Percutaneous AV Fistula Creation

Ellipsys EndoAVF® System

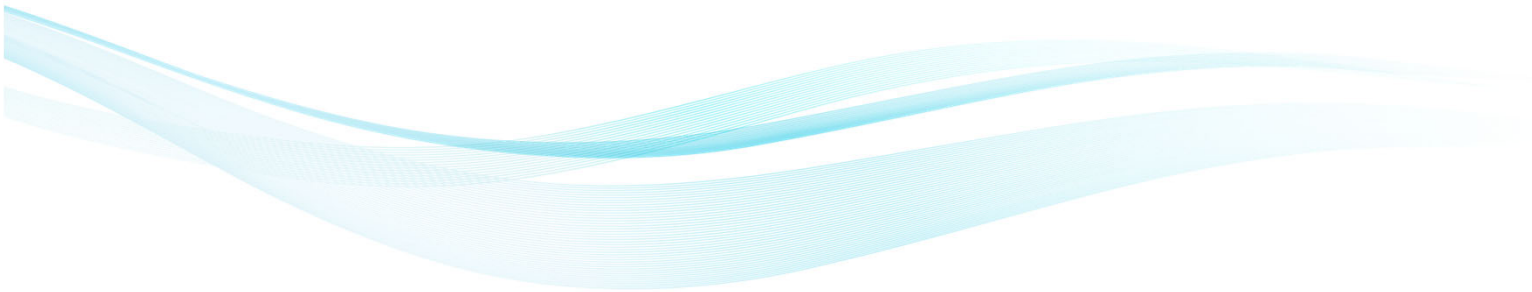
Presented by Forest Rawls Jr CHT,CCHT-A ,FNKF

