The HeRO Graft

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Faculty Disclosure

I disclose the following financial relationships:

- **CryoLife/Hemosphere, Inc. &**
- **W.L. Gore and Associates.**

  - paid consultant, speaker, instructor

Je déclare les informations suivantes:

- **CryoLife/Hemosphere, Inc. &**
- **W.L. Gore and Associates.**

  - payé consultant, conférencier, formateur

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Outline

- Central vein occlusion challenges
- Current options
- Indications
- Planning
- Implant procedure
- Data

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

- **LE access**
  - infection/steal
- **Central vein reconstruction**
  - morbid / complications
- **“Destination” Dialysis Catheter**
  - infection / poor dialysis adequacy

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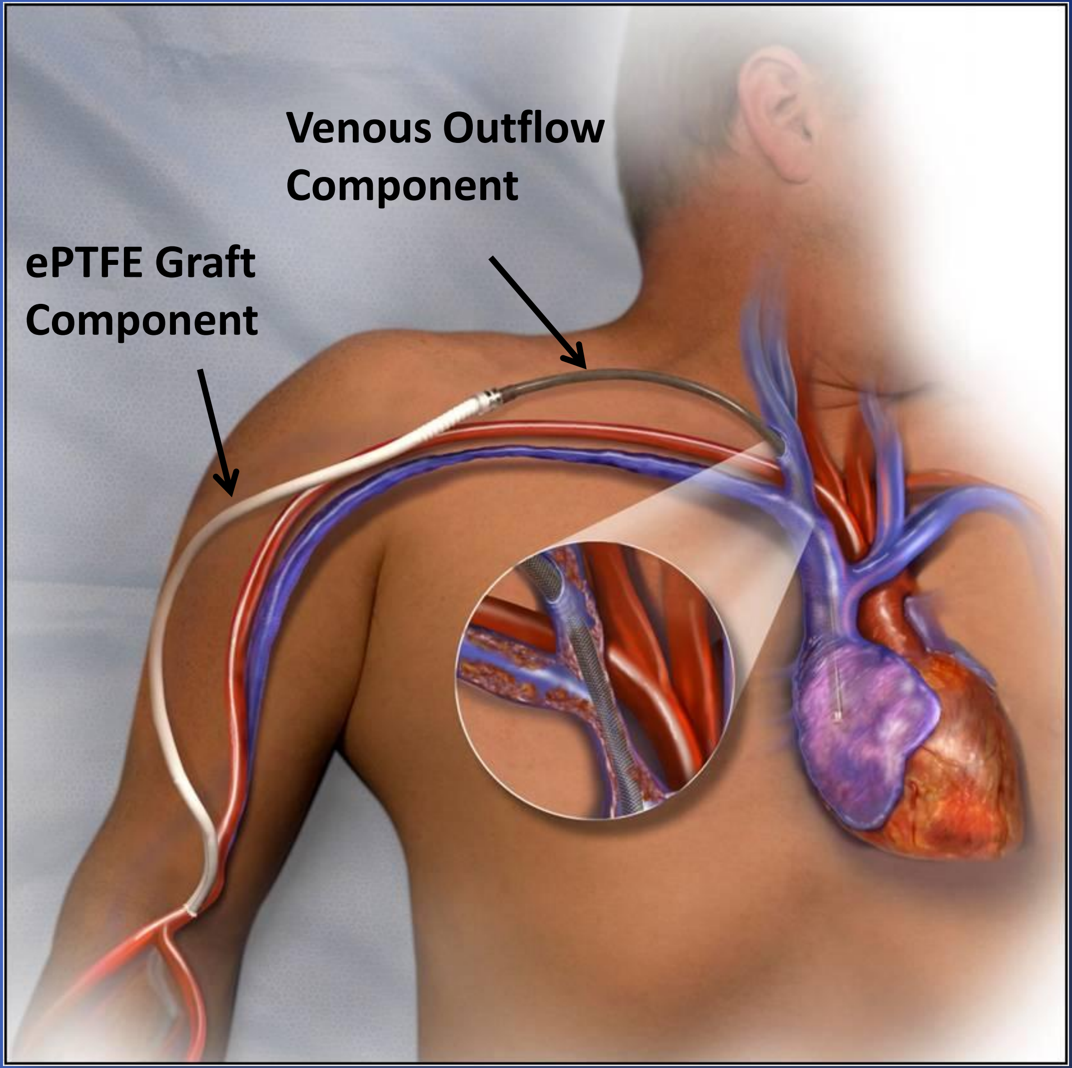
A Brief Overview

- HeRO™ **<u>He</u>**modialysis **<u>R</u>**eliable **<u>O</u>**utflow
- Hybrid vascular access device "graft-cath"
- 2 primary components: ePTFE graft with Titanium connector, and radiopaque silicone outflow component (OC)
- Common access veins include: Subclavian and Internal Jugular
- End stage access device
- Indicated for catheter dependent patients with central venous stenosis and/or occlusion



Indications

- CV stenosis
- CV occlusion
- TDC dependence
- Maintain upper body access
- Access salvage

Why is this device important?

- Infection Reduction *
- Reduced Intervention *
- Reduced Healthcare spending *
- Improved dialysis adequacy *
- Access salvage
- Access Longevity

* over TDCs

Planning

- History
  - previous catheters
  - # previous access
- Physical exam
  - inflow
  - chest wall collaterals
  - neck, extremity, or facial edema
  - old access scars and location

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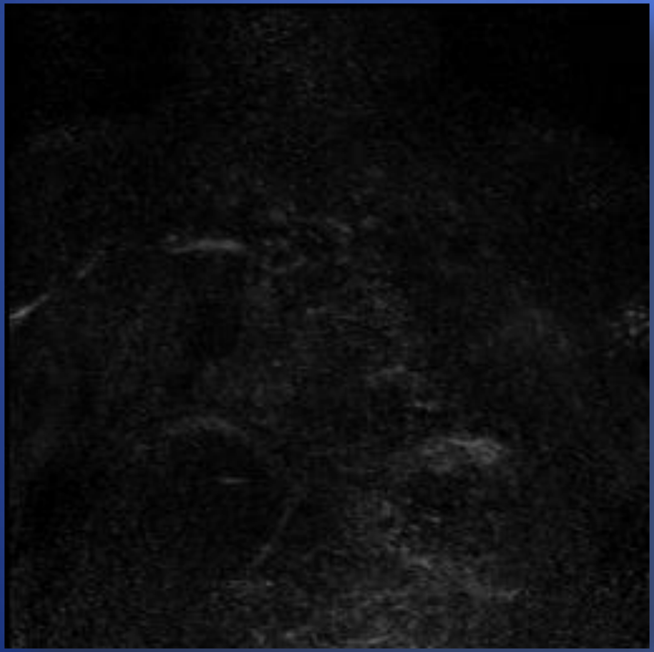
Planning / Imaging

- MRV (Feraheme)



