

A Survey of Physicians and Patients in Pakistan Assessing the Improvement of Visualization of the Cervix, Ease of Use, and Patient Comfort Using a Newly Designed Vaginal Speculum: A Pilot Study

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Purpose: The existing 2-bladed vaginal speculum has limitations and barriers to gynecologic diagnosis and treatment. This study aimed to evaluate three of these limitations (visualization of the cervix, ease of use, and relative comfort) using a newly designed vaginal speculum that was hypothesized to overcome these limitations.

Methods: This pilot prospective observational clinical study was conducted at five hospitals in Karachi, Pakistan. Six clinicians were surveyed using two questions on the visibility of the cervix and ease of use of the new vaginal speculum. A total of 100 patients were surveyed to determine the relative comfort of the new speculum.

Results: Clinicians rated the visualization of the cervix as “better” in 66% of women ($p=0.0007$). The newly designed vaginal speculum was reported by clinicians as “easier” to use in 57% of patients ($p=0.0808$). The survey results indicated that 53% of participants felt less discomfort with the new speculum ($p=0.2743$). There was a strong statistical correlation between clinician visualization of the cervix and ease of use ($+0.8234$, $p < 0.0001$), visualization and comfort ($+0.8978$, $p < 0.0001$), and ease of use and comfort ($+0.9101$, $p < 0.0001$).

Conclusion: This new vaginal speculum demonstrated improved cervical visualization and ease of use in a cohort of 100 Pakistani women. In addition, participants in this study reported less discomfort with the new speculum. There is a potential benefit for all gynecologic screening and treatment with this new vaginal speculum design, especially in resource-constrained countries and in certain disadvantaged populations. The newly designed speculum has been field-tested in multiple countries over the last 5 years. Further clinical studies with larger cohorts are warranted.

Plain Language Summary:

What are the new findings

- This study demonstrates that, after almost 2,000 years, this revolutionary design of the vaginal speculum provides for better visualization of the cervix, is easier to use and less uncomfortable for the patient.

How might it impact healthcare in the future

- This improved vaginal speculum may increase cervical cancer and precancer detection and improve the outcomes in gynecologic procedures, resulting in fewer deaths and complications. It may result in a more cost-effective and efficient exam. Finally, it may reduce the stigma and trauma from the often difficult and painful vaginal speculum exam. This may lead to more accurate and universal screening of women for cervical cancer, especially in disadvantaged areas.



Keywords: vaginal speculum, gynecology, pap test, cervical cancer, cervical dysplasia

Introduction

Throughout the world, many women find the vaginal exam with the existing 2-bladed speculum uncomfortable, and therefore, avoid the exam altogether.¹ This discomfort may be worse in women with vaginal atrophy, pelvic organ prolapse, vulvodynia, increased vaginal wall tissue due to obesity or multiparity, or women who have undergone sexual abuse or trauma.¹

The vaginal speculum has been of the same two-bladed, “duck-billed” design since ancient times. A brass, two-bladed vaginal speculum was excavated from the ashes of Pompeii when Mt. Vesuvius erupted in 79AD.² In the 1840s, “the father of American gynecology”, J. Marion Sims created a “vaginal speculum” by bending the handle of a pewter gravy spoon.³ For centuries, there has been little innovation to improve this design. Although novel designs have been produced, none have overtaken the traditional design, owing to a lack of rigorous research comparing the newer specula with the two-bladed. Previous literature reviews have revealed a paucity of study regarding the vaginal two-bladed speculum as to whether it is the optimal design for patient comfort, visualization of the cervix, and ease of use.⁴ The literature is even more scarce regarding speculum use in obese patients - a population already prone to stigma in the medical field and vulnerable to higher rates of cervical cancer-related death due to under-screening.⁵ There is a need for re-examining the current two-bladed design to ensure patients are receiving the highest standard of care and accuracy.

Investigators who used a sheathed speculum, a condom, or a glove to prevent lateral vaginal wall collapse reported greater visualization and greater frequency of visualization of the entire cervix than those who used a traditional two-bladed speculum alone.^{6,7} These data lend support to the design of the Bouquet Speculum™ - a 5-petaled speculum that opens radially and distributes force symmetrically in the vaginal canal, providing an unobstructed view of the cervix (Figure 1A and B).⁸ The Bouquet Speculum™ is an FDA-cleared and CE-marked five-petaled, clear, plastic disposable speculum with an attachable penlight for optimizing visualization. The speculum has a push dilator that clicks on its top for adjustability and comfort (Figure 1A and B).

