Surgery
UNIVERSITY OF TORONTO

CAVE
CENTRE FOR APPLIED VASCULAR ENGINEERING

FEVAR is the Best Treatment for Juxtarenal Aneurysms But There are Limitations

PACIFIC NORTHWEST ENDOVASCULAR CONFERENCE

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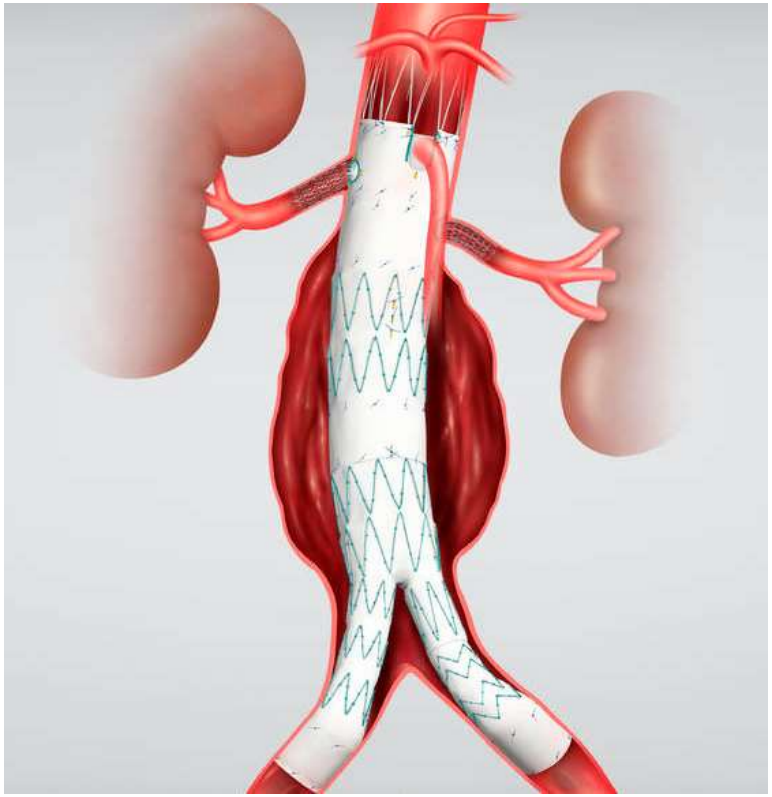
DISCLOSURE

Thomas L. Forbes, MD

- **Research Grants:** Cook Medical – Alpha Abdominal Graft

FENESTRATED STENT GRAFTS



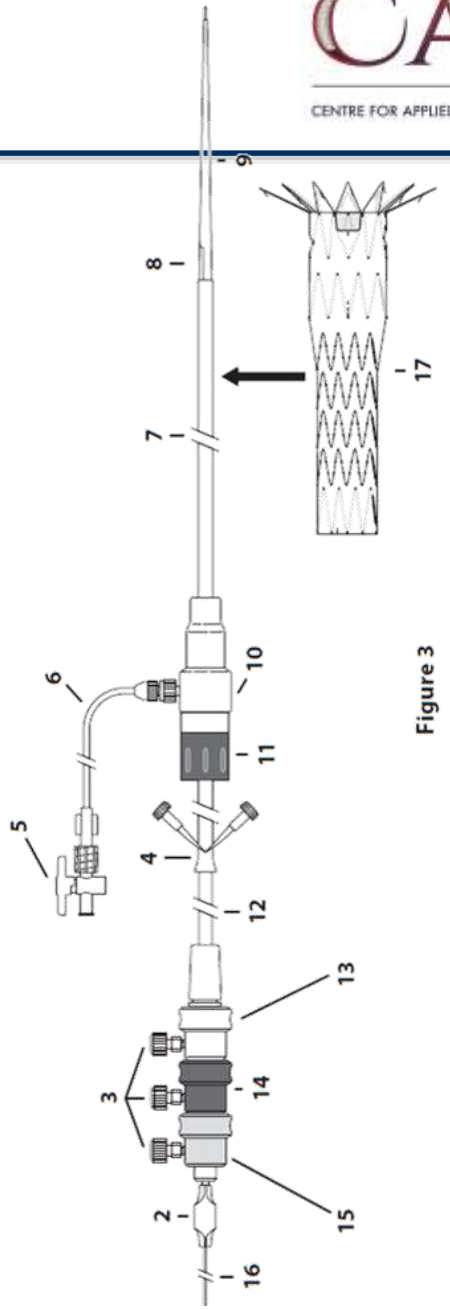
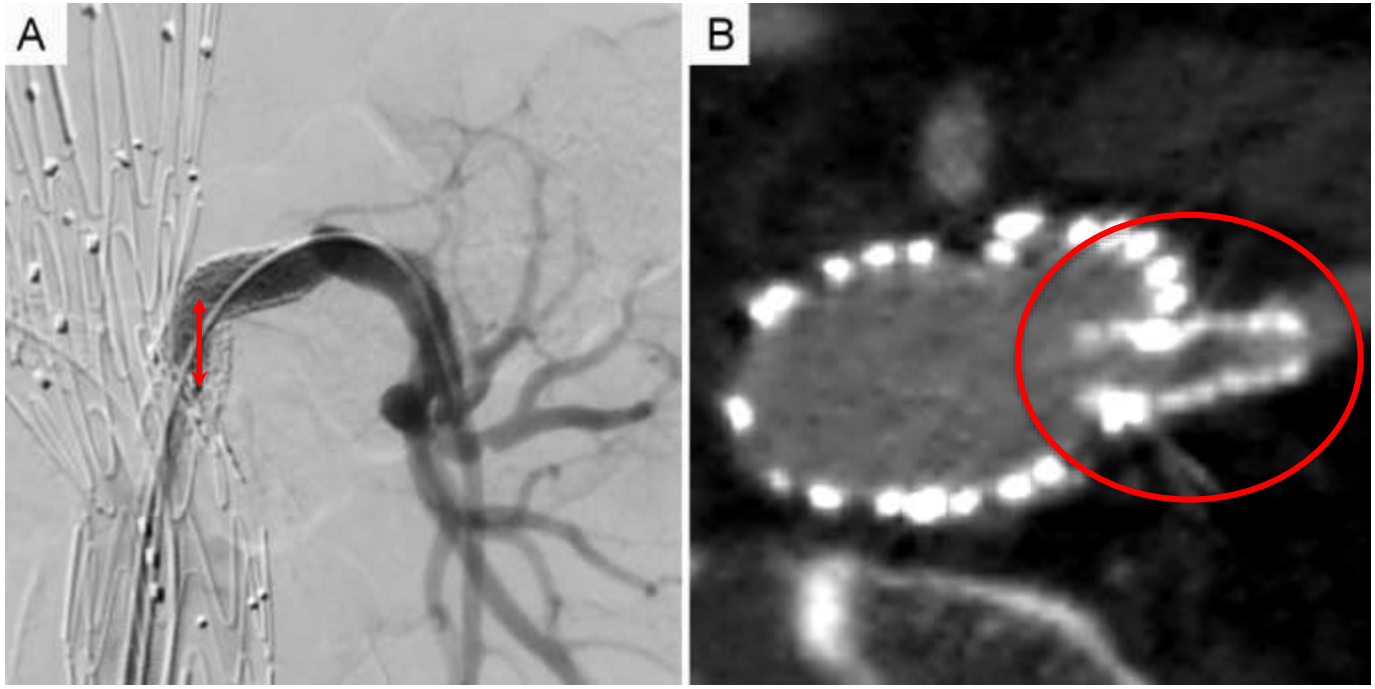


