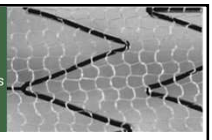
2019 VEITH Vascular Endovascular Issues Techniques Horizons



Update On The CGuard™ MicroNet

Covered Stent For CAS: Longer-Term Results: Advantages And Are There Late Downsides Like ISR Or Late Thrombosis?

Piotr Musialek, MD DPhil

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

Disclosure Statement of Financial Interest

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

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

Conventional Carotid Stents Do Have A Problem

Human carotid artery treated using a conventional stent; OCT

Image courtesy Joan Biela, MD PhD; Perceptual Imaging Lab, University of Barcelona

Post-CAS (minor) Strokes by 30d

ICSS Capture CREST…

P Musialek @ VEITH 2019

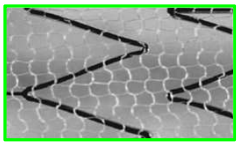
- CEA excludes the plaque

P Musialek @ VEITH 2019

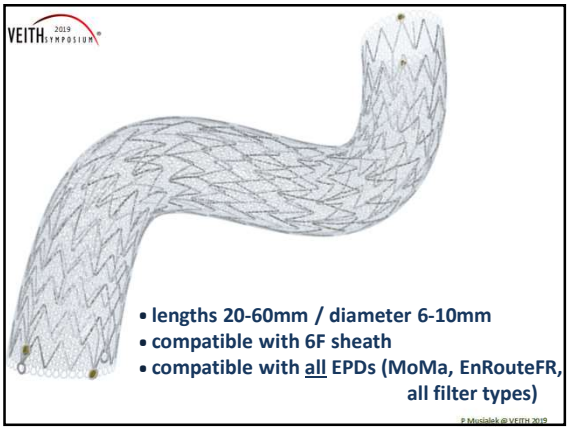
- CEA excludes the plaque
- In CAS, the stent should exclude the plaque too

P Musialek @ VEITH 2019

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



P Musialek @ VEITH 2019



- lengths 20-60mm / diameter 6-10mm
- compatible with 6F sheath
- compatible with all EPDs (MoMa, EnRouteFR, all filter types)

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JACC: CARDIOVASCULAR INTERVENTIONS VOL. 8, NO. 9, 2015
© 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION 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™

Joachim Schofer, MD,* Piotr Musialek, 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.

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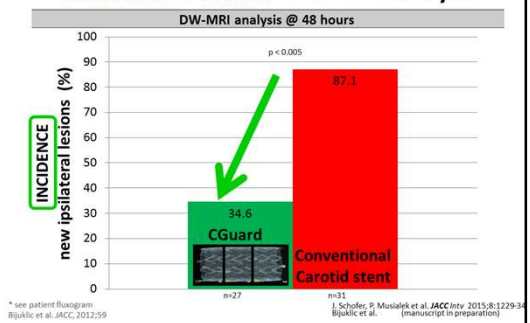
Filter-protected CAS procedures
CARENET vs PROFI: DW-MRI analysis



* 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)

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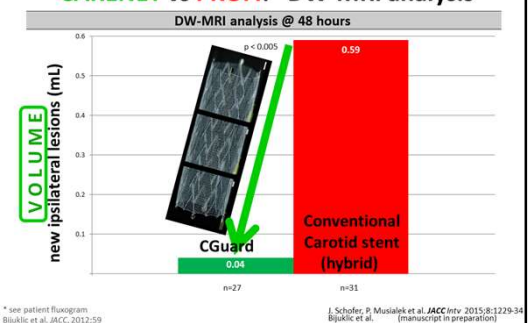
Filter-protected CAS procedures
CARENET vs PROFI: DW-MRI analysis



* 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)

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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

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The CGuard™ MicroNet-Covered Embolic Prevention Stent System

