Do You Need A HeRO?

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The Hemodialysis Patient

- Avg . age increasing
- 50% start HD over 65
- 45% ESRD d/t DM
- CHF/MI > 5x general population
- Multiple hospitalizations with ++++ venipuncture
- Age risk factor for successful access maintenance

Hayakawa, Kunihiro et al. 2007
Therapeutic, Apheresis and Dialysis,
Vol. 11, No.1

What percentage of kidney function does hemodialysis replace?

- 5%
- 15%
- 30%
- 45%

The Ideal Vascular Access

- Minimal surgical intervention
- Minimal dysfunction
- Consistently adequate
- Amenable to reliable, routine monitoring
- Consistent, effective cannulation
- Requires average maintenance intervention

The Reality of Vascular Access

- “Achilles Heel” of hemodialysis.
- There is no single access that meets even most of the ideal criteria
- Surgically created accesses, fistulae and PTFE grafts, yield more reliable flows for adequacy with much less risk of bacteremia
- DOQI guidelines make fistulae the access of choice

Assessment of Hemodialysis Catheter Use

The Good

- Immediate access, non-surgical placement
- Patients unable to have fistulas & grafts

The Challenges

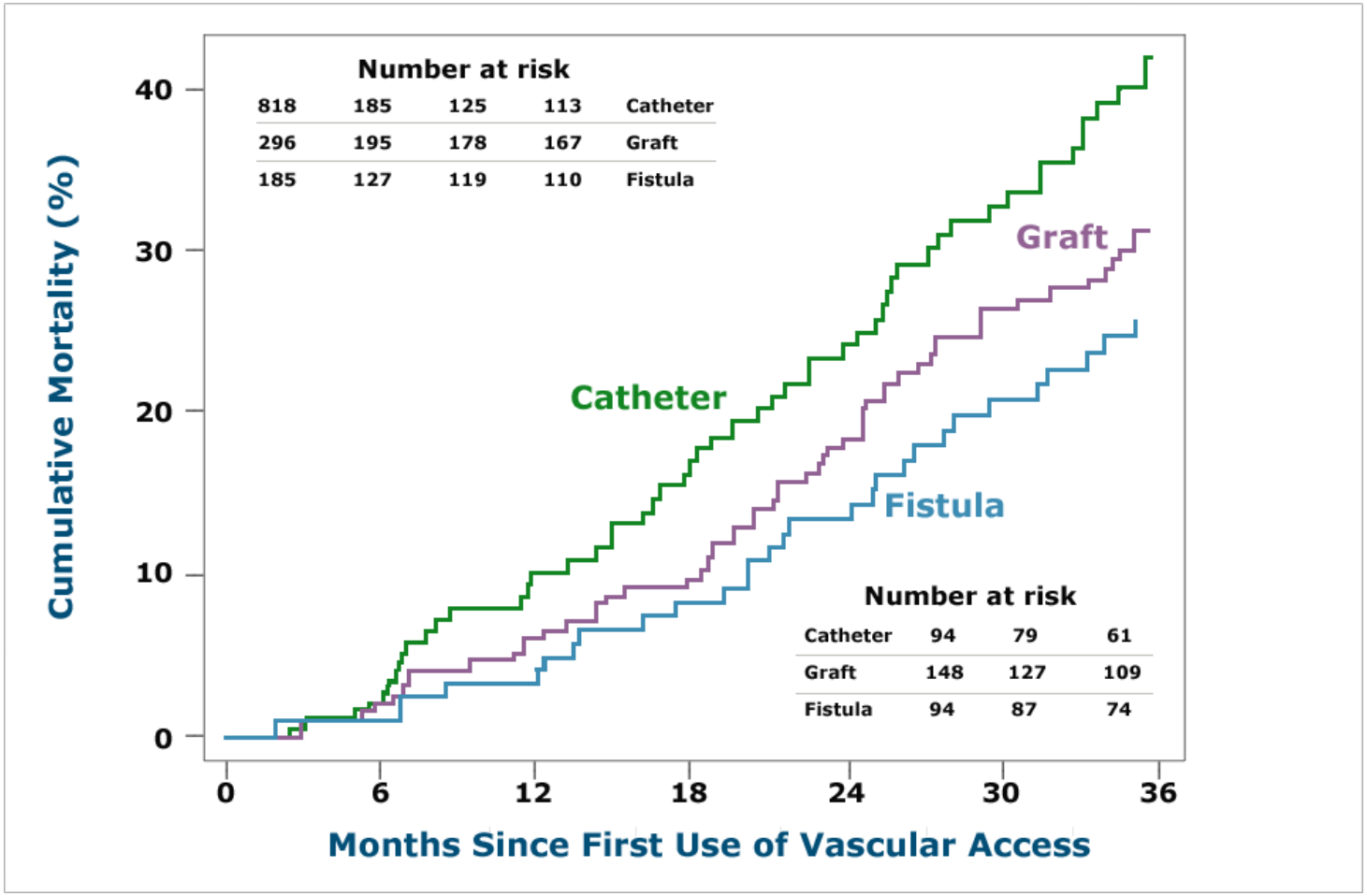
- **3-5x** higher complication rate[4]
- Increased hospitalization rates for infections[1]
  - Cost per infection ~**$23K- $45k, 17 day length of stay**[2]
- Accelerates **central venous stenosis**[3]

