



Innovations in Cerebrovascular Science Conference 2015

FLOW DIVERSION FOR POSTERIOR CIRCULATION THE SURPASS EXPERIENCE

Innovations in Cerebrovascular
Science Conference
March 11-12, 2016

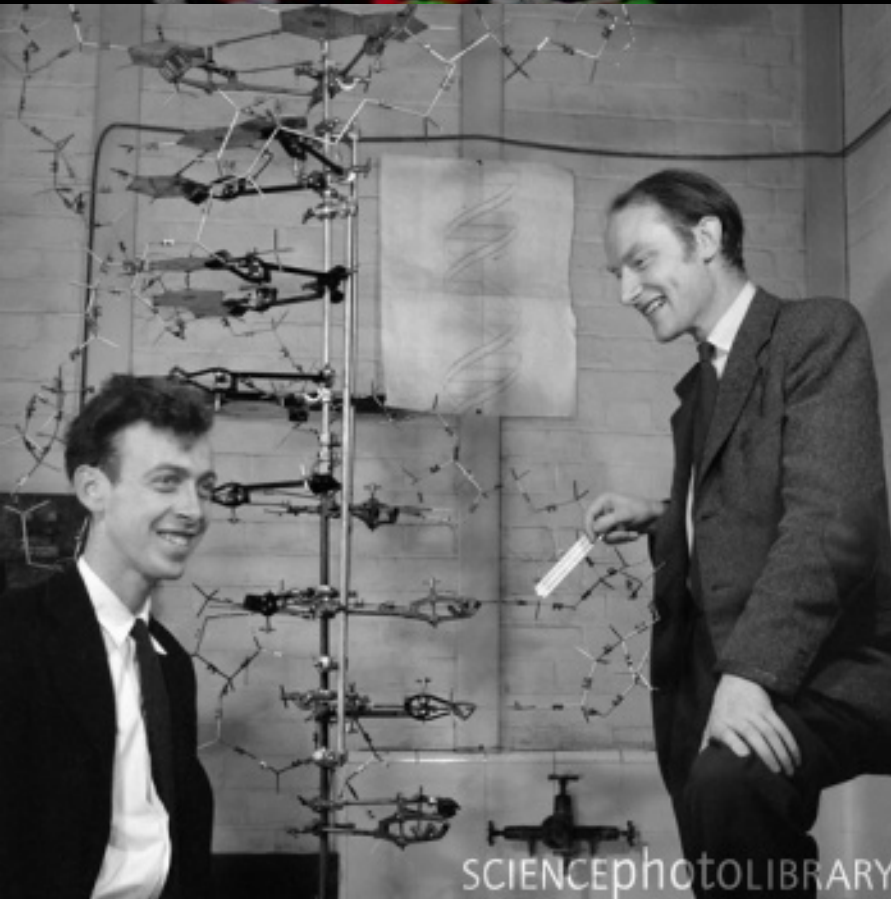
Ponte Vedra Inn & Club



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Department of Radiology, Neurology and Neurosurgery
Division Neuroimaging and Intervention
University of Massachusetts Medical School



Watson and Crick Fire and Mello



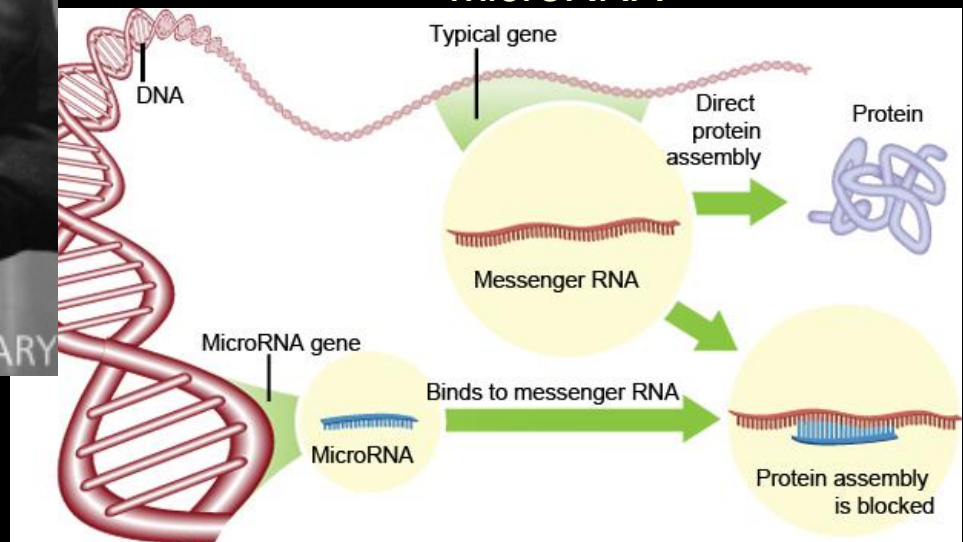
SCIENCEPHOTOLIBRARY



Craig
Mello
and S.
Fire
Nobel
Prize
Physiol



MicroRNA



Playful Mind

Collaboration and History

DISCLOSURES

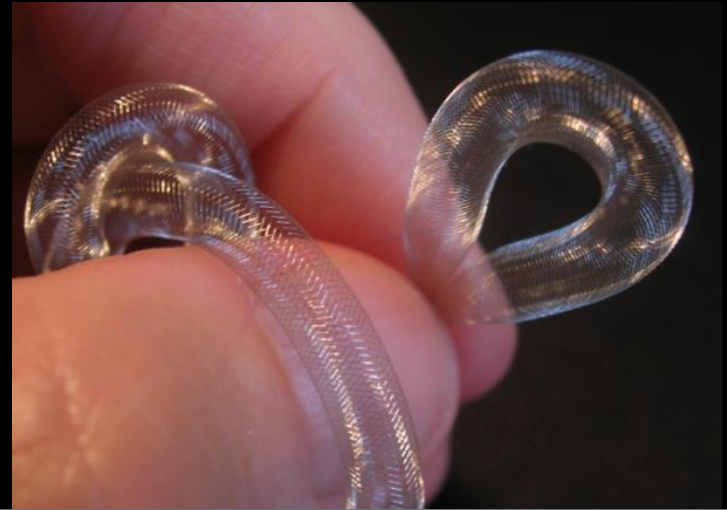
- Stryker Neurovascular (Consultant)
- Codman J&J (Consultant)
- InNeuroco (Stockholder, co-founder, CMO)
- Pulsar (Bridge loan)
- Philips (MAB, Research Grant, Equipment support)
- Postgraduate Course Harvard Medical School (Speaker)
- Baptist Hospital, Miami, Florida (Speaker)
- NIH (ROI 1R21EB007767-01; 5R01NS045753-04)
- 1-R21-NS061132-01A1

Surpass Study Group

- Christian Taschner, Julia Bernardy; Freiburg, Germany
- Joost de Vries, Jeroen Boogaarts; Nijmegen, The Netherlands
- Nobuyuki Sakai, Kobe, Japan
- Pedro Lylyk, Buenos Aires, Argentina
- Alessandra Biondi, Besancon, France
- Istvan Szikora, Budapest, Hungary
- Bernd Eckert, Hamburg, Germany
- Bruening, Hamburg, Germany
- Ralph Siekmann, Kassel, Germany
- Peter Kan, Tampa, Florida, USA
- Patrick Brouwer, Rotterdam, The Netherlands
- Ajay K. Wakhloo, Ajit S. Puri, Matthew Gounis; Worcester, USA

Surpass Flow Diverter

- Self-expandable braided device
- 48 - 96 Chrome-Cobalt wires
- FD preloaded in an over-the-wire microcatheter delivery system
- Navigated over 0.014" microwire



DELIVERY SYSTEM



DETAIL A

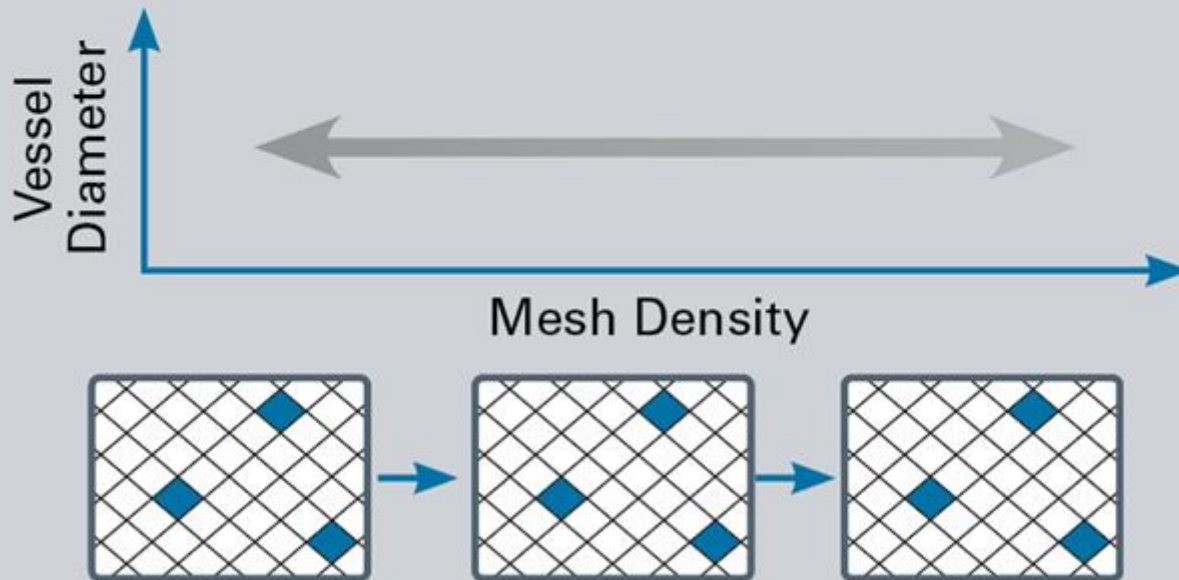


Available Sizes

Length (mm)	Diameter: 2mm	Diameter: 3mm	Diameter: 4mm	Diameter: 5mm
12mm	✓			
15mm	✓	✓	✓	
20mm	✓	✓	✓	✓
25mm		✓	✓	✓
30mm			✓	✓
40mm			✓	✓
50mm			✓	✓

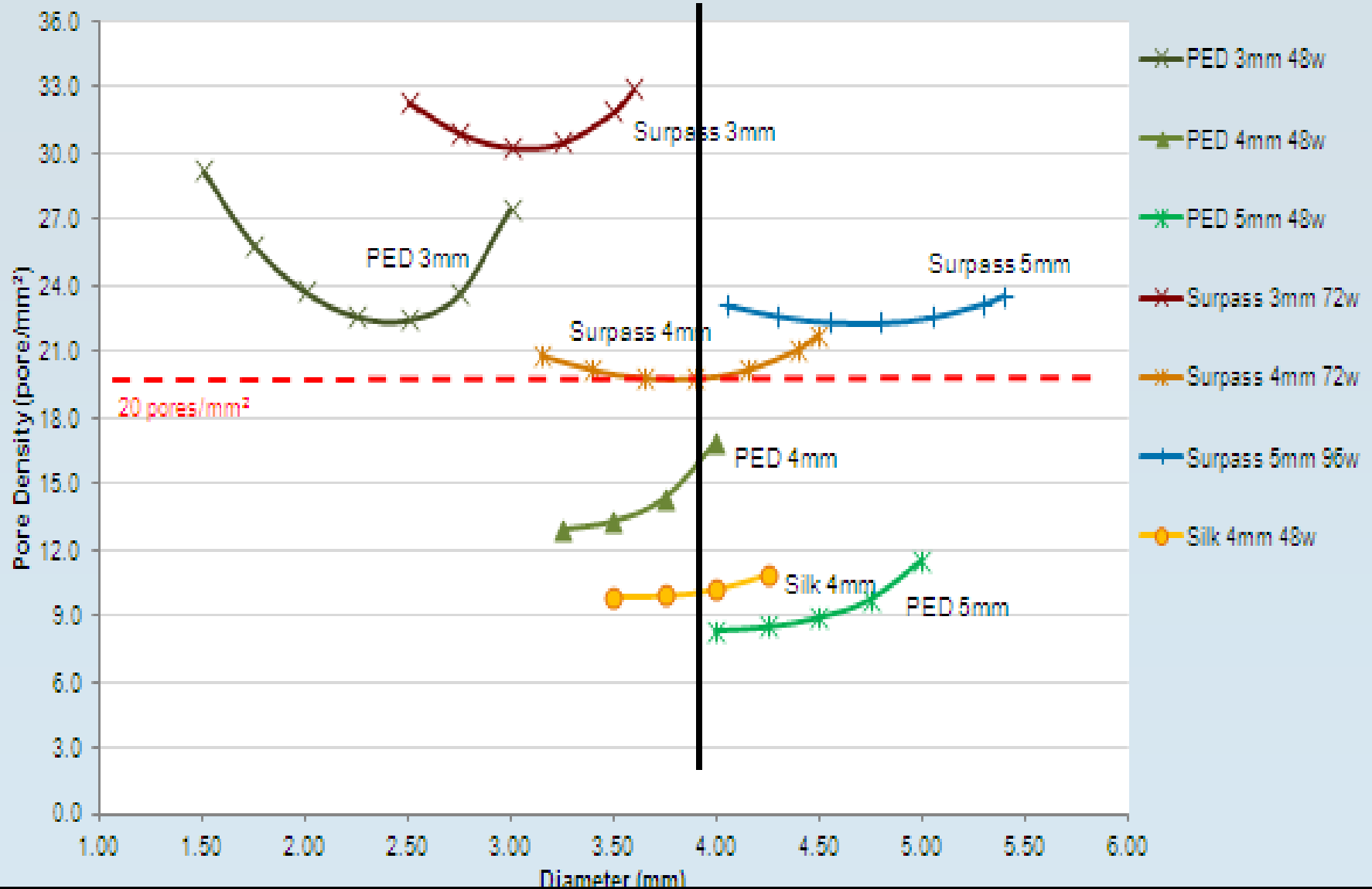
Uniform Mesh Density

72 Wire Braid (Surpass™)



Currently available Flow Diverters

Mesh Density

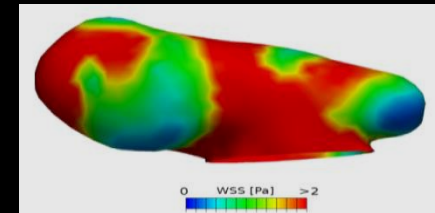
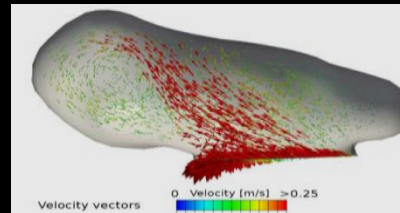


Flow Diversion

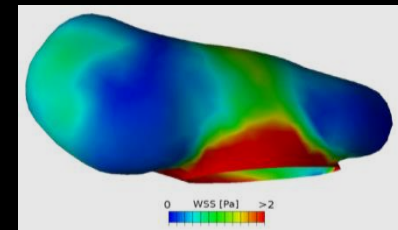
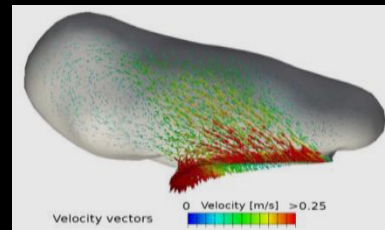
Why is *Mesh Density* important?

- Mesh density and braid angle affect fluid velocity
- Increasing wire count from 48 to 72
 - Reduces aneurysm inflow rate by **24%**
 - Shrinks the impact zone by almost **90%**

48 Wire Braid



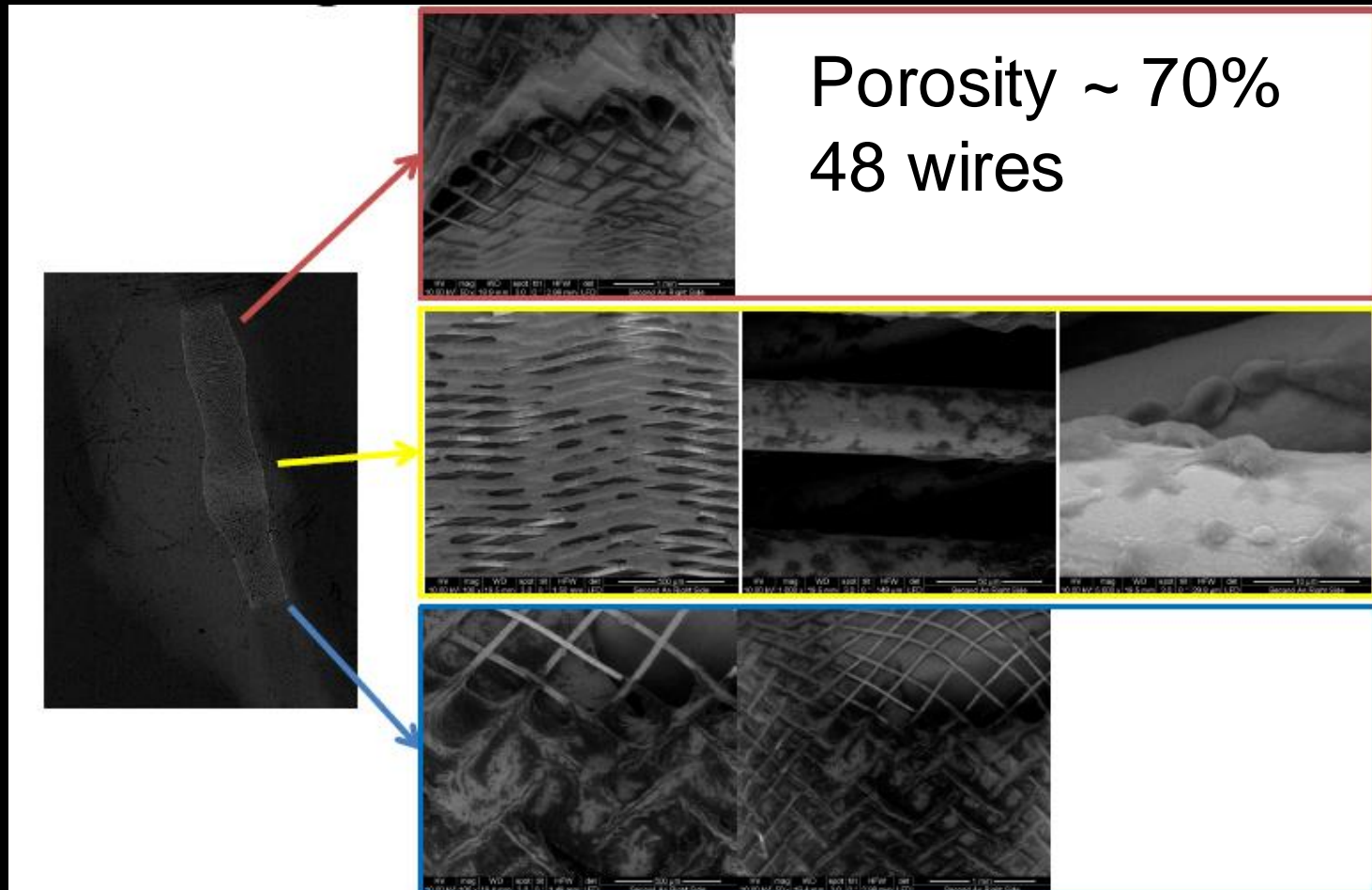
72 Wire Braid (Surpass™)



