INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 05/22/15 for the Period Ending 05/22/15

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
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SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 22, 2015

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

321 Columbus Avenue Boston, Massachusetts	02116
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation that Professor Piotr Musialek will present on May 22, 2015, at the EuroPCR 2015 Conference held from May 19 to May 22, 2015, in Paris, France (the "EuroPCR Conference"), with respect to the results of InspireMD, Inc.'s CGuard ™ Embolic Prevention System in PARADIGM (**P** rospective evaluation of **A** ll-comer pe **R** cutaneous c **A** roti **D** revascularization **I** n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C **G** uard™ **M** esh-covered embolic prevention stent system).

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On May 22, 2015, InspireMD, Inc. issued a press release announcing that the results of its CGuard ™ Embolic Prevention System in PARADIGM were reported at the EuroPCR Conference.

A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	2015 EuroPCR Presentation
99.2	Press release dated May 22, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INSPIREMD, INC.

Date: May 22, 2015

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

EuroPCR 2015
19th-22nd May, 2015 - Paris

CAROTID PARADIGM REVASCULARIZATION

Prospective evaluation of All-comer peRcutaneous cArotiD revascularization In symptomatic and increased-risk asymptomatic carotid artery stenosis using CGuard™ Micronet-covered embolic prevention stent system: The PARADIGM Study

P. MUSIALEK [1], A. MAZUREK [1], M. TRYSTULA [2], A. BORRATYNSKA [3], M. URBANCZYK [3], A. LESNIAK-SOBELGA[1], P. BANYS[3], A. BRZYCHCZY[2], L. PARTYKA[4], K. ZMUDKA[5], P. PODOLEC [1]

(1) Dept Cardiac and Vascular Diseases, Jagiellonian University & John Paul II Hospital, (2) Dept Vascular Surgery, John Paul II Hospital; (3) John Paul II Hospital, Krakow; (4) Krakow Cardiovascular Research Institute (KCRI); (5) Dept Interventional Cardiology, Jagiellonian University & John Paul II Hospital, Krakow, POLAND

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

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EuroPCR 2015
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Potential conflicts of interest

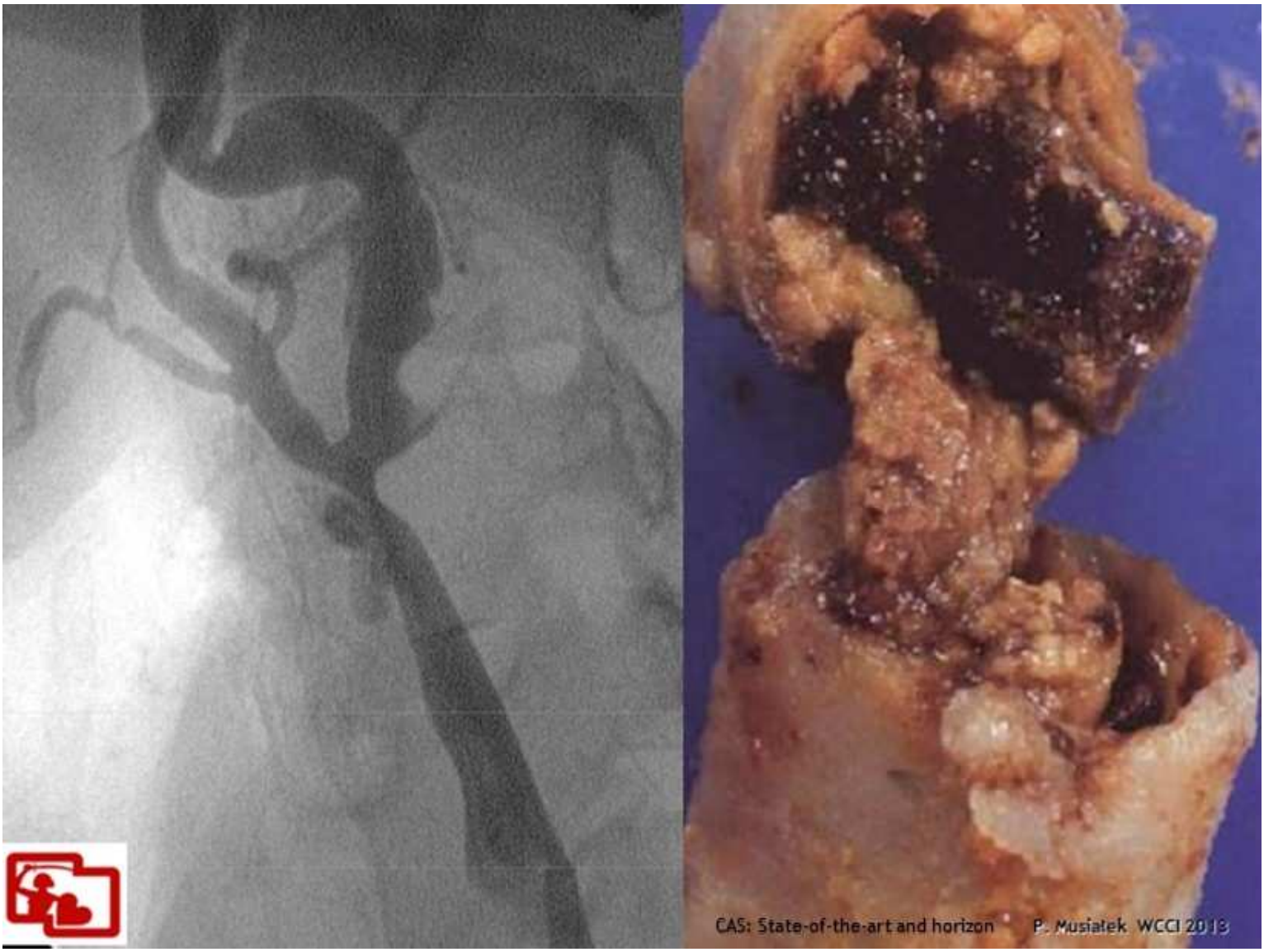
Speaker's name: Piotr Musialek

☑ **I have the following potential conflicts of interest to report:**

Consulting / Research Support / Speaker Bureau

ABBOTT VASCULAR
Balton Ltd
InspireMD
MEDTRONIC

NB. Research in this presentation is **not** industry-funded


CAS: State-of-the-art and horizon
P. Musialek 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

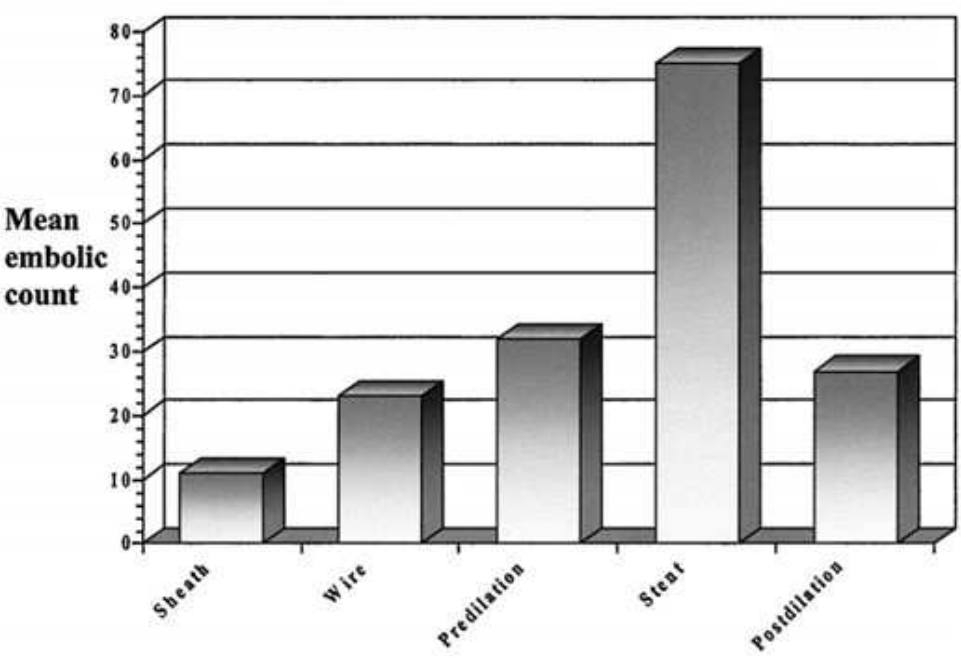


Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

Circulation. 2001;104:1999-2002

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 are those during stent healing !)

