Sexual function and PostPartum Health In Relation to Episiotomy and obstetric anal sphincter injury

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Oslo, February 2016

Kathrine
2. LIST OF PAPERS


The papers are referred to by their Roman numeral throughout the thesis.
3. ABSTRACT of the SAPPHIRE study

**Background and Aims:** Episiotomy is a commonly practiced surgical procedure on women worldwide. Different episiotomy techniques have been described in the literature, although international consensus on technique definition and categorization is lacking. The overall aim of the thesis was to assess how different episiotomies and perineal obstetrical tears might affect perineal pain perception, blood loss, sexual activity and dyspareunia. In addition, the thesis aimed at exploring whether doctors in Nordic countries differ in classification and preferences in episiotomy techniques.

**Methods:** Study 1 of this thesis was a prospective observational study of 300 women recruited postpartum due to an episiotomy. Episiotomy type was categorized by incision point distance from the posterior fourchette and by episiotomy angle with the (para)sagittal plane. Perineal pain perception on the first postpartum day was scored on a Visual Analogue Scale (VAS). Perineal pain and sexual activity was registered in a structured questionnaire 3 months after delivery.

Study 2 was a prospective cohort study of 42 women with obstetric anal sphincter injury (OASI) and 840 controls without OASI in their index delivery. The women responded to a questionnaire concerning sexual activity and dyspareunia one year after the index delivery.

Study 3 was a pictorial questionnaire survey among 296 Nordic doctors registering their preferred episiotomy technique, technique classification and their perception of clinical indication for episiotomy use.

Continuous data were categorized or dichotomized where appropriate and Chi-squared test was used in all four papers. Multivariate logistic regression analyses were
performed in Studies 1 and 2 to explore associations between various exposures and outcomes and to adjust for confounding factors.

**Results:** In Study 1, we found no differences in perineal pain perception the first postpartum day or relation to blood loss or dyspareunia 3 months after delivery when comparing midline, mediolateral, lateral and non-classifiable episiotomy technique. Nor did we find any difference between techniques in relation to puerperal wound infection (Papers I and II).

In Study 2, women with OASI were significantly more likely to postpone coitus till after three months postpartum compared to any of the groups of women with less severe degree of perineal trauma or episiotomy. When comparing second degree tears to episiotomy per se, we found no significant difference in percentage distribution of coital resumption between these two groups at the three time points studied. OASI was also the only significant predictor for dyspareunia one year after delivery (aOR 3.57, CI 1.39-9.19). Episiotomy was neither a risk factor for delayed onset of intercourse nor for dyspareunia. There were no differences between episiotomy and second degree laceration injury groups regarding delayed coital onset (p=0.45) or dyspareunia one year postpartum (p=0.67) (Paper III).

In Study 3, the majority of doctors participating in the survey (47%) drew a lateral episiotomy according to our classification by incision point and angle, but as many as 64% of these 138 doctors misclassified their drawn cut as a mediolateral episiotomy. Only 20% drew a mediolateral episiotomy, the great majority classifying it accurately, but 8% misclassified their mediolateral cut as a lateral episiotomy. One third of episiotomies were non-classifiable. There were significant differences between
Finnish and Norwegian vs. Danish and Swedish doctors in perception of clinical indications for episiotomy. Significantly more Finnish and Norwegian doctors considered instrumental delivery, a history of OASI, big baby, breech delivery and prolonged second stage as clinical indications for episiotomy use compared to their Danish and Swedish colleagues (p<0.01). Danish and Swedish doctors reported to be more restrictive with episiotomy use during vacuum or forceps delivery (Paper IV).

**Conclusions and clinical implications:** There seems to be little difference in perineal pain perception, postpartum blood loss, sexual activity and dyspareunia between women undergoing different episiotomy techniques. OASI was the strongest predictor for delayed sexual resumption and for dyspareunia one year postpartum. We found no support for episiotomy being a risk for delayed sexual resumption or for dyspareunia one year postpartum. Even though episiotomy should not be used routinely, we advocate that episiotomy should be used when indicated to reduce the risk of OASI. Our main finding of affected sexual activity after OASI strongly supports the need of reducing the rates of this obstetric injury to a minimum.

The SAPPHIRE study has also demonstrated that episiotomy practice both in Norway and in the Nordic countries has potential for further improvement, as demonstrated by unclear technique use documented in one third of deliveries at Norway’s largest delivery unit (Paper I) as well as in a Nordic self-reported pictorial questionnaire survey (Paper IV). We argue that there is a need for focused obstetric training both in Norway and internationally to optimize episiotomy performance in order to reduce obstetric anal sphincter injury rates and to optimize postpartum perineal health.
4. ABBREVIATIONS

BMI: Body Mass Index
OASI: Obstetric Anal Sphincter Injury
RCT: Randomized Controlled Trial
VAS: Visual Analogue Scale
VRS-5: 5-point Verbal Rating Scale
5. INTRODUCTION

5.1 Anatomy

The perineum corresponds to the outlet of the pelvis. It is generally defined as the surface region between the pubic symphysis and the coccyx. The perineum is below the pelvic diaphragm and is a diamond-shaped area enclosed anteriorly by the pubic arch, laterally by the ischiopubic rami, ischial tuberiosities and sacrotuberous ligaments, and posteriorly by os coccygis. Its definition can refer to only the superficial structures in this region, or it can be used to include both superficial and deep structures.

The superficial structures include the bulbospongiosus muscle, the superficial transverse perineal muscle and the ischiocavernosus muscle. The deeper muscles are the levator ani muscles and the deep transverse perineal muscle.

In females, a line drawn across the surface connecting the ischial tuberosity divides the space into two triangles:

- The anterior urogenital triangle, including the vaginal introitus

- The posterior anal triangle including the anal introitus

The perineal body (or central tendon of perineum) is a pyramidal fibromuscular tissue mass in the midline of the perineum at the junction between the urogenital triangle and the anal triangle. The perineal body is essential for the integrity of the pelvic floor, particularly in females. Its potential rupture during vaginal birth leads to widening of the gap between the anterior free borders of the bilateral levator ani muscles.
5.2 Classification of perineal injuries

Spontaneous perineal and vaginal injuries are common during childbirth, up to 80% of primiparous women need suturing after vaginal delivery (1). Tears can involve the vaginal walls and the perineal skin and may also extend into the rectum. Perineal injuries are classified as first through fourth degree, as shown in Table 1 below. First degree injuries involve the fourchette, perineal skin, and vaginal mucous membrane but not the underlying fascia and muscle. These injuries include periurethral tears which may bleed profusely. Second-degree injuries involve, in addition, the fascia and muscles of the perineal body but not the anal sphincter muscles. These tears can usually extend upward on one or both sides of the vagina, forming an irregular triangular injury (1). Injuries can also extend into the anal sphincter complex, involving the internal or/and external anal sphincter muscles, or the rectal mucosa itself, namely third or fourth degree perineal injuries, also named Obstetric Anal Sphincter Injury (OASI) (Table 1). Such advanced tears are clinically significant, because despite refinements in the surgical management immediately after delivery, many women suffer from complications after OASI. Women who sustain OASI are more likely to suffer long term anal incontinence and dyspareunia. (2,3).
Table 1 The ICD-10 classification codes for degree of perineal injury. ICD-10 is the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO).

<table>
<thead>
<tr>
<th>Degree of perineal injury</th>
<th>Description</th>
<th>ICD-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>First degree</td>
<td>Laceration of the vaginal epithelium or perineal skin only</td>
<td>O 70.0</td>
</tr>
<tr>
<td>Second degree</td>
<td>Involvement of the perineal muscles, but not the anal sphincter</td>
<td>O 70.1</td>
</tr>
<tr>
<td>Third degree 3A</td>
<td>Disruption of the anal sphincter muscles (&lt;50% of the external sphincter torn)</td>
<td>O 70.2</td>
</tr>
<tr>
<td>Third degree 3B</td>
<td>&gt;50% of the external sphincter torn</td>
<td>O 70.2</td>
</tr>
<tr>
<td>Third degree 3C</td>
<td>Additional disruption of the internal sphincter</td>
<td>O 70.2</td>
</tr>
<tr>
<td>Fourth degree</td>
<td>A total rupture of the anal sphincter muscles and the anal epithelia</td>
<td>O 70.3</td>
</tr>
</tbody>
</table>

5.3 Episiotomy

5.3.1 Definition

Episiotomy is defined as a surgical incision in the perineum during the last part of the second stage of delivery, which is when the baby is delivered. This procedure is done with scissors or sometimes with scalpel and requires repair by suturing (4).

Episiotomy is globally a commonly used surgical procedure performed on women (1).

5.3.2 Indications for performing episiotomy

Episiotomy is performed to increase the diameter of the vaginal outlet to facilitate the baby's delivery and is also done as prophylaxis against anal sphincter muscle injury. There is no consensus on congruent indications for episiotomy, but there are many
clinical traditions for performing an episiotomy, both fetal and maternal. Maternal indications include when the accoucheur believes there is a considerable risk of a third or fourth degree perineal injury or when the woman is too tired or unable to push properly. Another maternal indication may be if the delivering woman has undergone female genital mutilation, e.g. in the cases of restricted vaginal outlet due to mutilating surgery. Operative vaginal deliveries, such as vacuum extraction or forceps assisted delivery, are commonly considered indications for episiotomy due to increased risk for OASI during an instrumental vaginal delivery. Fetal distress has been considered an indication for episiotomy to shorten the second stage of delivery. A large baby may be an indication for episiotomy due to prolonged labor and increased risk of perineal injury or fetal distress. Breech delivery and occiput posterior fetal head presentations are yet two other possible clinical indications for performing an episiotomy.

5.3.3 Timing of episiotomy

Episiotomy should be performed during crowning of the fetal head during the second stage of delivery, typically when the fetal head is visible during a uterine contraction at a vaginal outlet diameter of 3-4 cm (1). When used in conjunction with forceps delivery, episiotomy can be performed after application of the blades. If performed too early, the bleeding from the episiotomy may be considerable during the interim between incision and delivery. If performed too late, lacerations are unlikely to be prevented (1).
5.3.4 History and epidemiology

The term episiotomy was contributed by Braun in 1857 and became the commonly used expression in the 20\textsuperscript{th} and 21\textsuperscript{st} century. Episiotomy was developed during the 18\textsuperscript{th} and 19\textsuperscript{th} centuries. The term “episiotomy” actually refers to cutting the pudenda or external genitalia and is therefore misleading, whilst “perineotomy” refers to making an incision of the perineum, the area between the vulva and the anus, and is the more accurate term. However, episiotomy is the term commonly used worldwide.

The potential advantages of perineal incision were first discussed in 1742 by Ould, a male midwife, who recommended an incision from the vaginal outlet toward the anus of women undergoing extremely difficult deliveries (5). The procedure was introduced in the United States by Taliaferro in 1851, although it was not widely advocated in this country for many years (1). After 1900 two American physicians, Stahl and Hirst, increasingly advocated the use of episiotomy. It was however Pomeroy and DeLee that introduced a change in climate of opinion in American Obstetrics in the early 20\textsuperscript{th} century, not only in regard to episiotomy, but to the entire process of delivery (6).

