1-Year Results of a New Mesh-Covered Carotid Stent: SCAFFOLD Trial

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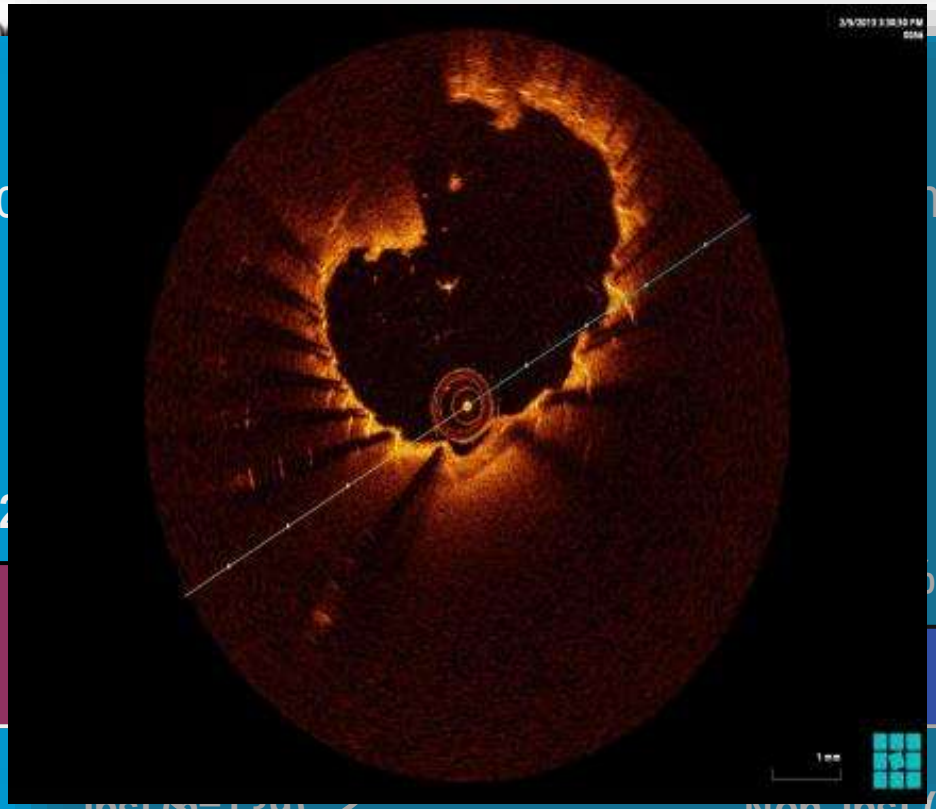
Disclosures

