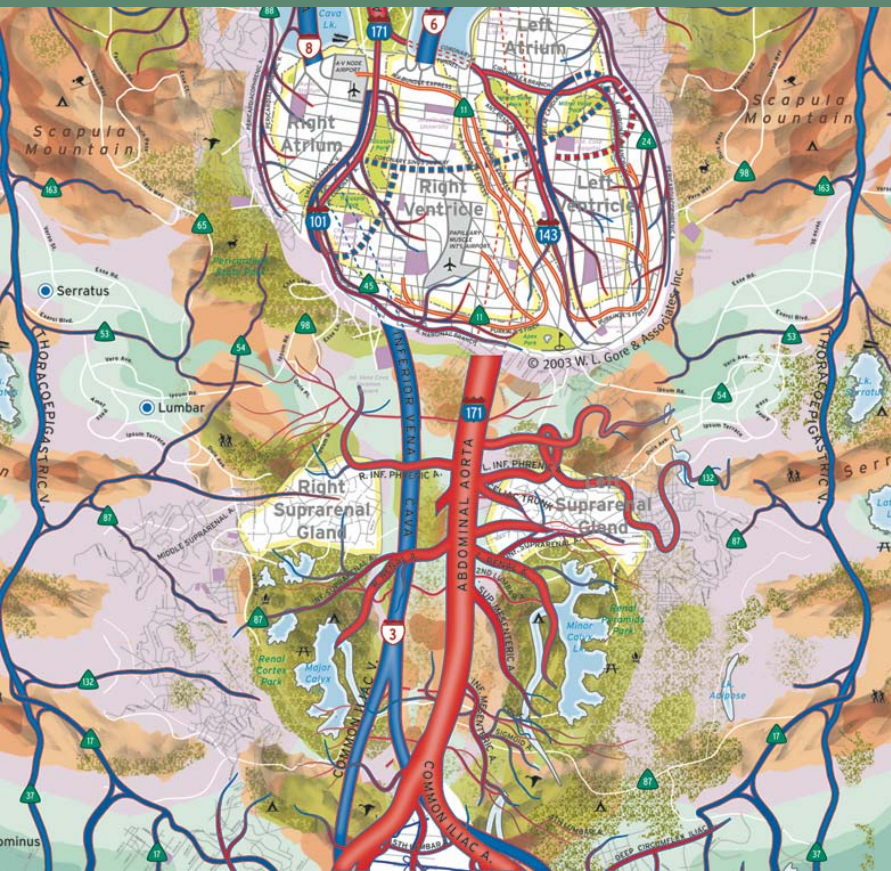
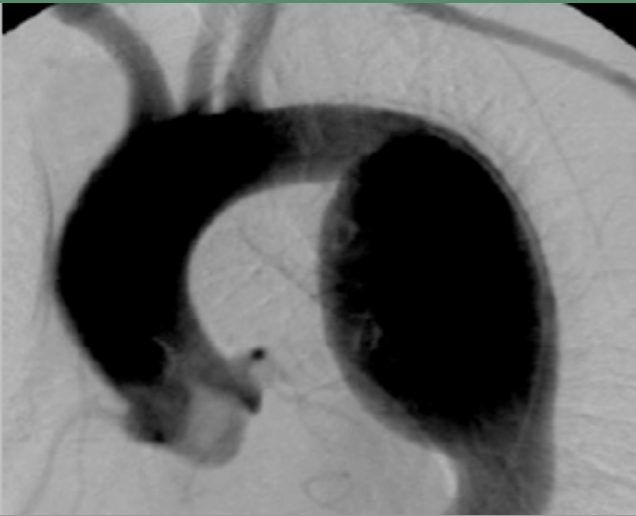


# Community Awareness Program



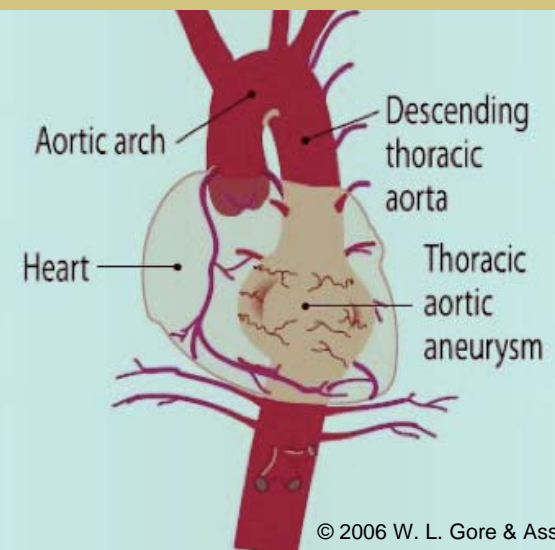
## Endovascular Repair of Thoracic Aortic Aneurysms (TAA)