Although it is a common obstetrical procedure, the use of episiotomy has decreased over the past 25 years (7,8). In the Nordic countries today, episiotomy use is restricted since liberal use has been reported to cause increased perineal trauma, suturing and healing complications (7,9). Still, episiotomy use has been reported to be fourfold higher in Norway (19\%) and Finland (24\%) the last decade compared to Denmark (5\%) and Sweden (5.8\%) (10) in 2010. Interestingly, Norway and Finland are also the two Nordic countries with the lowest OASI rate.
In the UK, during the first half of the 20th century, episiotomy was very common practice, with rates up to 96% among nulliparous and 71% among multiparous women (11). However, since the 1970s, its routine use has been challenged and episiotomy was submitted to randomized controlled trials. The results from these trials led to the adoption of selective and not routine use of episiotomy (9). Consequently, according to National Health Service Maternity Statistics 2010-11, the rates of episiotomy in the UK had declined to be around 15% (NHS Information Centre 2011).

Approximately 65% of American women who delivered vaginally in 1979 had an episiotomy, compared to 39 percent by 1997 (12). By 2003, the episiotomy rate in the United States had decreased further to approximately 18 percent (13). Through the 1970s, it was common practice in industrialized countries to cut an episiotomy in almost all women having their first vaginal delivery. A reason for its popularity was the straight surgical incision, which was easier to repair than the ragged laceration that might otherwise result with a spontaneous tear. Another commonly believed benefit of routine episiotomy was that it prevented pelvic floor complications, such as vaginal wall support defects and incontinence. A number of observational studies and randomized trials, however, have shown that routine midline episiotomy is associated with increased incidence of anal sphincter and rectal tears (14-17). The Cochrane review on episiotomy for vaginal birth from 2009 by Caroli and Mignini (9) compared restrictive versus routine episiotomy performance for both the midline and mediolateral episiotomy technique. In the eight randomized controlled trials (RCT) with 5,541 women included in this review, 75% of women in the routine use group
had episiotomy, versus 28% in the restrictive use group. The authors found no differences between restrictive and routine episiotomy use in terms of OASI risk. However, the review concluded with lower rates of posterior perineal trauma (first and second degree lacerations), surgical repair and healing complications in the restricted-use group one week after delivery. Episiotomy performance itself was included in the author’s definition of posterior perineal trauma. The incidence of anterior perineal trauma was found to be lower in the routine-use group. With these findings it was concluded that midline episiotomy did not protect the perineal body, but rather contributed to anal incontinence by increasing the risk of third- and fourth-degree perineal injuries. Long term complaints or risk of OASI was not assessed in this review.

Most clinical guidelines today, including the American College of Obstetrics and Gynecologists (18) and the Royal College of Obstetrics and Gynaecology (19) have for these reasons recommended restricted use of episiotomy to defined clinical indications, as opposed to routine use.

5.3.5 Episiotomy types practiced today in the industrialized world

There are four types of episiotomy in current use; the midline, mediolateral, lateral and anterior episiotomy. Figure 1 illustrating the first three mentioned techniques. The midline technique is commonly used in the United States of America and Canada (20) even though it is well established that a significantly higher risk of anal sphincter injury is associated with midline episiotomy compared to the mediolateral technique (21,22). It is assumed that the reason for this increased injury risk is that a midline cut
will easily rupture further downwards towards and into the anal sphincter muscle during the delivery of the baby. The argumentations for the midline technique have been that it produces a symmetrical wound, easily approximated in the midline; that important muscles are not injured by the incision itself; and that scar tissue when formed involves the tendinous insertions of the muscles already composed largely of connective tissue (23).

The mediolateral technique is the technique of preference in Europe and it is also recommended by the National Institute for Health and Care guidelines (19). The first and foremost advantage of this mediolateral technique, if performed with an optimal and wide enough angle, is that it reduces the risk of OASI (24-26). Emerging research suggests that there may indeed be a wide variation in the actual angle, but also in the incision point made by accoucheurs when they report using mediolateral episiotomy. A European survey revealed that individual interpretations of angles for mediolateral episiotomy were anywhere between 30 and 90 degrees among European hospitals (27). Several clinical studies and surveys have confirmed this discrepancy in episiotomy technique performance, mediolateral episiotomies are often performed with much too narrow an angle. In a study by Tincello et al. (28), the correct angle of incision was calculated at between 40-60 degrees, based on the descriptions and recommendations of four text books. Tincello et al. distributed a pictorial questionnaire to collect data on how doctors and midwives performed a mediolateral episiotomy, indicating that only 46% of doctors and 33% of midwives performed an episiotomy with a midline start, angled at least 40 degrees. The pictorial questionnaire findings were later investigated in an observational study by a UK group where actual
measurements of sutured episiotomies were taken immediately after repair (29). A similar methodological approach was used on a cohort of 236 primiparous women in the Czech Republic (30). In both studies the angle of 40-60 degrees was chosen as a reference angle to define a mediolateral episiotomy. In the UK cohort, no midwives and only 13% of doctors performed a mediolateral episiotomy adequately (29), whereas 41% of midwives and 39% of doctors complied with the chosen criteria in the Czech study (30). The marked difference between the UK and the Czech Republic in the proportion of episiotomies with an angle of 40 degrees or higher after suturing, suggests that the episiotomy performance differs between these two countries. Wong et al. conducted an interview administered questionnaire with 61 midwives and 39 doctors. The authors found that midwives depicted episiotomies that were significantly more acute than the 45 degrees they described them to be (31). Naidu et al. demonstrated that nearly two thirds of 106 delegates who were prompted to cut a mediolateral episiotomy at 60 degrees, underestimated the angle (<55 degrees; 44%), or overestimated the angle (>66 degrees; 18%). In a study by Grigoriadis et al. 42% of responders to a questionnaire survey among 131 Greek obstetricians reported to perform lateral episiotomies, 44% mediolateral and 14% midline episiotomies. The definition of a mediolateral episiotomy, however was an episiotomy directed towards the ischial tuberosity, and no incision point was described. This mediolateral group may therefore have included lateral incision points and hence have been lateral episiotomies. The definition of lateral episiotomy in the study, was described as “any other incision with a wider angle”, meaning the lateral group potentially were not
lateral episiotomies by definition, but in fact could have been mediolateral with too wide an angle or lateral incision points with too wide an angle.

As mentioned above, evidence has come to light that when one performs a mediolateral episiotomy at least 60 degrees from the midline that it may in fact protect against OASI (24-26). Stedenfeldt et al. demonstrated a “U-shaped” association between episiotomy angle and OASI with increased risk (OR 9.00; 95% CI 1.1-71.0) of OASI when the episiotomy angle was either smaller than 15 degrees or above 60 degrees. However, these measurements were all performed on scarred episiotomies as opposed to episiotomies at the time of incision or as opposed to sutured episiotomies in the immediate postpartum period. Suture and scar angles differ from incision angles when episiotomy is performed on stretched perineum during crowning of the fetal head, as discussed below. The time from delivery to clinical assessment was 2.9 years (mean) for the OASI group and 2.2 years (mean) for the control group, hence clinical assessment was not performed at an identical postpartum time interval, with respect to time from delivery, on the participating women. As mentioned above, shrinkage in angle of approximately 20 degrees was found when comparing incision to suture angle in mediolateral episiotomy (26). Evaluating episiotomy angle (based on a scar) 2-3 years after delivery, and also at different postpartum time intervals for all participants, as Stedenfeldt et al. did, is problematic. A scarred episiotomy angle measurement of 60 degrees could likely represent an incision angle performed at 80-90 degrees, which is an incorrect performance of both the mediolateral and the lateral episiotomy angle per se. Results from this study should therefore be interpreted with caution and may not be applicable or generalizable for episiotomy angles and risk of OASI.
Figure 1

Figure 1 Episiotomy intrapartum incision lines. 1:midline 2:mediolateral 3:lateral episiotomy technique. The figure illustrates incision points and incision angles with the (para)sagittal plane when episiotomy is performed on distended perineum during crowning of the fetal head. Reprinted from Paper I with permission from International Urogynecology Journal.
5.3.6 Classification of episiotomy

The episiotomy techniques have evolved over the years and different approaches have been favored during different decades. Altogether seven different episiotomy incisions are described in obstetric literature and the following description of different episiotomy techniques is taken from a review article by Kalis et al. (20). Figure 2 illustrates these different episiotomy types.

**Figure 2** Types of episiotomies, performed during the second stage of labor, at crowning of the fetal head.

1: midline episiotomy,
2: modified median episiotomy,
3: ‘J’-shaped episiotomy,
4: mediolateral episiotomy,
5: lateral episiotomy,
6: radical lateral (Schuchardt incision),
7: anterior episiotomy (white arrow).

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1. **Midline episiotomy**

This episiotomy is also called median or midline episiotomy. The incision commences at the posterior fourchette and is directed straight downwards towards the anus.
2. Modified median episiotomy

A modification of median (midline) episiotomy is performed by adding two transverse incisions in opposite directions just above the anal sphincter, so that the transverse cut measures 2.2 cm in total. The use of this modification is believed to increase the diameter of the vaginal outlet by 83% compared to standard median (midline) episiotomy (32).

3. J-shaped episiotomy

This episiotomy commences with a midline incision and is then curved laterally to avoid the anus. In this technique curved scissors are used starting in the midline of the vagina until the incision is 2.5 cm from the anus. Then the “J” is made by directing the incision towards the ischial tuberosity away from the anal sphincter (20).

4. Mediolateral episiotomy

The incision commences at the posterior fourchette and is directed obliquely, downwards, although the exact definition in terms of angle is often unclear.

5. Lateral episiotomy

The incision commences 1 or 2 cm lateral to the midline and is directed downwards towards the ischial tuberosity. Lateral episiotomy is rarely mentioned in the obstetric literature. However, the lateral technique is probably commonly used unintentionally, when the accoucheur has meant to perform a mediolateral episiotomy, but commenced the incision lateral to the midline.

6. Radical lateral episiotomy (Schuchardt incision)

Radical lateral episiotomy can be considered to be a non-obstetrical incision. The incision commences 1-2 cm lateral to the midline, towards the ischial tuberosity and
thereafter curved around the rectum. It may be performed at the beginning of radical vaginal hysterectomy to permit easy access to the parametrium or to enable extraction of a neglected vaginal pessary (20).

7. *Anterior episiotomy*

The anterior episiotomy is also known as deinfibulation (the opening of the scar associated with some types of female genital mutilation e.g. suturing of the labiae minora) (33,34).

5.3.7 *Perineal injury - healing complications*

Morbidity rates rise as perineal injury severity increases. Venkanesh et al. (1989) reported a 5-percent incidence of third and fourth degree perineal tears in 20 500 vaginal deliveries. Approximately 10 percent of these 1 040 primary repairs had a postoperative wound disruption, two thirds of which required surgical correction. Williams and Chames (2006) found that mediolateral episiotomy was the most powerful predictor of wound disruption, whereas Goldaber et al (1993) reported that 21 of 390 women (5.4%) with fourth degree lacerations experienced significant morbidity (1).

Few studies address perineal wound infection, and most studies have been retrospective. Data may also have been incomplete because women develop symptoms after discharge from the hospital (35). Goldaber et al. retrospectively reviewed the medical records of 390 women with fourth degree perineal repair. The authors found that 1.8% had dehiscence alone, 2.8% had infection and dehiscence and 0.8% had infection alone. (35). Uygur et al. retrospectively reviewed the hospital medical
records over a 2 year period for patients with episiotomy dehiscence, identifying 37 patients, all with mediolateral episiotomy. The authors found that infection was the obvious cause of dehiscence in the majority (25/37) of the women (36). While 12 of the patients with episiotomy dehiscence were allowed to heal by secondary intention, 25 patients underwent early repair. Patients were seen 2 weeks after being discharged. Among the patients treated by early repair, 3 patients had a superficial separation of skin edges. Healing was complete in the rest of patients treated by early repair of episiotomy dehiscence (36).

