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Original Article

Utility of a Finger-Mounted Tissue Oximeter with Near-Infrared Spectroscopy to Evaluate Limb Ischemia in Patients with Peripheral Arterial Disease

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Objective: To investigate whether a finger-mounted tissue oximeter is useful in evaluating limb blood flow in patients with peripheral arterial disease (PAD).

Materials and Methods: Seventy-two patients with PAD were included, and the ankle-brachial index (ABI), transcutaneous oxygen pressure ($TcPO_2$), and skin perfusion pressure (SPP) were measured. The regional tissue oxygenation saturation (rSO_2) was measured using a finger-mounted tissue oximeter at the ankle, dorsal foot, and each dorsal and plantar toe. Correlations between rSO_2 and ABI and between $TcPO_2$ and SPP were analyzed. The patients were divided into three groups: Fontaine IIa (F-IIa), IIb (F-IIb), and III and IV (F-III/IV) groups. The difference in rSO_2 between each group was analyzed.

Results: Significant correlations were observed between rSO_2 and $TcPO_2$ and between rSO_2 and SPP. $TcPO_2$ and SPP in the F-III/IV group were significantly lower than those in the F-IIa group. rSO_2 in the F-IIb and F-III/IV groups was significantly lower than that in the F-IIa group.

Conclusion: The measurement of rSO_2 using finger-mounted tissue oximetry is quick, simple, and painless. It can be used on any skin area and is useful to evaluate limb circulation in patients with PAD.

Keywords: limb blood flow, near-infrared spectroscopy, peripheral arterial disease, regional hemoglobin oxygen saturation

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Introduction

The prevalence of peripheral arterial disease (PAD) has been reported to be in the range of 3–10%, increasing to 15–20% in persons over 70 years, and 0.1% of the population develops new cases of critical limb ischemia (CLI) every year in Europe and North America.[1–3] In Japan, the prevalence of PAD has been reported to range from 1–3%,[4–6] and the incidence is increasing. Clinical symptoms of PAD progress from intermittent claudication, rest pain, and skin ulcers to gangrene of the limbs. CLI, which is defined by the presence of rest pain, skin ulcers, or gangrene, is the most severe stage of PAD and is associated with high rates of mortality and amputation.[1] Evaluating limb blood flow in the management of patients with PAD is essential. Several traditional diagnostic modalities, such as the measurement of the ankle-brachial index (ABI),[1] skin perfusion pressure (SPP),[7] and transcutaneous oxygen pressure ($TcPO_2$),[8,9] have been developed to evaluate limb blood flow and are widely accepted.[2,3,8] However, these methods have some limitations.[8] ABI measurement is painful and is limited to the area above the ankle; it is

also unreliable for incompressible calcified vessels.[8] SPP measurement, which is performed with a laser Doppler and pressure cuff, has been developed to evaluate more areas in the peripheral limbs.[7] However, patients often experience intolerable pain caused by the cuff pressure. $TcPO_2$ measurement requires 15 min to warm the sensor's electrode, a flat skin surface for the placement of sensors, and a steady, stable position.[9] Therefore, using traditional diagnostic modalities in patients with CLI who have rest pain or skin ulcers is difficult. Hence, the development of a new method, which can be used on any skin area and is quick, simple, precise, and painless, is essential.

Near-infrared spectroscopy (NIRS) is a simple, painless, and complication-free technique to evaluate tissue oxygenation.[10,11] However, NIRS is not reliable in evaluating limb blood flow and is not recommended for the management of PAD, as per the present guidelines.[2,3,8] Improvement of the NIRS device is required to evaluate limb blood flow. Recently, a finger-mounted tissue oximeter using the NIRS technique (Toccare: Astem Co., Ltd., Kawasaki, Japan) was developed. This device measures the regional tissue oxygenation saturation (rSO_2) using a spatially resolved NIRS technique, and animal studies using mice have shown a correlation between the rSO_2 in the craniofacial site and the blood pH or inspired oxygen fraction.[11] Moreover, this device was reported to be useful to evaluate the condition of a fetus transvaginally and the condition of infants by measuring rSO_2 at the scalp.[12,13] This study aimed to investigate, for the first time, whether a finger-mounted tissue oximeter is useful in evaluating limb blood flow in patients with PAD.