	Inflow Rate (mL/S)	Aneurysmal Inflow	Turnover Time	Impact Zone (mm ² / %)
Before Stenting	2.241	42%	0.099s	137 / 74%
48 wires 33 microns	1.302	25%	0.171s	92 / 50%
72 wires 32 microns	0.991	19%	0.217s	10 / 6%
96 wires 32 microns	0.779	15%	0.277s	10 / 6%

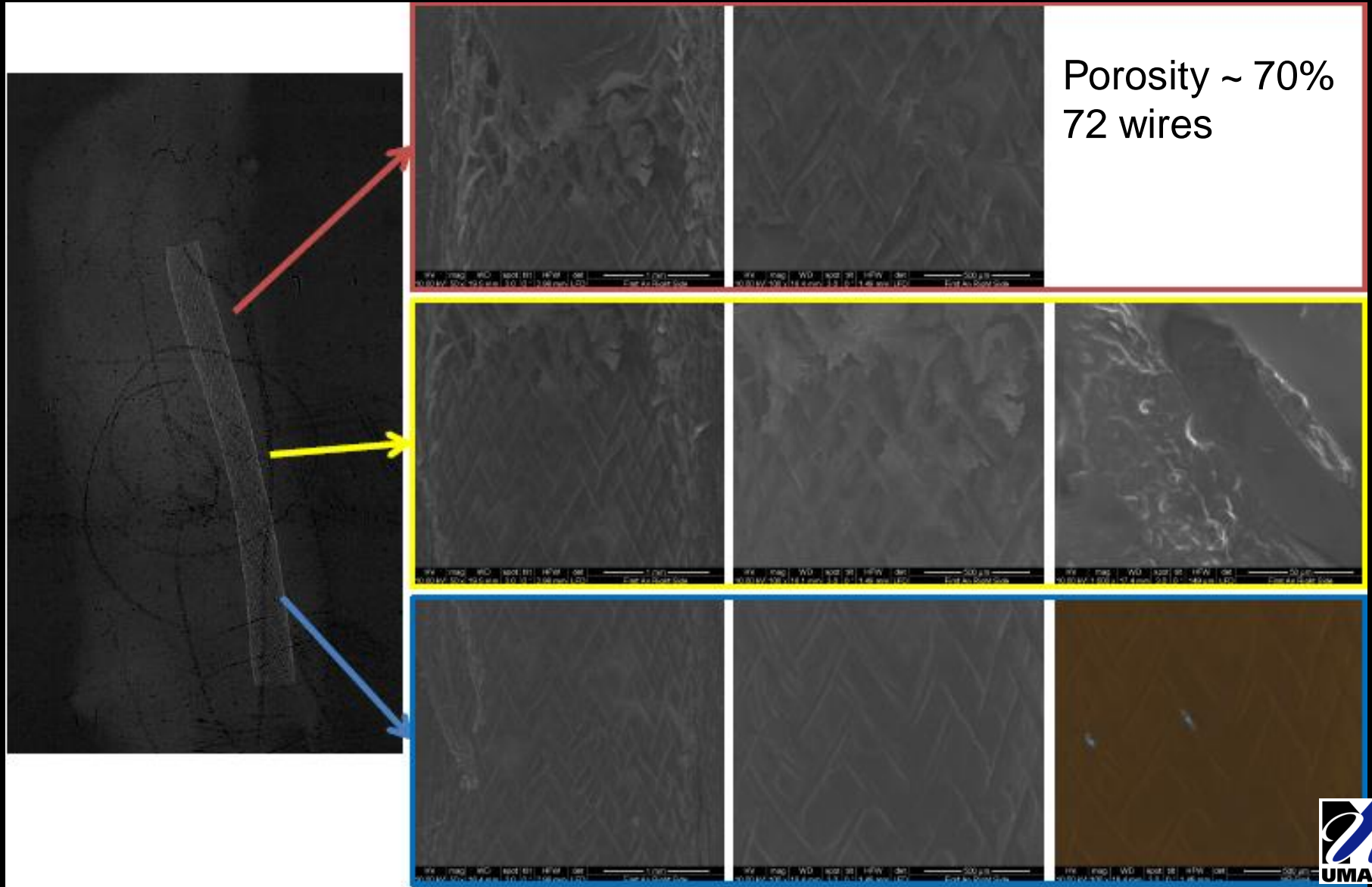
In Situ Tissue Engineering

Canine, side-wall aneurysm – **7 days** post FD implant



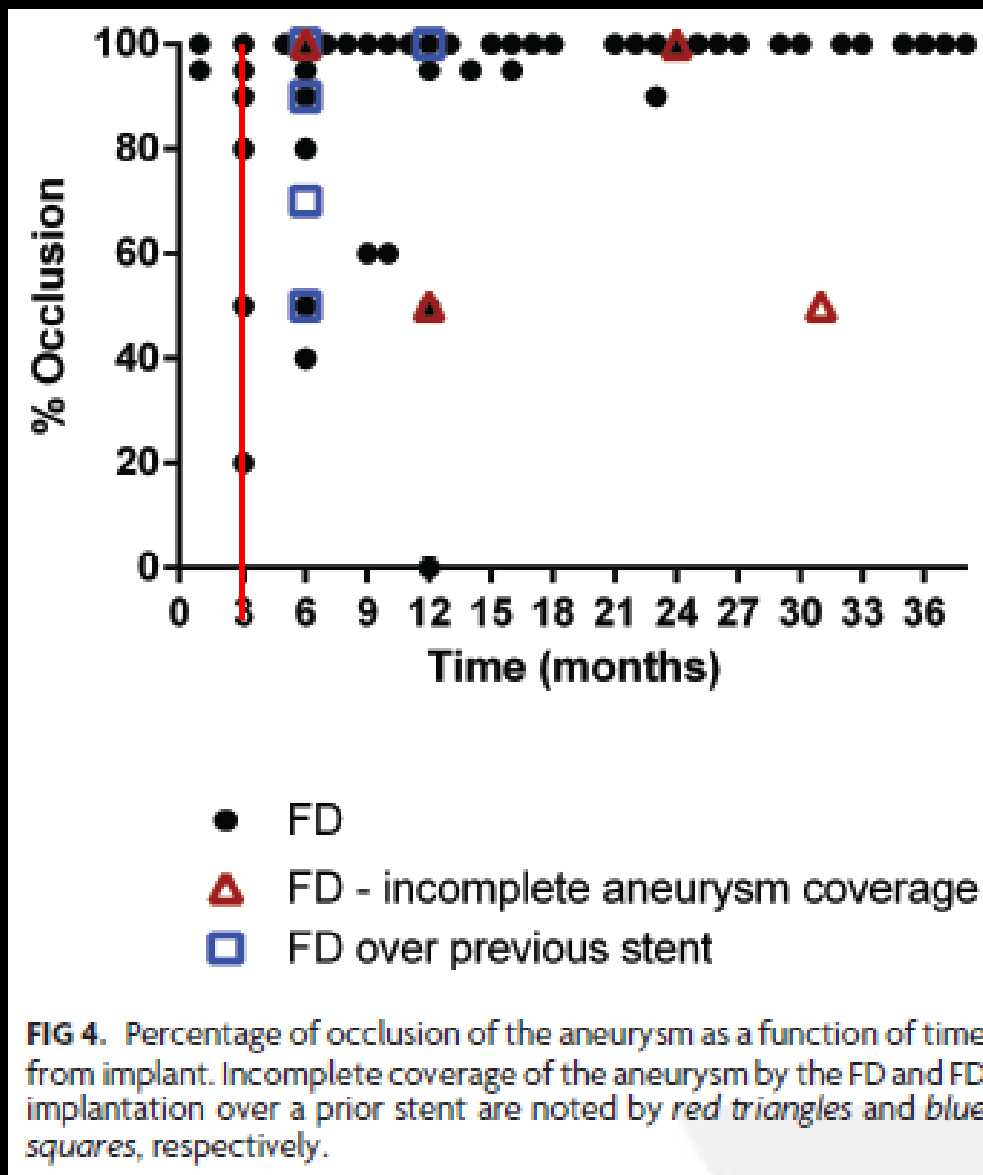
In Situ Tissue Engineering

Canine, side-wall aneurysm – **7 days** post FD implant



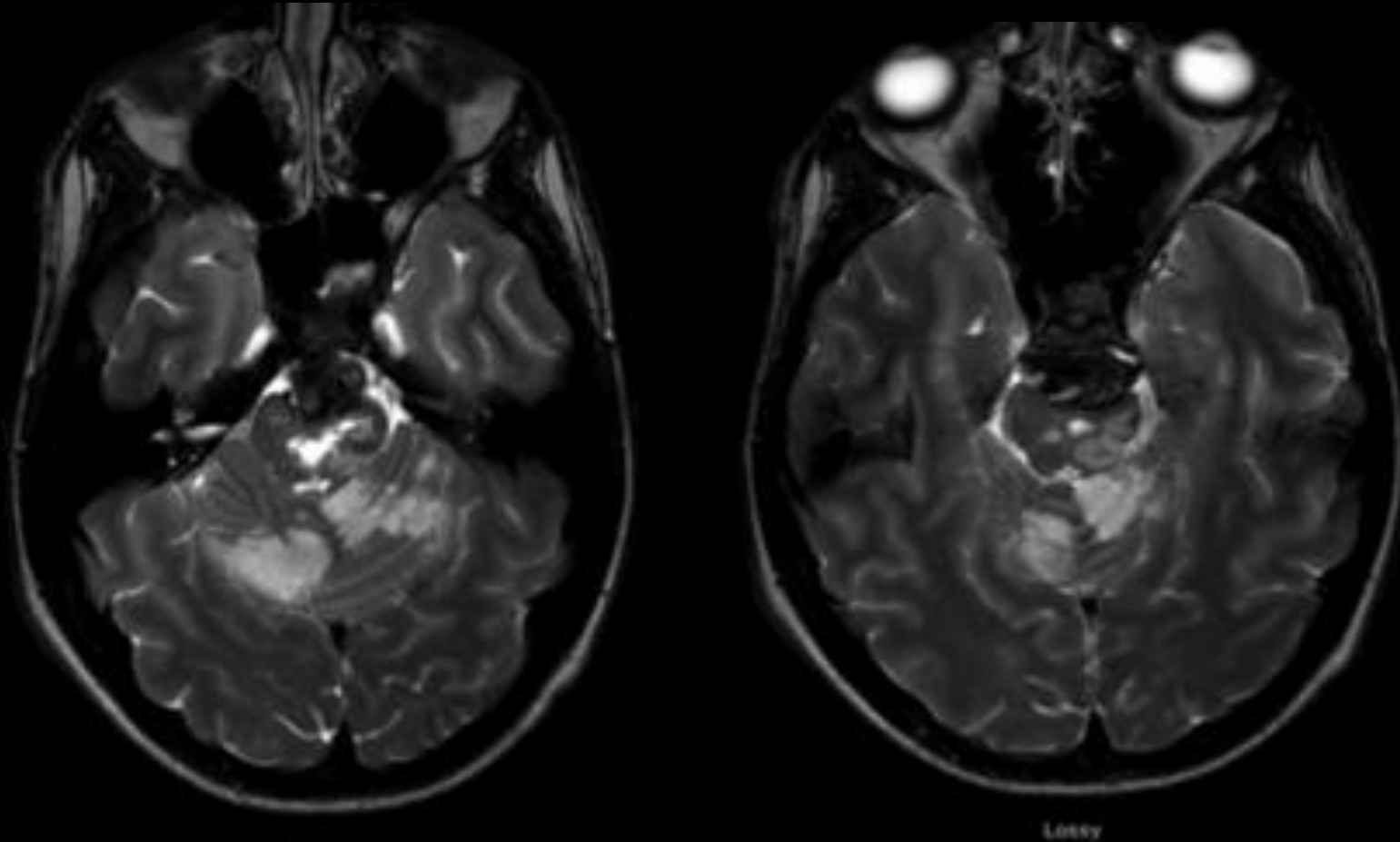
Initial Observations - Progressive aneurysm obliteration after Surpass™ FD

Use of Dual
Antiplatelet
Agents



Dissecting Basilar Trunk Aneurysm

16-year young boy with stroke, speech problems, hemiparesis and inability to walk
Progressive deterioration on dual antiplatelet treatment and anticoagulation

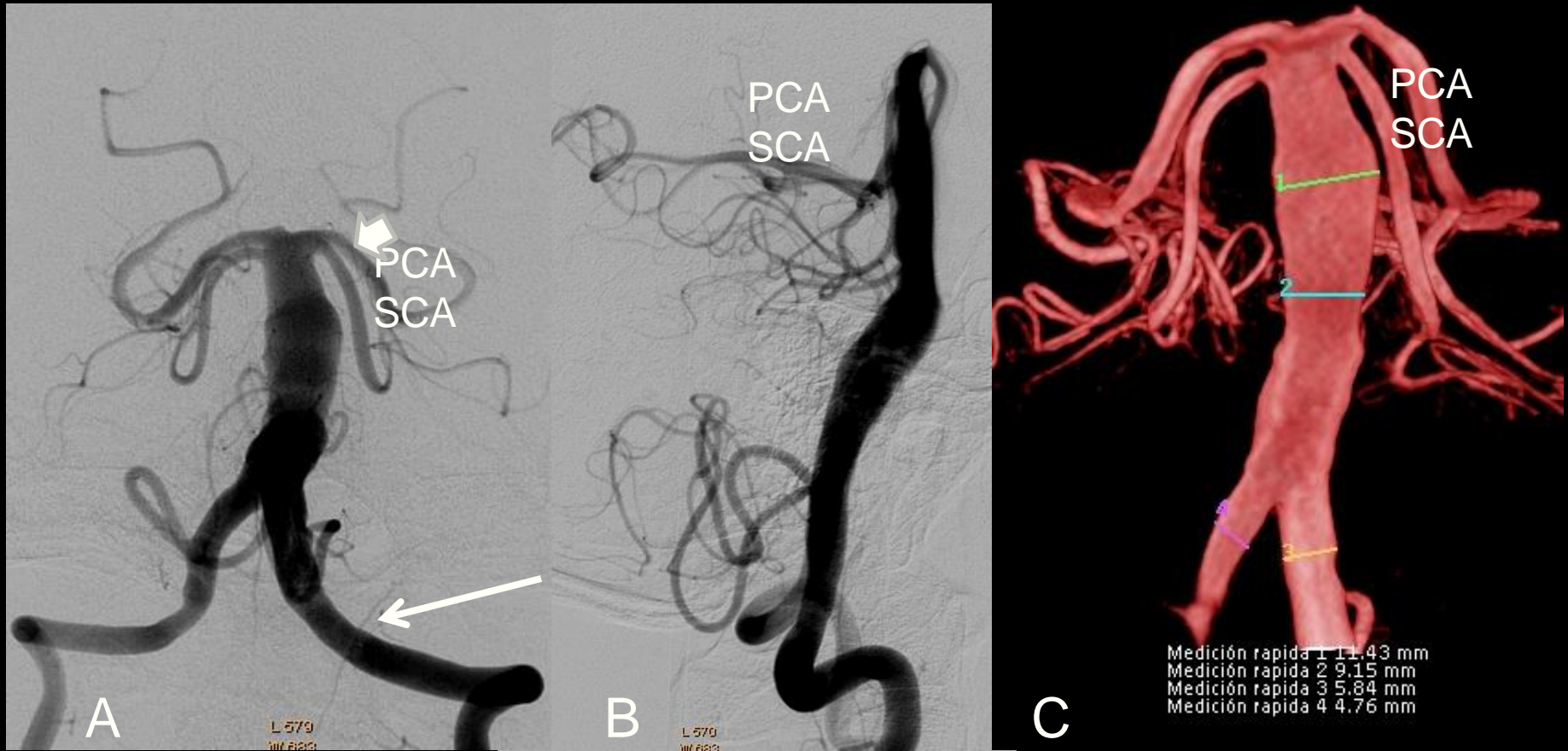


Postoperative Day 1

4 Months After



Initial Observations - Role of Contralateral Vertebral Artery Occlusion to prevent Endoleak

