Minimally Invasive Limited Ligation Endoluminal-assisted Revision (MILLER) for treatment of dialysis access-associated steal syndrome

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Dialysis-associated steal syndrome (DASS) is defined as a clinical condition caused by arterial insufficiency distal to the dialysis access owing to diversion of blood into the fistula or graft. The incidence of symptomatic DASS requiring treatment is 1–8%. The etiology is iatrogenic and symptoms are quite debilitating. Banding of the access inflow has largely been abandoned because of the inherent problem with balancing fistula flow with distal flow complicated by a high incidence of subsequent access thrombosis. In this study, we are reporting a modification to the traditional banding procedure, which markedly improves banding outcomes. We are reporting 16 patients who underwent a new standardized minimally invasive banding procedure performed in an outpatient setting with minimal morbidity. This modified banding procedure requires a small (1–2 cm) skin incision for the placement of a ligature and utilizes a 4 or 5 mm diameter endoluminal balloon to achieve and standardize the desired reduction of inflow size. All 16 patients had immediate symptomatic and angiographic improvement after the procedure. Follow-up showed none of the patients had recurrence of symptoms or thrombosis of the access. In our experience, this procedure is an excellent treatment option because of its simplicity and should be considered as a first-line treatment for patients with DASS.

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Steal is physiologic and occurs in 73% of arteriovenous fistulas, and 91% of arterio-venous grafts (AVG).[1–4] It is usually asymptomatic not requiring treatment. It seems physiologic steal is universal, but symptomatic steal occurs in patients who are unable to develop collateral or direct flow to offset steal.[5,6] Severe symptomatic ischemia is characterized by hand weakness, rest pain, and tissue necrosis. It requires treatment in 1% of arteriovenous fistulas and 2.7–4.3% of AVG,[7] although it varies from 1–8% in different studies.[1–3] Steal syndrome differs from ischemic neuropathy in the time of onset (immediate in ischemic neuropathy) and severity of symptoms (more severe pain and paralysis in ischemic neuropathy) without clinical evidence of ischemia of the involved extremity in patients with ischemic neuropathy.

Diagnosis of dialysis-associated steal syndrome (DASS) requires three criteria to be fulfilled: (1) symptoms highly suggestive of DASS, (2) absent forearm pulses, and (3) radiographic criteria. Patients with DASS have three radiographic variations. Most patients have no visualized contrast flowing into the downstream artery. Some patients will have contrast flow into the downstream artery which refluxes right back into the arteriovenous access. Rarely there is a radiographic wisp of contrast flowing downstream toward the hand, which takes more than 10 s to reach the palmer arch.

Treatment options include: sacrifice of the access, flow reduction procedure (banding), percutaneous transluminal angioplasty (PTA) of arterial stenosis, and various revascularization surgeries as achieved in Distal Revascularization and Interval Ligation (DRIL),[7] and Revision Using Distal Inflow (RUDI).[8] Patients usually have limited options for new access creation making sacrifice of the access a less than optimal choice. Historically, banding of the access inflow has had limitations. If the band is too tight, it causes poor dialysis efficiency or thrombosis of the access, and if too loose, it does not alleviate symptoms.[7,9–11] PTA of the inflow artery is a good choice if the cause of steal syndrome is stenosis of the proximal artery, whereas PTA of the distal artery can improve flow if focal stenosis is noted angiographically. Revascularization surgeries are complex and met with various degrees of success. We have developed an improved and standardized flow reduction procedure, which is called the 'MILLER' (Minimally Invasive Limited Ligation Endoluminal-assisted

Revision). This technique overcomes the inherent difficulties of sizing associated with banding. It can be easily and safely performed in an outpatient setting with good outcomes and minimal-associated morbidity.