Materials and Methods

Study approval

Informed consent was obtained from all participants. This study was approved by the Ethical Committee of Hamamatsu University School of Medicine (approval number: 16-057). The study protocol was registered at the UMIN Clinical Trials Registry (UMIN-CTR; ID: UMIN000025021).

Participants

This was a single-center observational study. Between July 2016 and July 2018, a total of 72 consecutive patients with PAD (mean age 73.8 ± 8.9 years; men = 53, women = 19) who were treated at the outpatient vascular surgery clinic at the University Hospital of Hamamatsu University School of Medicine were included in this study. **Table 1** shows the patients' characteristics. The diagnosis of PAD was defined as an ABI < 0.9. Data on each patient's demographics, clinical symptoms, comorbid conditions, and vascular risk factors (Fontaine classification,[14] age, sex, body mass index, smoking history, hypertension, hyperlipidemia, diabetes mellitus, coronary artery disease, cerebrovascular disease, and hemodialysis) were recorded. The definition of each condition was as follows: smoking history (either current or in the past) was present; hypertension was defined as the use of medications for hypertension or a systolic blood pressure > 140 mmHg and/or a diastolic blood pressure > 90 mmHg; hyperlipidemia was defined as the use of medications for hyperlipidemia or a total serum cholesterol concentration > 220 mg/dL; diabetes mellitus was defined as the present or past use of medication for diabetes; coronary artery disease was defined as the present use of medication, past percutaneous coronary intervention, or coronary artery bypass grafting history; and cerebrovascular disease was defined as a history of stroke, transient ischemic attacks, or hemodialysis treatment.

Evaluation of limb blood flow using traditional diagnostic modalities

ABI, $TcPO_2$, SPP, and rSO_2 values were measured in both

Table 1 Baseline characteristics of patients with peripheral arterial disease

	Fontaine classification				
	IIa (n=19)	IIb (n=12)	III (n=10)	IV (n=31)	P value
Age (mean±SD; years)	74.1±6.4	73.9±6.2	77.3±12.4	73.8±8.9	N.S
Male sex	16 (84)	7 (58)	7 (70)	23 (74)	N.S
Body mass index (mean±SD)	22.9±2.5	20.5±3.0	21.1±4.0	21.1±3.5	N.S
Smoking (%)	14 (74)	8 (67)	6 (60)	20 (65)	N.S
Hypertension (%)	18 (95)	8 (67)	8 (80)	25 (81)	N.S
Hyperlipidemia (%)	8 (42)	5 (42)	6 (60)	15 (48)	N.S
Diabetes mellitus (%)	14 (74)	6 (50)	5 (50)	21 (68)	N.S
Coronary artery disease (%)	6 (32)	6 (50)	3 (30)	16 (52)	N.S
Cerebrovascular disease (%)	3 (16)	2 (17)	4 (40)	4 (13)	N.S
Hemodialysis (%)	2 (11)	2 (17)	4 (40)	21 (68)	< 0.001

SD: standard deviation; N.S: not significant

limbs of participants at their first admission. All procedures and measurements were performed in the supine position. The temperature of the laboratory was maintained at 25°C. As in the procedure reported previously, systolic blood pressures in the brachial and posterior tibial arteries were measured using an 8-MHz Doppler probe (BP-203, Omron, Kyoto, Japan), and the ABI was calculated. The $TcPO_2$ at the ankle and dorsal foot was measured using a transcutaneous monitor (TCM 4 series, Radiometer, Copenhagen, Denmark), according to the procedure reported previously.[15] The SPP at the ankle and dorsal foot was measured using a SPP system (SensiLase PAD 3000, Vasamed Eden Prairie, MN, USA).[7]

