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Breast

NIRO200NX: Reliable Monitoring System for Buried Deep Inferior Epigastric Perforator Flap

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Background: The deep inferior epigastric perforator (DIEP) flap is a useful tool for breast reconstruction and tends to be transferred into the breast envelope as the buried flap from an aesthetic point of view. However, it is difficult to monitor the blood flow in the buried DIEP flap after reconstructive microsurgery. Near-infrared spectroscopy devices have recently been used for monitoring the blood flow of various organs. NIRO200NX (Hamamatsu Photonics) continuously measures the tissue oxygen index (TOI) and quickly reflects changes in flap blood flow. In this study, we investigated whether and how much the NIRO200NX applies to monitoring the blood flow of the buried flap.

Methods: We included 156 patients who underwent breast reconstruction using a DIEP flap from October 2013 to May 2022, comprising 57 exposed and 99 buried-type DIEP flap cases. We measured TOI using NIRO200NX, in combination with conventional evaluation methods, including color check, pinprick test, and Doppler sound.

Results: A criterion of TOI 50 gave the best evaluations. All the 57 exposed-type flap cases showed no false evaluations, and NIRO200NX performed precise judgment. In 99 buried-type flap cases, NIRO200NX correctly evaluated 96 cases. For those buried-type cases, we found only two false-positive and one false-negative case. The misjudgments by NIRO200NX were likely caused by hematoma.

Conclusion: We propose NIRO200NX as a reliable device for monitoring the blood flow of the DIEP flap and predicting the outcomes of breast reconstruction by the DIEP flap transfer. *(Plast Reconstr Surg Glob Open 2024; 12:e6096; doi: 10.1097/GOX.0000000000006096; Published online 26 August 2024.)*

INTRODUCTION

Breast cancer is the most common type of cancer in women worldwide.[1,2] After a mastectomy, reconstructive surgery using autologous tissue can significantly improve patients' quality of life. The majority of patients who opt for autologous breast reconstruction undergo a so-called deep inferior epigastric artery perforator (DIEP) flap reconstruction.[3,4] Breast reconstruction using a free DIEP flap is a common surgery to transfer abdominal skin and subcutaneous fat onto the reconstructed area, and there are two types: exposed type and buried type (Fig. 1). In the exposed type, the abdominal skin is transplanted onto the resected region (Fig. 1A). In the buried type, the breast envelope is preserved (Fig. 1B). The DIEP flap is immediately implanted after mastectomy below the breast envelope with nipple (nipple-sparing mastectomy) or without nipple (skin-sparing mastectomy). Alternatively, the breast envelope is expanded using an expander, and later, a DIEP flap is implanted under the breast envelope (Fig. 1B). To date, patients tend to prefer the buried type from an aesthetic point of view.[5,6] However, it is difficult to monitor the blood flow in the buried DIEP flap after reconstructive microsurgery.[7–10]

The DIEP flap is based on a direct cutaneous perforator of the deep inferior epigastric artery and vein. Although free DIEP flap transfer has become popular in breast reconstruction,[3,4] there are a few cases in which the flap fails to survive and becomes necrotic.[11–13] This failure is likely due to postoperative thrombosis, and its early detection is the key to flap salvage. Early detection of impaired blood flow and reoperation is critical for the successful recovery of the DIEP flap.

Although typical methods for postoperative monitoring of the free flap are observation of the color of the skin flap, pinprick test, and monitoring the Doppler blood flow

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sounds, they are performed intermittently, and the evaluations remain subjective, even by experienced doctors and nurses.[14] As an optional objective method, measurements of blood sugar levels and carbon dioxide levels are used,[15–18] and they remain intermittent, and the skin flap must be exposed. For the buried type, those monitoring methods need a small portion of the flap exposed as a monitoring flap for observation, sampling, and evaluation.

