Non-invasive Tissue Oximetry for Flap Monitoring: An Initial Study

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ABSTRACT

The ideal monitoring tool to evaluate free flap success should be noninvasive, continuous, and reliable. A new device, the ViOptix Tissue Oximeter (ODISsey™) based on near-infrared spectroscopy was evaluated in 30 patients undergoing autologous tissue perforator free flap breast reconstruction with continuous monitoring of the flap during elevation, transfer, and the postoperative period. The device accurately reflected the ischemic drop in oxygen saturation during flap transfer, and the hyperemic response after flow was reestablished. There were no flap failures, but in two patients, the device indicated a venous thrombosis before it was clinically obvious and allowed for expeditious flap salvage. The noninvasive nature of the device, the ability to replace and move the probe in the postoperative period, and the measurement of end organ oxygenation are all advantages over other currently available techniques.

KEYWORDS: Noninvasive flap monitoring, near-infrared spectroscopy

Loss of a free flap is a devastating experience to both the surgeon and the patient. Thrombosis rate of free flap surgery has improved over time and now is reported to be 10% or less.1–4 Typical causes of thrombosis are related to anastomotic errors, kinking of the vessels, compression of the vessels either related to a tight closure or hematoma, and thrombosis secondary to various coagulation disorders. Salvage rates for anastomotic thromboses are 50% or better and are directly related to the amount of time that elapses from the event to the correction.1–5

Early in the era of microsurgery, flap monitoring was performed with only clinical observation of skin color, capillary refill, and dermal bleeding. Although this is still the benchmark, issues related to staffing and to the occasional difficulty of making a clinical determination of a flap’s perfusion have led to the search for more objective methods.6–9 Techniques that have been used and are still in use 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 techniques are external Doppler monitoring, implantable Doppler monitoring, and assessment of cutaneous blood flow using laser Doppler flowmetry.7,8 The limitation of the external Doppler is directly related to the ability to access the recipient vessels. The implantable Doppler provides continuous direct monitoring of anastomotic patency with nearly instantaneous feedback on arterial and venous patency. The cost associated with the disposable probes and the fact that it is invasive are limiting factors. Laser Doppler flowmetry, although noninvasive, is restricted because its effectiveness depends upon the experience of personnel for interpretation.2 Ideally, the laser Doppler, or any monitor, should flag hemodynamic

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deterioration prior to clinical manifestations. Improvements in tissue oximetry have made this technique more reliable but not for the monitoring of cutaneous flaps.

Limitations of the currently available monitors and the limited availability of reliable personnel for clinical flap monitoring prompted the study of the ViOptix ODISsey™ Tissue Oximeter (ViOptix Inc., Fremont, CA; Fig. 1) as a possible adjunct or replacement of the clinical monitoring protocol currently in place at Long Island Jewish Hospital.

MATERIALS AND METHODS
From January 26, 2005 to September 14, 2005, 30 patients undergoing autologous tissue perforator free flap breast reconstruction were enrolled in the study. Two additional patients refused to participate. All patients were given informed consent and enrolled in a protocol approved by the Institutional Review Board at Long Island Jewish Hospital in New Hyde Park, New York. The monitoring study was in addition to the clinical monitoring protocol already in place. Limitations of the monitor restricted data collection to a single flap in patients undergoing bilateral reconstruction.

The monitoring device under investigation is the ODISsey™ Tissue Oximeter Inc, manufactured by ViOptix, Inc. The ODISsey™ Tissue Oximeter measures tissue oxygen saturation. The ODISsey™ uses an optical tissue characterization based on measuring scattering and absorption of near-infrared light, which is related to the oxygen content of the hemoglobin in that particular tissue. Light scattering occurs in tissue and therefore characterizes 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 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 important for the prediction of venous insufficiency.

The ODISsey™ device utilized consisted of a single channel with a sensor connected to a console by means of a fiber-optic cable. The console contained a computer that processed, displayed, and recorded the collected data.

The continuous monitoring probe had a sensor patch that was rectangular in shape and had a measuring surface area of 5 × 5 mm. The device was configured with four photo detectors and two laser light sources. The measuring depth for this sensor was between 0 and 5 mm.

The flap-monitoring protocol currently in place consists of the patient spending the first night after surgery in the postanesthesia care unit and having the flap monitored clinically by nursing personnel every hour. The next 2 days are spent in a nursing unit with trained personnel who monitor the flap clinically every 2 hours. Intermittent evaluations by house staff and the attending are also performed. All surgery was 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 and colleagues. During the study period, an attempt was made to monitor the flap with the ODISsey™ device beginning in the operating room and extending through the first 2 days postoperatively. Care was taken to not place the monitoring probe directly over a marked perforator. Placement of the probe directly over a vessel could interfere with the data because the ODISsey™ device was designed to measure tissue O2 saturation and not the O2 saturation in a blood vessel. Initially, readings were taken from all four zones of the flap or the ipsilateral medial and lateral ends of the flap in a bilateral reconstruction. Because most of these areas were either eliminated or almost never exposed postoperatively, the switch was made early in this study to monitor only zone 1. The exposed skin island, at the very least, replaced the nipple areolar complex.

