doi:10.25143/prom-rsu_2022-01_dt

RĪGA STRADIŅŠ UNIVERSITY

Vita Začesta

Anal Sphincter Muscle Activity Changes in Women after Delivery

Doctoral Thesis for obtaining a doctoral degree
"Doctor of Science (*Ph.D.*)"

Sector – Clinical Medicine
Sub-Sector – Obstetrics and Gynaecology

Riga, 2022

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Abstract

An episiotomy is one of the most common surgical interventions in obstetrics. Mediolateral episiotomy is usually performed on the right side. Recent advances in pelvic floor electromyography (EMG) allow to perform functional analysis of external anal sphincter with a minimally invasive anal probe. An individual asymmetry of the sphincter exists, and it is strongly associated with postpartum incontinence, primarily when the trauma occurs on the dominant side of innervation.

This Thesis aims to evaluate the external anal sphincter innervation zone distribution and EMG amplitude before and after delivery and to observe the effect of episiotomy on changes of sphincter innervation.

The study is a prospective cohort study. Three hundred pregnant women were recruited to the study, and two surface EMG measurement sessions (before and 6–8 weeks after delivery) with multichannel cylindrical anal probes were performed. One hundred women participated in the third measurement session at one-year follow-up. The distribution of innervation zones and global EMG signal amplitude average rectified value was assessed, and the amplitude asymmetry index was calculated. The outcomes were compared before and after delivery between different delivery types (caesarean section, mediolateral episiotomy, spontaneous lacerations and intact perineum) and according to the asymmetry index. Additionally, the anal incontinence score was evaluated before and after delivery.

The results showed a significant reduction of innervation zones in the right ventral quadrant after delivery with right side episiotomy. After delivery, a significant decrease in global EMG amplitude was observed in women with amplitude asymmetry on the right side and in those who underwent mediolateral right episiotomy. The incontinence score slightly but not significantly increased 6–8 weeks after the delivery in 20 % of caesarean and 30 % of vaginal deliveries.

The main conclusions of the study are that 1) episiotomy reduces external anal sphincter muscle activity, 2) multichannel surface electromyography is a promising method to analyse the anal sphincter activity. EMG signals detected during pregnancy could be used to decide the optimal side of episiotomy, thus reducing the damage to the sphincter innervation caused by the episiotomy itself.

Keywords: multichannel sEMG, external anal sphincter, innervation zone, episiotomy, delivery type, incontinence.

Anotācija

Anālā sfinktera muskuļa aktivitātes izmaiņas sievietēm pēc dzemdībām

Epiziotomija ir viena no biežākajām ķirurģiskajām manipulācijām dzemdniecībā. Mediolaterālo epiziotomiju parasti veic labajā pusē. Jaunākie atklājumi iegurņa pamatnes elektromiogrāfijā (EMG) ļauj veikt ārējā anāla sfinktera funkcionālu analīzi ar minimāli invazīvu anālo detektoru. Pastāv funkcionāla sfinktera asimetrija, un tā ir cieši saistīta ar inkontinenci sievietēm pēc dzemdībām, īpaši tad, ja trauma bijusi dominējošajā inervācijas pusē.

Darba mērķis ir novērtēt ārējā anālā sfinktera inervācijas zonu sadalījumu un EMG signālu amplitūdu pirms un pēc dzemdībām, kā arī noteikt epiziotomijas ietekmi uz anālā sfinktera inervācijas izmaiņām.

Šis ir prospektīvs kohortas pētījums, kurā tika iekļautas trīssimt grūtnieces, kas piedalījās divās EMG mērījumu sesijās (grūtniecības 3. trimestrī un 6–8 nedēļas pēc dzemdībām). Trešajā mērījumu sesijā, kas notika gadu pēc dzemdībām, piedalījās simts sieviešu. EMG mērījumus veica ar cilindriskiem daudzkanālu anāliem detektoriem. Tika novērtēts inervācijas zonu sadalījums un globālās EMG signālu amplitūdas vidējā rektificētā vērtība, un noteikts amplitūdas asimetrijas indekss. Rezultātus salīdzināja pirms un pēc dzemdībām starp šādām grupām: dzemdības ar ķeizargriezienu, mediolaterālu epiziotomiju, spontāniem plīsumiem, un dzemdībām bez plīsumiem, kā arī un atbilstoši asimetrijas indeksam. Novērtēja arī anālās inkontinences skalu pirms un pēc dzemdībām.

Rezultāti liecina par ievērojamu inervācijas zonu samazināšanos labās puses ventrālajā kvadrantā pēc dzemdībām ar labās puses epiziotomiju. Ievērojama globālās EMG amplitūdas samazināšanās pēc dzemdībām tika novērota sievietēm, kurām bija amplitūdas asimetrija dominējoši labajā pusē un kurām dzemdībās veica mediolaterālu labās puses epiziotomiju. Anālās inkontinences rādītāji nedaudz, bet ne statistiski ticami, pieauga 6–8 nedēļas pēc ķeizargrieziena dzemdībām 20 % un pēc vaginālo dzemdībām 30 % sieviešu.

Šā pētījuma galvenie secinājumi ir šādi: pirmkārt, epiziotomija samazina ārējā anālā sfinktera muskuļa aktivitāti, otrkārt, daudzkanālu virsmas elektromiogrāfija ir daudzsološa metode ārējās anālās sfinktera aktivitātes analīzei, un grūtniecības laikā reģistrētos EMG signālus varētu izmantot, lai noteiktu epiziotomijas grieziena optimālo pusi, tādējādi samazinot epiziotomijas iespējami radītos inervācijas bojājumus.

Atslēgvārdi: daudzkanālu virsmas elektromiogrāfija, ārējais anālais sfinkters, inervācijas zona, epiziotomija, dzemdību veids, inkontinence.

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Abbreviations

AAI	amplitude asymmetry index
AI	anal incontinence
ANOVA	analysis of variance
ARV	averaged rectified value
CMC	coefficient of multiple correlations
CS	Caesarean section
EAS	external anal sphincter
EMG	electromyography
EAS	external anal sphincter
EMG	electromyography
FI	faecal incontinence
GA	global amplitude
HRAM	high-resolution anorectal manometry
IAS	internal anal sphincter
ICC	intraclass correlation coefficient
iEMG	intramuscular electromyography
IZ(s)	innervation zone(s)
LD	left dorsal
LV	left ventral
MLE	mediolateral episiotomy
MRI	magnetic resonance imaging
MVC	maximal voluntary contraction
NRFHR	non-reassuring foetal heart rate
NMJ	neuromuscular junctions
OAB	overactive bladder
OASI(s)	obstetrical anal sphincter injury(-ies)
ODS	obstructed defecation syndrome
PC	personal computer
POP	pelvic organ prolapse
RCT	randomised controlled trial
RD	right dorsal
RV	right ventral
PFDs	pelvic floor disorders
PFM	pelvic floor muscles
PNTML	pudendal nerve terminal motor latency
sEMG	surface electromyography

SUI	stress urinary incontinence
STROBE	strengthening the reporting of observational studies in epidemiology
TPUS	transperineal / translabial ultrasound
US	ultrasound
UUI	urgency urinary incontinence
VD	vaginal delivery

Introduction

There is an ongoing discussion on the safest mode of childbirth to prevent pelvic floor disorders (PFDs). Pelvic floor disorders include urinary incontinence and faecal or anal incontinence and are highly prevalent among adult women after delivery. These disorders impair the quality of life dramatically and have an increasingly severe economic impact with population ageing. A questionable issue is whether episiotomy reduces or increases the risk of PFDs, specifically obstetric anal sphincter injuries (OASI) and faecal incontinence (FI). A mediolateral episiotomy (MLE) is one of the most frequent surgical interventions performed in obstetrics. Several indications exist regarding the length and angle of the episiotomy, but there is still a lack of international standardisation on whether episiotomy should be performed on the right or the left side. Usually, the operator decides the side of episiotomy according to his hand dominance, with the consequence that almost all the episiotomies are on the right side.

Recent advances in pelvic floor electromyography have made functional analysis of the external sphincter (EAS) possible with a minimally invasive rectal probe. This analysis has shown an individual asymmetry of the muscle activity that characterises each subject differently (Merletti et al., 2004). Functional asymmetry of EAS innervation is present in most women, and it is strongly associated with postpartum incontinence, especially when the trauma occurs on the dominant side of innervation (Enck et al., 2004). Although EMG is a well-established electrophysiological test, research on multichannel surface EMG (sEMG) applied to obstetrics are still at a pioneer stage. The present Thesis focuses on evaluating multichannel sEMG on the EAS muscle, promoting its application in current obstetrics to make vaginal childbirth safer. The specific objective is to investigate and evaluate strategies for preventing or reducing the possible iatrogenic damage during delivery with episiotomy.

Relevance of the subject matter of the study

The main accomplishment of the present work is that a series of follow-up studies were carried out on the application of multi-channel surface electromyography in obstetrics for the first time. To date, there are few studies on the pelvic floor evaluation by sEMG using anal detectors, but none of them has evaluated the effect of delivery type and obstetric manipulations on sphincter muscle activity. Pelvic floor disorders related to obstetric trauma are becoming more frequent worldwide, and the increase of the costs related to incontinence contributes dramatically to the health care systems. This Thesis offers a new perspective on the pre-existing debate about the safest delivery mode. This study proposes the introduction of a new method of pelvic floor assessment into clinical practice, which could help avoid iatrogenic damage during delivery – multichannel surface EMG with anal probes.

A recent comprehensive review published in "Frontiers in Neurology" (Campanini et al., 2020) quoted two of the articles included in the present Thesis stating: "*The latter application is particularly important for reducing the risk of anal sphincter partial denervation resulting from an episiotomy (Merletti et al. 2016, Zacesta et al. 2018, Cescon et al. 2014)*".

Aim of the study

This study aims to evaluate whether the analysis of external anal sphincter muscle EMG activity during pregnancy could help in the management of delivery.

Study objectives

The specific objectives of the present Thesis are listed below:

- to evaluate innervation zone distribution of external anal sphincter in pregnant women before and after delivery;
- to evaluate the effect of episiotomy on the distribution of innervation zones after delivery;
- to compare EMG amplitude changes of the external anal sphincter in women who had vaginal delivery or caesarean section;
- to evaluate external anal sphincter EMG amplitude distribution and detect asymmetry index in pregnant women;
- to detect EMG amplitude differences before and after delivery in women after mediolateral episiotomy according to the side of asymmetry;
- to evaluate the anal incontinence score changes before and after delivery and their relationship to EMG findings.

Study hypothesis

The first hypothesis is that after vaginal delivery, the EMG amplitude and the number of innervation zones from the external anal sphincter decrease.

The second hypothesis is that after episiotomy, according to their asymmetry and episiotomy site, the women with differing sphincter innervation will have varying levels of damage. Information acquired by sEMG before delivery on innervation zone distribution and EAS asymmetry could help choose the correct side of episiotomy, thus avoiding iatrogenic damage.

Novelty of the study

The present study is the first to demonstrate the role and the ease of multichannel sphincter EMG in the obstetric population. Even if EMG is a well-known method for evaluating skeletal muscles, its application in sphincters has been limited by the lack of non-invasive electrodes and advanced signal processing techniques. This study provides innovative information on EMG as a promising tool to avoid iatrogenic sphincter innervation damage in delivery with episiotomy. Since almost all the episiotomies are performed on the right side due to operators' handedness, and patients may have asymmetric innervation patterns, we could reduce the damage if we knew in advance the innervation pattern of a patient. Figure 1 shows possible damage to innervation zones (IZ) due to episiotomy in subjects with different innervation patterns. If the IZs are located more dorsally around the anus, the risk of damage during episiotomy is medium or low. If the IZs are located ventrally and are symmetric, the damage risk is very high. If the IZs are located ventrally and predominantly on one side, we could choose the side of episiotomy and avoid iatrogenic damage.

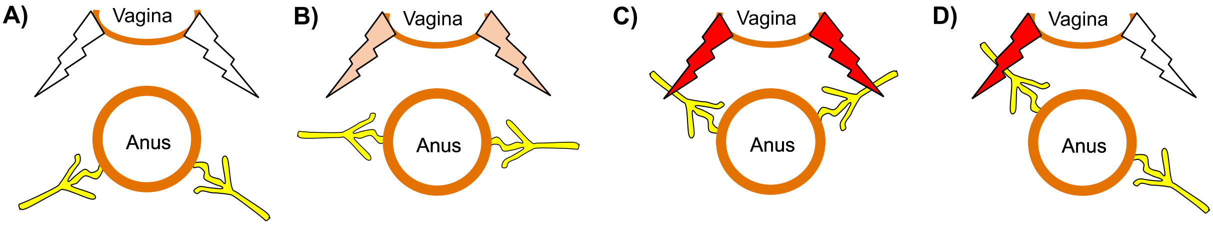

Figure 1 **Schematic representation of possible sphincter damage due to episiotomy**

A) dorsal lateral innervation: Low risk. B) lateral innervation: medium risk. C) ventral lateral innervation: high risk. D) on one side innervation is lateral on the other is ventral, in this case the side of episiotomy is crucial. Arrows: episiotomy cut. Yellow: pudendal nerve fibres. Red colour indicates high risk episiotomy. (Adapted from Merletti, 2016).

The present study shows that sEMG is a promising tool to evaluate anal sphincter changes before and after surgical manipulations. Moreover, sEMG is minimally invasive and well-tolerated by patients; it is accurate and could have clinical applications for gynaecologists and obstetricians and colorectal surgeons.

1 Literature review

1.1 Episiotomy

1.1.1 Definition and types

An episiotomy is the surgical enlargement of the posterior aspect of the vagina by an incision to the perineum during the last part of the second stage of labour (Carroli & Mignini, 2012). The incision is performed with scissors or a scalpel. The decision to perform an episiotomy is a clinical judgement, and routine use of episiotomy is no more advised.

There are different types of episiotomy incisions described in literature and shown in Figure 1.1:

(1) **Median or midline incision**, also called perineotomy, mostly performed in the USA, starts within 3 mm of the midline of the posterior fourchette and extends downwards between 0 and 25 degrees of the sagittal plane (American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Obstetrics, 2016) .

(2) **"T" shape incision** is a modification of the median episiotomy in which bilateral transverse incisions are made at the inferior apex to create an inverted T-shaped incision. "T" shape incision increases the area of the vaginal opening 83 % more than a median episiotomy alone. (May, 1994).

(3) **Mediolateral incision** (usually performed on the right side), the most common in Europe, begins within 3 mm of the midline in the posterior fourchette and is directed laterally at an angle of at least 40–60 degrees from the midline towards the ischial tuberosity (American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Obstetrics, 2016).

(4) **Lateral incision** starts at 1 to 2 cm lateral to the midline and is directed laterally toward the ischial tuberosity. It is rarely used, except in Finland and Greece.

(5) **"J" shape incision** starts at the fourchette, is initially extended caudally in the midline, and then curved laterally at an angle, similar to the letter J. In ideal circumstances, the anatomical structures incised by "J" shape incision should include just the vaginal epithelium, perineal body, and the perineal body's junction with the bulbocavernosus muscle and perineal skin, and not transverse perineal muscle; however, it is difficult to ensure that.

(6) **Radical lateral (Schuchart) incision** is a fully extended episiotomy, which carries deep into one vaginal sulcus and is curved downward and laterally around the rectum. Usually, it is performed for radical vaginal hysterectomy or trachelectomy and very rare in obstetrics (Kalis et al., 2012).

(7) **Anterior incision or defibulation** is only indicated in the case of previous female genital mutilation.

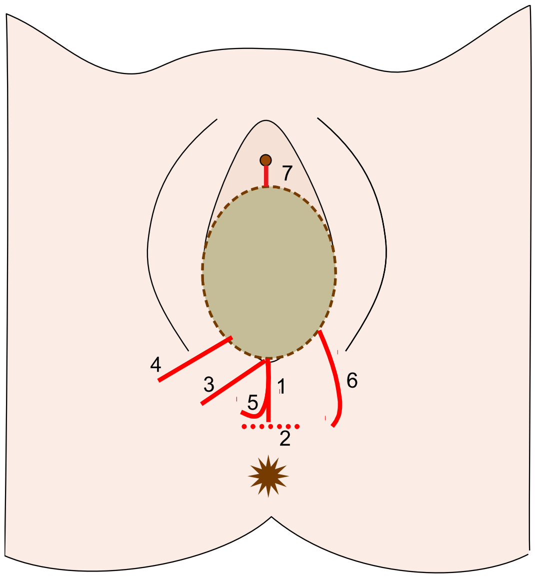

Figure 1.1 **Types of episiotomy**

1: median incision, 1 + 2: "T" incision, 3: mediolateral incision, 4: lateral incision, 5: "J" incision, 6: radical lateral (Schuchardt incision), 7: anterior episiotomy.

The two most widely used types of episiotomy are midline and mediolateral episiotomy. Midline episiotomy or perineotomy is associated with a higher risk of anal sphincter injury than mediolateral episiotomy (Pergialiotis et al., 2014). Mediolateral episiotomy has been considered to be associated with increased blood loss (Combs et al., 1991; Stones et al., 1993). Besides, a mediolateral episiotomy has historically been thought to result in more perineal pain and dyspareunia. However, there are conflicting data on that, and the balance of evidence suggests that there are no differences in pain outcomes between the two procedures (Coats et al., 1980; Fodstad et al., 2014; Necesalova et al., 2016).

1.1.2 Evolution of practice

The evolution of episiotomy could be divided into four principal periods involving many socio-cultural factors. The first period extended from 1742 until 1920, and it is characterised by the generalisation of episiotomy as the surgery of last resort. The second period lasted from 1920 until 1980 and was important by disseminating of preventive policies making episiotomy a common practice in Anglo-Saxon countries. During the third period, from 1980 until 1995, the systematic use of episiotomy spread worldwide; meanwhile, in Anglo-Saxon countries, the rate of episiotomy started to decrease due to the influence of evidence-based medicine. From 1996 till nowadays, the fourth period is characterised by a decrease in the rates of episiotomy internationally, except for some countries in East Asia and some less industrialised countries (Clesse et al., 2019).

The history of episiotomy starts in 1742, when a medically trained midwife named Sir Fielding Ould of the Rotunda Hospital in Dublin performed it for the first time, describing it as an emergency procedure to preserve the child's life (Graham, 1998). At that time, this procedure was infrequent because of the risk of infection and the absence of anaesthesia. There is very little documental evidence about episiotomy in the 18th century. A German physician Michaelis reported performing a midline incision in 1799 (Muhleman et al., 2017; Schoon, 2001). In 1820 Ritgen suggested making bilateral incisions perpendicular to the vaginal orifice. The first mediolateral episiotomy was performed in France by Dubois in 1847, followed by Taliaferro in the USA in 1951 (Schoon, 2001). The term "episiotomy" was used for the first time in Braun's publication in 1957 (Kalis et al., 2012; Muhleman et al., 2017; Schoon, 2001; Thacker & Banta, 1983). The introduction of anaesthesia and asepsis favoured the further spread of episiotomy worldwide. Still, the use of episiotomy remained very restricted; Episiotomy's use was restricted for a long time; it wasn't until the late 1800s that clinical practitioners began to advocate it more widely, fighting several opposing ideas. The first one was that the physiological vision of birth was not related to any surgical intervention, the second was the fear of patient resistance felt by physicians, the third was the unpredictability of perineal lacerations, and the last was the lack of suturing materials (Clesse et al., 2019; Graham, 1998).

The period of acceptance and resistance against episiotomy was followed by a spread of routine episiotomy from the 1920s till the 1980s. The first gynaecologists who promoted prophylactic use of episiotomy to minimise childbirth pain and maternal efforts were Pommeroy in 1918 and DeLee in 1920 (Clesse et al., 2019; Graham, 1998). The move of childbirth to hospital settings encouraged the acceptance of routine episiotomy and led to widespread use of this manipulation. It was also supported by the 10th edition of Williams, published in 1950: "Except for cutting and tying the umbilical cord, an episiotomy is the most common operation in obstetrics (..). It substitutes a straight, clean surgical incision for the ragged, contused laceration (..); such an incision is easier to repair and heals better than a tear. (..) It spares the baby's head (..) of brain injury, (..) the operation shortens the duration of the second stage of labour." Other Anglo-Saxon countries adopted routine episiotomy in the late 1970s, while the rest of the world favoured elective practice of episiotomy till the 1980s (Clesse et al., 2019; Klein, 1988). While the number of countries adopting routine episiotomy policy was growing, the first professional criticism also appeared, and arguments in favour of routine episiotomy were rejected, lack of evidence-based medicine approach was emphasised, and association of episiotomy with increased postpartum pain, dyspareunia, oedema, infections, and increased blood loss was highlighted. Randomised controlled trials were carried out to prove the uselessness of systematic episiotomy, and a new approach – selective episiotomy instead of routine – was introduced.

The evaluation of the practice has led to the conclusion that nowadays there is no justification for routine episiotomy, but there is no reason to avoid episiotomy at all costs too, since the available studies demonstrate that selective mediolateral episiotomy, performed when needed, is not associated with any long-term complications (Bo et al., 2017; Carroli & Mignini, 2012; Sagi-Dain et al., 2018; Serati et al., 2019).

1.1.3 Episiotomy rates worldwide

Since 1996 when World Health Organization recommended an episiotomy rate of approximately 10 % (*WHO recommendations: intrapartum care for a positive childbirth experience*, 2018), episiotomy rates have generally been in decline. Still, the countries with an overall rate of episiotomy less than 10 % are quite rare. Sweden (6.6 % in 2010), Iceland (7.3 % in 2010) and Denmark (4.9 % in 2010) are the only countries with a small overall episiotomy rate (Blondel et al., 2016; Graham et al., 2005). One reason could be the emphasis on the physiological delivery concept in these countries. Meanwhile, Asian countries have very high overall episiotomy rates, with the following leading countries: India (68 % in 2008), Thailand (91 % in 2005), China (85 % in 2003, and 41.2 % to 69.7 % in 2016), (Graham et al., 2005; Lam et al., 2006; He et al., 2020). For China, where there were 17.23 million births in 2016, there could be as many as 7.33 million episiotomies a year. After restrictive episiotomy was urged by the China Maternal and Child Health Association in 2019, the rate of episiotomy significantly decreased in China, still remaining up to 45 % (He et al., 2020). Moreover, in a study evaluating the attitude and experience of episiotomy practice among obstetricians and midwives, 42.11 % of the clinicians considered the current rate of episiotomy (45 %) to be correct or too low (Yang et al., 2021). Altering practice patterns regarding episiotomy may be complicated because clinicians, who learned episiotomy as an essential step in performing any vaginal delivery, would be unwilling to change practice. Differing episiotomy rates worldwide in 2010 are shown in Figure 1.2 (Clesse et al., 2018).

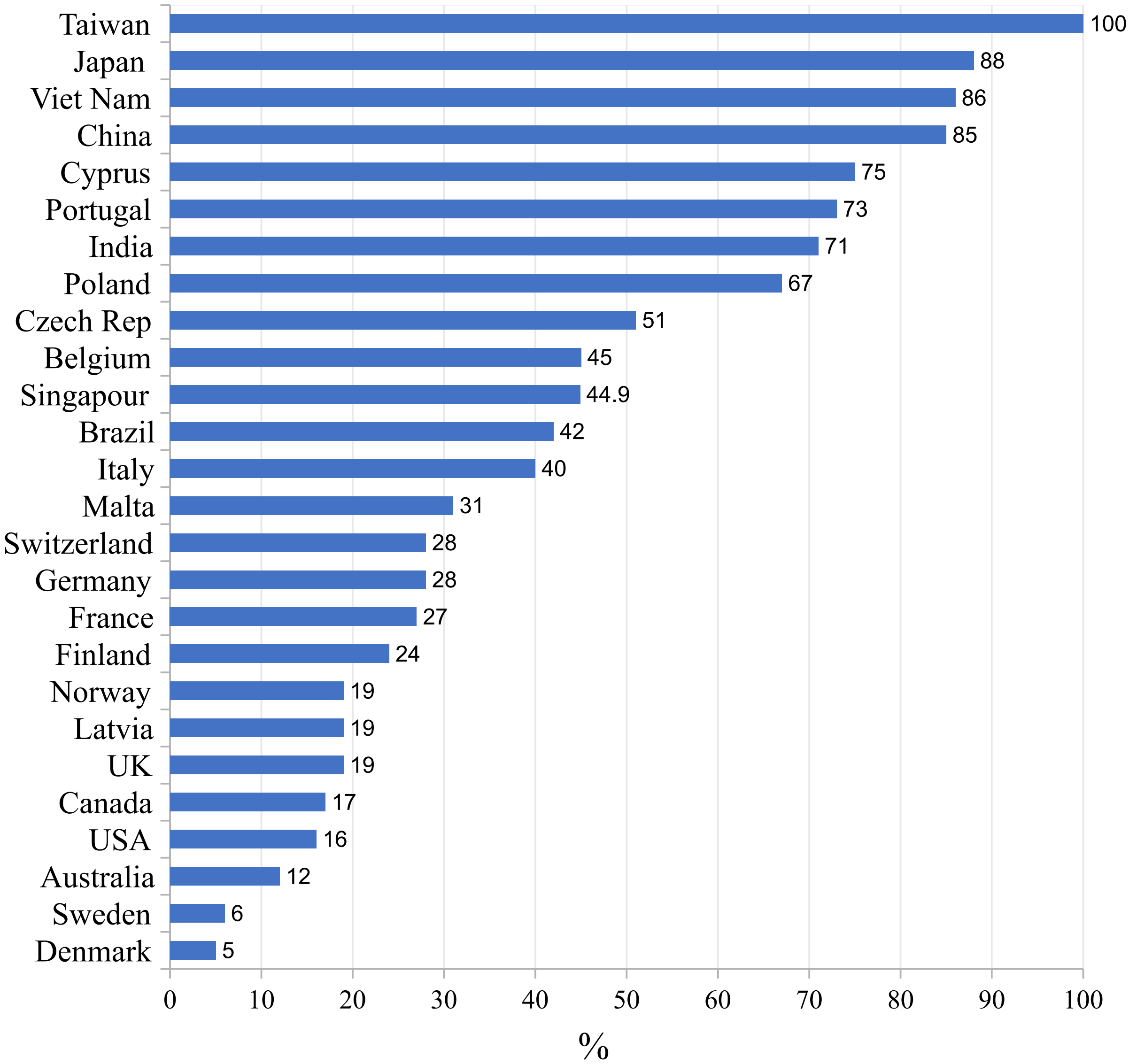

Figure 1.2 **Episiotomy rates worldwide**

Dynamic analysis of episiotomy rates has shown that 26 countries in Europe and North America have a downward trend, often remaining below 30 %. However, it is known that these results correlate with an increased number of Caesarean sections (Clesse et al., 2018). The changes in episiotomy rates between 2014 and 2010 are shown in Figure 1.3.

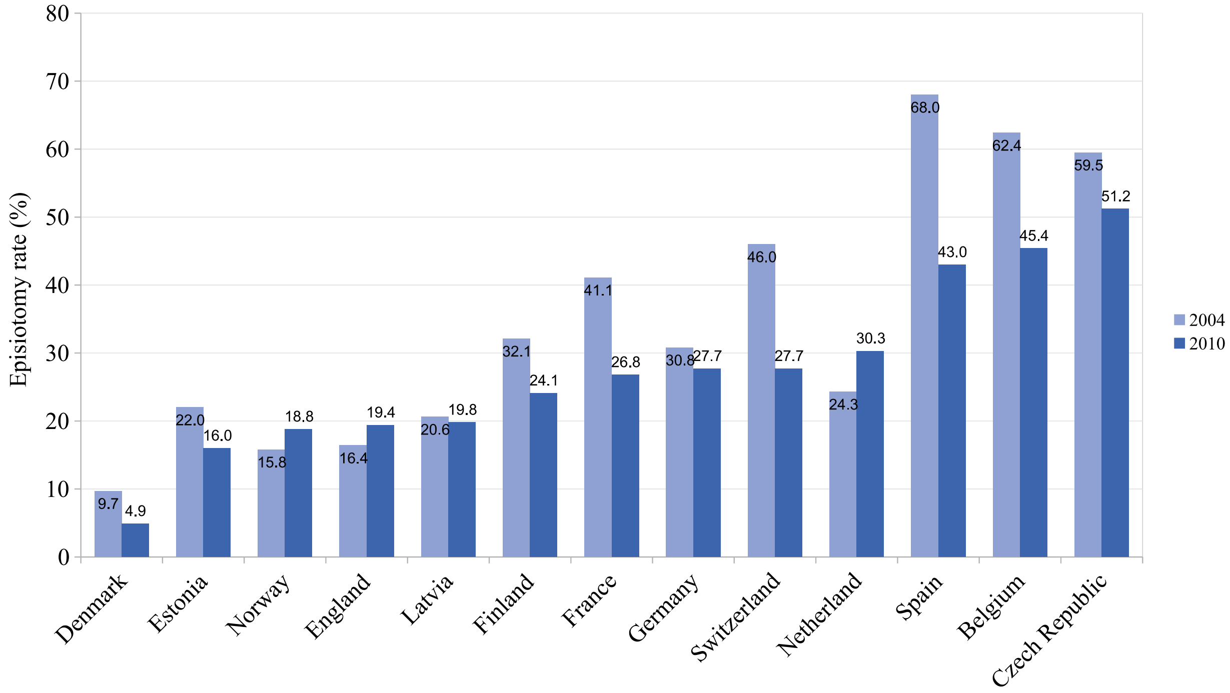

Figure 1.3 **Episiotomy rates in Europe 2004 vs. 2010**

Note that not all European countries show a decreasing trend. The newest published European Perinatal Health Report from Euro-Peristat Network does not include episiotomy rate as a core indicator in 2015; still, various Euro-Peristat reports show that episiotomy rates remain high in Europe, e.g., 42.3 % of all deliveries and 62.4 % of primiparous deliveries in Belgium (2017), 20.1 % among all women and 34.9 % of primiparous deliveries in France (2016), 35.1 % in Croatia (2017), 22.21 % in Lithuania with a wide inter-hospital range from 36.0 % till 6.9 % (data from 2018), 25.7 % in Luxembourg (2016), 11.6 % among spontaneous vaginal deliveries and 45.2 % in instrumental VD in Malta (2019). Instrumental deliveries have a high episiotomy rate also in Australia: 77.6 % vs. 22.3 % among non-instrumental VD (year 2018, data from Australian Institute of Health and Welfare).

Episiotomy rates are influenced by more than just medical reasons. In the United States, white race and commercial insurance were associated with episiotomy in an insurance database study. (Friedman et al., 2015). Hospital factors, including the rural location or academic centre, were associated with reduced rates of episiotomy. Other studies have reported that private practitioners do two to four times as many episiotomies as trainees or midwives (Friedman et al., 2015; Howden et al., 2004; Muraca et al., 2019). Legal issues may play a role, too. In China, in case of severe perineal tears in the absence of an episiotomy, the hospitals assume all the responsibility in a lawsuit, and medical records of patients with third-degree or fourth-degree tears are incorporated into midwives' professional files, which may impede future promotion (Yang et al., 2021). Another reason for high episiotomy rates in Asia is the traditional view that Asian women have shorter perineal length than Caucasians, putting them at increased risk of perineal tears (Sangkomkamhang et al., 2019; Quoc Huy et al., 2019).

In the USA, episiotomy use markedly and consistently declined between 1979 and 2004. Decreasing episiotomy rates corresponded to decreasing rates of anal sphincter laceration (Frankman et al., 2009). Episiotomy rates in the US are shown in Figure 1.4 (Clesse et al., 2018).