- Conventional venography

Equipment

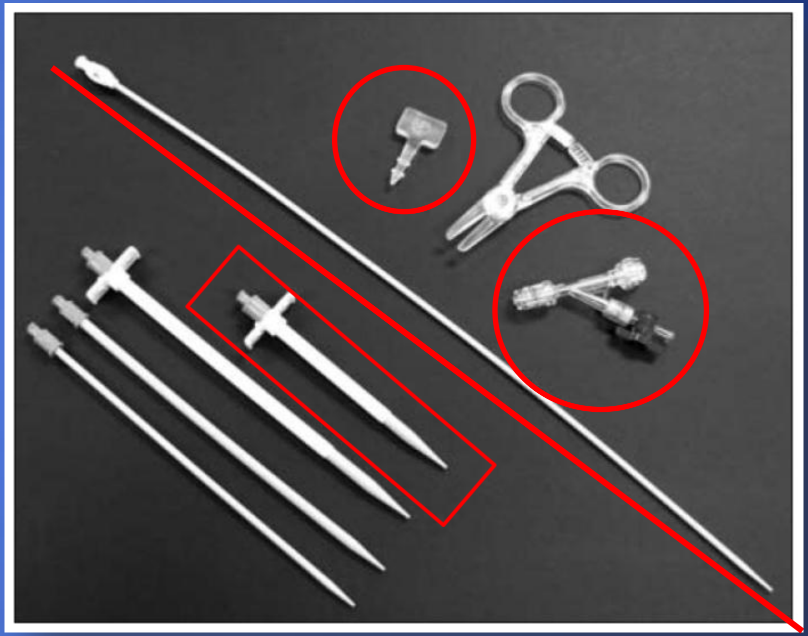
Venous Outflow Component

Arterial Graft Component

Accessory Component Kit

HeRO® Implant Accessories

- Included in the Accessory Kit:
  - 12F & 16F sequential dilators
  - 20F Peel-away sheath with dilator – long and short option
  - 10F Delivery Stylet
  - Y-port with stopcock valve
  - Clamp
  - Hemostasis plug



Venous Outflow Component

- Silicone inside & out
- Kink and crush resistant nitinol reinforced braid
- Radiopaque marker
- 5mm ID
- 6.3mm (19F) OD
- 40cm long

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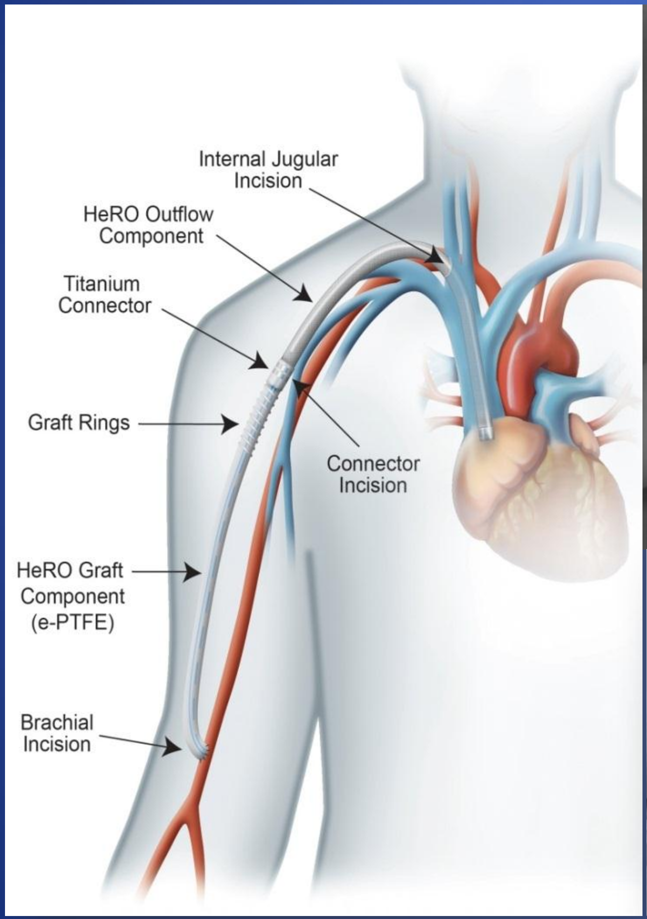
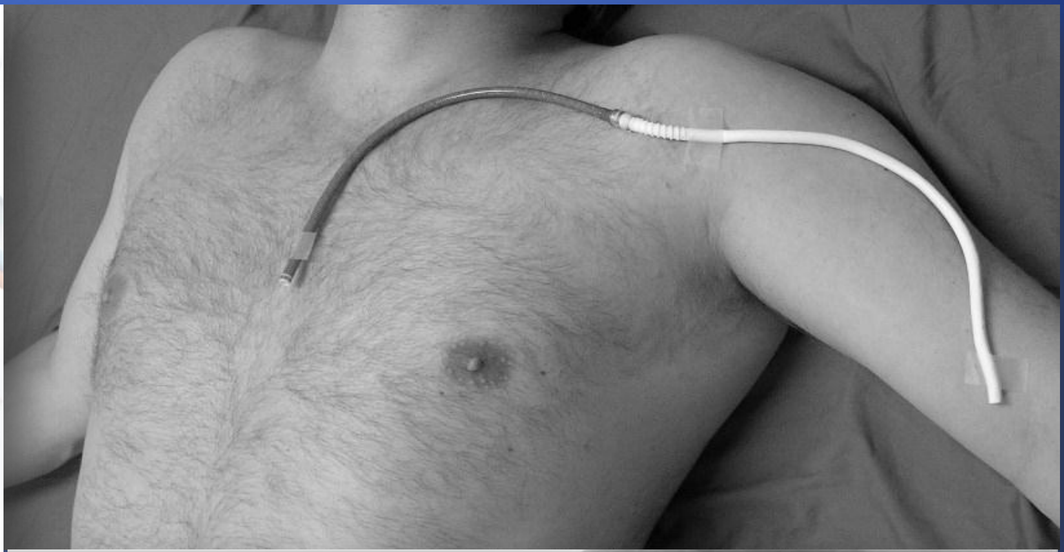
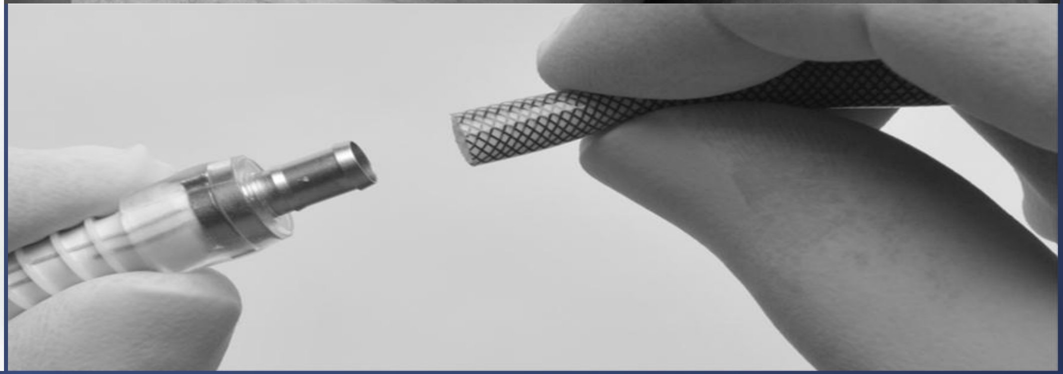
Arterial Graft Component

- Standard ePTFE graft
- Titanium connector
- Beading near connector
- 6mm ID
- 7.4mm OD
- 53cm long