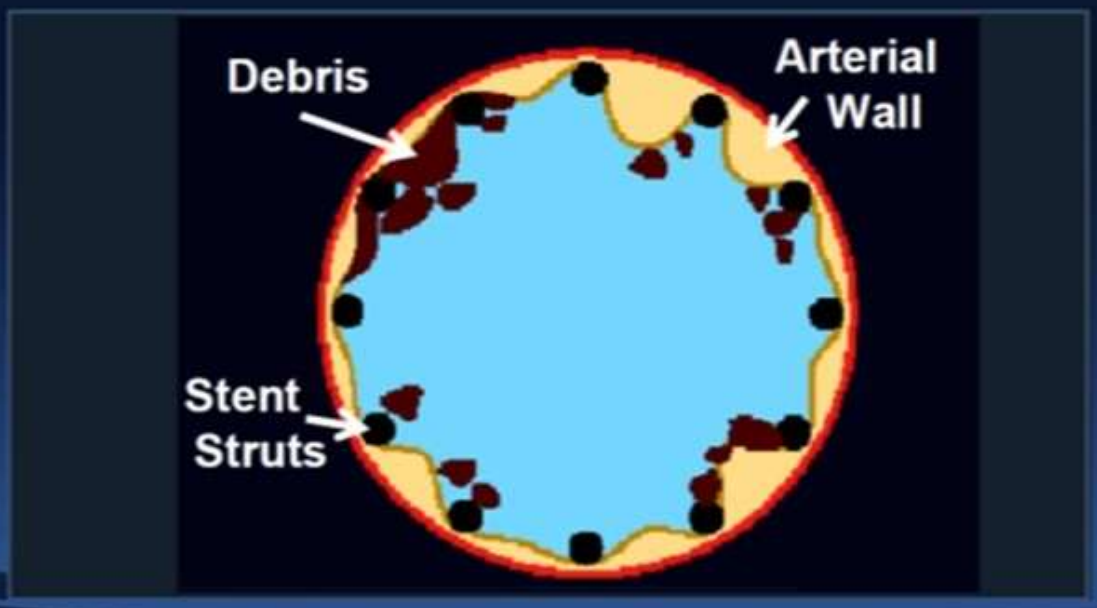
Free cell area	Total population		Symptomatic population	
	All events	Post-procedural events	All events	Post-procedural events
<2.5 vs [2.5, 5]	1.00	1.00	1.00	1.00
<2.5 vs [5, 7.5]	0.054	0.072	0.048	0.024
<2.5 vs >7.5	0.27	0.006	0.0006	$2.8\ 10^{-6}$

Eur J Vasc Endovasc Surg Vol 33, February 2007

CAS using conventional carotid stents in high-risk lesions

Conventional Carotid Stent

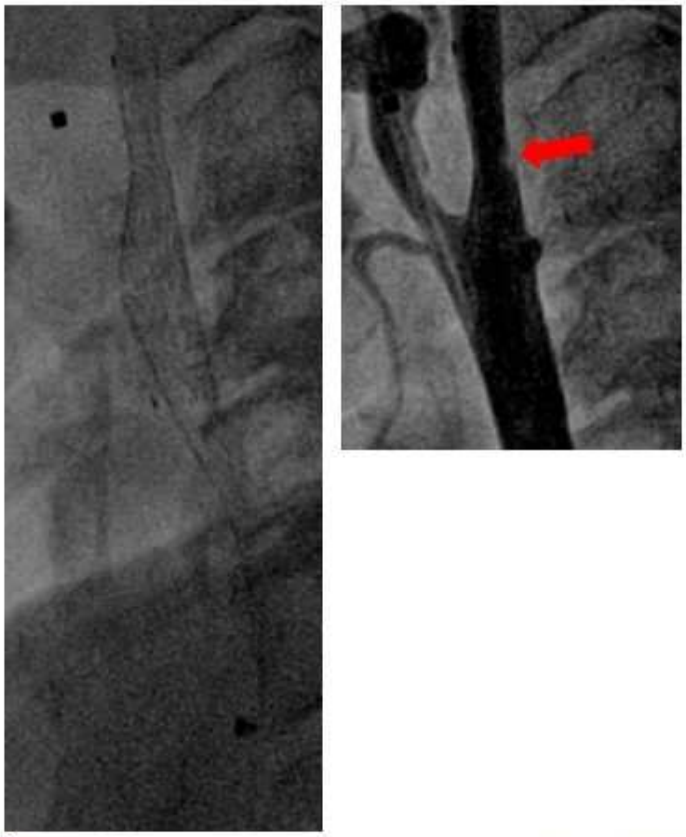
Plaque protrusion may lead to early and late distal embolization



