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Case Report

Initial experience with the Ellipsys Vascular Access System for percutaneous arteriovenous fistula creation in adolescents: A case report ☆

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ABSTRACT

This retrospective, single center, case report describes the first use of the Ellipsys Vascular Access System for percutaneous arteriovenous fistula (pAVF) creation in children. Two adolescent (<20 year of age) patients (18 and 19-year-old females), one of whom was developmentally delayed, were not considered candidates for traditional surgical arteriovenous fistula creation. pAVF creation was successful in both patients using the Ellipsys device and physiologic maturation of the fistula was achieved within 8 weeks of creation with subsequent 2 needle cannulation. No complications or adverse events were encountered. pAVF creation with the Ellipsys device can be safely performed in adolescents. Further studies will be needed to validate the expanded use of these devices in children.

Introduction

Percutaneous arteriovenous fistula (pAVF) creation with the Ellipsys Vascular Access System (Avenu Medical, San Juan Capistrano, CA) and the WavelinQ EndoAVF System (Bard Peripheral Vascular, Inc., Tempe, AZ) have been recently described as an alternative to surgical arteriovenous fistulae (sAVF). Their technical success, safety and efficacy has been well established in adults (>21 years of age) [1–3]. As compared to sAVF, pAVF may confer improved patency rates and overall reduced costs [4,5].

The point prevalence of end stage kidney disease (ESKD) among children (<21 years of age) in the United States was 8959 or 98.7 per million population with a total of 1173 children with a new diagnosis of ESKD in 2017 [6]. Since 2006, 81.5% of the incident pediatric ESKD patients started therapy with hemodialysis (HD) with an indwelling catheter [7]. A cross sectional point prevalence in May 2017 among pediatric HD patients demonstrated that 44% were being dialyzed

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with an AVF, as compared to 64.5% among adults [7]. Technical challenges and limited pediatric surgical expertise are major barriers to AVF placement [8]. The use of pAVF devices presents an opportunity toward increasing rates of permanent vascular access among pediatric patients.

While initial experiences with pAVF devices in adults have been favorable, there is limited data to show its efficacy and safety in children. This brief report describes the use of the Ellipsys Vascular Access System in 2 adolescents (<20 years of age) in a tertiary children's hospital with particular focus on technical success, complications, patency and physiologic and clinical maturation as defined by the Kidney Dialysis Outcomes Quality Initiative [9,10].

Case Report

This single center retrospective case report complied with the *Health Insurance Portability and Accountability Act*. Informed consent and *Institutional Review Board* approval was not required for this case report.

Case 1

An 18-year-old female (74 kg) with HD dependent ESKD was referred to interventional radiology for possible pAVF placement. The existing HD access was through a right internal jugular central venous catheter (CVC). Prior surgical evaluation did not reveal a suitable target for creation of a distal radio-cephalic fistula. Preprocedure ultrasound (US) of the proximal forearms demonstrated bilateral vessel diameters appropriate for the Ellipsys device (2 mm diameter of the perforating vein (PV), 2 mm diameter of the proximal radial artery and less than 1 mm between the 2 vessels). The patient underwent pAVF placement in the right forearm.

The procedure was performed under general anesthesia in conjunction with a brachial plexus nerve block for vasodilation. Creation of the pAVF with the Ellipsys was performed via the cephalic vein (the patient did not have contiguous basilic vein outflow) as previously described [2]. After creation of the anastomosis, balloon dilation was performed using a 6 mm × 40 mm Sterling balloon (Boston Scientific Corporation, Marlborough, MA). Post procedure brachial artery inflow was then measured as an index for future comparison. No immediate post procedural complications were encountered and the patient was discharged on the same day.

Follow up US examination was performed at 1 week and 4 weeks post procedure. Brachial artery inflow, target vein (TV) diameters and flow rates were recorded (Table 1). Due to decreased brachial artery and TV flow at the 4 week US, a fistulogram was performed from a distal radial access and demonstrated minimal stenosis at the anastomosis along with several competing veins arising from the PV leading to paired brachial veins (Fig. 1). A 6 × 40 mm Sterling balloon was used to treat the anastomotic stenosis and the competing outflow veins were coil embolized using 7 mm × 30 cm Concerto 3D detachable coils (Medtronic, Minneapolis, MN). Increased brachial artery inflow was demonstrated post procedure.

