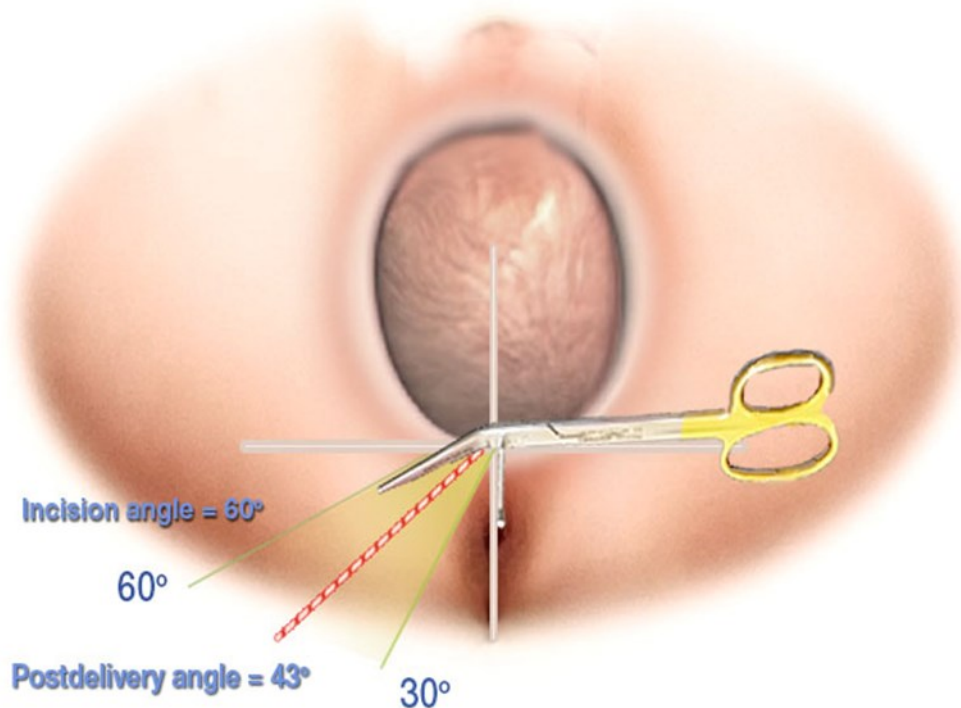


## EPISCISSORS-60™

The first scissors ever designed to give an accurate mediolateral episiotomy



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***Fulfilling a RCOG recommendation to cut the episiotomy at 60 degrees to the midline at crowning***

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## THE SCIENTIFIC RATIONALE

*Research studies show that an episiotomy with a post-delivery suture angle of  $<30^{\circ}$  or  $>60^{\circ}$  is significantly more likely to cause Obstetric Anal Sphincter Injury (OASIS). A post-delivery angle of  $>40^{\circ}$  is in the safe zone and can only be achieved by an incision angle of  $60^{\circ}$ . Studies also show clinicians are unable to correctly estimate the angle due to perineal distension at crowning.*

*Indeed, the Royal College of Obstetricians and Gynaecologists (RCOG) recommend that **“Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to ensure that the angle is 60 degrees away from the midline when the perineum is distended”***

*EPISCISSORS-60<sup>®</sup> achieved a post-delivery angle of  $>40^{\circ}$  in four trials. A recent 2 centre United Kingdom study showed nearly a 20% reduction in OASIS when the EPISCISSORS-60 replaced the existing episiotomy scissors (van Roon 2015, In press).*

# OVERVIEW

## BACKGROUND

Anal incontinence (AI) (i.e. incontinence of liquid faeces and flatus) can have a devastating impact on a person's quality of life. It is well known that obstetric anal sphincter injury (OASIS) is a major risk factor for anal incontinence (AI), leading to a nine-fold increase in AI in women compared to men. A ten year prospective follow-up study of women with OASIS revealed an AI incidence of 36% [Fornell 2005]. A meta-analysis of 717 patients found that 30% of women were symptomatic one year after OASIS [Pollack 2004]. The probability of longer-term anal incontinence and urgency is thought to be as high as 53-80% with significant effects on quality of life [Evers 2012, Sorensen 2013].

