



# Outcomes of Reintervention in Percutaneous Deep Venous Arterialization

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## Abstract

**OBJECTIVE:** This study was performed to describe the outcomes of reintervention procedures for a stenotic or occluded percutaneous deep venous arterialization (pDVA) and to compare outcomes following pDVA in patients not requiring repeat intervention.

**METHODS:** This was an observational case series with retrospective chart and radiology image review from January 2018 to July 2022. Sixty-two patients received pDVA using “off-the-shelf” devices. Baseline data including patient characteristics, time to reintervention, and technical success in reintervention were recorded. The primary endpoints were pDVA patency, wound healing, and amputation-free survival (AFS).

**RESULTS:** Twenty-one cases (33.9%) qualified for reintervention. At the 1-month follow-up, 52.6% of patients had improved critical limb-threatening ischemia (CLTI; resolved rest pain or improvement/resolution of ulceration from baseline), with 57.9% experiencing wound healing. However, subsequent follow-up intervals demonstrated decreasing CLTI improvement and wound healing. Graft patency decreased at 1 month after secondary intervention to 41.2%. A Kaplan-Meier amputation analysis of reintervention vs non-reintervention demonstrated a nonsignificant difference in AFS at 6 months with a *P*-value of .05.

**CONCLUSION:** Reintervention for stenotic or occluded DVA conduits provides further clinical improvement in the short term. Subsequent patency beyond 1 month shows a nonsignificant but clinically relevant difference in AFS overall for a 6-month period in the reintervention group compared to the non-reintervention group. Further studies are needed to validate these findings.

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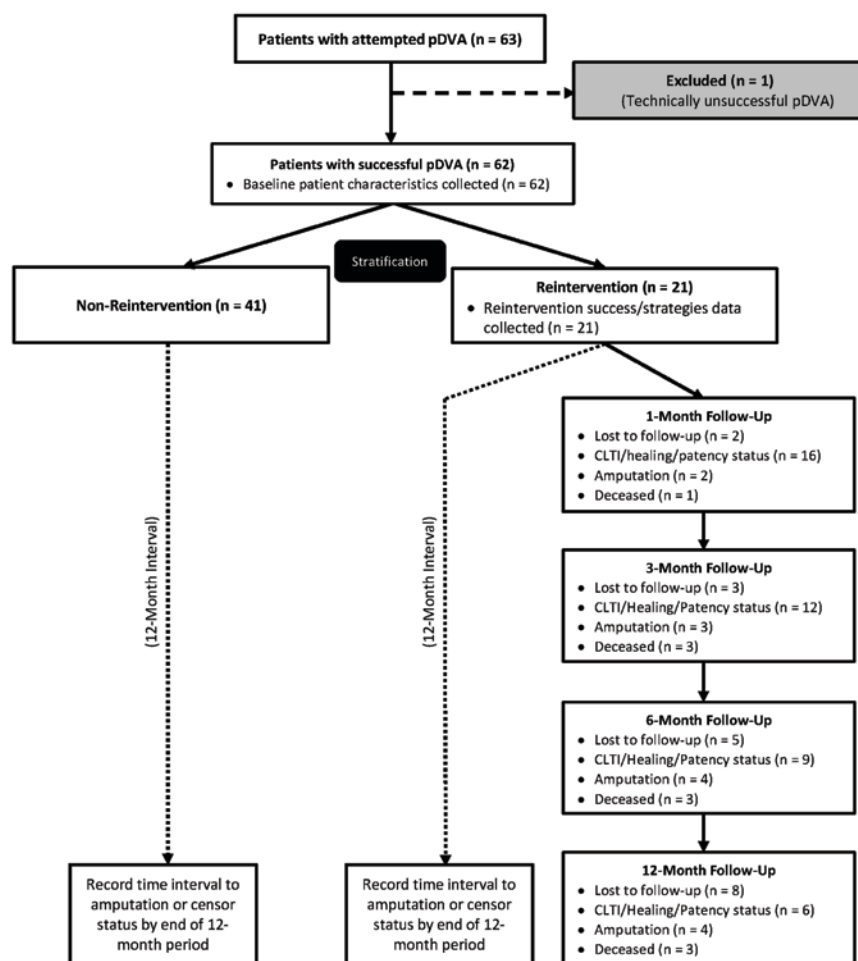
**Key words:** critical limb-threatening ischemia, percutaneous deep venous arterialization, reintervention

