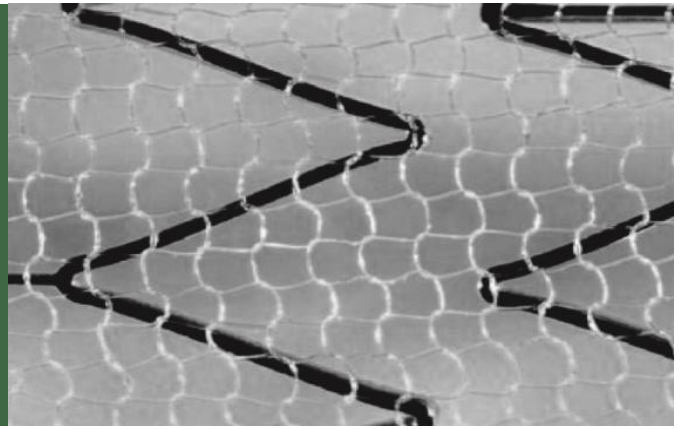
2018

VEITH

VASCULAR ENDOVASCULAR ISSUES TECHNIQUES HORIZONS



Update On Results With The CGuard™ MicroNet Covered Stent (InspireMD) For CAS: Does It Prevent Strokes: Does It Cause ISR Or Other Long-Term Problems: Can It Have Value In Other Vascular Beds?

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Disclosure Statement of Financial Interest

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

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

OPINIONS
matter

(ASSUMPTIONS – less so)

HYPOTHESES

may be interesting

but what **is critical** to the decision-making Physician…

are

FACTS

FACT #1

2018 VEITH Vascular Endovascular Issues Techniques Horizons

ZERO evidence
that OMT is sufficient to prevent strokes

FACT #1

2018 VEITH Vascular Endovascular Issues Techniques Horizons

ZERO evidence
that OMT is sufficient to prevent strokes

We CONTINUE
to receive patients with SYMPTOMS (incl. Strokes) DESIPTE OMT

FACT #2

Assumptions are not powered to dismiss

Large-scale level 1 evidence (ACST, >3100 pts)

”Systematic Review and Analysis”…

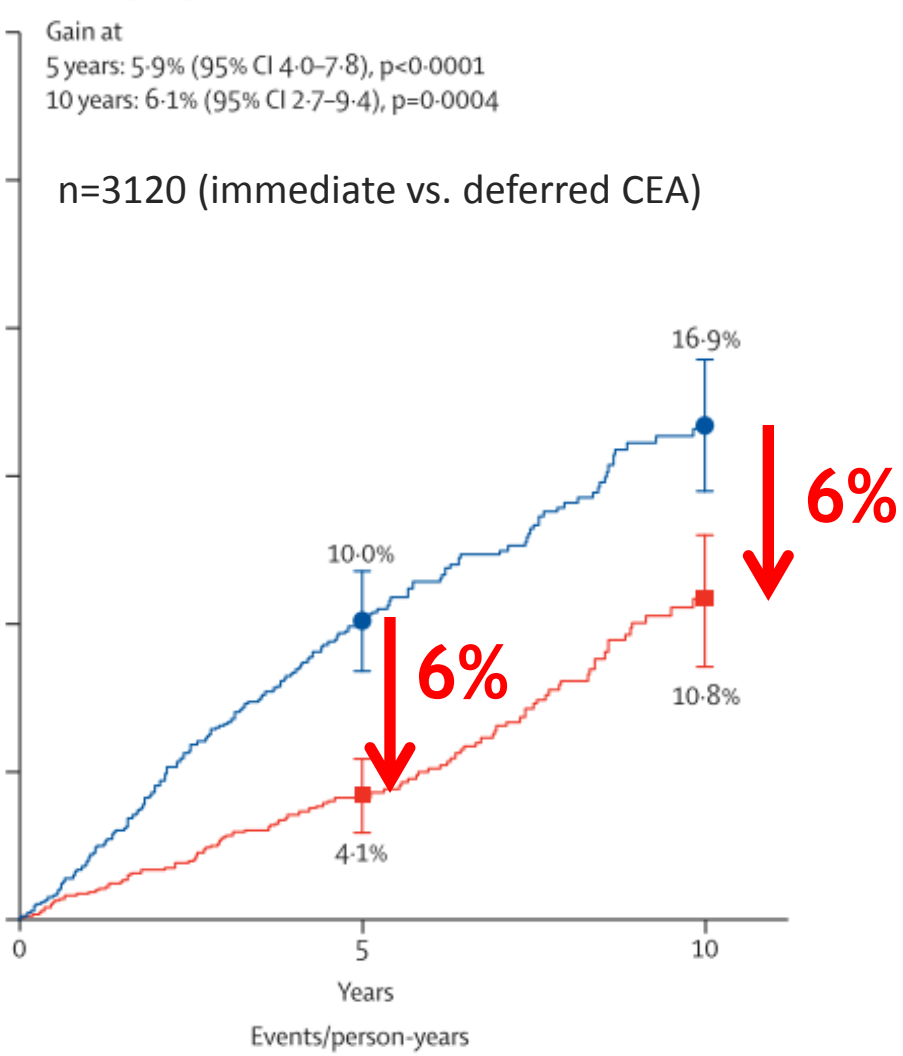
where is ACST ? (n=3120)

Table 1. Average Annual Stroke +/−TIA Rates of Patients With Asymptomatic Severe (>50%) Carotid Stenosis Managed With Medical Intervention Alone (%)*

		Ipsilateral Stroke		Ipsilateral Stroke/TIA		Any Territory Stroke		Any Territory Stroke/TIA	
Study	Sample Size	Raw Data	KM Estimates	Raw Data	KM Estimates	Raw Data	KM Estimates	Raw Data	KM Estimates
Johnson, 1985[76]	121	3.3	. . .	19.0	. . .	. . .	. . .	. . .	. . .
Toronto, 1986[2]	113	0	. . .	7.9 (all TIA)	. . .	1.9	. . .	10.7	11.0
VACS, 1993[10]	233	2.4	. . .	5.2	. . .	3.0	. . .	6.1	. . .
ACAS, 1995[11]	834	2.3	2.2	4.5	3.8	3.8	3.5	. . .	. . .
ECST, 1995[77]	127	2.3	1.9	. . .	. . .	. . .	. . .	. . .	. . .
ACBS, 1997[78]	357	1.2	1.4	3.4	4.2	2.1	2.5	5.8	. . .
CHS, 1998[82]	185	1.3	1.0	. . .	. . .	2.6	2.3	. . .	. . .
NASCET, 2000[3]	216	. . .	3.2	. . .	. . .	. . .	. . .	. . .	. . .
ACSRS, 2005[79]	1115	1.3	1.7	3.1	3.4	. . .	2.1	. . .	4.1
ASED, 2005[80]	202	1.2	1.0	3.2	3.1	2.4	2.2	5.6	5.1
SMART, 2007[81]	221	0.6	. . .	. . .	. . .	0.7	. . .	. . .	. . .

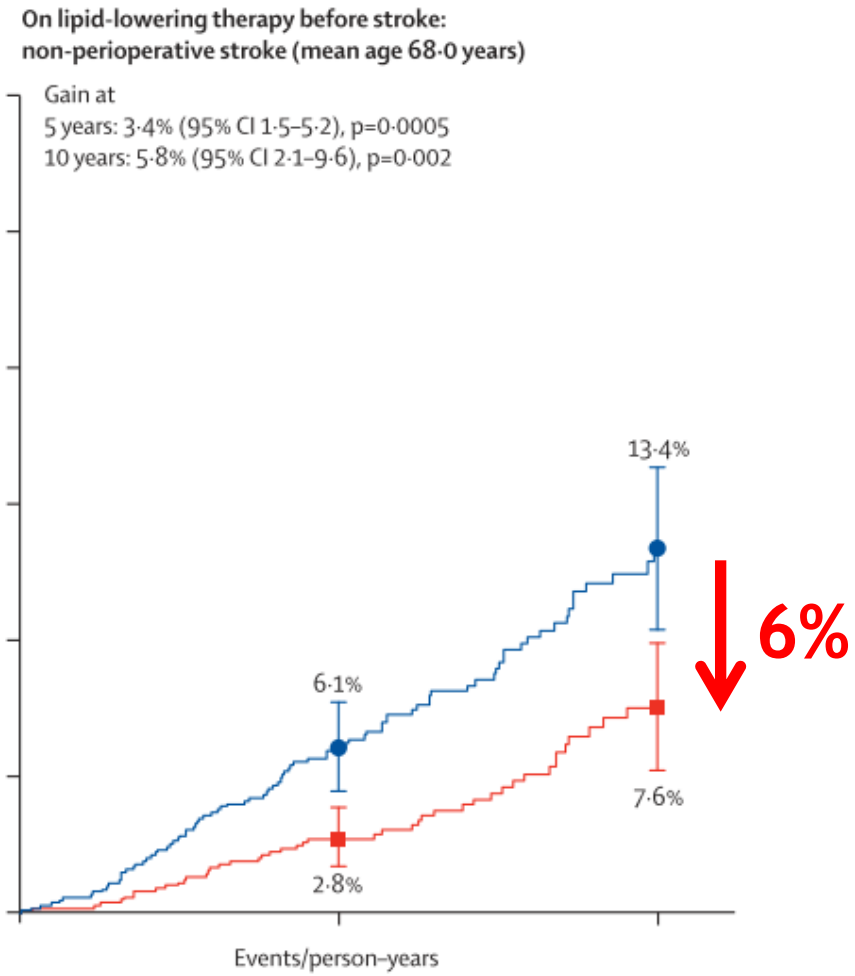
*ACAS indicates Asymptomatic Carotid Atherosclerosis Study; ECST, European Carotid Surgery Trial; ACBS, Asymptomatic Cervical Bruit Study; NASCET, North American Symptomatic Carotid Endarterectomy Trial; ACSRS, Asymptomatic Carotid Stenosis and Risk of Stroke Study; ASED, Asymptomatic Stenosis Embolus Detection Study; SMART, Second Manifestations of ARTerial disease Study.

Stroke reduction with carotid stenosis revascularization



A. Halliday et al. (10-year ACST data) *Lancet* 2010

Stroke reduction with carotid stenosis revascularization in patients on lipid-lowering Tx



A. Halliday et al. (10-year ACST data) *Lancet* 2010

FACT #2

Assumptions are not powered to dismiss Large-scale level 1 evidence (ACST, >3100 pts)

If someone wants to dismiss it, they need to show new (different) level 1 evidence!

FACT #3

Conventional Carotid Stents Do Have A Problem

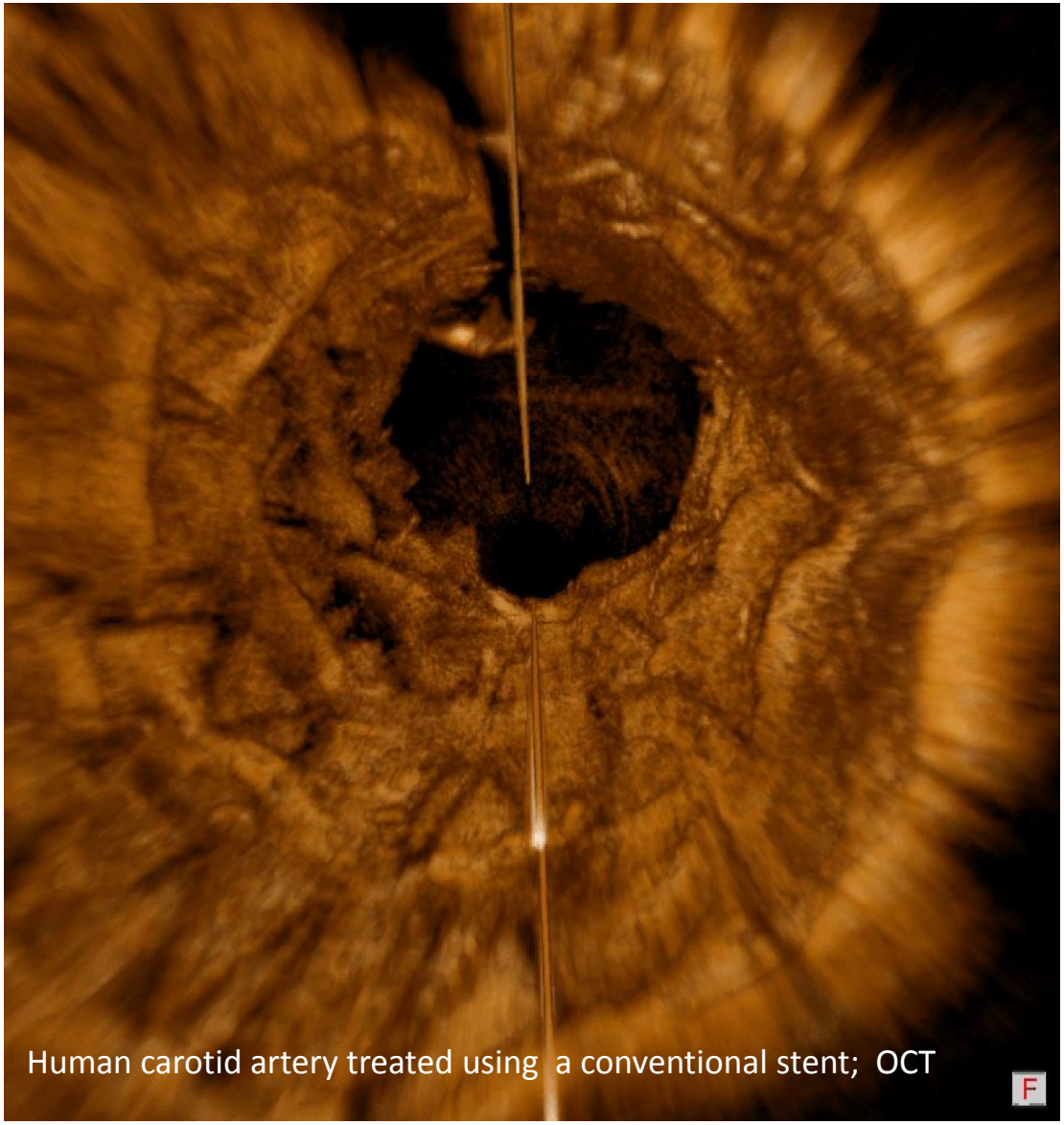


Image courtesy Joan Rigla, MD PhD; Perceptual Imaging Lab, Univerity of Barcelona

FACT #4

- CEA excludes the plaque

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- In CAS, the stent should exclude the plaque too

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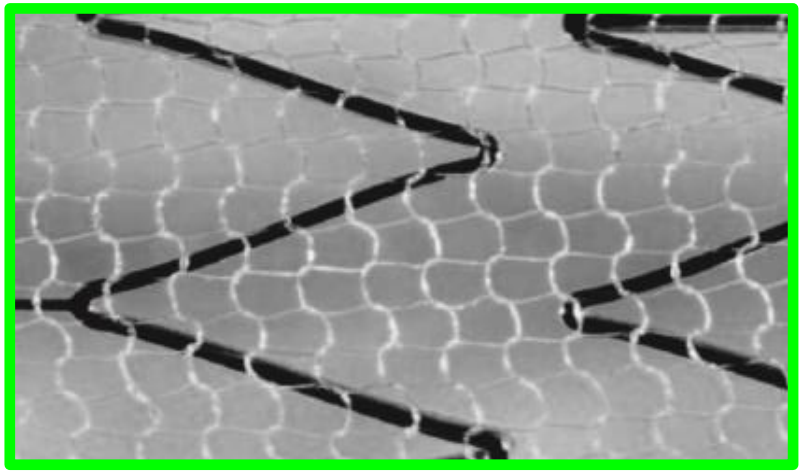
- In CAS, the stent should exclude the plaque too



FACT #5

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)

JACC: CARDIOVASCULAR INTERVENTIONS
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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 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.

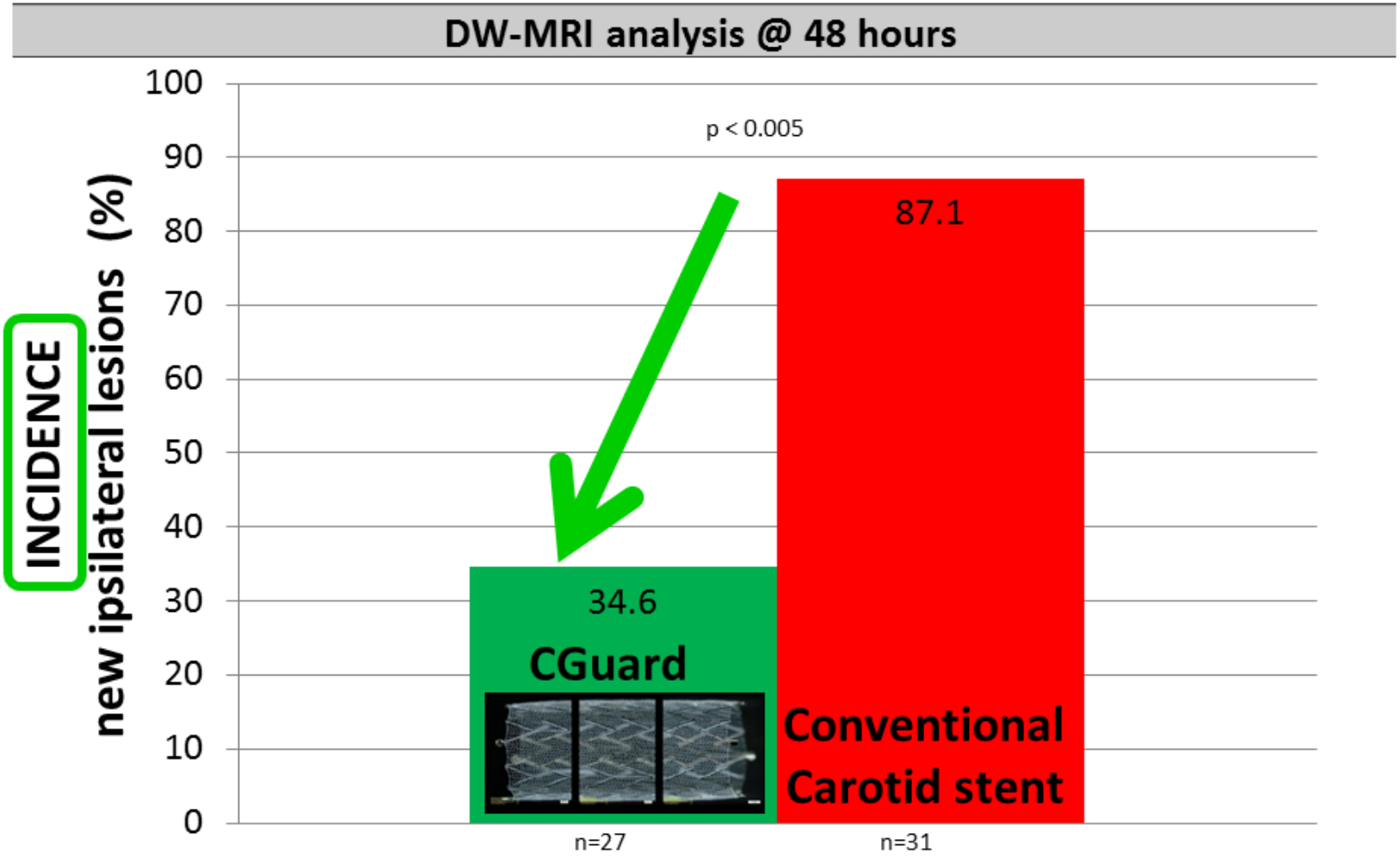
BACKGROUND The risk of cerebral embolization persists throughout the carotid artery stenting procedure and remains during the stent healing period.

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.

P Musialek @ VEITH 2017

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

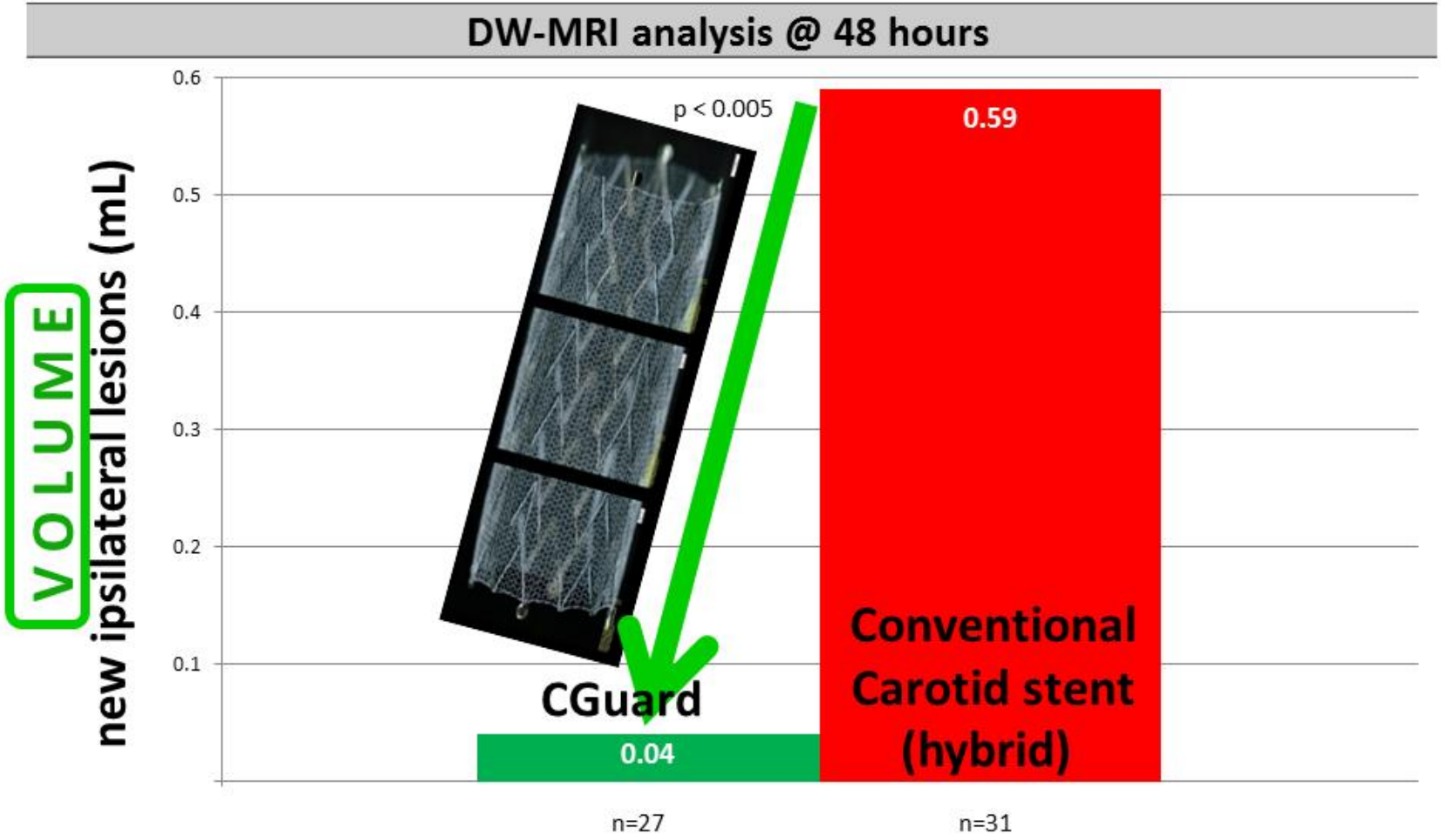


* see patient fluxogram
Bijuklic et al. *JACC*, 2012;59

J. Schofer, P. Musialek et al. ***JACC** Intv* 2015;8:1229-34
Bijuklic et al. (manuscript in preparation)

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis



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CARENET DW-MRI analysis*

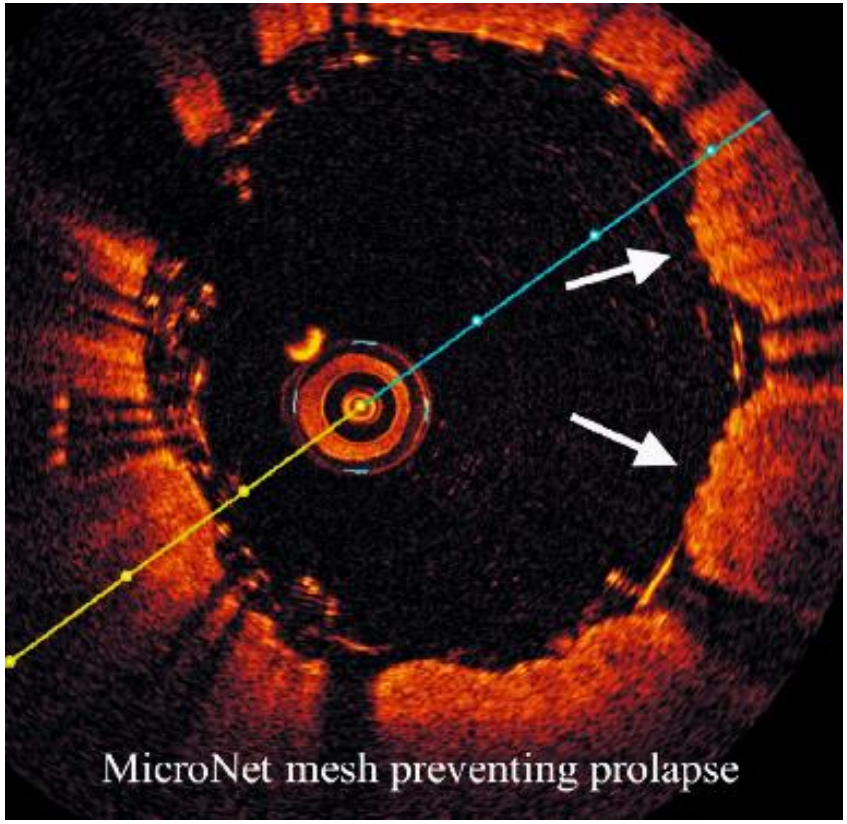
All but one peri-procedural ipsilateral lesions

