

Background

Cervical Cancer

- Every 2 minutes, a woman dies of cervical cancer²
- Over 500,000 women diagnosed with cervical cancer per year around the world (2nd largest cancer-related cause of death in middle-low income countries)
- Lack of resources and patient follow up preclude middle-low income countries from providing adequate screening and vaccine administration¹

Problem Statement

The global adoption of optical techniques for the detection of cervical precancers is prevented by impractically high cost and procedural complexity of existing techniques.

Current Protocols

Conventional Method:

Pap Smear → Colposcopy → Biopsy → Cryotherapy

Current Raman Protocol:

1. Speculum
2. Large cotton swab
3. Saline
4. Small cotton swab
5. Acetic acid stain
6. Raman probe
7. Biopsy instrument
8. Colposcope

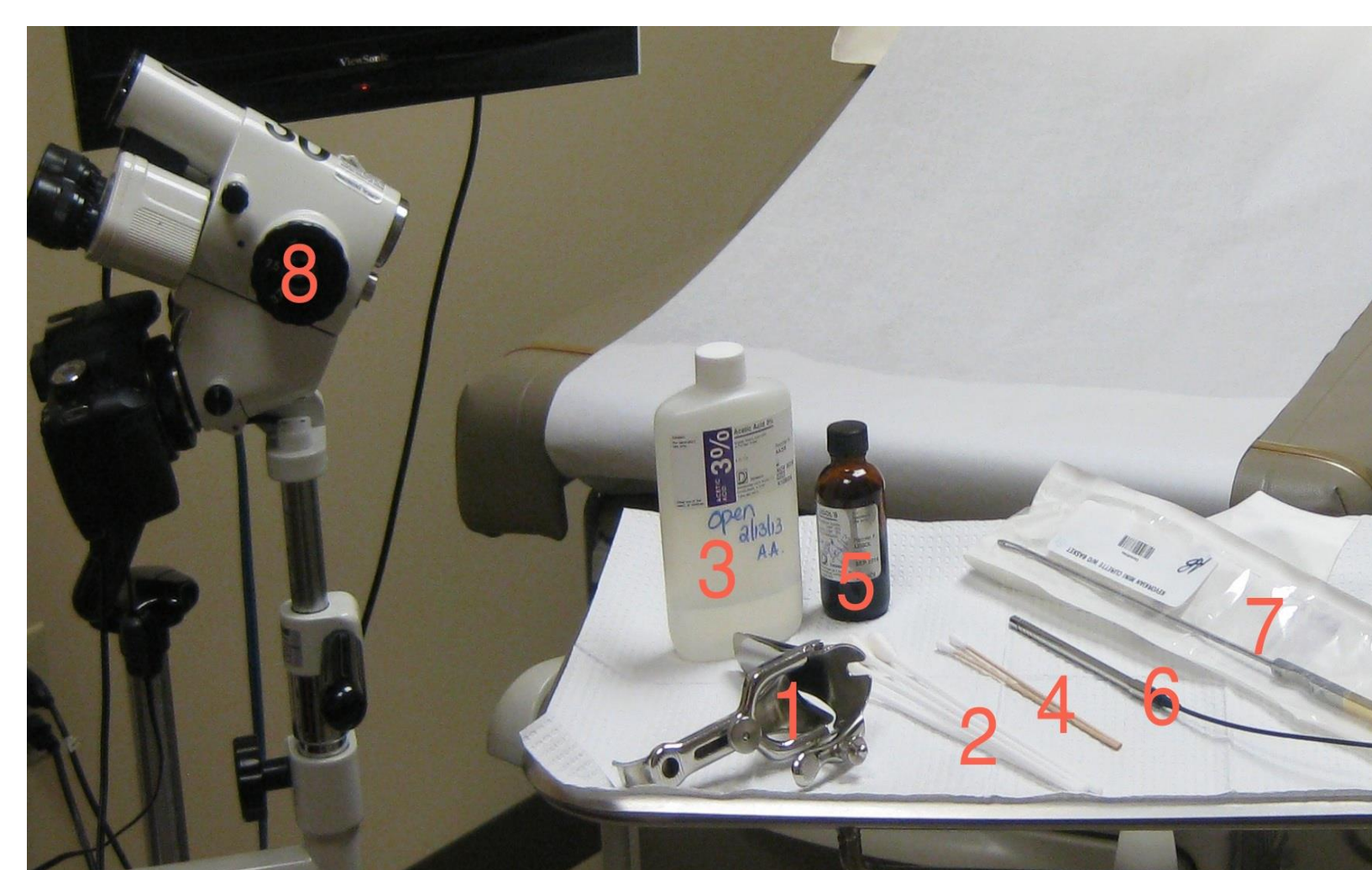


Figure 1. Instruments in Existing Raman Protocol

Needs Assessment

Actions

- Block ambient light
- Deliver probe to the cervix
- Provide a view of the cervix
- Move obstructive tissue
- Remove cervical mucus
- Enable application of diagnostic stains

