

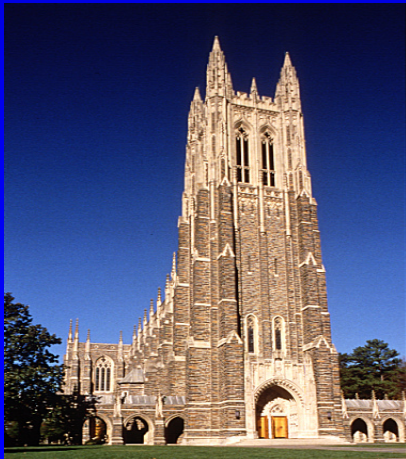
HeRO

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Disclosures

Consulting, Clinical Trials and Opinion

Hemosphere

Ark Therapeutics

Baxter

Lemaitre

Johnson & Johnson/Ethicon

Endologix

Zymogenetics

Gore Medical

Atrium Medical

NovoNordisk

Pervasis Therapeutics

Nanovasc

Research

American Heart

ACS

NIH

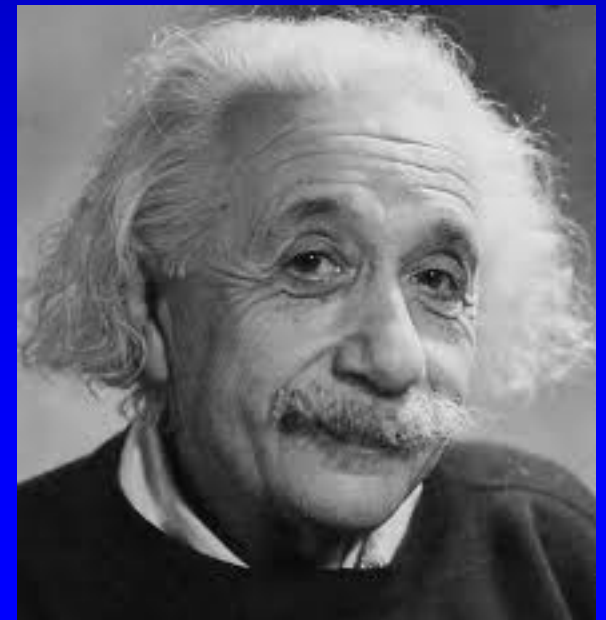
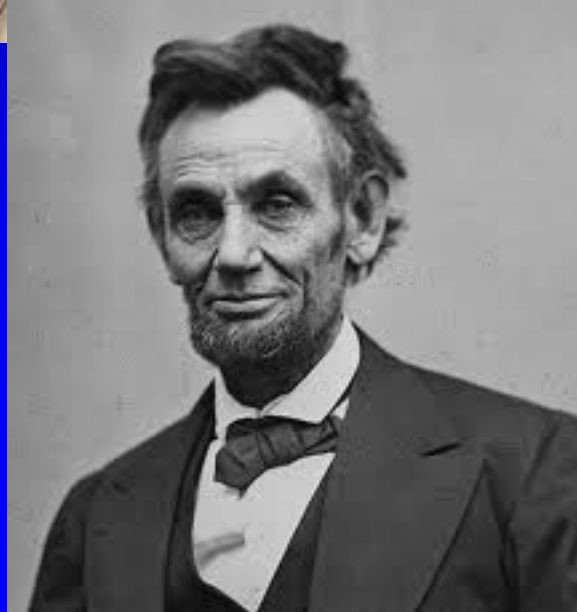
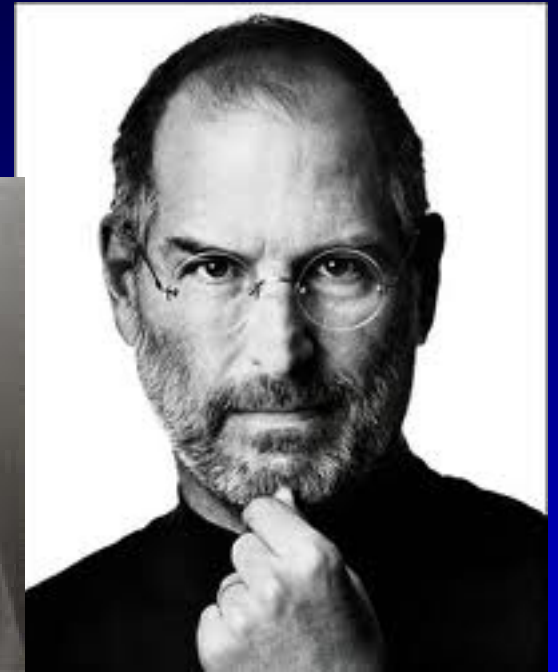
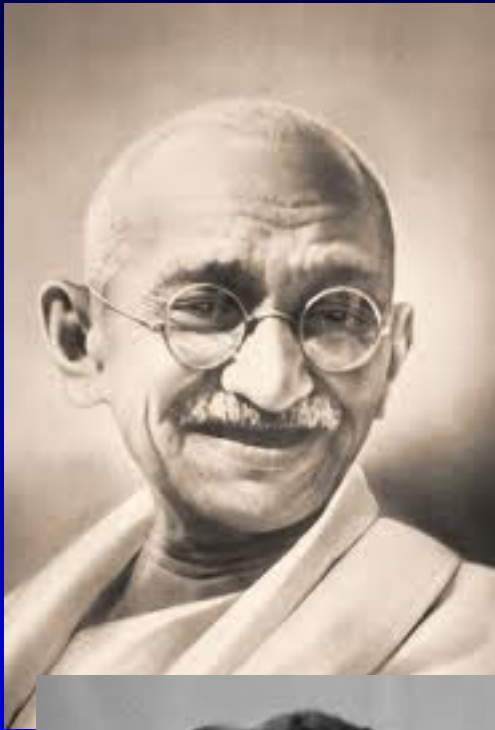
ADA

