A New Diagnostic Algorithm for Early Prediction of Vascular Compromise in 208 Microsurgical Flaps Using Tissue Oxygen Saturation Measurements

Alex Keller, MD*†

Abstract: The purpose of the study was to evaluate the detection of vascular complications earlier than clinical evidence using a noninvasive near-infrared tissue oximeter monitor. Early detection of circulatory compromise allows for earlier re-exploration and better outcomes.

The monitoring method studied was the ViOptix T.Ox Tissue Oximeter (ViOptix Inc., Fremont, CA). The device uses an optical tissue characterization based on measuring scattering and absorption of near infrared light. Tissue oxygen saturation and its derivates were evaluated as candidates for a more sensitive algorithm to predict vascular flap complications. Criteria studied in various combinations were the absolute value of tissue oxygen saturation (StO2), the amount of its change ($\Delta$StO2) and the rate of its change ($\Delta$StO2/$\Delta$t).

There were 208 monitored breast flaps in 145 patients (62 bilateral and 83 unilateral). In 1 patient, 2 flaps were used to make a single breast. Patients were monitored intraoperatively and postoperatively for 36 hours.

No flap being monitored was lost. Among the 208 flaps monitored, 5 patients exhibited complications that were predicted by the tissue oximeter before clinical signs were evident. If blood flow was completely occluded by kinking of the vessels, compression of the vessels either related to a tight closure or hematoma, and thrombosis secondary to various coagulation disorders are the more typical causes of thrombosis. The amount of time that elapses from the time of anatomic thromboses to its correction is directly related to salvage rates. Currently, salvage rates for free flaps due to anatomic thromboses are 50% or greater.

Flap monitoring via clinical observation of skin color, capillary refill, and dermal bleeding remains the benchmark, but issues related to hospital staffing and to the difficulty of making a clinical determination of a flap’s perfusion have hastened the search for more objective monitoring methods. Methods that have been used and are currently used include internal and external thermometry, laser Doppler flowmetry, internal and external Doppler monitoring, quantitative fluorescein fluorescence, pulse oximetry, and transcutaneous oxygen monitoring. The most popular of these methods are external Doppler monitoring, implantable Doppler monitoring, and assessment of cutaneous blood flow using laser Doppler flowmetry. The external Doppler is inadequate due to its ability to effectively access the recipient vessels. The implantable Doppler provides continuous direct monitoring of anastomotic patency with real time auditory feedback on arterial and venous patency. However, the invasive nature of the probes, the difficulties associated with interpreting the audio signals, especially in the case of partial occlusive events, and the resultant issues with specificity and sensitivity, all prove to be limiting in its utilization. Laser Doppler flowmetry, although noninvasive, is restricted as its effectiveness is skill dependent and relies upon the experience of personnel for interpretation. Ideally, a monitor should identify hemodynamic deterioration before any clinical manifestations. Improvements in transcutaneous oxygen measurement have made this technique more reliable, however, not for the monitoring of cutaneous flaps.

Due to the limitations of the currently available monitors as well as the often limited availability of reliable and highly trained personnel for competent clinical flap monitoring, a subsequent and larger study of the ViOptix T.Ox Tissue Oximeter (ViOptix Inc., Fremont, CA) in free flap breast reconstructive surgery was undertaken. Results of this larger study of 208 free flaps are presented and discussed in this paper. The study was a continuation of an earlier preliminary study.

METHODS AND MATERIALS

In this study, 208 flaps in 145 patients (62 bilateral and 83 unilateral) undergoing autologous tissue perforator free flap breast reconstruction were enrolled in a flap monitoring study from January 2005 to January 2008. Of the flaps monitored, 197 were deep inferior epigastric perforators (DIEP) flaps, 10 were s-GAP flaps, and 1 was an SIEA. Patients were monitored intraoperatively and postoperatively for 36 hours. This monitoring study was in addition to the clinical monitoring protocol already in place. All patients were given informed consent and enrolled in a protocol approved by the Institutional Review Board at Long Island Jewish Hospital in New York, NY.
Hyde Park, New York. Early in the study a single monitor restricted data collection to a single flap in patients undergoing bilateral reconstruction.

