Early Clinical Experience with 5 MAX ACE-A New Clot Extraction Device

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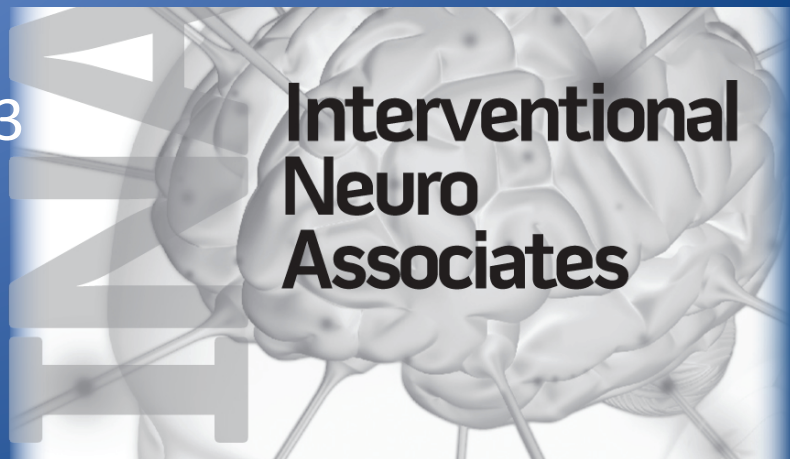
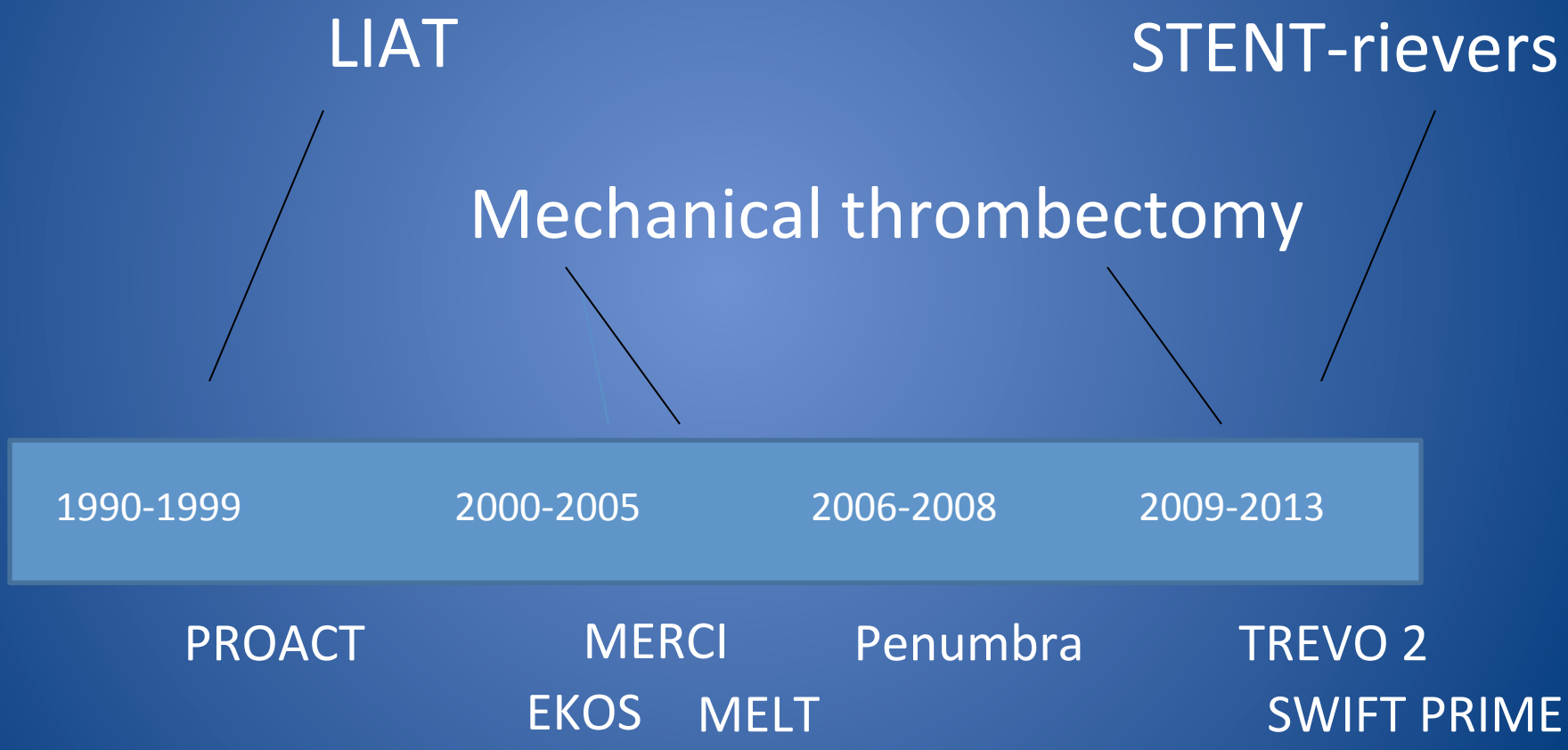


Disclosures

- Sponsored breakfast symposium
- No independent fees
- Data independently reviewed by presenter (not by sponsor)

Timeline of Interventional Stroke Treatment



RECAN RATES WITH VARIOUS DEVICES

- LIAT
- Merci
- Penumbra
- Trevo
- Solitaire FR

- Pro-UK ~60%
- Merci registries~69-70%
- Pen. pivotal trial~82%
- Trevo~78% (TICI 2B)
- SWIFT~61%

Recanalization in IMS 3

BY OCCLUSION SITE

- ICA 38%
- M1 44%
- M2 44%
- Mult M2 23%

BY DEVICE

- MicroSonic SV+IA 71%
- Merci 73%
- Penumbra 85%
- Solitaire FR 75%

Problems with early generation devices

- Device fractures
- Downstream emboli
- poor navigability of guide catheters and/or microcatheters
  - Bulky balloon guide with Merci
  - Stiff 1st generation Penumbra catheters