In a recently published in vitro study comparing the Bouquet Speculum™ to the existing two-bladed traditional speculum, the Bouquet Speculum™ showed better cervical visualization than the existing two-bladed speculum while maintaining the ability to instrument through the opened speculum. In addition, this in vitro study demonstrated radial distribution of intravaginal forces using the Bouquet Speculum™, which may translate to improved comfort for the patient.⁹ To determine the translatability of this in vitro study, this observational in vivo study was conducted to compare the Bouquet Speculum™ to the traditional two-bladed speculum regarding patient comfort, ease of use, and visualization of the cervix. This is a pilot study and the first clinical trial.

The Bouquet Speculum™ has been field-tested in 14 countries over the last five years with excellent results in both diagnostics and treatment procedures. Diagnostically, the Bouquet Speculum™ has been used for pap tests, HPV-DNA probe testing, Visual Inspection with Acetic Acid (VIA), colposcopy, STD screening, forensic rape kits, and hysteroscopy. Figure 1C demonstrates lateral vaginal wall collapse with the standard two-bladed speculum, potentially obstructing the view of other parts of the cervix that may contain abnormal cells. In comparison, Figure 1D demonstrates a complete circumferential view of the cervix with the Bouquet Speculum™. For procedures involving a vaginal speculum, it has been used for cryoablation, thermoablation, cold-knife excision, Loop Electrical Excision Procedure (LEEP), chorionic villus sampling, endometrial biopsy, and Intrauterine Device (IUD) insertion and removal.¹⁰ Figure 1E and F demonstrate the access to the cervix for the procedures mentioned above.

A recently published perspective article suggested universal screening and treatment for cervical cancer and precancers for \$7.50 at the point of care using the Bouquet Speculum™ and a novel Cervical Cancer Cure Kit.¹¹

Materials and Methods

Study Design

Following ethical approval (RVU exempt ref no: 2023–094 and Ziauddin University ERB ref no: 6920323RHGYN), an observational study involving 100 women aged 18–65 years who had previously undergone vaginal speculum examination

