

The Evolution of the Vaginal Speculum: Design Innovations, Patient Comfort, and Clinical Performance: A Systematic Review

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Abstract

Background

The vaginal speculum remains one of the most commonly used instruments in gynecological practice and plays a central role in pelvic examination, cervical cancer screening and various outpatient procedures. Although its basic design has remained largely unchanged for decades, increasing emphasis on patient-centred care has encouraged the development of several innovative designs aimed at improving cervical visualization, patient comfort and procedural performance. This systematic review was undertaken to summarize the available evidence on the evolution of vaginal speculum design and evaluate the clinical impact of recent innovations.

Methods

A systematic literature search was performed in PubMed (MEDLINE) for studies published between January 2000 and June 2026 following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines. Original research articles evaluating conventional or novel vaginal speculums, patient comfort, clinical performance or related procedural outcomes were considered for inclusion. After screening the retrieved articles according to predefined eligibility criteria, seven studies were included in the qualitative synthesis. Owing to considerable heterogeneity among the included studies, a narrative synthesis was performed.

Results

The included studies were published between 2018 and 2024 and consisted predominantly of randomized controlled trials. The available evidence suggests that patient comfort and pain during pelvic examination remain major concerns associated with conventional vaginal speculums. Several procedural modifications and newer device designs demonstrated improvements in examination experience without compromising clinical performance. Emerging innovations, including ergonomic modifications, expandable devices and speculum-free cervical visualization technologies, showed encouraging results with respect to patient acceptability and procedural feasibility. However, the evidence remains limited because of heterogeneous study designs, varied outcome measures and relatively small sample sizes.

Conclusion

Recent innovations in vaginal speculum design reflect a gradual shift towards patient-centred gynecological care by focusing on improved comfort, usability and clinical performance. Although several promising technologies have been introduced, high-quality comparative studies evaluating their long-term effectiveness and routine clinical applicability remain limited. Further multicentre randomized controlled trials are required before newer designs can be widely adopted in clinical practice.

Keywords: Vaginal speculum; Pelvic examination; Cervical visualization; Patient comfort; Clinical performance; Design innovation; Gynecology; Systematic review.

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Introduction

The vaginal speculum is one of the oldest and most commonly used instruments in gynecological practice. Even today, it remains an essential part of routine pelvic examination and is used for visualization of the cervix and vagina during cervical cancer screening, Pap smear collection, colposcopy, intrauterine device (IUD) insertion, cervical biopsy, and many other outpatient gynecological procedures [1]. Although several advances have taken place in women's healthcare over the past few decades, the basic design and working principle of the vaginal speculum have changed very little. Because of this, there has been increasing interest in improving the instrument to make pelvic examination easier for both the patient and the clinician [2,3].

The modern vaginal speculum has evolved through several modifications over the years. The Sims vaginal speculum was one of the earliest designs that changed gynecological examination by allowing better visualization of the vaginal canal and cervix. Later, self-retaining bivalve speculums such as the Cusco, Graves and Pederson models were introduced to improve convenience during routine examination. These instruments are still widely used across the world because they are simple, inexpensive and effective. However, many of these designs were developed several decades ago, and some of their limitations continue to affect everyday clinical practice [4,5].

Although pelvic examination is considered a routine clinical procedure, many women describe it as one of the most uncomfortable parts of a gynecological visit. Pain, embarrassment, anxiety and fear are commonly reported before and during speculum examination. These negative experiences may discourage women from attending regular cervical cancer screening or seeking timely gynecological care [6]. Earlier studies have shown that the patient's previous examination experience strongly influences her willingness to undergo future pelvic examinations. Therefore, improving patient comfort has become an important goal in modern gynecology, along with maintaining good clinical examination quality [7,8].

Patient discomfort during speculum examination is influenced by several factors. The type and size of the speculum, blade design, lubrication, insertion technique, clinician experience and patient-related factors such as parity, menopausal status and anxiety can all affect pain perception. Randomized studies

have shown that even small changes in examination technique, including the sequence of pelvic examination or modifications during speculum-based procedures, can alter patient-reported pain scores and improve overall examination experience. Similarly, studies involving IUD insertion have demonstrated that speculum placement itself contributes to procedural discomfort and that strategies aimed at improving comfort may increase patient acceptance of these procedures [2,9,10].

