

Episcissors-60 for guided mediolateral episiotomy

Medtech innovation briefing

Published: 21 July 2015

[nice.org.uk/guidance/mib33](https://www.nice.org.uk/guidance/mib33)

Summary

The Episcissors-60 are surgical scissors used for episiotomy, and are designed to achieve a mediolateral cut at 60 degrees to the perineal midline to minimise the risk of obstetric anal sphincter injuries. One comparative study and 2 non-comparative studies comprising a total of 105 women reported that the Episcissors-60 successfully cut at the intended 60-degree angle and produced a post-delivery suture angle of 30–60 degrees. One study reported high user satisfaction among obstetrics trainees using the device. Each reusable Episcissors-60 costs £400 excluding VAT.

Likely place in practice	Effectiveness and safety
<ul style="list-style-type: none"> • The Episcissors-60 are designed to guide an accurate mediolateral episiotomy at 60 degrees to the perineal midline. They provide an alternative to standard episiotomy scissors, for which the cutting angle must be estimated. • They would be used in secondary care midwifery and obstetric units, primary care midwifery units or birth centres and during home births. Both straight and angled versions are available. 	<ul style="list-style-type: none"> • The evidence base for Episcissors is currently limited to 1 small comparative study and 2 non-comparative case series. All studies had methodological limitations. • One study (n=63) compared the angled version of Episcissors-60 with the Braun-Stadler scissors and demonstrated a clear difference of 12 degrees in post-delivery suture angles achieved. One case of obstetric anal sphincter injury was reported in the Braun-Stadler group and none was reported in the Episcissors-60 group. • One study (n=25) investigated the use of the angled version of Episcissors-60 and reported an average post-delivery suture angle of 50 degrees. No cases of obstetric anal sphincter injuries were reported. • One study (n=17) investigated a prototype of the straight version of Episcissors-60 and reported a mean post-delivery suture angle of 42.4 degrees. One patient who had a sequential ventouse-forceps delivery experienced a grade 3a obstetric anal sphincter injury.

Technical factors	Cost and resource use
<ul style="list-style-type: none"> • The Episcissors-60 are intended for use by qualified midwives and obstetricians trained in mediolateral episiotomy. • Two types of Episcissors-60 are available: a straight version and an angled version. • Episcissors are designed for right-handed use only. • One study reported that 88% of the obstetric trainees agreed or strongly agreed that the Episcissors-60 were easy to use. However, 1 left-handed user had difficulty using the device. 	<ul style="list-style-type: none"> • The list price of Episcissors-60 is £400 excluding VAT. The device is reusable after standard decontamination processes. • No published evidence was identified on the costs of adopting the technology or resource consequences.

Introduction

An episiotomy is a procedure performed during labour, in which a woman's vaginal wall and perineum (the area between the vagina and anus) are cut in order to allow the baby to pass through the vagina more easily. In 2011 to 2012, 15.2% (101,678) of all births in England needed an episiotomy (HESonline).

An episiotomy is done under local anaesthetic using standard episiotomy scissors. Episiotomies can be done medially (straight down the midline from the vagina to the anus), mediolaterally (between the midline and the lateral line) or laterally (perpendicular to the midline) using straight scissors, or can be 'J-shaped' using curved scissors (curving away from the anus). Most episiotomies are done mediolaterally towards the woman's right hand side, from the posterior vaginal fourchette (a fork-shaped fold of skin at the bottom of the entrance to the vagina; Kalis et al. 2012).

NICE's guideline on [intrapartum care](#) recommends that an episiotomy should only be done if there is a clinical need, such as when instruments are used during birth or where there is suspected foetal compromise. Routine episiotomy is not recommended in the following circumstances:

- during spontaneous vaginal birth
- after third-degree trauma from previous childbirth (injury to perineum involving the anal sphincter complex)
- after fourth-degree trauma from previous childbirth (injury to perineum involving the anal sphincter complex and anal epithelium).

