Perc AVFs

Getting from Bruit to TDC Free HD

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The Regional Medical Center
Orangeburg, SC

Disclosures

• *Boston Scientific Corp.*	*Advisory Board*
• *Bard BD*	*Speakers Group*
• *CTI-Humacyte*	*Clinical Events Group*
• *W.L. Gore*	*Advisory Board, Speakers Group*

What 's Available – Reimagining Deep Fistulas

- Ellipsys Device : Avenu Medical
- EverlinQ Device: Bard –B.D. **(Formerly TVA Medical)**

Quick History of Deep Fistulas

Kidney International, Vol. 11 (1977) p. 71–74

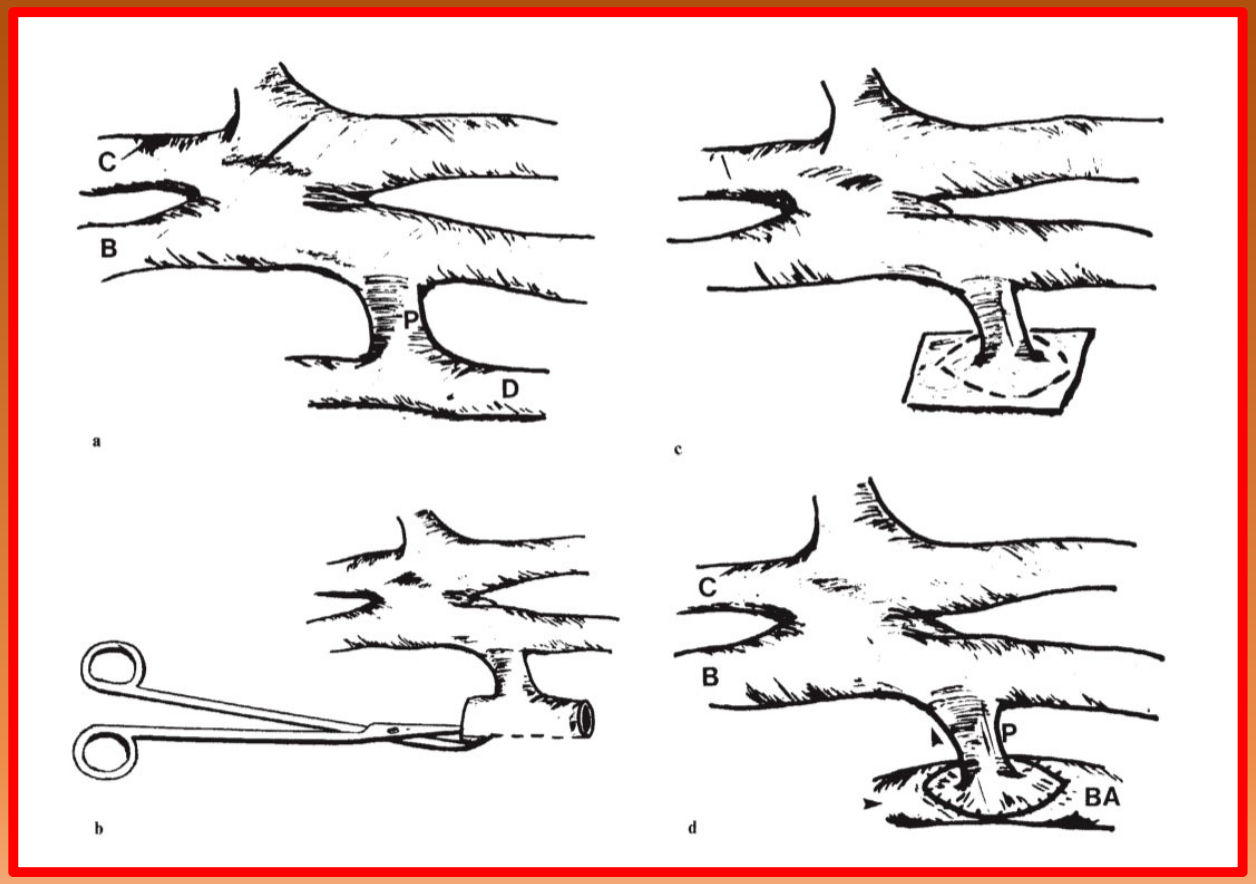
TECHNICAL NOTE

Proximal forearm fistula for maintenance hemodialysis

KENNETH C. GRACZ, TODD S. ING, LIAN-SEN SOUNG, KENT F. W. ARMBRUSTER, SANDRA K. SEIM, and FREDERICK K. MERKEL

Departments of Surgery and Medicine, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois and Department of Medicine, Christ Hospital, Oak Lawn, Illinois

Deep Anatomy – Gracz Fistula Creation



ORIGINAL ARTICLE

Outcomes of Upper Arm Arteriovenous Fistulas for Maintenance Hemodialysis Access

Jason T. Fitzgerald, MD; Andres Schanzer, MD; Andrew I. Chin, MD; John P. McVicar, MD; Richard V. Perez, MD; Christoph Troppmann, MD

- The Mean Time to First Use for All Fistulas was 3.8 ± 2.1 Months.
- Aside from the usual problems of delay with BV transposition there were no significant differences in outcomes among the 3 types of upper arm AVFs.
- It is tempting to speculate that the BMAC-AVF might have superior performance because of the potential dual outflow tracts.

Arch Surg. 2004;139:201-208

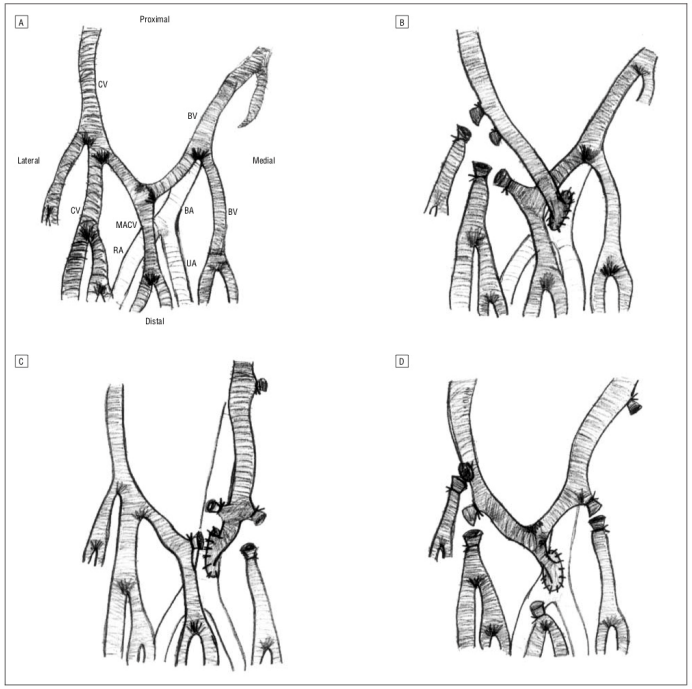


Figure 1. Diagram of the 3 types of upper arm arteriovenous fistula (AVF) used for hemodialysis. A, Normal anatomy of the right antecubital fossa is depicted, showing the cephalic vein (CV), median antecubital vein (MACV), basilic vein (BV), brachial artery (BA), radial artery (RA), and ulnar artery (UA). B, The brachiocephalic AVF. C, The brachiobasilic AVF. D, The brachial artery–to–median antecubital vein AVF.

3 types of AVF, with the exception of a higher proportion of women (8 of 9) in the BBNS-AVF group ($P = .003$).

