



Nitinol micromesh technology for Carotid artery treatment

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Disclosure

Speaker name: Max Amor, MD.

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☒ I do not have any potential conflict of interest

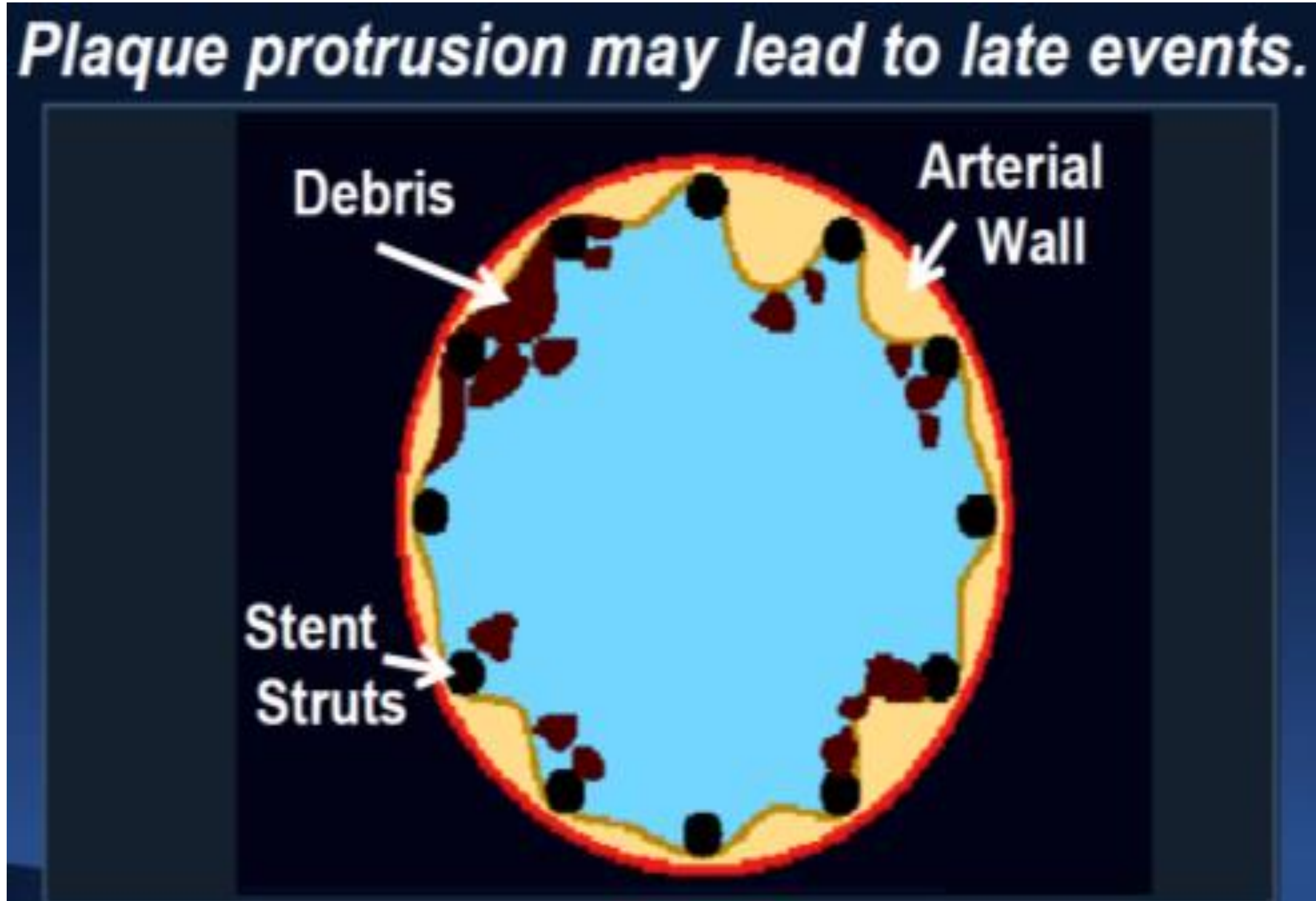
Endovascular Carotid artery treatment requires Prevention of embolisation

Peri-procedural/ Temporary embolic protection

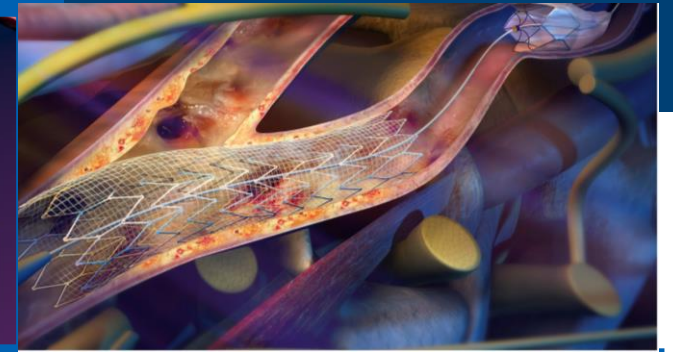
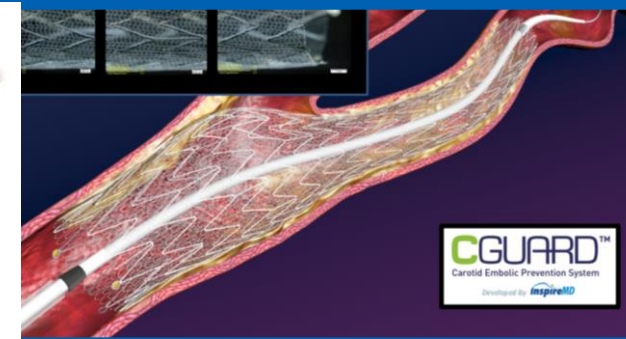
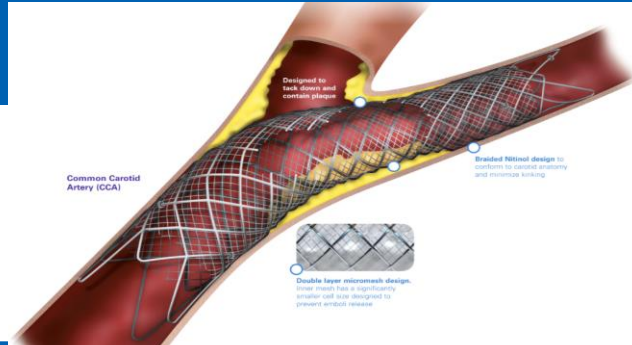
Several protecting devices to block distal embolisation of detached debris (Access , Post-stenting dilatation...)

Post-procedural/ Sustained embolic protection

Causes of Late Embolization



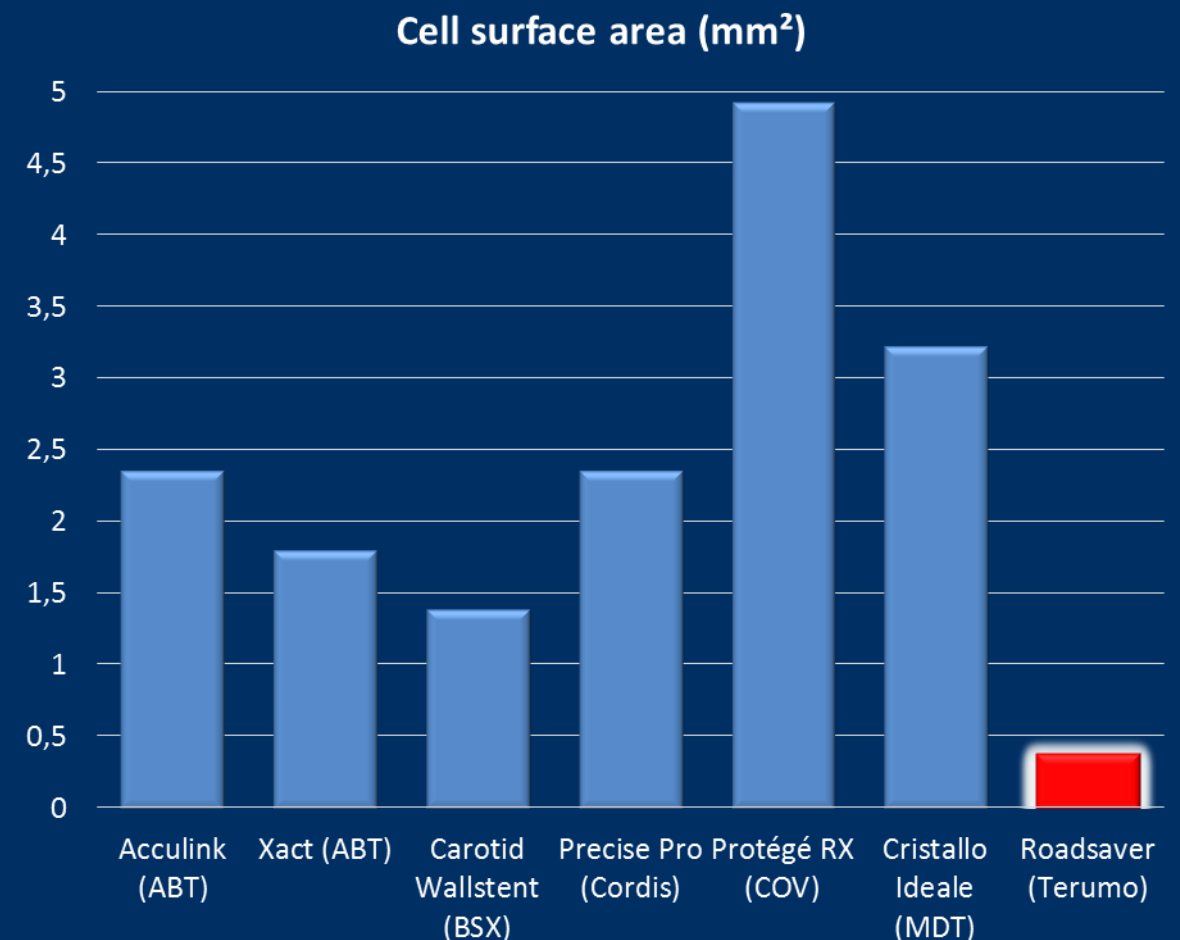
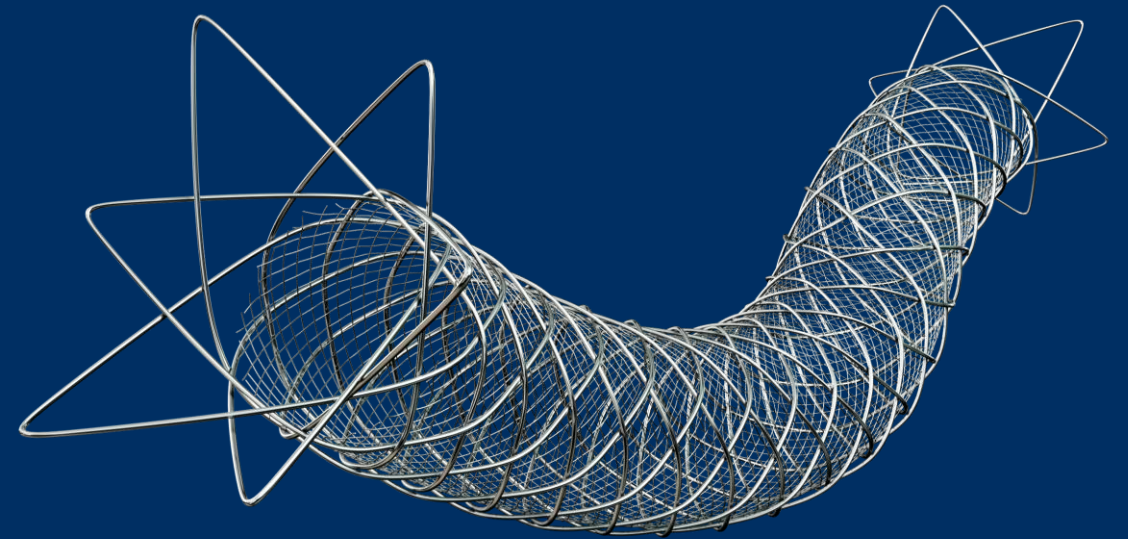
Tentative Summary of the main characteristics of the 3 Micromesh Stents