The Unfortunate

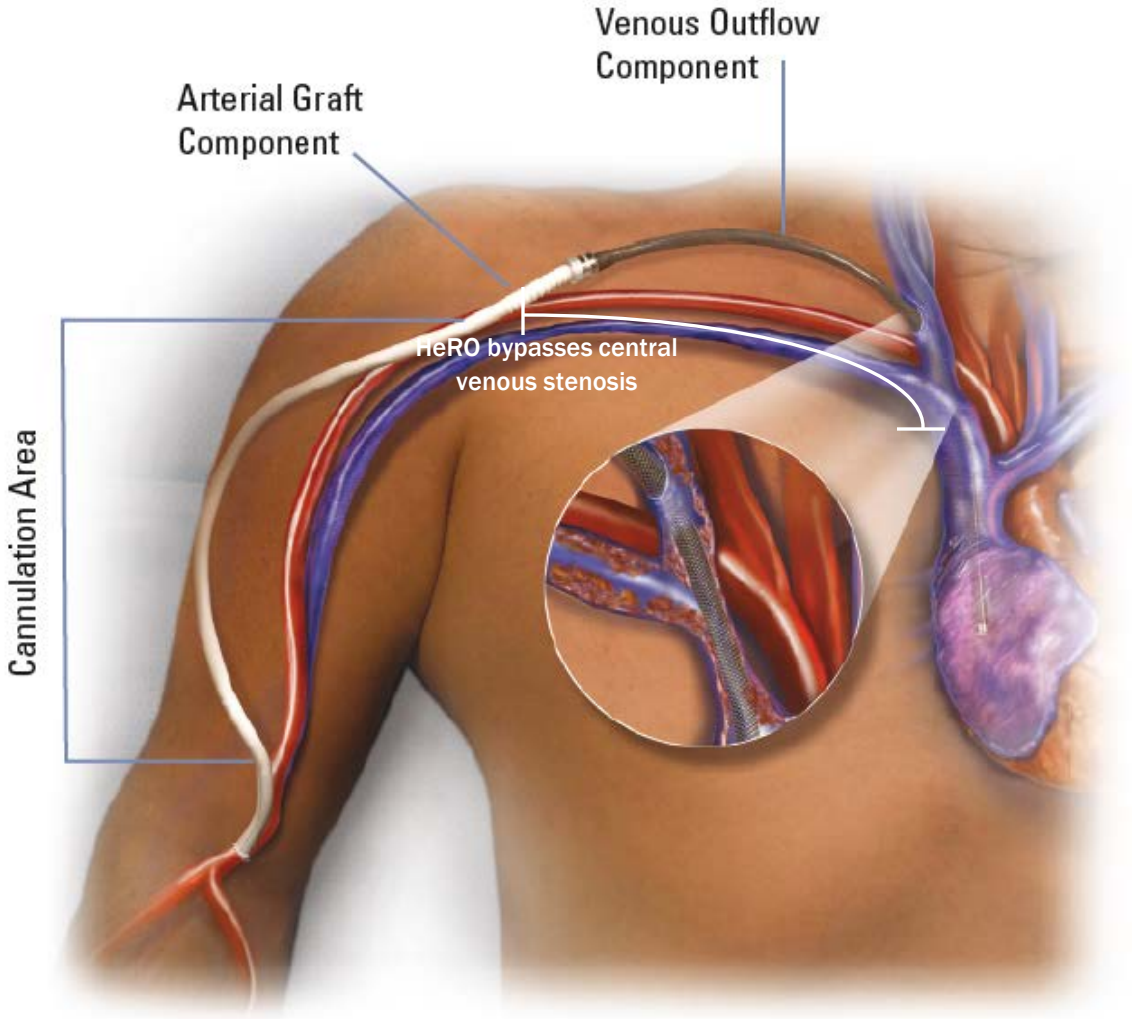
- Higher morbidity & mortality [4,5]
  - 2 to 3-fold increased risk of death
  - 5 to 10-fold increase risk of infection

