# Near Infrared Spectrometry (NIRS) monitoring is much simpler than MEP's

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**Professor of Surgery**

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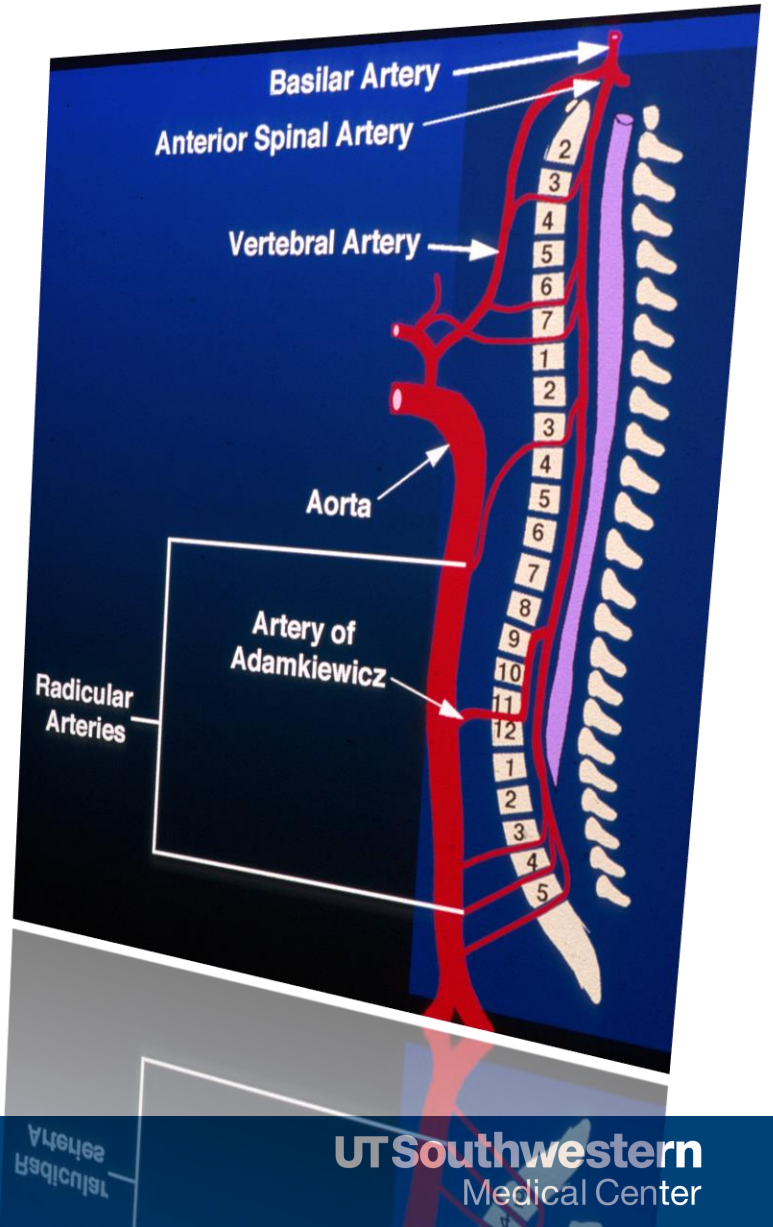
# Extraordinary times

# Disclosure

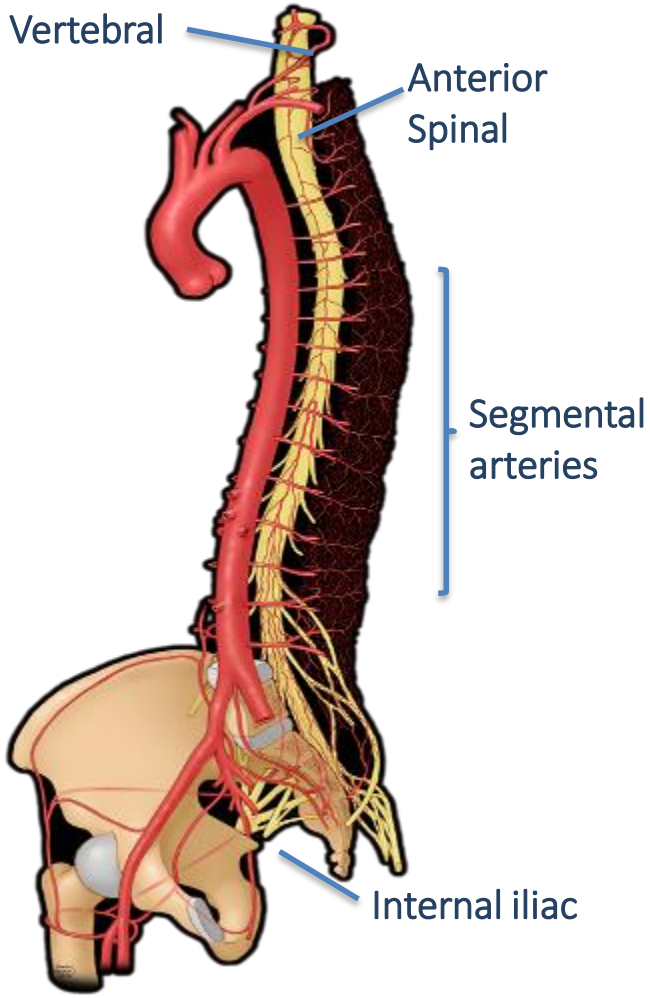
- Honoraria / Consultant / Research
  - W.L. Gore
  - Cook Medical Inc
- Some devices presented here are investigational and have have not been approved by the FDA
- Acknowledgement
  - Gustavo Oderich, MD
    Mayo Clinic, Rochester, MN, USA
  - Darren Schneider, MD
    Weill Cornell – New York-Presbyterian, New York, NY, USA

# Spinal cord ischemia (SCI)

- Spinal cord ischemia (SCI) is a devastating complication after open and endovascular repair of thoracoabdominal aortic aneurysms (TAAA)
- Spinal drains are routinely used to ameliorate the frequency and severity of SCI, but their use may result in inherent morbidity and mortality