	Roadsaver	CGuard™	Gore Carotid
Company	Microvention /Terumo	Inspire MD	WL Gore
Material (Stent/ Micromesh)	Nitinol / Nitinol	Nitinol/ PET	Nitinol/ PTFE/ CBAS Coating
Size of delivery	5F	6F	6F
Size of Pores μ	375-500	150-180	500
Flared tips	yes	no	no
Retrievable/Repositionable	yes	no	no
Accuracy	++	+++	++
Conformability	+++	++	++
Crossability	+++	+	++
ECA preservation	yes	?	??
Page ▪ 5 EPD compatibility	All	All	All

Roadsaver – dual layer micromesh Carotid stent

- Braided Nitinol carotid stent with a built-in Nitinol micromesh for sustained embolic protection



**Are we able to provide
delayed embolic protection
without losing
the long term benefit of Carotid
Nitinol Stent ?**

First clinical cases
33 Patients with high risk carotid
artery lesions treated
with Roadsaver dual layer stent

Midterm results

Single center experience

Clinique Louis Pasteur Essey Les Nancy France

Details of procedure

- DAPT before : All
- 24Men , 9 Women . From 49 y to 88 y (Mean 72 ± 10 y)
- 8 Symptomatic 25 Asymptomatic
- Sedation : Midazolam: All
- Femoral Approach : All
- Protection : 32 : Filters 28, MOMA 4
- Atropine before inflation :All
- Direct Stenting : 8
- Post-Dilatation: All

Patient and Carotid Lesion Characteristics

Patient			Lesion					
N & initials	Sex& Age	Symp	Side & Severity	Including bifurcation	Calcified	Irregular & or Ulcerated	Echogenicity	Length mm
1 V.G	M80y	No	Right 80%	Yes	Yes	No	Mixed	15
2 R.H	M83y	No	Right 80%	Yes	Yes	Yes	Mixed	20
3 S.H	M65y	YES	Left 80%	No	No	Yes	Hypo	15
4 H.Y	M84y	No	Right 80%	No	Yes	Yes	Hyper	15
5 C.P	M75y	No	Left 90%	yes	No	Yes	Hypo	15
6 T.R	M85y	YES unsta	Right 99%	Yes	No	Yes	hypo	20
7 A.M	F80y	No	Right 75%	Yes	Yes	Yes	Mixed	20
8 T.G	M75y	No	Right 80%	Yes	Yes	no	Hypo	20
9 T.J	F62y	No	Left 85%	No	Yes	Yes	Hypo	15
10 R.C	M65y	No	Left 90%	No	No	Yes	Hypo	20

Patient and Carotid Lesion Characteristics

Patient			Lesion					
N & initials	Sex& Age	Symp	Side & Severity	Including bifurcation	Calcified	Irregular & or Ulcerated	Echogenicity	Length mm
11 G.P	M52y	No	Left 80%	No	Yes	Yes	Hypo	15
12 D.F	M73y	No	Left 80% Bilat stenosis	Yes	No	Yes	Hypo	20
13 S.B	F79y	Yes	Right 90%	Yes	No	Yes	Hypo	25
14M.M	F80y	No	Right 80% Bilat stenosis	Yes	Yes	Yes	Hyper	20
15 B.J	M49y	Yes	Right 50%	No	No	Floating	Hypo	20
16 R.S	M 81y	No	Left 80%	Yes	No	Yes	Mixed	20
17 A.M	M 77y	No	Left 80%	Yes	Yes	Yes	Hyper	15
18 P.J	M 75y	No	Left 70%	Yes	No	Yes	Mixed	20
19 L.C	M 66y	No	Left 80%	Yes	No	Yes	Hypo	20
		No	Right 75%	No	No	Yes	Hypo	15
20 T.J	F 88y	Yes	Right 80%	Yes	Yes	Yes	Hyper	20

Patient and Carotid Lesion Characteristics

Patient			Lesion					
N & initials	Sex& Age	Symp	Side & Severity	Including bifurcation	Calcified	Irregular & or Ulcerated	Echogenicity	Length mm
21 S.E	F85y	No	Right 80%	No	Yes	Yes	Hyper	20
22 S.F	M64y	No	Left 80% Right Stent 2012	Yes	No	Yes	Hypo	20
23 P.M	M86y	Yes	Right 99%	Yes	No	Yes	Hypo	25
24G.C	M68y	No	Left 80%	No	Yes	No	Hyper	15
25 G.S	M58y	No	Right 80%	No	Yes	No	Hyper	25
26 K.L	F73y	No	Right 80%	Yes	Yes	Yes	Hyper	20
27B.R	M 71y	No	Right 99%	Yes	Yes	Yes	Hyper	20
28R.H	F 86y	No	Left 70%	No	No	Yes	Hypo	15
29B.R	W 63y	No	Left 75%	Yes	No	Yes	Mixte	20
30D.D	M 70y	No	Left 75%	No	No	No	Hypo	20
31S.R	M 81y	Yes	Right 80%	Yes	No	Yes	Hypo	20

Complications after 48 h before discharge and 30th day

- **No significant local complications requiring surgery**
- **No clinical neurological events**
- **No new silent defects or anomalies at the 24h CT scan**

Protocol of Follow-up of RoadSaver Patient

- **Medical therapy :**
 - Clopidogrel & Aspirin during one month
 - Clopidogrel or Aspirin thereafter
 - Statins
- **2D Echo & Doppler :**
 - One Month
 - 6 month
- **Physician , cardiologist following the patient, and the patient**
 - 1month
 - 6month
 - One year

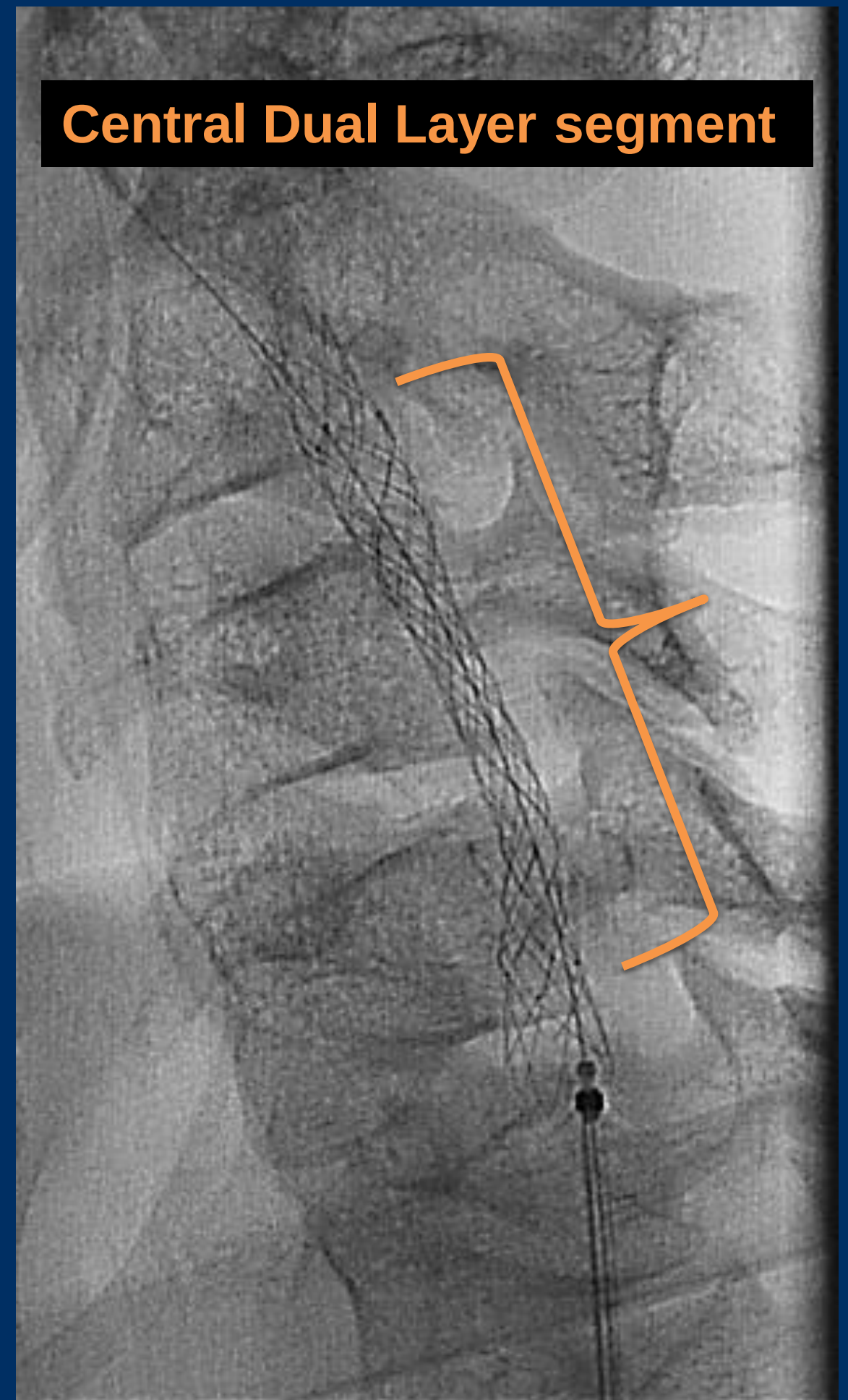
Follow –up for 33 patients with high risk carotid lesions treated by Micromesh Carotid Roadsaver Stent

- **Mean Follow up period: 16,7±6,6 months (23 to 6 months)**
 - 1 Male pt lost for FU : 76 y asymptomatic Pt
 - 1 Women 86 y died 7months after procedure (6m Echo : NI)
 - 1 Male 76y died one year after procedure (Heart Failure)
- **2D Echo Examination for all patients after 6 months**
 - 33 pts explored by echo
 - All External carotid artery patent
 - 4 External ostial carotid stenosed (2 new lesions)
 - **No Stented Carotid restenosis at 6 months**
- **No new neurological event during FU**