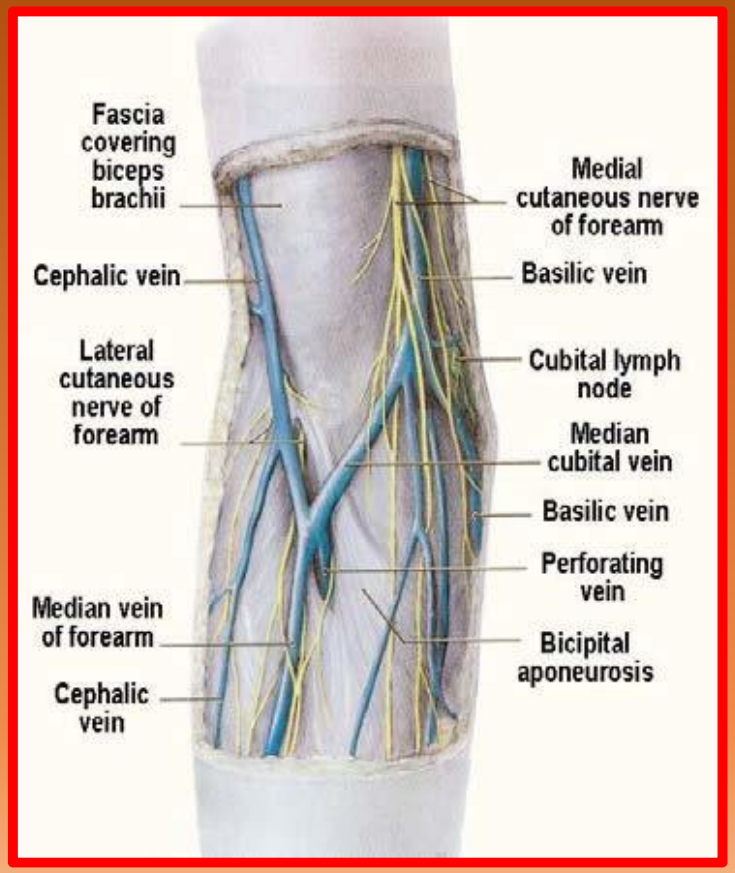
PROCEDURES

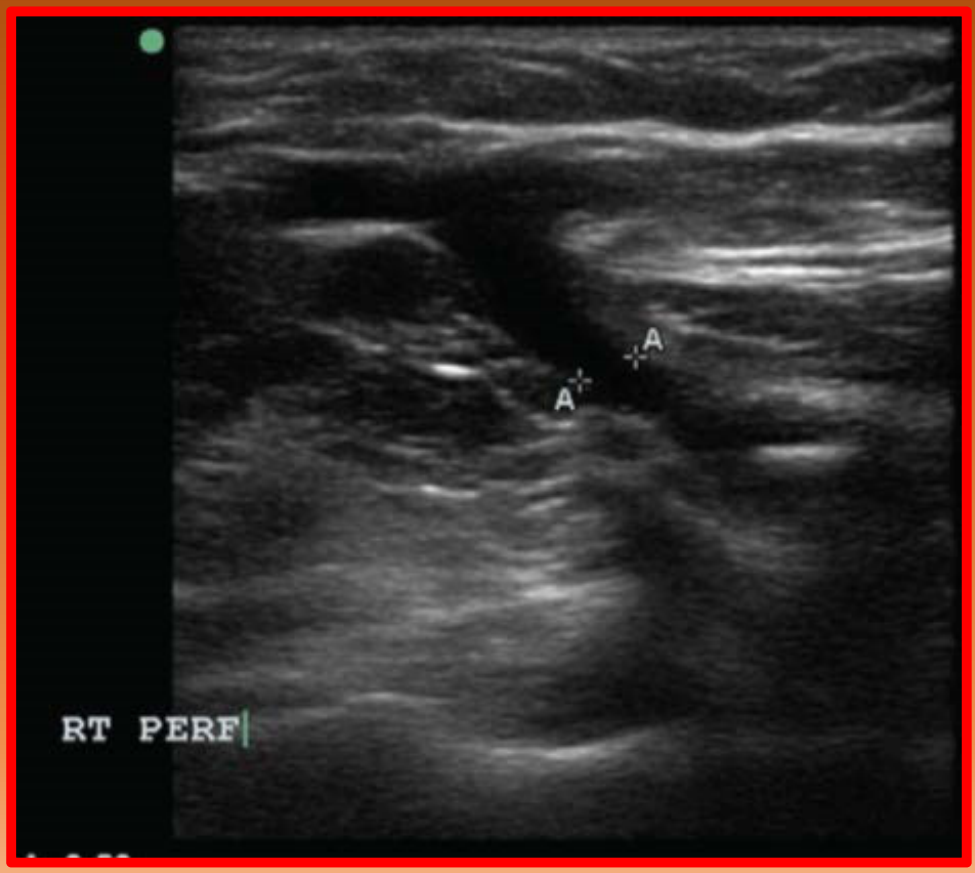
Four surgeons placed all 3 types of upper arm AVF. The total number of each AVF type placed is listed in **Table 2**. The BMAC-AVFs were placed in increasing numbers later in the study and accounted for the differences in mean follow-up among the 3 types of upper arm AVFs (Table 2). Technical success, defined as the detection of blood flow in the venous outflow tract by means of palpation or Doppler ultrasonography, was achieved in all 86 patients at the end of the procedure.

MATURATION, COMPLICATIONS, AND REINTERVENTIONS

Mean±SD follow-up was 7.2±6.6 months. Table 2 shows the main outcome measurements for each type of AVF, including *P* values for all significant end points. There were no statistically significant differences among times to first use among the AVF types. However, the BBNS-AVF showed a trend toward longer time to first use at a mean of just longer than 6 months ($P = .06$, analysis of variance). This 6-month wait was associated with the increased need for reintervention ($P = .02$) in the form of delayed basilic outflow superficialization.

Applied Percutaneous Fistula Anatomy





Proximal Radial Artery as Inflow Site for Native Arteriovenous Fistula

Stephen D Bruns, MD, William C Jennings, MD, FACS

BACKGROUND: Most vascular surgeons favor an initial radial-cephalic anastomosis at the wrist for dialysis access when possible. As populations age and more chronically ill patients are offered dialysis, this native arteriovenous fistula (NAVF) is less frequently available. A brachial-cephalic anastomosis is generally considered to be the second choice for NAVF site. We report our experience in a series of patients where the proximal radial artery (PRA) serves as the primary inflow vessel.

STUDY DESIGN: We reviewed 139 consecutive dialysis access operations performed by the senior author. One hundred fourteen had an NAVF constructed. Seventy-three of these procedures in 71 patients involved the PRA as arterial inflow and are the subject of this report.

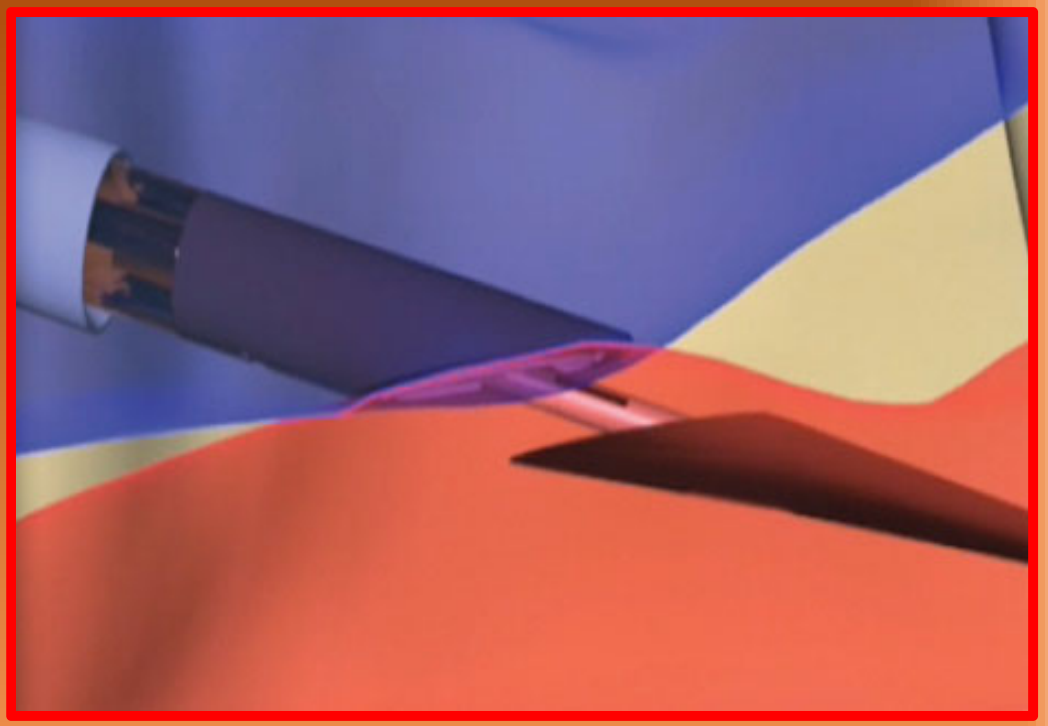
RESULTS: Mean age was 57 years. Thirty-six of the 71 were men. Seventy-one percent of the patients were diabetic and more than half had previous access surgery. Twenty-nine patients underwent preoperative ultrasonographic evaluation for feasibility and planning of the NAVF fistula. The 1-month patency rate for patients undergoing PRA fistula was 98%. Cumulative patency was 80% during the followup period of up to 42 months. No infectious or ischemic complications were noted during the study period.

CONCLUSIONS: We find the anterior position and mobility of the PRA offers a simple and tension-free anastomosis to the median antebrachial vein or one of its tributaries. This anastomotic site frequently allows dialysis in both the forearm and upper arm. The PRA allows for adequate arterial inflow while avoiding the risk of steal syndrome found with brachial artery fistulas. More extensive procedures or use of prosthetic grafts can be avoided. (J Am Coll Surg 2003;197:58–63. © 2003 by the American College of Surgeons)

Ellipsys-Avenu Medical

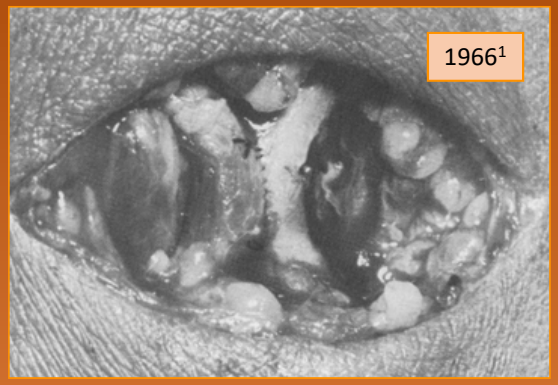
- Ultrasound imaging only
- Advancing needle within the vein lumen under ultrasound guidance
- Radial Artery to Perforating Vein
- One Percutaneous puncture 6 Fr, into cephalic vein just above origin of the perforating vein.
- “Tissue Welding”, Not affected by vessel wall calcification
- Usual time of procedure around 30-45 minutes.
- Angioplasty of the anastomosis immediately following creation.

