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## CLINICAL ARTICLE

## Sheathed versus standard speculum for visualization of the cervix

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## ABSTRACT

**Objective:** To determine whether modifying a plastic speculum with a flexible sheath would improve visualization and decrease pain during vaginal examination. **Methods:** We conducted a prospective randomized controlled trial of 136 women undergoing vaginal speculum examination at an outpatient obstetrics and gynecology faculty practice. Patients underwent examination via a standardized technique with either a medium-sized plastic speculum (standard) or an identical speculum modified with a flexible polypropylene sheath (sheathed). Investigators recorded the percentage of the cervix visualized. After speculum insertion, patients recorded pain using a 10-cm visual analog scale. **Results:** There were no substantial demographic differences between the standard ( $n = 67$ ) and the sheathed ( $n = 68$ ) groups. Investigators were able to visualize a significantly greater percentage of the cervix using the sheathed speculum compared with the standard speculum ( $95.1\% \pm 8.2\%$  vs  $78.2\% \pm 18.4\%$ ;  $P < 0.001$ ), representing a 21.6% improvement in visualization, and were able to visualize the entire cervix in 42 (61.8%) patients when using the sheathed speculum compared with 11 (16.4%) patients undergoing standard speculum examination ( $P < 0.001$ ). Patients undergoing examination with the sheathed speculum reported a nonsignificant decrease in pain scores (1.0 vs 1.2;  $P = 0.087$ ). **Conclusion:** A sheathed speculum significantly improves visualization of the cervix, without compromising patient comfort.

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## 1. Introduction

Speculum examination is used to obtain cervical cytology screening, perform gynecologic procedures, and evaluate patients with vaginal and cervical disorders. A successful speculum examination requires adequate visualization of the cervix in the gentlest manner possible. Throughout history, there have been almost 600 new or modified vaginal speculum designs, although very few were developed with rigorous study to determine whether they improved visualization or altered patient comfort [1]. Performing examinations with bivalve specula can be challenging owing to difficulty visualizing the cervix and upper vagina because of lateral vaginal wall laxity. To overcome this, some clinicians will cut off the ends of an examination glove finger or the end of a condom and slide these over the speculum blades, creating a sheath to retract the lateral vaginal walls [2,3]. Another option is to use a larger speculum, which may increase pain. These modifications can make it difficult to open the speculum blades and may cause pain when tension from the glove finger or condom pinches the blades against the cervix when withdrawing the speculum. Using a flexible sheath to improve visualization has not been studied.

The aim of the present study was to determine whether using a speculum modified with a flexible polypropylene sheath would

improve visualization and decrease patient discomfort compared with the use of a standard speculum.

## 2. Materials and methods

A randomized single-blind trial was conducted at the Department of Obstetrics and Gynecology, Florida Hospital, USA, from August 17, 2012, to February 28, 2013. Consecutive patients between the ages of 18 and 50 years who presented to the outpatient obstetrics and gynecology faculty practice with conditions requiring vaginal speculum examination were screened for participation. The Florida Hospital Institutional Review Board approved the study, which was conducted according to Consolidated Standards of Reporting Trials guidelines [4]. Investigators informed participants of the risks and benefits of the study and obtained written informed consent. All patients volunteered to participate without incentives.

The primary goal of the study was to determine whether a sheathed speculum would improve the examiner's ability to visualize more of the patient's cervix. Therefore, because vaginal delivery can lead to increased lateral vaginal wall laxity, participation also required at least 1 vaginal delivery equal to or greater than a gestational age of 20 weeks and the presence of a cervix. Pregnancy can also cause patulous vaginal sidewalls, making speculum exams difficult, so we also offered participation to pregnant women who met the enrollment criteria. Demographic information was also collected (Table 1).