RESOLVED

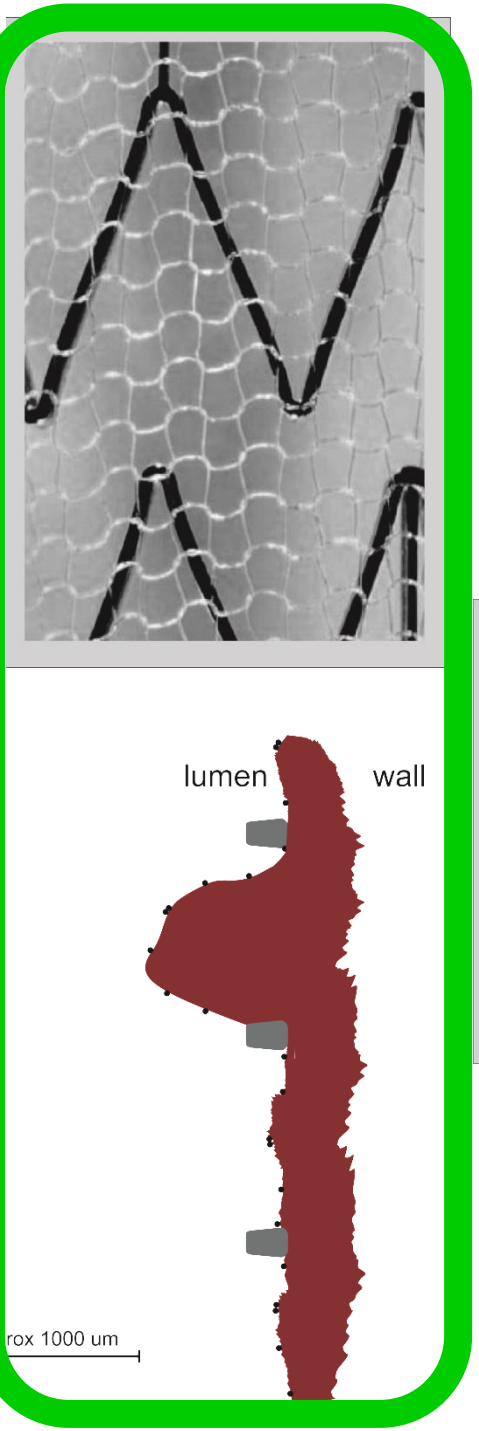
DW-MRI analysis @ 30 days*	
Incidence of new ipsilateral lesions	1
Average lesion volume (cm^3)	0.08 ± 0.00
Permanent lesions at 30 days	1

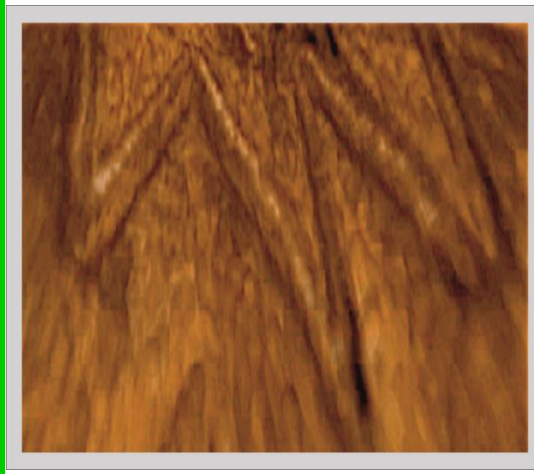
***External Core Lab analysis (US)**

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

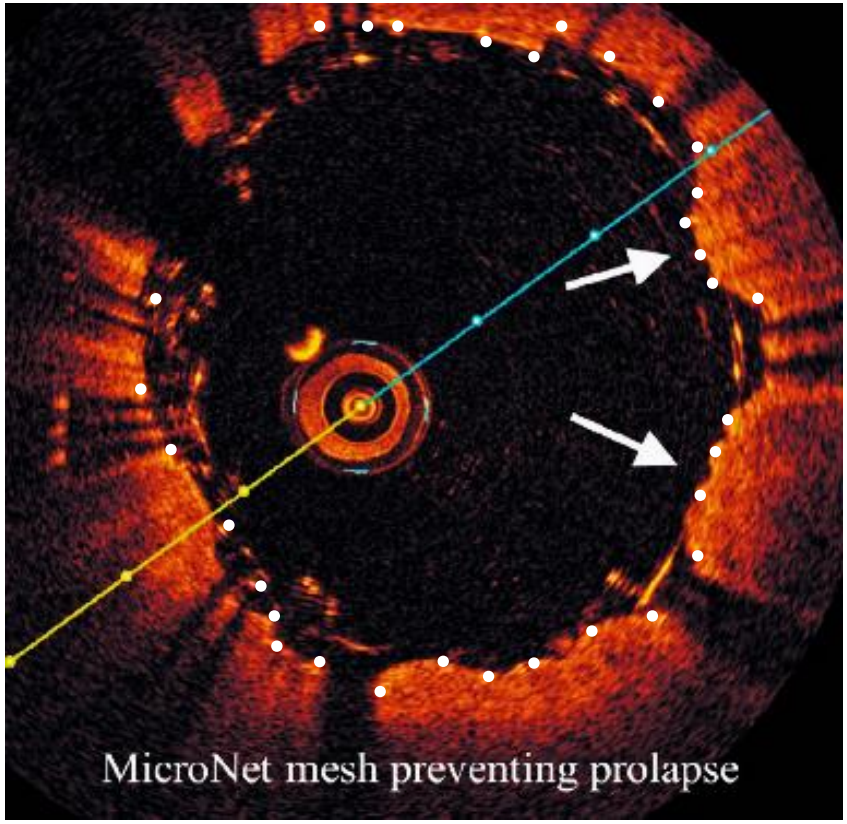


Tomyuki Umemoto et al.
EuroIntervention 2017

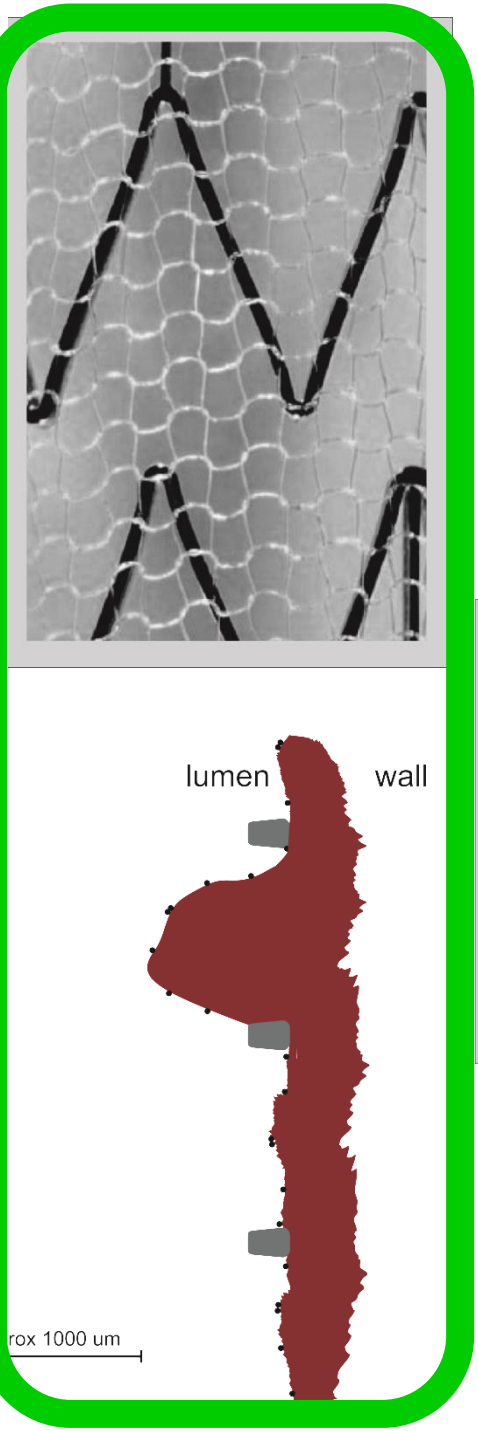


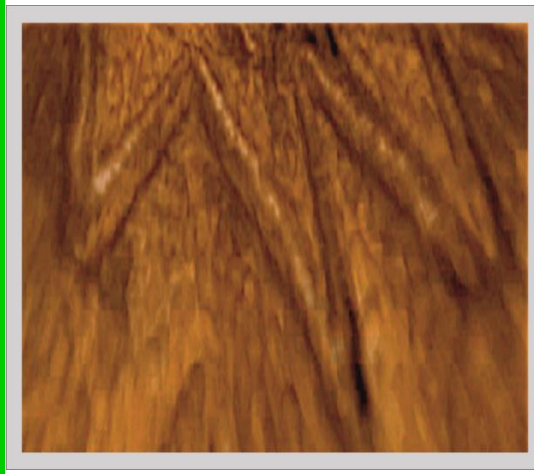


Musialek & Stabile
EuroIntervention 2017



Tomyuki Umemoto et al.
EuroIntervention 2017





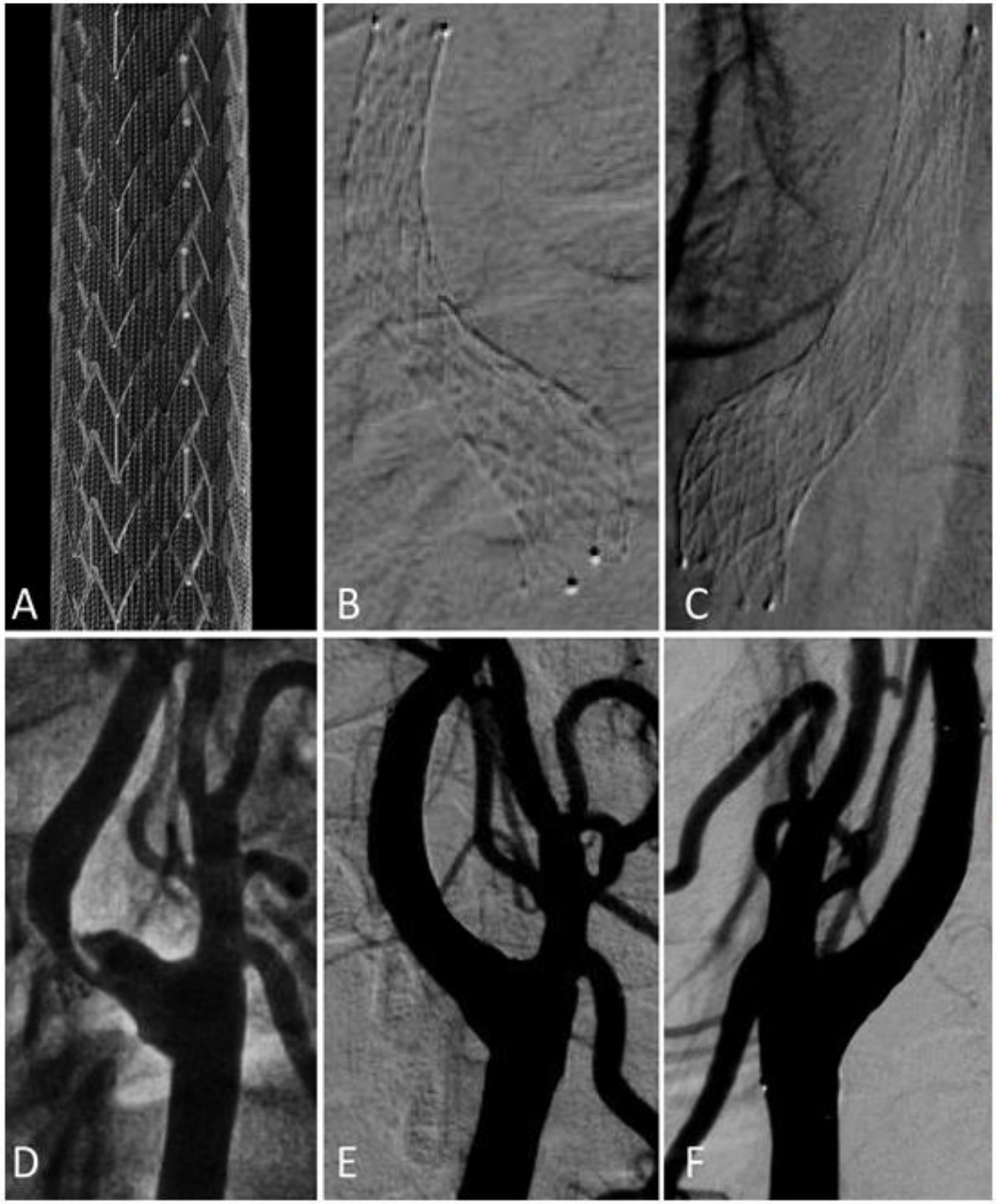
Musialek & Stabile
EuroIntervention 2017

FACT #6

Also, CGuard™ enables

routine
Endovascular Reconstruction
of the Carotid Bifurcation

(systematic CEA-like effect of CGuard™ CAS)



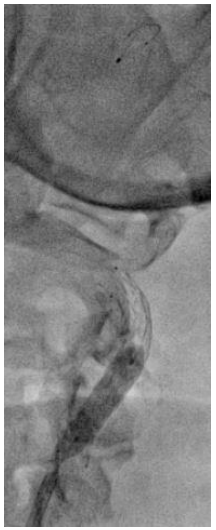
CAROTID PARADIGM REVASCULARIZATION

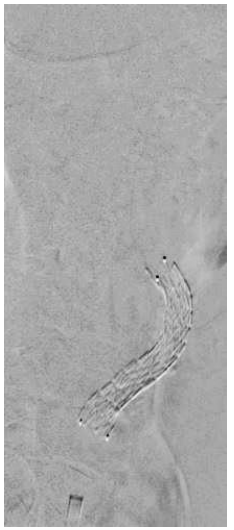
systematic

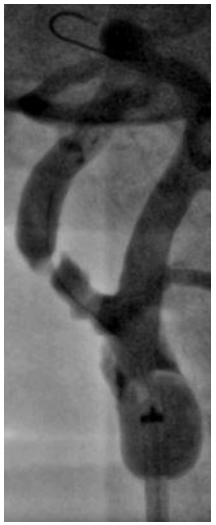
CEA-like effect of CAS

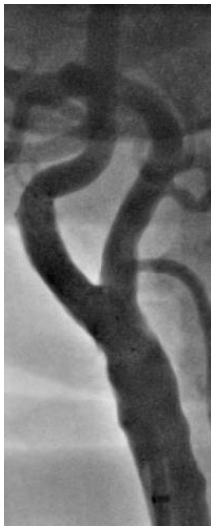
EuroIntervention 2016;12:e658-70

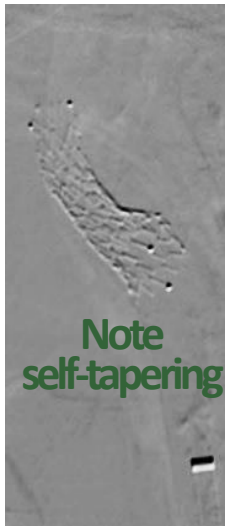
Endovascular Solution for All-Comers











Endovascular Reconstruction of the Carotid Bifurcation

Prevention of embolism, High radial force, Conformability

FACT #7

Procedural risk level

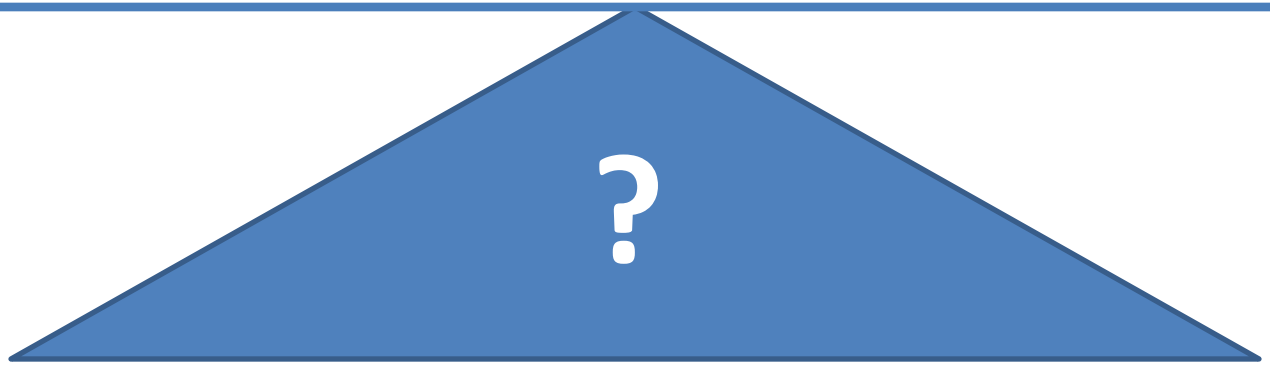
(vs. the disease natural history risk)

is <u>critical</u> for physician decision-making

”Asymptomatic” Carotid Stenosis Decision-making

PHARMACOTHERAPY + INERVENTION

ISOLATED PHARMACOTHERAPY



”Asymptomatic” Carotid Stenosis Decision-making

PHARMACOTHERAPY + INERVENTION

ISOLATED PHARMACOTHERAPY

Fundamental Issue

”People” with Carotid Stenosis

Vascular Clinic Referral Patient	≠	**General Popu--lation Subject**
annual ipsilateral stroke risk 2.5-3.0%		**annual ipsilateral stroke risk ≈0.5%**

Musialek & Hopf-Jensen *J Endovasc Ther* 2017;24:138-148

$CHADS_2$ Calculator for Atrial Fibrillation

Evaluates ischemic stroke risk in patients with atrial fibrillation

Criteria		Poss. Point
Congestive heart failure Signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction	Yes No	+1
Hypertension Resting BP > 140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment	Yes No	+1
Age 75 years or older	Yes No	+2
Diabetes mellitus Fasting glucose > 125 mg/dL or treatment with oral hypoglycemic agent and/or insulin	Yes No	+1
Stroke, TIA, or TE Includes any history of cerebral ischemia	Yes No	+2
Vascular disease Prior MI, peripheral arterial disease, or aortic plaque	Yes No	+1
Age 65 to 74 years	Yes No	+1
Sex **C**ategory (female) Female gender confers higher risk	Yes No	+1

Results:

Total Criteria Point Count: **0**

Reset Form

Stroke Risk per 100 Person Years/Warfarin Rx Interpretation

0 Points:	0.25 ON Rx; 0.49 NO Rx
1 Point:	0.72 ON Rx; 1.52 NO Rx
2 Points:	1.27 ON Rx; 2.50 No Rx
3 Points:	2.20 ON Rx; 5.27 NO Rx
4 Points:	2.35 ON Rx; 6.02 NO Rx
5-6 Points:	4.60 ON Rx; 6.88 NO Rx

Musialek & Hopf-Jensen *J Endovasc Ther* 2017;24:138-148

PARADIGM

Methods (cont'd):

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

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)

FACT #8

CGuard™ - CAS can achieve peri-procedural and 30-day complication rate

at the level of ≈1%

- not only in ”selected” patients bus also in All-comers

clinical

Evidence

10^{+} studies

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

euro PCR 2016 LATE BREAKING TRIALS

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)

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

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

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'.

FACT #9

Evidence is accumulating that CGuard™ accompanied by OMT (that is ALWAYS the fundament)

shows effective stroke prevention throughout 3 years

in absence of device-related issues

PARADIGM – Extend

	1-12 mo	12-24 mo	24-36 mo
	n=251	n=185	n=93
ipsilateral stroke	**0**	**0**	**0**
any stroke	**0**	**1** (cerebellal)	**1** (brain stem)
stroke-related death	**0**	**0**	**0**
MI or other non-cerebral VA	**0**	**3**	**2**
any death	**6** (CHF-2, Ca-2, PE-1, urosepsis -1)	**5** (CHF-2, Ca-2, MI-1)	**2** (Ca-1, MI-1)
in-stent velocities	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	PSV **0.75**±0.27 m/s EDV **0.18**±0.06 m/s

PARADIGM – Extend

By 36 months

- Normal healing
- No ISR signal

	1-12 mo	12-24 mo	24-36 mo
	n=251	n=185	n=93
ipsilateral stroke	0	0	0
any stroke	0	1 (cerebellal)	1 (brain stem)
stroke-related death	0	0	0
MI or other non-cerebral VA	0	3	2
any death	6 (CHF-2, Ca-2, PE-1, urosepsis -1)	5 (CHF-2, Ca-2, MI-1)	2 (Ca-1, MI-1)
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CGUARD™
Carotid Embolic Prevention System

CAROTID PARADIGM REVASCULARIZATION

36-month data

PARADIGM

@ 36 months

Favourable Clinical Outcome

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

sustained stroke prevention

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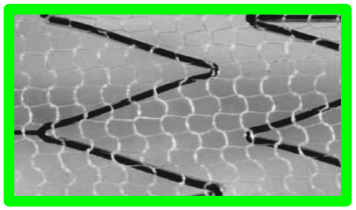
The Outcome Difference

