

ASCCP Colposcopy Standards: Role of Colposcopy, Benefits, Potential Harms, and Terminology for Colposcopic Practice

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Objectives: The American Society for Colposcopy and Cervical Pathology Colposcopy Standards address the role of and approach to colposcopy and biopsy for cervical cancer prevention in the United States. Working Group 1 was tasked with defining the role of colposcopy, describing benefits and potential harms, and developing an official terminology.

Methods: A systematic literature review was performed. A national survey of American Society for Colposcopy and Cervical Pathology members provided input on current terminology use. The 2011 International Federation for Cervical Pathology and Colposcopy terminology was used as a template and modified to fit colposcopic practice in the United States. For areas without data, expert consensus guided the recommendation. Draft recommendations were posted online for public comment and presented at an open session of the 2017 International Federation for Cervical Pathology and Colposcopy World Congress for further comment. All comments were considered for the final version.

Results: Colposcopy is used in the evaluation of abnormal or inconclusive cervical cancer screening tests. Colposcopy aids the identification of cervical precancers that can be treated, and it allows for conservative management of abnormalities unlikely to progress. The potential harms of colposcopy include pain, psychological distress, and adverse effects of the procedure. A comprehensive colposcopy examination should include documentation of cervix visibility, squamocolumnar junction visibility, presence of acetowhitening, presence of a lesion(s), lesion (s) visibility, size and location of lesions, vascular changes, other features of lesion(s), and colposcopic impression. Minimum criteria for reporting include squamocolumnar junction visibility, presence of acetowhitening, presence of a lesion(s), and colposcopic impression.

Conclusions: A recommended terminology for use in US colposcopic practice was developed, with comprehensive and minimal criteria for reporting.

Key Words: role of colposcopy, benefits, potential harms, terminology

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The practice of colposcopy is a cornerstone of cervical cancer prevention. In conjunction with screening and treatment of precancers, colposcopy has played a pivotal role in reducing the incidence and mortality from cervical cancer over the past 50 years.^{1,2} Despite its central role in cervical cancer prevention, the accuracy and reproducibility of colposcopy are limited. Important factors that may contribute to these limitations in the United States include (1) the lack of standardized terminology, (2) the lack of recommendations for colposcopy practice and procedures, and (3) the lack of quality assurance measures. Recognizing the limitations of current colposcopy approaches in the United States, the American Society for Colposcopy and Cervical Pathology (ASCCP), in collaboration with investigators from the US National Cancer Institute, set out to review evidence and develop recommendations for colposcopy practice in the United States.³

A starting point of this effort was to define the role of colposcopy as a test used in the prevention of cervical cancer. As with any screening, triage, or diagnostic procedure, the risks and benefits of a test must be evaluated and weighed. Another major component of this effort was to revisit and standardize terminology for colposcopy practice in the United States. The goal was to simplify and clarify reporting of colposcopic findings to enhance uptake by US colposcopists practicing in diverse work environments. The rationale, guiding principles, and the review of the evidence as it specifically applies to terminology and nomenclature for US colposcopy practice are described.

METHODS

Working Group 1 (WG1) was charged by the ASCCP Colposcopy Standards Steering Committee with describing the role of colposcopy in cervical cancer prevention (charge no. 1), outlining the benefits (charge no. 2) and potential harms (charge no. 3) of colposcopy, and with proposing an official ASCCP terminology

for reporting colposcopic findings (charge no.4). Working group and steering committee members included experts in colposcopy and cervical cancer prevention, with representatives from the fields of gynecology, gynecologic oncology, pathology, adolescent medicine, family medicine, and epidemiology. Initially, the working group met via a series of phone conferences to delineate the charges and to develop the plan to complete these charges. The working group later convened in person at the 2016 Annual ASCCP meeting in New Orleans, LA, along with the entire ASCCP Colposcopy Standards Committee, to further refine the charges and continue the development process.

Literature Search

A systematic literature search was conducted to identify studies with relevant information about the role of colposcopy, benefits, potential harms, and terminology. A separate search for each charge was performed using the search terms appropriate for that charge selected from the following: colposcopy, standards, statistics, numerical data, therapeutic use, therapy, use, uterine cervical neoplasms, cytology, diagnosis, epidemiology, prevention and control, secondary, benefit of colposcopy, adverse effects, contraindications, psychology, classification, and pathology. The Colposcopy Standards Steering Committee elected to use PubMed for the literature search because of its comprehensiveness. The PubMed search was performed on June 1, 2016, and yielded 459 citations.

