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Long-Term Results from the Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access

Clinical Paper Review
Prepared by PVH Scientific Communications *for Health Care Professionals*

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Journal *J Vasc Interv Radiol 2022;*33(10), 1143-1150. https://doi.org/10.1016/j.jvir.2022.05.016

Purpose

To present 5-year results from the pivotal study of ultrasound-guided percutaneous arteriovenous fistula (pAVF) creation for hemodialysis access using the Ellipsys™ vascular access system device.

Methods

- Retrospective review of the Ellipsys pivotal study participants with long-term follow-up
- The pivotal study was a prospective, single-arm, multi-center study; 12-month outcomes are published[1]
- All participants had pAVFs created with an Ellipsys device
- Medical records were reviewed for years 1-5
- Definitions:
  - Mature: achieving brachial artery flow of ≥500 mL/min and a target vein diameter of ≥4 mm or completing 2-needle cannulation at the prescribed rate
  - Sustained fistula use: successful use of fistula on a continuous basis at prescribed rate, at least 2 of 3 sessions
  - Patency: detectable flow beyond the anastomosis by imaging or physical exam
  - Assisted primary patency: time to first thrombosis
  - Secondary/cumulative patency: time to abandonment
  - Functional patency: time from 2-needle cannulation to abandonment

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Results

- 85 of the 107 pivotal study participants were available for long-term follow-up
  - Median follow-up: 50 months (range, 12-60 months)
- 99% (84/85) had a mature fistula
- Median time to 2-needle cannulation: 105 days
- Sustained fistula use: 92% (78/85)
- Procedure rate (years 1-5): 0.93 per patient per year (PPPY)
- Procedure rate (years 2-5): 0.32 PPPY

Outcomes at 5 years

Assisted primary patency†	74.0%
Secondary patency†	82.0%
Functional patency†	91.8%
Deaths	32 (80/1,000 patient years)

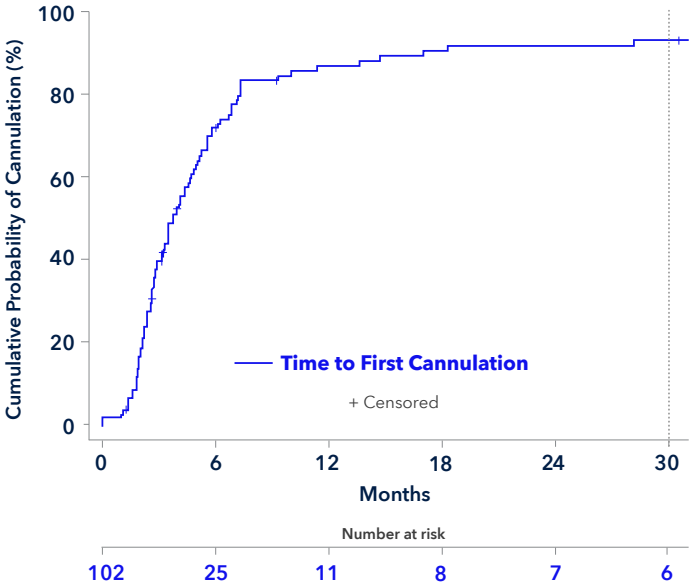
† Per Kaplan-Meier estimate

Interventions throughout follow-up

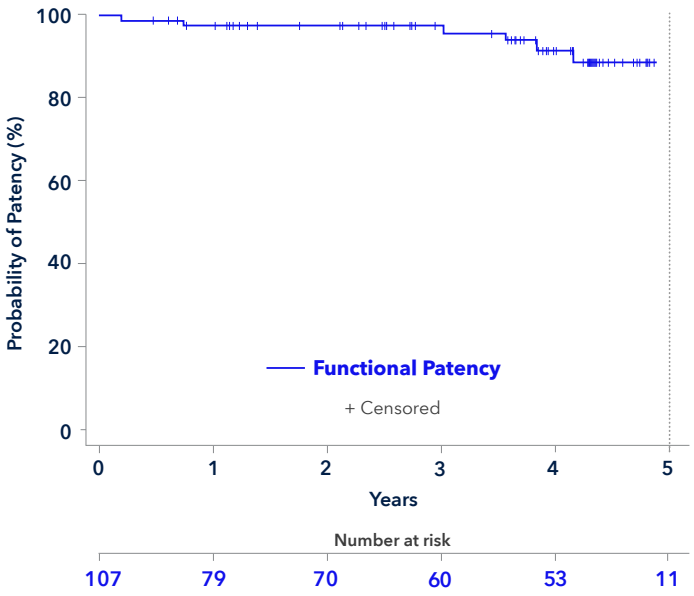
Total additional procedures	91 procedures in 27 participants (31.8%)
Indication†	
pAVF dysfunction	43 procedures in 18 participants (21.2%)
Thrombosis	22 procedures in 5 participants (5.9%)
Cannulation injury	17 procedures in 11 participants (12.9%)
Arm swelling	8 procedures in 4 participants (4.7%)
Type of procedure†	
Balloon angioplasty	71 procedures in 25 participants (29.4%)
Thrombectomy	12 procedures in 2 participants (2.4%)
Stent graft	6 procedures in 3 participants (3.5%)
Surgical repair	4 procedures in 4 participants (4.7%)
Deep coil embolization	1 procedure in 1 participant (1.2%)
Branch ligation	1 procedure in 1 participant (1.2%)

† Patients may have had multiple indications and/or procedures, and therefore, may be counted in more than one row.

