Comparison of Ellipsys Percutaneous and Proximal Forearm Gracz-Type Surgical Arteriovenous Fistulas

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

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Purpose:

To compare outcomes between patients with a percutaneously created arteriovenous fistula (p-AVF) made with the Ellipsys™ vascular access system and patients with a surgically created Gracz-type surgical arteriovenous fistula (s-AVF).

Methods:

Single-center, retrospective study of a prospectively maintained database

- Patency status and flow were evaluated by duplex ultrasound 1-2 days post-procedure, 4 weeks post-procedure, and every 3-6 months thereafter
- Endpoints and definitions:
  - Procedural technical success: presence of thrill/bruit and fistula flow in the outflow vein(s) by duplex ultrasound at completion of procedure
  - Maturation: AVF blood flow of ≥500 ml/min and an outflow vein diameter ≥5 mm
  - Primary patency: time from creation to re-intervention, abandonment, or reaching an event (e.g., death, transfer to peritoneal dialysis, or kidney transplantation)
  - Secondary patency: time from creation to either abandonment or reaching an event
  - Primary failure: abandonment/conversion before becoming physiologically mature or being used for dialysis
  - Time to successful clinical use (cannulation): time from creation to successful two-needle cannulation for treatment to achieve the dialysis prescription
  - Intervention: any secondary unplanned procedure on the AVF (surgical or endovascular)
- Subgroup analysis was conducted on s-AVF patients with inflow provided by only the proximal radial artery (PRA s-AVF), to more closely match the procedural anatomy of the p-AVFs

Results:

This analysis included:

- N=89 Ellipsys system p-AVFs
- N=69 Gracz s-AVFs

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Results: (continued)

Table 1: Baseline characteristics

	p-AVF (Ellipsys system) (N=89)	Gracz s-AVF (N=69)	P value
Age (years)	66.0 (28.0, 86.2)	67.9 (33.2, 87.7)	0.3
BMI (kg/m²)	26.2 (16.5, 45.1)	28.7 (16.5, 50.2)	0.1
Male	58 (65.2)	35 (50.7)	
Diabetes	32 (36)	33 (47.8)	0.1
Chronic kidney disease status			0.07
Pre-dialysis	39 (43.8)	19 (27.5)	
Kidney failure	49 (55)	49 (71)	
Apheresis	1 (1.1)	1 (1.4)	
Previous ipsilateral AVF	34 (38.2)	29 (42)	0.6
Dialysis with a central catheter	48 (53.9)	50 (72.5)	0.02

Data are median (min, max) or n (%)
BMI: body mass index, p-AVF: percutaneous arteriovenous fistula, s-AVF: surgical arteriovenous fistula

Table 2: Procedure characteristics

	p-AVF (Ellipsys system) (N=89)	Gracz s-AVF (N=69)	P value
Technical success	89 (100)	69 (100)	0.9
Procedure time (mins)	14 (8, 31)	70 (45, 128)	<0.001
Anastomosis			<0.001
Brachial	0 (0)	40 (58)	
Radial	89 (100)	21 (30)	
Ulnar	0 (0)	8 (12)	
Outflow vein			<0.001
Cephalic vein	12 (24)	25 (36)	
Basilic vein	9 (10)	20 (29)	
Cephalic & basilic vein	59 (66)	24 (34.8)	

Data are median (min, max) or n (%)
p-AVF: percutaneous arteriovenous fistula, s-AVF: surgical arteriovenous fistula

Table 3: Outcomes

	p-AVF (Ellipsys system) (N=89)	Gracz s-AVF (N=69)	P value
Follow-up (days)	266 (1,674)	472 (2, 1016)	<0.001
Maturation by 4 weeks	68 (76)	51 (76)	NS
Maturation by 6 months	76 (85)	53 (79)	NS
Time to cannulation (days)	57 (1, 426)	68 (1, 403)	NS
Number of interventions (per patient)			0.5
0	52 (58)	34 (49)	
1	24 (27)	22 (32)	
2 or more	13 (15)	13 (19)	
Primary patency failure at 12 months*	64%	47%	0.1
Secondary patency failure at 12 months*	12%	20%	0.3
Primary failure through 12 months	8%	17%	Not reported

*cumulative incidence per Kaplan-Meier estimate
Data are median (min, max) or n (%)
p-AVF: percutaneous arteriovenous fistula, s-AVF: surgical arteriovenous fistula