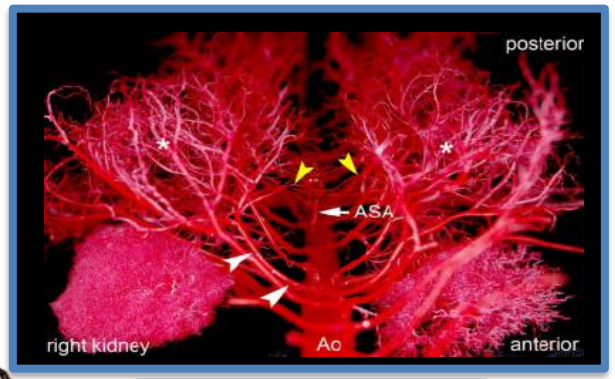


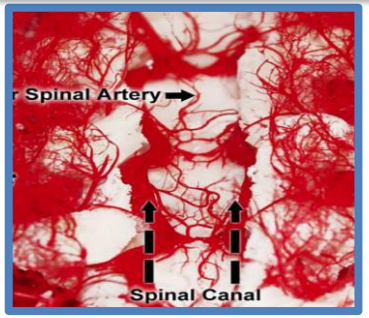
# Spinal Cord Perfusion

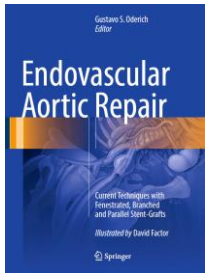




Paraspinal musculature




***Randal Griepp (multiple sources)***

***Oderich 2017***

# IONM (MEP & SSEP) for F/BEVAR

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

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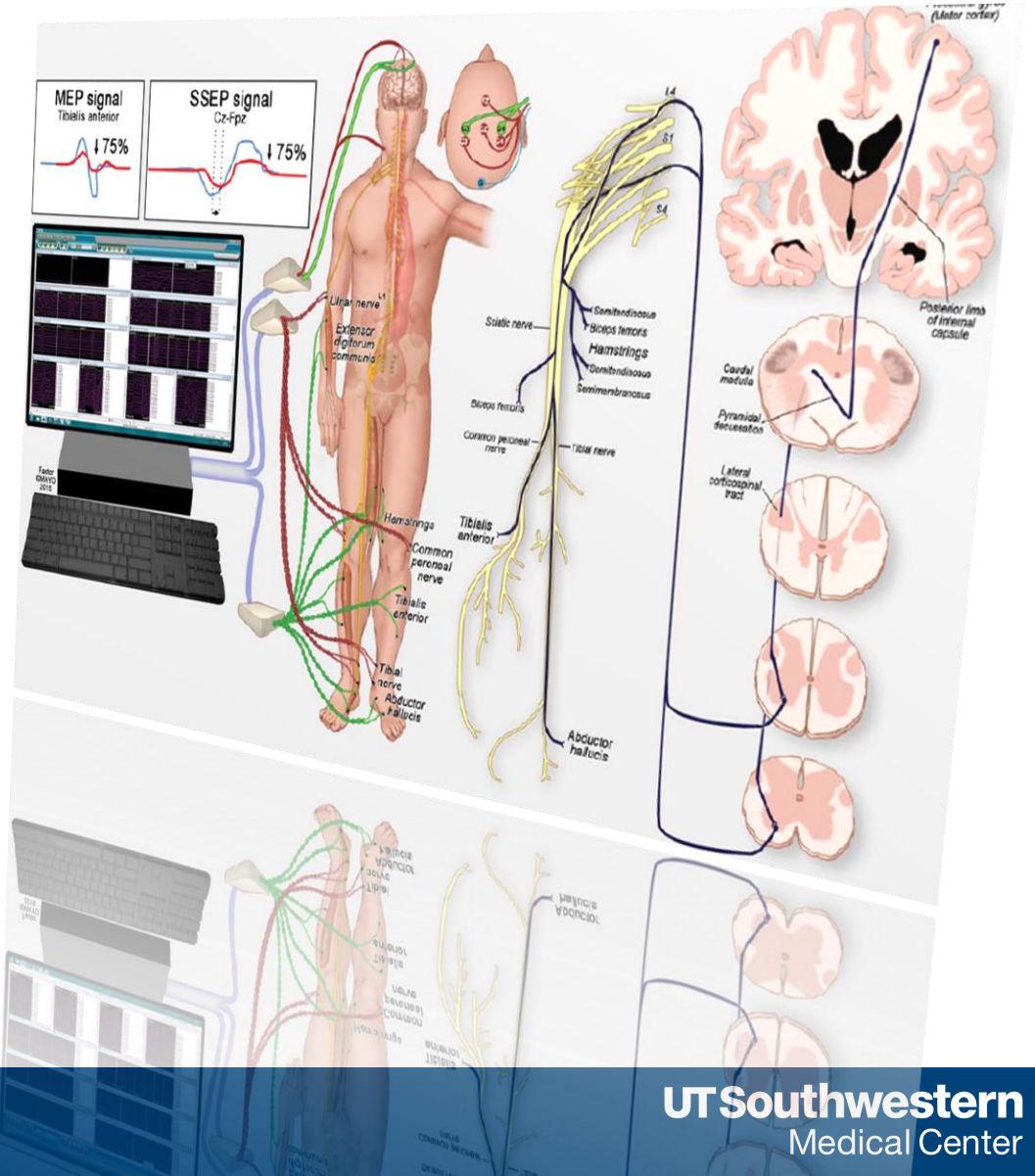
**Neuromonitoring, Cerebrospinal Fluid Drainage, and Selective Use of Iliofemoral Conduits to Minimize Risk of Spinal Cord Injury During Complex Endovascular Aortic Repair**

Peter V. Banga, MD[1,2], Gustavo S. Oderich, MD[1], Leonardo Reis de Souza, MD[1,3], Jan Hofer, RN[1], Meaghan L. Cazares Gonzalez, R.NCS.T[4], Juan N. Pulido, MD[5], Stephen Cha, MS[6], and Peter Gloviczki, MD[1]