1 2009 USRDS, Cost of ESRD, Prevalence Tables
2 Ramanathan V et al; Healthcare costs associated with hemodialysis catheter-related infections: a single center experience; Infect Control Hosp Epidemiol; 2007;4 28:606-9
3 Martin-Lester M; Fistula First, Catheters Last: If we Have to Use them let's Take Care of Them – analysis from DOPPS study; ERSD: State of the Art and Charting the Challenges for the Future; Boston, 2009
4 2008 Clin J Am Soc Nephrology, Raheela Rehman, Rebecca Schmidt, and Alvin Moss
5 2011 Journal of Am Soc Nephrology, Jeffrey Perl, et. al "Hemodialysis Vascular Access Modifies the Association between Dialysis Modality and Survival"

Access Type and Mortality Review of the CHOICE study

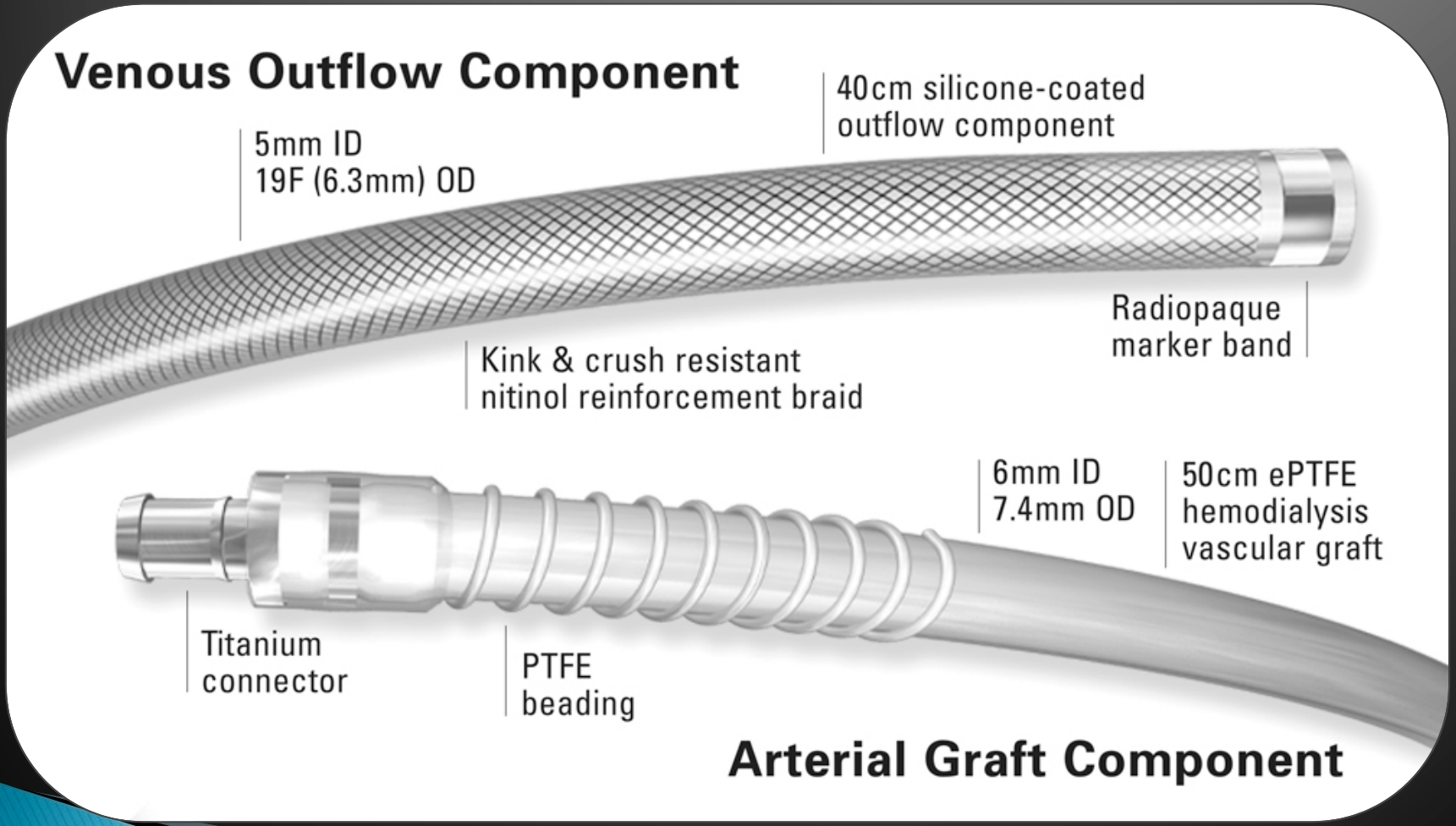


The HeRO Graft (Hemodialysis Reliable Outflow)



The HeRO™ device is a completely implanted subcutaneous graft with an outflow component that bypasses central venous stenosis.

HeRO Graft Has Two Components



HeRO
Hemodialysis Reliable Outflow

Indications for Use

The HeRO vascular access device is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the K/DOQI guidelines' as patients who:

- **Have become catheter-dependent** or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).