Near-infrared spectroscopy technique

A finger-mounted tissue oximeter (Toccare)[11–13] (**Fig. 1A**) was used to measure the rSO_2 at the ankle and dorsal foot in both limbs of patients with PAD. This tissue oximeter probe consists of near-infrared light-emitting diodes (LEDs) and detector photodiodes (**Fig. 1A**). The detector photodiodes are located 6 and 8 mm away from the LEDs. This device was set to measure the rSO_2, up to a depth of 0–5 mm from the oximeter probe.[13] The rSO_2 was calculated as the oxyhemoglobin level divided by a combination of oxyhemoglobin and deoxyhemoglobin levels.[12] The obtained rSO_2 values were saved automatically to a micro SD card. The advantages of this device include the light weight of the module (0.1 kg), its mobility, and the short sampling time (0.5 s). At this time, the cost of this device is approximately JPY 400,000.

Comparison between the groups of patients with PAD

Patients were divided into four groups according to the Fontaine classification: Fontaine IIa group (F-IIa), Fontaine IIb group (F-IIb), Fontaine III group (F-III), and Fontaine IV group (F-IV). F-IIa and F-IIb were defined as those with claudication symptoms after >200 m and <200 m of walking, respectively. Patients classified as F-IIa or F-IIb were assigned to the claudication group, and patients classified as Fontaine III or IV were assigned to the CLI group. In the affected limbs of patients with PAD, the rSO_2 was also measured at each dorsal and plantar toe (**Fig. 1B**), which was difficult to measure when using traditional diagnostic modalities. ABI, $TcPO_2$, SPP, and rSO_2 values at each area were measured in the affected limbs and expressed as medians and interquartile ranges. These values were compared between the claudication group (i.e., F-IIa/IIb) and the CLI group (i.e., F-III/IV), and among the three groups (F-IIa, IIb, and III/IV).

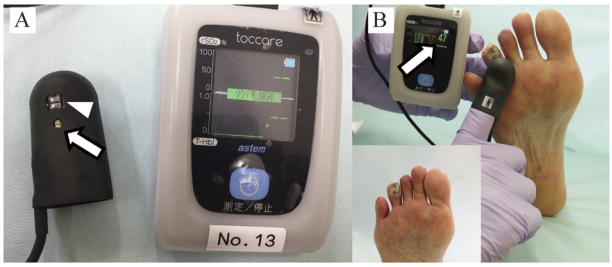

Fig. 1 Measurement of the regional hemoglobin oxygen saturation (rSO_2) using a finger-mounted tissue oximeter.
(**A**) A finger-mounted tissue oximeter using the near-infrared spectroscopy technique (white arrow: optical source; arrow head: optical detector). (**B**) rSO_2 measurement at the dorsal side of the fourth toe near the ulcer (white arrow: rSO_2 value).

Statistical analysis

Scatter plots comparing the rSO_2 values and those of ABI, $TcPO_2$, or SPP in both limbs were generated. The correlations between these values were analyzed using the nonparametric Spearman rank correlation test, and positive correlations were classified as poor, r = 0–0.2; weak, r = 0.2–0.4; moderate, r = 0.4–0.7; or strong, r = 0.7–1.0. A significant correlation was defined as $P<0.05$.

The characteristics of each group of patients with PAD were analyzed using the χ^2 test. ABI, $TcPO_2$, SPP, and rSO_2 values in patients with PAD were expressed as medians. The differences in these values between the claudication group (i.e., F-IIa/IIb) and the CLI group (i.e., F-III/IV) were assessed with Mann–Whitney U tests, and the differences in these values among the three groups (F-IIa, IIb, and III/IV) were compared using the Kruskal–Wallis test with the Bonferroni–Dunn post hoc analysis because the assumption of homogeneity of variance was violated. A P value <0.05 was considered statistically significant. All analyses were performed using IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA).