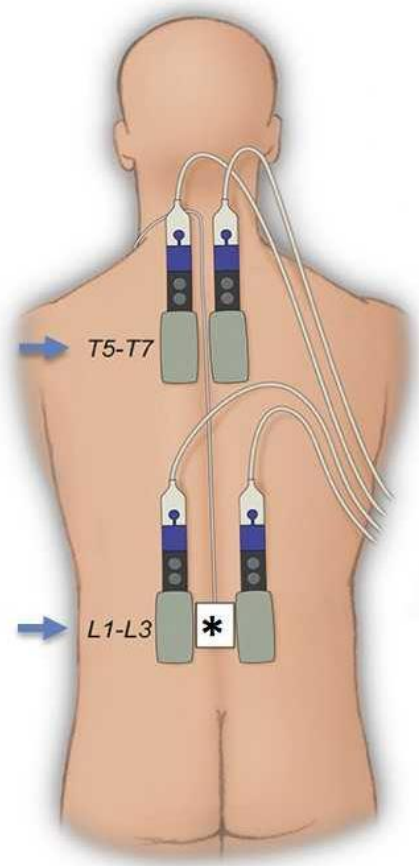


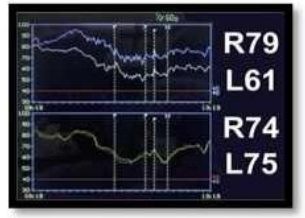

- 49 pts (90%, TAAAs)→<u>All CSF drainage</u>
- SCI, 3 pts (6%)
- 63%→>75%↓ MEP/SSEP amplitude
- MEP/SSEP back to baseline but in 1 pt

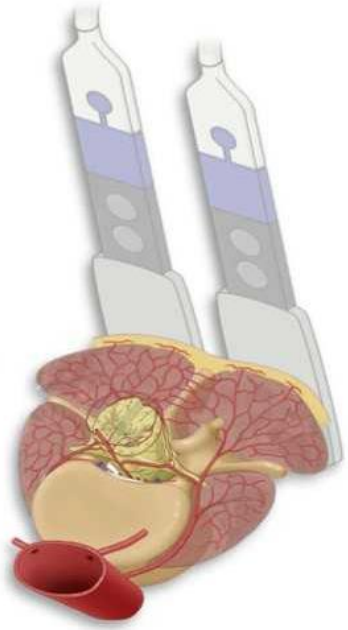
**J Endovasc Ther. 2016;23:139-49**

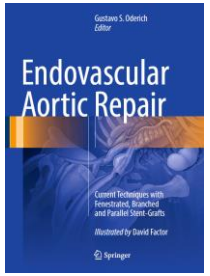
# Near InfraRed Spectroscopy (NIRS)

- NIRS measures transcutaneous tissue oxygenation
- Paraspinous muscle $O^2$ saturation is a reflection of spinal cord collateral network perfusion



