Interventional Carotid Disease Management

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***Consultant/Advisory Board*:** Medtronic, Microvention, Imperative Care, Xenter, RapidPulse, Rapid Medical, Boston Scientific

***National PI/Steering Committees*:** StrokeNET DSMB, EMBOLISE, SUCCESS, SBIR/STTN, ETTN Study section, RapidPulse

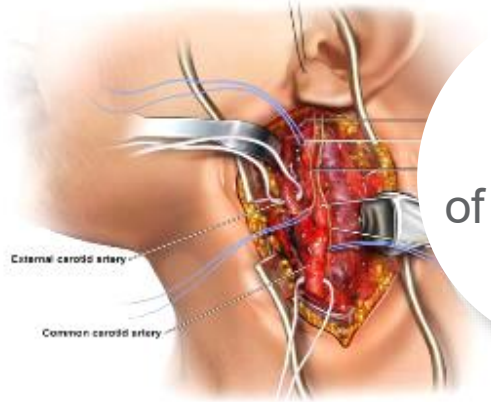
Objectives

- The surgical management options for of carotid stenosis
- Embolic protection in carotid stenting
- Patient specific surgical decision-making algorithm
  - CEA vs. CAS vs. TCAR

Surgical Management – Historical Perspective

SURGICAL:
Carotid Endarterectomy (CEA)

65+ years



~75% of procedures

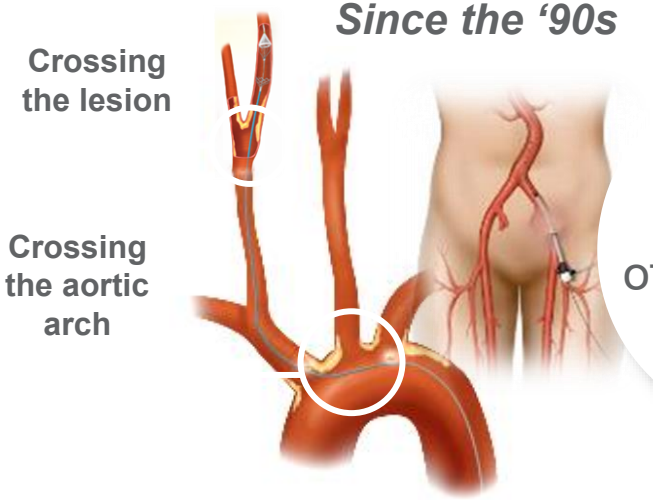
✗ SIGNIFICANT adverse events

✓ **LOW** 30-day stroke risk

A Dated Standard of Care

ENDOVASCULAR:
Transfemoral Carotid Artery Stenting (CAS)

Since the '90s



~15% of procedures*

✓ LOWER adverse events

✗ **HIGHER** (~2x) 30-day stroke risk

A Niche Procedure

Source: Modus Health Group *Excludes TCAR procedures

[1]CREST Trial: Brott TG, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med*. 2010 Jul 1;363(1):11-23.

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Surgical Management – CEA vs CAS

- Carotid endarterectomy (CEA)
  - Several decades of experience & trials have made carotid endarterectomy (CEA) the standard of care for the stroke prevention in patients with high-risk carotid stenosis
- Carotid angioplasty and stenting (CAS)
  - Historically CEA was favored over CAS due to increased embolic risk with CAS

TRIAL	CAS	CEA	CONSIDERATIONS
EVA-3S[1]	9.6%	3.9%	Experience Embolic protection
SPACE[1]	6.8%	6.3%	Experience
ICSS[2]	8.5%	4.7%	Experience Embolic protection

[1]Any stroke or death at 30 days
[2]Any stroke or death at 120 days

JNS

CLINICAL ARTICLE

J Neurosurg 138:199–204, 2023

Not a trifecta: complementary use of carotid artery revascularization techniques in the era of hybrid neurosurgery

Bennett R. Levy, BA,[1] Muhammad Waqas, MBBS,[2,3] Andre Monteiro, MD,[2,3] Justin M. Cappuzzo, MD,[2,3] Ammad A. Baig, MD,[2,3] Wasiq I. Khawar, BA,[3] Jason M. Davies, MD, PhD,[2–6] Kenneth V. Snyder, MD, PhD,[2,3,5,6] Adnan H. Siddiqui, MD, PhD,[2,3,5–7] Howard A. Riina, MD, MPhil,[8] and Elad I. Levy, MD, MBA[2,3,5–7]

CONCLUSIONS This real-world experience reflects the current practice of hybrid neurosurgery at two high-volume tertiary care centers and suggests that all three treatment modalities have comparable safety and effectiveness if patients are properly selected.

Outcomes

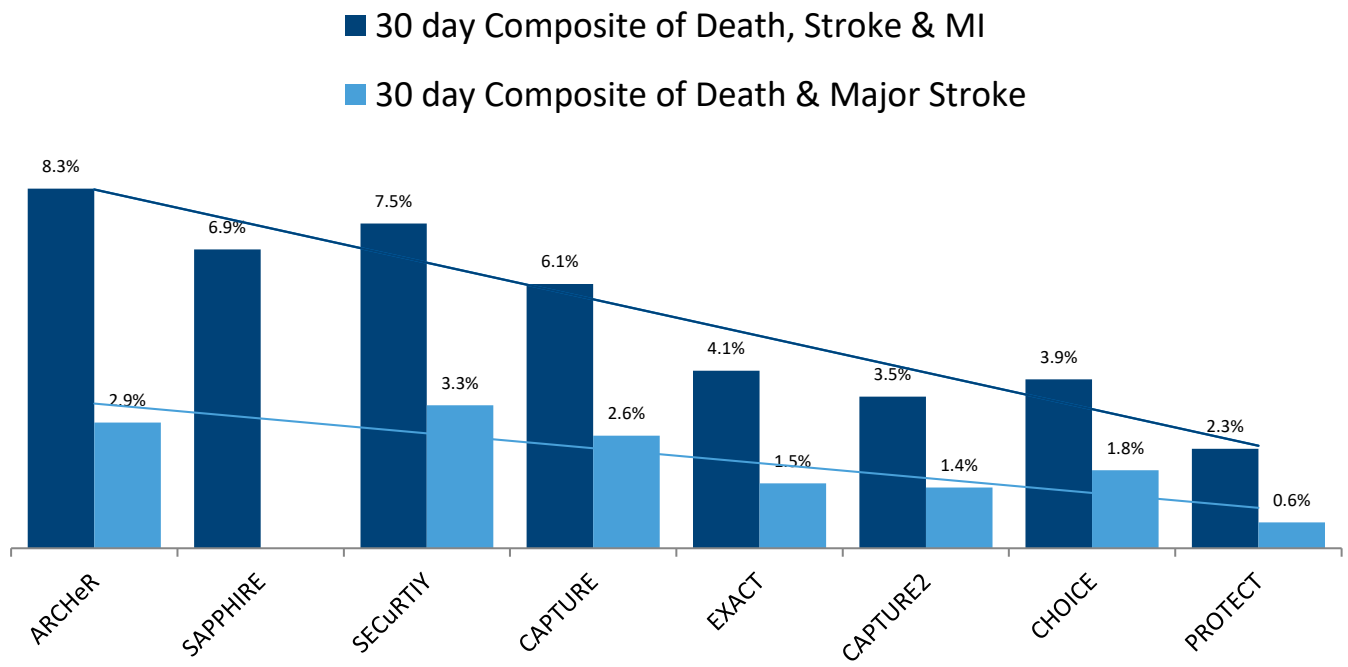
TABLE 1. Comparison of baseline characteristics and outcomes among CAS, CEA, and TCAR treatment groups

Variable	CAS, n = 583	CEA, n = 165	TCAR, n = 32	p Value
Mean age (SD), yrs	69.6 (10.8)	71.1 (9.9)	74.4 (7.9)	**0.019**
Male sex, n (%)	376 (64.5)	91 (55.1)	19 (59.4)	0.096
Diabetes mellitus, n (%)	197 (33.8)	46 (27.9)	6 (18.8)	0.096
Hypertension, n (%)	408 (70)	108 (65.5)	26 (81.3)	0.189
Hyperlipidemia, n (%)	423 (72.6)	106 (64.2)	23 (71.9)	0.122
Atrial fibrillation, n (%)	87 (14.9)	13 (7.9)	3 (9.4)	0.051
Lt-sided lesion, n (%)	284 (48.7)	92 (55.8)	17 (53.1)	0.256
Symptomatic, n (%)	460 (78.9)	133 (80.6)	24 (75)	0.683
Intraprocedural TIA or stroke, n (%), 95% CI	13 (2.2), 1–3.4	0 (0), NA	1 (3.1), –2.9 to 9.1	0.069
30-day TIA or stroke, n (%), 95% CI	22 (3.8), 2.2–5.4	3 (1.8), –0.2 to 3.8	2 (6.3), –2.1 to 14.7	0.267
30-day mortality, n (%), 95% CI	21 (3.6), 2.1–5.1	4 (2.4), 0.1 to 4.7	1 (3.1), –2.9 to 9.1	0.857

Similar 30-day clinical outcomes: CEA, CAS, and TCAR when patients were selected based on anatomical and clinical characteristics

