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Multi-center Experience of 164 Consecutive Hemodialysis Reliable Outflow [HeRO] Graft Implants for Hemodialysis Treatment☆

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WHAT THIS PAPER ADDS

- We present a novel vascular access device which allows for successful hemodialysis despite the presence of central venous stenosis and/or occlusion. Currently, there is no other device on the market like the Hemodialysis Reliable Outflow (HeRO) graft. There have been various descriptions of this device in the literature, but this manuscript offers the largest review to date on its performance in terms of patency, interventions, and infection; which is then compared to the arteriovenous graft and tunneled dialysis catheter literature. Additionally, this review elucidates the longest multi-patient follow up on the HeRO graft to date.

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ABSTRACT

Objective: To report a multi-center experience with the novel Hemodialysis Reliable Outflow (HeRO) vascular access graft.
Materials and methods: Four centers conducted a retrospective review of end stage renal disease patients who received the HeRO device from implant to last available follow-up. Data is available on 164 patients with an accumulated 2092.1 HeRO implant months.
Results: At 6 months, HeRO primary and secondary patency is 60% and 90.8%, respectively and at 12 months, 48.8% and 90.8%, respectively. At 24 months, HeRO had a primary patency of 42.9% and secondary patency was 86.7%. Interventions to maintain or re-establish patency have been required in 71.3% of patients (117/164) resulting in an intervention rate of 1.5/year. Access related infections have been reported in 4.3% patients resulting in a rate of 0.14/1000 implant days.
Conclusions: In our experience the HeRO device has performed comparably to standard AVGs and has proven superior to TDCs in terms of patency, intervention, and infection rates when compared to the peer-reviewed literature. As an alternative to catheter dependence as a means for hemodialysis access, this graft could reduce the morbidity and mortality associated with TDCs and have a profound impact on the costs associated with catheter related infections and interventions.

Introduction

Establishing and maintaining vascular access remains a constant challenge for those that care for patients with end stage renal disease (ESRD). As our patients enjoy longer lives secondary to advances in medicine, access maintenance is becoming even more demanding. Adequate venous outflow is essential in creating a well-functioning arteriovenous (AV) access, and as outflow

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options progress centrally the daunting task of access establishment becomes much more problematic and technically challenging. Eventually, adequate venous outflow options progress too far centrally for placement of traditional AV access, or cease completely secondary to central venous stenosis and/or occlusion. When this occurs, traditional access algorithms suggest lower extremity AV access or condemnation to tunneled dialysis catheters (TDCs); both of which significantly increase the patient's risk of developing a serious blood stream infection.[2,3] In extreme cases, exceedingly morbid and complex procedures have been described that require median sternotomy or thoracotomy in order to establish venous outflow via a right atrial anastomosis or require insertion of destination trans lumbar or hepatic catheters.[4,5]

Tunneled dialysis catheter related complications, such as blood stream infection and catheter malfunction, subject ESRD patients to a higher likelihood of morbidity and mortality as well as more frequent hospitalizations. Danese et al. estimated that TDC infection-associated mortality can be as high as 34%.[6] Furthermore, the current TDC rate in the United States is estimated to be 27%.[7] In addition to this stressor to the health system and drain on resources, these complications translate to healthcare expenditures of an estimated one billion dollars annually.[8]

A novel device has been developed to meet the challenging anatomic demands of such patients with the intent to liberate this population from their catheter dependence. The Hemodialysis Reliable Outflow (HeRO) vascular access device (Hemosphere, Inc., Minneapolis, MN) was made commercially available in the United States in May 2008 after the FDA approved the device for use in catheter dependent patients with central venous stenosis and/or occlusion. The purpose of this study was to further evaluate the overall performance and outcomes of the HeRO device on a larger scale in the post-market approval phase, while also comparing its performance to that of TDCs and conventional arteriovenous grafts (AVGs) based on existing literature with respect to patency, bacteremia, and intervention rates.

Materials and Methods

Study design

A retrospective review of 164 consecutive patients receiving the HeRO device was conducted at four institutions (Duke University Medical Center, Bamberg County Hospital, University of Miami and Baylor Health Systems) between May 2008 and February 2011. Data was collected from time of implant to last available follow-up. Analysis was performed on the following data points: demographics, medical co-morbidities, procedure-related adverse events, access-related adverse events, bacteremia rates, HeRO patency, and intervention rates. Patency and bacteremia data was assessed at 6, 12, and 24 months. This study was approved by the Institutional Review Board at each participating site and a waiver of consent was granted due to its retrospective nature and de-identification of data.

