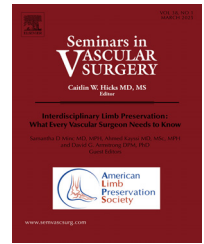


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Review article

Percutaneous approach to deep vein arterialization for the “no-option” chronic limb-threatening ischemia patient

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ABSTRACT

Chronic limb-threatening ischemia is an advanced stage of peripheral artery disease characterized by rest pain or tissue loss. Treatment of patients classified as “no-option” CLTI remains particularly challenging, as historically their primary treatment has been limited to major amputation. Venous arterialization has emerged as a promising alternative in this difficult-to-treat population. Advances in optimized technology and endovascular techniques, particularly deep venous arterialization, have had encouraging outcomes for long-term limb salvage. Successful limb preservation relies on proper patient selection, a compliant patient, and a robust multidisciplinary clinical team to support the complex processes of deep venous arterialization maturation and wound healing. This review will discuss the historical background of venous arterialization, patient selection criteria, and surgical techniques for percutaneous deep venous arterialization, and postoperative management after the index procedure, including wound care, surveillance, and reintervention strategies for successful limb salvage.

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1. Introduction

Peripheral artery disease (PAD) is an increasingly common disease in the United States, affecting nearly 8.5 million people [1]. Chronic limb-threatening ischemia (CLTI), the end stage of PAD, results in rest pain or nonhealing wounds, with the dreaded sequela of CLTI being major amputation. If not revascularized, patients with CLTI are estimated to have a 50% limb loss rate in the first year [2]. Over the past decade, CLTI caused approximately 75,000 amputations annually, with more than \$25 billion in health care expenditures [3]. The 1-year mortality rate associated with major amputation reaches 40%, with

a 5-year mortality rate of 80%. Given the morbidity and mortality of major amputation, vascular surgeons and interventionalists have adopted an aggressive approach to revascularization in patients with CLTI to achieve limb salvage.

There is a particularly challenging group of patients with CLTI who are classified as “no option” because they are considered to have no arterial revascularization options based on the following criteria: (1) “desert foot” (ie, no named arterial target vessels in the foot for revascularization), (2) lack of venous conduit for an arterial bypass, (3) extensive soft-tissue loss rendering the foot nonsalvageable, (4) severe comorbid conditions precluding any intervention, and (5) a nonfunctional limb [4] (Table 1). Historically these patients have either un-

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Table 1 – Classification of patients with “no-option” chronic limb-threatening ischemia.

Type	Criteria
1	Desert foot or no arterial targets
2	Lack of venous conduit
3	Extensive tissue loss
4	Severe comorbid conditions
5	Nongunctional

dergone major amputation to alleviate their CLTI symptoms or succumbed to their comorbidities, resulting in mortality.

Venous arterialization is becoming an increasingly prevalent revascularization technique in patients with no-option CLTI, predominately no-option due to desert foot and occasionally due to lack of a venous conduit. Prior studies have suggested these patients with no-option CLTI can range in age from 50 through 80 years, have a slightly higher male prevalence (66% to 68%), and 40% to 45% of patients are non-White [5]. They also have an extremely high prevalence of comorbidities known to result in small vessel and microvascular disease; nearly 80% of patients have diabetes, 25% to 40% have chronic kidney disease, and 18% to 25% have end-stage renal disease. Without intervention, rates of mortality or limb loss can range from 50% to 80% at 1 year [5]. Although a particularly challenging patient population from both a comorbidity standpoint and an anatomy standpoint, venous arterialization in the appropriately selected patient may provide an alternative to limb loss, improving quality of life, preserving ambulation, and increasing rates of survival [5].

2. Historical background of venous arterialization

The goal of venous arterialization in the foot for patients with no arterial revascularization options is to arterialize the deep foot venous network, recruiting flow not only through the deep venous tissues in the foot, but also to the superficial dermal and subdermal venous network, also known as Lejar's venous plexus [6]. The ultimate goal of venous arterialization is to develop a robust neovascularization network, converting them to a new arterialized network of vessels in the foot that may not even rely on the patency of the venous arterialization in the long term (Fig. 1). This can be done with an open, endovascular, or hybrid approach to arterialize the deep or superficial venous system.

This technique of creating a lower extremity arterial-venous (AV) connection was first described in 1902, when the end-to-end anastomosis of the femoral artery and femoral vein was created for treatment of gangrene [7]. However, this was not successful due to the inability to overcome the valves of the vein and provide arterial flow in the distal portion of the lower extremity. Decades later, multiple case studies demonstrated the success of venous arterialization with a distal AV anastomosis in the foot via the medial marginal vein (MMV) [8,9]. Other case studies have demonstrated venous arterialization with a more proximal AV bypass, with the lysis of ve-

nous valves with a valvulotomy, facilitating antegrade flow through the venous network into the foot [10].

More contemporary methods of venous arterialization have evolved over the past decade, including deep venous arterialization (DVA) via off-the-shelf means or through commercial systems recently approved by the US Food and Drug Administration [11] or hybrid superficial venous arterialization (HySA). A DVA is created via a percutaneous connection between a tibial vessel—most often the posterior tibial artery—and the adjacent tibial vein just proximal to the location of the distal tibial artery stenosis and occlusion. After percutaneous venous valve lysis of the distal tibial vein and lateral plantar vein (LPV), a covered stent is deployed from the arterial crossover point to the foot to facilitate direct arterial flow into the deep venous network of the foot, feeding the LPV and its collaterals (Fig. 2). In comparison, an HySA procedure uses the great saphenous vein (GSV) as the conduit, providing arterial flow into the foot via the MMV and its perforators into the deep venous network into the foot. During this procedure, an open end-to-side anastomosis is created between the below-the-knee popliteal artery or a proximal tibial artery and the GSV (Fig. 3). Via the MMV on the dorsal surface of the foot, either by open or percutaneous methods, the valves of the MMV and the GSV are lysed. Side branches of the GSV are ligated during the initial procedure and an angiogram ensures flow from the GSV and the MMV into the deep venous system of the foot via perforators (Fig. 4).