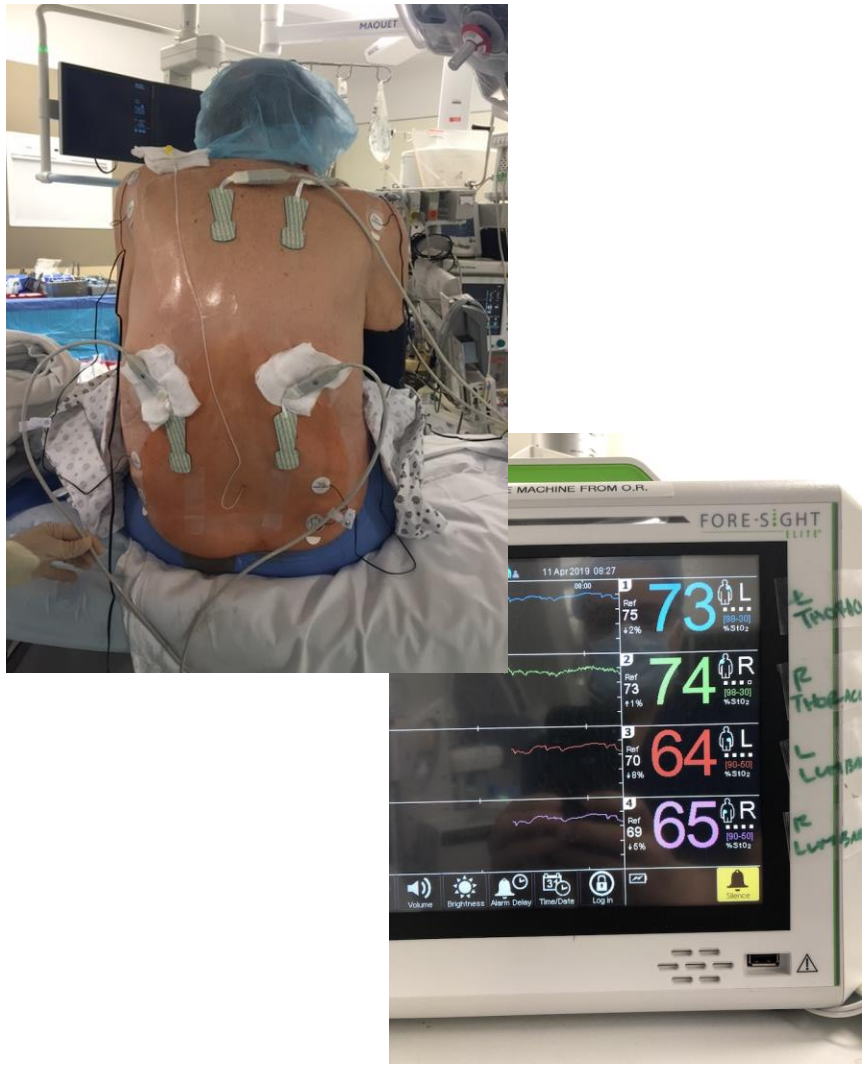






*Oderich 2017*

# NIRS Advantages

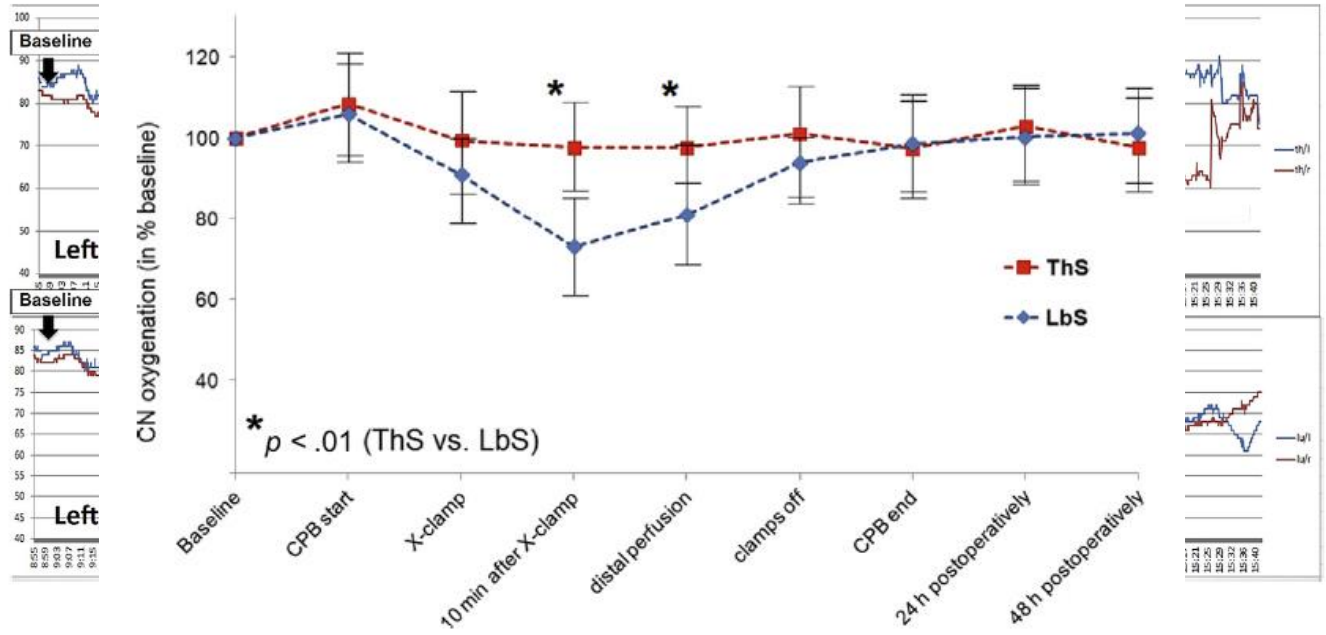
- Non-invasive
- Widely available and low cost
- Lower extremity ischemia and anesthetics don't interfere with monitoring
- No need for specialized interpretation
- Postoperative monitoring & early changes detection



# Near-infrared Spectroscopy Monitoring of the Collateral Network Prior to, During, and After Thoracoabdominal Aortic Repair: A Pilot Study

C.D. Etz [a,b,*,d], K. von Aspern [a,d], S. Gudehus [c], M. Luehr [a], F.F. Girrbach [a], J. Ender [c], M. Borger [a], F.W. Mohr [a]

[a] Department of Cardiac Surgery, University of Leipzig, Heart Center Leipzig, Saxony, Germany
[b] Department of Cardiothoracic Surgery, Mount Sinai School of Medicine, New York, NY, USA
[c] Department of Anesthesiology, University of Leipzig, Heart Center Leipzig, Saxony, Germany


- Aortic cross clamp and CPB change lumbar CN perfusion
- SCI associated with greater reduction in saturations

***Etz, et al. Eur J Vasc Endovasc Surg 2013***

# Spinal Drain Complications

## Cerebrospinal fluid drainage complications during first stage and completion fenestrated-branched endovascular aortic repair

Jussi M. Kärkkäinen, MD, PhD,[a] Nolan C. Cirillo-Penn, MD,[a] Indrani Sen, MD,[a] Emanuel R. Tenorio, MD, PhD,[a] William J. Mauermann, MD,[b] George D. Gilkey, MD,[b] Timothy J. Kaufmann, MD, MS,[c] *and* Gustavo S. Oderich, MD,[a] *Rochester, Minn*

187 pts with 240 endovascular procedures with CSF drain

| CSFD-related complications | n | % / patients |
|---|---|---|
| Any complication | 21 | 10 |
| Severe | 8 | 4 |
| Moderate | 9 | 5 |
| Minor | 4 | 1 |

# Spinal cord protection protocol:

Elective Fenestrated and Branched Endovascular Thoraco-abdominal Aortic Repair with Supracoeliac Sealing Zones and without Prophylactic Cerebrospinal Fluid Drainage: Early and Medium-term Outcomes

Maciej T. Juszczak, Anna Murray, Andreas Koutsoumpelis, Massimo Vezzosi, Jorge Mascaro, Martin Claridge, Donald J. Adam