Figure 3

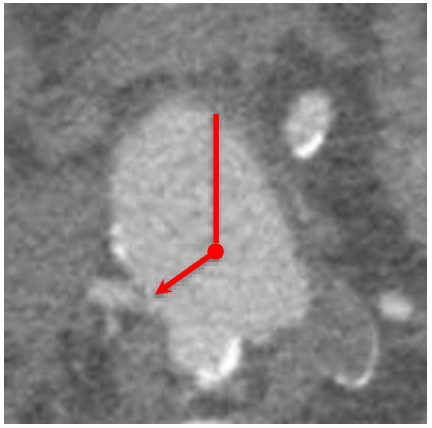
MISALIGNMENT

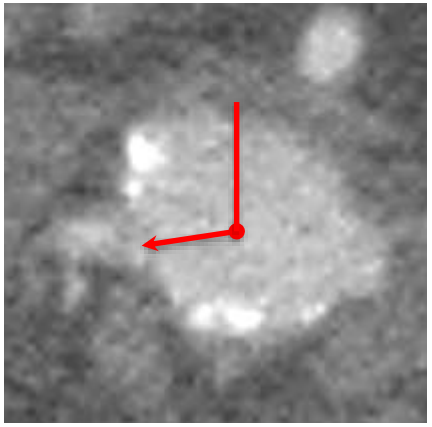
Vertical **Horizontal**



MISALIGNMENT

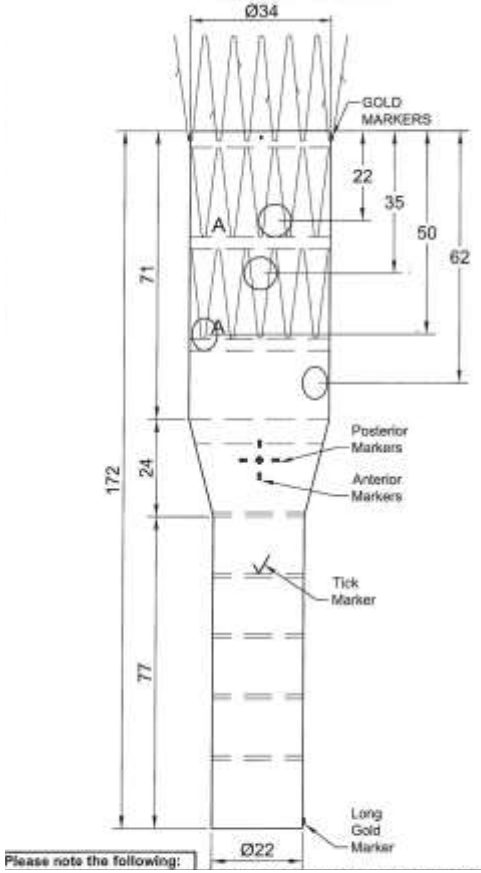
Stent Graft Planning





NON STANDARD DEVICE REQUEST PAGE 2 of 2

Version 2



REINFORCED LARGE FENESTRATION #1
Strut Free
DIAMETER: 8mm
DIST FROM PROX EDGE: 22mm
CLOCK: 12:45
IVD: 17mm

REINFORCED LARGE FENESTRATION #2
Strut Free
DIAMETER: 8mm
DIST FROM PROX EDGE: 35mm
CLOCK: 12:00
IVD: 24mm

REINFORCED SMALL FENESTRATION #1
WIDTH: 6mm
HEIGHT: 8mm
DIST FROM PROX EDGE: 50mm
CLOCK: 9:45
IVD: 25mm

REINFORCED SMALL FENESTRATION #2
WIDTH: 6mm
HEIGHT: 8mm
DIST FROM PROX EDGE: 62mm
CLOCK: 1:45
IVD: 33mm

- DOUBLE DIAMETER REDUCING TIES

Plus:

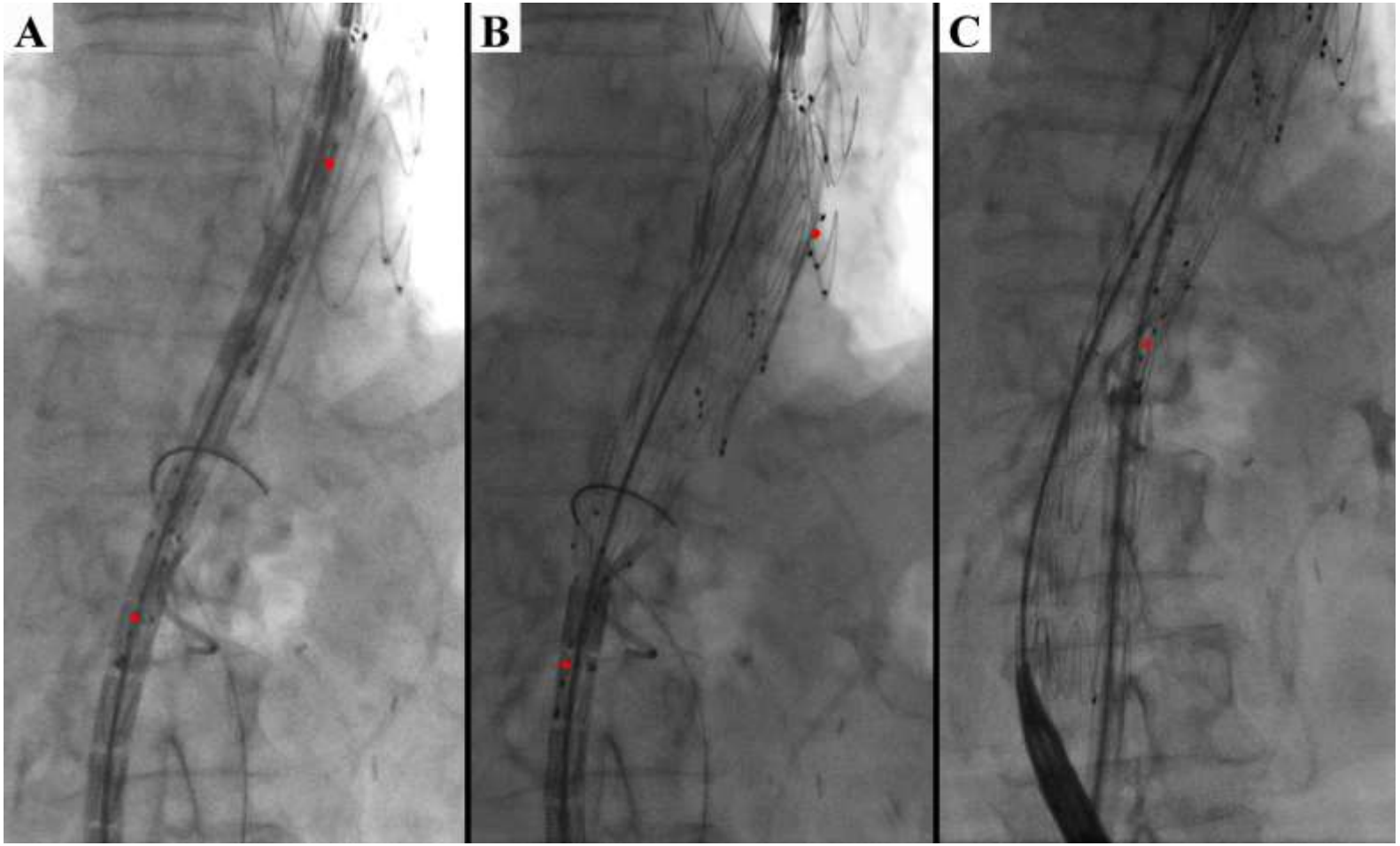
AAA-BIFURCATED-GRAFT
(As per ZFEN-D-12-28-94)

Ipsilateral Leg Extension:
ZSLE-16-39-ZT

Also:
ZBIS-10-45-41
ZSLE-16-39-ZT

Please note the following:

MISALIGNMENT - ROTATION

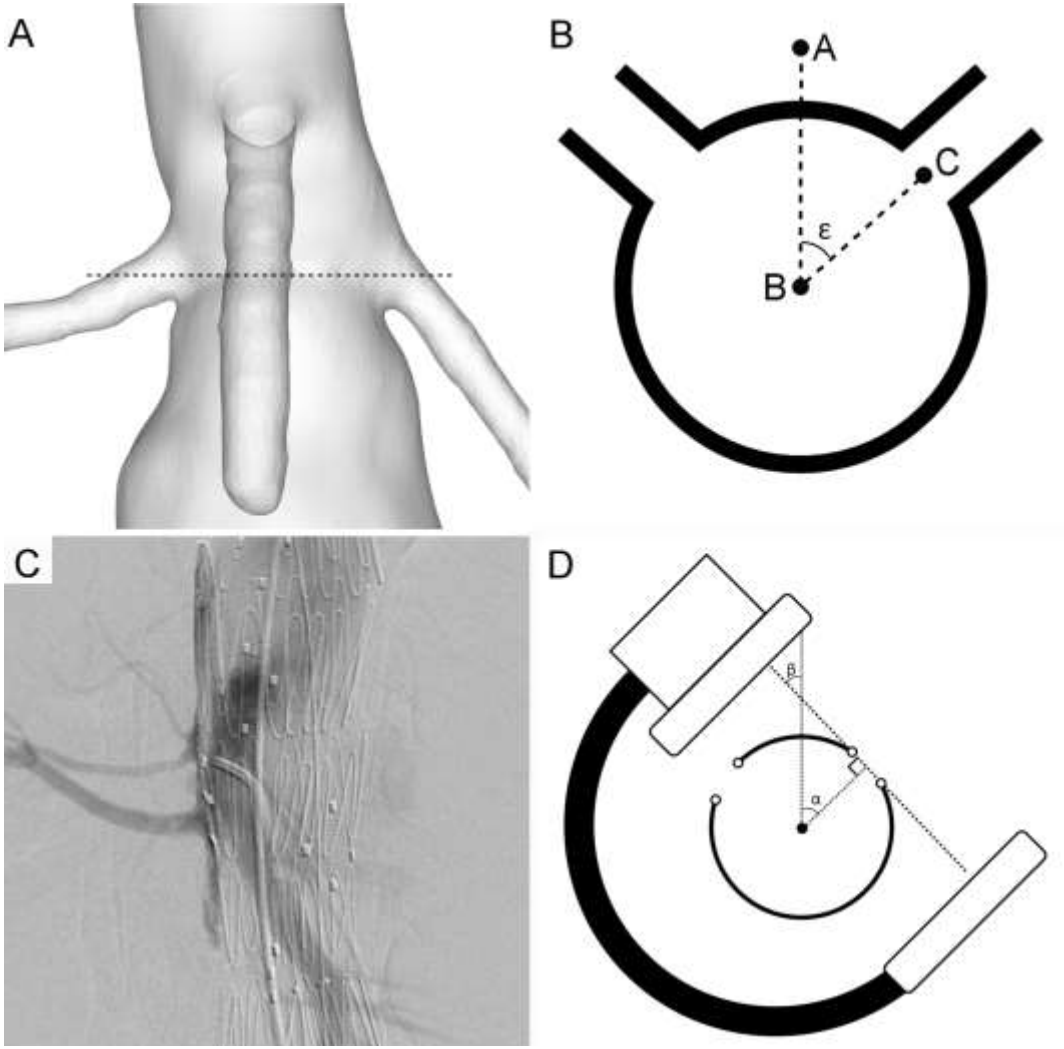


What are the short term effects of intraoperative fenestration misalignment in with FEVAR?

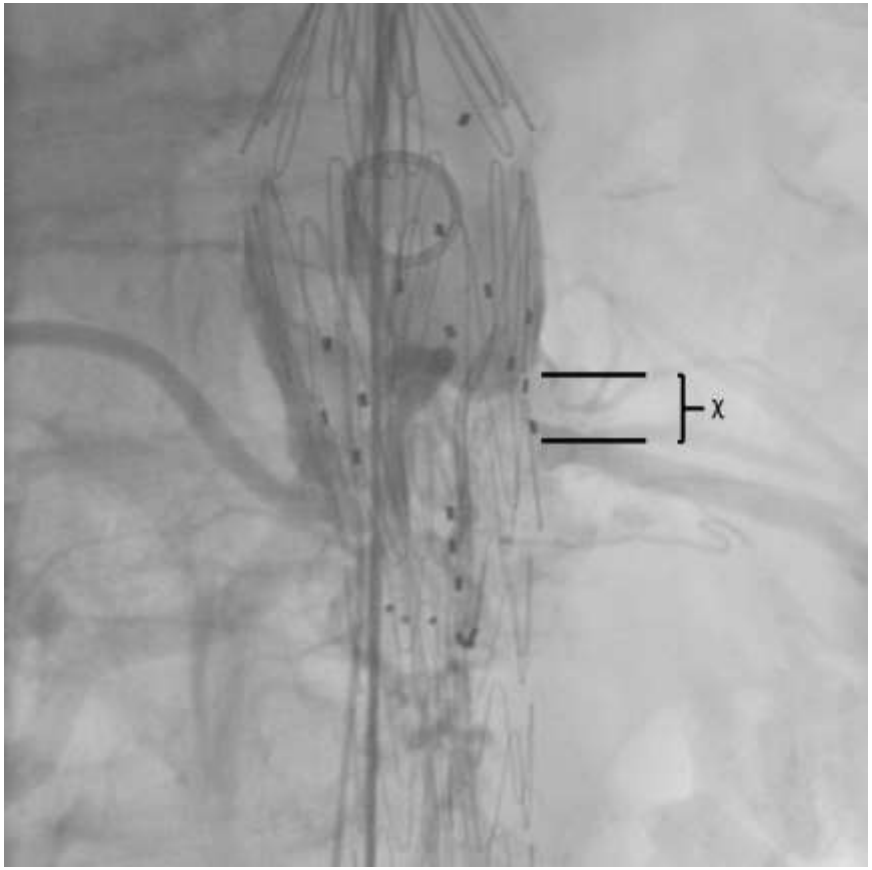
1. *What is the incidence of vertical and horizontal misalignment?*

2. *Is misalignment associated with poor clinical outcomes?*

HORIZONTAL MISALIGNMENT



VERTICAL MISALIGNMENT



RESULTS

Table 1. Patient Demographics and Comorbidities [Mean ± SEM or No (%)]