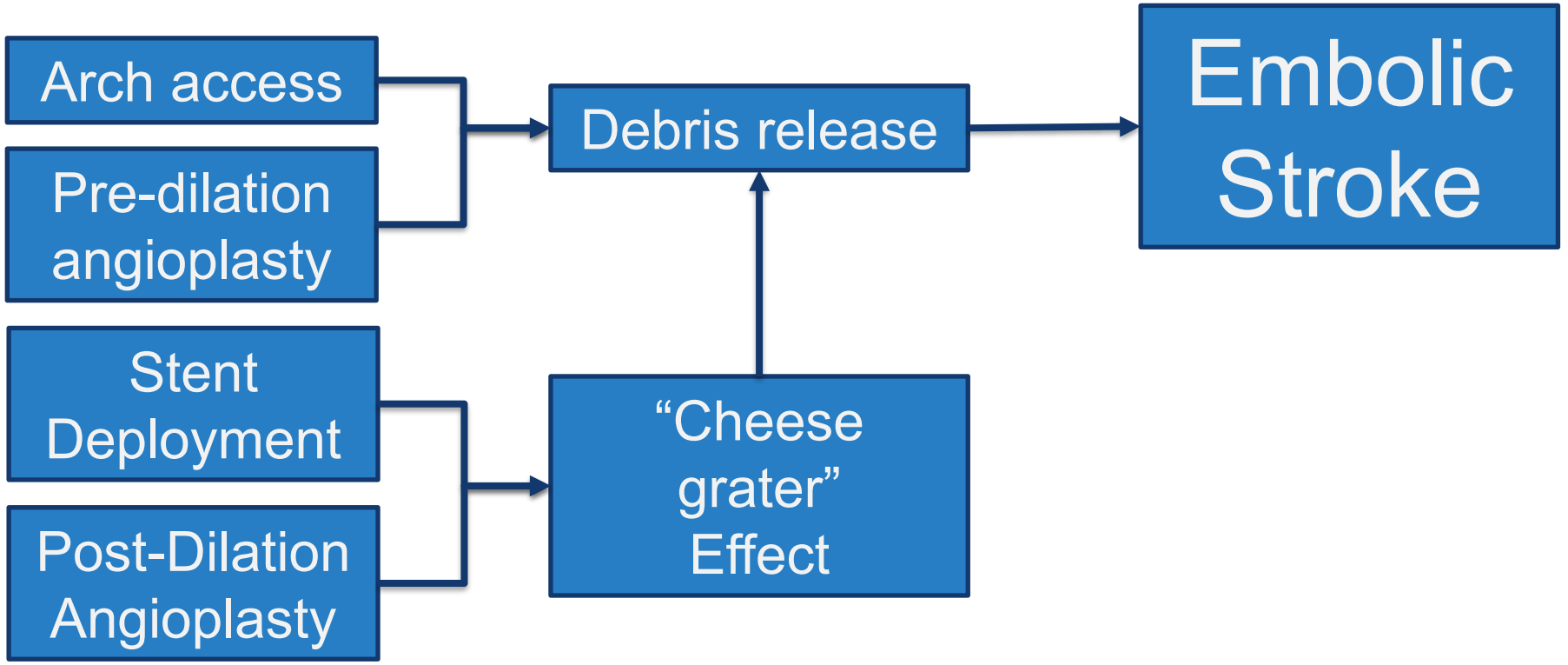
Surgical Management - CAS

- Subsequent CAS trials have improved dramatically over time due to improved operator experience and device development



Embolic Protection – The Key to Successful CAS

Etiology of embolic events



Embolic Protection – The Key to Successful CAS

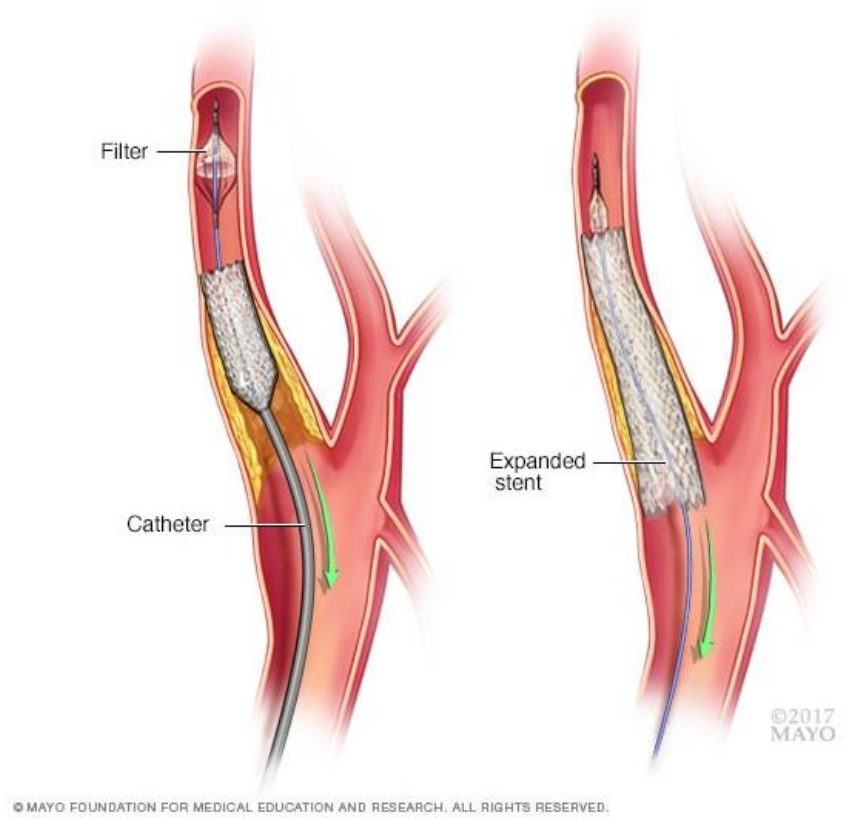
Techniques for embolic protection

- Distal protection
- Proximal protection

Embolic Protection – The Key to Successful CAS

Techniques for embolic protection

- Distal protection
  - **Filters**
- Proximal protection

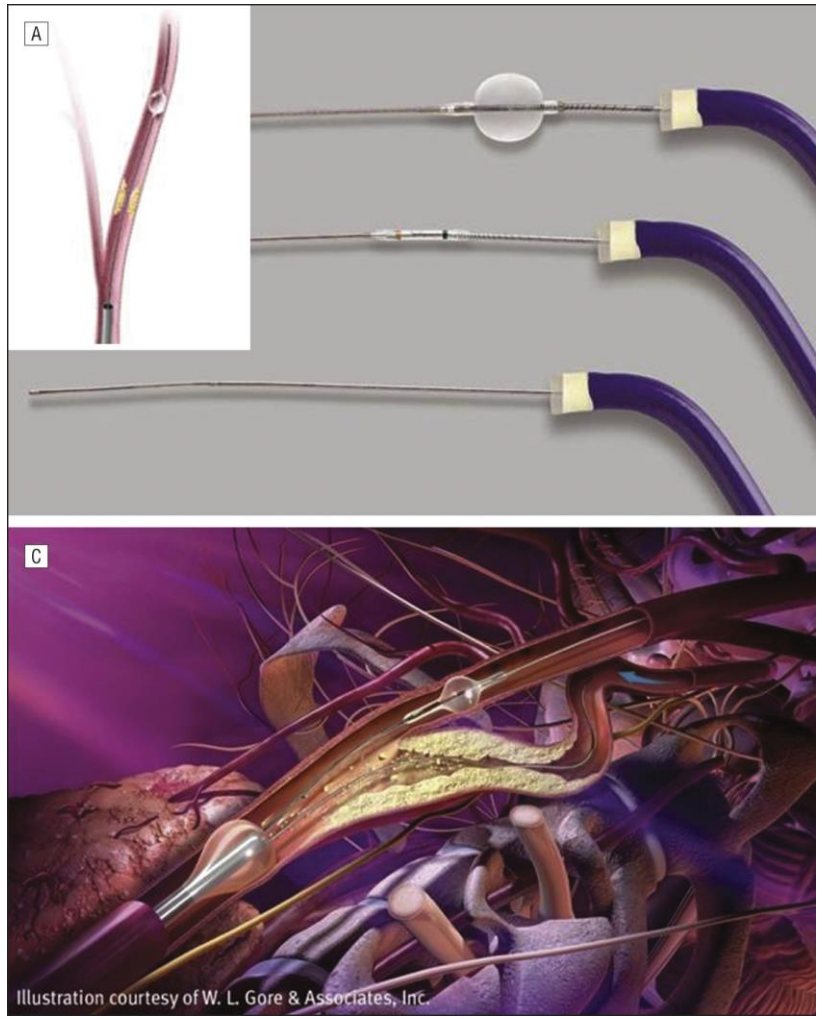


Emboshield Nav6 (Abbott)

Embolic Protection – The Key to Successful CAS

Techniques for embolic protection

- Distal protection
  - Filters
  - **Balloons**
- Proximal protection

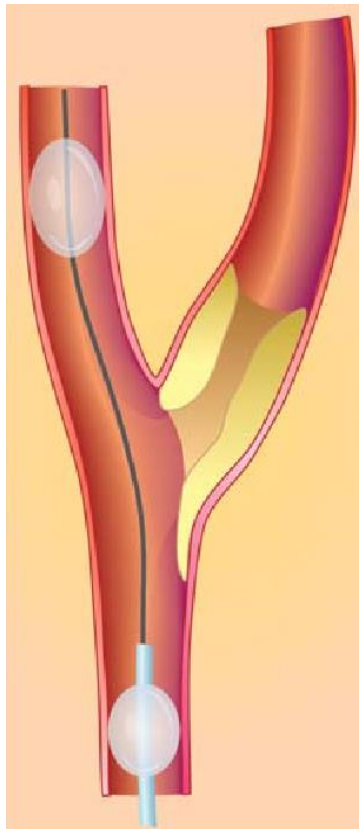


PercuSurge GuradWire System (Medtronic)

