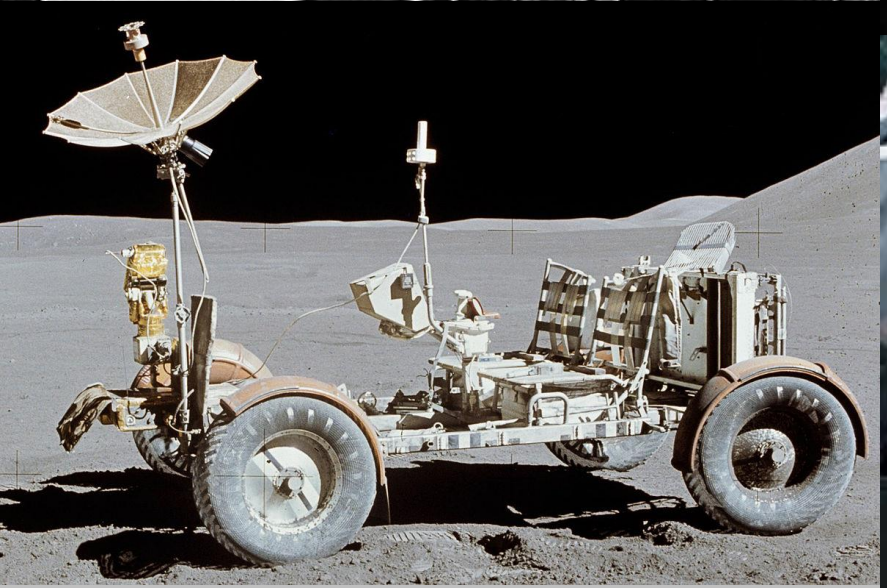
Development of Endovascular Techniques (for Stroke)

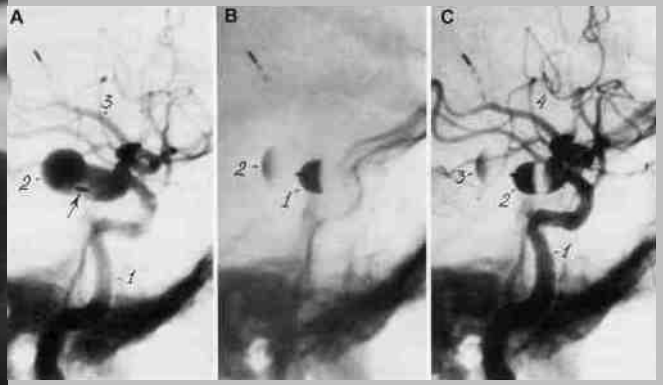
Dr Adam Rennie
Consultant Neuroradiologist
The National Hospital for Neurology and Neurosurgery
Great Ormond Street Hospital