Results

Examination of limb blood flow using each evaluation modality

Six limbs of patients with PAD had already been amputated at the first admission. Therefore, the ABI, $TcPO_2$, SPP, and rSO_2 were measured in 138 limbs. However, measuring the ABI in 11 limbs (nine PAD limbs, two non-PAD limbs) was impossible because of intolerable pain with cuff pressure during the measurement. Moreover, at the ankle, measuring $TcPO_2$ in four limbs (all limbs with PAD) and SPP in 13 limbs (all limbs with PAD) was impossible owing to involuntary movements, pain, difficulty in maintaining a stable position, and intolerable pain with cuff pressure. At the dorsal foot, $TcPO_2$ could be measured in all limbs; however, it was impossible to measure SPP in 13 limbs (all limbs with PAD) owing to involuntary move-

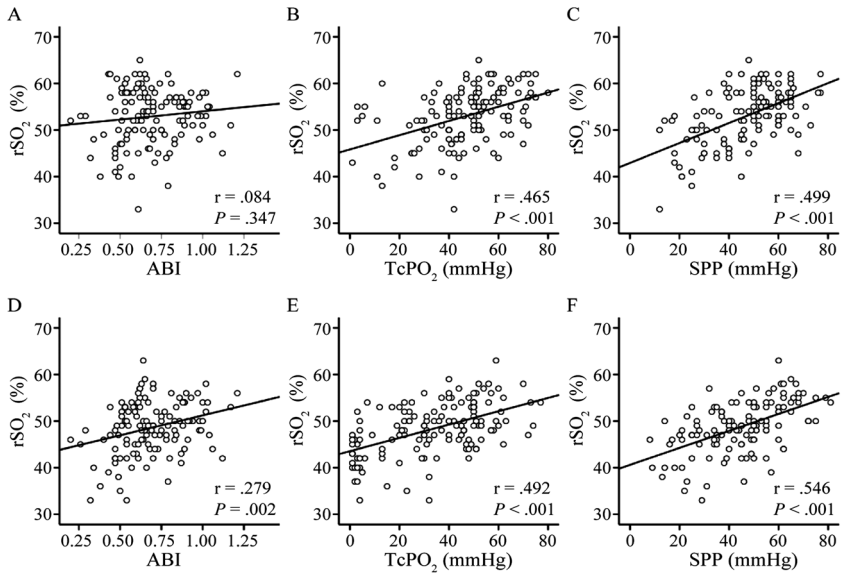

Fig. 2 Relationship between the regional hemoglobin oxygen saturation (rSO_2) and the value of traditional diagnostic modalities at the ankle and dorsal foot.
Scatter plots of the values of (**A**) the ankle-brachial index (ABI) and rSO_2 at the ankle (n=127) (P=0.347, r=0.084), (**B**) transcutaneous oxygen pressure ($TcPO_2$) and rSO_2 at the ankle (n=134) (P<0.001, r=0.465), (**C**) skin perfusion pressure (SPP) and rSO_2 at the ankle (n=125) (P<0.001, r=0.499), (**D**) ABI and rSO_2 at the dorsal foot (n=127) (P=0.002, r=0.279), (**E**) $TcPO_2$ and rSO_2 at the dorsal foot (n=138) (P<0.001, r=0.492), and (**F**) SPP and rSO_2 at the dorsal foot (n=125) (P<0.001, r=0.546) (Spearman's test).

ments and intolerable pain with cuff pressure. In contrast, the rSO_2 could be measured in all limbs at both the ankle and dorsal foot. Therefore, the examination success rate was 92.0% (127 limbs) for the ABI, 97.1% (134 limbs) for $TcPO_2$ at the ankle, 100% (138 limbs) for $TcPO_2$ at the dorsal foot, 90.6% (125 limbs) for SPP at the ankle, 90.6% (125 limbs) for SPP at the dorsal foot, and 100% (138 limbs) for rSO_2 at both the ankle and dorsal foot.