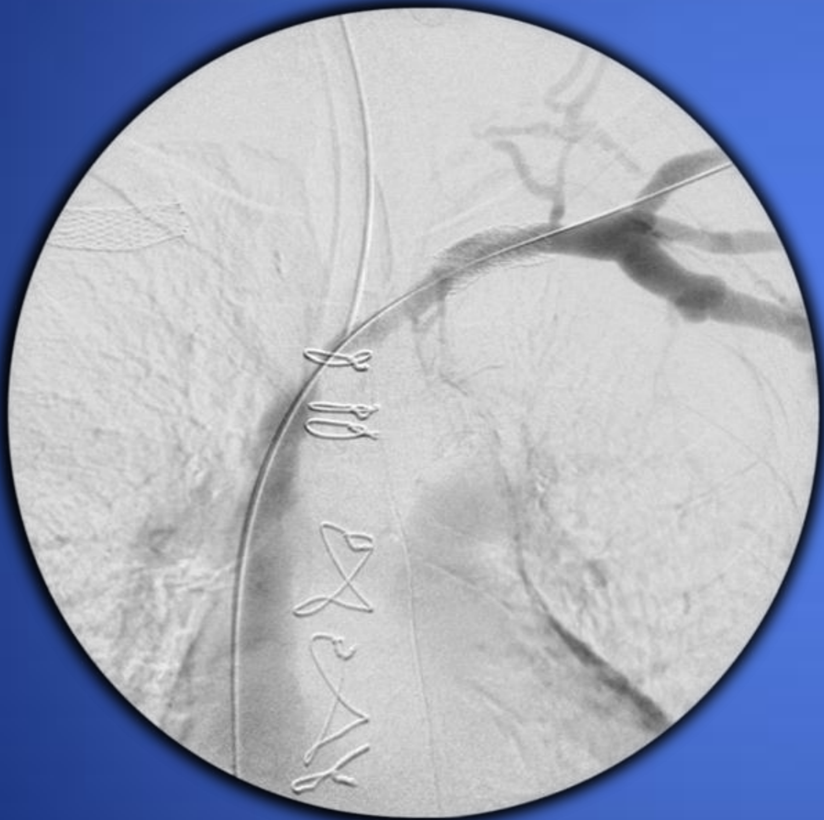
Implant Procedure





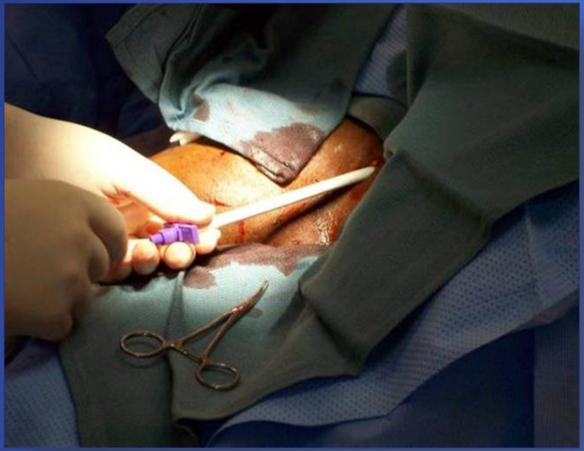


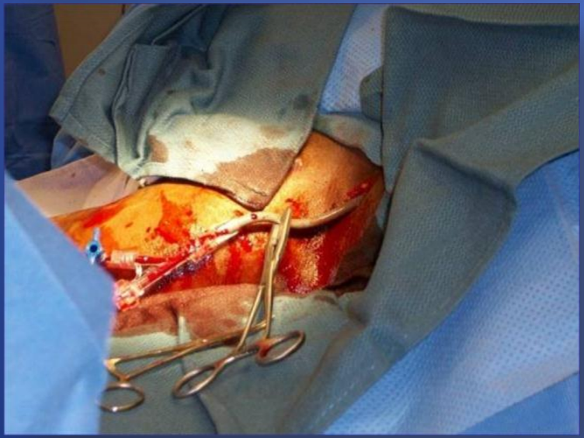
Obtain Central Venous Access



- Catheter cut down or percutaneous
- Angiogram
- Angioplasty

Insert Outflow component (OC)





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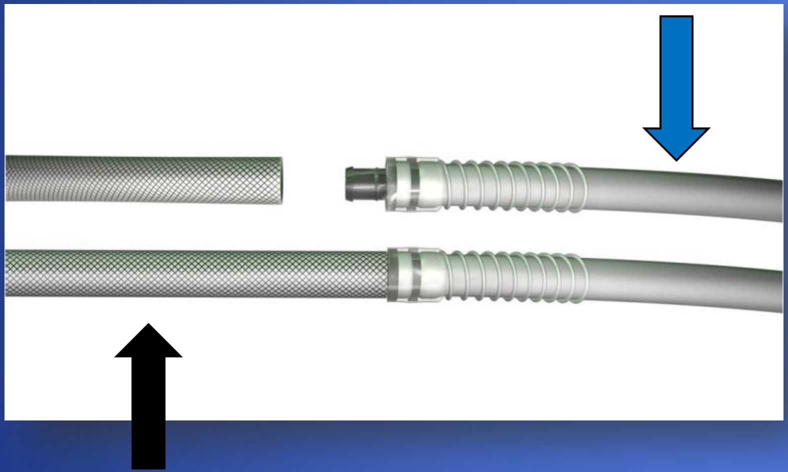
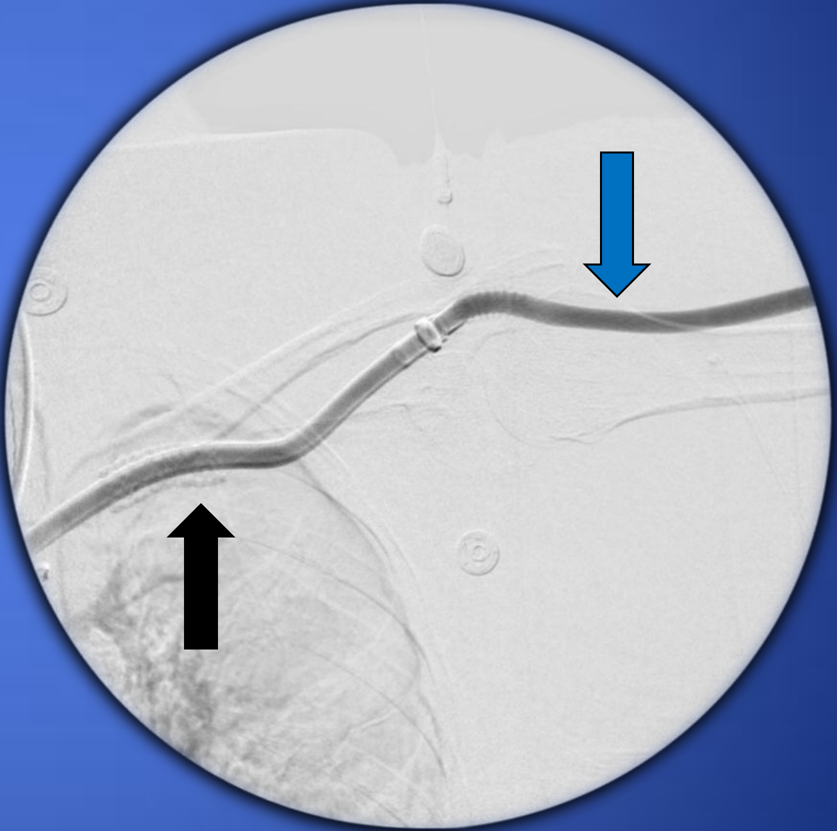
Connect Outflow component to PTFE

ePTFE graft



Silicone outflow component



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Complete arterial anastomosis

