Aggressive approach to salvage non-maturing arteriovenous fistulae: a retrospective study with follow-up

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ABSTRACT: Purpose: To establish a standardized approach for the maturation of non-maturing arteriovenous fistulae. Methods: Consecutive patients (n=122) with non-maturing fistulae presented to our outpatient vascular access center for percutaneous interventions to assist in maturation. The techniques used included flow rerouting, competing branch vein elimination, staged balloon angioplasty, and limited controlled extravasation. Results: Successful fistula maturations were achieved in 118/122 patients. Fistulae were divided into two classes according to initial vessel size: class 1 (6.0-8.0 mm diameter, >6 mm deep) and class 2 (2.0-5.0 mm diameter) fistulae were evaluated for differences in technical procedures and clinically successful fistula maturation. Class 1 and class 2 fistulae were evaluated for mean number of procedures to maturation (1.6 and 2.6, respectively), and time to maturation (5 and 7 weeks, respectively). Follow-up for 109 of the initial 118 patients was achieved (mean=24 months, range=0.25-60 months). Class 1 and class 2 fistulae had primary patencies of 17 and 39% at 6 months; and secondary patencies of 72 and 77% at 12 months, 53 and 61% at 24 months, and 42 and 32% at 36 months, respectively. Primary and secondary patencies (Mann-Whitney test, p=0.44 and p=0.38, respectively) of class 1 and class 2 fistulae did not differ significantly, and secondary patencies were comparable to other fistula salvage studies. Conclusion: Fistula salvage attempts should not be limited by factors such as a diffusely small diameter or an inaccessibly deep position. (J Vasc Access 2009; 10: 183-91)

Key words: Dialysis, Fistula maturation, Salvage, Thrombosis, Angioplasty, ESRD, Arteriovenous fistula

INTRODUCTION

Early fistula failure has been defined as an inability to cannulate the fistula and/or support flow rates adequate for dialysis (350 mL/min) within 3 months of fistula creation (1). Up to 60% of arteriovenous fistulae (AVFs) fail to mature (2-5). Historically, endovascular techniques were unable to salvage up to 52% of non-maturing fistulae due to diffusely narrow outflow throughout the entire fistula body or access thrombosis (1, 6, 7). Recent advances in endovascular interventions have achieved primary patency rates ranging from 34-68%, with secondary patency as high as 93% at 1 year (1, 3, 4, 8). Clark et al (3), along with others (1, 9-11), has linked non-maturation of AVFs to stenotic lesions within the access, while Beathard et al has proposed that competing side branches unrelated to stenosis account for inadequate maturation (1, 12). Endovascular interventional techniques proved to be successful at treating both problems using percutaneous transluminal angioplasty (PTA) to treat focal stenoses, and coil embolization and ligation to eliminate competing branch veins (1, 3, 8, 9, 11, 13).

In particular, Nassar et al used balloon angioplasty of focal stenoses and coil embolization of accessory veins to salvage 83% of non-maturing fistulae, but concluded that 16.8% of fistulae were unsalvageable due to complete occlusion of the outflow tract, or the venous outflow tract being prohibitively deep, tortuous, or strictured (8). In our outpatient vascular access clinic, we have developed an immature fistula classification and a corresponding protocol which allows the salvage of nearly all unusable small diameter and deep AVFs using aggressive staged balloon angioplasty maturation (S-BAM).

METHODS

Patient population

One hundred and twenty-two consecutive patients (68 male and 54 female) with non-maturing AVFs were referred to our vascular access outpatient clinic by 18 sur-
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rounding dialysis centers between July 2004 and December 2006. All patients provided written informed consent. The study was conducted in accordance with the Declaration of Helsinki.

Patients with a patent fistula were included in the study. Thrombosed fistulae were excluded from the study. The maturation procedures were performed by a team of interventional nephrologists and radiologists. A retrospective analysis of patient records, digital images and reports was conducted. All relevant patient data (including demographics, AVF sites, initial AVF diameter, number of maturation procedures, procedural complications, and AVF use at dialysis) was recorded for each patient. Fistula salvage was achieved for 118 of the original 122 patients. Three years after the initial database was established, follow-up data for the 109 patients who were able to be contacted was collected in order to evaluate the longevity of the salvaged accesses (the remaining nine patients could not be tracked for follow-up).

