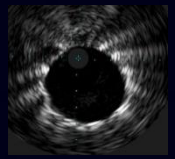
TCT 2022 Featured Research



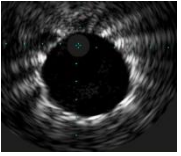
Carotid Artery Endovascular Reconstruction Using Micronet-Covered Stents in Patients with Symptoms or Signs of Cerebral Ischemia

Piotr Musialek, MD DPhil
for CGuard OPTIMA Investigators

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

CGuard OPTIMA Trial NCT04234854

OPtimal sequestration of high-risk carotid lesions with effecTive lumen reconstruction usIng MicroNet–covered stents And the endovascular route



CGuard OPTIMA Trial INVESTIGATORS

CGuard
OPTIMA

Piotr Musialek, MD DPhil
Laura Capoccia, MD PhD
C. Alejandro Alvarez, MD
Adam Mazurek, MD PhD
Lukasz Tekieli, MD PhD
Wladyslaw Dabrowski, MD
Bogdan Janus, MD PhD
Anna Szwiec, MD PhD
Maciej Mazgaj, MD
Artur Klecha, MD PhD

S. Tomasz Kowalczyk, MD
Jaroslaw Miszczuk, MD PhD
Oleg Krestyaninov, MD PhD
Magdalena Knapik, MD
Mariusz Trystula, MD PhD
Ivo Petrov, MD PhD
Petar Polomski, MD
Krzysztof Malinowski, MSc PhD
Max Amor, MD
Andrej Schmidt, MD PhD

INVESTIGATOR – INITIATED STUDY

CRF 2022 TCT

11 Centers, 4 Specialties, 7 Countries

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.

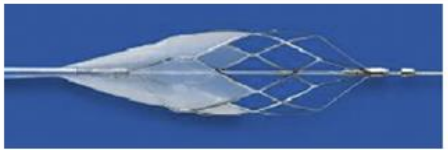
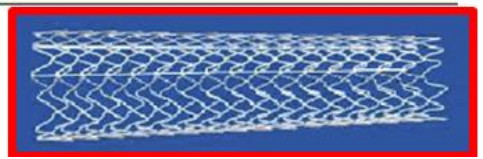
Affiliation/Financial Relationship	Company
Grant/Research Support	Abbott Vascular, InspireMD
Consulting Fees/Honoraria	InspireMD, Abbott Vascular, Medtronic
Major Stock Shareholder/Equity	N/A
Royalty Income	N/A
Ownership/Founder	N/A
Intellectual Property Rights	N/A
Proctoring	InspireMD, Medtronic
Other	US IDE (CGUARDIANS) Co-PI

Faculty disclosure information can be found on the app

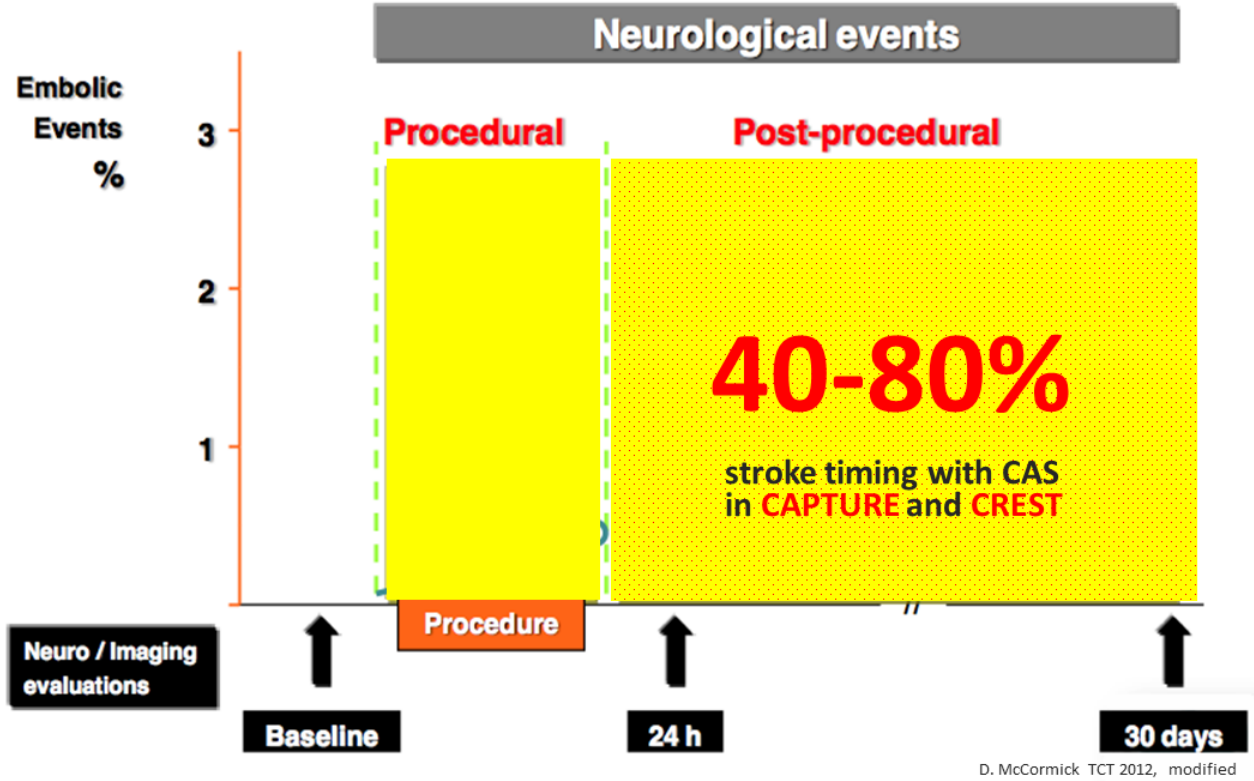
CREST-1

N Engl J Med 2010;363:11-23.

	Periprocedural Period				
	CAS (N=1262)	CEA (N=1240)	Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	no. of patients (% ±SE)		*percentage points*		
Death	9 (0.7±0.2)	4 (0.3±0.2)	0.4 (–0.2 to 1.0)	2.25 (0.69 to 7.30)†	0.18†
Stroke					
Any	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major ipsilateral	11 (0.9±0.3)	4 (0.3±0.2)	0.5 (–0.1 to 1.2)	2.67 (0.85 to 8.40)	0.09
Major nonipsilateral‡	0	4 (0.3±0.2)	NA	NA	NA
Minor ipsilateral	37 (2.9±0.5)	17 (1.4±0.3)	1.6 (0.4 to 2.7)	2.16 (1.22 to 3.83)	0.009
Minor nonipsilateral	4 (0.3±0.2)	4 (0.3±0.2)	0.0 (–0.4 to 0.4)	1.02 (0.25 to 4.07)	0.98†
Myocardial infarction	14 (1.1±0.3)	28 (2.3±0.4)	–1.1 (–2.2 to –0.1)	0.50 (0.26 to 0.94)	0.03
Any periprocedural stroke or postprocedural ipsilateral stroke	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major stroke	11 (0.9±0.3)	8 (0.6±0.2)	0.2 (–0.5 to 0.9)	1.35 (0.54 to 3.36)	0.52
Minor stroke	41 (3.2±0.5)	21 (1.7±0.4)	1.6 (0.3 to 2.8)	1.95 (1.15 to 3.30)	0.01
Any periprocedural stroke or death or post-procedural ipsilateral stroke	55 (4.4±0.6)	29 (2.3±0.4)	2.0 (0.6 to 3.4)	1.90 (1.21 to 2.98)	0.005
Primary end point (any periprocedural stroke, myocardial infarction, or death or postprocedural ipsilateral stroke)	66 (5.2±0.6)	56 (4.5±0.6)	0.7 (–1.0 to 2.4)	1.18 (0.82 to 1.68)	0.38

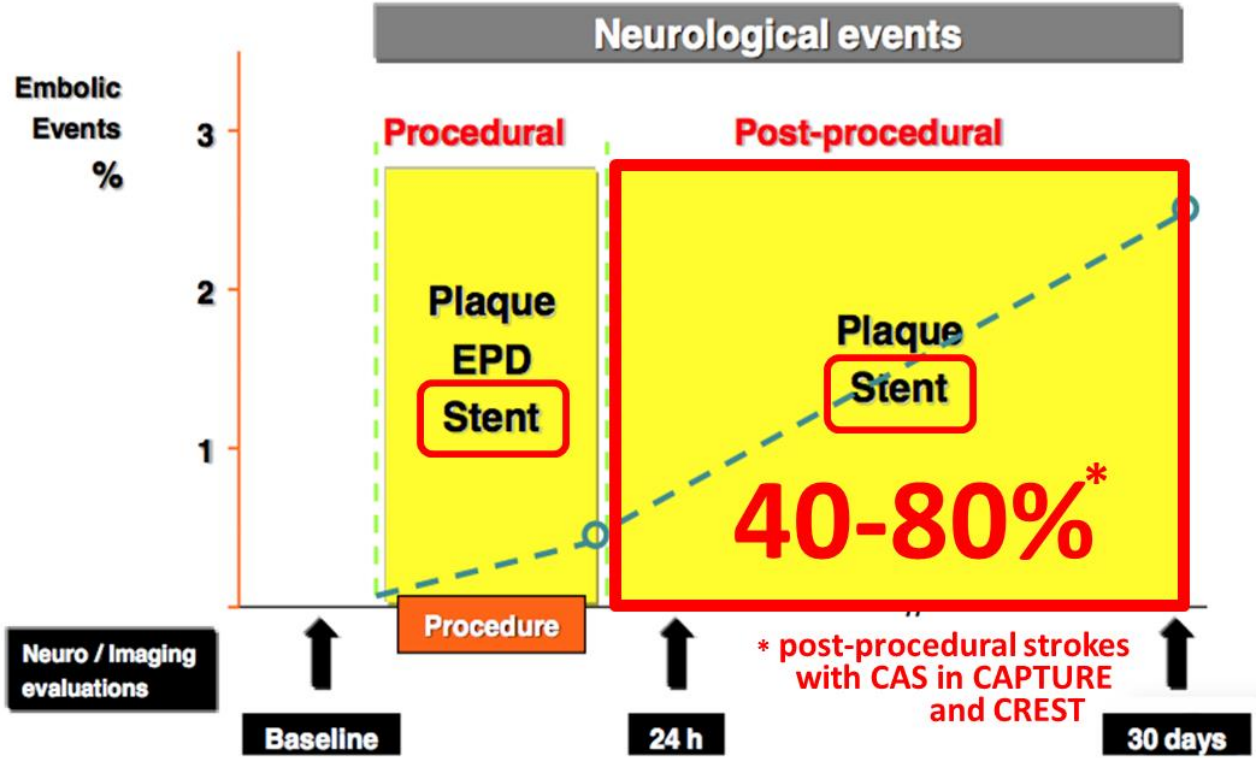




Timing of neuro-embolic events after CAS



D. McCormick TCT 2012, modified

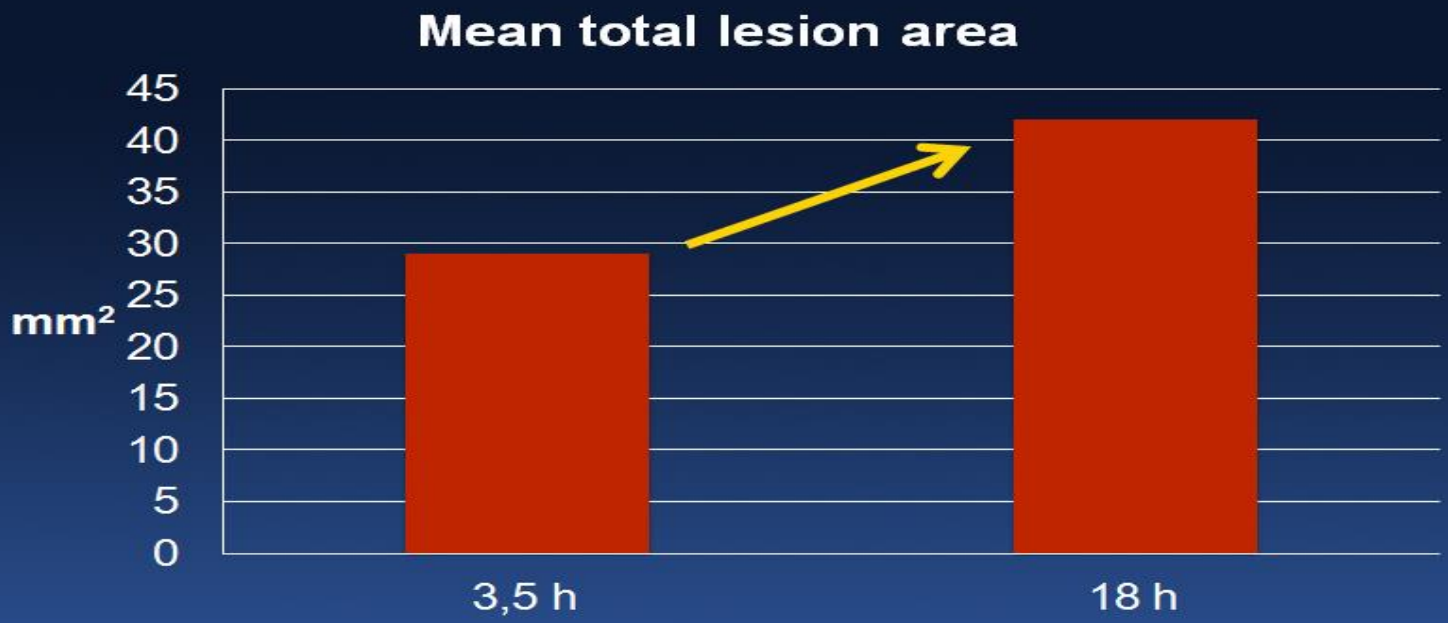
Timing of neuro-embolic events after CAS



D. McCormick TCT 2012, modified

Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS



Schofer J et al, JACC Cardiovasc interv 2008

CEA, The Gold Standard

”CEA…

by removing the plaque

removes

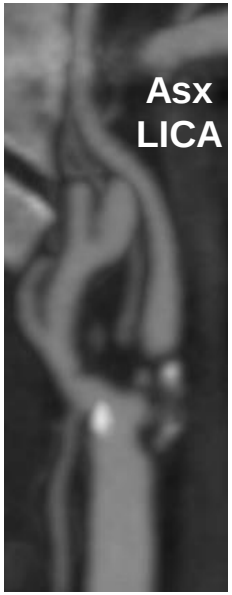
plaque-related problems”

NB. The MicroNet-Covered stent is currently NOT available in the US outiside the FDA-IDE Trial

The ”Gold Standard”… How GOLD ?

