Stent choice is more important than protection device in CAS

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Disclosure of Interest

Speaker Name: Ahmed BOUZID.

- I do not have any potential conflict of interest

- 15-20% of Stroke/TIA are secondary to carotid lesions.
- First CEA was performed in 1953 and the first CA Angioplasty was performed in 1977.
- NASCET study for symptomatic in 1991 and ACAS study for asymptomatic in 1995.

Protection or Nonprotection in Carotid Stent Angioplasty
The Influence of Interventional Techniques on Outcome Data From the SPACE Trial

Olav Jansen, PhD; Jens Fiehler, PhD; Marius Hartmann, PhD; Hartmut Brückmann, PhD

i-MEET NEXT GENERATION

SPACE Randomized trial CAS vs CEA
Symptomatic patients
N: 563
With EPD : 145, EPD Without:418

No statistically significant difference between the two groups *(p=0.40)*

CAS	No. of Adverse Events With Protection (total n=145)	No. of Adverse Events Without Protection (total n=418)
Ipsilateral stroke or death	12 (8.3%, 95% CI: 4.3–14.0%)	26 (6.5%, 95% CI: 4.1–9.0%)
Ipsilateral stroke ≥Rankin3 or death	8 (5.5%, 95% CI: 2.4–10.6%)	18 (4.5%, 95% CI: 2.6–6.7%)

Small series

DOI: 10.1161/STROKEAHA.108.534289

Protection or Nonprotection in Carotid Stent Angioplasty
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Pooled analysis of SPACE and EVA3S show non significant difference in OE rate during CAS with or without protection device , (p=0.90 , 95% CI 0.56-1.56)

Trial	OE Rate	OE Rate % (95% CI)
N		
Pr		
SPACE	12/145	8.1% (5.5–11.3%)
EVA 3S	18/227	

Small series

Inexperienced operators

OE:ipsilaterla stroke or ipsilateral stroke/ death within 30 days

DOI: 10.1161/STROKEAHA.108.534289

Carotid Angioplasty and Stenting With and Without Cerebral Protection

Clinical Alert From the Endarterectomy Versus Angioplasty in Patients With Symptomatic Severe Carotid Stenosis (EVA-3S) Trial

EVA-3S Investigators

EVA3S Randomized trial CAS vs CEA
Symptomatic patients
N: 527
With EPD : 145 Without EPD Without:418

TABLE 2. Risk of Stroke or Death Within 30 Days of CAS With or Without Cerebral Protection

	CAS With Cerebral Protection* (n=58)	CAS Without Cerebral Protection† (n=15)	Unadjusted Odds Ratios (95% CI)	Age-Adjusted‡ Odds Ratios (95% CI)
Any stroke	5 (8.6%)	4 (26.7%)	3.9 (0.9–16.7)	2.8 (0.6–12.8)
Major stroke	1 (1.7%)	2 (13.3%)	8.8 (0.7–100.0)	5.8 (0.5–71.0)
Any stroke or death	6 (10.3%)	4 (26.7%)	3.2 (0.8–13.0)	2.5 (0.6–10.8)
Any major stroke or death	2 (3.4%)	2 (13.3%)	4.3 (0.6–33.3)	3.8 (0.5–31.6)
Any procedural stroke§	3 (5.2%)	2 (13.3%)	2.8 (0.4–18.7)	2.3 (0.3–15.7)

European Heart Journal (2004) 25, 1550–1558

ELSEVIER

EUROPEAN SOCIETY OF CARDIOLOGY

Clinical research

Embolic protection devices for carotid artery stenting: better results than stenting without protection?

Ralf Zahn[a,*], Bernd Mark[a], Nikolaj Niedermaier[b], Uwe Zeymer[a],

Prospective registry :1483 patients

Table 3 Hospital medication and hospital events

	Protection devices $n=668$ (100%)	No protection devices $n=815$ (100%)	p-value	OR (95% CI)
Hospital medication				
Aspirin	620/659 (94.1%)	767/813 (94.3%)	0.832	0.95 (0.61–1.48)
Ticlopidine/Clopidogrel	622/632 (98.4%)	528/555 (95.1%)	0.001	3.81 (1.53–6.63)
Phenprocoumon	26/631 (4.1%)	31/809 (3.8%)	0.781	1.08 (0.63–1.84)
Statins[a]	313/391 (80.1%)	55/70 (78.8%)	0.776	1.09 (0.59–2.04)
Angiotensin converting enzyme inhibitors[a]	259/392 (66.1%)	45/70 (64.3%)	0.772	1.08 (0.64–1.84)
ß-blockers[a]	255/397 (64.2%)	43/67 (64.2%)	0.993	1.00 (0.58–1.72)
Hospital events				
Ipsilateral amaurosis fugax	1/666 (0.2%)	6/789 (0.8%)	0.094	0.20 (0.02–1.63)
Ipsilateral TIA	17/666 (2.6%)	23/789 (2.9%)	0.673	0.87 (0.46–1.65)
Ipsilateral stroke	11/666 (1.7%)	32/789 (4.1%)	0.007	0.40 (0.20–0.79)
• ipsilateral minor stroke	4/666 (0.6%)	15/789 (1.9%)	0.029	0.31 (0.10–0.94)
• ipsilateral major stroke	8/666 (1.2%)	17/789 (2.2%)	0.165	0.55 (0.24–1.29)
Ipsilateral stroke/TIA/amaurosis fugax	29/666 (4.4%)	58/789 (7.4%)	0.016	0.57 (0.36–0.91)
Any ischaemic event contralateral	6/666 (0.9%)	17/789 (2.2%)	0.056	0.41 (0.16–1.05)
Myocardial infarction	0 (0%)	0 (0%)	1	–
Death	2/668 (0.3%)	0 (0%)	0.118	–
All non-fatal strokes and all death	14/666 (2.1%)	39/789 (4.9%)	0.004	0.41 (0.22–0.77)
Any death/stroke/TIA/amaurosis fugax	31/666 (4.7%)	58/789 (7.4%)	0.032	0.62 (0.39–0.96)

OR=odds ratio, CI=confidence interval.

