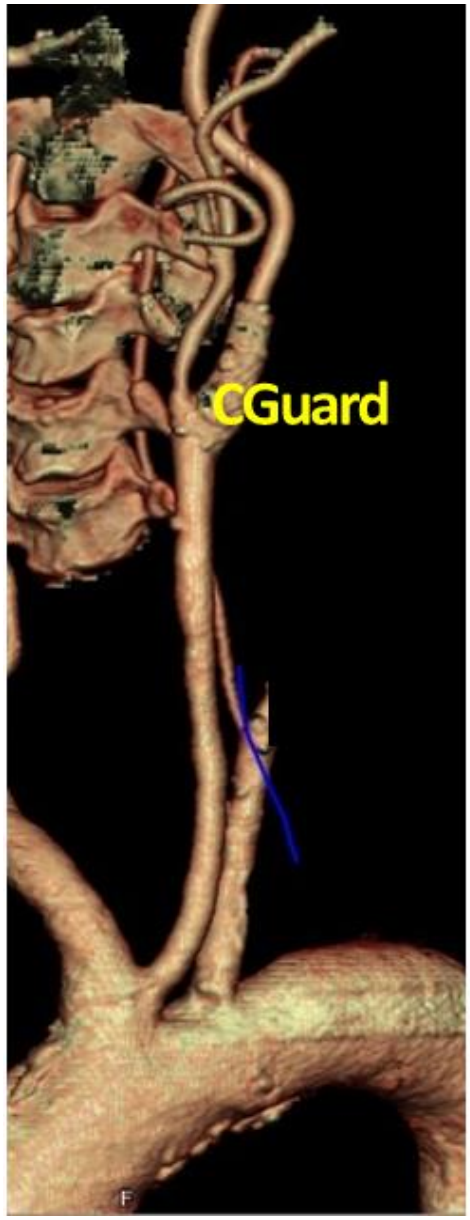


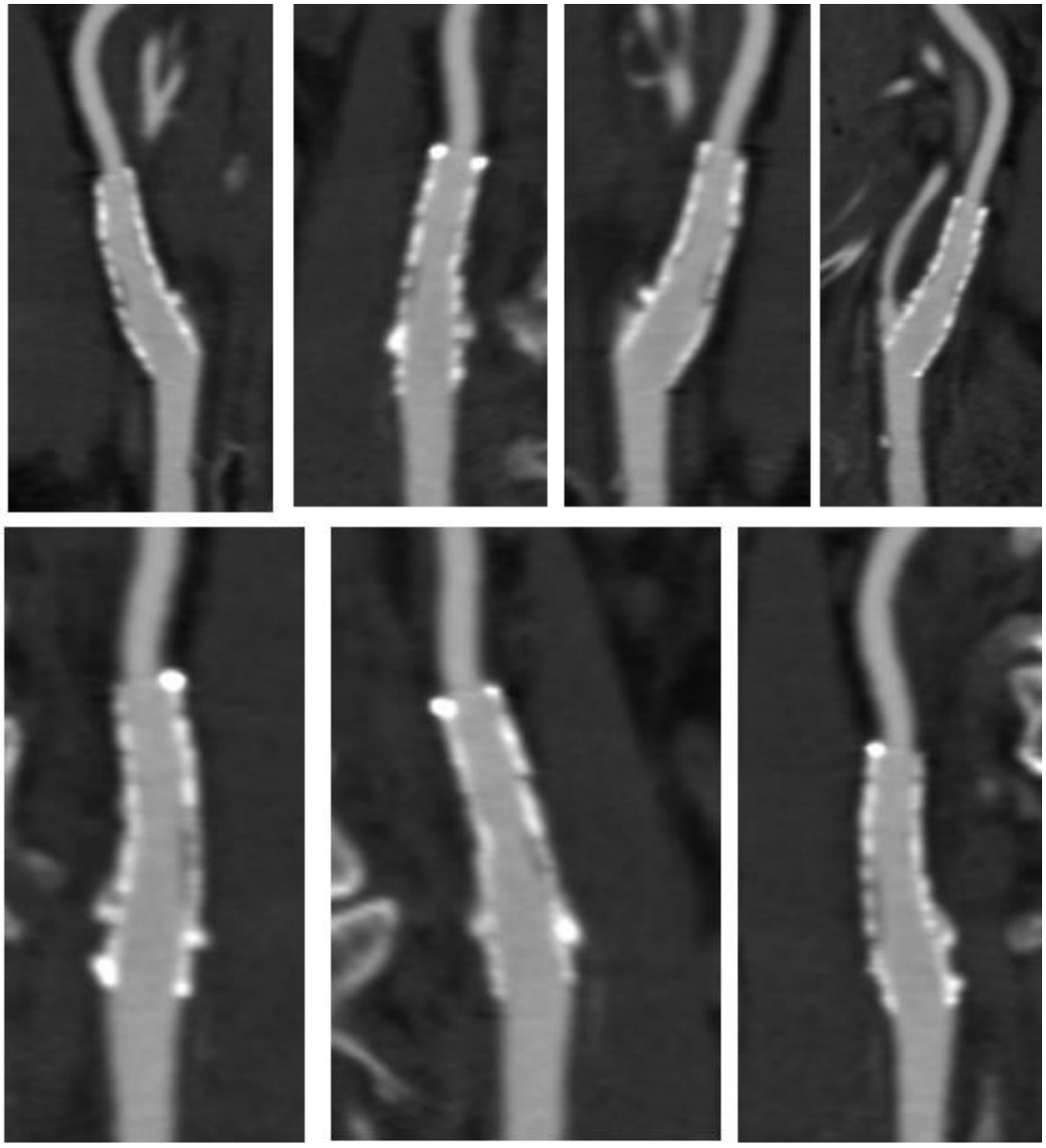
CA-S 3 13-1689-3 10x H&E.tif

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

BMS = non mesh-covered CGuard nitynol frame; InspireMD data / used with permission

Normal Long-Term Healing

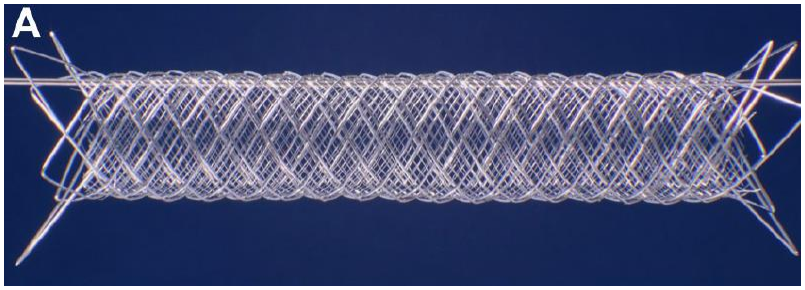


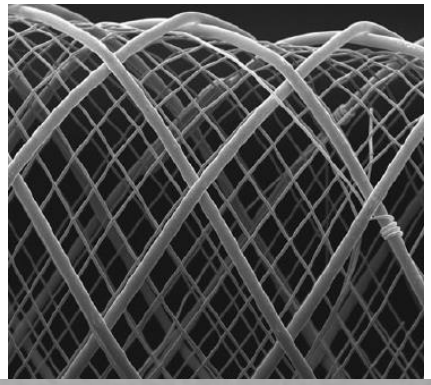


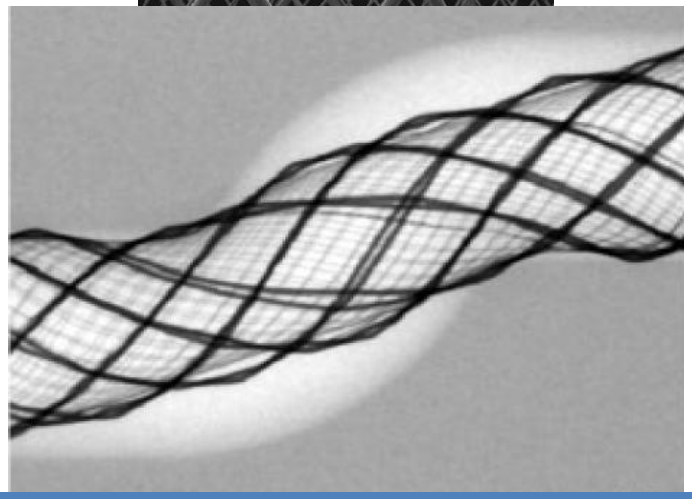
mechanical

Properties

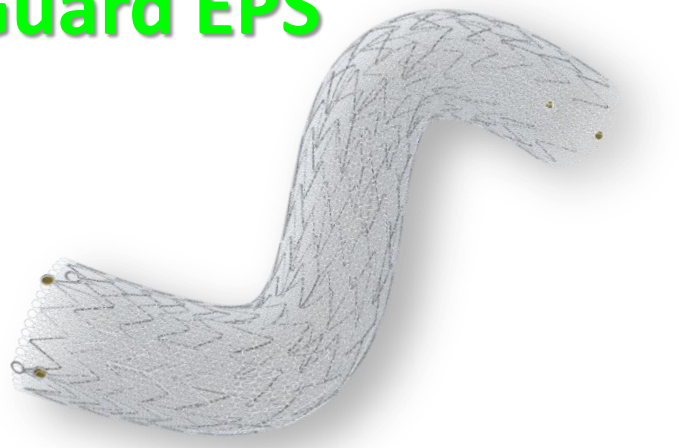
RoadSaver / Casper

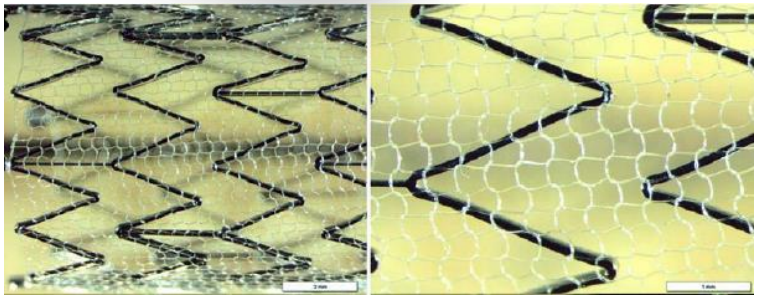


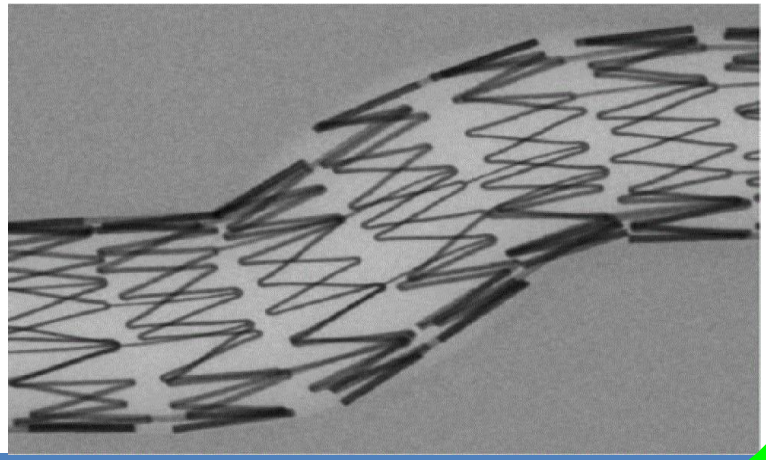




CGuard EPS

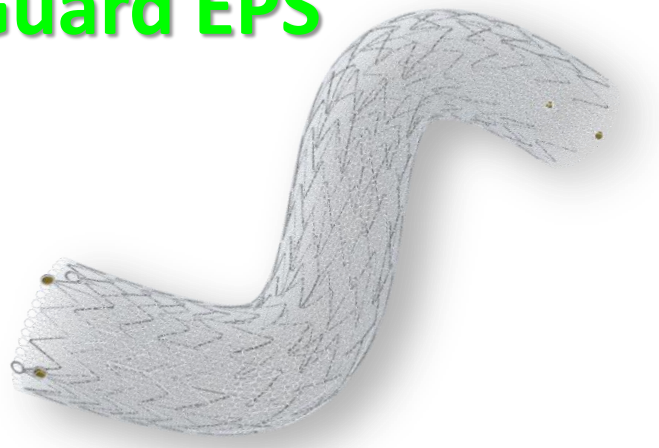


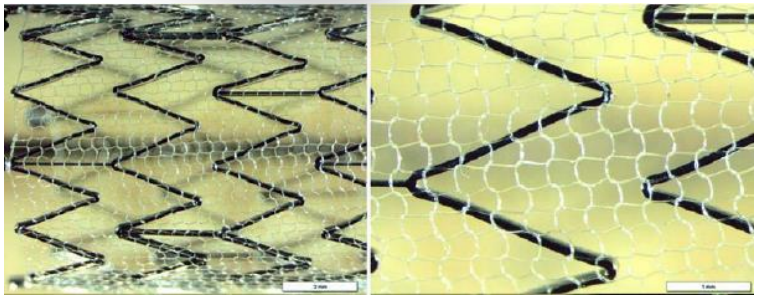


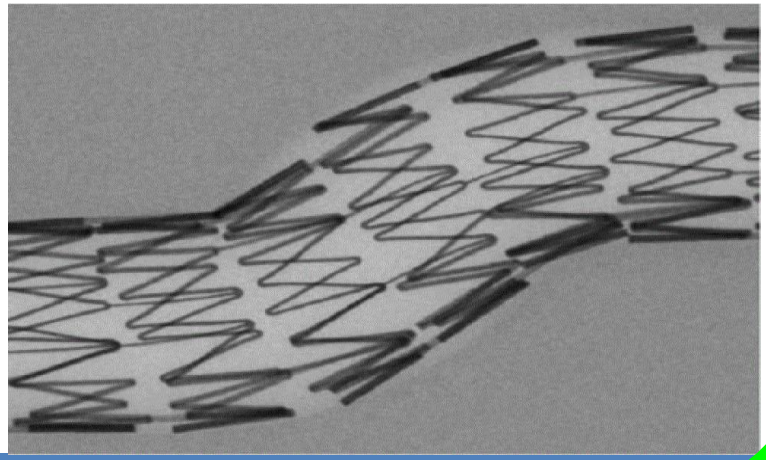


C. Wissgott and colleagues. *J Endovasc Ther.* 2015;22:634-39
C. Wissgott and colleagues. *J Endovasc Ther.* 2017;24:130-7

CGuard EPS



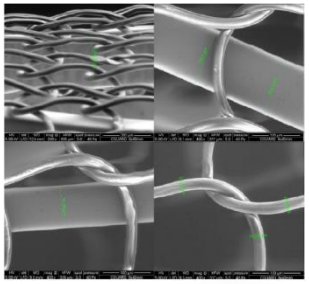




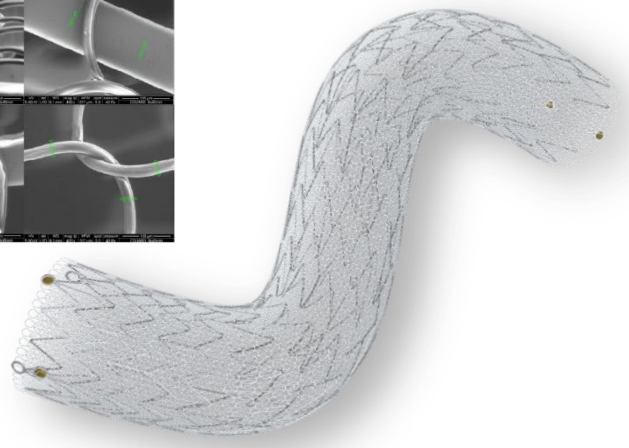
C. Wissgott and colleagues. *J Endovasc Ther.* 2015;22:634-39
C. Wissgott and colleagues. *J Endovasc Ther.* 2017;24:130-7

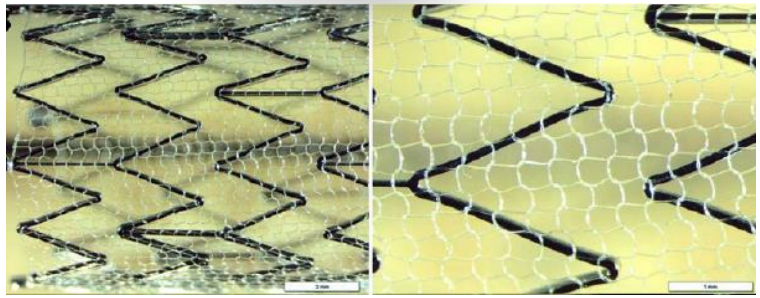
CGuard EPS

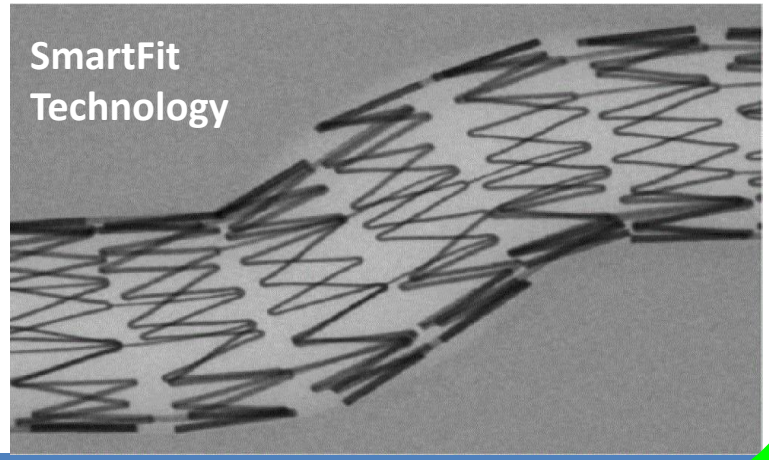
- Radial Force as the PRECISE stent
- NO foreshortening/elongation
- Widely open-cell structure of the stent frame results in a FULL APPOSITION

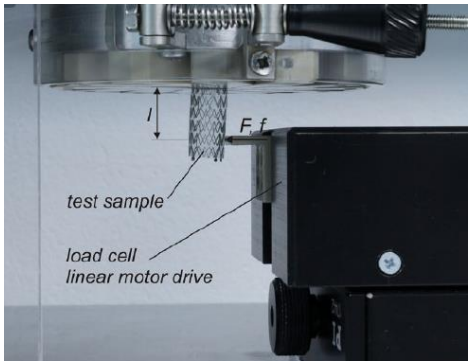


SEM

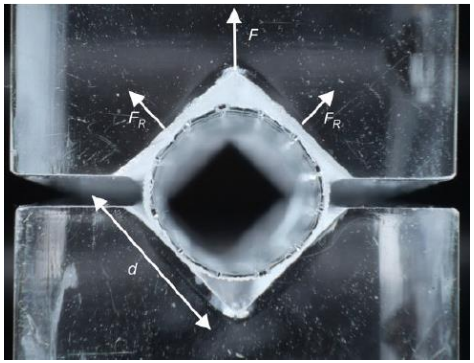








Bending Stifness



Radial Force

C. Wissgott and colleagues. *J Endovasc Ther.* 2015;22:634-39
C. Wissgott and colleagues. *J Endovasc Ther.* 2017;24:130-7

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 8, NO. 9, 2015

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2015.04.016

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

CGuard™

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.

