


Update on The Retrievable Rescue Stent-Graft For Treating Aortic and Vena Cava Injuries:
 What is it, How Does it Work and Current Status

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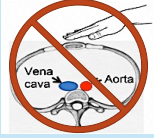


I have NO financial disclosures

Noncompressible Hemorrhage: Military and Civilian Firearm Trauma

Deaths:
 #1: Brain Trauma
 #2: Vascular Injury


Mortality > 80%



Manual Compression Is Not Effective

Need a More Effective Damage Control Approach

Challenges of Exsanguinating Hemorrhage



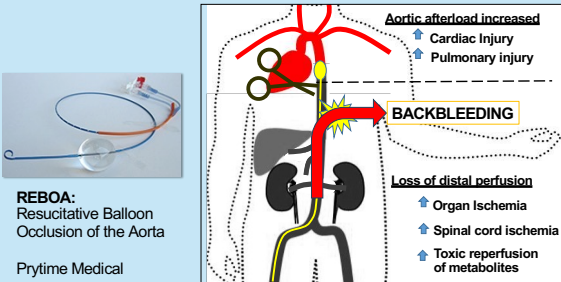
Unable to immediately mobilize:

- Vascular surgeon
- Imaging/diagnostics
- Permanent stentgraft inventory

Damage Control Allows for Transport:

- Between Hospitals
- Within a Hospital (ED to OR)
- Simultaneous injuries (i.e. Cranial decompression)

Aortic Occlusion Itself is a Stressful Event for the Body



REBOA:
 Resuscitative Balloon Occlusion of the Aorta
 Prytime Medical

Aortic afterload increased

- ↑ Cardiac Injury
- ↑ Pulmonary injury

BACKBLEEDING

Loss of distal perfusion

- ↑ Organ Ischemia
- ↑ Spinal cord ischemia
- ↑ Toxic reperfusion of metabolites

Ultimate Objective In Vascular Trauma:

Perfusion Preserving Hemorrhage Control

Permanent Stentgrafts for Emergent Hemorrhage Control

Maintain Distal Perfusion

Disadvantages

- Cannot be removed if misplaced or obsolete
- Strict sizing criteria not favorable for emergencies
- Challenges for injuries near branches in emergencies

The Rescue Retrievable Stent Graft

Porcine Model of Aortic Hemorrhage

A Rescue Stent Graft Controls Thoracic and Abdominal Aorta Vascular Injury WHILE PRESERVING DISTAL PERFUSION

(Go, J Trauma Acute Care Surg, 2020)

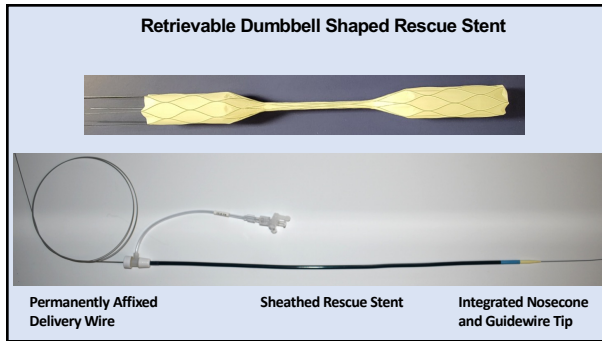
A Dumbbell Shaped RESCUE Stentgraft Allows Suture Repair While the Stent is in Place

(Kenawy et al. JVS VS. 2023)

Aortic Control From a More Anatomically Favorable Location

- Eliminates need to dissect clamp sites
- Useful when visualization is impaired, i.e. hemorrhage
- Avoidance of clamp related ischemia

