

The Penumbra ACE™ catheter is an efficient, safe, and cost-effective mechanical thrombectomy device for large vessel occlusions (LVO) in acute stroke

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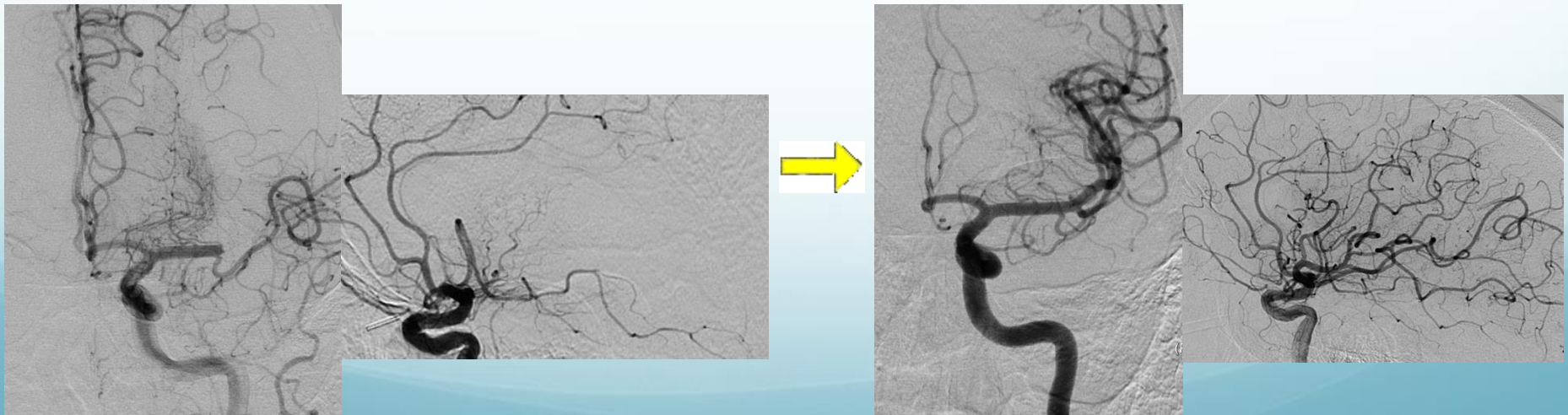
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Presenter Disclosure

- Dr. Gabriel A. Vidal
 - ✓ *Penumbra, Inc.*
 - Consulting Relationship: Speakers bureau

The Ultimate Thrombectomy Device?

- Opens artery quickly
- Removes thrombus intact and completely
- Safe and simple procedure
- Cost effective



Need for Speed

Final Multivariable Model Risk Ratios

	Risk Ratio	95% CI	p-value
Time to Reperfusion (every 30 minutes)	0.90	0.82-0.99	0.02

Every 30 minute delay in reperfusion is associated with a 10% relative reduction in probability of good clinical outcome (mRS 0-2).



Need for Quality Revascularization



Revascularization Predicts
Good Outcome
For ICA, M1 Occlusion

	TICI=0	TICI=1	TICI=2a	TICI=2b	TICI=3	
	n= 32	n= 16	n= 67	n= 80	n= 5	
% 90 Day mRS 0-2	3.1%	12.5%	19.4%	46.3%	80%	
	6.3%		35.5%			p < .0001
	13.9%			48.2%		p < .0001

Need to remove clot intact

Significance of New Emboli?



