Patient distress and satisfaction with optical spectroscopy in cervical dysplasia detection

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OBJECTIVE: The aim of this investigation was to evaluate the impact of optical spectroscopy, a new approach for the detection of cervical dysplasia, on patient well-being and satisfaction.

STUDY DESIGN: Patient distress and satisfaction with optical spectroscopy compared with the Papanicolaou test and colposcopically directed biopsy were measured in a volunteer sample of 314 women with no history of abnormal Papanicolaou test findings.

RESULTS: Participants reported significantly less pain and anxiety ($P < .001$) during optical spectroscopy than during the Papanicolaou test or colposcopically directed biopsy. Generally, participants found spectroscopy equal to the Papanicolaou test and to biopsy on a variety of questions that measured satisfaction. There were statistically significant differences between spectroscopy and the Papanicolaou test or biopsy on issues such as the discomfort and fear caused by the test, the amount of time taken, the room lighting, and perceptions of accuracy.

CONCLUSION: That patients reported less distress during spectroscopy than during a Papanicolaou test, colposcopy, or biopsy suggests the possibility of improved adherence to cervical cancer screening and follow-up in settings in which it is used. (Am J Obstet Gynecol 2003;189:1136-42.)

Key words: Cervical dysplasia, optical spectroscopy, patient satisfaction, pain, anxiety

When new diagnostic technologies are introduced into health care practice, the evaluation of their impact on patient physical, functional, or emotional well-being is critical.[1-3] Technology that is diffused into practice without such assessment may result in an increase in health care costs without improvement of health or in the creation of unanticipated negative effects. The research of patient perceptions during the technology development process can identify potential problems that can be remedied before dissemination begins. The field of obstetrics and gynecology provides ideal opportunities for the investigation of the impact of health care technology in general because of the numerous new technologies that are introduced and in particular because of the importance of patient compliance to successful cervical cancer prevention and early detection.

To improve cervical cancer prevention and early detection, health care providers have sought to overcome barriers that prevent the patient from complying with screening recommendations. Research has indicated that women experience discomfort and distress while undergoing the Papanicolaou test; this may influence whether they pursue testing and therefore whether they benefit from screening's protection.[4-9] Negative beliefs about and barriers to cervical cancer screening include discomfort, embarrassment, lack of confidence in results, and worry about the cleanliness of the instruments.[4,5,7-10] Specifically, embarrassment and lack of confidence in the effectiveness of the test have been found to be related to a lower number of lifetime screenings.[4] Evaluation of new cervical neoplasia detection technologies should characterize not only their safety and accuracy but also whether they can overcome some of these barriers faced by women.

Currently undergoing testing by our group is the use of optical spectroscopy to detect and properly classify cervical neoplasia. In previous studies with a research device that captures emission spectra at 3 light wavelengths, we have derived a method for cervical cancer screening and detection (sensitivity, 82%; specificity, 68%).[11] There are 2 clinical trials underway that use a revised research devise that measure emission spectra at 16 wavelengths. One trial tests optical spectroscopy in a

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screening population, and the other tests the device in a diagnostic population. Both trials compare spectroscopic information to the gold standard biopsy, and the samples are stratified on menopausal status and hormone use. Because the new method is less invasive than the Papanicolaou test and colposcopically directed biopsy (because it involves holding a probe gently against the surface of the cervix, rather than scraping cells or removing tissue), we hypothesized that patients would experience less distress and express higher satisfaction with optical spectroscopy than with usual care procedures. Therefore, we undertook an evaluation of patient perceptions of optical spectroscopy in comparison with the Papanicolaou test and colposcopically directed biopsy to measure patient satisfaction with the procedure and to eliminate barriers to its use before deployment in medical practice.

Material and methods

Design and sample. This study uses a within-subjects design to test differences in distress during the usual care procedures and optical spectroscopy. The hypotheses were tested in a clinical trial of optical spectroscopy in 314 female volunteers, none of whom had a history of abnormal Papanicolaou test findings.