## INCIDENCE OF OASIS

Obstetric Anal Sphincter Injuries (OASIS) occurs in 5.9% in first births in the UK according to recent HES data. There are approximately 325,000 primiparous births alone each year, and nearly 20,000 cases of OASIS in this group. The incidence in higher order births is 1.5% for normal births and 3.4% for instrumental births, averaging about 2% overall. The number of new OASIS cases is nearly 10,000. Based on these robust estimates, the overall incidence of OASIS in the UK is 30,000 new cases each year [Patterns of maternity care in English Hospitals 2013, RCOG press].

## RELATIONSHIP OF OASIS TO EPISIOTOMY ANGLE

An episiotomy is the most commonly performed operation worldwide. Episiotomies are performed to enlarge the birth passage at the time of crowning of the baby's head, and are given in 15% of UK births [HES data].

OASIS is caused by episiotomies resulting too close to the midline ( $<30^{\circ}$ ), which can mechanically disrupt the anal sphincter. Studies show an incidence of nearly 20% in cases with midline episiotomies, practised mainly in the United States [Fenner 2003].

It is also caused by episiotomies too far from the midline ( $>60^{\circ}$ ), as these fail to relieve the pressure on the perineum [Stedenfeldt 2012]. The incidence of OASIS was 10% if the post-delivery sutured episiotomy angle was  $< 25^{\circ}$  and 0.5% if the angle was  $\geq 45^{\circ}$ . They also found that the incidence of OASIS reduces by 50% for every  $6^{\circ}$  the episiotomy is away from the midline [Eogan 2006]

Therefore, the angle at which the episiotomy is performed is crucial in reducing the number of injuries sustained by the sphincter muscles of the back passage (anus). Indeed, the Royal College of Obstetricians and Gynaecologists (RCOG) recommend that ***"Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to ensure that the angle is 60 degrees away from the midline when the perineum is distended"*** [RCOG Green Top Guideline 29, June 2015]

To reduce OASIS, episiotomies need to be within the post-delivery **SAFETY ZONE** ( $40-60^{\circ}$ ).

## CURRENT PRACTICE OF PERFORMING EPISIOTOMIES: THE EVIDENCE

Current practice of performing episiotomies is by 'eyeballing' the angle.

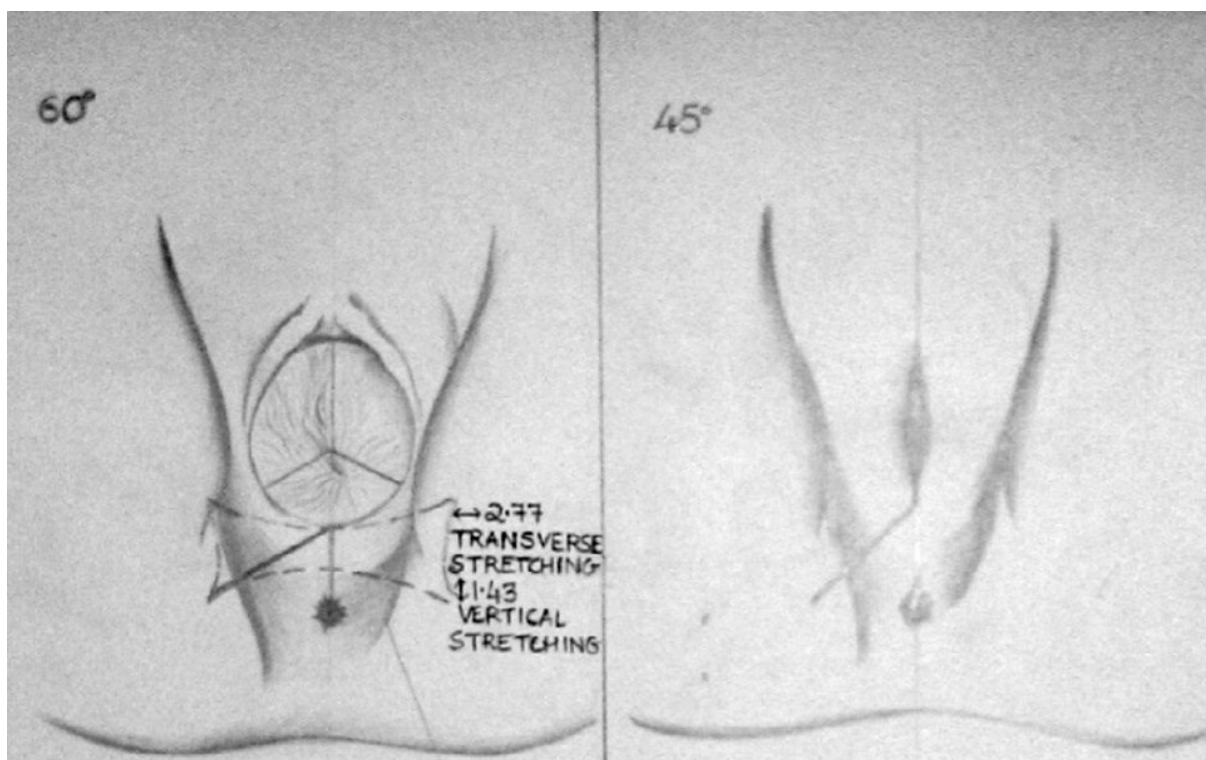
Research studies have shown that doctors and midwives are unable to correctly estimate the angle at the time of birth. Reporting in the paper 'Are mediolateral episiotomies actually mediolateral?' Andrews et al [BJOG 2005] found 'No midwife and only 22% of doctors performed truly mediolateral episiotomies. It appears that the majority of episiotomies are not truly mediolateral but closer to the midline'.