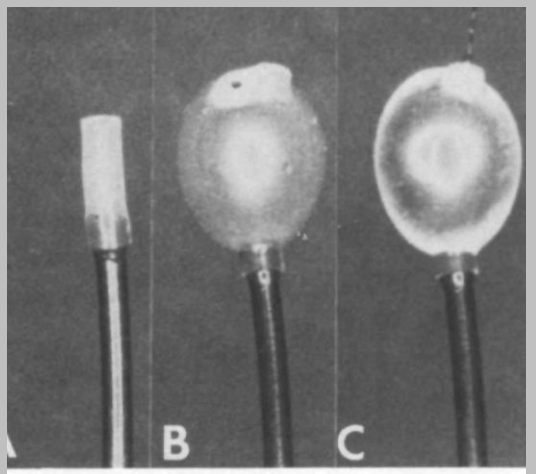
Timeline

1970s

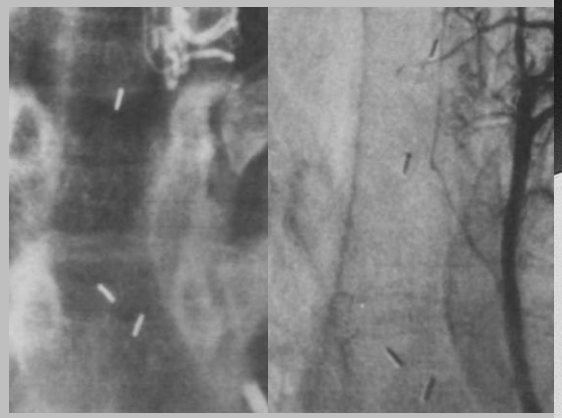


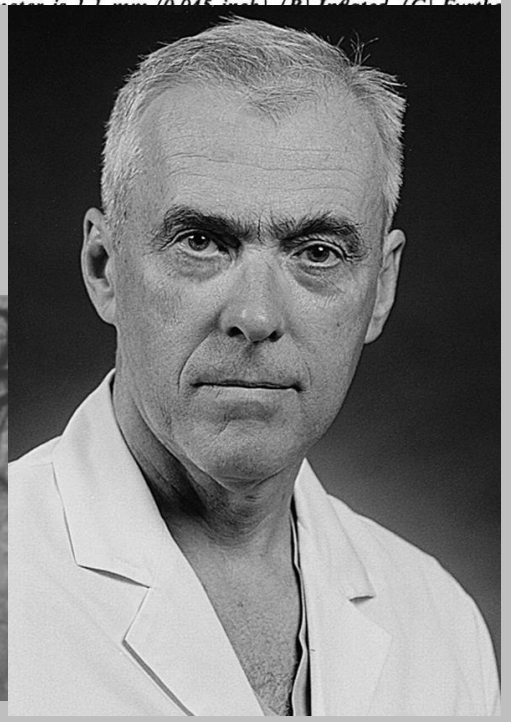
1970





GURE 2. *Balloon and silicone microcatheter (4×*
agnification). (A) Uninflated. The black catheter measure
86 mm (0.034 inch) in diameter. Uninflated balloo





Catheter Development

opacified above the level of the fistula because of the shunt. The balloon catheter was introduced through the carotid catheter, guided under fluoroscopy through the fistula, into the jugular vein, inflated and released

1975 Detachable latex balloon, CCF and giant cavernous aneurysms
Stiff. Cavernous segment only

A detachable balloon for therapeutic transcatheter occlusions
Hieshima GB, Grinnell VS, Mehringer CM

1981 2F soft polyethylene catheter with a detachable silastic balloon

But high stroke and death rates……

More precise and controllable techniques needed…..

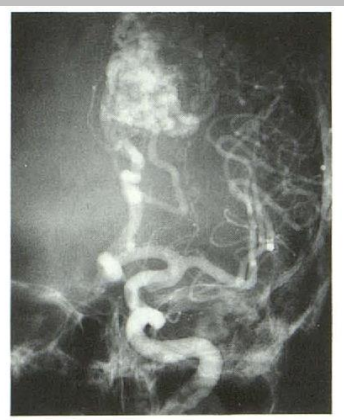
1980s

Mid 1980s
Microcatheter Development

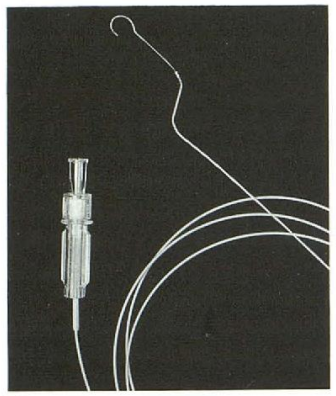
- Target Therapeutics

- Proximal polyethylene portion with softer distal section
- The Tracker

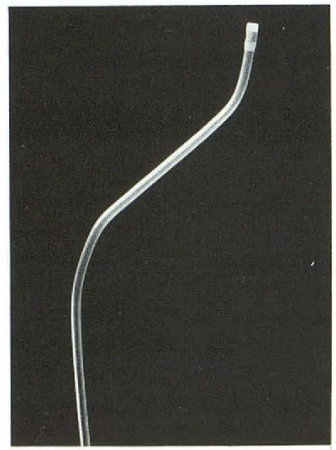
- Microguidewire with deformable tip



A



B

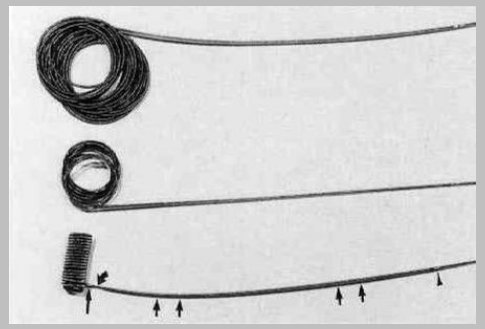


C

Late 1980s
Detachable Coils

1988 - Hilal
- Short pushable stiff coils
- Non retrievable (!)

1989 – Guglielmi
- Soft, retrievable
- Platinum GDC coil
- Electrolytic detachment



1990 - First aneurysm GDC coiled

neck and in four of 26 wide-necked aneurysms. A 70% to 98% thrombosis of the aneurysm was acl
22 of 26 aneurysms with a wide neck and in three of 16 small-necked aneurysms. One aneurysm c
be treated due to a technical complication. Two cases required postprocedural surgical clipping of a
aneurysm.

