The HeRO Device Versus Conventional Arteriovenous Grafts In Dialysis Patients

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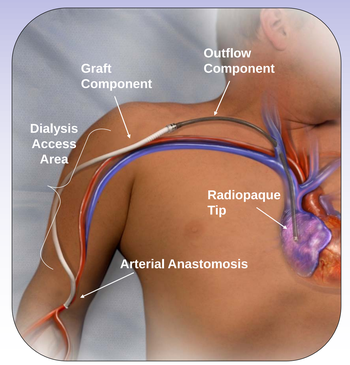
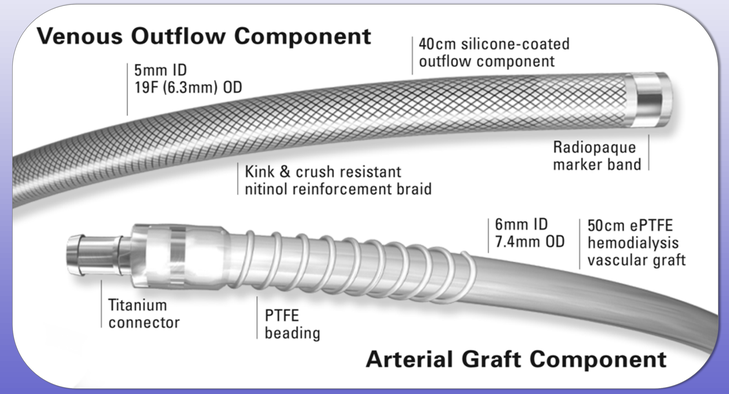
PURPOSE



Venous outflow stenosis is a major cause of dialysis graft dysfunction and access loss. The HeRO® device is a graft that flows directly into the central venous circulation, does not require a venous anastomosis, and bypasses both peripheral and central venous stenoses. Although the device is best suited for patients unable to support a fistula or conventional graft due to venous outflow stenosis, as part of a broad Food and Drug Administration evaluation, a clinical trial was conducted evaluating this technology in a graft-eligible patient population, regardless of outflow stenosis.

METHODS

This United States multi-center, randomized (2:1) clinical trial evaluated the safety and efficacy of the HeRO device compared to conventional expanded polytetrafluoroethylene grafts collecting data on patency, interventions, adequacy of dialysis, and adverse events in 70 graft-eligible patients followed for a minimum of 12 months.



RESULTS

Fifty patients received the HeRO device and 20 received a conventional graft. Patient cohorts were similar in baseline characteristics and included a large percentage of diabetics with many previous accesses. Adequacy of dialysis was comparable between the two groups. At 12 months, the HeRO device primary and secondary patency rates were 36% and 70%, respectively; the control primary and secondary patency rates were 35% and 60%, respectively. There were no statistical differences in primary or secondary patency between cohorts at 12-months. There was a statistically significant difference in median days to loss of secondary patency for HeRO at 238.0 days versus 102.5 days for the control cohort. The rate of device intervention was 2.2/year for HeRO and 1.6/year for the control cohort; these intervention rates were not statistically different. The percentage of patients experiencing a bacteremia were comparable between the two groups.

Demographics & Medical History

	HeRO[1]	Control Graft	P-value[2]
Number of patients	52	20	
Male (%)	46.2	50.0	0.798
Mean age (years)	62.9	66.1	0.352
Mean BMI	28.9	28.0	0.664
Diabetic (%)	65.4	70.0	0.786
Coronary artery disease (%)	75.0	75.0	>0.999
Hypertension (%)	94.2	95.0	>0.999
De novo access (%)	36.5	25.0	0.414
Re do access (%)	63.5	75.0	0.414
Mean number of previous accesses	3.9	4.2	0.814

[1]Includes two enrolled patients that did not receive the HeRO device
[2]Continuous measures compared using Student's t-test; dichotomous measures compared using Fisher's exact test

Adequacy of Dialysis

	HeRO	Control Graft	P-Value[1]
Mean Kt/V (±SD; range)	1.6 (±0.3; 0.9-2.3)	1.7 (±0.4; 0.9-2.6)	0.5488
Mean URR (%) (±SD; range)	72.8 (±6.0; 61.0-83.8)	72.4 (±6.3; 60.0-84.0)	0.9945
Mean blood flow rate (ml/min) (±SD; range)	1415.0 (±513.9; 538.4-3692.2)	1237.1 (±569.5; 563.8-2272.1)	0.2849

[1]P-values from Student's t-test comparing HeRO to control graft

Patency & Intervention Results

	HeRO	Control Graft	P-value
12 month patency[1] % (n/N) 95% Confidence Interval			
Assisted primary patency	84.0 (42/50) (70.9-92.8)	80.0 (16/20) (56.3-94.3)	0.732
Primary patency	36.0 (18/50) (22.9-50.8)	35.0 (7/20) (15.4-59.2)	>0.999
Secondary patency	70.0 (35/50) (55.4-82.1)	60.0 (12/20) (36.1-80.9)	0.574
Median days[2] to loss of:			
Assisted primary patency	114.0	103.5	0.938
Primary patency	118.0	114.5	0.442
Secondary patency	238.0	102.5	0.032
Intervention rates[3]	2.2/year	1.6/year	0.100

[1]P-value from Fisher's exact test comparing HeRO to control graft
[2]P-value from Kruskal Wallis test comparing HeRO to control graft
[3]P-value from Poisson regression analysis comparing HeRO to control graft

Bacteremia Data

	HeRO	Control Graft
All bacteremias % (# events/# patients)	21.2 (17/11)	20.0 (6/4)
Related bacteremias[1] % (# events/# patients)	5.8 (3/3)	5.0 (2/1)
Non-device related bacteremias[1] % (# events/# patients)	19.2 (14/10)	15.0 (5/3)

[1]As adjudicated by independent Clinical Events Committee, after reviewing medical records, case report form data, laboratory values and imaging results, made up of non-investigator nephrologist, interventional radiologist and vascular surgeon

CONCLUSION

This study demonstrates the ability of the HeRO device to provide dialysis adequacy and 12 month patency rates similar to conventional arteriovenous grafts. The HeRO device outperformed conventional grafts in median days to loss of secondary patency, possibly due to the advantageous absence of the trouble-prone venous anastomosis in the HeRO device.

The HeRO device should be considered as an access option when evaluating catheter-dependent patients as well as patients dialyzing with a failing graft or fistula due to venous outflow stenosis.

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