



# Impact of Pedal Arch Patency on Below-the-Ankle Revascularization Outcomes

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## Abstract

**Background.** The purpose of this study was to investigate the effect of below-the-ankle (BTA) angioplasty on angiographic pedal arch patency and its association with clinical outcomes in patients with chronic critical limb ischemia (CLI). **Methods.** A single-center review of 60 consecutive Rutherford class 5 and 6 patients (age,  $69.1 \pm 1.5$  years; 58.3% males) undergoing revascularization of 81 BTA lesions (53 dorsalis pedis, 16 pedal arch, 12 lateral plantar) was performed. Postintervention arteriograms were classified as demonstrating a complete (CPA), incomplete (IPA), or absent (APA) pedal arch. Clinical endpoints included overall survival (OS), amputation-free survival (AFS), and freedom from minor amputation (FFA-minor) at 6 and 12 months, as well as wound healing. A subgroup analysis comparing patients with CPA and IPA was performed. **Results.** The technical success rate was 95%. The 6- and 12-month rates of OS, AFS, and FFA-minor were 95% and 95%, 62% and 57%, and 63% and 63%, respectively. Twenty-three major amputations and 9 minor amputations were recorded. There was a 43% wound healing rate after  $7.4 \pm 0.8$  months. Subgroup analysis showed no difference in OS, AFS, or wound-healing metrics between the CPA vs IPA groups ( $P > .05$ ). A significant association was found between 12-month FFA-minor and a CPA ( $P < .001$ ). There were 6 minor and 1 major procedure-related complications. **Conclusions.** The degree of pedal arch recanalization did not impact survival and wound healing in this cohort. However, obtaining a complete pedal arch was found to be associated with avoidance of minor amputation.

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**Key words:** below-the-ankle revascularization, critical limb ischemia, wound healing

Optimized medical therapy, wound care, and prompt revascularization are recommended in order to promote wound healing and decrease the risk of limb amputation in patients with chronic critical limb ischemia (CLI).<sup>1</sup> Advances in endovascular techniques and equipment enable the treatment of distal pedal outflow vessels that are frequently affected in diabetic patients with CLI, allowing the establishment of in-line flow to the pedal wound bed, which is the goal of revascularization.<sup>2-5</sup>

Despite a paucity of data compared with endovascular therapy (EVT) of more proximal segments, a growing body of literature supports below-the-ankle (BTA) angioplasty as a safe and technically feasible strategy to restore flow to the foot and digits.<sup>6-13</sup> Angiographic pedal arch patency has been associated with improved limb salvage and wound healing in studies involving femoropopliteal or tibial EVT and infrapopliteal bypass.<sup>14-16</sup>

Recent retrospective studies have found that additional BTA angioplasty resulted in an improved wound healing rate and reduced time to achieve healing when compared with tibial EVT alone.<sup>10,11</sup> However, it is unclear whether angiographic endpoints in pedal intervention are predictive of survival and limb salvage. The aim of this study is to investigate the effect of BTA angioplasty on angiographic pedal arch patency and its association with clinical outcomes in patients with CLI.

## Methods

This Health Insurance Portability and Accountability Act (HIPAA)-compliant retrospective cohort study was approved by the institutional review board, and informed consent was waived.

TABLE 1. Patient demographics and procedural history.