- **Are not candidates for upper extremity fistulas or grafts** due to poor venous outflow as determined by a history of previous access failures or venography

- **Are failing fistulas or grafts** due to poor venous outflow as determined by access failure or venography.

- Have **poor remaining venous access sites** for creation of a fistula or graft as determined by ultrasound or venography.

- Have a **compromised central venous system** or central venous stenosis (CVS) as determined by history of previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling) or venography.

- Are receiving **inadequate dialysis clearance** (i.e., low Kt/V) via catheters. K/DOQI

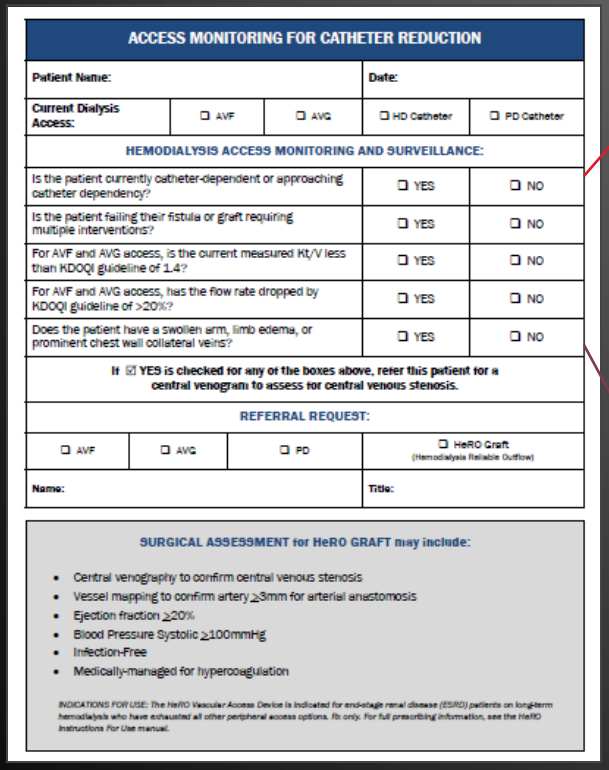
Patency

- Provides continuous blood flow
- Less prone to fibrin sheath occlusion than a CVC
- Hypothesized that patency and intervention rates would be superior to an AVG because the devise is not subject to neointimal hyperplasia at the venous anastomosis

Bacteremia

- Significant reduction in device/procedure related bacteremia compared to CVC as it is completely subcutaneous
- Overall bacteremia rate regardless of relationship to the device and/or the implant procedure was 1.41/1,000days.
- (CVC literature rate of 2.3/1,000 days)

