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Innovations in Brain Aneurysm Treatment

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KALEIDA HEALTH

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Disclosure Statement of Financial Interest

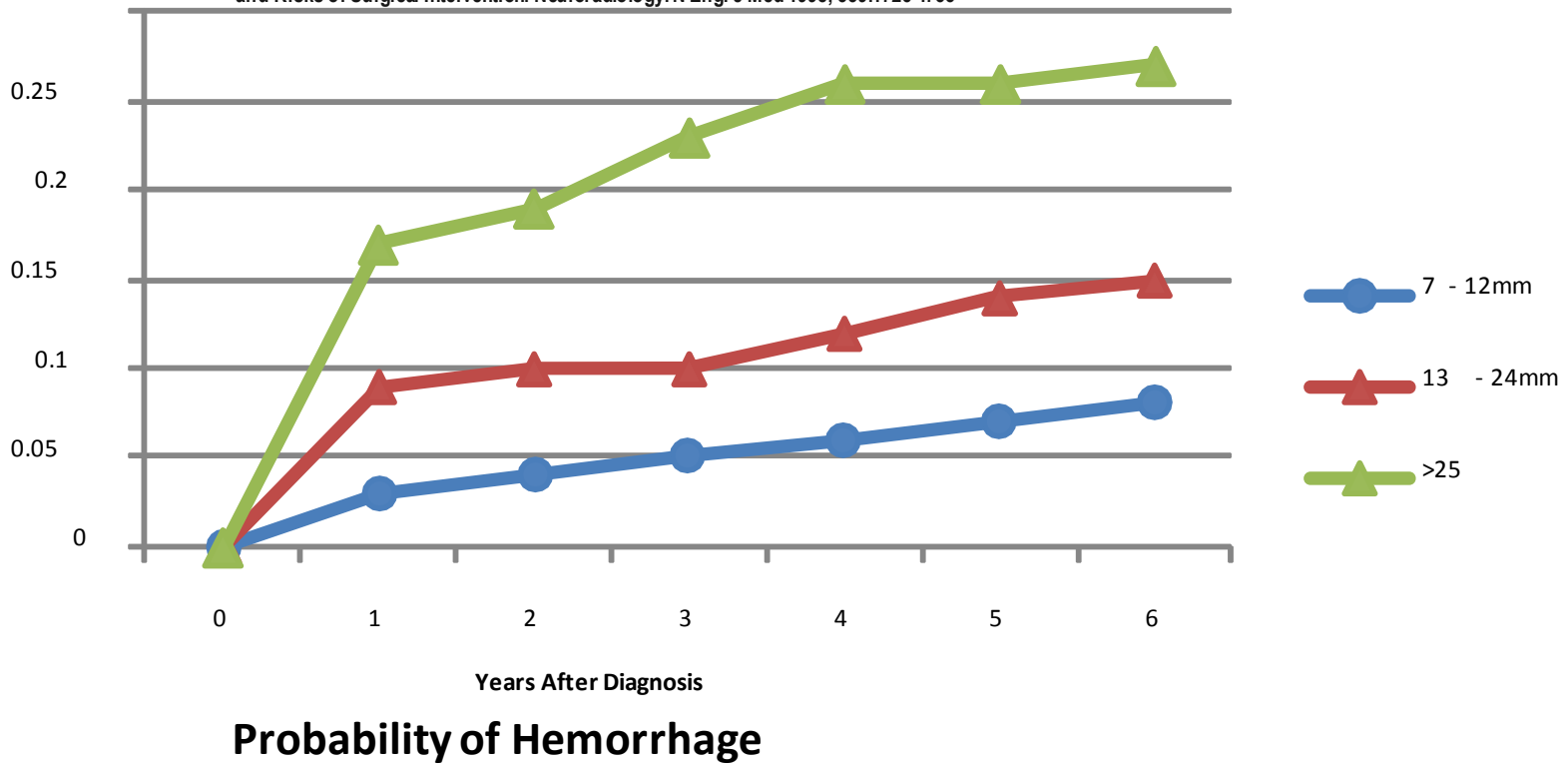
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Toshiba, Medtronic, Microvention
• Consulting Fees/Honoraria	• None
• Major Stock Shareholder/Equity	• Claret, Boston Scientific, Claret, Medina, Ostial, Apama, Ocular
• Royalty Income	• None
• Ownership/Founder	• None
• Intellectual Property Rights	• None
• Other Financial Benefit	• None

Unruptured Aneurysms
Annual Risk of Hemorrhage Rate

(patients without previous history of SAH)

Source:
3. The International Study of Unruptured Intracranial Aneurysms Investigators. Unruptured Intracranial Aneurysms – Risk of Rupture and Risks of Surgical Intervention. Neuroradiology. N Engl J Med 1998; 339:1725-1733



Lots of Data, No clear cut standards
ISUA results provide some guidance, but…
Small aneurysms(<7mm) “rarely rupture” yet…
Most ruptured aneurysms < 5mm in practice

Unruptured Aneurysms

When do we treat??

- > 7 mm
- < 7mm and
  - Previous hx of SAH
  - Family history
  - Patient choice
  - Morphoilogy
  - Certain locations

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How to Treat?

Clipping(surgery) vs Endovascular

- Every case must be individualized!
- Find a surgeon/team who can coil and clip!!
- Consider:
  - Anatomy and location
  - Age
  - General health
  - Access
  - Patient informed Choice

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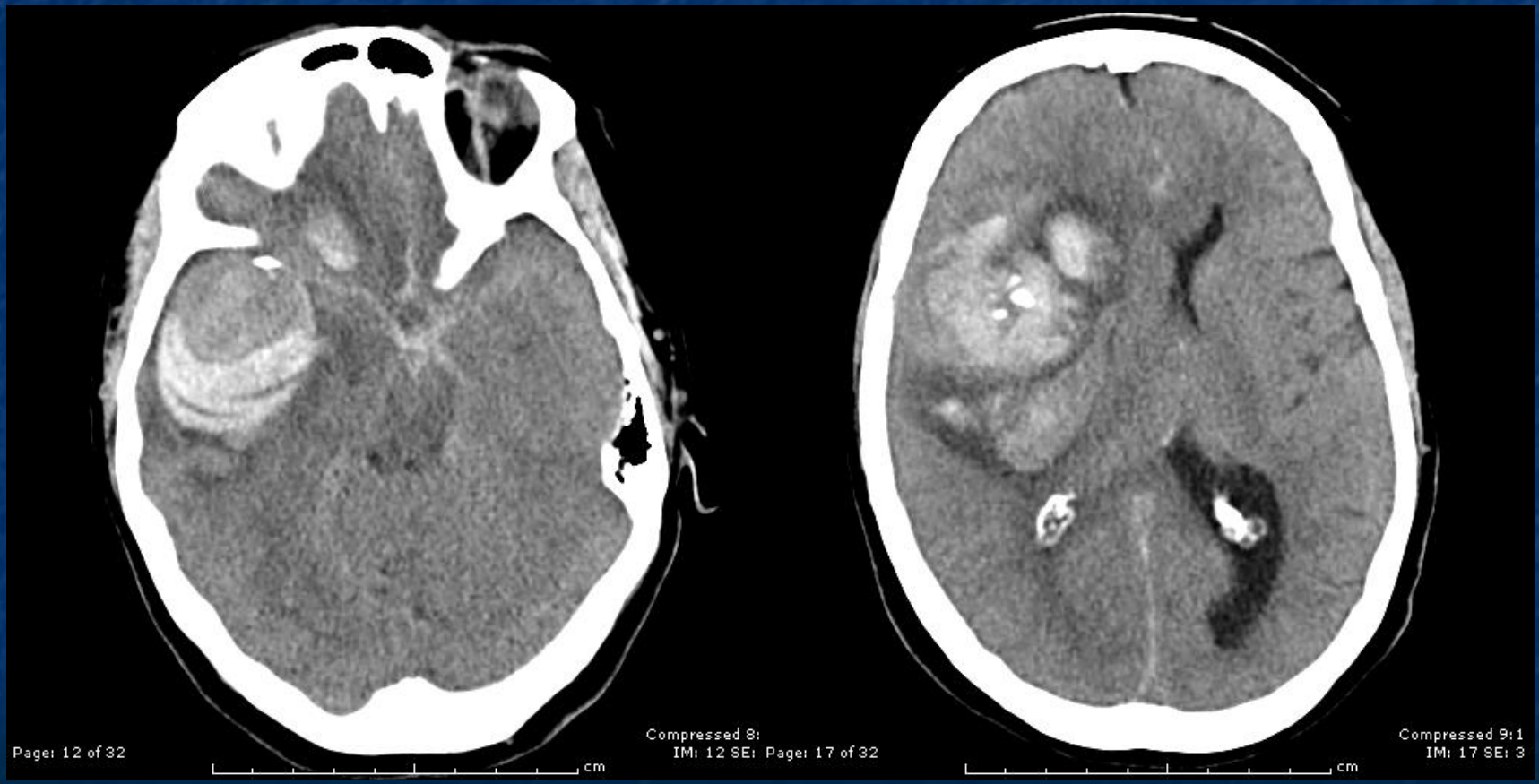
Tough Choices

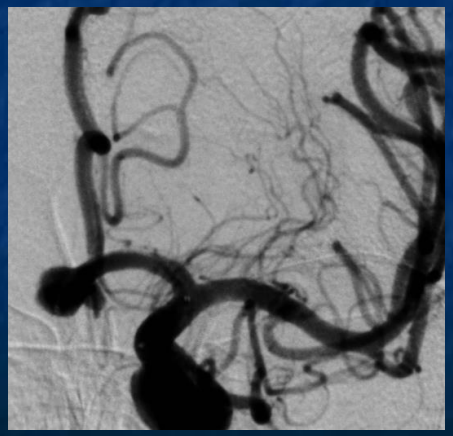
Rupture: Hemorrhage/Mass effect

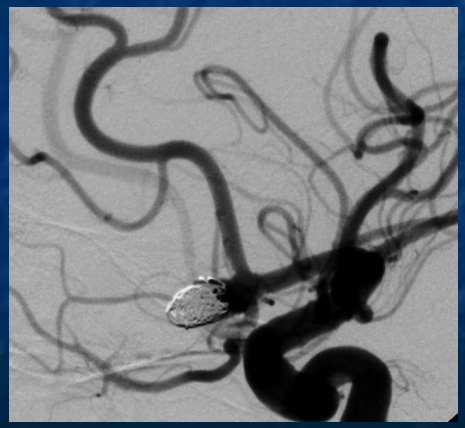


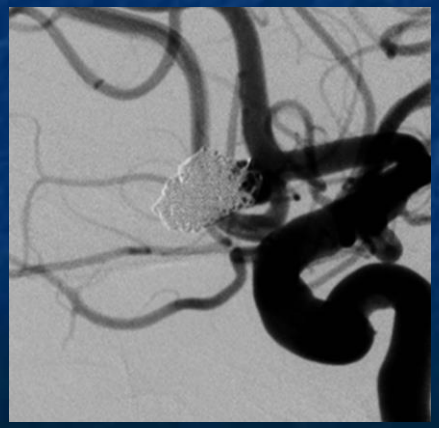
Coil FAST and Decompress/Clip

General Rules

- Endovascular has less morbidity
  - Especially in elderly
- Surgery may be more efficacious
  - Especially in younger patients







Recannalization X 2

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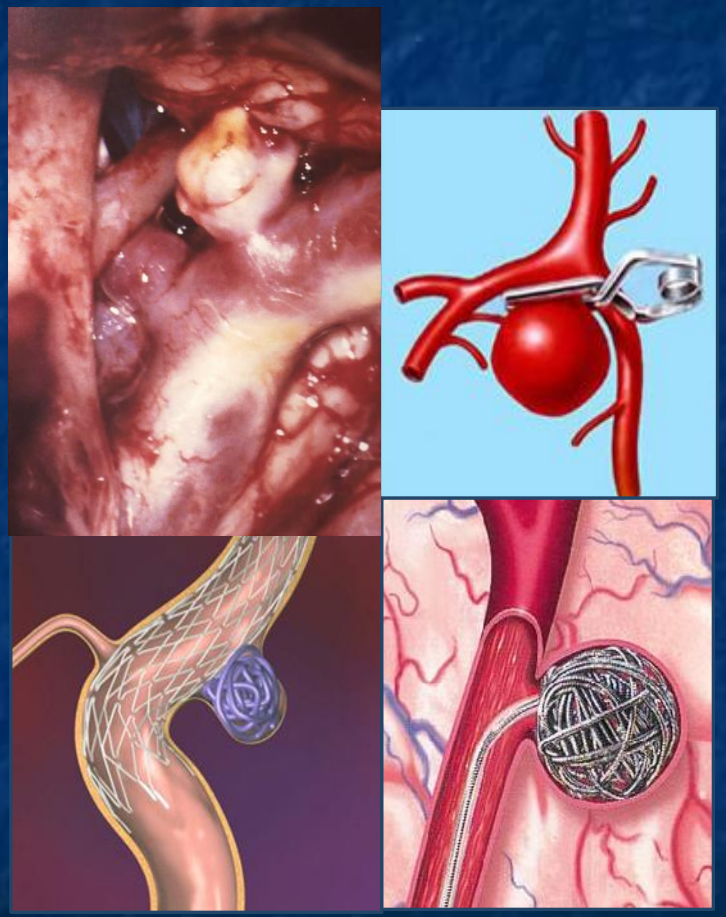
Clipping of residual aneurysm
Can your surgeon clip **and** coil???

If all you have is a hammer…

Conventional Therapy

- Open Surgical Techniques
  - Clipping seals aneurysm to exclude it
  - Bypass/parent artery exclusion
- Endovascular
  - Bare metal and bioactive coils
  - Aneurysm bridging stent
  - Liquid embolics
  - Parent artery occlusion



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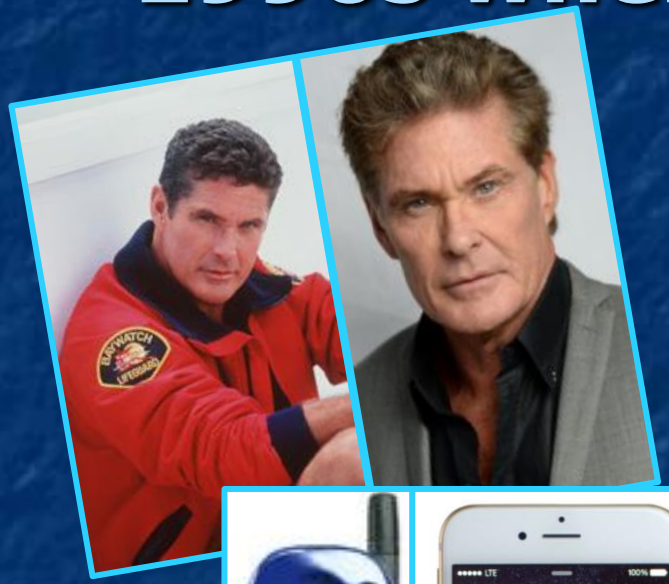
A lot has changed since the early 1990s when coils were invented