Recent Data

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esvs Journal

Multi-center Experience of 164 Consecutive Hemodialysis Reliable Outflow [HeRO] Graft Implants for Hemodialysis Treatment☆

S.M. Gage [a,*], H.E. Katzman [b], J.R. Ross [c], S.E. Hohmann [d], C.A. Sharpe [e], D.W. Butterly [f], J.H. Lawson [a,g]

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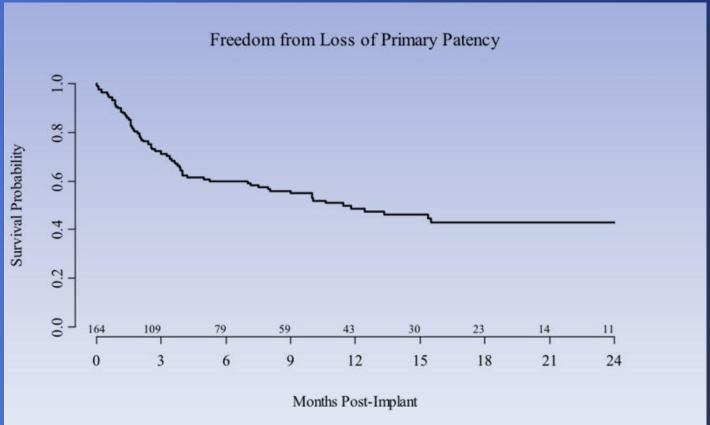
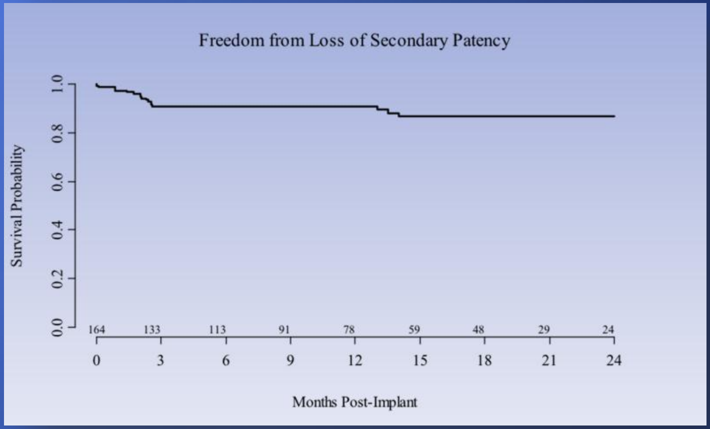
Patency

Table 4
HeRO patency, intervention, and infection data.

Variable	% [95% CI]
HeRO Patency[a]	
Primary at 6 months	60.0% [51.7, 67.3]
Secondary at 6 months	90.8% [84.9, 94.4]
Primary at 12 months	48.8% [39.9, 57.0]
Secondary at 12 months	90.8% [84.9, 94.4]
Primary at 24 months	42.9% [33.3,52.0]
Secondary at 24 months	86.7% [78.9,91.8]
HeRO intervention rate[b]	1.5/year [1.30, 1.67]
Access-related infections[c,d]	4.3% (6/140)

[a] Kaplan-Meier estimates with corresponding 95% CI.
[b] Rate per patient-year of follow-up; 257 events in 174.4 total patient years.
[c] % (n/N).
[d] Data only available from 3 sites.





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Patency Comparison of Published HeRO data, AVG Literature, and TDC Literature

Table 5
Patency comparison of published HeRO data, AVG literature, and TDC literature.

Study	Current HeRO multicenter		Gage et al. review May 2010[15,a]	Katzman et al. study Sept. 2009[9]	AVG literature[11]		TDC literature[9]	
Months	6 mo	12 mo	6 mo	8.6 mo	6 mo	12 mo	6 mo	12 mo
Patency								
Primary, %	60	48.8	68.3	38.9	58	42	50	36
Secondary, %	90.8	90.8	87.8	72.2	76	65	55	37

[a] 39 of the 41 patients in the Gage review are included in this current Multi-center review.

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Bacteremia and Intervention Comparison of Published HeRO Data, AVG Literature, and TDC Literature

Table 6
Bacteremia and intervention comparison of published HeRO data, AVG literature, and TDC literature.

Study	Bacteremia rate per 1000 days	Intervention rate per year
Current HeRO Multicenter	$\boxed{0.14}$	$\boxed{1.5}$
Gage et al. Review May 2010[15]	1.29	1.38
Katzman et al. Study Sept. 2009[9]	0.7	2.5
AVG Literature Control[9]	NA[a]	1.6–2.4
TDC Literature Control[9]	$\boxed{2.3}$	$\boxed{5.8}$

[a] Information not available.

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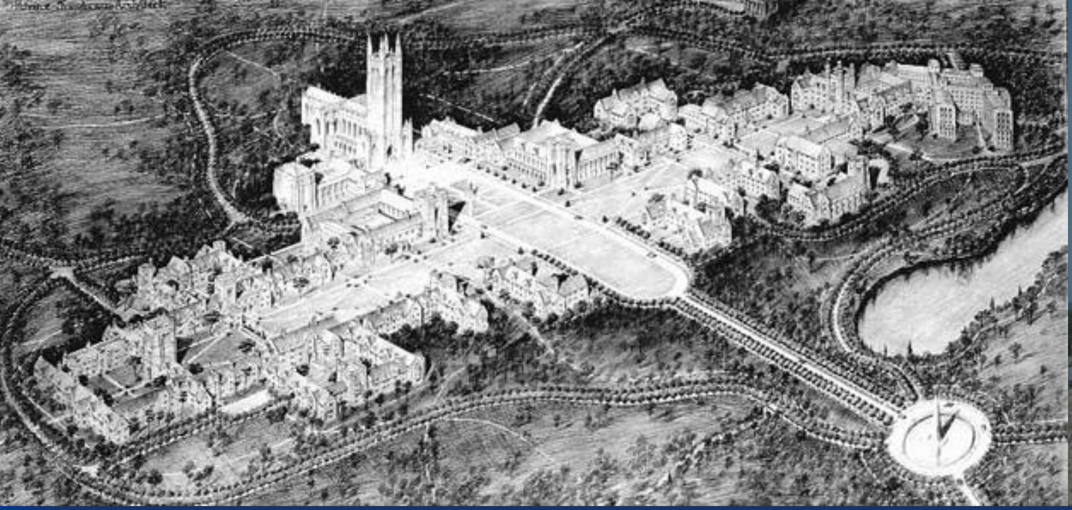
Conclusions

- HeRO graft allows establishment of access in setting of central venous occlusive disease
- Maintain upper body access
- Reduced morbidity and mortality
- Reduced cost to healthcare system
- Patency & intervention rates are comparable to standard AVGs
- Infection and intervention rates superior to TDCs
- Access salvage and longevity



