

CENTRAL VENOUS RECANALIZATION AND SUBSEQUENT IMPLANTATION OF THE HeRO® DEVICE IN CATHETER DEPENDENT PATIENTS

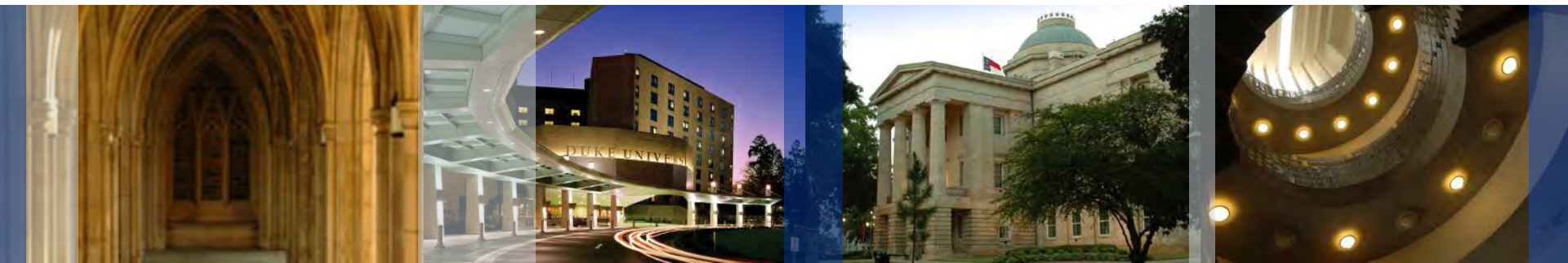
**Shawn M. Gage PA-C, P. Joshua O'Brien MD,
Charles Y. Kim MD, and Jeffrey H. Lawson MD, PhD.**

Section of Vascular Surgery and Division of Interventional Radiology
Duke University Medical Center
Durham, North Carolina, United States of America



DukeMedicine

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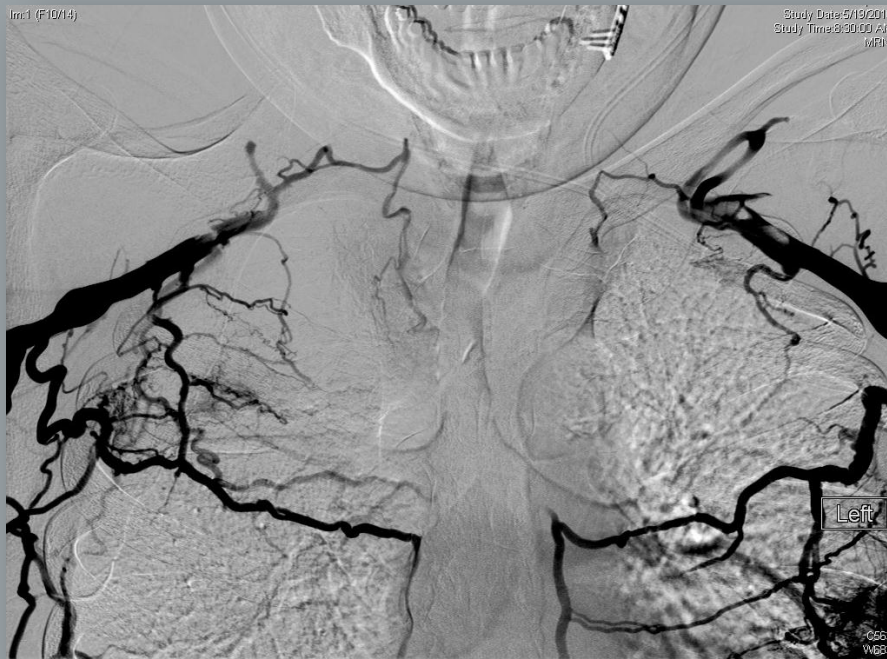


Disclosures

- Shawn M. Gage – Hemosphere, Inc.
 - consultant
- P. Joshua O'Brien – none
- Charles Y. Kim - none
- Jeffrey H. Lawson – Hemosphere, Inc.
 - research funding
 - consultant



The Problem: Central venous occlusion



- Recurrent central venous instrumentation
- Central venous catheters
- Balloon Angioplasty
- Central venous stents
- Shear stresses
- HD associated Inflammation
- Aggressive venous intimal hyperplasia