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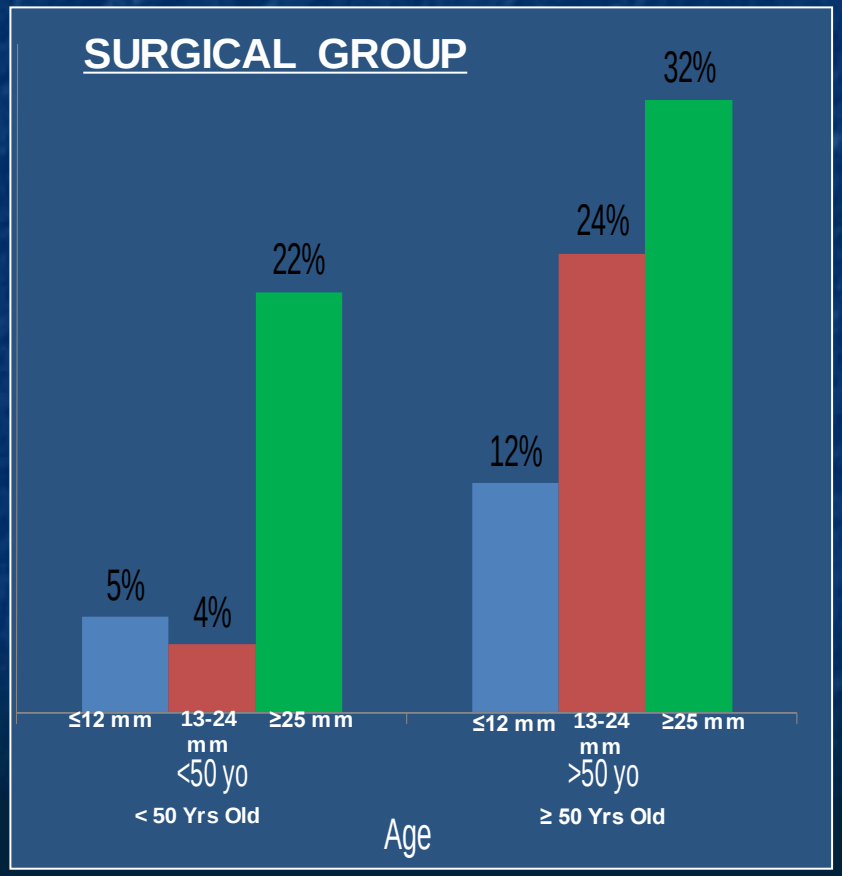
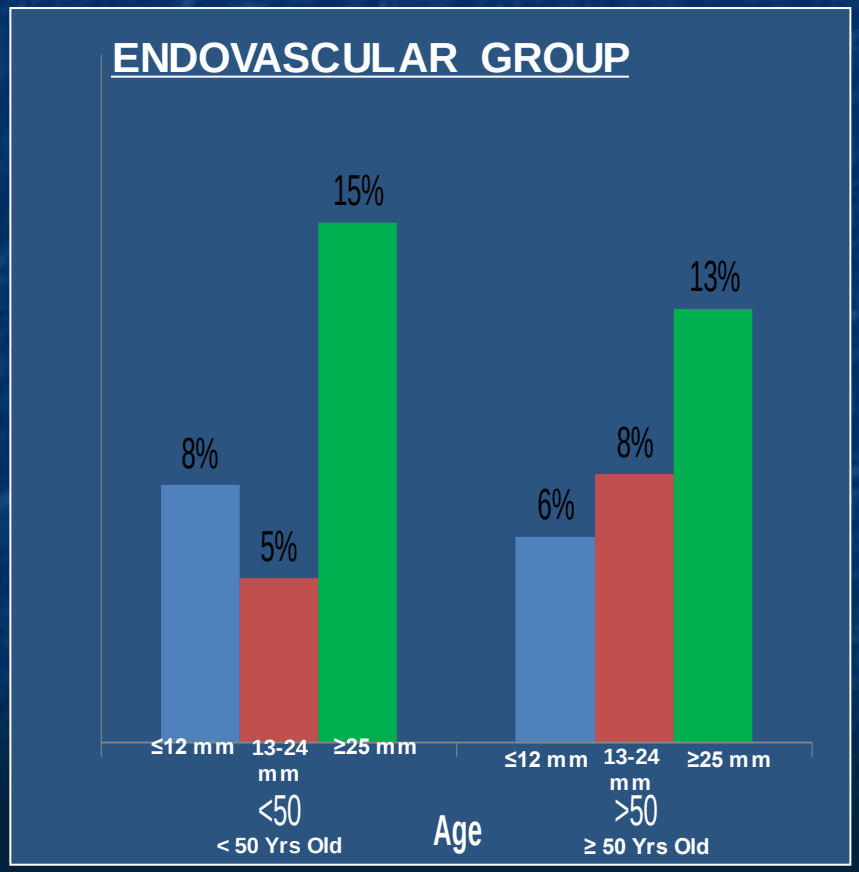
Overall Outcomes Improved with Endovascular Treatment

Poor Outcomes @1 yr: Death, MRS >2 or impaired cognitive status





The International Study of Unruptured Intracranial Aneurysms Investigators. Unruptured Intracranial Aneurysms – Risk of Rupture and Risks of Surgical Intervention.Neuroradiology. N Engl J Med 1998; 339:1725-1733

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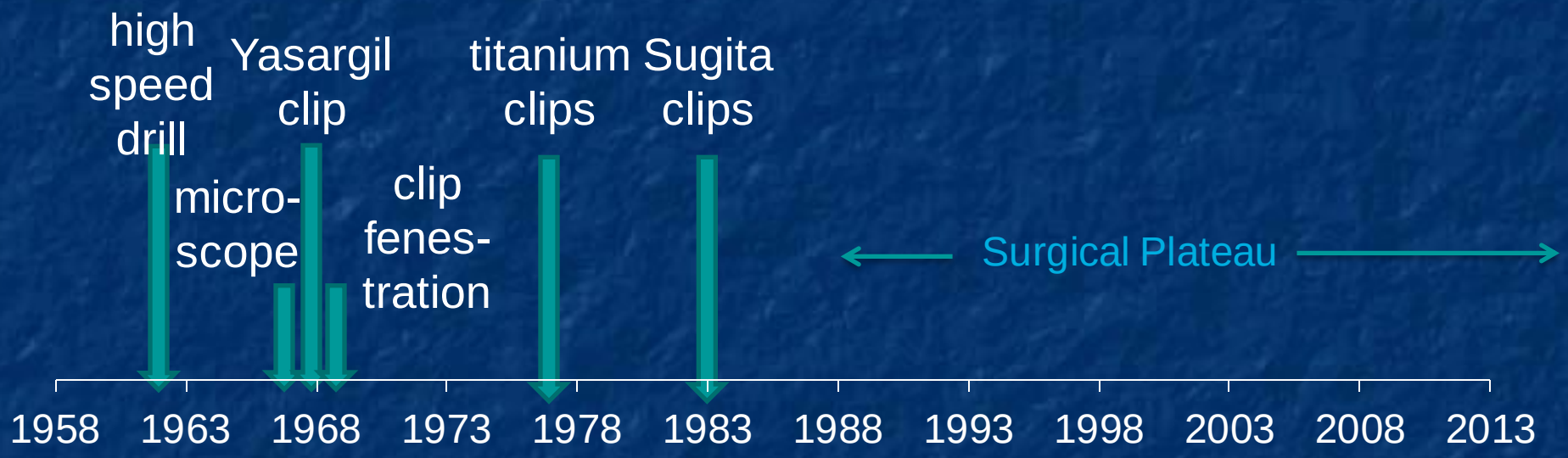
Endovascular Options for Aneurysm

A Technology Explosion!!

- Coiling
- Balloon-assisted coiling
- Stent-assisted coiling
- Flow Diverters
- Second generation microstents
- Second generation flow diverters
- Bifurcation stents/devices

Does your surgeon have all the tools???

Timeline of Clip Ligation



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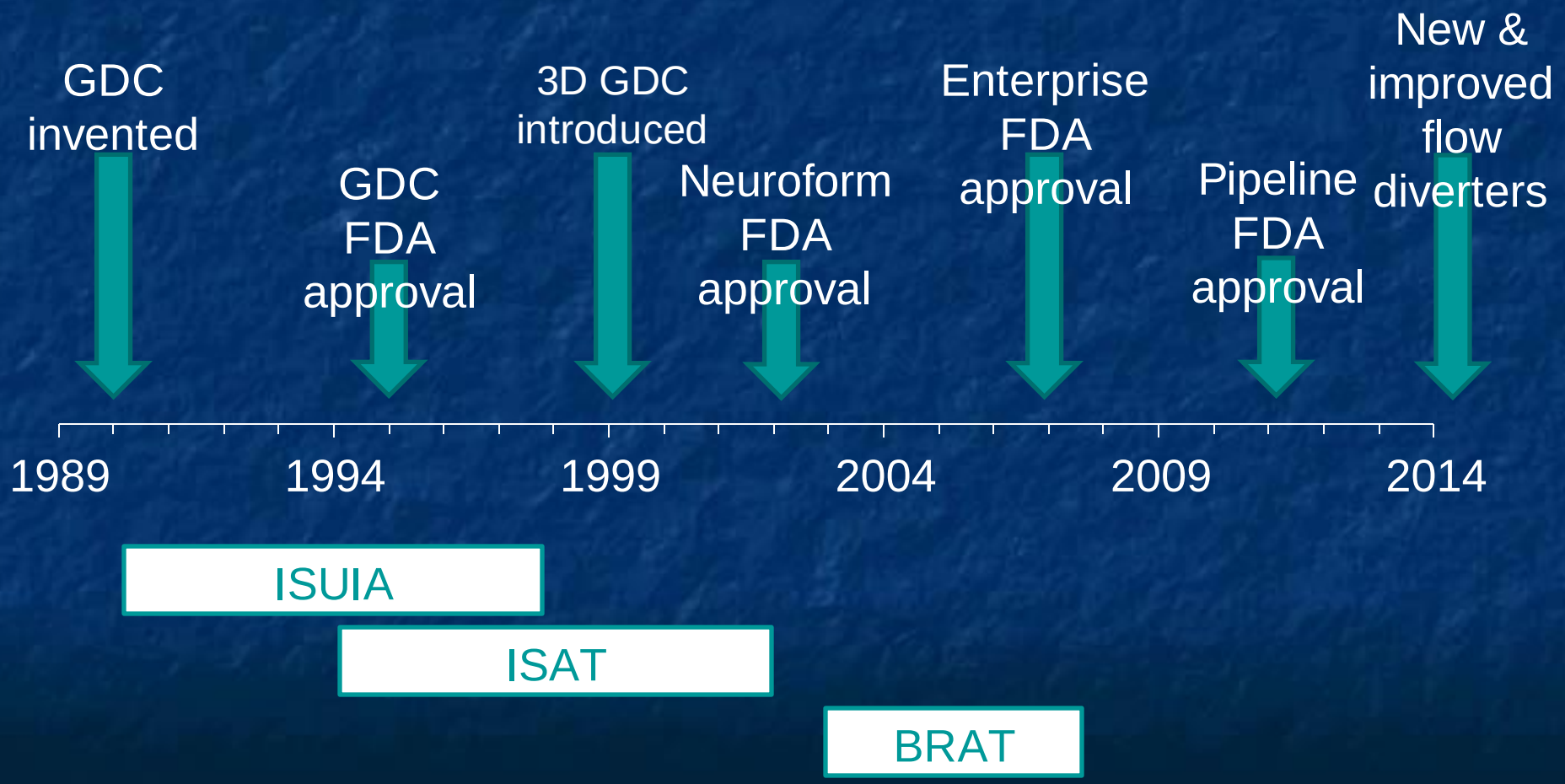
Timeline of Endovascular Technology

Evolving at Warp Speed!



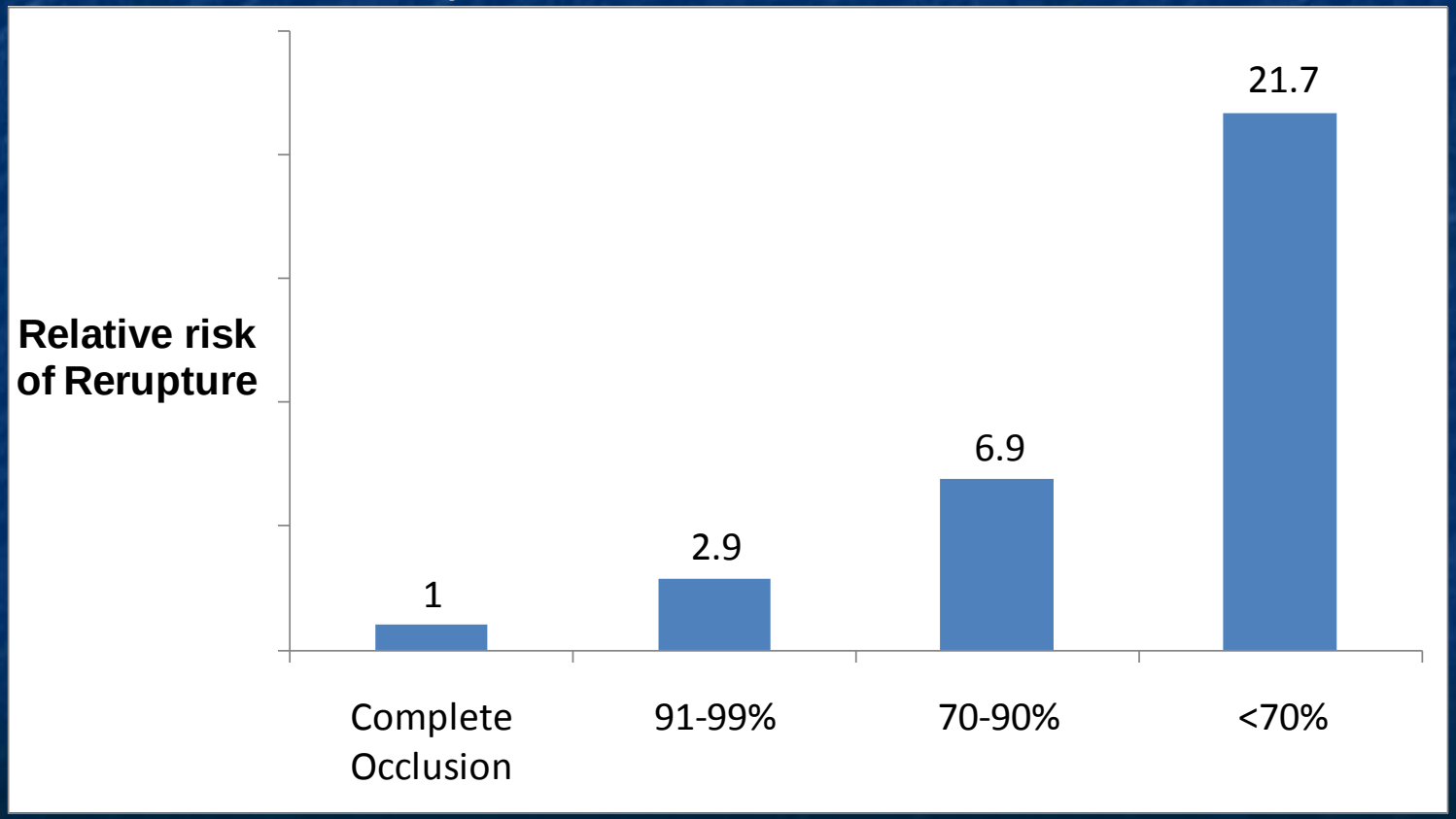
Primary coiling – The Problem

15

Incomplete Occlusion → Retreatment

CARAT Study

"…degree of aneurysm occlusion is a strong predictor of risk of subsequent rupture… and justifies attempts to completely occlude aneurysms"



Source:
16. Johnston SC, Dowd CF, Higashida RT, Lawton MT, Duckwiler GR, Gress DR. Predictors of rehemorrhage after treatment of ruptured intracranial aneurysms: The Cerebral Aneurysm Rerupture After Treatment (CARAT) Study. Stroke. 2008; 39: 120–125

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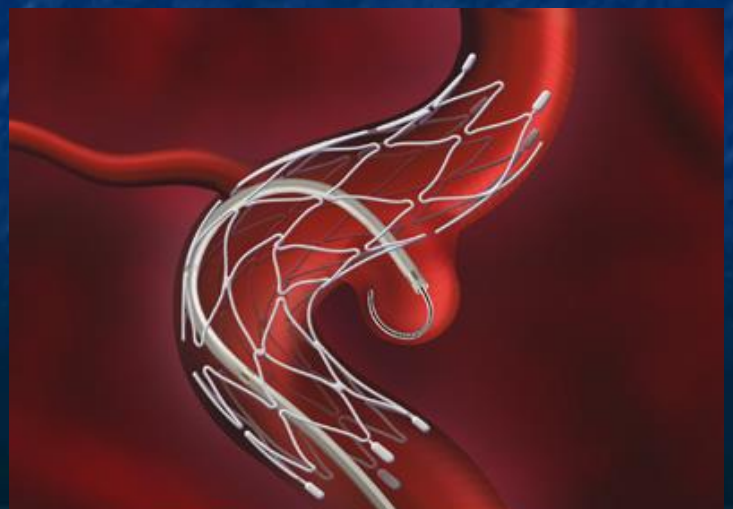
First Leap: Stent and Balloon Assisted Coiling

- Better occlusion rates and fewer recurrences
- Treatment of wide-neck, large/giant aneurysm became a realistic possibility



Stent-Associated Flow Remodeling Causes Further Occlusion of Incompletely Coiled Aneurysms

Matthew F. Lawson, MD*
William C. Newman, BA‡
Yueh-Yun Chi, PhD§
J. D. Mocco, MD, MS*
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Conclusions

- Stent assisted coiling causes progression of occlusion, possible by a flow remodeling effect
- Odds of progression of occlusion of stent-coiled aneurysms were 18.5x that of non-stented aneurysms

Flow Diverters

Flow Diverters: *Evolution of a Concept*

- The concept of comes from observations of intra-aneurysmal flow patterns in models of stented intracranial aneurysms
- Placement of a low porosity stent across the aneurysmal neck redirects flow away from the aneurysm and back into the parent artery

***Stroke. 2011;42:* 2363-2368.**

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Flow Diversion and Hemodynamic Simulation