- No Disclosures

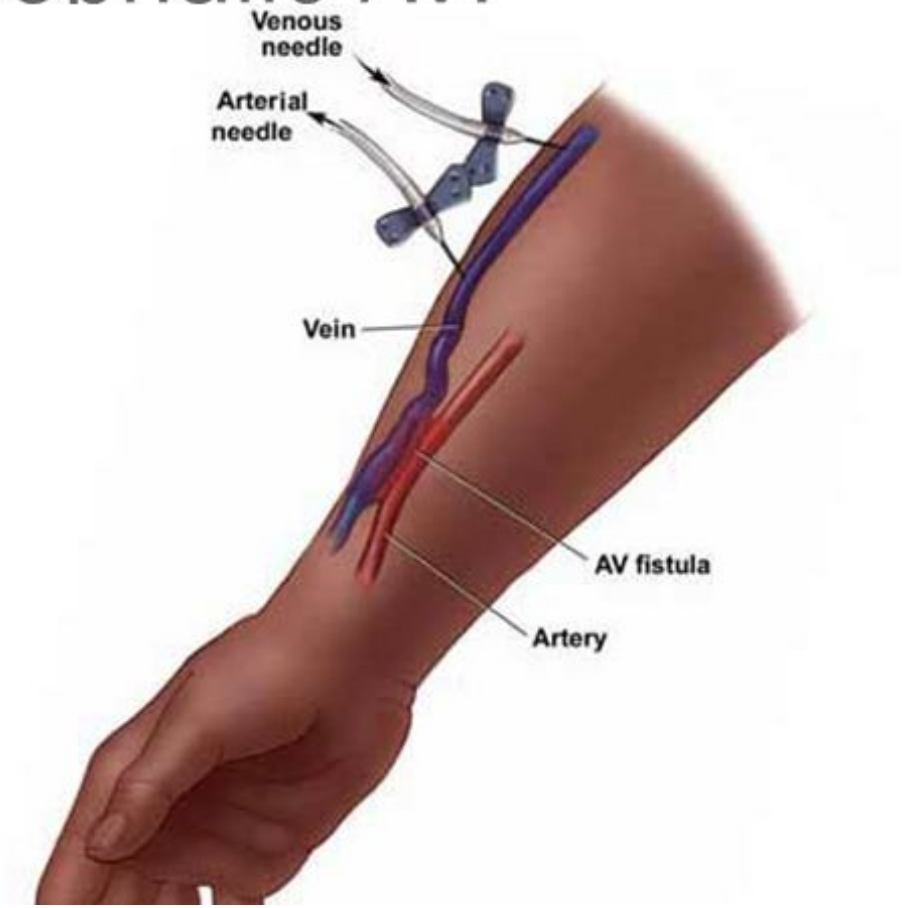
Various Access Types

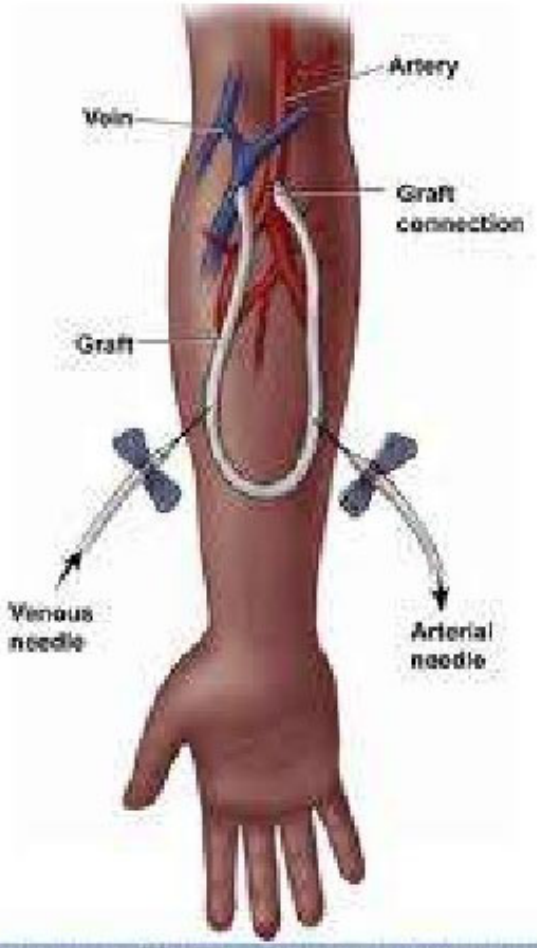
Some old

Some new



Radiocephalic AVF




Artery
Vein
Graft connection
Graft