Follow up US was performed 2 weeks after this maturation procedure, demonstrating continued improvement in brachial artery inflow with physiologic maturation of the pAVF, as defined by the updated Kidney Dialysis Outcomes Quality Initiative guidelines [9,10]. At that point, the pAVF was deemed appropriate for needle cannulation, approximately 8 weeks from creation. Due to restrictions put in place during the COVID-19 pandemic, in-person training for two needle cannulation of the fistula was delayed. As a consequence, cannulation of the pAVF was performed approximately 8 months after the secondary procedure. Interval surveillance during this time demonstrated continued patency of the pAVF with no decrease in flows nor reported symptoms.

Case 2

A 19-year-old female (46 kg) with developmental delay and ESKD was referred to interventional radiology for pAVF placement. Existing HD access was through a right internal jugular CVC. Pre procedural US demonstrated appropriate vessel sizes for pAVF in both forearms but PV tortuosity favored placement in the left proximal forearm. The cephalic and basilic venous systems were noted to be contiguous.

The procedure was performed under general anesthesia in conjunction with a brachial plexus nerve block. Creation of the pAVF with the Ellipsys was performed via the cephalic vein outflow. After creation of the anastomosis, balloon dilation was immediately performed using a 6 mm × 40 mm Sterling balloon. No immediate post procedural complications were encountered and the patient was discharged on the same day.

Post procedural brachial artery inflow, TV diameter and flow rates on US follow up demonstrated persistently elevated brachial artery inflow but decreasing flows in the cephalic and basilic venous systems (Table 1). Dialysis fistulogram was performed from a distal radial arterial access demonstrating a competing vein arising from the PV draining into the brachial vein as well as an accessory cephalic vein in the mid upper arm (Fig. 2). Coil embolizations of the competing vein and the accessory cephalic vein were performed using 7 mm × 30 cm Concerto 3D detachable coils.

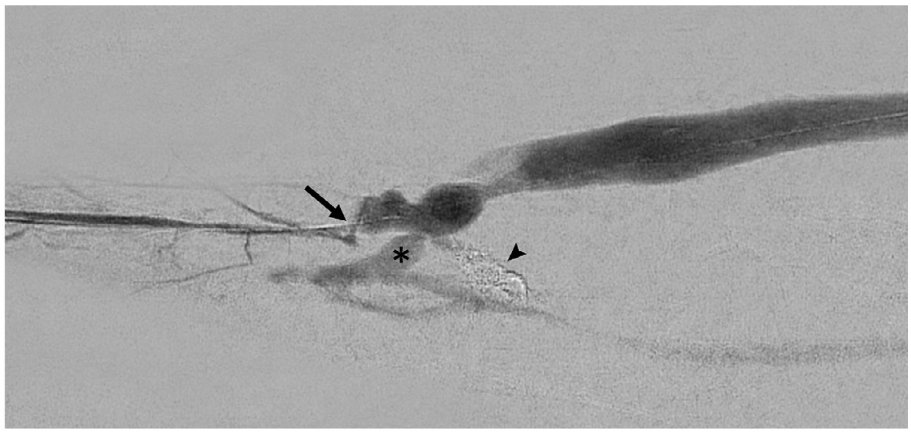
Follow up US performed 2 weeks after this maturation procedure demonstrated persistent sufficient brachial artery inflow with physiologic maturation of the pAVF, ready for needle cannulation, approximately 8 weeks from creation. Due to COVID-19 restrictions, 2 needle cannulation of the pAVF was delayed until approximately 6 months after the secondary procedure. Interval surveillance during this time demonstrated continued patency of the pAVF with no decrease in flows nor reported symptoms.

Discussion

To our knowledge we describe the first pediatric experience of pAVF creation with the Ellipsys Vascular Access System in 2 adolescents in a tertiary children's hospital. Neither patient experienced any significant adverse events or complications as defined by the Society of Interventional Radiology nor reported any adverse symptoms from pAVF placement [11].

Over the past several years, pAVF devices have provided adult patients with ESKD an additional method of obtaining permanent HD access. As Chand et al. outlined however, pediatric patients are especially susceptible to barriers that limit their access to an arteriovenous fistula. While several factors

a.



