

Outcomes Comparison of HeRO and Lower-Extremity Arteriovenous Grafts in Patients with Long-Standing Renal Failure

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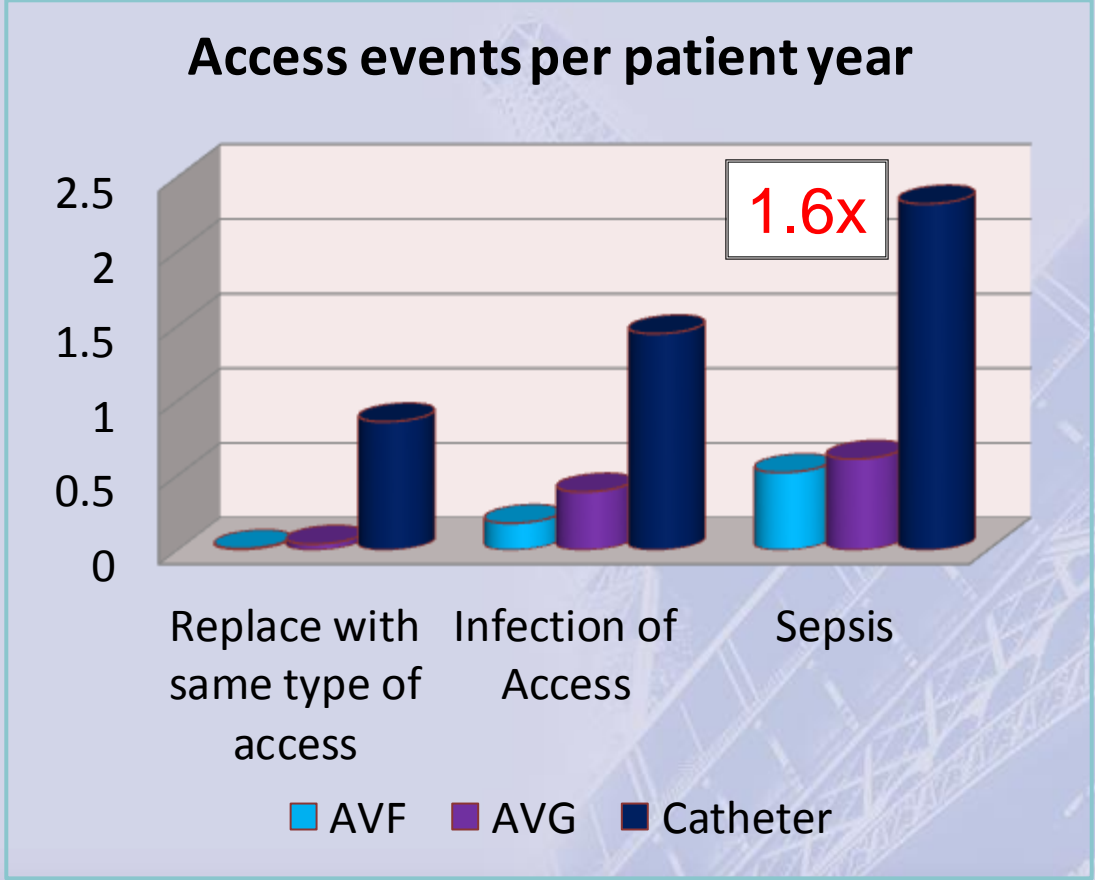
Disclosure

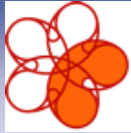
Jason K. Wagner, MD:

- I do not have any potential conflict of interest

The Catheter Problem

- >350,000 patients on HD
- 17.7% prevalence of catheters for access
- Change from Catheter to AV access shown to decrease mortality: RR:3.43 -> 1.37





- **Preferred: Fistulae**
- **Acceptable: AVG of synthetic or biological material**
 - Chest wall or “necklace” prosthetic graft or lower-extremity fistula or graft; all upper-arm sites should be exhausted
- **Avoid catheters**

The Society for Vascular Surgery: Clinical practice guidelines for the surgical placement and maintenance of arteriovenous hemodialysis access

J Vasc Surg 2008;48:2S-25S

- **Lower extremity and body wall access sites are used only after all upper extremity access sites have been exhausted (GRADE 1 recommendation, very low quality evidence).**

HeRO (Hemodialysis Reliable Outflow)

- e-PTFE graft attached to nitinol-reinforced silicone outflow component

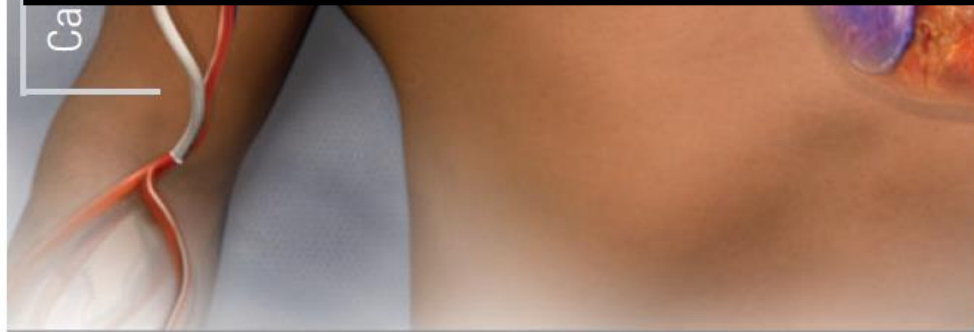
Venous Outflow Component

| 40cm silicone-coated

Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients

J Vasc Surg 2009;50:600-7.