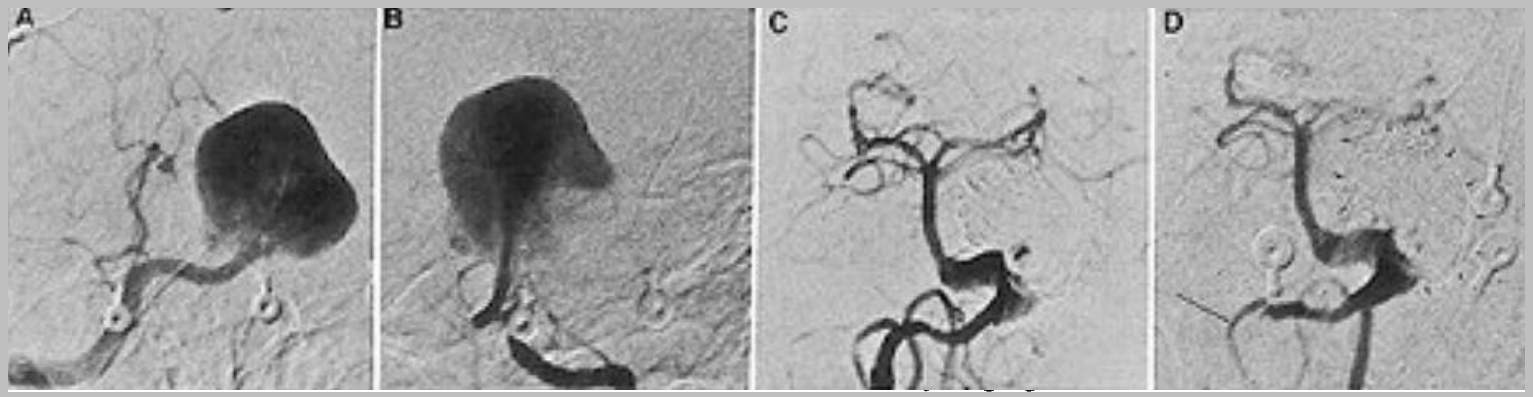
One patient (originally in Hunt and Hess Grade V) experienced procedural rupture of the a
requiring an emergency parent artery occlusion. He eventually died 5 days later. Another patient (orig
Grade IV) had coil migration and posterior cerebral artery territory ischemia. A third patient dev
permanent neurological deficit (hemianopsia) after complete occlusion of a wide-necked basilar bi
aneurysm. One patient, harboring an inoperable giant basilar bifurcation aneurysm, died from a
bleeding 18 months after partial occlusion.

Overall morbidity and mortality rates related to treatment were 4.8% (two cases) and 2.4% (os
respectively (2.6% and 0% if considering only patients in Hunt and Hess Grades I, II, and III).

It is suggested that this technique is a viable alternative in the management of patients with poster

ing detachable platinum coils
been developed [1,2] To date

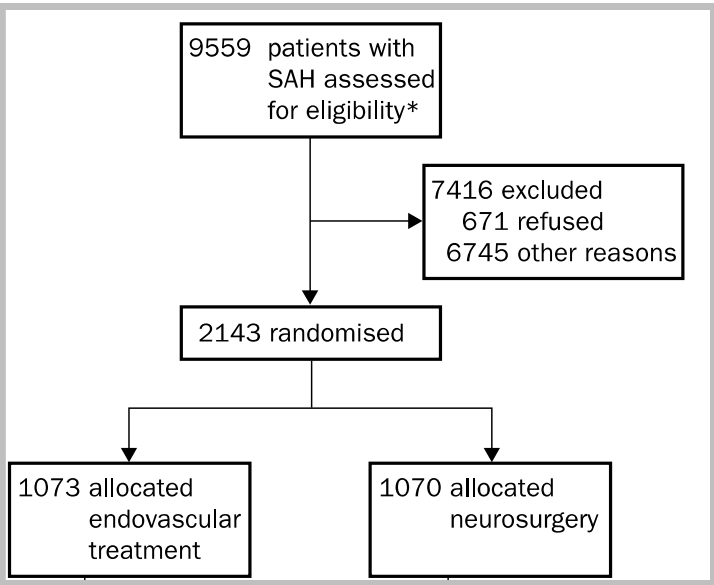
- 42 patients with posterior circulation aneurysms (part of 120 patient cohort)
- Death in 2
- Stroke with permanent morbidity in 1



1990s

THE LANCET

International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial



1994 pilot phase
1997 full study
2002 Lancet paper

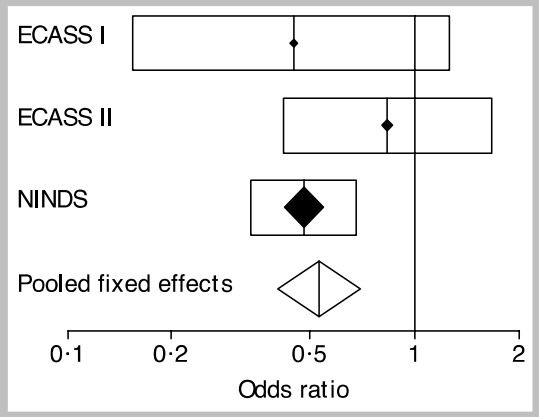
23.7% endovasc pt dead or dependent at 1 yr
30.6% clipped pt dead or dependent at 1 yr