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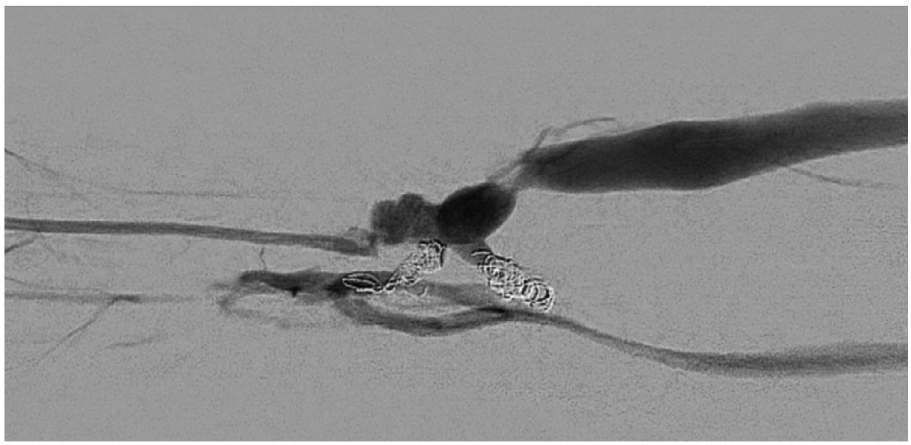

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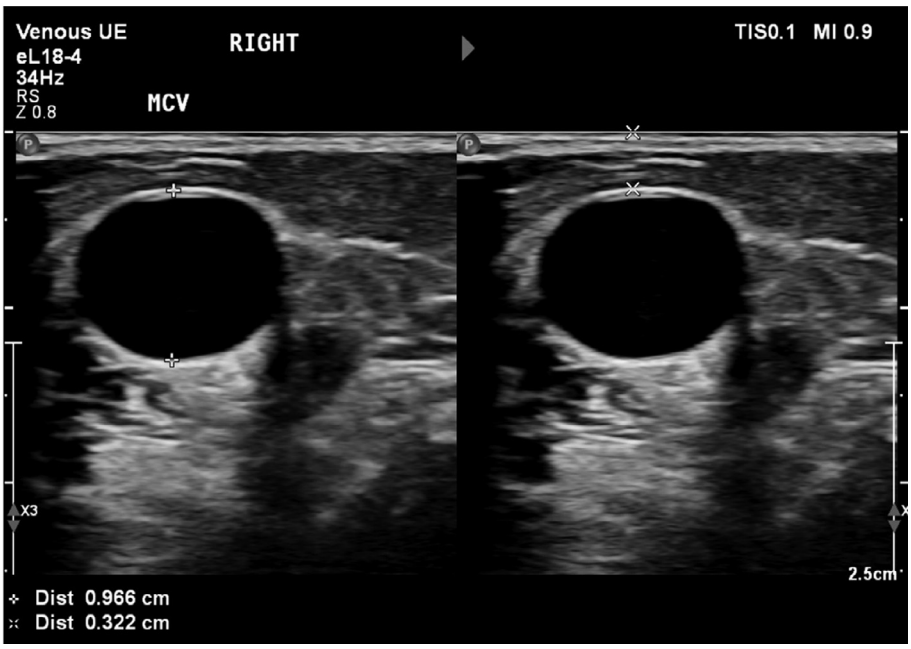


Fig. 1 – Eighteen-year-old female with ESRD. pAVF creation was performed 7 weeks prior to these images. (a) Initial fistulogram from a right radial access demonstrated embolization coils in a competing vein arising from the perforating vein (arrowhead) and minimal stenosis of the anastomosis (arrow). A second competing vein is also noted arising from the perforating vein (asterisk). (b) Fistulogram post embolization of the competing vein and angioplasty of the anastomosis shows improved outflow throughout the pAVF. Physiologic maturation of the pAVF was achieved 2 weeks post procedure. (c, d) Ultrasound evaluation of the cephalic vein outflow 24 weeks post creation. pAVF, Percutaneous arteriovenous fistula; MCV, Median cephalic vein; DUA, Distal upper arm.