HHMI

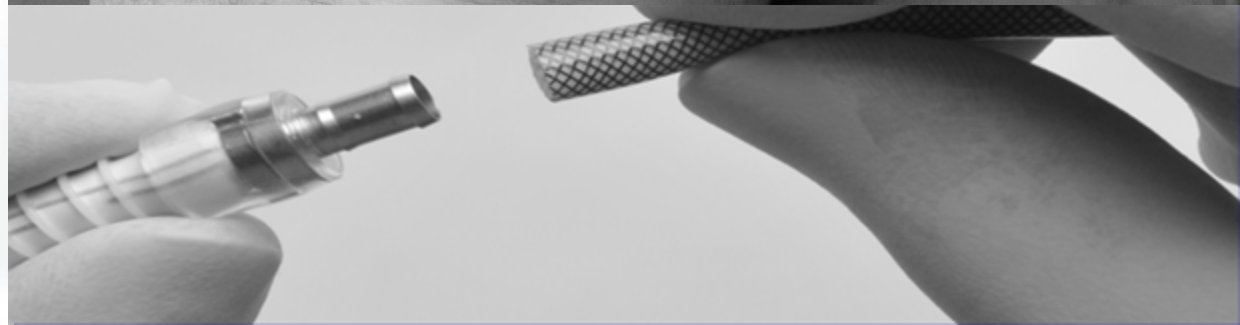
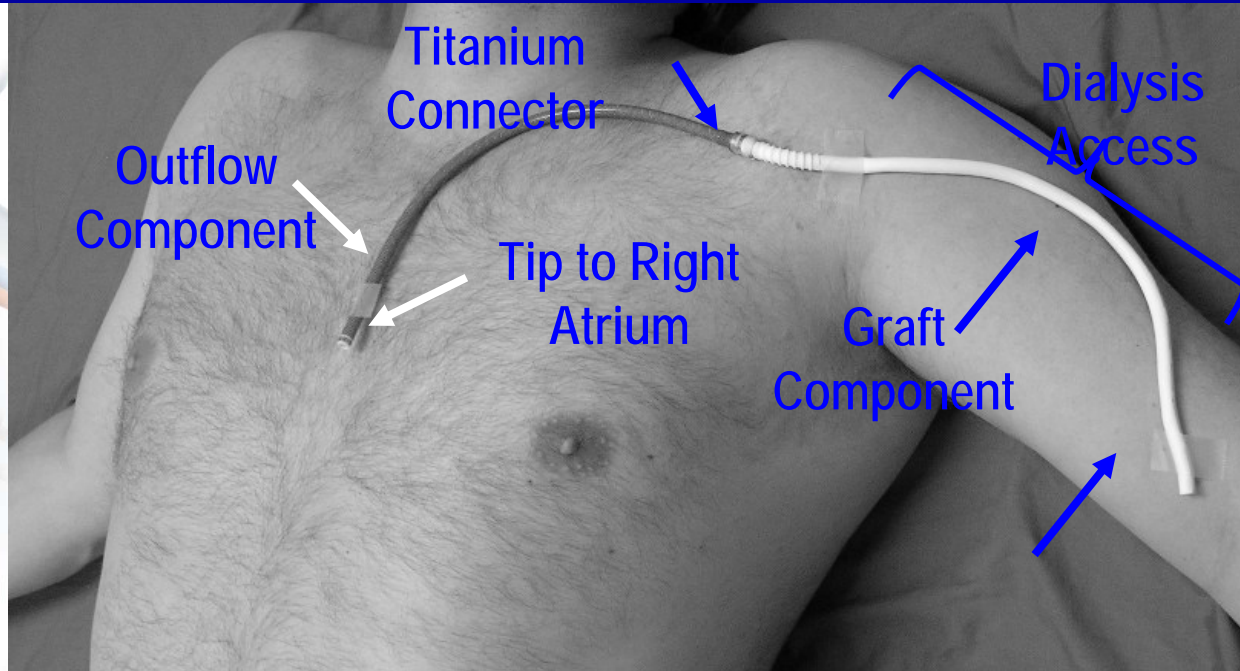
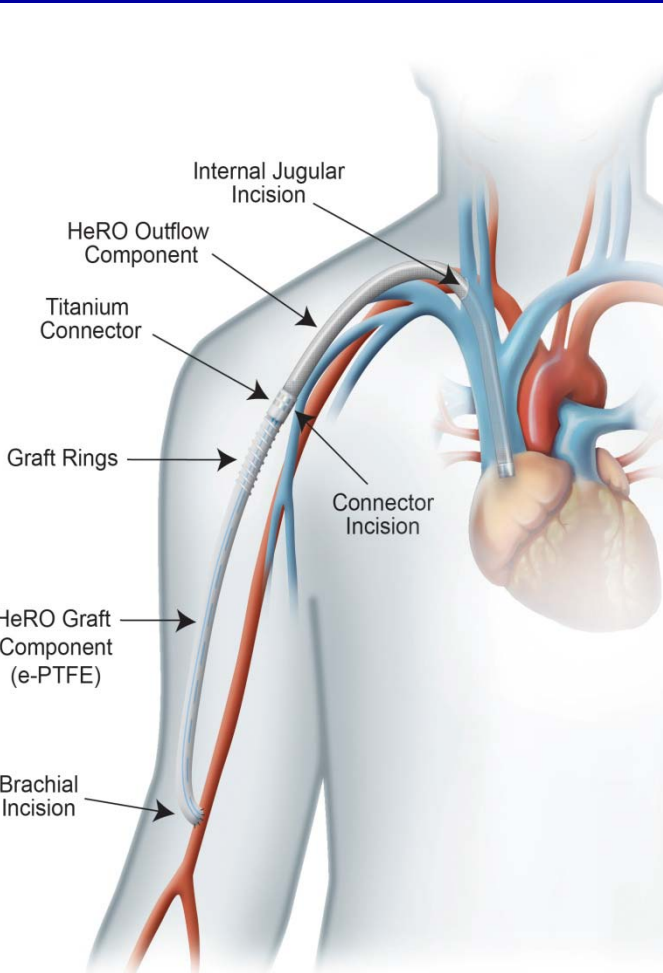
Superheroes