- Intravenous TPA 1995
- Intra-arterial 1999
- Merci Retriever 2004
- Penumbra Aspiration 2008
- Solitaire 2012
- Trevo 2012
- Penumbra 3D

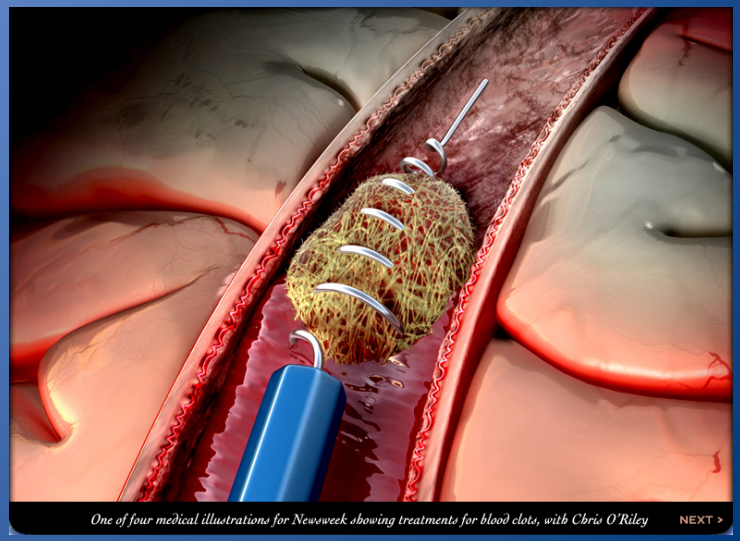
Advances in Stroke Therapy

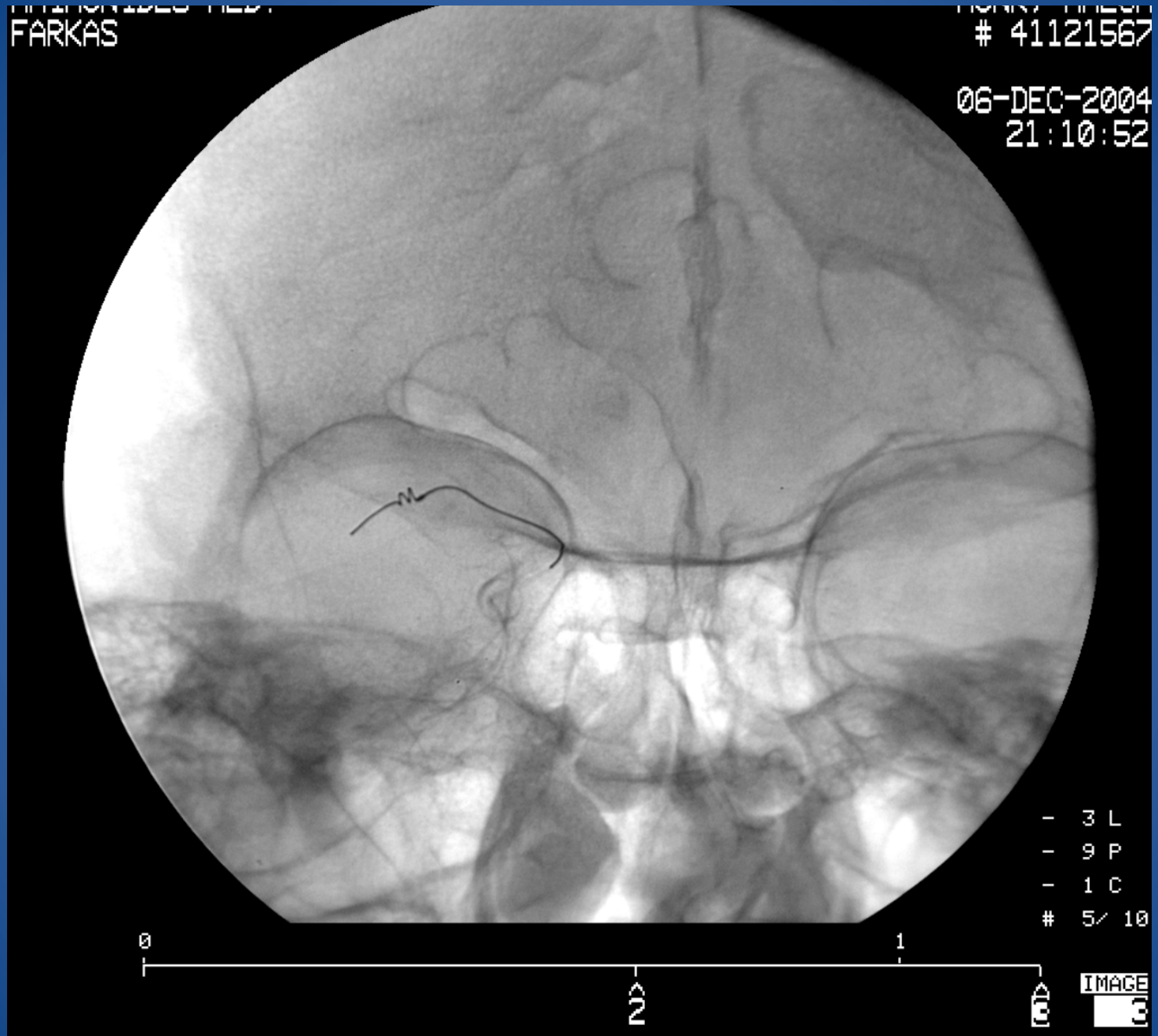
Balloon

- Myocardial infarction,
  - Angioplasty in part achieves recanalization in coronary vessels through controlled cracking and dissection of underlying atherosclerotic lesions on which supervening thrombus has developed.
- Brain different.
  - Occlusions are often embolic in origin,
  - Vessels are often normal without underlying Calcfiied atheroma.
  - Spongy cerebral clots often bounce back into the occlusive position after balloon angioplasty.

