Strategies to Reduce Catheter Use in 2014

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(I have no commercial affiliations or conflicts of interest to report)

Fibrin Sheathing

Central Venous Stenosis

Arm Edema

Infection


Image Courtesy of Tom Vesely, MD
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Fistula First … Catheter Last

Catheter Reduction Strategies

- Catheter avoidance
  - Timely placement of the “best” access
  - Urgent start PD
  - Early cannulation grafts
    - Atrium Flixene™
    - Gore Acuseal™
- Catheter removal
  - Timely removal of the “worst” access
  - HeRO graft

Decision points

- Fistula First *(unless a graft is better)*
  - Are we early enough to mature an avf?
  - Will the patient live long enough to benefit from an avf?
- Disciplined follow-up
  - Intervene when failing to mature (6-8wks)
  - Decide when enough is enough
  - Remove catheter after 3 successful cannulations

Timeline (Best case scenarios)

- AVF matures without assistance (40%)
  - Placement → Use **(2 months)**
- AVF matures with assistance (60%)
  - Placement → Proc1 → Use **(3 months)**
  - Placement → Proc1 → Proc2 → Use **(4 months)**
- AVF fails after salvage attempts (20%)
  - Placement → Proc1 → Proc2 → Fail → Avg → Use
    - 8wks 4 4 4 3 **(6 months)**
- AVG
  - Placement → Use **(3 weeks)**

Urgent Start PD

Useful for patients who crash into dialysis without prior access planning (80%?)

- Place PD catheter instead of TDC
- Initiate low volume/supine PD in hospital
- Continue this in home dialysis unit
- Educate on treatment options
  - Continue PD (complete training)
  - Change to HD (avf/avg then transfer to in-center)

Benefits of urgent start PD

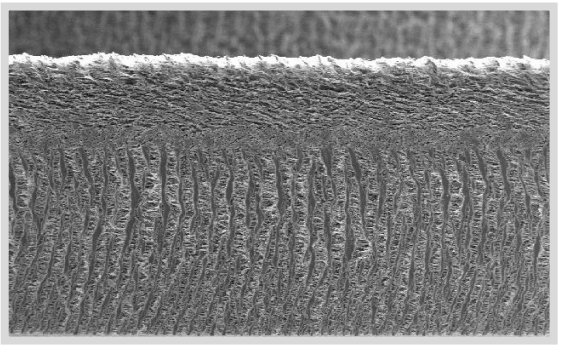
- TDC avoidance
  - Lower infection, hospitalization, mortality
- Immediate Medicare enrollment
  - Payment
    - Hospital, access surgeon, dialysis facility, nephrologist
  - PD training payment
- Effective way to grow home therapies

Early Cannulation Graft

- Patients with urgent dialysis need
  - No fistula option (or graft is felt to be best)
  - Very borderline upper arm fistula option
- Patients with failing fistula or graft
- Graft options/details

FLIXENE™ Vascular Graft (Atrium product)

Durable Cannulation Zone:



- **Wall Construction**
  - Tri-laminate (3 layers)
  - 100% PTFE (no additional material added or needed)

- **Shown To Reduce Common Graft Related Complications**
  - Reduce Pseudoaneurysms[1]
  - Reduce Seromas[1]
  - Higher Rate of Complication Free Patients compared to standard PTFE group[4]

1. Schild AF, Schuman ES, Noicely K, et al. Early cannulation prosthetic graft (Flixene™) for arteriovenous access. *J Vasc Access.* 2011 Jul-Sep;12(3):248-52
2. Schild AF. et al. New Graft fro Low Friction Tunneling in Vascular Access Surgery, Journal of *Vasc Access* 2004
3. Scarritt T, Paragone C, O'Gorman R, Kyriazis D, Maltese C, Rostas J. **Traditional vs. Early Access Grafts for Hemodialysis Access: A Single Institution Comparative Study**.. *The American Surgeon*, February 2014. pp. 155-158.
4. Chiang, N, Ria Hulme K, Haggart P, Vasudevan. Comparison of FLIXENE™ and Standard PTFE Arteriovenous Graft For Early Hemodialysis *Journal of Vascular Access*, 2014