The monitoring device studied is the ViOptix T.Ox Tissue Oximeter (Fig. 1) manufactured by ViOptix, Inc. The T.Ox Tissue Oximeter measures tissue oxygen saturation (StO₂) using near-infrared spectroscopy. The device leverages an optical tissue characterization based on the measurement of the scattering and absorption of near infrared and visible red light, which are related to the oxygen content of the hemoglobin in the tissue studied.¹³ Light scattering occurs in tissue and characterizes a tissue’s optical properties. Absorption of light is caused by chromophores inside tissue. In the near-infrared spectrum, water and hemoglobin are the major absorbers in tissue. It is this absorption and scattering that allows for the calculation of its StO₂ tissue oxygen saturation.

Changes in total tissue blood volume can be calculated from the summation of concentrations in oxygenated and deoxygenated hemoglobin. This value is especially valuable in predicting venous insufficiency.¹² Tissue oxygen saturation and its derivates were evaluated as candidates for a more sensitive algorithm to predict vascular flap complications. Criteria studied in various combinations were the absolute value of tissue oxygen saturation (StO₂), the amount of its change (ΔStO₂) and the rate of its change (ΔStO₂/Δt). The tissue oximeter documents changing flap physiology in real time and captures and displays the data graphically.

The T.Ox device used consists of a single channel with a sensor connected to a console by means of a fiber-optic cable. The console contains a computer that processes, displays, and records the collected data. The continuous monitoring sensor has a rectangular adhesive patch and a measuring surface area of 5 × 5 mm. The device is configured with 2 laser light sources and 4 photodetectors. The measuring depth for this sensor is from 0 to a maximum of 10 mm, decreasing to a penetration depth of 5 mm in patients with darker skin.

The previous flap-monitoring protocol in use consisted of the patient spending the first night following surgery in the post anesthesia care unit and having the flap monitored through clinical observation by the nursing personnel every hour. The patient spent the next 2 days in a nursing unit staffed with trained personnel who clinically monitored the flap every 2 hours. Intermittent evaluations by house staff and the attending were also performed. All surgeries were performed by the author. All patients had perforating vessels marked the night before surgery with a unidirectional handheld 8-MHz Doppler in the manner described by Blondeel et al.¹³,¹⁵

During the study, attempts were made to monitor the flap with the T.Ox device beginning in the operating room and extending through the first 2 postoperative days via the T.Ox sensor affixed to the exposed skin island (Fig. 2). Caution was taken not to place the monitoring sensor directly over a previously marked perforator since placement directly over a vessel could limit the relevance of the data to the oxygen level in the vessel itself, as opposed to detecting broader information regarding the end perfusion of the surrounding flap tissue. Initially, readings were taken from all 4 zones of the flap, or the ipsilateral, medial, and lateral ends of the flap in a bilateral reconstruction. Since some of these areas of tissue were either discarded or buried intraoperatively, a switch was made early in the study to monitor zone 1 tissues only. The exposed skin island replaced, at the very least, the nipple areolar complex. In some instances where the monitor and/or sensor were unavailable, the flap was not monitored with the device during a portion of the study. Additionally, if the sensor limited visibility during a portion of the surgery, it was removed. The intense focused light from the overhead operating light can interfere with the performance of the device and make continuous monitoring of the flap during portions of the procedure impossible. Finally, because during this study the nursing staff were instructed only to allow the monitor to run, and not instructed in the actual operation of it, data was lost due to power interruptions and dislodging of the sensor.

FIGURE 1. ViOptix T.Ox Tissue Oximeter (ViOptix Inc., Fremont, CA) and adhesive sensor.