Relationships between rSO_2 and traditional diagnostic modalities

Figure 2 shows the relationships between the rSO_2 values and the traditional diagnostic modalities (measurement of the ABI, $TcPO_2$, and SPP): rSO_2 at the ankle and ABI (n=127, P=0.347, r=0.084, **Fig. 2A**), rSO_2 and $TcPO_2$ at the ankle (n=134, P<0.001, r=0.465, **Fig. 2B**), rSO_2 and SPP at the ankle (n=125, P<0.001, r=0.499, **Fig. 2C**), rSO_2 at the dorsal foot and ABI (n=127, P=0.002, r=0.279, **Fig. 2D**), rSO_2 and $TcPO_2$ at the dorsal foot (n=138, P<0.001, r=0.492, **Fig. 2E**), and rSO_2 and SPP at the dorsal foot (n=125, P<0.001, r=0.546, **Fig. 2F**). With regard to the relationship between rSO_2 and ABI, neither ankle nor dorsal rSO_2 correlated significantly with the ABI. Significant positive correlations were found between rSO_2 and $TcPO_2$ and between rSO_2 and SPP at the ankle and dorsal foot.

Comparison between the groups of patients with PAD

The 72 patients were divided into four groups: 19 in the F-IIa group, 12 in the F-IIb group, 10 in the F-III group, and 31 in the F-IV group (**Table 1**). Therefore, 31 patients were categorized into the claudication group (i.e., F-IIa/IIb) and 41 patients into the CLI group (i.e., F-III/IV). The ABI and $TcPO_2$ at the ankle and dorsal foot, SPP at the ankle and dorsal foot, and rSO_2 at the ankle, dorsal foot, and each dorsal and plantar toe were measured in 72 limbs with PAD. However, the ABI, $TcPO_2$, and SPP were impossible to measure in all patients because of intolerable pain, difficulty to maintain a stable position, and involuntary movements. Therefore, the ABI was measured in 66 limbs with PAD, $TcPO_2$ at the ankle in 70 limbs, $TcPO_2$ at the dorsal foot in 72 limbs, SPP at the ankle in 66 limbs, and SPP at the dorsal foot in 65 limbs. rSO_2 at the ankle and dorsal foot were measured in all patients with PAD. There was no significant difference in the ABI value between the claudication and CLI groups or among the groups of patients with PAD (**Fig. 3A**). However, significant differences were observed between the $TcPO_2$, SPP, and rSO_2 values at the ankle and dorsal foot between the claudication and CLI groups. Moreover, significant differences were also observed between the F-IIa and F-III/IV groups in the $TcPO_2$ values at the ankle and dorsal foot (ankle,