Near-infrared spectroscopy (NIRS) devices have recently been used for monitoring the blood flow of various organs as a continuous and noninvasive method. Some NIRS devices can monitor the regions with a depth of 2–3 cm and are used in the neurosurgery field.[19–21] Among these NIRS devices, NIRO200NX [Hamamatsu Photonics; hereafter, NIRO (Fig. 2)], continuously measures the tissue oxygen index (TOI) and quickly reflects changes in flap blood flow.[22–24] In this study, we investigated whether and how much the NIRO device applies to monitoring the blood flow of the buried DIEP flap.

Takeaways

Question: Is NIRO200NX (NIRO), one of the near-infrared spectroscopy devices, applicable to monitoring the blood flow of the buried deep inferior epigastric perforator (DIEP) flap?

Findings: We measured tissue oxygen index (TOI) using NIRO in 57 exposed and 99 buried-type DIEP flap cases. When we set a criterion of TOI 50, NIRO detected thrombosis in all the exposed-type flaps precisely. Of the 99 buried-type flaps, it detected 96 cases correctly, and the misjudgment of three cases was due to hematomas.

Meaning: NIRO successfully monitored the DIEP flap of both exposed and buried types using a criterion of TOI 50.

METHODS

Patients

This study was approved by the institutional ethics board (approval no. 2023-113) at Aichi Medical University. Of the 167 patients who received breast reconstruction by the DIEP flap from October 2013 to May 2022 in Aichi Medical University Hospital, 11 cases with bilateral breast reconstruction or insufficient data were excluded. Eventually, we included 156 patients whose flaps were monitored using the NIRO device postoperatively. They comprised 57 exposed and 99 buried DIEP flap cases (Fig. 3). Table 1 illustrates the patient demographics and complications (mean age, immediate or delayed reconstruction, exposed or buried, a complication of microvascular thrombosis at anastomosis site, or hematoma around the flap).

Surgical Procedures

Before surgery, we performed contrast-enhanced computed tomography in all cases and selected the best perforator of the deep inferior epigastric artery, with a large caliber and good location on the right and left sides. Then, we confirmed their blood flow by ultrasound and marked the location on the abdominal skin surface. During the operation, the DIEP flap was elevated based on both right and left perforators; then we clamped either perforator and evaluated the blood perfusion by each perforator, using indocyanine-green (ICG) fluorescence angiography.[25] We selected the dominant perforator, ligated another perforator, and trimmed out the skin with poor blood flow from the DIEP flap. After microsurgical

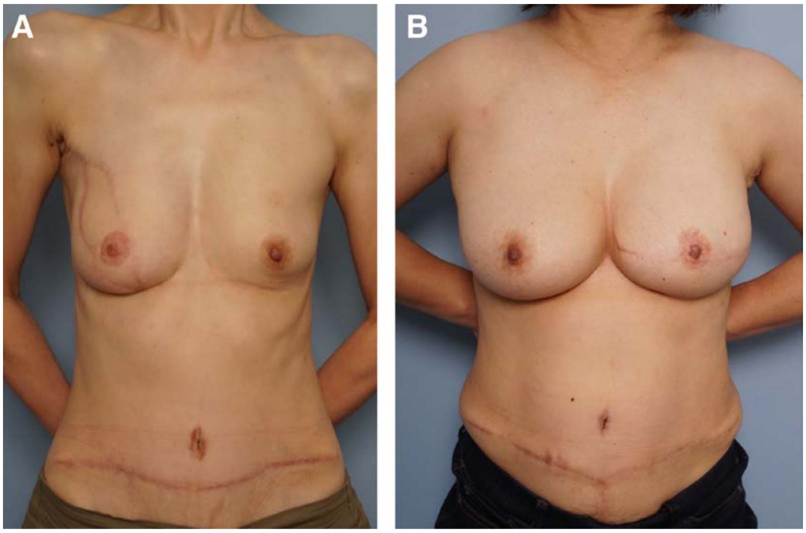

Fig. 1. Two types of breast reconstruction using a free DIEP flap. A, Frontal view after right breast reconstruction by exposed DIEP flap. The skin paddle can be seen on the reconstructed breast. B, Frontal view after left breast reconstruction by buried DIEP flap. The skin paddle is not visible from the frontal view. Only the small skin flap is exposed on the lateral side of the breast as the monitoring flap.