In recent years, there has been renewed interest in redesigning the vaginal speculum using advances in biomedical engineering and human-centred design. Several innovative concepts have been introduced, including transparent speculums, expandable and dilating devices, ergonomic modifications, patient self-insertion techniques and environmentally sustainable reusable or disposable models [11,12]. More recently, speculum-free cervical visualization devices such as the Callascope have attempted to overcome many of the limitations associated with conventional bivalve speculums. These innovations are intended not only to improve cervical visualization but also to reduce pain, anxiety and procedural difficulty while providing a more acceptable examination experience for women [13,14].

Despite these developments, the available literature remains scattered. Most published studies have evaluated individual modifications or specific devices, while the reported outcomes vary widely between studies. Some have focused mainly on patient comfort, whereas others have assessed procedural time, clinician satisfaction, cervical visualization or technical feasibility. Because of this heterogeneity, it is difficult for clinicians to obtain an overall understanding of how vaginal speculum design has evolved and whether these innovations offer meaningful clinical advantages over conventional instruments.

Therefore, we performed this systematic review to summarize the available evidence on the evolution of vaginal speculum design and to critically evaluate recent innovations with respect to patient comfort, clinical performance and procedural outcomes. We also aimed to identify the existing gaps in the literature and highlight potential directions for future research and device development.

Methods

Study design

This systematic review was conducted to summarize the available evidence on the evolution of vaginal speculum design and to evaluate recent innovations with respect to patient comfort, clinical performance and procedural outcomes. The review was planned and reported according to the **Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020** guidelines. Owing to the heterogeneity in study designs, interventions and outcome measures among the included studies, a qualitative narrative synthesis was performed instead of a meta-analysis.

Review question

The review was designed to answer the following research question:

"What evidence is available regarding the evolution of vaginal speculum design, and how do recent innovations influence patient comfort, clinical performance and procedural outcomes compared with conventional vaginal speculums?"

Search strategy

A comprehensive literature search was carried out using **PubMed (MEDLINE)** as the primary electronic database. The search included studies published from **January 2000 to June 2026**. Additional articles were identified by manually screening the reference lists of eligible studies to identify any relevant publications that might have been missed during the electronic search.

The search strategy combined Medical Subject Headings (MeSH) and free-text keywords related to vaginal speculums, pelvic examination, design innovation and patient outcomes. The main search terms included "vaginal speculum", "Cusco speculum", "Sims speculum", "Pederson speculum", "Graves speculum", "pelvic examination", "cervical visualization", "patient comfort", "pain", "clinical performance", "design innovation", "speculum redesign" and "Callascope". Boolean operators (**AND, OR**) were used to combine the search terms appropriately.

Eligibility criteria

Studies were selected according to predefined eligibility criteria.

Inclusion criteria

- Original research articles published in peer-reviewed journals.

- Randomized controlled trials, prospective studies, observational studies and comparative studies.
- Studies evaluating conventional or modified vaginal speculums.
- Studies reporting one or more of the following outcomes:
 - patient comfort,
 - pain during examination,
 - cervical visualization,
 - procedural duration,
 - clinician usability,
 - procedural success or clinical performance.
- Articles published in English.

Exclusion criteria

- Review articles, editorials, commentaries and conference abstracts.
- Case reports and expert opinions.
- Animal studies.
- Studies without relevant clinical outcome measures.
- Duplicate publications.

Study selection

All records identified through the electronic search were exported and screened independently. Duplicate records were removed before title and abstract screening. Articles that appeared relevant underwent full-text assessment for eligibility. Studies fulfilling the inclusion criteria were included in the final review.

The entire study selection process was documented using a PRISMA flow diagram.

