CASE STUDY

WavelinQ™ EndoAVF Creation Prior to Hemodialysis Initiation

Left proximal radial artery to lateral radial vein AV fistula placed in a patient pre-dialysis, who went on to have two-needle cannulation and successful hemodialysis without the need for catheter placement.

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The opinions and clinical experiences presented herein are for informational purposes only. The results presented in this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes. The clinician has been compensated by Becton, Dickinson and Company to participate in this case study.

Product Overview

The WavelinQ™ EndoAVF System is a non-surgical alternative for AV fistula creation. Using two thin, flexible, magnetic catheters and a burst of RF energy, proceduralists can create an endovascular AV fistula.

The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. It is contraindicated for patients with target vessels <2.0 mm in diameter.

Patient Background

A 74-year-old male was referred by his nephrologist for vascular mapping and evaluation due to stage 4 chronic kidney disease. The patient had a complex past medical history including hypertension, coronary artery disease, type 2 diabetes mellitus, congestive heart failure, anemia, gout, alcoholism, cholelithiasis, cerebrovascular disease, left ventricular ejection fraction less than 50%, moderate to severe pulmonary artery hypertension, and insomnia.

Patient medications included allopurinol 100 mg twice daily, Lipitor 10 mg daily, diltiazem 120 mg daily, folic acid 1 mg daily, Lasix 40 mg twice daily, hydralazine 10 mg three times a day, insulin prn, Nexium 20 mg daily, spironolactone 25 mg daily, thiamine 100 mg daily, vitamin B complex 1 tab daily, Coumadin 3 mg daily. No known drug allergies.

In clinic, he was found to be afebrile and vital signs were within normal limits.

WavelinQ™
EndoAVF System

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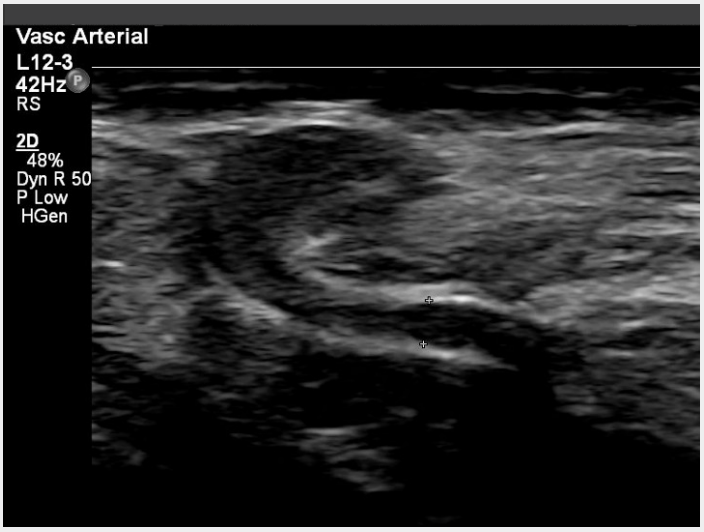
Vessel Mapping

Duplex evaluation of the upper extremities bilaterally indicated that the patient was an anatomically-appropriate candidate for endovascular arteriovenous fistula (endoAVF) creation in both the right and left upper extremities. The patient was right-extremity dominant. Because of its lack of tortuosity, the perforator vein in the left upper extremity was deemed best suited for endoAVF creation with the WavelinQ™ EndoAVF System.