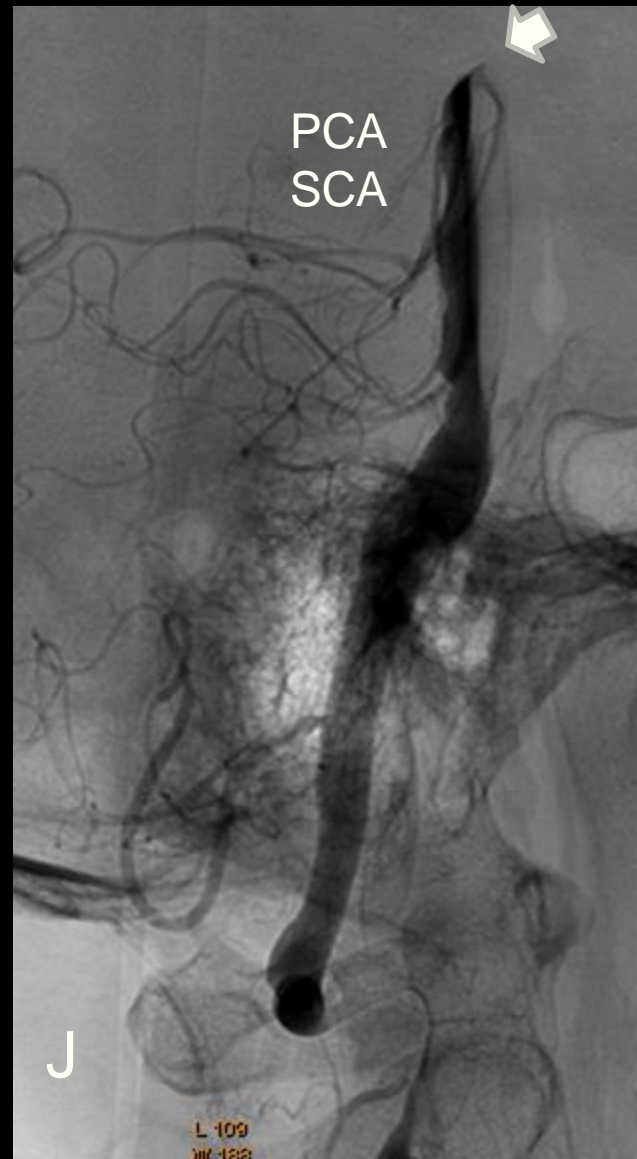
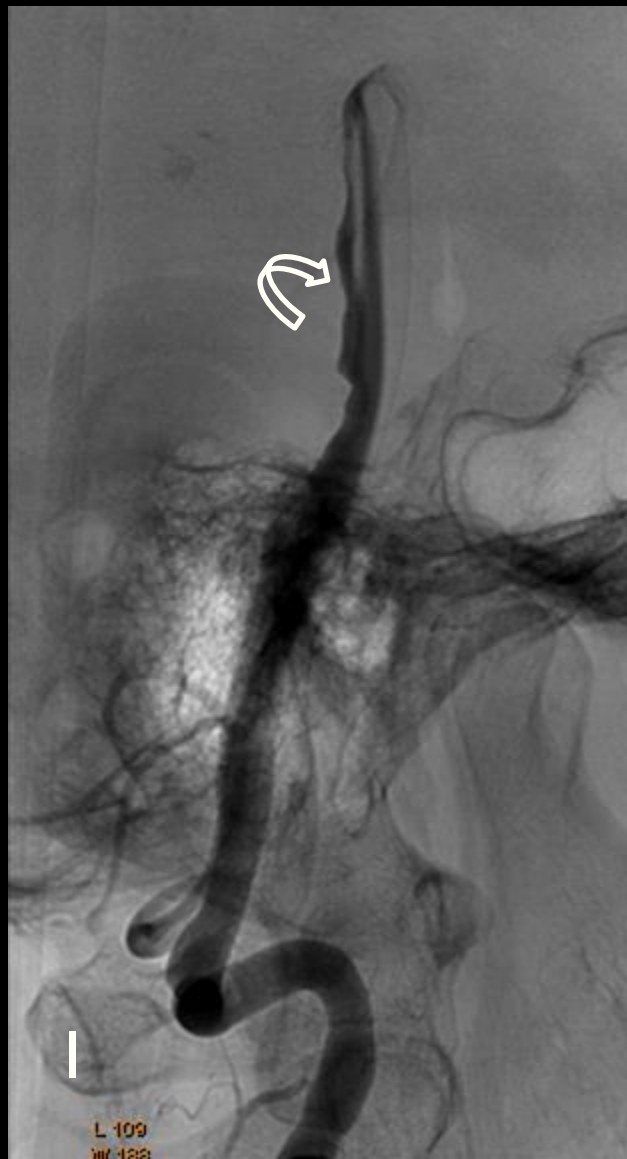


60-year-old male with a history of a right middle cerebral artery ischemic infarction and new lower cranial nerve deficit associated with a fusiform basilar artery aneurysm.

Single 4.4 mm x 80mm long 1st Gen SURPASS FD

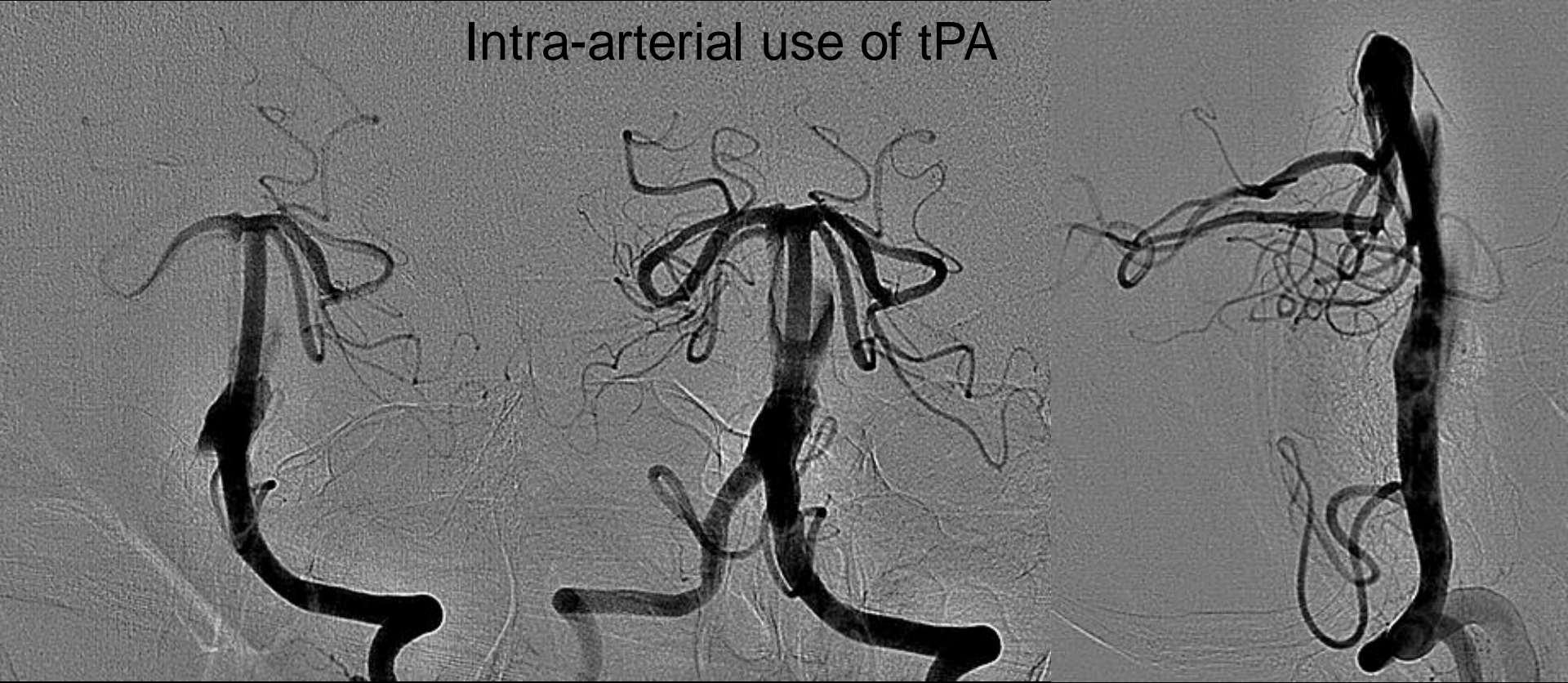


Surpass FD is currently not FDA approved

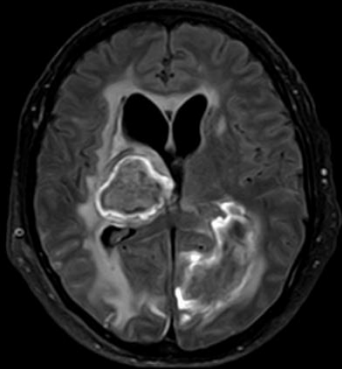


2-day FU

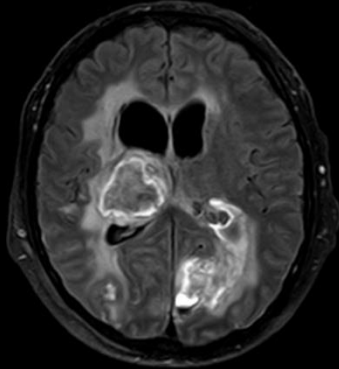
Intra-arterial use of tPA



Single 4.4 mm x 80mm long 1st Gen SURPASS FD



27-Jul-2010



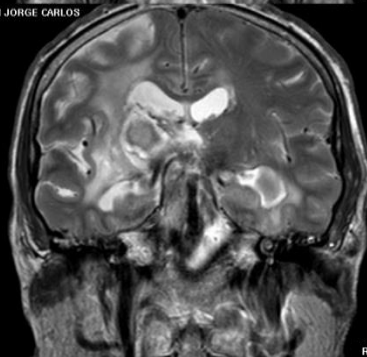
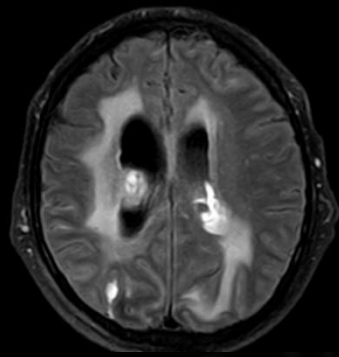
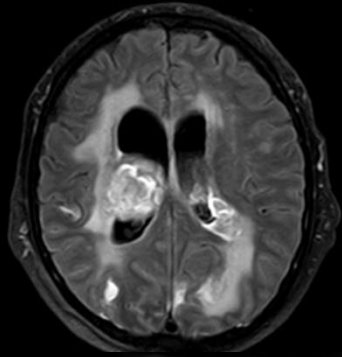
27-Jul-2010 RIMORINI JORGE CARLOS



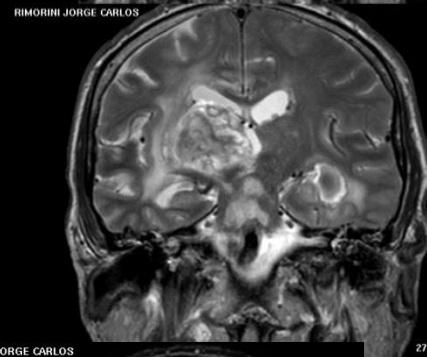
16:27:42
27-Jul-2010



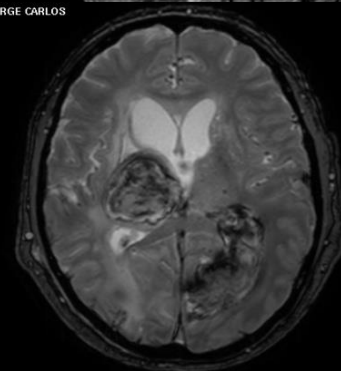
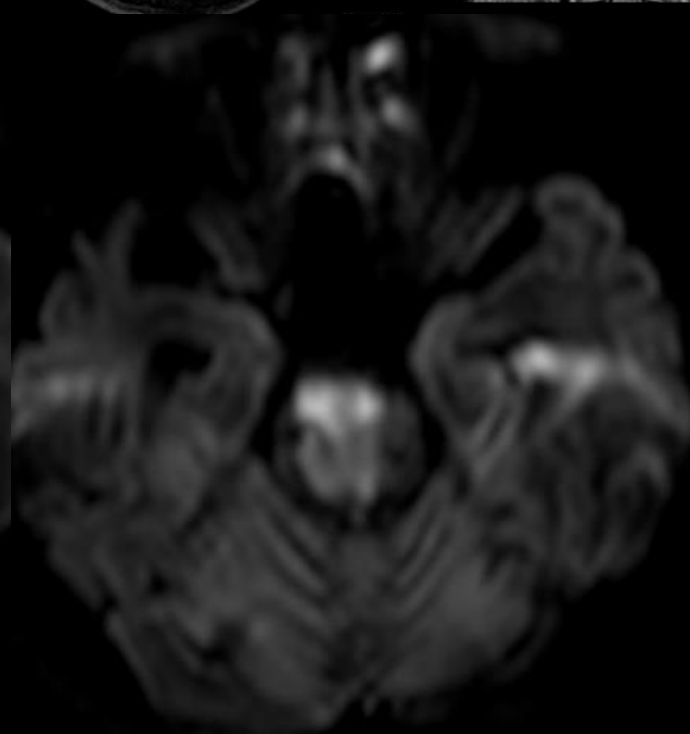
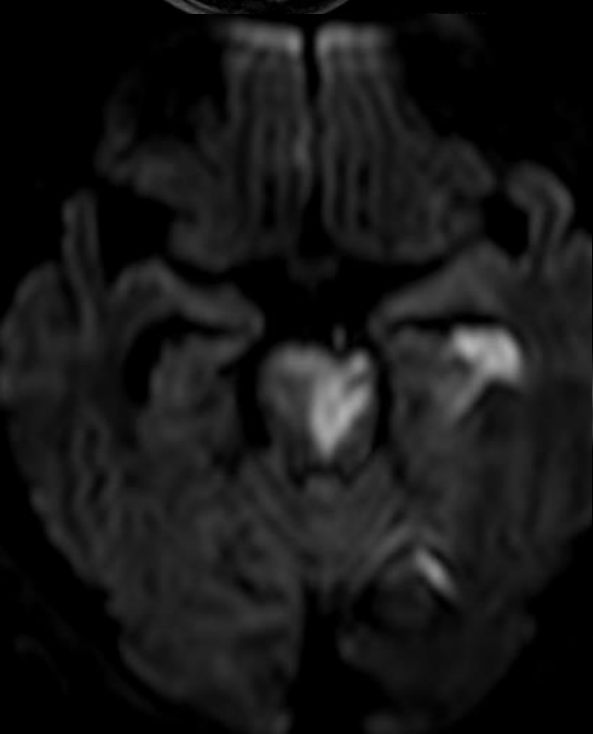
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27-Jul-2010