- WL Gore
  - Consultant
  - Institutional Research Support

The logic behind a new mesh-covered stent



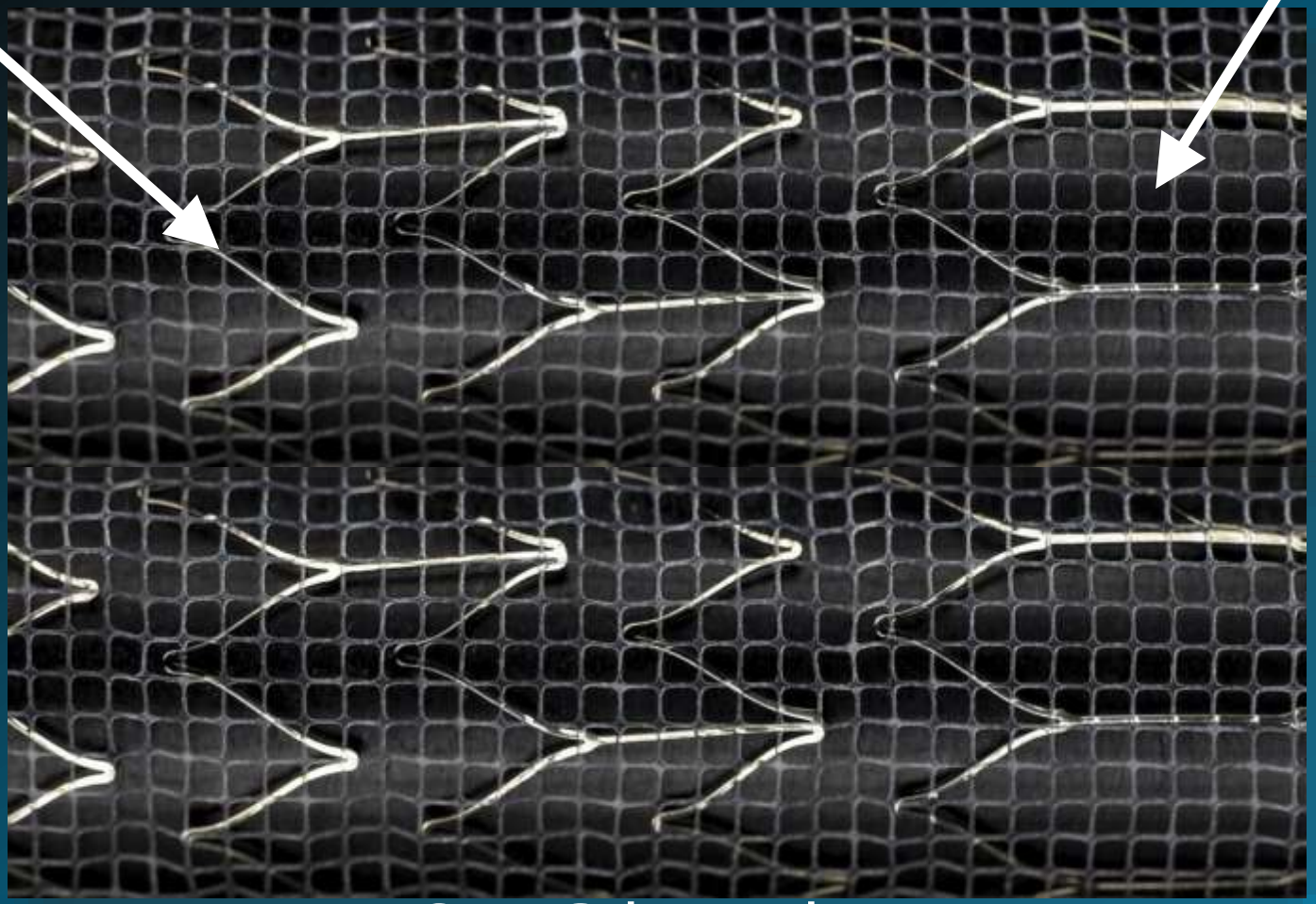
Design goals for Gore Carotid Stent

- Flexibility/conformability
  - Improved device navigation
  - Open cell stent platform enables device to conform to difficult anatomies
- High scaffolding capability
  - Closed cell lattice to trap atherosclerotic/thrombotic material and prevent protrusion
  - Perioperative stroke prevention
- Minimize thrombus formation
  - CBAS® Heparin Surface

Gore Carotid Stent (GCS)

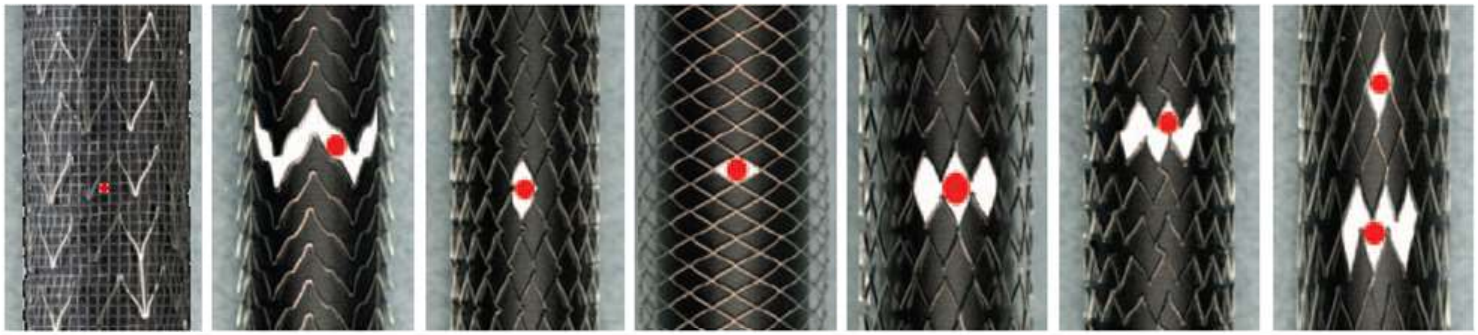
Stent Frame

Stent Lattice



CBAS heparin-bonded coating

Gore SCAFFOLD Lattice Structure: comparison to other CAS



Manufacturer	W.L. Gore and Associates*	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
Device	GORE® Carotid Stent	ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE
Stent Type	Straight, Hybrid Design	Tapered, Open Cell	Tapered, Closed Cell	Straight, Closed Cell	Tapered, Open cell*	Straight, Open cell	Tapered, Combination
Cell Size $(mm)^2$	0.28	16.60	4.00	1.36	10.40	9.00	3.30 (center) 13.50 (ends)