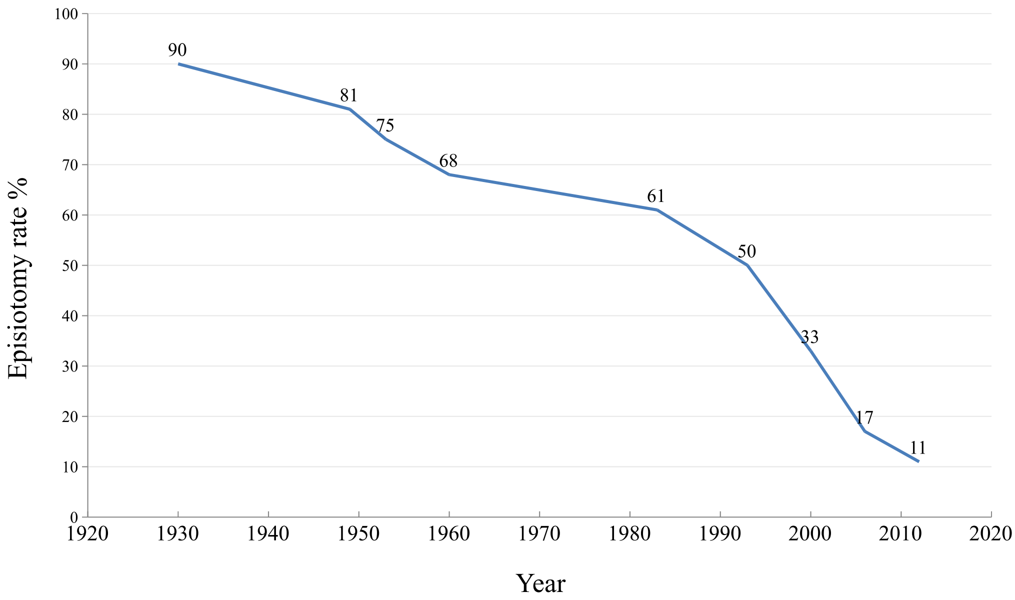

Figure 1.4 **Episiotomy trend in the USA**

The episiotomy rate in Latvia is stable at around 13–16 %. This rate is comparable with most of the European countries. Even if the percentage is relatively low, it is above the WHO recommendations, and in absolute numbers, corresponds to about 2400 episiotomies per year (in 2019). In contrast, the OASI rate in Latvia is much lower (0.4 %) compared to other European countries. Figure 1.5 shows the episiotomy and OASI trends in Latvia in the last decade (data from the Health statistics database).

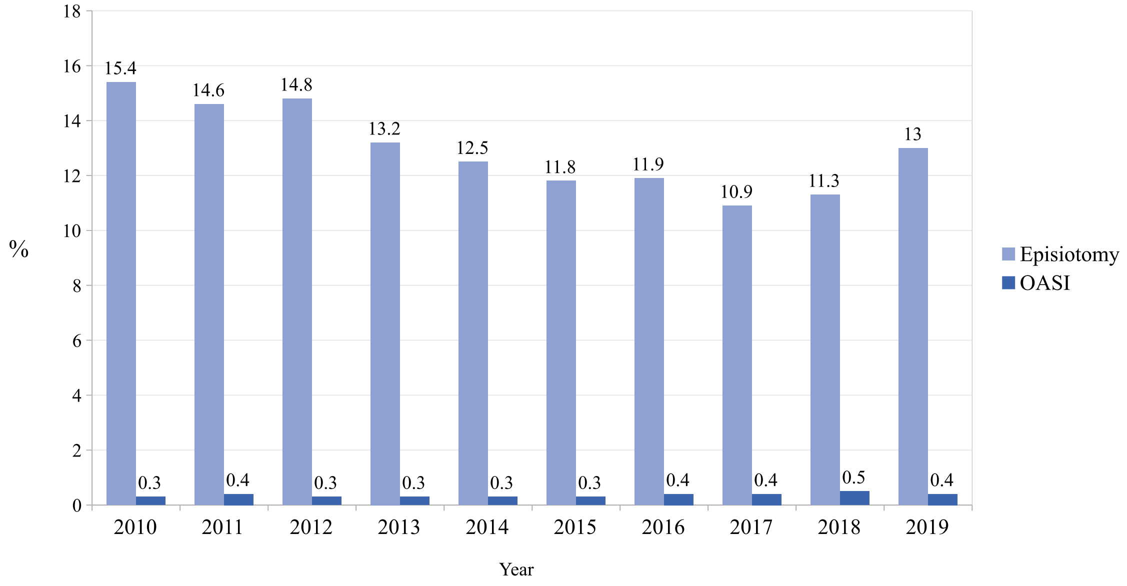

Figure 1.5 **Episiotomy and OASI rates in Latvia from 2010 to 2019**

1.1.4 Current recommendations for episiotomy

Three critical questions are addressed in recommendations of the use of episiotomy: whether, when and how to incise.

Routine episiotomy is no more recommended because of insufficient evidence-based data demonstrating its benefits. The decision to perform episiotomy depends on the clinician's opinion and is based on the clinical scenario at the time of delivery. An episiotomy is suggested when the patient has a high risk of a third or fourth-degree laceration or when the foetal heart rate is non-reassuring, and accelerated vaginal delivery is necessary. Neither operative vaginal delivery nor shoulder dystocia alone is considered an absolute indication for the episiotomy. Verbal consent of the patient and adequate anaesthesia are required for the episiotomy. Common complications of episiotomy, such as the extension of the incision deeper into the perineum or the anal sphincter complex, postpartum pain, dyspareunia, infection, breakdown, vulvovaginal haematomas, should be taken into account (Fodstad et al., 2016; Necesalova et al., 2016).

Carrolli demonstrated several benefits of selective episiotomy policies vs policies based on routine episiotomy: less posterior perineal trauma, less suturing and fewer complications, no difference for most pain measures and severe vaginal or perineal trauma were observed with restrictive episiotomy, but there was an increased risk of anterior perineal trauma (Carroli & Mignini, 2012). Also, Shmueli showed that routine episiotomy does not protect nulliparous women and may be associated with an increased risk of OASI for multiparous, promoting selective episiotomy (Shmueli et al., 2017). The evaluation is difficult because of the small number of randomised controlled trials (RCT). Thus, most of the decisions are based on retrospective studies. A recent review including 12 RCT with 6177 women and comparing selective versus routine episiotomy showed that in women where no instrumental delivery is anticipated, selective episiotomy policies result in fewer women with severe perineal or vaginal trauma (Jiang et al., 2017).

Regardless, mediolateral episiotomy should not be dismissed in all cases since it has a protective effect for obstetrical anal sphincter injuries. A retrospective population-based analysis of almost 400,000 women in Finland showed that OASIS occurrences were significantly lower in hospitals with a higher frequency of episiotomy in primiparous women, while in multiparous women, there was no significant correlation (Räisänen et al., 2012). A large population-based Dutch study, including 280,000 deliveries, confirmed the strong protective effect of MLE against OASIS (De Leeuw et al., 2001). Also, a retrospective study in the UK, including more than 10,000 births, showed that women giving birth without a MLE were 1.4 times more likely to experience OASIS (Revicky et al., 2010).

In the case of women with **operative vaginal delivery** and selective or routine episiotomy policies, data are controversial. No apparent difference was shown in severe perineal / vaginal trauma between selective and routine episiotomy in Murphy's randomised controlled trial (Murphy et al., 2008). Also, a retrospective study by Steiner demonstrated that even in obstetrical emergencies such as shoulder dystocia, foetal macrosomia, non-reassuring foetal heart rate (NRFHR), occiput-posterior position and in instrumental-assisted deliveries, a routine MLE might not reduce third and 4th-degree perineal tears (Steiner et al., 2012). On the contrary, a retrospective cohort analysis by Van Bavel showed that the use of a MLE during both vacuum delivery and forceps delivery was associated with a fivefold to tenfold reduction in the rate of OASIS in both primiparous and multiparous women (van Bavel et al., 2018). Different observational studies showed that mediolateral or lateral episiotomy was protective against OASIS and may be considered in vacuum-assisted delivery in primiparous women, whereas mediolateral and median episiotomy in the parous women may increase the rate of OASIS at vacuum deliveries (Lund, 2016; Muraca et al., 2019; Sagi-Dain & Sagi, 2015).

The choice between midline or mediolateral episiotomy is favoured to mediolateral since midline episiotomy has a clear association with increased OASIS (Carroli & Mignini, 2012; Hartmann et al., 2005; Klein et al., 1994; Lai et al., 2009). A systematic review demonstrated that mediolateral episiotomy has a beneficial effect in preventing OASIS (Verghese et al., 2016). Therefore, the Royal College of Obstetricians and Gynaecologists, The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, The Society of Obstetricians and Gynaecologists of Canada, and, in certain circumstances, also The

American College of Obstetricians and Gynaecologists advised mediolateral incisions when an episiotomy is performed (American College of Obstetricians and Gynecologists’ Committee on Practice Bulletins–Obstetrics, 2016; Harvey et al., 2015; Wilson & Homer, 2020)

The timing of episiotomy is clearly defined: when the delivery of the foetus is anticipated within the following three to four contractions or when the head is visible during a contraction to a diameter of 3-4 cm (Cunningham et al., 2018). If performed too early, the bleeding from the cut may be considerable. If it is performed too late, lacerations will not be prevented.

Regarding **direction and angle** of mediolateral episiotomy, the following conditions should be taken into account: the final angle of the incision should be at 30 to 60 degrees from the midline to minimise the occurrence of sphincter injury, it means that the incision is initiated within 3 mm of the midline in the posterior fourchette and cut at an angle that may be almost perpendicular to the midline (80 to 90 degrees as the foetal head is crowning); because after delivery, this angle becomes smaller, approaching 45 degrees, since the perineum is no longer stretched and distorted by the foetal presenting part. Obstetricians should remember that perineal stretching of 170 % in the transverse direction and 40 % in the vertical direction occurs at crowning (Kapoor et al., 2015), leading to significant differences between episiotomy incision angles and suture angles. It was shown that there is a 20 ° difference between the incision angle of an episiotomy (typically performed when the head is crowning) and the sutured angle once healed (Kalis et al., 2008a). Episiotomies incised at 60 ° achieve suture angles of 43–50 °; those incised at 40 ° result in a suture angle of 22 ° (Andrews et al., 2006a; Harvey et al., 2015). The angle of the episiotomy affects the occurrence of OASIS: too acute (vertical) suture angle (< 30 °) and too lateral (> 60 °) increases the risk of OASIS. Suture angles of 40–60 ° are in the safe zone. The impact of the starting point of the episiotomy (mediolateral vs lateral) appears less important (Andrews et al., 2006a; Harvey et al., 2015). Stedenfeldt showed that scarred episiotomies with depth > 16 mm, length > 17 mm, incision point > 9 mm lateral of midpoint and angle range 30–60 ° are significantly associated with a lower risk of OASIS (Stedenfeldt et al., 2012). A 50 % relative reduction in the risk of third-degree tear was achieved for every 6.3 degrees larger the angle of episiotomy is from the perineal midline (Eogan et al., 2006). The incision is usually between 3 and 5 cm in length (Coats et al., 1980; Cunningham et al., 2018; Fodstad et al., 2014).

Even if these incision guidelines exist (see Figure 1.6), the practice can be different.

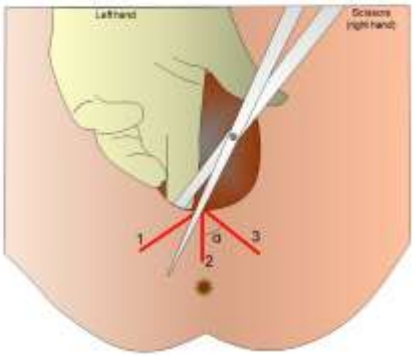

Figure 1.6 **Episiotomy description in guidelines**

1: Right MLE. 2: Medial Episiotomy. 3: Left MLE. The angle of the episiotomy is between the midline and the episiotomy.

Studies on self-reported episiotomy performance among midwives and gynaecologists show that significant variation exists, misperception between mediolateral and lateral is common, and the length and the angle in real work situations tends to be smaller than in the guidelines (Fodstad et al., 2016; Kalis et al., 2012; Tincello et al., 2003). Moreover, episiotomies performed by doctors were significantly longer and more angled than those performed by midwives (Tincello et al., 2003).

The weakest aspect regarding episiotomy is **the lack of indicators on which side to make an incision**. Usually, it is performed with the right-hand operator on the woman's right side, but there is no evidence for this choice. Since it is demonstrated that functional asymmetry of EAS innervation exists in healthy women, and it is significantly associated with incontinence symptoms after childbirth-related sphincter injuries (Enck et al., 2004; Wietek et al., 2007), the question of the correct side remains important when the iatrogenic damage is an issue.

1.2 Pelvic floor disorders after delivery

1.2.1 Definition

Pelvic floor disorders include stress urinary incontinence (SUI), urgency urinary incontinence (UUI), overactive bladder (OAB), faecal or anal incontinence (FI, AI) and pelvic organ prolapse (POP) (Hallock & Handa, 2016). The author, later in the text, will focus on issues related to faecal and anal incontinence mainly since these pathologies are directly dependent on the sphincteric function and sEMG measurements.

Faecal incontinence is defined as the recurrent, involuntary loss of solid or liquid stool or mucus from the rectum. **Anal incontinence** is the impairment to control the elimination of gas and stool (Haylen et al., 2010).

PFD have an enormous impact on people’s lifestyle, which may lead to significant psychological effects, and are highly prevalent among adult women after delivery, having a substantial economic impact and are growing with population ageing (Hallock & Handa, 2016; Sung et al., 2010; Wu et al., 2011).

1.2.2 Pelvic floor anatomy and physiology

The perineum can be divided into two triangular parts: the anterior triangle, which contains the external urogenital organs and is known as the urogenital triangle, and the posterior triangle, which contains the termination of the anal canal and is known as the anal triangle. The urogenital triangle can be divided into two compartments: the superficial and deep perineal spaces, separated by the perineal membrane and includes the following muscles: superficial transverse perineal muscle, the bulbospongiosus muscle, and the ischiocavernosus muscle. The anal triangle includes the anal canal, the anal sphincter complex, and ischioanal fossae. The anal sphincter complex consists of the external anal sphincter and the internal anal sphincter (IAS), separated by the conjoint longitudinal coat. Although they form a single unit, they are distinct in structure and function. Structurally, the EAS is subdivided into three parts: the subcutaneous, superficial and deep.

The pelvic floor (pelvic diaphragm) is a musculotendinous sheet covering the pelvic outlet and consists mainly of the symmetrically paired levator ani. The levator ani is a broad muscular sheet of variable thickness attached to the internal surface of the true pelvis and is divided into iliococcygeus, pubococcygeus (in female subdivided in puborectalis and pubovaginalis), and ischiococcygeus muscles. The puborectalis is the most caudal component of the levator ani complex, and it is situated cephalic to the deep EAS, from which it is almost inseparable; thus, the puborectalis has both functions: as part of the sphincter mechanism and the pelvic floor. The pelvic floor supports the urogenital organs and the anorectum. The muscles of the levator ani differ from most other skeletal muscles in that they maintain constant tone (except during voiding, defaecation and the Valsalva manoeuvre); they can contract quickly at the time of acute stress (such as a sneeze or a cough) to maintain continence. Important in women is that pelvic floor muscles distend considerably during delivery to allow the baby's passage and then contract after delivery to resume normal functioning (Sultan et al., 2009).

The **pudendal nerve innervates EAS**. Since IAS is a continuation of the rectum's circular fibres, it has the same innervation: sympathetic (L5) and parasympathetic nerves (S2–S4). The pudendal nerve is a mixed sacral nerve (motor 20 %, sensory 50 %, and autonomic 30 %) that provides cutaneous and muscular innervation to most of the perineum.

The pudendal nerve derives its fibres from the ventral branches of the S2, S3, S4 nerves and leaves the pelvis through the lower part of the greater sciatic foramen; it then crosses the ischial spine and re-enters the pelvis through the lesser sciatic foramen. It passes along the internal pudendal vessels upward and forward along the ischioanal fossa's lateral wall within the pudendal (Alcock's) canal (Wallner et al., 2006; Woodman & Graney, 2002). It is presumed that during a prolonged second stage of labour, the pudendal nerve is vulnerable to stretch injury due to its relative immobility at this site (Sultan et al., 2009). The inferior rectal branch of the pudendal nerve innervates the EAS bilaterally. The pudendal nerve then divides into two terminal branches: the perineal nerve and the dorsal nerve of the clitoris. See the anatomy of pudendal nerve in Figure 1.7.

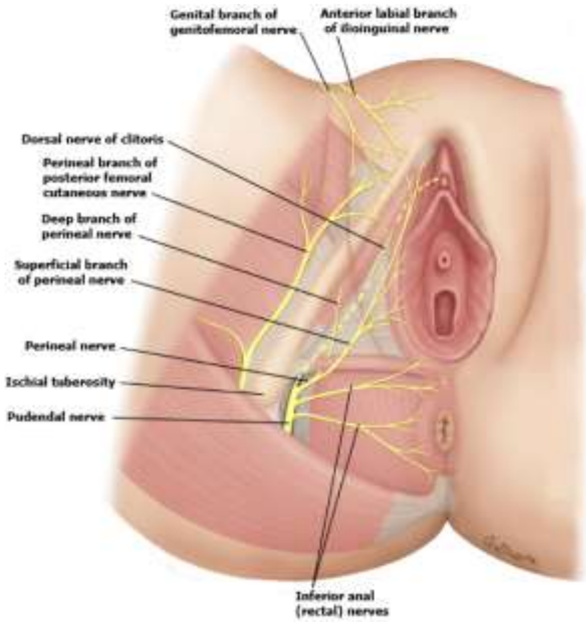

Figure 1.7 **Pudendal nerve branches**

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The two halves of the EAS – left and right – are innervated independently, as there is apparent unilateral denervation activity after unilateral pudendal nerve lesions; and the anal reflex may be absent only unilaterally (Vodušek, 2004). **Functional asymmetry of pelvic floor innervation** exists in healthy subjects (Enck et al., 2004; Hamdy et al., 1999; Wietek et al., 2007). Significant asymmetry can increase the risk for faecal incontinence if pelvic floor trauma occurs on the dominant side of innervation (Enck et al., 2004; Wietek et al., 2007).

The EAS contributes up to 30 % of the unconscious resting tone (Sultan et al., 2009). The IAS is responsible for up to 80 % of anal resting pressure and liquid stool continence. The external anal sphincter is primarily responsible for flatus continence and produces about 80 % of the maximum squeeze pressure on manometric tests (Woodman & Graney, 2002).

Normal bowel continence depends upon several factors, including anal sphincter function, anorectal sensation and anorectal reflexes, cognitive function, stool volume and consistency, colonic transit, rectal distensibility. Within the anorectum, normal continence is achieved thanks to complex mechanisms involving the interaction of the internal, external anal sphincter, puborectalis muscle and sensory information under local, spinal and central control (Papaconstantinou, 2005). Structural, functional and neurological factors contributing to the maintenance of continence are listed in table 1.1, and not to forget are also such factors as regular rectal evacuation and psycho-behavioural factors (Sultan et al., 2009).

Table 1.1

Factors contributing to the maintenance of continence

Component	Sphincteric	Suprasphincteric
Structural	Internal anal sphincter External anal sphincter Conjoined longitudinal muscle Vascular anal cushions Longitudinal anal muscle folds	*M. puborectalis* *M. iliococcygeus* *M.Pubococcygeus* Perineal resting position (level of descent) Rectal capacity Rectal transverse folds Rectal flap valve effect of the anterior wall Endopelvic musculofascial supported Rectosigmoid sphincter
Functional	Anal resting tone Anal canal / high pressure zone length Resting anal pressure gradient Voluntary anal squeeze pressure Anal motility Anal sensation Rectoanal contractile reflexes Rectoanal inhibitory reflex	Tonic *levator ani* contractions Anorectal angle Rectosigmoid angle Postural pelvic floor reflex Rectal sensation Rectal compliance Rectal tone Rectosigmoid motility Rectosigmoid pressure gradient Rectosigmoid high pressure zone Anorectal pressure gradient Stool volume Stool consistency Gastrointestinal motility
Neurological	Pudendal nerve Sympathetic (Hypogastric) nerves Parasympathetic (pelvic) nerves	Pudendal nerve Sympathetic nerves Parasympathetic nerves Afferent nerves Intrinsic (enteric) nerves

After childbirth, the function of the sphincter can change. The development of incontinence may be caused by injuries to the anal sphincter mechanism or changes in the anal sphincter muscle activation (Hallock & Handa, 2016). Anal sphincter mechanism can be damaged in three ways:

(1) direct anal sphincter muscle disruption, most commonly at first vaginal delivery;
(2) traction neuropathy of the pudendal nerve, which may be cumulative with successive deliveries; and
(3) combined mechanical and neurological trauma (Fitzpatrick & O'Herlihy, 2001). The injury to the pudendal nerve can cause its demyelination and subsequent EAS and puborectalis denervation, following muscle re-innervation (Fynes & O'Herlihy, 2001; Snooks et al., 1984; Sultan et al., 2009).

Also, pudendal nerve damage during vaginal delivery may occur in 3 ways:

(1) direct injury to the pelvic nerves, e.g. forceps delivery or compression by the foetal head;
(2) traction injury to the pudendal nerves during the descent of the foetal head in the second stage of labour;
(3) abnormal perineal descent which can persist for several months after delivery and is associated with stretching and disruption of the pelvic floor muscles, resulting in reduced tone (Fitzpatrick & O'Herlihy, 2001).

Neurophysiological tests support this mechanism of injury, including pudendal nerve motor latency and concentric needle electromyography, demonstrating the denervation of pubovisceral muscles and anal sphincter after 40 to 80 per cent of vaginal births (Allen et al., 1990). Mostly, neuromuscular injury resolves during the first year after delivery; however, in some cases, electrophysiologic tests show denervation injury five to six years after delivery (Snooks et al., 1986, 1990); till now, there is no explanation why neuromuscular function will recover in some women, while in others permanent damage can be found.

1.2.3 Pelvic floor disorders rates worldwide

PFDs are very common and often coexist (Lawrence et al., 2008; Rortveit et al., 2010; Wu et al., 2015). Although any age group and gender can be affected, there is an increased incidence of anal incontinence with female gender, advancing age, and deteriorating mental and physical status and overall health (Nelson, 2004; Papaconstantinou, 2005). Variations in definitions create variability in estimates of their prevalence and incidence. Besides, differences in study and survey methodology, target populations, and questionnaire design increase the variability between studies. In the United States, the prevalence of at least one PFD was 23.7 %, and 9.0 % of women had faecal incontinence (Nygaard, 2008). Among the community-dwelling population, these numbers were 37 % for any one or more disorders and 25 % for anal incontinence; moreover, 50 % to 80 % of women with one pelvic floor disorder had at least one other pelvic floor disorder (Lawrence et al., 2008). In Australia, FI was found in 20.7 % among women (Botlero et al., 2011). In the UK, 5.7 % of women reported faecal incontinence (Perry, 2002); in Sweden, this number was 10.9 % (Walter et al., 2002); in Germany, in general adult population 4.4–6.7 % (by health status). In the Czech Republic, FI was found in 5.6 % of gynaecological patients, 4.4 % in the community, and 54.4 % in nursing home residents. One study looked for AI among pregnant women (Nelson, 2004); AI within the preceding year was reported by 8.6 % of women at 16 weeks of gestation, faecal incontinence only 0.6 %, and isolated flatus incontinence at least once a week – in 4.2 % (Hojberg et al., 2000). In a survey six months after delivery, 29 % reported anal incontinence since delivery (Guise et al., 2007).

PFDs are more common among women who have delivered at least one child (Abramov et al., 2005; Evers et al., 2012; Handa et al., 2012; MacLennan et al., 2000); additionally, the rate of PFDs increases with increasing parity: among parous women, it has been estimated that 50 per cent of incontinence and 75 per cent of prolapse can be attributed to pregnancy and childbirth (Patel et al., 2006). The effect of parity decreases in postmenopausal women when age as a risk factor becomes more critical (Brown, 1999; Nygaard, 2006). Figure 1.8 shows the prevalence of FI and AI (MacLennan et al., 2000).

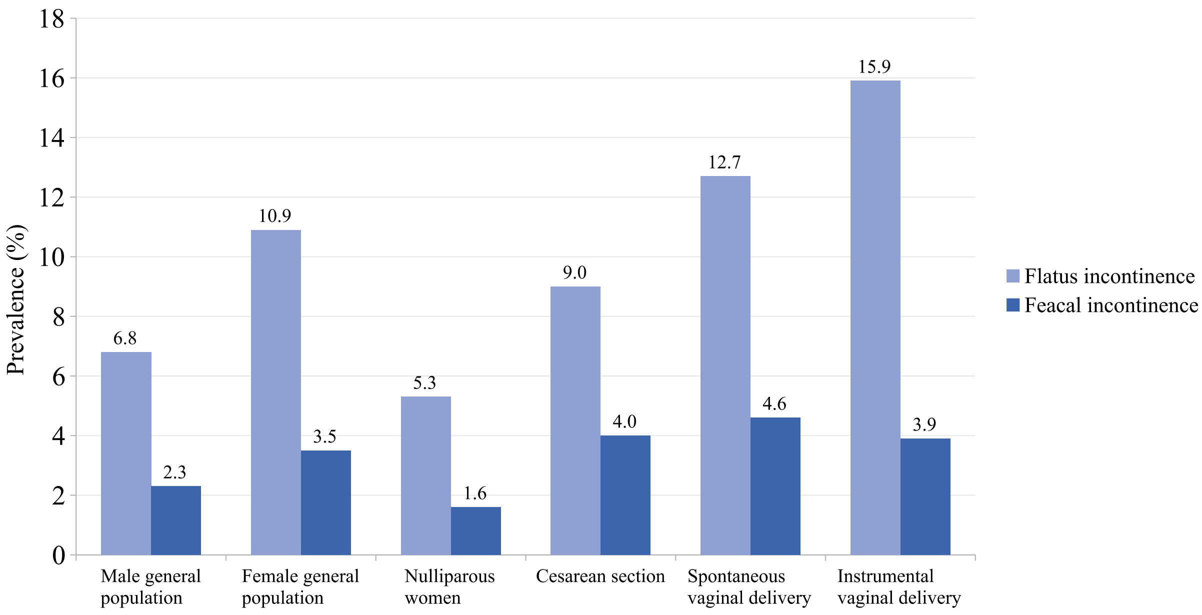

Figure 1.8 **Prevalence of faecal and flatus incontinence in general female and male populations, and mode of delivery among women**

1.2.4 Quality of life, economic impact and risk factors associated with PFD

Quality of life

All PFDs, and AI particularly, can have a devastating impact on daily life. The inability to control important bodily processes causes loss of confidence and self-respect, embarrassment, social stigmatisation, depression and anxiety (Dunivan et al., 2010). Many women with incontinence problems do not share this condition with their family members, friends, and even caregivers (Bharucha et al., 2015). It explains why AI is under-recognised. One study reported that only 2.7 % of patients with FI had a medical diagnosis (Dunivan et al., 2010), and in one study, less than one-third of patients with FI had disclosed this to a provider (Johanson & Lafferty, 1996).

Health care costs associated with PFD and FI

FI adversely affects the quality of life and is associated with higher health care costs, both direct and indirect. Direct costs can be described as costs related to receiving or providing treatment, hospital charges, costs for medications or incontinence pads, diagnostic tools, surgical interventions, also transport. Indirect costs are costs to society or the person from work changes or absences, e.g., lost productivity, lost wages, premature retirement, lost income for family members who take care of incontinent patients. Consequent costs are those for treating the sequelae of the incontinence, like skin lesions. Faecal incontinence is one of the most important reasons for arranging nursing home care for afflicted family members, thus increasing total care costs (Miner, 2004). In the US, severe FI was associated with 55 % higher total direct primary care costs than continent patients and 77 % higher gastrointestinal-related health care costs (Dunivan et al., 2010). In the Netherlands, total costs were estimated at 2169 EUR per faecal incontinent patient per year, and more than half of these costs were indirect non-medical costs (Deutekom et al., 2005). Another study considering only direct medical treatment costs of FI after childbirth found the costs to be 17 116 USD per patient (Mellgren et al., 1999). The costs are increasing with time: it was calculated that the direct costs associated with ambulatory care for all PFDs have almost doubled between 1996–1997 and 2005–2006, reaching the average annual cost of 298 million USD in 2005–2006 (Sung et al., 2010).

Perineal trauma is the fourth most common indication for claims made in obstetrics, and 31 million GBP were awarded in legal pay-outs for this indication in 10 years in the UK, with the highest pay-out for an OASI equal to 1.6 million GBP (Jha & Sultan, 2015).

Childbirth trauma as a risk factor for AI

A group of women at risk of AI following delivery includes those with obstetrical anal sphincter injury (OASI) during childbirth (Abramowitz et al., 2000; Harvey et al., 2015; De Leeuw et al., 2001) or injury to the pudendal nerve. Other risk factors are irritable bowel syndrome and neurologic diseases such as diabetes (Nelson, 2004). Women who had an anal sphincter laceration during childbirth were most likely to report anal incontinence five to ten years after delivery (Evers et al., 2012). Another long term follow-up showed that 29.2 % of women have a lower quality of life because of AI more than ten years after delivery with OASI (Jangö et al., 2020), compromising their social life, sports activities, self-esteem and sexual life.

1.2.5 Obstetrical anal sphincter injuries

Obstetrical anal sphincter injuries, in literature also described as severe perineal tears, include both third and fourth-degree perineal lacerations. Initially, the severity of perineal lacerations was classified into four grades: grade 1 (superficial vaginal or perineal skin), grade 2 (vaginal muscles), grade 3 (in or through external anal sphincter muscle), and grade 4 (external and internal anal sphincters and anorectal lumen) (Cunningham et al., 2018), but due to the lack of consistency in the classification of a partial anal sphincter which caused frequent misattribution of partial EAS laceration as a 2^{nd} degree, more specific classification was introduced and adopted by WHO and the International Consultation of Incontinence (Haylen et al., 2010; A. Sultan et al., 2009; *WHO recommendations: intrapartum care for a positive childbirth experience*, 2018). Nowadays, grade 3 is further refined as involving the anal sphincter complex and is divided into 3a, 3b, 3c, so all perineal lacerations are classified as follows in table 1.2 (American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Obstetrics, 2016; Harvey et al., 2015).

Table 1.2

Classification of perineal lacerations

First degree	Injury to perineal skin only
Second degree	Injury to perineum involving perineal muscles but not involving the anal sphincter
Third degree	Injury to perineum involving anal sphincter complex
3a	Less than 50 % of external anal sphincter thickness torn
3b	More than 50 % external anal sphincter thickness torn
3c	Both external anal sphincter and internal anal sphincter torn
Fourth degree	Injury to perineum involving anal sphincter complex (external anal sphincter and internal anal sphincter) and anal epithelium

A button-hole injury (only the vaginal and rectal mucosa are involved) should not be classified as a third or fourth-degree tear if found in isolation (Harvey et al., 2015).

The incidence of OASIS may vary a lot according to many variables, including hospital practice, use of any type of episiotomy (mediolateral or midline), type of delivery (spontaneous or assisted vaginal), and type of instrument used (forceps or vacuum); parity, age, race and obstetrical care provider. Overall, studies looking at the incidence of OASIS based on the WHO's International Classification of Diseases report an incidence of 4 % to 6.6 % of all vaginal birth, with higher rates in assisted deliveries (6 %) than in spontaneous vaginal deliveries (5.7 %) (Harvey et al., 2015). There is a significant increase in the incidence of OASIS over three decades in the Nordic countries, and substantial difference by countries: Denmark 3.6 %, Norway 4.1 % and Sweden 4.2 %, compared to Finland 0.6 % (Ekéus et al., 2008; Laine et al., 2009). The authors assume that higher episiotomy frequency and the classic method of protecting perineum, which is still in use in Finland, but not in other Nordic countries, might be the contributing reasons for such a big difference (Laine et al., 2009). Training the obstetricians and midwives in perineal support techniques can reduce the incidence of OASIS by 23 % (Naidu et al., 2017). Also, in Australia, OASI rates among primiparous are increasing: from 4.1 % in 2001 to 5.9 % in 2011 (Ampt et al., 2015).

OASI rates in Europe in 2010 and episiotomy rates are shown in Figure 1.9. The left Y-axis refers to OASI rates, and the right Y-axis to episiotomy rates (Blondel et al., 2016).