Device description

The HeRO graft is an implantable, completely subcutaneous, hybrid "graft-catheter" vascular access device approved for catheter-dependent patients with limited venous outflow. More specifically, the HeRO graft is reserved for those patients whose venous outflow options have progressed too far centrally (proximal to the axillary vein) to implant standard upper extremity access, those who have developed central vein stenosis resistant to angioplasty and/or stenting, or patients with central vein occlusion. In those patients with complete central vein occlusion, HeRO grafts could only be implanted if their occlusions were successfully crossed or if they had occluded around a previously placed TDC. This device can bypass central venous stenosis and/or occlusion by traversing the lesion endovascularly and positioning the tip of the outflow component at the cavo-atrial junction or any available large outflow target vein (Fig. 1). This device consists of two components: a conventional ePTFE graft component and a silicone venous outflow component connected via titanium coupler. The graft component is a standard 6 mm internal diameter (ID) ePTFE vascular conduit. The outflow component is an endolumenal, large bore, single lumen, nitinol braid-reinforced, silicone tube with an ID of 5 mm and OD of 19 Fr (6.3 mm), which does not require a venous anastomosis (Fig. 2). The graft component requires 2–4 weeks of tissue incorporation, the same as is required by standard ePTFE AVGs, to allow for safe cannulation for hemodialysis. The HeRO graft is accessed for hemodialysis in the same manner as conventional AVGs.

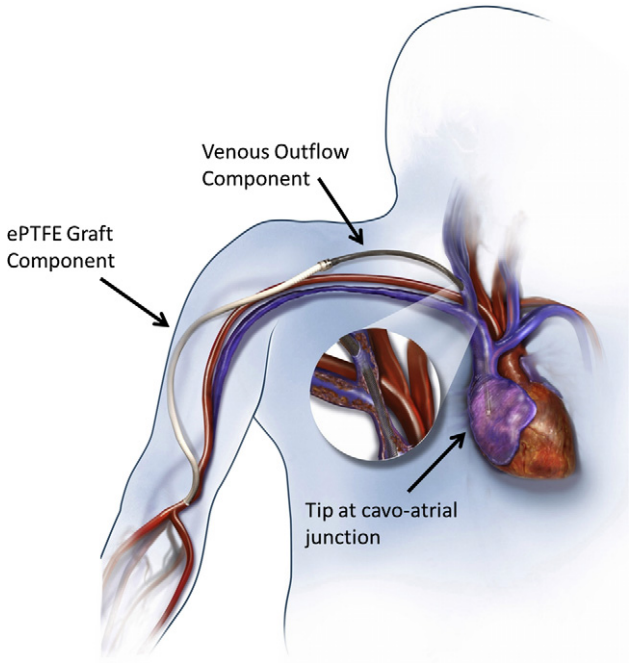

Figure 1. Illustration of HeRO components inserted via right IJV with brachial artery inflow. (Courtesy of Hemosphere, Inc.).

Surgical implant procedure

Prior to implantation, all patients underwent a complete history and physical exam. Adequate arterial inflow was assessed and declared by physical exam. Each patient required upper extremity

Figure 2. Outflow component and ePTFE graft coupled (top), and uncoupled (bottom) with titanium coupler visible. (Courtesy of Hemosphere, Inc.).

and central phlebography to assure a thorough evaluation of the central venous system and to confirm the requisite of this device. Only patients with moderate to severe central venous stenosis and/or occlusion received the HeRO device. All HeRO grafts were implanted in the operating room in a hybrid fashion utilizing a combination of both open surgical and endovascular techniques. General endotracheal tube anesthesia was required for all HeRO implants given the need to tunnel across the chest wall and shoulder. The silicone outflow component is first inserted into the internal jugular, subclavian, or femoral vein via Seldinger technique or via catheter (TDC or other central venous catheter) exchange. Central venous angiography is used to confirm proper placement of the outflow component tip at the cavo-atrial junction. Once venous access is established, the distal end of the outflow component is tunneled from the venous insertion site to a counter incision at the delto-pectoral groove. Arterial exposure commences and inflow is established from the artery or inflow conduit of choice. The ePTFE graft component is tunneled subcutaneously from the counter incision at the delto-pectoral groove to the arterial exposure, over the biceps muscle, in a superficial soft C-curve or large teardrop loop (tight C) configuration to provide a maximal segment for cannulation. The two components are then coupled at the counter incision using the titanium connector. A standard arterial anastomosis is performed at the target artery to provide inflow for the HeRO (Fig. 3). Please note that this is a general guideline for straightforward, upper extremity implants. Depending on the