P Musialek @ ePCR 2018

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 8, NO. 9, 2015

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
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)

CGuard™

30d data

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

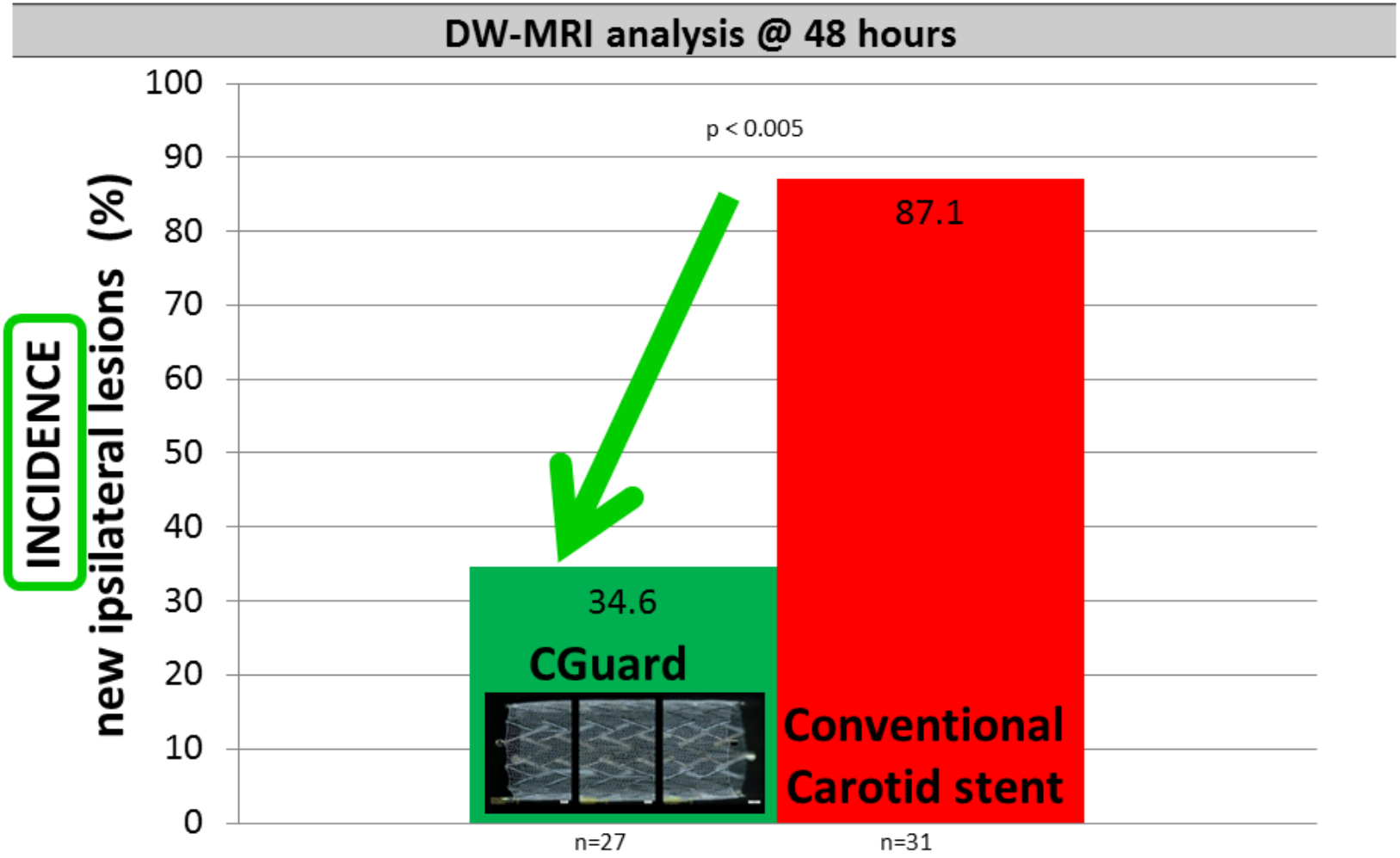
OBJECTIVES This study sought to evaluate the feasibility of the CGuard Carotid Embolic Protective Stent system—a novel thin strut nitinol stent combined with a polyethylene terephthalate mesh covering designed to prevent embolic events from the target lesion in the treatment of carotid artery lesions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

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

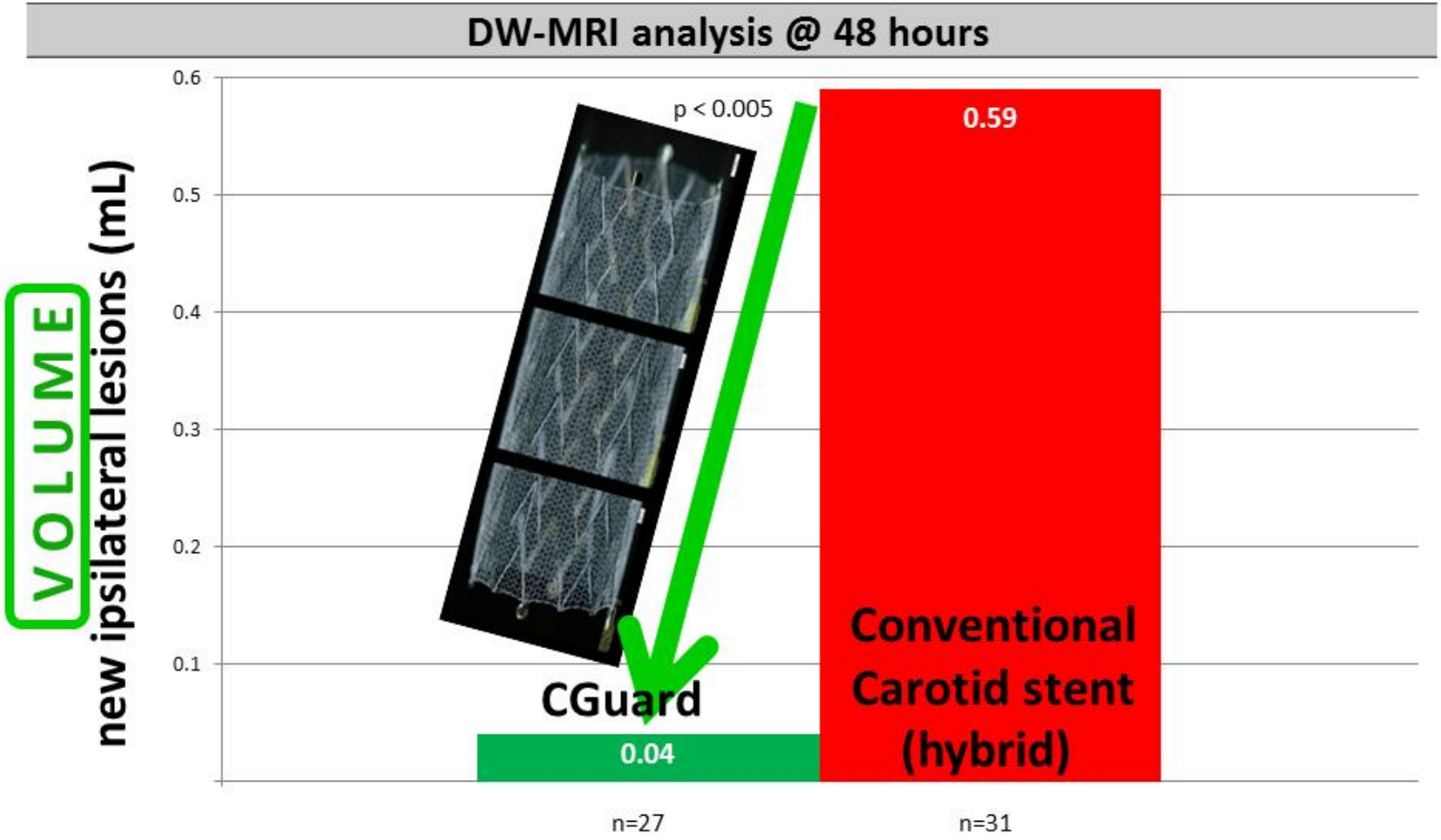


* see patient fluxogram
Bijuklic et al. *JACC*, 2012;59

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



* 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)

CARENET DW-MRI analysis*

All but one peri-procedural ipsilateral lesions

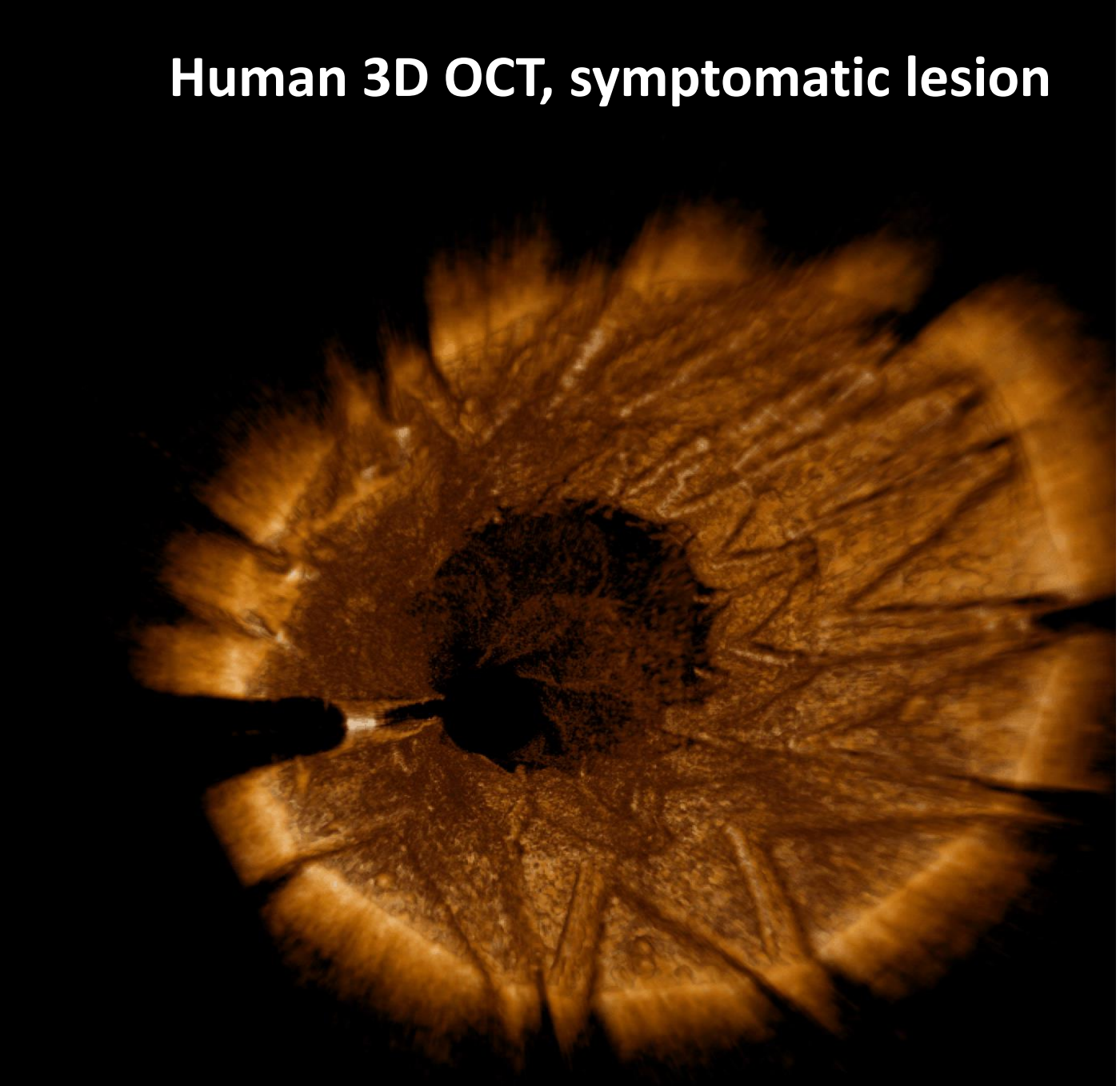
RESOLVED

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)**

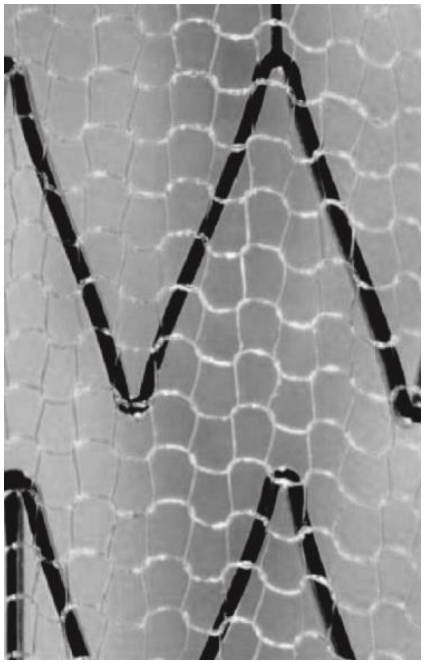
J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34

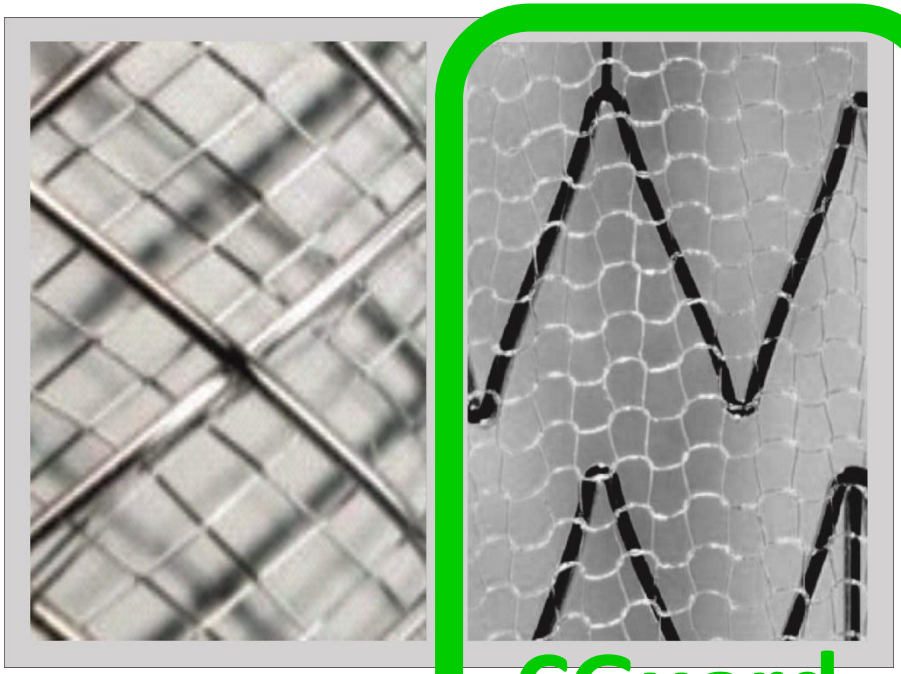
Human 3D OCT, symptomatic lesion



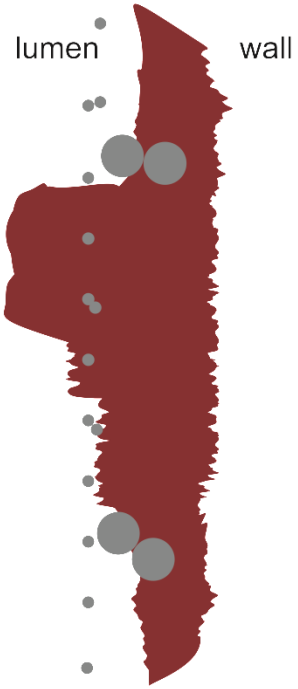
P. Musialek, E. Stabile. *EuroIntervention* December 2017
Image courtesy Dr Joan Rigla, University of Barcelona Perceptual Lab