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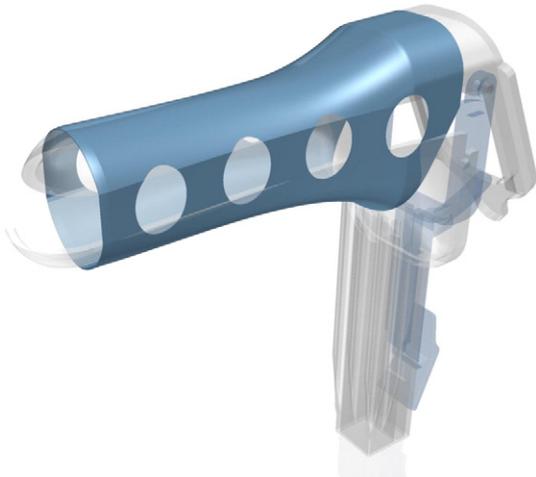
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**Table 1**  
Participant demographics.<sup>a</sup>

Characteristics	Sheathed (n = 68)	Standard (n = 67)
Age, y	36.3 ± 6.2	36.9 ± 6.6
Body mass index <sup>b</sup>	26.9 ± 5.1	27.5 ± 6.5
Number of vaginal deliveries >20 weeks	1.57 ± 0.74	1.81 ± 1.13
Pregnant	5 (7.4)	8 (11.9)
Indication		
Well-woman examination	55 (80.8)	53 (79.1)
Cervical cultures	7 (10.3)	6 (9.0)
Pap test only	1 (1.5)	2 (3.0)
Uterine or cervical procedure	5 (7.4)	5 (7.5)

<sup>a</sup> Values are given as mean ± SD or number (percentage).

<sup>b</sup> Calculated as weight in kilograms divided by the square of height in meters.



**Fig. 1.** Illustration of the sheathed speculum.

Screening excluded women who had vulvar atrophy, pain or lesions, vestibulodynia, vaginitis, dyspareunia, interstitial cystitis, or chronic pelvic pain, and women who were menopausal (as determined by amenorrhea for 12 months or more, use of hormone therapy, or elevated follicle-stimulating hormone levels) because these conditions can cause pain during speculum examination. Patients not fluent in English were also excluded from participation.

After enrollment, participants were randomly assigned to either the standard or the sheathed speculum arm using a permuted-block,

computer-generated schedule (blocks of 4, which were sealed in opaque envelopes in sequential order unknown to either the participants or the investigators).

Patients underwent speculum examination (by either D.A.H. or M.L.C.) via a standardized examination technique identical for each patient. For the standard arm, investigators used a medium-sized plastic bivalve (Graves) speculum (KleenSpec; Welch Allyn, Skaneateles, NY, USA). Patients in the sheathed arm underwent examination with a nearly identical speculum modified with a single-use, flexible, transparent polyurethane sheath designed to retract the vaginal sidewalls (ClearSpec; ClearSpec, Boca Raton, FL, USA) (Figs. 1 and 2). ClearSpec provided the sheathed specula for the study. The polyurethane sheath was latex-free, wrapped completely around the blades of the speculum, and was attached with adhesive. It compressed flat when the blades were closed to facilitate insertion (Fig. 2) and contained circular openings on each side to enable visualization of the vaginal sidewalls and collection of vaginal sidewall samples. Both specula measured 3 cm across the tip of the blades and had a halogen light, which inserted into the base.

Patients were placed on an examination table in the dorsal lithotomy position with their feet in stirrups and buttocks just over the edge of the table. A privacy drape prevented patient visualization of which speculum was used. Investigators placed 0.3 mL of room-temperature sterile lubricant (Surgilube; Savage Laboratories, Melville, NY, USA) on each speculum by smearing a thin coating of lubricant over both blades in order to reduce pain during speculum insertion [5]. All speculum examinations were performed the same way, using a standardized insertion technique. Investigators educated participants prior to examination that 0 represented “no pain” and 10 “the worst pain imaginable,” then patients were instructed to make a single vertical mark on a 10-cm, non-hatched visual analog scale (VAS) to indicate their level of pain. After a pause to allow the patient to mark her score, any other procedures such as cervical cultures/cytology screening or speculum removal were performed without marking the VAS.

In order to determine what percentage of the cervix was visualized, we used a standardized diagram of a cervix superimposed on a grid of equal-sized squares for each patient (Fig. 3). Immediately after opening the speculum, investigators drew the amount of cervix visualized onto the diagram. Two independent observers blinded to the type of speculum used counted the squares that represented the amount of cervix visualized, then calculated the percentage of visible cervix. The mean of the 2 values was used as the final measurement of cervix visualization.

