Multimodal Spectroscopy as a Triage Test For Women at Risk For Cervical Neoplasia:

RESULTS OF FOLLOW UP DATA

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Disclosure Information

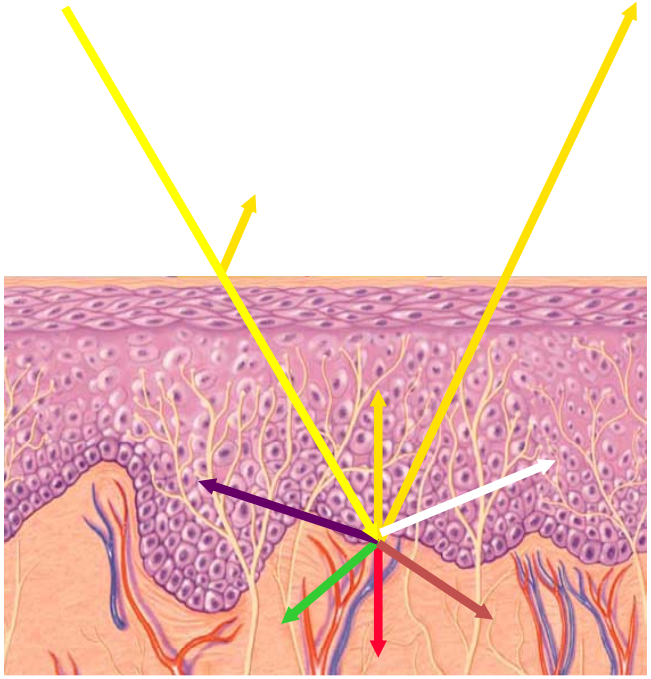
- The study sponsor was Guided Therapeutics, Inc.
- None of the authors have any potential conflicts of interest to disclose
- Dr. Chakhtoura is a member of the Speaker's Bureau of GSK

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

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

Background

Challenge in evaluating efficacy of new technology is verification bias – *How gold is the gold standard in verifying presence or absence of disease?*

ALTS reduced verification bias*

- Expert colposcopy
- Quality controlled consensus histopathology
- Up to 2 year follow up

***ALTS Group. Results of a randomized trial on the management of cytology interpretations Of ASCUS . June 2005. American Journal of Obstetrics and Gynecology**

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**

Clinical Evaluation of Multimodal Cervical Spectroscopy: Mitigation of Verification Bias

- Expert colposcopy with adequacy data collected
- Multiple steps to detect cervical lesions (e.g., Lugol's in addition to acetic acid)
- Automated detection of possible interfering factors (e.g., ambient light, blood/mucus)
- Quality assured histopathology review (Follow up I)
- Up to 2 year follow up data (Follow up II)

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

Comparison of MHS Study Follow Up Results with ALTS

	ALTS/Immediate Colposcopy Arm	ALTS/HPV Triage Arm	MHS Pivotal Study	
			HPV	MHS
Number of cases with follow up	1163	1161	802	802
Number of cumulative CIN2/3	189	186	45*	45*
Sensitivity	53.6 (CIN3 only)	72.3 (CIN3 only)	77.8 (CIN2/3)	86.7 CIN2/3)

*** Excludes HPV quantity insufficient (n=4) or lost (n=1) and MHS spectra not analyzable (n=1)**

Conclusions – MHS Follow up Study

- Sensitivity for CIN2/3 of current standard of care was 61.4% (81/132)
- Similar to ALTS - 65% for CIN3
- MHS detected 46.9% more CIN2+ than the standard of care ($p < .001$)
- MHS detected 86.3% of cumulative CIN2+ missed by the current standard of care

Thank You

The National Cancer Institute

The Georgia Research Alliance

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 see and treat in the same visit and reimbursable in US using colposcopy CPT 57452
- LightTouch Manufactured by Guided Therapeutics, Inc. / Norcross, Georgia, USA