Difference in outcome has persisted over 18 yr follow up

Endovascular Treatment of Stroke

1983 Zeumer et al Basilar thrombolysis via microcatheter

1995 ECASS I and 1998 ECASS II
1995 NINDS
Alteplase up to 3 hours
Reduction in odds of unfavourable outcome



Odds ratios (with 95% CIs) and fixed-effects pooled odds ratio describing the relative reduction in the odds of an unfavourable outcome with alteplase given within 3 h of onset of stroke

Longer time windows ineffective

Drive to extend 3 hour window and improve low recanalisation rates for large vessel occlusion

1998 Prolyse in Acute Cerebral Thromboembolism (PROACT-I)

Aim: Safety and efficacy of IA proUK up to 6 hrs

IA saline as control arm

40 randomised (26 proUK, 14 control)

More MCA recanalization with proUK (57% vs 14%)

More sICH (15% vs 7%)

Ended early as IV tPA approved by FDA (up to 3 hrs)

1999 PROACT-II

54 USA centres, 180 patients randomised
Acute MCA occlusion <6hrs

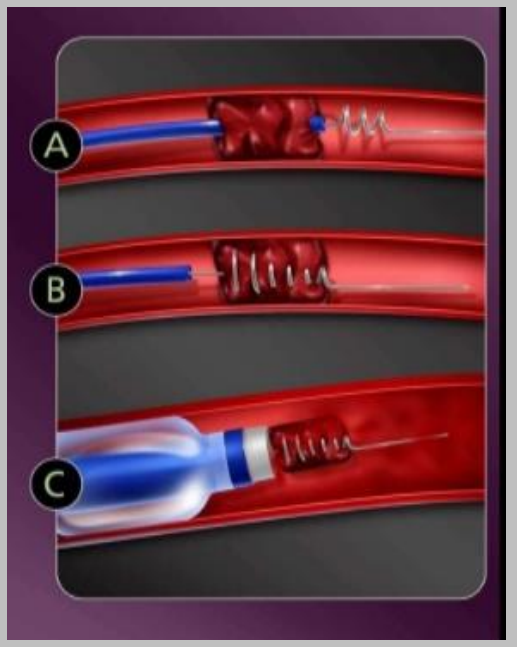
IA proUK + heparin 121 vs. heparin only 59
No mechanical manipulation
mRS 0-2 40% in proUK group
mRS 0-2 25% in IV heparin group

sICH
10% of proUK
2% heparin (nnt to harm 12)

Results failed to persuade FDA to approve IA proUK
Poor recanalization of ICA occlusions

2000s

2005 MERCI Trial



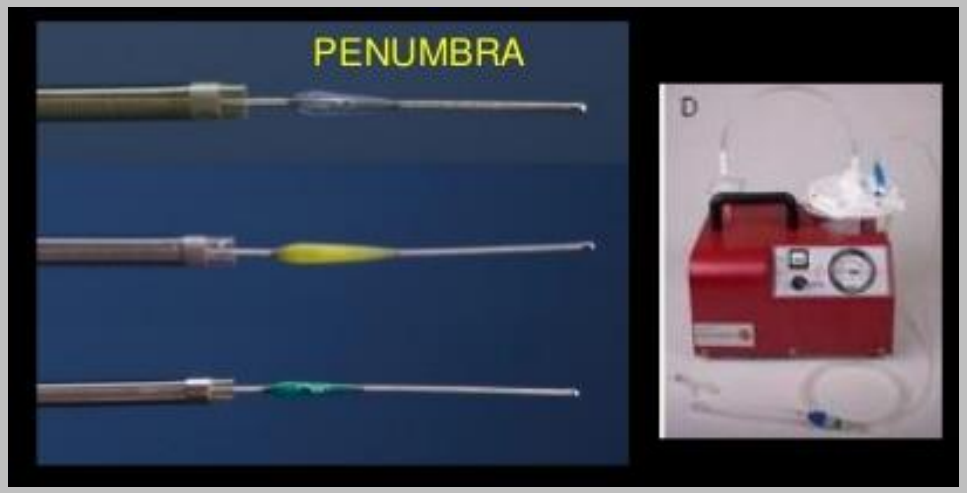
Initially used to ensnare lost coils
Enrolled 151 pt, 25 centres
Merci vs Merci and BMT
MCA stroke <8 hrs (and a few basilars!)
46% vessel recanalisation (cf 18% PROACT II)
mRS 0-2 36% in recanalised
Lower mortality, better outcome in recanalised

But…

No randomisation to medical treatment alone
sICH 11/151
Mortality overall 43% at 90 days

FDA approved embolectomy with Merci device in Aug 2004
Embolectomy reimbursed better than IV tPA

Late 2000s
Other devices….



