



From Eyeball to Exact: A Meta-Analysis of an Innovation in Episiotomy with Angle-Guiding Devices

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Abstract

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Background : Episiotomy is a surgical incision performed to enlarge the vaginal outlet during childbirth, but an inaccurate mediolateral angle may increase the risk of obstetric anal sphincter injury (OASIS).

Scope : This systematic review focused on randomized controlled trials evaluating dedicated angle-guiding devices for mediolateral episiotomy, including Episissors-60, Episiguide, and the Episimeter.

Aims : To compare guided episiotomy devices with conventional eyeball technique in achieving appropriate episiotomy angles and reducing OASIS.

Methods : A systematic search of PubMed, ScienceDirect, and Wiley was conducted according to PRISMA 2020 principles. Eligible studies included women undergoing vaginal birth in whom a guided device was compared with conventional scissors or routine practice. The primary outcome was post-suture episiotomy angle. Secondary outcomes were OASIS incidence, incision characteristics, pain, practical limitations, and risk of bias.

Results : Four randomized controlled trials involving 543 participants were included. Guided devices produced higher post-suture episiotomy angles than conventional technique (standardized mean difference 0.88, 95% CI 0.69–1.06; $Z = 9.33$; $P < 0.00001$), although heterogeneity was substantial ($I^2 = 97\%$). Based on the pooled contingency table, OASIS was more frequent in the eyeball group than in guided group (OR 4.85, 95% CI 1.38–17.07; $P = 0.0069$).

Conclusion : Angle-guiding devices may improve episiotomy angle accuracy and may reduce OASIS risk, but the evidence remains limited by few trials, sparse OASIS event, indirect comparisons between devices, and substantial heterogeneity.

Keywords : Episiotomy angle, Guided Episiotomy, Mediolateral Episiotomy, Meta Analysis, Obstetric Anal sphincter injury

INTRODUCTION

Episiotomy is a surgical incision of the perineum performed to enlarge the vaginal opening and facilitate childbirth, particularly during the second stage of labor.¹ It is one of the most commonly performed obstetric procedures worldwide, with an estimated global prevalence of 56.3%.² The rates are significantly higher in some Asian countries, with reports indicating 100% in China and 92.6% in Cambodia.³ In Indonesia, the prevalence of episiotomy is approximately 33%.⁴

Obstetric Anal Sphincter Injuries (OASIS) remain one of the most significant challenges in obstetric practice, despite the widespread use of episiotomy as a preventive measure. These injuries, which can result in long-term complications such as fecal incontinence, sexual dysfunction, and chronic perineal pain, pose a substantial burden on women's health and quality of life. While the rate of OASIS has decreased in many countries due to improved delivery technique and perineal protection, its prevalence remains particularly in low-resource settings.^{5,6} A variety of factors contribute to the risk of OASIS, including maternal age, parity, birth weight, and delivery technique. However, the angle and type of episiotomy incision are crucial determinants in reducing the incidence of these injuries.^{7,8}

While episiotomy may reduce the duration of labour and prevent severe perineal trauma in selected cases, it is not without risks. One of the most significant complications associated with episiotomy is obstetric anal sphincter injuries (OASIS), which can lead to long-term morbidity such as fecal incontinence and chronic pain.⁹⁻¹¹ The risk of OASIS is influenced by several factors, including the type and angle of the episiotomy.¹²

Mediolateral episiotomy is generally preferred over a midline incision because it directs the cut away from the anal sphincter complex.¹² The biomechanical rationale is that the distended perineum at crowning changes the angle between the cutting angle and the final post-suture angle. An incision made too close to the midline may become more medial after repair, increasing the risk of extension into the anal sphincter, whereas an excessively lateral incision may increase bleeding, pain, or inadequate perineal support. Therefore, many authors recommend a cutting angle approximately 30–60 degrees or 40–60 degrees depending on the definition used.¹³⁻¹⁵

To address this issue, several innovations in angle-guiding devices have been developed to assist healthcare providers in performing episiotomies within the recommended safe zone.^{14,16} Among the most widely used devices are Episcissors 60®, Episiguide, and Episimeter. Episcissors 60® features an integrated guide that aligns at a 60° angle, supported by a stiff but movable spring.¹⁴ The Episiguide, made of stainless steel, is placed on the perineum during crowning to guide an accurate incision angle.¹⁶ The Episimeter is a horseshoe-

shaped transparent template made of vellum paper, marked with angular measurements from 0° to 60°. ^{17,15,18}

