



Exploring personalized postoperative non-invasive tissue oximetry in DIEP flap breast reconstruction

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Abstract

Early detection of vascular compromise after autologous breast reconstruction is crucial to enable timely re-exploration for flap salvage. Several studies proposed non-invasive tissue oximetry for early identification of ischemia of deep inferior epigastric perforator (DIEP) flaps. The present study aimed to explore the utility of non-invasive tissue oximetry following DIEP flap surgery using a personalized oxygenation threshold.

Methods Patients undergoing immediate/delayed DIEP flap surgery were included in this prospective observational study. DIEP flap tissue oxygenation (StO₂) was monitored continuously using near-infrared spectroscopy. A baseline measurement was performed by positioning one sensor at the marked position of the major inferior epigastric perforator on the abdomen. A new sensor was positioned postoperatively on the transplanted tissue. In unilateral procedures, postoperative StO₂ values of the native breast were also obtained. Measurements were continued for 24 h.

Results Thirty patients (42 flaps) were included. Fourteen patients (46.7%) had an uncomplicated postoperative course. A minor complication was observed in thirteen patients; in five patients, at least one major complication occurred, requiring re-exploration. Median StO₂ readings were significantly lower in patients with major complications compared to uncomplicated cases. In fourteen unilateral DIEP flap procedures, StO₂ values of the native breast were similar to the preoperative baseline measurement (92%; $p = 0.452$).

Conclusions Non-invasive tissue oximetry following DIEP flap surgery could aid in early detection of vascular compromise. StO₂ values of the native breast and abdominal wall preoperatively can be used interchangeably and can serve as personalized reference value.

Level of evidence: Level IV, diagnostic / prognostic study.

Keywords DIEP flap · Autologous breast reconstruction · Tissue oximetry · NIRS · Non-invasive tissue monitoring · Personalized threshold

Introduction

Advances in microsurgical techniques contributed to deep inferior epigastric perforator (DIEP) flap becoming the preferred choice of postmastectomy autologous breast reconstruction [1, 2]. Current literature shows overall success rates of free flap transfer up to 98% [3–5]. Nevertheless, postoperative (partial) flap compromise, for which immediate re-exploration is required to minimize the risk of flap loss, still occurs in 5–25% of the procedures [3, 6]. The time between the onset of malperfusion and surgical intervention is directly related to the salvage rate, and if re-exploration is not performed within 12 h, ischemic tissue damage is likely to be irreversible [6–8]. Total or partial loss of a DIEP flap

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has a major negative impact on the physical and psychological well-being of the patient [5]. Therefore, early detection of vascular compromise, enabling timely re-exploration is crucial in preventing complications contributing to flap failure.

In order to prevent ischemic events following free tissue transfer, real-time and objective monitoring of flap perfusion is crucial. The ideal monitoring technique should be safe for the patient, rapidly responsive, accurate, reliable, applicable to all types of flaps, easy to use, and cost-effective [9, 10]. To date, there is no single device available meeting all previously mentioned criteria [10–12]. Rather subjective and intermittently performed methods, such as clinical observation of skin color and flow measurements using Doppler ultrasonography remain gold standard for assessment of flap viability [2, 3, 11, 13].

Non-invasive tissue oximetry allows for continuous bedside monitoring of regional tissue oxygen saturation (StO_2) [14]. Since its introduction as a monitoring tool for flap viability [4, 15], several studies suggested that tissue oximetry could be used as a reliable diagnostic modality for early detection of tissue hypoxia in free flaps [16, 17]. To date, no consensus has been established on adequate interpretation strategies of StO_2 data in the clinical setting [15, 18]. Nevertheless, among the existing studies the criterion described by Keller et al. [17] (StO_2 values below the absolute value of 30%, or a decrease of 20% from baseline values for longer than 60 min in duration, are considered predictors for circulatory compromise and are mostly adopted [6, 18, 19]. However, anatomical and physiological factors might influence StO_2 values within and across patients, as well as across different types of flaps [19].

The aim of the present study was to confirm the usefulness of non-invasive tissue oximetry in postoperative monitoring of DIEP flaps for autologous breast reconstruction, and to incorporate a personalized tissue oxygen threshold for more accurate interpretation of changes in StO_2 values.

