Mass General Brigham

Update on the 3D Radiation Free Electromagnetic IOPS from Centerline: New Developments Advantages and Limitations

Matthew J. Eagleton, MD
Chief, Vascular and Endovascular Surgery MGB
Robert Linton Professor of Surgery, HMS

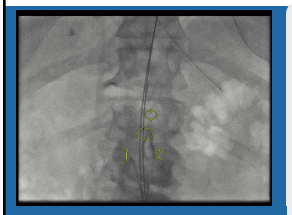
VEITH Symposium 2024
November 19, 2024

Disclosures

- Chair, Scientific Advisory Board for Centerline Biomedical

Clinical and Safety Issue

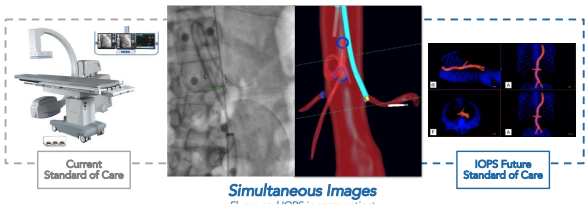
Imaging Systems Lacks Visualization and Exposes Radiation Risk



- Poor visualization and navigation
- Increased procedure times
- Contrast media is harmful to patients
- X-ray fluoroscopy subjects caregivers to radiation exposure

IOPS® Intra-Operative Positioning System

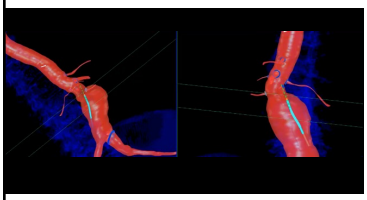
3D image guidance to enhance navigation and reduce dependency on fluoroscopy during interventions



Simultaneous Images
Fluoro and IOPS in same patient

IOPS Advantage

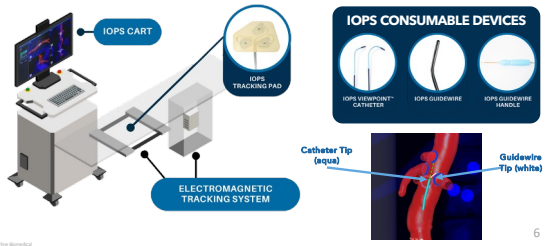
Enhanced Real-time Navigation to Mitigate Procedure Time and Radiation Exposure



- **3D visualization** with real-time, multi-color guidewire and catheter tracking
- Improves **procedure times and costs** from enhanced navigation
- Mitigates **radiation exposure** and contrast dye use

IOPS System

Seamlessly Integrates into Existing OR Setup

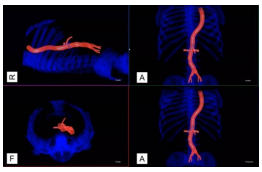


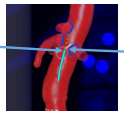
Clinical Experience

Centerline Biomedical

IOPS 3D Display and Vessel Map

Structural vessel map prepared from pre-op CTA Image registration performed using cone beam CT





8

Clinical Experience

Gaining Significant Recognition in Publications and Presentations

6 Peer Reviewed Journal Publications

40+ Scientific Presentations

Multi-Center Safety & Efficacy Study

MOTION clinical study proves safety & efficacy

Methodology

Multicenter, **O**pen Label, Prospec**T**ive Performance and Safety Study of the **I**ntra-**O**perative Positioning System During E**N**dovascular Repair Procedures

- 30 patients enrolled
  - Cleveland Clinic Foundation (n=20)
  - University of North Carolina (n=10)
- Time points
  - Intraoperative
  - Prior to discharge
  - 10 days post-op
- Patient event monitoring
  - Serious adverse events
  - Non-serious adverse events

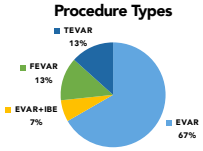
10

MOTION study proved safety and efficacy

Demographics

- Mean age 75 ±8.2
- 83% white, 80% men
- Comorbidities:
  - CAD: 67%
  - HTN: 90%

Procedure Types



Safety and Efficacy

- 100% technical success
- Zero serious adverse events
- Zero non-serious adverse events

Conclusion

IOPS is safe and effective as an adjunct to fluoroscopic guidance; further research is required regarding potential for decreased radiation, contrast, and operative time.

