

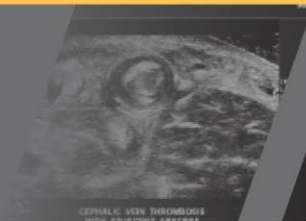
2024 MID-ATLANTIC CONFERENCE  
12th ANNUAL CURRENT CONCEPTS IN  
**VASCULAR THERAPIES**

2024



Hilton Virginia Beach Oceanfront  
Virginia Beach, Virginia

APRIL 18-20



2024 MID-ATLANTIC CONFERENCE  
12th ANNUAL CURRENT CONCEPTS IN  
**VASCULAR THERAPIES**

**2024**



***Sid Bhende MD***

***Sentara Vascular  
Specialists***

***April 20<sup>th</sup> 2024***

***CEA, TF CAS & TCAR are Clinically Equal and  
CMS Decision to Deregulate was Correct***



# Disclosures



# Disclaimer

I perform more CEA than CAS

NEVERTHELESS

My goal is to convince everyone today that  
CAS (TCAR) is NON-INFERIOR to CEA



# Outline

- Overview
  - CEA vs TF CAS vs TCAR
- Literature Review
  - Head to Head Results



# Carotid Endarterectomy - CEA

- First successful CEA was performed by Dr. Michael DeBakey in 1953
- However first published report of CEA was in 1954 by Eastcott
- NOTHING has changed about the surgery in the past 70yrs!





# 1953 Chevy Corvette



No Autopilot  
No Bluetooth  
No Navigation  
No Power doors  
No Power windows  
No seat warmers



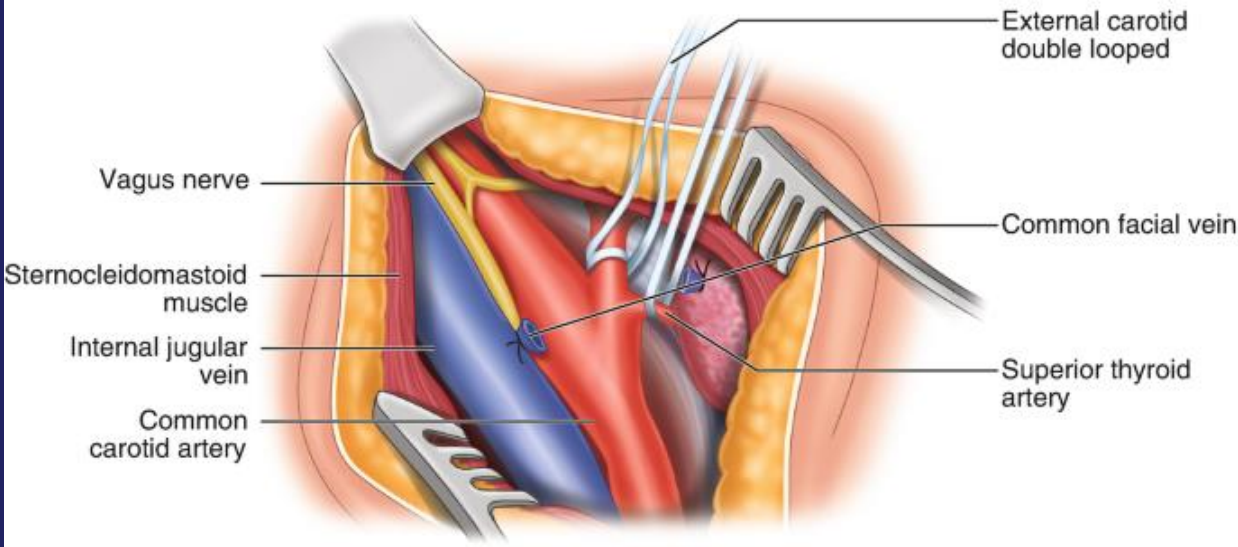
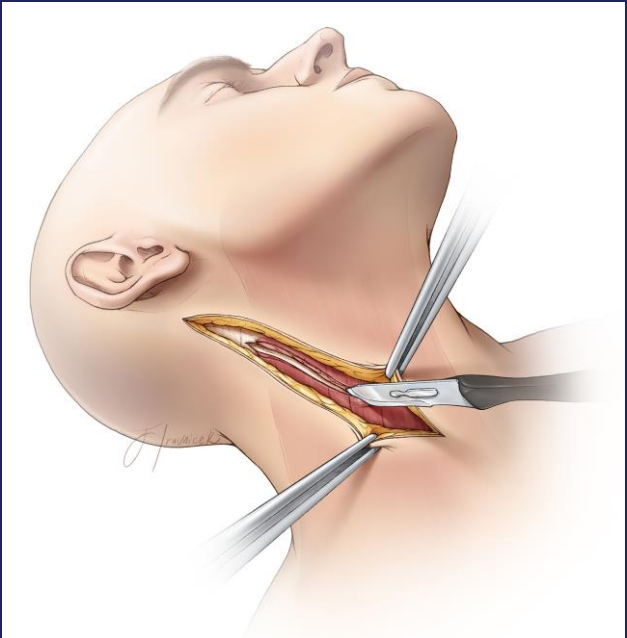
# CEA Steps

- BIG Neck incision
- Exposure of carotid artery and mobilization of veins and nerves
- Arteriotomy and +/- Shunting
- Plaque removal
- Closure with patch





# CEA Steps



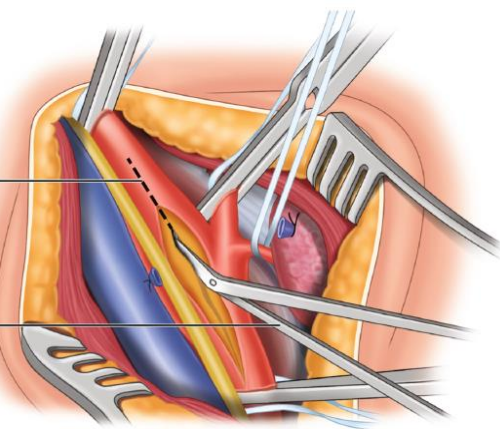
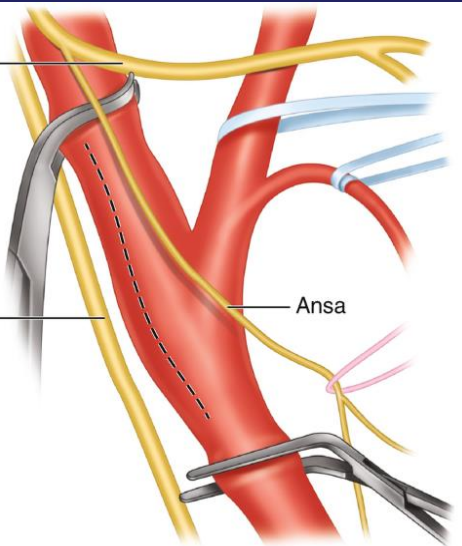
Hypoglossal nerve

