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SensiLase Studycast System: A Platform for Critical Limb Diagnostics and Electronic Referral Program

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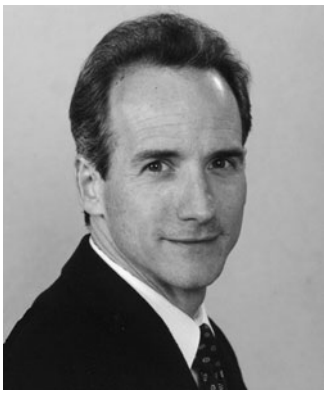

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Abbreviations and Acronyms

ABI = ankle brachial index
CLI = critical limb ischemia
DM = diabetes mellitus
HIT = health information transfer
LPC = limb preservation center
PAD = peripheral arterial disease
PCP = primary care physician
PVR = pulse volume recording
SD = standard deviation
SPP = skin perfusion pressure
TBI = toe-brachial index
$TcPO_2$ = transcutaneous partial pressure oxygen or transcutaneous oxygen tension

Problem: Peripheral arterial disease (PAD) and critical limb ischemia (CLI) impede lower extremity wound healing. The highest-risk patient populations have foot ulcers, ischemic disease, diabetes mellitus, and/or compromised kidney function. Optimal wound healing protocols require evaluation of both tissue and arterial perfusion. The most widely known test, ankle brachial index (ABI), has general but limited utility in foot ulcer patients. False negatives secondary to medial artery calcification are common and ABI alone is not considered predictive of wound healing. As many high-risk patients consider their medical home to be their primary care physician (PCP) not a limb preservation center (LPC), high-risk patients can be underserved secondary to inadequate awareness of the disease, limited diagnostics, and inefficient referral.

Solution: Access to clinically appropriate, tissue-diagnostic tools for high-risk populations coupled with health information transfer (HIT) between PCP and LPCs provides the opportunity to bring PAD/CLI expertise to a patient's medical home. Coordinated data management coupled with PAD/CLI protocols can promote timely and appropriate referral and subsequent intervention.

New Technology: SensiLase® Studycast® System provides a noninvasive diagnostic and data management system specifically designed for high-risk patients. Studycast software automates and simplifies HIT between the PC and critical limb care experts at the LPC. Data can be integrated with existing electronic medical record systems.

Indications for Use: SensiLase Studycast is indicated for perfusion assessment in patients at high risk for peripheral ischemia.

Caution: Results of SensiLase System testing should be used in conjunction with other diagnostic information in formulating therapeutic plans.

UNMET NEED

Peripheral arterial disease (PAD) and critical limb ischemia (CLI) are epidemic yet underserved in high-risk populations (elderly, diabetic, smoking history, kidney disease, and foot ulcers). PAD patients with diabetes are at extreme risk for polyvascular disease (PVD)—occlusion in other arteries—leading to heart attack and stroke. As the peripheral arterial bed is the ideal site for overall PVD detection,[1] tests that reliably and easily identify PAD are critical. The most widely known test ankle brachial index (ABI) can be falsely normalized in this patient group and is not particularly useful for foot ulcer evaluation. Therefore, tissue perfusion assessment coupled with HIT services that streamline communication, distribute results electronically and enhance workflow is critical.

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PRODUCT TECHNOLOGY

The SensiLase® Studycast® System generates two noninvasive vascular tests: skin perfusion pressure (SPP) and pulse volume recording (PVR) (Fig. 1). SPP, a quantitative evaluation of microcirculatory perfusion in the skin, is measured using a laser Doppler sensor and an occlusive pressure cuff to evaluate reactive hyperemia. The system produces laser light, which is emitted into the skin at 785 nm. The laser light penetrates the skin up to 1.5 mm and is scattered. Light that hits moving red blood cells is "Doppler shifted," but light returning from tissue is not shifted. Returned light enters the instrument, where an algorithm extracts flow information and provides a value at which capillary flow returns. A graph displays pressure and perfusion during cuff deflation and indicates the pressure at which skin perfusion is found to return. Other information observable from the graph includes percentage perfusion increase above baseline, total response time, perfusion reappearance time, and perfusion contour. PVR uses air plethysmography to evaluate variations in the volume of blood passing through a limb during each cardiac cycle. In combination, these tests help determine the severity and level of disease in the extremities.

Studycast software and services provide web-accessible SensiLase data. SensiLase System studies are uploaded in 2 min or less and feature two-way physician notification services. Studycast permits consolidation of studies from multiple locations in one place. All data fields are independently searchable.

PRODUCT INNOVATION

The SensiLase Studycast service, as a web-based data management system and picture archiving and communication system (PACS), provides transmission of tests for interpretation from any internet-connected device. Coordinated use of SensiLase Studycast at a primary care site with oversight from limb preservation experts provides streamlined HIT and referral process. Tests performed by primary care are routed for vascular interpretation. The complete report (vascular history, findings, and recommendations) is automatically routed to the primary care physician (PCP) and administration. Interpretation templates are data driven to provide thorough reports. The turnaround time for generating reports required for utilization, billing, and documentation are substantially reduced when using digital structure reporting.[2] Studycast service meets Health Insurance Portability and Accountability Act (HIPAA) compliance, allows for customizable reports, and permits multiple users access to the data from any internet-connected device.

