Understand. Innovate. Deliver.™

Dialysis Access Options

Donna C. Syracuse, RN
Merit Medical
Global Clinical Education and Program Manager
ANNA Keystone Chapter
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Agenda

- Dialysis Access Overview
- Order of Preference for Dialysis Access
- Types of Dialysis Access

Course Objectives

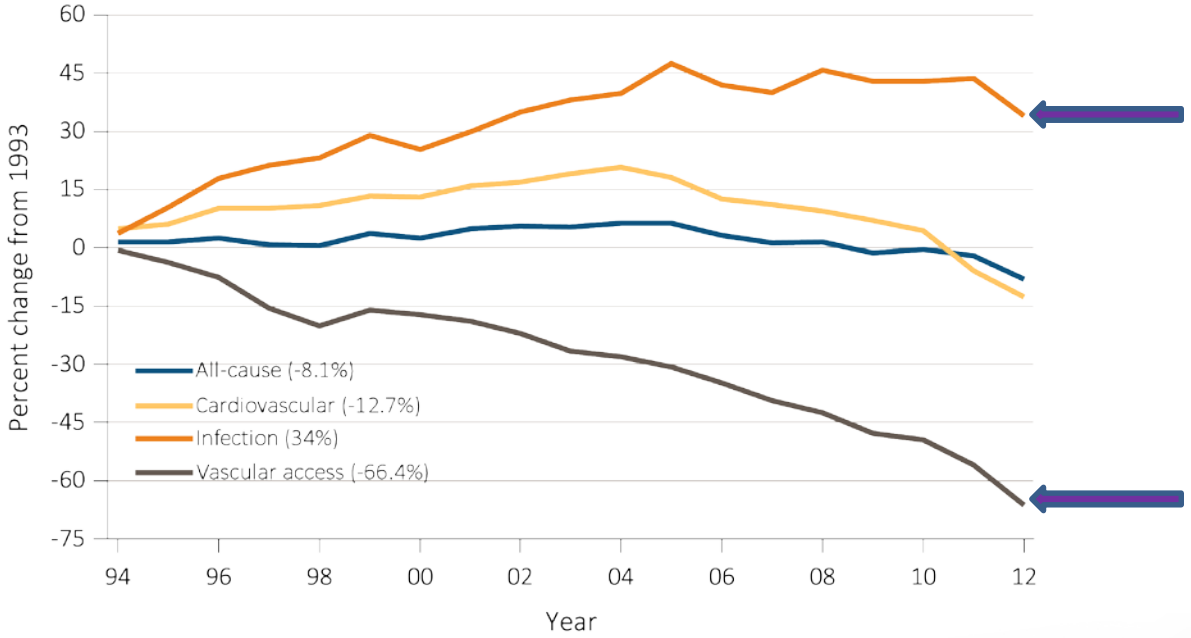
- Participants will be able to identify the types of access for dialysis
- Participants will be able to understand the differences in each access type
- Participants will be able to manage the care and cannulation of each vascular access type
- Participants will be able to identify potential candidates for peritoneal dialysis

Dialysis Access Overview

- Nearly 400,000 individuals in the United States rely on a vascular access to receive hemodialysis treatment[1]
- Vascular access is a leading cause for hospitalization and morbidity in patients with CKD stage 5[1]

Trends

Trends in adjusted all-cause, cause specific hospitalization rates, hemodialysis



- *Data Source: Reference tables: G.3 and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, & primary diagnosis; ref: ESRD patients, 2010. Percent changes from 1993 for the year 2012 are shown in parentheses. Abbreviations: ESRD, end-stage renal disease.*

Vol 2, ESRD, Ch 4

Treatment Guidelines Review

Order of Preference for Vascular Access

Hemodialysis (KDOQI)

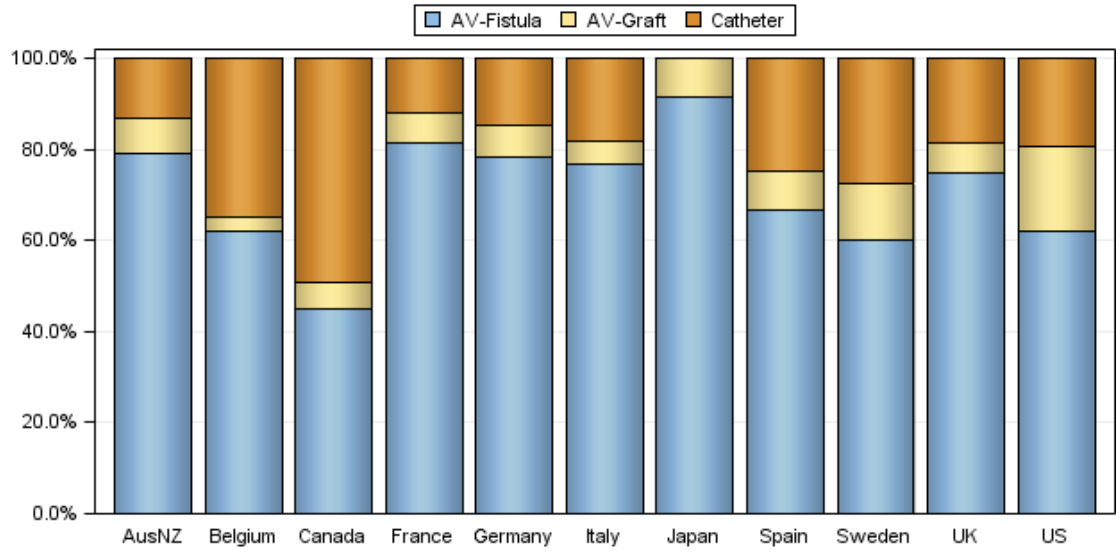
1. Primary autologous arteriovenous fistula (AVF)
2. Arteriovenous graft (AVG)
3. Hemodialysis catheter (HDC)

Outcome Goals (KDOQI)

- Functional AVF placement rate of > 65% of patients[1]
- Cuffed catheter for permanent dialysis access in < 10% of patients[1]

- Current AVF placement rate is 60.6%[2]
- Use of CVC is 20%[2]
- Usage of CVC ≥ 90 days is 7.3%[2]