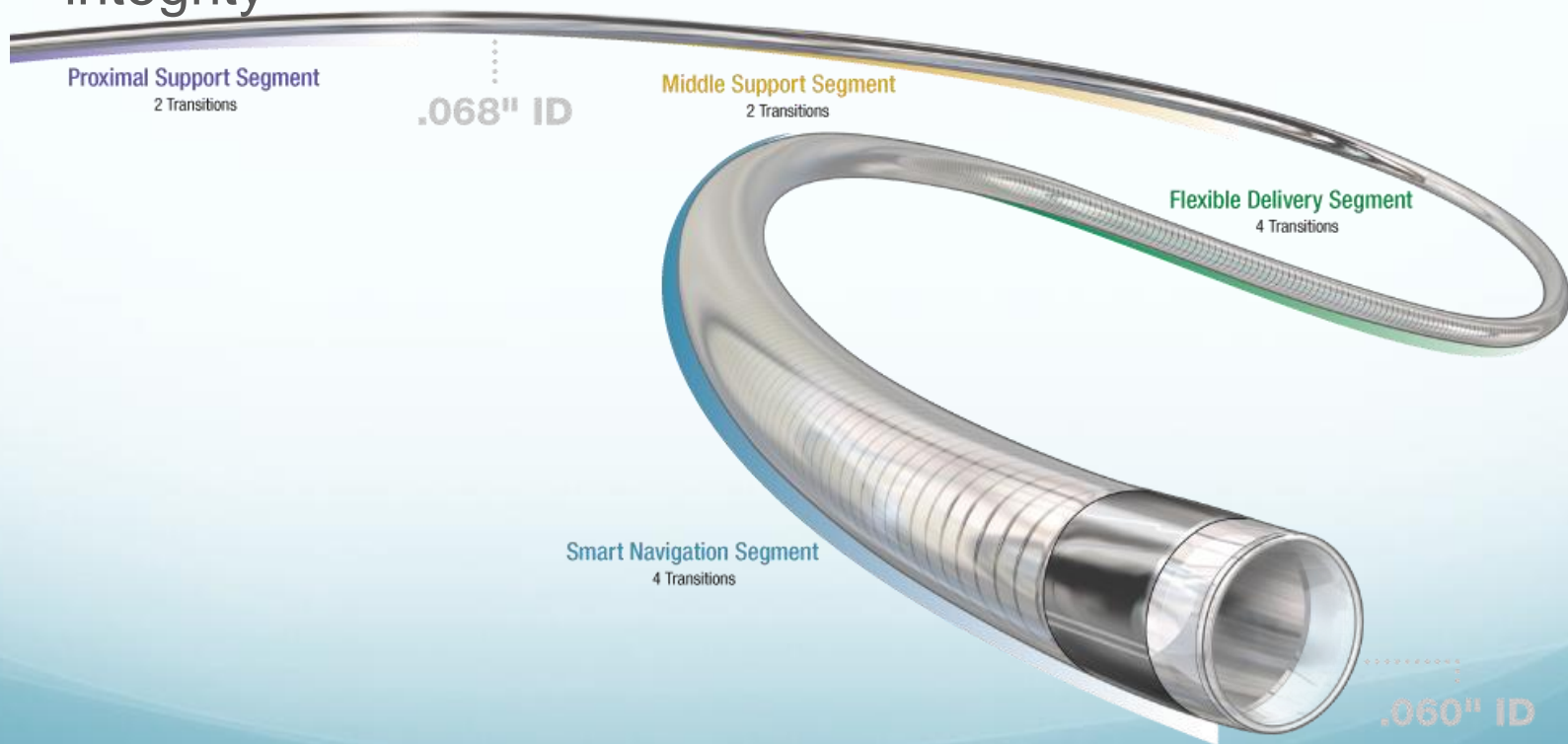
90-day mRS Outcome by Presence of New Emboli
(ICA, M1 Occlusion)