Current Options

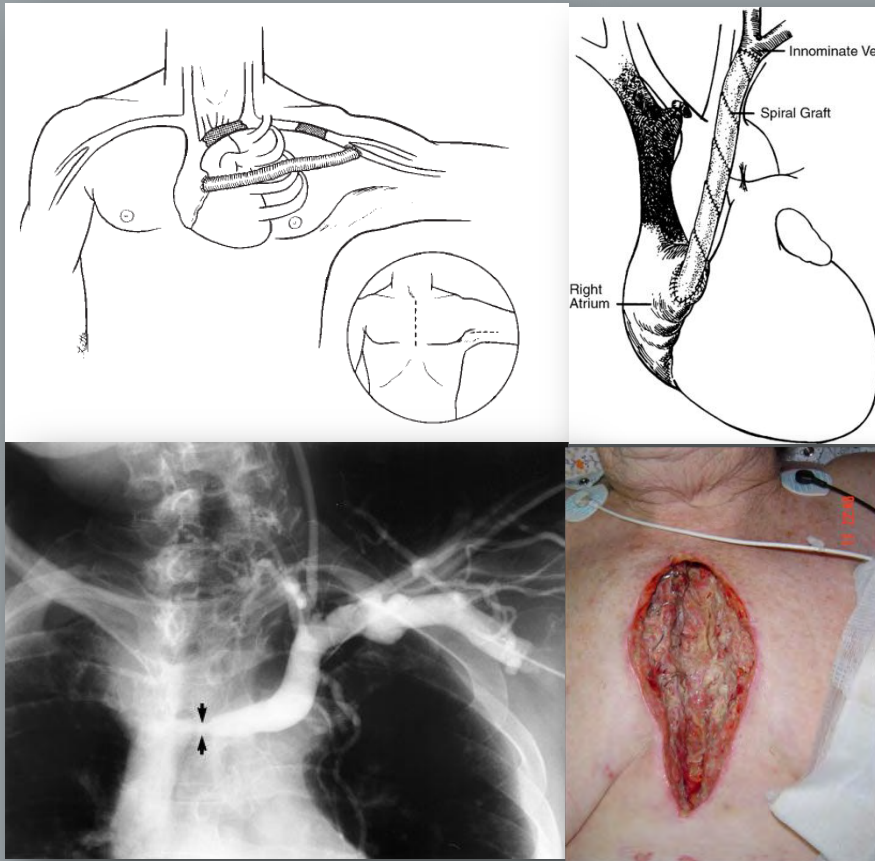
- Lower extremity AV access
 - increased risk of infection
 - greater risk for LE steal





Current Options

Direct bypass to right atrium or CV reconstruction

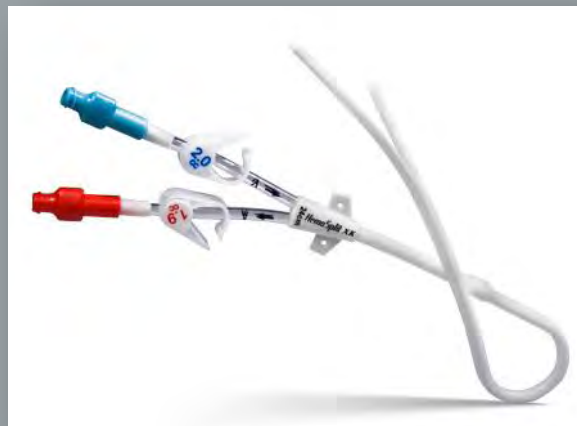


- Requires sternotomy or thoracotomy
- High morbidity
- Sternal wounds
- Graft infections
- Pleural or pericardial effusions



Current Options

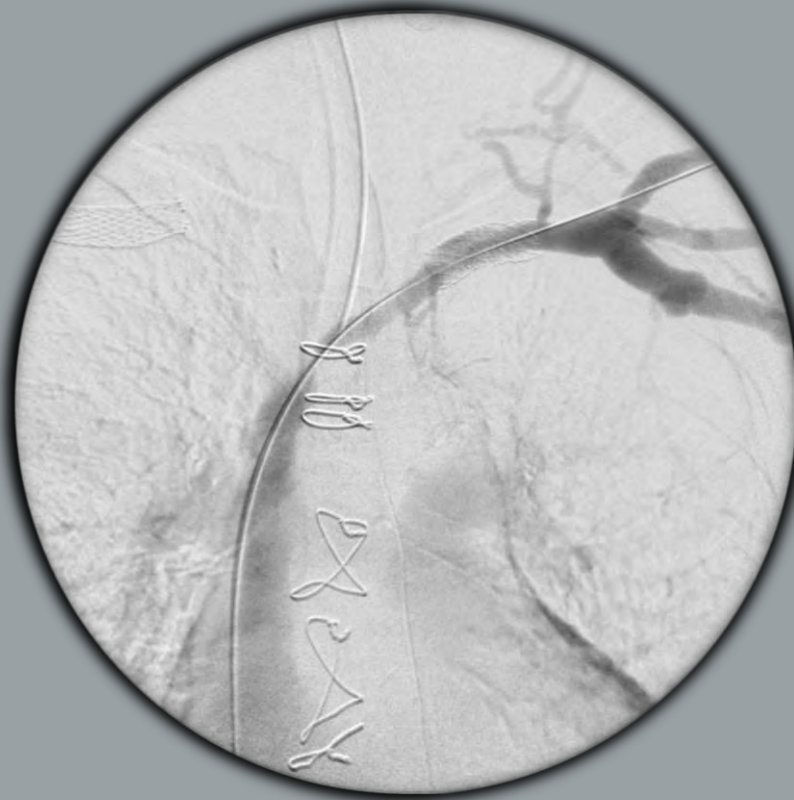
- “Destination” Dialysis Catheter
 - Increased infection risk
 - poorer dialysis adequacy
 - greater number of interventions
 - highest cost to healthcare system