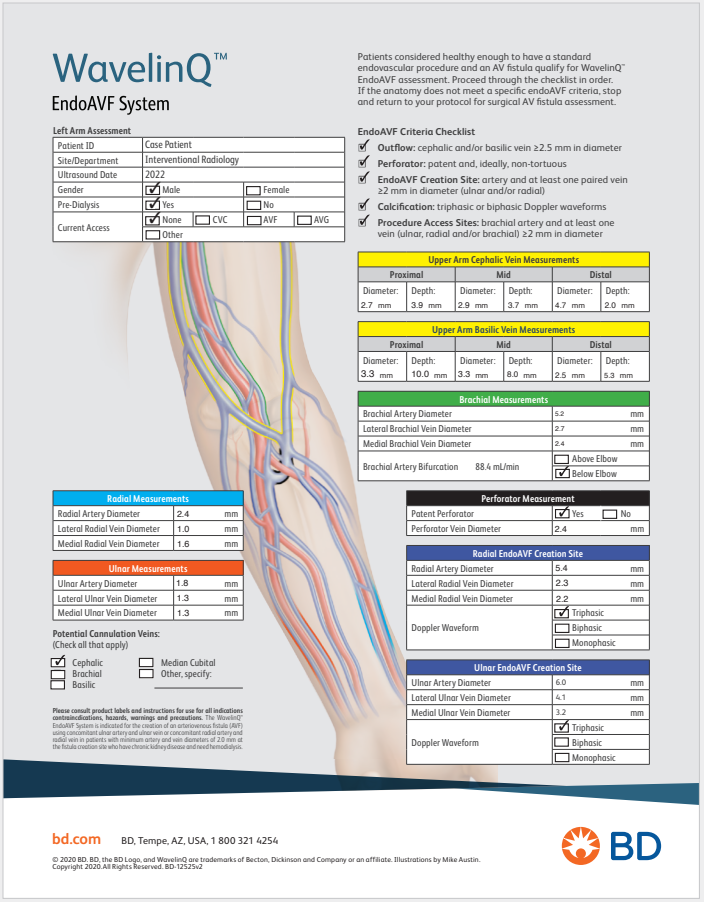


Pre-procedure vessel mapping.

Vessel mapping study of the left upper extremity revealed the following vessel diameters:

- Perforator 2.4 mm
- Brachial artery 5.2 mm with flow of 88 mL/min
- Proximal radial artery 5.4 mm
- Lateral radial vein 2.3 mm
- Medial radial vein 2.2 mm
- Proximal ulnar artery 6.0 mm
- Lateral ulnar vein 4.1 mm
- Medial ulnar vein 3.2 mm

The cephalic vein measured 2.0 mm distally to 3.9 mm centrally. The depth of the cephalic vein throughout its course was between 2.7 mm and 4.7 mm. No definite connection to the basilic vein was identified on screening ultrasound exam.



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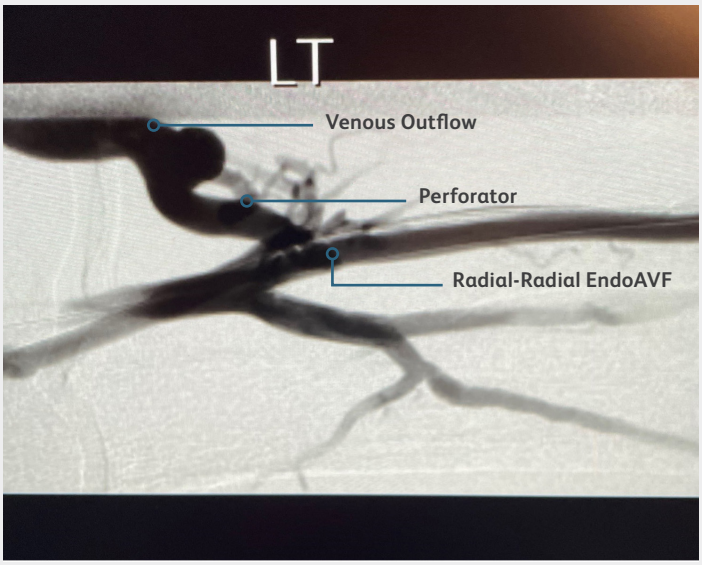
Procedure

On the day of the procedure, the patient underwent ultrasound-guided left supraclavicular brachial plexus block with 2% lidocaine.

Utilizing real-time ultrasound guidance, a 20-gauge needle and a transitional dilator, access into the distal left lateral radial vein was performed and a 5 French sheath was placed. Dedicated venogram was performed. Catheter was advanced to the level of the perforator vein and dedicated venogram was performed. Catheter was then advanced beyond the perforator vein and into the lateral brachial vein and venogram was performed.

