

WHITE LIGHT SPECTROSCOPY FOR FREE FLAP MONITORING

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White light spectroscopy non-invasively measures hemoglobin saturation at the capillary level rendering an end-organ measurement of perfusion. We hypothesized this technology could be used after microvascular surgery to allow for early detection of ischemia and thrombosis. The Spectros T-Stat monitoring device, which utilizes white light spectroscopy, was compared with traditional flap monitoring techniques including pencil Doppler and clinical exam. Data were prospectively collected and analyzed. Results from 31 flaps revealed a normal capillary hemoglobin saturation of 40–75% with increase in saturation during the early postoperative period. One flap required return to the operating room 12 hours after microvascular anastomosis. The T-stat system recorded an acute decrease in saturation from ~50% to less than 30% 50 min prior to identification by clinical exam. Prompt treatment resulted in flap salvage. The Spectros T-Stat monitor may be a useful adjunct for free flap monitoring providing continuous, accurate perfusion assessment postoperatively. © 2012 Wiley Periodicals, Inc. *Microsurgery* 00:000–000, 2012.

Free flap reconstruction has become an integral part of the care of patients with breast cancer, head and neck cancer, and limb salvage after trauma. Free tissue transfer requires that new arterial and venous anastomoses be created at the site of reconstruction. If either the arterial or venous connections fail, the flap will die. The incidence of reoperation ranges from 2% to nearly 9% of all free tissue transfer cases.^{1–3} Free flap breast reconstruction has a slightly lower rate of failure,^{4,5} whereas head and neck reconstruction has a rate slightly higher.^{3,6,7} Occlusion of the venous anastomosis is the most common complication, leading to venous congestion and tissue injury.⁸ Despite increasing success rate, with more experience, any surgeon can have a flap that develops signs of vascular occlusion, which necessitates surgical intervention. About one quarter to one half of flaps can ultimately be salvaged with current clinical monitoring and early detection of compromise.^{6,7,9}

Because of the potential for flap failure and the ability to salvage the flap if complications are recognized early, monitoring of free flaps has become an integral part of the overall success rates for microvascular surgery. Flap salvage is highly dependent on time to diagnosis, and therein lies the opportunity for technology to improve patient outcomes.^{4,8,10} The longer the delay, the more tissue loss that occurs and the lower the success rate of intervention; conversely, an earlier detection leads to reduced loss. Several methods are used to test for perfusion, but all have clinically failed at one time or another.

The majority of surgeons use the pencil Doppler and clinical examination for flap monitoring.^{11,12} However, interest in other methods to complement, or even replace, clinical exam and Doppler monitoring are increasing in popularity. Multiple studies have examined the reliability of alternative monitoring systems including the implantable Doppler, near-infrared spectroscopy (NIRS), and indocyanine green injections.^{13–17}

Our study investigates the use of visible white light spectroscopy (VLS) for free flap monitoring. White light spectroscopy is a relatively new technology that non-invasively measures hemoglobin saturation at the capillary level; thus, it can render a true end-organ measurement of tissue perfusion. We hypothesize that by virtue of the ability of the device to identify immediate changes in flap perfusion, that it could be used as an effective post-operative monitor in microvascular surgery by allowing for early detection of ischemia and thrombosis.

METHODS

Patients undergoing microvascular free flap reconstruction at a single institution over a 16-month period were eligible for inclusion in our study with Institutional Review Board approval. Inclusion criteria included undergoing free flap reconstruction with a flap containing a skin paddle to which the probe could be attached. Exclusion criteria included an allergy to adhesive. The Spectros (Portola Valley, CA) T-Stat monitoring device uses a small monitoring probe that emits a cool white light that can be attached to the surface of the flap after microvascular anastomosis. The different spectroscopic properties of hemoglobin are leveraged to measure the relative amounts of oxygenated and deoxygenated hemoglobin. StO₂% is defined as the percentage of total hemoglobin in the oxygenated form and tissue oximetry readings are displayed in real-time. The detection of blood flow occurs at the capillary level. The monitor and probe are shown in Figure 1.