RESULTS

The incidence of DASS requiring treatment in our practice was 1.33% (approx.). In our study, all patients (100%) had significant symptomatic improvement. The mean follow-up is 3 months and the longest follow-up is 11 months. One patient 6.25% had moderate residual but tolerable symptoms secondary to severe atherosclerotic arterial disease. Banding was carried out to 4 mm in 87.5% (14/16) and 5 mm diameter in 12.5% (2/16) of patients. Three patients developed steal symptoms after they had angioplasty of the venous outflow for access dysfunction. An immediate complaint of pain and severe coldness of the hand resulted in the need for a MILLER procedure before one patient left the angiography table. The remaining two patients had high suspicion for developing steal symptoms on angiography but returned after a few days with symptoms and signs of DASS and had a MILLER procedure performed. One patient had an arterial ischemic ulcer with acute tissue necrosis on the dorsum of the hand. It healed within 1 week following the procedure. Another patient with fingertip necrosis was banded and then referred for amputation. Post-amputation healing was uneventful.

No infections have been reported at the cut down site. No aneurysms have developed proximal to the ligature. One hundred percent of the patients have a working access within the follow-up period. Two patients (12.5%) required some type of intervention on their access unrelated to a steal syndrome.

DISCUSSION

Distal ischemia of the access bearing extremity without angiographic evidence of occlusive arterial lesions defines true DASS. The hemodynamics of steal follows the principle of blood flow traveling the path of least resistance. The instant an access is created physiologic steal is present. It is usually asymptomatic and does not require treatment. When resistance in the access becomes significantly less than in the native arteries, the patient develops symptomatic steal.[5,6] Previous studies have identified independent DASS risk factors such as female gender, diabetes,[1,9] and previous access surgery in the ipsilateral stealing extremity.[9]

Access creation requires establishing flow equilibrium between an arteriovenous access and the downstream artery. If there is an equilibrium shift favoring blood flow to the downstream artery, patients will have problems with low blood flows or access thrombosis. If flow is mostly going to the access, patients will develop steal syndrome. In our opinion, the angle between the inflow artery, access anastomosis, and downstream artery is an important determinant of preferential blood flow (Figure 1). The overall size of the arterial anastomosis and relative resistance between the access and downstream artery are other determinates of DASS. Many patients develop steal over time as dynamic forces such as high blood flow, atherosclerosis increasing resistance in the downstream artery, and endovascular interventions causing a shift in flow equilibrium.

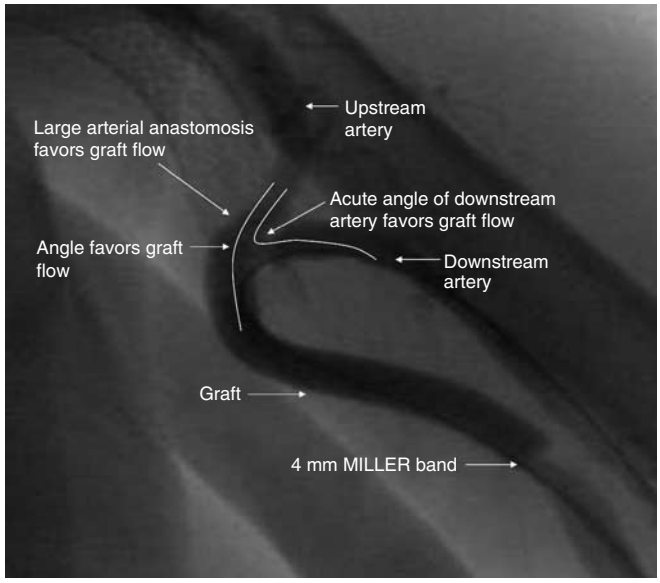


Figure 1 | Identifies two of the main flow characteristics that we believe are the major determinates of DASS. Firstly, the arterial anastamosis is larger than the downstream artery feeding the hand. This favors graft flow. Secondly, the upstream and downstream arteries form an acute angle diverting flow preferentially into the graft. This patient had severe ischemic symptoms until the 4 mm MILLER ligature was placed.