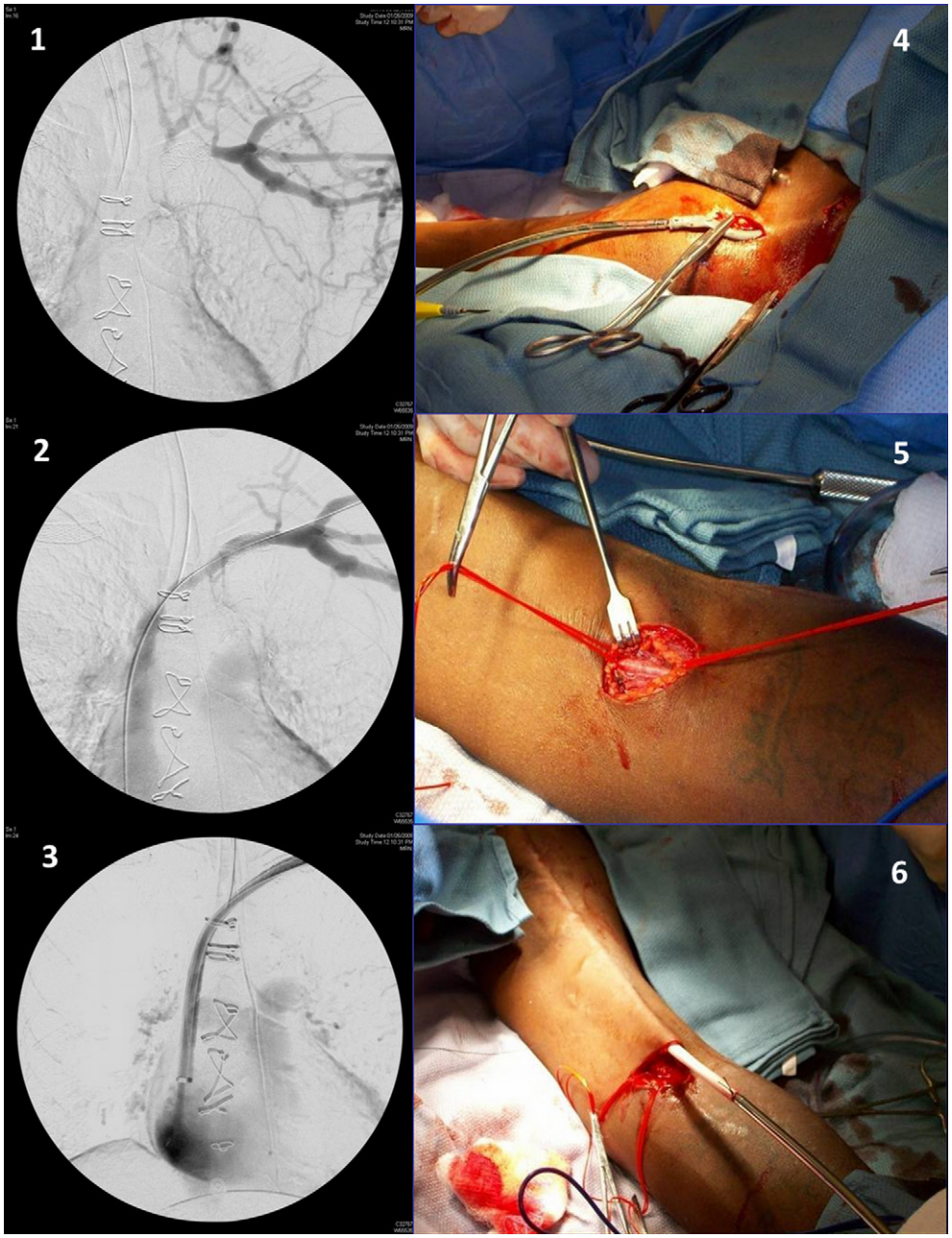

Figure 3. HeRO implant procedure. Left subclavian vein in-stent occlusion (1). Crossed left subclavian vein lesion (2). Outflow component at cavo-atrial junction (3). Outflow component tunneled to delto-pectoral groove (4). Brachial artery exposure (5). ePTFE graft tunneled to brachial artery exposure (images courtesy of Shawn M. Gage and photos courtesy of Hemosphere, Inc.).

complexity of the patient, anatomical differences, or location of the body, these steps can be performed in a diverse order and the components can be connected in varying locations of the body.