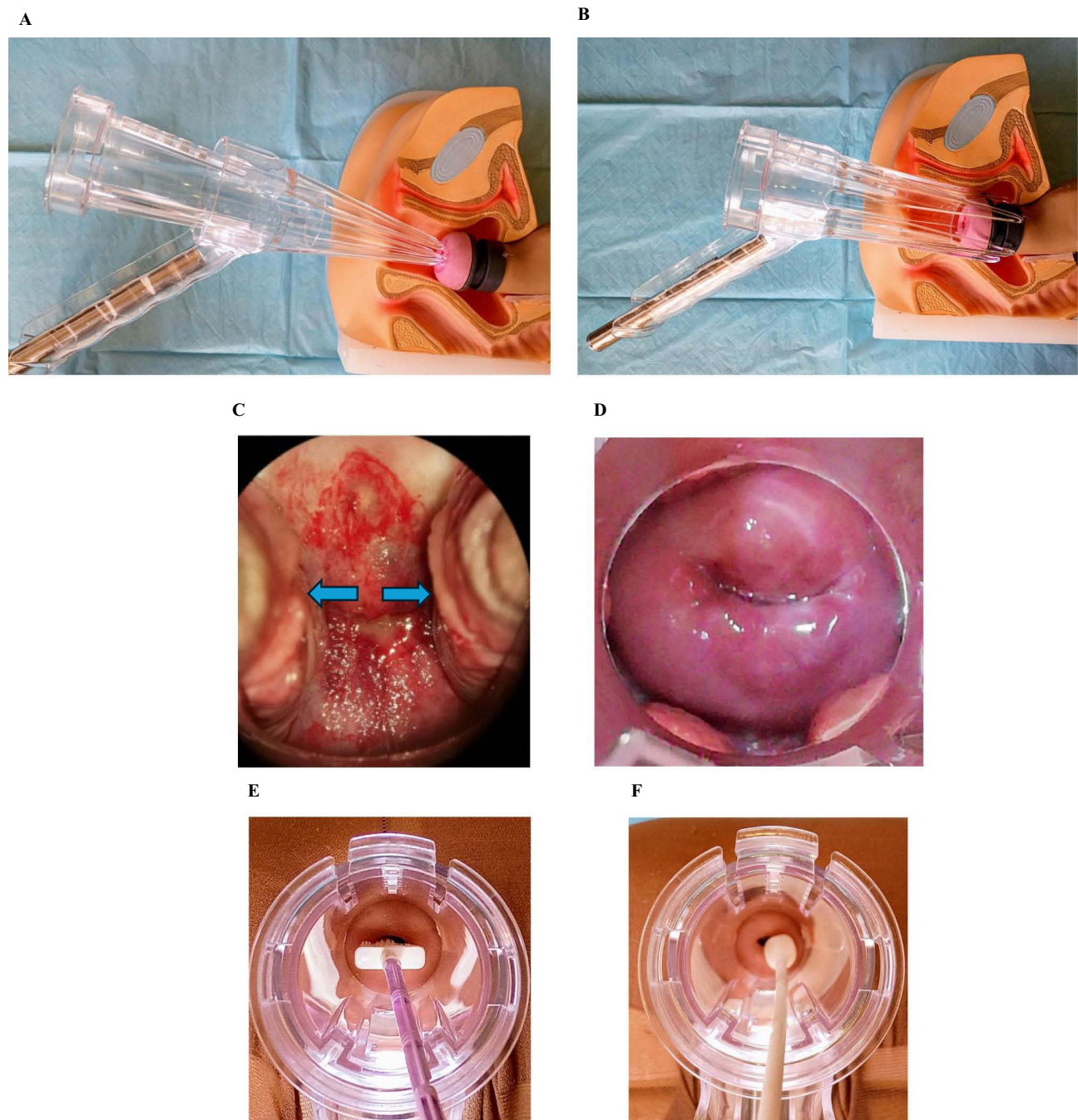


Figure 1 (A) Bouquet Speculum™ (closed). (B) Bouquet Speculum™ (open). (C) Incomplete visualization of the cervix due to lateral vaginal wall collapse (blue arrows) with a two-bladed traditional speculum. (D) Complete visualization of the cervix without lateral vaginal wall collapse with the Bouquet Speculum™. (E) Cytobroom inside the Bouquet Speculum™ for pap tests. (F) Cotton-tipped applicator inside the Bouquet Speculum™ for cryoablation of cervical dysplasia.

was conducted. Participants signed consent forms to be examined with the Bouquet Speculum™ during their pap test or other gynecological visits at Ziauddin University Hospital in Karachi, Pakistan. After the examination, the patient was asked to rate their comfort level, and the physician was asked to rate the ease of use of the speculum and the extent of visualization of the cervix. The results from the physician and the patient surveys were then sent to Rocky Vista University (RVU) for data analysis.

Sample Size Determination

The sample size of this study was 100 patients from five clinical sites. This was based on the known accuracy (65%) of the existing 2-bladed speculum in obtaining endocervical cells, the area where metaplasia occurs, and the most common areas for cervical dysplasia and cancer development.¹²

The formula ($n = 2 (Z\alpha + Z [1-\beta])^2 \times P \times q/d^2$) was used to compare the two proportions (65% for obtaining endocervical cells vs ideal of 100%). $n = 2 (1.96 + 1.64)^2 \times 35 \times 65/(35)^2 = 48$. This (n) was doubled to account for the potential that the surveys were not completed by either the clinician or patient.¹³

Additionally, FDA guidance for pilot studies on medical device sample sizes is not required to be statistically driven and generally falls in the range of 60–100 subjects.¹⁴

Inclusion and Exclusion Criteria

To optimize the results, the criteria for patients to enter this study included subjects between the ages of 18 and 65 years with prior experience with vaginal speculum examination with a two-bladed speculum. Patients who did not meet the criteria to be evaluated included women who were not in the age range of 18–65 years and any women who had a history of hysterectomy with removal of the uterine cervix.

The Investigational Speculum

Physicians at Ziauddin University Hospital were educated on how to utilize Bouquet Speculum™ via video presentation and written step-by-step instructions. The instructional video demonstrates a pap test using Bouquet Speculum™ on a pelvic model. Lastly, an online live meeting was conducted between RVU and Ziauddin Hospital to display the Bouquet Speculum™ and the five-petal expansion and contraction.

