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2021

VEITH SYMPOSIUM

New Multicenter Data Showing the Long-Term Value of the C-Guard MicroNet Covered Stent for High Risk Lesions (Thrombotic, Calcified and Symptomatic): From the Flow-Guard and Other Trials

Piotr Musialek, MD DPhil and **D. Christopher Metzger**, MD

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Conflicts of Interest

PM is a recipient of public grants for basic and clinical research in atherosclerisis and cardiovascular regeneration.
PM has acted as a proctor, an advisory board member, and a consultant for Abbott Vascular, InspireMD, and Medtronic.
PM is an initiator and Principal Investigator in Investigator-Run Clinical Studies in Cardiovascular Interventional Medicine.

DCM and PM are Co-PIs in the CGuardians FDA IDE Clinical Trial

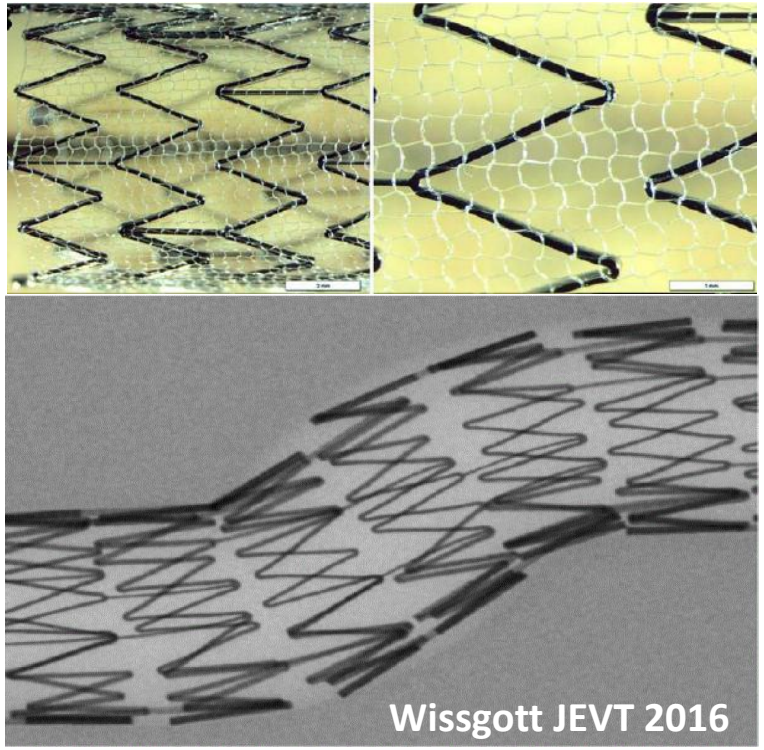
The **MOST 'open'** amongst open-cell stents (metallic FRAME) & the **MOST 'close'** amongst close-cell stents (MicroNet mesh)

CGuard MicroNET – covered
2nd generation carotid stent

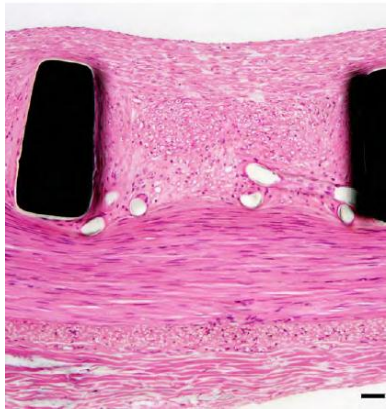
UNIQUE
mechanical
properties

RESPECT
of anatomy

FULL
apposition



NORMAL
healing



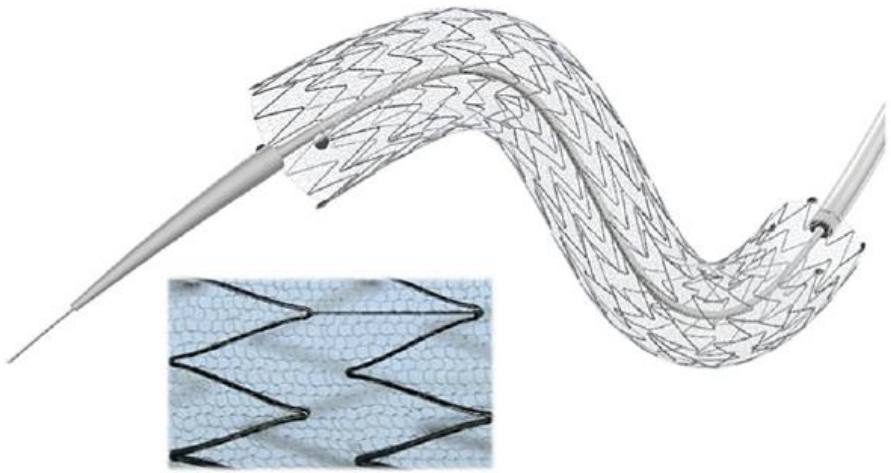
P Musialek @ VEITH 2021

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

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPhil,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD‖

FIGURE 1 CGuard System



The CGuard System is a carotid stent wrapped with MicroNet mesh, mounted on a self-expandable delivery system. The CGuard System is CE-marked and is available in an array of diameters (6 to 10 mm) and lengths (20 to 60 mm).

P Musialek @ VEITH 2021

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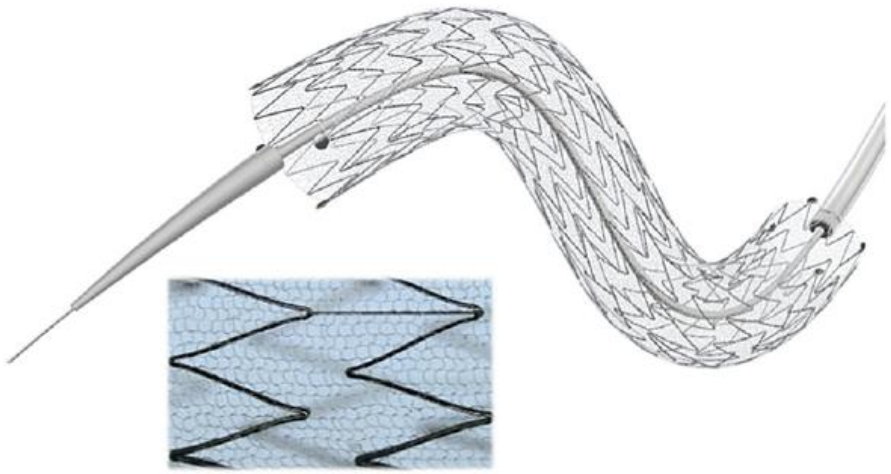

The CGuard System is a carotid stent wrapped with MicroNet mesh, mounted on a self-expandable delivery system. The CGuard System is CE-marked and is available in an array of diameters (6 to 10 mm) and lengths (20 to 60 mm).

DW-MRI: prior to CAS, 48h post-procedure, and at 30 days

- minimized peri-procedural cerebral embolism
- eliminated post-procedural embolism

JACC Intv 2015

P Musialek @ VEITH 2021

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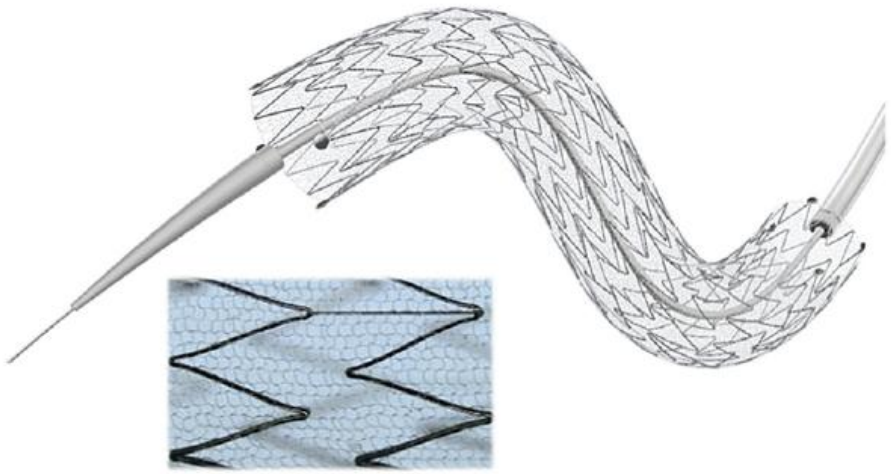

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JACC Intv 2015

OK…

….”but”

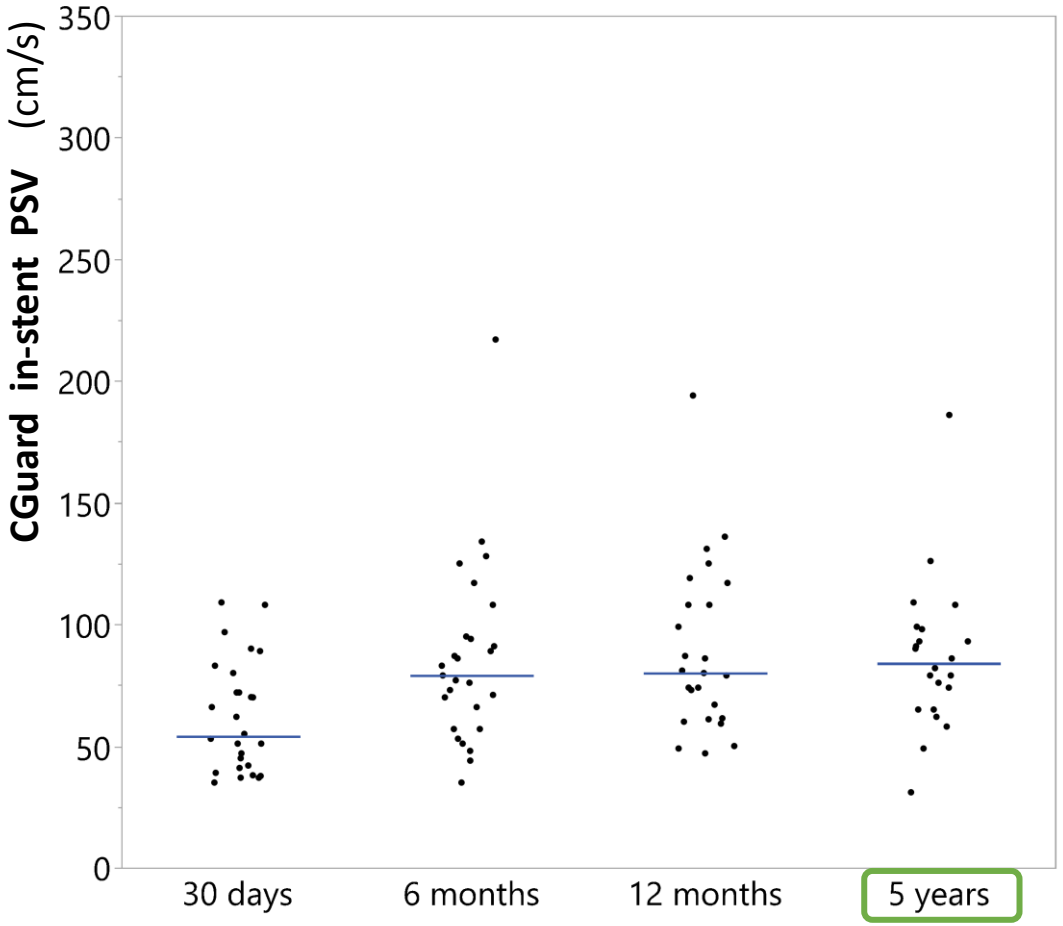
…. long-term?

P Musialek @ VEITH 2021

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

The CGuard CARENET Trial
(Carotid Embolic Protection Using MicroNet)

CARENET: 5y data



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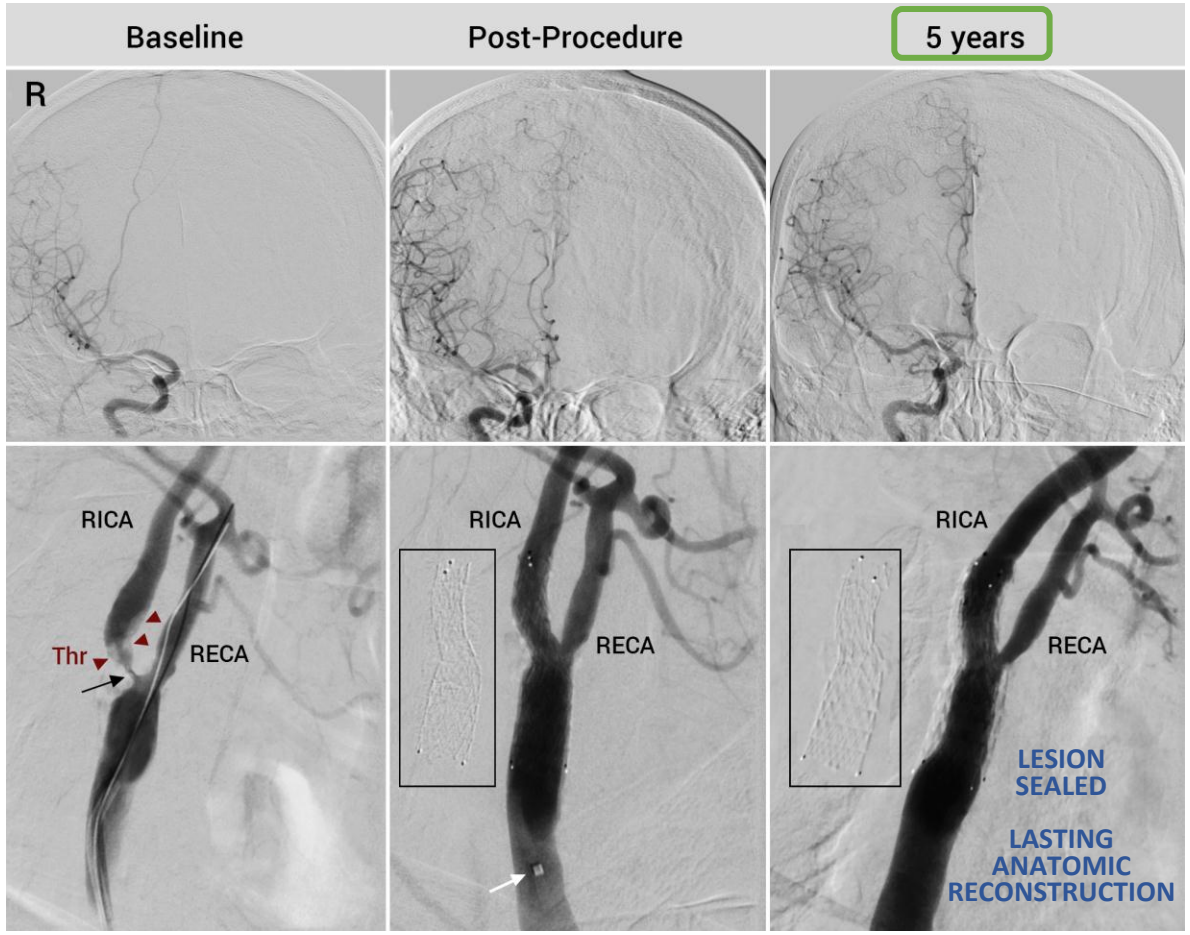
JACC Intv 2015



Musialek et al. 2021

MicroNET-covered stents for embolic prevention in patients undergoing carotid revascularisation: twelve-month outcomes from the PARADIGM study

- Normal healing
- No restenosis/thrombosis concern

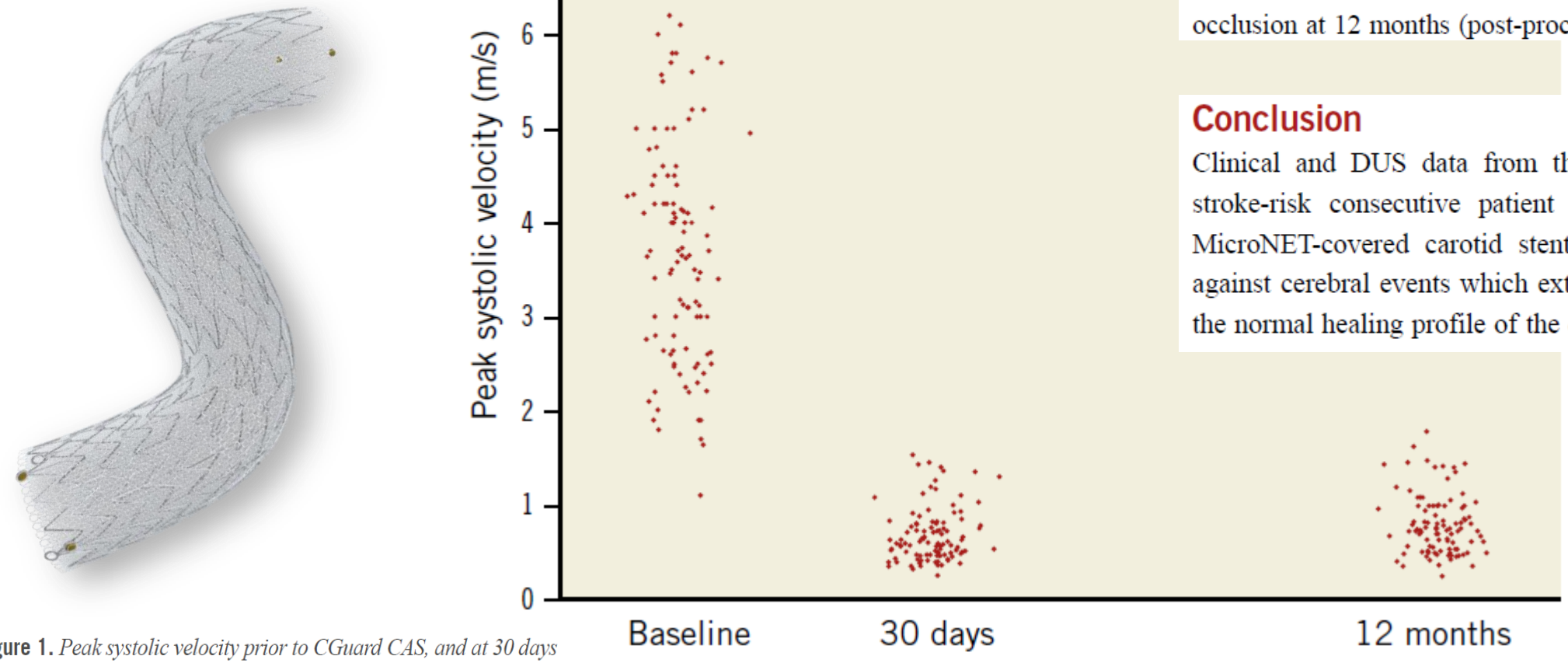


Figure 1. *Peak systolic velocity prior to CGuard CAS, and at 30 days and 12 months after the procedure. Individual patient/artery data for all study subjects.*

Prior to CAS, 6/106 (5.6%) external carotid arteries (ECAs) were occluded on the target lesion side, whereas 3/100 (3.0%; severe ECA stenosis prior to CAS in all) occluded at CAS. No ECA occlusion occurred between CAS and 30 days and there was no new ECA occlusion at 12 months (post-procedural ECA occlusion rate 0%).

Conclusion

Clinical and DUS data from this symptomatic and increased-stroke-risk consecutive patient series are consistent with the MicroNET-covered carotid stent providing effective protection against cerebral events which extends post-procedurally and with the normal healing profile of the device.

A Mazurek et al. *EuroIntervention* 2020

BEST POSTER ESC 2020

Long-term outcomes from the micronet-covered stent system routine use for carotid revascularization in primary and secondary stroke prevention: 5-year evidence from the PARADIGM-Extend prospective academic study

A. Mazurek[1], A. Borratyńska[2], T. Tomaszewski[2], A. Lesniak-Sobelga[1], P. Wilkolek[1], U. Gancarczyk[1], M. Brozda[1], E. Sobieraj[1], M. Sikorska[1], L. Czyz[1], M. Urbanczyk[3], M. Trystula[4], T. Drazkiewicz[4], P. Podolec[1], P. Musialek[1]

[1]Jagiellonian University Department. of Cardiac & Vascular Diseases and Cathlab, John Paul II Hospital, Krakow, Poland, [2] John Paul II Hospital Department of Neurology and Outpatient Neurology Clinic, Krakow, Poland, [3] John Paul II Hospital Dept. of Radiology, Krakow, Poland, [4] John Paul II Hospital Dept. of Vascular Surgery, Krakow, Poland

PARADIGM-Extend = Prospective evaluation of All-comer peRcutaneous cArotiD revascularization in symptomatic and Increased-stroke-risk asymptomatic carotid artery stenosis using CGuard™ Micronet-covered embolic prevention stent system – clinical study extension

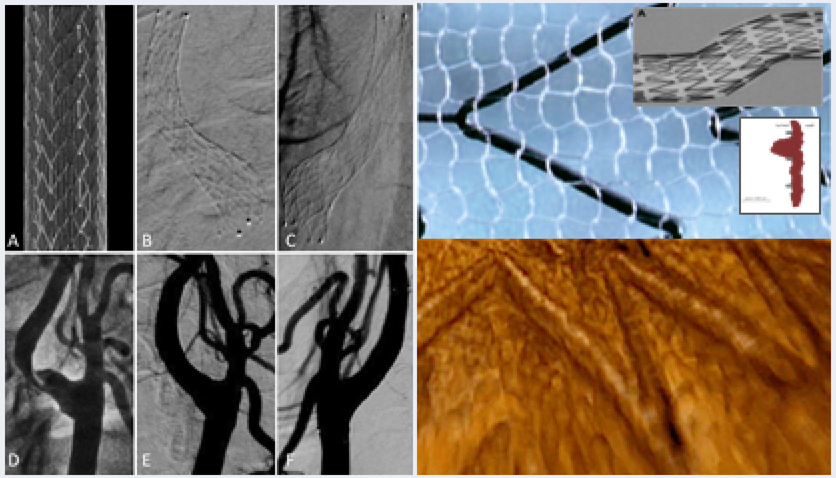
Background

The CGuard™ EPS system is a dual layer (hybrid) stent which consists of nitinol, open-cell frame wrapped with ultra-closed-cell polyethylene terephthalate (PET) MicroNet

Principal stent features:

- large open cell area of the nitinol frame (21.66 mm^2)
- high flexibility and high conformability consistent with the open cell stent design
- ultra-low cell area of MicroNet (0.023-0.032mm^2) with the MicroNet fibre thickness of 20μm prevent the "cheese grater effect"
- optimal radial force - 0.055 N/mm (comparable to the Precise stent)
- placement predictability/ precision and lack of foreshortening after implantation.

Diffusion-weighted magnetic resonance imaging indicates that micronet-covered embolic prevention stent system effectively minimizes peri-procedural and prevents lesion-related post-procedural cerebral embolism in carotid artery stenting but long-term clinical evidence is missing.



Purpose

To evaluate long-term clinical/neurologic and duplex ultrasound (DUS) outcomes of the MicroNET-covered stent system routine use in unselected, consecutive patients with a confirmed indication for carotid revascularization for primary or secondary stroke prevention.

Methods

PARADIGM-EXTEND is in all-comer, all-referrals-tracked study with no exclusion criteria other than lack of NeuroVascular Team-determined indication. Clinically asymptomatic patients receive revascularization only in case of increased-stroke-risk characteristics. Adverse events are independently adjudicated.

Results

- **480 patients (39-87 yo, 59.8% symptomatic, 142 women), 514 arteries - crossed 30 day follow up period**
- 100% MicroNet-covered embolic prevention stent system use (ie, not a single other stent type has been used throughout study duration).
- **Proximal/distal intra-procedural neuroprotection use was 39.2%/60.8%.**
- Large balloon/high-pressure stent optimization was routinely performed, leading to a single-digit (6.7%) mean post-procedural residual angiographic stenosis.
- Adequate heparinization, with ACT control (≥250 s)
- Independent neurologist and duplex evaluation are performed before and after (48h and 30 days, then yearly) carotid revascularization.