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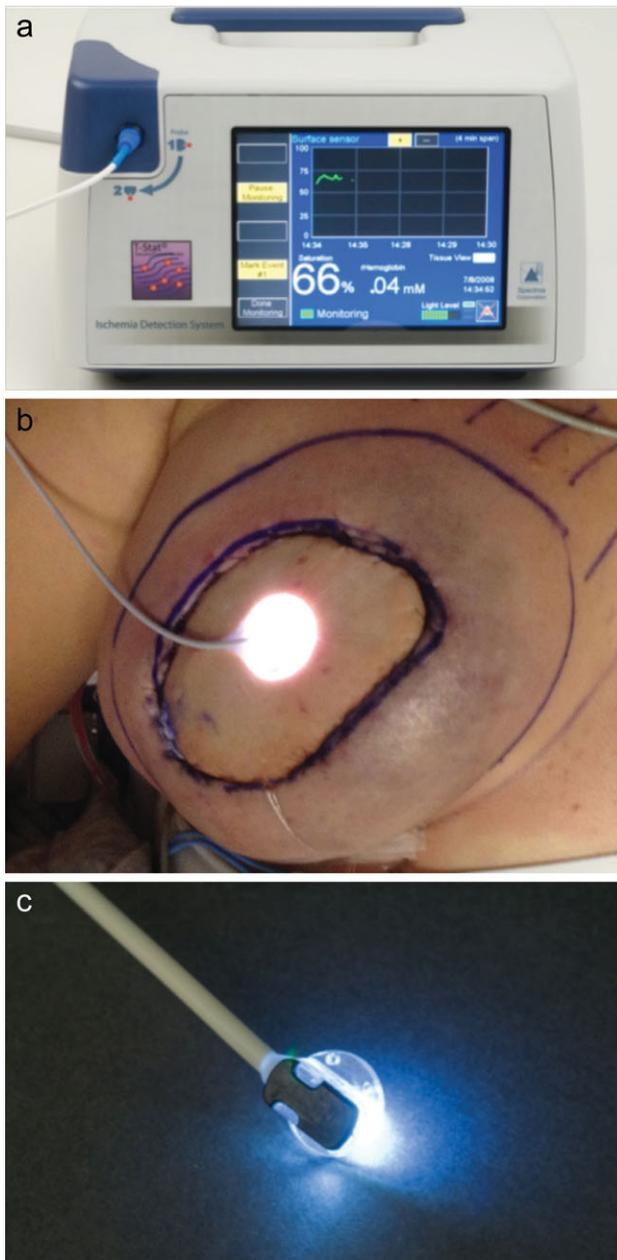


Figure 1. The Spectros (Portola Valley, CA) T-Stat (a) monitor, (b) 2.5 cm probe with self-adhesive backing on breast flap, (c) small 1 cm probe lit. Photos courtesy of Spectros Corporation. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

The T-Stat probe was placed on the skin paddle of the flap immediately following surgery. Recordings began upon placement of the probe and continued for 3–5 days postoperatively depending on patient condition or discharge. Disruptions occurred when the monitor was unplugged for patient transport or ambulation.

All patients are sent to a specialized flap monitoring unit for at least 48 hours postoperatively. All staff on the

Table 1. Types of Free Flaps and Number Monitored

Flap	Number
Muscle sparing-TRAM	18
Deep inferior epigastric artery	8
Tensor fascia lata	2
Free-TRAM	1
Gracilis	1
Radial forearm	1
Superior gluteal artery perforator	1

TRAM, transverse rectus abdominus myocutaneous

unit have been trained in clinical flap assessment. The senior author's standard protocol for flap monitoring was used in addition to the T-Stat. This includes timed assessments (every hour for the first 24 hours, then every 2 hours for 48 hours, and every 4 hours until discharge) by the nursing staff with pencil Doppler and clinical assessment of flap color, capillary refill, and temperature. Nursing staff were instructed in the use of the T-Stat but instructed to use the Doppler and clinical assessment only in flap evaluation. The T-Stat was considered experimental as its reliability was under investigation during the study period.