Heroes



Hemodialysis with Reliable Outflow (HeRO)





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

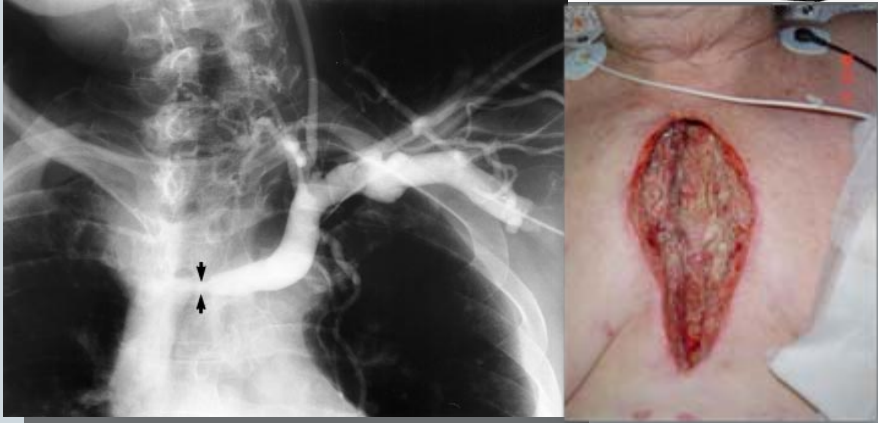
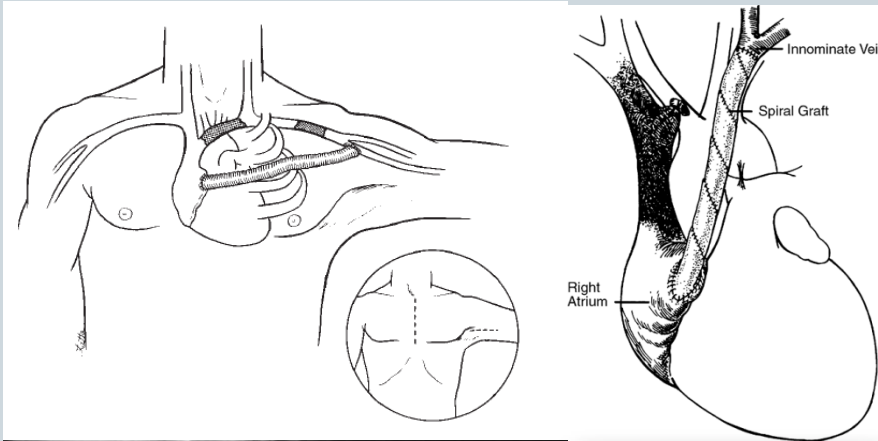
- Lower extremity AV access
 - increased risk of infection
 - greater risk for LE steal





Current Options

Direct bypass to right atrium or CV reconstruction

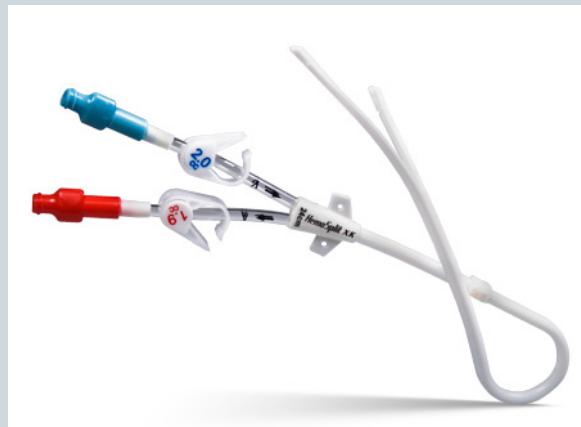


- Requires sternotomy or thoracotomy
- High morbidity
- Sternal wounds
- Graft infections
- Pleural or pericardial effusions



Current Options

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



State-of-the Art???

Left

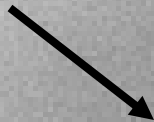
C.W. 50 yo BF with No Access

State-of-the Art???

RT

Death via Catheter Sepsis!!