3. Patient selection for venous arterialization

Appropriate patient selection for this procedure is essential for the success of venous network maturation, wound healing, and limb salvage. Although this procedure has the potential for limb salvage in an otherwise no-option situation, DVAs are associated with the need for close follow-up; often multiple, repeat interventions to facilitate maturation; a high-rate of symptom sequela; and delayed surgical approach to tissue loss. Multiple expectations need to be set, including: (1) the potential for multiple procedures to allow for the maturation of the DVA (to enhance the flow volumes, continue to optimize inflow, or to directionalize flow into the foot by reducing stealing from venous branches); (2) clinical sequela, including worsening of forefoot pain secondary to a stealing fistula circuit, lower extremity edema, potential for worsening of forefoot ischemia, and deconditioning; (3) amputation of the gangrene tissue will be delayed until maturation of the DVA, often after a 6- to 10-week maturation period; and (4) overall wound healing will take 6 to 9 months. It is also important to educate the patient that once the neovascularization network has developed a robust, high-resistive, arterialized network in the foot, described as “conversion,” often the DVA or HySA will occlude; however, the ability to maintain enough perfusion for wound healing and alleviation of rest pain remains [13].

For patients who experience tissue loss, wounds must be stable to allow for a DVA maturation process. Rapid progression of forefoot gangrene or infection associated with ascending foot cellulitis or systemic signs of infection are contraindicated. Utilization of venous arterialization for rest pain should be done sparingly, as often in these patients, the creation

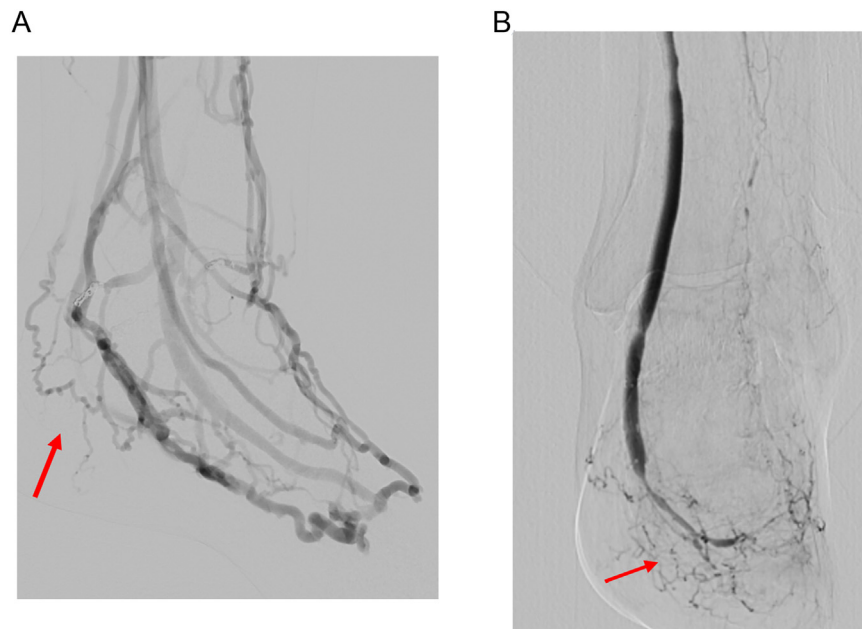


Fig. 1 – (A) Early development of Legar's venous network. (B) Late development of neovascularization network.

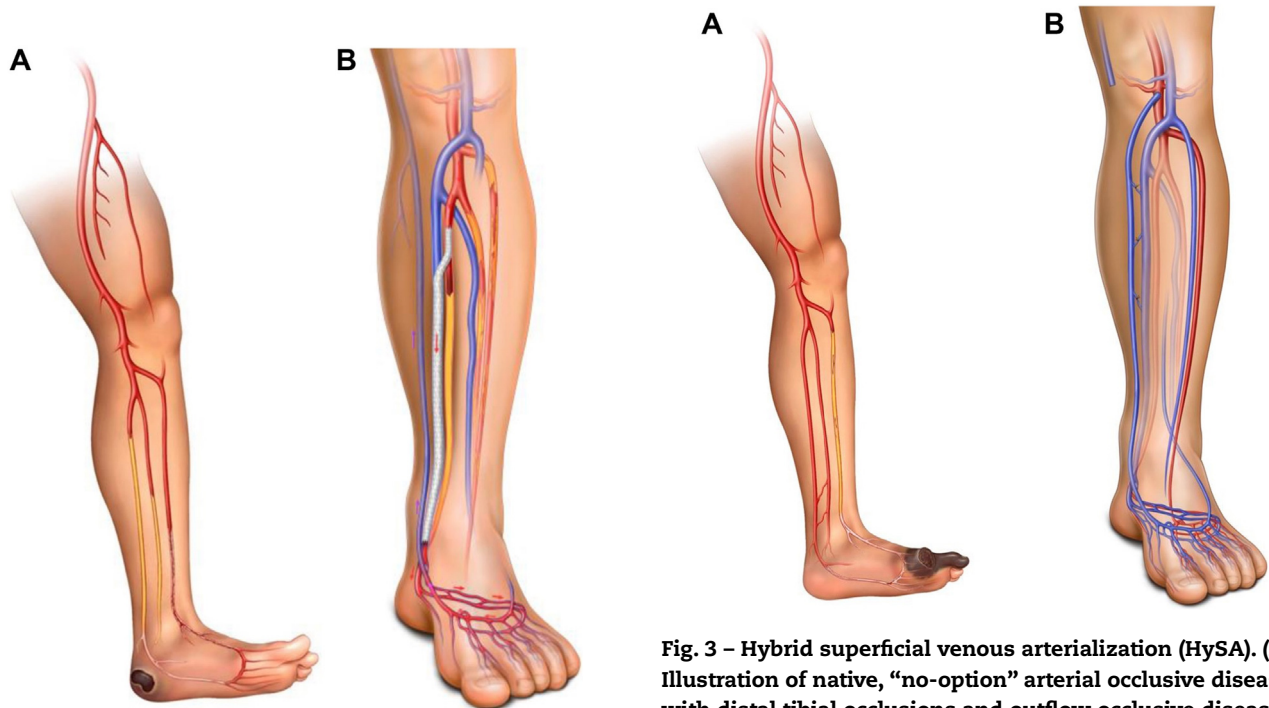


Fig. 2 – Deep venous arterialization (DVA). (A) Illustration of native, “no-option” arterial occlusive disease with distal tibial occlusions and outflow occlusive disease. (B) Illustration of a DVA with a crossover stent from the posterior tibial artery to the posterior tibial vein, providing arterialized flow to the deep venous system of the foot. Reprinted from Montero-Baker et al [12], with permission.