Material and methods

This study was performed in line with the principles of the Declaration of Helsinki. Institutional review board approval (METC 16–04-037) was obtained prior to conducting this prospective observational study. An informed consent was obtained, in which patients agreed to the use of their data and publication in a scientific journal.

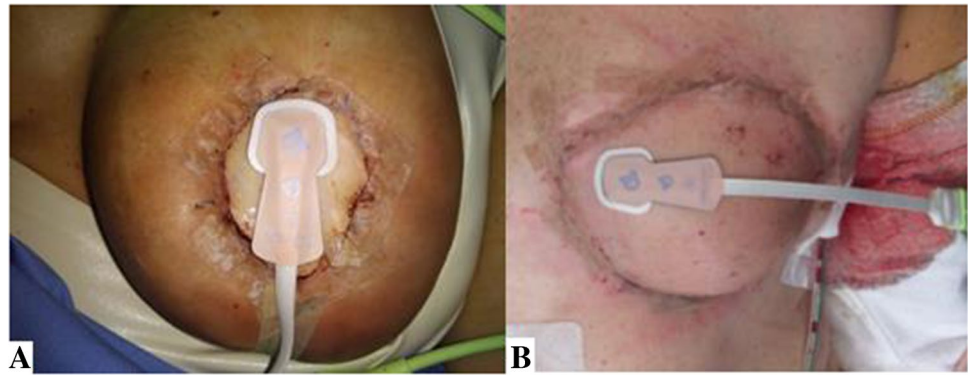
Study subjects

Female patients undergoing unilateral or bilateral, immediate or delayed DIEP flap breast reconstructive surgery at one university medical center were included.

Non-invasive tissue oxygenation

Tissue oxygenation values of the DIEP flap were continuously measured using near-infrared spectroscopy, which is based on the Lambert–Beer law. The proportion of light absorbed by oxyhemoglobin (HbO_2) and deoxyhemoglobin (Hb) was determined using five wavelengths within the near-infrared spectrum (700–1100 nm) [15, 20]. Specific absorption spectra of HbO_2 and Hb allow for estimation of the concentration of both hemoglobin forms [6, 21]. In the current study, the FORE-SIGHT MC-2030 oximeter (formerly Casmed, Branford, CT, USA, currently Edwards Lifesciences, Irvine, CA, USA) was used to monitor StO_2 . To incorporate a personalized baseline measurement, a single disposable self-adhesive sensor was positioned on the abdominal area at the position of the major inferior epigastric perforator prior to surgery. Guided by a preoperative computed tomography (CT) and/or a magnetic resonance imaging (MRI) scan and a handheld Doppler ultrasonography device, the anatomical location of the major perforator was assessed from which the baseline StO_2 was derived by calculating the mean/median from measurements approximately 5 min in duration. When after preoperative assessment more perforators were found appropriate to use for the reconstruction, an individual baseline measurement was performed for each perforator. Immediately following surgery, a new sensor was placed on the DIEP flap as close to the major flap perforator as possible, near to the reference point for the postoperative Doppler measurement. The surgeon reported which perforator was used during surgery and the corresponding baseline measurement was utilized for analysis. The sensors accompanying the tissue oximeter device cannot be sterilized; hence, it was necessary to use a new sensor for the tissue oxygenation assessment postoperatively. A DIEP flap dimension of at least 50 mm by 30 mm was required to allow proper sensor placement. In case of a unilateral breast reconstruction, postoperative StO_2 values of the native breast were obtained as well, with another sensor positioned on the lower site of the breast below the areola. At the time of patient arrival at the recovery room, the sensors were connected to the clinical oximeter to initiate the postoperative continuous measurement for 24 h, see Fig. 1. This study had a prospective observational design. Therefore no decisions regarding possible flap viability were made based on the tissue oximetry values. Clinical observation (i.e., capillary refill, flap color, temperature) and Doppler measurements were performed according to hospital protocol and were leading for decision-making.

