

Safety and efficacy of a modified HeRO dialysis device in achieving early graft cannulation: A single-institution experience

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ABSTRACT

Hemodialysis Reliable Outflow (HeRO) grafts (Merit Medical Systems, Inc, South Jordan, Utah) provide a means for access in catheter-dependent hemodialysis patients but typically require several weeks for tissue incorporation. Modifying the HeRO graft with an ACUSEAL graft (W. L. Gore & Associates, Newark, Del) can allow immediate cannulation, thus reducing catheter dependence time and its associated complications. A retrospective review of patients at our institution from 2013 to 2016 who underwent placement of a modified HeRO dialysis system with ACUSEAL graft was performed. Complications and outcomes were analyzed, with patency rates and hours to successful cannulation being major end points. Modified HeRO grafts were successfully placed in 10 catheter-dependent patients. Postoperative complications included two thromboses and one hematoma. At 6 months of follow-up, mean time to graft cannulation was 33.7 hours, with 100% success; the primary and secondary patency rates were 70% and 90%, respectively. Our modification allows an accelerated use of the HeRO system, reducing catheter dependence time with acceptable postoperative complications and patency rates. (*J Vasc Surg Cases and Innovative Techniques* 2017;3:175-9.)

Arteriovenous fistulas placed in the upper extremities are usually the first choice for arteriovenous access in chronic hemodialysis patients.¹ With improved survival rates, patients often outlive their vascular accesses and frequently exhaust all means of upper extremity access. These patients are often left with a tunneled dialysis catheter (TDC) for their hemodialysis needs; however, its use is associated with increased risk for central venous stenosis and occlusion.^{2,3} When this occurs, the upper extremity access sites must be abandoned, leaving these patients with less preferred options, such as arteriovenous grafts or TDCs in the lower extremities.

In 2008, the Food and Drug Administration approved the Hemodialysis Reliable Outflow (HeRO) Graft (Merit Medical Systems, Inc, South Jordan, Utah), which provides an alternative to upper extremity arteriovenous access for these complex patients with central venous

occlusion or stenosis. A drawback of the HeRO dialysis graft is the need for an interim TDC because the graft requires several weeks of tissue incorporation before attempted cannulation, leading to increased TDC dependence time and its associated complications. At our institution, the HeRO device is altered by using the early-access GORE ACUSEAL Vascular Graft (W. L. Gore & Associates, Newark, Del) for the arterial component, which allows immediate cannulation and reduces catheter dependence times.

We performed a retrospective review of our institution's data on HeRO devices that were modified using an ACUSEAL graft to gain initial information on patency, cannulation success, and complications. We hypothesized that this alteration of the HeRO device is both safe and efficacious in allowing early cannulation with minimal complications.

METHODS

This is a retrospective, single-institution review of patients who underwent modified HeRO graft placements between January 2013 and April 2016. The patients eligible for the modification were identified by having multiple failed accesses and concurrent central venous occlusive disease. We collected patient demographics, clinical background, perioperative parameters, and complications and outcomes data. Categorical variables were presented using frequencies and percentages; continuous variables were described using means, standard deviations, and percentiles of interest (ie, median and range or interquartile range). Primary and secondary patency rates as well as hours to successful cannulation were analyzed. All HeRO patients