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

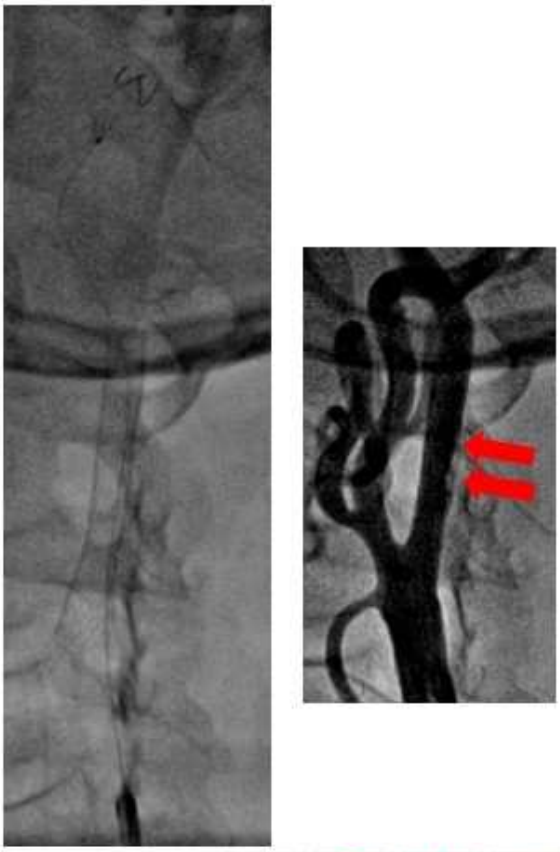
current best-in-class

Hybrid stent



current best-in-class

Closed-cell stent



Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS

Schofer J et al, JACC Cardiovasc interv 2008

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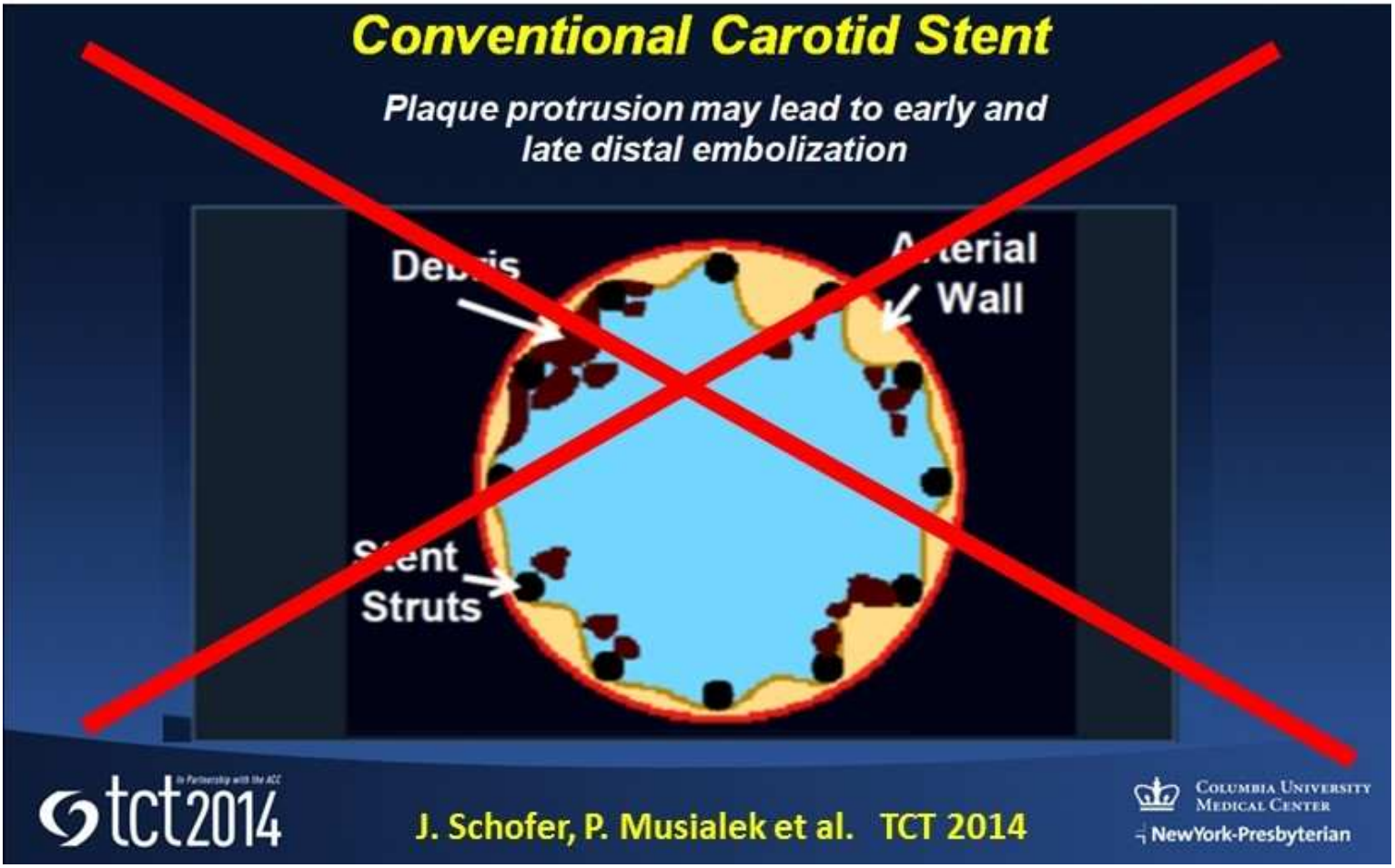
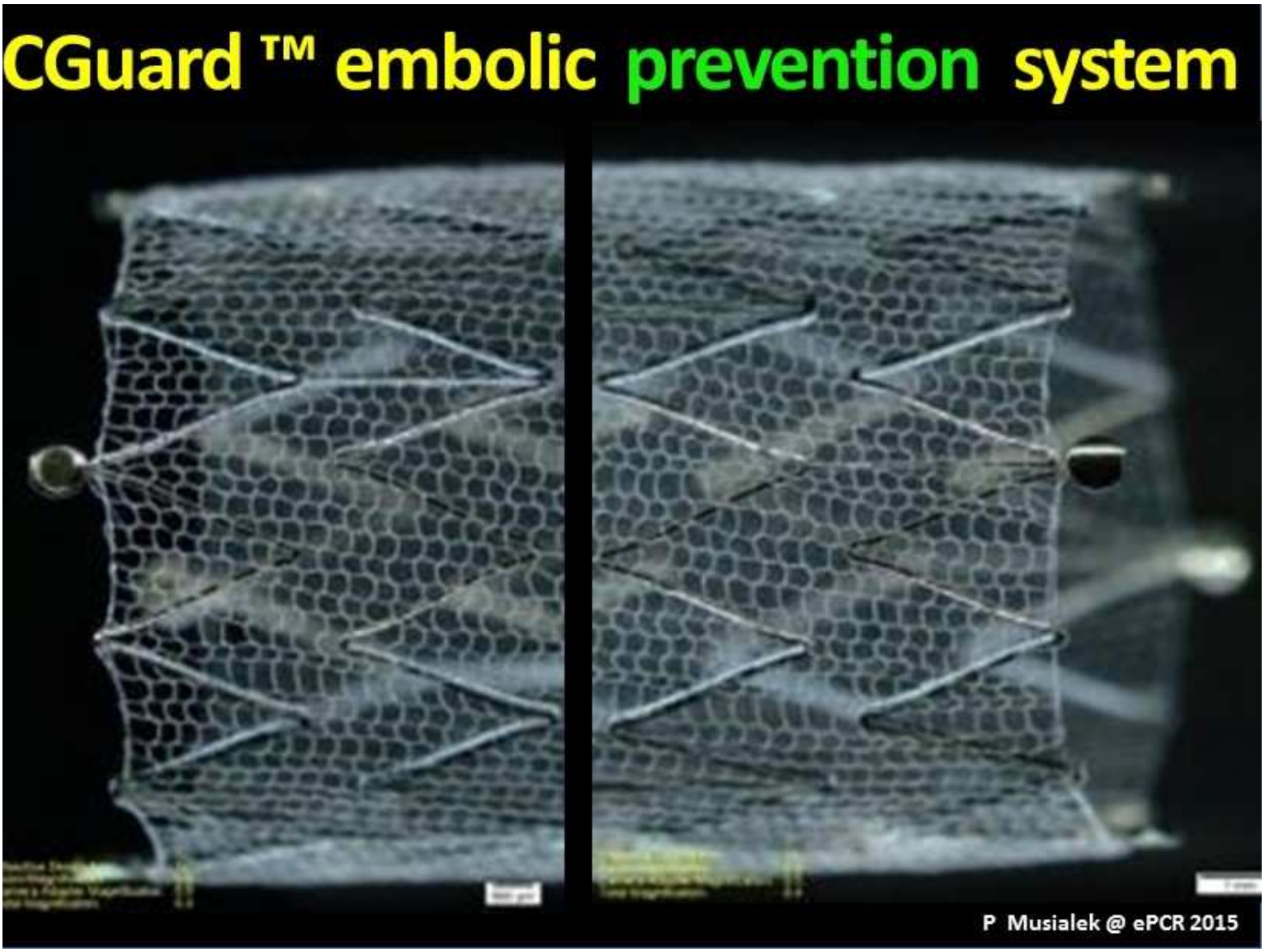
CAS using conventional carotid stents in high-risk lesions