A first-pass review of the abstracts was performed by WG1 members, and 112 articles found to be pertinent were selected for further review. Only articles written in English were included. A second-pass review of the selected articles was performed with abstraction of data on the relevant articles. For terminology, studies that evaluate the accuracy and reproducibility of current International Federation for Cervical Pathology and Colposcopy (IFCPC) terminology were targeted. For many of the articles, a summary statement was made that identified the article's relevance to a given charge. Additional articles were identified from the references of the selected articles and from additional searches by members of WG1.

A survey of the ASCCP membership was designed and carried out along with Working group 3 of the ASCCP Colposcopy Standards effort.³ Working Group 1 contributed questions specific to ASCCP members' current use of terminology and preferences regarding updating the terminology, along with a question on the potential harms of colposcopy. The survey results and the literature review findings informed the recommendations for an official ASCCP terminology to be used by colposcopists in the United States.⁴ For topics lacking substantial data in the literature, the ASCCP Colposcopy Standards Steering Committee and WG1 members provided input to guide the decision-making (i.e., expert opinion).

Development of Recommendations

Draft recommendations were developed based on the abstracted evidence and expert consensus. The recommendations were presented to the Steering Committee in October 2016 and reviewed for content and consistency among the working groups. Revisions were presented to all working group members of the ASCCP Colposcopy Standards Project for discussion and further revision in January 2017, and a vote among working group members was held shortly after. Sixty-seven percent affirmative votes were required for approval of individual recommendations. All recommendations were approved at the first vote, and most were approved unanimously with only minor comments. After further editing and notification of stakeholder professional organizations, recommendations were posted on the ASCCP website for public

comments between March 13 and 22, 2017; additional modifications were made in response to the comments. Finally, all working group recommendations were presented at the IFCPC 16th World Congress in Orlando, FL on April 5, 2017, followed by a plenary discussion. Final revisions were made by the Steering Committee based on comments received at this meeting.

RESULTS

Role of Colposcopy

Colposcopy is defined as the use of a specific instrument, a colposcope, for the real-time visualization and assessment of the uterine cervix, specifically the transformation zone (TZ), for the detection of cervical intraepithelial neoplasia (CIN)/squamous intraepithelial lesions (SIL) and invasive cancer. The ASCCP Colposcopy Standards project recognizes the use of colposcopy for other situations (vaginal or vulvar evaluation, high-resolution anoscopy, assessment of sexual assault victims, etc.); however, this document addresses only the colposcopic evaluation of the cervix in the context of cervical cancer prevention.

Magnification and illumination, usually in the form of a lens system and strong light source or digital imaging system, are fundamental to colposcopy. Characteristics of the cervical TZ and any abnormalities are assessed. The application of 3% to 5% acetic acid and Lugol iodine solution is used to identify potential lesions. Changes are visually assessed colposcopically and help direct biopsy placement. Visual changes include response to acetic acid (acetowhitening), characteristics of lesion borders, surface contours, lesion size, vascular patterns, and degree of iodine uptake.⁵⁻⁸ Because of the subjective nature and inherent inaccuracy of the colposcopic impression regardless of whether or not a colposcopic grading system is used, it is recommended that all potential lesions be biopsied.⁹⁻¹²

Colposcopy practice includes the complete colposcopy visit from visual assessment of the cervix to biopsy sampling if indicated. Colposcopy should be viewed as a risk assessment tool that directs subsequent management with biopsies, treatment, or observation. When a lesion(s) is/are present, colposcopy-directed biopsies of 2 to 4 sites are taken to establish a histopathologic diagnosis of the most severe disease present, confirm a lack of CIN/SIL/cancer, or assess for possible therapy. For low-risk women with a normal colposcopic impression, deferring biopsies may be acceptable.¹⁰ In select high-risk situations, an initial colposcopy may be followed immediately by a loop excision of the entire TZ, providing both diagnosis and treatment during the same encounter.^{10,13,14}