Fig. 1 Sensor positioning, respectively after immediate (A) and delayed DIEP flap breast reconstruction (B)



Statistical analysis

For the a priori sample size calculation, a difference in StO_2 of 10% and a delta StO_2 per hour of 10% were considered clinically relevant changes, taking into account the inaccuracy of the clinical oximeter of 4.7%. With alpha set at 0.05, a statistical power ($1-\beta$) of 0.95, and σ of 13.75 (maximum – minimum divided by 4, i.e., $99-44/4$), the estimated sample size was 28 patients (the maximum and minimum StO_2 detectable values are 99 and 44%, respectively). Results were analyzed based on the total number of flaps. Data were divided into three groups based on postoperative complications. No complications, minor complications (e.g., ecchymosis), and major complications (all complications requiring re-exploration). Depending on data distribution, variables were presented as means \pm standard deviation (SD) or median [interquartile range] (IQR).

Differences in StO_2 values between groups were assessed using the one-way Anova or Kruskal Wallis test. If a significant result was yielded, pairwise comparisons were performed using a Bonferroni correction. In case of a significant result from the Kruskal Wallis test, pairwise comparisons with a manual Bonferroni correction were used. The manual Bonferroni correction was performed by multiplying the derived p -value by the number of pairwise comparisons. To assess differences between preoperative and postoperative StO_2 values, a paired samples T -test or Wilcoxon signed rank test was used, depending on data distribution. For comparison of StO_2 values between the native breast and the preoperative measurement, the independent samples T -test or Mann–Whitney U -test was used.

For all tests, a two-tailed p -value < 0.05 was considered statistically significant. All analyses were performed using SPSS (version 25.0, SPSS Inc., Chicago, IL, USA) for Windows.

Results

Thirty patients, who underwent DIEP flap breast reconstruction, were included. In four patients who gave their consent, the dimension of the skin-island of the DIEP flap was too small. Patients could therefore not be included in this study. There were no patients excluded for other reasons. The mean age at the time of surgery was 51 ± 13 years (Table 1). Patients had a mean body mass index of 27.5 ± 4.3 kg/m². Approximately 50% of patients received adjuvant therapy prior to surgery, consisting of radiation therapy, chemotherapy, endocrine therapy, immunotherapy, or a combination of these. Two patients had a history of tobacco smoking.

Fourteen patients (46.7%) underwent unilateral breast reconstruction, while sixteen (53.3%) underwent a bilateral reconstruction. This resulted in a total of 46 DIEP flaps, consisting of 28 immediate (60.9%) and 18 (39.1%) delayed procedures. In four flaps, the skin island was too small to allow proper sensor placement; these cases were excluded from the study. As a result, data of 42 DIEP flaps (in 30 patients) were analyzed. The mean flap weight of all DIEP flaps was 755 ± 235 g (782 ± 199 g and 690 ± 254 g for immediate and delayed DIEP flap procedures respectively; $p = 0.768$). The median ischemic time period was 42 [34–51] min, as shown in Table 2. In addition, in the unilateral DIEP flap reconstruction, postoperative StO_2 values of the native breast were also obtained. The median StO_2 reading from the native breast was 92 [92–93]%. This value was not significantly different compared to the

Table 1 Patient characteristics

Number of patients	30
Age (y)	51 ± 13
BMI (kg/m ²)	27.5 ± 4.3
Smoking (n (%))	2 (7%)
(Neo) adjuvant therapy (n (%))	14 (47%)

BMI, body mass index

Table 2 DIEP flap reconstruction characteristics

DIEP flaps (<i>n</i>)	42
Type of reconstruction (<i>n</i> (%))	
Unilateral	14 (33%)
Bilateral	28 (67%)
Timing of reconstruction (<i>n</i> (%))	
Primary	25 (60%)
Secondary	17 (40%)
Ischemic time (min)	
Median [IQR]	42 [34–51]
Flap weight (g)	
Mean of total ±SD	755 ± 235
Primary	782 ± 199
Secondary	690 ± 254

DIEP flaps, deep inferior epigastric perforator flap; *IQR*, interquartile range; *SD*, standard deviation; There was no significant difference in flap weight between primary and secondary DIEP flap reconstructions ($p = 0.768$)

preoperative baseline measurement on the abdomen (92 [91–93]%; $p = 0.452$).