International VA Data – DOPPS 4



	AusNZ	Belgium	Canada	France	Germany	Italy	Japan	Spain	Sweden	UK	US
AV-Fistula (N Ptnts)	336	283	213	396	512	451	1,377	361	312	336	2,551
AV-Fistula (Wgtd %)	79.1%	61.8%	45.0%	81.3%	78.3%	76.7%	91.4%	66.6%	60.1%	75.0%	62.0%
AV-Graft (N Ptnts)	41	16	28	35	45	24	130	41	61	32	724
AV-Graft (Wgtd %)	7.9%	3.2%	5.9%	6.7%	6.9%	4.9%	8.5%	8.5%	12.3%	6.6%	18.5%
Catheter (N Ptnts)	57	159	219	64	92	114	2	149	142	76	717
Catheter (Wgtd %)	13.0%	35.0%	49.1%	11.9%	14.8%	18.4%	0.1%	24.9%	27.7%	18.5%	19.5%

DOPPS 4 (2011)

Types of Dialysis Access

- Arteriovenous Fistula (AVF)
- Arteriovenous Graft (AVG)
- Hemodialysis Catheter (HDC)
- Peritoneal Dialysis Catheter

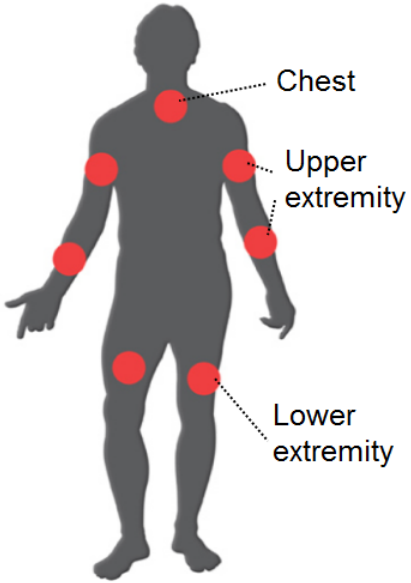
AVF

- The joining of an autologous artery and a vein for use as a hemodialysis site

Types / Locations of AVF

- Order of preference for placement of fistulae[1]
  1. Wrist (radiocephalic)
  2. Elbow (brachiocephalic)
  3. Transposed brachial basilic vein fistula

- Alternative locations include[1]:
  - Thigh
  - Chest



"Location of graft placement is determined by each patient's unique anatomical restrictions, the surgeons' skill, and anticipated duration of dialysis."[1]

[1]NKF KDOQI 2006 Guidelines for Vascular Access, Section 1, Guideline 2.
*Image shown is not meant to be inclusive of all possible locations

Cannulation of AVFs

- 1 to 4 months before cannulation is possible for dialysis[1]

- Rule of 6's (KDOQI):
  - Flow > 600 mL/min
  - Diameter ≥ 6mm
  - No more than 6mm deep
  - Evaluated for nonmaturation if after 6 weeks from creation it does not meet the aforementioned criteria

[1]NKF KDOQI 2006 Update to Guidelines for Vascular Access, Section 1, Guideline 8.

Cannulation of AVFs - Assessment

Examine AVF or AVG Prior to HD Treatment	
LOOK FOR:	Signs of infection
	Steal syndrome
	Stenosis
	Cannulation site problems
LISTEN FOR:	Bruit
	Outflow vein
	Direction of blood flow
FEEL FOR:	Skin temperature
	Thrill
	Stenosis
	Vein diameter
	Cannulation sites
	Steal syndrome

Core Curriculum for the Dialysis Technician. Fifth Edition. Module 5: Vascular Access.

Advantages of AVFs

- Best long term results such as:
  - Patency
  - Low stenosis rate
  - Low infection rate
  - Low morbidity

- If done pre-ESRD, no other temporary access is needed for immediate use

NKF KDOQI 2000 Guidelines, Section 1, Guidelines 3, B and C. Online edition, downloaded on 05/05/2011.

Disadvantages of AVFs

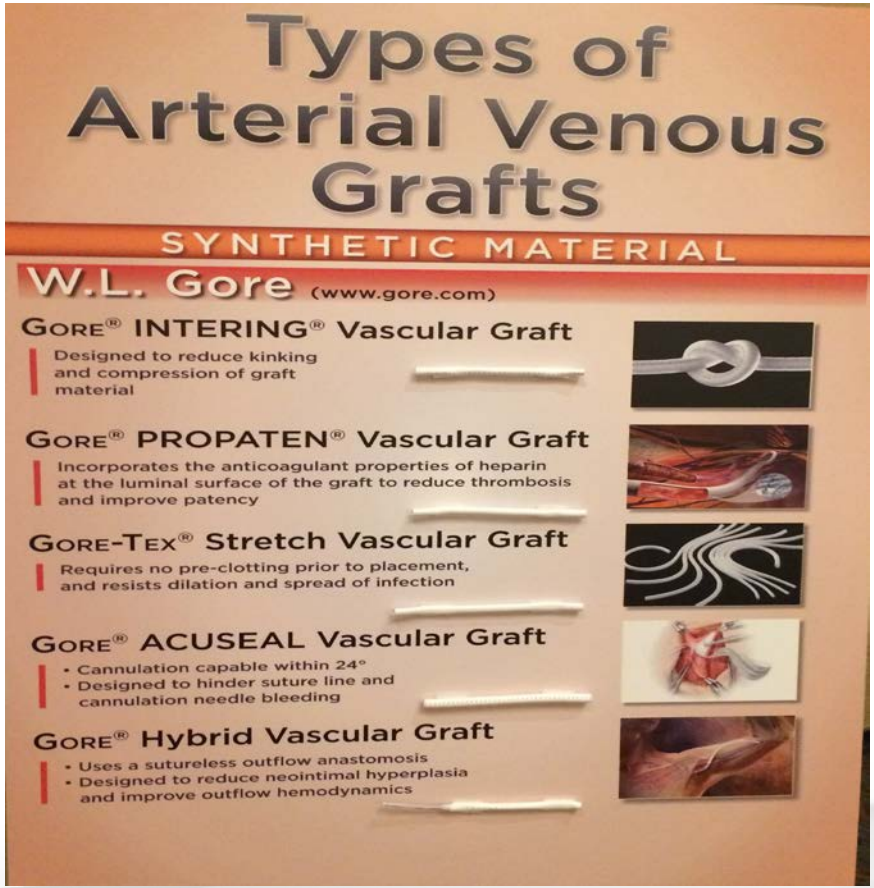
- At least 1-4 months to mature/heal[1]
  - Most patients need immediate access
- 38% of patients are not able to have an autogenous AVF[2]
- Infection:
  - 1% - 4%[3]
- Persistent swelling of the hand or arm, inadequate flow, venous stenosis, aneurysm formation, ischemia in access arm, thrombosis