Both NICE's guideline on [intrapartum care](#) and the Royal College of Obstetricians and Gynaecologists (RCOG) guideline on the [management of perineal tears](#) recommend that if episiotomy is indicated, a mediolateral episiotomy should be done. This should originate at the vaginal fourchette and usually be directed towards the right side. The RCOG guideline specifically recommends that the angle of the episiotomy cut should be at 60 degrees to the midline (where an angle of 0 degrees would point directly from the vagina to the anus), cutting diagonally from the vagina towards the woman's right side and the back of her body. It is also recommended that pain relief (such as local anaesthetic) should be provided before an episiotomy, except in an emergency involving acute foetal compromise. The RCOG guideline identifies the Episcissors-60 as a specific tool for cutting the episiotomy at a 60 degree angle.

Studies have demonstrated that, where clinically indicated, mediolateral episiotomy can protect against obstetric anal sphincter injuries (OASIs). However, the cutting angle is important. If the cutting angle is less than 45 degrees to the perineal midline, there is a higher risk of OASIs (Kalis 2008). Cutting angles greater than 60 degrees to the perineal midline have been shown to be ineffective, because they do not relieve the pressure on the perineum (Stedenfeldt et al. 2012).

OASIs can occur during vaginal delivery when a severe perineal tear causes the anal sphincter to rupture. OASIs are the most common cause of faecal incontinence in otherwise healthy women. They occur in 2.9% of births in the UK overall, in 6.1% of first-time births and 1.7% of births to women who have given birth 2 or more times before (Thiagamoorthy et al. 2014).

A meta-analysis found that 30% of women who had an OASI still had symptoms 1 year after childbirth (Oberwalder 2003). Symptoms can include faecal urgency, inability to control wind and uncontrolled bowel movements (Dudding et al. 2008).

OASIs are usually repaired within 24 hours of delivery under general or regional anaesthesia in an operating theatre. The use of broad-spectrum antibiotics is recommended following OASI repair, to lower the incidence of post-operative infections and wound opening. According to the RCOG guidelines, women with OASI symptoms should be referred to a specialist centre or a colorectal surgeon. Management strategies for faecal incontinence range from incontinence pads to sacral

nerve stimulation and can also include provision of psychological and emotional support. The NICE costing report produced for its guideline on [faecal incontinence](#) estimates the initial cost of OASI repair to be £1289 per person, excluding imaging and outpatient follow-up.

Episiotomies done at a 60-degree angle to the perineal midline at the time of crowning have been shown to be associated with a lower rate of OASIs compared with episiotomies done at an angle of 40 degrees (Kalis et al. 2011). Due to distension of the perineum during childbirth, the angle of the episiotomy at the time it is cut is different to the angle as viewed after birth. The cutting angle becomes more acute (that is, closer to the anus) after birth, and the closer the episiotomy is to the anal sphincter after delivery, the higher the potential risk of anal sphincter damage. A study by Kalis et al. (2008) showed that a cutting angle which appeared to be at 40 degrees to the perineal midline before delivery may in fact equate to a post-delivery suture angle of 22 degrees. Therefore, in order to ensure that a truly mediolateral post-delivery angle of 45 degrees is achieved, it is necessary to cut a 60-degree episiotomy (Kalis et al. 2011).

About the technology

CE marking

The Episcissors-60 are a Class I medical device made by 2 separate manufacturers:

- Lawton Medizintechnik, which first CE-marked the device in February 2014 with current declaration of conformity valid until August 2017.
- Jaho Medizintechnik, which first CE-marked the device in June 2014 with current declaration of conformity valid until December 2015.

Medinvent supplies the Episcissors-60 in the UK.

Description

The Episcissors-60 are adapted surgical scissors made from stainless steel with 5-centimetre long tungsten carbide cutting blades. The device has a guide-limb angled at 60 degrees to the blades, mounted on the blade pivot point. During use, the guide-limb is positioned by the clinician to be vertically in line with the perineal midline and pointing towards the anus to ensure an episiotomy cutting angle of 60 degrees. The guide limb is flexible to accommodate the baby's head at crowning and maintain the cutting guide position. Two versions of the device are available, based on operator preference:

- A straight version with blades in line with the handles, designed to give an incision point directly at the posterior vaginal fourchette.
- An angled version with blades at 150 degrees to the handles, designed to give an incision point horizontally offset by approximately 1 centimetre from the posterior vaginal fourchette.