New Emboli (Core Lab)	N	mRS \leq 2	
		N	(%)
No	172	52	30.23%
Yes	28	5	17.86%

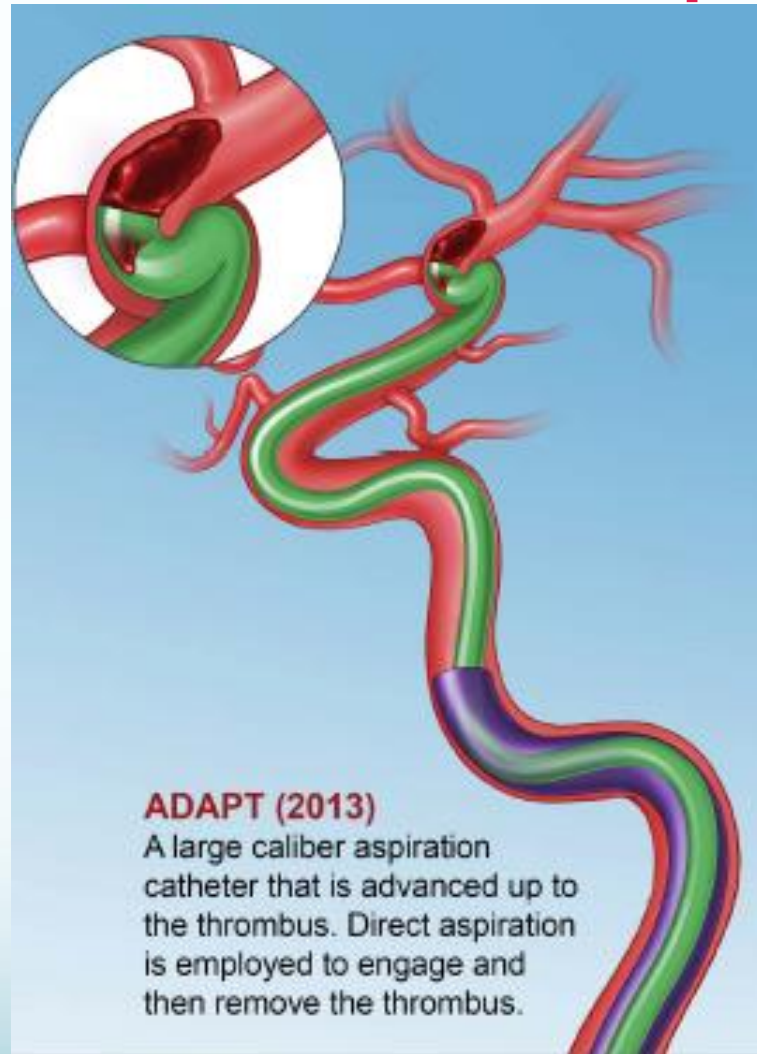
*12%
difference*

ACE™ DESIGN

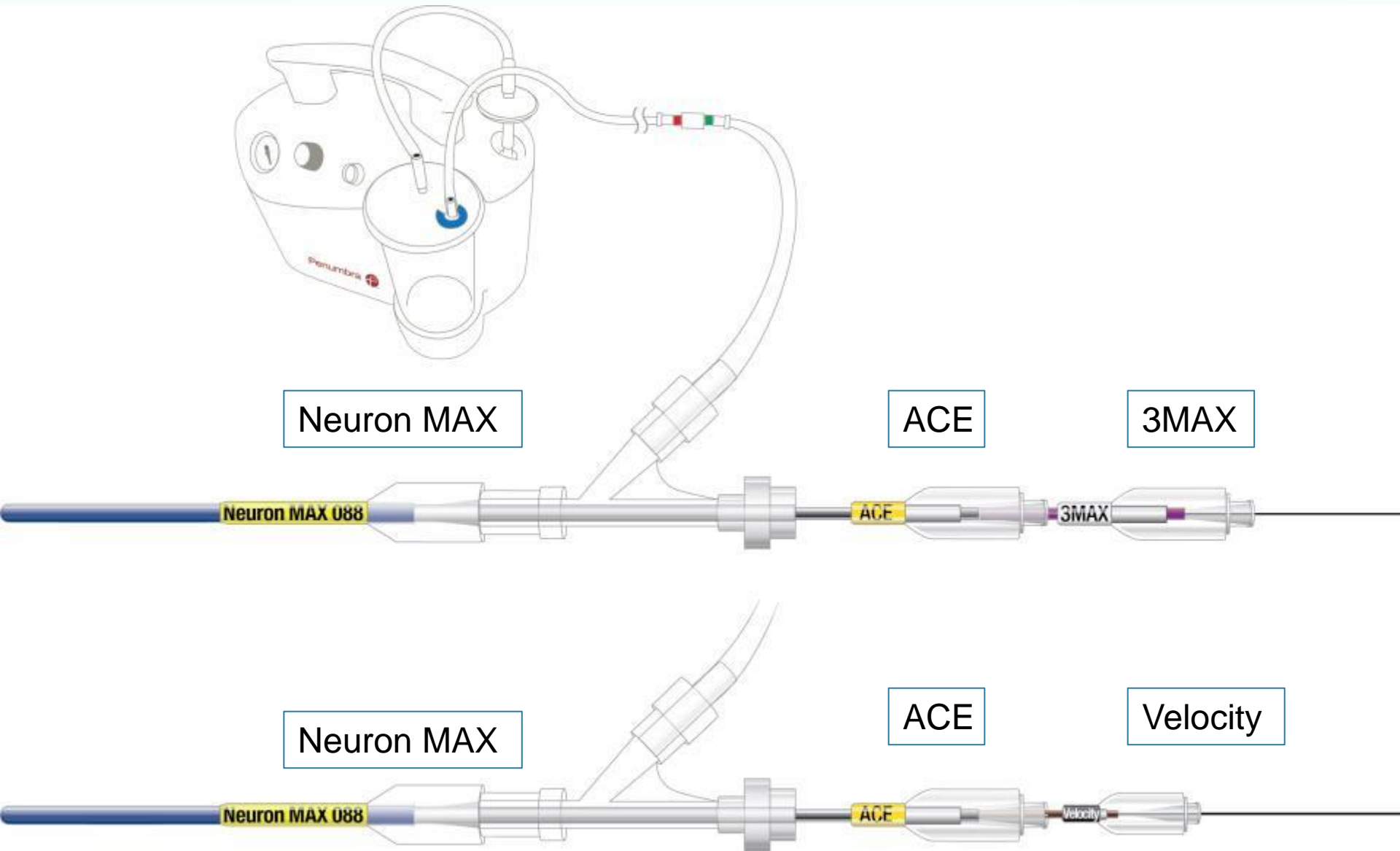
- ✓ **12 Transition Zones** enable outstanding force transmission and exceptional kink resistance
- ✓ **Advanced Polymer** provides flexibility for superior tracking
- ✓ **Nitinol Round Wire Reinforcement** maintains lumen integrity



ADAPT technique



Set-up



Ochsner Experience

- 31 cases involving stroke patients who were treated with the recently introduced ACE as first-line therapy for LVO strokes from **October 2013 to July 2014** (11 months) were collected
- Types of data recorded:
 - ✓ Age/Gender
 - ✓ Time last known normal
 - ✓ Time of patient arrival to OMC
 - ✓ Presentation and discharge NIHSS
 - ✓ Time of groin puncture
 - ✓ Study completion
 - ✓ TICl score before and after procedure
 - ✓ Procedural complications
 - ✓ Discharge mRS