Peri-procedural safety and clinical outcomes:

- peri-procedural death or major ischemic stroke (IS) rate was 0%.
- two events were adjudicated as minor IS (0.42%) – extension of prior infarct scar in a patient with prolonged hypotension; diplopia, that recovered after 24h with new lesions on brain imaging
- myocardial infarction (MI) (type 2; 0.21%) - two-vessel non-revascularizable CTO.

30-day follow-ups:

- total death/stroke rate at 30 days - 0.83%, and total death/stroke/MI rate at 30 days was 1.04%
- one IS haemorrhagic transformation leading to death (0.21 %)
- one bleeding-related death (0.21%)
- no major IS by 30 days (0.0%)

Long-term follow-up

	12 mo	24 mo	36 mo	48 mo	60 mo
	n = 354	n= 248	n= 173	n=106	n=46
Ipsilateral stroke	1* (device unrelated)	0	0	0	1* (device unrelated)
Any stroke	1	2 (1-cerebellum)	1 (brain stem)	1 (contralateral)	1
Stroke related death	0	0	0	0	1
MI or other non - cerebral VA	1	3	2	2	0
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Duplex ultrasound (DUS) in-stent/ lesion velocites (m/s)

	PSV ± SD	EDV ± SD
Baseline	3.76 ± 1.34	0.64 ± 0.71
Post-procedural	0.69 ± 0.28	0.18 ± 0.09
12 mo	0.78 ± 0.40	0.21 ± 0.11
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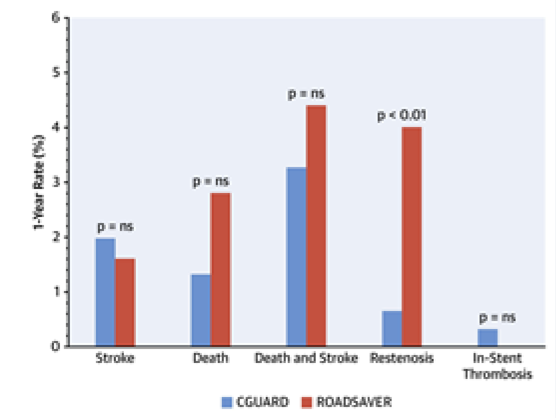
Use of Dual-Layered Stents for Carotid Artery Angioplasty: 1-Year Results of a Patient-Based Meta-Analysis; (RoadSaver-250; CGuard-306)



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PARADIGM-Extend long-term clinical and duplex ultrasound evidence is consistent with normal healing and sustained safety and stroke prevention efficacy of the micronet-covered embolic prevention stent system used routinely, on top of optimized medical therapy, for stroke prevention in symptomatic and increased-stroke-risk asymptomatic subjects with carotid stenosis with the NeuroVascular Team-established recommnendation for carotid artery revascularization.

Corresponding author

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Phone : +48 126142287, +48126143399 Fax : +48 126143332; Email : pmusialek@szpitaljp2.krakow.pl

BEST POSTER ESC 2020

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CAROTID PARADIGM REVASCULARIZATION

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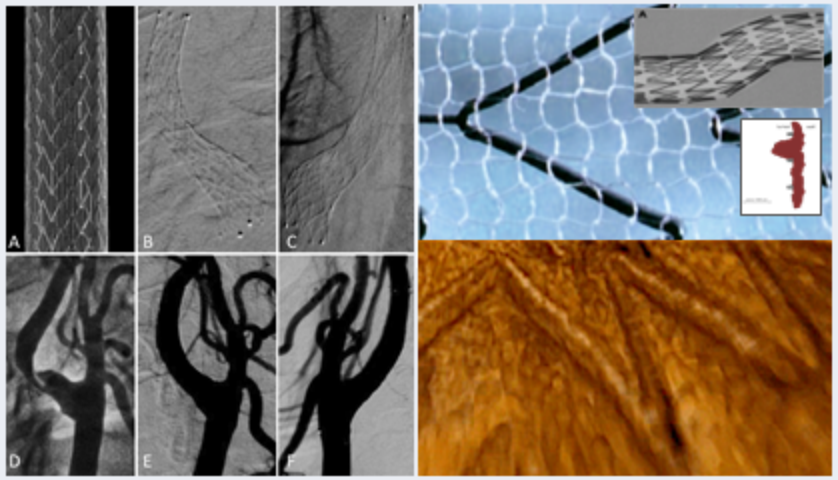

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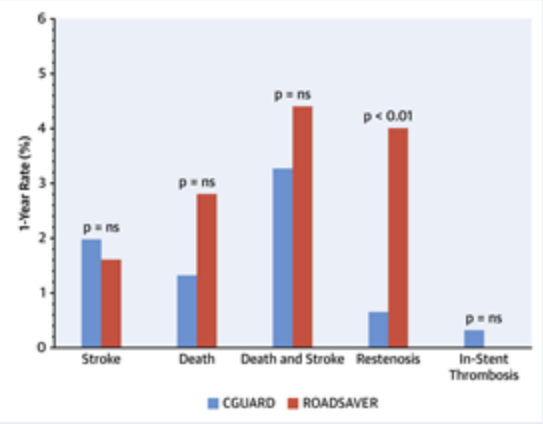

Stabile E et al. JACC Cardiovasc Interv. 2020;13(14):1709-1715. doi:10.1016/j.jcin.2020.03.048

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Challenging lesion subsets

CALCIUM

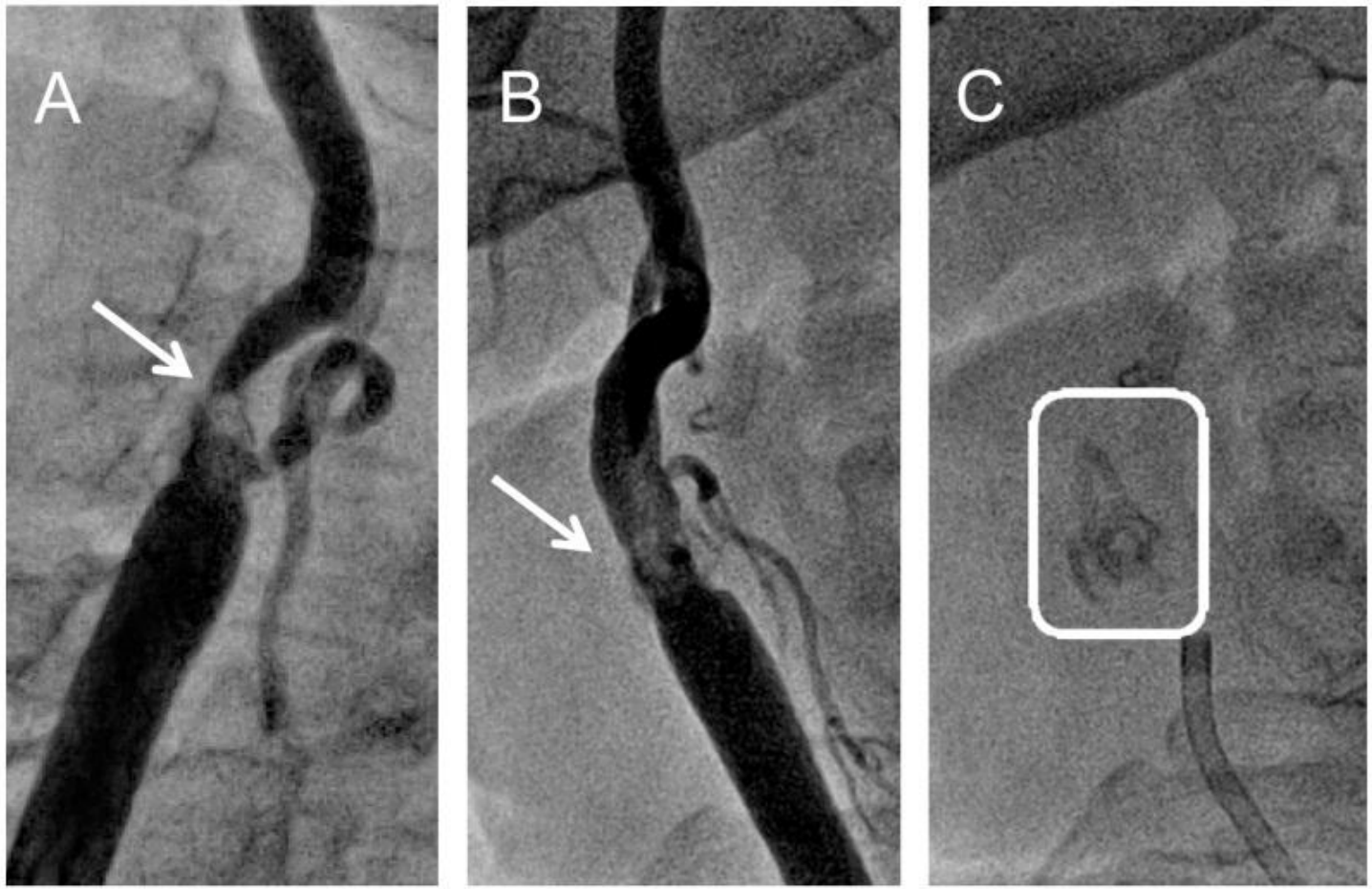
Received: 29 January 2019 | Revised: 13 March 2019 | Accepted: 23 March 2019
DOI: 10.1002/ccd.28219

ORIGINAL STUDIES

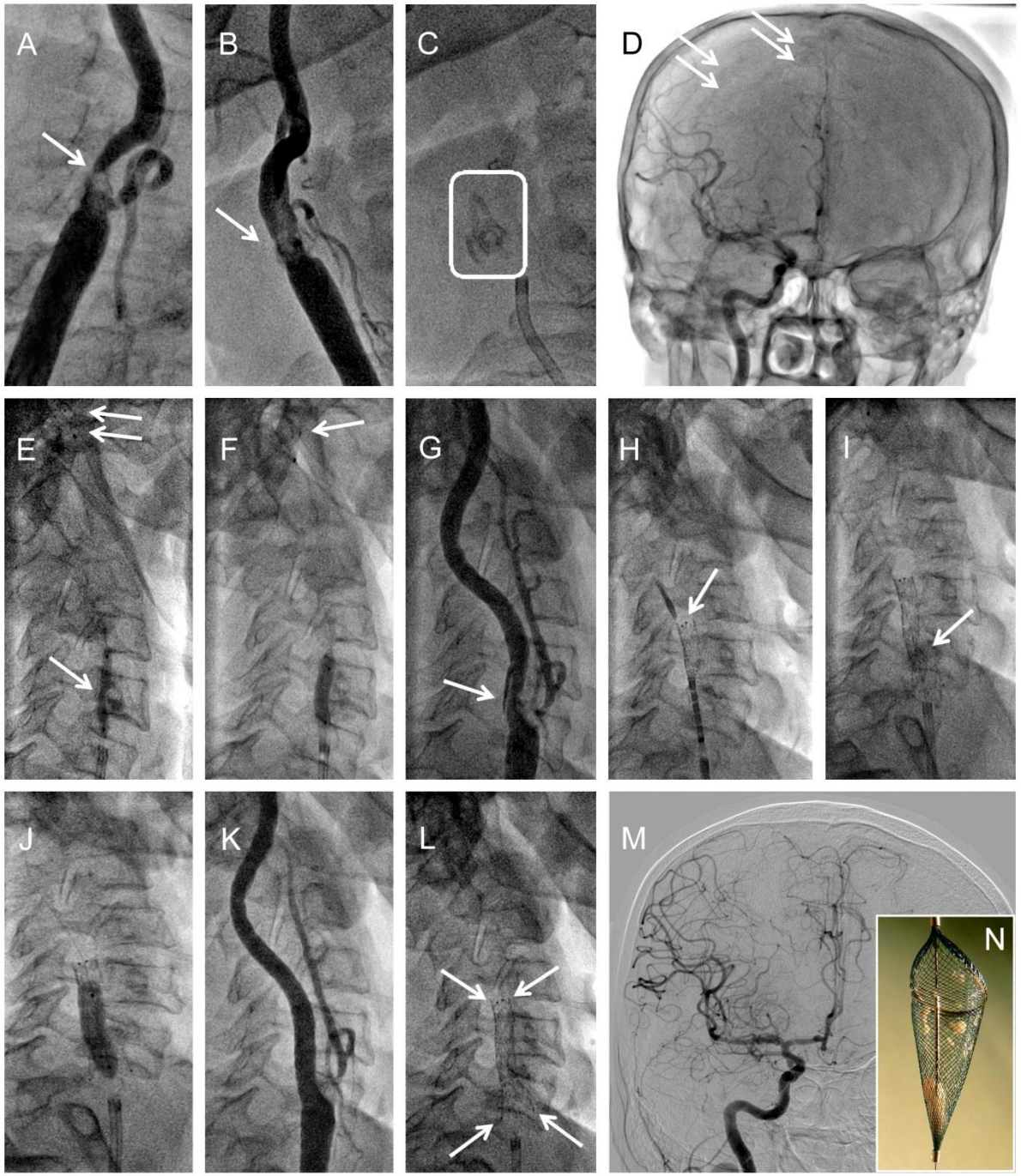
WILEY

Highly-calcific carotid lesions endovascular management in symptomatic and increased-stroke-risk asymptomatic patients using the CGuard™ dual-layer carotid stent system: Analysis from the PARADIGM study

Adam Mazurek MD[1] | Lukasz Partyka MD, PhD[2] | Mariusz Trystula MD, PhD[3] | Jacek Jakala MD, PhD[2] | Klaudia Proniewska MSc, PhD[2] | Anna Borratynska MD, PhD[4] | Tomasz Tomaszewski MD[4] | Magdalena Slezak MSc[3] | Krzysztof P. Malinowski MSc[3,5] | Tomasz Drazkiewicz MD, PhD[2] | Piotr Podolec MD, PhD[1] | Kenneth Rosenfiled MD[6] | Piotr Musialek MD, DPhil[1]



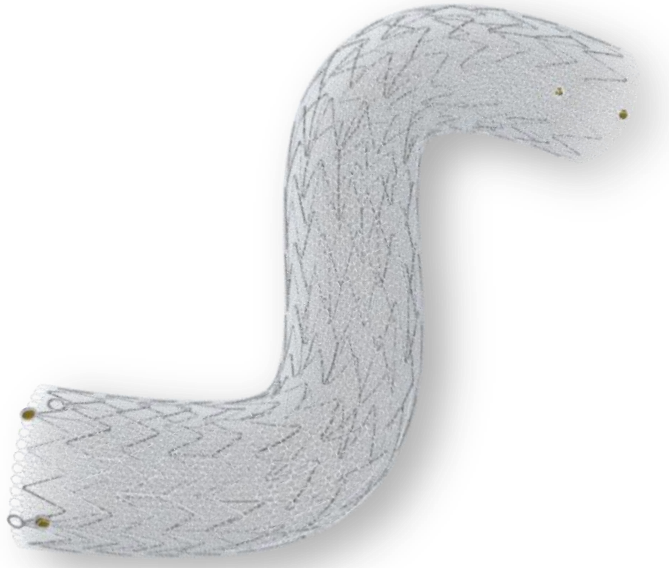
P Musialek @ VEITH 2021



HIGHLY-CALCIFIC Carotid Artery Stenosis

Endovascular Reconstruction

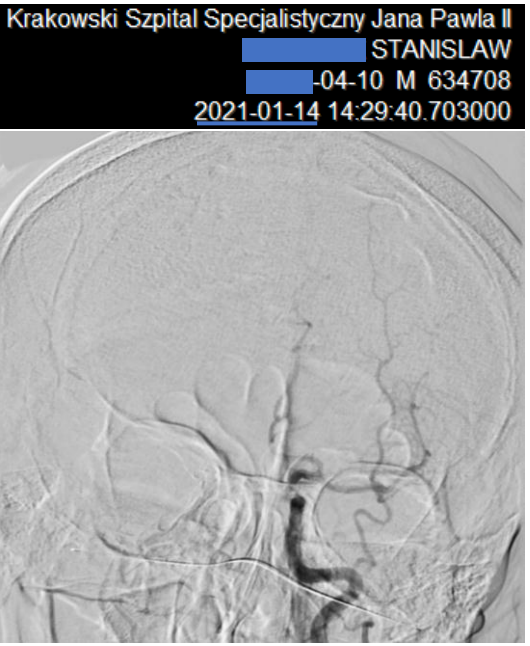
(from PARADIGM-AC)



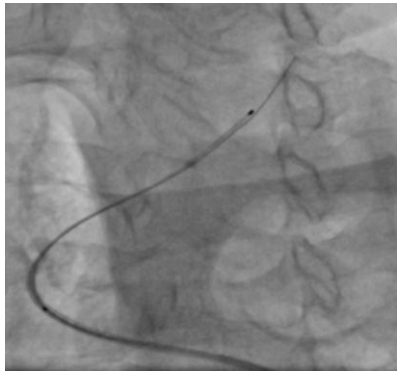
Challenging lesion subsets

THROMBUS

CGuard MicroNET Stent to treat acute ischaemic stroke

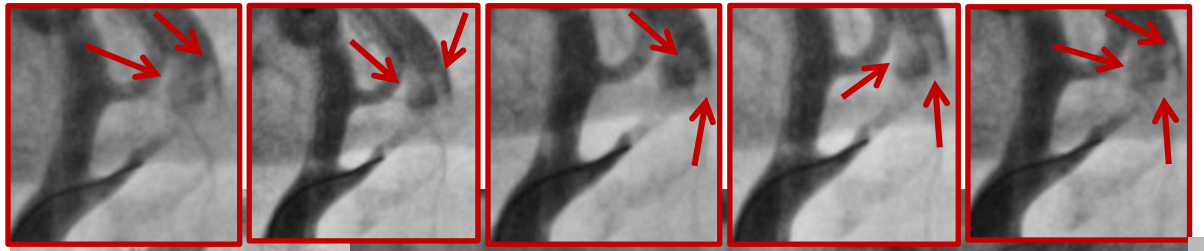


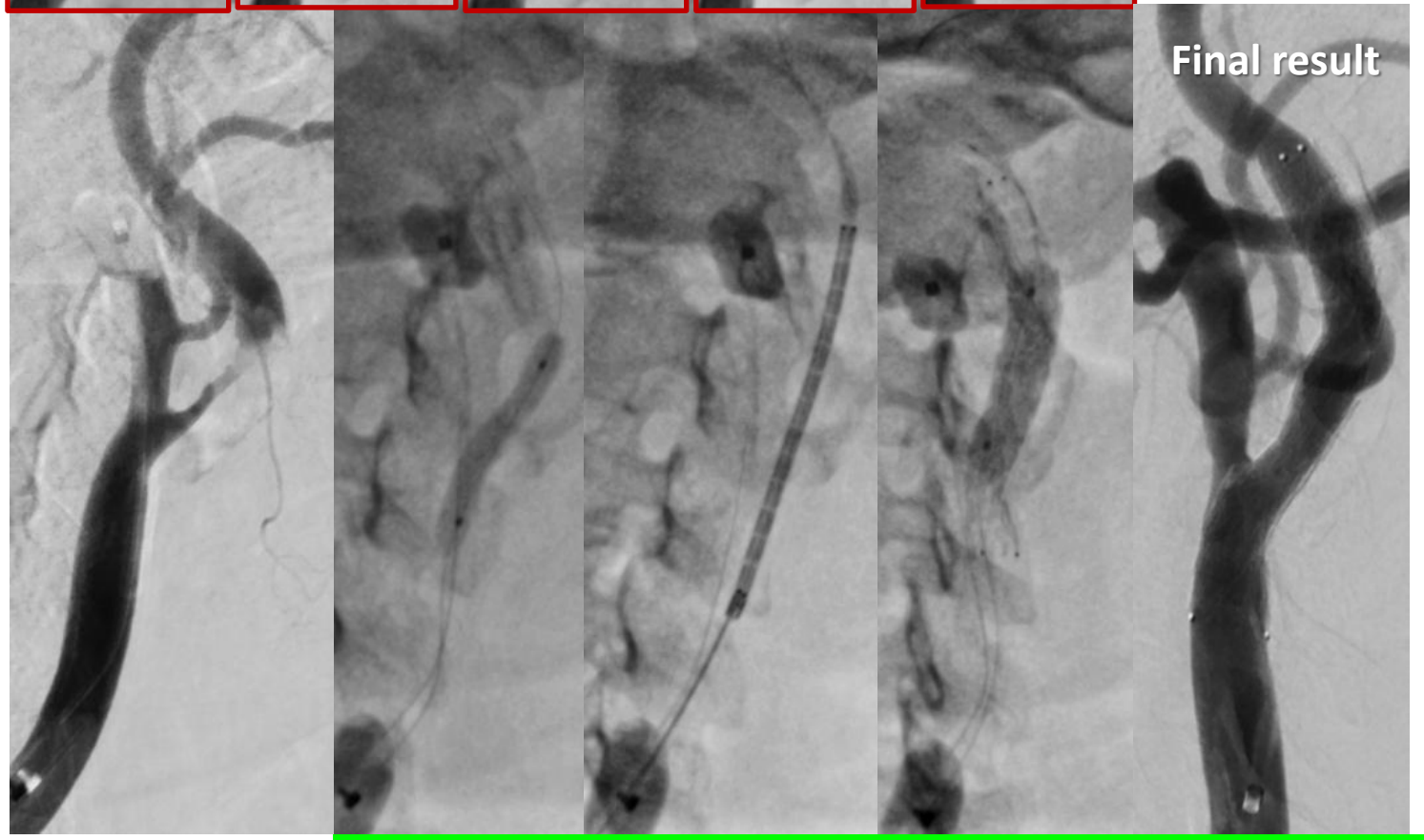
- R-limbs heamiparesis
- TOTAL motoric aphasia
- Severe sensoric aphasia



IFU-heparinization (ACT 261s)

Haemodynamically critical, floating thrombotic lesion

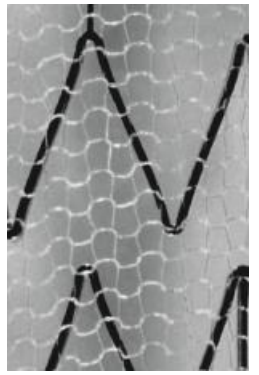




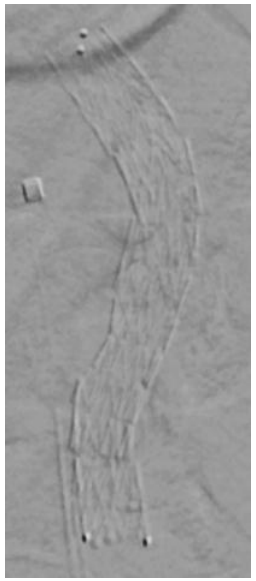
IMMEDIATE Regression of symptoms

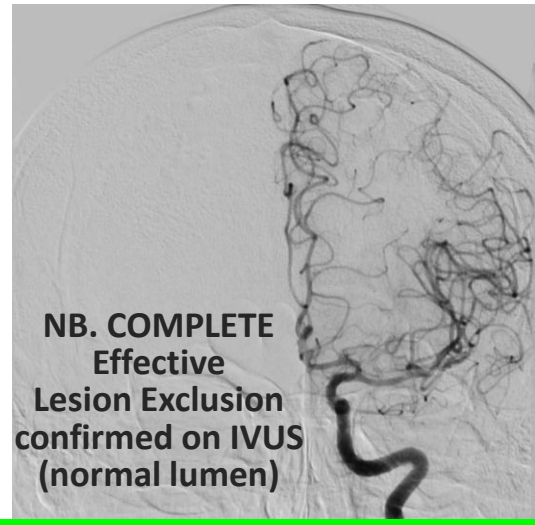
Final result

CGuard



MicroNET



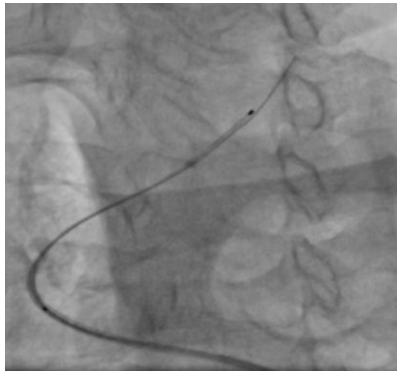


SAFE & uncomplicated, with optimal angiographic and clinical outcome

CGuard MicroNET Stent to treat acute ischaemic stroke

Krakowski Szpital Specjalistyczny Jana Pawła II
[redacted] STANISLAW
[redacted]-04-10 M 634708
2021-01-14 14:29:40.703000

