Neurosurgical Society of Alabama Annual Conference June 2, 2019

WHAT'S NEW FOR CEREBRAL ANEURYSMS



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Disclosure

No commercial interest





Origins of Cerebral Aneurysm Treatment

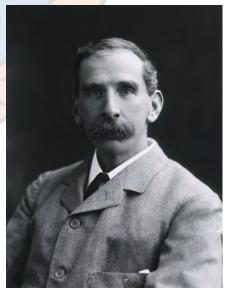
 December 1785 John Hunter ligated artery proximal to a popliteal aneurysm (patient died 3 days later)





Origins of Cerebral Aneurysm Treatment

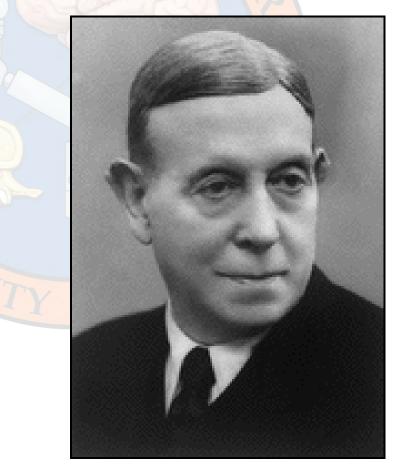
- 1885 Sir Victor Horsley performed right common carotid artery ligation for intracranial aneurysm discovered during craniotomy for a suspected brain tumor
- Patient was well at 5 year followup





Origins of Cerebral Aneurysm Treatment

 1927 first cerebral angiography performed by Egas Moniz





Origins of Cerebral Aneurysm Treatment

- 1931 Norman Dott wrapped a ruptured aneurysm with muscle from the patient's leg
- 1933 Dott attempted to ligate the neck of aneurysm with suture





Origins of Cerebral Aneurysm Treatment

 1937 Walter Dandy clipped an intracranial aneurysm with a simple Vshaped silver clip

> INTRACRANIAL ANEURYSM OF THE INTERNAL CAROTID ARTERY CURED BY OPERATION WALTER E. DANDY, M.D. BAJTHORE, Mp.

Case Report.—A rather frail, small, sallow man, age 43, applied at the Johns Hopkins Dispensary February 16, 1927, because of complete paralysis in the distribution of the right occloation of third) preve. The family history was negative. His general health was good until last year when his stomach "went had" from drinking. He was hospitalized from July to Septenher, 1926, for this geatric disorder which was pronoued "ulcer." He has been a very heavy drinker for the past 18 months. *Precent History*—Six days ago he was awakened by a severe pain in the right

Present History.—Six days ago he was awakened by a severe pain in the right frontal region. During the afternoon there was a very severe shooting pain in the right eye, but it lasted only a moment. He slept poorly that



Fig. 1.—Photograph of patt taken before operation. Note probis on the right, and the reme pull of the erychall outday to available of the works of the reme pull of the erychall out-

--nearly five weeks after the onset of his trouble--when Dr. Frank Ford referred him to me with the thought that a surgical effort might be worth while. There had been no improvement in the local condition in the interim. The following findings were reported by Dr. Frank Walsh, of the Ophthalmological Department, March 12,

night because of the pain. On the following morning dipologia was first noted and in the verning the right eyelid drouped. The eye was completely closed the next morning. The pain became less severe but two days later became greatly intensified and prevented his sleeping. Since then the pain has been present but less severe. Examination at that time showed a complete paralysis of the right, third cranial nerve (Fig. 1). There were no other positive findings. The eyerground, visual fields and reflexes were normal. A diagnosis of aneurym along the circle of Wills was made. A recongenologic examination of the head revealed no abnormality. The patient returned to the dispensary from time to time until March 10, 1027

^{1037:} "The upper lid is completely closed and can only be moved slightly by the frontalis muscle (Fig. 1). The globe is abducted to 45° and only moves laterally and slightly down when it rotates inward (Fig. 1). The pupil is 45' Mm. in diameter and one-fourth larger than the left. It reacts slightly to light, directly and consensually. Visual acuity $20/4\sigma$ right and $2\sigma/25$ left. Visual fields normal. Fourth and sixth nerves are functioning." The Wasserman reaction was negative.

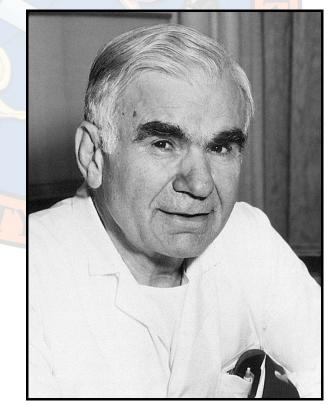
Operation—March 23, 1927: A small hypophysel approach was made on the right side, using the concelled incision. There was marked cortical atrophy, evidenced by the pools of fluid in the subarachmoid spaces (doubtless the result of his heavy drinking). The removal of this fluid and that from the cisterna chiamatic gave ample room for exposure of the chiasmal region upon retraction of the frontal and temporal lokes. A pea-sized aneurysm projected from the outer wall to the internal acrostid artery and adjacent to the entry of the posterior communicating artery (Fig. 4). The aneurysm, however, did not involve this vessel, but arook from the internal acrostid by a narrow neck





Origins of Cerebral Aneurysm Treatment

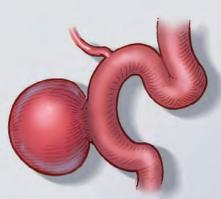
 1966 Gazi Yasargil reports the use of the operating microscope for intracranial aneurysm surgery (Theodore Kurze first to use it in 1957)





Treatment of Unruptured Aneurysms

- Prevalence of unruptured intracranial aneurysms (UIA) is thought to be about 3.2% (95% CI, 1.9%–5.2%) of general population¹⁻²
- However, management of UIAs still unclear and controversial





Vlak et al, Lancet Neurol 2011
 Go et al, Circulation 2014



Natural History: ISUIA

ISUIA phase 2: 1692 patients with 2686 UIAs, mean 4.1 years, 61 centers in North America and Europe¹

 Table 4.
 Five-Year Cumulative Rupture Rates (%) According to Size and Location of Unruptured Aneurysm*

	<7 mm				
	Group 1	Group 2	7–12 mm	13–24 mm	≥25 mm
Cavernous carotid artery (n=210)	0	0	0	3.0	6.4
AC/MC/IC (n=1037)	0	1.5	2.6	14.5	40
Post-P comm (n=445)	2.5	3.4	14.5	18.4	50

AC indicates anterior communicating or anterior cerebral artery; IC, internal carotid artery (not cavernous carotid artery); MC, middle cerebral artery; and Post-P comm, vertebrobasilar, posterior cerebral arterial system, or the posterior communicating artery.

*Reprinted from *The Lancet*,⁴ with permission from Elsevier. Copyright © 2003, Elsevier Ltd.

Class II Evidence



1. Weibers et al, Lancet 2003



Natural History: ISUIA

- Criticisms of ISUIA
 - Number of patients in certain categories small
 - Size cutpoint shifted between phase 1 and phase 2 of ISUIA
 - Selection bias: patients selected for no treatment
 - Differential followup





Natural History: UCAS Japan

- 6697 patients, mean 1.7 years
- Annual rupture rate 0.95%
 - 3-4mm<mark>: 0.3</mark>6%
 - 5-6mm: 0.50%
 - 7-9mm: 1.69%
 - 10-24mm<mark>: 4.37%</mark>
 - ≥25mm: 3<mark>3.4%</mark>
- ACOM (HR 1.90), PCOM (HR 2.02)
- Daughter sac (HR 1.63)



Class II Evidence



1. UCAS Japan Investigators, NEJM 2012

Natural History: Helsinki

- 142 patients, Helsinki, Finland, 1956-1978¹
- 34 SAH from 3064 person-years, 1.1%
- Predictors
 - Current smoking (adjusted hazard ratio 2.50, 95% CI 1.03-6.10 P=.044)
 - Acom location (4.28, 1.38-13.28, P=.012),
 - Age (inversely; 0.95 per year, 0.91-1.00, P=.043)
 - UIA diameter ≥ 7 mm at baseline (2.68, 1.16-6.21, P=.021)
- Class II Evidence



1. Juvela & Korja, Neurosurgery 2017



ORWAY

FINLAN

RUSSIA

SWEDEN

Natural History: Meta-analysis

- 19 studies (1966-2005), 6556 UIAs in 4705 patients¹
- Varied widely in size, duration, prospective vs retrospective
- Annual rupture rates (studies with mean followup):
 - <5 years: 1.2%
 - 5-10 years: 0.6%
 - >10 years: 1.3%
- Annual rupture rate <7mm: 0.4%

Class II Evidence



1. Werner et al, Stroke 2007



Natural History: Meta-analysis

- Risk factors for rupture¹:
- Age >60 years (RR, 2.0; 95% CI, 1.1–3.7)
- Female sex (RR, 1.6; 95% CI, 1.1–2.4)
- Japanese or Finish descent (RR, 3.4; 95% CI, 2.6–4.4)
- Symptomatic aneurysm (RR, 4.4; 95% CI, 2.8–6.8),
- Diameter >5 mm (RR, 2.3; 95% CI, 1.0–5.2)
- Posterior circulation aneurysm (RR, 2.5; 95% CI, 1.6– 4.1).



1. Werner et al, Stroke 2007



Natural History: Family History

- Prospective study of 113 patients with 148 UIAs in the FIA Study¹
- Nearly all <7mm, no history of SAH, mean 1.5 years
- Risk of rupture 1.2% per year (95% CI, 0.14%–4.3%)
- 17-fold higher than that seen in patients with comparably sized and positioned aneurysms in ISUIA
- Class II Evidence



1. Broderick et al, Stroke 2009



Natural History: Enlargement

- 1002 patients with 1325 aneurysm followed with MRA¹
- 18 patients with interval aneurysm growth (1.8%)
- 18.5% annual hemorrhage rate for patients with documented growth
- 90.3% of growing aneurysms would be detected before hemorrhage with 6-month interval MRAs
- Class II Evidence



1. Inoue et al, J Neurosurg 2012



Natural History Recommendations

- Prior history of aSAH may be considered to be an independent risk factor for future hemorrhage secondary to a different small unruptured aneurysm
 - AHA Class IIb, Level of Evidence B
 - CNS Class II
- Patients with aneurysms with documented enlargement during follow-up should be offered treatment in the absence of prohibitive comorbidities
 - AHA Class I, Level of Evidence B
 - CNS Class II





Natural History Recommendations

- Treatment of UIAs in patients with a family history of IA is reasonable even in aneurysms at smaller sizes than spontaneously occurring las
 - AHA Class IIa, Level of Evidence B
 - CNS Class II





Medical Management: Smoking

- ISUIA phase 1: 61% current, 19% former smokers¹
- ISUIA phase 2: 44% current, 33% former smokers²
- UCAS Japan: 17% current or former smokers³
- Helsinki: Heavily smoking (> 20 cigarettes per day) men and currently smoking women adjusted relative risks of aSAH 7.3 (95% CI, 3.8-14.3) and 2.1 (95% CI, 1.2-3.6), respectively, compared with men who had never smoked and with women who were not current smokers⁴
- ACROSS Group: of 432 SAH patients, 30% were smokers (95%CI 23-37%)⁵

Class III Evidence



- 1. ISUIA, NEJM 1999
- 2. Weibers et al, Lancet 2003
- 3. UCAS Japan Investigators, NEJM 2012
- 4. Juvela et al, Stroke 1993
- 5. Shiue et al, J Neurol Sci 2012

Medical Management: Hypertension

- Kuopio Finland: of 467 UIA and 1053 ruptured, antihypertensive medication more frequent in UIA (73% versus 62%) with higher age-adjusted incidence. Ruptured more often untreated hypertension (29% versus 23%)¹
- ACROSS Group: of 432 SAH patients, 21% had hypertension (10-30%)²

Class III Evidence



Lindgren et al, Ann Med 2014
 Shiue et al, J Neurol Sci 2012



Medical Management Recommendations

- Patients with UIA should be counseled regarding the importance of smoking cessation
 - AHA Class I, Level of Evidence B
 - CNS Class III
- Patients with UIA should monitor blood pressure and undergo treatment for hypertension
 - AHA Class I, Level of Evidence B
 - CNS Class III
- Aneurysmal growth may increase the risk of rupture, and intermittent imaging studies to follow UIAs managed conservatively should be considered
 - AHA Class I, Level of Evidence B
 - CNS Class II





FDA Approved Coils in 1995

J Neurosurg 75:1-7, 1991

Special Article

Electrothrombosis of saccular aneurysms via endovascular approach

Part 1: Electrochemical basis, technique, and experimental results

GUIDO GUGLIELMI, M.D., FERNANDO VIÑUELA, M.D., IVAN SEPETKA, M.S., AND VELIO MACELLARI, M.S.