Based on a pilot study at the Florida Hospital Department of Obstetrics and Gynecology, we estimated that the mean percentage visualization



**Fig. 2.** Photograph of flexible sheath in open and closed positions.

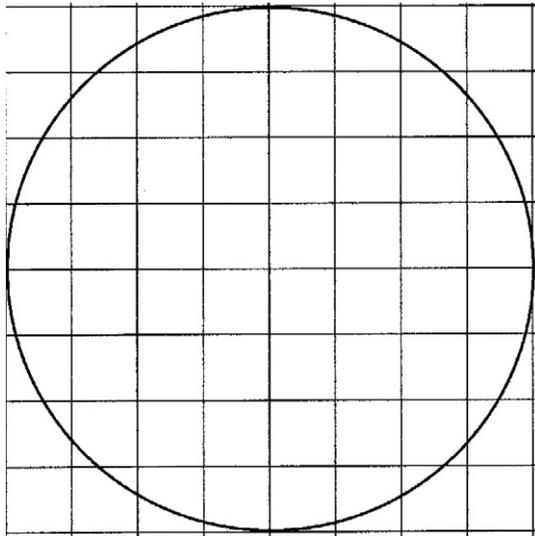


Fig. 3. Illustration of the tool used to record cervix visualization.

with the standard speculum would be  $60\% \pm 16\%$ . Assuming that a 20% improvement in visualization would be clinically significant, the study would need 39 patients in each arm, assuming an  $\alpha$  value of 0.05, a power of 90%, and a 1:1 allocation ratio using a 2-sided test. We assumed that approximately 10% of participants would be excluded after

Table 2  
Mean percentage of cervix visualized.<sup>a</sup>

	Sheathed (n = 68)	Standard (n = 67)	All (n = 135)	P value <sup>b</sup>
Percentage of cervix visualized	95.1 $\pm$ 8.2	78.2 $\pm$ 18.4	86.8 $\pm$ 16.5	<0.001

<sup>a</sup> Values are given as mean  $\pm$  SD unless otherwise indicated.

<sup>b</sup> Determined by Wilcoxon 2-sided z test.

randomization owing to previously unknown vaginal or vulvar conditions. Therefore, 43 participants would need to be recruited for the cervix visualization endpoint.

The VAS is a reliable, validated instrument for pain assessment [6,7]. Results from a previous study of pain during insertion of a medium plastic speculum prepared with lubricant showed mean pain levels of  $1.4 \pm 1.6$  cm on a 10-cm VAS [5]. Using a decrease in pain of 0.9 cm on the VAS as a clinically significant difference between arms [6,7], the study would need 62 patients in each group, assuming an  $\alpha$  value of 0.05, a power of 90%, and a 1:1 allocation ratio using a 2-sided *t* test. We estimated that approximately 10% of participants would be excluded after randomization owing to previously unknown vaginal or vulvar conditions; therefore, 68 women were recruited for each arm of the study.

All statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC, USA). Variables were first inspected for accuracy and missing data. Comparisons between the 2 devices regarding percentage visualization of the cervix and the VAS were analyzed via Wilcoxon and Pearson  $\chi^2$  test for categorical variables. All reported *P*