Clot Retrievers

- Hope to reduce or eliminate the need for thrombolytics
- Reduce hemorrhage rates so treatment can be extended
- Faster recanalization than thrombolytics

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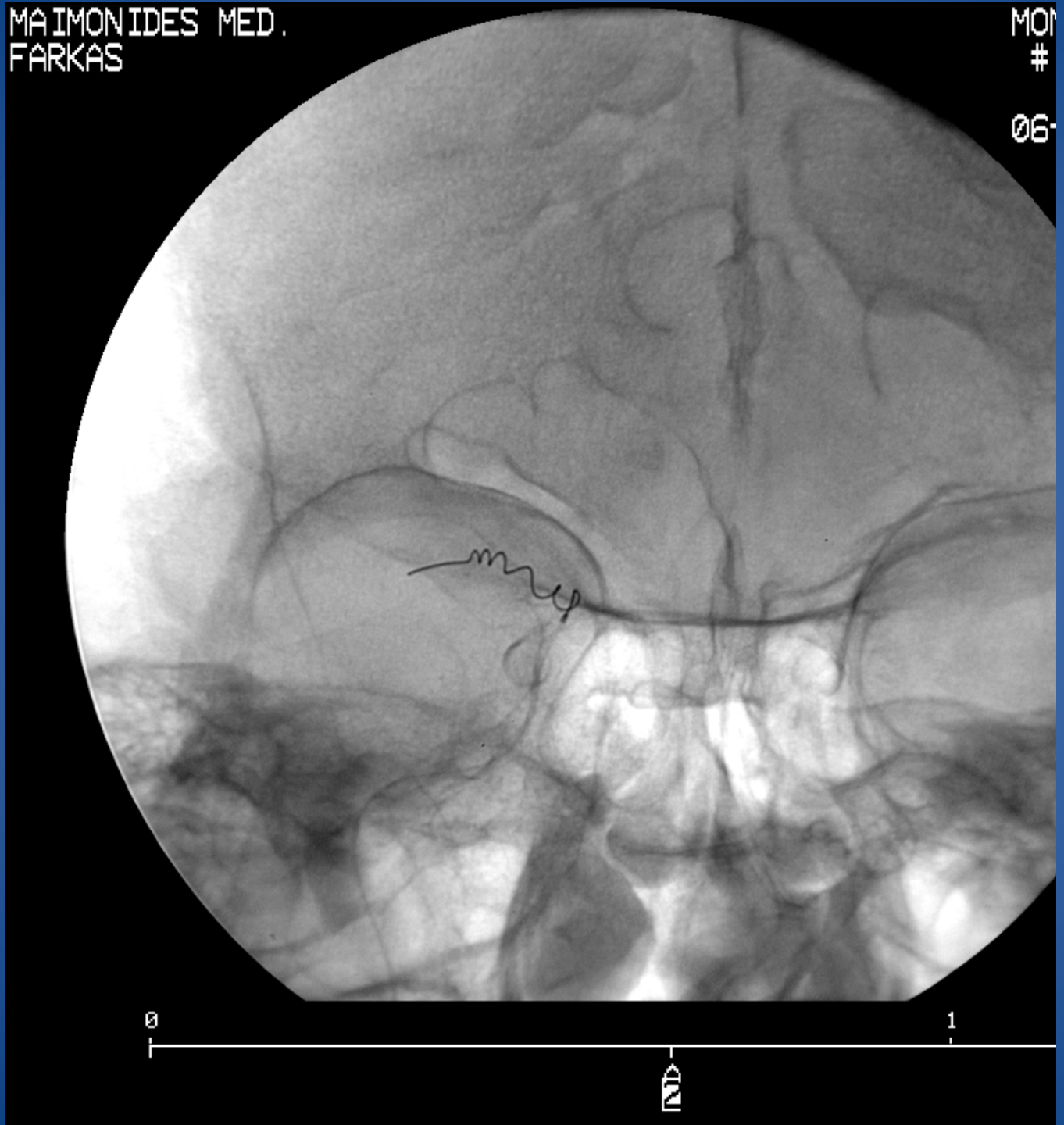
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Aspiration System