For patients with critical limb-threatening ischemia (CLTI), percutaneous deep venous arterialization (pDVA) is a novel therapeutic approach in those with non-reconstructible arterial disease or following clinically ineffective interventions and in whom an above-ankle amputation is otherwise considered inevitable.<sup>1,2</sup> Procedurally, pDVAs involve the creation of a fistulous communication between a donor tibial artery and the adjacent dominant venae comitantes, which is then supported by a stent graft to establish retrograde venous flow to the foot.<sup>3</sup> The goal of pDVA is to restore straight-line oxygenated blood flow and tissue perfusion to ischemic tissues to allow healing of existing wounds or planned minor amputation. Reductions in major amputation are expected to reduce the associated high risk of mortality and further limb complications.<sup>4</sup>

Several prospective studies and meta-analyses have found limb salvage rates of 70% to 75% and wound healing rates of

68% to 75%, with DVA patency ranging from 53% to 71%.<sup>5-9</sup> Reintervention for DVA circuits with occlusion or reduced flow is not uncommon, with 67% to 74% of patients suffering occlusion of a pDVA and 52% to 54% requiring subsequent reintervention.

Predictive duplex ultrasound models for pDVA failure and angiographic patterns of failure have been described.<sup>9,10</sup> Surveillance is recommended, as it is likely that reintervention for failed (occluded) or failing pDVA is needed to maintain graft patency until successful wound healing occurs. Although the need for reintervention following primary pDVA creation is high, the long-term outcomes of reintervention in these patients have not been well characterized. In this study, we evaluate both the success rate as well as the long-term outcomes of reintervention for a failing or failed pDVA.



**FIGURE 1.** Disposition chart of included participants and data collection. “Lost to follow-up” indicates lack of patient follow-up even after sufficient time had passed. Time-to-event data (dotted lines) was recorded for amputation or censoring for the Kaplan-Meier curve in Figure 4. Stratified 1-, 3-, 6-, and 12-month follow-up data was collected only for the reintervention cases and reported in Figure 4. Sample size values for the 1-, 3-, 6-, and 12-month follow-up reflect the total number of patients in that category over time. pDVA, percutaneous deep venous arterialization; CLTI, critical limb-threatening ischemia.

## Methods

### Indications for initial pDVA and reintervention

Patients classified as having had “no-option” disease (characterized by chronic total occlusion, prior failed endovascular or open surgical procedures, and an angiographic absence of reconstituted arteries in the lower leg or foot suitable for surgical bypass) were selected for this study. Optimized medical therapy was utilized in all cases if possible, including but not limited to moderate- to high-dose statins, antiplatelets with or without factor Xa inhibitors, and cilostazol. Patients qualified as reintervention cases if restenosis or occlusion of the pDVA graft was discovered on follow-up laboratory or imaging studies and pDVA reintervention was considered clinically necessary by the attending physician.

The initial pDVA was performed using noncommercial or “off-the-shelf” devices. The Outback catheter (Cordis) was used to establish an arteriovenous conduit, allowing puncture from the donor tibial artery into an inflated balloon positioned within the adjacent vein via pedal or tibial venous access. Alternatively, an Outback catheter was inserted retrogradely via pedal venous access to puncture a positioned balloon that was inflated in the donor tibial artery. pDVA was completed with angioplasty, balloon valvulotomy, and placement of a 5 mm diameter Viabahn stent graft (Gore) of an adequate length to cross the arteriovenous fistula and extend below the lowest visualized tibial venous valve. Duplex ultrasound surveillance was performed within 2 weeks and then monthly thereafter, adjusting to clinical indications with more frequent evaluation in the case of ongoing or worsening ischemia, wounds, or gangrene and handheld Doppler examination suggested pDVA dysfunction. Reintervention was performed for applicable cases involving restenosis or occlusion. To allow successful restoration of flow in the pDVA, percutaneous transluminal angioplasty/drug-coated balloon angioplasty, additional stent-graft placement or venous Supera woven nitinol stents (Abbott), and/or retrograde venous access were utilized as necessary.<sup>10</sup>

### Defining measures of technical success and clinical outcome

Technical success at the time of pDVA reintervention was characterized using 2 measures: graft patency and return of pedal venous arch flow in patients immediately following reintervention. All reintervention case DVAs were occluded and had no venous arch flow at baseline. Graft patency post reintervention was described as Patent Non-Stenotic, Residual Stenosis (stenosis or occlusion at any level of the foot as described by the operator in the medical record operative note), or Occluded. Blood flow to the level of the pedal venous arch was described as having Brisk Flow, Reduced Flow, (as described by the operator), or Absent Flow.