[a] Data available only in a subset of patients.

- Routine practice , recent and ongoing carotid trials (CREST,ACT1, ACST2,SPACE2…) have imposed the systematic use of EPDs.

What do we expect from carotid stent?

Acutely:

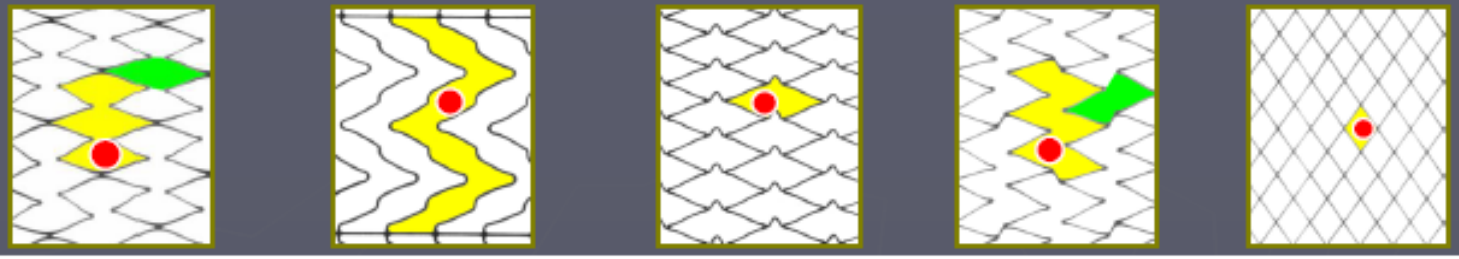
- Scaffolding of the plaque ++
- Recoil resistance ,dissection treatment
- Conformability to carotid artery anatomy (CCA 8mm, ICA :5mm
- Crossability, radio-opacity, positioning accuracy,Easy to deploy, EPD compatibilty , access compatibility

Chronicaly:

- Resistance to compression and migration
- Long term patency

Stent Design

Proximal



	PROTÉGÉ® RX (Tapered, 8-6mm)	RX ACCULINK™ (Tapered, 8-6 mm)	Xact® (Tapered, 8-6mm)	PRECISE® (Straight, 8 mm)	WALLSTENT® (Straight, 8 mm)
Pore Diam. (mm)	1.12	1.10	1.00	1.12	0.92
Pore Size (mm2)	2.65	12.50	3.46	2.43	0.948
Cell Area (mm2)	7.19	12.50	3.46	7.39	0.948

Distal

	PROTÉGÉ® RX (Tapered, 8-6 mm)	RX ACCULINK™ (Tapered, 8-6mm)	(Tapered, 8-6mm Xact)	PRECISE® (Straight, 8 mm)	WALLSTENT® (Straight, 8 mm)
Pore Diam. (mm)	1.08	1.06	0.96	1.12	0.92
Pore Size (mm2)	1.80	10.78	2.23	2.43	0.948
Cell Area (mm2)	4.48	10.78	2.23	7.39	0.948

Available Carotid stents

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Open versus Closed Cell versus Mesh-Covered Stents