Methods

- Patient selection based on on CTA/Perfusion findings
- Successful reperfusion defined by **TICI scores of 2b-3**
- Symptomatic hemorrhage (sICH) defined as **parenchymal hematoma type 2** associated with a worsening NIHSS of 4 points or more
- Good functional outcome measured as **mRS 0-2** at discharge

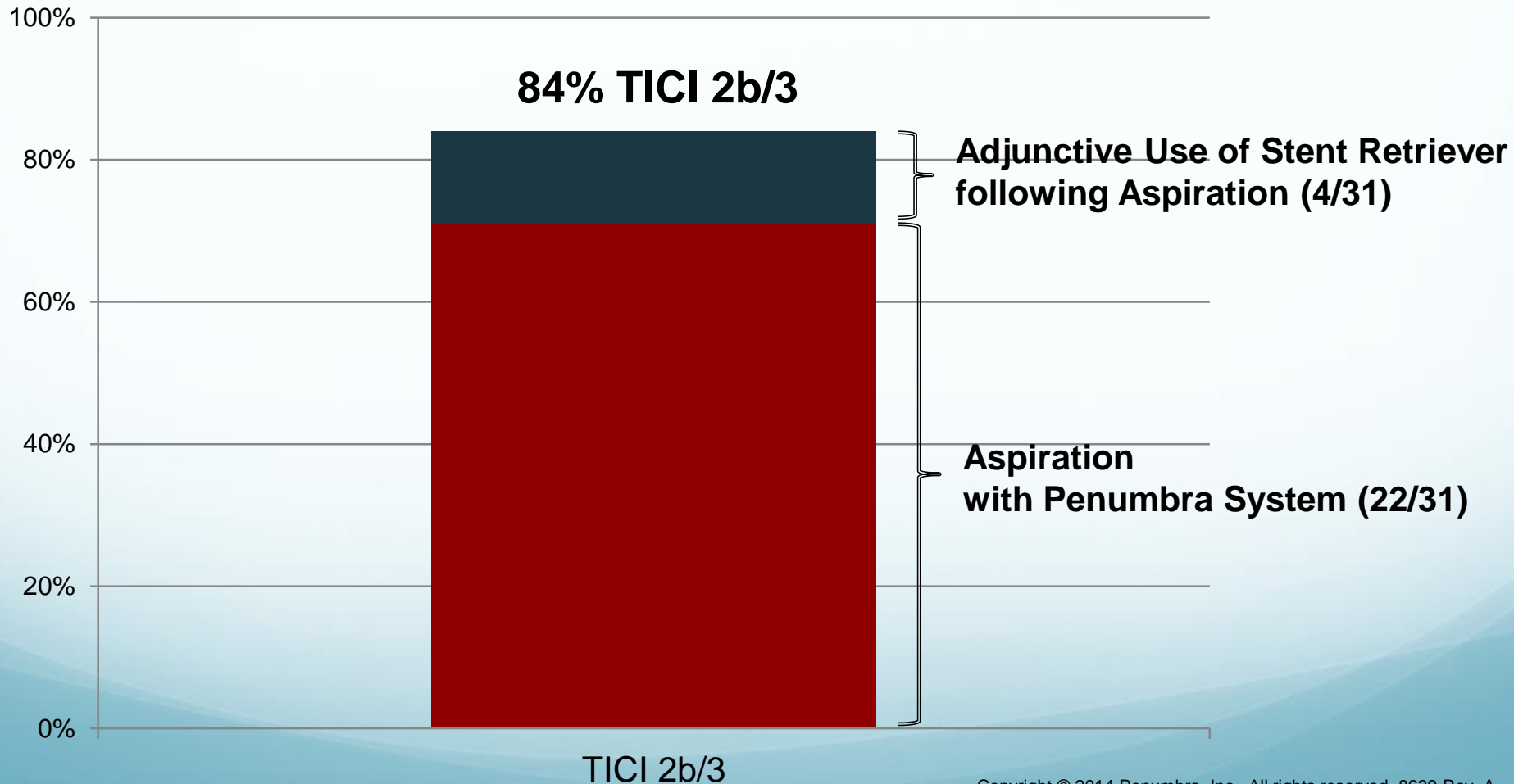
Patient Characteristics

Patients (N)	31
Age (years) [mean/(SD)]	66.3 ± 17.8
Baseline NIHSS [mean/(SD)]	19.4 ± 5.7
Avg LKN to arterial puncture	10 h 37 min
<i>Target Vessel Location:</i>	
MCA	77.4% (24/31)
ICA	19.4% (6/31)
Vertebrobasilar	3.2% (1/31)
<i>Occlusion Location:</i>	
Left	48.4% (15/31)
Right	48.4% (15/31)
Other	3.2% (1/31)

Results

Post Procedure Revascularization	
TICI 2b/3	84% (26/31)
TICI 3	61% (19/31)
Arterial puncture to TICI 2b-3 reperfusion (min) [mean/(SD)]	40.0 ± 14.0 (N=26)
Adjunctive Use of Stent Retrievers (any revascularization outcome)	19% (6/31)