Previous studies have evaluated these devices separately, but comparative evidence remains limited.^{14,16-18} Existing trials differ in device type, clinical setting, operator experience, episiotomy indication, and outcome reporting. Moreover, the available evidence has rarely been synthesized in a way that clearly separates episiotomy angle accuracy from clinical outcomes such as OASIS. This creates a practical evidence gap. First, it is important to determine if these tools reliably optimize the post-suture angle. Second, evidence must show whether this change translates into fewer OASIS events. Finally, clinicians need to know if any single device outperforms the others.

This systematic review and meta-analysis aimed to evaluate randomized controlled trials comparing dedicated angle-guiding devices with conventional eyeball mediolateral episiotomy. The novelty of this review is its focused synthesis of Episcissors-60, Episiguide, and Episimeter as a group of angle-standardization innovations.

METHODS

This systematic review and meta-analysis was designed and reported in accordance with the PRISMA 2020 statement.¹⁹ The protocol was not prospectively registered before study selection and data extraction. The author has submitted this review to PROSPERO for registration, and the registration number will be included in the manuscript as soon as it becomes available.

Studies were selected according to a PICOS framework. The population included women undergoing vaginal delivery in whom mediolateral episiotomy was performed or indicated. The intervention was any dedicated angle-guiding device for episiotomy, including Episcissors-60, Episiguide, or Episimeter. The comparator was conventional scissors, routine practice or eyeball technique without a dedicated angle guide. Eligible studies were randomized controlled trials reporting at least one prespecified outcome. Non-randomized studies, non-English articles, conference-only reports without full text, duplicate publications, and articles with unavailable full text were excluded.

A systematic article search was conducted in PubMed, ScienceDirect, and Wiley. The core search strategy combined device terms and outcome term: “(((Episimeter) OR (Episiguide)) OR (Episcissors)) AND (episiotomy)) AND (((Obstetric anal sphincter injuries) OR (OASIS)) OR (Perineal Trauma))”. In PubMed, Medical Subject Headings and free-text terms were combined where applicable, including “episiotomy”, “obstetric anal sphincter injuries”, “perineal trauma”, “mediolateral episiotomy”, and the device names. The same Boolean logic was adapted for