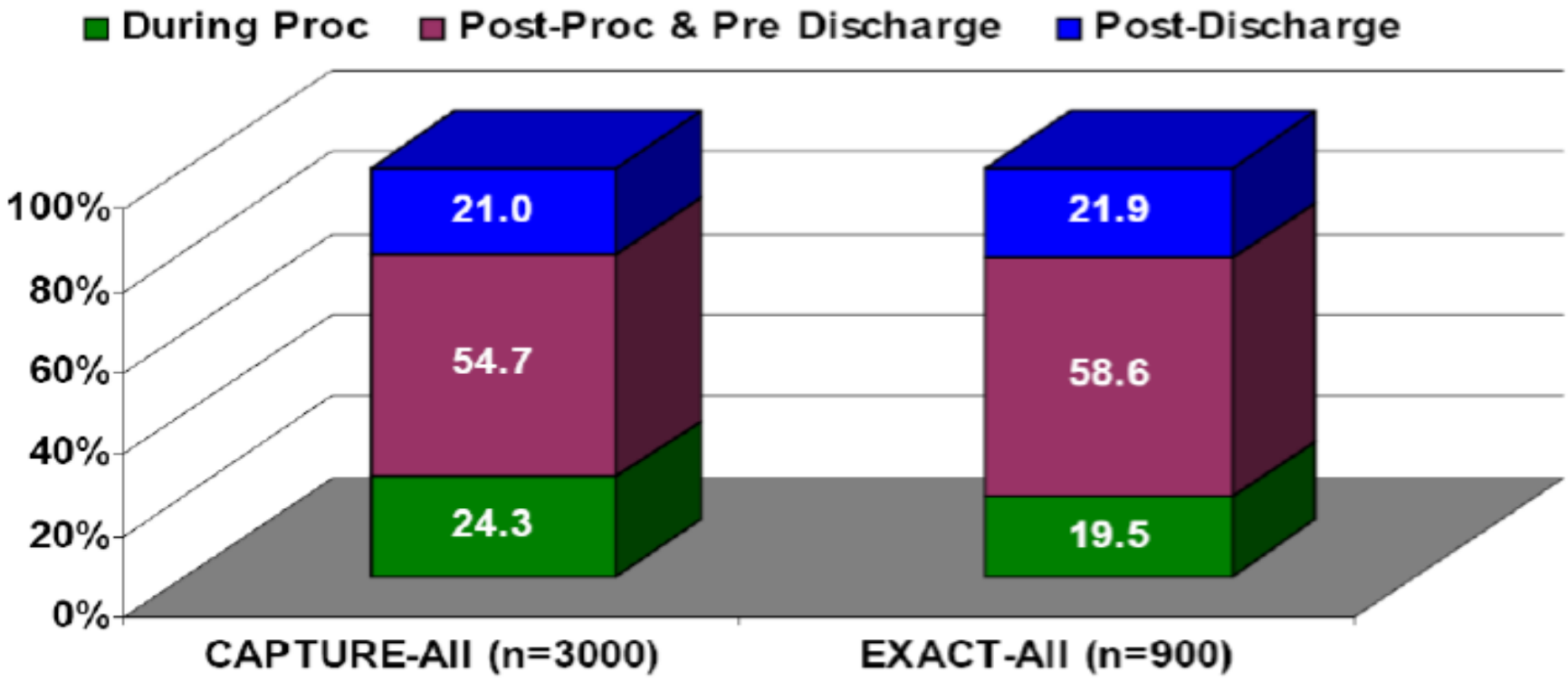
Stent Name	Stent Image	Stent Design	Free Cell Area	Specifics of Design	Stent Diameter (unconstrained)	Stent Length (unconstrained)
Acculink		Open Cell	11.5mm 2	Self-expanding nitinol stent	5 - 10mm (15 - 30Fr)	20 - 40mm
Protégé		Open Cell	10.7mm 2	Self-expanding nitinol stent	6 - 10mm (18 - 30Fr)	20 - 60mm
Precise Pro Rx		Open Cell	6mm2	Self-expanding nitinol stent	5 - 10mm (15 - 30Fr)	20 - 40mm
Adapt		Closed Cell	4.4mm2	Self-expanding nitinol stent	6 - 10mm (18 - 30Fr)	21 - 44mm
X-Act		Closed Cell	2.5mm2	Self-expanding nitinol stent	7 - 10mm (21 - 30Fr)	20 - 40mm
Wallstent		Closed Cell	1.1mm2	Braided construction	7 - 10mm (21 - 30Fr)	22 - 59mm
Cristallo Ideale		Hybrid	3.2mm2	Multisegment nitinol	6 - 11mm (18 - 33Fr)	20 - 40mm
Gore		Mesh Covered	0.5mm2	PTFE mesh (heparin coated) on nitinol stent)	unable to obtain specifics	
Roadsaver		Mesh Covered	0.4mm2	Nitinol double layer micromesh	5 - 10mm (15 - 30Fr)	25 - 43mm
InspireMD Cguard		Mesh Covered	0.18mm 2	PET MicroNet on nitinol stent	6 - 10mm (18 - 30Fr)	20 - 60mm

http://dx.doi.org/10.1053/j.semvascsurg.2017.04.007

The impact of stent design on outcomes: Procedural Stroke

Timing for Events in CAS:

More than 70% of events after CAS occur after the procedure



From M.Bosiers, and others

Delayed stroke and Death at 1-30 days:

Stratified by Stent design

	Total population		
	Patients	All events	Post-procedural events
Open cell	937	39	32
Closed cell	2242	51	29
Total	3179	90	61
Cell type			
Open cell		4.2%	3.4%
Closed cell		2.3%	1.3%
Total	3179	2.83%	1.9%

2/3 of events delayed

Bosiers et al. Eur J Vasc Endovasc Surg 2007;33:135

Delayed stroke and Death at 1-30 days:

Stratified by Stent design and symptoms

Stent name	
X-act	Precise
Nexstent	Protégé
Wallstent	Acculink
	Exponent

Table 5. *P*-values for the test that event rates differ between stents

Population	Outcome	*p*-value
Total	All events	0.018
	Post-procedural events	0.002
Symptomatic	All events	0.006
	Post-procedural events	<0.0001
Asymptomatic	All events	0.248
	Post-procedural events	0.790

Bosiers et al. Eur J Vasc Endovasc Surg 2007;33:135

SVS Registry :Evaluation of stent cell design on carotid stenting outcomes

N: 2322 patients

Thirty-day outcomes for cell design by symptomatology

	OPEN			*CLOSED*		
Thirty-day outcomes	*SYMPT (n = 796) n (%)*	*ASYMP (n = 979) n (%)*	P *value*	*SYMPT (n = 265) n (%)*	*ASYMP (n = 282) n (%)*	P *value*
Death, stroke, or MI	42 (5.28)	31 (3.17)	.0302	12 (4.53)	8 (2.84)	.3639
Death, stroke, or TIA	55 (6.91)	37 (3.78)	.0035	15 (5.66)	12 (4.26)	.5545
Mortality	10 (1.26)	15 (1.53)	.6890	6 (2.26)	4 (1.42)	.5343
Stroke	29 (3.64)	16 (1.63)	.0093	5 (1.89)	4 (1.42)	.7453
MI	8 (0.75)	7 (0.72)	1.0000	3 (1.13)	1 (0.35)	.3587
TIA	19 (2.39)	9 (0.92)	.0200	6 (2.26)	4 (1.42)	.5343

ASYMP, Asymptomatic; *CLOSED*, closed cell stent; *MI*, myocardial infarction; *OPEN*, open cell stent; *SYMPT*, symptomatic; *TIA*, transient ischemic attack. *P* values were based on Fisher exact test. Outcomes are defined as occurring intraoperatively, predischarge, or between discharge and 30 days. Rates are per patient.

