



SensiLase and the Hyperbaric Medicine Service

In the context of the hyperbaric problem wound referral it is important to distinguish and emphasize distinct diagnostic differences that exist between SensiLase and transcutaneous oxygen tension measurement (TCOM) technologies.

SensiLase technology produces a determination of reactive blood pressure, i.e. capillary opening pressure, following brief proximal occlusion. It does not assess whether or not a lesion is adequately *oxygenated* or otherwise- the very basis for consideration of HBO therapy. Further, in the setting of demonstrated local hypoxia per TCOM, one must next determine whether or not hypoxia is reversible during hyperbaric delivery of oxygen, via 100% O₂ testing at 1.0 ATA. Embarking on a course of HBO therapy in the setting of a hypoxic wound but clinically significant regional arterial disease (that is likely causing distal hypoxia), and/or any notable cardio-respiratory oxygenation shortcomings, would be therapeutically irresponsible, would expose patients to unnecessary risks, and serve to unnecessarily strain health care funding sources where clinical improvement would be highly unlikely.

Sensilase technology was never designed to, nor can it, make this critical determination, namely demonstration of reversible local hypoxia, thereby representing the physiologic capacity to respond locally (the wound) to centrally delivered hyperoxia.

The attached '*Wound Wednesday*' document is a perfect case in point. In this patient profound local hypoxia (4 mmHg O₂) was evident in a setting where the SensiLase laser Doppler measurement was essentially normal, i.e. a value that has been reported as consistent with predication of wound healing...and clearly this wound wasn't healing. Why; because it was profoundly hypoxic per TCOM. As an aside, the TCOM site of measurement in this case would have been best selected more distally, at the perfusing metatarsal/digital arteries. Selection of the mid-dorsum could have produced a normal state of oxygenation (healthy tarsal arch) in the setting of occlusive disease within those distal arteries.

It is important to note here that studies that compared SensiLase to TCOM's have invariably been undertaken in the context of healing predictability. They have not been compared in the context of hyperbaric problem wound referrals, their evaluation and subsequent case management...simply because this was never the design intent of SensiLase. Likewise, TCOM's are not employed to predict outcome from courses of HBO therapy as this was not its design intent.

There is more. SensiLase likewise lacks the capability for use in-chamber. It is here that TCOM's can ensure that a therapeutic level of tissue oxygenation has been achieved. Finally, and no less importantly, is identification of hyperbaric medicine's therapeutic endpoint. This is considered achieved when perilesional oxygen tensions have increased to the point of normal oxidative function, namely oxygen values in excess of 40 mmHg.

SensiLase is unable to guide this algorithmic decision-making process.

There has been concerted marketing and promotional efforts at the wound care center service line level to adopt SensiLase at the expense of TCOM's. As we listened to their leading sales representative, his most robust arguments in favor of SensiLase were that it was a faster and an easier diagnostic technology to use. While there was indeed merit in these two observations, merit ceased when SensiLase was compared to TCOM's in the evaluation and case management of the hyperbaric referral. It failed entirely as it could not address the diagnostic questions across the range of diagnostic need, because again this was not its design intent.

If wound center providers have been convinced as to the value and merit that SensiLase will bring to their practice they have every right to request that it be acquired. It must not, however, be acquired at the expense of transcutaneous oximetry in wound centers that incorporate hyperbaric medicine. It will then become necessary to undertake a cost-benefit analysis if SensiLase is being considered in the wound/ hyperbaric service line as there would now be two diagnostic technologies and in our view SensiLase provides nothing diagnostically that TCOM's can't determine. It is also our view that the cost of acquisition of SensiLase is overly excessive.

This writer has no conflict of interest to report.