CAROTID PARADIGM REVASCULARIZATION

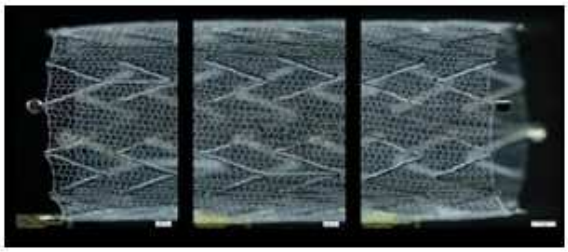



CGuard ™ embolic prevention system
P Musialek @ ePCR 2015

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



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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)

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PARADIGM

Methods:

- academic cardio-vascular centre
- investigator-initiated study
- not industry-funded
- all-comer patient inclusion (six month referral sample)
- 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**

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)

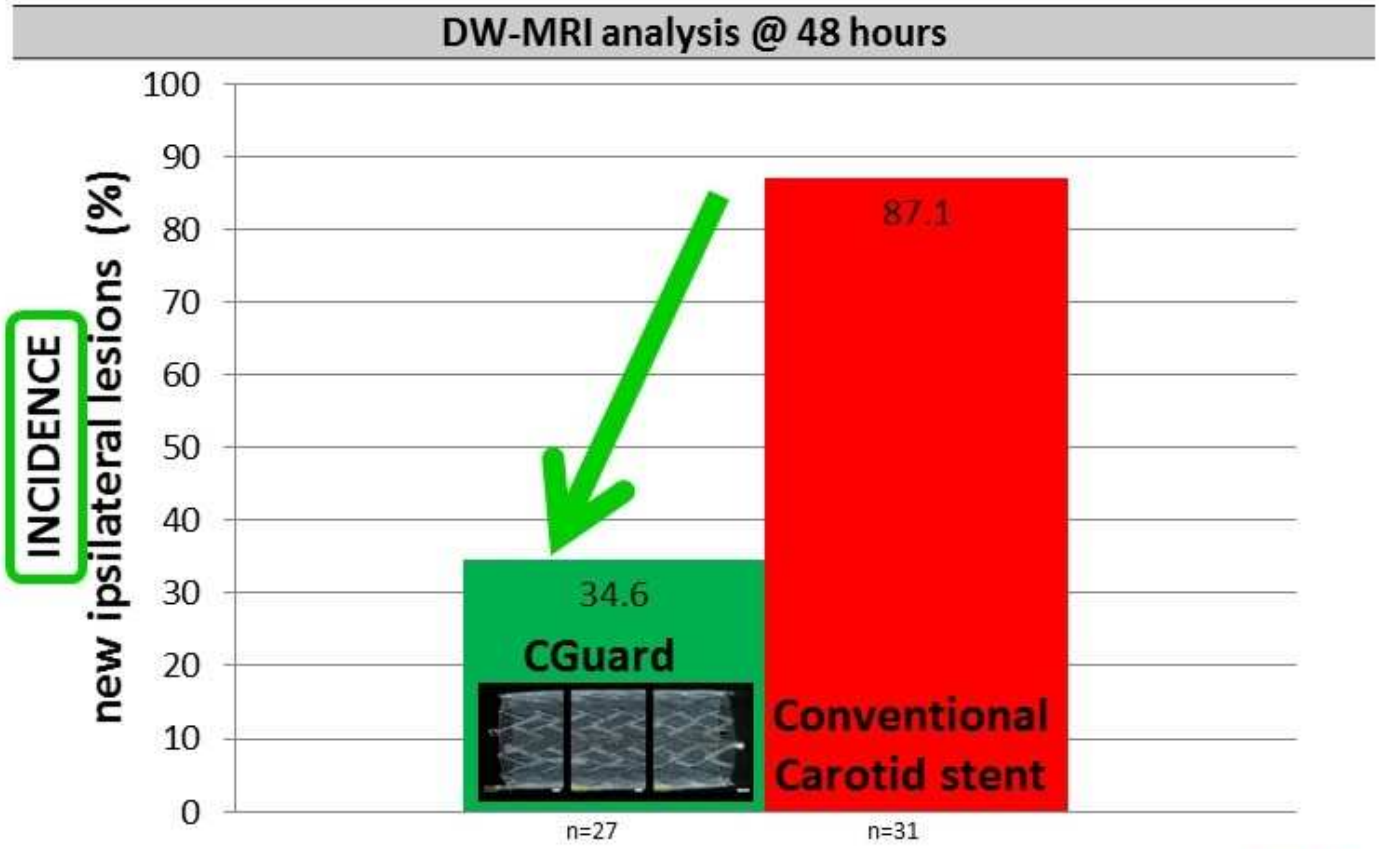
NB. 1. DWI evidence of effective MicroNet prevention against cerebral embolization (CARENET/PROFI)
2. Residual stenosis after CAS as independent predictor of in-stent restenosis

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

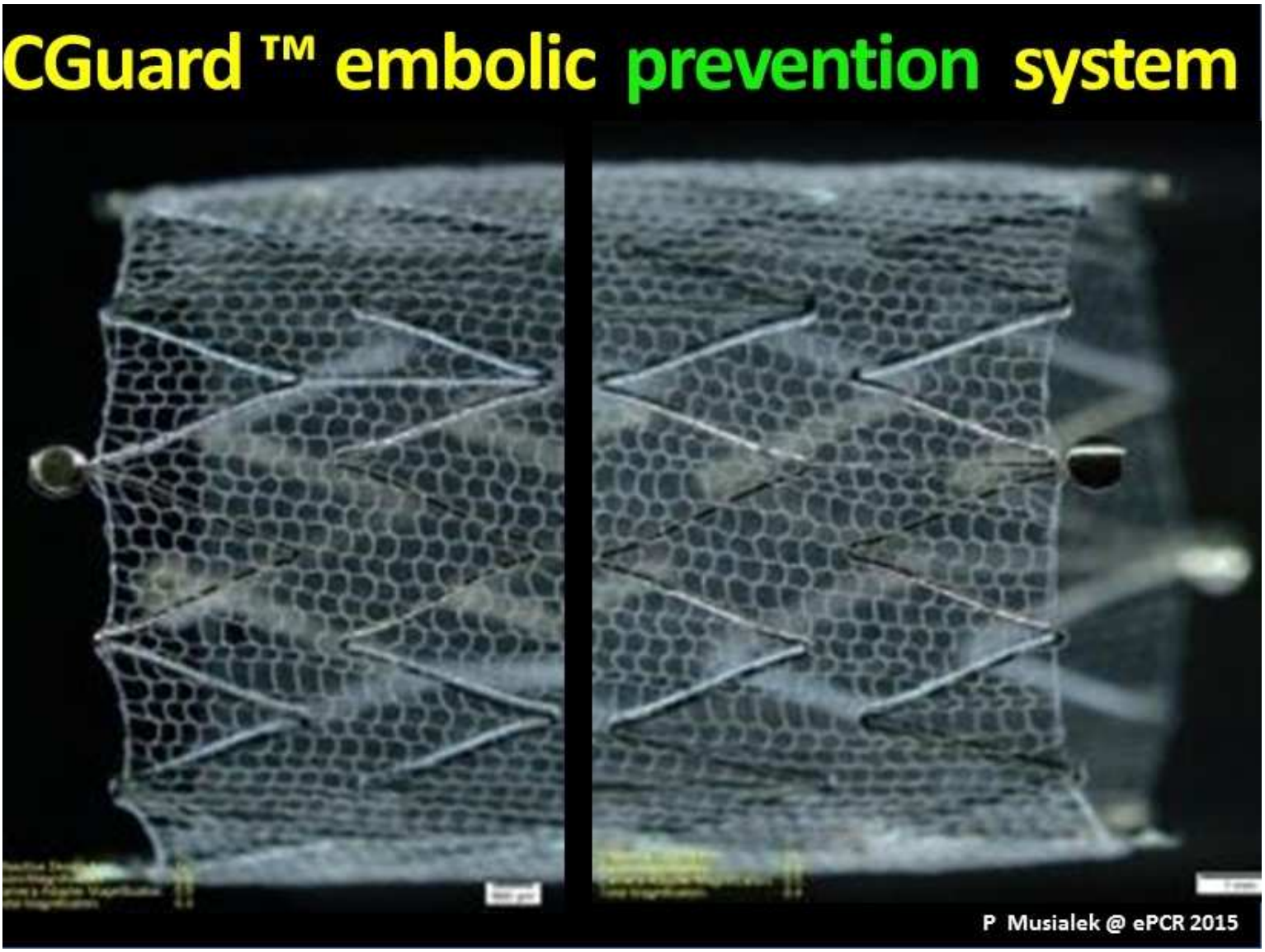
* Pieniazek P, Musialek P et al. *J Endovasc Ther* 2008;15:249-62.
Cremonesi A et al. *EuroInervention* 2009;5:589-98.
Pieniazek P, Musialek P et al. *J Endovasc Ther* 2009;16:744-51.