	All Patients (n = 60)	CPA (n = 25)	IPA (n = 35)	P-Value
Age (years)	69.1 ± 1.5	70.2 ± 2.1	68.4 ± 2.2	.74
Male gender	35 (58.3%)	14 (56%)	21 (60%)	.80
Hypercoagulable state	3 (5%)	2 (8%)	1 (2.8%)	.57
Atrial fibrillation	13 (21.7%)	4 (16%)	9 (25.7%)	.53
Coronary artery disease	33 (55%)	13 (52%)	20 (57.1%)	.79
Cerebrovascular accident	11 (18.3%)	6 (24%)	5 (14.3%)	.50
Diabetes mellitus	49 (81.7%)	21 (84%)	28 (80%)	.75
Hypertension	53 (88.3%)	23 (92%)	30 (85.7%)	.69
Hyperlipidemia	38 (63.3%)	14 (56%)	24 (68.6%)	.42
Chronic renal disease	33 (55%)	13 (52%)	21 (60%)	.68
Smoker (current or previous)	29 (48.3%)	10 (40%)	19 (54.3%)	.33
Preprocedural medications				.45
Single-antiplatelet therapy	8 (13.3%)	2 (8%)	6 (17.1%)	
Dual-antiplatelet therapy	31 (51.7%)	15 (60%)	16 (45.7%)	
Combined antiplatelet and anticoagulation	21 (35%)	8 (32%)	13 (37.1%)	

Data presented as mean ± standard error or number (%). CPA = complete pedal arch; IPA = incomplete pedal arch.

**Patient selection.** Consecutive patients who underwent EVT for lower-extremity CLI at a single community hospital system were identified through retrospective review of electronic medical records. Only Rutherford class 5-6<sup>17</sup> CLI cases involving revascularization of a named pedal artery (dorsalis pedis, medial and lateral plantar, pedal arch) were included regardless of proximal intervention. Cases involving iliac, femoropopliteal, and/or tibial revascularization without BTA intervention were excluded, even if pedal access was employed. Sixty patients (age, 69.1 ± 1.5 years; 58.3% men) were identified whose demographics and comorbidities are listed in **Table 1**. Wound status and vascular lesion characteristics are shown in **Table 2**. All patients underwent a single EVT session to treat a total of 81 pedal lesions in addition to 84 tibial lesions. There were no patients who underwent BTA angioplasty without concurrent tibial revascularization. Thirty-three of the 60 patients (55%) underwent concurrent femoropopliteal intervention.

**Procedure.** The goal of EVT in all cases was to establish direct, inline flow to the affected wound bed in the foot. When lack of direct flow to target wound bed remained following femoropopliteal or tibial EVT, plain balloon angioplasty was performed in the pedal arteries to improve angiosome-directed angiographic perfusion. In order to achieve this, advanced techniques such as the pedal-plantar loop technique<sup>9</sup> and retrograde pedal access technique<sup>18,19</sup> were selectively employed as needed. All pedal artery lesions underwent balloon angioplasty. Pedal artery atherectomy

was used prior to angioplasty per operator discretion using the Jetstream device (Boston Scientific) in 1 case and the Diamondback 360° device (Cardiovascular Systems, Inc) in 2 cases. Pedal artery stent placement was not performed. Completion arteriograms were classified as complete (CPA), incomplete (IPA), or absent (APA) pedal arch. CPA was defined as angiographic continuity between a plantar artery and the dorsalis pedis; IPA was defined as patency of either a plantar artery or the dorsalis pedis; and APA was defined as absence of both plantar arteries and the dorsalis pedis (**Figure 1**).<sup>15,16</sup>

**Postprocedural care.** Patients were started on dual-antiplatelet therapy (aspirin 81 mg daily with a clopidogrel 300 mg loading dose immediately at the conclusion of the procedure followed by 75 mg of clopidogrel daily) or continued their existing antiplatelet/anticoagulation regime. Patients were seen for follow-up by the operating physician to assess wound healing. Selective reintervention was driven by patient symptoms, status of wounds, and congruent findings on non-invasive testing of recurrent occlusion or hemodynamically significant stenosis within a previously treated vessel supplying the wound bed(s).

**Study endpoints and data analysis.** *Technical success* was defined as recanalization of an obstructing lesion that resulted in patent angiosome-directed pedal outflow to the target wound bed, regardless of whether CPA was achieved. *Clinical endpoints* included overall survival (OS), amputation-free survival (AFS),

TABLE 2. Wound and procedural details.