Proposed Solution

Central Venous Recanalization

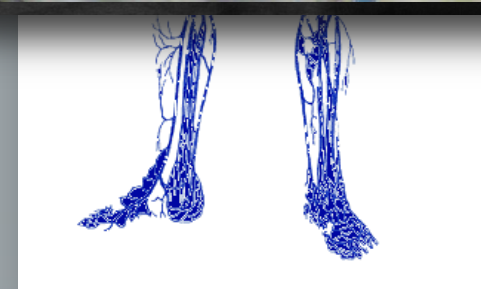
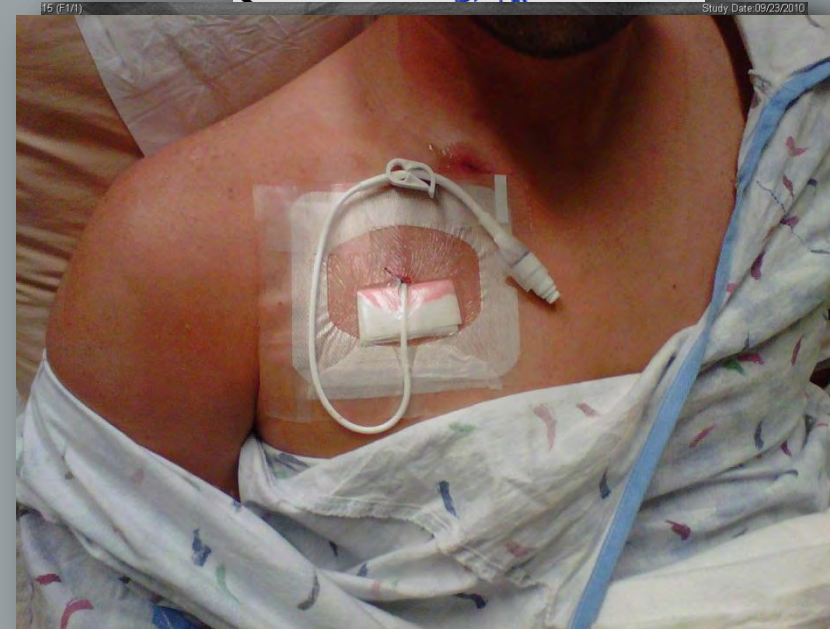
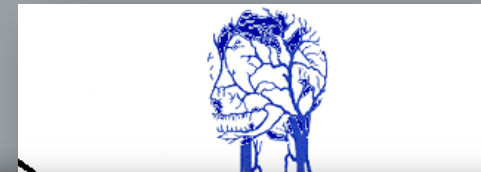


With Hemodialysis Reliable Outflow as adjunct



Recanalization Procedure

- Upper and lower extremity venous access
- Multi-projection imaging
- Low profile catheters
- Sharp recanalization
- Through-and-through guidewire access
- Balloon angioplasty
- Access place-holder