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis



J. Schofer, P. Musialek et al. *JACC Intv* 2015 (in press)
K. Bijuklic et al. *JACC*, 2012;59:1383-9.


CGuard ™ embolic prevention system
P Musialek @ ePCR 2015

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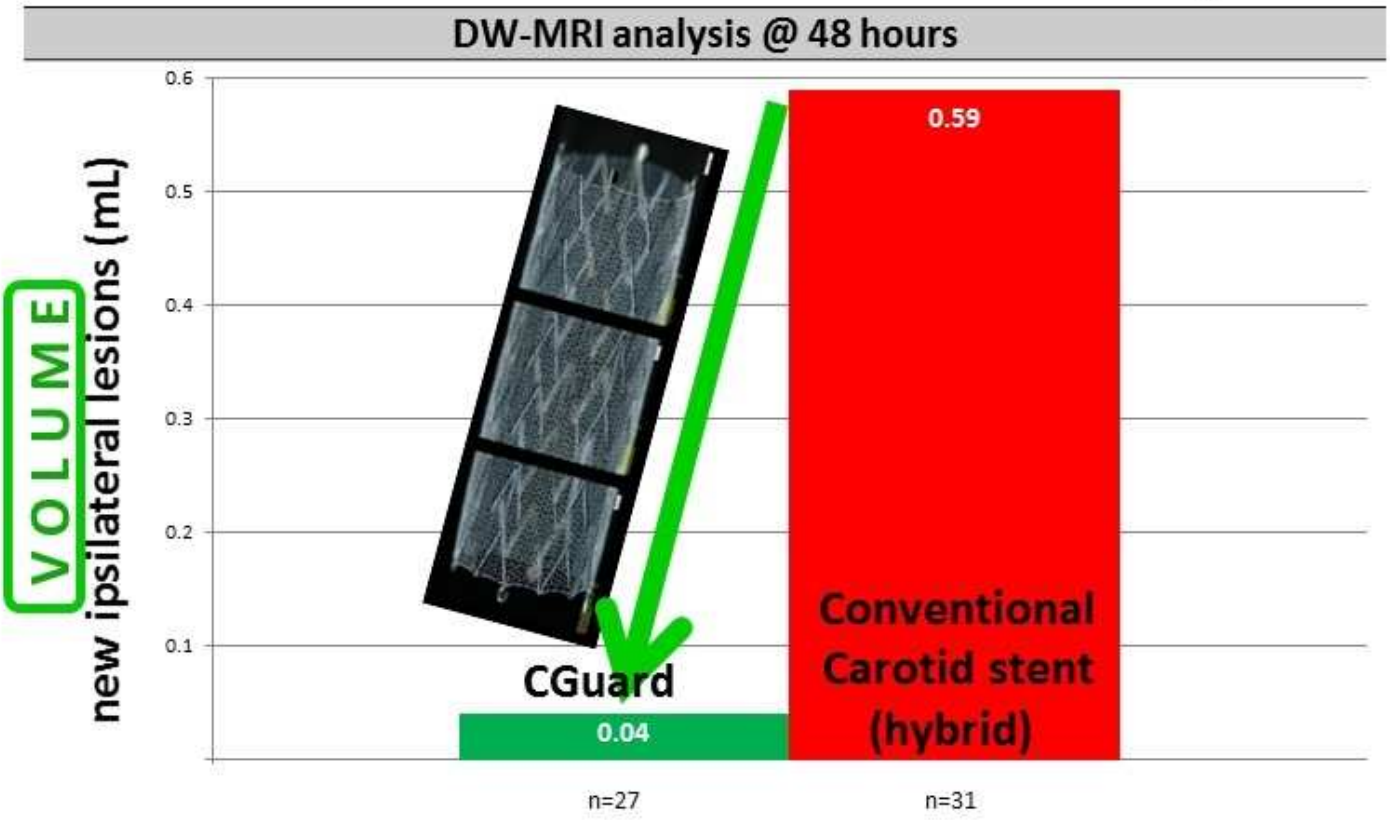

J. Schofer, P. Musialek et al. *JACC Intv* 2015 (in press)
K. Bijuklic et al. *JACC*, 2012;59:1383-9.

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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**

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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.

Methods (cont'd)

PARADIGM: investigator – independent

- **external study data verification**

KCRI
Krakow Cardiovascular Research Institute

- **external angiographic analysis**

Core Imaging Analysis Laboratory
KCRI
Krakow Cardiovascular Research Institute

- **external statistical analysis**

Study Flow Chart (1)

97 carotid stenosis patient **referrals***

(external >> internal)

*Dept. of Cardiac & Vascular Dieases, John Paul II Hospital, Krakow, Poland; 10.2014–03.2015

Study Flow Chart (1)

97 carotid stenosis patient **referrals***

(external >> internal)

Neuro-Vascular Team

- Neurologist
- Interventional Angiologist
- Vascular Surgeon
- Cardiologist

Gupta K et al. A multispecialty consensus-based approach to carotid revascularization. *J Invasive Cardiol*. 2014;26:123-7.
Tomai F et al. Carotid artery revascularization selected by consensus of a cardiovascular team. *EuroIntervention* 2014;9:1294-300.
Kole MK et al. A multidisciplinary carotid revascularization board. *Surg Neurol Int*. 2012;3:117.

*Dept. of Cardiac & Vascular Dieases, John Paul II Hospital, Krakow, Poland; 10.2014–03.2015

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 occluded + h/o prior ipsil. large infarct with hemorrhagic transformation
n = 1: severe haemodynamic instability (ICA stenosis asympt.)

Gupta K et al. A multispecialty consensus-based approach to carotid revascularization. *J Invasive Cardiol*. 2014;26:123-7.
Tomai F et al. Carotid artery revascularization selected by consensus of a cardiovascular team. *EuroIntervention* 2014;9:1294-300.
Kole MK et al. A multidisciplinary carotid revascularization board. *Surg Neurol Int*. 2012;3:117.