Patient data, complications, reoperations, flap failures, oximetry readings, and outcomes were prospectively collected. Patients were excluded from the study if at least 48 hours of data were not collected or if there were breaks in data collection for greater than 2 hours.

RESULTS

Over a 16-month period, 35 patients met inclusion criteria and agreed to participation. Nine patient data sets, 22% of 41 data sets, were excluded due to incomplete data acquisition (e.g., monitor malfunction, accidental probe disconnection). Twenty-seven patients and thirty-two data sets were included in the study. Twenty-six females and one male participated in the study. The average age of participants was 48-year-old. The types of flaps monitored can be seen in Table 1. Thirty-one flaps were utilized for breast reconstruction while one flap was monitored after head and neck reconstruction. Twenty females underwent bilateral breast reconstruction while eight participants required left breast reconstruction and three required right-sided reconstruction. The average tissue oximetry readings can be seen in Figure 2. Data analysis revealed that the normal capillary hemoglobin saturation reading is 40–75%. There is a gradual increase in saturation in the early post-operative period, likely reflecting the physiologic changes associated with ischemia–reperfusion after microvascular flap surgery.

During the study period, one flap returned to the operating room for a change in clinical exam noted in the early postoperative period. Twelve hours after microvascular

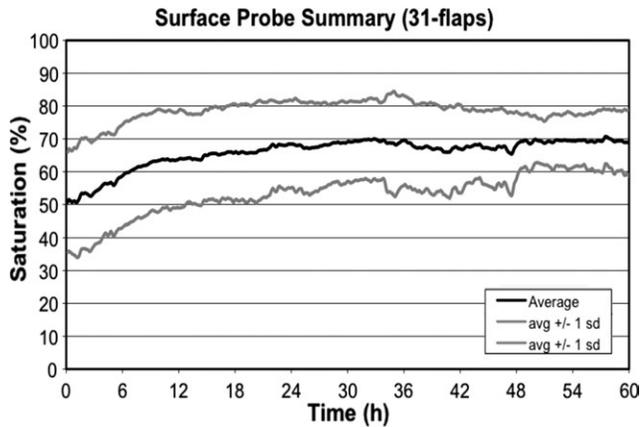


Figure 2. Data collected from monitoring of 31 successful free tissue transfers. Time 0 = time of probe application at conclusion of the case. The black line represents the average StO₂%. The gray lines represent one standard deviation above and below the average value at each time point.

anastomosis, an acute decrease in saturation from ~50% to less than 30% occurred. The T-Stat probe identified vascular compromise 50 min prior to identification by clinical exam and pencil Doppler. Prompt treatment of venous congestion by anastomotic revision resulted in successful salvage of the flap. The tissue oximetry curve from the immediate postoperative period can be seen in Figure 3. After flap salvage, spectroscopy readings showed gradual increase in perfusion and return to normal levels.

DISCUSSION

Early identification of vascular compromise after free flap surgery directly correlates with salvage rates.^{3-5,8} Monitoring with clinical exam is the gold standard but is not continuous. In our study, the use of visible white light spectroscopy allowed continuous monitoring and demonstrated accurate detection of early compromise of blood flow after free tissue transfer.

Visible Light Spectroscopy (or VLS) was introduced this decade to take advantage of improvements in light sources and detectors since the first commercial NIRS devices were introduced. By using visible light, which is absorbed by hemoglobin 100 times stronger than infrared light, and by using broadband light with thousands of wavelengths of light, multispectral VLS offers a more robust capillary tissue oxygenation assessment. Conceptually this allows VLS to respond to smaller changes in tissue oxygenation and to respond more rapidly.

