

Effects of Patency of Run-off Arteries on Distal Bypass in Critical Limb Ischemia

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Background: In distal bypass, it is necessary to consider the location of the ulcer and anatomy of the vessels. However, there exist certain cases in which there is no choice for selection of distal anastomosis. We examined the relationship between the quality of the run-off artery and hemodynamic influence of the distal bypass.

Patients and methods: Fifty-nine patients with 70 limbs who underwent distal bypass for CLI from January 2010 to December 2017 were included. We classified them into the anterior tibial artery (ATA) group or posterior tibial artery (PTA) group by the peripheral anastomotic site, classified them with good run-off reconstruction or poor run-off reconstruction by the quality of the run-off artery, and also classified them with patent arch or occluded arch by the patency of the communicative branch at the tip of the pedal arch. We measured skin perfusion pressure (SPP) and evaluated the wound healing time.

Results: In both the ATA group and the PTA group, postoperative SPP increased significantly than preoperative SPP with both good run-off and poor run-off reconstruction. The wound healing rate did not differ between good run-off and poor run-off reconstruction in both the ATA group and the PTA group. On the other hand, the wound healing rate was higher with patent arch than with occluded arch.

Conclusions: Distal bypass improved SPP and wound healing regardless of distal anastomotic site. Patency of communicative branch of pedal arch significantly improved wound healing rate in the ATA group. It was suggested that distal anastomosis should be placed to the PTA if quality of the DPA and the PlaA was comparable and the communicative branch of the pedal arch was occluded.

Key words: Peripheral artery disease, Arterial sclerosis obliterans, Distal bypass

INTRODUCTION

Recently, the number of patients with hemodialysis has rapidly increased and exceeded 300,000 in 2010 in Japan, which is correlated to the increase in diabetes mellitus (DM). Long-term hemodialysis patients with diabetes mellitus tend to develop peripheral artery disease (PAD), which is commonly accompanied by in-

frapopliteal artery occlusion and critical limb ischemia (CLI). Orimoto et al. have reported high amputation rate (5-year limb salvage rate 53.8%) of hemodialysis patients with foot lesions¹⁾.

We have performed distal bypass as first-line option of treatment for such patients, because distal bypass is more effective than endo-

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vascular treatment (EVT) to revascularize the infrapopliteal artery. Outcomes of endovascular treatment (EVT) for infrapopliteal lesions are not sufficient and the reintervention rate is high²⁾. Distal bypass has become more important as diabetes and hemodialysis patients increase.

It is also important to reveal the better selection of targeting artery for distal bypass. "Angiosome concept" has been suggested as one of means for that. In 2006, Attinger et al. published their study looking into the clinical implications of the angiosome concept on revascularization and limb salvage. Since then, several reports have been published both supporting and not supporting the angiosome concept for distal bypass and EVT; it still remains controversial^{3)~6)}. Moreover, patients with diabetes or hemodialysis often have occluded peripheral run-off arteries and do not keep anatomical angiosomes. Thus, we need "beyond the angiosome" concept for such patients.

In 2013, Rashid et al. reported that the quality of the pedal arch was more relevant to wound healing after distal bypass than the angiosome concept⁷⁾. In addition to the patency of the distal run-off artery, selection of the distal anastomotic site is also important for the outcome of the distal bypass, but reports on this relationship are not adequate.

In this study, we investigated the effects of the patency of the run-off arteries on distal bypass in critical limb ischemia with foot lesions.

MATERIALS AND METHODS

Subjects

This retrospective study included 59 patients with 70 limbs on whom distal bypass surgery for CLI with foot ulcers was performed from January 2010 to December 2017. Patient demographics, results of noninvasive evaluation of

the ischemic limbs, and wound healing time were investigated. We classified them into 2 groups: limbs treated with distal bypass graft anastomosed to the anterior tibial artery (ATA) as the ATA group and those with distal bypass grafts anastomosed to the posterior tibial artery (PTA) as the PTA group. Targeting artery for the distal bypass was selected by the operator considering quality of the artery and its run-off artery. We also investigated patient characteristics, such as comorbidities, and outcomes of the wounds.