- R-limbs heamiparesis
- TOTAL motoric aphasia
- Severe sensoric aphasia



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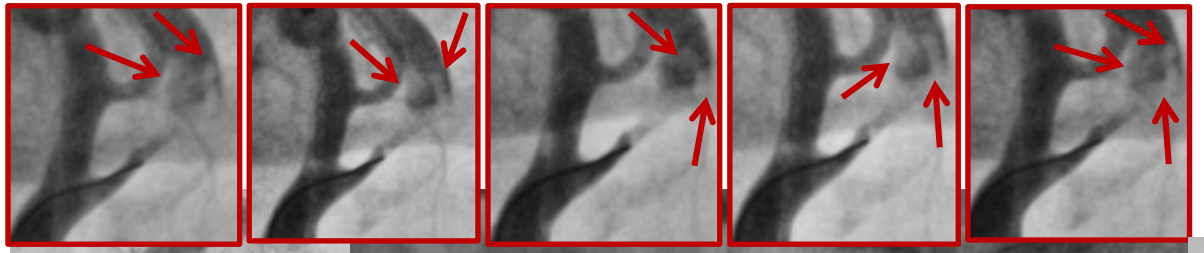

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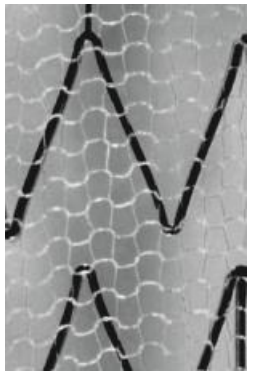
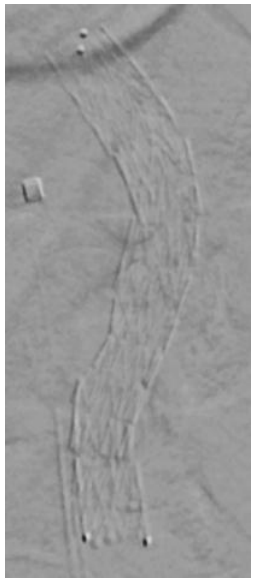
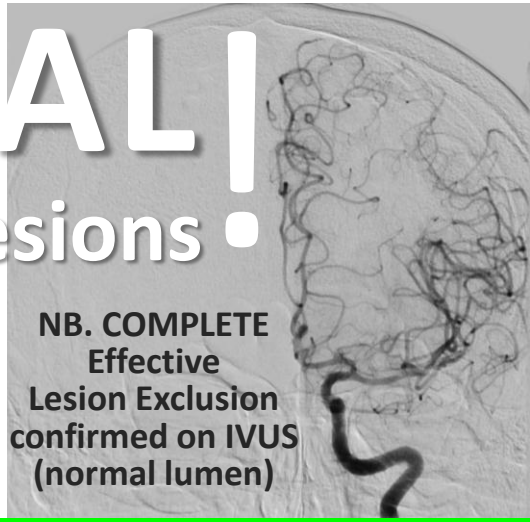


MicroNET



FLOW REVERSAL!

is a MUST in ENDO Tx of these lesions



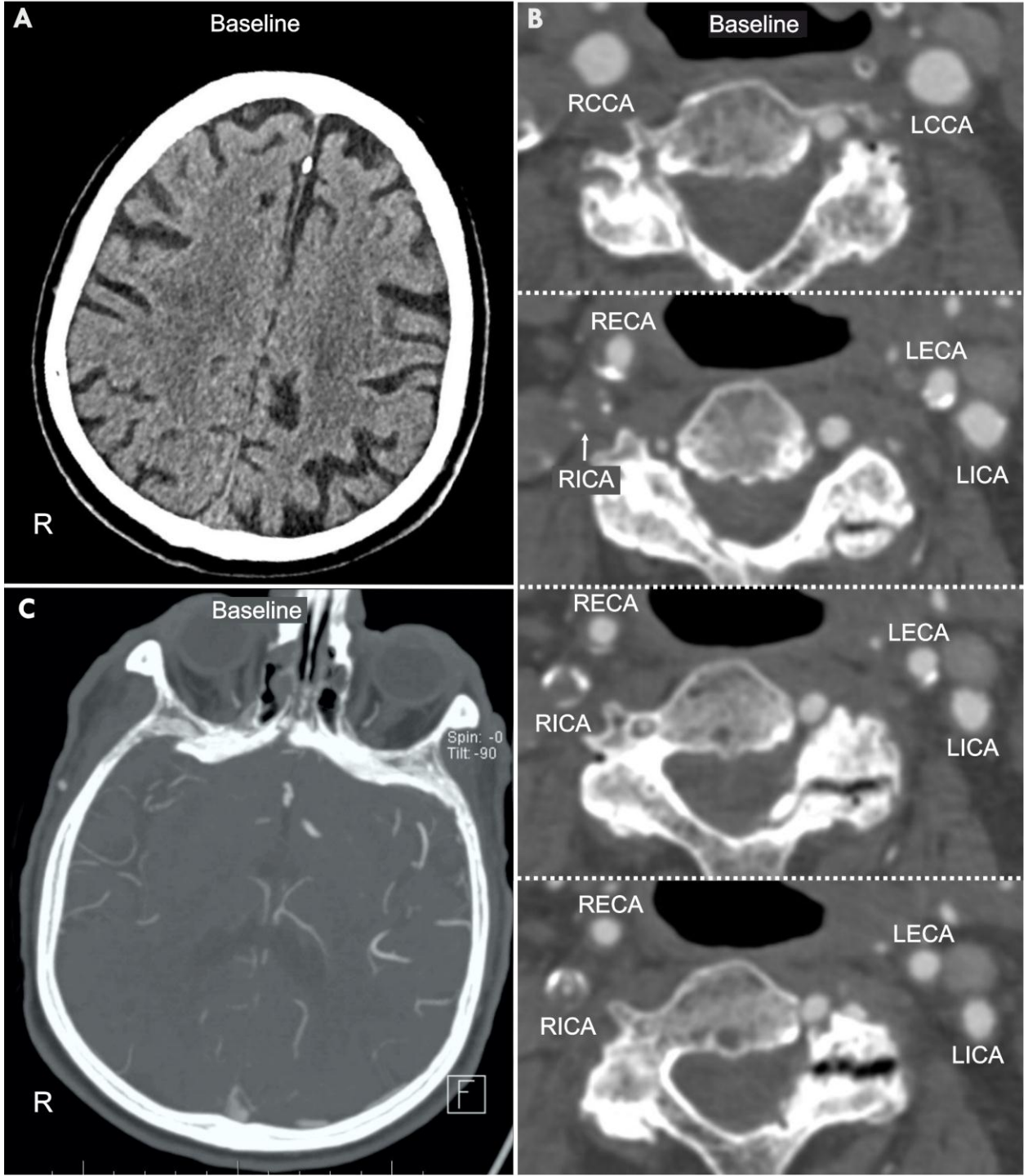
NB. COMPLETE Effective Lesion Exclusion confirmed on IVUS (normal lumen)

SAFE & uncomplicated, with optimal angiographic and clinical outcome

Novel Large-Diameter Controlled-Expansion Stentriever, Embolic-Prevention Stent and Flow Reversal in Large-Thrombus-Burden ICA Proximal Occlusion Stroke

Lukasz Tekieli, MD, PhD,[a,b,c] Krzysztof Banaszkiewicz, MD, PhD,[c,d] Zbigniew Moczulski, MD,[c,e] Małgorzata Urbańczyk-Zawadzka, MD,[c,e] Piotr Musialek, MD, DPhil[b,c]

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 14, NO. 21, 2021



P Musialek
@ VEITH 2021

Novel Large-Diameter Controlled-Expansion Stentriever, Embolic-Prevention Stent and Flow Reversal in Large-Thrombus-Burden ICA Proximal Occlusion Stroke

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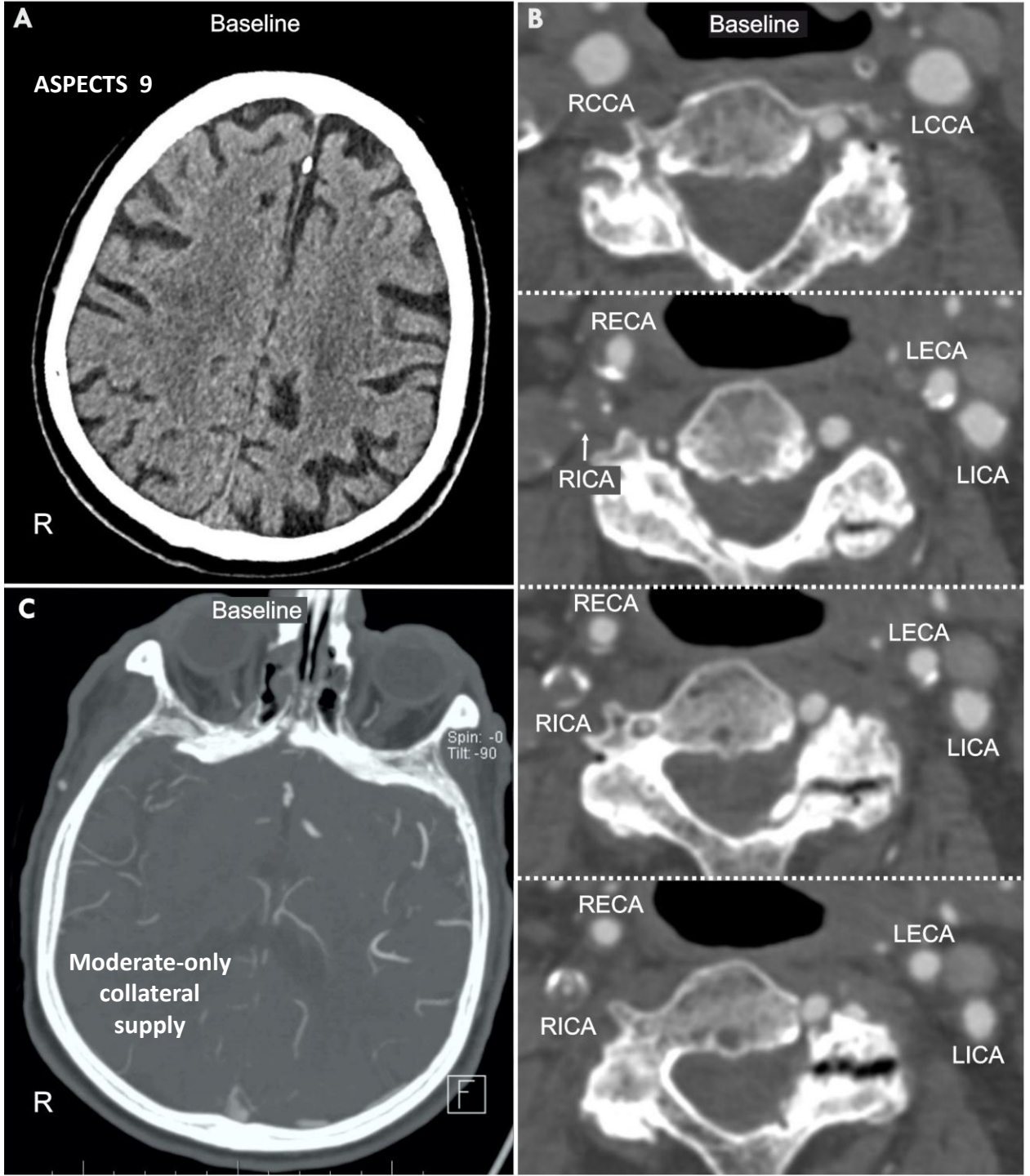

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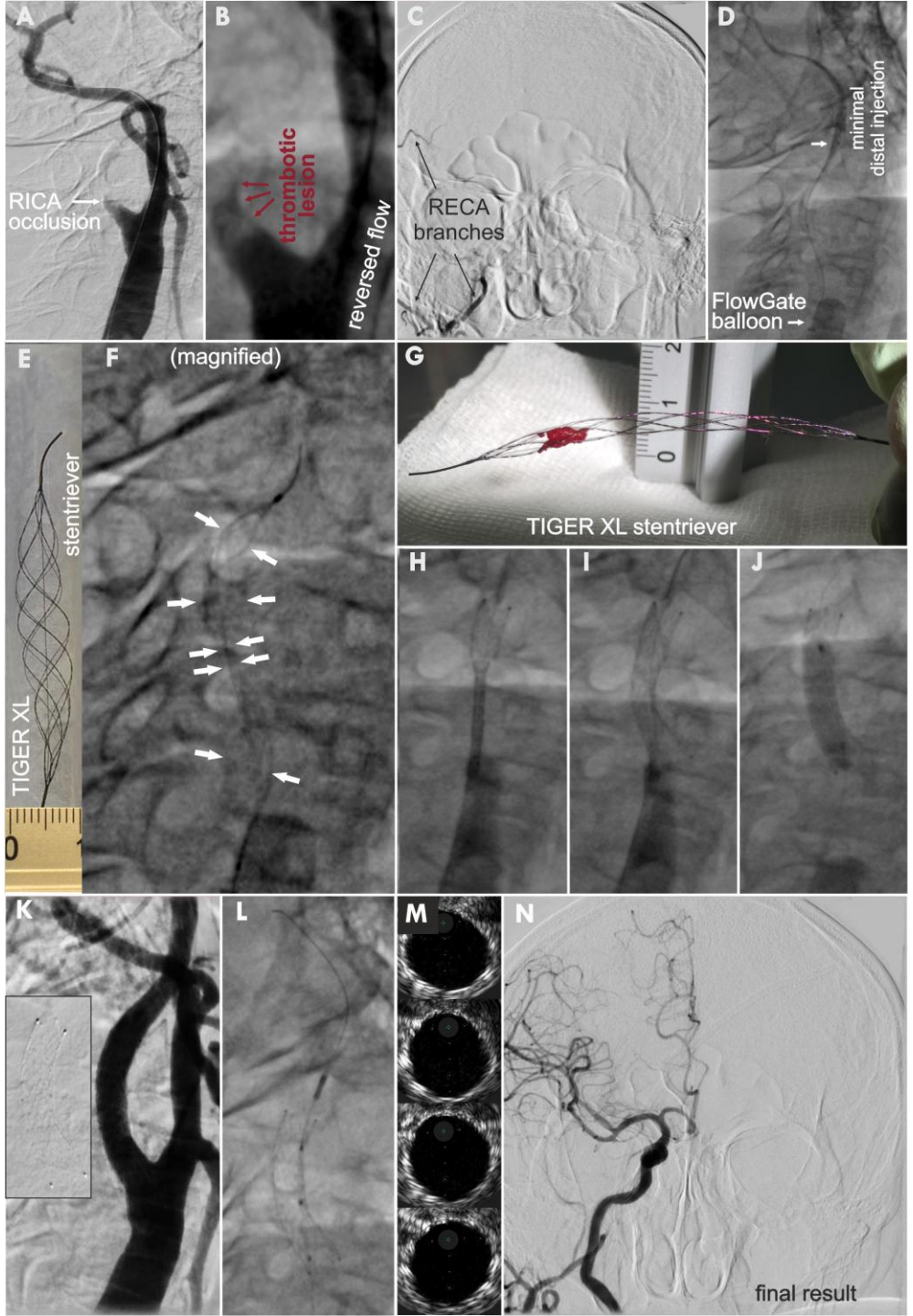
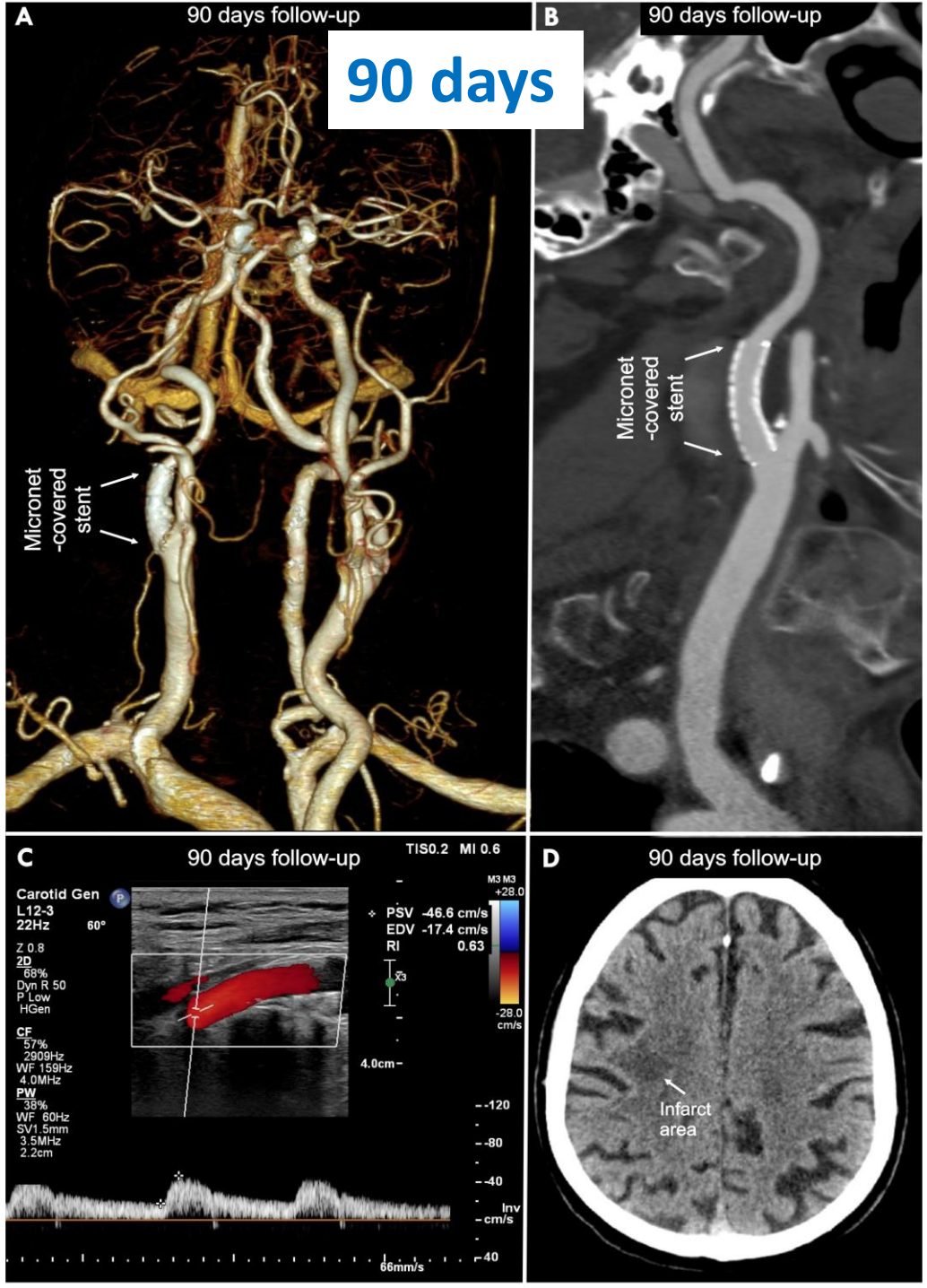




