



Since the first HeRO implant in 2006, more than 70 publications and presentations capturing data from ~450 patients have been authored about the HeRO Graft. Below is an overview of key publications, abstracts, presentations and their clinical conclusions.

## MULTI-CENTER TRIALS PRE-FDA SUBMISSION

**Journal of Vascular Surgery (JVS), Sept 2009**

**Author:** Katzman, McLafferty, Ross, Glickman, Peden, Lawson

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

First peer-reviewed prospective, non-randomized FDA multi-center (7 sites) clinical trial with data for 36 patients.

- 69% reduction of bacteremia compared to catheter literature (no bacteremia after bridging period)
- Intervention rate = 2.5/year (equivalent to graft literature)
- Patency equivalent to graft literature
- Kt/V was 1.7 (above KDOQI target of 1.4)

	AVG	HeRO Graft	Catheters
<b>Bacteremia Rates</b> (Infections/1,000 days)	0.11	0.7	2.3
<b>Intervention Rates</b> (Per patient year)	1.6 – 2.4	2.5	5.8
<b>12 Month Secondary Patency Rates</b>	65%	78%	37%
<b>Adequacy of Dialysis</b> (Mean Kt/V)	1.37 – 1.62	1.7	1.29 – 1.46

Data from HeRO Bacteremia Study and IFU. On file at Hemosphere, Inc.

## MULTI-CENTER TRIALS POST-FDA CLEARANCE

**American Society of Nephrology (ASN) poster, Nov 2010**

**Author:** Gage, Lawson, Butterly, Ross, Katzman, Hohmann and Woolard

**Title:** Multi-center experience of 161 consecutive HeRO graft implants

Post-approval retrospective review with data contributed by four prestigious centers: Duke University, University of Miami, Baylor Health Systems, Bamberg County Hospital

	HeRO Graft
<b>Bacteremia Rates</b> (Infections/1,000 days)	0.18
<b>Intervention Rates</b> (Per patient year)	1.70
<b>12 Month Secondary Patency Rates</b>	88.3%

## BOOK CHAPTER

**Vascular Surgery (Northwestern Vascular Symposium), Book Chapter, Dec 2010**

**Author:** Katzman (Miami, FL)

**Title:** The HeRO Vascular Access Device from Concept to Application: Technology, Clinical Trial Data and Current Clinical Experience

	Duke University of Medicine (n = 41)	Baylor Health Care System (Dallas) (n = 21)	University of Miami (n = 33)
<b>Bacteremia Rates</b> (Infections/1,000 days)	0.42	0.50	0.27
<b>Intervention Rates</b> (Per patient year)	1.4	1.5	1.1
<b>6 Month Secondary Patency Rates</b>	88%	88%	95%

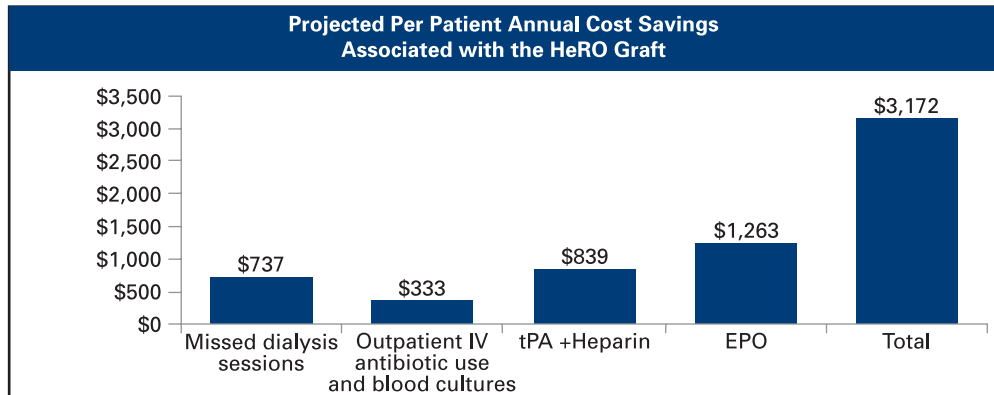
## ECONOMIC BUNDLING MODEL FOR DIALYSIS PROVIDERS

**American Society of Nephrology (ASN) poster, Nov 2010**

**Author:** Larry Yost, RPh, and Lesley Dinwiddie, MSN

**Title:** Impact of the use of the HeRO Graft vs. Tunneled Dialysis Catheters on Dialysis Provider Economics

- \$3,172 average annual savings per patient when converting a catheter-dependent patient to the HeRO graft
- \$65 million total dialysis provider savings when projected to the entire catheter-dependent population



## PUBLISHED CASE STUDIES

**Seminars in Dialysis, Mar-Apr 2010**

**Author:** George Nassar (Methodist Hospital, Houston, TX)

**Title:** Long-term performance of the hemodialysis reliable outflow (HeRO) device: the 56-month follow-up of the first clinical trial patient

- Still using HeRO for dialysis 4+ years later
- NO reported infections
- Very low intervention rate (0.6/year)
- Excellent Kt/V = 2.25