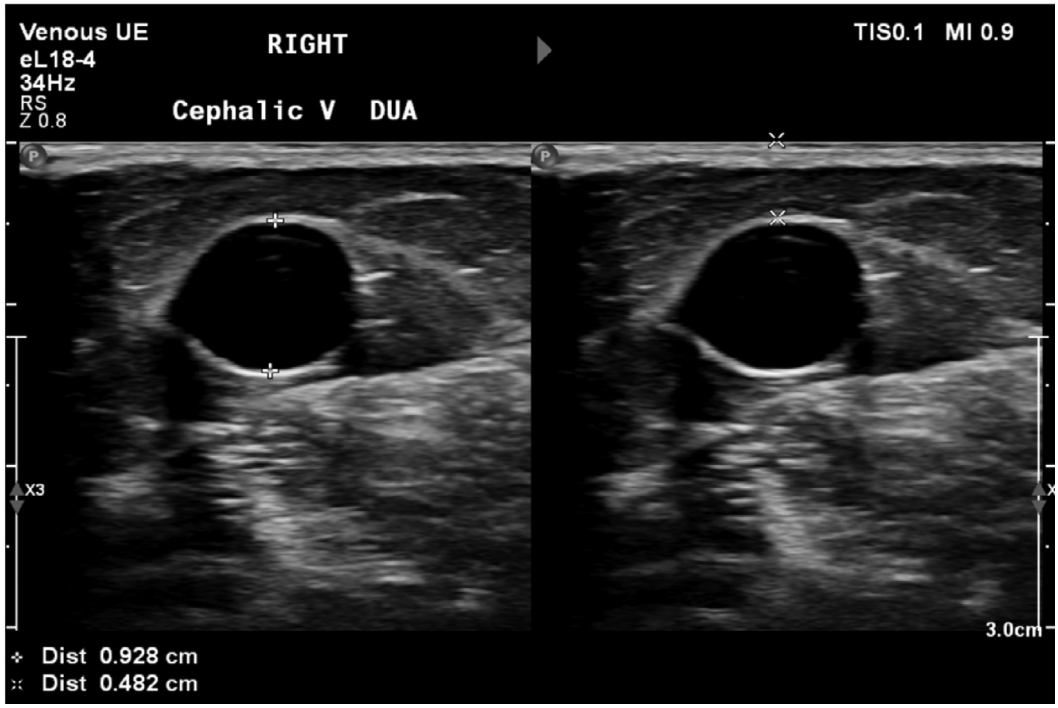
d. 

Fig. 1 – Continued

contribute to the low rate of prevalent fistulas in children, one major reason has been the lack of surgical expertise in fistula creation [8]. The use of pAVF devices therefore provides a unique opportunity for interventional radiologists to help these patients.

Safety of pAVF devices was demonstrated by Mallios et al., who described a series of over 200 patients who underwent pAVF creation with the Ellipsys device without a single adverse event [12]. The 2 patients in this case report had successful creation of a pAVF with no signs or symptoms associated with steal syndrome, likely attributable to the moderate flow of these fistulas [13].

There is a growing body of literature that suggests the patency rates of pAVFs, particularly those created by the Ellipsys device, exceed that of sAVFs [4,5,14,15]. In a series of over 100 patients, Beathard et al. demonstrated 6, 12, and 24 month patency rate of 97.1%, 93.9%, and 92.7% of pAVFs created with the Ellipsys device, as compared to Stompous et al.'s large multicenter cohort study of sAVFs demonstrating 12 month patency rates of 48% [16,17]. The use of the Ellipsys device in two

Table 1 – Pre and post procedure target vein diameter, depth and flow measurements by ultrasound.

	Age/ gender	Weight (kg)	Preprocedure		Postprocedure				
			Target vein diameter (mm)	Target vein depth (mm)	Time from creation	Brachial artery inflow (mL/min)	Target vein diameter (mm)	Target vein depth (mm)	Target vein flow (mL/min)
Patient 1	18/F	74	4.7	4.7	Immediate	420			
					1 week	715	5.2	6.7	365
					4 weeks	597	6.5	4.7	268
					8 weeks	806	7.4	4.9	599
					24 weeks	764	9.3	4.8	602
Patient 2	19/F	46	3.9/3.1*	3.0/3.9	Immediate	463			
					1 week	1225	4.2/4.6	5.1/3.9	249/362
					4 weeks	1312	4.4/5.3	6.4/6.0	316/95
					8 weeks	1513	6.2/6.6	5/2.6	721/811
					20 weeks	1266	8/6.6	2.6/3.6	587/1124

* Patient 2 has both cephalic and basilic venous outflow. Target vein diameter, depth, and flow measurements are reported in this manner (cephalic/basilic).