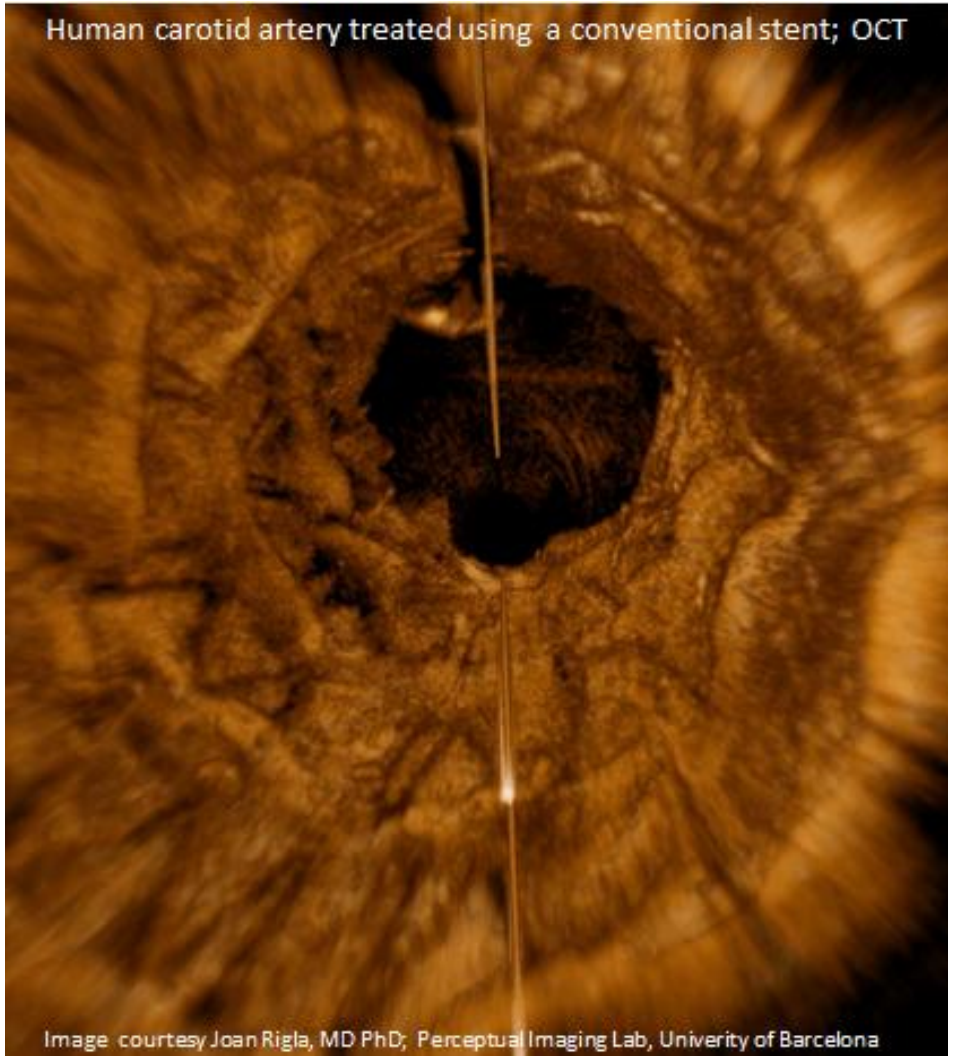
CLINICALLY
and
ANATOMICALLY

EFECTIVE

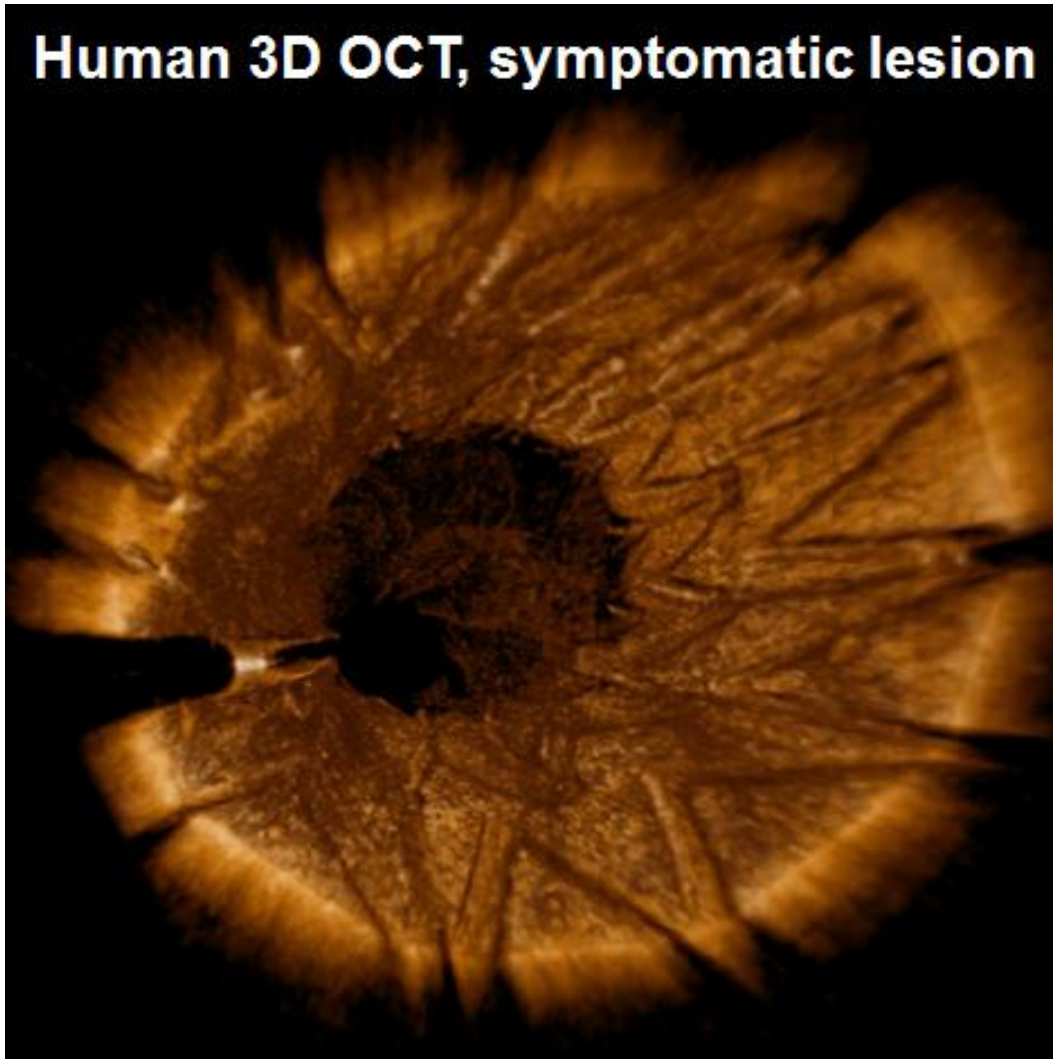
ENDOVASCULAR
RECONSTRUCTION

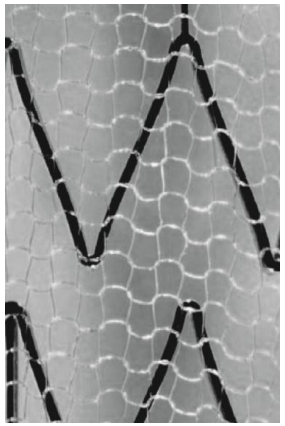
JACC Intv 2021

The CREST Study stent



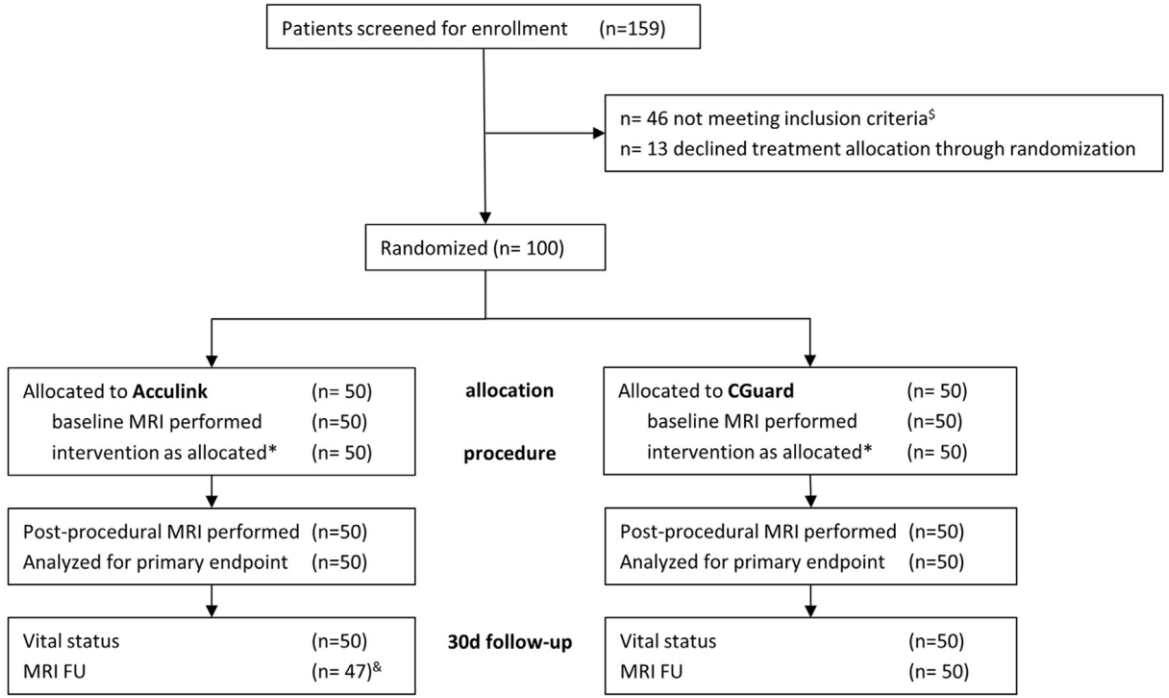
MicroNet-Covered Stent





Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization

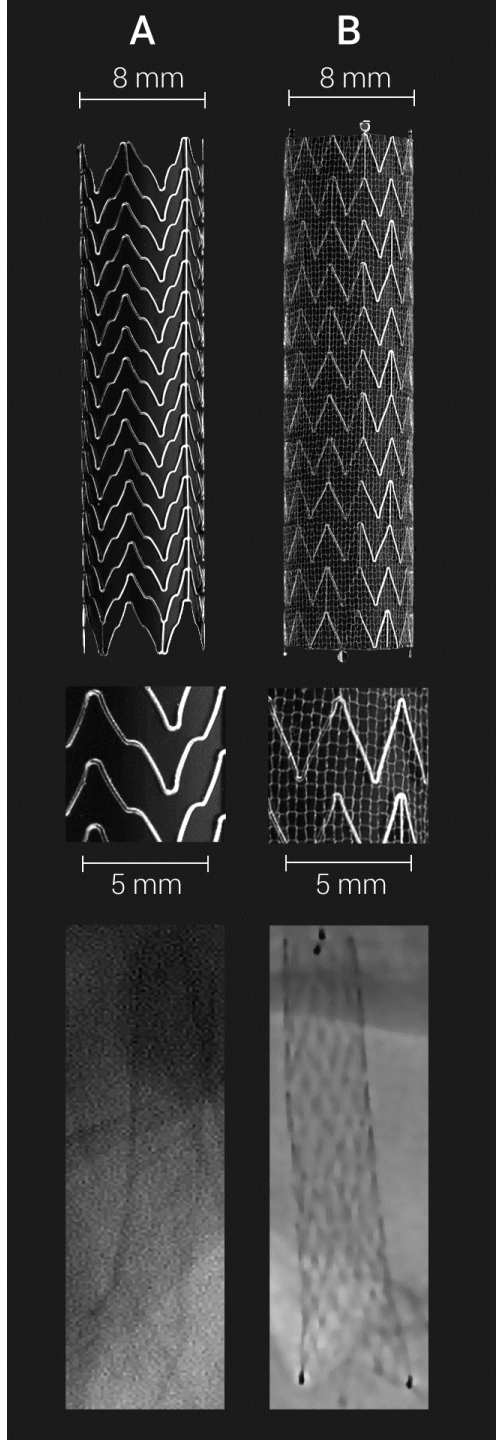
Andrey Karpenko, MD, PhD,[a] Savr Bugurov, MD,[a] Pavel Ignatenko, MD, PhD,[a] Vladimir Starodubtsev, MD, PhD,[a] Irina Popova, MD, PhD,[a] Krzysztof Malinowski, MSc,[b] Piotr Musialek, MD, DPhil[c]



* All CAS with EmboShield NAV6 as per the Centre routine

$ Reasons for not meeting inclusion criteria were: atrial fibrillation (n=14), severe renal failure (n=12), restenotic lesion (n=9), and unsuitability for MRI examination (n=11)

& 2 patients declined on-site follow-up due to travel distance, at the follow up visit the MRI scanner was not functional in 1 (the patient declined re-visit)



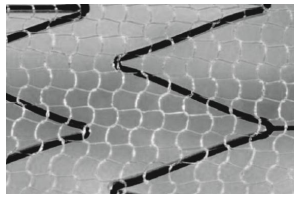
Randomized Controlled Trial of conventional versus Micronet-covered stent use in percutaneous neuroprotected carotid artery revascularization:

Peri-procedural and 30-day **diffusion-weighted magnetic resonance (DWI) imaging** and clinical outcomes

HEAD-TO-HEAD 100 consecutive increased-risk patients (25% symptomatic) **RANDOMIZED 1 : 1**

Distal EPD (Emboshield) in all

MicroNET-Covered
open-cell nitinol frame
2nd generation stent



vs.

Conventional (workhorse)
open-cell nitinol
1st generation stent

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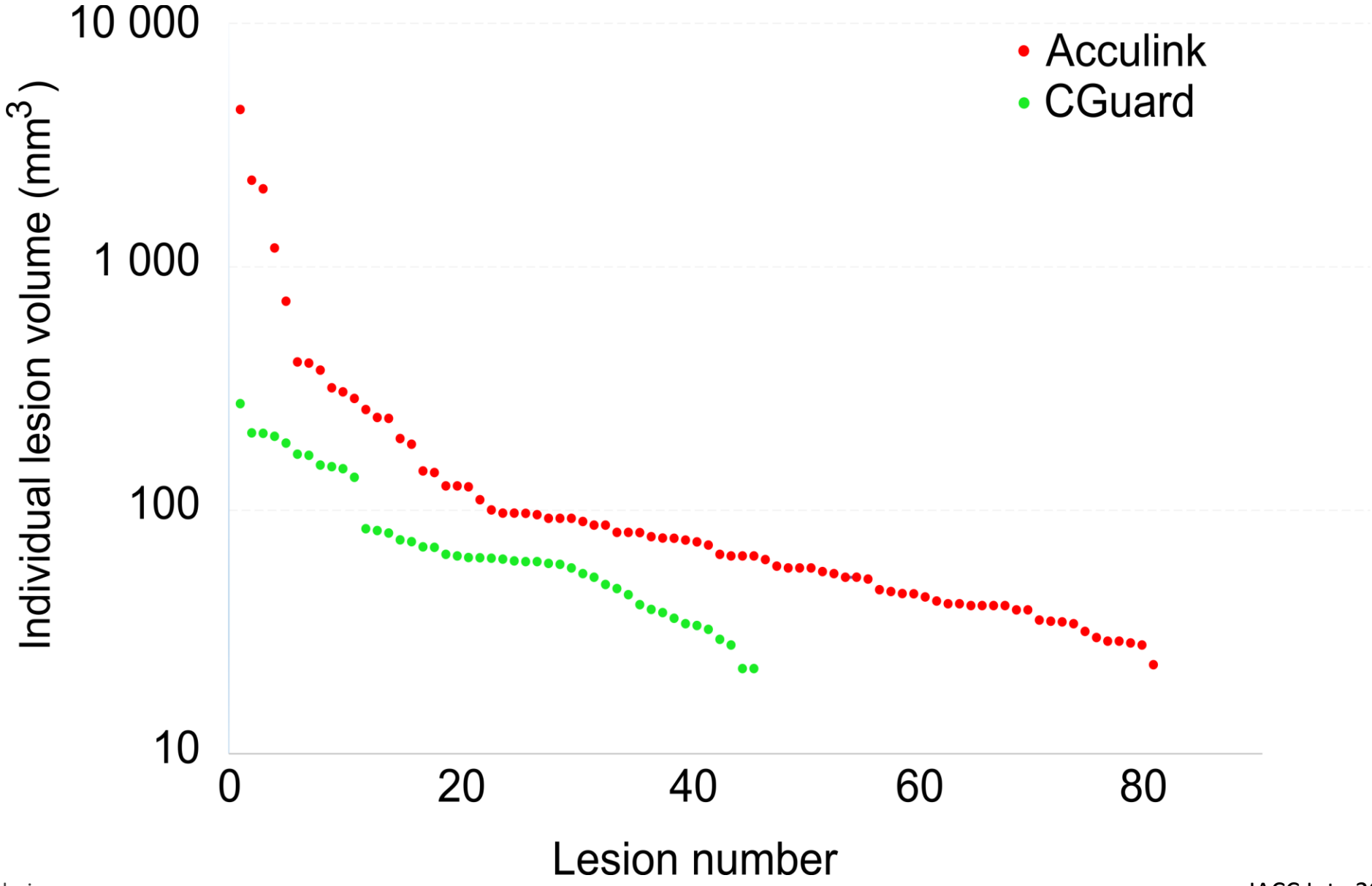
Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization

Post-Procedural Cerebral DW-MRI

Ipsilateral Lesions by Volume – RAW DATA



External CoreLab blinded analysis

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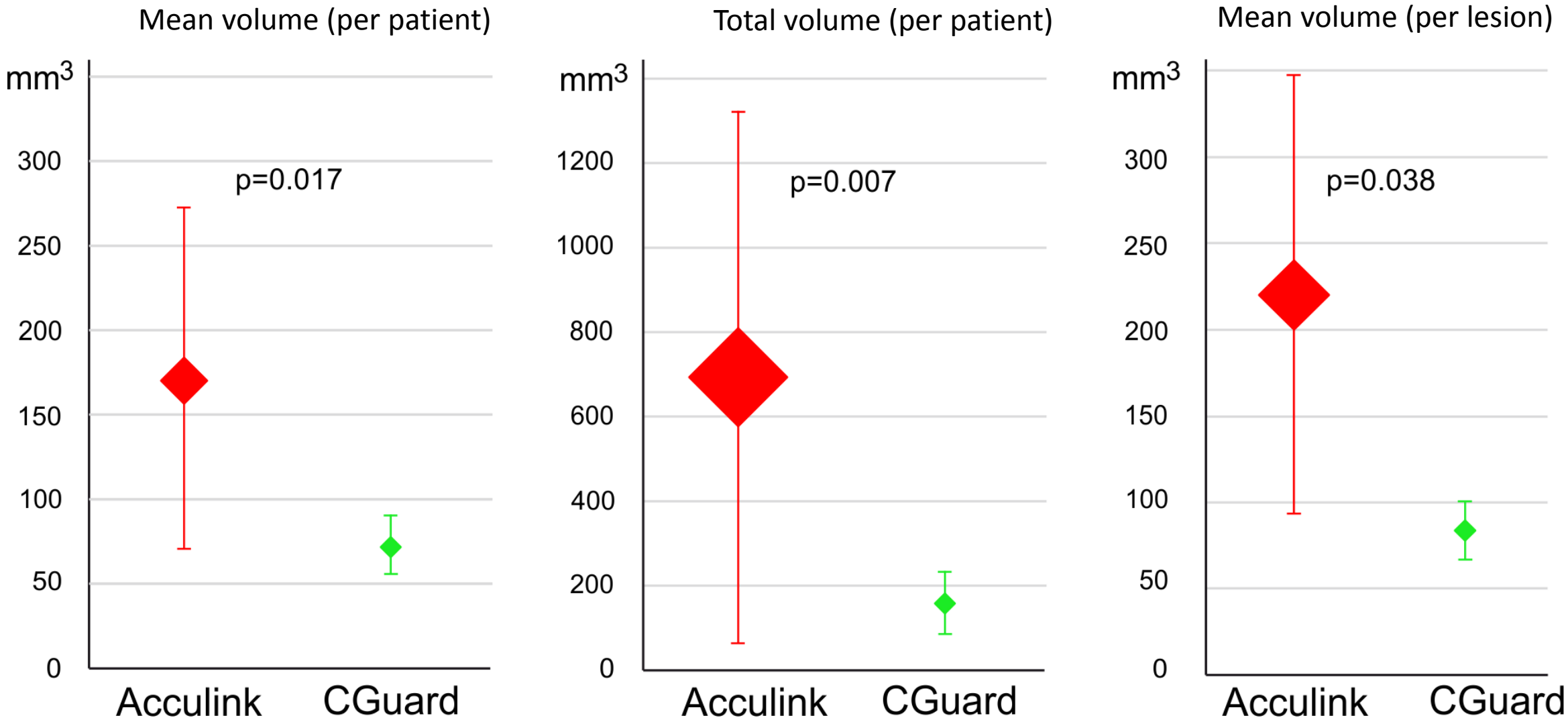
Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization



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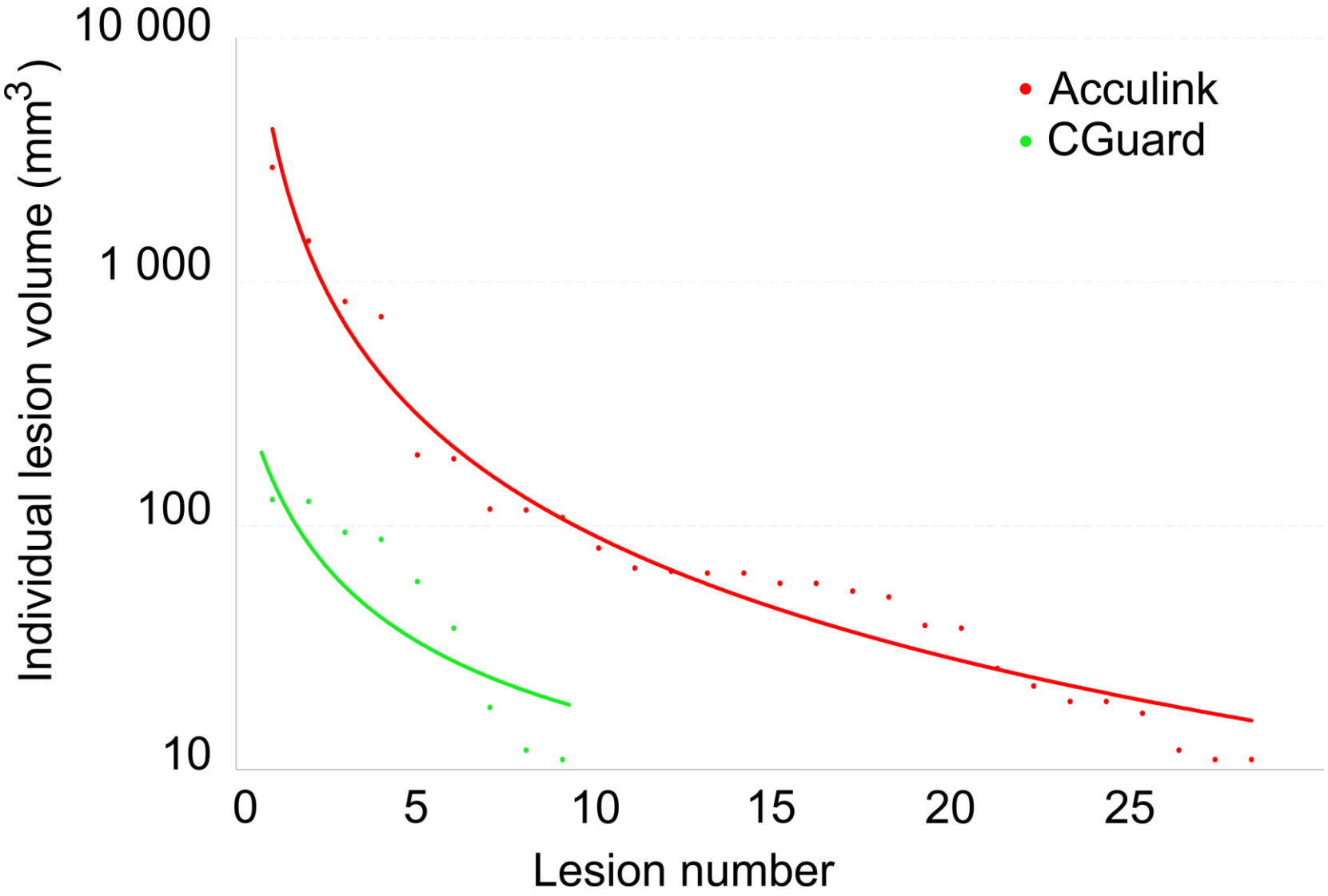
Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization

CAS LESIONS that became PERMANENT (FLAIR, 30 days)



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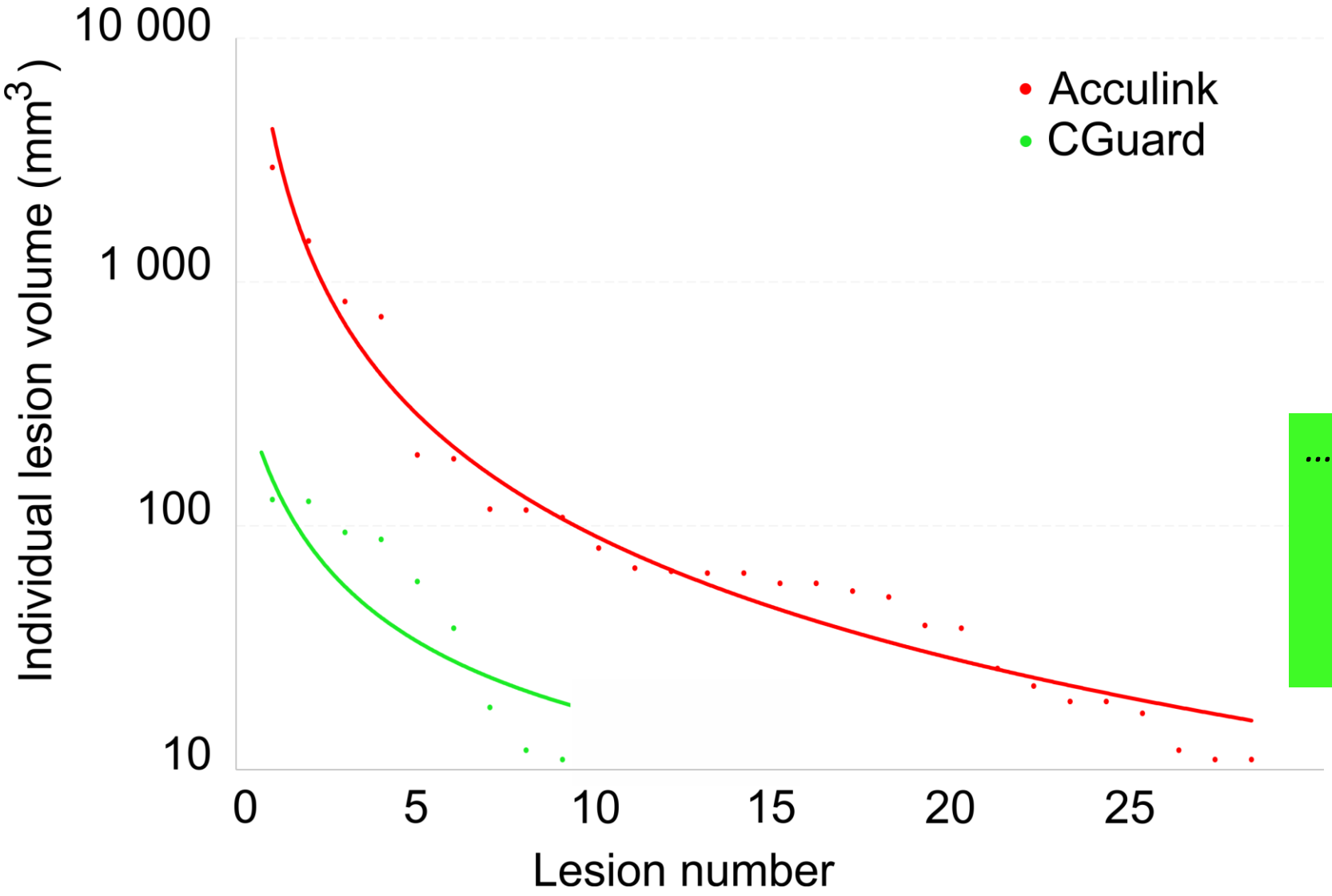