[1]NKF KDOQI 2000 Guidelines, Section 1, Guidelines 3, 8, and 9. Online edition, downloaded 05/05/2011.
[2]Scott E, et al. Conduits for hemodialysis access. J Sem Vasc Surg 2007; 158-63.
[3]Lew, ASAIO 2000;46:S6-S12, and Albers, Advances in Renal Replacement Therapy 1996;3:208-17

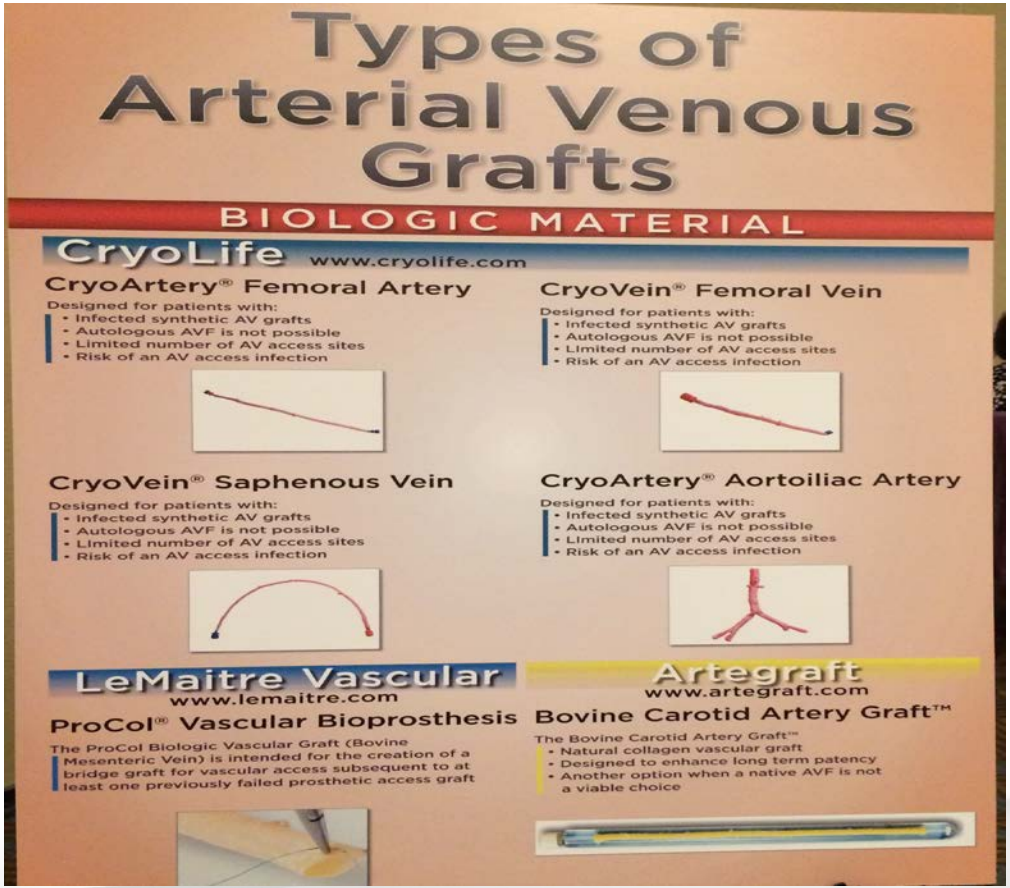
AV Grafts (AVGs)

- Synthetic Graft
- Cryopreserved Human Allograft
- Xenograft
- HeRO® Graft

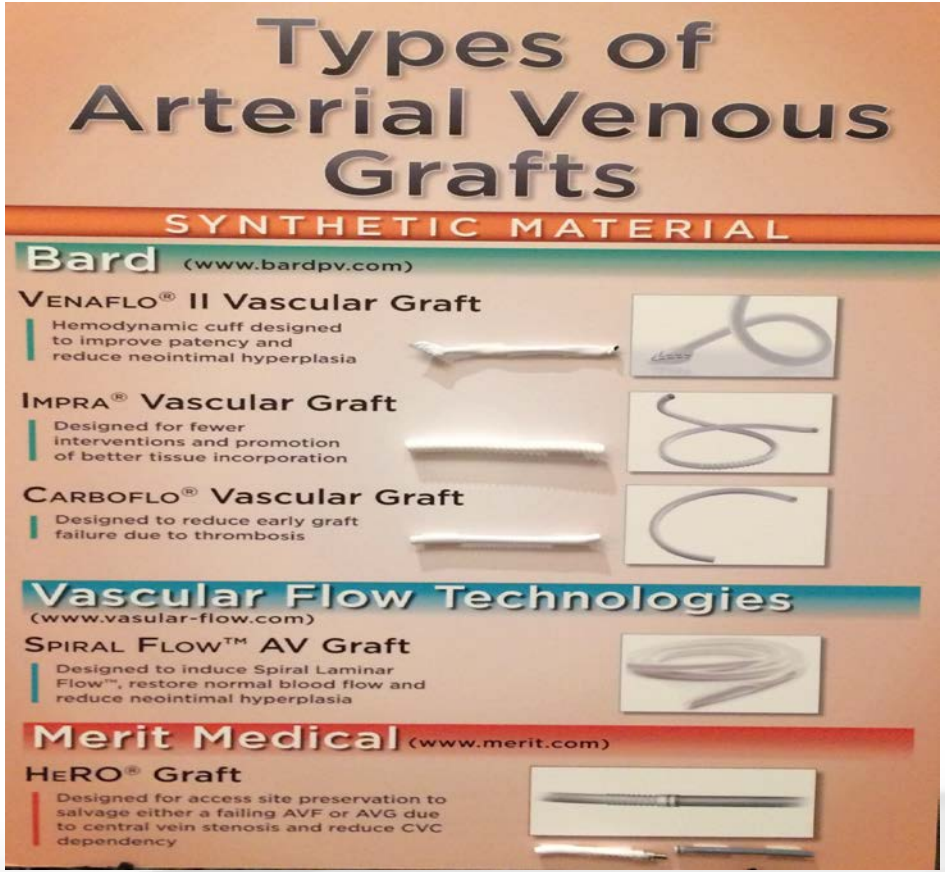
Types of Grafts



Types of Grafts



Types of Grafts



Configurations of AVGs

- Forearm loop graft
- Upper-arm graft
- Lower-extremity graft*
- Chest wall or “necklace” prosthetic graft*

*All upper-arm sites should be exhausted

[1]NKF KDOQI 2000 Guidelines, Section 1, Guideline 2. Online edition, downloaded 05/05/2011.
[2]Scott E, et al. Conduits for hemodialysis access. J Sem Vasc Surg 2007; 158-63.