GCS pore size 20% the area of WALLSTENT cell size

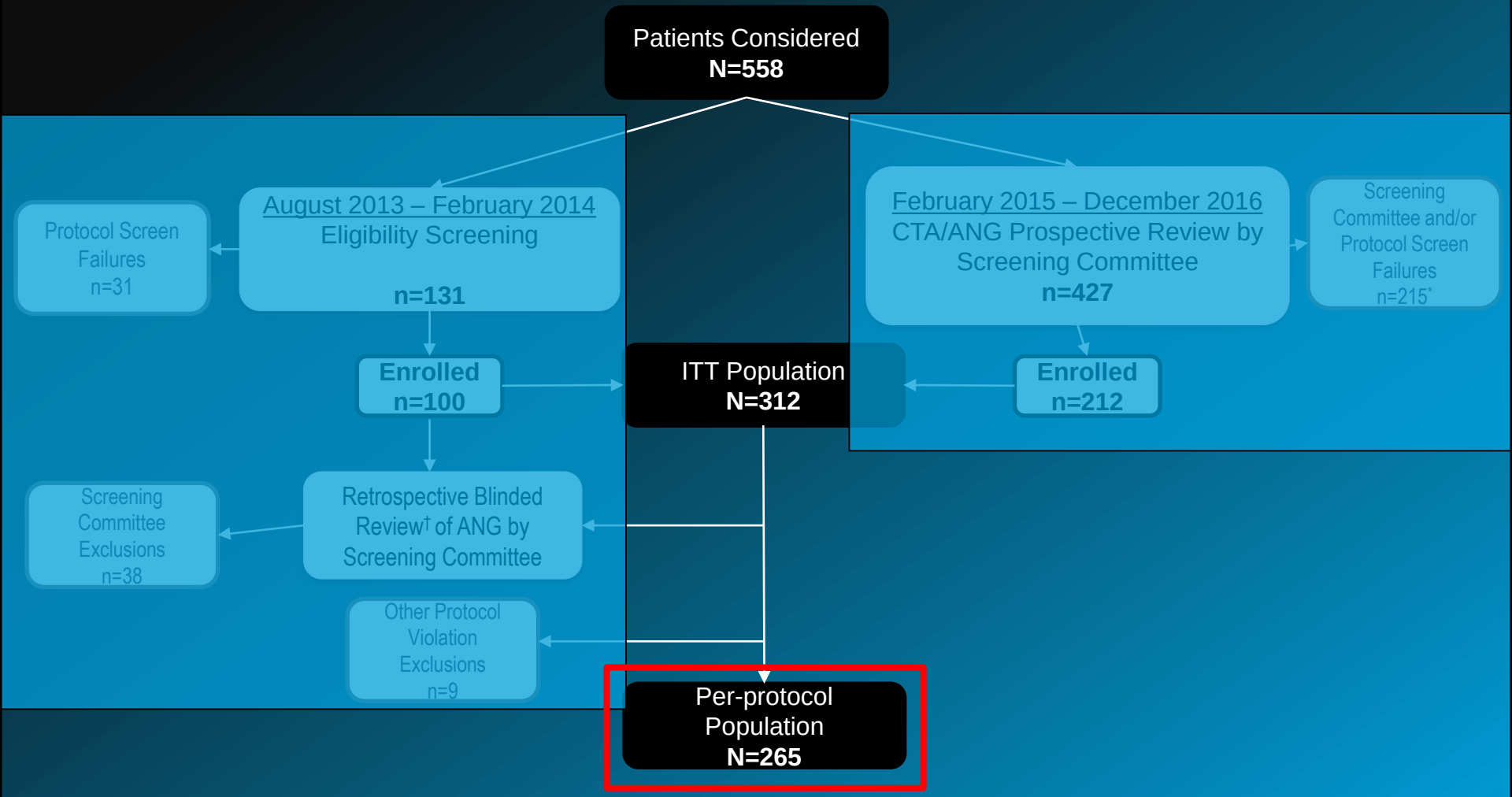
SCAFFOLD: trial description

Device	Gore SCAFFOLD mesh-covered stent
Objective	Evaluate the performance of the SCAFFOLD stent in treating bifurcation carotid artery stenosis at high risk for CEA
Study Design	Prospective, multicenter, single-arm, open label
Subjects	312 patients with bifurcation carotid artery stenosis
Principle Investigators	William A. Gray MD (IC) Philadelphia PA Peter Schneider MD (VS) Honolulu HI
Investigational Centers	30 US sites
Evaluation	Baseline, Procedure, 1 month, 1 year, 2 years, 3 years
Primary Endpoint	30-day death, all stroke, myocardial infarction plus ipsilateral stroke to 1 year

SCAFFOLD: Trial Overview

- Eligibility criteria
  - De novo atherosclerotic/post CEA restenotic CCA or ICA bifurcation lesions
    - Symptomatic (<180 d) and ≥50% (by angiography) stenosis
    - Asymptomatic ≥80% (by angiography) stenosis
  - High risk for CEA (anatomic or comorbid)
- FDA-mandated enrollment design:
  - Stage 1: review 6 month data from first 100 patients
  - Stage 2: continue enrollment contingent on Stage 1 review
- FIM August 6 2013, enrollment completed Dec. 2 2016

SCAFFOLD: Patient Disposition



SCAFFOLD: Patient characteristics (ITT)

	N=312
Male, n (%)	202 (64.7%)
White, n (%)	299 (95.8%)
Age, mean (SD)	73.2 (8.8)
Symptomatic, n (%)	40 (12.8%)
Diabetes, n (%)	125 (40.1%)
HTN, n (%)	291 (93.3%)
H/O CAD, n (%)	196 (62.8%)

SCAFFOLD Patient Selection: STAGE 1

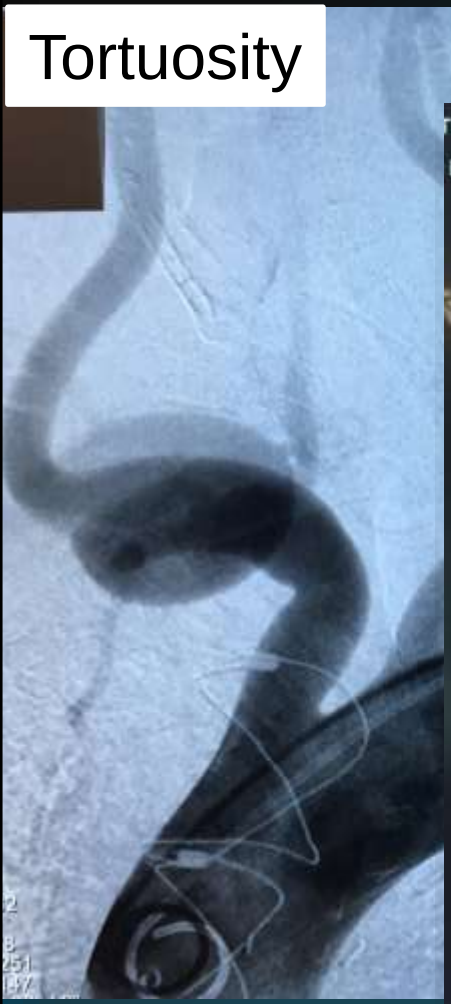
100 patients enrolled and retrospectively reviewed for adherence to protocol I/E