The greatest determinate of steal appears to be the angle relationship between the arterial anastomosis, upstream artery, and downstream artery. The overall size of the anastomosis may be less important. Although we are not changing the arterial anastmostic angles with the MILLER procedure, the resistance created in the access outflow shifts the equilibrium and diminishes steal symptoms. More studies in the future are required to help us better understand these observations.

If patients have symptoms of steal and a 4 mm anastomosis is noted angiographically with adequate angiographic runoff into the downstream artery, then the patients need to be evaluated for other causes of symptoms such as peripheral neuropathy. None of our patients with DASS had a 4 mm anastomosis. Moreover, in our practice, we routinely dilate the arterial anastomosis to 5–6 mm during procedures such as a routine thrombectomy without development of steal symptoms.

So far none of our patients have developed aneurysmal dilatation proximal to the site of banding. We do not expect any patient to develop aneurysmal dilatation in the future as no needle cannulation occurs in this very proximal segment of the access. Pressures are generally low proximally owing to a small intraluminal radius and low wall tension. Flow also can readily escape into the downstream artery effectively decompressing this segment.

DASS is usually associated with the access placed above the trifurcation of the brachial artery. It is rarely reported with radiocephalic (Brescia–Cimino) and high radial artery anastomotic fistulas. In our study, 94% of patients had an access originating from the brachial artery and only 6% patients had the access originating from the radial artery. Initial sensory symptoms of coldness and parasthesias of the hand are the hallmarks of arterial DASS. Symptoms are usually mild and do not require intervention as most patients will improve in few weeks.[7] Rest pain, pain or intolerable coldness during dialysis, and motor symptoms with hand weakness or atrophy of the hand muscles are indications for intervention, hopefully before the development of ulcers or gangrene of the digits.

The importance of making the diagnosis of true DASS is critical for the success of the procedure. All three criteria of diagnosing DASS should be met before undertaking the procedure. Good contrast flow to the hand when angiography is performed with outflow access compression (occluded) has been strong indicator of success with this procedure. This study is important to rule out any downstream artery stenosis. Thus far, the presence of mild-to-moderate atherosclerotic disease has not prevented success of the procedure.

The aim of treatment is to alleviate DASS symptoms while retaining arteriovenous access patency. The simplest treatment for ischemia is ligation of the fistula, thereby eliminating steal and improving distal perfusion. Even though symptoms resolve, the patient requires another access to continue renal replacement therapy. Till now, the only reportedly reliable option to treat DASS surgically is either DRIL[7] or RUDI. DRIL consists of ligation of the artery distal to the fistula and placement of a bypass vein graft with a proximal anastomosis at least 5 cm above the access and a distal anastomosis immediately below the arterial ligation. The bypass re-establishes distal perfusion of the hand, and should maintain adequate flow to the dialysis access. With RUDI, as name suggests, the fistula is revised using more distal inflow. DRIL and RUDI are open procedures and carry the usual surgical and anesthetic risks.

Non-standardized banding was widely used in the past but has produced disappointing results and has now been largely abandoned because of poor reliability. Banding reduces the blood flow through the vascular access by creating a focal lesion of high resistance (stenosis) within the access circuit, thus improving distal perfusion. There is a paucity of data on long-term follow-up after banding. One study describing long-term follow-up after this technique reported a patency rate of 62.5% at 6 months and 38.5% at 1 year.[12] Another study using the same technique reported that banding achieved symptomatic relief in 10 patients; however, it resulted in thrombosis of the access (arteriovenous fistulas) with patency rate of 9% at 6 months.[5] The main problem is proper adjustment of the size of the ligature to obtain sufficient reduction in the blood flow rate while maintaining the patency of the access. In the MILLER procedure, standard predictable caliber is achieved by choice of balloon size.