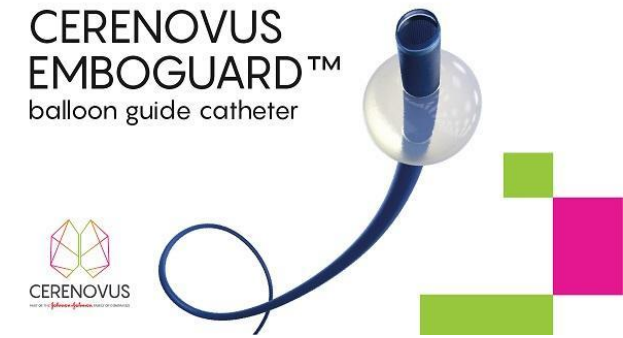
Embolic Protection – The Key to Successful CAS

Techniques for embolic protection

- Distal protection
  - Filters
  - Balloons
- Proximal protection
  - **Flow arrest**



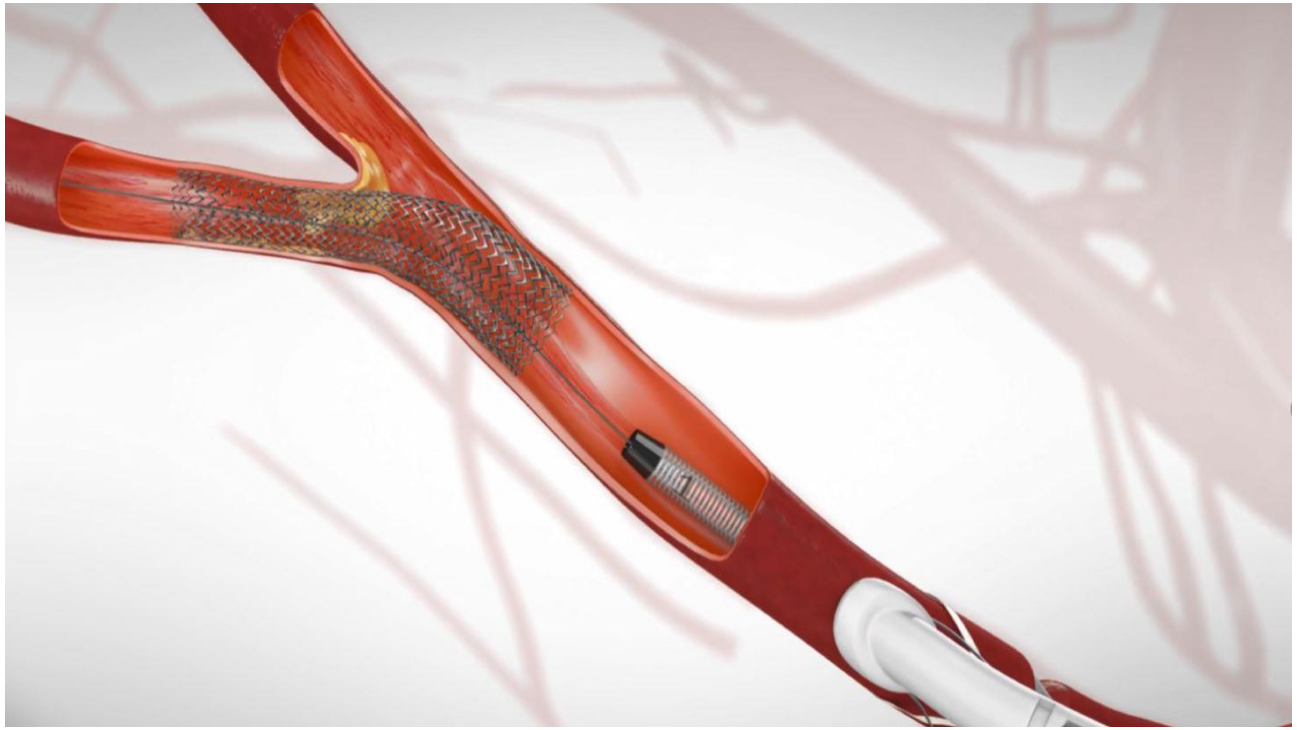
Mo.Ma System
(Medtronic)



Embolic Protection – The Key to Successful CAS

Techniques for embolic protection

- Distal protection
  - Filters
  - Balloons
- Proximal protection
  - Flow arrest
  - **Flow reversal**

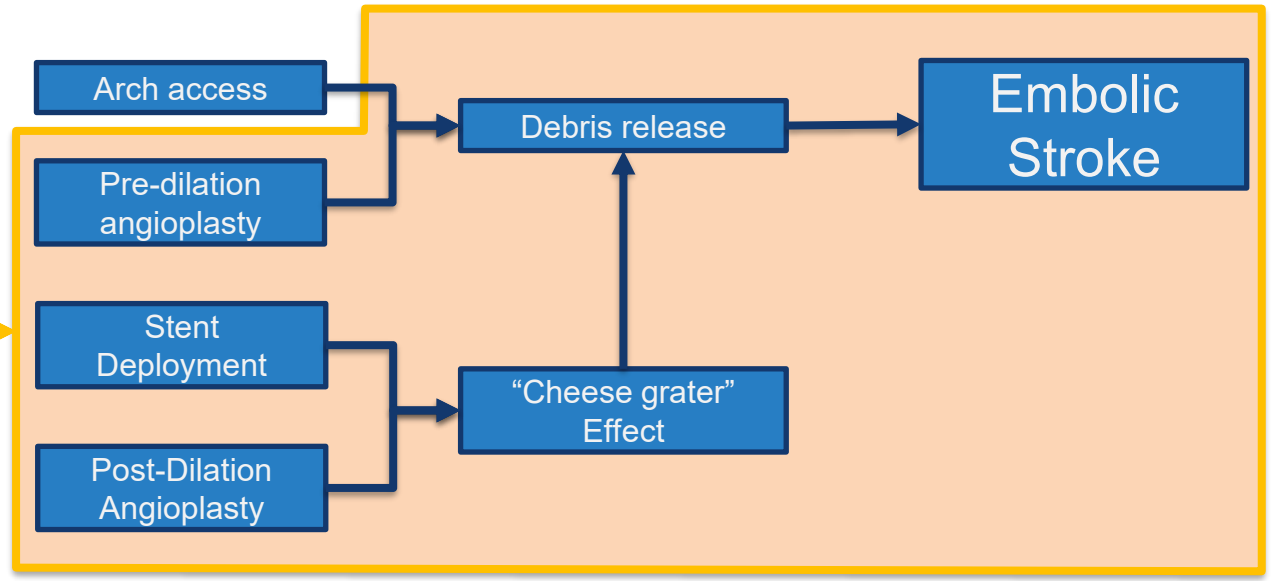


TCAR System
(Silk Road Medical)

Embolic Protection – The Key to Successful CAS

Techniques for embolic protection

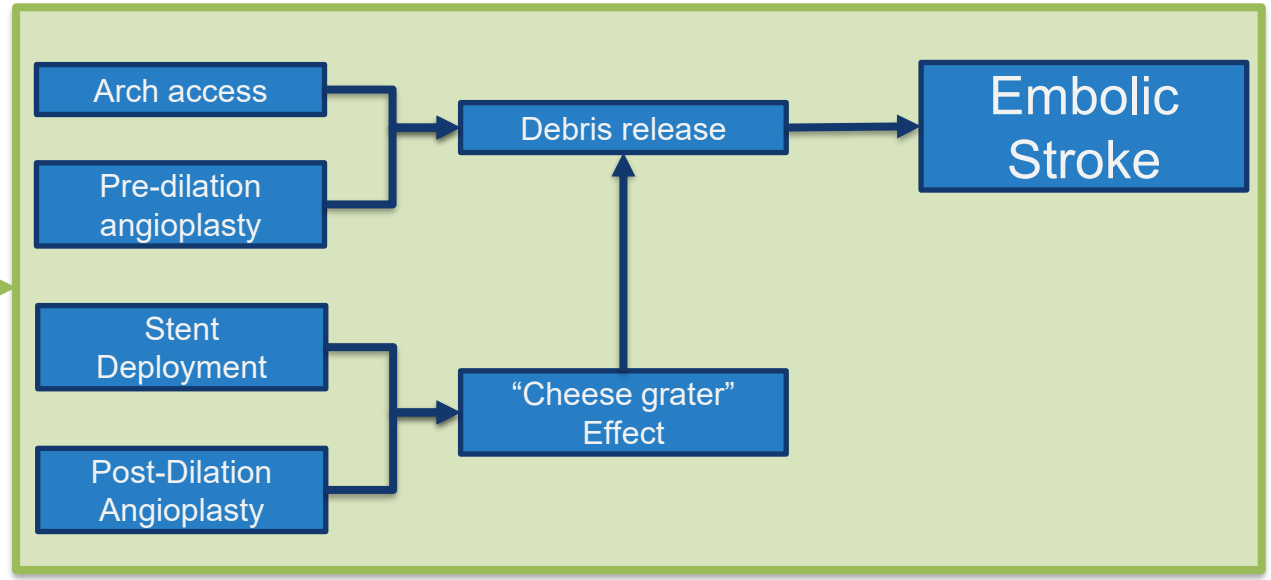
- Distal protection
  - Filters
  - Balloons
- Proximal protection
  - Flow arrest
  - Flow reversal