Vagus nerve

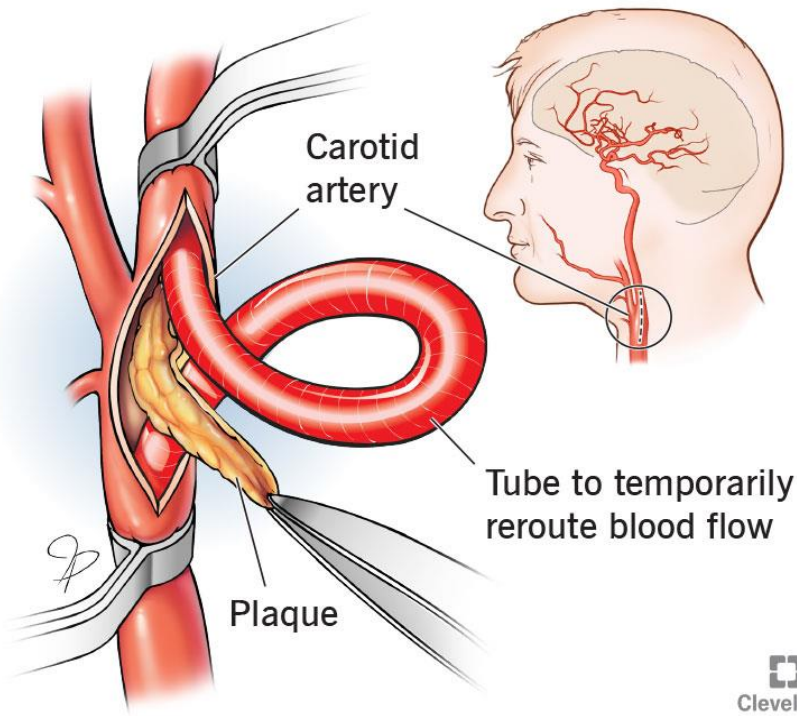
Ansa

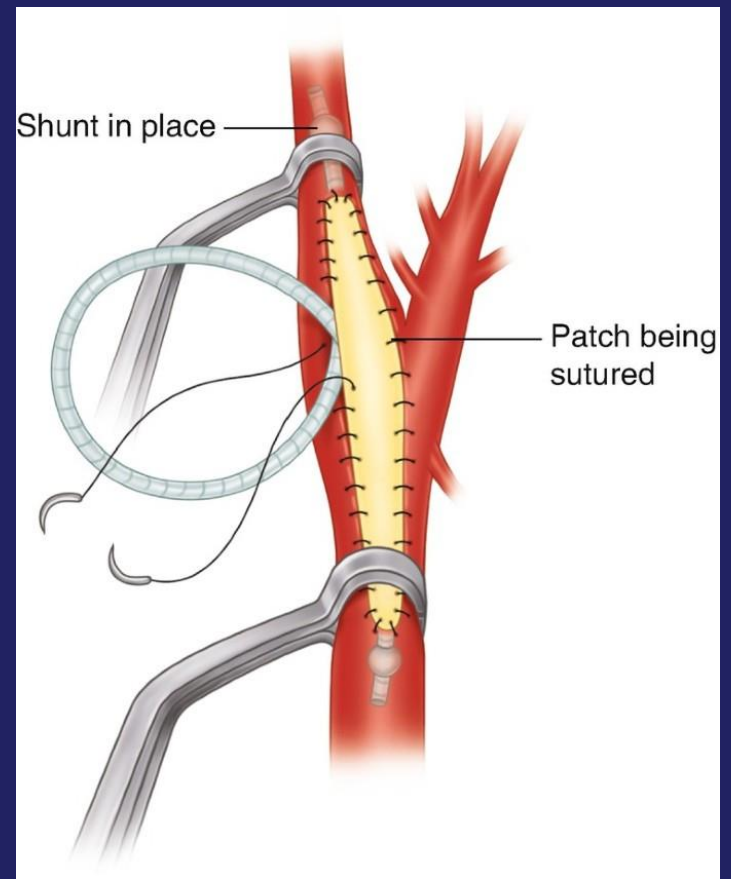
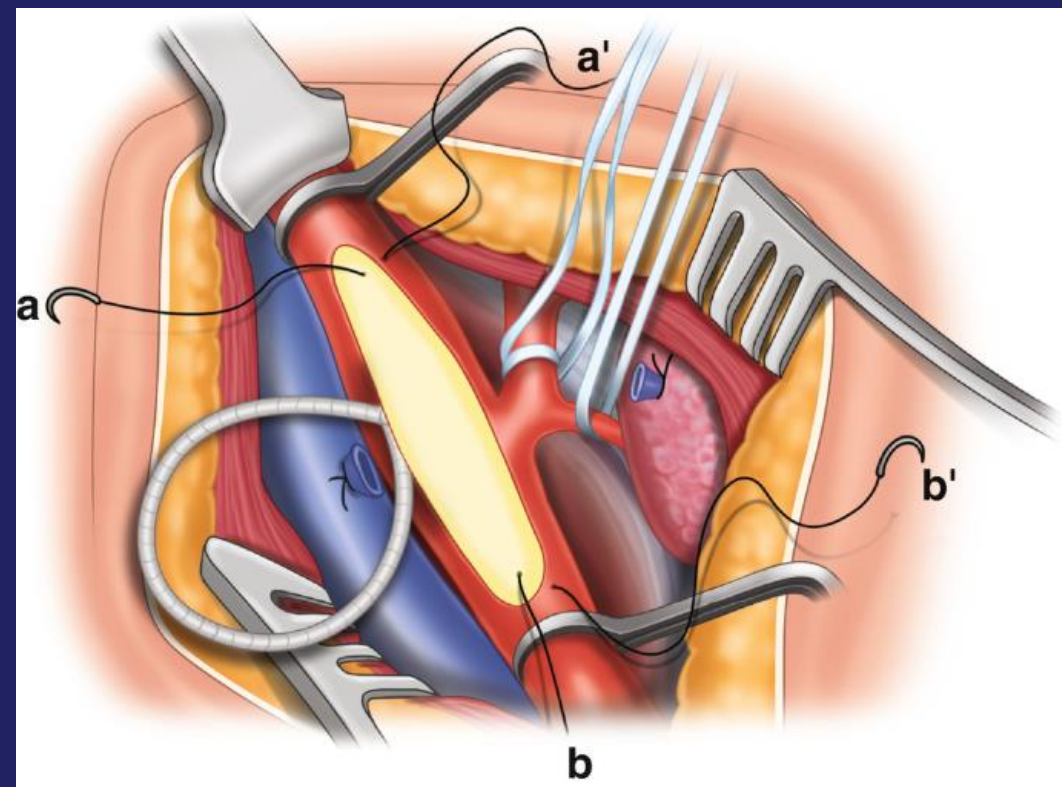
Incision

Potts scissors

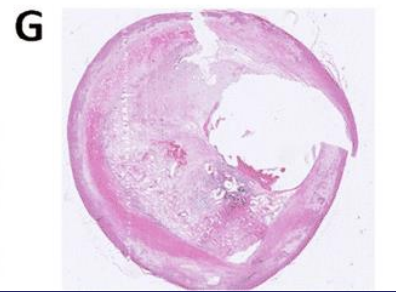
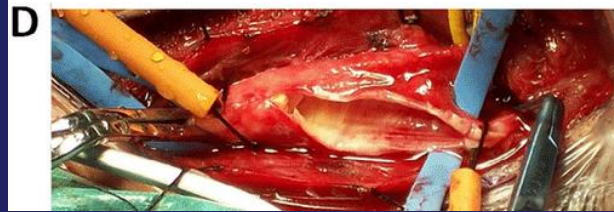
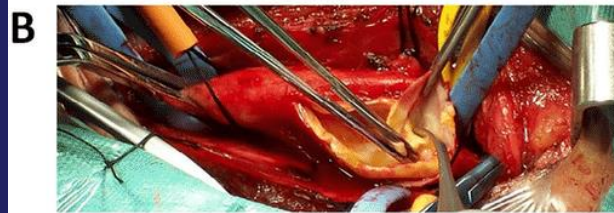


## Carotid Endarterectomy









# Complications of CEA

1. Stroke risk
2. Myocardial infarction
3. Nerve Injury
4. Infection
5. Bleeding/Hematoma
6. Clamp injury
7. Dissection from shunt placement



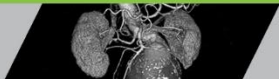
# TF CAS - TransFemoral CA Stenting

- In 1981, Klaus Mathias performed the first carotid artery balloon angioplasty
  - Several complications – elastic recoil, dissection, plaque embolization
  - Procedure abandoned
- In 1994 - Carotid stenting became popular after favorable results in coronary interventions





# 1994 Chevy Corvette





# TF CAS - Transfemoral CA Stenting

- Indications:
  - High surgical risk patients – unstable angina, recent MI, severe pulmonary disease, severe CHF
  - Radiated neck, Presence of tracheostomy
  - Contralateral carotid occlusion
  - Prior CEA with restenosis
  - Anatomically inaccessible lesion



# TF CAS Steps

- Ultrasound guided femoral artery access
- Arch and carotid angiography
- 6 Fr long sheath
- Wires and catheters
- EPD (Emboic protection device)
- Balloon
- Stent(s)