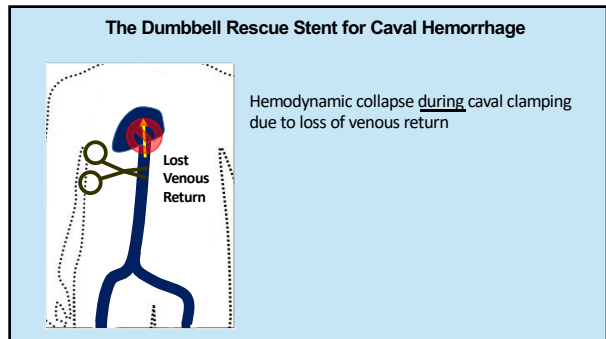
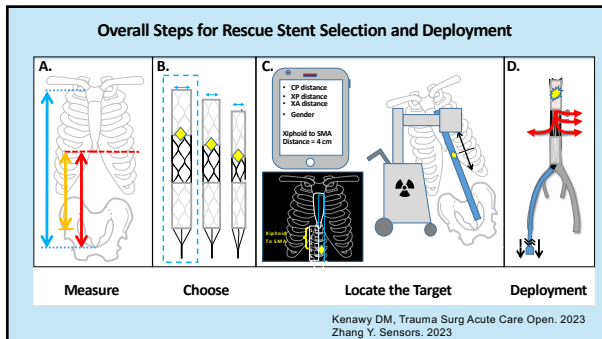
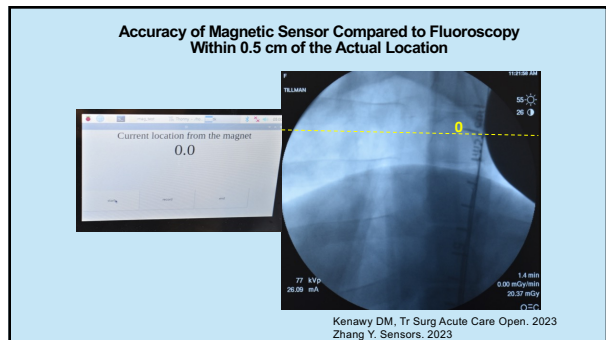
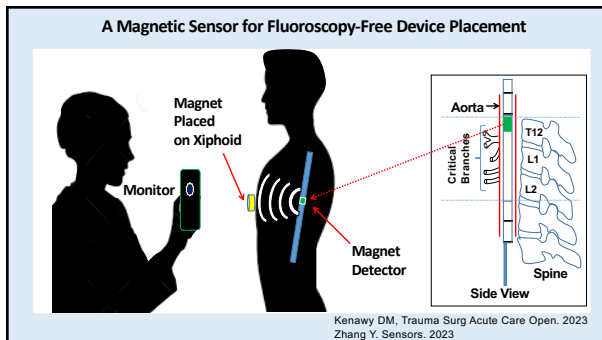
(Kenawy et al. JVS VS. 2023)



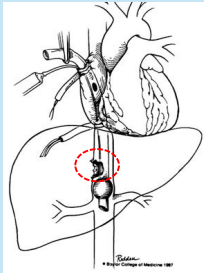
The Rescue Stent Offers Numerous Advantages Over REBOA or Crossclamp

- Preserves perfusion
- Preserved cardiac function
- Prevents acidosis
- Reduced post repair vasopressors
- Prevents backbleeding (Liters)
- Prevented hypotension that occurs after crossclamp or REBOA release

Go. J Tr and Acute Care Surg. 2020
Kenawy, JVS Vasc Sci. 2023



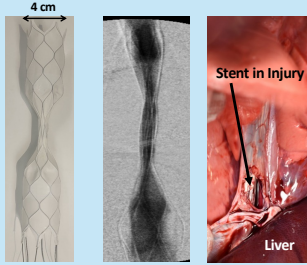
"Endo" Shock Shunt for Retrohepatic Caval Injuries