While it is generally accepted that fistulae be allowed to mature for 6-8 weeks before investigating reasons for maturation failure (14), the median age of a non-maturing hemodialysis (HD) access at presentation to our outpatient clinic was 16 weeks. Table I lists the patient demographics.

Techniques used

Flow rerouting is a deliberate process of diverting blood flow into veins known to have straight line flow to the central circulation. Under road map guidance, a guidewire is used to traverse the intended fistula vein. Balloon angioplasty then follows the guidewire and a pathway of least resistance is created (Fig. 1). S-BAM with long-length balloons (80-100 mm) entails sequentially dilating the entire length of the fistula body in order to increase the fistula target size for cannulation (Fig. 1). Dilatation of the fistula was performed with an angioplasty balloon to treat any focal stenoses or simply to upsize the entire length of the fistula. Angioplasty was performed to 18 atm of pressure (Ultrathin Diamond balloons 3-12 mm diameter, Boston Scientific, Natick, MA), and 6-8 atm of pressure (XKL balloons 14-16 mm diameter, Boston Scientific, Natick, MA). The total time from start of inflation to end of deflation was generally less than 20 sec. Any residual stenoses were then fully effaced using ultra high pressure balloons up to 36 atm (Conquest/Atlas balloons 5-16 mm diameter, Bard, AZ).

**Limited controlled extravasation (LiCE)** is an arterial inflow control technique and systematic process of angioplasty across proximal vein (toward central and outflow), followed by distal vein (toward periphery and arterial anastomosis) to avoid inflow pressure exerting pressure forces on angioplasty-weakened tissues. The LiCE technique utilizes either an inflow occlusion balloon, or manual pressure on the arterial anastomosis (Fig. 1). Inflow control must be maintained during all phases of balloon inflation/deflation to avoid intra-fistula pressure spikes with sub-
sequent back-pressure injuries, complicating angioplasty across long segments of the vein.

Competing branch vein elimination involves coil embolization or surgical ligation of competing branch veins (Figs. 1, 2). Veins were considered to be significant (3-8 mm diameter) only if they had a persistent high-velocity imaged flow, or a palpable thrill following angioplasty of the main fistula channel. Coil embolization (Nestor, Cook, Bloomington, IN), was the method of choice for veins deeper than 3 mm. Surgical ligation of competing branch veins was used to eliminate superficial veins (<3 mm deep).

Study design

Diagnosis and classification - The K-DOQI “Rule of 6s” describes fistula characteristics associated with minimal risk of infiltration and the ability to deliver the prescribed blood flow throughout a dialysis treatment. The guideline suggests a fistula can be used when it is at least 6 mm in diameter, less than 6 mm deep, and has a blood flow greater than 600 mL/min. Based on this technical guideline, a 6 mm diameter fistula should be ready for use (14). In clinical practice, however, this same 6 mm diameter fistula, if greater than 6 mm deep, was very difficult to cannulate at dialysis and cannulation attempts frequently resulted in infiltration. This experience led us to the conclusion that fistula diameter and depth are interdependent factors and the appropriate diameter for a fistula is relative to the depth of the target vein. We therefore divided immature fistulae into two classes. Class 1 (n=47) AVFs were technically mature by K-DOQI definitions, but clinically immature due to their relative depth. Class 2 (n=75) AVFs were both technically and clinically immature. As a result, these two types of immature fistulae were treated according to different protocols.

Prior to undergoing the maturation procedure, detailed ultrasonography (Terason T3000, 5 MHz probe, Teratech Corp., Burlington, MA) of the AVF was performed to determine the vein size, fistula vein depth, location of competing branch veins (if any), and the best site for micropuncture needle cannulation.

Class 1 AVF protocol - Class 1 AVFs (6.0-8.0 mm diameter) could be used at dialysis, but were generally associated with cannulation problems due to a relatively deep position within the subcutaneous tissue (Fig. 3).