In fourteen patients (46.7% of patients, accounting for 19 flaps, 45% of all flaps), an uncomplicated postoperative course was observed. In these procedures, postoperative StO_2 readings showed to be relatively stable (with maximum fluctuations of 3%) throughout the entire measurement and did not differ significantly from preoperative StO_2 values (median values of 92 [89–92] and 93 [91–93], respectively). Figure 2 depicts an example of StO_2 readings in case of an uncomplicated recovery.

One of the patients with an uncomplicated postoperative course showed an atypical pattern of StO_2 values. In

contrast to the other uncomplicated cases, the ischemic time period during this particular procedure was relatively long, 130 min, as compared to the median of 42 min. Tissue oximetry readings showed a two-step recovery phase of each approximately 2 h in duration (Fig. 3). After 6 h, postoperative StO_2 values were similar to baseline values.

A minor complication (e.g., ecchymosis) was observed in thirteen patients (43.3% of patients, accounting for seventeen flaps, 41% of total flaps). In these cases, postoperative median StO_2 values were not significantly different as in the uncomplicated procedures. Patients with either no or minor complications were discharged from the hospital after a median of 5 [4–5] days of hospital stay.

In five patients (16.7%), at least one major complication occurred in which re-exploration was required. A unilateral DIEP flap reconstruction was performed in four patients. A bilateral reconstruction was performed in one patient; in both DIEP flaps, a complication occurred. In total, a major complication was noticed in five DIEP flap reconstructions (12% of all flaps), and one re-exploration was due to a donor site complication. Patient 1 was diagnosed with fat necrosis. This was debrided during surgery. Patient 2 was diagnosed with an arterial inflow problem. During the re-operation, the arterial anastomosis was kinked, which was corrected by repositioning of the pedicle. In patient 3, evacuation of a haematoma was performed: during the re-exploration, a minor arterial bleeding of the pectoralis muscle was found. In patient 4, a bilateral reconstruction was performed. On the left side, the patient received a large flap (1200 g). The used perforator was insufficient to create an optimal perfusion for this flap, leading to partial loss of the caudal side of the flap. Therefore, 100 g of the flap was ultimately removed. In the right DIEP flap, venous congestion occurred. During

Fig. 2 Example of tissue oximetry readings in case of uncomplicated recovery. Pre-operative baseline StO_2 values were averaged and added as a personal reference (dotted line)