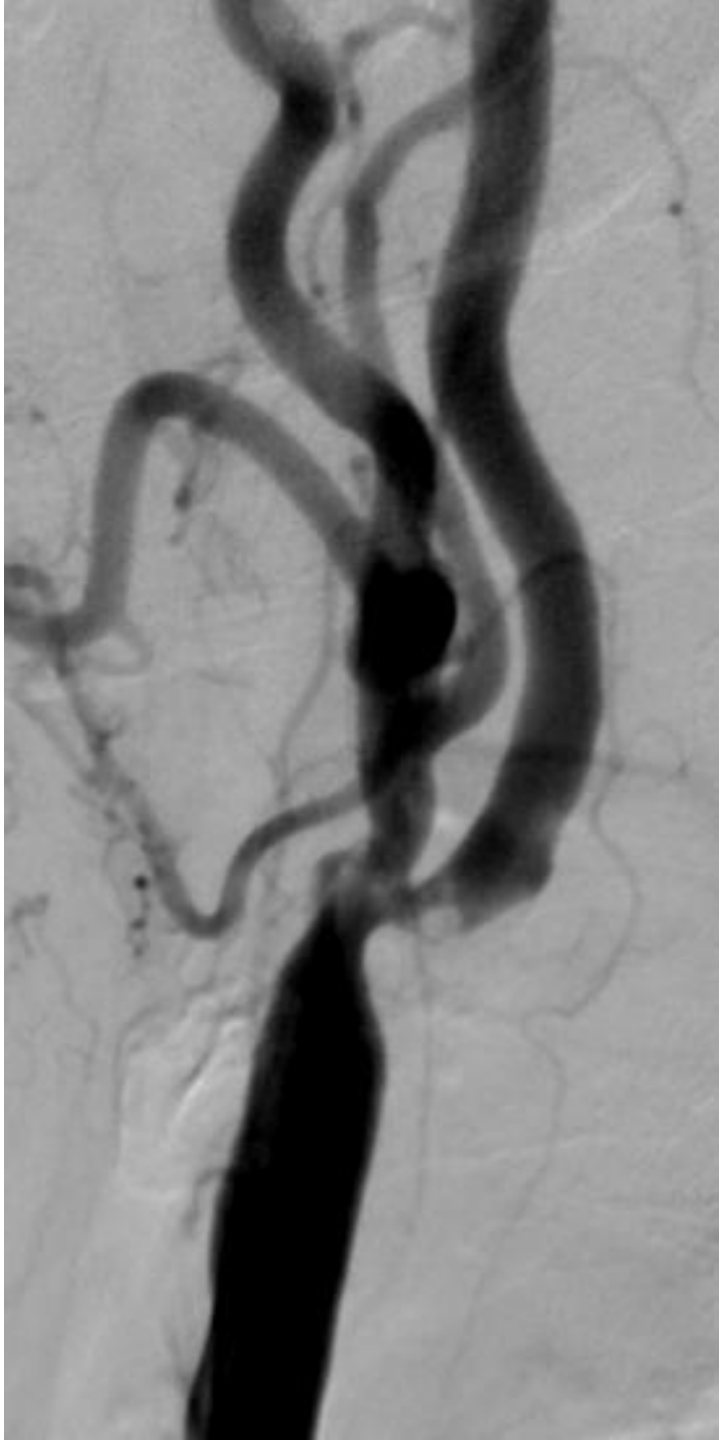
Between the MicroNet-Covered Stent

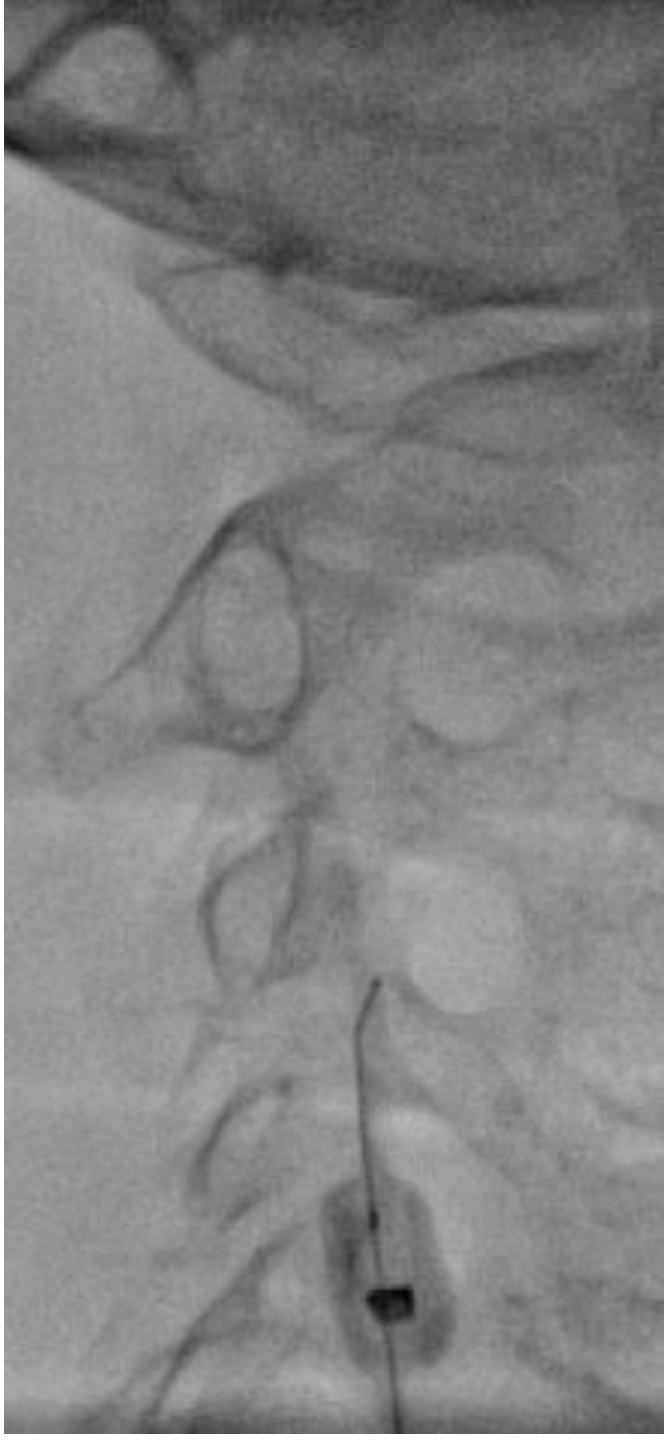


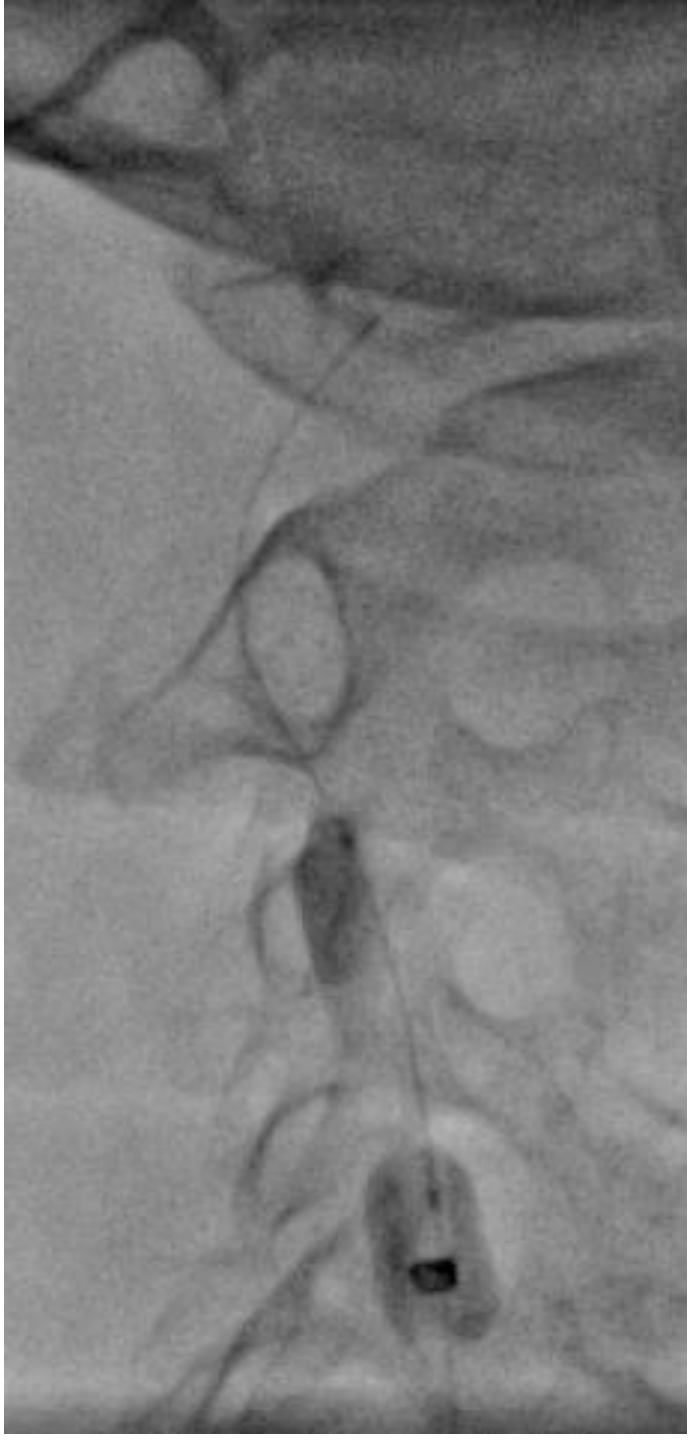
Vs.

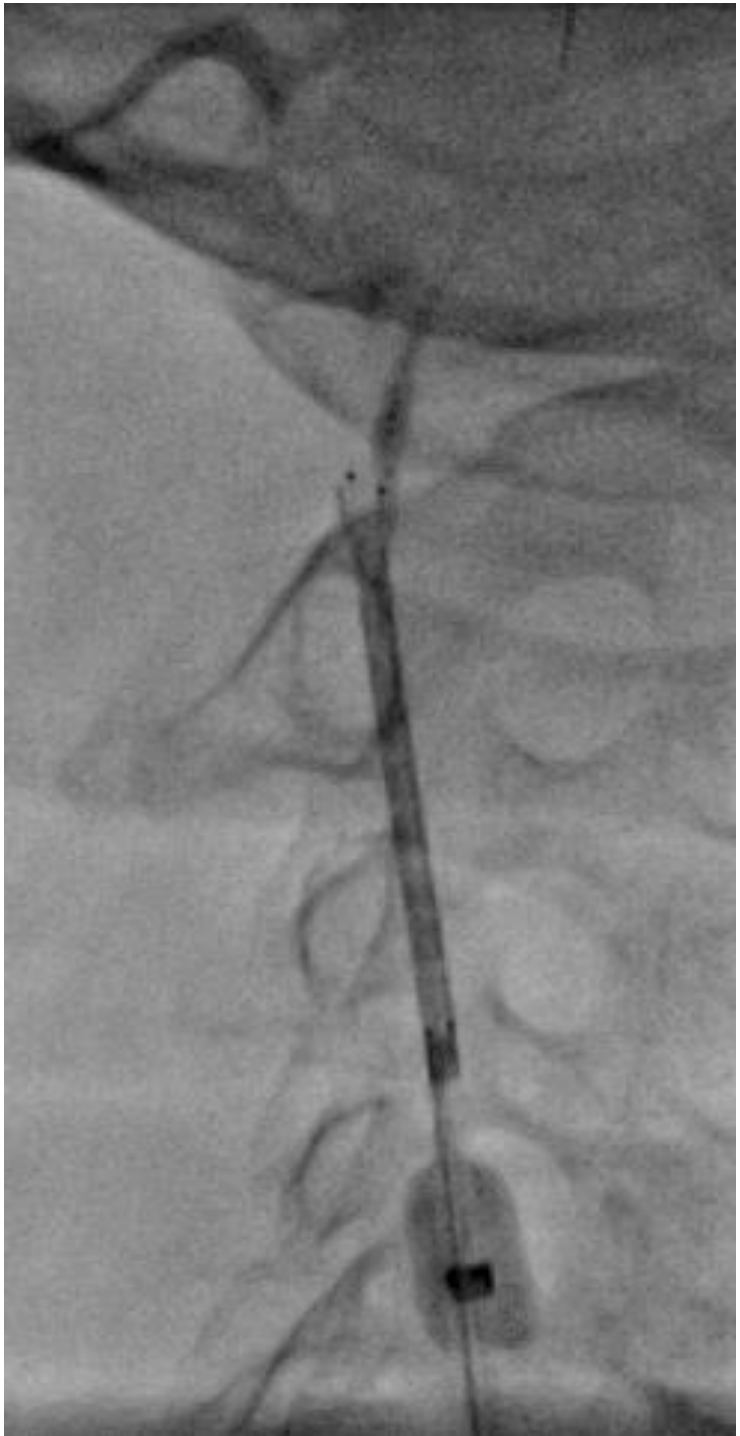
Conventional Carotid Stent(s)

is driven by HIGH-RISK Plaques and Patients



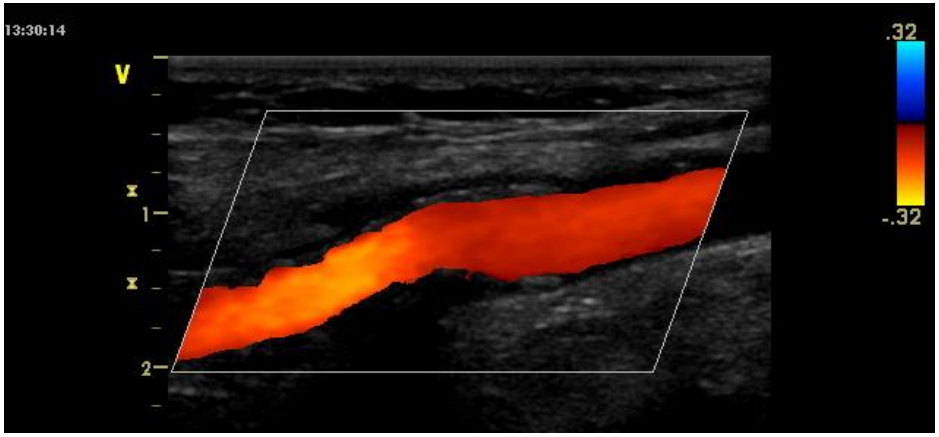



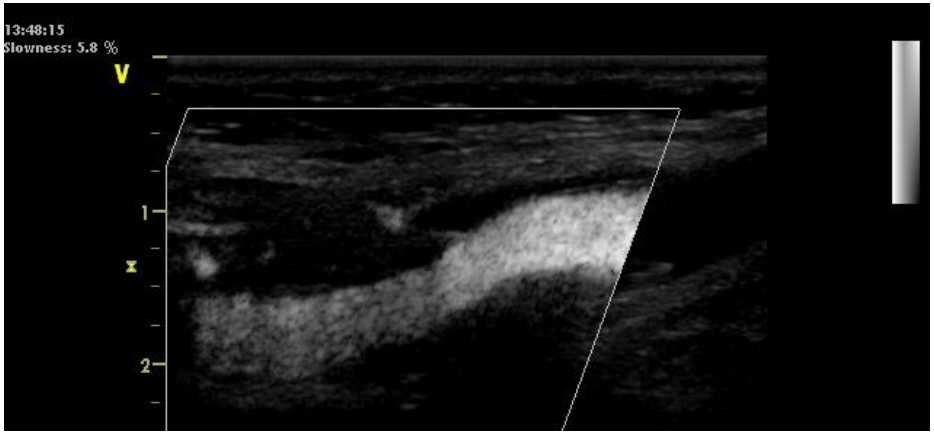




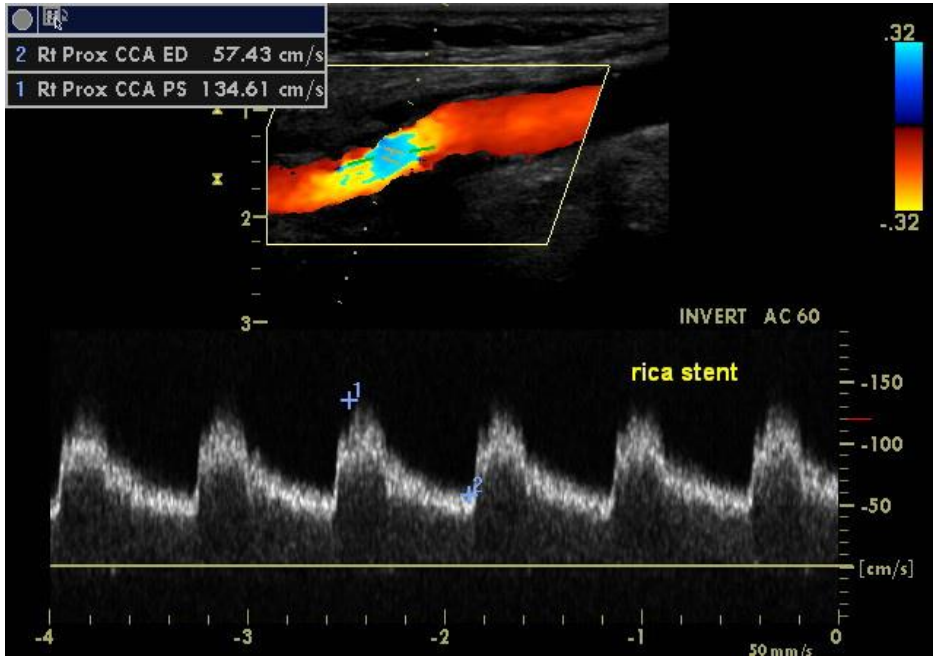
Flow reversal time 7min 10sec
Intolerance in the last 80sec
(active aspiration still !! performed)

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

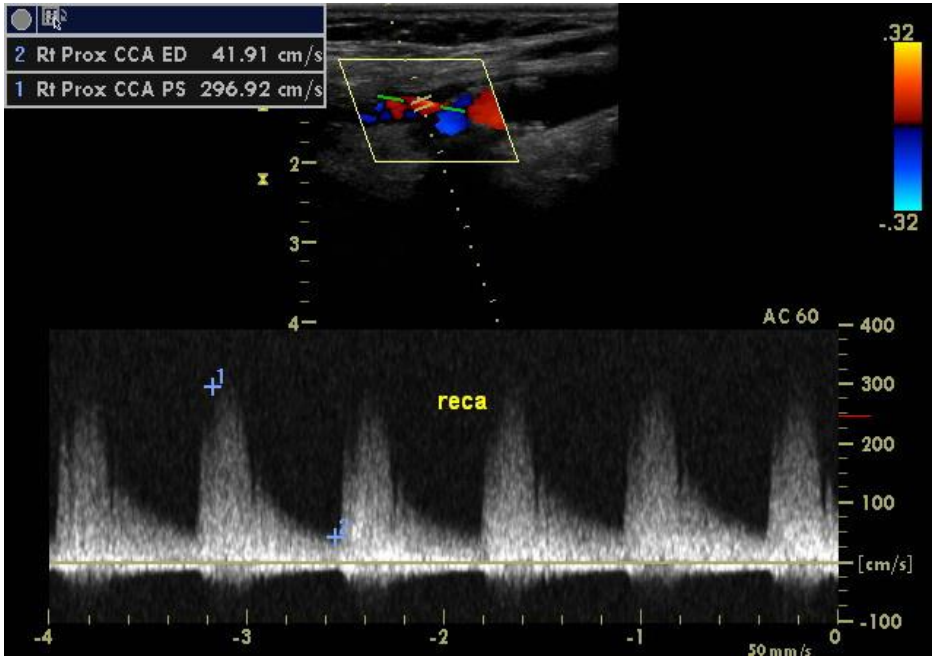




Normal stent image



Normal velocities



ECA patent

P Musialek @ VEITH 2018

FACT #10

There is more than that…

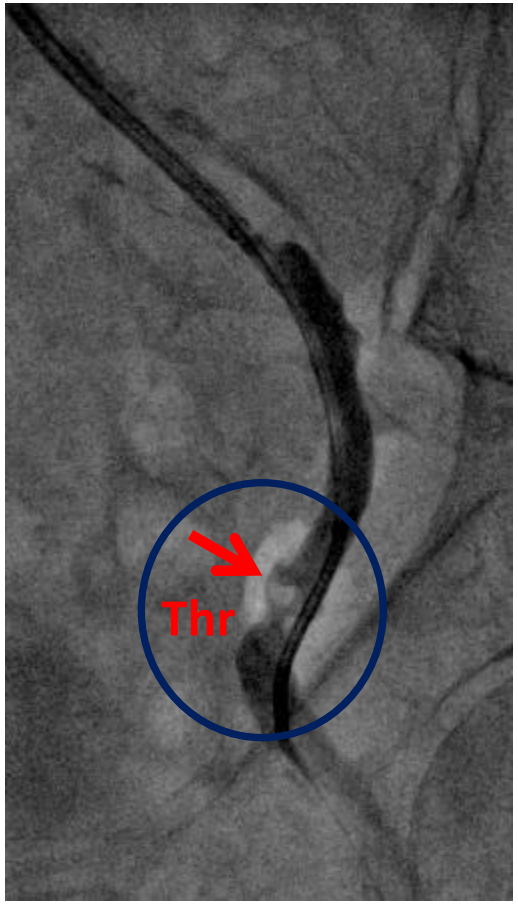
Moving beyond routine CAS…

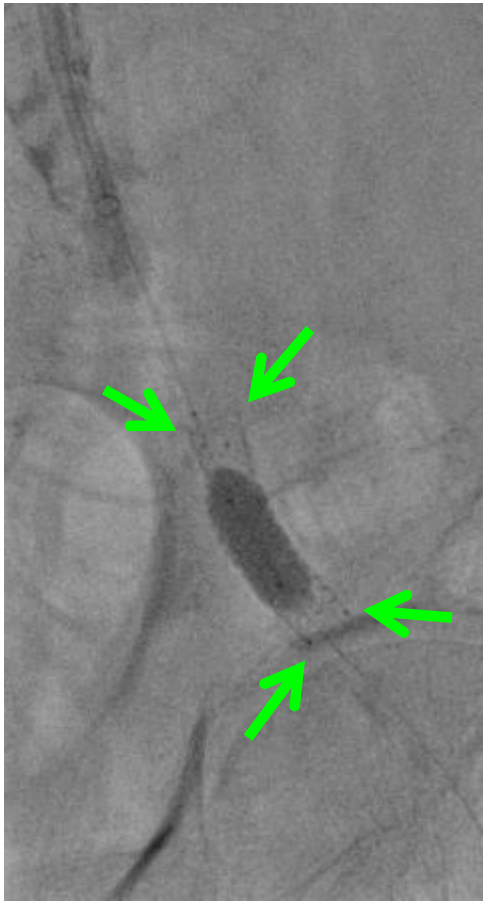
2018 VEITH Vascular Endovascular Issues Techniques Horizons

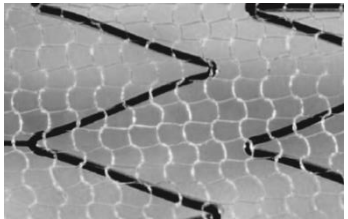
CGuard™ MicroNet Covered Stent:

ADDRESSING UNMET NEEDS IN OTHER VASCULAR BEDS

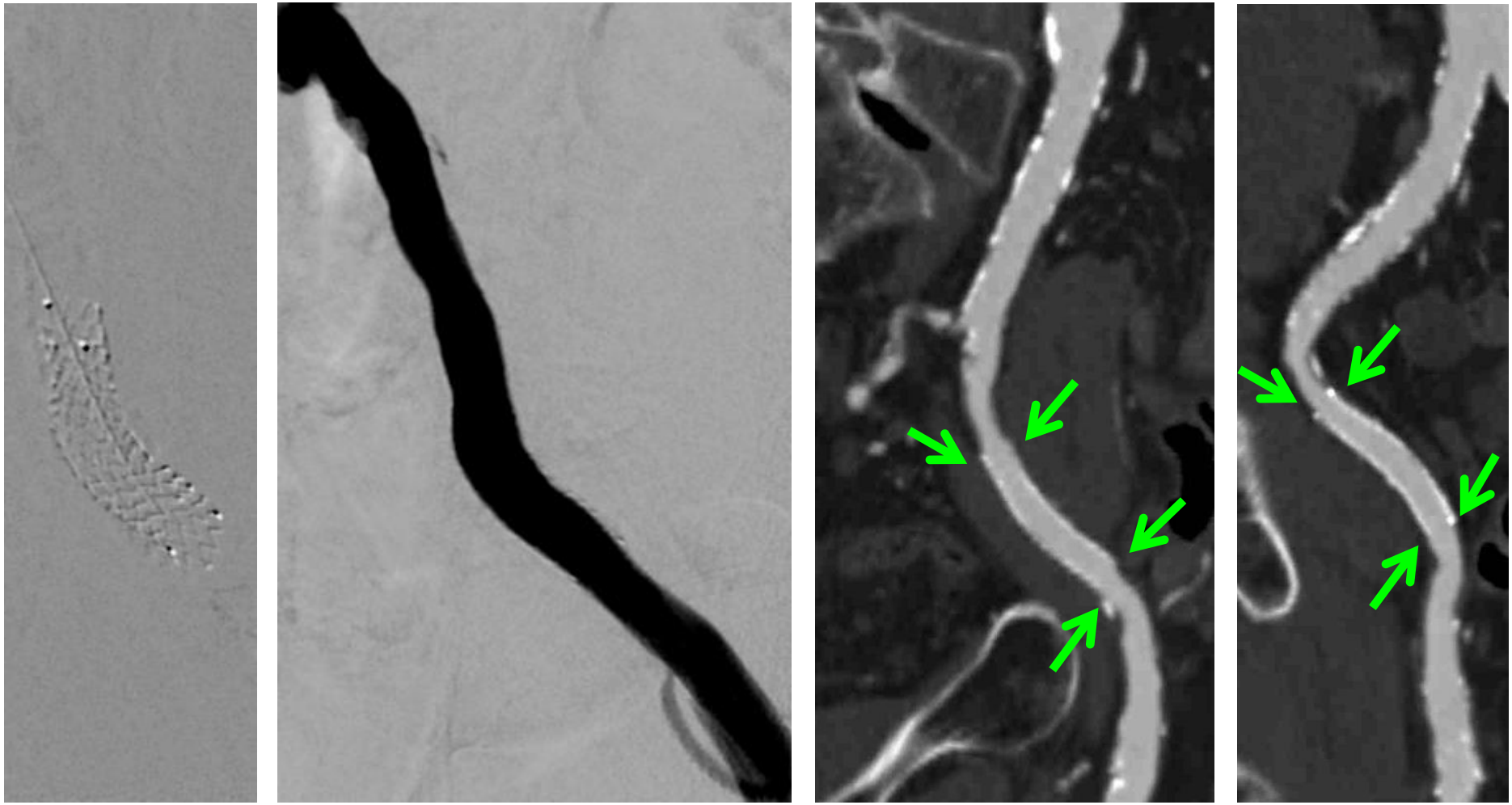
Thrombus-containing/high-embolic risk lesions in iliacs or subclavians







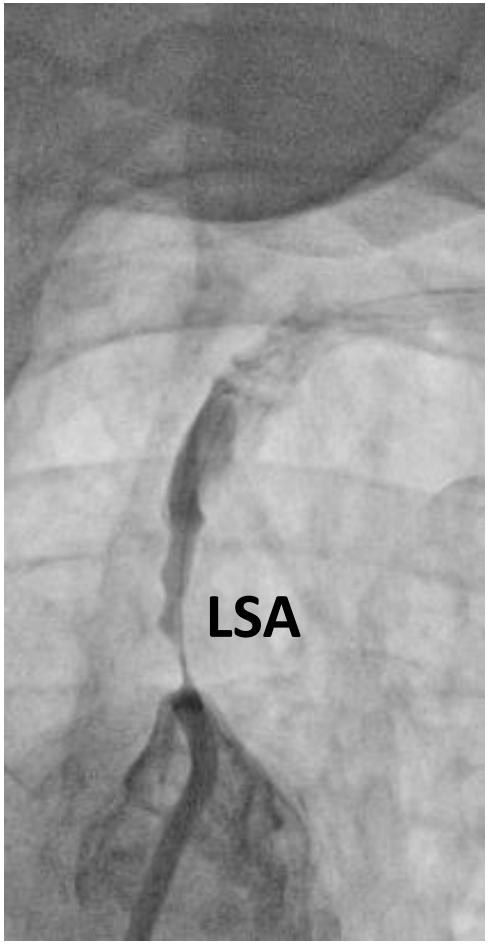
Thrombus-containing/high-embolic risk lesions in iliacs or subclavians