Outcomes measured included CLTI symptoms, wound healing, and graft patency. CLTI was determined by a ranking of 4 to 6 on the Rutherford classification of peripheral artery disease as determined by the attending physician at any period of follow-up based on patient symptoms. Clinically non-worsening CLTI symptoms were defined as unchanged wound size or severity of

ischemic pain without the development of new wounds, infection, or ischemic pain. Reintervention outcomes were measured at 1-, 3-, 6-, and 12-month follow-up intervals, including CLTI symptoms such as rest pain or progressive gangrene/necrosis, wound healing, and graft patency.

### Data collection

A retrospective patient chart and angiographic image review was performed for pDVA reintervention procedures performed in both a single community hospital and an office-based lab setting by 2 operators between January 2018 and July 2022. Demographic information such as initial age, sex, race/ethnicity, initial pDVA procedure date, and anatomical location of the pDVA was compiled. For reintervention cases, time between initial and reintervention procedures was recorded. To gauge the technical success of the reintervention, data including reintervention strategies used, extent of recanalization, and restoration of pedal venous arch blood flow was also recorded. Follow-up data at 1 month, 3 months, 6 months, and 12 months were assessed to determine CLTI symptom status, wound healing, and pDVA patency. The primary outcome measured was the frequency of each data point mentioned within the reintervention sample population. Finally, time-to-amputation information was collected across both the reintervention and non-reintervention groups. Only patients with unsalvageable disease that required major amputation, such as a below-the-knee (BKA) or above-the-knee amputation (AKA), were considered to meet the criteria for time-to-amputation. Patients with unsalvageable wounds at the level of the foot but not progressing beyond the malleolus only required a minor amputation and were not included in time-to-amputation, since minor amputations reflected preserved limb functionality. Further patient groupings and study schema are provided in **Figure 1**.

### Statistical analysis

Simple mean, median, range, and/or proportions were calculated for the various demographic information and comorbidity categories. A z-test for proportions or independent t-test for means was used where applicable to determine significance with a 95% threshold. pDVA patients were also stratified by reintervention status (reintervention vs non-reintervention). A Kaplan-Meier plot was generated in Posit to model amputation in reintervention vs non-reintervention subjects, with loss to follow-up and/or death being censored. A 95% confidence interval (CI) was also produced for amputation outcomes using a log-rank test, approximated using a Chi-squared distribution, to quantify a P-value for significance testing.

## Results

### Patient characteristics and initial presentation

Baseline patient characteristics, including comorbidity information, are described in **Table 1**. The median age in both the

**TABLE 1. BASELINE PATIENT CHARACTERISTICS**

Characteristic	Reintervention (n = 21)	Non-reintervention (n = 41)
<b>Age</b>		
Mean	67.8	70.9
Median	72	72
Range	31-91	46-95
<b>Sex</b>		
Male	13 (61.9%)	23 (56.1%)
Female	8 (38.1%)	18 (43.9%)
<b>Race/Ethnicity</b>		
White/Caucasian	6 (28.6%)	17 (41.5%)
Black/African American	4 (19.0%)	10 (24.4%)
Hispanic/Latino	8 (38.1%)	9 (22.0%)
Asian	1 (4.8%)	2 (4.9%)
Other/Refused to answer	2 (9.5%)	3 (7.3%)
<b>Smoking</b>	10 (47.6%)	13 (31.7%)
<b>Diabetes</b>	19 (90.5%)	32 (78.0%)
<b>Hypertension</b>	19 (90.5%)*	29 (70.7%)
<b>Dyslipidemia</b>	18 (85.7%)	27 (65.9%)
<b>Cerebral events</b>	5 (23.8%)	5 (12.2%)
<b>Coronary artery disease</b>	12 (57.1%)	22 (53.7%)
<b>Obesity</b>	9 (42.9%)	8 (19.5%)
<b>Hemodialysis</b>	5 (23.8%)	10 (24.4%)
<b>Other predisposing conditions</b>	15 (71.4%)	23 (56.1%)

