The past, present and future of the WavelinQ™ 4F EndoAVF System

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Disclosure

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The physician has been compensated by Becton, Dickinson and Company to participate in this presentation.
“Taking a new step, uttering a new word, is what people fear most.”

Dostoevsky, Crime and Punishment
Goals of successful dialysis access

- Usable for dialysis
- Minimal complications
- Optimal patient experience
Arteriovenous fistula (AVF)

- Preferred access for dialysis
- Until recently, only created via open surgery
- Limited number of surgical creation sites
- Single-vessel outflow is most common

Diagram showing various types of fistulas:
- Radiocephalic
- Brachiocephalic
- Brachiobasilic
- Proximal radial
Variable maturation results with surgical AVF

• 28-53% fail to mature\(^1\)

• **3-4 months** average AVF maturation time\(^2\)

• **Flow limiting lesions**, often at the site of surgery, are associated with maturation failure

• **3.4 interventions** per year needed on average to maintain a working AVF\(^3\)

2. USRDS 2017.
Surgical fatigue & inconvenience for patients

• Multiple pre-operative visits with surgeon, anesthesia & others
• Experience of failed prior AVFs
• Procedures to facilitate AVF maturation
• Pain
• Emotional drain of diminishing “lifeline”
Low-pressure, split-flow endoAVF

- Multiple outflow vessels can dilate and mature
- Lower flow rates through any single vessel
- Minimal vessel trauma
- Preserves future surgical options

Image of an endoAVF at day 30 viewed from a dissected iliac artery of a sheep model.

- Split outflow enables multiple cannulation zones
- Perforating vein sends outflow from deep to superficial venous system
- Consistent channel created with short burst of RF energy
**Procedure Outcomes**: WavelinQ™ 4F EndoAVF System

**Procedure Success**
- N=91
- 97% Procedure Success

**Safety Analysis**
- 3% (3/91) device related serious adverse events
- 6% (5/91) of patients experienced a procedure-related serious adverse event
- Zero access related complications
  - Proper vessel access and hemostasis are important
  - Manual compression is recommended

**Procedure success**: Successful endoAVF creation confirmed via intraprocedural fistulography or by duplex ultrasound performed post-procedure.

**Serious adverse event**: Defined as an adverse event that (1) lead to death, (2) led to serious deterioration in the health of the subject, that either resulted in a life threatening illness or injury, or a permanent impairment of a structure or body function, or inpatient or prolonged inpatient hospitalization, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or function, (3) led to fetal distress, fetal death or a congenital abnormality or birth defect.

*4F Pooled Analysis Population, N=91*
Data pooled in November 2018 from 7 sites across 3 studies within Germany, United Kingdom, and Paraguay. Enrolled subjects had chronic kidney disease and were in need of hemodialysis (including pre-dialysis patients) and were anatomically suitable for endoAVF creation. Subjects were treated with the WavelinQ™ 4F EndoAVF System. BD data on file.
Maturation success with WavelinQ™ EndoAVF System

NEAT Study Criteria
The fistula should be free from thrombosis or stenosis and have:

• A brachial arterial flow rate of at least 500 ml/min
• A minimum vein diameter of 4 mm.

N=60

BD Data on file. NEAT study evaluated patients with an endoAVF created by the WavelinQ™ 6F System.
Cannulation success
with WavelinQ™ 4F EndoAVF System

85%
2-Needle Cannulation Success
Dialysis Patients at 6 Months*
(±5.3%)

Defined as successful 2-needle cannulation and dialysis through the endoAVF

1.5 month
Median Time to Cannulation
IQR 1.1-2.0
Mean 2.0±1.6 mo

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*Kaplan-Meier Estimate
Fewer interventions with WavelinQ™ 4F EndoAVF System

<table>
<thead>
<tr>
<th>Intervention</th>
<th>4F Pooled Effectiveness (N=91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsequent vein embolization</td>
<td>5</td>
</tr>
<tr>
<td>Balloon angioplasty</td>
<td>10</td>
</tr>
<tr>
<td>Stent</td>
<td>2</td>
</tr>
<tr>
<td>Thrombectomy and thrombolytic therapy</td>
<td>4</td>
</tr>
<tr>
<td>Transposition</td>
<td>5</td>
</tr>
<tr>
<td>Surgical AVF/AVG</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total Interventions</strong></td>
<td><strong>33</strong></td>
</tr>
</tbody>
</table>

78% of patients (71/91) were intervention-free 6 months post WavelinQ™ 4F EndoAVF procedure.
Fewer interventions vs. surgical AVF

~6X fewer post-creation interventions per patient-year with WavelinQ™ 6F EndoAVF compared to a propensity-score matched surgical AVF cohort

* Includes infection due to CVC while AVF maturing

Cannulating WavelinQ™ 4F EndoAVF

Images courtesy of Nick Inston, M.D., PhD and Robert Jones, M.D.

Disclaimer: These patient images are shared as an example of potential outcomes for endoAVF patients. Individual patient outcomes can and do vary based on condition of the patient, severity of disease, extent of surgery, and response to treatment.
Looking toward the future

*Where might WavelinQ™ 4F EndoAVF System offer an advantage in my practice?*

- Pre-dialysis
- Limited surgical options
- Fistulas with alternative outflow (basilic and brachial vein)
For pre-dialysis patients

Minimally-invasive procedure, does not require surgery
  • Low doses of contrast imaging used during procedure
    – Doses can be low and no adverse impact on kidney function in pre-dialysis patients has been demonstrated.