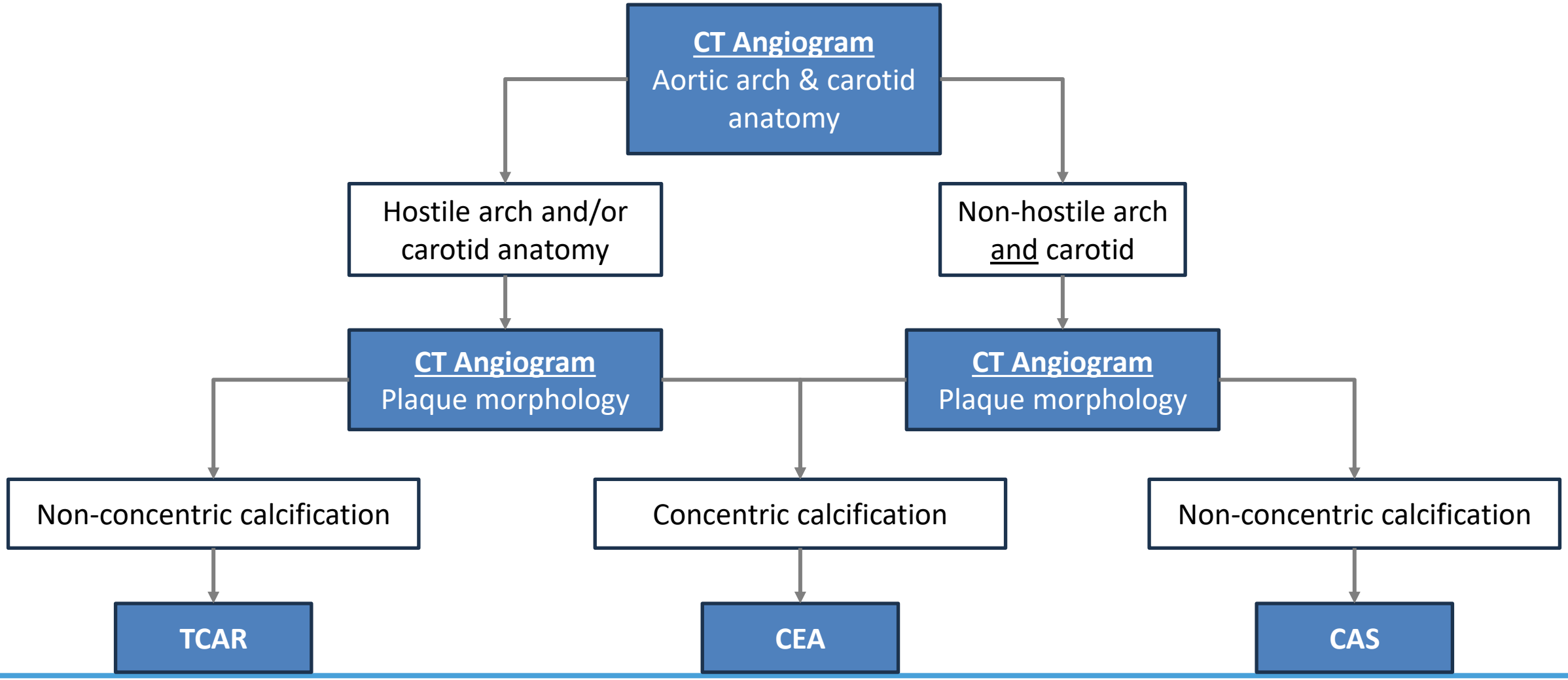
Embolic Protection – The Key to Successful CAS

Techniques for embolic protection

- Distal protection
  - Filters
  - Balloons
- Proximal protection
  - Flow arrest
  - Flow reversal — TCAR



Patient specific treatment algorithm



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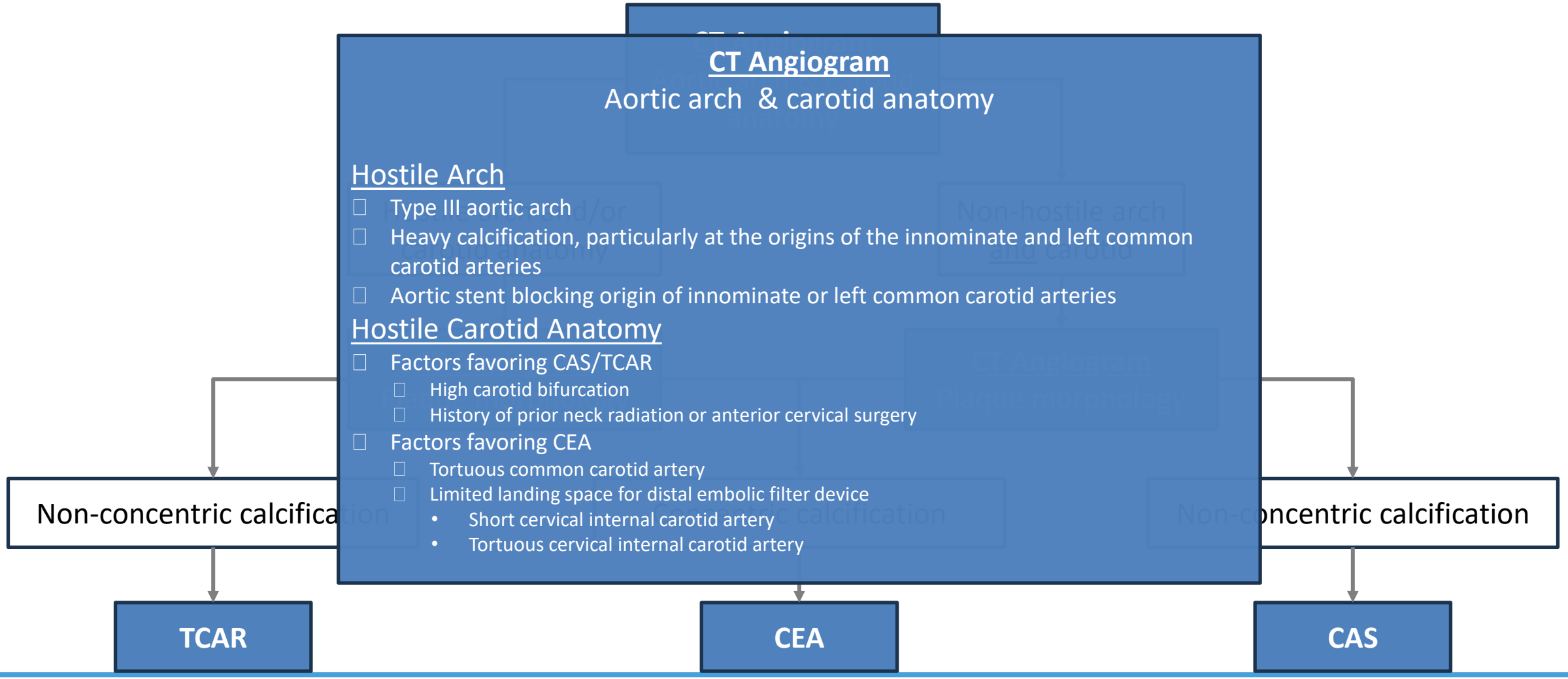
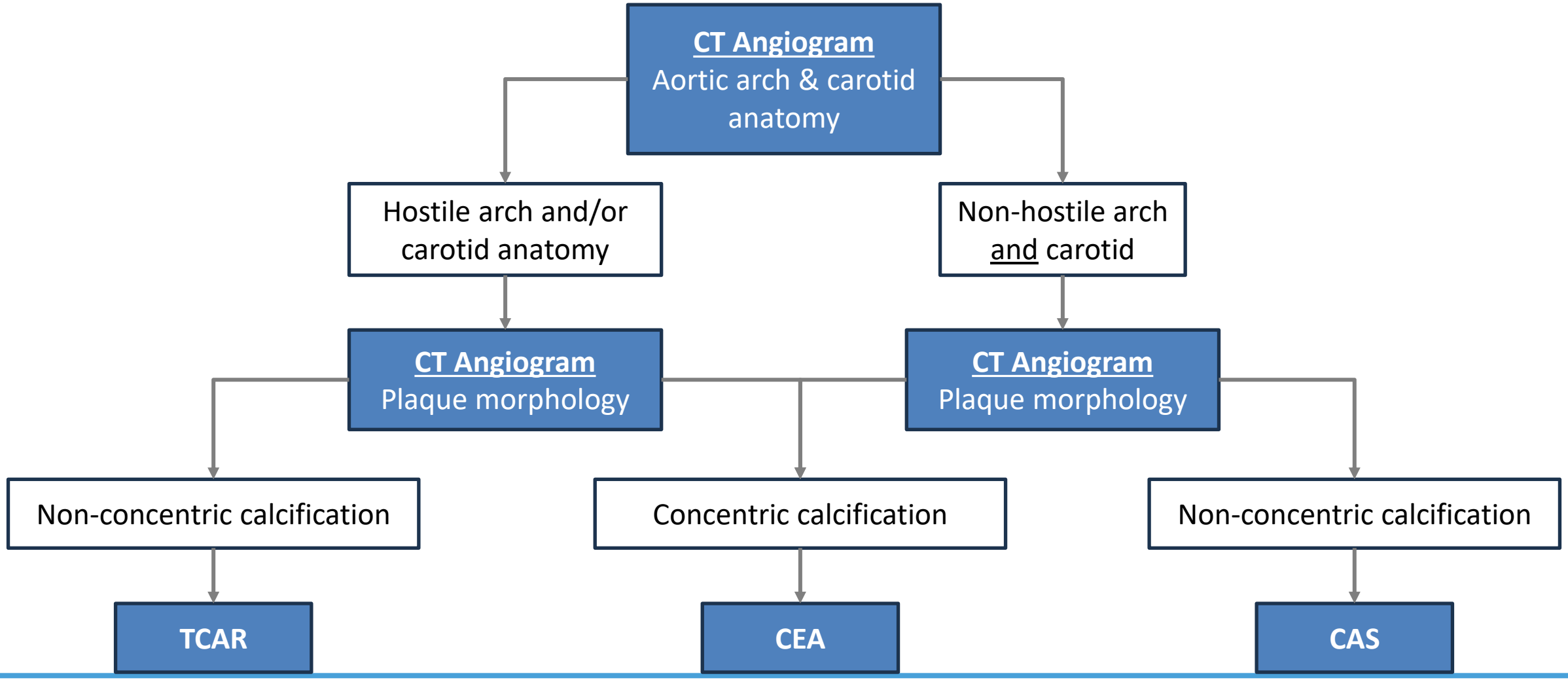