is effective in reducing peri- and post-procedural cerebral embolism

Routine DW-MRI data in CARENET; results reproduced by 2+ other studies

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CGuard™ CAS EVIDENCE

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

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

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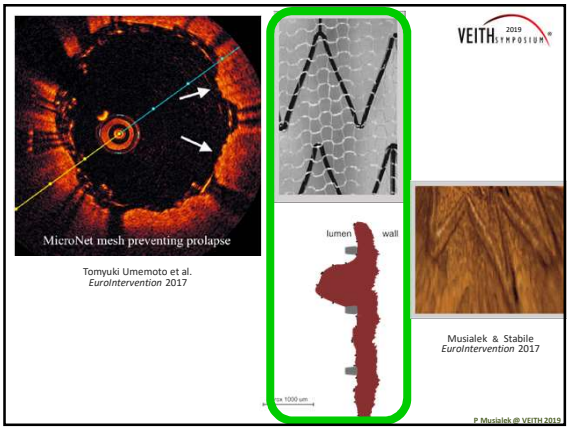
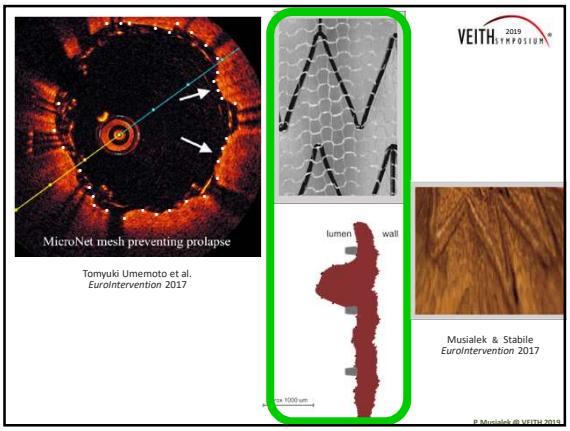


Tomyuki Umemoto et al.
EuroIntervention 2017

Musialek & Stabile
EuroIntervention 2017

P Musialek @ VEITH 2019



Tomyuki Umemoto et al.
EuroIntervention 2017

Musialek & Stabile
EuroIntervention 2017

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VEITH 2019 SYMPOSIUM

clinical

Evidence

15+ studies

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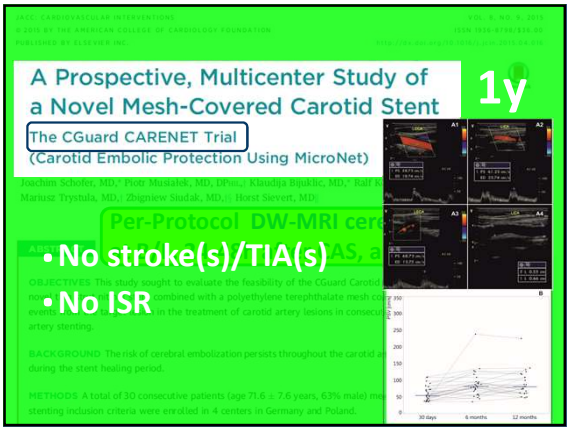


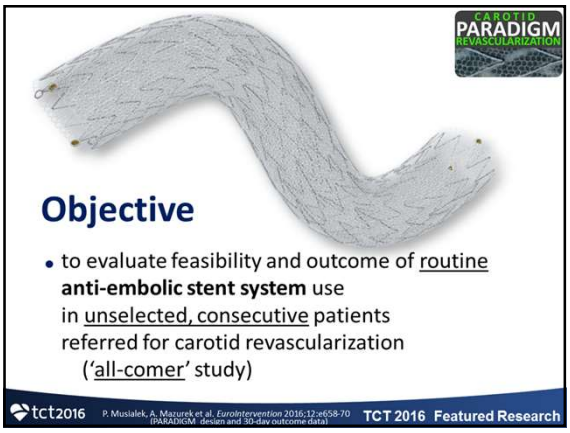
Prospective evaluation of **A**ll-comer pe**R**cutaneous c**A**roti**D** revascularization in sympto-matic and **I**ncreased-risk asymptomatic carotid artery stenosis using the C**G**uard™ **M**icronet-covered embolic prevention stent system