The Penumbra Pivotal Stroke Trial

Safety and Effectiveness of a New Generation of Mechanical Devices for Clot Removal in Intracranial Large Vessel Occlusive Disease

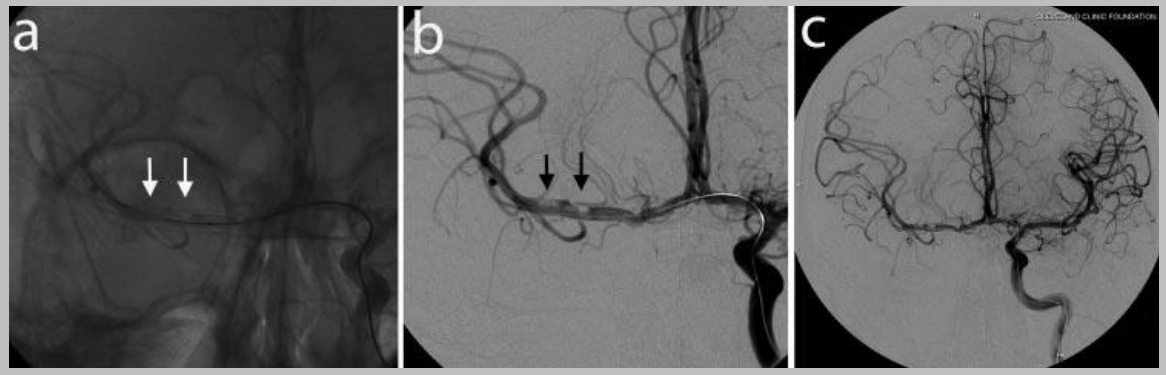
The Penumbra Pivotal Stroke Trial Investigators

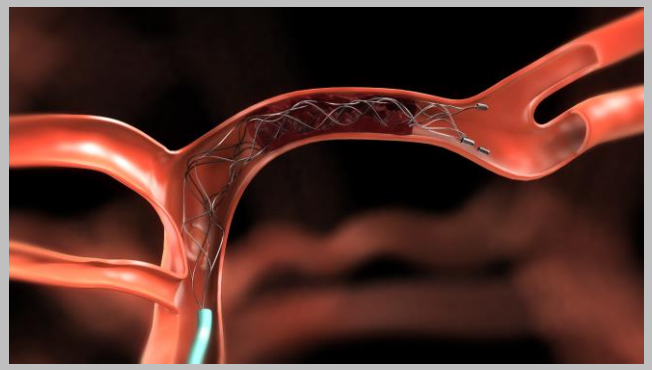
***Stroke*. 2009;40:2761-2768**

125 patients, single arm study, 81.6% recanalisation

Recanalization of an Acute Middle Cerebral Artery Occlusion Using a Self-Expanding, Reconstrainable, Intracranial Microstent as a Temporary Endovascular Bypass

Michael E. Kelly, MD; Anthony J. Furlan, MD; David Fiorella, MD, PhD 2008





2010s

2012

Solitaire flow restoration device versus the Merci Retriever in patients with acute ischaemic stroke (SWIFT): a randomised, parallel-group, non-inferiority trial

Jeffrey L Saver, Reza Jahan, Elad I Levy, Tudor G Jovin, Blaise Baxter, Raul G Nogueira, Wayne Clark, Ronald Budzik, Osama O Zaidat, for the SWIFT Trialists

	Solitaire (roll-in; n=31)	Solitaire (randomly allocated; n=58)	Merci (randomly allocated; n=55
Successful recanalisation without symptomatic intracranial haemorrhage (primary endpoint)	55% (16/29)	61% (34/56)	24% (13/54)
Angiographic efficacy endpoints			
Successful recanalisation with study device (assessed by core laboratory)	63% (17/27)	69% (37/54)	30% (16/53)
Successful recanalisation with study device (assessed at study site)	77% (24/31)	83% (45/54)	48% (26/54)
Use of rescue treatment*	23% (7/31)	21% (12/58)	44% (24/55)
Successful recanalisation at end of procedure (assessed at study site)	94% (29/31)	89% (48/54)	67% (37/55)
Clinical efficacy endpoints at 90 days			
Good neurological outcome†	63% (17/27)	58% (32/55)	33% (16/48)

Trevo versus Merci retrievers for thrombectomy revascularisation of large vessel occlusions in acute ischaemic stroke (TREVO 2): a randomised trial

Raul G Nogueira, Helmi L Lutsep, Rishi Gupta, Tudor G Jovin, Gregory W Albers, Gary A Walker, David S Liebeskind, Wade S Smith, for the TREVO 2 Trialists