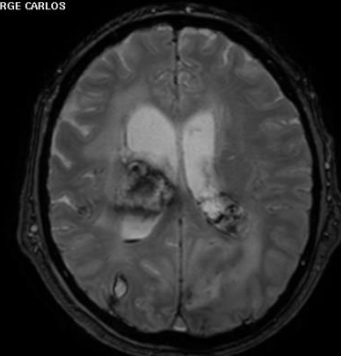
16:27:42
RIMORINI JORGE CARLOS



16:27:42
27-Jul-2010

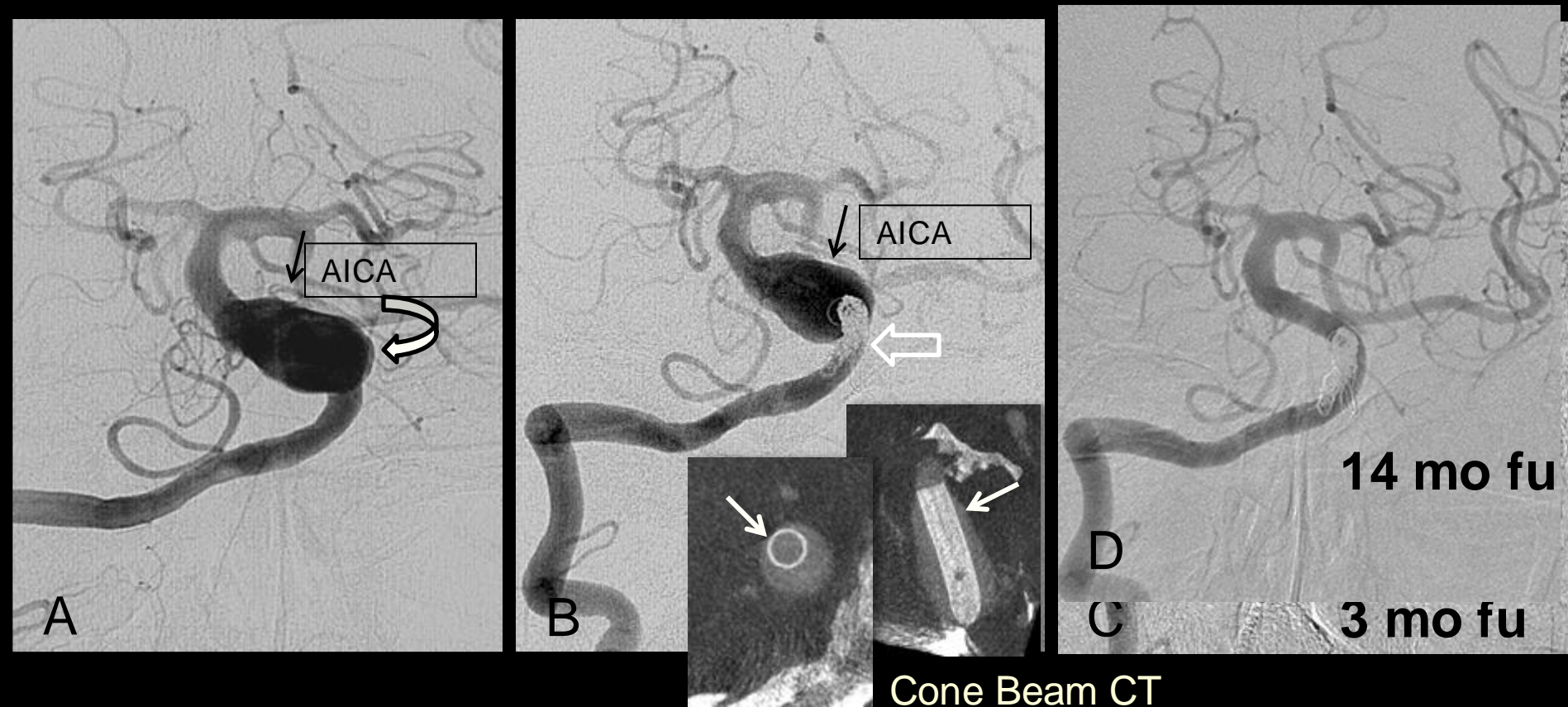


RIMORINI JORGE CARLOS



Role of contralateral VA occlusion

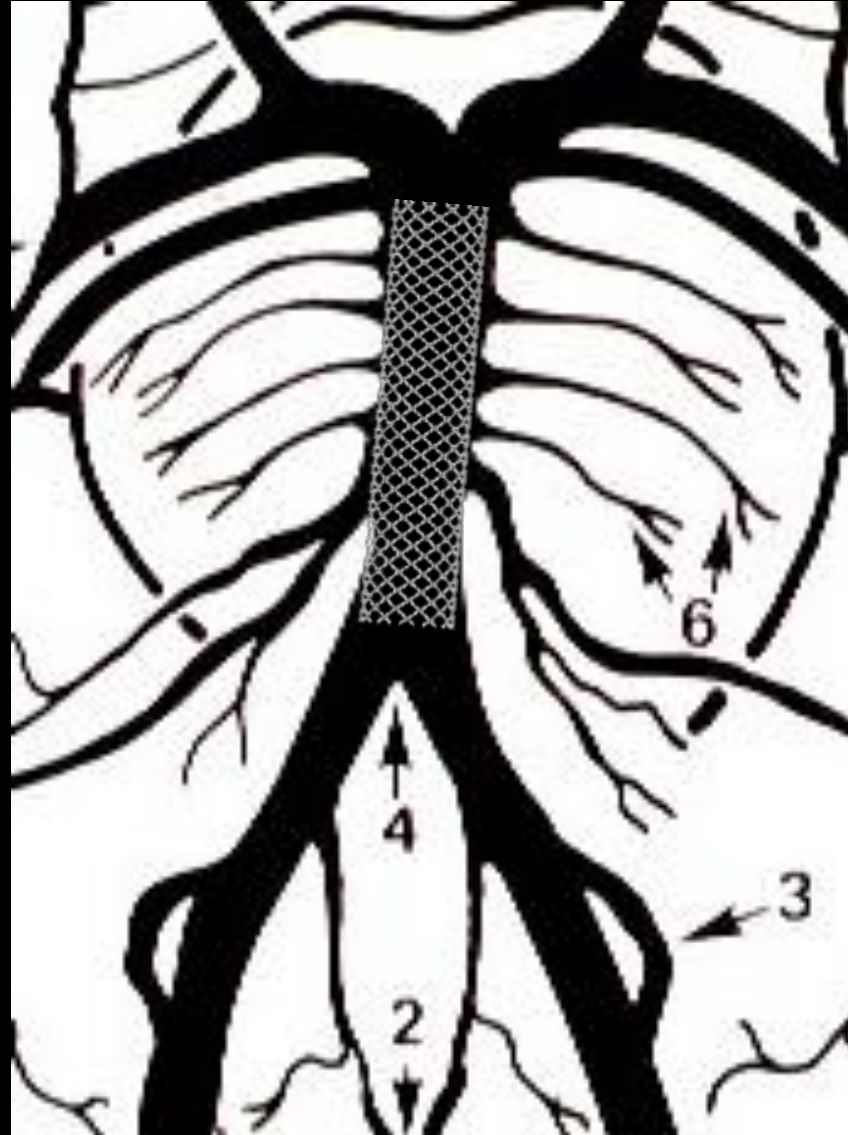
- Symptomatic Vertebro-basilar fusiform aneurysm
- Coil occlusion of left Vertebral artery to avoid “endoleak”



Surpass FD 5.3mm x 50mm

Study Objective

Presence of
dense
perforators



SURPASS FD multicenter registry

Patient Data

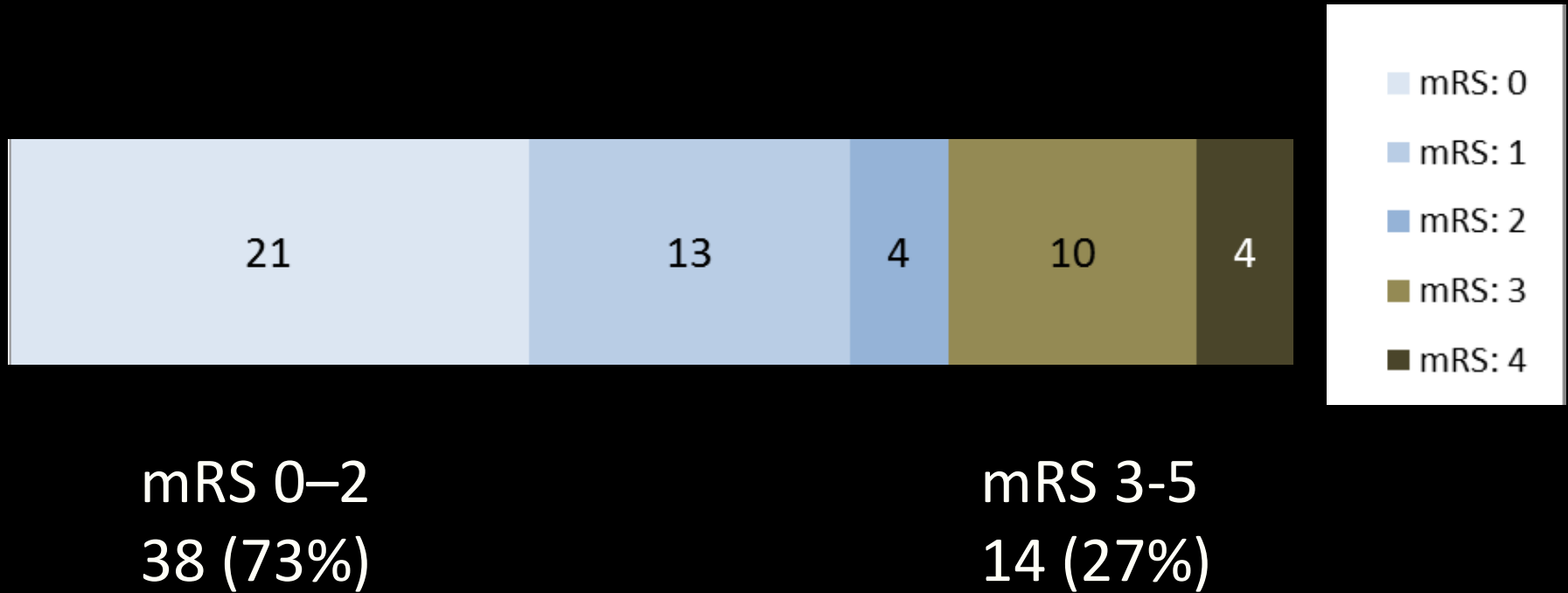
General information	
Patients	52
Aneurysms	52
Women (%)	21 (41%)
Mean age (yr) [range]	54 [16-79]

SURPASS FD multicenter registry

Presentation/Indication for Treatment

General information	
Acute SAH	7/52 (13%)
Stroke/TIA	7/52 (13%)
Cranial nerve deficit/mass effect	14/52 (27%)
Incidental findings/headaches	20 (38%)
Recurrent after coiling/stenting/failed clipping	16 (31%)

Baseline mRS (n=52)



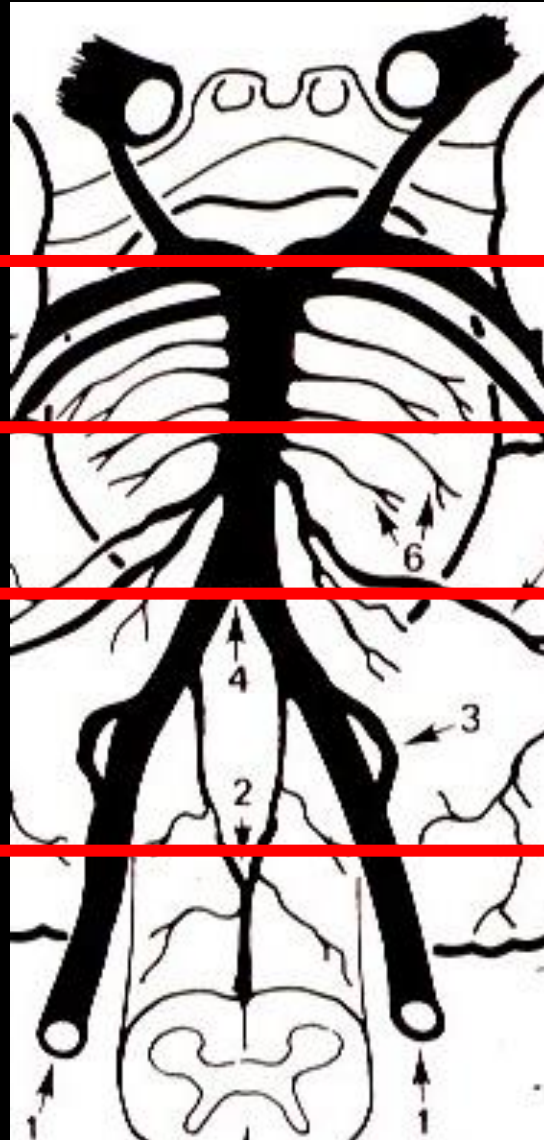
Aneurysm location (n=52)

PCA

Basilar trunk

VB Junction

Vertebral artery



6 (12%)

15 (29%)

11 (21%)

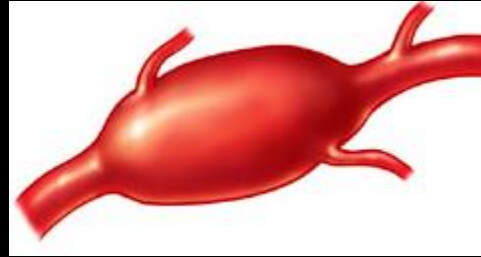
20 (38%)

Aneurysm sizes (n=52)

< 5 mm	4 (8%)
5 – 9.9 mm	13 (25%)
10 – 20 mm	17 (33%)
> 20 mm	17 (33%)

Aneurysm type (n=52)

Fusiforme



39 (75%)

Wide-neck Saccular



12 (23%)

Blood-blister type



1 (2%)

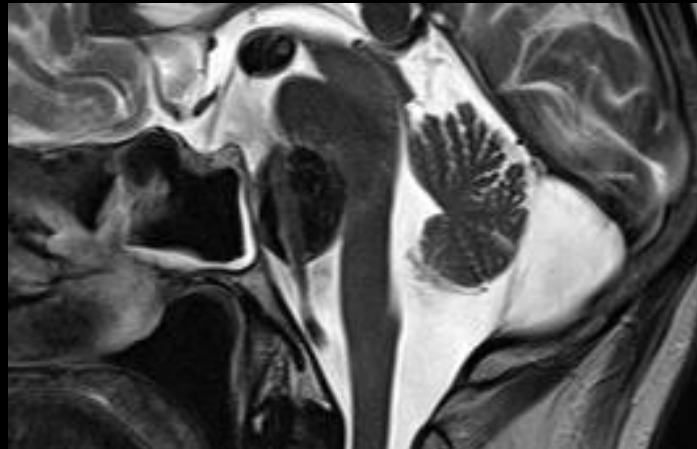
Aneurysm characteristics

Pretreated
(Coil, Stent, Clip,
failed surgery)



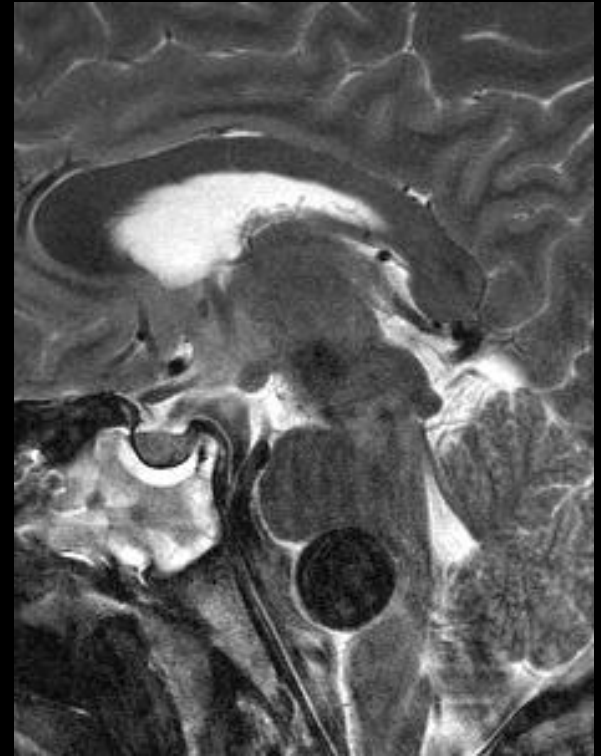
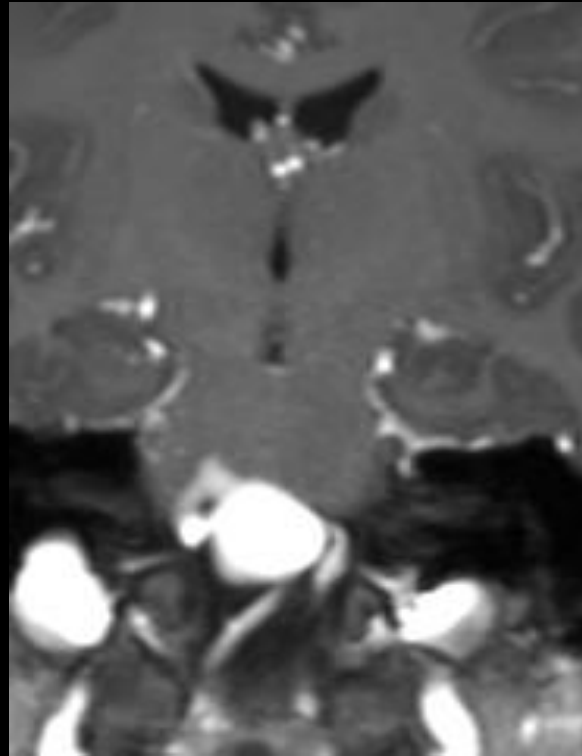
16 (31%)

Partially
thrombosed



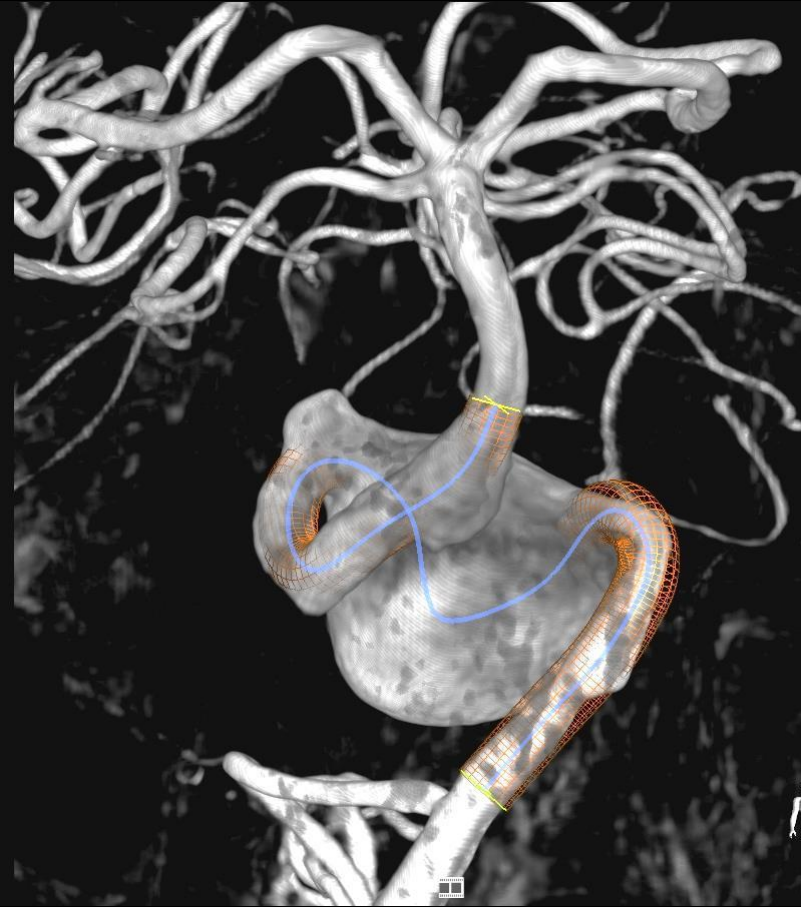
14 (27%)

Symptomatic basilar tip aneurysm



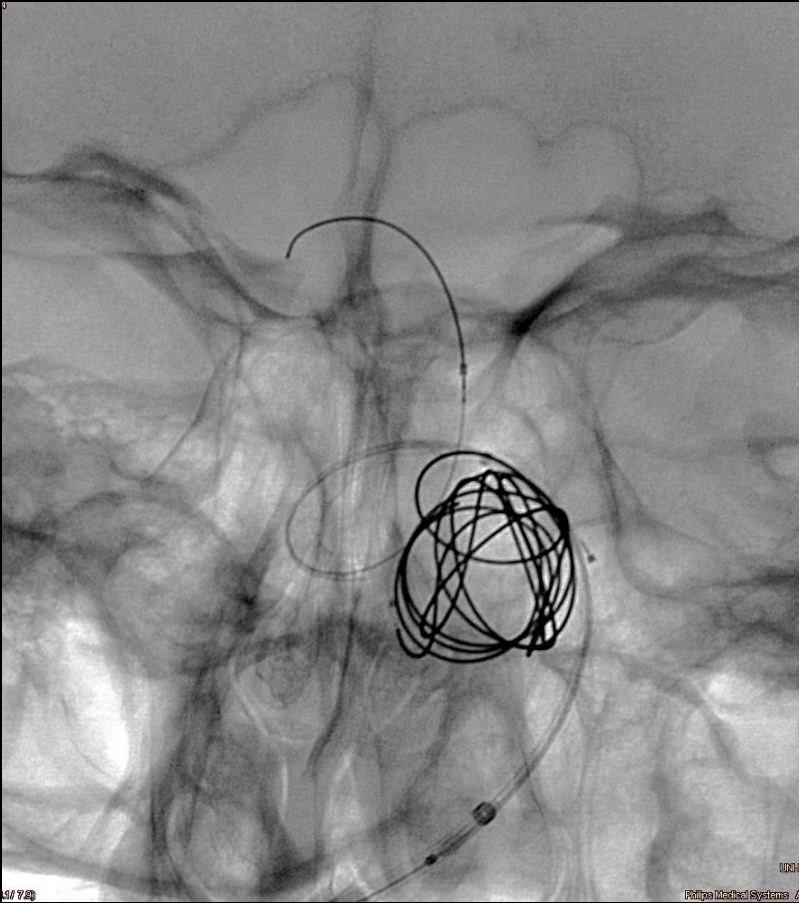
29-y-o-m w progressive incapacitating headaches and gait disturbance