Definitions

Bacteremia literature control

We used Katzman's et al. meta-analysis of 15, prospective, randomized controlled trials on cuffed, internal jugular vein TDCs as our bacteremia literature control rate (2.3/1000 catheter days).[9] Bacteremia rates for AVGs were calculated by Murad whose meta-analysis reported on 83 studies, and the calculated infection rate was 14.9%.[10] Our access related infection (ARI) data will be compared to the bacteremia data.

Patency and intervention literature control

Again, Katzman et al. conducted a meta-analysis of six retrospective and prospective TDC studies to generate the patency and intervention literature controls out to 6 and 12 months.[9] Primary-assisted patency was not calculated in this study because only one patient required an intervention to maintain primary patency. The meta-analysis generated an overall catheter intervention rate of 5.8 per year and primary patency at 6 and 12 months of 50% and 36%, respectively. The AVG primary patency literature control rates at 6 and 12 months of 58% and 42% respectively, and secondary patency at 6 and 12 months of 76% and 65% respectively, were based on a published meta-analysis of 34 studies.[11]

Access related infection

Access Related Infection was defined as at least one positive blood culture following HeRO implant with at least one or more clinical manifestations such as, fever, hypotension, peri-graft cellulitis, or frank graft infection requiring systemic treatment and/or HeRO graft explantation. This differs from the Katzman study in that their 'bacteremia' data only took into account blood stream infection and not specifically whether or not the HeRO graft was the culprit based on local signs and symptoms. Also, unlike the Katzman article, bacteremia events were not classified into separate cohorts such as the "bridging period" or "HeRO alone period". The ARI data in this review takes into account all-comers from HeRO implant date to explant, ligation, patient death, or last available follow up. The ARI data was analyzed as a rate per 1000 days.

Patency

Primary patency is defined as time from implant to first loss of HeRO patency. Secondary patency is defined as implant time through restoration of patency following graft thrombosis, until ultimate graft failure and abandonment.

HeRO days

HeRO days were defined as accumulated days from HeRO implant to earliest of explant, ligation, or death, and last follow-up visit. For purposes of measuring the primary end point bacteremia rate, this is comparable to the term "catheter days," meaning days with an indwelling catheter as commonly referred to in the catheter literature.

Statistical analysis

Continuous data were summarized using descriptive statistics (i.e. mean, standard deviation, minimum, maximum). Categorical data were summarized with counts and percentages. The intervention rate was calculated as the total number of interventions reported, divided by total HeRO years. The ARI rate was calculated as the total number of ARIs reported, divided by total HeRO days, and then multiplied by 1000 to obtain the rate per 1000 days. Exact Poisson 95% confidence intervals (CI) were calculated for the intervention and ARI rates. Kaplan–Meier estimates and their corresponding 95% CIs were used to summarize primary and secondary patency at 6, 12, and 24 months post implant. Kaplan–Meier curves for freedom from loss of primary and secondary patency were also created.

Table 1
HeRO recipient demographics.

Demographic	% (*n*/*N*)
Age[a]	55.9 ± 14.3 (162) [21–88]
Male	48.8% (79/162)
Race	
Black/African American	78.3% (126/161)
White/Caucasian	13.0% (21/161)
Hispanic	8.7% (14/161)
Diabetic	46.3% (76/161)
Mean follow-up (months)[a]	12.8 ± 9.1 (164) [0.07–32.9]
Deaths	17.7% (29/164)

[a] Mean ± SD (N), [Range].