# Definition

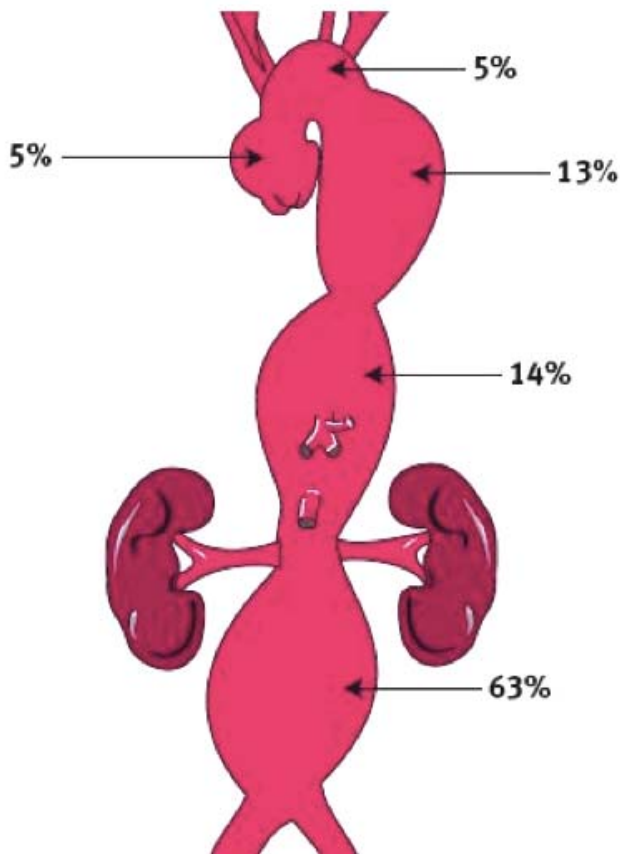


***Aortic aneurysm*** – a dilation or bulge of the wall of the aorta which causes the diameter of the aorta to grow to more than 1.5 times its normal diameter<sup>1</sup>

***Descending Thoracic Aorta*** – the portion of the aorta between the left subclavian artery and the diaphragm<sup>2</sup>



# TAA Epidemiology

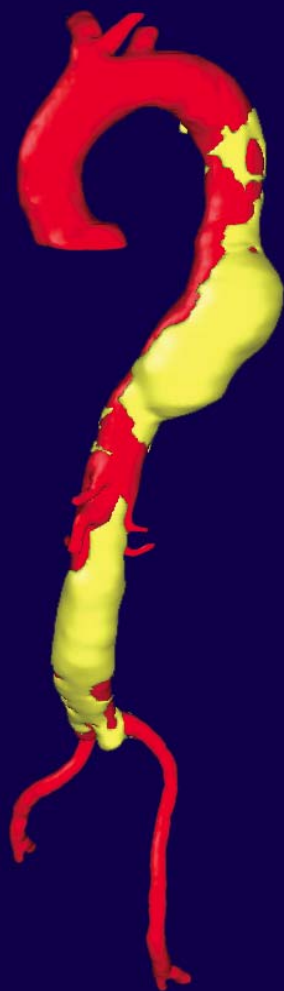


Incidence and Location of Aortic Aneurysms in 1500 patients<sup>7</sup>

## Incidence:

- TAA is diagnosed in approximately 15,000 to 25,000 people in the US annually<sup>1,3</sup>
- TAA is diagnosed in 5.9 to 10.4 per 100,000 people per year<sup>4,5</sup>
- Incidence is increasing due to<sup>6</sup> :
  - Aging population (increased prevalence)
  - Increased access to sophisticated imaging