…and

6 vs. 0 ***NEW*** DWI lesions

2 vs. 0 ***strokes*** **@30days**

JACC Intv 2021

FDA-IDE Clinical Trial:

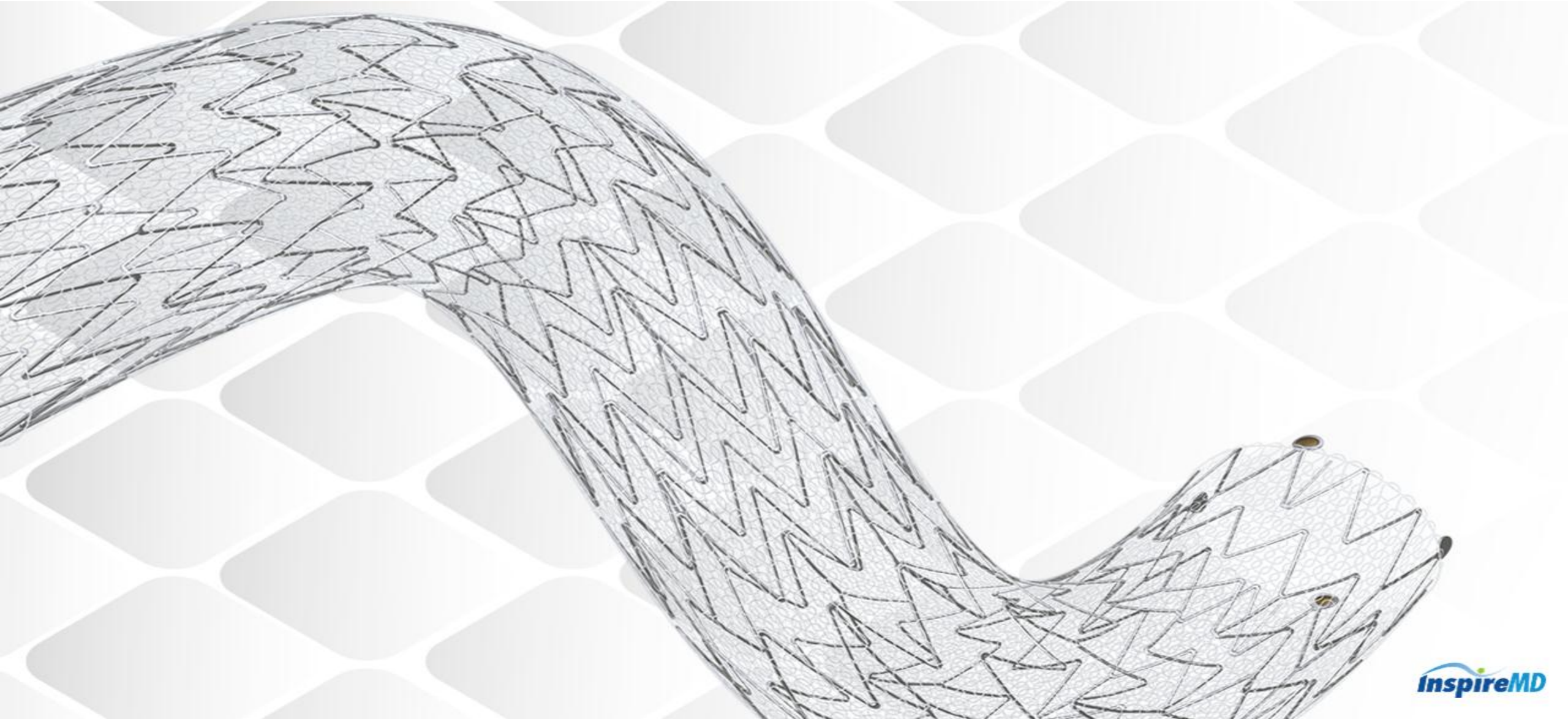
CGUARDIANS

NCT 04900844

FDA-IDE Clinical Trial:

CGUARDIANS

NCT 04900844



FDA-IDE Clinical Trial:

CGUARDIANS

NCT 04900844

Co-PIs **D. Christopher Metzger (US)**
P. Musialek (Europe)

DSMB G. Ansel – Chair, N. Hopkins, B. Gersh
CEC M. Burket – Chair, R. Sakhulja, P. Faries

Standard FDA Inclusion/Exclusion criteria for Clinically Symptomatic or Asymptomatic CS
(anatomic *or* clinical high-risk for CEA)

Primary Outcome Measure
Composite of **D+S+MI ≤ 30** days *or* **ipsilateral stroke 31–365** days post-index procedure

Recruitment goal = 315 patients
Study Centers = 18 US + 6 Europe (up to 40 total)

Multi Specialty: Interv. Cardiology, Vascular Surgery, Vascular Medicine/Angiology, Neurology, Neurosurgery

InspireMD

FDA-IDE Clinical Trial:

CGUARDIANS

NCT 04900844

ENROLLING (according to plan)

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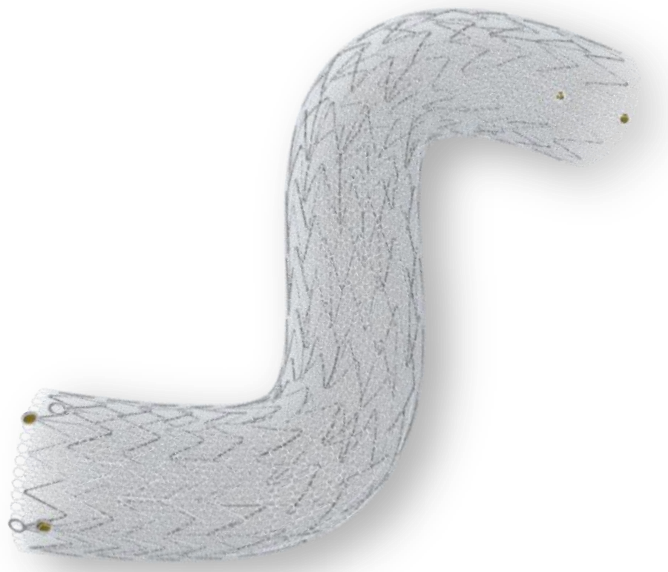
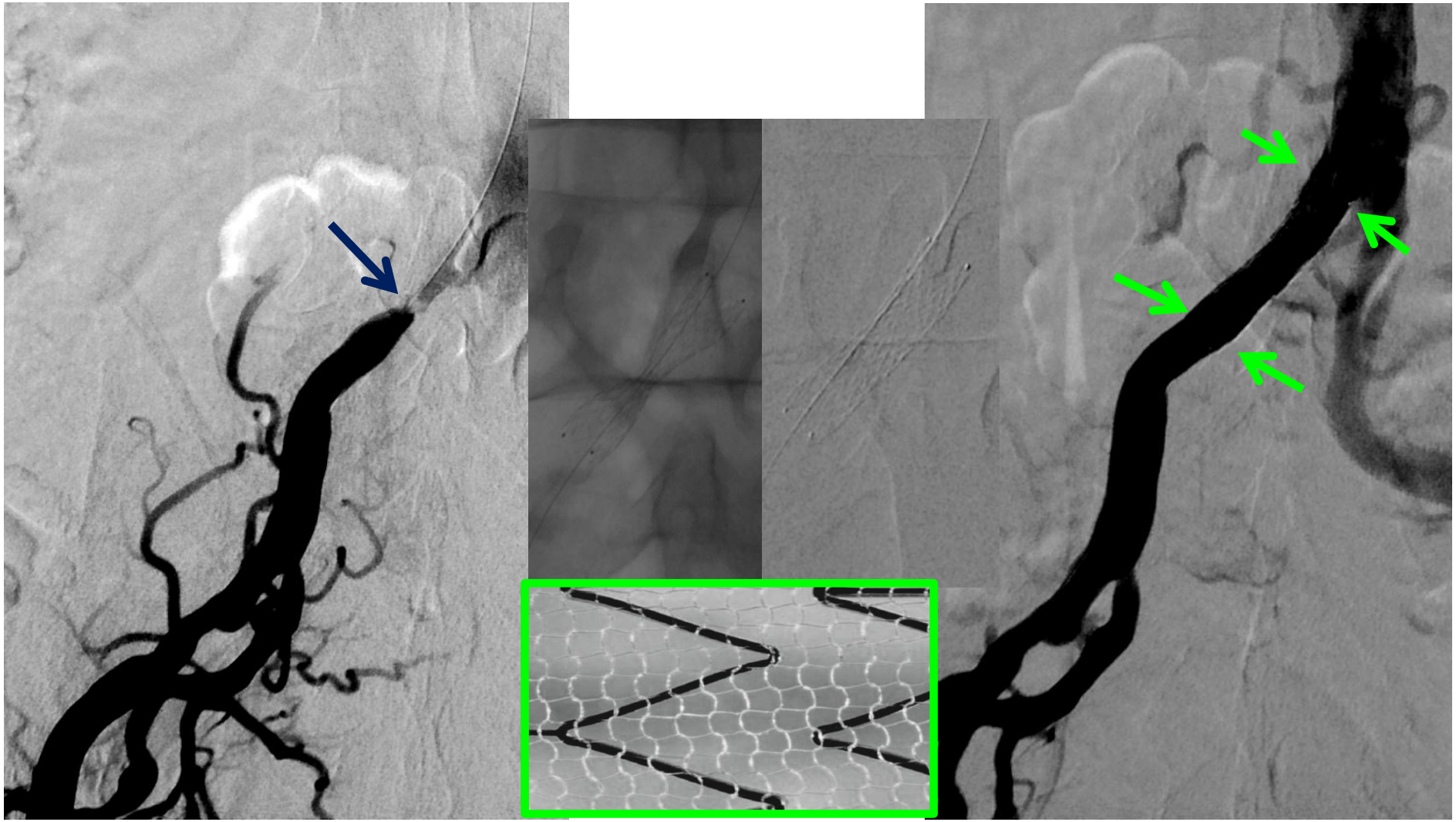
InspireMD

High-Risk Lesions **beyond** the Carotids



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



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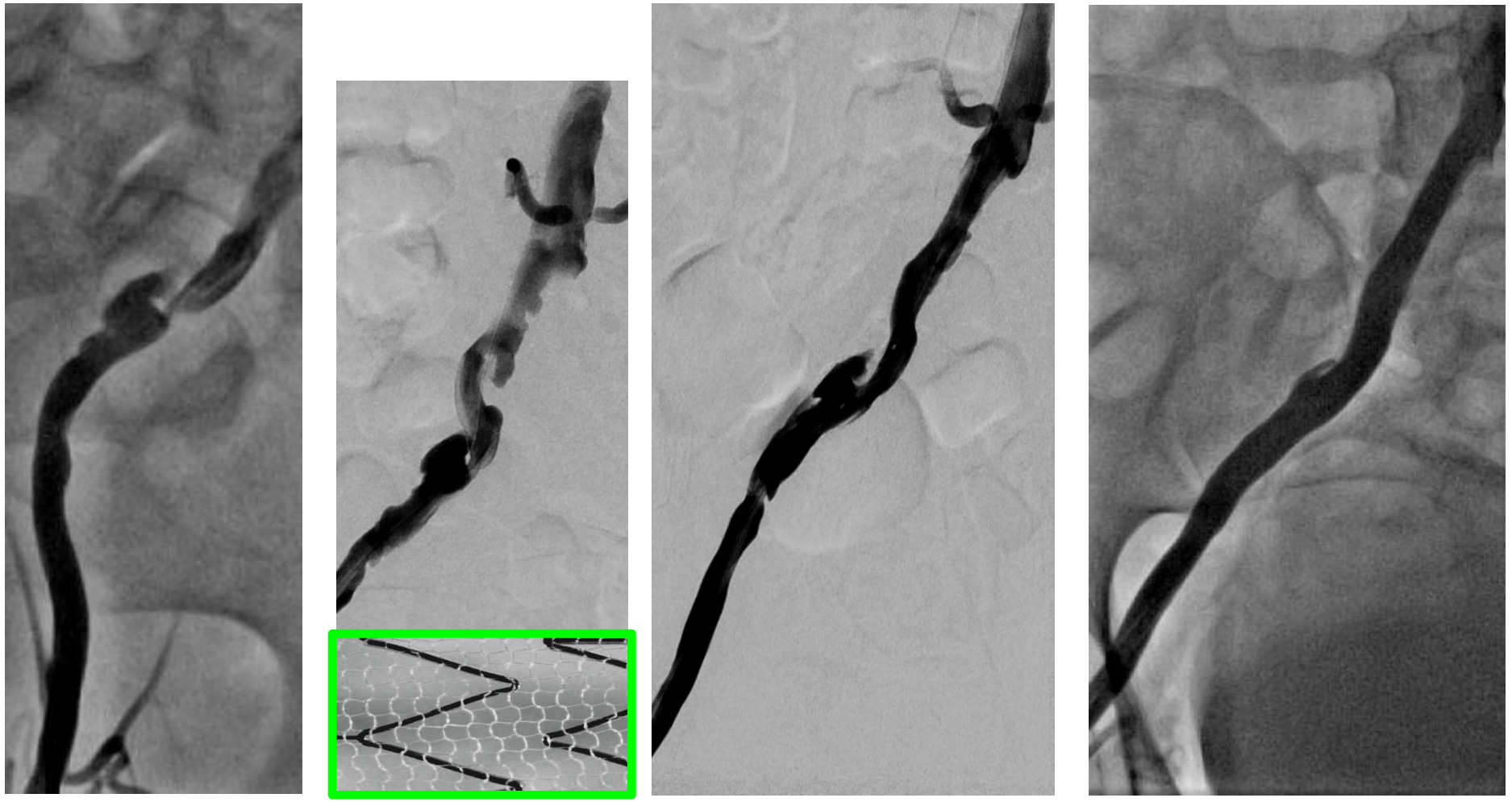
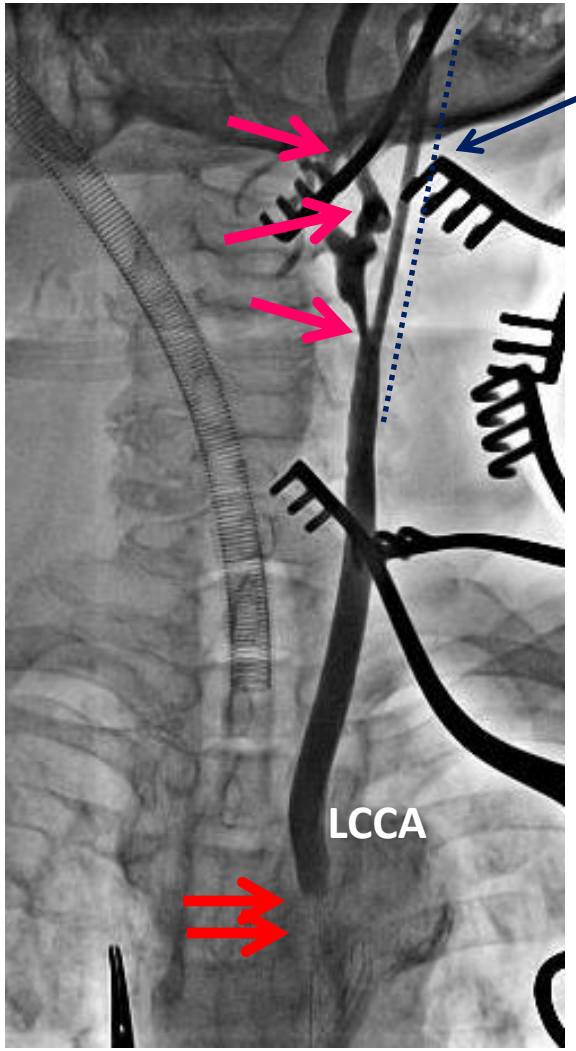


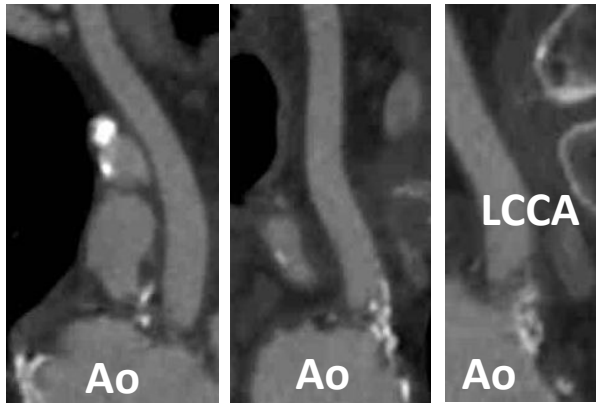
Ostial CCA lesions

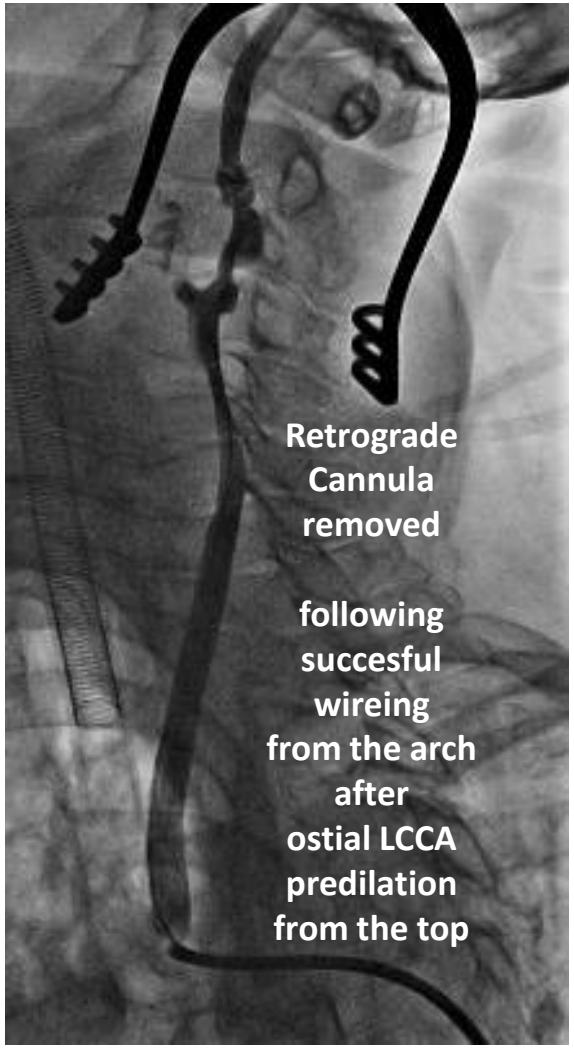
(note adequate radial force and placement percision need)



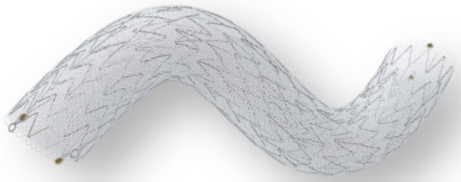
LCCA Retrograde Cannulation from the neck

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





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



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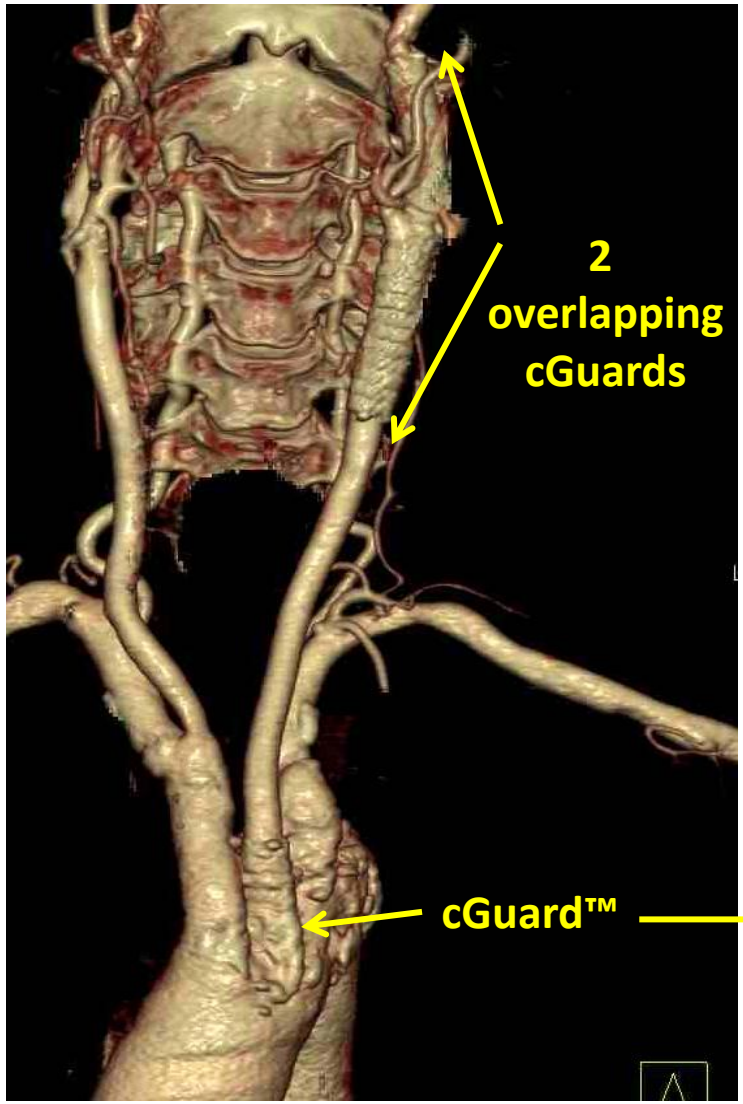
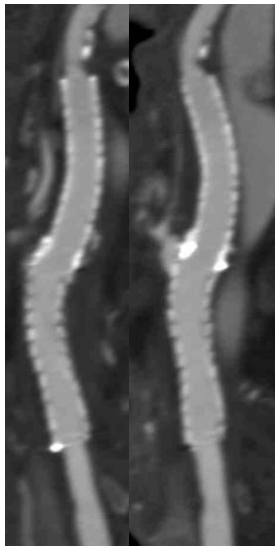
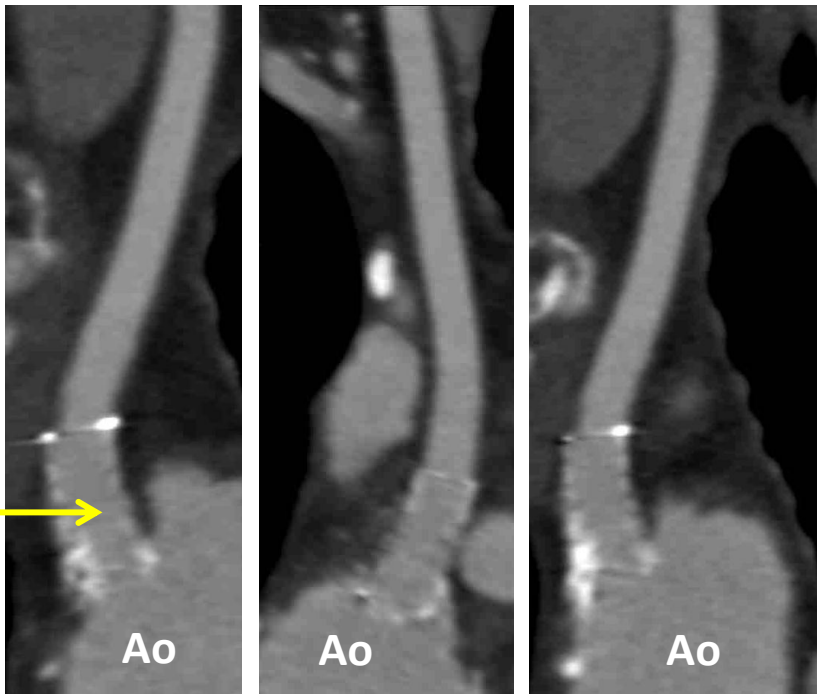