Fig. 3 – Hybrid superficial venous arterialization (HySA). (A) Illustration of native, “no-option” arterial occlusive disease with distal tibial occlusions and outflow occlusive disease. (B) Illustration of a HySA with an open end-to-side anastomosis between the popliteal artery and great saphenous vein. Reprinted from Montero-Baker et al [12], with permission.

of an arterialized venous network will lead to worsening ischemic rest pain as the network matures and stealing venous branches decreases forefoot perfusion, sometimes referred to as a “DVA storm.” If DVA or HySA is performed for the indica-

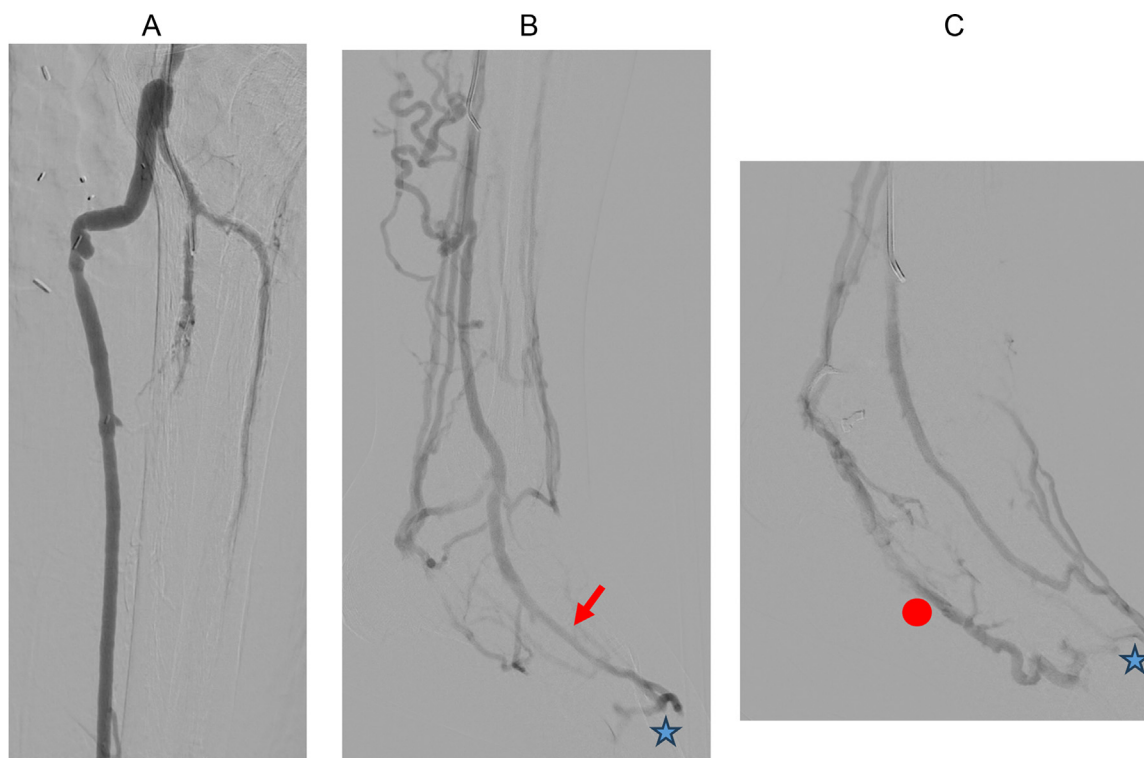


Fig. 4 – Angiogram of hybrid superficial venous arterialization. (A) Proximal popliteal artery to great saphenous vein (GSV) anastomosis. (B, C) Arterialized GSV perfusing the medial marginal vein (arrow) and feeding the deep system and lateral plantar vein (circle) via perforators (star).

tion of rest pain, it should be ensured that at least 1 of the non-donor tibial arteries (eg, the peroneal artery) is providing a robust network of no-named collaterals to support the forefoot perfusion while the venous arterialization matures. It should be noted that these patients are at risk of developing forefoot gangrene during the maturation process.

Comorbidities that exclude patients are severe aortic stenosis; heart failure class III/IV, given potential exacerbation of heart failure after the AV fistula creation; patients with poor ejection fraction ($< 20\%$), given slow flow will compromise patency of the bypass; and patients who are high mortality risk with a life expectancy < 2 years. Venous arterialization should be avoided in frail, deconditioned patients, particularly nonambulatory patients, as the first 3 months after the initial procedure may exacerbate any underlying frailty and deconditioning states.

From an anatomic standpoint, the patient needs 1 DVA donor artery, typically the posterior tibial artery and, less frequently, the peroneal or anterior tibial artery; this needs to be patent, either by baseline appearance or after recanalization, for at least 2 to 3 cm after the origin. Optimization and treatment of the inflow arteries, including the superficial femoral artery, popliteal artery, tibioperoneal trunk, or proximal tibial arteries, must be performed before or at the time of the DVA creation. In addition to the donor artery, an additional tibial vessel providing relatively reasonable, arterial collateral flow to the foot is critical to maintain viability to the foot after a

covered stent is placed across the donor artery into the tibial vein. For patients with only 1 patent tibial artery, consideration for a distal DVA or an HySA is recommended, given the end-to-side configuration of the AV anastomosis of an HySA (Figs. 3 and 4).

From a venous standpoint, the patient must be free of any evidence of acute or prior deep venous thrombosis, a patent and relatively straight LPV measuring at least > 2 to 3 mm in size, patent posterior tibial vein (PTV) and, ideally, a patent GSV, as this will serve as one of the main outflow tracts for a DVA. In patients who are being considered for an HySA, the GSV must be free of thrombophlebitis, measure at least 2.5 mm, have a direct connection to the MMV, and there must be evidence of perforators from the MMV to the deep venous system (Fig. 5). The quality of the LPV must be assessed, demonstrating limited scarring and tortuosity; as with chronic foot wounds, this can easily develop over time (Fig. 6). A summary of patient and anatomic criteria for DVA is included in Table 2.

Lastly, a multispecialty team collaboration is essential for success in this patient population; vascular surgery or interventionalists, podiatry, or orthopedic surgery, along with a robust vascular laboratory are the backbone of this team. Also critical is infection disease colleagues and proper diabetes management. Nutrition consults are typically needed in the long term, and ongoing physical therapy to engage in appropriate exercises to avoid progressive deconditioning as

Table 2 – Patient selection for percutaneous deep venous arterialization.