Jim J et al. JVS 2011;54:71-79

Incidence of embolism associated with carotid artery stenting: open-cell versus closed-cell stents

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N = 96 (76 symptomatic)

Transfemoral filter protected
(FilterWire N =86, AngioGuard N = 5)

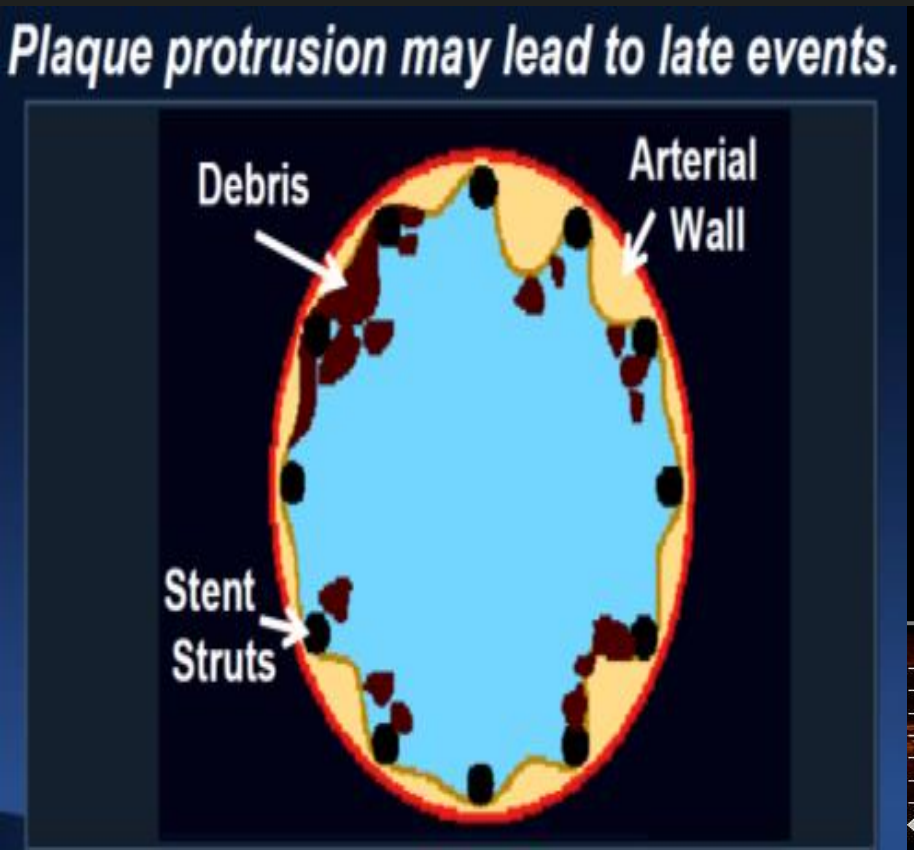
Randomly allocated to:
PRECISE (N=48)
WALLSTENT (N=48)

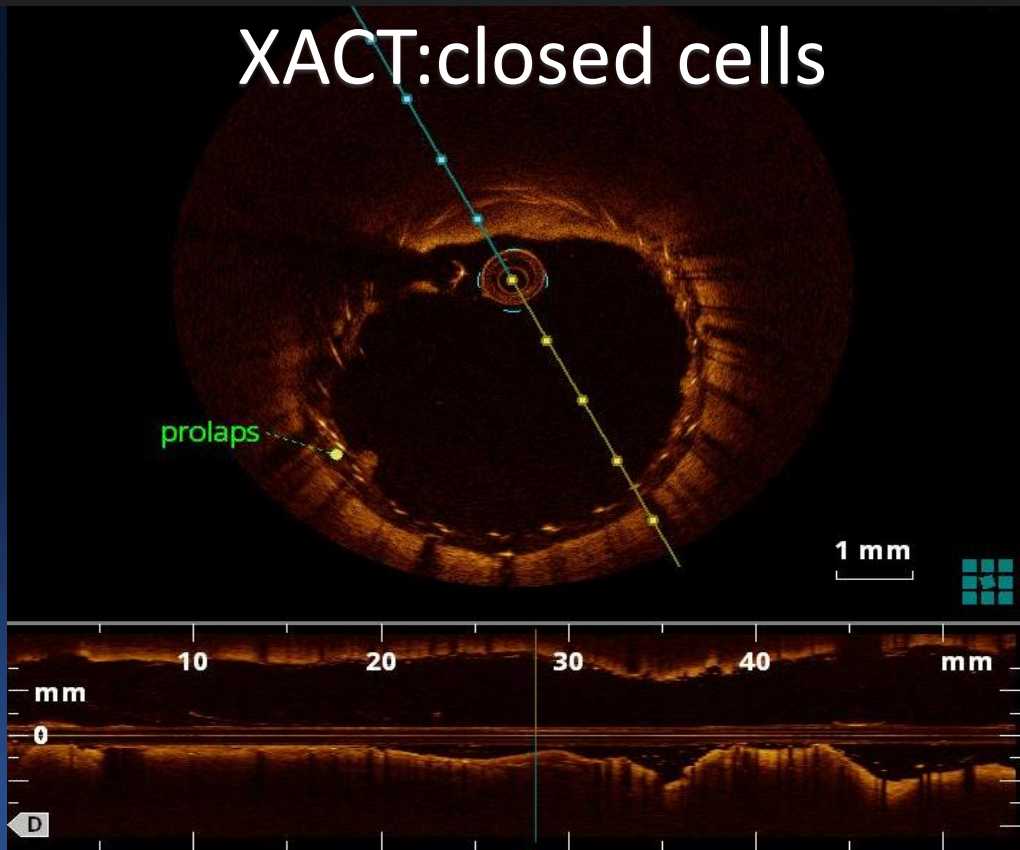
TABLE 2: Comparison of outcomes between the closed-cell and open-cell stent groups

Outcome	Overall	Closed-Cell Stent Group	Open-Cell Stent Group	p Value
procedural				
distal branch embolism	1 (1.0%)	0	1 (2.1%)	1.000
in-stent filling defect	2 (2.1%)	1 (2.1%)	1 (2.1%)	1.000
residual ulcer or gap	35 (36.4%)	29 (60.4%)	6 (12.5%)	<0.001
captured debris in EPD	35 (36.4%)	14 (29.2%)	21 (43.8%)	0.138
new lesion on postop DWI*	36 (39.6%)	12 (27.3%)	24 (51.1%)	0.020
clinical†				
total	4 (4.3%)	4 (8.5%)‡	0	0.117
TIA	2 (2.2%)	2 (4.3%)‡	0	0.495
stroke	1 (1.1%)	1 (2.1%)‡	0	1.000
death	1 (1.1%)	1 (2.1%)‡	0	1.000

J Neurosurg 119:642–647, 2013

- The embolic protection devices protect against embolic release & possible stroke during procedure
- **BUT most strokes occur post procedural in the first 48 h.**
- Sustained embolic protection is indispensable.