A colposcopist is a clinician who has undergone specialized training to develop proficiency in the performance of colposcopy and additional skills needed to accurately diagnose lower genital tract neoplasia. These skills must be accompanied by a comprehensive knowledge of the cervical cancer screening process, lower genital tract disease, and evidence-based management of abnormal screening and diagnostic tests. Colposcopy training is a standard component of obstetrics-gynecology residency programs as well as many family medicine residencies. Beyond these settings, colposcopy training generally involves didactic instruction followed by clinical preceptorship experience. Adequate training fosters the clinician's ability to recognize invasive cervical cancer as well as premalignant lesions, obtain biopsies of abnormal areas, and assess whether criteria for the reliable exclusion of invasive cancer have been met. These skills, along with the management of subsequent histopathology results, are essential for the accurate diagnosis, surveillance, and management of CIN/SIL and invasive cervical cancer.

The main indication for colposcopic examination is the evaluation of women at increased risk for cervical neoplasia, including those with:

- abnormal or inconclusive cervical cancer screening tests¹³
- symptoms or signs of possible cervical cancer, including any suspicious cervical abnormality found during pelvic examination, abnormal genital tract bleeding, or unexplained cervicovaginal discharge¹⁵
- past cytologic and/or pathologic anogenital tract abnormalities, treated or untreated.^{16,17}

Benefits of Colposcopy

Colposcopy has been the standard of care for the evaluation of abnormal cervical cytology since its introduction in the United States in the 1970s. Before this, essentially all women with significant cervical cytologic abnormalities underwent a cone biopsy or hysterectomy as combined diagnostic evaluation and therapy. The introduction of colposcopy with targeted biopsies provided accurate identification of cervical disease when present, as well as reassurance of the absence of disease in many cases, without the attendant risks and potential complications of conization. This has resulted in a drastic reduction in the number of excisional procedures performed by limiting them to those who have confirmed cervical cancer precursors or are at high risk of occult invasive cervical cancer.^{18,19}

Effective treatment of preinvasive disease of the cervix requires colposcopic assessment of the cervical TZ, especially the extent of any lesions and the ability to visualize the squamocolumnar junction (SCJ). The selection of the most appropriate treatment modality is dependent upon characterization of the lesion(s) present on the cervix, extension of lesions into the endocervical canal or outward onto the vagina, visibility of the SCJ, and severity of the most significant abnormality.

Current guidelines for the initial management of high-grade cervical cytologic abnormalities allows for an immediate diagnostic excisional procedure during the initial colposcopy encounter.¹³ Verification of a high-grade colposcopic impression is necessary for the use of this option. This “see-and-treat” approach using excisional therapy has the potential to improve compliance with therapy, reduce the risk of loss to follow-up, and avoid using ablative therapy on occult cancer.¹⁴

Colposcopy plays an equally important role on the opposite side of the cervical neoplasia spectrum—specifically, in reducing overtreatment of low-grade lesions. This is particularly important in young women who have a high prevalence of abnormal cervical cytology with frequent spontaneous regression of cervical neoplasia, particularly CIN2. Current guidelines allow for observation of patients with low-grade as well as some high-grade cervical neoplasia in selected young women, if the colposcopic findings support this approach.¹³

In summary, colposcopy is an important step in the initial evaluation of abnormal cervical cancer screening test results. It allows the identification of invasive cervical cancers followed by definitive therapy, without the need for an excisional procedure in most cases. When precancer is identified, colposcopy provides the information needed to individualize the treatment approach by characterizing lesion size, location, and severity. By allowing excisions to be tailored to lesion extent and TZ size, colposcopy is critical to a “see-and-treat” approach to managing high-grade cervical cytologic abnormalities in selected patients. Colposcopy also allows the identification and surveillance of a subset of women whose cervical disease can be safely observed over time.

Potential Harms of Colposcopy

In general, the overall procedural risks of significant bleeding, infection, and long-term morbidity from colposcopy are low. During the procedure, many women experience discomfort from a prolonged speculum examination, application of acetic acid, and cramping or pain from biopsies. Cramping may occasionally persist for 24 hours, but pain and discomfort are generally limited to the time of the procedure itself. A traumatic colposcopy experience may prevent some women from obtaining adequate cervical screening in the future. Moreover, a small percentage of women report a negative influence on sexuality.²⁰ It is unclear whether the diagnosis of an abnormal screening test versus the colposcopy itself contributes to these negative feelings.