	Aligned [N=29]	Misaligned [N=36]	P-Value
Demographics			
Age	74 ± 2	78 ± 1	0.02
Male Gender	27 (93)	26 (72)	0.05
Body Mass Index	29.8 ± 1.1	29.4 ± 1.2	
Comorbidities			
Hypertension	24 (82)	30 (83)	> 0.5
Dyslipidemia	22 (76)	30 (83)	> 0.5
Chronic Renal Failure	11 (37)	12 (33)	> 0.5
Coronary Artery Disease	16 (55)	25 (69)	0.3
Stroke	5 (17)	0 (0)	0.01
MI or Prior PCI/CABG	13 (45)	16 (44)	> 0.5
COPD	13 (45)	16 (44)	> 0.5
Type 2 Diabetes	10 (34)	8 (22)	0.4
Peripheral Vascular Disease	7 (24)	15 (42)	0.18
Tobacco use	25 (86)	28 (77)	> 0.5
Pervious Abdominal Surgery	5 (17)	4 (11)	> 0.5
Previous Aortic Surgery	2 (7)	0 (0)	0.19

RESULTS

Table 4. Procedural details and 30-Day/In-hospital post-operative clinical outcomes

	Aligned [N=29]	Misaligned [N=36]	P-Value
Total Procedural Time (min)	262 ± 15	351 ± 25	0.007
Mean Fluoroscopy Time (min)	85 ± 6	106 ± 8	0.04
Mean Contrast Volume (ml)	193 ± 13	239 ± 20	0.07
Hospital Length of Stay (days)	5 ± 0.5	10 ± 1.5	0.005
30-day Complications			
Atrial fibrillation	1 (3)	2 (6)	> 0.5
Paraplegia	1 (3)	4 (11)	0.37
Myocardial infarction	2 (7)	2 (6)	> 0.5
Ischemic Colitis	0 (0)	4 (11)	0.12
Renal Failure	0 (0)	1 (3)	> 0.5
Death	0 (0)	4 (11)	0.12
No. of Endoleaks			
Type 1	0 (0)	0 (0)	> 0.5
Type 2	4 (14)	2 (6)	0.39
Type 3	3 (10)	2 (6)	> 0.5
Intraoperative Target Vessel Cannulation Failure	0 (0)	4 (11)	0.12
Intraoperative Target Vessel Complication [1]	1 (3)	8 (8)	0.04
End-organ Ischemia and/or Death	1 (3)	11 (31)	0.008

MISALIGNMENT

- >50% of patients had some degree of horizontal or vertical misalignment intraoperatively

- Patients with misalignment had
  - Higher incidence of composite adverse events (31% vs 3%)
  - Longer operative and fluoroscopy times
  - Higher rates of intraoperative target vessel complications

A non-planning cause of misalignment is rotation

Are there predictors of FEVAR Rotation?

1. What are the short-term clinical outcomes in patients with intra-operative stent graft rotation?

2. Are there anatomical markers of the arterial geometry that can predict stent graft rotation?

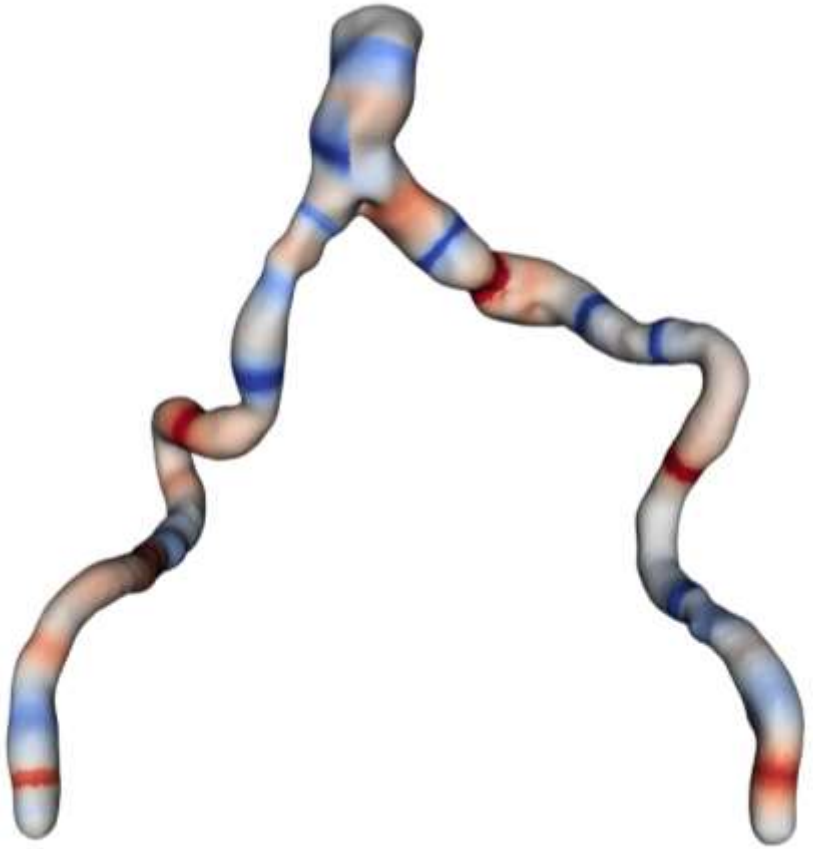
ILIAC ARTERIES

- **Local geometric properties**
  - **Calcification**
  - **Radius**
    - **Maximum Inscribed Sphere Radius**
  - **Curvature**