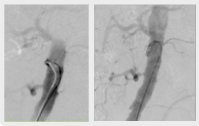
11

Clinical Experience

Reduced Procedure Time, Radiation Exposure, and Contrast Dose

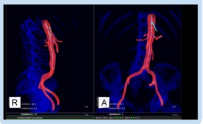
Case 1: Without IOPS

- Difficulty cannulating SMA
- 33.4 mins. of fluoro
- 1,294 mGy
- 100 ml of contrast deployed
- OR Time: 3 hours 12 minutes



Case 2: With IOPS

- SMA cannulated in < 40 seconds
- 10.9 mins. of fluoro
- 326 mGy
- 10 ml of contrast deployed
- OR Time: 1 hour 20 minutes



CONCLUSION

- **67% Less** X-Ray Time
- **75% Less** Exposed Radiation
- **~2 Hrs Less** OR Time
- **90% Less** Contrast Use

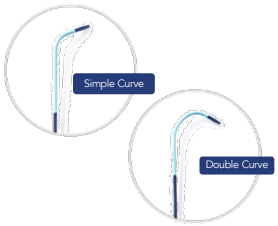
IOPS Portfolio Development

Centerline Biomedical

Next-Gen 6Fr Viewpoint™ Catheters
Designed to Accommodate Procedure Needs

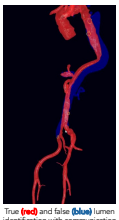
viewpoint

- FDA 510(k) cleared
- 6 French profile
- 0.035" guidewire compatibility
- Simple and Double curve tip shapes
- 75cm and 125cm lengths

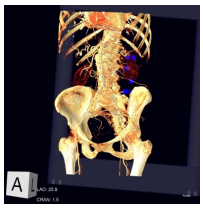


14

IOPS Software Version 1.5 and Spintegration™
Advanced mapping capabilities, including of dissections and calcified plaque



True (red) and false (blue) lumen identification with communication between lumens (yellow circles)

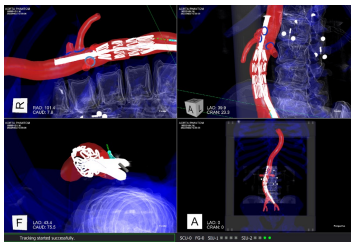


Vessel and calcified plaque mapping

15

IOPS Software Version 1.5 and Spintegration™
Mid-case spin displays deployed device within the anatomical model

Fenestrated endograft mapped with Spintegration



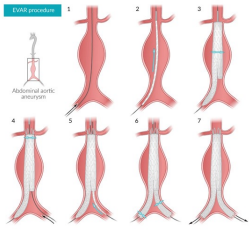
Four simultaneous projections of endograft using Spintegration

Recent Clinical Applications
6Fr Viewpoint Catheter and Spintegration

Centerline Biomedical

18

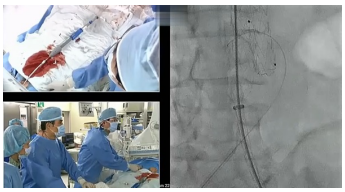
Clinical Experience: Viewpoint 6Fr & Spintegration™
Use for EVAR device gate cannulation



EVAR Procedure
1. Wire access
2. Main graft placement
3. Main graft deployment
4. **Gate cannulation**
5. Limb graft placement
6. Limb graft deployment
7. Wire removal

Clinical Experience: Viewpoint 6Fr & Spintegration™

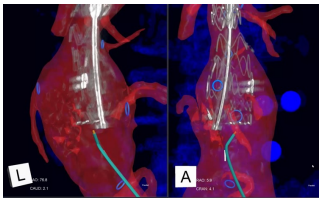
Example of the procedural challenge to gate cannulation



VG

Clinical Experience: Viewpoint 6Fr & Spintegration

University of Virginia – Dr. Behzad Farivar and Dr. Erin Buchanan



VG

Conclusion

Advantages of IOPS

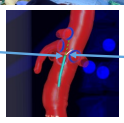
- Non-radiation based high-frame-rate navigation system
- Intelligent sensorized IOPS Guidewire and Catheters, also compatible with other 0.035" devices
- Removable Guidewire Handle supports backloading and catheter exchange
- Portable, mobile cart able to move between rooms
- Compatible with all available fixed imaging systems
- Advanced capabilities to build 3D, multi-color models of patient anatomy from existing CT scans
- Allows the position and orientation of the catheters, guidewires and implanted devices to be shown inside the 3D vessel images in real time
- Spintegration enables 3D intraoperative image updates

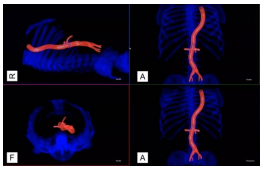
22

Thank you.

IOPS 3D Display and Vessel Map

Structural vessel map prepared from pre-op CTA Image registration performed using cone beam CT





30