**Table 1. In house spinal cord protection protocol**

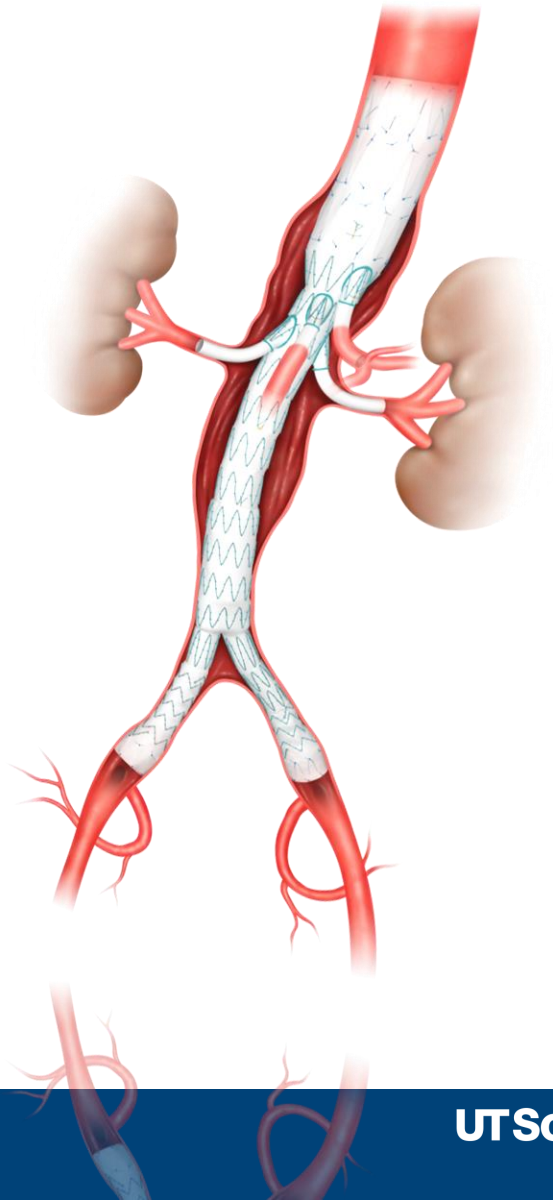
| |
|---|
| Stop antihypertensive medication three days before operation |
| Preserve antegrade perfusion of left subclavian and at least one hypogastric artery |
| Minimise embolisation during graft manipulation |
| Minimise lower limb ischaemia–reperfusion injury (early removal of delivery sheaths, separate sheaths for target vessel cannulation, pre-loaded devices) |
| Minimise intra-operative blood loss and post-operative risk of GI haemorrhage (PPI) |
| Staged procedures where appropriate (based on extent of coverage and spinal collateral network) |
| Maintain MAP > 80 mmHg |
| Patient recumbent at 30° for 36 h minimum |
| CVP < 15 mmHg |
| Maintain oxygen delivery for entire hospital admission (Hb > 10, $pO_2$ > 9, $SaO_2$ > 95%) |
| Correct any coagulopathy (aim for platelet count > 100, PTR < 1.5) |
| Gradual mobilisation from 48 h and gradual re-introduction of antihypertensives |
| No prophylactic CSF drainage |

167 pts with proximal SC $\geq$ 40mm without prophylactic SCF drain
SCI 2 (1.2%) *p*=.001 [OR =19.9]

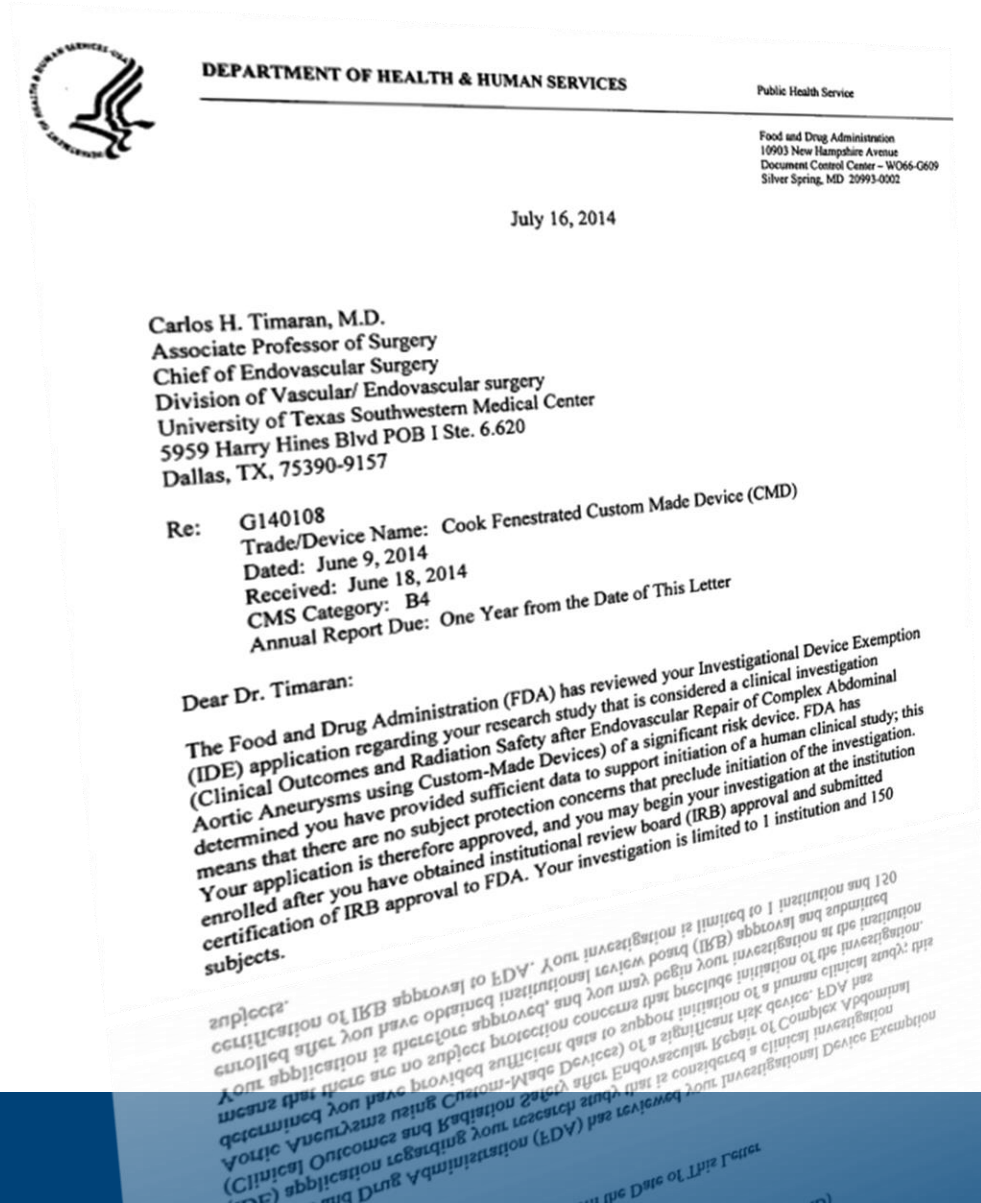
Eur J Vasc Endovasc Surg. 2019 May;57(5):639-648

# SCI after TAAA EVAR

- The need for or the effectiveness of spinal drains for TAAA EVAR has not been demonstrated.
- Initial experience of spinal cord protection without the routine use of spinal drains during TAAA EVAR using NIRS & IONM