Successful Revascularization by Approach



Safety and Outcomes

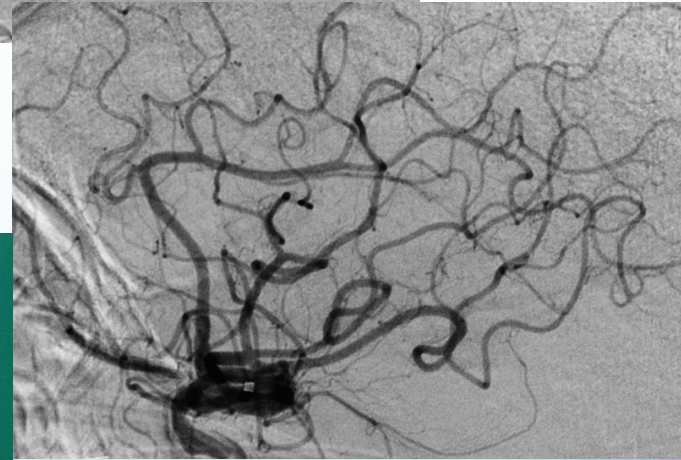
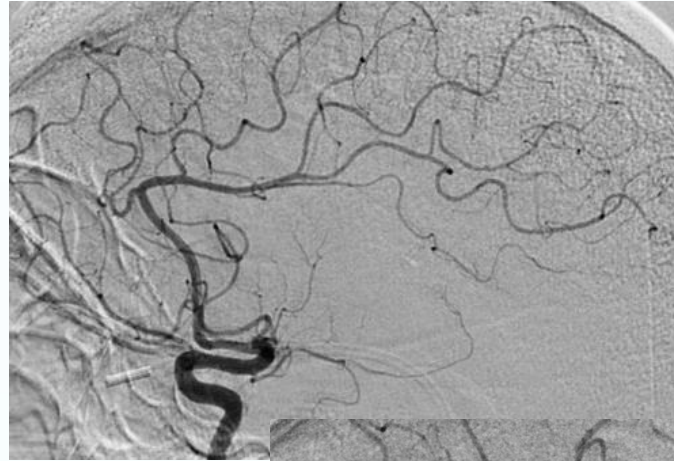
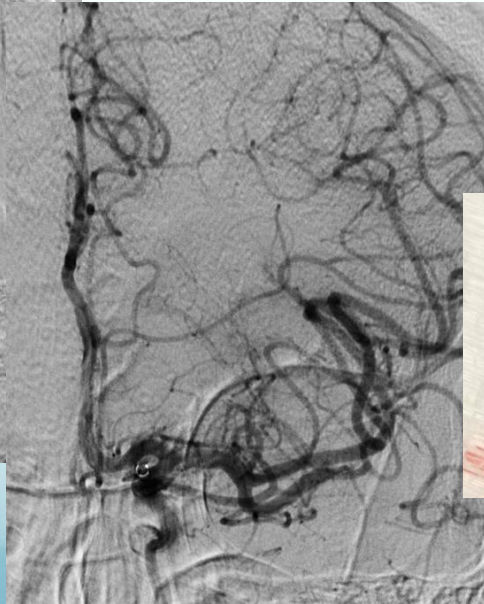
<i>Procedure related complications</i>	
sICH	6.5% (2/31)
Extravasation	3.2% (1/31)
Mortality	6.5% (2/31)
mRS at discharge [mean/(SD)]	2.3 ± 1.8
mRS 0-2 at discharge	61.3% (19/31)

Tips for Saving Time

- First few cases
 - ✓ 5 Fr sheath
 - ✓ Davis dx catheter
 - ✓ Rosen/J-tip exchange length wire
 - ✓ NeuronMax
- Faster technique
 - ✓ 8 Fr sheath
 - ✓ Neuron MAX™/Davis dx catheter construct
 - No need to exchange
 - Prompts equipment to be ready faster