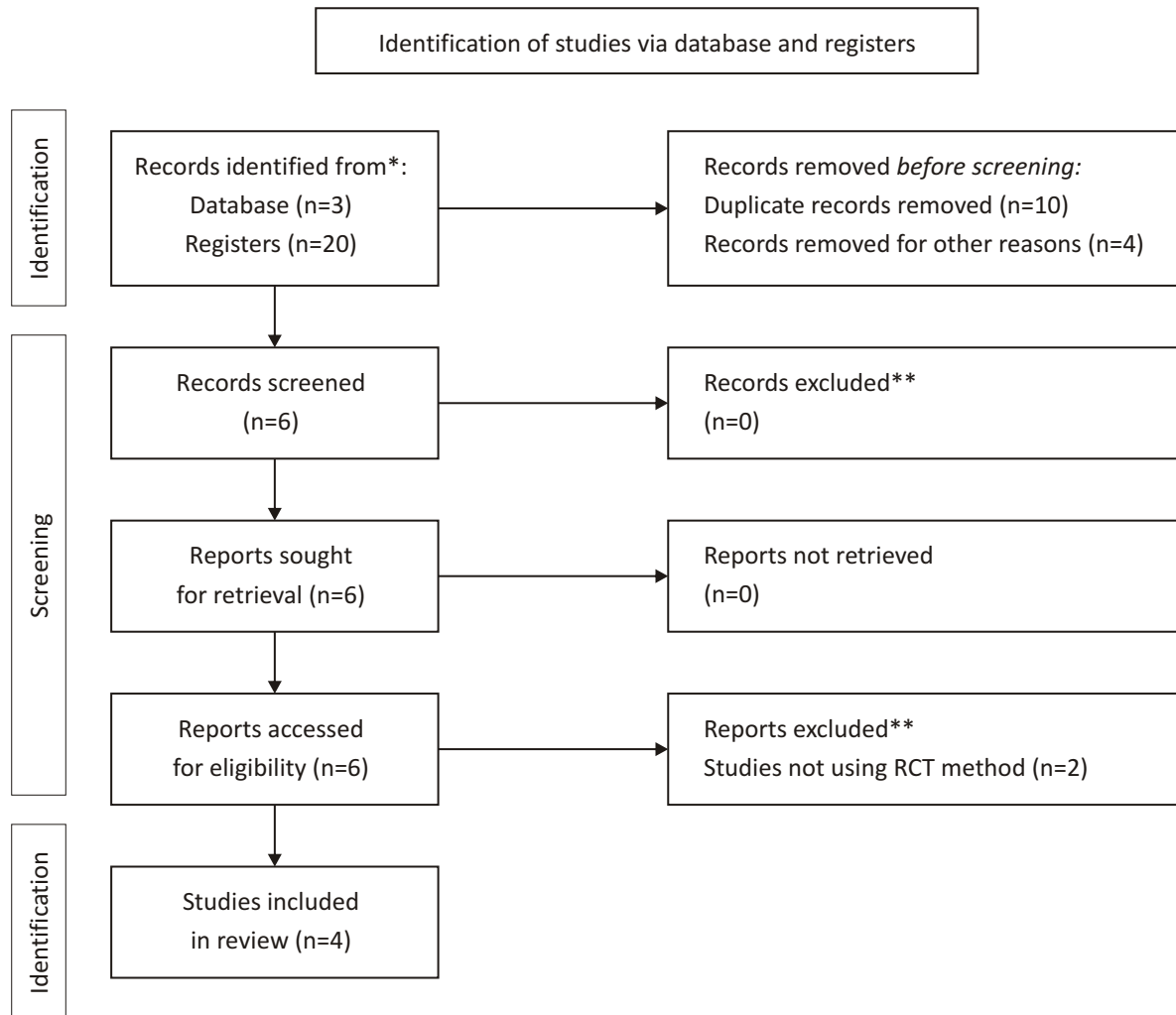


Figure 1. Flowchart of Article search

ScienceDirect and Wiley.

Titles and abstracts were screened independently by three reviewers. Full text of potentially eligible articles were assessed using the inclusion and exclusion criteria. Disagreements were resolved by discussion and, when consensus was not achieved, by consultation with the lead author. Extracted data included author, year, country, study design, sample size, device type, comparator, episiotomy angle, OASIS events, perineal pain, incision-related characteristics, device limitations, and study-level risk of bias.

The primary outcome was post-suture episiotomy angle because it directly reflects whether the incision achieved the desired mediolateral direction after tissue recoil and repair. Secondary outcomes were OASIS incidence, incision length or other incision characteristics, perineal pain, device-related limitations, and risk of bias. Device comparison was considered indirect because no included trial directly randomized participants between two different guided devices.

Risk of bias was assessed using the Cochrane Rob2 domains for randomized trial, bias arising from the randomization process, deviations from intended intervention, missing outcome data, outcome measurement, and selection of the reported result. Each domain was judged as low risk, some concerns, or high risk, and an overall judgment was assigned for each study.

Twenty articles were retrieved from three database. Ten duplicates were removed, and 4 articles were excluded due to not meeting inclusion criteria. A total of 6 titles and abstracts were screened. Among these, 2 were excluded because they were not using RCT. Finally, 4 articles met the inclusion criteria. A flowchart of the article selection process can be seen in [Figure 1](#).

The four included randomized controlled trials were conducted in Iran, India, and Thailand and involved 543 participants. The interventions included Episcissors-60, Episiguide, and Episimeter. The comparators were conventional scissors, routine practice, or non-guided

TABLE 1
Study characteristics in the selected studies

Author, year	Study design	Country	Sample Size (n)	Devices	Key Findings
Hajhashemi M, <i>et al.</i> (2023)	RCT	Iran	64	Episcissors-60	● Episcissors had significantly higher episiotomy angles. No cases of OASIS in the Episcissors group.
Sawant G, <i>et al.</i> (2015)	RCT	India	63	Episcissors-60	● Episcissors produced episiotomies angled 12° more laterally. No OASIS in the Episcissors group and one evenet in control.
Thanapongpibul C, <i>et al.</i> (2022)	RCT	Thailand	88	Episioguide	● Higher post-suture angle compared with conventional scissors.
Sriram SN, <i>et al.</i> (2024)	RCT	India	328	Episiometer	● Higher episiotomy angle and fewer OASIS events than conventional technique; no significant difference in perineal pain.

eyeball mediolateral episiotomy. Table 1 summarizes the study characteristics and key findings.

