CHALLENGING EVAR´S: LONG TERM OPTIMIZATION WITH ONYX

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DISCLOSURE

No Disclosures
THE ROLE OF LIQUID EMBOLIZATION

- Type I Endoleaks
- Type II Endoleaks
- Gutters
Onyx is a liquid embolic agent ethylene vinyl alcohol (EVOH) copolymer dissolved in dimethyl sulfoxide (DMSO).

It comes in two formulations:

Onyx 18 (6% EVOH) and Onyx 34 (8% EVOH).

Onyx 18 has a lower viscosity and, therefore, may flow further in the endoleak cavity. Both formulas solidify within 5 minutes of injection.
Long-term success embolization with Onyx was 76%
11 patients with type II endoleak

Mean follow-up time
26 months
Overall clinical success 73%

The best clinical results are achieved when Onyx occluded the entire nidus
Technical Note: “Remote” Transarterial Embolisation Technique of Lumbar Artery Type 2 Endoleaks with Onyx

R. Chung, R. Morgan
Predictors and outcomes of endoleaks in the Veterans Affairs Open Versus Endovascular Repair (OVER) Trial of Abdominal Aortic Aneurysms

Brajesh K. Lal, MD, Wei Zhou, MD, Ziyi Li, MPH, Tassos Kyriakides, PhD, Jon Matsumura, MD, Frank A. Lederle, MD, Julie Freischlag, MD

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Volume 62, Issue 6, Pages 1394-1404 (December 2015)
DOI: 10.1016/j.jvs.2015.02.003
TIME FROM ENDOLEAK DETECTION AND RESOLUTION

![Graph showing time from endoleak detection and resolution](image_url)

| Time from endoleak detection (years) | Type II | Other Types of endoleaks | Upper 95% CI Type II | Lower 95% CI Type II
<table>
<thead>
<tr>
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<tr>
<td>8</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
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<tr>
<td>9</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
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Type II Endoleaks | Parallel curves for different types of endoleaks, with Kaplan-Meier survival analysis. The graph shows the cumulative probability of resolution over time for Type II and other endoleak types, indicating significant differences with a p-value of 0.0001 (Chi-Square test).

Legend:
- Type II endoleaks
- Other types of endoleaks
- Upper 95% CI Type II
- Lower 95% CI Type II

Table: Time from endoleak detection and resolution

<table>
<thead>
<tr>
<th>Type II</th>
<th>Other Types</th>
<th>Type II Total</th>
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<tbody>
<tr>
<td>52</td>
<td>23</td>
<td>75</td>
</tr>
<tr>
<td>14</td>
<td>11</td>
<td>25</td>
</tr>
<tr>
<td>11</td>
<td>8</td>
<td>19</td>
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<tr>
<td>7</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>6</td>
</tr>
</tbody>
</table>

Chi-Square test: 15.0134, p-value: 0.0001
Intrasac flow velocities predict sealing of type II endoleaks after endovascular abdominal aortic aneurysm repair

Frank R. Arko, MD, Konstantinos A. Filis, MD, PhD, Scott A. Siedel, MD, Bonnie L. Johnson, RVT, Angelia R. Drake, BSN, RN, Thomas J. Fogarty, MD, Christopher K. Zarins, MD

Journal of Vascular Surgery
Volume 37, Issue 1, Pages 8-15 (January 2003)
DOI: 10.1067/mva.2003.55
MANAGING TYPE II ENDOLEAKS

Although a common complication Type II Endoleaks are not always benign and require innovative treatment strategies

By Naveed U. Saqi, Md; Kristoffer M. Charlton, Md; and Ali Azizzadeh, Md, FACS

A n endoleak is defined as persistent blood flow in the aneurysm sac extrinsic to the endograft and is the most common complication occurring after endovascular aneurysm repair (EVAR). It has been reported to occur in 10% to 30% of patients at any time during follow-up.1,2 Type II endoleak results from collateral retrograde flow from the aortic branches, usually from the lumbar arteries, inferior mesenteric artery, or middle sacral artery.1 Because type II endoleaks are the most common type of endoleak after EVAR, they are generally considered to have a benign prognosis. Although this complication has been extensively studied, unresolved issues still remain. The merit for intervention, the optimal timing of intervention, the most efficacious modality for diagnosis, and the treatment of type II endoleaks that occur subsequent to EVAR remain controversial.

