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
AV Grafts

200 Hours Course for Person In Charge
OUR OLD DEPENDABLE FRIEND
Replace Incision with Puncture

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
Ellipsys® Vascular Access System

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

The ELLIPSY SYS 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*
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

## Surgery vs. Ellipsys

<table>
<thead>
<tr>
<th></th>
<th>Surgery AVF</th>
<th>Ellipsys¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Month Functional Patency</td>
<td>60%</td>
<td>92%</td>
</tr>
<tr>
<td>Functional usability @ 12 months</td>
<td>50%</td>
<td>83%</td>
</tr>
<tr>
<td>Time to Dialysis</td>
<td>136 days</td>
<td>100 days</td>
</tr>
<tr>
<td>Technical Success</td>
<td>100%</td>
<td>99%</td>
</tr>
<tr>
<td>Primary Efficacy Success</td>
<td>60-70%</td>
<td>89%</td>
</tr>
<tr>
<td>Device Related SAEs</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Procedure Related SAEs</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Maintenance Rate Pt./Yr.</td>
<td>3.5</td>
<td>3.1</td>
</tr>
</tbody>
</table>

BASIC PHYSICAL EXAM

• LOOK

• LISTEN

• FEEL
### Physical Examination for all AVF

<table>
<thead>
<tr>
<th>20 SECOND PROCEDURE</th>
<th>Normal Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pulse</td>
<td>• Soft pulse/easily compressible</td>
</tr>
<tr>
<td>• Thrill</td>
<td>• Inflow area thrill</td>
</tr>
<tr>
<td>• Arm Elevation Test</td>
<td>• Continuous Bruit outflow</td>
</tr>
<tr>
<td>• Augmentation Test</td>
<td>• Detects Stenosis</td>
</tr>
<tr>
<td></td>
<td>• Ensures adequate inflow</td>
</tr>
</tbody>
</table>
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