Procedures. The research protocol was approved by The University of Texas M.D. Anderson Cancer Center Surveillance Committee (Institutional Review Board). Study participants volunteered for the study, which was promoted through local media outlets. Women older than 18 years who were not pregnant, had an intact cervix, and had had a Papanicolaou test in the past but had no history of an abnormal Papanicolaou test result were eligible for the clinical trial. To be eligible for the interview portion of the study, women also had to speak and understand either English or Spanish. The data were collected from March 2000 through April 2001. During this time, 317 women enrolled in the clinical trial; 314 of them (99%) participated in the interview portion of the study. A research nurse explained the study to participants, screened them for eligibility, and obtained informed consent for the clinical trial. Afterward, the research interviewer explained the interview portion of the study and obtained informed consent for the interview. The clinical trial involved undergoing a pelvic examination, Papanicolaou test, colposcopy, spectroscopic measurement, and biopsy of sites measured by spectroscopy.

The optical spectroscopy system measures fluorescence emission spectra at 16 excitation wavelengths, which range from 330 nm to 480 nm in 10-nm increments with a spectral resolution of 5 nm. The system incorporates a fiber-optic probe, a xenon arc lamp coupled to a monochromator to provide excitation light and a polychromator and thermoelectrically cooled charge-coupled device camera to record fluorescence intensity as a function of emission wavelength. The fiber-optic probe consists of 25 excitation fibers and 12 collection fibers that are arranged randomly on a 2-mm-diameter quartz fiber at the tip.

Before the probe was used it was disinfected with Metricide (Metrex Research Corp, Orange, Calif) for 20 minutes. The probe was then rinsed with water and dried with sterile gauze. The disinfected probe was guided into the vagina, and its tip was positioned flush with the cervical epithelium. Then fluorescence excitation emission matrixes were measured from the 2 cervical sites. Acetic acid, which enhances the fluorescence and the reflectance differences between normal and dysplastic tissue, was applied to the cervical epithelium before the placement of the probe. Measurement of each excitation emission matrix required approximately 2 minutes. The probe was placed on 1 squamous and 1 columnar site. If the columnar epithelium was not colposcopically visible, then 2 normal squamous sites were measured.

After the spectroscopic measurement, the same areas were biopsied. Thirty-eight of the women opted to forgo the biopsy; however, they did not differ significantly by age, ethnicity, marital status, education, or psychological distress levels before the examination from the patients who had the biopsy. Women who participated in the clinical trial and agreed to undergo a biopsy received $50 as compensation for participation. All participants who completed the interviews received gift certificates worth approximately $10 as compensation.

After providing written signed consent for participation, all patients completed an interview with a female interviewer to assess demographic variables and global psychologic distress. At the end of this pre-examination interview, the interviewer provided a brief explanation of 4 of the procedures that were included in the examination: Papanicolaou test, colposcopy, optical spectroscopy, and biopsy. The interviewer accompanied the patient into the examination room; after each procedure, she asked the patient to rate her pain and anxiety during the procedure, using a number from 0 to 10. The interviewer also observed and recorded the number of distress vocalizations produced by the patient during each procedure. The procedures always were done in a consistent order: Papanicolaou test and other specimen collection, colposcopy, optical spectroscopy, and biopsy. This was done because of the logic of the overall study design (ie, colposcopy had to precede both spectroscopy and biopsy so that the appropriate areas to measure could be identified; biopsy had to come after spectroscopy so that tissue would be available for spectroscopy measurements). After the examination, the participant completed an interview to assess satisfaction with the Papanicolaou test, optical spectroscopy, and biopsy.