In a UK 3 months prospective audit, Johnson et al found that 11% of 341 women with a sutured perineal tear experienced a perineal wound infection based on the criteria of any two infection markers. The infection markers were perineal pain, wound dehiscence and/or purulent vaginal discharge (37). The audit was however performed as a telephone interview and not as a clinical examination by a health care professional.

In secondary outcome analyses of the only conducted RCT comparing correctly performed mediolateral and lateral episiotomies, Karbanova et al. found no significant differences regarding surgical reintervention, the occurrence of hematoma, or episiotomy dehiscence between the two episiotomy techniques during the first 10 postpartum days. Seven of 21 perineal dehiscences required resuturing. No infections were registered at 24 hours or 72 hours postpartum. At day 10, an episiotomy suture infection was observed in 4 (1.5%) of 263 women in the mediolateral group and 5 (1.7%) of 290 women in the lateral group. No difference in antibiotic use owing to infection was found (38).
5.3.8 Episiotomy technique types and risk of OASI

Midline episiotomy technique and risk of OASI

Midline episiotomies are reported to increase the risk of obstetric anal sphincter injury (OASI) (21,22,39-41). This is of little surprise as the cut commences at the posterior fourchette, directed downwards towards the anus where potential extensions are more likely to affect the anal sphincter muscles compared to mediolateral and lateral cuts, directed away from the anus.

Mediolateral episiotomy technique (incision and suture angle) and risk of OASI

There is emerging evidence that the angle of episiotomy incision does indeed affect the risk of OASI. A study of 56 women with a mediolateral episiotomy and a clinically identified third degree perineal tear with 46 episiotomy controls without OASI (all examined three months after delivery) discovered that the mean angle of the mediolateral episiotomy scar was significantly more acute in patients who had sustained an apparent anal sphincter injury during delivery after episiotomy compared with controls (24). The study showed a 50% relative reduction in the risk of sustaining third-degree tear for every 6 degrees away from the perineal midline that the scar was angled. The authors calculated that if the angles of episiotomy scar measured in this study were between 35 and 44 degrees, the risk of OASI would decrease to 1.1% and if the angles were 45 degrees and higher the adjusted risk of OASI would drop further to 0.5% (24).

Given that the perineum is distended due to the crowning fetal head (or breech) and edema of perineal tissues at the time of incision, it seems likely that the angle of
incision at the moment of episiotomy will be larger than at the time of repair and beyond. To test this hypothesis, the terms “incision angle” and “suture angle” of episiotomy were introduced by Kalis et al. The authors documented that the incision angle of an episiotomy differs significantly from the angle of suture (30). When the mediolateral episiotomy was cut at a recommended angle of 40 degrees at the time of crowning, the median angle between episiotomy and midline corresponded to 20 degrees after repair. None of the suture angles of the 42 episiotomies performed at the time of the crowning of the head was higher than 30 degrees. These two studies (24,30) conclude that an incision angle of 40 degrees is still too acute to be recommended as a definition (or performance) of mediolateral episiotomy.

A study by Kalis et al. found the median suture angle, when incised at 60 degrees, became 45 degrees after suture and the median scar angle 48 degrees (26). This study (26) and a study by van Dillen et al. (42) found that there was a poor correlation between the suture and scar angles of mediolateral episiotomy. Only three women (7%) had a suture angle more acute than the reference angle of 38 degrees (26). Kalis et al suggest that an incision angle of episiotomy of 60 degrees is suitable for the implementation of a large randomized control trial comparing different types of episiotomy and it seems that this angle could be proposed as a part of a definition (and performance) of mediolateral episiotomy. The paucity of data to support this tentative conclusion would however require larger future trials. In the aftermath of these above mentioned study findings, EPISCISSORS-60 have been developed, to secure an optimal mediolateral episiotomy incision angle of 60 degrees (43). Results from studies assessing the risk of OASI before and after introduction of EPISCISSORS-60
(44) or comparing EPISCISSORS-60 with Braun-Stadler episiotomy scissors (45) are promising. Van Roon et al. found a 14% reduction in OASI incidence in nulliparous women with operative vaginal delivery with episiotomy after the introduction of EPISCISSORS-60. Overall there was an 18% reduction of OASI incidence in nulliparous vaginal deliveries after the introduction of EPISCISSORS-60 (44). Patel et al. evaluated the angle of EPISCISSORS-60 in 25 spontaneous vaginal deliveries. The authors demonstrated a post-delivery suture angle of 50 degrees and no cases of OASI were detected in this cohort of Indian women with clinically indicated episiotomy (46).

**Lateral episiotomy technique and risk of OASI**

Lateral episiotomy is rarely described in the literature. However, results from the pictorial questionnaire study previously mentioned (28) revealed that one-third of the professionals began the episiotomy lateral to the midline (28). It was not clear whether this was due to incorrect training in mediolateral episiotomy of if they were deliberately choosing a lateral episiotomy. A European study revealed that 7% of institutional definitions of mediolateral episiotomy stated that the incision point is located 1 or 2 cm form the midline (27). Lateral episiotomy is a method generally used in Finland where the rate of severe perineal lacerations is the lowest among Nordic countries (10,47-49). Whether this is due to the use of the lateral episiotomy, or due to other factors e.g. the traditional use of the hands-on perineal support during crowning to protect the perineum is unclear. A recent descriptive study claimed that lateral episiotomy is used as frequent as mediolateral episiotomy (42% vs. 44%) in Greece
(50), or in some cases selectively in instrumental deliveries (27). Large observational studies have reported that lateral episiotomy reduces the risk of anal sphincter injury (48,51). However, evidence from randomized controlled trials between lateral and appropriately performed mediolateral episiotomy, evaluating short and long term postnatal outcomes, is limited. In the only randomized controlled trial conducted comparing correctly performed mediolateral and lateral episiotomies authors found no difference in risk of OASI comparing correctly performed mediolateral and lateral episiotomies. Mediolateral episiotomy followed an angle of at least 60 degrees from the midline and performed on 390 women. Lateral episiotomy started 1-2 cm laterally from the midline and was directed towards the ischial tuberiosty and was performed on 400 women. The authors found no difference between lateral and mediolateral episiotomy technique in terms of incidence or extent of vaginal or perineal trauma. Nor did they find a difference between techniques in terms of incidence of OASI. Unfortunately the paper lacks methodological documentation on how correctly performed episiotomy techniques were secured. However, the authors describe how careful clinical training, such as educational seminars together with practical workshops, were arranged for all obstetric staff before study commencement and that regular seminars where held throughout the study period (25).

Another difficulty in assessing the value of episiotomy in reducing risk for OASI in non-RCT studies is the potential “confounding by indication” effect. When episiotomy use is restricted to high-risk patients for OASI only, it may present as a risk factor for OASI due to a confounding by indication (52).
5.4 Complications of perineal injuries

5.4.1 OASI and anal incontinence

It is well known that OASI is a major risk factor for anal incontinence in women. A 10-year, prospective, follow-up study of women with OASI revealed an anal incontinence incidence of 36% (53) and a meta-analysis of 717 patients found that 30% of women were symptomatic one year after OASI (54). The risk of longer-term anal incontinence and urgency has shown to be as high as 53%-80% (55-57). A study by Williams et al. concluded that a third degree perineal tear causes a significant emotional and psychological impact on women’s physical and emotional well-being (58).

5.4.2 Perineal pain and discomfort

Perineal pain and dyspareunia appear to be related to the extent of perineal trauma (59-62). In general, some studies assessing perineal pain and dyspareunia in relation to different degrees of perineal trauma have methodological limitations, such as mixing heterogeneous degrees of perineal injuries (63-67) or failing to specify degree of perineal trauma (68,69). Analyses of first and second degree spontaneous tears as one single variable (63,70,71) comparing such a categorized group to episiotomies, probably results in falsely low pain perception in the spontaneous tear group. Another problematic aspect is studies mixing different episiotomy techniques (63,70,72). In a study by Glazener et al., problems related to intercourse were more often reported by women who experienced perineal pain, depression or tiredness (73).
5.4.3 Blood loss

Very few studies address blood loss in relation to episiotomy or degree of perineal trauma. Mediolateral and lateral episiotomies have been postulated to cause more blood loss as well as more perineal pain and dyspareunia compared to the midline technique (6,21,33,74-76), although no randomized controlled trials or large observational studies exploring this notion have been published previously. To our knowledge only a few studies have assessed episiotomy technique and association to blood loss per se. Baksu et al. (77) compared midline to mediolateral episiotomies and found a significant difference in blood loss between midline and mediolateral technique when repair was performed after placental removal. However, no differences between techniques and blood loss were found when repair was done before delivery of the placenta.

5.5 Sexual activity postpartum

5.5.1 Sexual resumption after delivery

Postpartum sexual activity can be affected by a number of factors, including breastfeeding, perineal pain and discomfort or urinary or anal incontinence (59). Also, motherhood is a multifactorial transition that incorporates many changes in couples’ marital and sexual relationship, including fatigue, mood and dissatisfaction with bodily appearance as well as postpartum depression and psychological adaptation to the new stage of parenthood. Timing of resumption of coitus after OASI has been reported in previous studies from Sweden and the United States (61,78). Rådestad et al. found that adjusted relative risks for not having had sexual intercourse within 3 and 6 months
were 2.1 and 2.2 for tears in the anal sphincter muscles and rectum. The authors reported no associations between episiotomy and delay in resumption of intercourse at three months after adjusting for relative risks (78). Their questionnaire was albeit sent one year after delivery and results for three months may have been affected by recollection bias. Midline and mediolateral episiotomies were additionally recorded as one single group and not addressed separately in the analyses. Morof et al. investigated the sexual health experiences of both depressed and non-depressed women. Of 484 responders, 12% had an Edinburgh Postnatal Depression Scale score of 13 or more. This study revealed that women who were depressed were less likely to have resumed sexual intercourse by 6 months postpartum, engaged in less varied sexual activities and were more likely to report sexual health problems than non-depressed women (79).

5.5.2 Dyspareunia after delivery

Some studies conclude that impairment of sexual function is common among primiparous women after a vaginal birth (61) and that episiotomy itself is a risk factor for postpartum dyspareunia compared to an intact perineum (63,64,80) or perineal delivery tears (81). Still, the literature is conflicting when comparing episiotomies and spontaneous tears. Röckner et al. found no difference in dyspareunia comparing women with spontaneous perineal tears to women with episiotomies (72). However, their spontaneous tear group included lacerations of all degrees, as did their episiotomy group.
Signorello et al. reported that relative to women with an intact perineum, women with a second degree perineal tear were 80% more likely and those with third or fourth degree perineal tears were 270% more likely to report dyspareunia at 3 months postpartum. However their second degree perineal tear group also included episiotomies, all of the midline technique (61).

