

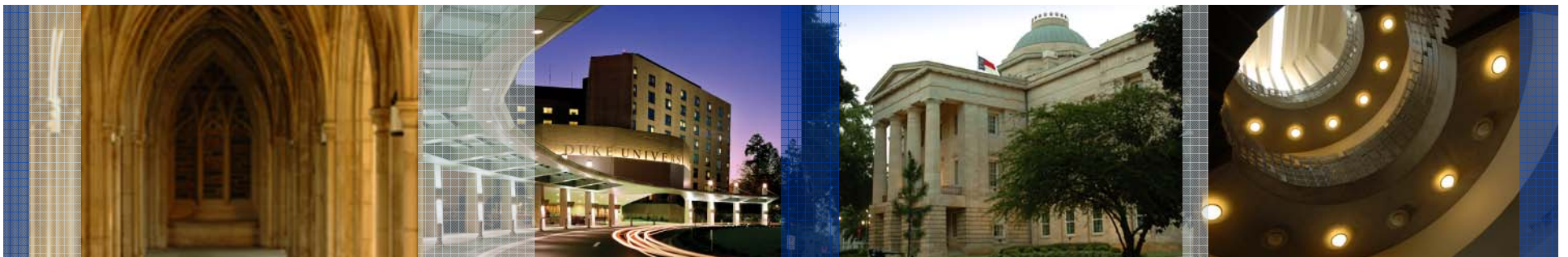
Single-Center Experience of 41 Consecutive HeRO Implants

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- Shawn M. Gage – None
- David A. Peterson – None
- Jeffrey H. Lawson – Hemosphere, Inc.
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Objectives

- Review a single center's experience with a novel hybrid vascular access device
- Compare HeRO patency and intervention rates to Multicenter HeRO trial and current standard arteriovenous graft (AVG) and tunneled dialysis catheter (TDC) patency rates
- Compare HeRO infection rates to Multicenter HeRO trial and current standard AVG and TDC infection rates
- Assess for any relevant statistical correlation to patency and infection rates