M, 54 y
CEA

M, 54 y
CEA



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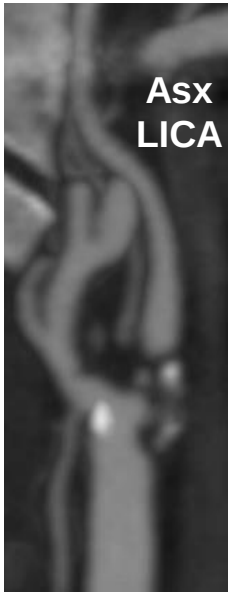
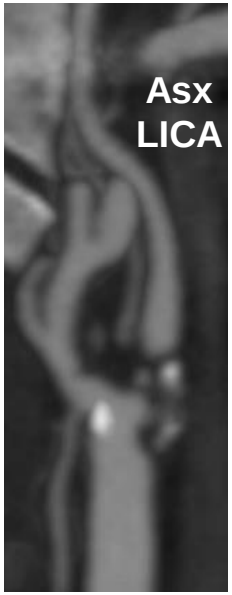


Peri-Procedural **Stroke**
mRS **4** @ 90d

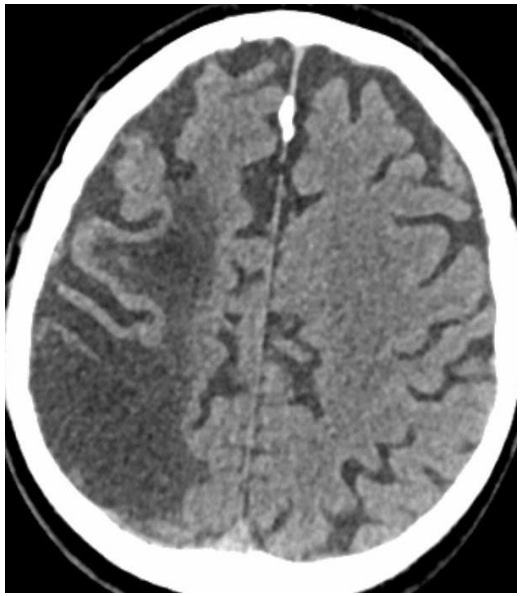
The ”Gold Standard”… How GOLD ?

M, 54 y
CEA



Peri-Procedural **Stroke**
mRS **4** @ 90d

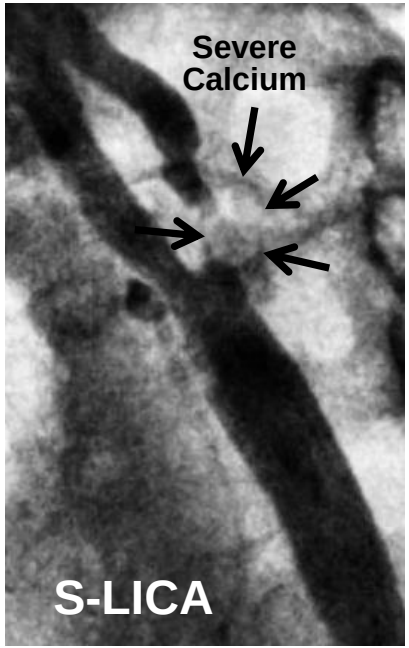
W, 61 y
CEA



Stroke 5 days post CEA
mRS **3** @ 90d

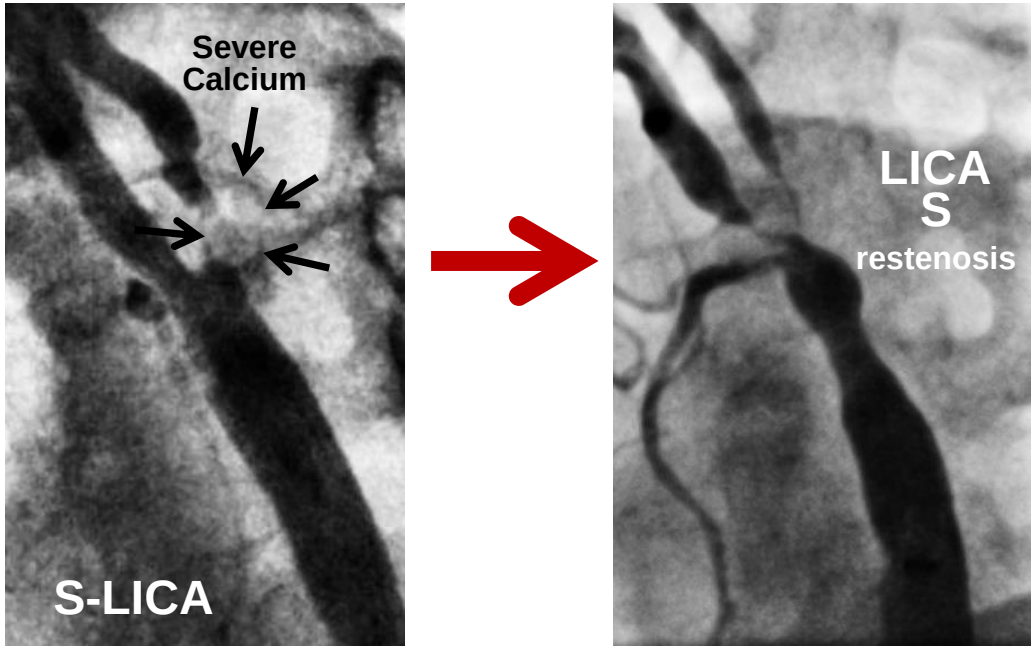
M, 69 y
CEA

The ”Gold Standard”… How GOLD ?



M, 69 y
CEA

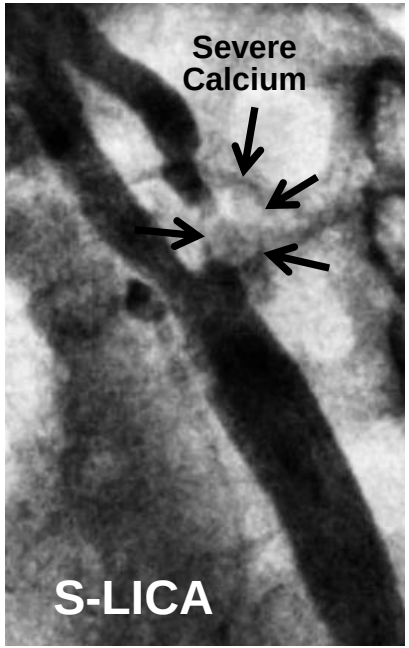
The ”Gold Standard”… How GOLD ?



Symptomatic Restenosis
14-mo post CEA

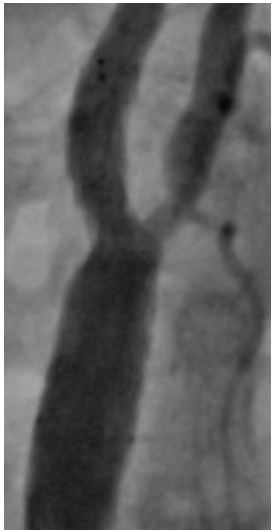
M, 69 y
CEA

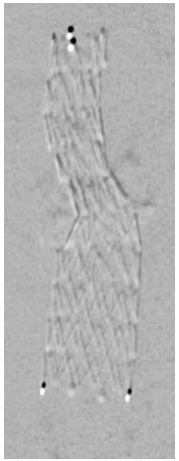
The ”Gold Standard”… How GOLD ?



Symptomatic Restenosis
14-mo post CEA

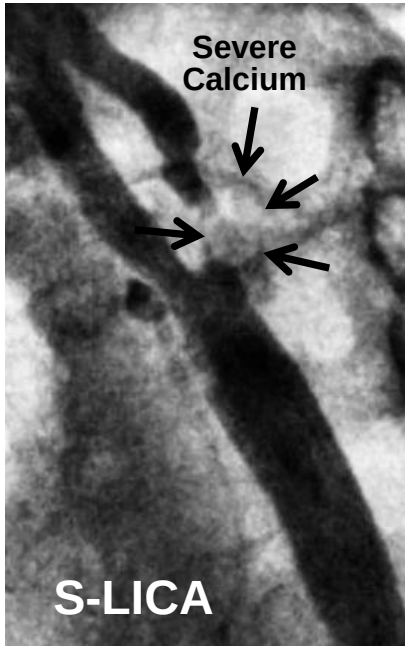
NB. MicroNet-Covered Stent –Treated RICA OK





M, 69 y
CEA

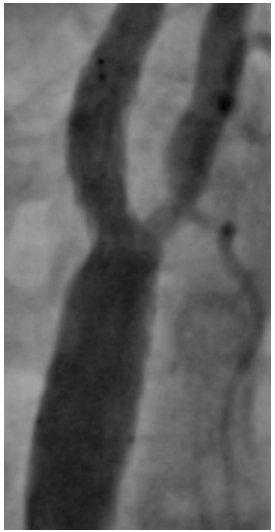
The ”Gold Standard”… How GOLD ?

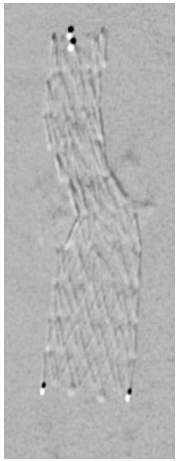


Symptomatic Restenosis
14-mo post CEA

→ Resolved
with a MicroNet-Covered Stent

NB. MicroNet-Covered Stent –Treated RICA OK





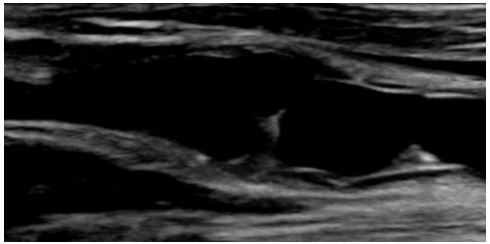
M, 67 y
CEA

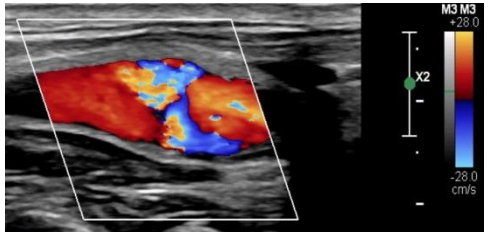
The ”Gold Standard”… How GOLD ?

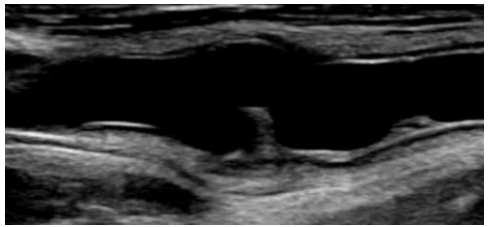
Crescendo TIAs post Discharge

M, 67 y
CEA

The ”Gold Standard”… How GOLD ?







Crescendo TIAs post Discharge

M, 67 y
CEA

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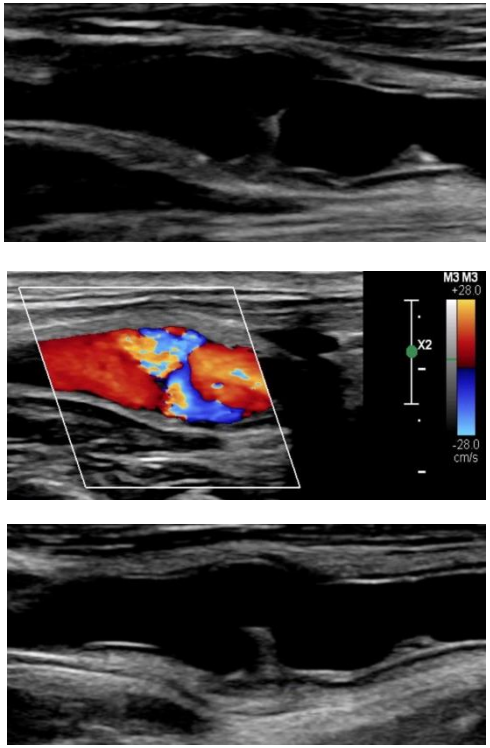