AVG Complications

- Extremity edema
- Graft rupture
- Stenosis
- Thrombosis
- Pseudoaneurysm
- Infection

NKF KDOQI 2006 Guidelines, Section 1, Guidelines 6. Online edition downloaded on 05/08/2013.

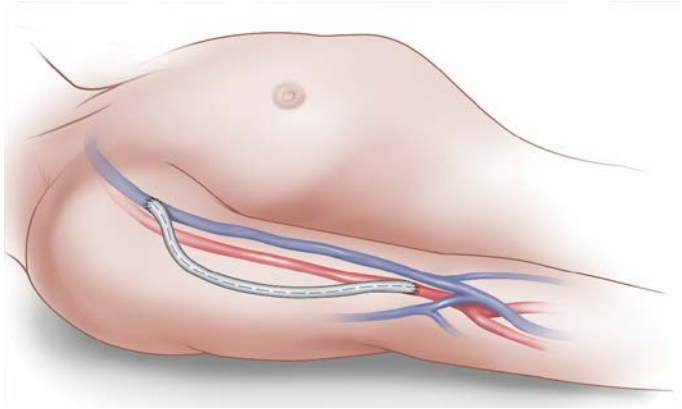
When to Consider Synthetic AVG

- An autologous fistula does not mature
- Rationale:
  - "The sum of the available data, until recently, supported PTFE over other biological and other synthetic materials, based on:
    - Lower risk for disintegration with infection
    - Longer patency
    - Better availability
    - Improved surgical handling."[1]

[1]NKF KDOQI 2000 Guidelines, Section 1, Guideline 4. Online edition, downloaded on 05/05/2011.

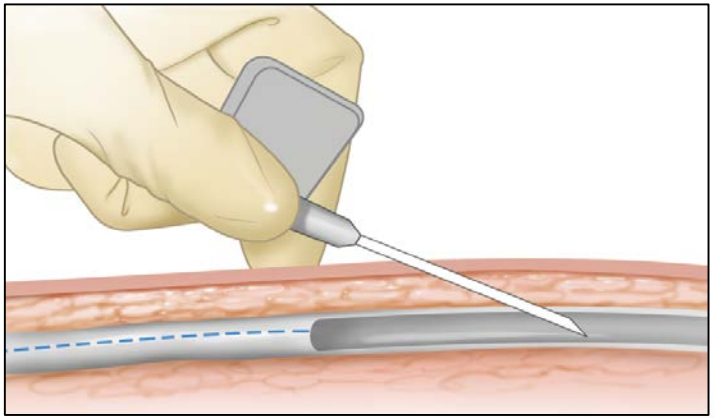
Types of Synthetic AVGs

- Different Materials
  - PTFE, ePTFE, Polyurethane, Carbon impregnated PTFE
- Early Cannulation
- Hybrid graft



Cannulation of Synthetic AVGs

- At least 2 weeks after placement
- Not until swelling has subsided
- Rotation of cannulation sites



Cannulation of Early Access AVGs

Graft	Time to Cannulation
Vectra® Vascular Access Graft	24 hours[1]
FLIXENE® Vascular Graft	72 hours[2]
GORE® ACUSEAL Vascular Graft	24 hours[3]

[1]Vectra Vascular Access Graft Instructions for Use, document number: 14160.Q. 11/2002.
[2]Flixene Product Brochure, Atrium Medical, document number: 0321A. 07/2010.
[3]GORE ACUSEAL Vascular Graft Instructions for Use, March 2011, downloaded from www.goremedical.com on 06/17/2013.

Clinical Data for Synthetic AVGs

AVG Literature[1]	
Bacteremia Rates (Infections/1,000 days)	0.11
Adequacy of Dialysis (mean Kt/V)β	1.37 - 1.62
Cumulative Patency at 1 Year	65%
Intervention Rate (per year)	1.6 - 2.4

βNote: Every 0.1 decrease in Kt/V increases the mortality rate by 7%[3] and is significantly (P<0.05) associated with 11% more hospitalizations, 12% more hospital days, and a $940 increase in Medicare inpatient expenditures.[4]

[1]Katzman et al., J Vasc Surg 2009; IFU: Comparisons to catheters and AVGs are from literature review on file.

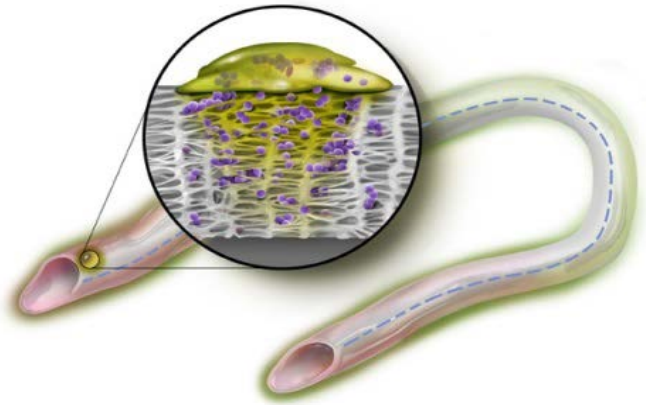
Advantages of Synthetic AVGs

- 2nd choice of vascular access[1,2]
- Time to maturation for cannulation: 2 weeks[2]
- Cost effective
- No upfront hospital investment
- Off-the-shelf ready

[1]NKF KDOQI 2000 Guidelines, Section 1, Guideline 4. Online edition downloaded on 05/05/2011.
[2]Cronerwett and Johnson, Rutherford's Vascular Surgery, Elsevier, 2011, online edition.