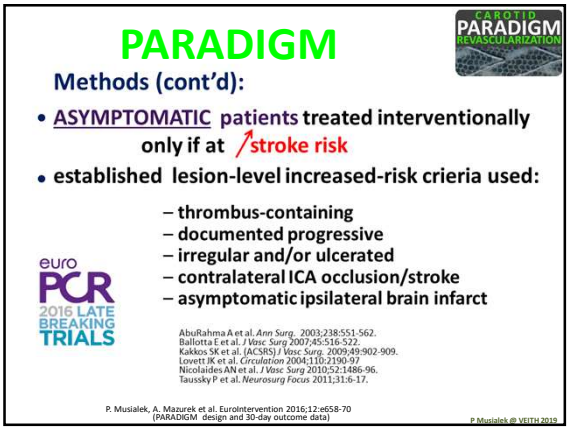
The PARADIGM Study

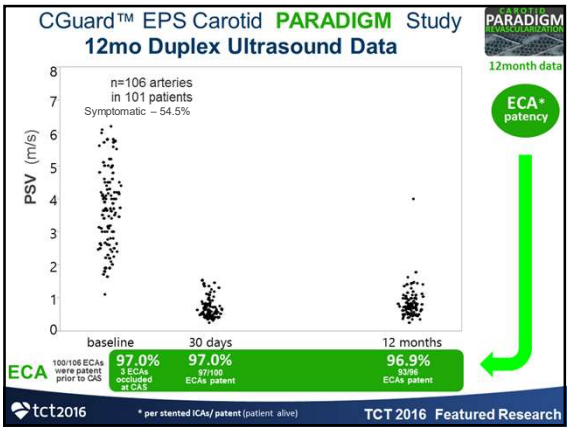
CAROTID PARADIGM REVASCULARIZATION

euro PCR 2016 LATE BREAKING TRIALS

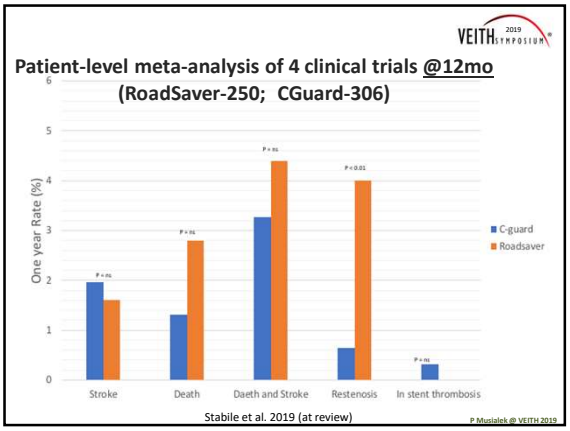
P Musialek @ VEITH 2019

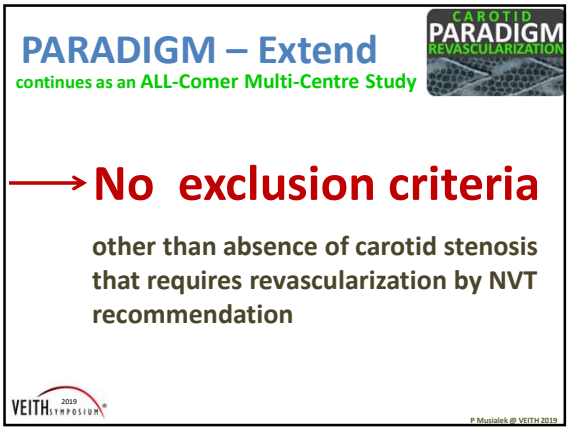

CAROTID PARADIGM REVASCULARIZATION
Objective
• to evaluate feasibility and outcome of routine anti-embolic stent system use in unselected, consecutive patients referred for carotid revascularization ('all-comer' study)
tct2016
P. Musialek, A. Mazurek et al. EuroIntervention 2016;12:e658-70 (PARADIGM design and 30-day outcome data)
TCT 2016 Featured Research

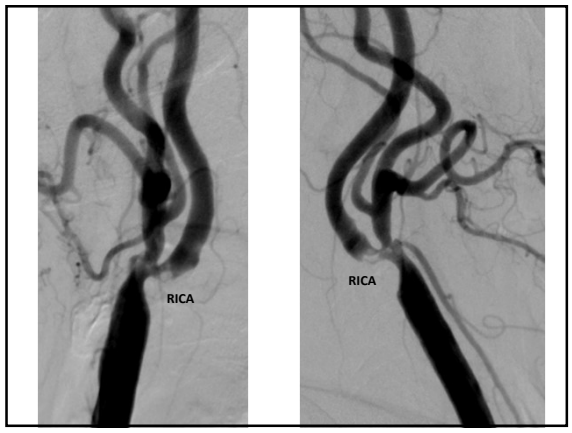

PARADIGM
CAROTID PARADIGM REVASCULARIZATION
Methods (cont'd):
• ASYMPTOMATIC patients treated interventionally only if at stroke risk
• established lesion-level increased-risk crieria used:
– thrombus-containing
– documented progressive
– irregular and/or ulcerated
– contralateral ICA occlusion/stroke
– asymptomatic ipsilateral brain infarct
euro PCR 2016 LATE BREAKING TRIALS
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.
P. Musialek, A. Mazurek et al. EuroIntervention 2016;12:e658-70 (PARADIGM design and 30-day outcome data)
P Musialek @ VEITH 2019