Patient specific treatment algorithm



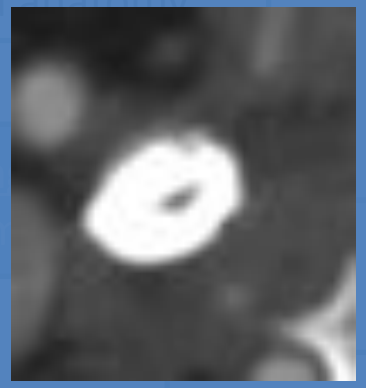
Patient specific treatment algorithm

CT Angiogram

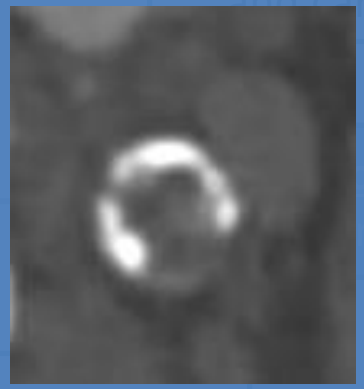
Plaque morphology

Concentric Calcification

- Best viewed on axial CT angiogram



Concentric Calcification



Non-concentric Calcification

Non-concentric calcification

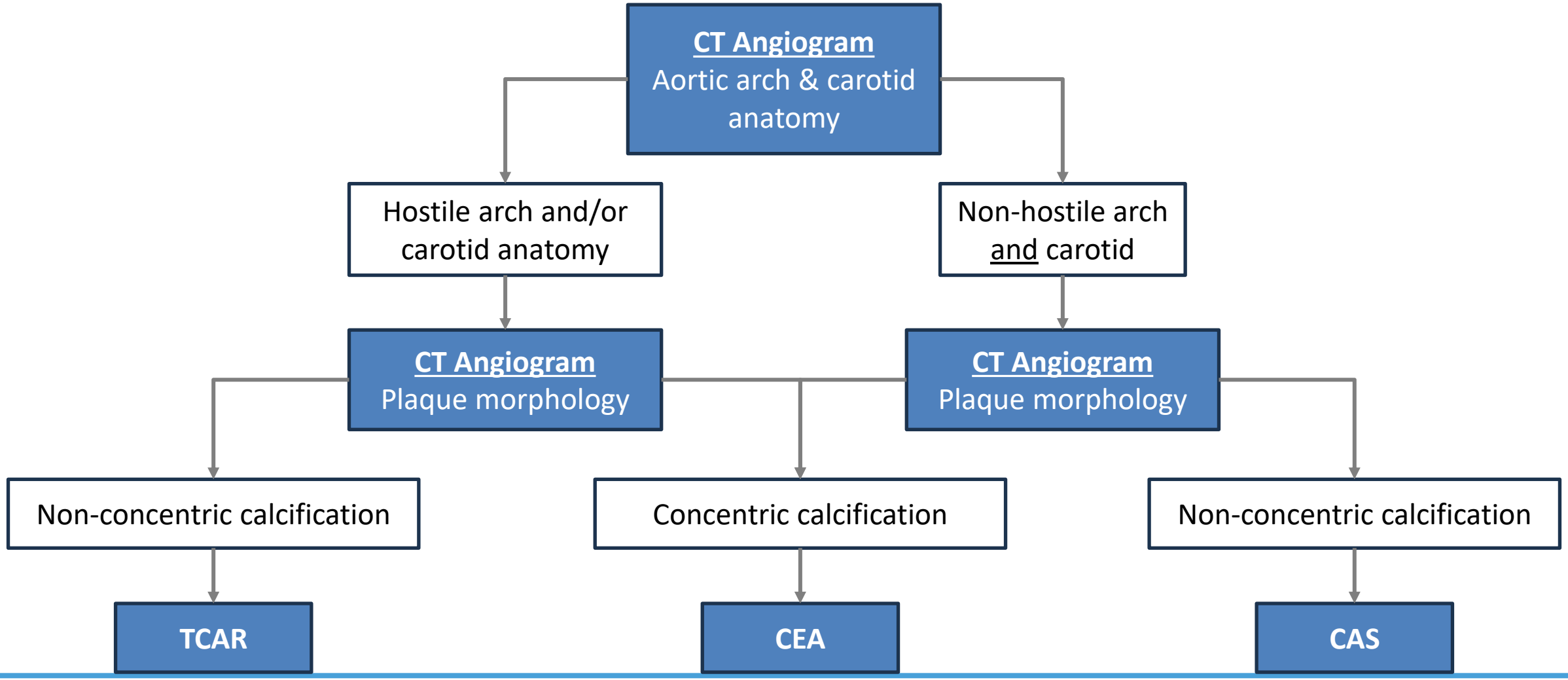
Non-concentric calcification

TCAR

CEA

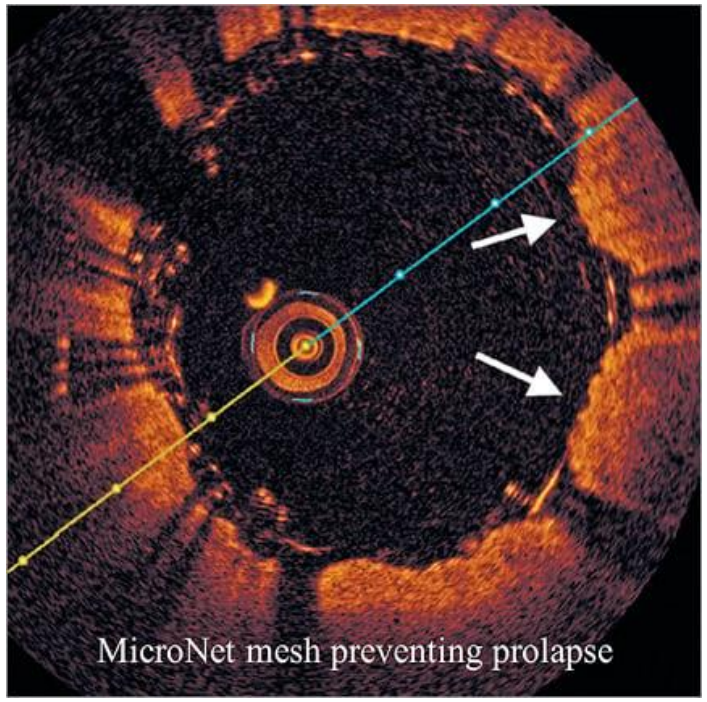
CAS

Updated patient specific treatment algorithm



CGuard

- Investigational Device in USA



INSPIREMD

Dual Layer Design

Combines the largest open-cell frame of available carotid stents with the smallest mesh pore size[3]

MicroNet™®

Prevents plaque Protrusion through the stent, for lasting embolic protection demonstrated for up to 48 months[1]

SmartFit™ technology

Eliminates the need for tapered version and supports accurate vessel wall apposition[2,3]

CLINICAL RESEARCH

DOI: 10.4244/EIJ-D-16-00866

Optical coherence tomography assessment of new-generation mesh-covered stents after carotid stenting