Venous needle
Arterial needle

AV Grafts

OUR OLD DEPENDABLE FRIEND

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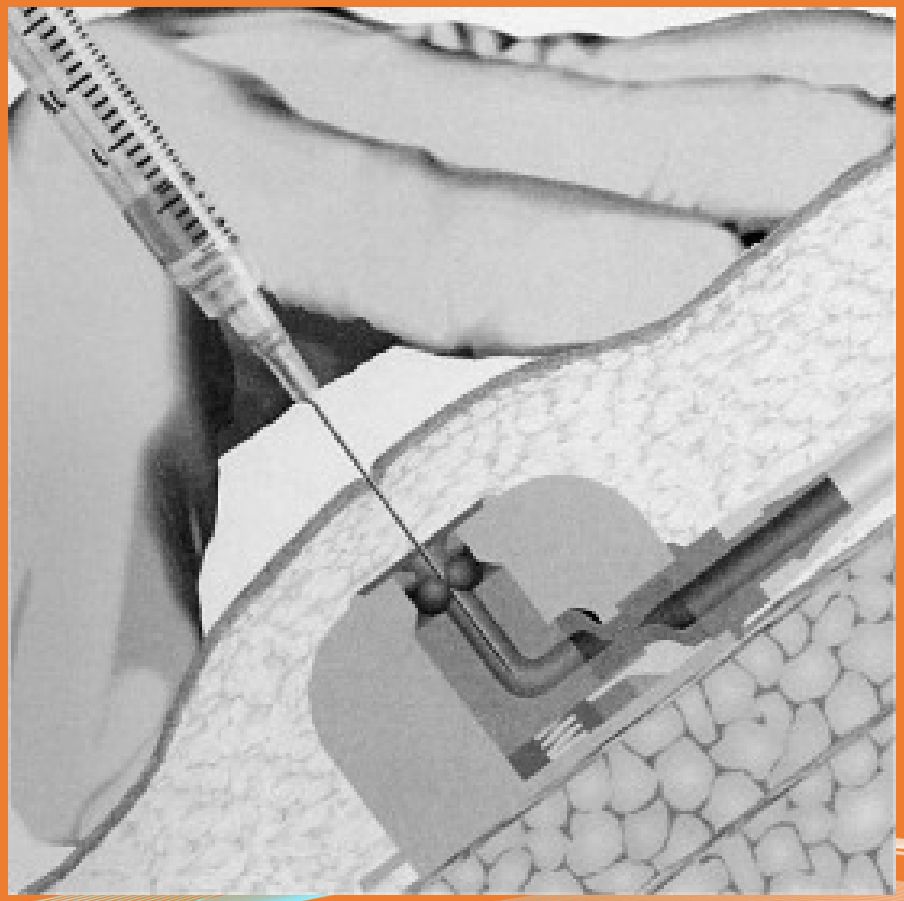
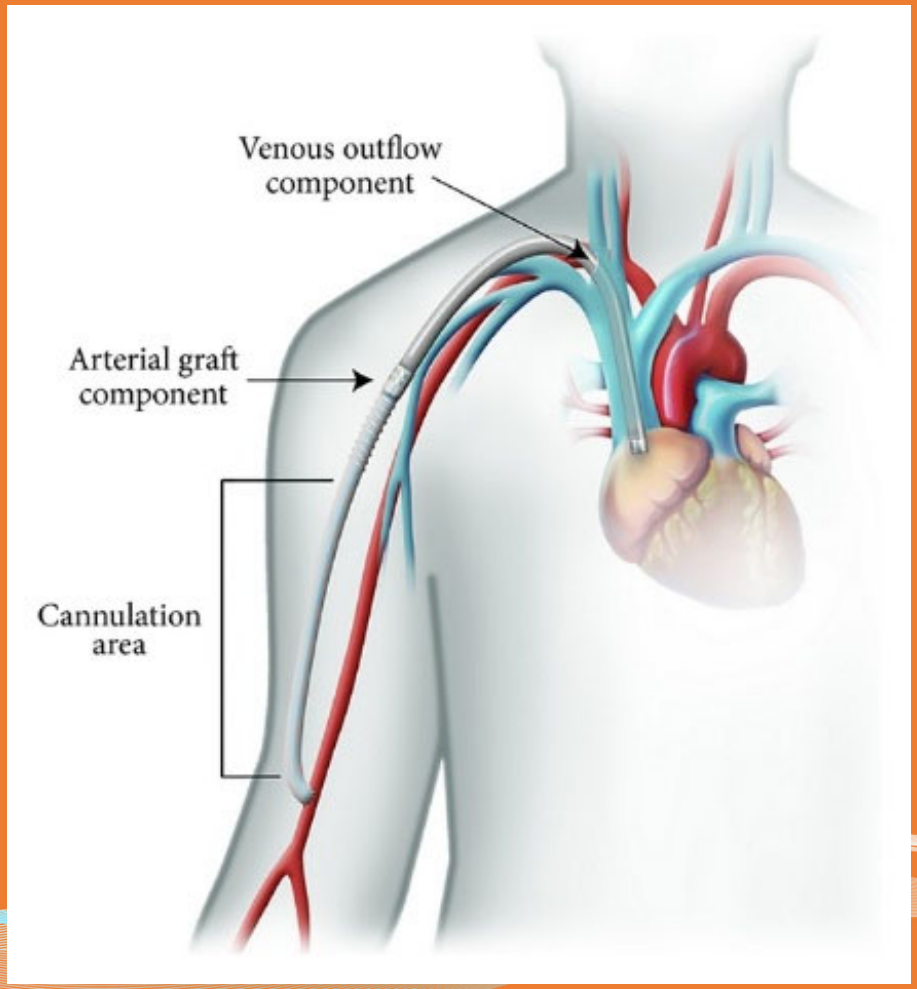