Reperfusion
Catheter 041

Matched 041
Separator™

Matched 032
Separator

Reperfusion

Matched 026
Separator

Catheter 026

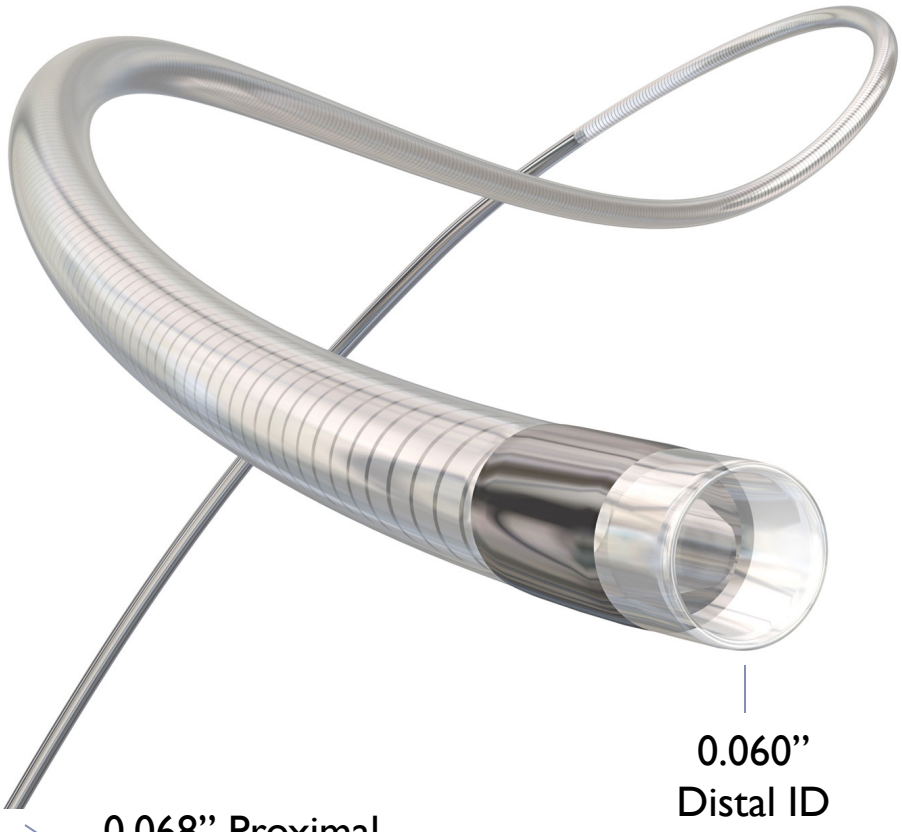
Mean time to recan

- Check data from all existing trials

Evolution of Penumbra catheter systems

- .026, .032, .041 2008
- .054 2010
- MAX system 2011
- MAX ACE 2013

ACE Design



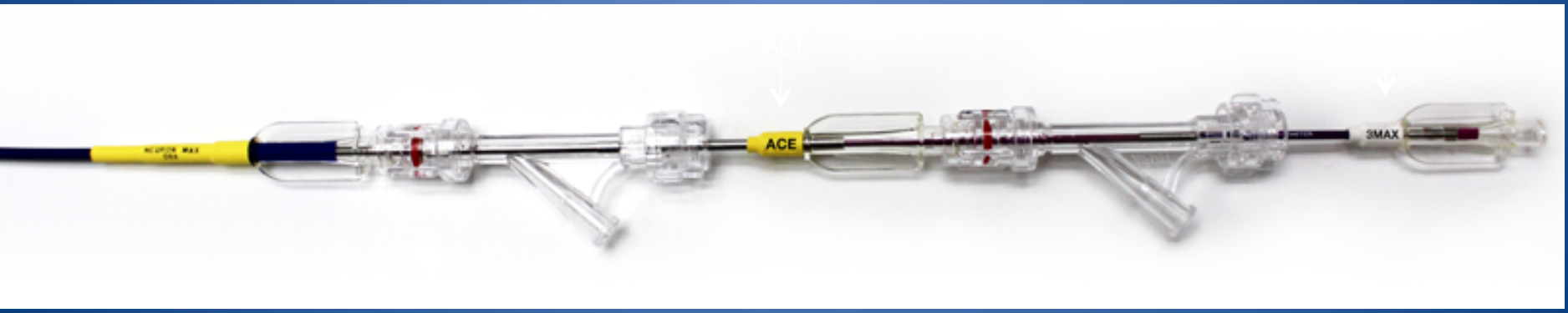
- 0.060”/0.068” Tapered Lumen
  - Highest suction force to capture and extract clot
- 12 Transition Zones
  - Effective force transmission
  - Kink resistance

Lutheran technique

- Coaxial system,
- 6 Fr sheath, 5 Fr diag. exchange for Neuron Max 088 (difficulty directly advancing neuron max through the access site over select cath)
- 5 Max ACE, Velocity, 14 wire
- Can fit 5 Max Sep. or Sep 3D through it