Identifying a HeRO Graft Candidate



ACCESS MONITORING FOR CATHETER REDUCTION

Patient Name:			**Date:**	
Current Dialysis Access:	❑ AVF	❑ AVG	❑ HD Catheter	❑ PD Catheter
HEMODIALYSIS ACCESS MONITORING AND SURVEILLANCE:				
Is the patient currently catheter-dependent or approaching catheter dependency?			❑ YES	❑ NO
Is the patient failing their fistula or graft requiring multiple interventions?			❑ YES	❑ NO
For AVF and AVG access, is the current measured Kt/V less than KDOQI guideline of 1.4?			❑ YES	❑ NO
For AVF and AVG access, has the flow rate dropped by KDOQI guideline of >20%?			❑ YES	❑ NO
Does the patient have a swollen arm, limb edema, or prominent chest wall collateral veins?			❑ YES	❑ NO
If ☑ YES is checked for any of the boxes above, refer this patient for a central venogram to assess for central venous stenosis.				
REFERRAL REQUEST:				
❑ AVF	❑ AVG	❑ PD	❑ HeRO Graft (Hemodialysis Reliable Outflow)	
Name:			**Title:**	

SURGICAL ASSESSMENT for HeRO GRAFT may include:

- Central venography to confirm central venous stenosis
- Vessel mapping to confirm artery ≥3mm for arterial anastomosis
- Ejection fraction ≥20%
- Blood Pressure Systolic ≥100mmHg
- Infection-Free
- Medically-managed for hypercoagulation

INDICATIONS FOR USE: The HeRO Vascular Access Device is indicated for end-stage renal disease (ESRD) patients on long-term hemodialysis who have exhausted all other peripheral access options. Rx only. For full prescribing information, see the HeRO Instructions For Use manual.

Currently catheter-dependent or approaching catheter dependency?	❑ YES	❑ NO
Failing their fistula or graft requiring multiple interventions?	❑ YES	❑ NO
Current measured Kt/V less than KDOQI guideline of 1.4?	❑ YES	❑ NO
Flow rate dropped by KDOQI guideline of >20%?	❑ YES	❑ NO
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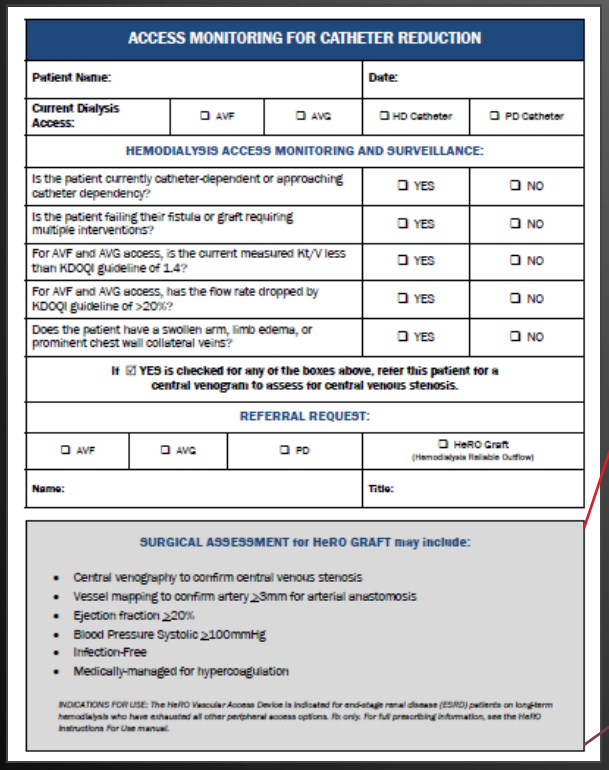
Surgical Assessment for HeRO Graft may include:



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Case # 1

- Age = 60's
- CRF d/t DN
- Not a transplant candidate
- Not a PD candidate

Anatomy

- **Right IJ occluded**. Stump of right innominate available. **Axillary vein occluded**
- **Left innominate diffuse stenosis** extending into the proximal SCV plus distal **subclavian and axillary vein occlusion**
- **Not a transplant candidate** – dense circumferential **calcification iliac arteries** plus hypoplasia
- **Not a PD candidate** – adhesions
- **PAD** – bilateral claudication, only left fem pulse palpable. Not suitable for thigh graft or AVF.