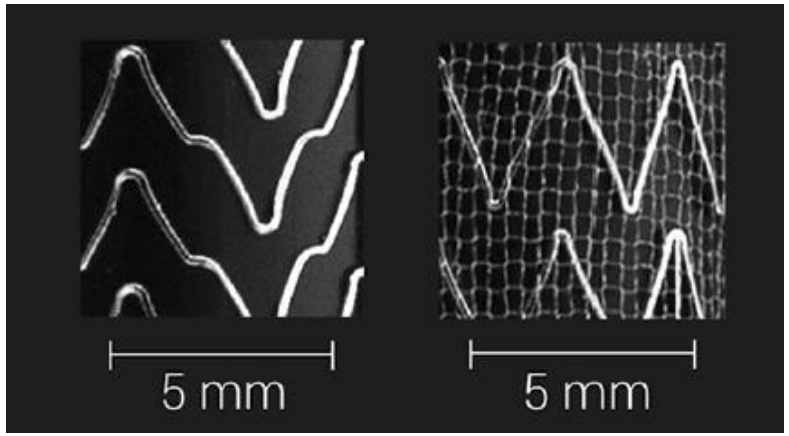
Tomoyuki Umemoto1*, MD; Gianmarco de Donato2, MD; Andrea Pacchioni3, MD; Bernhard Reimers4, MD; Giuseppe Ferrante4, MD, PhD; Mitsuaki Isobe1, MD, PhD; Carlo Setacci2, MD

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

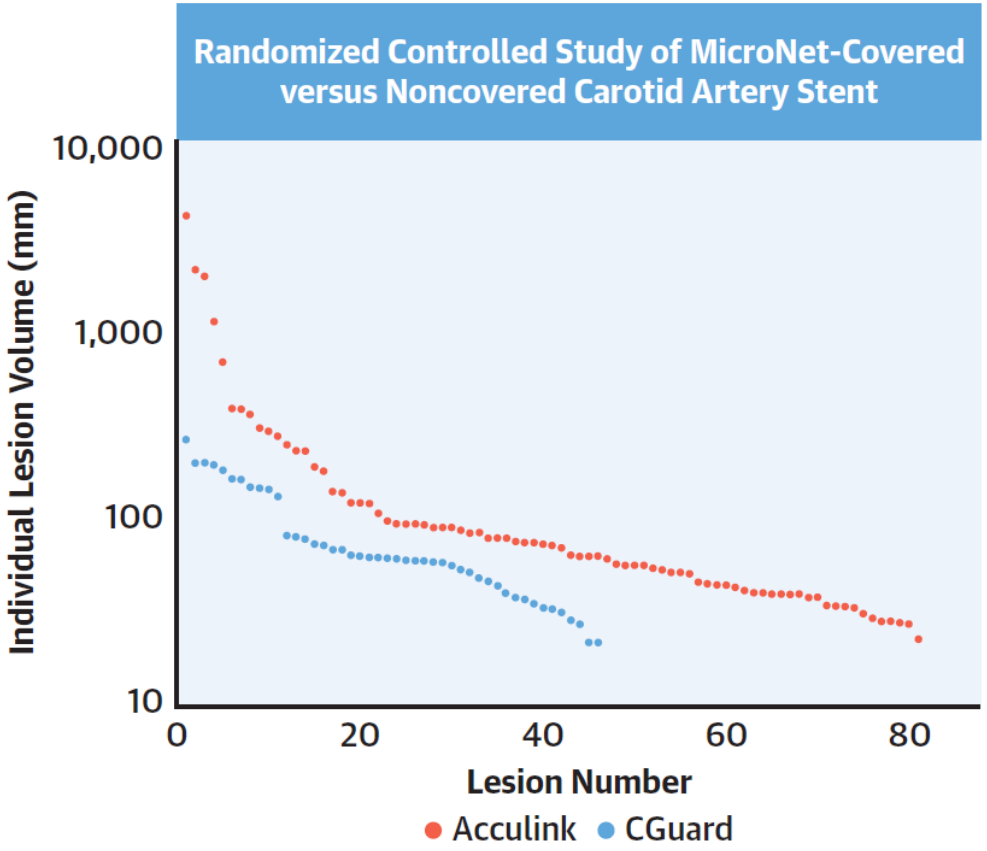
Andrey Karpenko, MD, PhD,[a] Savr Bugurov, MD,[a] Pavel Ignatenko, MD, PhD,[a] Vladimir Starodubtsev, MD, PhD,[a] Irina Popova, MD, PhD,[a] Krzysztof Malinowski, MSc,[b] Piotr Musialek, MD, DPhil[c]

CONCLUSIONS The MicroNet-covered stent significantly reduced periprocedural and abolished postprocedural cerebral embolism in relation to a conventional carotid stent. This is consistent with the MicroNet-covered stent's sustained embolism prevention, translating into cerebral protection not only during but also after CAS. The present findings may influence decision making in carotid revascularization. (The SIBERIA Trial [Acculink™ Versus CGuard™]; NCT03488199) (J Am Coll Cardiol Intv 2021;14:2377–2387)

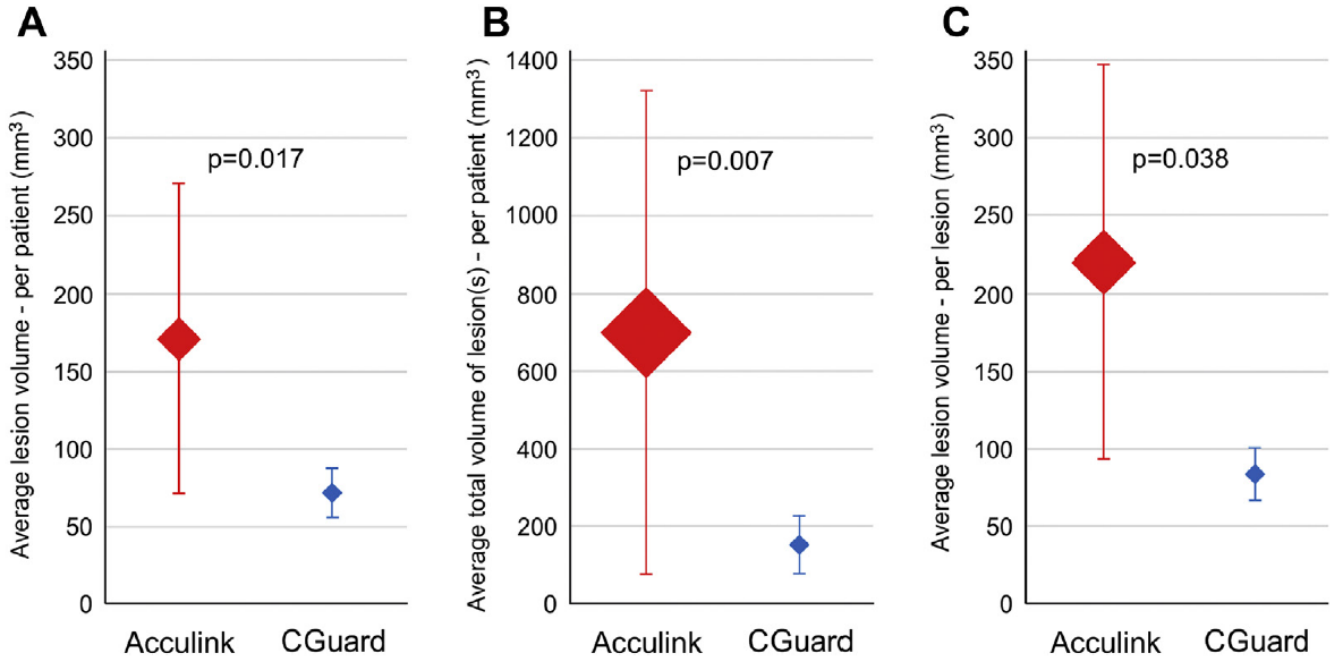
- Prospective randomized- single center clinical trial
- 100 patients randomized
  - Acculink
  - cGuard
- CAS
  - DAPT
  - NAV6 used in all procedures
  - Pre and post procedural angioplasty



Karpenko A, Bugurov S, Ignatenko P, Starodubtsev V, Popova I, Malinowski K, Musialek P. Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization. JACC Cardiovasc Interv. 2021 Nov 8;14(21):2377-2387. doi: 10.1016/j.jcin.2021.08.005. PMID: 34736737



Karpenko, A. et al. J Am Coll Cardiol Intv. 2021;14(21):2377-2387.



Reduction of peri-procedural ischemia on DWI-MRI

- Overall embolic load to brain minimized in CGuard group
- Minimize “cheese grater” effect

Carotid Stenting and Angioplasty with Double Layer Open and Closed Cell CGuard Stent

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Matthew Moser MD

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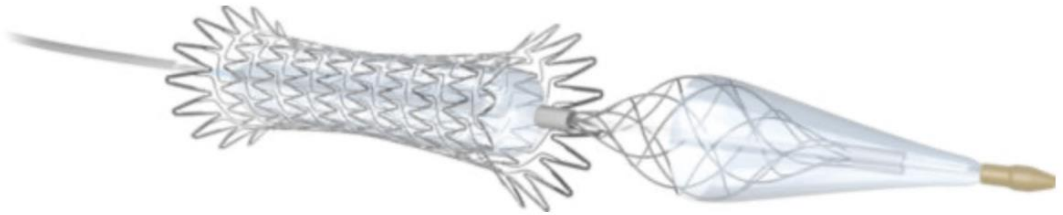
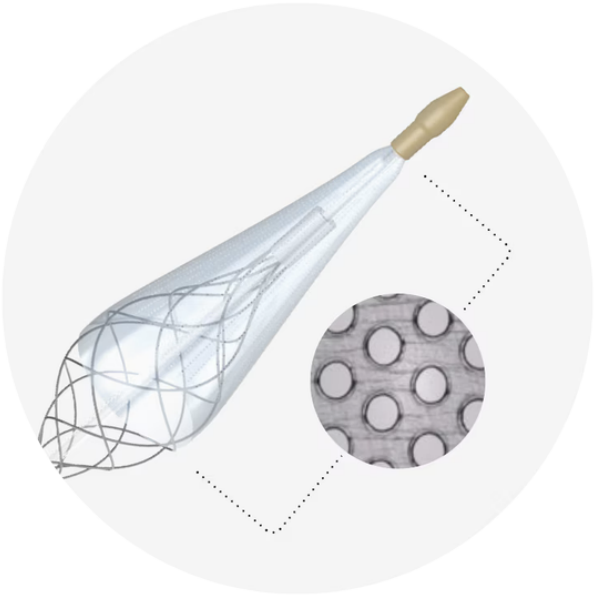
Neuroguard Integrated Embolic Protection System