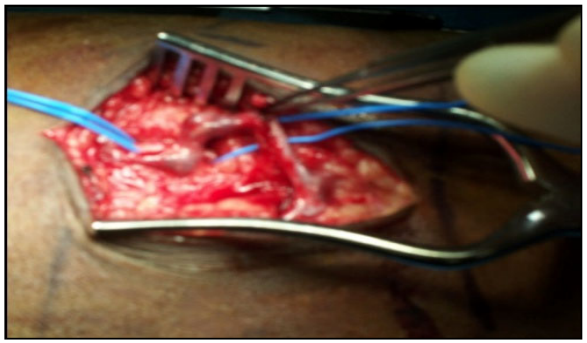

Venous outflow component
Arterial graft component
Cannulation area

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.

AVF: Current Gold Standard

- Has not changed since *1966*
- Exacting and tedious open surgery
  - 45-90 mins
- High failure/non-maturity rate
  - 30-60% at 1 year



Surgical AVF @ 1 year

Ellipsys® Vascular Access System

- 6F, single catheter
- Ultrasound guided
- Venous access
- Immediate and permanent fused anastomosis
- FDA and CE Mark approved

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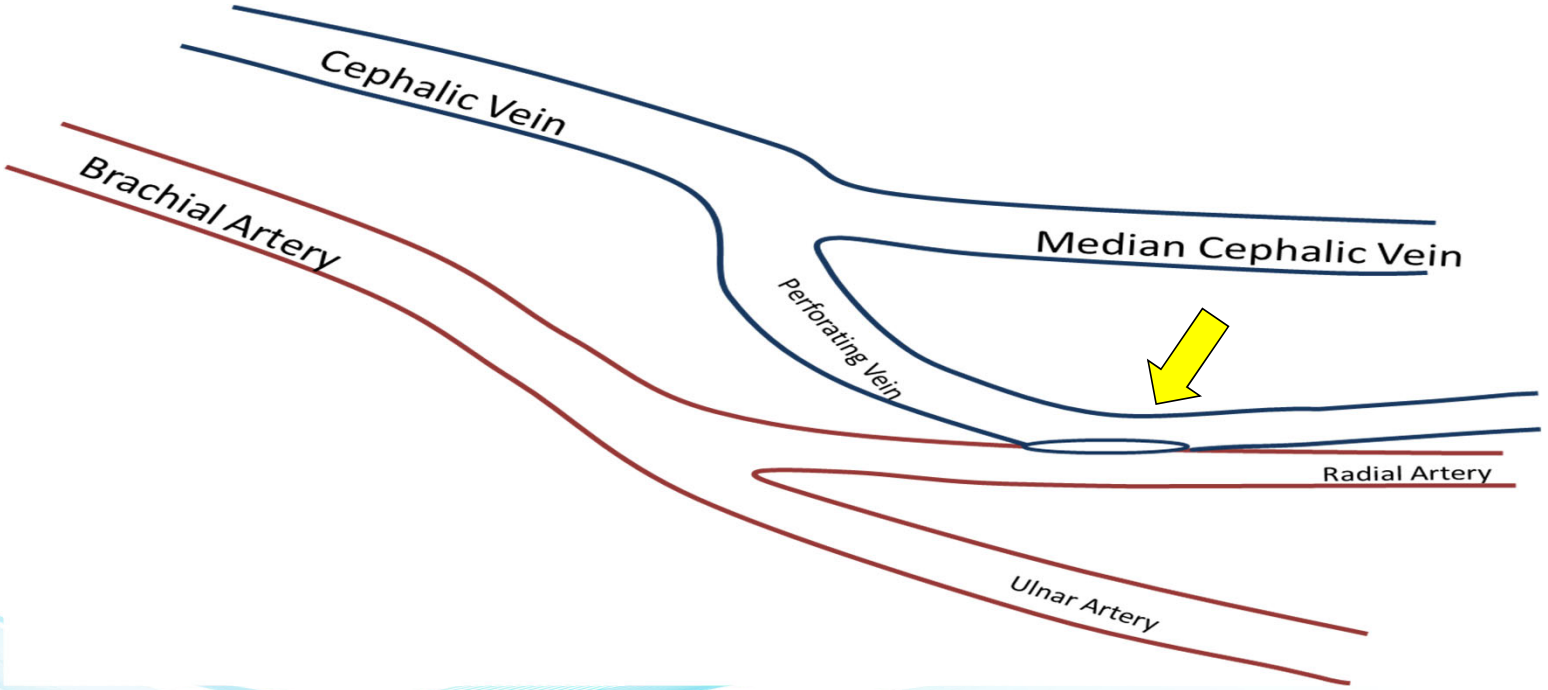
Perforating Vein/Proximal Radial Artery (PRA) Fistula

