

○ SensiLase PAD-IQ®

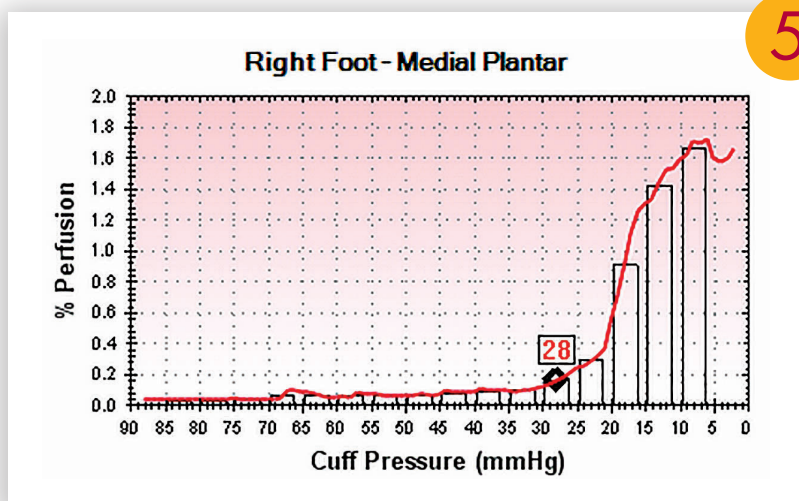
Clinical Utility of Angiosome - Specific Skin Perfusion Pressure Measurements for the Amputation Prevention Team in Treating CLI

Skin Perfusion Pressure (SPP)

- Skin Perfusion Pressure uses laser Doppler and pressure cuffs to evaluate reactive hyperemia.
- The lasers detect microcirculatory blood flow and are placed under the pressure cuffs.
- Cuffs are automatically inflated until capillary blood flow is occluded.
- Following confirmed occlusion, cuff pressure is automatically released; SPP is the cuff pressure at onset of perfusion return.

SensiLase PAD-IQ System

- PAD-IQ permits simultaneous bilateral testing which promotes testing efficiency.
- PARC Hemodynamic Definition of CLI¹: SPP<40mmHg with tissue loss and SPP<30mmHg with ischemic rest pain.
- This type of provocative functional maneuver is well-documented to accurately detect ischemia within specific angiosomes.
- SPP is used to diagnose PAD/CLI, assess wound healing response and measure endovascular therapy effectiveness with pre/post intervention perfusion measures.



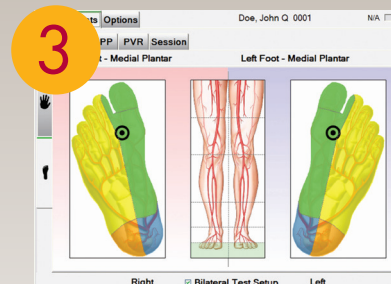
Ischemia confirmed



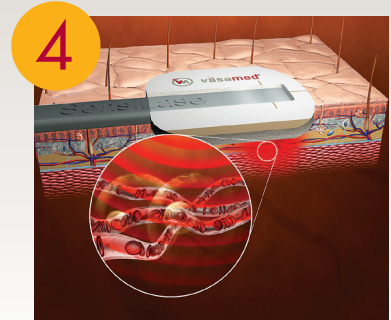
Ischemic ulcer?