"Smoking" refers to subjects with a history of previous or current tobacco use. "Cerebral events" refers to subjects with a history of cerebral transient ischemia or infarction. "Other predisposing conditions" refers to subjects who have had 1 or a combination of chronic kidney disease, end-stage renal disease, congestive heart failure, malignant cancer, or chronic inflammatory conditions (lupus nephritis, Buerger's/Raynaud's disease, etc.). \* denotes a significant difference in proportions between the "reintervention" and "non-reintervention" groups.

reintervention and non-reintervention groups was 72 years. Men comprised a greater percentage of the reintervention group compared with the non-reintervention group. Diabetes, hypertension, and dyslipidemia were the most common comorbidities present in both groups. Of the reintervention patients, 42.9% suffered from obesity compared with 19.5% in the non-reintervention group. However, the presence of hypertension ( $P=.038$ ) was the only predisposing condition to yield a statistically significant difference between reintervention and non-reintervention patients.

Sixty-two patients received pDVAs, with 21 of them qualifying for reintervention. Of the reintervention cases ( $n = 21$ ), 19% were conducted in the anterior tibial vessels, while 81% were performed

TABLE 2. INITIAL PRESENTATION OF REINTERVENTION CASES

TABLE 2. RUTHERFORD CLASSIFICATION OF DEEP VEIN THROMBOSIS			
Values			
Cohort (n = 62)			
Reinterventions	33.0%		
Non-reinterventions	66.1%		
Average time (days)	102.1		
Range (days)	327		
Rutherford Class	Reintervention (n = 21)	Non-reintervention (n = 41)	
4	1 (4.8%)	4 (9.8%)	
5	13 (61.9%)	19 (46.3%)	
6	7 (33.3%)	18 (43.9%)	
	Anterior tibial	Posterior tibial	P-value
Reintervention (n = 21)	4 (19.0%)	17 (81.0%)	.666
Non-reintervention (n = 41)	6 (14.6%)	32 (78.0%)	.780
% reintervention by location	4/10 (40.0%)	17/49 (34.7%)	.754
“% reintervention by location” refers to the fraction of reinterventions performed vs total percutaneous deep venous arterializations (pDVAs) (reintervention or non-reintervention for either anterior or tibial vessels). Rutherford Class is determined at initial pDVA, not at reintervention, to provide a baseline comparison between the 2 study groups of interest (reintervention vs non-reintervention).			

TABLE 3. TECHNICAL SUCCESS OF REINTERVENTION

Characteristics	Percent of subjects
<b>Graft patency</b>	
Patent non-stenotic	86
Residual stenosis	9
Occlusion	5
<b>Return of blood flow</b>	
Brisk flow	76
Reduced flow	19
Absent flow	5
Proportion of percutaneous deep venous arterialization (pDVA) graft patency and return of pedal venous arch flow in patients immediately following reintervention (n = 21). All reintervention case pDVAs were occluded and had no venous arch flow at baseline. Patency and blood flow was based on operator interpretation from angiography imaging during the reintervention procedure.	

TABLE 4. SURVIVAL ANALYSIS STATISTICS BY TIME FRAME

Time frame	Statistic
<b>12 months</b>	
Chi-squared statistic	1.9
P-value	.2
<b>6 months</b>	
Chi-squared statistic	4
P-value	.05
Statistical significance analysis of survival models utilizing the log-rank test. The variable of interest was the occurrence of an above-the-knee or below-the-knee amputation. Patients who died or were lost to follow-up were censored. Twelve-month data was reorganized for the 6-month study time frame analysis by noting whether patients were censored or had a major amputation by the 6-month follow-up interval. An $\alpha = 0.05$ was used to determine significance with 1 degree of freedom.	

in the posterior tibial vessels. Of the non-reintervention cases (n = 41), 14.6% of pDVAs were completed at the anterior tibial, while 78% were at the posterior tibial. There was no significant difference in the proportion of anterior tibial pDVAs ( $P=.66$ ) or posterior tibial pDVAs ( $P=.78$ ) between reintervention and non-reintervention. Similarly, there was no statistically

significant difference in the frequency of reintervention among all anterior tibial pDVAs vs posterior tibial pDVAs ( $P=.75$ ). Rutherford classification at initial pDVA as well as reintervention characteristics are summarized in **Table 2**.