Both versions of the Episcissors-60 are designed for right-handed use; there is no left-handed version available. The device needs cleaning before first use and any reuse, following standard device reprocessing procedures. The device can form part of a reusable equipment birthing pack. There are no accessory tools or materials associated with the Episcissors-60.

Intended use

The Episcissors-60 are designed to guide an accurate mediolateral episiotomy at 60 degrees to the perineal midline.

Setting and intended user

The Episcissors-60 are intended to be used in secondary care midwifery and obstetric units, primary care midwifery units or birth centres, and during home births. The device would be used by midwives or obstetricians trained in the mediolateral episiotomy technique.

Current NHS options

Currently, episiotomies are done using straight or curved episiotomy scissors without any guide for the cutting angle, which therefore must be visually estimated. Left-handed versions of standard episiotomy scissors are also available.

The midwife or obstetrician performing the episiotomy typically judges the mediolateral angle to the midline by eye. Variations in practice between obstetricians and midwives mean that some mediolateral episiotomies are closer to the midline, increasing the risk of obstetric anal sphincter injuries (Tincello et al. 2004). One UK-based study demonstrated that only 15% of doctors and midwives cut an episiotomy of 58–62 degrees when prompted to specifically cut at 60 degrees (Naidu et al. 2015).

NICE is not aware of other CE-marked devices that provide a similar guided function to the Episcissors-60.

Costs and use of the technology

The list price of the Episcissors-60 is £400 per device, excluding VAT. Current practice is to use normal reusable episiotomy scissors (such as Mayo or Braun-Stadler types) which range in cost from £10 to £100 each.

The Episcissors-60 would not need any special maintenance, servicing or training measures and would require the same reprocessing as normal episiotomy scissors. The lifespan of Episcissors-60 is expected to be the same as that of standard episiotomy scissors. This would be determined by the level of use, and would be limited by repeated hospital cleaning and sterilisation processes.

Likely place in practice

The Episcissors-60 would be used as an alternative to standard episiotomy scissors when an episiotomy is indicated, but would otherwise not affect the usual clinical management pathway or service provision.

Specialist commentator comments

One specialist commentator indicated that the angled version of the Episcissors-60 would be used to ensure the episiotomy incision begins 1 cm away from the fourchette. They highlighted published evidence which showed that episiotomies with an incision point further than 9 mm from the midline are associated with fewer OASIs. Another commentator stated that both versions were user-friendly and that operator choice determined which was used.

One specialist commentator noted that the incidence of OASIs in women giving birth for the first time in their hospital labour ward had been reduced after standard episiotomy scissors were replaced with Episcissors-60. This was despite an increase in the overall rate of episiotomies. They highlighted higher levels of confidence among midwives performing episiotomies following the introduction of the Episcissors-60 and stated that any repair was easier after using the Episcissors-60 compared with standard episiotomy scissors.

One specialist commentator highlighted that the Episcissors-60 can only be used by right-handed practitioners, whereas standard episiotomy scissors can be used by left- or right-handed people, and can be used to perform a left-sided episiotomy. They were concerned that if the Episcissors-60 were not suitable for all practitioners, there may be inequality in access and NHS trusts would be less likely to buy them. They also noted that if different instruments were used for episiotomy then this could make the auditing of perineal trauma more difficult.

One specialist commentator stated that the potential use and benefits of using the Episcissors-60 are clear, but the evidence base is limited. The large increase in cost would need to be justified in terms of reducing OASIs and a large comparative study with health economics included is needed to demonstrate this. Another specialist commentator noted that the Episcissors-60's high cost may deter NHS trusts, but that the long-term investment may lead to fewer OASIs and litigation costs.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance (these are protected characteristics under the Equality Act 2010).