Measures. After each procedure, patients were asked to rate their pain and anxiety on a 0- to 10-point scale. In

Table I. Demographic characteristics and psychologic baseline measures

Characteristic	*Measurement*
Ethnicity (n [%])	
White	158 (50.8%)
Black	49 (15.8%)
Asian	12 (3.9%)
American Indian	1 (0.3%)
Hispanic	86 (27.7%)
Other	5 (1.6%)
Marital status(n [%])	
Single	43 (15.5%)
Married/living with a partner	176 (63.5%)
Divorced/separated	52 (18.8%)
Widowed	6 (2.2%)
Education (n [%])	
High school	13 (4.2%)
High school graduate	41 (13.2%)
College	256 (82.6%)
Age and psychological measure*	
Age	44.5 ± 11.72
State anxiety score	30.2 ± 8.77
Trait anxiety score	33.4 ± 9.79
Depression score	15.2 ± 8.43

Missing from the 314 total were 5 values for age, 3 values for ethnicity, 37 values for marital status, and 4 values for education level.
*Data given as mean ± SD.

studies of distress during gynecologic examinations, such single-item scales have been found to differentiate between experimental conditions that are designed to affect pain and anxiety and to be sensitive to changes in pain and anxiety over the course of a colposcopic examination.[12-14] In a pilot test, we evaluated both the 0- to 10-point rating of pain and anxiety and a visual analog scale with 76 patients who were undergoing colposcopy. The rating systems were moderately to highly correlated (0.75-0.91 for pain; 0.83-0.94 for anxiety). Patients preferred the numeric rating, so it was used in the present study.

A preliminary set of satisfaction questions was drafted on the basis of attributes of optical spectroscopy and the usual care procedures (eg, amount of time taken by the procedures, patient comfort during the procedures). These preliminary questions were pilot tested, and patients were asked open-ended questions regarding their likes and dislikes about each procedure. After the pilot test, additional questions were written that were based on the patient areas of concern that were elicited in the open-ended questioning. Participants responded to the questions about both positive and negative aspects of the procedures (eg, "Were you uncomfortable?" "Did the nurse/doctor answer your questions?" "Did it take too long?") on a 3-point scale ("yes, a lot," "yes, a little," and "no"). There were 14 items in the final set of questions.

General psychologic distress was measured for descriptive purposes. Anxiety was assessed with the use of the Spielberger State-Trait Anxiety Inventory.[15] This is a 40-item scale that provides information about a person's current and usual levels of anxiety. It is widely used in research on clinical and student populations and has good internal consistency reliability (0.85-0.95).[16] Depression was measured with The Center of Epidemiologic Studies Depression Scale,[17,18] which is a 20-item, self-report questionnaire that measures symptoms of depression in the general population. The scale is well validated, has high internal consistency (0.80), and has been used with medical patients and the general population.

The interviewers for the study completed a 3-week training before conducting interviews independently. The first 2 weeks involved learning the interview and clinic procedures through a review of a standardized training manual, observation of study interviews that were conducted by experienced staff members, and practice of the interview with another staff member. In the third week, interviewers conducted study interviews under the observation of the project coordinator, who provided feedback and coaching to the interviewer. The interviewers started interviewing patients independently in the fourth week.

Analysis. In the analysis of pain and anxiety that are associated with the procedures, each study participant had a maximum of 4 observations, 1 observation for each test procedure. Therefore, the comparison of the ratings of pain, anxiety, vocalization, and satisfaction for the procedures was conducted with general linear mixed-model regression analysis (SAS PROC MIXED; SAS Institute, Cary, NC) to accommodate within individual correlations. The individual was the repeated measure, and treatment procedure was a fixed effect. The correlation among the outcome measures for the 4 examination procedures was assumed to be unstructured. Age and ethnicity were included in all models. Pairwise comparisons for differences among procedures used the Tukey method for multiple comparisons adjustment. Differences in means were considered significant if the adjusted probability value was $\leq .05$.

Satisfaction with examination procedures compared the biopsy procedure to spectroscopy and the Papanicolaou test procedure to spectroscopy. Graphs include the percentage of women who rated the procedures equally and the percentage of women who rated 1 procedure higher than the other procedure.