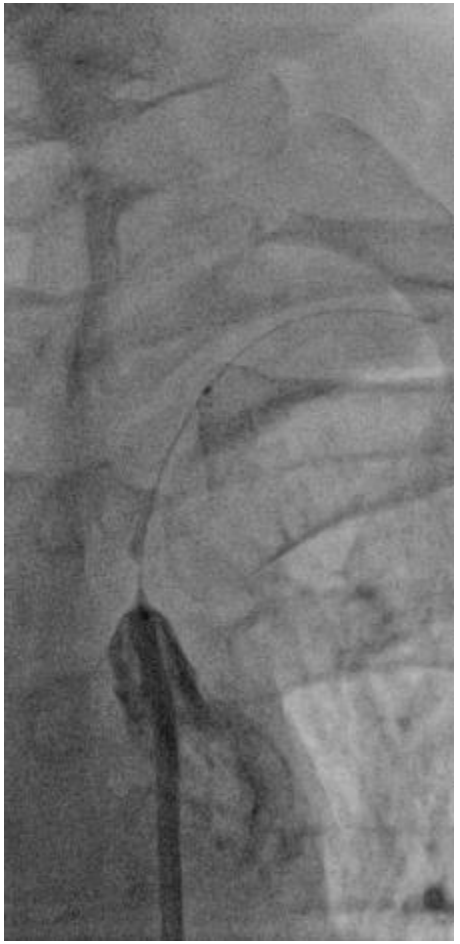


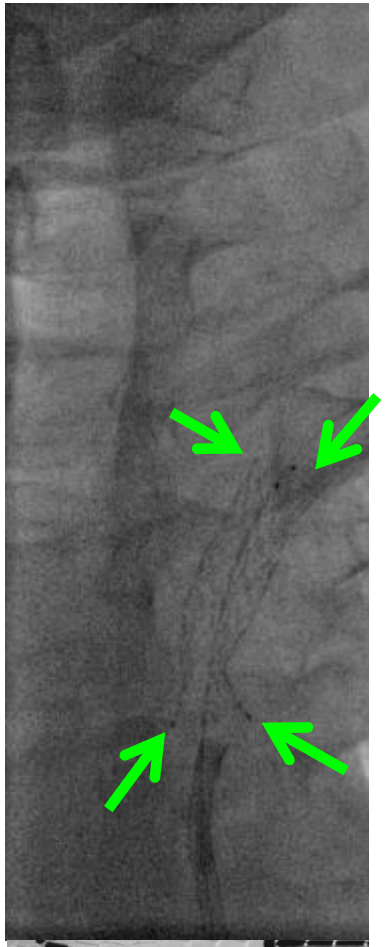
OPTIMAL procedural result

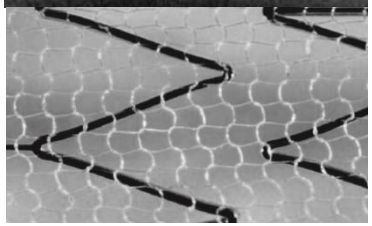
Normal 6mo follow-up

Thrombus-containing/high-embolic risk lesions in iliacs or subclavians







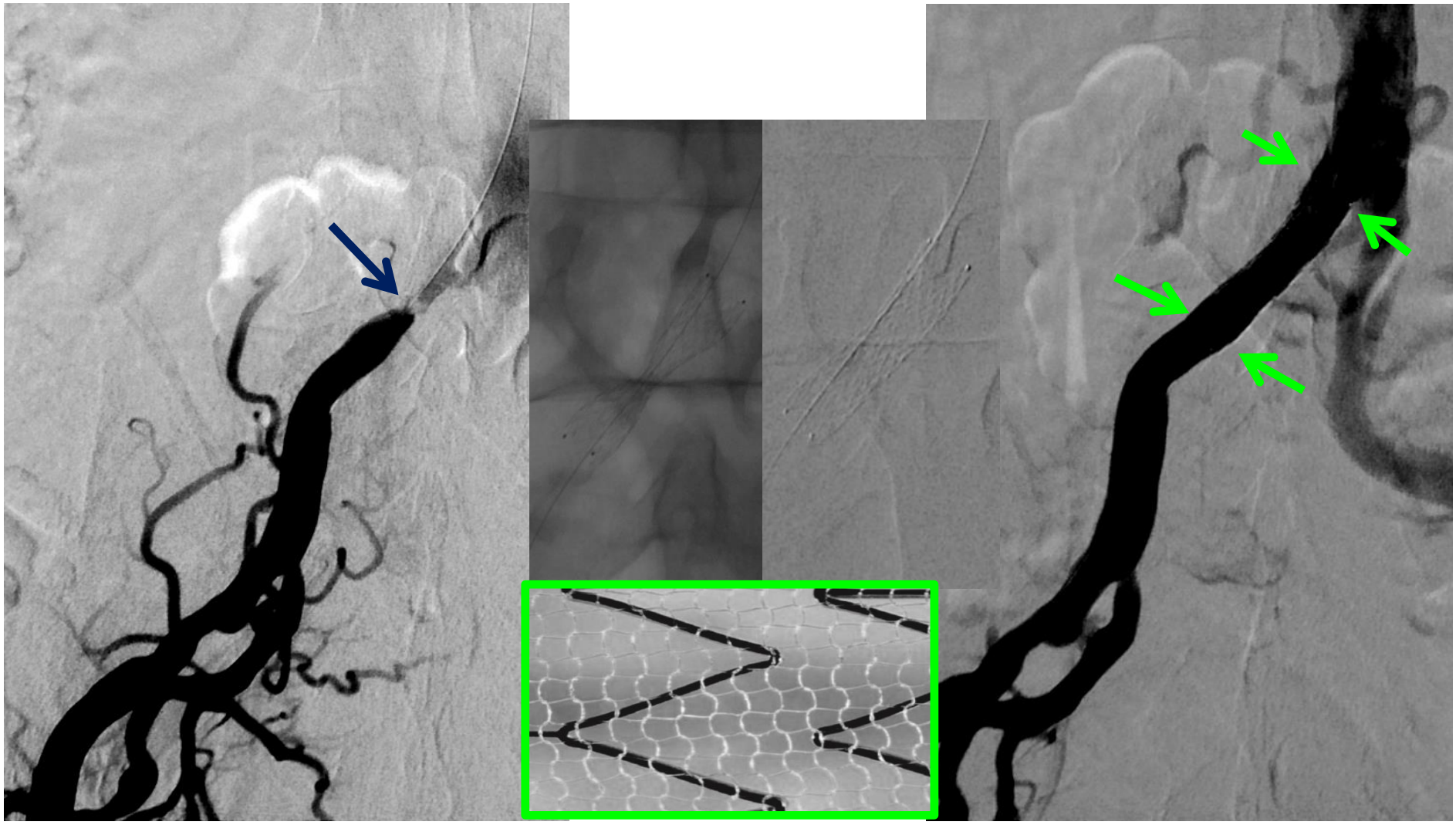


Thrombus-containing/high-embolic risk lesions in iliacs or subclavians

Procedural result

Normal 6mo follow-up

Thrombus-containing/high-embolic risk lesions in iliacs or subclavians



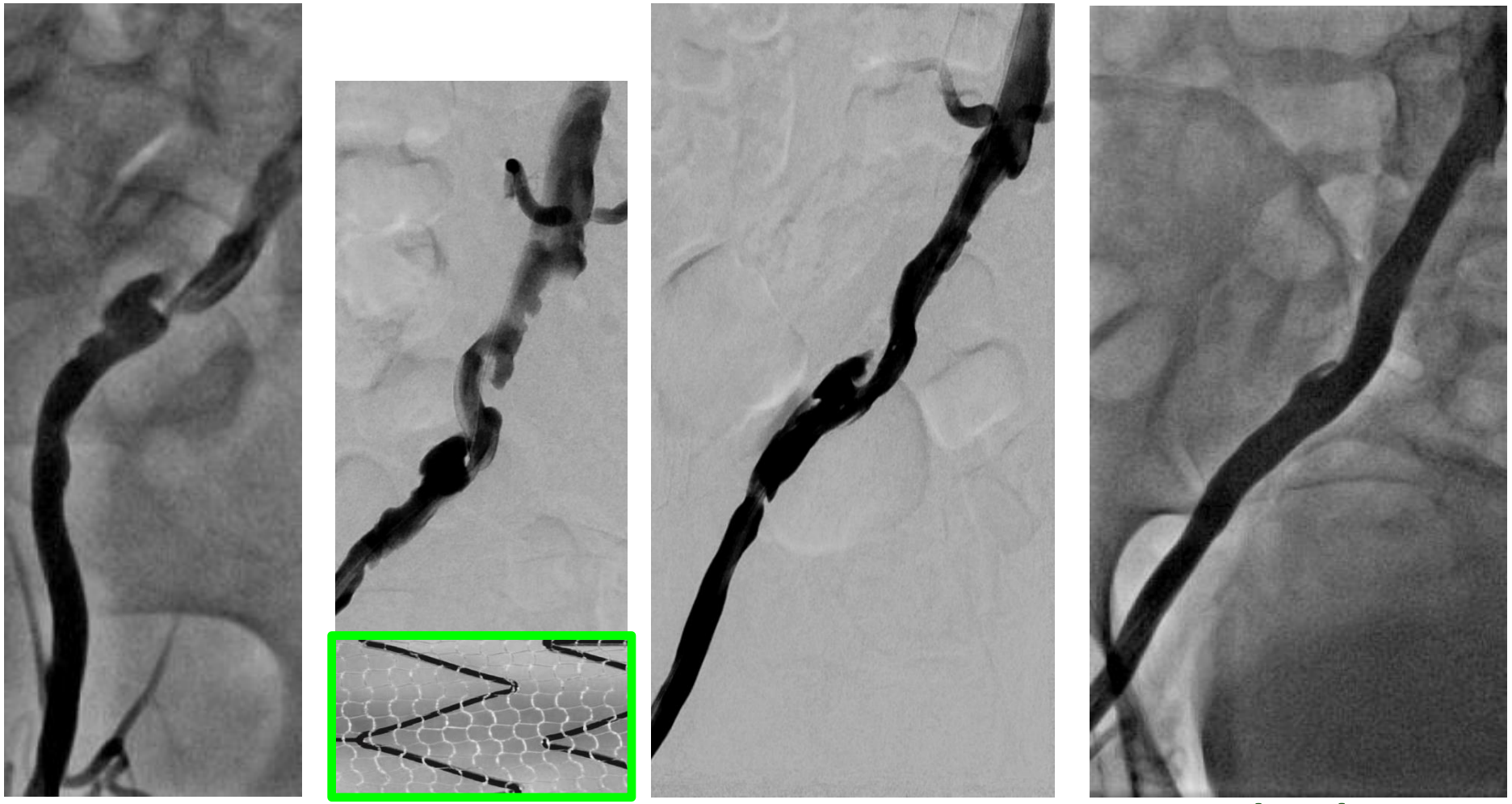
Procedural result

Thrombus-containing/high-embolic risk lesions in iliacs or subclavians

CGuard™

Normal Result @follow-up

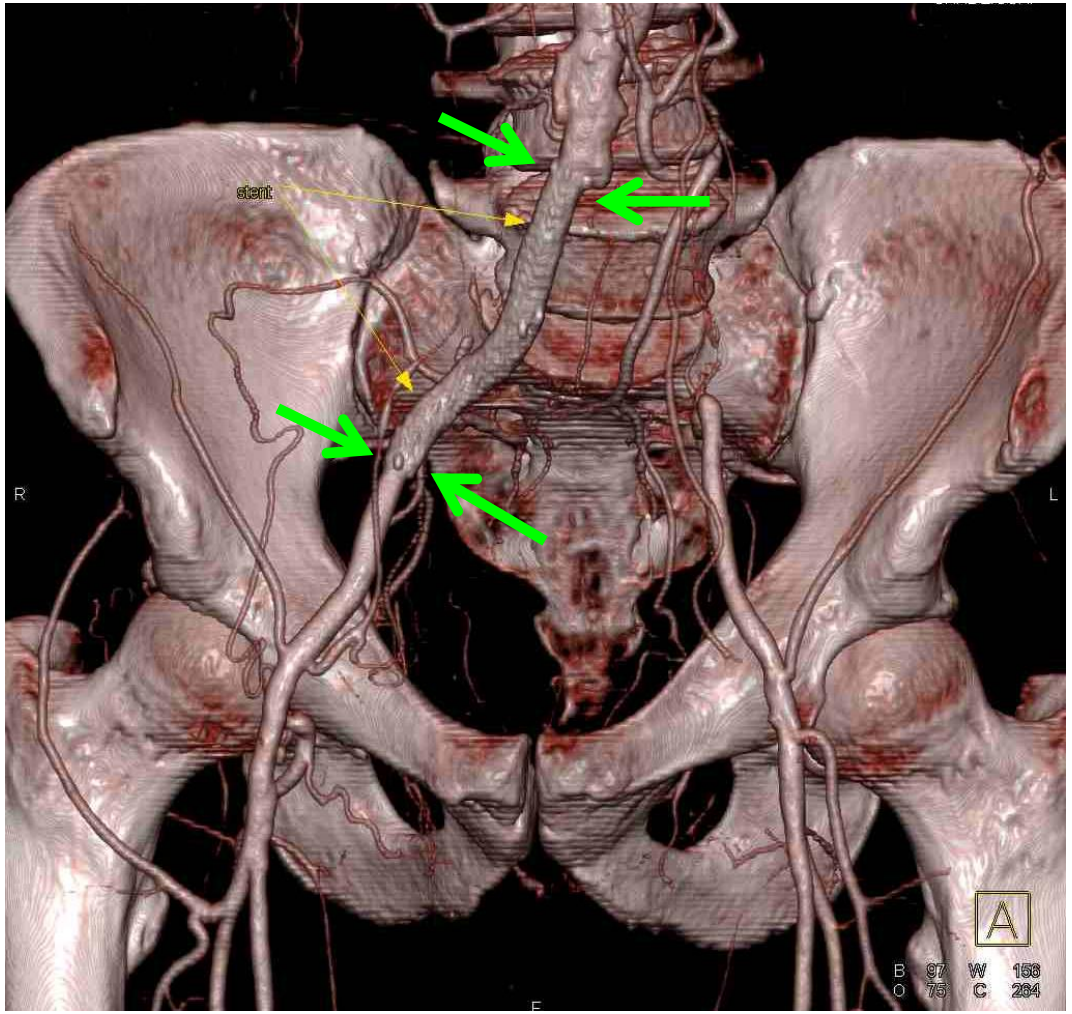
Thrombus-containing/high-embolic risk lesions in iliacs or subclavians and



Procedural acute outcome

Thrombus-containing/high-embolic risk lesions in iliacs or subclavians

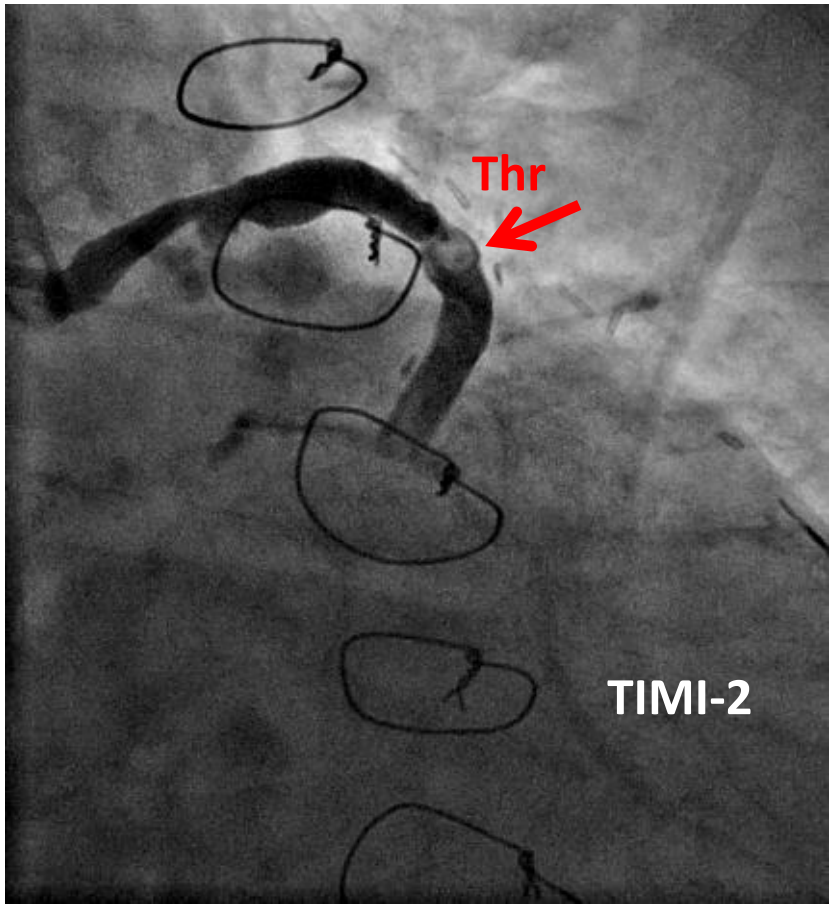
OPTIMAL 6mo result

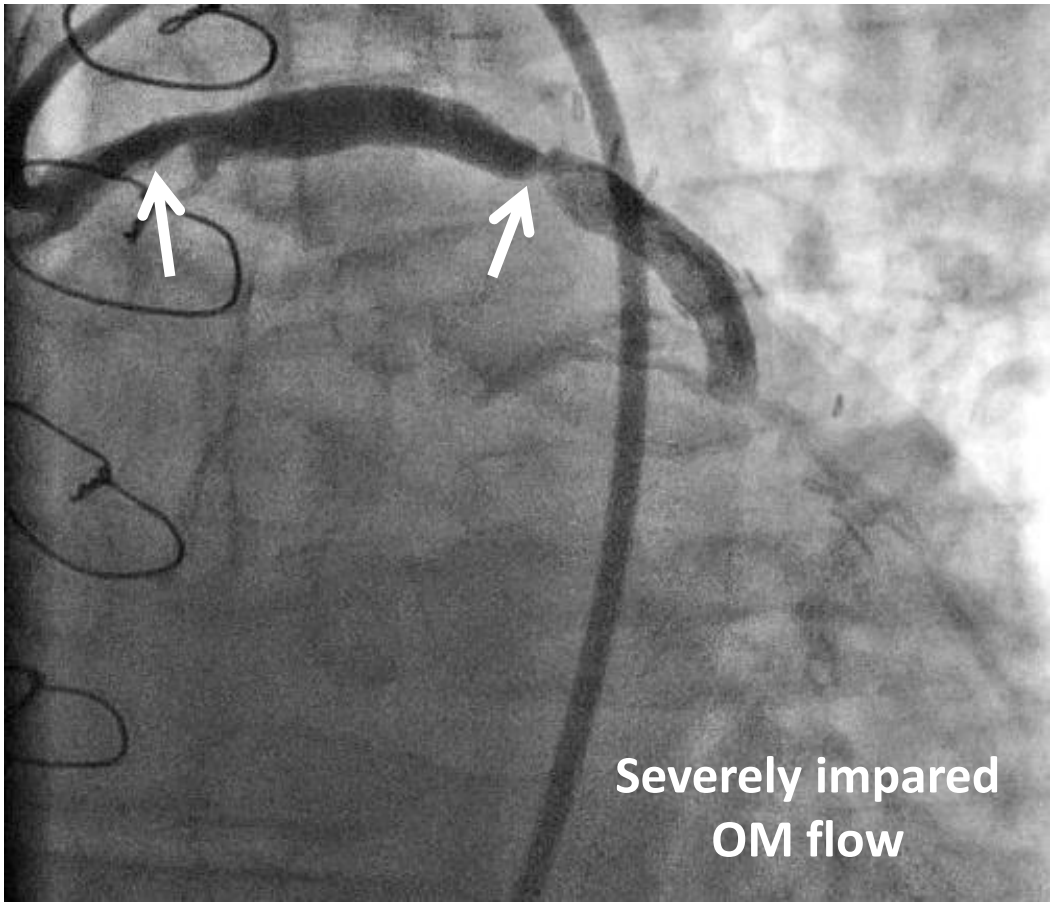


Pt ready for fem-fem (NB. several prior attempts to recanalize LCIA had failed)

Large-diameter SVG disease problem

AK, 58y, NSTE Acute Myocardial Infarction

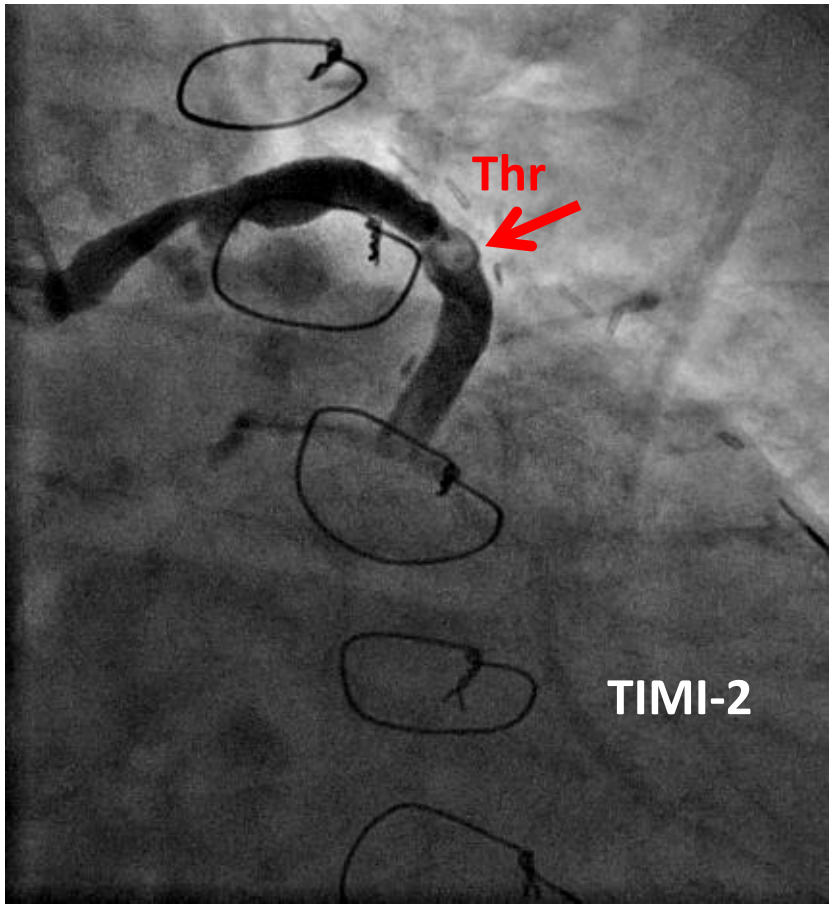


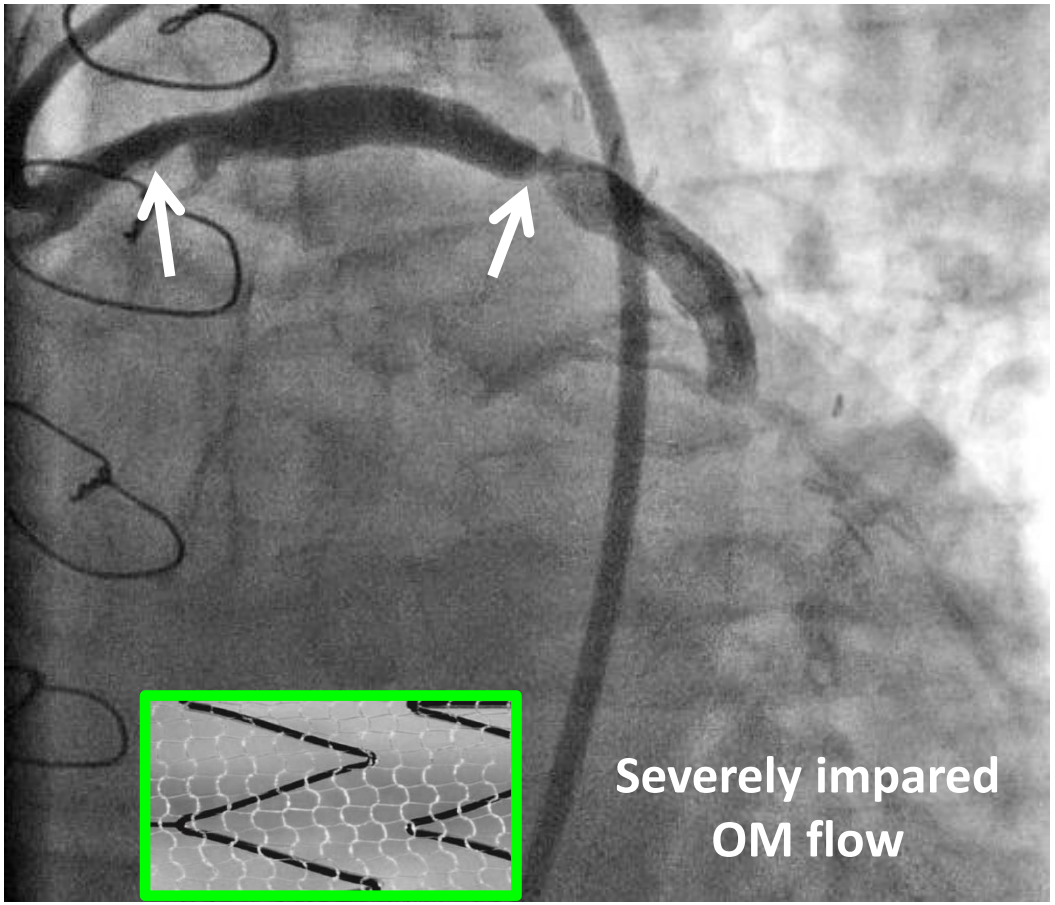


SVG RD 7.5 mm (!)

