

Guided *Therapeutics*™

New Rapid Scan Technology for Detecting Cancer





Cervical Cancer – A Costly, Worldwide Killer



Affects all age groups
Second only to breast cancer

500,000 cases of precancer in the U.S.

11,070 cases of cancer in the U.S.

3,870 deaths in the U.S.

\$2.8 billion to treat cervical cancer in U.S.

\$6+ billion + to diagnose cervical cancer in U.S.



Guided
Therapeutics[™]

Competing Technology



Pap test developed in 1941
Still in use today

Large infrastructure required
Misses disease
High false positive rate

LightTouch Technology

New, painless technology to detect pre-cancer of the cervix



Multimodal spectroscopy

Low cost device

Single-use disposable

Video imaging system

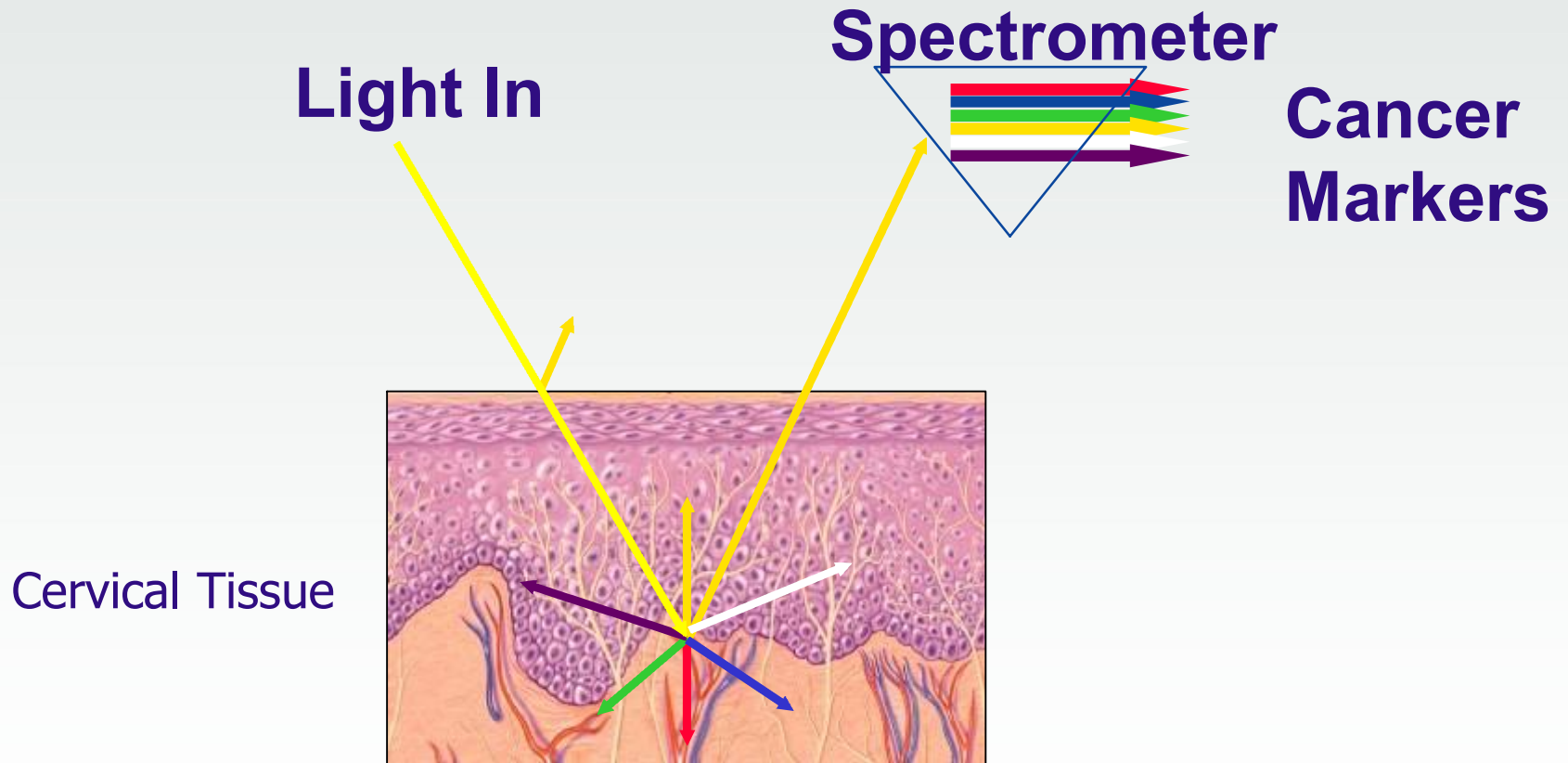
1 minute to scan cervix

Touch screen technology

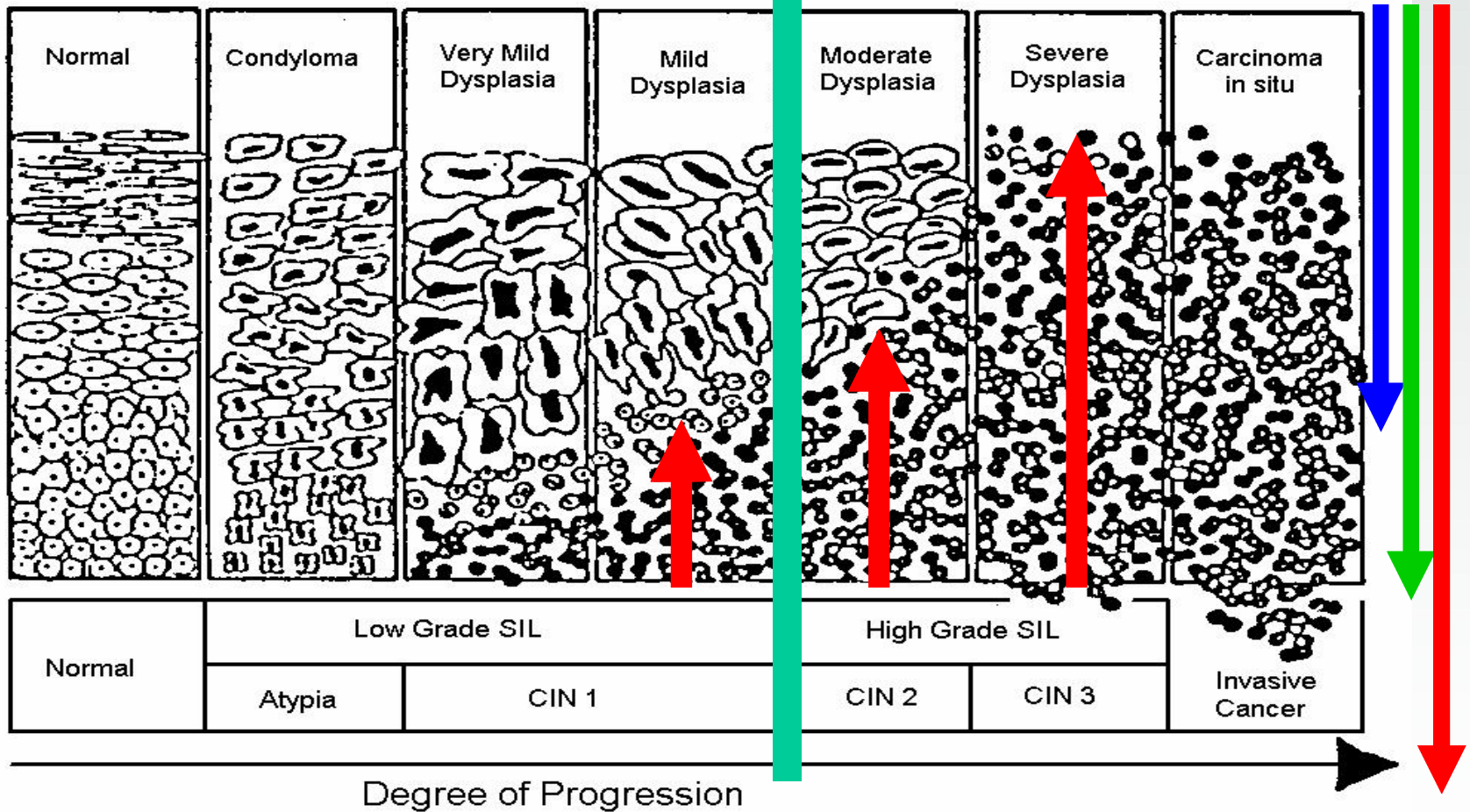
Guided
TherapeuticsTM

LightTouch Technology

Biophotonics



LightTouch Technology



Streamline the Ob-Gyn Practice



Efficient

Technician operated

Result is immediate

Affordable

Similar in cost to other GYN devices

Payback in less than one year

Accurate

Finds disease earlier

Reduces false positives

Preview of FDA Results

Landmark NCI study
35% of disease is missed
Only 26% of biopsies have disease



Guided Therapeutics FDA pivotal trial confirms
32% of disease missed
Only 19% of biopsies had disease

