


Unblinded Engineering Consult

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Greenberg Stent
Summit XII

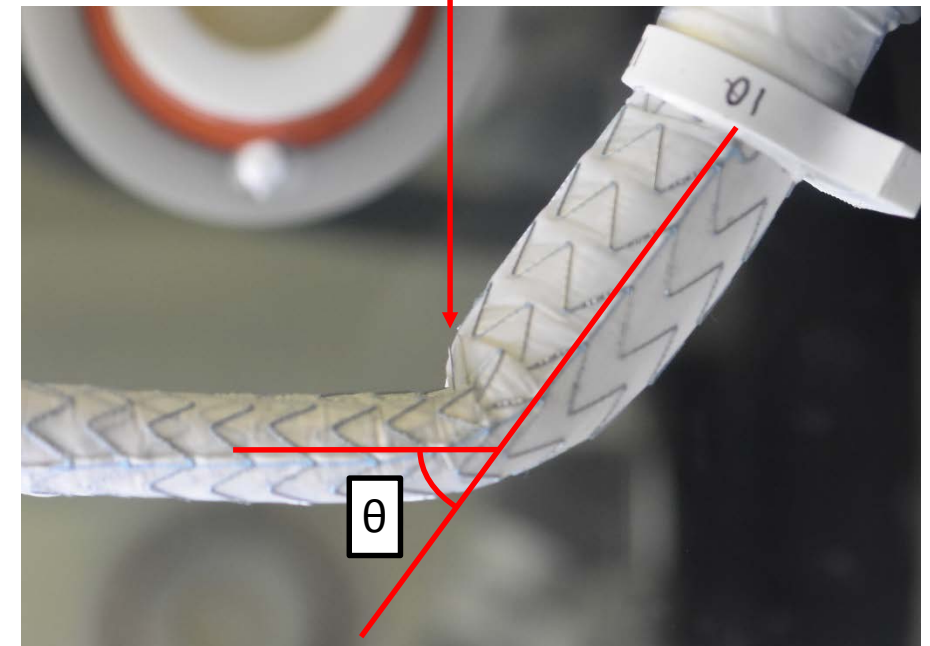
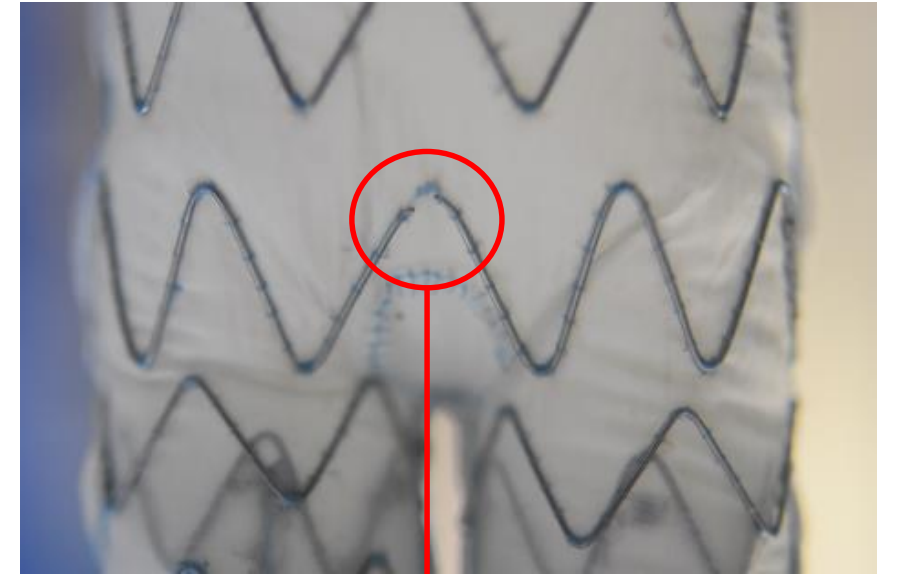