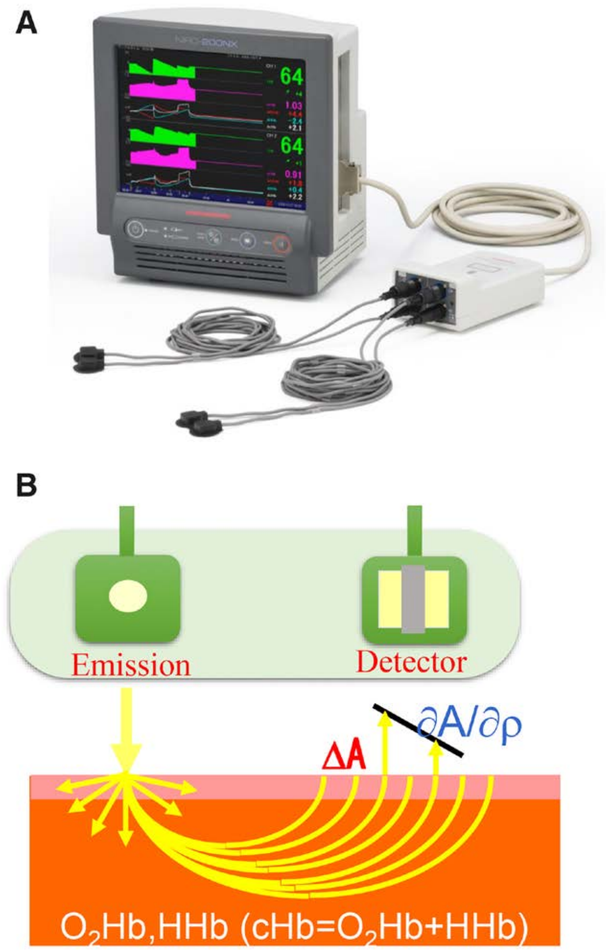

Fig. 2. Principle and mechanism of NIRO. A, NIRO device with two probes. The NIRO device enables measuring two points. B, The measurement principles of NIRO device. A single probe includes both emission and detector. O2HB, oxyhemoglobin; HHb, deoxyhemoglobin; cHB, total hemoglobin; A, light attenuation; ρ, the distance from light impulse source; ∂A/∂ρ, light input. Used with permission of Hamamatsu Photonics.

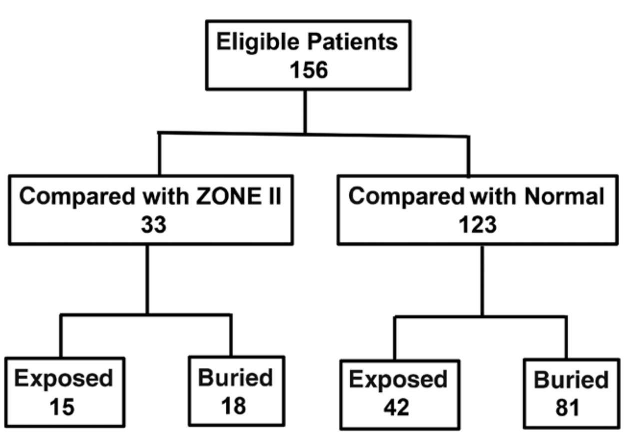

Fig. 3. Patient distributions.

anastomosis between the recipient and pedicle vessels, we placed the DIEP flap on the breast defect vertically with zone I up or down, depending on the easiness of anastomosis. Usually, we fold the caudal region of the flap and shape the projection. When we choose the buried type, we de-epithelialize the skin surface of the DIEP flap and bury it in the breast envelope, except for an area of 20 × 10 mm, which is exposed to the outside and used as a monitoring flap.[8,9,26]

Nurses meticulously monitor skin flap health with regular checks (every 2 hours initially, then every 4) for the first 3 days. They assess blood flow via Doppler sounds, flap color, and a TOI metric on the NIRO monitor. Any irregularity triggers a pinprick test for confirmation.