Howard E. Katzman, MD,^a Robert B. McLafferty, MD,^b John R. Ross, MD,^c Marc H. Glickman, MD,^d Eric K. Peden, MD,^e and Jeffery H. Lawson, MD, PhD,^f *Miami, Fla; Springfield, Ill; Bamberg, SC; Norfolk, Va; Houston, Tex; and Durham, NC*



Lower Extremity Arteriovenous Grafts

Prosthetic lower extremity hemodialysis access grafts have satisfactory patency despite a high incidence of infection

J Vasc Surg 2010;52:1546-50

Irma L. Geenen, MD,^{ab} Lydia Nyilas, MD,^a Michael S. Stephen, MD,^a Virginia Makeham,^c Geoffrey H. White, MD, PhD,^a and Deborah Jean Verran, MD,^a Sydney, New South Wales, Australia; and Maastricht, The Netherlands

Prosthetic thigh arteriovenous access: Outcome with SVS/AAVS reporting standards

J Vasc Surg 2004;39:381-6

John D. Cull, David L. Cull, MD, Spence M. Taylor, MD, Christopher G. Carsten III, MD, Bruce A. Snyder, MD, Jerry R. Youkey, MD, Eugene M. Langan III, MD, and Dawn W. Blackhurst, DrPH, Greenville, SC

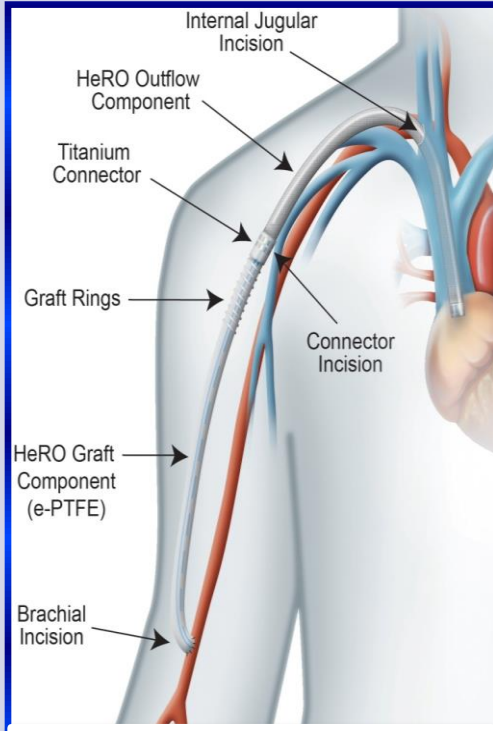
• Retrospective reviews of LEAVG

- 27-41% Infection
- 1.3% Limb Ischemia
- 1% Steal
- 1.68 Interventions per year

Table II. Patency rates

<i>Variable</i>	<i>%</i>
Primary graft failure	5.2
Primary patency	
1 year	53.9
2 years	39.6
5 years	19.3
Primary assisted patency	
1 year	53.9
2 years	39.6
5 years	19.3
Secondary patency	
1 year	75.3
2 years	63.8
5 years	50.6

Purpose of this study



HeRO

In patients with central venous obstruction:
What is the better alternative to catheter dependent dialysis?

- **Primary outcome**
 - Patency
 - Need for intervention
- **Secondary outcomes**
 - Infection
 - All-cause mortality