The goal for the first S-BAM procedure is dilation up to 8-10 mm diameter. Micropuncture needle (21 g) access was gained into the fistula under ultrasound guidance (Terason, Burlington, MA). Injections of intravenous contrast were studied using fluoroscopy (GE OEC 9800) and intravenous contrast angiography (Oxilan, Guerbet, Bloomington, IN). A 6Fr vascular sheath was placed and initial angioplasty was generally performed toward the arterial inflow in order to dilate stenoses up to 6 mm diameter at the arterial anastomosis and juxta-anastomotic segments. Then, a 7Fr vascular sheath was inserted toward the fistula outflow and flow rerouting, long-length balloon angioplasty, and elimination of competing branch vessels were performed in order to promote maturation. Many of the 6-7 mm deep fistulae were ready for use after the first maturation treatment. Deeper fistulae required more...
sits, as they needed to undergo more S-BAM procedures in order to achieve a larger fistula diameter. S-BAM, in combination with LiCE, was performed to avoid hematoma formation.

The body of the fistula can be matured with dilatation of the fistula from 6-8 mm up to 16 mm in diameter, as necessary. Dilations are generally performed in 2-3 mm diameter increments every 3 weeks.

Class 2 AVF protocol - Class 2 AVFs were comprised of 2.0-5.0 mm diameter fistulae and typically required more complicated maturation procedures. The same equipment and contrast was used as for class 1 AVFs. The first visit was the most technically difficult due to the small vein size and multiple competing branch veins (Fig. 4).

The goal for the first S-BAM procedure is dilation of the fistula to a 6 mm diameter. Following the initial cannulation, under ultrasound guidance, a fistulogram was performed to assess the AVF before intervention. A bidirectional approach was optimal for stabilization of the fistula vein during dilation of nearly all segments of the fistula, from the arterial anastomosis to the outflow veins. The artery was imaged using a 4Fr Bem diagnostic catheter. A sheathless approach and 0.018-inch wire and catheter systems with corresponding ultra-low profile long-length (80-100 mm long) symmetry balloons (Boston Scientific, Natick, MA) were initially used to perform dilations and avoid fistula lumen obliteration by the vascular sheaths. Heparin (approximately 3000 u) was helpful in preventing thrombosis related to slowing flow during manipulations.

During the initial maturation procedure, a primary fistula flow pathway was initially determined; if multiple pathways existed, a venous mapping was used (Fig. 4). Flow rerouting was then performed. The least tortuous pathway was selected and angioplasty eliminated short and long segment stenoses creating a low resistance fistula. S-BAM, in combination with LiCE, limited procedure complications. Following angioplasty, any remaining complicating branch veins were ligated or coil-embolized (Fig. 2).

Regardless of the initial vessel size, the goal for the first maturation procedure was to dilate these veins to 6 mm diameter and achieve a technical success. Only the most superficial fistulae (Fig. 5) were clinical successes following dilation at this point. The majority of class 2 fistulae required additional S-BAM procedures to achieve the target diameter of 8-10 mm. S-BAM was performed (Fig. 1) every 3 weeks, increasing balloon diameter in increments of 2-3 mm each session. Some of the deep class 2 fistulae (Fig. 6) were further dilated, up to 16 mm diameter (Fig. 2).

Technical and clinical success - technical success was achieved when a fistula had both a palpable holosystolic thrill and high-velocity flow visible on angiography. Clinical success was achieved when a patient received a minimum of three successful HD treatments after the necessary procedures.

Follow-up

Three years after the initial database was established, follow-up data was collected in order to evaluate the longevity of the salvaged accesses. Following completion of the maturation process (Fig. 2), patients were referred for a fistulogram by their dialysis center at first signs of fistula dysfunction, such as prolonged bleeding, high venous pressure, pulsatility, or difficult needle cannulation. All relevant data was obtained from chart reviews and patients.

Fig. 4 - Determination of primary fistula flow pathway.

Fig. 5 - Ultrasound image of a superficial class 2 fistula.
who did not undergo additional procedures at our center were contacted by telephone to determine the end of secondary patency.

**Complications**

In accordance with the Society of Interventional Radiology (SIR) criteria, major complications are defined as those that required hospitalization, caused permanent adverse sequelae, and death. Minor complications are defined as those that required nominal interventions (15).

**Patency**

In accordance with the SIR reporting standards, primary patency is defined as time between the initial intervention and the following repeat intervention; secondary patency is defined as the time of patency from the initial intervention to until the access was surgically revised, abandoned, or until transplantation, death, and loss to follow-up (15).