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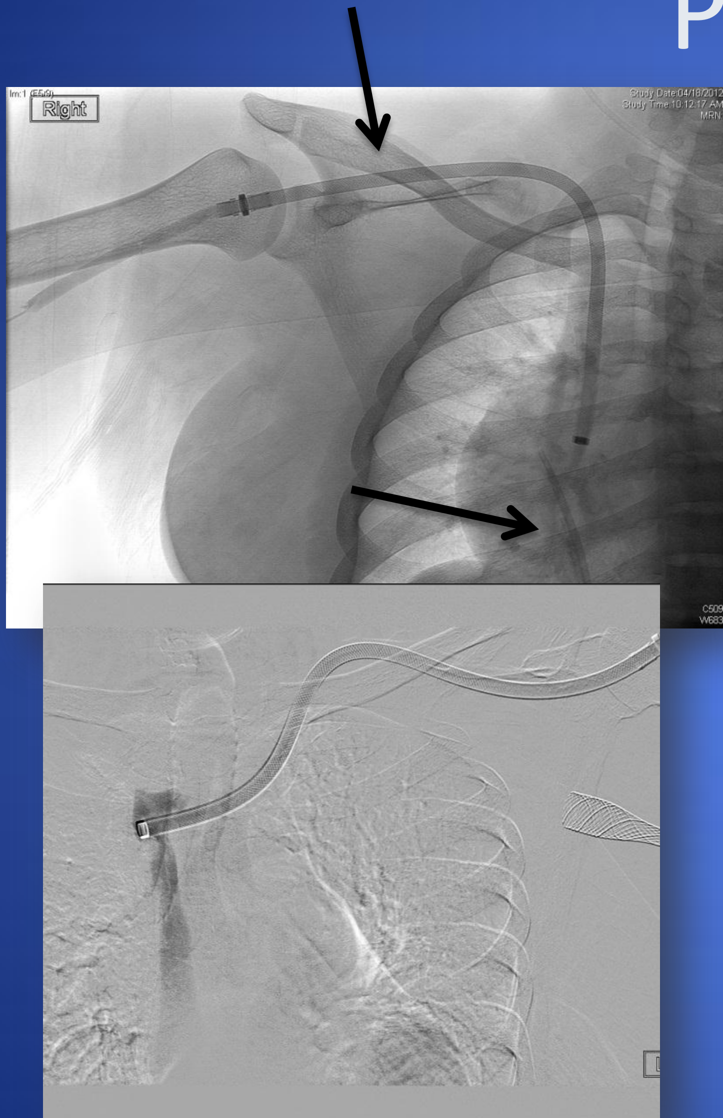
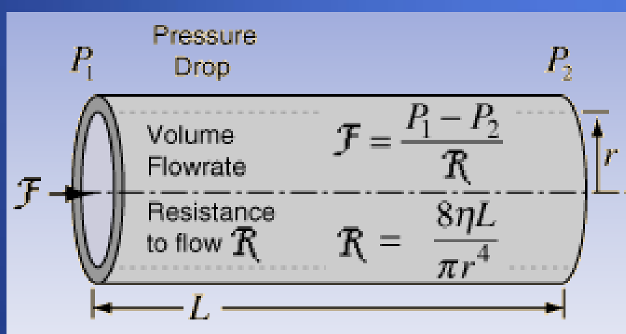
Pitfalls



- OC positioned too high
- Coupler too lateral
- OC and graft NOT tunneled to same plane
- Crushed Beading
- Inadequate inflow
- Communicate with Anesthesia when opening HeRO

Myths

- More likely to cause steal
- Cannot be used in patients with poor EF
- Titanium coupler causes thrombosis[1]



$$\text{Volume Flowrate} = \frac{\text{Pressure difference} \times \text{radius}^4}{\frac{8}{\pi}\ \text{viscosity} \times \text{length}}$$

Poiseuille's Law
(pwas-weez)

[1]Grezaffi JA, Bryant J, Lessne ML, Kim C: Early experience with percutaneous interventions for failing HeRO arteriovenous grafts. Presented at the Society for Interventional Radiology, Chicago, IL, March 2011

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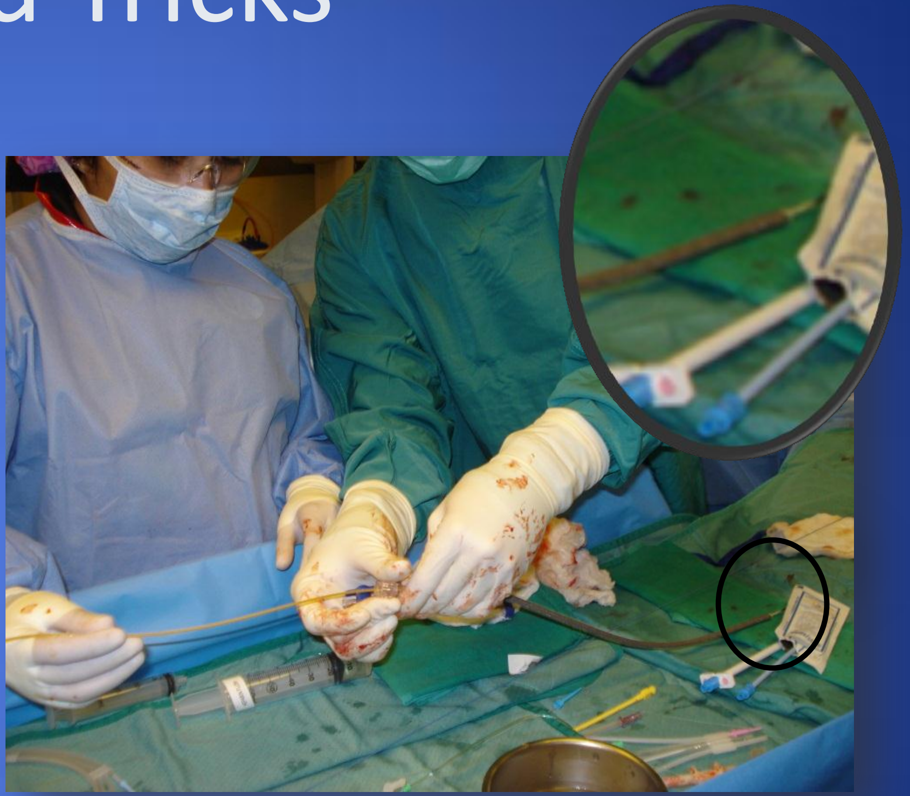
Tips and Tricks

- Use stiff wire
- Angioplasty outside of the body
- Use 6mm balloon if delivery stylet does not work
- Completely remove peel-away sheath
- Graft-OC connection