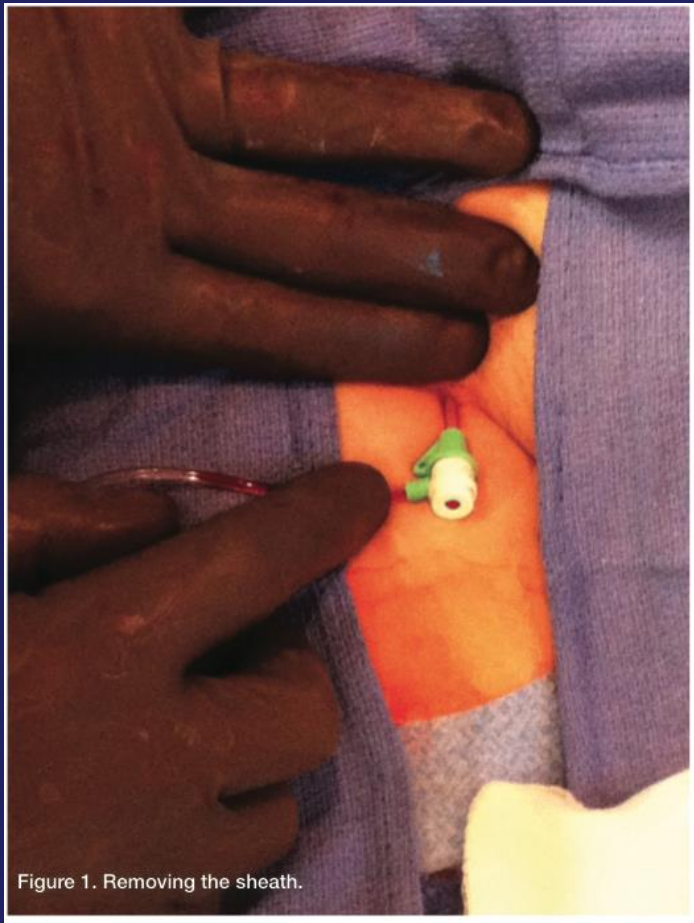
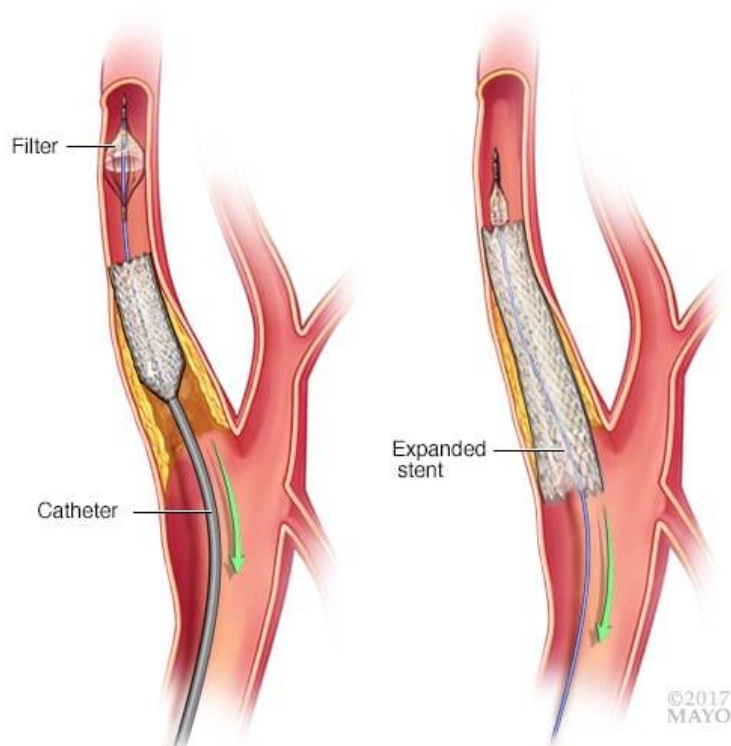
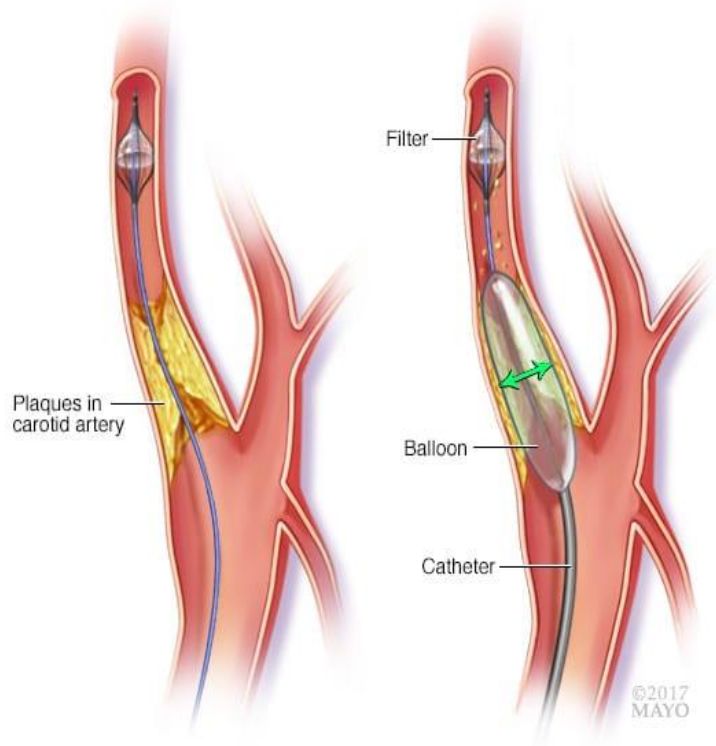
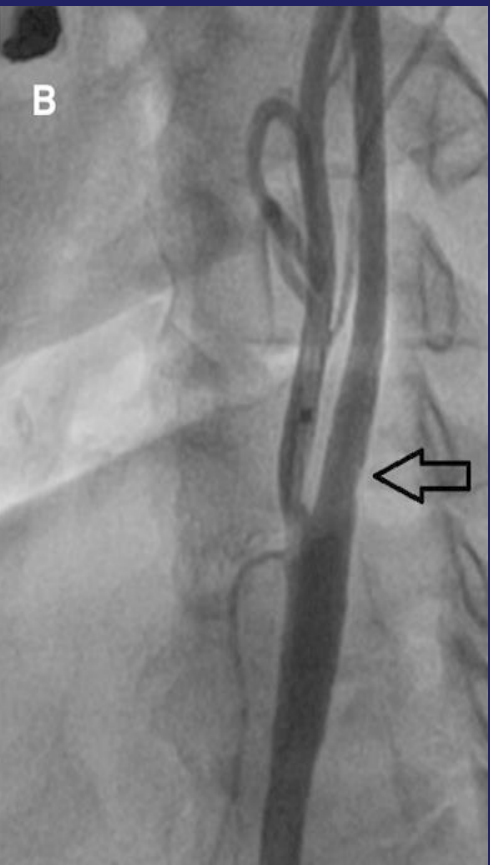
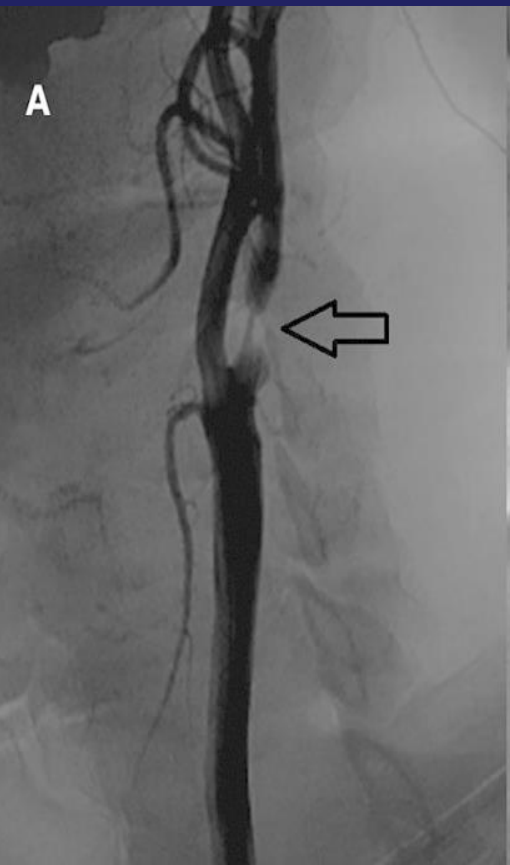


Figure 1. Removing the sheath.