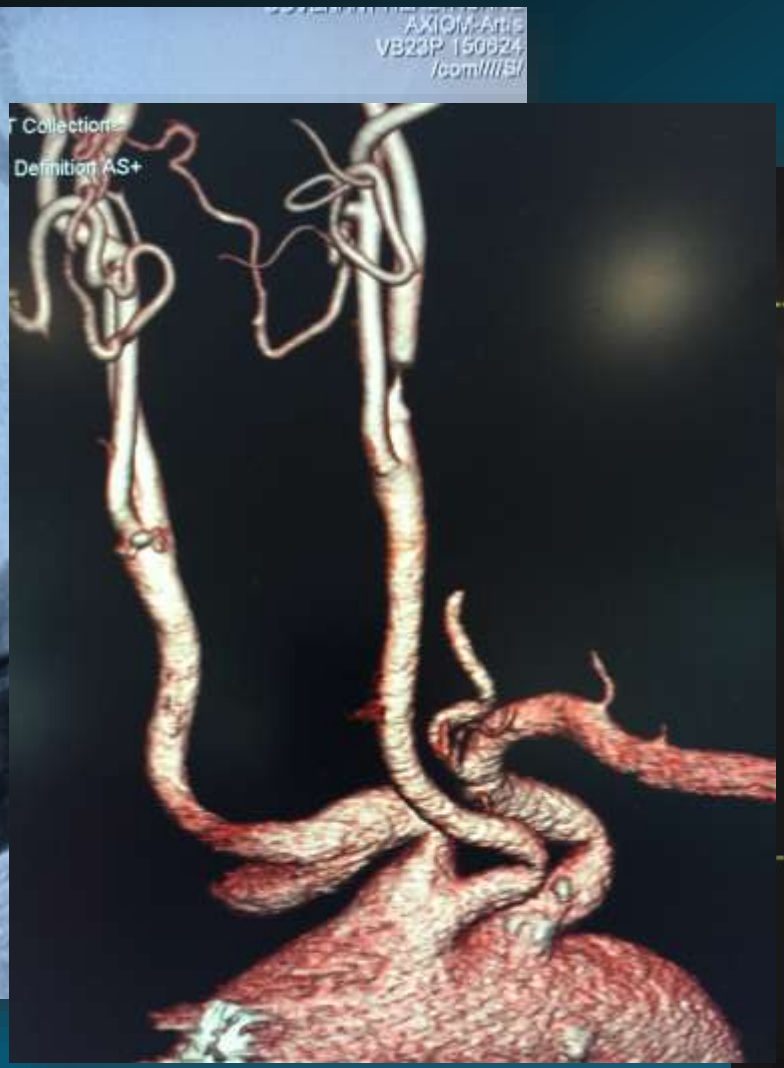
IC6. Patient has a target lesion located at the carotid bifurcation and/or proximal ICA.	14
AE10. Pat morpholo t of guide catl or stent syst	10
AE3. Patient has severe lesion calcification that may restrict the full deployment of the carotid stent.	9

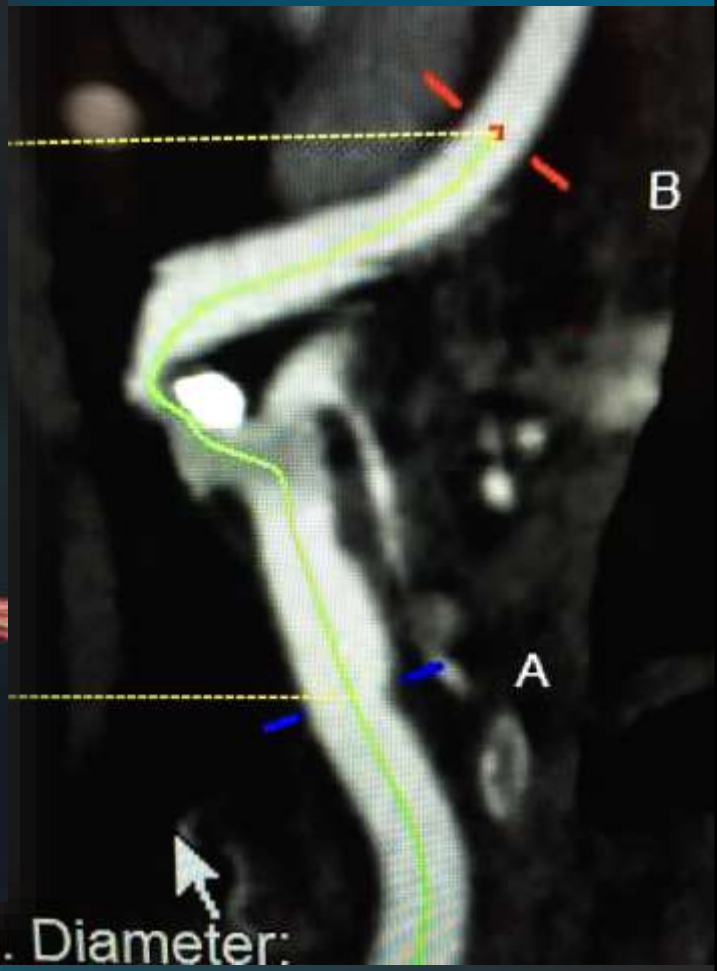
41% of patients violated inclusion/exclusion criteria

