

**HeRO[®] Device Implants at the
University of Miami –
44 Months of Experience**

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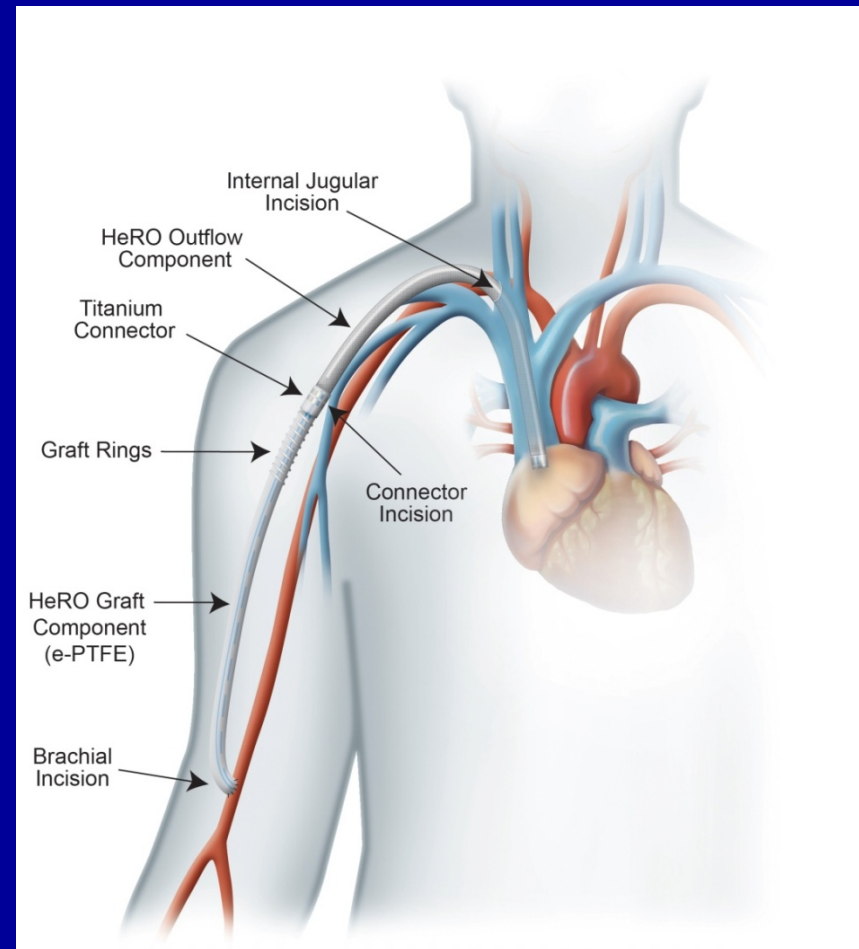
Background

- The HeRO[®] device is a new long-term subcutaneous implant for hemodialysis AV access; FDA cleared for “access-challenged” patients due to poor venous outflow
- U.S. FDA clinical study demonstrated¹:
 - 69% reduction in catheter-related bacteremia
 - Improved adequacy of dialysis and intervention rates versus long-term catheters
 - Flow rates, patency rates and maintenance comparable to grafts

¹ 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. Accepted for publication by the Journal of Vascular Surgery

HeRO Vascular Access Device

- A conventional ePTFE graft attached to a nitinol-reinforced silicone venous outflow component
- Device provides continuous arterial blood flow, bypasses central venous stenosis, and requires no graft-to-vein anastomosis
- Device accessed in same manner as conventional graft



Study Objective

- Objective: To gather single-center retrospective data on consecutive HeRO patients focusing on access history, interventions, patency and infections

Demographics & Access History

Successful implants % (n/N)	100 (33/33)
Male % (n/N)	57.6 (19/33)
Age (mean; range)	57.2 (27-88)
Prior Access History	
No. patients with previous access procedure % (n/N)	90.9 (30 ¹ /33)
Previous fistula (mean; range)	1.4 (0-5)
Previous graft (mean; range)	1.3 (0-5)
Previous catheter (mean; range)	1.9 (0-8)
¹ Two patients with unknown access history	

Patency and Interventions

HeRO Implant Location	
Right IJ placement % (n/N)	48.5 (15/33)
Left IJ placement % (n/N)	36.4 (12/33)
Femoral placement % (n/N)	18.2 (6/33)
HeRO Implantation Time (months) (mean; range)	11.2; (2 – 44)
Primary Patency at 6 Months % (n/N)	47.6 (10/21)
Secondary Patency at 6 Months % (n/N)	95.2 (20/21)
Intervention Rate (per year)	1.1

Deaths & Infections

Deaths % (n/N)	33.3 (11/33)
Diabetic complications/hypoglycemia	9.1 (1/11)
Cardiac	90.9 (10/11)
Infections % (n/N); rate/1,000 days	9.1 (3/33); 0.27

Conclusion & Discussion

- Study demonstrated:
 - High implant success rate
 - Low intervention rate compared to graft literature
 - Low bacteremia rate
 - Patency rates comparable to U.S. clinical trial and graft literature
- HeRO can reduce the number of catheter-dependent patients; thorough vessel mapping highly recommended
- HeRO ideally suited for patients who are catheter-dependent or dialyzing via a failing fistula or graft due to venous obstruction

Questions