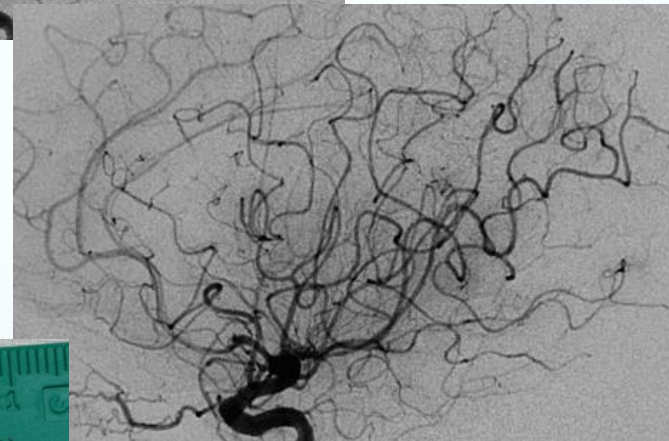
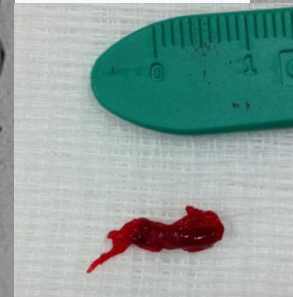
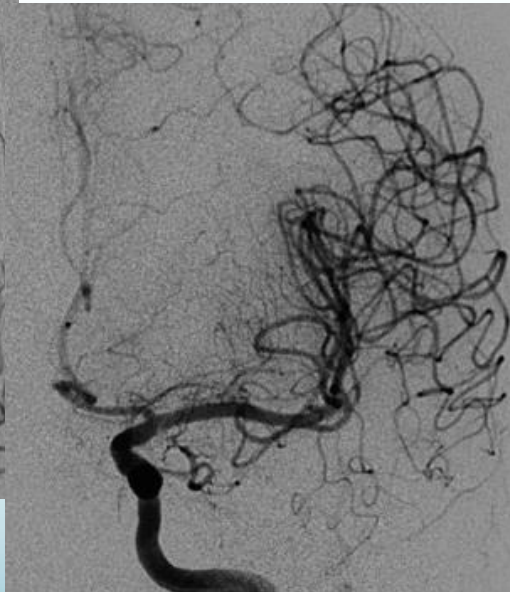
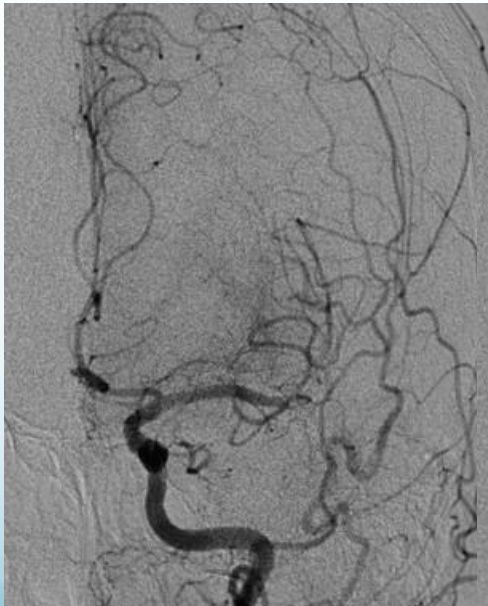
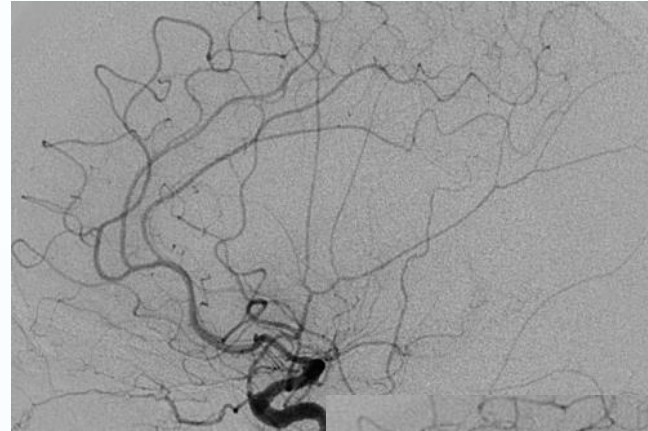
Example Case 1

- 60 yo female
- Presentation NIHSS = 24
- Puncture ~ 9 hours from LKN
- TICl 3 flow in 30 minutes
- Discharge NIHSS = 1 → home



Example Case 2

- 75 yo female
- Presentation NIHSS = 30
- Puncture ~ 20 hours from LKN
- TICI 3 in 29 minutes
- Discharge NIHSS = 8 → rehab