OPTIMAL angiographic + clinical + duplex result @ 12mo

(and LECA patent)



Conventional Carotid Stent Design Permits Atherosclerotic Plaque In-Stent Progression

Appropriately sized and implanted Precise stent (2005)

Precise Stent 5.0x30mm (implanted 2005)

increasing " in-stent restenosis" → 2016 SYMPTOMATIC

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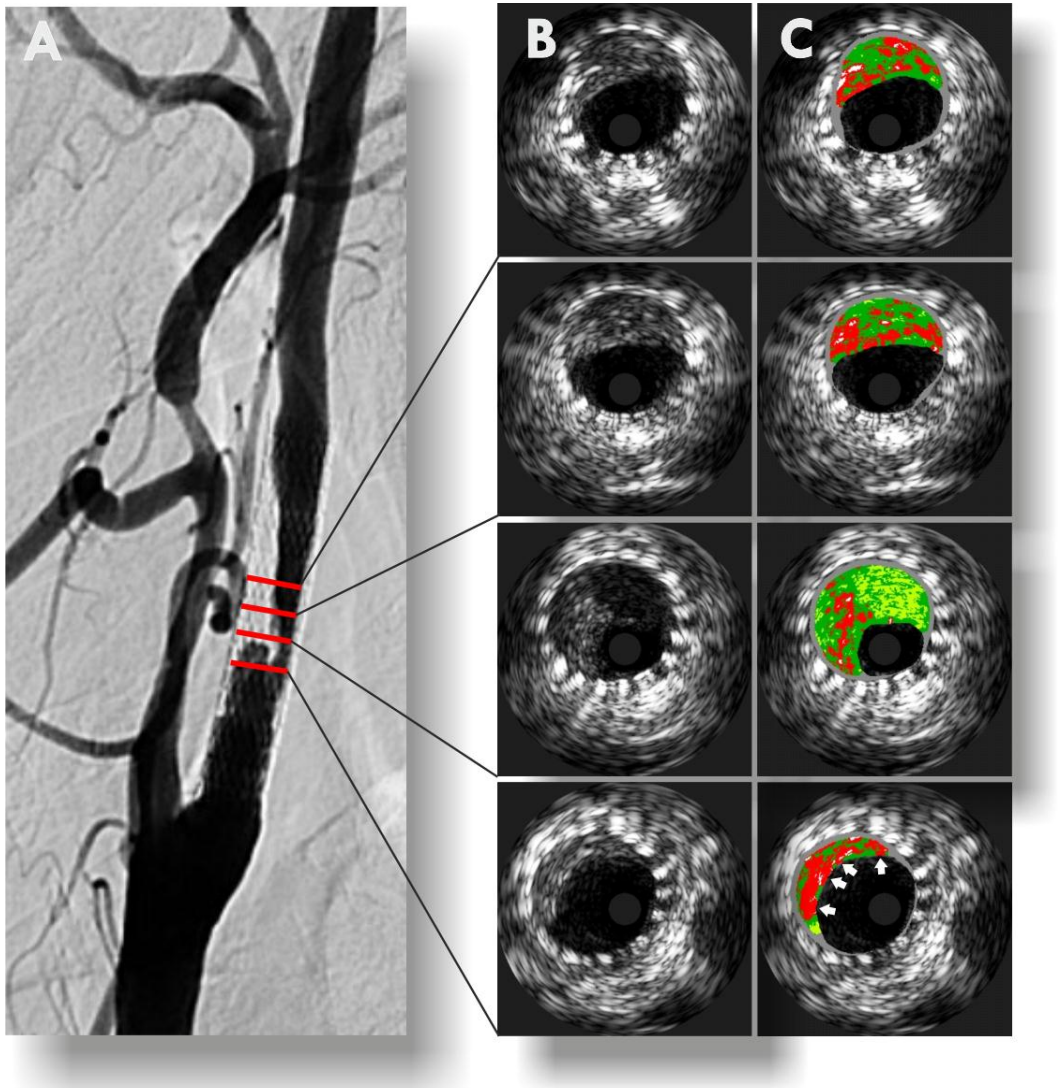

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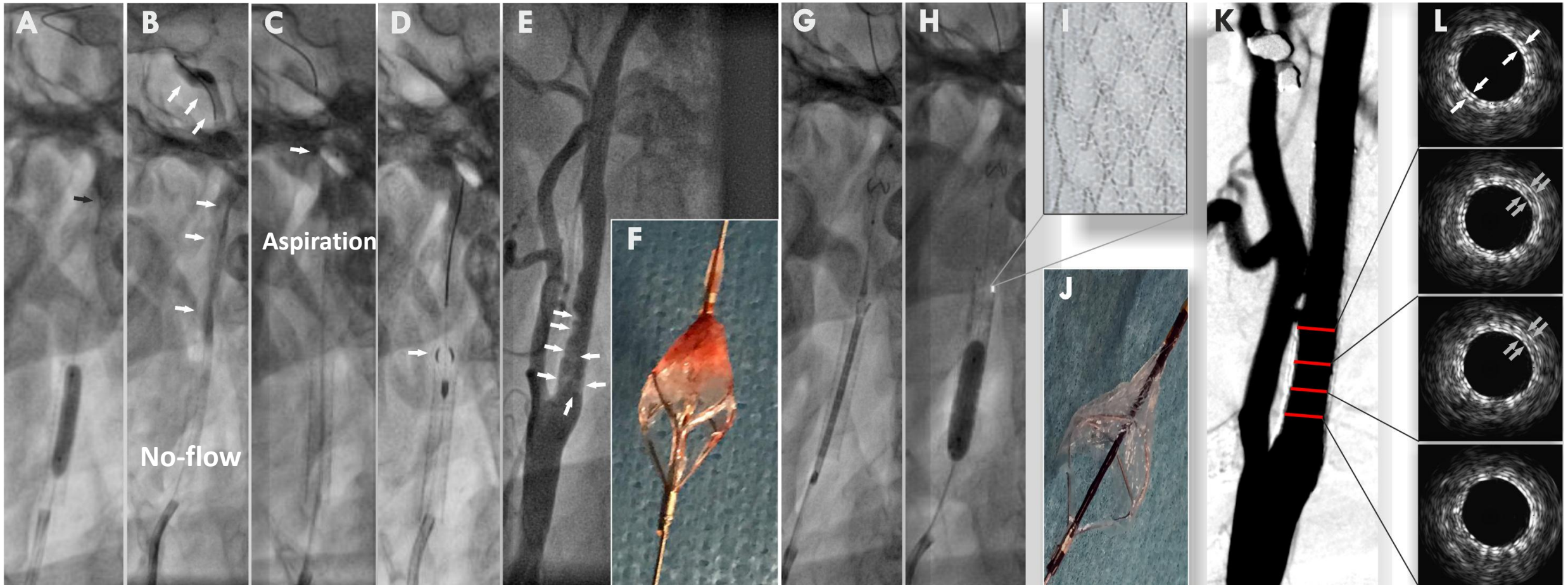
Tekieli et al. *Eur Heart J* 2021

Conventional Carotid Stent Design Permits Atherosclerotic Plaque In-Stent Progression



→ TREATED with MICRONET-COVERED STENT **PLAQUE SEQUESTRATION** (2016)

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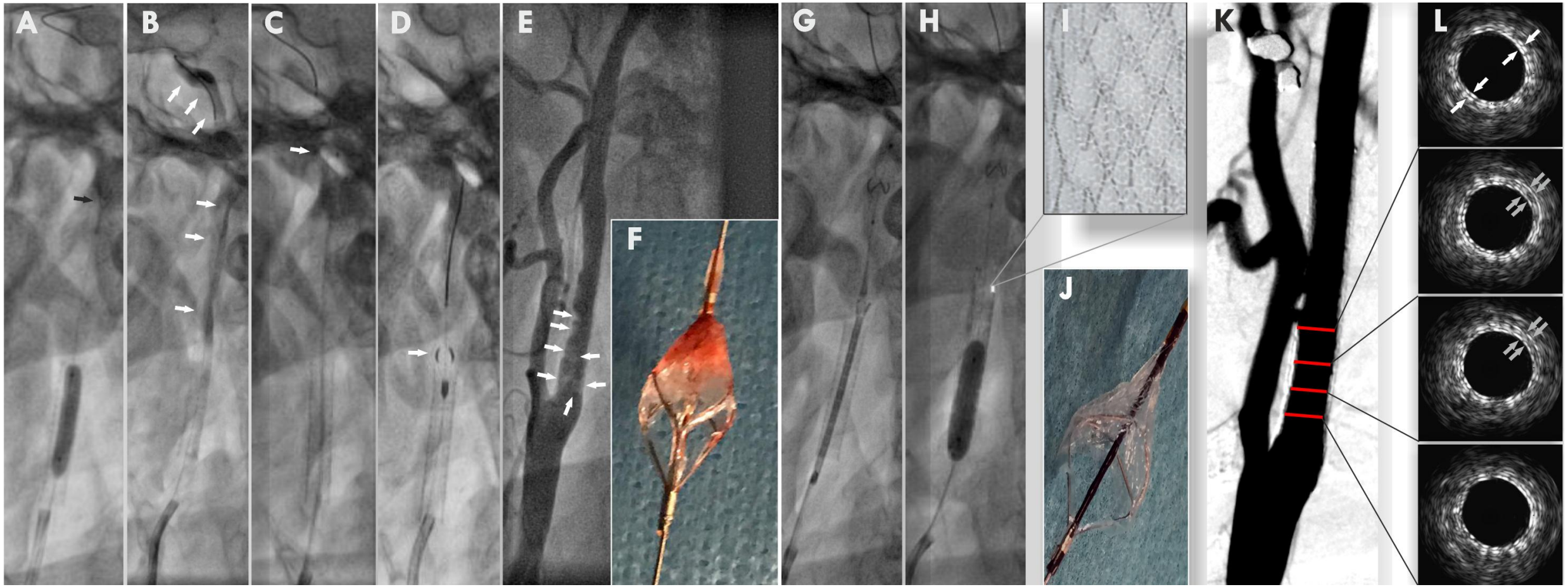
Conventional Carotid Stent Design Permits Atherosclerotic Plaque In-Stent Progression



→ TREATED with MICRONET-COVERED STENT **PLAQUE SEQUESTRATION** (2016)

EFFECTIVE RECONSTRUCTION OF NORMAL ANATOMY

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Conventional Carotid Stent Design Permits Atherosclerotic Plaque In-Stent Progression

→ TREATED with MICRONET-COVERED STENT **PLAQUE SEQUESTRATION** (2016)

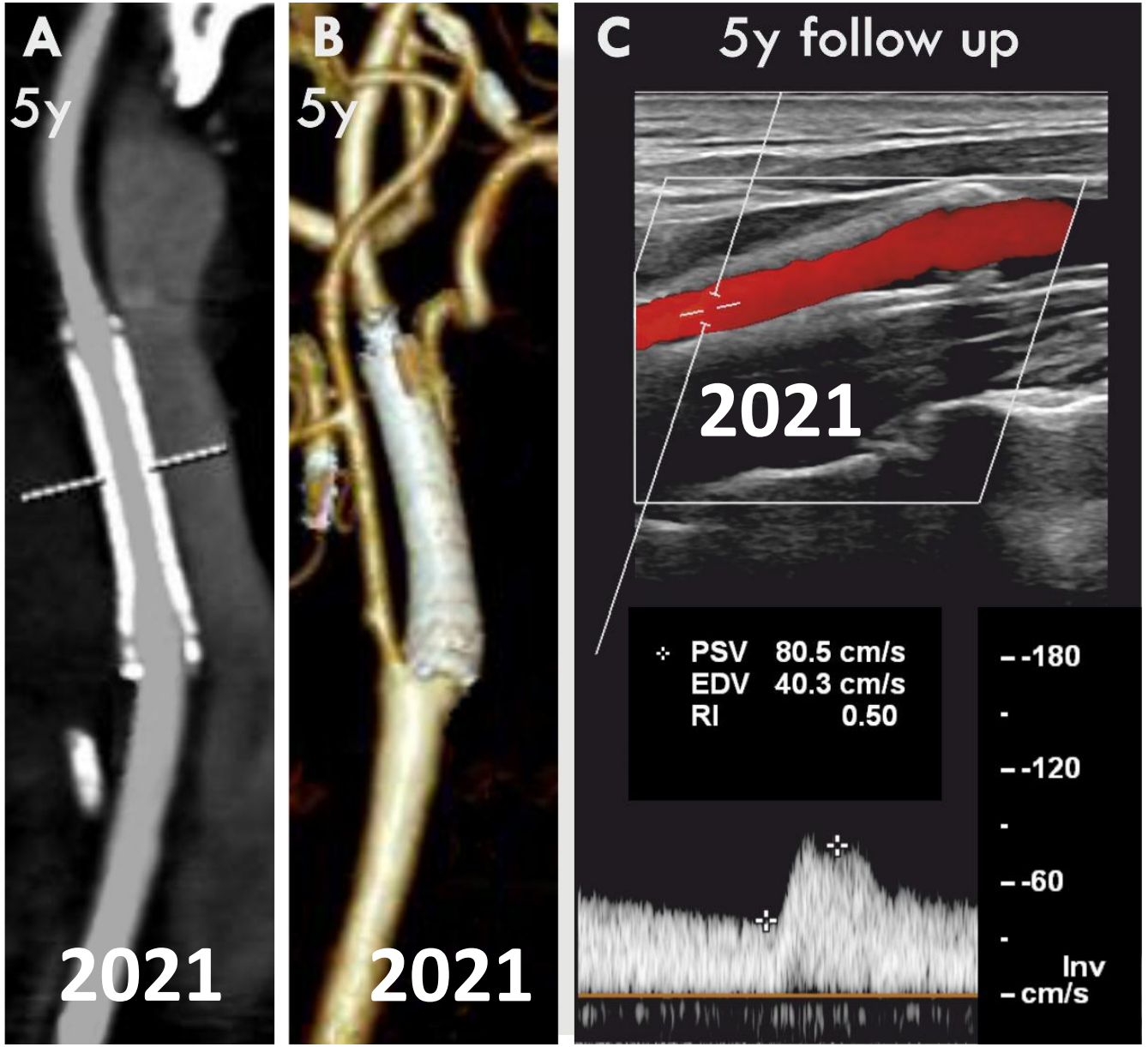
ANATOMIC

& CLINICAL

RESULT

MAINTAINED

LONG-TERM



PATIENT

CURED

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Conventional Carotid Stent Design Permits Atherosclerotic Plaque In-Stent Progression

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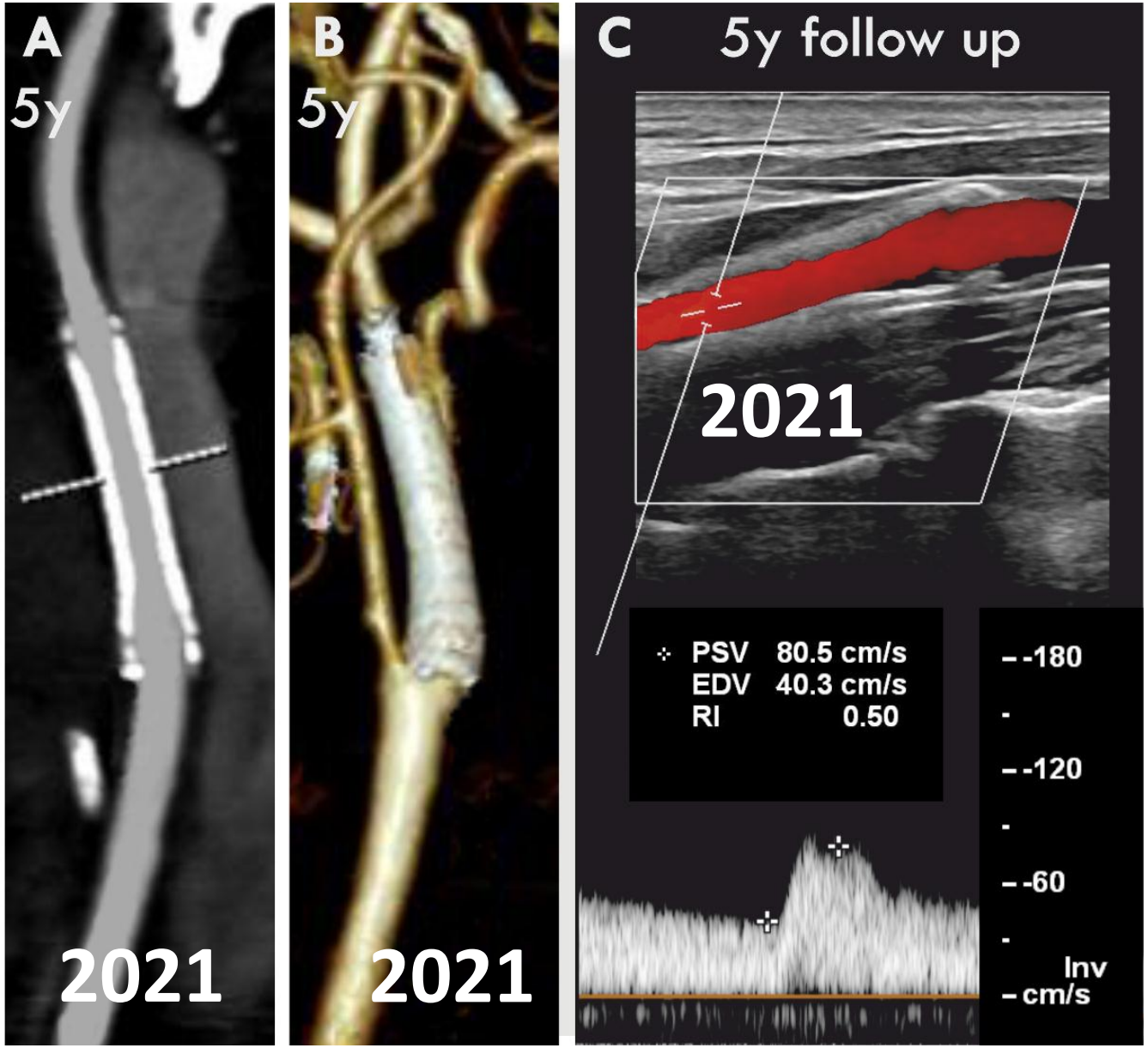
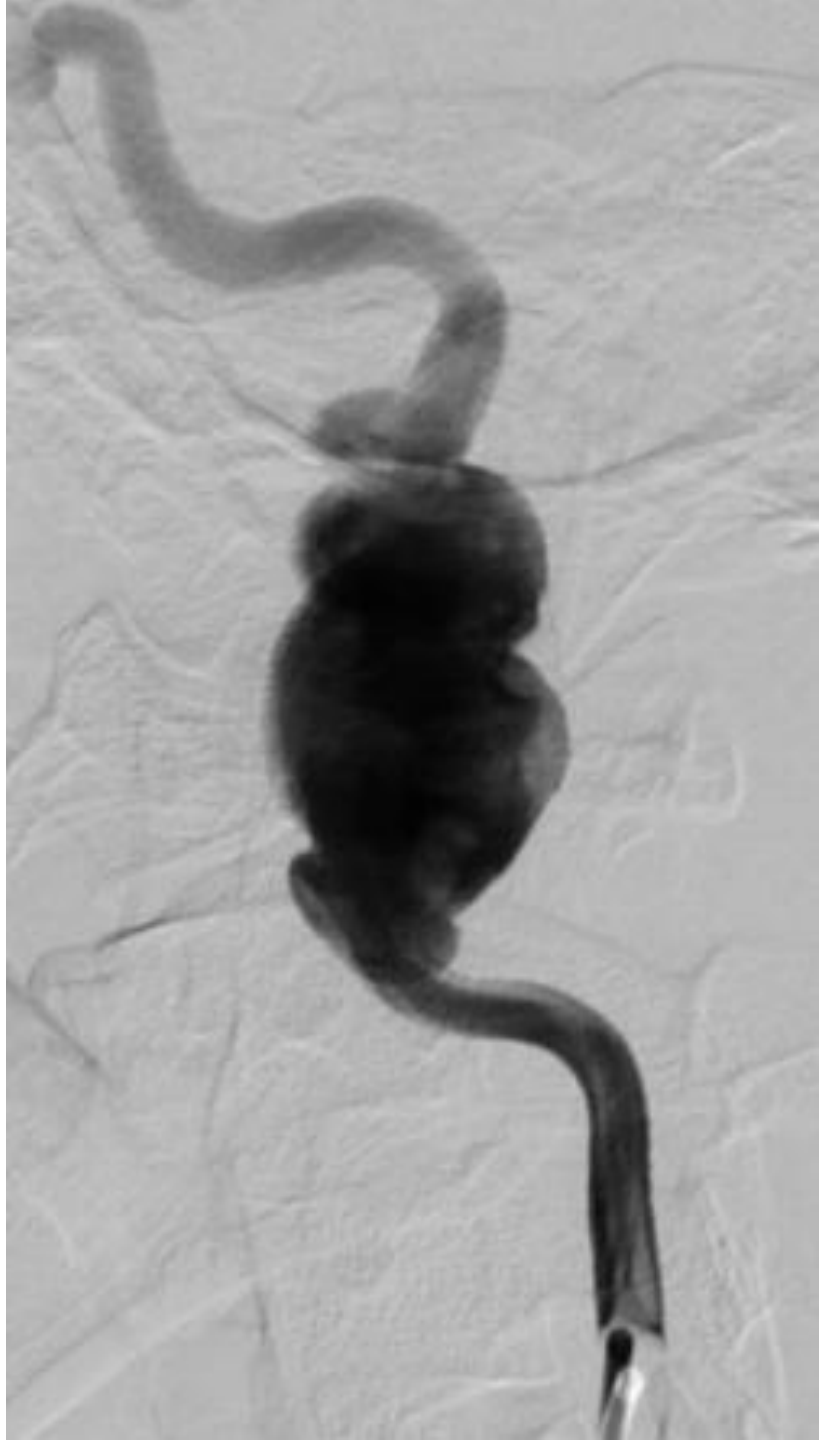
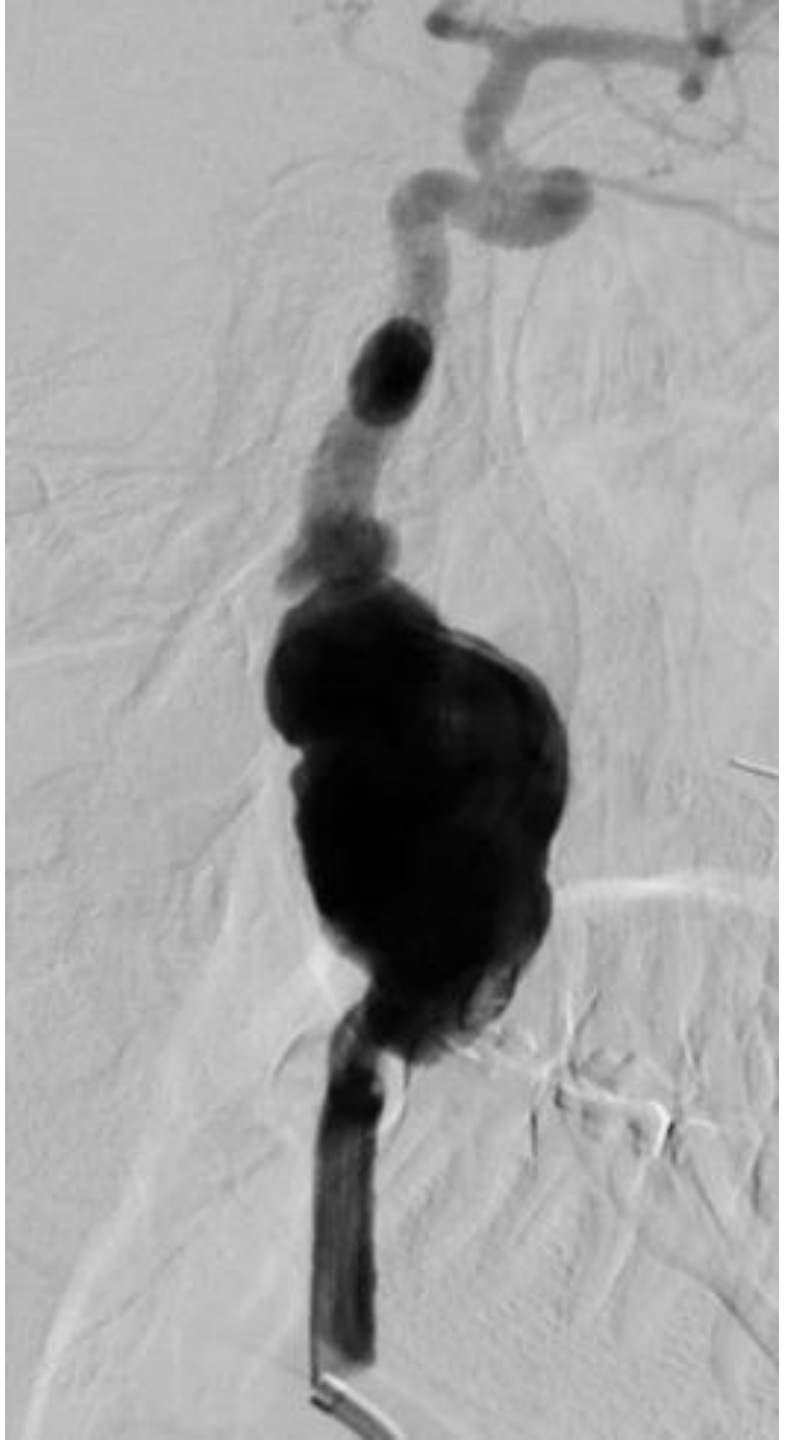
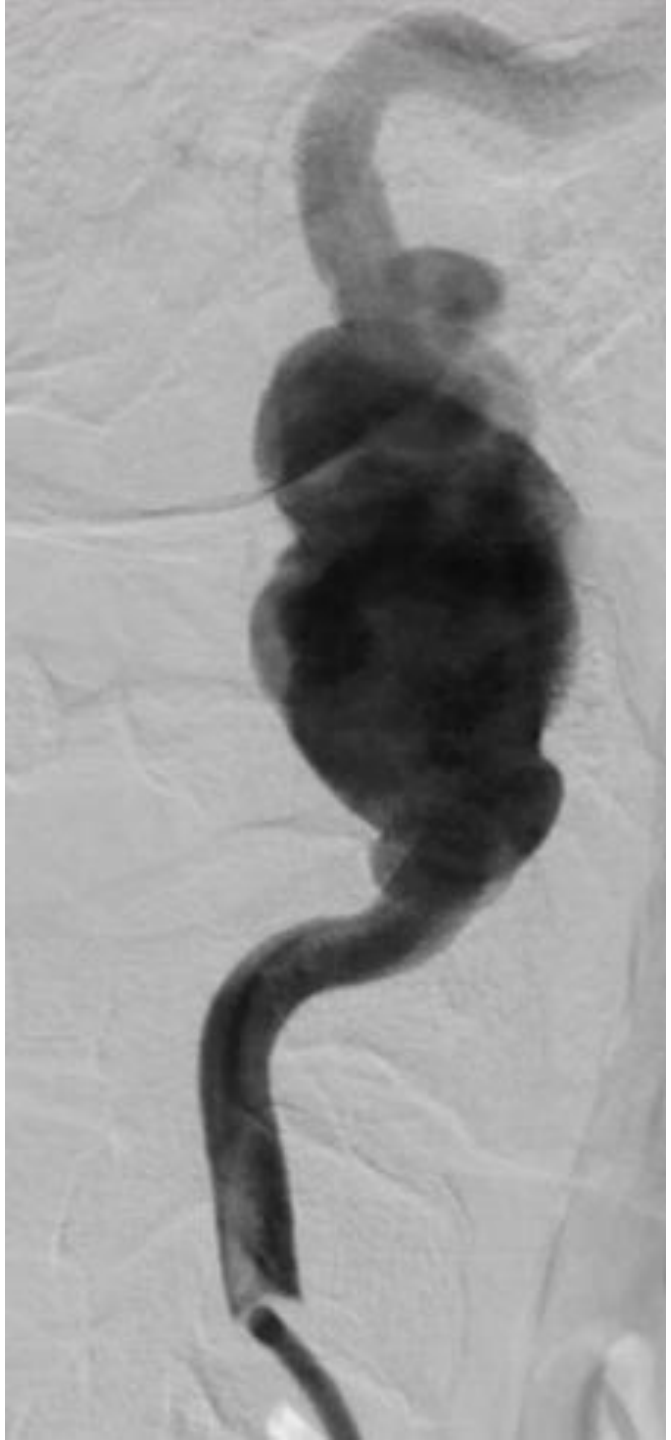