Survey Questionnaires

The study results were limited to three answer choices per question: better, same, or worse for the visualization survey; easier, same, and more difficult for the ease-of-use survey; and better, same, and worse for the comfort level in the patient survey. The three choices were deliberately designed to be simple and unambiguous. Outcomes from the physician's perspective would assess visualization of the cervix and ease of use, whereas outcomes from the patient's perspective would assess comfort.

Patient Involvement Statement

The patients were not involved in the design, conduct, reporting, or dissemination of research findings. The study was conducted in accordance with HIPAA guidelines, protecting the anonymity of the patients and obtaining consent, allowing participants to opt out of the study at any given time.¹⁵ All personal information was redacted and protected, especially with the transfer of data from the Ziauddin University Hospital to the RVU for data evaluation.

Results

Proportions

Responses to the three questions were obtained and analyzed regarding visual perception of the cervix, patient comfort, and ease of use. The responses were categorized as follows: better, same, and worse for visual perception; better, same, and worse for comfort; and easier, same, and more difficult for ease of use (Figure 2).

A proportion test was conducted to assess the significance of the “better” (or “easier”) responses. The set of hypotheses was the null hypothesis (H_0), $p = 0.05$, versus the alternative hypothesis (H_a), $p > 0.05$. The visual component of the physicians' survey was superior to the standard speculum with a p-value of 0.0007 obtained, indicating statistical and clinical significance. The ease-of-use component of the physicians' survey and the level of comfort as reported on the patients' survey was superior clinically to the existing speculum but not statistically significant at ($p = 0.0808$ and $p = 0.274$, respectively).¹⁶ (Table 1). With a visualization of the cervix superior to the standard two-bladed speculum, and the sample size being limited to 100 participants, it is possible that both ease of use and comfort factors might attain statistical significance with a larger sample size (200–250 observations).

