In-line Flow Following Endovascular Intervention as a Positive Predictor in Healing Pedal Amputations

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Statement of Purpose

The purpose of this study is to examine healing rates after pedal amputations following endovascular intervention with and without restoration of in-line flow to the foot.

Methodology & Procedures

Patients undergoing transmetatarsal, ray, and digital amputations within Kaiser Northern California from January 2008 through December 2014 were identified. All patients had endovascular intervention prior to amputation, and post-procedural imaging was reviewed retrospectively to determine whether or not in-line flow was in fact restored. ***In-line flow was defined as unobstructed flow to at least one pedal vessel of normal or near normal caliber.***

The primary outcome measure was healing, divided into three categories:

- Optimal - complete healing within 30 days from amputation.
- Delayed - healing greater than 30 days but less than 90 days from surgery, often due to local dehiscence.
- Failure - wound persistence, incidence of bypass procedure, or progression to proximal amputation.

Patient demographic and comorbidity data were collected and tested for association with our primary outcome.

The comorbidities assessed were diabetes mellitus, coronary artery disease, hypertension, peripheral vascular disease, end-stage renal disease, and smoking status.

Descriptive statistics were compiled to describe the demographic and clinical characteristics. Chi-square and Fisher's exact tests were used to compare categorical variables.

Literature Review

To date, no studies have examined the relationship of in-line flow to healing pedal amputations. However, it is clear that maximizing in-line flow is important to successfully treat ischemic wounds. A recent systematic review evaluated outcomes after partial foot amputations in dysvascular patients without concomitant revascularization. The results were stark; with only 50% of patients healed within three months, and a mere 75% were healed within a year of surgery. Moreover, the postoperative course may be complicated by wound necrosis or major amputation in up to 42% in this patient cohort. [1]

Successful restoration of in-line flow is associated with Ankle-Brachial Index (ABI) values approaching normal and decreased incidence of major amputation during intermediate-term follow up.[2-3] This is in contrast to patients in whom revascularization is incomplete; post-procedure ABI values remain consistent with moderate disease.[3] Small cohort studies have shown that restoring inline flow may result in successful healing of amputations and ischemic wounds, although time to healing was not documented.[2] Specific to ischemic wounds, Okazaki et al. found mean wound healing times of 106 days following open revascularization and 194 days following endovascular intervention.[4] This is much longer than existing data on time to healing following pedal amputation. After revascularization, transmetatarsal amputations amenable to primary closure were found to heal at 1.6 months on average compared to an average 6.8 months in patients requiring delayed primary closure or amputation with secondary healing.[5] However, wound recurrence or amputation failure is not uncommon and may be a sign of restenosis within stented vessels.[2]

When amputation is necessary, the application and optimal form of revascularization is still unclear. For example, some studies are unable to document significantly improved amputation outcomes after revascularization compared to historical rates and instead support that tissue healing is more dependent on other factors such as degree of infection.[5] In addition, endovascular approaches may be beneficial for brief periods of increased tissue demand, but less than 50% of vessels remain patent six months after revascularization.[4] Currently, a void exists regarding the specific impact of restoring in-line flow on healing rates of pedal amputations.

Table 1: Demographics

Table 1. Demographic Data

	Optimal/Delayed Healing	Failure
Age (years)	71.0 ± 11.1	69.6 ± 10.0
Gender		
Male (n)	85	116
Female (n)	63	46
Race		
Asian (n)	15	9
Black (n)	33	34
Hispanic (n)	21	30
White (n)	72	76
Multiracial (n)	7	13

Data displayed as mean ± standard deviation where appropriate

Table 2: Healing Analysis

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Variable	Optimal/Delayed Healing (n)	Failure (n)	P-value
Hypertension			0.71
Present	142	154	
Absent	6	8	
Diabetes			**0.01**
Present	125	152	
Absent	23	10	
Cardiac disease[1]			0.21
Present	104	124	
Absent	44	38	
End-stage renal disease			0.07
Present	32	50	
Absent	116	112	
History of tobacco use			0.18
Present	109	108	
Absent	39	54	
Level of amputation			**0.04**
Ray	36	47	
Transmetatarsal	31	49	
Digital	81	66	
In-line flow[2]			**0.02**
Present	101	90	
Absent	43	68	
Infection			**<0.01**
Absent	124	64	
Mild	17	76	
Major	3	13	
Undocumented	4	9	

[1] Diagnosed with coronary artery disease, cardiovascular disease, or congestive heart failure

[2] Eight patients with missing data: 4 in "Optimal/Delayed Healing" group and 4 in "Failure" group