Relevant Comorbities

- IHD class II angina – medical management only – primarily NTG
- Polymyalgia – intermittent steroids
- CVA nonlateralizing 2000 – no recurrence Rx plavix
- Coagulopathy – APLA +ve
- T2DM since 1973 – diet only
- Contrast ALLERGY
- Dialyzing with L FEM CVC
- Previous SVC syndrome L side

ACCESS HISTORY Patient # 1

Oct 2003 Initiated HD Rt. IJ cath D/C 2004 TB lymphadenitis
Nov 2003 Rt brachiocephalic AVF occluded Aug 2004
Aug 2004 Lt IJ cath
Aug 2005 Lt IJ cath replaced (fibrin sheath)
Mar 2006 Lt IJ cath replaced D/C Mar 2009
Jun 2008 Lt brachiobasilic AVF SVC syndrome worse
Dec 2009 partial second stage transposition (inadequate length) occluded Jan 2010
Mar 2009 Lt IJ cath replaced
May 2009 fibrin sheath disruption
Sept 2009 fibrin sheath disruption
Nov 2009 migrating out – repositioned
Nov 2009 replaced Palindrome – removed 3 days later – tunnel infection
Nov 2009 Rt fem catheter – poor flows
Jan 2010 replaced Rt fem cath – removed 4 days later – poor flows
Jan 2010 Rt fem Hemostar cath
Aug 2010 Rt fem Hemosplit cath
Nov 2010 replace Rt fem hemosplit cath
Nov 2010 Rt IJ Hemostar cath
Dec 2010 Poor flows – SVC syndrome worse
Feb 2011 PD evaluation – turned down
Feb 2011 Lt fem cath – prep for HeRO insertion
Feb 21, 2011 HeRO insertion

ONE YEAR COSTS PRIOR TO HeRO

- Lines: 6 Palindromes/Hemosplits
  1 Other Total $3000
- tPA: 17 uses 2 vials/use Total $2720
- $5720 – down the drain!
- Cost of HeRO: venous component $1955
  arterial component $920 component kit $455
  = $3370
- Let's go to Cleveland!!!!!!!

The Return

- Patient exhausted, symptomatic anemia – admitted, transfused
- SVC syndrome worse – left arm edematous, peri-orbital edema. Breathing ok – slept head up. Gradually got better.
- Cannulation started 2 week post-op and fem cath removed
- Did ok for 2 months

Graft Thrombosis

- Cause felt to be pull back of venous limb into the stenosed SVC
- OR April 28 – replaced venous limb with longer segment.
- Thrombosed April 29 – successful thrombolysis. D/C plavix – therapeutic coumadin

Vascular Steal ???

- Hand symptoms noted 2 days after thrombolysis – mild, not mentioned to MD
- Progressively more bothersome – nocturnal, relieved by warming.
- Serial duplex exams: Feb flow rate >500cc/min Mar 700cc/min ulnar artery occlusion, radial calcified and hypoplastic but patent
- Angio: proximal vessels normal, radial patent to palmar arch, ulnar densely calcified, difficult to visualize digital arteries.

More Problems

- Return to OR: chronic occlusion of ulnar – no thrombus retrieved, radial hypoplastic, good backbleeding. No additional treatment done.
- Returned from PARR with right ulnar neuropathy !!
- Neurology consult – not Ischemic Monomelic Neuropathy No suggestions
- Anaesthesia consult
- No tissue at risk – wait and see what happens
- Consistently improved from that point on – intermittent hand pain – LEFT worse than right

Follow – Up

- No further issues – good quality dialysis – PRU was 63% prior to HeRO and 82% after
- Patient became alive again – better appetite, motor strength improved, mentation improved, less edema
- This lasted for almost exactly 1 year

Repeat Thrombosis

- Noted when she appeared for a regular dialysis day
- Suspected causes: subtherapeutic coumadin plus borderline BP
- Successful thrombolysis – dialysis run same day no problem
- Repeat thromboses April 24 and May 2.
- May 2 RSCP – STEMI – Takotsubo cardiomyopathy. Never recovered. Gradually drifted downward and passed away May 22.