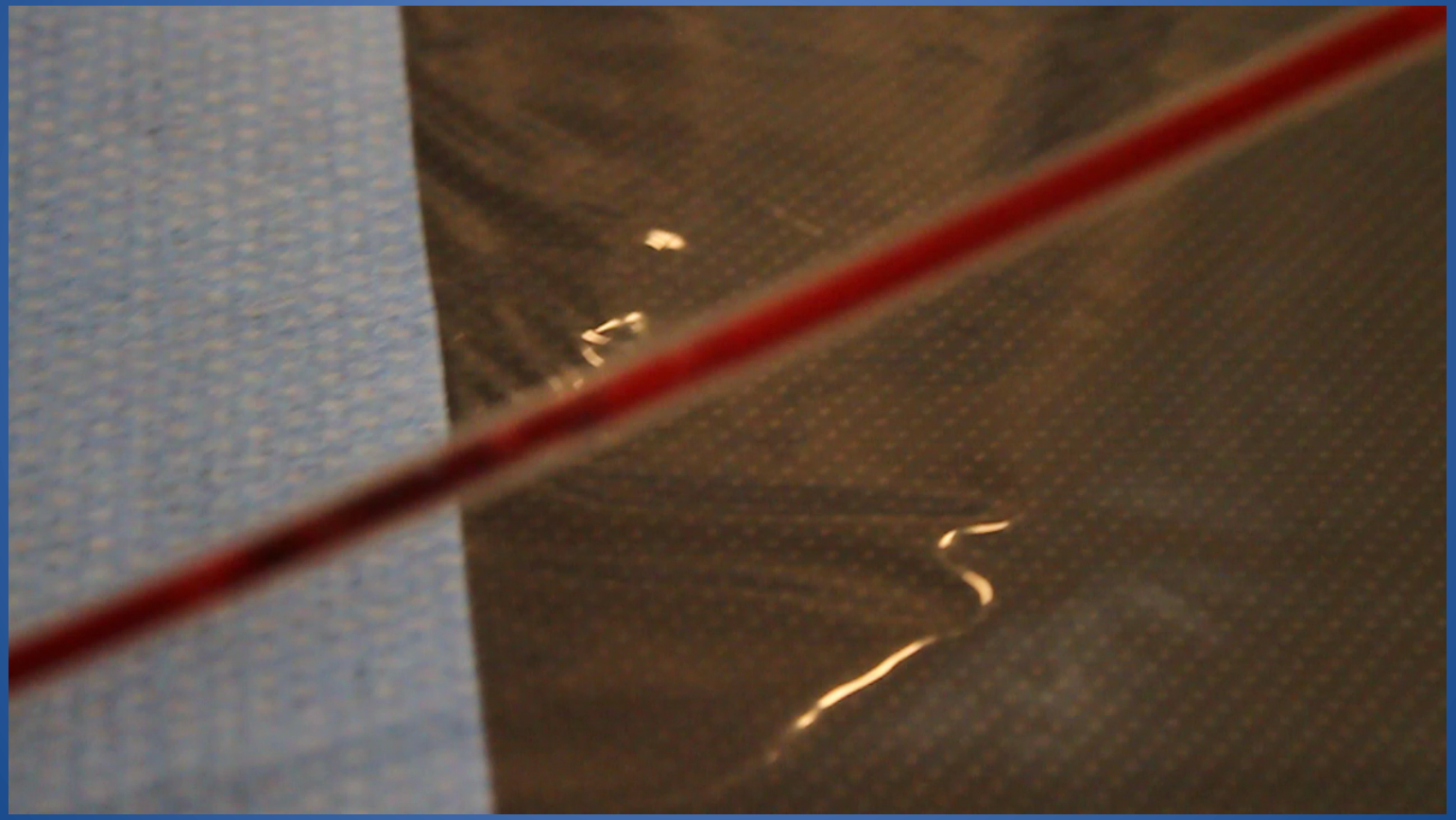
Access Setup

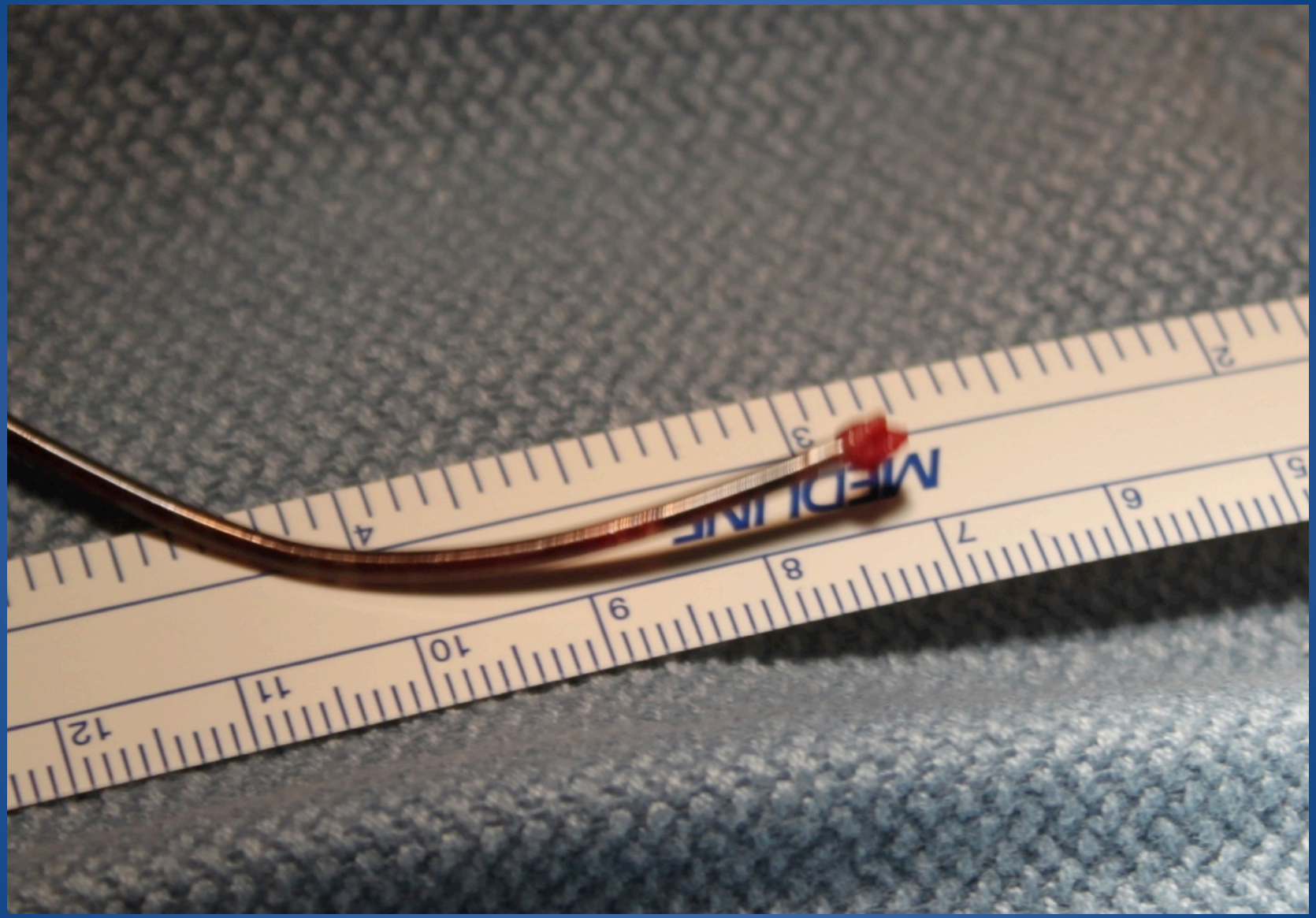
- Track ACE over Velocity or 3MAX
  - Velocity: Low Profile, 160 cm, compatible with stent retrievers
  - 3MAX : Best fitting catheter