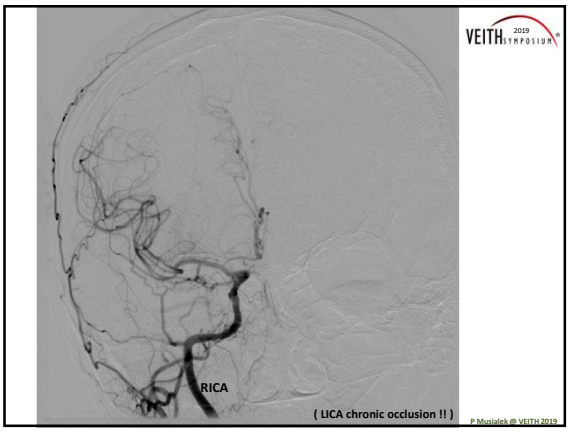

CGuard™ EPS Carotid PARADIGM Study
12mo Duplex Ultrasound Data
CAROTID PARADIGM REVASCULARIZATION
12month data
ECA* patency
n=106 arteries in 101 patients
Symptomatic – 54.5%
PSV (m/s)
baseline
30 days
12 months
ECA
100/106 ECAs were patent prior to CAS
97.0%
3 ECAs occluded at CAS
97.0%
97/100 ECAs patent
96.9%
93/96 ECAs patent
tct2016
* per stented ICAs/ patent (patient alive)
TCT 2016 Featured Research

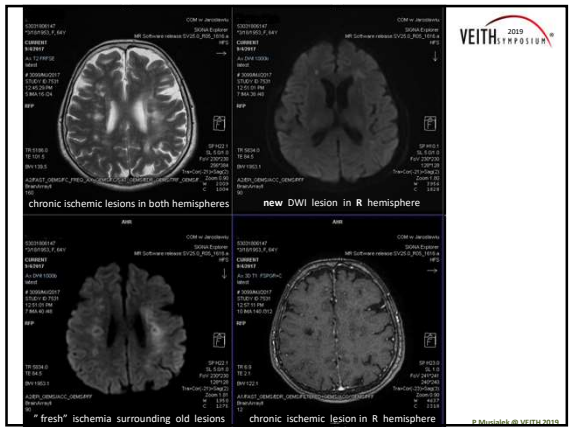

CGuard: Normal Healing Profile
VEITH 2019 SYMPOSIUM
CGuard
P Musialek @ VEITH 2019

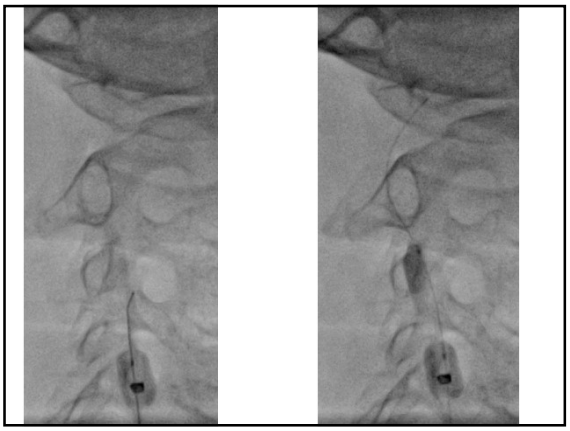

VEITH 2019 SYMPOSIUM
Patient-level meta-analysis of 4 clinical trials @12mo
(RoadSaver-250; CGuard-306)
One year Rate (%)
C-guard
Roadsaver
Stroke
Death
Daeth and Stroke
Restenosis
In stent thrombosis
Stabile et al. 2019 (at review)
P Musialek @ VEITH 2019

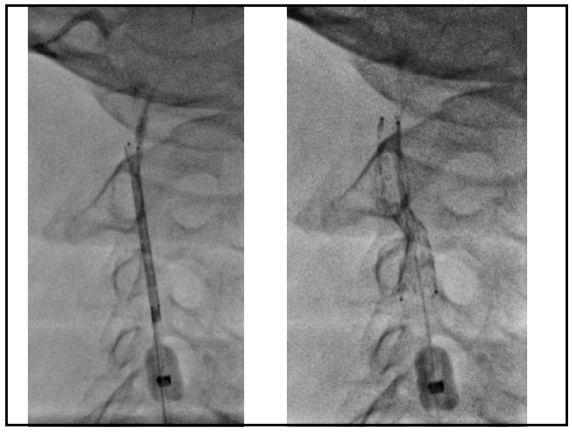

PARADIGM – Extend
continues as an ALL-Comer Multi-Centre Study
CAROTID PARADIGM REVASCULARIZATION
No exclusion criteria
other than absence of carotid stenosis that requires revascularization by NVT recommendation
VEITH 2019 SYMPOSIUM
P Musialek @ VEITH 2019