Symptomatic basilar tip aneurysm

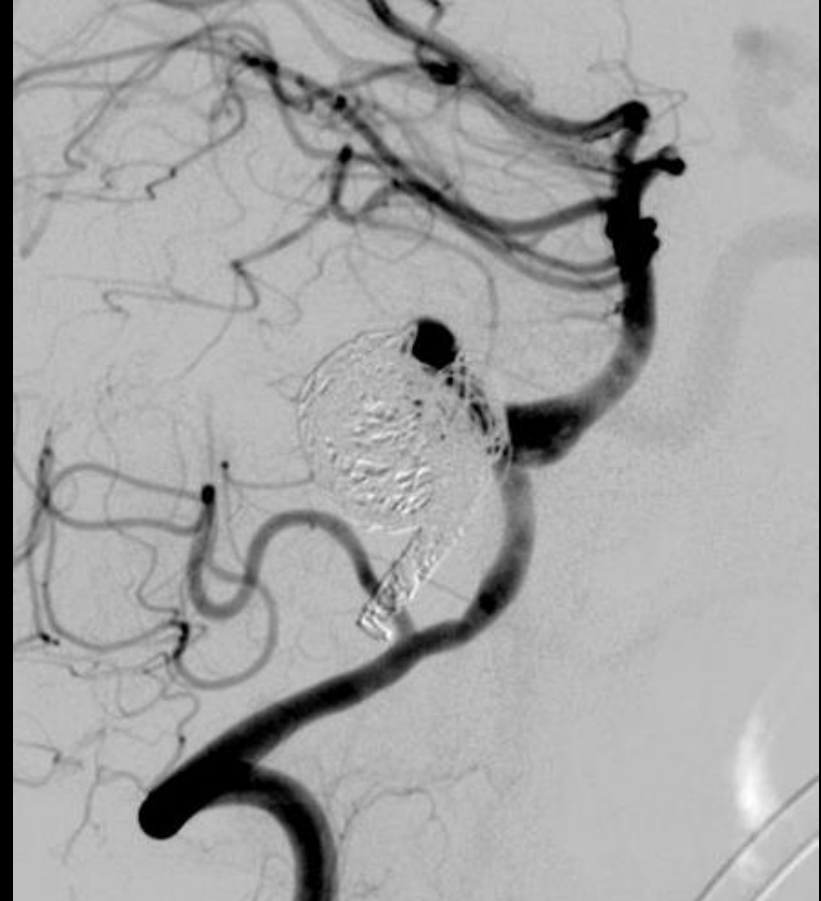


Symptomatic basilar tip aneurysm

Combined use of coils



Symptomatic basilar tip aneurysm



24 hour follow-up

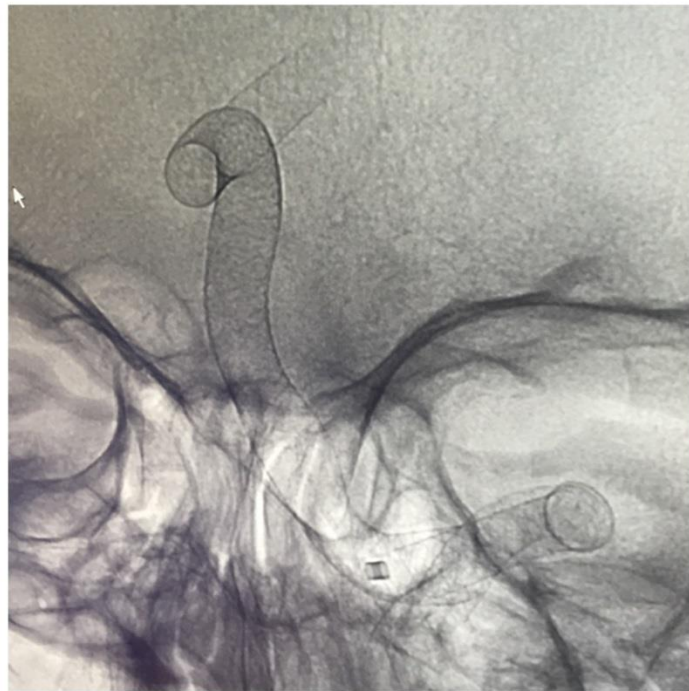
Aneurysm treatment

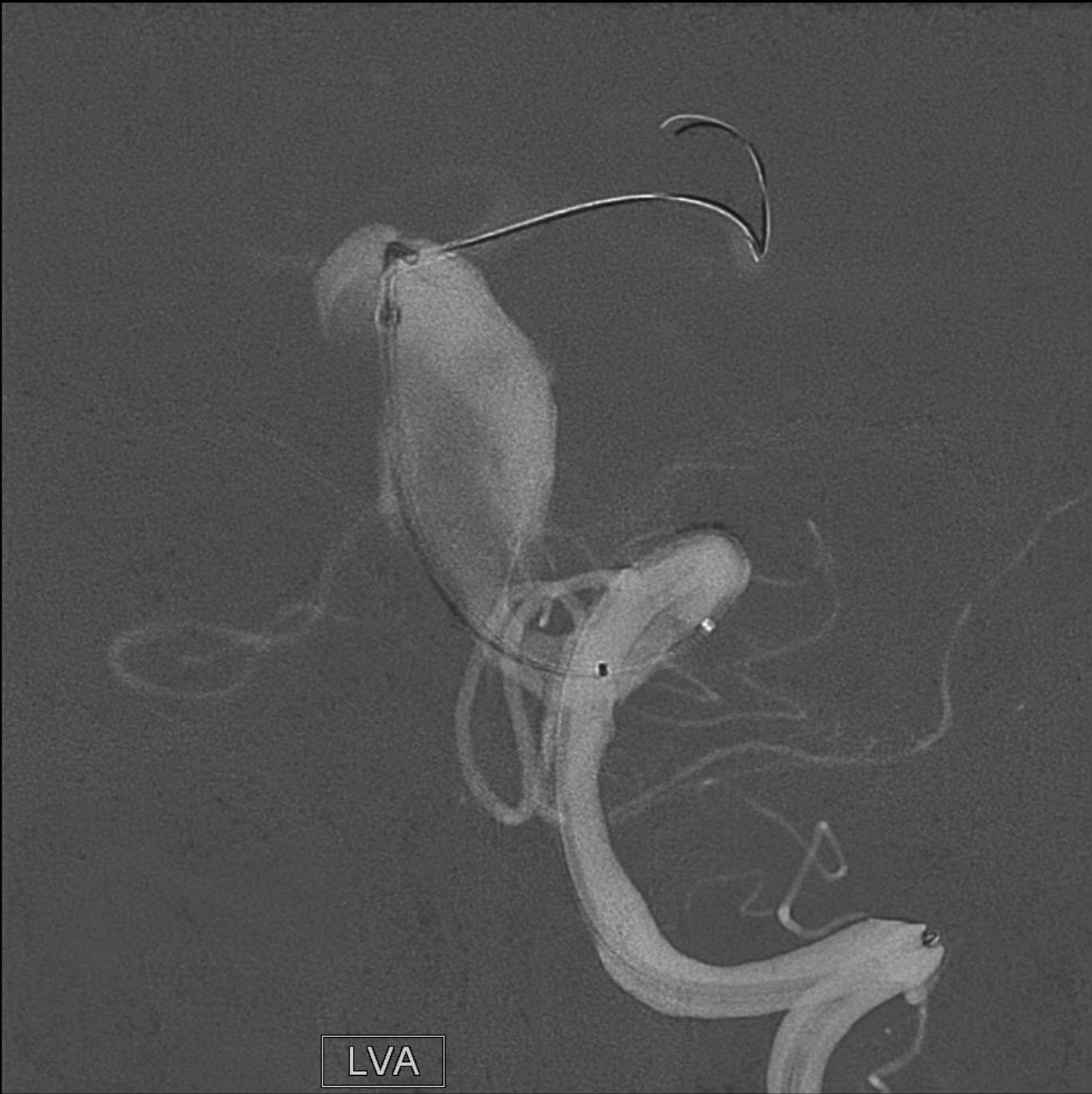
Technical success rate

51/52 (98%)

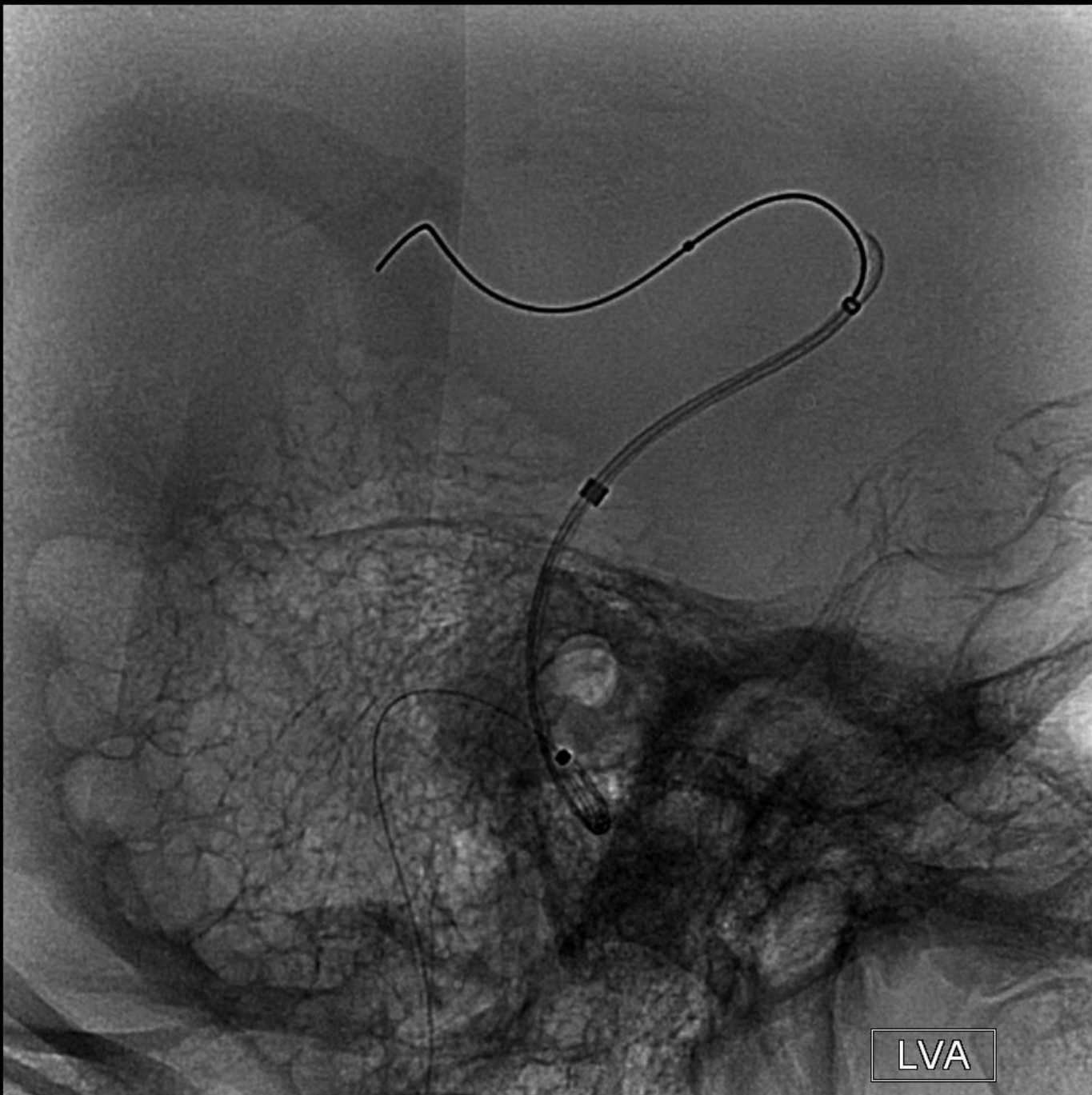
Average # of FD / case

1.4 (range 1 – 3)