Across four randomized controlled trials (RCTs) from Iran, India, and Thailand (total n=543) (Table 1), the use of dedicated episiotomy angle-guiding devices was consistently associated with improved episiotomy angle compared with conventional scissors, with several studies also suggesting a reduction in obstetric anal sphincter injuries (OASIS).

Episiotomy incision length was examined in studies such as Hajhashemi *et al.* (2023), the Episcissor device achieved significantly higher episiotomy angles than standard technique, indicating better adherence to a more lateral mediolateral episiotomy trajectory; notably, no OASIS cases were observed in the Episcissors arm and only 2 cases of grade 3 sphincter rupture occurred in the Mayo group. Sawant *et al.* (2015) similarly reported that Episcissors produced episiotomy incisions approximately 12° more lateral than controls, reflecting a clinically meaningful shift toward the recommended angle range; this trial recorded zero OASIS events in the intervention group versus one event in the control group using Braun-Stadler scissor. In Thailand, Thanapongpibul *et al.* (2022) evaluated the Episioguide and found that it yielded significantly higher episiotomy angles relative to conventional scissors, reinforcing the device's role in standardizing incision direction and reducing operator variability. The largest included RCT, Sriram *et al.* (2024), assessed the Episiometer and demonstrated significantly higher episiotomy angles in the device group alongside a significantly lower incidence of OASIS compared with routine practice and

found no significant difference in the perineal pain.

Taken together, findings across diverse settings and device types indicate angle-guiding tools reliably increase episiotomy angle toward more optimal lateral orientation and may translate into clinically important reducing in severe perineal trauma, particularly OASIS, when compared with conventional episiotomy approaches.

Risk of bias assessment is shown in Figure 2. Most studies had low risk for missing outcomes data and outcome measurement because angle and OASIS outcomes were objectively assessed and outcome data were largely complete. Concerns were mainly related to randomization procedures, limited blinding, operator dependence, and incomplete information on whether all outcomes were prespecified. Sawant and Kumar (2015) was judged as high overall risk because of concerns in the randomization process and limited reporting of allocation concealment. Sriram *et al.* (2024) was judged as low overall risk, while the remaining studies had some concerns.

Figure 3 present the meta-analysis of OASIS incidence rate using guided and non-guided tools. Four Studies involving a total of 543 participants (63 in the Episcissor group, 44 in the Episioguide group, 164 in the Episiometer group, and 272 in the control group) were included. The pooled analysis showed that angle-guiding episiotomy tools significantly consistently facilitate episiotomy in higher degree angles (SMD 0.88, 95% CI 0.69-1.06; Z = 9.33 (P<0.00001). However, heterogeneity was substantial (Chi²=87.08, df=3; P<0.00001; I²=97%), indicating that the magnitude of effect differed across