Department of Neurological Sciences, Therapeutic Neuroangiography, University of Rome Medical School, Rome, Italy: Department of Radiological Sciences, Endovascular Therapy, University of California Medical Center, Los Angeles, California; and Target Therapeutics, San Jose, California

 \checkmark Eleven experimental saccular aneurysms were created on the common carotid artery of swine. Between 3 and 15 days after creation of these aneurysms, they were thrombosed via an endovascular approach, using a very soft detachable platinum coil delivered through a microcatheter positioned within the aneurysm. This detachable platinum coil was soldered to a stainless steel delivery guidewire. Intra-aneurysmal thrombosis was then initiated by applying a low positive direct electric current to the delivery guidewire. Thrombosis occurred because of the attraction of negatively charged white blood cells, red blood cells, platelets, and fibrinogen to the positively charged platinum coil positioned within the aneurysm. The passage of electric current detached the platinum coil within the clotted aneurysm in 4 to 12 minutes. This detachment was elicited by electrolysis of the stainless steel wire nearest to the thrombus-covered platinum coil. Control angiograms obtained 2 to 6 months postembolization confirmed permanent aneurysm occlusion as well as patency of the parent artery in all cases. No angiographic manifestation of untoward distal embolization was noted. Due to the encouraging results of this research, this technique has been applied in selected clinical cases which are described in Part 2 of this study.

KEY WORDS · electrothrombosis · embolization · detachable coils

 $electrothrombosis \ \cdot \ electrolysis \ \cdot \ aneurysm \ \cdot \ endovascular \ therapy \ \cdot$

J Neurosurg 75:8-14, 1991

Special Article

Electrothrombosis of saccular aneurysms via endovascular approach

Part 2: Preliminary clinical experience

GUIDO GUGLIELMI, M.D., FERNANDO VIÑUELA, M.D., JACQUES DION, M.D., AND GARY DUCKWILER, M.D.

Department of Neurological Sciences, Therapeutic Neuroangiography, University of Rome Medical School, Rome, Italy; and Department of Radiological Sciences, Endovascular Therapy, University of California Medical Center, Los Angeles, California

 \checkmark Fifteen patients with high-risk intracranial saccular aneurysms were treated using electrolytically detachable coils introduced via an endovascular approach. The patients ranged in age from 21 to 69 years. The most frequent clinical presentation was subarachnoid hemorrhage (eight cases). Considerable thrombosis of the aneurysm (70% to 100%) was achieved in all 15 patients, and preservation of the parent artery was obtained in 14. Although temporary neurological deterioration due to the technique was recorded in one patient, no permanent neurological deficit was observed in this series and there were no deaths. It is believed that this new technology is a viable alternative in the management of patients with high-risk intracranial saccular aneurysms. It may also play an important role in the occlusion of aneurysms in the acute phase of subarachnoid hemorrhage.

KEY WORDS · aneurysm · electrothrombosis · detachable coils · embolization · interventional neuroradiology · endovascular therapy



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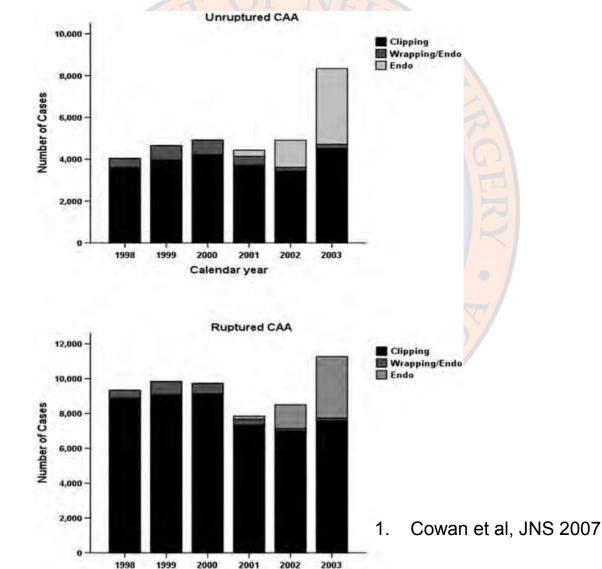
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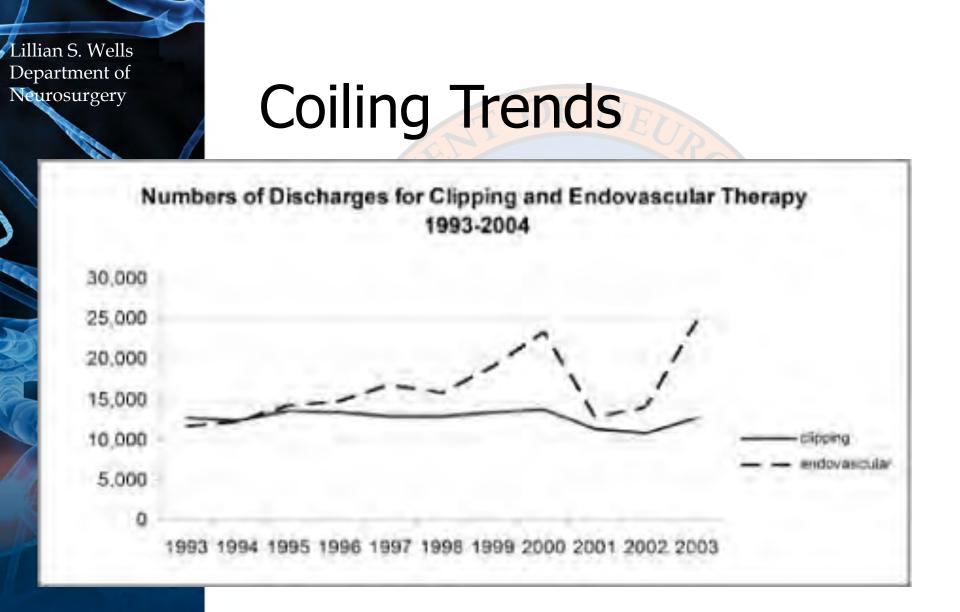
Where have we come with coiling since?

Coiling Trends



Calendar year

UFHealth



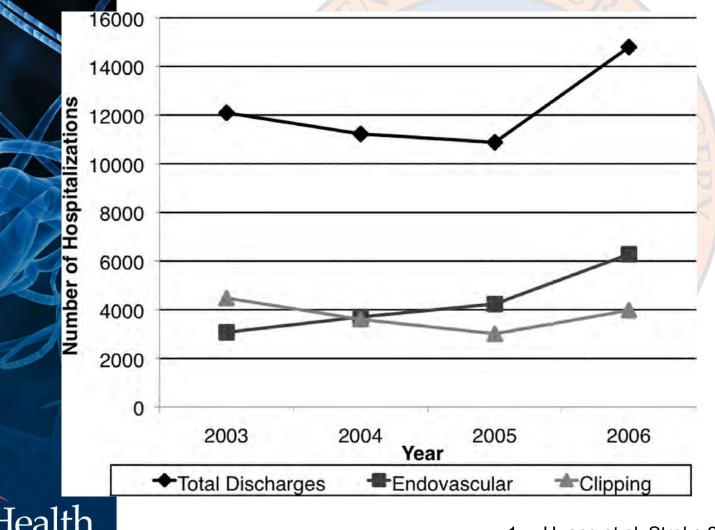
UFHealth UNIVERSITY OF FLORIDA HEALTH

1. Andaluz et al, JNS 2008



UNIVERSITY OF FLORIDA HEALTH

Coiling Trends



1. Huang et al, Stroke 2011

Unruptured Aneurysms: ATENA

- 649 patients with 1100 unruptured aneurysms ≤15mm
- Balloon-remodeling 37%, stentassisted 7.8%
- Aneurysm occlusion
 - Complete 59%
 - Neck remnant 21.7%
 - Aneurysm remnant 19.3%
 - Unable to treat 4.3%
 - 1. Pierot et al, Analysis of Treatment by Endovascular Approach of Nonruptured Aneurysms, Stroke 2008



ATENA

- Treatment-related adverse events 15.4%
- Intra-procedural rupture 2.6% (asymptomatic 50%, fatal 16.7%)
- Neurological complications 5.4% (permanent 2.6%, fatal 0.9%)
- For patients pre-procedure mRS 0, 96% continued to be mRS 0, 3.4% mRS 1, 0.4% mRS 2, 0.2% mRS 3
 - 1. Pierot et al, Analysis of Treatment by Endovascular Approach of Non-ruptured Aneurysms, Stroke 2008



ATENA

- One month morbidity 1.7%
- One month mortality 1.4%



1. Pierot et al, Analysis of Treatment by Endovascular Approach of Nonruptured Aneurysms, Stroke 2008

Ruptured Aneurysms: CLARITY

- 405 patients with aneurysmal SAH
 - WFNS I/II 65.7%
 - WFNS IV/V 30.6%
- Thromboembolic events (resulting in permanent deficit): 3.2%
- Intraoperative rupture (resulting in permanent deficit): 0.5%