Figures 1A and 1B

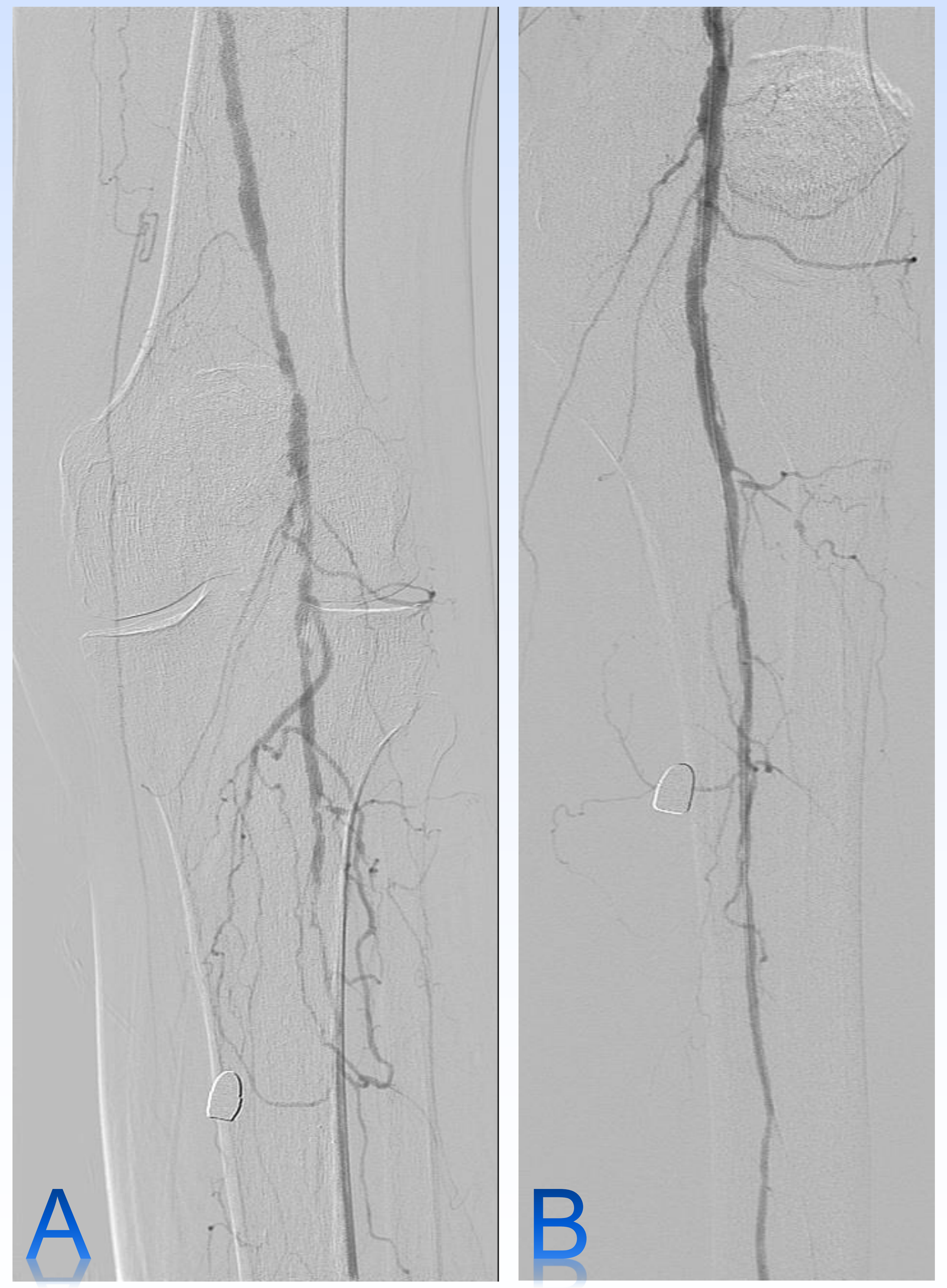

Figure 1A shows the popliteal and proximal peroneal arteries pre-intervention. Figure 1B shows the popliteal and proximal peroneal following successful angioplasty.

