

ViOptix™ newsletter

ViOptix NEWSLETTER
SPRING 2009

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Microsurgery
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208 Flap
Study Results
Presented at
the American
Society
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Upcoming
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Introducing T.Ox™

T.Ox™ means Tissue Oximetry
and is the new brand name for
the ViOptix Tissue Oximeter.



T.Ox Remote Monitoring

See for yourself, wherever you are!

New wi-fi enabled T.Ox Tissue Oximeters are capable of wireless transmission of T.Ox data from the console to any internet accessible device including PDAs, smart phones and personal computers.

This exciting new technology provides you with a new level of confidence in flap monitoring and greater safety to patients, especially on general care floors, where nurse-to-patient ratios are lower than in more specialized units. T.Ox Remote will enable the staff to confidently decide when to call the surgeon. And you can view the data yourself before deciding if you need to see the patient immediately or have the OR prepped.

T.Ox Remote makes it possible for clinicians to identify flap distress earlier and initiate appropriate intervention more rapidly to improve patient outcomes.

T.Ox Remote is now up and running at leading US hospitals. To get started with T.Ox Remote, ask your ViOptix representative or call ViOptix toll free at 888.302.1790.



Using the T.Ox Tissue Oximeter in your Microsurgery Practice

The cost of not recognizing and intervening when a microsurgical flap has a vascular compromise can be significant, both in terms of patient outcomes and associated costs.

T.Ox helps you make a better informed decision about flap viability. Helping to reduce the occurrence of take-backs in microsurgical flap patients and intervening appropriately when a vascular compromise does occur can produce economic benefits.

T.Ox makes detection of vascular flap problems more efficient. By using T.Ox clinicians can quickly and easily assess the status of a microsurgical flap and monitor changes in perfusion status, thus facilitating more timely interventions to reduce patient risk and improve outcomes.

The T.Ox System uses near-infrared spectroscopy to provide continuous, real-time tissue oxygen saturation measurements that facilitate identification of flap complications before they become clinically evident.

The T.Ox System provides you with alerts in two key ways. First T.Ox provides you with a “number” which is the real time StO₂ reading that is updated every four seconds. Second T.Ox provides you with a trending graph which provides insight as to what type of problem exists, its onset, and its duration. You can also get this information at any time on your iPhone, BlackBerry or computer so you have the clinical confidence that comes from being able to see your patient’s flap monitor for yourself, wherever you are.

T.Ox also simplifies the monitoring of flap patients in a busy PACU or ICU and enables the general floor nurse to confidently decide when to call the surgeon.

A growing body of clinical experience shows that T.Ox tissue oximetry provides surgeons with better information to assist in determining the viability of a flap and the need for surgical re-exploration.

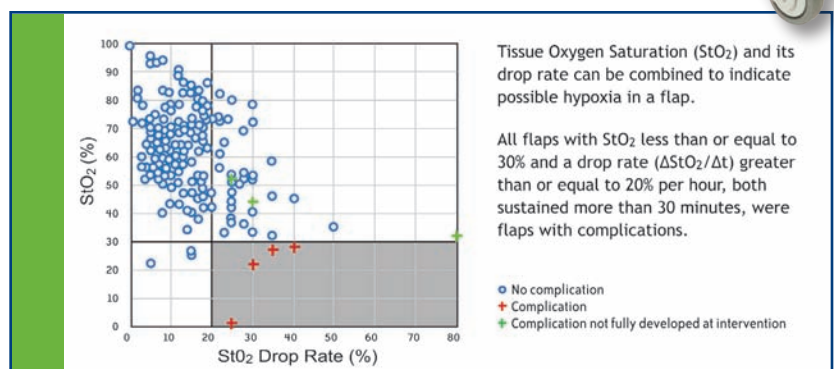


New T.Ox Features

Remote monitoring with T.Ox is now available. Now you can view T.Ox data from your patients from wherever you have access to a web browser, including your PDA or computer.

