Different Approaches For WavelinQ™ 4F EndoAVF System Vascular Access

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Disclosure

Speaker name: Robert Shahverdyan, M.D.

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
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- Other(s)
- I do not have any potential conflict of interest

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Uses of WavelinQ™ 4F EndoAVF System

 **Primary Access Creation**
  First option to provide a patient with a functioning fistula who are ineligible for RCAVF

 **Secondary Option to RCAVF**
  Provided to patients that have a failed RCAVF

 **Alternative to Surgery**
  Patients that refuse surgical AVF creation
Primary/Secondary Option

- Ideal RCAVF candidates should still receive surgery\(^1\)
  - Radial artery $\geq 2.0$ mm
  - Absence of atherosclerosis or calcification
  - Strong 2+ radial pulse
  - Cephalic vein at the wrist $\geq 2.5$ mm

- Non-ideal or failed RCAVF should be evaluated for endoAVF

\(^1\) Kim et al. J Vasc Surg 2015; 62:442-7
Alternative to Surgery

~30% PATIENTS

REFUSED SURGICAL CREATION

Major Reasons Patients Claim to Refuse AVF/AVG for a CVC

Case Example – Alternative to Surgery

Patient Demographics

- **Age**: 29
- **Sex**: male
- **Access History**:
  - *CVC on* right-side
  - *Failed RCAVF on* left-side
- **Comorbidities**: occluded left radial artery, hypertension, failing kidney transplant
- **Anatomy**
- **Patient refused surgical creation**
Case Example – Procedure
Case Example – Procedure
Case Example – Procedure
Case Example – Alternative to Surgery

Patient Demographics
• Age: 29
• Sex: male
• Access History:
  • CVC on right-side
  • Failed RCACF on left-side
• Comorbidities: occluded left radial artery, hypertension, failing kidney transplant
• Anatomy
• Patient refused surgical creation

Outcomes
• Procedure outcome
  - 48 minutes
  - 4 ml contrast agent
  - 336 ml/min flow
• How long to mature
  - <4 weeks
• Current status
  - no HD yet, patent according to nephrologist
Case Example – FU

Cephalic Diameter: 5.7 mm

Flow Rate: 612 ml/min
Additional Ways I Use WavelinQ™ 4F EndoAVF System

- **Conditioning Fistula**
  Pre-dilate/arterialize undersized veins for future surgical AVF

- **Two-stage Brachial Vein Transposition**
  Arterialize the brachial vein from the proximal forearm to prepare long venous segment for transposition
Conditioning/Two-Stage Fistulae

- **Conditioning Fistula**
  - Has perforating vein
  - Superficial veins ≤ 2.5 mm
  - EndoAVF can arterialize veins for upper arm AVF

- **Two-Stage Brachial Transposition**
  - Inadequate perforating and superficial veins
  - Arterializes the brachial vein from proximal forearm for additional vein segment not typically available for surgery

![Diagram of vascular access systems](attachment:diagram.png)
Case Example: Brachial Vein Elevation

Patient Demographics

- **Age**: 66
- **Sex**: male
- **CVC on the right-side**
- **No prior surgical fistula**
- **Comorbidities**: HIT, PE
- **Anatomy**
Case Example – Procedure
Case Example – Procedure
Case Example: Brachial Vein Elevation

Patient Demographics
- Age: 66
- Sex: male
- CVC? yes, right-side
- Access history? none
- Comorbidities: HIT, PE
- Anatomy

Outcomes
- Procedure outcomes:
  - 90 minutes (first 4F case)
  - 8 ml contrast agent
  - 560 ml/min flow
- Maturation in <4 weeks
- Planned elevation 4 weeks later
- Current status: patent >12 mo.
Case Example: Brachial Vein Elevation
Case Example: Brachial Vein Elevation

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Unterschrift

Diagnose: TM 7. E in Auffüllung

Therapie: 1. Vorsehung der Venenüberschneidung
2. Duplexuntersuchung - fahrlässig über (Palmaris 8 cm, A. pop.)
3. Silikonseid (hochisiert) in (5x)

Anordnung: 1. Lage im Arm 2-4 Fuhren
2. 10 Fuhren ultrazollack (zu und schnell)
3. Silikonseid nach Duplexunter. in 6 Wochen
4. Langzeitbettruhe in 2.3 Wochen

[Hand diagram with veins highlighted]
Case Example: Brachial Vein Elevation
Conclusion

**WAVELINQ™ 4F EndoAVF System** proximal forearm location enables a variety of strategies to provide patients with a functional fistula.

- Primary creation
- Secondary option to failed RCAVF
- Alternative to surgery
**WAVELINQ™ 4F EndoAVF System IFU**

**INDICATIONS**
The everlinQ 4 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**
1. Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation.
2. Known allergy or reaction to any drugs/fluids used in this procedure.
3. Known adverse effects to moderate sedation and/or anesthesia.
4. Distance between target artery and vein > 1.5 mm.
5. Target vessels < 2 mm in diameter.

**WARNINGS, CAUTIONS, PRECAUTIONS**

**Warnings**
1. The everlinQ 4 System is only to be used with the approved commercially available devices specified above. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system.
2. The everlinQ 4 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.
3. Use caution when performing electrosurgery in the presence of pacemakers.
4. Improper use could damage insulation that may result in injury to the patient or operating room personnel.
5. Do not plug device into the electrosurgical pencil with ESU on.
6. Keep active accessories away from patient when not in use.
7. Do not permit cable to be parallel to and/or in close proximity to leads of other devices.
8. Do not wrap cable around handles of metallic objects such as hemostats.
9. Consult the ESU User’s Guide on its proper operation prior to use.
10. Do not use closure devices not indicated to close the artery used for access.

**Cautions**
1. Only physicians trained and experienced in endovascular techniques should use the device.
2. Adhere to universal precautions when utilizing the device.
3. 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.
4. Avoid sharp bends. This may cause the device to become inoperable.
5. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable.
6. Do not bend the rigid portion of the catheter near the electrode or backstop.
7. Do not touch or handle the active electrode. Electrode dislodgement may occur.
8. 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.
9. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

**Precautions**
1. Care should be taken to avoid the presence of fluid on the ESU.
2. 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.
3. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed.
4. 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.
5. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.

**DISCLAIMER:** The WAVELINQ™ 4F EndoAVF System has been previously referred to as the everlinQ™ endoAVF System.