Transhepatic Permucath

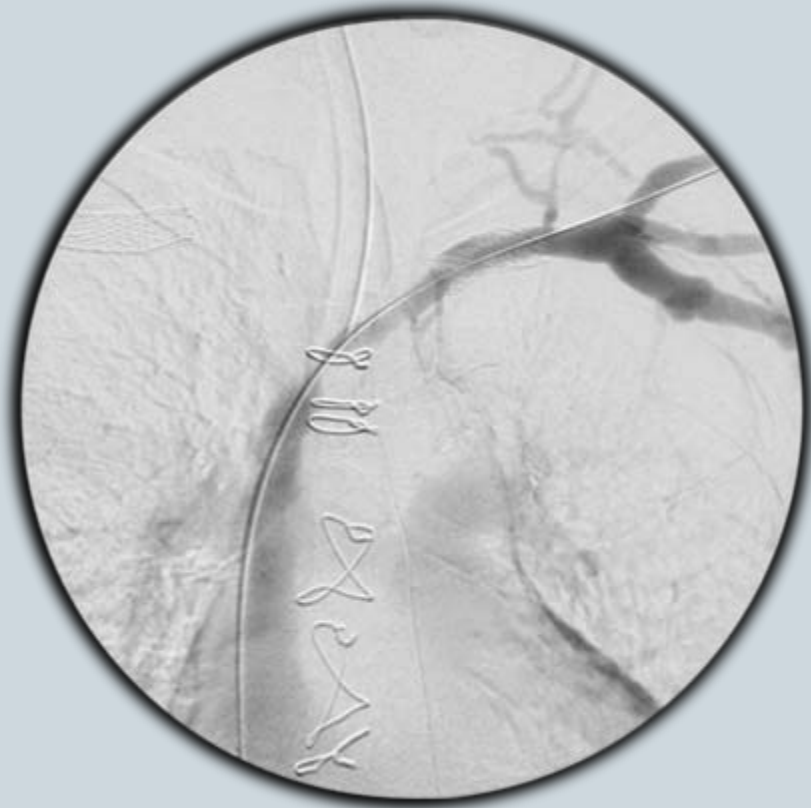


C.W. 50 yo BF with No Access



Proposed Solution

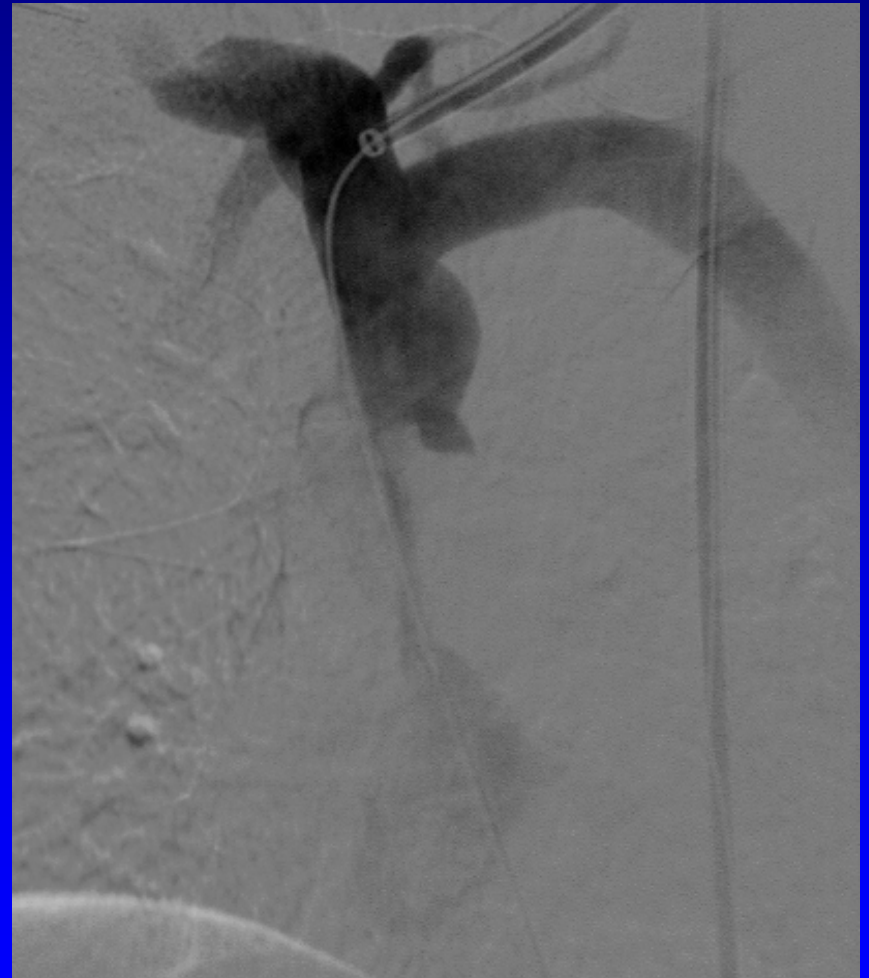
Central Venous Recanalization



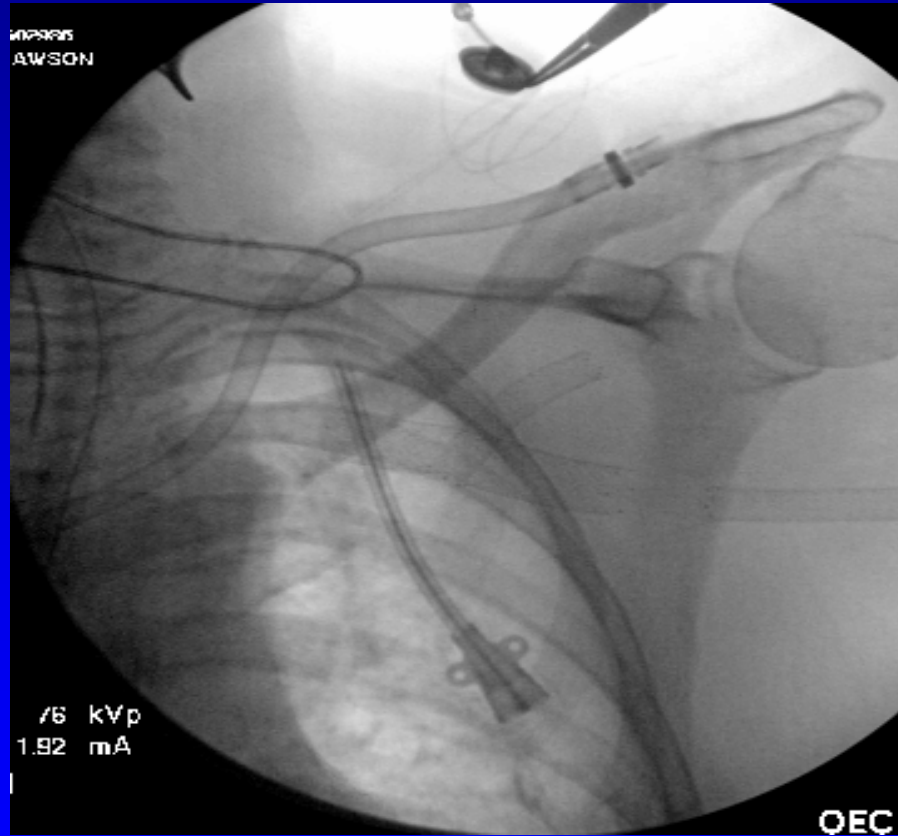
With Hemodialysis Reliable Outflow as adjunct