T.Ox DUAL lets you monitor two flaps with one console for more convenient monitoring of bilateral breast reconstruction patients.

Rate of Drop Alarm: Another important new feature is the rate-of-drop alarm. This clinically-validated¹ criterion helps you better identify flap compromise before it is clinically evident. In a recent 208 flap clinical study, two indicators of hypoxia, StO₂ ≤ 30% and its drop rate, were used simultaneously. All flaps with StO₂ ≤ 30% and a drop rate ≥ 20% per hour, both sustained more than 30 minutes, were flaps with



complications. The drop rate alarm has been incorporated into the latest software for the T.Ox Tissue Oximeter and provides you with an added level of confidence in flap monitoring.

¹A New Diagnostic Algorithm for Early Prediction of Vascular Compromise in 208 Microsurgical Flaps Using Tissue Oxygen Saturation Measurements, Alex Keller, MD, Presented at the American Society of Plastic Surgeons, November 2008.



Research Study Results Underscore the Efficacy of ViOptix T.Ox Tissue Oximeter for Microsurgical Flap Assessment and Monitoring

T.Ox has been clinically validated as evidenced by research studies conducted and presented at major conferences in 2008 and 2009.

At the recent annual meeting of the American Society for Reconstructive Microsurgery in Maui, Hawaii, research findings were presented by clinicians and scientists from leading institutions.

Comparison of T.Ox to Implantable Doppler

At the American Society of Reconstructive Microsurgeons (ASRM) in Hawaii in January 2009 Robert Lohman, MD from the Cleveland Clinic Foundation presented the results of a study "Methods of Free Flap Monitoring in a Non-Specialized Unit" comparing different methods of free flap monitoring: clinical and hand held surface Doppler examination by the routine nursing staff, Implantable Doppler, and Tissue Oximetry (ViOptix T.Ox). In this study of 38 free flap patients, T.Ox Tissue Oximetry detected complications first in all 5 out of 5 complications; T.Ox had no false negatives and no false positives and T.Ox identified flaps with vascular compromise one hour earlier than the internal Doppler. The researchers further concluded that T.Ox allows early transfer of patients to the floor and care by less experienced nursing personnel.

Pre-Operative Imaging with T.Ox

Risal Djohan, MD also from the Cleveland Clinic presented results of their study on pre-operative imaging and T.Ox in DIEP flap breast reconstruction.

T.Ox data was used to supplement information from CT Angiogram to help determine the selection of the optimal perforator or specific branches of perforators. T.Ox was also used to measure flap perfusion status at the donor site intraoperatively to help identify areas of greater or lesser perfusion in order to assist in trimming and shaping the flap.

The study concluded that T.Ox confirmed the findings of CTA and enabled more precise design and harvest of flaps, and may ultimately lead to flaps that are more reliable with potentially less risk of fat necrosis.

Detection and Classification of Perfusion Differences in a Partial Venous Obstruction Model

From the University of Wisconsin, John Russell, MS, presented a study evaluating the relationship between venous stenosis and tissue oxygen saturation in an animal flap model. The research concluded that T.Ox is an accurate quantitative method for monitoring flap perfusion and for assisting with the determination of the presence of venous congestion. T.Ox detected partial venous restriction with corresponding reductions in StO₂.