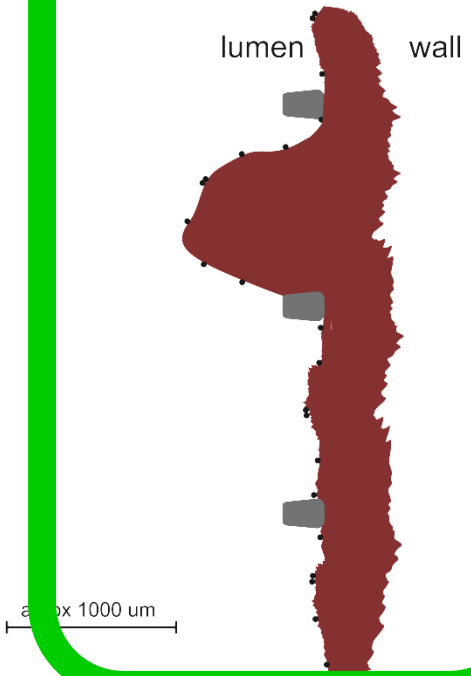
CGuard™ EPS



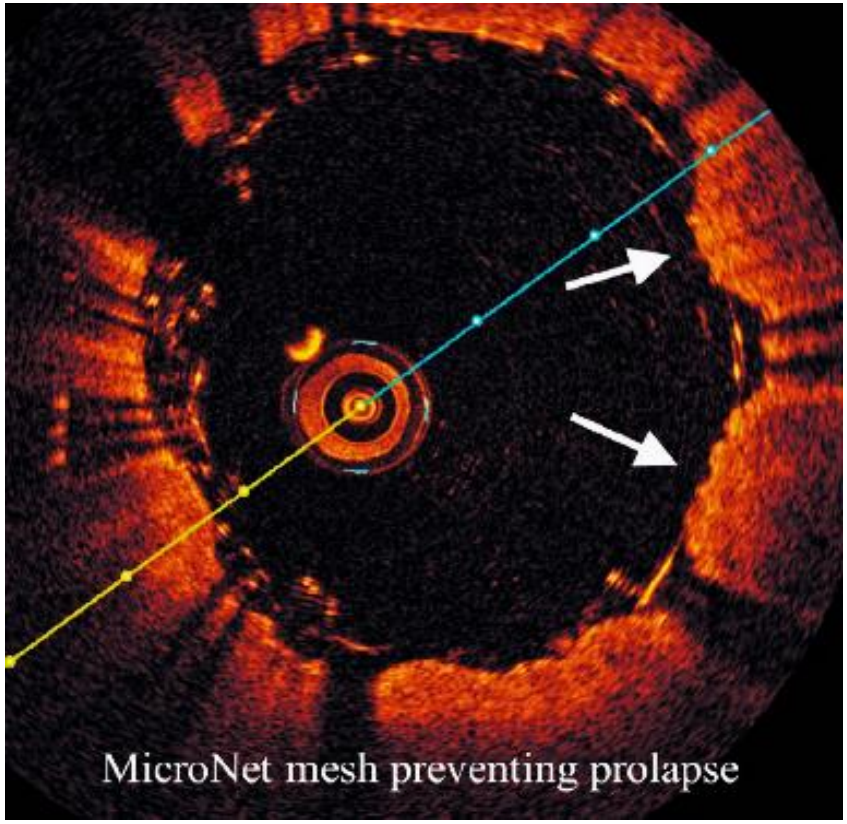


CGuard

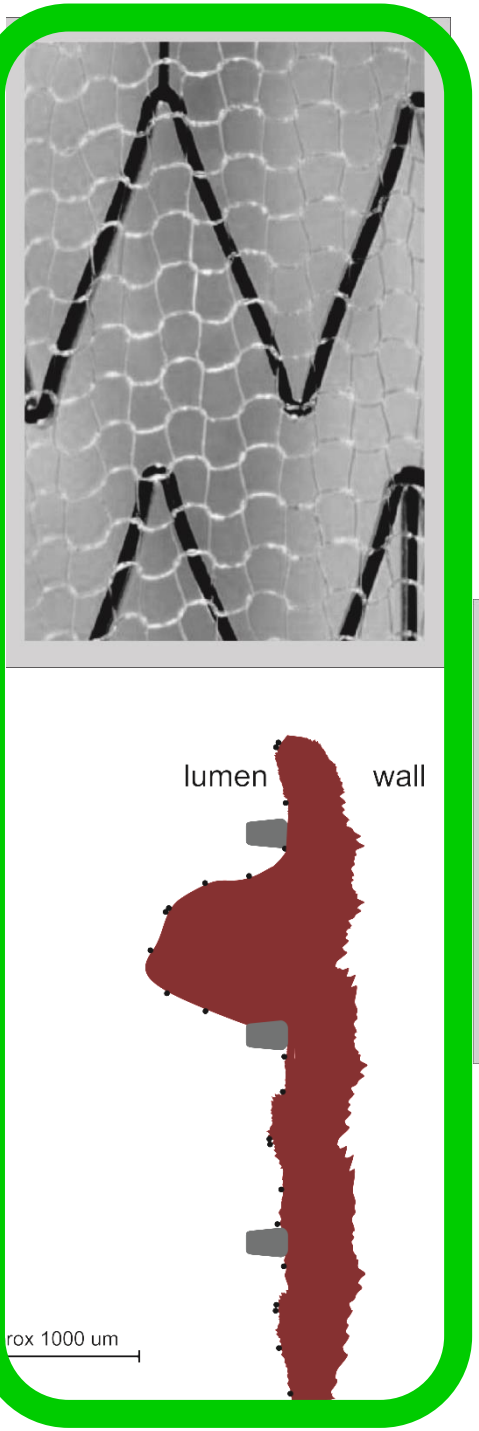


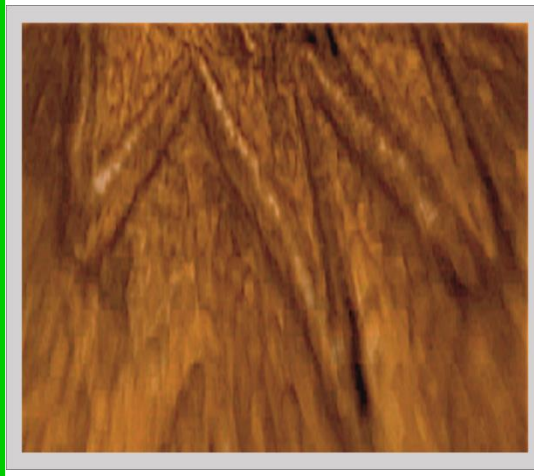


Musialek & Stabile
EuroIntervention 2017

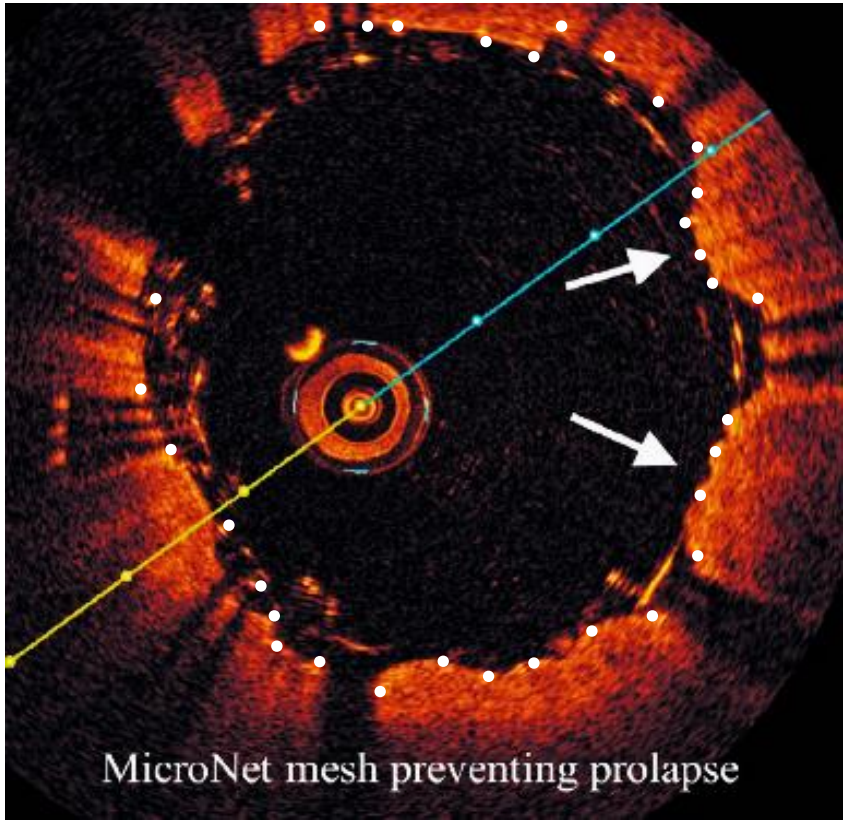


Tomyuki Umemoto et al.
EuroIntervention 2017

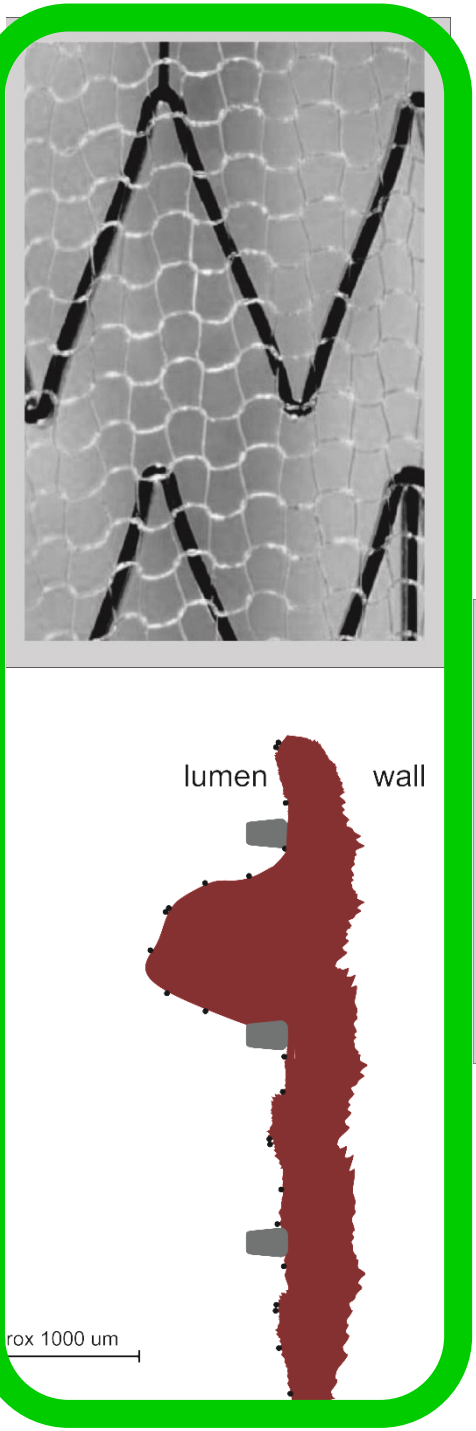


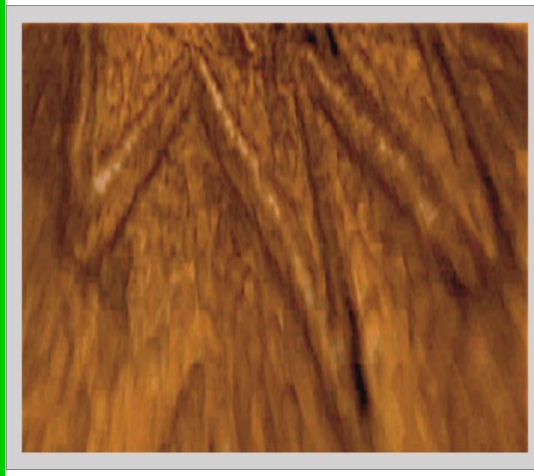


Musialek & Stabile
EuroIntervention 2017



Tomyuki Umemoto et al.
EuroIntervention 2017





Musialek & Stabile
EuroIntervention 2017

CGuard™ CAS EVIDENCE

J. Schofer, P. Musialek, et al. JACC Interv 2015;8:1229-1234

CGuard™ CAS EVIDENCE

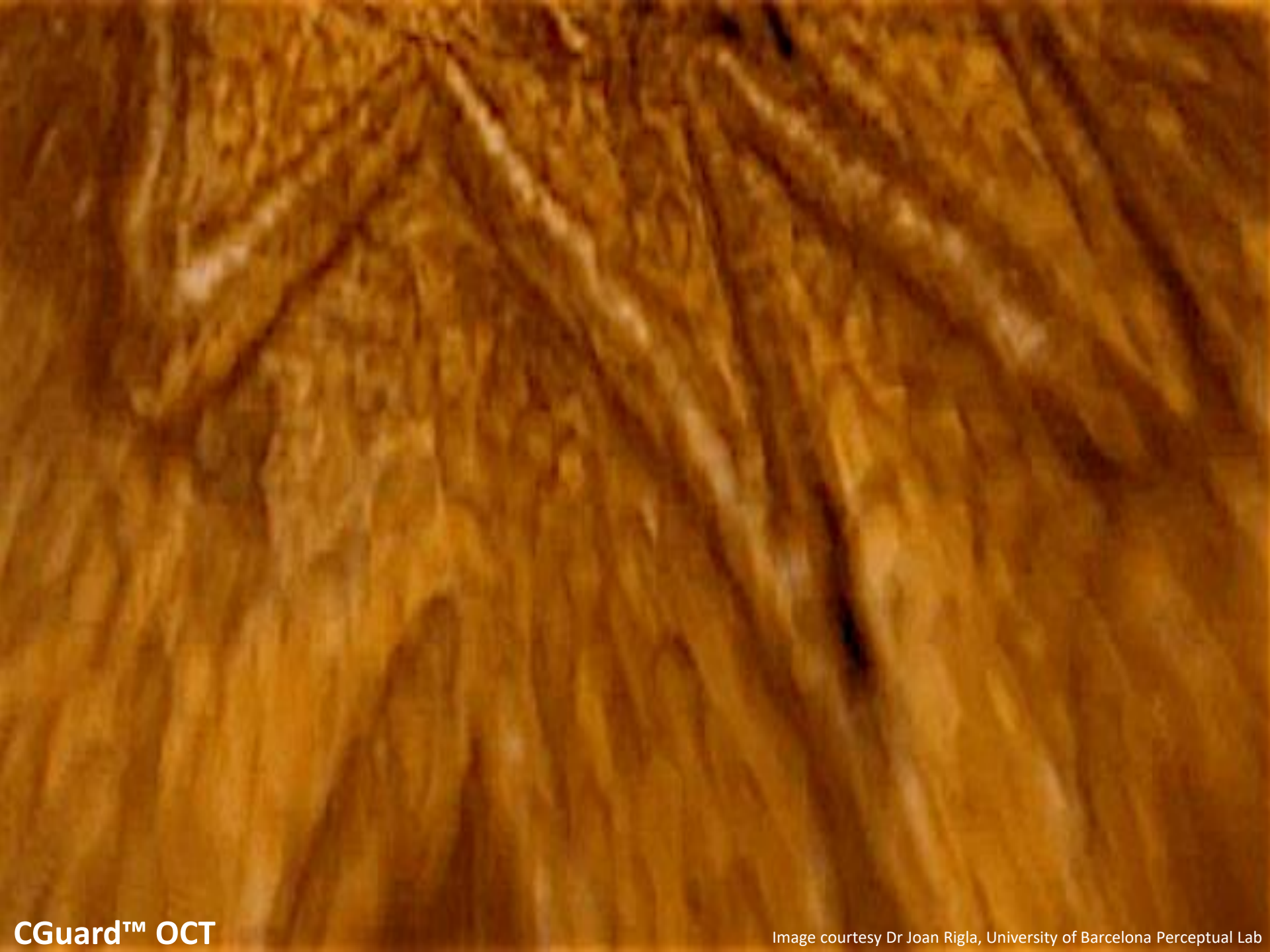
- Intra-procedural cerebral embolization is **minimized**