Patient criteria	Arterial anatomic criteria	Venous anatomic criteria	Wound criteria
Compliant, socially supported patient, motivated for multiple follow-ups Proper informed consent aware of potential symptom sequelae, such as edema, pain, worsening gangrene, and repeat interventions Exclusion of patients with severe aortic stenosis, heart failure class III/IV, poor ejection fraction (< 20%) Exclusion of patients with high mortality risk and life expectancy < 2 y; frail, deconditioned, or nonambulatory patients	Optimized inflow arteries Patent donor DVA artery, patent for at least 2–3 cm after the origin Additional tibial vessel providing reasonable arterial collateral to the foot	No evidence of acute or prior deep venous thrombosis or superficial thrombophlebitis Patent and relatively straight lateral plantar vein measuring > 2–3 mm Patent posterior tibial vein and ideally patent great saphenous vein to serve as outflow for DVA	Stable gangrene, ability to remain consistent for another 6- to 10-wk period No systemic signs of infection or evidence of ascending/uncontrolled foot infection Mild location infection control before DVA, if present
Abbreviation: DVA, deep venous arterialization.			

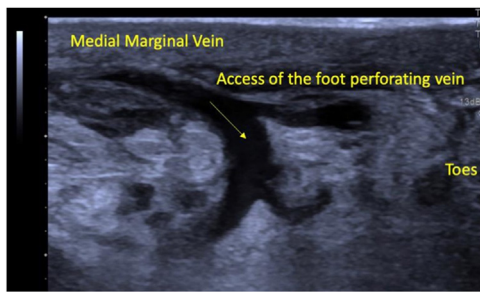


Fig. 5 – Ultrasound scan of the perforating vein from the medial marginal vein to the deep venous system of the foot [12]. Reprinted from Montero-Baker et al [12], with permission.

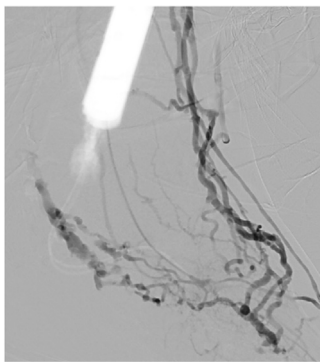


Fig. 6 – Venography of potential deep venous arterialization candidate with evidence of chronic thrombosis of the lateral plantar vein.

weight-bearing status changes. Occasionally, we have found the need for assistance from palliative care for pain management during the first 3 to 4 months during the DVA maturation process.

4. Venous anatomy of the foot

Familiarity with the venous network in the foot is essential to interpreting and optimizing the arterialized venous circuit. As in the leg, there are superficial and deep venous networks in the foot that connect via multiple perforators. The GSV drains the dorsal venous arch of the foot, including the medial and lateral marginal veins, and the PTV drains the deep plantar arch in the foot. In the typical superficial venous anatomy, as shown in Fig. 7, the lateral marginal vein drains into the small saphenous vein, while the MMV drains into the GSV. For the deep system, the plantar digital veins drain into the plantar metatarsal veins, which connect to the plantar venous arch; this connects to the lateral and medial plantar vein, which meet to form into PTVs (Fig. 8). There tends to be at least 2 to

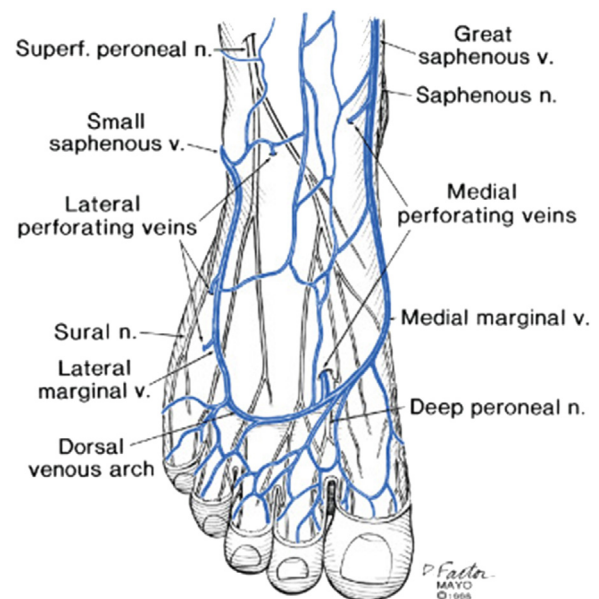


Fig. 7 – Illustration of the superficial venous system anatomy. Reprinted from Bergan [14], with permission.

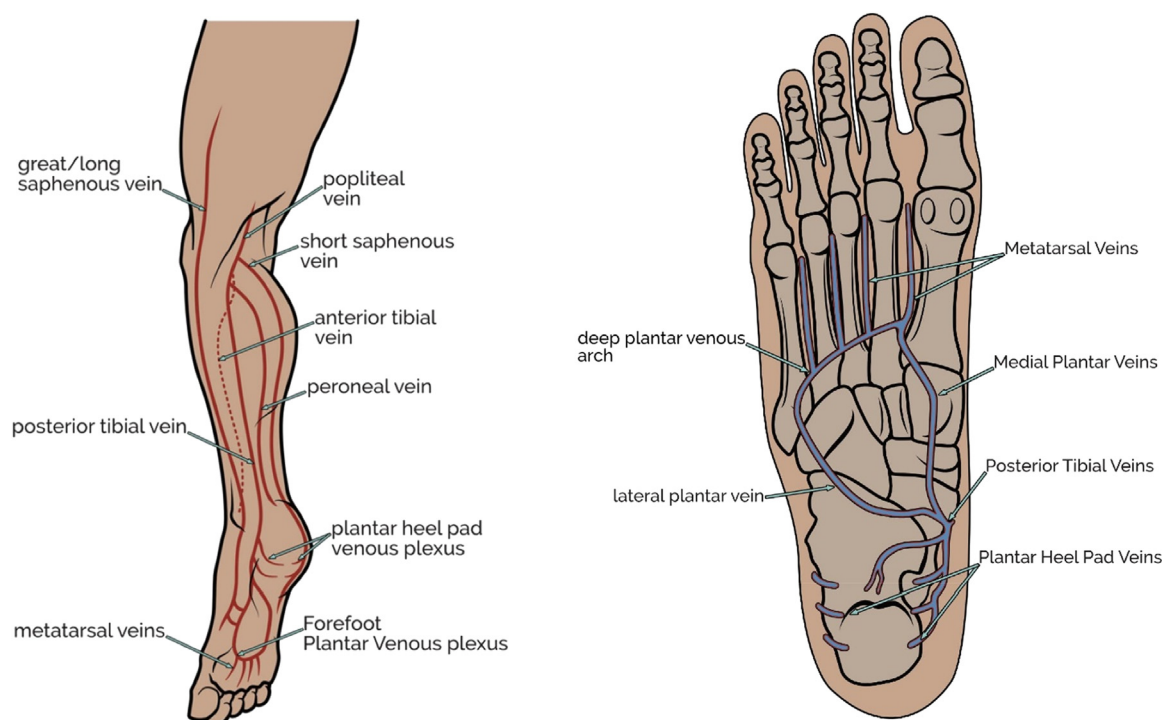


Fig. 8 – Illustration of the deep venous anatomy of the foot and lower leg. Reprinted from Horwood [15], with permission.

