Is Transfemoral CAS Being Overused One Year After CMS Changed the NCD 20.7

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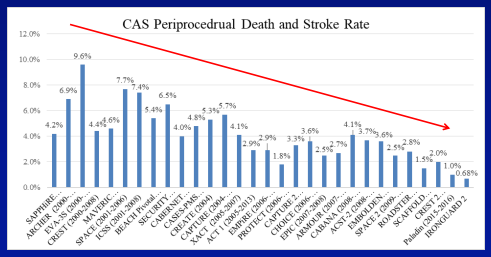
Disclosures

- Consultant: BD, Boston Scientific, Contego Medical, Cordis, Endologix, Inspire MD, Medtronic, Rapid Medical, Shockwave, Penumbra, Vivasure, Nectero, Reflow
- Stock options: Inspire MD and Centerline Biomedical, Reflow
- VIVA Physicians, Board Member
- Research Studies: Abbott, Endologix, Surmodics, W.L. Gore, Terumo Aortic, NIH, Boston Scientific, Merit, Contego Medical, Inspire MD, Reva Medical, Penumbra, Medalliance, Nectero

2023 Status

- CMS – only <10% of carotid patients qualify
- Private payers
  - Some mirror medicare
  - Some mirror FDA labeling
  - Some don't cover it at all (Experimental)
- This stifled innovation

Improving Outcomes Over Time



What has changed

- CAS undergone scientific scrutiny
- Four large multicenter RCTs with 6772 patients showing equivalence with CEA in procedural outcomes, long-term stroke prevention and durability
- We have learned who best to apply the technology on

CAS Should Not Be Only for High-Risk Patients

- Crest Trial outcomes stratified by symptoms
  - ≥50% symptomatic and ≥70% asymptomatic
  - No significant differences between CAS and CEA for the primary endpoint of death, stroke, or myocardial infarction (MI) in either subgroup
  - 5.2% versus 4.5%; hazard ratio, 1.18; 95% CI, 0.82 to 1.68; P=0.38.
  - In total, 1321 symptomatic and 1181 asymptomatic patients.

Stroke. 2011;42:675-80.

New Data Since Last NCD Update

Study/Year	Patients (n)	EPD Use	30-Day S/D/MI	Comment
CREST, 2010	CAS = 594 CEA = 587	YES	CAS = 3.5% CEA = 3.6%	ASR, >60% stenosis, Primary endpoint# CAS = 5.6%, CEA 4.9% (p = NS). S/D at 4 yrs CAS = 4.5%, CEA = 2.7% (p = 0.07). No difference between groups at 10 yrs.
ACT-1, 2016	CAS = 1,089 CEA = 364	YES	CAS = 3.3% CEA = 2.6%	ASR, Stenosis >70%, Primary endpoint was CAS = 3.8%, CEA = 3.4%* (p = NS).
SPACE-2, 2019	CAS = 197 CEA = 203 MED = 113	Optional (36%)	CAS = 2.5% CEA = 2.5% MED = 0%	ASR, Stenosis >70%, Primary endpoint CEA = 2.5%, CAS = 3.0%, MED = 0.9%; (p = NS).* In all CAS patients with major secondary outcome events, no EPD was used.
ACST-2, 2021	CAS = 1,811 CEA = 1,814	YES (85%)	CAS = 3.9% CEA = 3.2%	ASR, Stenosis >60%, Non-procedural stroke during follow-up CAS = 5.2%, CEA = 4.5%.

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No Differences in Outcomes

Any Post Procedural Stroke

Trial/Study	Any Post-Procedural Stroke		
	CAS	CEA	p Value
ACT-1 Up to 5 years	6.9%	5.3%	0.44
Space-2 At 1 year	1.5%	1.5%	1
ACST-2 Mean f/u 5 years	5.3%	4.5%	0.33

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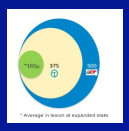
Micromesh Stent Technology

- Decrease risk of plaque embolization and protrusion
- Associated with lower stroke risk



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CGUARD Data 30 Day and 1 Year

Event rate in % (n)	ITT (N=316)	Per Protocol^
Death, Stroke or MI^	0.95% (3)	0.63% (2)
Death#	0.32% (1)	0.00% (0)
Any stroke#	0.95% (3)	0.63% (2)
Major Stroke#	0.63% (1)	0.32% (1)
Minor Stroke#	0.32% (2)	0.32% (1)
MI#	0.00% (0)	0.00% (0)
Death or any stroke^	0.95% (3)	0.63% (2)
Death or major stroke^	0.63% (2)	0.32% (1)

30-day S/D/MI

Event*	ITT	Per Protocol**
30-day DSMI + Ipsilateral stroke between 31 and 365 days	1.95 % (6)	1.70% (5)
30-day DSMI	0.95% (3)	0.63% (2)
Ipsilateral stroke between 31 and 365 days	1.00% (3)	1.04% (3)
TLR	0.98% (3)	1.01% (3)