	All Patients (n = 60)	CPA (n = 25)	IPA (n = 35)	P-Value
<b>Wound location</b>				
Single digit	27 (45%)	14 (56%)	13 (37.1%)	.19
Multiple digits	14 (23.3%)	2 (8%)	12 (34.3%)	.03
Dorsal forefoot	19 (31.7%)	8 (32%)	11 (31.4%)	>.99
Plantar forefoot	2 (3.3%)	1 (4%)	1 (2.9%)	>.99
Heel	9 (15%)	2 (8%)	7 (20%)	.28
TMA site	5 (8.3%)	2 (8%)	3 (8.6%)	>.99
Rutherford class 5	34 (56.7%)	16 (64%)	18 (51.4%)	.43
Rutherford class 6	26 (43.3%)	9 (36%)	17 (48.6%)	
<b>Access site(s)</b>				
Contralateral CFA	31 (51.7%)	11 (44%)	20 (57.1%)	.43
Ipsilateral CFA/SFA	31 (51.7%)	14 (56%)	17 (48.6%)	.61
Posterior tibial	2 (3.3%)	0	2 (5.7%)	.51
Anterior tibial	3 (5%)	3 (12%)	0	.07
Dorsalis pedis	13 (21.7%)	6 (24%)	7 (20%)	.76
Pedal-plantar loop technique	6 (10%)	6 (24%)	0	<.01
Retrograde pedal access technique (including SAFARI)	18 (30%)	9 (36%)	9 (25.7%)	.57
<b>Angioplasty</b>				
Peroneal	9 (15%)	2 (8%)	7 (20%)	.28
Anterior tibial	51 (85%)	21 (84%)	30 (85.7%)	>.99
Dorsalis pedis	53 (88.3%)	22 (88%)	31 (88.6%)	>.99
Pedal arch	16 (26.7%)	8 (32%)	8 (22.9%)	.56
Posterior tibial	24 (40%)	14 (56%)	10 (28.6%)	.06
Lateral plantar	12 (20%)	6 (24%)	6 (17.1%)	.75
<b>Atherectomy</b>				
Peroneal	2 (3.3%)	1 (4%)	1 (2.9%)	>.99
Anterior tibial	15 (25%)	7 (28%)	8 (22.9%)	.77
Dorsalis pedis	3 (5%)	1 (4%)	2 (5.7%)	>.99
Posterior tibial	7 (11.7%)	5 (20%)	2 (5.7%)	.12
<b>Postintervention patent run-off vessels</b>				.11
1	21 (35%)	5 (20%)	16 (45.7%)	
2	34 (56.7%)	17 (68%)	17 (48.6%)	
3	5 (8.3%)	3 (12%)	2 (5.7%)	
<b>Pedal lesion characteristics</b>				.75
Occlusion	12 (20%)	4 (16%)	8 (22.9%)	
Stenosis	48 (80%)	21 (84%)	27 (77.1%)	

Data presented as mean ± standard error or number (%).

CFA = common femoral artery; CPA = complete pedal arch; IPA = incomplete pedal arch; SAFARI = Subintimal Arterial Flossing with Antegrade Retrograde Intervention; SFA = superficial femoral artery; TMA = transmetatarsal amputation.

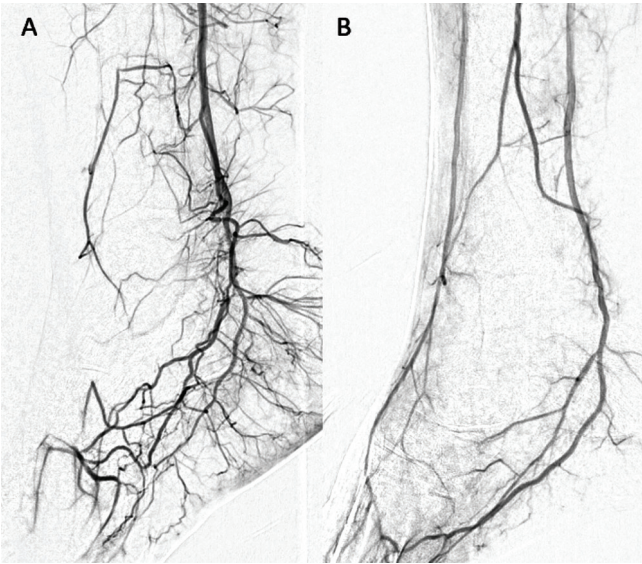


FIGURE 1. Pedal arch types. (A) Incomplete pedal arch. (B) Complete pedal arch.

