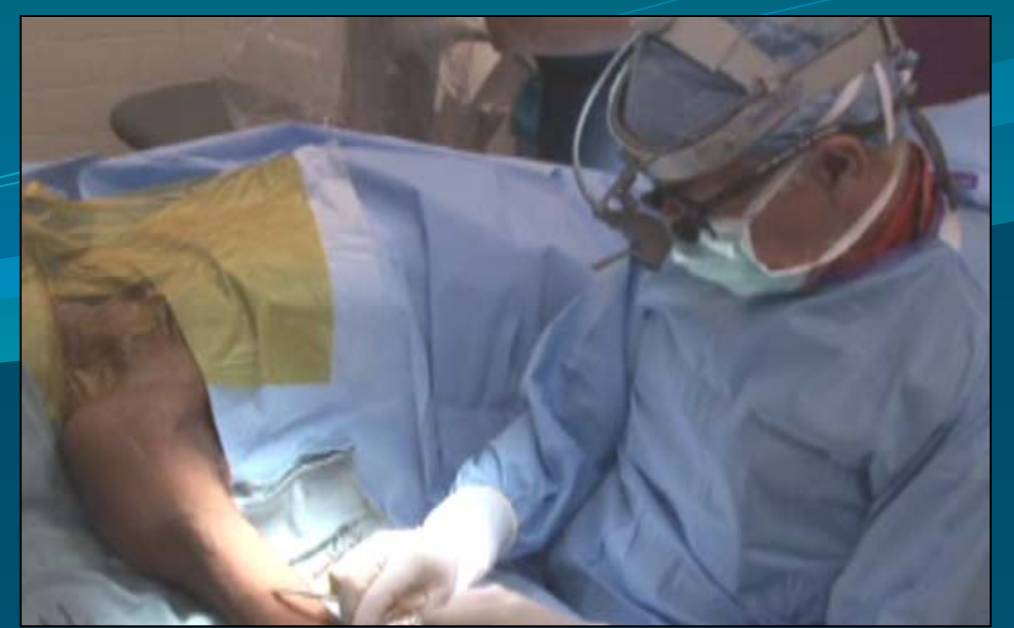


What We Have Learned After Four Years Of Implanting the HeRO Vascular Access Device



John R. Ross, MD, Chief of Surgery, Bamberg County Hospital, Bamberg, SC

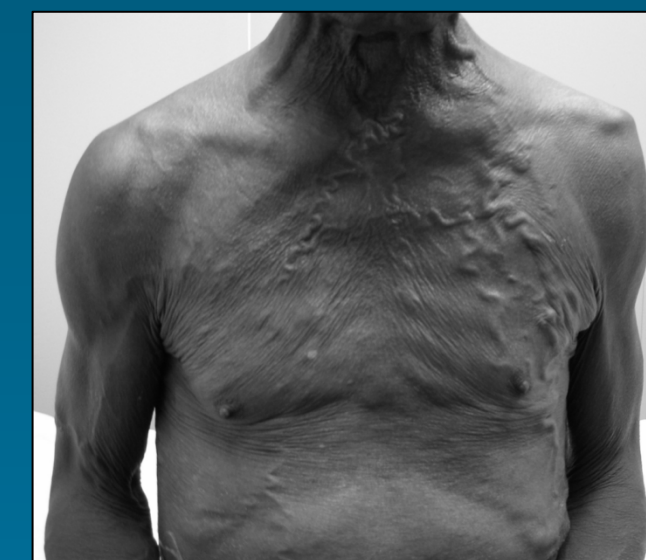
OBJECTIVES

The number of hemodialysis patients with central venous stenosis or superior vena cava (SVC) occlusion is increasing resulting in multiple failed accesses and catheter dependency. Due to catheter-related morbidities, a long-term AV vascular access catheter alternative is preferred.

The HeRO® Vascular Access Device is a subcutaneous graft, with central outflow requiring no venous anastomosis, thus able to bypass stenosis of the central veins. FDA clinical trials of HeRO in catheter-dependent patients demonstrated a 69% reduction in bacteremia rates as well as improved adequacy of dialysis compared to catheter literature.¹

With four years of HeRO experience at our institution, we believe we have identified the physiologic and anatomical conditions that can benefit from this technology and have developed an endovascular implant technique to aid device placement in this difficult patient population.

PATIENT PROFILES



Total SVC Occlusion



Totally Occluded Left Brachiocephalic Vein

Patients A-E were considered catheter-dependent for a variety of reasons and referred for possible HeRO placement.

Patient A: Complete occlusion of the SVC all the way down to the right atrium.

Patient B: Bilateral venograms show no suitable veins in the periphery.