	Trevo group	Merci group	Odds ratio (95% CI)	p value
Primary efficacy endpoint				
Assigned device TICI ≥2 reperfusion as per core laboratory (intra-arterial lytic equals failure)	76/88 (86%)	54/90 (60%)	4·22 (1·92–9·69)	<0·0001*; <0·0001†

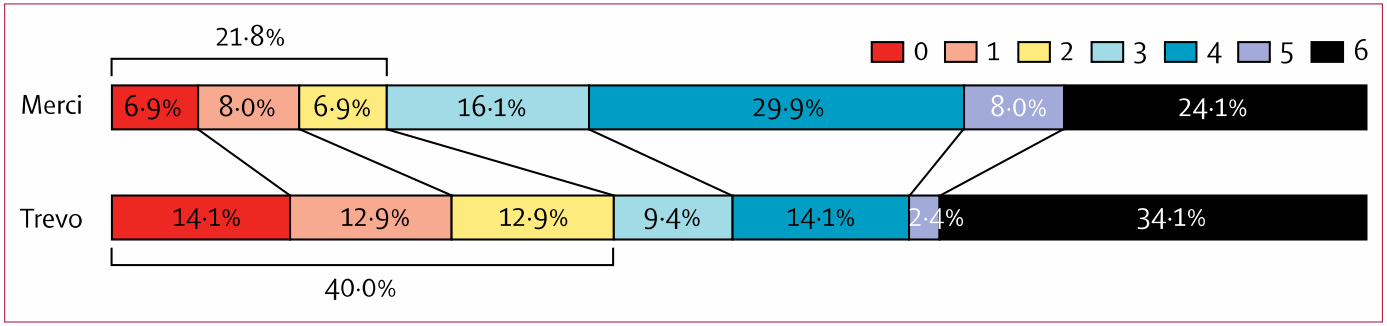
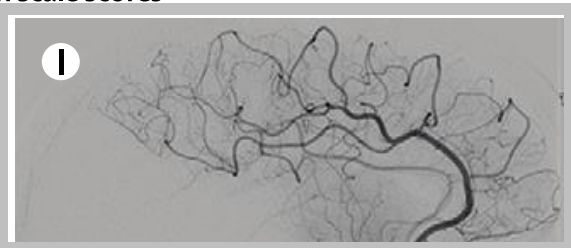


Figure 3: **90 day modified Rankin scale scores**



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MARCH 7, 2013 VOL. 368 NO. 10

Endovascular Therapy after Intravenous t-PA versus t-PA Alone for Stroke

Joseph P. Broderick, M.D., Yuko Y. Palesch, Ph.D., Andrew M. Demchuk, M.D., Sharon D. Yeatts, Ph.D., Pooja Khatri, M.D., Michael D. Hill, M.D., Edward C. Jauch, M.D., Tudor G. Jovin, M.D., Bernard Yan, M.D., Frank L. Silver, M.D., Rüdiger von Kummer, M.D., Carlos A. Molina, M.D., Bart M. Demaerschalk, M.D., Ronald Budzik, M.D., Wayne M. Clark, M.D., Osama O. Zaidat, M.D., Tim W. Malisch, M.D., Mayank Goyal, M.D., Wouter J. Schonewille, M.D., Mikael Mazighi, M.D., Ph.D., Stefan T. Engelter, M.D., Craig Anderson, M.D., Ph.D., Judith Spilker, R.N., B.S.N., Janice Carrozzella, R.N., B.A., R.T.(R.), Karla J. Ryckborst, R.N., B.N., L. Scott Janis, Ph.D., Renée H. Martin, Ph.D., Lydia D. Foster, M.S., and Thomas A. Tomsick, M.D., for the Interventional Management of Stroke (IMS) III Investigators

IMS III

SYNTHESIS

Endovascular Treatment for Acute Ischemic Stroke

Alfonso Ciccone, M.D., Luca Valvassori, M.D., Michele Nichelatti, Ph.D., Annalisa Sgoifo, Psy.D., Michela Ponzio, Ph.D., Roberto Sterzi, M.D., and Edoardo Boccardi, M.D., for the SYNTHESIS Expansion Investigators*

A Trial of Imaging Selection and Endovascular Treatment for Ischemic Stroke

Chelsea S. Kidwell, M.D., Reza Jahan, M.D., Jeffrey Gornbein, Dr.P.H., Jeffry R. Alger, Ph.D., Val Nenov, Ph.D., Zahra Ajani, M.D., Lei Feng, M.D., Ph.D., Brett C. Meyer, M.D., Scott Olson, M.D., Lee H. Schwamm, M.D., Albert J. Yoo, M.D., Randolph S. Marshall, M.D., Philip M. Meyers, M.D., Dileep R. Yavagal, M.D., Max Wintermark, M.D., Judy Guzy, R.N., Sidney Starkman, M.D., and Jeffrey L. Saver, M.D., for the MR RESCUE Investigators*