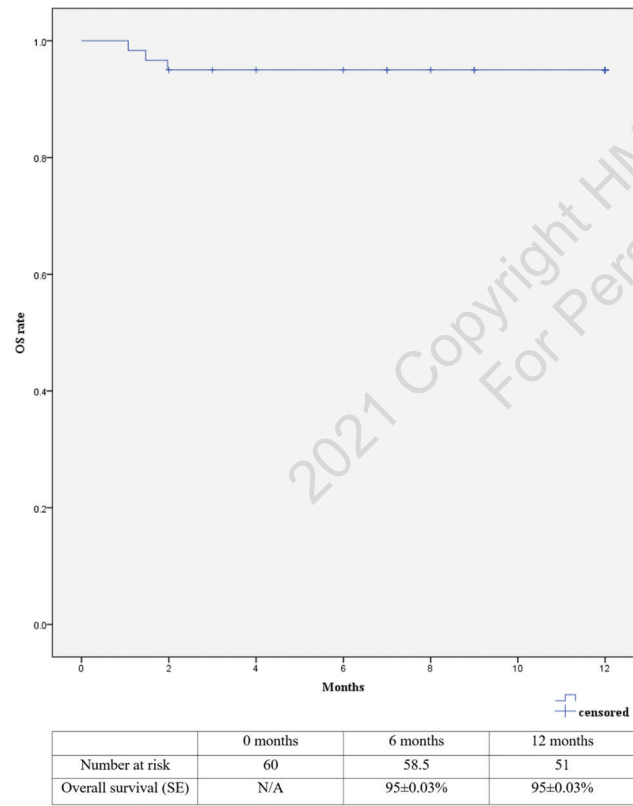


FIGURE 2. Overall survival. N/A = not applicable; SE = standard error; OS = overall survival.

and freedom from minor amputation (FFA-minor) at 6 and 12 months. AFS was defined as time from index procedure to either death or major amputation (through or above the ankle).<sup>20</sup>