Previous studies of midline or mediolateral episiotomies in regards to coital resumption or dyspareunia generally differ in results (11,61,72,81-83). Lateral episiotomies have not previously been studied in relation neither to time of postpartum sexual resumption, nor dyspareunia. Studies reporting dyspareunia specifically after OASI, in comparison to all other degrees of spontaneous tears as well as to episiotomy (categorized separately), are limited (60,84). Barrett et al. found that dyspareunia in the first 3 months after delivery was, after adjustment, significantly associated with type of delivery, perineal damage and having experienced dyspareunia before pregnancy. In multifactorial analyses, only type of delivery and history of pre-pregnancy dyspareunia remained significant. Dyspareunia at six months was significantly associated with breastfeeding and a history of pre-pregnancy dyspareunia in both univariate and multivariate analyses. The association of dyspareunia (at 6 months) with type of delivery, was neither (84). De Souza et al. did not address dyspareunia specifically, but used the Female Sexual Function Index at three different time points to assess scores over time according to mode of delivery or perineal injury. Pain is one parameter in the Female Sexual Function Index. In this Australian cohort of 440 primigravid women, the authors found that at 12 months postpartum, sexual function had returned to early pregnancy levels, irrespective of mode of delivery or
perineal injury (85). Andrews et al. conducted a prospective study of 241 women having their first vaginal delivery and found that 40% of women were sexually active at 7 weeks and that this was not affected by the type of perineal trauma sustained. Pain on intercourse did not differ significantly between the different degrees of perineal trauma when using VAS, nor when using a 4-point Verbal Rating Scale to assess coital pain. Episiotomies and second degree tears were however grouped together. Separate analyses of episiotomy (all mediolateral type) compared to second degree tears were additionally performed. At day 5, women who had an episiotomy experienced significantly more pain at rest and sitting compared to women sustaining a spontaneous second degree tear, but there were no significant differences between these two groups in regards to pain on intercourse at 7 weeks postpartum. Compared to second degree tears and episiotomies, women with OASI had significant more pain at 7 weeks, at rest, sitting and moving, but not in regards to coital pain (60).
6. AIMS OF THE THESIS

The overall aim of the thesis was to bridge the knowledge gap of how obstetric perineal injuries and episiotomies affect postpartum maternal health, especially in relation to perineal pain perception, blood loss, sexual activity and dyspareunia. In addition, the thesis aimed at exploring whether doctors in Nordic countries differ in classification and preferences in episiotomy techniques.

The specific aims of the individual substudies were as follows

**Study 1 (resulting in Paper I and Paper II):**

- to describe the types of episiotomies performed at a large Department of Obstetrics in Norway during one year study period,
- to explore the association between different episiotomy techniques and perineal pain perception the first postpartum day in the same population,
- to investigate if there were any difference between various episiotomy techniques in degree of postpartum blood loss,
- to identify whether different episiotomy techniques were associated with variations in perineal pain perception and sexual activity three months after delivery.

**Study 2 (resulting in Paper III):** To assess sexual activity and dyspareunia one year after delivery related to degree of perineal trauma and delivery mode.

**Study 3 (resulting in Paper IV):** To explore potential differences between Nordic doctors, concerning episiotomy technique of preference, classification of techniques as well as potential differences in perception of clinical indications for episiotomy use.
7. MATERIALS AND METHODS

7.1 Study populations

Study 1 and 2 of the present SAPPHIRE PhD study was conducted at Oslo University Hospital, Ullevål, Norway. The obstetrical unit at this hospital is the largest in Norway, with an annual delivery rate of 7200 pregnancies.

Study 3 of the SAPPHIRE PhD study was based on a survey conducted in Bergen, Norway, at the biennial meeting of the Nordic Federation of Societies of Obstetrics and Gynecology.

Table 2 below summarizes the study populations used in this PhD study.

Table 2 Overview of study populations

<table>
<thead>
<tr>
<th>Main study outcome</th>
<th>Population</th>
<th>Data source</th>
<th>Study design</th>
<th>Study period</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study 1 (Paper I)</strong> Episiotomy technique, perineal pain and blood loss</td>
<td>300 postpartum women with episiotomy</td>
<td>Clinical postpartum examination, personal interview, individual medical records</td>
<td>Prospective observational study</td>
<td>March 2010-March 2011</td>
</tr>
<tr>
<td><strong>Study 1 (Paper II)</strong> Episiotomy technique, perineal pain and sexual activity 3 months postpartum</td>
<td>208 postpartum women (among the 300 above) with episiotomy</td>
<td>Questionnaire</td>
<td>Prospective observational study</td>
<td>June 2011 – June 2012</td>
</tr>
<tr>
<td><strong>Study 2 (Paper III)</strong> Resumption of coitus after delivery and dyspareunia one year postpartum</td>
<td>42 postpartum women with OASI and 840 controls</td>
<td>Questionnaire, hospital obstetrical database, individual medical records</td>
<td>Prospective cohort study</td>
<td>August 2009-August 2011</td>
</tr>
<tr>
<td><strong>Study 3 (Paper IV)</strong> Episiotomy technique preference, classification and indication</td>
<td>297 Nordic doctors</td>
<td>Questionnaire</td>
<td>Survey</td>
<td>A 3 day conference in June 2012</td>
</tr>
</tbody>
</table>
7.1.1 Study 1

Study 1 was a prospective observational study where women with an episiotomy were recruited from the Maternity ward at Oslo University Hospital, Ullevål, with the intent to assess episiotomy technique performance and perineal pain perception the first postpartum day and 3 months after delivery.

The inclusion criteria were (i) episiotomy performed during vaginal delivery, (ii) delivery at more than 28 weeks gestation, (iii) age >18 years and (iv) knowledge of the Norwegian or English language.

All women with an episiotomy, whom were available in their hospital room, were approached and invited to participate. Three hundred women accepted to enroll in the study, all of whom signed an informed written consent agreeing to a postpartum perineal examination to assess the episiotomy technique performed. The consent also agreed to an interview addressing postpartum perineal pain perception the first day after delivery. Perineal pain measurements were scored on an 11-point Visual Analogue Scale (ranging from zero to ten) by 208 of the 300 participants. By signing the consent form, these 208 women also accepted to be contacted later for a follow-up study.

Both recruitment, the postpartum examination in order to assess the episiotomy technique used and the interview were performed (by KF) during day time (office hours), evenings and weekends. All women were examined in the lithotomy position, legs in stirrups and flexed at the hip joints. The examination day varied from 0-3 days postpartum. During examination a transparent plastic film, with the midline already drawn upon it, was placed on the perineum. The midline was determined anatomically from the midpoint of the introitus, running upwards through the clitoris, downwards
and past the anal orifice. The women’s episiotomy suture line was thereafter drawn on the film using a permanent marker pen. The posterior fourchette, vaginal orifice and the anal orifice were also marked. With the film placed on a flat surface, mm length of the episiotomy and mm distance from the posterior fourchette to the incision point were later measured using a tape measure. The episiotomy angle from the sagittal or parasagittal plane was measured in degrees using a protractor. Measurements of episiotomy angle, length and incision point on the plastic films were performed (by KF) and later confirmed by a senior colleague (KL).

Estimated blood loss the first 2 hours after delivery and all other clinical variables were collected (by KF) from the paper patients’ medical records as well as from electronic medical records. The participants were also asked during the interview (with KF) to verify all information on labor recordings in their medical records, such as mode of delivery, type of analgesia or pain relief during labor and to elaborate on any previous deliveries. All the registered data were later checked against electronic medical records, and data were entered into a Microsoft Excel database.

Three months after delivery a postal questionnaire was distributed to all participants that had scored perineal pain on the first postpartum day (n=208). The questionnaire addressed perineal pain relating to the episiotomy scar, perineal wound infection in the puerperal period, breastfeeding as well as sexual activity. In the questionnaire participants were asked to score perineal pain both by VAS and by a Verbal Rating Scale, VRS-5. Pain experiencing women were additionally asked in which situations pain in relation to the episiotomy scar occurred. The given options were at rest, in a seated position, when changing positions, when walking, during
defecation, micturition or intercourse. If pain occurred in any other situation, participants were asked to specify.

7.1.2 Study 2

This study is a continuation of the “Perineum Study”, which consisted of 2 846 pregnant women recruited prospectively during routine ultrasound examination in second trimester at Oslo University Hospital, Ullevål, from September 2009 to August 2010, as shown in the flowchart in Paper III. This routine ultrasound examination is offered to all pregnant women in Norway in gestational week 18-20, and 98% attend, resulting in a non-selected study population. Participants answered a questionnaire in Norwegian (Q1) concerning urinary and anal incontinence, general health condition and worries related to pregnancy and delivery. Demographic data, obstetrical history, educational level, household income, and country of origin were also collected. Results have been published previously (86). All participants gave written informed consent, also agreeing to receive further questionnaires after the index delivery.

Of these 2 846 participating pregnant women, 42 subsequently delivered with an obstetric anal sphincter injury (OASI, defined as perineal injury degree 3 or 4; however all OASI cases in our study were 3\textsuperscript{rd} degree tears). This cohort of 882 women, 42 with OASI and 840 randomly selected controls, 20 controls per case, selected from the initial study population of 2 846, who delivered without OASI, were sent a structured questionnaire by postal mail one year after delivery. The questionnaire (Q2) addressed time of resumption of coitus after delivery, questions on whether there were current problems with intercourse after delivery and specification
of such problems. Specifications were prelisted as 1) Pain at the vaginal orifice during penetration, 2) Pain during deep penetration, 3) Feeling of having too wide a vaginal introitus, 4) Feeling of having too tight or sore a vaginal introitus, 5) Coital garulitas, 6) Anal incontinence, 7) Urinary incontinence, 8) Fear of incontinence of any kind, 9) Lack of sexual desire, 10) Self-reported written specification of any other type of problem. The questionnaire also addressed birth control use and breastfeeding in addition to potential worries concerning socioeconomic status or in regards to motherhood, family or partner relationships. Questions concerning these worries were chosen from the validated Cambridge Worry Scale (87), which was modified to address postpartum women who were not pregnant. The Q2 questionnaires were merged with data from the Oslo University Hospital (Ullevål) local obstetrical database and also merged with data from the first pregnancy questionnaire form (Q1), resulting in a large number of detailed data concerning labor and delivery, maternal demographic data and fetal data. The information from the hospital obstetrical quality registry database was used to assess any inclusion bias in the women that did participate in the studies as compared to those who did not with respect to obstetrical variables.

**Definition of the outcome variables**

Delayed sexual resumption was defined as “more than 8 weeks postpartum” for several reasons. Women in Norway are encouraged to attend a health check 6-8 weeks postpartum, and we hypothesized that many women wait till after this clinical appointment before sexual resumption. The results from Study 1 and the primary
analyses of the Study 2 confirmed this assumption and revealed that 50% of the participating women reported sexual resumption at 8 weeks after delivery.

Dyspareunia was defined as pain at the vaginal introitus during penetration and/or as deep penetrational pain.

### 7.2.3 Study 3

This study was a survey conducted among Nordic doctors to investigate which types of episiotomy techniques doctors in the Nordic countries preferred. We also explored their personal classification of preferred episiotomy type and indications for episiotomy use. All participants were delegates at the biennial Nordic obstetric and gynecological conference in June 2012, in Bergen, Norway. Conference delegates were invited by one of three investigators to participate in the survey during a three day conference (with 500-600 registered delegates).