FIGURE 2. ViOptix T.Ox single patient use adhesive sensor (ViOptix Inc., Fremont, CA) affixed to exposed skin island.
FIGURE 3. Normal flap physiology when the flap is in (A) the operating room and (B) the recovery room. Note: the dark blue curve on the top of each figure corresponds to the StO₂ measurement data, the red curve corresponds to the running average of the StO₂ and the blue curve in the bottom represents the StO₂ drop rate (in StO₂% units per hour).

FIGURE 4. Flaps with complication: A, venous congestion; B, an initial vessel kink; and C, a subsequent vessel kink.
RESULTS

No flap being monitored was lost in this study. Among the 208 flaps monitored, 5 patients exhibited complications that were predicted by the tissue oximeter before clinical signs were evident. This allowed for expeditious flap salvage. A total of 8 additional surgeries were performed for vascular problems:

- Two hematomas (1 without vascular compromise, 1 with compromise).
- Four venous (1 superficial vein thrombosis, 1 superficial vein kink, 2 deep vein thromboses).
- Two arterial thromboses.

For a typical flap with no complications, the $\text{StO}_2$ value will drop from its baseline when flap is elevated and divided and then following revascularization the $\text{StO}_2$ value will increase and return to its baseline, as shown in Figure 3A. After the surgery is complete, the $\text{StO}_2$ values remain at a stable level, as shown in Figure 3B.

### TABLE 1. Diagnostic Accuracy

<table>
<thead>
<tr>
<th>Criterion</th>
<th>$\text{StO}_2 \leq 30%$ and $\Delta \text{StO}_2/\Delta t \geq 20%$/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>True positive (a)</td>
<td>4 + 3*</td>
</tr>
<tr>
<td>False positive (b)</td>
<td>0</td>
</tr>
<tr>
<td>False negative (c)</td>
<td>0</td>
</tr>
<tr>
<td>True negative (d)</td>
<td>201</td>
</tr>
<tr>
<td>Sensitivity (a/[a + c])</td>
<td>100%</td>
</tr>
<tr>
<td>Specificity (d/[b + d])</td>
<td>100%</td>
</tr>
<tr>
<td>PPV† (a/[a + b])</td>
<td>100%</td>
</tr>
<tr>
<td>NPV‡ (d/[c + d])</td>
<td>100%</td>
</tr>
</tbody>
</table>

*These 3 cases are represented by the green “x” symbols shown in Figure 6A. For these cases, the criteria were not fully satisfied at the time of early intervention. These 3 cases are considered true positives for reasons explained in the text.

†Positive predictive value.

‡Negative predictive value.

FIGURE 5. Trend curve of $\text{StO}_2$ for a patient with arterial compromise.

FIGURE 6. A, $\text{StO}_2$ and its drop rate can be combined to indicate possible hypoxia in a flap. All flaps with $\text{StO}_2 \leq 30\%$ and $\Delta \text{StO}_2/\Delta t \geq 20\%$/hr sustained for more than 30 minutes were flaps with complications (Region IV in B).
One patient (patient 024) experienced 3 flap complications in series: the development of venous congestion during the initial surgery (Fig. 4A), a thrombosis of the superficial vein after a second anastomosis was performed to resolve this venous congestion (Fig. 4B), and a second kink of the superficial vein. Because of confidence in the fall in StO₂ gained from the second event with this patient, the decision to reoperate the third time was made on a falling StO₂ before there was clinical evidence of flap compromise.

Patient 58 started to have arterial compromise at the time of the initial surgery that went clinically unrecognized (Fig. 5). The tracing after the completed anastomoses failed to show the expected upward trend in StO₂ (Fig. 3A). When the patient was extubated and brought to the recovery room the StO₂ fell slightly and this reflected the lower oxygen level in the blood as measured on the pulse oximeter. When the problem was recognized the patient was taken back to the operating room and the arterial anastomosis was redone.

DISCUSSION
StO₂ and its drop rate are 2 hypoxia indicators used simultaneously in flap monitoring. The drop rate indicator ($\Delta StO₂/\Delta t$), when it is equal to or greater than 20% per hour sustained for more than 30 minutes, predicted vascular complications (Fig. 6; Table 1).