Perform vascular assesment



Correlate with wound angiosome



Assess angiosome perfusion

Clinical Questions

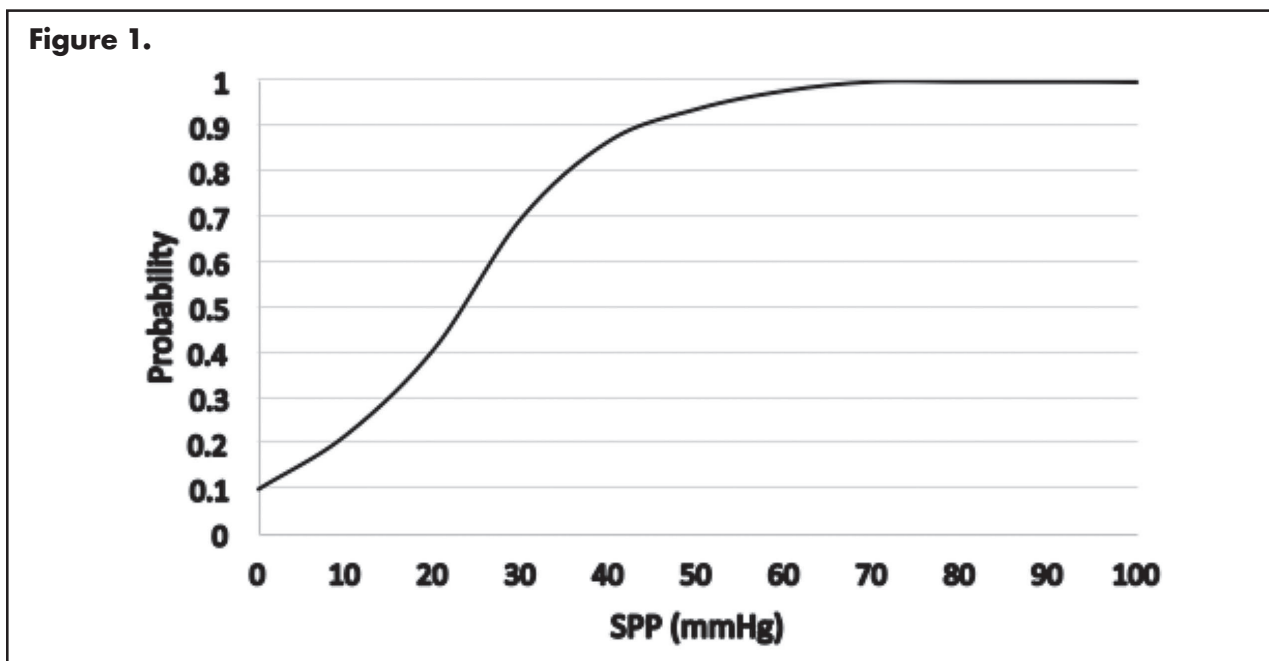
- The ABI is 1.1 in this patient with a non-healing ulcer. It must be falsely elevated. Now what?
- I have angiographic improvement post EVT but did EVT improve perfusion to the ischemic angiosome?
- Was the single tibial vessel intervention enough or is more needed?
- Did the intervention sufficiently improve perfusion so that wound healing is likely?
- Did the post EVT perfusion maintain at 3 months? 6 months?

Clinical Evidence Confirms that PAD-IQ SPP is the Optimal Diagnostic to Provide these Answers