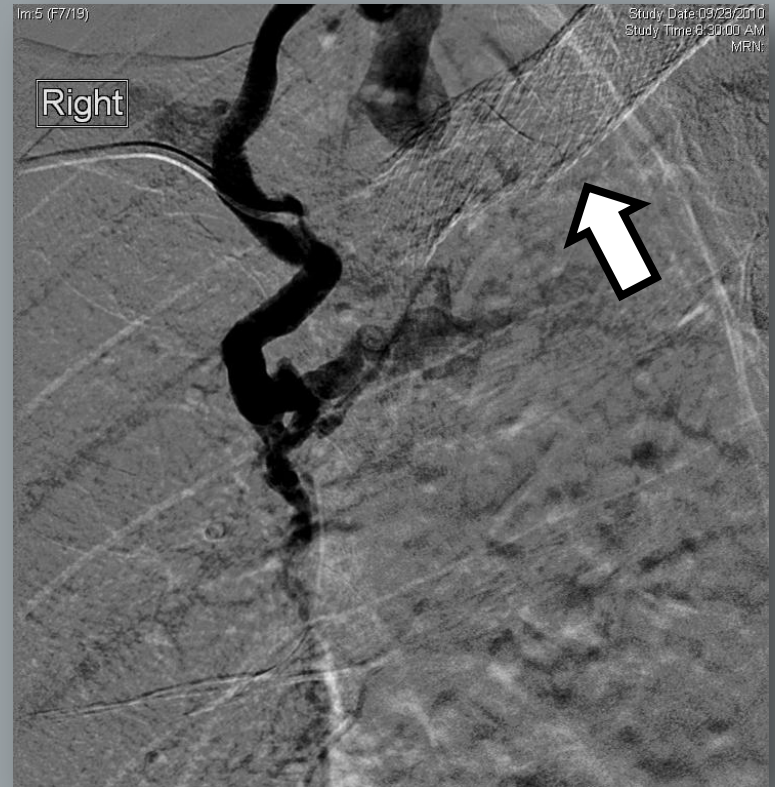




Right BCV & SVC Occlusion



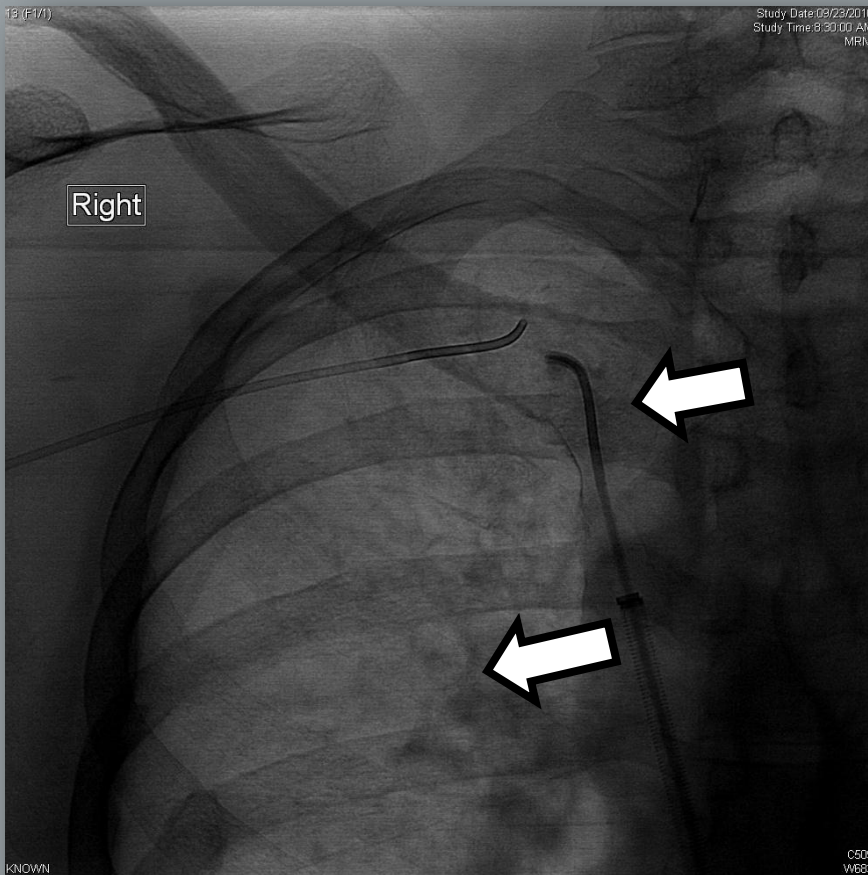
Collateral veins



Occluded Left BCV stent



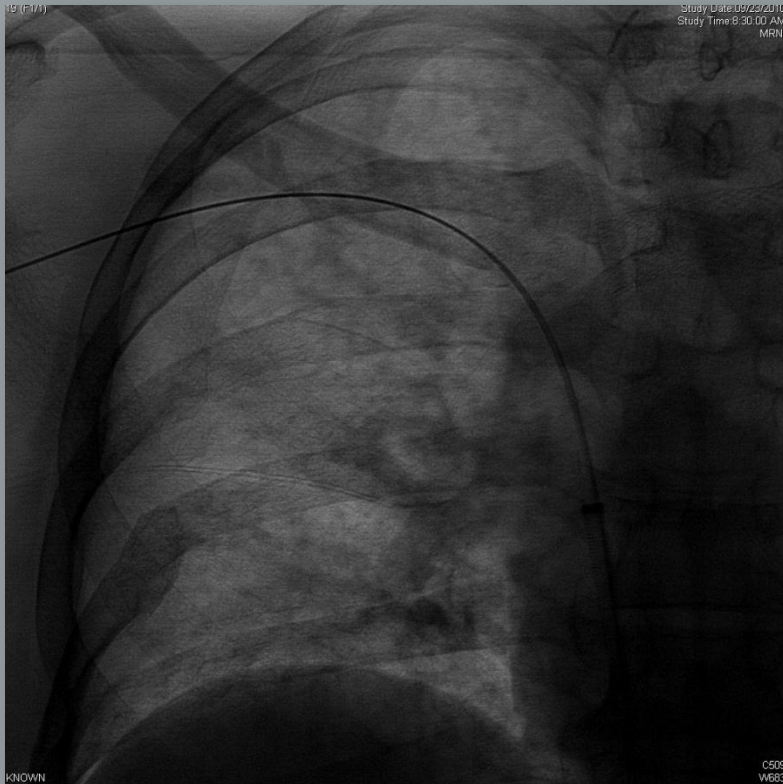
Axillary and Femoral vein access



- Low profile directional catheters
- Long rigid sheath
- TIPS needle



Crossed occlusion

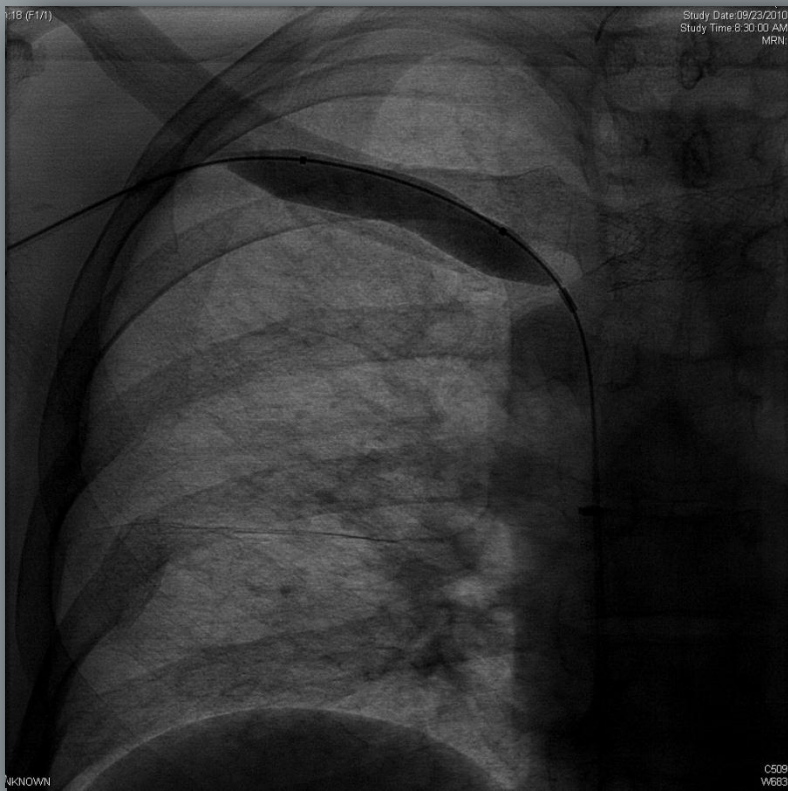


- Through and through venous access
- “body floss”
- “trackability”





