

A Clinical Update On An Alternative Vascular Access For the CATHETER-DEPENDENT HEMODIALYSIS PATIENT

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DISCLAIMER

Information contained in this Clinical Bulletin is based upon current data available at the time of publication. Information is intended to help clinicians become aware of new scientific findings and developments. This Clinical Bulletin is not intended to define a standard of care and should not be construed as one. Neither should the information be interpreted as prescribing an exclusive course of management.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every health care professional making use of information in this Clinical Bulletin is responsible for interpreting the data as it pertains to clinical decision making in each individual patient.

Made possible through an educational grant from
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What is the order of preference for vascular access options in hemodialysis?

The gold standard for vascular access in hemodialysis patients is the arteriovenous fistula (AVF). The 2006 KDOQI Clinical Practice Guidelines for Vascular Access in Hemodialysis¹ state the order of preference for vascular access as:

- Arteriovenous fistulae are preferred;
- Arteriovenous grafts (AVG) made of synthetic or biological material are acceptable;
- Short and long-term tunneled dialysis catheters (TDC) should be avoided, if possible.

AVFs are associated with the fewest complications and hospitalizations when compared with other access modalities.^{2,3} According to data from the 2007 United States Renal Data System (USRDS), for patients with a catheter, rates of vascular access infection are four times higher than for those who have a graft, and eight times higher than for those who have a fistula.² Accordingly, the Fistula First Initiative recommends that catheter use be reduced, and that more patients receive an AVF.⁴

HEMODIALYSIS VASCULAR ACCESS

- 1 What is the order of preference for vascular access options in hemodialysis?
- 2 What are options for patients who are not candidates for an arteriovenous fistula or arteriovenous graft due to central venous stenosis or occlusion?
- 3 What is the HeRO™ Graft and its indications for use?
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What are options for patients who are not candidates for an arteriovenous fistula or arteriovenous graft due to central venous stenosis or occlusion?

For patients who are not candidates for an AVF or conventional AVG, or for those in whom these options have failed, the risk of catheter dependency and other catheter-related problems create significant concerns. TDCs are associated with a high incidence of infectious complications and mortality and should not be used unless all other options have failed.¹ Other problems related to catheters include less effective dialysis secondary to reduced blood flow rates, mechanical complications, and central venous stenosis (CVS) and/or occlusion.⁵ Of the 104,252 patients who began hemodialysis in 2009, 82% were using either a catheter alone or a catheter with a maturing AVF or AVG.² Ironically, the continued high rate of TDC placement, with increased risk of CVS or occlusions may eventually preclude the placement of a permanent dialysis access, and thus increase the number of patients dependent upon TDCs for chronic dialysis.⁶ CVS leads to outflow obstruction of AVFs or AVGs, severe venous hypertension, arm swelling, and compromise of upper limb accesses. KDOQI recommends percutaneous intervention with transluminal angioplasty as the preferred treatment for CVS. Stent placement combined with angioplasty is indicated in elastic CVS or if a stenosis recurs within a 3-month period.¹ When there is the need for more than two angioplasty procedures within a 3-month interval, surgery may be considered.¹ More severe forms may be treated by ligation of the AVG or AVF, or use of the HeRO Graft, a device that was studied in a multicenter clinical trial demonstrating a statistically significant reduction in bacteremia rates compared with CVCs.^{5,7} If these options fail, a change in renal replacement modality to either peritoneal dialysis or renal transplant should be considered.⁸

This resource focuses on *The Hemodialysis Reliable Outflow (HeRO[®]) Graft*, an alternative for vascular access in select hemodialysis patients who are catheter-dependent.

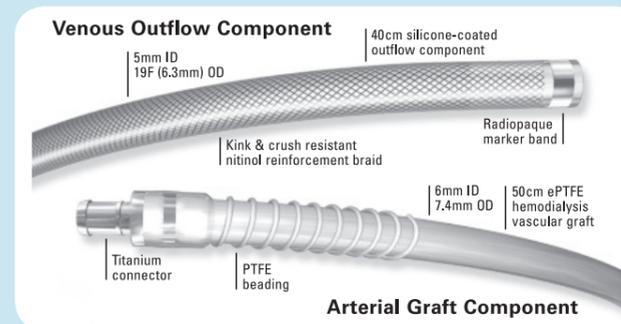
What is the HeRO[®] Graft and its indications for use?