Figures 2A and 2B

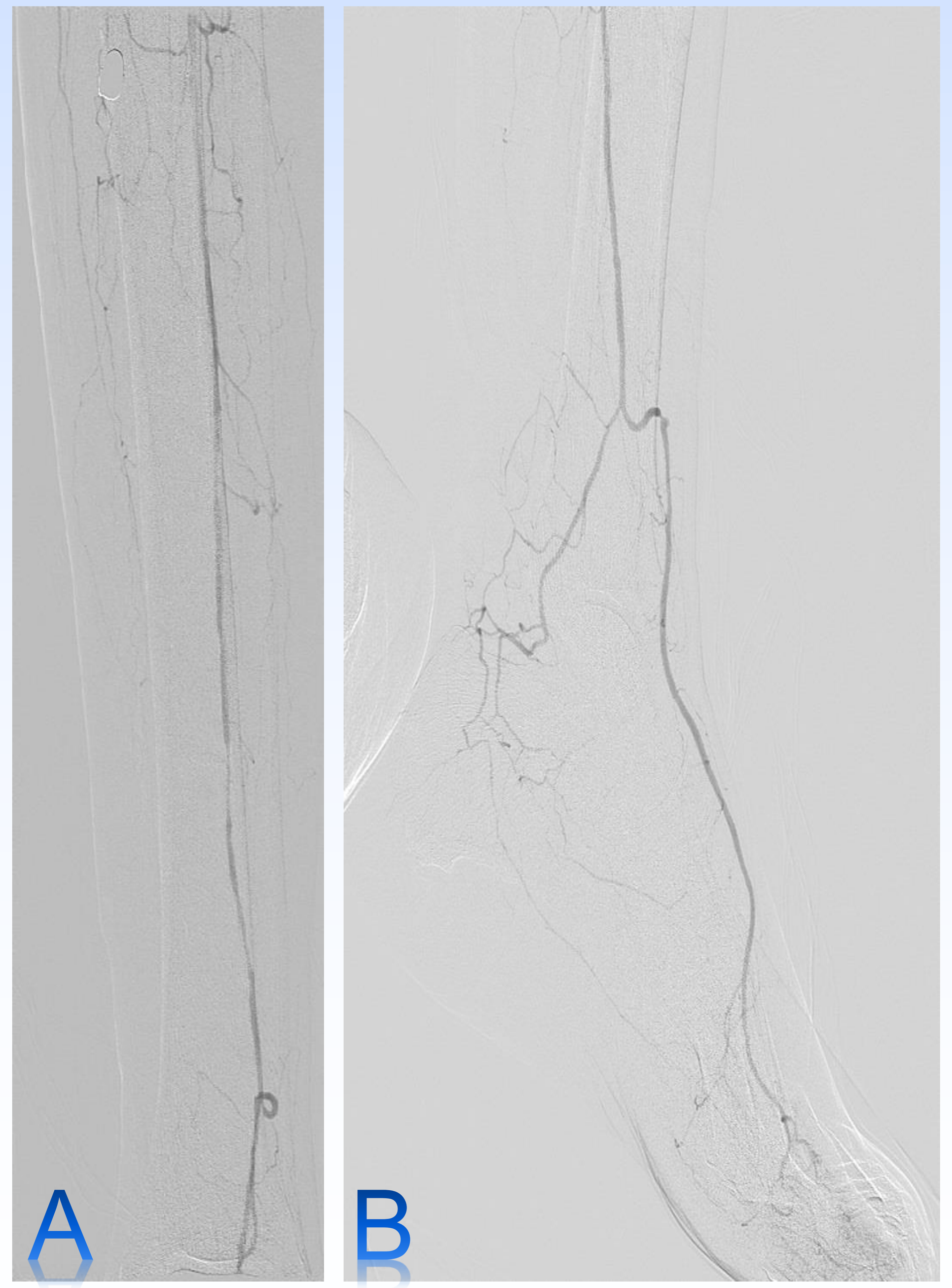

Figure 2A shows the peroneal artery pre-intervention. Figure 2B demonstrating a large perforating branch of the peroneal reconstituting to the dorsalis pedis artery, providing in-line flow to the foot.

Results

- Mean time to amputation from revascularization was 27.3 ± 23.9 days (range: 0–107 days).
- In-line flow was established in 191 (63.3%) cases.
- 101 (70.1%) patients with optimal or delayed healing had in-line flow restored vs 90 (57.0%) with clinical failure.
- 68 (43.0%) patients without in-line flow had clinical failure.
- There was an association between presence of in-line flow and incidence of healing (**p=0.018**). However, this association disappeared when comparing optimal and delayed healing groups (**p=0.61**).
- Other factors associated with clinical failure were sex, presence of diabetes, surgical site infection, and level of amputation (**p <0.05**).

Analysis & Discussion

The proper timing and method of revascularization is debated for lower extremity wounds. In addition, the degree to which vessels must be reconstituted and the implications for pedal amputations remains unknown. Here we are able to demonstrate that endovascular restoration of in-line flow has a significant influence on the proportion of patients likely to heal pedal amputations. Post-procedural evaluation of in-line flow may therefore be valuable in developing a prognosis for healing in this patient population.

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