40-micron IEP filter

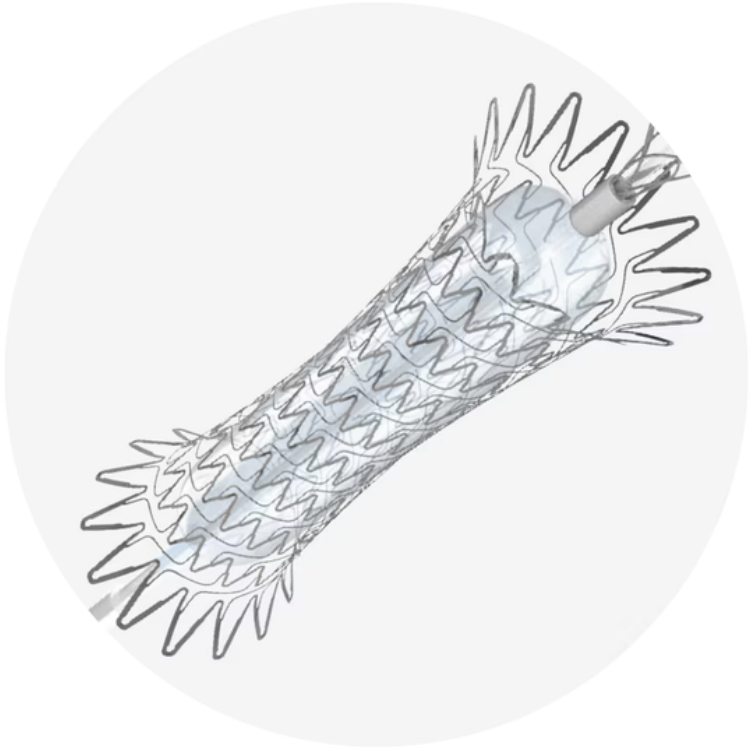
- Captures more micro-embolic debris: proprietary 40-micron filter pores are approximately three times smaller than traditional filters[†,1,2,8,9]
- Physician-controlled filter can be adjusted to the anatomy to help prevent particles from passing around the filter[‡,3]

Neuroguard Integrated Embolic Protection System

Purpose-built stent[3]

- **FlexRing™* technology** – provides the benefits of both open- and closed-cell stents with flexibility and radial strength[‡,4,5]
- **Maximum coverage** – closed-cell asymmetrical hourglass designed for maximum plaque coverage and minimal outward pressure at lesion[‡,4]
- **Designed for precision** – built for precise and predictable deployment[‡,4,5]
- **Exceptional strength** – verified radial resistive strength, which may minimize the risk of deformation due to calcium[‡,5]
- **Consistent conformity** – demonstrated flexibility and conformability to the vessel wall, even in tortuous anatomy, with kink resistance up to > 270 degrees[‡,4]
- **Built to fit** – short landing zone means the system could be used on more than 94% of patient anatomies[§,3,6,7]

Neuroguard Integrated Embolic Protection System



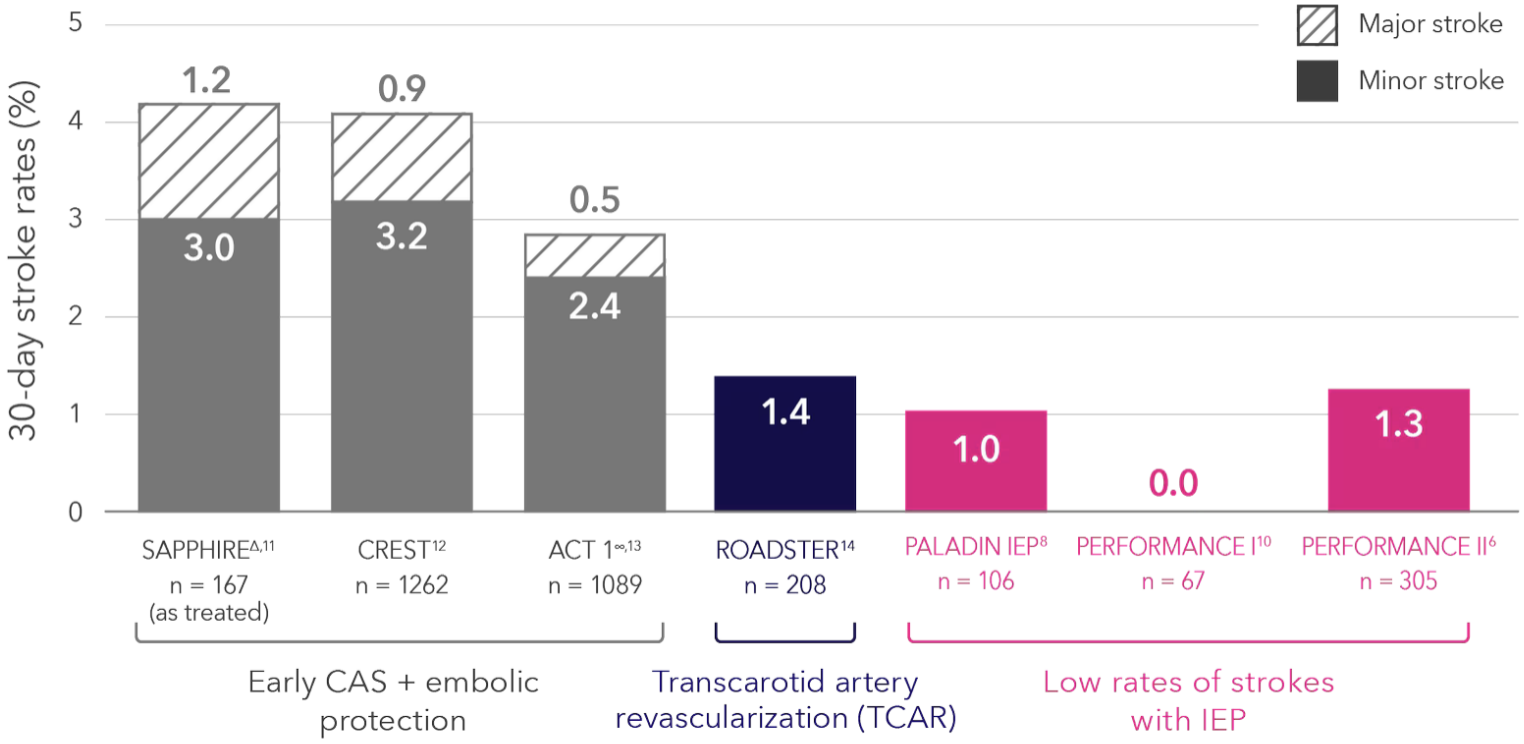
Integrated post-dilation balloon

- Reduces catheter exchanges and improves procedural efficiency[‡,◊,3]
- Facilitates crossing the lesion with fewer passes[‡,◊,3]

Low rates of stroke with IEP[6,8,10–14]

Two clinical studies of the Neuroguard IEP™* System demonstrated 99% freedom from any stroke through 30 days[#] and the lowest one-year stroke outcomes for CAS pivotal trials.[6,10,11,15-18]

Minor and major stroke rates in carotid stenting through 30 days



CAS, carotid artery stenting; CEA, carotid endarterectomy; IEP, integrated embolic protection; TCAR, trans-carotid artery revascularization