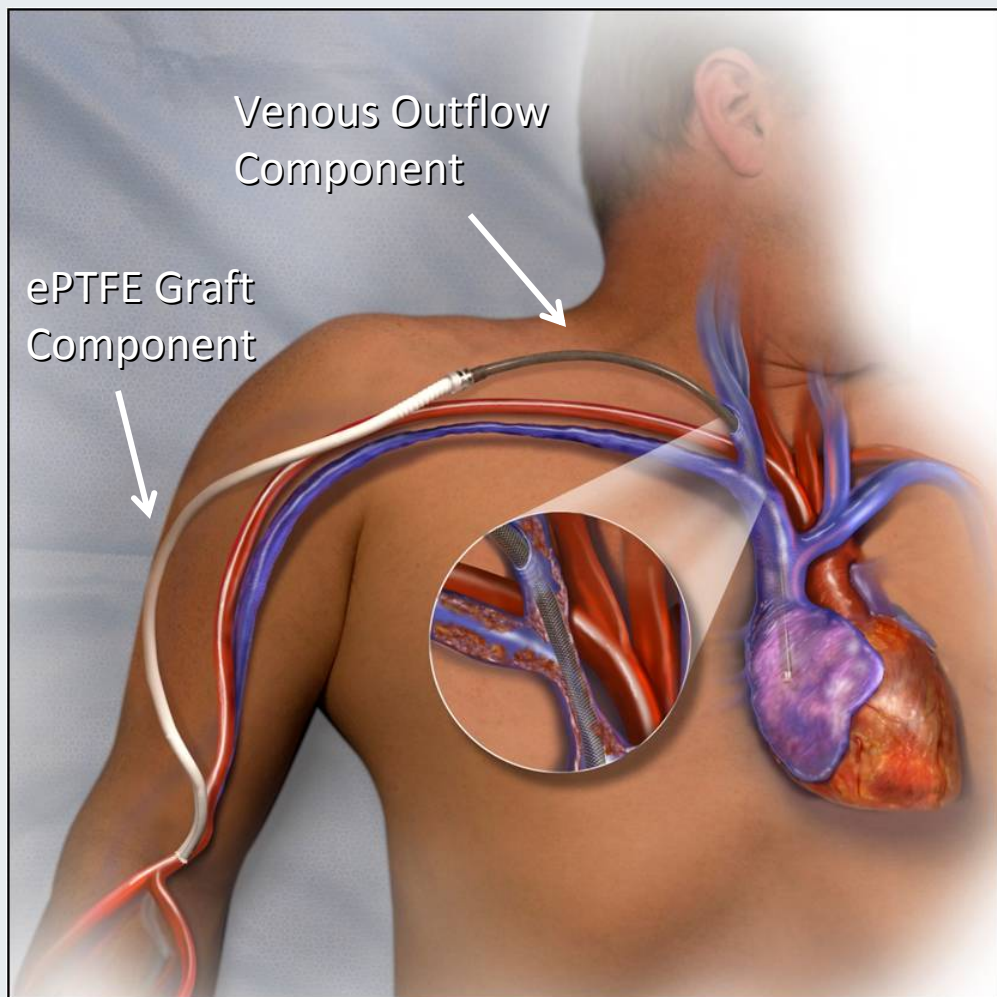
Background

- 41 consecutive HeRO implants between February 2006 and January 2010
- 13 month hiatus between 2nd & 3rd implant
- Single surgeon
- All implants technically successful
- All patients were catheter dependent



A Brief Review

- HeRO™ Hemodialysis Reliable Outflow
- Hybrid vascular access device “graft-cath”
- 2 primary components: ePTFE graft with Titanium connector 6mm ID, and radiopaque silicone outflow component with braided nitinol reinforcement 5mm ID
- Common access veins include: Subclavian and Internal Jugular
- End stage access device
- Indicated for catheter dependent patients with central venous stenosis and/or occlusion





Demographics

| <i>Metric</i> | <i>Duke</i> | <i>Multi Center Trial</i> |
|------------------------------|--------------|---------------------------|
| Successful implants, % (n/N) | 100 (41/41) | 94.7 (36/38) |
| Male, % (n/N) | 34.2 (14/41) | 50.0 (19/38) |
| Age, mean (range) | 56.0 (26-83) | 62.7 |
| Race, % (n/N) | | |
| Black/African American | 82.9 (34/41) | 36.8 (14/38) |
| White/Caucasian | 17.1 (7/41) | 50.0 (19/38) |
| Hispanic | 0.0 | 13.2 (5/38) |
| Native American | 0.0 | 0.0 |
| Asian | 0.0 | 0.0 |