J. Schofer, P. Musialek, et al. JACC Interv 2015;8:1229-1234

CGuard™ CAS EVIDENCE

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

J. Schofer, P. Musialek, et al. JACC Interv 2015;8:1229-1234



CGuard™ OCT

Image courtesy Dr Joan Rigla, University of Barcelona Perceptual Lab

12 months

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 K
Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD‖

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 8, NO. 9, 2015
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2015.04.016

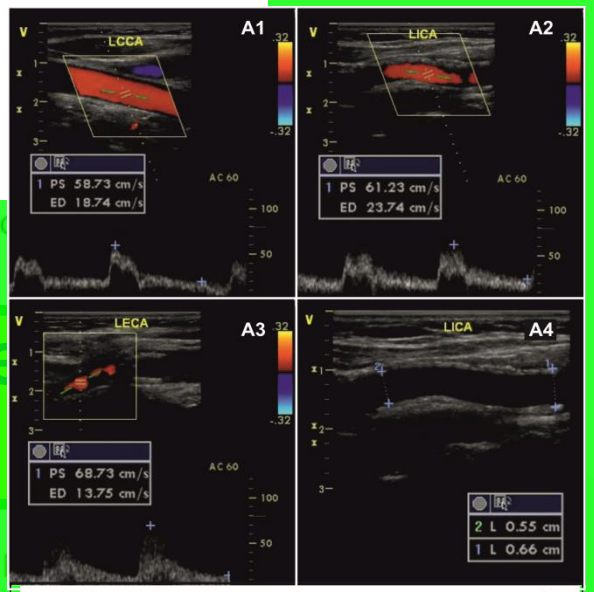
Per-Protocol DW-MRI cere
str
ABS
OBJECTIVES This study sought to evaluate the feasibility of the CGuard Carotid
nov
events from the target lesion in the treatment of carotid artery lesions in consecut
artery stenting.

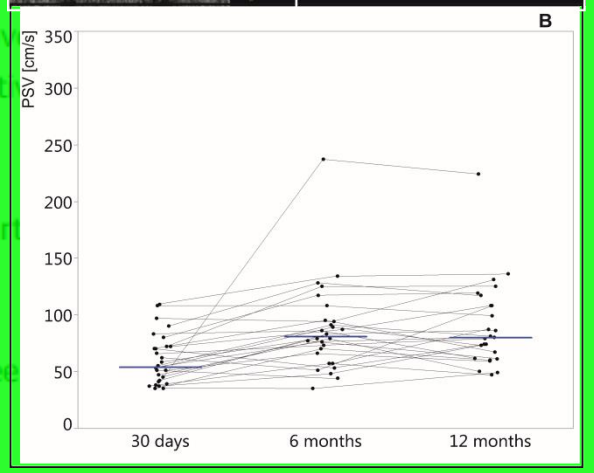
BACKGROUND The risk of cerebral embolization persists throughout the carotid ar
during the stent healing period.

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

- No stroke/TIA(s)
- No ISR issue

(manuscript at review)



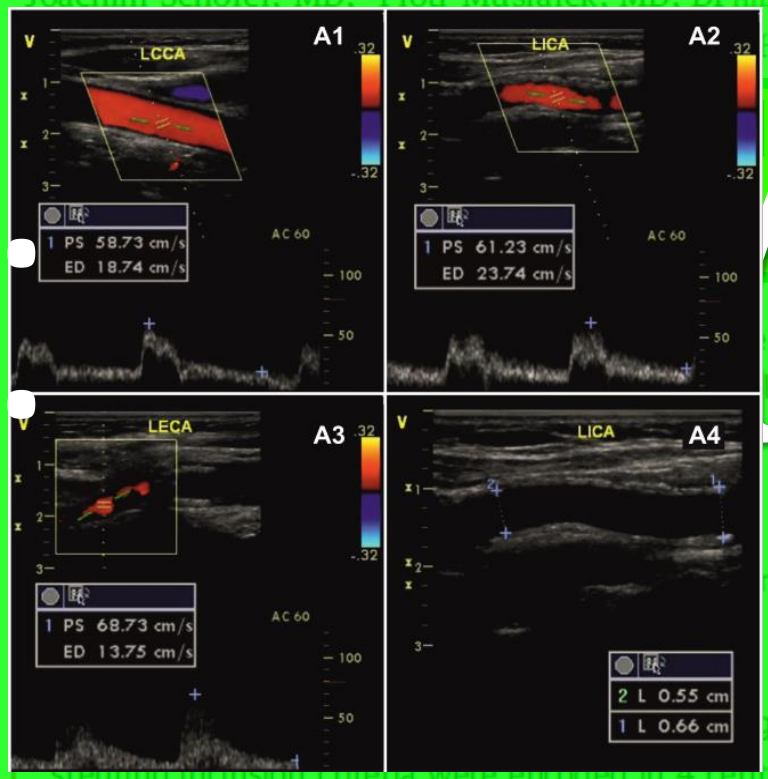


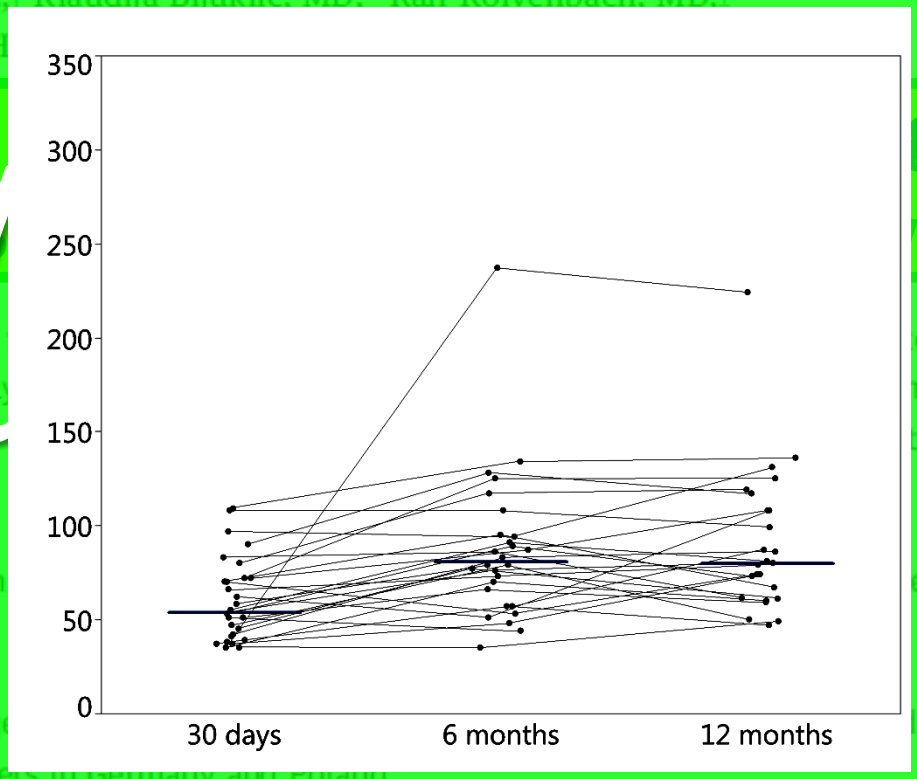
12 months

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

The CGuard CARENET Trial

(Carotid Embolic Protection Using MicroNet)





(manuscript at review)

P Musialek @ ePCR 2018

The PARADIGM Study

Prospective evaluation of **A**ll-comer peR**R**cutaneous c**A**roti**D** revascularization in sympto-matic and **I**ncreased-risk asymptomatic carotid artery stenosis using the C**G**uard™ **M**icronet-covered embolic prevention stent system

The PARADIGM Study

euro PCR 2016 LATE BREAKING TRIALS

EuroIntervention 2016;12-online publish-ahead-of-print May 2016

CLINICAL RESEARCH

CGuard™

euro PCR 2016 LATE BREAKING TRIALS

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

Piotr Musialek[1]*, MD, DPhil; Adam Mazurek[1], MD; Mariusz Trystula[2], MD, PhD; Anna Borratynska[3], MD, PhD; Agata Lesniak-Sobelga[1], MD, PhD; Malgorzata Urbanczyk[4], MD; R. Pawel Banys[4], MSc; Andrzej Brzychczy[2], MD, PhD; Wojciech Zajdel[5], MD, PhD; Lukasz Partyka[6], MD, PhD; Krzysztof Zmudka[5], MD, PhD; Piotr Podolec[1], MD, PhD

1. Jagiellonian University Department of Cardiac & Vascular Diseases, John Paul II Hospital, Krakow, Poland; 2. Department of Vascular Surgery, John Paul II Hospital, Krakow, Poland; 3. Neurology Outpatient Department, John Paul II Hospital, Krakow, Poland; 4. Department of Radiology, John Paul II Hospital, Krakow, Poland; 5. Jagiellonian University Department of Interventional Cardiology, John Paul II Hospital, Krakow, Poland; 6. KCRI, Krakow, Poland

The PARADIGM study

target

100 consecutive CAS pts / 12mo*

* determined by typical yearly volume

CAROTID PARADIGM REVASCULARIZATION

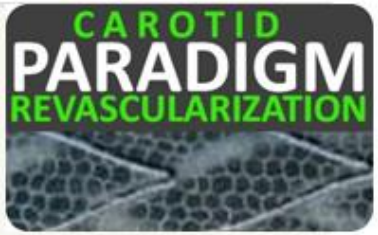
Objective

- 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)

PARADIGM study: referrals flow chart

139 carotid stenosis patient referrals



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

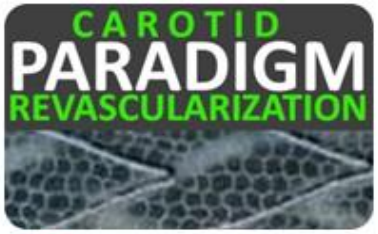


Table 1. Clinical characteristics of the study patients (n=101).

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

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.

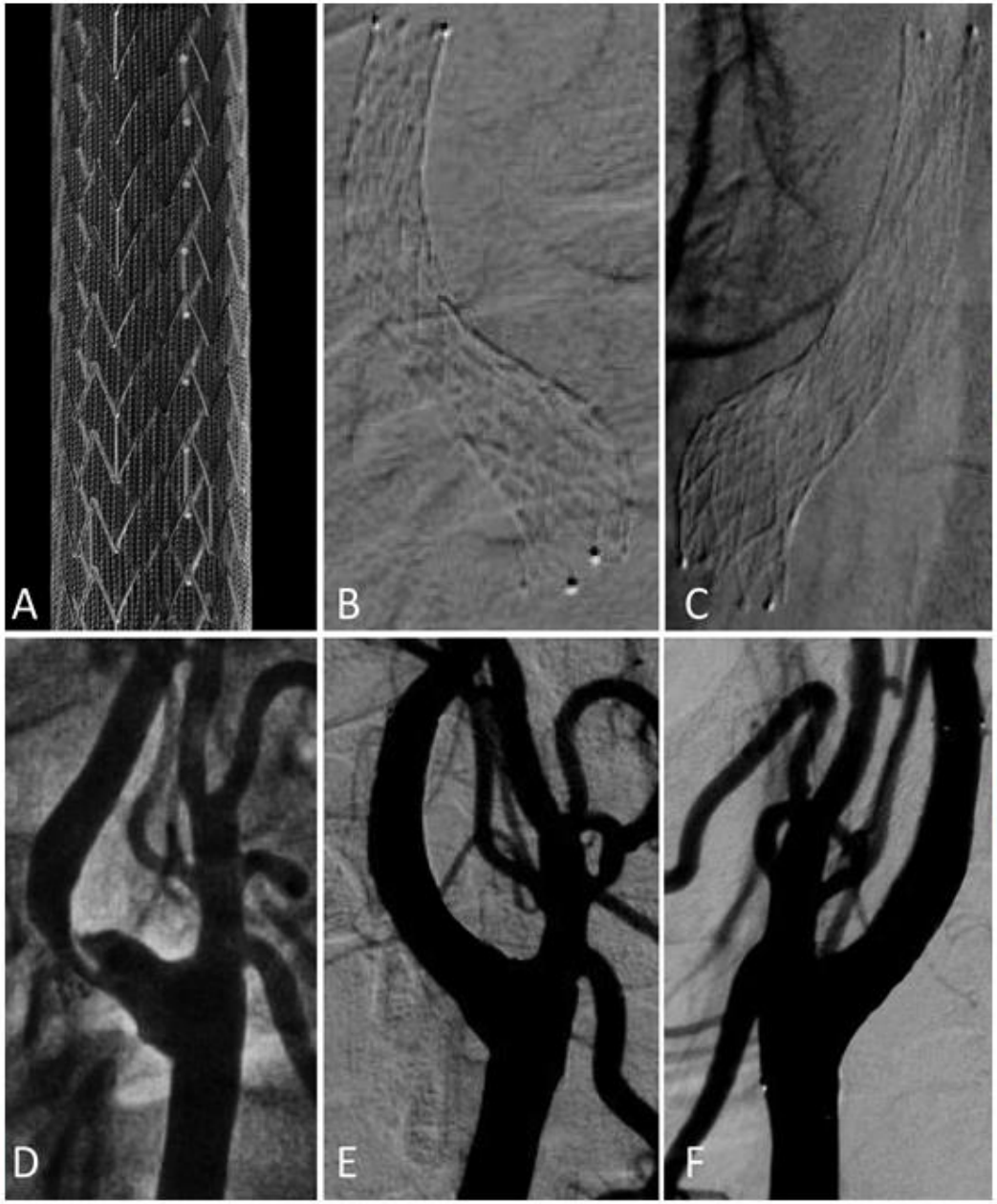
	All (n=106 lesions)	Symptomatic n=55	Asymptomatic n=51	*p*-value
After CAS				
Stent length (QA, CoreLab)[§]				N/A
Nominal 30 mm	29.82±0.68	29.83±0.76	29.80±0.59	
(min-max)	(27.83-32.62)	(27.83-32.62)	(28.83-31.89)	
Nominal 40 mm	39.89±0.59	39.80±0.70	39.97±0.51	
(min-max)	(38.88-41.43)	(38.88-41.43)	(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

⇒ **'CAE-like' effect of CAS**

EuroIntervention 2016;12:e658-70



CAROTID PARADIGM REVASCULARIZATION

systematic

CEA-like effect of CAS

EuroIntervention 2016;12:e658-70

euro PCR 2016 LATE BREAKING TRIALS

PARADIGM

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%

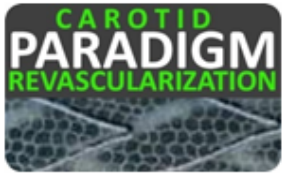
(100% follow-up, independent neuro evaluation)

*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'.