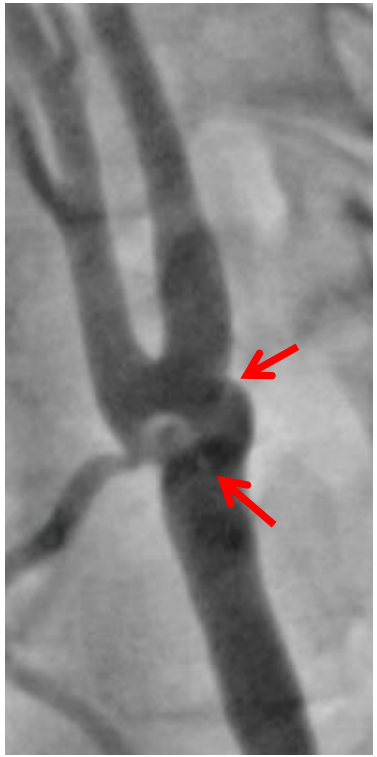

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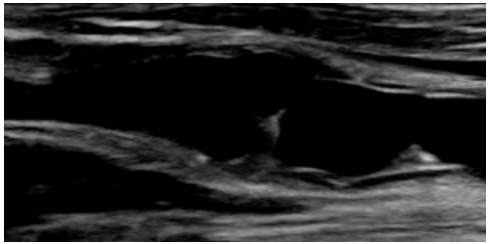
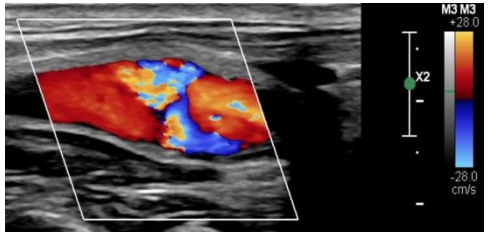
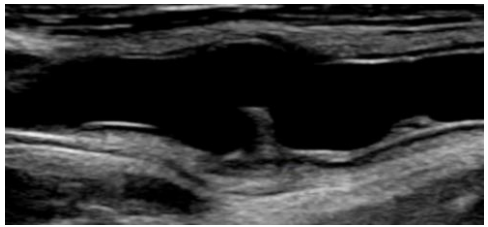
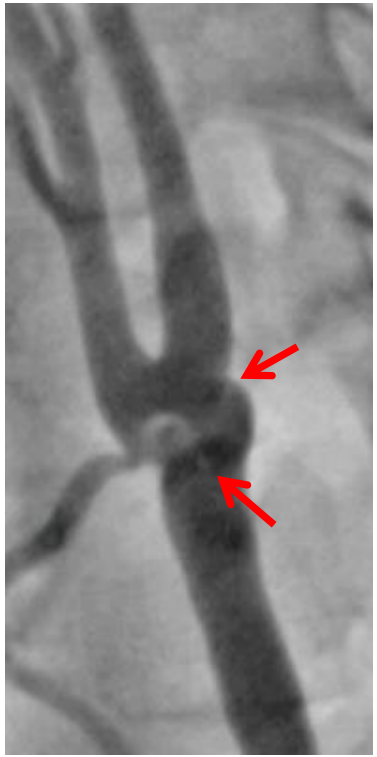
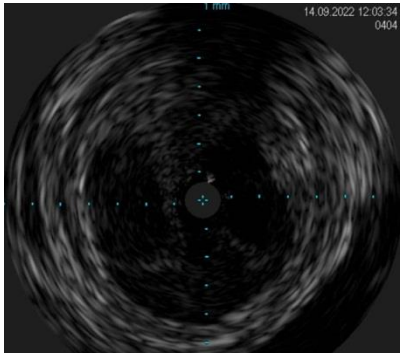
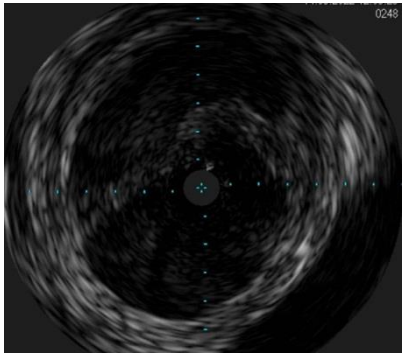


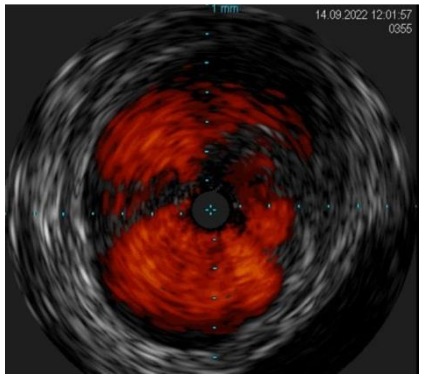








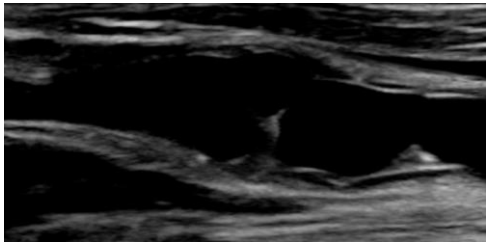


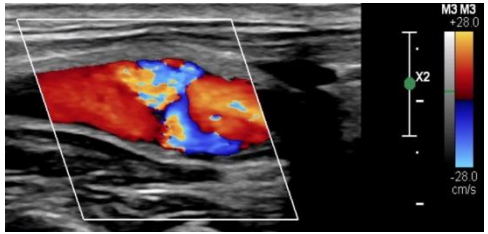


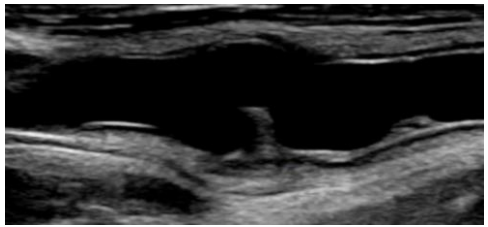
Crescendo TIAs post Discharge

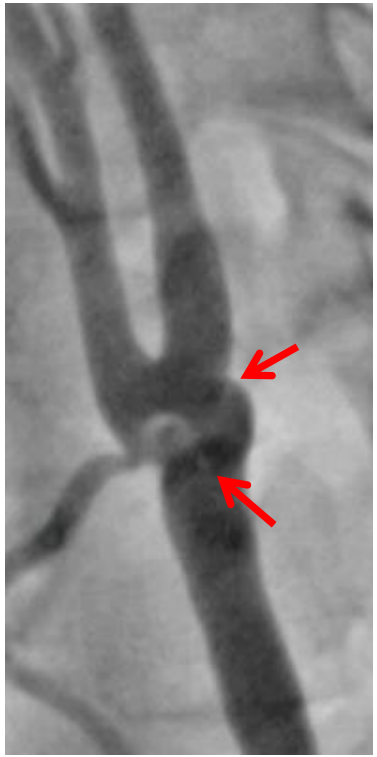
M, 67 y
CEA

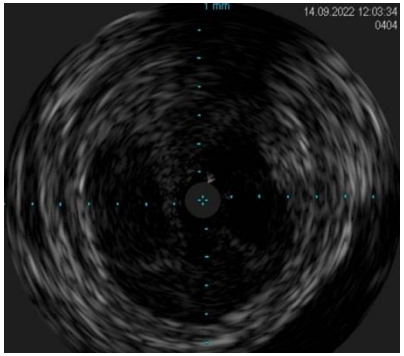
The ”Gold Standard”… How GOLD ?

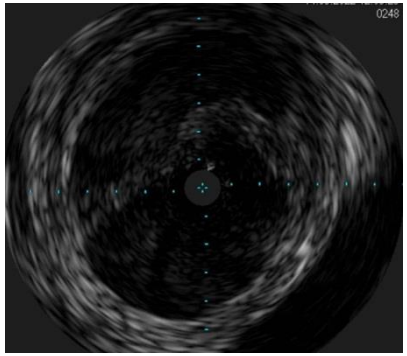


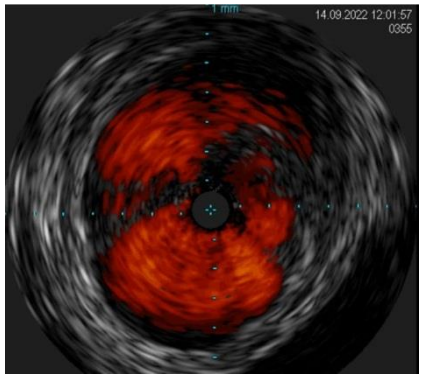










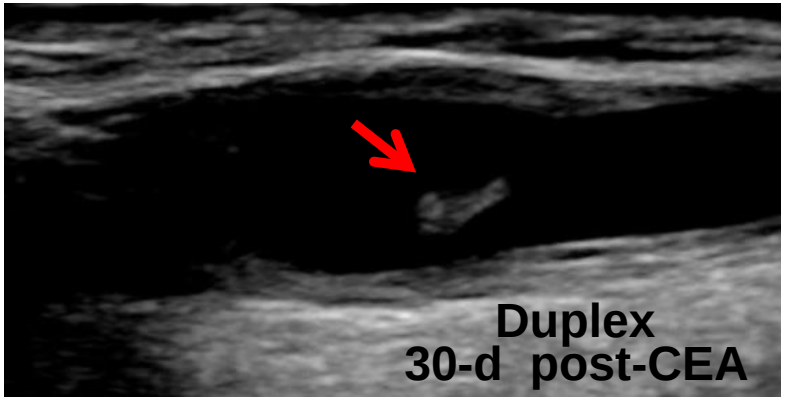


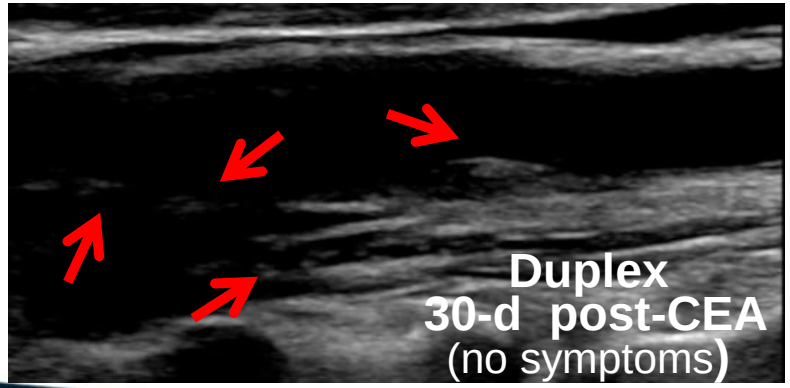
Crescendo TIAs post Discharge

→ **Resolved with a MicroNet-Covered Stent**

W, 59 y
CEA

The ”Gold Standard”… How GOLD ?





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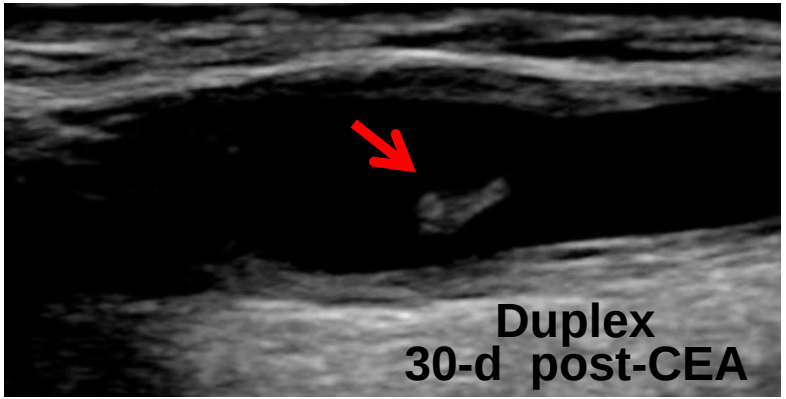
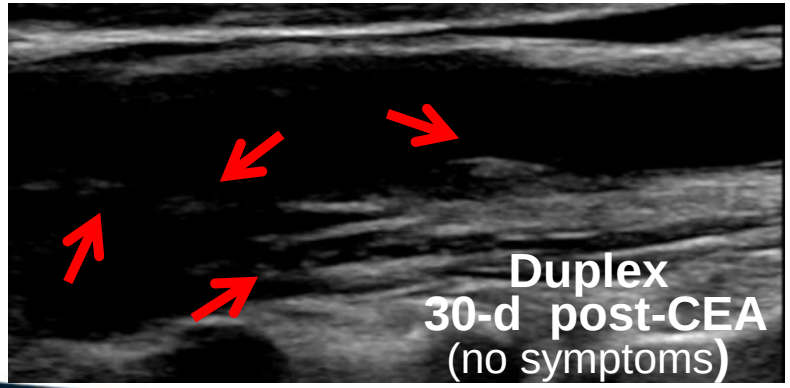
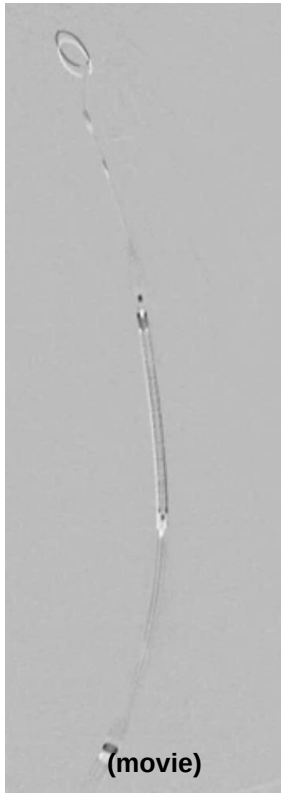
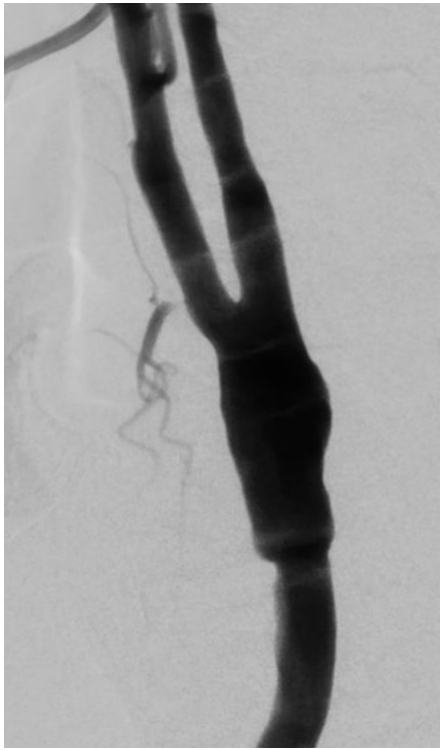




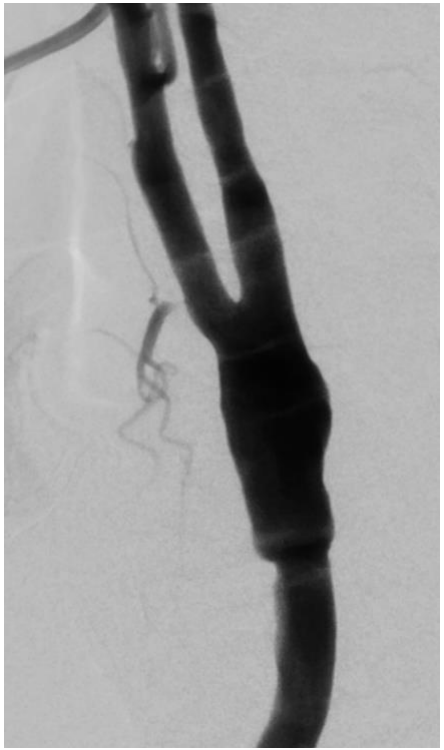


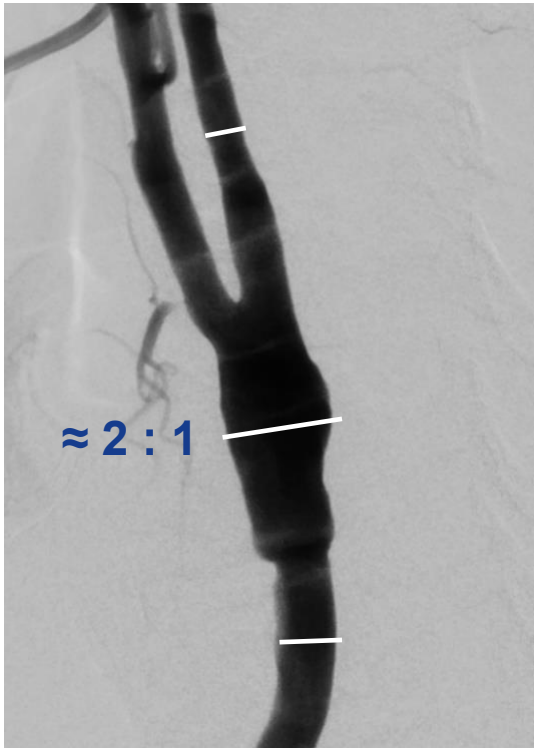
→ Resolved
with a MicroNet-Covered Stent