# TAA Facts



- **Mortality:** 6,000 deaths annually due to TAA<sup>3</sup>
- **Male to female ratio<sup>8</sup>:** ~ 1:1
- **Average age at diagnosis:** 76 for women and 63 for men<sup>5</sup>
- **5-year Survival (untreated patients):** 19 to 39%<sup>4,9</sup>
- **Annual procedures volume:** >18,000 thoracic aortic repair procedures (includes TAA and other aortic diseases)<sup>3</sup>
- **Percent of AAA patients who also have TAA:** 12%<sup>10</sup>

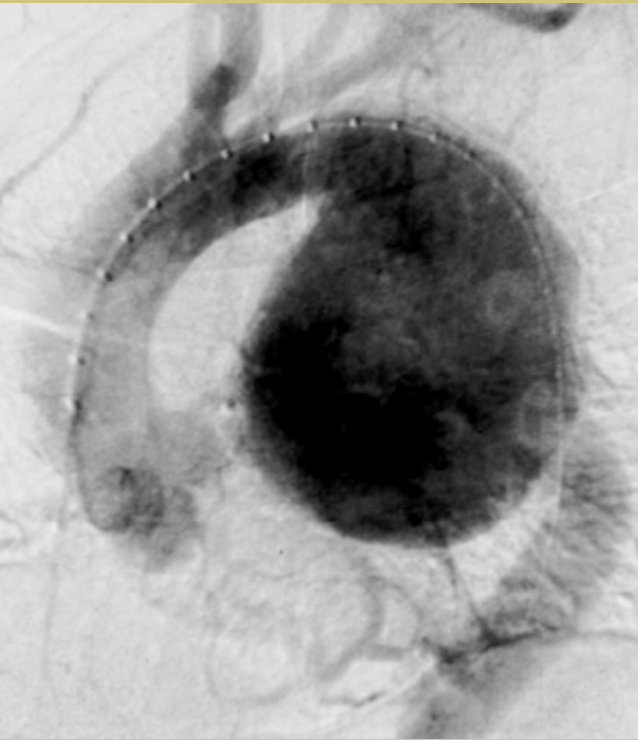


# Clinical Challenge

- The majority of patients with thoracic aortic aneurysms are asymptomatic<sup>11</sup>
- 5-year cumulative probability of rupture: 20% (31% for Thoracic Aortic Aneurysms 6 cm or more)<sup>5</sup>
- Over 75% of patients with ruptured thoracic aortas die within 24 hours after the onset of symptoms<sup>12</sup>
- Overall fatality as a result of rupture: 94 to 97%<sup>4,12</sup>

**How many of your patients have an undiagnosed TAA?**

# Risk Factors for Aneurysm Development<sup>1</sup>



- Over 60 years of age
- High blood pressure
- Current or former smoker
- Arteriosclerosis
- Family history of aneurysms



# Symptoms

TAA is often called a “silent killer” because there are no obvious symptoms of the disease. Only half of patients with TAAs notice symptoms.<sup>1</sup>

- Most thoracic aortic aneurysms are found incidentally during testing for other disorders<sup>11</sup>
- Possible TAA symptoms include:
  - Pain in the chest, back, neck, or jaw<sup>1</sup>
  - Coughing, hoarseness, or dyspnea<sup>1</sup>
  - Plethora and edema (from compression of superior vena cava)<sup>11</sup>
  - Most patients are hypertensive<sup>13</sup>
- Symptoms indicating a rupture may include:<sup>14,15</sup>
  - Chest or back pain
  - Hemoptysis/hematemesis
  - Cardiovascular collapse