LVA

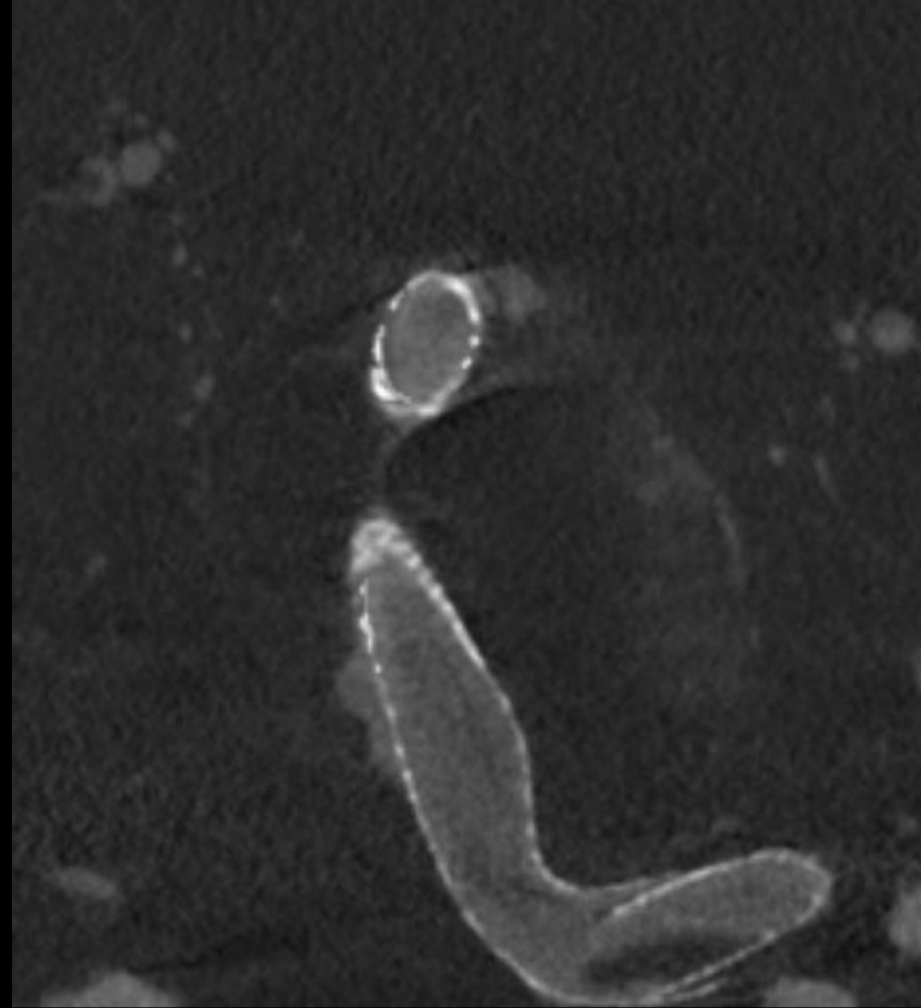


LVA

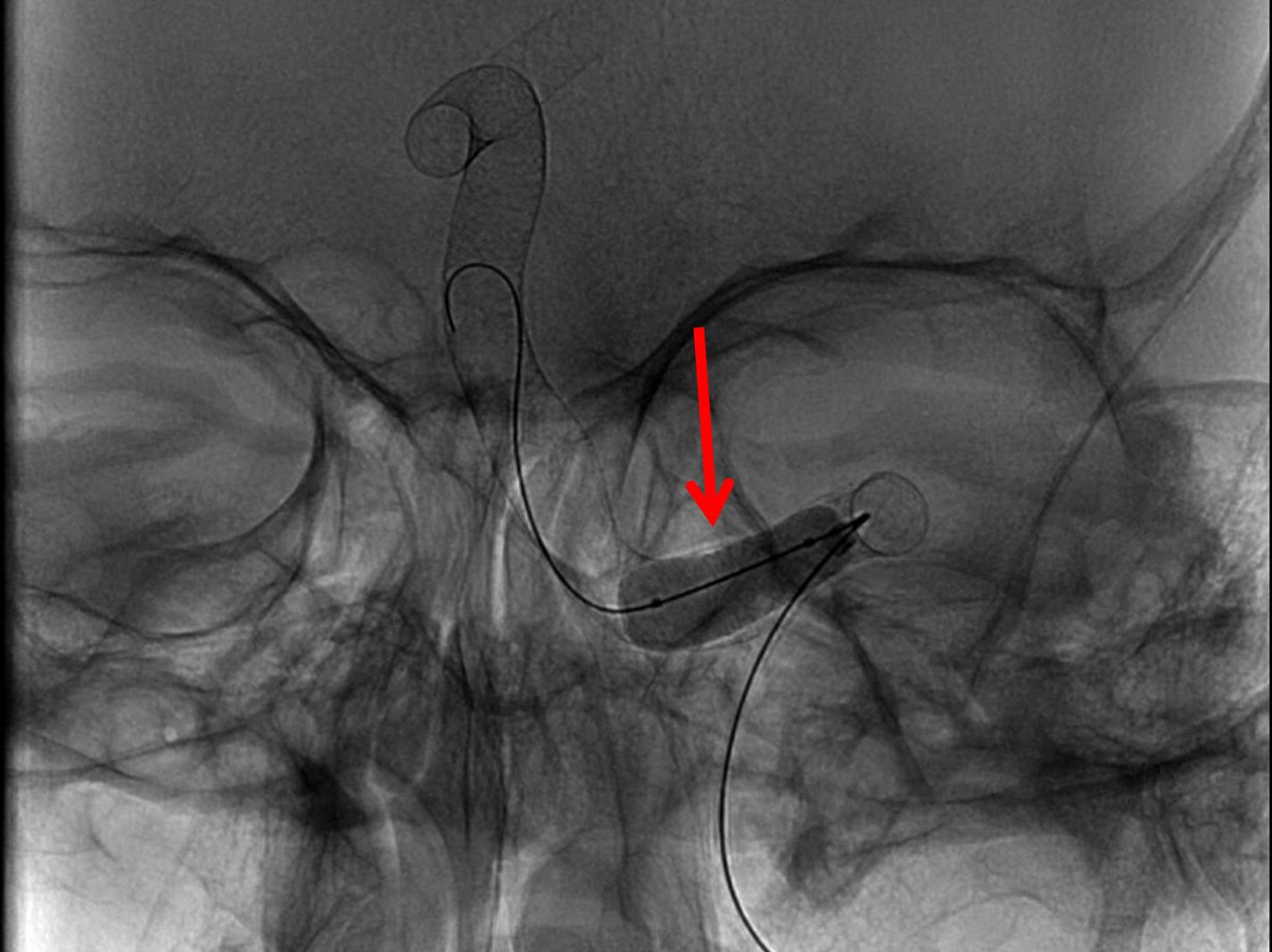
LVA



Malapposition of telescoping FDs



...requiring post dilation LVA



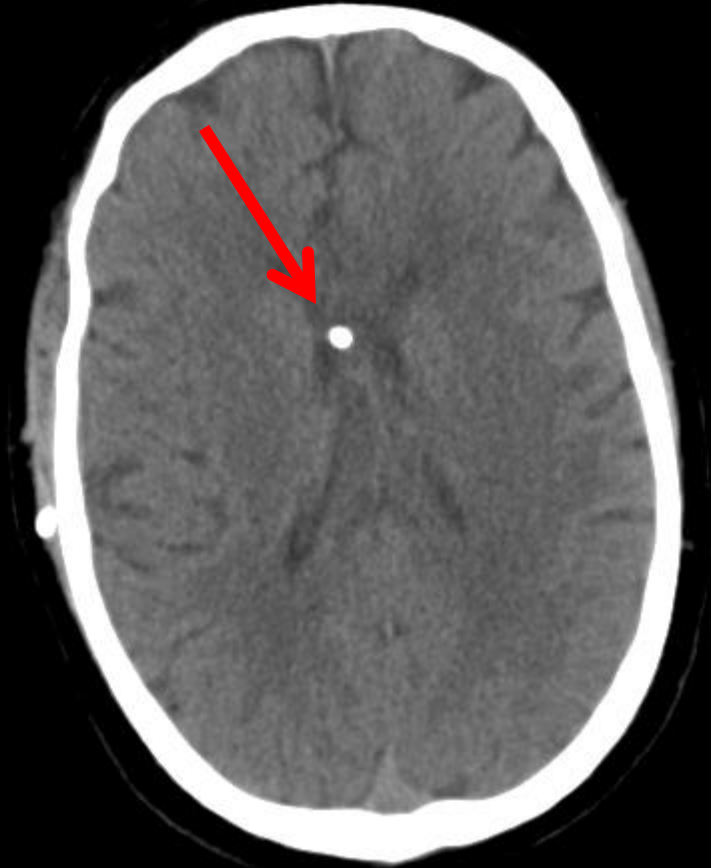
6 weeks follow-up



Requirement: Intraoperative placement of a shunt due to hydrocephalus via burr hole

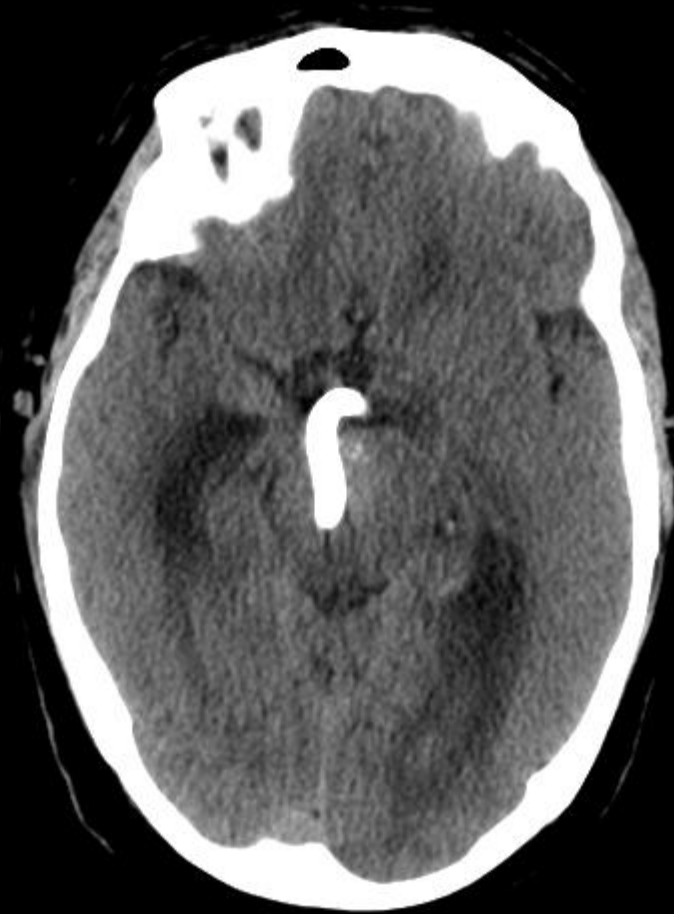


Before shunt



After shunt

Requirement: Placement of a shunt due to hydrocephalus



Before shunt



After shunt

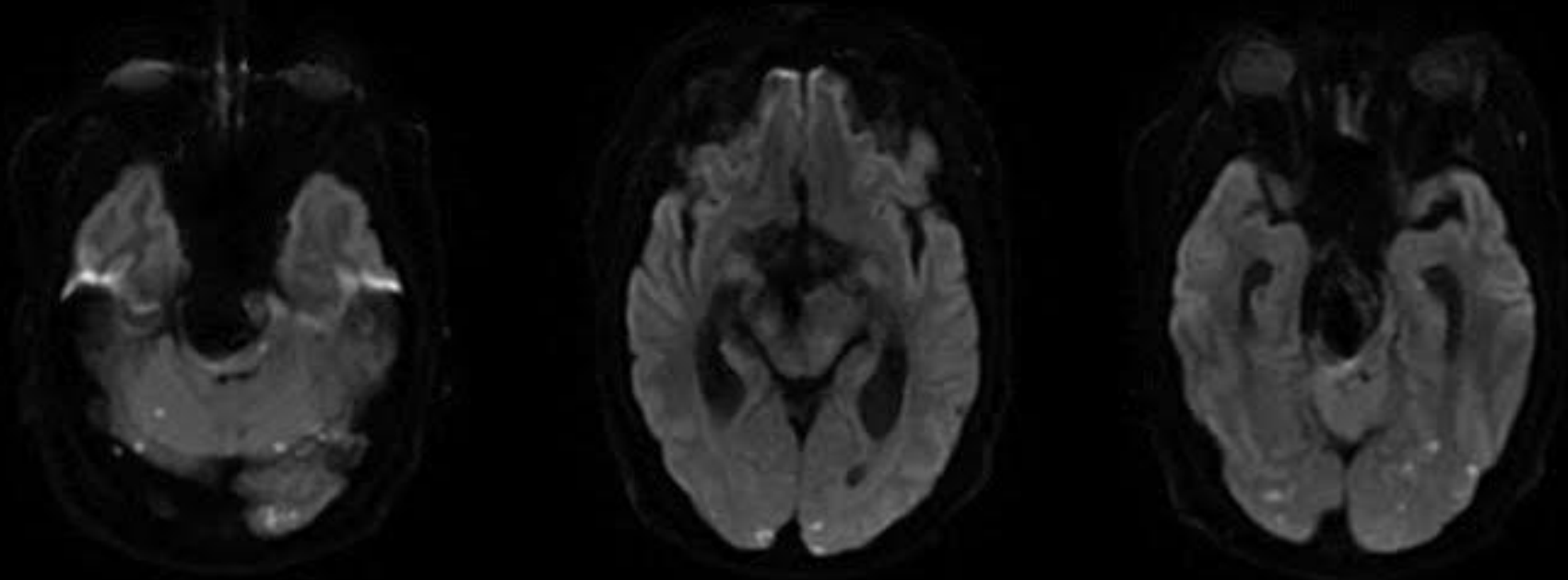
Requirement: Placement of a shunt due to hydrocephalus



