Spectros

T-Stat

Venous Occlusion Measured with T-Stat

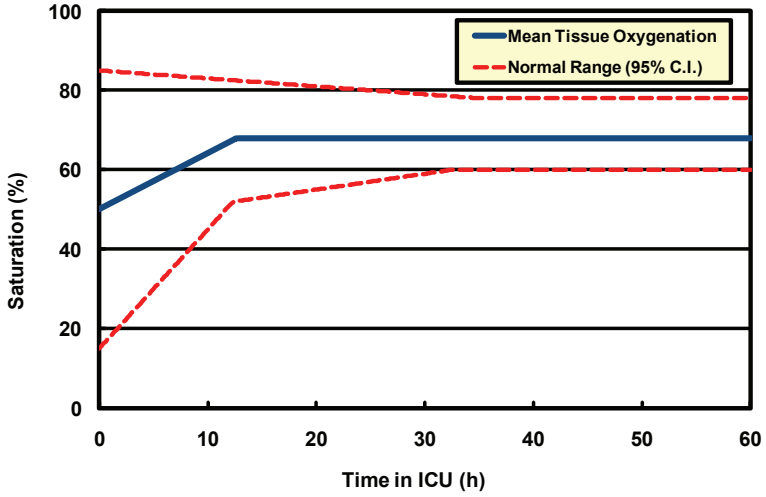
PLASTIC SURGERY

Background

The free flap has become the method of choice as a means to reconstruct or close large cutaneous defects. In the last 10 years, success rates of over 95 percent have been reported [1-4]. Despite these successes, microvascular failure remains a significant issue. As salvage rates for failed flaps decrease with increasing delays between the onset of ischemia and its clinical recognition [5], frequent monitoring of free flaps and early take back to the O.R. are the standard of care to reduce flap failure.

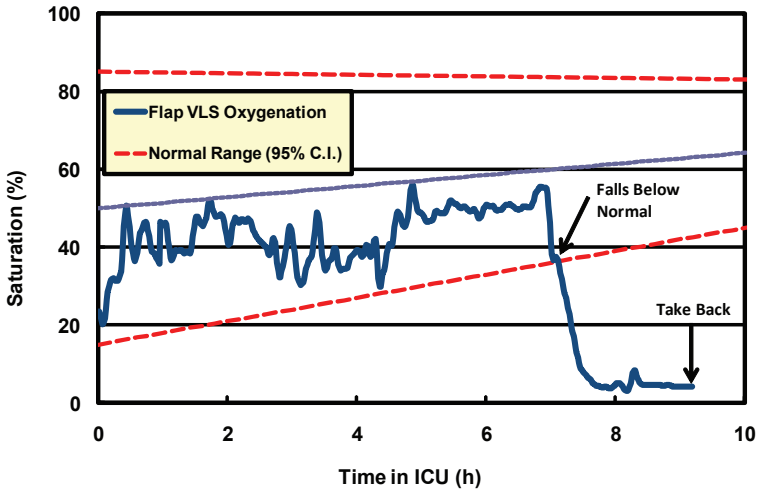
Flap Recovery

Normals: 27 patients undergoing DIEP breast reconstruction were monitored using the T-Stat microvascular tissue oximeter for a post-operative period of 60 hours. The flaps were continuously monitored using a 2.5 cm diameter surface disk sensor placed on the flap surface. A total of 30 flaps were monitored, with no cases of microvascular failure in this cohort. The mean tissue saturation recorded by the T-Stat for this population is shown below (red lines indicate the range of normal limit at 95% confidence).



Flap Failure

One patient undergoing DIEP breast reconstruction who experienced microvascular failure of the flap is presented. Clinical detection was based on clinical signs at 9 hours into her ICU stay. Tissue oxygenation as measured by the T-Stat over this period is shown (dashed red lines indicate normal range). During the first 7 h, the tissue saturation of the flap remained within the normal range. At 7 h, the saturation of the flap decreased markedly, and fell below the lower limit nearly 2 h PRIOR to other clinical signs being present.



Summary

The use of the T-Stat gives earlier warning signs when time is most critical in the success of saving a compromised free flap. T-Stat VLS is an effective, non-invasive monitor for free flaps. VLS tissue saturation measures are absolute and easy to interpret by bedside staff. By providing continuous monitoring, the T-stat is able to detect flap compromise earlier than the standard clinical signs by several hours, which can mean the difference between a successfully flap and a potential flap loss. Based on collective free flap data, T-Stat VLS gives reliable, quantitative, and effective early warning of flap failure, and therefore increases salvage success rates, and reduces flap mortality.

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Spectros T-Stat Microvascular Tissue Oximeter

T-Stat VLS was the first device to be labeled by the FDA as “sensitive to Ischemia” and has been proven in multiple trials to be an easy-to-use, reliable, and quantitative tool for assessing the adequacy of oxygen delivery to tissue. T-Stat VLS provides a continuous, non-invasive and localized measurement, sensitive to local ischemia. The T-Stat measures an absolute capillary-weighted oxygen saturation closely related to a local venous saturation measure. Accuracy exceeds conventional NIRS measures as VLS is a broadband white LED light, measuring at hundreds of wavelengths instead of the usual 2-4 found in typical NIRS.

References

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4. Nakatsuka T, Harii K, Asato H, et al. Analytic review of 2372 free flap transfers for head and neck reconstruction following cancer resection. J Reconstr Microsurg. 2003;19:363-369.
5. Siemionow M, Arslan E. Ischemia/reperfusion injury: A review in relation to free tissue transfers. Micorsurgery 2004;24:468-475.

Spectros markets advanced molecular sensing and imaging devices that shed light on ischemia and cancer. The company's lead product, the T-Stat Tissue Oximeter, was the first medical device FDA-approved as sensitive to ischemia, an insufficient blood flow to tissue. T-Stat is the only commercially-available tissue oximeter that utilizes state-of-the-art visible light spectroscopy (VLS) technology. In clinical use, T-Stat is a real-time, absolute, non-invasive, and continuous tissue monitor that analyzes 260 wavelengths of light.

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