# Diagnostic Methods: Imaging Evaluation<sup>11</sup>

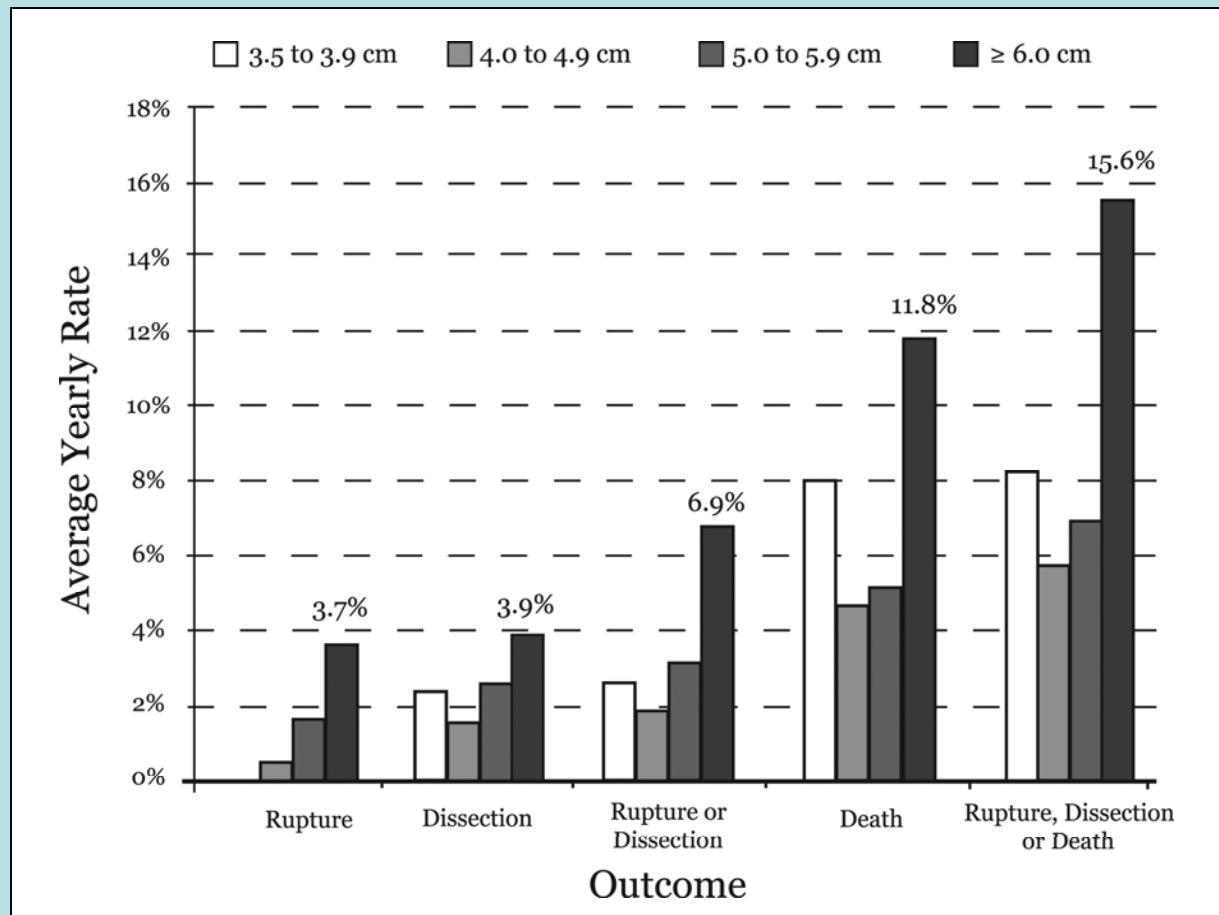
- Chest X-Ray
- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT)
- Angiography
- Transesophageal Ultrasound (TEU)



# When to Treat?

- Because of increased likelihood of rupture, elective repair of TAA is recommended when:
  - The maximal aneurysm diameter is 5 - 6 cm or more or,<sup>5,9,11,16,17,18</sup>
  - The aneurysm is symptomatic or,<sup>5,11</sup>
  - The aneurysm is complicated by dissection<sup>5</sup>
  - Smaller aneurysms may be considered for repair if they are rapidly enlarging<sup>14</sup>

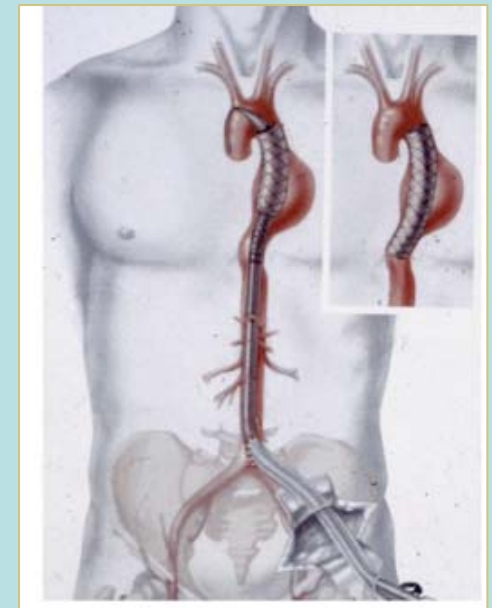
# Average Yearly Rate of Complications<sup>18</sup>