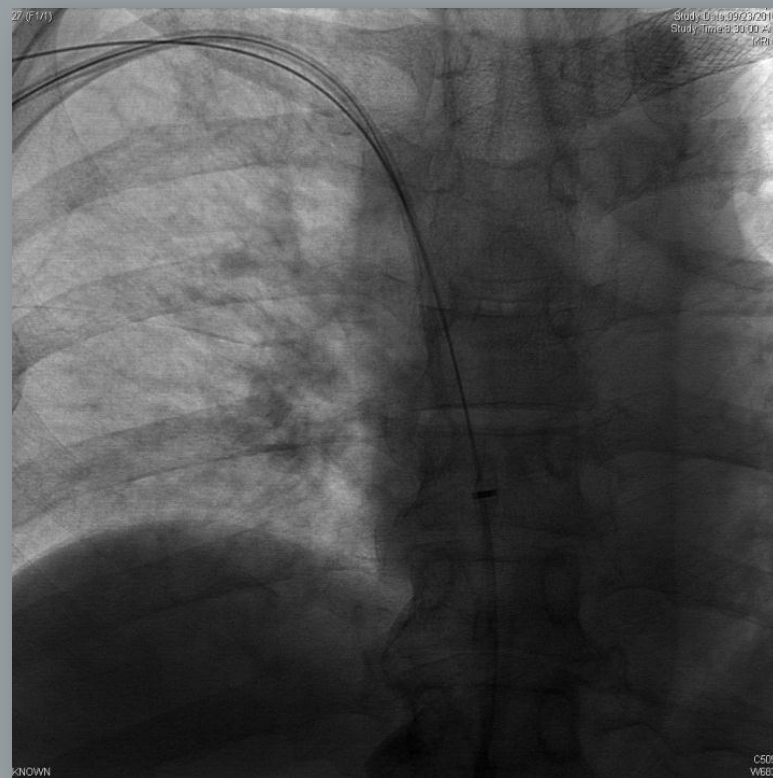
Balloon Angioplasty



- Dilate tract



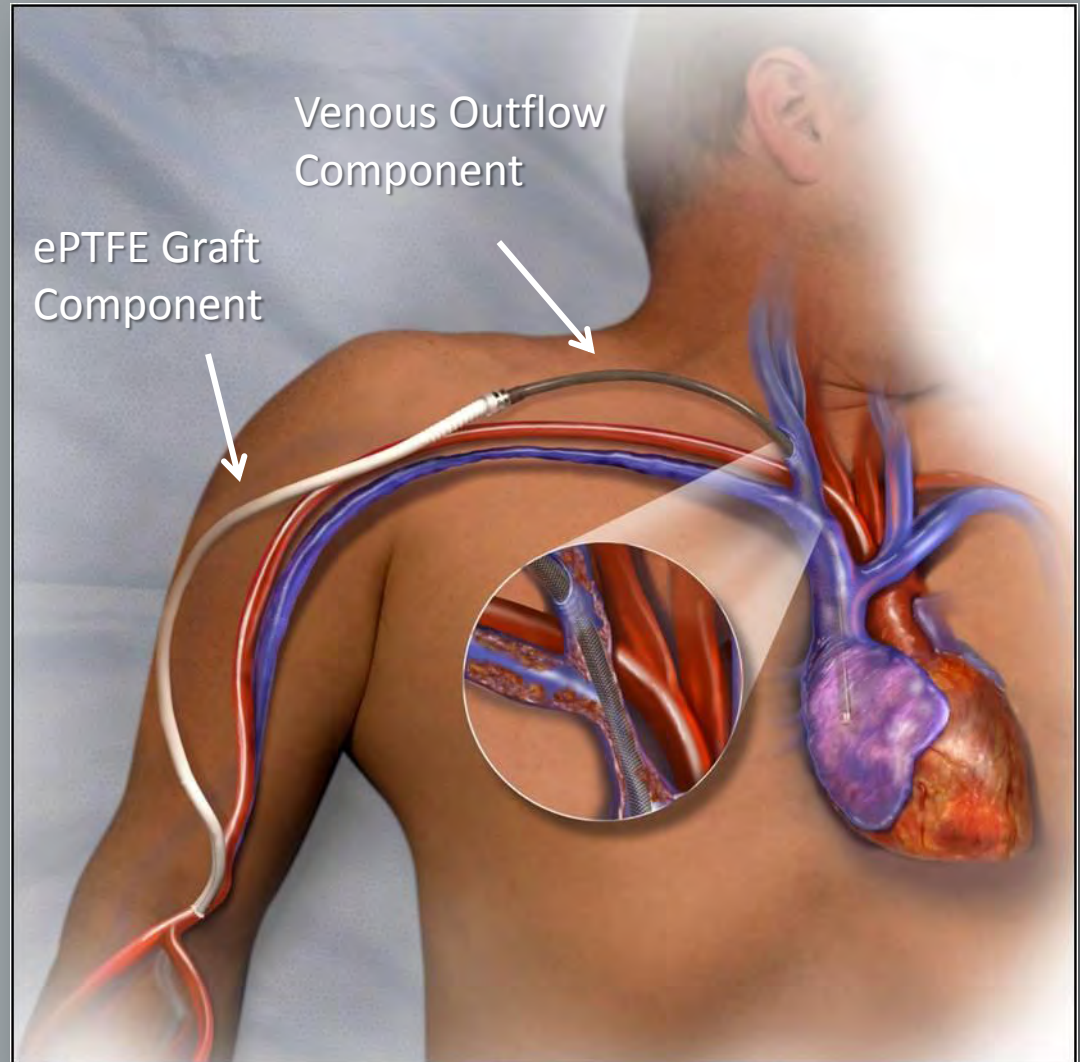
Low profile catheter implanted as place-holder