Occluded SVC with Access to the RA via the L Subclavian Vein

- 66 year old woman with multiple extremity access grafts currently dialyzed through a left internal jugular TDC
- History of prior SVC occlusion managed with angioplasty and stenting



History Of Occluded SVC, but access to the SVC via the Subclavian

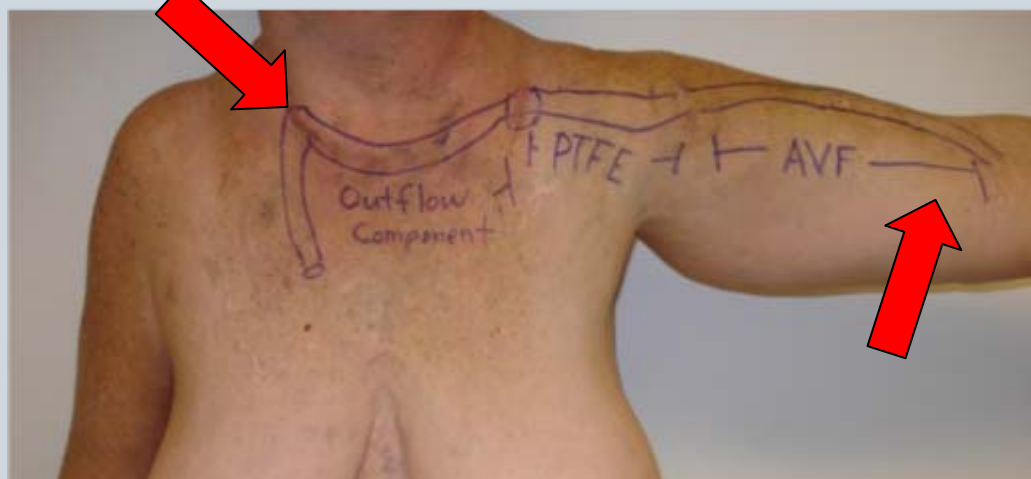




Implantation Specifics

HeRO Implant Side

HeRO Implant Side	% (n/N)
Right	58.5 (24/41)
Left	39.0 (16/41)
Right → Left	2.4 (1/41)

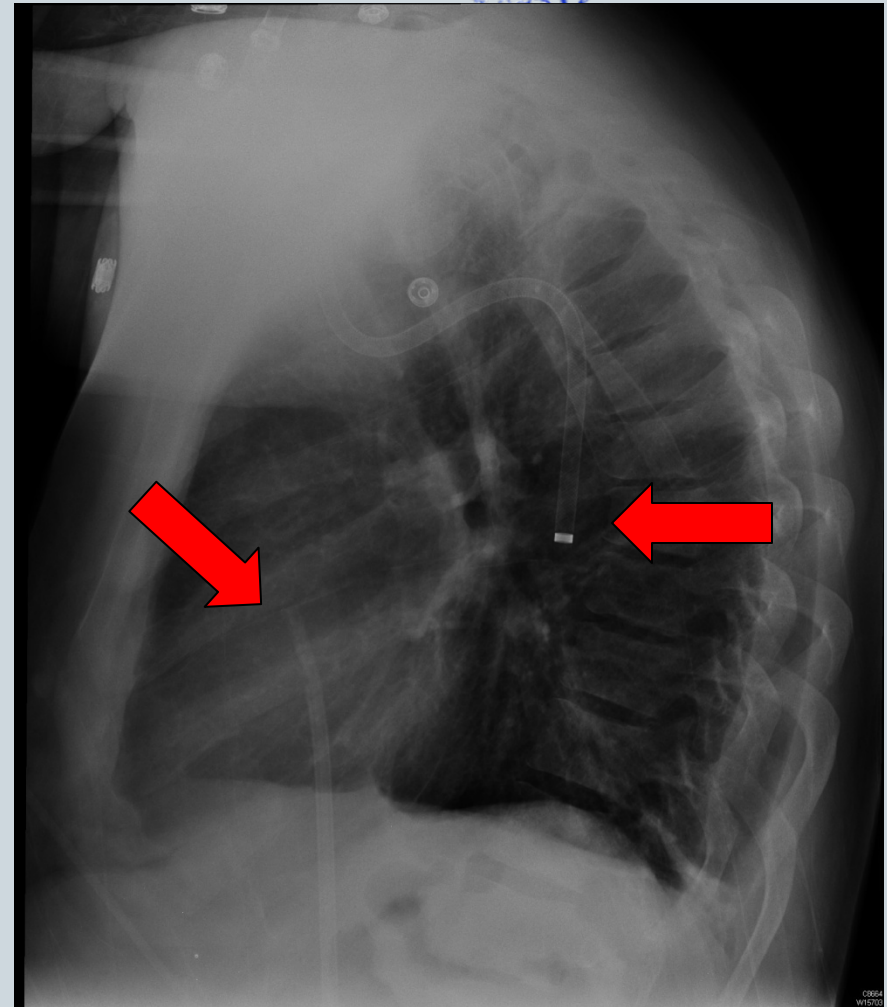




Implantations Specifics



<i>Outflow Vein</i>	
Outflow	% (n/N)
SVC	90.2 (37/41)
Azygos	7.3 (3/41)
IVC	2.4 (1/41)