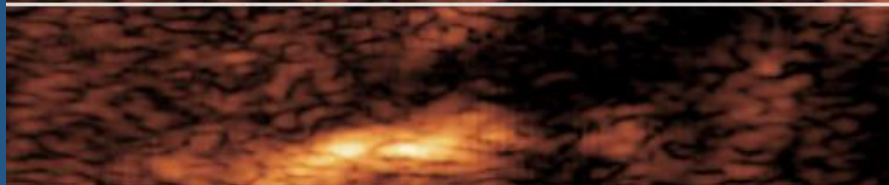
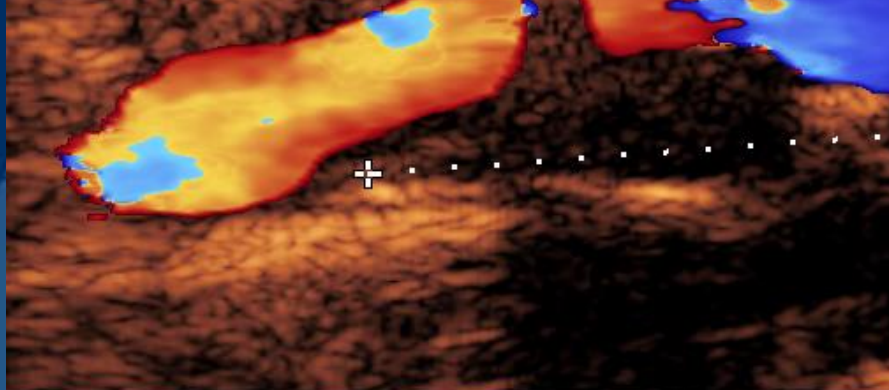
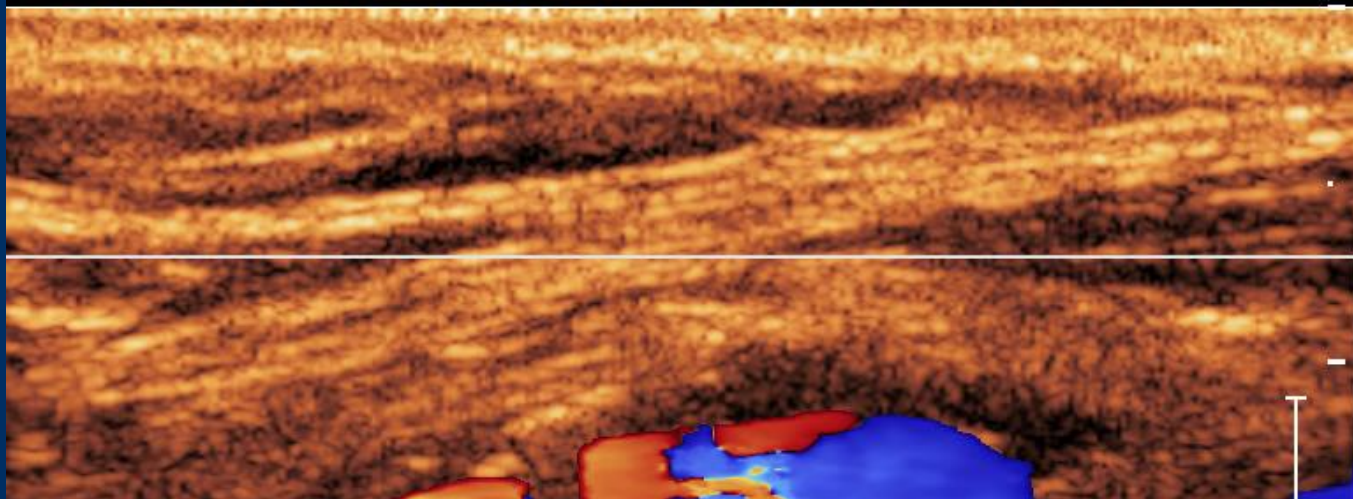
Pts)
(23 to 6 months , 16,7±6,6 months)

	Events	30 th days	6 months	1 year
Clinical	Delayed embolisation	no		
	Neurological events	no	no	No
Anatomical	External Carotid Occlusion	no	no	No
	Restenosis		no	no
Stent Geometry	Migration	no	no	no
	Compression	no	no	no
	Deformation			

Long LICA Lesion



C4 C3
+32
-32
cm/s



TOUSSAINT, GABRIEL
46151120140124

JPEG 2000 10:1 (lossy)\96 (Dérivé)

ITm0.2 IM 1.1
24/01/2014 11:15:48
20140124.111548

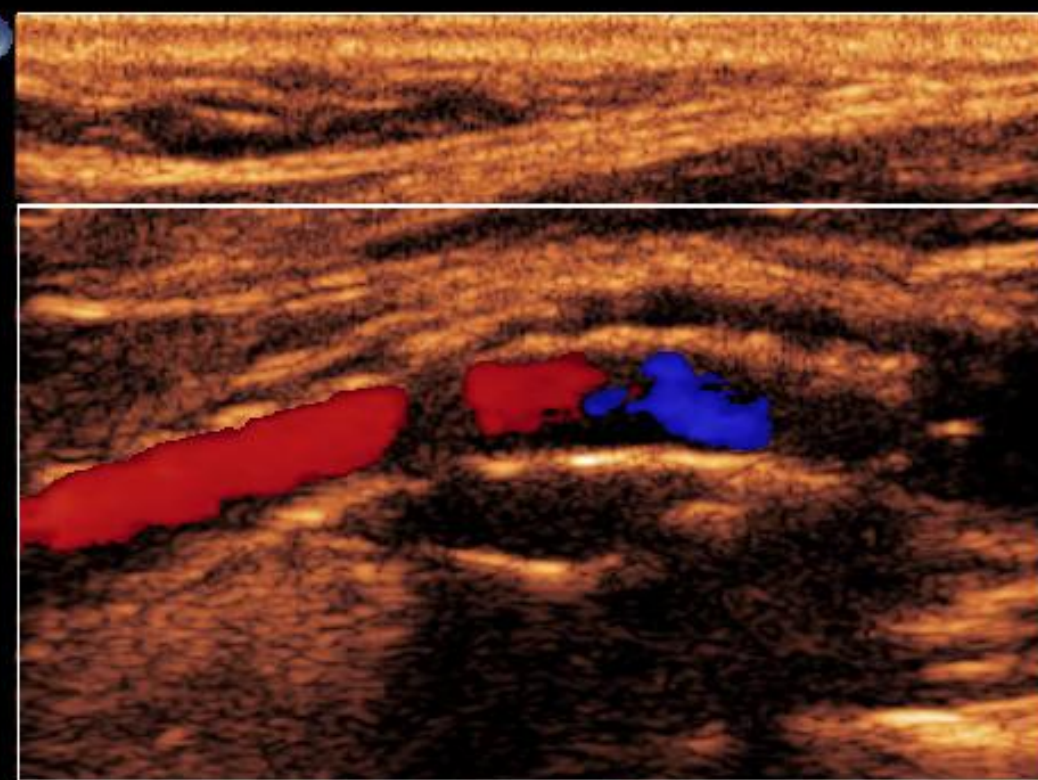
L11-3/ZC

SCP Cardiovasculaire

CI 22Hz
4.0cm

2D
65%
C 55
P Bas
Pén

Coul
71%
5.0MHz
FP Moy.
Moy



C4 C3
+32
-32
cm/s

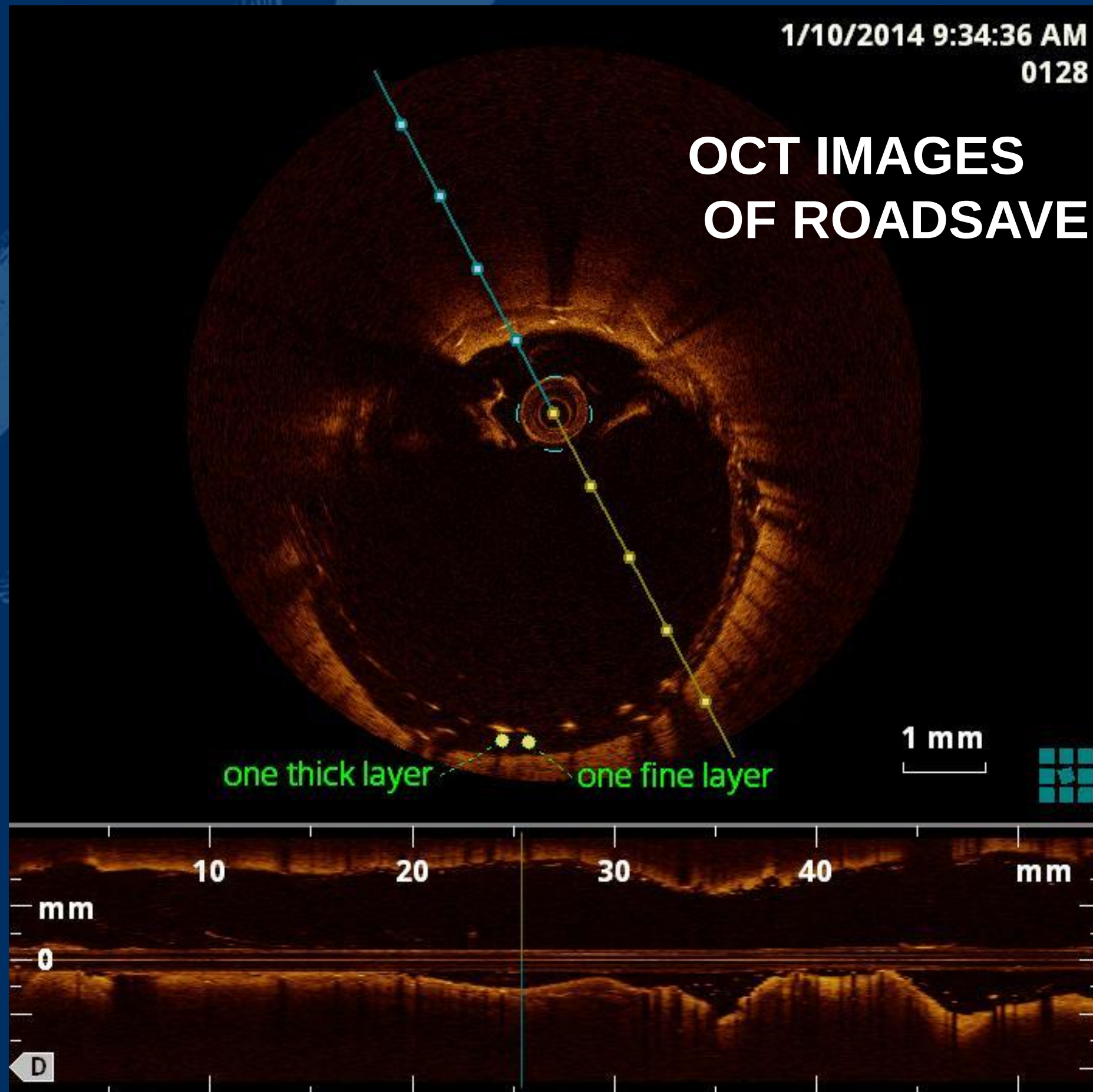
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*** bpm