1. Cognard et al, Clinial and Anatomic Results in the Treatment of Ruptured Intracranial Aneurysms, Neurosurgery 2011

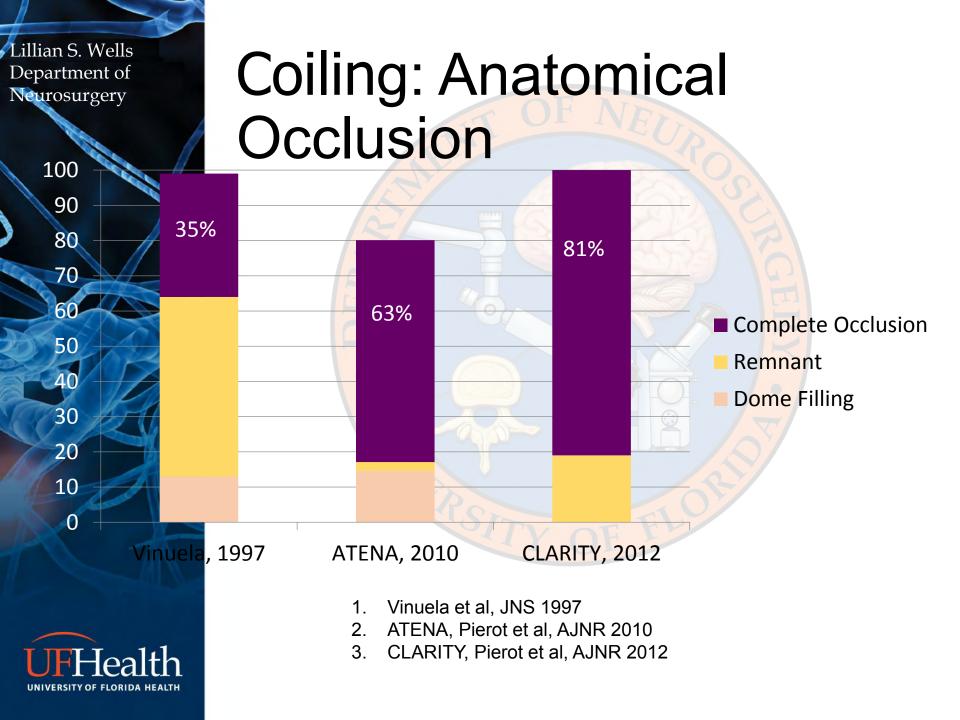


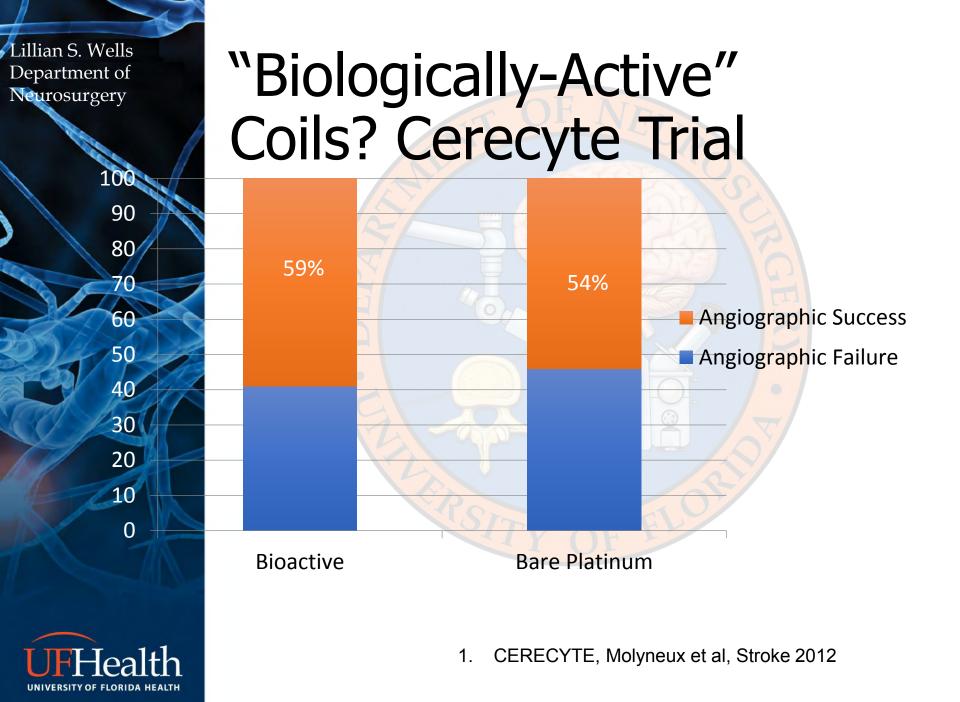
CLARITY

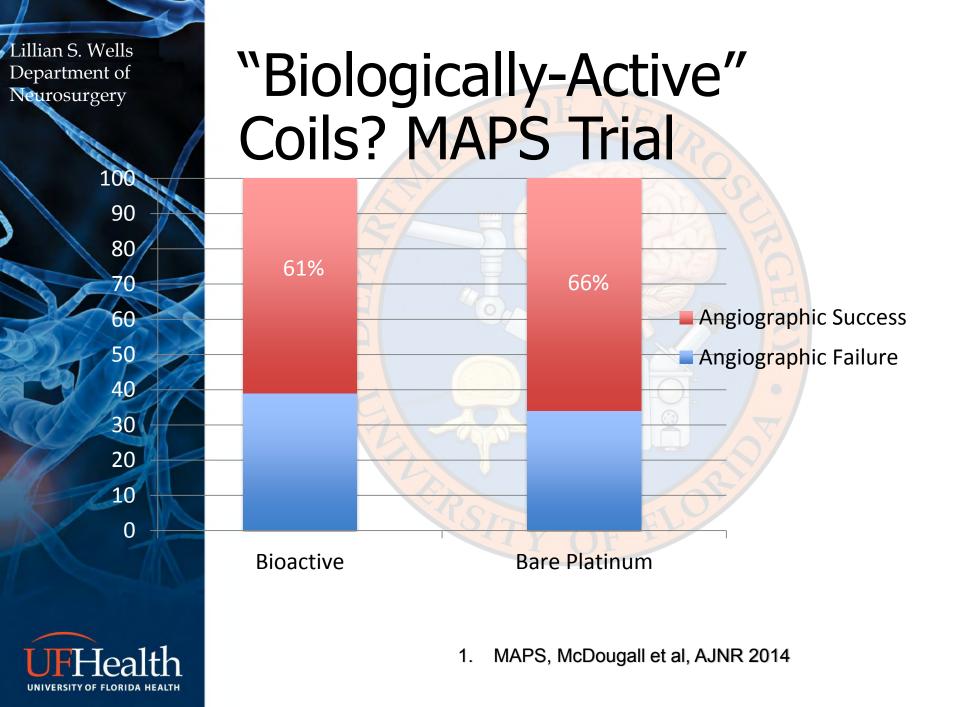
- Early rebleeding 0.5%
- Permanent treatment morbidity: 3.7%
- Permanent treatment mortality: 1.5%
- 3-6 month followup: 23.3% dead or dependent



1. Cognard et al, Clinial and Anatomic Results in the Treatment of Ruptured Intracranial Aneurysms, Neurosurgery 2011







Ruptured CA Guidelines

 <u>AHA/ASA Guidelines for aSAH 20121</u>: For patients with ruptured aneurysms judged to be technically amenable to both endovascular coiling and neurosurgical clipping, endovascular coiling should be considered (Class I Level B)



Unruptured CA Guidelines

 <u>AHA/ASA Guidelines for unruptured</u> <u>CA 2015¹</u>: Patients with UIAs who are considered for treatment should be fully informed about the risks and benefits of both endovascular and microsurgical aneurysm clipping (Class I Level B)





Stent-Assisted Coiling

- Where have we come with stentassisted coiling?
- Advanced stent techniques
 - Y-stenting
 - 92% Raymond I-II, 11% complications, 93% mRS 0-2¹





1. Fargen, Hoh, et al, Neurosurgery 2013

Advanced Techniques

Cross-Circulation Stenting



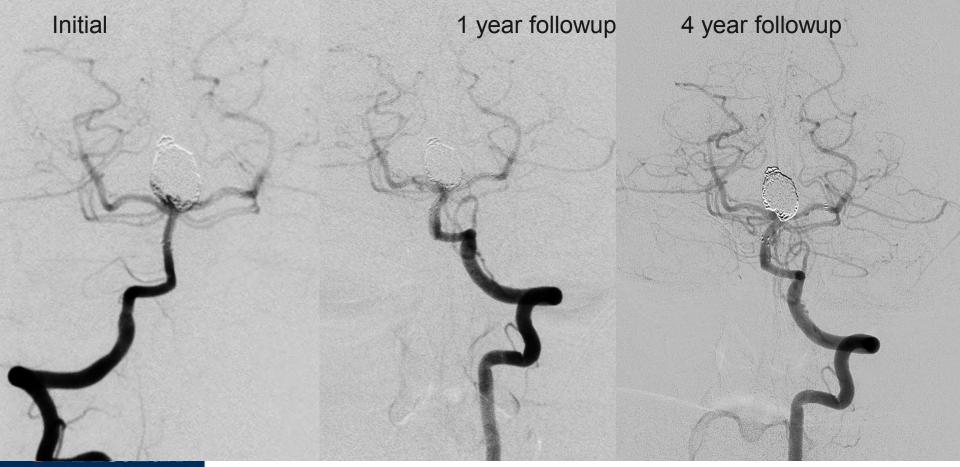


 100% complete or near-complete occlusion (>95%), 5.6% permanent morbidity, 5.6% mortality¹

1. Albuquerque et al, Neurosurgery 2011

Flow Remodeling

Flow Remodeling Phenomenon



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Flow Remodeling

- Flow Remodeling Phenomenon
 - When comparing stented vs non-stented aneurysm coiling
 - Multivariate analysis: stent use (P<0.001), decreasing aneurysm size (P<0.05), and increasing packing density (P<0.05) associated with progression of occlusion¹

Table 5a	n = 109		
	<u>Odds Ratio</u>	<u>959</u>	<mark>% CI</mark>
Stent (y vs. n)	18.54	4.337	79.222
Size	0.84	0.724	0.983
Packing Density	1.09	1.021	1.170

1. Lawson, Hoh et al, Neurosurgery 2011

Risk of Complications with SAH

- Multicenter registry for 2nd generation stent¹
 - 16 aSAH of 141 patients
 - 12% mortality
- Single center series of 37 patients²
 - 7 required EVD or VPS
 - 6 (86%) had hemorrhages
- Single center series of 65 patients³
 - 15.4% major complications
 - 7.7% hemorrhagic, 7.7% in-stent thrombus
 - 4.6% fatal hemorrhage
 - 1. Mocco. Hoh et al, JNS 2009
 - 2. Tumialan et al, JNS 2008
 - 3. Armenta et al, Neurosurgery 2012



Balloon Remodeling: 67 F Hunt Hess 4 SAH





51 F Hunt Hess 3 SAH





85 F Hunt Hess 3 SAH





85 F Hunt Hess 3 SAH



Balloon Remodeling in Ruptured CAs

 CLARITY (Clinical and Anatomic Results in the Treatment of Ruptured Intracranial Aneurysms)^{1,2}