### Technical success in reintervention

Following reintervention, 86% of DVAs experienced total resolution of pDVA circuit stenosis or occlusion (**Table 3**). In comparison, 9% experienced partial clearance (residual stenosis or occlusion at any level of the foot as described by the operator in the medical record operative note), and 5% had total occlusion remaining at the end of reintervention. Similarly, 76% of these cases experienced return of brisk blood flow to the level of the pedal venous arch immediately following reintervention, 19% had reduced or sluggish flow (as described by the operator), and 5% had absent flow.

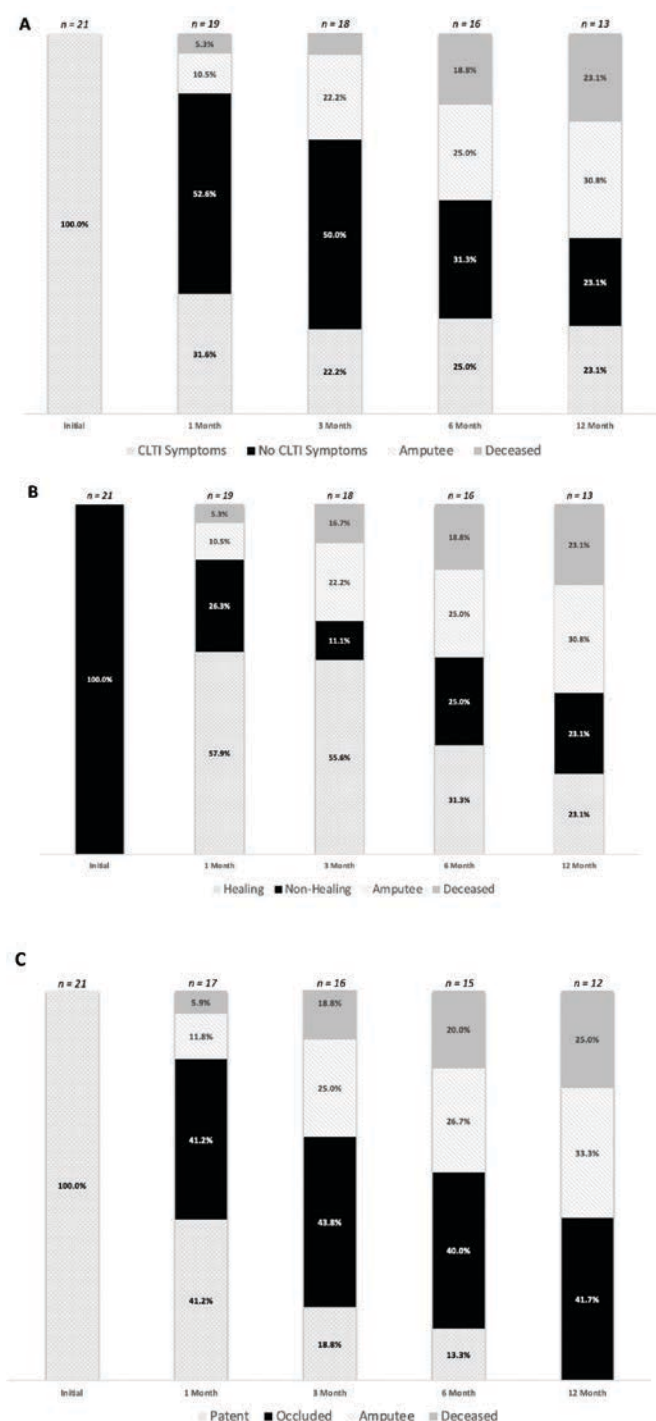
### Long-term outcomes of reintervention

Subsequent outcomes after successful reintervention patients were measured at 1-, 3-, 6-, and 12-month follow-up (**Figure 2**). Achievement of "No CLTI" status (no clinical evidence of further rest pain or worsening of gangrene/necrosis from baseline) occurred in 52.6% at 1 month, 44.4% at 3 months, and 31.3% at 6 months. Similarly, the proportion of wound healing was 57.9% at 1 month, 55.6% at 3 months, and 31.3% at 6 months. Graft patency decreased to 41.2% at 1 month, 18.8% at 3 months, and 13.3% at 6 months. At 1 month, 2 patients required an AKA/BKA, increased to 3 patients at 3 months, and further increased to 4 patients at 6 months. One patient was deceased at the 1-month follow-up, and 3 patients were deceased by the 3-month interval.