Ellipsys



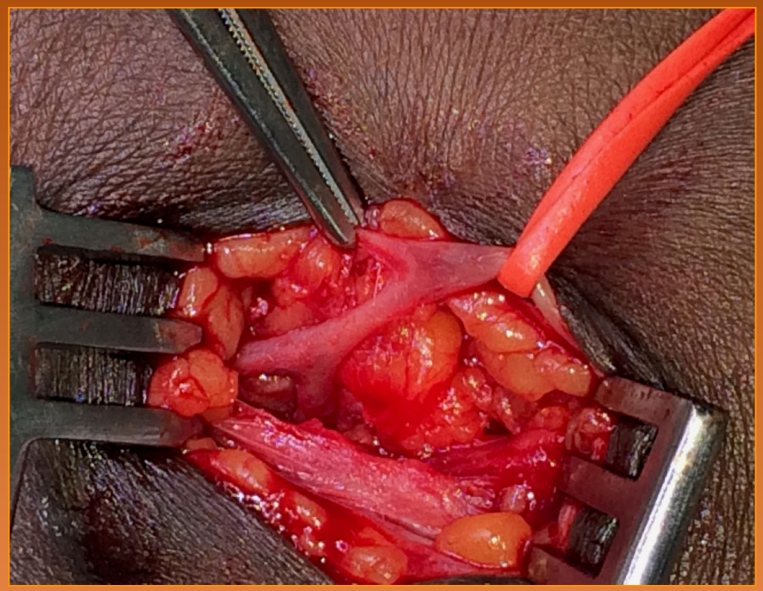
Surgical vs EndoAVF®

- Minimally invasive
- AVF between in-situ vessels
  - No vessel mobilization – twisting, dislocation
  - No surgical trauma – dissection
- Consistent anastomotic geometry

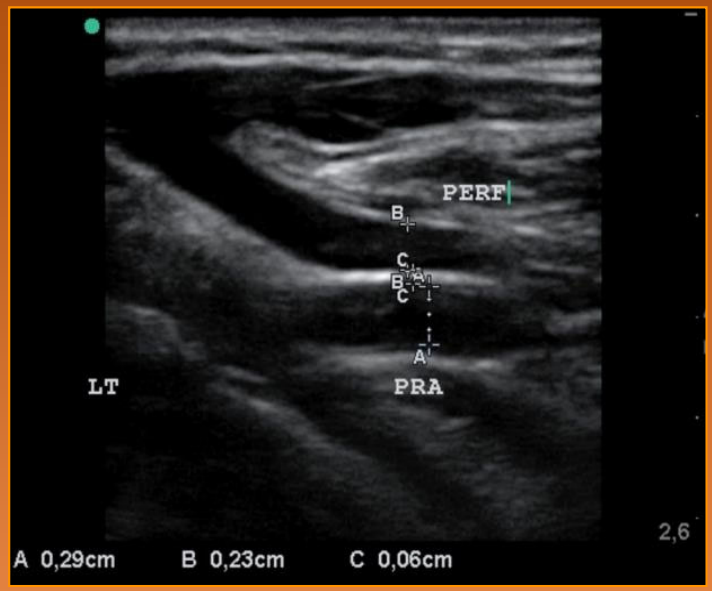


[1]Brescia MJ, Cimino JE, Appel K, Hurwich BJ. Chronic hemodialysis using venipuncture and a surgically created arteriovenous fistula. *N Engl J Med* 1966; 275:1089-92.

Replace Dissection with Ultrasound



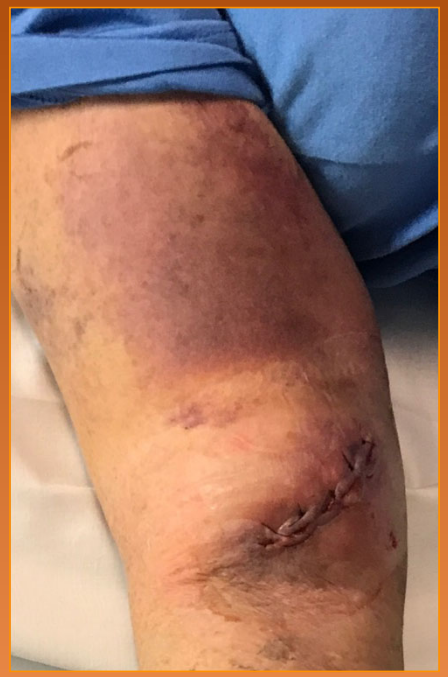
Vessels dissected

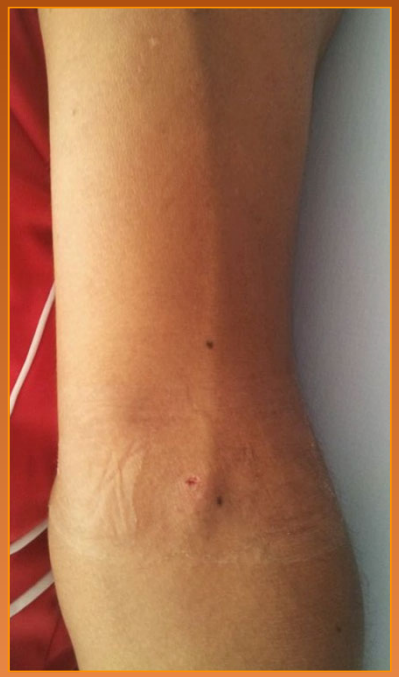


Vessels in-situ

Hull JE, Elizondo-Riojas G, Bishop W, Voneida-Reyna YL. Thermal Resistance Anastomosis Device for the Percutaneous Creation of Arteriovenous Fistulae for Hemodialysis. *J Vasc Interv Radiol* 2017; 28:380-7.