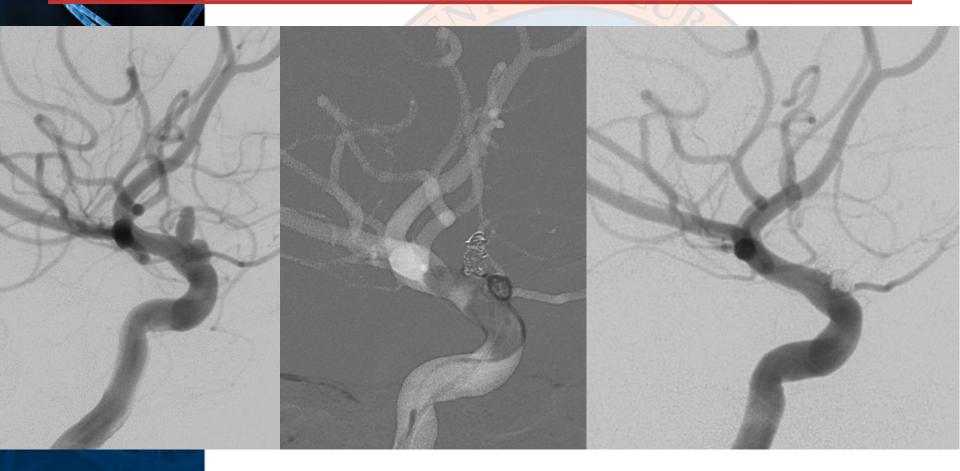
	Primary Coiling (n=608)	Balloon Remodeling (n=160)	P-value
Complications	17.4%	16.9%	NS
Cumulative Morbidity & Mortality	5.1%	3.8%	NS
Cumulative Global Morbidity & Mortality	19.6%	16.2%	NS
Intraoperative rupture	4.4%	4.4%	NS
Adequate Occlusion	88.7%	94.9%	0.017

1. Pierot et al, AJNR 2012

2. Pierot et al, Radiology 2011



50 F Headaches





12 month followup





Balloon Remodeling in Unruptured CAs

 ATENA (Analysis of Treatment by Endovascular Approach of Nonruptured Aneurysms)^{1,2}

	Primary Coiling (n=325)	Balloon Remodeling (n=222)	Stent-Assisted
Adverse events	10.8%	11.7%	
Thromboembolic	6.2%	5.4%	
Intraoperative rupture	2.2%	3.2%	
Morbidity	2.2%	2.3%	
Mortality	0.9%	1.4%	
Immediate complete ഠര്ഡ്ചുട്ട്നു001	63.7%	65.9%	43.4%*



1. Pierot et al, Radiology 2009

2. Pierot et al, AJNR 2010

Balloon Remodeling

- Literature Review¹
 - Thromboembolic: 23 studies: 867 coiled, 273 balloon
 - Perforation: 21 studies: 993 coiled, 170 balloon

	Primary Coiling	Balloon Remodeling
Thromboembolic	8.0%	8.1%
Aneurysm perforation (SAH cases)	3.4%	1.7%
Aneurysm perforation (nonSAH cases)	1.4%	1.8%
Initial total occlusion	49%	73%
Followup total occlusion	54%	72%



1. Shapiro et al, AJNR 2008

If Balloon works, Why Stent?

Series from Thomas Jefferson¹

	Balloon Remodeling (n=32)	Stent-assisted (n=69)	P-value
SAH cases	65.6%	11.5%	<0.001
Complications	9%	6%	NS
Complete occlusion	50%	75.4%	0.01
Progressive occlusion	42.8%	76.6%	0.02
Retreatment	15.6%	4.3%	0.05



1. Chalouhi et al, AJNR 2013

When Do I Balloon?

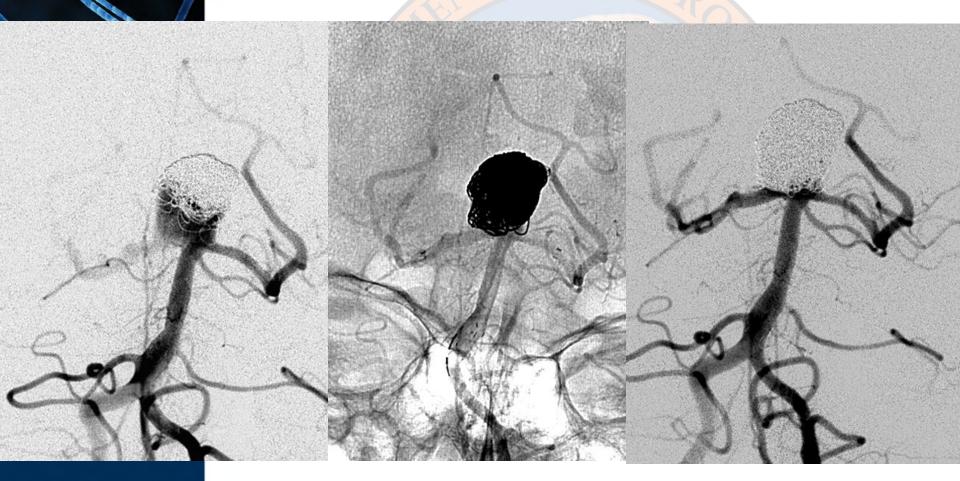
- Contraindication to dual antiplatelet therapy
- Nickel allergy
- SAH and complex aneurysm
 - Primary coil or balloon-remodel to protect dome
 - Delayed treatment with stent when safe for dual antiplatelet therapy



49 F Hunt Hess 3 with MI



49 F Hunt Hess 3 with MI





Acta Neurochir (2012) 154:27–31 DOI 10.1007/s00701-011-1214-z

CLINICAL ARTICLE

Intentional partial coiling dome protection of complex ruptured cerebral aneurysms prevents acute rebleeding and produces favorable clinical outcomes

Ben Waldau • John F. Reavey-Cantwell • Matthew F. Lawson • Shady Jahshan • Elad I. Levy • Adnan H. Siddiqui • J. Mocco • Brian L. Hoh



15 pati<mark>ents</mark>

- age 51±13 years
- Hunt Hess 3-5 (n=7); Fisher 3-4 (n=9)
- Aneurysm size 13 ± 5.4 mm; neck size 5.0 ± 3.0 mm
- 12 anterior circulation
- Balloon-assistance in 4 cases
- Definitive treatment performed 92±90 days later
 - No interval rebleeding
 - Clipping (n=8), stent-coiling (n=5), onyx (n=1), further coiling (n=1)

<u>Clinical Outcome</u> Good (GOS 4-5): 13 Fair (GOS 3): 1 Death (GOS 1): 1

64 F Hunt Hess 3 s/p clipping in 1990

sh



64 F Hunt Hess 3 s/p clipping in 1990



CAUD -1.6

UF HEA

64 F Hunt Hess 3 s/p clipping in 1990



Flow Diversion

- Flow Diversion dependent on metal surface area coverage
- Previous Stents: 6.5-9.5%
- Flow Diversion: 30-35%







Flow Diversion



SITY O



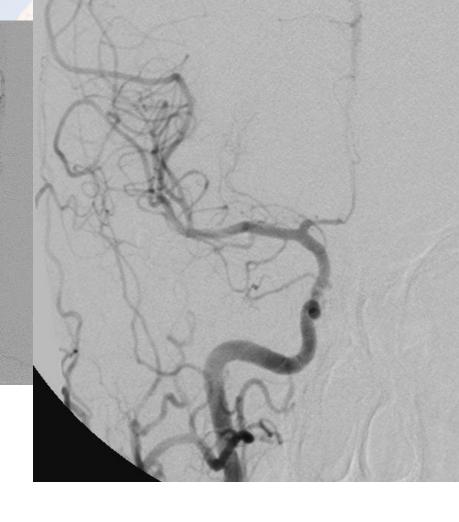
Flow Diversion





Flow Diversion







PUFS Trial

Pipeline for Uncoilable or Failed Aneurysms Study

- 107 patients
- Mean aneurysm size 18.2mm, 20.4% were giant
- Major ipsilateral stroke or neurologic death 5.6%
- Ipsilateral ICH 1.9%

	1 year
Complete occlusion	86.8%
Residual neck	5.5%
Residual aneurysm	5.5%
Carotid occlusion	2.2%

1. PUFS Trial, Becske et al, Radiology 2013

PUFS Trial

Pipeline for Uncoilable or Failed Aneurysms Study

- 98 patients had ophthalmologic followup
- 39 (40%) presented with ophthalmologic deficit attributable to aneurysm
 - 25 (64%) improved
 - 1 (2.6%) worsened
- 5 (5%) developed new deficits
- 6 (6%) with deficits not attributable to aneurysm improved



IntrePED

International retrospective study of the Pipeline Embolization Device

- 793 patients with 906 aneurysms
- Neurologic morbidity and mortality 8.4%
- Spontaneous rupture 0.6%
- ICH 2<mark>.4%</mark>
- Ischemic stroke 4.7%

	Posterior circulation	ICA <10mm	OB I
Neurologic morbidity/mortality	16.4%	4.8%	OF FL
Ischemic stroke	7.3%	2.7%	
Neurologic mortality	10.9%	1.4%	1. Kallmes et al, AJNR 20

Ophthalmic Artery Patency

- 95 patients with ophthalmic artery covered by device
- Ophthalmic artery at mean angiographic followup 7.5 months
 - Patent 89%
 - Diminished flow 4%
 - Occluded 7%
 - 1 patient was symptomatic

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1. Chalouhi et al, Neurosurgery 2015

Anterior Choroidal Artery Patency

- 29 patients with anterior choroidal artery covered by device
- Anterior choroidal artery at mean angiographic followup 15.1 months
 - Patent 96.5%
 - Occluded, but asymptomatic 3.5%

weurosurgery

Review of Reported Complications Associated with the Pipeline Embolization Device

Kyle M. Fargen, Gregory J. Velat, Matthew F. Lawson, J Mocco, Brian L. Hoh

WORLD NEUROSURGERY 77 [3/4]: 402-407, MARCH/APRIL 2012

Table 1. Summary of Complications After Pipeline Embolization Device Deployment for Unruptured Aneurysms

Study	Number of Patients	Major Complications (%)	Deaths (%)
PUFS, 2011 (12)	111	9 strokes, 1 ICH (9%)	2 (2%)
Lylyk et al., 2009 (5)	53	0 (0%)	0 (0%)
Szikora et al., 2010 (11)	18	1 rupture (6%)	1 (6%)
Nelson et al., 2011 (10)	30	1 rupture, 1 stroke (7%)	0 (0%)
Lubicz et al., 2011 (6)	20	1 stroke (5%)	1 (5%)
Fischer et al., 2011 (2)	88	3 ICH, 2 thromboses, 1 rupture (7%)	1 (1%)
McAuliffe et al., 2011 (8)	54	0 (0%)	0 (0%)
Total	374	20 (5.3%)	5 (1.3%)



But, we still clip aneurysms

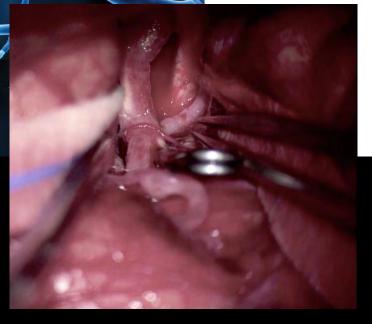
- Wide aneurysm neck > 4mm
- Dome-to-neck ratio <2:1
- Small aneurysm
- Branch vessel coming out of aneurysm



Advances in Surgical Clipping

Video ICG angiography





ICG videoangiography

ICG videoangiography

- Helsinki experience¹:
- ICG-VA with clipping of 239 aneurysms in 190 patients
- 59% ruptured, 51% unruptured
- Unexpected neck residuals 6%
- Unexpected branch occlusions 6%



ICG VA vs Intraop DSA

- 155 aneurysm clippings at a single center: 49 (32%) underwent both ICG and IOA
- Post-ICG clip adjustment rate 4.1%
- Overall ICG-IOA agreement 75.5%
- ICG-IOA discordance rate requiring clip adjustment 14.3%
 - 3 aneurysm remnants
 - 4 vessel occlusions

BRAT

J Neurosurg 116:135-144, 2012

The Barrow Ruptured Aneurysm Trial

Clinical article

CAMERON G, MCDOUGALL, M.D.,¹ ROBERT F. SPETZLER, M.D.,¹ JOSEPH M. ZABRAMSKI, M.D.,¹ SHAHRAM PARTOVI, M.D.,² NANCY K. HILLS, PH.D.,³ PETER NAKAJI, M.D.,¹ AND FELIPE C. ALBUQUERQUE, M.D.¹

Divisions of 'Neurological Surgery and 'Neuroradiology, Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, Phoenix, Arizona, and 'Department of Neurology, University of California, San Francisco, California

Object. The purpose of this ongoing study is to compare the safety and efficacy of microsurgical clipping and endovascular coil embolization for the treatment of acutely ruptured cerebral aneurysms and to determine if one treatment is superior to the other by examining clinical and angiographic outcomes. The authors examined the null hypothesis that no difference exists between the 2 treatment modalities in the setting of subarachnoid hemorrhage (SAH). The current report is limited to the clinical results at 1 year after treatment.