CEA Result: FINE √



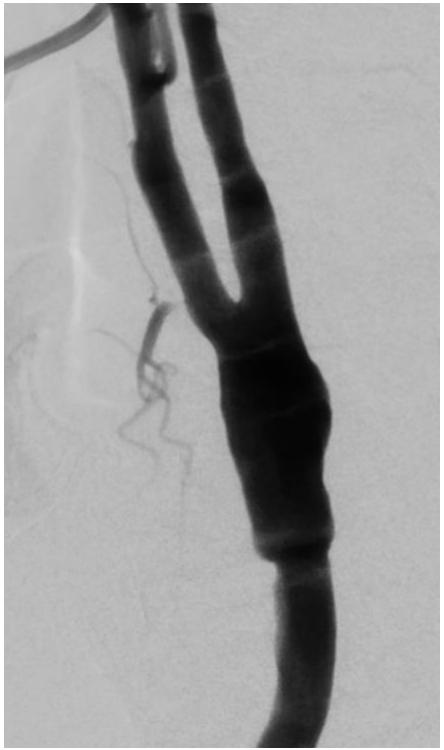
CEA Result: FINE √

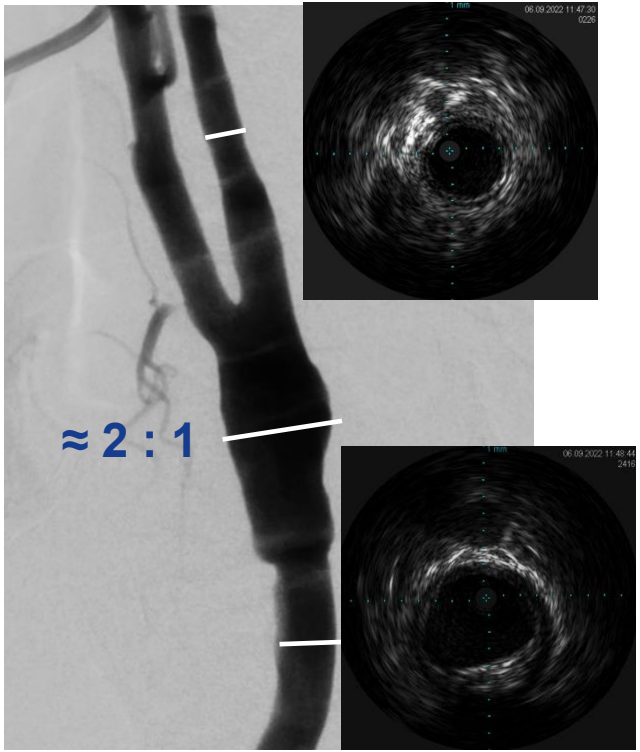


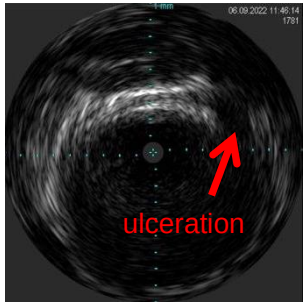


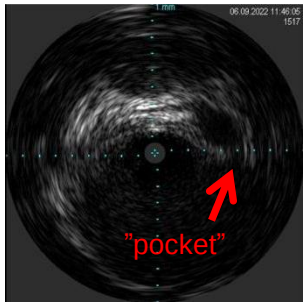
CEA Result: FINE √

… Really? … Really???









Slowered Flow in the ’Broadend’ Segment + Ulceration

⇒ **Increased ? Thrombogenicity**

The ”Gold Standard”… How GOLD ?

”**an optimal result**”
(no death/stroke/MI)

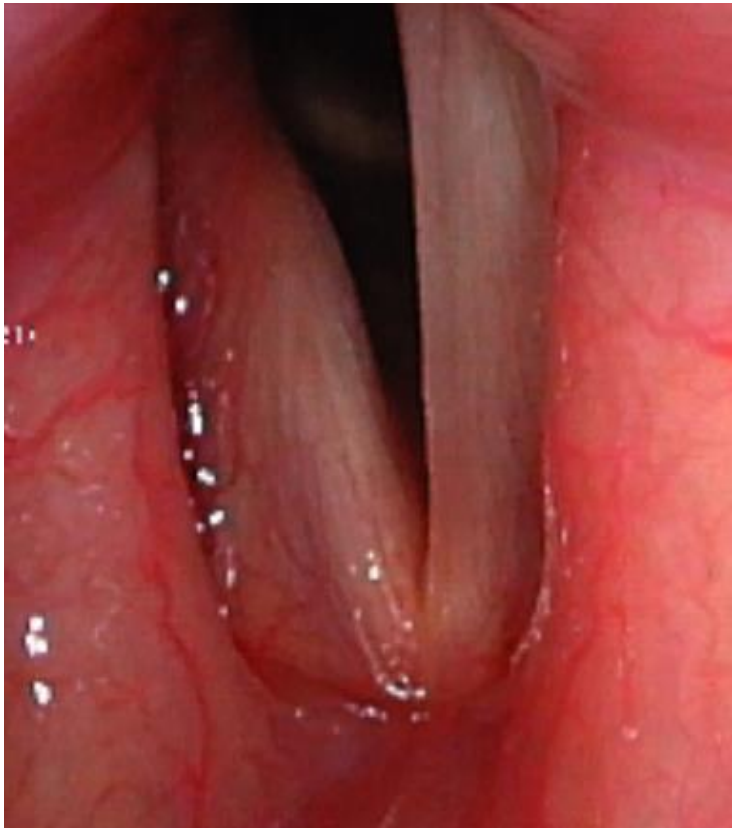
1. **loss of sensation**

2. **recurrernt**
   skin injury
   when shaving…

no way to resolve

The ”Gold Standard”… How GOLD ?

”**an optimal result**”
(no death/stroke/MI)



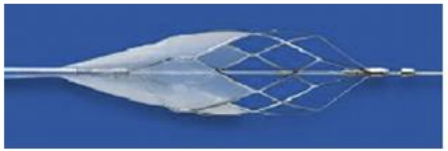
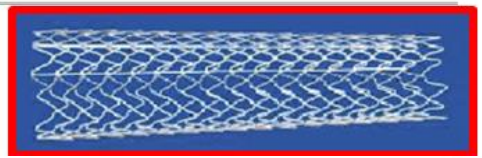
Vocal fold paralysis

CREST-1

N Engl J Med 2010;363:11-23.

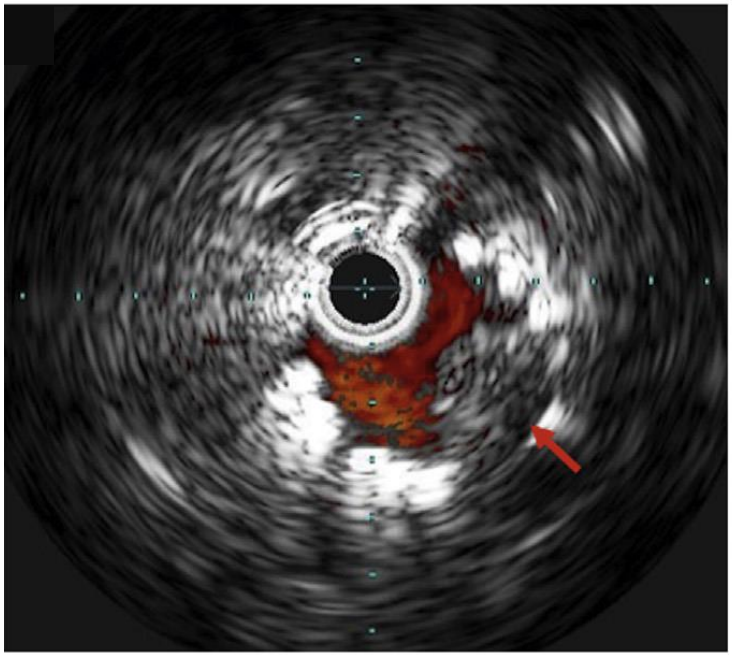
	CAS (N=1262)	CEA (N=1240)	Periprocedural Period: Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	no. of patients (% ±SE)		*percentage points*		
Death	9 (0.7±0.2)	4 (0.3±0.2)	0.4 (−0.2 to 1.0)	2.25 (0.69 to 7.30)†	0.18†
Stroke					
Any	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major ipsilateral	11 (0.9±0.3)	4 (0.3±0.2)	0.5 (−0.1 to 1.2)	2.67 (0.85 to 8.40)	0.09
Major nonipsilateral‡	0	4 (0.3±0.2)	NA	NA	NA
Minor ipsilateral	37 (2.9±0.5)	17 (1.4±0.3)	1.6 (0.4 to 2.7)	2.16 (1.22 to 3.83)	0.009
Minor nonipsilateral	4 (0.3±0.2)	4 (0.3±0.2)	0.0 (−0.4 to 0.4)	1.02 (0.25 to 4.07)	0.98†
Myocardial infarction	14 (1.1±0.3)	28 (2.3±0.4)	−1.1 (−2.2 to −0.1)	0.50 (0.26 to 0.94)	0.03
Any periprocedural stroke or death or post-procedural ipsilateral stroke	92 (7.3±0.7)	62 (5.0±0.6)	2.3 (0.4 to 4.2)	1.50 (1.10 to 2.04)	0.01
Major stroke	11 (0.9±0.3)	8 (0.6±0.2)	0.2 (−0.5 to 0.9)	1.35 (0.54 to 3.36)	0.52
Minor stroke	41 (3.2±0.5)	21 (1.7±0.4)	1.6 (0.3 to 2.8)	1.95 (1.15 to 3.30)	0.01
Any periprocedural stroke or death or post-procedural ipsilateral stroke	55 (4.4±0.6)	29 (2.3±0.4)	2.0 (0.6 to 3.4)	1.90 (1.21 to 2.98)	0.005
Primary end point (any periprocedural stroke, myocardial infarction, or death or postprocedural ipsilateral stroke)	66 (5.2±0.6)	56 (4.5±0.6)	0.7 (−1.0 to 2.4)	1.18 (0.82 to 1.68)	0.38

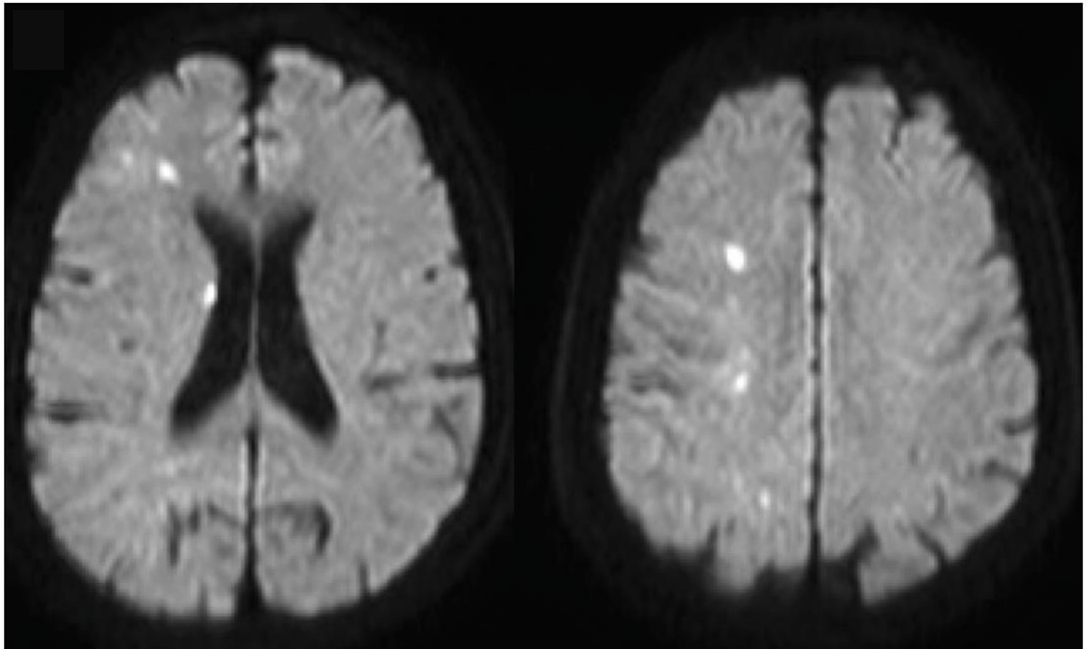
WHERE exactly was the problem?