Large-diameter SVG disease problem

AK, 58y, NSTE Acute Myocardial Infarction

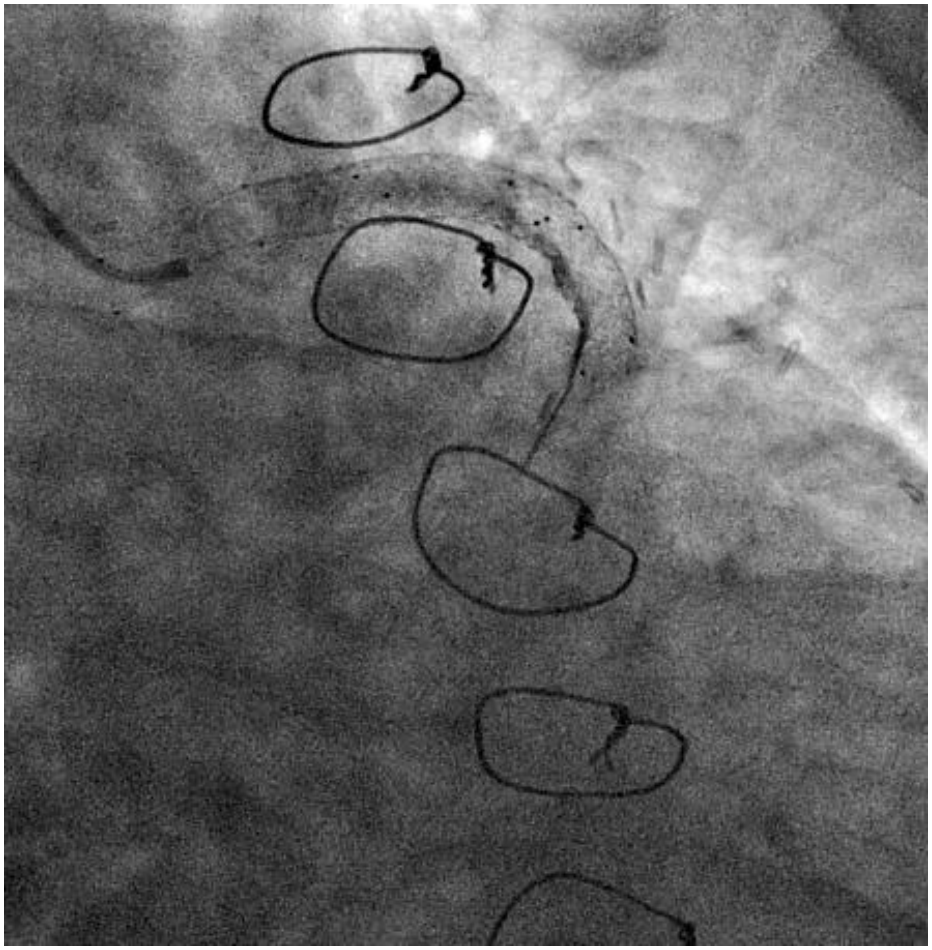


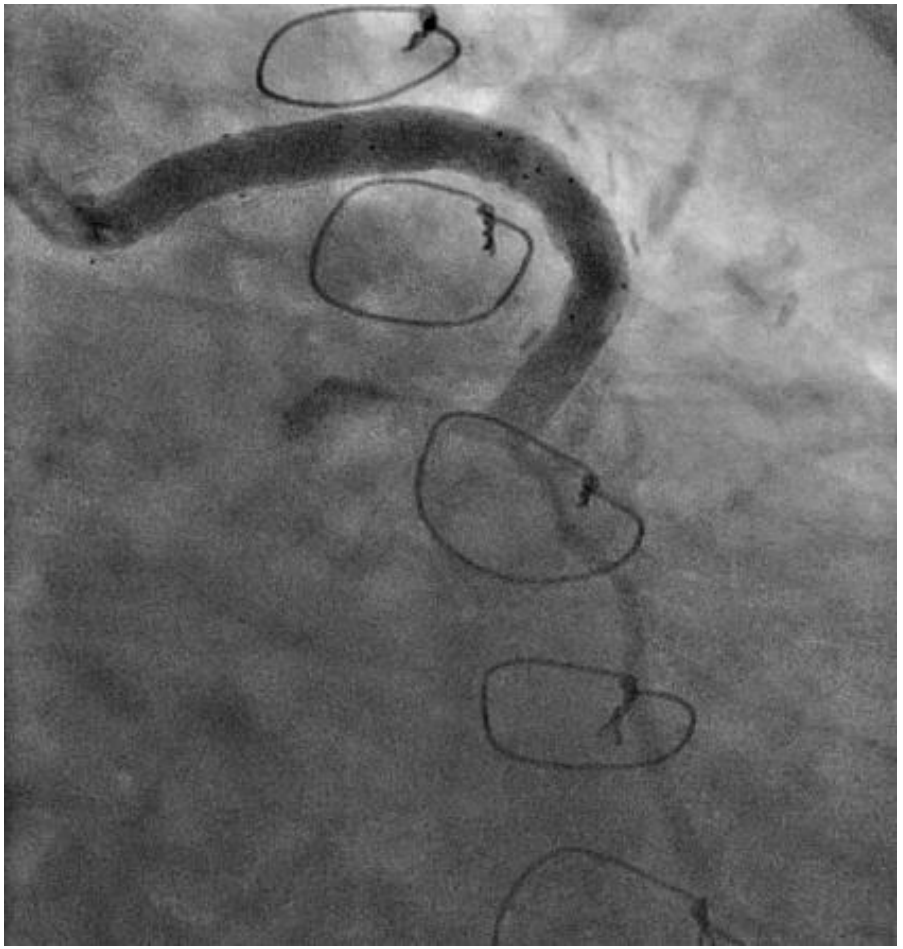


SVG RD 7.5 mm (!)

Large-diameter SVG disease / NSTE-acute MI

post PCI/direct stenting with overlapping MicroNet–covered CGuard™ stents

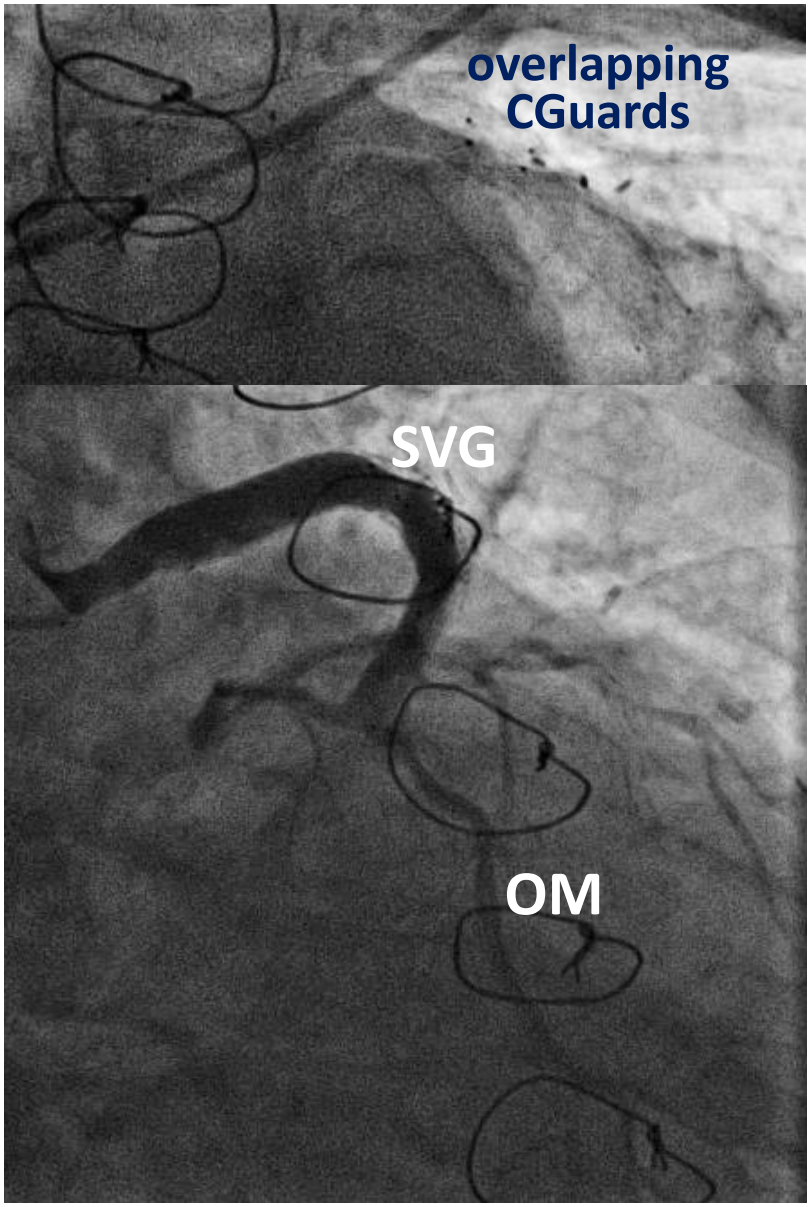


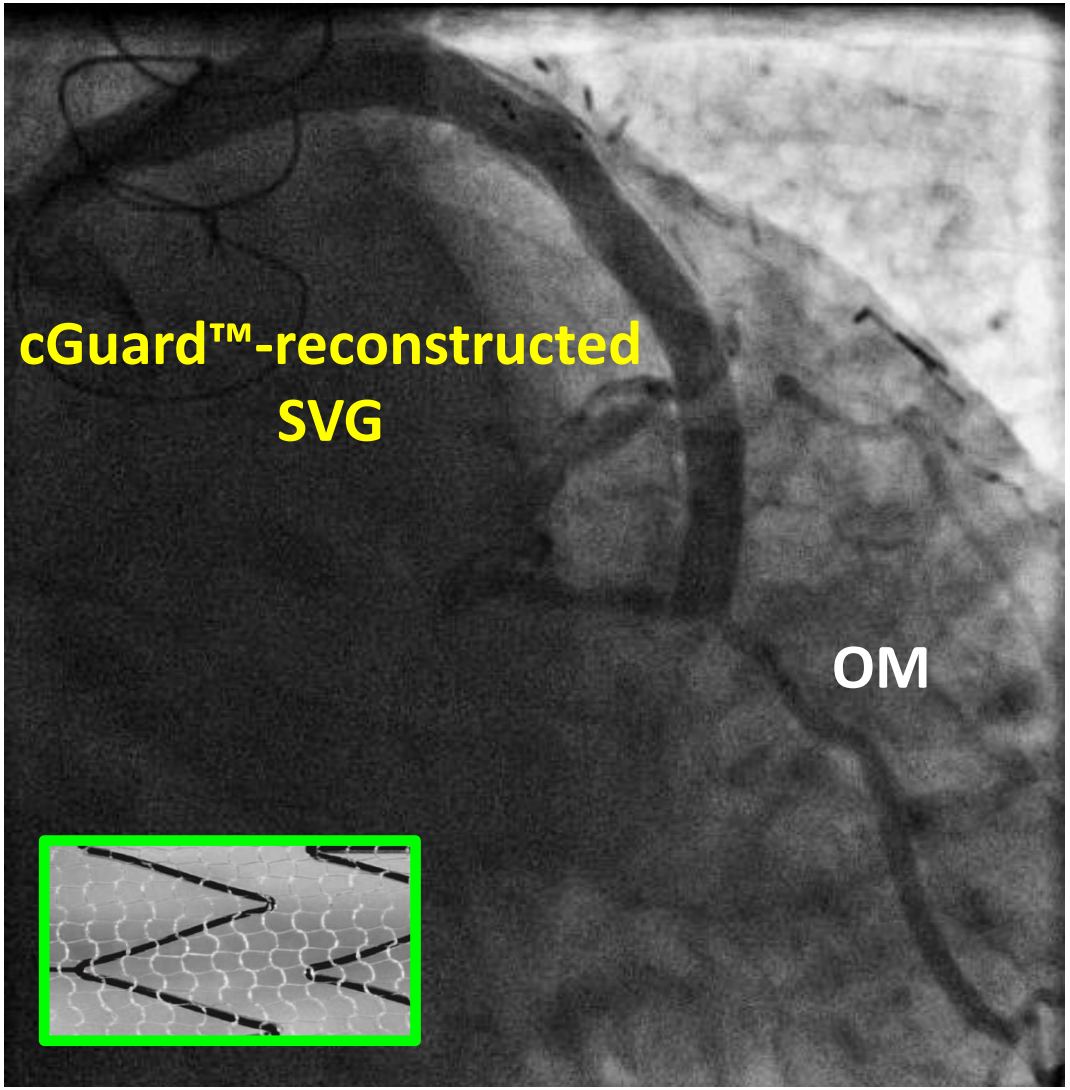


NB. absence of distal embolizm, normal OM flow, no further troponin rise

OPTIMAL acute result

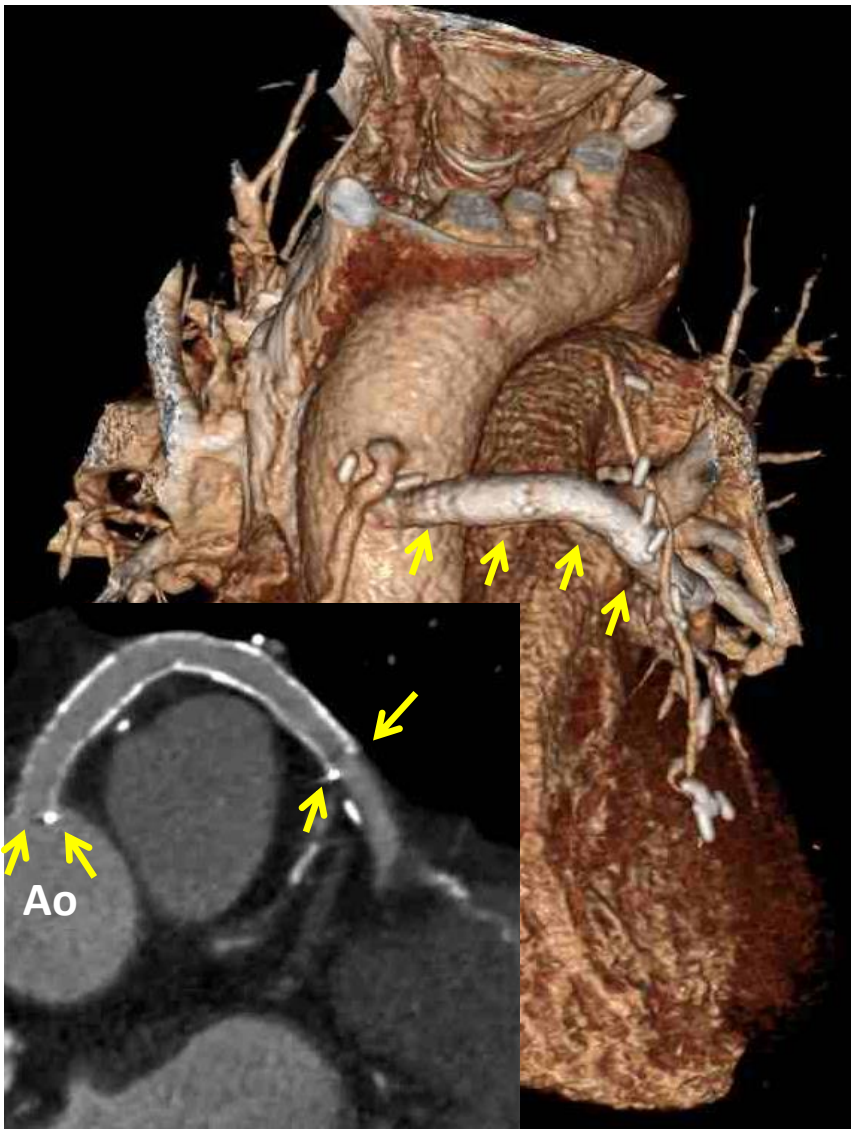
Large-diameter SVG disease treated with CGuards (angio @3mo)

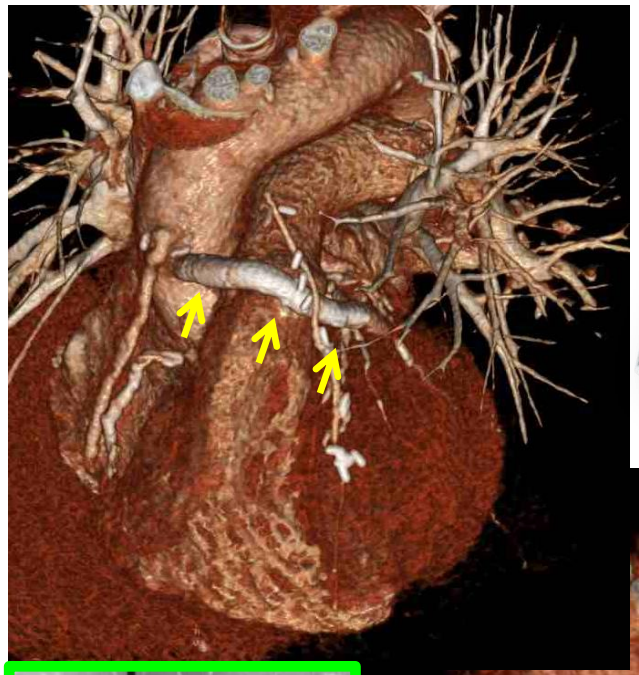


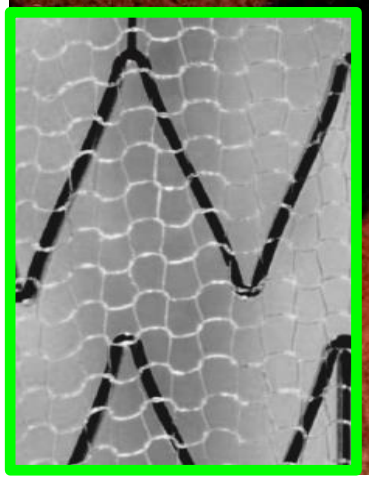


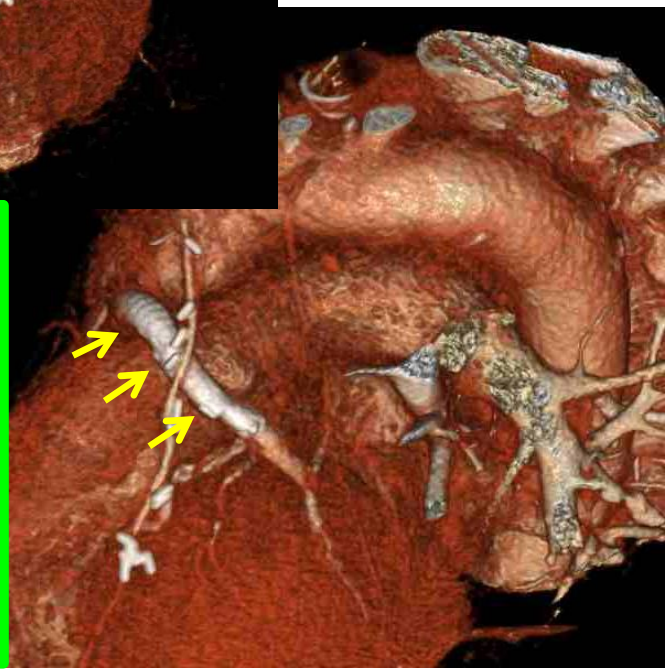
OPTIMAL result @ 3mo

Large-diameter SVG disease treated with CGuards (CT-angio @6mo)







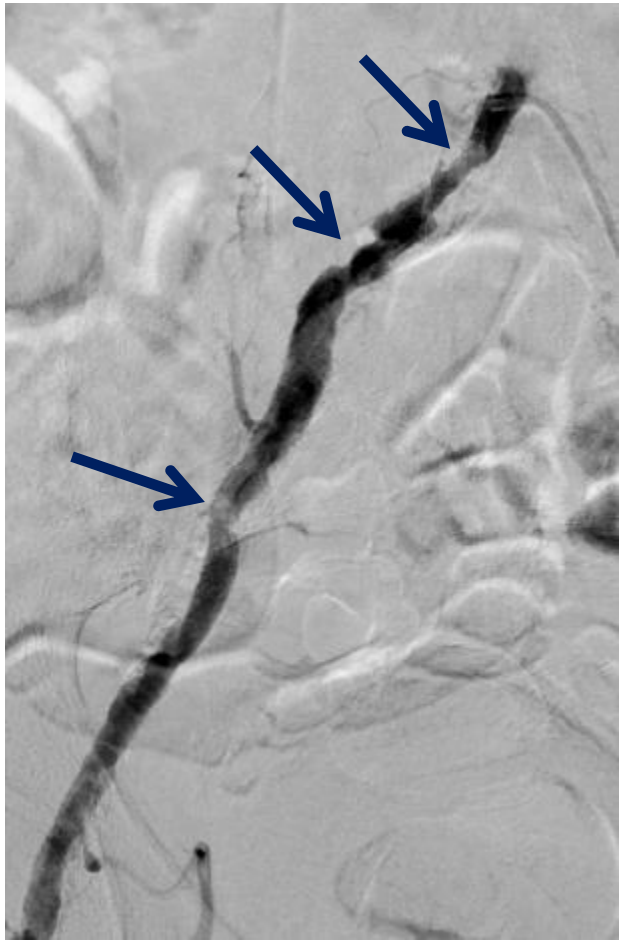


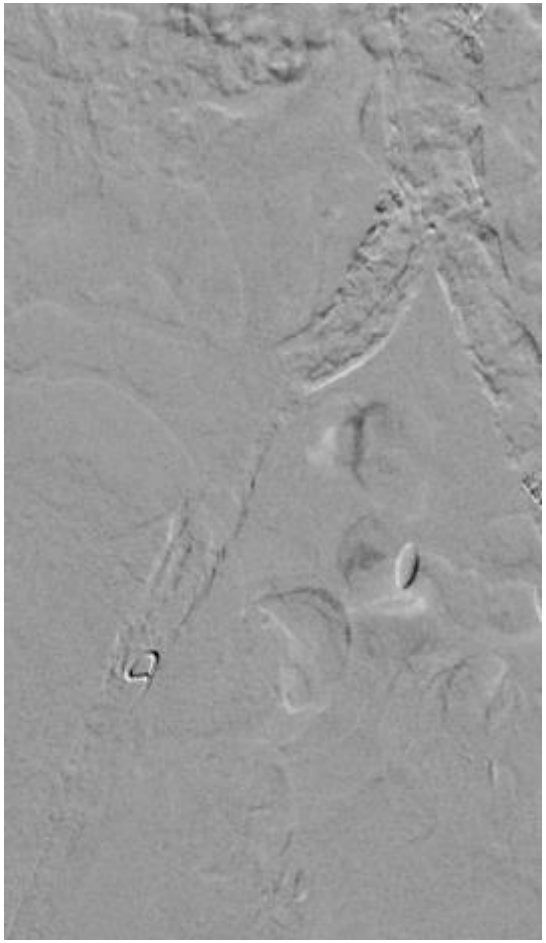
NOTE ostial placement precision feasibility

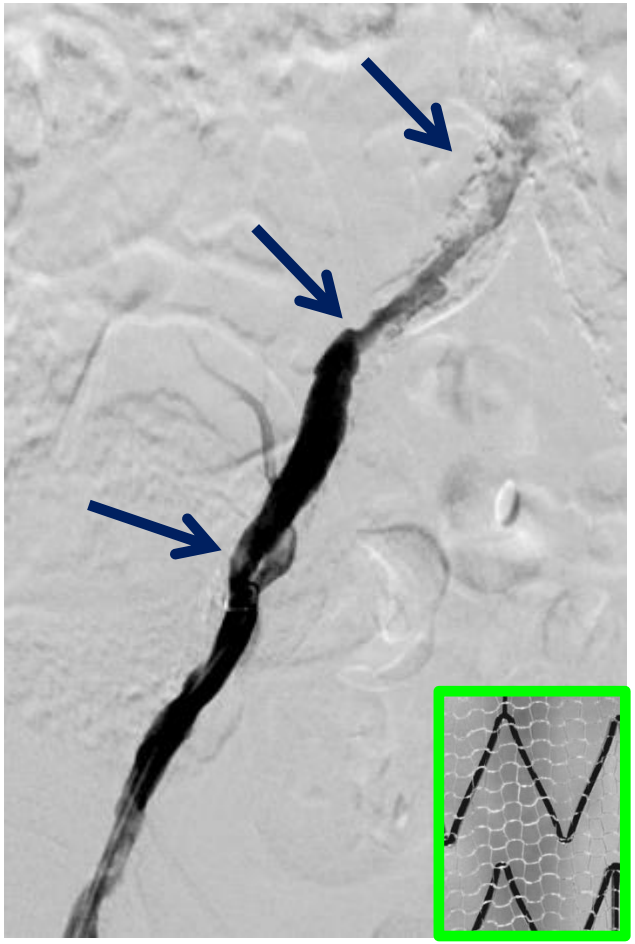
OPTIMAL result @ 6mo

(V) Higly calcific disease

(note: adequate radial force need)



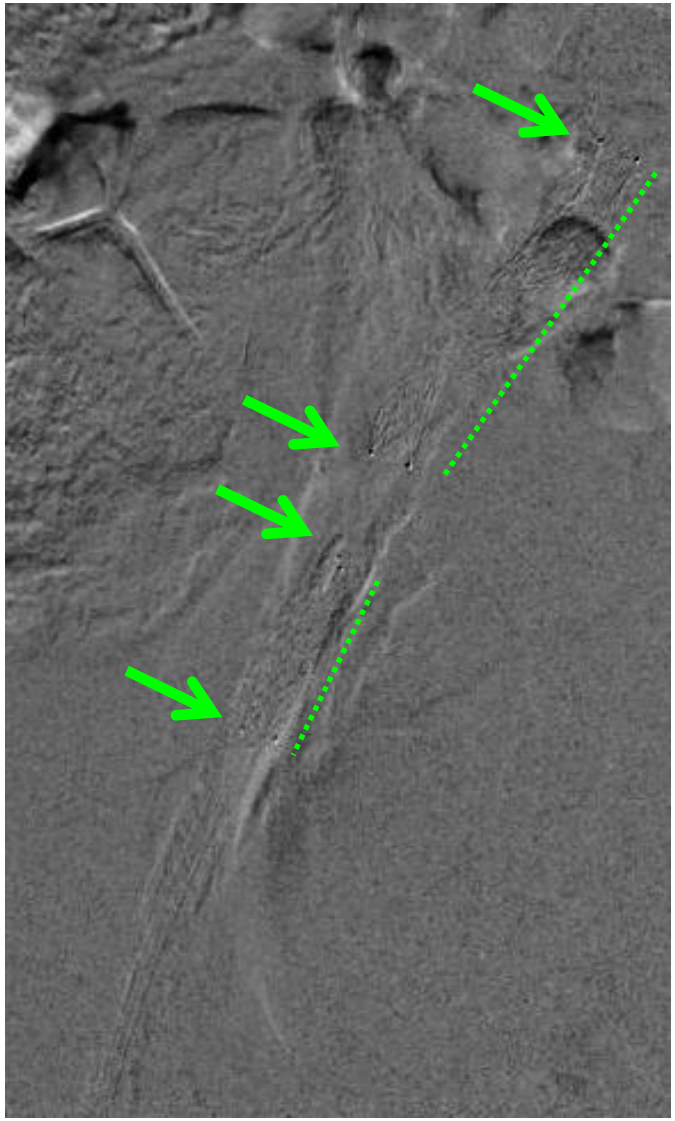




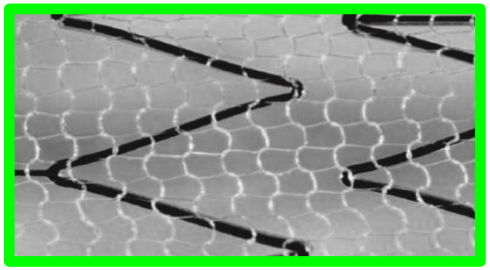
(V) Higly calcific disease

(note adequate radial force need)