In a prospective study, only 13% of the episiotomies were found to be more than 40 degrees [Andrews 2006]. Interestingly, an earlier study found doctors and midwives are unable to correctly estimate the angles even on paper. Only one-third of episiotomies were  $> 40^{\circ}$  [Tincello 2003].

More recently, Silf [Midwifery, 2014] found that only 12% doctors and midwives were able to cut between 40-60 degrees at crowning in a simulation model. In another study, only 15% clinicians were able to cut at 60 degrees when prompted [Naidu, 2015, in press]

## WHY IS GETTING THE EPISIOTOMY ANGLE RIGHT SO DIFFICULT?

Research shows the angle at time of incision of episiotomy needs to be  $60^{\circ}$  to achieve  $>40^{\circ}$  after delivery. This is due to stretching or distension of the perineum by 2.7 times in the transverse dimension and 1.4 times in the vertical dimension [Zemcik 2012].



## WHAT ABOUT EYEBALLING IN OTHER MEDICAL SPECIALTIES?

Helen Young and colleagues compared 'eyeballing' with formal counting methods for proliferation indices in cancer pathology. They found poor correlation and results with eyeballing were significantly less accurate and risked misclassification of tumours [Young *J Clin Pathol* 2012]. Similarly, ultrasonographers don't rely on 'eyeballing' to take fetal measurements. Even in blood flow Doppler studies, eyeballing has been shown to be inferior to actual measurement [Broholm *Eur J Vasc Surg* 2012]. Breast surgeons would not rely on eyeballing to decide the size of implants. They would use tape measures and callipers. Orthopedic surgeons would rely on measurement aids rather than eyeball while fitting their equipment.

## RELATIONSHIP OF OASIS TO SPONTANEOUS PERINEAL TEARS

The National Perinatal Epidemiology Unit (NPEU) reported on a survey conducted by the Office of National Statistics [Redshaw 2010]. Significant second degree perineal tears requiring suturing occurred in 38% of births. Recent studies have shown the incidence of OASIS in these women to be 40-50% higher than in women given mediolateral episiotomies [Revicky 2010, Gurol-Urganci 2013], despite their being huge variations in episiotomy angles. This is because 2<sup>o</sup> tears generally extend into the anal sphincter complex and disrupt the muscles.