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

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

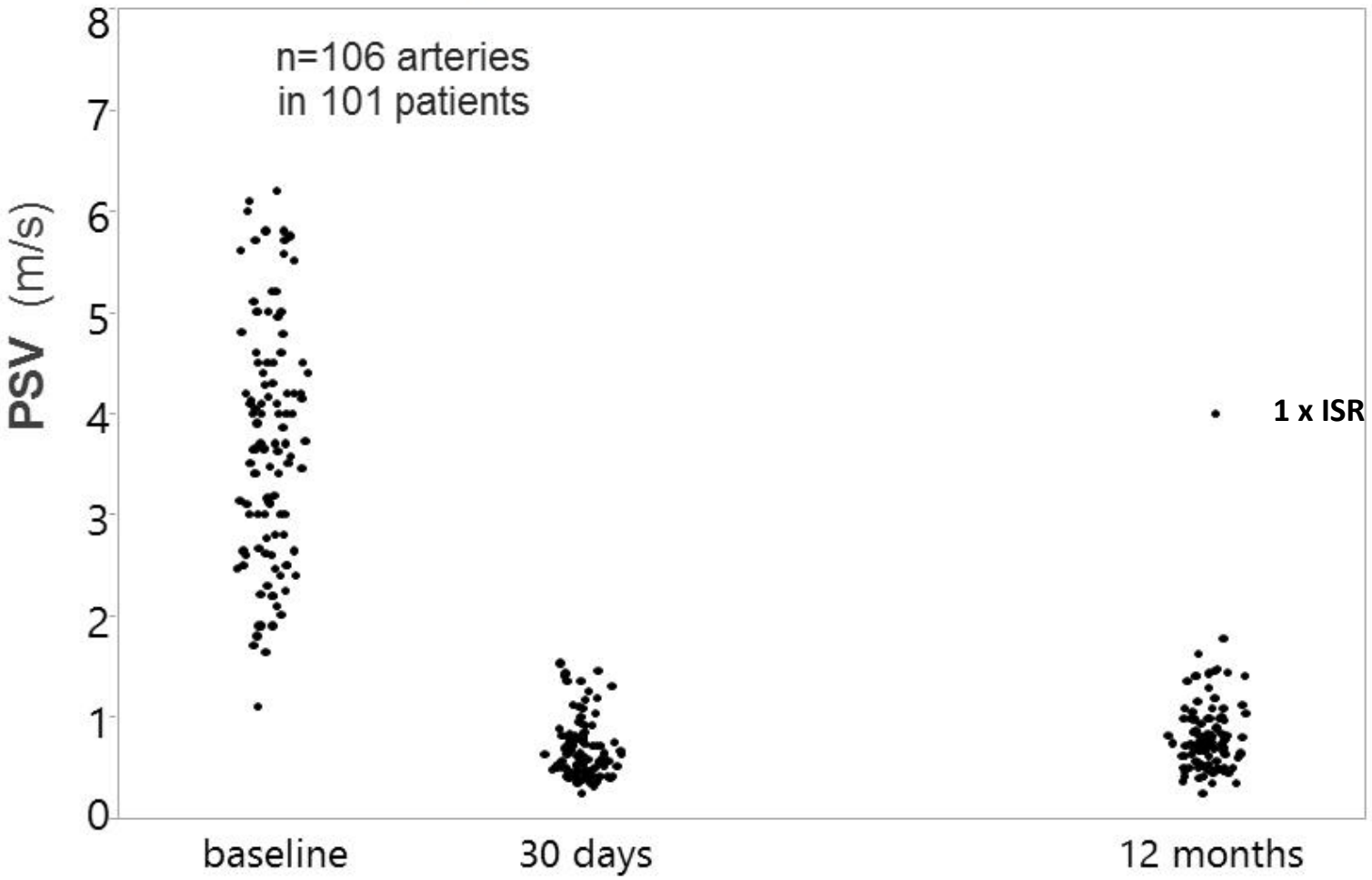
in n=101 ↑ stroke-risk patients

(55% symptomatic)

CGuard™ EPS Carotid **PARADIGM** Study

12mo Duplex Ultrasound Data

12month data



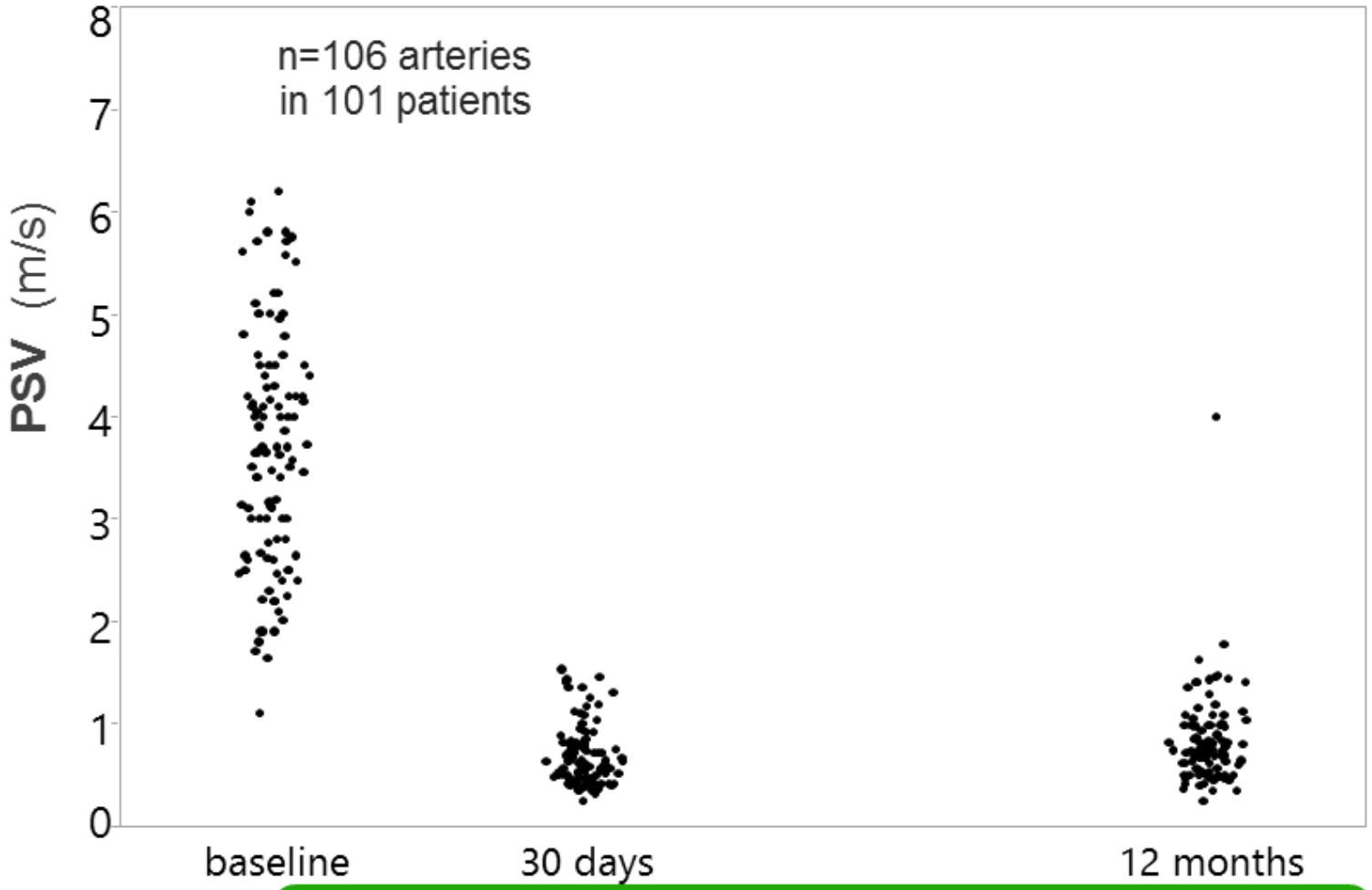
1 x ISR (DEB-PTA)

CGuard™ EPS Carotid **PARADIGM** Study

12mo Duplex Ultrasound Data

CAROTID PARADIGM REVASCULARIZATION

12month data



ECA* patency

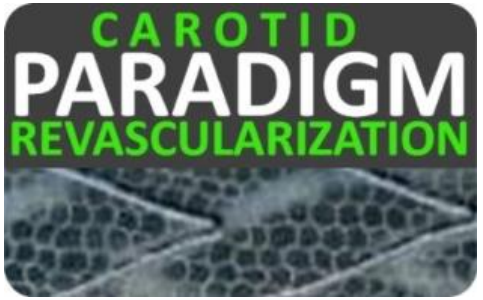
ECA

100/106 ECAs were patent prior to CAS

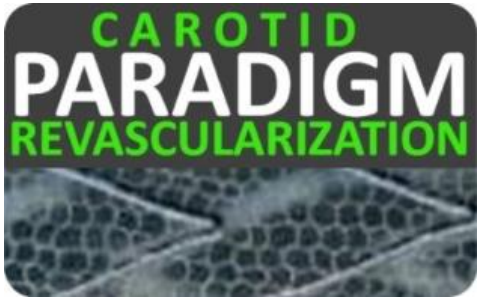
baseline	30 days	12 months
97.0% 3 ECAs occluded at CAS	**97.0%** 97/100 ECAs patent	**96.9%** 93/96 ECAs patent

PARADIGM – Extend

continues as an ALL-Comer Study



PARADIGM – Extend

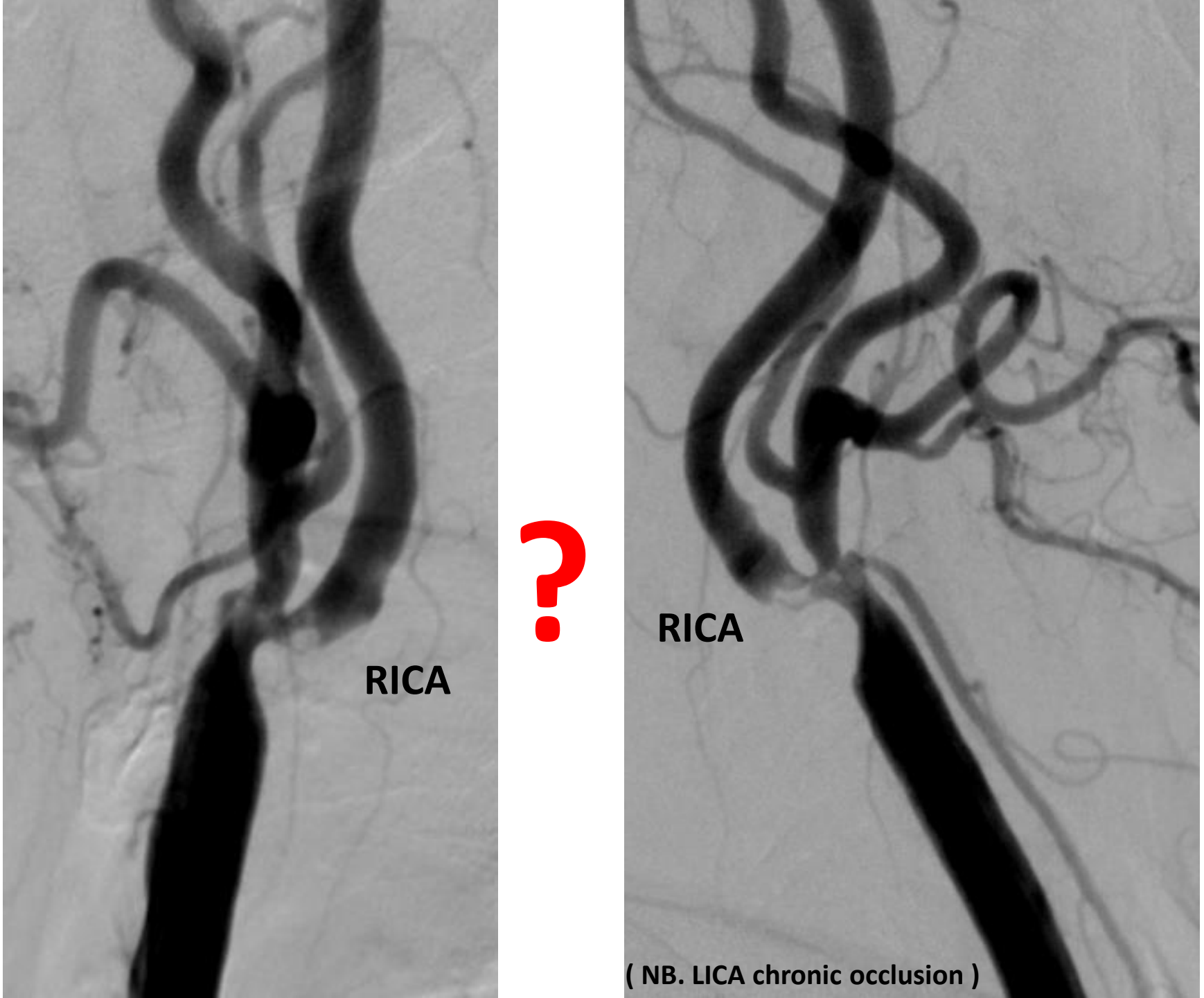


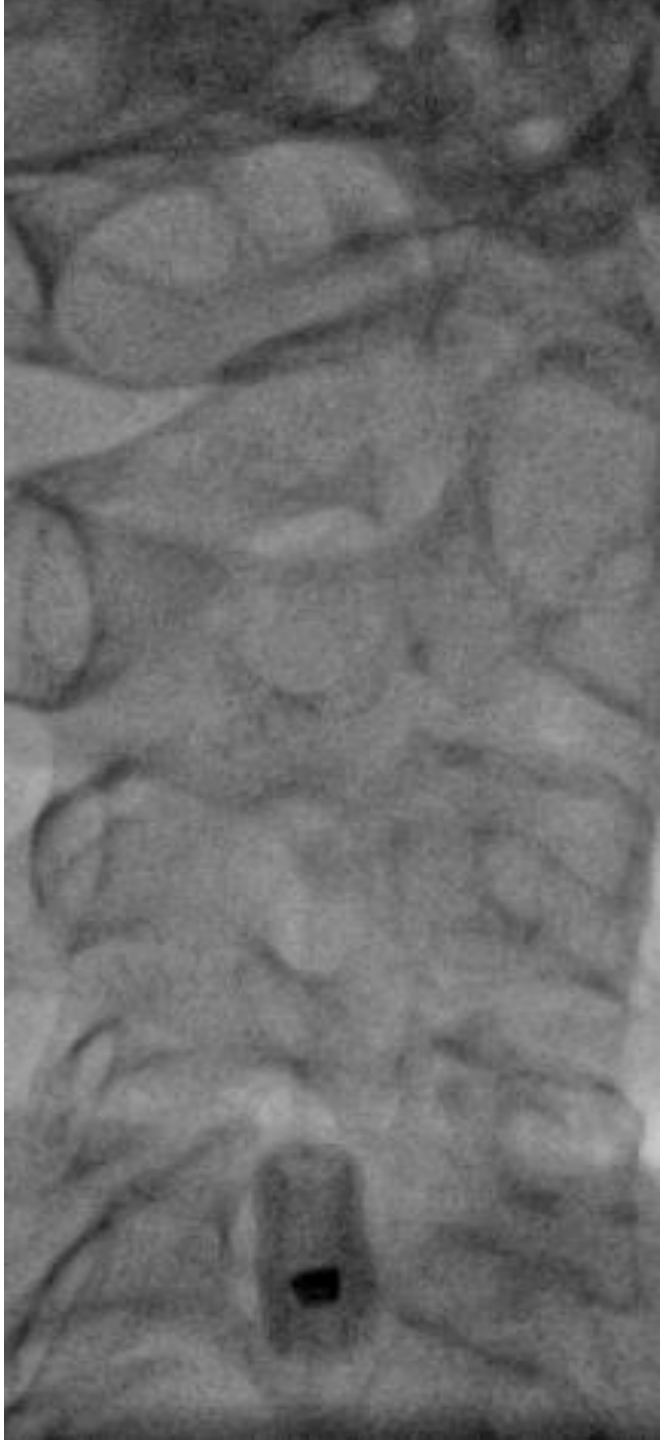
continues as an ALL-Comer Study

↕

ZS, lady, 64 years **November 8, 2017**

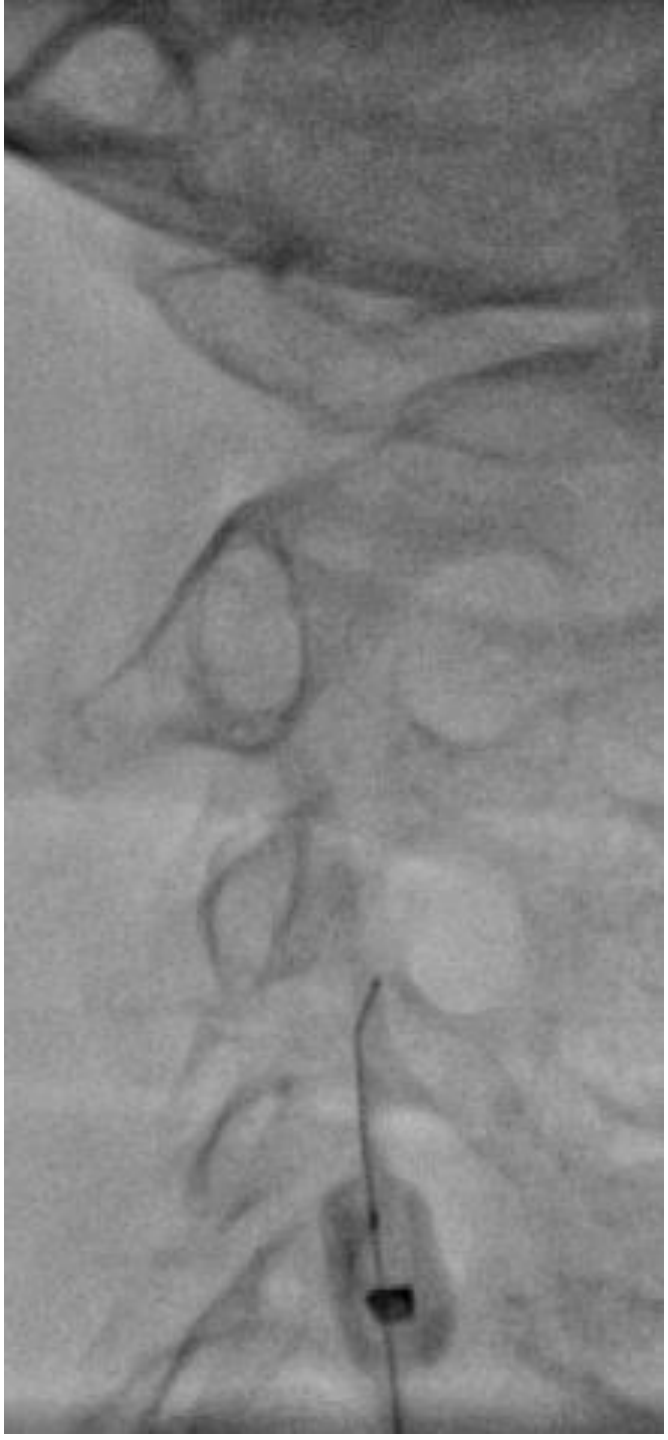
- h/o 3 minor strokes (2003, June 2017, July 2017)
- diagnosed with LICA chronic occlusion (DUS, CT-angio)
- RICA 4.7/1.4 m/s, soft, highly irregular plaque suggestive thrombus
- MRI – September 2017
- referral delayed to GI bleeding requiring transfusion
- currently recurrent TIAs from both L and R hemisphere…