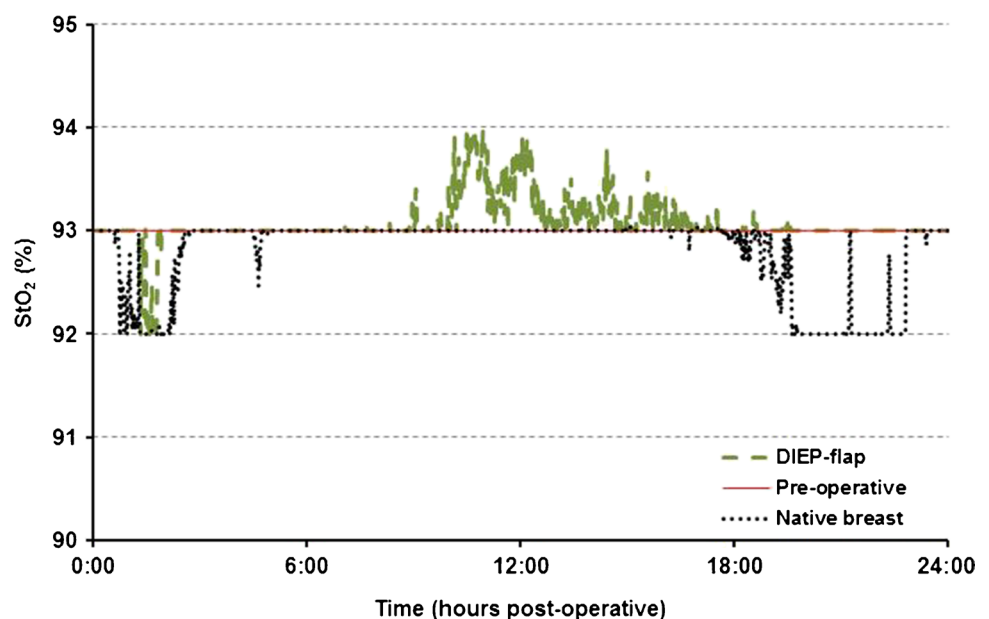
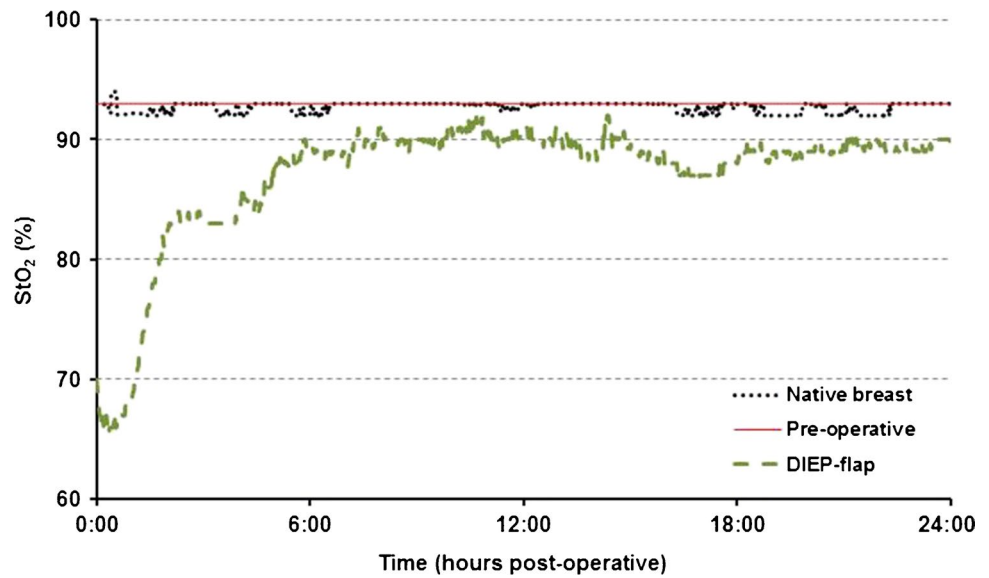


Fig. 3 Tissue oximetry readings of a patient with a prolonged ischemic time (130 min). The averaged preoperative baseline StO₂ value is added as a personal reference (dotted line)



re-exploration, the venous anastomosis appeared to be kinked, which was corrected by repositioning. Patient 5 did not have any complications on the DIEP flap, but developed a massive acute bleeding in the donor site (1500 mL blood loss), which had a major impact on the StO₂-values and on the outcome of the clinical assessment of the DIEP flap. The median StO₂ readings were significantly lower in patients with major complications compared to patients with an uncomplicated postoperative course: 80 [79–84]% vs. 92 [89–92]% ($p < 0.001$). Furthermore, patients with a complicated course (minor and/or major) showed a significantly higher body mass index (BMI) ($30.0 \pm 3.7 \text{ kg/m}^2$ and $32.1 \pm 4.9 \text{ kg/m}^2$, respectively) than patients with an uncomplicated course ($24.9 \pm 3.4 \text{ kg/m}^2$; $p < 0.001$). Additionally, the flap weight of DIEP flap procedures which were followed by major complications ($1040 \pm 173 \text{ g}$) was significantly higher compared to patients with no complications ($608.0 \pm 161.6 \text{ g}$; $p < 0.001$) or minor complications ($829.5 \pm 217.5 \text{ g}$; $p = 0.049$). As shown in Table 3, flap weight was also significantly different between patients

without complications ($608.0 \pm 161.6 \text{ g}$; $p < 0.001$) and minor complications ($829.5 \pm 217.5 \text{ g}$; $p = 0.003$).

Postoperative StO₂ values did not significantly differ from preoperative (baseline) values ($p = 0.069$ and $p = 0.104$ in patients without complications or minor complications, respectively). In patients with major complications, postoperative StO₂ readings were significantly lower compared to preoperative values ($p = 0.013$).