Measurement of TOI Using the NIRO Device

NIRS is an optical technique that relies on the relative transparency of tissue to near-infrared light. Several different NIRS systems are available for commercial use, all using continuous wave spectroscopy. The NIRO (Hamamatsu Photonics, Hamamatsu, Japan) system is designed to monitor cerebral blood flow. Near-infrared light, when introduced from an "emission probe" via the scalp, propagates diffusively into the adult human brain before reemerging from the scalp, where it can be collected via the "detector" and measured.

NIRO uses the modified Beer-Lambert law (mBL) to measure concentration changes in oxygenated (Δ[HbO2]) and deoxygenated hemoglobin (Δ[HHb]).[23] The principle of mBL is yield to reference 23. This device also uses spatially resolved spectroscopy, which allows for quantitative measurements of cerebral oxygenation expressed as TOI, the ratio of oxygenated hemoglobin to total hemoglobin, synonymous with regional oxygen saturation (rSO2) and tissue oxygen saturation (StO2), expressed as a percentage (%). TOI is used to calculate the differential equation of light attenuation concerning distance from the light input (∂A/∂ρ)[23] (Fig. 2B). TOI represents a mixture of SaO_2 and SvO_2 and reflects the trend of change in SvO_2. Therefore, TOI can evaluate tissue perfusion to predict postoperative outcomes.

The NIRO device enables measuring two points and has large and small optional probes. One NIRO probe includes both emission and detector. The important thing in using NIRS for cerebral monitoring is to choose an appropriate emission-detector distance to maximize the sensitivity to cerebral blood oxygenation and to remove noise by scalp blood flow. The single NIRO probe has the best emission-detector distance for adult brain monitoring.

We measured the TOI, attaching small probes onto zones I and II of the DIEP flap defined by Hartrampf[27] for 33 cases (15 exposed and 18 buried). Zone I is known to exhibit good blood flow, and zone II is on the opposite side. Then, we measured the TOI of the transferred DIEP flaps and healthy control sides of the breast for 123 cases (42 exposed and 81 buried), as shown in Fig. 2.

RESULTS

In our study, we defined the presence of microvascular thrombosis at the anastomosis site as "positive," as it is critical for the outcomes. NIRO measures the blood flow of

Table 1. Patient Demographics and Complications

	Exposed Flap		Buried Flap		
	Cases	%	Cases	%	*P*
No. patients	57	36.5	99	63.5	-
Age (y), mean ± SD	50.2 ± 6.62		47.6 ± 7.47		0.031*
Immediate reconstruction	1	1.8	11	11.1	0.057†
Reoperation	3	5.3	7	7.1	0.747†
Thrombosis	3	5.3	6	6.1	1†
Hematoma	0	0	5	5.1	0.159†

*Student *t* test.
†Fisher exact test.

Table 2. Comparison of TOI between Zone I and Zone II of the Flap

Time from Initial Surgery (h)	Zone I TOI (Mean ± SD)	Zone II TOI (Mean ± SD)	*P*
1	81.5 ± 14.7	70.6 ± 10.3	<0.001*
6	80.1 ± 15.9	71.9 ± 11.1	0.004*
12	81.7 ± 13.6	69.8 ± 10.4	<0.001*
24	76.1 ± 11.3	67.7 ± 11.0	0.028*

*Student *t* test.

Fig. 4. Gross appearance of the breast after the reconstruction. Two small probes are attached to the buried reconstructed breast (left side) and the other breast (right side), respectively.

two points simultaneously. We measured TOI in 33 cases (15 exposed and 18 buried cases), both zone I and zone II, and collected and analyzed the data every hour. For all 15 exposed and 18 buried cases, the TOI was higher in zone I than in zone II, with statistically significant differences at 1, 6, 12, and 24 hours after the operation (Table 2). This agrees with the previous reports[27,28] demonstrating that the contralateral zone exhibits lower blood flow than zone I.