Both an abnormal cervical cancer screening result and colposcopy can be anxiety-provoking for women.²¹ Most women report feelings of worry and anxiety in the interim period between the time of being notified of an abnormal screening result and the colposcopy appointment.²² After colposcopy, women worry less about the procedure itself and more about having human papillomavirus (HPV) infection or cancer.²³ Some studies have shown that educational interventions help allay fear and anxiety about the procedure, whereas others have not shown a benefit to this approach.^{24,25}

There is potential harm in performance of colposcopy by an unskilled clinician. Colposcopy requires adequate training and experience to attain proficiency and maintain competence in performing the procedure. The false-negative rate (missed high-grade squamous intraepithelial lesion/invasive cancer) for colposcopy depends on the expertise of the colposcopist and number of biopsies taken; it ranges from 13% to 69%.^{26–29} Failure to accurately identify the SCJ can result in missed cancers. An increased understanding of the natural history of HPV infection and its progression to cervical neoplasia has recently decreased the indications for colposcopy, with a subsequent reduction in the number of colposcopies being performed.³⁰ For those with low-risk cervical screening results, serial colposcopic examinations are indicated less frequently and, therefore, the cumulative likelihood of visualizing an abnormality is diminished. Moreover, as HPV testing has been incorporated into follow-up algorithms, women with persistent HPV infection and negative cytology are being referred to colposcopy who may have very small lesions, which are difficult to identify. As a result of these changes in indications for colposcopy referral, the importance of each individual colposcopic examination is higher, increasing the need for skilled colposcopists.

In summary, the procedural risks and long-term morbidity associated with colposcopy are very low. Experienced colposcopists are necessary to minimize the risks of false-negative results, particularly because colposcopy continues to be performed less often.

Terminology

Working Group 1 was charged with developing a standardized descriptive terminology for colposcopic practice within the United States (Table 1). The 2011 IFCPC terminology was used as a template for the ASCCP terminology recommendations and was adapted to fit colposcopic practice in the United States (Table 2).⁵

The general assessment of the colposcopic examination including assessment of the SCJ has historically been described as satisfactory/unsatisfactory or adequate/inadequate, as in the current ASCCP consensus management guidelines.¹³ These terms were updated because at present, they are ambiguous and may be misinterpreted by patients in a clinical setting. The general assessment of the cervix was modified from the IFCPC nomenclature, to include an assessment of both visibility of the cervix, as a whole, and of the SCJ, specifically, using the terms “fully

TABLE 1. Standardized ASCCP Terminology for Colposcopic Practice

Category	Features/Criteria	Details	
General assessment	Visualization of the cervix	Fully visualized Not fully visualized due to: _____	
	Visualization of the SCJ	Fully visualized Not fully visualized	
Acetowhite changes	Any degree of whitening after application of 3%–5% acetic acid	Yes/no	
Normal colposcopic findings	Original squamous epithelium: mature, atrophic		
	Columnar epithelium		
	Ectopy/ectropion		
	Metaplastic squamous epithelium		
	Nabothian cysts		
	Crypt (gland) openings		
	Deciduosis in pregnancy		
Abnormal colposcopic findings	Submucosal branching vessels		
	Lesion(s) present (acetowhite or other)	Yes/no	
	Location of each lesion	Clock position	
		At the SCJ (yes/no)	
		Lesion visualized (fully/not fully)	
	Size of each lesion	Satellite lesion	
		No. quadrants the lesion involves	
		Percentage of surface area of TZ occupied by lesion	
	Low-grade features	Acetowhite	
		Thin/translucent	
Rapidly fading			
Vascular patterns			
Fine mosaic			
Fine punctation			
Margins/border:			
Irregular/geographic contour			
Condylomatous/raised/papillary			
Flat			
High-grade features	Acetowhite		
	Thick/dense		
	Rapidly appearing/slowly fading		
	Cuffed crypt (gland) openings		
	Variegated red and white		
	Vascular patterns		
	Coarse mosaic		
	Coarse punctation		
	Margins/border		
	Sharp border		
Inner border sign (Internal margin)			
Ridge sign			
Peeling edges			
Suspicious for invasive cancer	Contour: flat		
	Fused papillae		
	Atypical vessels		
	Irregular surface		
	Exophytic lesion		
	Necrosis		