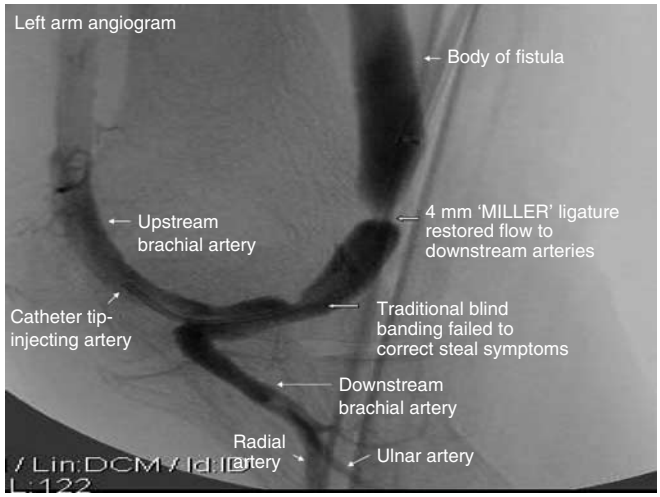


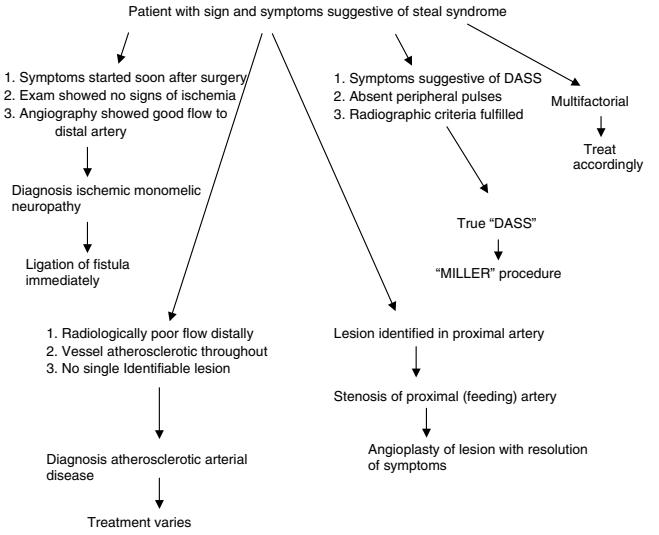
Figure 2 | A 68-year-old female with right upper arm brachial artery to cephalic vein fistula presented with DASS. She was referred to her vascular surgeon who placed a clip proximally attempting to correct the steal syndrome. The patient then returned with persistent severe steal symptoms and underwent a MILLER procedure, which sized the flow restricting band to 4 mm. The patient had an immediate resolution of symptoms.

The procedure described here essentially is a modified version of banding. It improvises on the inherent failure associated with blind banding. Traditionally, the band is either too tight (chokes off blood flow in the access) or too loose to improve the patient's steal symptoms. In this procedure, an endoluminal balloon gives the exact desired inflow size. Sizing is a simple decision based on angiographic criteria. The only two logical choices are a 4 or 5 mm diameter band. A 3 mm diameter band would cause too much restriction in access flow and possible thrombosis, and a 6 mm diameter band would be ineffective in redirecting flow into the native 3–5 mm diameter forearm arteries. Figure 2 illustrates a surgical ligature, performed blindly which failed to correct the steal. Also identified in the image is a 4 mm MILLER ligature which adequately corrected the steal. The current follow-up for this patient is 11 months with a working access and elimination of symptoms. In our study, 14 patients had banding to size 4 mm and two patients to 5 mm size.

A MILLER procedure has the advantage of being significantly less invasive than a DRIL procedure. This procedure can be performed quickly and safely in an outpatient setting. It is easily reversible using balloon angioplasty technique to either stretch or break the band if access flow is too slow. It has a minimal-associated morbidity considering the entire procedure consists of a small (1–2 cm) skin incision coupled with a 5F puncture into the access in order to place the sizing balloon. For these reasons, it seems that the MILLER procedure is an excellent option for the patient suffering with this debilitating condition. Although we have demonstrated short-term success, further follow-up will be critical to in advocating this procedure before the other surgical alternatives.