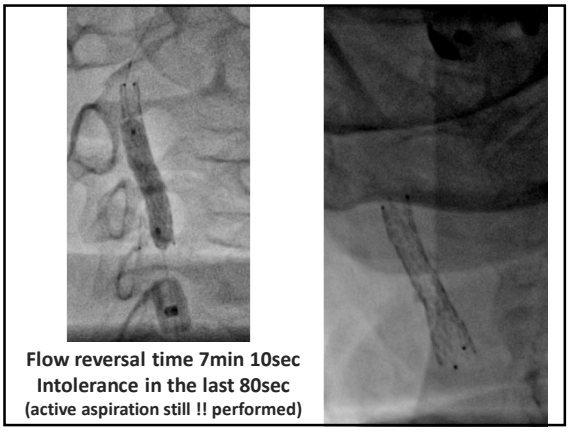

RICA
RICA


VEITH 2019 SYMPOSIUM
RICA
(LICA chronic occlusion !!)
P Musialek @ VEITH 2019

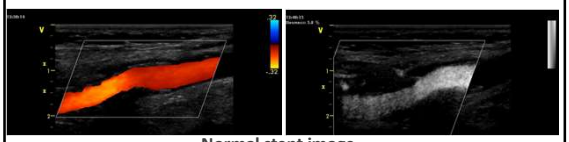

VEITH 2019 SYMPOSIUM
chronic ischemic lesions in both hemispheres
new DWI lesion in R hemisphere
" fresh" ischemia surrounding old lesions
chronic ischemic lesion in R hemisphere
P Musialek @ VEITH 2019



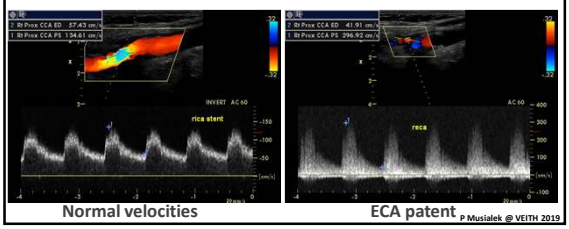



Flow reversal time 7min 10sec
Intolerance in the last 80sec
(active aspiration still !! performed)

Patient A/S, discharged home, unremarkable follow-up



Normal stent image



Normal velocities ECA patent

Appropriate Procedural Heparinization & DAPT, and Optimal Device Implantation: The fundaments for normal healing and optimal long-term result

With any CAS procedure[1] (similar to any coronary stenting procedure), rigorous double antiplatelet therapy (DAPT) plus rigorous heparinization under the activated clotting time (ACT) control are essential to prevent ST (see study by Musialek et al[2] and Nicosia et al[3] for literature on CAS-required classic pharmacotherapy). In case DAPT is not administered as a pretreatment (note that DAPT pretreating is understandably unfeasible in AIS), loading doses of 2 antiplatelet drugs need to be given not later than during the CAS procedure to prevent ST[4]. Consistent with CAS routine requirements, the CGuard instructions for use (IFU) state "WARNING: Administer heparin dose sufficient to maintain ACT >250 sec to prevent thrombus formation on the devices" and "Patients should be put on an appropriate regimen of antiplatelets."

Care should be taken to conform intravascular devices IFU's, including periprocedural anticoagulation.

Following De Vries et al[1] report, we reviewed, for the UFH doses, our procedural records of the last 250 CGuard implantations in our centers. These show that in only 30.4% patients our initial UFH dose of 100 IU/kg was sufficient to achieve the the CGuard IFU-mandated ACT of >250 second, prompting, in the remaining majority, heparin next dose(s) of median 3000 IU. Thus, our total ACT-guided UFH dose was (median) 10000 IU (range 6000–19000 IU; note the presence of heparin-resistant patients that may particularly require ACT-adjusted heparinization).