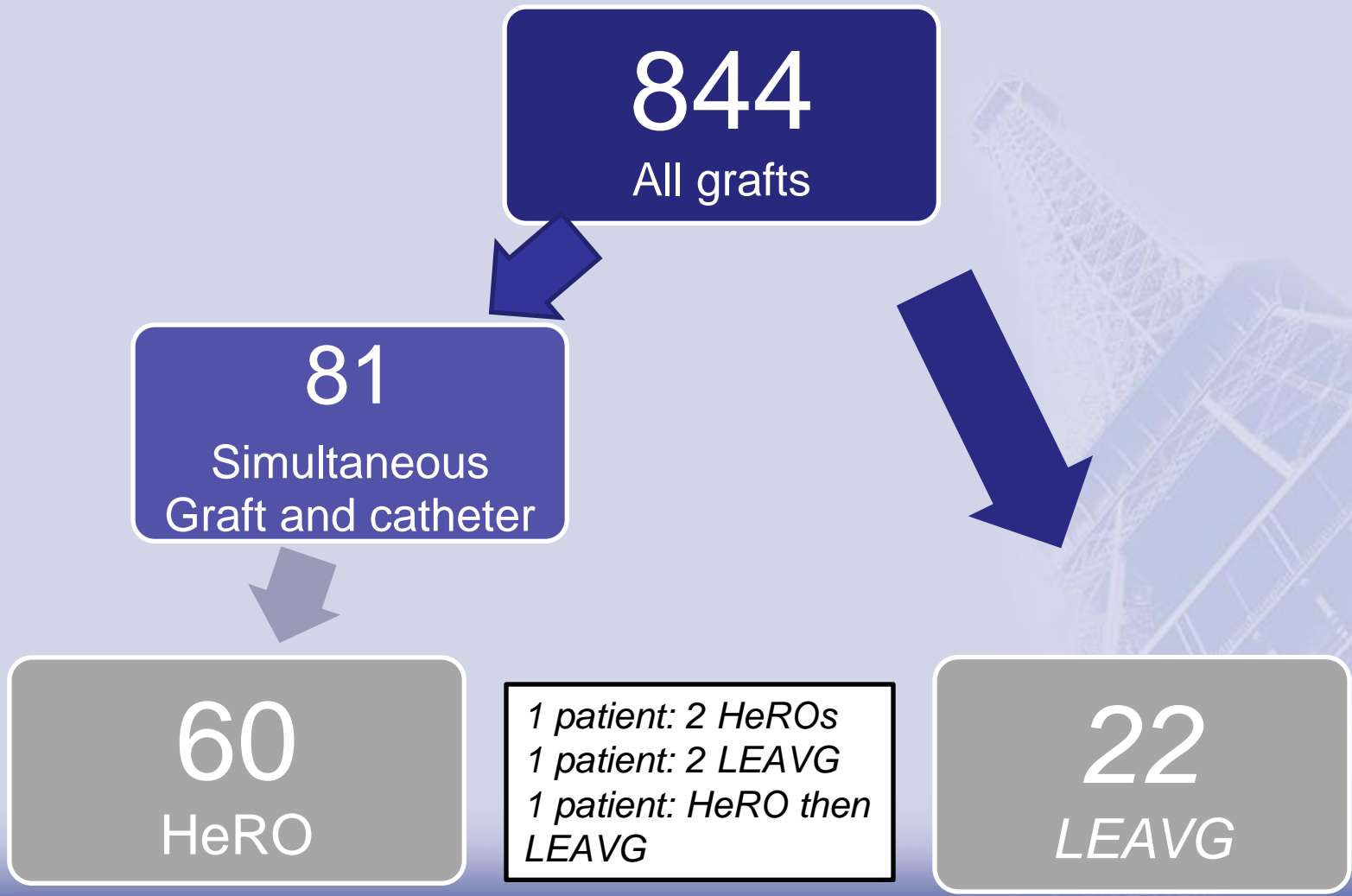


LEAVG

Methods

- Retrospective review of all HeRO device and LEAVG implantations from January 1, 2004 to August 31, 2010
- Patient identified using CPT codes
 - **LEAVG:** 36830 (nonautogenous graft insertion)
 - **HeRO:** 36830 (nonautogenous graft insertion) and 36558 (insertion of tunneled central venous catheter w/o port (>5yrs))
- IRB approval

Patient Identification



Patient Demographics

	HeRO N=59	Thigh AVG N=20	P-value*
Age	58.2 ± 14.2	53.2 ± 17.0	0.1854
Male	49.2%	30%	0.1935
Female	50.9%	70%	
Height	65.7 ± 6.0	65.4 ± 3.2	0.5452
Weight	192.7 ± 56.3	160.4 ± 24.9	0.0178
BMI	32.0 ± 10.0	26.4 ± 4.0	0.0248
Race			
African-American	88.1% (52/59)	90% (18/20)	0.1969
Caucasian	8.5% (5/59)	0% (0/20)	
Other	3.4% (2/59)	10% (2/20)	
Hx of Bacteremia	50.9% (30/59)	10% (2/20)	0.0013
Diabetes			
None	39.0% (23/59)	60% (12/20)	0.0788
Type I	44.1% (26/59)	40% (8/20)	
Type II	17.0% (10/59)	0% (0/20)	

No difference in presence of HTN, CHF, CAD, CVD, COPD, HL, tobacco use, depression or DVT

Previous HD Access

	HeRO N=59	Thigh AVG N=20	P-value
# of Prior AVG	1.8 ± 1.3 (0-5)	2.1 ± 1.3 (1-4)	0.5152
# of Prior AVF	1.3 ± 0.9 (0-4)	0.5 ± 0.5 (0-1)	0.0167
#of Prior HD Catheters	6.3 ± 5.0 (1-27)	4.1 ± 3.3 (0-11)	0.0896