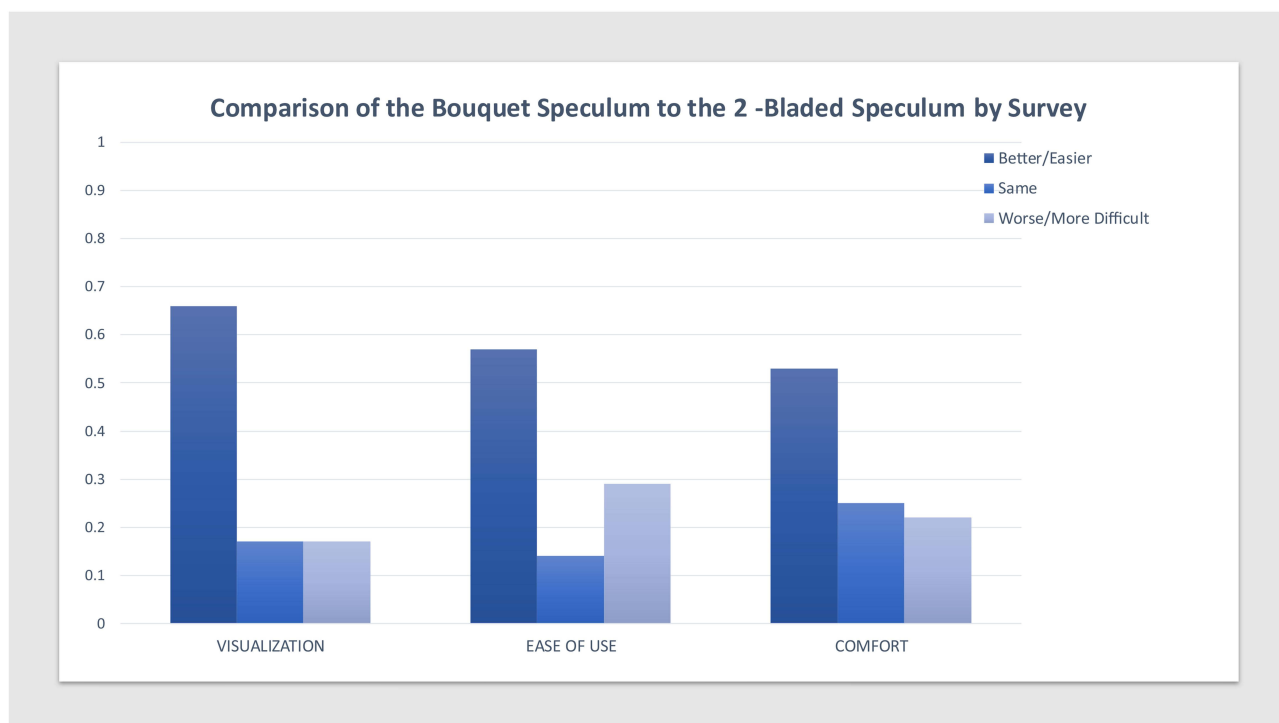


Figure 2 The first survey question for the clinicians was an assessment of the visualization of the cervix with the Bouquet Speculum™. The results indicated better visualization in 66% ($p=0.0007$) of the patients. The second survey question evaluated ease of use of the Bouquet Speculum™ for the clinician. The results indicated that in 57% ($p=0.0808$) of the patients, the clinicians found the new speculum easier to use. The third survey question was assessed by the patients on the relative comfort of the Bouquet Speculum™. The results indicated that 53% ($p=0.2743$) of the patients rated the new speculum as less uncomfortable.

Correlation

The degree of correlation among the three possible relationships was evaluated (visualization vs ease of use, visualization vs comfort, and ease of use vs comfort). Gamma statistics (correlation coefficients for ordinal categorical variables) were used to assess associations between the three factors. Similar to traditional correlation measures, gammas range from -1 to $+1$, and the closer the value is to 1, the more correlated are the two variables. A value of zero indicates no correlation.

Table 1 Physician and Patient Survey Results

Cervical Visualization	Frequency	Standard Error	P-value
Better	66	66 ± 4.7	0.0007
Same	17	17 ± 3.8	
Worse	17	17 ± 3.8	
Ease of Use	Frequency	Standard Error	P-value
Easier	57	57 ± 5	0.0808
Same	14	14 ± 3.5	
More Difficult	29	29 ± 4.5	
Comfort	Frequency	Standard Error	P-value
Better	53	53 ± 5	0.2743
Same	25	25 ± 4.3	
Worse	22	22 ± 4.1	

The degree of correlation between visualization and ease of use is summarized as raw counts in Table 2 along with the gamma statistics and the associated p-value. A significant correlation was found between physicians' ratings of visualization and ease of use of the Bouquet SpeculumTM. This was confirmed with a gamma statistic of 0.8234 and p-value of < 0.0001. The degree of correlation between visualization and comfort is summarized as raw counts in Table 3 along with the gamma statistics and p-values. When testing for a significant correlation between physician's rating of visualization and comfort, there was a significant correlation found. This was confirmed with gamma statistics of +0.8978 and a p-value < 0.0001. The degree of correlation between ease of use and comfort is summarized as raw counts in Table 4 along with gamma statistics and p-values. A significant correlation was found between the physician's ease of use score and the patient's comfort rating. Among all the correlations evaluated, ease of use vs comfort was found to have the

Table 2 Visualization vs Ease of Use

		Ease		
Visual		Easier	Same	More Difficult
	Better	53	3	10
	Same	4	8	5
	Worse	0	3	14
	Total	57	14	29
Statistic	Value	P-value		
Gamma	0.8234	<0.0001		

Table 3 Visualization vs Comfort

		Comfort		
Visual		Better	Same	Worse
	Better	52	9	5
	Same	1	12	4
	Worse	0	4	13
	Total	53	25	22
Gamma	Value	P-value		
Statistic	0.8978	<0.0001		

Table 4 Ease vs Comfort

		Comfort		
Ease		Better	Same	Worse
	Easier	49	6	2
	Same	1	13	0
	More Difficult	3	6	20
	Total	53	25	22
Gamma	Value	P-value		
Statistic	0.9101	<0.0001		

strongest correlation with a gamma statistic of +0.9101 and p-value < 0.0001. Although the three correlations found did not vary significantly between the two, they all showed strong positive correlations.

Discussion

This pilot study on a new vaginal speculum demonstrated the feasibility of the methodology and based on the promising results, may offer an alternative to the existing 2-bladed speculum. To the best of our knowledge, this is the first clinical study to involve a five-petaled vaginal speculum. Three variables were subjectively measured at Ziauddin University Hospitals in the study of the Bouquet SpeculumTM in 100 women in Karachi, Pakistan. Six physicians who used the Bouquet SpeculumTM performed between 16 and 18 vaginal speculum exams each and rated the visualization of the cervix as better in 66% ($p=0.007$) of women in whom a vaginal speculum exam was performed. This finding was clinically and statistically significant. Physicians rated the Bouquet SpeculumTM as easier to use in 57% ($p=0.0808$) of women, which was clinically significant but not statistically significant. The last survey was administered to patients who rated the Bouquet SpeculumTM as less uncomfortable from their memory of previous 2-bladed speculum exams in 53% ($p=0.2743$) of the cases. This was not considered statistically significant but is significant for patients' comfort when performing a vaginal speculum examination. There was a strong statistical correlation between a clinician's visualization of the cervix and the ease of use of the Bouquet SpeculumTM. Similarly, there was a strong correlation between the ability to visualize the cervix and the physician's perceived ease of use and the patient's comfort. In other words, the easier it was to visualize the cervix and use the speculum, the less uncomfortable the patient was.