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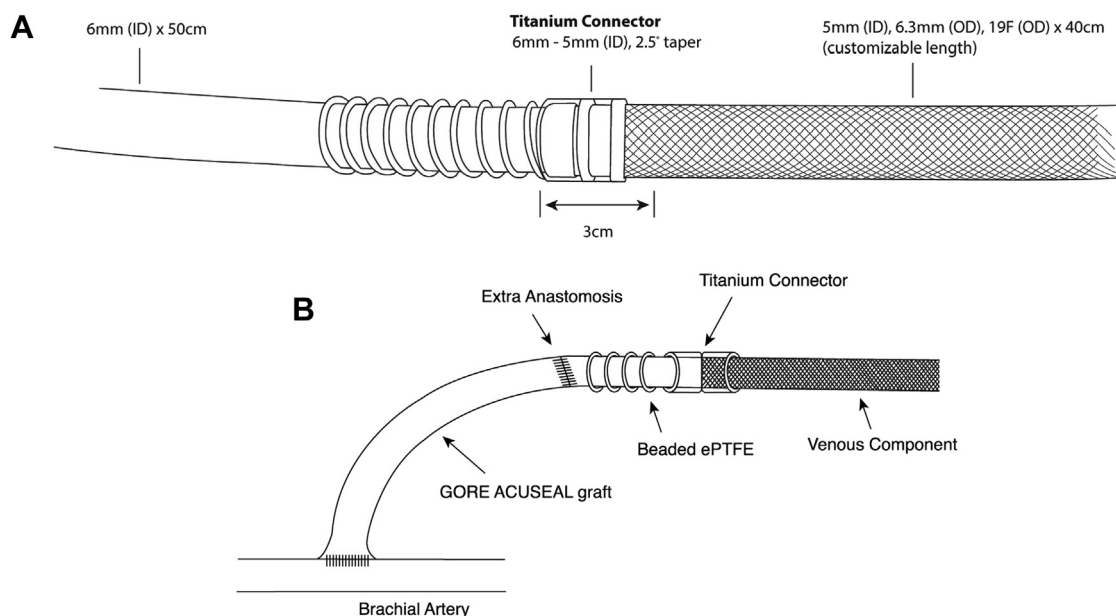


Fig. HeRO graft. **A**, Venous and arterial components. **B**, Alteration of the HeRO graft's arterial component using an ACUSEAL graft, demonstrating the extra anastomosis site. ePTFE, Expanded polytetrafluoroethylene; ID, inner diameter; OD, outer diameter.

underwent bilateral upper extremity arterial and venous duplex ultrasound examinations as well as venography to evaluate disease extent and to choose the appropriate upper extremity for graft placement. All patients already had TDCs for dialysis. Intraoperatively, a guidewire was placed through the TDC, after which the TDC was removed. The guidewire allowed the venous outflow component of the graft to be placed through a stenosed segment. Balloon angioplasty of the tract was performed and the venous outflow was placed at the level of the cavoatrial junction, which was confirmed by venography.

The HeRO graft consists of two elements: the venous outflow component, made of a braided, nitinol-reinforced, radiopaque, silicone catheter with a 5-mm internal diameter; and the arterial inflow component, which has a 6-mm internal diameter expanded polytetrafluoroethylene (ePTFE) hemodialysis graft with PTFE beading proximal to the titanium connector (Fig. A). Beading refers to the process of superheating ePTFE to assemble it into rings.

The venous outflow component is placed through the stenotic or occluded internal jugular or subclavian vein to the plane of the cavoatrial junction. The distal end of the venous component is tunneled to the deltopectoral groove and connected to the titanium connector. With nonmodified HeRO grafts, the arterial ePTFE component is sewn in standard fashion to the ipsilateral brachial artery distally and connected proximally with the titanium connector.

At our institution, we considerably shorten the maturation period by replacing the lateral end of the ePTFE beaded segment with the ACUSEAL graft in an

end-to-end fashion with either a 6-0 or 5-0 Prolene suture. This graft is a 6-mm or tapered 4- to 7-mm trilayer, low-bleeding graft that includes an elastomeric middle membrane between inner and outer layers of ePTFE to allow immediate access.

The extra anastomosis and the graft are then tunneled to the targeted artery and sutured as a side-to-end anastomosis (Fig. B). Although this alteration creates an extra anastomotic site, it also allows removal of TDCs.

Informed consent was not required for this retrospective chart review as the Institutional Review Board approved the waiver of consent and experimental protocol for this study.

RESULTS

Ten patients underwent successful placement of altered HeRO devices for early access during the 3-year period. No standard HeRO dialysis grafts were placed during this time. Most of the patients had hypertension, hyperlipidemia, and anemia; the main causes of end-stage renal disease were hypertension, lupus, and nephrotic syndromes (Table I). Bilateral innominate vein and subclavian vein occlusions were seen in nearly all of the patients (Table I). Two patients had bilateral arterial disease and bilateral central and internal jugular venous occlusions that required placement of the HeRO venous component in the inferior vena cava.