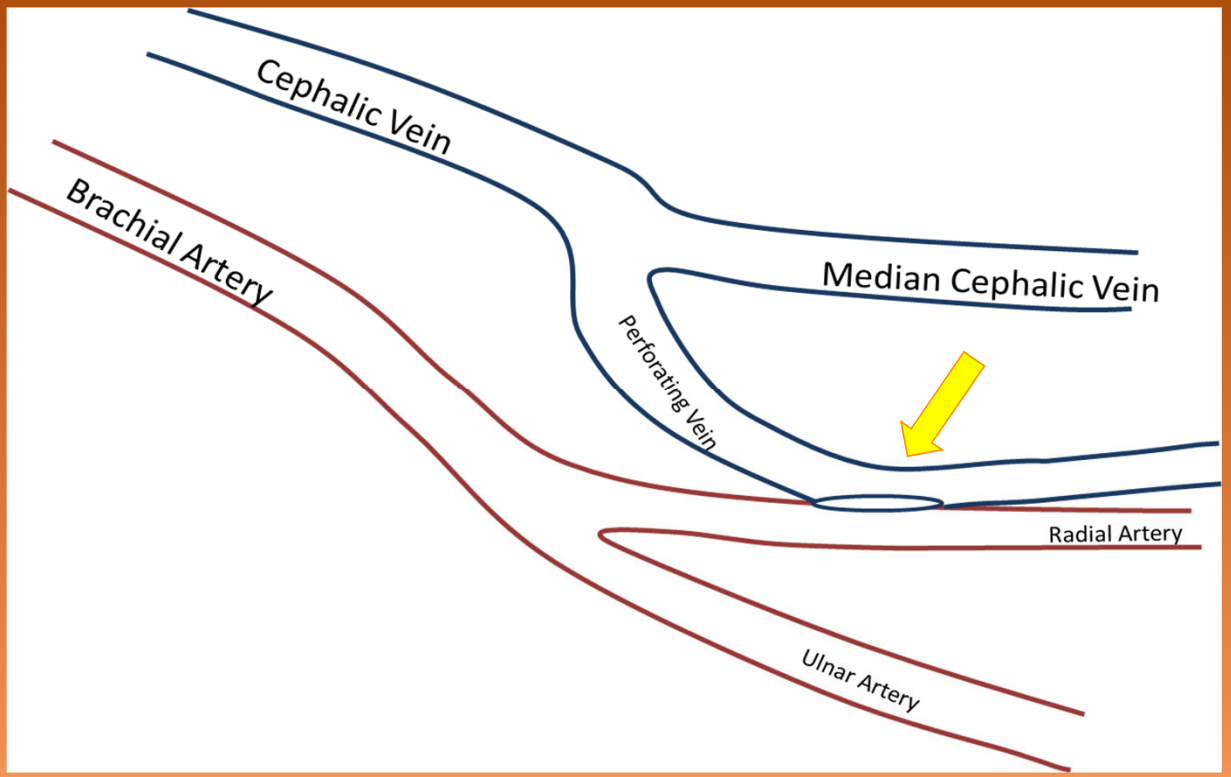
Replace Incision with Puncture

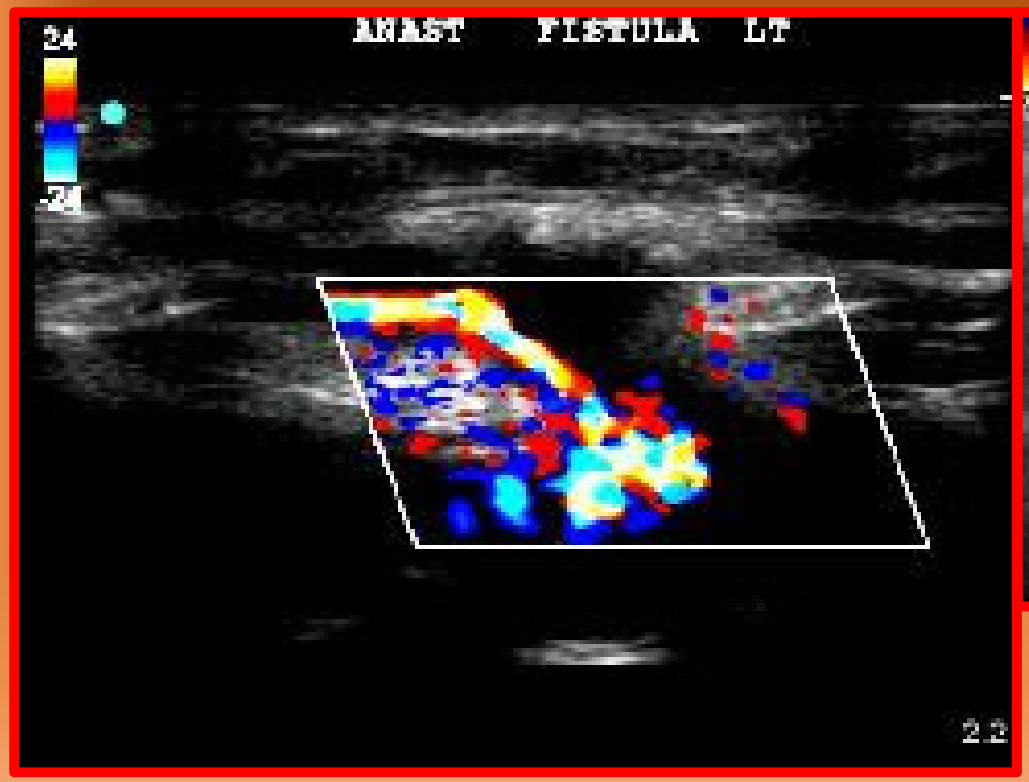




Hull JE, Elizondo-Riojas G, Bishop W, Voneida-Reyna YL. Thermal Resistance Anastomosis Device for the Percutaneous Creation of Arteriovenous Fistulae for Hemodialysis. *J Vasc Interv Radiol* 2017; 28:380-7.

Perforating Vein/Proximal Radial Artery (PRA) Fistula

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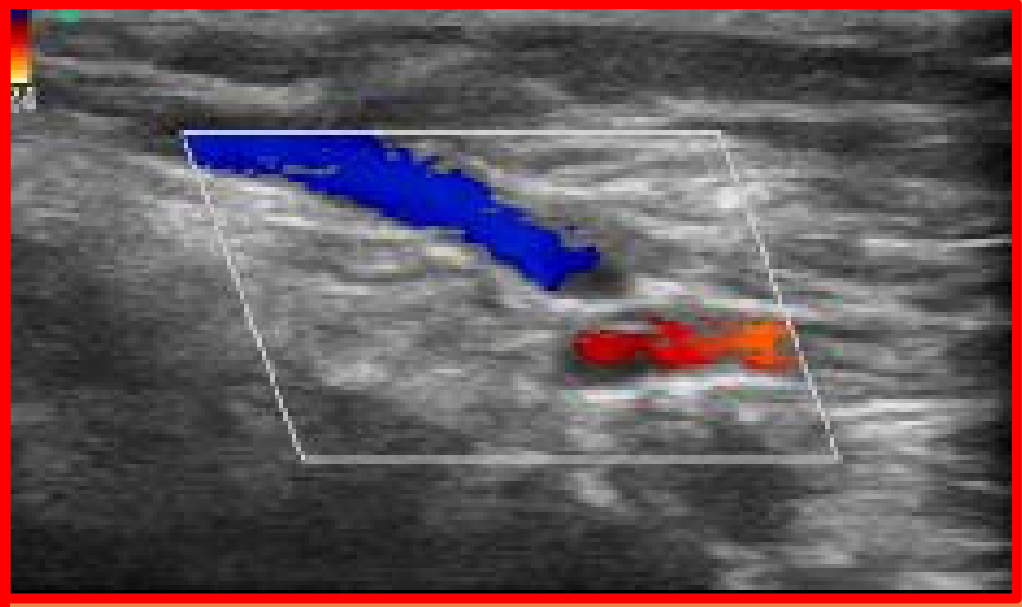
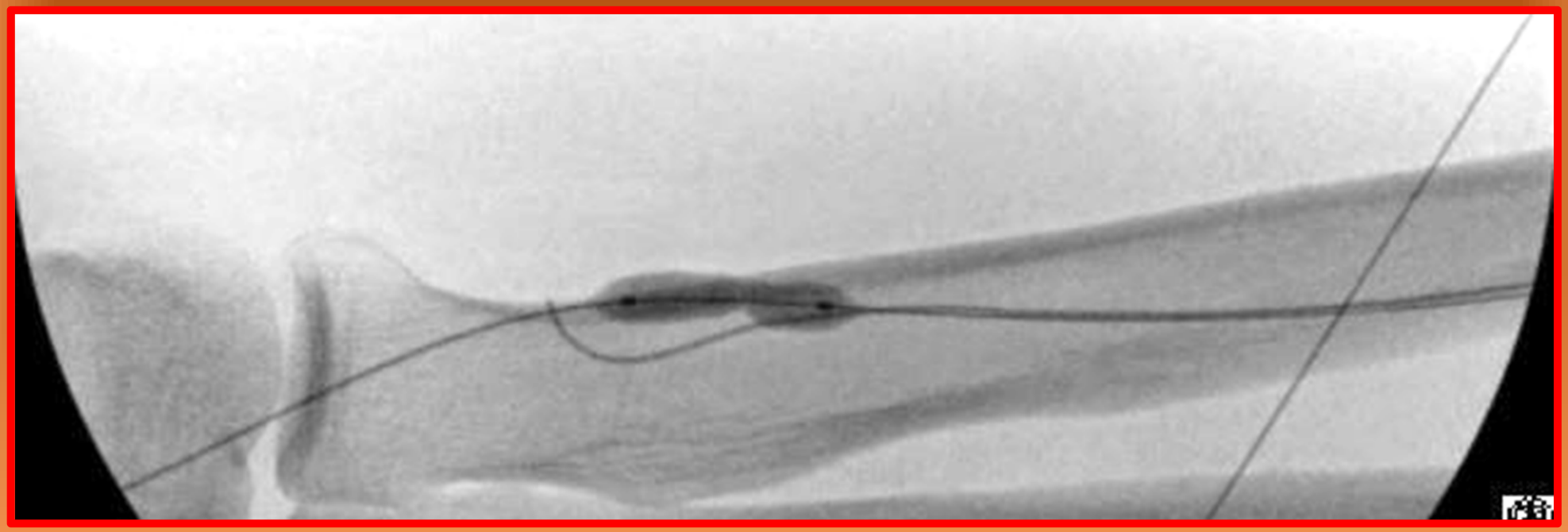


Reinterventions Performed via Radial Artery



Results of U.S. FDA Trial

- Primary efficacy endpoint 86% (92/107) vs. surgical target goal > 49% (p=0.0001)
- Primary safety endpoint: No device related serious adverse events
- Secondary endpoints:
  - Two-needle dialysis in 88% (71/81)
  - Number of days to dialysis: 100

Hull JE, Jennings WC, Cooper RI, Waheed U, Schaefer ME, Narayan R. The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation For Hemodialysis Access. *JVIR* 2018 Feb.

CLINICAL STUDY

The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access

Jeffrey E. Hull, MD, William C. Jennings, MD, Randy I. Cooper, MD, Umar Waheed, MD, Matthew E. Schaefer, DO, and Rajeev Narayan, MD

ABSTRACT

Purpose: To evaluate safety and efficacy of arteriovenous fistulas (AVFs) created with a thermal resistance anastomosis device.

Materials and Methods: A prospective single-arm trial at 5 sites enrolled 107 patients. Patients underwent ultrasound (US)-guided anastomosis creation between the proximal radial artery and perforating vein with the Ellipsys Vascular Access System (Avenu Medical, Inc, San Juan Capistrano, California) followed by separate maturation procedures. Primary endpoints were brachial artery flow volume $\geq$ 500 mL/min and target vein diameter $\geq$ 4 mm in $>$ 49% of patients and absence of device-related complications at 90 days.