Time to first cannulation



Functional patency



Outcomes in years following 2NC	1-Year	2-Year	3-Year	4-Year
Functional Patency	97.5%	97.5%	97.5%	91.8%

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Discussion

- Long-term follow-up data show that pAVFs that were successfully created and matured had good functional patency through 5 years with low maintenance and no serious complications.
- Since the pivotal study enrollment, the procedure has been modified to include balloon angioplasty of the anastomosis and perforating vein immediately after fistula creation, during the index procedure. This has decreased the early thrombosis rate to 3%, maturation procedures to < 1 per patient, and time to maturation to a mean of 11 days.[2-6]
- Overall PPPY was 0.93 and dropped to 0.32 PPPY during years 2-5, which may be due to the low to moderate flow thought to reduce intimal hyperplasia and stenosis, and thus reduce secondary procedures and reduce fistula failures.
- The availability of pAVF creation devices expands fistula creation to additional site-of-service locations, including office-based laboratories and can be performed by more specialties, including surgeons, interventional nephrologists and interventional radiologists.

Author Conclusions

These data demonstrate that pAVF are durable, providing effective dialysis long term while requiring low rates of access maintenance procedures and lacking major complications.

Funding Source

A grant was provided by Medtronic for this investigator-initiated study.

References:
1. Hull JE et al. *J Vasc Interv Radiol* 2018; 29:149-158.e5.
2. Hull JE et al. *J. Vasc Interv Radiol* 2020; 31:1373-1381.
3. Shahverdyan R et al. *J Vasc Interv Radiol* 2020;31:1365-1372.
4. Mallios A et al. *J Vasc Access* 2020; 21:997-1002.
5. Mallios A et al. *J Vasc Surg* 2020; 72:2097-2106.
6. Mallios A et al. *J Vasc Surg* 2018; 68:1150-1156.

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If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety and warning information. If you are located outside the United States, see the device manual for detailed information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

Ellipsys system Reference Statement

Indications

The Ellipsys™ system is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.

Contraindications

The Ellipsys™ system is contraindicated for use in patients with target vessels that are <2 mm in diameter. The Ellipsys™ System is contraindicated for use in patients who have a distance between the target artery and vein > 1.5 mm

Warnings

- The Ellipsys™ system has only been studied for the creation of an AV fistula using the proximal radial artery and the adjacent perforating vein. It has not been studied in subjects who are candidates for surgical fistula creation at other locations, including sites distal to this location.
- The Ellipsys™ system is not intended to treat patients with significant vascular disease or calcification in the target vessels.
- The Ellipsys™ system has only been studied in subjects who had a patent palmar arch and no evidence of ulnar artery insufficiency.
- Use only with the Ellipsys™ Power Controller, Model No. AMI-1001.
- The Ellipsys™ Catheter has been designed to be used with the 6 F Terumo Glidesheath Slender™*. If using a different sheath, verify the catheter can be advanced through the sheath without resistance prior to use.
- Use ultrasound imaging to ensure proper placement of the catheter tip in the artery before retracting the sheath, since once the distal tip of the catheter has been advanced into the artery, it cannot be easily removed without creation of the anastomosis. If the distal tip is advanced into the artery at an improper location, complete the procedure and remove the catheter as indicated in the directions for use. It is recommended that a follow-up evaluation of the patient is performed using appropriate clinical standards of care for surgical fistulae to determine if any clinically significant flow develops that require further clinical action.

Precautions

- This product is sterilized by ethylene oxide gas.
- Additional procedures are expected to be required to increase and direct blood flow into the AVF target outflow vein and to maintain patency of the AVF. Care should be taken to proactively plan for any fistula maturation procedures when using the device.
- In the Ellipsys™ study, 99% of subjects required balloon dilatation (PTA) to increase flow to the optimal access vessel and 62% of subjects required embolization coil placement in competing veins to direct blood flow to the optimal access vessel. Prior to the procedure, care should be taken to assess the optimal access vessel for maturation, the additional procedures that may be required to successfully achieve maturation, and appropriate patient follow-up. Please refer to the "Arteriovenous Fistula (AVF) Maturation" section of the labeling for guidance about fistula flow, embolization coil placement, and other procedures to assist fistula maturation and maintenance.
- The Ellipsys™ System is intended to only be used by physicians trained in ultrasound guided percutaneous endovascular interventional techniques using appropriate clinical standards for care for fistula maintenance and maturation including balloon dilatation and coil embolization.
- Precautions to prevent or reduce acute or longer-term clotting potential should be considered. Physician experience and discretion will determine the appropriate anticoagulant/antiplatelet therapy for each patient using appropriate clinical standards of care.

Potential Adverse Effects

Potential complications that may be associated with creation and maintenance of an arteriovenous fistula include, but may not be limited to, the following:

- Total occlusion, partial occlusion or stenosis of the anastomosis or adjacent outflow vein
- Stenosis of the central AVF outflow requiring treatment per the treatment center's standard of care
- Failure to achieve fistula maturation
- Incomplete vessel ligation when using embolization coil to direct flow
- Steal Syndrome
- Hematoma
- Infection or other complications
- Need for vessel superficialization or other maturation assistance procedures.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.