Examples of SCAFFOLD I/E violations

Tortuosity







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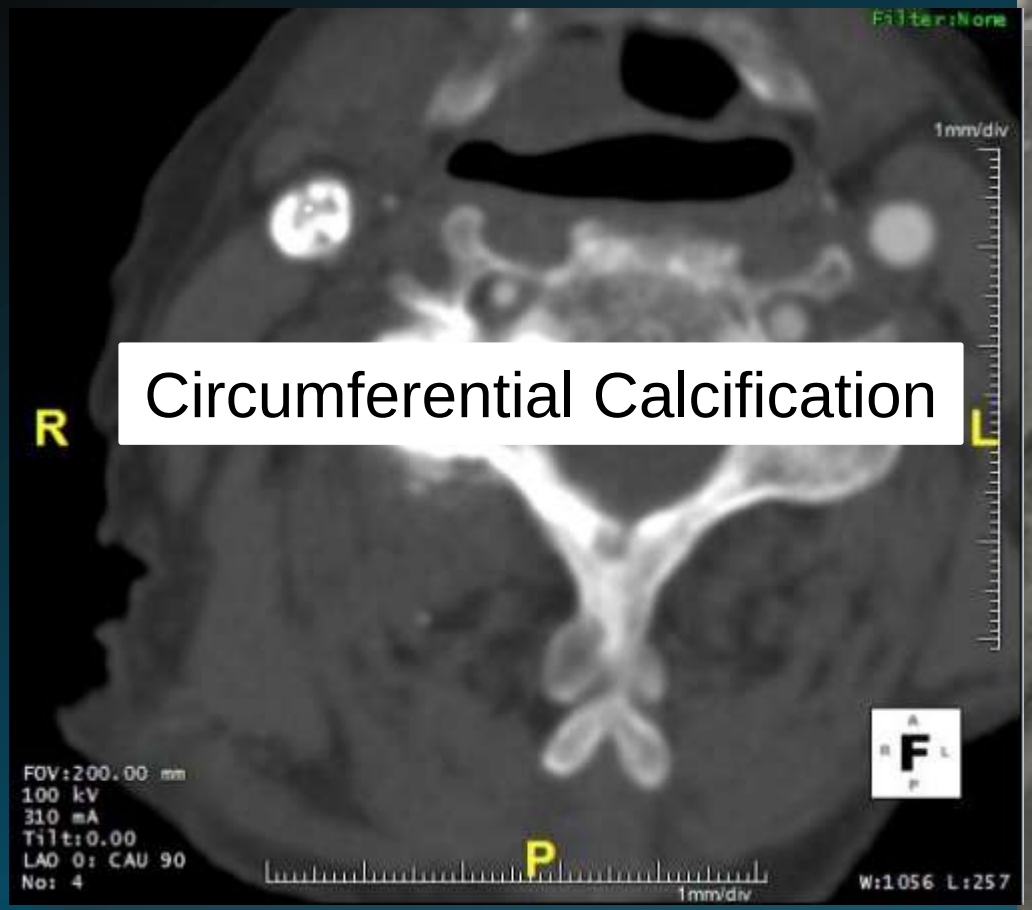
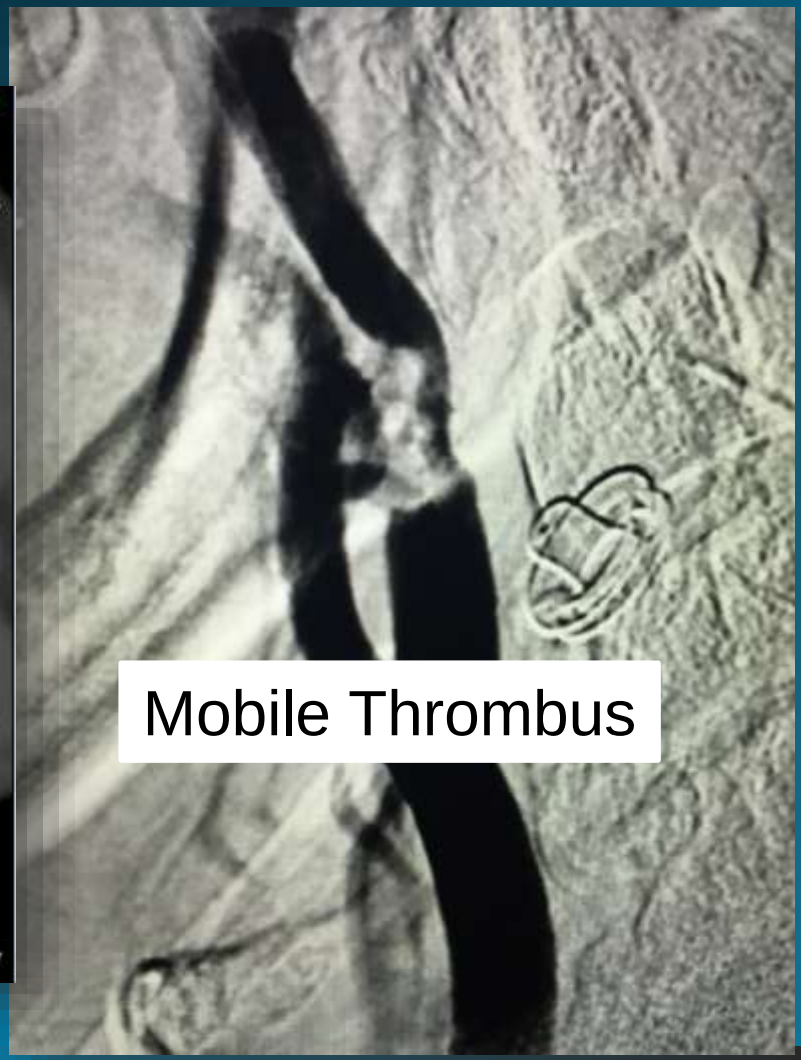