# Physician-sponsored Investigational Device Exemption (IDE)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2014

Carlos H. Timaran, M.D.
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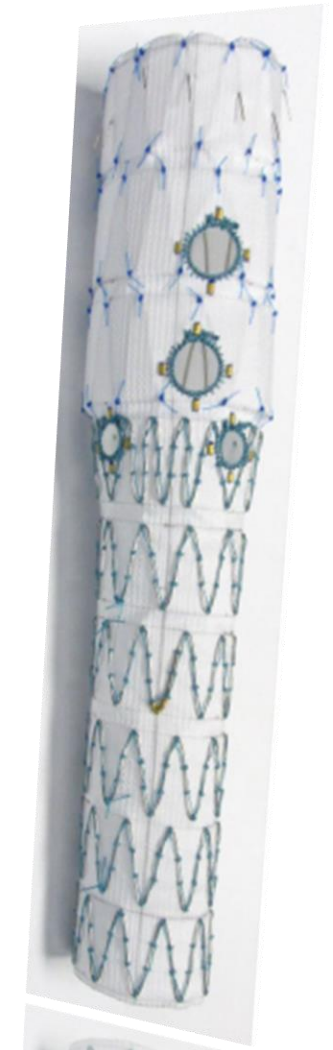
University of Texas Southwestern Medical Center
5959 Harry Hines Blvd POB I Ste. 6.620
Dallas, TX, 75390-9157

Re: G140108
Trade/Device Name: Cook Fenestrated Custom Made Device (CMD)
Dated: June 9, 2014
Received: June 18, 2014
CMS Category: B4
Annual Report Due: One Year from the Date of This Letter

Dear Dr. Timaran:

The Food and Drug Administration (FDA) has reviewed your Investigational Device Exemption (IDE) application regarding your research study that is considered a clinical investigation (Clinical Outcomes and Radiation Safety after Endovascular Repair of Complex Abdominal Aortic Aneurysms using Custom-Made Devices) of a significant risk device. FDA has determined you have provided sufficient data to support initiation of a human clinical study; this means that there are no subject protection concerns that preclude initiation of the investigation. Your application is therefore approved, and you may begin your investigation at the institution enrolled after you have obtained institutional review board (IRB) approval and submitted certification of IRB approval to FDA. Your investigation is limited to 1 institution and 150 subjects.



# IONM (MEP & SSEP) + NIRS for F/BEVAR

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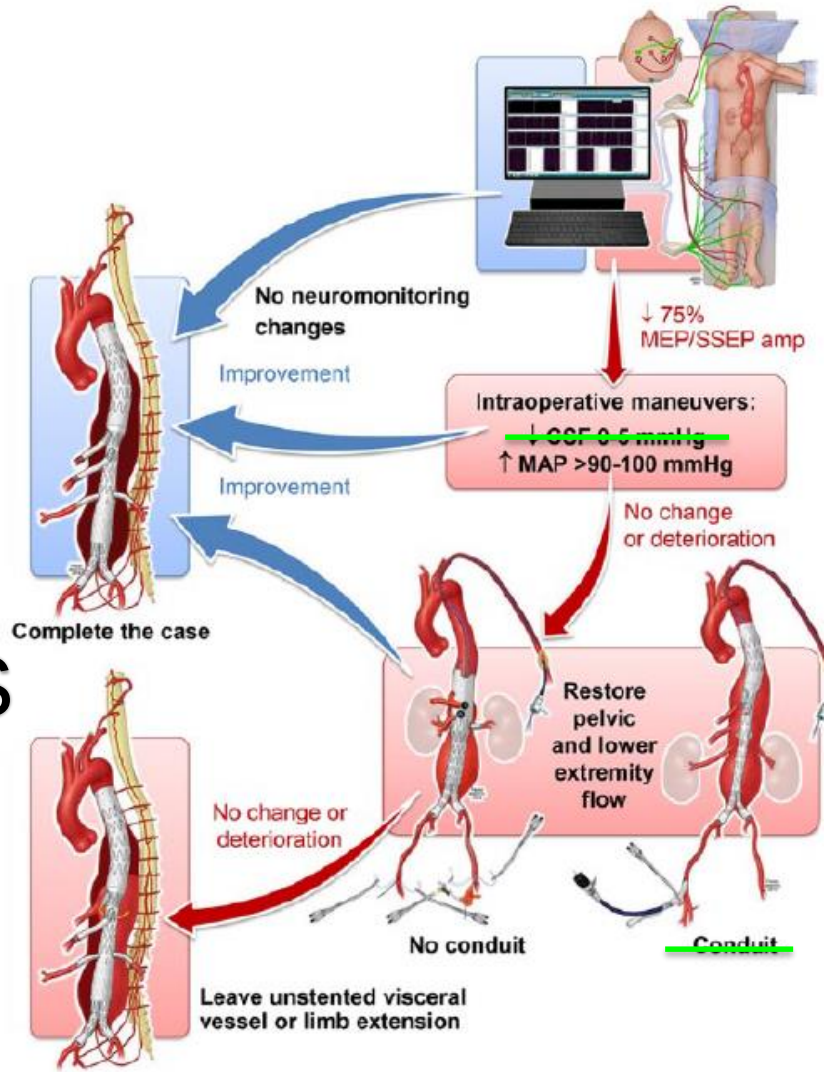
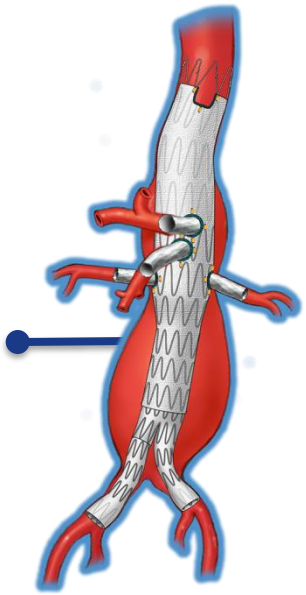
- No preop CSF drains
- CSF drains only for persistent NIRS &/or MEP deficits or symptoms
- Selective CSF drains for partial CN
- PQ access + early revasc