Results: AVFs with fused anastomoses were created in 95% (102/107) of patients. Maturation procedures included anastomotic balloon dilation in 72% (77/107), brachial vein embolization in 32% (34/107), cubital vein ligation in 31% (33/107), and surgical transposition in 26% (28/107) of patients. Primary flow and diameter endpoints were achieved in 86.0% (92/107) of patients, exceeding performance goal of 49% ($P < .0001$). No major adverse events were attributed to the device. Cumulative patency was 91.6%, 89.3%, and 86.7% at 90 days, 180 days, and 360 days. Target dialysis veins were cephalic, basilic, and brachial veins in 74% (73/99), 24% (24/99), and 2% (2/99) of patients. Two-needle dialysis was achieved in 88% (71/81) of patients on hemodialysis at a mean 114.3 days ± 66.2. Functional patency was 98.4%, 98.4%, and 92.3% at 90 days, 180 days, and 360 days.

Conclusions: The Ellipsys® Vascular Access System met primary safety and efficacy endpoint goals in the US pivotal trial.

AJKD

Original Investigation

Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicenter Novel Endovascular Access Trial (NEAT)

*Charmaine E. Lok, MD, MSc,[1,2] Dheeraj K. Rajan, MD,[2,3] Jason Clement, MD,[4] Mercedeh Kiaii, MD,[5] Ravi Sidhu, MD, MEd,[6] Ken Thomson, MD,[7] George Buldo, MD,[8] Christine Dipchand, MD, MSc,[9] Louise Moist, MD, MSc,[10] and Joanna Sasal, MD,[11] on behalf of the NEAT Investigators**

Background: Hemodialysis arteriovenous fistulas (AVFs) are suboptimally used primarily due to problems with maturation, early thrombosis, and patient nonacceptance. An endovascular approach to fistula creation without open surgery offers another hemodialysis vascular access option.

Study Design: Prospective, single-arm, multicenter study (Novel Endovascular Access Trial [NEAT]).

Settings & Participants: Consecutive adult non−dialysis-dependent and dialysis-dependent patients referred for vascular access creation at 9 centers in Canada, Australia, and New Zealand.

Intervention: Using catheter-based endovascular technology and radiofrequency energy, an anastomosis was created between target vessels, resulting in an endovascular AVF (endoAVF).

Outcomes: Safety, efficacy, functional usability, and patency end points.

Measurements: Safety as percentage of device-related serious adverse events; efficacy as percentage of endoAVFs physiologically suitable (brachial artery flow ≥ 500 mL/min, vein diameter ≥ 4 mm) for dialysis within 3 months; functional usability of endoAVFs to provide prescribed dialysis via 2-needle cannulation; primary and cumulative endoAVF patencies per standardized definitions.

Results: 80 patients were enrolled (20 roll-in and 60 participants in the full analysis set; the latter are reported). EndoAVFs were created in 98% of participants; 8% had a serious procedure-related adverse event (2% device related). 87% were physiologically suitable for dialysis (eg, mean brachial artery flow, 918 mL/min; endoAVF vein diameter, 5.2 mm [cephalic vein]). EndoAVF functional usability was 64% in participants who received dialysis. 12-month primary and cumulative patencies were 69% and 84%, respectively.

Limitations: Due to the unique anatomy and vessels used to create endoAVFs, this was a single-arm study without a surgical comparator.

Conclusions: An endoAVF can be reliably created using a radiofrequency magnetic catheter-based system, without open surgery and with minimal complications. The endoAVF can be successfully used for hemodialysis and demonstrated high 12-month cumulative patencies. It may be a viable alternative option for achieving AVFs for hemodialysis patients in need of vascular access.

Am J Kidney Dis. 70(4):486-497.

NEAT Trial

- 59 of 60 (98%) successful fistula creation
- 52/**60 (87%) physiologic suitability for dialysis**
- **3 AVFs failed to mature, 1 had intraprocedural thrombosis, 2 inadvertently sacrificed, 1 death.**
- **Functional endoAVF usability with 2 needle cannulation was 28 of 44 (64%) in the full-analysis-set cohort.**
- **Mean time to 2 needle cannulaiton of the endoAVF was 118 days in the baseline dialysis participants and 32.4 days in the baseline non-dialysis-dependent participants after they initiated dialysis**

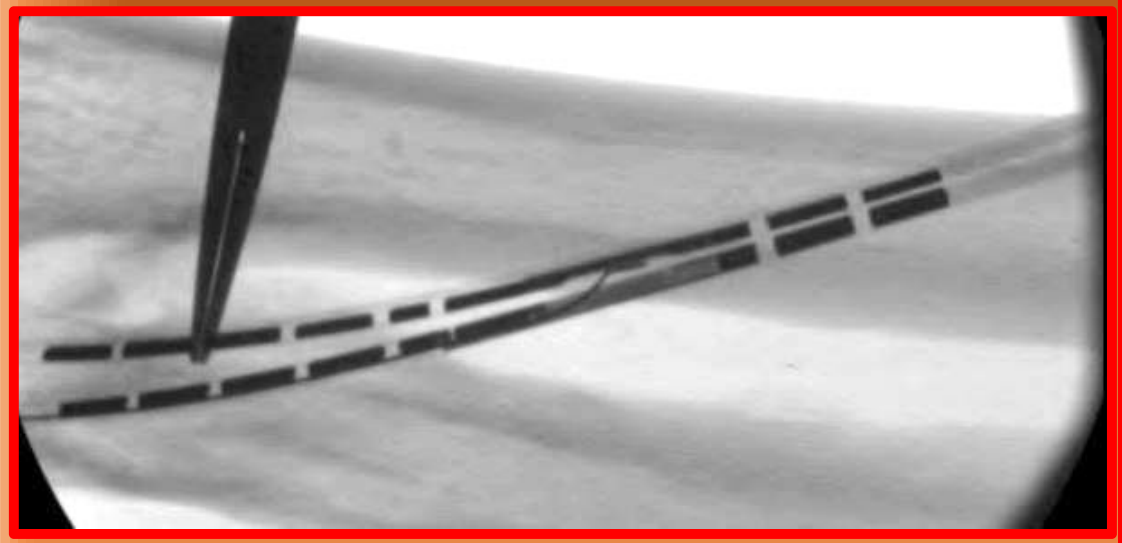
EverlinQ – Bard BD (Formerly TVA Medical)

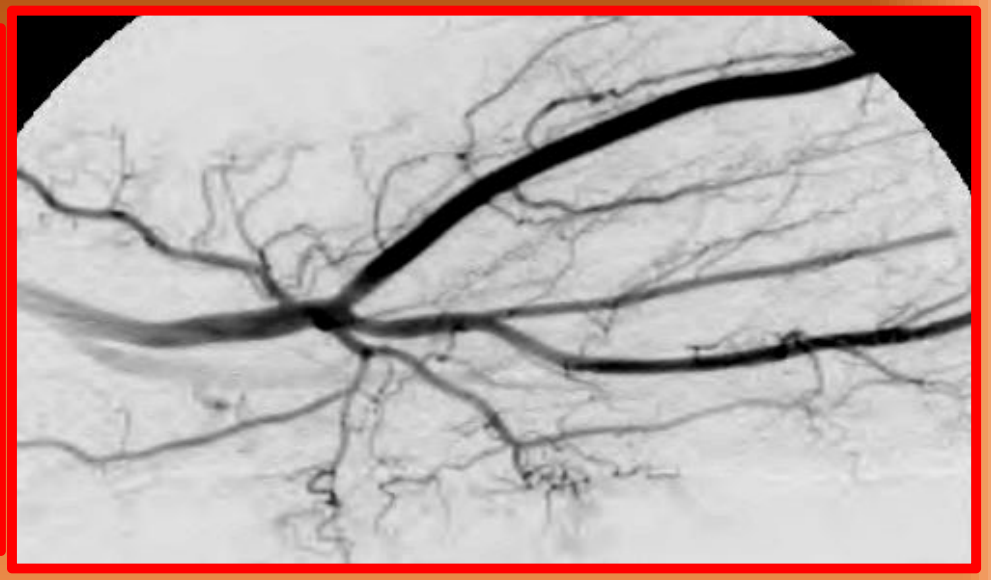
- Brachial Artery & Brachial Vein punctures
- Ultrasound & fluoroscopy to position devices
- Radiofrequency energy to create anastomosis (hindered by Calcified vessel wall)
- Multiple Angles to confirm correct position of the devices
- No PTBA of the anastomosis, Embolization of the accessed brachial vein.