Next, we measured the TOI of both the transferred DIEP flap and the contralateral intact breast that was not surgically dissected (Fig. 4) for the following 123 cases (42 exposed and 81 buried) and analyzed all the cases. We set TOI 50 as the criterion of "positive," as this criterion is applied to neurosurgery operations.[29] Of the total 156 cases, 57 cases were exposed, and 99 were buried cases, respectively (Table 3). There were eight cases of thrombosis after the operation. At just after surgery, all cases indicated TOI of more than 50. In seven thrombosis cases, TOI decreased to less than 50 within 24 hours after surgery. In one thrombosis case, TOI was found to be less than 50 within 72 hours after surgery.

Table 3. The Relation between Thrombosis and TOI (TOI < 50 as the Criterion)

	Thrombosis	TOI ≥ 50	TOI < 50
Total cases (N = 156)	−	145	2
	+	1	8
Exposed type (57 cases)	−	54	0
	+	0	3
Buried type (99 cases)	−	91	2
	+	1	5

Of the 57 exposed cases, three cases exhibited TOI less than 50, all of which had thrombosis (true-positive), and 54 showed TOI of 50 or more, all of which had no thrombosis. These results indicate that NIRO, with the criterion as TOI 50, judges the blood flow of exposed flaps precisely. Out of the 99 buried cases, seven cases exhibited TOI less than 50. Out of them, five cases had thrombosis (true-positive), and two did not (false-positive). In one of the false-positive cases, the TOI immediately after the operation was 85, which fell to 48 within 18 hours after the operation. At the reoperation, we found a hematoma between the mastectomy flap and the DIEP flap due to hemorrhage. After hemostasis and removal of the hematomas, the buried flap successfully survived. In the other false-positive case, the TOI immediately after the operation was 64, which fell to 48 within 24 hours and stayed between 45 and 55. Twenty-four hours after the operation, we observed color changes and swelling of the skin envelope, suggesting the presence of a hematoma under the envelope. The monitoring flap region displayed normal color. The Doppler sound measured on the flap appeared normal. The buried flap successfully survived without reoperation.

Out of 92 cases with TOI of 50 or more, there was one false-negative case in which the exposed region of the buried flap for monitoring changed to gray, suggesting impairment of the blood flow. At the reoperation, the flap contained a hematoma, and there was thrombosis in the venous anastomosed site. The hematoma around the flap was removed, and venous thrombosis was resected and repaired, resulting in flap recovery. All the other 91 cases retained TOI of 50 or more for at least 72 hours after the operation, followed by successful results without complication.

Table 3 summarizes the results of the judgments. In all our cases, sensitivity was 80%, and specificity was 99.3%. For exposed type cases, NIRO performed precise judgment. Both sensitivity and specificity were 100% in our

Table 4. The Relation between Thrombosis and TOI (Below 75% of Healthy Side as the Criterion)

	Thrombosis	TOI More Than 75% of Healthy Side	TOI Less Than 75% of Healthy Side
Total cases (123 cases)	−	96	21
	+	1	5
Exposed type (42cases)	−	36	5
	+	0	1
Buried type (81cases)	−	60	16
	+	1	4

Table 5. The Relation between Thrombosis and TOI (Below 70% of Healthy Side as the Criterion)

	Thrombosis	TOI More Than 70% of Healthy Side	TOI Less Than 70% of Healthy Side
Total cases (N = 123)	−	110	7
	+	1	5
Exposed type (42 cases)	−	39	2
	+	0	1
Buried type (81 cases)	−	71	5
	+	1	4

Table 6. The Relation between Thrombosis and TOI (Below 68% of Healthy Side as the Criterion)

	Thrombosis	TOI More Than 68% of Healthy Side	TOI Less Than 68% of Healthy Side
Total cases (N = 123)	−	112	5
	+	1	5
Exposed type (42 cases)	−	40	1
	+	0	1
Buried type (81 cases)	−	72	4
	+	1	4

exposed flaps. For the buried-type cases, we found only two false-positive and one false-negative case. Sensitivity was 71.4%, and specificity was 98.9% in our buried flaps. The misjudgments by NIRO were likely caused by hematoma around the flap.