### Amputation-free survival

A Kaplan-Meier curve was generated for the comparison of amputation status between the reintervention and non-reintervention groups, where the outcome of interest was occurrence of an AKA or BKA (**Figure 3**). All patient intervals begin at the time of the initial pDVA (time t = 0), regardless of reintervention





status, to reflect the comprehensive outcome of the entire course of treatment. Patients were censored if they died or were lost to follow-up before the end of the study period; 95% CIs are provided for both lines.

Generally, the trend of amputations in the non-reintervention group differs from the reintervention group. By the 3-month interval, all reported amputation events had occurred in the non-reintervention group, whereas only 1 patient required a major amputation at this interval in the reintervention group. At 6 months, there were 2 reported amputees in the reintervention group. Patients in the reintervention group therefore tended to undergo amputation at a relatively more gradual rate than patients in the non-reintervention group. Conducting a log-rank test with 1 degree of freedom yielded a Chi-squared value of 1.9 with a corresponding *P*-value of 0.2 (**Table 4**). The margin of error in our CIs are largely due to having a relatively small sample size in this study.

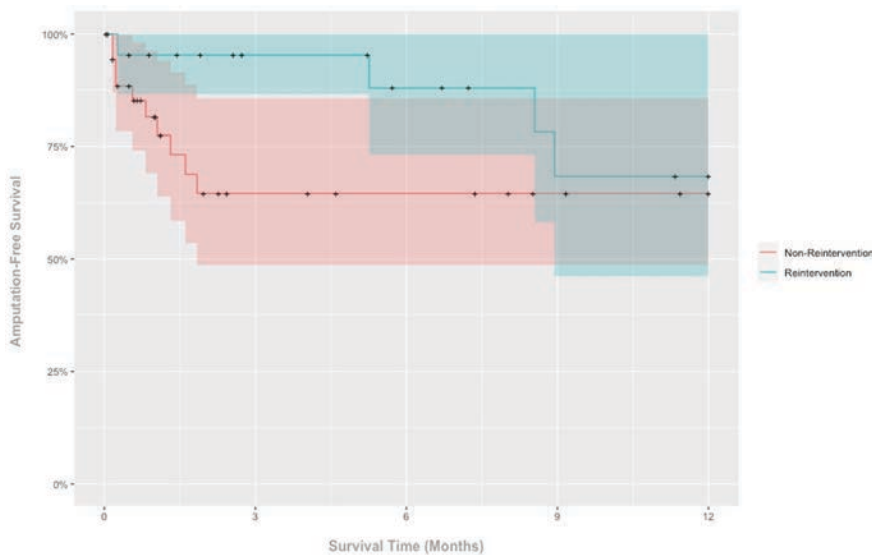
The CIs in the period from approximately 2 months to 5 months did not overlap between the 2 groups and reflected a possible point of interest within this period. Adjusting the time frame with 6 months as the “end-of-study” period and conducting a log-rank test with 1 degree of freedom yielded a Chi-squared value of 4 with a corresponding *P*-value of .05 (**Table 4**).

## Discussion

Reintervention rates were common, with 33.9% of cases in this study requiring a clinically driven reintervention of a prior pDVA, as reported in **Table 2**. Predisposing conditions including hypertension, dyslipidemia, and obesity tended to be more common in the reintervention group than the non-reintervention group, although only hypertension had a significant difference.