Utilizing real-time ultrasound guidance, a 21-gauge needle and a transition dilator, access into the left brachial artery was performed and a 5 French sheath was placed. 200 mcg of Nitroglycerin, 2.5 mg of Verapamil and 2500 units of heparin were administered through the side arm of the arterial sheath. Dedicated angiogram of the left upper extremity was performed. Wire was advanced into the radial artery.

With 0.014" wires in correct position extending from the lateral radial vein into the lateral brachial vein and from the brachial artery into the radial artery, the magnetic WavelinQ™ EndoAVF catheters were then advanced. The location for the anastomosis was chosen just opposite the large perforating vein. Imaging was performed in various projections showing proper coaptation of the catheters in the widest view. Radiofrequency energy was then delivered through the venous catheter for 0.7 seconds at 60W of power. There was immediate visualization of the venous device aligning with the receiving arterial device. Catheters were withdrawn. Follow-up imaging immediately showed excellent flow from the proximal left radial artery to the proximal left lateral radial vein and into the perforating vein and cephalic vein.



Post-creation fistulogram.

Further imaging was performed to capture additional projections. Wires were carefully advanced from the venous access into the lateral brachial vein and two 7-mm coils were deployed into the distal-most aspect of the left lateral brachial vein just adjacent to the perforator vein to promote further development of outflow into the cephalic vein. The venous sheath was removed and hemostasis was obtained with manual compression. A sterile dressing was applied. The arterial sheath was then removed and hemostasis was obtained with manual compression. Sterile dressing was applied. The patient tolerated the procedure well. Excellent thrill was palpated in the cephalic vein at the end of the procedure.

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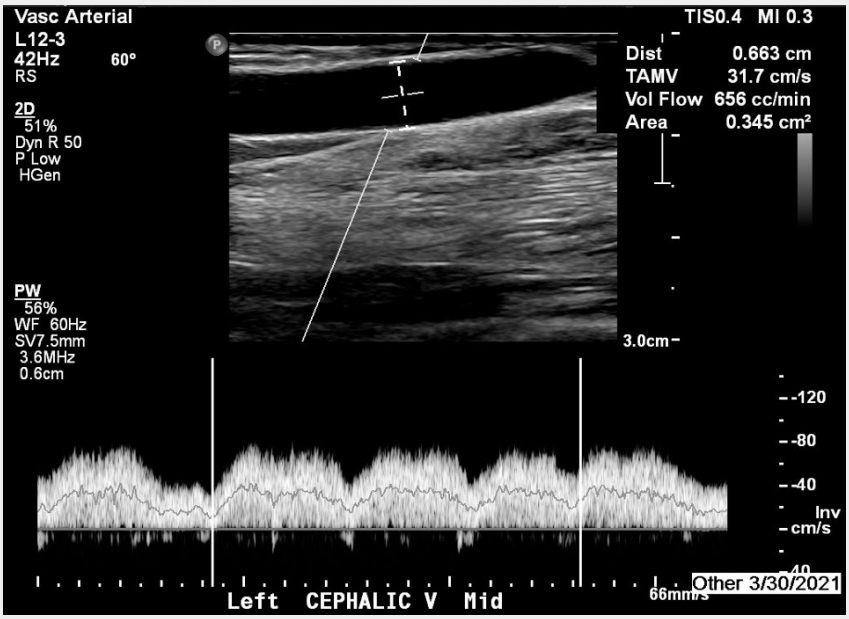

2-week post-procedure ultrasound.

Access for dialysis.

Follow-Up

Follow-up duplex ultrasound was performed two weeks later with the brachial artery measuring 6.6 mm in diameter. Flow through the distal brachial artery at the level of the anastomosis measured 1454 mL/min. Flow through the medial brachial vein measured 437 mL/min. Flow through the mid cephalic vein measured 656 mL/min.