Results

Demographics and implant specifics

A total of 164 patients underwent successful HeRO implantation across 4 medical centers, resulting in an accumulation of 2092.1 HeRO months. Follow up ranged from 0.07 to 32.9 months with a mean of 12.8. Mean age was 55.9 with a range of 21–88 years. The distribution of gender was nearly equal with females predominating slightly at 51.2%. The vast majority of patients (78.3%) were of African American descent which is consistent with the renal failure patient demographic in our region (Southeast US). During the period of follow up, 29 patients (17%) expired (Table 1). The number of HeROs placed was nearly equal bilaterally with 51.8% being placed on the right. The vast majority of HeROs (59.7%) were inserted via the internal jugular vein (IJV), although, multiple anatomical sites were utilized in addition, including the subclavian, common femoral, and axillary veins (Table 2).

Access related infection results

ARI data was available from only 3 sites $N = 140$, which translates to 1927.1 HeRO months follow up. Data was recorded from implant to last available follow up. Overall, 8 ARIs occurred in 6

Table 2
HeRO implant specifics.

Anatomical location	% (*n*)
Insertion side:	$N = 139$[a]
Right	51.8% (72)
Left	48.2% (67)
Insertion vein:	$N = 139$[a]
Internal jugular	59.7% (83)
Subclavian	23.7% (33)
Common femoral	6.5% (9)
Axillary	5.0% (7)
External jugular	2.9% (4)
Other	2.2% (3)

[a] Data only available from 3 sites.

Table 3
HeRO patency by site.

Site	Primary patency[a] KM estimate [95% CI]	Secondary patency[b] KM estimate [95% CI]
Bamberg:		
6 Month	51.0% [34.9–65.1]	80.1% [65.1–89.8]
12 Month	40.8% [25.7–55.4]	80.1% [65.1–89.8]
24 Month	34.9% [20.5–49.8]	80.1% [65.1–89.8]
Baylor:		
6 Month	53.3% [31.7–70.9]	87.0% [64.8–95.6]
12 Month	47.4% [25.8–66.3]	87.0% [64.8–95.6]
24 Month	47.4% [25.8–66.3]	87.0% [64.8–95.6]
Duke:		
6 Month	62.0% [47.6–73.4]	98.1% [87.6–99.7]
12 Month	45.1% [29.9–59.2]	98.1% [87.6–99.7]
24 Month	38.7% [21.8–55.3]	85.5% [60.1–93.8]
Miami:		
6 Month	72.7% [54.1–84.8]	93.9%[77.9–98.4]
12 Month	67.9% [47.9–81.6]	93.9%[77.9–98.4]
24 Month	62.7% [41.6–77.9]	93.9%[77.9–98.4]

[a] No difference across sites in primary patency rates; Log-rank p-value = 0.135.
[b] No difference across site in secondary patency rates; Log-rank p-value = 0.251.

patients (4.3%) resulting in a rate of 0.14/1000 implant days, which was considerably lower than the TDC bacteremia literature control rate of 2.3/1000 catheter days (95% CI: 0.06, 0.27) and the AVG bacteremia control rate of 14.9%.[9,10]

Patency and intervention

At 6 months HeRO primary patency was 60% and secondary patency was 90.8%. HeRO primary and secondary patency at 12 months was 48.8% and 90.8%, respectively. And at 24 months, HeRO had a primary patency of 42.9% and secondary patency was 86.7%. There was no significant difference in terms of patency across the 4 centers (Table 3). Overall, 257 interventions to maintain or re-establish patency occurred during 174.4 total patient years resulting in a HeRO intervention rate of 1.5/year (Table 4 and Figs. 4 and 5). For those patients in which secondary patency could not be regained, another attempt at an upper body HeRO of the contralateral limb was first investigated. If no suitable options in the upper body were apparent, a lower limb AVG was considered as the next option. And finally, if no suitable options for a lower limb AVG were possible, the patient was then relegated to a destination TDC via the femoral, transl umbar, or transhepatic approach.

Discussion

Since its approval in 2008 the HeRO graft has shown great promise as a durable vascular access device. Technically, the implant procedure has become very feasible and follows suit in the emerging world of hybrid vascular surgery. This approach to establishing and maintaining vascular access has become absolutely necessary in order to expand the number of total body vascular access sites when the requisite for venous outflow is paramount. Currently there is no other device on the market that accomplishes what the HeRO can in terms of maintaining central venous outflow. Central venous angioplasty and stenting has been the treatment of choice for stenotic or pre-occlusive lesions to date, but multiple reports note that this therapy has poor durability in general; prone to rapid, recurrent re-stenosis and/or acute occlusion, which has proven consistent with our observation as well.[12,13] Catheter dependent patients with occlusion of the central veins have largely been abandoned for upper body access. A few small case reports describe a direct bypass or arteriovenous shunt to the right atrium or central vein reconstruction to circumvent this dilemma. Unfortunately, these operations require thoracotomy or sternotomy which places the patient at significant intraoperative risk and exposes them to increased post-operative morbidity.[4,5]