Co-morbidities & Habits

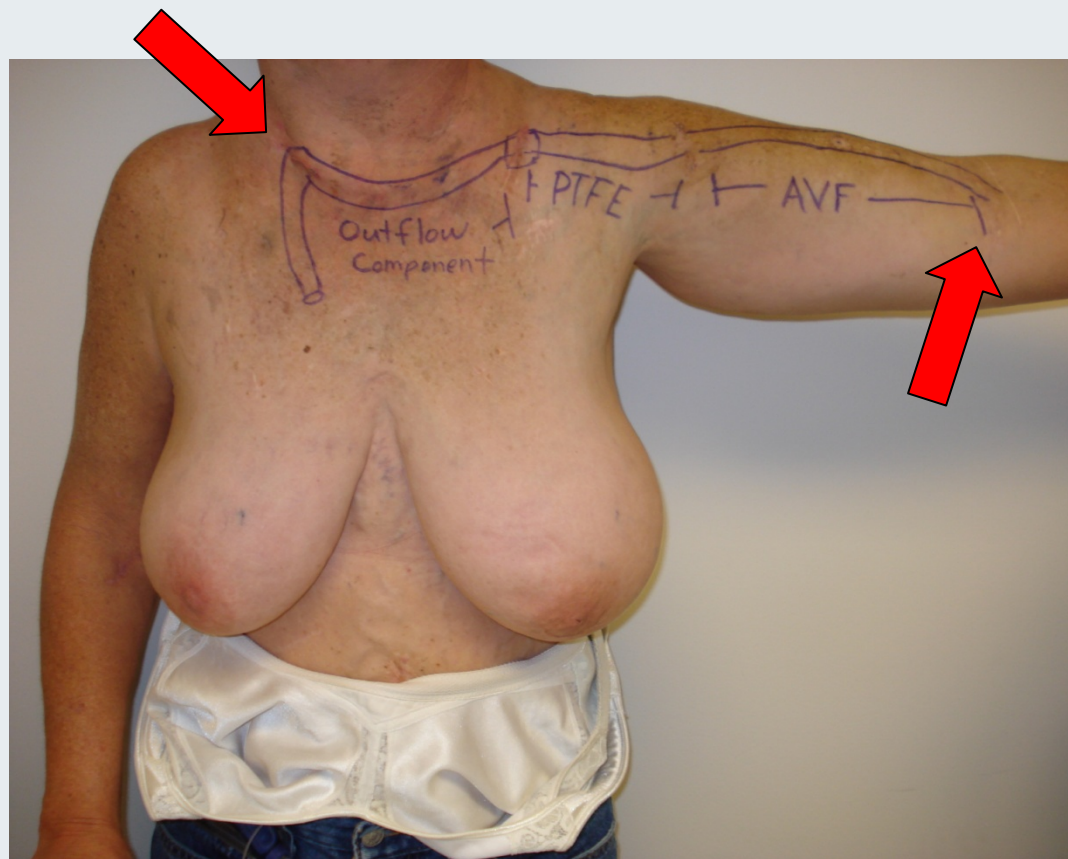
| <i>Co-morbidities & Habits</i> | <i>Duke</i> | <i>Multi Center Trial</i> |
|---|--------------|---------------------------|
| Diabetes Mellitus, % (n/N) | 51.2 (21/41) | 68.4 (26/38) |
| Hypertension, % (n/N) | 92.7 (38/41) | 100.0 (38/38) |
| Peripheral Arterial Disease, % (n/N) | 22.0 (9/41) | |
| Tobacco Use, % (n/N) | 51.2 (21/41) | |



Implantation Specifics

HeRO Implant Side

| HeRO Implant Side | % (n/N) |
|-------------------|--------------|
| Right | 58.5 (24/41) |
| Left | 39.0 (16/41) |
| Right → Left | 2.4 (1/41) |

