Blinded Engineering Consult

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Greenberg Stent Summit
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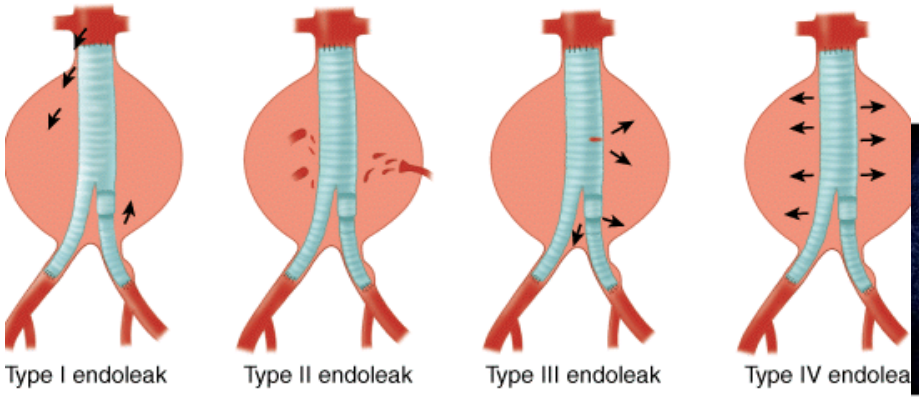
Blinded Engineering Consult

- Engineer: What I would worry about if it was my device - Potential concerns with different management options

What Every Engineer (should) Know

- All systems and materials have FAILURE modes / limits.



ource: Brunicardi FC, Andersen DK, Billiar TR, Dunn DL, Hunter JG, Matthews JB,
ollock RE: *Schwartz's Principles of Surgery, 9th Edition:* http://www.accessmedicine.com

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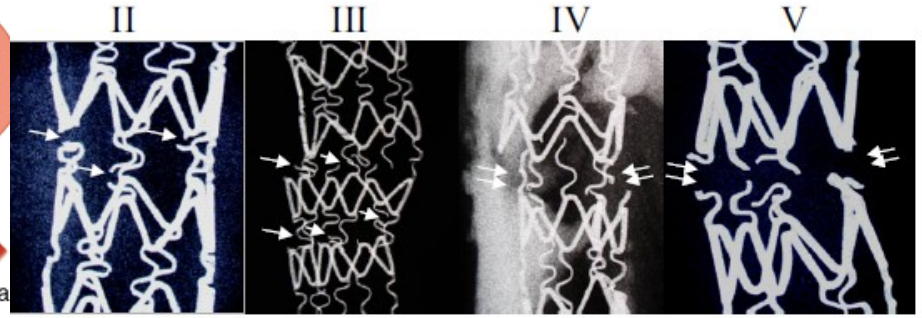

- The regulatory bodies expect us to understand and characterize these failures.

First Thoughts

The following devices all have at least two things in common:

1. They look pristine!

2. They've never been implanted

Topic

Review 3 failure modes

1. Bare Stent Fracture
2. Mid-body Stent Fracture
3. Bare Stent Separation

General Impression – Why I May **Not** be Worried

- Bare stent fractures are a known failure mode seen in infrarenal devices – bare stent fractures don't necessarily lead to clinical sequelae
- With a single simple fracture, device is likely stable
- A single fracture is likely to remove negative stresses impacting stent
- Fracture is away from the fabric
- Bare stent already has sharp barbs by design
- Absence of sequelae indicate that the risk associated with the implant should be no greater than with any conventional procedure
- Repair device interactions would be consistent with any concerns of proximally extending with a cuff
- Bare stent fracture should not impact integrity of other stents on device

Bare stent fracture

General Impression – What I **May** Worry About

- Although bare stent fractures are a known failure mode, root causes can come from design, manufacturing and/or clinical issues
  - ✓ Is the design flawed?
  - ✓ What if ALL bare stents had ONE fracture?
  - ✓ Should I worry about a certain lot of material?
  - ✓ Should I worry about a certain anatomy: angulation / oversizing?
- Multiple strut fractures in single bare stent would significantly heighten concern
- Potential sequelae would be Type Ia endoleak or migration
- Repair device interactions would be consistent with any concerns of proximally extending with a cuff