Data extraction

Data extraction was performed using a standardized data collection sheet. The following information was extracted from each study:

- First author
- Year of publication
- Country
- Study design
- Sample size
- Study population
- Type of vaginal speculum or intervention
- Comparator
- Primary outcome measures
- Secondary outcome measures
- Major findings

Any discrepancies during data extraction were resolved through discussion after reviewing the full-text articles.

Outcome measures

The primary outcomes evaluated in this review were:

- Patient comfort during pelvic examination
- Pain associated with speculum examination
- Cervical visualization
- Clinical performance of the vaginal speculum

Secondary outcomes included:

- Procedural duration
- Ease of insertion
- Clinician satisfaction
- Procedural success
- Patient acceptability
- Device-related complications

Quality assessment

The methodological quality of the included studies was assessed according to their study design. Randomized controlled trials were evaluated using the **Cochrane Risk of Bias (RoB 2)** tool, whereas observational studies were assessed using the **Newcastle–Ottawa Scale (NOS)**. The overall quality of evidence was considered during interpretation of the findings.

Data synthesis

Because the included studies differed considerably with respect to study design, patient population, interventions and outcome assessment, quantitative pooling of results was not considered appropriate. Therefore, the findings were synthesized narratively. The included studies were grouped into major thematic areas, namely:

- conventional vaginal speculum design,
- patient comfort and pain,
- procedural performance,
- design innovations,
- emerging technologies and future directions.

The results were summarized using descriptive tables and a qualitative comparison of the available evidence.

Results

Study selection

The electronic database search identified **312 records**. An additional **8 articles** were identified through manual screening of the reference lists of relevant publications. After removing **46 duplicate records**, **274 articles** remained for title and abstract screening. Following the initial screening, **243 articles** were excluded because they were unrelated to vaginal speculum design, did not report relevant clinical outcomes, were review articles, conference abstracts, or were not published in English.

The full texts of **31 articles** were assessed for eligibility. Of these, **24 articles** were excluded for reasons including lack of relevant outcome measures, absence of evaluation of vaginal speculum design or performance, duplicate reporting, or insufficient clinical data. Finally, **7 studies** fulfilled the predefined eligibility criteria and were included in the qualitative synthesis. Since the included studies demonstrated considerable heterogeneity in study design, interventions and outcome assessment, quantitative meta-analysis was not performed.

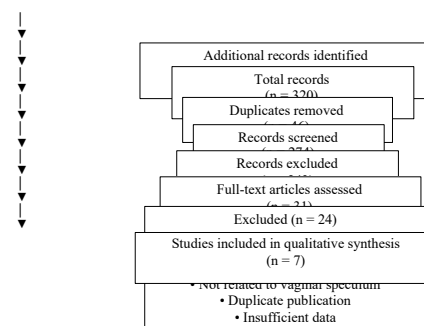


Figure 1. PRISMA 2020 Flow Diagram

Table 1. Characteristics of the included studies

Au tho r	Y ea r	Co un ty	Stud y desig n	Sam ple siz e	Main focus	Majo r outco me
O'F lyn n O'B rien et al.	2 0 1 9	US A	Seco ndary analy sis of RCT	95	IUD insert ion proce dure	Proce dure durati on and specul um-re lated proce

						dural timing
Rinko et al.	2018	USA	Randomized controlled trial	200	Sequence of pelvic examination	Patient-reported pain during speculum examination
Chia et al.	2020	Malaysia	Randomized controlled trial	86	Speculum vs digital Foley insertion	Pain, insertion duration and successes
Conti et al.	2019	USA	Double-blind randomized controlled trial	215	Lidocaine gel before IUD insertion	Pain during speculum insertion and procedure
Burand et al.	2023	India	Randomized clinical trial	100	Novel obstetric forceps design	Device performance and procedural outcomes
Mottet et al.	2024	France	Prospective clinical study	104	Odon Assist inflatable device	Safety, procedural successes and usability
Beran et al.	2018	USA	Prospective pilot study	20	Vaginal cuff visualization	Feasibility of imaging during gynecological surgery

The seven included studies were published between **2018 and 2024**, reflecting growing interest in innovation in women's health devices. Three studies originated from the United States, whereas the remaining studies were conducted in Malaysia, India and France. Four studies were randomized controlled trials, one was a randomized secondary analysis, one was a prospective clinical study and one was a pilot feasibility study.