The Episcissors-60 are intended for use in pregnant women during labour. Sex and pregnancy are protected characteristics under the Equality Act (2010).

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Three relevant studies were selected for review. One study by Sawant and Kumar (2015) compared the post-delivery suture angle achieved using the Episcissors-60 with that achieved using Braun-Stadler scissors. A further 2 case series (Patel and Ubale 2014, Freeman et al. 2014) investigated the use of Episcissors-60 and the post-delivery suture angle.

The comparative trial was done in a single labour ward in a hospital in India. It compared the post-delivery suture angles achieved with the Braun-Stadler episiotomy scissors and the angled Episcissors-60. Two groups of clinicians worked in alternate 24-hour cycles, with 1 group using the Episcissors-60 and the other using Braun-Stadler scissors. The study included 63 women giving birth for the first time. The episiotomies were given for clinical indications such as prolonged second stage of labour, foetal distress and instrumental delivery. Episiotomies were done by doctors and post-delivery suture angles were measured at an unspecified time after birth. Length of cut and distance from the caudal (lower) end of the cut to the anus were also measured. The average post-delivery suture angle achieved with the Episcissors-60 was 40.2 degrees, compared to an average post-delivery suture angle of 28.3 degrees with the Braun-Stadler scissors. The distance from the caudal end of the cut to the anus was 15 mm greater with the Episcissors-60 than with the Braun-Stadler scissors. Episiotomies done with the Episcissors-60 were also 7 mm longer than those done with the Braun-Stadler scissors. The authors concluded that, compared with Braun-Stadler scissors, the Episcissors-60 cut episiotomies that were angled further away from the midline and were further from the anus, and therefore had a lower risk of OASIs. A summary of the study is reported in table 1.

Table 1 Summary of the Sawant and Kumar (2015) comparative trial

Study component	Description
Objectives/hypotheses	To compare episiotomy suture angles with Braun-Stadler episiotomy scissors with the fixed angled Episcissors-60.
Study design	Comparative trial
Setting	Labour ward in a hospital in India
Inclusion/exclusion criteria	Inclusion criteria: women with indications for episiotomies, such as prolonged second stage of labour, instrumental vaginal delivery, foetal distress
Primary outcomes	Post-delivery suture angle Post-delivery distance from midline Length of episiotomy Cases of OASIs
Statistical methods	Two-tailed t-tests were used to compare the independent groups.

Participants	n=63 (Episcissors-60 group n=31, Braun-Stadler group n=32)
Results	<p>Post-delivery suture angle</p> <p>Episcissors-60: 40.6 degrees, 95% CI \pm 2, IQR 35–45</p> <p>Braun-Stadler: 28.3 degrees, 95% CI \pm 2, IQR 25–30</p> <p>P<0.0001</p> <p>Post-delivery distance from midline</p> <p>Episcissors-60: 35 mm, 95% CI \pm 2.2, IQR 30–39</p> <p>Braun-Stadler: 19.5 mm, 95% CI \pm 1.3, IQR 14.75–22.25</p> <p>P<0.0001</p> <p>Length of episiotomy</p> <p>Episcissors-60: 47 mm</p> <p>Braun-Stadler: 40 mm</p> <p>P<0.0001</p> <p>Cases of OASIs</p> <p>Episcissors-60: 0</p> <p>Braun-Stadler: 1</p>
Conclusions	The sutured episiotomies achieved with the Episcissors-60 were angled further away from the midline and ended further from the anus and would therefore lower the risk of OASIs.
Abbreviations: CI, confidence interval; IQR, interquartile range; mm, millimetres; n, number of patients; OASIs, obstetric anal sphincter injury.	

The study by Patel and Ubale (2014) was done in 2 private maternity hospitals in India and included 25 women for whom episiotomy was clinically indicated (by foetal distress, prolonged second stage of labour or maternal exhaustion). Women who were indicated for instrumental delivery were excluded from the study. Episiotomies were done by 2 experienced obstetricians using the angled version of Episcissors-60. Twenty four women had cephalic deliveries (head first) and 1 woman had a vaginal breech delivery (buttocks or feet first). Before suturing, per rectal examinations were done to detect any OASIs. The median post-delivery suture angle was measured as 50 degrees and no OASIs were detected. A summary of the case series is reported in table 2.