Nonviable Treatment Options

Treatment Option	Why not?
Surgical Conversion	Very unlikely to be necessary

Top 2 Treatment Options

- In the absence of endoleak or migration
  - ✓Enhanced surveillance for a period of time
  - ✓Standard of care surveillance once device proves stable, as it likely that that bare stent will be well incorporated in the aorta
- In the presence of endoleak or migration
  - ✓Placement of proximal extension
  - ✓Placement of longer fenestrated device across main body and viscerals
  - ✓Endostaple

Bare stent fracture

Technical Considerations for Viable Treatments

Enhanced Surveillance

Benefits	Risks
• No additional endovascular or open surgical procedure	• Sudden or undetected change in sac pressurization attributable to endoleak • Increased radiation / contrast exposure from additional CTs • Heightened patient concern

Proximal Extension / FEVAR

Benefits	Risks
• Additional support for additional implant.	• Additional procedure • Overlap fatigue

Mid-body stent fracture

General Impression – Why I May **Not** be Worried

- As with the bare stent – stent fractures are a known adverse event
- Given redundancy of stents the overall support of the stent-graft should not be adversely affected
- The position of the device relative to the anatomy is not expected to be affected by this failure mode
- As with the bare stent, negative stresses on the stent of concern should be reduced/eliminated
- Potential of other stents to fracture is not changed

Mid-body stent fracture

General Impression – What I **May** Worry About

- Although fractures are a known failure mode, root causes can come from design, manufacturing and/or clinical issues
  - ✓ What is the root cause?
  - ✓ Is the design flawed?
  - ✓ What if ALL devices had ONE fracture?
  - ✓ Should I worry about a certain lot of material?
  - ✓ Should I worry about a certain anatomy: angulation / oversizing?
- The singular concern of this failure mode is a Type IIIb endoleak, which is expected to be a function of not just the stent fracture, but position and angulation of the device relative to the anatomy

Nonviable Treatment Options

Treatment Option	Why not?
Surgical Conversion	Very unlikely to be necessary

Mid-body stent fracture

Top 2 Treatment Options

- In the absence of endoleak
  - ✓Enhanced surveillance. It is possible that a Type IIIb endoleak could arise at any point in the future given remodeling of the anatomy.
- In the presence of endoleak
  - ✓Device needs to be re-lined with a short body bifurcate or AUI

Mid-body stent fracture

Technical Considerations for Viable Treatments

Enhanced Surveillance

Benefits	Risks
• No additional endovascular or open surgical procedure	• Sudden or undetected change in sac pressurization attributable to endoleak • Increased radiation / contrast exposure from additional CTs • Heightened patient concern

Re-lining of Device

Benefits	Risks
• Should cover hole from Type IIIb	• Additional procedure • If AUI, then a secondary procedure is now required

Bare stent separation

General Impression – Why I May **Not** be Worried

- I’m worried

Bare stent separation

General Impression – What I **May** Worry About

- Type Ia endoleak
- Device remodeling leading to severe kink / stenosis
- Complete separation of the graft and collapse into the sac – Aortic thrombosis

Nonviable Treatment Options

Treatment Option	Why not?
Any kind of surveillance	The implant is very unstable

Top 2 Treatment Options

- Surgical conversion
  - ✓Based on the configuration of the device and anatomical considerations surgical conversion is a viable / necessary option
- Complete re-lining of device
  - ✓Device needs to be re-lined with a short body bifurcate or AUI
  - ✓May want to strongly consider treating through the visceral section to ensure stability of second device
  - ✓Detached system needs to be completely excluded from pressurization

Bare stent separation

Technical Considerations for Viable Treatments

Surgical Conversion

Benefits	Risks
• Ensures complete repair	• Significant short term impact on patient • Patient may be unfit for open repair

Proximal Extension / FEVAR

Benefits	Risks
• Potential to completely exclude first device	• Additional procedure • Overlap fatigue • Instability of first device may impact viability of second device