Patency & Intervention Rates

	<i>Duke 6 months</i>	<i>Multi Center Trial 8.6 mo mean f/u ¹</i>	<i>AVG literature 6 months ²</i>	<i>TDC literature 6 months</i>
Patency				
Primary, %	68.3 ^a	38.9	58	50 ^{5, 6}
Secondary, %	87.8 ^b	72.2	76	55 ^{5, 6}
Intervention Rates, per year	1.38	2.5	1.6-2.4 ^{3,4}	5.8 ^{5, 6}

1. Katzman HE, et al. Initial Experience and Outcome of a New Hemodialysis Access Device for Catheter-Dependent Patients. J Vasc Surg 2009;50:600-07.
2. Sidawy AN, et al. Recommended Standards for Reports Dealing with Arteriovenous Hemodialysis Access. J Vasc Surg 2002;35:603-10.
3. Bosman PJ, et al. A Comparison Between PTFE and Denatured Homologous Vein Grafts for Haemodialysis Access: A Prospective Randomized Multicenter Trial. Eur J Vasc Endovasc Surg 1998;16:126-32.
4. Madden RL, et al. A Comparison of Cryopreserved Vein Allografts and Prosthetic Grafts for Hemodialysis Access. Ann Vasc Surg 2005; 19:686-91.
5. Rocklin MA, et al. Comparison of cuffed tunneled hemodialysis catheter survival. Am J Kidney Dis 2001;37:557-63.
6. Duszak R, et al. Replacement of failing tunneled hemodialysis catheters through pre-existing subcutaneous tunnels: a comparison of catheter function and infection rates for de novo placements and over-the-wire exchanges. J Vasc Interv Radiol 1998;9:321-7.

a. (n/N) 19/28 patients
b. (n/N) 32/36 patients

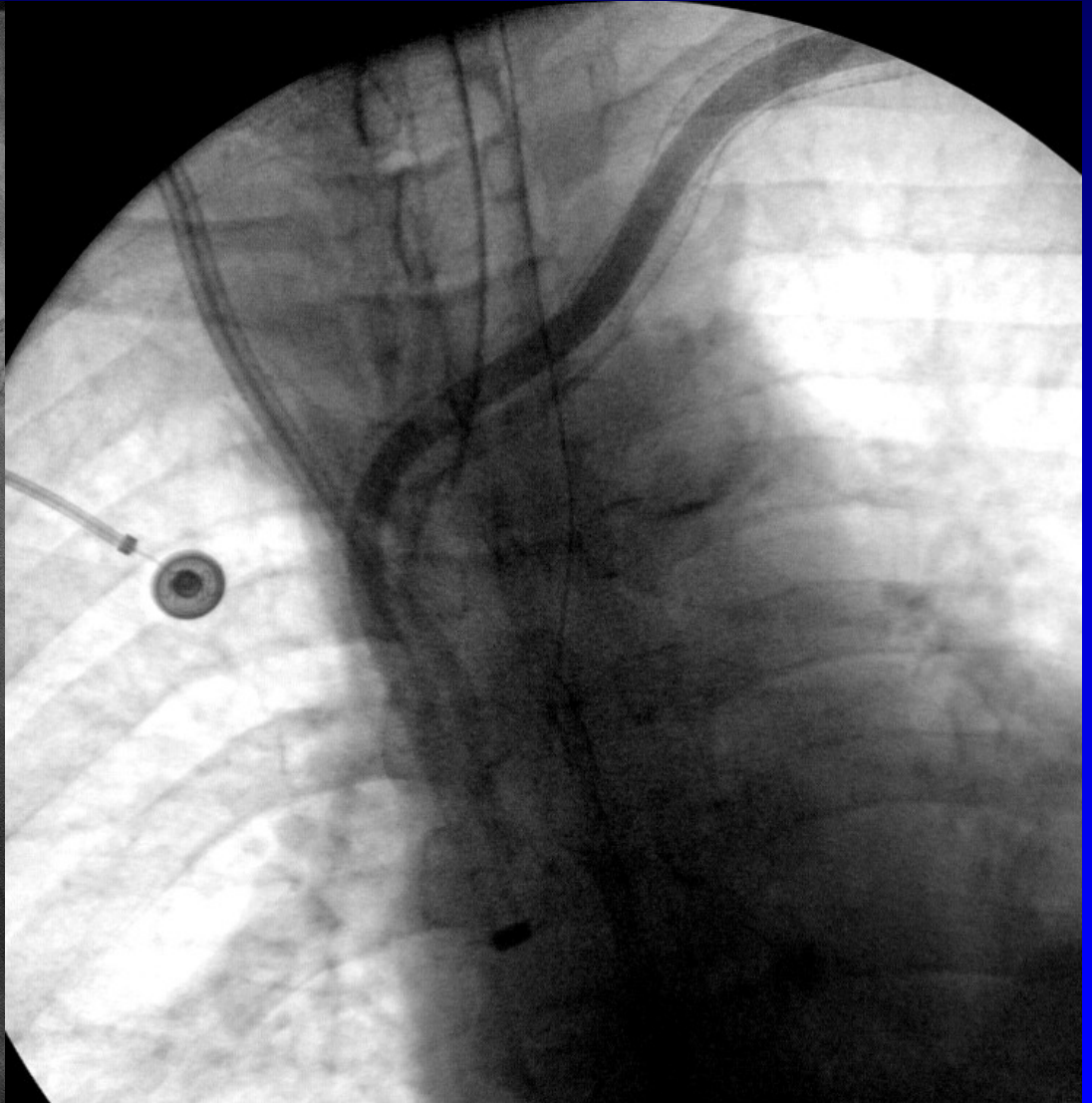
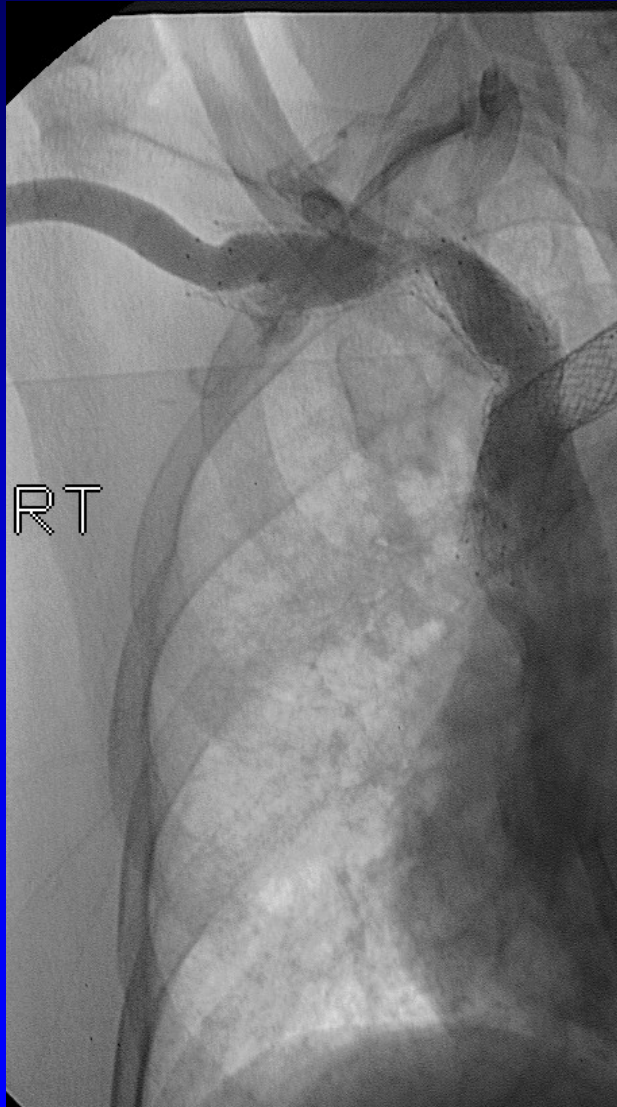