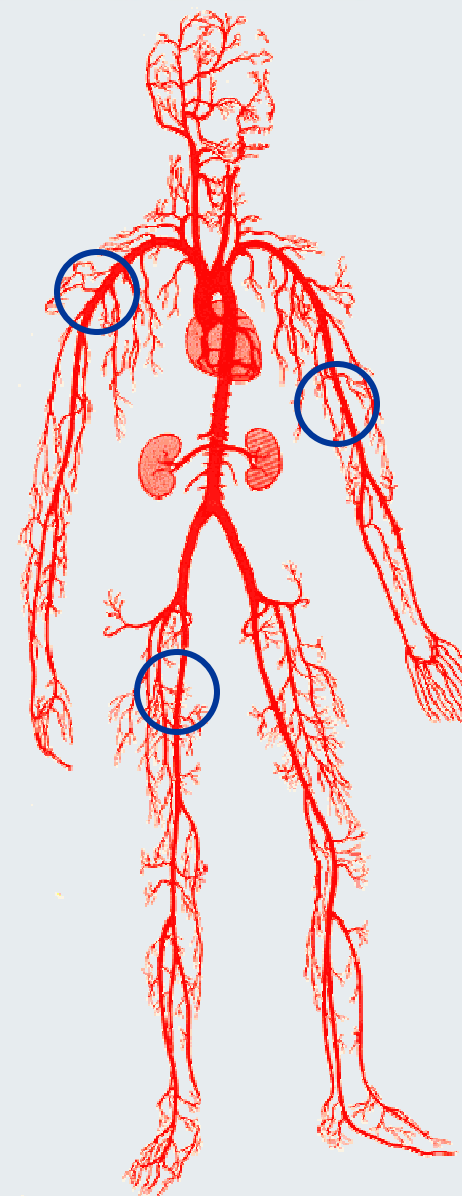




Implantation Specifics

HeRO Inflow

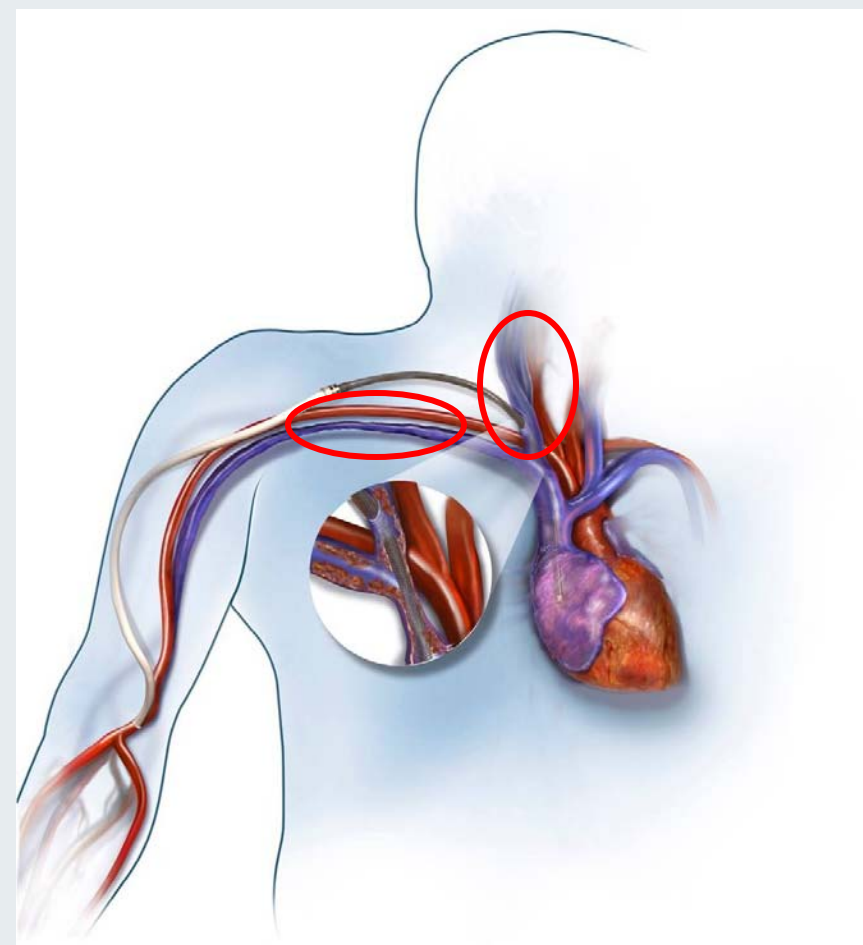
| Inflow | % (n/N) |
|--|--------------|
| BRACH | 68.3 (28/41) |
| AX | 14.6 (6/41) |
| BrachioBasilic Vein Cuff | 4.9 (2/41) |
| BrachioCephalic AVF | 4.9 (2/41) |
| SFA | 4.9 (2/41) |
| Basilic Vein Outflow from forearm loop AVG | 2.4 (1/41) |





Implantation Specifics

| <i>Insertion Vein</i> | <i>% (n/N)</i> |
|-----------------------|----------------|
| Subclavian Vein | 48.8 (20/41) |
| LSCV | 34.2 (14/41) |
| RSCV | 14.6 (6/41) |
| Internal Jugular Vein | 36.6 (15/41) |
| RIJV | 19.5 (8/41) |
| LIJV | 17.1 (7/41) |
| Axillary Vein | 4.9 (2/41) |
| Common Femoral Vein | 4.9 (2/41) |
| External Jugular Vein | 2.4 (1/41) |