Pedal arch

The quality of the pedal arch in each case was evaluated by reviewing the preoperative digital subtraction angiography. Patency of distal run-off arteries was confirmed by vascular surgeons: the run-off artery of the ATA was defined as the dorsalis pedis artery (DPA) and that of the PTA was defined as the plantar artery (PlaA). Preoperatively, according to the patency of the run-off artery, they were divided to good run-off reconstruction or poor run-off reconstruction. We also assessed patency of communicative branch between the DPA and the PlaA: anatomically named deep plantar artery or deep plantar branch of dorsal artery of foot. According to patency of communicative branch, they were divided into patent arch or occluded arch.

Skin perfusion pressure (SPP) measurement

Noninvasive evaluation of microcirculation on the dorsal and plantar sides was performed using SPP before and after the procedure (within a month) by a clinical vascular technologist (T.S.) in all cases. After each patient was placed in the supine position in a comfortable room maintained at room temperature around 25°C, SPP was measured using a PAD 4000 device (KANEKA MEDICAL PRODUCT, Oosaka, Japan). A laser Doppler probe was

placed under an 8.0-cm-wide blood pressure cuff wrapped around the middle of the first and second metatarsals on the dorsal and plantar aspects of the foot, where was enough distant from the wound. The SPP value was defined as cuff pressure at which microcirculatory perfusion was first detected after cuff deflation.

Statistical analysis

Data were expressed as mean \pm standard deviation (SD) and numbers with percentages. Normality of the distribution of continuous variables was determined using the Shapiro-Wilk test and the homoscedasticity was determined using the F test. Comparisons of the data before and after the procedure were analyzed using the paired t-test for normally distributed variables and Wilcoxon signed-rank test for non-normally distributed variables, respectively. Comparisons of two independent groups were evaluated using the Student's t-test for parametric variables and Mann-Whitney U test for nonparametric variables. Categorical variables were analyzed using Fisher's exact

test. The Log-Rank test was used for survival analysis. P-values <0.05 were considered significant. EZR version 1.28 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user for R (The R Foundation for Statistical Computing, Vienna, Austria), was used for statistical analyses.

RESULTS

The mean age of the patients was 68 ± 9 years old. Sixty-two (89%) were male and 44 (63%) were hemodialysis patients. There were no significant differences in comorbidities and severity of wound between the ATA group and the PTA group. Severity of wound was represented with Rutherford and Wifl classification. All of the limbs were CLI, classified into Rutherford 5 or 6 (respectively 89%, 11%). No cases with severe infection or SIRS were included in the study. Baseline clinical characteristics of the study subjects were shown in Table 1. We analyzed 59 patients with 70 limbs treated with distal bypass surgery. Thirty-

Table 1. Patient characteristics

	Total (n=70)		ATA group (n=33)		PTA group (n=37)		p-value
Age (years)	68 \pm 9		67 \pm 8		69 \pm 9		0.855
Male	62	89%	29	88%	33	89%	0.246
Hypertension	54	77%	23	70%	31	84%	0.254
Hyperlipidemia	11	16%	5	15%	6	16%	>0.9
Diabetes mellitus	45	64%	20	61%	25	68%	0.621
Hemodialysis	44	63%	24	73%	20	54%	0.139
Ischemic heart disease	35	50%	14	42%	21	57%	0.338
Cerebral vascular disease	16	23%	11	33%	5	14%	0.085
Smoking	34	49%	16	50%	18	49%	>0.9
Rutherford	5	62	29	88%	33	89%	
Classification	6	8	4	12%	4	11%	>0.9
	1	9	7	21%	2	5%	
	2	8	2	6%	6	16%	
Wifl classification	3	31	14	42%	17	46%	
	4	22	10	30%	12	32%	0.192

ATA: anterior tibial artery, PTA: posterior tibial artery

three limbs were classified into the ATA group and 37 limbs were classified into the PTA group. In the ATA group, 21 limbs had patent DPA and 12 limbs had occluded DPA. In the PTA group, 22 limbs had patent PlaA and 15 limbs had occluded PlaA. In total, good run-off consisted of 43 limbs and poor run-off consisted of 37 limbs. We performed bypass surgery with “in situ” vein grafts in 25 limbs (36%) and “reversed” vein grafts in 37 limbs (53%). There were no significant differences in operative characteristics in both groups (Table 2).