The system provides a customizable clinical and technology platform for collaborating departments and/or community clinics to direct patient care both short and long term. High-risk patients may require advanced diagnostic assessments, vascular intervention, and ancillary care to heal their wounds. Combining tissue perfusion data with other vascular and wound information into a critical limb care database optimizes care and demonstrates accountability of service. These attributes minimize operator error and offer utility to primary care and limb preservation experts in their varied care roles for the patient.

PEER-REVIEWED DATA

SPP has demonstrated utility in PAD/CLI detection, wound healing prediction, and optimizing limb salvage.

- Castronuovo *et al.*[3]—53 patients (61 limbs), prospective study (100% ulcers/gangrene). SPP reliably predicted wound healing and accurately identified CLI.

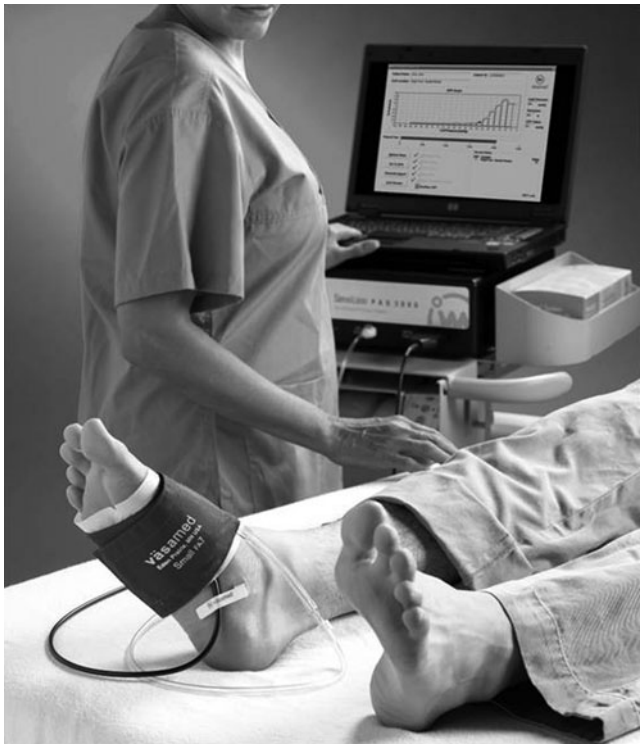

Figure 1. Skin perfusion pressure testing and pulse volume recording.

Table 1. *A comparison of current screening diagnostics for peripheral arterial disease*

Identified Criteria for Comparison	*Microcirculatory Assessment Skin Perfusion Pressure*	*Macrocirculatory Assessment Transcutaneous Oxygen Tension*	*Pulse Volume Recording*	*Peripheral Pressure Measurements (ABI, TBI, and Segmental Pressures)*
Assessment parameter	Microcirculatory perfusion	O_2 saturation	Macrocirculatory perfusion	Macrocirculatory perfusion
Useful in patients with				
Calcified arteries	Yes	Yes	Yes[5]	No
Inaudible pulses/Doppler	Yes	Yes	Yes	No
Edema	Yes	No	Yes	Sometimes
Callus	Yes	No	Yes	No
Able to perform testing in the presence of				
Anemia	Yes	No	Yes	Yes
Hypoxia	Yes	No	Yes	Yes
Labor intensive/time consuming	No	Yes	No	Yes
Approximate procedure times	3–5 min	30–60 min	≤ 1 min	10–20 min
Calibration required	No	Yes	No	No
Contact gel/solution required	No	Yes	No	Yes
Use of electrodes required	No	Yes, warmed to 42°C–44°C	No	No
Testing procedure is challenging	No	Yes	No	Yes
Training requirements	Minimal	Extensive	Minimal	Extensive

ABI, ankle brachial index; TBI, toe-brachial index.

- Kondo *et al.*[4]—24 patients (44 limbs), prospective study (100% diabetes mellitus [DM]/hemodialysis). SPP was more sensitive to quantify ischemia compared with ABI; validation metric was digital subtraction angiography.
- Okamoto *et al.*[5]—140 patients (266 limbs), prospective study (100% hemodialysis patients). SPP was more effective in identifying PAD than transcutaneous partial pressure oxygen or transcutaneous oxygen tension ($TcPO_2$), ABI, or toe-brachial index or toe-brachial indices (TBI); validation metric was multidetector-row computed tomography angiogram.
- Yamada *et al.*[6]—211 patients (403 limbs), retrospective study. SPP was a more accurate, objective measurement for assessing severity of PAD and predicting wound healing compared with ABI, TBI, or $TcPO_2$.
- Lo *et al.*[7]—100 patients (100% chronic wounds), prospective study. SPP was more accurate in predicting wound healing potential (92%) than $TcPO_2$ (67%). All patients were followed up to 12 months or healing.
- Tsuji *et al.*[8]—47 patients (69 limbs), prospective study (100% ischemic wounds). SPP was shown to predict wound healing in patients undergoing vascular surgery for CLI. SPP accurately predicted wound healing and was useful in planning optimal amputation level.