Continued next page

TABLE 1. (Continued)

Category	Features/Criteria	Details
		Ulceration
		Tumor or gross neoplasm
		A suspicious lesion may not be acetowhite
	Nonspecific	Leukoplakia
		Erosion
		Contact bleeding
		Friable tissue
	Lugol staining	Not used
		Stained
		Partially stained
		Nonstained
Miscellaneous findings	Polyp (ectocervical or endocervical)	
	Inflammation	
	Stenosis	
	Congenital TZ	
	Congenital anomaly	
	Posttreatment consequence (scarring)	
Colposcopic impression (highest grade)	Normal/benign	
	Low grade	
	High grade	
	Cancer	

visible” and “not fully visible” for each. The IFPC terminology additionally uses “transformation zone type (1, 2, 3)” in the general assessment. For increased clarity of communication, the specific designation of TZ types as 1, 2, or 3 are not included in the WG1 recommendations. Our literature review demonstrated that the use of TZ type was not reproducible among clinicians, particularly for TZ type 2, and there was no evidence that TZ type improves prediction or management of cervical disease.^{26,31} Rather, the clear descriptors fully or not fully visible for both the cervix and the TZ are recommended.

The next category of the standardized terminology is “acetowhite changes.” Acetowhitening is the primary feature of the colposcopic examination that is consistently and reproducibly associated with cervical disease, and its presence warrants biopsy.^{3,10,13,29,32,33} When preceded by a high-risk screening test result (HSIL atypical squamous cells - cannot rule out high-grade; atypical glandular cells; or HPV-16/18 positive), mild or translucent acetowhite changes (even if interpreted visually as squamous metaplasia or low-grade changes) merit biopsy. Acetowhite changes are

therefore a core finding of the colposcopic examination and should be reported as a separate category.

The next categories of the standardized terminology are normal and abnormal colposcopic findings. The ASCCP uses the terms “low-grade” and “high-grade” changes, which correspond to the IFPC nomenclature of “Grade 1” = minor and “Grade 2” = major. The terms low-grade and high-grade colposcopic features simplify terminology and mirror those used for the overall colposcopic findings/impression and those used for cytologic and histologic reporting of SIL.^{34,35}

Under the category of abnormal colposcopic findings, acetowhite changes, vascular changes, location of lesion(s), and size of lesion(s) are the features most predictive of high-grade SIL.^{10,29,32,33,36} The term “lesion(s)” includes discrete areas of acetowhitening as well as nonacetowhite abnormalities of concern such as erosions or exophytic changes. Consideration was given to scoring systems such as the Reid Index and the Swede score, but we did not find evidence that these formal scoring systems consistently predict high-grade disease beyond the more subjective

TABLE 2. Key Differences Between the 2017 ASCCP and 2011 IFPC Terminology

	ASCCP	IFPC
General assessment: cervix visibility	Fully/not fully visible	Adequate/inadequate
General assessment: SCJ visibility	Fully/not fully visible	Completely/partially/not visible
General assessment: TZ type	Not used	Transformation zone types 1, 2, 3
Abnormal colposcopic findings	Low-grade features	Grade 1 (minor)
	High-grade features	Grade 2 (major)
Excision type	Not used	Excision types 1, 2, 3

assessment.^{6,7,37} Moreover, only a small minority of the ASCCP membership reported currently using such a scoring system when surveyed.⁴ Lesion present (yes/no) was designated as a separate category, emphasizing that the presence of a lesion warrants a biopsy³; presence of a lesion was also among the core criteria for reporting (see hereinafter).

The final categories of the standardized ASCCP terminology include miscellaneous findings and colposcopic impression. Because it is not unusual for multiple lesions to be present in a colposcopic examination, overall colposcopic impression should be reported as the impression of the highest grade lesion present.