Methods. The authors screened 725 patients with SAH, resulting in 500 eligible patients who were enrolled prospectively in the study after giving their informed consent. Patients were assigned in an alternating fashion to surgical aneurysm clipping or endovascular coil therapy. Intake evaluations and outcome measurements were collected by nurse practitioners independent of the treating surgeons. Ultimately, 238 patients were assigned to aneurysm clipping and 233 to coil embolization. The 2 treatment groups were well matched. There were no anatomical exclusions. Crossing over was allowed, but primary outcome analysis was based on the initial treatment modality assignment. Postreatment care was standardized for both groups. Patient outcomes at 1 year were independently assessed using the modified Rankin Scale (mRS). A poor outcome was defined as an mRS score > 2 at 1 year. The primary outcome was based on the assigned group; that is, by intent to treat.

Results. One year after treatment, 403 patients were available for evaluation. Of these, 358 patients had actually undergone treatment. The remainder either died before treatment or had no identifiable source of SAH. A poor outcome (mRS score > 2) was observed in 33.7% of the patients assigned to aneurysm clipping and in 23.2% of the patients assigned to coil embolization (OR 1.68, 95% CI 1.08–2.61; p = 0.02). Of treated patients assigned to the coil group, 124 (62.3%) of the 199 who were eligible for any treatment actually received endovascular coil embolization. Patients who crossed over from coil to clip treatment fared worse than patients assigned to coil embolization, but no worse than patients assigned to clip occlusion. No patient treated by coil embolization suffered a recurrent hemorrhage.

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Conclusions. One year after treatment, a policy of intent to treat favoring coil embolization resulted in fewer poor outcomes than clip occlusion. Although most aneurysms assigned to the coil treatment group were treated by coil embolization, a substantial number crossed over to surgical clipping. Although a policy of intent to treat favoring coil embolization resulted in fewer poor outcomes at 1 year, it remains important that high-quality surgical clipping be available as an alternative treatment modality. (DOI: 10.3171/2011.8.INS101767)

BRAT

- 500 (of 725 screened) aSAH patients at a single center
- Randomized to clipping (n=238) or coiling (n=233)
- Primary outcome: modified Rankin Scale at 1 year (mRS>2)



BRAT

TABLE 1: Patient and aneurysm characteristics in the BRAT*

	No. Assigned to Clip Group	No. Assigned to	p Val-
Characteristic	(%)	Coil Group (%)	ue†
total no. of patients	238	233	
mean age in yrs	53.1 ± 12.8	54.3 ± 12.0	0.33
female	166 (69.7)	166 (71.2)	0.72
race/ethnicity			0.33‡
Caucasian	152 (63.9)	158 (67.8)	
Hispanic	63 (26.5)	50 (21.5)	
African American	13 (5.5)	9 (3.9)	
Asian	3 (1.3)	8 (3.4)	
other	7 (2.9)	8 (3.4)	
comorbidities			
diabetes	20 (8.4)	17 (7.3)	0.66
hypertension	103 (43.3)	104 (44.6)	0.77
smoking	147 (61.8)	145 (62.2)	0.91
cocaine	21 (8.8)	21 (9.0)	0.92
methamphetamines	17 (7.1)	20 (8.6)	0.53
status at presentation			
mean GCS score	12.3 ± 3.6	12.5 ± 3.6	0.75
mean Hunt & Hess grade	2.6 ± 1.1	2.6 ± 1.1	0.94
mean Fisher grade	2.7 ± 0.7	2.7 ± 0.6	0.77
aneurysm feature			
size in mm§			0.61
mean	6.8 ± 4.1	6.6 ± 4.0	
median; IQR	6.0; 4–8	6.0; 4–8	
location			0.62‡
posterior circulation	38 (16.0)	32 (13.7)	
anterior circulation	1/4 (73.1)	169 (72.5)	
angiography negative	26 (10.9)	31 (13.3)	
other	not applicable	1 (0.4)	

TABLE 2: Hunt and Hess grades at presentation in 471 patients in the BRAT*

Hunt &	Hess Grade	No. Assigned to Clip Group (%)	No. Assigned to Coil Group (%)		
	I	32 (13.4)	31 (13.3)		
	П	92 (38.7)	93 (39.9)		
	III	71 (29.8)	61 (26.2)		
	IV	29 (12.2)	34 (14.6)		
	V	14 (5.9)	14 (6.0)		



1. McDougall et al, JNS 2012

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BRAT

- Excluded: 6 patients died before treatment, 57 patients with nonaneurysmal SAH
- Cross-over
 - 38% (75/199) assigned to coiling were clipped
 - 1.9% (4/209) assigned to clipping were coiled
 - Anterior circulation: 0.6% clip to coil, 42% coil to clip
 - Posterior circulation: 8.0% clip to coil, 16.0% coil to clip
 - 1. McDougall et al, JNS 2012
 - 2. Spetzler et al, JNS 2015

BRAT: Intent-to-Treat

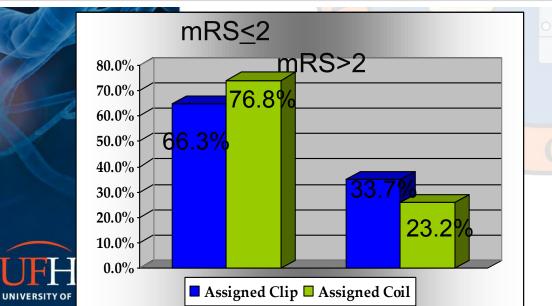
TABLE 3:

Proportion of patients with poor outcome (mRS score > 2) at 1 year in the BRAT

Clip Group			Coil Group				
Subgroup	No.*	No. w/ mRS Score >2 (%)) Subgroup	No.*	No. w/ mRS Score >2 (%)	OR (95% CI)	p Value
assigned clip	205	69 <mark>(33.7)</mark>	assigned coil	198	46 <mark>(23.2)</mark>	1.68 (1.08–2.61)	0.02
assigned clip & received clip	180	61 (33.9)	assigned coil & received coil	109	20 (18.4)	2.28 (1.30-4.13)	0.005
crossover: assigned coil & received clip	65	22 (33.9)	crossover: assigned clip & received coil	4	3 (75.0)	0.17 (0.01-1.42)†	0.14
total actually treated w/ clip	245	83 (33.9)	total actually treated w/ coil	113	23 (20.4)	2.01 (1.20-3.46)	0.01

* Total number of patients in each category in whom the mRS score at 1 year was available.

† Reference group; those assigned to coil embolization who crossed over to surgical clipping.



D = 10.5% P = 0.02 OR = 1.55 P = 0.03

1. McDougall et al, JNS 2012

BRAT: Actual Treatment

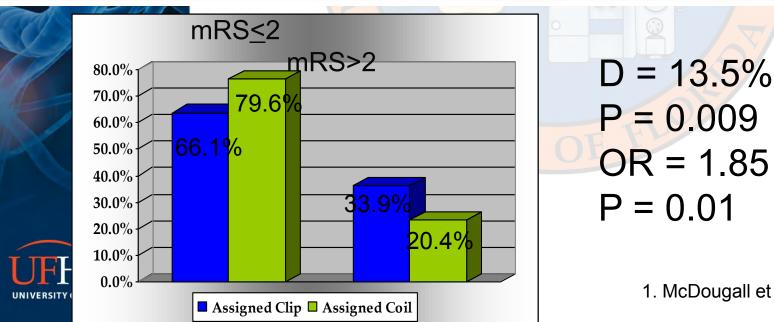
TABLE 3:

Proportion of patients with poor outcome (mRS score > 2) at 1 year in the BRAT

Clip Grou		Coil Group					
Subgroup	No.*	* No. w/ mRS Score >2 (%)) Subgroup	No.*	No. w/ mRS Score >2 (%)	OR (95% CI)	p Value
assigned clip	205	69 (33.7)	assigned coil	198	46 (23.2)	1.68 (1.08-2.61)	0.02
assigned clip & received clip	180	61 (33.9)	assigned coil & received coil	109	20 (18.4)	2.28 (1.30-4.13)	0.005
crossover: assigned coil & received clip	65	i 22 (33.9)	crossover: assigned clip & received coil	4	3 (75.0)	0.17 (0.01-1.42)†	0.14
total actually treated w/ clip	245	i 83 <mark>(33.9)</mark>	total actually treated w/ coil	113	23 (20.4)	2.01 (1.20–3.46)	0.01

* Total number of patients in each category in whom the mRS score at 1 year was available.

† Reference group; those assigned to coil embolization who crossed over to surgical clipping.



1. McDougall et al, JNS 2012

BRAT: Three Year Results

- 349 patients
- 3 year mRS>2: coiling 30% vs clipping 35.8% (P=0.25)
- Posterior circulation mRS>2: coiling 25% vs clipping 61.8% (P=0.004)



1. Spetzler et al, JNS 2013

BRAT: Six Year Results

- 336 of 408 patients (82%)
- Poor outcome (mRS >2)
 - Coil assigned 35%
 - Clip assigned 41% (P=0.24)
- Posterior circulation mRS>2: coiling 31% vs clipping 62.9% (P=0.01)



BRAT: Six Year Results

PICA aneurysms:

- 18/21 were randomized to clipping
- At every time point, PICA aneurysms had worse outcomes than non-PICA aneurysms



1. Spetzler et al, JNS 2015

BRAT: Six Year Results

- No difference in rebleeding
- Retreatment
 - 4.6% of clipped patients required retreatment
 - 16.4% of coiled patients required retreatment (P<0.0001)
- Complete aneurysm obliteration
 - 96% of clipped aneurysms
 - 48% of coiled aneurysms (P<0.0001)



Analysis of saccular aneurysms in the Barrow Ruptured Aneurysm Trial

Robert F. Spetzler, MD,¹ Joseph M. Zabramski, MD,¹ Cameron G. McDougall, MD,¹ Felipe C. Albuquerque, MD,¹ Nancy K. Hills, PhD,³ Robert C. Wallace, MD,² and Peter Nakaji, MD¹

Departments of ¹Neurosurgery and ²Neuroradiology, Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, Phoenix, Arizona; and ³Department of Neurology, University of California, San Francisco, California

OBJECTIVE The Barrow Ruptured Aneurysm Trial (BRAT) is a prospective, randomized trial in which treatment with clipping was compared to treatment with coil embolization. Patients were randomized to treatment on presentation with any nontraumatic subarachnoid hemorrhage (SAH). Because all other randomized trials comparing these 2 types of treatments have been limited to saccular aneurysms, the authors analyzed the current BRAT data for this subgroup of lesions.