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OCT IMAGES OF ROADSAYER



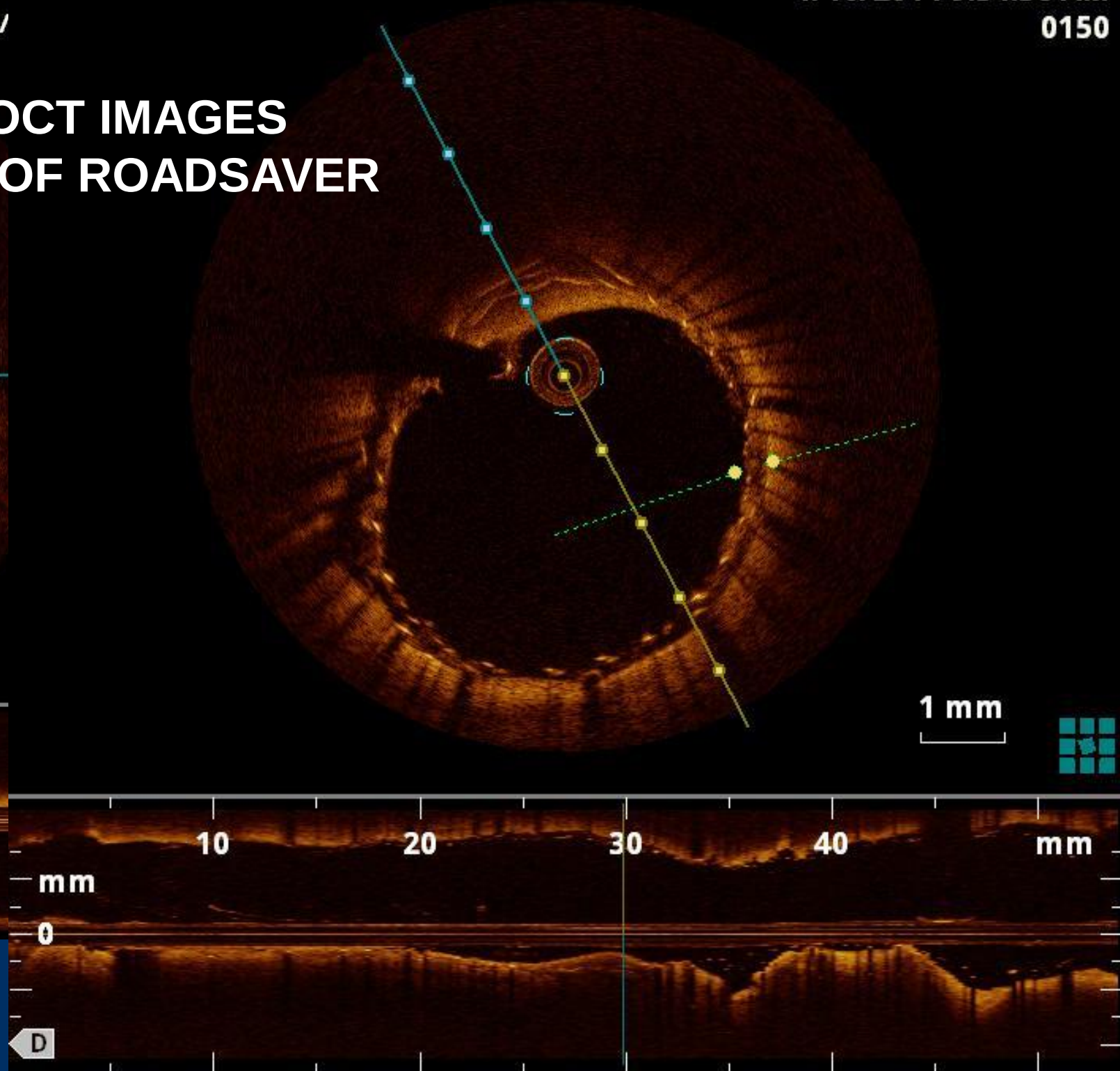
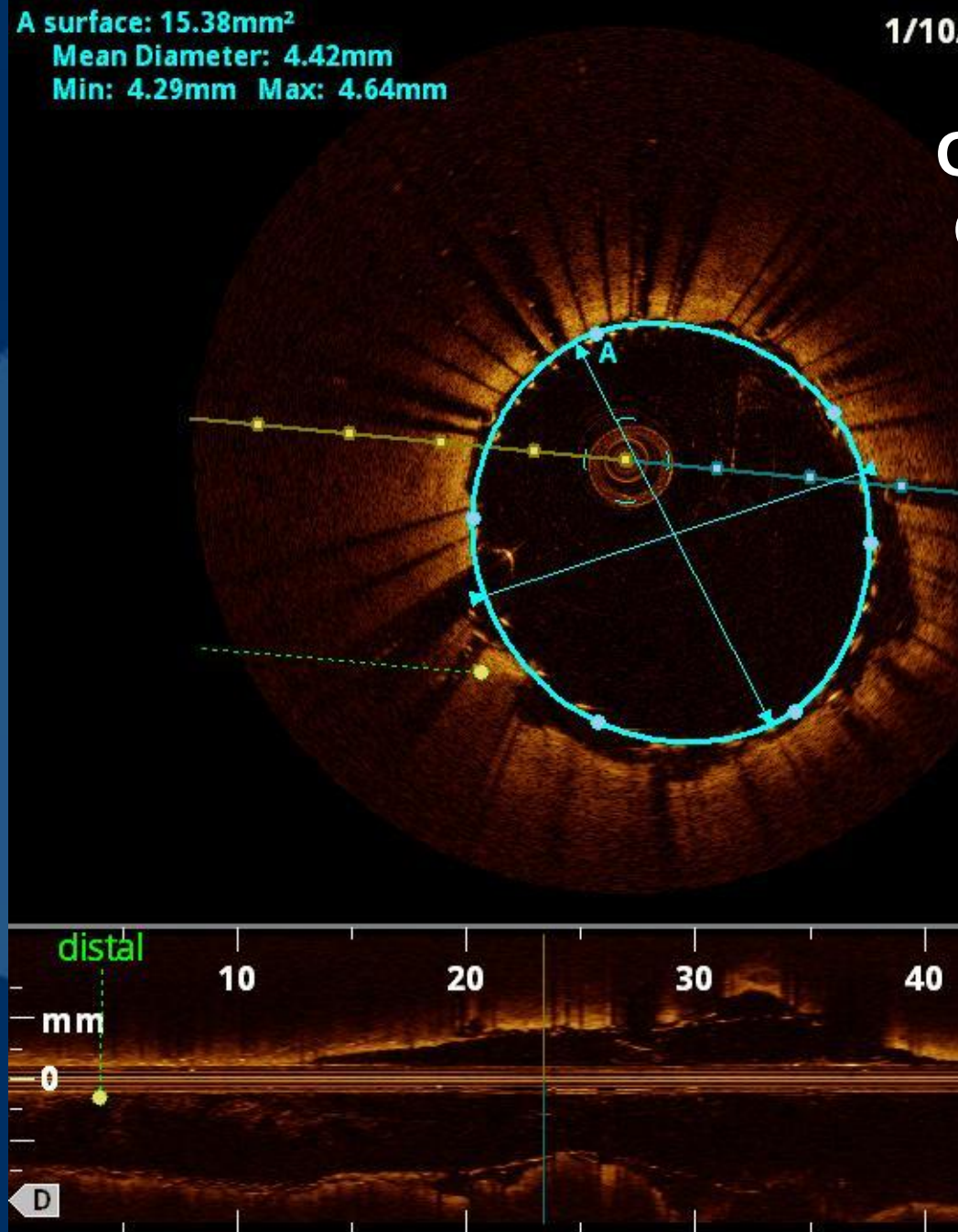
Harmonious deployment

A surface: 15.38mm²
Mean Diameter: 4.42mm
Min: 4.29mm Max: 4.64mm

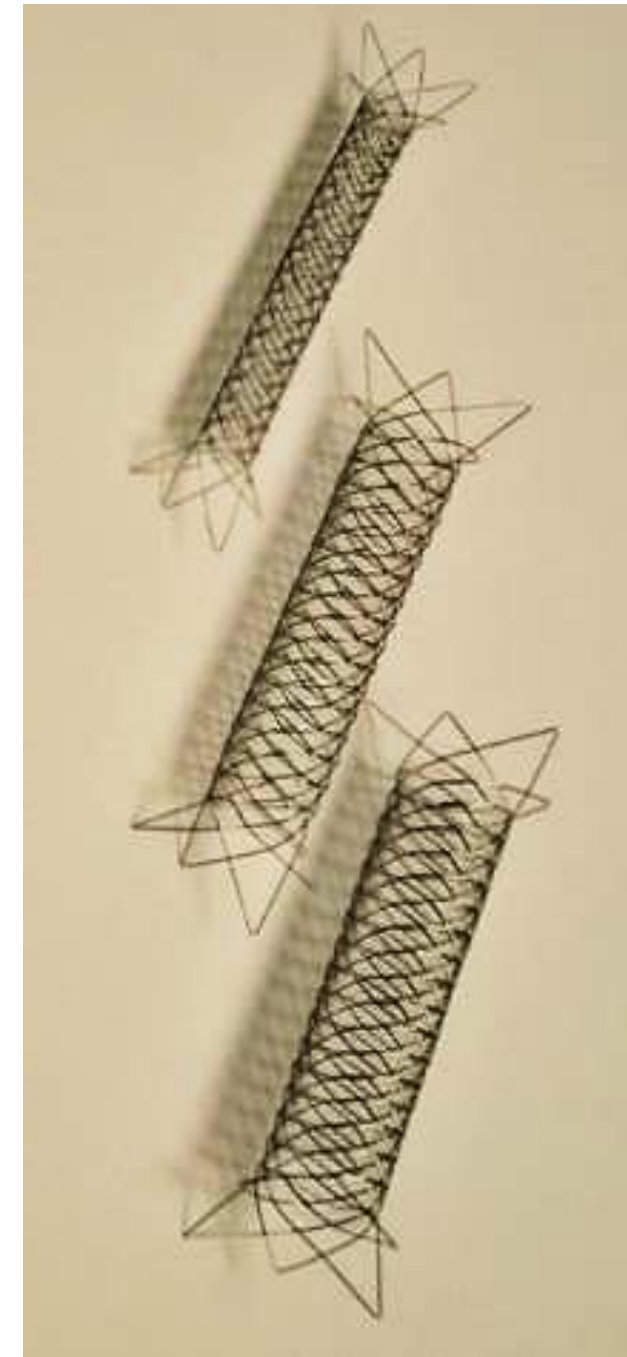
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OCT IMAGES OF ROADSAYER