In some instances where the monitor and/or probe was unavailable, the flap was not monitored with the device during a portion of the study. If the probe was in the way during a part of the surgery, it was removed. Light from the overhead operating light interfered with the performance of the device and made continuous monitoring of the flap during portions of the procedure impossible. Lastly, because nursing personnel was instructed to only allow the monitor to run and not instructed in the operation of it, data was lost due to power interruptions and dislodging of the probe.

RESULTS
There were no flap losses in the study group. There were three returns to the operating room because of
Figure 2  Ischemic interval during flap transfer shows drop in tissue $O_2$ saturation followed by rapid increase in the $O_2$ tissue saturation upon revascularization.

Figure 3  (A) In this patient, the reactive hyperemia after revascularization is shown. (B) There was a gradual decline in tissue $O_2$ over the first postoperative day. (C) The tissue $O_2$ saturation levels continued to declined to nearly pretransfer values on the second postoperative day.
thrombotic anastomotic events. Two of these events, both in the same patient, occurred to only one of the two venous anastomoses.

The ischemic period during which the flap was transferred was reflected by a fall in the oxygen saturation of the flap (Fig. 2). After the flap was revascularized, the oxygen saturation increased. The reactive hyperemia after revascularization was characterized by a rise in tissue oxygen saturation. In the postoperative period, tissue oxygen varied over time; however, in general, there was a decline to a resting value (Fig. 3). This value was not necessarily the same as the pretransfer value (Fig. 4). This case demonstrates a larger drop in O2 saturation than was usually found. Clinically the flap appeared healthy and therefore, no intervention was undertaken. The drop in O2 saturation from the value after the transfer may represent the decline from the reactive hyperemia as well as the removal of the supplemental oxygen.

In the two instances of venous congestion observed in the operating room, the time interval of measurement was too short to observe a significant tissue oxygen saturation (StO2) drop (Figs. 5 and 6). A rise in the oxygen saturation after the flap was revascularized was noted. Although the ODISsey™ device does not monitor tissue hemoglobin level, a rise in tissue hemoglobin would be expected. This has been demonstrated to represent venous insufficiency.13 The situation was corrected with an anastomosis of the superficial venous system to increase flap drainage. During this interval, the probe was removed because it was in the way, but when it was reapplied, the O2 had risen. This continued throughout the monitoring period.

Another flap became mottled in the early postoperative period. Clinically there appeared to be a light blue mottling over a pink background. Capillary refill and bleeding on pinprick were normal. Soon after this was observed, the O2 saturation in the flap fell, as shown in Fig. 7, but the appearance of the flap did not change. In a few hours the clinical flap appearance improved as did the O2 saturation, and then the O2 saturation continued to remain in the preflap elevation range. It is unclear if this represents a small kink or compression of the vein that resolved on its own, microemboli, or normal variations in flap perfusion.

In two instances, there was a venous thrombosis in the postoperative period. In one case, the superficial vein, which was a second venous drainage, kinked and thrombosed. This was reflected as a drop in oxygen saturation, as shown in Fig. 8, which was present before the flap took on a more congested appearance. With a return trip to the operating room, the anastomosis was revised and the tissue oxygen improved. Shortly thereafter the tissue oxygen fell again. The flap did not appear to have increased congestion, but based upon the previous findings the patient was returned to the operating room. Again the secondary vein was thrombosed and the anastomosis was revised. Tissue oxygen increased and the patient had an uneventful recovery from this point with no fat necrosis in the flap.

The other patient with venous thrombosis had a precipitous drop in tissue oxygen saturation with only a mild color and slight decrease in capillary refill time to the flap. In fact, the physician was called to fix the monitor because the oxygen saturation reading on the monitor was almost zero (Fig. 9). Prompt return to the operating room also salvaged this flap. In retrospect, the venous thrombosis probably occurred during transfer from the postoperative care unit to the nursing floor.

DISCUSSION

The ideal flap or replant monitor should provide continuous noninvasive monitoring of perfusion or flap metabolism with rapid detection of arterial or venous occlusion. Tissue oximetry is the only way to measure
end organ perfusion. Although a pulse oximeter also operates using near-infrared spectroscopy, this device measures oxygen saturation in the arterial system and not oxygen delivered to the tissue (personal communication, Jian-min Mao, Ph.D. and Mohamod Elmandjra, Ph.D., September 2005).

The ODISsey™ (ViOptics, Inc., Fremont, CA) measures tissue oxygen saturation. Although the device records the information to a Windows™-based computer, “trending” of the data are not analyzed. It would be useful to follow the slope of the drop in the oxygen saturation level as an indicator of anastomotic problems. As pointed out with the laser Doppler, “trending” adds to the usefulness of the information obtained. Furthermore, with the addition of telephone and Internet to a computer-enabled monitor such as the ODISsey™, senior personnel could more closely follow a flap.