FLIXENE™ Vascular Graft (Atrium product)

Key Features and Benefits:

- **Durable Cannulation Zone:**
  - Reduce Pseudoaneurysms[1] **(?)**
  - Reduce Seromas[1]
- **Is Safe to Cannulate Within 24-72 hrs[1]**
  - Shown to Reduce Catheter Rates compared to standard PTFE[3]
- **No Additional Steps Required for Early or Standard Cannulation**
  - Follow KDOQI guidelines

1. Schild AF, Schuman ES, Noicely K, et al. Early cannulation prosthetic graft (Flixene™) for arteriovenous access. *J Vasc Access.* 2011 Jul-Sep;12(3):248-52
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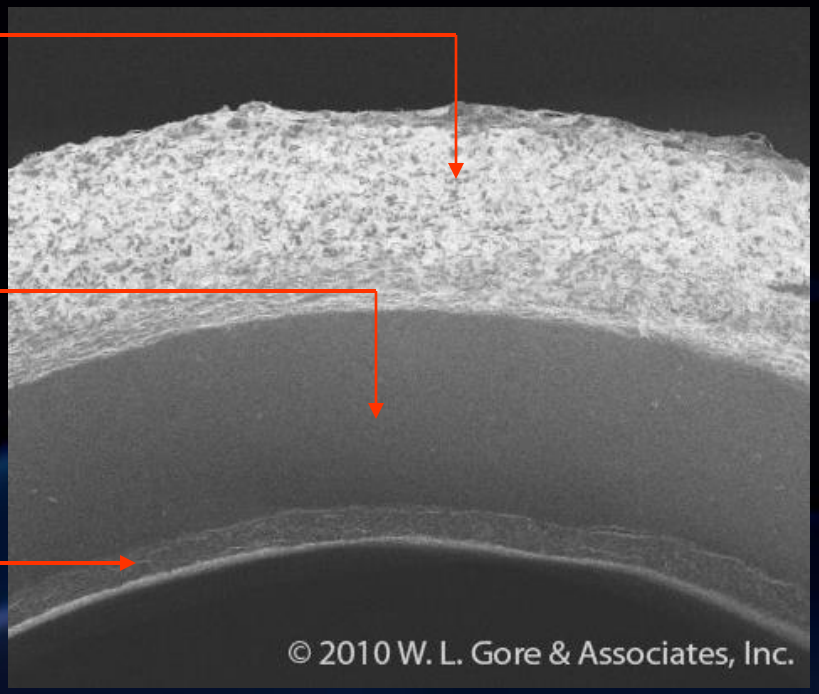
Acuseal™ Vascular Graft (Gore Product)

