



Noninvasive Diabetes Screening: Results From a Multi-Site Clinical Study

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Introduction

SCOUT™* is a noninvasive tool being developed for rapid, convenient screening for diabetes and pre-diabetes. SCOUT is designed to not require blood draws or fasting while providing an immediate test result



Objectives

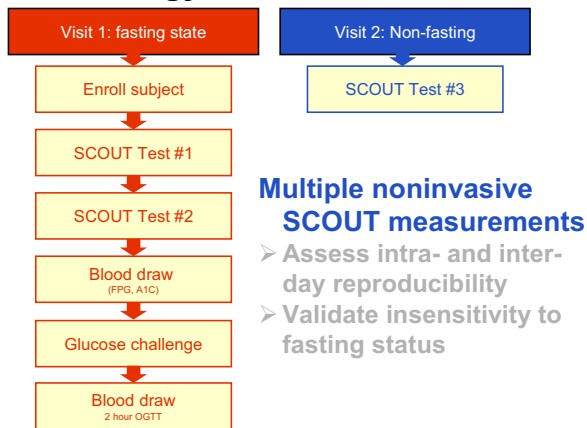
- Collect spectral and blood measurements for development of algorithm that relates skin fluorescence to disease status
- Refine thresholds that define good spectral measurements
- Forecast prospective SCOUT performance in main phase of pivotal study

Study overview

- Evaluation of SCOUT as a screening tool relative to screening performance of FPG and A1C
- OGTT determines screening 'truth'
 - 2-hour 75g glucose defines positive screen
 - Abnormal Glucose Tolerance: ≥ 140 mg/dL
- 3,080 subjects enrolled at 18 clinical sites

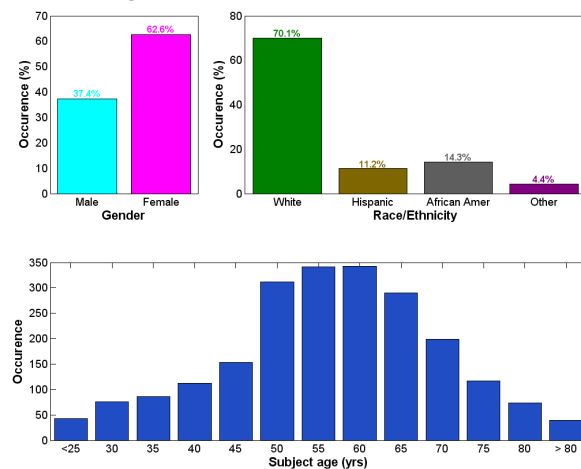


Methodology

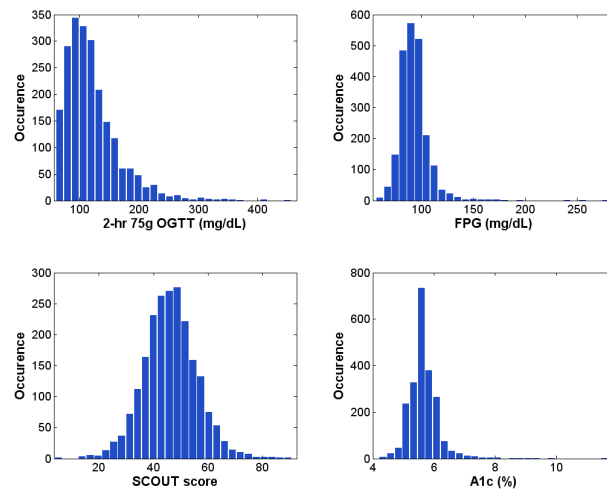


Study demographics

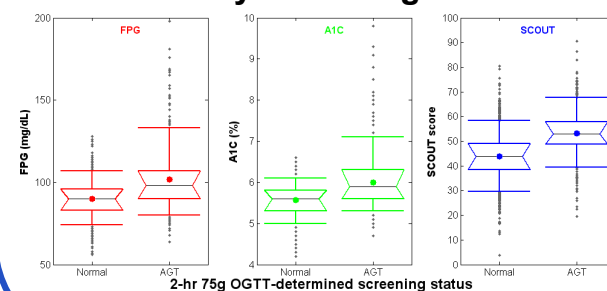
- 2184 subjects selected for algorithm development
- Broad demographics and range of skin color
- Valid blood chemistry results
- Artifact-free fluorescence spectra
- AGT prevalence = 24.8%



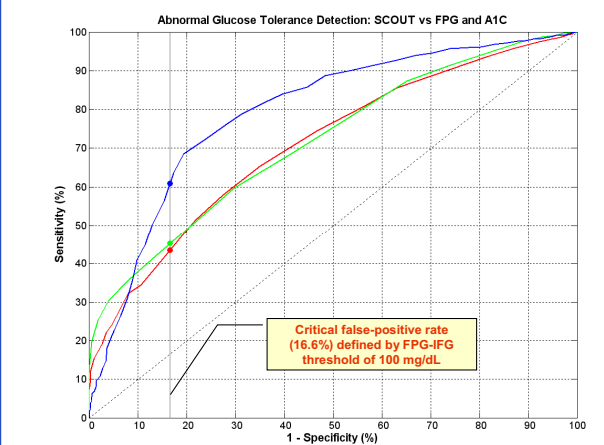
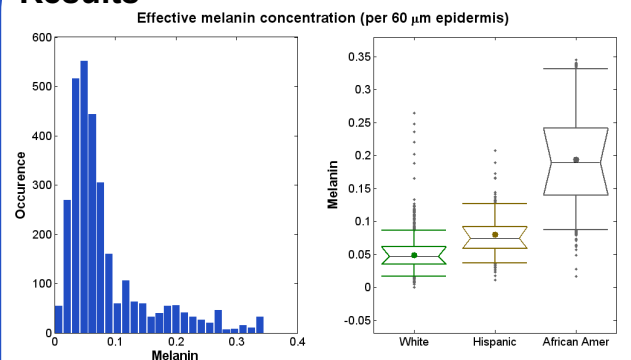
Test value distributions



Test values by screening status



Results



Performance Summary

	Threshold	SENS @ 16.7% FPR	Relative SENS Δ (%)	AUC (%)
SCOUT	52	61.0	-	79.4
FPG	100 mg/dL	43.5	40.2	70.9
A1C	5.9%	45.3	34.7	71.5

Summary and Next Steps

- Successful demonstration of noninvasive screening in large, multi-site study
- SCOUT offers performance AND convenience advantages over conventional screening methods
- Pivotal study set to begin at 16 sites, involving ~4000 subjects

*Caution - Investigational Device. Limited by Federal Law to Investigational Use.