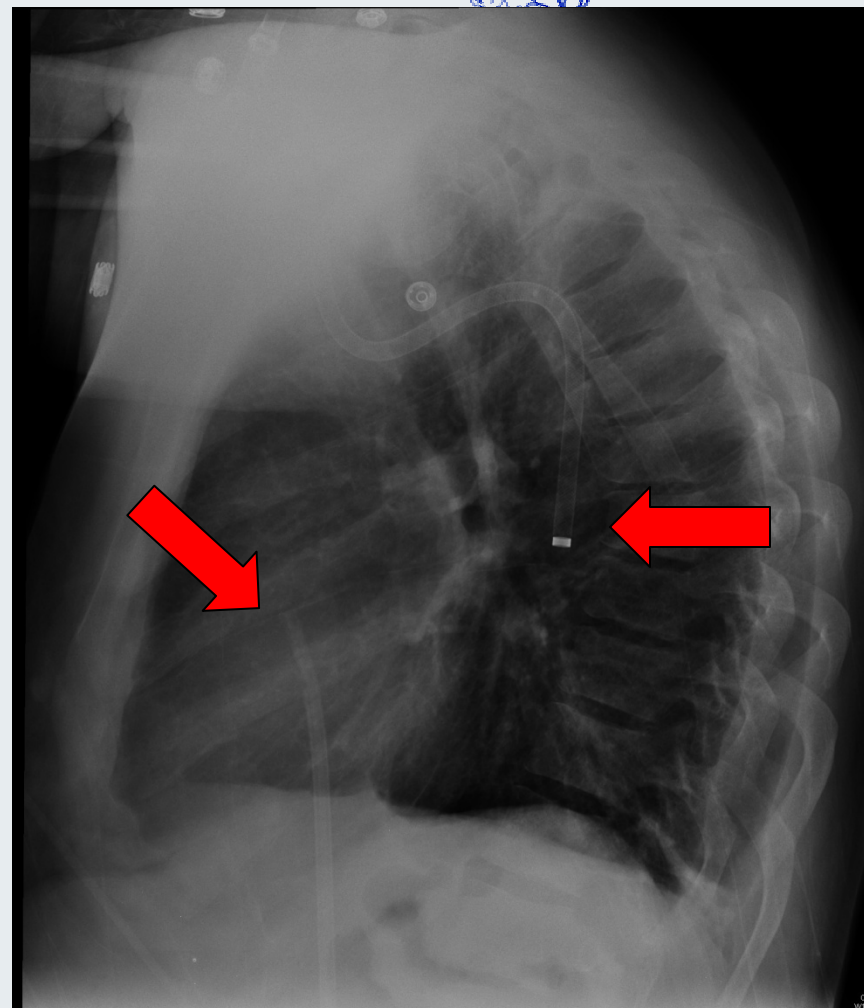


Implantations Specifics



Outflow Vein

| Outflow | % (n/N) |
|---------|--------------|
| SVC | 90.2 (37/41) |
| Azygos | 7.3 (3/41) |
| IVC | 2.4 (1/41) |