The participants were asked to list country of employment, years of clinical practice, field of specialty within gynecology and obstetrics and country of obstetrical training. Further survey questions included whether clinicians practiced episiotomy or not, indications for episiotomy performance and specific questions about episiotomy practice during instrumental delivery. All participants were asked to draw an episiotomy as accurately as possible in regards to incision point, angle and length of the cut as how they would perform one in their clinical practice. Episiotomies were drawn on an anatomically sized (1:1) color photograph of a perineum with a crowning fetal head. Participants were also asked to specify the type of episiotomy they had
drawn, choosing from given alternative names or to provide a different name, if appropriate.

The drawn episiotomies were analyzed by the first author (KF) and confirmed by the last author (KL). After inserting a line on the photograph from the clitoris to the anal orifice, episiotomy length and the shortest distance from the posterior fourchette to the incision point were measured in mm using a tape measure. The episiotomy angle from the sagittal or parasagittal plane was measured in degrees using a protractor. We had categorized the episiotomy groups a priori to the survey, based on previous publications and recent discussion in the literature (20,24,28,31,43,88-91). The participants were unaware of our predefined classifications and our definition of the episiotomy types.

Based on episiotomy measurements (incision point distance from the posterior fourchette and angle from the sagittal plane), the drawn episiotomies were categorized into four predefined groups: midline, mediolateral, lateral and non-classifiable episiotomy group.

A midline/mediolateral incision point was defined as an incision commencing 0-5 mm from the posterior fourchette and a lateral incision point as commencing ≥ 10 mm lateral to the fourchette. Incision points ranging from 6-9 mm from the posterior fourchette were considered non-classifiable.

A correct mediolateral angle was defined as an angle ranging between 50 and 80 degrees, due to new evidence suggesting that an angle of at least 60 degrees is necessary to minimize the risk of OASI (26,43). We allowed a slightly narrower mediolateral angle than 60 degrees (down to 50 degrees), due to the fact that a photo
(even if shown in an anatomical true scale) is not equivalent to a clinical setting. Additionally, eyeballing a correct angle on a photographic questionnaire might be more difficult than eyeballing a correct angle during an actual clinical delivery setting.

A correct lateral episiotomy angle was defined as ranging between 45 and 80 degrees. We allowed a narrower angle for the lateral episiotomies compared to mediolateral technique, since a lateral incision commences at least 10 mm lateral to the fourchette, meaning it is directed further away from the anal sphincter, even with a narrower angle compared to a mediolateral incision.

Episiotomies with an incision point commencing 6-9 mm from the posterior fourchette were defined as non-classifiable (neither classifiable as lateral, nor mediolateral episiotomies) regardless of angle.

### 7.2 Statistics

Continuous data were analyzed in a linear regression model as well as dichotomized or categorized where appropriate. Chi square test was used in all studies and a p-value of 0.05 was chosen as level of statistical significance.

In Studies 1 and 2 (Paper I, Paper II and Paper III), univariate analysis was performed to identify the significant factors associated to the outcomes, and variables with $p<0.05$ were included in the multivariate analyses. Multivariate regression analyses were used to adjust for possible confounding factors of relevance, such as delivery method, parity, preterm delivery, epidural analgesia, OASI or any additional spontaneous vaginal tear as well as birth weight, where appropriate.
In Study 3 (Paper IV), results were presented as descriptive, and distributions were presented as percentages. Data reported included mean and ± SD. Chi-squared test was used on categorical data.

Statistical analyses were performed using SPSS (Statistical Program of Social Sciences, version 18.0, Chicago, IL, USA), PASW (Predictive Analytics SoftWare, SPSS Inc, version 20 and version 22, Chicago, IL, USA).

7.3 Ethical considerations

Study 1 and Study 2 are both part of the “Perineum Study” which was approved by the Regional Committee for Medical Research Ethics in South-Eastern Norway (REK) in 2009 (ref. S-08810d/20941). The PhD student and the collaborators view the sensitive patient questions in Study 1 and 2 as appropriate in relation to the aim of the study, as well as in accordance with the study approval from REK. The study followed the Helsinki declaration and the Norwegian Health Research legislation and was approved by the institutional Personal Data Officer. Informed consent was obtained from the women participating in Study 1 and Study 2, presented in Paper I, Paper II and Paper III.

Study 3 was a voluntary and an anonymous survey among Nordic clinicians and exempt from formal ethical board review process. However, the PhD student and her collaborators view the questionnaires as appropriate in relation to the aim of the study, with a good ethical research justification.
8. SUMMARY OF RESULTS

8.1 Episiotomy techniques; perineal pain and blood loss

Of the 300 episiotomies that were clinically examined and evaluated postpartum, the majority were lateral (44%). We also found that mediolateral episiotomy angles were significantly narrower than lateral episiotomy angles (p<0.01).

One third of episiotomies were non-classifiable according to our postpartum definitions of midline, mediolateral and lateral technique, with no difference between doctors and midwives in rate of non-classifiable episiotomies.

Doctors however differed from midwives in performing longer episiotomies (p<0.01), but episiotomy angle did not vary between professions (p=0.08).

No differences between episiotomy techniques in relation to perineal pain perception the first postpartum day (p=0.74) or in estimated blood loss (p=0.38) were found. No differences in pain or blood loss were found when comparing midline and lateral incision points (Paper I).

Three months after delivery very few women (24.6%) had pain in relation to the episiotomy scar, equaling a resolution of pain in 73.2% compared with the first postpartum day. The majority of women who still experienced pain at three months (70.5%) rated their pain as “mild” on the Verbal Rating Scale (VRS-5). We found no statistical significant difference in VAS score distribution between the different episiotomy techniques (Paper II). Women with OASI had significantly higher VAS-scores than women without OASI (Paper II, p= 0.02).
8.2 Episiotomy techniques; sexual activity 3 months postpartum

Of the 179 women with an episiotomy that responded to the 3 months follow up questionnaire, 62% had resumed intercourse three months after delivery. No association between different episiotomy techniques and onset of postnatal intercourse was found. The vast majority of pain experiencing women (75%) reported that their pain occurred during coitus, but no significant difference between different episiotomy techniques and coital pain (Paper II) was found.

8.3 Perineal injury; coital resumption and dyspareunia

In this prospective cohort study, 42 OASI cases and 840 controls, in total 882 women, were invited to answer a questionnaire one year postpartum concerning sexual activity and 561 women responded. Half of the responders (51.4%) reported to have resumed intercourse by 8 weeks postpartum, increasing to 75.2% by 12 weeks and 94.7% one year postpartum.

When categorizing resumption of coitus by 8 weeks, by 3 months and after 3 months in relation to degree of perineal trauma and method of birth, a significant difference in rates of resumption related to degree of perineal injury was found. Women with OASI were significantly more likely to postpone coitus till after three months compared to any of the groups of women with less severe degree of perineal injury or episiotomy. When comparing second perineal degree injuries to episiotomy per se, we found no significant difference in percentage distribution of coital resumption between these two groups at the three time points studied.
In multivariate regression analysis OASI was the strongest predictor for delayed coital onset, defined as after 8 weeks (aOR 5.52, CI 1.59-19.16). OASI was also the only significant predictor for dyspareunia one year after delivery (aOR 3.57, CI 1.39-9.19). Episiotomy was neither a risk factor for delayed onset of intercourse nor for dyspareunia. There were no differences between episiotomy and second degree perineal injury groups regarding delayed coital onset (p=0.45) or dyspareunia one year postpartum (p=0.67) (Paper III).

8.4 Nordic doctors; episiotomy preference and classification

This Nordic survey included 297 doctors in a pictorial questionnaire concerning episiotomy technique of preference and perception of indication for episiotomy uses. The classification of episiotomy technique of preference was heterogeneous among Nordic doctors. The majority of survey participants (47%) drew a lateral episiotomy according to our classification by incision point and angle, but as many as 64% of these 138 doctors misclassified their drawn cut as a mediolateral episiotomy. Only 20% drew a mediolateral episiotomy, the great majority classifying it accurately, but 8% misclassified their mediolateral cut as a lateral episiotomy. One third of episiotomies were non-classifiable, meaning either an incision point ranging between 6-9 mm from the posterior fourchette (n=24) or with a correct mediolateral or lateral incision point, but with too narrow or too wide an angle (n=76). Of the 100 non-classifiable episiotomies, the majority (84%; n=84) had named their drawn cut a “mediolateral episiotomy”, when as many as 55 of those 84 participants had drawn a true lateral incision point (>10 mm from the posterior fourchette), but with too narrow
an angle according to our definition of a correct lateral episiotomy. In general, doctors in Finland, Sweden and Norway more often favored lateral episiotomies compared to doctors in Denmark and Iceland.

When evaluating incision points per se, regardless of the drawn episiotomy angle, 66% of participants had drawn a lateral incision point (≥10 mm from the posterior fourchette) and only 26% a mediolateral incision point (0-5 mm from the posterior fourchette). We found that doctors working in Finland, Sweden and Norway were more prone to a lateral incision point compared to doctors in Denmark and Iceland.

There were significant differences between Finnish and Norwegian vs. Danish and Swedish doctors in perception of clinical indications for episiotomy. Significantly more Finnish and Norwegian doctors considered instrumental delivery, a history of OASI, big baby, breech delivery and prolonged second stage clinical indications for episiotomy use compared to their Danish and Swedish colleagues (p<0.01). Danish and Swedish doctors reported to be more restrictive with episiotomy use during vacuum or forceps delivery, with 92% and 87% reporting that they “never” or “very seldom/sometimes” performed an episiotomy during operative vaginal delivery. In contrast, the majority of doctors in Norway, Finland and Iceland reported practicing episiotomy in >50% of instrumental deliveries, varying from 57% (Norway) to 76% (Finland).
9. DISCUSSION

9.1 Methodology

9.1.1. Study design and study population

The SAPPHIRE Study 1 was a prospective observational study, where 300 women with episiotomy were recruited to participate in a clinical examination and an interview concerning pain perception during the first days after delivery of their hospital stay. They were also invited to participate to a follow-up three months later to a postal questionnaire. Recruitment of patients (by KF) took place any week day, following any time of delivery (whether delivery occurred during day or night) and recruitment also took place during holidays. We therefore believe that the participants were a random selection of the delivering women in our department, and that the study population was not seriously hampered with inclusion bias. However, there was a bias concerning the country of origin among study participants, as understanding of Norwegian or English was a mandatory prerequisite to participate. The delivery population in our obstetric department at Oslo University Hospital, Ullevål, includes 21% non-western immigrants among the delivering women (92,93), and few of these participated in our studies. We defined this group of non-western immigrants as first or second generation immigrants from Asia, Africa, South and Central America, Middle-Eastern countries and Turkey. In our total study population, 11% of participants were non-western immigrants. Only 7% of the 208 participants who responded on the perineal pain score study during the first day after delivery were non-western immigrants. The non-western immigrants who lacked knowledge of the Norwegian or English language were not recruited to participate (n=3), because a major part of the
study required language skills. Since 11% is a considerably smaller percentage than the total population of 21% of non-immigrant women delivering at our hospital, the smaller proportion of non-western immigrants potentially reflects an inclusion bias.

Sample size calculations were not performed prior to our Study 1 as we did not know what findings to expect in regards to percentages of different episiotomy techniques used in our Department and we therefore consider our study to be a pilot study exploring this aspect. However, preliminary sample calculations on the number of women needed if wanting to compare two different techniques to one another were calculated to be approximately 70 in each group. We therefore decided to double this number and include 300 study participants altogether, also as we expected some drop-outs for the longitudinal part of the study. Previous studies, evaluating perineal pain perception comparing a group of women with episiotomies and a control group of women with intact perineum, have included study groups ranging from 100 to 254 (60,70,71,94) and we therefore considered a study group of 300 as being adequate for our study aims.