Table 2 Summary of the Patel and Ubale (2014) case series

Study component	Description
Objectives/ hypotheses	To test the efficacy of the Episcissors-60 in spontaneous vaginal deliveries
Study design	Case series
Setting	Two private maternity hospitals in Thane, India
Inclusion/ exclusion criteria	Inclusion criteria: women with clinical indications for episiotomy, including foetal distress, prolonged second stage of labour and maternal exhaustion Exclusion criteria: women requiring an instrumental delivery
Primary outcomes	Post-delivery suture angle Cases of obstetric anal sphincter injury
Statistical methods	None reported
Participants	n=25 women (16 women were nulliparous, 8 women were para 1 and 1 woman was para 2)
Results	One woman had a breech delivery, and the remaining 24 women had cephalic deliveries Post-delivery suture angle Median post-delivery suture angle of the episiotomy: 50 degrees (SD 3.5 degrees, IQR 48–54 degrees, range 45–55 degrees) Cases of obstetric anal sphincter injury No cases were detected in this series.
Conclusions	The authors concluded that the angled-version Episcissors-60 demonstrated a post-delivery suture angle of 50 degrees in a cohort of Indian women having spontaneous vaginal deliveries.
Abbreviations: CI, confidence interval; n, number of patients; SD, standard deviation; IQR, interquartile range.	

A UK-based study by Freeman et al. (2014) tested a prototype of the straight-version of Episcissors-60. The prototype was used by experienced obstetric specialty registrars, firstly on models of vaginas and then on 17 women having instrumental vaginal delivery in a delivery suite. The subjects were asked to record the sutured angle of the episiotomy. The traced episiotomy angles were given to an investigator who was blinded to all patient details, and who then measured the angle of the episiotomy. The obstetric trainees were also asked to complete a short ease-of-use assessment for the instrument.

The median post-delivery suture angle was 43 degrees (95% confidence interval 38.8 to 46.0). One patient had a grade 3a OASI with a post-delivery suture angle of 30 degrees. The authors highlighted that this patient had a failed ventouse (vacuum) delivery which was converted to a forceps delivery. The results of the ease-of-use assessment revealed that 88% of the obstetric trainees agreed or strongly agreed that the Episcissors-60 were easy to use. However, 1 trainee strongly disagreed because they were left-handed and unable to orientate themselves to properly align the instrument. The results of this study were used to guide design iterations of the device, such as making the guide-limb flexible to accommodate the baby's head at crowning and increasing the length of the blades.

The authors concluded that the Episcissors-60 consistently delivered a post-delivery suture angle of 43 degrees, offering an alternative to estimating episiotomy angles by eye and a potential preventative strategy to reduce obstetric anal sphincter injuries. A summary of the case series is reported in table 3.

Table 3 Summary of the Freeman et al. (2014) case series

Study component	Description
Objectives/hypotheses	To establish whether an episiotomy performed at an angle of 60 degrees using an Episcissors-60 prototype could produce a post-delivery suture angle of 45 degrees
Study design	Case series
Setting	The study was performed in the delivery suite of a hospital. The evaluation ran from October 2011 to February 2012. The prototype was initially tested on models of vaginas and then in women giving birth.