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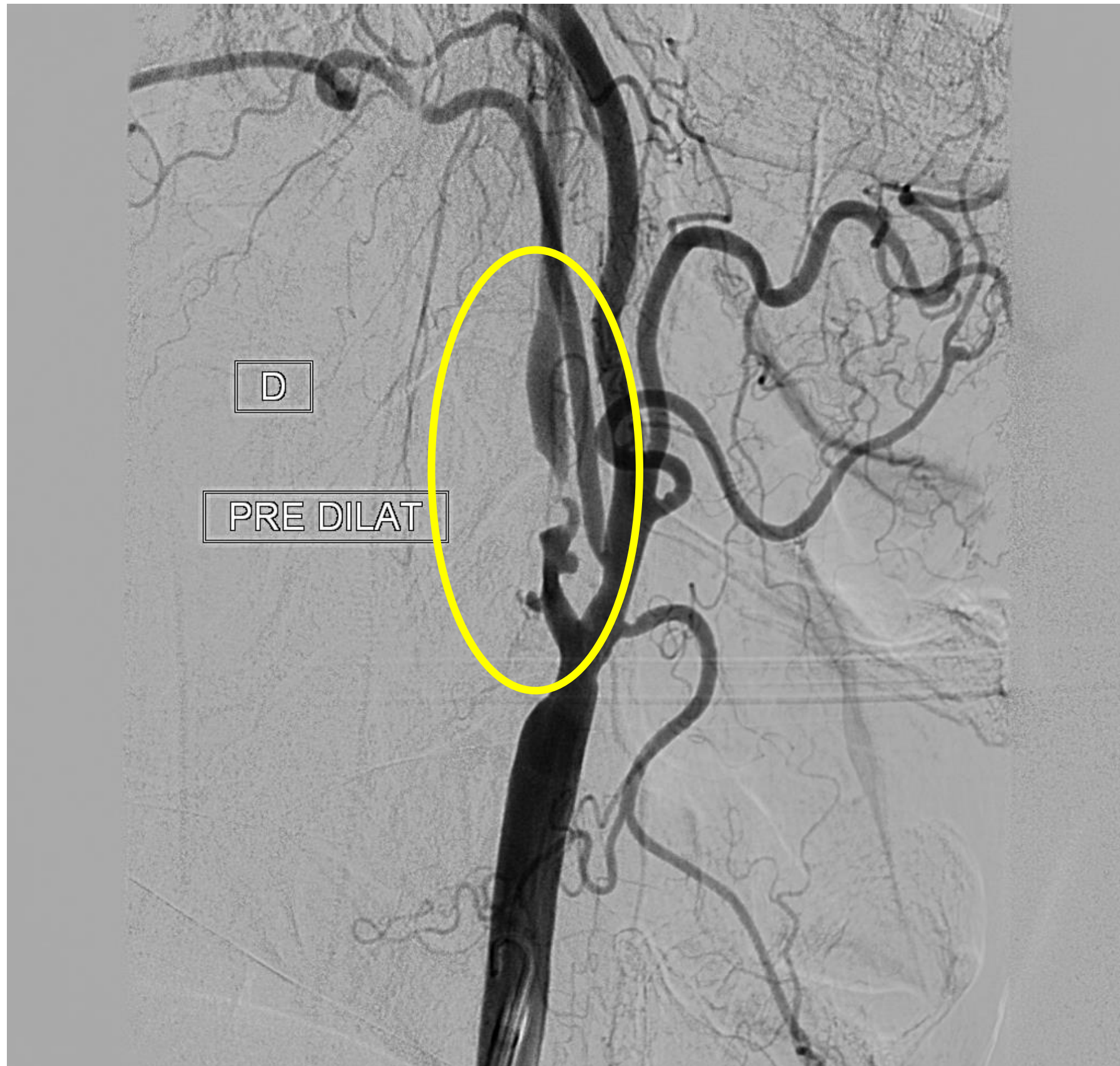