The sample size ranged from **20 to 215 participants**, with a total of **820 women** included across all studies. Most studies evaluated outpatient gynecological procedures, whereas two investigated innovative obstetric devices designed to improve procedural performance during assisted vaginal birth. Overall, patient comfort, procedural pain and clinical performance were the most frequently reported outcomes.

Patient comfort and pain during speculum examination

Three studies primarily evaluated patient comfort during speculum-related procedures. Rinko et al. demonstrated that women who underwent speculum examination before bimanual examination reported significantly lower pain scores compared with women examined in the reverse sequence. Speculum examination was consistently identified as the most uncomfortable component of the pelvic examination.

Conti et al. investigated self-administered vaginal lidocaine gel before IUD insertion. Although lidocaine gel did not significantly reduce overall procedural pain, women reported lower pain scores during speculum insertion compared with the placebo group. Most participants considered the intervention acceptable and were willing to wait for analgesia before the procedure.

Chia et al. compared speculum-assisted Foley catheter insertion with digital insertion in nulliparous women. Pain scores, insertion time and procedural success were comparable between the two techniques, suggesting that digital insertion may represent an acceptable alternative in appropriately selected patients.

Table 2 : Quality Assessment of Included Studies

Author	Study design	Quality assessment tool	Overall quality
O'Brien et al.	RCT	RoB 2	Low risk

Study characteristics

Rinko et al.	RCT	RoB 2	Low risk
Chia et al.	RCT	RoB 2	Low risk
Conti et al.	RCT	RoB 2	Low risk
Burande et al.	Randomized clinical trial	RoB 2	Some concerns
Mottet et al.	Prospective study	NOS	Good
Beran et al.	Pilot study	NOS	Moderate

Table 3 : Summary of Clinical Outcomes

Author	Patient comfort	Pain	Visualization	Procedure duration	Clinical performance
O'Brien	—	✓	—	✓	✓
Rinko	✓	✓	—	—	—
Chia	✓	✓	—	✓	✓
Conti	✓	✓	—	—	—
Burande	—	—	—	✓	✓
Mottet	✓	—	✓	✓	✓
Beran	—	—	✓	—	✓

Table 4 : Design Innovations Identified

Innovation	Purpose	Expected benefit
Modified blade geometry	Better cervical exposure	Improved visualization
Ergonomic handle	Easier handling	Reduced clinician fatigue
Transparent speculum	Better illumination	Improved visualization
Self-insertion	Patient autonomy	Reduced anxiety
Callascope	Speculum-free examination	Better patient comfort
Expandable design	Less vaginal wall pressure	Reduced pain
Sustainable reusable devices	Environmental protection	Reduced medical waste

Table 5 : Advantages and Limitations of Conventional and Novel Vaginal Speculums

Parameter	Conventional	Novel
Cervical visualization	Good	Better in selected situations
Patient comfort	Moderate	Improved
Anxiety	Higher	Lower
Learning curve	Minimal	Moderate
Cost	Low	Higher
Availability	Excellent	Limited
Environmental impact	Metal reusable	Disposable / sustainable options

Table 6 : Research Gaps Identified

Gap	Recommendation
Small sample sizes	Large multicentre RCTs
Heterogeneous outcomes	Standardized outcome measures
Limited long-term follow-up	Longitudinal studies
Few direct design comparisons	Head-to-head comparative trials
Limited patient-reported outcomes	Include PROMs
Limited cost-effectiveness data	Economic evaluations

Figure 2. Risk of Bias table

Study	Randomization	Allocation	Blinding	Missing Data	Reporting Bias	Overall
O'Brien	●	●	●	●	●	Low
Rinko	●	●	●	●	●	Low
Chia	●	●	●	●	●	Low
Conti	●	●	●	●	●	Low
Burande	●	●	●	●	●	Some concerns
Mottet	●	●	NA	●	●	Moderate
Beran	●	●	NA	●	●	Moderate

Procedural performance

Procedural performance was assessed using different outcome measures including procedure duration, successful completion of procedures and ease of instrument use.