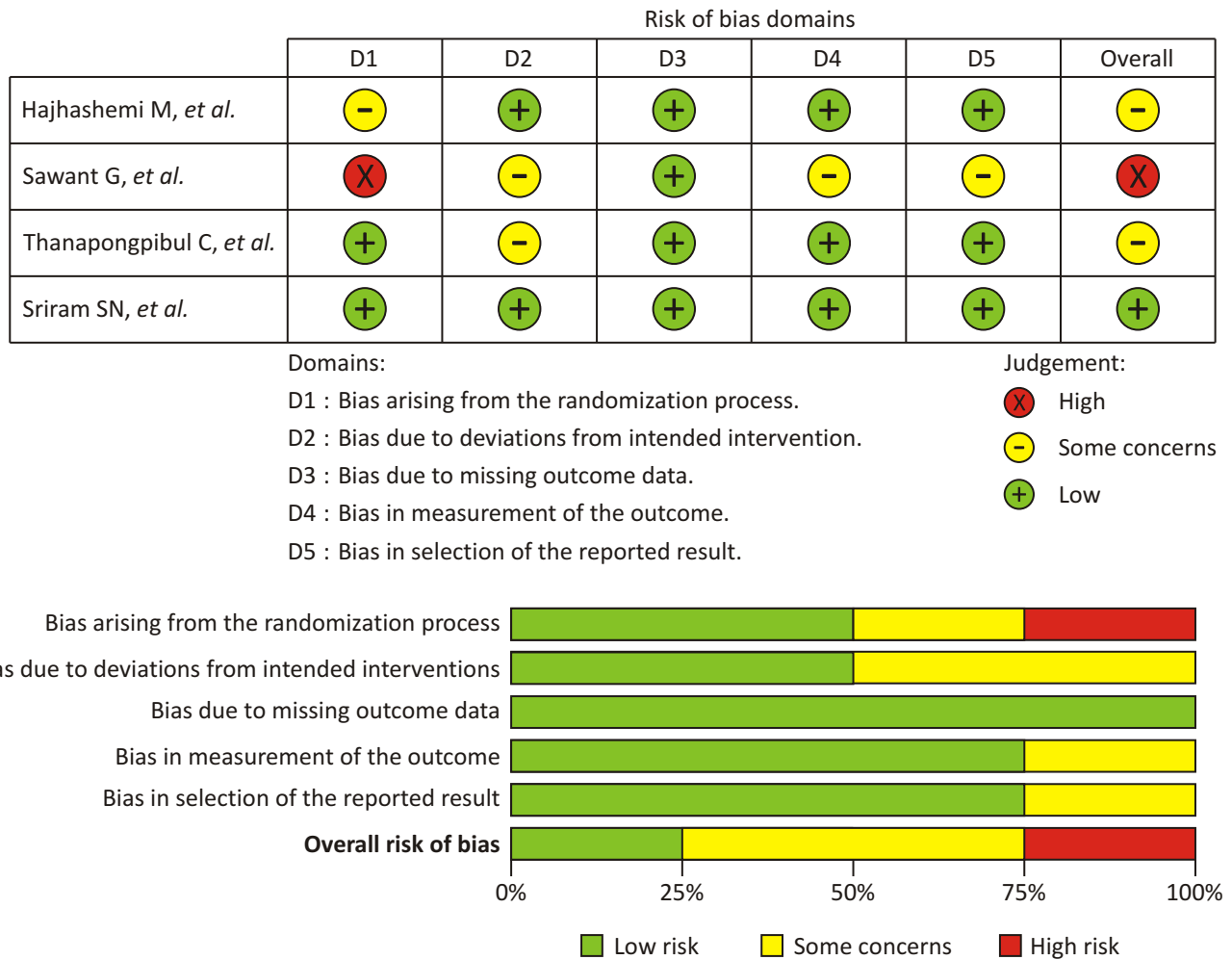


Figure 2. Risk of Bias Assessment generated by the robvis tool

trials. The result should be interpreted as an average direction of benefit rather than a uniform effect that can be generalized to every device and clinical setting.

Across the four trials, OASIS occurred in 3 of 271 participants in the guided group and in 14 of 272 participants in the eyeball group. Based on the pooled contingency table, the odds of OASIS were higher in the eyeball group than in the guided group (OR 4.85, 95% CI 1.38017.07; $\chi^2=7.31$; $P=0.0069$). Because OASIS was a rare outcome and several studies reported zero event in one or both arms, this estimate should be interpreted cautiously. It supports a clinically plausible reduction in OASIS with guided technique, but it does not prove superiority of one guided device over another.

DISCUSSION

This systematic review found that dedicated angle-guiding devices for mediolateral episiotomy were associated with higher post-suture episiotomy angles

than conventional eyeball technique. This finding was consistent across the four included randomized controlled trials and clinically relevant because post-suture angle is closely related to the final direction of the incision relative to the anal sphincter complex.