Then, we analyzed the cases using other criteria, including "TOI below 75% that of healthy side[30]" and "a decrease of TOI more than 20 within 1 hour.[31]" When we set TOI below 75%, 70%, and 68%, that of the healthy side, the false-positive cases counted 21, 7, and 5, respectively, out of 123 cases where both healthy and operated sides were measured (Tables 4–6). There were four cases (positive) with a rapid decrease in TOI of more than 20, all of which exhibited thrombosis (ie, all true-positive). Of the cases that did not show a rapid decline, five cases had thrombosis (false negative), as shown in Table 7.

Table 7. The Relation between Thrombosis and TOI (Decrease of TOI More Than 20 within 1 Hour as the Criterion)

	Thrombosis	TOI Not Decreased More Than 20 within 1 h	TOI Decreased More Than 20 within 1 h
Total cases (N = 156)	−	147	0
	+	5	4
Exposed type (57 cases)	−	54	0
	+	2	1
Buried type (99 cases)	−	93	0
	+	3	3

DISCUSSION

Free flap failure or vascular compromise remains a dreadful complication of microvascular free tissue transfer. NIRS is a novel technique for free flap monitoring that has the propensity for early detection of vascular compromise when compared with the current gold standard, clinical monitoring. NIRS has the potential to be an objective, accurate, and continuous postoperative free flap monitoring technique with a greater flap salvage rate than clinical monitoring alone.[32] Among NIRS devices, we applied NIRO used for monitoring the blood flow in the neurosurgery field, to breast reconstruction surgery for the first time. NIRO successfully monitored the DIEP flap of both exposed and buried types. When we set a criterion of TOI 50, NIRO detected thrombosis in all the exposed type flaps precisely. Out of 99 buried-type flaps, it detected 96 cases correctly, and the misjudgment of three cases was likely due to hematomas.

Implantable probes have been reported recently for monitoring of the buried flap. Frey et al reported that the implantable Doppler probe was applied more frequently in buried flaps than in skin-paddle flaps.[33] Kohlert et al reviewed noninvasive and invasive monitoring methods and especially focused on implantable Doppler.[34] Keith Sweitzer et al reported NIRS monitoring of three consecutive patients, setting the NIRS probe on a buried flap, like an implantable probe.[35] Their NIRS probe is designed for use on intraoral surfaces. In contrast, our NIRO system can measure the blood flow of the buried flap through the mastectomy flap. We do not need to implant the probe on vessels or buried flaps during surgery.

NIRO has many merits for breast reconstruction using free DIEP flap transfer. One of the significant benefits of NIRO is that it enables fast and continuous monitoring. All of the events that present TOI below 50% in our cases occurred within 24 hours. NIRO detected abnormalities of blood flow before the flap color changed. NIRO is a better device for evaluating the blood flow of the transferred DIEP flap than observation of the color of the skin flap and other intermittent monitoring, including the pinprick test and the Doppler blood flow sounds. It reduces the task of doctors and nurses. They only have to assess the blood flow by observing the skin color and checking the Doppler sound when the TOI falls to less than 50%.