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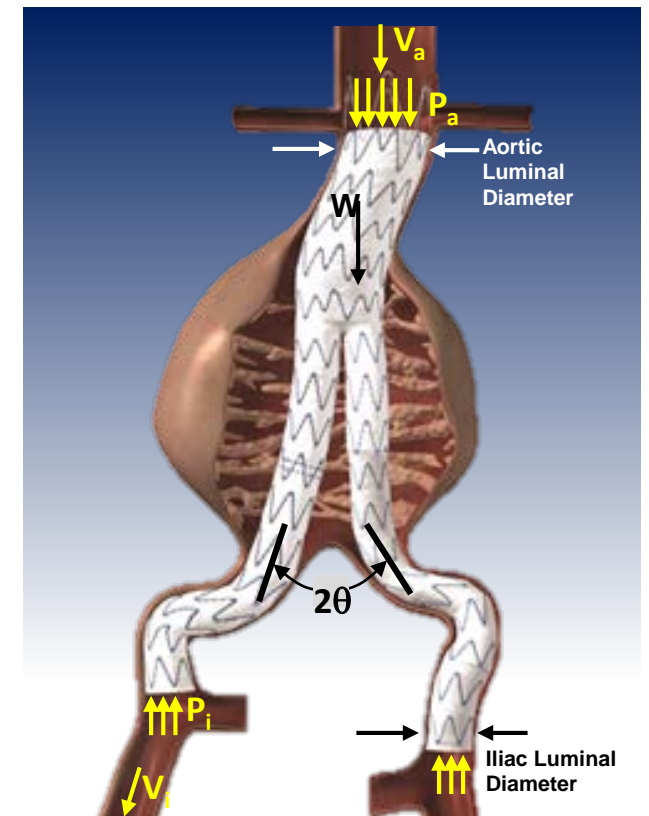
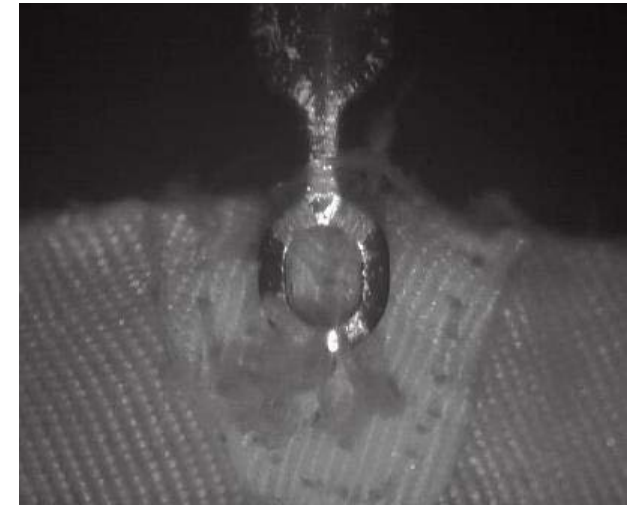
Transition Stent Fracture

