

SKI Vascular Center is First Ambulatory Surgical Center in the Nation to Utilize FDA-Approved Ellipsys System for Non-Surgical Dialysis Fistula Creation

Local Interventional Nephrologists Randy Cooper, MD and Umar Waheed, MD, Pioneer Breakthrough Endovascular Arteriovenous Fistula (endoAVF®) Technology for ESRD Patients

Tempe, AZ – December 6, 2018 – Tempe-based interventional nephrologists Randy Cooper, MD and Umar Waheed, MD, and their team at [SKI Vascular Center](#), this week became the first ambulatory surgical center in the US to create a percutaneous arteriovenous fistula (AVF), using the Ellipsys® Vascular Access System, a game-changing innovation for patients with End-Stage Renal Disease (ESRD).

The recently FDA-approved Ellipsys System is a minimally-invasive, single catheter-based system designed for ESRD patients requiring hemodialysis. Pioneered in Arizona by Drs. Cooper and Waheed, the new procedure and technology bring patients a unique non-surgical option for AVF creation, a procedure that had previously not changed in over 50 years.

A significant advancement for dialysis patients and clinicians, the Ellipsys System, developed by [Avenu Medical](#) (San Juan Capistrano, CA), transforms an open surgery connecting an artery to a vein into a minimally invasive procedure using a needle and a catheter. Using a percutaneous approach, the Ellipsys procedure replaces an incision with a needle puncture, ultrasound imaging replaces surgical dissection, and sutures are replaced with tissue fusion. The procedure can be performed in a physician-based procedural center, but can also be used in hospitals and ambulatory surgery centers. After the procedure, the patient leaves with just a band aid.

Since 1966, the AV fistula was surgically created in an operating room by sewing a major vein and artery together in the arm. When this is done, blood from the artery will pass through the vein increasing its flow rate and diameter. This makes the vein suitable for the insertion of needles required for hemodialysis treatment. The AVF is the best method for vascular access reducing hospitalization and mortality with the additional benefits of longer term patency, improved flow rates and fewer complications than other methods of vascular access.

No stranger to the groundbreaking technology, Drs. Cooper, Waheed and the SKI Vascular Center were one of the participating sites in the US Pivotal Trial for Ellipsys and are now the first site in the state of Arizona (and first Ambulatory Surgical Center in the nation) to perform Ellipsys procedures, post-FDA approval. In total, the SKI team have treated over 40 patients with the technology leading up to FDA approval.

“It is rewarding to be able to offer a simpler, more efficient and less-invasive option for patients requiring vascular access,” said Dr. Cooper, who is also a **Clinical Assistant Professor at the University of Arizona**. “We’re proud to have been a site in the clinical trial and to be the first ASC in the country to provide this now FDA approved quality of life improvement opportunity for ESRD patients. With no incision, quicker recovery time, and the general simplicity of the fistula creation, this procedure is so much easier on the patient. Just yesterday we successfully performed three cases, and we look forward to many more to come.”

“We’ve been very optimistic about this technique and technology since we completed the pivotal trial,” said Dr. Waheed, who is also the managing partner for the SKI Vascular Centers. “Now we’ve had a chance to follow those patients since the trial concluded three years ago and have seen first hand that they require significantly less maintenance procedures to maintain their fistulas. In addition, many patients have been requesting a percutaneous AVF since the end of the clinical trial and were unable to get one prior to FDA approval. Now that Ellipsys is FDA approved, we’re excited to finally be able to start offering patients this minimally invasive procedure again.”

SKI Vascular Center is part of the Southwest Kidney Institute, an interconnected network of 47 offices and 70 providers in Arizona. Its staff of highly trained professionals offers an array of the most technologically advanced procedures for the prevention and treatment of dialysis access-related complications and various vascular diseases.

Media: To arrange an interview with Dr. Cooper or patient success stories, or to receive more information about the new Ellipsys Vascular Access System, please contact Paul Williams at 310/569-0023 or paul@medialinecommunications.com.