The 2011 IFCPC terms excision type (1, 2, 3) were not included in the WG1 recommendations. Excision types are meant to correlate with the IFCPC's TZ type (1, 2, 3); TZ types were also not incorporated into the recommended ASCCP terminology, as noted previously. In other regions of the world, it is common to perform cervical ablation with a TZ type 1. In the United States, most practitioners are performing loop electrosurgical excision alone procedure (LEEP) for the treatment of cervical dysplasia.³⁸ The LEEP can be tailored and performed as an ectocervical excision alone or as an ectocervical excision followed by an endocervical excision, or "top hat" depending on the location of the lesion. For comparison purposes, the standard ectocervical LEEP corresponds with the IFCPC type 1 or 2 excision (type 1 = fully visible SCJ; type 2 = not fully visible SCJ), whereas the LEEP with top hat corresponds with the IFCPC type 3 excision.

Criteria for Reporting the Colposcopic Examination

Accurate and complete documentation of the colposcopic examination is an important component of the patient record. It facilitates communication between clinicians and provides essential information for diagnosis, treatment, and clinical research. Ideally, all colposcopists should report comprehensive findings; however, given the wide variation in practice patterns within the United States, all colposcopists need to report, at minimum, core criteria that allow for appropriate patient management.

Comprehensive documentation of the colposcopic examination should include a more detailed description of the findings. A diagram or marked image annotating the findings can also be included, depending on the medical record system in use.

Comprehensive criteria for reporting findings at colposcopic examination include:

- cervix visibility (fully visualized/not fully visualized)
- SCJ visibility (fully visualized/not fully visualized)
- acetowhitening (yes/no)
- lesion(s) present (acetowhite or other) (yes/no)
- lesion visualized (fully visualized/not fully visualized)
- location of lesion(s)
- size of lesion(s)
- vascular changes
- other features of lesion(s) (color/contour/borders/Lugol's uptake/etc.)
- colposcopic impression (normal/benign; low grade; high grade; cancer)

Core or minimum criteria for reporting findings at colposcopic examination include:

- SCJ visibility (fully visualized/not fully visualized)
- acetowhitening (yes/no)
- lesion(s) present (acetowhite or other) (yes/no)
- colposcopic impression (normal/benign; low grade; high grade; cancer)

DISCUSSION

Colposcopy is well established as the key procedure needed to evaluate abnormal or inconclusive cervical cancer screening tests as well as symptoms or physical findings concerning for cervical cancer. Its accuracy in identifying cervical neoplasia is dependent upon the knowledge and skill of the colposcopist. Specialized training is required to perform colposcopy and to manage its findings appropriately.

Like any medical procedure, the benefits and risks of causing harm should be understood and weighed in the context of the individual patient. The main benefit of colposcopy is the accurate identification of cervical precancer and early invasive cancer. Multiple colposcopically directed biopsies of the most severe lesion visualized inform further management of the patient. This allows surveillance of lesions unlikely to progress, thereby avoiding overtreatment, and timely treatment of most high-grade disease. In certain cases where there is strong evidence that high-grade disease is present, colposcopy is needed to ascertain the appropriateness of immediate excision of the TZ without prior biopsy confirmation.

Fortunately, the risk of harm from the colposcopy procedure is small compared with its potential benefits. To minimize potential harm, colposcopy should be performed only when indicated and by a well-trained, knowledgeable provider to reduce inaccurate diagnosis and resultant inappropriate management. Procedural risks include bleeding, infection, vaginal discharge, and pain or discomfort. These are generally mild and limited to the procedure itself or for a short time interval after. Possible harms that are less well understood include patient anxiety, heightened awareness of HPV infection and cervical disease, and impact on self image and sexuality.

Despite the longevity of colposcopy in clinical practice, there continues to be a lack of standardization of several aspects of the procedure in the United States, including terminology and documentation in the medical record.³⁹ A standardized, concise, reproducible way of describing and documenting colposcopic findings is a priority of this initiative. Based on the 2011 IFCPC terminology, the recommended terminology was developed with careful consideration of evidence of reproducibility, accuracy, and impact on patient management. In addition, the input of current US colposcopy providers regarding their documentation methods and terminology preferences was considered. The result is recommendations for a colposcopy terminology with which to communicate colposcopic findings using core and comprehensive criteria. Widespread use of these recommendations is expected to enhance provider-to-provider communication and improve patient management. This standardized terminology will also facilitate future clinical research, guideline development, and quality assessment and improvement initiatives. Future efforts should focus on implementation, reproducibility and performance of this standardized ASCCP terminology.

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