Dorsal and plantar SPP before surgery were 23 ± 12 mmHg and 28 ± 11 mmHg respectively, and those after surgery were 52 ± 21 mmHg

and 57 ± 22 mmHg, respectively ($p < 0.001$, $p < 0.001$). In the ATA group, they were 22 ± 12 mmHg and 29 ± 11 mmHg before surgery and 55 ± 24 mmHg and 55 ± 20 mmHg after surgery, respectively ($p < 0.001$, $p < 0.001$). In the PTA group, they were 21 ± 11 mmHg and 27 ± 11 mmHg before surgery and 49 ± 17 mmHg and 59 ± 24 mmHg after surgery, respectively ($p < 0.001$, $p < 0.001$). In the ATA group with good run-off reconstruction, they were 22 ± 8 mmHg and 28 ± 11 mmHg before surgery and 59 ± 23 mmHg and 57 ± 20 mmHg after surgery, respectively ($p < 0.001$, $p < 0.001$). In the ATA group with poor run-off reconstruction, they were 28 ± 15 mmHg and 31 ± 13 mmHg be-

Table 2. Operation characteristics

		Total (n=70)		ATA group (n=33)		PTA group (n=37)		p-value
Revascularization	Good run-off	43	61%	21	64%	22	59%	0.808
	Poor run-off	37	53%	12	36%	15	41%	
Proximal anastomosis	CFA	26	37%	10	30%	16	43%	0.396
	SFA	13	19%	6	18%	7	19%	
	DFA	1	1%	1	3%	0	0%	
	PA	20	29%	9	27%	11	30%	
	Graft	10	14%	7	21%	3	8%	
Graft	In situ	25	36%	13	39%	12	32%	0.019
	Reversed	37	53%	13	39%	24	65%	
	Non-reversed	8	11%	7	21%	1	3%	
Patency rate at 1 year	Primary	40	57%	19	58%	21	57%	>0.9
	Secondary	54	77%	25	76%	29	78%	>0.9

CFA: common femoral artery, SFA: saphenous femoral artery, DFA: deep femoral artery, PA: popliteal artery

Table 3. Pre- and post-operative SPP

			Pre-operative	Post-operative	p-value
ATA group	Good run-off (n=21)	Dorsal SPP	22 ± 8	59 ± 23	<0.001
		Plantar SPP	28 ± 11	57 ± 20	<0.001
	Poor run-off (n=12)	Dorsal SPP	28 ± 15	51 ± 25	0.005
		Plantar SPP	31 ± 13	51 ± 21	0.012
PTA group	Good run-off (n=22)	Dorsal SPP	24 ± 11	54 ± 18	<0.001
		Plantar SPP	24 ± 8	53 ± 22	<0.001
	Poor run-off (n=15)	Dorsal SPP	26 ± 11	53 ± 19	<0.001
		Plantar SPP	26 ± 12	56 ± 25	0.001

SPP: skin perfusion pressure (mmHg)

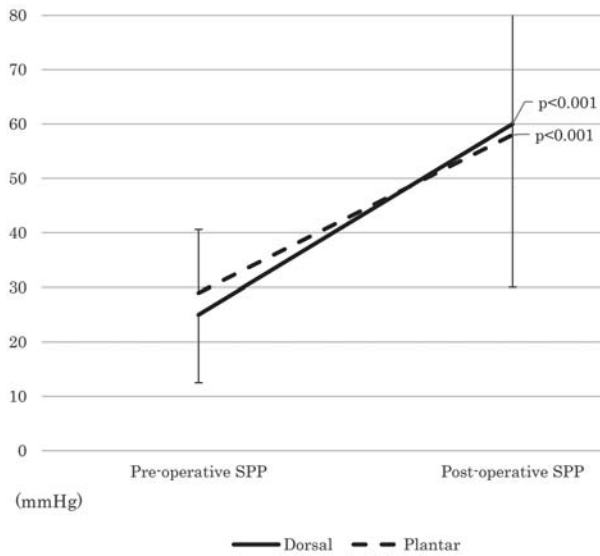


Fig. 1A. Pre- and post-operative SPP in the ATA group with good run-off. Dorsal and plantar SPP increased in the ATA group with good run-off.