# Treatment Options



- Medical management/monitoring (“watchful waiting”)
- Open surgical repair
- Endovascular stent-graft repair

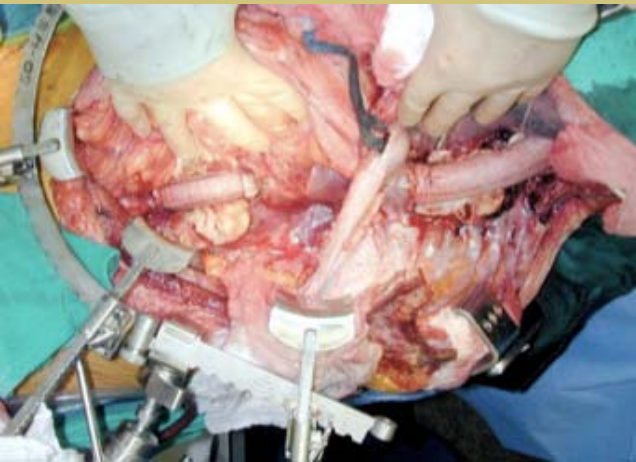


# Medical Management / Monitoring



- Wait, watch, and control hypertension<sup>1</sup>
- Typically reserved for aneurysms < 5 or 6 cm that are not rapidly expanding or causing symptoms<sup>1</sup>
- Most commonly monitored with CT or MRI scans every 6 months<sup>1</sup>

# Open Surgical Repair



- Replacement of the weakened portion of the aorta with a synthetic graft<sup>19</sup>
- Access via anterior or lateral thoracotomy
- Often performed with either partial or full cardiopulmonary bypass to temporarily redirect blood flow around the aneurysm<sup>13,20</sup>



# Open Surgical Repair

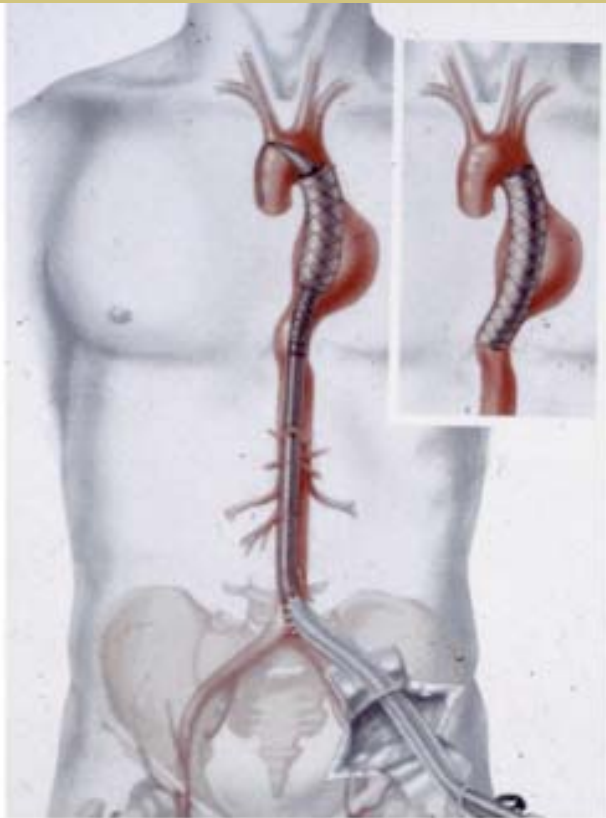
## Benefits

- 5-year survival: 58 - 70%<sup>10,14</sup> vs. 19 to 39% for untreated patients<sup>4,9</sup>

## Challenges

- 30-day operative mortality (for elective procedures): 8 - 20%<sup>5,14,15,18,21</sup>
- Survivors suffer from morbidity rates of up to 50% related to renal, intestinal, and spinal cord ischemia<sup>14</sup>
- Neurologic complication rate (paraplegia, paraparesis, stroke): 8 - 15%<sup>14,15</sup>
- Average 7 to 10 days hospitalization<sup>1</sup>