MR RESCUE

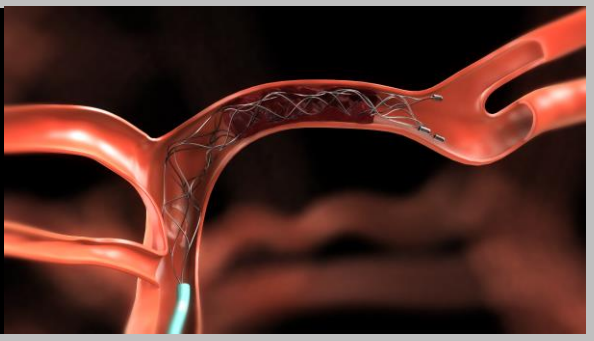
Poor recruitment
Slow treatments
Poor recanalisation
Little vascular imaging
NIHSS as selector not CTA

The NEW ENGLAND JOURNAL of MEDICINE

2015
Re-birth of IA stroke treatment

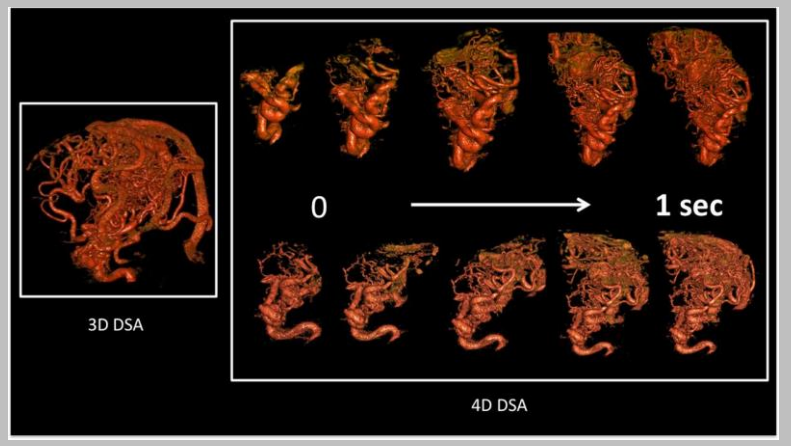
- EXTEND-IA
- SWIFT PRIME
- MR CLEAN
- ESCAPE
- REVASCAT

- More imaging pre
- Faster treatment
- Better devices (aspiration & stent)
- Better recanalisation

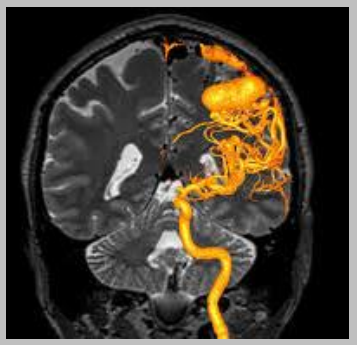



2019

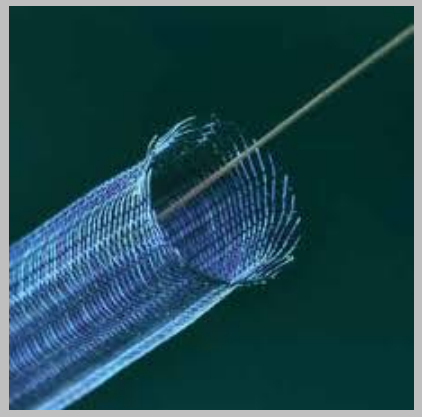
New Devices

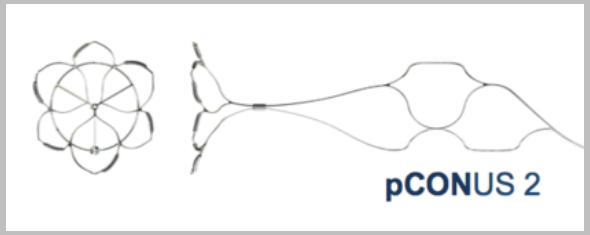


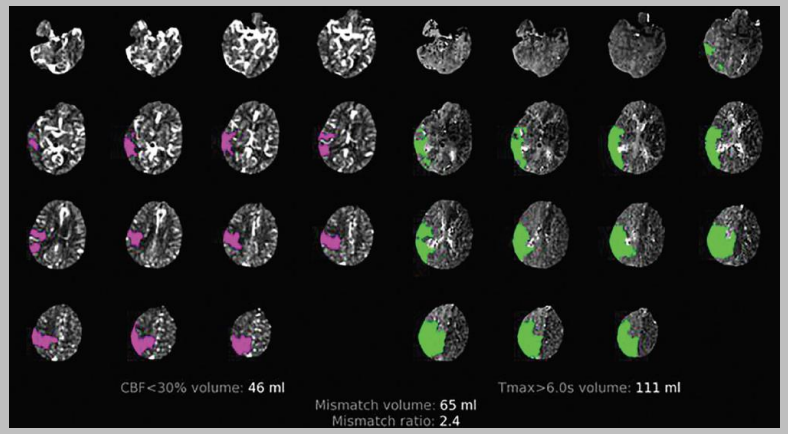
- pCONUS 2
- Silk Vista Baby
- Small dual lumen balloons
  - E.g. sceptre 2 mm