Clinical experience with the HeRO device is growing. In a 75 patient post-market study of the HeRO device focusing on procedural outcomes, an implant success rate of 100% was reported in an access-challenged patient population.[14] In September 2009, Katzman et al reported results of the FDA clinical trial of the HeRO device in catheter-dependent patients. In this 36 patient evaluation, at a mean 8.6 months follow up, primary patency was 38.9% and secondary patency was 72.2%. Patency results were found to be similar in a single center review of 41 consecutive implants reported by Gage et al. in May of 2010.[15] In that review, primary and secondary patency at 6 months was 68.3% and 87.8%, respectively. In this current review, we have observed the longest multi-patient

Table 4
HeRO patency, intervention, and infection data.

Variable	% [95% CI]
HeRO Patency[a]	
Primary at 6 months	60.0% [51.7, 67.3]
Secondary at 6 months	90.8% [84.9, 94.4]
Primary at 12 months	48.8% [39.9, 57.0]
Secondary at 12 months	90.8% [84.9, 94.4]
Primary at 24 months	42.9% [33.3,52.0]
Secondary at 24 months	86.7% [78.9,91.8]
HeRO intervention rate[b]	1.5/year [1.30, 1.67]
Access-related infections[c,d]	4.3% (6/140)

[a] Kaplan-Meier estimates with corresponding 95% CI.
[b] Rate per patient-year of follow-up; 257 events in 174.4 total patient years.
[c] % (n/N).
[d] Data only available from 3 sites.

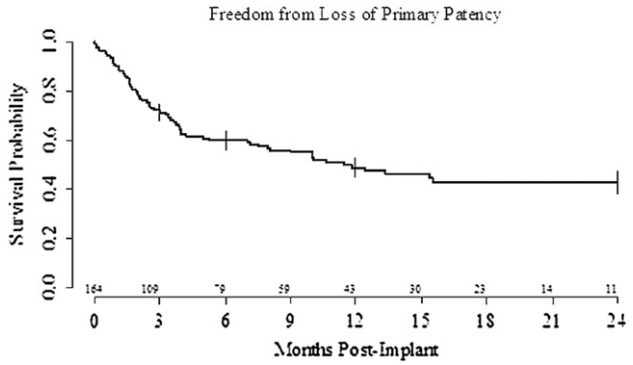

Figure 4. Kaplan–Meier curve illustrating primary patency. Standard error bars at 3, 6, 9, 12, and 24 months.

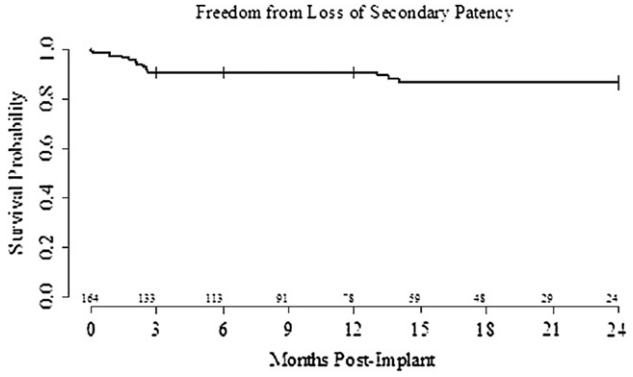

Figure 5. Kaplan–Meier curve illustrating secondary patency. Standard error bars at 3, 6, 9, 12, and 24 months.

Table 5
Patency comparison of published HeRO data, AVG literature, and TDC literature.

Study	Current HeRO multicenter		Gage et al. review May 2010[15,a]	Katzman et al. study Sept. 2009[9]	AVG literature[11]		TDC literature[9]	
Months	6 mo	12 mo	6 mo	8.6 mo	6 mo	12 mo	6 mo	12 mo
Patency								
Primary, %	60	48.8	68.3	38.9	58	42	50	36
Secondary, %	90.8	90.8	87.8	72.2	76	65	55	37

[a] 39 of the 41 patients in the Gage review are included in this current Multi-center review.

follow up on patency to date for the HeRO graft; 24 months. Again, patency results were reproducible in this study with 6 month primary and secondary rates at 60% and 90.8%, respectively, and 12 month primary and secondary rates at 48.8% and 90.8%, respectively (Table 5). Most impressively, however, are the patency rates that were observed out to 24 months. These patency rates were nearly identical to those of the 12 month data with a primary patency rate of 42.9% and secondary patency at 86.7%.