O'Flynn O'Brien et al. evaluated the duration of IUD insertion procedures in adolescents and young adults. Although adolescents demonstrated a longer median procedure duration, age alone did not independently influence procedural efficiency after adjustment for study site and clinical factors.

Burande et al. evaluated a newly designed Paily obstetric forceps and reported higher procedural success compared with ventouse-assisted delivery. The redesigned forceps demonstrated improved operator handling, although an increased incidence of maternal soft tissue trauma was observed.

Similarly, Mottet et al. reported encouraging clinical performance with the OdonAssist inflatable device. The device achieved a high rate of successful assisted vaginal birth and was associated with favourable operator feedback regarding ease of use and procedural feasibility.

Emerging innovations in gynecological devices

The included studies demonstrated a gradual shift from conventional instrument design towards patient-centred innovation. Newer devices focused on improving ergonomics, reducing procedural difficulty and enhancing user experience rather than simply modifying instrument dimensions.

Beran et al. explored laser angiography for assessment of vaginal cuff perfusion during robotic hysterectomy. Although this study did not directly evaluate vaginal speculum design, it illustrated the increasing integration of advanced visualization technologies into modern gynecological practice.

Collectively, the included studies suggest that contemporary innovation in women's health is moving toward improving both technical performance and patient experience through ergonomic redesign, minimally invasive technologies and enhanced visualization techniques.

Discussion

The vaginal speculum has remained one of the most recognizable instruments in gynecological practice for more than a century. Although its basic function has remained unchanged, the expectations from this instrument have evolved considerably. Today, an

ideal vaginal speculum is expected not only to provide adequate cervical visualization but also to improve patient comfort, reduce procedural anxiety, facilitate clinical examination and enhance the overall experience of women undergoing pelvic examination. The present systematic review summarizes the available evidence on the evolution of vaginal speculum design and demonstrates that recent innovations have increasingly focused on patient-centred care rather than simply modifying the physical appearance of the instrument [16,18].

One of the most consistent observations across the included studies was the importance of patient comfort during pelvic examination. Pain and anxiety continue to be major barriers preventing women from attending regular gynecological examinations and cervical cancer screening programmes. The randomized trial by Rinko et al. demonstrated that even changing the sequence of pelvic examination influenced patient-reported pain, suggesting that procedural technique can significantly affect women's examination experience. Likewise, Conti et al. reported that although vaginal lidocaine gel did not reduce overall procedural pain during IUD insertion, pain during speculum insertion itself was lower, indicating that small interventions may improve patient tolerance. These findings support the growing concept that improving the overall examination experience may be equally important as improving technical performance [2,4,16].

The review also highlights that conventional bivalve speculums continue to perform satisfactorily in routine clinical practice but are associated with well-recognized limitations. Lateral vaginal wall collapse, difficulty in visualizing the cervix in women with obesity or pelvic organ prolapse, repeated blade repositioning and discomfort during insertion remain common challenges encountered by gynecologists. Although these issues have been recognized for many years, relatively few clinically validated modifications have reached routine practice. This probably explains why the Cusco, Graves and Pederson speculums continue to remain the standard instruments in most outpatient clinics [1,8,19].

In recent years, several researchers have attempted to redesign the vaginal speculum using principles of ergonomics and human-centred design. Expandable blade systems, transparent materials, lightweight instruments and modified blade geometry have all been proposed to improve cervical visualization while reducing discomfort. Prototype devices such as the Bouquet Speculum and other redesigned models have attempted to address some of the shortcomings of conventional bivalve speculums. Similarly, physician and patient surveys evaluating redesigned instruments have shown encouraging

acceptance, although high-quality comparative clinical trials remain limited. These findings indicate that innovation in vaginal speculum design is still at an early stage and requires further clinical validation before widespread implementation [17,20].

