Single Center Experience With The Ovation Stent Graft For EVAR: Advantages, Limitations And Use With Chimney Grafts

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Disclosure
- Speaker name: Venkatesh Ramaiah, MD, FACS
- Signature: 
- I have the following potential conflicts of interest to report:
  - Consulting – Endologix Medical Educator
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s) – National Co-Principal Investigator LIFE Study
- I do not have any potential conflict of interest

Ovation iX

14F OD
Ultra-low profile system enables smooth access to the aneurysm
Staged deployment of suprarenal stent allows simple, precise placement
Polymer-filled sealing ring creates a custom seal and protects the aortic neck
Low permeability PTFE enables effective aneurysm exclusion and device patency
Conformable, kink resistant iliac limbs designed to reduce risk of occlusion
Cross-Over Lumen
Facilitates reliable contralateral gate access even in challenging anatomies

O-Ring Sealing Technology

O-Ring Sealing in Aorta
O-rings are designed to seal by blocking the flow of blood between two closely spaced surfaces
- O-rings are designed to seal by blocking the flow of blood between aortic wall and graft
- O-ring designed to conform to irregular luminal surface in aortic neck
- O-ring insulates aortic neck from blood pressure

Calcified Neck

Self Expanding Stent Graft
Polymer in sealing orifice reduces leak rate, allowing stem to dilate without increasing graft diameter
Ovation Abdominal Stent Graft
Polymer in sealing orifice reduces leak rate, allowing stem to dilate without increasing graft diameter

Reverse Taper

Self Expanding Stent Graft
Ovation Abdominal Stent Graft
Chronic outward force from oversized stent, combined with balloon pressures can result in wall dilatation and early intimal hyperplasia
Ovation Platform Protects the Aortic Neck

Ovation Global Pivotal study demonstrates encouraging results with stable neck diameter and expands well through a variety due to the unique sealing ring technology which reduces the chronic outward force and insulates the neck from blood pressure.

Aortic Neck Dilatation Over Time

- Baseline
- 1 Year Growth
- 2 Year Growth
- 3 Year Growth
- 4 Year Growth

Proximal Neck diameter average expansion (mm)

Ovation System

Novel Design Paradigm

The Ovation System is comprised of two key components delivered sequentially:
1. Suprarenal stent with integral anchors deployed in stages to secure the system and reduce the risk of migration
2. Biocompatible polymer delivered to inflate novel sealing rings for a robust and conformable seal

The Ovation Experience at Arizona Heart

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The Ovation System at Arizona Heart
- First experience Feb 8th 2013
- 293 grafts implanted to date
  - 100% technical success
- Initial interest in Ovation System:
  - Short, challenging necks
  - Tight, calcified and tortuous access

86 yr old 7cm AAA /COPD/PVD/CAD/Cr 3.4

Short Neck
87yr old with Contained Ruptured AAA

Severely Calcified Vessels

Unable to Cross R iliac

Options / Profiles

Ovation at AZ Heart - Results

293 grafts implanted to date, 41% had neck lengths 10mm or less, 36% had access vessels less than 6mm

- One groin complication (pseudo aneurysm) resolved with ultrasound guided injection of thrombin.
- 1 External Iliac Artery complication (minor rupture due to predilatation) treated by covering with Iliac Limb
- Five intra-operative Type IA endoleaks in extremely challenging cases. All endoleaks were treated & resolved at initial implantation.
  - Four by placing a Palmaz stent
  - One resolved by Palmaz Stent and placing coils between the proximal and distal sealing rings.
AZ Heart Case Study

- 77 year old male
- 8.5 cm symptomatic aneurysm

Significant juxtarenal angle of 77° at IR+13. Vessel dilates between IR+13 and IR+16. Accurate deployment is essential. Calcium and thrombus noted in seal zone.

Length to hypogastrics long bilaterally

Proximal Right common iliac aneurysmal

AZ Heart Case Study

6 Month Follow-up

Ovation System at AZ Heart Results

293 patients treated with Ovation. 283 have completed 1yr follow up

100% Technical Success
100% Freedom From Endoleaks Type I / II / III
100% Freedom From Migration
100% Freedom From Conversion
100% Freedom From Rupture
99.5% Freedom From Limb Occlusions
  • (1) limb occlusion, secondary to CFA/Closure
98.6% Freedom From Secondary Procedures
  • (1) Dissection of EIA distal to graft
  • (1) Trans metatarsal amputation
  • (1) Bilateral fasciotomy secondary to previously placed occluded endograft – graft was relined with Ovation

The Workhorse System

Versatility of the Ovation Prime® System in challenging and straightforward anatomies.

Facilitate EVAR for Off-Label Aneurysmal Necks in Urgent Setting and/or High Risk Patients

The Ovation® System has not been approved in any geography for treatment of this application.
Double Chimney/Vent Procedure

82 yo male, 9cm Abd Aneurysm

Pre-op Planning

18 months Post-implant

Is Polymer Sealing a Better Platform for Chimneys/Parallel Grafts??
78 yr old, 7cm AAA

75 yr old, 6.5 cm Juxta Renal AAA

76 yr old, short/angled AAA neck

8 cm AAA, Calcified distal aorta

6.5 cm Juxtarenal AAA
6cm Juxtarenal AAA, severe calcified access

AZ Heart Ovation Results: Chimney

1 patients treated with Ovation from 2013 to date

100% Technical Success
100% Freedom From Type 1a Endoleaks ("gutter" endoleak)
100% Freedom From Endoleak Type I / III / IV
100% Freedom From Conversion
100% Freedom From Rupture
100% Freedom From Limb Occlusions
2 renal stenosis/occlusions, secondary renal stenting

Chimney Procedures: Stroke and Renal Complications

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Chimney Procedures

- Patient Selection
  - Deciding between infrarenal EVAR and Chimney EVAR
- Technique
  - Arm access
  - Chimney stents: iCAST, Viabahn
  - Simultaneous balloon inflation kissing deployment with polymer ring

EVAS and Parallel Grafts

Future: Combination of Current Polymer Technology