The SAPPHIRE Study 2 was a cohort study based on a non-selected pregnant population Oslo University Hospital. The women giving birth in our hospital represent all parity groups, heterogeneous obstetrical history and different socioeconomic statuses. All women scheduled for the routine ultrasound appointment during the one year recruitment period were invited to the Perineum study in 2009-2010 by an invitation letter and a questionnaire (Q1) sent along with the scheduled ultrasound appointment. This ultrasound examination is offered to all pregnant women in Norway in the second trimester and 98% attend, giving us a possibility to contact this large
non-selected population. Of the 7 256 invited pregnant women, 2 846 consented to participate and completed the questionnaire (Q1). By consenting to participate, the women also agreed to receive further questionnaires at a later stage, enabling further follow-up studies as the SAPPHIRE Study 2 (Q2) addressing resumption of coitus and sexual complaints one year postpartum in relation to degree of perineal injury.

The response rate on the initial questionnaire (Q1) was 45% (86), and this resulted in an inclusion bias among the initial pregnant study population of 2 846 women and the population of delivering women in our hospital during this time period with respect to parity and country of birth. The clinical data of the 2 846 recruited participants were compared with clinical data of all women who had delivered in the same time period as our recruited study population. There were no differences in mean age between responders and non-responders, but the distribution of nulliparous women in the study cohort was higher (63%) compared to the total delivery population in our hospital (52%). Women with non-Western background were fewer among the responders, but this was also expected, as the questionnaire (Q1) and patient information were written in Norwegian (86). We discuss in further detail, in the following chapter of the thesis, how low response rates are common in questionnaire surveys, but not necessarily cause harmfully biased results.

Sample size calculations were not performed prior to our SAPPHIRE Study 2 as we did not know how many of the 2 846 recruited women who would come to deliver with OASI. That number turned out to be 42 women, eligible for Q2 (in addition to 20 randomly selected controls per OASI case among the initial study population of 2846 women), equalling an OASI incidence of 1.5%. This OASI incidence corresponds to
the current low OASI incidence at our hospital. There is no reason to believe that study participants with OASI differ from the remaining OASI population at our hospital.

SAPPHIRE Study 3 was a pictorial questionnaire survey conducted at a Nordic 3 day conference with approximately 500-600 registered delegates. Recruitment took place by personal approach and invitation to participate from 3 investigators. Not all conference delegates were reachable during the conference, but none of the approached delegates refused to participate. We cannot exclude an inclusion bias in our study, as conference delegates may be more or less clinically active or eager to follow-up clinical updates compared to non-participating doctors. As many as 80% of our survey participants were consultants and even though 34% and 32% stated their subspecialty to be obstetrics or to perform equally much work in obstetrics and gynecology, respectively, 34% stated their subspecialty to be gynecology. A subspecialty gynecologist may not be as aware of episiotomy practice or name-labeling of different episiotomy techniques as doctors working in clinical obstetrics. Additionally, trainees (representing only 20% of the responders) most likely perform episiotomies more often than their senior doctors. On the other hand, trainees are also likely to be taught episiotomy performance by their senior doctors.

Yet another aspect is that our survey participating doctors may not be representative for obstetrical practice in their country of practice, nor at their local hospital. Our survey reflects attitudes and personal perceptions that are not in fact based on data from local obstetrical databases. We could have chosen a different methodology for our survey and e.g. sent questionnaires to individual units in the different Nordic countries and asked for objective data on episiotomy rates. However,
personal and active face-to-face invitation during a meeting probably resulted in a higher response rate than we would be able to obtain through a postal questionnaire study. A postal questionnaire might also have proven difficult as it would require doctors to take time from their busy and hectic clinical schedules or completing questionnaires in their spare time. We therefore considered our direct and personal survey approach at a conference with participants from all Nordic countries better in obtaining the data needed in the study.

9.1.2. Self reporting questionnaires and response rates

In the first part of SAPPHIRE Study 1 the 300 women were personally interviewed and clinically examined by the PhD student (KF), which resulted in a high response rate, only 7 patients of the 310 women approached refused participation. The remaining three were excluded due to lack of knowledge of the Norwegian or English language. The reasons given for refusing participation were not finding the time, not finding the study of interest or spouses unwilling to allow participation.

The 11-point Visual Analogue scale (VAS) used to assess perineal pain was explained to each participant in a personal interview, being beneficial to participants who did not know what such a scale represented. Thus, all women interviewed on the first postpartum day (n=208), scored perineal pain in the first part of the Study 1.

The second part of the Study 1 was a postal questionnaire 3 months after delivery to all women who had scored perineal pain on the first postpartum day, and used the same 11-point VAS to assess pain in addition to questions concerning sexual activity. Response rates again where high (87.7%). In Study 2 however, the sexual
activity questionnaire (Q2) was sent to participants one year after delivery, resulting in a lower response rate (63%) than in Study 1.

Obtaining high response-rates on self-administered questionnaires is difficult. A low response rate is common in questionnaire surveys (95,96). Even so, a low response-rate does not necessarily imply a selection bias in itself (95,97). Stigum et al. carried out a supplementary study in 1992 to explore whether participants and in a sexual behavior survey differed in their patterns of sexual behavior from non-participants. He found no statistical differences in sexual behavior between the two groups (96). Also a Finnish report has shown that non-response is fairly random with respect to sexual behavior (98).

In case of low response rates, a comparison of responders vs. non-responders can however, reveal selection bias. Such analyses were included in regards to obstetrical data for the responders and non-responders in Paper III, but no difference between these two groups was found.

A validated sexual function questionnaire was not used in the SAPPHIRE study, as the aim was not to address female sexual function or female sexuality per se, but to assess potential differences in time to coital resumption and potential problems with coitus one year postpartum in relation to degree of perineal injury.

It is not uncommon to use non-validated questionnaires in epidemiological studies when the aim is to get a general overview, and not to assess topics in depth. The Norwegian Institute of Public Health has conducted several epidemiological survey studies on health and sexual behavior in Norway using non-validated questionnaires, but including simple questions like “Are you sexually active or not”,
with the response options being “yes” and “no”. If the answer was yes, the degree of sexual problems were measured by the question “Have you experienced any of the sexual problems listed below during the past 12 months/or since sexual activity was retained after birth” (96). The simple specific questions about coital difficulties one year after delivery were therefore considered to be appropriate to assess the outcome measures of interest in this thesis. A weakness of the study, concerning sexual activity and dyspareunia, is the lack of information on such complaints and potential problems prior to delivery. There is however no reason to believe that the OASI responders in this study were more likely to have had sexual complaints before delivery as compared to the non-OASI women, or the other way around.

Questions from the validated Cambridge Worry Scale were also used in the one year postpartum questionnaire, although modified to women who were no longer pregnant (87,99). The Cambridge Worry Scale measures women’s worries on a scale from 0 (not a worry) to 5 (a major worry) with the intent to assess worries concerning personal health, relations to friends and family, economical situation, personal health behavior (smoking, drinking) and also worries related to pregnancy (labor and delivery) as well as the baby’s health. This scale was chosen to assess the general level of study participants’ worries, but also to explore a possible association between such worries and sexual activity after delivery.

9.1.3. Perineal injury classification

The episiotomy performance in Study 1 was carefully documented in a clinical postpartum examination of 300 women with episiotomy. A clinical examination was
chosen as the method in this study to collect exact information on episiotomy measurements in terms of incision point, angle and length. Such detailed information is not possible to achieve from hospital medical records, or medical birth registries or based on the medical staff’s self-reported episiotomy technique performed. The latter is not a trustworthy method, as intended techniques are commonly performed incorrectly, and episiotomy techniques are often misclassified (27,28,91,100), as this thesis has confirmed (Papers I and IV).

The clinical examination was therefore a novel approach and it is the most accurate way to classify episiotomy performance and categorization of different techniques in a clinical prospective observational study. The clinical evaluation and examination was conducted postpartum and not during crowning of the fetal head at the time of episiotomy incision during delivery. The incision point distance to the posterior fourchette in mm postpartum and the episiotomy suture angle in degrees postpartum do therefore not equal the actual incision angles or the actual mm distance from the posterior fourchette if measurements had been performed during delivery when the perineum is stretched during crowning of the fetal head. Therefore, categorization of episiotomy technique was based on previous studies of episiotomy technique performance (26,28-30,42), also describing the shrinkage in episiotomy incision angle compared to episiotomy suture angle. Two of these studies by Kalis et al. (26,30) showed that a mediolateral incision angle, performed during crowning of the fetal head, is reduced 15-20 degrees when re-measured after suture. We hypothesized that lateral episiotomies would have a similar reduction in angle when
comparing incision angle to suture angle, but this postulation would need to be confirmed in future clinical trials.

Another bias of the postpartum measurements may be that the clinical examination day varied from 0 to 3 days postpartum. This time interval variation from delivery to examination may have influenced the amount of perineal edema and hence compromised optimal clinical measurements. As there is no way of documenting or classifying the amount of perineal edema in different individuals, and neither had several clinical examinations per patient, it cannot be excluded that this factor may have contributed to incorrect classification of angle and incision point. Individual variations in degree of perineal edema, even if the examination day had been set to a specific time interval after delivery, could albeit also have influenced potential measurements. However, edema has unlikely hampered results to a large degree, as this part of the perineum is relatively flat and any potential edema would have been equally distributed equally throughout the tissue. The optimal time of measuring and evaluating episiotomy performance would indeed have been during delivery at the time of incision. Unfortunately, the study design did not allow performance of such measurements as it would require an informed written consent from participants prior to labor. Since the episiotomy rate at Oslo University Hospital, Ullevål, is approximately 28%, it would have taken a considerably longer time period of recruitment if clinical evaluations were to be performed at the time of episiotomy incision in the labor ward. Additionally, it would require 24 hour presence in the labor ward (by KF) in order to carry out clinical examinations, as one sole examiner was intended to perform all examinations, in order to reduce potential variations in
examination performance. Postpartum measurements were therefore chosen, both due to logistics and to the limited time available for the PhD-student to complete the study, but also on account of similar methods in previous studies used to evaluate episiotomy performance.

A strength of Study 1 is that a clinical examination was performed to document the exact angle and length of the episiotomy, as well as the cutting point, enabling exact categorization of the episiotomies and additional perineal injury, and enabling analyses of the association of these components with pain perception, blood loss and postpartum wound infection.

The study did not incorporate a control group without episiotomy, as it was designed to clinically investigate how episiotomies were performed with the intent to assess outcomes such as perineal pain. A control group without episiotomy would have further increased the value of this study, enabling assessment of pain perception among women with first and second stage injuries, or no perineal injury at all. However, in Study 2 we included both women with and without episiotomy and different delivery methods and therefore perineal pain related to all degrees of perineal injury could be assessed.

In Study 2, perineal injury was classified by the attending midwife or doctor, and recorded in the patient records and in the obstetrical quality registry database. The classification of the perineal injury in the individual medical records (considered the gold standard) was double checked against the database for all the 561 women who responded to our questionnaires (Q1 and Q2). The different degrees of perineal injury; degree one through four, in addition to intact perineum and episiotomy, were all
categorized separately in the analyses. The separate categorization is a strength of the study, as many previous publications in relation to perineal pain, dyspareunia and/or time to resumption of coitus have merged different degrees of perineal injury into one group (11,63-67).