$$\kappa(s) = \frac{|c'(s)\ x\ c''(s)|}{|c'(s)|^3}$$

  - **Torsion**

$$\tau(s) = \frac{[c'(s)\ x\ c''(s)] \bullet c'''(s)}{|c'(s)\ x\ c''(s)|^2}$$



GEOMETRIC VARIABLES

TORTUOSITY

$$\chi = {}^{L}/_{D}$$

GEOMETRIC VARIABLES

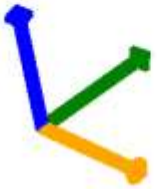
TORSION

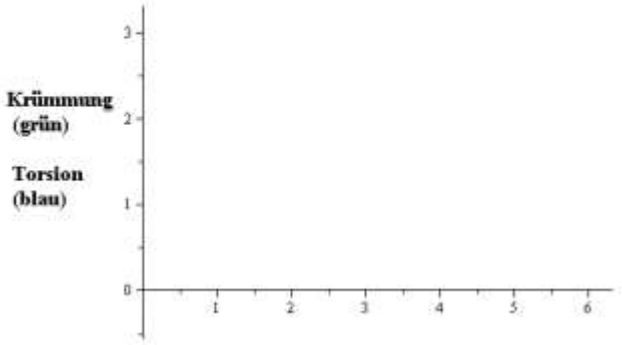
Measures the local deviation of the centerline from the osculating plane

Measures how sharply the centerline twists out of the plane of curvature

$$\tau = \frac{\det(r', r'', r''')}{\|r' \times r''\|^2} = \frac{(r' \times r'') \cdot r'''}{\|r' \times r''\|^2}.$$

Torus-Knoten mit Tangentialvektor (braun), Normalenvektor (grün) und Binormalenvektor (blau)





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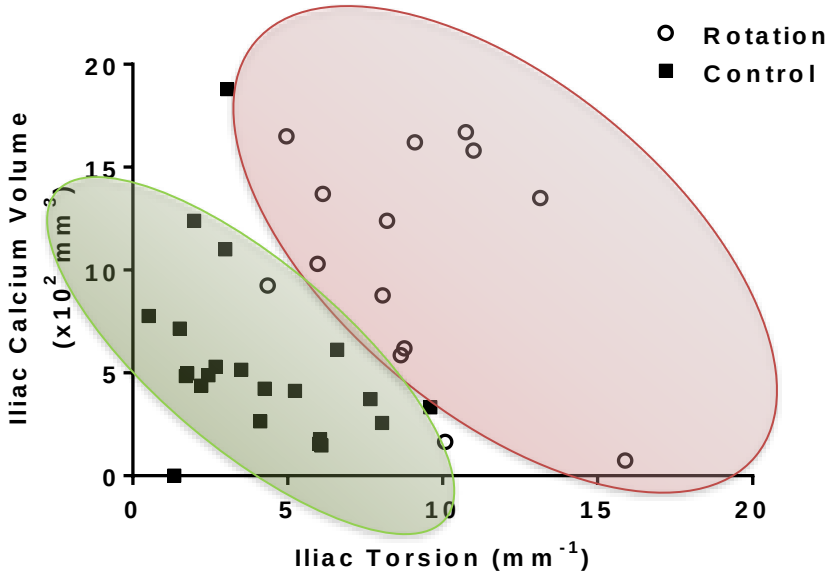
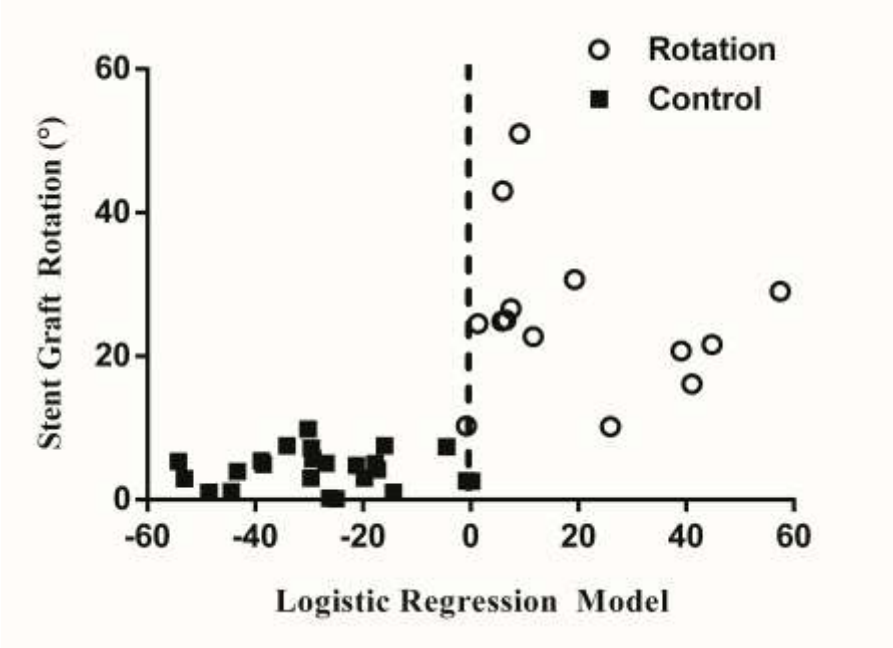




$$R = 6.03\left(\sum Torsion\ (mm^{-1})\right) + 0.0276\big(Calcium\ Volume\ (mm^3)\big) + 0.221\big(DeviceLength\ (mm)\big) - 101.4$$

FEVAR ROTATION

- Patients who experience stent graft rotation have significantly higher rates of severe post-operative complications (36% vs 0%)
- FEVAR rotation causes fenestration misalignment and is predictable
- Iliac artery torsion and calcification are associated with stent graft rotation

WHAT CAN A SURGEON DO TO MINIMIZE DEVICE ROTATION?