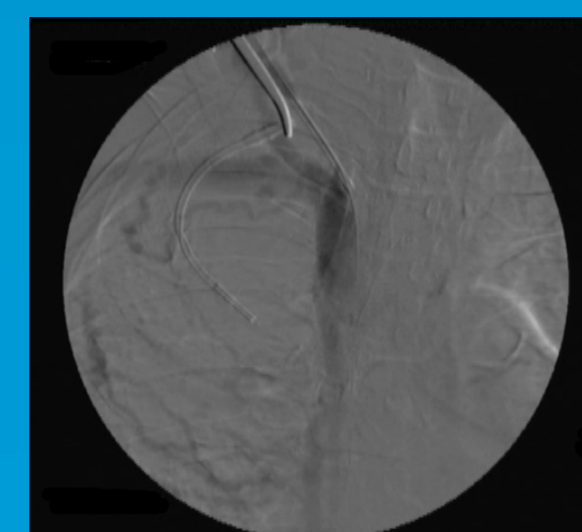
Patient C: History of multiple thrombotic episodes, bilateral ischemia and cardiomyopathy.

Patient D: Complete occlusion of the SVC.

Patient E: Complete occlusion of the SVC.



Total SVC Occlusion



Diffuse Collaterals



Left-Side Access Only

IMPLANT TECHNIQUE IN CHALLENGING VENOUS ANATOMY

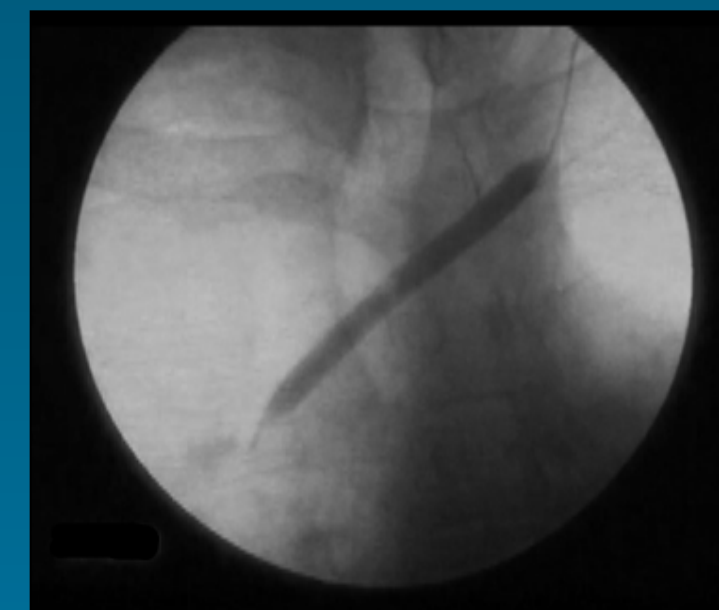


Fig. 1 Pre-implant angioplasty

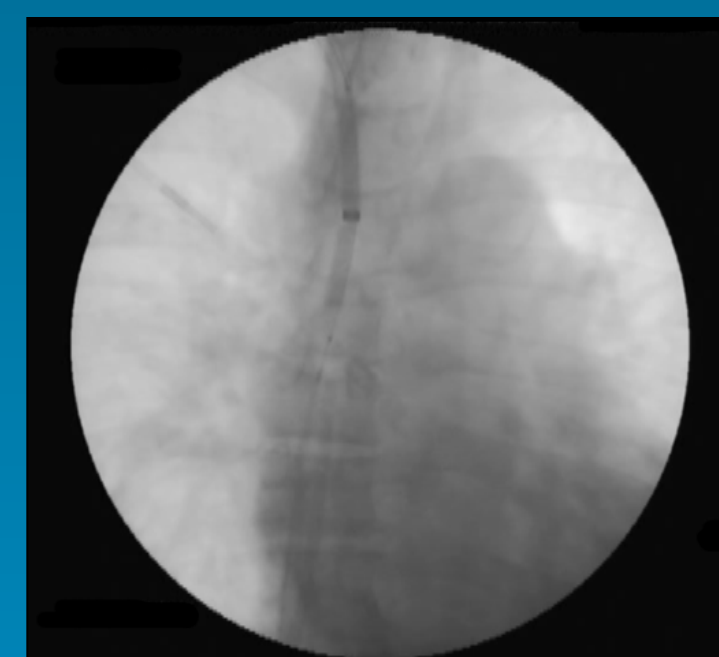


Fig. 2 Outflow component placement technique using balloon to guide into right atrium



Fig. 3 Post-implant outflow component positioned in right atrium

First, a temporary catheter is placed during angiographic evaluation to later facilitate access to the inferior vena cava at the time of HeRO implant.