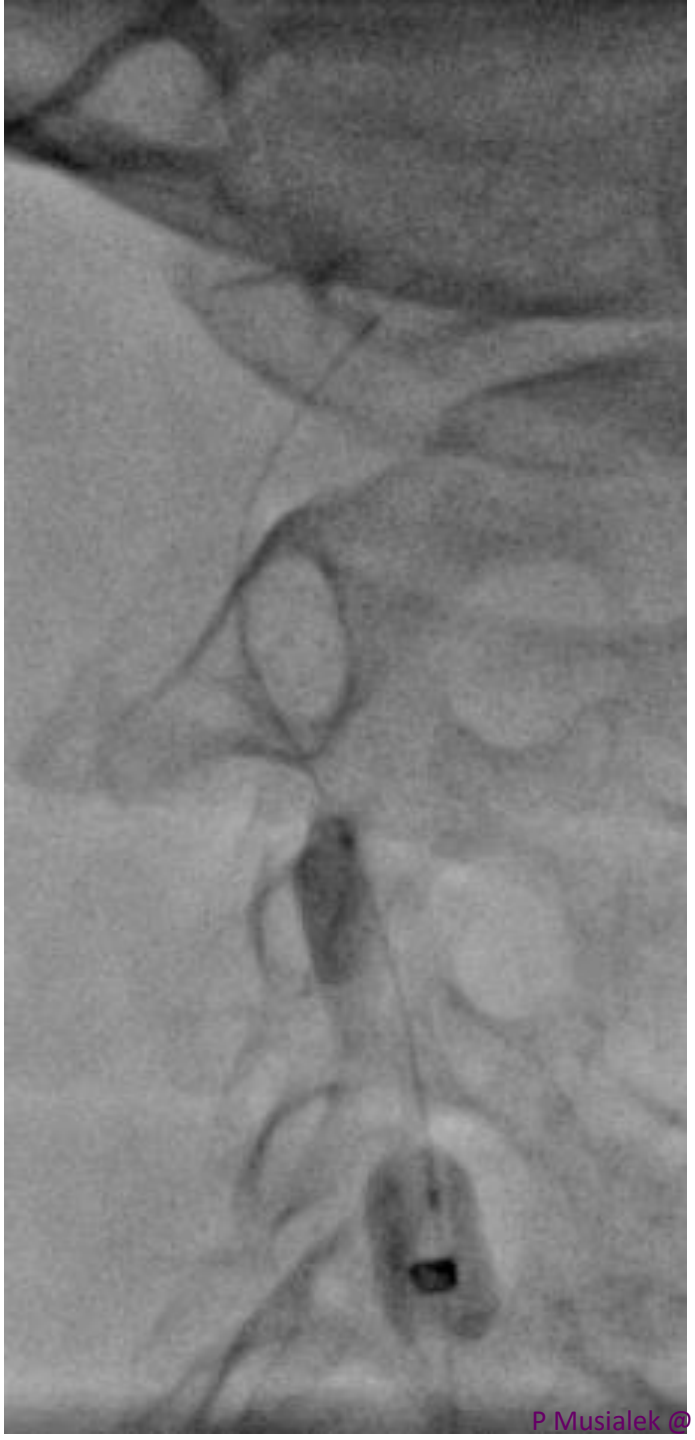

RICA
?
RICA
(NB. LICA chronic occlusion)



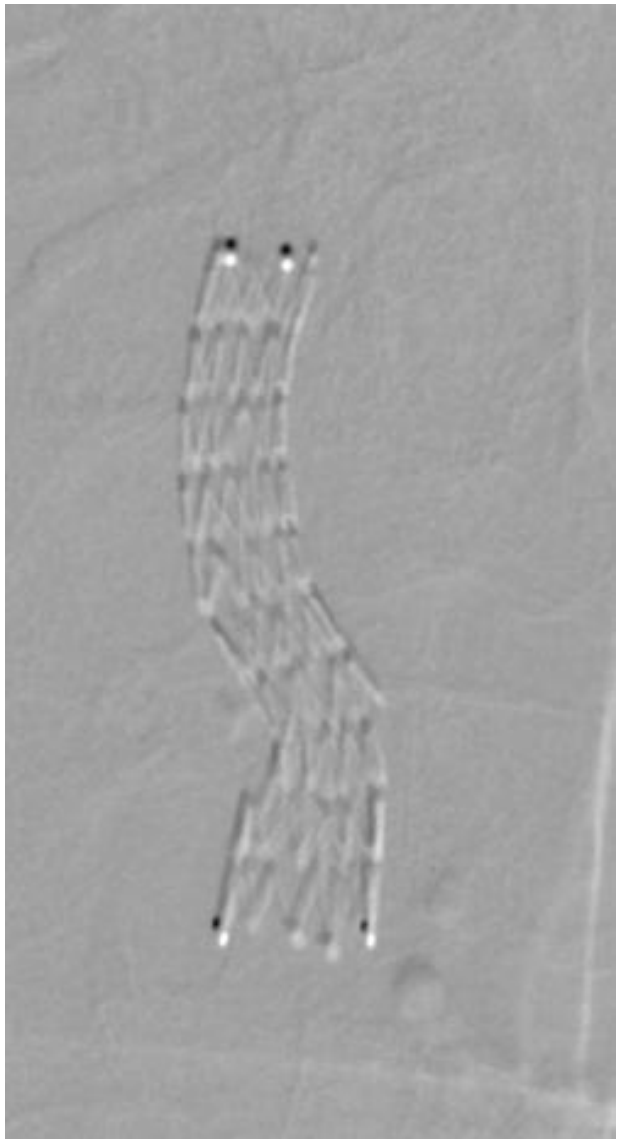
Back pressure 58/47mmHg

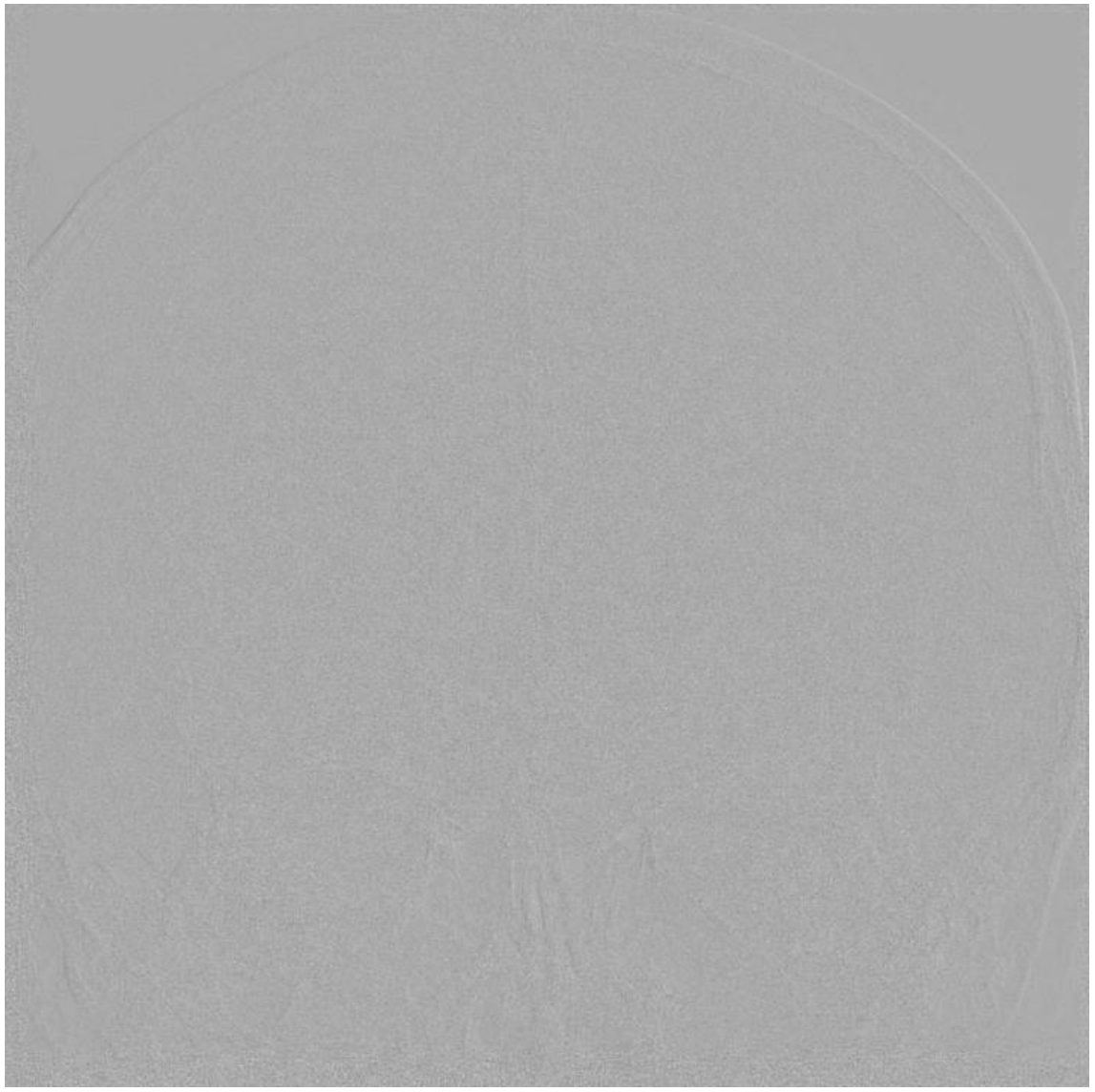
(4min tolerance test)

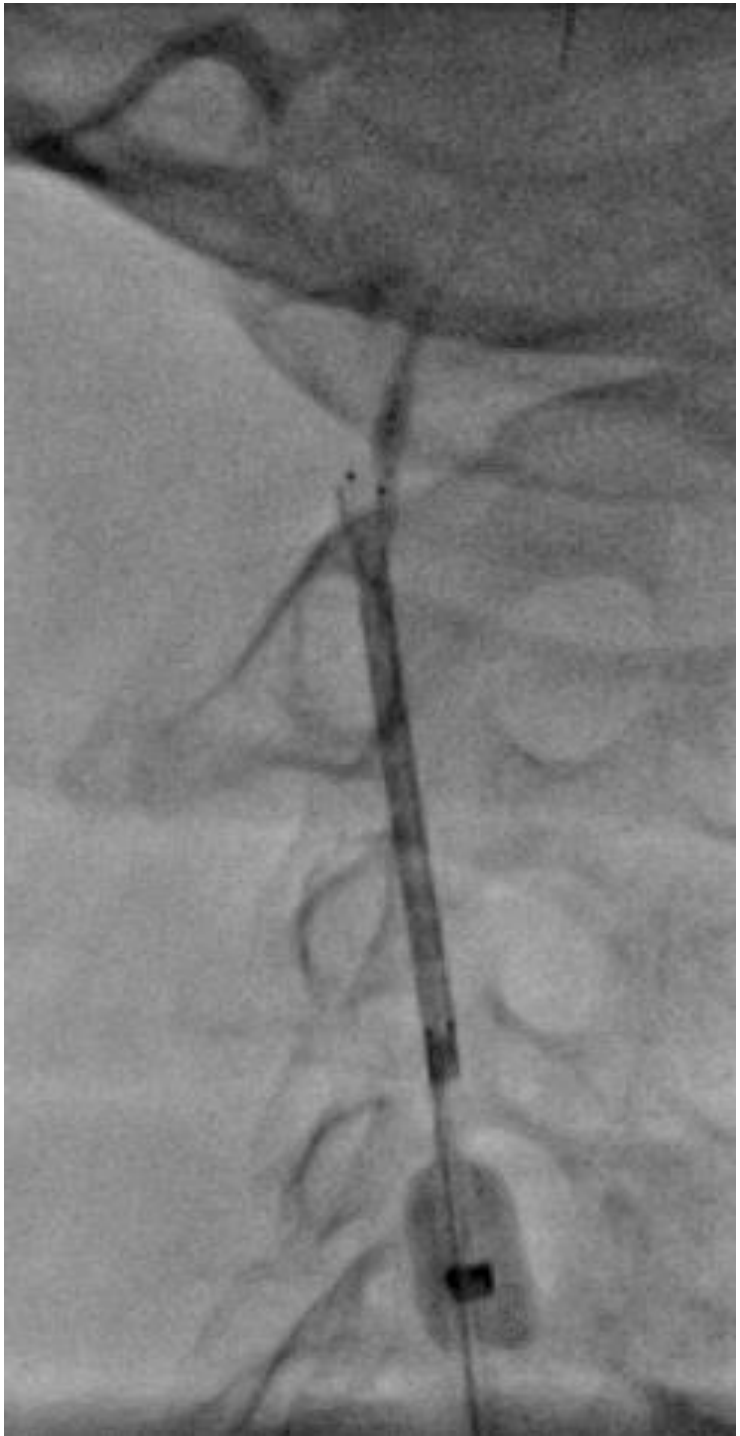




Final Result





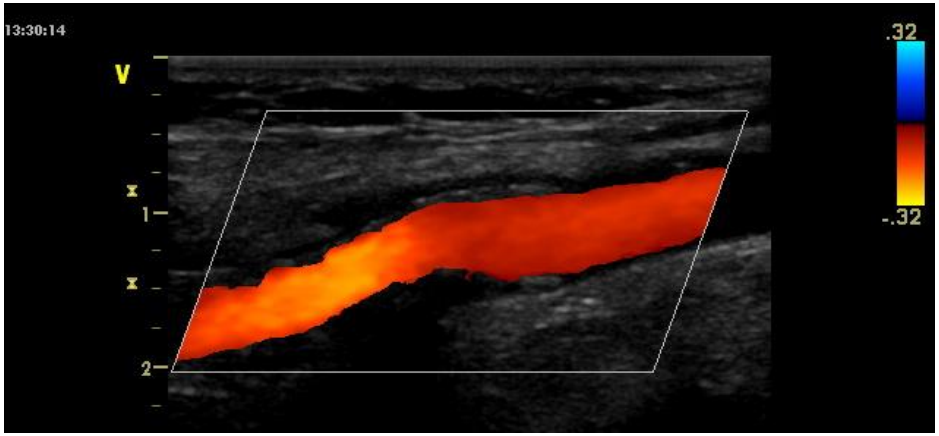


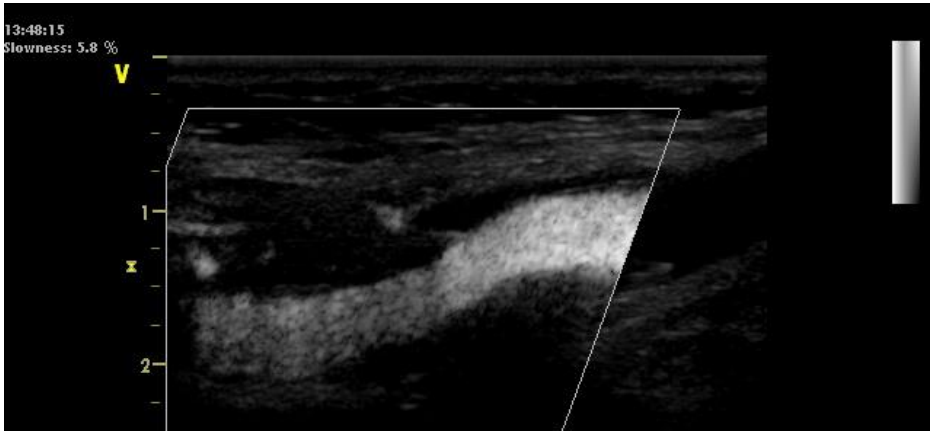
Flow reversal time 7min 10sec

Intolerance in the last 80sec

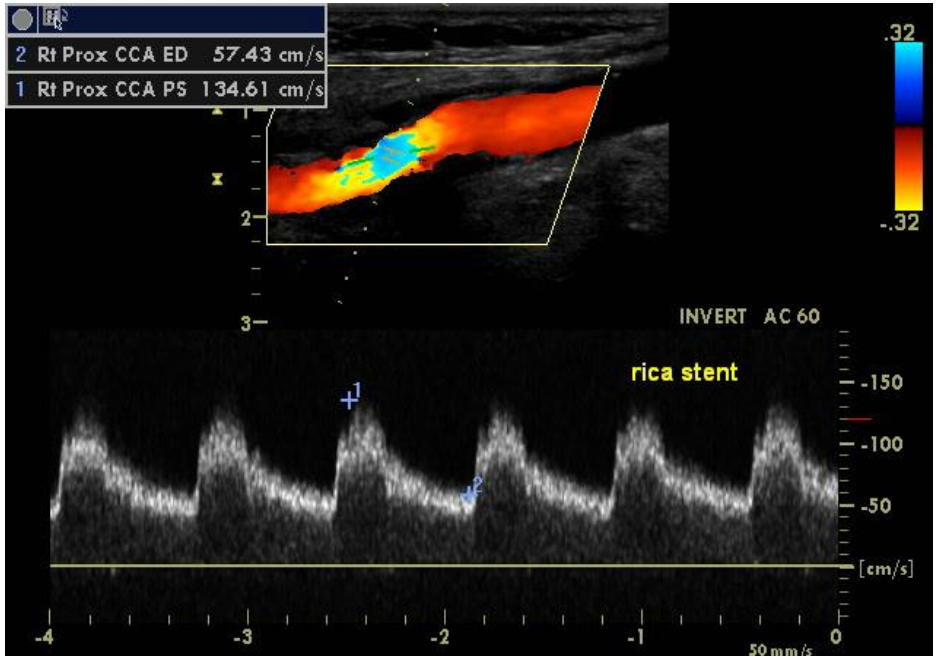
(active aspiration still !! performed)

