Advances in Percutaneous Autogenous Hemodialysis Fistula Creation

The most recent developments in achieving a truly percutaneous method for creating functional autogenous hemodialysis fistulas.

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Since the introduction of the Quinton-Scribner shunt in 1960 and the Brescia-Cimino autogenous fistula in 1966, there have been many incremental advances in hemodialysis access.[1,2] These include new autogenous fistulas, prosthetic dialysis accesses, different materials, and modifications of current concepts, including the Hero catheter (CryoLife, Inc., Kennesaw, GA). These advances have led to improved hemodialysis initiation times, quality of dialysis, maintenance of accesses, and outcomes in patients. Despite these advances, the requirement for initial surgical placement remains. This step is occasionally associated with significant wait times, costs, resource utilization, and complications.

THE NEED FOR A PERCUTANEOUS SOLUTION

Given the aforementioned limitations, a desired goal is to move hemodialysis creation outside of the operating room and move to percutaneous placement. There are many potential advantages to a completely percutaneous procedure, including faster times to initiating hemodialysis, quicker maturation times, and reduced costs and complications. The autogenous arteriovenous fistula (AVF) is the most desirable, given its improved patency and lower infection rates. However, the initial maturation failure rate is an issue that has yet to be consistently overcome. Furthermore, all hemodialysis accesses are prone to eventual failure, primarily due to formation of venous stenosis caused by trauma from the surgical access creation, flow-related shear stresses, and percutaneous interventions.

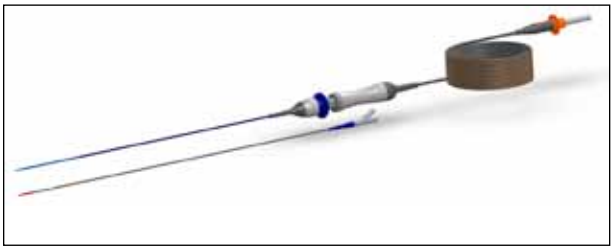

Figure 1. The TVA Medical Flex-1 device.

Any percutaneous fistula creation would involve the creation of an artery-to-vein anastomosis or an artery/graft-to-graft/vein anastomosis. Keeping this in mind, there have been isolated reports of created percutaneous fistulas, but most of these are modifications of prior working fistulas or grafts that were surgically created and then failed[3-6] In an animal study, Trerotola et al[7] created an entirely percutaneous hemodialysis graft that met with later failure but no subsequent known further investigation, modification, translation to human use, or larger study. There are other prior failed methods, attempts, and devices that have not reached implementation in humans. An initial report described the surgical creation of an arterial anastomosis with percutaneous creation of the venous anastomosis with stent grafts in humans.[8,9] More recently, the Gore Hybrid vascular graft (Gore & Associates, Flagstaff, AZ) is being placed in such a manner but requires surgical creation of an arterial anastomosis. No large study determining its efficacy has been published as of the writing of this article.

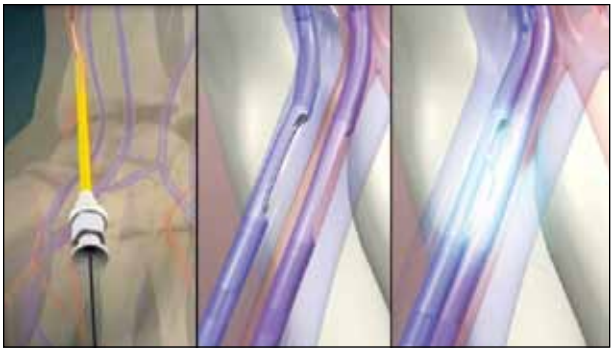

Figure 2. After arterial and venous access is achieved, the magnetic devices are inserted. Energy is then delivered, an AVF is created, and no implant is left behind.

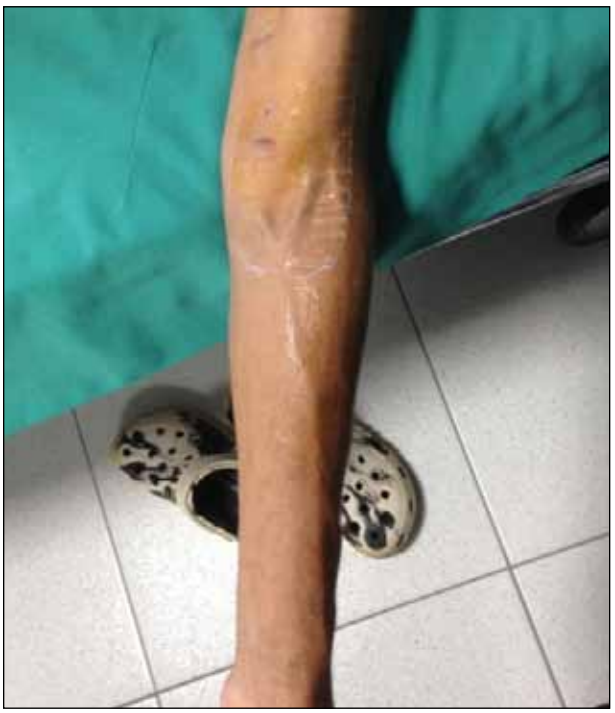

Figure 3. An initial pilot study patient 24 hours after percutaneous AVF creation.

NEW TECHNOLOGIES

There are other companies that are developing percutaneous access creation technologies, which include Phraxis, Inc. (New Brighton, MN) and Caymus Medical (San Juan Capistrano, CA). Caymus is working on an autologous AVF creation device, called the Vessel Select vascular access system, whereas Phraxis is developing a subcutaneous AV graft technology. Caymus and Phraxis have presented animal data demonstrating early preclinical proof of concept.

We have investigated the use of radiofrequency energy to percutaneously create an arteriovenous, sutureless anastomosis in humans with success. The TVA Medical Flex system (TVA Medical, Inc., Austin, TX) requires percutaneous delivery of an arterial and a venous catheter (Figure 1). When the catheters are appropriately positioned and aligned via magnets, the energy is delivered with subsequent creation of an AVF (Figure 2).

The first-in-human study was performed with a subsequent human clinical study completed (Figure 3). Fistula patency and effective hemodialysis delivery have been documented, with 6-month follow-up data to be presented in Europe later this year. No major complications were observed, and a majority of patients have gone on to initiate clinically sufficient hemodialysis via their percutaneously created autogenous fistula for several months. We are beginning a Phase 2 study in early 2014. Because no surgical anastomosis is created and no prosthetic material is placed, the potential advantages are many, including reduced procedural wait times, costs, improved patency, and lower infection rates.

CONCLUSION

A pivotal point is now being reached within the hemodialysis access creation field. Further refinements are required with proper investigative validation. However, multiple techniques and devices are now being developed and investigated with prospects of a truly percutaneous solution likely becoming available for routine clinical use within the next 1 to 3 years. ■

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