Because the distributions of outcome variables were skewed, the mixed model regression analyses was conducted with the use of log transformations of the raw data to assess the robustness of the original analyses. The results of these analyses were similar to the analyses of the raw data and, for this reason, are not presented. All the analyses were conducted with the use of the Statistical Analysis System 8.1 software (SAS Institute).

Table II. Comparison of mean pain, anxiety, and vocalization by procedure

	Pain			*Anxiety*			*Vocalization*		
	Mean	*95% CI*	*n*	*Mean*	*95% CI*	*n*	*%*	*95% CI*	*n*
Spectroscopy	0.98*	.79, 1.17	309	1.89*	1.63, 2.15	309	13.33*	9.49, 17.18	300
Papanicolaou test	1.59†	1.35, 1.83	309	2.39†	2.10, 2.69	309	14.38*	10.40, 18.36	299
Colposcopy	2.58‡	2.28, 2.88	307	2.67‡	2.36, 2.99	307	45.79†	40.12, 51.46	297
Biopsy	1.61†	1.37, 1.85	274	2.70†‡	2.36, 3.05	273	20.15*	15.30, 25.00	263

Means and percentages are unadjusted. For each outcome measure, means or 95% CIs with a different footnote symbol differ significantly. Means and percentages with the same footnote symbol do not differ significantly. (For example, mean pain differed significantly between all procedures except Papanicolaou test and biopsy. Mean Papanicolaou test and biopsy pain ratings did not differ significantly.) Age and ethnicity were included in all models, and the Tukey multiple comparison procedure was used to test for outcome differences between procedures.

Table III. Satisfaction with procedure

Item	*Papanicolaou test (unadjusted mean ± SD)*	*Spectroscopy (unadjusted mean ± SD)*	*Biopsy (unadjusted mean ± SD)*
1. Did the nurse/doctor explain what would be done in a way you could understand?	2.96 ± 0.22*	2.93 ± 0.29*	2.93 ± 0.29*
2. Was the nurse/doctor gentle?	2.95 ± 0.22*	2.98 ± 0.15*	2.95 ± 0.23*
3. Were you uncomfortable?	1.53 ± 0.64*	1.39 ± 0.59†	1.53 ± 0.65*
4. Did the procedure take too long?	1.18 ± 0.47*	1.34 ± 0.58†	1.12 ± 0.41*
5. Did the nurse/doctor answer your questions?	2.95 ± 0.24*	2.96 ± 0.20*	2.95 ± 0.21*
6. Did the nurse/doctor seem to know what she/he was doing?	2.99 ± 0.08*	3.00 ± 0.06*	3.00 ± 0.06*
7. Was the procedure frightening?	1.27 ± 0.51*	1.24 ± 0.48*	1.43 ± 0.61†
8. Did you find the instruments used for this test frightening?	1.17 ± 0.45*	1.14 ± 0.41*	1.18 ± 0.45*
9. Were there too many people in the examination room?	1.43 ± 0.68*	1.42 ± 0.66*	1.43 ± 0.66*
10. Was the test painful?	1.36 ± 0.55*	1.20 ± 0.43†	1.49 ± 0.61‡
11. Did you like the lighting in the room (lights on or off) during the test?	2.46 ± 0.62*	2.67 ± 0.55†	2.47 ± 0.65*
12. Was the temperature of the room too hot, too cold, or just right?	0.84 ± 0.37*	0.85 ± 0.36*	0.84 ± 0.37*
13. If you have abnormal cells on your cervix, do you think this test will find them?	4.21 ± 0.79*	4.43 ± 0.61†	4.79 ± 0.42‡
14. If you do not have abnormal cells on your cervix do you think this test will show a normal result?	4.26 ± 0.81*	4.36 ± 0.74†	4.67 ± 0.70‡

Scoring: Items 1 through 11 (1 = no; 2 = yes, a little; 3 = yes, a lot), item 12 (1 = just right; 0 = too hot or too cold), items 13 and 14 (1 = definitely no; 2 = probably no; 3 = maybe; 4 = probably yes; 5 = definitely yes). For each outcome measure, means with a different footnote symbol differ significantly. Means with the same footnote symbol do not differ significantly. Age and ethnicity were included in all models, and the Tukey multiple comparison procedure was used to test for outcome differences between procedures.