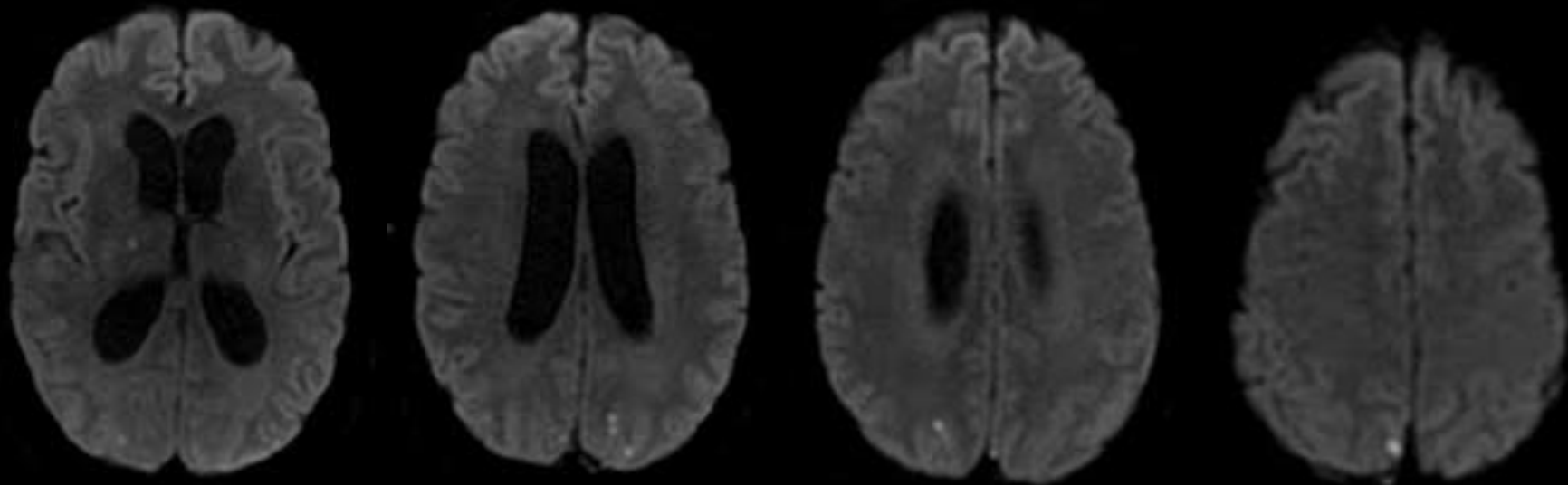
Before shunt



After shunt



Follow-up DWI/MRI



Progressive Aneurysm Growth

74-y-o-m: history of aortic aneurysm, COPD, MI
arterial hypertension, obesity

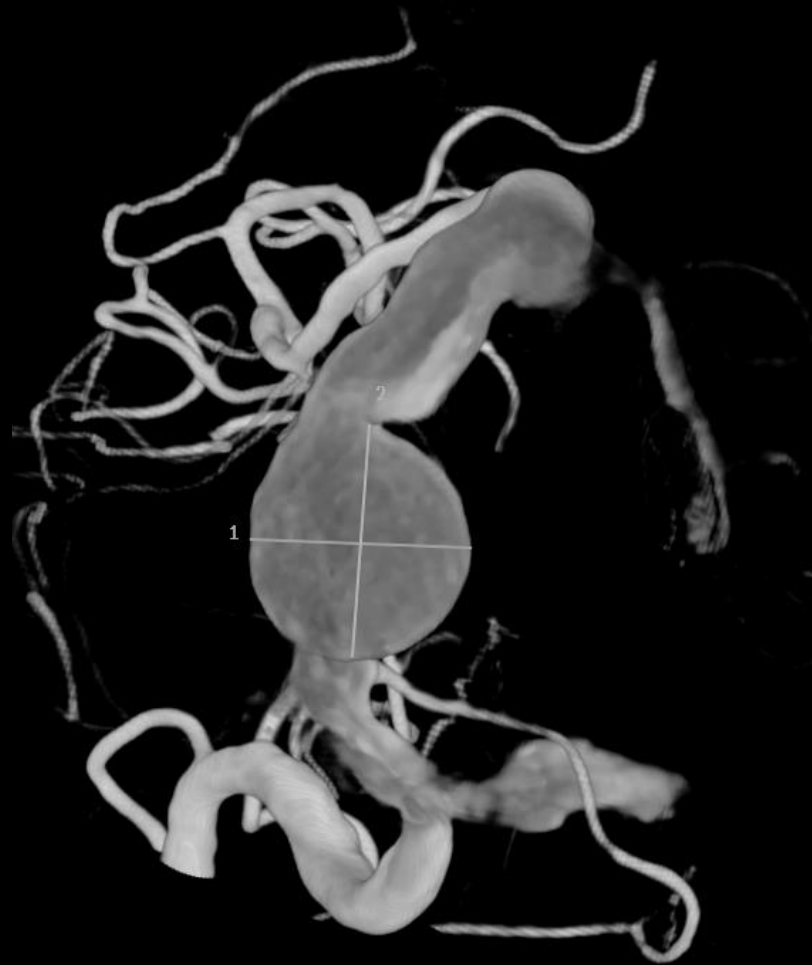


10-16-09



05-09-11

no measurement;
incomplete filling
with contrast

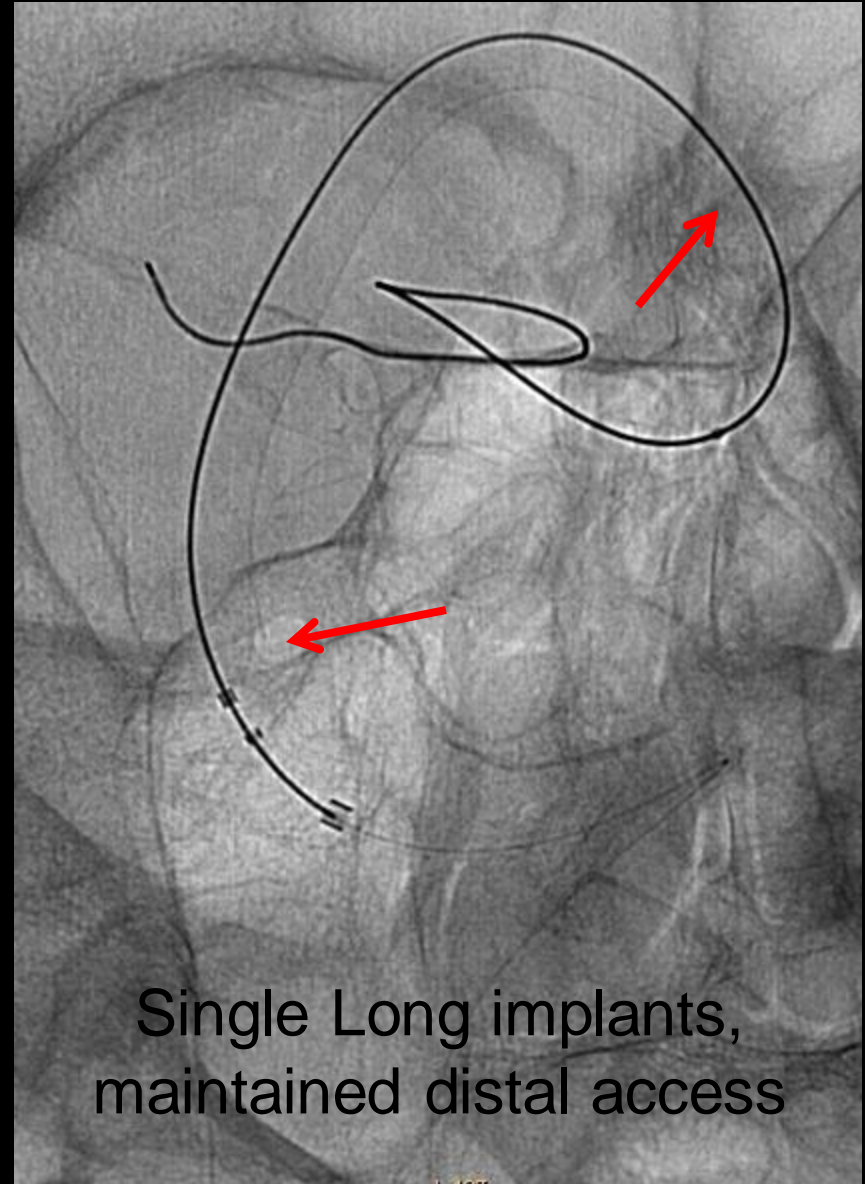


Quick Measurement 1 17.51 mm
Quick Measurement 2 18.45 mm

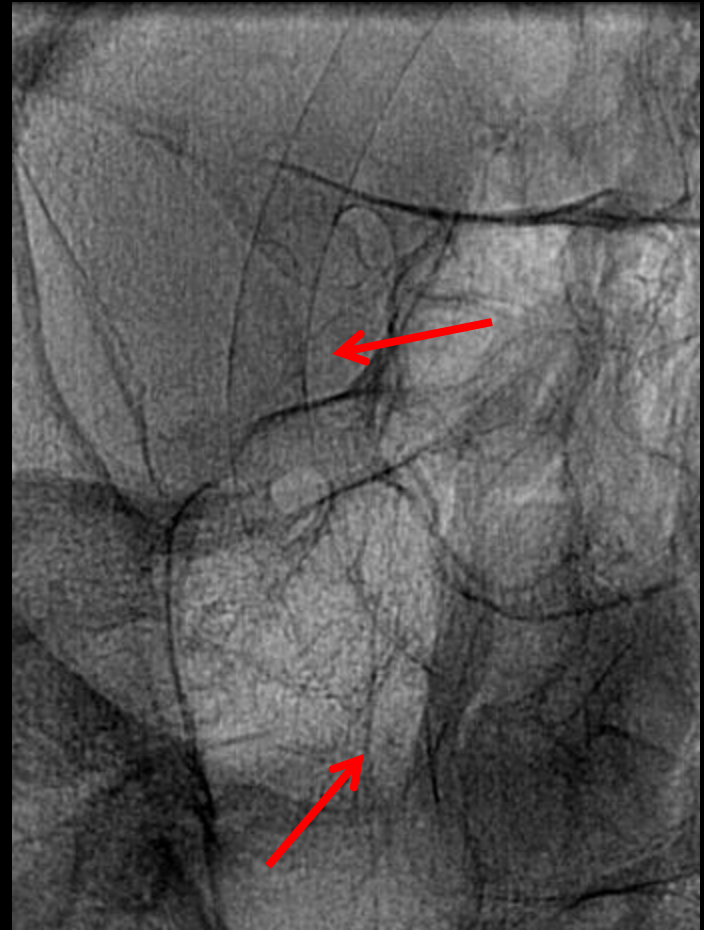
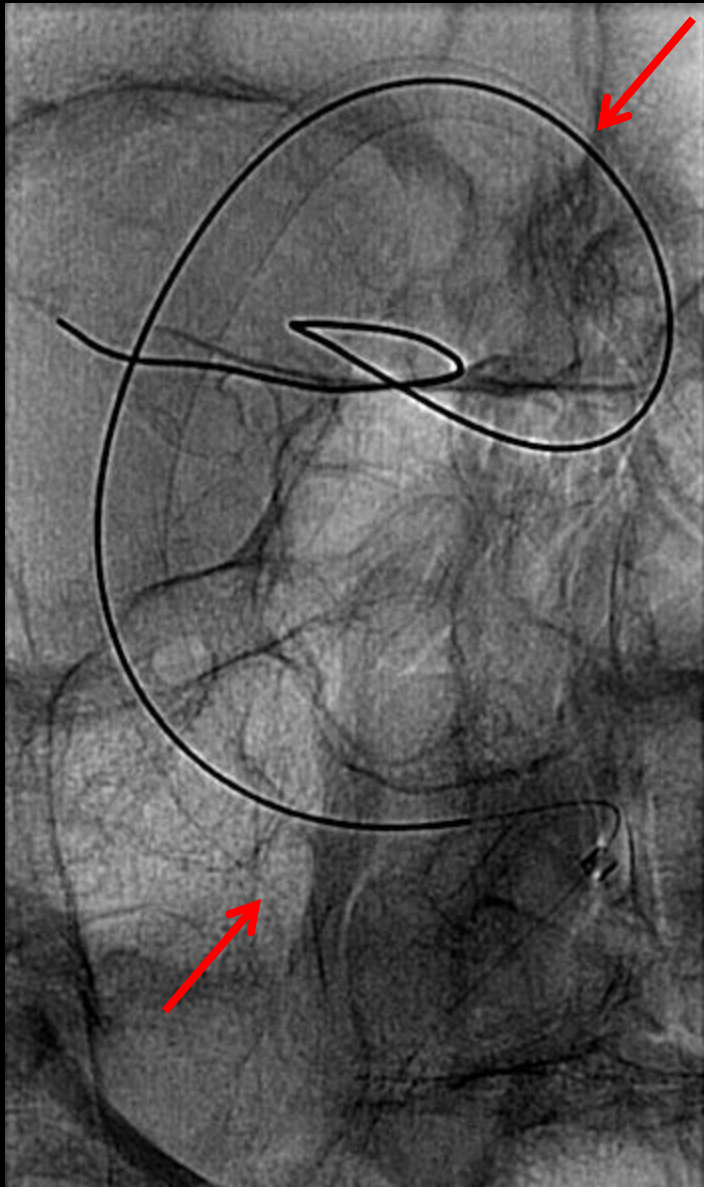
verte

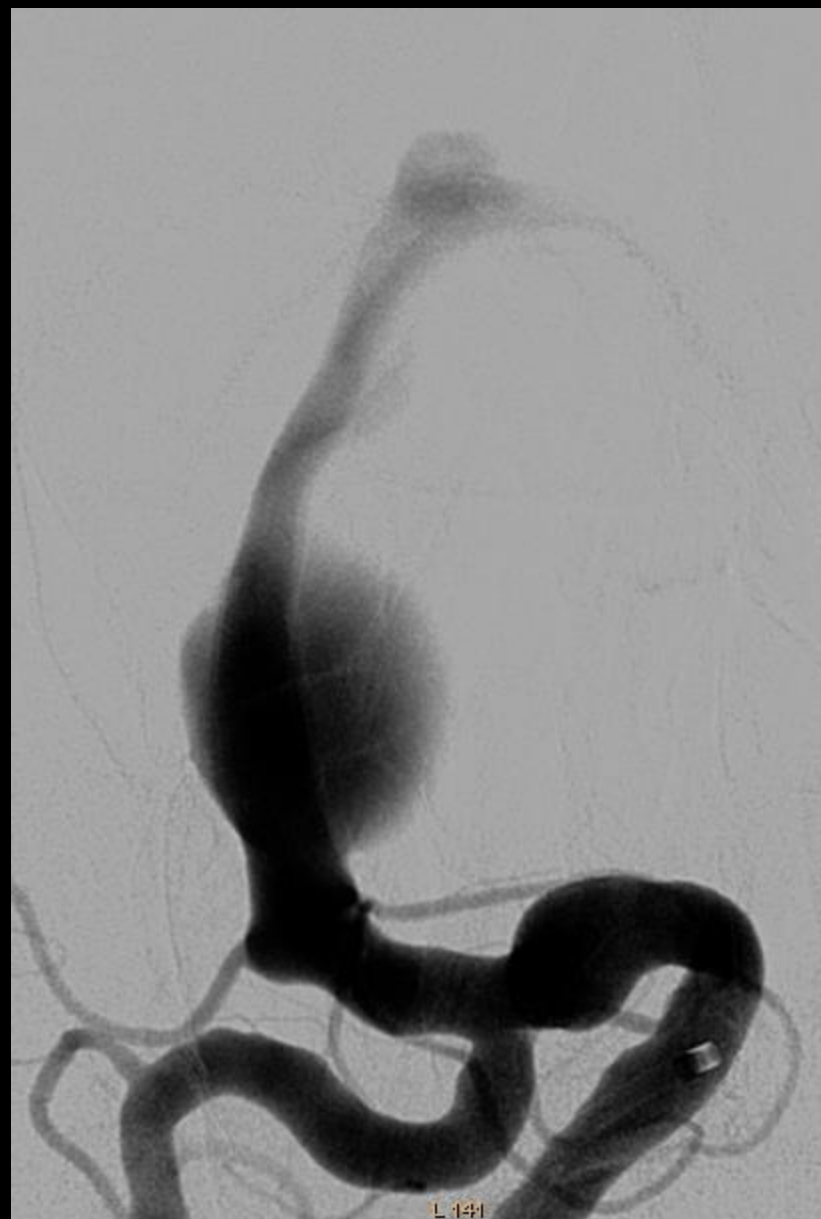
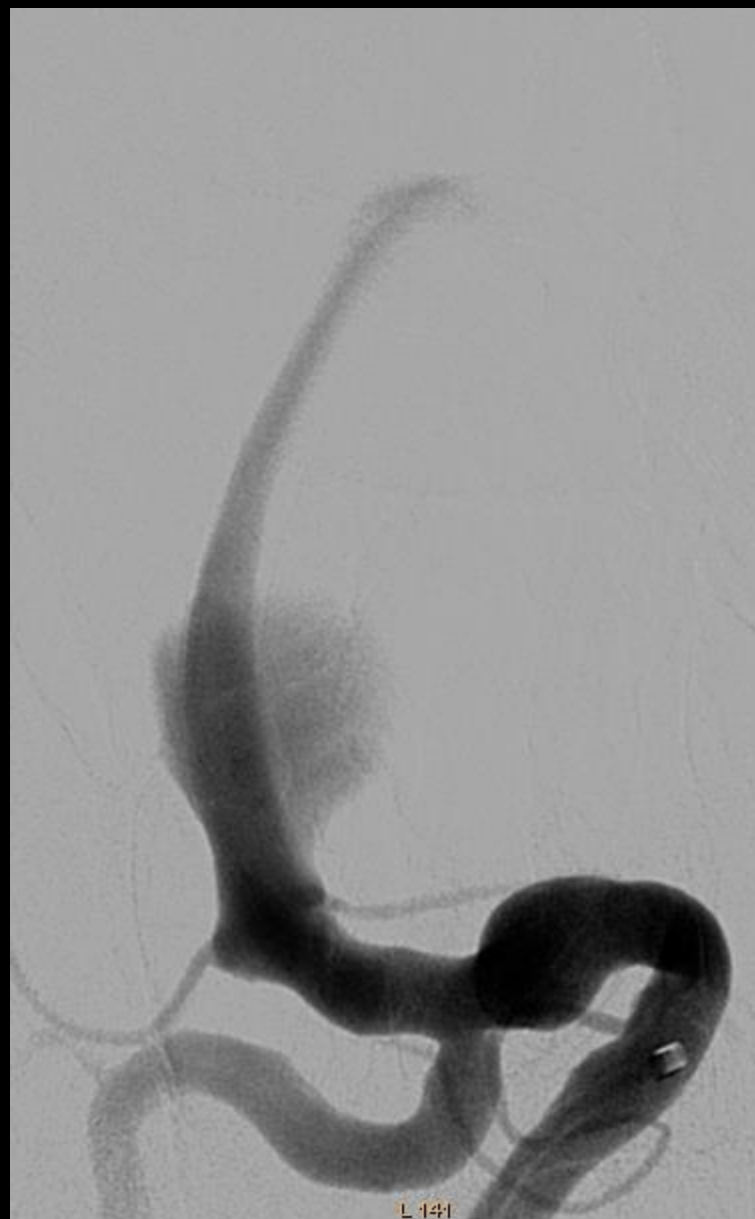


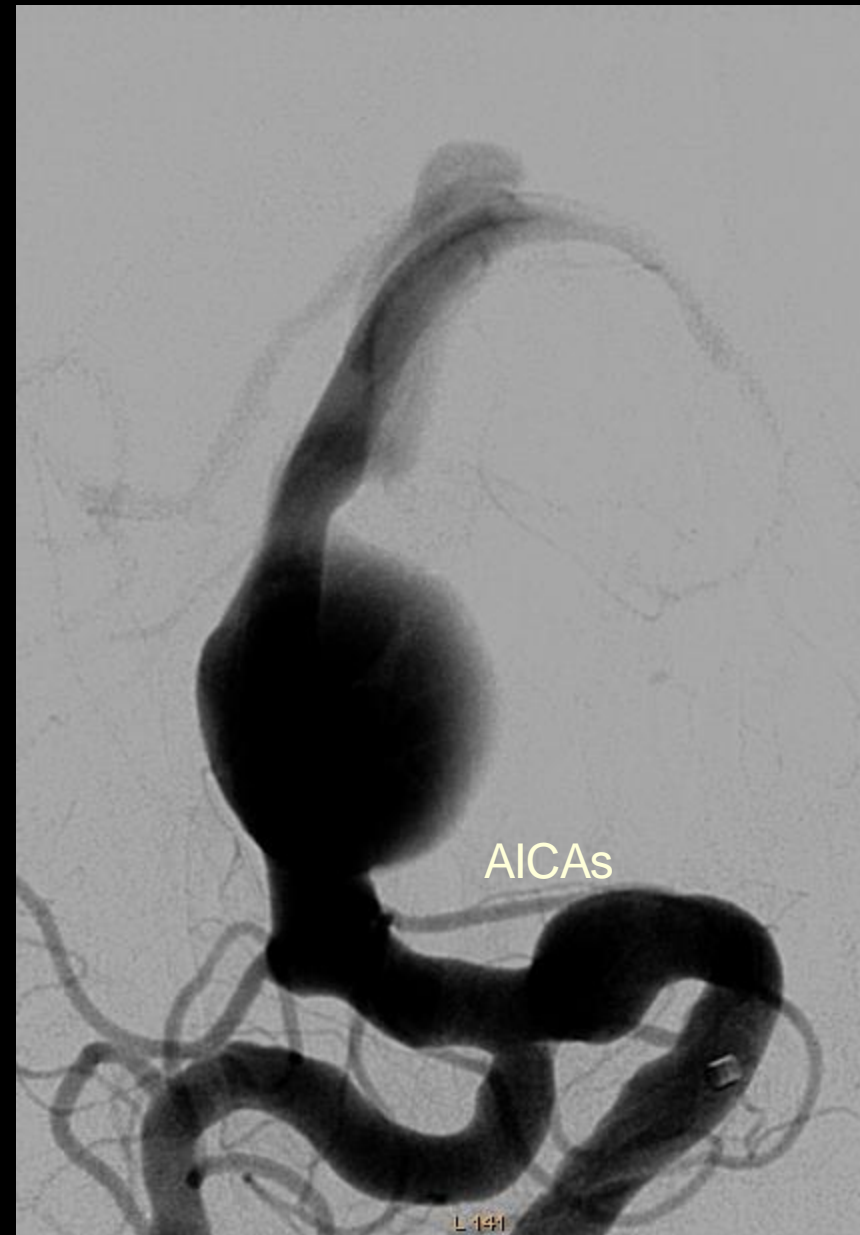
74-y-o-m: history of aortic aneurysm, COPD, MI
arterial hypertension, obesity