3 valves in each of the lateral and medial plantar veins, along with valves at each branching point in the distal foot extending into the plantar metatarsal and digital veins.

During the initial DVA creation, the arterial flow is directed from the PTV stent into the LPV. The mid foot pedal venous loop that fills from the DVA typically has outflow from the foot via the adjacent, paired PTV, and via perforators to the superficial, dorsal venous arch, draining via the GSV and small saphenous vein. As the DVA matures, particularly in patients with worsening forefoot gangrene, rest pain, edema, or high-flow volumes on duplex, repeat interventions are geared toward finding the deep metatarsal plantar vein pathways and lysing their associated valves to encourage forward foot flow, along with potentially coil embolizing perforating branches that are stealing flow away from the distal foot (Fig. 9).

5. Percutaneous DVA

A proximal, percutaneous DVA is now commonly performed with either off-the-shelf products or with the US Food and Drug Administration–approved LimFlow system (Inari Medical), which includes a proprietary crossover device (ARC); a venous capture device (V-Ceiver); a forward cutting valvulotome (Vector); and a propriety, tapered, polytetrafluoroethylene-covered nitinol stent. Newer techniques and studies are currently investigating distal DVAs for patients with relatively normal tibial arteries until the level of the distal leg or ankle. In these scenarios, a variety of crossover techniques are performed to create a distal AV fistula, typically at the level of the ankle, which is maintained with or without an uncovered stent. This preserves more proximal collaterals from the donor artery, while also reducing the DVA storm [16].

5.1. Venous access

LPV access is the first critical step in creating the DVA circuit. Mapping out the entire pathway of the LPV from the PTV is critical, and one wants to identify the most distal portion of the LPV that is straight and relatively superficial. Warming the operating room and placing a sterile tourniquet on the leg to enhance the venous congestion of the foot will augment the ability to access the LPV. We prefer a shorter, pedal access needle, followed by a 0.014-in, hydrophilic-tipped wire to gently traverse the LPV. Access can be maintained with a slender 5Fr sheath. Venography to ensure the patency of LPV and the PTV, along with ensuring the wire has taken a straight path close to the donor artery at the crossover point is critical; care is taken to avoid the small bridging vein between the paired PTV or selection of the peroneal vein in the more proximal leg (Fig. 10).

5.2. Creation of the AV fistula

Ideally, the location of the AV cross over should be placed at the distal portion of the healthy-appearing donor tibial artery. The most common location of the crossover point is the proximal to mid posterior tibial artery with the adjacent PTV. If a very proximal crossover point is selected, one must ensure that arterial perfusion of the foot from other tibial vessels is not jailed by the crossover stent. There are multiple techniques to creating the percutaneous fistula. Re-entry devices, such as the LimFlow ARC and V-Ceiver, BeBack Catheter (Cook Medical), Outback (Cordis), or Pioneer Plus (Phillips Medical) can be introduced into the arterial system with a snare or inflated balloon in the vein as a target. The needle from the re-entry device pierces the vein, either piercing the balloon for confirmation of the venous target or entry of a wire into the

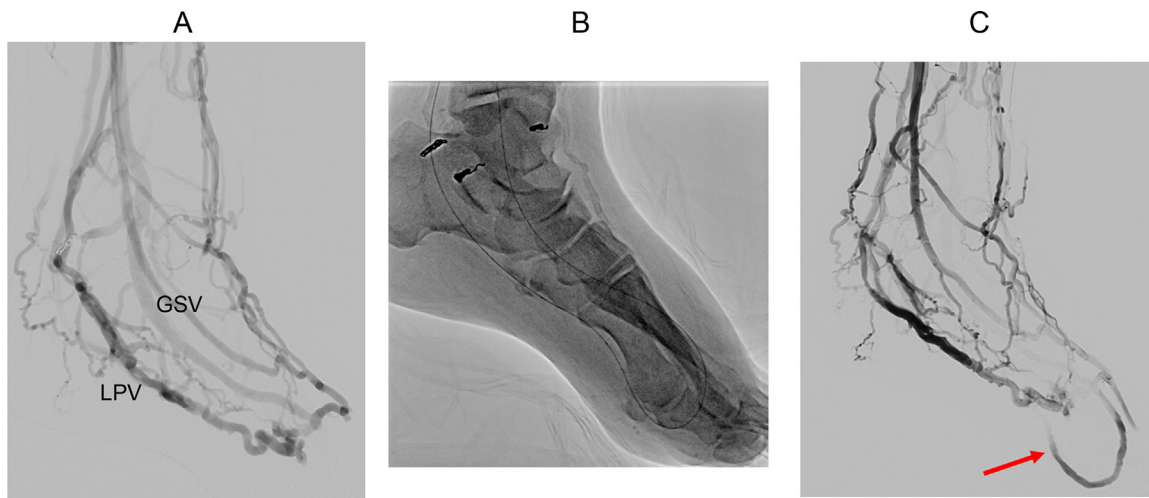


Fig. 9 – Re-intervention to promote flow into the plantar metatarsal veins (A) pre-intervention, with filling of the mid-foot venous loop, including the lateral plantar vein (LPV) with direct outflow via the great saphenous vein (GSV), small saphenous vein, and paired posterior tibial vein. (B) Wiring of a plantar metatarsal vein; note previous coils in the proximal foot to remove stealing venous branches from the deep venous arterialization circuit. (C) Filling of the plantar metatarsal vein after valve lysis with a cutting balloon and venoplasty of the venous loop (arrow).



Fig. 10 – Lateral plantar vein access (LPV). (A) Pedal micropuncture access of the LPV with the posterior tibial vein (PTV) wired. (B) Venography confirming the patency of the LPV and PTV, along with the trajectory of the PTV.

snare. If re-entry devices are not available, the “gun-sight technique,” when 2 snares are placed parallel in artery and vein and a needle is placed percutaneous through both snares, subsequently advancing a guide wire through both [17] (Fig. 11).

Once through-and-through access between arterial and venous systems is created, the fistula is dilated using a 3.5-mm balloon. If the proximal artery and crossover point is highly calcified, utilization of intravascular lithotripsy can be considered to facilitate re-entry or stent expansion.