Hoover Maneuver

Thrombus *in toto* aspirated through pump tubing

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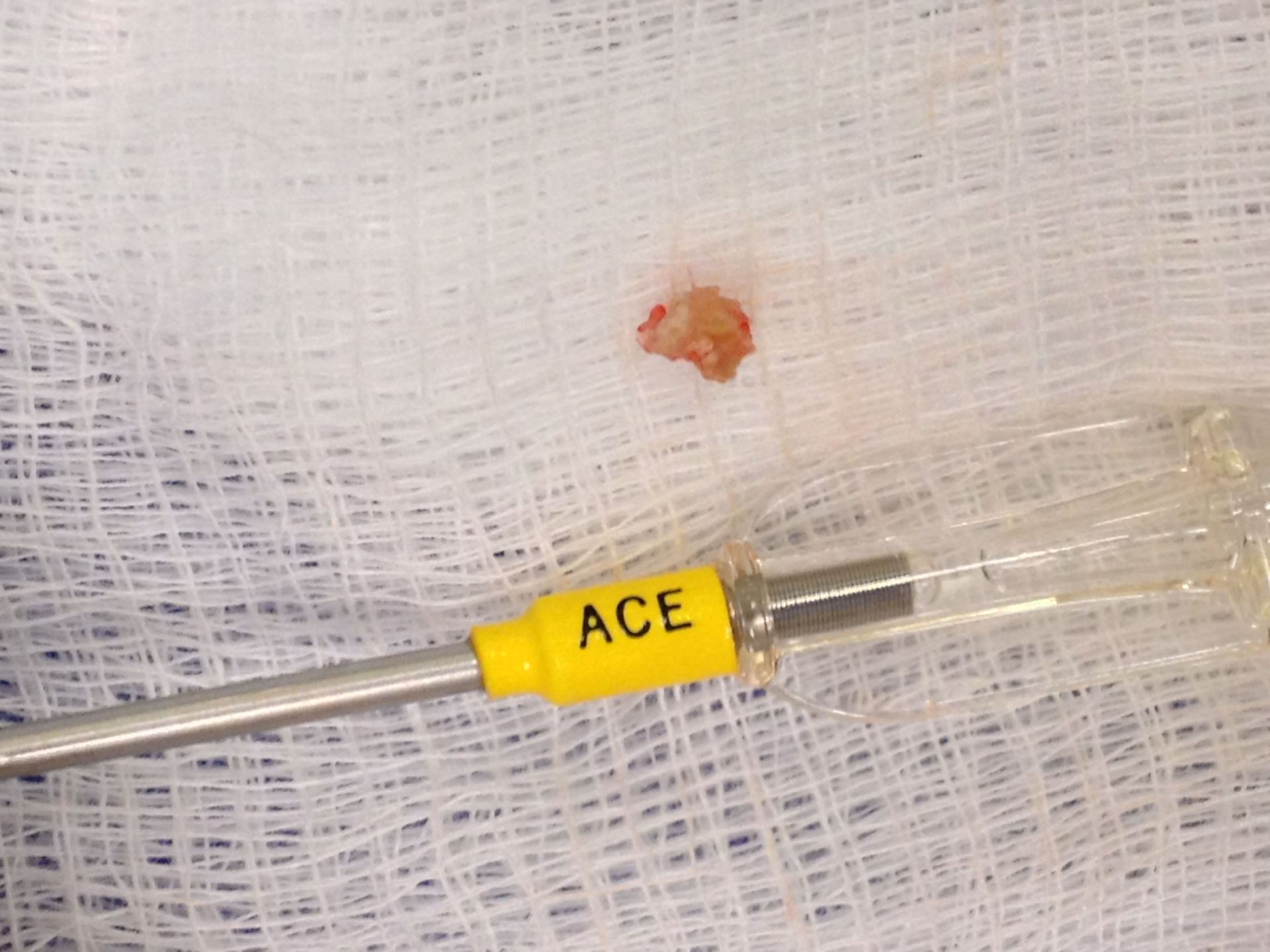

ACE

INA 5 MAX ACE comparative analsysis

- Consecutive analaysis of acute stroke patients divided in two groups: ACE (5 MAX ACE first device used) vs NON-ACE (other device used first)
- Demographics, clinical, radiographical, procedural data collected and compared using *t*-test/chi square analysis

Baseline Data

GROUP	AGE (years)	GENDER	INITIAL NIHSSS	PRE-Tx TICI	VESSEL
ACE (n=15)	75+/-13	M=7, F=8	15+/-7	0=13 1=1 2B=1	ICA=2 M1=9 M2-1 BA=3
NON ACE (n=23)	76+/-12	M=4, F=8*	19+/-7**	0=19 1=3 (missing=1)	ICA=4 M1=10 M2=7 BA=2
Initial device used for NON-ACE* **					
3 MAX	4 MAX	5 MAX	Sep 3D	Trevo	Solitaire
2	1	4	1	2	1