The diagnostic accuracy of the tissue oximeter is significantly high in this study, with no false negatives or false positives encountered. The $P$ value given by Fisher exact test is less than 0.001.

Five patients had StO₂ levels that came close to, but did not drop below 30%. There are normal physiologic events that can cause the StO₂ to fall. We hypothesize that included in that group are position changes of the flap related to the patient being upright or supine, microemboli, and perhaps partial kinking of a vessel. We know that the StO₂ in a finger will fall and rise if a finger is raised above the head or lowered well below the heart. Nasal oxygen will cause an elevation of the StO₂ of 5% to 10% despite only modest or no change in oxygen saturation on the pulse oximeter. As shown in Figure 7, the patient experienced a physiologic event, the cause of which remains undetermined. The flap appeared mottled, but not blue for 2 hours which caused concern, but without clinical information suggesting a thrombosis. The flap recovered without any intervention as did the StO₂ that dropped during that interval.

Another patient in this group went into a rapid supraventricular tachycardia that did not respond to multiple rounds of intravenous medications, as shown in Figure 8. She deteriorated and required CPR followed by emergent cardioversion which resulted in a normal sinus rhythm and a return of the StO₂ to normal.

The pattern of StO₂ and Hgb (where Hgb is the concentration of hemoglobin in a volume of tissue beneath the sensor) are altered in a compromised flap. If blood flow was completely occluded by either venous or arterial thrombosis, a diagnosis could be made in about 1 hour. The StO₂ will fall to ≤30% and the drop rate will exceed ≥20%/h. The example in Figure 9A is of a DIEP flap that was not elevated or needed and had the vein clamped. Figure 9B is a DIEP flap that was not elevated or needed that had the artery clamped. These graphs depict pure vessel occlusion with known start times of the event.

FIGURE 7. A, The flap island. B, The StO₂ changes measured during the event.

FIGURE 8. A drop in StO₂ was measured in a patient experiencing supraventricular tachycardia in which cardiac output was reduced.
CONCLUSIONS

The use of the new diagnostic algorithm with the T.Ox Tissue Oximeter (ViOptix, Inc., Fremont, CA) used postoperatively was successful in predicting flap complications within 1 hour of the onset of the occlusive event with a high diagnostic accuracy in the 208 flap procedures. Further, the tissue oximeter provided accurate quantitative information that enabled the detection of vascular complications before they were noticeable through clinical observation. Typically, when flap complications are observed clinically, it is often too late to successfully salvage the flap. The use of the tissue oximeter ensures that flap complications are recognized early enough to allow for the possibility of flap salvage.

Similarly, in the Repez et al study,16 continuous-wave near infrared spectroscopy (NIRS) monitoring was found to reliably detect and identify early stages of arterial and venous thrombosis, and was seen as a credible method for noninvasive postoperative flap surveillance. In the study, 10 flaps (20%) developed 13 anastomosis thromboses (2 arterial and 11 venous). As in our study, NIRS detected all cases of flow failure prior to clinical observation with no false positives or negatives. Consistent patterns of NIRS parameter changes made it possible to differentiate between changes caused by arterial and venous thrombosis with significant accuracy before surgical intervention. In that study, the salvage rate was 70%, and overall flap viability was 94%.16 In our study, no flap being monitored with the tissue oximeter was lost.

The implantable Doppler has shown utility in making real-time assessments of the venous outflow before definite clinical changes became apparent, and this led to early surgical intervention and flap survival. Yet, due to the invasive nature of the implantable Doppler, dislodgement of the probe has led to false-positive surgical explorations.17 Malfunctions have also been reported with the use of this device.5,6

The study of tissue oximetry using the T.Ox Tissue Oximeter for free flap monitoring shows this technique to be safe, reliable, and noninvasive with a high degree of diagnostic accuracy and specificity in this study of 208 free flaps. Based on the findings, the use of the T.Ox Tissue Oximeter for the monitoring of free flaps is advocated.

REFERENCES