Final Thoughts

Devices all look great on paper

The body is a hostile environment that can cause significant issues for implants

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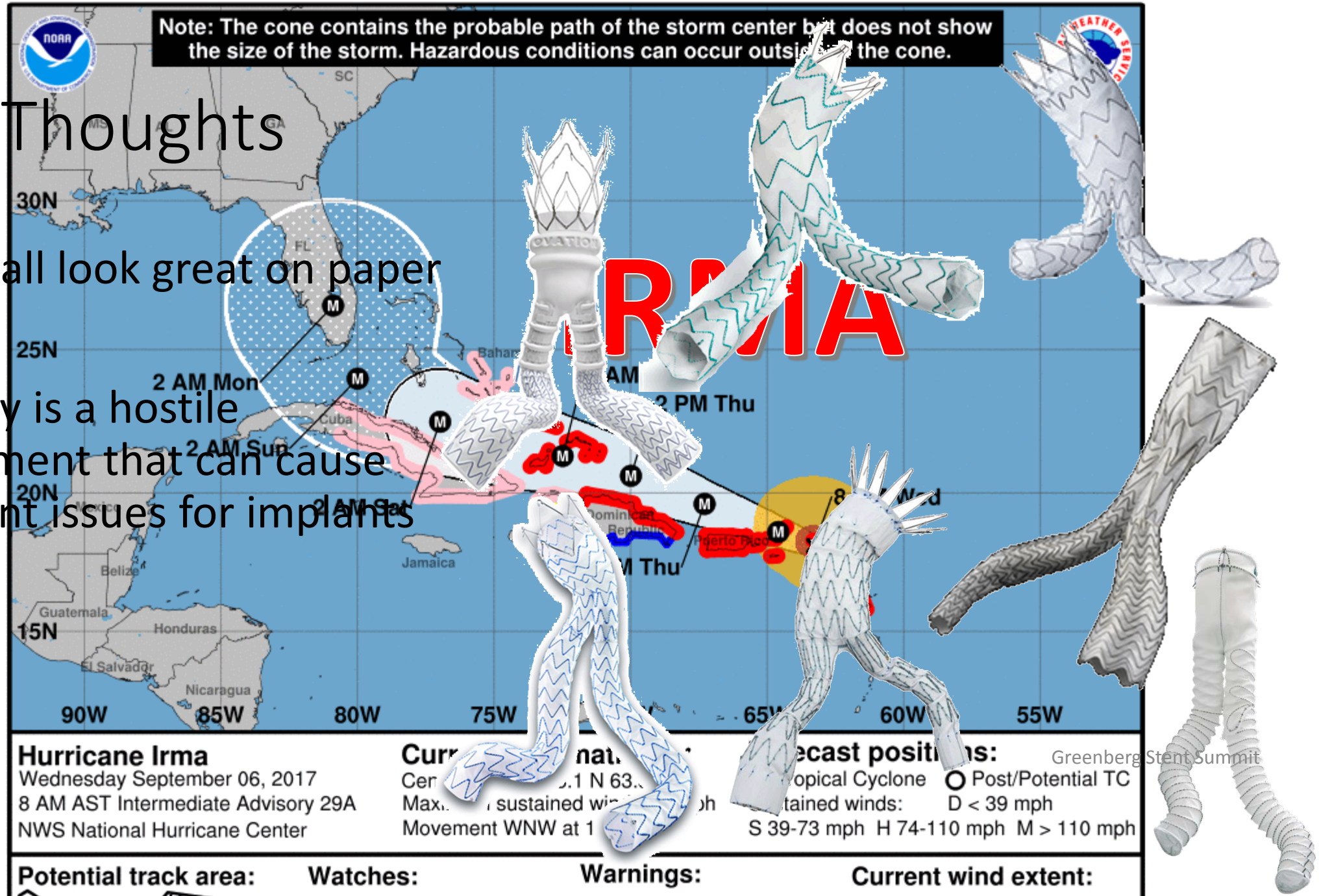

Greenberg Stent Summit

WE ARE
AORTIC BY DESIGN

AORTIC
BY DESIGN

INSPIRED by a belief that quality designs lead to a **better quality of life**.

DRIVEN by a **passion** and **respect** for the aortic anatomy.

COMMITTED to crafting advanced endovascular solutions for **every patient**.

THANK YOU

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