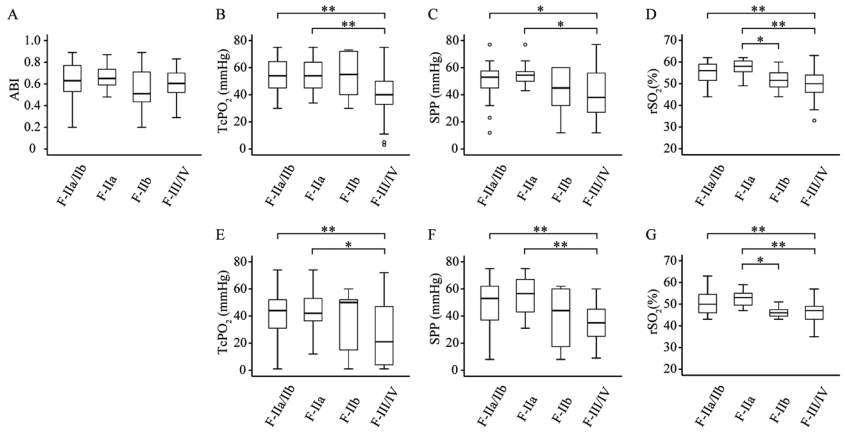

Fig. 3 Comparison of traditional diagnostic values and the regional hemoglobin oxygen saturation (rSO_2) among each group of patients with peripheral arterial disease.
The median and interquartile range (IQR) of the diagnostic values of the ankle-brachial index (ABI) (**A**) (P=0.209), transcutaneous oxygen pressure ($TcPO_2$) at the ankle (**B**) (P=0.003), skin perfusion pressure (SPP) at the ankle (**C**) (P=0.016), rSO_2 at the ankle (**D**) (P<0.001), $TcPO_2$ at the dorsal foot (**E**) (P=0.011), SPP at the dorsal foot (P=0.001) (**F**), and rSO_2 at the dorsal foot (**G**) (P<0.001) in each group (*P<0.05, ** P<0.01).

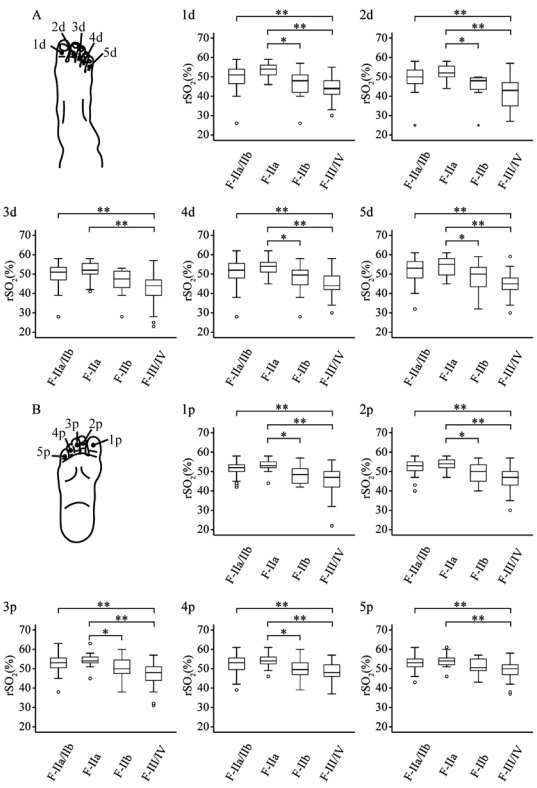

Fig. 4 Comparison of the regional hemoglobin oxygen saturation (rSO_2) among each group of patients with peripheral arterial disease.
Left figures represent the measurement skin area (**A**, 1d–5d: 1st–5th dorsal toe) (**B**, 1p–5p: 1st–5th plantar toe). The median and interquartile range of the rSO_2 in each measurement skin area are shown (*P<0.05, ** P<0.01).

P = 0.005; dorsal foot, P = 0.013) (**Figs. 3B** and **3E**). Significant differences were also observed between the F-IIa and F-III/IV groups in the SPP values at the ankle and dorsal foot (ankle, P = 0.013; dorsal foot, P < 0.001) (**Figs. 3C** and **3F**). However, neither $TcPO_2$ nor SPP showed significant differences between the F-IIa and F-IIb groups at either the ankle or the dorsal foot. In contrast, the rSO_2 showed significant differences at the ankle and the dorsal foot between the F-IIa and F-IIb groups (ankle, P = 0.038; dorsal foot, P = 0.001). The rSO_2 also showed significant differences between the F-IIa and F-III/IV groups (ankle, P < 0.001; dorsal foot, P < 0.001) (**Figs. 3D** and **3G**).