Secondary Procedures

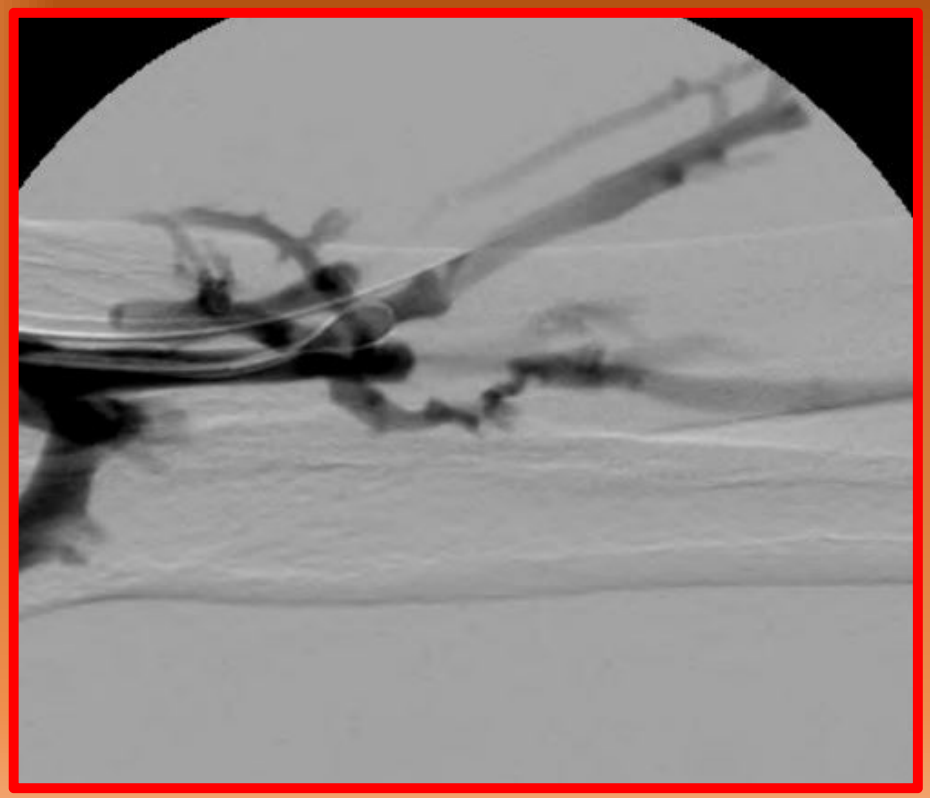
- 24 Secondary interventions in 19 subjects
- 5 BVT, 5 Coil embolizations of tributary veins, 3 endoAVF ligations, 2 thrombin injections, 2 PTBAs, 1 Thrombolysis, 2 Thrombectomies, 2 surgical artery repairs and 2 new AVFs or grafts.

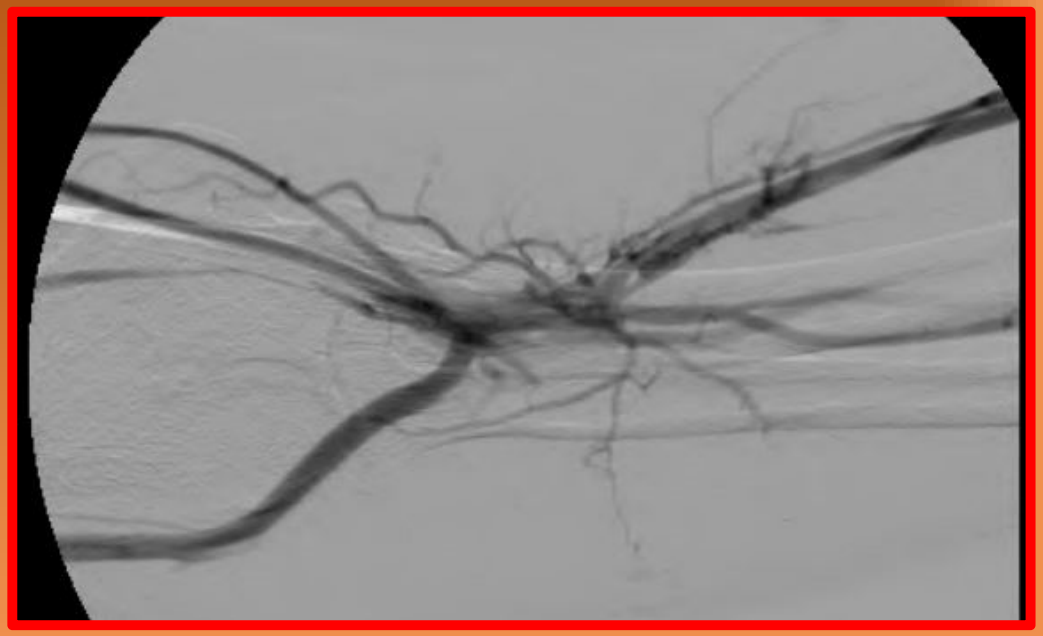
EverlinQ



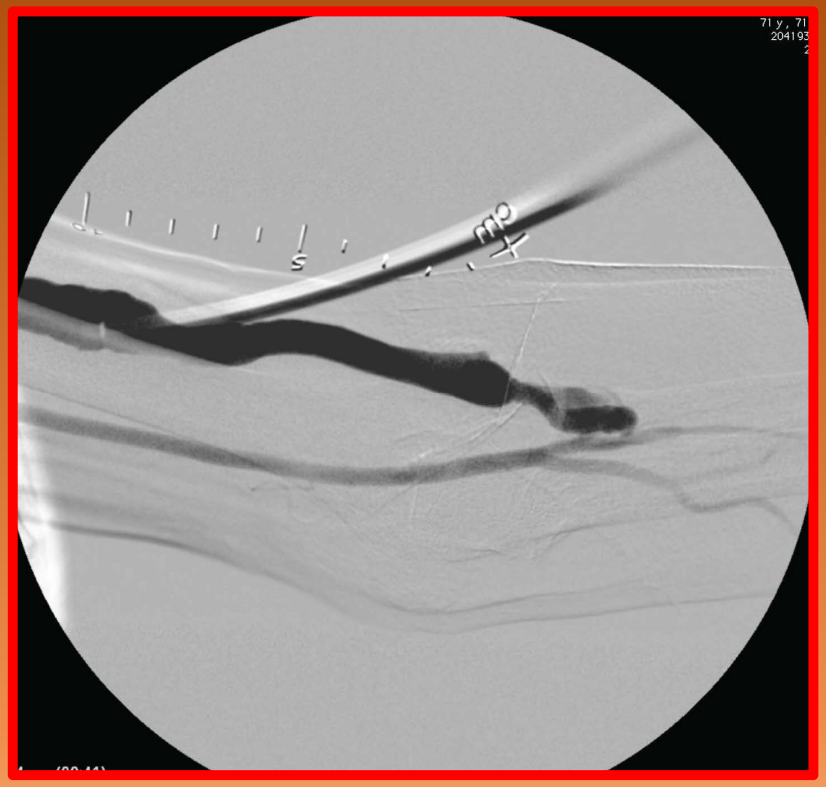


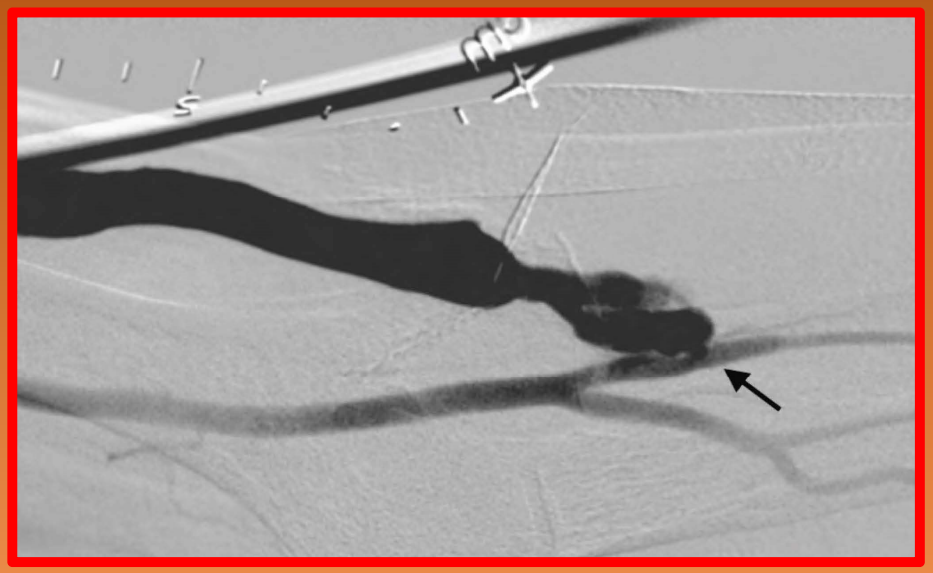
EverlinQ





Small Anastomosis

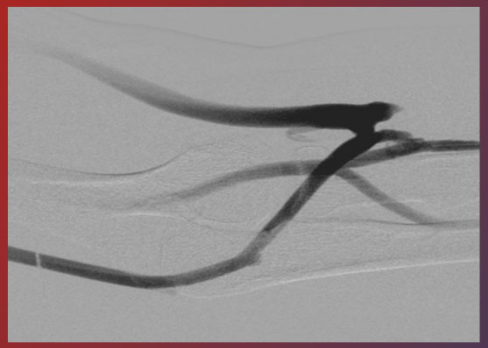


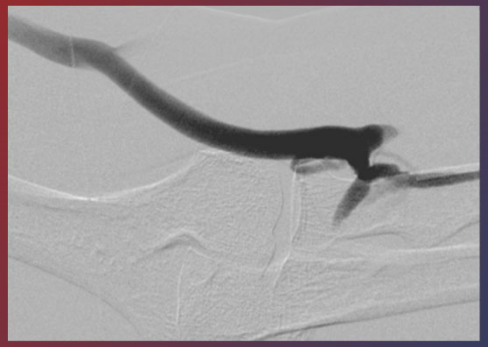


Protocol

- 1 week f/u Color Assisted Duplex- Goal >500cc/min.
- If not ready for dialysis then follow-up at 4 weeks.
- PTBA/ Flow redirection when ready for dialysis to bring flow to 600cc/min to 800 cc/min.