VLS technology has been used in gastroenterology and surgery applications with success. Friedland et al. demonstrated the ability to detect changes in colonic mucosal oxygenation using VLS before and after vascular stenting in chronic mesentery ischemia patients.¹⁸ In 2006, Amir et al. described their experience with VLS in

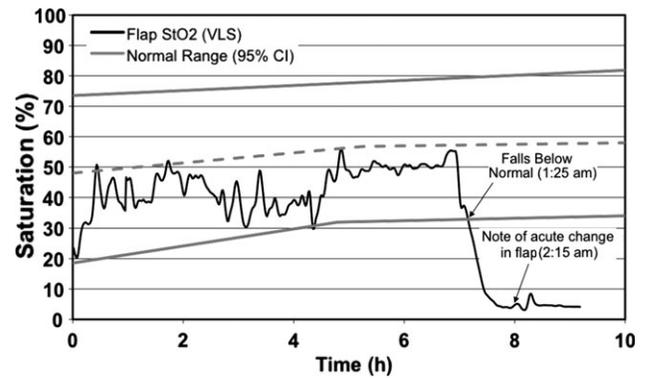


Figure 3. Data collected during monitoring of one free flap used in breast reconstruction that demonstrated flap compromise and required return to the operating room for exploration. The black line is data collected from the compromised flap. The dashed gray line is the mean percent StO₂ in viable flaps and the solid gray lines represent one standard deviation above and below mean percent StO₂ values.

detection of cerebral blood flow during circulatory arrest mimicking conditions seen by the brain during cardiopulmonary bypass.¹⁹

Conceptually, the application of VLS technology to microvascular surgery seems advantageous as the ability to capture capillary perfusion is essential to the effectiveness of the operation. Initial use of VLS technology in microvascular surgery has recently been examined and published. Cornejo et al. described their experience using the Spectros T-Stat system to monitor 12 free flaps.²⁰ During the study period there was one flap failure accurately diagnosed by the Spectros system prior to loss of implantable Doppler or clinical evidence of decline. Whether early recognition would have enabled flap salvage is unknown as the patient in their report was unstable for return to the operating room.

Our study provides further evidence for the applicability of VLS in free flap surgery with a larger study group. While the product achieved its purpose of continuous, accurate flap monitoring during our investigation, we found that there is a learning curve involved with the use of the device which requires elements of patience and practice. Prior to initiation of the study, physicians and nursing staff were trained in the use of the monitor and probe. Physicians were also instructed in the application of the probe, data acquisition, data storage, and basic data analysis. After experimentation with the 1-cm probe, which occasionally led to unreliable readings due to probe motion, we ultimately opted for the larger skin probe (2.5 cm) having the advantage of a self-adhesive layer on the underside of the probe. This eased application and kept the probe a defined distance away from the skin thus improving monitoring consistency.

The day-to-day use of the probe and monitor was generally without complication. The data acquisition, storage,

and retrieval were also simple. Minor problems were encountered with patient transport as the monitor does not have a battery back-up and therefore must be unplugged and restarted at each new location. The fiber optic cable is 2 m long, which is sufficient length to allow the patient to get out of bed to a chair and move about in bed as needed. When the patient begins to ambulate, however, the probe can become dislodged. On most occasions the probe simply pulled off the patient, but occasionally the cable broke from the monitor. Both of these events ended flap monitoring, as probes are single use. Modifications in the design based on our experience are underway. Despite this learning curve, both nursing staff and physicians subjectively felt the T-stat improved flap monitoring by confirming clinical exam findings.

In comparison to other available adjuncts to clinical assessment of free flaps, VLS offers the advantage of detecting not only whether flow is present, but also whether adequate perfusion is present. Both the pencil and implantable Doppler provide information on the presence of flow, but neither can indicate whether sufficient flow is present for flap viability. Additionally, the implantable Doppler detects flow at the anastomosis and not at the surface of the flap where perfusion is most critical. The implantable Doppler also has been criticized for a high false positive rate. Ferguson and Yu reviewed their experience with the implantable Doppler in 16 patients undergoing head and neck reconstruction with a buried flap.²¹ They noted a false-positive rate of 31%, leading to unnecessary surgical exploration.