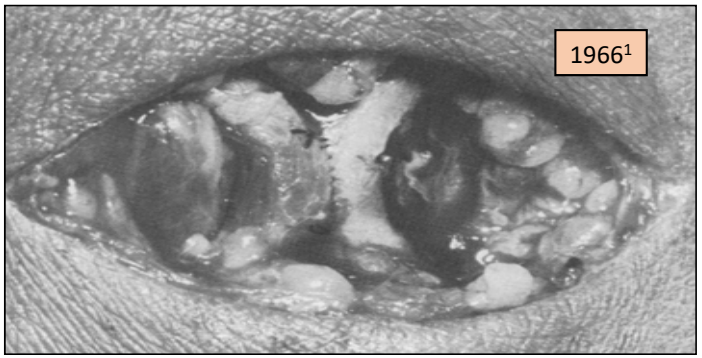


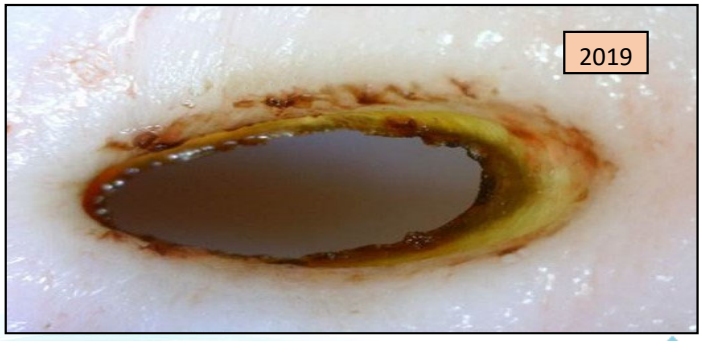
EndoAVF®

- Minimally invasive
- Short maturation time – useable quickly
  - Reduce CVC time
- Dramatic reduction in failures – early or late
- Improved functionality, patency
- Less need for ongoing maintenance procedures (angioplasty, stenting, etc.)