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Results: (continued)

Subgroup Analysis on proximal radial artery (PRA) s-AVF:

- At 12 months, PRA s-AVFs had similar primary patency compared to p-AVFs (65% vs 64%, p=0.7858), but higher secondary patency failure rate vs. p-AVFs (34% vs 12%, p=0.0435)

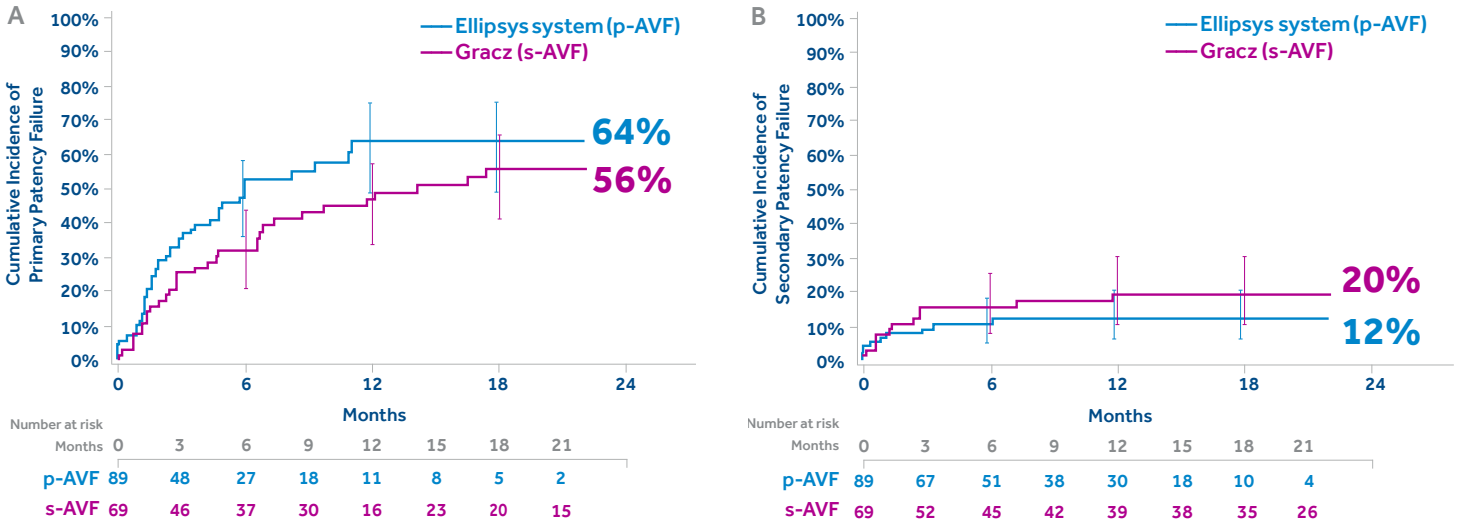

Figure 1: Cumulative incidence of vascular access primary patency failure (A) and secondary patency failure (B).

Discussion:

- Both procedures achieved 100% technical success rate, but the procedure time was significantly shorter in the p-AVF group as compared to the s-AVF group (14 mins vs. 74 mins., p<0.001)
- The Ellipsys system reduces issues associated with pain and inflammation
- The primary failure rate of 8% in the p-AVF group was less than half the 17% rate observed in the s-AVF group
- The majority (58%) of patients in the p-AVF group did not require an intervention over the course of the study
- There was no difference between groups in time required to reach maturity at 6 months (85% in the p-AVF group and 79% in the s-AVF group), which is markedly higher than 40% maturity at 6 months observed in a large (n=877 participants) multi-center trial[1]

Author's Conclusion:

Both p-AVF created with the Ellipsys system and Gracz s-AVF demonstrated high technical success rates and secondary patency rates. The p-AVF procedure takes significantly less time. When distal radial artery AVF is not feasible, p-AVF may be an appropriate option for creating a safe and functional access, while maintaining future forearm s-AVF creation options.

Funding Source:

Not funded by industry

References

[1] Dember LM, Beck GJ, Allon M, Delmez JA, Dixon BS, Greenberg A, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. *JAMA*. 2008;299(18):2164-71.

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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™ vascular access system
Brief statement

Indications for Use:
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.

Important Information: Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device.

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