Mazurek A, Bugurov S, Musialek P.
Stroke. 2019 Nov 4:STROKEAHA119027176. doi: 10.1161/STROKEAHA.119.027176. [Epub ahead of print]

VEITH 2019 SYMPOSIUM

Serruys PW, Di Mario C. Who was thrombogenic: the stent or the doc-

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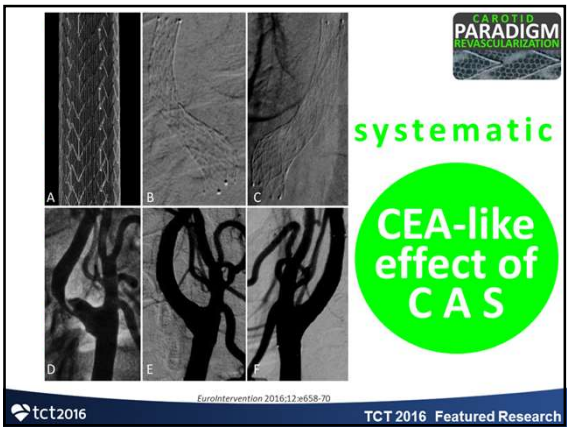


PARADIGM – Extend

continues as an ALL-Comer Multi-Centre Study

- 402 patients / 436 arteries
  NeuroVascular Team decision-making on endovascular revascularization
- Age 48-87 years, 56.4% symptomatic
- Crossed the trial first follow-up window (30d)
- 100% CGuardEPS use, Proximal/distal EPD ≈ 50% : 50%
- Angiographic diameter stenosis was reduced from 84±8% to only 6.9±5% (p<0.001, 'CEA-like' effect of CAS)

VEITH 2019 SYMPOSIUM

P Musialek @ VEITH 2019

PARADIGM – Extend

continues as an ALL-Comer Multi-Centre Study

402 patients / 436 arteries

- *Peri-procedural outcome*

  0 death/major stroke – 0%
  1 minor stroke – 0.25%
  1 MI (type2) **– 0.25%**

- *By 30 days*

  1 haemorrhagic transformation of prior ischaemic cerebral infarct leading to **death – 0.25%**

  1 bleeding-related death – 0.25%

VEITH 2019 SYMPOSIUM

P Musialek @ VEITH 2019

PARADIGM – Extend

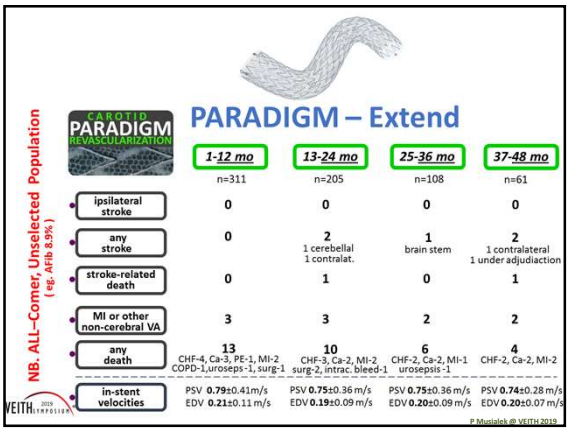
continues as an ALL-Comer Multi-Centre Study

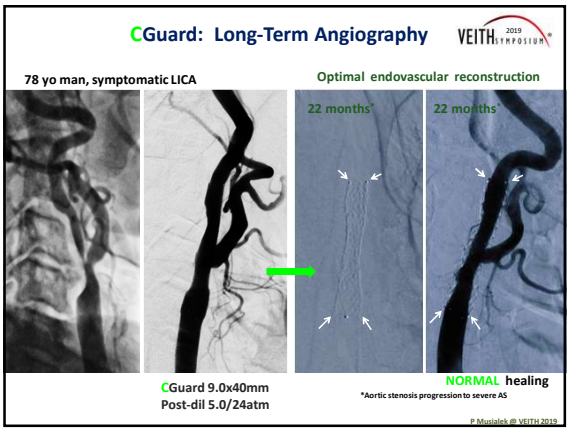
402 patients / 436 arteries

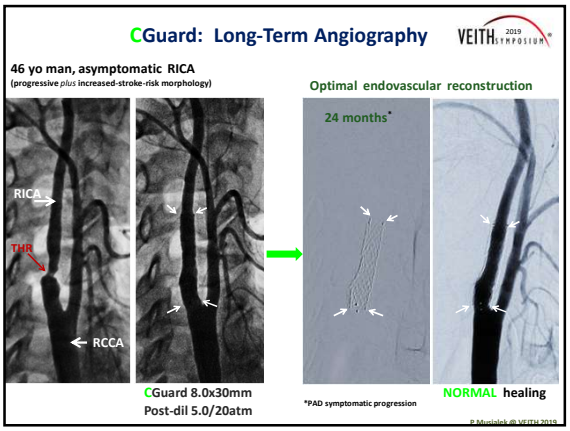
- **Total**
  30-day death/MI/any stroke **– 0.995 %** (4/402)
- **no post-proc. ischaemic stroke by 30 days – 0.0 %** (0/402)
- *Then clinical (inc. Neurology exam) and Duplex follow-up every 12 months*