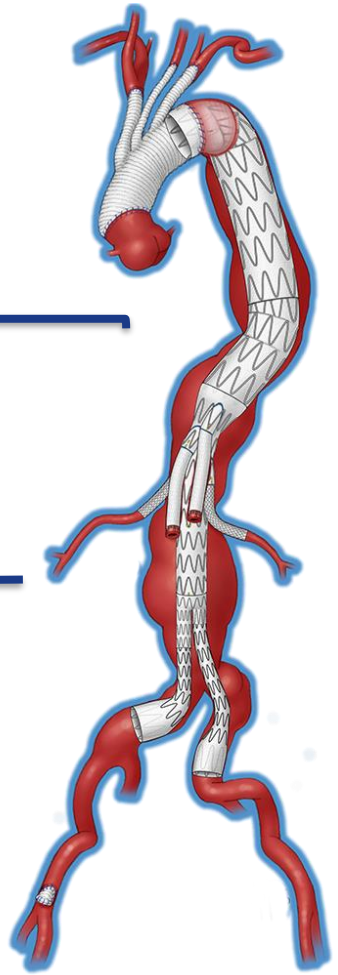
34 patients enrolled

All patients had IONM & NIRS (48 hrs)
selective spinal CSF drainage

10 Extent 4
TAAA (29%)



24 Extent 1-3
TAAA (71%)



Staged repair for all type I-III TAAAs

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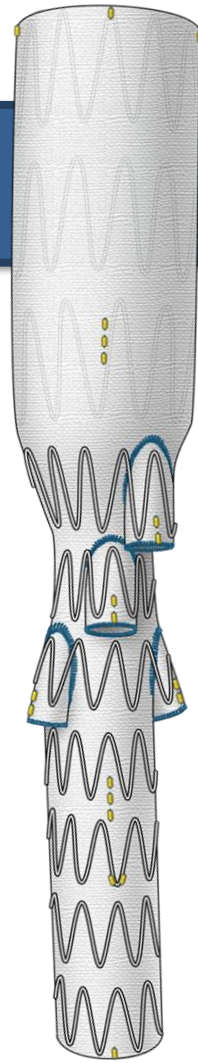
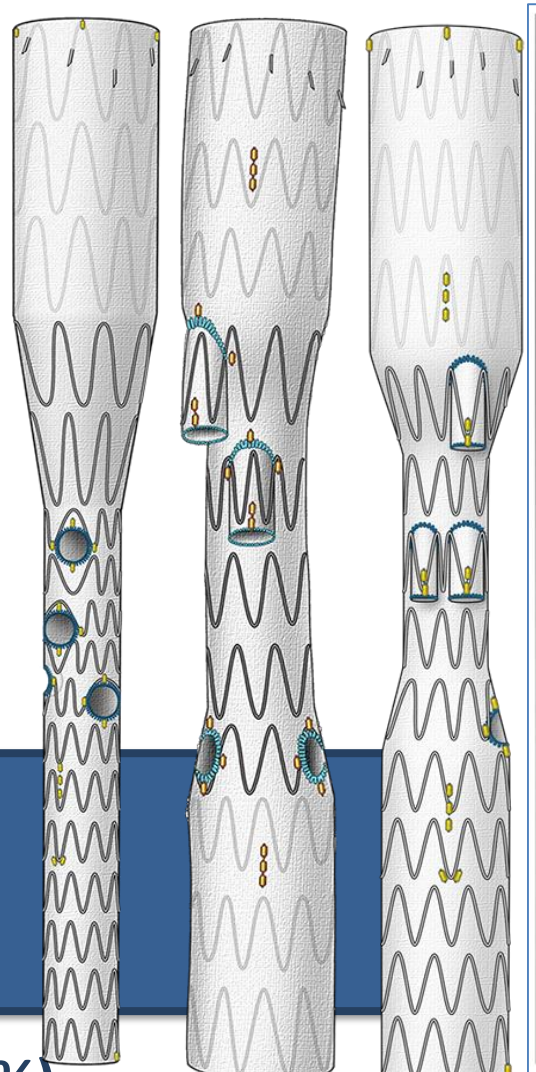
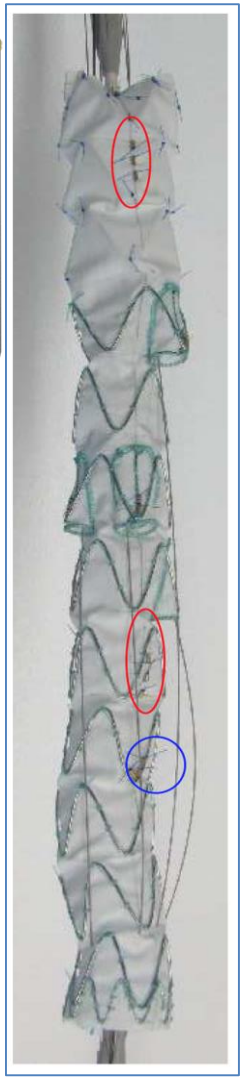
# Device design