Need for Quality Revascularization

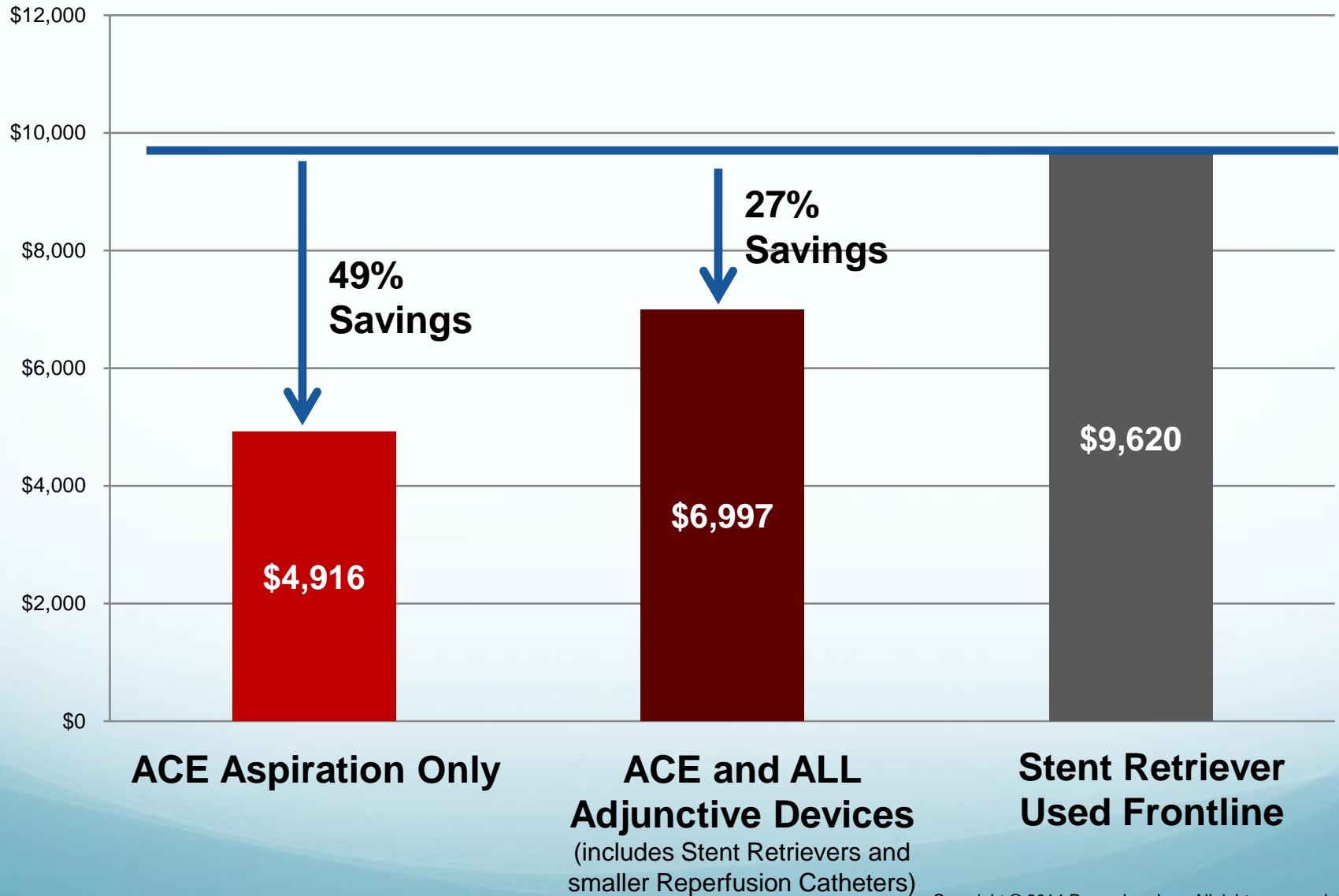
Revascularization Predicts Good Outcome

	< TICI 2b	TICI 2B	TICI 3	
	n = 5	n = 7	n = 19	
% at discharge mRS 0-2	20%	57%	74%	
	20%	69%		$p = 0.06$

Cost Analysis

- Cost of device as totaled for each case and compared with what the cost would be for an uncomplicated case using the Solitaire device
- Costs were calculated including only tools for thrombectomy and did not include:
 - ✓ Diagnostic catheters
 - ✓ Wires/microwires
 - ✓ Sheaths
 - ✓ Closure device
- Price estimates for comparison using device list prices were:
 - ✓ Cello (\$1100)
 - ✓ Marksman (\$1100)
 - ✓ Solitaire (\$7200)
 - ✓ Prowler or similar microcatheter (\$750)

Cost Analysis



Conclusion

- ACE™ and ADAPT represent the latest thinking in achieving high revascularization of LVOs in a rapid and cost effective manner, leading to good outcomes and increased hospital revenue

Ochsner Clinic Foundation

New Orleans, Louisiana



- Comprehensive Stroke Center
- Received a 3.87 million grant from CMS Innovation Center develop a stroke management and QI system in Louisiana called “Stroke Central”

Ochsner CerebroVascular Program

- Physicians
 - ✓ 4 Vascular neurologists
 - ✓ 5 Neurosurgeons
 - ✓ 5 Neurointensivists
 - ✓ 2 Interventional neuro-radiologists
 - Radiology
 - Neurology
- NeuroCritical Care Unit
 - ✓ 2009 – 6 beds
 - ✓ 2012 – 20 beds
 - ✓ 2014 – 34 beds
- Dedicated Neurosciences floor (Neuro trained nursing)
 - ✓ Primary vascular neurology service
 - ✓ NeuroSurgery
 - ✓ EMU