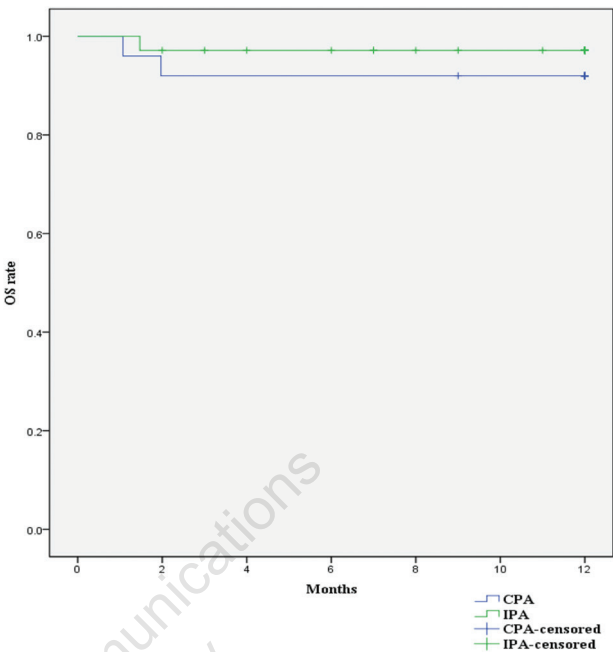
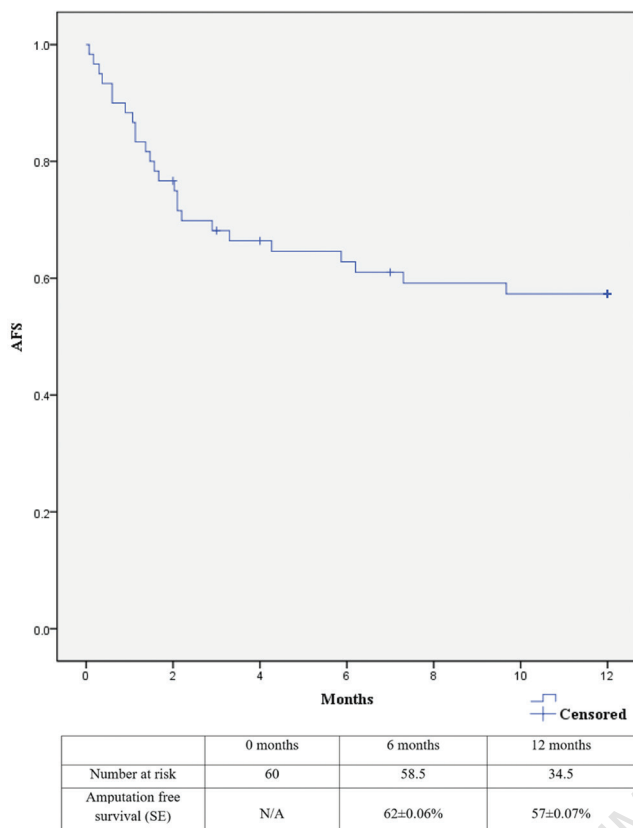


FIGURE 3. Overall survival by pedal arch. N/A = not applicable; CPA = complete pedal arch; IPA = incomplete pedal arch; OS = overall survival; SE = standard error.

FFA-minor was defined as avoidance of a toe or ray amputation in the absence of ipsilateral major amputation or death.<sup>7</sup> Wound healing rate and time were assessed throughout the duration of follow-up. Wound healing was defined as complete epithelialization without major amputation.<sup>10</sup> These endpoints were also reported for a subgroup analysis comparing patients with CPA vs IPA after the procedure. Adverse procedure-related events were reported according to the Society of Interventional Radiology reporting standards.<sup>21</sup>

**Statistical analysis.** Continuous variables were expressed as mean ± standard error. The Chi-square test and Fisher’s exact test were used to compare binomial variables, with the latter utilized when cell sizes were <5. The Mann-Whitney U-test was used to compare continuous variables. Kaplan-Meier survival curves were generated, and subgroup analyses were performed to compare pedal arch groups and clinical endpoints using the log-rank (Mantel-Cox) test. Two-tailed statistical significance was set at  $P<.05$ . All statistical analyses were performed using SPSS software, version 20 (IBM Corporation).



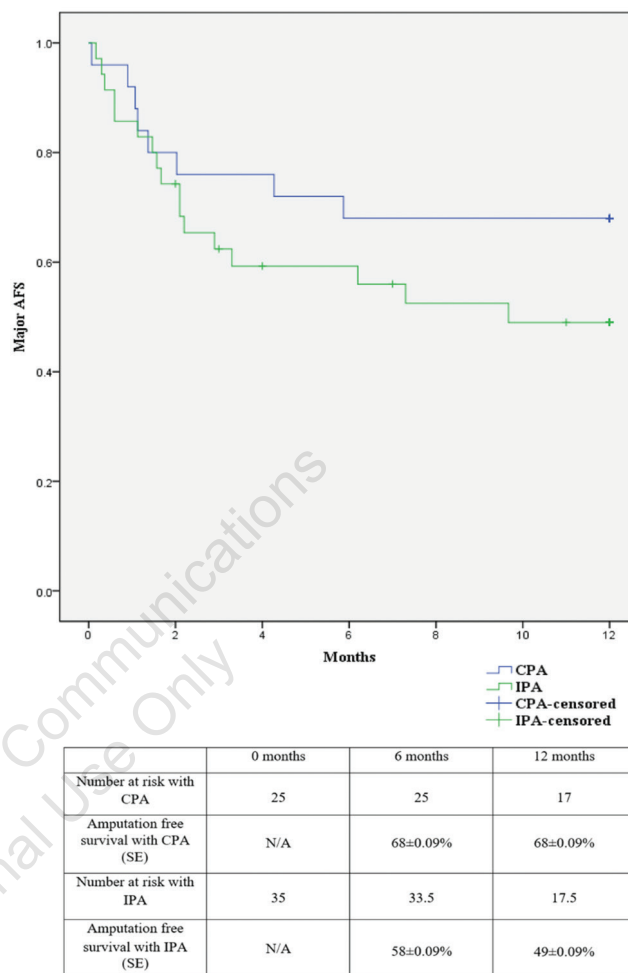
**FIGURE 4.** Amputation-free survival (AFS). N/A = not applicable; SE = standard error.