83 y ,male , Right Internal asymptomatic carotid stenosis



Roadsaver Stent

Severe Symptomatic RICA stenosis with **multiple ulcerations**



After ROADSAYER Stent 10x30mm placed under filter protection





Symptomatic chronic Dissection & Ulcerated RICA Stenosis



P2

N5
LICA



N 5 Final Result

Rot +26°
Ang -1°
FD 19 cm

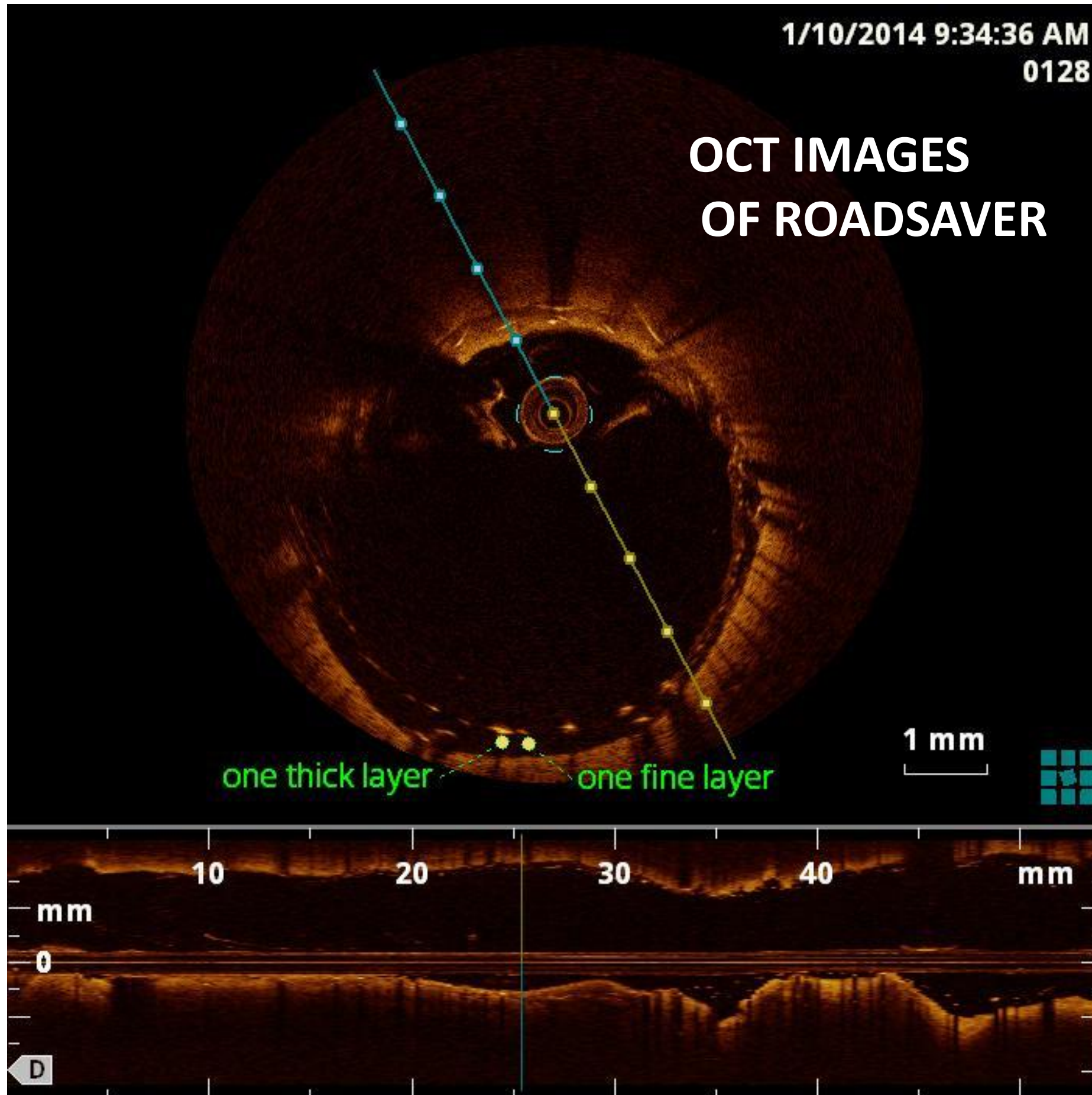


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3:33
14:45:41

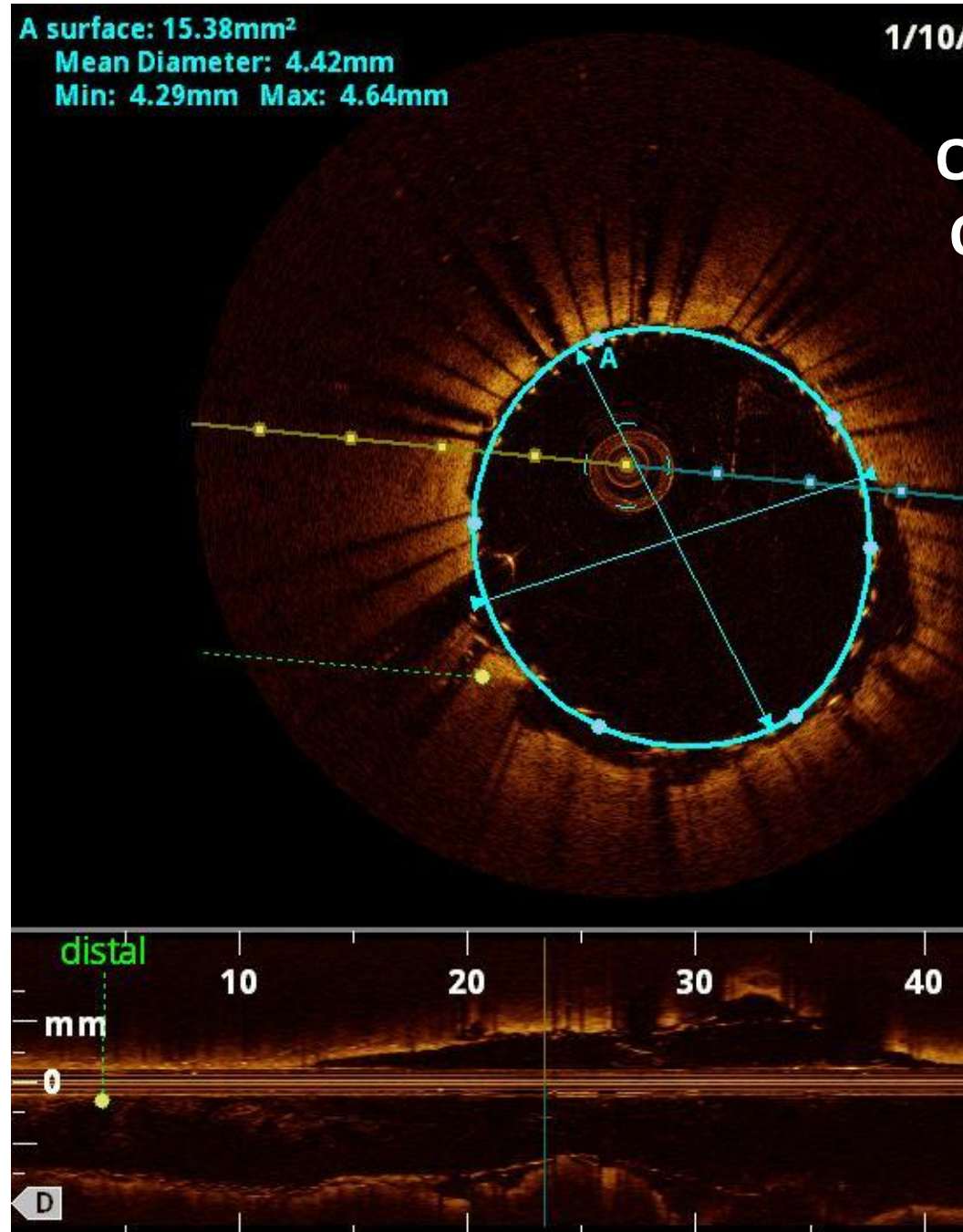


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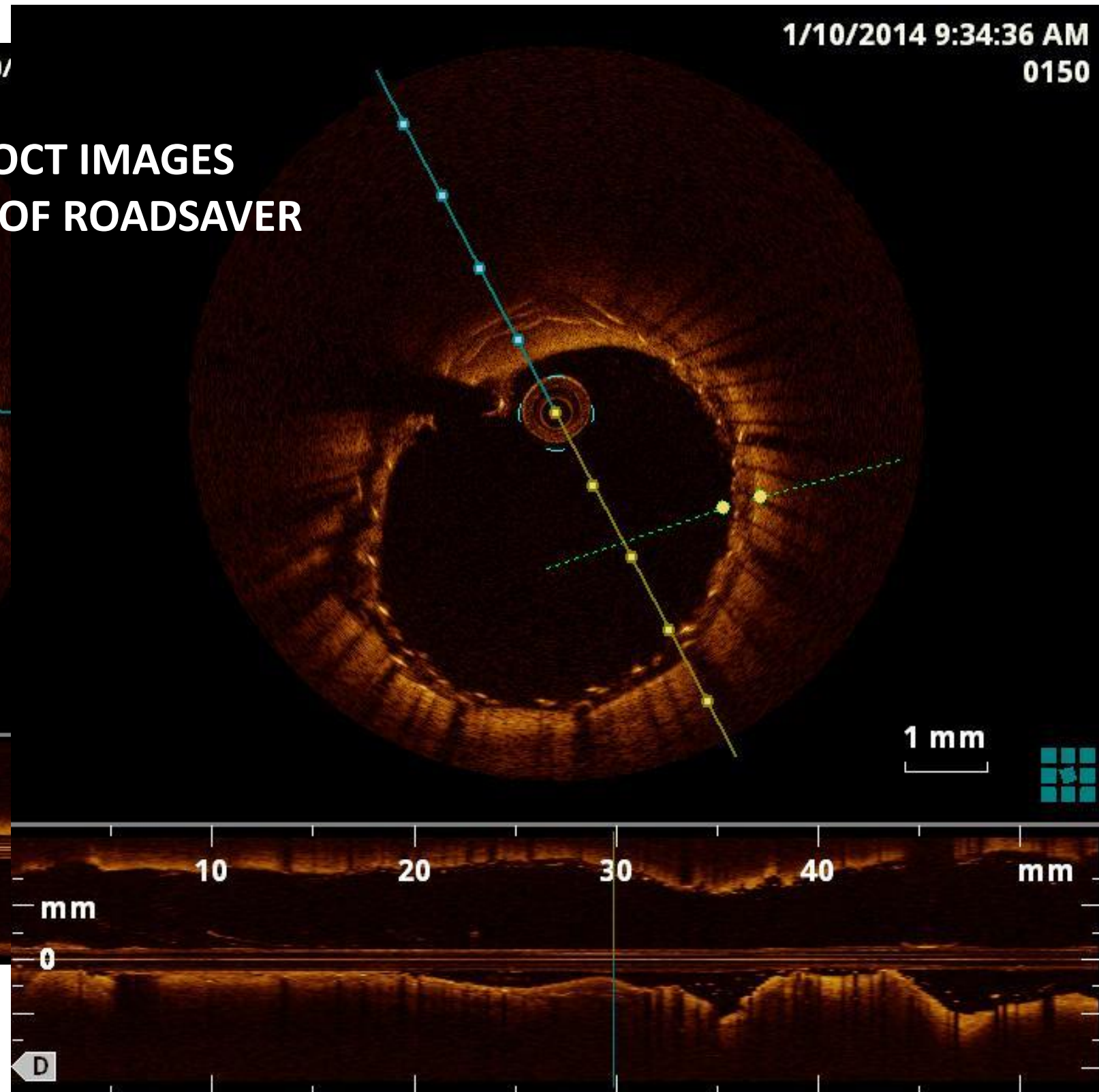
OCT IMAGES OF ROADSAVER



