MULTIMODAL SPECTROSCOPY AS A TRIAGE TEST FOR WOMEN AT RISK FOR CERVICAL NEOPLASIA:

RESULTS OF A 1,607 SUBJECT PIVOTAL TRIAL

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Disclosure

- The study sponsor was Guided Therapeutics, Inc.
- None of the authors have any potential conflicts of interest to disclose
- Speaker's Bureau for GSK

Pivotal Trial Clinical Sites

University of Texas Southwest – Dallas, Texas

Principal Investigator – Claudia Werner, MD

Emory University School of Medicine – Atlanta, Georgia

Principal Investigator – Lisa C. Flowers, MD

University of Miami – Miami, Florida

Principal Investigator – Leo B. Twiggs, MD / Co PI – Nahida Chakhtoura, MD

Saint Francis Hospital Univ. of CT – Hartford, Connecticut

Principal Investigator – Manocher Lashgari, MD

University of Arkansas – Little Rock, Arkansas

Principal Investigator – Alexander Burnett, MD

Medical College of Georgia – Augusta, Georgia

Principal Investigator – Daron G. Ferris, MD

Orange Coast/SaddleBack Women's Medical Group

Principal Investigators – Marc Winter, MD / Daniel Sternfeld, MD

Clinical Rationale
Cervical Cancer Screening

Current screening and triage methods cause

- Delays in diagnosing significant disease - 30% to 40% False Negative Rate

- Excessive false positive rate – Only 20% of biopsies are positive for CIN2/3

Expensive - billions of dollars of unnecessary cost

LightTouch -Technology Advancement

- Advances in the electro-optics, illumination sources and sensors

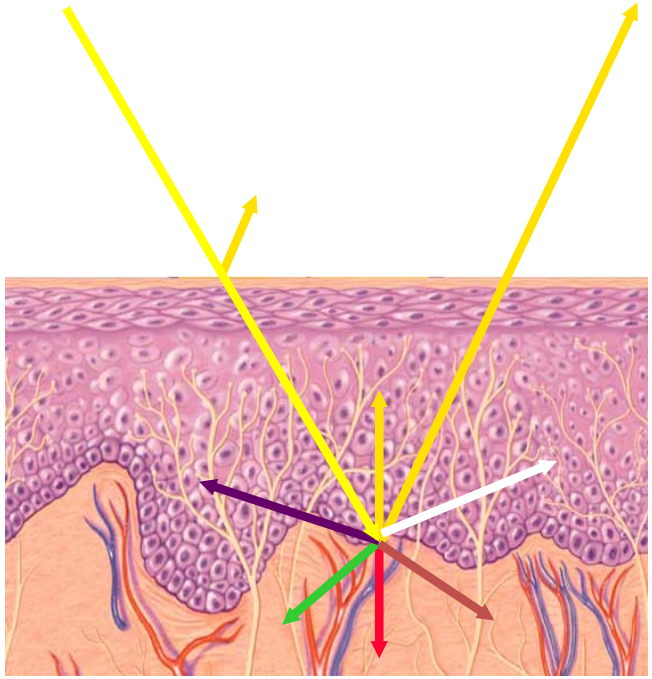
•Efficiencies in performance and cost of multimodal hyperspectroscopy (MHS)

Development of clinically relevant and convenient devices for the detection of cervical neoplasia

Potential Solution: Better Technology

Light In –

Multiple wavelengths used to penetrate different tissue depths



1. *Fluorescence Spectra -*

   Reveal metabolic changes associated with neoplasia

2. *Reflectance Spectra –*

   Reveal morphological changes associated with neoplasia

LightTouch Cervical Spectroscopy

Cervical Neoplasia Detection System

- Measures fluorescence and reflectance spectra at multiple points on the cervix in one minute
- Immediate, objective result
- Low cost device and single patient use disposable
- Built in video colposcope – permits visualization and treatment in the same visit and reimbursable in US using colposcopy CPT 57452
- LightTouch Manufactured by Guided Therapeutics, Inc. / Norcross, Georgia, USA