Disadvantages of Synthetic AVGs

- Prone to infection: up to 35%[1]
- High re-infections for “Jump Grafts”
  - 6% to 10%[2,3]
- Needle hole bleeding
- Stiff: not compliant, not pulsatile
- Venous outflow track stenosis[4]

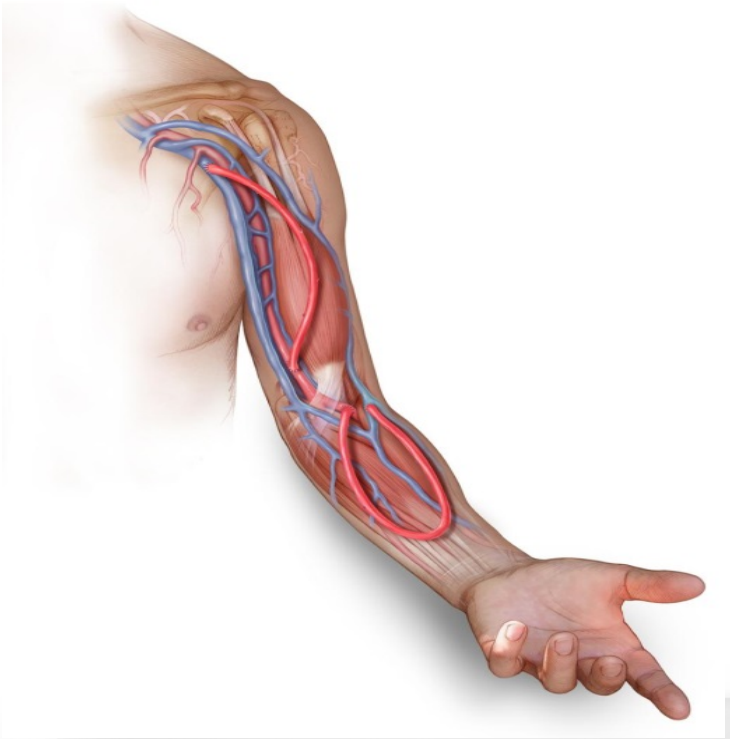


[1]Akoh J. J Vas Access 2009; 10:137-47.
[2]Schwab et al. Ann Vasc Surg 2000; 14:63-6.
[3]Raju et al, Ann Surg 1987;206:666-73
[4]Matsuura J. Contemp Dial & Neph; 1999:30-2.

Cryopreserved Human Allografts

When to Consider Cryopreserved Human Allografts

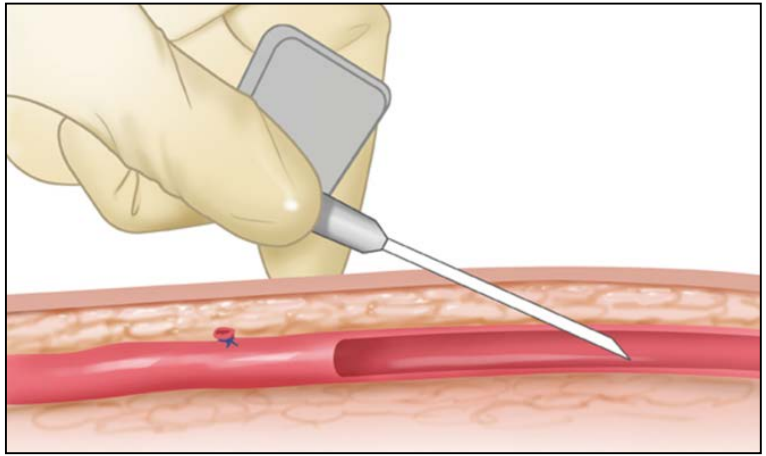
- Infected synthetic AVGs
  - Up to 35% get infected[1]
- AVF is not possible
  - Lack of suitable native vein
  - Failed AVF
    - 38% of autologous sites fail to mature[2]
- At risk of infection
- Limited number of sites



[1]Akoh J. J Vas Access 2009; 10:137-47.
[2]Scott E et al. J Sem Vasc Surg 2007;158-63.

Cannulation of Cryopreserved Human Allografts

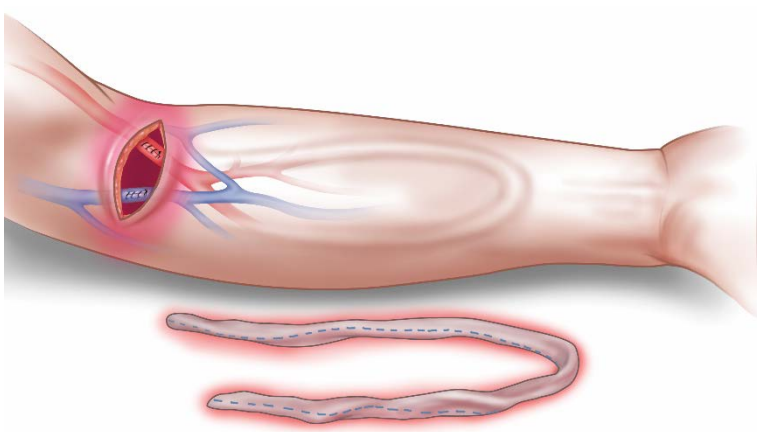
- Access is possible 10 to 14 days after implantation[1,2]
- Hybrid cannulation techniques
- Buttonhole technique

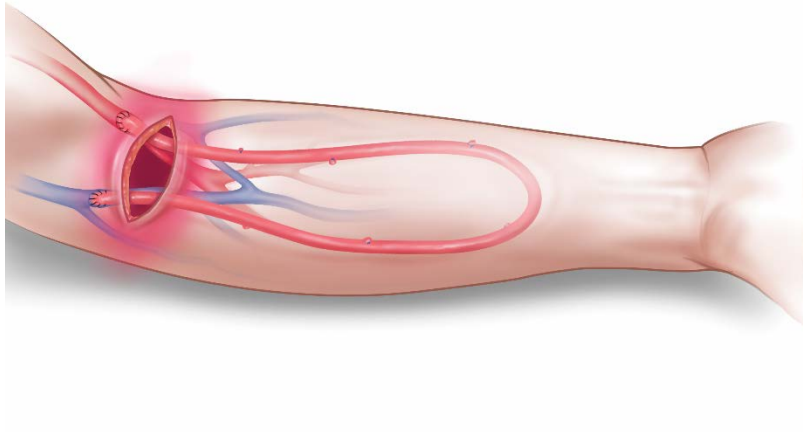


[1]Matsuura J, et al. Ann Vasc Surg 2000;12:50-5.
[2]Matsuura J, et al. Cardiovasc Surg 2002. 10;6:561-65.
[3]NKF KDOQI 2006 Guidelines, CPG 3.4. Online edition, downloaded on 05/10/2011.
[4]Gallachio MH et al. Gallachio MH et al. Successful utilization of cryopreserved human femoral vein or bovine carotid artery in establishment of button-holes for hemodialysis. Presented at the VASA Meeting, May 2012, Orlando, FL.

Advantages of Cryopreserved Human Allografts Save the Access Site

- KDOQI: *"Management of an AVG infection is a balance between achieving resolution of the infection while preserving the vascular access."*[1]





[1]NKF KDOQI 2006 Guidelines, Section CPG 6.9. Online edition, downloaded on 05/06/2011.