5.3. Venous valve lysis

After the AV fistula has been created, lysis of valves throughout the PTV and the LPV is required to facilitate forward flow. Valve lysis can be achieved with a variety of techniques, including high-pressure, noncompliant balloon venoplasty, cutting balloon angioplasty, laser ablation, or percutaneous delivery of a valvulotome. This should be performed before covered stent placement; this will facilitate full expansion of the covered stent and recalcitrant valves can be difficult to lyse after covered stent placement. Valve lysis is performed throughout the PTV and the LPV, just proximal to the level of the venous access site.

Once the crossover point has been predilated and the venous valves have been sufficiently lysed, a covered stent can be deployed from the level of the ankle, and typically down to the mid calcaneus, through the entire PTV and at least 1.5 to 2 cm into the donor artery.

5.4. Technical success

Technical success is defined by completion angiogram with features of brisk flow through the DVA, the pedal venous loop in the foot and outflow through the paired PTV and superficial system, along with preserved arterial antegrade flow to the foot. Concerns for flow-limiting stenosis or high resistance in the foot from retained valves should be investigated if flow through the DVA is slower than that of the native arterial system.

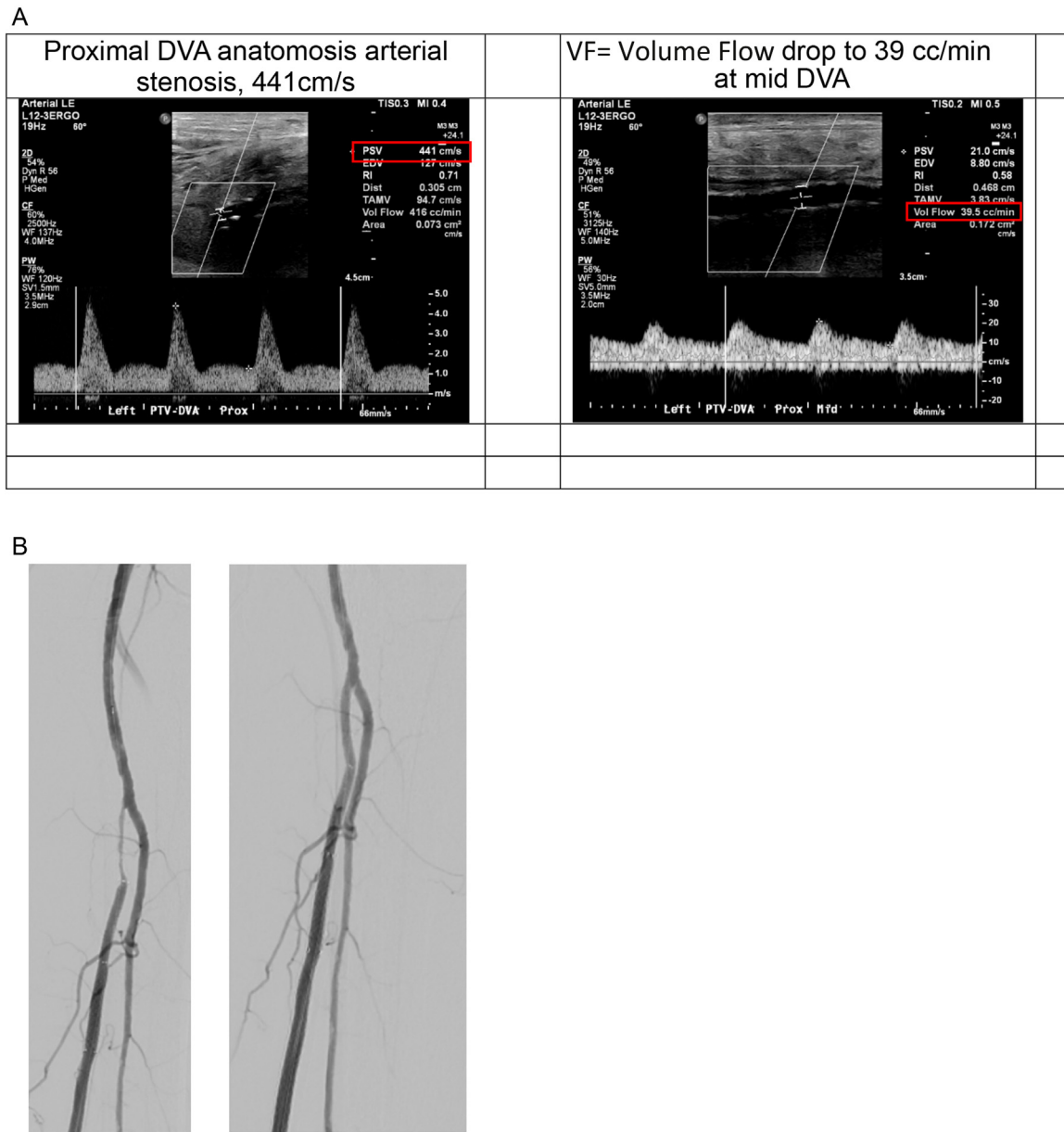


Fig. 13 – Low-flow duplex. (A) Proximal arterial stenosis leading to low flow through the the deep venous arterialization (DVA) and posterior tibial vein (PTV). (B) Subsequent angiogram demonstrating proximal PT restenosis, treated with intravascular lithotripsy and coronary stenting. VF, XXXX.

For stable gangrene, or after infection control has been completed, after the 6- to 10-week window has passed and clinical evidence confirms improved tissue oxygenation and perfusion, the patient undergoes a 2-stage open transmetatarsal amputation. During the first stage, the open amputation is performed along with further resection of any remaining necrotic tissue. A saline-moistened wet-to-dry dressing is applied and changed twice daily. The authors prefer to wait approximately 48 hours to perform a repeat washout in the operating room. During this second stage, minimal fascial coverage over the resected metatarsal shafts is performed, followed by application of a dermal substitute graft and use of a negative pressure wound vacuum-assisted closure to support healing.

Before any foot amputation, an angiogram is typically performed to ensure there is evidence of arterial perfusion and neovascularization beyond the LPV. In addition, it is critical to map the distal PTV, LPV, and pedal venous loop to ensure that the important plantar venous arc network remains intact and undisturbed during the procedure.

6.2. Weight-bearing status

There are no contraindications to a full weight-bearing status postoperatively after a DVA. If a patient has dry gangrene or limited tissue loss to the toes, full weight bearing is encouraged to decrease the duration of deconditioning and swelling during the early stages of venous arterialization maturation.