The biological and technical rationale for these findings is plausible. During crowning, the perineum is stretched and the apparent cutting angle may narrow after delivery and suturing. A clinician attempting to estimate the angle visually may there cut too close to the midline, particularly in urgent deliveries or when operator experience is limited. Devices such as Episcissors-60, Episio-guide, and Episio-meter are designed to externalize the angle reference at the bedside, helping the operator maintain a more lateral trajectory despite perineal distension.^{14,16,20,21}

The pooled contingency table suggested lower OASIS incidence in the guided group. This consistent with previous research, when correctly angled can reduce the risk of anal sphincter extension compared with poorly

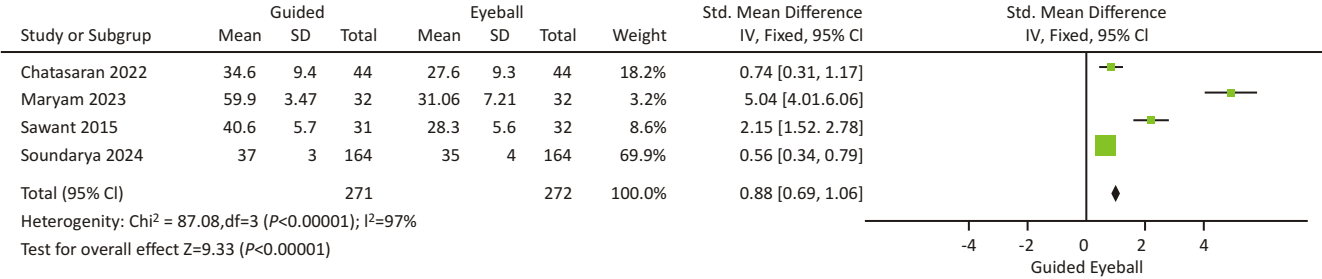


Figure 3. Forest Plot generated by Revman tool

TABLE 2
Pooled OASIS incidence included studies

Variables		Oasis	No Oasis	
Guided		3	268	271
Eyeball		14	258	272
		17	526	543
X	7,305944285			
df	1			
P	0,006872687			
OR	4.85			

angled incisions.^{12,22–24} Nevertheless, OASIS is a rare outcome, and the total number of events in the included trials was small. The confidence interval around the OASIS estimate was wide, meaning that the true magnitude of benefit may be smaller or larger than the point estimate.^{25,26,7}

The high Heterogeneity for the angle outcome is an important limitation. The included trials differed in device type, sample size, population, delivery setting, operator training, episiotomy indication, and outcome measurement. The largest trial evaluated the Episiotometer, while smaller trials evaluated Episcissors-60 and Episiotoguide. Therefore, the pooled estimate should not be interpreted as direct evidence that one device is superior to another. The present review supports the concept of angle guidance as a technique-standardization strategy, but device ranking would require head-to-head randomized trials or a sufficiently powered network meta-analysis.

From an implementation perspective, the devices may have different advantages. Episcissors-60 may be easier for clinicians already familiar with conventional scissors because the angle guide is integrated into the instrument.¹⁷ Episiotometer may be more affordable and easier to disseminate in low-resource setting, although it requires preparation and correct placement.¹⁶

Episiotoguide may standardize the cutting direction but its acceptability, discomfort during placement, and effect on workflow require better prospective measurement. These practical considerations are important for maternity units, primary health facilities, and midwifery-led services where variability in episiotomy technique may be high.²⁷

Several limitations should be acknowledged. First, only four trials were included, limiting statistical power and preventing reliable subgroup analysis or meta-regression. Second, no trial directly compared one guided device with another, therefore, all device comparisons are indirect. Third, OASIS was rare, producing sparse event data and wide confidence intervals. Fourth, heterogeneity for the angle outcome was substantial, suggesting that pooled result may be influenced by differences in device design, operator experience, population characteristics, and measurement methods. Another limitation is that the review protocol was not prospectively registered before the conduct of the review. Although the methods were structured according to PRISMA 2020, the absence of prospective registration may reduce transparency and should be considered when interpreting the findings.

CONCLUSION

Angle-guiding devices for mediolateral episiotomy may improve post-suture angle accuracy compared with conventional eyeball technique and may reduce OASIS incidence. However, the current evidence is based on only four randomized controlled trials, sparse OASIS event, indirect comparison between devices, and substantial heterogeneity for angle outcome. These devices should therefore be viewed as promising technical aids rather than definitive replacement for training, clinical judgment, and comprehensive perineal protection strategies. Future multicentre randomized trials should prespecify primary and secondary outcomes, use standardized angle and OASIS definitions, report patient discomfort and cost-effectiveness, and directly compare available devices in different clinical

REGISTRATION AND PROTOCOL

This systematic review was registered in PROSPERO under registration number CRD420261402158.

CONFLICT OF INTEREST

The authors declared no conflicts of interest. No funding was received for this study.

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