Disadvantages of Cryopreserved Human Allografts

- Sensitization
- Pseudoaneurysm & aneurysm formation
  - Matsuura[1]: 2% (3/43)
  - Matsuura[2]: 0% (0/44)
  - Lin[3]: 4% (2/45)
  - Bolton[4]: 40% (8/20)
  - Takamoto[5]: 0%
  - Baraldi[6]: 0%

[1]Matsuura J, et al. Cardiovasc Surg 2002. 10;6:561-65.
[2]Matsuura J, et al. Ann Vasc Surg 2000;12:50-5.
[3]Lin P, et al. Am J Surg 2002;184:31-6.
[4]Bolton et al. J Vasc Surg 2002;36:464-8.
[5]Takamoto S, et al. Trans Proceed 1998;30:3917-19.
[6]Baraldi A, et al. Trans Am Soc Artif Intern Organs 1989:196-9.

Xenograft

Types of Xenografts

- Bovine carotid artery
- Bovine mesenteric vein

Cannulation of Xenograft

- At least two weeks[1]
- The physician will determine when the bioprosthesis may be accessed

[1]Procol IFU, http://www.hancockjaffe.com/PDF/ProCol%20Instructions%20for%20Use.pdf#zoom=100, 03/2010.

Advantages of Xenograft

- Cannulation: indicated 10 days after implant[1]
- No hospital upfront investment
- 5 minute prep time[1]
- Shelf life: 3 years[1]
- No special storage[1]
- Sterile[1]
- Biologic tissue[1]

[1]www.artegraft.com, downloaded on 04/20/2011..

Disadvantages of Xenograft

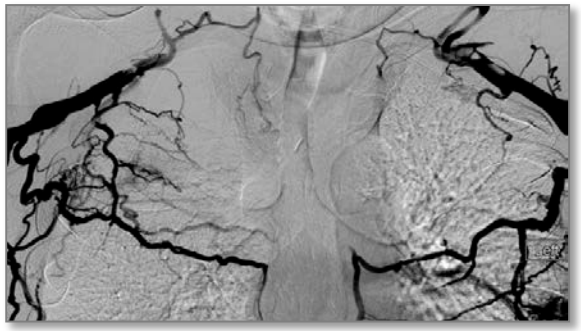
- Primary infections (9% to 20%)[1]
- Pseudoaneurysms (1% to 8%)[2,3]
- True aneurysms (1% to 7%)[1]
- KDOQI: “higher complication rates than PTFE”[4]
- No data for treating infected fields
- Irradiated
- Gluteraldehyde fixed

[1]Scott et al. Semin Vasc Surg 2007; 20:158-63.
[2]Haimov M et al. Ann Surg. 1974 Sep;180(3):291-5.
3Farber A. Rutherford’s Vascular Surgery 7th Ed. Biological Grafts. Online edition downloaded on 06/29/2010.
[4]NKF KDOQI 2006 Guidelines, CPG 2.1, 4,G. Online edition downloaded on 5/6/2011.
[5]Gouk et al. J Biomed Mater Res Part B: App Biomater 84B:205-217, 2008.

HeRO® Graft

When to Consider HeRO Graft

HeRO (Hemodialysis Reliable Outflow) Graft is the **ONLY** fully subcutaneous AV access solution clinically proven to maintain long-term access for hemodialysis patients with **central venous stenosis**.



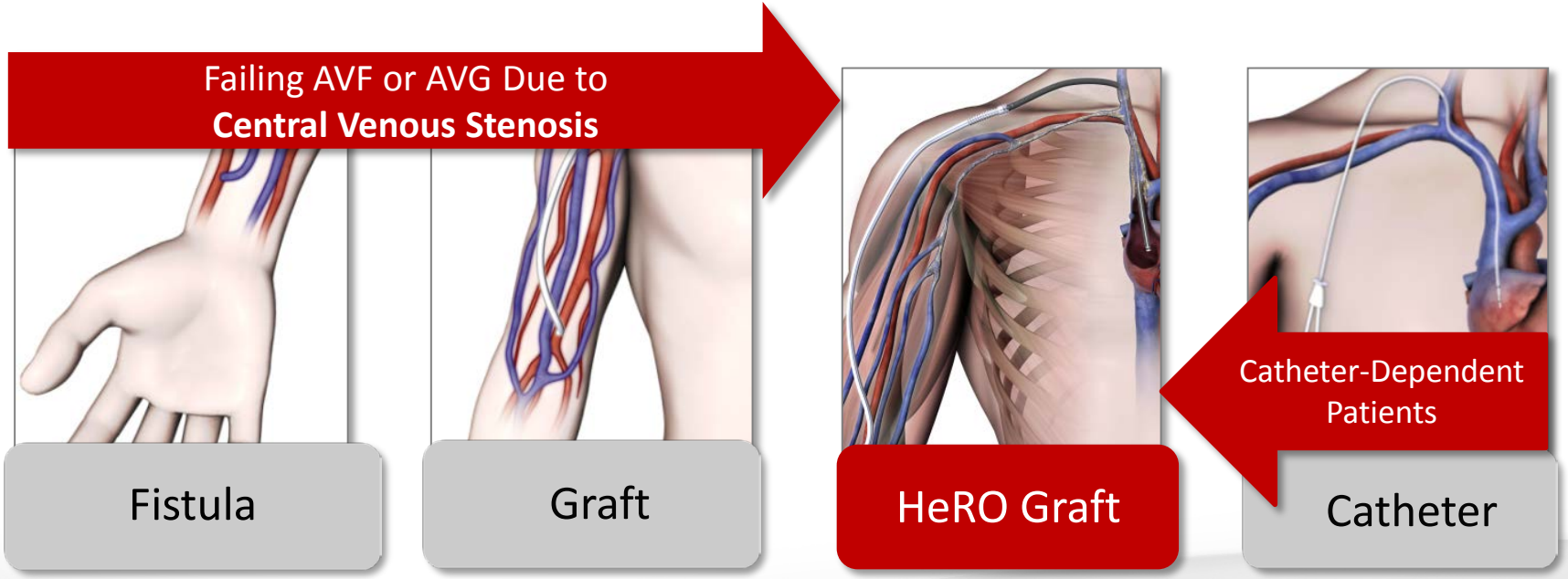
Above: Venogram of bilateral central venous stenosis