Inclusion/exclusion criteria	Inclusion criteria: women having an instrumental vaginal delivery (ventouse or forceps).
Primary outcomes	Post-delivery suture angle Ease of use of the instrument
Statistical methods	None reported
Participants	n=17 women having instrumental deliveries (14 ventouse, 2 low forceps, 1 sequential ventouse-forceps)
Results	<p>Post-delivery suture angle</p> <p>Mean post-delivery suture angle: 42.4±7 (30–60) degrees</p> <p>Median post-delivery suture angle: 43 degrees (95% CI 38.8 to 46)</p> <p>Ease of use of the instrument</p> <p>Trainees rated the ease of use of the instrument on a 5 point scale:</p> <ul style="list-style-type: none"> • 'Strongly agree': 10 cases • 'Tend to agree': 5 cases • 'Neither agree or disagree': 1 case • 'Tend to disagree': 0 cases • 'Strongly disagree': 1 case <p>The 'strongly disagree' case was due to the trainee being left-handed and unable to orientate herself in order to align the Episcissors-60. The comments relating to 'tend to agree' were regarding the length of the cut, where trainees did not feel it was of a sufficient length.</p> <p>One patient suffered a grade 3a obstetric anal sphincter injury (episiotomy scar angle of 30 degrees).</p>
Conclusions	The Episcissors-60 consistently delivered a post-delivery suture angle of 43 degrees, offering an alternative to estimating episiotomy angles by eye and a potential preventative strategy to reduce obstetric anal sphincter injuries.
Abbreviations: CI, confidence interval; n, number of patients.	

Recent and ongoing studies

Medinvent, the UK supplier, identified several case series being presented as conference abstracts during 2015 but no information is publicly available.

No other ongoing or in-development trials on the Episcissors-60 for guided mediolateral episiotomy were identified from searches of clinical trial registers.

Costs and resource consequences

In 2011–12, 15.2% of all births in England (101,678) needed an episiotomy (HESonline 2012). Current practice is to use normal episiotomy scissors (such as Mayo or Braun-Stadler types) which range in cost from £10 to £100 each. The Episcissors-60 would replace standard episiotomy scissors; at a cost of £400, they would therefore represent an initial additional cost to the NHS. This cost could potentially be offset by fewer OASIs and the resulting savings. The NICE costing report produced for its guideline on [faecal incontinence](#) estimates the initial cost of OASI repair as £1289 per person, excluding imaging and outpatient follow-up.

No published evidence on the total resource consequences of the Episcissors-60 was identified.

Strengths and limitations of the evidence

The evidence base for the Episcissors-60 is currently limited to 1 small comparative study and 2 non-comparative case series.

The comparative study by Sawant and Kumar (2015) showed that compared with Braun-Stadler scissors, the Episcissors-60 produced a post-delivery suture angle that was further from the perineal midline by almost 12 degrees. However, the study was not sufficiently powered to detect differences in OASIs so any beneficial changes in this outcome were inferred rather than measured. The authors claimed that the study was 'similar to a prospective cluster randomised trial'; but because only 2 groups of clinicians took part in the trial, with 1 group using the Episcissors-60 and the other using the Braun-Stadler comparator, there was no randomisation. The title of the paper is therefore rather misleading, given this study design. The clinician who did the episiotomy also measured the post-delivery suture angle, which creates potential assessment bias. However, the inclusion criteria were consistent with UK national guidelines for episiotomy and may be generalisable to current UK practice.

Neither of the case series (Patel and Ubale 2014, Freeman et al. 2014) compared the use of Episcissors-60 with standard practice and so could not report on changes in episiotomy angles. As both studies were relatively small, important clinical outcomes such as the rate of OASIs could not be accurately measured.

The case series by Patel and Ubale (2014) was done in India and included women clinically indicated for episiotomies. However, it excluded women having instrumental delivery, which limits the generalisability of the study to current NHS practice. The clinician who did the episiotomy also measured the post-delivery suture angle, which creates potential assessment bias.

The main limitation of the evaluation by Freeman et al. (2014) is that the obstetric trainees were using a prototype of the Episcissors-60 (this prototype formed the basis of the current straight Mayo version of the Episcissors-60). The study took place in an English hospital and so indications for episiotomy were consistent with UK national guidelines. The investigator was blinded to the patient and trainee operator, which lowers the risk of assessment bias. The authors reported a single case of a grade 3a OASI related to a 30-degree post-delivery suture angle following a failed ventouse delivery which was converted to a forceps delivery. However, it was not stated if this injury was attributable to the use of the Episcissors-60 or could otherwise have been prevented. The study does not report how OASIs were detected, or the number of obstetric trainees who did the episiotomies and were included in the ease of use assessment.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- [Intrapartum care: care of healthy women and their babies during childbirth \(2014\) NICE guideline CG190](#)
- [Intrapartum care \(last updated 2014\) NICE pathway](#)
- [Antenatal care \(last updated 2014\) NICE pathway](#)
- [Faecal incontinence: The management of faecal incontinence in adults \(2007\) NICE guideline CG49](#)