Circumferential Calcification



Mobile Thrombus

SCAFFOLD Patient Selection: STAGE 2

Additional 212 patients enrolled, subject to a screening committee for eligibility

- *Modeled after TAVR trial screening committees*, 3 physicians from different disciplines (NIR, IC, IR) reviewed CTA and/or angiograms for inclusion/exclusion criteria based on original protocol

- Patients either accepted or rejected for enrollment in SCAFFOLD based on this review

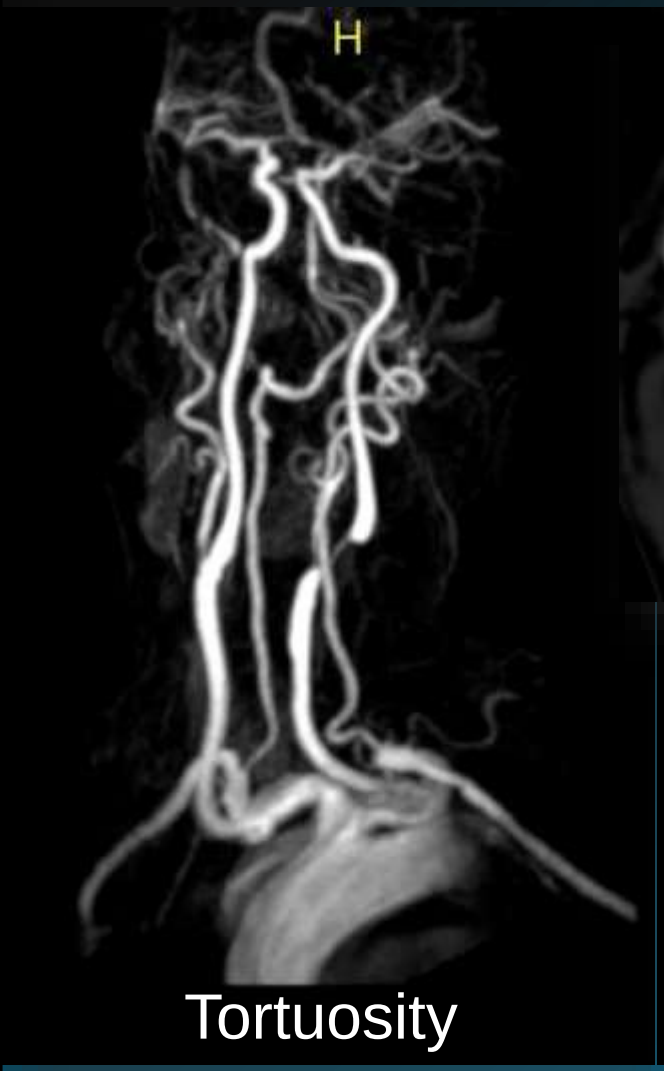
SCAFFOLD Patient Selection: STAGE 2

Patients prospectively rejected by screening committee

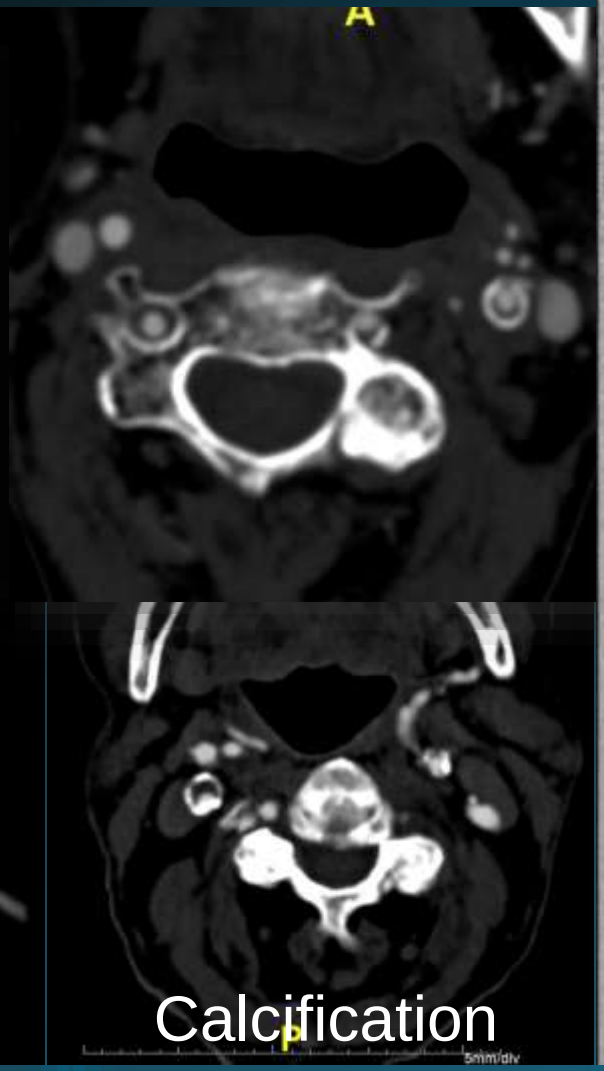
AE3. Patient has severe lesion calcification that may restrict the full deployment of the carotid stent.	71
AE10. Patient has tortuous anatomy or disease morphology which would prohibit the safe place prote acce	68
AE7. Patient has ≥50% stenosis of the CCA proximal to the target lesion.	37
AE8. Patient has known mobile plaque, thrombus, or excessive calcification in the aortic arch.	33