Evaluation of the patients with symptoms of hand ischemia has been a daunting problem in the past. It is easier now that we have developed an objective protocol at our center. Studying the arterial anatomy angiographically is of primary importance. Understanding the hemodynamics of the affected limb by a detailed clinical examination and arteriography is necessary to establish the diagnosis. If ischemia is owing to arterial insufficiency and focal arterial stenosis is identified, an endovascular PTA can correct the steal and improve the perfusion to the downstream artery. Patients with diffuse severe peripheral arterial disease posess a significant treatment challenge for which neither endovascular treatment nor surgical revascularization can provide relief. Treatment should be individualized depending upon severity of symptoms, availability of another site for access placement, age of the patient, and comorbid conditions. For patients with diagnosis of true DASS, in our opinion, the first option offered to the patient should be a 'MILLER' procedure because it is safe, effective, minimally invasive, and has extremely low associated morbidity.

Our suggested approach to suspected post-access ischemia is as follows (Algorithm 1):



Conclusion

In our experience, ischemia of the hand associated with dialysis angioaccess creation is an under-treated problem. All interventionalists, especially in a high volume dialysis access practice, will eventually not only see but will also create a steal syndrome during a routine angioplasty of a venous outflow stenosis. If we are more vigilant about patient's symptoms, we may identify more patients who are suffering with steal syndrome Given this eventuality, it is important that we have the skill set necessary to correct steal immediately. Patients should no longer suffer endless delays to correct a syndrome, which can be easily corrected with the MILLER procedure.

MATERIALS AND METHODS

This paper presents all of the patients (16) requiring intervention who presented to our freestanding hemodialysis access care center with various symptoms associated with DASS from February 2005 to November 2005. All patients underwent physical examination and angiographic evaluation for objective criteria before being classified as DASS.

Table 1 | Characteristics of 16 patients with DASS

Characteristics	*n*
Age	63 (range 42–90)
Men	8
Women	8
Diabetics	8
Hypertension	15
Race	
Caucasian	8
Afro-American	6
Asian	2
Type of access	
Fistula	10
Graft	6

DASS, dialysis-associated steal syndrome.

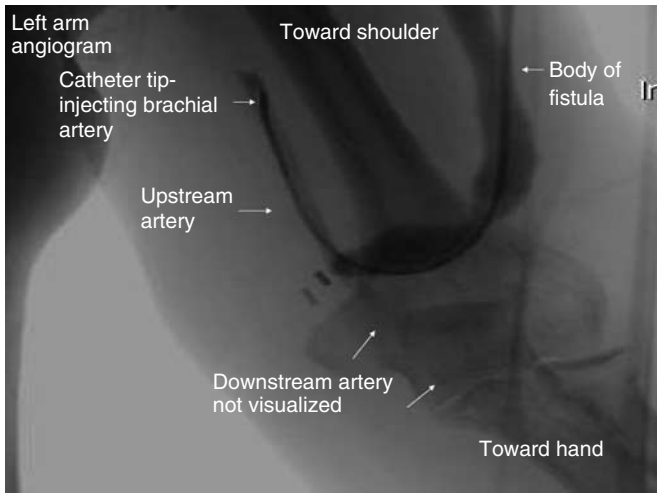


Figure 3 | This is a left upper arm brachial artery to cephalic vein fistula. A catheter is placed into the proximal (upstream) artery and 5 cm^3 of contrast are injected over 1 s. Nearly 100% of arterial flow enters the fistula. No contrast is noted distal to the fistula anastomosis. This is typical of DASS.