The strength of this pilot study is its simple survey design with prospectively collected data. It was relatively easy to advertise and recruit for this study as the Bouquet SpeculumTM is not experimental, but rather FDA-cleared and CE-marked, and has been commercialized and used globally. The limitations of this study for the assessment of visualization are that no visual images were taken, which makes physician reports more subjective. For physicians' ease of use reporting, there is minimal training involved, but the Bouquet SpeculumTM is slightly different from the existing 2-bladed speculum which may have confounded the results for this variable.

The last variable was the assessment of patient comfort level. There was a lack of standardization regarding the length of time since the last vaginal speculum examination, the BMI of the patient, the number of previous vaginal speculum exams, and the parity of the patient. Additional limitations include the sample size of 100 patients and six physicians. This study cannot be blinded, as both the clinician and the patient can easily distinguish between a 2-bladed speculum and the Bouquet SpeculumTM.

Conclusion

The Bouquet SpeculumTM is an innovative change to the existing 2-bladed speculum which has limitations in visualizing the cervix for many vaginal speculum exams, may be difficult to use by inexperienced clinicians, and is uncomfortable and anxiety-provoking for some patients. This pilot study supports the field-trials and the claim that the Bouquet SpeculumTM is better at visualizing the cervix, easier to use, and less uncomfortable than the existing 2-bladed vaginal speculum.

Further studies are underway in the US with a larger cohort of Sunrise Community Health Clinics (<https://clinicaltrials.gov/study/NCT06496295>) to confirm the results of this study and to address some of the limitations mentioned above. The Bouquet SpeculumTM has proven to be an alternative to the traditional 2-bladed vaginal speculum, especially for novice providers in underserved areas and for patients with certain physical or emotional concerns when it comes to the level of comfort.

Data Sharing Statement

The data used in this research were securely stored with the corresponding author and are available upon request.

Ethics Approval

This study involved human participants and was approved by the Ziauddin University Ethical Review Board (ERB) (ref no: 6920323RHGYN). All participants provided informed consent before participating in the study.

This pilot study complies with the Declaration of Helsinki on ethical principles for medical research involving human subjects.

Acknowledgments

The authors would like to acknowledge Ziauddin University Clinical Trial Unit who performed this pilot study. The following physicians participated in the survey study for visualization of the cervix and ease of use: Dr. Rubina Hussain (PI), Dr. Habiba Sharaf Ali, Dr. Sumbul Sohail, Dr. Ome Kulsoom, and Dr. Hina Rahjani. Additionally, the authors would like to acknowledge the following physicians for their field-testing of the Bouquet SpeculumTM: Dr. Balogun, MD, New York Presbyterian Hospital, Dr. Rodrigo Orozco Fernández, Jefe de Servicio de Obstetricia y Ginecología, Co-Director de TEC - Training & Education Center in Málaga, Hospital Quironsalud Málaga, Dr. Melsa Omay, Founding Board member, Goodlife Access and Goodlife Ivuriro Clinics, Rwanda, Dr. Samuel K. Ndinjakat CEO/Founder, Grace Gardens Hospital Ndop, Cameroon, and Dr. Daniel Kimani, CEO/Founder, Global Cancer Care and Research Institute-Kenya.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

Funding for this study at the Ziauddin University Hospitals was provided by Cure Cervical Cancer, Inc., a non-profit organization.

Disclosure

The corresponding author, JB, is the inventor of the Bouquet SpeculumTM and owns patents (US 8,460,187 B2 and US 11,931,012 B2) for their designs and shares in the associated company (Viospex, the US, and Spain). Currently, JB does not receive any financial benefits as the speculum has yet to generate revenue. The other authors have no conflicts of interest to declare for this work.

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