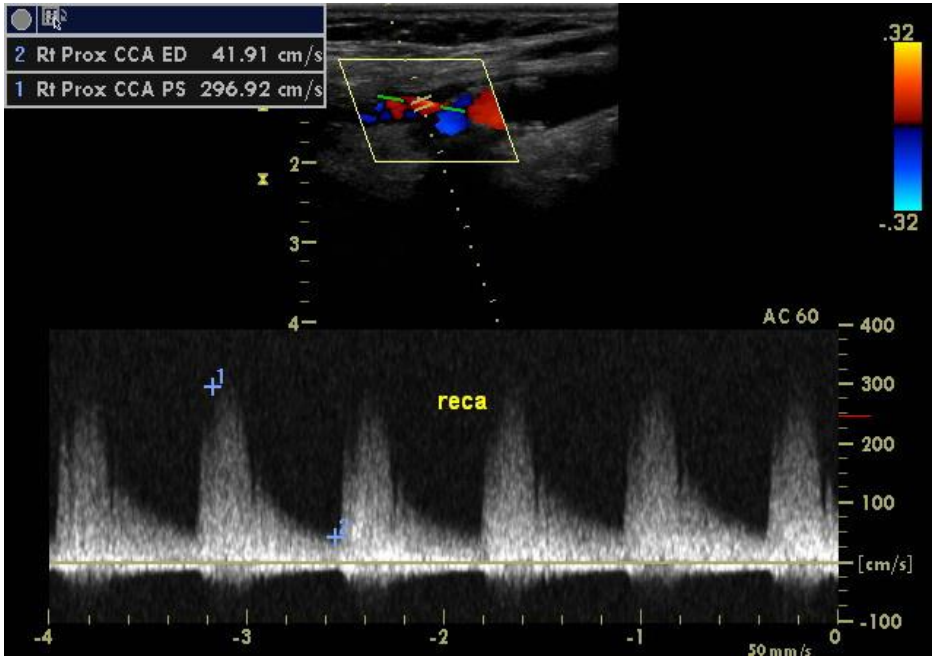
Patient A/S, discharged home @ Day2 post procedure





Normal stent image





Normal velocities

ECA patent

PARADIGM – Extend

continues as an ALL-Comer Study

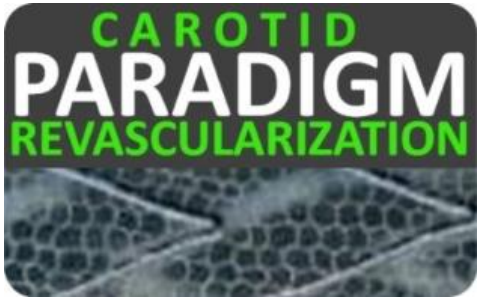
May 2018 update
(2-year data)

- 251 patients / 263 arteries
  NeuroVascular Team decision-making on revascularization

- Age 51-87 years, 57.1% symptomatic
- Crossed the trial first follow-up window (30d)
- 100% CGuardEPS use
- Angiographic diameter stenosis was reduced from 83±9% to only 6.7±5% (p<0.001, 'CEA-like' effect of CAS)

PARADIGM – Extend

251 patients / 263 arteries



- *Peri-procedural outcome*

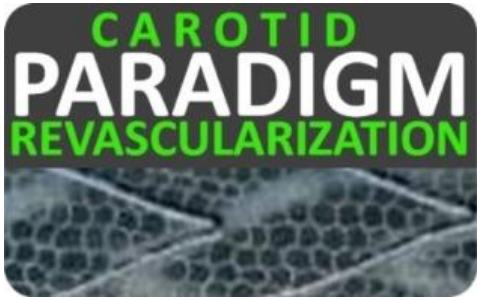
  0 death/major stroke – **0%**
  1 minor stroke – 0.4%
  1 MI (type2) **– 0.4%**

May 2018 update
(2-year data)

- *By 30 days*

  1 haemorrhagic transformation of prior ischaemic cerebral infarct, leading to **death – 0.4%**

PARADIGM – Extend



251 patients / 263 arteries

May 2018 update
(2-year data)

- *Peri-procedural outcome*

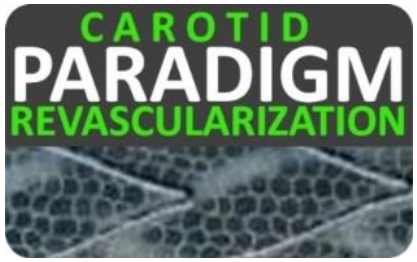
  0 death/major stroke – **0%**
  1 minor stroke – 0.4%
  1 MI (type2) **– 0.4%**

- *By 30 days*

  1 haemorrhagic transformation of prior ischaemic cerebral infarct, leading to **death – 0.4%**

Total 30d death/major stroke/minor stroke rate **– 0.8%**
Total 30d death/major stroke/minor stroke/MI **– 1.2%**

PARADIGM – Extend



251 patients / 263 arteries

May 2018 update (2-year data)

- *Clinical outcomes 1-12 months*

  0 strokes or stroke-related deaths – 0%

- *Clinical outcomes 12-24 months*

  1 cerebellar stroke with de novo AFib

  0 carotid-territory strokes or stroke-related deaths – 0%

PARADIGM – Extend

251 patients / 263 arteries

Cumulative analysis → **May 2018 update (2-year data)**

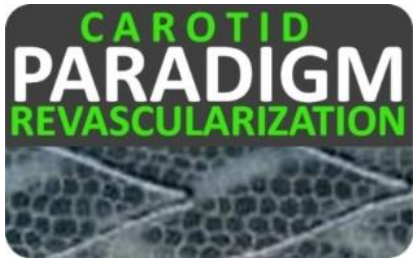
- *ISR*

  By 24 months

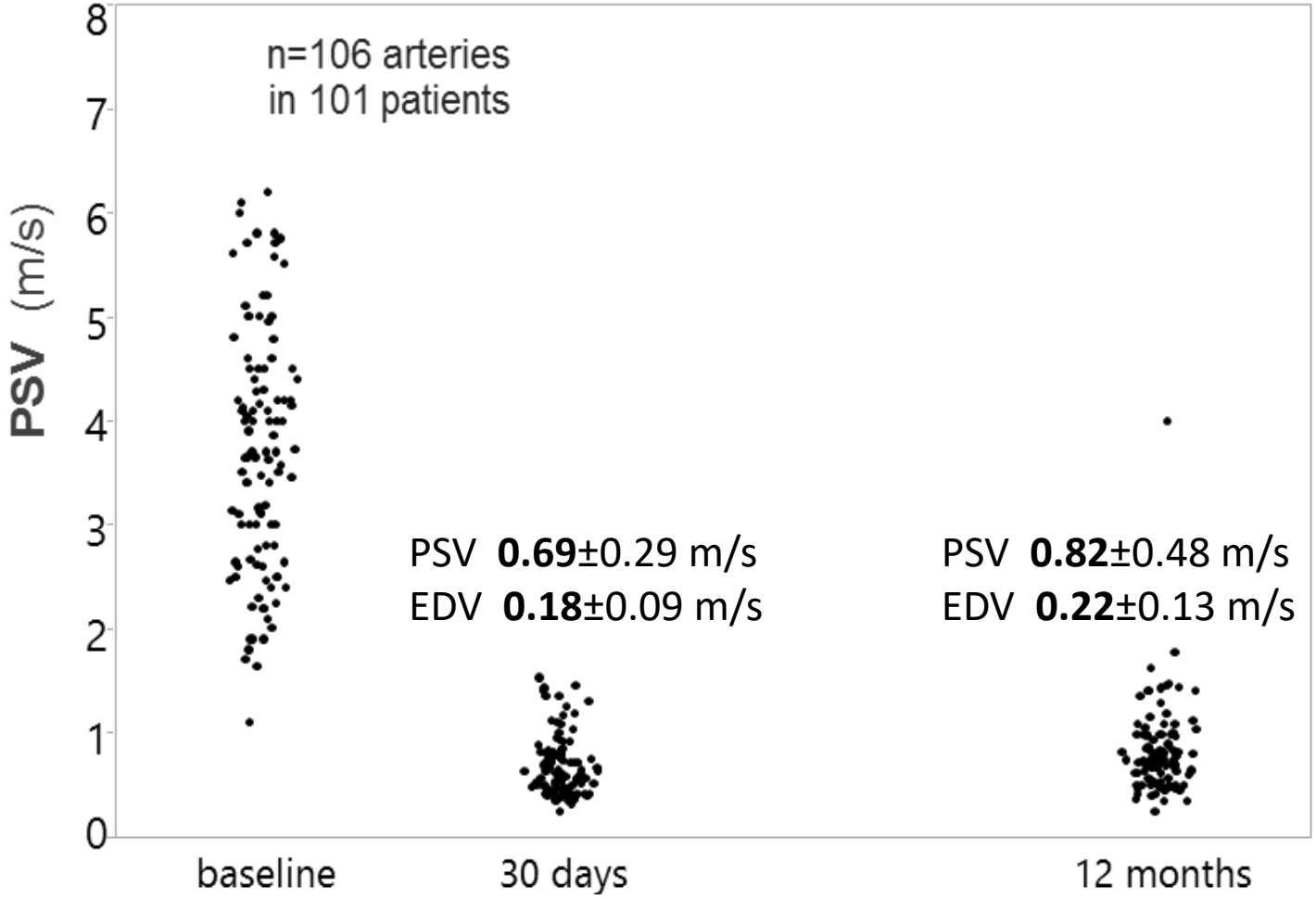
  1 asymptomatic ISR – detected at 12 mo; treated with DEB-PTA
  no relapse by 24 mo

  1 clinically silent stent occlusion in a patient who initiated neck radiotherapy course 2 months after CAS due to cancer relapse

Evolution of in-stent velocities in the PARADIGM Study



May 2018 update
(2-year data)



12 – 24 mo

- No Neuro Events

except 1 cerebellar minor stroke (MRI- verified) in an AFib patient

- No **ISR**

PSV **0.73**±0.31 m/s
EDV **0.19**±0.09 m/s

(patients who completed 24mo window)

24 months

P Musialek @ ePCR 2018

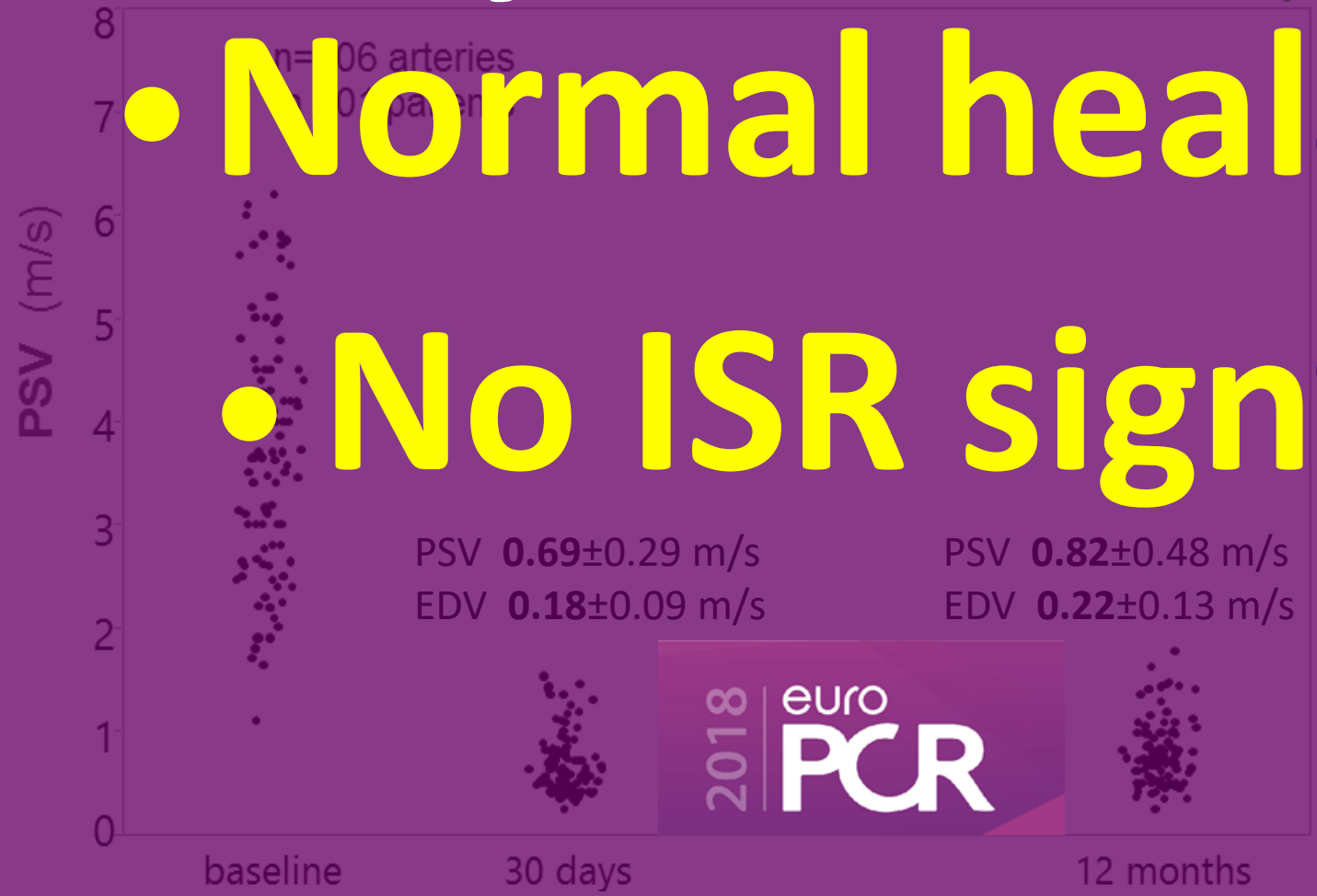
Evolution of in-stent velocities in the PARADIGM Study

CAROTID PARADIGM REVASCULARIZATION

May 2018 update
(2-year data)

12 – 24 mo
- No Neuro Events
  except cerebellar minor stroke (MRI- verified) in an AFib patient
- No ISR

By 24 months
- Normal healing
- No ISR signal



PSV **0.69**±0.29 m/s
EDV **0.18**±0.09 m/s

PSV **0.82**±0.48 m/s
EDV **0.22**±0.13 m/s

PSV **0.73**±0.31 m/s
EDV **0.19**±0.09 m/s

(patients who completed 24mo window)