METHODS The primary BRAT analysis included all sources of SAH: nonaneurysmal lesions; saccular, blister, fusiform, and dissecting aneurysms; and SAHs from an aneurysm associated with either an arteriovenous malformation or a fistula. In this post hoc review, the outcomes for the subgroup of patients with saccular aneurysms were further analyzed by type of treatment. The extent of aneurysm obliteration was adjudicated by an independent neuroradiologist not involved in treatment.

RESULTS Of the 471 patients enrolled in the BRAT, 362 (77%) had an SAH from a saccular aneurysm. Patients with saccular aneurysms were assigned equally to the clipping and the coiling cohorts (181 each). In each cohort, 3 patients died before treatment and 178 were treated. Of the 178 clip-assigned patients with saccular aneurysms, 1 (1%) was crossed over to coiling, and 64 (36%) of the 178 coil-assigned patients were crossed over to clipping. There was no statistically significant difference in poor outcome (modified Rankin Scale score > 2) between these 2 treatment arms at any recorded time point during 6 years of follow-up. After the initial hospitalization, 1 of 241 (0.4%) clipped saccular aneurysms and 21 of 115 (18%) coiled saccular aneurysms required retreatment (p < 0.001). At the 6-year follow-up, 95% (95/100) of the clipped aneurysms were completely obliterated, compared with 40% (16/40) of the coiled aneurysms (p < 0.001). There was no difference in morbidity between the 2 treatment groups (p = 0.10).

CONCLUSIONS In the subgroup of patients with saccular aneurysms enrolled in the BRAT, there was no significant difference between modified Rankin Scale outcomes at any follow-up time in patients with saccular aneurysms assigned to clipping compared with those assigned to coiling (intent-to-treat analysis). At the 6-year follow-up evaluation, rates of retreatment and complete aneurysm obliteration significantly favored patients who underwent clipping compared with those who underwent coiling.





BRAT: results on saccular aneurysms¹

- BRAT: 500 aSAH randomized to clip vs coil²
- Crossover: 38% assigned to coiling were clipped; 1.9% assigned to clipping were coiled
- <u>1-Year mRS>2²</u>: Clip 33.7%, Coil 23.2%, P=0.03
- <u>3-Year mRS>2 (n=349)³</u>: Clip 35.8%, Coil 30%, P=0.25, but posterior circulation Clip 61.8%, Coil 25%, P=0.004
- <u>6-Year mRS>2 (n=336)</u>⁴: Clip 41%, Coil 35%, P=0.24, but posterior circulation Clip 62.9%, Coil 31%, P=0.01



- 1. Spetzler et al, JNS 2018
- 2. McDougall et al, JNS 2012
- 3. Spetzler et al, JNS 2013
- 4. Spetzler et al, JNS 2015



BRAT: results on saccular aneurysms¹

- 362 (77%) saccular aneurysms: 178 clipped, 178 coiled, 6 died before treatment
- Crossover: 36% assigned to coiling were clipped; 1% assigned to clipping were coiled
- <u>1-Year mRS>2</u> (n=317): Clip 33%, Coil 27%, P=0.29
- <u>3-Year mRS>2 (n=307)</u>: Clip 33%, Coil 34%, P=0.84
- <u>6-Year mRS>2 (n=297)</u>: Clip 40%, Coil 38%, P=0.76
- <u>Retreatment</u>: Clip 0.4%, Coil 18%, P<0.001



1. Spetzler et al, JNS 2018



NEW TECHNOLOGY 1. Flow Diversion 2. Neck bridging 3. Intra-saccular



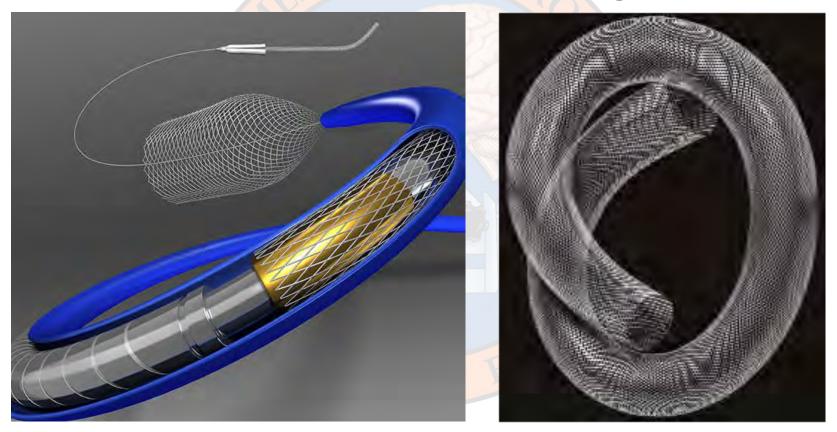


NEW TECHNOLOGY 1. Flow Diversion 2. Neck bridging 3. Intra-saccular





Flow Diversion Stenting







Current Generation Flow Diverters

Flow Diverter	Available Diameter	Available Length	Material	Design	Deployment	Resheathable?	Manufacturer-Reported Strengths
Pipeline	2.5–5 mm	10–35 mm	Cobalt chrome w/ platinum tungsten	48 braided strands	Pusher wire w/ unsheath- ing	Yes, full length (Flex)	Flex has 4-point Flex technol- ogy & is fully resheathable compared to original
Surpass	2–5 mm	12–50 mm	Cobalt chrome w/ platinum tungsten	2-mm, 3- to 4-mm, & 5-mm (48, 72, 96) braided strands, respectively	3.7-Fr distal catheter w/ pusher catheter	Yes, up to 11 mm btwn catheter tip & pusher must remain	Surpass Streamline has 67%, 61%, & 34% less tracking force than Legacy, Pipeline, or FRED, respectively
SILK	2–5 mm	15–40 mm	Nitinol w/ platinum	48 braided strands	Push-pull deployment	Yes, SILK (+) up to 90%	SILK (+) available in tapered sizes, has enhanced visibility compared to SILK
FRED	3.5–5.5 mm	7–56 mm	Nitinol w/ interwoven tantalum	Dual-layer braided design; 48 braided strands in- ner, 16 braided stands outer stent	Push-pull deployment	Yes, up to 80%	Unique integrated dual-layer design that can be simulta- neously deployed or partially retrieved by single operator
p64	2.5–5 mm	12–36 mm	Nitinol	64 braided strands	Mechanical detachment	Yes	Complete deployment w/ full recoverability

TABLE 1. Summary of characteristics of endoluminal flow diverters



1. Rajah et al, Neurosurg Focus 2017



Improved Safety with 2nd Generation Flow Diverter¹

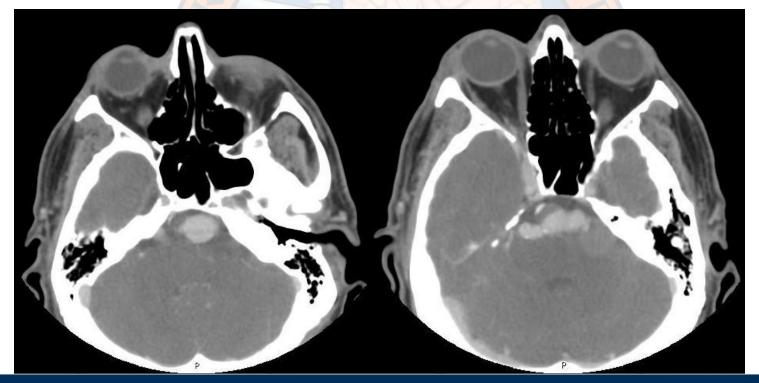
- Single institution
- 252 Pipeline classic, 316 Pipeline Flex
- Procedural Success: Classic 96%, Flex 98% (P=0.078)
- Major Morbidity or Death: Classic 5.6%, Flex 1.9% (P=0.019)
- Multivariate Predictors of Major Complication
 - In situ thrombosis (OR 4.3, P=0.006)
 - Classic device (OR 3.7, P=0.008)
 - MCA or ACA (OR 3.5, P=0.034)



1. Colby et al, JNS 2018



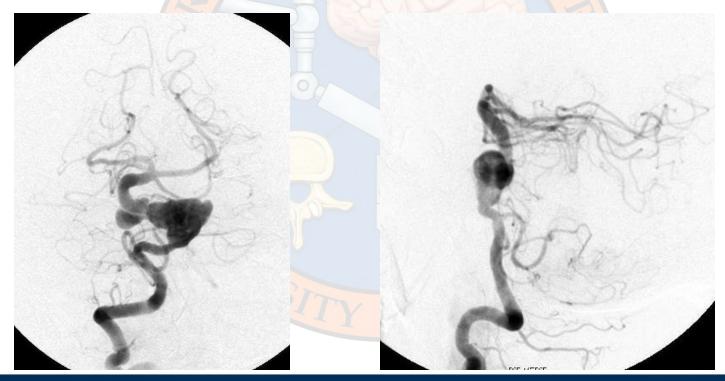
60 year old man with otalgia





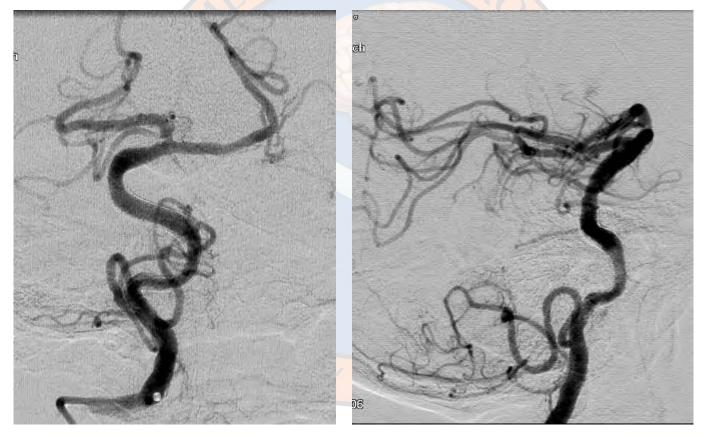


60 year old man with otalgia



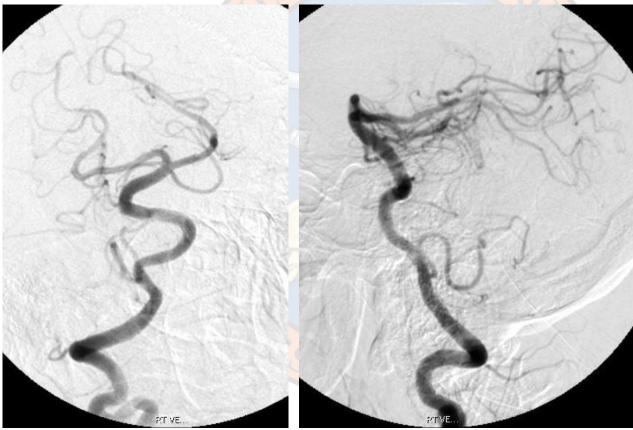












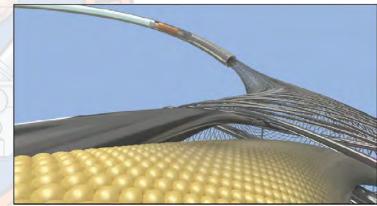
2 year followup





Modified Coating

- Pipeline Flex with Shield: phosphorylcholine coating that reduces thrombogenicity and possibly reduces the need for dual antiplatelet therapy¹
- 50 patient registry²
 - 6 no antiplatelet preprocedure
 - 3 single antiplatelet
 - All dual antiplatelet postprocedure
 - No major stroke or death 30-days postprocedure
- Case report: patient on aspirin only³