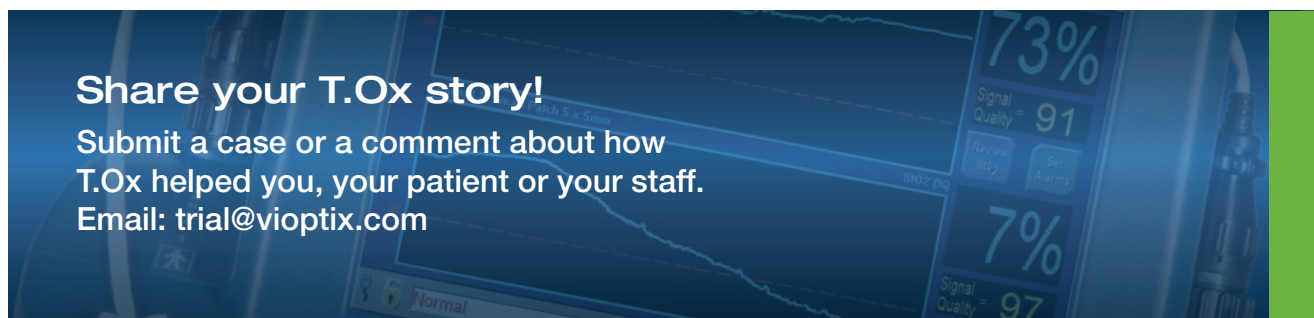
Measurement of Normal Flap Physiology in 236 Perforator Free Flaps

T.Ox tissue oxygen saturation measurements were taken by Alex Keller, MD, of North Shore Long Island Jewish Health System, to make observations concerning normal and abnormal

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Share your T.Ox story!

Submit a case or a comment about how T.Ox helped you, your patient or your staff.
Email: trial@vioptix.com



Continued from page 3.

flap physiology, intraoperatively and in post-operative monitoring in 236 perforator free flaps. Observations from this study, in a poster presented at ASRM 2009 include:

- During flap elevation and division real-time StO₂ measurements reflected a drop in StO₂, followed by a recovery of StO₂ upon revascularization
- T.Ox was used as an intraoperative tool to identify areas of lesser or greater perfusion across the perforator flap and to assist in selection of tissue with the best chance of survival
- T.Ox measurements were taken on skin flaps post-mastectomy to help differentiate between poorly perfused tissue and tissue that may be bruised but is still viable
- Supplemental oxygen increased local tissue StO₂ levels, even with no change in Pulse Ox readings
- Extubation decreased StO₂
- Mild pressure on the flap did not change StO₂
- Changes in patient position such as getting out of bed can cause a decrease in the StO₂
- A venous occlusive event is usually preceded by a short period of elevated StO₂, followed by a gradual decline
- An arterial occlusion will show a direct decline in StO₂ that levels off at significantly lower levels, reflecting residual blood remaining in the venous system

Presentation of 208 Microsurgical Flap Clinical Study. *American Society of Plastic Surgeons 2008 Annual Meeting*

Criteria studied in various combinations were the absolute value of tissue oxygen saturation (StO₂), the amount of its change (Δ StO₂) and the rate of its change (Δ StO₂/ Δ t). 208 flaps were monitored.

Five patients exhibited complications predicted by the tissue oximeter before clinical signs were evident, 8 additional surgeries performed for vascular problems (2 Hematoma, 4 Venous, 2 Arterial).

The new algorithm predicted post-op complications within one hour of the onset of the occlusive event.

The investigator concluded that T.Ox facilitates detection of vascular complications before they are clinically apparent; that salvaged flaps should have less fat necrosis because ischemic time can be shortened and no flap being monitored was lost.

upcoming meetings

Ohio Valley Society of Plastic Surgeons,
May 15-17, 2009, Indianapolis

California Society of Plastic Surgeons,
May 28-31, 2009, Olympic Valley, CA

Symposium in Reconstructive Microsurgery at the
Mayo Clinic, June 4-7, 2009, Rochester, MN

Southeastern Society of Plastic & Reconstructive
Surgeons, June 6-10, 2009, San Juan, PR

Breast Surgery & Body Contouring Symposium,
August 26-29, 2009, Santa Fe

ASPS - Plastic Surgery 2009,
October 23-28, 2009, Seattle

QMP Reconstructive Symposium,
November 20-22, 2009, St. Louis

Try T.Ox - Risk Free!
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or email: trial@vioptix.com



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FM 99848
Lit. No. 90-0107A

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