Peripheral Aneurysm Coiling using Large Volume Ruby Coils: Results from the Multicenter ACE Registry

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On behalf of

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Disclosure

Penumbra, Inc.

Consultant
Packing Density: Why is it important?

Packing density promotes complete and stable coil embolization in peripheral aneurysms

Recent publication indicated a packing density $\geq 24\%$ is optimal\(^1\)

- Protects against compaction or recanalization in long term follow-up ($\geq 12$ months)

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The ACE study demonstrated the safety and efficacy of the Ruby™ Coils in achieving high Packing density, leading to complete aneurysm obliteration and stable vessel embolization.
ACE Trial

Outcome measures:

- Packing density with the number of coils deployed
- 6 months occlusion rate (optional 1 year follow-up)
- Time of fluoroscopic exposure
- Device-related serious adverse events (Immediate post-procedure)
Ruby Coil
Large Volume Detachable Coil

- Long and **Soft** embolization coil
- Similar in size to .035" coils
- 1-click mechanical detachment
- Multiple softness levels
  - **Standard coils** – to “Frame”
  - **Soft coils** – to “Fill”
    - aneurysms and pack vessels
Delivery

Designed to be delivered through high flow Microcatheters

Ruby® Coil
LANTERN® Microcatheter

Conventional 35 Coil
035 Diagnostic Catheter

Conventional 18 Coil
18 System Microcatheter

Coil Thickness

.020"

.021"

.012"
LANTERN
Coil Delivery Microcatheter

Dual Markers
Facilitates Precise Coil Deployment

Coil Wound Construction
Enables Confident Large Volume Coil Delivery by Preventing Ovalization

Low Profile, High-Flow
2.6F, .025" ID for High Flow Access to Small Tortuous Vessels

Radiopaque Distal 3 cm
Increased Visibility

8 Transition Zones
For Advanced Trackability
Ruby Volume Advantage

One 30 cm Ruby Coil
28% Packing

One 30 cm 18 system coil
7% Packing

7.5 mm glass aneurysm
Ruby Softness Advantage

Conventional Detachable Coil

Large Volume Soft Coil

SOFT COILS TIGHTLY PACK FORMING DENSE METAL OCCLUSION

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Methods

- ACE was a prospective registry with patients enrolled from March 2012 to April 2016
- 78 peripheral lesions were treated in 67 patients across 15 centers
# Procedure Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
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</thead>
<tbody>
<tr>
<td>Total Patients, N (Lesions)</td>
<td>67 (78)</td>
</tr>
<tr>
<td>Age, Median [IQR]</td>
<td>59 Years [IQR 48 – 71]</td>
</tr>
<tr>
<td>Female, % (n/N)</td>
<td>44.8% (30/67)</td>
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<tr>
<th>Safety Results</th>
<th></th>
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<tbody>
<tr>
<td>Device Related SAEs</td>
<td>0</td>
</tr>
<tr>
<td>Procedural SAEs</td>
<td>3/67 (4.4%)*</td>
</tr>
</tbody>
</table>

*Splenic infarction documented in one patient post embolization. One patient developed a splenic rupture, treated by splenectomy. The remaining patient had 2 embolizations; expired due to polytrauma complications (after family made decision to begin comfort care).
Results: Aneurysm

<table>
<thead>
<tr>
<th>Clinical Results</th>
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<tbody>
<tr>
<td>Mean Aneurysm Diameter</td>
<td>2.1 ± 1.4 cm*</td>
</tr>
<tr>
<td>Packing Density, Median [IQR]</td>
<td>26.8% [IQR 18.6 – 33]</td>
</tr>
<tr>
<td>Number of Coils Deployed, Median [IQR]</td>
<td>6.5 [IQR 4 – 14]</td>
</tr>
<tr>
<td>Fluoroscopy Time, Median [IQR]</td>
<td>29.0 Minutes [IQR 21 – 36]</td>
</tr>
</tbody>
</table>

*Aneurysm locations included splenic, renal, mesenteric, iliac, and vertebral arteries.
Long-term Outcomes of Coil 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

ABSTRACT

Purpose: To evaluate the correlation between packing density and the incidence of coil compaction or recanalization of visceral artery aneurysms (VAAs) after coil packing.