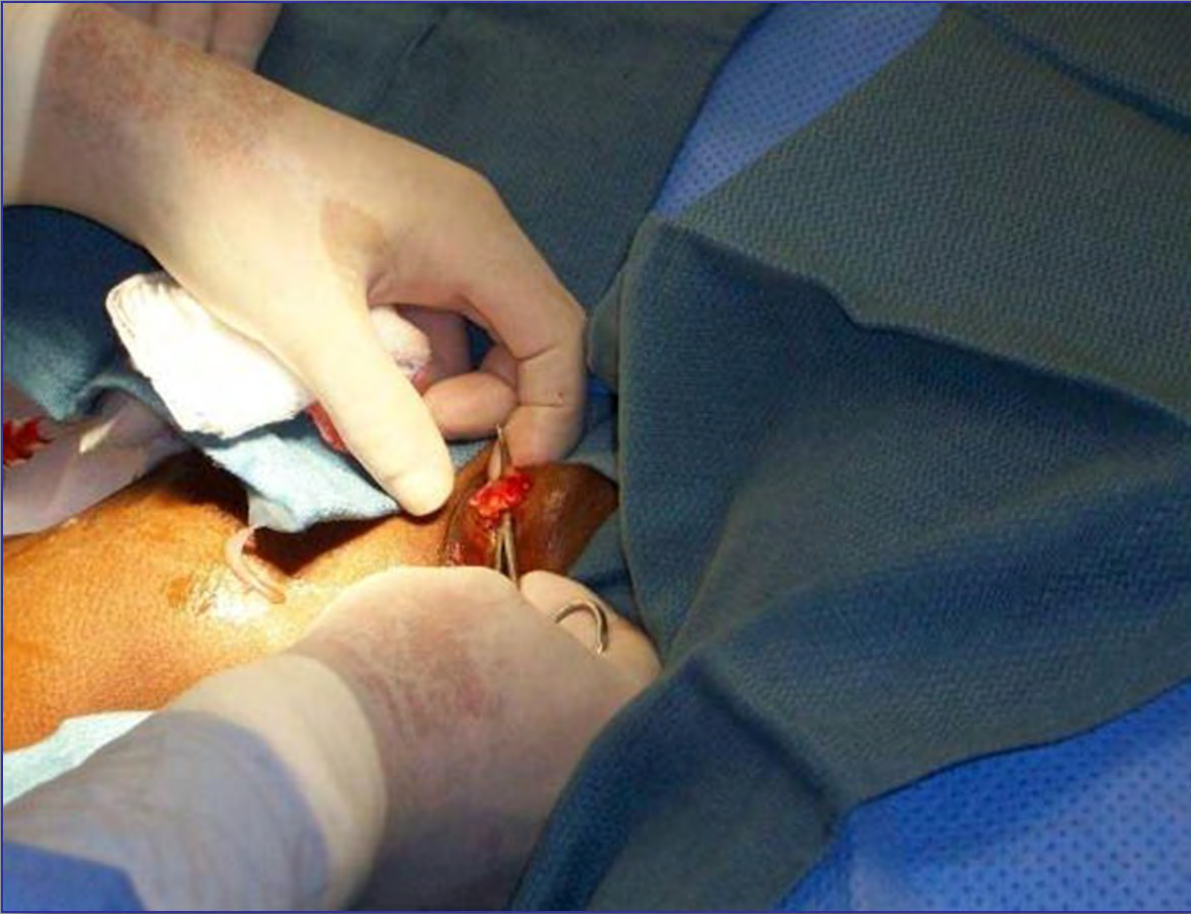
A Brief Review

- HeRO™ Hemodialysis Reliable Outflow
- Hybrid vascular access device “graft-cath”
- 2 primary components: ePTFE graft with Titanium connector 6mm ID, and radiopaque silicone outflow component with braided nitinol reinforcement 5mm ID
- Common access veins include: Subclavian and Internal Jugular
- End stage access device
- Indicated for catheter dependent patients with central venous stenosis and/or occlusion