The rates of clinically driven reintervention in this study were slightly lower than previously reported experiences. The PROMISE I trial found that 16 of 31 (52%) successfully treated patients required reintervention.<sup>7</sup> The ALPS study, meanwhile, found that 67% of patients experienced a pDVA occlusion within a median time of 2.6 months, with 54.8% of all patients requiring some clinical reintervention.<sup>6</sup> Our cohort of patients underwent reintervention at a lower rate than the PROMISE I and ALPS studies, although the decision-making regarding necessary pDVA reintervention may vary with different operators. The average

**FIGURE 2.** Long-term outcomes stacked frequency bar graphs. Sample size is adjusted at each interval to account for loss to follow-up. “Amputation” and “Deceased” patients are followed through the entire 12-month period to reflect changes in the sample population over time. “Amputation” patients represent a general therapeutic failure of percutaneous deep venous arterialization (pDVA) reintervention across the studied interval. “Initial” on the x-axis refers to an initial baseline timepoint immediately following reintervention. (A) Stacked bar graph of critical limb-threatening ischemia (CLTI) symptoms at follow-up intervals. CLTI symptoms were determined by a ranking of 4 to 6 on the Rutherford classification of peripheral artery disease as determined by the attending physician at time of follow-up based on patient symptoms of rest pain or progressive gangrene/necrosis. (B) Stacked bar graph of wound healing status at follow-up intervals. Wound healing was determined by shrinking wound size compared with size at time of reintervention and at previous follow-up appointments as measured or observed by the attending physician. (C) Stacked bar graph of pDVA graft patency at follow-up intervals. Patency was determined by observing blood flow via duplex ultrasound and/or follow-up fluoroscopic angiography imaging.



**FIGURE 3.** Unadjusted Kaplan-Meier survival curve of amputation-free survival (AFS) in 21 percutaneous deep venous arterialization (pDVA) reintervention patients ( $n = 21$ ) vs 41 non-reintervention patients ( $n = 41$ ) over a 12-month period; 95% confidence intervals are provided. “+” indicates censored subjects. The time of the initial pDVA, regardless of reintervention status, is the reference point for each subject’s time interval to AFS.

time to reintervention was approximately 102 days from the initial pDVA. There was no significant difference in the need for reintervention for anterior tibial pDVAs compared with posterior tibial pDVAs. However, there is a general tendency to prefer graft construction in the posterior tibial vessels, given that the number of posterior tibial pDVAs is 5 times the number of anterior tibial pDVAs. Notably, there was a large variation in time to reintervention, with the shortest time being 2 days and the longest time being 329 days post initial pDVA procedure. Further analysis of this discrepancy in future studies may yield insight for better understanding the underlying clinical or anatomic risks for early reintervention.

Reintervention was associated with a substantial improvement in CLTI symptoms (presence of rest pain or progressive gangrene/necrosis) and wound healing in most patients at 1-month follow-up after pDVA reintervention (**Figure 2**). However, beyond 1 month there was a reduced percentage of wound healing and major amputations requirement, although only a minority of patients needed an above-ankle amputation. These trends seem to suggest that reintervention provides benefit for CLTI treatment initially but yields diminishing returns over time (**Figure 2**), suggesting an important role for aggressive surveillance in these patients and consideration of further interventions if anatomically feasible to maintain DVA flow. Notably, the loss to follow-up and interval mortality represents a confounding variable in fully interpreting limb salvage outcomes after reintervention.

The Kaplan-Meier curve (**Figure 3**) demonstrates a nonsignificant difference in amputation-free survival (AFS) between the reintervention and non-reintervention groups. The reintervention

group had overall equivalent amputation rates over a 12-month period compared with the non-reintervention group. While there is no statistically significant difference overall, the 2 CIs do not overlap up to 5 months and may represent a possible difference for this period in terms of patient AFS. Hypothesis testing conducted to a 6-month extent instead demonstrated a borderline result that might prove to be significant with a larger sample size.

The relationship between the need for repeat procedures and the long-term success of reintervention is complex. A loss of DVA patency would be expected to have an association with adverse clinical outcomes, and the finding of similar AFS between patients requiring reintervention compared with those maintaining de novo patency confers clinical benefit from the secondary procedures. In patients requiring repeat procedures, a clinical outcome (rest pain, progressive gangrene/necrosis,

absence of Doppler signals at the level of the foot, etc.) was the main indication for the reintervention.

It is difficult to predict how patients might fare clinically in the long term without these additional procedures. One could therefore argue that reintervention was necessary to salvage the initial pDVA in those select patients, which helped maintain a comparable amputation rate to the non-reintervention group over a 12-month interval. Conversely, physiologic changes developing after an interval of having a functional DVA, such as the development of angiogenesis or precapillary venoarterial anastomosis, may preserve limb salvage despite DVA failure. Additional data to better understand the mechanism of action for DVA will help clarify this issue, and perhaps provide better measures for determining in which patient reintervention is beneficial.