Endoluminal Reconstruction

Rebuilding the vessel lumen

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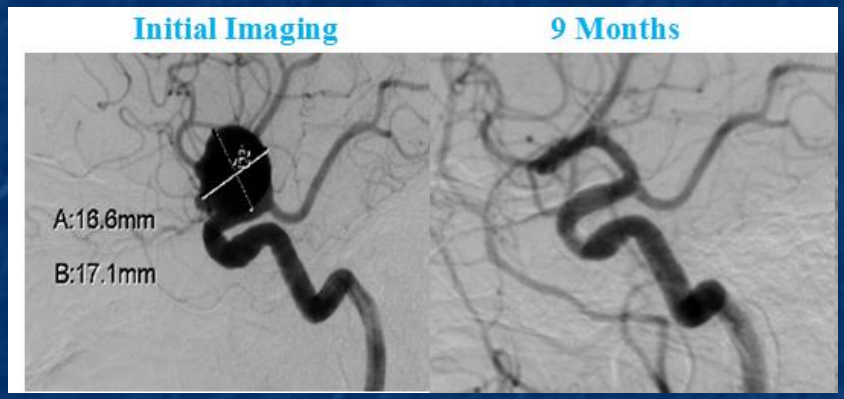
Virtual deployment models:



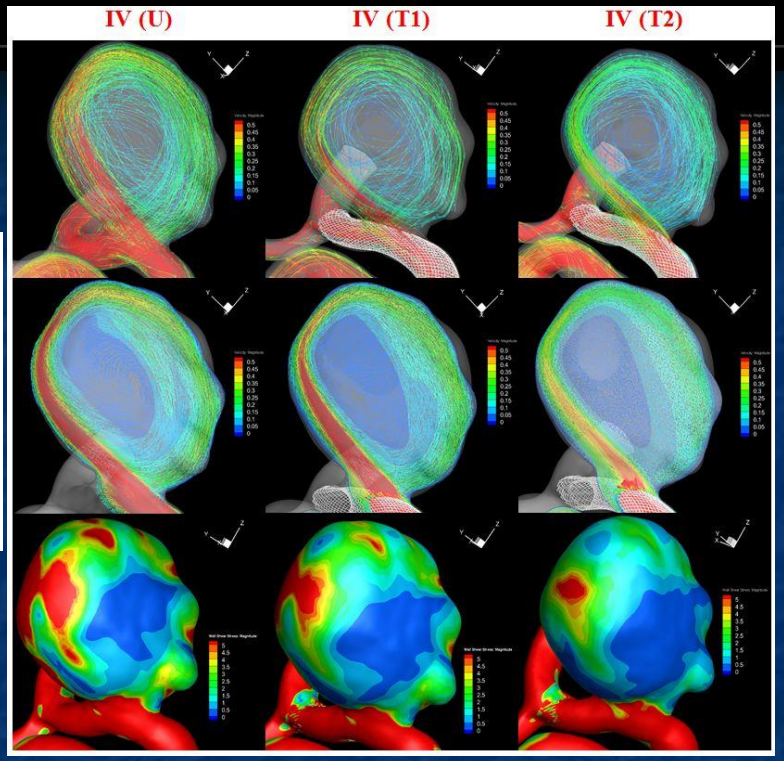


Figure 32. 3D streamlines (first row), intra-aneurysmal velocity vectors (second row), and WSS distributions (third row) for Aneurysm IV.

Aneurysm Case	Scenario		Average WSS	Average Aneurysmal Velocity Magnitude	Inflow Rate	Turnover Time
Aneurysm IV	IV (U)		100.00%	100.00%	100.00%	100.00 %
	IV (T1, T2)	1st PED	68.23%	79.70%	80.00%	125.00 %
		2nd PED	40.91%	60.60%	61.35%	162.99 %

Endoluminal Reconstruction

Two main action mechanisms

1. **Flow Diversion** away from the aneurysmback into the parent artery
2. **Re-endothelization** – formation of a new scaffold upon which endothelial cells can grow

Data suggest that a stent with an overall porosity of 50–70% (30–50% metallic coverage) significantly reduces inflow rate into an aneurysm

Liou TM, Li YC. Effects of stent porosity on hemodynamics in a sidewall aneurysm model. J Biomech 2008;41:1174–83

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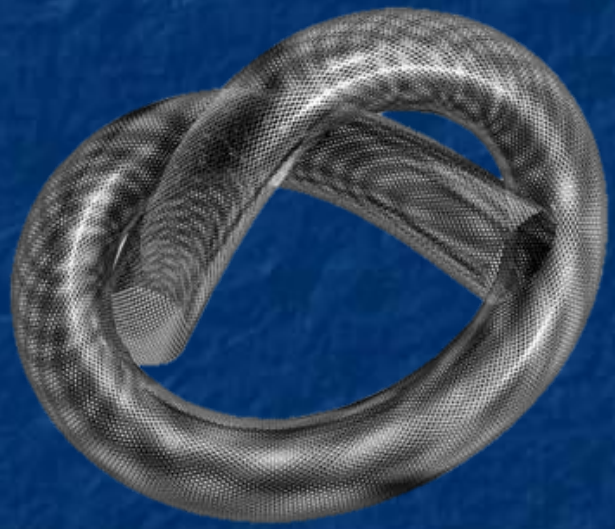
Pipeline Embolization Device

The first flow diverter

- Braided mesh cylinder
- Platinum nickel-cobalt chromium alloy
- Self-expanding, 35% metallic coverage
- Variable diameter and
- Pore size is 0.02 to 0.05 mm^2



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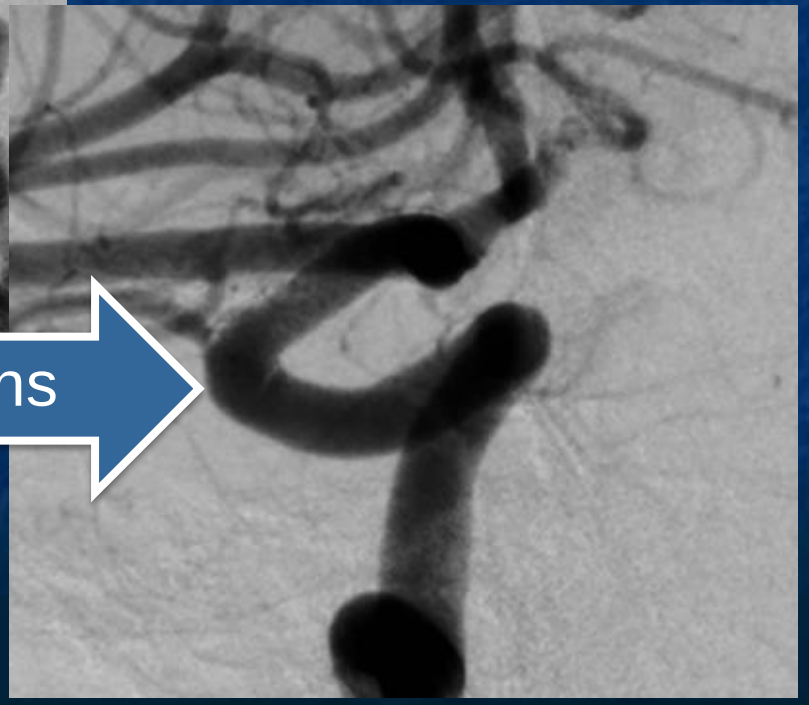
Pipeline Embolization Device

Treatment of large and giant and wide-necked aneurysms.

Endoluminal Flow Diversion

Cavernous

3 months



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NEUROSURGERY
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Post-market experience with Pipeline

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Early Postmarket Results After Treatment of Intracranial Aneurysms With the Pipeline Embolization Device: A US Multicenter Experience

BACKGROUND: The Pipeline embolization device (PED) is the latest technology available for intracranial aneurysm treatment.

OBJECTIVE: To report early postmarket results with the PED.

METHODS: This study was a prospective registry of patients treated with PEDs at 7 American neurosurgical centers subsequent to Food and Drug Administration approval of this device. Data collected included clinical presentation, aneurysm characteristics, treatment details, and periprocedural events. Follow-up data included degree of aneurysm occlusion and delayed (> 30 days after the procedure) complications.

RESULTS: Sixty-two PED procedures were performed to treat 58 aneurysms in 56 patients. Thirty-seven of the aneurysms (64%) treated were located from the cavernous to the superior hypophyseal artery segment of the internal carotid artery; 22% were distal to that segment, and 14% were in the vertebrobasilar system. A total of 123 PEDs were deployed with an average of 2 implanted per aneurysm treated. Six devices were incompletely deployed; in these cases, rescue balloon angioplasty was required. Six periprocedural (during the procedure/within 30 days after the procedure) thromboembolic events occurred, of which 5 were in patients with vertebrobasilar aneurysms. There were 4 fatal postprocedural hemorrhages (from 2 giant basilar trunk and 2 large ophthalmic artery aneurysms). The major complication rate (permanent disability/death resulting from perioperative/delayed complication) was 8.5%. Among 19 patients with 3-month follow-up angiography, 68% (13 patients) had complete aneurysm occlusion. Two patients presented with delayed flow-limiting in-stent stenosis that was successfully treated with angioplasty.

CONCLUSION: Unlike conventional coil embolization, aneurysm occlusion with PED is not immediate. Early complications include both thromboembolic and hemorrhagic events and appear to be significantly more frequent in association with treatment of vertebrobasilar aneurysms.

KEY WORDS: Endovascular treatment, Flow diversion, Intracranial aneurysm, Pipeline device

Neurosurgery 71:1080–1088, 2012 DOI: 10.1227/NEU.0b013e318270b0d9 www.neurosurgery-online.com

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JNS Journal of Neurosurgery
Official Journals of the AANS since 1944

Journal of Neurosurgery
Jun 2012 / Vol. 116 / No. 6 / Pages 1258-1266

ARTICLE

Panacea or problem: flow diverters in the treatment of symptomatic large or giant fusiform vertebrobasilar aneurysms
Clinical article

Adnan H. Siddiqui, M.D., Ph.D.[1,2,3], Adib A. Abla, M.D.[1,3], Peter Kan, M.D., M.P.H.[1,3], Travis M. Dumont, M.D.[1,3], Shady Jahshan, M.D.[1,3], Gavin W. Britz, M.D., M.P.H.[4], L. Nelson Hopkins, M.D.[1,2,3], and Elad I. Levy, M.D.[1,2,3]

- High morbidity and mortality for posterior circulation aneurysms
- Epipheny…."One 'n Done"

Buffalo Experience:

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Use of Coils in Conjunction With the Pipeline Embolization Device for Treatment of Intracranial Aneurysms

Lin N[1], Brouillard AM, Krishna C, Mokin M, Natarajan SK, Sonig A, Snyder KV, Levy EI, Siddiqui AH.

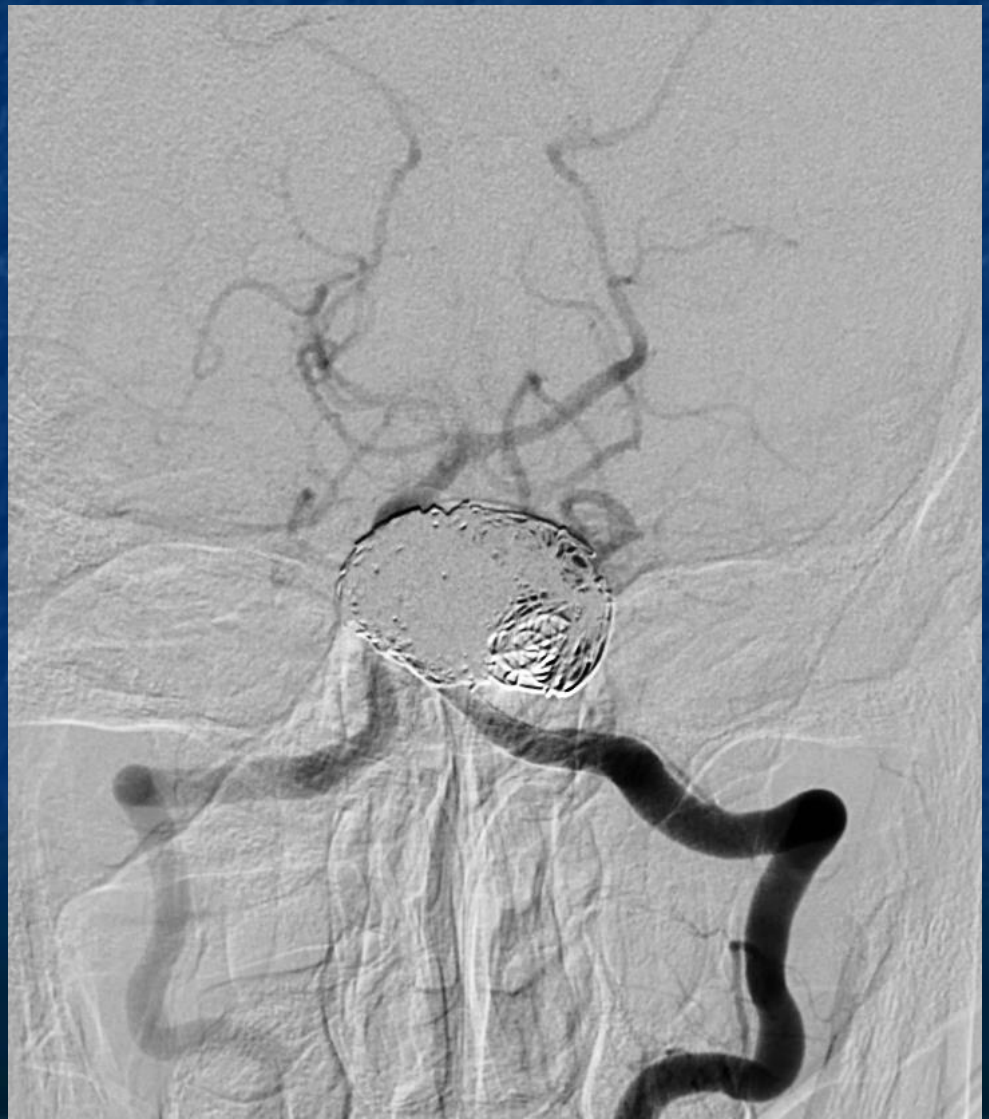
Conclusion: PED+coils may be a safe and effective treatment for aneurysms with high risk of rupture (or rerupture) and complex anatomy. Coiling in conjunction with PED placement provided a higher aneurysm occlusion rate and reduced the need for retreatment.

PED in conjunction with coils

- 36 yo F with headaches and discovery of giant vertebro-basilar aneurysm

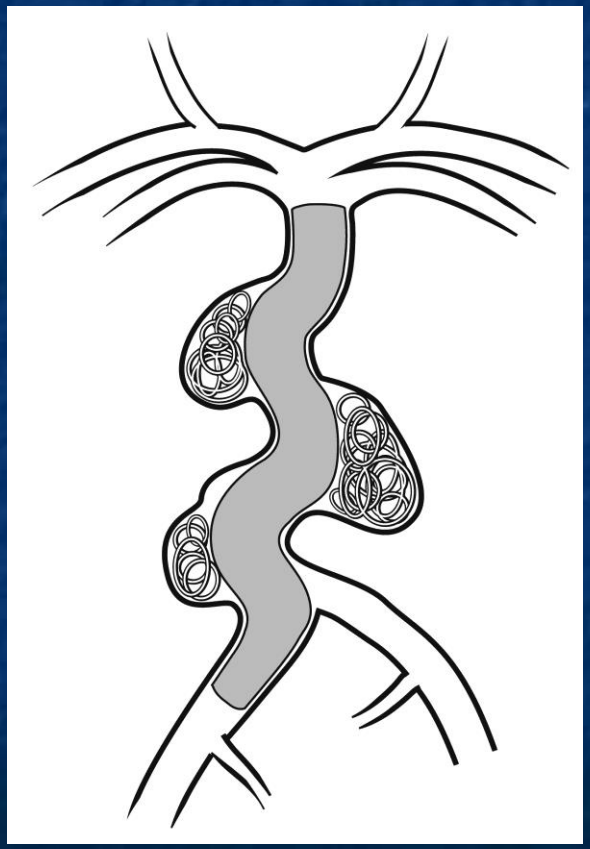
Baseline images: vertebral runs

Final result



Lessons Learned

- Judicious use of coils
  - As a scaffold for PED placement
  - Promote thrombosis



Reconstruct basilar artery and coil the saccular component

Sacrifice contralateral VA in case of VBJ aneurysm

JNS JOURNAL OF NEUROSURGERY
OFFICIAL JOURNALS OF THE AANS SINCE 1944

The safety of Pipeline flow diversion in fusiform vertebrobasilar aneurysms: a consecutive case series with longer-term follow-up from a single US center