CGuard™



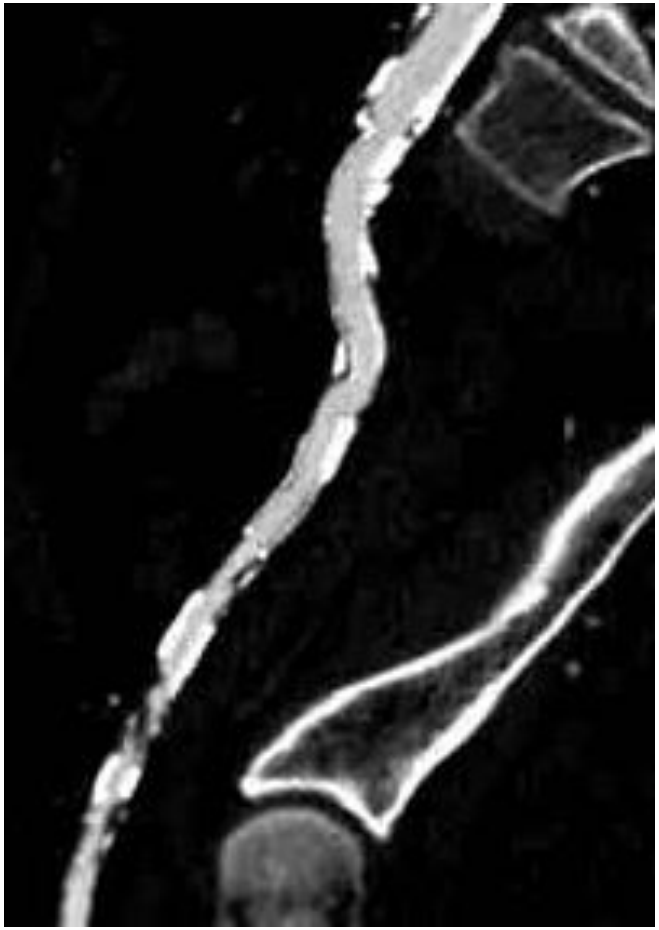
Acute Procedural Result

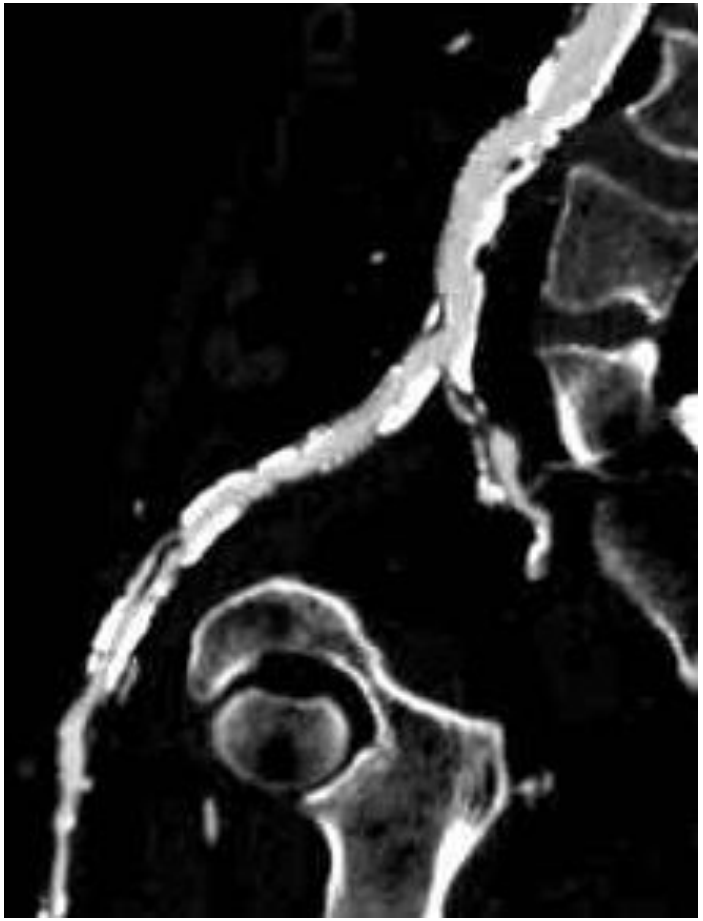


(V) Higly calcific disease

(note: adequate radial force provided)

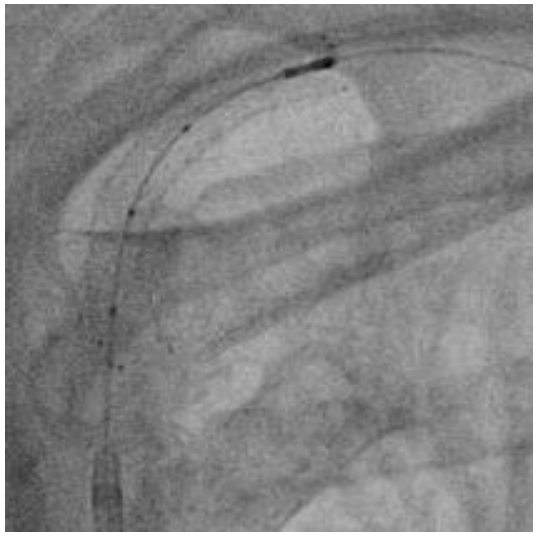
CGuard™

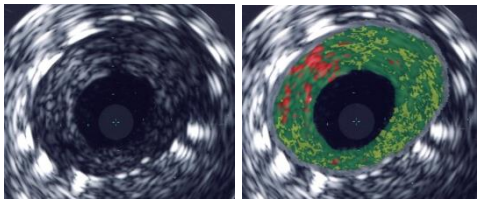


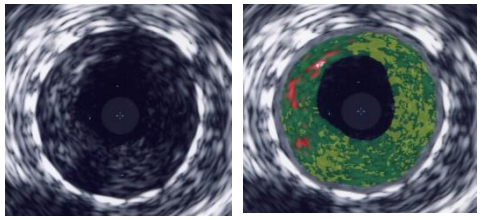


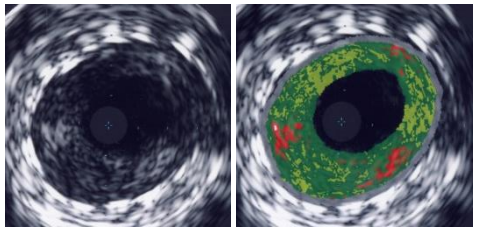
OPTIMAL result @ 6mo

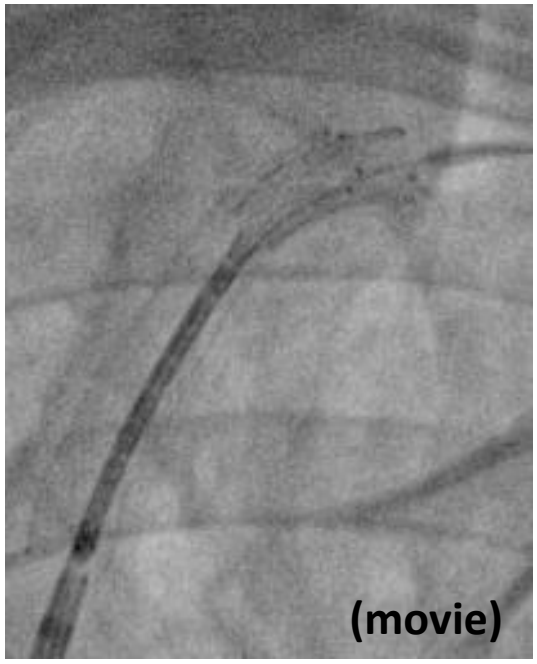
Neo-Atherosclerosis In A Conventional LSA Stent: Treated With CGuard™ under IVUS

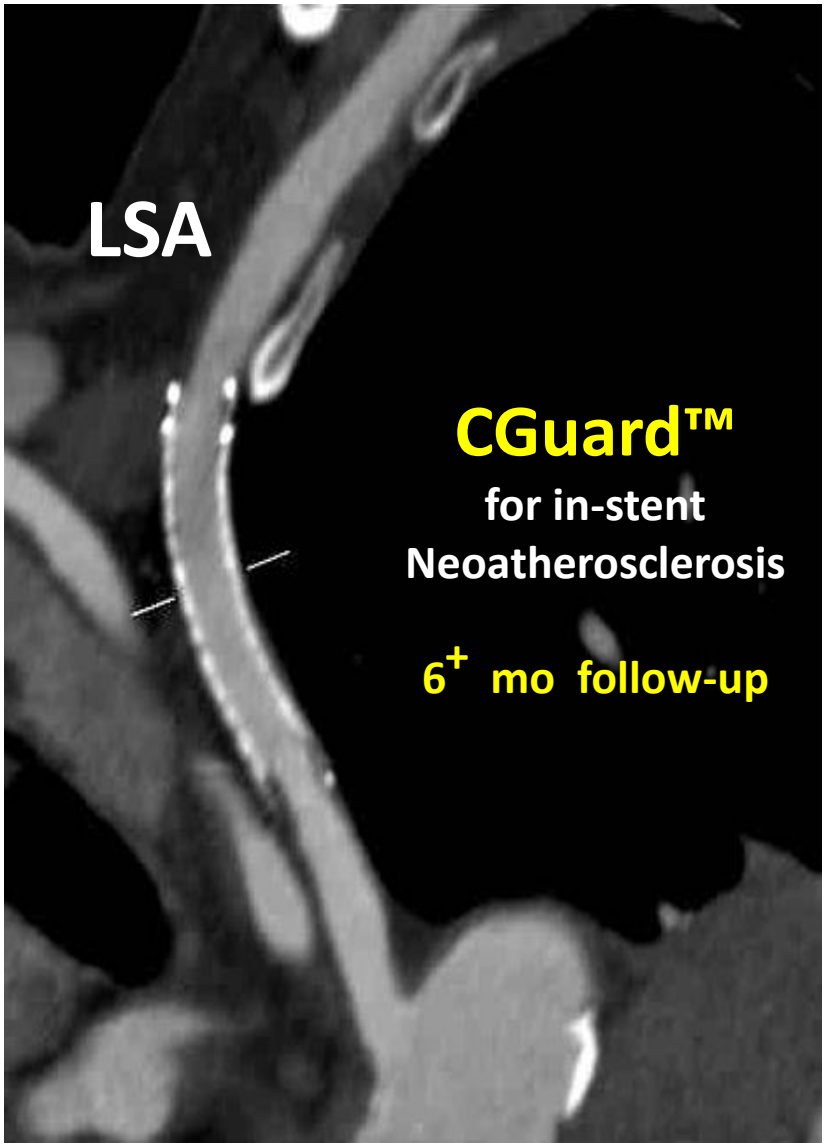






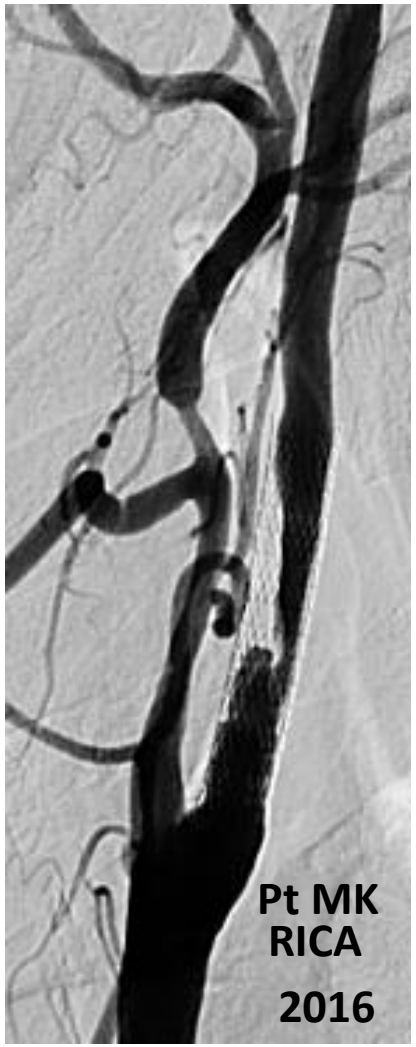


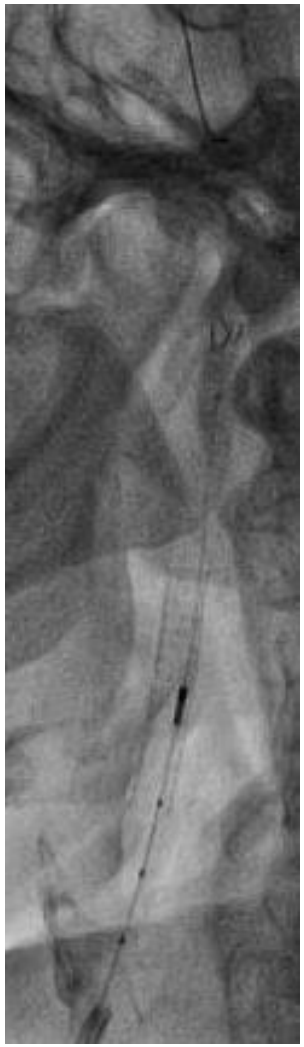


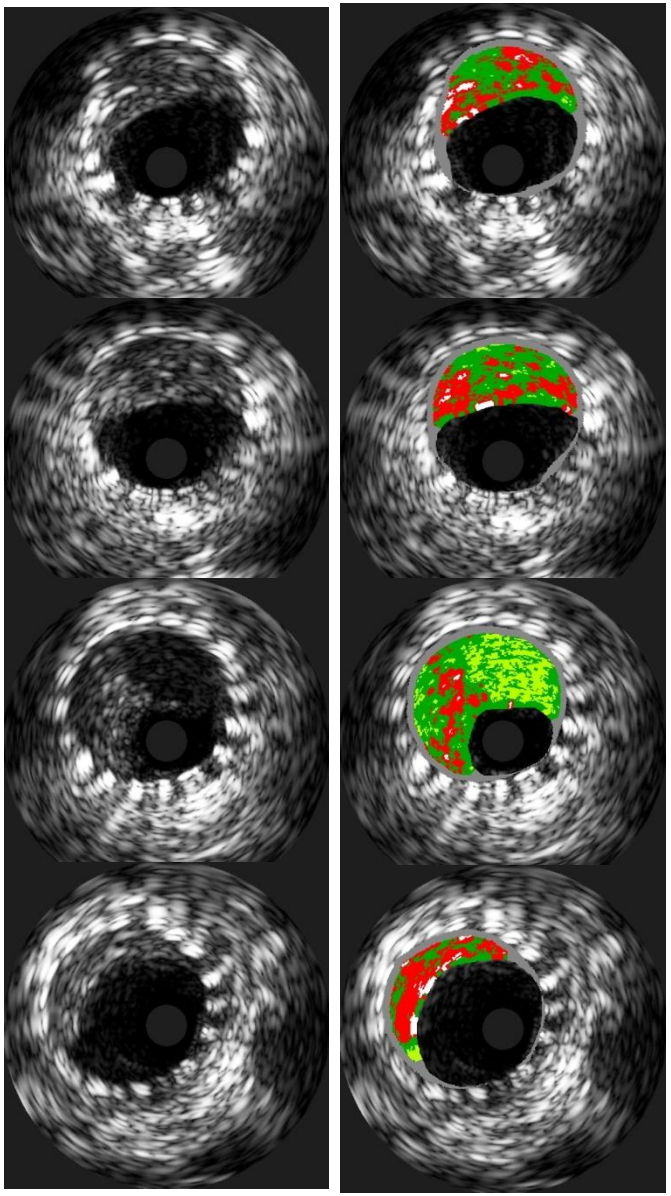


P Musialek @ VEITH 2018

Conventional Carotid Stent Design Allows Atherosclerotic Plaque In-Growth (ie., Neo-Atherosclerosis)







Precise 5.0x30mm (2005)

2014-2016 *"increasing in-stent restenosis"*

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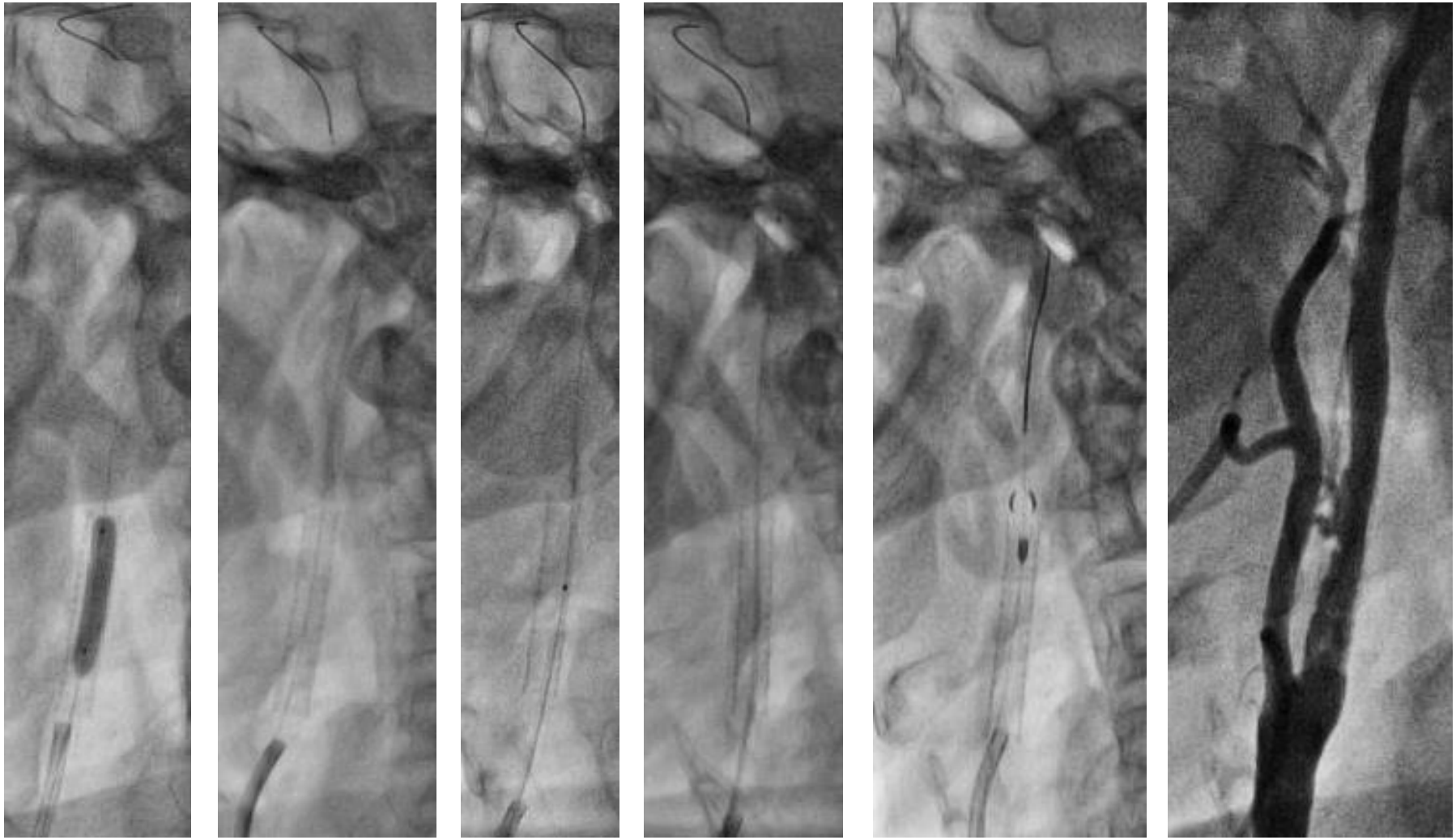
Atherosclerotic Plaque Growth Into The Open-Cell Stent Lumen

Treated with Neroprotected PTA Under IVUS – and CGuard™



PTA

No flow
(movie)

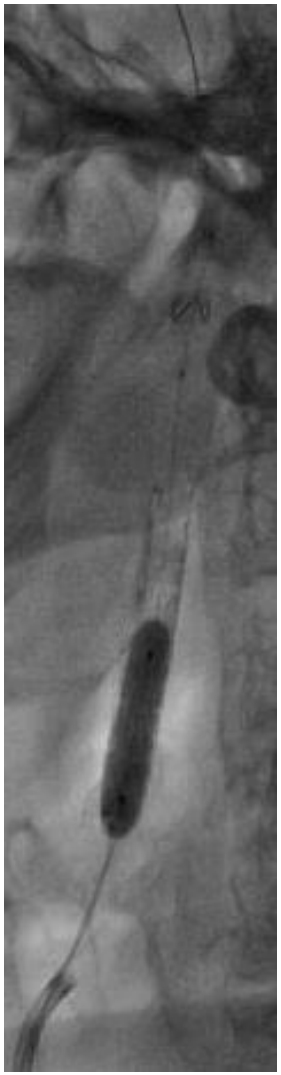
Aspiration

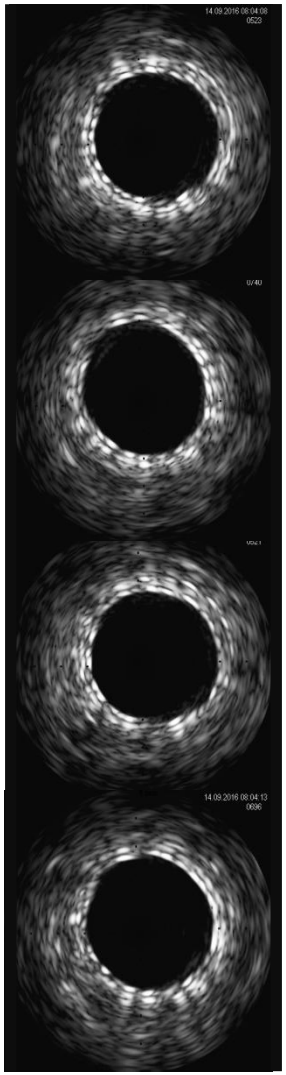
'Half-open'
Filter
Removal

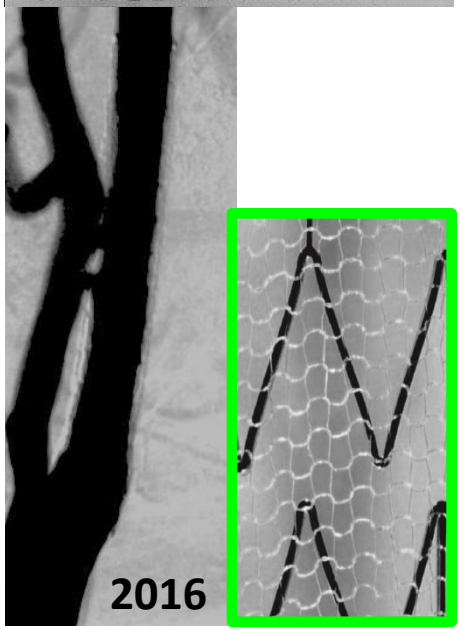
P Musialek @ VEITH 2018

Atherosclerotic Plaque Growth Into The Open-Cell Stent Lumen

Treated with Neroprotected PTA Under IVUS – and CGuard™



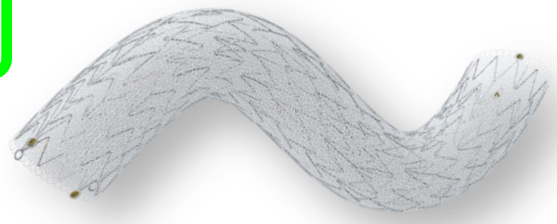


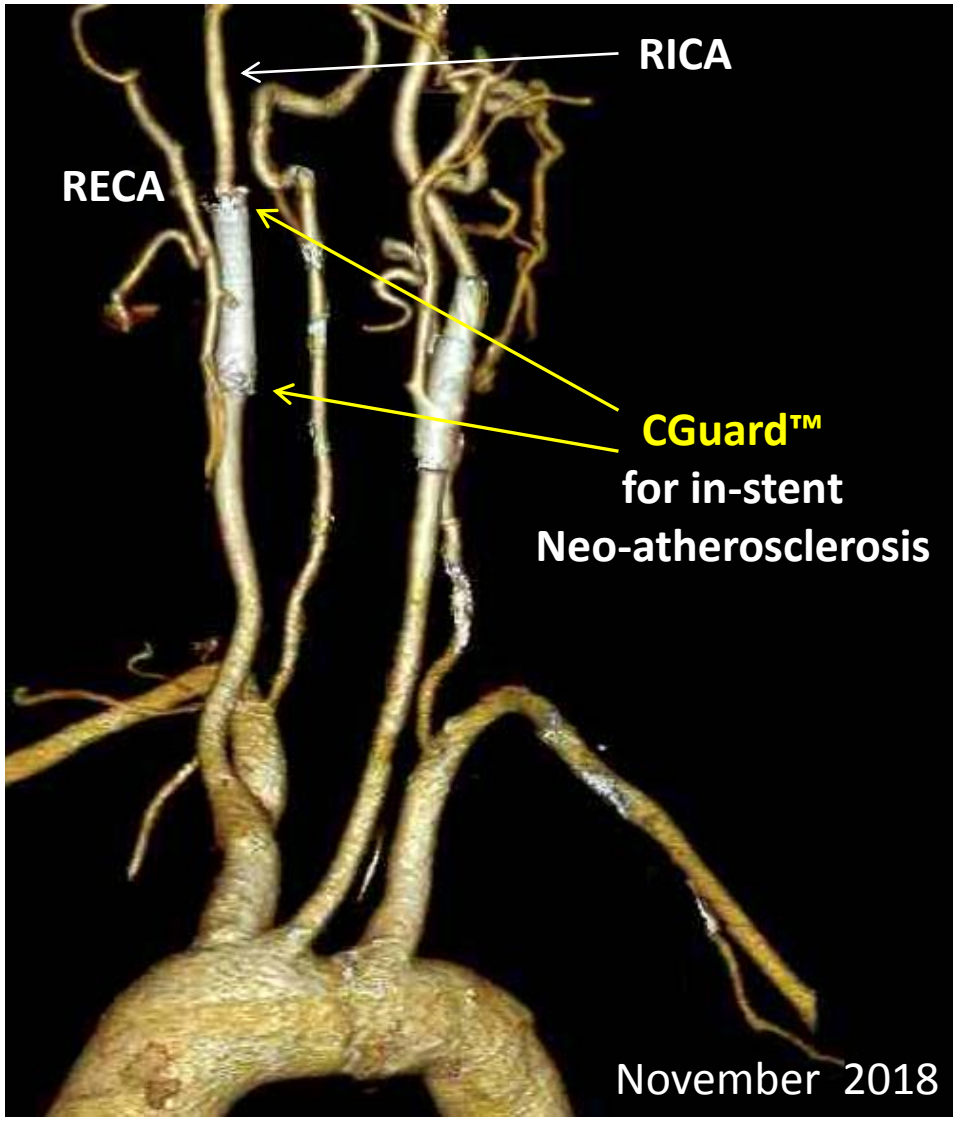


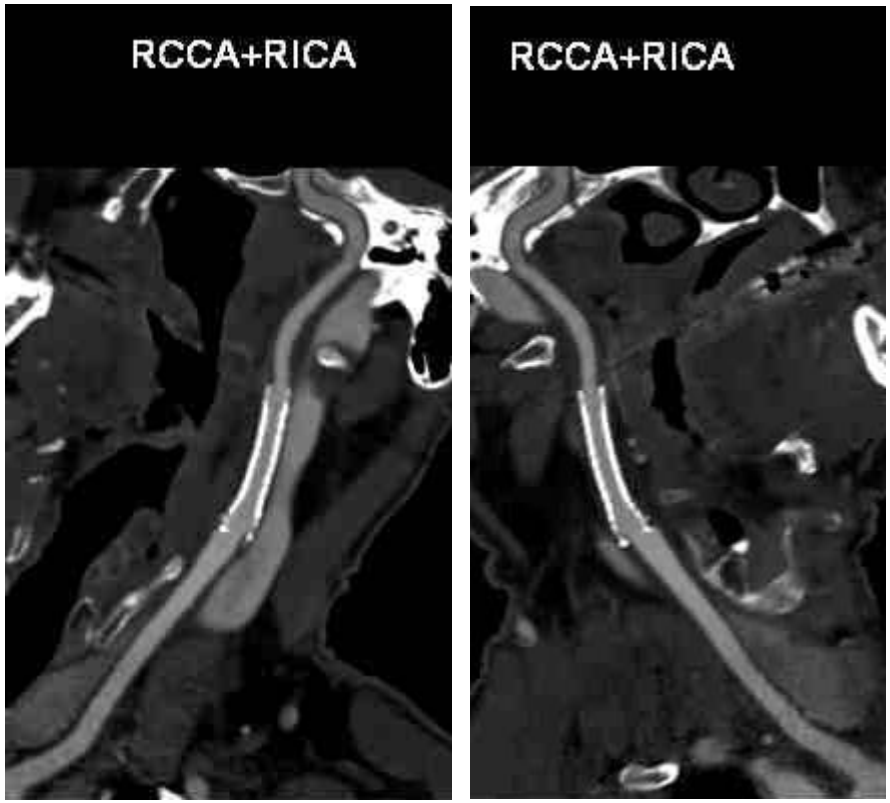
CGuard™ 8.0 x 40mm

CGuard™ For Symptomatic In-stent Neoatherosclerosis:

2-year follow-up







2018

(24 months)

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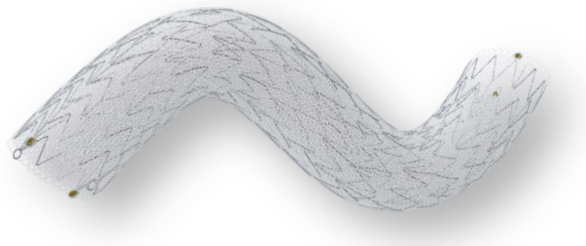
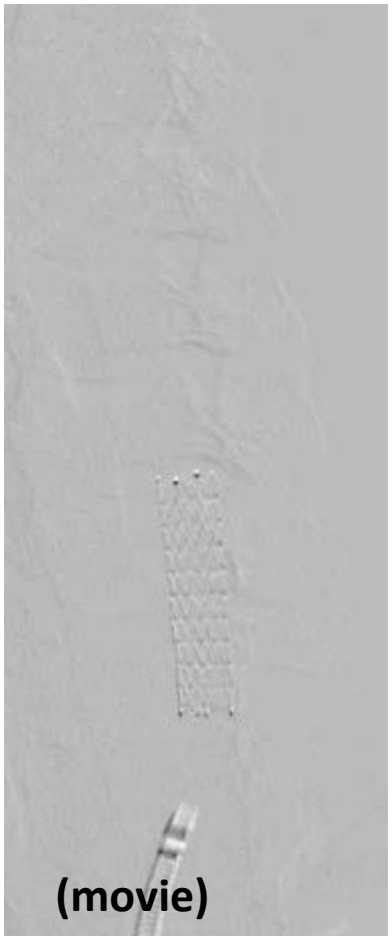
Aneurysm/Dissection

with recurrent symptoms

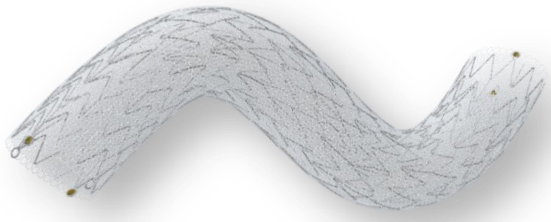




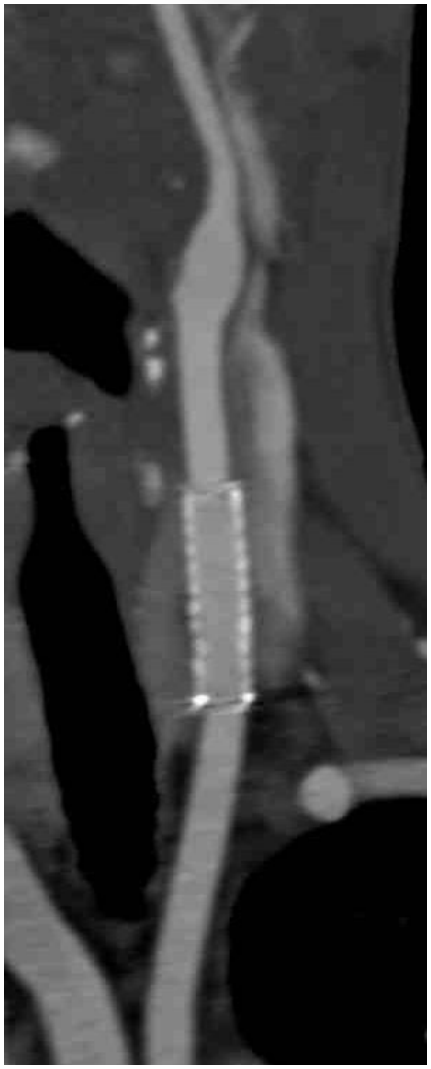
Immediate Post-Procedural Result

Aneurysm/Dissection

with recurrent symptoms



CGuard™

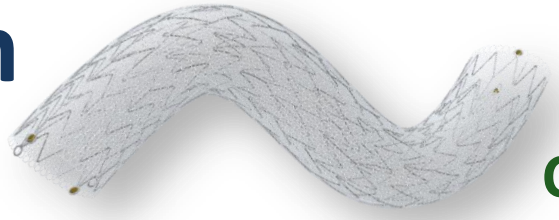


Totally SEALED @ 24h

P Musialek @ VEITH 2018

Aneurysm/Dissection

with recurrent symptoms



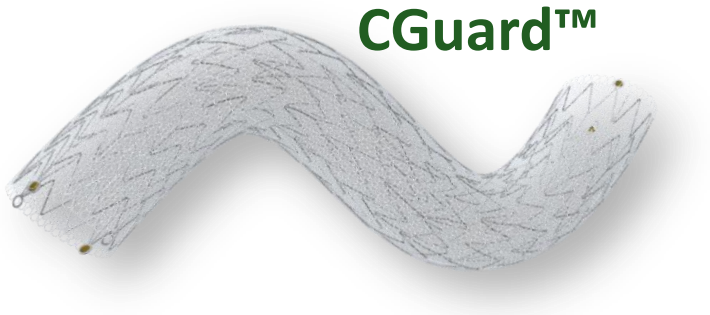
CGuard™

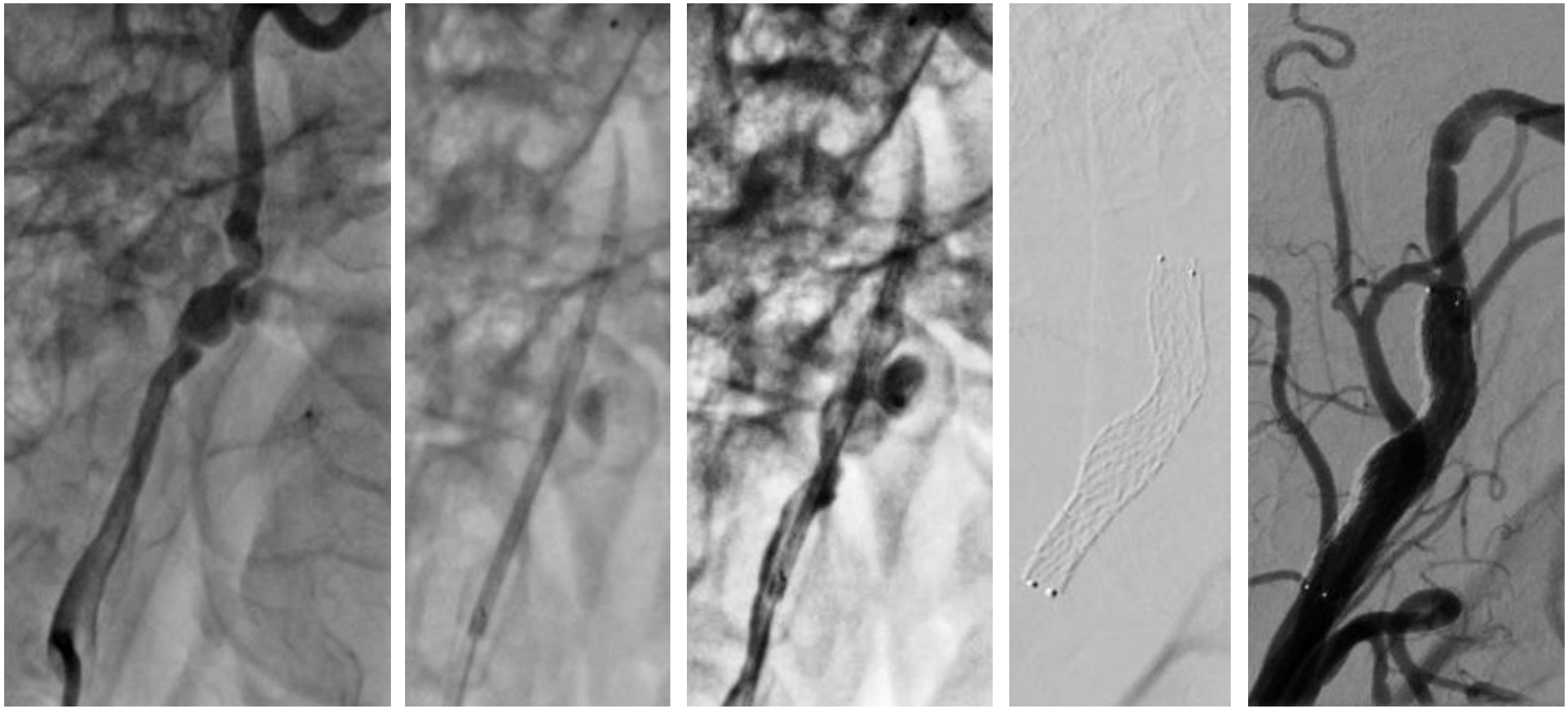
Normal Follow-up @ 6 months

P Musialek @ VEITH 2018

Aneurysm/Dissection

with recurrent symptoms

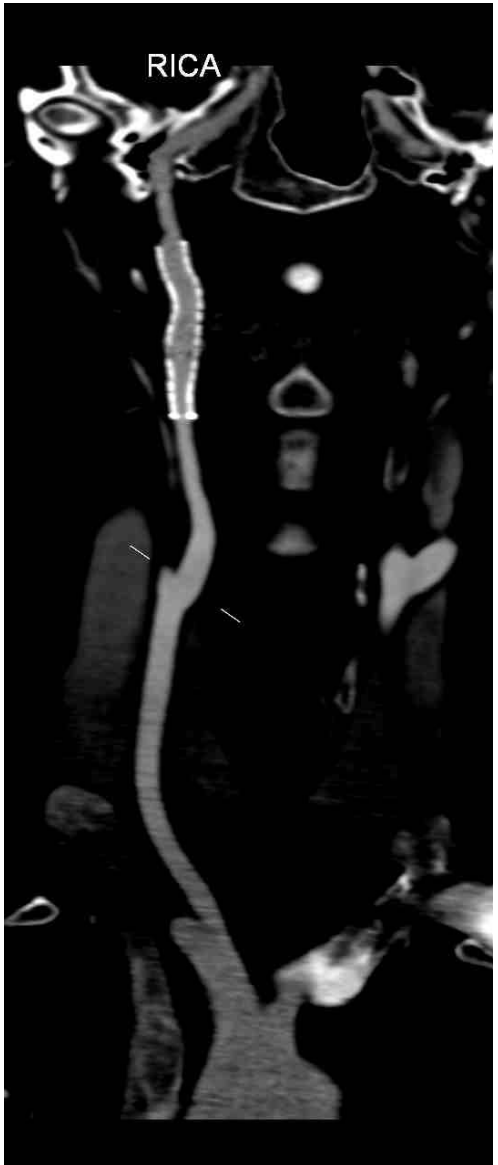




Immediate SEALING

Aneurysm/Dissection

with recurrent symptoms



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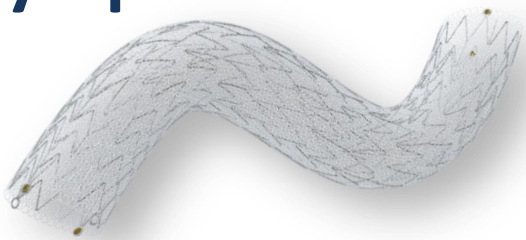
Normal Result @ 6 mo

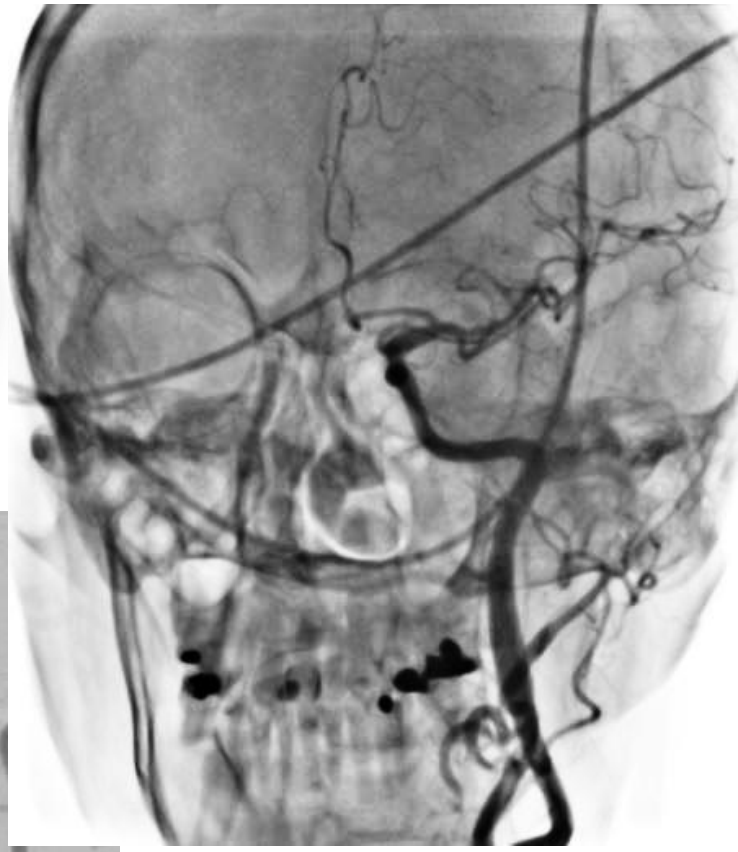
(Patient Asympt.)

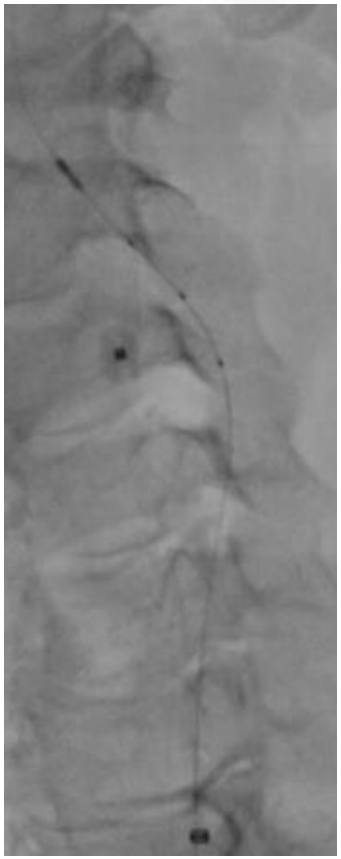
Non-Healing Dissection

with recurrent symptoms

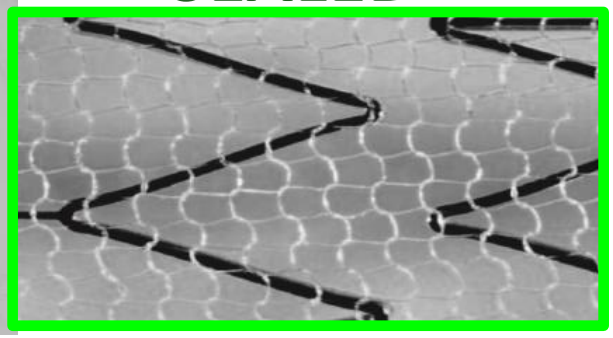
CGuard™







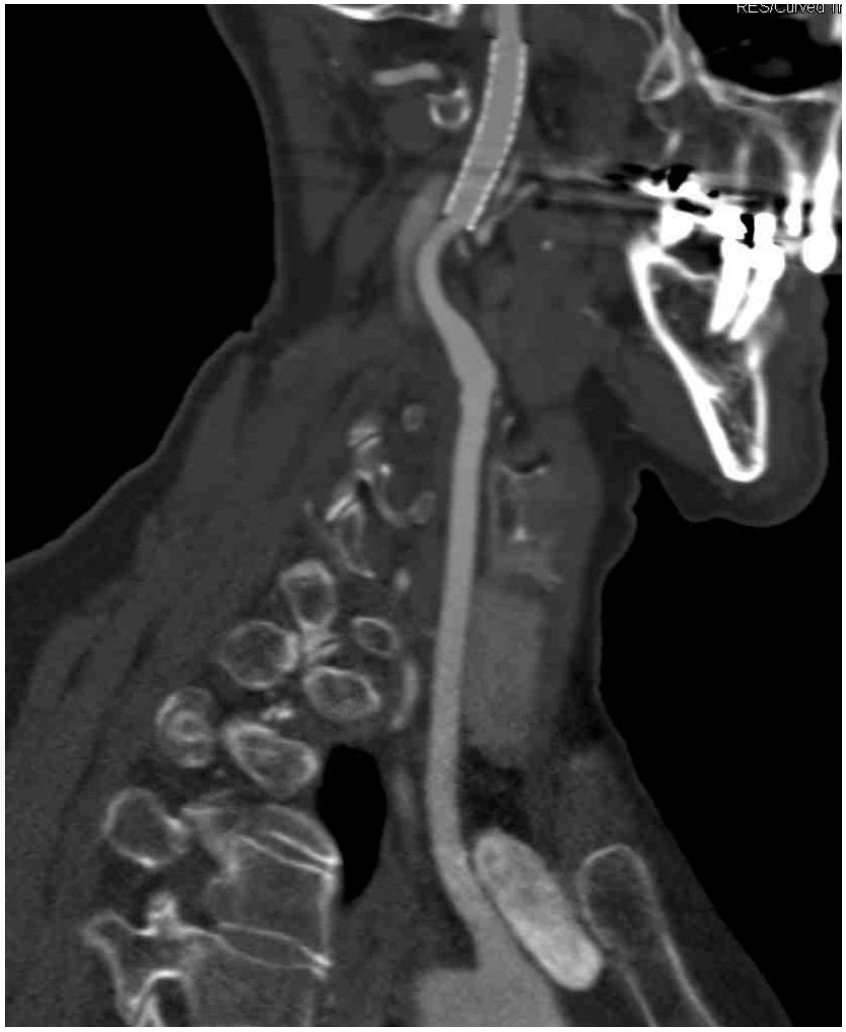
Immediately SEALED



MoMa, IVUS

Non-Healing Dissection

with recurrent symptoms



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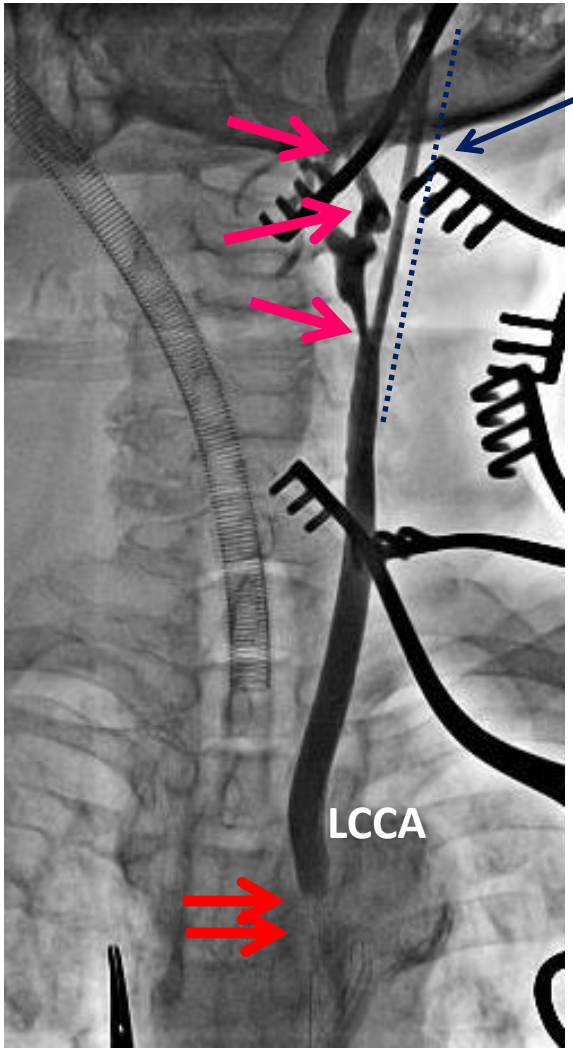
Normal 12 mo Follow-up Result

P Musialek @ VEITH 2018

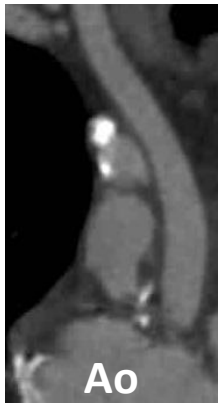
Ostial CCA lesions

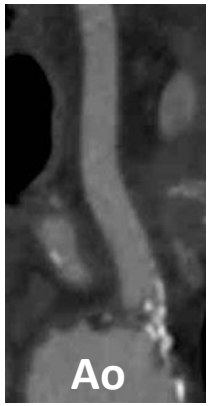
(note adequate radial force and placement percision need)

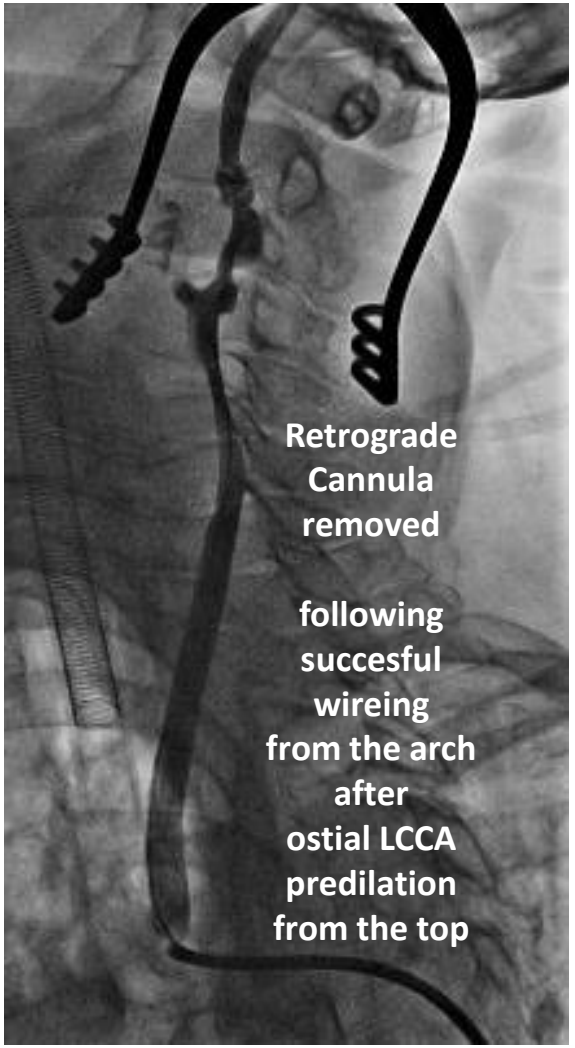


LCCA Retrograde Cannulation from the neck

(to wire and predilate the subtotal ostial LCCA; NB. failed access from the arch)