**CAROTID ARTERY STENTING**



**PRE STENT**



**POST STENT**



# TF CAS - Data

- CREST TRIAL – Carotid Revascularization Endarterectomy vs Stent Trial
  - Started enrolling in 2000, but published in 2010
  - Prospective Randomized Multicenter trial comparing CEA vs CAS to determine superiority
  - NIH sponsored trial and Industry (Abbott)



# TF CAS - Data

- CREST TRIAL – Carotid Revascularization Endarterectomy vs Stent Trial
  - 108 Centers in USA and 8 in Canada
    - Team – Surgeon, Interventionalist, Neurologist
      - 477 Certified Surgeons, 224 Certified Interventionalists





# CREST

- 2500 patients randomized to CEA vs TF CAS
  - CEA arm – were given ASA only
  - TF CAS arm – were given ASA + Plavix or ASA + Ticlid for at least 30 days
- Post procedure every patient evaluated by Neurologist for NIHSS and modified Rankin score



# CREST

- Primary Endpoints
  - CVA, MI or death during periprocedural period (within 30 days of procedure)



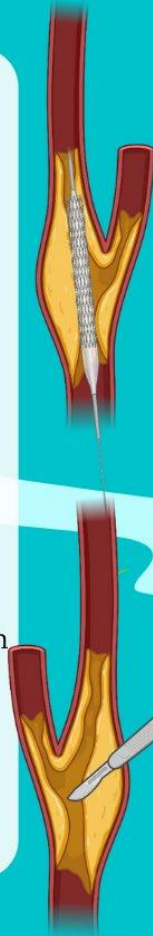
## RESULTS

### Stenting (CAS) vs. Endarterectomy (CEA):

- **Primary composite outcome similar** in CAS and CEA
    - Periprocedurally (CAS 5.2% vs. CEA 4.5%)
    - 4-year followup (CAS 7.2% vs CEA 6.8%,  $p=0.51$ )
    - Similar results at 10 year follow-up [2].
  - **Different rates of stroke and MI** in the perioperative period (within 30 days of randomization)
    - **Higher risk of stroke seen in CAS** (4.1% vs 2.3%,  $p=0.01$ )
- \* Quality of life analysis showed that stroke had greater adverse effects
- **Higher risk of MI seen in CEA** (1.1% vs 2.3%,  $p=0.03$ )

### Secondary Outcomes:

- Age differences: lower risk of primary endpoint in younger patients with CAS and older patients with CEA
  - crossover at 70 years old ( $p=0.02$ )
- No significant differences due to sex ( $p=0.34$ ) or symptomatic status ( $p=0.84$ )
- Cranial Nerve palsy higher in CEA patients (0.3%, vs. 4.7%)
  - \* well-known complication, long-term cranial nerve deficits are rare [5].



## CONCLUSIONS

- **4-year composite primary outcomes** of death, MI, or stroke were similar for both CAS and CEA.
- **Higher perioperative rates of stroke in CAS** patients, and **higher perioperative rates of MI in CEA** patients.
  - Quality-of-life analysis indicated that stroke had a more negative impact. Opportunity for improvements to perioperative safety of CAS.
- **Different outcomes were also seen based on the patient's age.**
  - **CAS** demonstrated better outcomes for patients <70 yo, while older patients had better outcomes with **CEA**. This difference was attributed to age-related vascular changes (tortuosity, calcification) [1].

## LIMITATIONS

- No comparison to medical therapy (addressed in upcoming CREST-2 trial) [3].
- Use of only one stenting system (RX Acculink)
- Rigorous certification for interventionists; improved patient safety but limits generalizability to community practice

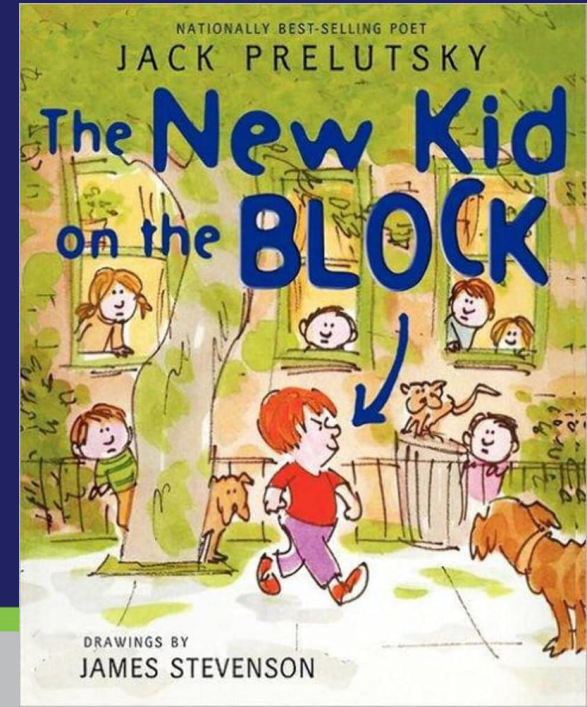
# Carotid Dilemma

- CEA vs TF CAS
  - How do we decide what to do for our patient?
  - CEA has higher risk of MI
  - TF CAS has higher risk of CVA
  - Is there a way to deliver a carotid stent and keep the stroke rate low?



# New Kid on the Block

- TCAR (TransCarotid Artery Revascularization)
  - First introduced in US in 2012 by Drs. Criado and Chang
  - Combination of surgery + stent
  - Commercially available in 2016





# 2024 Chevy Corvette



# TCAR Steps

- CCA exposure at base on neck
- Percutaneous femoral vein access
- Direct sheath access into CCA
- Establish Flow Reversal
- Carotid angiography
- Balloon angioplasty (Pre-Dilatation)
- Deploy Stent(s) +/- Post balloon dilatation





# Dedicated TCAR® Toolset

Access	Guidewires	Neuroprotection	Carotid Stent	Balloons
✓	✓	✓	✓	✓

ENHANCE® Transcarotid Peripheral Access Kit\*



ENROUTE® Transcarotid Stent System\*



Open vs. Closed Cell

ENROUTE®  
0.014"  
Guidewire

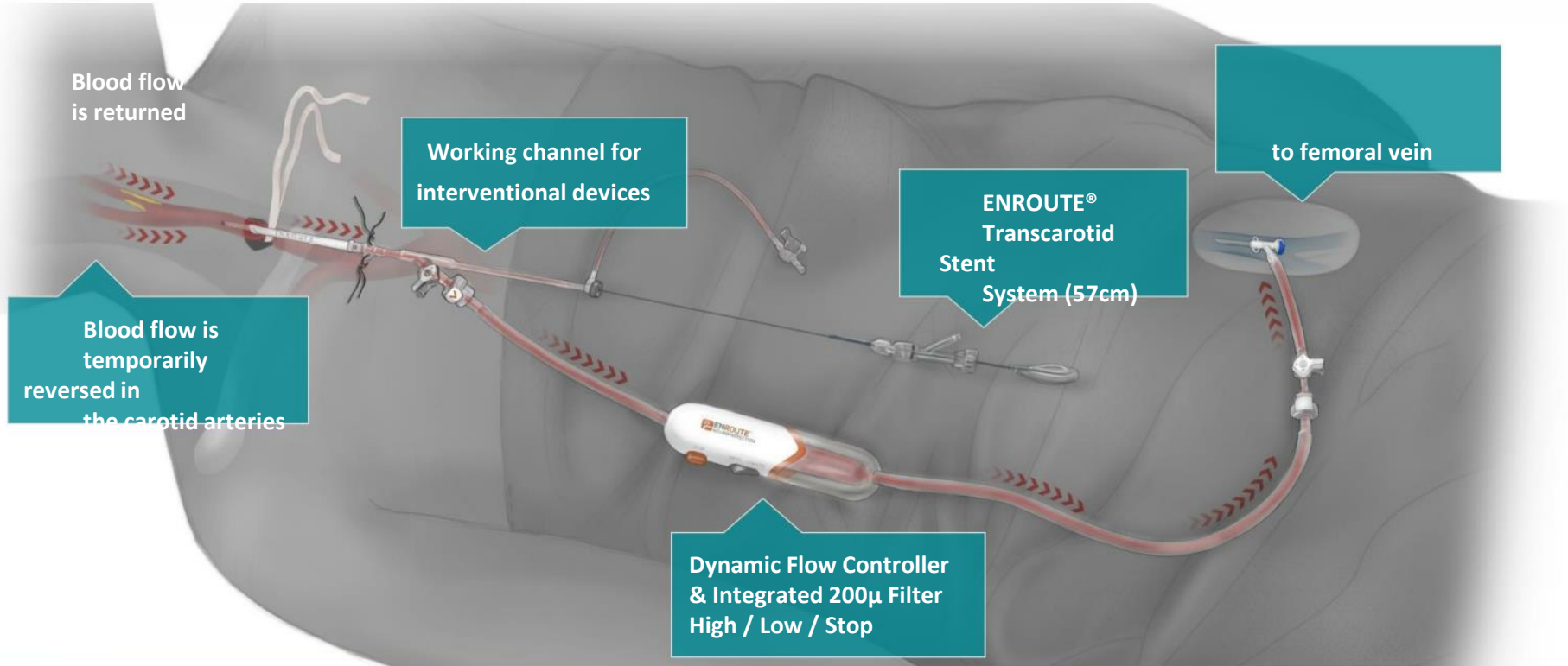


ENROUTE® Transcarotid  
Neuroprotection System\*



\*FDA-cleared Transcarotid Labeling for ENROUTE® Transcarotid Neuroprotection System, ENROUTE® Transcarotid Stent System, ENROUTE Enflate® RX Balloon Dilatation Catheter, and ENHANCE® Transcarotid Peripheral Access Kit