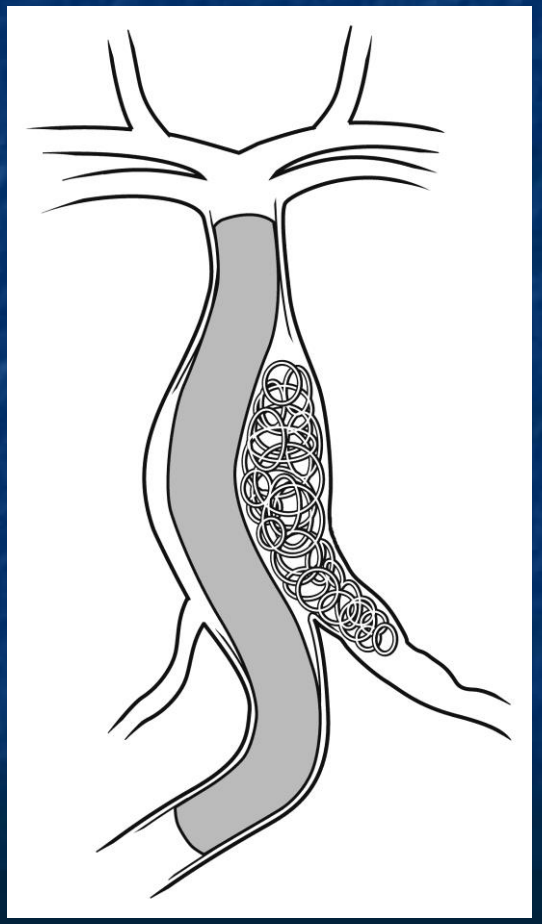
Sabareesh K. Natarajan, MD, MS,[1,2] Ning Lin, MD,[1–3] Ashish Sonig, MD, MS, MCh,[1,2] Ansaar T. Rai, MD,[4] Jeffrey S. Carpenter, MD,[4] Elad I. Levy, MD, MBA,[1,2,5,6] and Adnan H. Siddiqui, MD, PhD[1,2,5–7]

Conclusions Flow diversion with selective adjunctive techniques is evolving to become a safer treatment option for posterior circulation aneurysms. This is the longest clinical follow-up duration reported for a single-center experience of Flow-diversion treatment of these aneurysms

VBJ Aneurysm

- 54 yo M with ataxia and diplopia and work up showing giant vertebro-basilar aneurysm

Vertebral Runs: Baseline – bilateral vertebral runs



Aneurysm supplied by both VA's → need to sacrifice one VA

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Working Plan

Pipeline via Marksman

Coiling via PX SLIM

Final Result

Follow-up

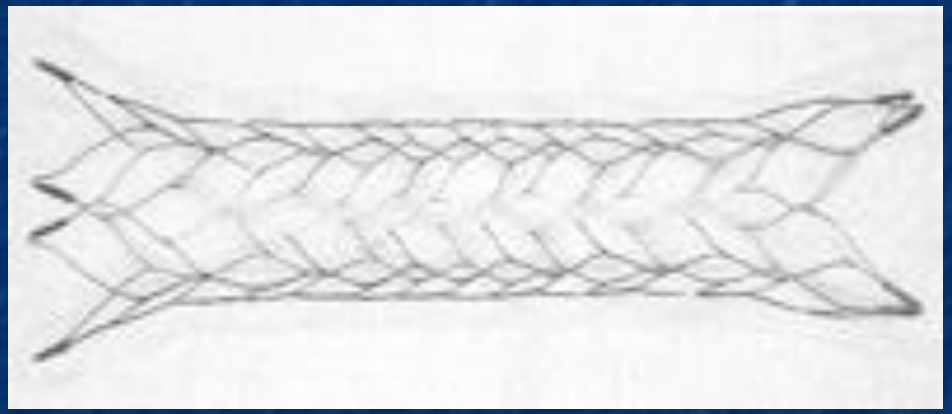
- Doing well at 3-month follow-up visit
- Improving diplopia

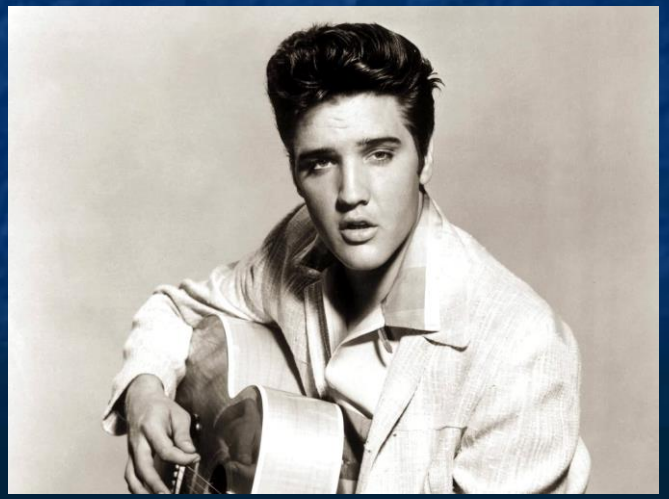
- MRA showed no residual filling of the aneurysm

THE NEXT GENERATIONS

LOTS OF NEW AND EXCITING ADVANCES

LVIS
(LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT)

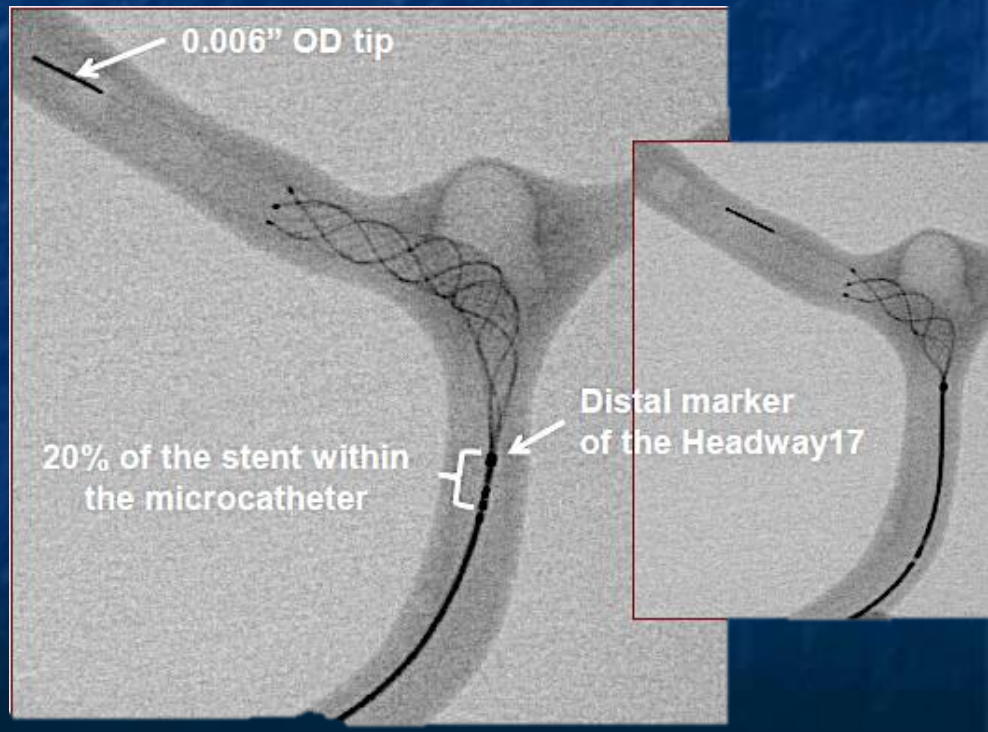




(NOT ELVIS)

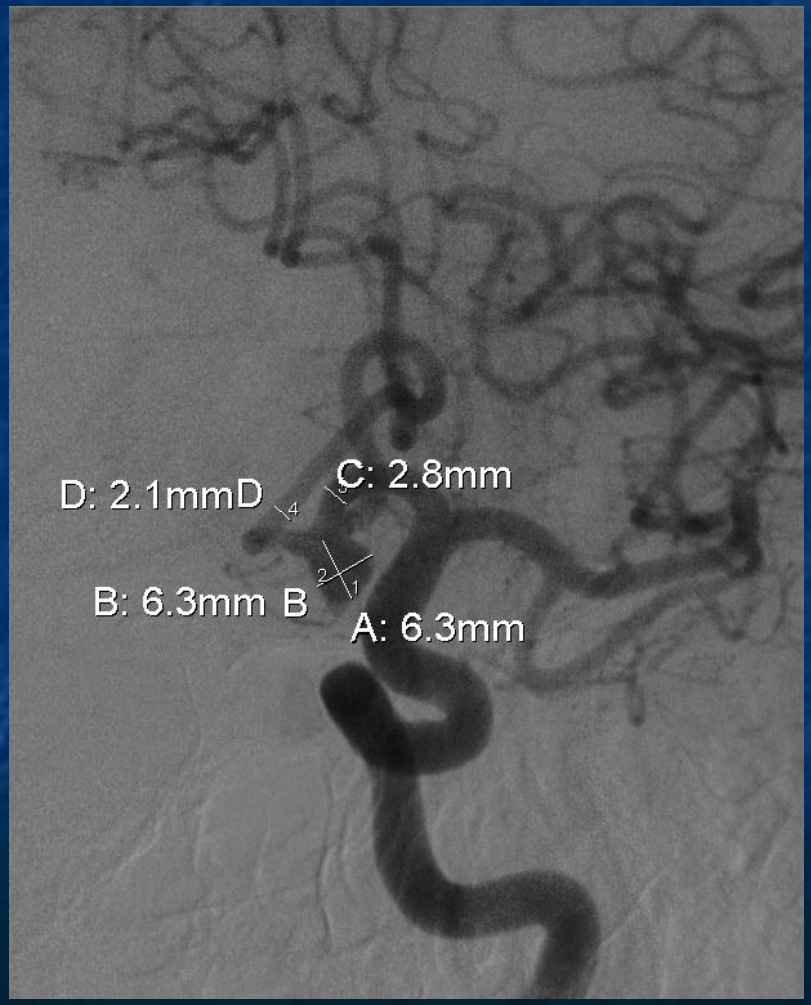
LVIS Device: Low-profile Visualized Intraluminal Support

- Radiopaque proximal and distal markers
- Flared ends
- 2 radiopaque strands



LVIS Jr. Stent-Coiling

- 70 y/o male with incidentally identified ACom aneurysm
- Plan:
  - Jail SL 10 with an LVIS Jr.
  - Coil the aneurysm through the jailed SL 10



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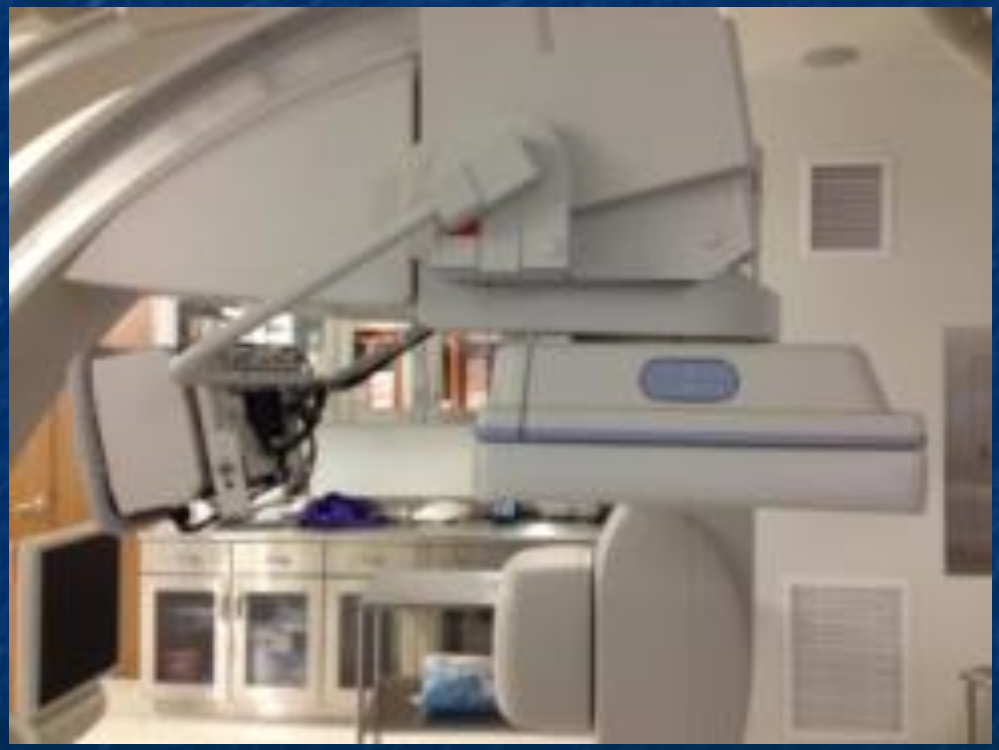
Headway 17 navigated into the contra-lateral A2 SL 10 navigating toward the aneurysm

LVIS-coiled aneurysm

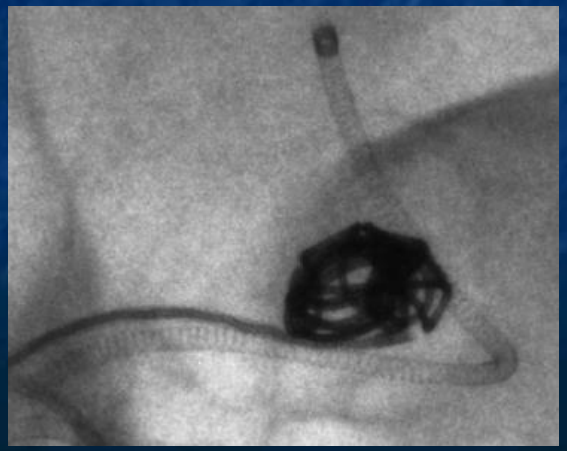
Microangio Fluoroscopy



Not Yet FDA Approved

Microangio Fluoroscopy

- Ultra-high intraprocedural magnification of stent struts, coils, microwires, microcatheters
- Visualization from 250 down to 30 microns



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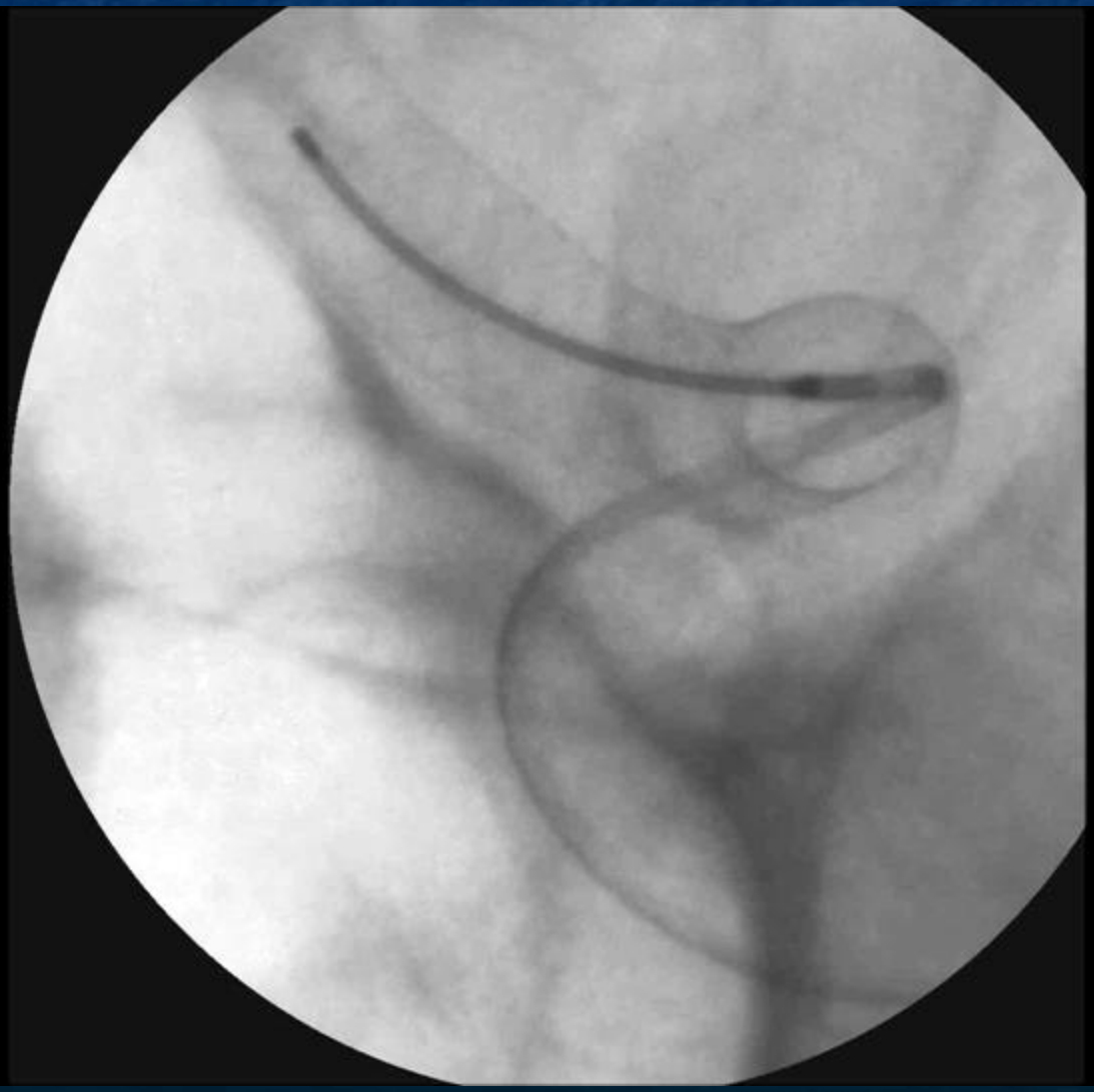
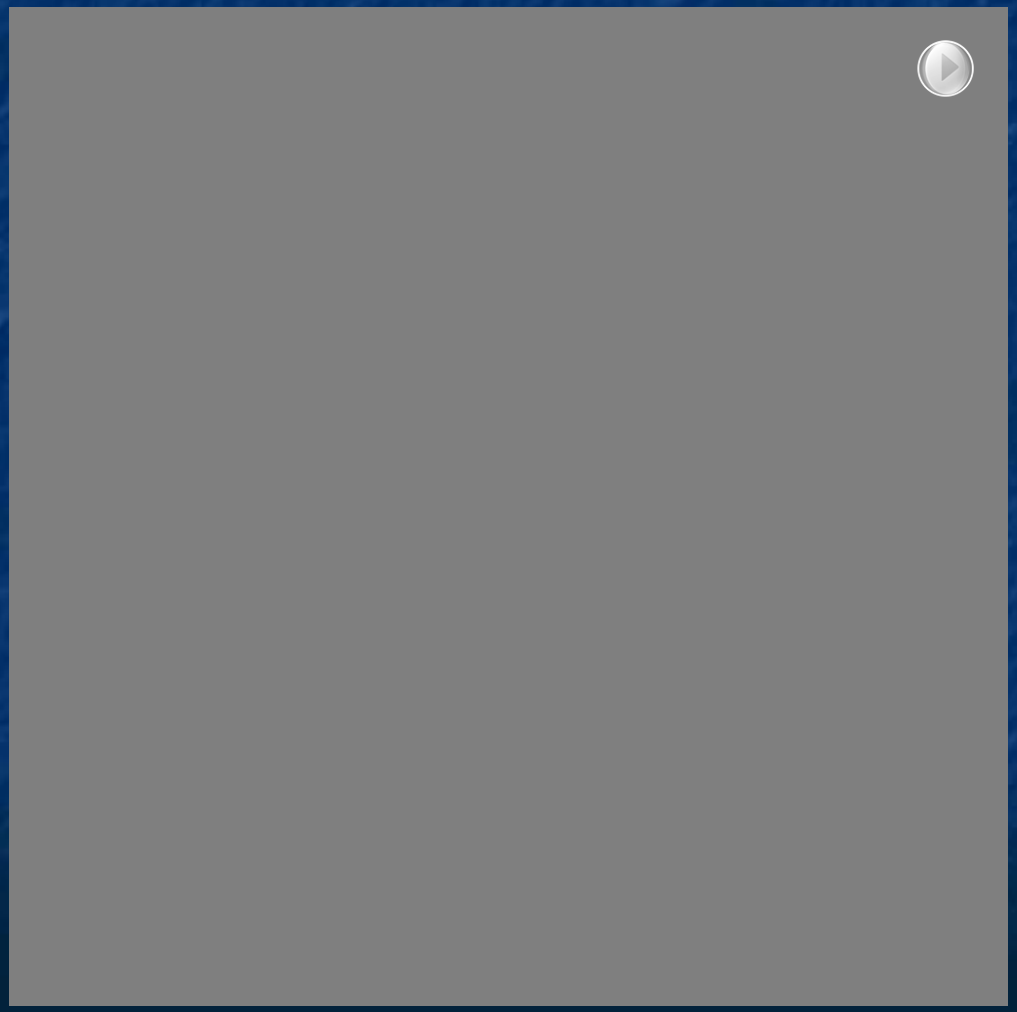
Pipeline Stent Deployment