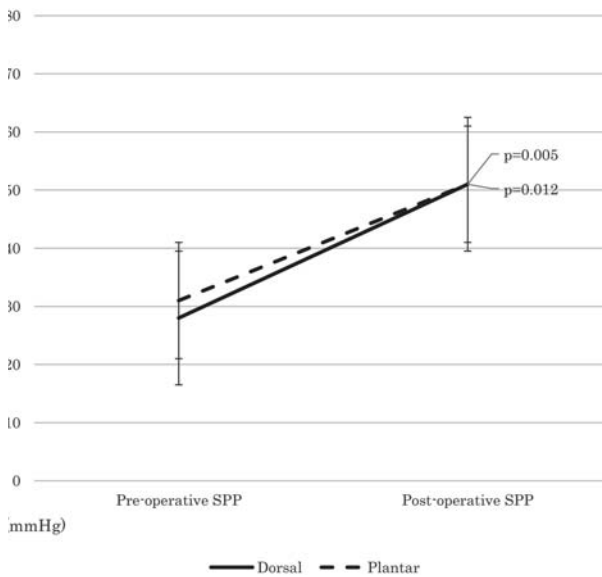


Fig. 1B. Pre- and post-operative SPP in the ATA group with poor run-off. Dorsal and plantar SPP increased in the ATA group with poor run-off.

fore surgery and 51 ± 25 mmHg and 51 ± 21 mmHg after surgery, respectively ($p=0.005$, $p=0.012$). In the PTA group with good run-off reconstruction, they were 24 ± 11 mmHg and 26 ± 8 mmHg before surgery and 54 ± 18 mmHg

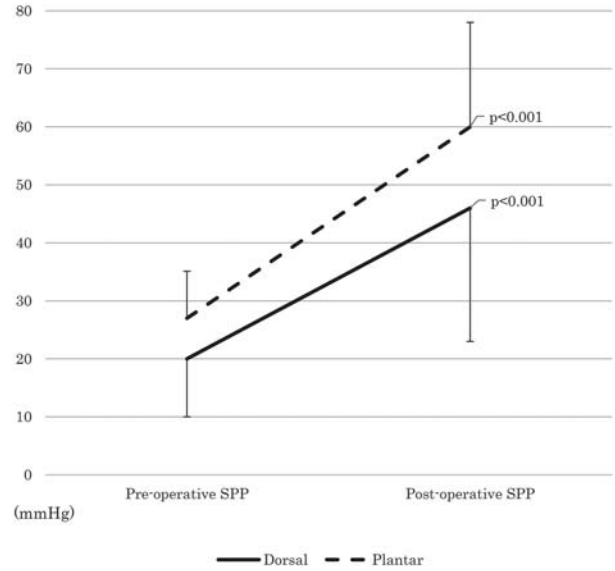


Fig. 2A. Pre- and post-operative SPP in the PTA group with good run-off. Dorsal and plantar SPP increased in the PTA group with good run-off.

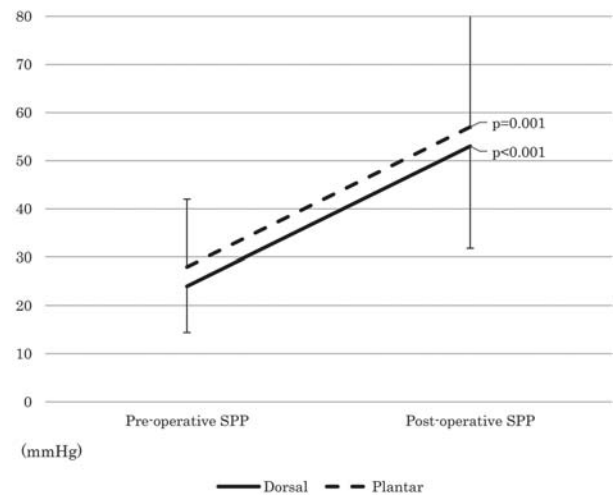


Fig. 2B. Pre- and post-operative SPP in the PTA group with poor run-off. Dorsal and plantar SPP increased in the PTA group with poor run-off.