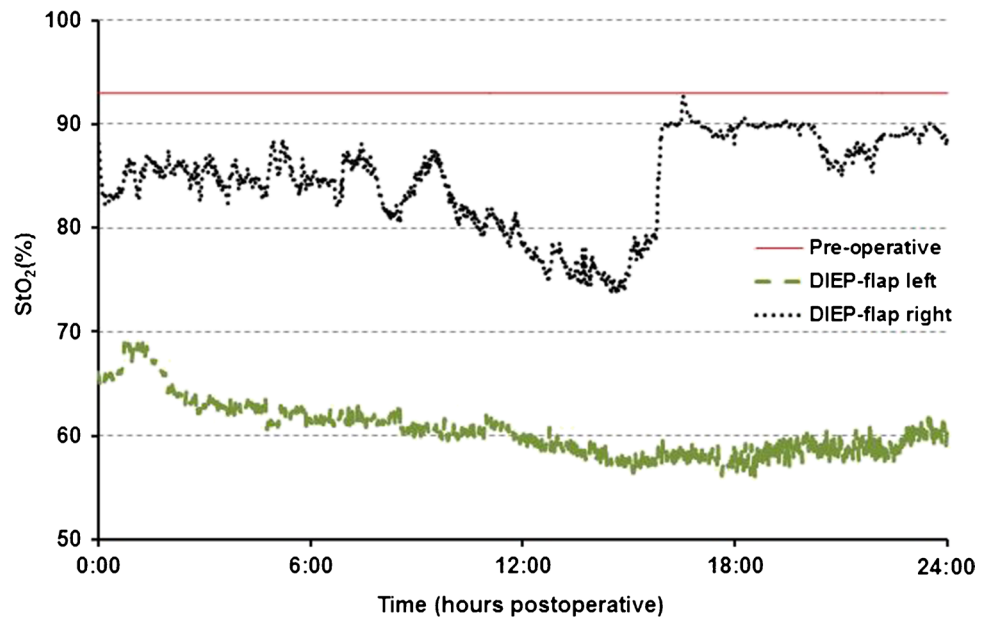
In all cases, no StO₂ values below the absolute value of 50% were observed. In cases in which surgical flap re-exploration was required, a decrease of 20% or more from baseline values for more than 60 min was observed in two out of six cases (33.3% of cases). The most substantial decrease observed in this study was a relative 37% decrease from baseline for more than 4 h in duration, which occurred in one particular patient (Fig. 4). During early postoperative recovery, it appeared that blood flow towards the caudal side of the left flap was impeded, for which revisional surgery was required to allow tissue salvage. On the fifth

Table 3 Demographic and clinical data

	No complications (n = 19)	Minor complications (n = 17)	Major complications (n = 6)	p-value*	p-value**	p-value***
Age (y)	51 ± 8	53 ± 8	57 ± 10	$p > 0.05$	$p > 0.05$	$p > 0.05$
BMI (kg/m ²)	24.9 ± 3.4	30.0 ± 3.7	32.1 ± 4.9	$p = 0.001$	$p < 0.001$	$p > 0.05$
Ischemic time (min)	45 [35–56]	41 [35–46]	37 [27–46]	$p > 0.05$	$p > 0.05$	$p > 0.05$
Flap weight (g)	608 ± 162	830 ± 218	1040 ± 173	$p = 0.003$	$p < 0.001$	$p = 0.049$
StO ₂ baseline (%)	93 [91–93]	92 [91–92]	93 [86–93]	$p > 0.05$	$p > 0.05$	$p > 0.05$
StO ₂ postoperatively (%)	92 [89–92]	91 [88–92]	80 [79–84]	$p > 0.05$	$p < 0.001$	$p = 0.002$

BMI, body mass index; StO₂, tissue oxygen saturation; n, number of flaps. *Difference between no complication and minor complication groups. **Difference between no complication and major complication groups. ***Difference between minor complication and major complication groups. Presented p-values are Bonferroni corrected

Fig. 4 Tissue oximetry readings of a patient in whom re-exploration was required due to a delayed blood flow towards the caudal side of the left flap. Pre-operative baseline StO_2 values were averaged and added as a personal reference (dotted line)



postoperative day, 100 g of the total flap weight had to be surgically removed due to compromised tissue perfusion.