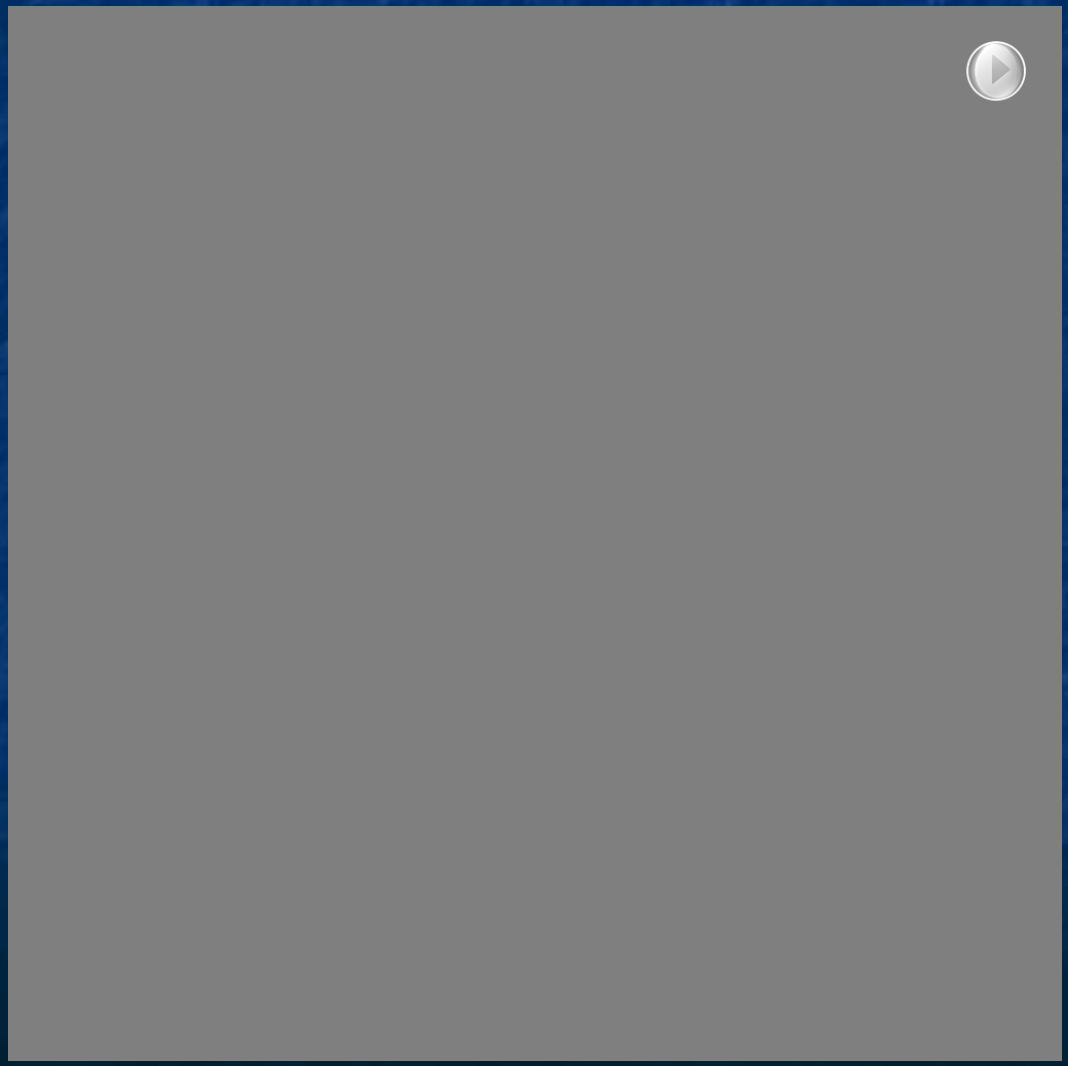
DSA Post treatment



MAF Case

- Patient: 30 yo female
- Treatment: LVIS + coils

DSA- Pre treatment



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LVIS deployment - MAF

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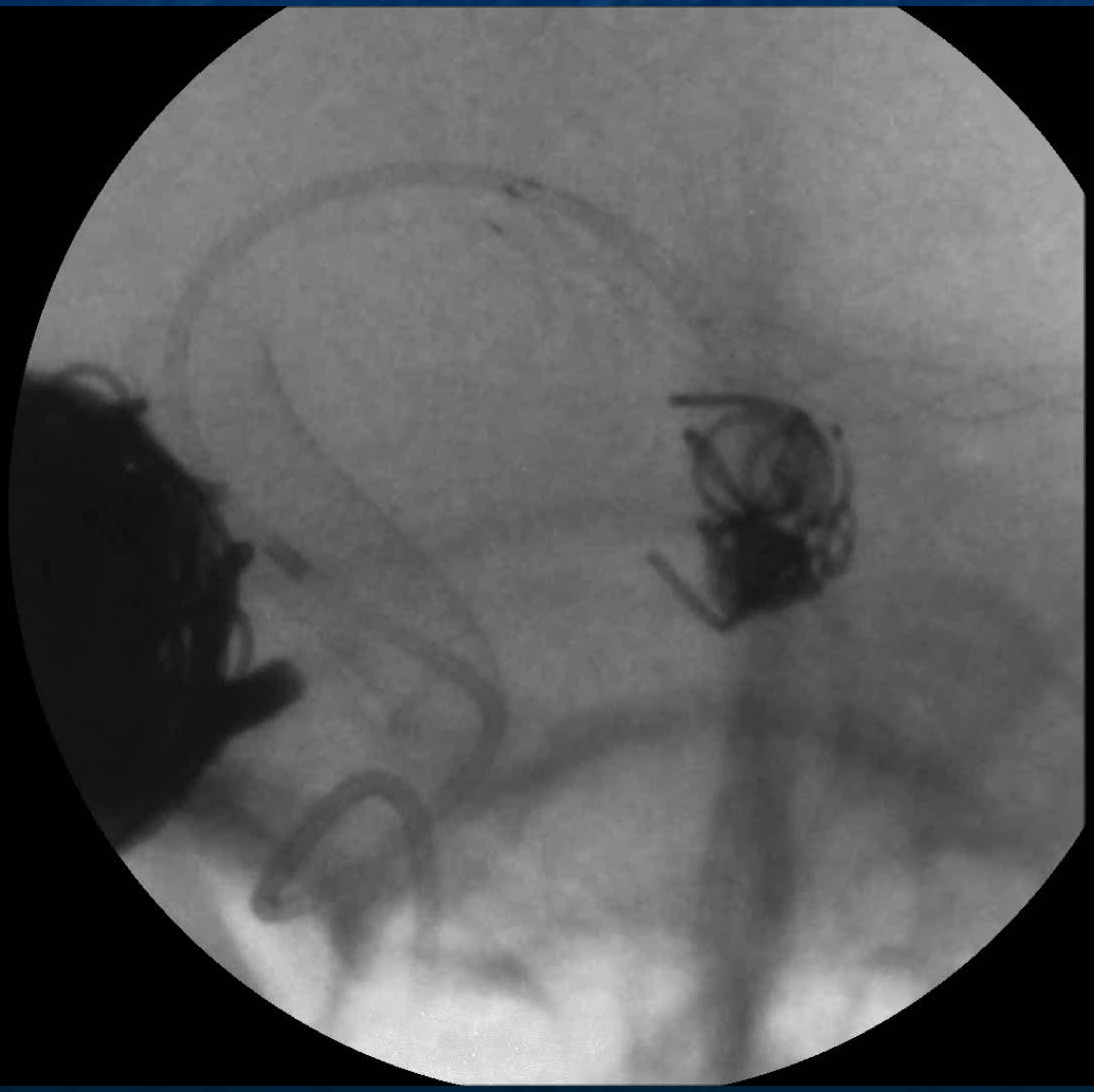
Coiling - MAF



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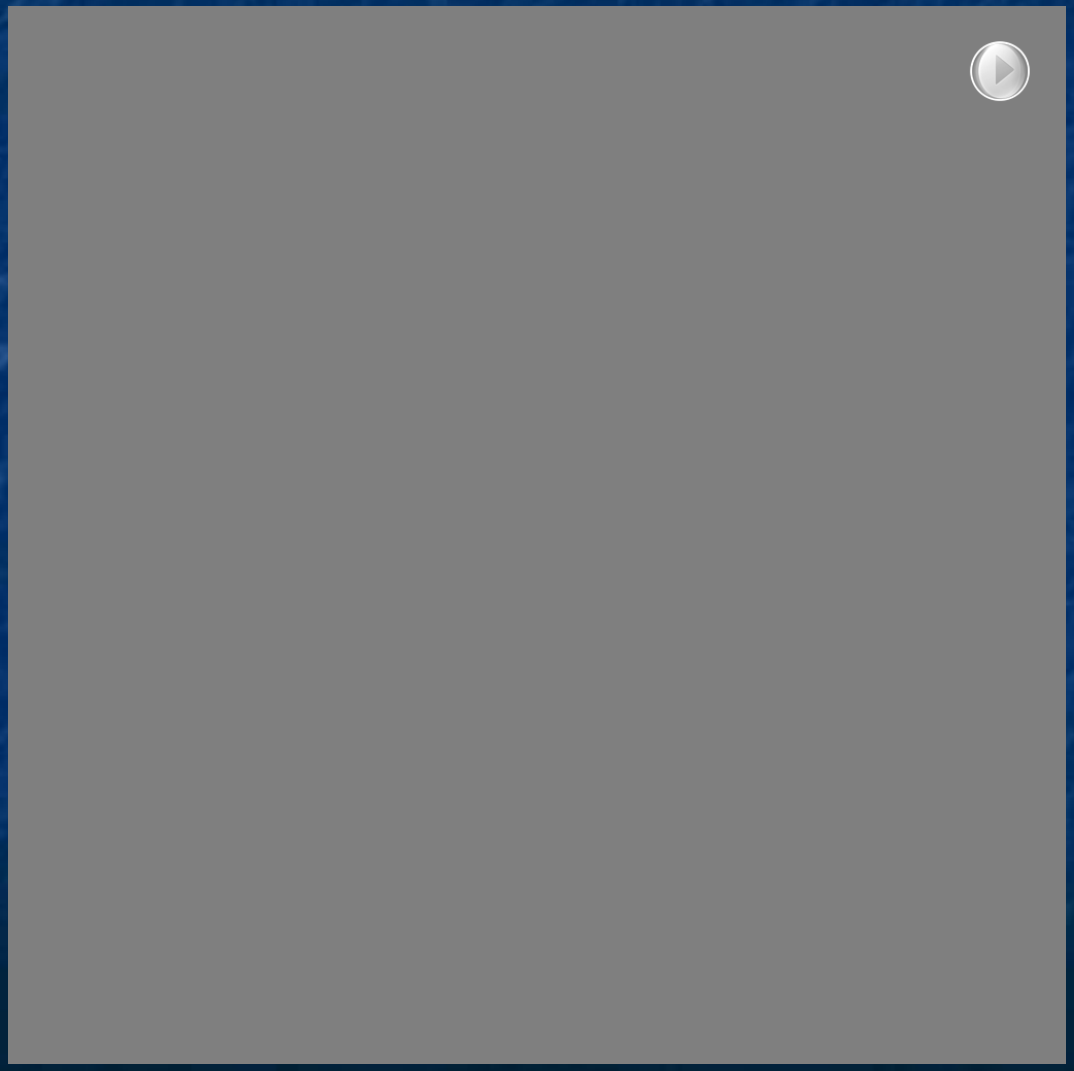
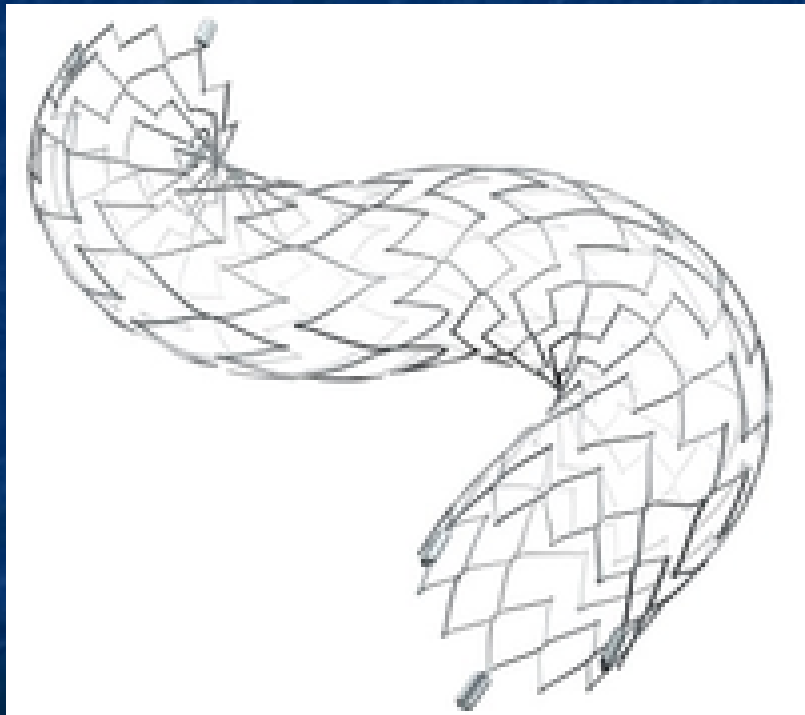
DSA Post Treatment



Neuroform-ATLAS stent

- The Neuroform Atlas Stent is a new 4th-generation adjunctive open cell stent

- All sizes of the Neuroform Atlas Stent, from 3.0mm up to 4.5mm in diameter, through a low-profile Excelsior SL-10 microcatheter.