**Statistical analysis**

A Mann-Whitney rank test was used to compare primary and secondary patency rates at 6, 12, 24, and 36 months for class 1 and class 2 fistulae. For the purpose of statistical analysis, transposed brachiobasilic accesses were considered together with brachiocephalic accesses as upper arm accesses.

**RESULTS**

**Technical and clinical success**

Technical success was achieved in 118/122 patients. Clinical success was achieved in all 118 patients who had a technical success. The four technical failures were patients who presented with an occluded venous outflow tract which could not be traversed using a 0.018-inch wire.

In patients with class 1 and class 2 AVFs, angioplasty was performed across nearly all segments of the fistula circuit. Flow rerouting and interruption of competing branch vessels was performed primarily in forearm AVFs (Tab. II).

S-BAM maturation procedures in class 1 AVFs (89% >6 mm deep; average depth=7.8 mm; forearm, n=11; upper arm, n=36) were performed over an average vein span of 19.1 cm (range, 5-35 cm), increasing the diameter 1.5-2.5 times the original size. In class 2 fistulae (32% >6 mm deep; average depth=6.4 mm; forearm, n=52; upper arm, n=23), the average length treated with angioplasty was 19.6 cm (range: 5-35 cm) and the veins were dilated 1.5-4.3 times the original diameter. Class 1 and class 2 fistulae required an average of 1.6 and 2.6 procedures (corresponding to 5 and 7 weeks) to mature, respectively.

**Follow-up**

The mean follow-up was 24 months (range, 0.25-60 months); 109 of the original 118 patients with salvaged fistulae were able to be reached for follow-up. Of the nine patients lost to follow-up, six had class 1 AVFs and three had class 2 AVFs (Tab. I).
Over the course of 3 years, class 1 and class 2 patients required 1.9 and 1.2 interventions per access-year, respectively. Class 1 (n=6) and class 2 (n=7) patients required a total of 22 thrombectomy procedures to maintain access patency. Fourteen patients with upper arm fistulae required 24 cephalic arch venous stents. Eight of these patients received their initial stent during the first maturation procedure. Other interventions during the follow-up period included treatment for steal syndrome (n=4) and development of pseudoaneurysms (n=4). Steal syndrome was treated with Miller banding procedures (n=5) and coil embolization of the distal radial artery (n=1) (16, 17). Pseudoaneurysms were treated with angioplasty of venous outflow stenoses and banding (flow reduction) to minimize intra-access pressures. In one case, a stent-graft was placed in the mid-fistula to treat an angioplasty mediated “blow-out” pseudoaneurysm in a forearm fistula.

Complications

Minor, self-limited venous rupture occurs to some degree in 100% of our patients; 5% of our patients experienced moderate venous rupture. No major complications were encountered during the maturation procedures or within the follow-up period.

Patency rates

Analysis was performed to determine primary and secondary patencies of the salvaged fistulae (Fig. 7). The primary patency at 6 months for class 1 and class 2 AVFs was 17 and 39%, respectively. Secondary patencies for class 1 and class 2 fistulae were 72 and 77% at 12 months, 53 and 61% at 24 months, and 42 and 32% at 36 months, respectively. A Mann-Whitney test performed to compare the primary and secondary patencies of class 1 and class 2 fistulae yielded non-significant p-values (0.44 and 0.38, respectively), suggesting that no significant difference in outcomes existed between the two groups.

DISCUSSION

The percentage of AVFs maturing within 6 weeks of creation without any surgical or radiologic intervention is as low as 38% (18). The remaining 62% of AVFs will require a prolonged period of time to mature. Salvage procedures involve dilation of stenoses to improve fistula flow and channeling of fistula flow into a single lumen by eliminating competing branch veins. These interventions create a high flow single channel which will dilate and grow over time in order to achieve clinical usefulness. In this study, we expanded on these basic concepts and added flow rerouting, S-BAM, and the use of long length balloons, all to improve flow and fistula maturation rates (19).

