The Arsenal AAA sac filling system for EVAR: How does it work? What is its value?

Andrew Holden
Auckland Hospital
Auckland, New Zealand

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Disclosure

Speaker name:

Andrew Holden

I have the following potential conflicts of interest to report:

✓ Consulting – Clinical Investigator for Arsenal Medical

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest
EVAR has higher reintervention rates than OSR

- Higher re-intervention rate reduces the benefit of EVAR compared to OSR over the long term
  - Imaging surveillance costs\(^1\)
  - Exposure to radiation and contrast nephropathy\(^2,3\)

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Endoleaks are the Main Cause of EVAR Reinterventions

- Up to 60% of reinterventions are caused by endoleaks\(^1\)
- Up to 70% of endoleak reinterventions are caused by Type 2\(^1\)

\(^1\)Mehta J Vasc Surg 2010

Reintervention Strategies for Type 2 endoleaks have high failure rates

- Sac growth continues in 42-56% of patients after reintervention\(^1,2\)

- 19% and 38% failure rates with translumbar and transarterial embolization, respectively\(^3\)

- 28-40% of Type 2 endoleaks require multiple interventions\(^1,2\)

- 11/35 (31%) of patients with reintervention for Type 2 required late conversion to open surgery\(^1\)

Endovascular aneurysm sealing

Prophylactic branch and/or partial sac embolization\textsuperscript{1, 2}

- Significantly lower freedom from Type 2 endoleaks
  - at 6 months, but not long-term
  - no survival benefit
- 10% of patients receiving pre-EVAR embolization exhibited sac growth

\textsuperscript{1}Piazza et. al. J Vasc Surg 2013; \textsuperscript{2}Ronsivalle, et. al. J Endovasc Ther. 2010; \textsuperscript{3}Bockler et. al. J Vasc Surg 2015
Endovascular aneurysm sealing

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Nellix EVAS technology\(^3\)

- Early learning curve experience in challenging anatomic group
- Type 2 endoleak rate of 2%!
- 91% freedom from reintervention at 17 months mean follow up

Reductions in post-EVAR reintervention rates may be realised with sac sealing and stabilization technologies

Sac Sealing Product for Aortic Aneurysms
- Funded by Medtronic plc

ResQFoam for incompressible hemorrhage
- United States Military funding
Arsenal Sac Sealing Product: Proposed Clinical Benefits

Reduce Type 2 endoleaks rates
- Completely seal the entire sac
- Penetrate and occlude branch vessels
- Preserve the ability to re-intervene when necessary

Stabilize the sac and stent graft
- Reduce risk of Type 3 endoleaks and migration with type 1 endoleaks

Long term goal to reduce the need for surveillance
Arsenal Sac Sealing Product Concept

- Build upon the performance of clinically proven stent grafts
- Direct filling of the aneurysm sac after graft placement
- Not limited by aneurysm geometry
Product Design Features

- Implant material engineered specifically for sac sealing
  - Room temperature storage
  - Limited on-site preparation
- Catheter tracked into the aneurysm (after the graft deployed) through a pre-existing sheath placed initially in the aneurysm sac
- Physician initiated automated injection (fill time 3 - 7 minutes depending on blood volume)
- Automatically stops when sac sealing complete
Polymer properties engineered for Sac Sealing

Thick, flowable dispensed material
Fills and Seals the excluded aneurysm sac

- Material flows into open areas around stent graft
- Forms a skin as the outer layer solidifies
- Forms a durable, elastic solid implant

*Simulated Type 2b endoleak: IMA inflow, lumbar outflow*
Comprehensive testing in difficult geometries

- Broad range of aneurysm geometries
- Simulated branch vessel flows

Small to Large aneurysm volumes

Multiple branch vessel geometries

Hostile necks
Automatic fill is consistent

<table>
<thead>
<tr>
<th>Small to Large Aneurysm Volume</th>
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<td>Varying Injection Location</td>
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<td>Hostile Necks 60-75°, 10-15mm</td>
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- Hostile Necks 60-75°, 10-15mm
- Simulated Type II Endoleak
Preparing for First in Human Studies

- Optimized to maintain graft visibility

- Biocompatibility studies underway

- First in Human clinical study late 2017
Conclusions

- Increasing awareness that T2EL and long term durability of conventional EVAR is problematic

- Direct treatment of the aneurysm sac may (replicating open surgical repair) address these issues

- Arsenal sac sealing product offers the potential to seal the aneurysm sac after conventional EVAR with proven stent grafts

- Early clinical experience expected late 2017
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