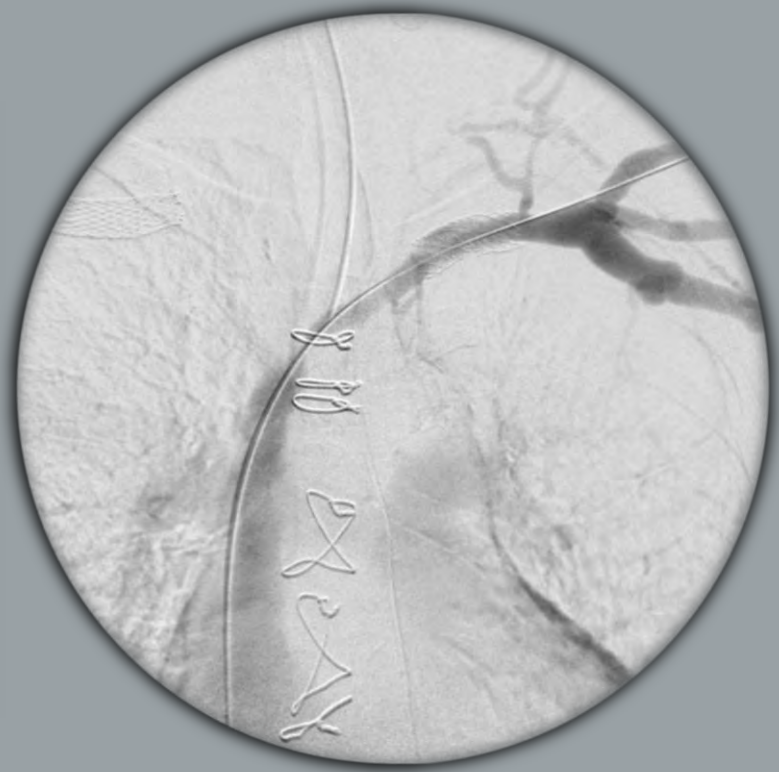
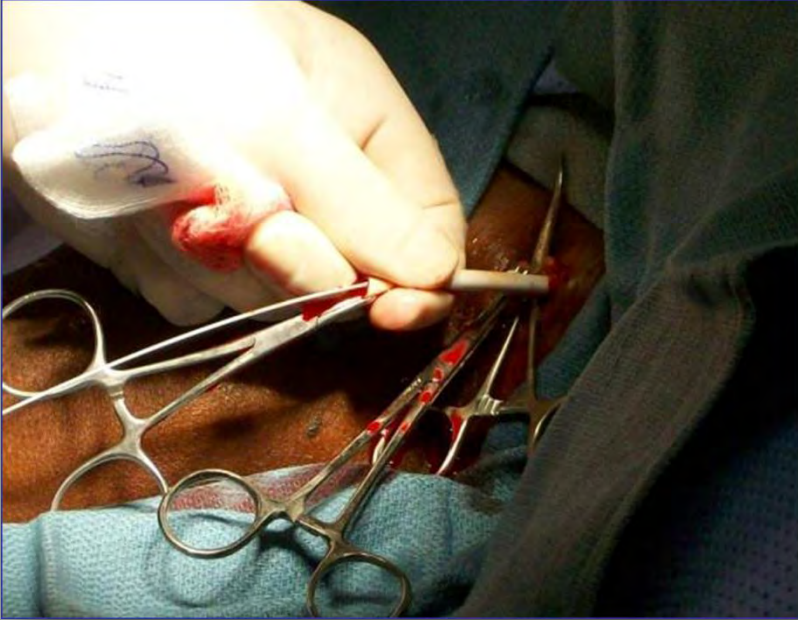