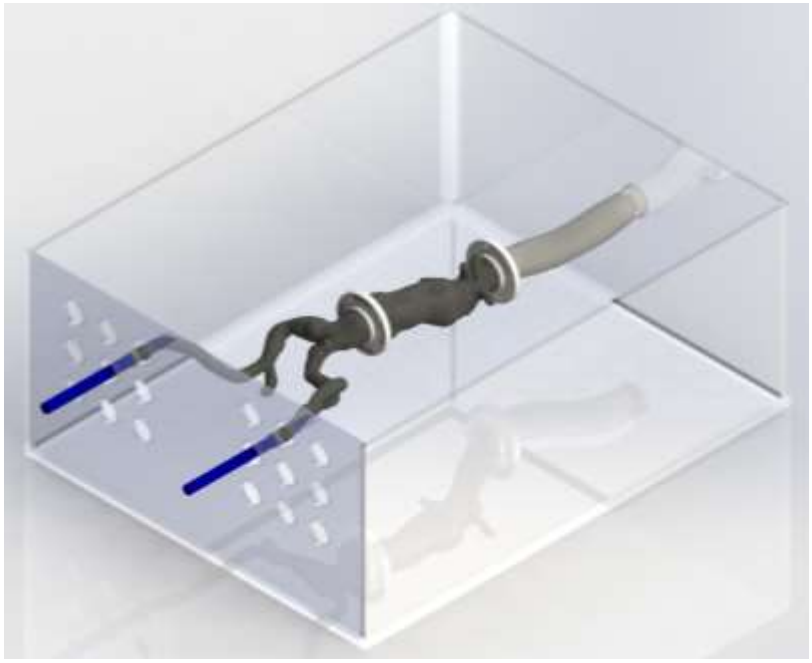
1. To develop a mechanically realistic aortoiliac bench top model

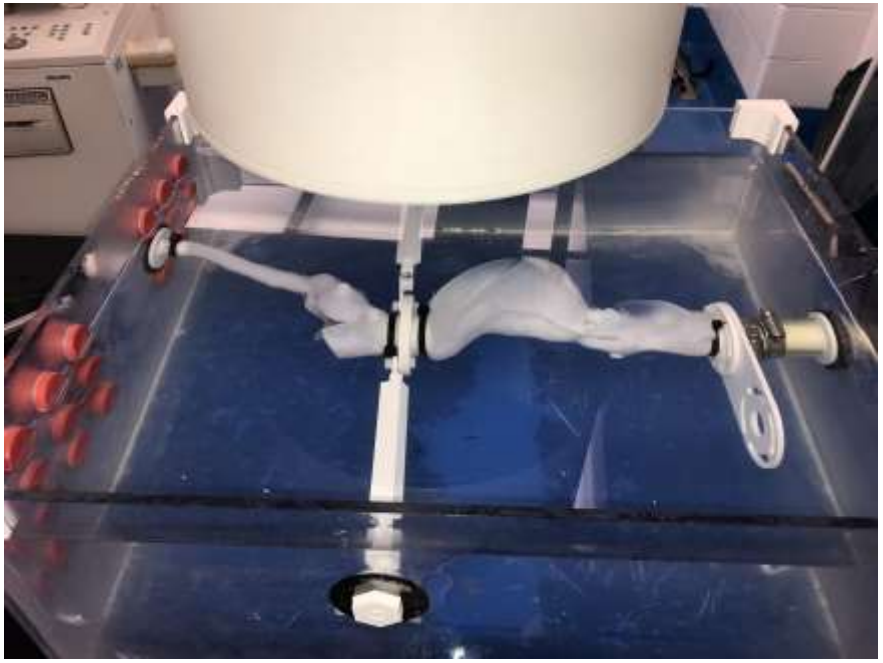
2. To validate quantitative anatomical markers which have been observed clinically

3. To evaluate the effect of operator technique on stent graft rotation

- Flexible models
  - Molds are 3D printed in PLA at a resolution of 0.2 mm
  - Polyvinyl alcohol cryogel is then cast using a 15% solution with 4 freeze thaw cycles
  - Effective rigidity is controlled by altering the thickness of the model walls
- Idealized models
  - Helically structured to have a constant torsion
  - Torsion specified by altering the pitch and radius of the helix
- Patient specific models
  - Segmented from pre-operative CT angiograms

