

Transcutaneous Oxygen Monitoring and Skin Perfusion Pressure Evaluation

A Direct Comparison of Technologies for the Assessment of Wound Healing and Vascular Disease Detection

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Characteristics of Peripheral Arterial Disease in Patients with Diabetes

Peripheral arterial disease (PAD)

- Greater frequency (2.5 to 6x) observed in patients with diabetes mellitus (DM) compared with matched non-DM patients
- Occurs 10 years earlier in patients with DM

Lower limb atherosclerosis in DM patients

- Characterized by preferential involvement of the lower leg
- Comparative PAD incidence rates:
 - DM population 70%
 - Non-DM population 20%

DM patients have multiple stenosed arterial segments

- Majority do not complain of claudication

Increased co-morbidity incidence (including amputation)

- 5x higher in patients with DM vs. non-DM

Focus on Tissue Perfusion

ABI

- Not a tissue perfusion tool for the DM foot patient
- Cannot be relied upon to predict wound healing potential

TcPO₂

- Clinical experts historically advise TcPO₂ use instead
 - Assumed to provide more relevant information (tissue perfusion)
 - Unaffected by presence of intimal calcification

Associated TcPO₂ Drawbacks

- Time-to-Test
- Mixed results secondary to tissue quality
- Operator and environment dependence

Burgeoning populations of co-morbid patients make it incumbent upon clinicians to identify additional tissue perfusion diagnostics

Site Profile

- Multi-disciplinary clinic setting
- Wound care and hyperbaric medicine (HBOT) center with monoplace chambers
- Panel Specialists include:
 - Wound Care/HBOT
 - Infectious Disease
 - Plastic Surgery
 - Vascular Surgery
 - Podiatry
- Certified Wound Care Nurses
- Certified HBOT Technicians
- Dedicated Study Coordinator



Our Site's Top Priority: Tissue Preservation

- *Ischemic vs. non ischemic: Is there adequate tissue perfusion for the wound to heal?*
 - Arterial flow translates from arteries/main vessels to distal arterial structures (capillaries and arterioles)
- *Best tool(s) to optimally assess main and distal arterial function?*
 - Must consider reliability, accuracy, patient / user friendliness, time, and economics
- *Are the findings applicable to various disease states and in compromised populations?*
 - Diabetics, renal impaired, elderly



Study conduct translates to evidence based medicine

Study Design

- Single site
- Prospective
- Nonrandomized
 - Each patient functioned as their own control
- IRB approved
- 100 new patients with LE wounds
- Followed to 16-weeks or healing

Four Technologies

- Skin Perfusion Pressure
- Pulse volume recording
- Transcutaneous Oxygen Monitoring
- Ankle-Brachial Index

Pairing of Test Modalities

- Skin Perfusion Pressure + Pulse volume recording



- Transcutaneous Oxygen Monitoring + Ankle-Brachial Index



Study Entrance Criteria

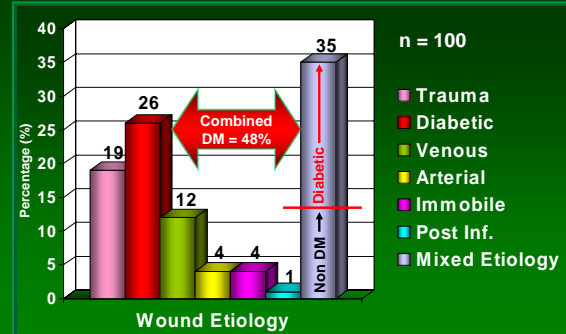
- Inclusion
 - 18 years of age or older
 - Presenting with lower extremity wound
 - Able and willing to provide Informed Consent
 - Able and willing to comply with study protocol and predefined study evaluations
- Exclusion
 - Systemic illness that may confound study results
 - Autoimmune disease (e.g., scleroderma, vasculitis, Systemic Lupus Erythematosus and skin malignancy)
 - Participating in another study that may confound outcomes of present study