Discussion

Early detection of vascular compromise in autologous breast reconstruction is essential to pursue successful flap salvage. This prospective observational study illustrated that non-invasive tissue oximetry can successfully identify patients at risk of major clinical complications following DIEP flap reconstruction: visual aspects of tissue oximetry readings in complicated cases were significantly different from uncomplicated procedures. In addition, a personalized tissue oxygen threshold was incorporated.

In almost all patients with uneventful recovery, postoperative StO_2 values of the DIEP flap immediately matched the preoperative baseline values. Five patients suffered from a major complication, requiring surgical re-exploration for salvage of the free flap. Tissue oximetry readings in these cases showed a significantly lower median StO_2 (80 [79–84]%) compared to preoperative baseline values (92 [89–92]%; $p=0.002$). This is in line with previous studies by Vranken et al., Keller et al., and Repez et al. [6, 17, 22] which suggested that postoperative StO_2 readings could identify vascular compromise in an early postoperative phase.

While general consensus on the required duration of postoperative monitoring is still lacking, the current study (with a 24-h continuous postoperative monitoring window) was able to detect major complications in a predefined timeframe. Previous studies used monitoring windows with varying durations, mostly between 24 and 48 h postoperatively [1, 17, 22]. A recent study by Carruthers et al. showed that

microvascular issues become visible during clinical evaluation in the initial 23 h following reconstructive surgery [23], suggesting that a 24-h time window should be adequate. These results in combination with the results of the current study suggest that continuous postoperative monitoring of the DIEP flap with the use of tissue oximetry for longer than 24 h would not provide additional important information and therefore a timeframe of 24 h of continuous postoperative tissue oximetry monitoring could be justified. Nevertheless, clinical observation (i.e., capillary refill, flap color, temperature) and Doppler measurements should be continued according to hospital protocol.

A substantial number of studies consider high BMI and high flap weight to be risk factors for complications following breast reconstructive surgery [24–28]. In this study, the BMI values of patients without complications were significantly lower compared to patients with minor or major complications ($32.1 \pm 4.9 \text{ kg/m}^2$). Weight of the DIEP flap was also significantly lower in patients without complications compared to patients with minor or major complications. These findings are in line with the literature.

One way to effectively assess flap perfusion in the early postoperative phase would be to apply a baseline value to objectify relevant changes in tissue StO_2 in real time [17]. The thresholds described previously by Keller et al., StO_2 below 30%, or a decrease of 20% from baseline values for longer than 60 min in duration, are considered predictive of circulatory compromise and used in several clinical centers [6, 17]. Various studies have questioned the thresholds as proposed by Keller and colleagues [13, 19, 29]; they suggested adaptations of the thresholds to an absolute value of 40%, or a decrease of 15% from baseline for longer than 60 min [13, 19]. In line with the studies of Steele et al. and

Hölze et al. [13, 29], in the current study, no absolute StO_2 values below 55% were observed. Furthermore, we found a relative decrease of 20% for at least 60 min was only observed in 33% of cases in which a re-exploration (6 out of 42 flaps) was needed.

There are several types of commercially available oximeters, all use different types of sensors and different wavelengths of near-infrared light. In addition, the assumed ratio between arterial saturation and venous saturation in the equation to calculate the reference values varies between devices [30]. In a study of Hyttel-Sorensen and colleagues, a comparison of three different oximeters showed different absolute measurement values for all the devices [31]. In the study of Hölzle (O2C (Oxygen 2 see, LEA CO., Gießen, Germany) as well in the study of Akita (TOS-OR (Fujita Medical Instruments Co., Ltd., Tokyo, Japan), a different type of oximeter was used compared to the study of Keller (ViOptix T.Ox Tissue Oximeter (ViOptix Inc., Fremont, CA, USA) [18, 19, 29]. This could also explain the variations in StO_2 patterns across uncomplicated cases between this study and the study by Vranken et al.; both studies included patients in the same medical center. While Vranken et al. used the INVOS™ 5100C Cerebral/Somatic Oximeter (Medtronic, Minneapolis, MN, USA), in the current study, the FORE-SIGHT MC-2030 oximeter was used [22]. Direct comparison of StO_2 values of different oximeters is therefore not recommended.