The natural history of type II endoleak is still not completely understood; however, it is widely accepted that those associated with aneurysm sac growth are not innocuous. A recent publication revealed a high incidence of secondary interventions (20%), continued aneurysm sac growth (37.9%), and a need for graft explantation (8.4%) in patients with type II endoleaks.3 The EUROSTAR trial revealed that patients with type II endoleaks require more secondary interventions and have higher rates of open conversion but no increased risk of rupture.4 Apart from the risks of each reintervention and graft explant, there is also a small but persistent risk of aneurysm rupture (0.5%–2.4%) in the setting of type II endoleak with aneurysm sac growth.4

Due to the incidence of endoleaks and device-related complications, EVAR patients require lifelong surveillance with serial radiologic imaging. It is argued that early advantages conferred by EVAR are substantially offset by the need for serial endograft surveillance and frequent secondary interventions. Imaging from a patient with an abdominal aortic aneurysm (AAA) who underwent routine EVAR and subsequently required intervention for aneurysm growth secondary to a type II endoleak is shown in Figures 1 through 5. Preoperative CT angiography (CTA) shows a 5.6-cm AAA (Figure 1). Diagnostic and completion angiography (Figure 2) show a successful EVAR procedure using an Excluder device (Gore & Associates, Flagstaff, AZ). Surveillance CTA at 6-month intervals show persistent aneurysm growth with no causes for concern (Figure 3).
TYPE II ENDOLEAK: EMBOLIZATION WITH GLUE
TAKE-HOME POINTS

• Type II endoleaks with aneurysm sac growth are not benign and should be treated by endovascular embolization.

• Current imaging modalities have improved the detection of type II endoleaks, but further improvements are still needed.

• Endograft explantation and open conversion is still required in some EVAR patients.

• Future innovations in next-generation endograft design should focus on eliminating the occurrence of type II endoleaks.
DOES ONYX HAVE A PLACE IN TYPE I LEAKS?
PROXIMAL SEAL STABILITY REMAINS KEY

- Rates of 2nd interventions in EVAR are high and not improving adequately
  - Average re-intervention rate of 3.7%/yr from recent registry data\(^1\) IDE trial data demonstrate average rate of 4.1%/yr\(^2\)

- Complicated anatomy results in more Type I endoleaks & higher re-intervention risk
  - Short neck length (<15mm)\(^3,4\)
  - Neck angulation (>40º)\(^5\)
  - More complicated patients are being treated as EVAR devices improve

<table>
<thead>
<tr>
<th>Re-intervention-free survival(^1)</th>
<th>1 yr</th>
<th>89.9%</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>2 yr</td>
<td>86.9%</td>
</tr>
<tr>
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<td>5 yr</td>
<td>81.5%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Increased odds of type I endoleak and need for re-intervention Risk Factor</th>
<th>OR (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Neck Length &lt; 15 mm</td>
<td>2.2 (1.4-3.5)(^3,†)</td>
</tr>
<tr>
<td></td>
<td>6.2 (2.9-13)(^4,†)</td>
</tr>
<tr>
<td></td>
<td>4.3 (2.1-8.7)(^4,‡)</td>
</tr>
<tr>
<td>Neck angulation &gt; 40º</td>
<td>5.9 (1.3-27.6)(^5,*)</td>
</tr>
</tbody>
</table>

Strategies for Treating Type I Endoleaks

Current solutions do not offer consistent effectiveness

**Palmaz effectiveness is limited**
- Byrne et al reported:
  - *Persistent type Ia endoleak in 8.6% (14/162) pts* at the end of primary procedure\(^1\)
  - Can preclude future re-interventions, e.g. FEVAR, EndoAnchors

**Mixed results with Cuffs**
- Jim J et al. reported:
  - 12% (18/151) re-developed *Type I/III Endoleaks* at 43 mos average f/u post Zenith Renu placement\(^2\)

**Limitations with Coils and Onyx**
- Require precise ID of leak paths: *non-target embolization risk*\(^3\)
- Time consuming\(^4\)
- Onyx could create CT artifacts precluding identification of endoleaks in F/U\(^4\)