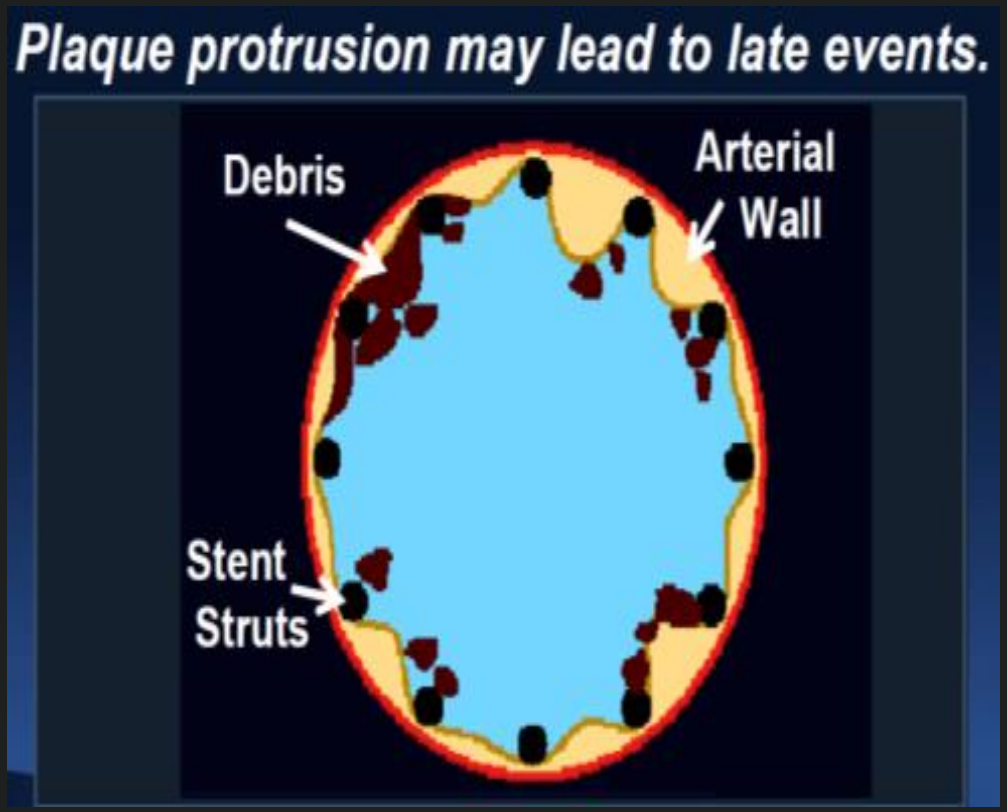


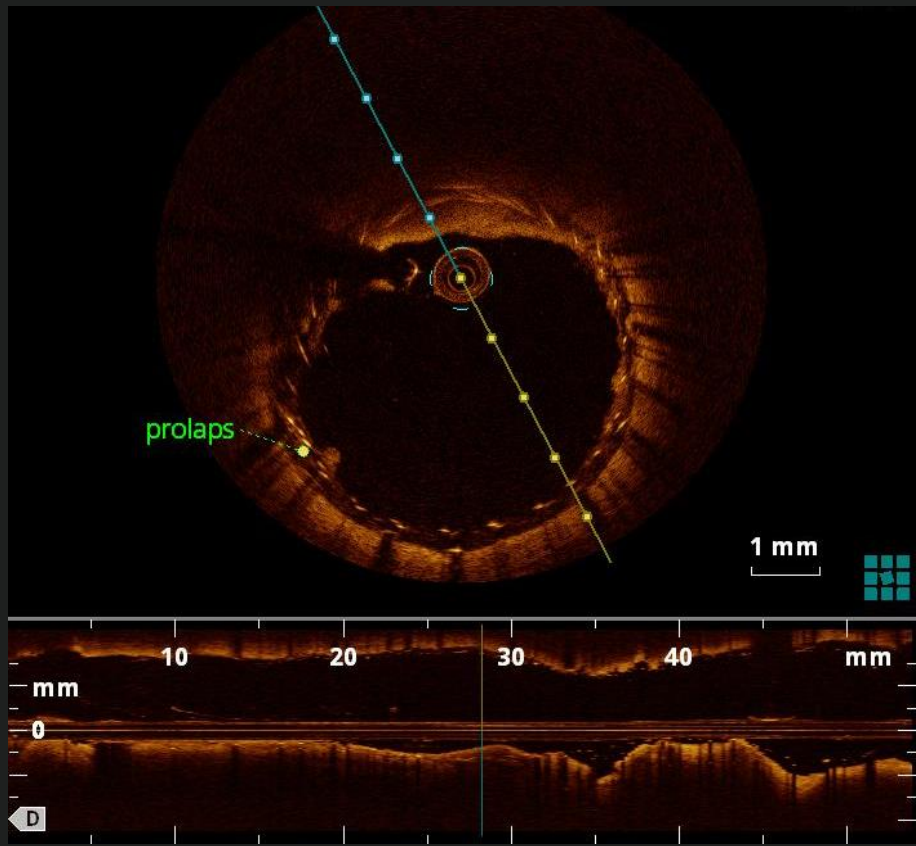


Are we able to provide delayed embolic protection without loosing the long term benefit of nitinol stents?