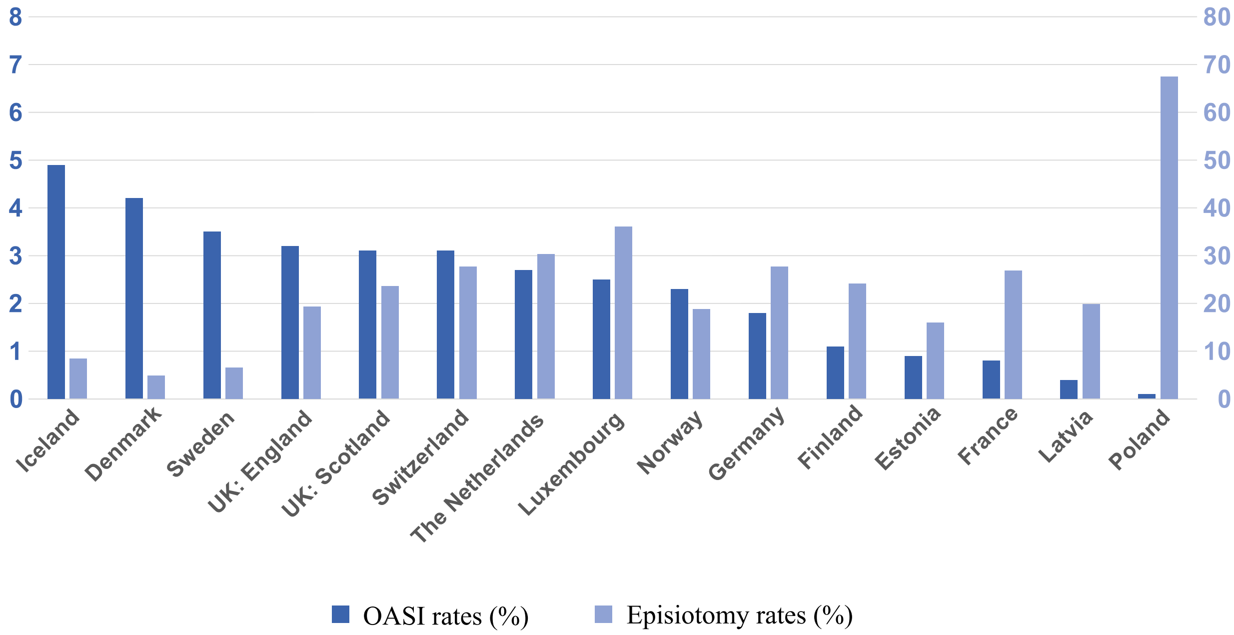

Figure 1.9 **OASI and episiotomy rates in Europe in 2010 (total vaginal deliveries)**

Risk factors for OASI

Common risk factors for sphincter damage during childbirth are forceps delivery, occiput posterior presentation of the foetus, nulliparity, foetal birth weight more than 4 kg and prolonged second stage of labour (Christianson et al., 2003; Dahl & Kjølhede, 2006; Kamm, 1998; Samarasekera et al., 2009; Sultan et al. 1994; 2009). A meta-analysis of 22 observational studies also added episiotomy, epidural anaesthesia, and labour augmentation to risk factors for OASI (Pergialiotis et al., 2014). Obstetrical anal sphincter injuries are more commonly associated with forceps deliveries than vacuum-assisted vaginal deliveries (De Leeuw et al., 2001). Women with complete sphincter injuries have anal incontinence more often than women with partial sphincter injuries (Palm et al., 2013). *Childbirth and Pelvic Symptoms study* (CAPS) identified six factors (or actions affecting delivery) related to OASI, that could be considered modifiable. After adjusting for maternal age, race, and gestational age, these factors are the following: forceps, vacuum, episiotomy, prolonged second stage of labour > 2 hours, occiput posterior foetal position at the time of crowning, and epidural use (Fitzgerald et al., 2007). These modifiable factors and their odds ratios are shown in Figure 1.10.

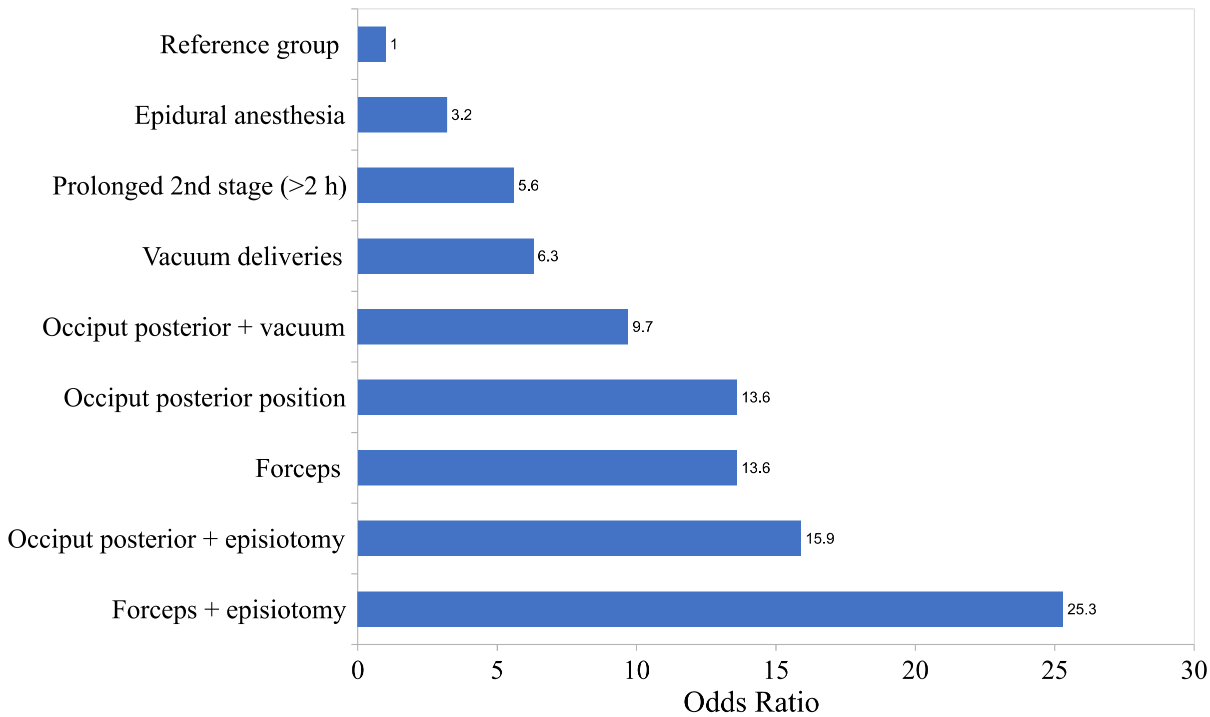

Figure 1.10 **Estimated odds ratio for factors being related to OASI during vaginal delivery**

Summary of different studies looking for various risk factors for OASI and their odds ratios is shown in Table 1.3 (all OR are significant):

Table 1.3

OASI risk factors

Risk factors for OASI	Odds ratio	Reference
Maternal risk factors		
Age (> 27)	1.9	Baghestan et al., 2010; Gerdin et al., 2007; Handa et al., 2001; Richter et al., 2002, 2006; Zetterström et al., 1999
Age (> 35)	1.1	Baghestan et al., 2010
Primiparity	3.5–9.8	Pergialiotis et al., 2014
Race (Reference – European)	0.56–2.5	Gerdin et al., 2007; Handa et al., 2001; Ramm et al., 2018
Diabetes	1.2–1.4	Gerdin et al., 2007; Handa et al., 2001
Perineal length < 25mm	1.4	Deering et al., 2004; Kapoor et al., 2015
Infant risk factors		
Birth weight > 4000g	2.2–3.0	Zetterström et al., 1999
Birth weight > 3500g	1.28–1.9	Meister et al., 2016; Perone, 2007; Ramm et al., 2018
Occiput-posterior presentation	2–7	Fitzgerald et al., 2007; Gerdin et al., 2007
Gestational age > 41 weeks	1.1–2.5	Baghestan et al., 2010; Zetterström et al., 1999
Delivery risk factors		
Vacuum delivery	1.5–6.3	Baghestan et al., 2010; Fenner et al., 2003; Fitzgerald et al., 2007; Handa et al., 2001; Jangö et al., 2020; Richter et al., 2002
Forceps	2.3–5.6	Baghestan et al., 2010; Fenner et al., 2003; Handa et al., 2001; McPherson et al., 2014; Richter et al., 2002
Vacuum + forceps	8.1	Baghestan et al., 2010; Murphy et al., 2011
Mediolateral episiotomy	0.21	Fenner et al., 2003; de Leeuw et al., 2001; Murphy et al., 2011
Midline episiotomy	2.3–5.5	Fenner et al., 2003; Murphy et al., 2011
Vacuum + episiotomy	0.6	Fitzgerald et al., 2007; Jangö et al., 2020; Pergialiotis et al., 2014
Epidural anesthesia	0.84–1.95–3.2	Fitzgerald et al., 2007; Gerdin et al., 2007; Jangö et al., 2020; Pergialiotis et al., 2014; A. B. Rygh et al., 2014
Prolonged 2nd stage (ref. = 1h)	1.5–1.6	Fitzgerald et al., 2007; Perone, 2007
1–2 hours	2.62	Ramm et al., 2018
2–3 hours	4.41	Ramm et al., 2018
> 3 hours	7.32	Ramm et al., 2018
Labour induction	1.08	Pergialiotis et al., 2014
Shoulder dystocia	2.7–3.3	Alhadi et al., 2001; Jangö et al., 2020
VBAC	1.4–5.5	Perone, 2007; Richter et al., 2002
Water birth	1.46	McPherson et al., 2014
Oxytocin augmentation	1.2–1.95	Jandér & Lyrenäs, 2001; Pergialiotis et al., 2014

Occult OASI and role of imaging methods in the diagnosis

Different OASIS rates in literature can also be explained with incorrect diagnosis during delivery since OASIS is often misdiagnosed at the time of delivery by obstetrical care providers (Harvey et al., 2015). One study reported that the overall rate of missed OASIS ranged from 26 % to 87 %. (Andrews et al., 2006b; Guzmán Rojas et al., 2013). The prevalence of OASIS increased significantly from 11 % to 24.5 % when a trained research fellow re-examined women, and besides, 1.2 % of women had an occult anal sphincter injury diagnosed only by US immediately after delivery (Andrews et al., 2006b). Physical examination significantly underestimates the frequency of postpartum sphincter disruption (Madoff et al., 2004), and the actual incidence of occult anal sphincter injury following vaginal delivery is much higher than commonly estimated. Occult sphincter defects have been detected by ultrasonography in up to 35 % of primiparous women after a normal vaginal delivery; with the associated incontinence rate from 13 % to 23 %, and between 4 % and 8.5 % of multiparous women; however, at least two-thirds of occult defects are asymptomatic postpartum (Oberwalder et al., 2003; Sultan et al., 1994). However, it is not certain that all these injuries are truly occult; they could be missed on clinical examination. There is evidence that many third-degree tears are misclassified as second-degree (Fernando et al., 2002).

The available imaging modalities include endoanal ultrasound (EAUS), transvaginal ultrasound (TVUS), transperineal / translabial ultrasound (TPUS), with or without three-dimensional (3D) imaging. EAUS is still considered the modality of choice and is also used widely by gastroenterologists and colorectal surgeons (Eisenberg et al., 2019). EAUS is superior to other diagnostic tools, like manometry or clinical assessment, to evaluate sphincter defects; when confirmed histologically, EAUS had an accuracy of 100 % (Sultan, 2003).

A typical ultrasound **image of the anorectum** consists of two discrete rings of tissue. The inner hypoechoic ring of tissue represents the IAS formed by the thickened continuation of the rectum's circular smooth muscle. The outer hyperechoic ring of tissue represents the longitudinal muscle and the EAS formed by the downward extension of the puborectalis skeletal muscle. The regular IAS is between 2 to 3 mm thick, and the standard EAS is 7 to 9 mm thick. EAS tears appear as hypoechoic areas in the ordinarily hyperechoic ring on EAUS, while IAS tears appear as hyperechoic breaks. It is due to the replacement of the normal striated muscle with granulation tissue and fibrosis (see Figure 1.11).

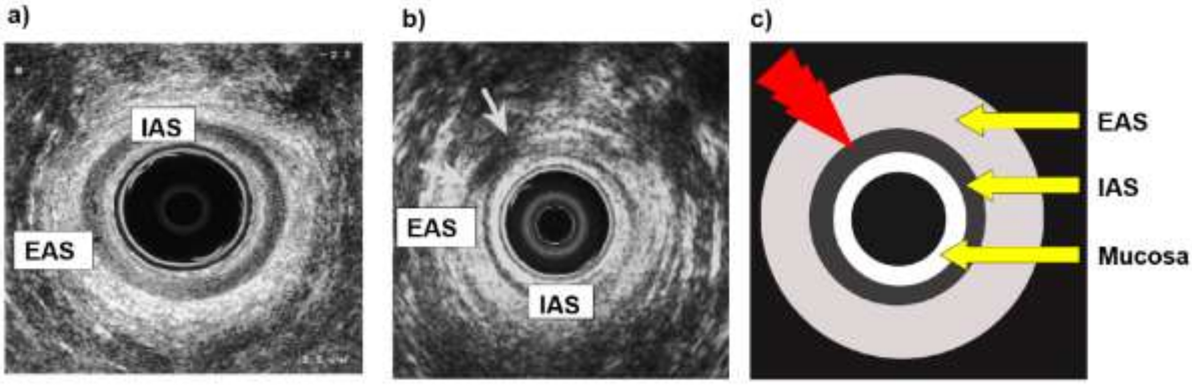

Figure 1.11 **Anal ultrasound showing the anal sphincter muscles in cross-section through the middle anal canal**

The darker homogenous ring is the internal anal sphincter smooth muscle (IAS). The heterogeneous white ring surrounding this is the external anal sphincter (EAS). a) normal anal sphincter, b) rupture of EAS and IAS between the white arrows, c) schematic view of US finding with EAS and IAS rupture.

The results obtained with EAUS are somewhat dependent upon the operator's experience. However, it is considered to be easy to learn, and intra and interobserver variability are low: kappa = 0.80 and 0.74 for intraobserver and interobserver agreement, respectively (Gold et al., 1999).

The **timing of ultrasound postpartum** can influence findings, too. Despite this, the immediate EAUS has the potential to identify missed injuries, thus preventing delay to anatomic repair; the sensitivity can be reduced because of difficulties in scan interpretation related to tissue oedema, lacerations, and bleeding (Dudding et al., 2008). Sphincter damage or sphincter relaxation under epidural anaesthesia may cause poor contact of the probe against the anal mucosa, leading to imaging artefact (Faltin et al., 2000). Other authors report early EAUS within one week after delivery (Starck et al., 2003; Varma et al., 1999). Also, at that time, the visualisation can be incomplete because of “true” defects due to inappropriate repair technique, or because of postoperative haematoma or oedema, or by devascularisation of the EAS fibres caused by sutures, thus intraobserver disagreement can reach 13 % (Starck et al., 2003). Late EAUS (more than two months after delivery) can detect missed injury, assess the results of primary repair, and be used to predict the outcome of future pregnancies.

It was noted that most endoanal scanners are located in specialised radiological or proctological centres and not in obstetric departments, and thus transvaginal ultrasound and transperineal ultrasound with vaginal or transabdominal probes, available in almost all obstetric units, have been evaluated as alternative imaging modalities. The transperineal approach was evaluated in search of less invasive, more user-friendly, more accessible and more patient-acceptable imaging.

Transvaginal US has low sensitivity when compared with EAUS, and only around half the number of internal or EAS defects can be detected because of the anatomic limitations this approach imposes on axial imaging of the anal canal (Frudinger et al., 1997).

Transperineal US may be comparable and more acceptable to the patient in the immediate postpartum period (Cornelia et al., 2002). Years ago, the transperineal US and the transvaginal US were considered not to be accurate modalities for assessing anal sphincters after delivery (Ros et al., 2017), and there have been only a few studies comparing these modalities, but the current understanding is that TPUS is at least as good as EAUS (Eisenberg et al., 2019). Unlike EAUS, in TPUS, there is no distortion of the anal canal by the transducer during the examination, and evaluation of the anal sphincter and mucosa is possible in the resting position. Both transvaginal and transabdominal probes can be used in TPUS, placing them in the area of the fourchette. The TPUS with the transvaginal probe has better resolution and high-quality imaging, but the drawback is decreased visualisation at the 12 o'clock position. A thorough examination of the pelvic floor by the transabdominal probe is possible simply by tilting the transducer, and it allows better visualisation at the 12 o'clock position (Eisenberg et al., 2019). Advantages of the transperineal US include the availability of commonly used transducers, the absence of distortion of the anal canal and better patient acceptability (Abdool et al., 2012). Dynamic 2-dimensional transperineal ultrasound evaluation before any suturing in the delivery room can be used as a screening tool for anal sphincter injuries and elevated anal incontinence risk (Bellussi et al., 2019).

Imaging has evolved from static 2D imaging to dynamic 3D volumetric imaging, and recently even four-dimensional (4D) imaging. **Three-dimensional (3D) ultrasound** uses computer software to reconstruct standard US images into a 3D image. 3D imaging enables the determination of length, thickness, area, and volume measurements which may be displayed as either multiplanar images or tomographic slicing, which allows better visualisation of defects (Abdool et al., 2012). 3D imaging improves diagnostic confidence in detecting damage to the anal sphincter complex (Christensen et al., 2005).

Two modalities of **magnetic resonance imaging (**MRI) are available in clinical practice: the invasive endoanal MRI using endoluminal coils and the non-invasive external phased array (Sbeit et al., 2021). Endocoil MRI is a more expensive and time-consuming investigation than EAUS, but in a setting where EAUS imaging is not accessible, MRI can be used to evaluate possible sphincter injuries (Kirss et al., 2019). Sensitivity and positive predictive values were 81 % and 89 %, respectively, for endoanal MR imaging and 90 % and 85 %, respectively, for EAUS (Dobben et al., 2008). MRI showed that sphincter measurements do not change substantially from pre-pregnancy to 6 months after the first birth, regardless of the mode of delivery, and anal sphincter compromise during pregnancy and birth is not always visible with imaging technology (Meriwether et al., 2019). While ultrasound is superior in identifying IAS tears, EAS atrophy is more identified by MRI. Additionally, the distinction between fat and muscle and the discrimination between an EAS tear and scar is better with MRI (Sbeit et al., 2021).

Repair of OASI

Usually, OASI is repaired immediately after delivery by a gynaecologist. There is no consensus in the literature whether colorectal surgeons should always be involved in acute OASI repair. A British survey showed that the number of acute OASI repairs per year was higher among gynaecologists vs. coloproctologists: 46 % of gynaecologists and 10 % of coloproctologists performed more than five repairs per year (Fernando et al., 2002). The approach to the use of antibiotics or laxatives was similar between both types of specialists, but the use of colostomy was very different: 30 % of coloproctologists recommended colostomy, while none of the gynaecologists either performed or requested colostomy. In the same survey, most coloproctologists recommended caesarean section for subsequent delivery; by contrast, most obstetricians allowed vaginal delivery with an elective episiotomy. Coloproctologists favoured the overlap technique for primary repair of OASI (89 %), while gynaecologists use both: end-to-end and overlap techniques (Fernando et al., 2002).

Meta-analysis of six RCTs showed that at one-year follow-up, immediate primary overlap repair of the EAS compared with immediate primary end-to-end repair appeared to be associated with lower risks of developing faecal urgency and anal incontinence symptoms. However, at the end of 36 months, there appeared to be no difference in flatus or faecal incontinence between the two techniques (Johanson et al., 2003). Other studies did not find any significant differences between the two methods, neither concerning the AI at 12 months nor EAS defects evaluated by US or anal manometry (Rygh & Korner, 2010). The Royal College of Obstetricians and Gynaecologists does not prefer one method over the other, stating that either an overlapping or end-to-end (approximation) method can be used, with equivalent outcome. However, it is important to repair third- and fourth-degree tears in an operating theatre, under regional or general anaesthesia, by appropriately trained practitioners (Pandit et al., 2018). Despite the debate, OASI treatment and follow-up is teamwork: when asked to whom they would refer a patient with FI six months after OASI, a coloproctologist was mentioned first, followed by a urogynaecologist and a physiotherapist (Best et al., 2012).

1.2.6 Correlation of the mode of delivery with pelvic floor disorders

Although PFDs are highly prevalent among parous women, severe PFDs are also found among nulliparous, and not all women with obstetrical risk factors develop PDFs immediately after delivery or later in their life. The complex interactions between physiology during pregnancy, childbirth mechanics, obstetric interventions, and other predisposing factors (e.g. genetics) remain unclear (Hallock & Handa, 2016).

Pregnancy specific factors promoting FI or AI during pregnancy are not well understood, but normal physiologic changes of late pregnancy, like increased transit time and increased intraabdominal pressure of the third trimester, may contribute to incontinence for women with pre-existing pelvic floor or anal sphincter dysfunction. The pelvic floor is a dynamic structure that adapts during pregnancy and delivery. Mechanisms of adaptation include: lengthening pelvic floor muscle fibres, expanding the levator hiatus, increasing elastase activity (Hallock & Handa, 2016). There are two principal pathophysiologic mechanisms during childbirth: nerve and muscle injury.

There are ongoing discussions on which may be the safest mode of childbirth to prevent PFDs. Some women ask for elective CS, primarily due to the fear of childbirth (Jenabi et al., 2019), usually expressed as a fear of pelvic floor injuries (Nama & Wilcock, 2011). A survey among medical professionals showed that vaginal delivery is the preferred mode of delivery, but more than half would more likely choose CS to preserve the pelvic floor (Bihler et al., 2019).

There is a lack of convincing evidence that pregnancy alone or undergoing labour increases FI or AI risk. Different observational studies have supported and refuted an increased risk of FI and AI for women undergoing vaginal birth compared with caesarean delivery.

Increased risk of FI or AI for vaginal delivery versus caesarean delivery was shown in the following studies:

1. *Kaiser Permanente Continence Associated Risk Epidemiology Study*: among more than 4000 women, almost twofold risk of AI was found in those women with a prior vaginal birth (compared with nulliparous, OR for CS was 0.89, for one vaginal delivery 1.39, for 2 VD – 1.4, for 3 VD – 1.66) (Lawrence et al., 2008; Lukacz et al., 2006).
2. A large Swedish national population-based study in 2019 included over 3.7 million people: parous women and nulliparous women, and age-matched men as a control group. It analysed women who gave birth by either vaginal or caesarean delivery only between 1973 and 2015 and linked the delivery mode data to AI diagnoses

between 2001 and 2015. The study concluded that women who underwent only vaginal deliveries were more likely to be diagnosed with AI than women who underwent only caesarean delivery: the OR for anal incontinence after vaginal delivery compared with caesarean delivery was 1.65. For the nulliparous women compared with men, the OR for anal incontinence was 1.89. The most substantial risk factors for anal incontinence after vaginal delivery were high maternal age, high birth weight of the child, and instrumental delivery (Larsson et al., 2019).

3. A 2008 systematic review of 18 studies, including more than 12,000 women, examined the mode of delivery and FI/AI symptoms in the first 12 months postpartum and concluded that women having any vaginal delivery compared with a caesarean section had an increased risk of developing symptoms of solid, liquid or flatus anal incontinence. The risk varies with delivery mode: for a forceps delivery, OR was 2.01, for a spontaneous vaginal delivery OR was 1.32. The risk increase was not statistically significant for vacuum-assisted deliveries alone versus spontaneous (Pretlove et al., 2008).

Studies reporting no difference in FI or AI between vaginal and caesarean delivery modes include:

(1) A systematic review of 21 studies, including over 31,500 women (6000 CDs and 25,000 VDs), found no difference in continence preservation in women with caesarean delivery versus vaginal delivery and recommended against this criterion for choosing elective primary caesarean delivery (Nelson et al., 2010).

(2) *The Mothers' Outcomes After Delivery study* (MOAD) was a prospective cohort study of pelvic floor outcomes in more than 1000 women recruited 5–10 years after delivery of their first child and followed up annually for up to 9 years. The study showed that compared with spontaneous vaginal delivery, caesarean delivery was associated with a significantly lower risk for stress urinary incontinence, overactive bladder, and pelvic organ prolapse, but not for anal incontinence, while operative vaginal delivery was associated with a significantly higher risk of anal incontinence and pelvic organ prolapse (Blomquist et al., 2018; Handa et al., 2011).

(3) *Twin Birth Study* is the largest randomised trial of planned caesarean or vaginal delivery, including over 2800 women with twin pregnancies, reported no difference in faecal or flatus incontinence at either three-month or two-year follow-up (Barrett et al., 2013).

Another disputable question remains the type of vaginal delivery. Some studies demonstrate controversial results on the risk of AI after operative vaginal birth compared with spontaneous vaginal delivery; still, the overall body of systematic reviews demonstrates that operative vaginal delivery is a risk factor of anal incontinence (Handa et al., 2012; Larsson et al., 2019; Pretlove et al., 2008). A randomised clinical trial to assess anal sphincter function following forceps or vacuum delivery showed that symptoms of altered faecal continence are significantly more common following forceps assisted vaginal delivery (Fitzpatrick et al., 2003), also MOAD study favoured vacuum delivery versus forceps in terms of AI (Pretlove et al., 2008).

In conclusion, we can say that all providers should counsel their patients about vaginal and caesarean delivery. Discussion of the risks and benefits of operative vaginal delivery or episiotomy should also include counselling about the risk of perineal lacerations and consequences (Meister et al., 2016).

1.3 Electromyography

Electromyography (EMG) is an electrodiagnostic technique for evaluating and recording the electrical activity of skeletal muscles. EMG detects the electrical potential generated by muscle cells when these cells are electrically or neurologically activated.

EMG signals can be detected with electrodes inserted inside the muscle (intramuscular electromyography (iEMG)) or with surface electrodes (surface electromyography (sEMG)).

Multichannel EMG is the summation of electrical contributions from individual motor units detected with multiple electrodes.

The types of electrodes used in iEMG can be divided into:

- coaxial needle electrodes (widely used by neurologists),
- bipolar needle electrodes, monopolar needle electrodes (larger recording surface, less specific).

The types of electrodes used in sEMG can be divided into:

- bipolar electrodes (pairs of external patches placed on the skin overlying the muscle),
- linear electrode arrays (multiple electrodes aligned in a row and equally spaced),
- bidimensional arrays (multiple electrodes positioned in bidimensional grids),
- high-density arrays (electrodes positioned in grids with several detection points in a reduced detection area),
- rectal or vaginal probes (multichannel electrodes arranged in cylindrical support).

Some electrodes can be used either for the detection of EMG or electrically induced muscle contraction. A possible application of electrical stimulation is to assess nerve conductivity and neuromuscular transmission (Krhut et al., 2018).

The bipolar arrangement is the most common form for detection of sEMG signals, which allows recording the difference between signals detected by two electrodes placed over the same muscle a certain distance apart. Signals recorded by the bipolar configuration can be affected by anatomical, geometrical, physical and detection parameters, such as the thickness of the tissue between the electrodes and the muscle, the length of the fibres, the tissue inhomogeneity, the inter-electrode distance, and the shape, size, location and orientation of the electrodes concerning the muscle fibres (Farina et al., 2002).

1.3.1 Electrophysiology of motor units

A **motor unit (MU)** is composed of an anterior horn cell, an axon, axonal branches, motor end-plates, and muscle fibres innervated by this cell. The ensemble of the neuromuscular junctions (NMJ) between the axonal branches and the muscle fibres is called the **innervation zone (IZ)** of that motor unit (see Figure 1.12).

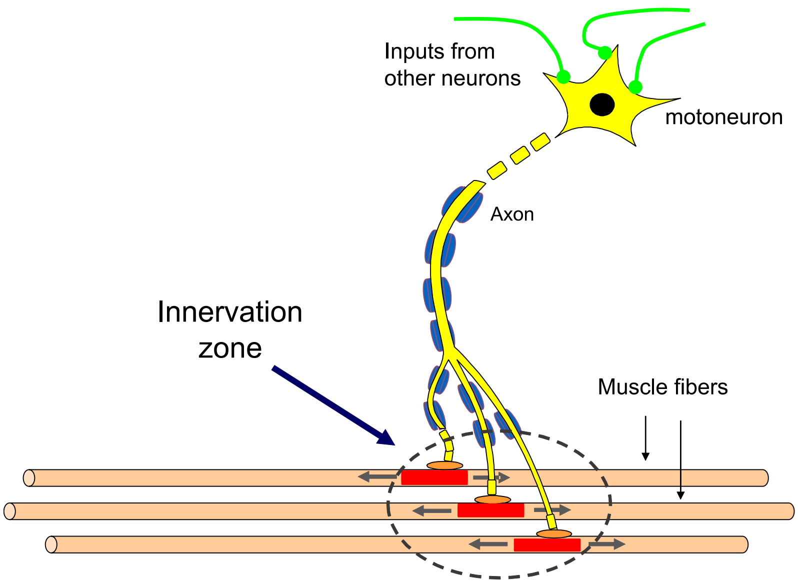

Figure 1.12 **Motor unit and its innervation zone**

A muscle fibre has a membrane resting potential of about −70 mV (internal negative). When the action potential of a neuron reaches the terminal branches of the axon and each neuromuscular junction, the release of acetylcholine locally leads to depolarisation and repolarisation (inversion of the membrane polarity) and triggers an action potential into each of the innervated muscle fibres (Merletti, 2016). The depolarisation–repolarisation cycle forms a depolarisation wave travelling along the surface of a muscle fibre. Since a MU consists of several muscle fibres, the electrode pair records potentials of all active fibres within this MU. The action potentials sum up to a so-called Motor Unit Action Potential (MUAP), which differs in form and size depending on the geometrical fibre orientation concerning the electrode(s) site (Medved & Cifrek, 2011). The EMG analysis of MUAPs, can be performed at two levels: quantitative (amplitude and frequency) and qualitative (pattern of the action potential). Simultaneous activation of multiple MU induces the contraction of a muscle. The number of recruited MU and their discharge frequency of excitation determines electric activity recorded by EMG. There is a direct relationship between the EMG amplitude and the muscle force (Krhut et al., 2018). Since the number of motor units activated increases with the increase in strength of muscle contractions, electrical activity is considered to be a representation of the level of strength developed by the muscles (Bocardi et al., 2018).

1.3.2 Surface Electromyography

An unfiltered and unprocessed signal comprising the superimposed MUAPs is called a raw EMG signal. In Figure 1.13 a raw surface EMG recording is shown.

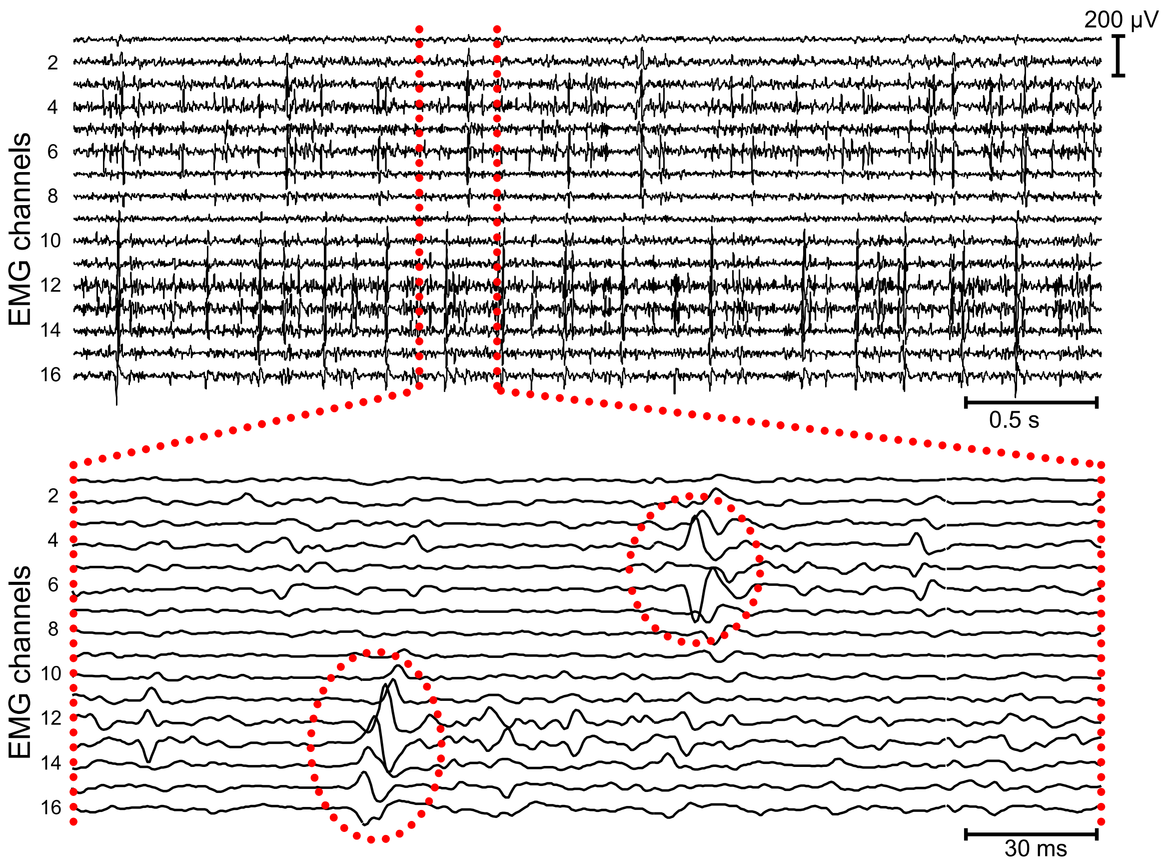

Figure 1.13 **Example of raw EMG signal**

The upper panel shows an example of raw EMG signal detected with a 16-channel linear array on the biceps brachii muscle. A subportion with a larger timescale is shown in the lower panel.

When each channel is detected by a pair of active electrodes positioned in proximity of a muscle, and a ground (reference or common) electrode is placed on a neutral tissue, the modality of detection is defined called bipolar or differential (see Figure 1.14).