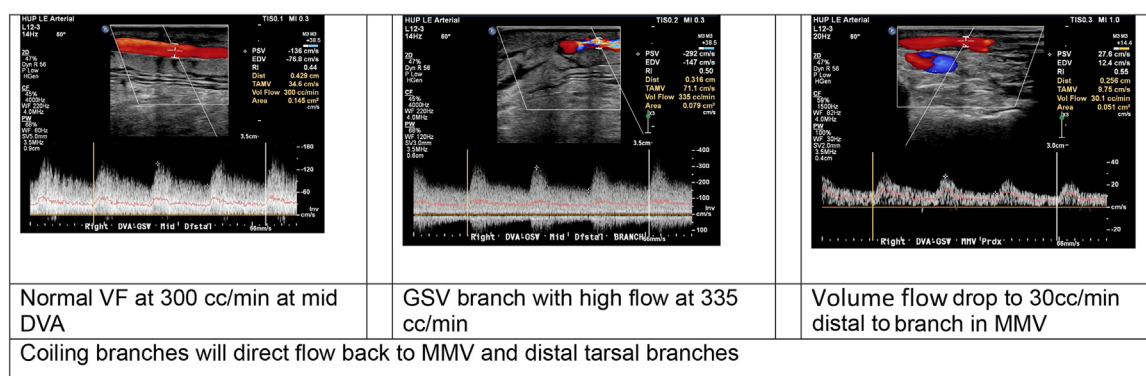


Fig. 14 – Arterial duplex evaluation of stealing branches. DVA, deep venous arterialization; GSV, great saphenous vein; MMV, medial marginal vein; VF, XXXX.

Table 3 – Critical characteristics of a post-deep venous arterialization arterial duplex.

Characteristic
Arterial duplex from common femoral to popliteal level.
Velocities and waveforms characteristic of the distal native tibial arteries.
Volume flow rate of the arterialized vein: the arterialized anastomosis (arterialized PTV within the stent graft) and pedal outflow (LPV distal to the stent graft) and pedal venous outflow (GSV, PTV, and ATV).
Evaluate any “stealing” branches distal to the anastomosis or stent.
Ankle-brachial index pressure should always be avoided. Physiologic studies of arterial perfusion should be limited to toe pressure only.
Abbreviations: ATV, anterior lateral vein; GSV, great saphenous vein; LPV, lateral plantar vein; PTV, posterior tibial vein.

Once a minor amputation occurs, full weight bearing continues to be recommended, with the use of a controlled ankle motion boot or a surgical shoe. If a partial weight-bearing status is required, it is imperative to ensure the patient uses an appropriate offloading surgical shoe to maintain functional activity.

6.3. DVA storm spectrum

Symptoms from arterial steal from a DVA resulting in edema, venous engorgement, forefoot pain, and ischemia can range from mild to severe, depending on the underlying arterial collaterals at baseline and flow volumes through the PTV and LPV. For mild symptoms, treatment includes compression to reduce edema and some superficial venous outflow, along with multimodal treatment for pain. Uncontrolled pain may be the first signs of worsening infection or need for a repeat intervention to reduce flow through the DVA, due to proximal steal branches, or the need for interrogation of metatarsal plantar veins for valve lysis and venoplasty to encourage forefoot flow. The need to perform this after the initial DVA is rare, but can become more likely over time as the DVA matures and the small venous, proximal perforators and branches become more robust.

6.4. Postoperative studies

A proper post-DVA duplex is extensive and includes the details listed in Table 3. This study is critical to guiding DVA maintenance and possible re-interventions during the maturation process. We recommend duplex before discharge, ev-

ery 2 weeks if symptoms or wounds are “unstable” or every 4 weeks if symptoms are “stable” or improving. If there are any sudden changes in symptoms or change in pulse/signal examination, this should trigger a duplex examination.

After a DVA, inflow arteries develop a low-resistant waveform with diastolic forward flow. Flow volumes through the fistula and venous network are expected to range from 100 to 350 mL/min. Vessel diameter should be measured from intima to intima, perpendicular to the vessel. The Doppler angle should be at 60 degrees. The time averaged mean velocity should be measured over a few cardiac cycles (Fig. 12).

6.5. Concerning duplex findings

6.5.1. Low flow

Flow volumes < 100 mL/min through the PTV and LPV can be due to a new inflow lesion, edge stent stenosis, or high resistance distally reducing flow through the DVA (Fig. 13).

6.5.2. High flow

Volumes exceeding 400 to 500 mL/min, particularly in the setting of worsening edema, forefoot pain, or ischemia, are indicative of the circuit bypassing the metatarsal veins and diverting flow to the lower pressure outflow GSV or PTV. Interrogation with an angiogram can be performed with coil embolization venoplasty to encourage flow to the distal metatarsals and evaluation of stealing branches for potential coil embolization to divert flow into the desired circuit (Figs. 9 and 14).