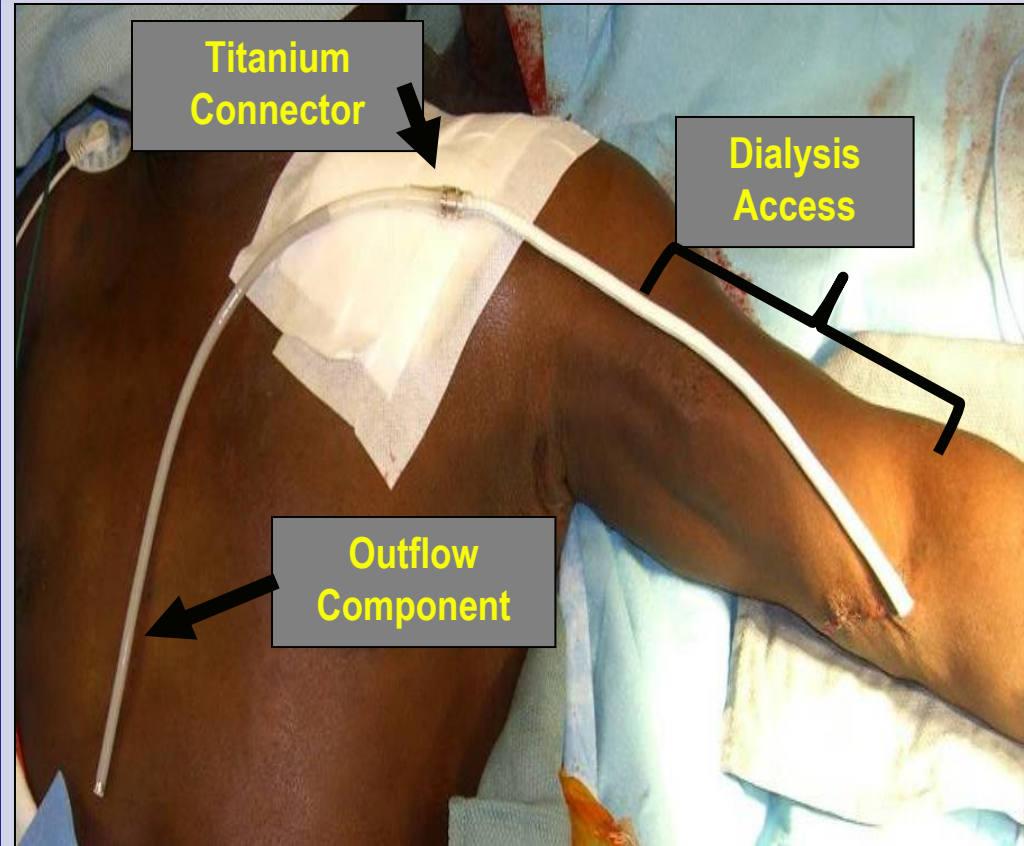
HeRO Implantation

Procedure

Standard brachial artery inflow	97%
Femoral artery loop configuration to IVC	3%

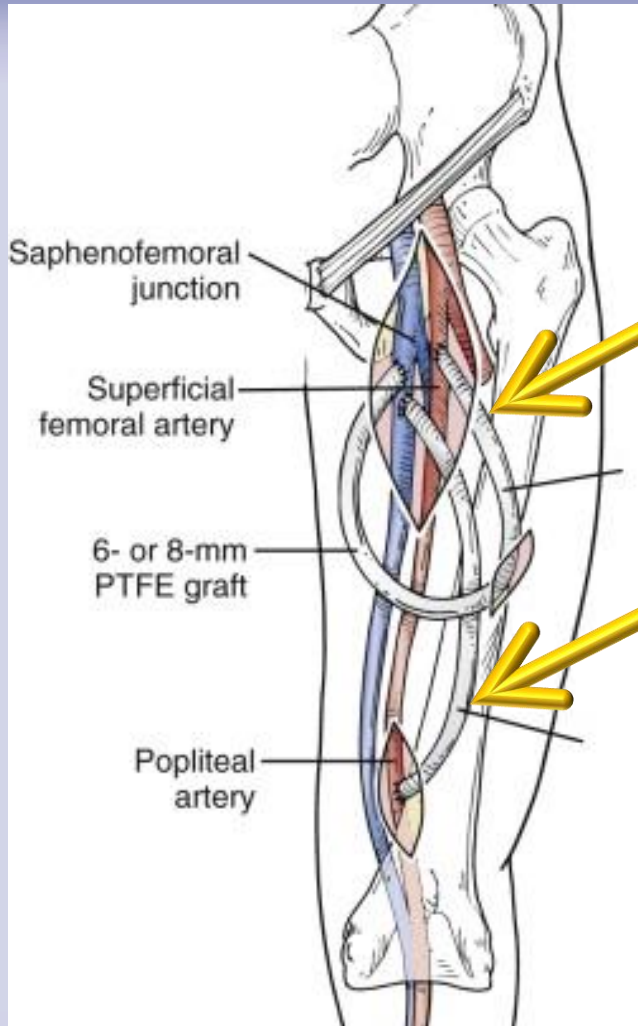
Peri-operative complications

Retroperitoneal hemorrhage	1
Brachial hematoma causing thrombosis of graft	1
Steal	1



Mean Follow-up 13.9 months

LEAVG Implantation



Rutherford 7th Ed

LEAVG

Loop Graft: Femoral artery to femoral vein	91%
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Straight graft: Popliteal artery to femoral vein	9%
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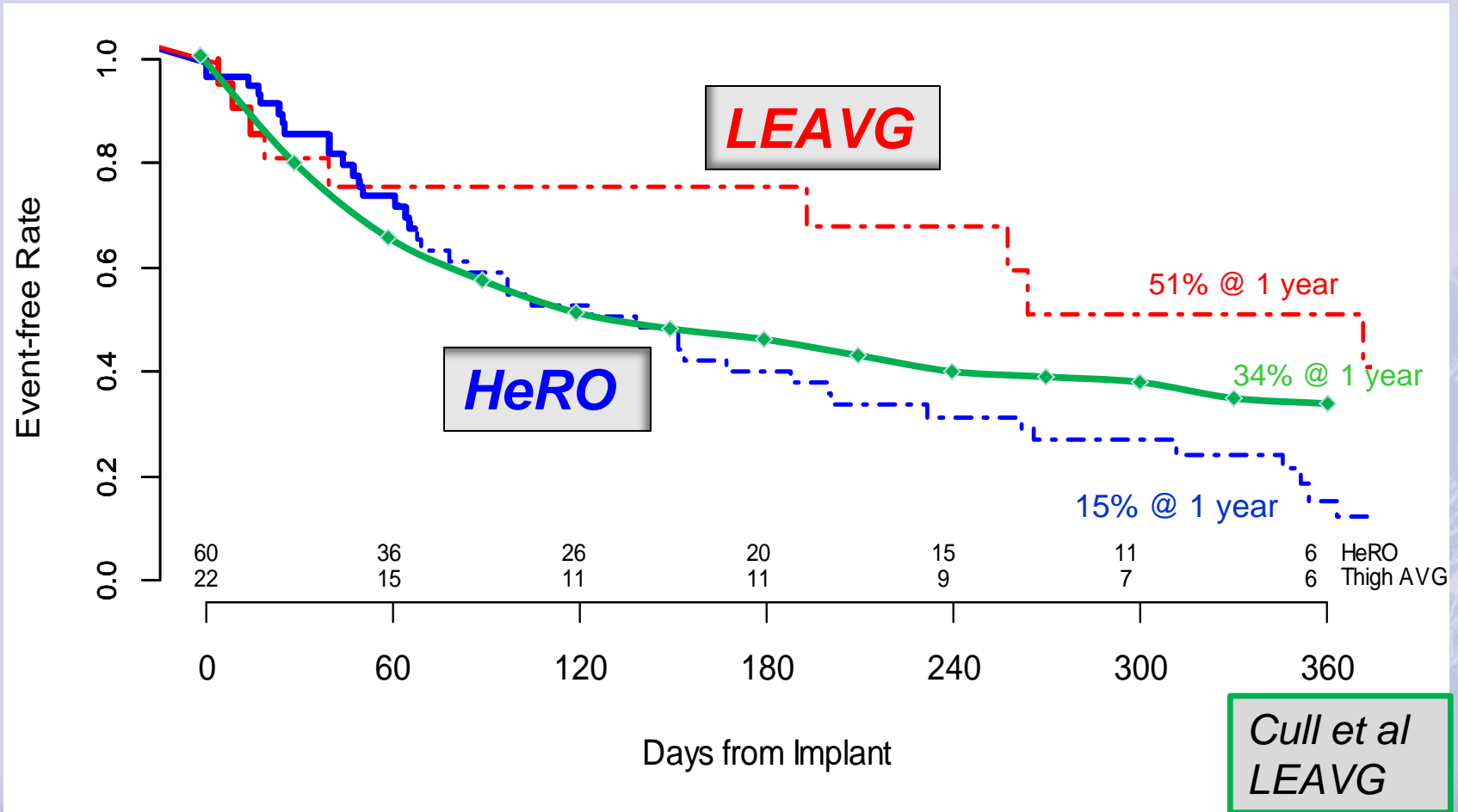
Graft Material