Single Long implants,
maintained distal access

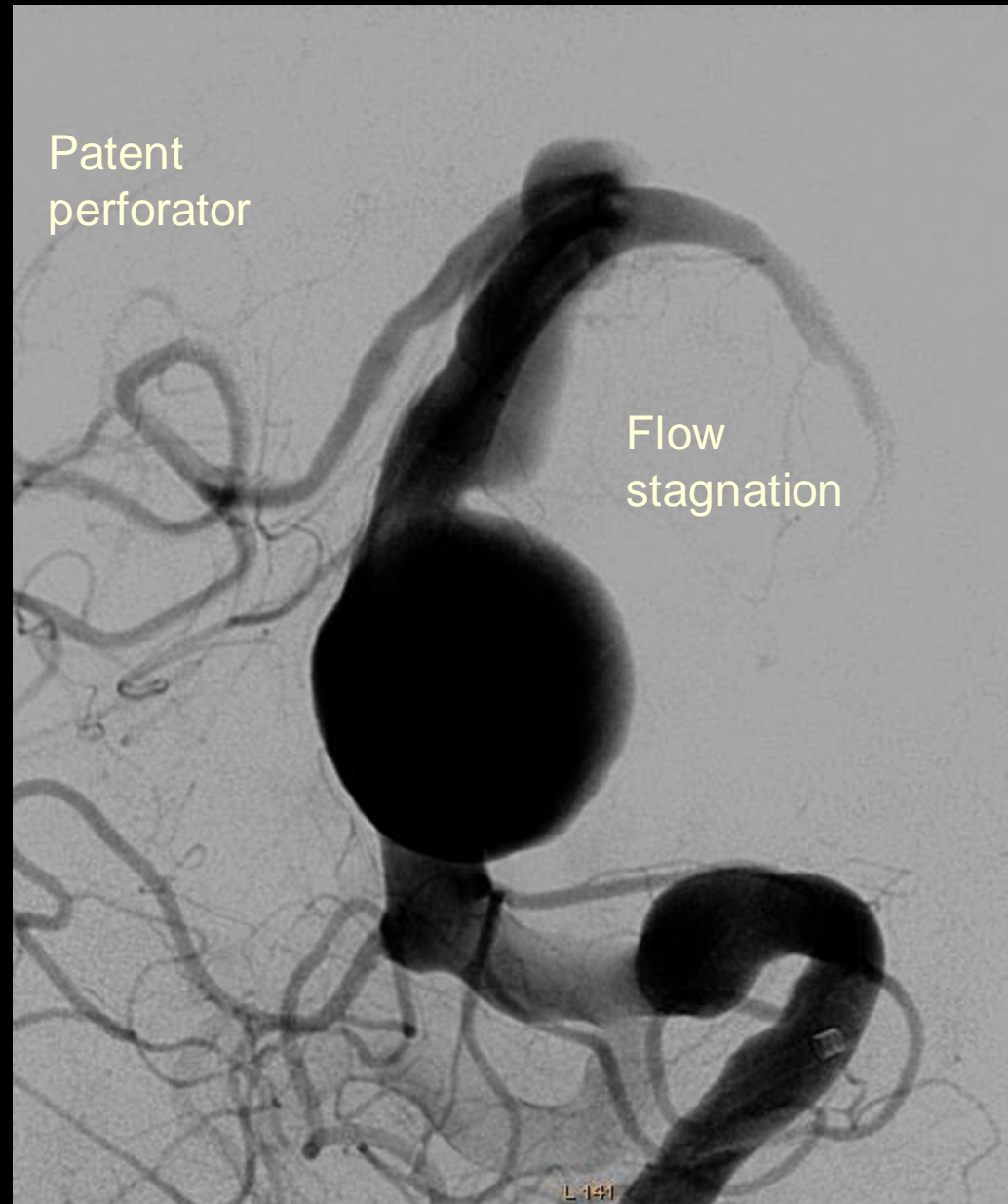






AICAs

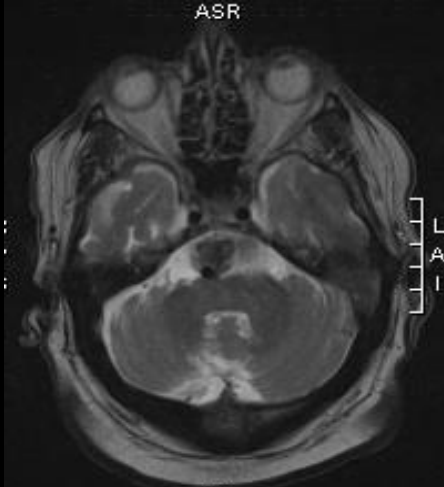
L 1491



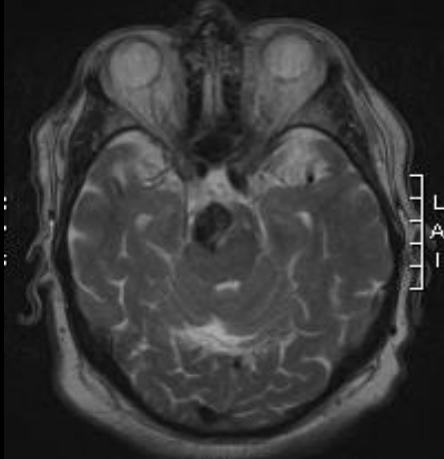
Patent
perforator

Flow
stagnation

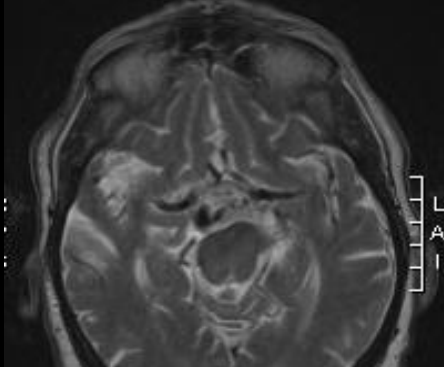
L 1491



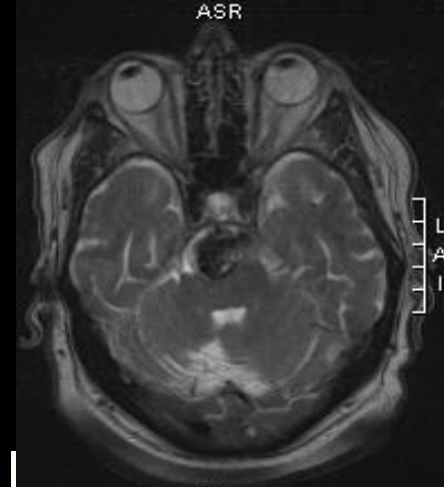
PIL
ASR



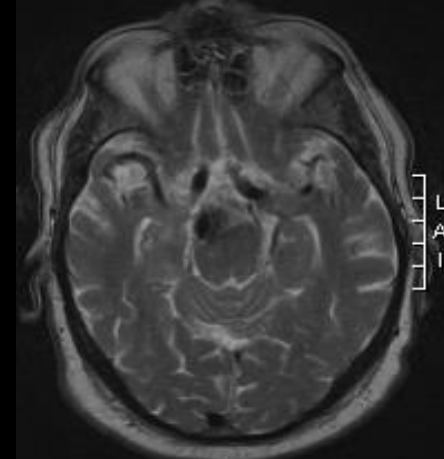
PIL
ASR



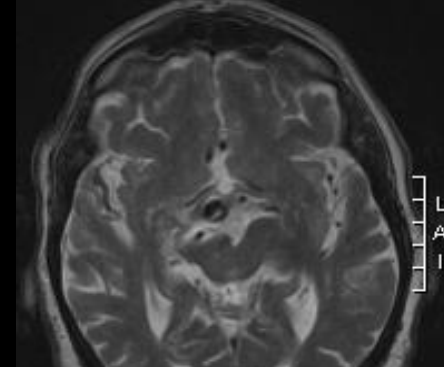
1 week follow-up MRI
No signs of
perforator occlusion



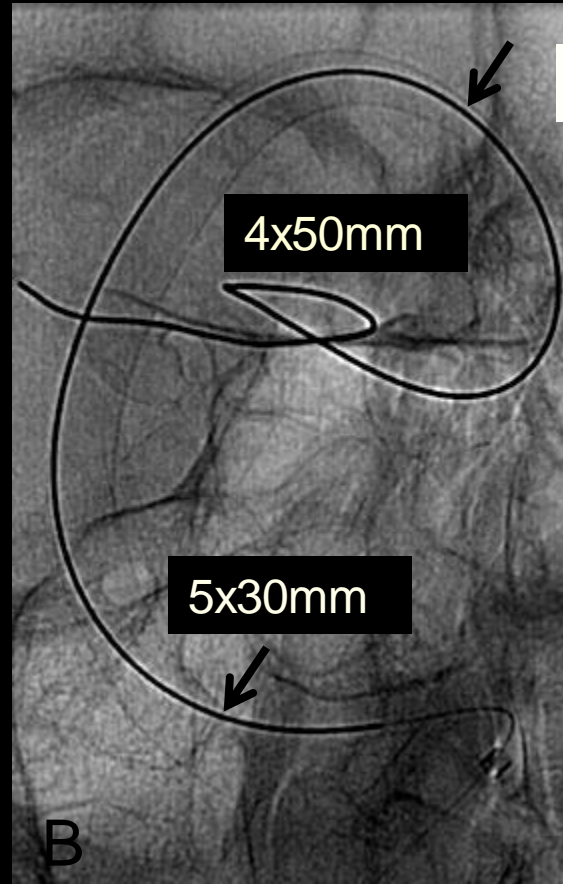
PIL
ASR



PIL
ASR



Basilar Trunk Aneurysm



** Surpass FD currently not FDA approved*

Aneurysm treatment

Procedural complications 9 (17.3%)

(binary; 95% CI:8.2%-30.3%)

Aneurysmal rupture	1/52
Dissection target vessel	2/52
Thrombus formation	6/52

Procedure complications correlated with age ($p < 0.05$)

Procedure complications did not correlate with location ($p = 0.304$)

Procedure complications did not correlate with # of FDs ($p < 0.2$)

Aneurysm treatment

New neurological deficit @ 24h follow up

(binary; 95% CI: 15.6%-41%)

Death	1/52
Tetraparesis	1/52
Hemiparesis	2/52
Cranial nerve deficits	6/52

New neurological deficit correlated with baseline mRS ($p=0.0018$)
location ($p=0.028$)
of FDs ($p=0.0266$)
aneurysm size ($p=0.0071$)
Neck size ($p=0.0359$)

Complications during hospital stay

Neuro	
Ischemia	4
Asymptomatic ICH	3
SAH	1

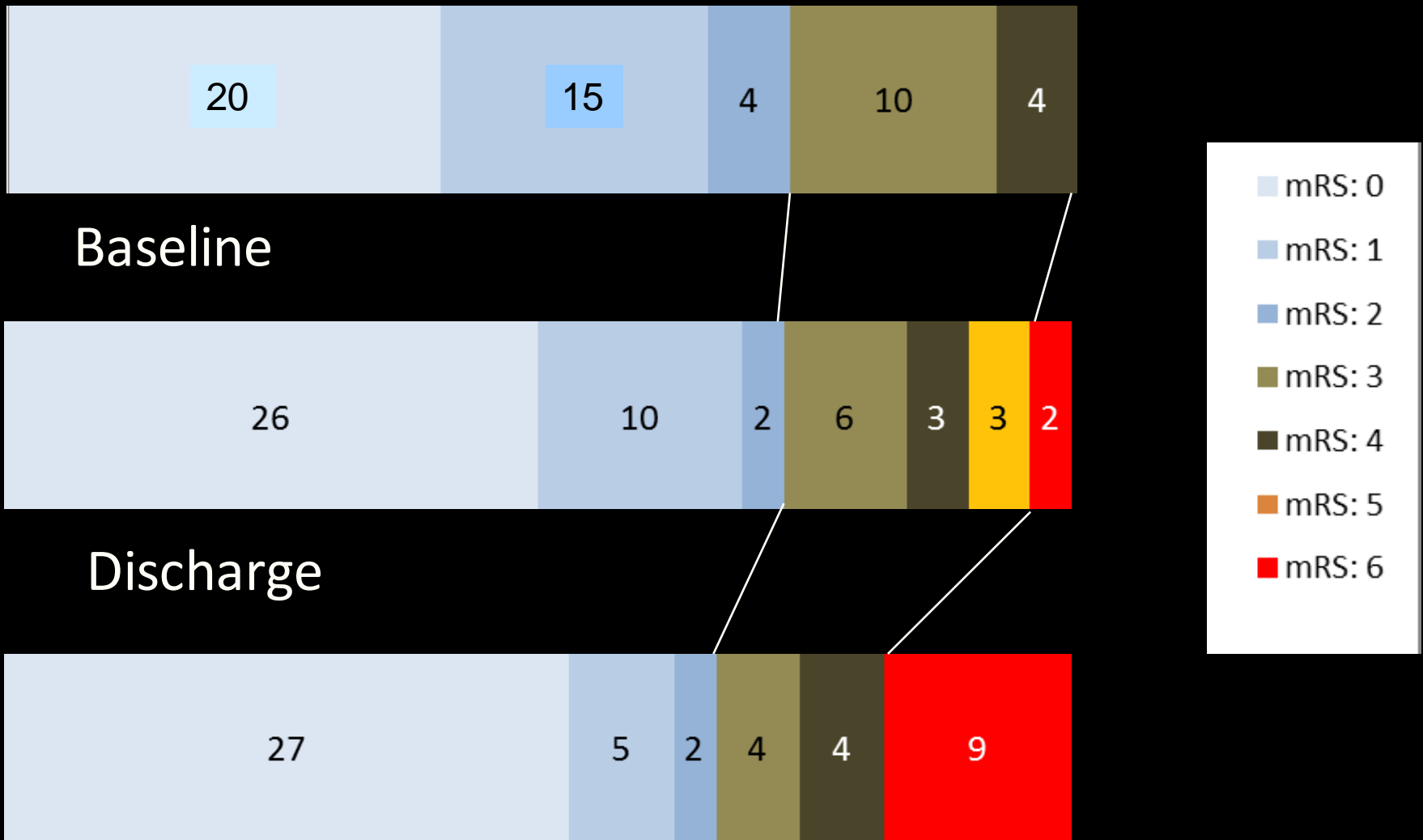
Clinically stable 39/52 pts (75%)

Clinically improved 7/52 pts (13%)

Clinically deteriorated 4/52 pts (8%)

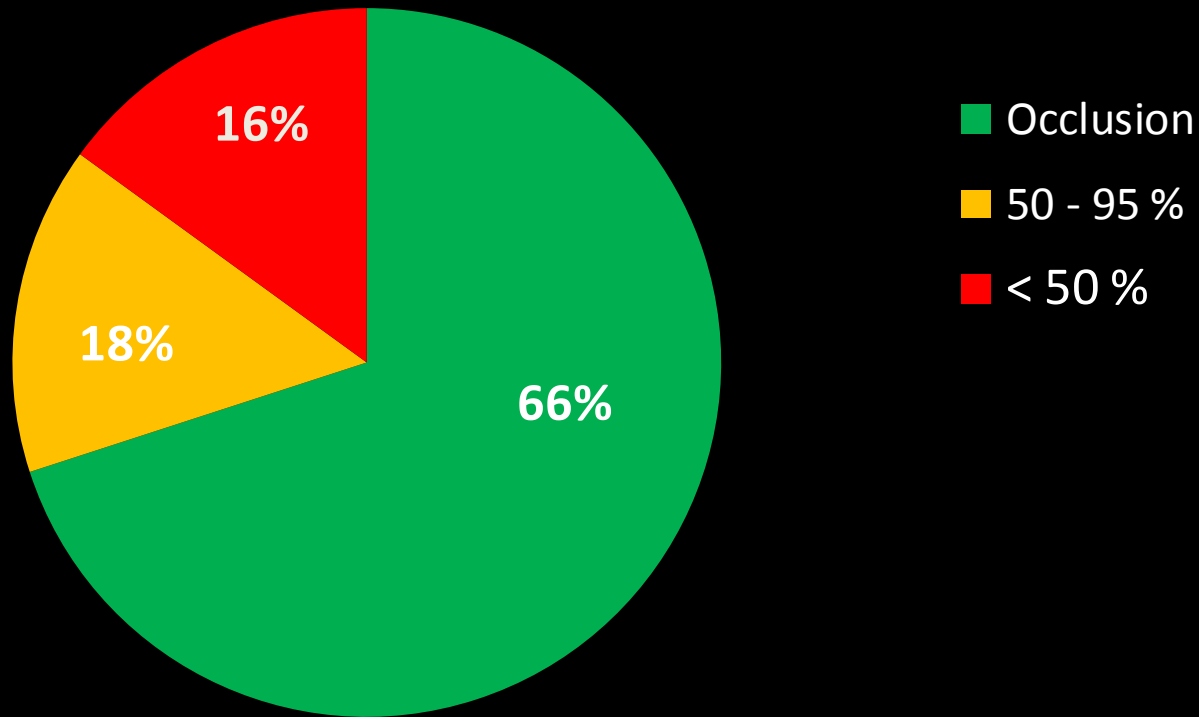
Death 2/52 pts (4%)

Clinical Outcome



Follow-up: mean 11.3 months (range 6 – 12.7)

Angiographic outcome (n=44; 85%)



Follow-up: mean 11.3 months (range 1 – 23)

mRS shift: All patients (n=51)

Baseline mRS	mRS at follow-up						
	mRS 0	mRS 1	mRS 2	mRS 3	mRS 4	mRS 5	mRS 6
mRS 0 (n=21)	20	1					
mRS 1 (n=12)	4	4	1	1	1		1
mRS 2 (n=4)	1		1		1		1
mRS 3 (n=10)	2			3			5
mRS 4 (n=4)					2		2

Improvement mRS 2/3	Improvement mRS 1	Stable mRS	Deterioration mRS 1	Deterioration mRS 2/3
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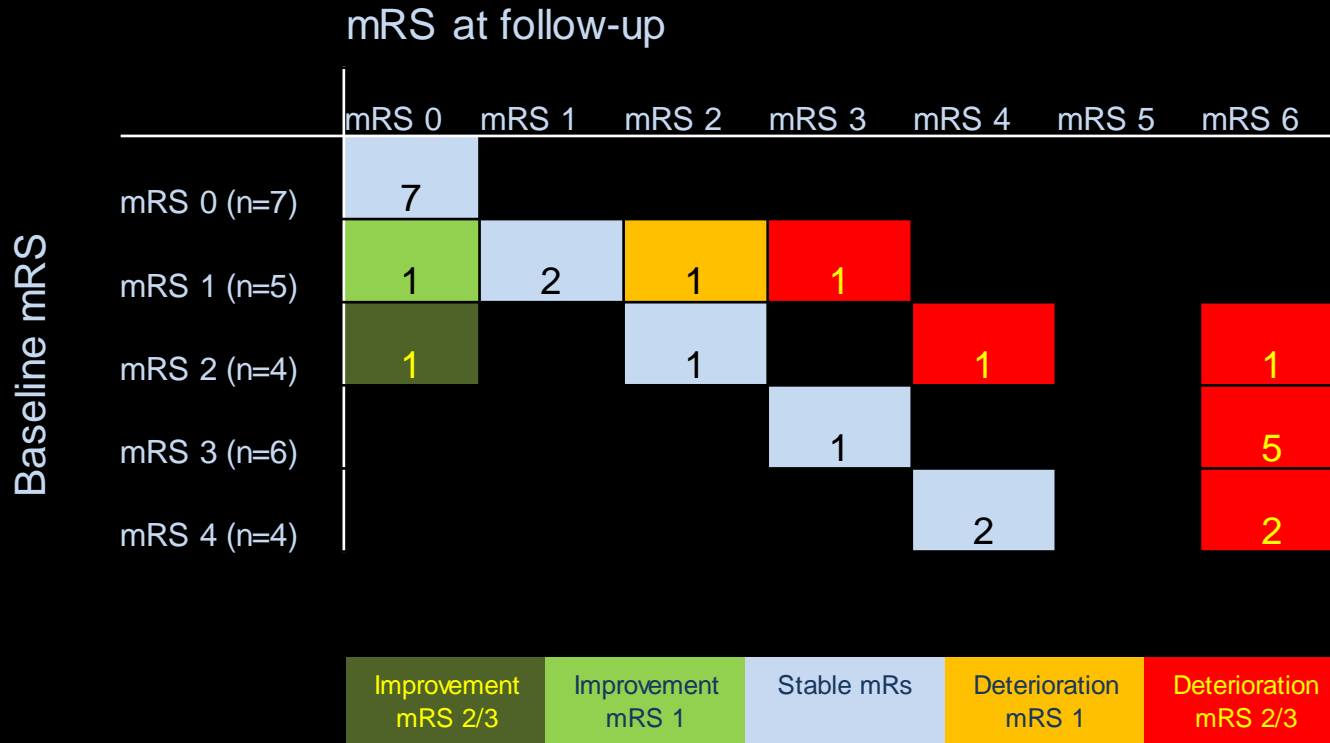
All cause mortality rate of 17.3% (95% CI: 7%-27.6%);
 13.5% directly related to procedure
 Morbidity 13.9% (95% CI: 3.6%-24.3%);

mRS shift: Vertebral artery aneurysm (n=19)

		mRS at follow-up						
		mRS 0	mRS 1	mRS 2	mRS 3	mRS 4	mRS 5	mRS 6
Baseline mRS	mRS 0 (n=13)	12	1					
	mRS 1 (n=5)	3	1					1
	mRS 2 (n=0)							
	mRS 3 (n=1)				1			
	mRS 4 (n=0)							

Improvement mRS 2/3	Improvement mRS 1	Stable mRS	Deterioration mRS 1	Deterioration mRS 2/3
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mRS shift: Basilar artery/VB junction aneurysm (n=26)



($p=0.002$)

Conclusion

Treatment of aneurysms located in the posterior circulation with the Surpass FD is feasible

It shows a variable safety profile

Good clinical outcomes were observed in patients bearing aneurysms of the vertebral artery

Worst outcome was observed in symptomatic patients with fusiform aneurysms of the basilar artery and the VB junction

Conclusion

In patients with fusiform basilar and VB junction aneurysms the clinical outcome seemed better in asymptomatic patients when compared to symptomatic patients

Overall morbidity and mortality 27%

Asymptomatic patient: morbidity 5% mortality 0%

Symptomatic patient: morbidity 44% mortality 28%

Conclusion

Mortality was positively correlated with

- Baseline mRS (p=0.0001)
- Age (p=0.018)
- Aneurysm location (p=0.02)
- Aneurysm size (p=0.0098)
- Neck diameter (p=0.06)
- Number of FDs (p=0.0002)

Discussion Points

Time for a multicenter study for large/giant basilar trunk/VB junction aneurysm?

Thanks