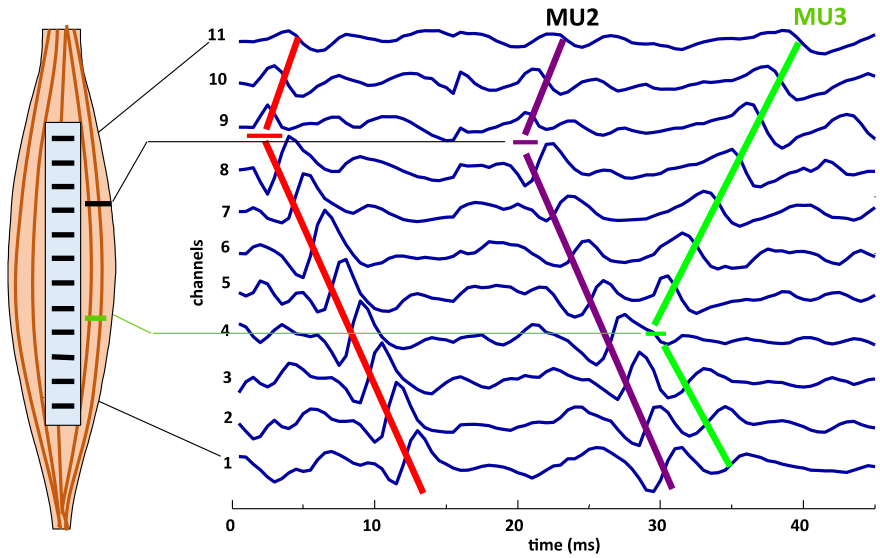

Figure 1.14 **Multichannel EMG detection**

Example of signal from the biceps brachii detected with a linear electrode array in a bipolar configuration. The action potentials of three motor units (MU1, MU2, MU3) are visible. Adapted from Merletti, 2004.

For recording EMG, amplifiers are necessary. The differential amplifier compares the information from all electrodes and discards the background electrical noise of the body. The remaining information from the target muscle is then amplified to reduce the impact of environmental noise or artefacts (Merletti, 2016). The signals detected and amplified are then digitally transmitted to acquisition systems, such as PC or tablets with wireless transmission protocols. Current amplifiers use Wi-Fi technology, and their size does not exceed the size of a mobile phone (see Figure 1.15).

Figure 1.15 **EMG amplifiers**

Examples of multichannel EMG amplifiers, desktop (A), portable (B), wearable (C) (from *OT-Bioelettronica*) sEMG does not require any specific preparation of the patient, it is non-invasive and painless. However, the patient should be capable of following the instructions given by the operator (to contract or to relax the muscles) since EMG signal acquisition is performed either at rest or maximal voluntary contraction (MVC) status.

1.3.3 Electromyography of the pelvic floor

The pelvic floor is a complex consisting of several muscles being activated synergically to hold continence. The muscles involved are both smooth (e.g. internal anal sphincter) and striated (e.g. EAS, levator ani and puborectalis, etc.). Electromyography can detect signals only from striated muscles close to the skin or mucosa surface; thus, the muscles suitable for EMG detection are only EAS, levator ani and puborectalis muscles.

Morphometry and histochemistry of EAS, levator ani and puborectalis muscles of normal human subjects show that the three muscles present a marked predominance of type 1 fibres (70 %), a feature of tonic slow-twitch muscles (Enck & Vodušek, 2006). The neurons innervating each side of pelvic floor muscles have to work in harmony and synchronously; thus, the pelvic floor is primarily seen as a functional unit, and the muscles involved in the closure of excretory tracts or supporting pelvic organs act in a strictly unified fashion as one muscle. Nevertheless, each muscle in the pelvis has its own (unilateral) peripheral innervation, and flexible activation patterns could be possible in principle (Vodušek, 2004).

EMG of the pelvic floor allows assessing if the nerve supply to a muscle is damaged. If some muscle fibres become denervated, it leads to a loss of functional activity within these muscle fibres. However, if the damage is partial, re-innervation may occur either by regrowth of the injured axon or by axonal sprouting of nearby unaffected axons. EMG can detect these changes since MUAP morphology is altered: denervation causes reduced EMG activity, the amplitude of MUAP may be reduced and its duration prolonged, while re-innervation can be detected by polyphasic MUAP (Fitzpatrick & O’Herlihy, 2001).

Different **types of probes** have been developed to assess the EMG activity of the pelvic floor. Superficial (adhesive around perineal zona), concentric needle electrodes, needle-guided wire electrodes, circular vaginal or anal probes have been investigated.

Since needle EMG is uncomfortable for the patients and records only from a small number of MU, failing to reflect global muscle activity, surface EMG can be a valid alternative. However, external patch electrodes (adhesive), placed over the perineal area, create technical problems related to possible shift, perineal fat thickness or hair. These electrodes also have low subject acceptability, while intravaginal probes may cause the crosstalk phenomenon (Flury et al., 2017). Crosstalk is a type of artefact, recording activity originating from neighbouring muscles rather than coming exclusively from the investigated muscles. Simultaneous co-activation of EAS and gluteus muscles is the most common type of crosstalk (Holobar et al., 2008). Minimising crosstalk is essential to improve signal quality in research focused on pelvic floor EMG (Bo et al., 2017). Other EMG artefacts may be caused by electrical equipment such as lights, transformers, electrocautery units, or by improper grounding, movement of the patient, electrodes being placed too far from the sphincter, becoming wet, having insufficient gain or falling off the patient (Qu et al., 2011). Cylindrical anal probes help to avoid artefacts caused by the displacement of electrodes.

The motor units of EAS are arranged circularly to form a contractile ring, and for the detection of their action potentials, the probe should be cylindric, and the electrodes should be distributed along the circumference to follow the primary muscle fibre orientation. Figure 1.16 shows different types of the first cylindric vaginal and anal probes with two electrodes.

Figure 1.16 **Vaginal and anal probes with bipolar electrodes**

1: EMG biofeedback and electrostimulation probes with 4 electrodes *Perisphera®* by BeacMed: a) anal, b) vaginal. 2: rectal EMG probe by *Thought Technology*. 3: *Periform®*+ intravaginal probe for muscle stimulation and EMG biofeedback. 4: bipolar intraanal and intravaginal probe *Anuform®* by *NEEN HealthCare*. 5: the *Liberty* intravaginal probe by *TensCare*. 6: dual purpose EMG and stimulation probes by *Laborie.*

Intra-anal probes may require a lubricant for insertion which is neither conductive, like US gel (it would create short circuits), nor oily (it would prevent the contact between mucosa and electrodes). Glycerol is suitable for sphincter sEMG.

1.3.4 Recent advances of multichannel surface EMG to sphincters

High density (HD) EMG is based on a large number (32, 64 or more) of small surface electrodes equally spaced, applied to the same muscle or a muscle group. Using many electrodes permits to have many observation points of the muscle activity. Recent advances in pelvic floor electromyography and the achievements of the research group guided by prof. Merletti allows the functional analysis of external anal sphincter with a minimally invasive anal probe (Merletti et al., 2004).

Multichannel sEMG through electrode arrays applied to anal sphincter muscle can record and identify individual MUAPs, their place of origin along the circumference, their repetitive firing frequency, and their progression along the muscle fibres at different levels within the anal canal (Merletti et al., 2004), see Figure 1.17.

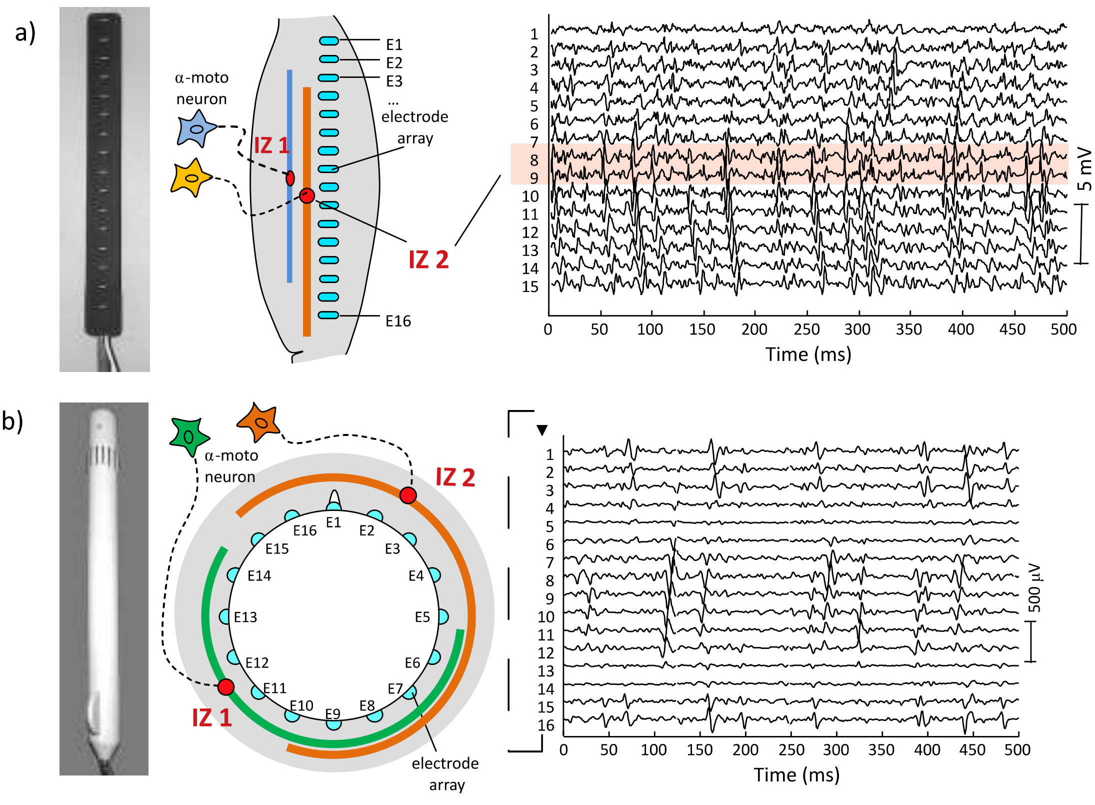

Figure 1.17 **Multichannel EMG of longitudinal muscle and sphincter**

a) EMG signals from biceps brachii with linear electrode arrays. b) EMG signals from external anal sphincter detected with the intra-anal probe with 16 electrodes. Adapted from Merletti et al., 2004.

Multichannel surface EMG allows simultaneous detection of bipolar EMG derivations from several locations, thus reducing artefacts (Enck et al., 2005).

The interpretation of multichannel EMG signals recorded by the EAS probe requires sophisticated **signal processing and modelling** One of the methods is signal decomposition. The multichannel recordings are the summation of the action potentials of the active MUs.

The **decomposition** of sEMG signals is the procedure for detecting and extracting the contributions of the single MU during contraction at different force levels. **Modelling** is a set of equations describing a physical system that allows, to a certain extent, to predict the system's changes due to modifications in the parameters. Modelling indicates the sensitivity of signal features to the physiological mechanisms and allows the estimation of system parameters that cannot be measured directly (Merletti et al., 2004).

Different new multiple electrodes and multiple arrays vaginal and anal probes have been developed recently. The principle of electrode situation on cylindric probes is shown in Figure 1.18.

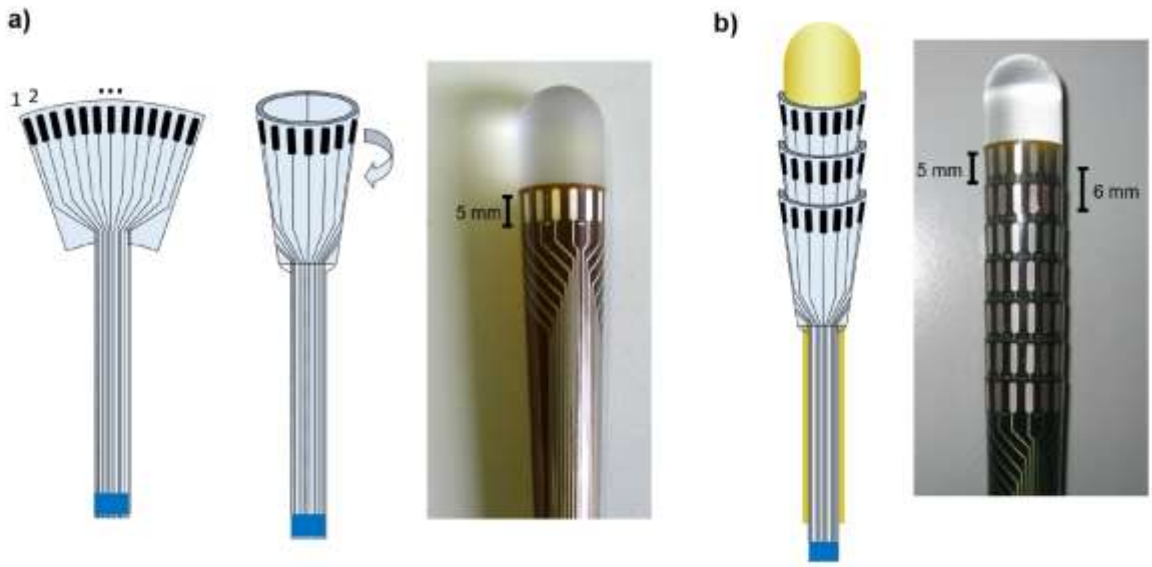

Figure 1.18 **Multichannel EMG anal probes**

a) a probe with a single array of electrodes. b) a probe with multiple arrays. Probes from the Laboratory for Engineering of the Neuromuscular System, Turin

A circular multiple array probe can detect MUs simultaneously at different depths, thus allowing the identification of a spatial location of the MUs. An example of signals detected with circular arrays fixed on a cylindrical probe inserted into the anal canal is shown in Figure 1.19.

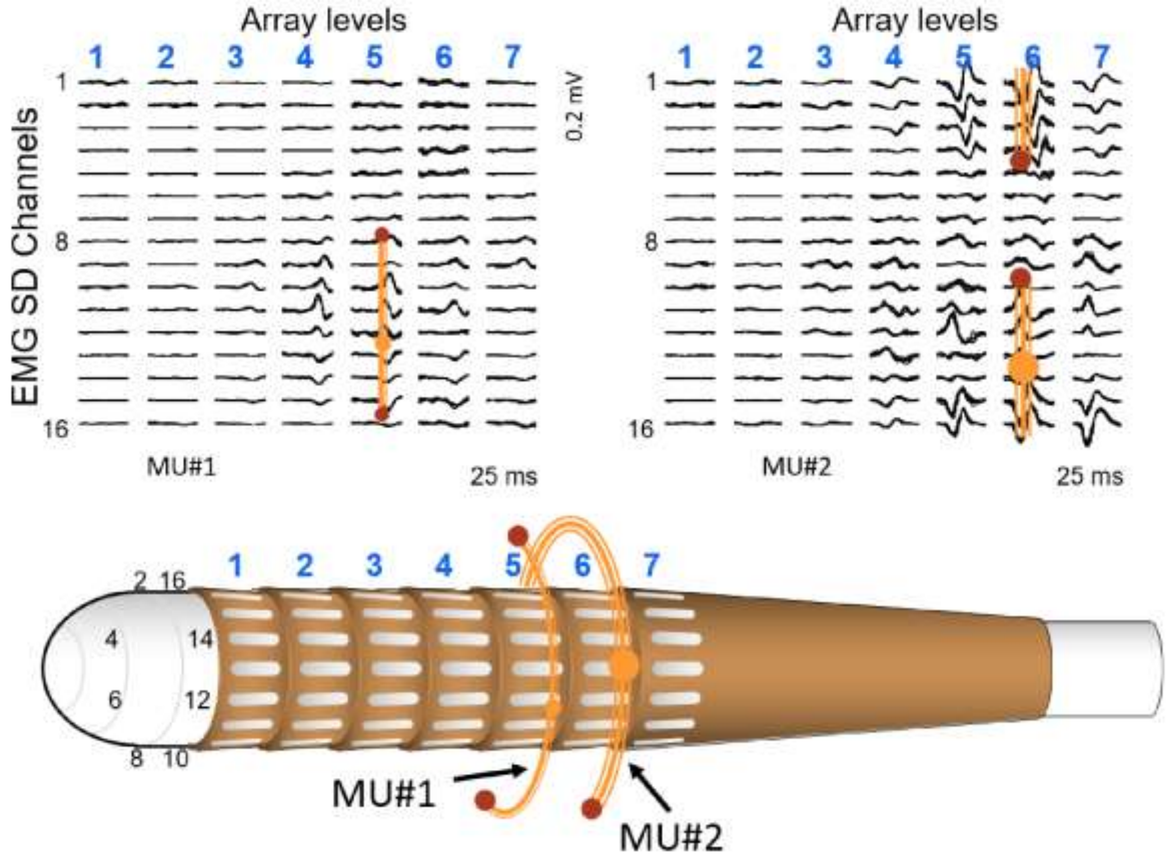

Figure 1.19 **Example of signals detected with multiple circular arrays on a cylindric anal probe**

The signals provide information on the structure and arrangement of some MU of EAS. Black numbers 1–16 are circular electrodes, blue numbers 1-7 are the depth levels. MU # 1 and its IZ is visible at level 3 from the 8th till the 16th channel. MU # 2 and its IZ is visible at level 2 from the 10th till the 4th channel.

Both vaginal and anal EMG probes should not stretch the PFM, and the electrode surfaces should be small and located close together and should not move concerning the vaginal wall or the anal canal (Paskaranandavadivel et al., 2020; Peng et al., 2016; Voorham-van der Zalm et al., 2013). Some of the multichannel anal probes of the authors mentioned above are shown in Figure 1.20.

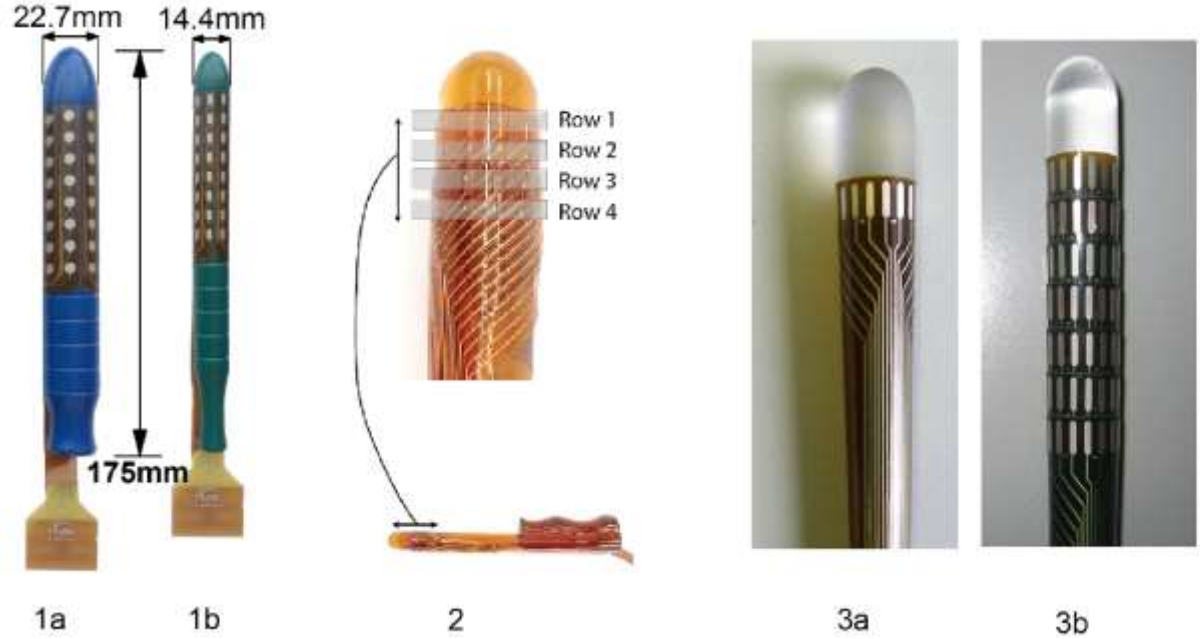

Figure 1.20 **Types of intra-anal multichannel EMG probes**

1: HD multichannel probes by Peng, a) vaginal, b) anal. 2: HD multichannel anal probe by Paskara.
3: Multichannel anal probes from LISiN (Turin), a) single array, b) multiple arrays.

The experimental setup for external anal sphincter EMG acquisition is thus composed of an amplifier (desktop or portable), a cylindrical probe with a circular array of electrodes arranged in a circumference, and a reference electrode to provide electrical reference to the amplifier, and that can be attached to the subject ankle or wrist, in an electrically neutral area. Figure 1.21 shows an example of an experimental setup.

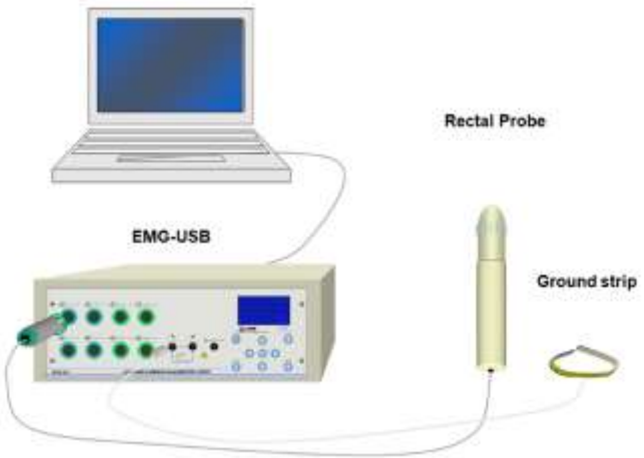

Figure 1.21 **Experimental setup with multichannel amplifier for the detection of EMG signals from the external anal sphincter**

The next research issue in HD EMG is the identification of innervation zones. Manual identification of the location of muscle IZs by visual analysis is a time-consuming procedure. Recent signal processing techniques allow identifying the innervation zone (IZ) location of individual motor units (Cescon, 2006). Different automatic offline algorithms can obtain a reliable and repeatable estimation of the IZ distribution of EAS from high-density sEMG (Cescon et al., 2011; Marateb et al., 2016; Mesin et al., 2009; Ullah et al., 2014), as shown in Figure 1.22.

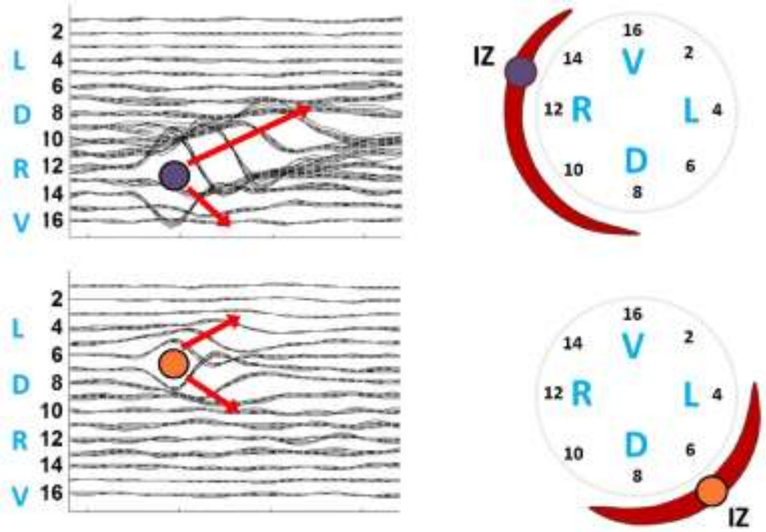

Figure 1.22 **Motor unit templates on the EAS**

Examples of sEMG detection of individual motor units from the EAS with a multichannel cylindric anal probe. The innervation zones (IZ) are visible from the EMG signals and are represented in the circular representation, where: L:left, D:dorsal, R:right, V:ventral quadrant.

The European project *"On Asymmetry in Sphincters"*, concluded in 2004, showed that it is possible to localise non invasively the EAS innervation zone, fibre length, EMG amplitude, muscle fibre conduction velocity, and single motor unit information can be obtained from the signals recorded with the circumferential array utilising innovative signal processing techniques. It was observed that the distribution of IZ of EAS was relatively uniform with large intersubject variability. Such distribution may be more or less symmetric (Enck, 2004; Enck et al., 2004).

1.3.5 EMG versus other techniques for evaluating pelvic floor muscles activity

There is no "gold standard" for evaluating PFM function and strength. The tested muscles are not accessible directly, and it can be challenging to evaluate them individually. Usually, test situations are not generalisable to everyday activities. In clinical practice and for scientific needs, different methods are used:

- methods to measure the ability to contract (clinical observation, vaginal palpation, ultrasound, MRI, electromyography),

- measures to quantify strength (manual muscle test by vaginal palpation, anorectal manometry, dynamometry, cones) (Bø & Sherburn, 2005)

Observation of an intact PFM contraction can be done clinically, by ultrasound, or with dynamic MRI. Ultrasound can be performed either with the probe placed suprapubically or at the perineum or with the probe inserted into the vagina or rectum. Pelvic-floor muscle location, volume, and anatomy can be measured with ultrasound and MRI. Additionally, dynamic imaging methods give information also on the lifting aspect of PFM function. US and MRI have been tested for reliability.

Since Kegel in 1948 first described vaginal palpation as a method to evaluate PFM function, dozens of different vaginal palpation methods have been developed to evaluate pressure, duration, muscle "ribbing," and displacement of the examiner's finger in a specific scoring system.

For quantification of pelvic floor muscle strength, **squeeze pressure** is commonly used, and maximum strength or endurance time are measured. The measurements can be done in the urethra, vagina, or rectum using manual muscle testing with vaginal palpation, pressure manometry, or dynamometry. Oxford grading Scale or PERFECT scheme are frequently used. **Modified Oxford scale** is is a 6-point scale described as:

0 = no contraction,

1 = flicker,

2 = weak,

3 = moderate (with lift),

4 = good (with lift),

5 = strong (with lift).

The **PERFECT** scheme (Power – Endurance – Repetitions – Fast contraction – Every Contraction Timed) was developed to simplify and clarify the PFM assessment (Laycock & Jerwood, 2001; Newman & Laycock, 2008). Studies of subjective rating scales show conflicting inter-rater and intra rater reliability (Grape et al., 2009).

Vaginal, urethral or rectal squeeze pressure can be measured by an **anorectal manometer (perineometer)**, showing the pressure in mm Hg as a measure of PFM strength. Anorectal manometry can measure parameters such as maximal resting anal pressure, amplitude and duration of squeeze pressure, the rectoanal inhibitory reflex, threshold of conscious rectal sensation, rectal compliance, rectal and anal pressures during straining (Wald, 1994). Decreased resting pressure suggests isolated IAS dysfunction, while decreased squeeze pressure suggests isolated EAS dysfunction. It is an objective method, yet different perineometers with different vaginal probe sizes and technical parameters are difficult to compare. The reliability of perineometers shows an overall satisfaction level. Additional benefits are their ease to use, relatively low cost and clinical availability (Grape et al., 2009). Figure 1.23 shows different types of perineometers or anorectal manometers that have been described in the literature.

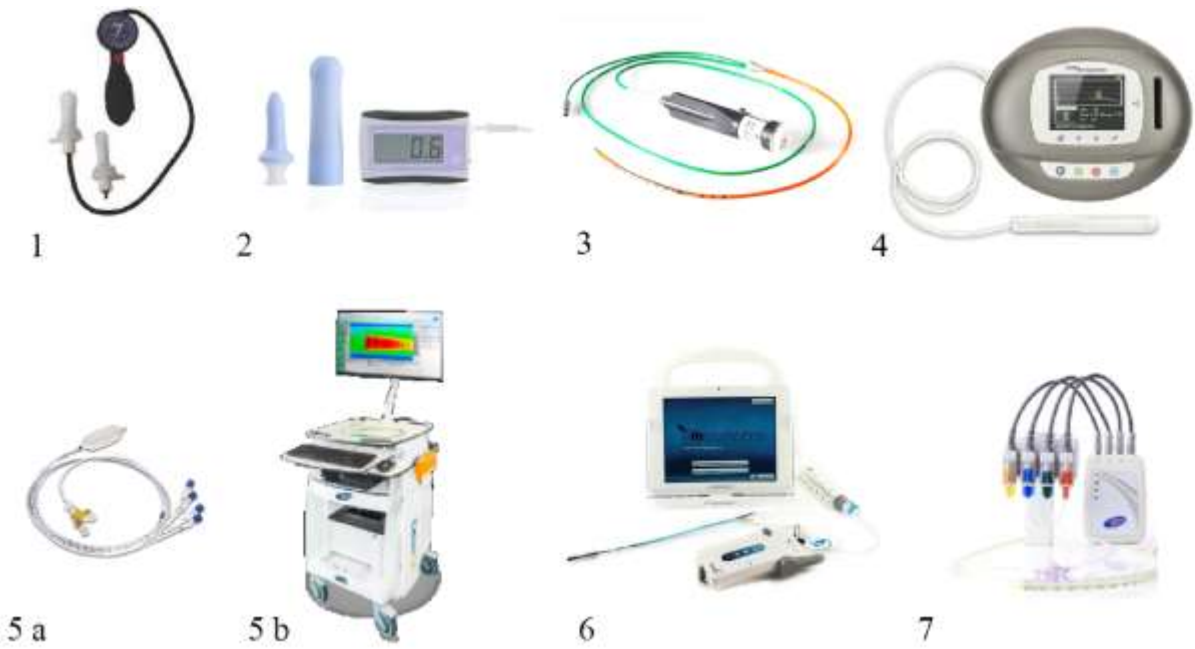

Figure 1.23 **Anorectal manometers / perineometers**

1 – Analogue perineometer by *Bionics Innovations*. 2 – Hand-held clinical biofeedback perineometer, *Peritron*™ by *MKS Medic*. 3 – High resolution anorectal manometer by *Diversatek Healthcare*. 4 – *THD® Anopress* system by *THD America*. 5 – *Solar GI* High Resolution anorectal manometry by *Laborie Medical Technologies:* a) catheter, b) system. 6 – Portable anal manometer *mcompass®* by *Medspira.* 7 – Totally portable wireless anorectal manometry system *Goby™ ARM* by *Laborie Medical Technologies.*

High-resolution anorectal manometry (HRAM) and three-dimensional high-definition anorectal manometry (HDAM) provide greater anatomic detail than water-perfused manometry and allow the assessment of anal sphincter symmetry and defects (Lee et al., 2013; Zifan et al., 2016). HRAM provides a dynamic recording of the anal sphincters and intraluminal rectal pressures and permits an objective evaluation of several aspects of anal and rectal function, including basal tone and contractility, recto-anal coordination, and reflex function (such as recto-anal inhibitory reflex) as well as rectal sensation thresholds (Sbeit et al., 2021). Moreover, HRAM enables the assessment of abnormal rectal sensitivity, both hypersensitivity and hyposensitivity, two conditions that may cause FI in different ways.

Dynamometers or dynamometric speculums are other options for PFM evaluation.

Both perineometers and dynamometers have one crucial disadvantage: the force measured can be affected by intraabdominal pressure or other muscle group contractions (e.g. gluteal muscles or adductor).

Studies comparing different PFM evaluation methods usually investigate digital palpation or perineometric measures. When literature studies mention EMG measurements, usually they refer to needle electrodes or vaginal probes. Digital palpation correlates with PFM sEMG findings. Recently, a new method – **four-dimensional translabial ultrasound** – was proposed as a reliable and minimally invasive method for real-time pelvic floor assessment during dynamic activities, and comparison with sEMG with vaginal probe showed a weak but significant correlation between the change in the levator plate angle and PFM sEMG activity (Martinho et al., 2020).

Barium defecography (performed in the seated position) or **MRI defecography** (supine position) are methods performed in patients with faecal incontinence to obtain visual information about the presence of enterocoele, rectocoele and rectal prolapse in addition to evaluating the length of the anal sphincter, anorectal angle, and pelvic descent, but do not give information about muscular strength (Lalwani et al., 2019). Recently**,** MRI defecography has gradually emerged as a modern modality substituting the traditional X-ray based defecography. It obtains images at various stages of defecation to evaluate how well the pelvic muscles are working and provide insights into rectal function.

Pudendal nerve terminal motor latency (PNTML) is a method using EMG to evaluate pudendal nerve damage. St. Mark's electrodes for stimulation and recording allow easy determination of pudendal nerve conduction by sphincter and motor latency. When electric stimuli are delivered (see Figure 1.24), APs are registered, and latency is defined as the time between the stimulation of the pudendal nerve and the commencement of the anal sphincter's depolarisation. In patients with an intact anal sphincter, either unilaterally or bilaterally, prolonged PNTMLs are associated with significantly decreased resting and squeeze pressures controlled by anal manometry (Loganathan et al., 2013).