- None of these resist further neck dilatation
- Frequently multiple devices needed, adding time & cost
- Palmaz, coils, Onyx not indicated for Tx of Type I Endoleak

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- Proximal landing zone issues 64%
Mean Follow up – 9 months

EVAR 170

Hostile Neck: 41 Patients

25%
Techniques (n = 38 / 170)

- Associated interventions
  - Iuxtarenal angioplasty 32 cases (84.2%)
  - Oversizing of the body (mean) 18% (range 8-32; SD ± 7.6)
  - Proximal aortic cuff extension 11 (28 %)
  - Chimney 19 (50 %)
  - Fenestration 3 (7,8 %)
  - RA Loss 1 (2,6 %)
No recurrent Endoleak at 10 months follow-up

Table 1. Summary of patients treated with Onyx embolisation.

<table>
<thead>
<tr>
<th>No</th>
<th>Pathology</th>
<th>Initial treatment</th>
<th>Endoleak</th>
<th>Indication for Onyx</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Juxtarenal AAA</td>
<td>Fenestrated EVAR with Ventana</td>
<td>1a</td>
<td>Unsuitable for fenestrated cuff. Unfit for open surgery.</td>
</tr>
<tr>
<td>2</td>
<td>Infra renal AAA</td>
<td>EVAR with oversized (42 mm) graft</td>
<td>1a</td>
<td>Oversized cuff/stent not available. Unfit for open surgery.</td>
</tr>
<tr>
<td>3</td>
<td>Chronic type B dissection &amp; infra renal AAA</td>
<td>Hybrid TEVAR with 3 vessel visceral bypass from right CIA</td>
<td>1b</td>
<td>Unsuitable for limb extension due to R CIA visceral artery bypasses.</td>
</tr>
<tr>
<td>4</td>
<td>Descending TAA</td>
<td>TEVAR to coeliac origin</td>
<td>1b</td>
<td>Unsuitable for hybrid procedure and fenestrated/branched endografts.</td>
</tr>
<tr>
<td>5</td>
<td>Infra renal AAA</td>
<td>Tube graft from outside hospital</td>
<td>1a</td>
<td>Infected graft. Unsuitable for fenestrated cuff. Unfit for open surgery.</td>
</tr>
</tbody>
</table>
Transcatheter Embolisation of Type 1 Endoleaks after Endovascular Aortic Aneurysm Repair with Onyx: When No Other Treatment Option is Feasible

J.-Y. Chun *, R. Morgan

Department of Radiology, St George’s Hospital, London, SW17 0QT, UK
Endoluminal treatment of type IA endoleak with Onyx

Joseph L. Grisafi, MD, Guillaume Boiteau, MD, Elizabeth Detschel, MD, Jonathan Potts, MD, Paul Kiproff, MD, Satish C. Muluk, MD

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DOI: 10.1016/j.jvs.2010.06.021
TRANSRADIAL TYPE I ENDOLEAK ETHYLENE VINYL ALCOHOL COPOLYMER (ONYX) EMBOLIZATION

ZACHARY L. BERCU, MD

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PLAN B  CONTAINED RUPTURE
CHIMNEY + APTUS => ACTIVE GUTTER ELIMINATION
ACTIVE GRAFT FIXATION

APTUS STAPLER
THE ROLE OF LIQUID EMBOLIZATION IN GUTTERS
Treatment of gutters: 2 Periscopes + 1 Chimney SMA
ADJUNCT IN HIGH FLOW AREAS
CHALLENGES
2009
5.3 CM
POSTOP CT 2009

Bird Beacon ?
TAKING CARE OF HIGH FLOW GUTTERS (COILS / ONYX™)

+ Another Chimney Graft
ENDOVASCULAR SEALING
THE HOLY GRAIL OF EVAR ????

Polymer will help against
Type II leaks
Type I leaks
Gutters ?

“I got it on eBay.”
MEDTRONIC  -  ARSENAL MEDICAL
Until then

ONYX CAN SOLVE THE GUTTER ISSUE?!

Thank you
CHALLENGING EVAR´S: LONG TERM OPTIMIZATION WITH ONYX

RALF R. KOLVENBACH