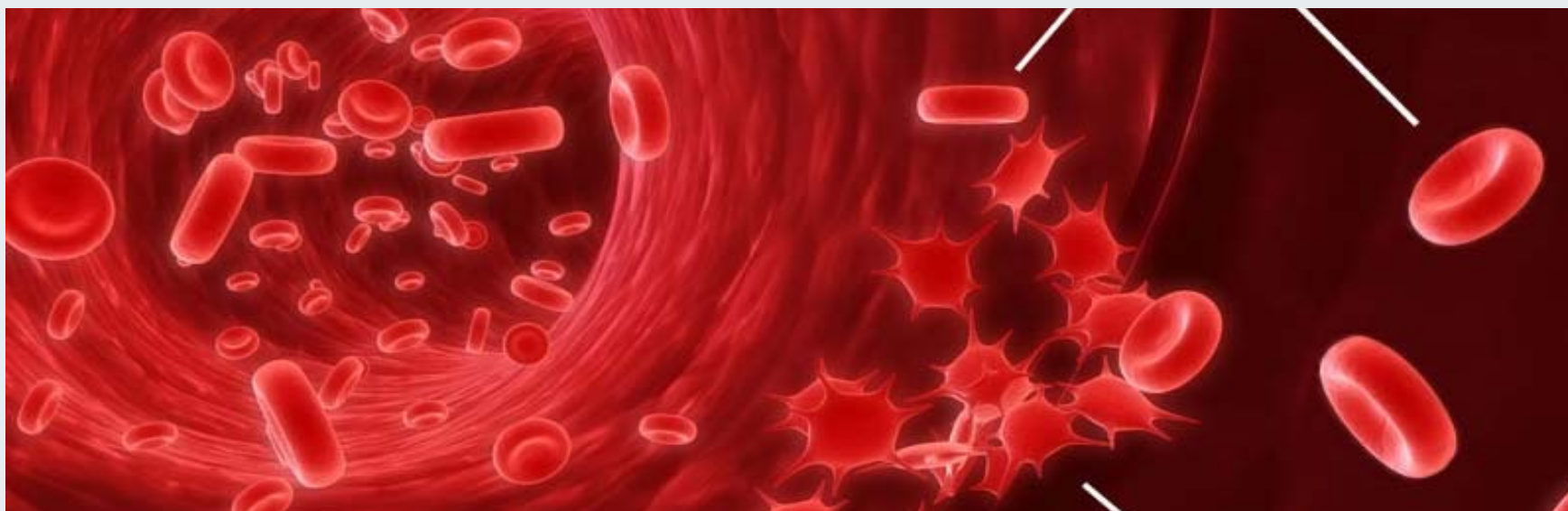




Antiplatelet / Anticoagulation Therapy

Antiplatelet & Anticoagulation Therapy Post -op

| | |
|--------------------------|--------------|
| ASA, % (n/N) | 53.7 (22/41) |
| Plavix, % (n/N) | 65.9 (27/41) |
| Coumadin, % (n/N) | 19.5 (8/41) |





Patency & Intervention Rates

| | <i>Duke 6 months</i> | <i>Multi Center Trial 8.6 mo mean f/u ¹</i> | <i>AVG literature 6 months ²</i> | <i>TDC literature 6 months</i> |
|---|--------------------------|--|---|--|
| Patency | | | | |
| Primary, % | 68.3 ^a | 38.9 | 58 | 50 ^{5, 6} |
| Secondary, % | 87.8 ^b | 72.2 | 76 | 55 ^{5, 6} |
| Intervention Rates, per year | 1.38 | 2.5 | 1.6-2.4 ^{3,4} | 5.8 ^{5, 6} |

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2. Sidawy AN, et al. Recommended Standards for Reports Dealing with Arteriovenous Hemodialysis Access. J Vasc Surg 2002;35:603-10.
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6. Duszak R, et al. Replacement of failing tunneled hemodialysis catheters through pre-existing subcutaneous tunnels: a comparison of catheter function and infection rates for de novo placements and over-the-wire exchanges. J Vasc Interv Radiol 1998;9:321-7.

- a. (n/N) 19/28 patients
- b. (n/N) 32/36 patients



Subgroup Data – Patency & Intervention

| <i>Demographic</i> | <i>Primary Patency at 6 Months % (n/N)</i> | <i>Secondary Patency at 6 Months % (n/N)</i> | <i>Intervention Rate (per year)</i> |
|------------------------|--|--|---|
| Age: | | | |
| < 57 years | 75.0% (15/20) | 90.0% (18/20) | 2.13 |
| 57+ years | 61.9% (13/21) | 85.7% (18/21) | 0.65 |
| Race: | | | |
| Black/African American | 67.6% (23/34) | 88.2% (30/34) | 1.6 |
| White/Caucasian | 71.4% (5/7) | 85.7% (6/7) | 0.44 |
| Gender: | | | |
| Female | 70.4% (19/27) | 88.9% (24/27) | 1.39 |
| Male | 64.3% (9/14) | 85.7% (12/14) | 1.35 |