2018 euro PCR

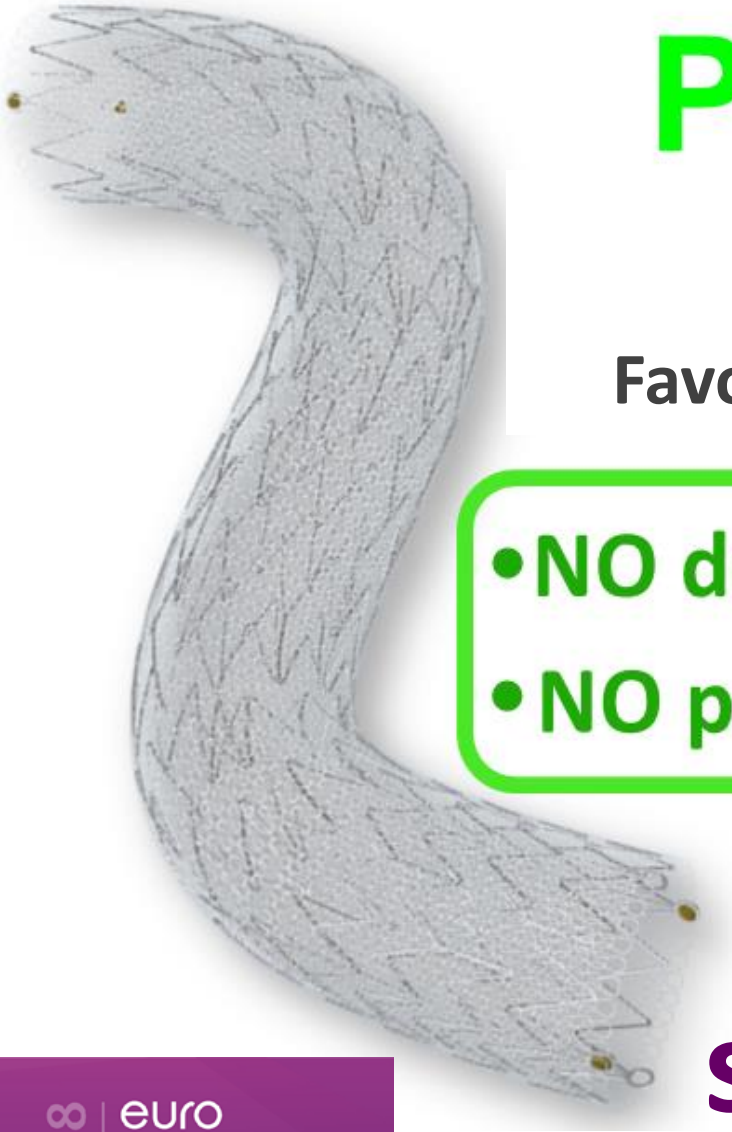
24 months

P Musialek @ ePCR 2018

CGUARD™
Carotid Embolic Prevention System

CAROTID PARADIGM REVASCULARIZATION

24-month data



PARADIGM

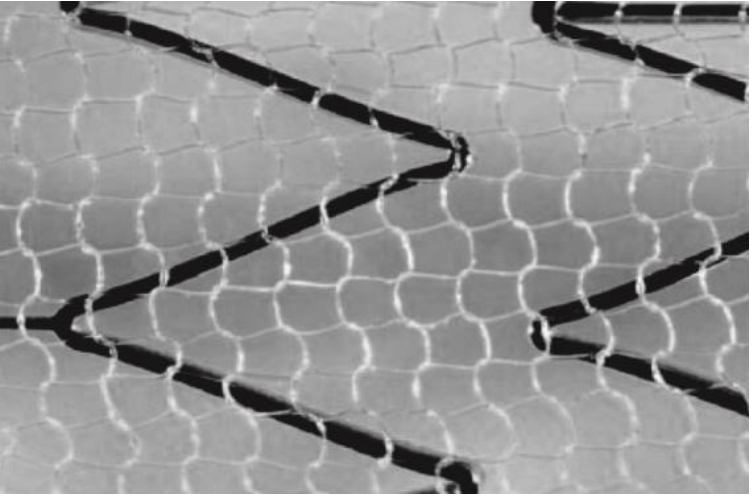
@ 24 months

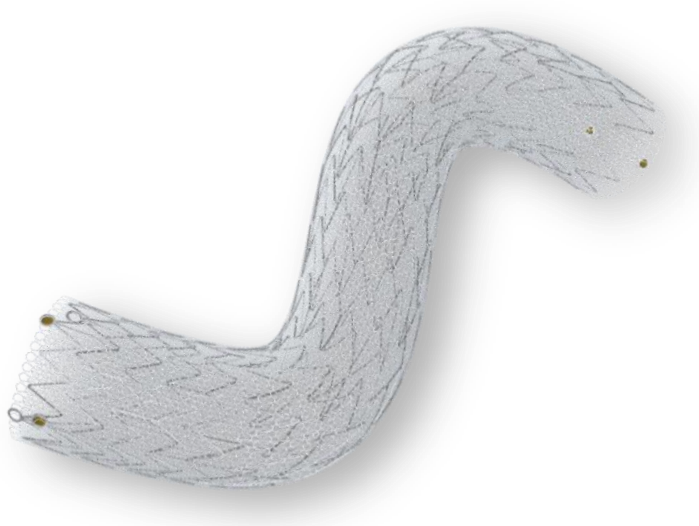
Favourable Clinical Outcome

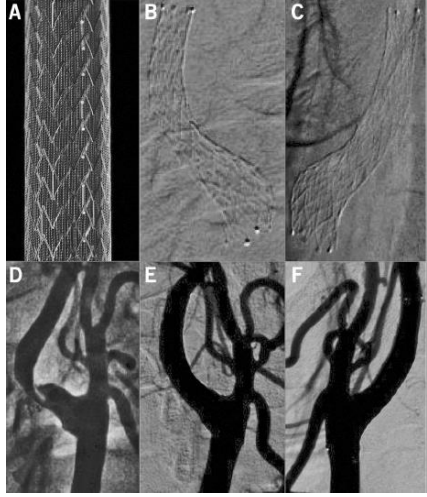
- NO device-related adverse events
- NO procedure-related events

sustained stroke prevention

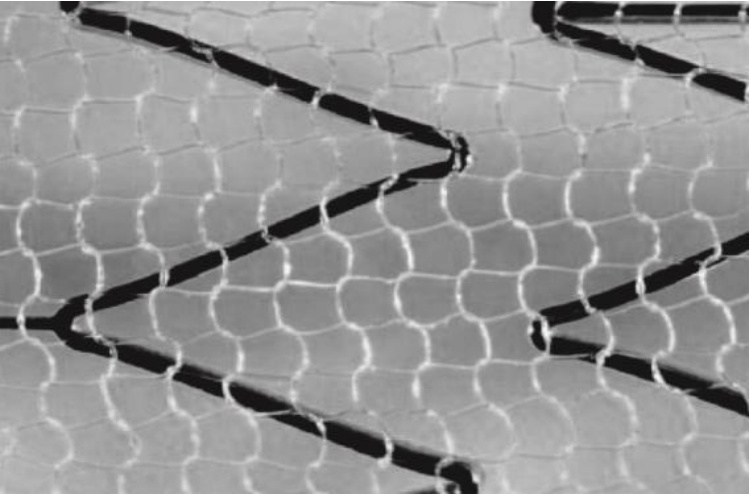
2018 euro PCR

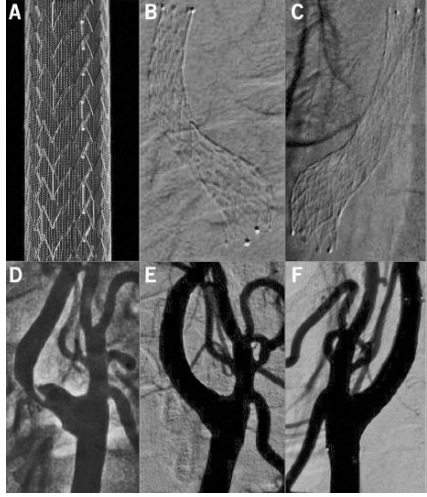






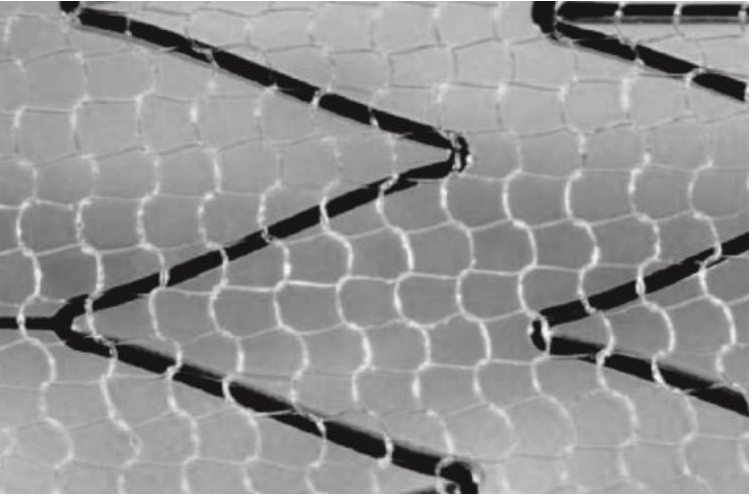
This concept has been desired.

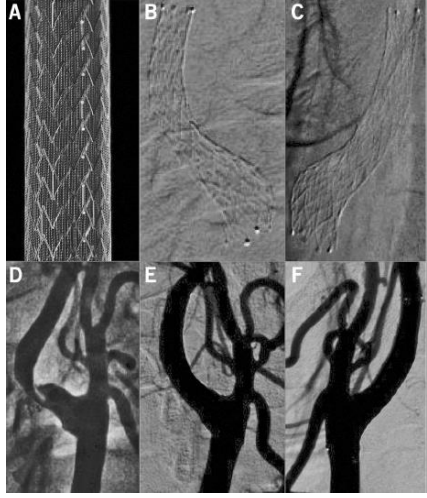




This concept has been desired.

And it works.



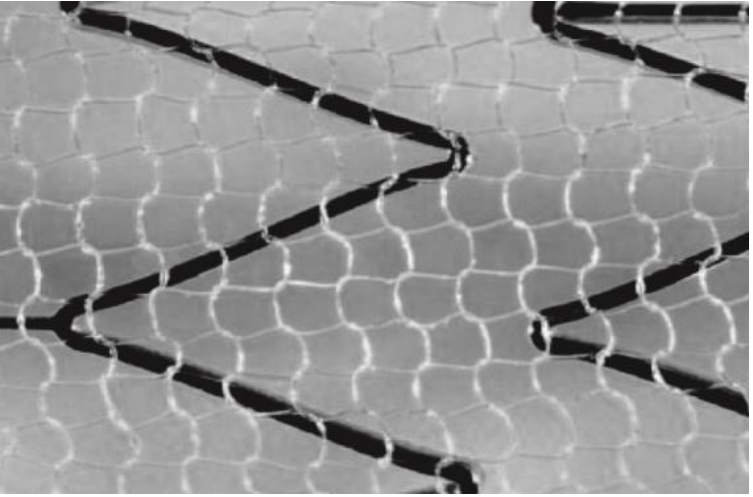


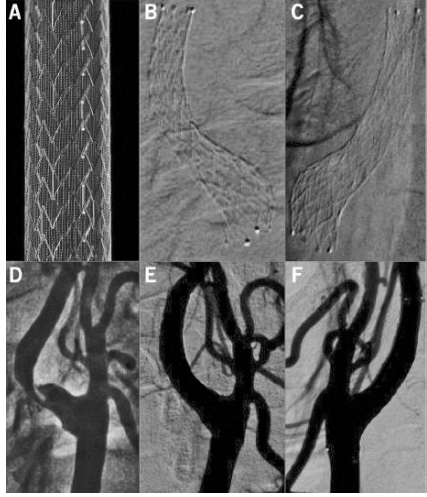
This concept has been desired.

And it works.

This is the future

of Carotid Artery Stenting



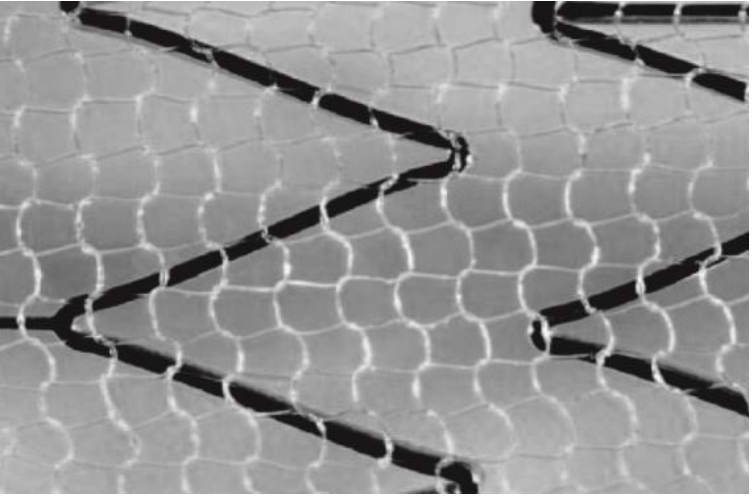


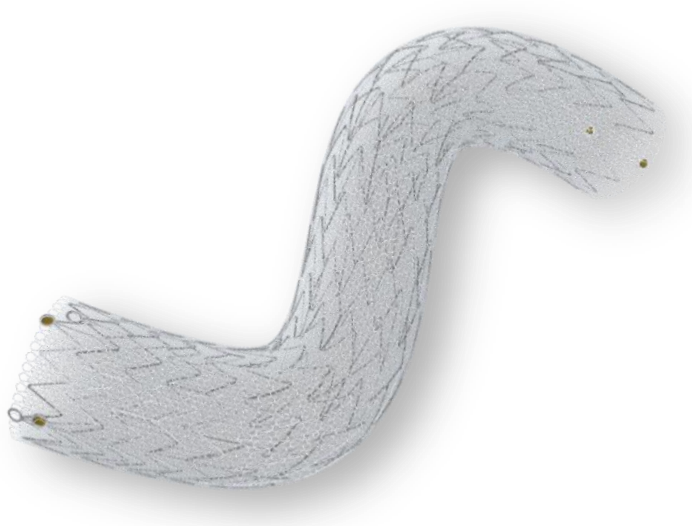
This concept has been desired.

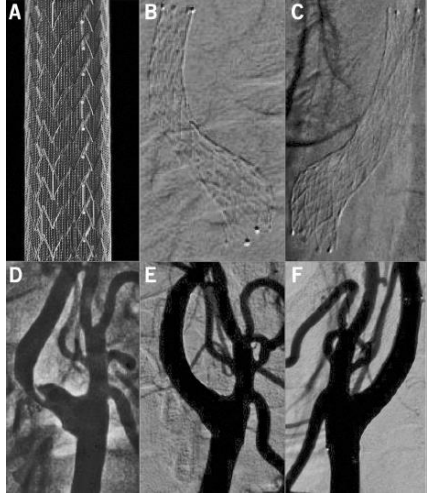
And it works.

This is the future

of Carotid Artery ~~Stenting~~







This concept has been desired.

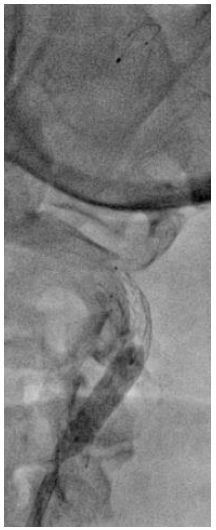
And it works.

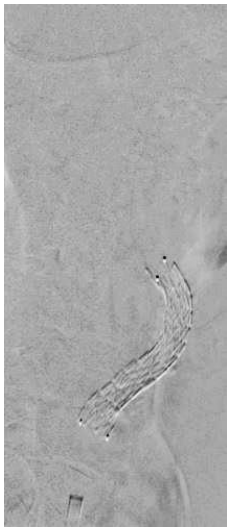
This is the future

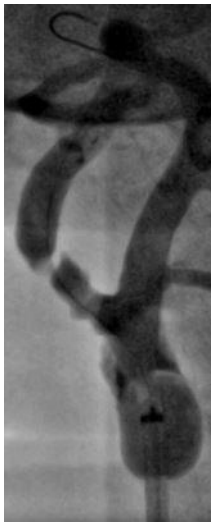
of Carotid Artery S[illegible]g

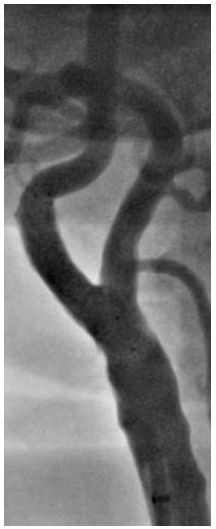
revascularization ?

Endovascular Solution for All-Comers









Endovascular Reconstruction of the Carotid Bifurcation

Prevention of embolism, High radial force, Conformability