LightTouch Study Design

- Each subject served as own control
- Referral Pap/HPV or other risk factor to qualify for study
- On day of study, each subject had endocervical samples taken for Pap and HPV, followed by colposcopy and biopsy
- Histology QA procedure used to reach diagnosis for each subject
- Follow up data (two year) collected if available

LightTouch Condensed Procedure

- Prep subject per gynecological exam; remove any excessive blood or mucus
- Calibrate LightTouch (20 seconds)
- Using live video feed, insert hollow sight tube through speculum into vaginal canal until tube makes contact with cervix, cervix is in focus and cervical os is centered as well as possible (15-20 seconds)
- Capture video image (<1 second)
- Collect LightTouch spectral data (1 minute)
- Capture second video image to make sure os is still visible (<1 second)
- Withdraw and dispose sight tube
- Test complete

Definitions

- *Final histology – Gold Standard*
  - Pathology QA review involved blinded review by two independent expert pathologists
  - Up to two year histopathology follow-up after LightTouch study

- *Standard of Care*
  - Includes Pap cytology, HPV testing and colposcopic impression

Study Group

- 1607 total
- 1407 analyzed
- Excluded women with discordant or insufficient histopathology, training cases (200)
- **802 with two year follow up**

Up to Two Year Follow Up

Clinical Site	Enrolled	Follow up Data not yet made Available	Lost to Follow Up	Follow Up Data
University of Texas Southwest	234	64	125	45
Emory University School of Medicine	348	48	81	219
University of Miami	313	0	115	198
University of Connecticut	394	0	164	230
University of Arkansas	48	48	0	0
Medical College of Georgia	130	126	3	1
Orange County California	140	11	20	109
TOTAL	**1,607**	**297**	**508**	**802**

LightTouch Triage Test

Using the result of LightTouch

- Normals-217/556 (39%) would not need further evaluation
- CIN1- 176/585 (30%) would not need further evaluation

- Significant cost savings

Subjects reclassified as CIN 2+ based on histopathology review and two year follow up

	Number of Subjects with CIN 2+	Number Detected by Light Touch	Sensitivity (%)
Reclassified as CIN2+ based on QA consensus histopathology*	20	16	80.0
Reclassified as CIN2+ based on up to 2 year follow up histopathology**	31	28	90.3
TOTAL	51	44	86.3

*initial review of enrollment biopsy
**based on histological patient follow up

MHS Detected 46.9% More CIN2+ Than the Standard of Care (n=802)

Follow up Procedure	Standard of Care*	MHS
Histopathology Review	80.2% (81/101)	90.1% (91/101)
2 Year Follow up	0.0 (0/31)	90.3% (28/31)
Total	61.4% (81/132)	90.2% (119/132)

* Includes Pap cytology, HPV and colposcopy

Study Conclusions

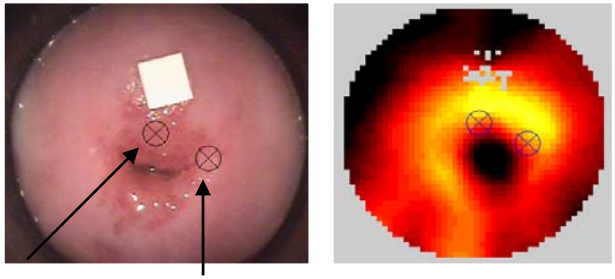
- Abnormal cytology had little value as a triage tool unless it was HSIL (high grade)
- LightTouch detected 91% of CIN2+ compared with 61% sensitivity for the current standard of care consisting of Pap, HPV and colposcopically directed biopsy
- LightTouch would have reduced the number of false positives by 39% for women with normal histology and by 30% for women with low grade dysplasia (CIN1 histology)
- Test is relatively simple to perform
  - No safety issues; less discomfort
  - Well accepted by patients

Opportunity to reduce cost to patients and healthcare system

LightTouch – Other Applications

- Cervical mapping of lesions

Cervical Maps of Subject with Dysplasia



Biopsy sites marked with X's

- Primary Screening

  Device designed for primary screening

  Fast, immediate result; portable

  Test can be conducted by nurse or technician

Thank You