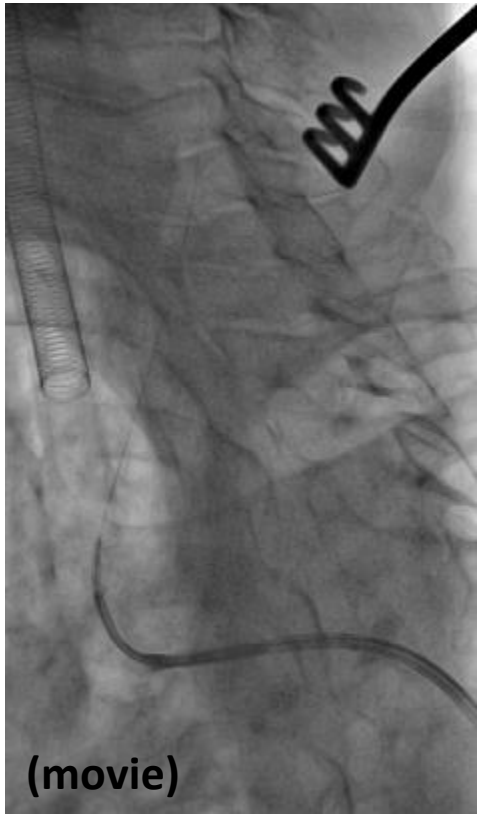


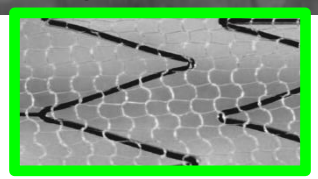


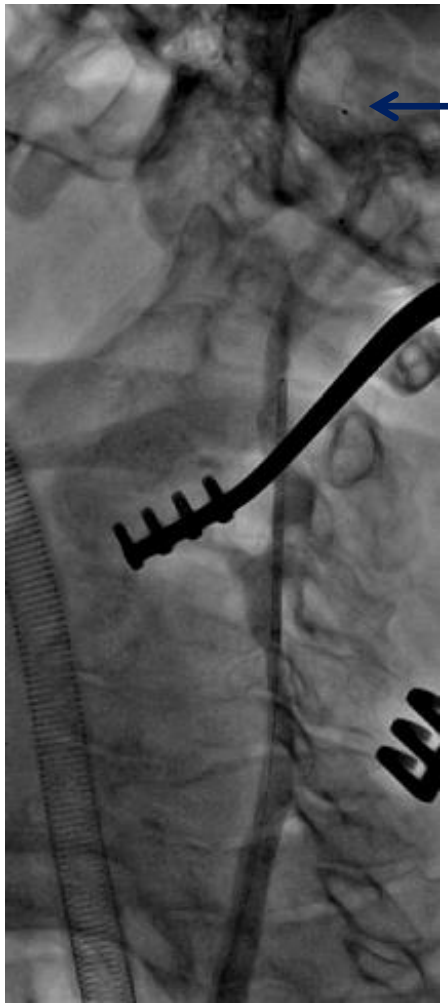
Lady 68 yo, retinal TIAs followed by <u>retinal stroke</u> while on OMT (mother to cathlab nurse)

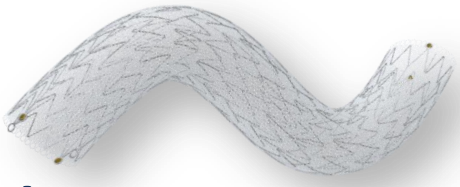
Ostial CCA lesions

(note adequate radial force and placement percision)



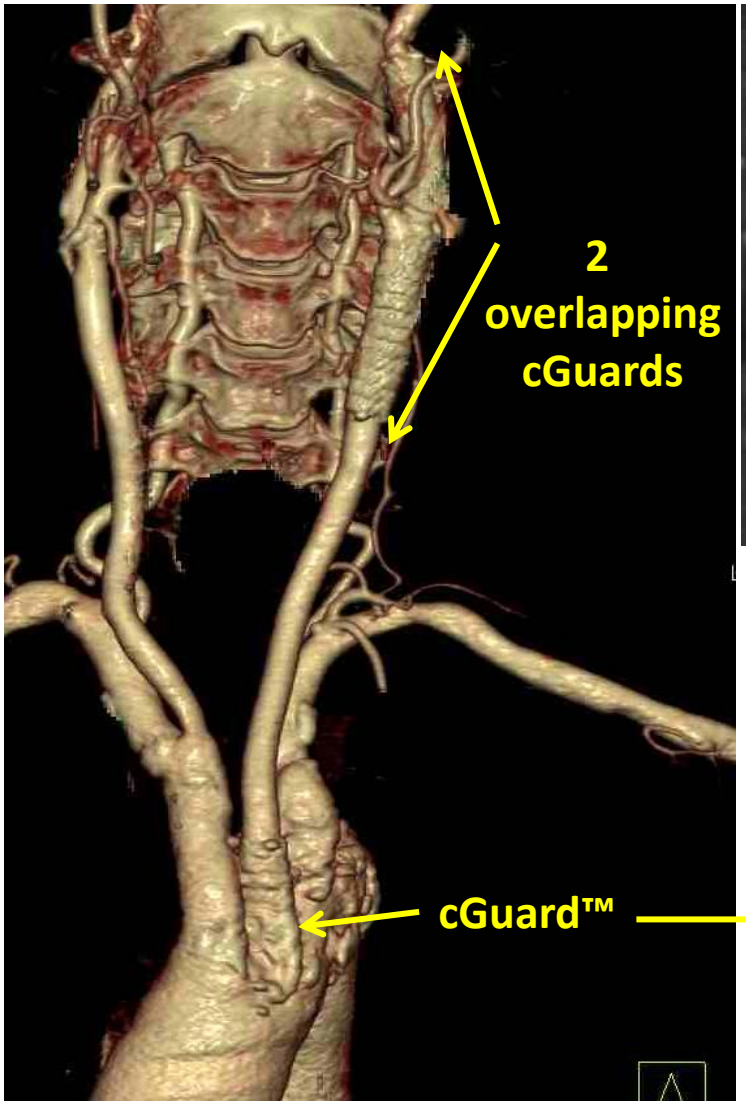


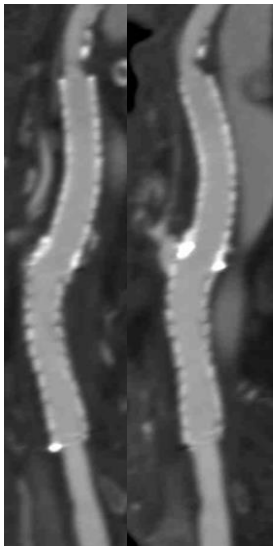




Ostial CCA lesions

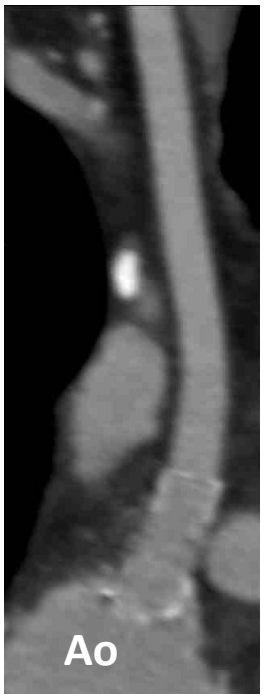
(note adequate radial force and placement percision)





OPTIMAL angiographic + clinical + duplex result @ 12mo

(and LECA patent)



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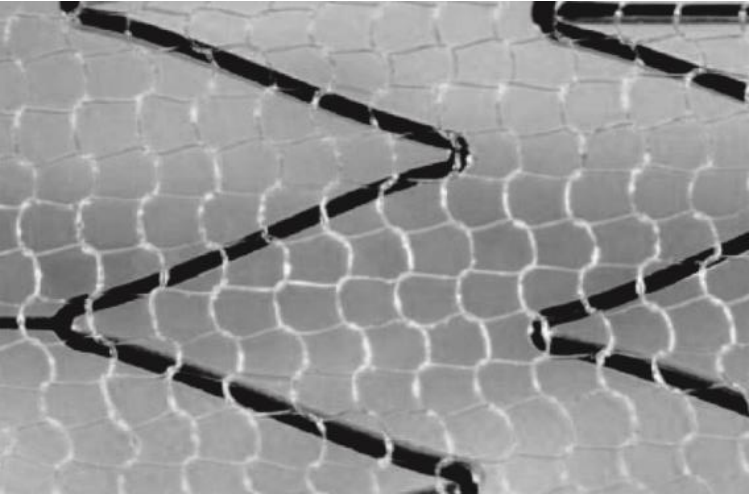
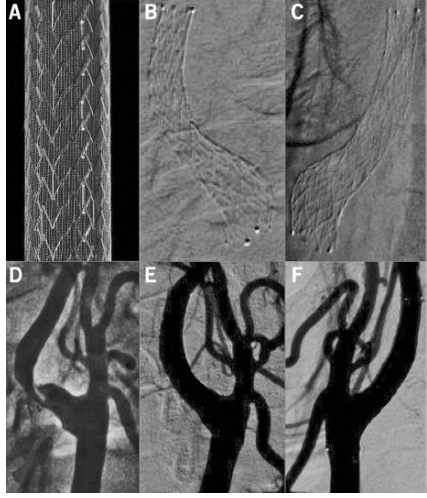


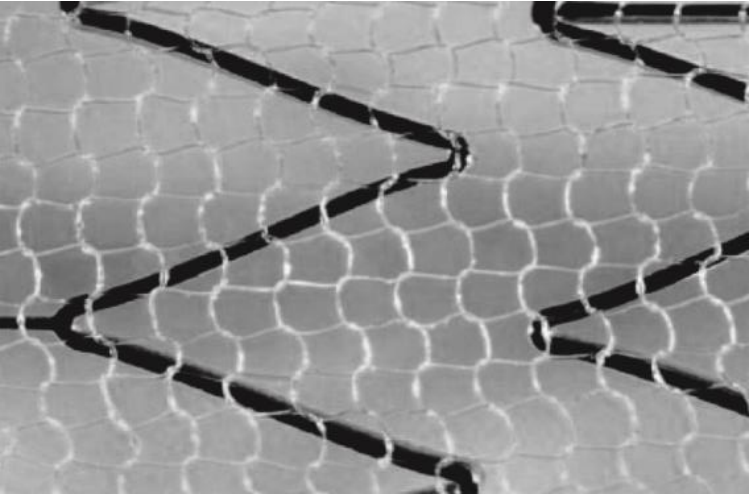


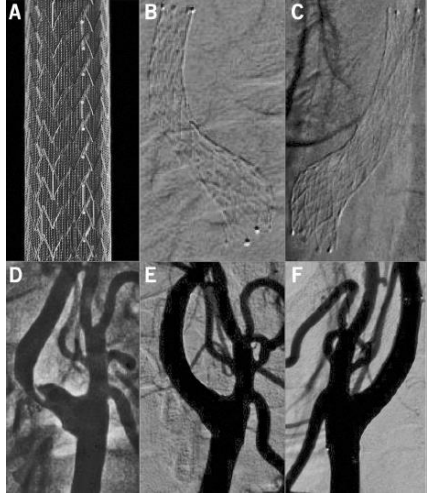
This concept has been desired.

And it works.

This is the future

of Carotid Artery Stenting





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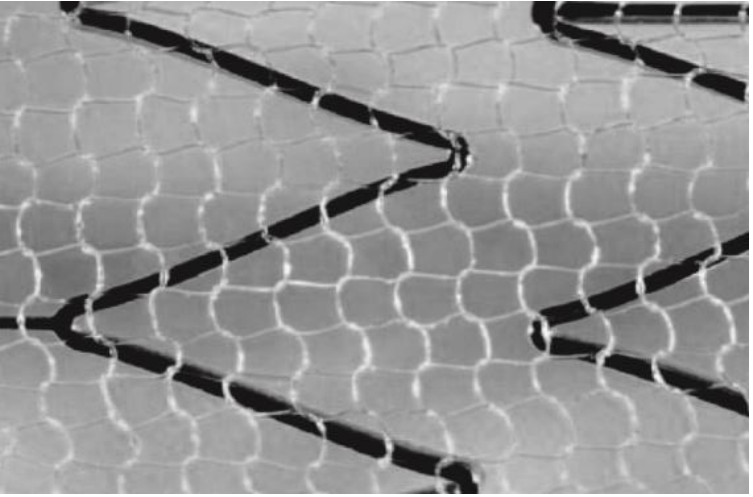
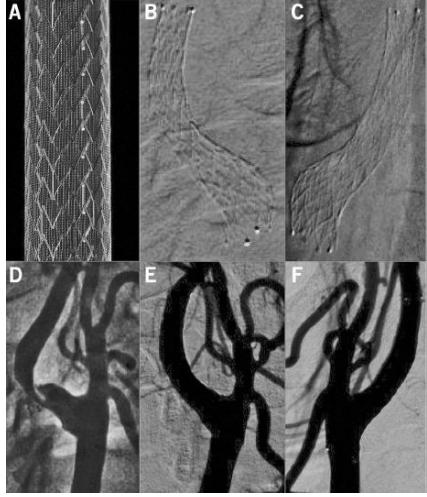
This is the future

of Carotid Artery ~~Stenting~~





This concept has been desired.

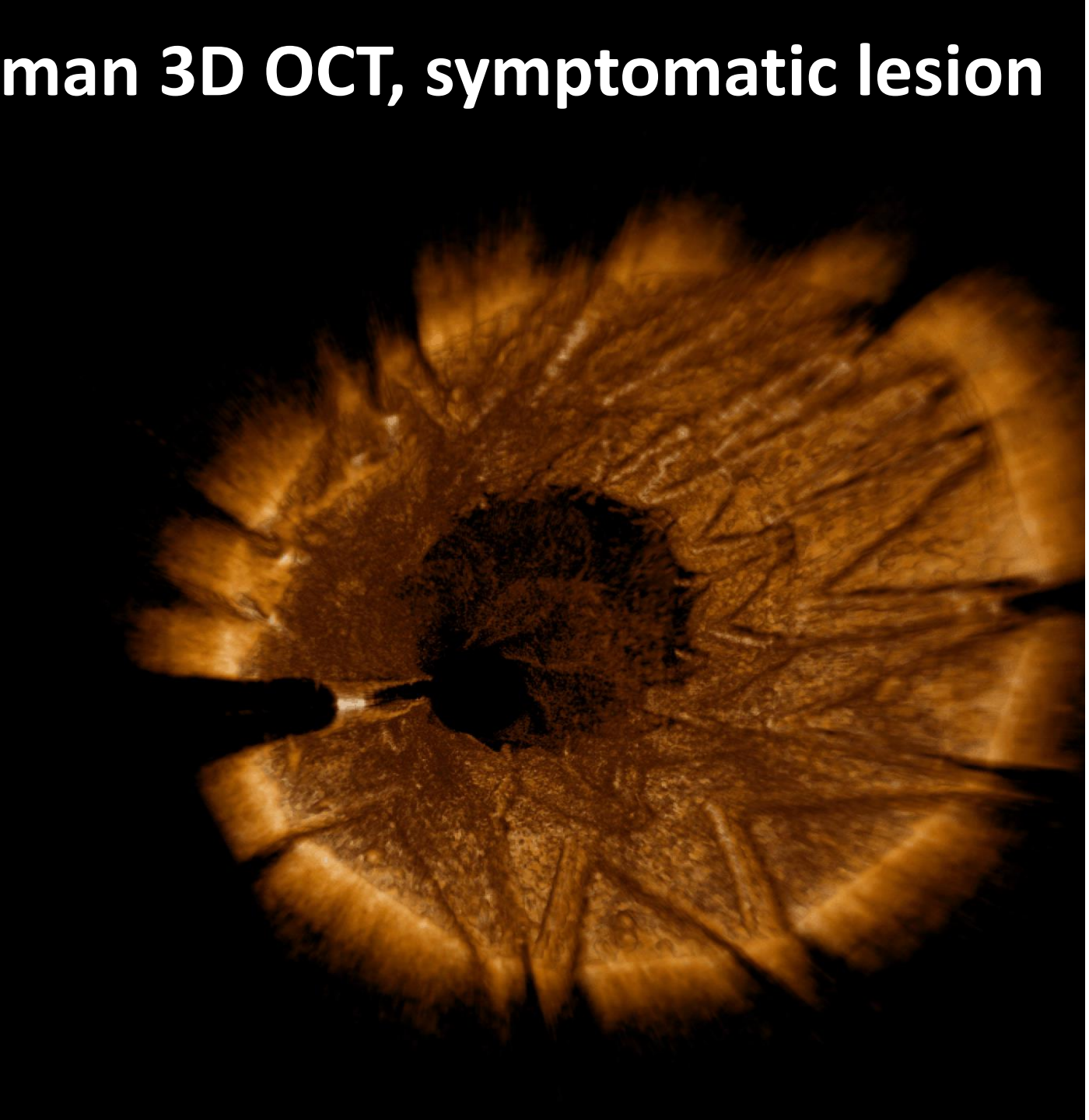
And it works.

This is the future

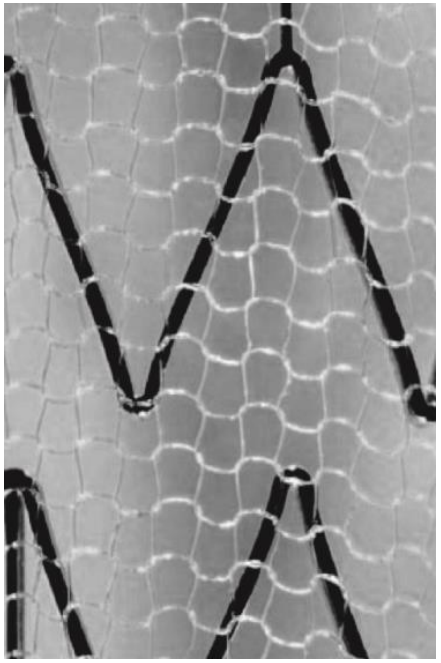
of Carotid Artery S[illegible]g

revascularization ?

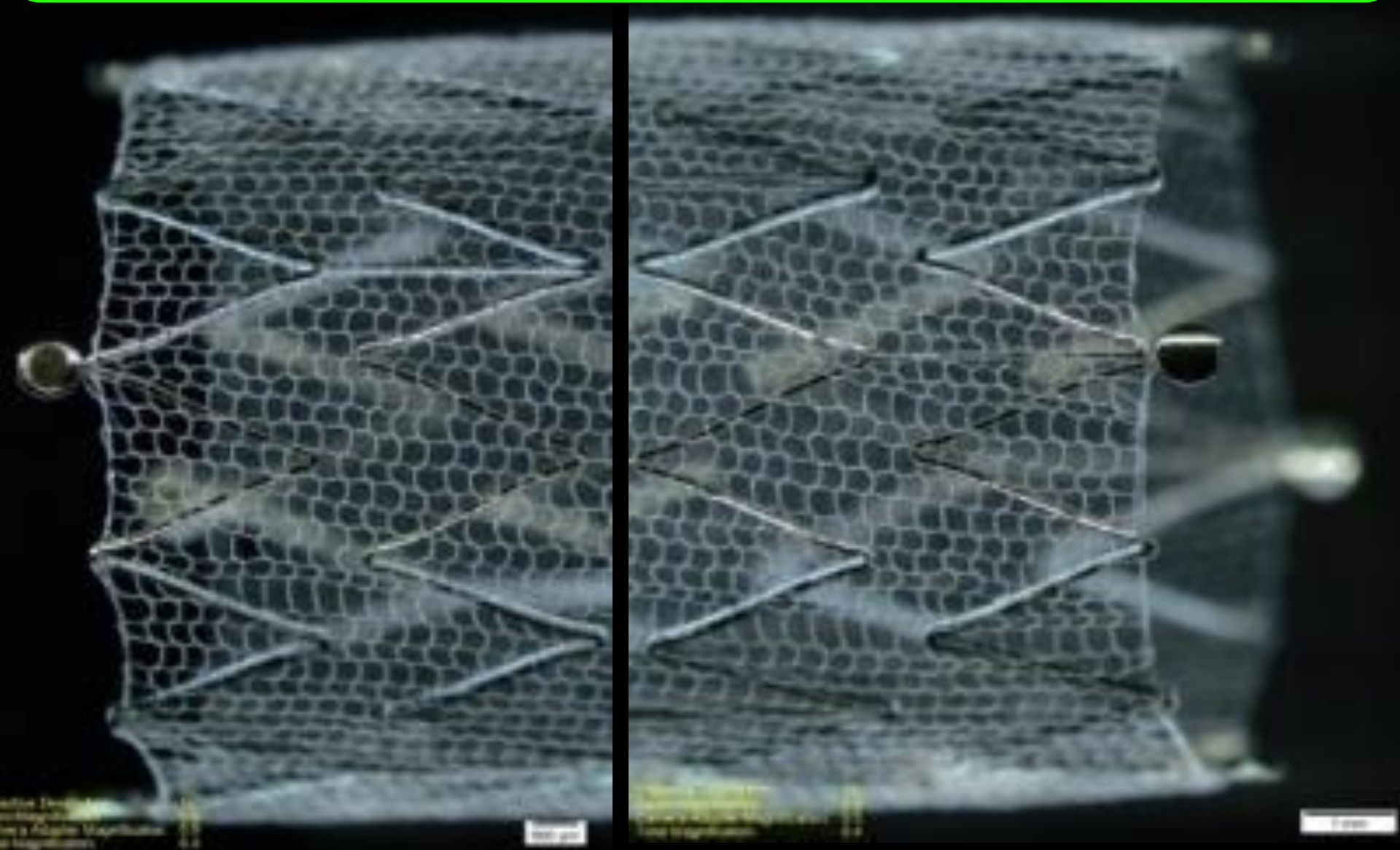
man 3D OCT, symptomatic lesion



CGuard™ EPS



CGuard™ embolic prevention system



One swallow does not a summer make but many swallows do: accumulating clinical evidence for nearly-eliminated peri-procedural and 30-day complications with mesh-covered stents transforms the carotid revascularisation field

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[2]Departments of Neurosurgery and Radiology, School of Medicine and Biomedical Sciences, University at Buffalo, State University of New York, Jacobs Institute, Gates Vascular Institute Kaleida Health, Buffalo, New York, USA

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Abstract

Atherosclerotic carotid artery stenosis (CS) continues to be a common cause of acute ischaemic stroke. Optimised medical therapy (OMT), the first-line treatment modality in CS, may reduce or delay – but it does not abolish – CS-related strokes. As per current AHA/ASA and ESC/ESVS/ESO guidelines, carotid artery stenting (CAS) is a less-invasive alternative to carotid endarterectomy (CEA) for CS revascularisation in primary and secondary stroke prevention.

Ten-year follow-up from the CREST trial in patients with symptomatic and asymptomatic CS confirmed equipoise of CAS and CEA in the primary endpoint. Nevertheless CAS – using a widely open-cell, first-generation stent and first-generation (distal/filter) neuroprotection – has been criticised for its relative excess of (mostly minor) strokes by 30 days, a significant proportion of which were post-procedural.

Atherosclerotic plaque protrusion through conventional carotid stent struts, confirmed on intravascular imaging, has been implicated as a leading mechanism of the relative excess of strokes with CAS vs. CEA, including delayed strokes with CAS. Different designs of mesh-covered carotid stents have been developed to prevent plaque prolapse. Several multi-centre/multi-specialty clinical studies with CGurad MicroNet-Covered Embolic Prevention Stent System (EPS) and RoadSaver/Casper were recently published and included routine DW-MRI cerebral imaging peri-procedurally and at 30 days (CGuard EPS).

Data from more than 550 patients in mesh-covered carotid stent clinical studies to-date show an overall 30-day complication rate of ~1% with near-elimination of post-procedural events. While more (and long-term) evidence is still anticipated, these results – taken together with optimised intra-procedural neuroprotection in CAS (increased use of proximal systems including trans-carotid dynamic flow reversal) and the positive 12-month mesh-covered stent data reports in 2017 – are transforming the carotid revascularisation field today.

Establishing effective algorithms to identify the asymptomatic subjects at stroke risk despite OMT, and large-scale studies with mesh-covered stents including long-term clinical and duplex ultrasound outcomes, are the next major goals.

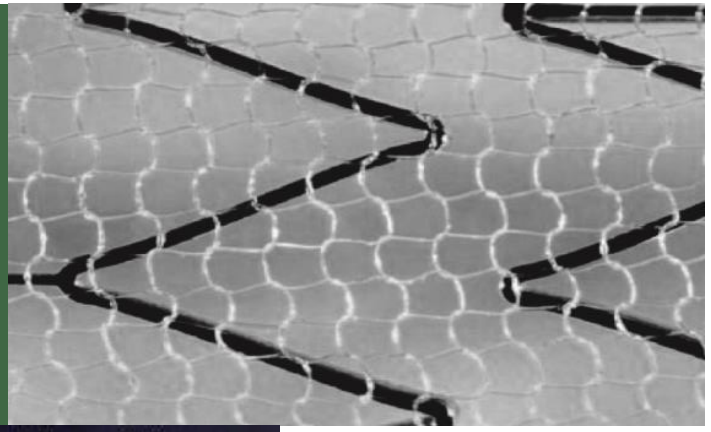
Key words: carotid artery stenting, mesh, stroke, endarterectomy, neuroprotection.

CGuard™ OCT

P Musialek @ VEITH 2018

2018 VEITH

VASCULAR ENDOVASCULAR ISSUES TECHNIQUES HORIZONS



THE VASCULAR WORLD TOGETHER IN NEW YORK

Update On Results With The CGuard™ MicroNet Covered Stent (InspireMD) For CAS: Does It Prevent Strokes: Does It Cause ISR Or Other Long-Term Problems: Can It Have Value In Other Vascular Beds?

Piotr Musialek, MD DPhil

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