Figure 1.24 **Pudendal nerve terminal motor latency (PNTML) electrodes for recording and stimulation in the anal sphincter** *(*from *Spes Medica)*

Regarding **reliability and repeatability** of sEMG for sphincter muscles or comparison with other methods, few studies have evaluated anal probes. Repeatability of the estimation of IZ distribution was tested in healthy volunteers using the anal probe (Enck et al., 2009). The coefficient of multiple correlations (CMC) demonstrated high repeatability (CMC > 0.8), comparing IZ distributions estimated from signals recorded by each array within the same session. A slightly lower value was obtained considering signals recorded during different sessions (CMC > 0.7), but a higher value (CMC > 0.8) was obtained after aligning the estimated IZ distributions (Enck et al., 2009). Repeatability tests of IZ detection with circular probes assured that the inter-operator and other factors influence the difference within one angular electrode distance, which means $2\pi/16$ radiants (Merletti, 2016). The sensitivity and specificity of sEMG, together with appropriate algorithms, were extremely high compared to other tools in diagnosing faecal incontinence (Nowakowski et al., 2014; 2017).

Other studies use a vaginal probe. In three test sessions (the last one month apart) in healthy women, using a vaginal probe, moderate activity, MVC, resting value and work (the area under the curve) showed good to high reliability (intraclass correlation coefficient (ICC) 0.83–0.96). Generally, choosing the highest contraction in one test session resulted in a slightly higher ICC than the average result of all three contractions (Grape et al., 2009). One study evaluated intrasession retest reliability of PFM EMG during rest and MVC in women with SUI and with weak PFM, and in healthy women, using a vaginal probe in women in a standing position (Koenig et al., 2017). This study found that the intraclass correlation coefficient was very high, but the standard error of measurements and minimal differences were relatively high.

Another study evaluated the intrasession, intraday, and interday reliabilities of different sEMG parameters in healthy continent women, using a vaginal probe with a circumferential electrode position. This study showed substantial reliability for intrasession measurements and moderate intraday measurements (Scharschmidt et al., 2020). Another study using trans-perineal sEMG, when electrodes were placed on the skin overlying both sides of the anus, demonstrated that PFM activation recorded by EMG was only weakly correlated with PFM strength measured by vaginal palpation, vaginal manometry, vaginal dynamometry. In contrast, the correlations between palpation, manometry, and dynamometry were moderate (Navarro Brazález et al., 2018). Significant test-retest reliability and significant clinical predictive validity were demonstrated using an intravaginal sensor on repeated evaluation one week later (Glazer et al., 1999). A study evaluating PFM by sEMG with the vaginal probe before and after surgical intervention for POP concluded that both digital palpation and sEMG were useful tools (Chen et al., 2014).

Comparing EMG activity recorded with vaginal probes or anal probes, the results could be different because the vaginal canal is only bilaterally attached to the PFM, while the PFM/EAS musculature more completely encompasses the anorectum. It means that a relatively smaller number of MUs can be found from vaginal probes compared to those detected from anal probes, and anorectal MUAPs encircle the lumen more extensively than did vaginal MUAPs (Peng et al., 2016).

In conclusion, surface EMG, compared to other sphincter activity evaluation methods, such as subjective rating scales and perineometers, is a reliable method; it is easy to use and standardise the test procedure. A limitation that should always be kept in mind is that sEMG with rectal probes gives information about sphincter muscle, not all PFMs.

2 Materials and methods

The idea of the present Thesis was inspired during the international multicentre project "Technology for Anal Sphincter analysis and Incontinence" (TASI-2), conducted by prof. Roberto Merletti and Dr. Corrado Cescon from Polytechnic of Turin, and to whom the author of the Doctoral Thesis was the national coordinator. The author's personal contribution to this study was as follows: the preparation of the project (approval of the study protocol with local authorities, design of questionnaires, organisation of experimental setting), collection of data (subject recruitment, maintenance of subject database, performance of measurement sessions), and interpretation of results (participation in the preparation of two manuscripts and disseminating the study's results). The multicentre project, involving nine clinical partners from five European countries (Latvia, Germany, Italy, Slovenia, Ukraine), was finalised with two publications by the international team, and the author of the present Thesis has written permission from the corresponding author to include the data in her PhD Thesis and to share the results (see Appendix 1). The author of the present Doctoral Thesis decided to broaden the scope of the study of sEMG in obstetrics and formulated additional research questions. Thus, a new protocol was created, and other subjects for a longer follow-up were recruited.

The main results of the study are summarised in the following publications:

- "Sphincter muscle activity before and after delivery. Does it depend on the type of birth?" by Začesta, Rācene, Cescon, Plaudis and Rezeberga, published in 2020 in *The Journal of Obstetrics and Gynaecology Research*.
- "Could the correct side of mediolateral episiotomy be determined according to anal sphincter EMG?" by Začesta, Rezeberga, Plaudis, Drusany-Starič, and Cescon, published in 2018 in *The International Urogynecology Journal*.
- "Effect of vaginal delivery on the external anal sphincter muscle innervation pattern evaluated by multichannel surface EMG: results of the multicentre study TASI-2" by Cescon, Riva, Začesta, Drusany-Starič, Martsidis, Protsepko, Baessler and Merletti, published in 2014 in *The International Urogynecology Journal*.

2.1 Study design, time-frame and population

The study was conducted as an observational prospective cohort study, divided into three phases to fulfil all the study's objectives.

The first phase of the Thesis includes the data acquired during the multicentre project TASI-2 between 2010 and 2012. The second phase of the study includes the data acquired in Latvia and Slovenia (Ljubljana) between 2010 and 2015. Additional data from the other centre were included to enlarge the analysed group, and Slovenia was chosen because of its similarity in obstetrical management to Latvia (the authorisation from the Ljubljana partners in Appendix 2). The third phase of the study includes the data acquired in Latvia between 2013 and 2016. A team of gynaecologists was trained and instructed to perform EMG measurements; each of them received the necessary equipment to conduct measurements independently.

The flow chart of the subjects in different phases of the study is represented in Figure 2.1.

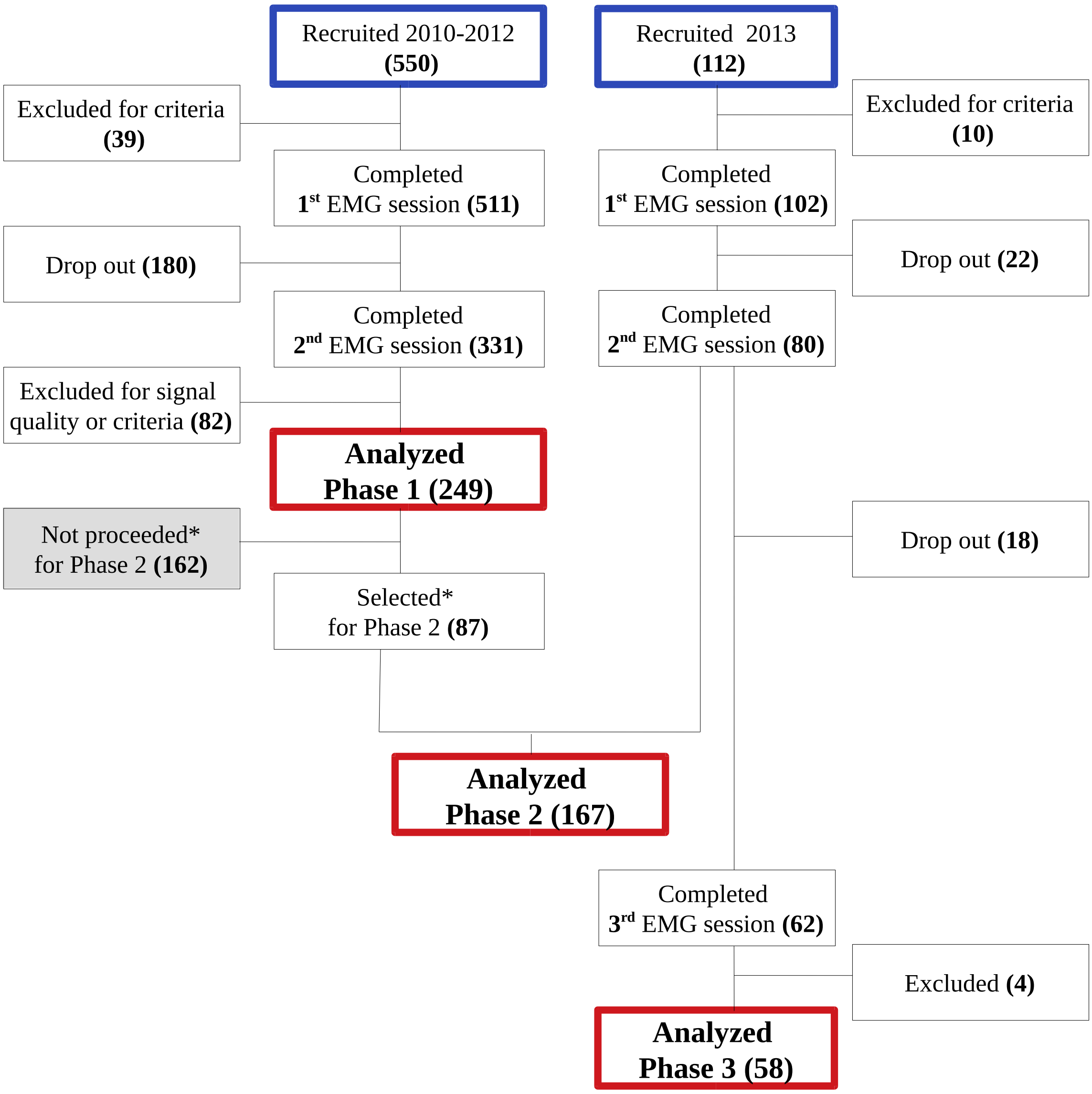

Figure 2.1 **Flow chart of the three study phases**

* Only the signals from Riga and Ljubljana were used for the analysis in phase 2.

Riga Maternity Hospital, Latvia's most comprehensive obstetric and prenatal care centre, served as the reference centre for measurement sessions in Latvia. The total number of subjects included in the study at Riga Maternity hospital is 179; out of them 77 subjects from 2010 till 2012, and 102 subjects from 2013 till 2016.

Figure 2.2 shows the subjects according to the clinical partners of the multicentre study (circles) and study phases (red lines), the area of the circles is proportional to the number of recruited subjects.

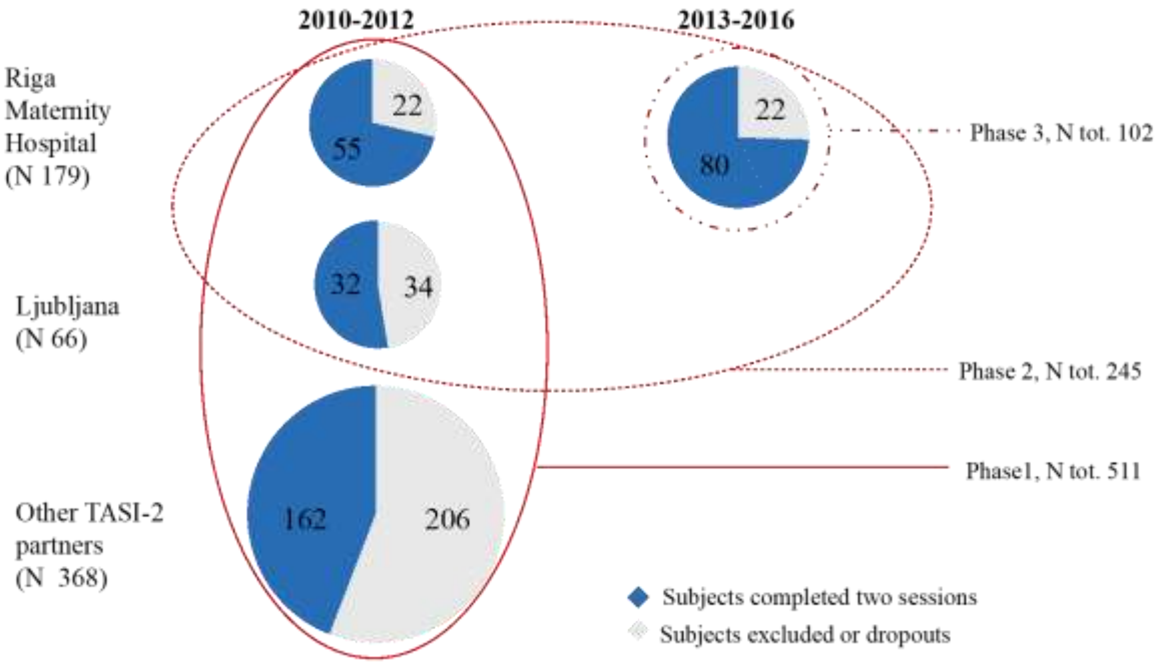

Figure 2.2 **Graphical representation of subject distribution according to the recruitment centres**

Three hundred pregnant women older than 18 years approaching outpatient clinics for antenatal care between 2010 and 2015 were invited to participate in the study during their second trimester. The outpatient department of The Riga Maternity hospital and the outpatient clinic “Quartus” in Riga were the collaborating clinics. Pregnant women were informed about the study by colleagues providing prenatal care, and those who were interested contacted the study coordinator (the author of the present Thesis) for additional information and fixed the appointment. The coordinator evaluated the woman's eligibility for the study, checked for the presence of exclusion criteria, discussed the project and answered the questions, and the women signed an informed consent form before the measurements.

Depending on the particular protocol, **two or three EMG measurement sessions** were conducted: before delivery (from the 28th till the 36th week of gestation), and six to eight weeks after delivery for each woman; additionally, the third measurement session was performed one year after the delivery in patients recruited between 2014 and 2016 at Riga Maternity hospital for the third part of the study.

2.2 Subject grouping

The subjects were grouped for the analysis according to the study objectives. The first phase of the study had the objectives to evaluate **innervation zone distribution** before and after delivery and evaluate the effect of episiotomy on the number of innervation zones. The subjects were divided into four groups: episiotomy group, spontaneous lacerations group, intact perineum group (vaginal delivery with no lacerations and no episiotomy) and caesarean section group. The primary outcome – the number of IZ – was compared between these four groups before and after delivery.

The objectives of phase 2 were to evaluate external anal sphincter **EMG amplitude distribution** and detect **amplitude asymmetry index (AAI)** in pregnant women. We wanted to observe whether EMG amplitude differences exist in women who underwent mediolateral episiotomy when their amplitude distribution is asymmetric on the left or right side. We expected that women with right asymmetric sphincter amplitude should have more considerable EMG amplitude reduction after right side episiotomy than women with asymmetry on the left side. Since we were interested in the effects of the side of episiotomy, first we divided the women into two groups:

1) "Episiotomy" – women who underwent mediolateral episiotomy,

2) "Other" – other types of delivery – women who underwent caesarean sections or had spontaneous lacerations or intact perineum (no damage) during delivery.

Besides, the women were divided according to the AAI: A) left or B) right according to the amplitude distribution during MVC. All the episiotomies were performed mediolaterally on the right side; thus, the groups were the following:

1A – Episiotomy right – AAI left

1B – Episiotomy right – AAI right

2A – Other – AAI left

2B – Other – AAI right

Changes in EMG amplitude distribution were compared before and after delivery between these four groups.

The objectives of the third phase of the study were to track EMG amplitude changes and clinical symptoms over a longer length of time (the third measurement session was performed one year after delivery) and to compare the EMG amplitude in women who had **vaginal**

delivery to those who had caesarean section. The women were divided into two groups according to the type of delivery: caesarean section (CS) and vaginal delivery (VD). Only patients with elective CS or CS during the 1st period were included in the group of CS in this part of the study.

2.3 Inclusion and exclusion criteria

Subjects corresponding following criteria were included:

- Expected first vaginal delivery
- Normally progressing pregnancy from the 28th till the 36th week of gestation
- Signed informed consent form

We excluded patients with the following conditions:

- Faecal incontinence before delivery
- Obstructive defecation syndrome (ODS Longo score > 7)
- Previous pelvic trauma or surgery
- Neurologic diseases which affect pelvic innervation, e.g. multiple sclerosis
- Myopathies
- Myasthenia gravis
- 3rd stage haemorrhoidal disease
- Diabetes with neuropathy before pregnancy
- Multiple pregnancies.

Additionally, women with breech delivery, instrumental vaginal delivery, prolonged second period (defined as more than 2 hours) and women with low-quality signals were excluded from data analysis after evaluating medical records regarding delivery and signal quality control.

The above exclusion criteria were chosen to homogenise the groups and avoid confounding factors influencing sphincter innervation.

2.4 Data collection and clinical questionnaires

Demographic data and clinical information regarding delivery (age, BMI, gestational time during measurement sessions, mode of delivery, use of oxytocin, epidural anaesthesia, induction of labour, presence and degree of lacerations, episiotomy side, length and angle, sphincter damage and characteristics, weight and head circumference of the newborn, duration of the 1st and the 2nd period) were acquired from medical records and analysed.

At each of the four measurement sessions, participants completed a questionnaire (see Appendix N 5). After evaluation for eligibility to be included in the study and signing an informed consent form, the women and the study physician completed the questionnaire, which included demographic data, patient's past medical history and evaluation for the obstructed defecation syndrome (ODS). During the second measurement session (about six to eight weeks after delivery), two other questionnaires were completed: one regarding the information about delivery and another one about bowel habits (including Wexner incontinence score and ODS Longo score), visual inspection of the perineal area was performed, and data were acquired regarding wound infections. If a patient had severe perineal lacerations, IAS and EAS integrity was evaluated, and if necessary, an appointment with a coloproctologist and the endoanal US was scheduled. The fourth questionnaire was completed at the third measurement session one year after delivery and contained the same information as the third one.

To exclude ODS, we used **modified Longo score**, an 8 point scale, inquiring about defecation frequency, straining, sensation of incomplete evacuation, recto / perineal pain / discomfort, activity reduction per week, laxatives, enemas, digitation, lifestyle alteration (Renzi et al., 2013). The total score is in the range of 0 (best) to 24. Original Longo score did not include lifestyle alterations, but recently Longo modified this scoring system and added a lifestyle change parameter to seven symptom-based parameters. Currently Modified ODS Longo score is the most commonly used scoring system to diagnose and decide treatment strategy for ODS patients and see relative and absolute change in ODS symptom score from baseline after intervention in the short term and long term follow-up trials at various intervals. (Altomare et al., 2007). There is no consensus on the cut-off score, and some authors use 7, others – 9 to decide for surgical intervention. We used this score to exclude patients with significant ODS, using a cut-off of 7. Each point is scored according to the frequency of symptoms (see Table 2.1) (Rashid & Khuroo, 2014).

Table 2.1

Modified Longo score for obstructed defaecation syndrome and constipation

N	Symptoms / Variables	0	1	2	3
1	Use of enemas / laxatives	never	less than once weekly	1–6 times weekly	every day
2	Difficulties to evacuate	never	less than once weekly	1–6 times weekly	every day
3	Anal /vaginal digitation	never	less than once weekly	1–6 times weekly	every day
4	Return to toilet to evacuate	never	less than once weekly	1–6 times weekly	every day

Table 2.1 continued

N	Symptoms / Variables	0	1	2	3
5	Feeling of incomplete / fragmental rectal evacuation	never	less than once weekly	1–6 times weekly	every day
6	Excessive straining at defaecation	never	less than once weekly	1–6 times weekly	every day
7	Mean time spent at the toilet	less than 5 min	6–10 min	11–20 min	more than 20 min
8	Lifestyle alterations	no alteration of lifestyle	mild alteration	moderate alteration	significant alteration of lifestyle

For faecal incontinence analysis Jorge-Wexner scoring system was used, which cross tabulates frequencies and different anal incontinence presentations (Gas / Liquid / Solid / Pad use) and the extent to which it alters the patient's life, and sums the returned score to a total of 0–20 (where 0 = perfect continence and 20 = complete incontinence) (see Table 2.2) (Damon et al., 2006; Jorge & Wexner, 1993).

Table 2.2

Anal incontinence scoring system according to Jorge and Wexner

Type of incontinence	Frequency				
	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alterations	0	1	2	3	4

0 = normal continence, 20 = total incontinence. Never = 0 (never), Rarely = less than once per month, Sometimes = greater than once per month and less than once per week, Usually = greater than once per week and less than once per day, Always = greater than or equal to once per day.

2.5 Experimental setup and EMG signal acquisition

EMG signals from the EAS were detected using a cylindric probe with 16 electrodes and acquired with a multichannel amplifier (*Trentadue*, OT-Bioelettronica, Turin, Italy). The probe was plastic support of 14 mm diameter including 16 equally spaced electrodes. The reference for electrode one and the depth for the anal insertion are marked on the probe. The *Trentadue* amplifier, a battery-powered device transmitting the data in real-time to a laptop PC through a Wi-Fi connection, was used to record EMG signals at a sampling frequency of 2 kHz (Figure 2.3)

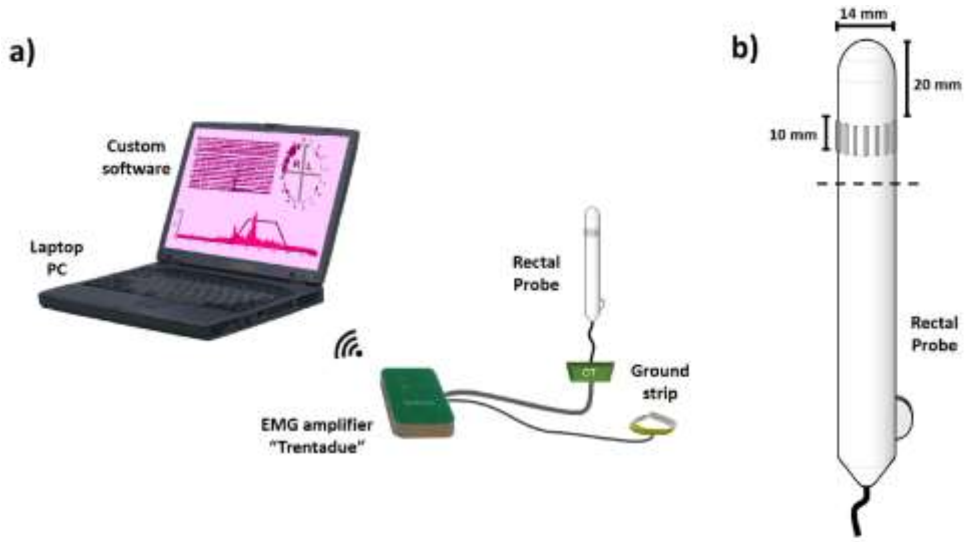

Figure 2.3 **Experimental setup**

a) Laptop with custom software and wireless amplifier, b) EMG probe.

During the EMG measurements, each subject was on the gynaecological chair in a lithotomic position while the operator held the EMG probe. Before the insertion, the probe's tip was lubricated with a drop of glycerol and inserted into the anal canal. The probe was inserted 15–20 mm into the anal canal to have the electrode array in correspondence with the anal verge (see Figure 2.4).

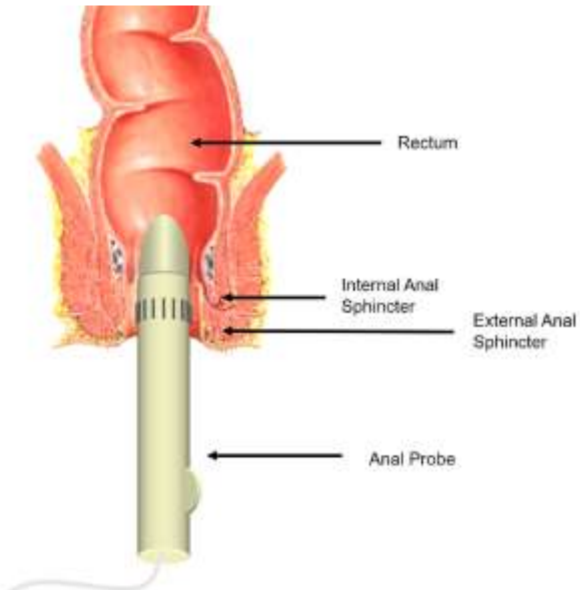

Figure 2.4 **Location of the probe in the anal canal**

The electrodes were positioned at the external anal sphincter level.

The electrodes' orientation was with the midline between the 1st and the 16th electrodes in the ventral position. The anal region was divided into four quadrants for the analysis, as shown in Figure 2.5.

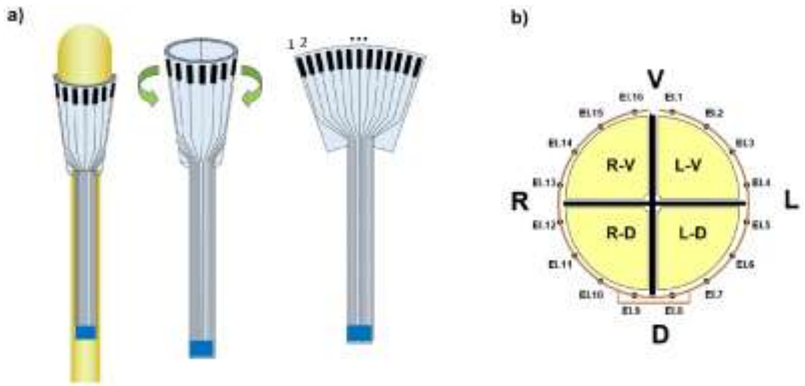

Figure 2.5 **Definition of quadrants of the EAS**

RV right ventral, RD right dorsal, LD left dorsal, LV left ventral.

The reference electrode (conductive material ground strip) was fixed to the woman's ankle and connected to the amplifier.

Each experimental session consisted of two series of EMG measurements performed as follows. Duration of each acquisition was 50 seconds. The acquisition started immediately after the probe's insertion in the anal canal, and the woman received the instruction to relax the sphincter as much as possible. After 20 seconds, the woman was asked to slowly increase the sphincter's contraction over 5 seconds and hold that maximum voluntary contraction (MVC) for 10 seconds. Then the woman was asked to decrease the force for 5 seconds until complete relaxation slowly. The MVCs were preceded and followed by a progressive increase and decrease in force to avoid movement artefacts due to sudden force changes (see Figure 2.6).

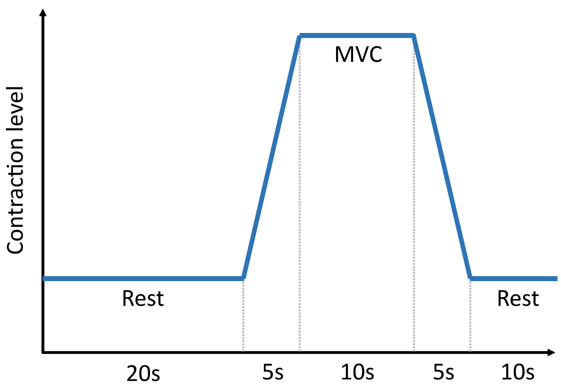

Figure 2.6 **Activation of the sphincter during the acquisition**

The acquisition was 50 seconds with 10 seconds of MVC starting after the 20 seconds of rest.

The 16 surface EMG signals were acquired in single differential derivation with an EMG-USB amplifier with gain variable from 100 to 10.000 in seven steps, 10–500Hz 3dB bandwidth, roll-off of 40dB/decade, noise level lower than one μV RMS), sampled at 2kHz, and stored on a PC after12-bit analogue-to-digital conversion. Slow signals produced by active smooth muscles (if any) were rejected because of the high-pass filter at 10Hz.

Figure 2.7 shows an example of multichannel EMG signal detected with the 16 electrode array on the EAS during a Rest-MVC-Rest contraction.

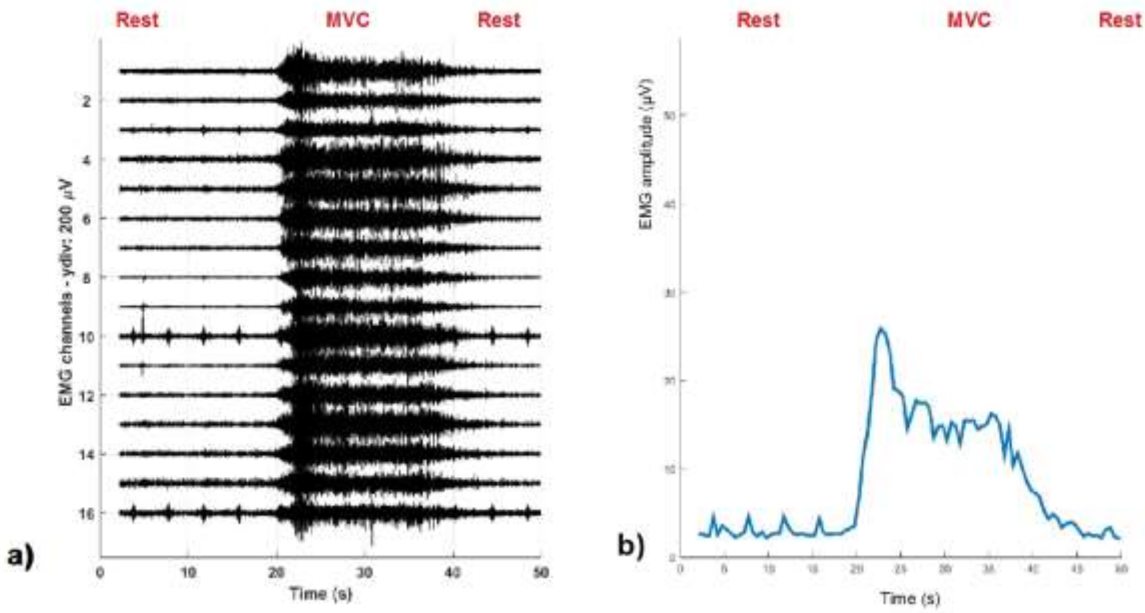

Figure 2.7 **EMG record at Rest – MVC – Rest status**

a) EMG amplitude for every of 16 channels, b) average EMG amplitude of all 16 channels

2.6 Signal analysis

2.6.1 Signal quality control

Signal quality was checked visually on the screen, displaying all 16 channels acquired in a monopolar configuration in real-time. The operator was instructed to check that the signals were stable and that no movement artefacts or contacts were present in the signals while the woman was at rest (i.e., not voluntarily contracting the sphincter). In the case of low image quality, the procedure was repeated. A screenshot of the acquisition software during a contraction is shown in Figure 2.8.

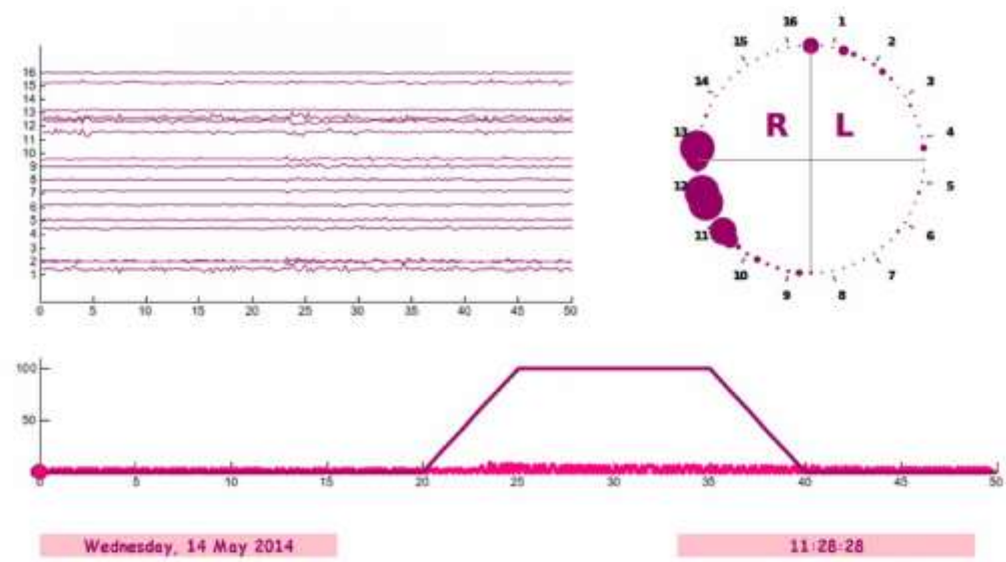

Figure 2.8 **Example of EMG signal during acquisition – screenshot of the PC**

The upper panel shows EMG signals on 16 channels in real-time, so the operator immediately can see if there is any problem. At the end of the acquisition, a circular representation of the probe appears showing the cumulative number of IZs, where the size of purple dots corresponds to the number of IZs at that particular channel (in the example shown, the right dorsal quadrant channels 11 to 13 have a larger number of IZs). The lower part of the screen represents the patient's EMG amplitude during the 50s acquisition.