At six weeks, the endoAVF was hemodynamically mature and cleared for cannulation; however, hemodialysis was deemed not needed for the patient at the time. Three months later, the patient was able to initiate hemodialysis with two-needle cannulation and avoided placement of a central venous catheter. At one year post-creation, the patient's WavelinQ™ endoAVF had been cannulated with no interventions needed.

The results presented in this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes.

WavelinQ™ EndoAVF System

Indications: The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis.

Contraindications: Target vessels <2.0 mm in diameter.

Warnings: The WavelinQ™ EndoAVF System is only to be used with the approved components specified in the instructions for use (IFU). Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. Use of the system with other components may interfere with proper functioning of the device. The WavelinQ™ 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. The WavelinQ™ EndoAVF System should not be used in patients who have known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. The WavelinQ™ EndoAVF System should not be used in patients who have a known allergy or reaction to any drugs/fluids used in this procedure. The WavelinQ™ EndoAVF System should not be used in patients who have known adverse reactions to moderate sedation and/or anesthesia. The safety and performance of the device via arterial wrist access has not been fully established. The incidence of vessel stenosis or occlusion that occurs in the radial and ulnar arteries after arterial wrist access has not been evaluated. Do not use the device to create an EndoAVF using arterial access via the radial or ulnar artery. The EndoAVF should only be created using brachial artery access. Use caution when performing electrosurgery in the presence of pacemakers or implantable cardioverter defibrillators. 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 powered on. Consult the ESU User Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access. Ensure the patient's arm is restrained to minimize movement during device activation; potential hazards of patient arm movement during activation are hematoma or pseudoaneurysm near the fistula site. The puncture site should be closed and hemostasis should be achieved by manual compression per the instructions in the IFU. Use of closure devices with the WavelinQ™ EndoAVF System may be associated with an increased risk of access site complications. The WavelinQ™ EndoAVF System has only been evaluated for the creation of an AVF between the ulnar artery and concomitant ulnar vein and between the radial artery and concomitant radial vein in the clinical studies described in the IFU. Refer to the latest National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines for recommendations and considerations for AV access creation in patients on or requiring hemodialysis. For patients expected to have prolonged durations on hemodialysis, a distal to proximal approach to AVF creation provides the best opportunity to preserve vessels for future vascular access sites following the individual patient ESKD Life-Plan. This device is coated with a hydrophilic coating at the distal end of the device for a length of 26.4 cm (10.4 in). Please refer to the AVF Creation section in the IFU for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating.

Cautions: Only physicians trained and experienced in endovascular techniques, who have received appropriate training with the device, should use the device. Endovascular technique training and experience should include ultrasound vessel access in the arm, guidewire navigation, radiographic imaging, placement of vascular embolization devices (including embolization coils), and access hemostasis. Adhere to universal precautions when utilizing the device.

Precautions: 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. Some patients who have veins deeper than 6mm may require superficialization. Pre-planned vessel superficialization is acceptable and not considered an additional intervention for fistula maturation, per KDOQI Clinical Practice Guideline for Vascular Access: 2018. Ensure the patient has adequate collateral blood flow to the hand before use of the device. Prior to the procedure, ensure that the access location, access vessels, and target AVF location are of appropriate size to account for the devices during use. Oversizing the device to the access vessel may increase risk of vessel injury, which may result in stenosis and/or occlusion. Vessel injury may impact future dialysis access options and/or the ability to perform future endovascular procedures from the target access vessels. Users should consider the potential risk of distal arterial stenosis and/or occlusion on end stage renal disease patients when selecting vascular access sites for the procedure. Adjunctive procedures are expected to be required at the time of the index procedure to increase and direct blood flow into the AVF target outflow vein to assist maturation. Care should be taken to proactively plan for any adjunctive procedures, such as embolization coil placement, when using the device.

Potential Adverse Events: The known potential risks related to the WavelinQ™ 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; aneurysm; 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 all indications, contraindications, hazards, warnings and precautions.

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