Lessons Learned/ Mistakes Made

- This is a stealogenic procedure (low resistance outflow)–thorough documentation of the arterial anatomy before starting
- Graft is sensitive to lowish BP's – could be a problem for some patients
- SVC syndrome can be made worse
- Coagulopathy – High impact
- Overall it's a good addition to the toolbox – it saved this patients life for a while and gave her good quality of life for about 1 year

Access History and Anatomy Case #2

- 81 yr old very frail
- Right forearm AVG 2003.
- Declot and graftoplasty Mar 2004
- Graftoplasty May 2004
- Declot and graftoplasty Dec 2004
- Graftoplasty Dec 2005
- Graftoplasty and **Subclavian venoplasty** Feb 2007
- Graftoplasty and **subclavian stent** Dec 2011 – extends into innominate vein
- **Instent stenosis** – access flow 310 cc/min
- 8 year old graft reaching end of life. No suitable left arm veins
- HeRO graft right arm with Flixene ligation right forearm graft. Next day dialysis.
- No further interventions

Lessons Learned about Case Selection

- **Arterial anatomy needs to be NORMAL** – brachial artery > 3mm and know the rest of the anatomy – risk of steal
- **Central vein STENOSIS** – can't deal with occlusion – have to be able to get a guide wire centrally. In most cases use the venous limb of the catheter and switch it out over a guidewire.
- **You can precipitate SVC syndrome** – or make it worse
- **BP > 100mmHg** Graft is very sensitive to hypotension
- **Heart function needs to be good** – check echo. Since there is no venous anastomosis the flows through the graft are usually high > 1l/min Restrict size of arterial anastomosis

To Date

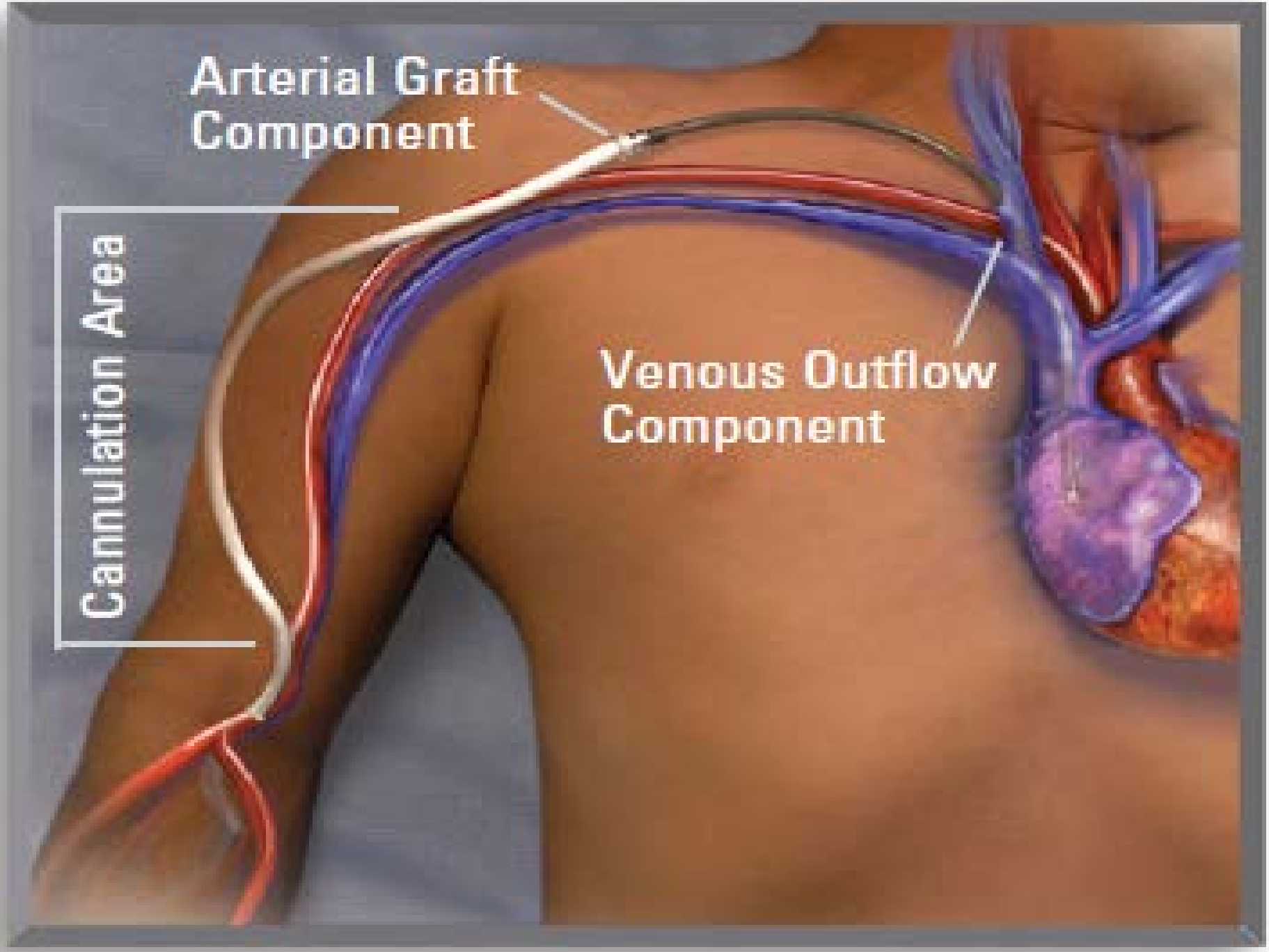
- 7 HeRO's
- 2 deaths unrelated to device
- 1 transplant
- 5 functioning