and 53 ± 22 mmHg after surgery, respectively ($p < 0.001$, $p < 0.001$). In the PTA group with poor run-off reconstruction, they were 24 ± 11 mmHg and 26 ± 12 mmHg before surgery and 53 ± 19 mmHg and 56 ± 25 mmHg after surgery, respectively ($p < 0.001$, $p = 0.001$). (Table 3, Fig. 1A, 1B, 2A, 2B). In both the ATA group and

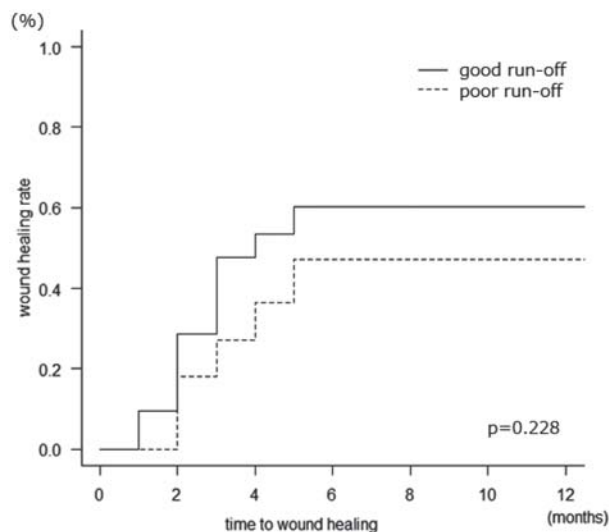


Fig. 3A. Wound healing rate in the ATA groups. Survival curves were defined as time from revascularization to wound healing. In the ATA group, there was no difference in the wound healing rate between good and poor run-off.

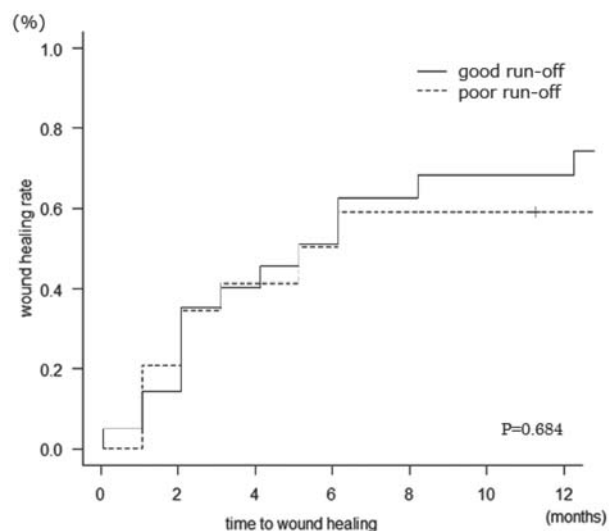


Fig. 3B. Wound healing rate in the PTA groups. In the PTA group, there was no difference in the wound healing rate between good and poor run-off.

PTA group, SPP of limbs with both good and poor run-off demonstrated significant improvement after the bypass surgery.