Failure to Eliminate the Plaque

with 1st Gen. Carotid Stents (Open-cell and Closed-cell)





Plaque prolapse was strongly associated with ischemic stroke by 30 days

Kotsugi et al. JACC Intv 2017;10:824-31

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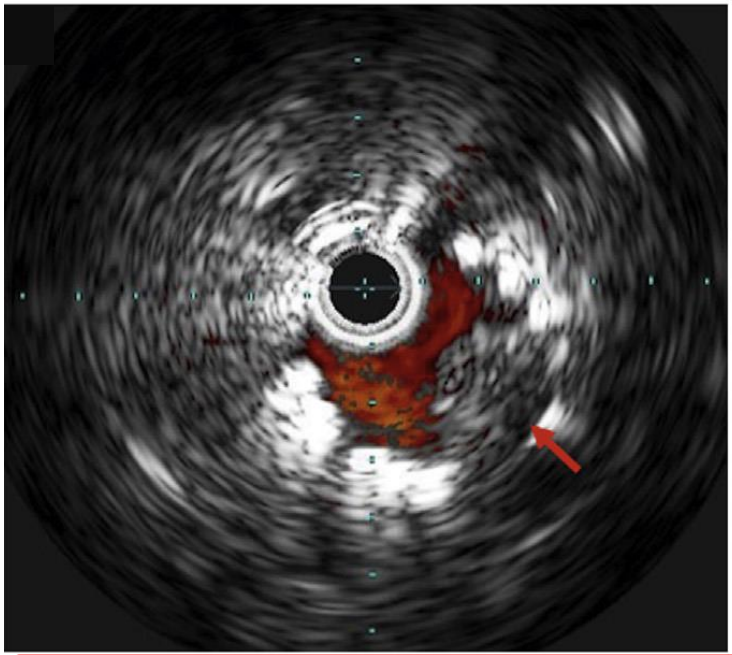

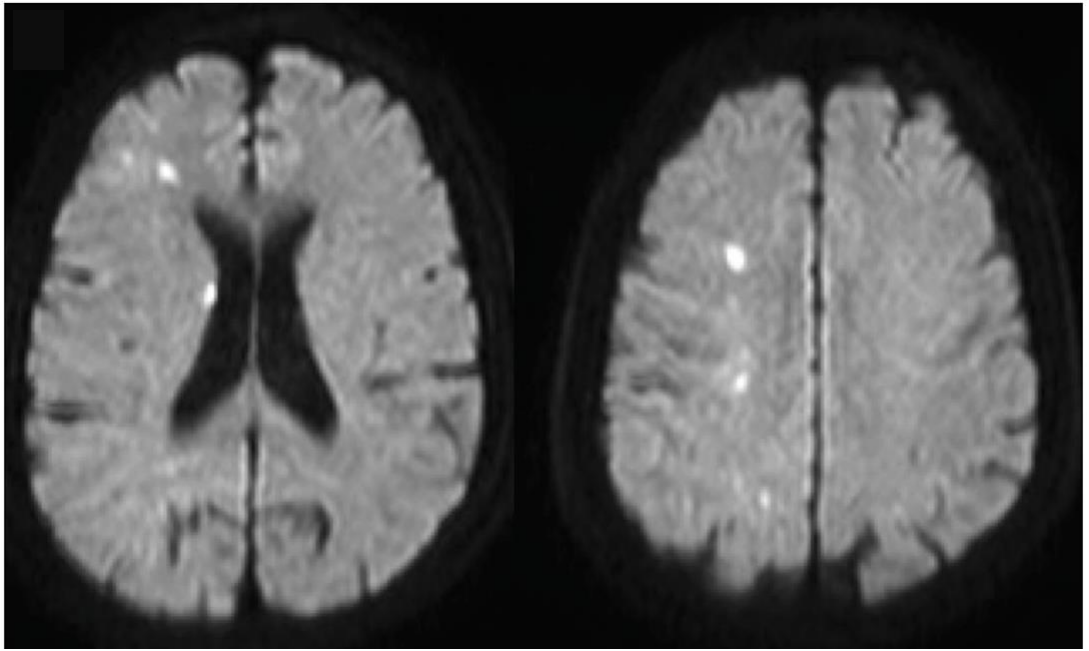

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The **MOST 'open'** amongst open-cell stents (metallic FRAME) & the **MOST 'close'** amongst close-cell stents (MicroNet mesh)

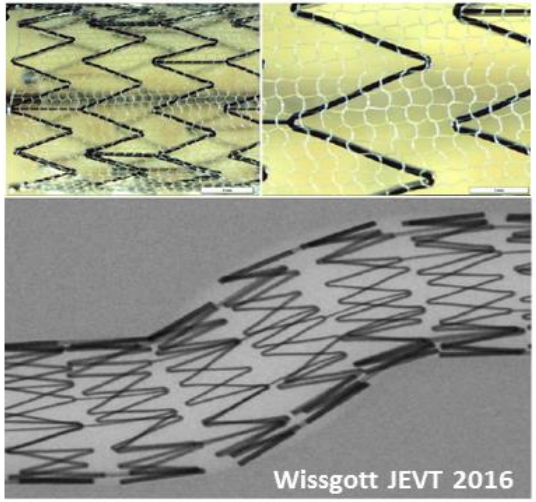
MicroNet -Covered Stent

CGuard MicroNET – covered
2nd generation carotid stent

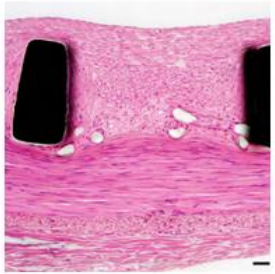
UNIQUE mechanical properties

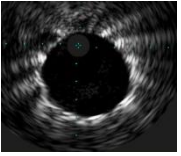
RESPECT of anatomy

FULL apposition



NORMAL healing





Hypothesis

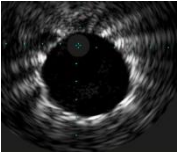
CGuard

OPTIMA

MicroNet-Covered Stent CAS
Enables

Safe
Plaque Prolapse-Free and Residual Stenosis-Free
endovascular reconstruction
of the diseased
Extracranial carotid artery

in consecutive patients with symptoms or signs
of cerebral ischemic injury



Methods: IIS

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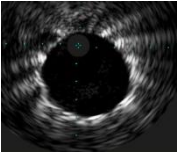
OPTIMA

- Multi-centric
- Multi-specialty (IC, VS, A/VM, IR/INR)
- Muli-national
- All-Comer Patients
  with Symptoms or Signs of cerebral injury, no age or other limits
- Classic lesion severity criteria (50% / 80%)
- EPD recommended
- Vascular access by Operator choice
- Study Device angiographic optimization recommended
- Final IVUS run (motorized pullback 1mm/s)
- Standard Medications, intraprocedural ACT >250s (IFU)

Angiographic Core Lab & IVUS Core Lab



Power

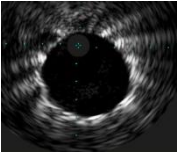
CGuard OPTIMA Trial NCT04234854

- Power calculation based on meta-analyzed IVUS large-scale studies of Plaque Prolapse in First-Generation (Single-layered) carotid stents by M Kotsugi et al. and T Okazaki et al. (n=494 stents, Precise - 224, Wallstent - 236, Protege - 34, PP incidence 44/494; 8.9%)

- Asumptions: 3% bilateral disease treatment as per the study criteria
  maximum 2% IVUS technical failure

- **90% power to detect ≥50% reduction in PP** against single-layer [open-/closed-cell] stents with 337 patients to obtain 340 MicroNet-covered stent-treated arteries visualized with IVUS (p0=0.086, pA=0.043)

Kotsugi et al. JACC Intv 2017;10:824-31 Okazaki et al. Eur Radiol 2019;29:77-84

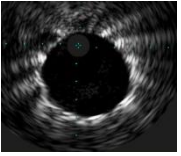


CGuard

OPTIMA

Study Population

	Total study group	Carotid-related cerebral symptoms*	Silent cerebral infarct#	p
n (%)	339 (100)	257 (75.81)	82 (24.19)	-
Age	69.77±8.39	68.5±8.69	69.59±7.4	0.272
Female	108 (31.86)	79 (30.74)	29 (35.37)	0.434
Stroke	154 (45.43)	154 (59.92)	0 (0)	-
TIA	91 (26.84)	91 (35.41)	0 (0)	-
Retinal stroke	3 (0.88)	3 (1.17)	0 (0)	-
A. Fugax	9 (2.65)	9 (3.5)	0 (0)	-
Diabetes mellitus	165 (48.67)	128 (49.81)	37 (45.12)	0.460
Hypertension	294 (86.72)	223 (86.77)	71 (86.59)	0.966
Hyperlipidemia	282 (83.19)	215 (83.66)	67 (81.71)	0.681
AF	47 (13.86)	36 (14.01)	11 (13.41)	0.892
Smoker§	215 (63.42)	162 (63.04)	53 (64.63)	0.793
CAD	178 (52.51)	131 (50.97)	47 (57.32)	0.316
h/o MI	83 (24.48)	59 (22.96)	24 (29.27)	0.247
LVEF	57.37±9.29	57.43±9.45	57.19±8.83	0.841
LVEF<45%	24 (7.08)	17 (6.61)	7 (8.54)	0.555
h/o PCI or CABG	121 (35.69)	84 (32.68)	37 (45.12)	0.041
PAD+	74 (21.82)	54 (21.01)	20 (24.39)	0.519
h/o contralateral CEA or CAS	31 (9.14)	24 (9.34)	7 (8.54)	0.826
h/o chest/neck radiotherapy	15 (4.42)	12 (4.67)	3 (3.66)	0.698
eGFR	72.87±20.71	73.1±19.19	72.18±24.87	0.761
eGFR 31-59 ml/kg min	108 (31.86)	87 (33.85)	21 (25.61)	0.163



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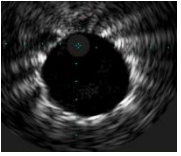

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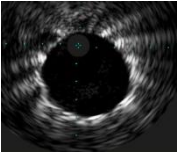
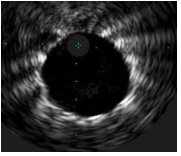


Baseline Characteristics of Lesions

CGuard OPTIMA

	Total	Carotid-related cerebral symptoms*	Clinically silent cerebral infarct#	p
n (%)	352	257	95	-
RICA	169 (48.01)	128 (49.81)	41 (43.16)	0.145
LICA	183 (51.99)	129 (50.19)	54 (56.84)	0.149
DUS*				
PSV (cm/s)	3.36±1.23	3.38±1.29	3.30±1.09	0.633
EDV (cm/s)	1.15±0.69	1.18±0.75	1.07±0.51	0.176
Angiography#				
DS by QCA (%)	77.90±12.16	78.51±12.61	76.20±10.70	0.100
≥90% DS by QCA	71 (20.17)	56 (21.79)	15 (15.79)	0.213
Thrombus-containing	47 (13.35)	41 (15.95)	6 (6.32)	0.018
Ulcerated	195 (55.40)	143 (55.64)	52 (54.74)	0.879
Severely calcific§	28 (7.95)	20 (7.78)	8 (8.42)	0.844
ECA patent	347 (98.57)	254 (98.83)	93 (97.89)	0.440



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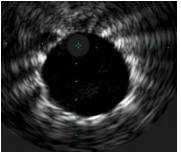

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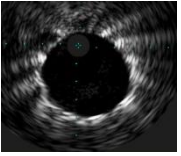

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Procedure Characteristics

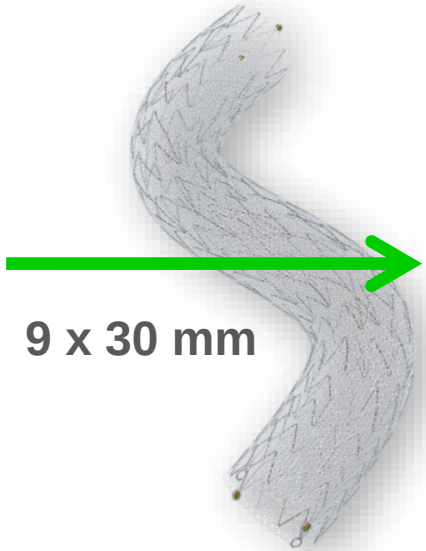
	Total	Ipsilateral cerebral symptoms	Ipsilateral clinically-silent cerebral infarct	p
n (%)	352	257	95	-
EPD use	351 (99.7)	257 (100)	94 (98.95)	0.100
Proximal	229 (65.06)	169 (65.76)	60 (63.16)	0.650
MoMa*	200 (56.82)	142 (55.25)	58 (61.05)	0.329
FlowGate‡	22 (6.25)	20 (7.78)	2 (2.11)	0.051
EnRoute†	7 (1.99)	7 (2.72)	0	0.104
Distal	122 (34.66)	88 (34.24)	34 (35.79)	0.786
Emboshield NAV	51 (14.49)	38 (14.79)	13 (13.68)	0.794
Spider	45 (12.78)	31 (12.06)	14 (14.74)	0.505
FilterWireEZ	26 (7.39)	19 (7.39)	7 (7.37)	0.994
Predilatation	286 (81.25)	206 (80.16)	80 (84.21)	0.387
Balloon diameter, range (min-max)	2.75 – 5.0	2.75 – 5.0	3.0 – 5.0	-
Balloon diameter, mean	3.88±0.44	3.88±0.47	3.90±0.37	0.680
MCS Stent‡				
7.0x20 mm	3 (0.85)	1 (0.39)	2 (2.11)	0.120
7.0x30 mm	11 (3.12)	7 (2.72)	4 (4.21)	0.477
7.0x40 mm	1 (0.28)	1 (0.39)	0 (0)	0.543
8.0x20 mm	8 (2.27)	7 (2.72)	1 (1.05)	0.350
8.0x30 mm	37 (10.51)	28 (10.89)	9 (9.47)	0.700
8.0x40 mm	26 (7.39)	22 (8.56)	4 (4.21)	0.166
9.0x20 mm	6 (1.70)	5 (1.95)	1 (1.05)	0.566
9.0x30 mm	80 (22.73)	53 (20.62)	27 (28.42)	0.121
9.0x40 mm	46 (13.07)	31 (12.06)	15 (15.79)	0.357
10.0x20 mm	11 (3.12)	10 (3.89)	1 (1.05)	0.174
10.0x30 mm	66 (18.75)	49 (19.07)	17 (17.89)	0.803
10.0x40 mm	54 (15.34)	41 (15.95)	13 (13.68)	0.600
10.0x60 mm	3 (0.85)	2 (0.78)	1 (1.05)	0.804
>1 MCS stent used	11 (3.12)	9 (3.50)	2 (2.11)	0.312
Stent other than MCS u	0	0	0	-
Post-dilatation balloon diameter‡	347 (98.58)	253 (98.44)	94 (98.95)	0.723
Balloon diameter range, min-max	4.0 – 8.0	4.0 – 8.0	4.5 – 8.0	-
Mean balloon diameter (mm)	5.74±0.75	5.68±0.75	5.90±0.73	0.013
Balloon ≥5.5mm	252 (71.59)	174 (67.70)	78 (82.11)	0.008
Balloon ≥6.0mm	152 (43.18)	102 (39.69)	50 (52.63)	0.030
IVUS-triggered post-dilatation	14 (3.98)	10 (3.89)	4 (4.21%)	0.436
Embolic material in protection device	59 (16.76)	46 (17.90)	13 (13.68)	0.250
IVUS run on procedure completion	352 (100)	257 (100)	95 (100)	-
Closure device	158 (44.89)	122 (47.47)	36 (37.89)	0.109