* missing data, n=11 ** missing data , n=5

*** missing data , n=14

Procedural Outcomes

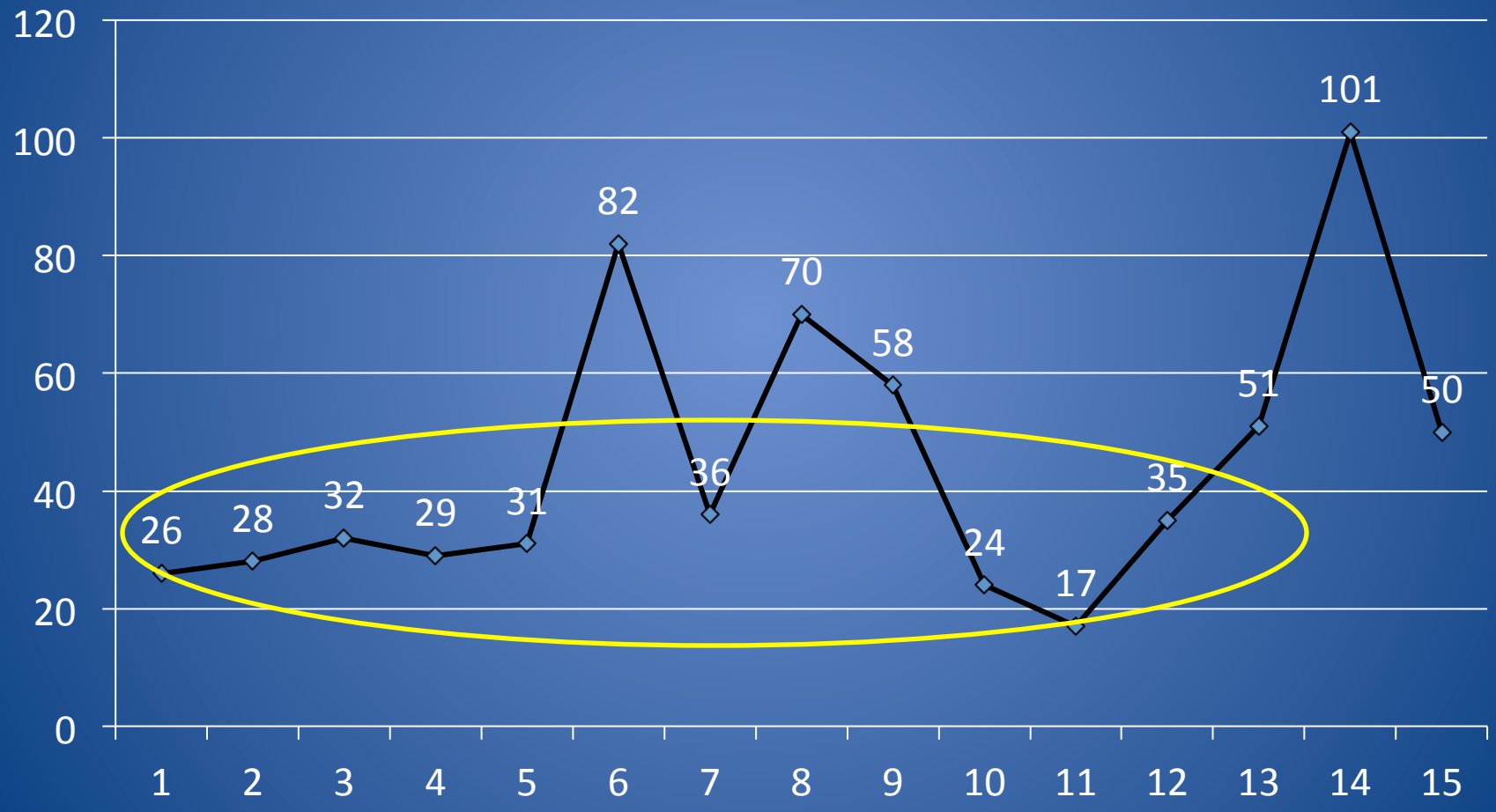
GROUP	Mean time to recan*	Post-treatment TICI**
ACE	**45+/- 24 min**	TICI 2A, n=1 TICI 2B, n=4 **TICI 3, n=10**
NON-ACE***	**105+/-55 min**	TICI 0, n=1 TICI 1, n=2 TICI 2A, n=3 **TICI 2B, n=6** TICI 3=5

* p=0.007

** p=0.031

*** missing data, 6

Mean time (minutes) to recanalization from groin puncture



Time Outliers

Pt	Recan time (minutes)	Age (years)	Lesion location
6*	82	60	BA
8*	70	70	ICA (IC+EC)
9	58	82	M1
13	51	92	M1
14**	101	91	M1/carotid stenosis
15***	50	85	BA

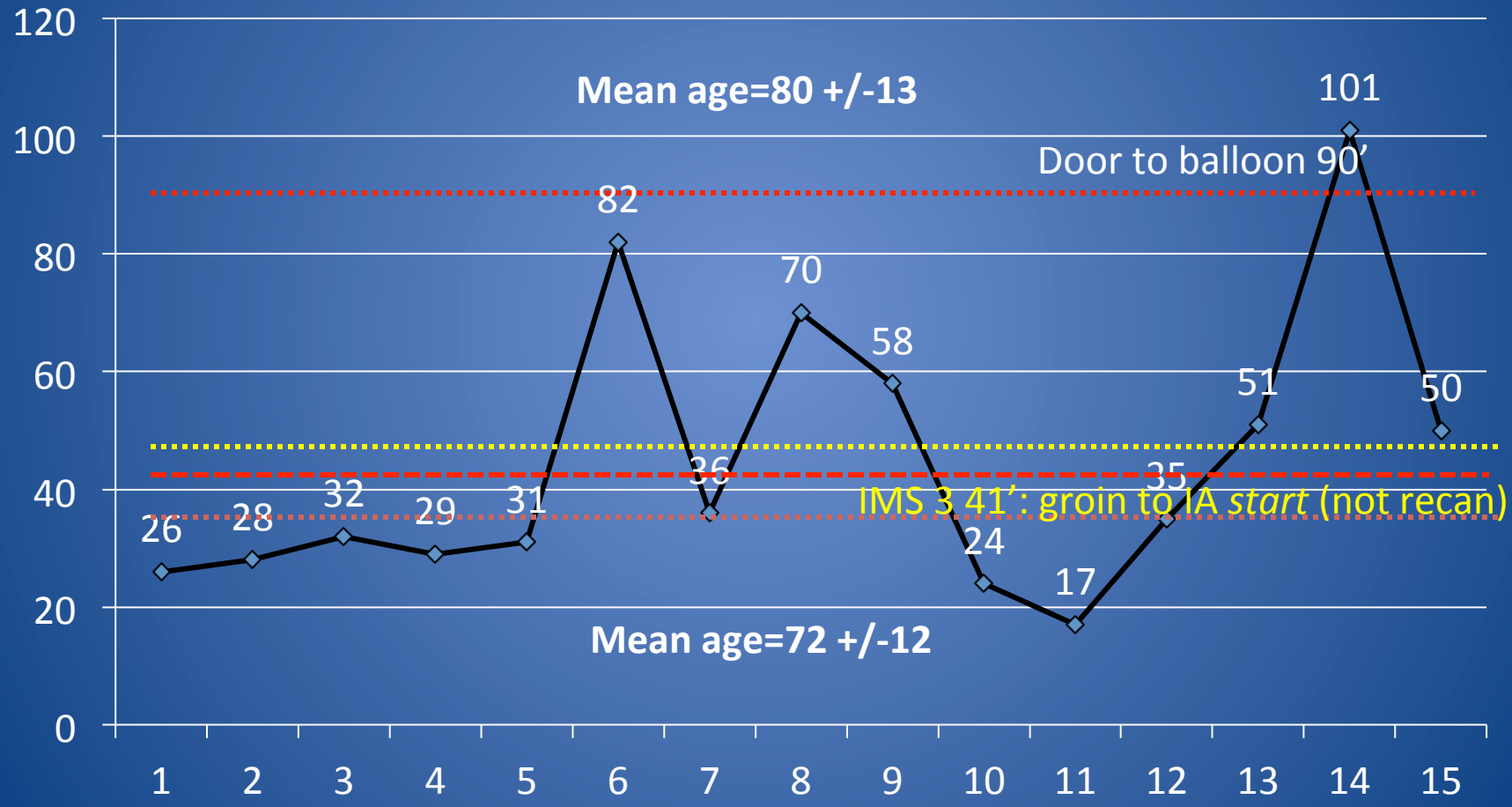
* Need for PTA/stent adjunctive therapy, n=2