Above: Patient with distended central veins due to stenosis/occlusion

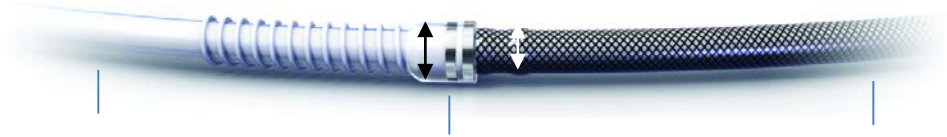
When to Consider HeRO Graft

HeRO Graft Candidates

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



Product Overview



Arterial Graft Component

6mm (ID) x 50cm

Titanium Connector

6mm - 5mm (ID), 2.5° taper

Venous Outflow Component

5mm (ID), 6.3mm (OD), 19F (OD) x 40cm (customizable length)

ePTFE Graft

- Beading (3-4cm) for kink resistance
- Orientation line on graft to guide placement during tunneling
- Titanium Connector

Silicone-Coated Nitinol Component

- No venous anastomosis
- Reinforced 48 braid nitinol: kink and crush resistant
- Removable and replaceable
- Radiopaque band (at distal tip)

HeRO Graft is classified by the FDA as a **vascular graft prosthesis.**

Super HeRO

SUPER HeRO®

Adapter

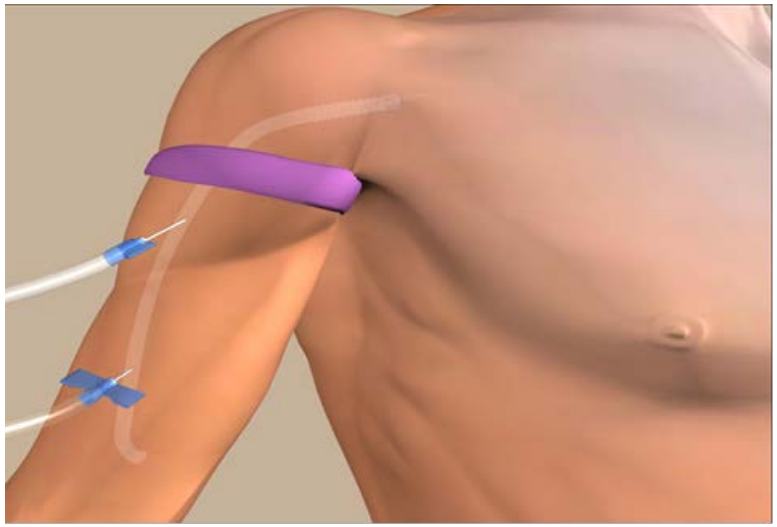
Support Seal

More Graft Options**

* See Instructions for Use (IFU) for more details.
**Graft is not included with the Adapter. See Instructions for Use (IFU) for more details on the grafts permitted for use with the HeRO Graft Adapter.

Cannulation of HeRO Graft

- Conventional synthetic AVG cannulation
- 3 Incision Sites
- NEVER cannulate the Venous Outflow Component
- 3” from Titanium Connector incision site
- Avoid fistula clamps



Advantages of HeRO Graft

- **Fewer Infections:**
  - 69% reduced infection rate compared with catheters[1]
- **Superior Dialysis Adequacy:**
  - 1.7 Kt/V, a 16% to 32% improvement compared with catheters[1]
- **High Patency Rates:**
  - Up to 87% cumulative patency at 2 years[1,2]
- **Cost Savings:**
  - A 23% average savings per year compared with catheters[3]

[1]Katzman et al., J Vasc Surg 2009; IFU: Comparisons to catheters and AVGs are from literature review on file.
[2]Gage et al., EJVES 2012.
[3]Dageforde et al., JSR 2012.

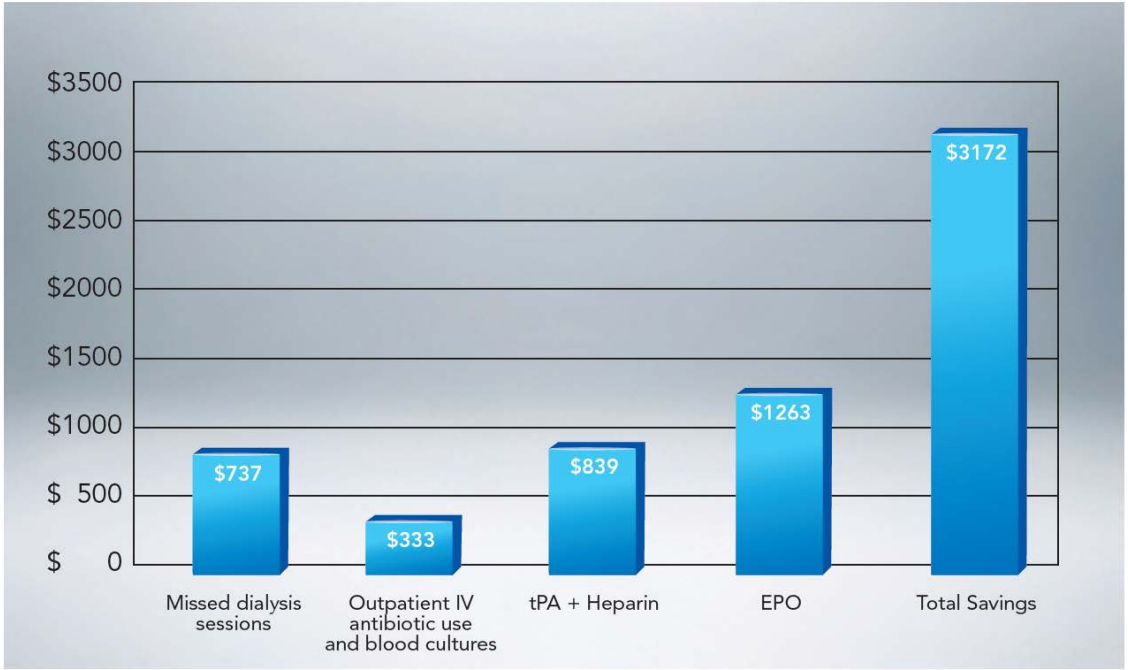
HeRO Graft Cost Benefits: Hospital

- **23% average savings** per year with the HeRO Graft compared with catheters[1]
- **Reduces catheter-related infections and hospital admissions** projected at $23k to $56k per stay[2,3]
- **Lowers interventions** and associated costs by more than 50% compared to catheters[4,5]

[1]Dageforde et al., JSR 2012.
[2]Ramanathan et al., Infect Control Hosp Epidemiol 2007.
[3]O'Grady et al., The Centers for Disease Control 2002.
[4]Katzman et al., J Vasc Surg 2009; IFU: Comparisons to catheters and AVGs are from literature review on file.
[5]Gage et al., EJVES 2012.