We also analyzed the relationship between the patency of run-off arteries and wound healing. The survival curve shown in Fig. 3A and Fig. 3B indicates that there was no significant

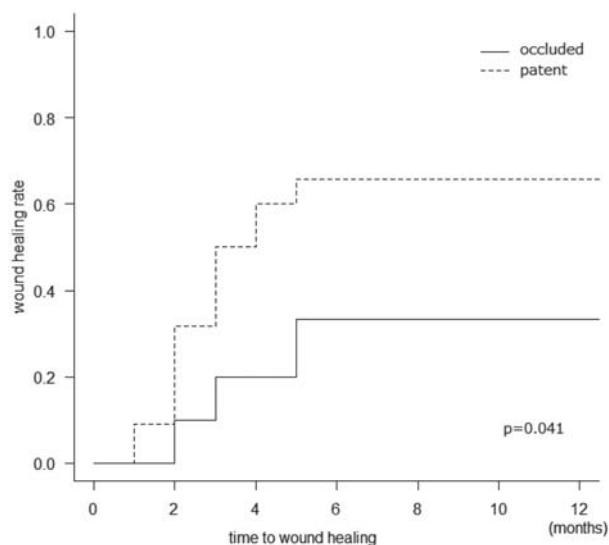


Fig. 4A. Wound healing rate depending on patency of communicative branch of pedal arch in ATA groups. In the ATA group, the wound healing rate is higher in the patent arch than in the occluded arch.

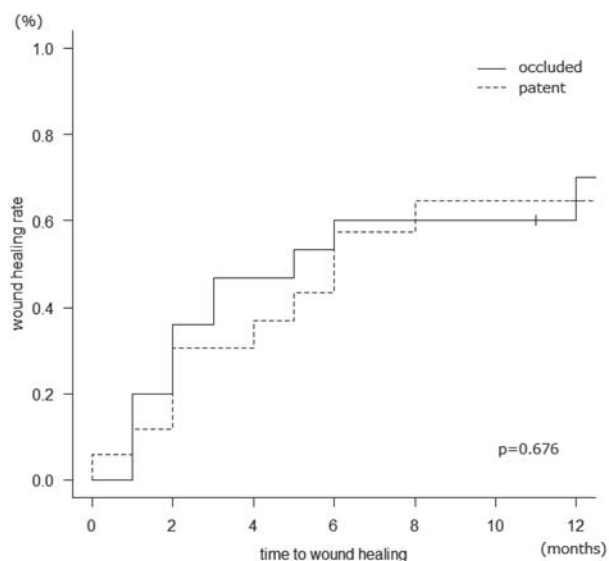


Fig. 4B. Wound healing rate depending on patency of communicative branch of pedal arch in PTA groups. In the PTA group, there was no difference in the wound healing rate between in the patent arch and in the occluded arch.

difference in wound healing between good run-off and poor run-off in the ATA group ($p=0.228$), and there was also no significant difference in that between limbs with good run-off had improved wound healing in the PTA group

($p=0.684$). We also classified the limbs with primary patency and secondary patency at a year after bypass surgery and assessed the wound healing rate in the ATA and PTA group with good run-off and poor run-off reconstruction. There was no significant difference in wound healing in relation to both primary and secondary patency at a year ($p=0.221$, $p=0.332$).

We examined the wound healing rate by stratification based on patency of communicative branch of pedal arch. There was no significant difference between patent arch and occluded arch in whole group and the PTA group. However, patent arch significantly improved the wound healing rate in the ATA group ($p=0.041$, Fig. 4A, 4B).

DISCUSSION

PAD in Japan is often accompanied by diabetes and hemodialysis in many cases, and tends to present CLI with infrapopliteal artery occlusion. In this study, more than 60% of patients exhibited diabetes and hemodialysis. Of the 57 limbs we reviewed in this study, only 4 (7.8%) pedal arches were completely patent, whereas 36 (70.6%) were partially occluded and 11 (21.6%) were completely occluded.

The concept of angiosome had been considered as a factor that contribute to the prognosis of CLI after distal bypass. The concept of angiosome was advocated in 1987 by Ivan Taylor, a plastic surgeon at Melbourne University. An angiosome is a three-dimensional anatomic unit of tissue fed by a source artery^{8)~10)}. He defined at least 40 angiosomes in the body, including six in the foot and ankle region: one fed by the ATA, two fed by the peroneal artery, and one fed by the PTA. Attinger et al. investigated the anatomy of arteries in the lower extremities using 50 cadaver dissections. There are 6 angiosomes in the foot and ankle originating from