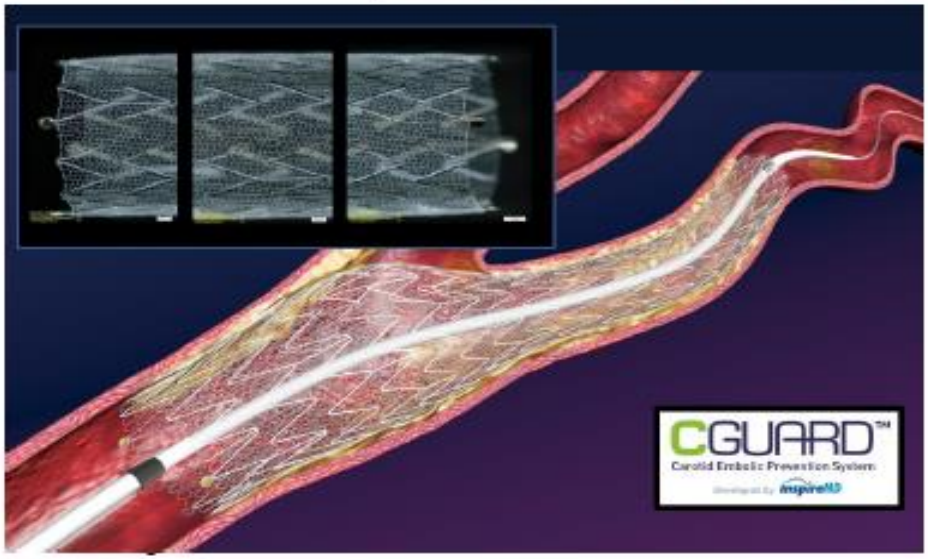
Micromesh may provide sustained embolic protection:

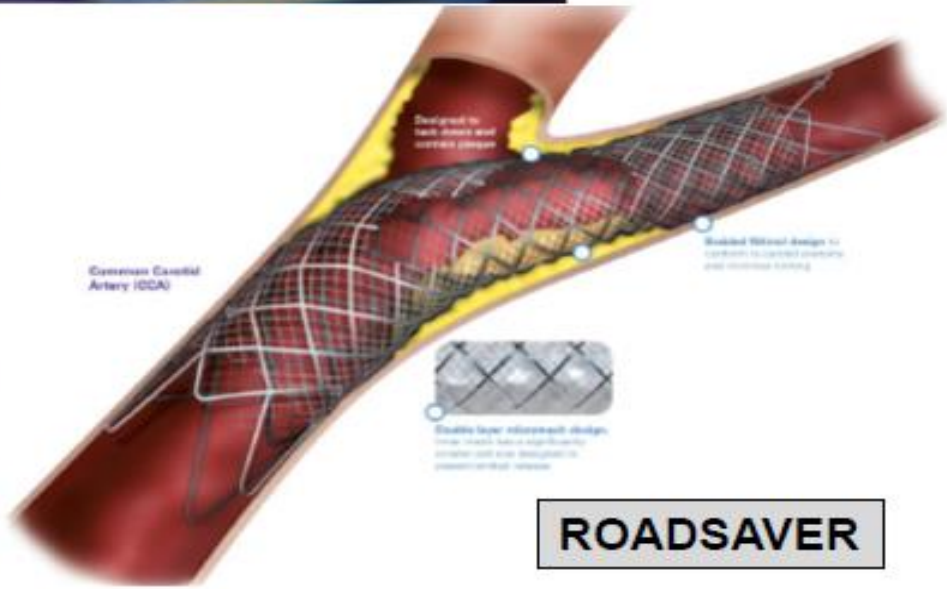
- By covering entirely the lesion
- Stops the plaque prolapse through struts