After EMG signal acquisition, a visual inspection was performed, and signal quality was checked. Artefacts and distorted signals were discarded (when present). The signals were classified into five different classes according to the overall signal quality. The quality was assessed based on the absence of artefacts due to contact problems and movement of the probe, power line interference, short circuits between electrodes, a saturation of the EMG channels, and noise level. Contact problems and electrode short circuits were likely due to insufficient or excessive lubricant. Signals were classified as Q1: very low quality, artefacts, interference or noise present in more than eight channels; Q2: low quality, problems present in four to eight channels; Q3: sufficient quality, problems present in two or three channels; Q4: good quality, problems present in one channel; Q5: very good quality, no contact problems, artefact, interference or noise. The patients with Q1 and Q2 signals (low-quality signals) in any of the two measurement sessions were discarded from the analysis. The channel signals of quality Q3 and Q4 were reconstructed interpolating the adjacent profitable channels (see Figure 2.9).

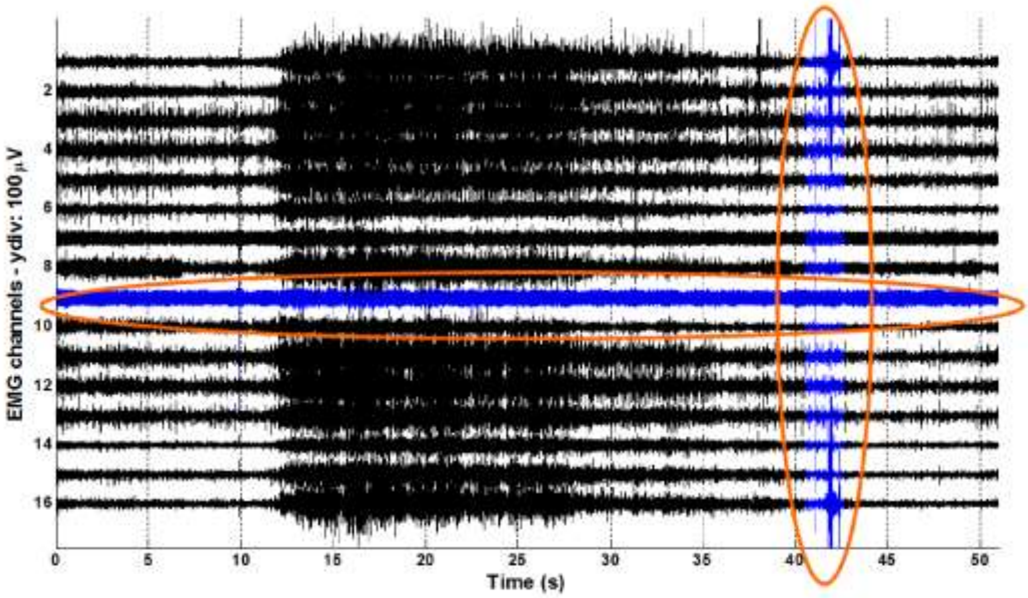

Figure 2.9 **EMG signals detected with the 16 electrodes rectal probe before the processing**

Signal portions considered "Artefacts" or "Bad channels" are drawn in blue.

2.6.2 Signal processing

Signals were divided into 50 epochs of 1 second, and the averaged rectified value (ARV) was extracted from each channel. Amplitude distribution was computed during the 10 s of MVC as the mean ARV for each channel (i.e., from epoch 26 to 35). The 2DCorr algorithm (Cescon et al., 2014; Mesin et al., 2009; Ullah et al., 2014) was applied to the MU templates to identify each MU's innervation zone described below.

2.7 Assessment of outcomes

2.7.1 Amplitude

The EMG signal global amplitude (GA) was computed as the mean value of the average rectified value (ARV) distribution of all 16 channels during MVC (see the blue line in Figure 2.10).

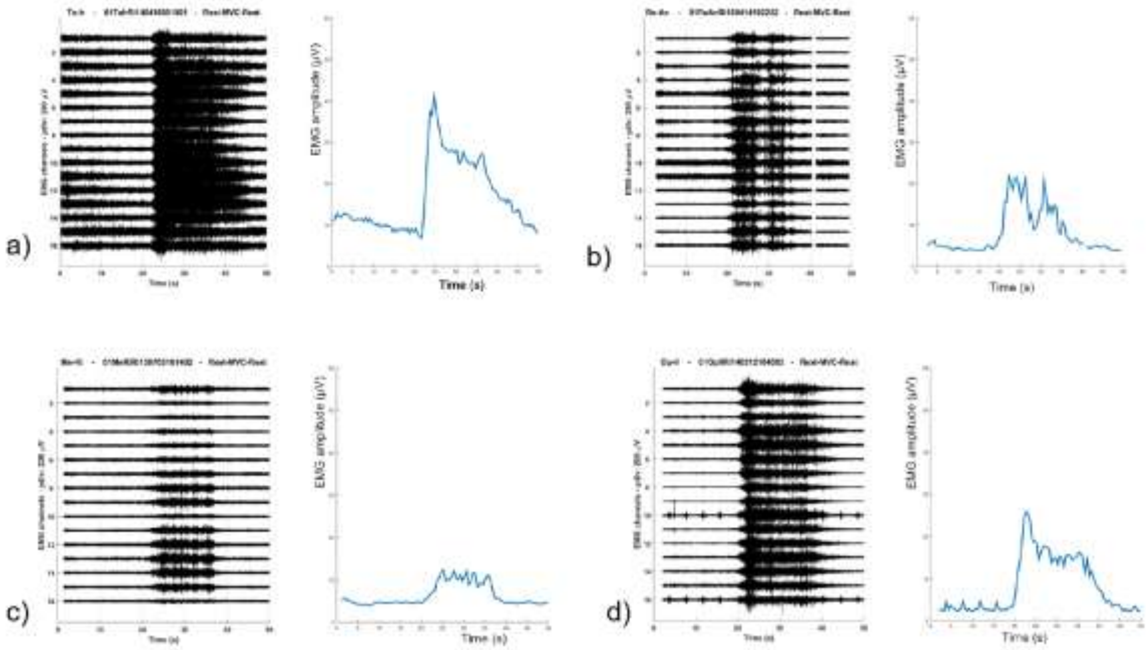

Figure 2.10 **EMG amplitude during rest and MVC in four different subjects**

The black lines correspond to EMG amplitude for every channel; the blue line is the mean amplitude value of all the channels. a) The patient had some activity immediately after the probe's insertion, and the rest value is achieved only after 10 seconds. This subject had a very high EMG amplitude during MVC. Note the remaining activity after MVC. b) This subject showed some fatigue during MVC. c) The subject had low mean amplitude during MVC. d) Minimal activity is visible during rest and the quick start of the MVC.

2.7.2 Amplitude asymmetry index

The amplitude asymmetry index was computed as the ratio between the average amplitude of the channels on the left (from 1 to 8) and the global amplitude and expressed as a percentage. In this way, AAI greater than 50 % indicated more significant signals on the right side, while AAI smaller than 50 % indicated left asymmetry. Since the percentage of asymmetry is a ratio between continuous variables (average rectified value of EMG signals), the probability of having precisely 50.000 % was negligible; thus, the problem was not present. Even the most symmetric signal had a slight unbalance (e.g. 49.999 % or 50.001 %). Figure 2.11 shows an example of single differential EMG signals detected on a representative subject with an AAI of 45 %.

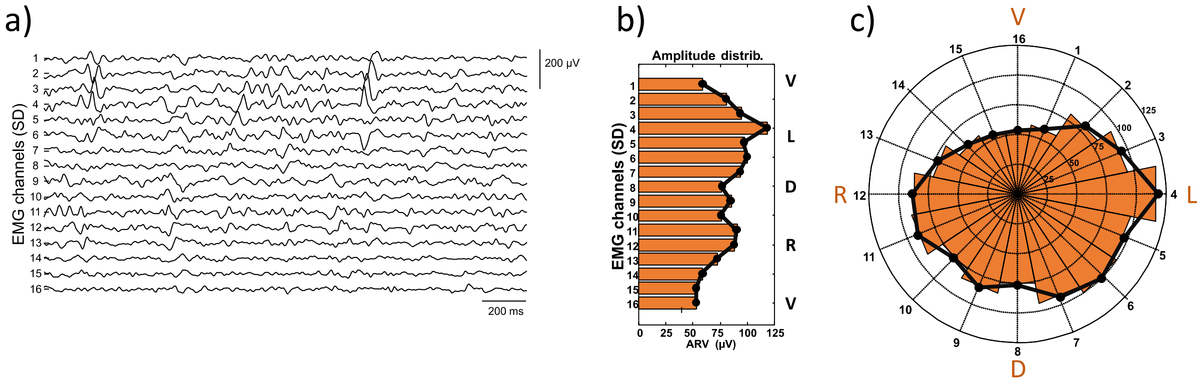

Figure 2.11 **Amplitude distribution**

Example of single differential EMG signals detected on a representative subject, b) amplitude distribution of the 16 channels during the maximal contraction (average rectified value of the signals between seconds 25 and 35). c) Distribution of amplitude as in panel b, represented in circular coordinates according to the electrode positions on the rectal probe. The subject is asymmetric with a predominance of amplitude on the left side (amplitude asymmetry index AAI = 45 %).

2.7.3 Innervation zone distribution

The MUs were divided by the 2DCorr algorithm into two groups according to the IZ position along the fibres: unidirectional when the IZ was at one extremity of the MU length and bidirectional when the IZ position was between the two fibre ends. Unidirectional MUs were divided into two groups: clockwise propagation and counter-clockwise propagation. Figure 2.12 shows the distribution of innervation zones identified on one patient during MVC.

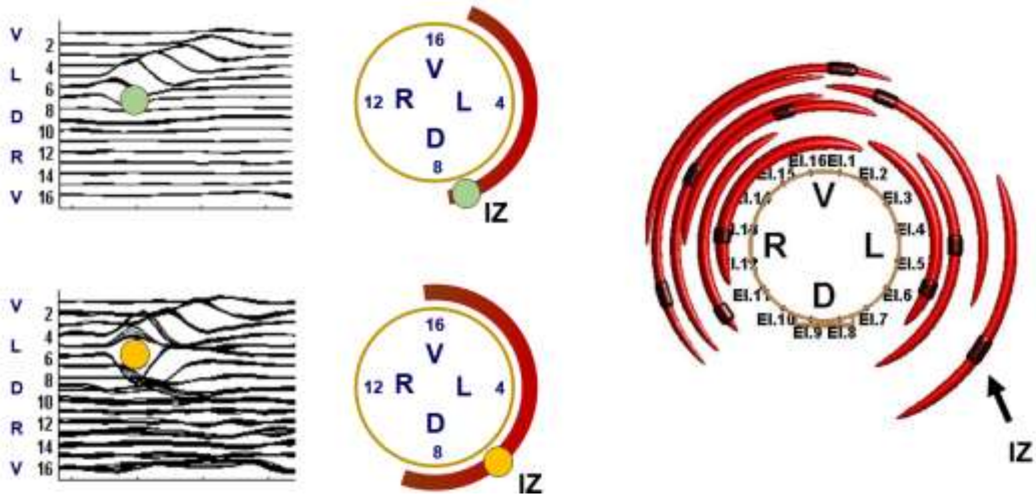

Figure 2.12 **Identification of the innervation zones**

The upper panel's motor unit is innervated under electrode 7 and has only one side of propagation; the MU in the lower panel is innervated under electrode 6 and has two sides of propagation. a) example of EMG record, b) circular representation of the position of the MU, c) example of a real patient where several MU were identified and represented as red lines with black IZs.

2.8 Examples of analysis

A coloured map with a spatiotemporal representation of amplitude and IZs distribution during rest and MVC was created for every patient before and after delivery. The total number of MUs was calculated and compared. Figure 2.13 shows an example of a woman with a right mediolateral episiotomy.

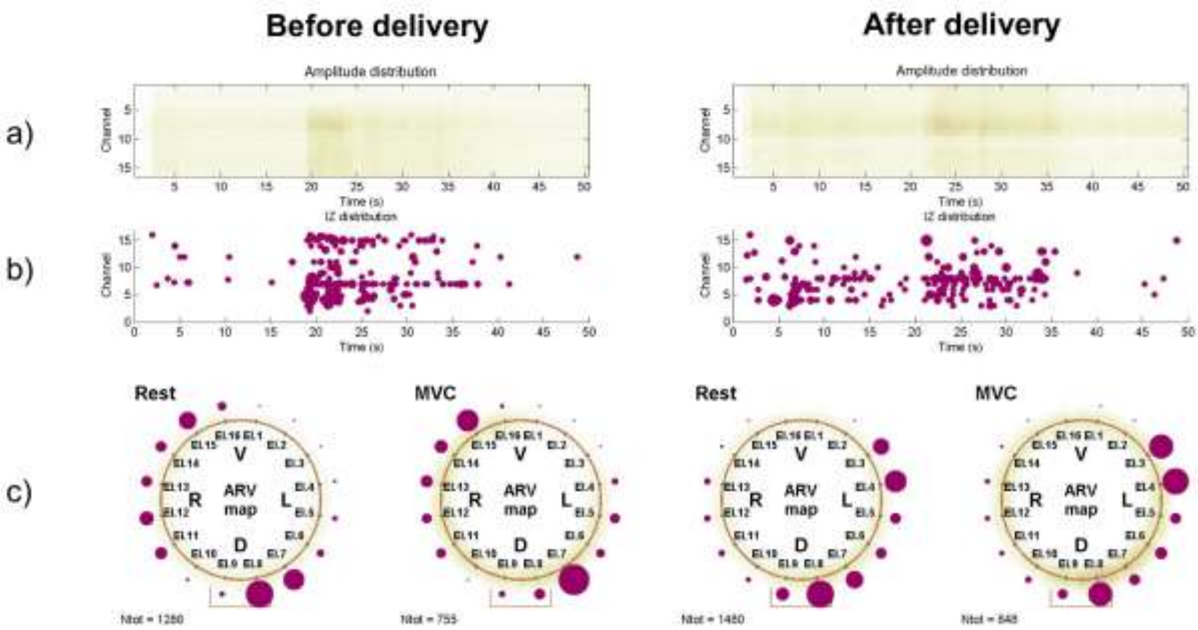

Figure 2.13 **Spatio temporal representation of amplitude and IZs distribution in a patient before and after delivery with right mediolateral episiotomy**

a) Spatio temporal distribution of amplitude (X axis: time, Y axis: channels) during 50 seconds. Darker shades correspond to higher amplitude. b) Spatio temporal distribution of IZs (X axis: time, Y axis: channels). Larger purple circles correspond to larger MUs. c) Distribution of amplitude and IZs during rest and maximal voluntary contraction (MVC). In this case, IZs and amplitude of the right ventral quadrant seem to be reduced after delivery.

2.9 Statistical analysis

For the first phase of the study, evaluating the number of innervation zones, a generalised mixed linear model was used to test for significant fixed effects and obtain appropriate 95 % confidence intervals. The model is a generalisation of standard linear models – such as ANOVA (ANalysis Of VAriance) – which allows random effects and non-normally distributed count responses, in our case, the IZ number, which is modelled as having Poisson distribution. The Poisson distribution expresses the probability of several events occurring in a fixed interval of time and space. In our case, the expected number of IZs is equal in each of the four EAS quadrants.

A convenience sample size of 500 women was selected for the first part of the study. This number was based on the average percentage of episiotomies performed in Europe to obtain at least 50 episiotomies given drop out of two-thirds. The sample size could not be computed with the usual tables since no previous data were available in the literature.

For the second phase of the study, where the primary outcome was the EMG signal global amplitude (GA), the clinical variables were compared using Kruskal-Wallis test. Before and after delivery, the GA differences were analysed for each group and compared with a non-parametric paired test (Wilcoxon signed-rank test).

The sample size for the second part of the study was computed using the following equation (2-paired sample, 2-sided equality):

$$n = \frac{2\sigma^2 \left(Z_\beta^\mu + Z_{\alpha/2}\right)^2}{(\mu_1 - \mu_2)^2} \tag{2.1}$$

n – sample size in each group (assumes equal sized groups, paired test)

Z_β^μ – desired power (0.84 for 80 % power)

σ – standard deviation of the outcome variable (6μV for EMG amplitude based on preliminary data analysis)

$Z_{\alpha/2}$ – desired level of statistical significance (1.96 for α = 0.05)

$(\mu_1 - \mu_2)^2$ – effect size (we wanted to detect a difference of at least 4μV)

According to equation 2.1, the desired sample size was 35 subjects per group. Based on the hospitals' routine procedures in the study, we expected to have approximately the same number of women in the two groups (episiotomy, other types of deliveries). We expected a balanced proportion of asymmetry of amplitude (left and right asymmetry). Thus, we planned to have a total of 140 participants. We expected a drop-out of about 30 % between the two measurement sessions, so we had to recruit at least 182 patients. We also expected that exclusion criteria after delivery could reduce our sample, so we decided to increase the number of patients needed for the 1st measurement session up to 250.

For the third phase of the study, a statistical power analysis was performed using the "G*Power V" software (Version 3.1.9.6,) (Faul et al., 2007), a freeware program for performing power analysis based on the statistics book of Cohen (Cohen, 2013). The analysis was conducted with the "F-Test (ANOVA)" option. The effect size was computed using the total population variance (4 μV, based on previous studies), the α error probability (set to 0.05), the Power 1-β (set to 80 %), and the minimum clinical difference (set to 2 μV based on the specifications of the amplifier and also based on previous studies on sphincter muscles using similar probes). The total sample size resulting from the computation was 40 subjects in total. Considering an estimated drop out of 30 % and considering that the CS rate was about 25 % at the reference hospital, 112 patients were invited to participate in the study.

The ARV values were analysed for both groups in each measurement session compared with the variance analysis (2-way ANOVA). A post hoc comparison was performed with the Student Neuman-Keuls (SNK) test.

2.10 Ethical issues

The study was conducted following the Declaration of Helsinki of the World Medical Association (WMA) "Ethical principles in human medical research" and according to nationally accepted ethical, legal and administrative requirements for human research, as well as relevant international requirements.

The study respected the privacy of subjects and the confidentiality of patient information and took steps to minimise the study's impact on subjects' physical and mental integrity and personality. The group of patients included in the study could benefit from the study results, as the second measurement after delivery showed whether there were problems with anal area innervation; if such were detected, physiotherapy was recommended to the subject. Research participants were volunteers who were aware of the research project. The study participants were informed of the objectives, methods, institutional affiliation, expected benefits and potential risks of the study, and the potential inconveniences this may cause. The subjects were informed that they had the right not to participate in the study or to withdraw their consent to participate in the study at any time without fear of undesirable consequences.

The study's equipment complied with hygiene and occupational safety standards and EU directives on electrical equipment (see Appendix 6). The recording of EMG signals did not adversely affect the pregnant woman, foetus, or pregnancy outcome.

All the participants signed an informed consent form before measurement sessions. The local Ethics Committee approved the study (see Appendix 7).

3 Results

3.1 Results of phase 1: evaluation of IZ distribution changes

511 women were recruited and performed the 1st measurement session in a multicentre study. 331 women participated at the 2nd measurement session, and the dropout rate was 35 %. After signal inspection and after discarding low-quality signals, 249 women with signal quality Q3–Q5 were divided into groups according to the type of delivery (vaginal or Caesarean section, N = 189 and 60 respectively), and in cases of vaginal delivery, they were divided into intact perineum (N = 32), spontaneous perineal tears / lacerations (N = 75) and mediolateral right episiotomy (n = 82). Figure 3.1 shows the percentage of every type of delivery.

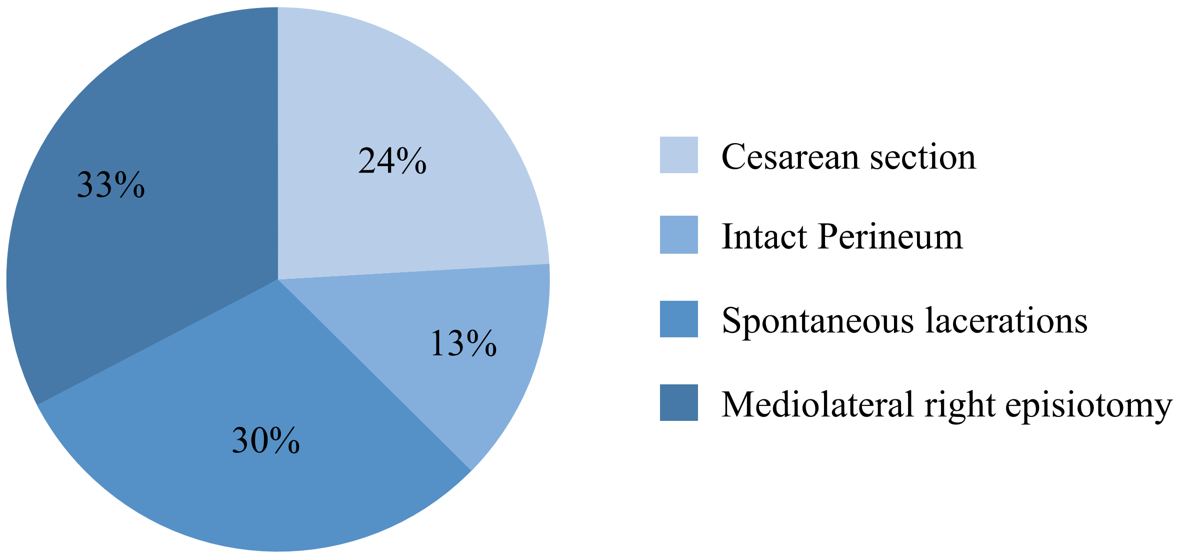

Figure 3.1 **Deliveries by types for the TASI 2 study**

Data regarding delivery were acquired from 73 of the 180 women who did not return for the second measurement. The distribution of delivery types for those women was: 39 % Caesarean section, 25 % episiotomies, 21 % spontaneous lacerations and 13 % with no evident damage, indicating that there was a higher proportion of Caesarean section and a lower proportion of lacerations and episiotomies in the non-returning population.

The distribution of maternal and infant parameters according to the delivery type is shown in Table 3.1.

Table 3.1

Distribution of maternal and infant parameters according to the delivery type*

Data	Caesarean section	Intact perineum	Spontaneous lacerations	Right mediolateral episiotomy
Total number in the group	60	32	75	82
% of total	24	13	30	33
Age (years)	33 ± 7	29 ± 5	30 ± 10	32 ± 8
BMI before pregnancy (kg/m 2)	23.1 ± 2.7	22.7 ± 1.4	22.8 ± 1.3	22.7 ± 1.4
Weeks at 1st measurement	31 ± 1	32 ± 2	32 ± 2	33 ± 1
Gestational age at delivery	40.1 ± 0.9	39.8 ± 1.2	39.7 ± 1.3	39.8 ± 1.3
Infant weight (kg)	3.4 ± 0.6	3.3 ± 0.4	3.4 ± 0.3	3.4 ± 0.5
Head circumference (cm)	34 ± 1	33 ± 2	33 ± 2	34 ± 2
Infant length (cm)	49 ± 2	49 ± 2	50 ± 2	50 ± 1
Kristeller (% of N)	NA	8	15	42
Labour induction (% of N)	6	34	22	29
Epidural anaesthesia (% of N)	NA	24	30	34
Oxytocin augmentation (% of N)	6	45	52	14

* Mean and standard deviations are indicated.

No statistically significant difference was observed for the subjects' BMI and infants weight parameters between the four groups of subjects. A significant difference was observed in subject age ($p < 0.01$), with older patients having more C-sections or episiotomy compared to subjects with spontaneous lacerations or no damage.

Among 75 spontaneous lacerations, 49 (20 % of total subjects) were the first degree lacerations, 22 cases (9 %) – second degree, 4 cases (2 %) – 3a-degree. No fourth-degree lacerations were observed. All but 3 out of 82 episiotomies were right side mediolateral, with the length between 2 and 4 cm (average 3cm) and the angle from 20 ° till 60 °. No routine episiotomies were performed, all had obstetrical indications.

The ARV of EMG amplitude and number of MU and IZs were counted individually before and after delivery. Graphical representation of MUs and ARVs of EMG amplitude according to their situation along the anal probe is shown in a patient with vaginal delivery with MLE pre and postpartum in Figure 3.2: significant reduction of IZs was observed on the right side after delivery, and also the ARV at right side electrodes was reduced after MLE.

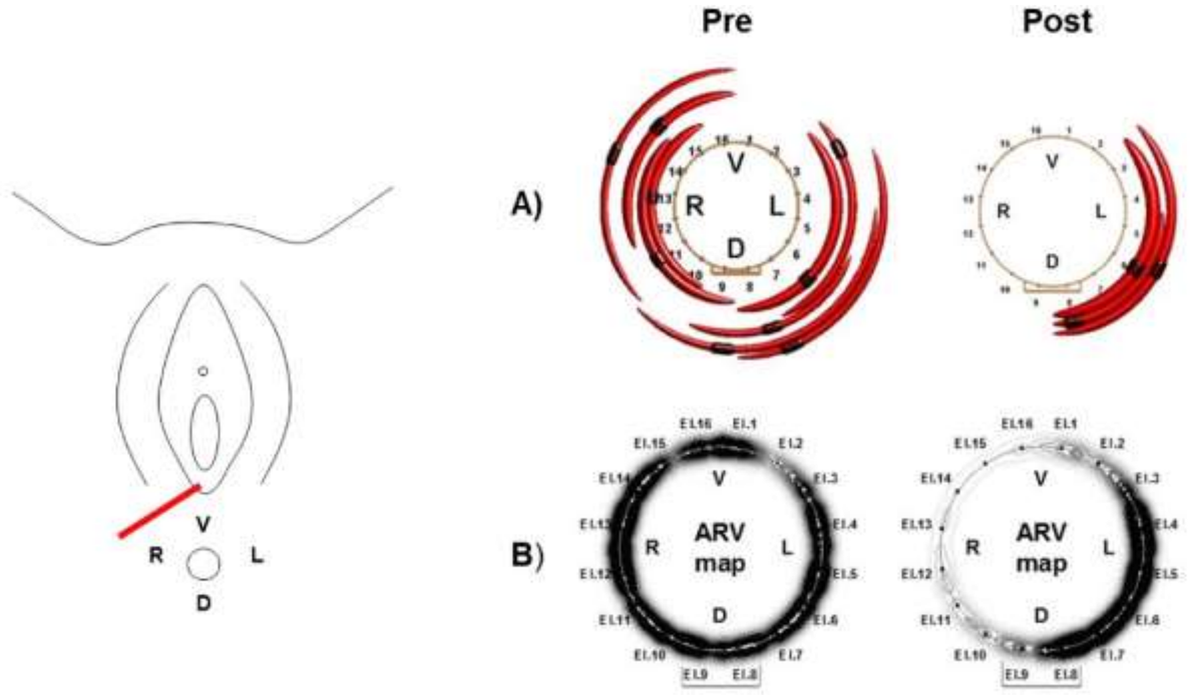

Figure 3.2 **The changes of IZs and ARV after MLE**

El-1 – El-16 indicate the electrodes, V, L, R, D – corresponding quadrants. Pre – before delivery, Post – after delivery with MLE. a) representation of MUs and IZs. Each red arc represents a motor unit. The black mark on each arc represents the innervation zone. b) representation of ARV. The more intense is the grey colour on the ARV circle, the higher is the amplitude at that electrode.

The following Figures illustrate two different patients with vaginal delivery with MLE. The IZs and ARV are compared in both rest and MVC status. The first subject was a 33-year-old woman with a BMI of 22.1; after induction of labour under epidural anaesthesia and stimulation with oxytocin, she gave birth to a baby of 4020 g, the first period 7 hours 30, the second period one hour 40 minutes. Episiotomy was performed at the angle 45 ° and 4 cm in length. After delivery, she had lost almost all the IZs on the right and some also on the left side at rest, slightly recovered on the left side during MVC, and the amplitude of EMG signals reduced in all four quadrants (see Figure 3.3).

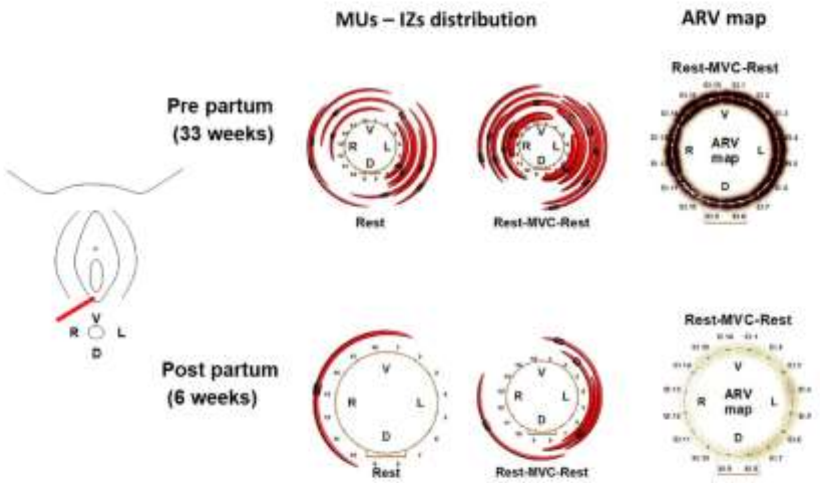

Figure 3.3 **Example 1 of MUs and IZs distribution and ARV mapping in a patient after MLE**

V, L, D, R – quadrants. Each red arch represents a motor unit. The black mark on each arch represents the innervation zone. The right panel represents ARV. The more intense is the grey colour on the ARV circle, the higher is the amplitude at that electrode.

The second subject, 28 years old, BMI 21.3, had a 3.3kg baby under epidural anaesthesia after 6 hours of the first period and one hour 10 minutes of the second period. She had a 2 cm long MLE at an angle of 30°. She had an even distribution of IZs and high ARV before delivery. After delivery, IZs disappeared at the right ventral quadrant at rest and MVC, and the amplitude was reduced on the right-side electrodes (El-12 until El-16) (see Figure 3.4).

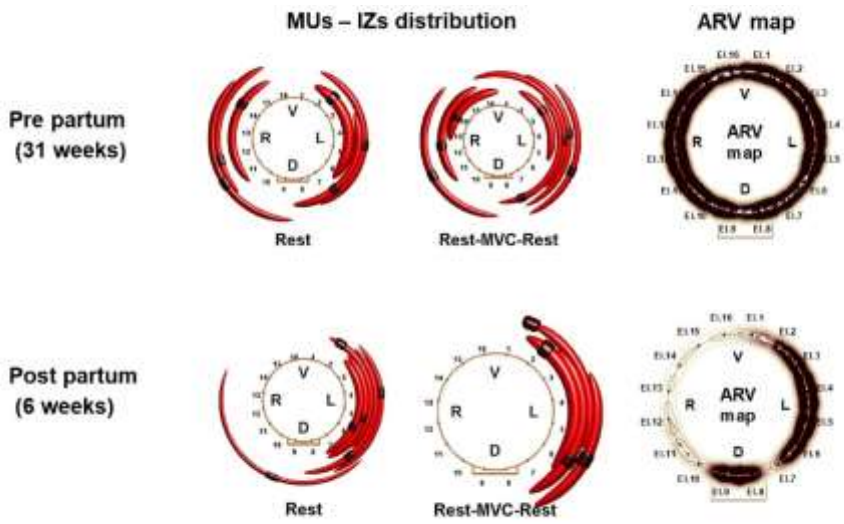

Figure 3.4 **Example 2 of MUs and IZs distribution and ARV mapping in a patient after MLE**

V, L, D, R – quadrants. Each red arch represents a motor unit. The black mark on each arch represents the innervation zone. The right panel represents ARV. The more intense is the grey colour on the ARV circle, the higher is the amplitude at that electrode.

Figure 3.5 compares the distribution of innervation zones for two subjects with different types of delivery: subject A had a SC during the first period, and subject B had a vaginal delivery with MLE 4 cm long at 40 °.