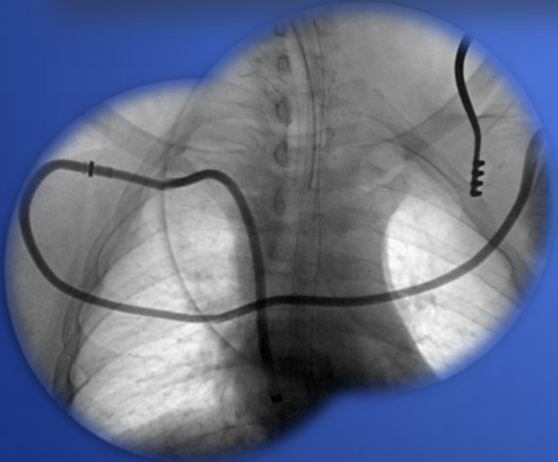


Declot Procedure

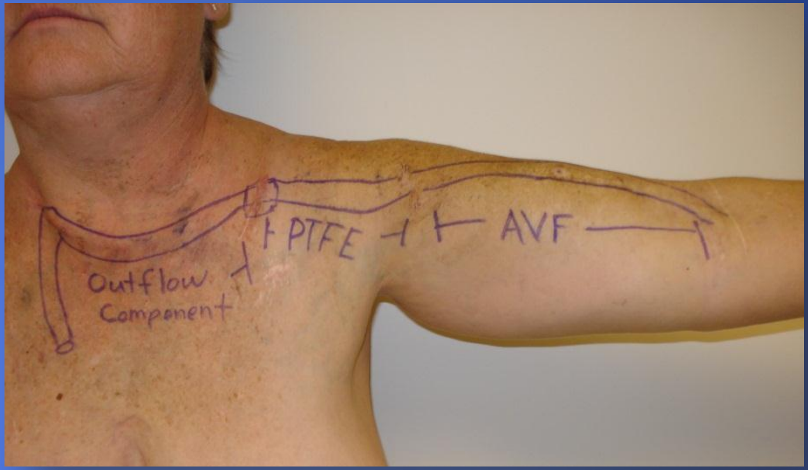
- Similar to standard AVG
- Similar time requirement
- Percutaneous or open
- Fogarty balloon or Angiojet
- Clot non-adherent to OC
- No venous anastomosis to manage

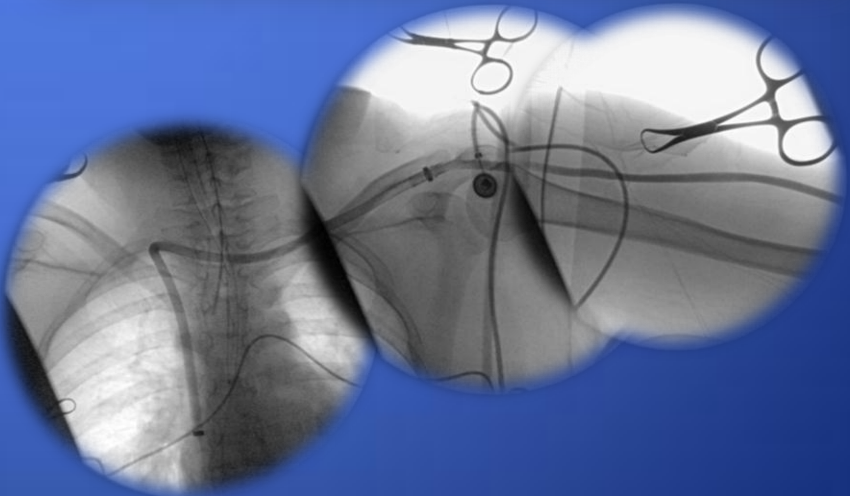
Modified Implant Techniques

Chest wall HeRO



Contralateral extremity inflow





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A C C E S S

A L G O R I T H M

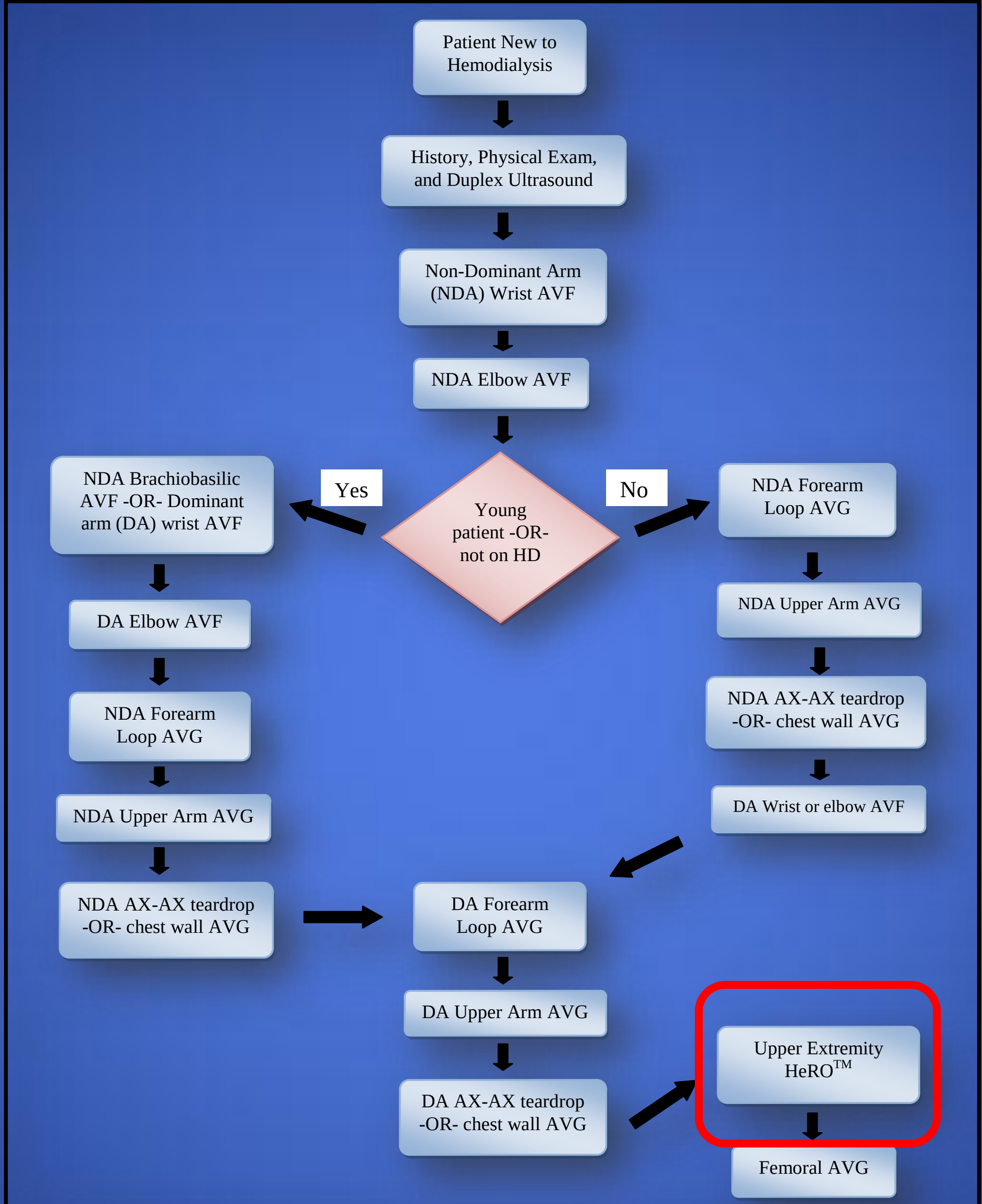

Figure 3: Algorithm demonstrating order of basic access site selection from new renal failure patient to end stage access patient.

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HeRO implant specifics

Table 2
HeRO implant specifics.

Anatomical location	% (*n*)
Insertion side:	$N = 139$[a]
Right	51.8% (72)
Left	48.2% (67)
Insertion vein:	$N = 139$[a]
Internal jugular	59.7% (83)
Subclavian	23.7% (33)
Common femoral	6.5% (9)
Axillary	5.0% (7)
External jugular	2.9% (4)
Other	2.2% (3)

[a] Data only available from 3 sites.

