Multi-center experience of 161 consecutive HeRO® graft implants

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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.

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.

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%).

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 1ª patency reported at 6 mos. 58% and 12 mos. 42% and 2ª 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.