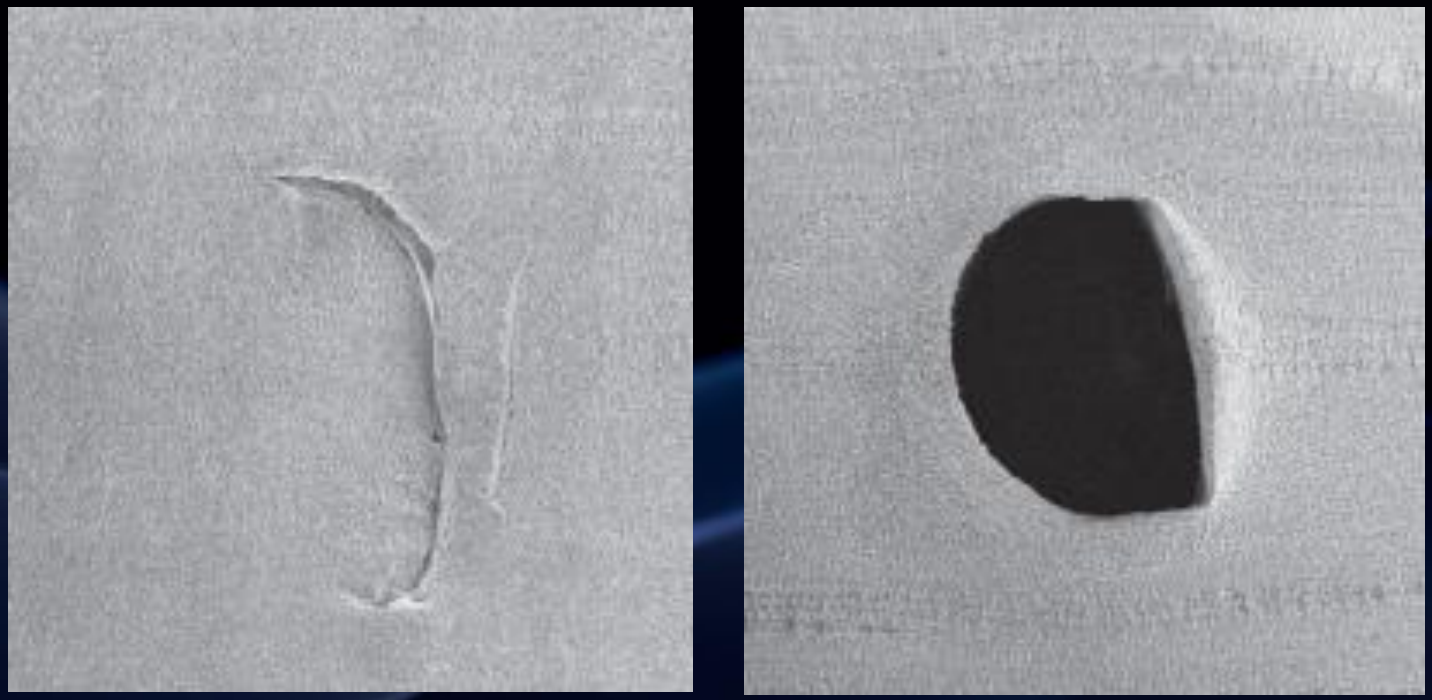
- **Outer Graft Layer**
  - Expanded polytetrafluoroethylene
- **Middle Graft Layer**
  - Elastomeric membrane
- **Inner Graft Layer**
  - Expanded polytetrafluoroethylene
    - CBAS® Heparin Surface



Tri-Layer Design

Hinders Cannulation Needle Hole Bleeding

Low Bleed versus Bleed



16 gauge cannulation needle hole through GORE® ACUSEAL Vascular Graft luminal surface (left)
Standard ePTFE graft luminal surface (right)

Summary
ACUSEAL Vascular Graft Clinical Study*

- Primary Efficacy Endpoint: Cumulative Patency

Cumulative Patency	GORE® ACUSEAL Vascular Graft	Historical Control
6 month follow-up	84%	75%
12 month follow-up	78%	66%

Time from Implantation to First Cannulation	Number of GORE® ACUSEAL Vascular Grafts Cannulated†
Within 24 Hours	n = 30 (22.2%)
Within 48 Hours	n = 48 (35.6%)
Within 72 Hours	n = 54 (40.0%)
Within 7 Days	n = 70 (51.9%)

No difference in hematoma, infections or steal syndrome from standard PTFE graft

Within 28 days of graft implantation, 75.6% of the implanted grafts had been successfully cannulated 3 consecutive times allowing the potential for the CVC to be removed

* *Data on file*

Early Cannulation Grafts

- Safe to use within 24 hours of placement
- Similar patency to typical PTFE grafts
- No difference in complications
  - Infection, hematoma, pseudoaneurysm*, steal
- Useful for…
  - Avoiding catheter in urgent situations
  - Faster removal of catheters
  - Revising failing graft/fistula

*** Might be improved?**

Early cannulation guidelines

(When used in first 2 weeks)

- Strict aseptic technique
  - Mask, sterile gloves, prep
- Small needles
  - 17g
- Lower blood flow rate
  - 200-300ml/min
- Hold pressure 10-15 minutes
- Lower or no heparin if immediately postop

Differences in clinical use

- Physical exam
  - Markedly reduced thrill
  - Difficult to hear bruit
- Cannulation
  - Firmer “feel” so greater pressure required at entry
  - Enhanced “pop” into graft