e-ptfe	68%
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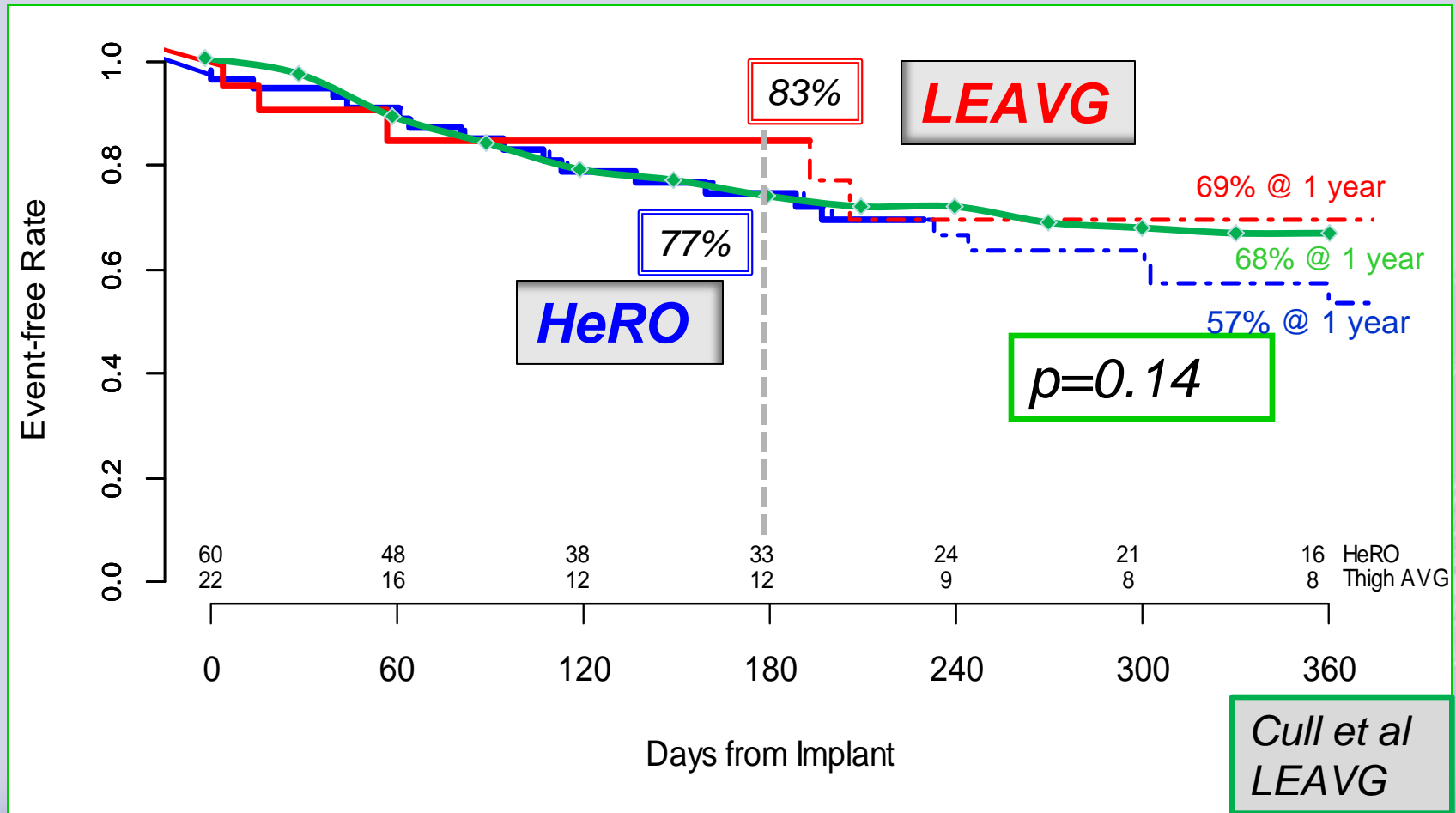
Bovine Mesenteric Vein	32%
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Mean Follow-up 11.8 months