*Dept. of Cardiac & Vascular Dieases, John Paul II Hospital, Krakow, Poland; 10.2014–03.2015

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

Study Flow Chart (2)

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- n=1 ICA diameter <2.0 mm + contralat. occlusion

71 ICAs treated endovascularly in 68 patients

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CAROTID PARADIGM REVASCULARIZATION

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)

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)

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

* veriified imaging

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)

PARADIGM: Results (3)

Index lesion quantitative characteristics (n=71 lesions)

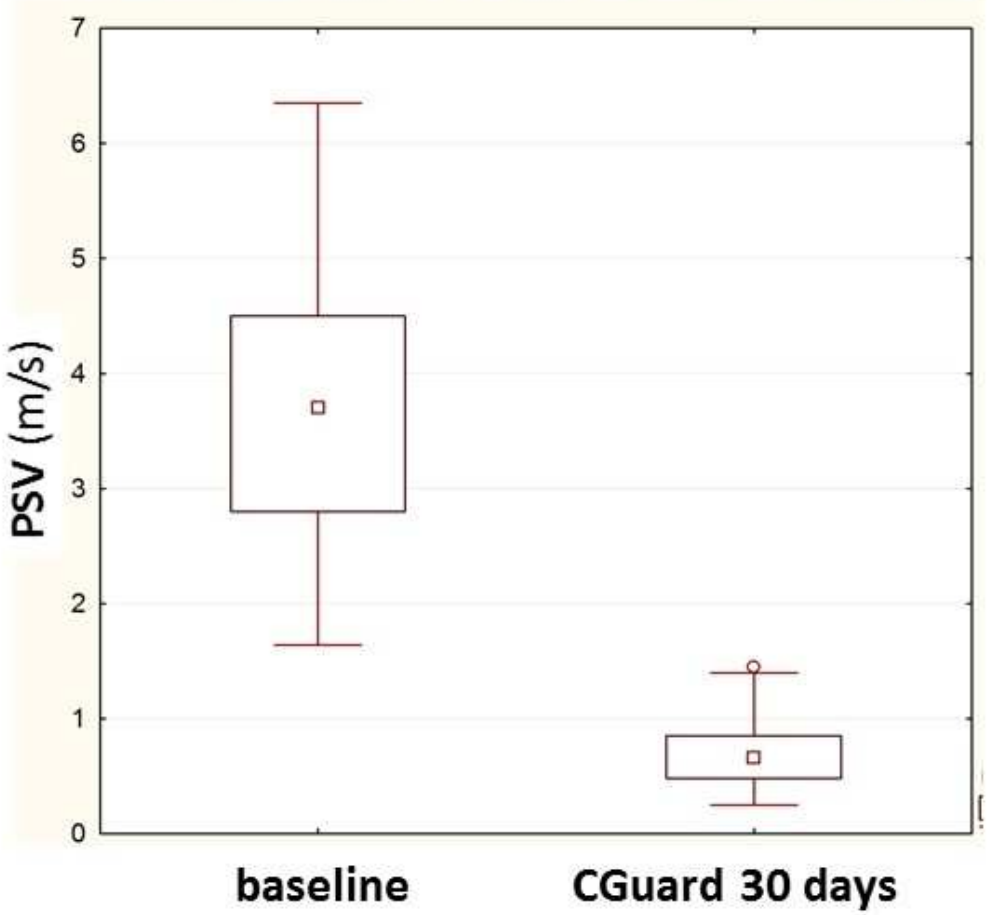
	All (n=71 lesions)	**Symptomatic** n=37	**Asymptomatic** n=34	p
Before CAS				
PSV, m/s	3.8 ± 1.3	3.7 ± 1.1	3.8 ± 1.5	0.862
EDV, m/s	1.3 ± 0.7	1.4 ± 0.6	1.3 ± 0.8	0.687
Diameter stenosis % (QA)	82 ± 9	79 ± 9	84 ± 9	0.021
CAS				
EPD type				0.092
Proximal*	35% (25)	44% (16)	26% (9)	
Distal**	65% (46)	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%**

PARADIGM: Results (5)



PARADIGM: Results (4)

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

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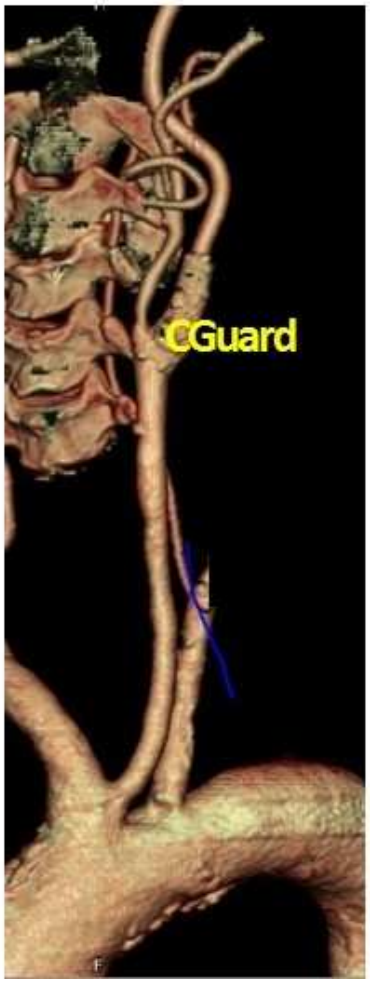
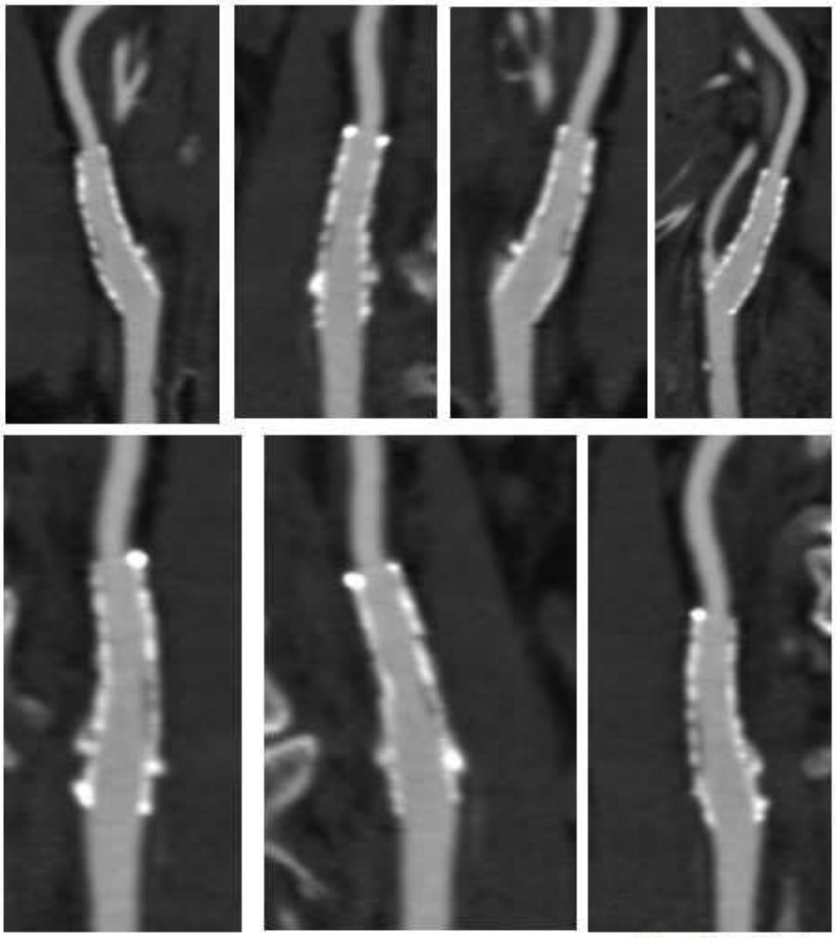
PARADIGM: Conclusions