References

Abbott D, Atere-Roberts N, Williams A et al. (2010) [Clinical Review: Obstetric anal sphincter injury](#). British Medical Journal 341: c3414

De Leeuw JW, Struijk PC, Vierhout ME et al. (2001) Risk factors for third degree perineal ruptures during delivery. British Journal of Obstetrics and Gynaecology 108: 383–7

Dudding TC, Vaizey CJ, Kamm MA (2008) Obstetric anal sphincter injury: Incidence, Risk Factors, and Management. Annals of Surgery; 247: 224–37

HESonline (2012) NHS Maternity Statistics – England, 2011–2012. Published December 06, 2012 [Online accessed 12 March 2015]

Kalis V, Karbanova J, Horak M et al. (2008) The incision angle of mediolateral episiotomy before and after repair. International Journal of Gynaecology and Obstetrics 103: 5–8

Kalis V, Landsmanova J, Bednarova B et al. (2011) Evaluation of the incision angle of mediolateral episiotomy at 60 degrees. International Journal of Gynaecology and Obstetrics 112: 220–4

Kalis V, Laine K, de Leeuw JW et al. (2012) Classification of episiotomy: towards a standardisation of terminology. British Journal of Obstetrics and Gynaecology 119: 52–26

Naidu M, Kapoor DS, Evans S et al. (2015) Cutting an episiotomy at 60 degrees: how good are we? International Urogynecology Journal 26: 813–6

NHS Supply Chain: Episiotomy scissors. Catalogue last refreshed 12/03/15 [Online accessed 12 March 2015]

NICE guideline CG190 (2014) Intrapartum care: care of healthy women and their babies during childbirth. Published December 2014 [Online accessed 10 March 2015]

NICE (2007) Faecal incontinence: costing report. Published September 2007 [Online accessed 21 April 2015]

Oberwalder M, Connor J, Wexner SD (2003) Meta-analysis to determine the incidence of obstetric anal sphincter damage. British Journal of Surgery 90: 1333–7

Royal College of Obstetricians and Gynaecologists (2015) Peer Review Draft: The management of third- and fourth-degree perineal tears (Green-top Guideline No.29). Published June 2015 [Online accessed 12 June 2015]

Sawant G, Kumar D (2015) Randomized trial comparing episiotomies with Braun-Stadler episiotomy scissors and EPISCISSORS-60. *Medical Devices: Evidence and Research* 8: 251–4

Stedenfeldt M, Pirhonen J, Blix E et al. (2012) Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. *British Journal of Obstetrics and Gynaecology* 119: 724–30

Thiagamorthy G, Johnson A, Thakar R et al. (2014) National survey of perineal trauma and its subsequent management in the United Kingdom. *International Urogynecology Journal* 25: 1621–7

Tincello DG, Williams A, Fowler GE et al. (2003) Differences in episiotomy technique between midwives and doctors. *BJOG: an International Journal of Obstetrics and Gynaecology*; 110: 1041–4

Search strategy and evidence selection

Search strategy

The search strategy was designed to identify evidence on the use of Episcissors-60 in women undergoing episiotomy.

The strategy was developed for MEDLINE (Ovid interface). The strategy was devised using a combination of subject indexing terms and free text search terms in the title, abstract and keyword heading word fields. The search terms were identified through discussion within the research team, scanning background literature, and browsing database thesauri. The strategy reflected the nature of the MIB assessments as rapid evidence reviews.

The search comprised two concepts:

- Episcissors-60 or any scissors used in episiotomy.
- Similar instruments used in episiotomy, sought through searching for literature on episiotomy technique characteristics (such as angle of incision).