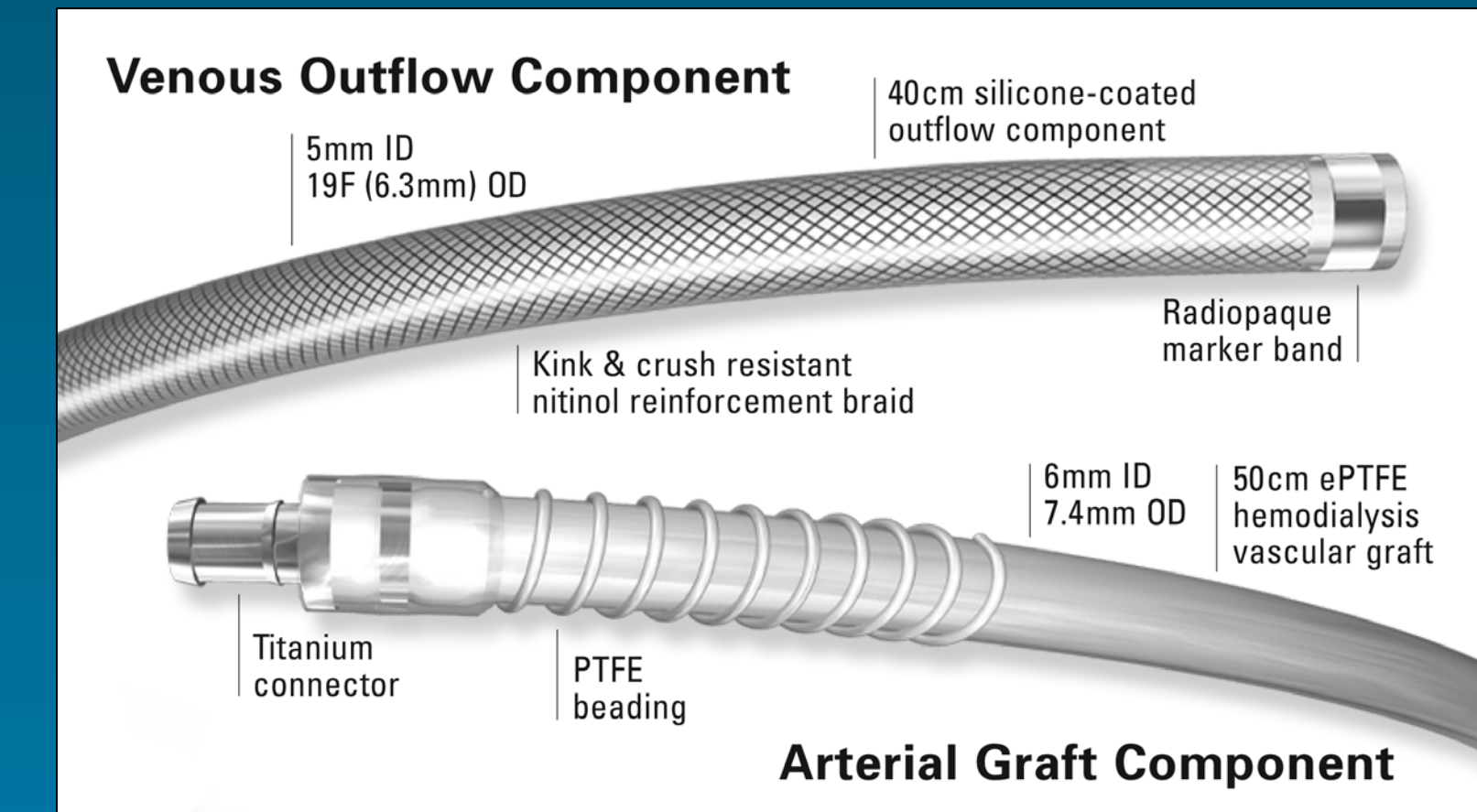
Second, angioplasty is performed (Figure 1). Our HeRO outflow component delivery technique to traverse stenosis requires an 8x8 angioplasty balloon with approximately 4cm of balloon outside and 4cm inside the outflow component, inflated up to 22 atmospheres (Figure 2). The balloon is inflated and deflated as it is pushed gently so that the outflow component is essentially pulled into the right atrium. Preferred outflow tip placement in the mid to upper right atrium is verified using fluoroscopy (Figure 3).

Third, a counter incision is made at the deltopectoral groove. The outflow component is tunneled to the counter incision. A target artery for the inflow anastomosis is selected and the artery is exposed. An uncompromised area is preferred, where the artery has an inner diameter of at least 3mm. The graft component is tunneled from the arterial anastomosis site up to the counter incision.

Lastly, the HeRO graft and outflow component are connected and the positioning verified, and the inflow anastomosis is completed. Once the graft is pulled into place, the outflow component is cut to length and pushed onto the graft titanium connector. Outflow component tip placement is re-verified with fluoroscopy, and the fully connected system is placed into the soft tissue of the deltopectoral groove. A standard arterial anastomosis is performed.