Surgical vs EndoAVF

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

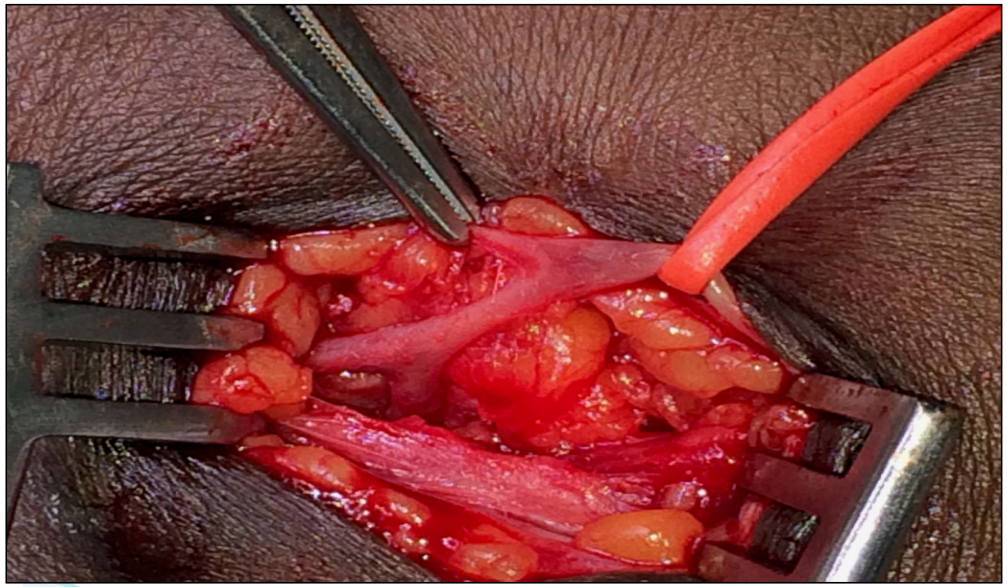
The ELLIPSYS SYSTEM

- Under high frequency ultrasound guidance The Ellipsys System uses a novel outer access cannula guidewire and vessel capture construct that creates a connection of the vein to the artery using an intravascular approach

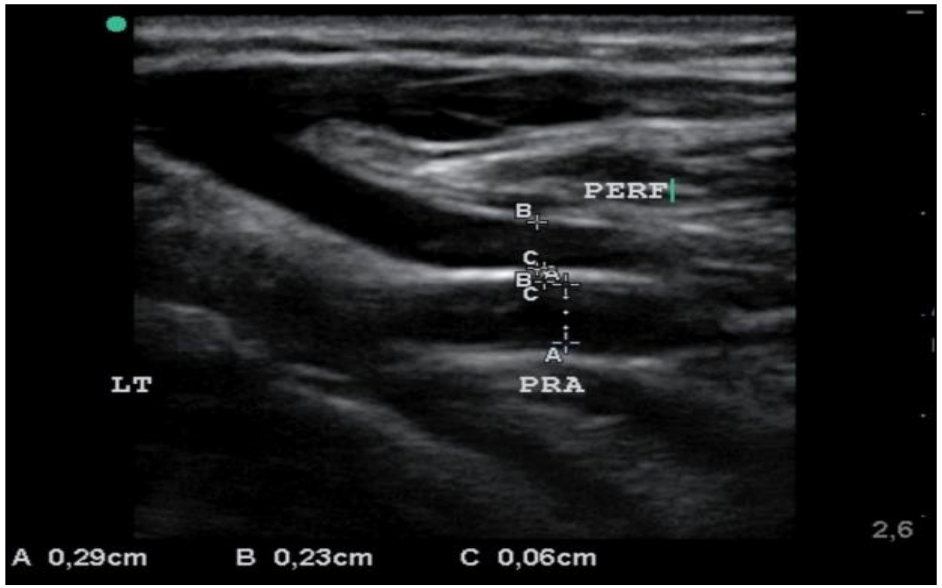
The Ellipsys System

- A select amount of low power thermal energy is used to cut the walls of the vessels and fuse the tissue creating an in-vivo anastomosis without leaving any foreign material in the resulting AV Fistula

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.

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.

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Surgery vs. Ellipsys

	Surgery AVF	Ellipsys[1]
12 Month Functional Patency	60%	92%
Functional usability @ 12 months	50%	83%
Time to Dialysis	136 days	100 days
Technical Success	100%	99%
Primary Efficacy Success	60-70%	89%
Device Related SAEs	0%	0%
Procedure Related SAEs	1%	1%
Maintenance Rate Pt./Yr.	3.5	3.1

[1]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.