the three main arteries that branch to the foot and ankle. The three branches of the PTA each supply distinct portions of the plantar foot. The two branches of the peroneal artery supply an anterolateral portion of the ankle and rear foot. The ATA supplies the anterior ankle, and its continuation, the dorsalis pedis artery, supplies the dorsum of the foot. Blood flow to the foot and ankle is redundant because the three major arteries feeding the foot have multiple arterial-arterial connections. They stated that detailed knowledge of the concept of angiosomes allows the vascular surgeon to choose the most effective revascularization for a given wound. In the field of EVT, Iida et al. have stated that acquiring direct flow based on the angiosome concept was important for limb salvage by EVT in patients with CLI. They analyzed patients with ischemic ulceration of Rutherford 5 or 6, who underwent EVT alone without bypass surgery. They classified these patients into a direct group or indirect group depending on whether feeding artery flow to the site of ulceration was successfully acquired or not acquired based on the angiosome concept. Then, freedom from amputation was compared between the direct group and the indirect group. SPP and the limb salvage rate were significantly higher in the direct group than in the indirect group¹¹⁾. On the other hand, Kawarada et al. demonstrated that single tibial artery revascularization, either of the ATA or the PTA, yielded comparable improvement in microcirculation (SPP) of the dorsal and plantar foot. They stated that approximately half of the feet revascularized had a change in microcirculation that was not consistent with the 2D angiosome theory¹²⁾¹³⁾. In the field of bypass surgery, Neville et al. stated that revascularization played a crucial role in the treatment of ischemic lower extremity wounds, and they be-

lieve that direct revascularization of the angiosome specific to the anatomy of the wound leads to a higher rate of healing and limb salvage. They investigated whether bypass to the artery directly feeding the ischemic angiosome had an impact on wound healing and limb salvage. In the direct revascularization group, 91% of wounds healed with a 9% amputation rate, and in the indirect revascularization group, 62% of wounds healed with a 38% amputation rate ($p=0.03$). In those wounds that did heal, total time to healing was not significantly different; direct revascularization in 162 days versus indirect revascularization in 160 days ($p=0.95$)⁶. Azuma et al. stated that the angiosome concept seemed unimportant, at least in non-end-stage renal disease cases. They demonstrated that the healing rate in the indirect revascularization group was slower than in the direct revascularization group, especially in patients with end-stage renal disease ($p<0.001$). However, the healing rates of the direct revascularization and indirect revascularization groups were similar after minimizing background differences with propensity score methods ($p=0.185$)³¹⁴. Biancari et al. reported a metaanalysis including both EVT and bypass surgeries. The risk of unhealed wound was significantly lower after direct revascularization (HR 0.64) compared with indirect revascularization. Direct revascularization was also correlated with a significantly lower risk of major amputation (HR 0.44). Pooled limb salvage rates after direct and indirect revascularization were at 86.2% vs. 77.8% at 1 year and 84.9% vs. 70.1% at 2 years, respectively. The analysis of three studies reporting only on patients with diabetes confirmed the benefits of direct revascularization in terms of limb salvage (HR 0.48). They stated that direct revascularization was better for wound healing and limb salvage than

indirect revascularization¹⁵¹⁶. Kabra et al. also reported a study including both EVT and bypass surgeries. Ulcer healing at 1, 3, and 6 months for direct revascularization vs indirect revascularization were 7.9% vs 5%, 57.6% vs 12.5%, and 96.4% vs 83.3%, respectively ($P=0.021$). The limb salvage in the direct revascularization group (84%) and indirect revascularization group (75%) was not statistically significant ($P=0.06$). They stated that direct revascularization should be considered whenever possible however indirect revascularization should not be denied as acceptable rates of limb salvage are obtained¹⁷. Thus, whether the angiosome concept is beneficial for revascularization or not remains controversial.