All 10 patients received hemodialysis through previously placed catheters at the time of the surgery. The central catheter locations and internal diameters of the ACUSEAL graft are demonstrated in Table II. Tapered 4- to 7-mm grafts became available later in the study

Table I. Patient variables and occlusive disease

Patient variables		Extent of occlusive disease	
Demographics		Location of venous occlusions	
Age, years, mean	46.8	Superior vena cava	3 (30)
Male	6 (60)	Right innominate	8 (80)
Female	4 (40)	Left innominate	7 (70)
African American	10 (100)	Right internal jugular	2 (20)
Body mass index	26.5	Left internal jugular	0 (0)
Comorbidities		Right subclavian	7 (70)
Hypertension	10 (100)	Left subclavian	8 (80)
Hyperlipidemia	8 (80)	External iliac	2 (20)
Diabetes	1 (10)		
Obesity	3 (30)		
Coronary artery disease	2 (20)		
Anemia	9 (90)		
Pulmonary disease	0 (0)		
Smoking	3 (30)		

Categorical variables are presented as number (%).

Table II. Central venous locations, laterality, and diameters

Location, No. (%)	Laterality, No.		Graft internal diameter, No. (%)	
	Right	Left	6 mm	Tapered 7 mm
Internal jugular, 7 (70)	4	3	4 (40)	3 (30)
Inferior vena cava, 2 (20)	2	0	1 (10)	1 (10)
Subclavian vein, 1 (10)	1	0	1 (10)	0

period and were used solely after their availability. Of the two inferior vena cava catheters, one was placed through a translumbar approach and the other through a transhepatic approach with the femoral artery providing inflow. All HeRO grafts were successfully placed at the cavoatrial junction on the first attempt and confirmed by venography, but one required immediate postoperative repositioning. The exact length of the ACUSEAL graft used varied per case, depending on patient specifics as well as anatomy. Arterial inflow was accessed through the brachial artery for 80% of the implants; the remainder were lower extremity accesses gained from the femoral artery. Time to attempted cannulation ranged from 24 to 49 hours, with a mean of 33.7 hours. Successful early cannulation (defined as <72 hours) was achieved in all modified HeRO grafts.

All patients received dual antiplatelet or a combination of antiplatelet and anticoagulation medications postoperatively that were continued throughout follow-up. Three patients were started on dual antiplatelet therapy with aspirin and clopidogrel, which is the standard postoperative algorithm for our institution. Warfarin and apixaban were used in 40% and 30% of patients, respectively, because of either a previous history of

anticoagulation or required additional therapy to antiplatelet medications.

Postoperative complications within a 30-day period developed in 20% of the patients; these included thrombosis and hematoma requiring reinterventions to maintain patency and functionality (Table III). Despite the postoperative complications, all HeRO grafts remained functioning within the 30-day time frame. Complications outside the postoperative period included infection, pseudoaneurysm, and thromboses (Table III). The majority (80%) of thromboses at 6 months and 1 year of follow-up were attributable to two patients; one had a hypercoagulable disorder and the other had repeated hypotensive episodes. Reintervention rates at 6 months and 1 year of follow-up correlate with the number of thromboses in these two patients.

Mean clinical follow-up after implantation was 15.6 months (standard deviation, ±10.3 months). The primary and secondary patency rates were 70% and 90%, respectively, at 6 months and 50% and 70% at 12 months of follow-up. Reintervention rates per HeRO graft to maintain patency were 1.6 and 2.3 at 6 and 12 months, respectively.

Table III. Postimplantation complications

Type of complication	Immediate	At 6 months	At 1 year
Thrombosis (n = 32)	4	13	15
Hematoma (n = 5)	1	2	2
Infection (n = 2)	0	1	1
Steal syndrome (n = 0)		0	0
Pseudoaneurysm (n = 1)		0	1

Table IV. Patency and reintervention rates

Reference	Reintervention rate per year	6-Month patency rates, %		12-Month patency rates, %	
		Primary	Secondary	Primary	Secondary
Gage ⁶	1.5	60.0	90.8	48.8	90.8
Nassar ¹⁰	2.2	47.0	76.7	34.8	67.6
Wallace ⁹	3.0	39.0	60.0	11.0	32.0
Our study	2.2	70.0	90.0	50.0	70.0

DISCUSSION

The alteration of the HeRO device with an early-access ACUSEAL graft was meant to decrease the use of TDCs and catheter dependence time while preserving the integrity, adequacy, and patency of the HeRO devices. No other immediate cannulation grafts were used in this study. We chose ACUSEAL over Flixene (Atrium Medical, Hudson, NH) because of the surgeon's preference and institutional availability. Vectra (Bard, Murray Hill, NJ) is no longer used at our institution as well. A prospective multicenter clinical trial using ACUSEAL demonstrated cannulation success as early as postoperative day 1 as well as patency and complication rates comparable to those of standard ePTFE.⁴