A 6-8 mm diameter fistula in a superficial position would likely mature without interventions. When patients with such fistulae were referred to our center, the most common reasons for non-maturation were poor flow or tortuous anatomy. Class 1 (6-8 mm diameter, >6 mm deep) fistulae were positioned deep within the subcutaneous fat of the upper arm (n=36) and the forearm (n=11). Aggressive staged angioplasty of both forearm and upper arm vessels up to 16 mm made needle cannulation possible for fistulae 6-20 mm deep by creating a sufficiently large subcutaneous target, facilitating needle placement at dialysis. Fistula segments more than 20 mm deep were nearly impossible to cannulate, despite our angioplasty protocol, since dialysis needles are only 25.4 mm (1 inch) long. Aggressive S-BAM dilations were concentrated on fistula segments juxtaposed to the arterial anastomosis since these segments tend to be the least deep. Dialysis units familiar with the buttonhole technique for needle cannulation had great successes in bringing these deep, dilated AVFs to clinical maturity (20). Nevertheless, all of our patients with deep AVFs achieved clinical success without the need for open surgical procedures to superficialize the vein. Our secondary patency results (53 and 61% at 2 yrs for class 1 and class 2, respectively) are comparable to those achieved by fistula elevation procedures (59%...
at 2 yrs, n=295) by Bronder et al (21).

Class 2 (2-5 mm) AVFs consist of smaller, more distal vessels and are located predominantly in the forearm (n=52/75). These small-diameter veins were technically very difficult to manipulate, primarily due to initial cannulation problems and the overall fragility of veins. Once dilated to a 6 mm diameter, these veins were treated no differently from the larger class 1 AVFs at subsequent interventions. Angioplasty procedures were staged to minimize patient discomfort and decrease procedural complications by allowing for healing of the vein and subcutaneous tissue between angioplasties (22). Two to three weeks was our standard time interval between interventions. Re-intervention on elderly patients with fragile skin and diminished subcutaneous fat occurred in intervals of at least 3 weeks.

S-BAM interventions were performed using long-length (10 cm) balloon angioplasty to minimize procedure time and avoid thrombosis. Assuming 1 cm of overlap between balloon inflations, a long-length balloon would require two inflations to dilate 18 cm of vein. By comparison, a short-length (4 cm) angioplasty balloon would require six inflations to cover the same length of vein. We have observed that short-length balloon angioplasty of the fistula vein results in a more fractured angiographic appearance (indicated by increased extravasation) than long-length balloons. The long-length balloons minimized vein tears at the shoulders of each balloon inflation and created a more even lumen, with improved fistula flow.

Critics of this technique may argue that angioplasty should be performed with short-length balloons and restricted to focal stenoses because it irritates the vessel wall, prompting a defensive response of the damaged area with venous spasm and intimal hyperplasia (23). We have observed this to be only conditionally true. We believe angioplasty performed with complete rupture of the circumferential muscular and elastic layers of the vein wall prevents the fistula from contracting back to its pre-angioplasty diameter. In our experience, it is the fracturing of the tunica intima, media and adventitia in the context of the waterhammer pulsating flow and arterial pressure that promotes the maturation process (24). We believe that the rare occurrence of venous spasm in S-BAM procedures confirms our theory. The secondary patencies of class 1 and class 2 fistulae at 36 months are comparable to those of other studies, suggesting our aggressive balloon angioplasty maturation technique does not sacrifice durability by triggering a hyperplastic response of the vessel intima (Tab. III).

Analysis of our data, stratified by initial fistula diameter, demonstrated similar long-term patency across all fistulae, regardless of initial fistula size (Fig. 7). Our low primary patencies for all fistulae were to be expected, given the maturation protocols we have outlined. For the class 1 and class 2 fistulae groups, the secondary patencies were not statistically different (Fig. 7), suggesting that diffusely stenosed fistulae were just as likely to be patent following angioplasty as large-diameter fistulae. This is contrary to a popular belief that diffusely narrowed fistulae are not worth salvaging because the long-term patency is poor. In a study by Nassar et al, diffusely narrowed and excessively deep fistulae were excluded from salvage procedures (8). Sidawy et al suggested that fistulae which are “too small or too deep” require revision or abandonment (25). Although we were able to salvage these fistulae, it does appear to come at the expense of numerous interventions.