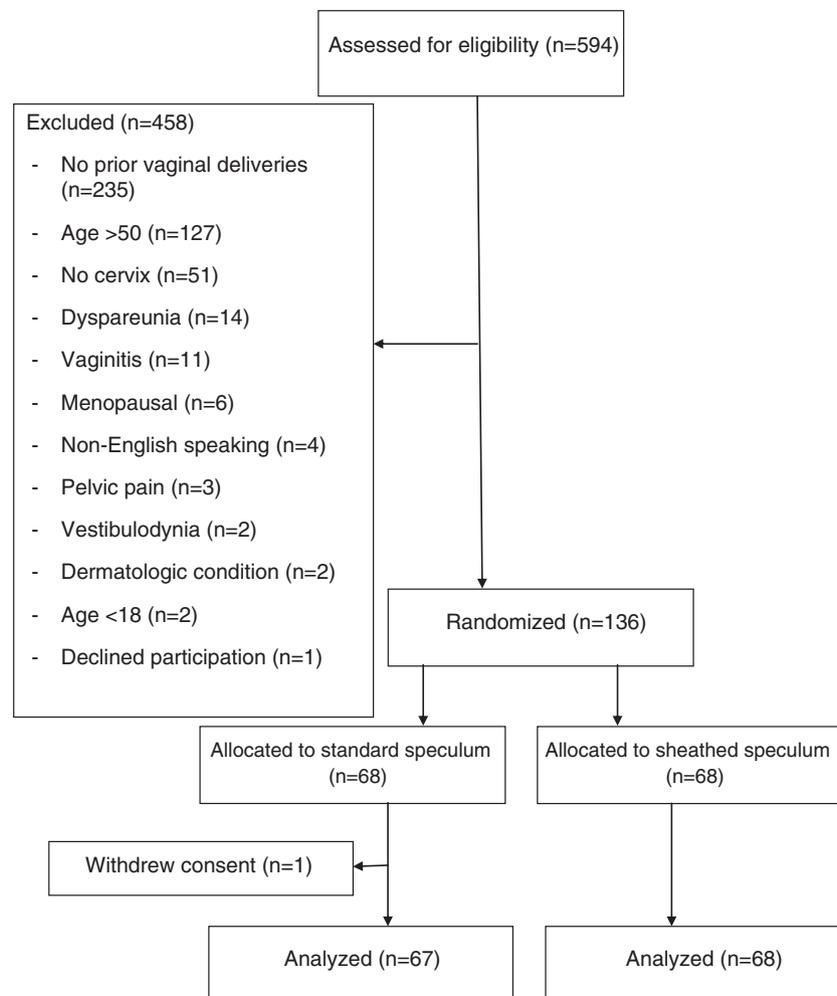


Fig. 4. Flow of patients through the study.

**Table 3**  
Mean VAS score after speculum insertion.<sup>a</sup>

	Sheathed (n = 68)	Standard (n = 67)	All (n = 135)	P value <sup>b</sup>
10-cm VAS	1.0 ± 1.3	1.2 ± 1.3	1.1 ± 1.3	0.87

Abbreviation: VAS, visual analog scale.

<sup>a</sup> Values are given as mean ± SD unless otherwise indicated.

<sup>b</sup> Determined by Wilcoxon 2-sided z test.

values are 2-sided and statistical significance was set at  $P \leq 0.05$ . Data for each participant were analyzed in the group to which they were assigned, regardless of whether the participant completed the study.

### 3. Results

A total of 594 women presented for vaginal speculum examination during the study period; 136 women were randomized (68 to each arm), with a total of 67 women in the standard speculum arm and 68 women in the sheathed speculum arm available for final analysis (Fig. 4). There were no marked differences in demographic data or indication for speculum examination between the groups (Table 1). The majority of patients presented for annual gynecologic visits (80% of all participants), with a smaller number of patients presenting for uterine or cervical procedures, cervical cytology screening only, or cervical cultures.

Investigators were able to visualize significantly more of the cervix when using the sheathed speculum (95.1%) compared with the standard speculum (78.2%), representing a 21.6% improvement in visualization (Table 2). Additionally, investigators were able to visualize the entire cervix significantly more often when using the sheathed speculum than when using the standard version (61.8% vs 16.4%;  $P < 0.001$ ). Mean visual analog pain scores were low for both groups. Patients in the sheathed speculum group reported slightly lower mean pain scores, although this was a nonsignificant difference (Table 3). There were no significant differences in either percentage of cervix visualized ( $P = 0.252$ ) or mean VAS score ( $P = 0.769$ ) between the 2 examiners.

There were no adverse events and none of the examinations required discontinuation in either group.

### 4. Discussion

The present study was a randomized trial designed to determine whether modifying a speculum with a flexible sheath would improve visualization of the cervix and decrease pain. The results indicate that using a sheath to retract the vaginal sidewalls significantly improves visualization of the cervix, without affecting patient comfort. This is a simple and reproducible method of improving visualization during speculum examination.