## SUMMARY

- RCOG recommends cutting an episiotomy at 60 degrees.
- Research studies show that episiotomies <30 degrees are associated with a 20-fold increase and episiotomies > 60 degrees are associated with a 9-fold increased risk of OASIS.
- 40-60 degrees post-delivery angles are the SAFE ZONE
- Research studies show that only 1/3<sup>rd</sup> of clinicians achieve an episiotomy >40 degrees
- Only 1/3<sup>rd</sup> of clinicians can estimate >40 degrees even on a piece of paper
- EPISCISSORS-60 were created to fulfil this unmet clinical need.

## EVIDENCE FOR EPISCISSORS-60

- The first scissors ever designed to cut an episiotomy at 60 degrees to the perineal midline. Studies have shown they achieve a post-delivery angle of 40-52 degrees [Freeman 2014, Patel 2014, Sawant 2015, van Roon 2015-in press].
- ***A recent 2 centre United Kingdom study showed nearly a 20% reduction in OASIS when the EPISCISSORS-60 replaced their existing episiotomy scissors [van Roon 2015, In press].***

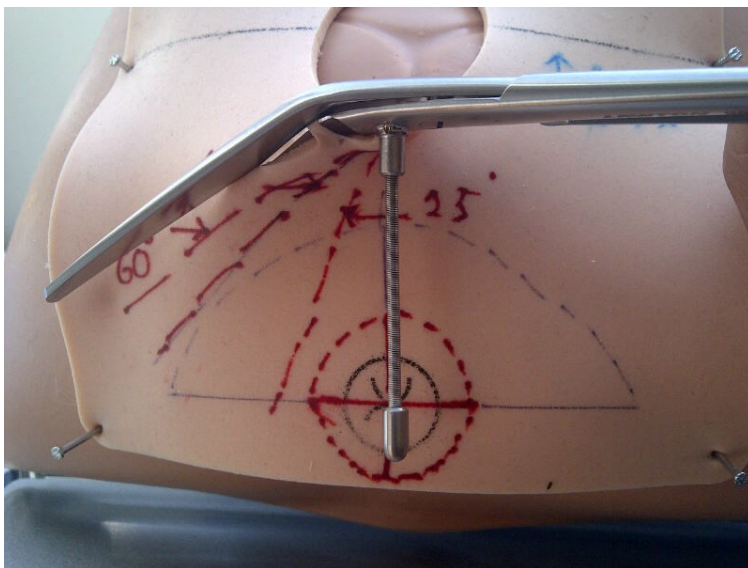
- A randomised trial showed a clear 10 degree difference in sutured episiotomy angles between the EPISCISSORS-60 and the Braun-Stadler episiotomy scissors [Sawant 2015].

## DESCRIPTION OF EPISCISSORS-60

- They are designed to prevent OASIS during episiotomies, making them safer.
- To last longer and cut sharper, they are entirely made in Germany from European steel, have tungsten-carbide inserts on their blades, and golden handles for easy recognition.
- They have a flexible guide-limb that accommodates perineal distension at crowning.
- They are available in two different versions:

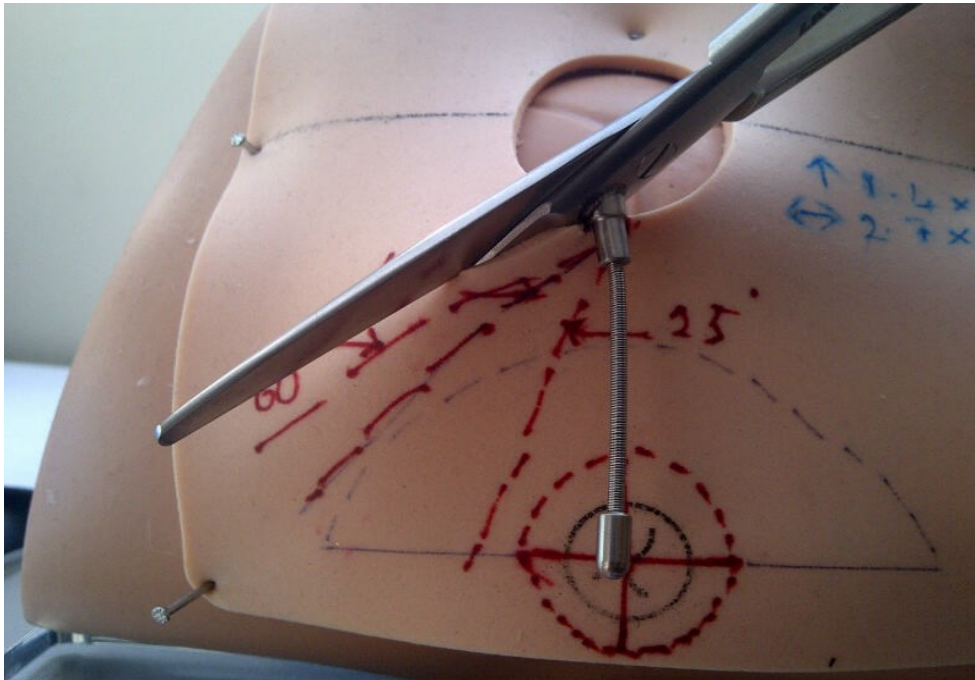
### 1] **60 degree Angled type:**

These scissors are entirely new. The blades are angulated at 60 degrees to the scissor handles. They are more ergonomical, and prevent 'wobbling' while incising the episiotomy. Here, the cut starts about 10-15 mm away from the midline, but is at 60 degrees. There is some research evidence to show these are safer than the traditional mediolateral episiotomies that originate from the posterior fourchette [Stedenfeldt 2012, Fodstad 2013]. Suture angles of 40-52 degrees were achieved [Patel 2014, Sawant 2015, van Roon 2015]



### 2] **Straight Mayo type:**

This is an adaptation of the commonly used Mayo scissors. As long as the guide-limb is positioned along the midline from the posterior fourchette to the anus, the episiotomy will be incised at 60 degrees. A suture angle of 43 degrees was achieved in a series of instrumental deliveries [Freeman 2014]



## OASIS –DIRECT AND INDIRECT COSTS

- OASIS costs per case=£1625 (repair, theatre consumables, endoanal scan and 1 follow-up visit)
- £425 in theatre consumables alone per case (source Fiona James, Theatre Manager, Poole Maternity theatre, United Kingdom)
- 33% of women with OASIS opt for elective CS in subsequent pregnancies. The reference cost for ELCS is £704 higher than for a vaginal delivery.
- Patients with previous OASIS do not get the high risk antenatal tariff in subsequent pregnancies despite having increased number of antenatal visits. (normal tariff £1126 v £1803 for high risk)
- A recent High Court Judgement awarded £1.6 million in damages to a single case of OASIS caused due to an acutely angled episiotomy.  
[http://www.irwinmitchell.com/newsandmedia/2013/October/Banker-Unable-To-Work-Due-To-Horrific-Behaviour-Of-Private-Doctor-Who-Delivered-Her-Baby#.UueAY\\_47wSY.email](http://www.irwinmitchell.com/newsandmedia/2013/October/Banker-Unable-To-Work-Due-To-Horrific-Behaviour-Of-Private-Doctor-Who-Delivered-Her-Baby#.UueAY_47wSY.email)

## COST NEUTRALITY OF EPISCISSORS-60 PURCHASE

The current practice is to use either ordinary Mayo type or Braun-Stadtler type episiotomy scissors. These can be single use or multi-use depending on each unit's choice of birth packs and perineal sets. Based on the recent RCOG data, there are 30,000 new cases per annum in the United Kingdom.



The direct medical costs of treating OASIS are £1625 per case, totalling £48.75 million. It could be viewed that this is the real cost of continuing with current practice.

A reduction in OASIS by only 2.5 cases in the first year itself will make the EPISCISSORS-60 purchase cost neutral

A reduction in OASIS by just 10 cases over 5 years would provide enough savings in consumables alone to make the EPISCISSORS-60 purchase cost neutral.

**Web: [www.medinvent.net](http://www.medinvent.net)**

**Email: [info@medinvent.net](mailto:info@medinvent.net)**