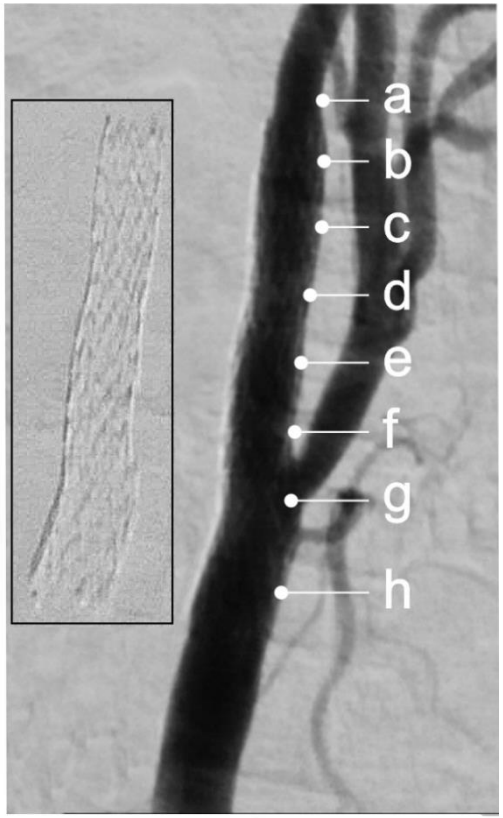
TF **337** (95.7 %)
TCR **13** (3.7 %)
TR **2** (0.6 %)

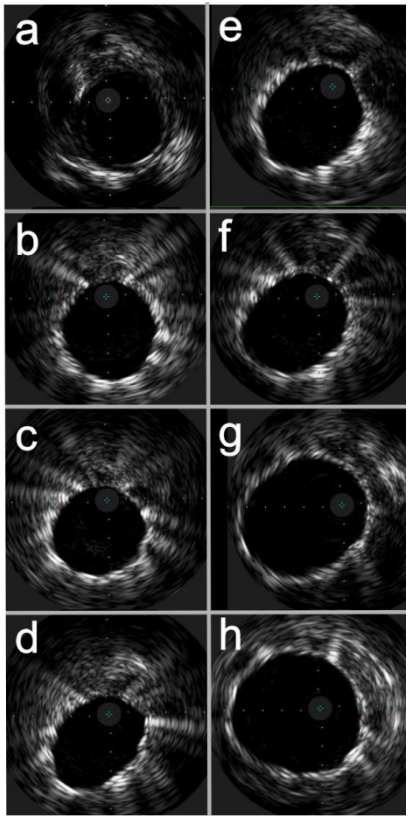
Technical success 100%

Procedural success 99.7%

M, 52y, Right Hemisph. Stroke 5 days before







CGuard OPTIMA Trial NCT04234854

Trans-Femoral MoMa Flow Reversal + MicroNet-Covered Stent

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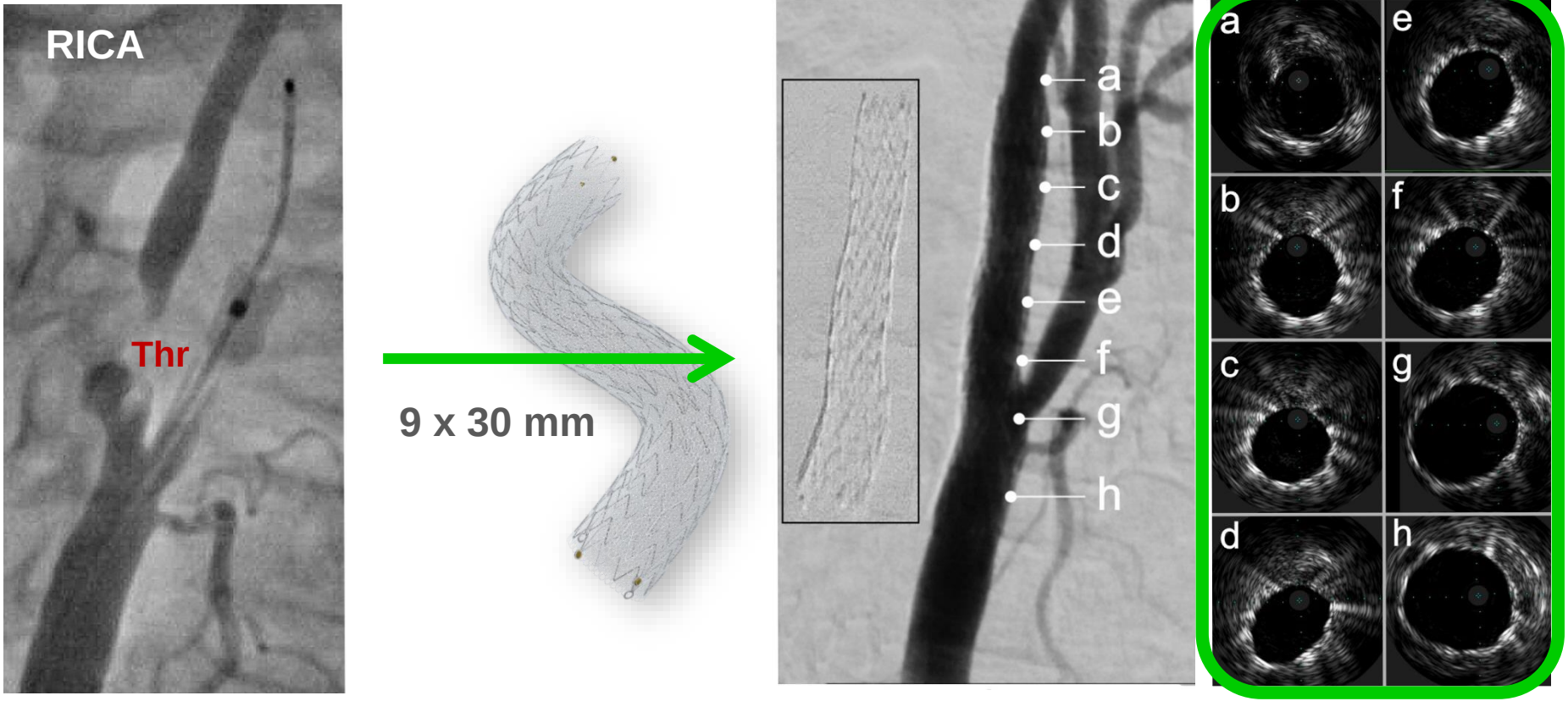
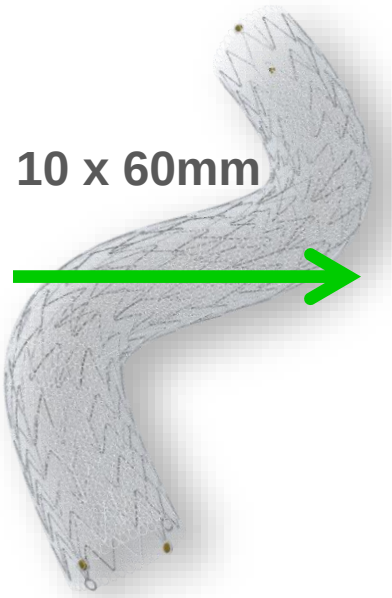
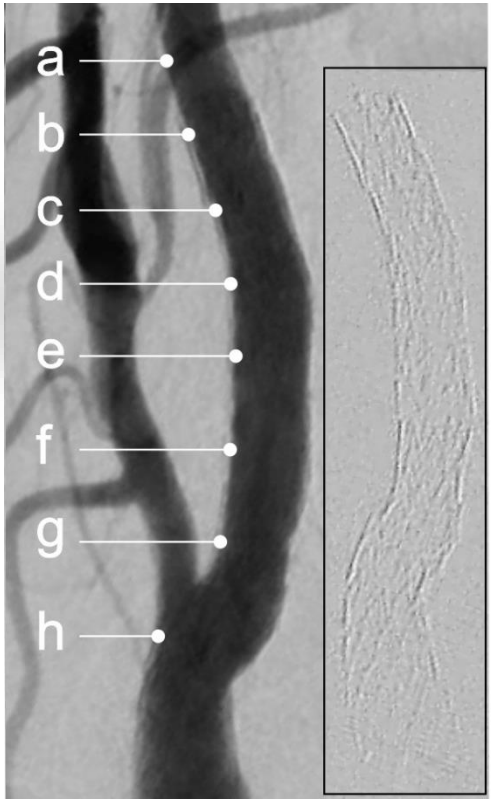
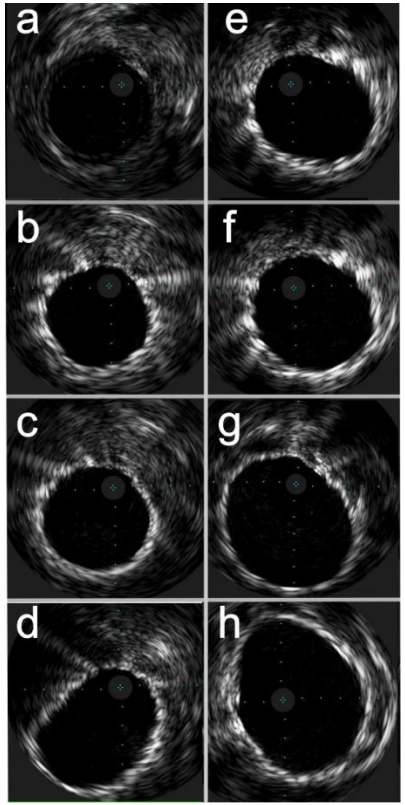


M, 64y, Progressive Tandem Stenosis, Asymptomatic Cerebral Infarct







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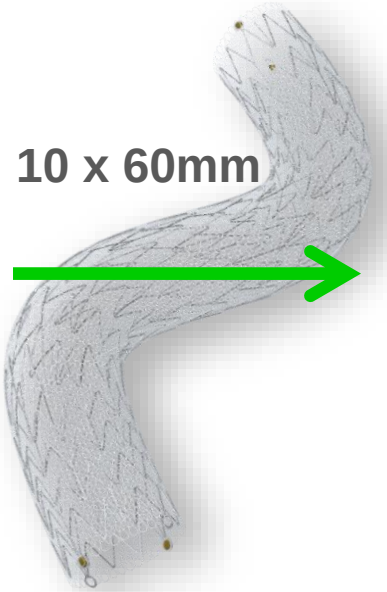
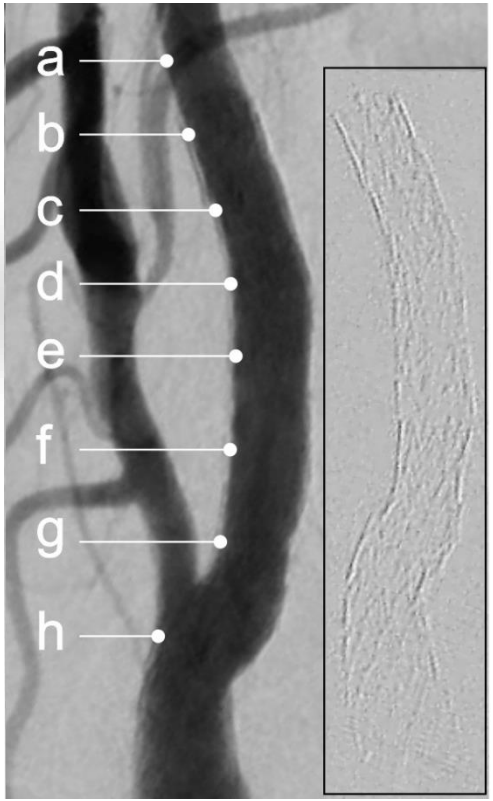
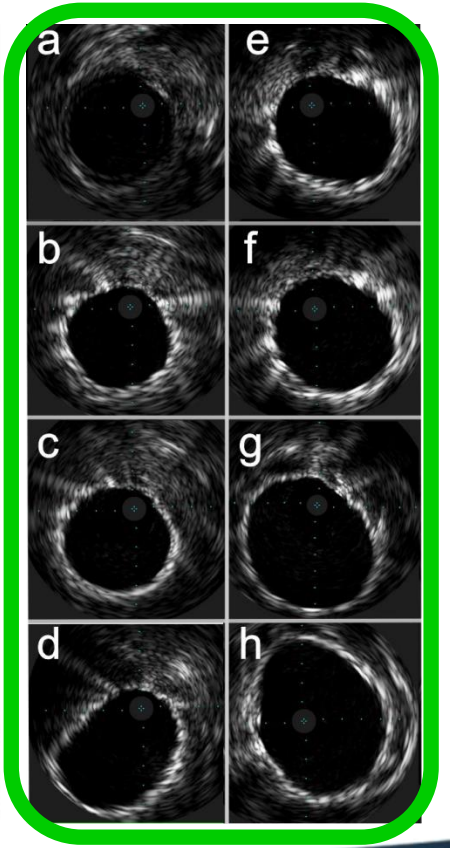
Trans-Femoral MoMa Flow Reversal + MicroNet-Covered Stent