Tekieli et al. *Eur Heart J* 2021

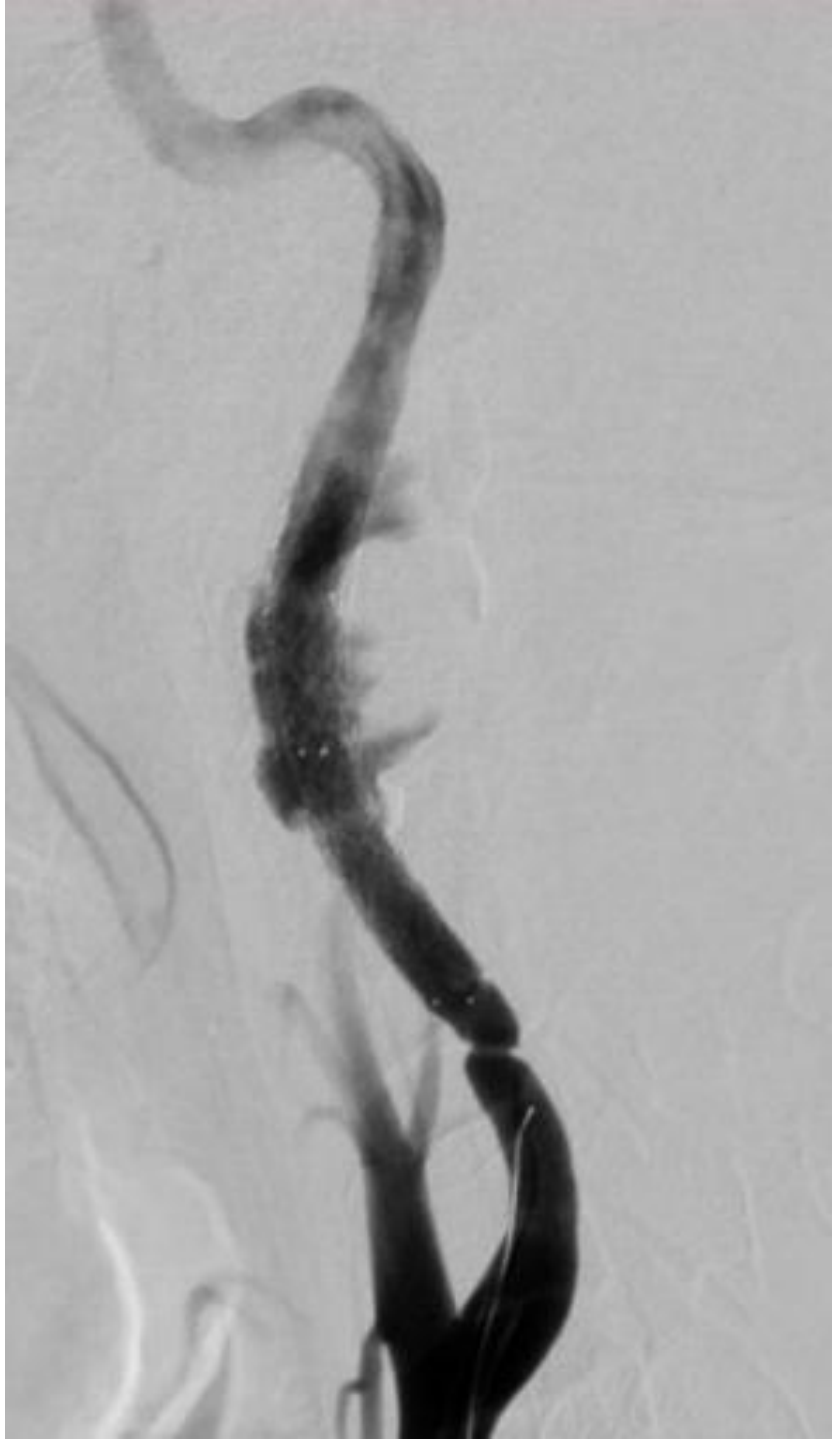
Aneurysms: Physiological Healing (Flow-Divertion)

43 yo Man, h. symptomatic

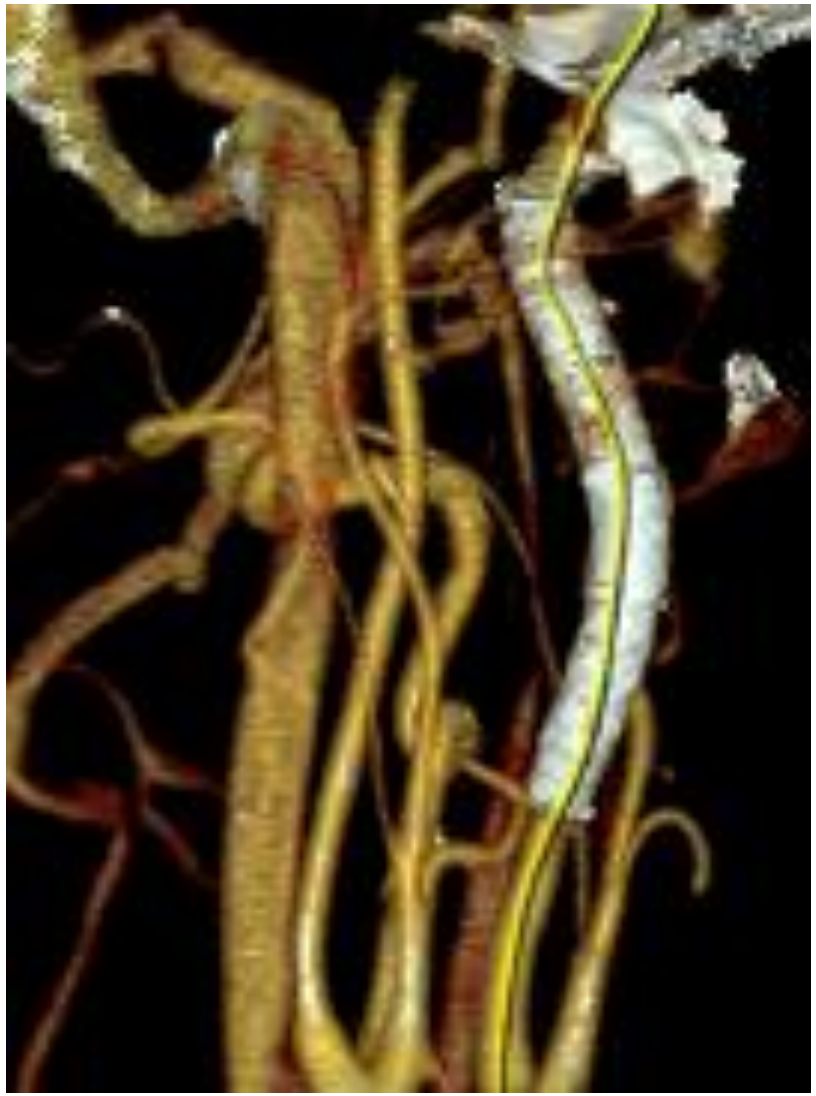
C-HEAL STUDY

NCT04434456



Immediate result

Immediate result

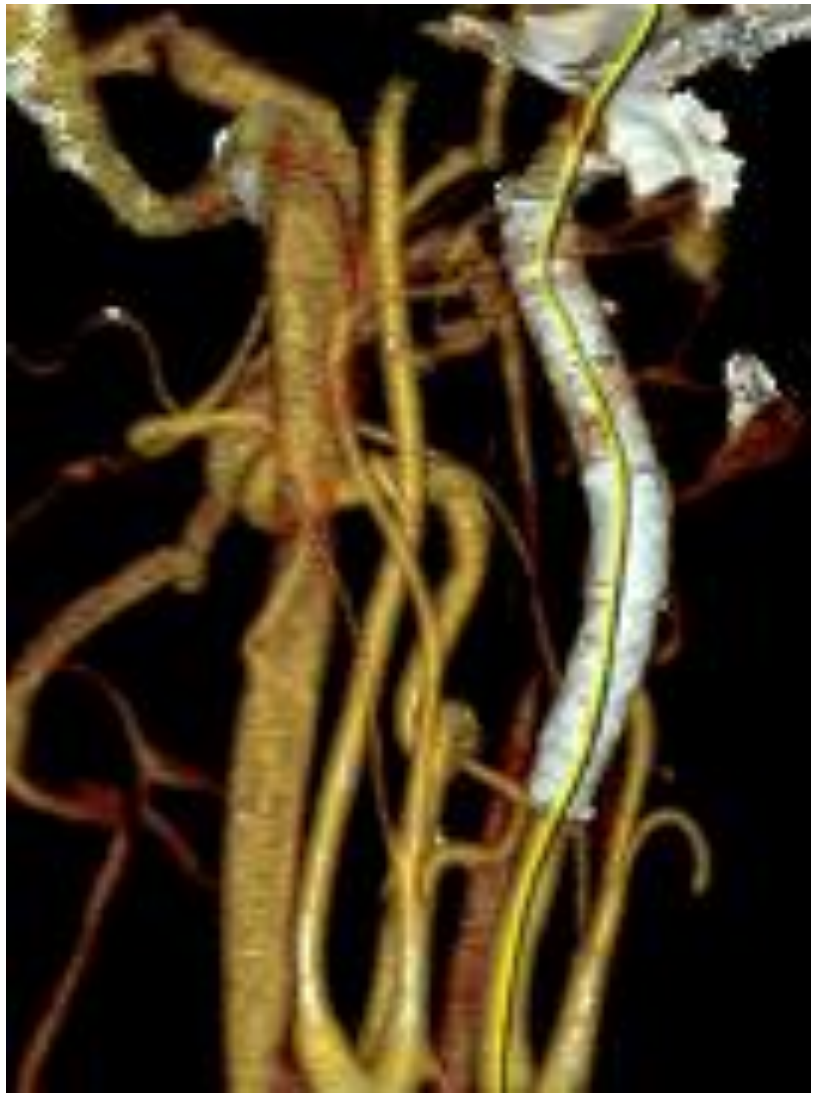


ANEURYSM
Total Exclusion @ 72h

Reconstruction of
NORMAL
ANATOMY

Acute Result Maintained @6mo CT Angio Control

P Musialek @ VEITH 2021



ANEURYSM
Total Exclusion @ 72h

Reconstruction of NORMAL ANATOMY

Patient CURED

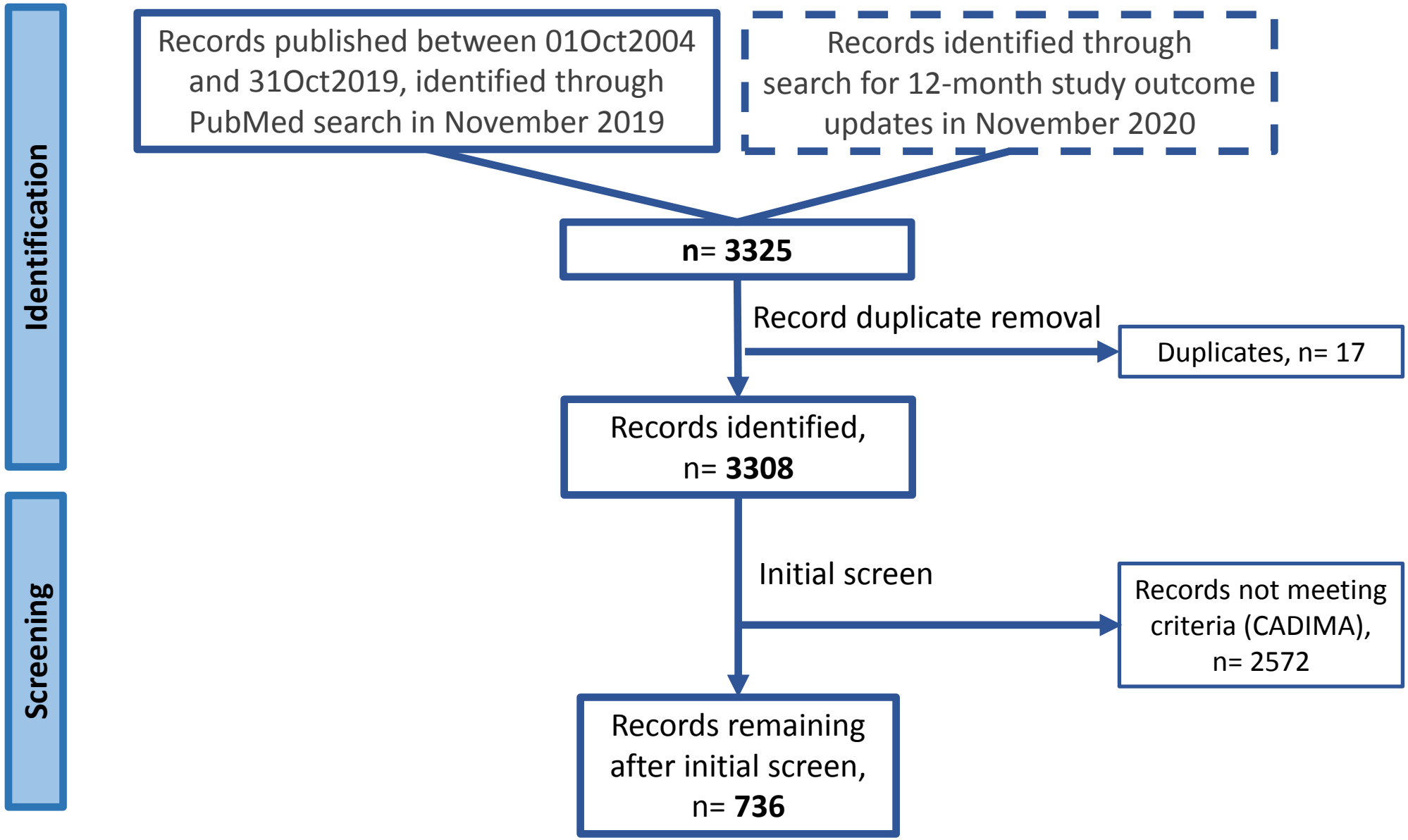
Levels of Medical Evidence

Sackett DL

CARMEN Collaborators

Meta-Analysis

CARMEN Systematic review and meta-analysis flowchart (PRISMA)



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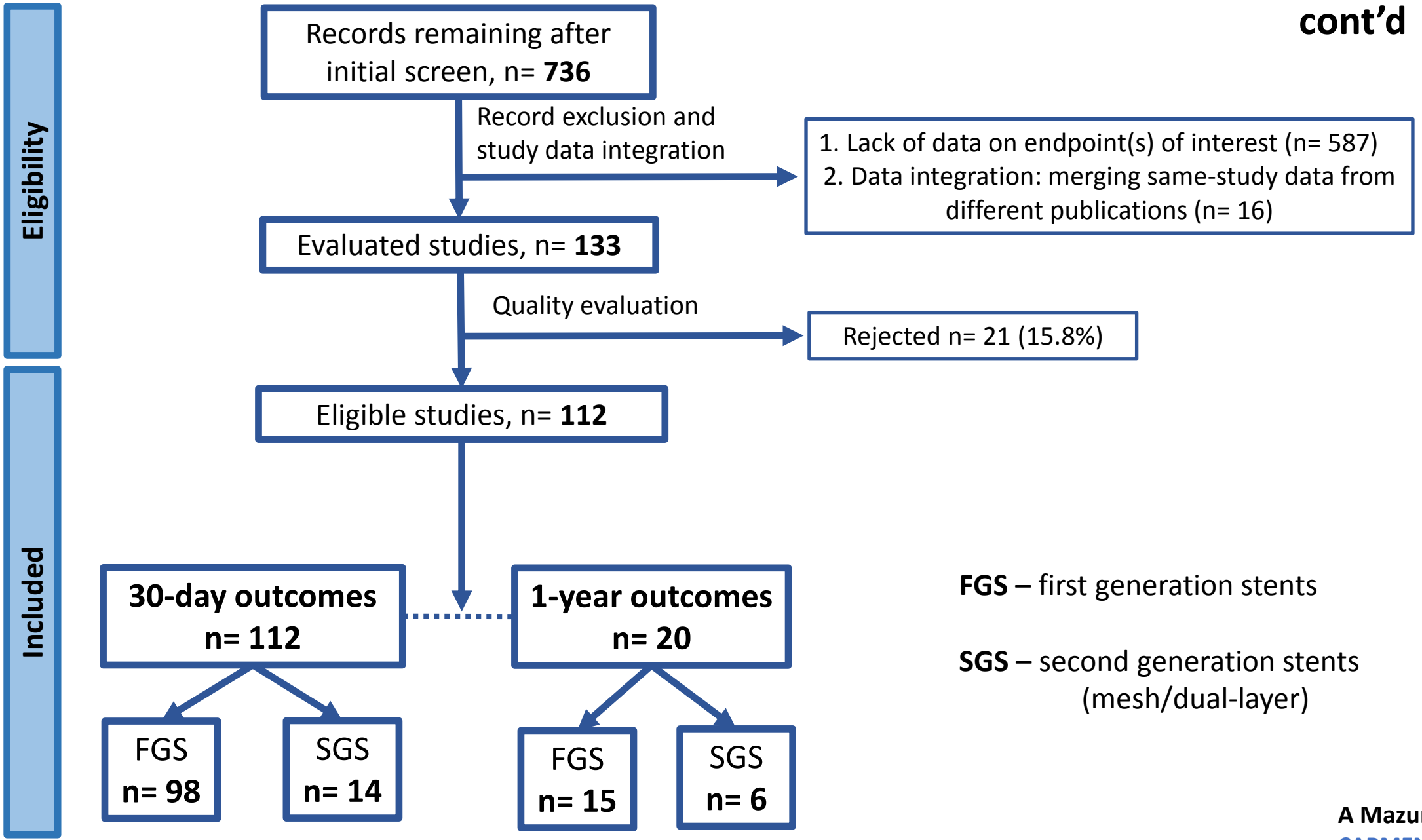
CARMEN Systematic review and meta-analysis flowchart (PRISMA)

cont'd



FGS – first generation stents

SGS – second generation stents (mesh/dual-layer)