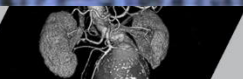
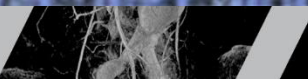
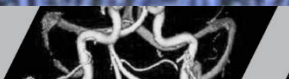
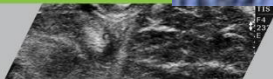
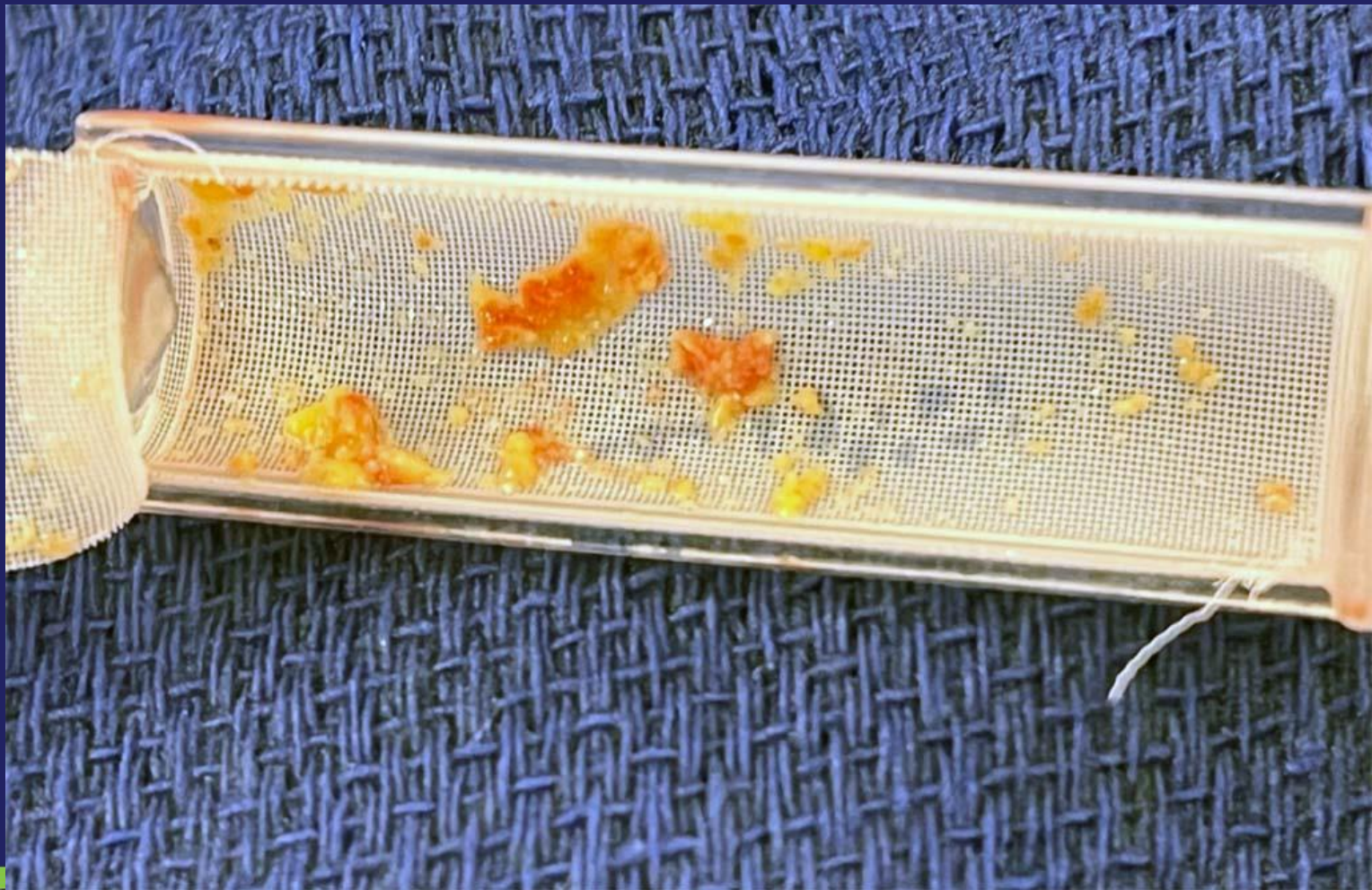
# ENROUTE® Transcarotid Neuroprotection & Stent System

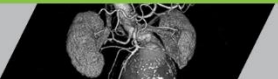
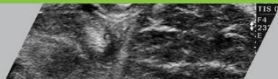
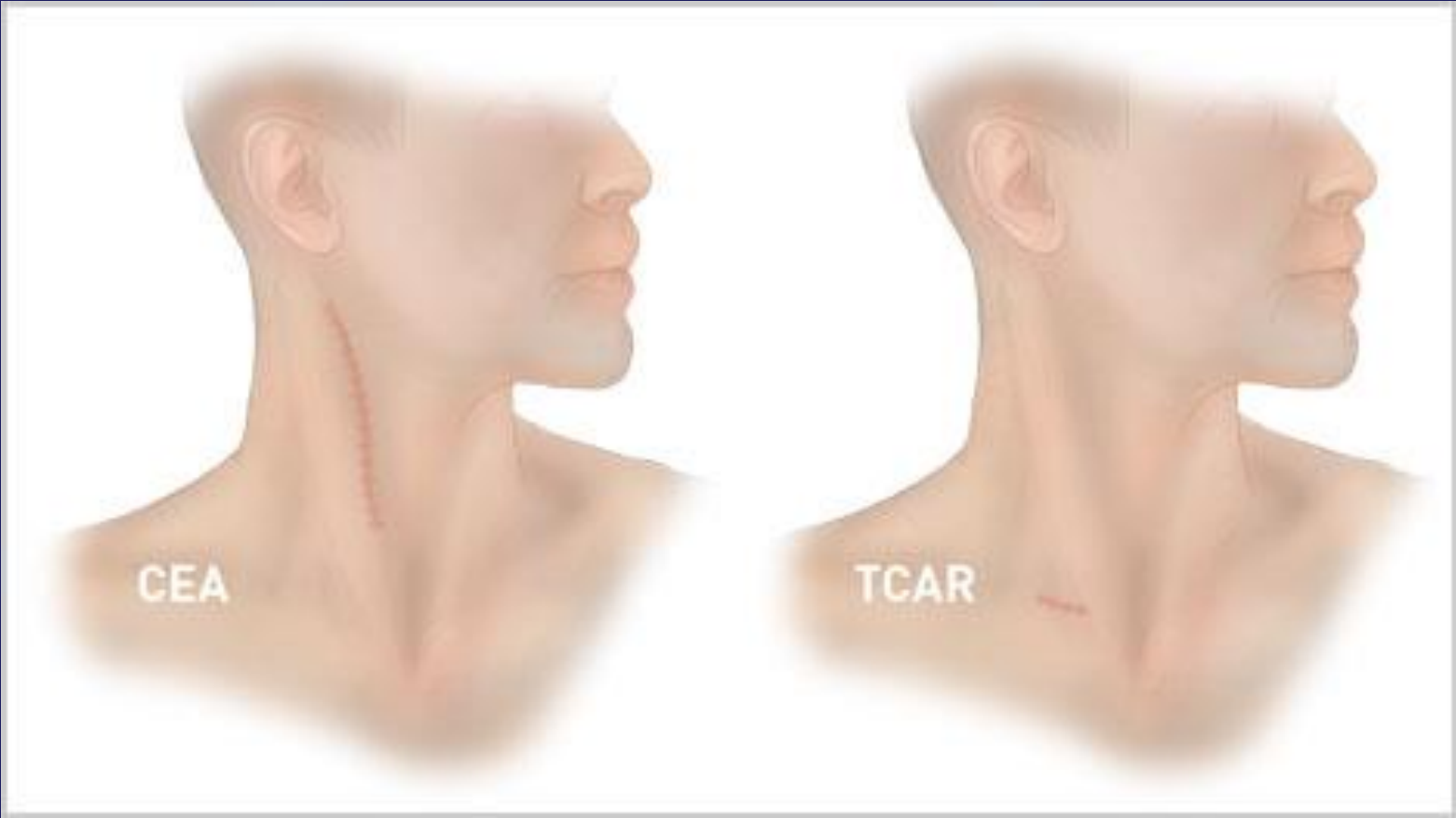