Characteristics

- Comfortable for patient
- No sharp edges or points
- Minimized diameter (< 2 cm)
- Disinfectable
- Biocompatible
- Non allergenic
- Easy for the practitioner to maneuver

Design Components

Access Tube

General Properties

- 1.5 cm outer diameter
- Increased stability during testing
- Increased patient comfort
- Lack of speculum
- No sharp edges
- Avoids sensitive areas
- Camera channel for visualization of cervix
- Probe channel for Raman instrument
- Fluid channel for saline rinse and stain application
- Inflatable channel for required canal expansion

Figure 2. Final Prototype

Imaging Channel



Figure 3. Visualization of resolution pattern within phantom at 3 cm measurement scenario

Camera Testing Results:

- Resolution: 640 x 480
- 3 cm away to capture quadrant of cervix
- Can capture clear images from 1 mm away
- Enables visualization of cervix
- Eliminates need for colposcope

Inflation Channel

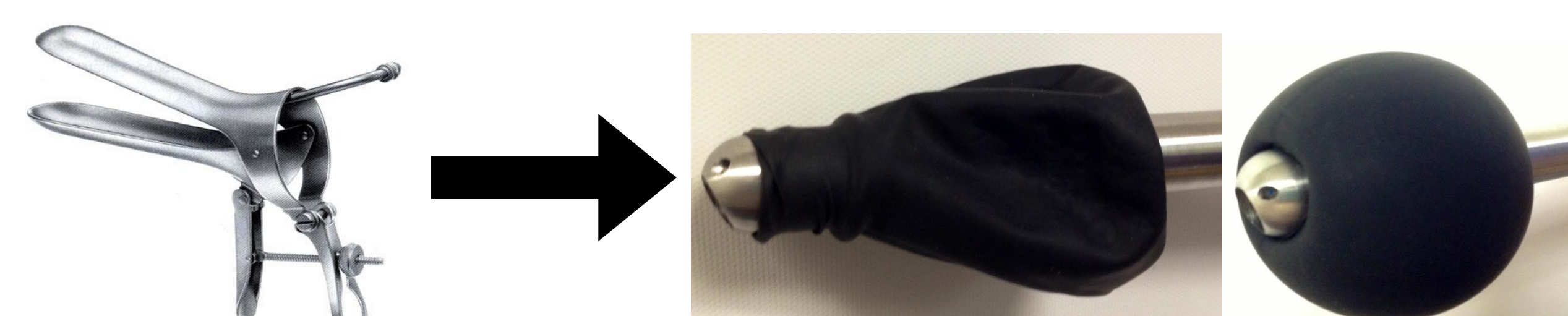


Figure 4. Replacement of speculum with novel inflatable design

Purposes:

1. Block ambient light to preserve Raman signature
2. Move the surrounding tissue out of the view of the cervix

Fluid Channel

- 0.3 cm outer diameter
- Purposes:
 - Saline solution for cleaning target tissue
 - Eliminates need for cotton swabs
 - Acetic acid stain used to visualize abnormalities
 - Streamlines staining process
- Saline solution flushed through the tube using a syringe at a rate of 5mL/s successfully cleaned egg white off the surface of skin



Figure 5. Fluid Application

Optical Probe Channel

- 0.3 cm outer diameter
- Probe components: 785 nm excitation laser
- Seven collection fibers used in the transport of Raman scattering to the spectrograph

