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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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

<table>
<thead>
<tr>
<th></th>
<th>Risk Ratio</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Reperfusion</td>
<td>0.90</td>
<td>0.82-0.99</td>
<td>0.02</td>
</tr>
</tbody>
</table>
(every 30 minutes)    |            |           |         |

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

1 Khatri P, Yeatts SD, Mazighi M, et al. Time to angiographic reperfusion is highly associated with good clinical outcome in the IMS III Trial. Paper presented at: International Stroke Conference; February 6-8, 2013; Honolulu, HI, USA.
Need for Quality Revascularization

Revascularization Predicts Good Outcome For ICA, M1 Occlusion

<table>
<thead>
<tr>
<th></th>
<th>TICI=0</th>
<th>TICI=1</th>
<th>TICI=2a</th>
<th>TICI=2b</th>
<th>TICI=3</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>32</td>
<td>16</td>
<td>67</td>
<td>80</td>
<td>5</td>
</tr>
<tr>
<td>% 90 Day mRS 0-2</td>
<td>3.1%</td>
<td>12.5%</td>
<td>19.4%</td>
<td>46.3%</td>
<td>80%</td>
</tr>
<tr>
<td>6.3%</td>
<td></td>
<td>35.5%</td>
<td></td>
<td></td>
<td>p &lt; .0001</td>
</tr>
<tr>
<td>13.9%</td>
<td></td>
<td>48.2%</td>
<td></td>
<td></td>
<td>p &lt; .0001</td>
</tr>
</tbody>
</table>

1 Tomsick T. Comparison of outcome by IA approach and interpretation in light of comparative trials. Paper presented at: International Stroke Conference; February 6-8, 2013; Honolulu, HI, USA.
Need to remove clot intact

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

<table>
<thead>
<tr>
<th>New Emboli (Core Lab)</th>
<th>N</th>
<th>mRS ≤ 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>172</td>
<td>52</td>
<td>30.23%</td>
</tr>
<tr>
<td>Yes</td>
<td>28</td>
<td>5</td>
<td>17.86%</td>
</tr>
</tbody>
</table>

12% difference

1 Tomsick T. Comparison of outcome by IA approach and interpretation in light of comparative trials. Paper presented at: International Stroke Conference; February 6-8, 2013; Honolulu, HI, USA.
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

ADAPT (2013)
A large caliber aspiration catheter that is advanced up to the thrombus. Direct aspiration is employed to engage and then remove the thrombus.

Set-up

Neuron MAX       ACE       3MAX

Neuron MAX       ACE       Velocity
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
  - TICI score before and after procedure
  - Procedural complications
  - Discharge mRS
Methods

- Patient selection based 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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients (N)</strong></td>
<td>31</td>
</tr>
<tr>
<td><strong>Age (years) [mean/(SD)]</strong></td>
<td>66.3 ± 17.8</td>
</tr>
<tr>
<td><strong>Baseline NIHSS [mean/(SD)]</strong></td>
<td>19.4 ± 5.7</td>
</tr>
<tr>
<td><strong>Avg LKN to arterial puncture</strong></td>
<td>10 h 37 min</td>
</tr>
</tbody>
</table>

**Target Vessel Location:**

<table>
<thead>
<tr>
<th>Location</th>
<th>Percentage (Cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCA</td>
<td>77.4% (24/31)</td>
</tr>
<tr>
<td>ICA</td>
<td>19.4% (6/31)</td>
</tr>
<tr>
<td>Vertebrobasilar</td>
<td>3.2% (1/31)</td>
</tr>
</tbody>
</table>

**Occlusion Location:**

<table>
<thead>
<tr>
<th>Location</th>
<th>Percentage (Cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>48.4% (15/31)</td>
</tr>
<tr>
<td>Right</td>
<td>48.4% (15/31)</td>
</tr>
<tr>
<td>Other</td>
<td>3.2% (1/31)</td>
</tr>
</tbody>
</table>
## Results

<table>
<thead>
<tr>
<th>Post Procedure Revascularization</th>
<th>TICI 2b/3</th>
<th>84% (26/31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TICI 3</td>
<td></td>
<td>61% (19/31)</td>
</tr>
<tr>
<td>Arterial puncture to TICI 2b-3 reperfusion (min) [mean/(SD)]</td>
<td>40.0 ± 14.0 (N=26)</td>
<td></td>
</tr>
<tr>
<td>Adjunctive Use of Stent Retrievers (any revascularization outcome)</td>
<td>19% (6/31)</td>
<td></td>
</tr>
</tbody>
</table>
Successful Revascularization by Approach

Aspiration with Penumbra System (22/31)

Adjunctive Use of Stent Retriever following Aspiration (4/31)

84% TICI 2b/3
## Safety and Outcomes

| Procedure related complications |  
|----------------------------------|---|
| 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
- TICI 3 flow in 30 minutes
- Discharge NIHSS = 1 \(\rightarrow\) 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

<table>
<thead>
<tr>
<th></th>
<th>&lt; TICI 2b</th>
<th>TICI 2B</th>
<th>TICI 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>% at discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mRS 0-2</td>
<td>20%</td>
<td>57%</td>
<td>74%</td>
</tr>
<tr>
<td></td>
<td>20%</td>
<td>69%</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>n = 5</td>
<td>n = 7</td>
<td>n = 19</td>
</tr>
<tr>
<td><em>p</em></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
</tbody>
</table>
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

ACE Aspiration Only

$4,916

49% Savings

ACE and ALL Adjunctive Devices (includes Stent Retrievers and smaller Reperfusion Catheters)

$6,997

27% Savings

Stent Retriever Used Frontline

$9,620
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.
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!
The Ultimate Thrombectomy Device
*Case for 5MAX™ ACE™

- Opens artery quickly
  ✓ Yes… avg 40 minutes to TICI 2b-3 in 84% of attempts

- Removes thrombus intact and completely
  ✓ Yes… avg 40 minutes to TICI 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