Results

Demographic characteristics of sample. The demographic characteristics that were surveyed included ethnicity or race, marital status, and educational level; baseline psychologic distress was measured (Table I). Characteristics were unremarkable, except for the diverse ethnic distribution and the high percentage of women who had undergone postsecondary training (83%). Approximately one half of the women were white, non-Hispanic (50.8%); 27.7% of the women were Hispanic; 15.8% of the women were black; 3.9% of the women were Asian, and 1.9% of the women were from another group. Mean psychologic distress scores were in the normal range.

Distress during procedures. Patients reported significantly less pain and anxiety during optical spectroscopy than during the Papanicolaou test, colposcopy, and biopsy (adjusted $P < .001$ for all comparisons with spectroscopy; Table II). Similarly, patients were less likely to make distress vocalizations during spectroscopy than during colposcopy ($P < .0001$), but there were no significant differences in the likelihood of vocalizations during spectroscopy and the Papanicolaou test or biopsy.

Participant age was not significantly related to pain and anxiety (pain: $P = .7453$; anxiety: $P = .0608$) or the probability of distress vocalizations ($P = .4744$). Ethnicity was not associated with any of the distress indicators.

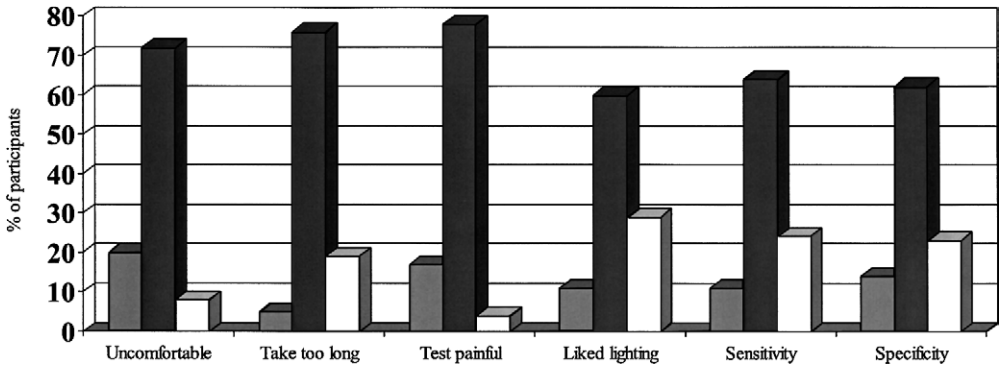

Fig 1. Comparison of patient ratings of satisfaction items about Papanicolaou testing and optical spectroscopy. The *closed bar* represents the percentage of participants who gave the same rating to Papanicolaou testing and optical spectroscopy for a particular domain of satisfaction. The *gray bar* represents the percentage of participants who rated Papanicolaou testing higher than spectroscopy, and the *open bar* represents the percentage of participants who rated spectroscopy higher than Papanicolaou testing. Domains in which the ratings were significantly different (adjusted $P<.05$) are displayed.

Satisfaction with procedures. Responses to certain satisfaction questions demonstrated high satisfaction across all 3 procedures (Table III). Nearly all participants responded "yes, a lot" when asked whether the provider explained the procedure well, answered questions, was gentle, and knew what he/she was doing. There were also no significant differences among the 3 procedures in the patient ratings of whether the instruments used for the test were frightening, whether there were too many people in the examination room, and satisfaction with the room temperature. Patients preferred the lighting in the examination room during spectroscopy (when the lights were off) to the lighting during the Papanicolaou test and biopsy (lights on). Participants responded that they were more uncomfortable and experienced more pain during the Papanicolaou test and biopsy than during spectroscopy. They also thought that the biopsy was more frightening than spectroscopy. However, they viewed the biopsy as more accurate in terms of both sensitivity and specificity than either the Papanicolaou test or spectroscopy. Spectroscopy was rated as more accurate than the Papanicolaou test. However, participants were more likely to respond that spectroscopy took too long compared with the other 2 procedures.