Pedal arch quality may contribute to the outcome of distal bypass more than the angiosome concept. Rashid et al evaluated the effects of pedal arch quality on the outcome of distal bypass surgery, adding to the angiosome concept. They reported that the wound healing and time to healing rates were directly influenced by the quality of the pedal arch rather than the revascularized angiosome. In their study, patients undergoing distal bypass for CLI were divided into three groups according to quality by angiography: complete pedal arch, incomplete pedal arch, or no pedal arch. Incomplete pedal arch was defined as either the dorsal or plantar artery being patent. Whether the dorsal or plantar artery was patent, or whether the ATA or PTA was selected as the distal anastomosis site was not taken into consideration⁷¹⁸.

In the present study, we reviewed patients with CLI treated with distal bypass surgery and divided them into groups according to the sites of the anastomosis and patency of the runoff vessels, then analyzed the relationship with change of SPP and wound healing.

The purpose of the present study was to

evaluate the influence of the run-off artery of the distal bypass on the foot hemodynamics and wound healing. We classified the limbs into the ATA group or the PTA group by selection of the peripheral anastomosis site for the distal bypass. Furthermore, we classified them as good run-off or poor run-off based on arterial patency. Then, we evaluated these groups by SPP change and wound healing rate after surgery.

SPP is an important parameter that can be measured noninvasively, and there is a strong correlation among SPP, toe pressure index, and wound healing. The feasible cut-off score is 40 mmHg (72% of sensitivity and 88% of specificity), as Yamada et al. reported¹⁹. In this study, the average SPP values before operation in the ATA and the PTA groups were below 40 mmHg and were significantly elevated over 40 mmHg after operation regardless of the peripheral anastomosis or run-off artery patency.

Comparison of post-operative SPP with good run-off or poor run-off revealed that there was no significant difference in dorsal and plantar SPP in both the ATA and PTA groups. Similarly, there was no significant difference in increment of dorsal and plantar SPP in both the ATA and PTA groups. This result is consistent with Kawarada's previous reports that single tibial artery revascularization yielded comparable improvement in microcirculation (SPP) of the dorsal and plantar foot.

Analysis of the wound healing rate demonstrated that there was no significant difference between the wound healing rate with good run-off or poor run-off in the ATA group, and similarly that there was no significant difference between those with good run-off or poor run-off in the PTA group. This result indicates that poor run-off reconstruction contributed to the wound healing as well as good run-off re-

construction did.

Patency of communicative branch of pedal arch did not affect wound healing rate in the whole group analysis. However, it was revealed that that did affect wound healing rate in a subgroup. In the ATA group, wound healing rate was higher in the limbs with patent communicative branch of pedal arch than in those with occluded. On the other hand, in the PTA group, there was no significant difference in wound healing rate between patent and occluded, which was similar to that of patent in the ATA group. This result suggests that wound healing rate particularly decreased in limbs with occluded communicative branch of pedal arch in the ATA group. From this result, it may be disadvantageous to make distal anastomosis on ATA in cases the collateral circulation including the pedal arch is poor. The reason for this is that amount of soft tissue, including muscles for collateral circulation, is more abundant around the PTA than around the ATA.

The present results showed that distal bypass surgery improved SPP adequately regardless of patency of run-off artery and that there was no significant difference in wound healing rate between good run-off reconstruction and poor run-off reconstruction. Based on the results of this study, the selection of distal anastomotic site does not affect outcome of distal bypass. Vascular surgeon can select distal anastomotic site by quality of vessel. In case with occluded communicative branch of pedal arch, revascularization to the ATA decrease wound healing rate. On the other hand, revascularization to the PTA result in better wound healing rate regardless if the communicative branch was patent or occluded. It should be mentioned that revascularization to the PTA was superior to that to the ATA regardless of

quality of pedal arch.

One of the limitations of this study is the small number of the cases, which may have affected the results of the SPP improvements and wound healing rate. Another is the nonrandomized selection of the distal anastomotic site of the graft. Further investigation is desirable.

CONCLUSION

Distal bypass demonstrated greater SPP increase and improved wound healing regardless of distal anastomotic site. Patent communicative branch of pedal arch significantly improved wound healing rate in the ATA group. It was suggested that distal anastomosis should be placed to the PTA if quality of the DPA and the PlaA is comparable and the communicative branch of the pedal arch is occluded.

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