The strengths of the study included the exclusion criteria, which prevented the inclusion of participants with conditions that might have caused pain with speculum insertion; the use of a standardized recording tool for cervical visualization; the use of a standardized insertion technique with nearly identical specula, which limited inter-observer variability; and the prospective randomized study design. The study was conducted at a general obstetrics and gynecology faculty practice that has approximately 22 000 patient visits per year by predominantly middle-income, insured patients. Most patients were seen for annual gynecologic visits—a common reason for undergoing speculum examination.

A limitation of the study was that it is not possible to conduct a double-blind investigation of speculum examinations, and this could have introduced examiner bias. However, an identical examination technique was used for every participant, which was designed to limit this. There are several components of a speculum examination, including insertion, sample collection, and withdrawal. We chose to evaluate only the insertion portion of the procedure, based on our observation

that the polyurethane sheath does not produce tension on the speculum blades and does not pinch the cervix. An interesting subject for future study would be to compare pain scores for the sheathed speculum with those for a similar speculum modified with an examination glove finger or condom.

Despite the frequency of vaginal speculum exams and the numerous speculum designs and modifications throughout history, there is very little evidence to assist clinicians with performing the gentlest examination while achieving optimal cervical visualization. Investigators have compared a new speculum that uses air to dilate the vagina with bivalve specula in randomized clinical studies [8,9]. One group evaluated examiner ease of visualizing the cervix on a 5-point Likert scale and also assessed patient discomfort during the examination [8]. They found that, while the metal Pederson-style bivalve speculum provided “easier” visualization of the cervix, patients found the dilating speculum more comfortable. The authors did not provide information on what percentage of the cervix was visualized. Another study comparing the same dilating speculum with a bivalve speculum found that both instruments enabled similar access to the endocervix for cytology sampling but that patients reported significantly decreased pain on a 5-point Likert scale with the dilating speculum [9]. The authors did not note the style of bivalve speculum used, the percentage of cervix visualized, or whether a standardized examination technique was performed.

A limitation of Graves, Pederson, and Cusco bivalve specula is the absence of lateral vaginal wall retraction, making complete visualization of the cervix and upper vagina difficult in some patients. To overcome this, clinicians can fashion a “homemade” sheath out of a condom or the finger of an examination glove by sliding these over the speculum blades [2,3]. However, some facilities have stopped using latex gloves to prevent allergic reactions in patients and healthcare workers [10]. We have tried other glove materials such as nitrile or vinyl and found that they do not provide as much stretch as latex gloves, which can make it difficult to open the speculum and can cause pinching of the cervix. The flexible sheath used for the present study does not cause tension on the speculum blades.

The sheathed modification studied here resulted in visualization of the entire cervix in almost 62% of patients, compared with only 16% of patients undergoing examination with the standard instrument. It is lateral vaginal wall laxity that obscures part of the cervix and vaginal fornices, leading to incomplete visualization. Whether or not complete visualization of the cervix is necessary for identification of vaginal disorders or adequate cervical cytology collection deserves further study. Although we did not examine patients without a cervix, encroachment of the lateral vaginal walls sometimes limits the ability to see the vaginal apex, which may have implications for detection of upper vaginal conditions such as postoperative granulation tissue or cellulitis. Additionally, we did not evaluate the effect of body mass index on visualization and believe this is an interesting subject for future studies.

In the present study, we used a 0.9-cm difference in the VAS because this seems to be the minimal clinically significant difference in the VAS pain score [6,7]. Although patients undergoing examination with the sheathed speculum reported slightly lower VAS scores, the mean difference of 0.2 did not reach statistical significance. We used a small amount of lubricating gel to cover both speculum blades because this reduces pain [5], and we believe that this led to the overall low VAS scores for both groups.

The addition of the polyurethane sheath is an inexpensive modification, with a proposed cost increase of approximately US \$0.50 per speculum (Navroze Mehta, ClearSpec; oral communication, December, 2012). In conclusion, adding a sheath to a bivalve speculum is a simple and reproducible modification that improves visualization of the cervix through maximal retraction of vaginal walls, without increasing patient discomfort.

### Conflict of interest

The authors have no conflicts of interest.

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