However, in Study 2, no information about the episiotomy technique used was available, only information on whether an episiotomy had been performed or not.

9.1.4 Perineal pain assessment

Of the 300 participating women, 208 scored perineal pain on the first day after delivery. The first postpartum day was chosen as the women’s stay in the Maternity ward varied from 2 to 4 days, and logistics made it easier to ask consenting women about perineal pain perception on the first postpartum day which was the same day the majority of participants agreed to enroll in the study. Pain is a subjective experience (perception), and self-reporting pain scores are commonly used. VASs (Visual Analogue Scales) are continuous graphical rating scales, first described by Hayes and Paterson in 1921. PubMed registers in January 2016 more than 21 000 publications with VAS scores, documenting its common use in pain perception studies. An 11-point VAS was used in this thesis, ranging from 0 to ten, for assessment of perineal pain perception in Paper I, as VAS scores was considered to be the most reliable way of rating such a subjective outcome as pain. Previous studies have shown that visual analogue scales are reliable scales and sensitive to changes, and only 7 % of those who respond, find it difficult to score, most prominent for the elderly (101). By definition, no elderly women participated in this thesis studying women in fertile age.
In a systematic review article by Hjermstad et al. from 2011, the authors aimed to investigate the use and performance of undimensional pain scales. In terms of compliance and usability, the study found that when reported, better compliance was reported for the Numerical Rating Scales (NRSs)/VRSs relative to the other scales in 15 studies, whereas 16 studies did not provide any such information. Lower compliance on the VAS was found in nine studies, associated with higher age, degree of trauma or other impairments. Compliance results were based on the number of patients who were able to perform the ratings, the number of correct answers, and error rates percentages. In some studies, test/retest scores and discriminant validity between patient groups also were used to indicate compliance (102). Based on this information, the 11-point (numerical) Visual Analogue Scale ranging from zero to ten was used in this thesis, as opposed to a standard continuous graphical Visual Analogue Scale.

In the 3 month follow-up study (Paper II), in addition to using an identical 11-point VAS for comparability, the women were also asked to rate their pain on a 5-point Verbal Rating Scale as “no pain”, “mild pain”, “moderate pain”, “severe pain” and “excruciating pain” as well as to elaborate on in which situations pain occurred. The study aimed to compare pain assessment scored on a numerical scale at the two time intervals (the first postpartum day and 3 months postpartum), but also to be able to evaluate potential pain scoring discrepancies between a numerical VAS and a Verbal Rating Scale. The reason for this was a hypothesis about numbers not necessarily being perceived identically among individuals, but that verbal ratings might perhaps be more concurrent. Regardless of outcome, it is an advantage to be
able to analyze perineal pain perception on two different and separate scales and that a comparison of numbers to verbal ratings would strengthen potential findings.

9.1.5 Dyspareunia and sexual activity

In SAPPHIRE Study 1, in the 3 month follow-up study, dyspareunia was defined as “pain during intercourse”. In Study 2 dyspareunia was addressed both as pain at the vaginal introitus during coitus and as deep penetrational pain in the questionnaire one year postpartum.

Validated questionnaires for sexual function, sexual satisfaction or dissatisfaction were not used in this study, and dyspareunia in itself may not be a measure for these outcomes. The aim was however, not to address female sexuality per se, but merely to investigate if there could be potential differences between different episiotomy techniques and degrees of perineal injury in relation to self-reported dyspareunia after delivery as well as in regards to time of resumption of coitus. As mentioned previously in this section, The Norwegian Institute of Public Health has conducted several epidemiological survey studies on health and sexual behavior in Norway using non-validated questionnaires, but simple questions like “are you sexually active or not”, with the response options being “yes” and “no”. The similar and simple specific questions about coital difficulties one year after delivery were therefore considered to be appropriate to assess the outcome measures of interest in this thesis.
9.1.6 Blood loss during delivery

There are several sources for vaginal blood loss during delivery, and separate bleeding from the episiotomy is not regularly registered in medical records. All blood loss data were estimations carried out by the accoucheur in charge of the delivery. Such estimations are rough estimations, and carry the bias of an individual assumption. Previous studies addressing episiotomy and postpartum hemorrhage have also used blood loss data based on individual estimations, but very few have used objective measuring methods of blood loss like evaluating changes in hemoglobin and decrease in hematocrit parameters compared pre- and post-delivery. These studies, however, mainly focus on risk factors for obstetric hemorrhage in general (103-105). Blood loss estimations during delivery are not a reliable source or especially suited to evaluate blood loss from the episiotomy incision itself and therefore results must be interpreted with caution.

9.1.7 Confounding factors

Pain perception, intercourse resumption after delivery and blood loss during delivery may be associated with many factors, and not only perineal injury or episiotomy technique. Therefore, multivariate analyses were performed in Study 1 and 2. The study exposures were adjusted for maternal age, parity, epidural use, delivery method, duration of the second stage of delivery, significant items from the Cambridge Worry Scale, socioeconomic status and educational level to assess confounding from these factors. In addition to these significant factors, we also analyzed a broad spectrum of maternal and fetal factors, as well as factors concerning parenthood, to explore their influence on sexual activity after delivery. All items from the Cambridge Worry Scale
were analyzed, but only those with association to the outcomes of interest were included in the multivariate analysis. Variables such as maternal BMI, breastfeeding, newborn birthweight, prematurity and multiple births were also analyzed, but not found associated with the outcomes.

A weakness of this study is that factors like postpartum depression, post-natal Post Traumatic Stress Disorder or other psychological parameters that may all impact sexual functioning and sexual activity, were not assessed. Many variables may influence sexual activity after delivery, as well as dyspareunia, but in this study the aim was to assess the documented obstetric factors only.

9.2 Discussion of the results

9.2.1 Episiotomy technique

The majority of existing literature on episiotomy has involved either midline episiotomy or mediolateral episiotomy. However, this research has been hampered by a lack of a clear and standardized definition of the direction of the episiotomy incision. Several recent studies demonstrate a lack of a standardized definition for mediolateral episiotomy and the level of knowledge of clinicians in this area is, consequently, considered unsatisfactory (27). A European survey documented wide variations in the definition of mediolateral episiotomy, where half of all hospitals failed to present descriptive data on their episiotomy procedure and 9% of these even confused the different types (27). The remaining institutions provided a total of 14 different definitions of mediolateral episiotomy. Even in the Cochrane review of episiotomy from 2009, an exact classification or definition of episiotomies is lacking (9), and
indeed the individual studies included in this Cochrane Review are variable and lacking in specific details. Furthermore, the descriptions of mediolateral episiotomy in standard obstetric textbooks differ widely. Some provide only descriptive terms, while others recommend a particular angle of incision away from the midline, most usually 45 degrees (9). It is possible to estimate the likely incision angle from the incision descriptions in other texts; these vary between 31 degrees and 63 degrees (106,107), suggesting wide variations in the practice of episiotomy worldwide. Since it is well established that a significantly higher risk of anal sphincter injury is associated with midline episiotomy compared with the mediolateral technique (21,22), the exact location of the incision and the angle it subtends with the midline plays a crucial role. Acutely angled mediolateral episiotomies increase the OASIS risk associated with midline episiotomy. This hypothesis is supported by a review suggesting that inconsistent incision angles may in part explain the different outcomes seen in different studies regarding mediolateral episiotomy (108).

Only 13% of episiotomies in Study I in this thesis were classified postpartum as being mediolateral and 44% were classified as lateral. As many as 36% of episiotomies were considered non-classifiable according to our postpartum definitions. The incision points in the non-classifiable group in Study 1 commenced 3.1-9.9 mm from the posterior fourchette (n=75). Whether these episiotomies were intended to be mediolateral or intended to be lateral is unclear. A pictorial questionnaire study by Tincello et al (28) showed that as much as one third of professionals began a mediolateral incision point lateral to the midline. This may be due to incorrect training in mediolateral episiotomy technique, and we cannot exclude incorrect training in
mediolateral or lateral episiotomy technique to be the cause of such a large non-classifiable group in our study. As the measurements were performed after delivery, the classification of a lateral incision point commencing ≥10 mm from the posterior fourchette may have been too strict; thereby grouping some correctly performed lateral episiotomies as non-classifiable. Nevertheless, a large number of the 300 episiotomies were performed inadequately.

Another bias of the postpartum measurements may be that the clinical examination day varied from 0 to 3 days postpartum. This time interval variation from delivery to examination may have influenced the amount of perineal edema and hence compromised optimal clinical measurements. As there is no objective way of documenting or classifying the amount of perineal edema in different individuals, and because there was only one clinical examination per patient in Study 1, this factor may have contributed to incorrect classification of angle and incision point. Individual variations in degree of perineal edema, even if the examination day had been set to a specific time interval after delivery, could albeit also have influenced potential measurements. However, edema has unlikely hampered the results to a large degree, as this part of the perineum is relatively flat and any potential edema would have been equally distributed equally throughout the tissue. The optimal time of measuring and evaluating episiotomy performance would indeed have been during delivery at the time of incision. Unfortunately, the study design did not allow performance of such measurements, as it would require an informed written consent from participants prior to labor. Since the episiotomy rate at Oslo University Hospital, Ullevål at the time of recruitment was approximately 28%, it would have required inclusion of a challenging
large number of pregnant women and a considerably longer time period of recruitment if clinical evaluations were to be performed at the time of episiotomy incision in the labor ward. Additionally, it would require 24 hour presence in the labor ward (by KF) in order to carry out clinical examinations, as one sole examiner was chosen to recruit participants in order to reduce potential variations in examination performance. Postpartum measurements were therefore chosen, both due to logistics and to the limited time available for the PhD-student to complete the study, but also on account of similar methods in previous studies used to evaluate episiotomy performance.

Even though Study 1 brings additional information to the literature on episiotomy and especially adds to the knowledge on lateral episiotomy technique in relation to postpartum perineal pain, blood loss and dyspareunia, further research is needed on the three most practiced episiotomy types in the industrialized world, namely the midline, mediolateral and lateral technique, in order to assess their value in optimizing obstetric outcomes and perineum health. Since RCTs on this particular topic is problematic, large observational studies are warranted, especially in relation to quality improvement of both mediolateral and lateral episiotomy performance.

The findings from Study 3 also revealed a large non-classifiable episiotomy group in addition to large misclassification rates within and across the Nordic countries. In a review published in 2012, during the same year as our study 3 was conducted, Kalis et al. suggested a standardization of episiotomy definition (20). This may be the necessary first step for both awareness of episiotomy performance amongst clinicians in general and also towards an international consensus on episiotomy definition in order to adapt to a correct and internationally unified episiotomy
techniques, which is an important area of focus in terms of education of obstetricians as well as midwives.

Achieving consensus amongst clinicians on the classification of the different types of episiotomy is crucial for a proper evaluation of this surgical procedure, along with its alleged benefits, as well as possible complications as OASI, when too narrow incision angles are used. Moreover, standardization of the surgical incision will enable data pooling (for meta-analyses) by reducing the heterogeneity between studies, and thus provide more valid conclusions.

**9.2.2 Perineal pain**

Almost all existing literature addressing episiotomy and postpartum perineal pain are performed on the midline or the mediolateral technique. Several studies have compared episiotomies to an intact perineum or to spontaneous second degree lacerations in relation to pain perception (60,71,94,109), but very few studies have compared different episiotomy techniques (21,110,111). Prior to Paper I, no study had previously included the lateral technique in a comparative study. Several authors had however postulated that the lateral episiotomy technique would be more painful than the mediolateral episiotomy technique (33,75,76).