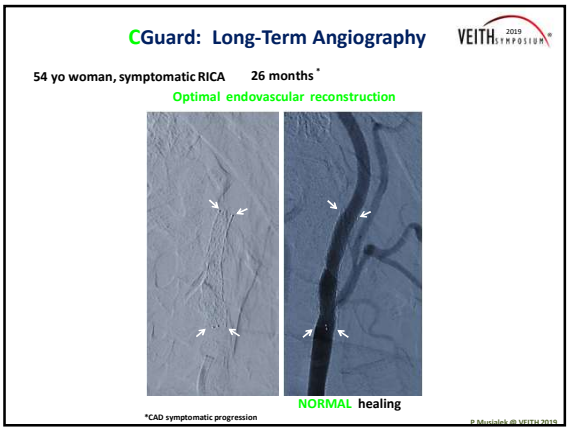
VEITH 2019 SYMPOSIUM

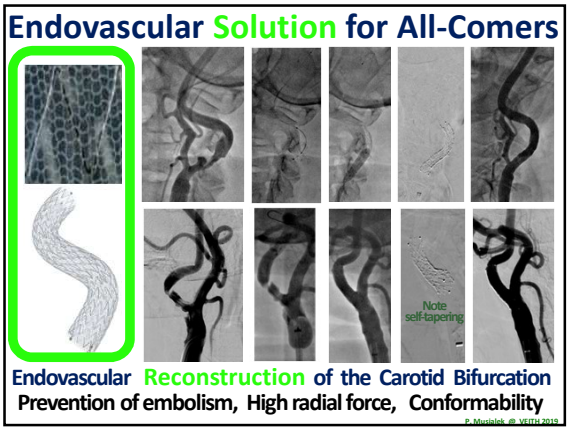
P Musialek @ VEITH 2019


PARADIGM – Extend
CAROTID PARADIGM REVASCULARIZATION
NB. ALL–Comer, Unselected Population (eg. Afib 8.9%)
1-12 mo
13-24 mo
25-36 mo
37-48 mo
n=311
n=205
n=108
n=61
ipsilateral stroke
any stroke
stroke-related death
MI or other non-cerebral VA
any death
in-stent velocities
0
0
0
0
0
2
1 cerebellal
1 contralat.
1
brain stem
2
1 contralateral
1 under adjudiaction
0
1
0
1
3
3
2
2
13
CHF-4, Ca-3, PE-1, MI-2
COPD-1,uroseps-1, surg-1
10
CHF-3, Ca-2, MI-2
surg-2, intrac. bleed-1
6
CHF-2, Ca-2, MI-1
urosepsis-1
4
CHF-2, Ca-2, MI-2
PSV 0.79±0.41m/s
EDV 0.21±0.11 m/s
PSV 0.75±0.36 m/s
EDV 0.19±0.09 m/s
PSV 0.75±0.36 m/s
EDV 0.20±0.09 m/s
PSV 0.74±0.28 m/s
EDV 0.20±0.07 m/s
P Musialek @ VEITH 2019


CGuard: Long-Term Angiography
VEITH 2019 SYMPOSIUM
78 yo man, symptomatic LICA
Optimal endovascular reconstruction
22 months*
22 months*
CGuard 9.0x40mm
Post-dil 5.0/24atm
NORMAL healing
*Aortic stenosis progression to severe AS
P Musialek @ VEITH 2019


CGuard: Long-Term Angiography
VEITH 2019 SYMPOSIUM
46 yo man, asymptomatic RICA
(progressive plus increased-stroke-risk morphology)
Optimal endovascular reconstruction
RICA
THR
RCCA
24 months*
CGuard 8.0x30mm
Post-dil 5.0/20atm
NORMAL healing
*PAD symptomatic progression
P Musialek @ VEITH 2019


CGuard: Long-Term Angiography
VEITH 2019 SYMPOSIUM
54 yo woman, symptomatic RICA
26 months *
Optimal endovascular reconstruction
NORMAL healing
*CAD symptomatic progression
P Musialek @ VEITH 2019


Endovascular Solution for All-Comers
Note self-tapering
Endovascular Reconstruction of the Carotid Bifurcation
Prevention of embolism, High radial force, Conformability
P. Musialek @ VEITH 2019


PARADIGM – Extend
Normal healing
No Stent Thrombosis
No abnormal ISR signal

CGUARD™
Carotid Embolic Prevention System

PARADIGM

PARADIGM–EXT.