Originally fluorescein injections were used to examine blood flow, but more recently ICG (Indocyanine green) injections have been employed to assess perfusion.¹⁷ ICG shows the presence of flow in the vessels at the time of the surgery with a shorter half-life than fluorescein allowing for repeat injections. However, like Doppler, this approach does not indicate the sufficiency of oxygen delivery. Additionally, this method is less practical for use outside of the operating room where most problems develop.

A widely studied modern technology has been near-infrared spectroscopy (NIRS), which measures deeply through tissue, assessing blood in veins as well as arteries. This technology is used in T.OxTM by ViOptix (Fremont, CA) which is marketed for use in perfusion monitoring of free flaps. In 2007, Keller reviewed his experience with NIRS in 30 patients undergoing free flap breast reconstruction.²² The device detected venous thrombosis before it was clinically obvious in two patients allowing flap salvage. Repez et al. noted accurate detection of thirteen anastomotic thromboses using NIRS.²³ Additionally, the team was able to differentiate between arterial and venous thromboses prior to surgical exploration with the data provided using the InSpectraTM

(Hutchinson Technology, Hutchinson, MN) system which employs NIRS technology. VLS offers an advantage over Doppler analysis as it detects whether adequate perfusion is present, but appears to be comparable to the NIRS system in that earlier detection of flap compromise seems to be possible.

Groups are now also interested in the role of flap monitoring away from the patient's bedside. This allows the clinician to feel confident in flap assessment despite not being physically present. Early results are promising.^{24,25} At the time of this writing, Spectros is developing an application to allow real-time monitoring of T-Stat data via handheld devices. ViOptix offers a similar product for wireless transmission of data.

The concern with any additional monitoring is the cost associated with the technology and its value. The Cook implantable Doppler costs approximately \$3500 for the monitor and \$500 per probe (Cook Medical, Bloomington, IN). The NIRS system costs approximately \$16,500 for the monitor while the probe costs \$150.¹⁴ In comparison, the estimated cost of T-Stat monitor is \$25,000 with each probe costing \$100 (Spectros Corporation). All prices vary based on hospital, location, and volume of purchase. Some studies have demonstrated the value of the implantable Doppler in buried flaps, but the question of whether newer technologies will ultimately save the health care dollars by increasing flap salvage rates remains to be answered.^{13,26,27}

There are limitations of this study as a complete assessment of the VLS technology and its application to plastic surgery. First, as mentioned above, the cost of the monitor and probes is a critical consideration. While the monitor has a significant upfront cost, the probe price is comparable to other single use devices on the market. As the crunch on health care dollars becomes more prevalent, the issue of whether the patient, insurance company, doctor or hospital pays each additional fee will become more salient. Because flap failure rates vary according to institution and from surgeon to surgeon, a large multicenter study would be required to assess a true value of the VLS technology in plastic surgery. Additionally, because flap failure rates were low in our study, a larger study would help determine whether all flap failures would be detected by VLS technology. VLS may be particularly useful for practitioners at lower volume centers where nursing staff may not be as accustomed to monitoring free flaps.

All of the flaps assessed in our study had an external skin paddle which allowed easy application of the self-adhesive probe. Whether the smaller probe, which can be sutured in place, would be practical for intraoral skin paddles requires further investigation. Additionally, we applied our probe to 31 flaps used for breast reconstruction and 1 flap used in head and neck reconstruction. A

study dedicated to the use of the VLS monitoring device in head and neck and extremity reconstruction would expand its potential applications.

CONCLUSIONS

The Spectros T-Stat system is a reliable continuous monitoring device with practical application to the monitoring of free tissue transfer. During our study, the device recognized flap decline 50 min before clinical assessment identified flap changes. In the field of microsurgical reconstruction, each minute is critical to flap salvage. With the Spectros T-Stat system, microsurgeons now have another tool to consider in improving flap monitoring. A multicenter randomized controlled trial is needed to fully assess the clinical utility of the multiple new technologies available for flap monitoring including VLS.

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