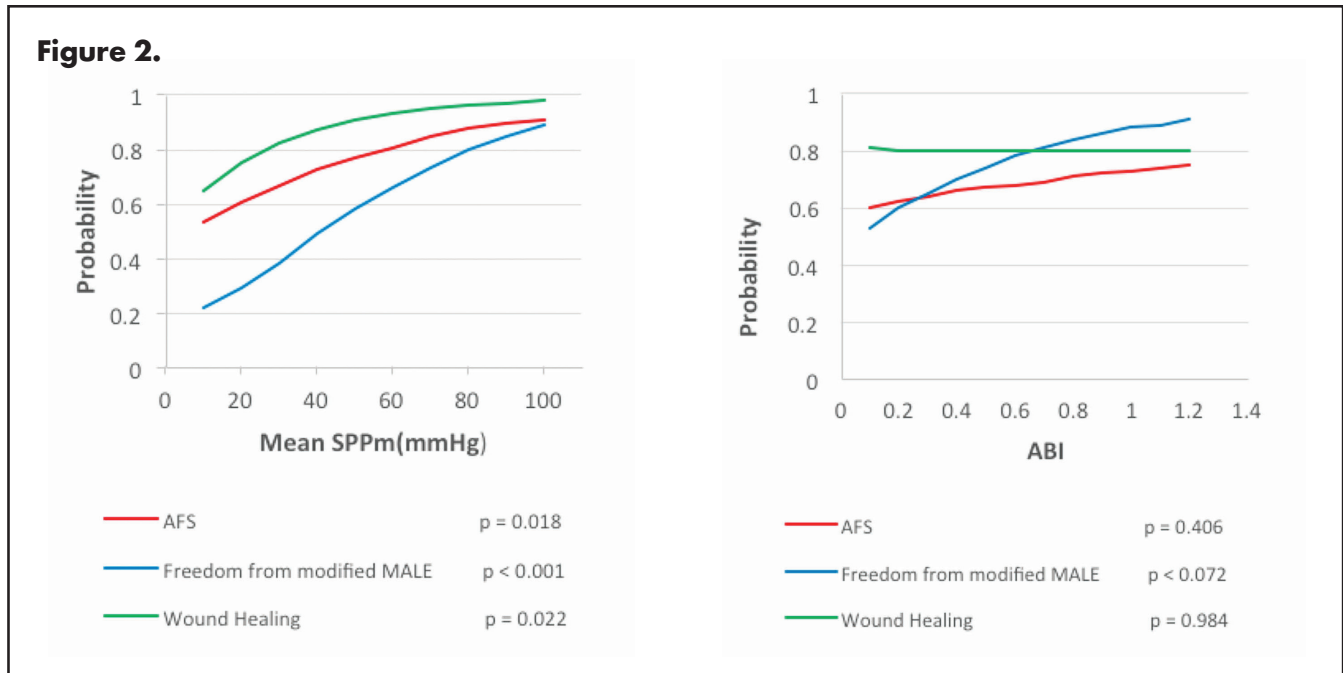
- Providing early, accurate prediction of wound healing^{2,3,4}
- Detection of PAD and CLI³
- Evidence of EVT^{3,4}
- Superior accuracy compared to ABI, TcPO₂ & TBI alone³

Clinical Evidence

Probability of Wound Healing. SPP is an Independent Predictor of Wound Healing Following EVT with 30mmHg to be the best cutoff for this prediction. J Endovasc Ther 2014²



Post EVT SPP Assessments Correlate with Clinical Outcomes. ABI does not.
J Endovasc Ther 2014²



Post EVT SPP Corroborates the Superiority of Direct vs. Indirect Flow.
Catheter Cardiovasc Interv 2010⁴

Figure 3.

	All (n = 203)	Direct (n = 118)	Indirect (n = 85)	P value
Lesion location before EVT				
Aorto-iliac lesion/calcification	16% (33)/76% (153)	13% (15)/75% (89)	21% (18)/6% (64)	0.11/0.99
Femoro-popliteal lesion/calcification	60% (123)/76% (154)	59% (70)/75% (89)	62% (53)/76% (53)	0.66/0.86
Tibio-peroneal lesion/calcification	99% (199)/7% (157)	97% (114)/74% (87)	100% (85)/82% (70)	0.14/0.15
Primary stenting for aorto-iliac lesions	17% (35)	12% (14)	19% (16)	0.19
Angioplasty alone for femoro-popliteal lesions	6% (12)	5% (6)	7% (6)	0.63
Stenting for femoro-popliteal lesions (cobalt/nitinol)	4% (9)/49% (100)	5% (6)/49% (58)	4% (3)/49% (42)	0.87
Angioplasty for tibio-peroneal lesions	82% (167)	83% (99)	80% (68)	0.47
Patency of peroneal artery after EVT	44% (89)	49% (56)	39% (33)	0.20
Target lesion revascularization (TLR)	23% (46)	23% (27)	22% (19)	0.92
SPP after EVT (mmHg)	57 ± 26 mmHg	67 ± 25 mmHg	41 ± 20 mmHg	0.0002
SPP Δ	33 ± 22 mmHg	40 ± 22 mmHg	18 ± 14 mmHg	0.0018

SPP is a Better Predictor of Successful EVT than ABI. J Endovasc Ther 2014²

Figure 4.