## Results

At initial arteriography, there were 0/60 CPAs (0%), 19/60 IPAs (32%), and 41/60 APAs (68%). On completion arteriography following BTA angioplasty, there were 25/60 CPAs (42%), 35/60 IPAs (58%), and 0/60 APAs (0%). The overall technical success rate of BTA revascularization was 95%. There were no statistically significant differences in patient demographics, comorbidities, and preprocedural antiplatelet/anticoagulation regimen between pedal arch groups (CPA and IPA during final arteriography) (**Table 1**).

The 6- and 12-month OS rates were 95% and 95%, respectively (**Figure 2**). Three mortalities were attributed to cardiac arrest on postoperative days 32, 44, and 59, with average occurrence of  $45.3 \pm 7.5$  days. Subgroup analysis by pedal arch status showed a 12-month OS of 92% for the CPA group (2 deaths) vs 97.1% for the IPA group (1 death);  $P=.40$  (**Figure 3**).

The 6- and 12-month AFS rates were 62% and 57%, respectively, with 23 major amputations (2 above knee, 21 below knee) occurring on average at  $2.5 \pm 0.5$  months (**Figure 4**). Subgroup analysis by pedal arch status showed the 12-month AFS was 68% for the CPA group (7 major amputations) vs 49% for the IPA group (16 major



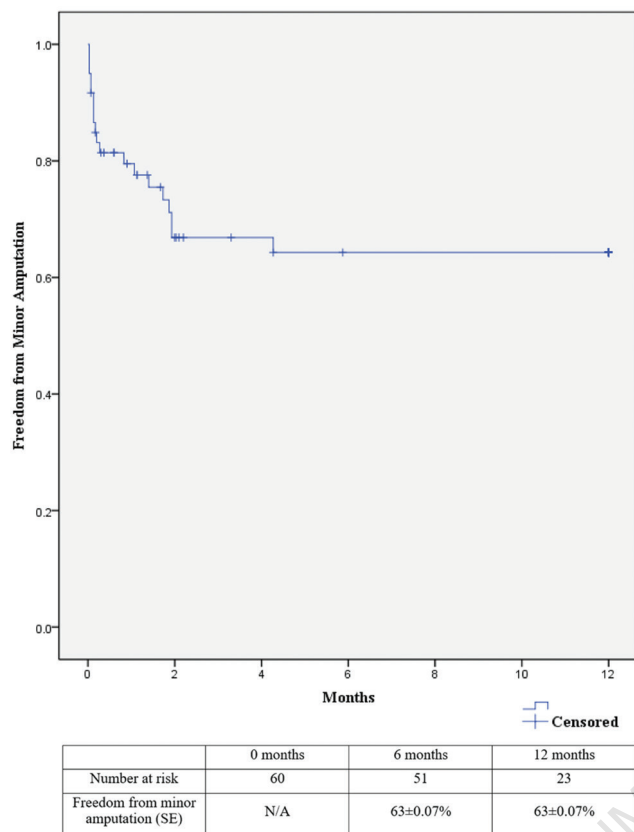
**FIGURE 5.** Amputation-free survival (AFS) by pedal arch. CPA = complete pedal arch; IPA = incomplete pedal arch; N/A = not applicable; SE = standard error.