BASIC PHYSICAL EXAM

- LOOK
- LISTEN
- FEEL

Physical Examination for all AVF

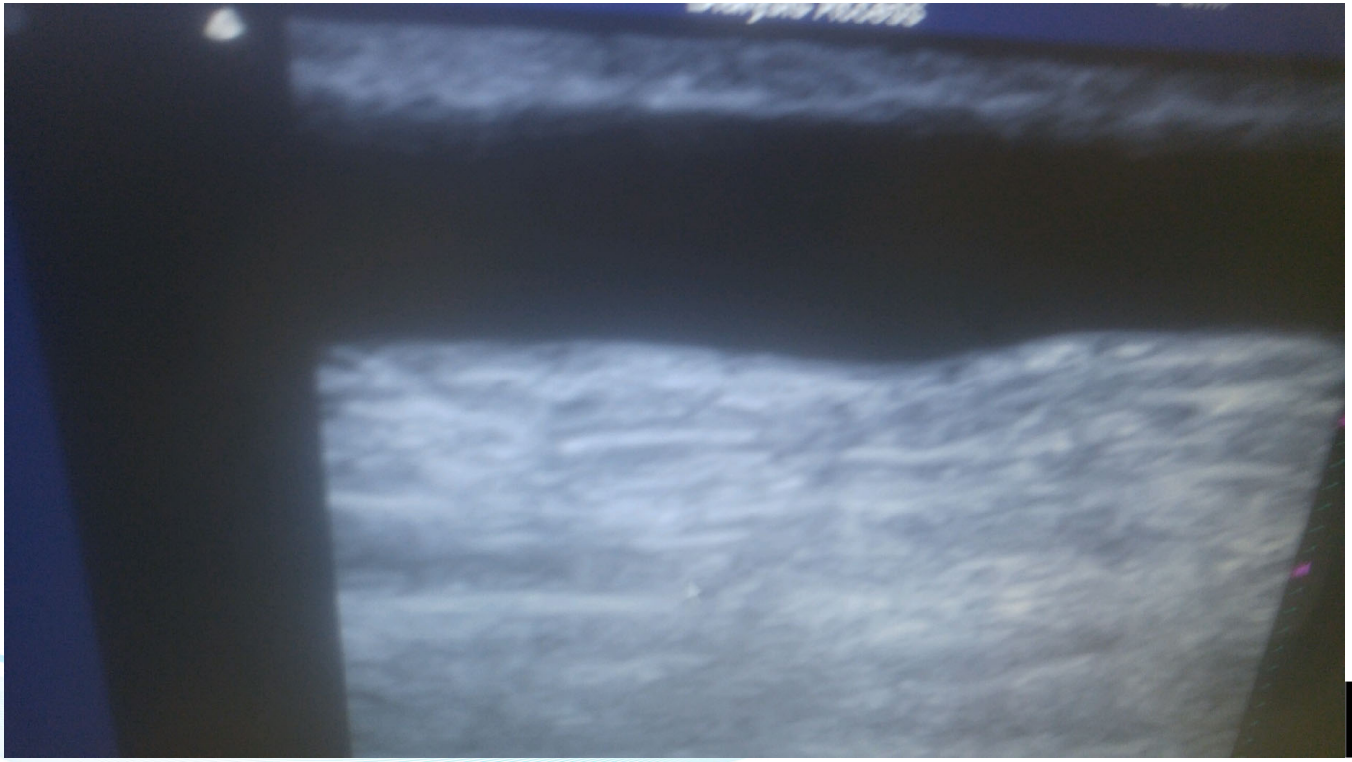
20 SECOND PROCEDURE

- Pulse
- Thrill
- Arm Elevation Test
- Augmentation Test

Normal Access

- Soft pulse/easily compressible
- Inflow area thrill
- Continuous Bruit outflow
- Detects Stenosis
- Ensures adequate inflow

Ultrasound of AVF



Marked AVF

Ellipsys Vascular Access System

- **Less Invasive**
  - Percutaneous vs. open
- **Faster**
  - 23 mins vs. 45-90 mins
- **Better**
  - No implant or sutures left behind
  - Lower complications
- **Cost Effective**
  - Decrease catheter prevalence
  - Reduces mortality, morbidity and hospitalization

Ellipsys Patients @ 1 year

THANK YOU