- 1. Marosfoi et al, JNIS 2018
- 2. Martinez-Galdamez et al, JNIS 2017
- 3. Hanel et al, BMJ Case Rep 2017

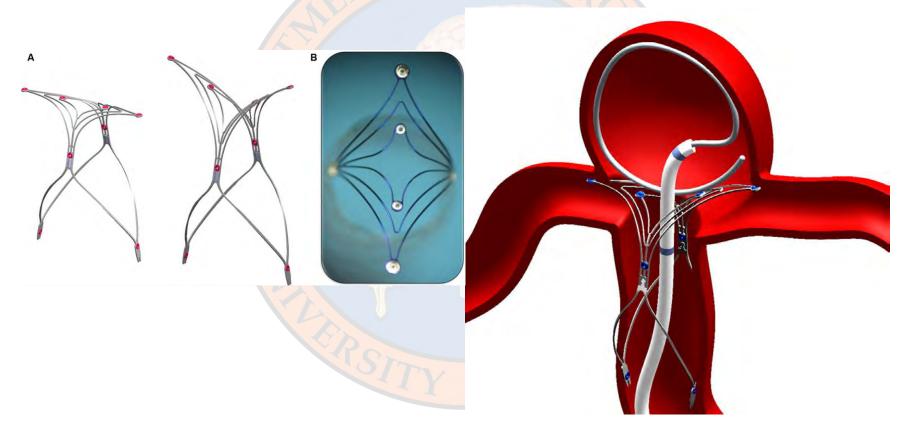


NEW TECHNOLOGY 1. Flow Diversion 2. Neck bridging 3. Intra-saccular





Pulse Rider







Pulse Rider







ANSWER: Registry PulseRider¹

Adjunctive Neurovascular Support of Wide-neck aneurysm Embolization and Reconstruction (ANSWER)

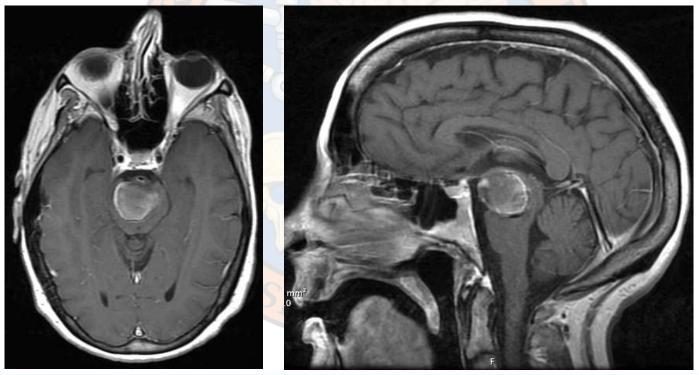
- Single arm registry of PulseRider, 10 US sites
- ICA terminus or basilar apex
- 34 patients
- Raymond 1-2: immediate 82.4%, 6-month 87.9%
- mRS 0-2 at 6 months: 94%
- 8.8% intraprocedural complications
- 11.8% transient neurologic morbidity
- 8.8% permanent neurologic morbidity



1. Spiotta et al, Neurosurgery 2017



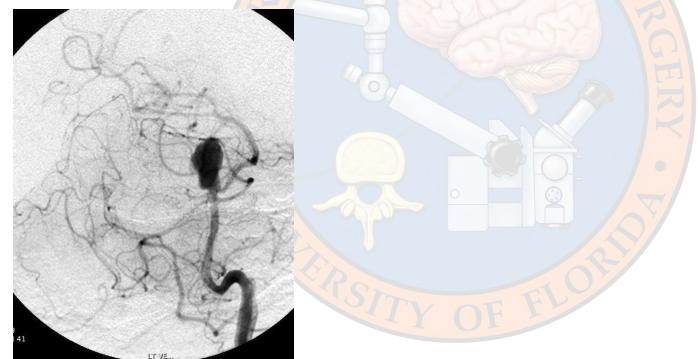
50 year old woman with left hemiparesis







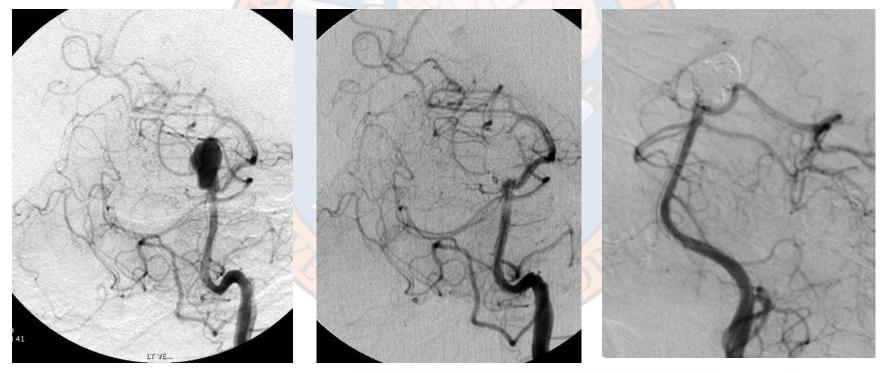
50 year old woman with left hemiparesis







50 year old woman with left hemiparesis







• 10 years later, recurrent left hemiparesis









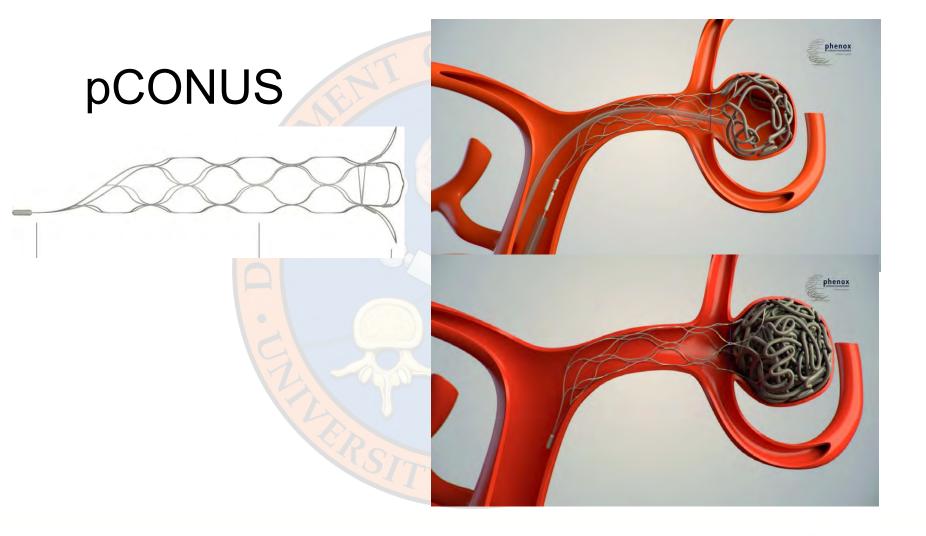
















pCONUS

- <u>Case series (Heidelberg)</u>¹: 22 aneurysms in 21 patients
- Successful deployment in 20 aneurysms in 19 patients
- Complications 5%: one case of minor stroke
- 6 months angiographic outcome: 95% adequate occlusion



 Ulfert et al, Clinical Neuroradiology 2018



pCONUS

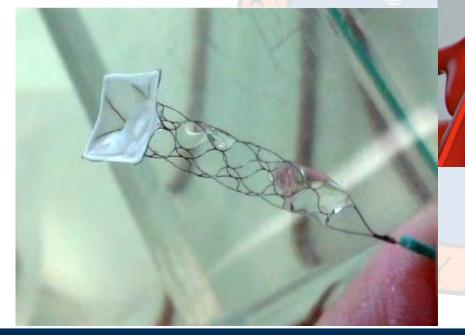
- MCA aneurysms (4 European centers)¹: 40 patients
- 1 month permanent morbidity 2.5%, mortality 0%
- 1 year permanent morbidity 2.5%, mortality 0%
- Angiographic outcome (mean 12 months, range 3-20):
 - Complete occlusion 67.7%
 - Neck remnants 29%
 - Aneurysm remnants 3.3%
- Retreatment 22.5%



1. Gory et al, Neurosurgery 2017



pCANVAS





Lillian S. Wells Department of Neurosurgery



henox









pCANVAS¹

- 17 patients
- Locations
 - MCA 10
 - ACOM 3
 - ICA bifurcation 3
 - Basilar tip 1
- Followup angiography (median 18.2 months, 7-38 months)
 - 8 complete occlusion
 - 3 neck remnants
 - 3 complete filling



1. Lylyk et al, Clin Neurorad 2018



pCANVAS¹

- Retreatment: 7 (1 on followup angiography, the device was found migrated to the dome)
- No complications
- All patients mRS 0 at followup



1. Lylyk et al, Clin Neurorad 2018



Barrel Vascular Reconstruction Device









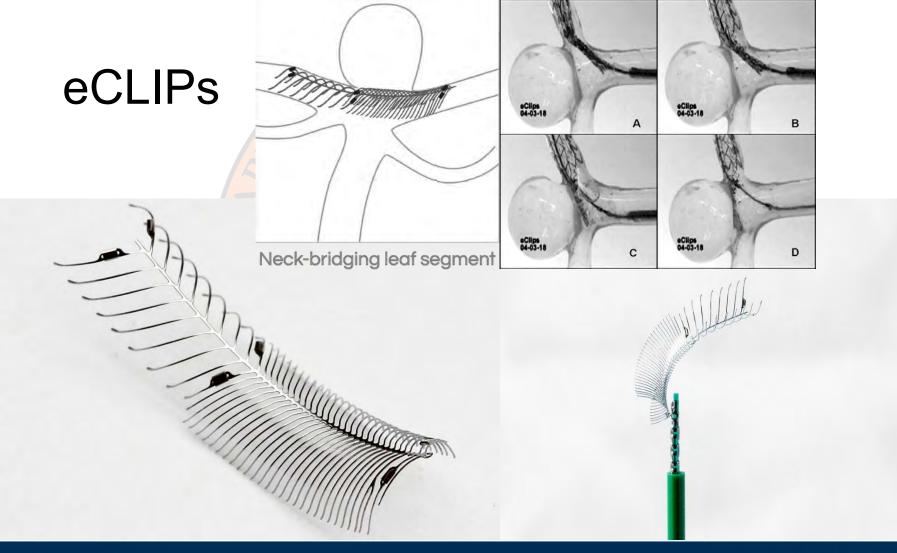
Barrel Vascular Reconstruction Device

- Multicenter post-marketing registry¹
- 20 patients, device successfully implanted in 19
- Primary effectiveness: 78.9% (12 complete occlusion, 3 neck remnants)
- Primary safety: 5.3% (major stroke or neurologic death at 12 months)
- Secondary endpoints: 10.5% ischemic stroke, 10.5% intracranial hemorrhage