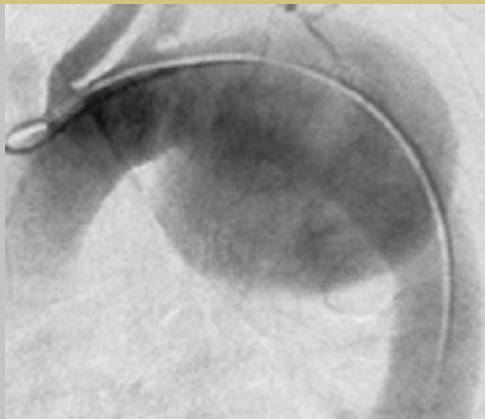
# Endovascular Stent-Graft Repair



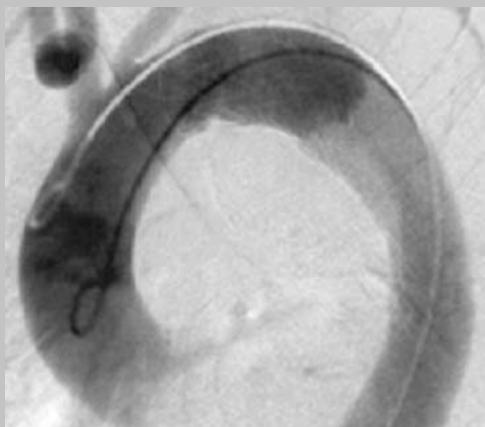
Endovascular  
Stent-Graft Repair

- Access via direct iliac, femoral, or aortic arteriotomy or via conduit<sup>22</sup>
- Stent-grafts are deployed using angiographic guidance<sup>22</sup>
- Anchoring of endoluminal device above and below TAA in normal arterial segments
- Tube-shaped stent-graft relines the vessel and excludes the aneurysm from circulation
- Exclusion and depressurization prevent TAA rupture
- May be performed under general, regional or local anesthesia

# Endovascular Technique



Pre Stent-Graft Deployment



Post Stent-Graft Deployment

[Click here to play animation.](#)





# Clinical Outcomes: Endovascular vs. Open Surgical Repair of DTA\*

## Study Methods

- A multi-center, prospective, non-randomized study conducted at 17 sites

## Study Design

- Controlled clinical trial
  - Test subjects treated with the GORE TAG® Thoracic Endoprosthesis (n=140)
  - Control subjects treated by open surgical repair
- One year clinical study endpoints
- Five year follow-up ongoing

## Results

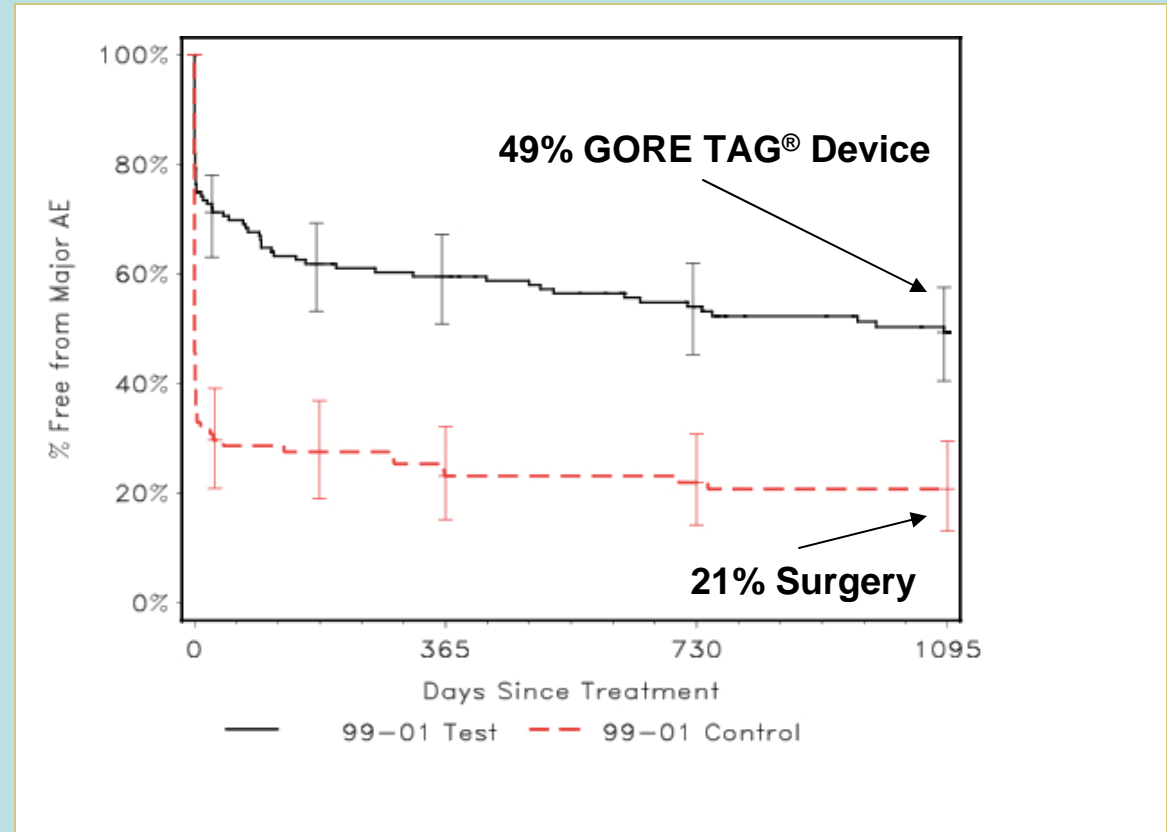
**At one year, the endovascular group, as compared to the open surgical control group, had:**