Results: Primary Patency

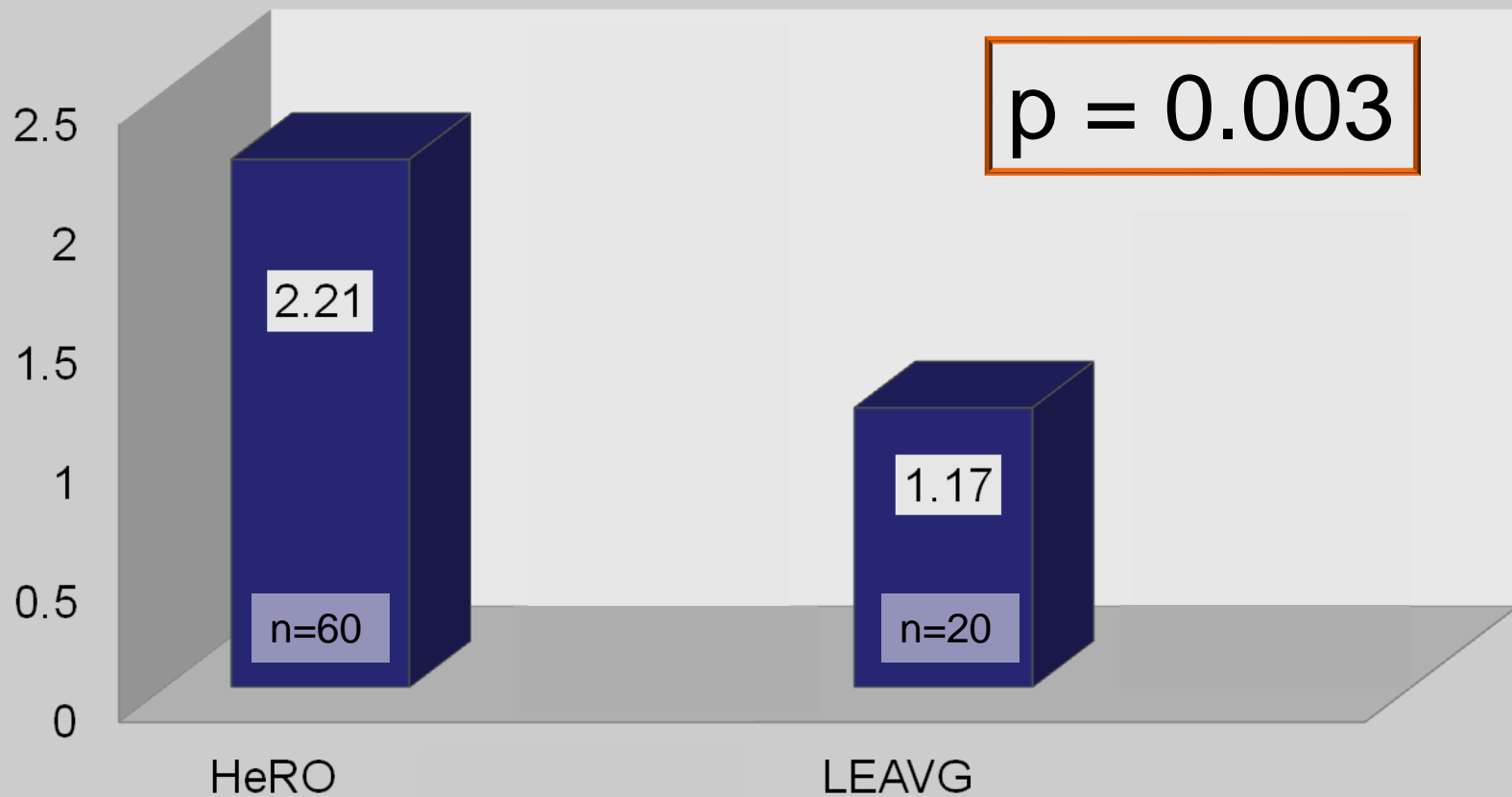


Results: Secondary Patency



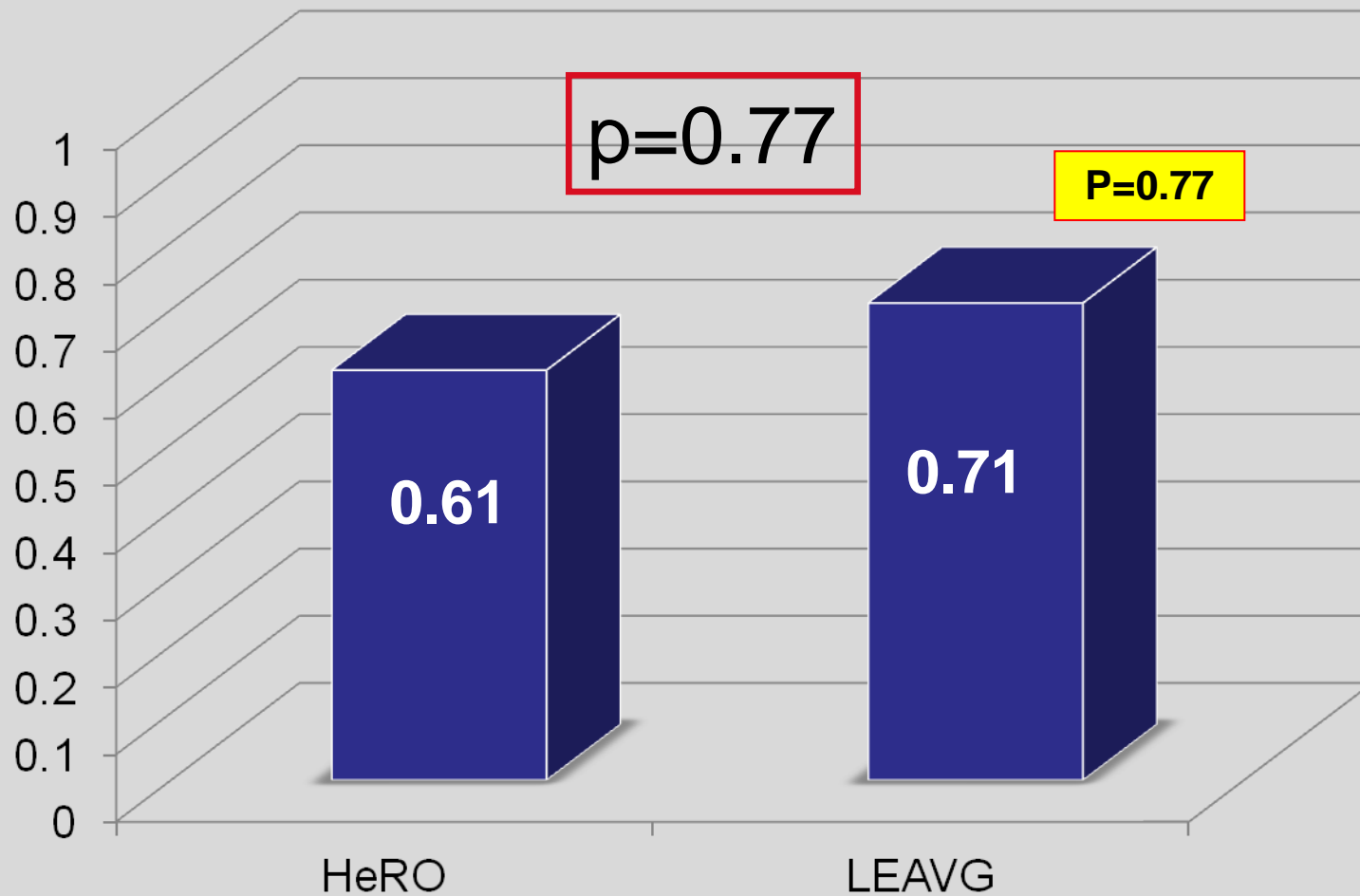
Results

Interventions per year

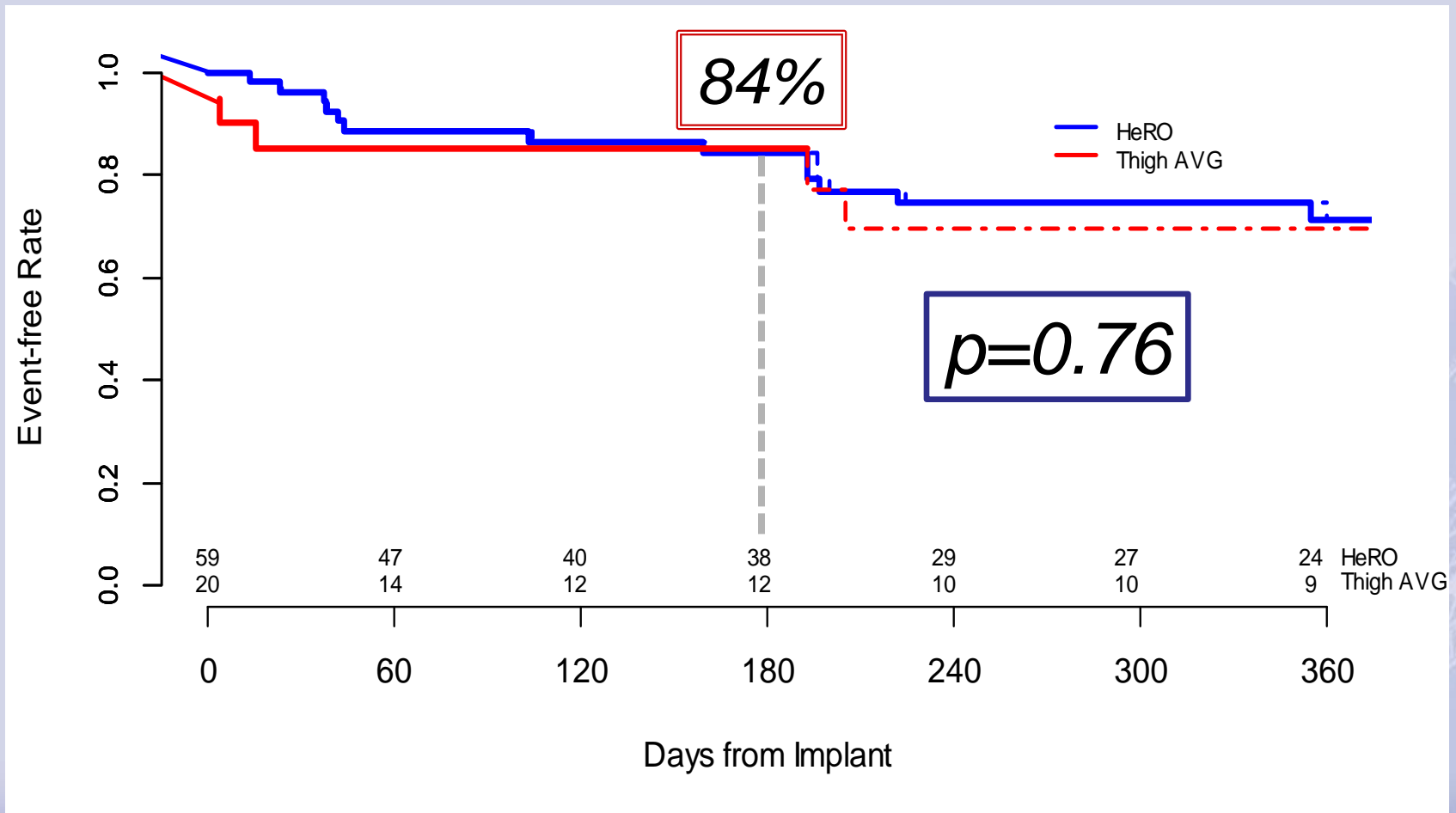