EXPERIMENTAL APPARATUS





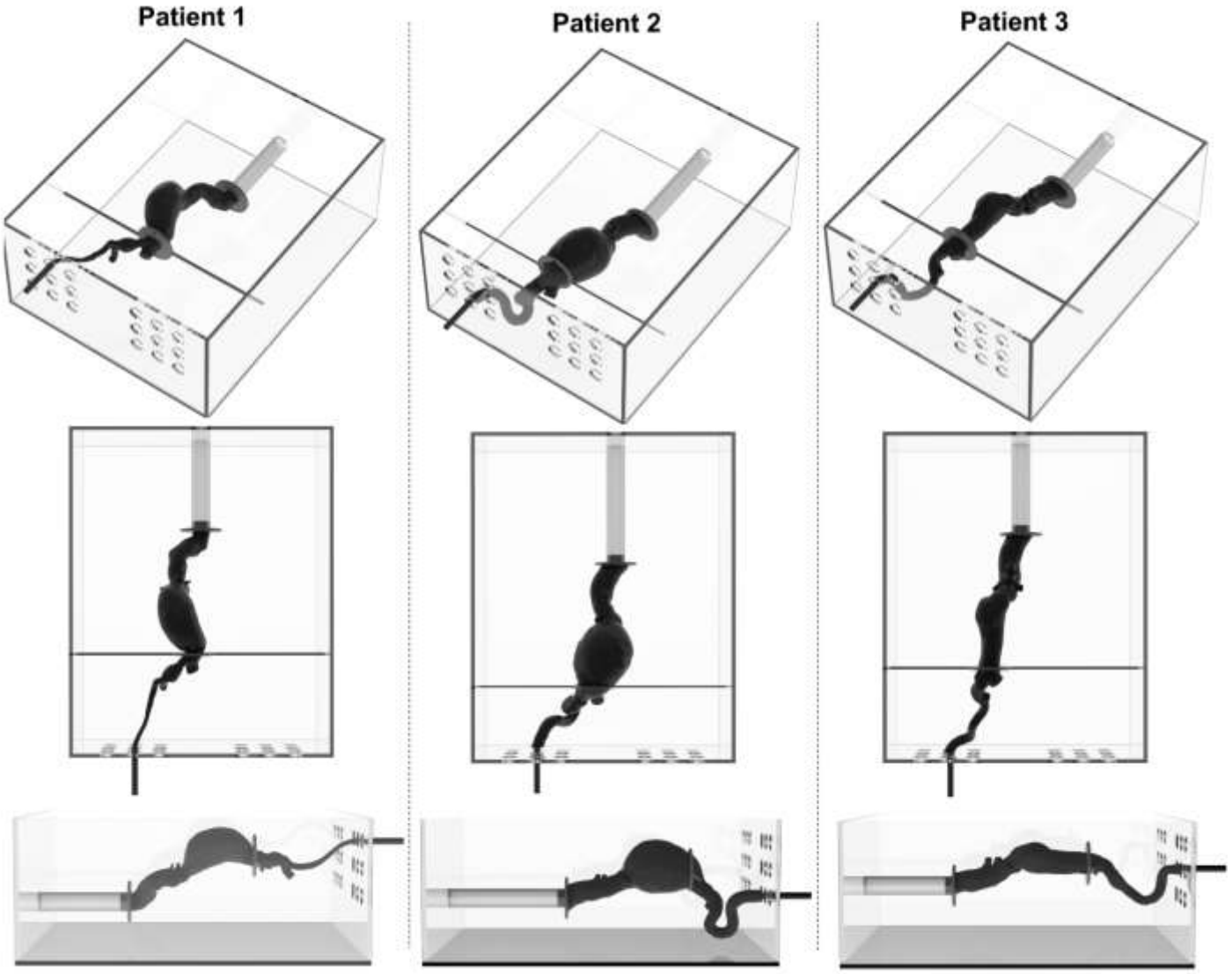

Patient 1
Patient 2
Patient 3

Table 4-1. Measured rotation during ZFEN deployment in patient specific aortoiliac phantoms compared with the observed intraoperative rotation during patient deployment.

Patient No.	Model Rotation (°)	Intraoperative Rotation (°)	Absolute Error (°)	Iliac Torsion (mm^{-1})	Iliac Calcium Volume (mm^3)
1	2.3	0.2	2.1	5.2	413
2	27	29	2	13.1	1352
3	34	30	4	8.2	1244

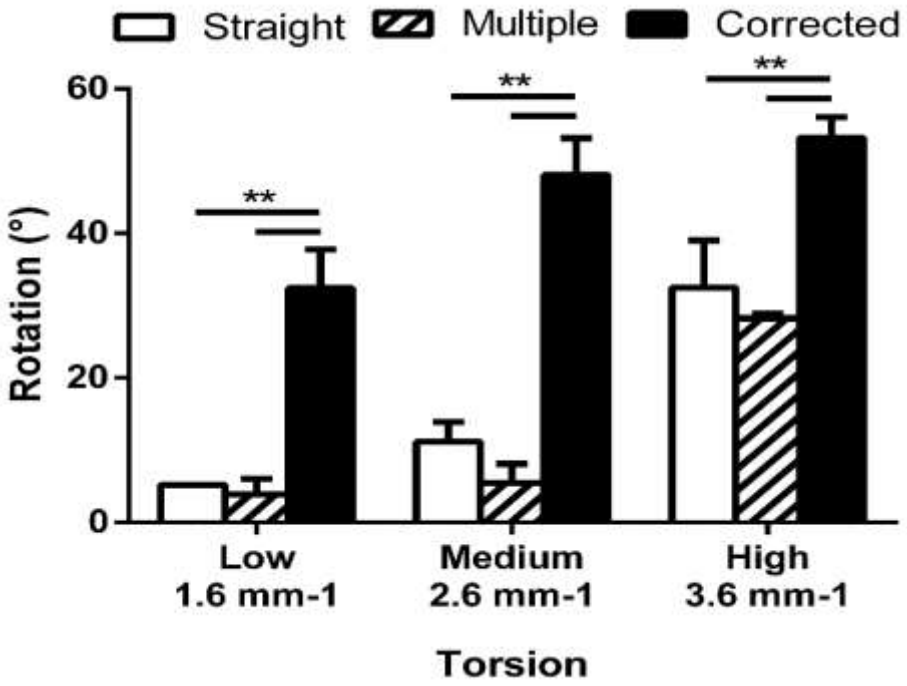


Figure 4-4. Evaluation of the effect of operator insertion technique in rigid idealized models at varying levels of torsion. **Straight:** No correction of device orientation during insertion. **Multiple:** Insert the device, note orientation, fully remove the device, correct the orientation accordingly, and re-insert. **Corrected:** Gradually correct the orientation of the device as needed during insertion.

FEVAR MISALIGNMENT & ROTATION

- Torsion and rigidity/calcification combined are direct causes of intraoperative stent graft rotation

- In-vivo correction of orientation significantly increases the observed rotation
  - If clinically safe, fully remove the device, adjust the orientation and reinsert the device

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