# Surgically Inspired CEA-Like Neuroprotection



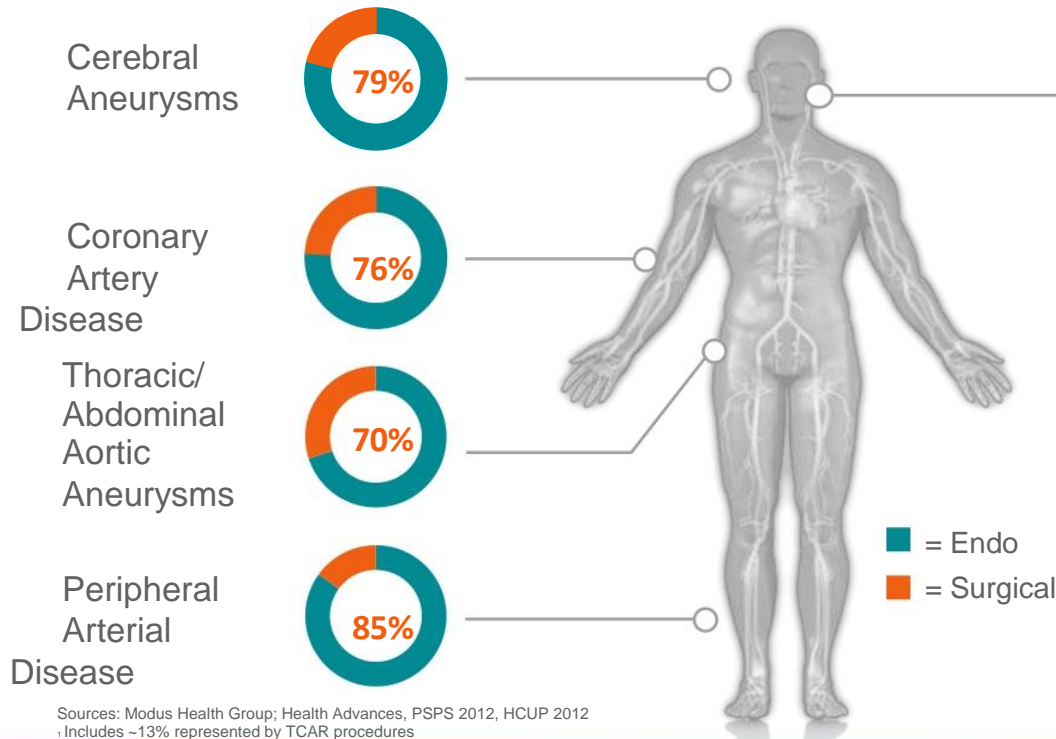






# The New Normal: Endovascular Procedures

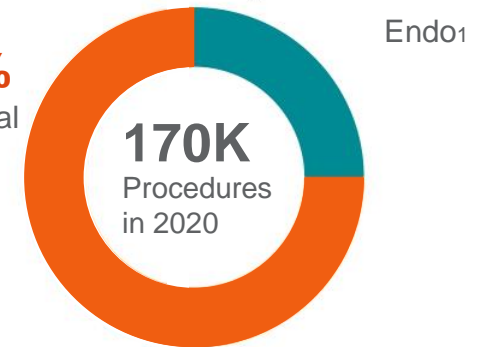
## Realizing the Benefits of a Less Invasive Treatment Option



### THE LAST FRONTIER:

Carotid Artery Disease:  
U.S.  
25%

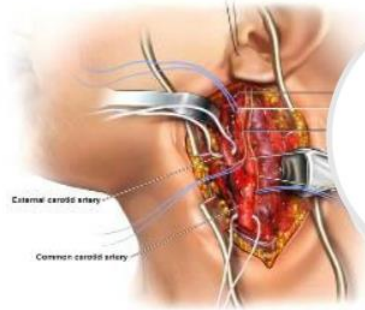
75%  
Surgical



Sources: Modus Health Group; Health Advances, PSPS 2012, HCUP 2012  
Includes ~13% represented by TCAR procedures

# SURGICAL: Carotid Endarterectomy (CEA)

65+ years



~75%  
of procedures



SIGNIFICANT



A Dated  
Standard of Care

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.

3 ©2023 SilkRoad Medical, Inc.

# ENDOVASCULAR: Transfemoral Carotid Artery

## Stenting

Crossing  
the  
lesion

(CAS) Since the '90s

Crossing  
the aortic  
arch



procedures\*



~12%  
of



adverse events

Procedure



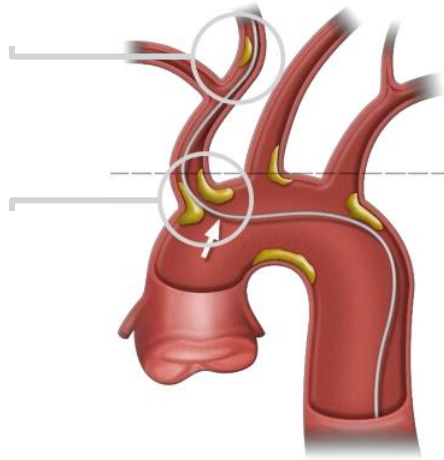


# Stent Safety and Durability

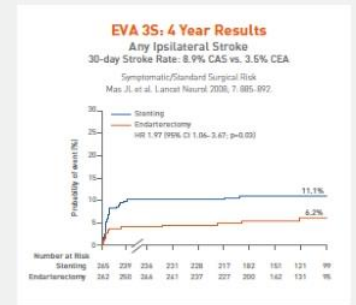
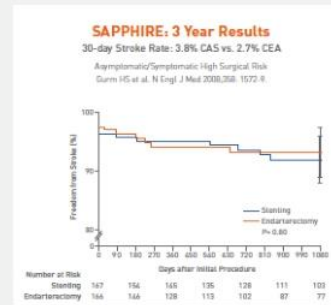
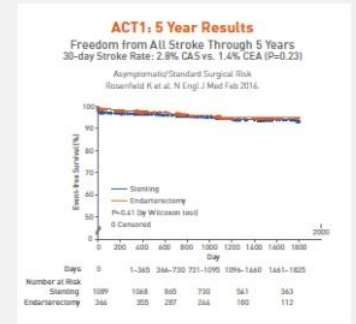
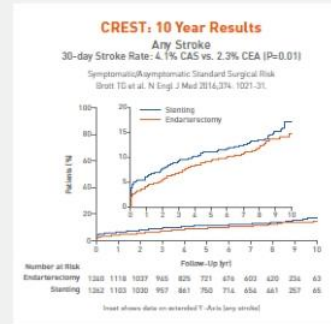
Crossing the lesion

Pitfalls of a **transfemoral approach** →

Crossing the aortic arch



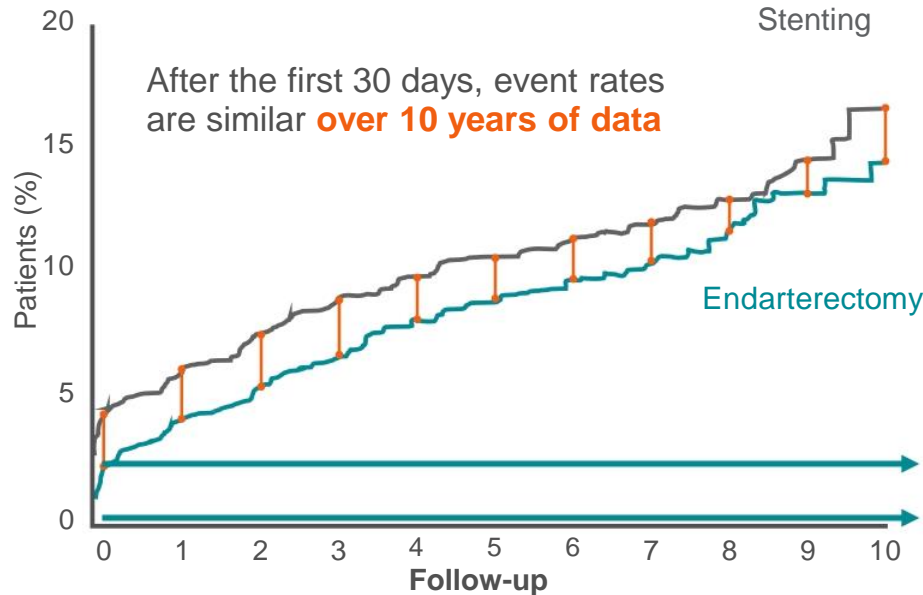
If the stent is **DELIVERED** safely, long term outcomes are equivalent to CEA



Brott TG, Calvert D, Howard G, et al. Long-term outcomes of stenting and endarterectomy for symptomatic carotid stenosis: a preplanned pooled analysis of individual patient data. *Lancet Neurol*. 2019;18(4):348-356.