Two Stage Procedure





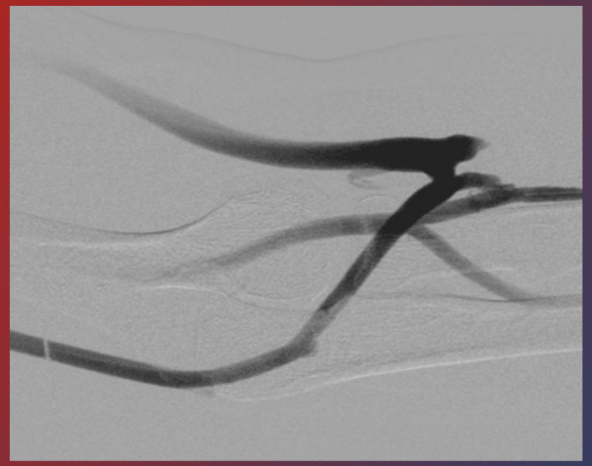
- BA flow mean 334 mL/min

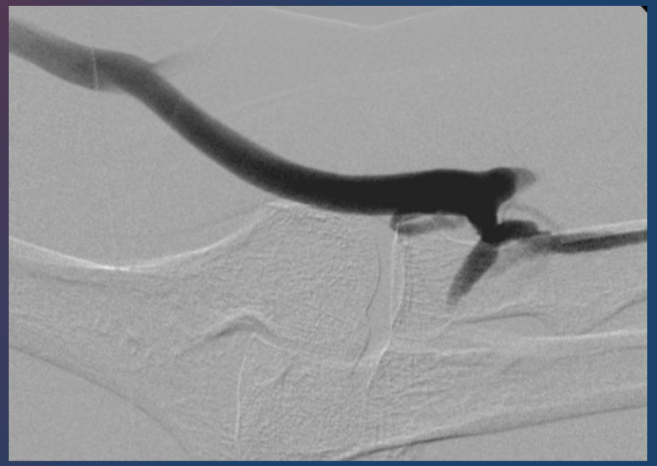
Procedure	Patients (%)
PTA proximal fistula	77 (72)
Embolization deep	34 (32)
Embolization branch	37 (35)
Cubital vein ligation	33 (31)
Transposition	28 (26)

- BA flow mean 932 mL/min

*Jennings WC, Mallios A, Mushtaq N. Proximal radial artery arteriovenous fistula for hemodialysis vascular access. J Vasc Surg 2017.

Multi-Outflow Fistula





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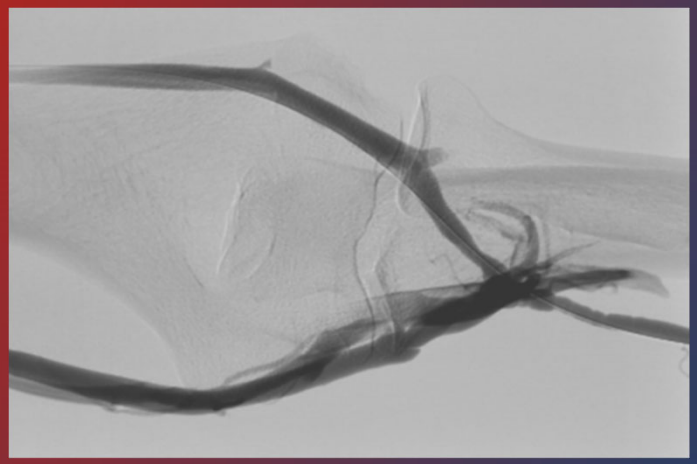
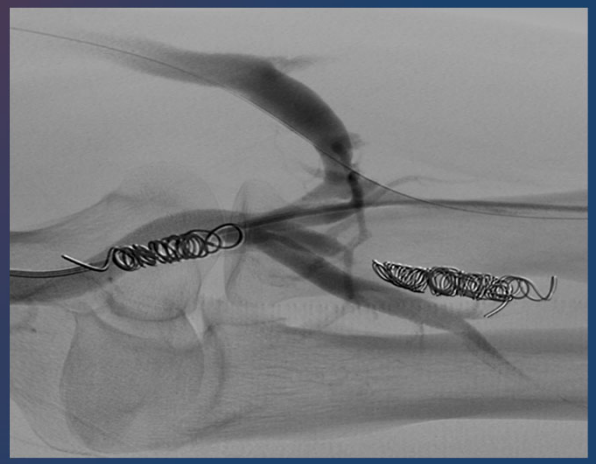
Multi-Outflow Fistula
Balloon Dilation
Deep Embolization





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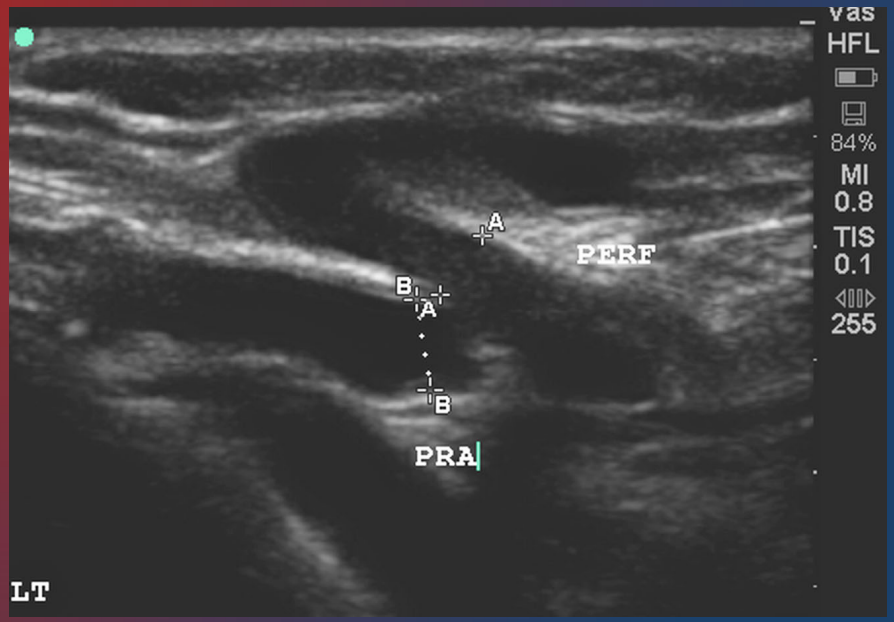

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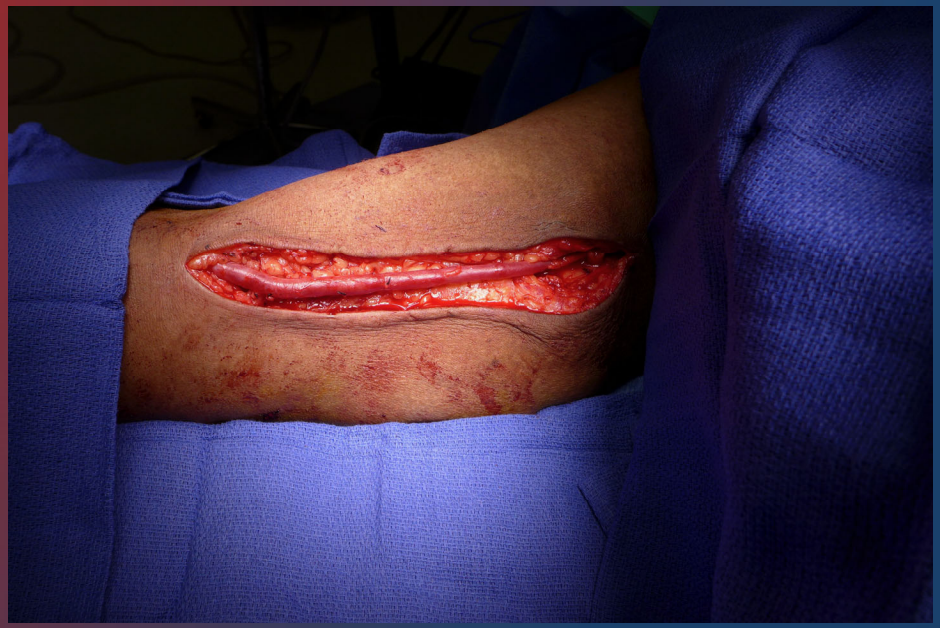
Transposition