Materials and Methods: Between July 2004 and April 2012, coil packing was performed for 46 true visceral aneurysms (16 splenic, 11 pancreaticoduodenal, eight renal, six hepatic, three superior mesenteric, one right gastric, and one gastroepiploic) in 42 patients. The size and volume of the aneurysm, packing density, and the incidences of compaction and recanalization were evaluated retrospectively.

Results: The mean follow-up period was 37 months ± 8 (range, 11–80mo). The mean packing density was 19% ± 8 (range, 5%–42%), mean aneurysm size was 19mm ± 8 (range, 5–40mm), and mean volume was 4,108mm³ ± 5,435 (range, 72–26,235 mm³). Compaction and recanalization occurred in two (4%) and 12 aneurysms (26%) respectively. The mean packing density was significantly lower in aneurysms with compaction or recanalization than in unaffected aneurysms (12% vs 22%; \( P = .00014 \)). There was a significant difference in mean packing density between small (< 20 mm; 22%) and large (≥ 20 mm) aneurysms (15%; \( P = .0045 \)). The mean size and volume were significantly larger for coil-compacted or recanalized aneurysms than for unaffected aneurysms (\( P < .05 \)). In aneurysms with a packing density of at least 24%, no compaction or recanalization occurred.

Conclusions: Coil compaction or recanalization after coil packing for VAAs more often occurs after insufficient embolization with low packing density and in patients with large aneurysms.
**Long-Term Follow Up**

<table>
<thead>
<tr>
<th>Follow Up from Index Procedure</th>
<th>Stable Occlusion</th>
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<tbody>
<tr>
<td>6 months</td>
<td>90.9% (20/22)</td>
</tr>
<tr>
<td>1 year</td>
<td>100% (15/15)</td>
</tr>
</tbody>
</table>

**2 Aneurysms Recanalized:**

- Splenic Artery Aneurysm – **Packing Density only 9.5%**
- Type II endoleak initially treated with coils and Onyx\(^1\). Recanalization likely observed as a result of recruitment of new feeding artery

\(^1\)Onyx is comprised of EVOH (ethylene vinyl alcohol) copolymer dissolved in DMSO
19 mm Splenic Artery Aneurysm

- 8 Ruby® Coils deployed
- 33.8% packing density achieved
- Stable Occlusion at 6-month and 1-year follow up

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## Results: Vessel Sacrifice and Malformations

<table>
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<tr>
<th>Clinical Outcomes</th>
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<tr>
<td>Number of Vessels, N</td>
<td>52</td>
</tr>
<tr>
<td>Number of Coils Deployed, Median [IQR]</td>
<td>3 [IQR 2 – 5]</td>
</tr>
<tr>
<td>Fluoroscopy Time, Median [IQR]</td>
<td>21.5 Minutes [15 – 29]</td>
</tr>
</tbody>
</table>
One recanalization occurred in a pregnant patient treated for a Pulmonary AVM. The embolization was stopped prior to complete occlusion to limit contrast and radiation dose due to pregnancy.
Conventional Fibered Coils: 20.4% Recanalization

Gastroduodenal artery recanalization after transcatheter fibered coil embolization for prevention of hepaticoenteric flow: incidence and predisposing technical factors in 142 patients.

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Results: Twenty-nine of 142 patients (20.4%) experienced GDA recanalization. The distance between the GDA origin and most cephalad coil was significantly greater in the recanalization group than in the non-recanalization group (9.6 mm vs. 12.6 mm, \( P = 0.01 \)). A prospective multivariate analysis established that the further the coil was from the origin the more likely the GDA was to recanalize. The two groups did not differ on the basis of any other factors examined.
Gastroduodenal Artery Sacrifice

- Pre Y90 mapping
- Complete cross sectional mechanical occlusion

Rahul Patel MD, Mount Sinai, NY

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Conclusion

Dense packing with Ruby® Coil enables stable long-term occlusion

Aneurysm exclusion and vessel sacrifice procedures were associated with:
1. short procedure times
2. low fluoroscopy exposure
3. few devices per case
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