** Device problem (crimped catheter), n=1

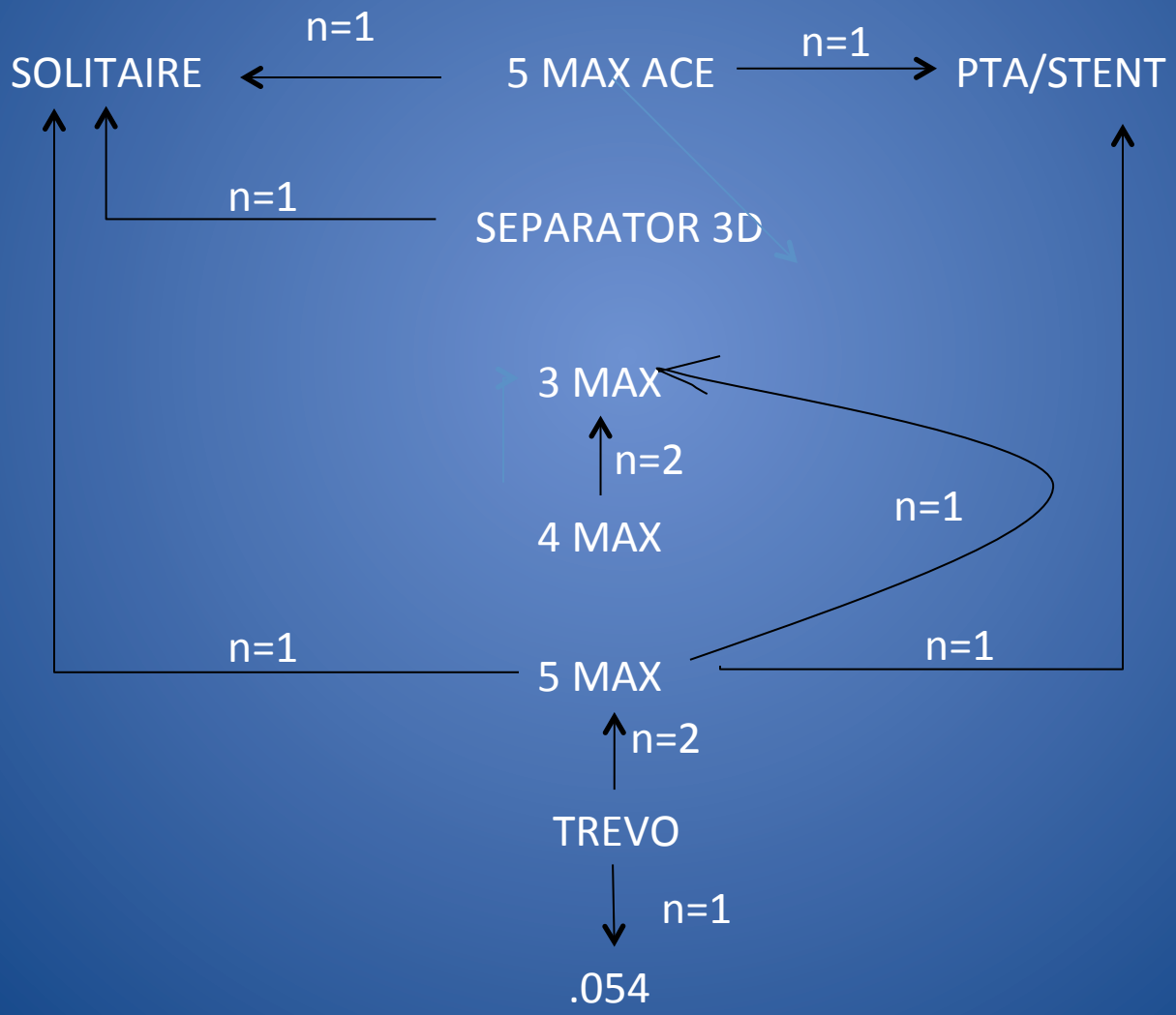
*** Additional diagnostic angiography prior to intervention of target vessel, n=1

Tortuous/other factors, n=3

Mean time (minutes) to recanalization from groin puncture



Need for rescue device



Clinical Outcomes

GROUP	D/C NIHSSS*	ICH**	D/C mRS	30-90 DAY mRS
ACE	**4+/-6**	**0**	1, n=3 2, n=1 3, n=1 4, n=5 6, n=1 (missing, n=4)	0, n=2 1, n=1 4, n=2 5, n=1 6, n=2 (missing, n=7)
NON-ACE	**10 +/-8**	**4 (17%)**	0, n=1 1, n=1 4, n=3 5, n=2 6, n=5	3, n=2 4, n=1 6, n=1 (missing 19)

* p=0.017 for change in NIHSSS (-11+/-5 points vs -8 +/-10 points

** p=0.035

ACE group individual outcomes

PATIENT	DISCHARGE mRS	30-90 DAY mRS
1	2	0
2	4	4
3	3	
4	1	
5	1	0
6	4	
7	4	
8		
9	4	6
10	4	5
11		4
12	1	
13	6	6
14		
15	(recent)	

Mortality in ACE patients

- Concommitant aortic stenosis, 1 withdrawal of care
- Death at 3 months due to medical condition

Conclusions

- 5 MAX ACE achieves efficient recanalization (in shorter times and higher degrees of reperfusion)
- Atraumatic
- Continued improvements in all aspects of stroke patient triage and interventional procedure may further shorten times to recanalization
- Other factors minimizing stroke related morbidity must still be addressed