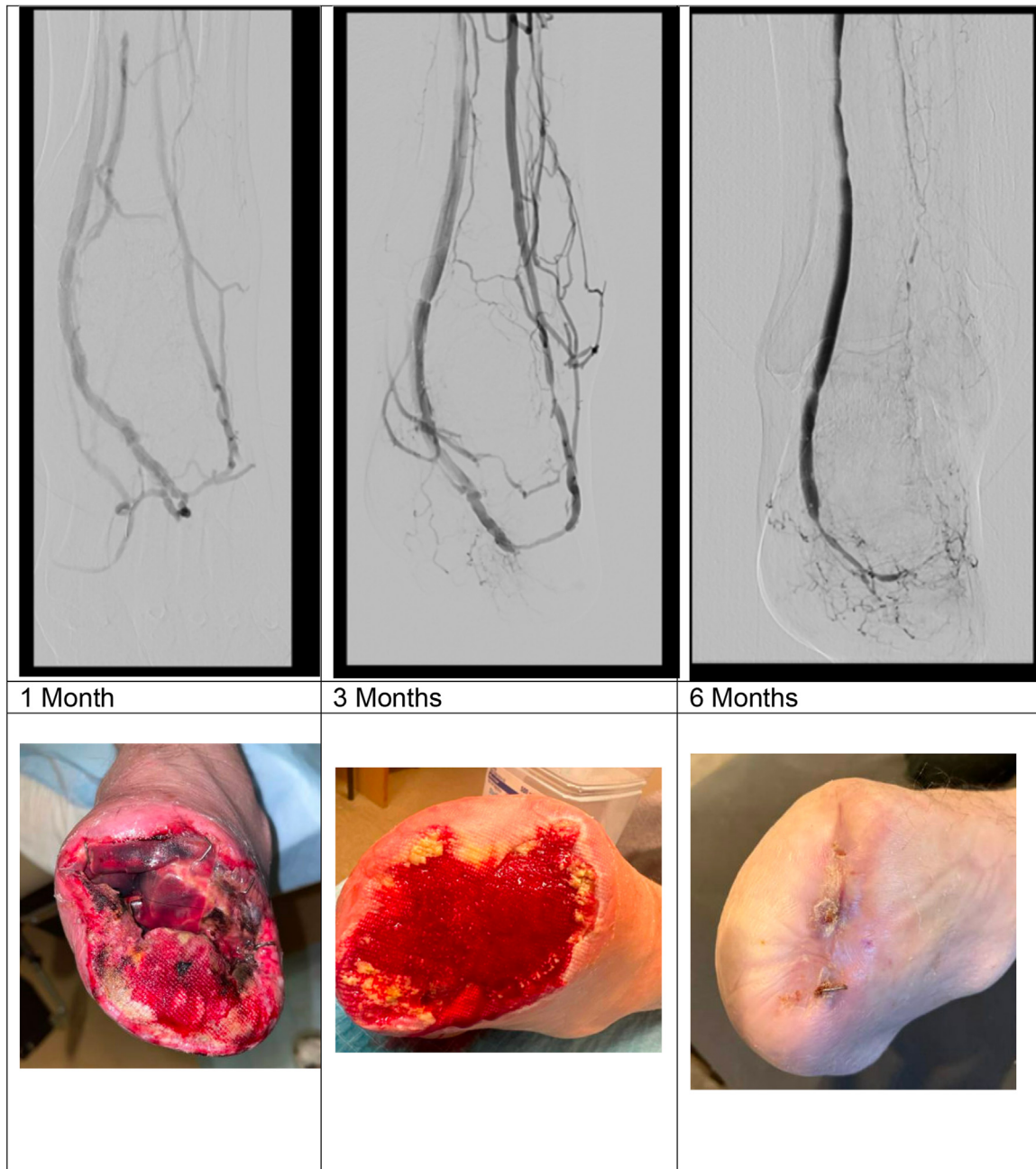


Fig. 15 – Progression of deep venous arterialization maturation over a 6-month period, with associated wound images. Note the increasing neovascularization over time, ultimately leading to a high-resistance vascular network throughout the entire foot, indicating conversion.

6.5.3. Inflow or edge stent stenosis

Although a strict peak systolic velocity cutoff for arterial stenosis is difficult in the setting of a fistula waveform, typically peak systolic velocity > 300 to 350 cm/s, particularly with new low-flow volumes distally, suggests a hemodynamically significant arterial or edge stent stenosis (Fig. 13).

6.5.4. Maintenance of the DVA and modes of failure

Surveillance and reinterventions are crucial to maintenance and maturation of the DVA, helping to prevent early failure and loss of patency. Zaman et al [18] developed a classification

system of DVA failure patterns to provide a framework for management reintervention strategies, as listed in Table 4. Their cohort revealed the most common DVA failures are type 1a and type 4, with only one-third of the patients having distinct and isolated patterns and the majority having a combination of multiple failure patterns. The most lesions in the proximal arterial anastomosis or within the graft can be treated with arterial antegrade access, crossed with a wire and treated with angioplasty and possible need for additional stent graft coverage. However, type 3b/4 lesions may be difficult to traverse with antegrade arterial

Table 4 – Modes of deep venous arterialization failure.

Type	Criteria
1	Occlusion and stenosis of the arterial inflow
1a	Denoting lesions proximal to the DVA site
1b	Lesions at the proximal stent edge of the DVA
2	Occlusion within the graft
3	Stenosis/occlusions that affect venous outflow
3a	Denotes lesions at the DVA distal stent edge
3b	Denotes lesions within transitional veins such as the medial or lateral plantar veins, and
3c	Denotes lesions within previously placed stents in the transitional veins
4	Lesions of the venous arch of the foot
5	“Undefined” because the exact location of the lesion causing DVA failure cannot be clearly identified

Abbreviation: DVA, deep venous arterialization.

approach and retrograde venous pedal puncture may be necessary [18].

6.5.5. DVA conversion

The progression of the DVA entails the pedal venous loop leading to forward flow and arterialization into the metatarsal veins. This leads to neovascularization not only in the deep tissues of the foot, but also in the superficial dermal and subdermal venous network. Ultimately, a robust neovascularization network is created that leads to high-resistant flow for the original DVA pedal circuit and eventual occlusion of the DVA, known as conversion. Fig. 15 demonstrates the typical maturation of a DVA over a 6-month period, with imaging consistent with DVA conversion.

7. Outcomes of venous arterialization

Multiple centers have published case series and smaller cohorts of patients showing the promising results of off-the-shelf DVA, open or percutaneous, and the HySA [19–21]. Results of a meta-analysis of 10 studies on percutaneous DVA, with a total of 233 limbs and a median follow-up period of 12 months, showed a technical success rate of 97% (95% CI 96.2%–97.9%), with reintervention rate of 37.4% (95% CI 39.9%–39.9%). Overall wound healing rate was 69.5% (95% CI 67.9%–71.0%) and the major amputation rate was 21.8% (95% CI 21.1%–22.4%) [22]. The LimFlow single-arm feasibility studies and long-term data from PROMISE I demonstrated a majority of DVA occluded after 180 days, but 67% of patients were fully healed at 6 months and 75% were fully healed at 12 months [23]. Two-year data from PROMISE II showed similar results with limb salvage rates; 65% and 82% of patients' wounds were completely healed and healing [24,25]. Although there are fewer case study reports with HySA, the Ferraresi et al [13] cohort of 36 patients had primary patency rates of 86.1% at 1 month and 20.7% at 3 months and secondary patency rates of 91.7% at 1 month and at 30.3% 3 months [13].

8. Conclusions

The patient population with no-option CLTI has historically been constrained to major limb amputation for their treat-

ment. However, with technology and techniques evolving around venous arterialization, there is an additional option for these patients. With the appropriate patient selection, meticulous care through maturation process, and providing the proper wound care, DVA provides an opportunity for limb salvage in an otherwise no-option patient.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Elizabeth Genovese, MS, MD- consultant for Inari Medical.

Brett Chatman, DPM- consultant for Inari Medical, Smith and Nephew.

CRedit authorship contribution statement

Jayne R. Rice: Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. Brett C. Chatman: Conceptualization, Investigation, Supervision, Writing – original draft, Writing – review & editing. Elizabeth A. Genovese: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Supervision, Validation, Writing – original draft, Writing – review & editing.

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