Another potential confounding variable is the variation in time-to-reintervention mentioned in **Table 2**. There is a wide variability in timing for when patients undergo a repeat procedure to revise a pDVA. The association between timing of reintervention and long-term success (eg, AFS, wound healing, graft patency, etc.) is unclear in this study. Future research might benefit from analysis of the relationship between time-to-reintervention and long-term outcomes in pDVA patients. Another potential study might look at whether technically unsuccessful reinterventions correlate with differences in clinical outcomes compared with technically successful reinterventions.

Recognizing the high rate of early failure with initial pDVAs, a strategy of planned “second look” angiography in patients undergoing pDVA may help improve patient outcomes. In prac-

tice, these might be performed approximately 1 month after the index intervention and provide an opportunity to identify and recalibrate arterial lesions to maintain desired flow rates (eg, brisk antegrade pDVA filling with maintained visualization of other remaining patent arterial collaterals) as well as treat the frequently observed recoil and recurrent stenosis in the venous outflow. This study provides some context as to the benefits of any reintervention, whether that involves engaged revision of an initial procedure or a postintervention check to confirm functionality of any given pDVA.

## Limitations

Limitations of our study include its retrospective nature and the relatively low number of reinterventions. Objective measures, such as toe pressures, ankle-brachial index, and transcutaneous oximetry (tcPO<sub>2</sub>), were not utilized here due to inconsistent measurement of these values during this retrospective study. Consequently, wound, ischemia, and foot infection grading could not be determined. Loss to follow-up also reduced the power of this analysis in determining a meaningful effect. A larger sample size in future studies may reduce the margin of error and demonstrate an overall significant difference between reintervention and non-reintervention statuses. Further studies with larger sample sizes are necessary to confirm the presented findings.

Another limitation includes the subjective interpretations used as data points in this study. For example, endpoints such as technical success of initial and reintervention pDVAs were subjectively interpreted by the operator during fluoroscopy. Additionally, there is variety in follow-up practice, such as incorporating tcPO<sub>2</sub> and duplex scan a few weeks post procedure,<sup>11</sup> which limits comparison with other institutions that do not include these measurements for pDVA follow-up.

An interesting statistical limitation in this study exists due to the criteria used herein to describe reintervention. To qualify for reintervention, patients must have received an initial pDVA and then existed for some period as non-reintervention patients before the clinician determined that they met the clinical criteria for reintervention. It is therefore unclear whether this transient non-reintervention period should contribute to the true non-reintervention group (patients who never received a reintervention). One option would be to count this period toward the true non-reintervention group, but this is not an accurate representation of non-reintervention as described in this study. Another option would be to entirely disregard this consideration, but this would exclude the potential therapy of the initial pDVA and would confound the extent to which the reintervention itself was therapeutic. Yet another option exists where this period can be treated as a separate third entity—“pre-reintervention”—but this would yield an inappropriate comparison with no logical interpretation of the results. Reintervention status is therefore a time-dependent covariate in which patients should technically

be considered “non-reintervention” for some time, even if they eventually undergo reintervention. This statistical problem has been well characterized as “immortal time bias” in the Stanford heart transplant study.<sup>12</sup> To date, there is currently no feasible statistical measure that accounts for time-dependent covariates in a meaningful function or graph. Therefore, there is limitation in comparing reintervention against non-reintervention cases without an unbiased statistical analysis of the data.

## Conclusion

There is some evidence in this early observation supporting the potential value and continued role of pDVA surveillance and appropriate reintervention to improve AFS. This study established a possible role for reintervention in providing relief to patients with CLTI up to 6 months, but there appears to be limited benefit for patients past 6 months post reintervention. In our practice, we have modified the reintervention strategy and implemented a planned “second look” angiography in pDVA patients at 1 month post procedure. This approach provides an opportunity to identify and recalibrate the graft as well as treat recoil and recurrent venous outflow stenosis to maintain desired flow. Because AKA/BKA is a major operation associated with greater mortality and poorer overall health outcomes, even short-term benefit may offer some protection to CLTI patients against future adverse events. Future directions will examine methods to improve pDVA reinterventions as well as refine the original pDVA procedure for patients. Additional data will clarify these important relationships and guide the best clinical management for these complex patient populations.

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