1. Gory et al, JNIS 2018

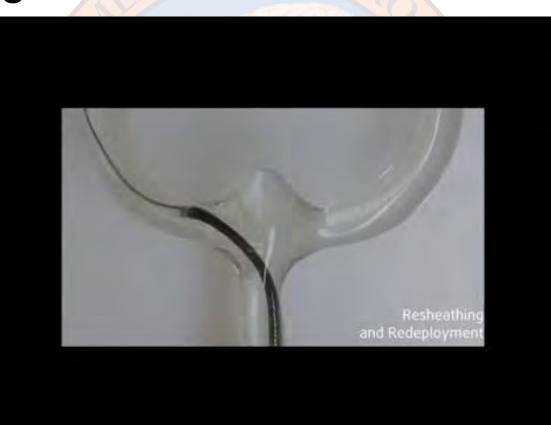








eCLIPs







eCLIPs Registry¹

- Single arm registry, 13 international centers
- 33 patients
- 25 (76%) successful placement, 8 nondeployments occurred during first year
- Complications: 2 periprocedural TIAs, 2 asymptomatic thrombotic events
- 2 delayed ruptures



1. Chiu et al, JNS 2018



eCLIPs Registry¹

- Angiographic outcome:
 - 81% Raymond grade 1-2
 - 43% improvement in Raymond grade

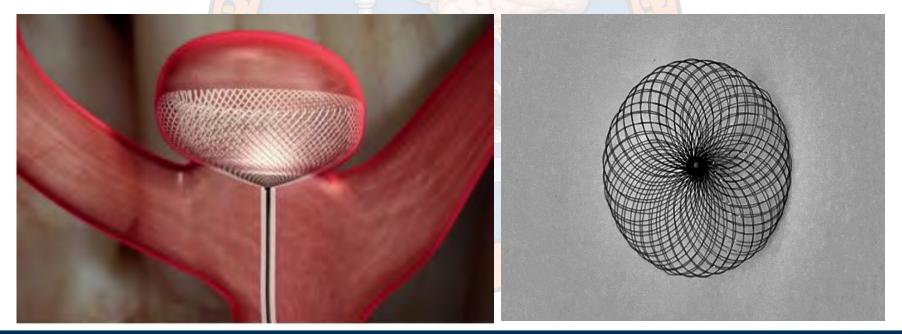


1. Chiu et al, JNS 2018



Flow diversion/disruption

 Contour: Cerus Endovascular conducting 45 patient single-arm trial in Europe





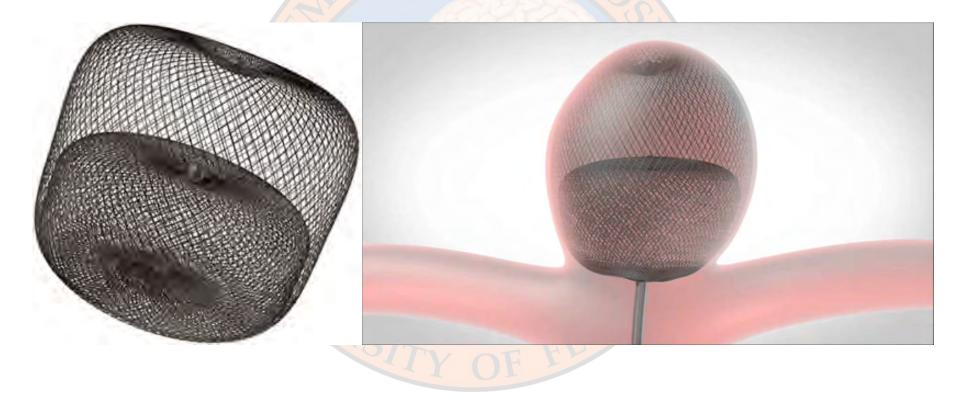


NEW TECHNOLOGY 1. Flow Diversion 2. Neck bridging 3. Intra-saccular





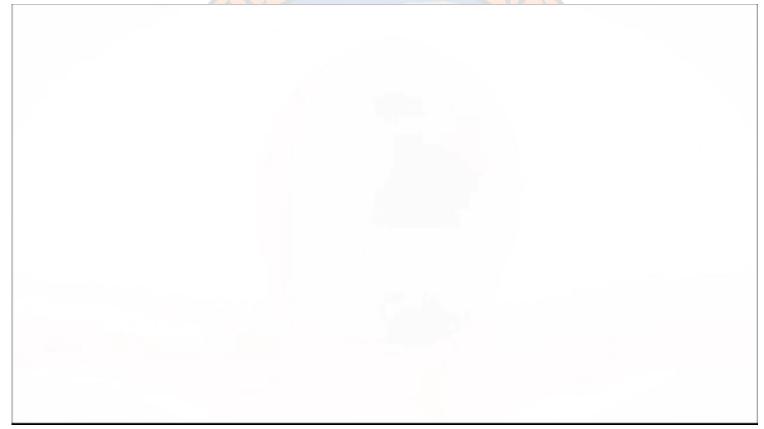
Intrasaccular







WEB Woven EndoBridge Device







WEB Pooled Study Results¹

WEBCAST, WEBCAST2, French Observatory

- 168 patients with 169 aneurysms
- Locations
 - MCA 86
 - ACOM 36
 - Basilar 30
 - ICA 17
- Ruptured 14
- 1 month morbidity 1.2%, mortality 0%



1. Pierot et al, JNIS 2017



WEB Pooled Study Results¹

WEBCAST, WEBCAST2, French Observatory

- 1 year angiographic outcome
 - Complete occlusion 52.9%
 - Neck remnant 26.1%
 - Aneurysm remnant 20.9%
- Retreatment 6.9%



1. Pierot et al, JNIS 2017



Intrasaccular Mesh Cage

Luna (now called Artisse)







Intrasaccular Mesh Cage

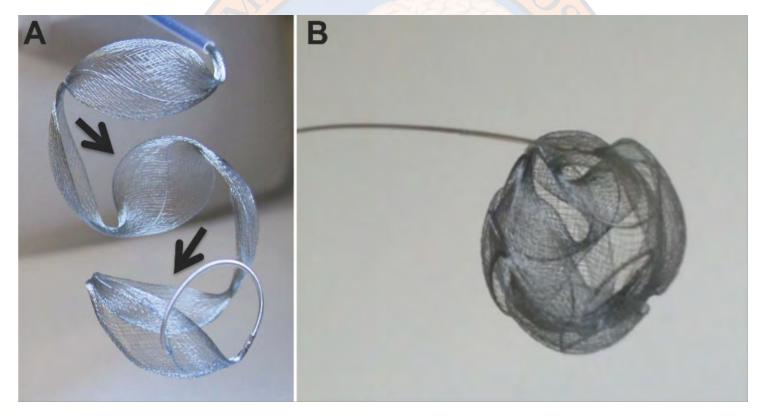
- Luna (now called Artisse)¹
- 15 patients
 - 1 failure to deploy
 - 4 with balloon assistance
- Complications: 1 aneurysm perforation, 1
 thromboembolic
- Immediate angiographic outcome
 - 1 complete
 - 9 near-complete
 - 4 no occlusion



 Piotin et al, JNIS 2012 (abstract at SNIS 9th Annual Meeting)



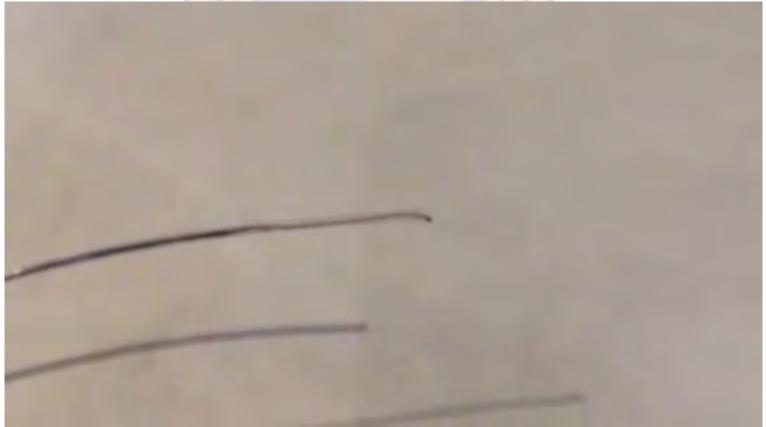
3D Mesh Coil







3D Mesh Coil







Medina Coil

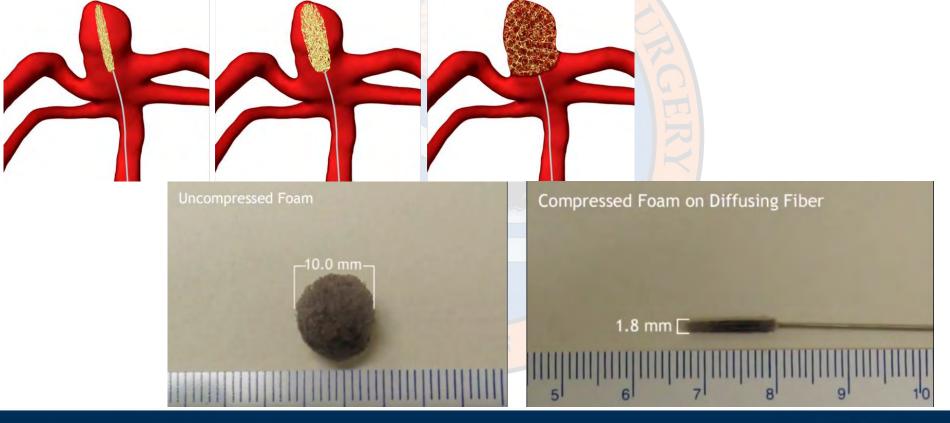
- <u>Case Series</u>¹: 12 patients with 13 aneurysms
- Medina alone 2
- Medina+standard coils 11
- Balloon-assist 4
- Complications: 1 thromboembolic with no clinical consequence
- Grade A occlusion: 61.5%, 6-month 83%, 2 cases of recanalization



1. Sourour et al, Neurosurgery 2018



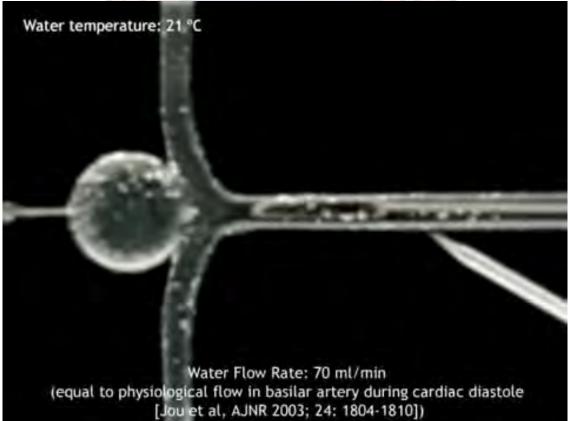
Shape Memory Polymer Foam







Shape Memory Polymer Foam







Conclusions

- Significant progress in the treatment of cerebral aneurysms
- Robust innovation and novel technologies





New Neuro-Vascular Hospita

A PARTY AND