Catheter Reduction Strategies

- Catheter avoidance
  - Timely placement of the “best” access
  - Urgent start PD
  - Early cannulation grafts
    - Gore accuseal
    - Atrium Flixene
- Catheter removal
  - Timely removal of the “worst” access
  - HeRO graft

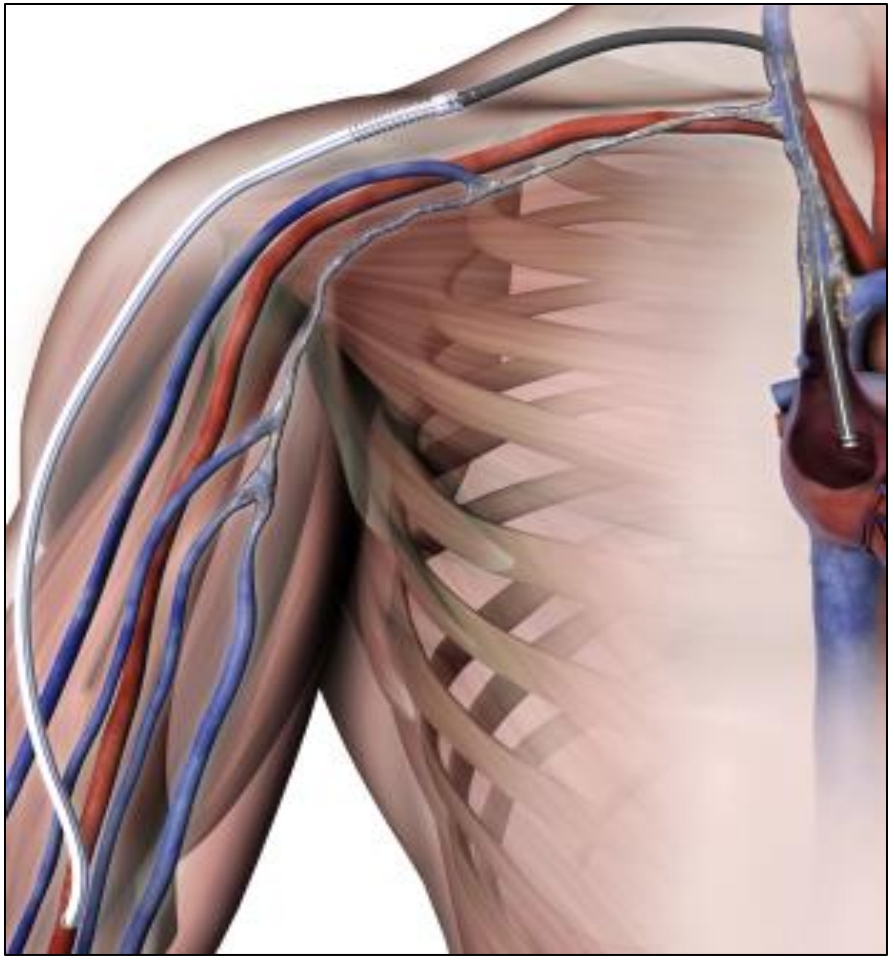
Removing Catheters

- Three

- Successful

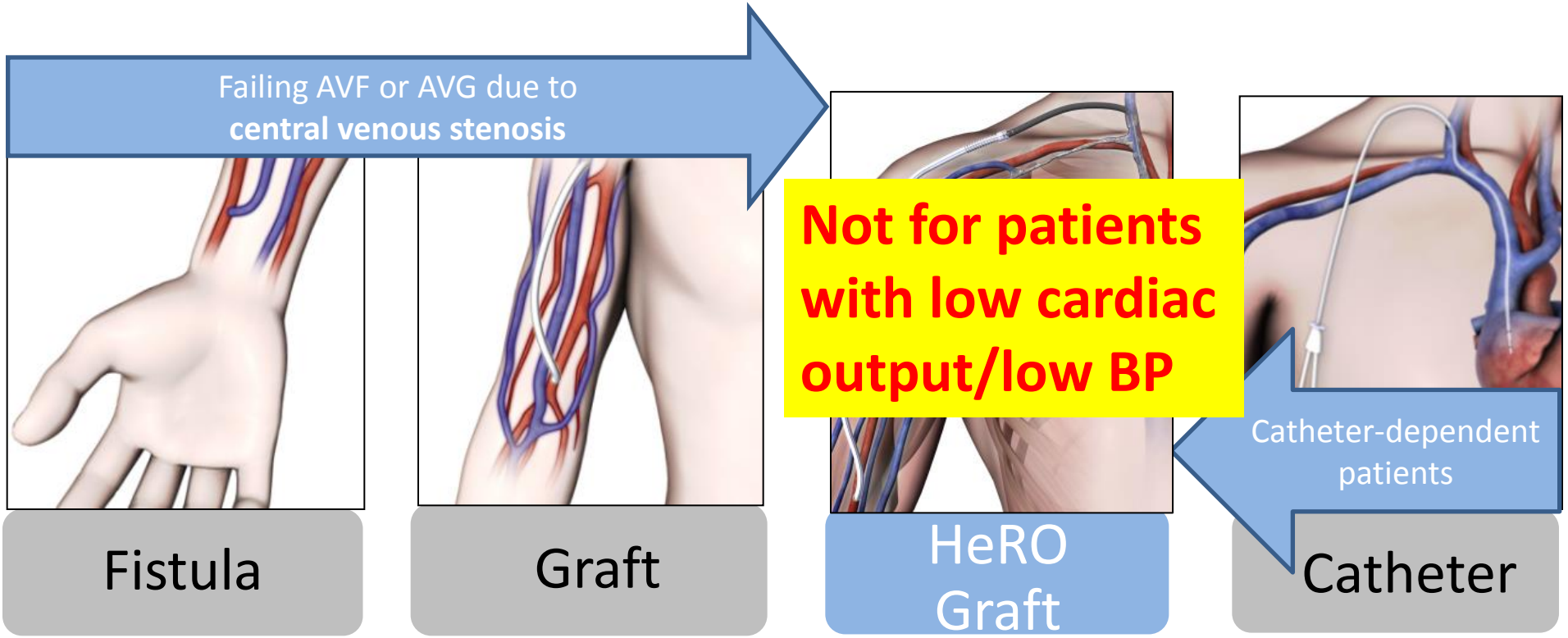
- Treatments

HeRO^{TM} Graft



Hemodialysis Reliable Outflow

Treatment Algorithm

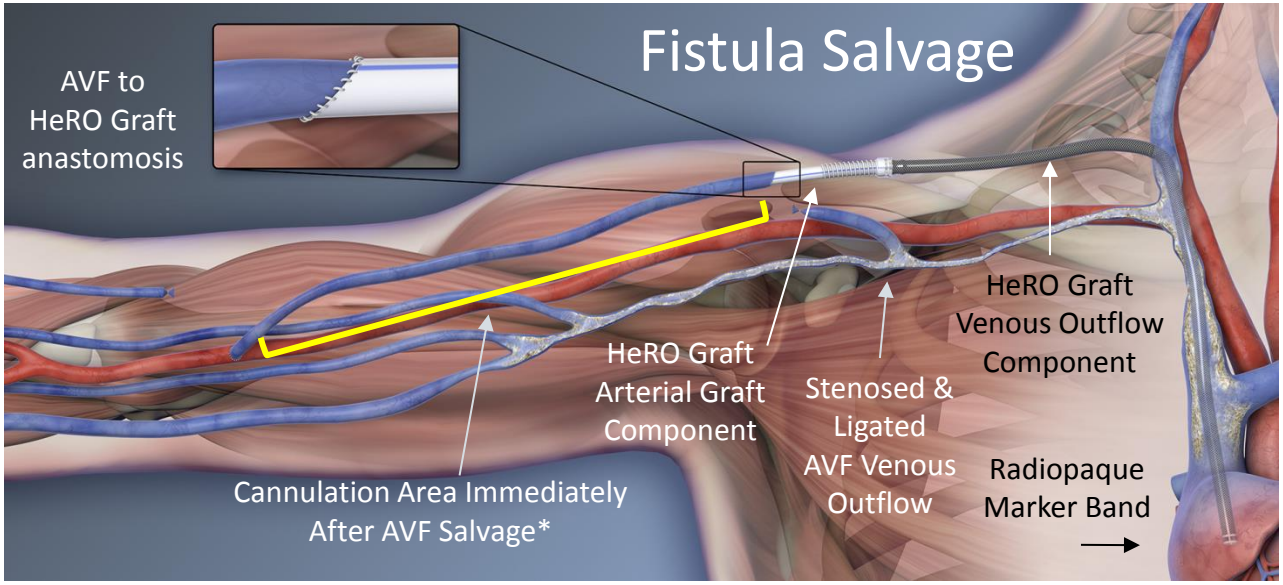