The StO_2 values observed in patients without complications and patients with minor complications were not significantly different, and in neither group values below 88% were detected. In patients with at least one major complication, on the other hand, median StO_2 values were significantly lower (80 [79–84]%). Postoperative values of this group were also significantly lower compared to the preoperative baseline values (93 [86–93]%). Due to the relatively small patient population and occurrence of complications in this current study, objective determination of fixed cut-off values below which surgical re-exploration is indicated was not feasible. Furthermore, as described in a study of Bickler et al., inter-individual differences in tissue oxygenation values with the present oximetry technology introduce a major challenge in determining a threshold for regional tissue desaturation [30]. Even though the improvement in monitoring techniques contributes to the ability to detect vascular compromise before clinical evidence for circulatory failure becomes apparent [17, 31, 32]. These findings illustrate that readings from different devices cannot be directly compared, indicating that device-specific, sensor-specific, and measurement site-specific cut-off values should be considered when determining tissue desaturation thresholds requiring immediate intervention to prevent adverse clinical effects [31, 33, 34].

Nevertheless, the current study included fourteen unilateral DIEP flap cases, incorporating the native breast as a

personalized reference measurement. StO_2 readings of the native breast showed similar values compared to preoperative baseline readings from the abdomen. This suggests that for unilateral as well as bilateral DIEP flap reconstructions, a personalized reference could be obtained. In case of a unilateral procedure, this would mean that if no baseline measurement could be performed preoperatively, postoperative monitoring of the DIEP flap with use of tissue oximetry could still be performed using a baseline from the contralateral breast. However, in ahead of implementing this reference, its reliability needs further analysis.

Evidence regarding the use of a personalized reference for postoperative DIEP flap monitoring using tissue oximetry remains limited. The StO_2 values of the preoperative measurement could be biased due to subjectivity while applying Doppler ultrasonography in order to detect to location of the major perforator in the flap still in situ. However, in most cases, a preoperative CT and/or MRI was conducted to localize the major perforator. Accordingly, preoperative StO_2 values could still be affected due to interference of other vessels. A more reliable method would be to measure the StO_2 values of the flap during surgery, when the flap is only vascularized by the dissected pedicle from the major inferior epigastric perforator. Nevertheless, there are no sterile sensors available in Europe to measure tissue oxygenation intraoperatively; therefore, a more reliable assessment is not achievable. Another option to assess tissue oxygenation intraoperatively would be the use of a hyperspectral imaging camera [35].

Nonetheless, the sample size in this study was limited. Thirty patients (42 flaps) were included, but in only six cases, a major complication occurred. This could be an explanation that in this study no false-positive cases were found. Another limitation was that no comparison could be made between an accurate and timely proper physical exam, Doppler measurements, and the NIRS-measurement in the early postoperative period. Therefore, no hard conclusions could be made if tissue oximetry would be superior to a physical exam or Doppler measurements. For that reason, a randomized control trial with a larger sample size and intervention and control group would be needed.

In conclusion, non-invasive tissue oximetry following DIEP flap breast reconstruction can enable early identification of patients at risk of major clinical complications in the first 24 h after surgery. Preoperative tissue oximetry values at the DIEP flap donor site and postoperative values at the native breast can be used interchangeably as a personalized reference threshold. Device-specific and measurement site-specific cut-off values should be identified instead of a general threshold for dangerous lower level for StO_2 .

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Author contribution All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by the first and second author. The first draft of the manuscript was written by the first author and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability Available on request.

Code availability Not applicable.

Declarations

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Institutional review board approval (METC 16–04-037) was obtained prior to conducting this prospective study.

Informed consent An informed consent was obtained, in which patients agreed to the use of their data and publication in a scientific journal.

Patient consent The authors affirm that human research participants provided informed consent for sharing their data and publication of the images in Fig. 1a and 1b.

Conflict of interest Anouk A.M.A. Lindelauf, Nousjka P.A. Vranken, Rutger M. Schols, Esther A.C. Bouman, Patrick W. Weerwind, and René R.W.J. van der Hulst declare no competing interests.

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