Figure 5 After anastomosis of the deep inferior epigastric artery and vein, this flap showed clinical signs of venous congestion despite patent anastomoses.

Figure 6 (A) This is the tissue O₂ saturation from the patient in Fig. 5. The superficial vein had been dissected for a distance and divided during flap elevation. Despite the increase in O₂ saturation after revascularization, the flap appeared congested. (B) The probe was removed to facilitate repositioning of the flap and anastomosis of the superficial vein to the mammary system for increased drainage. After the second venous anastomosis, the probe was replaced. The clinical appearance of the flap and the O₂ saturation improved. (C) The O₂ saturation continued to remain close to pre-elevation levels in the postoperative period.
In the venous occlusion or hypertension scenario, the capillary bed dilates, filling up with blood, while arterial inflow continues.\(^5\) A decrease in tissue oxygen saturation was not noted in the operating room in the case where the flap was congested and needed additional venous drainage probably because the time interval to see this was not long enough. Although one would expect tissue oxygen saturation to approach zero with ischemia, to be useful, the device must reflect the ischemic event with sufficient time available for successful salvage of the situation. That was the situation in the last case shown in Fig. 9 and led to a successful outcome.

In the case shown in Fig. 6, the venous insufficiency was observed clinically and intervened on while the \(O_2\) was still decreasing but was not yet a sole indicator of venous congestion. \(StO_2\) had decreased by \(\sim 20\%\) when the measurement was stopped for intervention. It has been reported\(^{13}\) that the restricted venous return could cause accumulation of the oxygenated hemoglobin. Using the CRITIKON\(^\text{TM}\) (Cerebral Redox Research Monitor Model 2001, Johnson and Johnson Medical Ltd, Ascot, Windsor and Maidenhead, UK), which is also a near-infrared spectroscopy monitor, the report showed an immediate increase in the total hemoglobin concentration when venous occlusion was performed in experimental animals. The explanation for the increase in total hemoglobin concentration is due to the accumulation of the oxygenated hemoglobin from the restricted venous return.\(^{13}\)

The lack of easily discernible venous change in a flap as evidenced by changes on the monitor is a problem with many of the flap-monitoring techniques. The clinical signs of venous insufficiency are often recognized late. In this series, the one case of complete venous thrombosis and the resultant fall in tissue oxygen saturation led to operative intervention and a successful outcome. Kamolz
and colleagues reported that with continuous free flap monitoring of tissue oxygen, a decrease in tissue oxygen was rapidly noted with arterial occlusion. However, the decrease in tissue oxygen occurred more slowly with venous insufficiency. Serial quantitative skin surface fluorescence is a technique that also has difficulty identifying venous occlusion solely on the basis of the fluorescence measurements. In an experimental study of tissue oxygen tension, the decline with venous insufficiency was less than that with arterial insufficiency. Of note was that with the use of the ODISseyTM monitor, the diagnosis of thrombosis of one of the two venous anastomosis was able to be made (Fig. 6).

The implantable Doppler has proved useful in making real-time assessments of the venous outflow before definite clinical changes became apparent. This has led to early operative intervention and flap survival. Because of the invasive nature of this device, dislodgement of the probe has led to false-positive explorations.

Normal variations in tissue oxygen and the relatively slow fall in the value of tissue oxygen during an ischemic or venous congestion interval currently are limiting factors in the use of the ODISseyTM monitor for flap monitoring. Adding “trending” of the tissue oxygen saturation to the monitor would improve the ability to detect problems before they are reflected in a significant decrease of the O2 saturation. Specificity and sensitivity have been evaluated for the laser Doppler and thermography. Software changes in ODISseyTM have corrected early problems with specificity of the tissue oxygen saturation readings.

Based on preliminary analysis of the limited number of patients studied, we feel confident that a

**Figure 8** This patient had thrombosis of the superficial (second) venous anastomosis. (A) During the first postoperative day, the tissue O₂ saturation fell. This decrease in the tissue O₂ saturation began before the flap took on a more congested appearance. (B) After revising the thrombosed venous anastomosis and returning to the recovery room, the tissue O₂ saturation rapidly fell without any change in flap appearance. The patient was returned to the operating room where the venous anastomosis was found to be thrombosed. It was again revised. (C) After the second revision of the venous anastomosis, the tissue O₂ saturation remained elevated above the pretransfer level for the next 36 hours.
tissue oxygen saturation reading of 30% or less requires operative correction. Because there is limited experience following tissue O2 saturation after free flap transfer, the variations in the O2 saturation must be interpreted with the clinical picture until more knowledge is gained. Further investigation and better software evaluation in real time for “trending” will overcome the limitations of this device. Lack of “normal” values made it initially difficult to rely on the ODISsey™ monitor; however, with our experience we now use it routinely with confidence for monitoring of exposed flaps.

REFERENCES