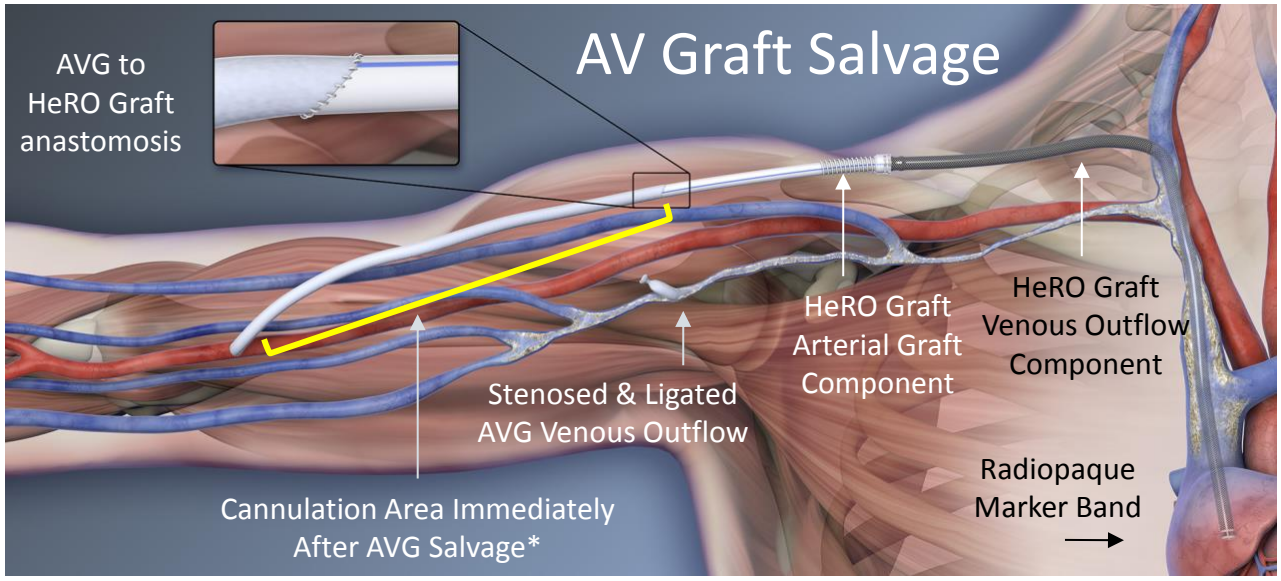
HeRO Graft Candidates

- Failing fistulas or grafts due to central venous stenosis
- Catheter-dependent or approaching catheter-dependency

HeRO® GRAFT

HeRO GRAFT for Fistula or Graft Salvage[1]





*If AVF is matured or AVG is incorporated. Follow your dialysis facility protocol for care and cannulation.

1) HeRO Graft IFU, L7163

Clinical Outcomes

	HeRO Graft Gage, et al. EJVES[1]	HeRO Graft Patency Study[2]	HeRO Graft Katzman, et al. JVS[2]	Catheter Literature[2]	AV Graft Literature[2]
Bacteremia Rates (Infections/1,000 days)	0.14	0.18	0.70	2.3	0.11
Adequacy of Dialysis (mean Kt/V)$^{\beta}$	NA	NA	1.7	1.29 - 1.46	1.37 - 1.62
Cumulative Patency at 1 Year	91%	88%	72%$^{\varphi}$	37%	65%
Intervention Rate (per year)	1.5	1.7	2.5	5.8	1.6 - 2.4

1) Gage et al., EJVES 2012. 2) Katzman et al., J Vasc Surg 2009; IFU: Comparisons to catheters and AVGs are from literature review on file. 3) Dhingra et al., Kidney Int 2001. 4) 2006 NKF KDOQI, Guideline 4.