The rSO_2 at each dorsal and plantar toe was measured easily in all participants in less than one second. rSO_2 measurements in the first toes of three patients, the second toes of one patient, the third toes of two patients, the fourth toes of four patients, and the fifth toes of two patients were impossible because of necrosis. The rSO_2 was measured in all toes, even those with ulcers, but not in those with necrosis. Significant differences between the claudication and CLI groups were observed in the rSO_2 values at all dorsal and plantar toes. Moreover, significant differences were observed between the F-IIa and F-IIb groups in the rSO_2 values at the dorsal and plantar toes (dorsal first toe, P = 0.025; dorsal second toe, P = 0.044; dorsal fourth toe, P = 0.035; dorsal fifth toe, P = 0.041; plantar first toe, P = 0.026; plantar second toe, P = 0.042; plantar third toe, P = 0.037, plantar fourth toe, P = 0.024) and the F-IIa and F-III/IV groups (all skin areas, P < 0.001) (**Fig. 4**).

Discussion

We showed the usefulness of a new finger-mounted tissue oximeter using the NIRS technique to evaluate limb ischemia. The use of traditional diagnostic modalities, such as the measurement of the ABI, SPP, and $TcPO_2$, was limited because of the long measurement time, pain during measurement, skin lesions, or maintaining a posture during the measurement. In our study, measuring the ABI or SPP was impossible in about 10% of the cases because of intolerable cuff pressure pain during measurement, and measuring the $TcPO_2$ at the ankle was impossible in about 3% of the cases because patients with PAD have difficulty maintaining a stable position. On the contrary, measuring the rSO_2 using the finger-mounted tissue oximeter was successful in all ischemic limbs. Even in patients with rest pain or skin ulcers, the rSO_2 could be measured quickly, simply, painlessly, and repeatedly at the bedside and on any skin area.

NIRS was developed in the 1980s and was used mostly to assess cerebral circulation.[16] Cheatle et al. first reported decreased oxygen consumption in patients with PAD using the NIRS technique,[17] and the usefulness of NIRS devices for the evaluation of patients with PAD was reported.[10,16,18,19] Previous NIRS devices, which were developed to assess adult cerebral circulation, were set to measure the rSO_2 1–3 cm deep from the oximeter probe and to evaluate mainly the skeletal muscle oxygenation in the lower limbs.[19–21] Evaluating skin oxygenation at the toe is important for the management of patients with CLI who tend to develop toe ulcers. However, previous NIRS devices were not appropriate for the evaluation of toe skin oxygenation because the NIRS measurement depth was too great for the toe.

The rSO_2 measured by previous NIRS devices was not recommended for the management of PAD based on the guidelines,[2,3,7,8] because the correlation between rSO_2 values using previous NIRS devices and the ABI was reported to be poor[22] and was not even compared with $TcPO_2$ or SPP, which represents skin perfusion. Because of the measurement depth of the previous NIRS devices, the rate of oxygen resaturation or recovery time after exercise was considered to be a proper parameter for NIRS devices to evaluate claudicants,[10,16] and these parameters correlated mostly with the ABI.[16,18,20,21] These reports suggested that previous NIRS devices were useful for the evaluation of muscle oxygenation after exercise in patients with PAD and claudication,[23] but not for that of skin oxygenation. Thus, they have not been clinically applied to patients with CLI to evaluate skin perfusion. In contrast, the finger-mounted tissue oximeter used in this study, which was originally manufactured to measure the rSO_2 through the fetal scalp, is set to measure the rSO_2 5 mm deep from the probe.[11–13] Therefore, this NIRS device can evaluate skin and subcutaneous tissue oxygenation at rest. As a result, the rSO_2 measured with the device correlated significantly with data obtained with other conventional devices, such as $TcPO_2$ and SPP. These results suggest that the rSO_2 measured with the device is reliable to assess skin perfusion.