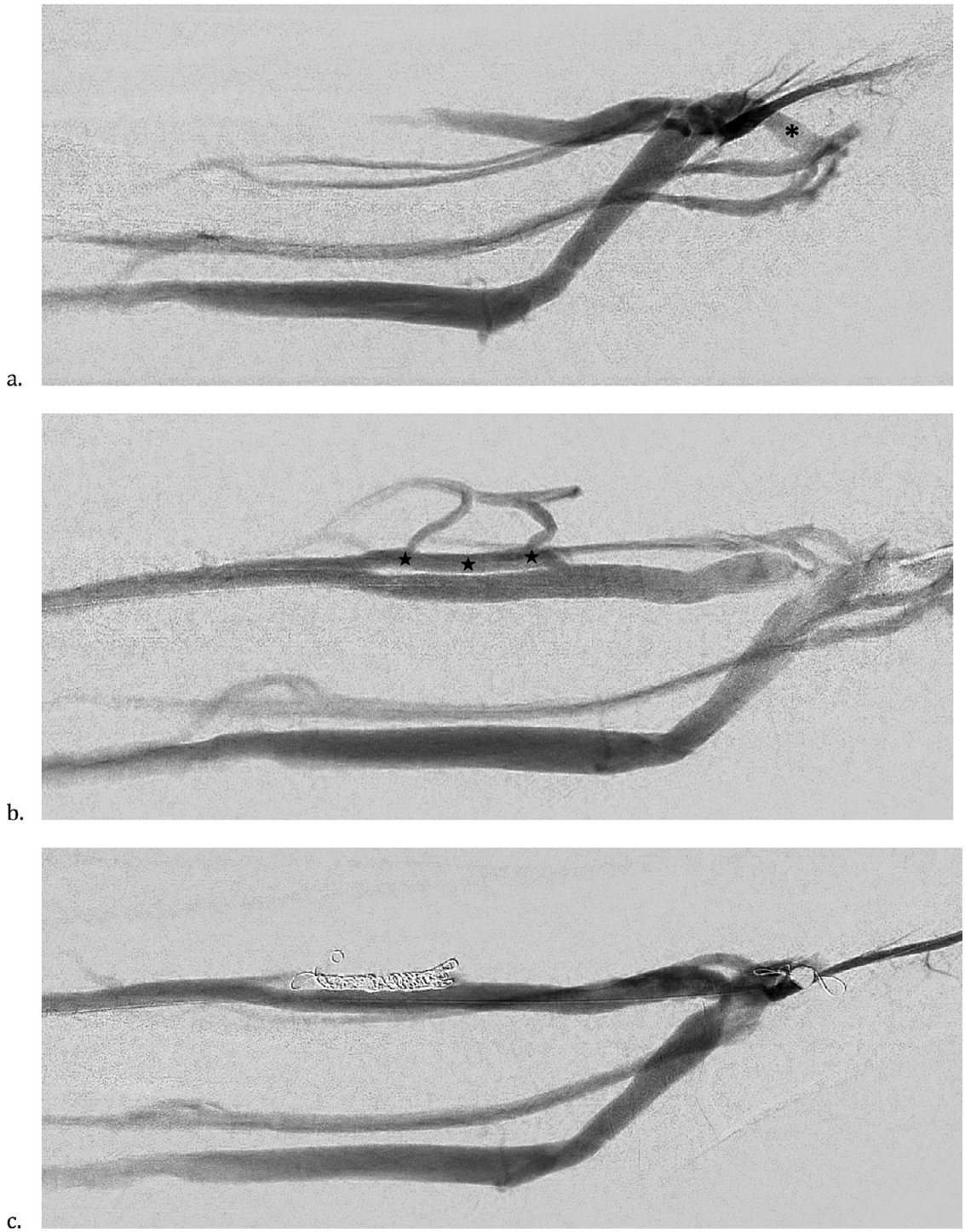


Fig. 2 – Nineteen-year-old female with ESRD and developmental delay. The patient underwent pAVF creation 7 weeks prior to these images. (a) Initial fistulogram from radial arterial access demonstrates the patent pAVF with a venous collateral arising from the perforating vein (black asterisk). (b) An accessory cephalic vein was also identified, felt to be impeding cephalic vein outflow maturation. (c) Fistulogram post coil embolization of the accessory cephalic vein and the perforating vein collateral demonstrates improved venous outflow in both the cephalic and basilic veins. Physiologic maturation of the pAVF was achieved 2 weeks post procedure.