Electronic referral programs clearly represent an improvement over traditional referral practices:

- O'Malley and Reschovsky[9]—4,720 PCPs and specialists survey of traditional referral and consult communication showed conflict over receipt of quality reports regarding patients with chronic conditions and support for monitoring patients with chronic conditions.

NON–PEER-REVIEW OBSERVATION

Bailey and Schechter[10]—100-patient prospective study compared paired noninvasive vascular test ($TcPO_2$/ABI and SPP/PVR) for PAD detection, wound healing prediction, and time-to-test (100% lower extremity wounds) (Table 1). SPP/PVR demonstrated to be superior to other vascular tests for the following uses:

- PAD detection: 96.2% (50/52) for SPP/PVR and 61.5% (32/52) for $TcPO_2$/ABI. Arterial disease was confirmed in 52/100 patients; however, an ABI was unable to be obtained in 32.7% (17/52). Of these 17 patients, 47.1% (8/17) had DM.
- Wound healing prediction: 93.2% (82/88) for SPP/PVR compared with 75% (66/88) for the $TcPO_2$/ABI.
- Time to test: 6.72 min (± standard deviation [SD]: 2.41) compared with $TcPO_2$/ABI testing time of 35.54 (± SD: 8.86) for assessing wound healing with a single site. Good clinical practice dictates a multisite (×3) testing with a cumulative mean of 18.43 min for SPP and PVR.

CAUTION, CRITICAL REMARKS, AND RECOMMENDATIONS

SensiLase System testing should be used in conjunction with other diagnostic information including other circulatory tests, clinical observations, and symptoms. Patients with severe tremors may not be amenable to testing with SensiLase System, because laser Doppler is sensitive to extreme, repetitive motion; the system software may not permit a result to be reported.

SensiLase Studycast System provides a perfusion diagnostic system and permits seamless integration of vascular ultrasound data into final reports. This is coupled with systematic structures, tools, and processes that assist creation, transfer, receipt, and recognition between PCPs and limb preservation centers to support management of patients with chronic illness.

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REFERENCES

1. Hirsch AT, Criqui MH, Treat-Jacobson D, Regensteiner JG, Creager MA, Olin JW, *et al.*: Peripheral arterial disease detection, awareness, and treatment in primary care. JAMA 2001; **286:** 1317.
2. Frommelt P, Gorentz J, Deatsman S, Organ D, Frommelt M, and Mussatto K: Digital imaging, archiving, and structured reporting in pediatric echocardiography: impact on laboratory efficiency and physician communication. J Am Soc Echocardiography 2008; **21:** 935.
3. Castronuovo JJ, Adera HM, Smiell JM, and Price RM: Skin perfusion pressure measurement is valuable in the diagnosis of critical limb ischemia. J Vasc Surg 1997; **26:** 629.
4. Kondo Y, Muto A, Dardik A, Nishibe M, and Nishibe T: Laser Doppler skin perfusion pressure in the diagnosis of limb ischemia in patients with diabetes mellitus and/or hemodialysis. Int Angiology 2007; **26:** 258.
5. Okamoto K, Oka M, Maesato K, Ikee R, Mano T, Moriya H, *et al.*: Peripheral arterial occlusive disease is more prevalent in patients with hemodialysis: comparison with the findings of multidetector-row computed tomography. Am J Kidney Dis 2006; **48:** 269.
6. Yamada T, Ohta T, Ishibashi H, Sugimoto I, Iwata H, Takahashi M, and Kawanishi J: Clinical reliability and utility of skin perfusion pressure measurement in ischemic limbs: comparison with other noninvasive diagnostic methods. J Vasc Surg 2008; **47:** 318.
7. Lo T, Sample R, Moore P, and Gold P: Prediction of wound healing outcome using skin perfusion pressure and transcutaneous oximetry: a single-center experience in 100 patients. Wounds 2009; **21:** 310.
8. Tsuji Y, Hiroto T, Kitano I, Tahara S, and Sugiyama D: Importance of skin perfusion pressure in treatment of critical limb ischemia. Wounds 2008; **20:** 95.
9. O'Malley AS and Reschovsky JD: Referral and consultation communication between primary care and specialist physicians: finding common ground. Arch Intern Med 2011; **171:** 56.
10. Bailey B and Schechter R: $TcPO_2$ and SPP Evaluation: a direct comparison of technologies for the assessment of wound healing and vascular disease detection. *Symposium on Advanced Wound Care/Wound Healing Society,* Dallas, TX, April 26–29, 2009, WHS Podium & Poster No. 32.