The women in Study 1 were asked to rate their pain perception on an 11-point Visual Analogue Scale, ranging from zero to ten. Most women reported low (0-3) or moderate (4-7) VAS scores, 37% and 43% respectively. Only 20% reported high postpartum pain scores.

Regardless of the large non-classifiable group being the result of suboptimal episiotomy performance and/or non-optimal measurements, no significant differences
in perineal pain perception were found when comparing midline, mediolateral, lateral and non-classifiable groups. It can, however, be argued that the very small midline episiotomy group and the small mediolateral group are too small to be compared to the lateral and non-classifiable groups. Therefore, different incision points from posterior fourchette (regardless of episiotomy angle) were categorized to create larger groups to the comparison analyses. The incision point categorizations in Study 1 were 0-3 mm (midline incision point, n=43), 3.1-9.9 mm (non-classifiable incision point, n=51) and ≥10 mm (lateral incision point, n=114). When comparing the different incision point groups, there were still no significant difference between groups in terms of perineal pain perception measured with VAS-scores, supporting the findings that lateral episiotomies were not associated with more pain than the other episiotomy techniques.

All women were asked about pain relieving medication intake and medical charts were screened for distribution of pain relieving medication in the Maternity ward. It is possible that the pain scores were influenced by the amount of pain killers self-administered by the participants, and that the VAS scores hence would be non-representative for the actual pain experience without medication. We did, however, find it difficult to obtain reliable information on the amount of pain killers taken by participating women. Pain killers were administrated to women who experienced pain, but it is unsure to what extent they used the medication, as many participants had problems memorizing the amount of pain relieving medication taken when they were asked to elaborate in the interviews.

The majority of participants (81%) had used a pain relieving medication like acetaminophens at some point after delivery. When comparing the group of women
with no analgesia after delivery with the group having taken pain relieving medication, no differences in VAS score distribution between those two groups was found.

Another factor that may be likely to influence pain perception is ethnicity. Different cultures may have different ways of expressing pain. In our pain scoring group, our non-western immigrant population was as low as 7% and therefore not likely to have pooled VAS-score distribution in any particular direction.

After Paper I was published, Karbanova et al. conducted a follow-up study of their randomized controlled trial with 790 primiparous women, comparing mediolateral episiotomy incised with an angle of at least 60 degrees to lateral episiotomy incised 1-2 cm from the midline and directed towards the ischial tuberosity. The primary outcomes were pain at 24 hours, 72 hours, and 10 days postpartum, measured by a visual analog scale, verbal rating scale, interference with activities of daily living, and amount of analgesic use. The authors found no significant differences in overall pain scores from any rating system or in the amount of analgesics used (38). These findings are in compliance with and support the observational study findings in Paper I and Paper II, comparing different episiotomy techniques and perineal pain perception the first day after delivery and at 3 months postpartum.

9.2.3 Blood loss

As described in the Paper I, postpartum blood loss varied from 100 to 2 000 ml and in most cases (74%) blood loss was estimated to 400 ml or less. No difference in mean postpartum blood loss was found when comparing midline, mediolateral and lateral technique. Postpartum blood loss was also dichotomized into normal (0-499 ml) and
excessive (≥500ml), but there were still no differences between episiotomy techniques. Repeating the analyses after exclusion of women with retained placentas and atonic hemorrhage of ≥1,000ml did not alter the results.

To our knowledge only two recent studies have addressed episiotomy technique (although only midline and mediolateral technique) and blood loss per se using objective measurements (77,112). Both these studies compared timing of episiotomy repair, before or after placental delivery, in median and/or mediolateral technique. Baksu et al. measured decreases in hemoglobin and hematocrit levels comparing values before birth to 24 hours post-delivery. Ozdegimenci additionally measured postpartum blood loss with calibrated collecting bags placed under the women immediately after birth. Baksu et al. found a significant difference in blood loss between midline and mediolateral technique when repair was done after placental removal. No differences between techniques were found when repair was done before placental delivery. This correlates with the blood loss findings in our study, as our department practices episiotomy repair before placental delivery. There is however still a need for further research on episiotomy technique and association to blood loss with more objective parameters like decrease in hemoglobin and hematocrit levels to better evaluate potential differences between midline, mediolateral and lateral episiotomy technique. It is however unlikely that such study would reveal major alterations in blood loss, based on our current findings. Also, most episiotomies result in far less bleeding that postpartum atonic uterine bleedings or cervical obstetrical lacerations, and are in themselves unlikely to significantly reduce hemoglobin levels, when properly performed.
9.2.4 Resumption of coitus and dyspareunia

In Study 1 participants were asked about time to sexual resumption 3 months postpartum. Sixty-two percent had resumed intercourse at 3 months. The time range of resumption ranged from 2 to 12 weeks, with a median of 8 weeks. This question on resumption was therefore a retrospective question for many responders, and answers may have been influenced by recollection bias. On the other hand, the vast majority of responders (160/179) were primiparous, and one might argue that primiparous women would be more aware than multiparous women of the time they choose to resume or attempt resumption of intercourse after a first delivery, and perhaps especially after having experienced a surgical intervention with episiotomy. When comparing different episiotomy techniques, no difference was found in time to coital resumption, nor was there a significant difference between short and long episiotomies in regards to coital resumption. A strength of this study includes the high response-rate (87.7% of episiotomy women) as well as the clinical evaluation and accurate postpartum classification of the episiotomy techniques performed.

In SAPPHIRE Study 2, the questionnaire was distributed to participants one year postpartum, which could pose a greater risk of answers on coital resumption being hampered by recollection bias compared to such a question being asked at 3 months postpartum. However, as the women were not contacted prior to one year postpartum in Study 2, a retrospective recall was the only option. If questionnaires had been sent, addressing the same issues at several postpartum intervals, response rates could have fallen throughout the one year follow-up period. Valuable one year postpartum response data might have been lost, if the same questions were asked many
times. The main finding of OASI being the strongest predictor for postponed coital resumption in multivariate analyses is of great value whatever way this information was collected. For the responders, the resumption question will be a retrospective question at any given time interval, unless participants are to be encouraged to give notice at the time they actually resume coitus, which is unlikely to be feasible.

The questions concerning dyspareunia, however, were if there were current issues. In SAPPHIRE Study 1 in the 3 month follow-up study, dyspareunia was defined by us as “pain during intercourse”. The vast majority of pain experiencing women (33/44) reported pain to occur during coitus, but no significant difference among different episiotomy techniques and coital pain was found. The great strength of the conclusions is again the clinical examination, evaluation and accurate categorization of all episiotomies in our study population. To our knowledge, no previous study has documented episiotomy techniques in a clinical examination setting with such comprehensive data (on both the midline, mediolateral, lateral and non-classifiable technique) for comparison in relation to sexual activity after delivery. One can however argue that the pain experiencing women in this study at 3 months postpartum were few and that larger studies are needed to validate the findings.

Few studies have addressed female sexuality after OASI, and even fewer in a long-term perspective of more than 6 months. In Study 2 dyspareunia was addressed both as “pain at the vaginal introitus during coitus” and as “deep penetrational pain”. Dyspareunia and coital difficulties were assessed one year postpartum, and separate multivariate analyses of spontaneous second degree tears compared to episiotomy were conducted, which is a more accurate approach in terms of most existing
literature. The multivariate analyses showed that at one year after delivery, neither episiotomy, nor spontaneous second degree tears were risk factors for dyspareunia. When comparing episiotomy to second degree tears in separate multivariate analyses, there were no differences in regard to dyspareunia between the two groups. This is a novel finding as previous studies comparing episiotomy to spontaneous tears vary in terms of dyspareunia. However, divergent results in relation to other studies may be influenced by the fact that many previous studies lack a correct grouping of different degrees of perineal injury, mixing heterogeneous degrees or failing to specify degree of perineal injury. Another explanation could be that previous studies have heterogeneous study designs, heterogeneous evaluation of exposure and/or outcome measure, as well as assessment at different postpartum intervals.

A clear limitation in this study is as previously mentioned, that lack of information regarding dyspareunia prior to delivery. However, initial recruitment took place during a routine US examination in gestational week 17-19, and pre-pregnancy sexual problems would then have had to be addressed as retrospective questions. There is no reason to assume that OASI occurs more often in women with sexual problems prior to pregnancy as compared to women that do not undergo anal sphincter injury during delivery. Non-responders and responders were compared in separate analyses, and these two groups did not differ in terms of obstetric variables. Despite lacking information about potential sexual problems prior to delivery, the conclusion of OASI being an independent and strong predictor for postponed coital onset as well as for dyspareunia one year postpartum, seems justified.
10. CONCLUSIONS

Study 1 showed that lateral episiotomy technique was the technique of preference in our department, used in 44% of the 300 women recruited with episiotomies. A large group (36%) of non-classifiable episiotomies was found. Much fewer women underwent midline and mediolateral episiotomies, 6.7% and 12.7% respectively. Doctors performed significantly longer episiotomies than midwives, but episiotomy angle or incision point did not vary between professions.

When comparing the different episiotomy groups, no significant differences between them in relation to perineal pain perception the first postpartum day or in relation to postpartum blood loss was found. Neither was there a difference in perineal pain perception or dyspareunia at 3 months comparing different episiotomy techniques and different episiotomy incision points.

Multivariate analyses showed OASI to be the strongest predictor for delayed sexual resumption after delivery as well as for dyspareunia one year postpartum. Episiotomy was not a risk factor for either outcome. When comparing episiotomy to second degree injuries per se, there were no differences in delayed sexual resumption, nor in dyspareunia one year postpartum between these two groups.

Suboptimal episiotomy practice, as found in one third of deliveries in Study 1 (Paper I) as well as in our pictorial questionnaire survey (Study 3, Paper IV), demonstrates a need for more training in order to optimize episiotomy performance with the main intent to help reduce obstetric anal sphincter injury to a minimum.
The EPISCISSORS-60

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11. FURTHER STUDIES

The ideal randomized controlled trial of the three most commonly performed episiotomy types may indeed be highly difficult to conduct, because inclusion of the midline episiotomy technique in such an RCT is not feasible, as it is well established that the midline technique poses a greater risk of OASI. However, future studies comparing optimal performance of the midline, mediolateral and lateral technique, with larger episiotomy group entities would indeed be very important for in greater detail study the health effects of this commonly performed procedure. Further studies on episiotomy technique are therefore dependent on observational study designs and that such studies should be conducted locally, regardless of the episiotomy type advocated for in local guidelines. This in order to evaluate the quality of episiotomy performance in different delivery units, with the overall aim to improve performance. Such studies will contribute to increased awareness and most likely future educational programs on optimal episiotomy techniques. Large national and international observational studies with carefully documented episiotomy incision point and correct angle performance would also be valuable in order to fill the knowledge gap and to produce more firm evidence on associations between different episiotomy techniques and OASI, additionally with respect to long term health effects of episiotomy.

The EPISCISSORS-60 invention has so far shown promising results in terms of securing optimal mediolateral angle performance, and consequently minimizing the risk of OASI. To date, the existing studies are small, and large scale studies comparing this new instrument to conventional scissors should be embarked on as well.
12. ERRATUM
13. REFERENCE LIST


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14. PAPERS I-IV