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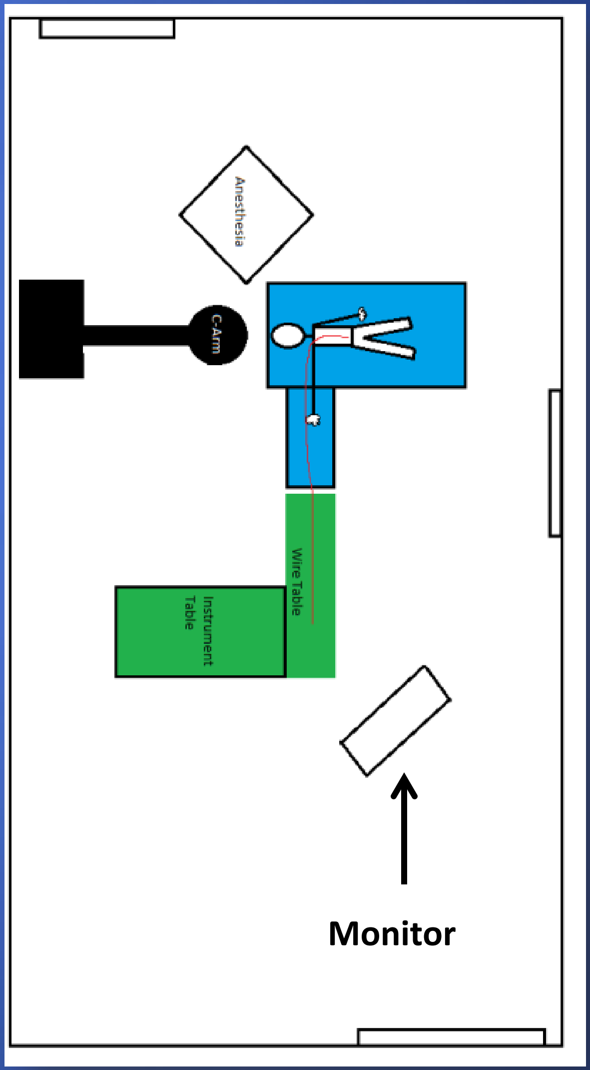
Logistics, Room & Bed Positioning

- Which extremity
- C-Arm location
- Monitor locations
- Instrument table
- Wire tables



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

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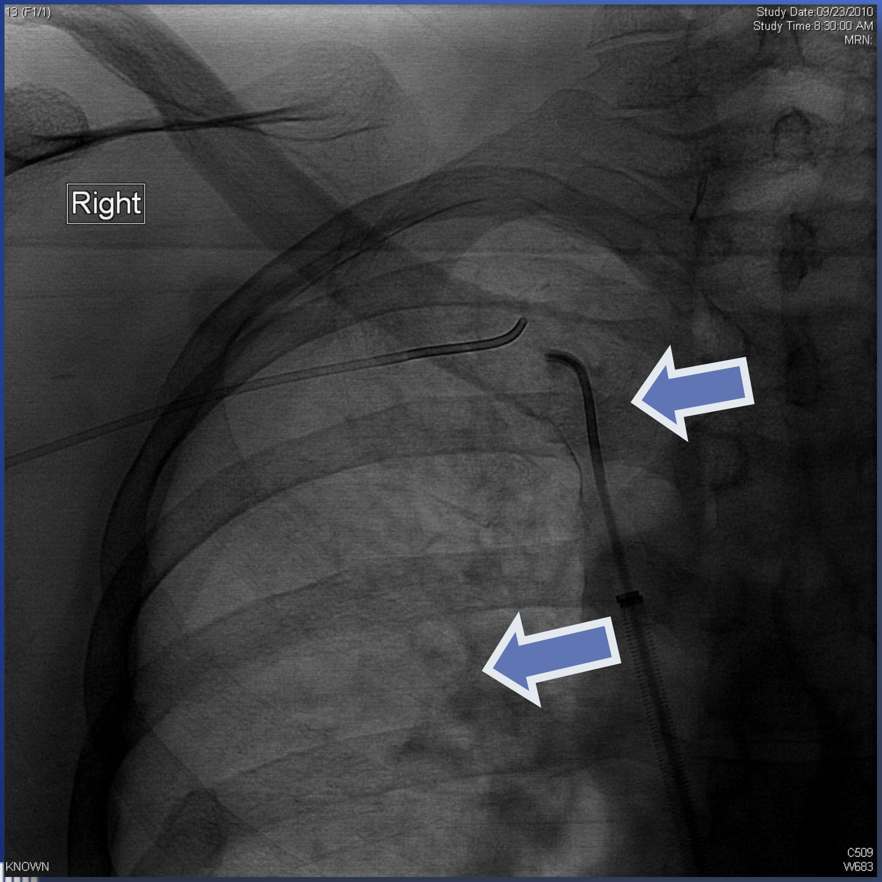
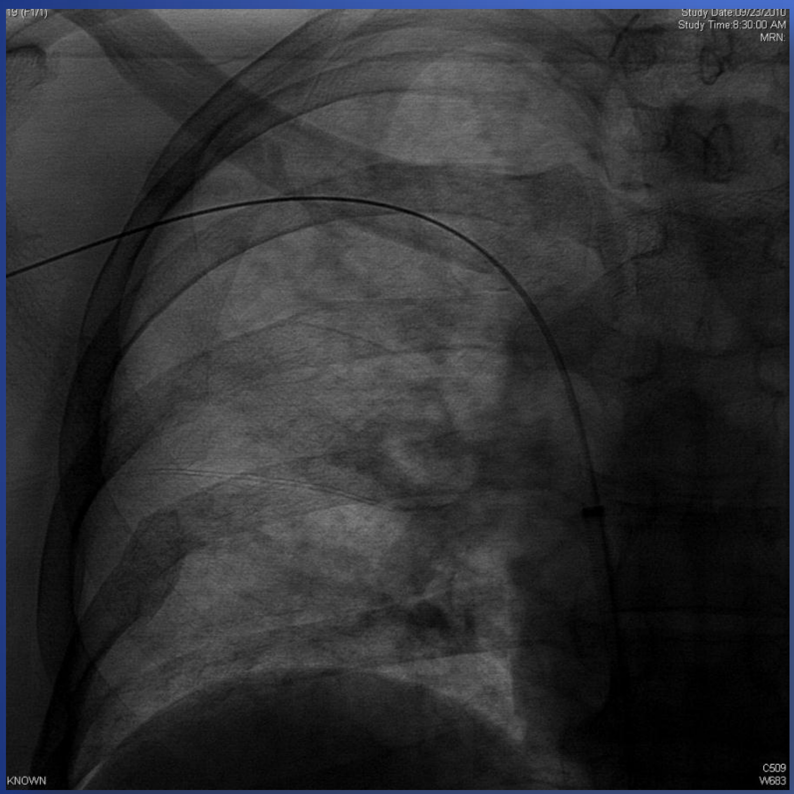
Axillary and Femoral vein access

