



Point of Care Tampon (POCkeT) Colposcope: Increasing Access to Cervical Cancer Screening for Resource-Limited Settings

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BACKGROUND

- Cervical cancer is the second leading cause of death for women world wide with 85% of deaths occurring in low and middle-income countries¹
- Cervical cancer is both preventable and treatable if caught early, but the burden of disease persists because of a lack of access to early diagnostics

PURPOSE

- Pilot study to compare our Generation 3 POCkeT colposcope to the standard of care Goldway colposcope in Lima, Peru
- Collect paired images with standard colposcope and POCkeT devices for 100 Peruvian women
- Determine concordance between devices to show capability of POCkeT as a diagnostic tool

METHODOLOGY

- Worked with OBGYN at La Liga Cancer center who performs colposcopy exams for women who are referred with abnormal papanicolaou tests
- Collected paired images of cervixes with standard colposcope and POCkeT device for each patient for white light and Lugol's iodine
- Sent 5 international doctors randomized and blinded images to diagnose
- Compared image analyzed result to actual pathology from patient to determine accuracy of diagnoses and concordance between devices



Figure 2. Standard of care Goldway Colposcope

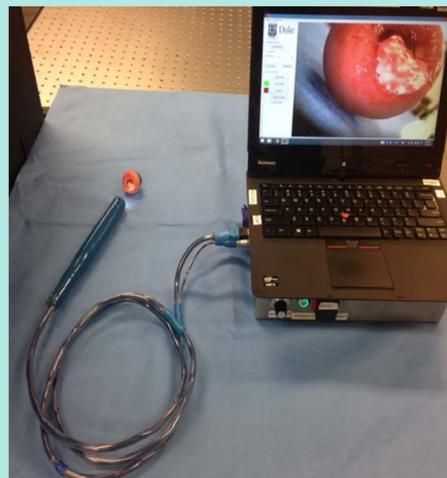


Figure 3. Generation 3 POCkeT Colposcope

RESULTS

Table 1. Reid Colposcopic Index (RCI) for diagnosing precancerous/cancerous cervical lesions²

Colposcopic Sign	Zero Point	One Point	Two Points
Lesion Margin	Flat, indistinct, feathered, scalloped	Smooth	Rolled/peeled
Vascularization	Vessels, fine punctuation/ mosaicism	No vessels	Vessels, coarse punctuation/ mosaicism
Color after acetic acid applied	Pure white, Intense shine	Grey white, Shiny	Oyster grey, Dull
Iodine Staining	Chestnut-colored mahogany	Mottled, marbled	Yellow staining

Scoring: 0-2 indicates minor lesion (CIN1), 3-5 indicates middle-grade lesion (CIN2), and 6-8 indicates significant lesion (CIN2 or 3)

Table 2. Pathology Breakdown for 73 interpretable images collected from 100 patients enrolled in study

Procedure Type	Total	Normal	CIN1	CIN2	CIN3	Invasive Disease	Pathology Not Yet Received
Colposcopy (73)							
Biopsy	51	12	22	5	4	6	2
No Biopsy	22	21	1	0	0	0	0
Total	73	33	23	5	4	6	2

Figure 4. Comparing paired images using white light (top) and Lugol's iodine images (bottom) for different stages of precancerous/cancerous lesions.

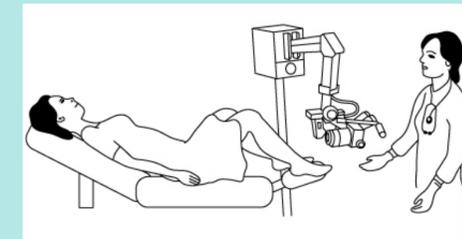
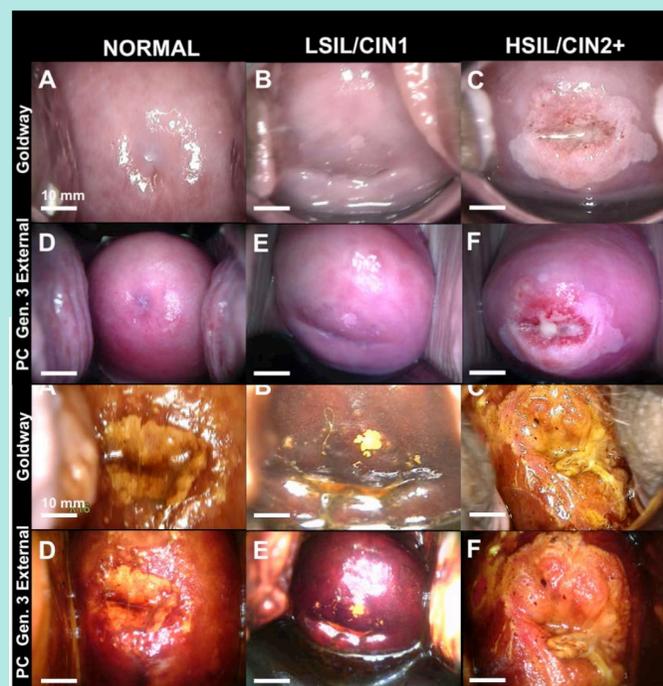


Figure 1. Colposcopy Exam Setup

CONCLUSION

Table 3. Concordance between systems at La Liga. Kappa statistic calculated using a weighted quadratic.

Gen. 3	Level of Agreement (%)	Agreement Coefficient (κ)	p-value
POCkeT Colposcope vs. Goldway (n=73)	84.6	0.5755	0.0000
POCkeT Colposcope vs. Pathology (n=71*)	71.8	0.2542	0.0079
Goldway vs. Pathology (n=71*)	77.2	0.3364	0.0012

- The POCkeT colposcope has comparable performance to the standard of care system when looking at white light and Lugol's images

*Available pathology reports

REFERENCES

1. WHO Guidelines for Screening and Treatment of Precancerous Lesions for Cervical Cancer Prevention. (2013). World Health Organization.
2. <http://screening.iarc.fr/colpoappendix5.php>
3. WHO | Human papillomavirus (HPV) and cervical cancer. (n.d.). Retrieved December 6, 2015, from <http://www.who.int/mediacentre/factsheets/fs380/en/>