HeRO Graft Cost Benefits: Dialysis Center

Impact of HeRO Graft in the Era of Dialysis Provider Bundling



Cost savings of over $3,100 (per patient/year) to the dialysis center when converting catheter-dependent patients to the HeRO Graft[1]

1) Yost and Dinwiddie, American Society of Nephrology (ASN), Nov 2010.

Disadvantages of HeRO Graft

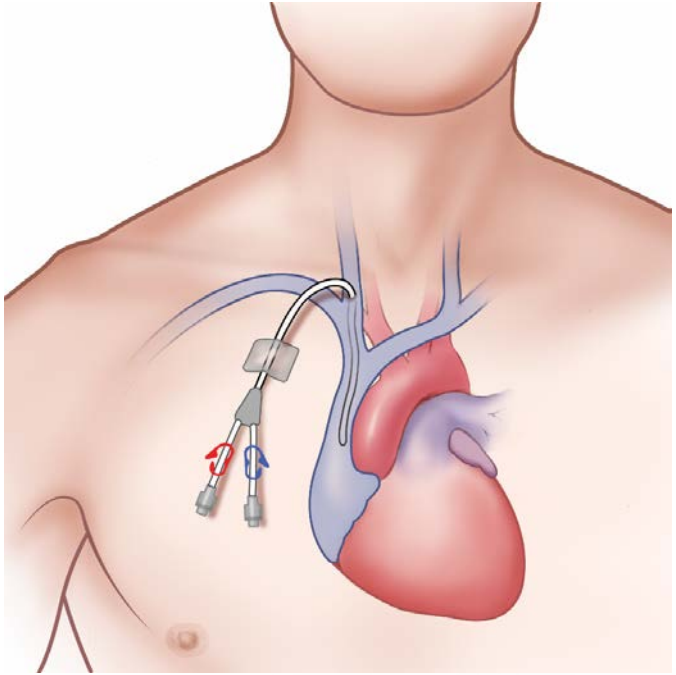
- Thrombosis[1]
- Graft kinking
  - If Titanium Connector is NOT implanted in an appropriate anatomical region.
- Infection
  - If the patient is NOT prophylactically treated in the peri-operative period with antibiotics based upon the patient's bacteremia history.[1]

[1]HeRO Graft IFU, 11-0114, Rev. H 2012-07

Hemodialysis Catheter (HDC)

Hemodialysis Catheter (HDC)

- What:
  - A HDC is a double-lumen flexible tube which is connected to the dialysis machine.
- When:
  - Need for immediate dialysis with no time for access maturation (of fistula or graft).



Sidawy A Rutherf.ord's Vascular Surgery 7th Ed., Section 10 – Hemodialysis Access
Conenwett and Johnson, Elsevier downloaded on 04/11/2011 online edition.

Location of HDC (KDOQI)

- Preferred: Right internal jugular vein
- Other options:
  - Right external jugular vein
  - Left internal and external jugular veins
  - Subclavian veins
    - Only when no other upper-extremity or chest wall options are available
  - Femoral veins
  - Translumbar and transhepatic access to the IVC

Advantages of HDCs

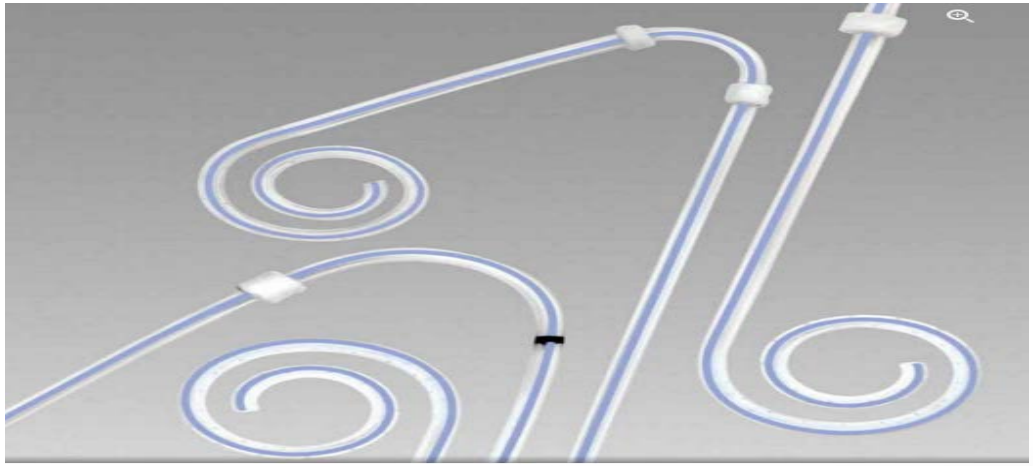
- Universal applicability
- Ability to be placed in multiple sites
- Avoidance of repeated skin punctures

Disadvantages of HDCs

- Infection: 20%, 2.3 infections per 1,000 patient days
- Failure to attain and maintain extracoporeal blood flow of 300 mL/min
- More than half have to be removed due to infection, malfunction
- Contributes to central venous stenosis/occlusion
- Discomfort of external device
- Lower blood-flow rates
  - Leading to longer dialysis times or less effective dialysis

Sidawy A Rutherf.ord's Vascular Surgery 7th Ed., Section 10 – Hemodialysis Access Conenwett and Johnson, Elsevier downloaded on 04/11/2011 online edition.

Peritoneal Dialysis (PD)



What is PD?

- Approximately 7% of dialysis patients use PD
  - ~27,733 patients
- Uses patient's peritoneum and peritoneal catheter to pull waste and extra fluid from patient's blood into the peritoneal cavity
  - Fluid drained and replaced with fresh fluid
- Continuous or manual exchanges

2012 USRDS Annual Data Report. 1: Incidence, Prevalence, Patient Characteristics, & Modality.

When to Consider PD

- Peritoneal access is for:
  - Patients who cannot tolerate hemodialysis (HD) due to:
    - Ischemic heart disease
    - Extensive vascular disease
    - Vascular access is problematic
    - Majority of young children
  - Patients who prefer home dialysis, but have no assistant for HD, or whose assistant cannot be trained for home HD.

Advantages of PD

- Good solution if the patient can't tolerate the rapid changes of fluid balance associated with hemodialysis – PD produces fewer swings in symptoms due to its continuous nature
- Minimizes the disruption of daily activities
- Allows patient to have more mobility

http://www.mayoclinic.com/health/peritoneal-dialysis/

Disadvantages of PD

- Infection
- Weight Gain
- Weakening of the abdominal muscles – hernia
- Not everyone is a candidate for PD
  - Contraindications
- Daily exchanges necessary

http://www.mayoclinic.com/health/peritoneal-dialysis/

In Summary