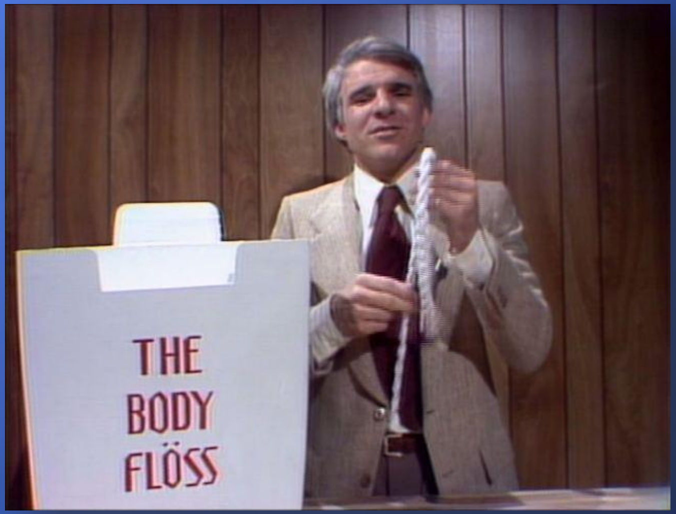


- Low profile directional catheters
- Long rigid sheath
- TIPS needle

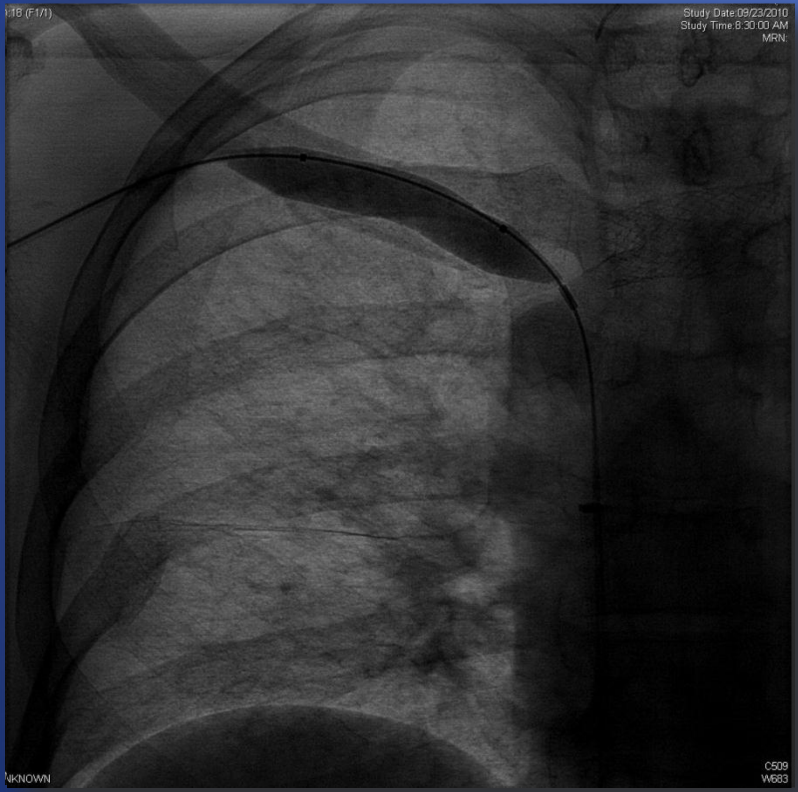
Crossed occlusion



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



Balloon Angioplasty



- Dilate tract

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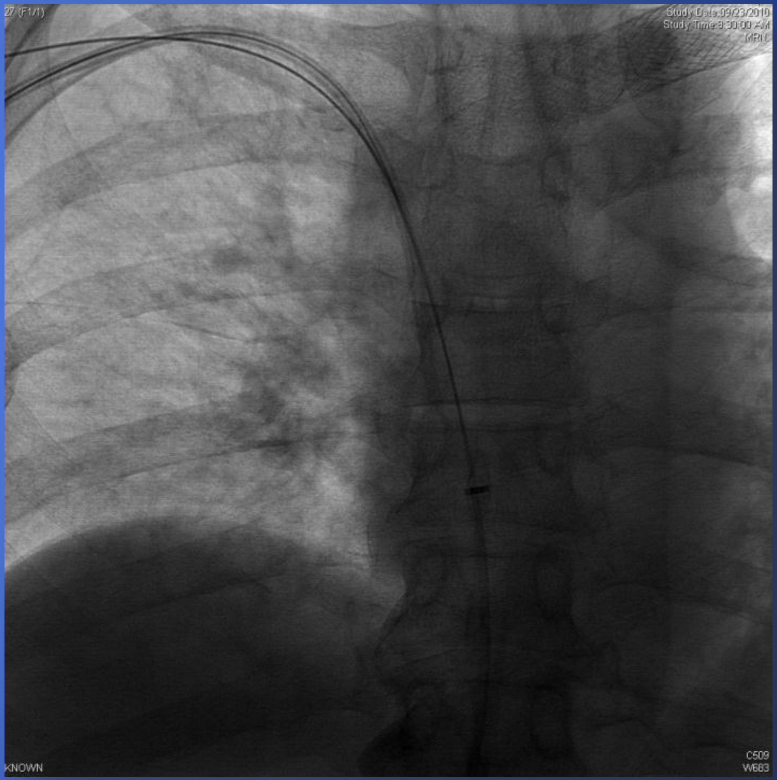
Low profile catheter implanted as place-holder

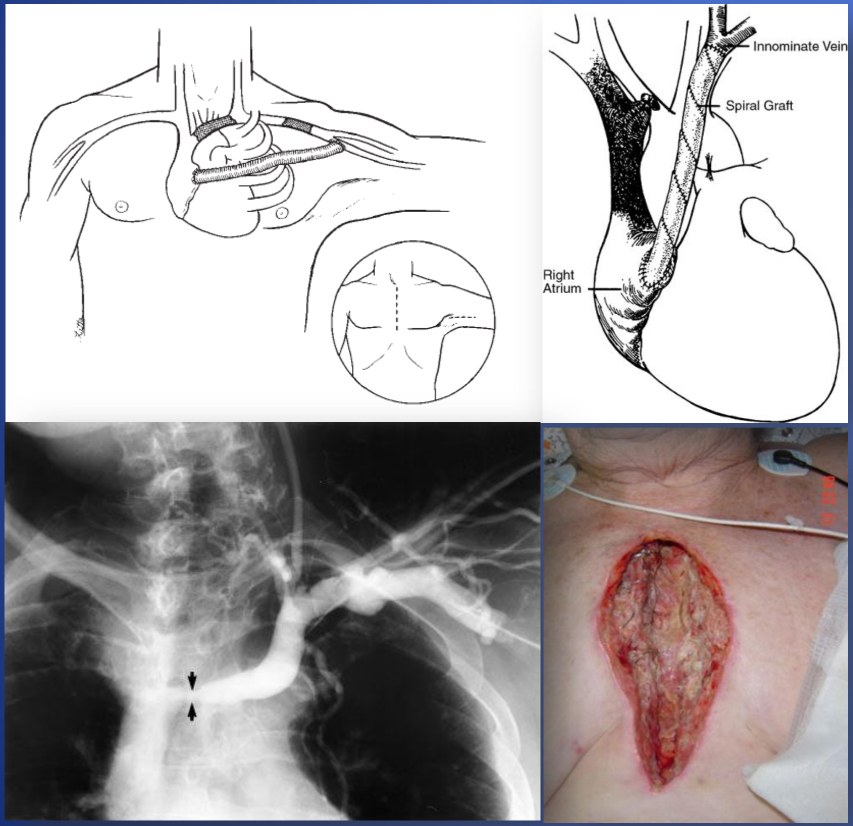


Current Options

- 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