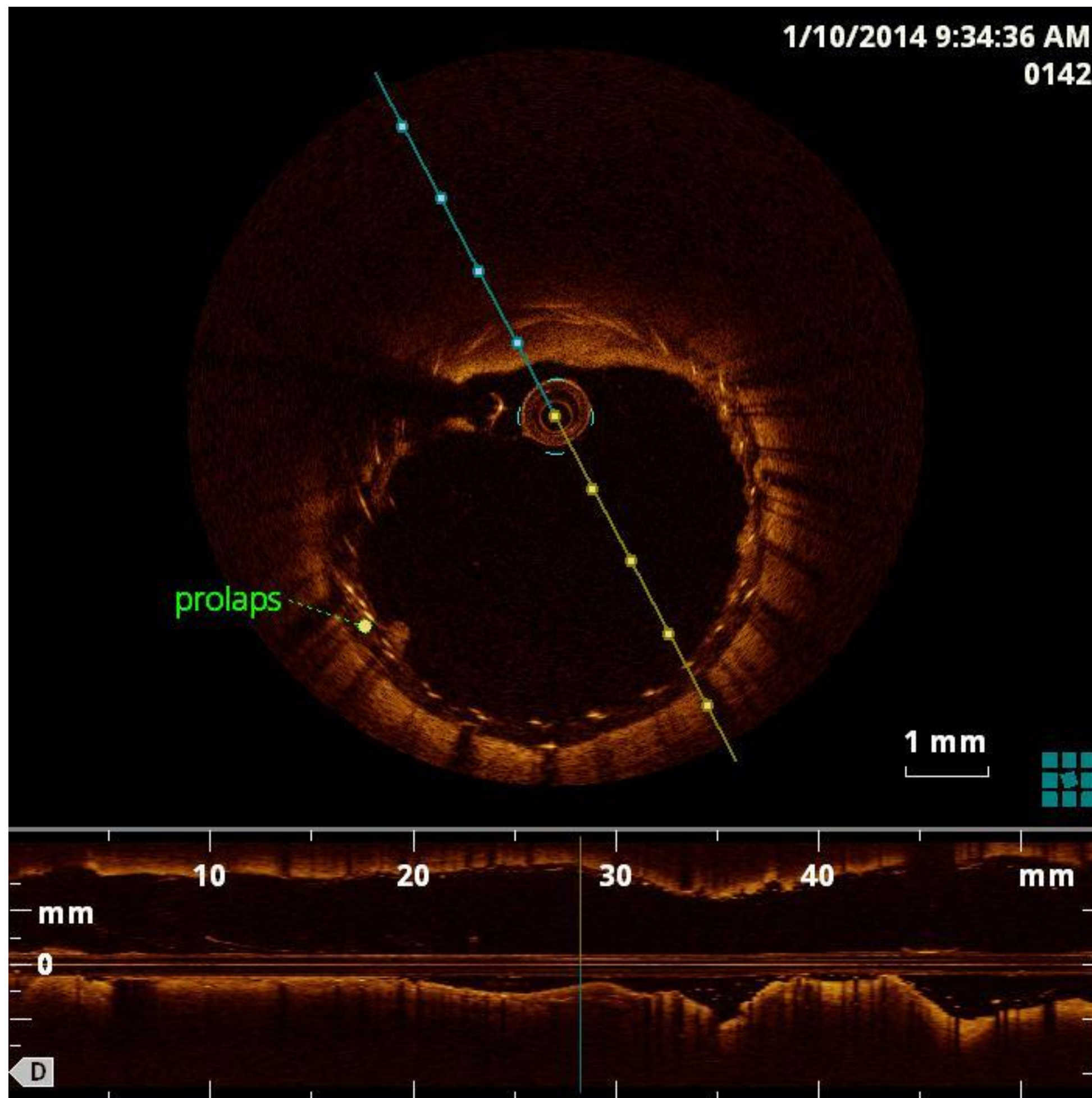
Harmonious deployment



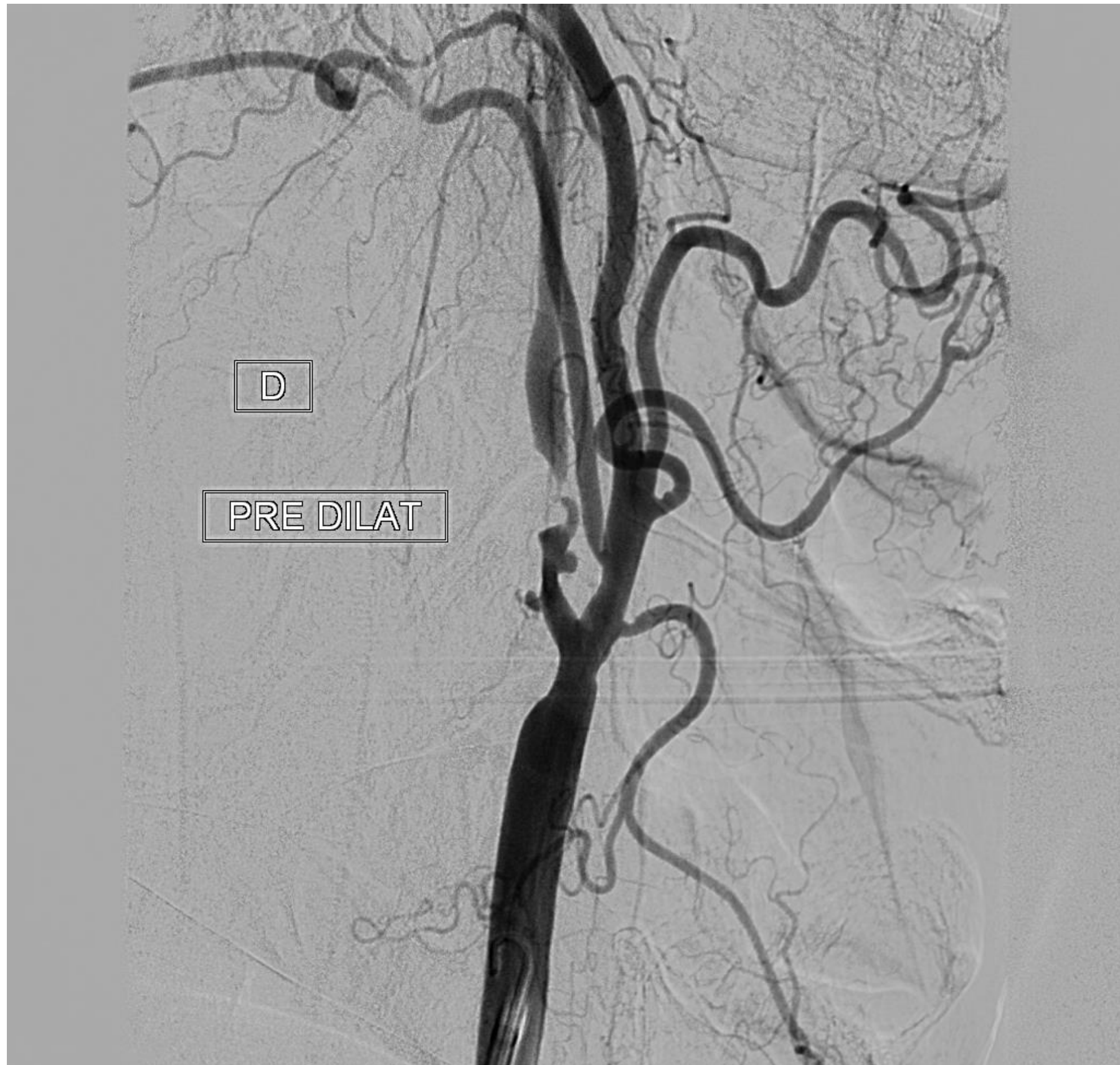
OCT IMAGES
OF ROADSAYER



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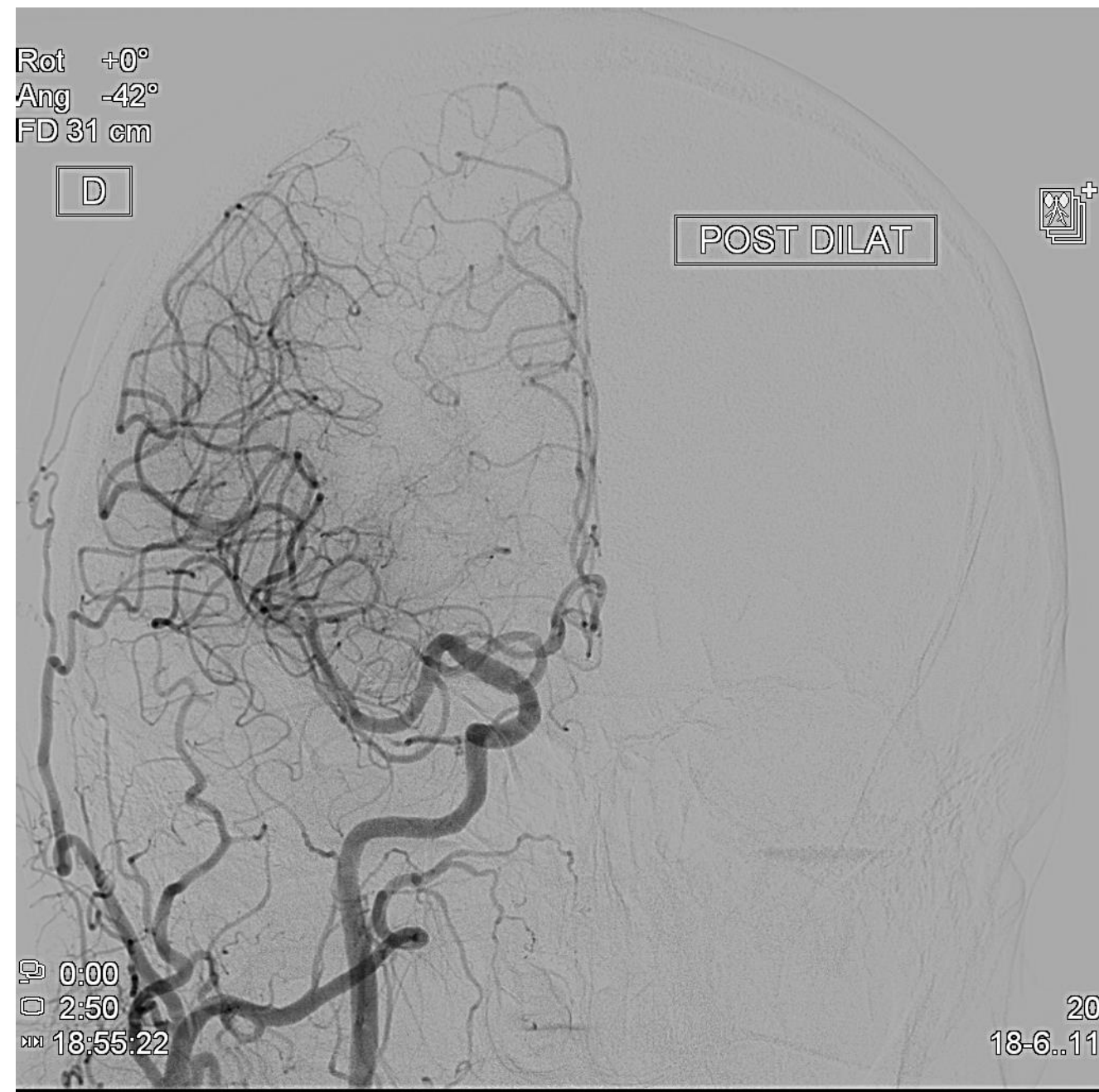