Patients continue dialysis treatment using a catheter for approximately three weeks until the HeRO graft tissue incorporation is complete.

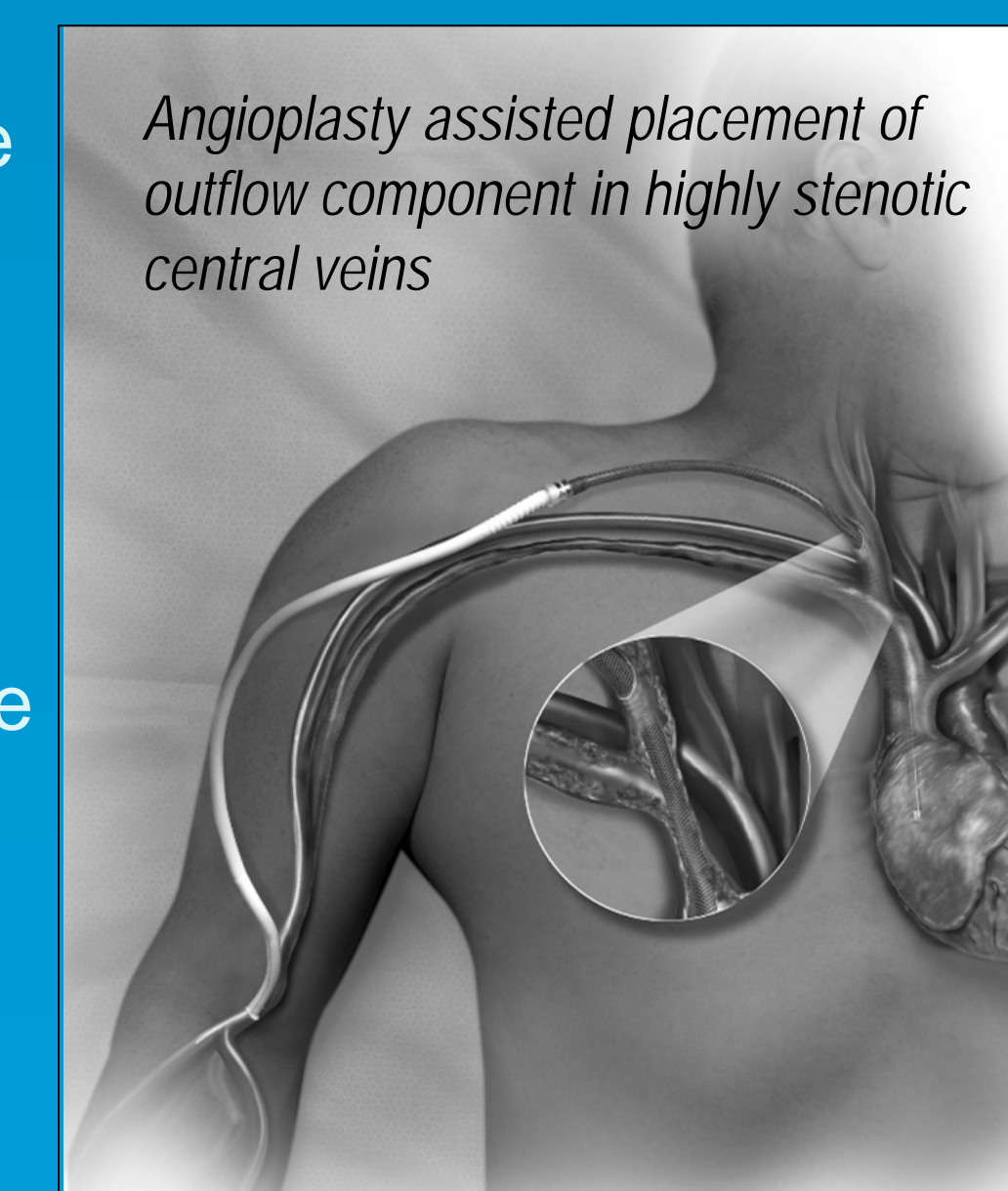
DEVICE DESCRIPTION



CONCLUSION:

Central venous stenosis or SVC occlusion can prevent placement of a successful AV access. The HeRO device can be implanted in patients with challenging anatomy avoiding the morbidities associated with long-term catheters.

The two key components of this implant technique are successful guidewire placement all the way into the right atrium via the inferior vena cava and serial dilations of the angioplasty balloon, which is extended beyond the HeRO outflow component to traverse stenosis.



¹ Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients
 Howard E. Katzman, Robert B. McLafferty, John R. Ross, Marc H. Glickman, Eric K. Peden, Jeffery H. Lawson
 Journal of Vascular Surgery - September 2009 (Vol. 50, Issue 3, Pages 600-607)