In comparisons of the Papanicolaou test and optical spectroscopy (Fig 1) and colposcopically directed biopsy and optical spectroscopy (Fig 2), most respondents rated the procedures as equal. This was true overall, butalso in the domains that are illustrated in the Figures, which only include domains on which the procedures were rated as significantly different (adjusted $P < .05$) by participants who perceived 1 procedure as better than the other.

Participants who gave the Papanicolaou test and optical spectroscopy different ratings were more likely to rate the Papanicolaou test as more uncomfortable and more painful than spectroscopy and were more likely to rate spectroscopy as taking too long compared with the Papanicolaou test (Fig 1). They were more likely to prefer the lighting conditions for spectroscopy to those during the Papanicolaou test. These participants were also more likely to rate spectroscopy as more sensitive and more specific than the Papanicolaou test.

Participants who judged spectroscopy and biopsy as unequal rated the biopsy as more uncomfortable, more painful, and more frightening than spectroscopy (Fig 2). They also found the environmental conditions (bright light) under which biopsy was performed as less favorable than those (near dark) under which spectroscopy was performed. In contrast, they were more critical of the amount of time taken by spectroscopy than that taken by biopsy, and they tended to rate the biopsy as more accurate and more sensitive than spectroscopy.

Comment

Most participants in this study, which evaluated patient distress and satisfaction related to competing methods of cervical dysplasia detection, found spectroscopy to be equal to or better than Papanicolaou testing and colposcopically directed biopsy. Satisfaction on most dimensions that were measured in the study was quite high, so the introduction of optical spectroscopy into clinical care should not decrease patient satisfaction.

Participants did identify 1 shortcoming: they clearly thought that spectroscopy took too long compared with other procedures. In this study, the insertion of the speculum, the Papanicolaou test, and specimen collection took an average of 3.9 minutes, and biopsies and hemostasis took 2.0 minutes on average. Spectroscopy required an average of 7.7 minutes. This extra time has the potential to affect overall satisfaction negatively, given

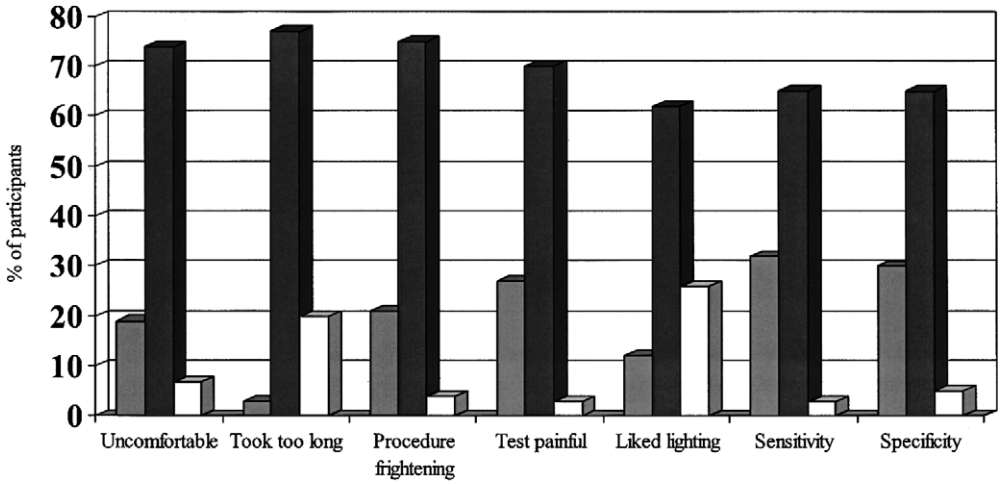

Fig 2. Comparison of patient ratings of satisfaction items about biopsy and optical spectroscopy. The *closed bar* represents the percentage of participants who gave the same rating to biopsy and optical spectroscopy for a particular domain of satisfaction. The *gray bar* represents the percentage of participants who rated biopsy higher than spectroscopy, and the *open bar* represents the percentage of participants who rated spectroscopy higher than biopsy. Domains in which the ratings were significantly different (adjusted $P < .05$) are displayed.