Severe Symptomatic RICA stenosis with multiple ulcerations



After ROADSAYER Stent 10x30mm placed under filter protection







Symptomatic chronic Dissection & Ulcerated RICA Stenosis



DEVICES USED

MICROCATHETER FINECROSS 1.8 Fr - Terumo

BRITE 8F 23 cm - Cordis

BRITE 9F 23 cm - Cordis

LAUNCHER 8F - Medtronic

STIFF 0.035 - Terumo

V21 0.018 X 300 cm - Boston Scientific

BMW 0.014 HYDRO 3CM EXCH (SING) - Abbott

HT PROGRESS 40 190 cm - Abbott

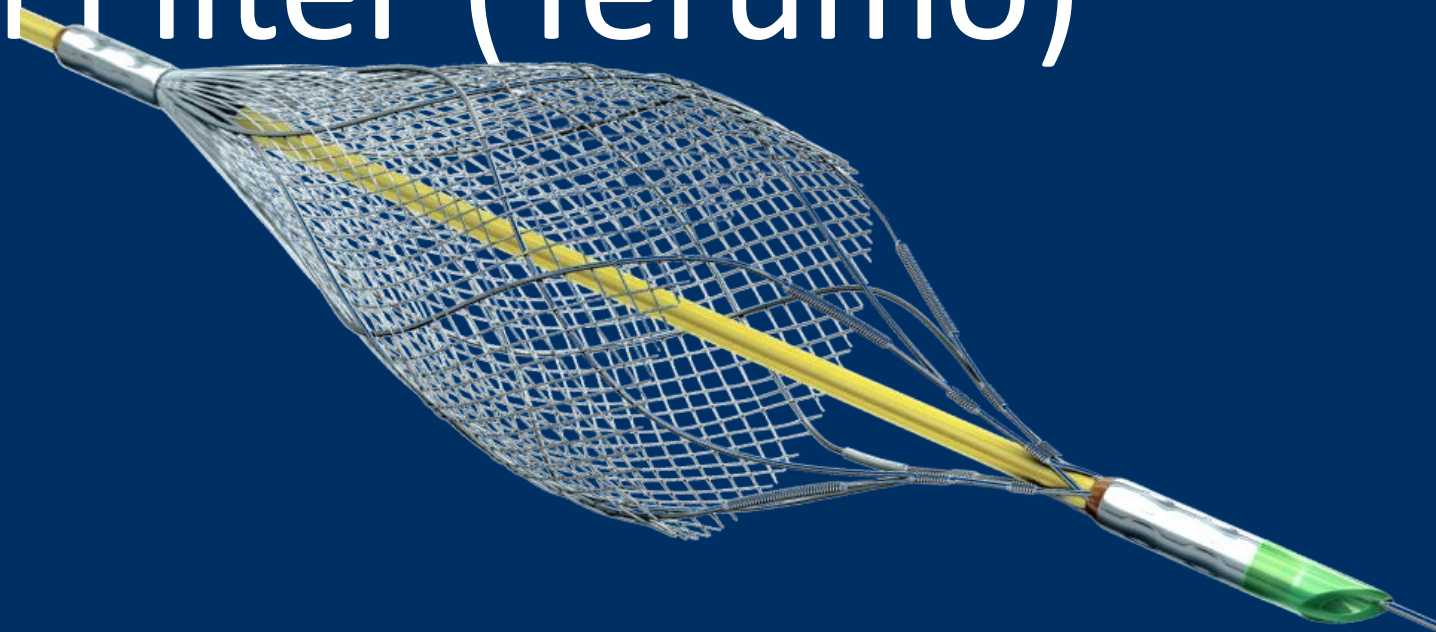
FIELDER FC 300cm - Terumo

Nitinol Micromesh Technology for temporary Embolic Protection

Novel, Concentric, Nitinol
Micromesh Embolic Protection
Device

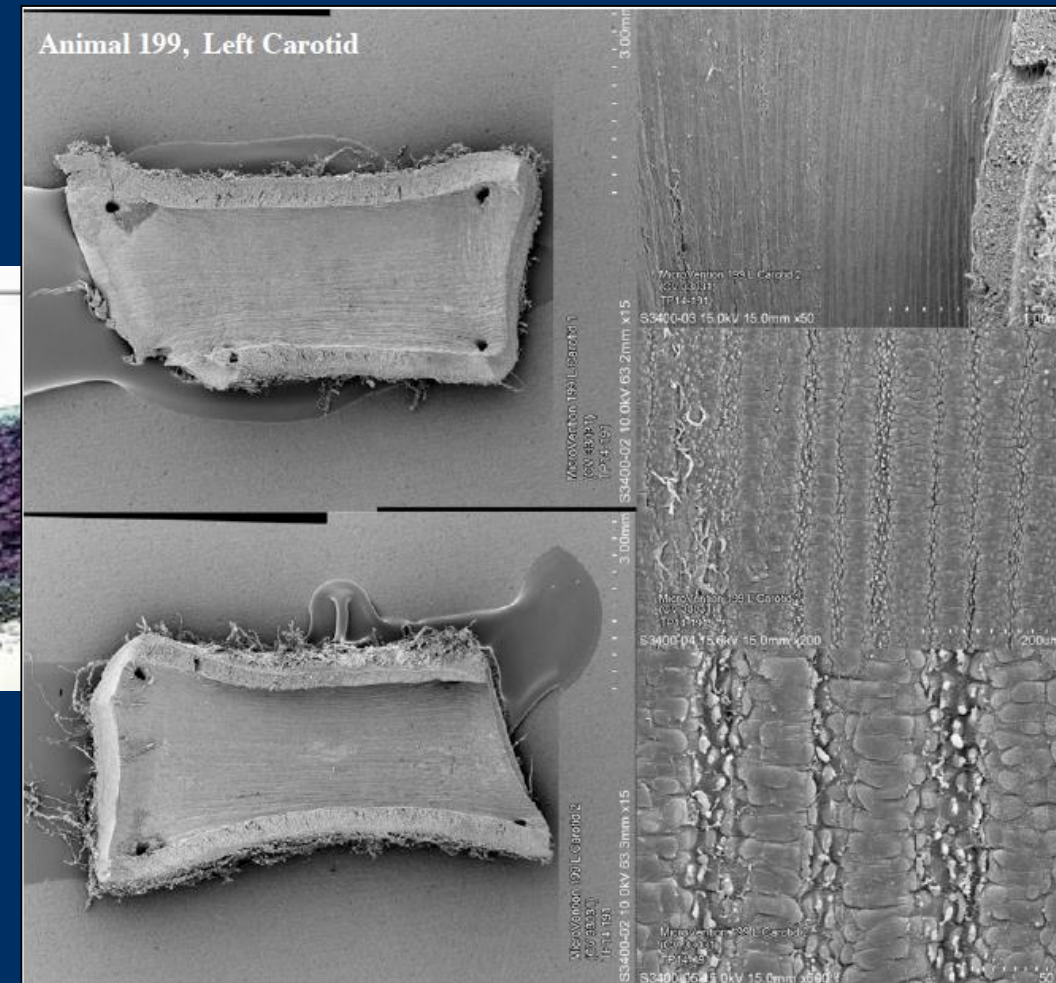
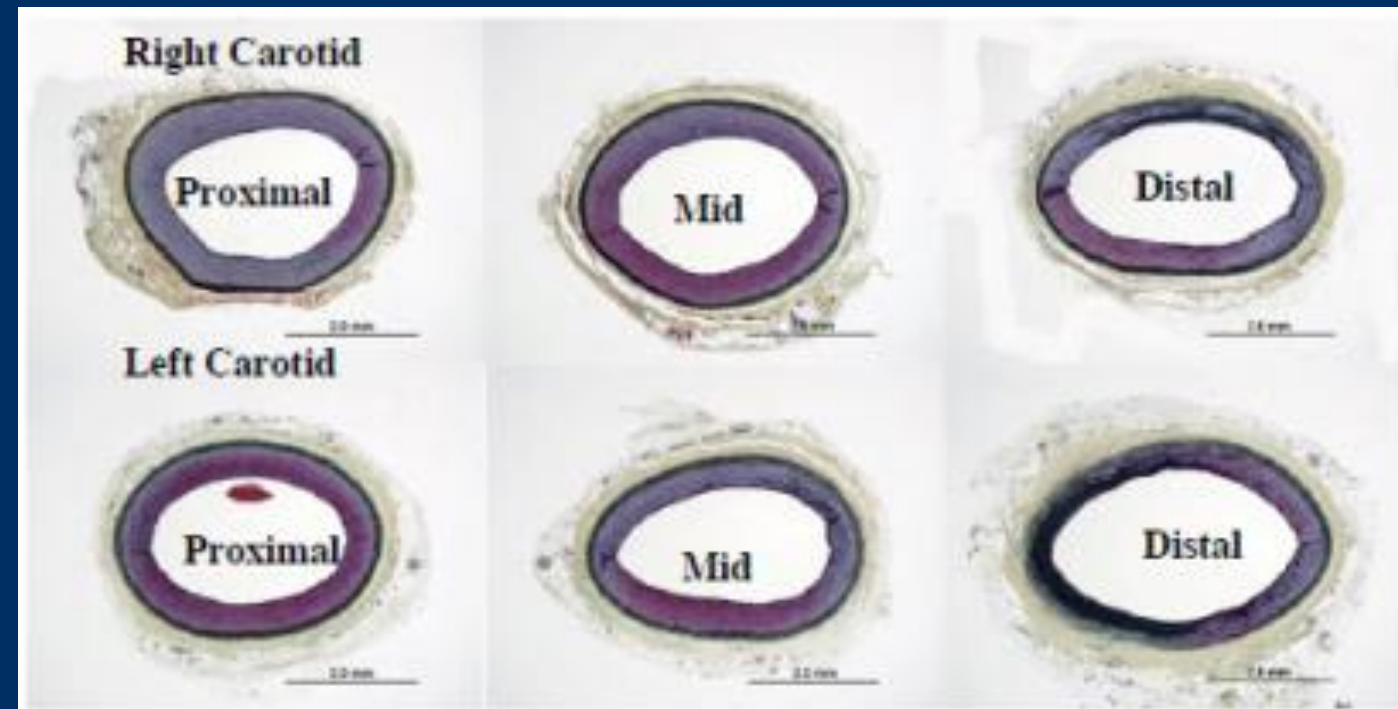
Nanoparasol Filter (Terumo)

- Concentric Nitinol micromesh filter with proximal Tantalum markers
- Avg. pore size 150 μ m
- 2 sizes
 - Large: $\varnothing$ 4.6 – 6.5mm
 - Small: $\varnothing$ 3.0 – 4.5 mm
- 3.5Fr RX Delivery catheter
 - Delivery via 0.014" guide wire of choice
 - Peel-away catheter
- 5Fr RX Retrieval Catheter



30-days Chronic Animal Results

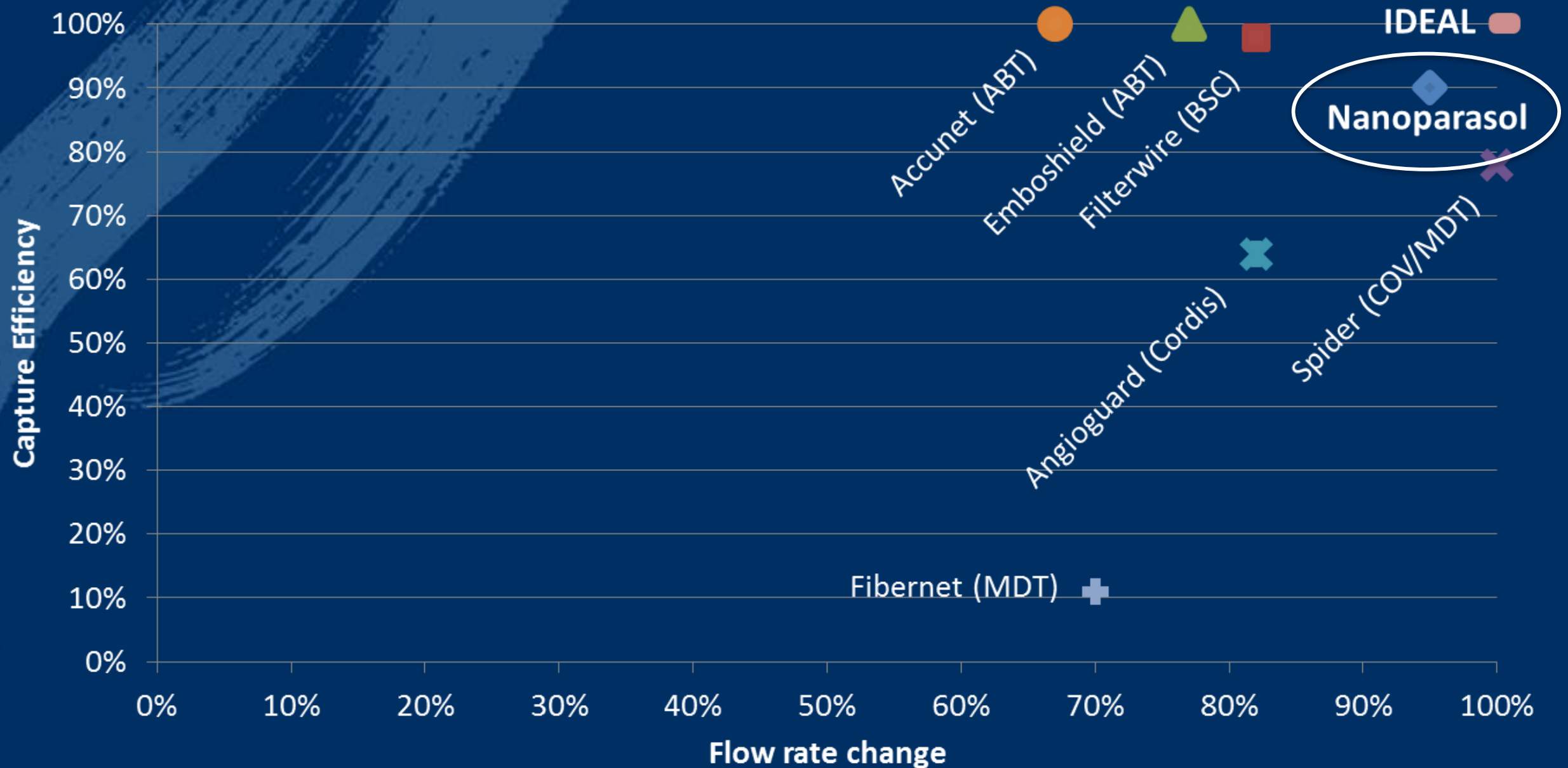
Sample Number	Medial Injury Score	Mean Intima/Medial Fibrin Score	Mean Intima/Medial Inflammation Score	Mean Adventitial Inflammation Score
199 Left Carotid	0.00	0.00	0.00	0.00
199 Right Carotid	0.00	0.00	0.00	0.00
199 Left Subclavian	0.00	0.00	0.00	0.00
199 Right Subclavian	0.00	0.00	0.00	0.00
299 Left Carotid	0.00	0.00	0.00	0.33
299 Right Carotid	0.00	0.00	0.00	0.00
299 Left Subclavian	0.00	0.00	0.00	0.00
299 Right Subclavian	0.00	0.00	0.00	0.00
300 Left Carotid	0.00	0.00	0.00	0.00
300 Right Carotid	0.33	0.00	0.00	0.00
300 Left Subclavian	0.00	0.00	0.00	0.00
300 Right Subclavian	0.00	0.00	0.00	0.00
308 Left Carotid	0.00	0.00	0.00	0.00
308 Right Carotid	0.00	0.00	0.00	0.00
308 Left Subclavian	0.00	0.00	0.00	0.00
308 Right Subclavian	0.00	0.00	0.00	0.00
Mean±SD	0.021±0.083	0.00±0.00	0.00±0.00	0.021±0.083



Nanoparasol used in Porcine Models 30-days Chronic Results

- No Inflammation
- No Vessel Injury

Capture Efficiency vs. Flow Change





- **Nitinol Micromesh Technology provides unmatched flexibility for versatile embolic protection purposes**
- **The use of a dual layer micromesh in carotid stents demonstrated promising safety and efficiency results**
- **The pre-clinical testing of the novel concentric Nitinol micromesh filter appears to be an interesting development, which needs to be clinically evaluated**

CONCLUSIONS