- >90% all-comer carotid artery stenosis patients, including >50% symptomatic presentations, can be treated endovascularly using the MicroNet-covered embolic prevention stent system CGuard
- endovascular revascularization with routine use of the MicroNet--covered embolic prevention stent system CGuard in an unselected patient polulation is extremely safe
- use of the MicroNet-covered embolic prevention stent system enables '**endovascular reconstruction**' of the diseased carotid artery across a wide lesion spectrum (from extremely tight and thrombotic to highly calcific) in absence of periprocedual clinical complications
- procedural safety of the MicroNet-covered embolic prevention system extends throughtout the stent healing period

CGuard 5 month follow-up





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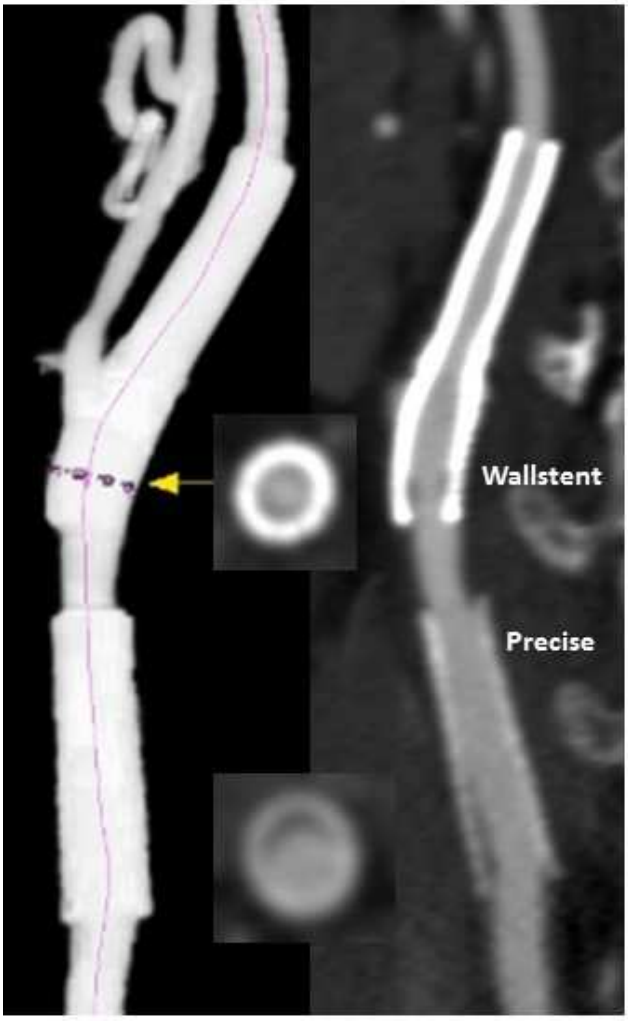
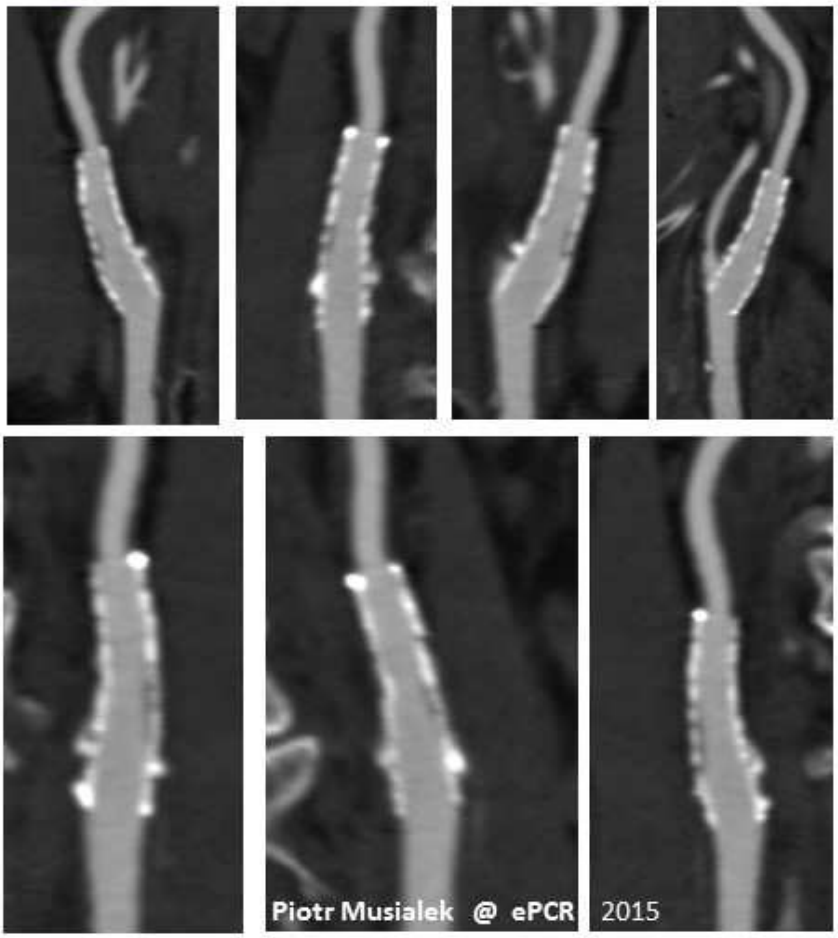
RCCA & RICA



LICA CGuard

@ 5 months



CGuard: Endovascular Solution For All-comers

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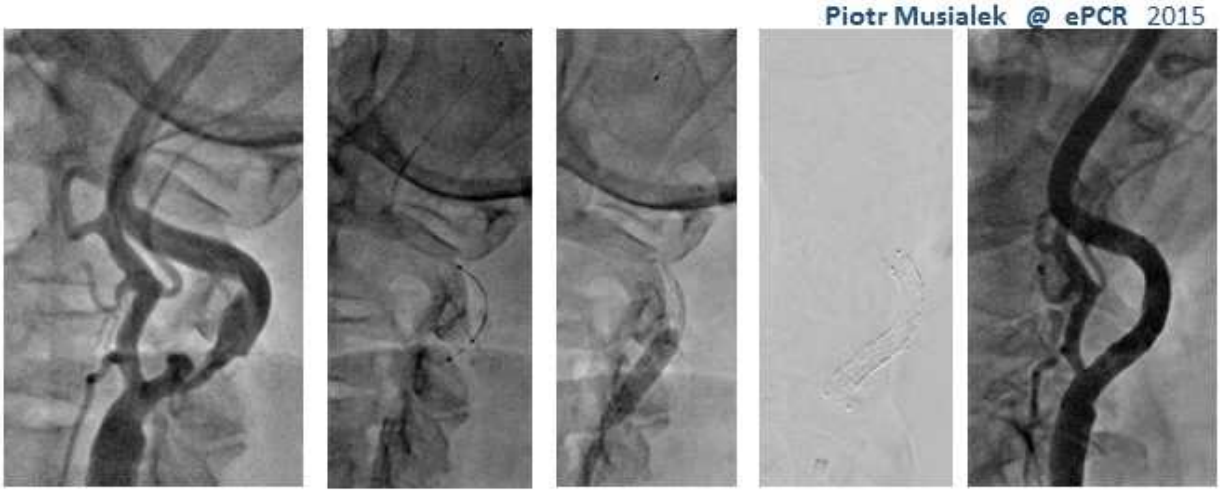
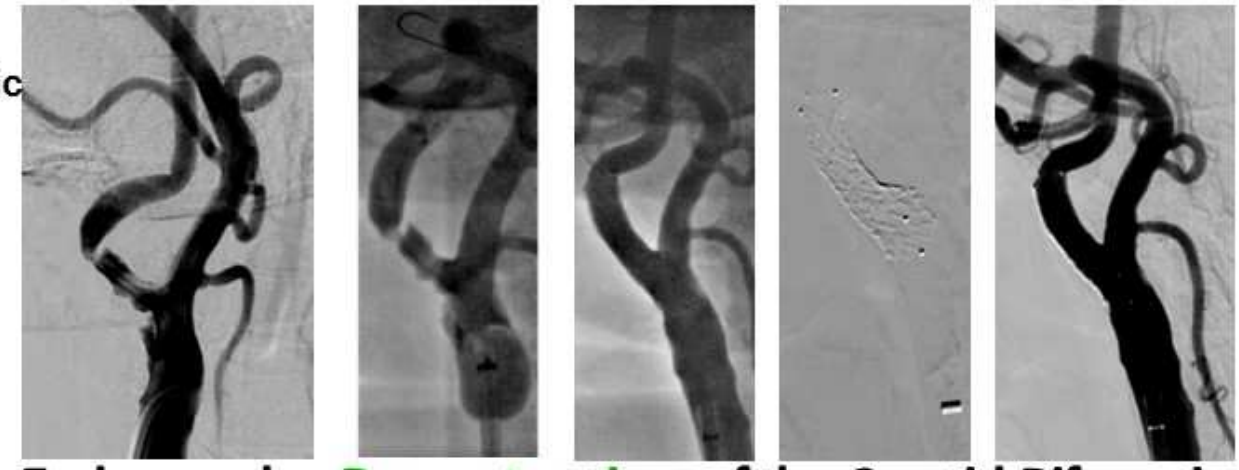
61 yo symptomatic LICA