- Function – Kink resistance
 - Fully intact stent not necessary for function
- Does the device failure lead to potential clinical failures?
 - Fractured stent leading to graft material holes and possible type III
 - Fatigue testing (accelerated) demonstrated no increased risk out to 10 years
- Adjunctive devices likely not needed to remediate the fracture



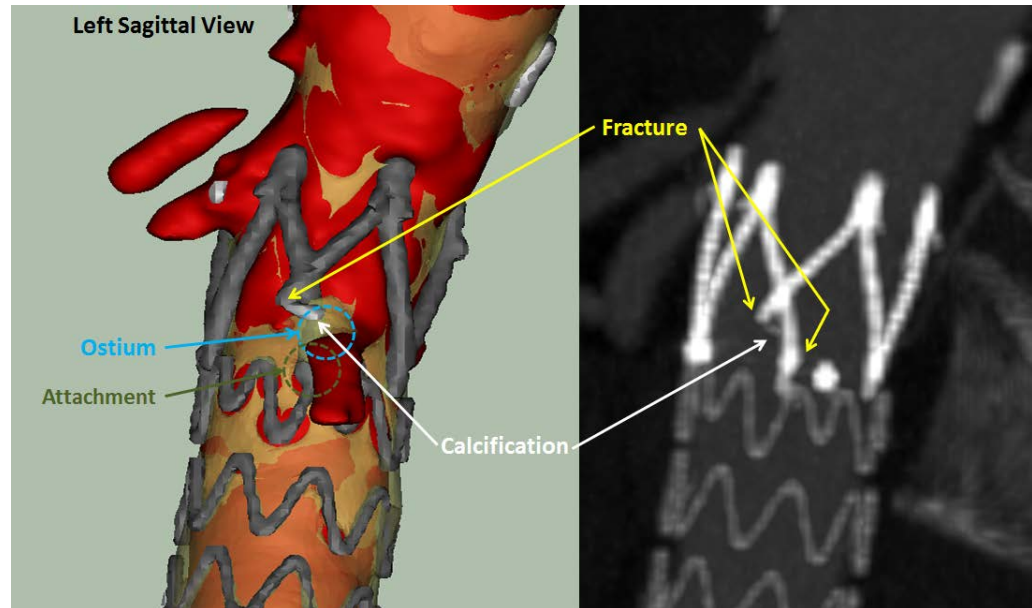
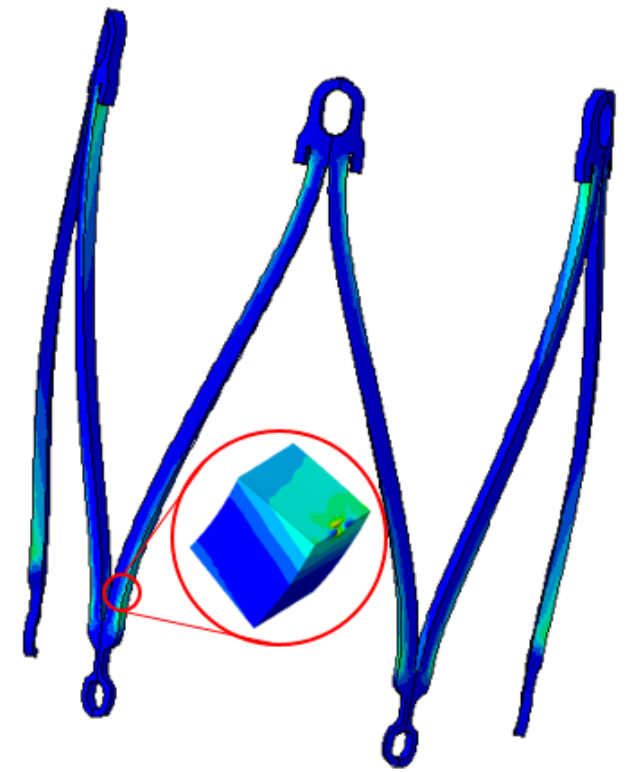
Suprarenal Partial Detachment

- Function – Secures graft position
- Clinical failure modes
 - Sac enlargement due to migration and loss of seal
- Abrasive wear of attachment suture
 - A single attachment failure shown to lead to successive failures
- Remediation testing investigated potential intervention options
 - Endoanchors
 - Relining with cuffs or AUIs



Suprarenal Stent Fracture

- Function – Secure graft position
 - Single fracture unlikely lead to functional failure
- Multiple stack-up of factors required for fracture
- Given factors, progression of fractures not likely
- Adjunctive devices likely not needed to remediate the fracture



Conclusions

- Does a device failure lead to a clinical failure?
 - Transition stent fracture – potentially
 - Suprarenal stent partial detachment – yes
 - Suprarenal stent fracture – unlikely
- Remediation options and testing required for device failures that potentially lead to a clinical failure