The FDA trial and Duke University single center review, both also evaluated intervention and bacteremia data. Interventions rates were 2.5 and 1.38 per year, respectively, while we observed a HeRO intervention rate of 1.5 per year in our review. This data is comparable to the standard AVG intervention rates reported in the peer review literature, but significantly better than the TDC intervention rate control of 5.8 per year (95% CI: 1.30, 1.67). All interventions performed in this review were done to maintain or re-establish HeRO graft patency. HeRO mechanical and or chemical thrombolysis was performed in an open or percutaneous fashion. HeRO thrombectomy is performed in a similar fashion as done for a standard AVG, and typically no more difficult given the lack of a venous anastomosis. Overall, the most common cause for HeRO graft thrombosis to date seems to be associated with intragraft stenosis and adherent clot as opposed to the titanium coupler connection site, which had been generally suspected to be the most likely cause.[16] Bacteremia data from the FDA trial and from Duke's single center review were similar with rates of 0.70 and 1.29 per 1000 days, respectively. However, in the current review we observed an ARI rate of 0.14 per 1000 implant days which is much lower than the previous HeRO data, but significantly lower than the TDC control data of 2.3 per 1000 catheter days (Table 6). Of those patients with an infection, five required complete explantation of the HeRO graft and 2 others only required excision and replacement of an isolated infected segment of the ePTFE graft. One subject developed an infection while the device was not in use; after it had thrombosed and was abandoned.

Only two patients (1.4%) developed clinically significant steal syndrome requiring removal of the HeRO graft. One patient required exchange of the HeRO for a TDC as that was their last viable site for access. The second patient required patch angioplasty of the brachial artery at the time of HeRO graft explantation. A common misconception is that the HeRO device has a propensity to cause steal syndrome given its lack of a venous anastomosis, and thus unopposed outflow and high output. However, in our clinical experience this has not been observed. We speculate that the low observed clinically significant steal rate is a function of the intrinsic hemodynamics of the device where both the length of the device (roughly twice the length of conventional grafts) and the diameter (5 mm ID outflow component) contribute to reduce the flow and preserve perfusion to the hand.

Table 6
Bacteremia and intervention comparison of published HeRO data, AVG literature, and TDC literature.

Study	Bacteremia rate per 1000 days	Intervention rate per year
Current HeRO Multicenter	0.14	1.5
Gage et al. Review May 2010[15]	1.29	1.38
Katzman et al. Study Sept. 2009[9]	0.7	2.5
AVG Literature Control[9]	NA[a]	1.6–2.4
TDC Literature Control[9]	2.3	5.8

[a] Information not available.

There were no intraoperative deaths but four were reported within the immediate 2 week postoperative period. One patient died of suspected right heart overload 1 week post HeRO implant and another died of a massive CVA at 2 weeks. The third patient died while still in the hospital 12 days post operatively secondary to a massive GI bleed. The fourth patient died of ARDS related respiratory failure ultimately as a result of a severe pulmonary effusion. This occurred secondary to the exchange of her long-term fenestrated tracheostomy (in the setting of intraoperative systemic heparinization) for the use of an alternative tracheostomy, which was thought to be more favorable for use with mechanical ventilation to provide general anesthesia. This led to a severe pulmonary effusion, and ultimately, death. None of these deaths were thought to be directly related to the surgical implantation of the HeRO device. Overall, 29 patients (17%) died during the mean follow up period of 15.4 months, attesting to the extreme morbidity of the end stage vascular access patients with central venous pathology.