Median age of presentation was 63 years (Table 1) and there were equal number of men and women in the study. There were 50% (8/16) Caucasian, 37.5% (6/16) African American, and 12.5% (2/16) Asians. Coexisting risk factors for vascular disease were hypertension 94% (15/16), diabetes 50% (8/16), and documented coronary artery disease 37.5% (6/16) of patients. Access distribution was 62.5% (10/16) autologous fistulas. Ninety-four percent (15/16) patients had access in the upper extremity and 88% (14/16) of the patients had access fed by a brachial artery. Only one patient, 6% (1/16), had an access feeding from the radial artery and remaining one patient, 6% (1/16), is feeding through femoral artery. Two patients (12.5%) had a forearm graft access originating from the brachial artery below the elbow. The most common reasons for intervention were numbness, tingling, and severe coldness in the hand (56% (9/16)) and rest pains (50% (8/16)). Other symptoms were pain during dialysis (45% (7/16)), weakness (19% (3/16)), tissue necrosis (12.5%

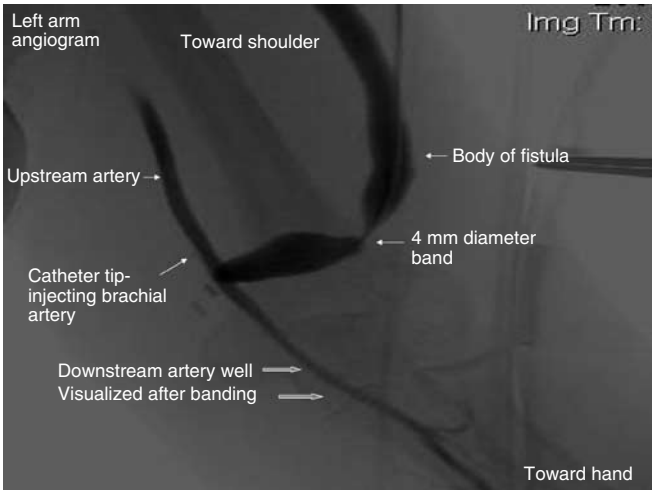


Figure 4 | Patient in Figure 1 post-MILLER procedure. A catheter is placed into the proximal (upstream) artery and 5 cm^3 of contrast are injected over 1 s. A MILLER ligature is noted at the large arrow. Contrast can be seen distal to the access anastamosis indicating a return of perfusion to the hand.

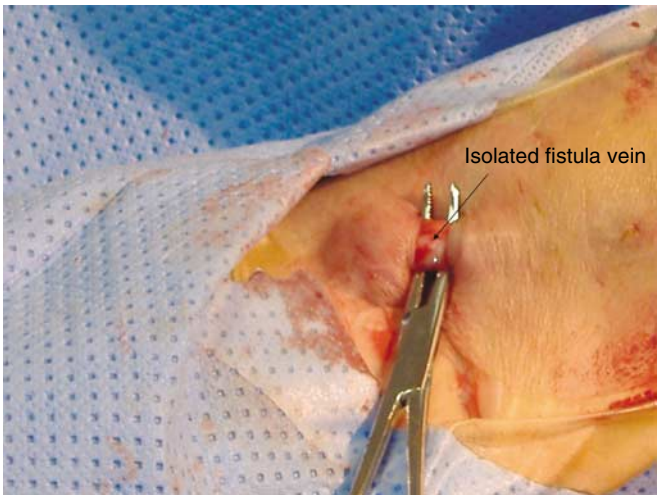


Figure 5 | Patient with right forearm fistula with isolated vein through a 1.5 cm incision.

(2/16)), and multiple symptoms in (62.5% (10/16)) patients. Banding was carried out to 4 mm in 87.5% (14/16) and 5 mm diameter in 12.5% (2/16) of patients.

