In the interest of maintaining academic integrity, I would like to disclose the following conflicts…

“I am a founder and board member of TVA Medical, an early stage medical device company that has developed the technology described in this presentation, and in which I have a financial interest.”

This presentation describes devices and procedures that are not approved by the FDA for clinical use in the United States.
3-4 hours of hemodialysis 4 times/week can maintain the anuric patient...

...but every patient needs a reliable way to be connected to the dialysis machine.

Dual lumen central venous catheters are easy to use and provide great access...

Dual lumen central venous catheters are easy to use and provide great access...

...but catheter infections and sepsis remain serious limitations.

Prosthetic AV grafts under the skin are relatively easy to construct...
...but they are easily infected and often develop thrombosis, requiring multiple re-interventions.

There is overwhelming consensus that the best option is a native arterio-venous fistula.

AV fistulas are clinically and economically superior:

<table>
<thead>
<tr>
<th></th>
<th>Mortality</th>
<th>Infection rate</th>
<th>Reoperation rate</th>
<th>Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Venous Catheter</td>
<td>72%-84%</td>
<td>3.02</td>
<td>2.86</td>
<td>$90K</td>
</tr>
<tr>
<td>AV Graft</td>
<td>40%</td>
<td>1.01</td>
<td>1.10</td>
<td>$79K</td>
</tr>
<tr>
<td>Surgical AV Fistula</td>
<td>34%</td>
<td>0.52</td>
<td>0.47</td>
<td>$64K</td>
</tr>
</tbody>
</table>

Challenges with Surgical AV Fistulas:

- Primary failure rate: 30-60%
- Mean maturation time: 4-9 months
- Average time to usable AVF: 5-12 months
- Average interventions for successful AVF: 2-3
- Occlusions (thrombosis): 17-25%

AV Fistulas are operator dependent, have a high failure rate, require frequent interventions to maintain functionality, and often take months before they are useable for hemodialysis.

Penetrating trauma occasionally results in AV fistula formation.

1 Rates reported are per patient per year. Mortality at 3 years
2 Perl J., et al. Hemodialysis Vascular Access Modifies the Association between Dialysis Modality and Survival. JASN June 1, 2011 vol. 22 no. 6 1113-1121
4 AV Fistulas are operator dependent, have a high failure rate, require frequent interventions to maintain functionality, and often take months before they are useable for hemodialysis.

Penetrating trauma occasionally results in AV fistula formation.
Endovascular Catheter-based AVF

Advantages:
- Percutaneous, non-surgical
- No implant left behind
- No incision so reduced wound infections and complications
- Facilitates AV fistula placement by interventional and endovascular specialties in outpatient setting
- Potential to improve AVF success rates:
  - No vessel trauma
  - No surgical anastomosis

Investigational device. This product is not approved for marketing by FDA and is not available for commercial sale.

Human deep venous anatomy

Paired magnetic catheters with electrosurgical cutting capabilities

RF electrode
Venous catheter
Arterial catheter

Paired magnetic catheters with electrosurgical cutting capabilities

Strong rare-earth NdFeBo magnets
Venous catheter introduced and advanced to site chosen for AVF

Arterial catheter introduced and advanced to same location

Catheters rotated to allow magnetic alignment

Venous electrode deployed and energized for 1.2 seconds with RF

Arterial injection shows widely patent AVF without extravasation

24 hours post-procedure
FLEX Study

Multiple Cannulation Options
- Forearm cephalic + upper arm cephalic
- Forearm cephalic + median cubital / basilic
- Forearm cephalic + basilic

Study Design and Baseline Characteristics

<table>
<thead>
<tr>
<th>Total (N=33)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Age, yrs (SD)</td>
<td>51.0 (11.4)</td>
</tr>
<tr>
<td>Male (%)</td>
<td>20/33 (61%)</td>
</tr>
<tr>
<td>Average BMI (SD)</td>
<td>24.3 (3.8)</td>
</tr>
<tr>
<td>BMI &gt; 25 (%)</td>
<td>10/33 (30%)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>19/33 (58%)</td>
</tr>
<tr>
<td>PVD (%)</td>
<td>2/33 (6.1%)</td>
</tr>
</tbody>
</table>

Primary endpoints:
- Technical success
- Fistula patency and vein maturation at 8-12 weeks with angiography and ultrasound
- Adverse events

Secondary endpoint:
- Creation of usable hemodialysis access (at least 75% of dialysis sessions for at least 4 weeks duration)
FLEX Study Summary

Clinical Results
• Demonstrated clinical success
• 97% technical fistula success (32/33)
• 96% patency at 6 months
• Avg. procedure time 49 min
• 27 patients initiated dialysis or dialysis ready
• 25 patients > 1 month dialysis
• Avg. 58 days to AVF maturation
• 1 serious device-related adverse event; mitigated with procedure change

Fistula Maturity

Technical

Fistula

Maturity

Clinical

Results

97%

96%

96%

96%

Surgical AVF

Catheter-based endoAVF

Successful AVFs

Successful endo AVFs 96%

Thrombosis 17-25%

Transstenosis 17-25%

Other Failures

Successful AVFs

Primary Objective

To characterize the safety of the FLEX system (6 months) in up to 70 patients with CKD who require a hemodialysis vascular access

Study Design

Multi-center, prospective, single-arm study. Canada, Australia, and New Zealand

Primary Endpoint

Percentage of patients who experience one or more serious device-related adverse events during the first 6 months following AVF creation

Additional Data Collected

Fistula efficacy: The percentage of AV fistulas that can provide prescribed hemodialysis aimed to achieve a spKt/V of > 1.2 or Urea Reduction Ratio (URR) of > 65% using 2 needle cannulation for ≥ 67% of the dialysis sessions over 4 consecutive week period within 6 months of fistula creation

Interventions

Ultrasound flow rates

Novel Endovascular Access Trial

PRIMARY OBJECTIVE

To characterize the safety of the FLEX system (6 months) in up to 70 patients with CKD who require a hemodialysis vascular access

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Multi-center, prospective, single-arm study. Canada, Australia, and New Zealand

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Interventions

Ultrasound flow rates

1st NEAT study patient @ 6 months
Conclusions

- Percutaneous catheter-based creation of AV fistulas is a new technique that has the potential to change the way dialysis access is created.
- The technique is safe, reproducible, and prescriptive.
- By putting this technique in the hands of interventional and endovascular specialist, earlier and more frequent creation of AVF may decrease dependence on central venous catheters.
- Early clinical data suggests that in-situ catheter-based AVFs may be superior to surgical AVF with respect to patency, need for re-intervention, and time to usability.
- Additional study is needed.
- Initiating North American/Australian/New Zealand study.
  Charmaine Lok M.D. principle investigator; Dheeraj Rajan M.D. Co-PI