Infection Rates

<i>HeRO Cohorts</i>	<i>No.</i>	<i>Total Days</i>	<i>Bacteremia events</i>	<i>Bacteremia rate/1000 days</i>	<i>(TDC) Control rate/1000 days¹</i>
Overall					
Duke	41	10,058	10	1.29	2.3
Multicenter ¹	36	9931	7	0.70	
Bridging Period					
Duke	39	2729	10	3.66	1.6-5.5
Multicenter ¹	32	1373	7	5.10	
Alone					
Duke	35	7120	3	0.42	2.3
Multicenter ¹	29	8525	0	0.00	

1. Katzman HE, et al. Initial Experience and Outcome of a New Hemodialysis Access Device for Catheter-Dependent Patients. J Vasc Surg 2009;50:600-07.

The HeRO Body Floss





Right BCV & SVC Occlusion



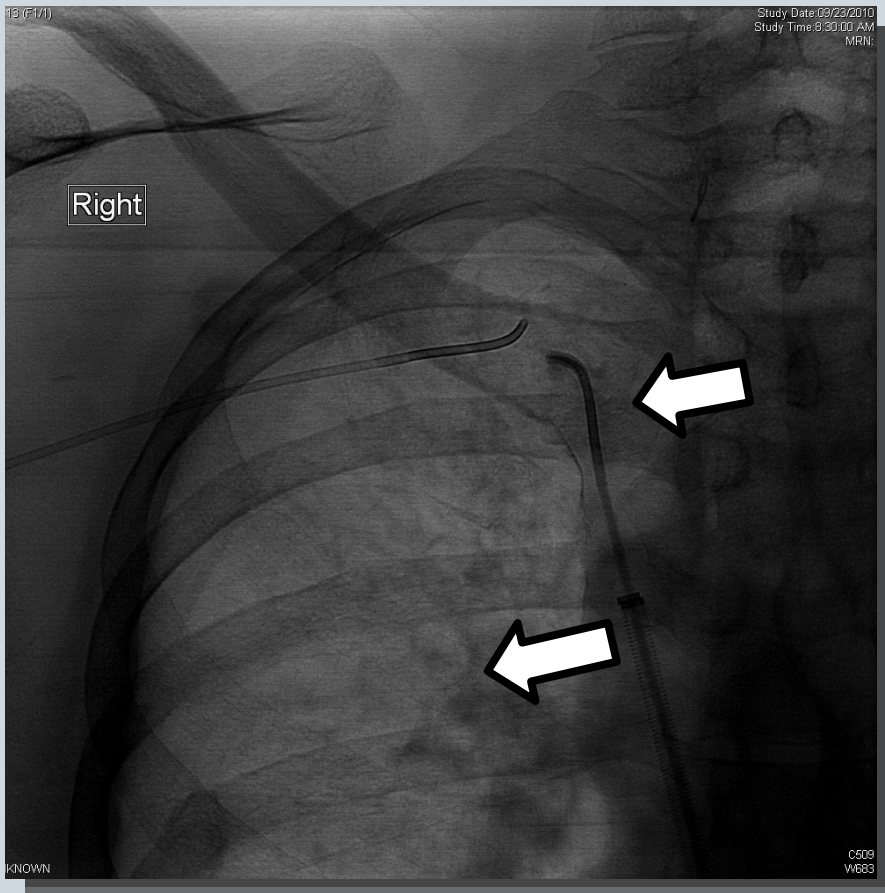