- One-fifth the paraplegia / paraparesis rate (3% vs. 14%)
- Paraplegia rates in the test and control groups of .07% and 8.5% respectively
- One-sixth the operative mortality (1% vs. 6%)
- Zero aneurysm ruptures at 3 years
- Lower aneurysm-related death through two years (3% vs. 10%)
- 80% less procedural blood loss on average (472 ml vs. 2,402 ml)
- Shortened average ICU stay (1 day vs. 3 days)
- Shortened average hospital stay (3 days vs. 10 days)
- Two times faster return to normal activity (30 days vs. 78 days)

\*GORE TAG® Thoracic Endoprosthesis: Summary of Results from US Pivotal Trial

# Clinical Outcomes: Endovascular vs. Open Surgical Repair of DTA\*

Freedom from major adverse events (MAE) through 3 years of follow-up.



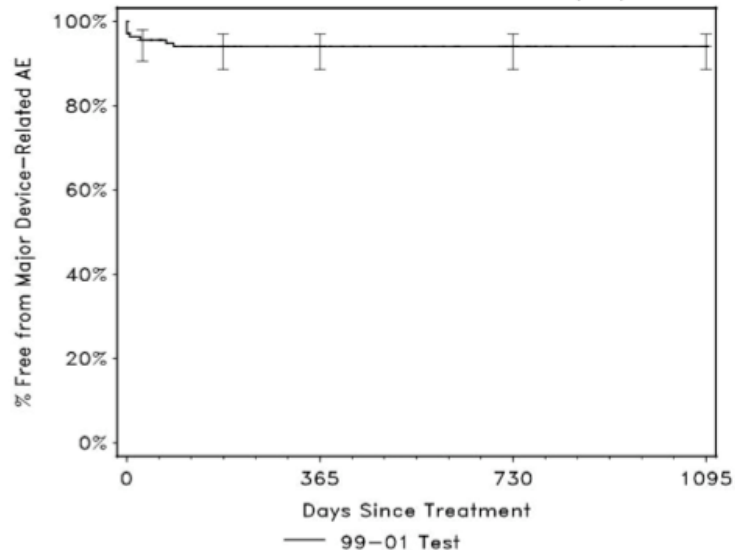
# Clinical Outcomes: Endovascular Stent-Grafts\*

**Freedom from Any Major Device-Related Event (through 3 years) for the GORE TAG® Device Group: 94%**

Regular and routine follow-up imaging visits (Chest x-ray and CT Scan) are required (1 month, 6 months, 12 months, and annually thereafter)

\*GORE TAG® Thoracic Endoprosthesis: Summary of Results from US Pivotal Trial

GORE TAG Device	
<b>Freedom From Any Major Device-Related Event</b>	<b>94%</b>
Major device-related events	Incidence (%)
Rupture	0
Treatment-related	2 (1%)
Endoprosthesis migration	1 (1%)
Aneurysm enlargement	3 (2%)
Branch vessel occlusion	1 (1%)
Endoleak	4 (3%)





# Case Reviews

Please insert pertinent pre- and post-procedure images from your experience.



# Our Experience

- Please insert information pertaining to your experience with endovascular treatment of TAA including case reviews, procedure volume, etc.

# Questions?





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