M, 64y, Progressive Tandem Stenosis, Asymptomatic Cerebral Infarct





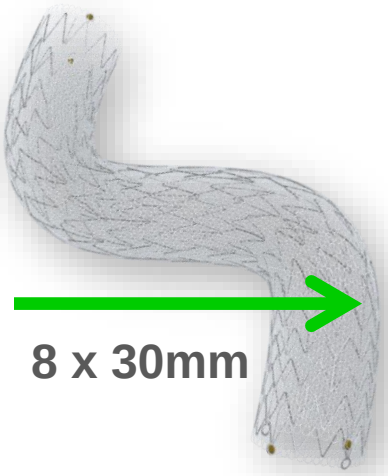


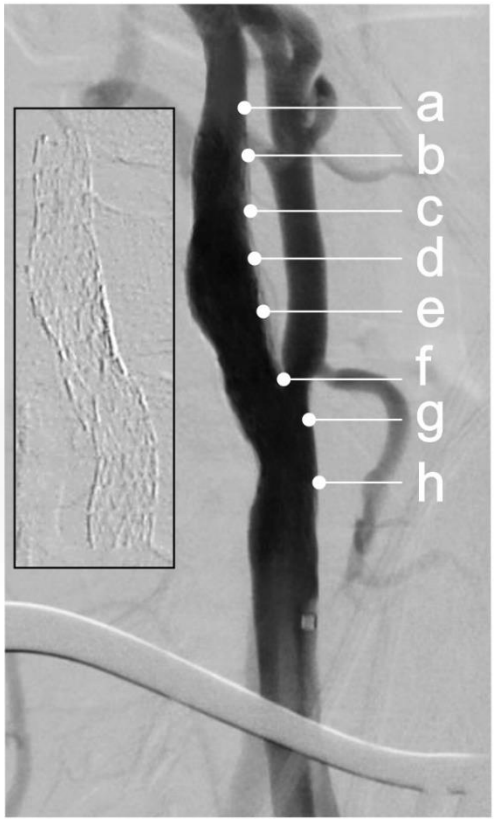
CRF TCT

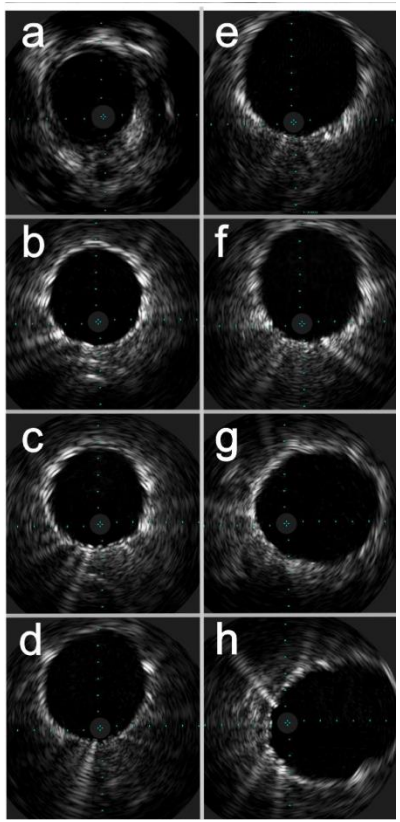
Trans-Femoral MoMa Flow Reversal + MicroNet-Covered Stent

P Musialek @ TCT 2022

M, 56y, L hemisp Stroke 10 days before, Severe iliac disease



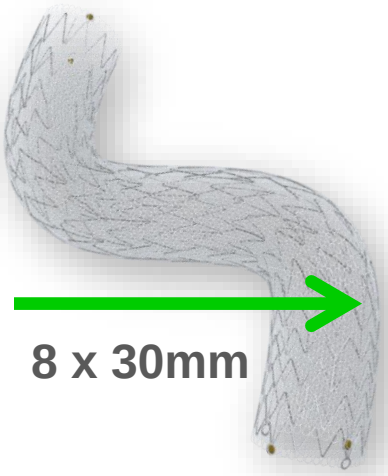


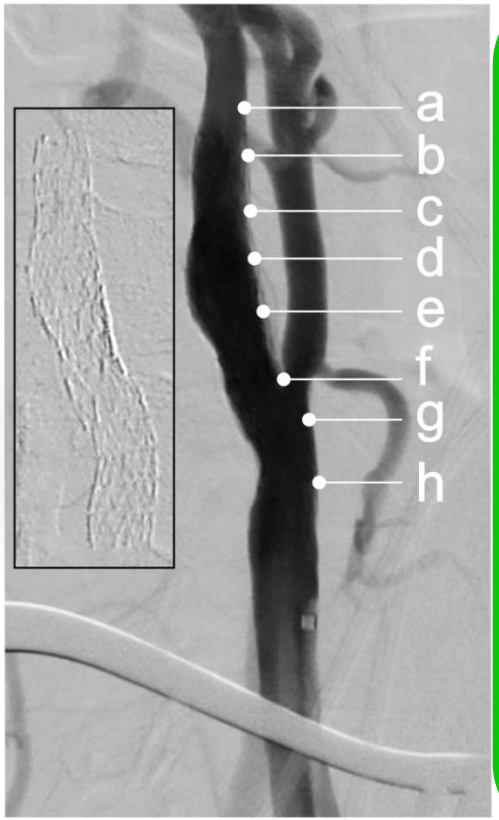


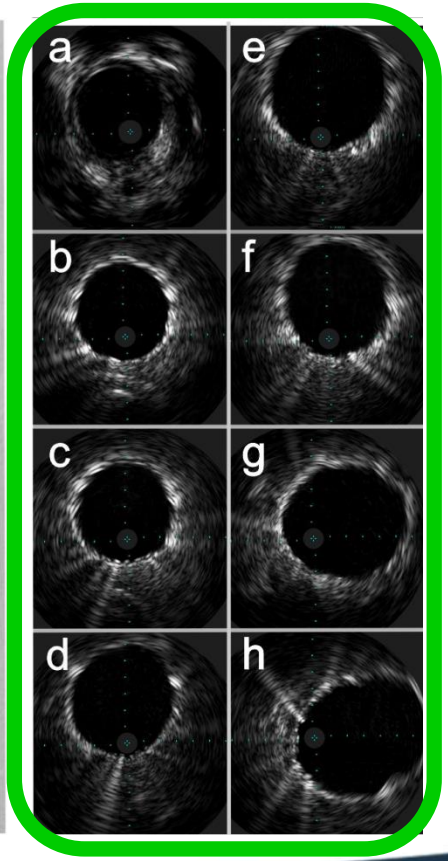
CGuard OPTIMA Trial NCT04234854

Trans-Carotid MoMa Flow Reversal + MicroNet-Covered Stent

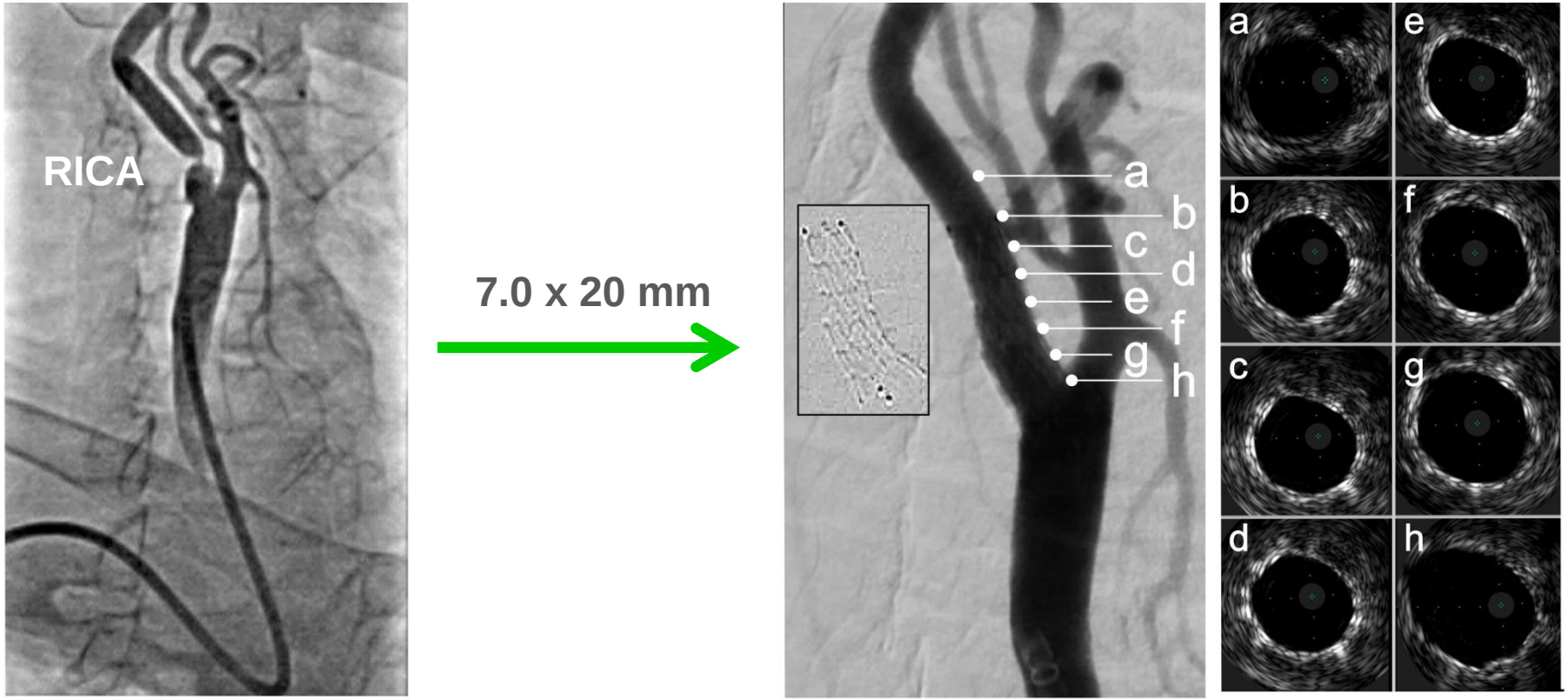
M, 56y, L hemisp Stroke 10 days before, Severe iliac disease







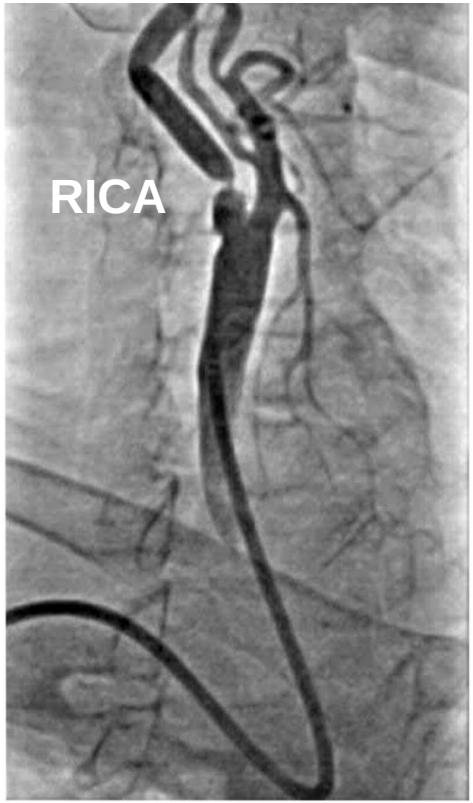
M, 71y, h/o larynx RadioTx, Leriche, 2 recent R hemisp Strokes



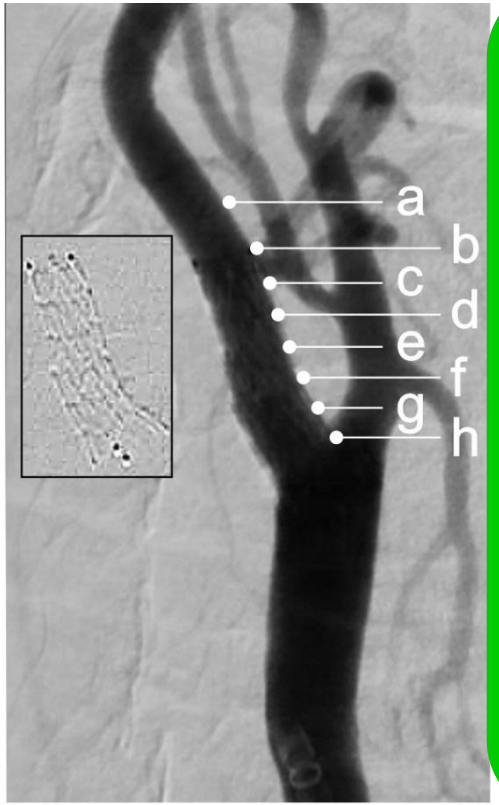
CGuard OPTIMA Trial NCT04234854

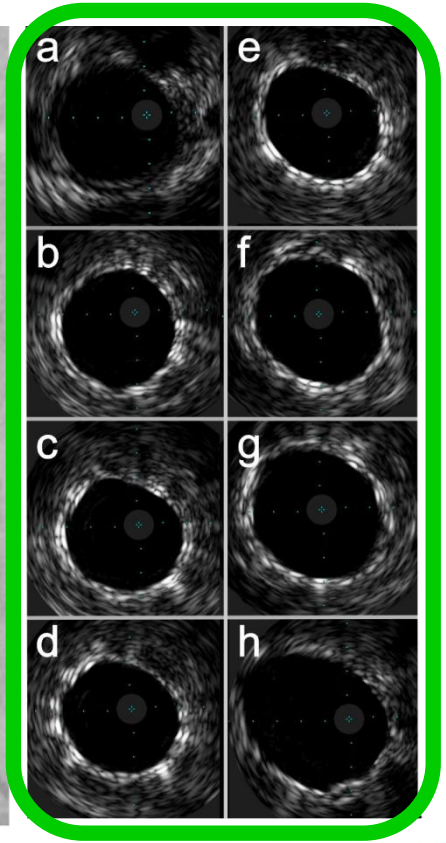
Trans-Radial MicroNet-Covered Stent CAS / Filter-Protected

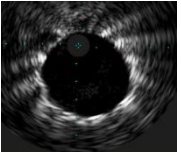
M, 71y, h/o larynx RadioTx, Leriche, 2 recent R hemisp Strokes