amputations);  $P=.16$  (**Figure 5**). On average, major amputations occurred at  $2.2 \pm 0.8$  months for the CPA group and  $2.6 \pm 0.7$  months for the IPA group ( $P=.74$ ).

The 6- and 12-month FFA-minor rates were 63% and 63%, respectively, with 19 minor amputations (10 digit, 9 transmetatarsal) occurring at an average of  $0.7 \pm 1.1$  months (**Figure 6**). Subgroup analysis by pedal arch status showed 12-month FFA-minor was 91% for the CPA group (2 minor amputations) vs 43% for the IPA group (17 minor amputations);  $P<.001$  (**Figure 7**). On average, minor amputations occurred at  $1.1 \pm 0.3$  months for the CPA group and  $0.8 \pm 0.3$  months for the IPA group.

The average duration of follow-up was  $18.3 \pm 1.5$  months, with no significant difference between pedal arch status groups ( $21.3 \pm 2.7$  months for the CPA group vs  $16.1 \pm 1.7$  months for the IPA group;  $P=.14$ ). Throughout the duration of follow-up, 26/60 patients achieved wound healing after  $7.4 \pm 0.8$  months. Subgroup analysis by pedal arch status showed the 18-month wound-healing





**FIGURE 6.** Freedom from minor amputation. N/A = not applicable; SE = standard error

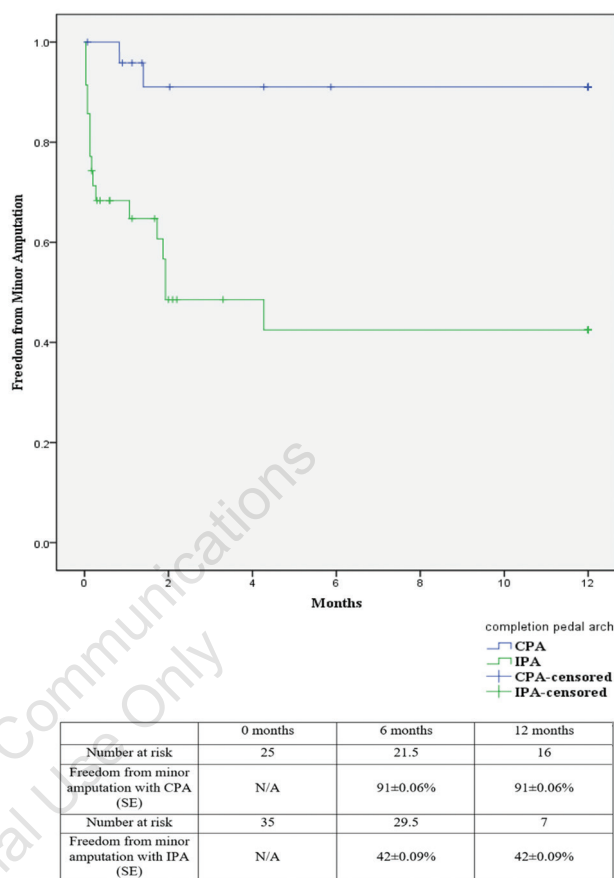
rate to be 52% for the CPA group (13/25) vs 37.1% for the IPA group (13/35). Wound healing occurred after a mean of  $7.0 \pm 1.2$  months in the CPA group vs  $7.9 \pm 1$  months in the IPA group ( $P=.96$ ).