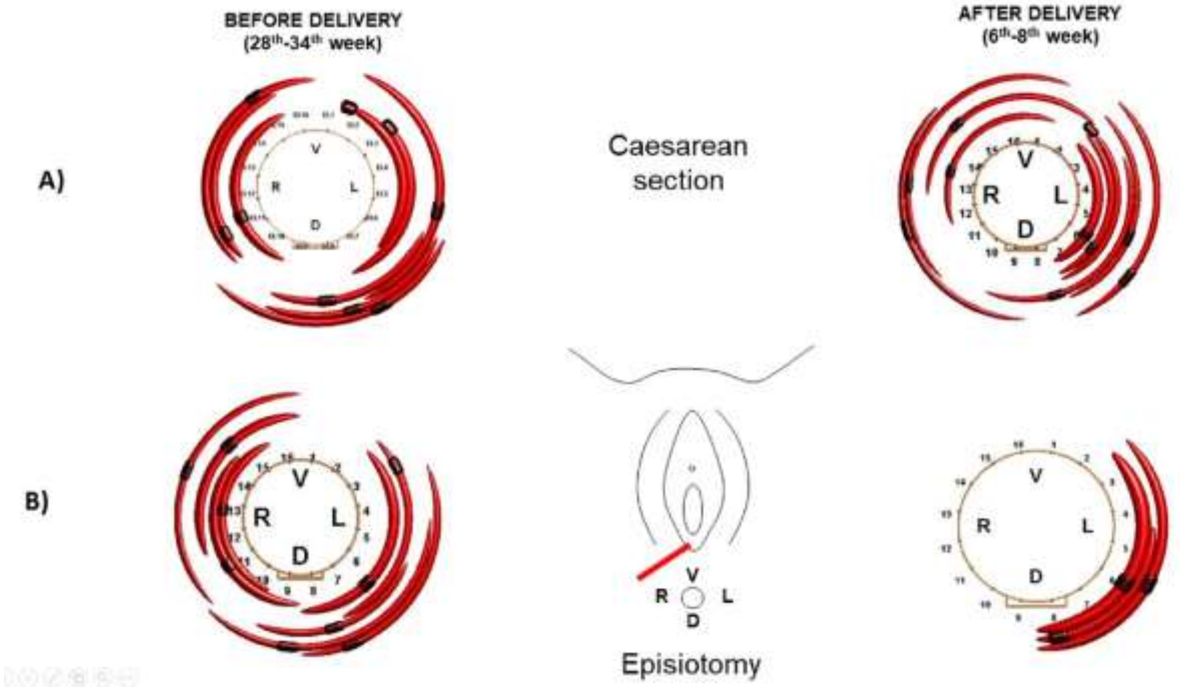

Figure 3.5 **Examples of motor units and their innervation zones for two delivery types**

A: a subject with a caesarean section, B: a subject with a vaginal delivery with episiotomy. V, L, D, R quadrants. Each red arch represents a motor unit. The black mark on each arch represents the innervation zone.

As seen in Figure 3.5, both A and B subjects before the delivery had similar and even distribution of IZs. Subject A after SC had maintained the same pattern also six weeks after delivery. Subject B had lost all the MUs and IZs 6 weeks after MLE s. Subject A after SC had maintained the same pattern also six weeks after delivery. Subject B had lost all the MUs and IZs 6 weeks after MLE.

Figure 3.6 shows the individual IZ counts for all the subjects before and after delivery: green line if after delivery, the number was higher than before, red line if lower than before. The black dot represents the number of IZs before delivery, while the other extremity of the green or red line represents the number of IZs after delivery. If the number of IZ did not change, only a dot is represented.

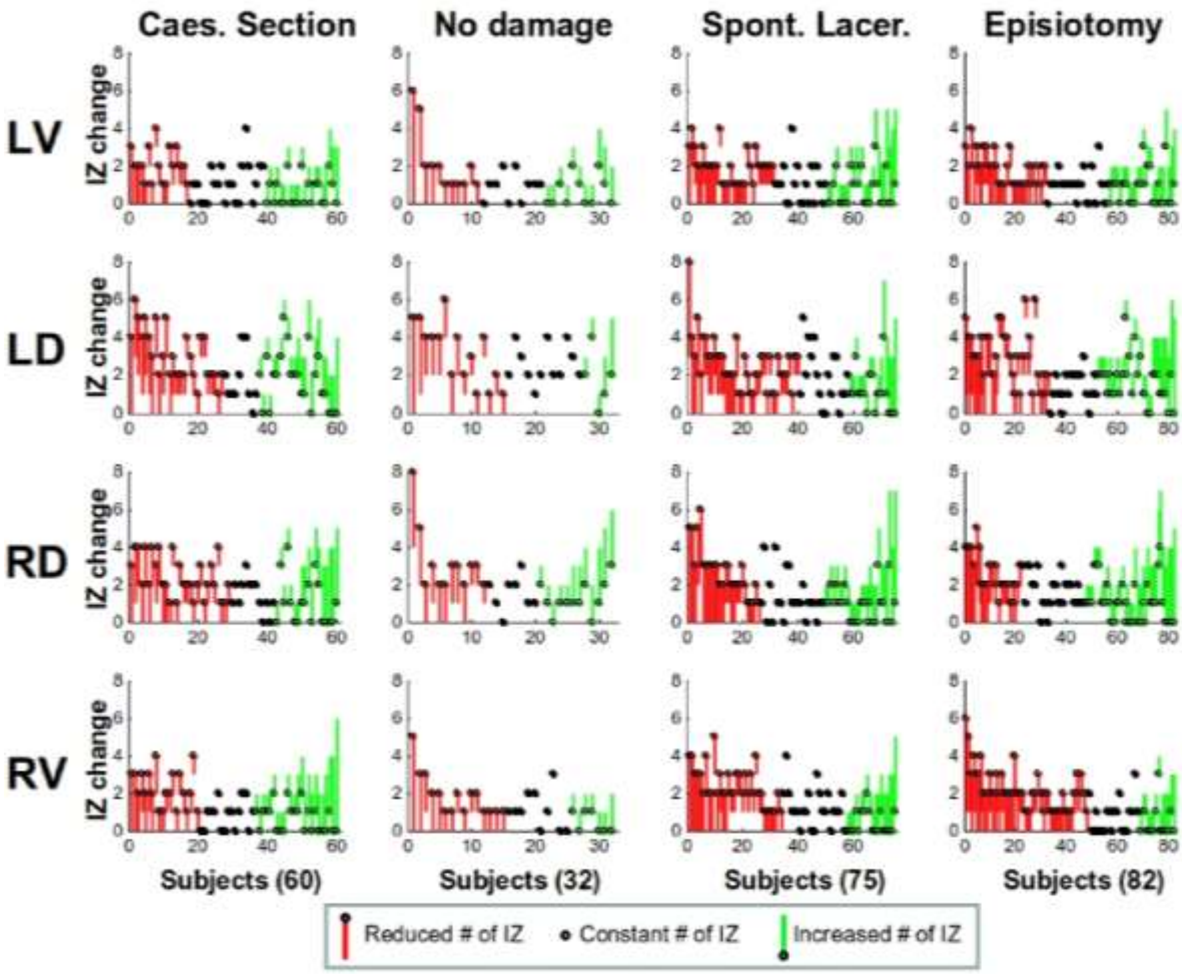

Figure 3.6 **Individual IZ counts before and after child delivery**

In rows, the quadrants of anal area are shown. LV – left ventral, LD – left dorsal, RD – right dorsal, RV – right ventral. The columns show the division according to delivery type.

In each panel, the subjects are ordered according to the delta IZ number, that is, the change of number of IZs after compared to before delivery; thus, on the left side, there are the women with a more considerable decrease of IZs (red), while on the right side of each panel are the women with a more considerable increase of IZs after delivery (green). In the middle portion of each panel, the women did not change the number of innervation zones after delivery. In the last panel (bottom right, corresponding to episiotomy group on the ventral-right quadrant), the "red" group (women who had a decrease in the number of IZs after delivery) is predominant compared to the other panels.

The mean difference of the IZs "before – after" shows the differences in the episiotomy group in the right ventral quadrant more than in the other quadrants (see Figure 3.7).

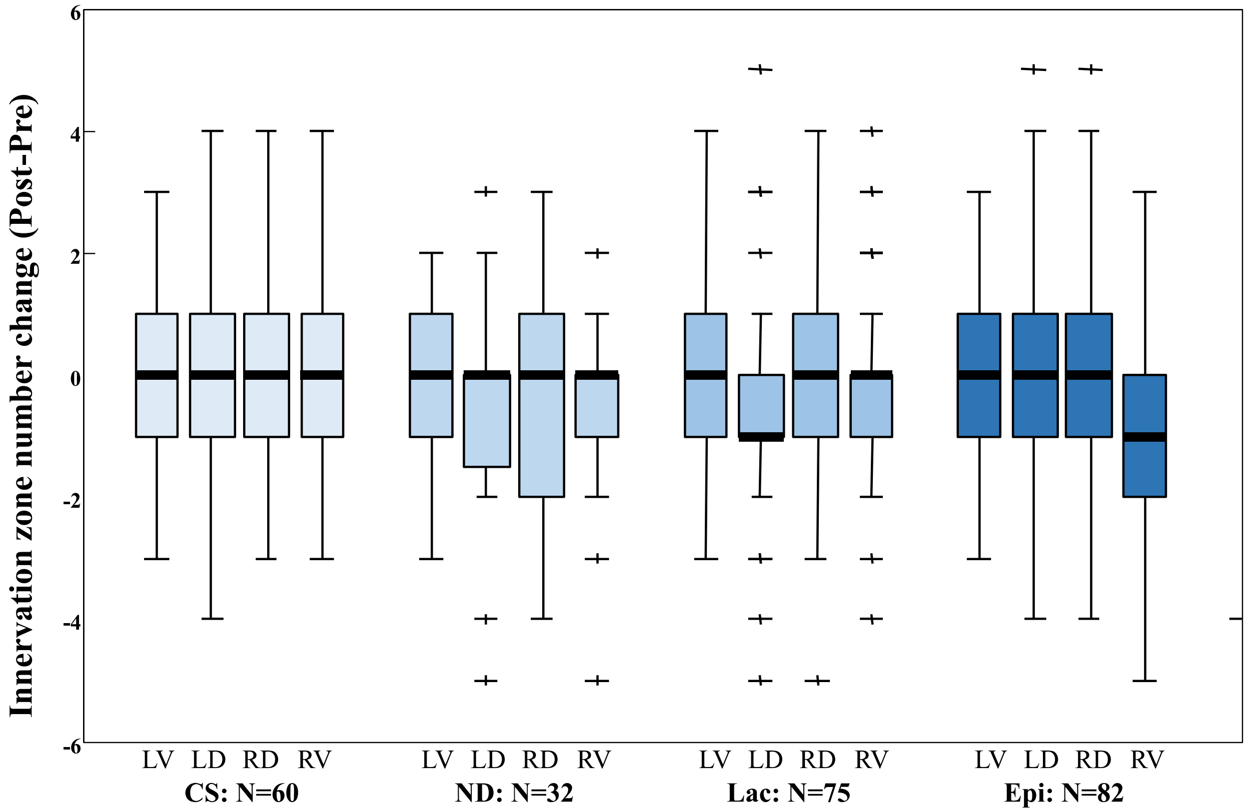

Figure 3.7 **The distribution of the difference between the innervation zones before and after delivery for the patients grouped according to type and quadrant**

Box whiskers plots of the changes of the number of innervation zones in the patients grouped according to the factors: type (CS – caesarean section, ND – vaginal delivery with no damage, Lac – spontaneous lacerations, Epi – episiotomy), and quadrants (LV, LD, RD, RV). The crosses represent outliers laying 1.5 times outside the interquartile range (IQR).

Table 3.2 shows the IZs difference estimates and their 95 % confidence intervals for two groups of subjects: Caesarean section and Episiotomy. The only significant difference is for the ventral right side of the women who had an episiotomy.

Table 3.2

Estimates of the difference (pre-post) in the number of IZs in the four quadrants

Delivery type	**Quadrants**			
	Left Ventral LV	**Left Dorsal LD**	**Right Dorsal RD**	**Right Ventral RV**
Caes. Section Mean [95 % CI]	0.05 [−0.40: 0.51]	−0.08 [−0.41: 0.25]	−0.04 [−0.42: 0.32]	0.17 [−0.25: 0.60]
Episiotomy Mean [95 % CI]	−0.13 [−0.53: 0.26]	−0.04 [−0.34: 0.24]	0.14 [−0.17: 0.46]	−0.62 [−1.03: −0.21]

Figure 3.8 shows the confidence intervals for the four groups of patients for the change in the number of innervation zones in the four different quadrants graphically. Bars not cutting the zero line show significant differences ($p < 0.05$). The numerical values were reported in Table 3.2.

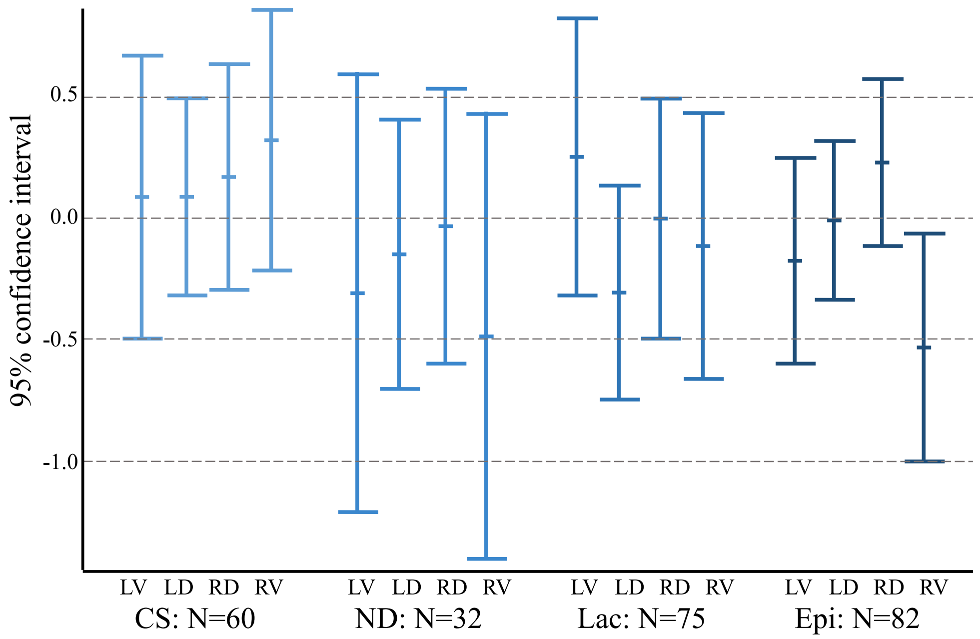

Figure 3.8 **Confidence intervals (95 %) of the change of innervation zones**

The patients are grouped according to the factors: type (CS – caesarean section, ND – vaginal delivery with an intact perineum, Lac – spontaneous lacerations, Epi – episiotomy), and quadrants (LV, LD, RD, RV).

The only negative interval remains the one for the episiotomy patients, right ventral quadrant.

Figure 3.9 provides a comprehensive synthesis of the results by showing the difference in the number of IZs in each EAS quadrant pre-and post-delivery (Caesarean sections comprise the control group and episiotomies the case group). The intensity of grey levels of the EAS quadrants depicts the change in IZ number (pre-delivery minus post-delivery).

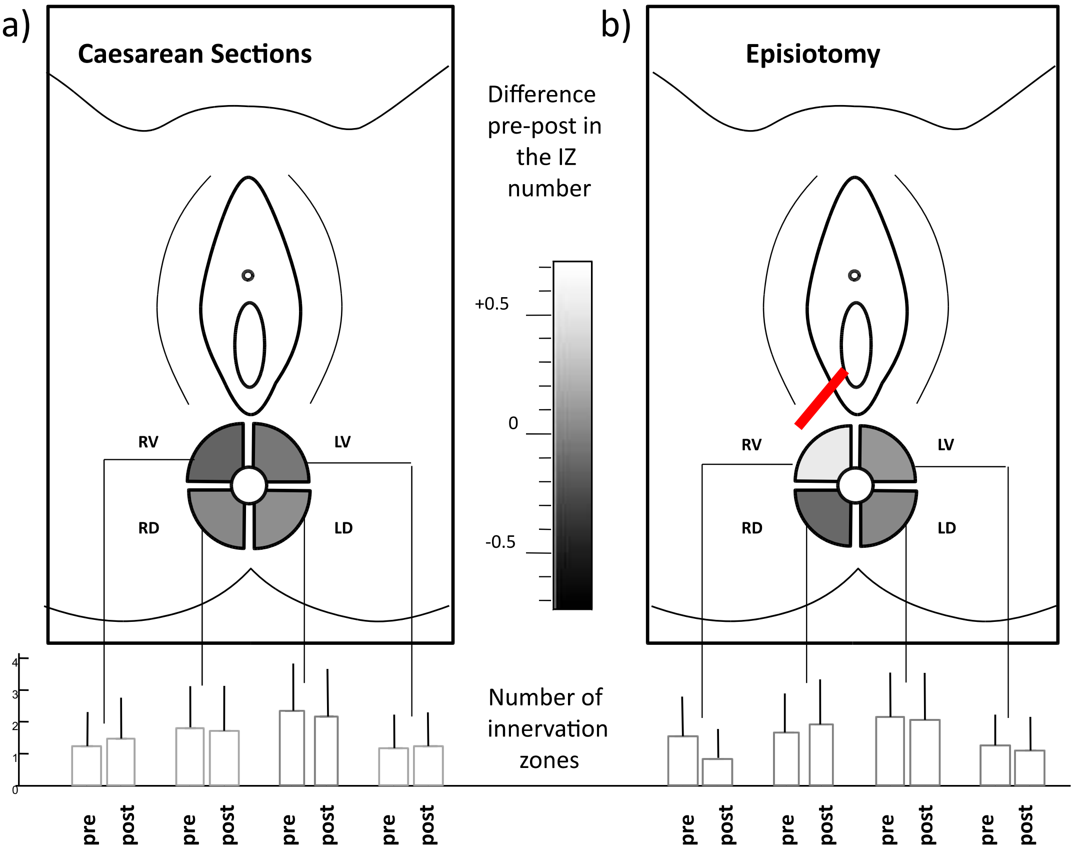

Figure 3.9 **Graphical representation of the estimates of the difference (pre to post-delivery) in the number of IZs**

a) Caesarean sections and b) episiotomy subjects. The four quadrants of the anal sphincter (LV, RD, LD, RV) are coloured in a shade of grey corresponding to the difference in the number of IZs, where lighter shades correspond to a decrease in the number of IZs and darker shades to an increase in the number of IZs.

The results of the analysis showed a statistically significant decrease in the number of IZs (mean = 0.62, 95 % CI [−1.03: −0.21]) in the right ventral quadrant of the EAS in women who had a mediolateral right episiotomy. Statistically significant changes in the number of innervation zones were not observed in the cases of caesarean sections or vaginal delivery with spontaneous lacerations.

3.2 Results of phase 2: amplitude asymmetry index

In total, 245 subjects from Riga Maternity hospital and Ljubljana Medical centre concluded the first measurement session, 179 and 66, respectively. 50 subjects did not return for the second session, 4 were excluded because of the exclusion criteria according to the delivery type (breech or instrumental), and 24 were excluded from analysis after signal quality control; total dropout and exclusion percentage was 34 %. 167 subjects were included for the analysis in the second session, out of them 131 from Riga Maternity hospital.

Table 3.3 summarises patient clinical data, time of measurement, questionnaire results, and delivery type. No parameter showed significant differences between groups.

Table 3.3

Clinical data for each patient group

Variable	**All recruited N = 245**	**All completed N = 167**	**AAI left N = 82**		**AAI right N = 85**		**Stat.**
			Episiotomy N = 28	**Other N = 54**	**Episiotomy N = 30**	**Other N = 55**	**Kruskal-Wallis**
Age (years)	28.3 ± 3.6	28.7 ± 3.8	29.0 ± 3.6	28.7 ± 3.8	29.2 ± 4.1	28.3 ± 3.7	p = 0.35
BMI (kg/m2)	23.1 ± 3.4	23.0 ± 3.5	23.7 ± 3.3	23.2 ± 4.3	23.1 ± 2.2	22.2 ± 4.0	p = 0.65
Infant weight (kg)	3.48 ± 0.53	3.48 ± 0.53	3.63 ± 0.60	3.47 ± 0.59	3.50 ± 0.37	3.41 ± 0.51	p = 0.87
Weeks at the 1st session	31.7 ± 2.7	31.8 ± 2.4	32.3 ± 2.4	31.7 ± 2.2	31.6 ± 2.4	31.8 ± 2.5	p = 0.58
Weeks from delivery to 2nd session	NA	7.2 ± 1.4	7.4 ± 0.8	6.6 ± 1.2	6.8 ± 1.7	7.2 ± 0.9	p = 0.21
Longo 1st session	0.75 ± 0.97	0.76 ± 1.03	0.79 ± 0.88	0.98 ± 1.11	0.40 ± 0.72	0.73 ± 1.13	p = 0.72
Longo 2nd session	NA	0.37 ± 0.89	0.43 ± 0.79	0.33 ± 0.80	0.36 ± 0.50	0.38 ± 1.13	p = 0.81
Wexner 2nd session	NA	0.28 ± 0.89	0.25 ± 1.06	0.19 ± 0.63	0.52 ± 1.38	0.23 ± 0.81	p = 0.69
Epidural (%)	NA	16	14	9	14	24	NA
Oxytocin (%)	NA	48	61	39	52	47	NA

None of the women had sphincter damage before pregnancy or wound complications or third or fourth-degree lacerations after delivery. The duration of pregnancy was 39.3 ± 2.01 weeks.

The 245 women's amplitude distribution was heterogeneous, with 118 (48 %) women asymmetric on the right side and 127 (52 %) on the left. Delivery types of the 167 women who completed both sessions were as follows: 35 % episiotomy on the right, 32 % spontaneous lacerations, 11 % no damage, and 22 % caesarean section.

Considering those 167 women, amplitude distribution before delivery was heterogeneous, with 85 (51 %) asymmetric on the right and 82 (49 %) on the left (see Figure 3.10).

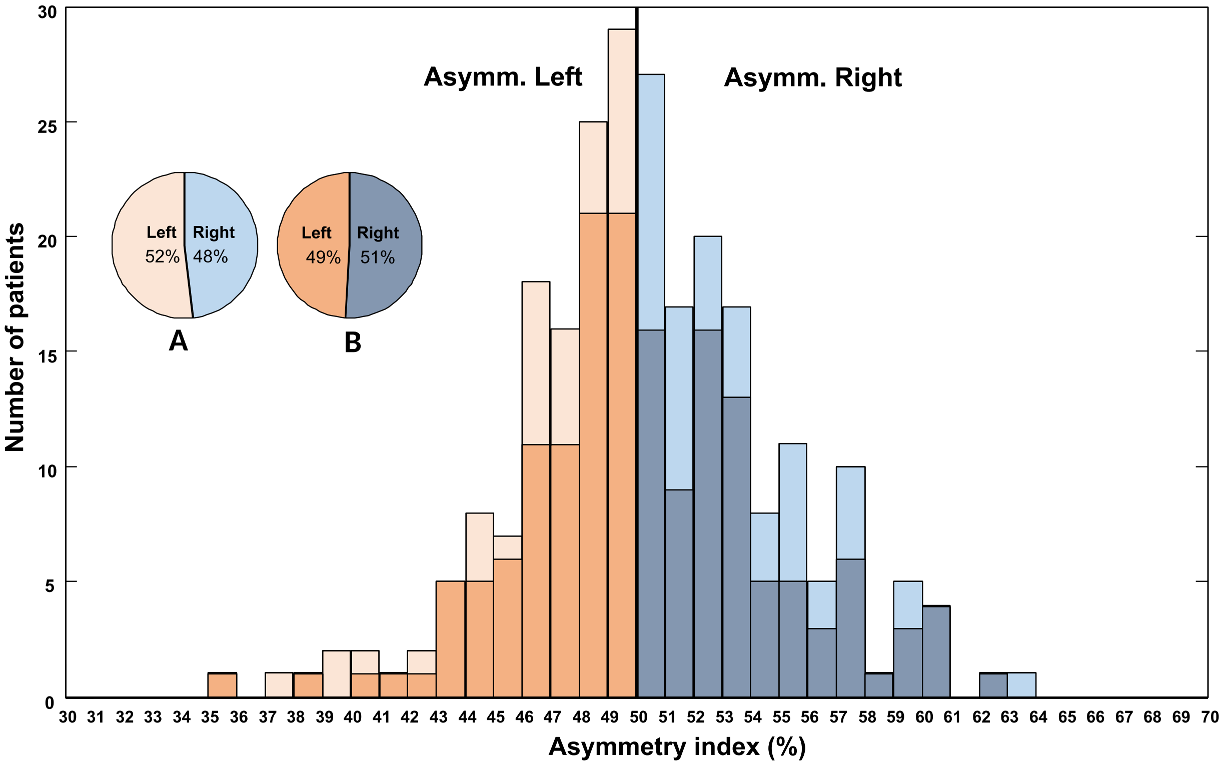

Figure 3.10 **Amplitude asymmetry index distribution in 245 women before delivery**

A) subjects that were measured the first session (N 245). B) Subjects completed both sessions (N 167). Darker colours represent AAI values before delivery of women who completed both measurement sessions.

EMG signal amplitude was similar between left and right innervated women before delivery. According to the delivery type, left and right asymmetric women were divided into four groups as described previously. Signals acquired after delivery showed an amplitude difference among the groups, and the reduction of EMG sphincter amplitude after MLE was seen in women who had AAI right. Among the four groups, the only significant change in global EMG amplitude after delivery was observed in women who had amplitude asymmetry on the right side and underwent mediolateral right episiotomy (Wilcoxon signed-rank test, $p < 0.01$). No significant EMG amplitude changes were observed between the caesarean section, spontaneous lacerations, or delivery with no damage. Moreover, no significant EMG amplitude changes were observed in women with amplitude asymmetry on the left side who underwent episiotomy on the right side (Figure 3.11).

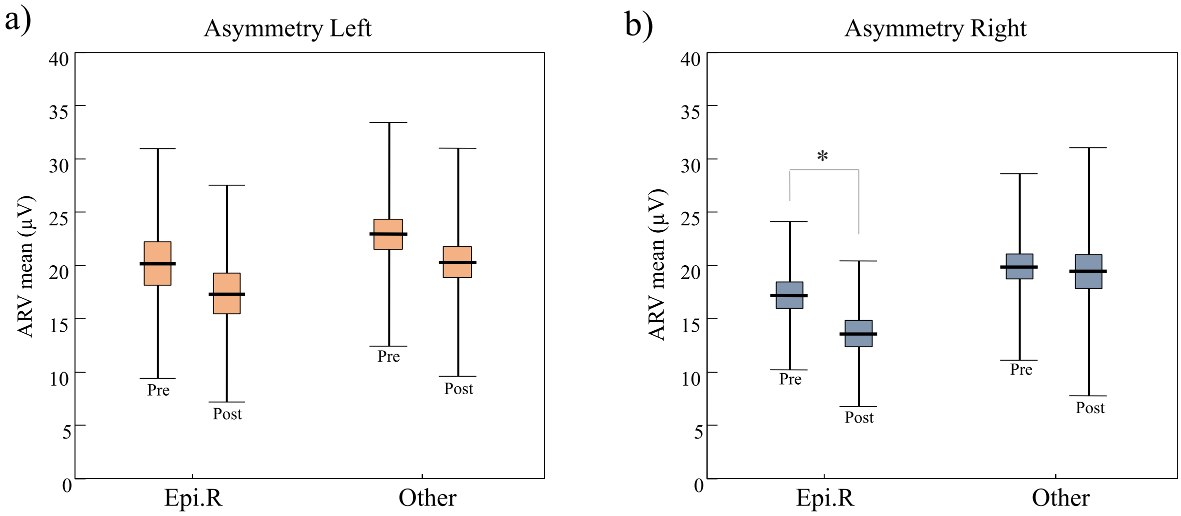

Figure 3.11 **Amplitude change after delivery: episiotomy versus other types of delivery**

Changes of mean global average rectified value during maximum voluntary contraction before and after delivery for women divided into two groups according to the amplitude asymmetry index: a) asymmetric left, b) asymmetric right. Red is left asymmetric, and blue is right asymmetric. * The only significant amplitude change is for women with right asymmetry who had episiotomy on the right side ($p < 0.01$).

3.3 Results of phase 3: EMG amplitude and clinical symptoms in one-year follow-up

One hundred and twenty women were invited, and 112 gave informed consent to participate in the study. Of these 112 women, ten were excluded due to medical conditions (like third-degree haemorrhoids, obstructive defecation syndrome, anal incontinence score > 1 at inclusion, insulin-dependent diabetes), 22 participated only at the first session, 17 interrupted the study after the second session. There were no differences in demographics and labour outcomes between the women who withdrew from the study and women who completed all three sessions. Two breech deliveries were excluded at the second session according to exclusion criteria. Since instrumental vaginal delivery is considered a risk factor for pelvic floor disorders, we excluded five vacuum or forceps deliveries from our study.

29 % of the women in the vaginal delivery group had an episiotomy, 48 % had first or second-degree spontaneous lacerations, 23 % had no pelvic floor damage, and none of the analysed women had third or fourth-degree lacerations. Only right mediolateral episiotomies were performed, and the average length and angle were 33 ± 0.9 mm and 42 ± 8 degrees, respectively.

An expert performed a visual inspection of the EMG signals to evaluate artefacts, missing contacts or short circuits. Out of the 62 who completed the three sessions, four patients were subsequently excluded due to low signal quality in at least one of the three sessions. The total dropout and exclusion percentage after three measurement sessions was 43 %. Two groups were compared in this study: vaginal delivery versus caesarean birth. A total of 58 women

(10 CS and 48 VD) were considered in the following analysis. No significant difference was observed in demographic and clinical data between the two groups of women (CS and VD) (see Table 3.4).

Table 3.4

Demographic variables for the two groups of women

Variable	CS (N = 10)	VD (N = 48)	Test type*	p-values
Age (years)	28.9 ± 3.4	28.0 ± 1.3	t-test	P = 0.43
BMI before delivery (kg/m2)	21.8 ± 1.3	22.7 ± 1.2	t-test	P = 0.56
Gestational age at delivery (week)	40.1 ± 0.9	39.8 ± 1.2	t-test	P = 0.87
Infants birth weight (kg)	3.74 ± 0.1	3.59 ± 0.6	t-test	P = 0.33
Longo score before delivery	1.2 ± 0.2	1.3 ± 0.3	rank-sum	P = 0.87
Use of oxytocin	50 %	44 %	Fisher	P = 0.49
Epidural anaesthesia	20 %	21 %	Fisher	P = 0.67
Labour induction	20 %	2 %	Fisher	P = 0.073
Length of the first period, (min)	253 ± 108	425 ± 176	t-test	P = 0.054
Length of the second period, (min)	N.A.	52 ± 27	NA	NA

* Student t-test was performed for continuous variables, rank sum test for categorical variables, and Fisher's exact test for Boolean data type. CS – caesarean section, VD – vaginal delivery.

Additional comparison among different types of VD showed no differences among four groups in maternal age, gestational age, infant weighs, and the length of the first and second period (Figures 3.12 and 3.13).

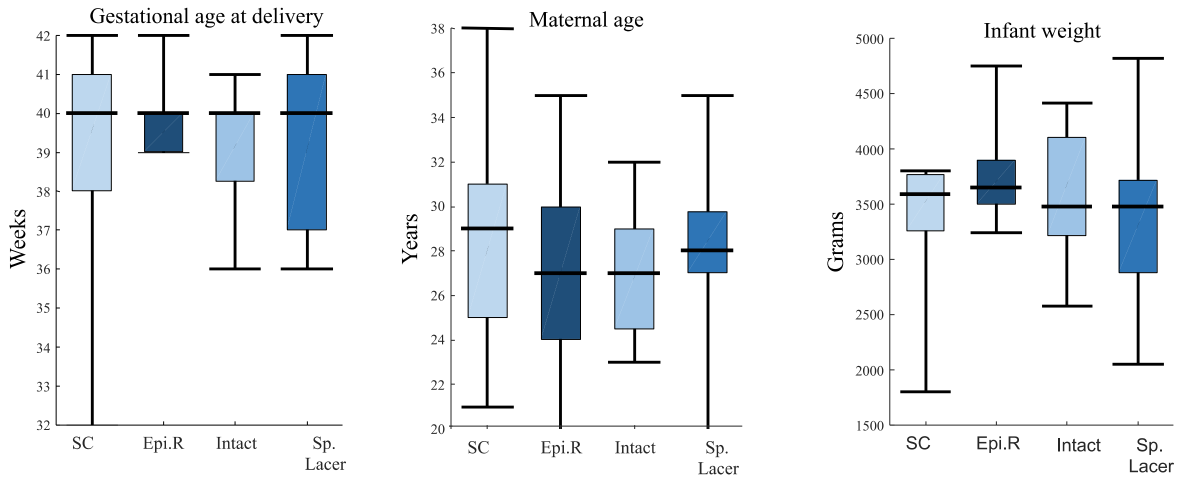

Figure 3.12 **Gestational age, maternal age and infant's weight for four types of delivery**

SC – caesarean section, Epi.R – right side MLE, Intact – intact perineum (no damage), Sp.Lacer – spontaneous lacerations. Median value and IQR are shown in the box whisker plot.