7.0 x 20 mm





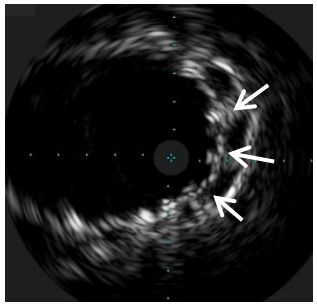


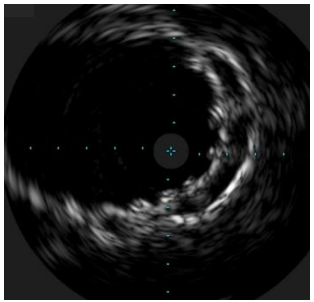
CGuard OPTIMA

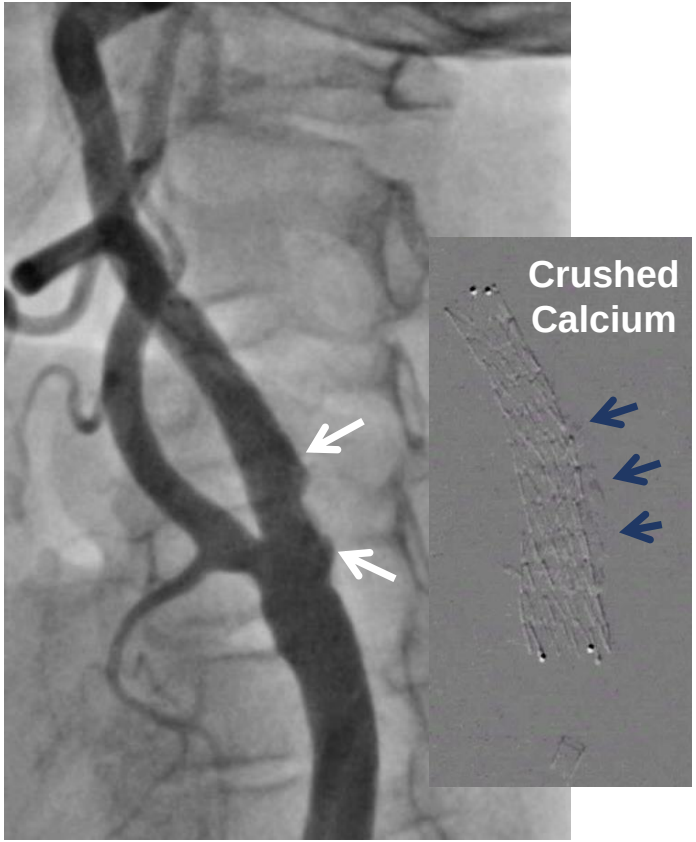
IVUS Results

Parameter		Incidence or Measurement value±SD*
MCS-treated arteries; n	total	352
Length of stents (mm);	total	11,950
Stent frames analyzed;	total	397,956
Frames per ICA reference segment;	total	53,164
Frames per 20mm stent;	mean (range)	649 (425–725)
Frames per 30mm stent;	mean (range)	920 (672–1280)
Frames per 40mm stent;	mean (range)	1258 (1082-1615)
Frames per 60mm stent;	mean1 (range)	1693 (1645–1735)
ICA reference CSA (mm^2)		16.38±4.08
MSA (mm^2)		15.98±4.02
Residual AS (mm^2)		0.4±2.52
Residual AS (%)		2.44±2.16
Stent asymmetry index[5]		0.87±0.09
Plaque prolapse		
Total number stents with PP		0 (0%)
Total number segments with PP		0 (0%)
Total frames with PP#		0 (0%)
PP segment length, mm		0 (0%)
PP segment peak depth, mm		0 (0%)
Malapposition		
Total number stents with malapposition# (n, %)		8 (2.19%)
Total number segments with malapposition		10
Total malapposed frames (% all stent frames)		425 (0.11%)
Malapposed segment length, mm		1.12±0.85
Malapposed segment peak depth, mm		0.64±0.19

Malapposition was very rare
(0.11% frames)



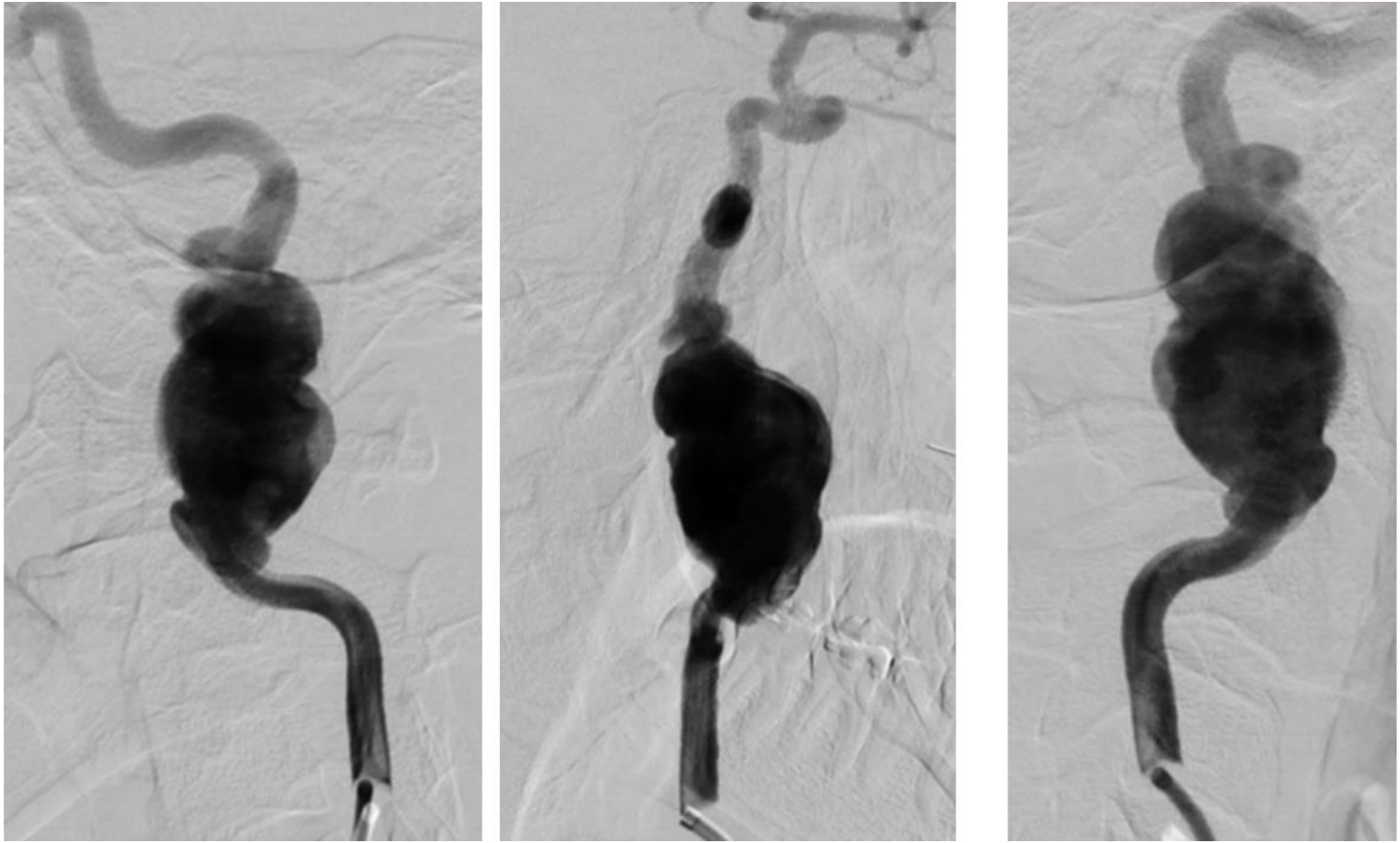




MicroNet-Covered Stent

Aneurysms: Physiological Healing (Flow-Divertion)

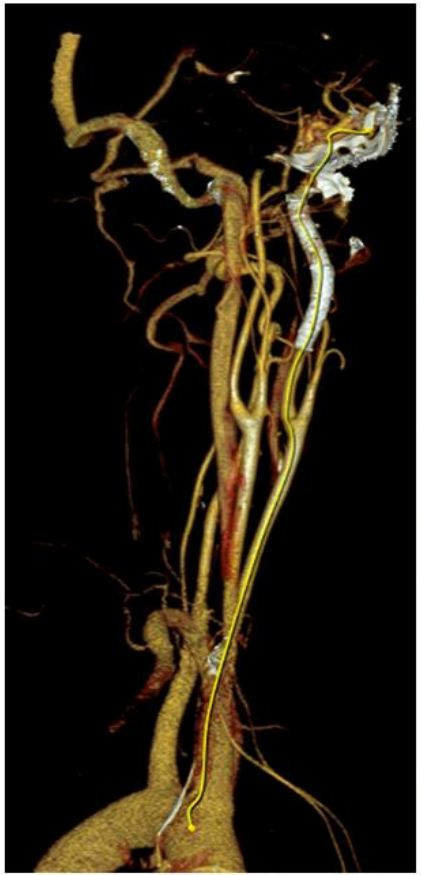
43 yo Man, highly symptomatic



C-HEAL STUDY

NCT04434456

Immediate result

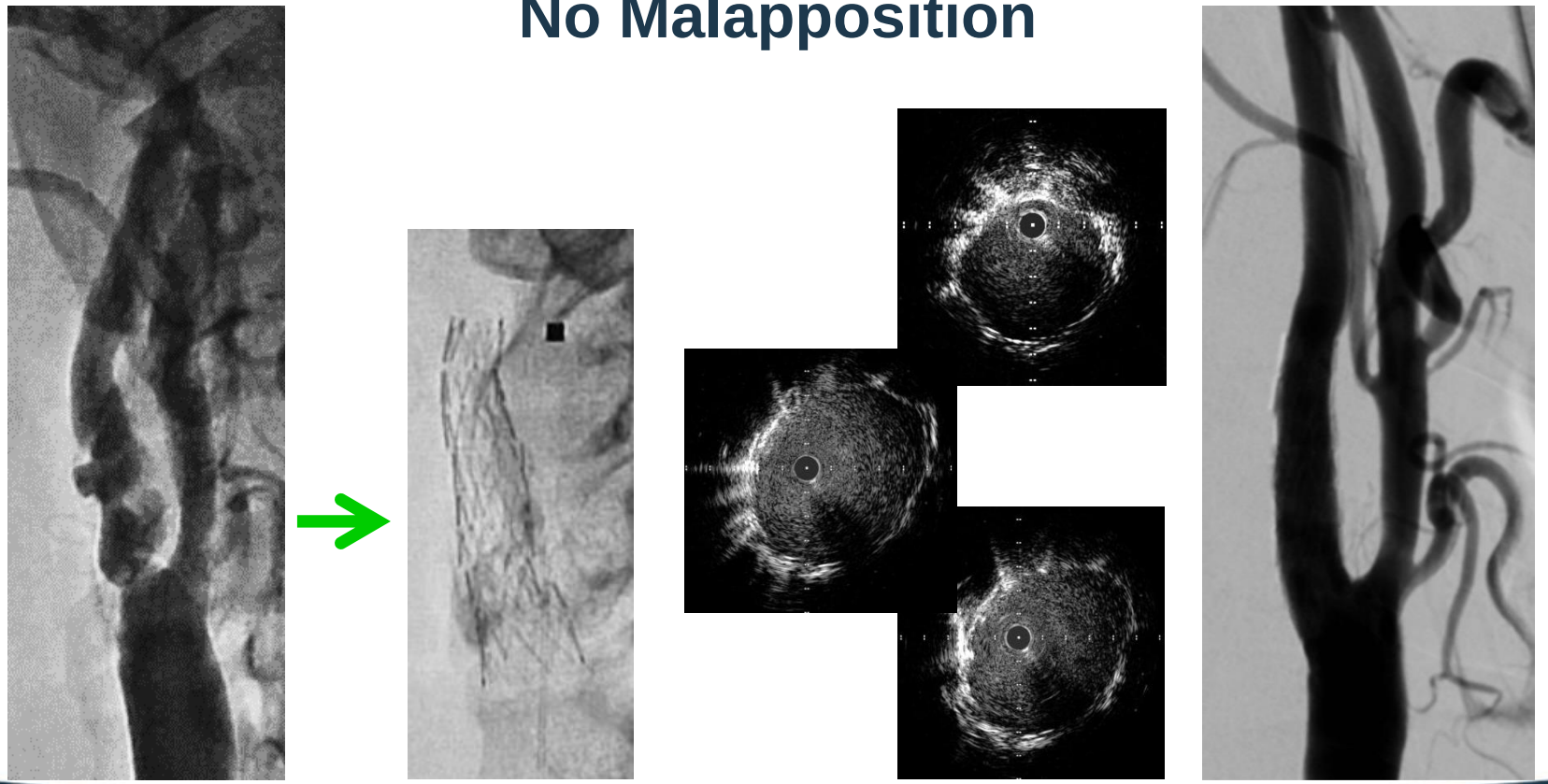


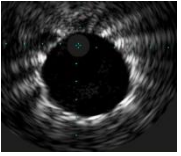
ANEURYSM
Total Exclusion @ 72h

Reconstruction of NORMAL ANATOMY

Acute Result Maintained @6mo CT Angio Control

A Great Majority of Severely Calcific Lesions Showed No Malapposition





Duplex Ultrasound Outcomes at 30-days

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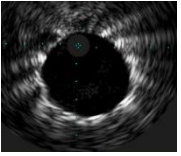
MCS stent	
PSV, m/s	0.70±0.28
EDV, m/s	0.21±0.08
Any in-stent material (n, %)	0 (0%)
ECA patency[#]	331 (95.39)[#]



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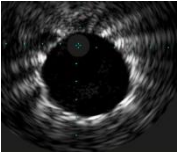
Clinical Outcomes by 30-days

Outcome	n (%) or mean (SD)
Periprocedural clinical outcomes	
Death	0 (0%)
Any stroke	2 (0.57%)
Major	0 (0%)
Minor	2* (0.57%)
Ipisilateral ischemic	2 (0.57%)
Hemorrhagic (any)	0 (0%)
Contralateral (any)	0 (0%)
TIA[5] (total)	7 (1.99%)
in relation to hyperperfusion syndrome	4 (1.42%)
MI	0 (0%)
Clinical outcomes 24h–30 days	
Death	0 (0%)
Any stroke	1 (0.28%)
Major	0 (0%)
Minor	1† (0.28%)
Ipisilateral ischemic	0 (0%)
Hemorrhagic (any)	0 (0%)
Contralateral	1 (0.28%)
TIA	0 (0%)
MI	0 (0%)
Clinical outcomes at 30 days (total)	
Death	0 (0%)
Any stroke	3 (0.85%)
Major	0 (0%)
Minor	3 (0.85%)
Ipisilateral ischemic	2* (0.57%)
Hemorrhagic (any)	0 (0%)
Contralateral	1 (0.28%)
TIA[5]	7 (1.99%)
MI	0 (0%)

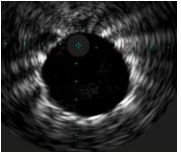


Conclusions

CGuard OPTIMA Trial
NCT04234854

CGuard
OPTIMA

- **TOTAL elimination** of CAS-associated Plaque Prolase with the routine MicroNet-covered 2nd generation carotid stent stent use in high-risk lesions (clinical symptoms or A/S infarct)



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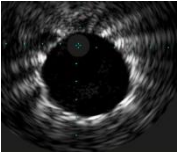

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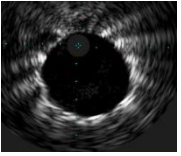

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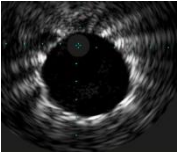
- Clinical outcomes **UNPRECEDENTED** in this Population
  30-day ipisilateral stroke rate – 0.57%, death / any stroke / MI – 0.85%,
  no stent thrombosis, no post-procedural device-related advese events

√



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