- Technically Demanding
- Complex Cardiac exposure/manipulation

Brunicardi, et al, Schwartz, 2004

Damage Hemorrhage Control with a Caval Rescue Stent



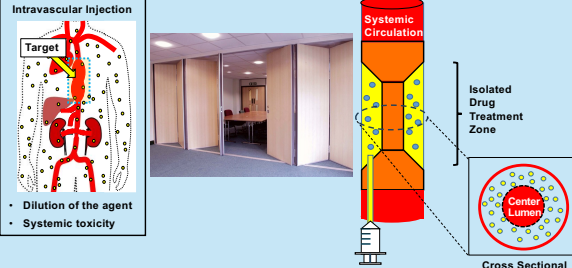
4 cm

Caval Rescue Stentgraft Caval Rescue Venogram Caval Rescue Injury Exclusion

Stent in Injury

Liver

Retrieval Stent Grafts for Focused Drug Delivery



Intravascular Injection

Target

- Dilution of the agent
- Systemic toxicity

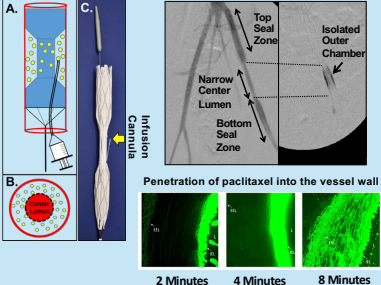
Systemic Circulation

Isolated Drug Treatment Zone

Center Lumen

Cross Sectional

Retrieval Stent Grafts for Anti-Restenotic Drugs



A. C.

Top Seal Zone

Isolated Outer Chamber

Narrow Center Lumen

Bottom Seal Zone

Infusion Cannula

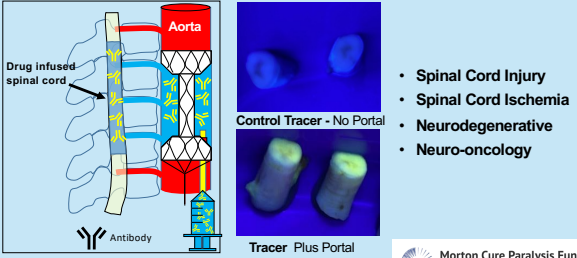
Penetration of paclitaxel into the vessel wall

2 Minutes 4 Minutes 8 Minutes

Advantages over Drug Coated Balloons:

- Less drug lost to the circulation
- Expand the types of drugs
- Allows liquid agents
- No loss of distal perfusion
- Reduced embolization of drug crystals

Retrieval Stent Grafts for Drug Delivery to the Spinal Cord And Portal Across the Blood Brain Barrier



Drug infused spinal cord

Aorta

- Spinal Cord Injury
- Spinal Cord Ischemia
- Neurodegenerative
- Neuro-oncology

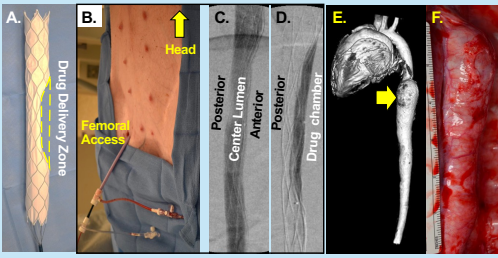
Control Tracer - No Portal

Tracer Plus Portal

Antibody

Morton Cure Paralysis Fund

Retrieval Stent Grafts for Creating Large Animals Models of and Eventually Drug Therapy of Aneurysms



A. B. C. D. E. F.

Drug Delivery Zone

Head

Femoral Access

Posterior

Center Lumen

Anterior

Posterior

Drug chamber

Summary for the RESCUE Retrievable Stentgraft

Retrievablestent-grafts are an important asset for Perfusion Preserving Hemorrhage damage control after vascular trauma

Non-fluoroscopic methods may promote rapid placement in emergencies

The Retrievable Stent Graft platform may offer an important armentarium to multiple drug delivery contexts

- Aneurysms
- Restenosis
- Spinal cord

Q-sub pending with the FDA to determine 510K vs PMA pathway for regulatory approval.



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Transformational Award
(PI: Tillman)



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Morton Cure Paralysis Fund
That All May Walk Again

(PI: Tillman)