Cut down on catheter for access





Wire access to IVC



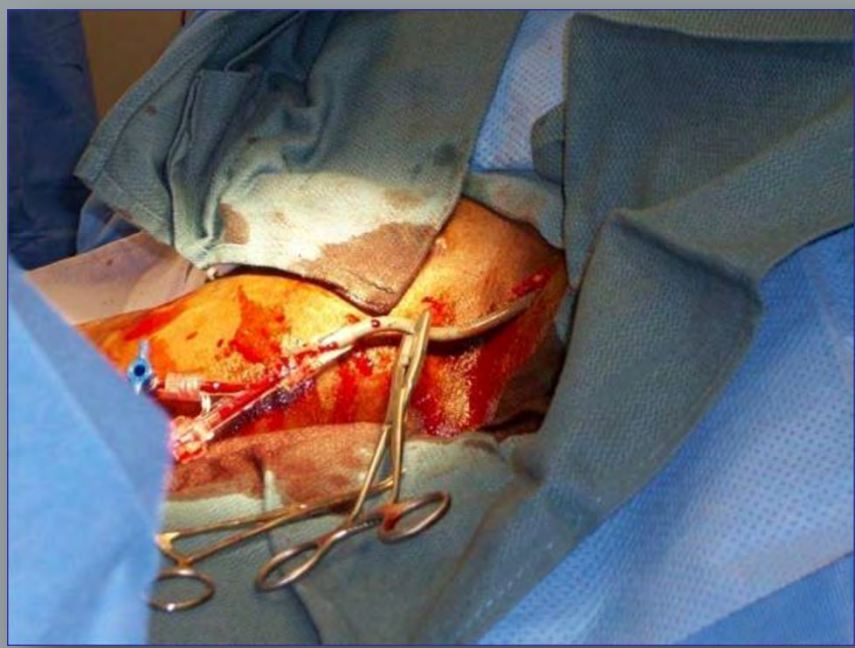


Peel-away sheath





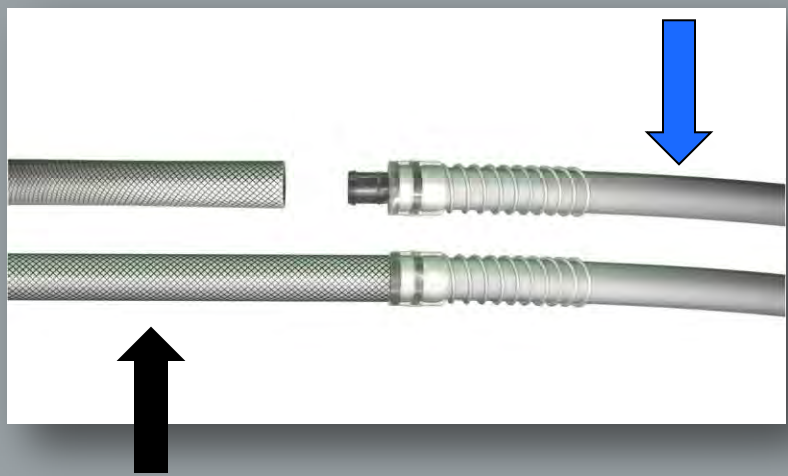
Outflow component





Connect Outflow component to PTFE

ePTFE graft



Silicone outflow component





Tunnel graft and obtain inflow





Patients and Methods

- Single center retrospective review
- 18 ESRD patients
- All with total central venous occlusion
- All dialysis catheter dependent
(femoral or trans-hepatic)



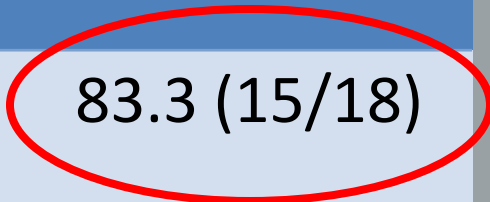
Results

<i>Demographics</i>	
Age, mean (range)	50.1 (25-74)
Male, % (n/N)	46 (8/18)
Race, % (n/N)	
Black/African American	78 (14/18)
White/Caucasian	22 (4/18)
BMI, mean (range)	32.6(16-48.2)



Results

<i>CVR Specifics</i>	
Successful CVR, % (n/N)	83.3 (15/18)
Thru & Thru access, % (n/N)	67 (10/15)
Catheter placed, % (n/N)	87 (13/15)
CVR to HeRO (days), mean (range)	32.5 (0-148)





Results

HeRO Implant Specifics

Successful implants, % (n/N) **93.3% (14/15)**

Side of body, % (n/N)

Right 64 (9/14)

Insertion vein, % (n/N)

Subclavian 36 (5/14)

Internal Jug 29 (4/14)

External Jug 14 (2/14)

Other 21 (3/14)



Patency Rates

Patency	6 <i>months</i>	12 <i>months</i>
Primary, % (n/N)	57% (4/7)	50% (2/4)
Secondary, % (n/N)	100% (7/7)	100% (4/4)



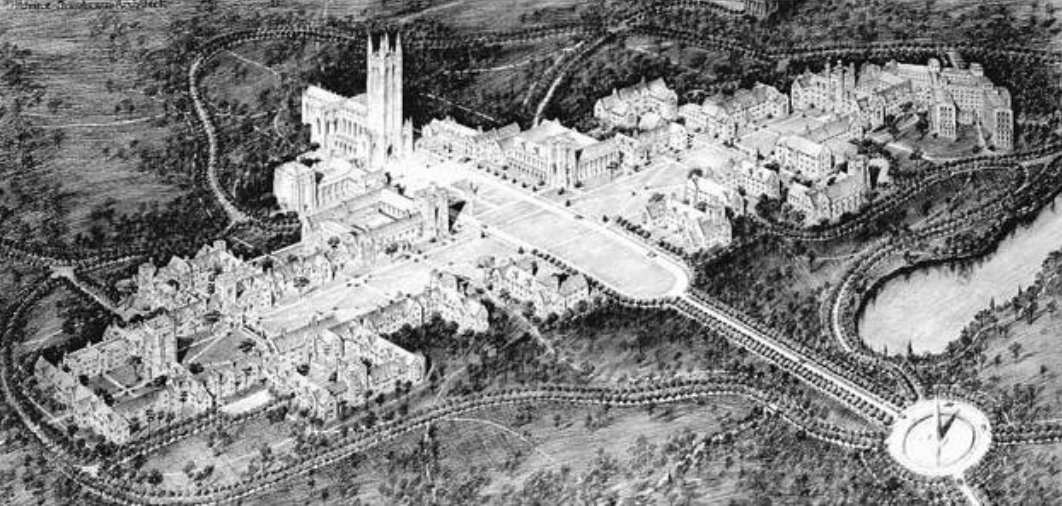
Results

- Intervention
 - Overall 71% FFI
- Infection
 - 1 HeRO related infection
 - required interposition replacement of ePTFE
- Death
 - 3 deaths (21%)
 - All unrelated to recanalization or HeRO implant



Conclusions

- Central venous recanalization is feasible
- HeRO device allows for durable access
- Maintain upper body access
- Patency & intervention is acceptable
- Reduced cost to healthcare system
- Reduced morbidity and mortality



Thank You



Shawn M. Gage, PA-C
Section of Vascular Surgery
Duke University Medical Center