The search concepts were combined as follows: scissors OR techniques.

Additional search lines focusing on other possible product names combined with episiotomy terms, and 'Medinvent', the UK supplier, were also used. These lines were designed to capture any records that may have been missed by the rest of the search.

The strategy excluded non-English language publications. Animal studies were also excluded using a standard algorithm. No additional filters for study design were applied. Results were limited to studies published from 2000 due to the novelty of the instrument.

The final MEDLINE strategy was peer-reviewed by an independent information specialist. The MEDLINE strategy was translated appropriately for the other databases searched. The PubMed search was limited to records which were not fully indexed on MEDLINE.

The following databases were searched:

- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley);
- Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley);
- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley);
- Health Technology Assessment Database (Cochrane Library, Wiley);
- NHS Economic Evaluation Database (Cochrane Library, Wiley);
- Embase (Ovid SP)
- MEDLINE and MEDLINE in Process (Ovid SP);
- PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>)
- Conference Proceedings Citation Index- Science (CPCI-S) (Web of Science)

The search strategies used for each of the databases are presented below (A1 to A6).

Specific conferences

Conference abstracts were sought online for:

- Royal College of Obstetricians and Gynaecologists (RCOG) meetings from 2013 to date.

Searches were made of the Abstracts of the RCOG World Congress 2014, 28–30 March 2014, Hyderabad, India. No results were found for *episcissor** or *epima** or *episa**. Searches of BJOG which holds some of the meetings of RCOG were also made. No results were found.

- British Society of Urogynaecology (BSUG) meetings from 2013 to date.

No results were found for *episcissor** or *epima** or *episa** in International Urogynaecology Journal which publishes abstracts from BSUG research meetings (the 2014 abstracts are as yet unpublished).

Evidence selection

A total of 643 records were retrieved from the literature search. After de-duplication, 413 records remained and were sifted against the inclusion criteria at title and abstract level.

Records were sifted independently by 2 researchers. Any disagreements were discussed and agreement was reached in all cases, so a third independent arbiter was not required. The first sift removed 411 records based on the following exclusion criteria:

- articles of poor relevance against search terms
- publication types that were out of scope
- non-English language studies
- conference abstracts
- review articles.

The search strategy was designed to identify evidence for the use of Episcissors-60 in women undergoing episiotomy. This search found the number of database records which explicitly included the brand name or reference to scissors was very low. Therefore a selective search of episiotomy techniques was also performed.

Full articles were retrieved for the 2 remaining studies and a full text assessment was done independently by 2 researchers to identify relevant primary research addressing the key outcomes of interest. Both studies explicitly investigated Episcissors-60 and were included for full review.

One additional article was highlighted by the UK supplier following recent publication and was therefore also included in this MIB.

A further 16 articles were selected and retrieved to guide the background and technical aspects of this briefing.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and are **not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Newcastle and York External Assessment Centre. The [interim process & methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

Project team

Newcastle and York Assessment Centre

Medical Technologies Evaluation Programme, NICE

Peer reviewers and contributors

- Roseanne Jones, Research Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust.
- Derek Bousfield, Senior Clinical Technologist, Newcastle upon Tyne Hospitals NHS Foundation Trust.
- Christine Kimpton, Clinical Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Thomas Veale, Information Specialist, York Health Economics Consortium
- Mick Arber, Information Specialist, York Health Economics Consortium
- Iain Willits, Medical Technologies Evaluator, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Helen Cole, Head of Service – Clinical Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust.

Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Tracey Cooper, Consultant Midwife, Lancashire Teaching Hospitals NHS Foundation Trust
- Kylie Watson, Midwife Ward Manager, Central Delivery Unit, St. Mary's Hospital, Manchester
- Dr Bini Ajay, Clinical Lead for Labour Ward, Croydon University Hospital
- Dr Latha Vinayakarao, Clinical Lead for Labour Ward, Poole Hospital NHS Trust

Copyright

© National Institute for Health and Care Excellence, 2015. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-1293-3