Procedure

The basic principle of access flow limiting is to increase the blood flow to the downstream (see Figures 3 and 4) artery by restricting flow to the access without compromising access function or patency. After a detailed physical examination, the diagnosis of DASS is confirmed angiographically (GE OEC 9800 plus). Access is gained through the main body of fistula in retrograde manner toward the arterial inflow. A 0.035 glide wire in conjunction with Berenstein catheter (4fr) is used to cross the arterial anastomosis. After placing the catheter in the artery, selective arteriography is performed. If no contrast flow is visualized beyond the access anastomosis contrast (loxilan 62%, 300 mg/ml, mfg. Guerbet LLC) flow timing

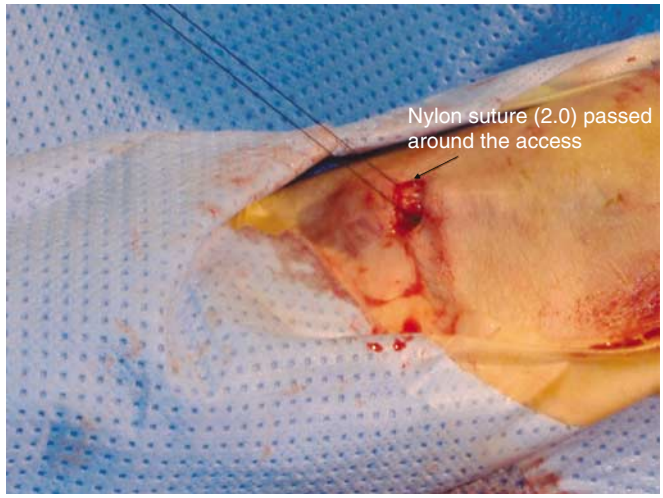


Figure 6 | A nylon suture (2.0) passed around the patients right forearm fistula vein before tying the MILLER ligature.

is performed with access compression to rule out severe atherosclerotic disease of the peripheral arteries.

Visualization to the vessel origin may be necessary to exclude more proximal inflow stenosis and aberrant anatomy. Orthogonal views are obtained to search for stenosis. If stenosis are present, appropriate PTA may be effective treatment for the DASS. If no focal stenosis is present, flow restriction is performed.

The procedure is performed using local anesthesia (1% xylocaine) and intravenous conscious sedation with Fentanyl (fentanyl citrate 50 μg/ml, from Hospira, Inc., Lake Forest, IL, USA) and Versed (Midazolam HCL 2 mg/2 ml, from Hospira, Inc., Lake Forest, IL, USA).

Through a small (1–2 cm) incision, the vein (fistula) or graft is carefully dissected using blunt dissection technique (Figure 5) so that a 2-0 monofilament ligature (Ethylon or Proline) can be passed around it (Figure 6). The site of incision is usually within 2–3 cm of the arterial anastomosis avoiding any problems with dialysis needle placement. After appropriately sizing the vessels, the procedure utilizes an endoluminal angioplasty balloon to achieve the desired (corrected) size of the access inflow. The predicted correct size of the inflow should be equal to or smaller than the size of the downstream artery. The corrected size of the inflow dictates the size of the balloon chosen for the procedure. An angioplasty balloon (ultra-thin diamond Balloon from Boston Scientific/Meditech) is then inflated to 18 atmospheric pressure in the juxta-anastamotic segment and the ligature is tied snugly around the outside of the access. The balloon is deflated and patient is evaluated for symptomatic and angiographic improvement. If the patient reports no symptomatic improvement and still is ongoing angiographic evidence of steal, the procedure can be repeated with a second ligature tied approximately 0.5 cm juxtaposed to the first ligature. The second suture effectively creates a segment of high resistance rather than a focal high resistance band. In some cases, an initial 5 mm ligature is downsized to a 4 mm ligature. A 3.5 mm ligature is a possibility, but has not yet been necessary.

The patient is then re-evaluated for additional intervention. The incision site is closed with 2.0 nylon sutures and the patient discharged to recovery for a short period. Subjective symptomatic improvement is often noted while the patient is still on the table or in the recovery area.

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