# CREST (10 Year Data)

## C Any Stroke



### No. at Risk

	0	1	2	3	4	5	6	7	8	9	10
Endarterectomy	1240	1118	1037	945	825	721	676	603	420	234	63
Stenting	1262	1103	1030	957	861	750	714	654	461	257	65

### Opportunity:

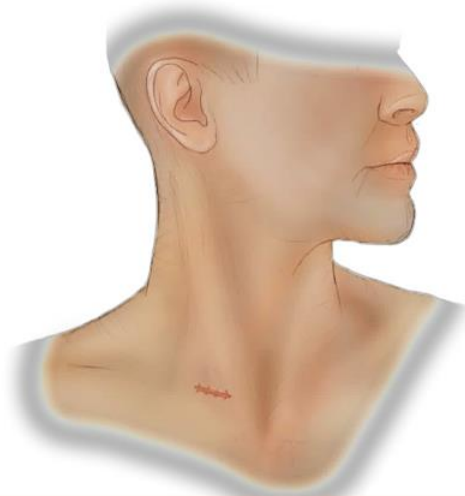
Combine low stroke rates with benefits of a less invasive procedure

TCAR is the solution that combines **low periprocedural stroke rates** with benefits of a less invasive procedure

Re-Intervention Data

Brott TG, et al. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis. *N Engl J Med.* 2016;374(11):1021-1031.

# TCAR Paradigm Shift: Transcarotid



The TCAR® System combines advantages from both worlds: **surgical principles** of neuroprotection and game-changing **endovascular technology**



Minimally Invasive



Avoids Aortic Arch



Avoids Cranial Nerve Plexus



High Rate Flow Reversal Neuroprotection



Accurate stenting

# The Less Invasive Standard in Stroke Prevention

## Benefits of a less invasive approach to carotid revascularization\*

		Significantly Favors CEA	Significantly Favors TCAR
In-Hospital VQI Outcomes	Stroke	=	=
	Death	=	=

Benefit	Significantly Favors CEA	Significantly Favors TCAR
Less Risk of MI		✓
Less Risk of Cranial Nerve Injury		✓
Less Time in OR		✓
Shorter Length of Stay		✓
Less Risk of Bleeding requiring Intervention**		✓



TCAR Incision



CEA Incision

2021 VQI Data

Learning Curve

Impact of Age

Additional MI & CNI Data

Malas MB, et al. TransCarotid Revascularization with Dynamic Flow reversal versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. *Ann Surg.* 2020 Sep 15. doi: 10.1097/SLA.0000000000004496. Epub ahead of print.

\*Patients matched based on symptomatic status, age, CAD, CHF, COPD, CKD, prior ipsilateral CEA, prior ipsilateral CAS, contralateral occlusion, ASA Class and statin use

\*\*With use of Protamine

# The Less Invasive Standard in Stroke Prevention

## Operating Room Efficiencies

### Procedure Time<sup>1</sup>

TCAR: **73 Minutes**

vs

CEA: **121 Minutes**



Ability to treat  
**67% more**  
patients vs CEA



**Local anesthesia is used more often with TCAR vs CEA<sup>2</sup>**

	TCAR	CEA
OR Time (minutes)	<b>73</b>	121
Cost per minute*	\$37	\$37
Total OR Time Cost	<b>\$2,701</b>	\$4,477

1. Malas MB, et al. TransCarotid Revascularization with Dynamic Flow reversal versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. *Ann Surg*. 2020 Sep 15. doi: 10.1097/SLA.0000000000004496. Epub ahead of print.

2. Malas MB, et al. Outcomes of TransCarotid Artery Revascularization (TCAR) versus Carotid Endarterectomy (CEA) in the TCAR Surveillance Project. Oral presentation at the Vascular Annual Meeting, June, 2019, Potomac, MD.

\*Based on national survey average

# TCAR Road To Standard of Care

## Driven by Consistent Freedom From Stroke Rates\*

98.7%\*

N=75

### PROOF

*Journal of Endovascular Therapy*  
First-in-Man validation of Concept.1

99.3%\*

N=136

### ROADSTER

*Journal of Vascular Surgery*  
Pre-Market Approval of the ENROUTE  
Neuroprotection System. ITT=98.6%2

98.7%†

N=3286

### TCAR vs TFCAS

*Journal of the American  
Medical Association*

Validation of superior outcomes

to TF-CAS3

### TCAR for HSR

*Annals of Surgery*

Real world VQI data validating  
outcomes equivalent to CEA for High  
Surgical Risk patients4

99.4%\*

N=632

### ROADSTER 2

*Stroke*

Post Approval registry validating the  
safety and efficacy of the  
ENROUTE 98.1%4

98.6%†

N=6384

98.6%\*

N=5066

### TCAR for SSR

*Journal of Vascular Surgery*

Real world VQI data validating

outcomes equivalent to CEA for  
Standard Surgical Risk patients5

\* at 30 days

† at hospital

1. Alpaolani A, et al. Transcarotid Artery Revascularization With Flow Reversal. *J Endovasc Ther.* 2017 Apr;24(2):265-270.

2. Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. *J Vasc*

*Surg.* 2015 Nov;62(5):1227-34.

3. Schemmerhorn ML, et al. Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting

With Stroke or Death Among Patients With Carotid Artery Stenosis. *JAMA.* 2019 Dec 17;322(25):2513-2522.

4. Kashyap VS, et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With

Significant Carotid Artery Disease. *Stroke.* 2020 Sep;51(9):2520-2528.

5. Malas MB, et al. Transcarotid Revascularization with Dynamic Flow Reversal versus Carotid Endarterectomy in the

Vascular Quality

Initiative Surveillance Project. *Ann Surg.* 2020 Sep 15. doi: 10.1097/SLA.0000000000004496. Epub ahead of print.

6. Liang P, Cronenweit J, Secemsky E, Eldrup-Jorgensen J, Malas M, Wang GJ, Nolan B, Kashyap VS, Motaganahalli RL,

Schemmerhorn ML. Expansion of Transcarotid Artery Revascularization to Standard Risk Patients for Treatment of Carotid Artery Stenosis. *JVS.* 2021; 74 (3): 27-28. doi: 10.1016/j.jvs.2021.06.048.

# PROOF Study

TCAR – First in Man Experience

PROOF Study Safety Results <sup>1,2</sup>	Result (n=75)
Subjects completing 30-day follow-up	71 (94.7%)
Primary Endpoint: Composite of any major stroke, myocardial infarction and death from the index procedure through the 30-day post-procedural period	0/71 (0%)
Minor stroke <i>Minor contralateral stroke adjudicated as not device or procedure-related</i>	1/71 (1.3%)
Cranial nerve injury (Hoarseness)	2/71 (2.7%)

Study	Procedure	Embolic Protection	Patients	% w/ New DW-MRI Lesions
ICSS <sup>3</sup>	CEA	Clamp, backbleed	107	17%
PROOF <sup>2</sup>	TCAR	Proximal Flow Reversal	56	23% (18% Ipsilateral)
PROFI <sup>4</sup>	Transfemoral CAS	Proximal occlusion (MoMA)	31	45%
ICSS <sup>3</sup>	Transfemoral CAS	Distal filter (various)	51	73%
PROFI <sup>4</sup>	Transfemoral CAS	Distal filter (Emboshield)	31	87%

<sup>1</sup>Pinter L, et al. Safety and feasibility of a novel transcervical access neuroprotection system for carotid artery stenting in the PROOF Study. *J Vasc Surg.* 2011 Nov;54(5):1317-23.

<sup>2</sup>Alpaslan A, et al. Transcarotid Artery Revascularization With Flow Reversal. *J Endovasc Ther.* 2017 Apr;24(2):265-270.