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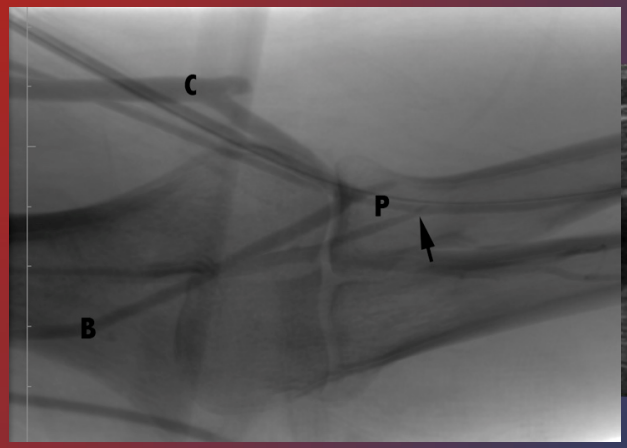
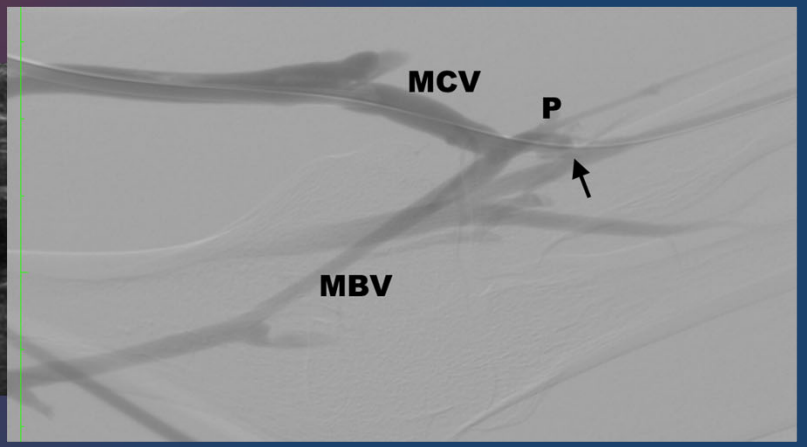
Multi-Outflow Fistula Balloon Dilation





* Hull et al. Thermal resistance anastomosis device for the percutaneous creation of arteriovenous fistulae for hemodialysis. JVIR 2015; on line, article in press.

Richmond Vascular Center

Stage II Procedures

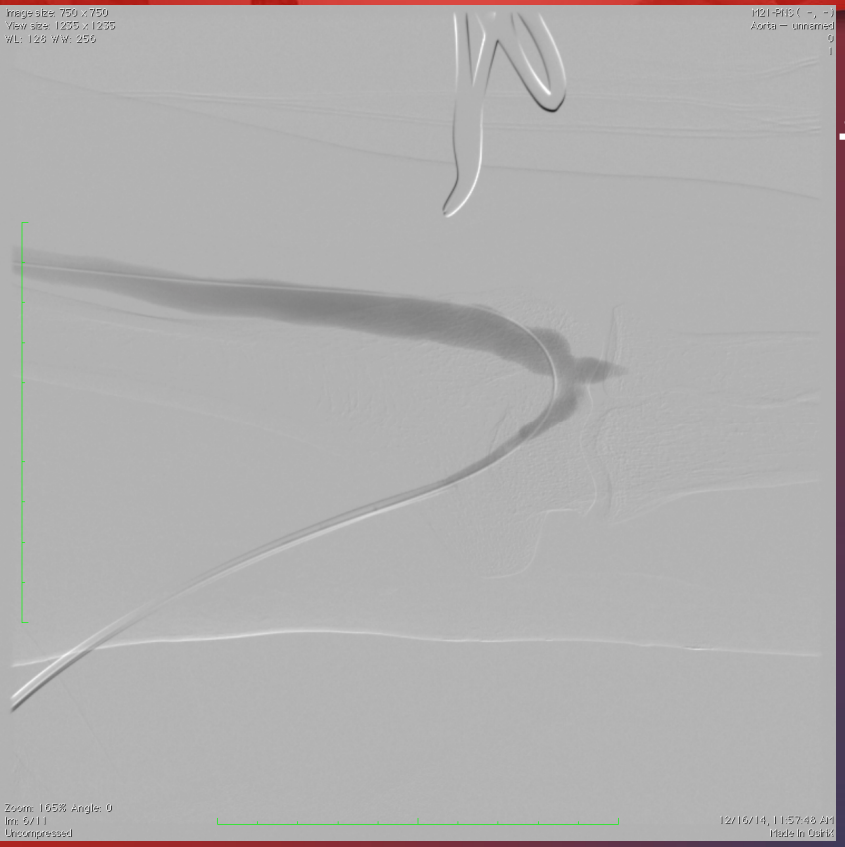
b14

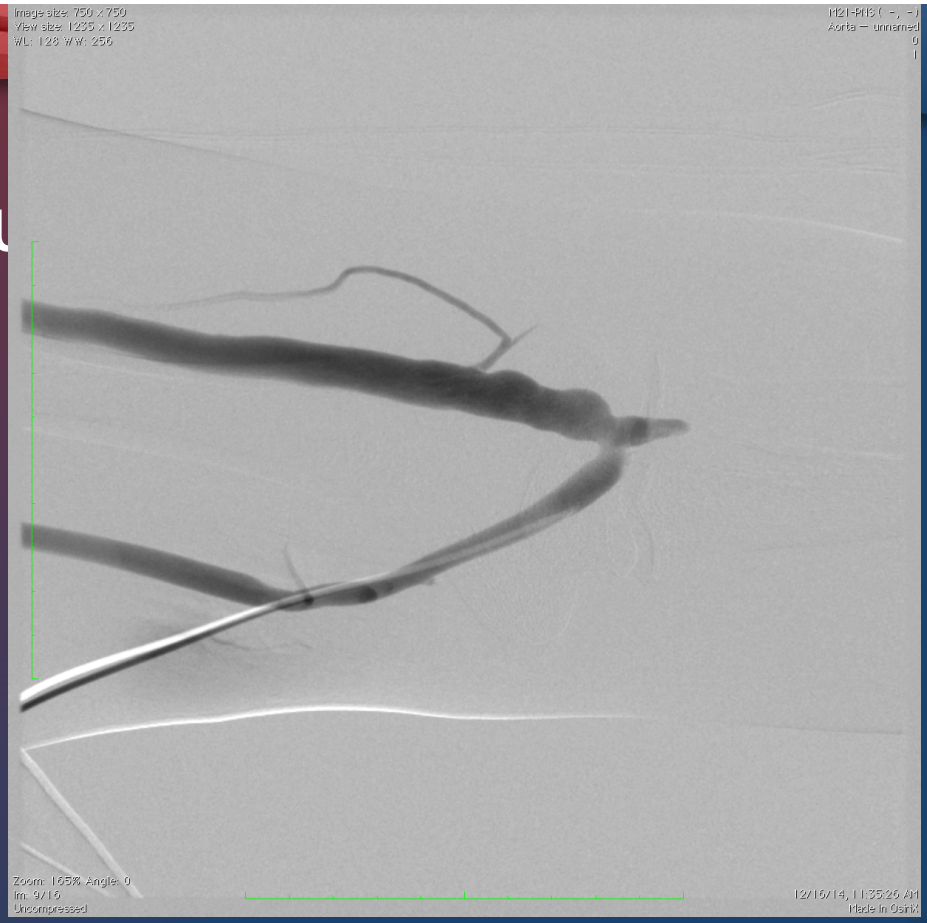
	Patients (%)	Days
Total maturation	**97 (91%)**	**35.1 ± 35.0**
PTA anastomosis	77 (72%)	22.8 ± 21.2
Embolization deep	34 (32)	26.2 ± 21.9
Embolization branch	37 (35)	23.3 ± 16.9
Cubital vein ligation	33 (31)	43.9 ± 46.3
Transposition	28 (26)	91.3 ± 45.4

Slide 33

b14 Do we really need this slide? Too much info and a lot of this is failry standard with the exception of the vessel sizes and even those are consistent with surgery.
bkellerman, 10/11/2017

i-Ou





Richmond Vascular Center

Many Elements to Successful EndoAVF Creation

- Screening with ultrasound. Up to 40% may have unsuitable anatomy
- Creation of the endoAVF.
- Maturation procedures
- Dialysis Unit Acceptance. May be the most important element!
  - Cannulation methods

Summary-Impression

- This is not a one step procedure & patients need to understand this.
- May have its greatest value in the Stage IV patient in whom time is not a critical element.
- More acceptable to patients coming to grips with their dialysis future.
- May make significant difference in patients starting dialysis with a catheter.
- Operators need to have a commitment to Access!!
- May be the ideal procedure for multidisciplinary collaboration.