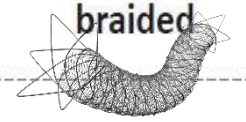


THE THREE MICROMESH CAROTID STENTS





Dual layer stents : Micromesh , Scaffold

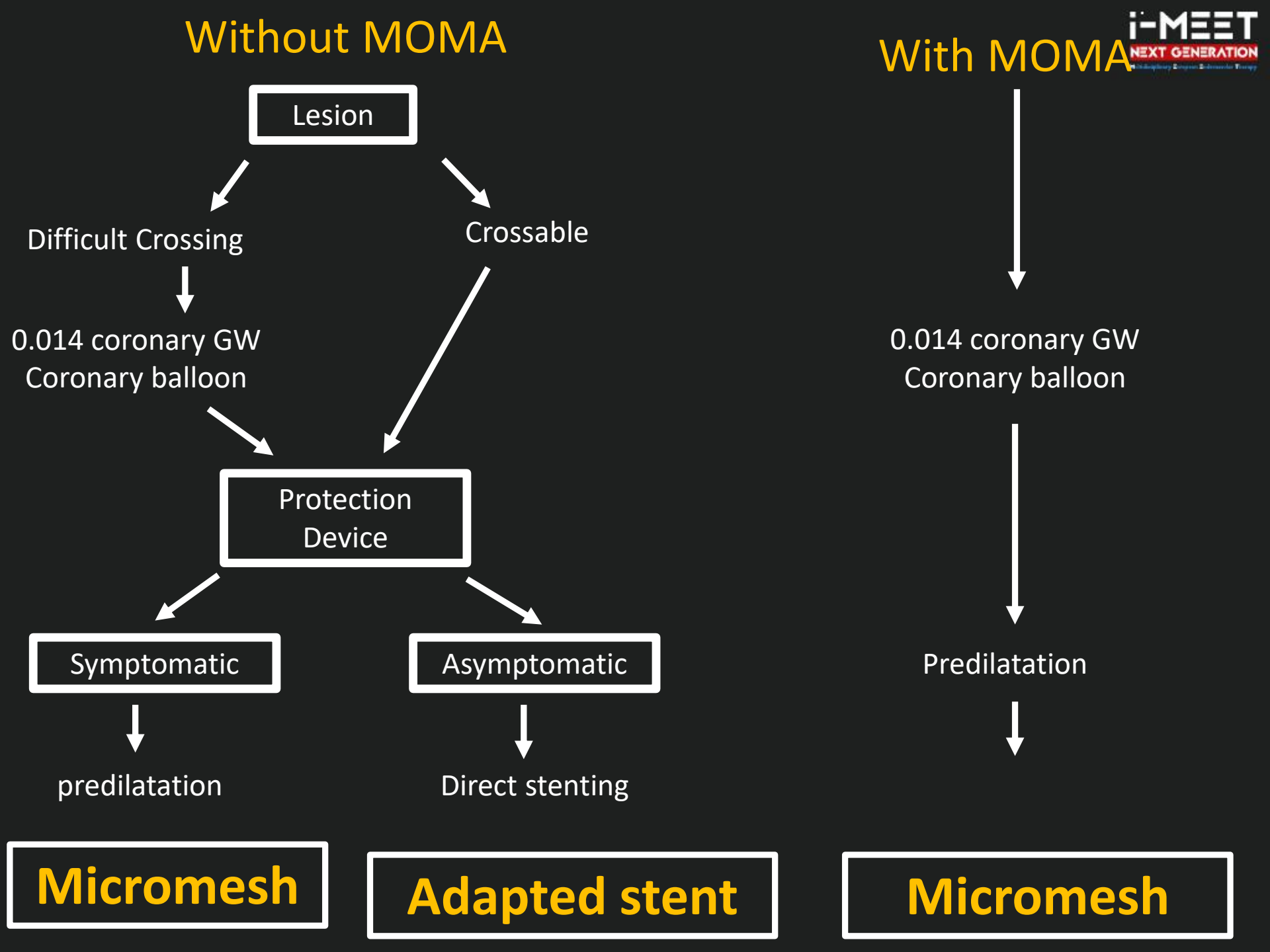
Name	RoadSaver *aka* Casper	Gore® Carotid Stent	CGuard™ Embolic Prevention Stent
			
Stent frame	closed-cell Nitinol	open-cell Nitinol	open-cell Nitinol
Mesh position in re--lation to frame	inside	outside	outside
Mesh material	Nitinol	PTFE	PET
Mesh structure	braided 	inter-woven 	single-fiber knitted 
Pore size	375 µm	500 µm	150 - 180 µm

Stent Selection including Micromesh

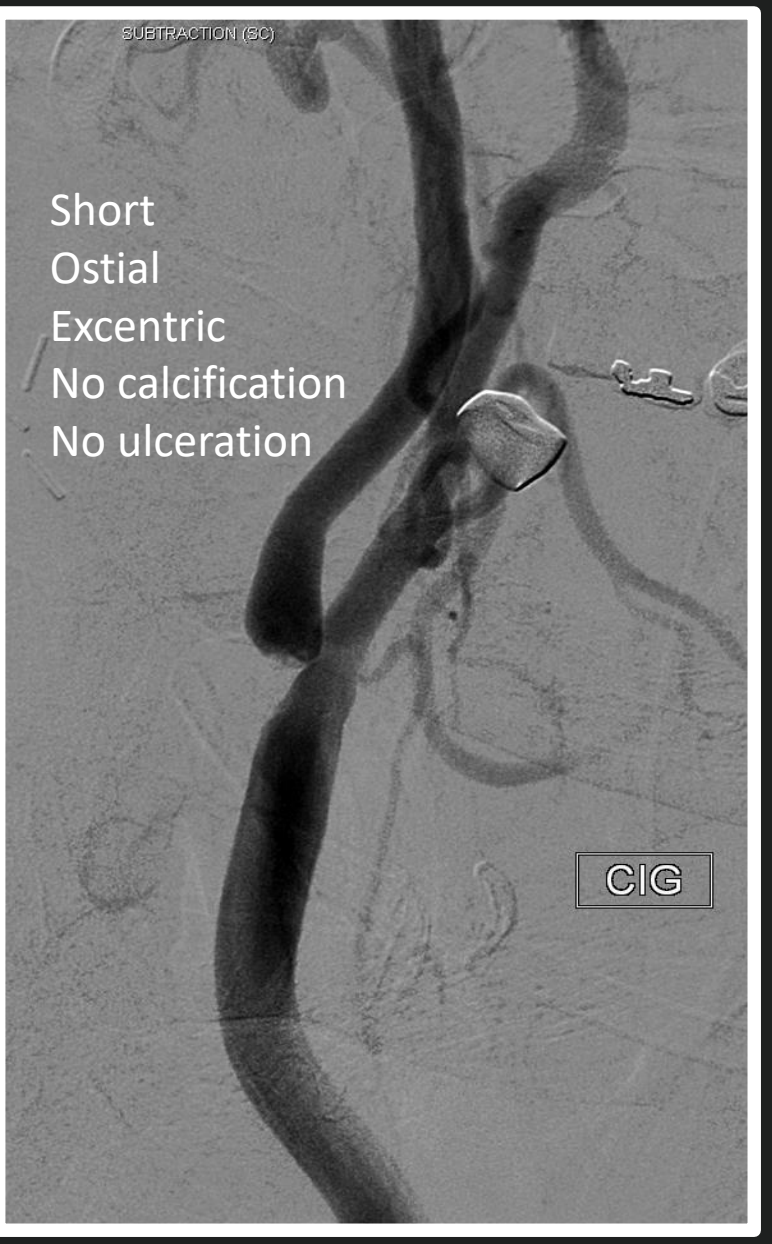
Type	Open Cells Stent		Closed Cells Stent			Micromesh	
Name Comp	Precise Cordis	Proteg EV 3	Wallstent BSC	Adapt BSC	Xact Abbott	Roadsaver Terumo	Cguard Inspire
Sympto	+	±	+++	+++?	++	+++	+++
Asymp.	+++	++	+	++	++	+++	+++
Bifurc.	++	+++	+++	+	±	+++	+
Ulcerate	++	++	+++	++?	+++	+++	+++
Calcifie	++	++	+	++	+++	+	++
Short	+++	+++	-	++	+++	+	+++
Long	++	++	+++	++	+	+++	+
Accurac	+++	++	+	++	+++	+	+++
Irr/Coni	+	+++	+++	++	+++	++	+
Restenosis	+++	+++	+++	+++	+++	+++	+++
Radioth	++	++	+++	-	+++	+++	+