<sup>3</sup>Bonati LH, et al. New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS). *Lancet Neurol.* 2010 Apr;9(4):353-62.

<sup>4</sup>Bijklic K, et al. The PROF1 study (Prevention of Cerebral Embolization by Proximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting): a prospective randomized trial. *J Am Coll Cardiol.* 2012 Apr 10;59(15):1383-9.



# ROADSTER Study

Prospective, Multi-Center, Single-Arm Trial of TCAR in High Surgical Risk Patients with Carotid Stenosis - *Pivotal Results*

- **DESIGN:** IDE study with OPC of 11% S/D/MI at 30 days
- **OBJECTIVE:** Evaluate safety and efficacy of TCAR Procedure with ENROUTE Transcarotid Neuroprotection System
  - Direct carotid access
  - High rate flow reversal
  - FDA-approved carotid stents
- **CONCLUSION:** The results of the ROADSTER trial demonstrate that the use of the ENROUTE Transcarotid NPS is safe and effective at preventing stroke during CAS.

Demographics and Technical Results		
	ROADSTER ROADSTER Pivotal ITT <sub>1</sub> (n=141)	CREST <sub>2</sub> CEA (n=1,240)
	High Surgical Risk	Standard Risk
Age (mean)	72.9 ± 9	69.2 ± 8.7
Age ≥ 75	47%	
Female	35%	28.5% <sub>3</sub>
Symptomatic	25.5%	33.6%
Local Anesthesia	53%	52.7%
Reverse Flow Time (median)	12.9 minutes	10.0%
		n/a

1. Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. *J Vasc Surg.* 2015 Nov;62(5):1227-34.  
 2. Brott TG, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med.* 2010 Jul 1;363(1):11-23.  
 3. Voeks JH, et al. Age and outcomes after carotid stenting and endarterectomy: the carotid revascularization endarterectomy versus stenting trial. *Stroke.* 2011 Dec;42(12):3484-90.  
 4. Gray WA, et al. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel meeting on the ACCULINK and ACCUNET Carotid Artery Stent System. *Circulation.* 2012 May 8;125(18):2256-64.

# ROADSTER Study

Prospective, Multi-Center, Single-Arm Trial of TCAR in High Surgical Risk Patients with Carotid Stenosis - *Pivotal Results*

ROADSTER <sub>1</sub>	PP (n=136) High Surgical Risk	ITT (n=141) High Surgical Risk	CREST <sub>2</sub> CEA Standard Risk
S/D/MI*	2.9%	3.5%	4.5%
<b>Stroke</b>	<b>0.7%</b>	<b>1.4%</b>	2.3%
Death	1.5%	1.4%	0.3%
MI	0.7%	0.7%	2.3%
Stroke/Death	<b>2.2%</b>	<b>2.8%</b>	2.6%
Cranial Nerve Injury (CNI)	0.7%	0.7%	5.3%
CNI Unresolved 6 Months	0%	0%	2.1% <sup>64</sup>

\* Hierarchical Primary Endpoint

All stroke, MI & death at 30-days

1. Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. *J Vasc Surg.* 2015 Nov;62(5):1227-34.  
 2. Brott TG, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med.* 2010 Jul 1;363(1):11-23.

# ROADSTER 2 Study

Post-Approval Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease – V. Kashyap MD; Stroke 2020

- **DESIGN:** Prospective, single arm, multicenter, post-approval study
- **OBJECTIVE:** Evaluate safety and efficacy of the TCAR Procedure with the ENROUTE Stent when used with the ENROUTE NPS and performed by a broad group of physicians with variable TCAR experience
- **CONCLUSION:** TCAR is a safe and effective procedure in a **broad user base** with varying TCAR experience levels. Excellent outcomes are achievable if you follow the protocol and society guidelines.

Demographics and Technical Results		
ROADSTER 2	PP (n=632)	ITT (n=692)
Age ≥80	21.2%	21.1%
Age ≥75 Female	41.8%	42.1%
Symptomatic	32.3%	32.2%
Local Anesthesia	26.3%	26%
Reverse Flow Time (median)	28.3%	28.3%
	10.9 minutes	11 minutes

ROADSTER 2: Kashyap VS, et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. *Stroke*. 2020 Sep;51(9):2620-2629.

# ROADSTER 2 Study

Post-Approval Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease – V. Kashyap MD; Stroke 2020

Clinical Results		
ROADSTER 2	PP (n=632)	ITT (n=692)
Procedural Success	97.9%	96.5%
S/D/MI*	1.7%	3.2%
<b>Stroke</b>	<b>0.6%</b>	<b>1.9%</b>
Death**	0.2%	0.4%
MI	0.9%	0.9%
Stroke/Death	<b>0.8%</b>	<b>2.3%</b>
Cranial Nerve Injury***	1.3%	1.4%

\*Hierarchical

\*\*One patient expired ~2 weeks post-procedure due to ruptured AAA

\*\*\*Out of the 10 patients with CNJ, 6 consented to an extended follow-up at 90 days. The CNJ resolved in all 6 of those patients.



0.6%

Stroke Rate in the FDA  
Analysis Population (PP)



81% of Physicians were  
New to TCAR



Excellent Outcomes  
Achievable with  
Adherence to Protocol

Kashyap VS, et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. *Stroke*. 2020 Sep;51(9):2620-2629.

# Carotid Dilemma

- CEA vs TF CAS vs TCAR
  - How do we decide what to do for our patient?
  - CEA has higher risk of MI and CNI
  - TF CAS has higher risk of CVA
  - TCAR is EQUIVALENT to CEA in Stroke risk & Death but has lower risk of MI and CNI



# CMS decision to Deregulate?

- On October 11<sup>th</sup> 2023
  - CMS statement – facilities are no longer required to be approved to perform CAS under the Carotid Artery National Coverage Determination (NCD 20.7)





# NCD 20.7 Reconsideration and Final Decision

Indications	B3. VQI-TSP* (No change)	B4. Carotid Stent Placement (Updated 10/11/2023)	B4. Carotid Stent Placement (Original thru 10/10/2023)
<b>Clinical Criteria</b>			
Surgical Risk Factor	<ul style="list-style-type: none"> <li>Standard Risk &amp; High Risk</li> </ul>		<ul style="list-style-type: none"> <li>High Risk</li> </ul>
Symptom Status & Degree of Stenosis	<ul style="list-style-type: none"> <li>Symptomatic &amp; ≥50% stenosis**</li> <li>Asymptomatic &amp; ≥70% stenosis**</li> </ul>		<ul style="list-style-type: none"> <li>Symptomatic &amp; ≥70% stenosis</li> </ul>
<b>Additional Criteria</b>			
Facility Requirements	<ul style="list-style-type: none"> <li>Facility standards and approval</li> </ul>	<ul style="list-style-type: none"> <li>Facility and physician standards for carotid stent program</li> </ul>	<ul style="list-style-type: none"> <li>CMS facility approval and certification</li> </ul>
Registry or Data Collection	<ul style="list-style-type: none"> <li>Registry participation (VQI-TSP)</li> </ul>	<ul style="list-style-type: none"> <li>Not required for coverage</li> </ul>	<ul style="list-style-type: none"> <li>Data collection</li> </ul>
Neurological Assessments	<ul style="list-style-type: none"> <li>Not specified</li> </ul>	<ul style="list-style-type: none"> <li>Pre &amp; post-op neurological assessments by a neurologist or NIHSS certified HCP</li> </ul>	<ul style="list-style-type: none"> <li>Not specified</li> </ul>
Imaging Guidelines	<ul style="list-style-type: none"> <li>Not specified</li> </ul>	<ul style="list-style-type: none"> <li>Duplex US and CTA/MRA or</li> <li>Duplex US and DSA when non-invasive imaging is inconclusive or CTA/MRA are contraindicated</li> </ul>	<ul style="list-style-type: none"> <li>Not specified</li> </ul>
Shared Decision Making	<ul style="list-style-type: none"> <li>Not specified</li> </ul>	<ul style="list-style-type: none"> <li>Shared decision-making with patients about CEA, CAS (including TCAR), and OMT before treatment</li> </ul>	<ul style="list-style-type: none"> <li>Not specified</li> </ul>

# Which Car Do You Want?



1954 Dr. Milligan  
Mobile  
AKA "CEA"



# Which Car Do You Want?



1994 TF  
CAS



# Which Car Do You Want?



2024 TCAR