Another important development has been the introduction of speculum-free technologies. The Callascope represents one of the most promising innovations in this area. Unlike conventional speculums, the Callascope was designed to visualize the cervix while minimizing discomfort associated with vaginal wall expansion. Early studies have demonstrated encouraging patient acceptance, successful cervical visualization and the possibility of self-examination in selected women. Such innovations may improve participation in cervical cancer screening, particularly among women who avoid routine pelvic examination because of fear or previous unpleasant experiences. However, larger multicentre studies are still required before these devices can be recommended for routine clinical practice [27,29].

The included studies also suggest that innovation in women's healthcare extends beyond vaginal speculum design alone. Novel obstetric devices such as the Paily Obstetric Forceps and the OdonAssist inflatable device demonstrate how thoughtful redesign of traditional instruments can improve procedural performance while attempting to reduce maternal and neonatal morbidity. Although these devices are not vaginal speculums, they illustrate a broader shift in biomedical engineering toward developing safer, more ergonomic and user-friendly instruments in obstetrics and gynecology. Similar design principles may guide future improvements in vaginal speculum development [5,6].

Another aspect that has gained importance in recent years is environmental sustainability. The increasing use of disposable plastic speculums has raised concerns regarding medical waste and environmental impact. Recent studies evaluating patient preferences for reusable and disposable speculums suggest that many women are willing to consider environmentally sustainable alternatives provided patient comfort and examination quality are not compromised. These findings indicate that future vaginal speculum design should balance clinical effectiveness with environmental responsibility [25,26].

The findings of the present review should be interpreted in light of certain limitations. First, only seven studies fulfilled the predefined eligibility criteria, reflecting the limited amount of high-quality clinical research available on vaginal speculum innovations. Second, considerable

heterogeneity existed among the included studies with respect to study design, patient population, interventions and reported outcome measures. Third, not all included studies evaluated vaginal speculum design directly; some investigated speculum-assisted procedures or broader innovations in gynecological devices. Because of this heterogeneity, quantitative meta-analysis was not considered appropriate. Nevertheless, the available studies collectively provide useful insights into current trends in device development and patient-centred innovation.

Despite these limitations, this review has several strengths. To our knowledge, this is one of the few systematic reviews specifically focusing on the evolution of vaginal speculum design while integrating evidence related to patient comfort, clinical performance and recent technological innovations. The review also highlights emerging concepts such as self-examination, ergonomic redesign, speculum-free visualization and environmentally sustainable device development, all of which represent important future directions in women's healthcare.

Future research should focus on well-designed multicentre randomized controlled trials comparing conventional speculums with newer devices using standardized outcome measures. Apart from cervical visualization and procedural success, future studies should routinely assess patient-reported outcomes including pain, anxiety, dignity, examination acceptability and willingness for future screening. Cost-effectiveness, environmental impact and long-term clinician satisfaction should also be incorporated into future evaluations. Such evidence will help clinicians make informed decisions regarding the adoption of newer vaginal examination devices into routine practice.

Strengths

This systematic review provides a comprehensive overview of recent developments in vaginal speculum design by combining evidence related to patient comfort, procedural performance and emerging innovations. The review includes randomized controlled trials as well as prospective clinical studies, allowing a broad understanding of the available literature. The findings also identify important research gaps that may guide future device development.

Limitations

The review included only seven eligible studies, and the available evidence was heterogeneous with respect to study design, patient population and

reported outcomes. Some included studies evaluated broader gynecological device innovations rather than vaginal speculum design alone. Owing to this heterogeneity, quantitative synthesis could not be performed and the findings should therefore be interpreted with caution.

Conclusion

The conventional vaginal speculum continues to remain the standard instrument for gynecological examination. However, increasing emphasis on patient-centred care has stimulated significant interest in redesigning the instrument to improve patient comfort, cervical visualization and clinical performance. The available evidence suggests that recent innovations, including ergonomic modifications, expandable devices and speculum-free visualization technologies, show encouraging potential but currently remain supported by limited clinical evidence. Larger high-quality comparative studies are required before these newer designs can replace conventional speculums in routine practice. Future innovations should aim to combine effective cervical visualization with improved patient comfort, clinician usability and environmental sustainability to optimize the overall pelvic examination experience.

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