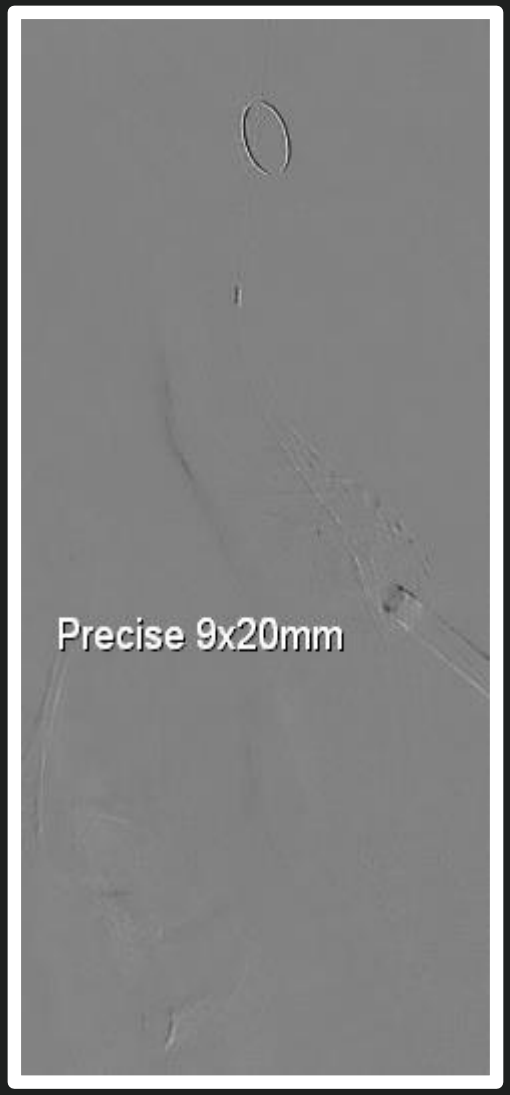
APPROACH IN OUR CENTER

Clinique Louis Pasteur
GRAND NANCY


Without MOMA
With MOMA
i-MEET
NEXT GENERATION
Lesion
Difficult Crossing
Crossable
0.014 coronary GW
Coronary balloon
Protection
Device
Symptomatic
Asymptomatic
predilatation
Direct stenting
0.014 coronary GW
Coronary balloon
Predilatation
Micromesh
Adapted stent
Micromesh

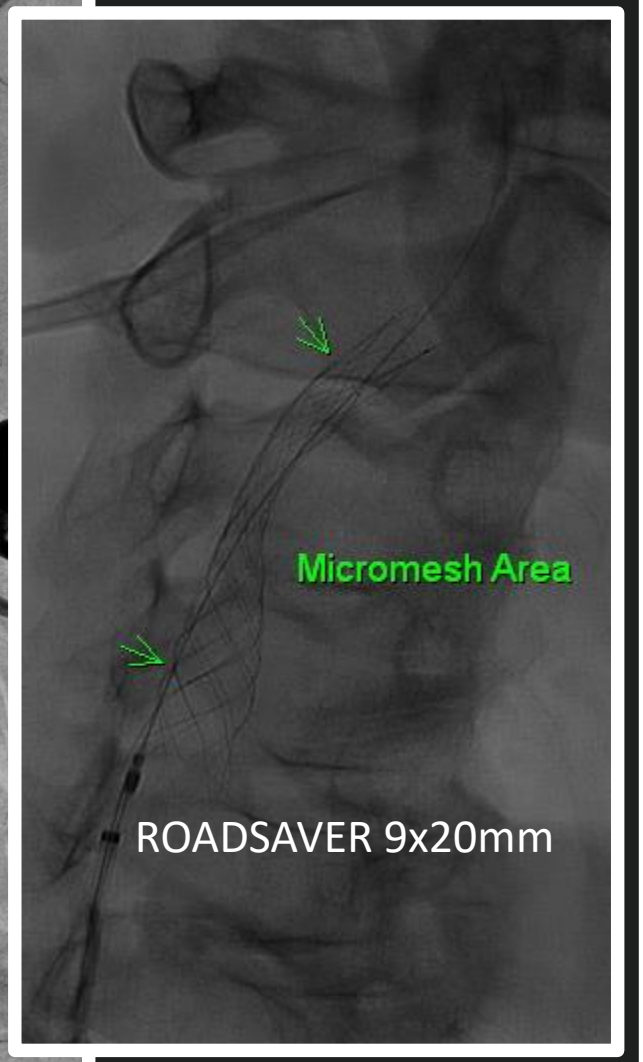
Case 01: Asymptomatic short RIC artery lesion





Case 02: Asymptomatic LCC artery lesion

Case 03: Asymptomatic RIC artery lesion



Case 04: symptomatic LIC artery lesion

Take Home messages:

- Carotid stenting is complementary to EPDs devices.
- Carotid stent design is a key in clinical outcomes.

Embolization prevention:

- EPDs during procedure
- Stent during and after procedure

Thank you