Overall, early cannulation was demonstrated in all patients without difficulty, thus reducing catheter dependence time. Postoperative complications (Table III) were amenable to reinterventions and resulted in no graft abandonments. Although the ACUSEAL graft literature has included reports of increased dialysis access steal syndrome compared with the standard ePTFE graft, our results did not demonstrate evidence of steal syndrome in these patients.⁴ An explanation may be that the HeRO dialysis system is a long device with an increased overall length of circuit, which is more likely to increase resistance and to limit flow, making it less prone to steal. One patient had thrombosis on postoperative day 1, which required open thrombectomy; we believe an intimal disruption on the posterior wall of the brachial artery created a thrombogenic environment. In addition, the venous component of the HeRO graft had traveled upward out of the cavoatrial junction. Under fluoroscopic guidance, it was repositioned at the level of the junction. This patient had

repeated thrombosis on postoperative day 14, and patency was re-established by percutaneous means. One hematoma and two remaining thromboses occurred in a patient on postoperative days 3, 11, and 19, respectively. The hematoma resolved with expectant management, and percutaneous thrombectomies were performed to maintain patency.

Complications and reintervention rates demonstrated in our study are equivalent to those of previous studies but were limited to two patients, one of whom had repeated hypotensive episodes; the other had a hypercoagulable disorder.⁵ The patient with repeated thromboses had an extensive history of hypotensive episodes and noncompliance with both midodrine, taken for postdialysis hypotension, and warfarin, for anticoagulation. The other patient with a high frequency of thromboses had an underlying hypercoagulable disorder. This patient had multiple failed previous arteriovenous accesses because of thrombosis without any clear source. Further hematologic laboratory testing confirmed a hypercoagulable trait of antiphospholipid syndrome requiring anticoagulation. After proper anticoagulation with warfarin, the frequency of thromboses was reduced significantly.

The pseudoaneurysm that developed on postoperative day 364 was caused by repeated large-bore needle puncture at the same location during dialysis (Table III) and was not related to the graft modification. The graft was repaired with a 6-mm ACUSEAL interposition. One HeRO-related primary infection occurred on postoperative day 53 that required complete graft excision at an outside hospital.

Although the literature is limited, most recent studies demonstrate improved patency rates (comparable to those of arteriovenous grafts), increased dialysis

adequacy, and decreased infection rates with HeRO catheters compared with TDCs.⁶⁻⁸ Three current studies that involved nonmodified HeRO grafts reported 6-month and 12-month primary and secondary patency rates^{6,9,10} (Table IV). Our 6-month primary and secondary patency rates are comparable to those reported by Gage et al and Nassar et al. Our primary and secondary patency rates at 12 months are also comparable to the rates at 12 months displayed in Table IV. However, our secondary patency rate at 12 months was notably lower than the 90.8% reported by Gage et al. Reintervention rates, as mentioned before, were also proportionate to the studies displayed in Table IV. By comparing the results in Table IV with the three studies involving original HeRO grafts, we can conclude that our modification of the HeRO graft does not compromise the original design or patency rates.

We believe that dual antiplatelet therapy with clopidogrel is paramount for extended patency in our modified HeRO grafts. Antiplatelet therapy with clopidogrel was shown to increase long-term patency and to reduce device thrombosis in the study of Gage et al, which is why our institution's standard algorithm includes dual antiplatelet therapy with aspirin and clopidogrel.

This study poses several limitations, including its retrospective nature, small size, lack of controls, and reporting bias, especially as the follow-up information was obtained by contacting the nearby dialysis centers. Despite these limitations, our results add further knowledge to the current HeRO literature.

CONCLUSIONS

HeRO graft placement can provide a means of access in these patients who otherwise would remain catheter dependent. Our institution's method of using an ACUSEAL graft for immediate cannulation allows an accelerated use of this system, reducing catheter dependence time. With successful immediate cannulation, few postoperative complications, and comparable patency

rates, our method for modification is a safe and efficacious method to enable early graft cannulation.

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