40% of Patients Rejected By the Screening Committee

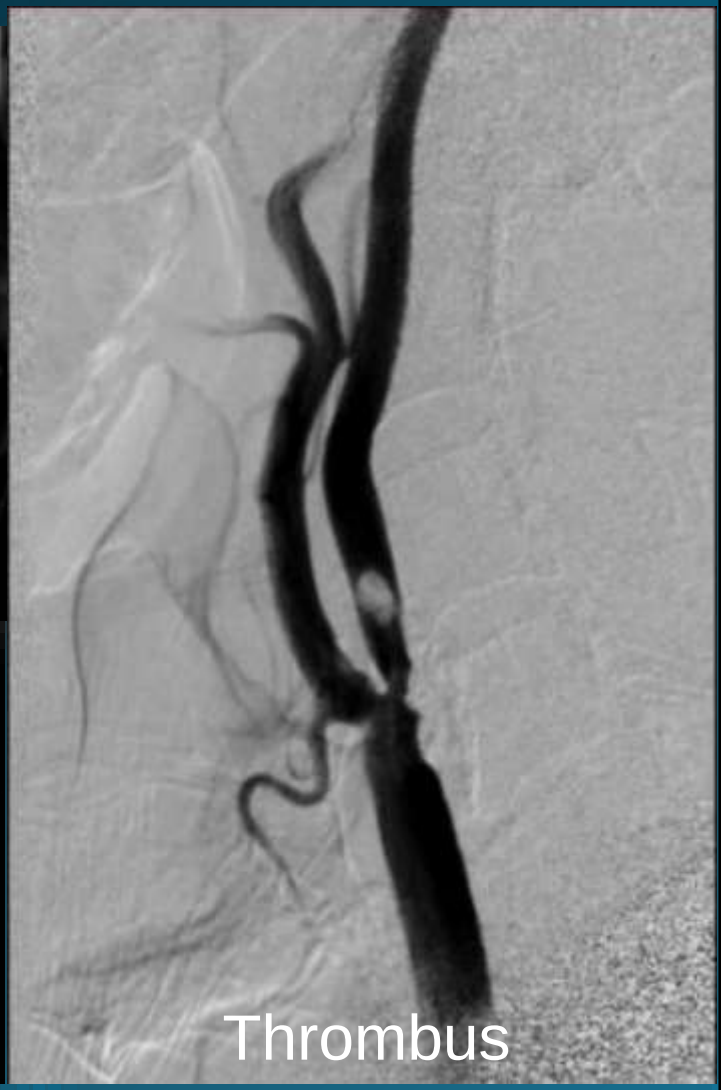
SCAFFOLD: Rejected cases from Stage 2



Tortuosity



Calcification



Thrombus

SCAFFOLD Procedural Data: Technical Success

Number of subjects	312
Gore carotid stent successfully implanted	100% (312/312)
Gore embolic filter successfully deployed	94.6% (295/312)
Additional EPD used	4.5% (14/312)

SCAFFOLD Primary Endpoints

	ITT	PP
30 Day Endpoint (N)	***311***	***264***
MAE	15 (4.8%)	8 (3.0%)
Death	2 (0.6%)	1 (0.4%)
Myocardial infarction	4 (1.3%)	4 (1.5%)
Q-wave MI	0 (0%)	0 (0%)
Stroke	9 (2.9%)	3 (1.1%)
Major stroke	5 (1.6%)	3 (1.1%)
Ipsilateral	4 (1.3%)	2 (0.8%)
Non-ipsilateral	0 (0%)	0 (0%)
Hemorrhagic (ipsi)	1 (0.3%)	1 (0.4%)
Minor stroke	4 (1.3%)	0 (0%)
Ipsilateral	2 (0.6%)	
Non-ipsilateral	2 (0.6%)	
1 Year Endpoint (N)	***290***	***244***
Ipsilateral Stroke (31-365d)	5 (1.7%)	3 (1.2%)