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B/l ICA access

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Final run

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FLOW DIVERTERS:
NEXT GENERATION

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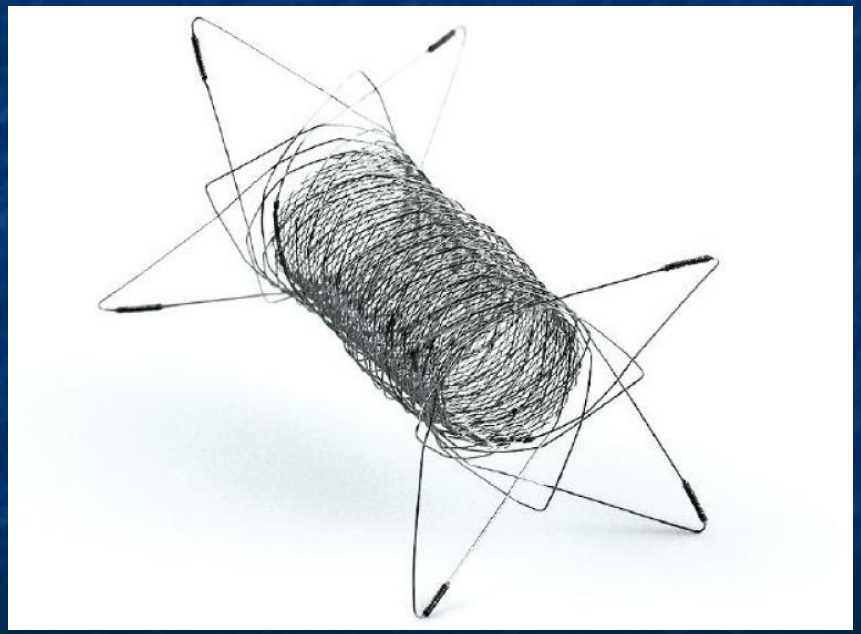
FRED
(FLOW RE-DIRECTION ENDOLUMINAL DEVICE)

A STENT WITHIN A STENT

Flow Re-Direction Endoluminal Device (FRED)

- Outer layer:
  - 1 mm cell size
  - 16-wire weave design
- Inner layer:
  - 48-wire braid design
  - Attached to outer layer in helix pattern



FRED Flow Diversion

29 y/o female with left ICA aneurysm, persistent headaches, and dizziness

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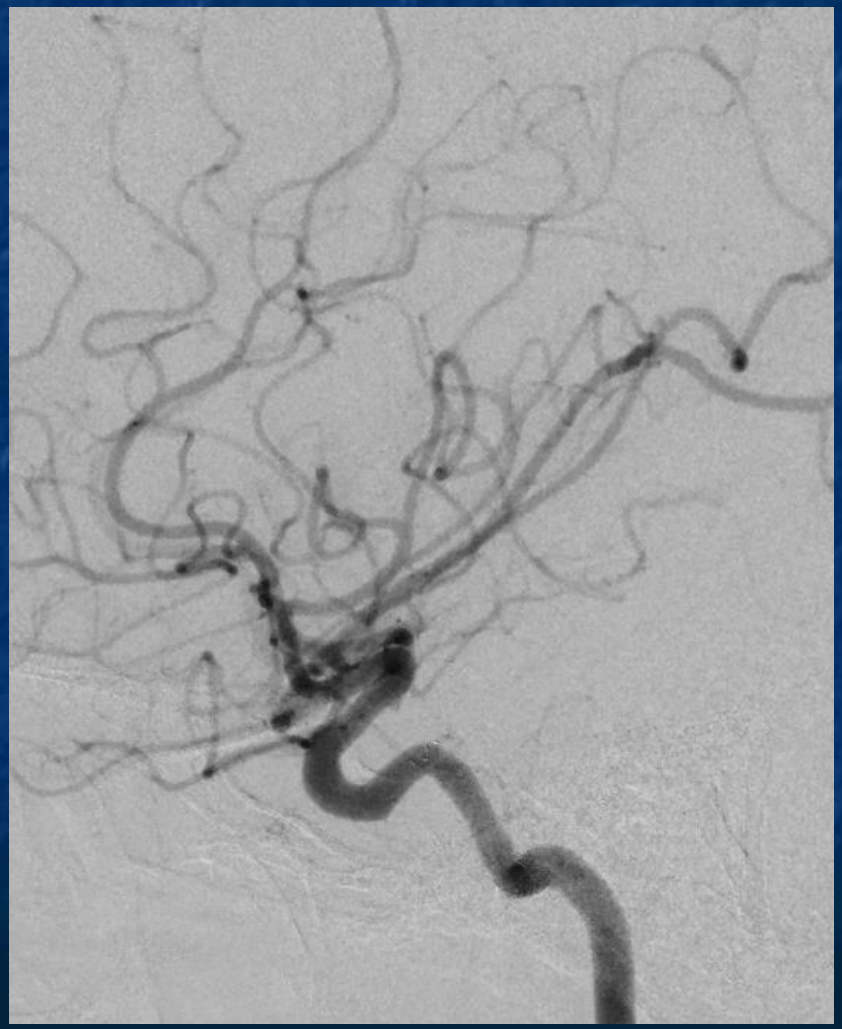
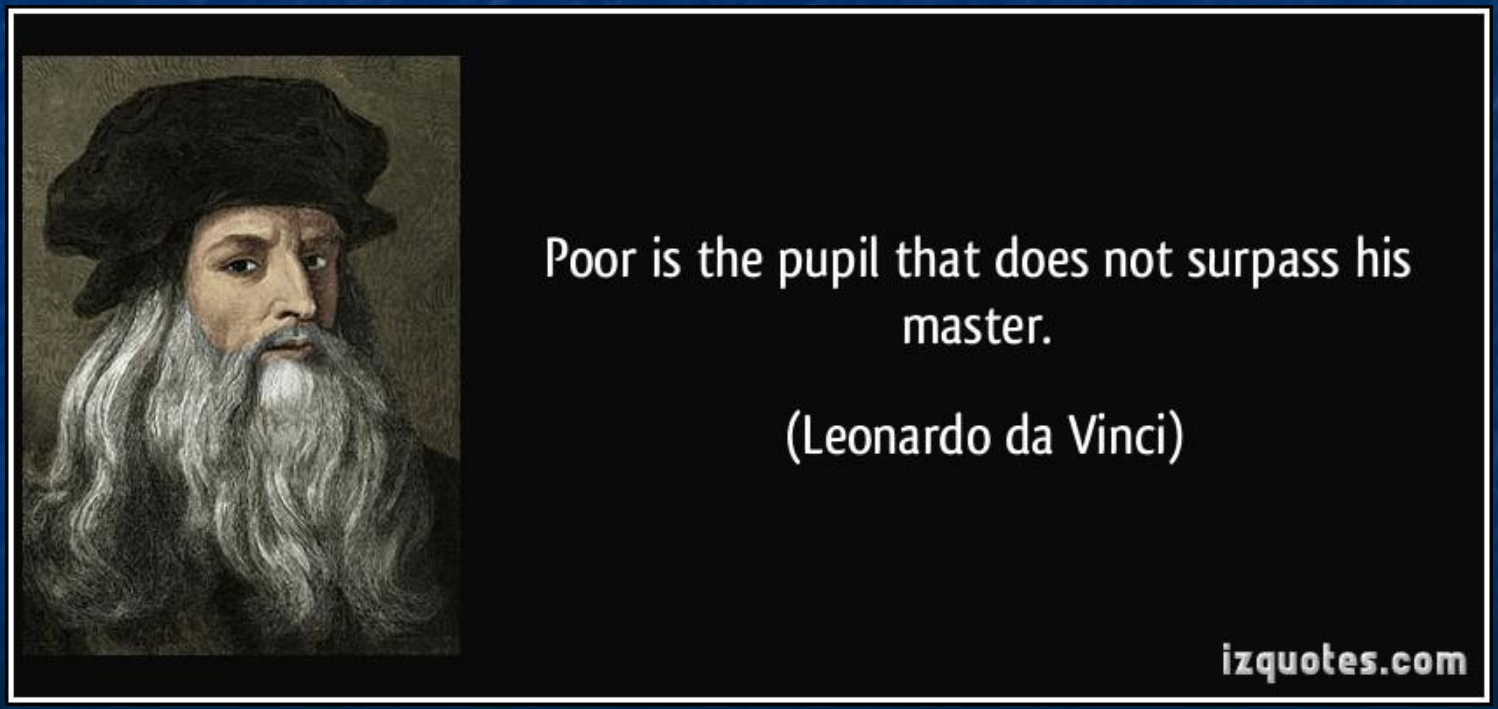
6 Month Follow Up

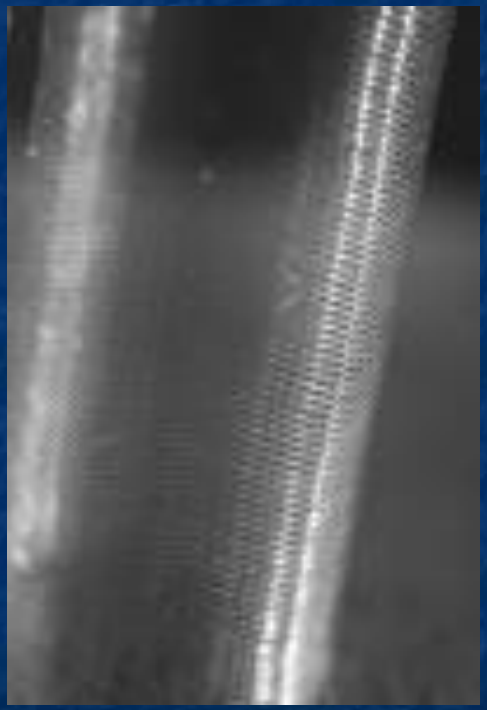


SURPASS


Poor is the pupil that does not surpass his master.
(Leonardo da Vinci)
izquotes.com

SURPASS

- cobalt–chromium
- low porosity (metal surface area coverage 30%)
- self-expanding tubular-shaped mesh structure with
- high pore density (21–32 pores/mm2)



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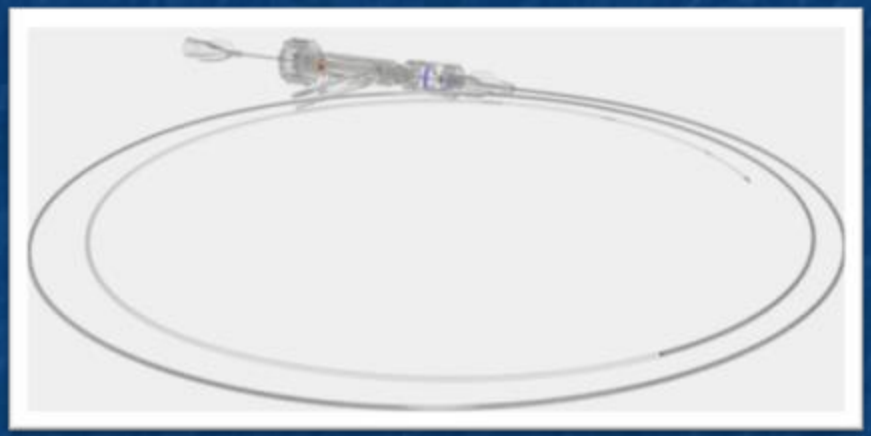
Surpass™ Flow Diverter

Flow Diverter

Delivery System



A self-expandable braided device preloaded in a microcatheter delivery system

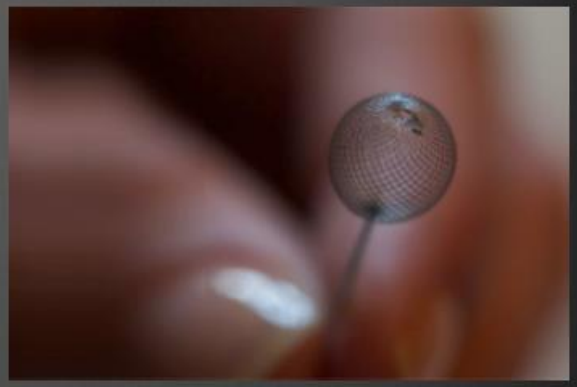
- Consistent mesh-density (from 72 wires to 96 wires)
- Longer device lengths offered across multiple diameters
- Customized preloaded over-the-wire system (0.014in microwire)

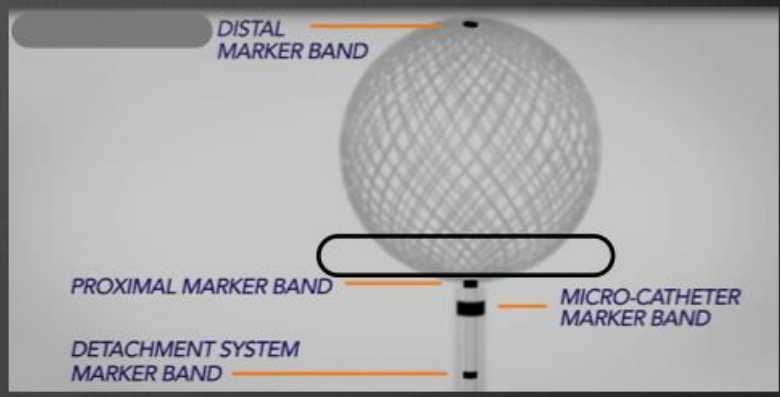
Intra-aneurysmal flow diversion

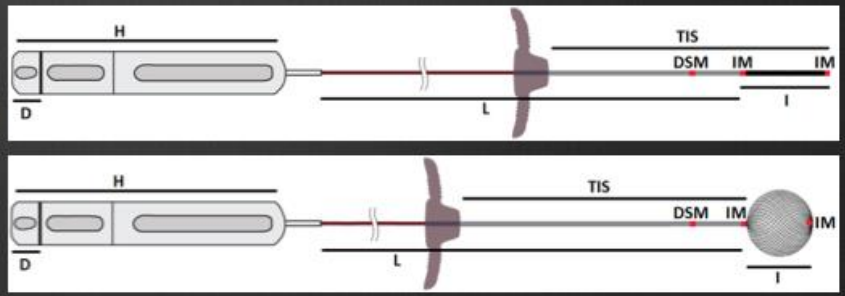
- Luna
- Web

LUNA (Nfocus/Covidien) AES Concept

- The LUNA Aneurysm Embolization System (AES) is a self-expandable, round-ovoid implant with delivery system
- The implant is made from a double layer of 72 Nitinol wire 25µ. Mesh (144 wires) secured at both proximal and distal ends and clearly marked with radiopaque markers
- Available size 4.5mm (B) - 8.5mm (G)
- The delivery system provides for distal navigation through a commercially available (0.027 compatible) microcatheter
- Microcatheter shaft with detachment controlled by operator activation of delivery handle
- CE marked February 2011

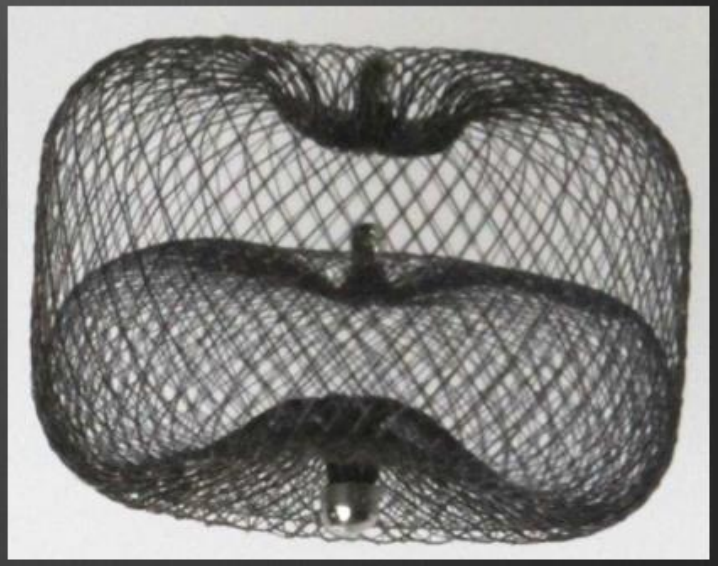






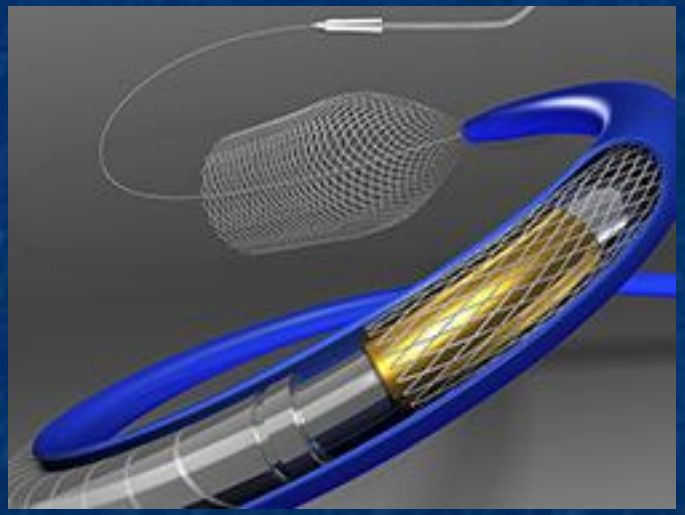
WEB (Sequent) Concept

- Intrasaccular
- Microcatheters 0.027 for device ≤ 7 mm to 0.032 compatible for device > 7 mm
- Two layers of Nitinol mesh (216 or 288 wires)
- 3 platinum markers
- Retrievable and detachable
- CE marked