@ 48 months

Favourable Cerebral Outcome

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

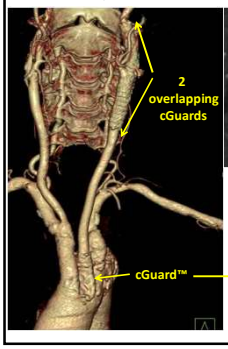
sustained stroke prevention

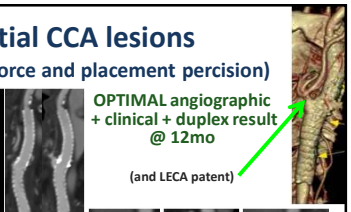
P Musialek @ VEITH 2019

VEITH 2019 SYMPOSIUM

Ostial CCA lesions

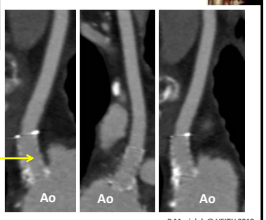
(note adequate radial force and placement percision)





OPTIMAL angiographic
+ clinical + duplex result
@ 12mo

(and LECA patent)



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Acknowledgements

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R. Paweł Banyś
Anna Borratyńska
Mateusz Brózda
Andrzej Brzychczy
Władysław Dąbrowski
Natalia Dłużniewska
Tomasz Drążkiewicz
Urszula Gancarczyk
Paulina Judziało
Marek Kazibudzki
Artur Klecha
Klaudia Knap
Artur Kozanecki
Agata Leśniak-Sobelga
Adam Mazurek
Jarosław Miszczuk
Marcin Misztal
Zbigniew Moczulski
Piotr Paluszek
Łukasz Partyka
Piotr Pieniążek
Piotr Podolec
Grażyna Stankiewicz
Tomasz Tomaszewski
Mariusz Trystuła
Małgorzata Urbańczyk
Piotr Wilkołek
Agnieszka Zwolińska

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Double-Layer Carotid Stents: From the Clinical Need, through a Stent-in-Stent Strategy, to Effective Plaque Isolation… the Journey Toward Safe Carotid Revascularization Using the Endovascular Route

Journal of Endovascular Therapy
2019, Vol. 26(4) 572–577
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DOI: 10.1177/1526602819861566
www.uvm.org
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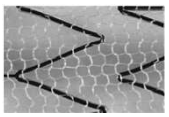
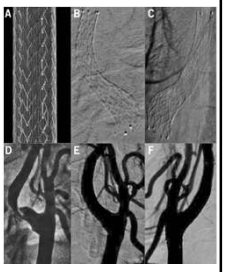
Keywords
carotid artery stenosis, carotid artery stenting, carotid endarterectomy, closed-cell stent, MicroNET, open-cell stent, plaque protrusion, stent-graft, restenosis, double-layer stent, unstable plaque

Both surgical and endovascular routes of carotid revascularization are associated with the risk of symptomatic and asymptomatic cerebral embolism.[1,2] Optimized pharmacotherapy, the mainstay of atherosclerosis management, can reduce or delay but not abolish the risk of stroke from atherosclerotic carotid artery stenosis.[3,4] Interventional elimination or sequestration of the thromboembolic carotid plaque[5,6] remains an important consideration in a significant proportion of patients if carotid-stenosis-related strokes are to be prevented rather than experienced. This is the focus and the stent free-cell area also affect the risk of embolism after stent placement. Thus, while optimized neuroprotection during CAS may minimize intraprocedural cerebral embolism,[8,10,11,9] the problem of early or delayed post-procedural embolism remains.[12–15] With optimal patient selection technique and antiplatelet therapy, post-stent embolic phenomena are largely related to intrastent plaque prolapse, balloon trauma, and subsequent embolization. This may occur after the period of intraprocedural cerebral protection using flow reversal techniques and/or filters.





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