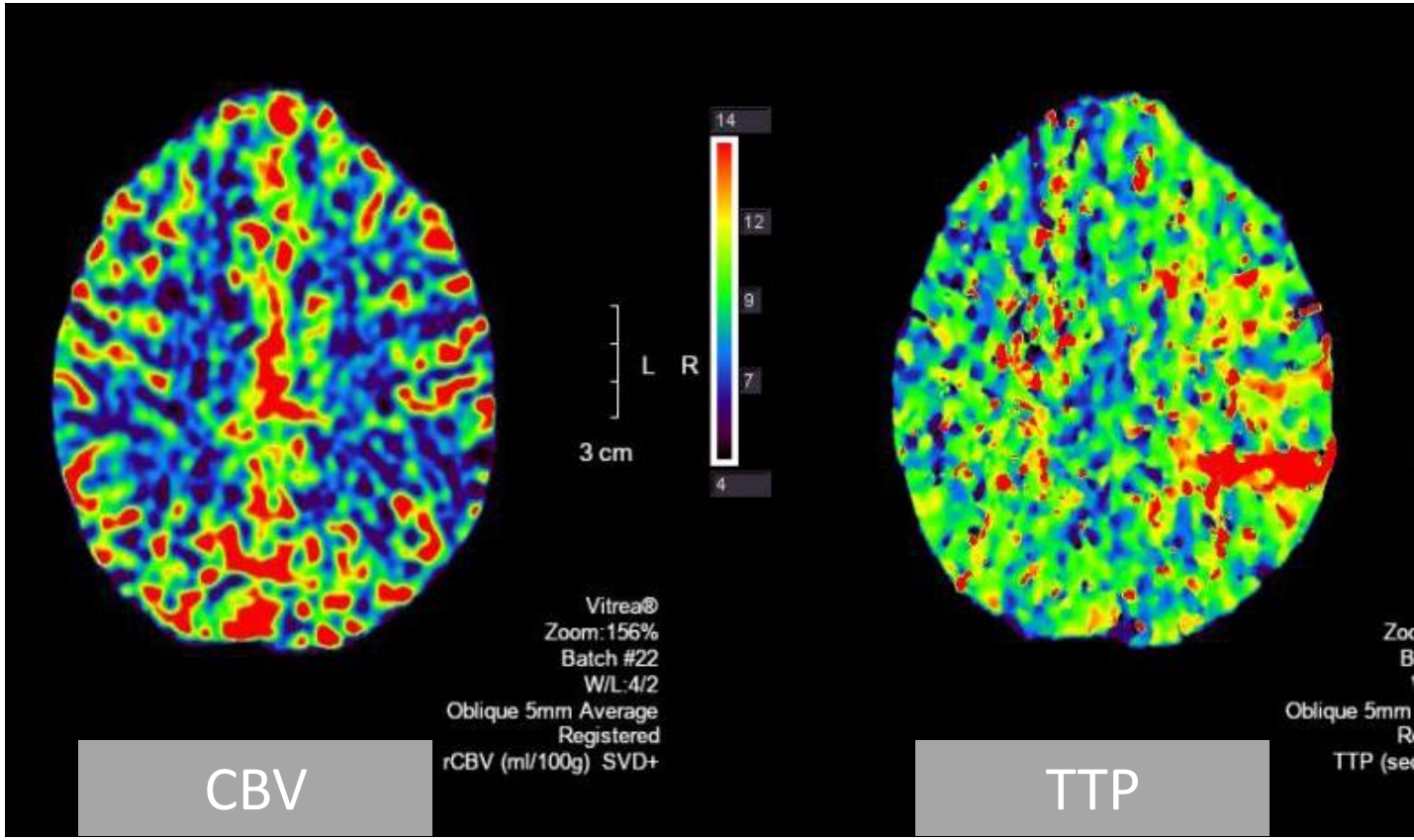
Retrograde Access to Common Carotid Artery

Another TCAR niche

65 year-old male presenting with acute right hemiparesis and aphasia

- PMHx CAD (s/p stent)
- NIH stroke scale: 6
  - LOC questions (1), facial palsy (1), RUE motor (1), sensory (1), language (2)
- Given tPA
- CTA
  - Severe proximal left ICA stenosis
  - Proximal left CCA thrombus
- CT perfusion
  - Subtle left hemispheric increased time to peak with preserved cerebral blood volume
- Carotid dopplers
  - Right ICA 121/17; left ICA 465/93

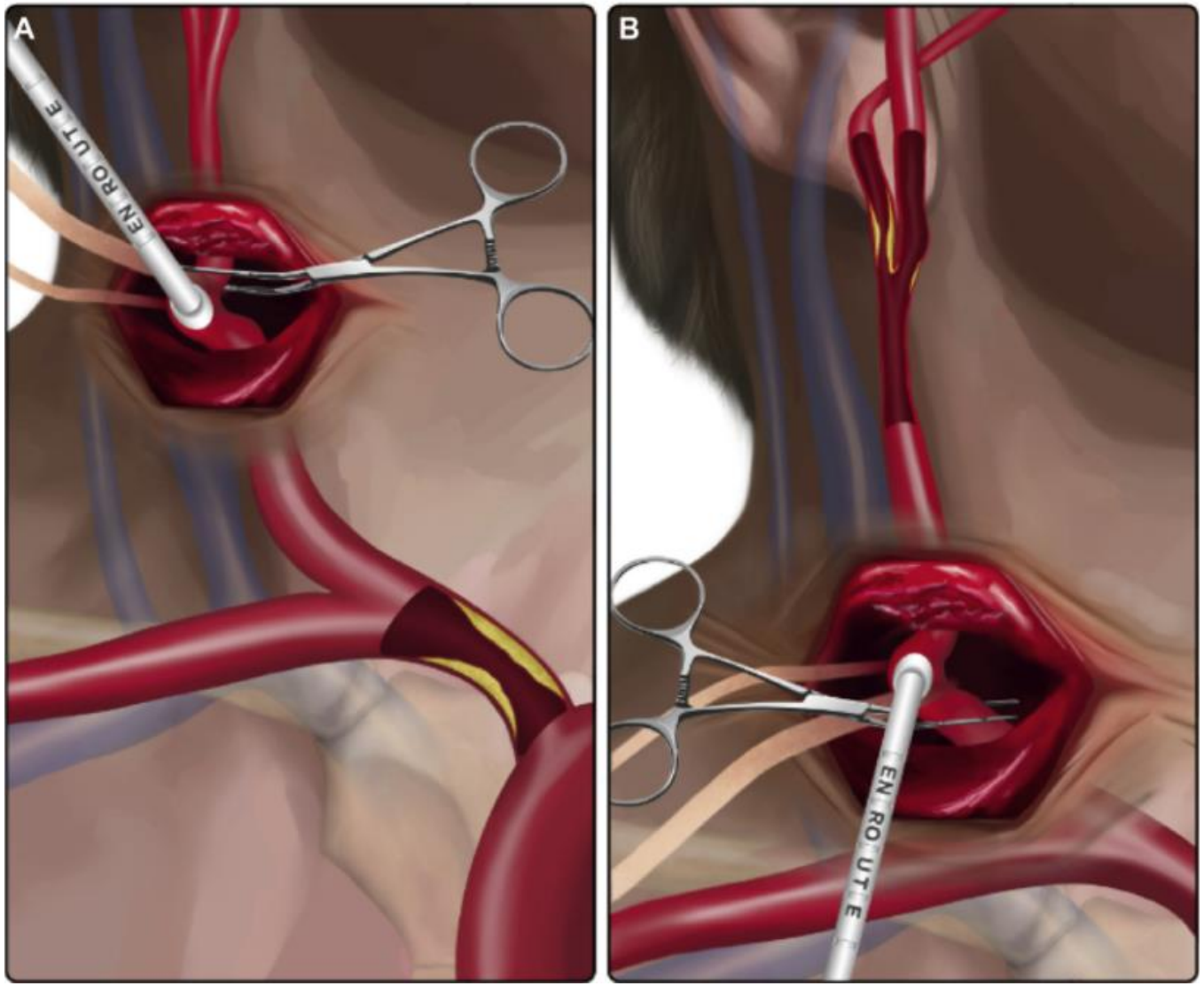
CTA and CT Perfusion



Decision Making

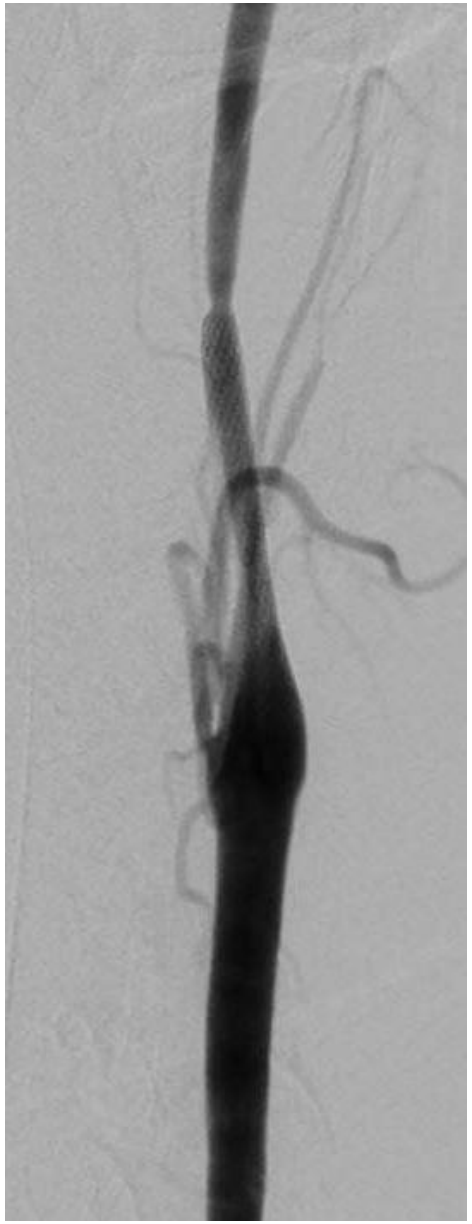
- Options
  - CEA
    - Does not directly address the CCA thrombus
  - CAS
    - Staged stenting of CCA & ICA vs single session
    - Difficult to obtain distal embolic protection while treating the CCA lesion
  - TCAR
    - Able to treat both lesions independently while maintaining flow reversal
    - Retrograde stenting is a less familiar procedure

Tandem TCAR




PROXIMAL LEFT CCA THROMBUS

Pre-TCAR



Post-TCAR

Pre-TCAR

Post-TCAR


Thank You

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