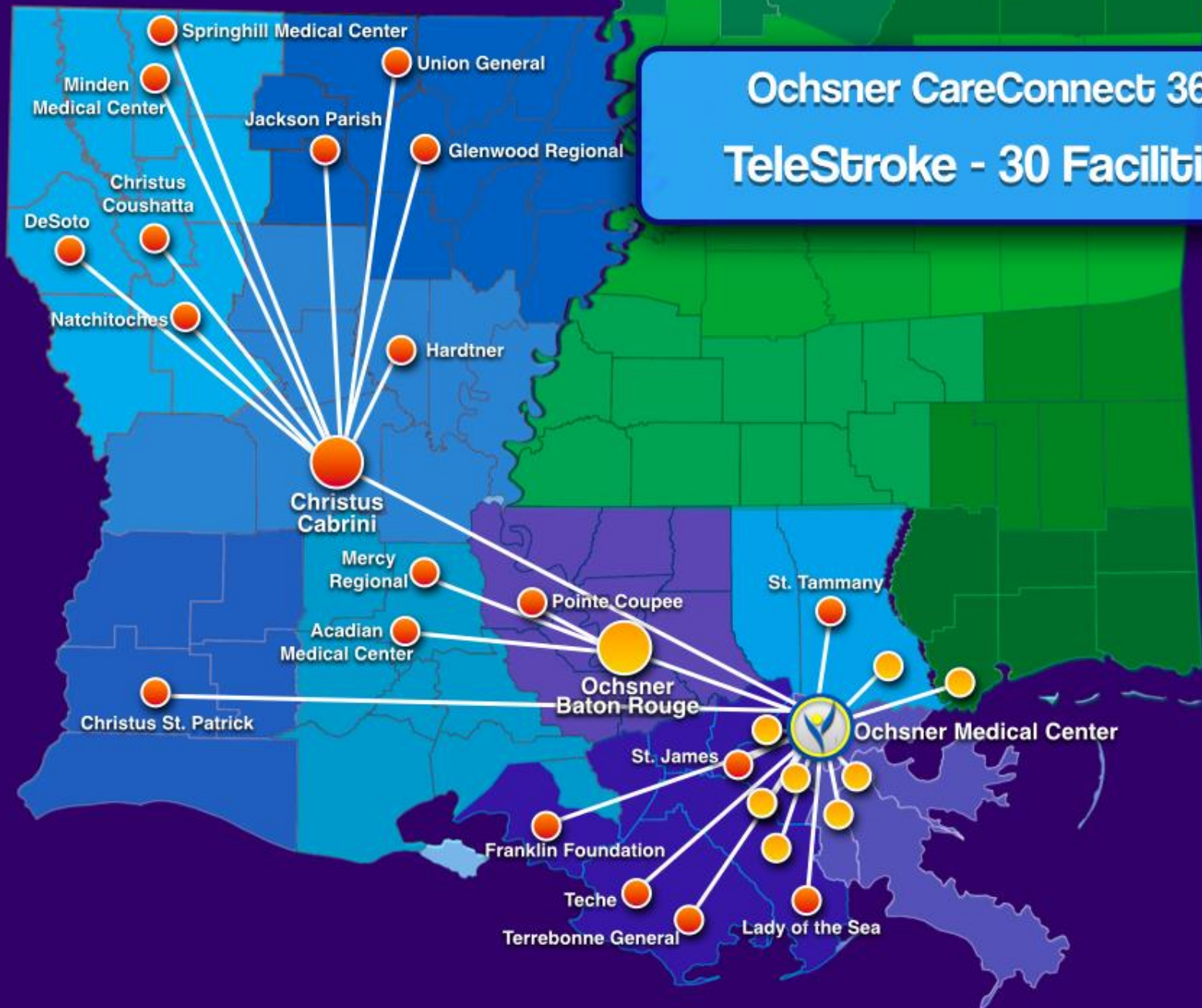
CTA / CTP

- Toshiba Aquillion One 320-Slice CT Scanner in ER
 - ✓ Whole brain CTP, CTA from peak opacification
- Images available on TeraRecon + PACS
- Decision to intervene based on NCCT, CT perfusion, CTA collaterals, symptom mismatch to core
- Usually greater than >50% penumbra, less than 1/3 MCA territory core

Experience and results

- Total tele-stroke consults
 - ✓ 2011 = 648
 - ✓ 2012 = 843
 - ✓ 2013 = 949
 - ✓ 2014 = 1132 → ~ 1400
- IV tPA initiations
 - ✓ 2011 = 68 tele-stroke
 - ✓ 2012 = 125 tele-stroke (45 @ OMC) → 170 total by team
 - ✓ 2013 = 168 tele-stroke (60 @ OMC) → 228 total by team
 - ✓ 2014 = 162 tele-stroke
 - → 194 projected
- Over 500 doses of IV tPA through tele-stroke!

Ochsner CareConnect 360 TeleStroke - 30 Facilities





The Ultimate Thrombectomy Device

*Case for 5MAX™ ACE™

- Opens artery quickly
 - ✓ Yes... avg 40 minutes to TICl 2b-3 in 84% of attempts
- Removes thrombus intact and completely
 - ✓ Yes... avg 40 minutes to TICl 2b-3 in 84% of attempts
- Safe and simple procedure
 - ✓ 6.5% rate of symptomatic hemorrhage
 - ✓ Easy quick setup
 - ✓ Great maneuverability (12 transition zones plus advance polymer)
- Cost effective
 - ✓ Possible saving of almost 50% when compared to stent-treiver construct