Pre-Cannulation Assessment

- LOOK for a uniform sized graft in the upper arm with NO irregularities or aneurysm formations.

- LISTEN for low pitch, continuous diastolic & systolic flow. HeRO Graft bruit may be softer due to absence of a venous anastomosis.

- FEEL the thrill. It will be strongest at the arterial anastomosis, but can be felt over the entire course of the graft. HeRO Graft should be easy to compress; however, note that HeRO Graft thrill may be less prominent due to the elimination of the venous anastomosis.


Arterial Graft Component
Cannulation Area
Venous Outflow Component

Recognizing HeRO (Hemodialysis Reliable Outflow) Graft Patients

HeRO Graft patients will typically have 3 incision sites:

- Venotomy site usually near the neck
- Connector site usually near the shoulder
- Arterial anastomosis site usually on the upper arm near the elbow or axilla


LOVE

Cautions

- Never cannulate the HeRO Graft Venous Outflow Component
- To reduce potential infection, remove bridging catheter immediately post successful HeRO Graft cannulation
- Flixene can be used as the graft component allowing for cannulation within 24 hours

KDOQI Graft Cannulation Guidelines

- Aseptic technique should be used for all cannulation
- Grafts generally should not be cannulated for at least two weeks after placement
- Swelling should have subsided so that palpation of the course of the graft can be performed
- Rotation of cannulation sites is needed to avoid pseudoaneurysm formation

HeRO Graft Considerations

- A light tourniquet may be used to slightly dilate the graft
- Cannulate 3″ (8 cm) from the connector incision to avoid damage to the graft rings
- Follow dialysis unit protocol for cannulation distance from the arterial anastomosis incision
- If cannulating toward the anastomosis incision, stay at least the length of the fistula needle from the incision site
- Avoid the use of fistula clamps for hemostasis

Literature Review

- Slow to accumulate – mostly case series and single case modifications
- Bacteremia rates lower than catheter because it is fully implanted
- Fibrin sheath is not a problem – problems develop at the arterial anast or else kinking at the connector site
- Patency better than AVG but equal intervention rate
- Costs are lower – mainly due to less antibiotics, less heparin and less tPA

Trends in the Literature

- Reduce sepsis rate by combining HeRO graft with an early cannulation graft (Flixene)– don't have to use a bridging catheter. Currently 80% use some sort of bridging catheter – 60% of these are femoral
- Attach the HeRO to a pre-existing access that is failing solely due to the development of a central vein stenosis. Use the part of the fistula or graft that is still functioning and extend it proximally with the HeRO
- If the upper body can't be used attach the HeRO somewhere in the lower body and insert the venous limb into the iliac vein.

Summary – Indications for Use

- This device is used in patients who can't have (or can't use) an upper body AVF because the central veins are stenosed or occluded
- Patient's current dialysis modality (fistula, graft, or catheter) is giving inadequate dialysis
- All other access options in that arm are exhausted – this will be the last device in that arm.
- This is still a graft – it's not a permanent solution! Have you looked at other options? PD? Transplant?