HeRO® GRAFT

Case Report

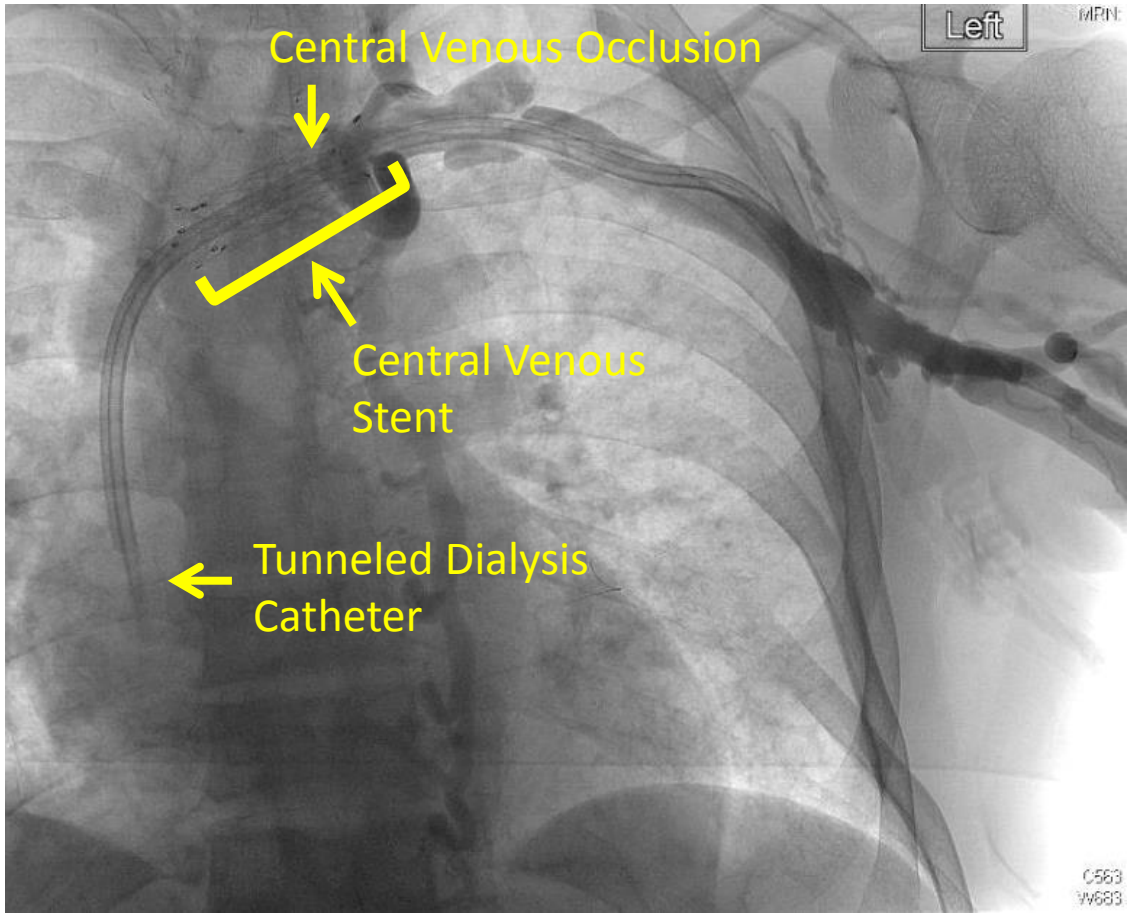
From Catheter to HeRO Graft

- A 50 year old African-American male with HIV and renal failure, and deemed “catheter-dependent.”
- He has been on hemodialysis for over 10 years, and has had 3 failed fistulas and 3 failed AV grafts.
- Both arms have been deemed “exhausted” for use.
- He had 4 tunneled dialysis catheters (TDCs) total (2 on each side).