In the post-market approval phase the HeRO device has performed comparably to standard AVGs as reported in the peer review literature. This retrospective evaluation of the HeRO graft in 164 patients represents the largest dataset available to-date on its performance and supports findings reported previously in a smaller ($n = 36$), prospective study of TDC-dependent patients and the Duke retrospective evaluation ($n = 41$). In our experience its performance has proven superior to tunneled dialysis catheters in terms of patency, intervention, and infection rates when compared to the peer reviewed literature.[9] Additionally, we have found the HeRO graft to perform similarly, in terms of patency, when compared to the AVG peer reviewed literature.[11] This device has shown great promise as an alternative to catheter dependence as a means for durable, permanent hemodialysis access and as a result could reduce the morbidity and mortality associated with TDCs. Furthermore, use of this device could have a positive impact on costs associated with catheter related infections and interventions. We realize the weaknesses that comparing data to historical review articles impose, nonetheless to date this serves as the best control statistics available. These preliminary results are favorable; however, data from additional prospective, randomized trials could add further clarity on the HeRO's performance and prove to make this device a permanent fixture in the vascular access algorithm.

Of the 75 patients in the Katzman review, 18 were included in this current Multi-center review.

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Conflict of Interest/Funding

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References

1 Gage SM, Lawson JH, Buttlerly DW, Ross JR, Katzman HE, Hohman SE, et al. Multi-center experience of 161 consecutive HeRO graft implants. In: Presented at the American Society of Nephrology. Denver, CO; November 2010.
2 National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. *Am J Kidney Dis* 2006;**48**(Suppl. 1): S1–322.
3 Nabi Z, Anwar S, Barhamein M, Al Mukdad H, El Nassri A. Catheter related infection in hemodialysis patients. *Saudi J Kidney Dis Transpl* 2009;**20**:1091–5.
4 Goodman L, Kay H, Teplick S, Mundth E. Complications of median sternotomy: computed tomographic evaluation. *Am J Roentgenol* 1983;**141**(2):225–30.
5 Duncan J, Baldwin R, Caralis J, Cooley D. Subclavian vein-to-right atrial bypass for symptomatic venous hypertension. *Ann Thorac Surg* 1991;**52**:1342–3.
6 Danese M, Griffiths R, Dylan M, Yu H, Dubois R, Nissenson A. Mortality differences among organisms causing septicemia in haemodialysis patients. *Hemodial Int* 2006;**10**:56–62.
7 Centers for Medicare & Medicaid Services (CMS); 2008. Annual report, End Stage Renal Disease Clinical Performance Measures Project. Retrieved from: http://www.esrdnetwork.org/assets/pdf/data/2008cpmannualreport.pdf.
8 Feldman H, Kobrin S, Wasserstein A. Hemodialysis vascular access morbidity. *J Am Soc Nephrol* 1996;**7**:523–35.
9 Katzman HE, McLafferty RB, Ross JR, Glickman MH, Peden EK, Lawson JH. Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients. *J Vasc Surg* 2009;**50**(3):600–7.
10 Murad MH, Elamin MB, Sidawy AN, Malaga G, Rizvi AZ, Flynn DN, et al. Autogenous versus prosthetic vascular access for hemodialysis: a systematic review and meta-analysis. *J Vasc Surg* 2008;**48**:34S–47S.
11 Huber TS, Carter JW, Carter RL, Seeger JM. Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: a systematic review. *J Vasc Surg* 2003;**38**:1005–11.
12 Bakken AM, Protack CD, Saad WE, Lee DE, Waldman DL, Davies MG. Long-term outcomes of primary angioplasty and primary stenting of central venous stenosis in hemodialysis patients. *J Vasc Surg* 2007;**45**(4):776–83.
13 Aytekin C, Boyvat F, Yağmurdur MC, Moray G, Haberal M. Endovascular stent placement in the treatment of upper extremity central venous obstruction in hemodialysis patients. *Eur J Radiol* 2004;**49**(1):81–5.
14 Katzman HE. HeRO device experience in vascular access-challenged patients. In: Poster Session Presented at 2009 Vascular Annual Meeting: Soc Vasc Surg; 2009 Jun 11–14. Denver, CO.
15 Gage SM, Peterson DA, Lawson JH. Single-center experience of 41 consecutive HeRO implants. In: Presented at VASA 12th Symposium 2010 May 12–14. Las Vegas, NV: J Vasc Access 2010; 11(Suppl. 2). p. S14.
16 Grezaffi JA, Bryant J, Lessne ML, Miller MJ, Kim CY, Gage SM, et al. Early experience with percutaneous interventions on failing HeRO arteriovenous grafts. In: Presented at the Society of Interventional Radiology. Chicago, IL; March 2011.