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Women Prefer LightTouch

Women's Responses to Cervical Interrogation by Fluorescent and Reflective Spectroscopy

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Abstract

Objective. To determine women's responses to cervical interrogation by fluorescent and reflective spectroscopy (FRS).

Materials and Methods. A convenience sample of women scheduled for a colposcopic examination was interrogated by a cervical FRS system. Thereafter, women completed a 24-item questionnaire that assessed their responses to among

subgroups using the χ^2 test for trend.
Results. Most women favored sampling (96.6%; 160/174) and selectively sampling (96.6%; 160/174) for cervical neoplasia. Fewer women (81.0%; 141/174) wanted FRS to replace the Pap smear. Most women were neither nervous (73.6%; 128/174) nor bothered (89.1%; 155/174) by the extra time for the FRS assessment. Women's acceptance was substantiated by 84.9% (146/174) and 90.8% (157/173) wanting their doctor to have and insurance company to pay for FRS, respectively.

Conclusions. Use of FRS as a colposcopic adjunct was supported very favorably by women. Fewer women reported FRS replacing Pap smears. These high rates of approval by women should help the implementation of FRS technology. ■

Key Words: fluorescent and reflective spectroscopy, patient preference, cervical neoplasia, cancer diagnosis

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Many scientific engineering entities are developing sophisticated tests designed to assess for cervical neoplasia. These tests use various wavelengths of energy to accentuate tissue autofluorescence within the epithelium [1-4]. Distinct differences in the amplitude and mean wavelength of certain light emitted or reflected by the interrogated tissue help to discriminate normal epithelium from cervical neoplasia. Researchers have measured the performance of these tests in comparison with cervical cytologic and histologic diagnoses. Preliminary results suggest several potential clinical roles for these novel, noninvasive, rapid, point-of-care diagnostic instruments.

Because colposcopic skills vary considerably and colposcopic diagnoses are not always in agreement with corresponding histologic interpretations, fluorescent and reflective spectroscopy (FRS) of the cervix may have usefulness by assisting colposcopists in locating cervical neoplasia and selectively sampling the most severe epithelium. Moreover, cervical spectroscopy may help improve the sensitivity of cervical cytologic analysis if used simultaneously as a Pap smear adjunct test [1]. This new technology may also be used as an intermediate triage test conducted on women after a minimally abnormal Pap smear result (i.e., atypical squamous cells). Although currently unlikely, FRS eventually may replace the Pap smear, provided certain technical difficulties can be resolved.

Although the current developmental focus of FRS has been centered appropriately on the technical character-

Vast majority of women said they
Wanted their doctor to have it
Liked it better than Pap
Would recommend it to a friend
Wanted insurance coverage

Guided
Therapeutics™

Technical and Commercial Progress

Conclusions from clinical studies



1,000 women in development studies

2,009 women enrolled in FDA trial

Outperforms Pap as triage test

Finds significant missed disease

NO adverse events

Intellectual Property

- 16 issued patents
- 4 patent applications
- Peer reviewed journal articles
- Posters and presentations in U.S., South America and Europe



Conclusions/Summary

A Better Chance Against Cervical Cancer



Global Opportunity
Continuing Revenue
Strong Intellectual Property
Experienced Board and Management Team
OB-GYN Thought Leaders on Board
FDA Review of PMA Application Underway

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Algorithm Development Study



648 subjects enrolled at 5 clinics across the USA

Subject withdrew consent before study completion	19
Pap test or Pathology result unavailable	42
Device Malfunction	15
Measurement Artifact (Analyzed separately)	62
USED FOR DEVELOPMENT	510

Pivotal Study Update

Dallas - 258
Grady - 517
Miami - 352
Hartford - 430
Arkansas - 48
MCG - 170
California - 234

2009 Subjects - Completed 4Q 2008

- 1,461 tested with the Alpha Device
- 548 tested with the Preproduction Device
- Results to be announced at ASCCP annual meeting March 2010