**Off-the-shelf**
*(CMD/Cook t-Branch®)*

***n*** **= 7 (20%)**
**3.8±0.6**
**vessels/patient**



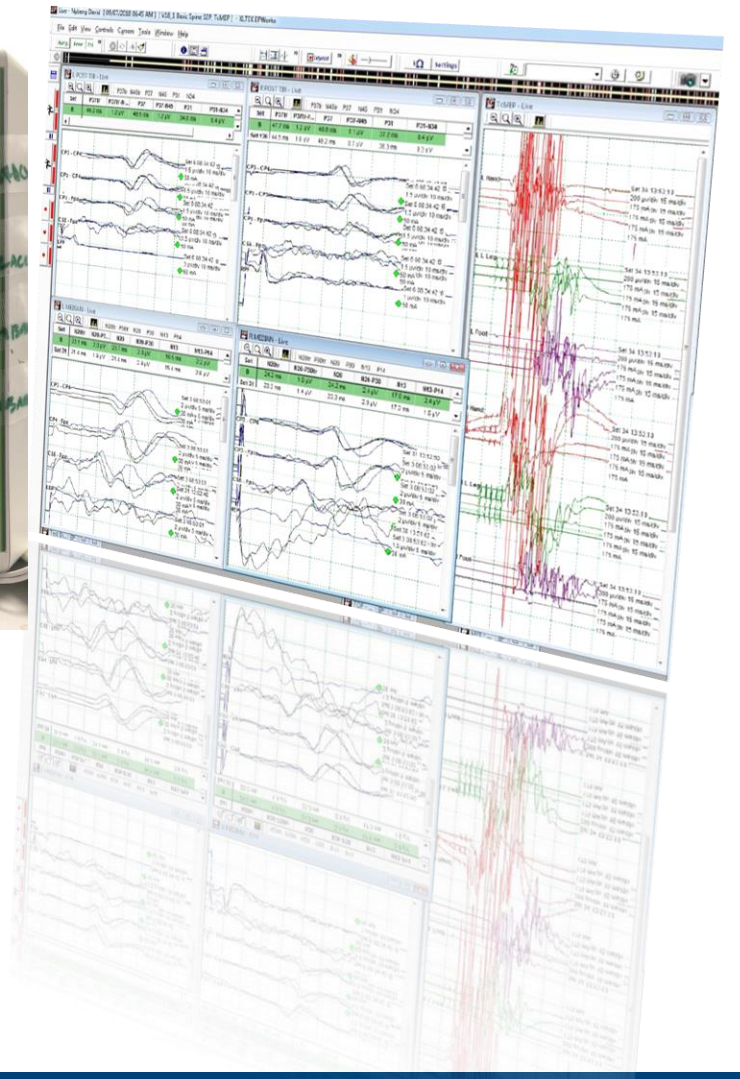


**CMDs**
*Fenestrations or branches*

***n*** **= 27 (80%)**
**3.8±0.5 vessels/patient**

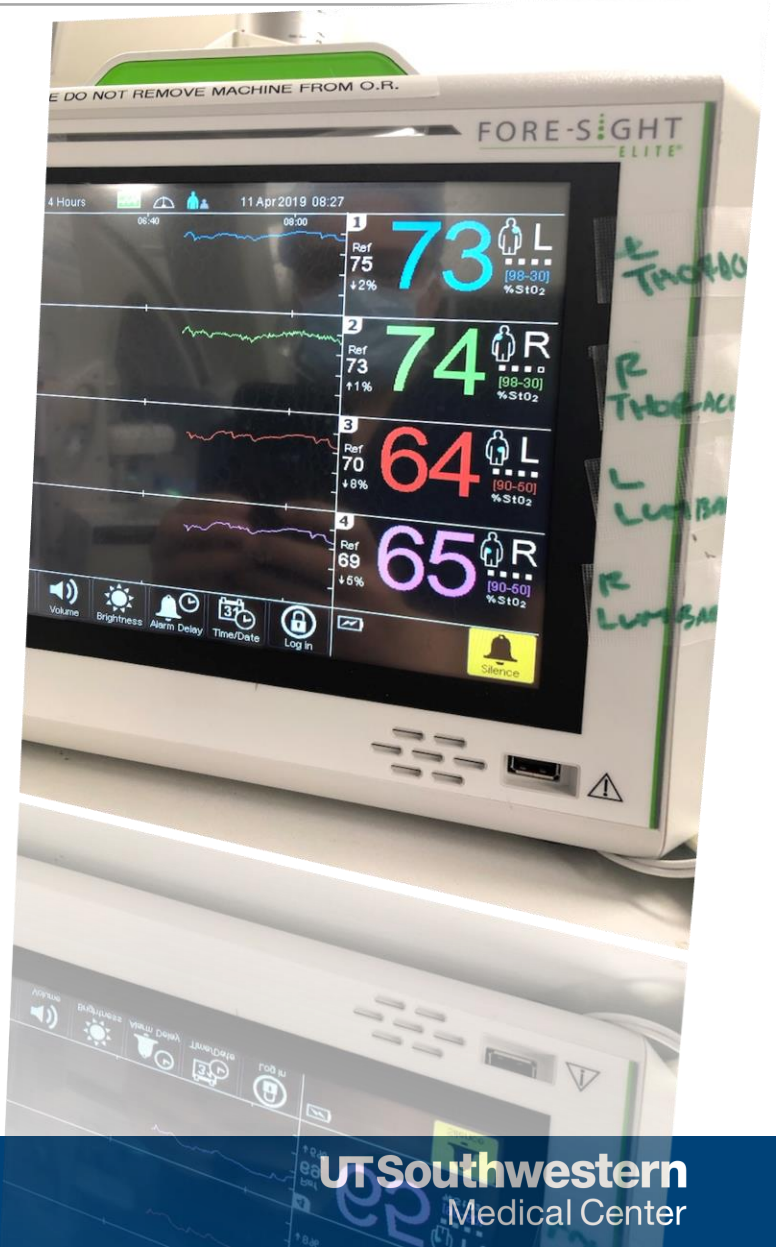
# NIRS + IONM & Selective Spinal Drain Use

- 34 patients (73%, male)
- 80%→>75%↓ MEP/SSEP amplitude
- No NIRS drop >20% in any patient (48 hrs)
- MEP/SSEP back to baseline but in 1 pt → Spinal drain placed → neuro intact

# IONM & Selective Spinal Drain Use

- One 30-day death (3%)
- Spinal CSF drain placed in 3 pts (9%)
  - 1 IOP for sustained ↓ MEP/SSEP
  - 2 preemptively (HA occlusion, deficit after 1st stage)
  - Paraplegia in 1 pt (3%) on POD 7 resolved with CSF drainage (DAPT)



# Conclusions

- F-BEVAR for TAAAs can be performed with low mortality and minimal risk of SCI without the need of routine spinal drains
- A standardized protocol that relies on perioperative maintenance of adequate arterial pressure is required.
- The use of NIRS (IONM) should be considered investigational
- Preliminary clinical data suggests NIRS may be a useful adjunct to monitor spinal cord collateral network perfusion during open TAAA repair
- Future studies are required to define the role and need of spinal drains for thoracoabdominal EVARs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