In a prospective study, the average number of procedures per access-year was 0.53 for a cohort of autogenous accesses (n=100) which matured through natural processes (26), though the number of fistula interventions per access-year has been reported as high as 0.72 (27). For grafts, the number of procedures per access-year ranged from 0.92 (18) to 2.4 (28). By contrast, frequent interventions appear to be the mainstay of salvaged fistulae. Falk

### TABLE III - COMPARISON OF SECONDARY PATENCIES IN MATURATION STUDIES

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Avg. Follow-up Time, Range (Months)</th>
<th>Treatment</th>
<th>3-mon.</th>
<th>6-mon.</th>
<th>12-mon.</th>
<th>24-mon.</th>
<th>36-mon.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turmel-Rodrigues '01 (10)</td>
<td>52</td>
<td>12 (1-24)</td>
<td>PTA only</td>
<td>88%</td>
<td>83%</td>
<td>79%</td>
<td>75%</td>
<td>N/A</td>
</tr>
<tr>
<td>Beathard '99 (28)</td>
<td>63</td>
<td>N/A</td>
<td>PTA, SO</td>
<td>82.5%</td>
<td>78%</td>
<td>74.7%</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Nassar '06 (7)</td>
<td>119</td>
<td>8.9</td>
<td>PTA, SO</td>
<td>100%</td>
<td>100%</td>
<td>95%</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Falk '06 (26)</td>
<td>65</td>
<td>10.6</td>
<td>PTA, SO</td>
<td>73%</td>
<td>72%</td>
<td>68%</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Own data - Class 1</td>
<td>47</td>
<td>(0.4-38)</td>
<td>PTA, CO,</td>
<td>93%</td>
<td>86%</td>
<td>72%</td>
<td>53%</td>
<td>42%</td>
</tr>
<tr>
<td>Own data - Class 2</td>
<td>75</td>
<td>(0.25-60)</td>
<td>LiCE, FR, SO</td>
<td>98%</td>
<td>92%</td>
<td>77%</td>
<td>61%</td>
<td>32%</td>
</tr>
</tbody>
</table>

Abbreviations used: PTA - percutaneous transluminal angioplasty; SO - surgical occlusion; CO - coil occlusion; LiCE - limited controlled extravasation; FR - flow rerouting

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has reported an average of 1.75 interventions per access-year, with an average follow-up of 317 days (29). In our study, the average number of procedures per access-year was 1.5, over 3 yrs of follow-up. Class 1 patients averaged 2.0 procedures per access-year. This patient group predominantly consisted of upper arm fistulae, which required numerous interventions and stents across the cephalic arch. By contrast, the smaller class 2 AVFs averaged 1.2 procedures per access-year. This patient group consisted predominantly of forearm AVFs, which were almost uniformly treated with flow rerouting into the basilic vein in order to avoid the problematic cephalic arch. The interventions required by these accesses were primarily at the juxta-anastomotic site. Although our approach necessitates a greater number of interventions, it avoids central venous catheters, hospitalizations, and access creation surgeries, making it preferable to the traditional system of access revision, graft placement, and prolonged central venous catheter use.

The limitations of this study include its retrospective nature and lack of randomization. However, these shortcomings must be placed in the context of a relatively large initial patient pool (122 patients), mean follow-up time of 24 months (range, 0.25-60 months), and similar patencies in class 1 and class 2 patients in the follow-up groups. Our statistical analysis includes 109 patients, with the date of the last visit declared the end of secondary patency if no further information could be obtained.

A 20% annual death rate has been documented for HD patients (30). Although our data was uncensored for patient deaths, we have provided a 20% per year attrition curve as a basis of comparison of our results with the outcomes that would be expected in an average cohort of dialysis patients (Fig. 7). Given the congruity between our secondary patency curves and this default curve, we believe that the accesses created through our protocol were durable and the predominant cause of the end of secondary patency was patient death.

A fistula classification system, combined with aggressive angioplasty in accordance with our techniques allows the interventionalist to quickly, safely and effectively mature a non-functioning fistula. S-BAM has allowed us to decrease maturation time and promote clinical success in both small-diameter and deep (>6 mm) AVFs. Despite differences in initial vein diameter, nearly all AVFs can undergo staged dilation to establish a functional fistula. As such, our protocol yields high rates of immediate success and long-term patency.

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