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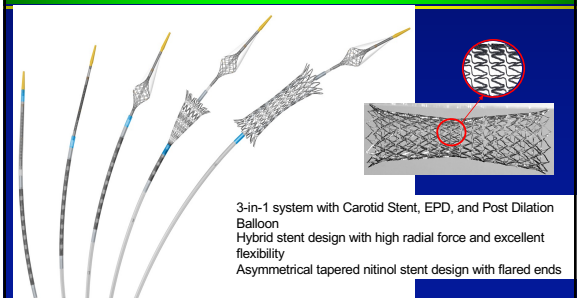
Neuroguard IEP Carotid Stent



3-in-1 system with Carotid Stent, EPD, and Post Dilation Balloon
Hybrid stent design with high radial force and excellent flexibility
Asymmetrical tapered nitinol stent design with flared ends

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Performance II Trial

30 Day and 1 Year Outcomes

N=305	Intention-to-Treat	Per-Protocol[1]
All stroke	1.31% (4)	0.98% (3)
Minor stroke	1.31% (4)	0.98% (3)
Major stroke	0.0% (0)	0.0% (0)
All Stroke - Asymptomatic Patients	0.81% (2)	0.81% (2)
All Stroke - Contralateral	0.0% (0)	0.0% (0)

n=270	Intention-to-Treat	Per-Protocol
30 Day Death/Stroke/MI + Ipsilateral Stroke between Day 31 to 12 Months	2.67% (8)	2.33% (7)
Ipsilateral Stroke, day 31 to 12 months	0.37% (1)	0.37% (1)
Minor stroke	0.37% (1)	0.37% (1)[1]
Major stroke	0.0% (0)	0.0% (0)
30 Day All Stroke + Ipsilateral Stroke Day 31 to 12 months	1.68% (5)	1.34% (4)
Neurological Death	0.0% (0)	0.0% (0)
CD-TLR	0.0% (0)	0.0% (0)
Target Lesion Revascularization	1.47% (4)	1.47% (4)

CD-TLR: Any revascularization procedure of the original treatment site associated with narrowing of > 50% as determined by the angiographic core lab within 12 months of the index-procedure.

One Minor Stroke Between Day 31 and 12 Months
No Major Strokes at One Year
No Neurological Deaths at One Year

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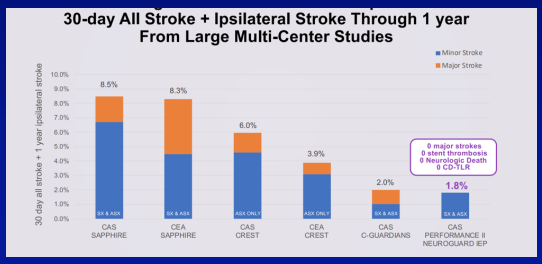
Performance II Trial 2 Year Outcomes

	Intention-to-Treat	Per-Protocol[1]
Neurological Death	0.0% (0)	0.0% (0)
Stent Thrombosis	0.0% (0)	0.0% (0)
Clinically-driven Target Lesion Revascularization (CD-TLR)[2]	0.4% (1/260)	0.4% (1/259)
Target Lesion Revascularization (TLR)[3]	2.7% (7/260)	2.7% (7/259)
In-Stent Restenosis (ISR)[4]	3.9% (10/260)	3.9% (10/259)

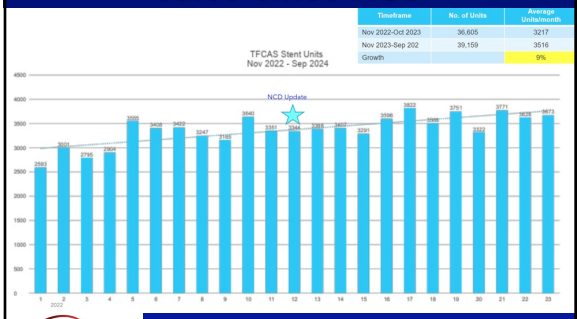
New Data in Context



October 11, 2023

- Carotid NCD altered
- Makes CEA, CAS and TCAR all safe choices
- No facility requirements to report to CMS
- Local credentialling and governance

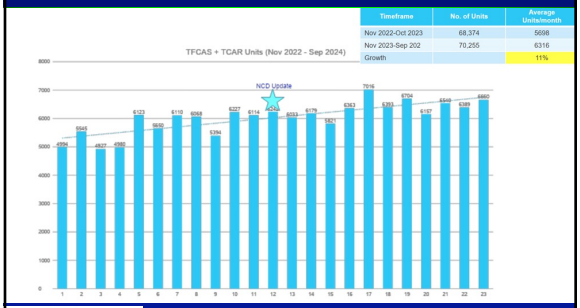
Change in TFCAS stent sales since NCD



Since NCD

- Big push for how do I relearn
- How do I get recredentialled
- Slow growth of training courses
- Return of local governance on outcomes
- CCF
  - 25 procedures for credentialling
  - 4 Specialties offer TFCAS with = outcomes

Carotid Market



Conclusions

- Carotid disease treatable with CEA, CAS or TCAR
  - >50% symptomatic
  - >70% asymptomatic patients
  - Better selection of patients for all therapies
  - Advances in stent and protection strategies has improved outcomes
  - 10% increase in cases both TFCAS and TCAR
  - No decremental outcomes since NCD

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