Demographics

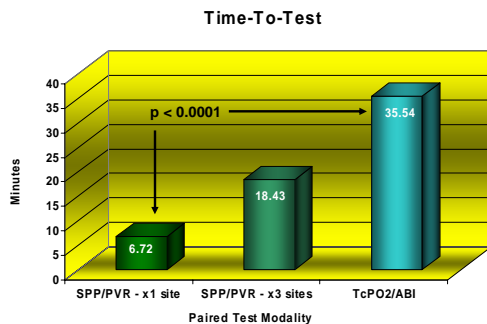
Variable	% (n=100)	Range
Mean Age (years)	69.3	20 – 96
Mean BMI*	28.4	13.4 – 48.8
Gender (female)	54	-
Diabetes Mellitus	48	-
Chronic Renal Failure	10	-
Tobacco Use	44	-

* Greater than 2/3 of study population either overweight (30%) or obese (37%) per CDC guidelines

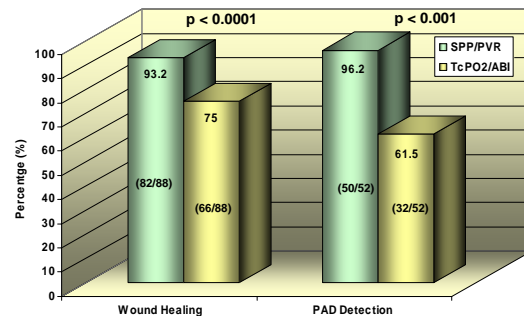
Wound Etiology



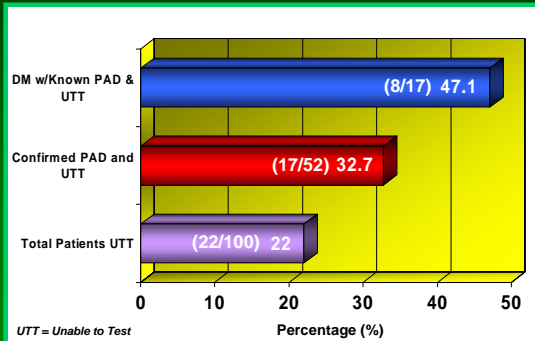
Study Results



Wound Healing and Disease Detection Outcomes



Of particular importance...ABI was unattainable in almost a quarter of our study population



Study Summary

In our investigation, SensiLase testing proved to be significantly superior to the ABI/TcPO₂ combination as demonstrated in statistically relevant:

- Reductions in test time(s)
- Improved accuracy in wound healing prediction rate
- Greater peripheral arterial disease detection rate

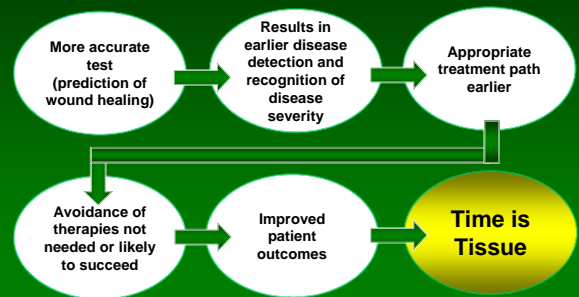
Substantially improved testing capability in compromised patient populations (i.e., those presenting with medial calcinosis)

- Diabetes mellitus
- Renal insufficiency
- Advanced age

Why is This Meaningful?

- Faster, easier test**
 - We can test every patient
 - Even in a busy wound care practice
- More patients being tested**
 - Leads to earlier disease detection
 - Better recognition of disease severity
 - Swifter implementation of optimal treatment pathway
- Clinic operations**
 - Improved efficiencies
 - Bottom line – time is money

An Improved Paradigm



Clinical Relevance

Transitioned from investigational to best practice

Our new standard:

- First line vascular/tissue perfusion assessment consists of SensiLase skin perfusion pressure and pulse volume recording measurements
- All new lower extremity wound patients receive vascular/tissue perfusion assessment as a component of their work-up

Thank You – Questions?