72 yo asymptomatic RICA



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Endovascular Reconstruction of the Carotid Bifurcation

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

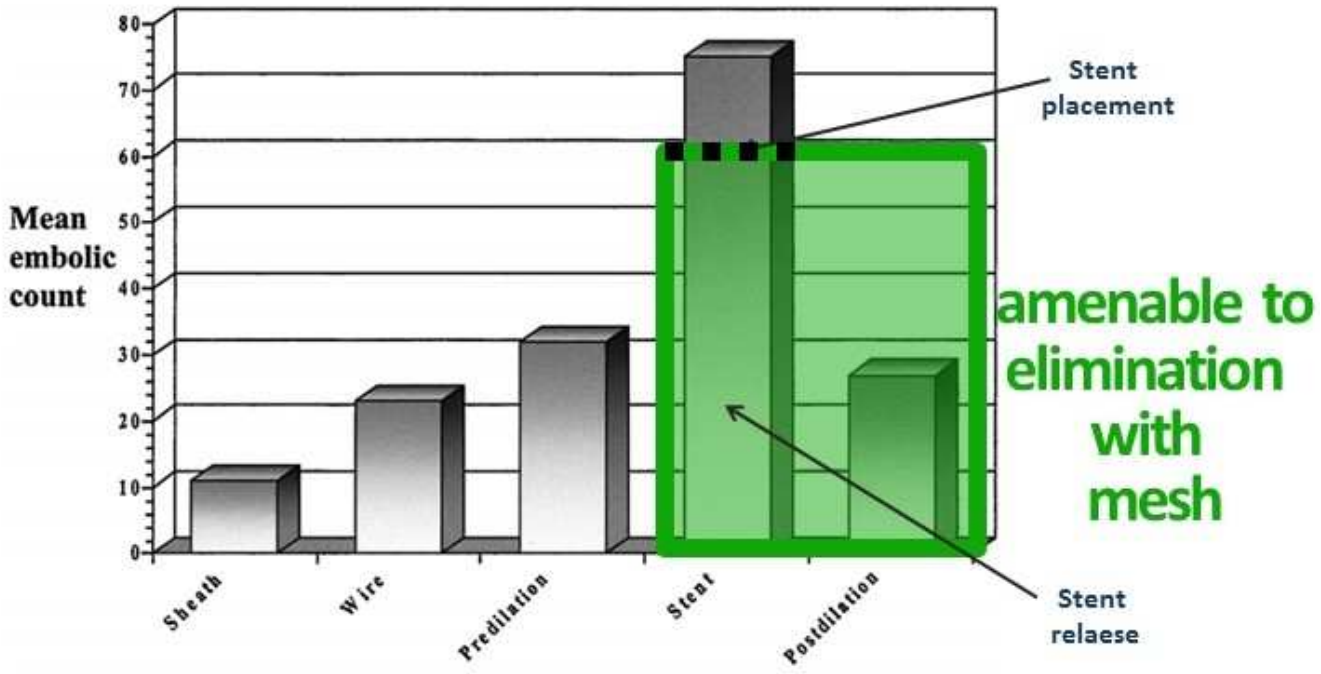

Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed. *Circulation.* 2001;104:1999-2002

P Musialek @ ePCR 2015

CGuard embolic prevention stent system

- Compatible with ALL EPD types √
- Deliverable in hard-access anatomies √
- Optimal visibility √
- Reliable, predictable, and extremely precise placement √
- No indication of foreshortening √
- Radial strength sufficient for v. hard lesions √

Piotr Musialek @ ePCR 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'

Piotr Musialek @ ePCR 2015

InspireMD's CGuard ™ Highlighted at Clinical Presentation at EuroPCR 2015 Conference

PARADIGM Evaluation Reports CGuard ™ Favorable Outcomes
in All-Comer Carotid Disease Population

BOSTON, MA – May 22, 2015 – InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in stent embolic protection systems ("EPS"), today announced that its CGuard ™ Embolic Prevention System reported positive results in PARADIGM, lead by principle investigator Prof. Piotr Musialek, at the EuroPCR conference on May 22, 2015 in Paris, France.

PARADIGM, an investigator-initiated **P** rospective evaluation of **A** ll-comer pe **R** cutaneous c **A** roti **D** revascularization **I** n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C **G** uard™ **M** esh-covered embolic prevention stent system, indicated that the CGuard™ system is appropriate for use in an all-comer carotid revascularization population and is associated with an extremely favorable angiographic and clinical outcome.

Dr. Musialek, commented, "Our experience with CGuard ™ continues to be very positive. Evidence shows the device's applicability for use in an all-comer population with no major adverse cardiac or neurological events (MACNE) during the procedure and at 30 days. We were also pleased with CGuard's anti-embolic performance as well as its flexibility. Impressively, we had a procedure success rate of 100%."

During his clinical presentation from the 71 CGuard procedures in unselected all-comer patients in the PARADIGM evaluation, Prof. Musialek summarized:

- Stent system success and procedure success rate were 100%.
- Periprocedural complications were 0%, and remained at 0% at 30 days.
- No MACNE occurred periprocedurally or at 30 days, by operator-independent neurologist and non-invasive cardiologist evaluation.

Prof. Musialek stated, "The system is unique in that it combines the most closed of the closed cell designs with the most open of the open cell designs," and concludes, "Our experience indicates routine use of CGuard, which we believe presents a significant technological and clinical advancement, may form a new paradigm in carotid revascularization."

Alan Milinazzo, CEO of InspireMD, commented, "We are pleased to see the very positive results from PARADIGM. Together with the other independent clinical studies presented at EuroPCR, it has confirmed confidence in our CGuard ™ Embolic Prevention system." "The customer response to the CGuard has been extremely positive during the conference and today's positive data will further support our expanding commercial activities."

Each year, more than 120 companies from the cardiovascular industry, including device and equipment manufacturers, attend EuroPCR, the leading cardiovascular event in Europe. This event allows attendees to discover new products and R&D projects, as well as interact with practitioners and industry partners to drive continued development and innovation in the cardiovascular field.

For more information about InspireMD and its offerings, visit www.inspiremd.com .

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet ™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard ™), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

Forward-looking Statements:

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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