Utility of extra biopsies during colposcopy: Experience with a cervical imaging system at an academic center

Hope Richards, MD; Resident Physician
Colleen Stockdale, MD, MS; Clinical Associate Professor

University of Iowa Hospital and Clinics
Department of Obstetrics and Gynecology
Iowa City, IA, USA

Disclosures

LUMA™ device provided July 2008 to October 2010 by MediSpectra, Inc, MA, USA (defunded 2010)

Background

Colposcopy has been the standard for biopsy of the cervix since the 1960s.

Allows for further characterization of possible pre-cancerous or cancerous lesions to guide management.

Detection of cervical dysplasia through colposcopy has been estimated to range from 50-80%.

ACOG PB 140. *Obstet Gynecol* 2013.
Ferris DG, Litaker M. *JLGTD* 2005.
Jeronimo J et al. *Obstet Gynecol* 2007.

Background

Improving sensitivity of colposcopy to detect cervical dysplasia/cancer has been undertaken by taking additional biopsies, however the optimum technique is unknown.

Recent studies have explored various strategies:

- Additional directed biopsies from unique, suspicious appearing lesions improved sensitivity of detecting CIN2 from 68.3% (1 biopsy) to 81.8% (2 biopsies) (Gage JC et al. *Obstet Gynecol* 2006).
- Random biopsies at the squamocolumnar junction when no lesions are visible have been shown to detect 19.7% of CIN2+ disease with one biopsy (Huh WK et al. *Obstet Gynecol* 2014) and 25.7% of CIN3+ with four-biopsies (one in each cervical quadrant) (Pretorius RG et al. *JLGTD* 2011).

Objective

Review the use of a cervical imaging system to determine its impact in identifying CIN2+ beyond initial clinician directed biopsy.

Methods

- FDA approved cervical imaging system (CIS) 2006
- Used as an adjunct to colposcopy
- 195 women (July 2008-Oct 2010)
- Post hoc analysis to determine diagnostic value of additional non-random biopsies
- IRB approved

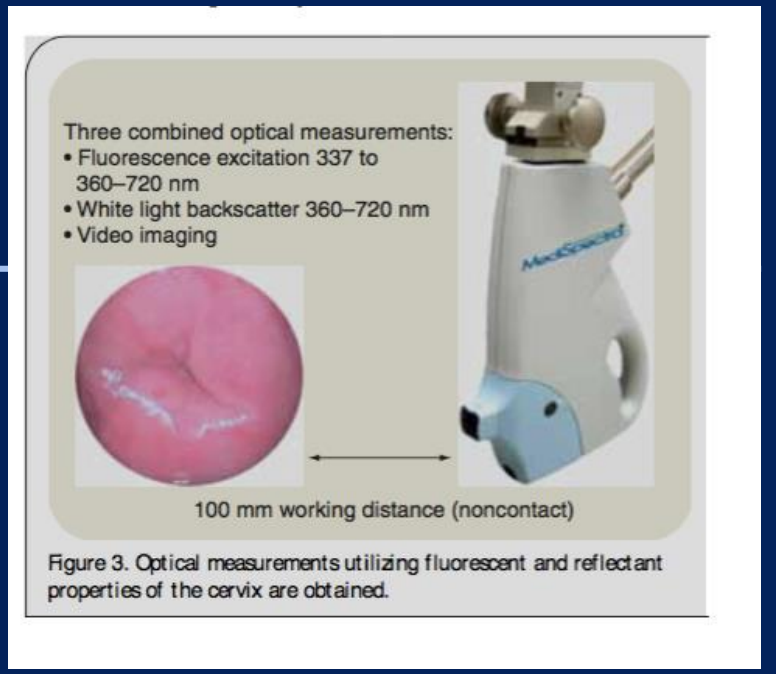

Figure 3. Optical measurements utilizing fluorescent and reflectant properties of the cervix are obtained.

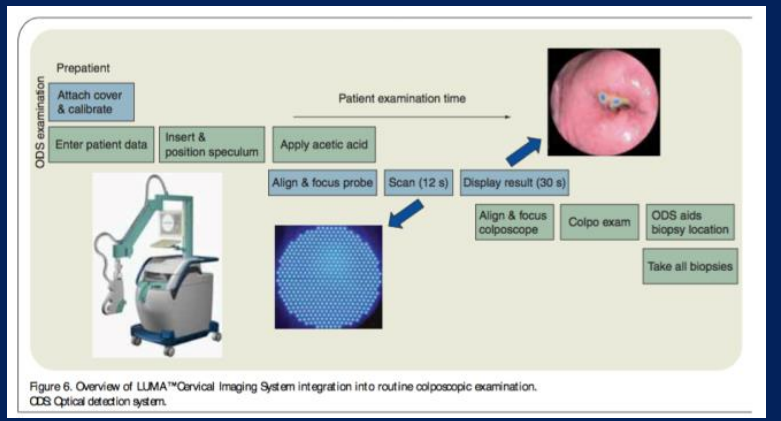

Figure 6. Overview of LUMA™Cervical Imaging System integration into routine colposcopic examination.
ODS Optical detection system.

Kendrick et al. *Expert Rev. Med. Devices.* 2007.

Results

195 Participants:

- Median age 27
- 65/195 (33%) identified as smokers
- 46/195 (24%) referred for HSIL on PAP smear

Results

53/195 were found to have CIN 2+

- 48/53 identified by routine colposcopy (+ biopsy)
- 5/53 identified with CIS
- 22/53 CIS missed CIN2+

Results

Clinician directed biopsy = 188

Thus, 48/188 directed biopsies CIN 2+ (nnt = ~4)

Additional CIS biopsy performed = 68

Thus, 5/68 additional biopsies CIN 2+ (nnt = ~14)

Limitations

No “gold standard” diagnosis utilized

- No biopsy requirement (endocervical sampling was required)
- No excisional procedure requirement

Machine limitations: 14/195 women did not have CIS performed

Conclusion

As identified by others, extra biopsies increase the sensitivity of traditional colposcopy- though relatively low yield compared to others.

What is not clear is whether the additional cases identified represent clinically significant disease.

Our study is particularly relevant as practitioners explore various diagnostic techniques to improve upon current practice.