Subgroup Data – Patency & Intervention

| <i>Co-morbidities & Habits</i> | <i>Primary Patency at 6 Months % (n/N)</i> | <i>Secondary Patency at 6 Months % (n/N)</i> | <i>Intervention Rate (per year)</i> |
|------------------------------------|--|--|---|
| Diabetes: | | | |
| No | 70.0% (14/20) | 90.0% (18/20) | 1.79 |
| Yes | 66.7% (14/21) | 85.7% (18/21) | 0.79 |
| PAD: | | | |
| No | 68.8% (22/32) | 87.5% (28/32) | 1.55 |
| Yes | 66.7% (6/9) | 88.9% (8/9) | 0.88 |
| Hypertension: | | | |
| No | 100.0% (3/3) | 100.0% (3/3) | 0.0 |
| Yes | 65.8% (25/38) | 86.8% (33/38) | 1.51 |
| Tobacco Use: | | | |
| No | 65.0% (13/20) | 85.0% (17/20) | 1.46 |
| Yes | 71.4% (15/21) | 90.5% (19/21) | 1.26 |



Subgroup Data – Patency & Intervention

| <i>Anticoagulation & Antiplatelet Therapy</i> | <i>Primary Patency at 6 Months % (n/N)</i> | <i>Secondary Patency at 6 Months % (n/N)</i> | <i>Intervention Rate (per year)</i> |
|---|--|--|-------------------------------------|
| ASA and/or Plavix: | | | |
| No | 57.1% (4/7) | 71.4% (5/7) | 1.47 |
| Yes | 70.6% (24/34) | 91.2% (31/34) | 1.37 |
| Coumadin: | | | |
| No | 66.7% (22/33) | 87.9% (29/33) | 1.50 |
| Yes | 75.0% (6/8) | 87.5% (7/8) | 0.81 |



Subgroup Data – Patency & Intervention

| <i>Arterial & Venous Considerations</i> | <i>Primary Patency at 6 Months % (n/N)</i> | <i>Secondary Patency at 6 Months % (n/N)</i> | <i>Intervention Rate (per year)</i> |
|---|--|--|-------------------------------------|
| Inflow Artery: | | | |
| Brachial | 71.4% (20/28) | 89.3% (25/28) | 1.06 |
| Axillary | 66.7% (4/6) | 83.3% (5/6) | 1.36 |
| Other | 57.1% (4/7) | 85.7% (6/7) | 2.66 |
| CV Occlusion: | | | |
| No | 72.0% (18/25) | 92.0% (23/25) | 1.08 |
| Yes | 66.7% (8/12) | 83.3% (10/12) | 1.19 |
| CV Stenosis: | | | |
| No | 70.6% (12/17) | 82.4% (14/17) | 1.05 |
| Yes | 70.6% (12/17) | 100.0% (17/17) | 0.96 |
| Via PermCath: | | | |
| No | 66.7% (14/21) | 14.3% (3/21) | 0.54 |
| Yes | 73.7% (14/19) | 5.3% (1/19) | 2.21 |



Infection Rates

| <i>HeRO Cohorts</i> | <i>No.</i> | <i>Total Days</i> | <i>Bacteremia events</i> | <i>Bacteremia rate/1000 days</i> | <i>(TDC) Control rate/1000 days¹</i> |
|--------------------------|------------|-------------------|--------------------------|----------------------------------|---|
| Overall | | | | | |
| Duke | 41 | 10,058 | 10 | 1.29 | 2.3 |
| Multicenter ¹ | 36 | 9931 | 7 | 0.70 | |
| Bridging Period | | | | | |
| Duke | 39 | 2729 | 10 | 3.66 | 1.6-5.5 |
| Multicenter ¹ | 32 | 1373 | 7 | 5.10 | |
| Alone | | | | | |
| Duke | 35 | 7120 | 3 | 0.42 | 2.3 |
| Multicenter ¹ | 29 | 8525 | 0 | 0.00 | |

1. Katzman HE, et al. Initial Experience and Outcome of a New Hemodialysis Access Device for Catheter-Dependent Patients. J Vasc Surg 2009;50:600-07.



Conclusions

- Excellent Device for access challenged patient
- Favorable characteristics for patency: non-diabetic, non-HTN, female, white/Caucasian, young, brachial anastomosis, and antiplatelet/anticoagulation
- Alternative applications (limb decompression, Lower extremity, outflow)
- Equivalent/Superior patency & infection rates (AVG)
- **Superior patency & infection rates (TDC)**



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