	All (n=123)	+Wound healing (81=97)	-Wound Healing (n=26)	P
Rutherford Category 6	27 (22.0%)	18 (18.6%)	9(34.6%)	0.079
Infected Wound	46 (37.4%)	30 (30.9%)	16 (61.5%)	0.004
Location of Ulcer or Gangrene				
Toe ATA site	61 (49.6%)	45 (46.4%)	16 (61.5%)	
Toe PTA site	41 (33.3%)	31 (32.0%)	10 (38.5%)	
Sole of foot	5 (4.1%)	4 (4.1%)	1 (3.8%)	
Dorsum of foot	3 (2.4%)	3 (3.1%)	0 (0%)	
Heel	8 (6.5%)	5 (5.2%)	3 (11.5%)	
Ankle	3 (2.4%)	2 (2.1%)	1 (3.8%)	0.368
ABI before EVT	0.71±0.21	0.78±0.22	0.71±0.26	0.340
SPP before EVT	24.3±13.0	25.5±13.7	19.5±8.2	0.043
Treated lesion				
Aoroiliac	15 (12.3%)	13 (13.4%)	2 (7.7%)	0.420
Femoropopliteal	70 (56.9%)	53 (54.6%)	17 (65.4%)	0.638
Infrapopliteal	91 (74.6%)	75 (78.1%)	16 (61.5%)	0.085
Below the ankle	31 (25.6%)	25 (26.3%)	6 (19.4%)	0.737

SPP is a Superior Predictor of Successful EVT compared to other Clinical Variables. J Endovasc Ther 2014²

Figure 5.

	All (n=123)	+Wound healing (n=97)	-Wound Healing (n=26)	P
Direct flow to ulcer or gangrene	69 (56.1%)	56 (57.7%)	13 (50.0%)	0.481
Positive wound blush	78 (63.4%)	70 (72.2%)	8 (30.8%)	<0.001
Number of crural vessels	1.65±0.78	1.65±0.79	1.65±0.75	0.980
Number of patent below-the-ankle vessels	1.84±1.04	1.88±1.06	1.67±0.91	0.407
ABI after EVT	0.80±0.15	0.81±0.15	0.76±0.12	0.114
SPP after EVT	40.7±16.1	44.2±15.6	27.5±10.4	<0.001
Repeat EVT	37 (30.1%)	30 (30.9%)	7 (26.9%)	0.523
Minor amputation	24 (19.5%)	19 (19.6%)	5 (20.8%)	0.443

1. Patel et al Evaluation and Treatment of Patients with Lower Extremity Peripheral Artery Disease J Am Coll Cardiol 2015; 65:931-41
2. Utsunomiya et al Predictive Value of Skin Perfusion Pressure after Endovascular Therapy for Wound Healing in Critical Limb Ischemia, J Endovasc Therapy 2014; 21:662-670
3. Okamoto et al Postprocedural Skin Perfusion Pressure Correlates With Clinical Outcomes 1 Year after Endovascular Therapy for Patients With Critical Limb Ischemia, Angiology 2015 ; 1-5.
4. Iida et al Importance of the Angiosome Concept for Endovascular Therapy in Patients with Critical Limb Ischemia, Catheter and Cardiovasc Inter 2010 May 1;75(6):830-6

Abbreviations:

- SPP – Skin Perfusion Pressure
- CLI – Critical Limb Ischemia
- PAD – Peripheral Arterial Disease
- PARC – Peripheral Academic Research Consortium
- EVT – Endovascular Therapy
- AFS – Amputation Free Survival
- MALE – Major Adverse Limb Event

For more information contact VÄSAMED at 800-695-2737

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