Pipeline Flex Embolization Device

- Same Pipeline stent
- Innovative delivery system
- Approved by FDA in Feb 2015
- Better maneuverability along curves
- New distal wire
- Designed to be resheathable



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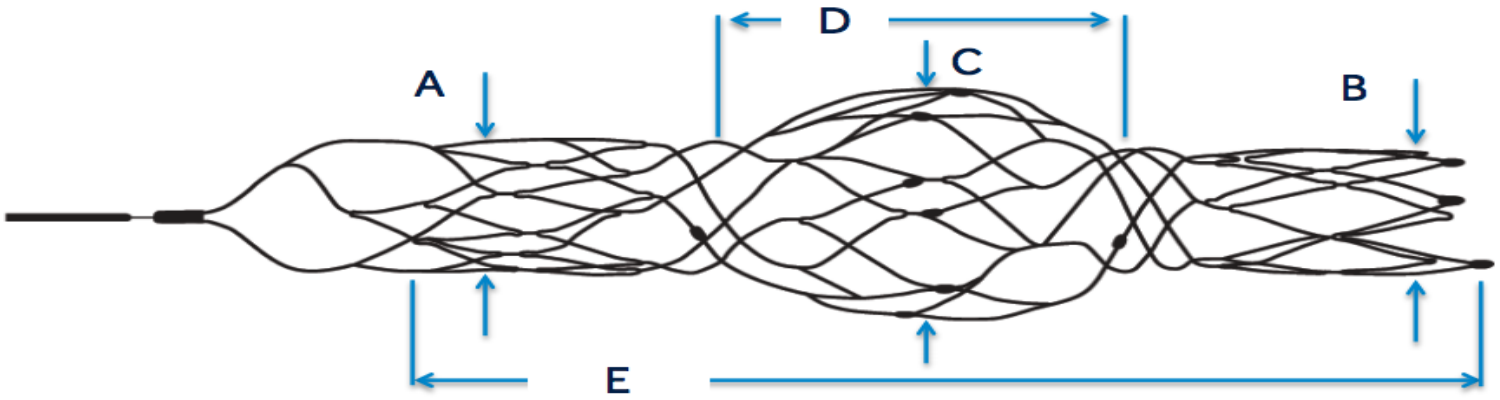
Barrel Device for Bifurcation Aneurysms

Device Specifications



Descriptor	Model Number	Recommended Vessel Sizes	A. Proximal End Diameter	B. Distal End Diameter	C. Center Herniation Section Diameter	D. Center Herniation Section Length	E. Usable Length
BV-3.5-5.0x20	BV-3550	2.0 - 3.0 mm	3.5mm	3.0mm	5.0mm	5.0mm	20mm

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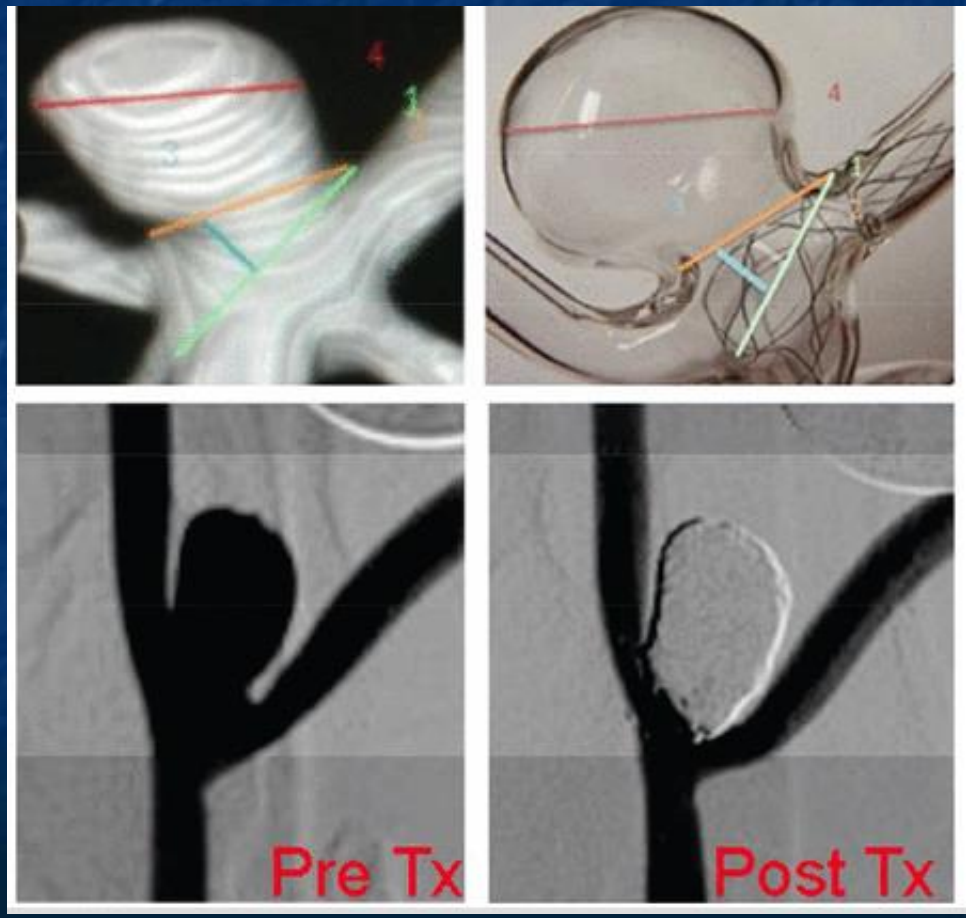
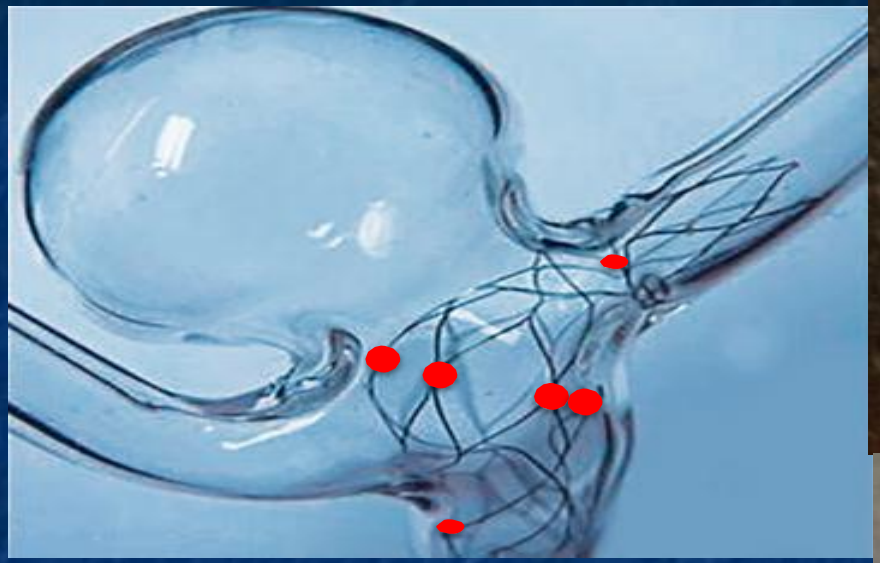
Barrel Shaped Bifurcation Aneurysm Bridging Device

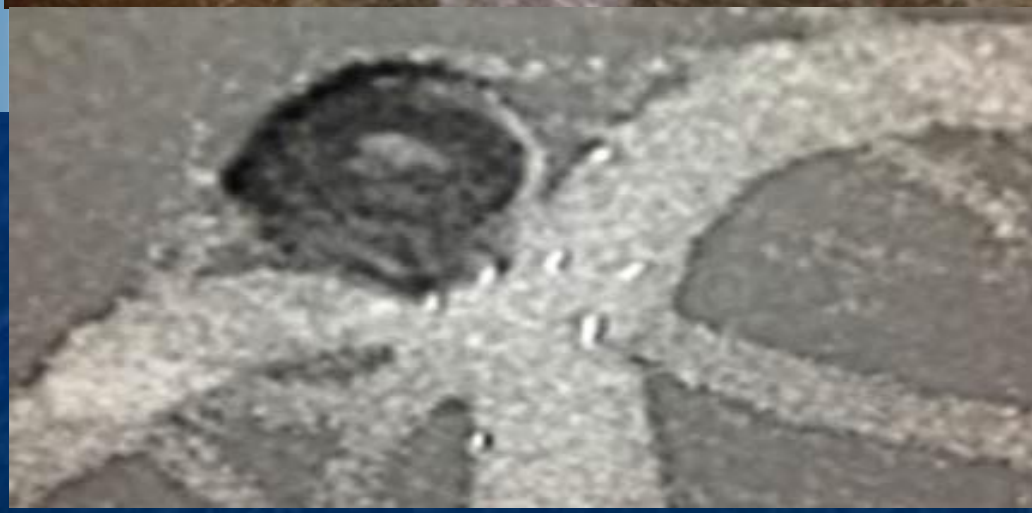
Barrel™ Vascular Reconstruction Device (VRD)

- Intended for use with embolic coils
- for the treatment of wide-neck bifurcating or branch intracranial aneurysms .
- Wide-neck is defined as having a neck width ≥ 4 mm or a dome-to-neck ratio < 2.



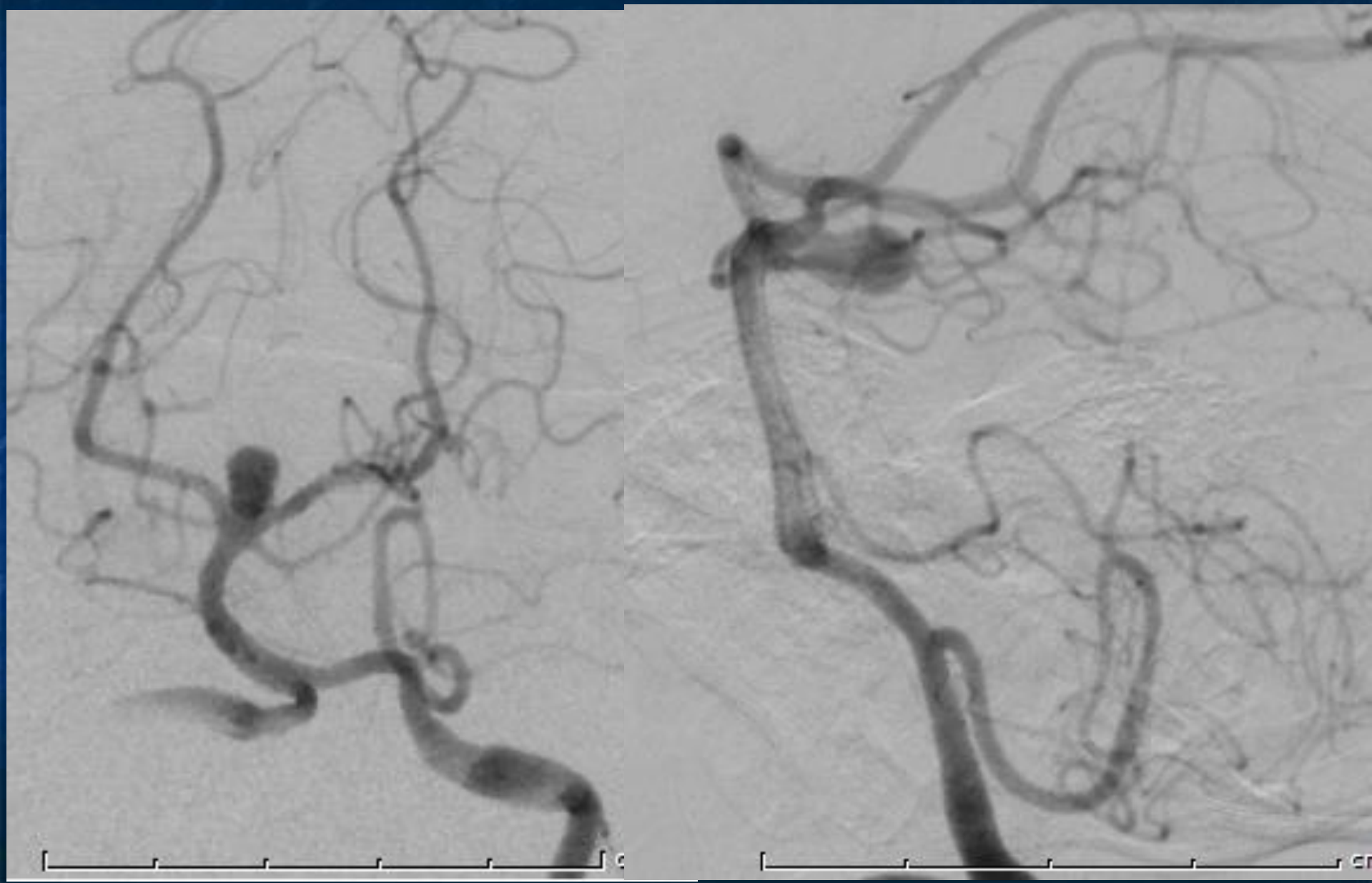
J NeuroIntervent Surg 2013;**5**:A10 doi:10.1136neurintsurg -2013-010870.17