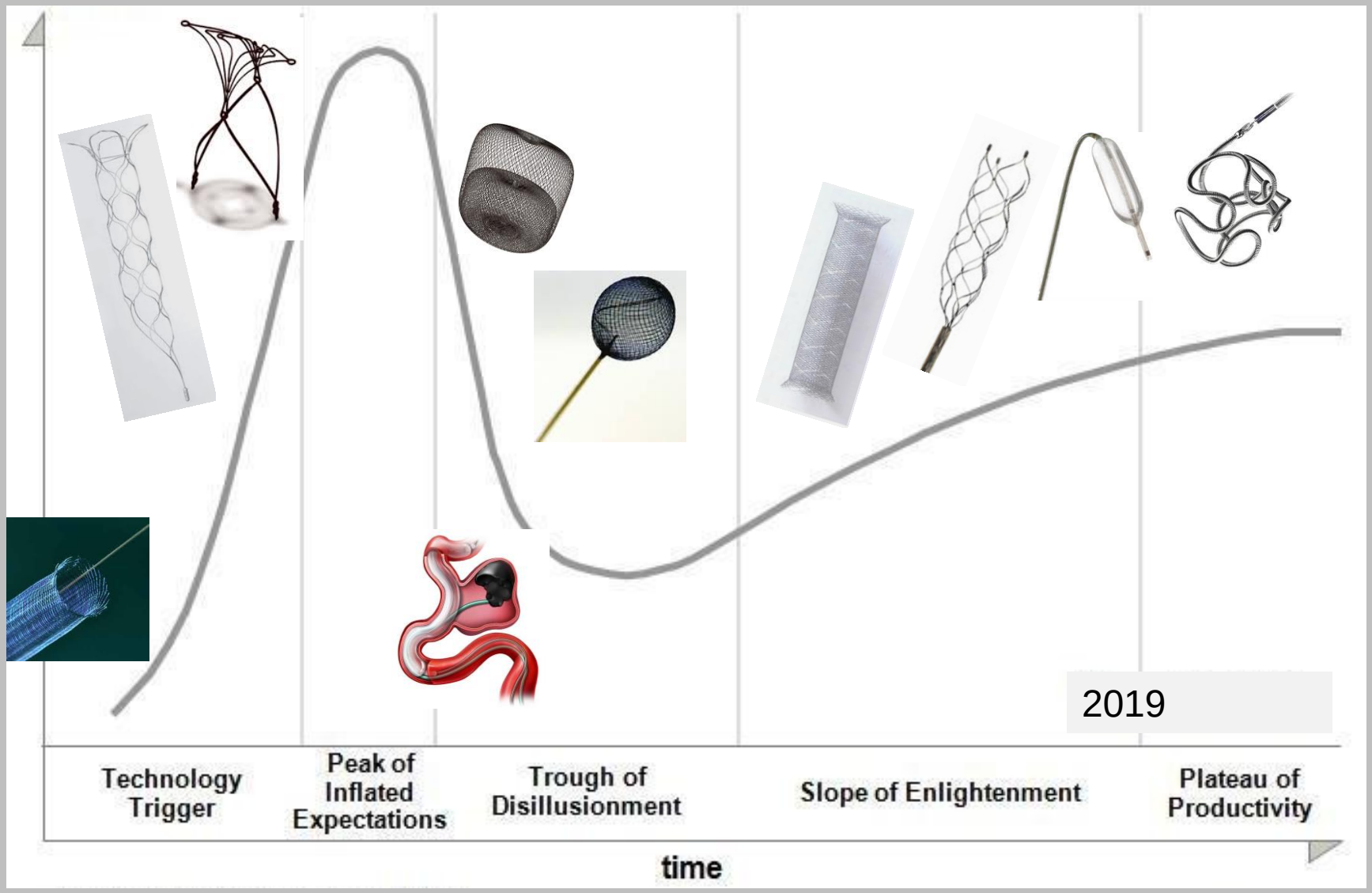
- Imaging
  - 4D DSA
  - Fusion software
  - Rapid perfusion imaging for stroke







Aneurysm therapies




The Future

The Future of Stroke

- Fast accurate reliable patient selection
- Refinement in technique and devices

- Tenable provision of stroke services
  - Locally
  - Nationally