The HeRO Graft is a long-term fully subcutaneous dialysis device that instead of a venous anastomosis, utilizes an outflow component that traverses central venous stenosis to provide continuous outflow into the central venous system.⁶ It was cleared for use by the Food and Drug Administration (FDA) in 2008, and was classified as a graft. The FDA states that it is indicated for end-stage renal disease patients on hemodialysis who have exhausted all other access options.⁹

The device has two parts: a 6-mm expanded polytetrafluoroethylene (ePTFE) graft to be anastomosed to a peripheral artery at one end with a titanium connector at the other end that connects with a 19F silicone tube (outer diameter of 6.3 mm, and

inner diameter of 5 mm) that is reinforced with a nitinol braid to prevent kinking (Fig 1). Like standard prosthetic access devices, the HeRO is cannulated by inserting dialysis needles into the graft component once the graft is tissue incorporated.⁶

Figure 1: Components of the HeRO Graft¹⁰



What are the evidence-based benefits and risks related to use of the HeRO[®] Graft?

Clinical trial data indicate that the HeRO Graft:

- has a significantly lower rate of bacteremia than that of TDCs
- improves adequacy of dialysis as compared with TDCs
- is comparable with AVG performance in terms of patency and intervention rates

The first peer-reviewed prospective, non-randomized FDA multi-center (7 sites) clinical trial gathered data for 36 patients. In their report of these data, Katzman et al, compared the HeRO graft with historical controls from the literature and identified a significantly lower bacteremia rate of 69% as compared with TDCs. They also reported that adequacy of dialysis was improved to 1.7 Kt/V, higher than that found in historical controls from the literature for AVGs and TDCs.⁵ (Table 1)

A multi-center experience with 161 consecutive HeRO graft implants (post-FDA approval) demonstrated that HeRO graft patency was comparable to AVG historical controls from the literature, with 12 month patency of 88% and 1.7 interventions per year.¹¹ (Table 1)

Nassar reported that in the longest HeRO clinical experience of the first clinical trial patient, no infectious complications related to the device occurred during 56 months of follow-up. Nassar concluded from this experience, along with the data cited above, that the HeRO Graft should be considered for use in access-challenged patients prior to committing them to long-term TDCs.¹²

Table 1: Clinical Outcome Comparisons with Historical Controls from the Literature

Multi-Center Data	AVG Literature	FDA Clinical Trial HeRO Graft*	Post-Market HeRO Graft**	Catheter Literature
Bacteremia Rates (Infection/1,000 days)	0.11	0.70	0.18	2.30
Intervention Rates (Per Patient Year)	1.6-2.4	2.5	1.7	5.8
12 Month Secondary Patency Rates	65%	78%	88%	37%
Adequacy of Dialysis (mean Kt/V)	1.37-1.62	1.70	NA	1.29-1.46

*Data from HeRO Bacteremia Study submitted for FDA Clearance published in the Journal of Vascular Surgery, Sept 2009, Katzman, MD, et al. Comparisons to AVG and catheters are from literature review on file at Hemosphere, Inc.

**Data presented at American Society of Nephrology, Nov 2010 with data contributed by Duke University, University of Miami, Baylor Health Systems, and Bamberg County Hospital.

How is patient suitability for the HeRO Graft determined?

Patients should be evaluated for HeRO Graft placement if they have become catheter-dependent or are approaching catheter-dependency because all other peripheral access options have been exhausted. Poor venous outflow should be determined by a history of previous access failures and venography. Failing fistulas or grafts can be suspected to have poor venous outflow by the presence of decreased Kt/V, swollen access arm, and/or collateral vein development. A compromised central venous system or central venous stenosis should be determined by vessel mapping, preferably venography. The preoperative evaluation should include upper extremity arterial and venous duplex studies. If a central venous stenosis or occlusion is suspected from the venous duplex, a central venogram may be needed to clarify venous anatomy before determining the appropriate treatment and/or placing the device. Additionally, a catheter-based arteriogram or CT arteriogram may be helpful if there is any suspicion of an arterial inflow problem at the proposed anastomotic site based on the non-invasive imaging.