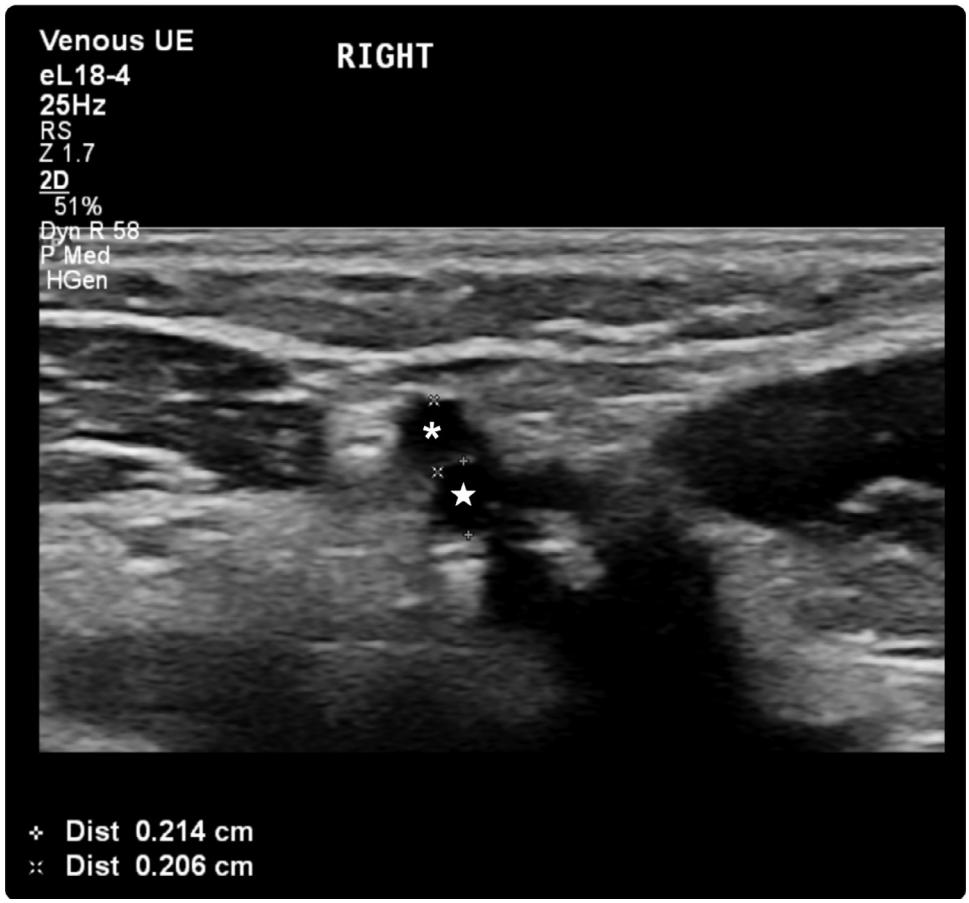


Fig. 3 – Ten-year-old male with ESRD on hemodialysis via a right internal jugular central venous catheter. Ultrasound evaluation for possible pAVF demonstrates the right perforating vein (white asterisk) and the proximal radial artery (white star) in the forearm meeting size criteria for the Ellipsys device. The vessels are touching with no distance in between.

adolescents have thus far been encouraging, demonstrating a 100% patency rate at 8 months (as of this writing) but more work will be needed to validate this finding to the broader pediatric population.

With endovascular AVFs, additional procedures may be required to attain physiologic maturation. Recently, Hull at al. reported the rate of secondary maturation procedures at 67% [18]. While this rate represents a decrease from the initial studies (likely owing to the inclusion of balloon angioplasty of the anastomosis during the index pAVF creation), this limited pediatric report demonstrated a greater need for secondary maturation procedures to attain maturation [1]. Further studies will be needed to validate this increased need for secondary procedures in this population, but our results may inform clinical decision making and informed consent in the interim. Of note, both secondary procedures were successful in achieving physiologic maturation within 8 weeks of creation.

While limited, the results of this report on pAVF device use in adolescents should be encouraging, particularly to a subset of pediatric patients who have had traditional barriers to obtaining an AVF suitable for dialysis. Given the low rate of incident fistulas in pediatric patients with ESKD and the rising rate of CVC use in this population, the introduction of pAVF devices could dramatically change the landscape of pediatric dialysis care and access [10]. Though the widespread applicability of these devices in children will need further validation, patients as young as 10 years of age may be candidates for the Ellipsys device (Fig. 3). The device offers a less invasive option to achieve the stated goals of the Fistula First Initiative [19]. Higher rate of secondary procedures to achieve maturation may be required. Further studies will be needed to validate the expanded use of these devices in children.

Patient Consent Statement

Written, informed consent for publication of these cases was obtained from the patients. Scanned documentation of their signatures is available upon request.

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