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Stent type comparisons: Pooled populations characteristics

	FGS	**SGS**	p	Open-cell FGS	Close-cell FGS	p open vs close	p open vs SGS	p close vs SGS
No of studies	98	14	-	29	12	-	-	-
No of patients	65,891*	2,152*	-	20,676*	7,598*	-	-	-
Age [mean] ± SD	70.1 (2.8)	71.9 (2.5)	0.02	70.4 (3.2)	69.3 (3.4)	0.60	0.32	0.13
Male [%]	68%	73%	0.046	68%	66%	0.92	0.12	0.15
Symptomatic [%]	45%	41%	0.40	43%	50%	0.61	0.94	0.45
Diabetic [%]	34%	32%	0.43	35%	36%	0.71	0.88	0.61
CAD [%]	51%	47%	0.55	48%	55%	0.59	0.98	0.98
AF [%]	6%	3%	0.37	3%	ND	-	0.99	-
Contralateral occlusion [%]	10%	16%	0.22	10%	12%	0.87	0.63	0.99

FGS – first generation stents; **SGS** – second generation stents (mesh/dual-layer)

*Data per total number of patients as per published patient characteristics

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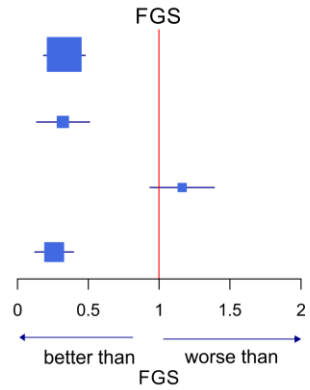
30-day Death/Stroke/MI

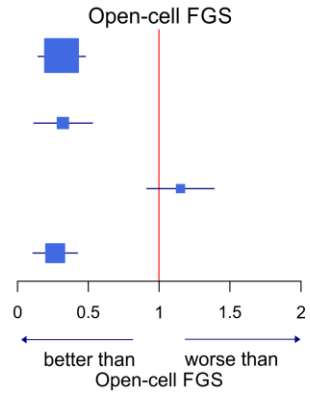
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.32 [0.17−0.46]
Casper/RoadSaver	585 10	23.1%	0.33 [0.14−0.51]
Gore Mesh Stent	311 15	12.3%	1.17 [0.94−1.41]
CGuard MicroNET Stent	1635 19	64.6%	0.26 [0.12−0.40]

Heterogeneity: I^2=87%, τ^2=0.0004, p<0.01



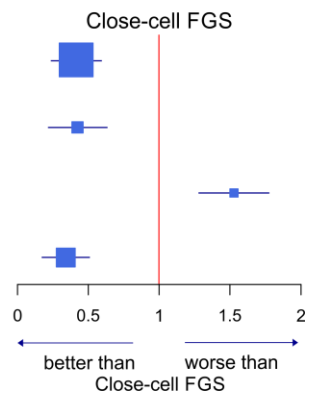
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.31 [0.14−0.48]
Casper/RoadSaver	585 10	23.1%	0.32 [0.11−0.52]
Gore Mesh Stent	311 15	12.3%	1.15 [0.91−1.40]
CGuard MicroNET Stent	1635 19	64.6%	0.26 [0.10−0.42]

Heterogeneity: I^2=84%, τ^2=0.0003, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.41 [0.23−0.59]
Casper/RoadSaver	585 10	23.1%	0.42 [0.21−0.63]
Gore Mesh Stent	311 15	12.3%	1.53 [1.28−1.79]
CGuard MicroNET Stent	1635 19	64.6%	0.34 [0.17−0.51]

Heterogeneity: I^2=73%, τ^2=0.0002, p<0.01



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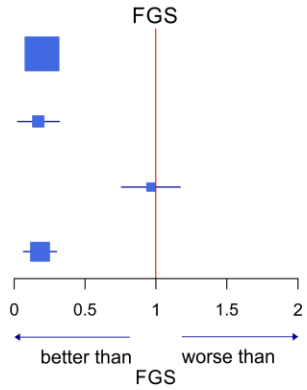
30-day Stroke

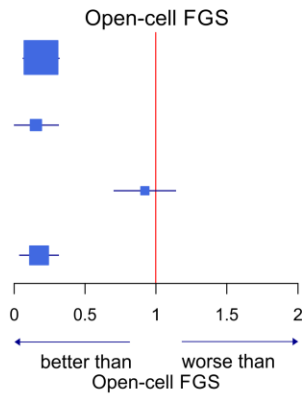
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.20 [0.08−0.32]
Casper/RoadSaver	585 5	23.1%	0.17 [0.02−0.31]
Gore Mesh Stent	311 9	12.3%	0.96 [0.75−1.17]
CGuard MicroNET Stent	1635 12	64.6%	0.18 [0.06−0.30]

Heterogeneity: I^2=87%, τ^2=0.0003, p<0.01



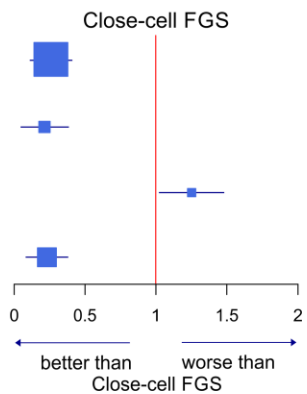
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.19 [0.06−0.33]
Casper/RoadSaver	585 5	23.1%	0.16 [0.00−0.32]
Gore Mesh Stent	311 9	12.3%	0.92 [0.70−1.14]
CGuard MicroNET Stent	1635 12	64.6%	0.17 [0.03−0.31]

Heterogeneity: I^2=83%, τ^2=0.0002, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.26 [0.11−0.41]
Casper/RoadSaver	585 5	23.1%	0.21 [0.04−0.38]
Gore Mesh Stent	311 9	12.3%	1.25 [1.02−1.48]
CGuard MicroNET Stent	1635 12	64.6%	0.23 [0.08−0.39]

Heterogeneity: I^2=72%, τ^2=0.0001, p<0.01



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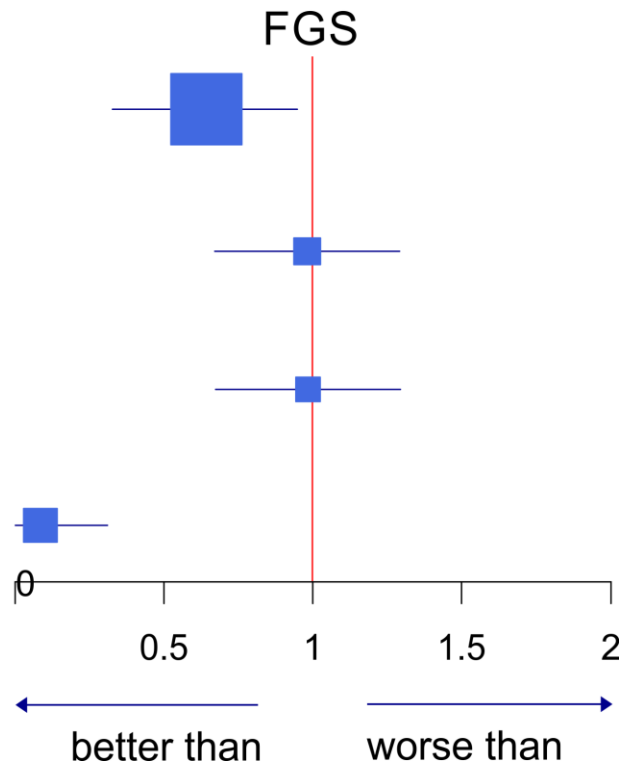
12-month Ipsilateral Stroke/Restenosis

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 57	100%	0.63 [0.32−0.93]
Casper/RoadSaver	348 29	29.2%	0.97 [0.66−1.27]
Gore Mesh Stent	290 23	24.4%	0.97 [0.66−1.28]
CGuard MicroNET Stent	553 5	46.4%	0.09 [0.00−0.31]

Heterogeneity: I^2=92%, τ^2=0.0012, p<0.01



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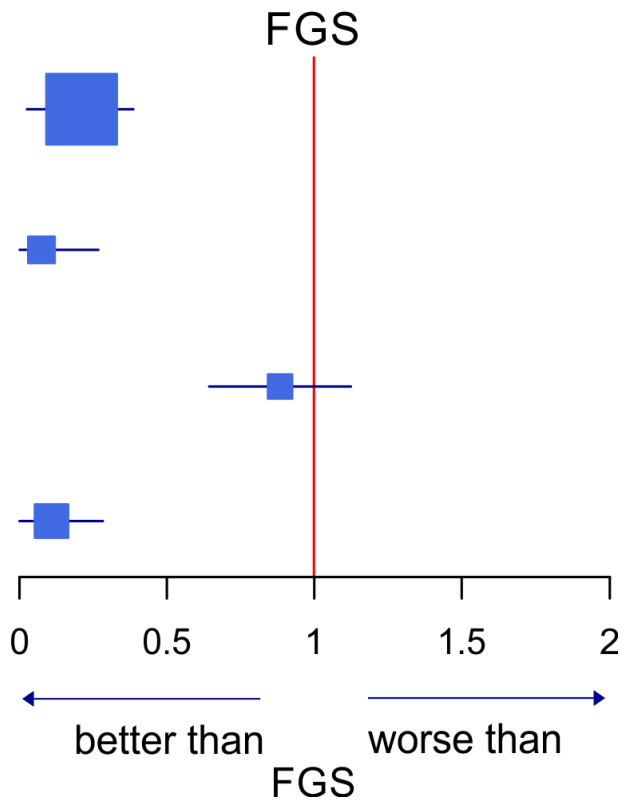
12-month Ipsilateral Stroke

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 15	100%	0.20 [0.02−0.39]
Casper/RoadSaver	348 3	29.2%	0.07 [0.00−0.27]
Gore Mesh Stent	290 9	24.4%	0.88 [0.64−1.13]
CGuard MicroNET Stent	553 3	46.4%	0.11 [0.00−0.28]

Heterogeneity: I^2=86%, τ^2=0.0002, p<0.01



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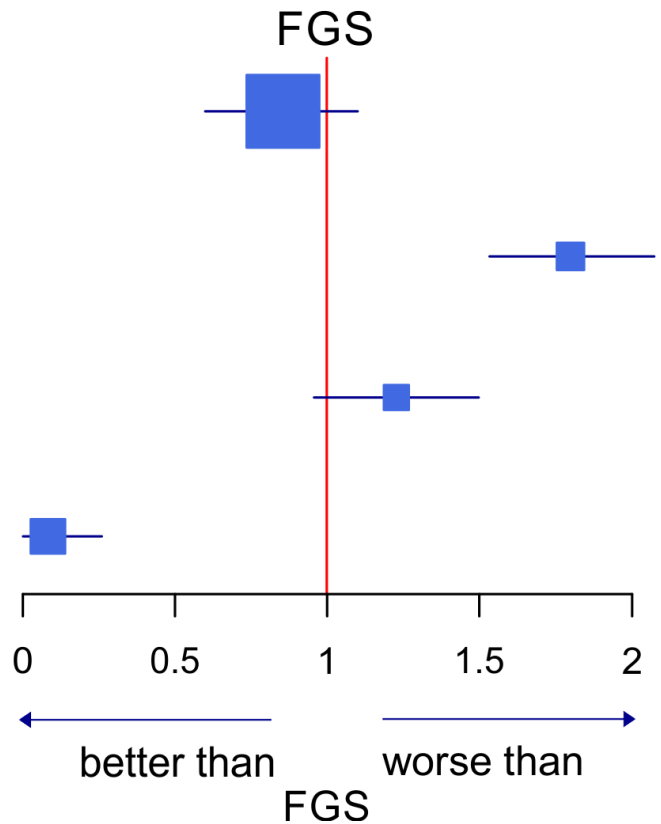
12-month Restenosis

Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 42	100%	0.85 [0.60−1.10]
Casper/RoadSaver	348 26	29.2%	1.80 [1.53−2.08]
Gore Mesh Stent	290 14	24.4%	1.22 [0.95−1.48]
CGuard MicroNET Stent	553 2	46.4%	0.09 [0.00−0.26]

Heterogeneity: I^2=88%, τ^2=0.0003, p<0.01



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CEA vs SGS meta-analysis

Major
RCTs
Involving CEA

1. CEA pooled data

SAPPHIRE
EVA 3S
SPACE-1
ICSS
CREST
ACST-1
ACT-1
Manhaim
SPACE-2

CEA in
Contemporary
Clinical Practice

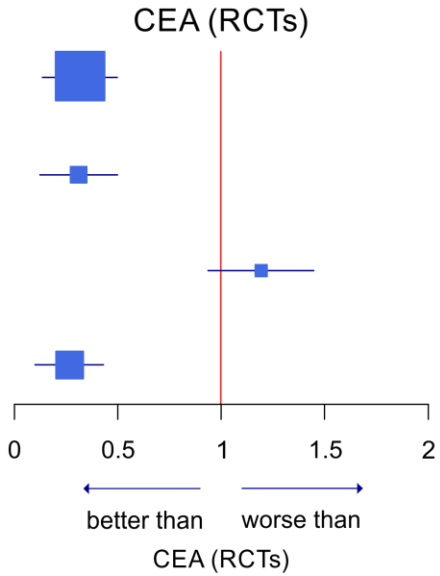
2. CEA in Vascular Quality Initiative (VQI) database*

* Dakour-Aridi H, et al. *Ann Vasc Surg.* 2020;65:1-9
Columbo JA, et al. *J Vasc Surg.* 2019;69:104-109

30-day Death/Stroke/MI

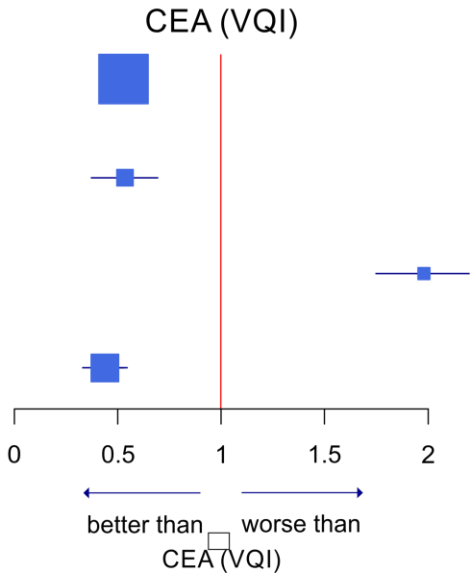
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.32 [0.14−0.50]
Casper/RoadSaver	585 10	23.1%	0.33 [0.12−0.54]
Gore Mesh Stent	311 15	12.3%	1.19 [0.94−1.45]
CGuard MicroNET Stent	1635 19	64.6%	0.27 [0.10−0.44]

Heterogeneity: I^2=81%, τ^2=0.0003, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 44	100%	0.53 [0.41−0.65]
Casper/RoadSaver	585 10	23.1%	0.54 [0.38−0.70]
Gore Mesh Stent	311 15	12.3%	1.98 [1.76−2.20]
CGuard MicroNET Stent	1635 19	64.6%	0.44 [0.33−0.55]

Heterogeneity: I^2=76%, τ^2=0.0001, p<0.01



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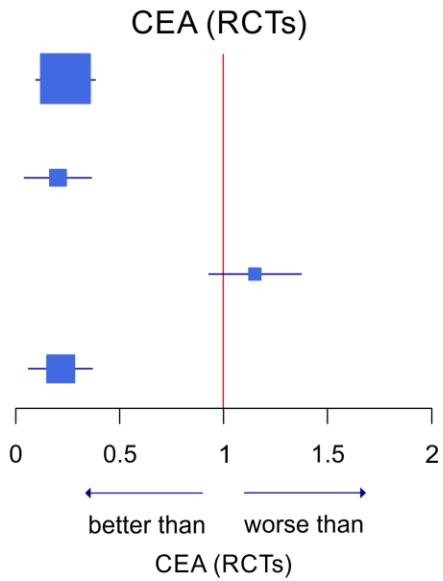
30-day Stroke

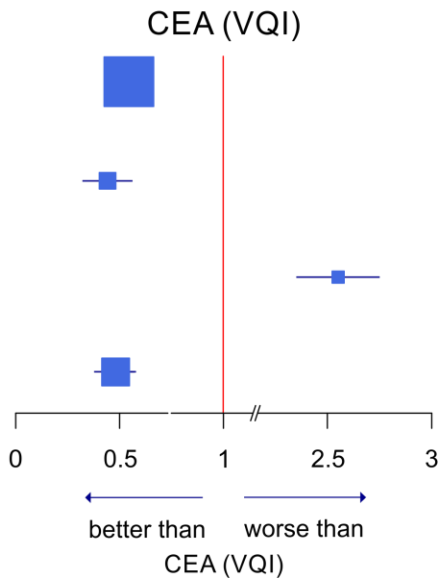
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.24 [0.10−0.38]
Casper/RoadSaver	585 5	23.1%	0.20 [0.04−0.36]
Gore Mesh Stent	311 9	12.3%	1.15 [0.92−1.37]
CGuard MicroNET Stent	1635 12	64.6%	0.22 [0.07−0.36]

Heterogeneity: I^2=71%, τ^2<0.0001, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	2531 26	100%	0.53 [0.44−0.62]
Casper/RoadSaver	585 5	23.1%	0.44 [0.32−0.56]
Gore Mesh Stent	311 9	12.3%	2.55 [2.35−2.75]
CGuard MicroNET Stent	1635 12	64.6%	0.48 [0.39−0.57]

Heterogeneity: I^2=40%, τ^2<0.0001, p=0.06



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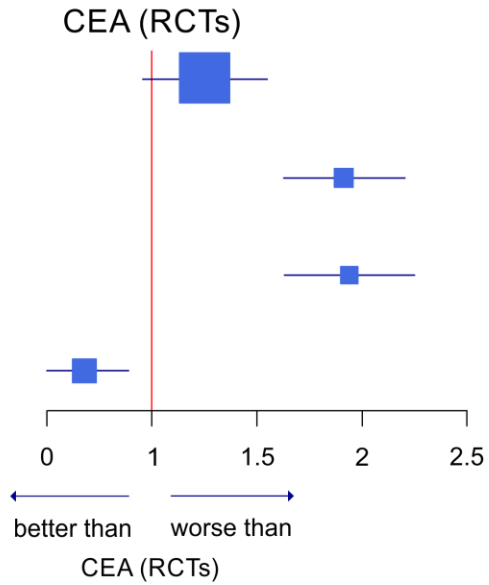
12-month Ipsilateral Stroke/Restenosis

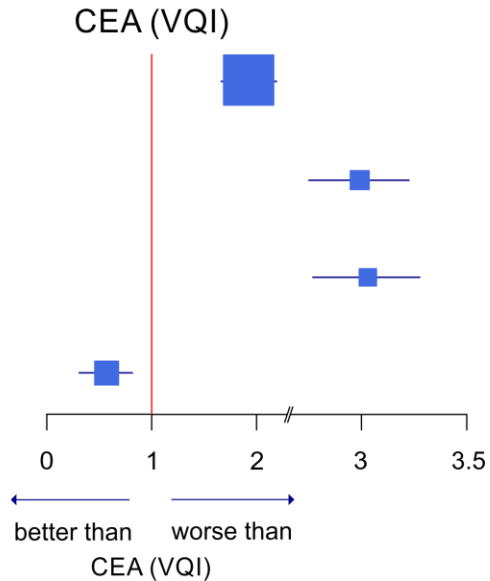
Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 57	100%	1.25 [0.95−1.55]
Casper/RoadSaver	348 29	29.2%	1.92 [1.63−2.21]
Gore Mesh Stent	290 23	24.4%	1.94 [1.63−2.25]
CGuard MicroNET Stent	553 5	46.4%	0.18 [0.00−0.39]

Heterogeneity: I^2=87%, τ^2=0.0004, p<0.01



Study	Patients Events	Weight	Risk Ratio [95% CI]
SGS	1191 57	100%	1.95 [1.70−2.20]
Casper/RoadSaver	348 29	29.2%	2.99 [2.75−3.23]
Gore Mesh Stent	290 23	24.4%	3.02 [2.77−3.27]
CGuard MicroNET Stent	553 5	46.4%	0.28 [0.15−0.41]

Heterogeneity: I^2=89%, τ^2=0.0003, p<0.01



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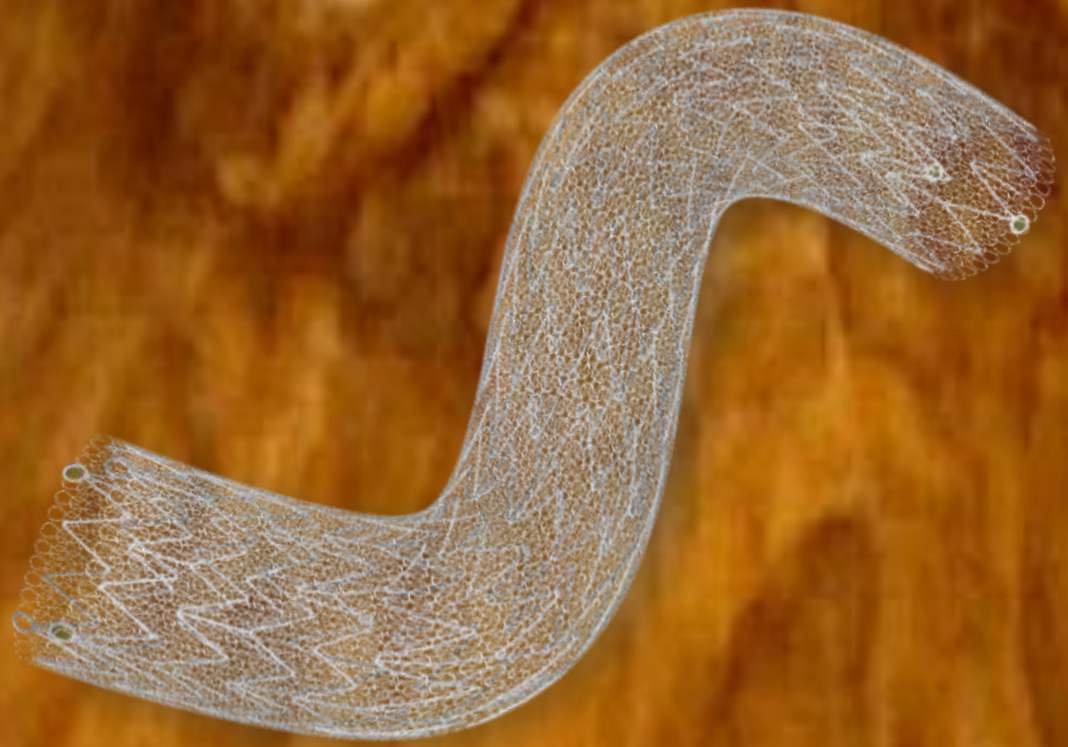
CGuard MicroNet-covered Stent

Expanding Clinical Evidence

CGUARDIANS	FDA-IDE	NCT04900844
TOP-GUARD	CGuard in transcervical Flow reversal CAS	NCT04547387
C-HEAL	Flow-diverter aneursym exclusion-and-healing	NCT04434456
OPTIMA	Intravascular evaluation of sympt. plaque exclusion	NCT04234854
PARADIGM-EXTEND	Multi-centric H risk All-comers with indication, No exclusions	NCT04271033
FLOW-GUARD	MicroNET stent in high-risk lesions beyond carotid bif.	NCT04461717

CGuard MicroNET-Covered Stent



A NEW STANDARD OF CARE