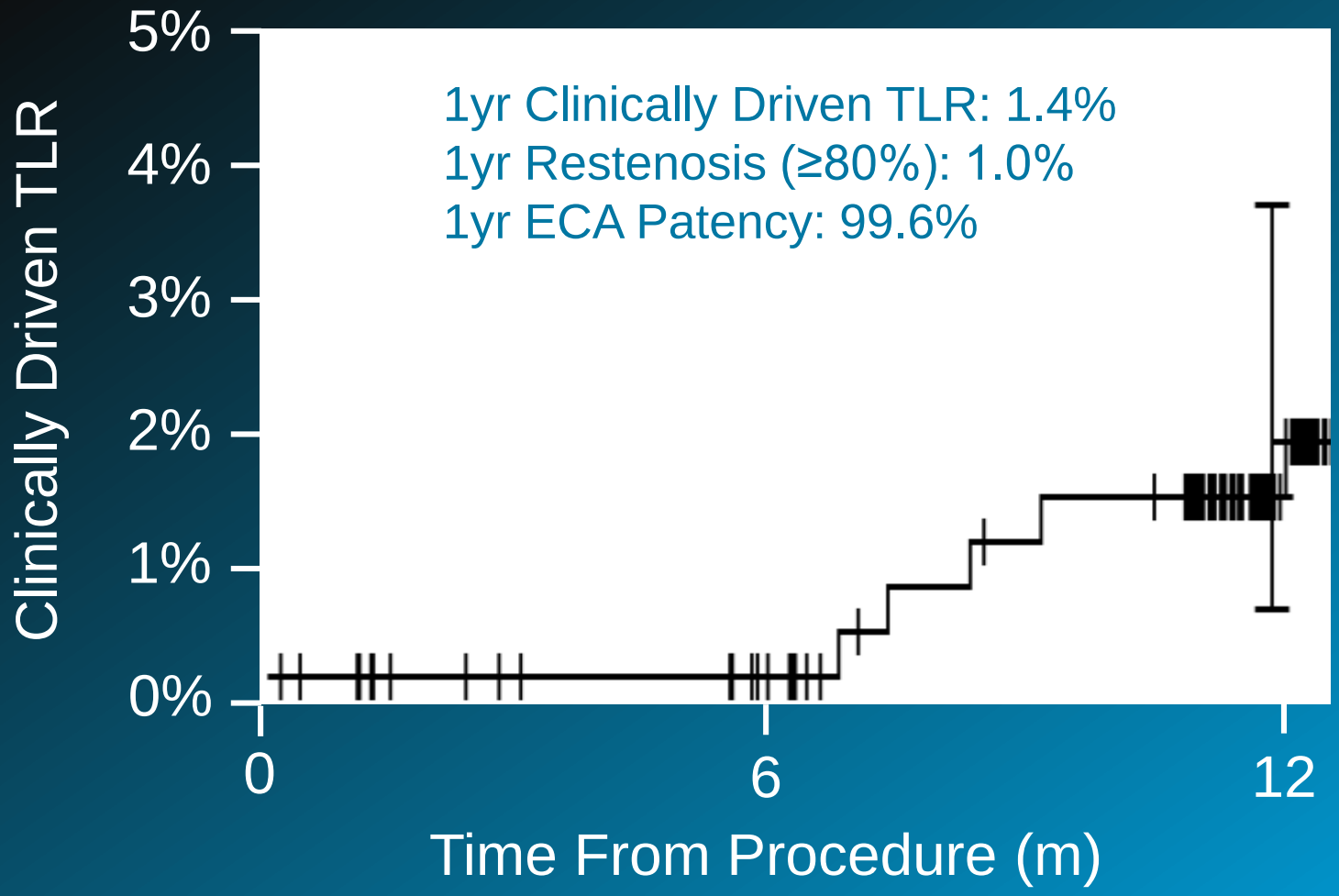
Listing of 31-365d Strokes

* Blue shading represents patients not meeting protocol

Patient Number	Symptomatology	High Risk Subgroup	Octogenarian Status	Type of Ipsi Stroke Event	Event Timing (day post-procedure)
1	Asymptomatic	Anatomic	<80 years	Minor, Ischemic	52
2	Symptomatic	Co-morbid	<80 years	Minor, Ischemic	60
3	Asymptomatic	Co-morbid	<80 years	Major, Ischemic (Minor d1; Acute MI d113)	118
4	Symptomatic	Co-morbid	<80 years	Minor, Ischemic	249
5	Symptomatic	Co-morbid	<80 years	Minor, Ischemic (TLR d280; 90% stenosis)	276

- *Patient 2 Exclusion Criteria: Previously placed stent in the ICA, CCA, or brachiocephalic; Severe tortuous anatomy; Lesion not in the ICA or at the bifurcation of ICA/CCA*
- *Patient 3 Exclusion Criteria: Severe calcification; stenosis in CCA proximal >50%*

Clinically-driven 1-year Target Lesion Revascularization (TLR): ITT



How Do These One Year Endpoints Compare?

	SCAFFOLD ITT	SCAFFOLD PP	ARCHER	BEACH
Ipsilateral Stroke (31-365d)	1.7%	1.2%	1.3%	2.5%
Clinically Driven TLR (1 Year)	1.4%	1.6%	2.2%	
TLR (1 Year)	4.9%	4.1%		4.7%

Summary

- SCAFFOLD trial is the largest multicenter controlled evaluation of mesh-covered CAS
- The SCAFFOLD trial using the mesh-covered Gore Carotid Stent demonstrated:
  - 100% technical success
  - Low 30d stroke rate (1.1%) when used per protocol
  - Low late stroke rate (1.2%) and clinically driven TLR (1.4%)
  - Maintenance of ECA patency

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