the negative emotions and beliefs women often associate with gynecologic procedures.[4,5,10] But during this study, the time that is required for the examination was extended artificially because the investigators were obtaining 16 excitation wavelength measurements to determine which wavelength provided the most accurate diagnostic information. Preliminary results indicate that accurate results can be obtained by the measurement of only 2 excitation wavelengths, which could reduce the measurement time substantially.[19]

Differences in pain and anxiety between optical spectroscopy and colposcopy and biopsy were larger than differences between spectroscopy and Papanicolaou testing, which indicates that patients who undergo colposcopy might view spectroscopy positively also. Research shows that having abnormal Papanicolaou test findings and undergoing further diagnostic testing is stressful. A positive result raises fears of cancer in most women and concerns about of loss of reproductive and sexual functioning, fear of medical procedures, and anxiety about their bodies "betraying" them.[20-22] Studies that evaluate pharmacologic and psychologic interventions to reduce pain during colposcopy have not demonstrated success in reducing pain.[6,13,23-27] Were spectroscopy able to eliminate the need for biopsy and the now-inevitable delays between initial examination, positive report, and biopsy, the process of obtaining a diagnosis would be dramatically less stressful. In general, approaches to the reduction of distress have included the provision of information before procedures[6] and distraction techniques during procedures,[23,24] but the effectiveness of such interventions may be affected by individual differences in coping style.[12]

Two factors (the use of volunteers and the order in which the procedures were performed) may limit the generalizability of the results. Volunteers may be less anxious about undergoing gynecologic examinations. Also, many of the participants learned about the study through favorable media coverage, which may have predisposed them favorably to optical spectroscopy. Additional research is needed to determine whether the results can be generalized to actual cervical cancer screening and diagnostic populations.

Although observed differences in distress could be attributed to the order of the procedures rather than the procedures themselves, it is unlikely. The finding that biopsy was more painful than spectroscopy is highly plausible biologically, given that biopsy involves removing tissue and spectroscopy does not. Furthermore, in pilot tests in which spectroscopy was not done, distress ratings of biopsy were comparable. The result we obtained also could be explained by a reduced tolerance for discomfort toward the end of the examination. If this were the explanation, however, we would expect that patients whose examinations before the biopsy were longer would have higher pain and anxiety scores during biopsy than patients whose examinations were shorter. Our data do not support this, because the length of time taken by the Papanicolaou test, colposcopy, and spectroscopy was not correlated with biopsy pain and anxiety ratings. Conducting the examinations in a specific order was important for optimal clinical care and for the logic of overall study design. Colposcopy had to precede both spectroscopy and biopsy so that appropriate areas to measure could be identified, and biopsy had to follow

spectroscopy so that tissue would be available for spectroscopy measurements.

The results of this study indicate that optical spectroscopy causes women less distress than standard procedures that are used to detect cervical dysplasia; therefore, the use of optical spectroscopy may enhance adherence to screening schedules and improve early detection. More may be learned about patient receptivity to the technology in tests that are conducted in settings in which women are undergoing screening Papanicolaou tests or colposcopy after having abnormal findings on a Papanicolaou test. Future research should evaluate how patients perceive this technology when it is the sole tool for diagnosis. Further investigation of patient perceptions of this emerging technology is expected to further refine its development, which should enhance its acceptance by patients and health care providers, broadening screening's scope, and ultimately decreasing cervical cancer's morbidity and mortality rates.

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