Results: Infection Rates

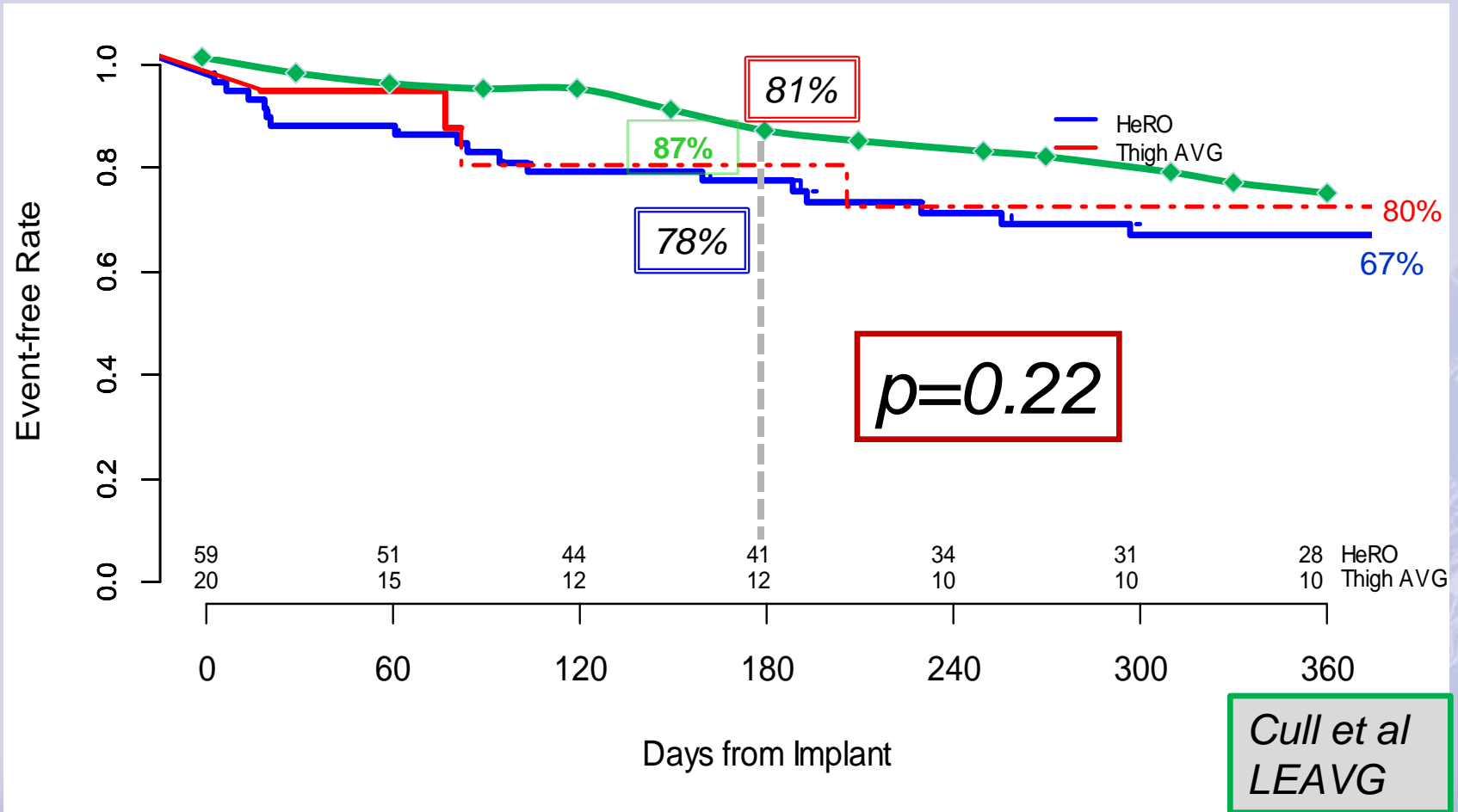
Infection Rate per 1000 days



Results: Survival Free of Device Infection



Results: All-Cause Mortality



Summary

HeRO
advantage
over LEAVG

- Maintain Upper Extremity access site with SVC venous drainage

LEAVG
advantage
over HeRO

- Reduced need for intervention

HeRO equal to
LEAVG

- Secondary Patency
- Infection Rate
- Mortality Rate