Measuring skin perfusion at each dorsal or plantar toe using conventional diagnostic modalities, such as measuring $TcPO_2$, SPP, or previous NIRS devices, has not been applied routinely for two reasons. First, conventional device probes were not manufactured to be attached to these skin areas, but to be placed on the thigh, calf, or dorsal foot; second, the depth of the NIRS in previous devices was 1–3 cm deep. Thus, the skin/subcutaneous tissue of the toe might be too thin to measure because bones or tendons are present at that depth. In this study, the finger-mounted tissue oximeter enabled the measurement of the rSO_2 at any skin area including ulcer regions without necrosis. Significant differences in rSO_2 values between the groups of patients with PAD were observed at any skin area in our study. The rSO_2 value was measured precisely at the toe where skin perfusion was difficult to measure using previous modalities.

Evaluating limb blood flow is essential to determine indications for revascularization,[1] which is highly recommended for patients with CLI who have rest pain, ulcers, and/or necrosis (F-III/IV).[24] In this study, we divided patients with claudication into the two subgroups of F-IIa and F-IIb. According to the literature, 80% of patients with claudication are stable for five years after the start of symptoms; however, the remaining 20% of patients advance to CLI, in which the F-IIb patients are more likely to develop CLI than F-IIa.[1] Other literature also recommended revascularization of patients with PAD and severe claudication.[24–26] Therefore, it is meaningful to differentiate between F-IIb and F-IIa patients not only from patient interviews about walking distances but also from objective values of the limb perfusion status. Unfortunately, previous measures, such as $TcPO_2$ and SPP as well as previous NIRS devices, failed to show the differences between the two groups. Furthermore, for patients with diabetes with/without dialysis, assessing the perfusion status at the more peripheral regions, such as the toes, is rather important. The NIRS device in this study enabled this assessment to be performed with ease for the first time and succeeded in differentiating between the two groups.

The measurement of $TcPO_2$ or SPP is useful for the management of PAD. Normal $TcPO_2$ levels are approximately 60 mmHg, while levels of 20 mmHg or less strongly suggest that revascularization will be required to achieve healing. Normal SPP levels of 50–70 mmHg are decreased to 10–20 mmHg in limbs with severe ischemia.[8,15] In this

study, rSO_2 levels of 45% at the ankle or dorsal foot were almost equivalent to the above-mentioned critical levels of $TcPO_2$ or SPP according to the scatter plots and linear formula. However, further studies are needed to determine the cut-off values of rSO_2 for wound healing.

This study had some limitations. First, the sample size was small, especially patients with mild PAD without CLI (F-IIa and F-IIb groups). Second, the relationship between wound healing and the rSO_2 value was not clarified in this study, and the cut-off value for wound healing could not be decided. Third, although rSO_2 values are considered to be influenced by skin pigmentation, we performed NIRS oximetry only in Japanese subjects; consequently, the data are representative of only Japanese patients.[27]

This device was originally developed to evaluate fetal brain blood flow; therefore, it is set to measure the rSO_2 5 mm deep from the probe.[13] It is unclear whether this depth is also optimal for the evaluation of lower limb blood flow of patients with PAD. Further studies are needed to determine the cut-off rSO_2 values for wound healing in patients with CLI using this device.

Conclusion

The use of a finger-mounted tissue oximeter enables the measurement of rSO_2 values in any skin area quickly, simply, precisely, and painlessly at the bedside. The rSO_2 value is correlated with the value of traditional diagnostic modalities and is significantly decreased in limbs with severe PAD. We showed the usefulness and reliability of the finger-mounted tissue oximeter to evaluate limb ischemia. This new device may be useful in determining therapeutic strategies for patients with PAD and may become one of the most useful devices to evaluate tissue oxygenation in patients with PAD.

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Disclosure Statement

All authors declare that no competing interests exist.

Author Contributions

Study conception: TY, MS, KI, NU
Data collection: TY, TK, EN, KK, YY, NU
Analysis: TY, MS, NU
Investigation: TY, MS, NY, KI, TS
Writing: TY, MS, NU
Funding acquisition: NU
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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