Collateral veins



Occluded Left BCV stent



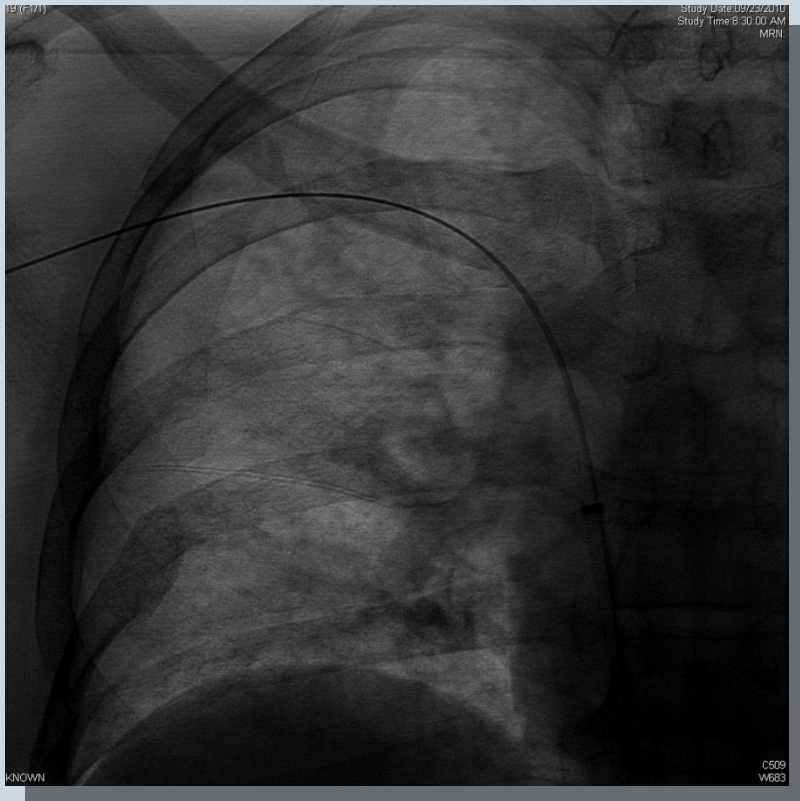
Axillary and Femoral vein access



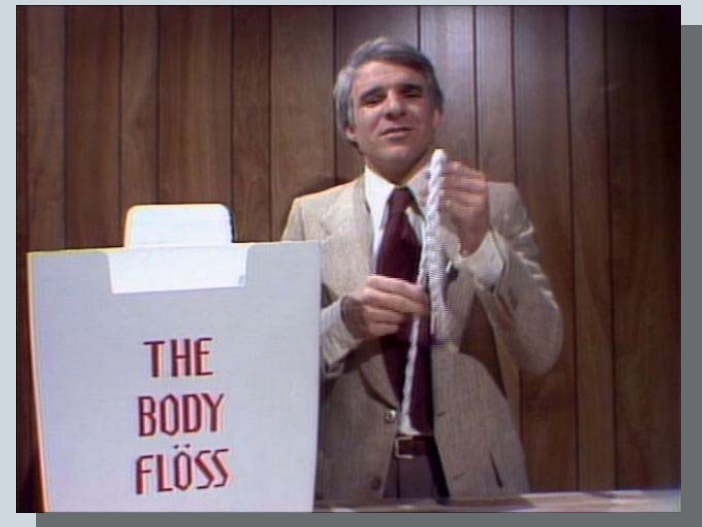
- Low profile directional catheters
- Long rigid sheath
- TIPS needle



Crossed occlusion



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





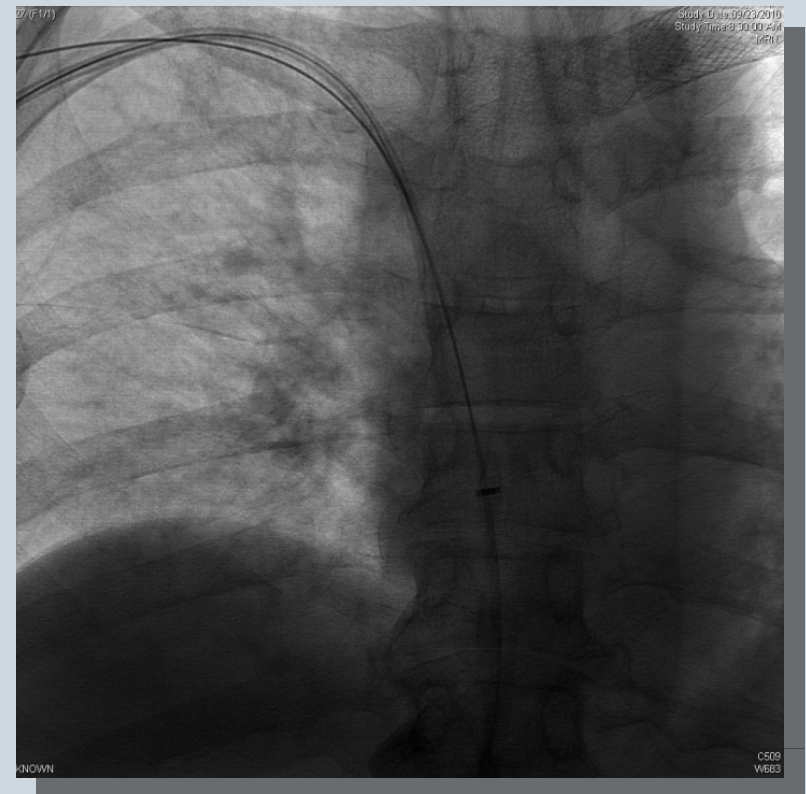
Balloon Angioplasty



- Dilate tract



Low profile catheter implanted as place-holder





Results

CVR Specifics

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)



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