Multi-center experience of 161 consecutive HeRO® graft implants

Shawn M Gage PA-C, Jeffrey H Lawson MD, David W Butterly MD, Duke University Medical Center, Durham, NC; John R Ross MD, Bamberg County Hospital, Bamberg, SC; Howard E Katzman MD, University of Miami, Miami, FL; Stephen E Hohmann MD, Jason D Woolard MD, Texas Vascular Associates / Baylor Health Systems, Dallas, TX

OBJECTIVES

To report post-market multi-center experience with the novel Hemodialysis Reliable Outflow (HeRO®) Vascular Access Graft.

INTRODUCTION

The HeRO graft (Hemosphere, Inc., Minneapolis, MN), is a hybrid long-term implantable subcutaneous AV access approved by the FDA for patients with central venous stenosis and/or occlusion rendering them otherwise catheter dependent for hemodialysis access (Figure 1). These patients are unsuitable candidates for conventional fistulas or grafts, which require normal venous outflow.

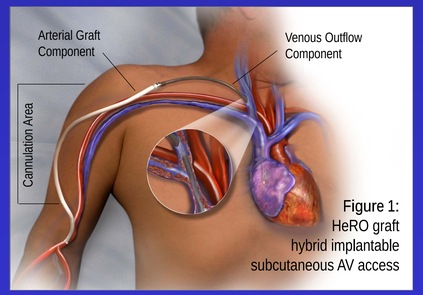


Figure 1: HeRO graft hybrid implantable subcutaneous AV access

[1]Katzman H, *et al.* Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients. *J Vasc Surg* 2009;50: 600-607
[2]Huber T, *et al.* Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: a systematic review. *J Vasc Surg* 2003;38: 1005-1011

Device Description: The device consists of two components: a standard 6 mm inner diameter (ID) expanded ePTFE graft and a 5 mm ID nitinol-reinforced silicone single lumen outflow component. During implant, percutaneous venous access is established via the internal jugular, subclavian, or femoral vein and the outflow component is inserted to traverse the central venous lesion. The distal tip of the outflow component is then advanced to the level of the cavo-atrial junction. Finally, the ePTFE graft component is anastomosed to the donor artery, tunneled subcutaneously, and attached via a titanium connector to the outflow component.

CannulationTechnique: Similar to that of a conventional graft, the HeRO requires 3-4 weeks of tissue incorporation prior to being accessed for dialysis. Most patients will require a bridging tunneled dialysis catheter during the tissue incorporation phase. The HeRO graft is cannulated in the same manner as a conventional graft. A light tourniquet may be helpful as HeRO does not have a venous anastomosis (Figure 2).

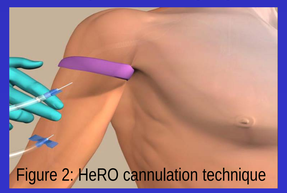


Figure 2: HeRO cannulation technique

METHODS

Four centers conducted a retrospective review of 161 consecutive post-market HeRO patients from implant to last available follow-up. The focus of this evaluation was on HeRO patency, intervention rates, and access-related bacteremia.

DEMOGRAPHICS

At the time of HeRO implant, the mean age of patients was 56.2, and mean time on dialysis was 5.7 years. To-date, a total of 1839.7 HeRO months of follow-up have accumulated in the present study (11.4 mean months) – see Tables 1 and 2.

Table 1: Demographics & Medical History

Age[1]	56.2 ± 14.2 (159) [21-88]
Male[2]	48.4% (77/159)
Years on dialysis[1]	5.7 ± 3.4 (39) [1-15]
Diabetic[2]	45.3% (73/161)
Race[2]	
Black/African American	77.9% (123/158)
White/Caucasian	13.3% (21/158)
Hispanic	8.9% (14/158)

[1]Mean ± SD (N), [Range]
[2]% (n/N)
Note: 2/60 patients from Duke participated in the pre-market FDA clinical study

RESULTS

At 6 months, HeRO primary patency was 59.8% and secondary patency was 89.5%. At 12 months, HeRO primary patency was 46.3% and secondary patency was 88.3% - see Table 2 and Figure 3.

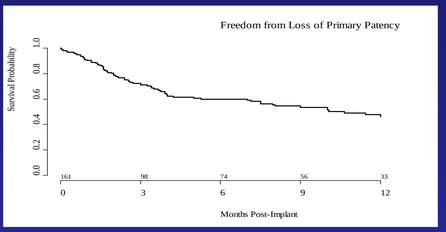
The yearly intervention rate was 1.70/year. Access-related infection data was available from three centers (n=137; HeRO months of follow-up =1674.7). Access-related infections were reported in 5.1% of patients, resulting in a bacteremia rate of 0.18/1,000 implant days. Deaths were reported for 29 patients (18.0%).

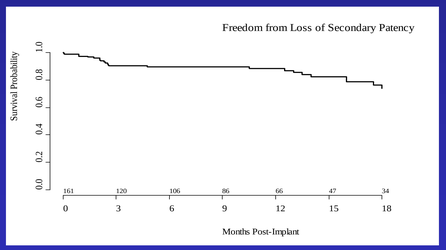
Table 2: Cumulative Results

Follow-up months[1]	11.4 ± 8.7 (161) [0.03-52.3]
Patency[2]	
Primary at 6 mos.	59.8% [51.2, 67.3]
Secondary at 6 mos.	89.5% [83.2, 93.5]
Primary at 12 mos.	46.3% [37.0, 55.1]
Secondary at 12 mos.	88.3% [81.5, 92.7]
HeRO intervention rate[3]	1.70/year
Access-related bacteremias	0.18/1000 implant days

[1]Mean ± SD (N), [Range]
[2]Kaplan-Meier estimates with corresponding 95% CI.
[3]Rate per patient-year of follow-up; 261 events in 153.3 total patient years.

Figure 3: Kaplan Meier Patency Curves





DISCUSSION

This retrospective study of the HeRO graft represents the largest dataset available to-date on HeRO performance and supports findings reported in a previous, smaller (n=36), prospective study of HeRO in catheter-dependent patients.[1] When compared to AV grafts, HeRO patency was comparable (AV graft 1° patency reported at 6 mos. 58% and 12 mos. 42% and 2° patency at 6 mos. 76% and 12 mos. 65%).[2] HeRO infection rates were lower than the rates reported for tunneled dialysis catheter literature (2.3/1,000).[1] The HeRO graft has become an excellent alternative for long-term hemodialysis access in patients previously considered catheter dependent.