Marker bands of Barrel device

indicating complete expansion and neck coverage



Case setup

Access – R radial 5fr, R femoral 6fr sheaths

Devices – Benchmark guide / Berenstein,

Stryker Excelcior XT17 (45˚) into aneurysm,

Codman Prowler Select Plus, Synchro2 into PCA

Barrel neck reconstruction device

Coils – Stryker Target 3D framing coils

Microvention hypersoft finishing coils

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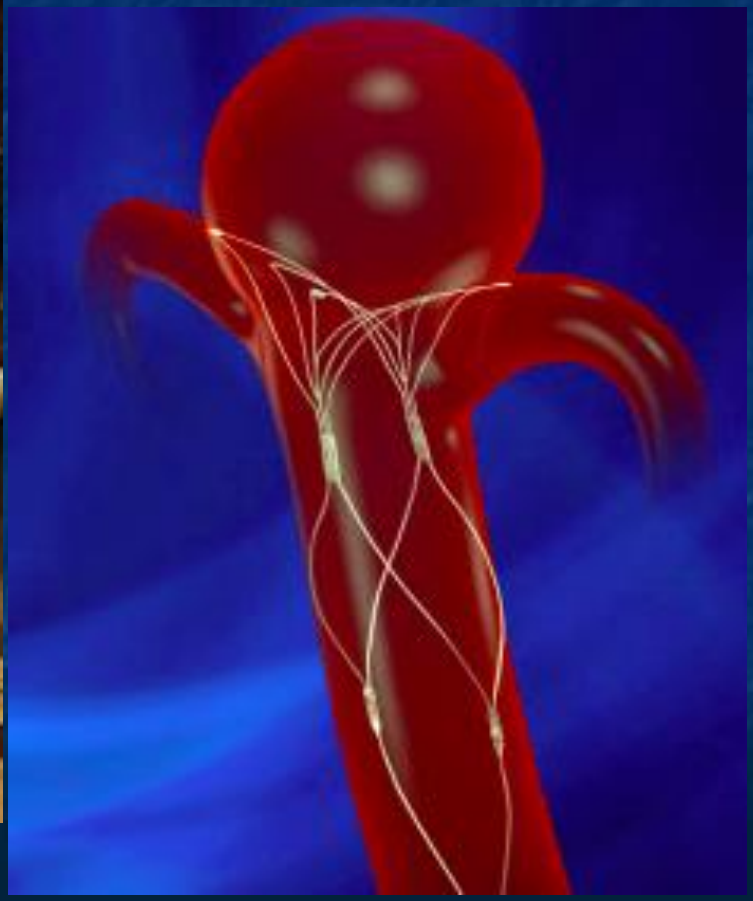
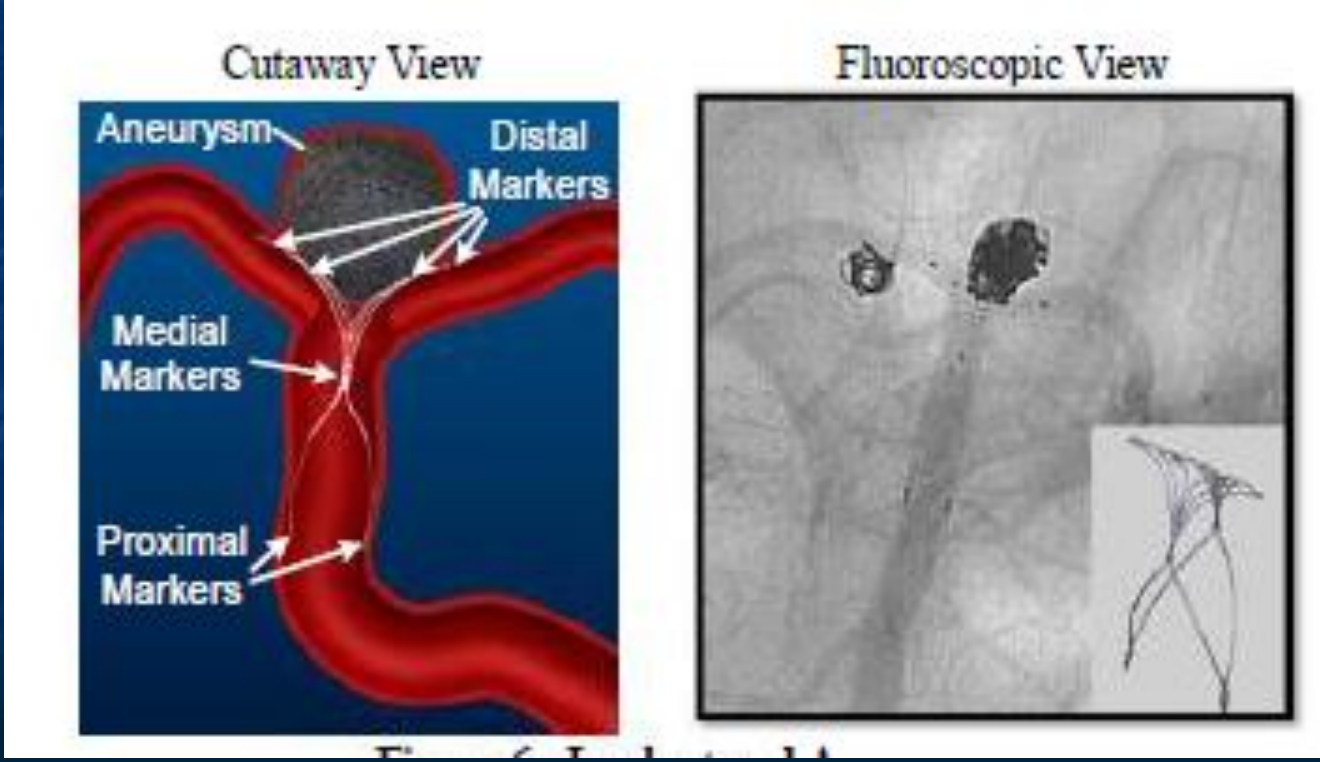
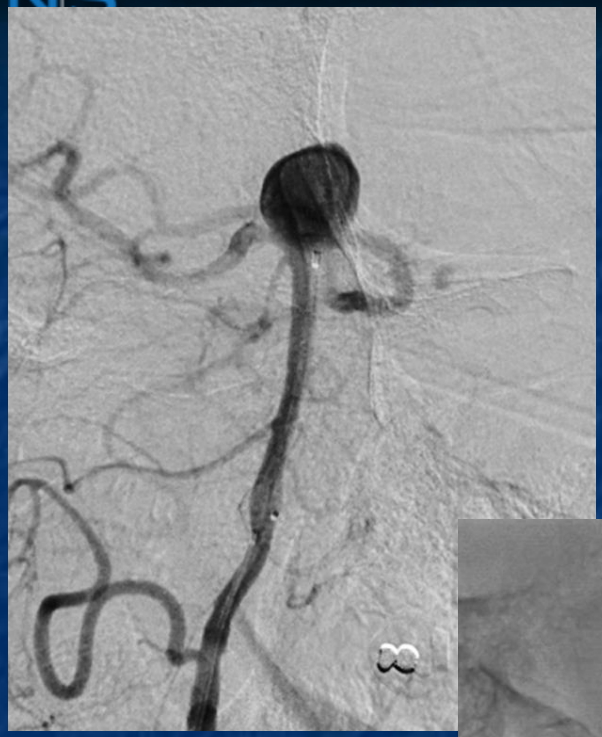
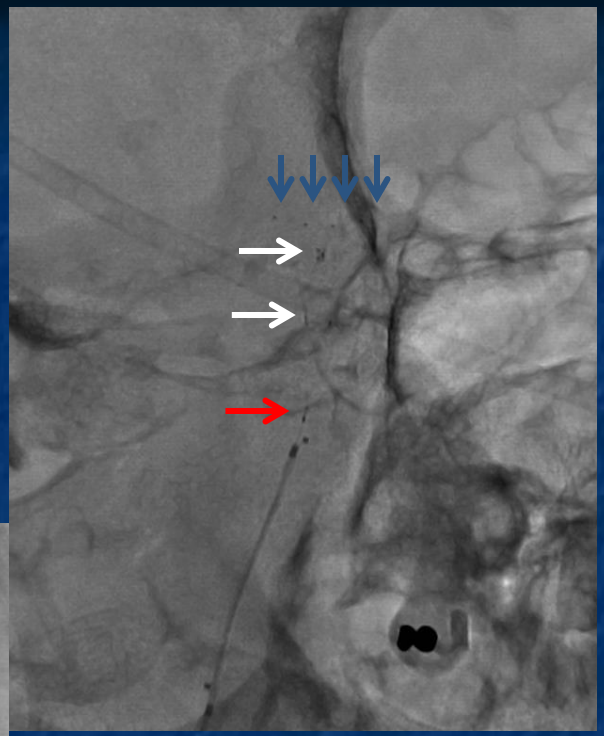
PulseRider: Neck Reconstruction



PulseRider - Aneurysm Neck Reconstruction Device







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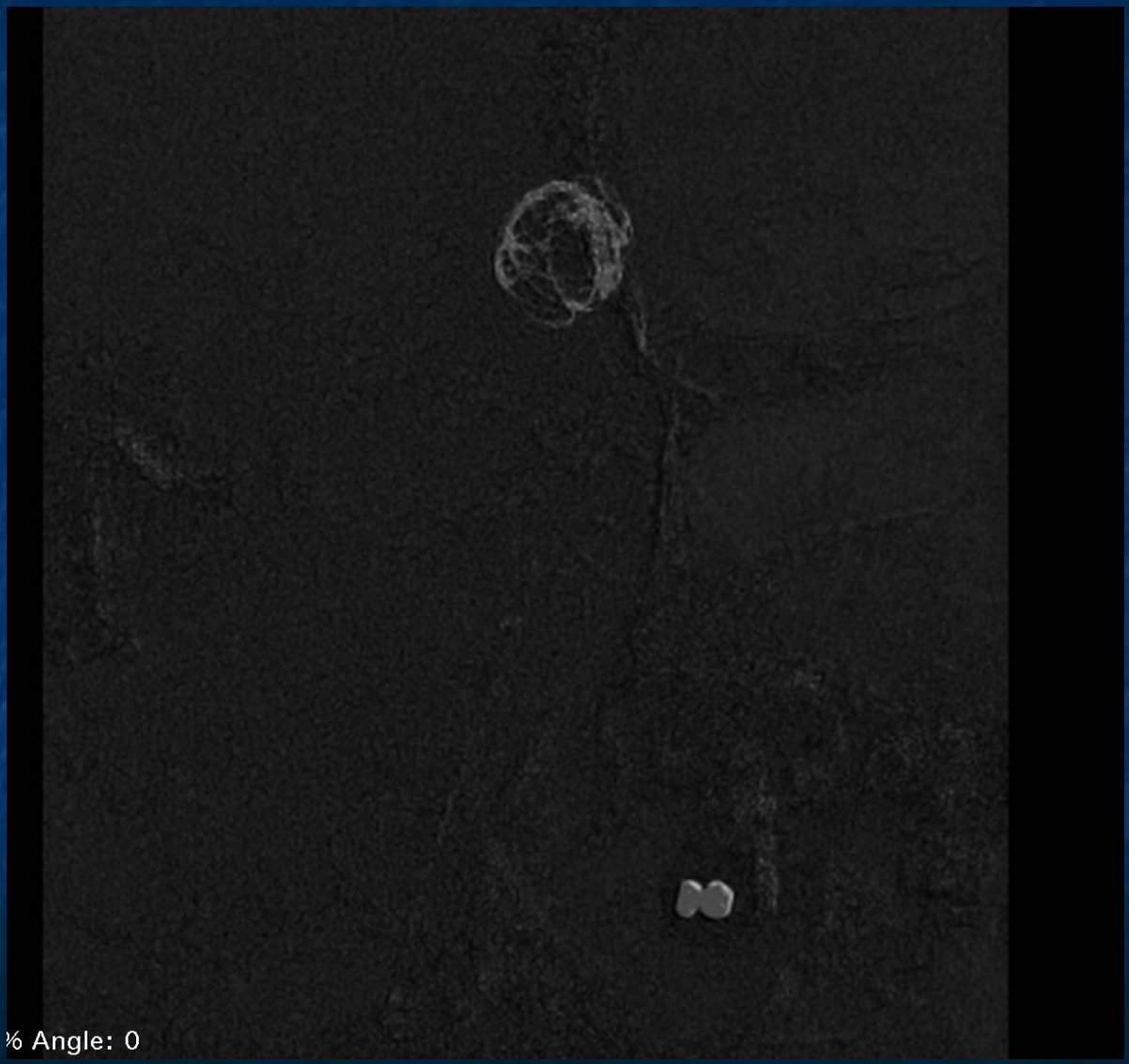
PulseRider – Deployment of Coils




Z: 1
C: 128
W: 255
IM: 8410007


Z: 1
C: 128
W: 255
IM: 8420006

Simulator Training In NeuroInterventions

Experience With a Simulator-Based Angiography Course for Neurosurgical Residents: Beyond a Pilot Program

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Bernard R. Bendok, MD§
Elad I. Levy, MD¶
Andrew Ringer, MD‖
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BACKGROUND: Simulation is an increasingly useful means of teaching in the era of duty hour restrictions. Since the completion of our diagnostic cerebral angiography simulator curriculum pilot program, we have performed this resident course at 2 Congress of Neurological Surgeons (CNS) annual meetings with larger participant numbers.

OBJECTIVE: To report the ongoing results of these courses.

METHODS: A 120-minute simulator-based training course was performed at 2 CNS annual meetings. Precourse written and simulator skills assessments were performed, followed by instructor-guided training on an endovascular simulator. Postcourse written and simulator practical assessments were then performed and compared with precourse scores.

RESULTS: Thirty-seven neurosurgery resident participants completed the course module: 16 completed the first course provided and 21 completed the second. Posttest written scores were significantly higher than pretest scores (mean ± SEM, 8.5 ± 0.40.3 vs 4.9 ± 0.3; $P < .001$). Instructor assessments of practical posttest scores of participants were significantly higher than pretest practical scores for both the CNS 2011 and CNS 2012 groups ($P < .001$).

CONCLUSION: The expansion of a curriculum-based, cerebral angiography simulator pilot program to trainees through courses at national neurosurgical meetings demonstrated excellent results with significant improvements in written test scores and instructor assessments of participant technical skills. With ever-expanding improvements in simulation technology and realism, simulator training for cerebral angiography may become an integral component of resident training in the future.

KEY WORDS: Angiography, Endovascular, Neurosurgery, Resident education, Simulator

Neurosurgery 73:S46–S50, 2013 DOI: 10.1227/NEU.0000000000000059 www.neurosurgery-online.com

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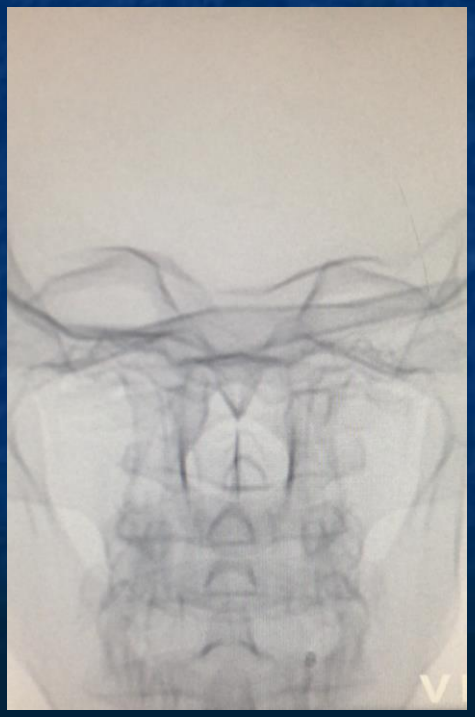
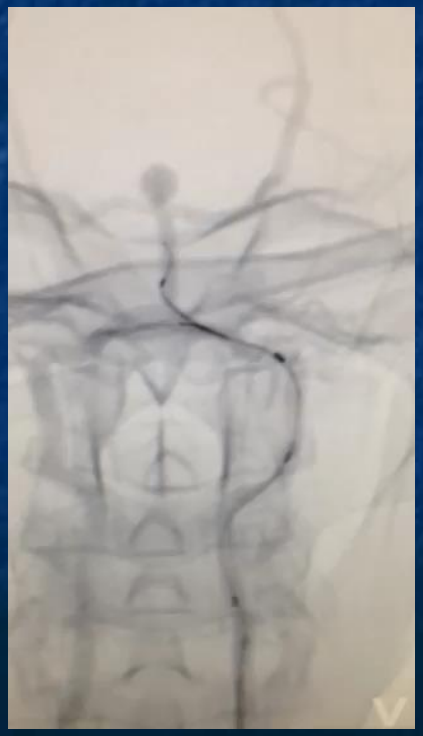
How to coil an aneurysm step by step

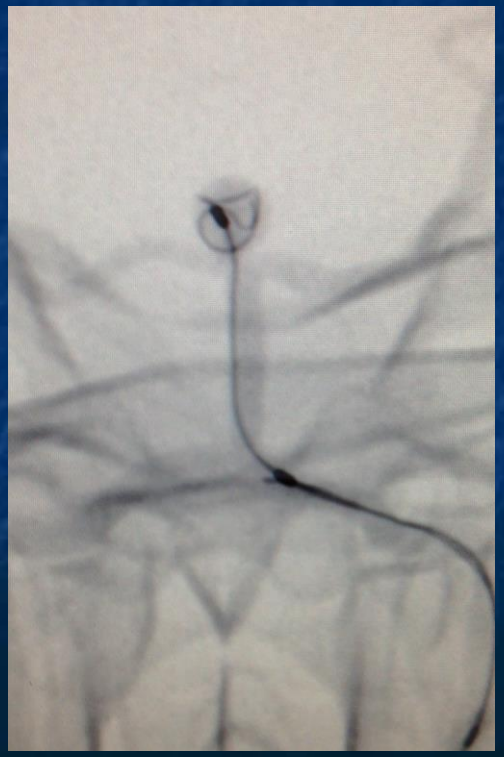
Getting Access



Microcatheter work

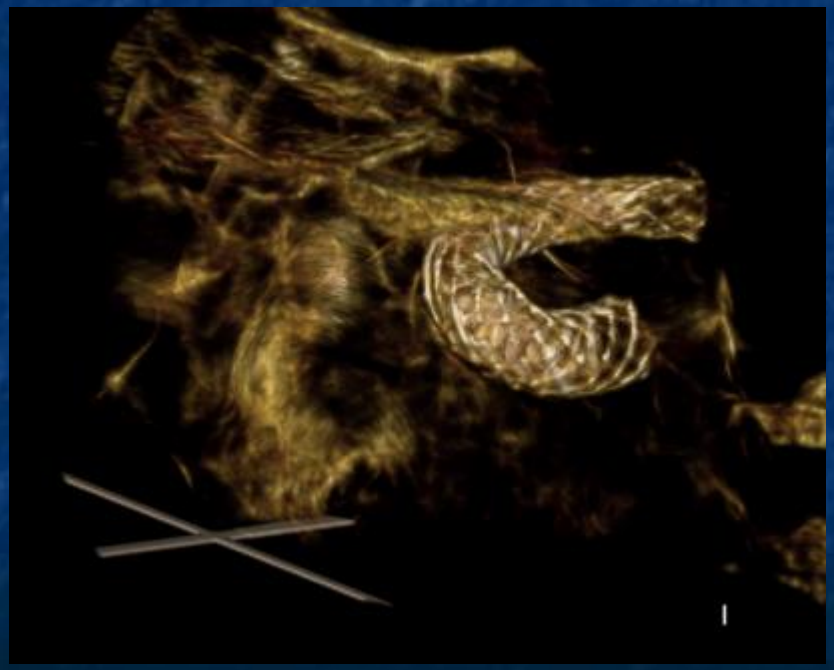


Coiling



Dyna CT/ LCI(Low contrast Injection)

- No Kink or Stenosis



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Thank You!!