The second benefit of NIRO monitoring is that the criterion of TOI 50, which had been applied in the neurosurgery field,[29] was appropriate for evaluating DIEP conditions. This criterion gave 97% (96 of 99) and 100% (57 of 57) correct judgment rates for buried and exposed cases, respectively. Various criteria have been reported for judging blood flow using NIRS instruments. Keller reported an abnormal condition as both a decrease in tissue oxygen

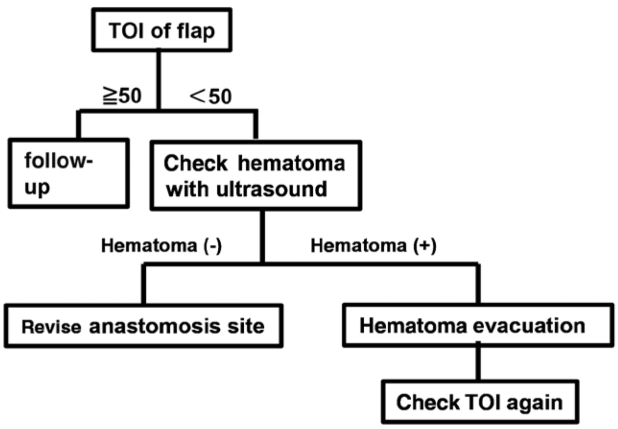

Fig. 5. Postoperative observation protocol.

saturation (StO_2) of 30% or less and a rate of 20% reduction or more per hour, which continues for 30 minutes or longer.[31] Repez et al defined "abnormal" as when the StO_2 decreases to 50% of the initial StO_2.[36] Akita et al simultaneously measured the oxygenation of both the skin flap and the healthy part and defined it as "abnormal" when the measured value of the skin flap becomes 75% or less than that of the healthy part.[30] In our study, the criterion as TOI below 75 gave rise to ~10% (21 out of 123) false-positive cases. The criterion of a rapid decrease in TOI of more than 20 looked over three and two buried and exposed cases, respectively. Although the criteria should be defined depending on the property of individual NIRS devices, our analysis of the data indicates that the criterion of TOI 50 fits the best for the NIRO device.

The third benefit of NIRO is that it applies to two different depths of tissue as a noninvasive method. The NIRO device can attach small and large probes. The small and large probes detect oxyhemoglobin and deoxyhemoglobin to a depth of 2 cm and 3 cm, respectively. For all of the DIEP flaps in our cases, we chose the small probe that fits well for the measurement of the buried flap and that prevented the measurement of blood flow of deeper tissue or lung.

As we presented false-positive cases, hematoma around the buried flap might affect the judgment. Our data and analysis urged us to generate a flow chart, as shown in Fig. 5. TOI below 50 needs surgical revision under the mastectomy flap with no delay. Accumulating data is required to establish this flow chart. If the reliability of NIRO is confirmed by further study, we will avoid the monitoring part of the flap in a nipple-sparing mastectomy in the future.

So far, we have found some disadvantages of NIRO. (1) Unstable SpO_2 and blood pressure may affect the data by NIRO measurements. In our study, all the patients were managed in the intensive care unit after the operation. Under the control of patients' conditions, including SpO2 and blood pressure, the data obtained by NIRO were stable. (2) By the movement of patients, detachment or loose attachment of the probe may occur, where NIRO may capture the room light, and error in the measurement system would occur. (3) Although rare, it is possible that thrombosis cannot be detected by hematoma on buried flap even if TOI is 50 or more. We had one false-negative buried-type case out of 96 cases. In this case, a shallow bypass of near-infrared light through the skin envelope might have been induced by a hematoma, and NIRO might measure the TOI at the skin envelope, not the buried flap. (4) Where the NIRS device is different, the oxygenation rates cannot be compared using the same standard because the algorithm for calculating the oxygenation rate is different in each device. So, the criterion TOI 50 is only used when we use the NIRO device to monitor the free DIEP flap. The limitation of our study is the small sample size. By accumulating data in the future, we may find factors that interfere with the judgment and measures toward a perfect one.

CONCLUSIONS

The NIRO device has the benefit of measuring the tissue blood flow deeper than the skin, like brain and buried tissue. We propose NIRO as a reliable device for monitoring the blood flow of the DIEP flap, whether the flap is exposed or buried type. The criterion of TOI 50 was appropriate for evaluating DIEP conditions. It predicts the outcomes of breast reconstruction by the DIEP flap transfer.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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