Multicenter Experience with the Penumbra Ruby™ Coil in the Peripheral Vasculature: ACE Study Initial Results

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Frank Arko, MD

- Penumbra Consultant
Background

Ruby™ Coil System (Penumbra Inc., Alameda, CA)

• New generation of softer and larger (.020””) platinum macro detachable coils

• Indicated for:
  • Embolization of Visceral aneurysms
  • Vessel Sacrifice
  • AVMs
  • Arterial and venous embolizations in the peripheral vasculature
PENUMBRA RUBY™ Embolization System

Compatible with .025” and .027” High Flow Microcatheters

Large Volume Platinum Coils

- 32mm x 60cm
- 2mm x 1cm

- Complex Standard
- Complex Soft

Penumbra PX SLIM™ Microcatheter

Penumbra Detachment Handle
RUBY COIL

LONGEST LARGE VOLUME DETACHABLE COIL – 60CM

Ruby™ Coil

High Flow Microcatheter
Penumbra PX SLIM™

Conventional 35 Coil
035 Diagnostic Catheter

Conventional 18 Coil
18 Microcatheter

Coil Thickness

.020"

.021"

.012"
RUBY Coil vs. Conventional Detachable Coil

PENUMBRA RUBY COIL
30 CM

CONVENTIONAL DETACHABLE COIL
30 CM
### Peripheral Embolization Coil Volume Comparison Chart

<table>
<thead>
<tr>
<th>Coil</th>
<th>Coil Thickness</th>
<th>Longest 4 mm Coil</th>
<th>Longest 8 mm Coil</th>
<th>Longest 12 mm Coil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penumbra Ruby™ Coil</td>
<td>.020”</td>
<td>1 Ruby</td>
<td>1 Ruby</td>
<td>1 Ruby</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mm × 35 cm</td>
<td>8 mm × 60 cm</td>
<td>12 mm × 60 cm</td>
</tr>
<tr>
<td>Covidien Concerto™ / Axium™</td>
<td>.0125”-.0145”</td>
<td>9 coils = 1 Ruby</td>
<td>4 coils = 1 Ruby</td>
<td>3½ coils = 1 Ruby</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mm × 10 cm</td>
<td>8 mm × 30 cm</td>
<td>12 mm × 30 cm</td>
</tr>
<tr>
<td>Boston Scientific Interlock™</td>
<td>.012”</td>
<td>6½ coils = 1 Ruby</td>
<td>8 coils = 1 Ruby</td>
<td>3½ coils = 1 Ruby</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mm × 15 cm</td>
<td>8 mm × 20 cm</td>
<td>12 mm × 50 cm</td>
</tr>
<tr>
<td>Terumo Azur® CX Hydrocoil</td>
<td>.014”-.015”</td>
<td>5½ coils = 1 Ruby</td>
<td>5 coils = 1 Ruby</td>
<td>3 coils = 1 Ruby</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mm × 13 cm</td>
<td>8 mm × 24 cm</td>
<td>12 mm × 34 cm</td>
</tr>
<tr>
<td>Codman Holipaq®</td>
<td>.014”</td>
<td>7 coils = 1 Ruby</td>
<td>4 coils = 1 Ruby</td>
<td>4 coils = 1 Ruby</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mm × 10 cm</td>
<td>6 mm × 30 cm</td>
<td>12 mm × 30 cm</td>
</tr>
</tbody>
</table>
RUBY Coil Detachment

- Instant 1-click mechanical detachment
- Precision micromachine coil release tip
Unique micromachine coil release tip designed to ensure instant reliable detachment

Micromachine coil release tip
Japanese Packing Density Study

Long-term Outcomes of Coil Packing for Visceral Aneurysms: Correlation between Packing Density and Incidence of Coil Compaction or Recanalization

Taku Yasumoto, MD, PhD, Keigo Osuga, MD, PhD, Hiroshi Yamamoto, MD, Yusuke Ono, MD, Maki Masada, MD, Koji Mikami, MD, Daigo Kanamori, MD, Masahisa Nakamura, MD, Kaisyu Tanaka, MD, Tetsuro Nakazawa, MD, PhD, Hiroki Higashihara, MD, PhD, Noboru Maeda, MD, PhD, and Noriyuki Tomiyama, MD, PhD

Achieving > 24% Packing Density demonstrated a more stable occlusion in Visceral Aneurysms
Aneurysm Coiling Efficiency (ACE) Study

- Multicenter experience with Ruby Coils in the ACE post market registry
- Is Packing Density the answer for stable long term occlusion?
  - Lack of patient compliance for follow up
  - Avoid referring physicians seeing patients requiring retreatment
Methods

• 68 cases involving peripheral aneurysms/malformations and vessel sacrifice from March 2012 to January 2015 were collected

• Cases at 10 centers were treated with Ruby Coils
  • 7 splenic artery aneurysms
  • 11 renal artery aneurysms
  • 3 mesenteric aneurysms
  • 1 hepatic
  • 1 iliac
  • 7 AVMS
  • 6 fistulae
  • 4 varices
  • 28 peripheral vessel sacrifices
# Aneurysms Results

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Number of aneurysms/malformations</strong></td>
<td><strong>N=40</strong></td>
</tr>
<tr>
<td><strong>Coils used per aneurysm (median)</strong></td>
<td><strong>6</strong></td>
</tr>
<tr>
<td><strong>Packing Density (mean)</strong></td>
<td><strong>28% (Range 19-61%)</strong></td>
</tr>
<tr>
<td><strong>Fluoroscopy Time (mean)</strong></td>
<td><strong>28 min</strong></td>
</tr>
<tr>
<td><strong>Procedural SAEs</strong></td>
<td><strong>0%</strong></td>
</tr>
<tr>
<td><strong>Post-Treatment</strong></td>
<td>Raymond Scale Class I Occlusion (N=39) 91.3%</td>
</tr>
<tr>
<td><strong>6-Month Follow-Up</strong></td>
<td>Stable/Complete Class I Obliteration (N=20) 92.9%</td>
</tr>
</tbody>
</table>
# Vessel Sacrifice Results

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Peripheral Vessel Sacrifice</td>
<td>N=28</td>
</tr>
<tr>
<td>Coils used per vessel (mean)</td>
<td>2.5</td>
</tr>
<tr>
<td>Fluoroscopy Time (mean)</td>
<td>21 min</td>
</tr>
<tr>
<td>Procedural SAEs</td>
<td>0%</td>
</tr>
</tbody>
</table>
INTERNAL ILIAC ANEURYSM COILING

Patient presented with:

- Hypotension
- Creatinine value of 5 mg/dL
- Contrast CT showing a large left pelvic hematoma associated with a 6-cm ruptured internal iliac aneurysm
INTERNAL ILIAC ANEURYSM COILING

348 cm of coils delivered in < 10 minutes
LSA and False Lumen

- Pt. with dissection, coverage of LSA
- Short proximal landing zone – coiled LSC, and also false lumen
- False lumen measured 38 mm
- RUBY coil deliverability through a microcatheter is advantageous while using this technique
LSA and False Lumen

- LSC
- PXSLIM 90 degree tip microcatheter
- Coils:
  - 32mm x 60cm Standard
  - 20mm x 60cm Soft (2)
Pre Treatment

Left Renal and Ovarian Vein  L Ovarian Vein
Post Treatment

Post Stent and Coils
Conclusions

- ACE study shows **safe and effective embolization**
- **Complete obliteration** immediately post-procedure with high packing density
- **Stable occlusion** at 6-month follow-up
- Clinical benefits include:
  - Reduced number of coils
  - Shortened procedure time
  - Less radiation
  - Reduced re-intervention rate