Results

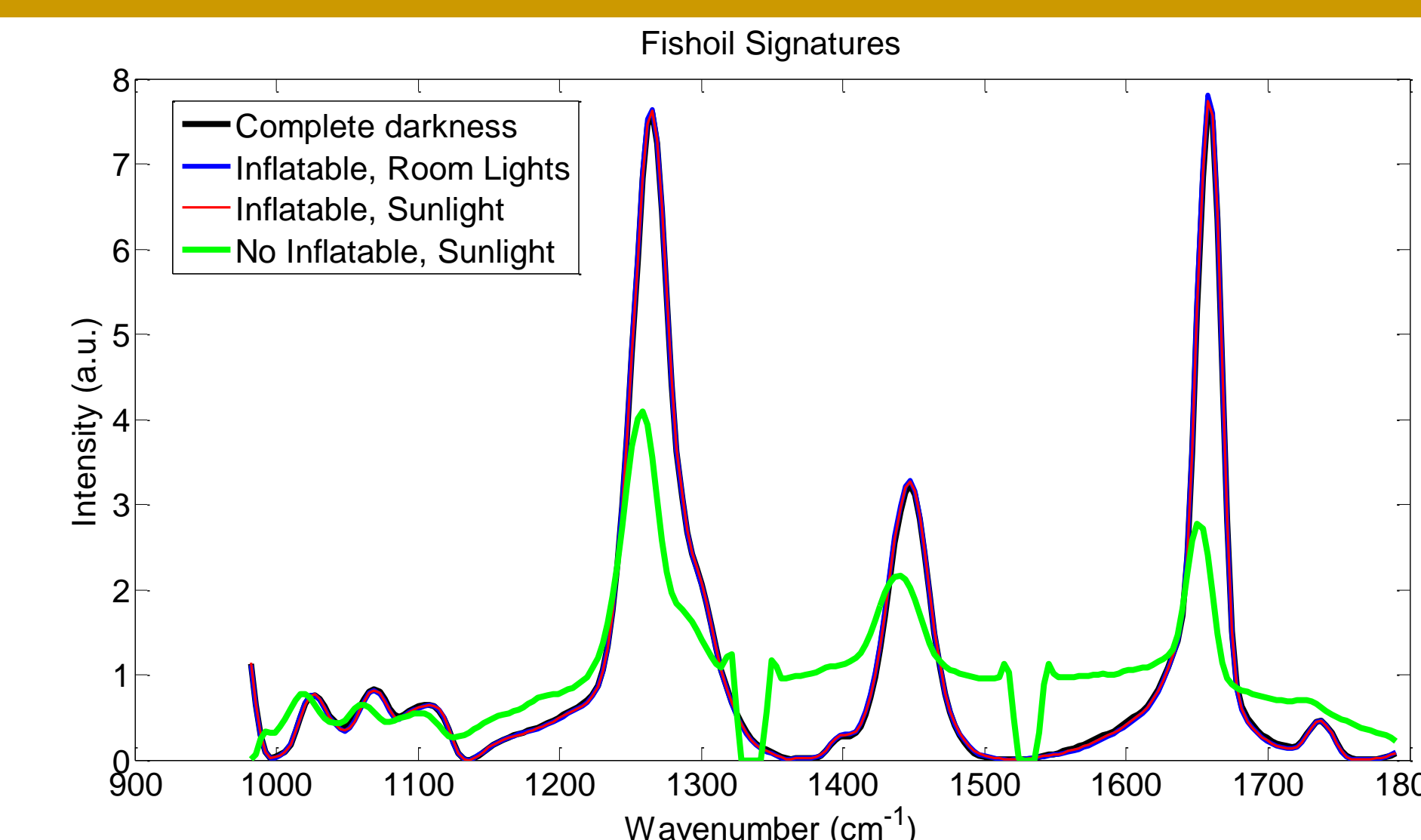


Figure 6. Comparison of Raman spectrum obtained in various conditions

- Data from various light conditions confirms that the device successfully blocks ambient light
- Visualization, cleansing, Raman delivery, and light blocking were all individually validated

	Components	Cost
Conventional Standards	• Pap Smear	\$143 per test
	• HPV Screening	\$193 per test
	• Colposcopy	\$361 per test
	• Biopsy	\$480 per test
	• Hospital Infrastructure	\$ millions
Existing Raman Protocol	• Colposcope	>\$2,000
	• Speculum	> \$25
	• Swabs	\$ 0.06 per use
	• Raman System	
Proposed Raman Protocol	• Access tube	\$92.21
	• Camera	\$159.98
	• Hand Pump	\$20.63
	• Inflatable	\$0.13 per use
	• Raman System	

Figure 7. Cost Comparison of Existing Protocol vs. Proposed Protocol

Conclusions

- This device streamlines the testing protocol and carries out all steps necessary to successfully implement the Raman exam
- Compared to the existing protocol, our proposed system greatly reduces the cost of implementing
- This device design holds promise in facilitating the acceptance of Raman spectroscopy as the standard of care for cervical precancer detection, as well as its adoption as a low-resource clinical option
- Future steps include soliciting approval from the IRB to proceed with human testing of our device's comfort, visualization, and clinical results

Acknowledgements

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1: <http://www.cancer.org/cancer/news/expertvoices/post/2013/01/30/cervical-cancer-is-an-international-issue.aspx>

2: Seth Berkley, M.D.; former president and CEO of GAVI Alliance