Based upon diagnostic findings, the nephrologist may refer the patient to a vascular surgeon, or if an interventionalist, may perform the optimal procedure(s). The treatment choice should be based, in part, upon perceived life expectancy, dialysis access longevity, and other co-morbid factors.¹³

Potential candidates will have:

- exhausted peripheral venous access sites suitable for fistulas or grafts
- a brachial artery diameter of > 3 mm
- cardiac ejection fraction of > 20%
- systolic blood pressure > 100 mm Hg
- absence of infection as determined by negative blood culture⁶

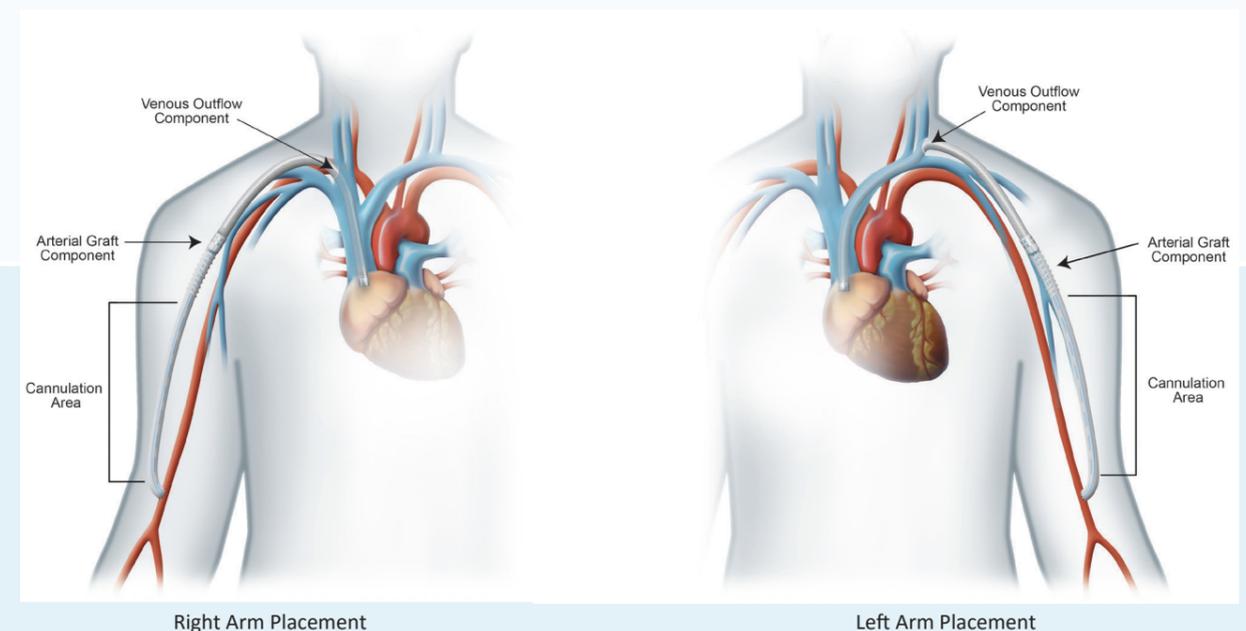
How can clinicians best ensure success after HeRO Graft placement?

Post-placement infection can be prevented by removing the bridging catheter as soon as possible and treating prophylactically with broad spectrum antibiotics. Prophylactic intravenous antibiotic therapy tailored to local bacterial experience should be considered if the patient is at increased risk for infection. Clotting of these grafts occurs and is thought to be related primarily to hypotension as this device is long (90 cm untrimmed). In order to promote adequate blood flow through the HeRO, it is recommended that the patient maintain a systolic blood pressure of > 100 mm Hg and an ejection fraction of > 20%.⁵ Blood pressure trends should be evaluated post placement and the use of antihypertensive drugs reviewed. Testing for hypercoagulability is indicated if suspected and should be treated with anticoagulants as needed. As with any peripheral access, avoid the use of fistula clamps after needle removal to prevent prolonged pressure on the graft. Thrombectomy is relatively quick and uncomplicated should it be necessary. Specific guidelines for using this device are available.¹¹

The "Three Rights to HeRO Graft Success"¹⁰

1. The Right Patient
 - Bilateral central venous pathology
 - Adequate cardiac function
 - Infection-free
2. The Right Surgeon
 - Endovascular skills (or partnered with an interventionalist)
 - Committed and experienced
3. The Right Management by the Interdisciplinary Team
 - Assessment and cannulation as per KDOQI Guidelines for Prevention of access thrombosis and infection

Figure 2: Examples of Potential HeRO Graft Placement¹¹



Right Arm Placement

Left Arm Placement