In the WavelinQ™ 4F EndoAVF System pooled clinical data:
  • 16% (4/25) of pre-dialysis patients started dialysis with a CVC
  • 78% of patients (71/91) were intervention-free at 6 months
For patients with poor vessels

- Failed or non-ideal RC-AVF
- CV injured through venipuncture
- ?? Will CV be suitable
- ??straight to BB
My experience with the conditioning fistula

Pre-procedure venogram
Marginal vessels in the upper arm: cephalic vein (CV), brachial vein (BrV), basilic vein (BaV) and perforator (P)

Post-WavelinQ™ 4F fistulagram
Vessels all have increased flow and potential to mature into suitable fistula conduits, although the CV appears to be dominant vessel
Basilic vein fistulas

- No CV option
- Ideal as a 1st stage brachiobasilic procedure
Brachial vein fistulas

- No CV & no BB option
- Use the deep system
- Ulnar or radial brachial
- No coils

![Diagram of hand and arm with blood vessels and 
WavelinQ™ 4F EndoAVF Radial-Radial and 
WavelinQ™ 4F EndoAVF Ulnar-Ulnar connections marked.]
Brachial vein fistula: case example

- Young patient
- Multiple previous venesections/cannulas
- Failed 1st stage BB AVF
- WavelinQ™ 4F radial-brachial endoAVF created 4 weeks before

Images courtesy of Nick Inston, M.D.
Images courtesy of Nick Inston, M.D.
WavelinQ™ 4F EndoAVF System + brachial vein fistula

Images courtesy of Nick Inston, M.D.
Conclusion

• Split-flow WavelinQ™ 4F EndoAVF System creates flexibility for future options

• WavelinQ™ 4F EndoAVF System creates a functional AV fistula without open surgery

• Potential for extending options requires further exploration to maximize their use for patient benefits
THANK YOU
**Indications**
The WavelinQ™ 4F EndoAVF System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

**Contraindications**
Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known allergy or reaction to any drugs/fluids used in this procedure. Known adverse effects to moderate sedation and/or anesthesia. Distance between target artery and vein > 1.5 mm. Target vessels < 2 mm in diameter.

**Warnings:**
The WavelinQ™ 4F EndoAVF System is only to be used with the approved commercially available devices specified in the instructions for use. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. The WavelinQ™ 4F EndoAVF System catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure potentially resulting in serious injury or death. Use caution when performing electrosurgery in the presence of pacemakers. Improper use could damage insulation that may result in injury to the patient or operating room personnel. Do not plug device into the electrosurgical pencil with ESU on. Keep active accessories away from patient when not in use. Do not permit cable to be parallel to and/or in close proximity to leads of other devices. Do not wrap cable around handles of metallic objects such as hemostats. Consult the ESU User’s Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access.

**Cautions:**
Only physicians trained and experienced in endovascular techniques should use the device. Adhere to universal precautions when utilizing the device. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the devices. Damage to the catheter body may cause the device to become inoperable. Avoid sharp bends. This may cause the device to become inoperable. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable. Do not bend the rigid portion of the catheter near the electrode or backstop. Do not touch or handle the active electrode. Electrode dislodgement may occur. Always use the hemostasis valve crosser to assist insertion of the venous catheter through the introducer sheath. Insertion into introducer sheath without hemostasis valve crosser may damage electrode. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

**Precautions:**
Care should be taken to avoid the presence of fluid on the ESU. Care should be taken during handling of the arterial and venous catheters in patients with implantable cardiac defibrillators or cardiac pacemakers to keep the distal 3 inches of the catheters at least 2 inches from the implanted defibrillator or pacemaker. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed. If the device does not perform properly during the creation of the endovascular fistula it is possible that a fistula will not be created or there may be some vessel injury. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.

**Potential Adverse Events:**
The known potential risks related to the WavelinQ™ 4F EndoAVF System and procedure, a standard AVF, and endovascular procedures may include, but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma, or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling, and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; sepsis; steal syndrome or ischemia; swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

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**Indications for Use**

The TVA Medical everlinQ System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

**Contraindications**

Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known allergy or reaction to any drugs/fluids used in this procedure. Known adverse effects to moderate sedation and/or anesthesia. Distance between target artery and vein > 2mm. Target vessels < 2mm in diameter. Do not use closure devices for arterial access hemostasis.

**Warnings**

The TVA Medical everlinQ System is only to be used with the approved components specified in the instructions for use. Do not attempt to substitute a non-approved component or to use any component of this system with any other medical device system. The everlinQ catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure potentially resulting in serious injury or death. Use caution when performing electrosurgery in the presence of pacemakers. Improper use could damage insulation that may result in injury to the patient or operating room personnel. Keep active accessories away from patient when not in use. Do not permit cable to be parallel to and/or in close proximity to leads of other devices. Do not wrap cable around handles of metallic objects such as hemostats. Consult the ESU User’s Guide on its proper operation prior to use.

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The known potential risks related to the everlinQ device and procedure, a standard AVF, and endovascular procedures may include but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling, and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; sepsis; steal or ischemia; swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

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WavelinQ™ EndoAVF System has been previously referred to as the everlinQ™ endoAVF System

Not intended for U.S.
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