There were 6 minor complications with 4 cases of femoropopliteal or tibial arterial emboli requiring aspiration thrombectomy and 2 cases of intraprocedural vasospasm and thrombus formation requiring intra-arterial nitroglycerin, mechanical thrombectomy, and heparinization for 24 hours. There was a single major complication requiring a postoperative day 4 endovascular reintervention to close an iatrogenic access-site arteriovenous fistula with a covered stent.

## Discussion

The current study did not find an association between the angiographic patency of the pedal arch after BTA angioplasty (CPA vs IPA) and OS, AFS, or wound healing. There was an advantage for a complete arch in terms of preventing minor amputations up to 12 months after the procedure, compared with an incomplete arch.

Nakama et al compared 140 patients undergoing infrapopliteal revascularization with additional BTA angioplasty with 117



**FIGURE 7.** Freedom from minor amputation by pedal arch. CPA = complete pedal arch; IPA = incomplete pedal arch; N/A = not applicable; SE = standard error.

patients who did not undergo additional BTA angioplasty and reported similar OS and AFS rates between the groups. The study also reported an OS rate of 85% and an AFS rate of 76.4% at 12 months in the additional BTA angioplasty group.<sup>10</sup> In comparison, the current study found OS and AFS rates of 95% and 57% at 12 months, respectively. The 12-month AFS was better for the CPA group (68%, 7 major amputations) compared with the IPA group (49%, 16 major amputations), but this did not reach statistical significance ( $P=.16$ ), which was likely due to the small sample size. OS and AFS rates in this cohort approach the natural history of untreated CLI patients with OS and major amputation rates of 88% and 22% reported at 12 months, respectively.<sup>22</sup> This finding likely reflects the presented cohort's comorbid disease severity and multilevel peripheral arterial disease without suitable bypass targets. Nakama et al also reported statistically significant differences in 12-month wound healing rates (59.3% vs 38.1%;  $P<.01$ ) and median time to wound healing (7 months [interquartile range, 2.3-12 months] vs 12 months [interquartile range, 2.9-12 months];  $P<.01$ ) when comparing additional BTA angioplasty vs no additional BTA angioplasty. In the current cohort, 43% of all

patients achieved wound healing with a median time to wound healing of 8 months [interquartile range, 4.0-9.3 months], yet no association to pedal arch status was found.

The finding of a significant association between 12-month freedom from minor amputation and a CPA following BTA angioplasty in this study is comparable with 2 single-arm studies (combined  $n = 228$ ) that reported a 33% minor amputation rate.<sup>7,23</sup> Both studies contained similar cohorts to the current study in terms of Rutherford class, comorbidities, and aggressive multilevel EVT. Although it is not considered a major outcome measure, the value of avoiding transmetatarsal amputation may have a considerable impact on the functional and ambulatory status of CLI patients. Suh et al demonstrated superior ambulatory function scores in diabetic patients undergoing first ray preservation compared with full transmetatarsal amputations, which was attributed to preservation of load-bearing segments in the forefoot.<sup>24</sup>

**Study limitations.** The current study suffers from several limitations, including its retrospective nature, the lack of a Rutherford class-matched control group that did not receive additional BTA angioplasty, and its small sample size, which limited the comparison between the CPA and IPA groups and prevented regression analysis. The small sample size of the current study and low number of CPA group minor amputations ( $n = 2$ ) does not allow for accurate comparison of the minor to major amputation conversion rate between pedal arch status groups. Wound severity and healing were not classified according to a standardized scale. Data regarding the proportion of patients receiving BTA angioplasty from all Rutherford class 5-6 cases requiring intervention was not available in this retrospective cohort. Pre and postprocedural non-invasive studies were not routinely obtained. Additionally, 12-month OS may not be the most applicable endpoint in this cohort, as a longer duration of follow-up may be required to elucidate a difference in outcomes.

## Conclusion

The degree of pedal arch recanalization following EVT, as assessed on completion angiography, did not have a significant impact on survival and wound healing in this limited cohort. Nonetheless, obtaining an angiographically complete pedal arch was found to be associated with avoidance of minor amputation.

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