Case Report: Riley (part 2)

From Catheter to HeRO Graft

- His central venous system had occluded bilaterally.
- A left-sided brachiocephalic vein stent was placed 2 years ago to try to salvage a poorly functioning left upper extremity AVG.
- When that access failed, a TDC was placed through the stenotic stent.



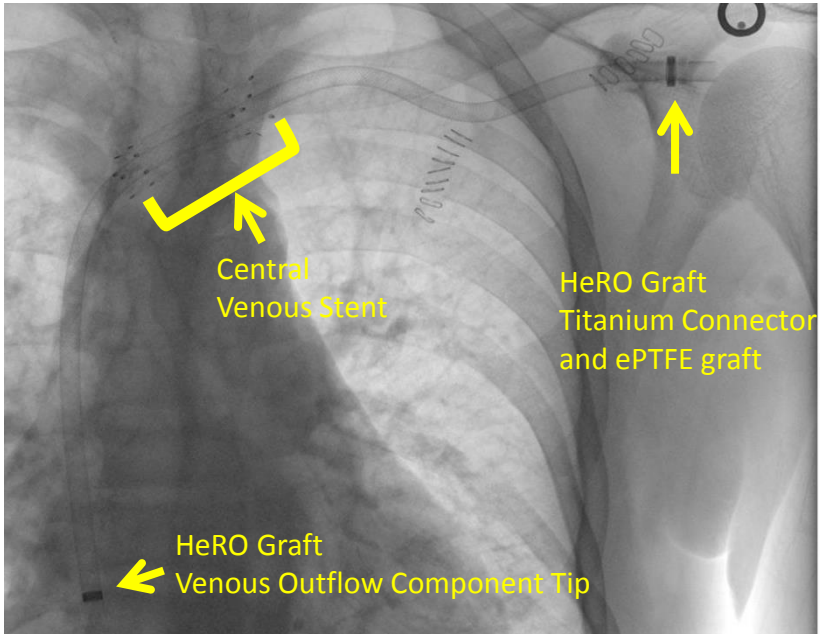
Fluoroscopic image of central venous occlusion, a central venous stent, and a TDC

Case Report: Riley (part 3)

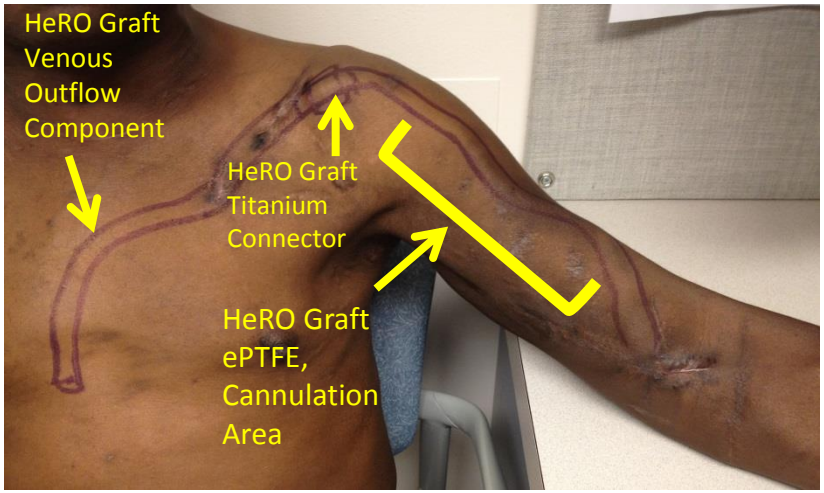
From Catheter to HeRO Graft

- A HeRO Graft was placed via the existing TDC.

- He is now using the HeRO Graft without difficulty, and his bridging femoral TDC was removed.



Above: Fluoroscopic image of HeRO Graft implanted through a stent



Above: Image of HeRO Graft after implantation

Summary

- Catheter use can be reduced drastically by utilizing several old and new strategies
  - Early referral for avf
  - Individualized selection of preferred access type
  - Efficient processes for following new accesses and removing catheters
  - Considering PD first
  - Utilizing early cannulation grafts, and HeRO graft when indicated