# Clinical Utility Pilot Study of a Novel Tissue-Trap Brush in Histologic Sampling of the Cervical Transformation Zone

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- Dr. Felix
- Dr. Winter

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# Introduction

- Brush devices have been proven to obtain diagnostic ectocervical and endocervical biopsy specimens in colposcopy (1, 2).
- Multiple or random colposcopic biopsies in high risk cohorts with abnormal screening is preferred under new ASCCP Colposcopy Standard Guidance.
- Targeting of the optimal site for the additional or random biopsy is prone to sampling error, targeting error, or tissue yield challenges.
- The additional sampling of the endocervix may be useful in certain clinical scenarios, as the transformation zone may extend there.





- An FDA compliant/cleared novel brush utilizing a propeller type design with one arm containing a shallow hooked fabric was evaluated in the laboratory (in-vitro) and in vivo (clinical case).
- The feasibility of obtaining a trans-epithelial diagnostic sample of tissue from all quadrants of the central portio was to be evaluated
- The sample adequacy, distribution of the biopsy relative to the cervical portio and endocervix was evaluated in vitro.
- The patient care experience, diagnostic quality of the sample, and operator "ease of use" was evaluated in-vivo



# Method 1: In-Vitro Lab Evaluation

- JF performed a simulation of a colposcopic transformation biopsy using the novel brush.
  - Fresh Hysterectomy specimen with 5-color painting of per quadrant of cervical portio and endocervix
  - Applying firm to moderate pressure on the cervix while inserting the tip into the endocervix, 3 complete revolutions clockwise, then counter-clockwise, removal, detaching brush head from handle, insert tip into formalin.
  - Tissue sample wiped free from hooked bristles while in vial and processed identically to conventional endocervical curettings.
  - Inspection of the histopathology slides of histochemical staining unique for each quadrant and the endocervix, along with diagnostic quality of the tissue pieces removed was evaluated.



# Method 2: In-Vivo Clinical Use

- 6 patients used during colposcopy.
- The brush head was moderately pressed on the central cervix, tip inserted into endocervix, and rotated 360 degrees clockwise and counter-clockwise three times. Brush head was detached, placed in formalin, and processed identically to conventional curettage specimens.
- Diagnostic quality of biopsy sample and evaluation of the patient reported pain and clinician observed cervical bleeding, as well as operator ease of use was evaluated (Likert Scale).



# Method 1: Histo-Chemical Dye Application and Procedure







Pre-procedure stainin Procedure Excavated TZ

**Post-Procedure Device** 

Post-



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# Method 1: Histological Biopsy Evidence





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# Method 2: Use During Colposcopy Prior To Excision Procedure







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## Patient 4: Brush Biopsy Specimen





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### Patient 4: Cone Biopsy





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#### Biopsy Diagnoses, Pain, Observed Bleeding Post-Biopsy

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<u>Age</u>	Referral Reason	<u>Po</u>	Brush bx Grade	Softbx 12 pain	Softbx 12 bleeding	Ease of Use Rating	# lesions seen
27				0	0	10	2
37	CIN 2/3 biopsy	CIN 1	CIN 1	0	0	10	2
49	Cin 2/3 biopsy	CIN 1	negative	2	0	10	2
49	CIN 1/2 biopsy	Cin 2	Negative	0	2	10	2
34	HSIL on biopsy,ECC	CIN 3	CIN 1	5	5	10	1
34	CIN 3 on biopsy	CIN 3	Negative		3	-	2
28	CIN 3 on biopsy	neg, koilocytosi	Negative	0	1	10	1
Mean scores				1.40	1.80	10.00	

Pain and Bleeding Likert Scale from 0= None to 10 Severe, Ease of Use Likert Score; 0=Simple to 10= Difficult



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# Conclusions

- Specimens are trans-epithelial and diagnostic both in-vivo and invitro relative to grade of dysplasia.
- In vitro setting allowed for evaluation of endocervical and four quadrant sampling which appears comprehensive.
- Sample appears minimally invasive with low pain and bleeding averages in-vivo. Ease of use confirmed in test cases.
- Shape of the tip in-vivo did not recess sufficiently into central portio and is under revision. Device characteristics and first use training thought to be responsible for mis-correlation in some brush cases compared with Loop Excision specimen.