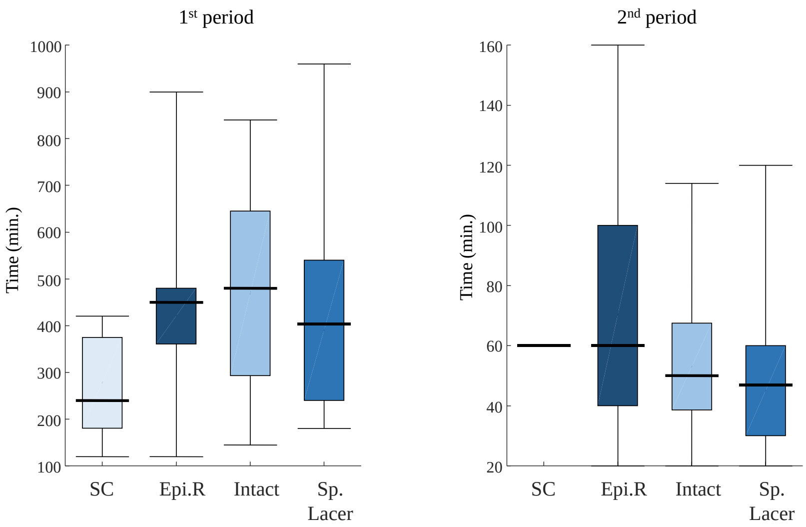

Figure 3.13 **Length of the first and the second period in four types of delivery**

SC – Caesarean section, Epi R – right side MLE, Intact – intact perineum (no damage), Sp.Lacer – spontaneous lacerations. Median and IQR are shown in the box whisker plot. No difference was observed among the groups.

Amplitude was evaluated at rest and MVC status in each subject at every measurement session for every channel. The ARV was calculated and compared between the groups and the types of delivery. The average amplitude is higher at lateral channels and is lower at ventral and dorsal channels in all patients before and after delivery. Figure 3.14 shows the amplitude distribution for 16 channels as a percentage from a uniform distribution in all the study subjects before and six weeks after delivery.

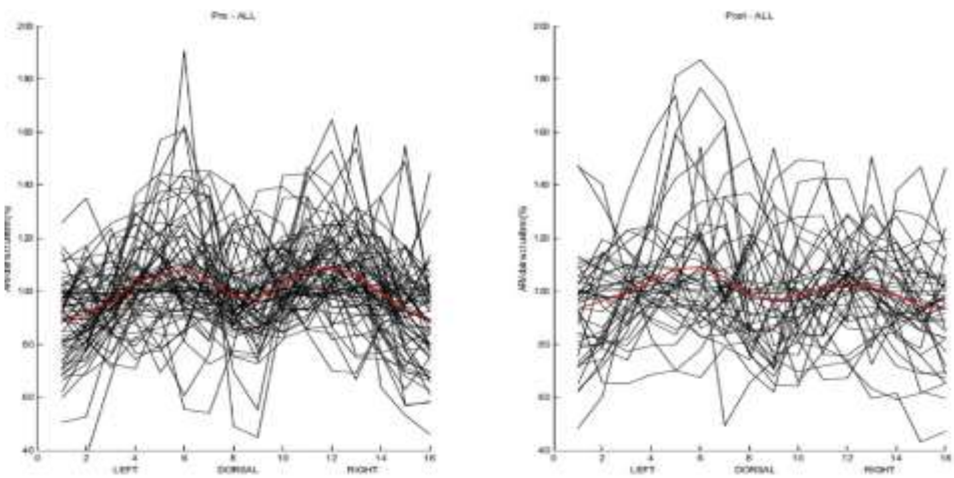

Figure 3.14 **Amplitude distribution represented as a percentage with respect to a uniform distribution**

The X-axis shows the 16 channels. The Y-axis is the percentage (above or below 100 % of the uniform distribution). The left panel (Pre) is amplitude before delivery. The right panel (Post) after delivery. All subjects are included. The red line is the mean value of all the distributions. The two peaks located around channels 5 and 12 show higher amplitude on lateral sides of the sphincter. After delivery, the mean value (red line) is lower at channel 12, which corresponds to the right ventral quadrant.

If separate per delivery type (episiotomy versus other types), the same pattern – higher amplitude laterally and lower at dorsal and ventral positions – is observed, and additionally, in the episiotomy group, the mean ARV after delivery reduces (see Figure 3.15)

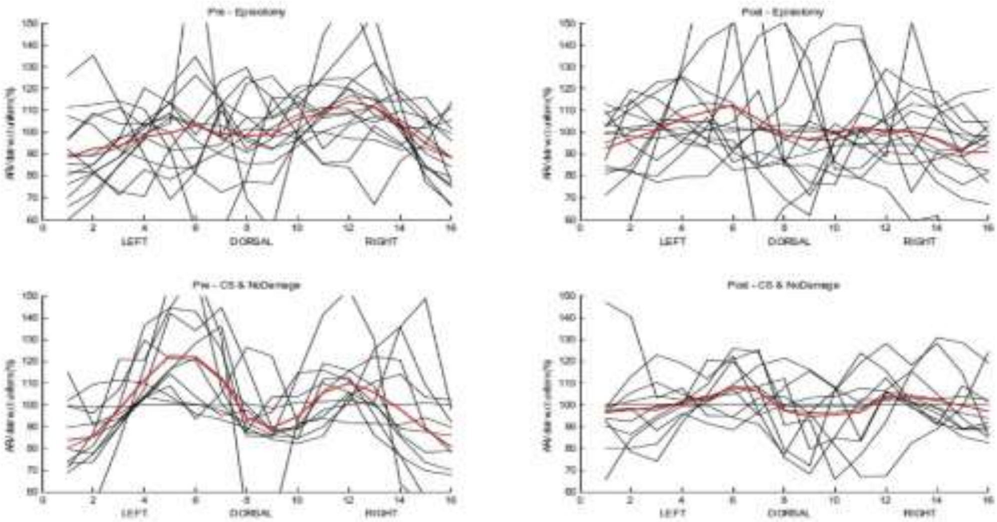

Figure 3.15 **Amplitude distribution represented as a percentage with respect to the uniform distribution**

The X-axis shows the 16 channels. The Y-axis is the percentage (above or below 100 % of the uniform distribution). The left panel (Pre) is amplitude before delivery. The right panel (Post) after delivery. All subjects are included. The red line is the mean value of all the distributions. The two peaks located around channels 5 and 12 show higher amplitude on lateral sides of the sphincter. After delivery, the mean value (red line) is lower at channel 12, which corresponds to the right ventral quadrant.

All the amplitude ARV at rest and MVC at three measurement sessions (before delivery, six weeks and one year after) divided per delivery type were analysed. At rest, amplitude and its intersubject variability are less prominent than at MVC. The differences between the four groups are not significant, as visible in Figure 3.16.

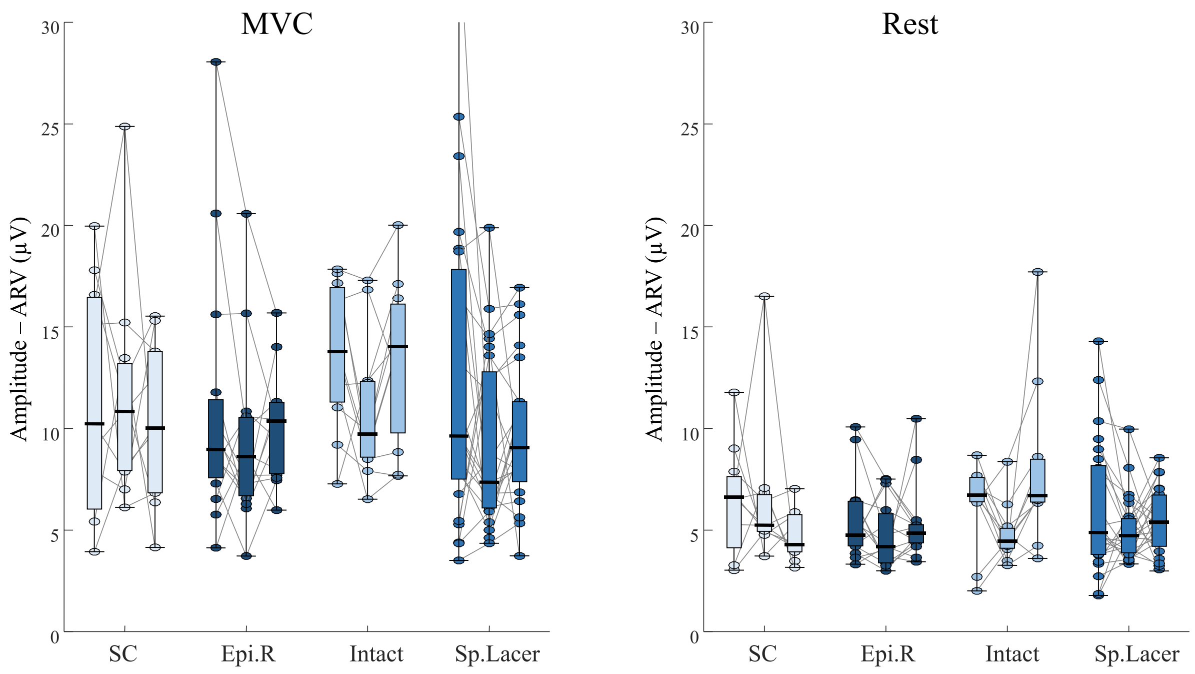

Figure 3.16 **ARV amplitude at rest and MVC in each delivery type at three measurement sessions**

Every group is shown at three measurement sessions in chronological sequence: the blue bars are ARV for SC group at the 1st, 2nd and 3rd session, the red bars – episiotomy group at the same sessions, green – intact perineum group and yellow – spontaneous lacerations group at three sessions. The left panel corresponds to MVC and the right panel – to the Rest. Median and IQR are shown, and outliers are represented as circles.

Since the objective was to compare vaginal delivery versus CS, all the vaginal delivery types were analysed as one group, and the comparison of amplitude was made between all VD versus CD. No differences were observed in ARV values between CS and VD groups before delivery. No differences were observed between the two groups after one year. The post-hoc SNK analysis of the 2-way ANOVA showed only one significant decrease in amplitude in the VD group in the second session compared to the first session from 10.1 to 8.6 μV with an effect size of 0.4 ($p = 0.025$) (Figure 3.17).

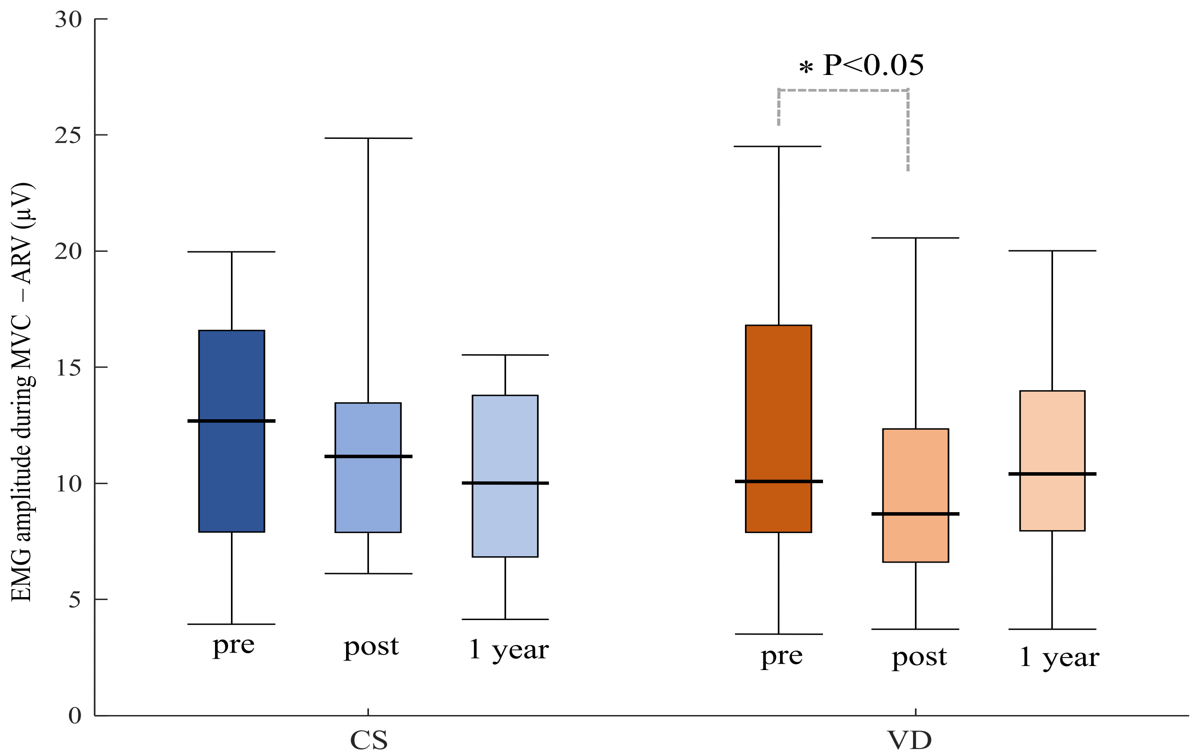

Figure 3.17 **Distribution of amplitude (ARV) in VD and CS groups during the three measurement sessions**

CS – caesarean section and VD: vaginal delivery. Pre: during pregnancy, Post: 6 weeks after delivery, 1 year: one year after delivery

Regarding clinical outcomes, the incontinence score was evaluated. Before delivery, the score was 0 for all women. The incontinence score slightly increased (but not significantly) after the delivery for both groups, Fisher test P = 0.67. The difference between the groups was not significant. About 30 % in CS and 20 % of women in the VD group showed a score equal to or greater than 1 six weeks after delivery, compared to 0 before delivery. The absolute values of the score were from 1 to 4. This percentage decreased to about 10 % one year after the delivery for both groups (see Figure 3.18).

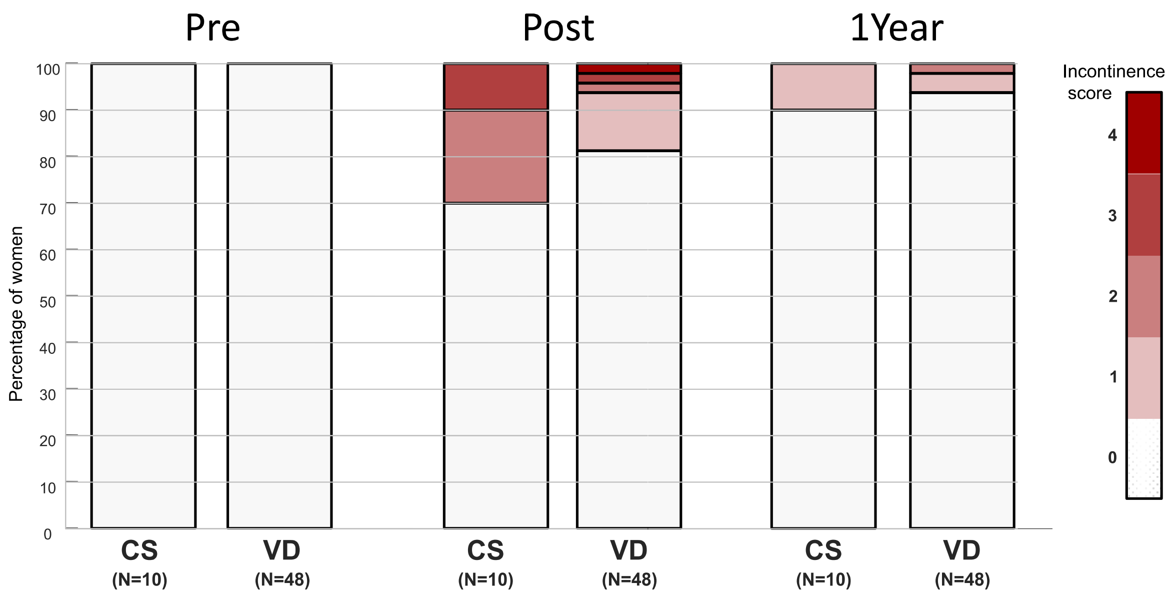

Figure 3.18 **Incontinence score changes between CS and VD before and after delivery**

Pre: before delivery, Post: 6 weeks after delivery, 1 Year: one year after delivery. The intensity of the colour corresponds to the increase of incontinence score.

No association was observed between the increase of incontinence score and the decrease of EMG signal amplitude.

3.4 Summary of the results

3.4.1 Innervation zone distribution

- IZ distribution is heterogeneous and has a large inter-individual variability.
- A higher number of IZs is observed laterally compared to the ventral and dorsal position (e.g. higher values under electrodes 5 and 12, which correspond to position 3 o'clock and 9 o'clock, respectively).
- IZ distribution changes after delivery. A significant reduction of IZs is observed in the right ventral quadrant after delivery with right side MLE. No significant differences can be observed in other quadrants.
- No significant changes are visible in IZs distribution after CS or after vaginal delivery with spontaneous lacerations or intact perineum.

3.4.2 EMG signals amplitude (average rectified value (ARV))

- The global EMG amplitude shows considerable inter-individual variability. Mean values of ARV before delivery at rest ranged between 4.1μV to 8.3μV, at MVC – between 8.1μV to 15.3μV.

- ARV slightly reduces after delivery in all subjects, significantly decreasing 6–8 weeks after vaginal delivery compared to caesarean delivery. No difference is visible one year after delivery compared to pre-delivery values in any group.

3.4.3 Amplitude asymmetry index

- The distribution of amplitude can be divided into two macro groups: Left or right asymmetry. 52 % of our participants had left asymmetry, while 48 % – right asymmetry.
- The asymmetry index can change after delivery: right asymmetric women became left asymmetric since amplitude reduces on the right side after delivery with episiotomy.
- After delivery, a significant decrease in global EMG amplitude is visible in women with amplitude asymmetry on the right side who underwent mediolateral right episiotomy.

3.4.4 Clinical outcomes

- The incontinence scores slightly but not significantly increase 6–8 weeks after the delivery in 20 % of caesarean and 30 % of vaginal deliveries (maximal score 4).
- 10 % of women have an increase in incontinence score one year after delivery (maximal score 2).

4 Discussion

Agreements and disagreements with other studies or reviews

To date, there are no studies with anal sphincter sEMG, including pregnant women before and after delivery; therefore, no direct comparison between our findings and other studies is possible.

The Thesis showed that sphincter muscle EMG amplitude asymmetry exists and that, after delivery, a significant decrease in global EMG amplitude is visible in women who had amplitude asymmetry on the right side and underwent mediolateral right episiotomy. The results are in line with previous studies in other populations, e.g. *The Project On ASymmetry In Sphincters*, showing sphincter innervation asymmetry and the possibility of iatrogenic damage in asymmetric subjects (Enck et al., 2004; Wietek et al., 2007). In the Thesis, the amplitude asymmetry index was computed as the ratio between the average amplitude of the channels on the left side and the global amplitude and expressed as a percentage (AAI greater than 50 % indicated more significant signals on the right side, while AAI smaller than 50 % indicated left asymmetry). Thus, the amplitude distribution was divided into two macro groups: left or right asymmetry. It differs from *the Project On ASymmetry In Sphincters*, where the subjects were divided into symmetric or asymmetric groups and not left or right dominant. To compute the symmetry index in Enck's study, the mean of the EMG amplitude (left-right) was divided by max (left, right) of the EMG amplitude; it defined the relative sEMG amplitude symmetry of both sides between 0 (symmetric) and ± 1 (asymmetric). It found 67 % of female subjects as symmetric and 32 % as asymmetric. In the study of Enck, the symmetry status correlated with the degree of incontinence, as assessed by the Wexner score: patients with severe incontinence (Wexner > 5) were significantly more frequent asymmetric than those with Wexner scores ≤ 5. Our study saw differences between the groups after delivery with episiotomy, meaning that even slight asymmetry can be attributed to later changes, although many women before delivery had AAI close to 50, and asymmetry was not salient.

Wietek et al. performed sEMG measurements in three cohorts: 40 pregnant women at 29–39 weeks of gestation, 15 of them 3 to 6 weeks postpartum and 50 other women with a perineal tear of third or fourth degree during their vaginal delivery 3 to 6 months before the EMG measurement (Wietek et al., 2007). Her study demonstrated that women with incontinence symptoms showed a significantly higher asymmetry index compared to the asymptomatic group, concluding that asymmetry of sphincter innervation is a significant risk factor for incontinence postpartum in those cases in which the trauma occurs on the dominant side of innervation in case of significant asymmetry. The results of the present Thesis are consistent with this finding regarding sphincter activity.

In our study, we found decreased sphincter muscle EMG amplitude after delivery with episiotomy. Amplitude is an indicator of muscle strength. For the pelvic floor assessment after delivery, the present Thesis results can be compared with studies where quantitative methods measure pelvic muscle strength after delivery. Both EMG amplitude and muscle strength measurements by anorectal manometry are objective measurements not affected by patients' or clinicians' interpretation.

The decrease of amplitude observed after delivery was reported previously in a study where subjective (Oxford scale) and objective (perineometry) assessments of PFMF were performed at 20 and 36 weeks gestation and 14 weeks and 12 months after vaginal delivery (Elenskaia et al., 2011). The study mentioned above evaluated the resting pressure and the maximum squeeze pressure of the PFM by an intravaginal air-filled balloon perineometer. Although there was a significant decrease in PFMF after childbirth, there was a recovery in squeeze pressure by one year irrespective of delivery mode, similar to our results. The authors hypothesised that there could be a physiological increase in PFMF during pregnancy in response to the increased load of the gravid uterus. It suggests that future studies that would evaluate the same women before pregnancy, during pregnancy and after delivery would be helpful to prove it, and postpartum measurements should not be compared to third-trimester measurements only. In the present Thesis, we recruited pregnant women, and we do not have the information about sphincter muscle before the pregnancy.

Another cross-sectional study used a perineometer placed in the vagina for PFM strength evaluation, including nulliparous women and women who had given birth in the previous six months (normal vaginal delivery with episiotomy, normal vaginal delivery without episiotomy or caesarean section) (Afshari et al., 2016). In the above study, women who had a vaginal delivery with episiotomy had lower pelvic muscle strength than the nulliparous women, women with normal vaginal delivery without episiotomy, and women with elective or emergency CS. The study of Afshari did not find any differences in pelvic floor muscle strength between nulliparous women and women with normal vaginal delivery or elective caesarean section six months after delivery, and the results of the present Thesis are in line with these findings, even if the results of the present Thesis considers anal sphincter muscle activity only, not all pelvic muscles.

The present Thesis results are in line with a recent meta-analysis of 11 studies where PFM strength was assessed through vaginal manometry. This meta-analysis found no differences in short term pelvic muscle strength between CS and VD; on the other hand, episiotomy or instrumented delivery was associated with reduced PFM strength compared with those who underwent CS (Driusso et al., 2020). The authors of the meta-analysis warned that this conclusion should be interpreted cautiously because of possible heterogeneity among the primiparous women included in the primary studies (maternal body mass index, newborn weight, race, and possible presence of co-morbidities) and the observational design of the studies.

The lack of studies similar to this one limits the possibilities of this discussion. It is impossible to directly compare the present Thesis findings with other studies that used EMG for PFM assessment after delivery because the previous studies were based on vaginal probes. Two small studies employing vaginal EMG probes and vaginal manometers contradict the conclusions of the Doctoral Thesis. A study including ten nulliparous and ten primiparous women showed decreased PFM strength 9-10 months after delivery (Marshall et al., 2002). Another study compared vaginal delivery with episiotomy and elective or emergency CS and observed decreased pelvic floor muscle strength and endurance 45 days after delivery in the VD group compared to CS (Botelho et al., 2010).

The reduction of pelvic muscle strength and decreased electrical activity in pregnant women compared to non-pregnant ones was demonstrated in a study using a vaginal probe with two electrodes (Resende et al., 2012). Their study compared 15 pregnant women in the third trimester to 15 healthy non-pregnant women. When compared to nulliparous women, pregnant women had poorer PFM function. They had less strength and electrical activity. It is impossible to interpolate these results to EAS activity only and compare directly to the results of the present Thesis since vaginal probes were used and the subjects were not the same.

In another study, Li et al. performed pelvic muscle electrophysiological examination 8-12 weeks after delivery with a muscle potential probe inserted into the vagina and connected to the PHENIX neuromuscular therapy instrument (Li et al, 2015). The focus in the Li's study was on pelvic organ prolapse and urine incontinence, not on anal incontinence as in the Thesis. Contrary to the Thesis results, they did not find a significant difference in early postpartum pelvic floor muscle strength between the caesarean section (66 cases) and vaginal delivery (83 cases) groups. No comparison between status before and after delivery was performed. In our study, we used anal probes, evaluating EAS, and performed three measurements in each group; we looked for the changes of the sphincter activity for the same woman. Our measurements were performed 6–8 weeks and one year after delivery, and we found a significant decrease in EMG amplitude in the VD group compared to the CS group 6–8 weeks after delivery and no difference after one year. 6–8 weeks after delivery is the time considered necessary for general recovery after childbirth. The recovery after one year and not after

6–8 weeks can be explained by more time necessary for the reinnervation. Reinnervation usually occurs from collateral sprouting by adjacent surviving motor units. According to one study, the estimated number of motor units did not increase considerably following nerve section and repair beyond two months (Gordon and Stein, 1982). Still, muscle reinnervation and functional improvement can take more time, and it has individual variations. If there is severe or complete denervation, with no nearby surviving axons, the only possible mechanism for reinnervation is regrowth of the axon from the injury site (in our case – episiotomy). As the axon regrows, it will reinnervate some, but not all, of the original muscle fibres.

Regarding clinical outcomes, in our study, the faecal incontinence score increased after delivery in both groups, without cardinal clinical impact, and there was no significant difference between CD and VD. Despite the increase in the absolute incontinence scores, the value was always below 5 out of 20, with a small clinical significance, and we could not find any association between EMG values and clinical signs. The author of the Thesis is aware that instrumental anorectal measurements do not always predict the severity of faecal incontinence (Heitmann et al., 2019; Young et al., 2017) since the heterogeneity of anorectal dysfunction exists and many other contributing factors, not only the function of EAS, should be taken into account.

The current literature about the impact of the mode of delivery on the pelvic floor function is controversial, both supporting and contradicting the results of the Thesis regarding anal incontinence. Different assessment instruments and definitions, as well as the time from delivery, are used. Previous studies mainly focused on pelvic floor dysfunction or pelvic organ prolapses, but it is still unclear if the mode of delivery or pregnancy itself leads to pelvic floor dysfunction. *Kaiser Permanente Continence Associated Risk Epidemiology Study* found anal incontinence in 16 % of the Caesarean delivery group (60/365) and 28 % (786/2.823) in vaginally parous women ($p < 0.05$) (Lukacz et al, 2006). It contradicts our study, where about 30 % in CS and 20 % of women in the VD group showed an increase in incontinence score six weeks after delivery and about 10 % one year after the delivery for both groups. Our study used the Wexner score, while the Kaiser study provides information only about the presence or absence of anal incontinence. In the Kaiser study, out of women who reported anal incontinence, 38 % had incontinence of flatus only, resulting in an overall rate of 10 % flatus and 17 % faecal incontinence. The results of both studies cannot be compared directly since, in the Kaiser study, more than half of the women were postmenopausal, with the mean age50.7 in the CS group and 58.8 in the vaginally parous group. Our study excluded the women with CS in the second stage, but the Kaiser study did not find differences between Caesarean groups, whether laboured or not. It suggests that anal incontinence results from mechanical disruption of the sphincter and terminal stretch of the pudendal nerve occurring at delivery and not during labour.

Larsson performed another population-based study, showing that women after vaginal deliveries were more likely to have AI than women who underwent only caesarean delivery (Larsson et al., 2019). Of the 185,219 women in the caesarean delivery group, 416 (0.22 %) were diagnosed with anal incontinence compared with 5171 (0.37 %) of 1.400.935 women in the vaginal delivery group (OR 1.65, 1.49–1.82; $p < 0.0001$). The percentage in absolute numbers was much lower than in our study, and it can be explained by a different diagnostic approach: we used questionnaires with Wexner score, while Larsson's study included confirmed AI diagnosis from the register. In Larsson's study, the risk for anal incontinence was higher also in women in the Caesarean delivery group compared to nulliparous women (OR 1.31, 1.16–1.46; $p < 0{\cdot}0001$), and nulliparous women had a higher risk of anal incontinence than men (OR 1.89, 1.75–2.05; $p < 0{\cdot}0001$), the groups not included in our cohort.

A meta-analysis using a comparable time frame to the Thesis – first 12 months postpartum – showed that women having any type of vaginal delivery compared with a caesarean section had an increased risk of developing symptoms of solid, liquid or flatus anal incontinence. For a spontaneous vaginal delivery, OR was 1.32, 95 % CI 1.04–1.68, $P = 0.02$ (Pretlove et al., 2008). Although when studies examining severe symptoms of anal incontinence such as solid or liquid anal incontinence were analysed, there was a trend towards more symptoms with vaginal delivery compared with caesarean section, but this did not reach statistical significance. It contradicts the findings of the Thesis, but the same authors of the meta-analysis warned that the mode of delivery might be a surrogate marker for other factors such as prolonged labour or increased infant birthweight. Our study excluded from further analysis women with the second stage of labour longer than 2 hours, and the infant weight was comparable between the groups. Similar to the conclusions of the Thesis, the meta-analysis concluded that we do not have sufficient evidence to advocate caesarean section for the reduction of incontinence symptoms in women without antenatal symptoms of anal incontinence. Also, Nelson (Nelson et al., 2010) concluded that no benefit could be demonstrated for Caesarean delivery over vaginal delivery in the preservation of anal incontinence.

The results of the Thesis regarding anal incontinence are consistent with the randomised trial of planned caesarean or vaginal delivery, including over 2800 women with twin pregnancies. In the *Twin Birth Study,* the rate of problematic faecal and flatal incontinence was low and similar for both groups; 18 (1.4 %) women in the planned CS group and 17 (1.3 %) women in the planned VB group reported problematic faecal incontinence ($P = 0.85$), and 62 (4.9 %) and 79 (6.2 %) reported problematic flatal incontinence (P = 0.15), in the planned CS and VB groups, respectively (Hutton et al, 2015).

The consistency of the results with the hypothesis

The results of the present Thesis are consistent with the first hypothesis and demonstrate reduction of IZs and EMG signal amplitude 6–8weeks after delivery. The results showed that the innervation zones on the side of episiotomy (right side) were reduced after delivery and, consequently, the EMG amplitude. The second hypothesis stated that after episiotomy, the women with asymmetric sphincter innervation would have different damage levels according to the side of asymmetry and the side of episiotomy, and the results of the study showed a significant decrease in global EMG amplitude after delivery in women who had amplitude asymmetry on the right side and underwent mediolateral right episiotomy.

Limitations

The main limitation of this study is that episiotomy was always performed on the right side, and the central assumption is that if the asymmetry were predominantly on the right side, a left episiotomy would have preserved the amplitude of the EMG signals postpartum. Since there were no episiotomies on the left side, it is assumed that the behaviour could be considered the same in a “mirrored” situation, i.e. asymmetry on the left and episiotomy on the right is comparable to asymmetry on the right and episiotomy on the left. It will take a long time and many more publications to persuade healthcare professionals to change their habits and choose the episiotomy side.

Another limitation of the study is the number of dropouts for the second and the third measurement (postpartum). It could be attributed to various reasons, including the respondents' reduced availability as primiparous women due to maternal responsibilities, relocation to different cities, or unpleasant memories of birth. None of the women complained about discomfort or pain during the first measurement. However, we were able to obtain delivery information of women who refused to continue the study. The distribution of delivery types and asymmetry for those women was similar to the others included, suggesting no bias in the proportion of the type of deliveries or asymmetry. The caesarean section did not modify the number of innervation zones in any quadrant in a statistically significant way. The same results can be observed for the vaginal delivery with no evident perineal damage and the spontaneous laceration group. An increase in the number of cases would not likely modify this conclusion. The percentage of dropouts is low compared to other similar design studies, e.g. the study assessing PFM force with perineometry during pregnancy and after delivery reported just 39 % of initially recruited women included in the final analysis (Elenskaia et al, 2011).

Strengths

The strength of our research is the prospective longitudinal design, which provides data of the same measurements with one antenatal and two postnatal assessments. To the author's knowledge, the present study is the first study on anal sphincter sEMG in pregnant women with three measurement sessions and one-year follow-up. This study uncovers new data from actual subjects recruited specifically for this study and allows reliable evaluation of EMG signal changes also in the long term. Another strength is that sEMG provides quantitative measurements, it does not dependent on subjects' or operators' interpretation. The number of participants included in the Thesis is high compared with other EMG studies for pelvic floor assessment in humans. The study showed that sphincter sEMG is a minimally invasive and painless method well accepted by patients. Another indirect benefit of the study for the society was the comprehensive work with colleagues and pregnant women, explaining the role of research in medicine – all the subjects were recruited to attend three measurement sessions in their spare time. The study uses innovative technology – HD EMG – and novel signal processing techniques: new software was created for the study and is ready to be introduced for other future studies, which is important since very few investigators work with anal probes, and even fewer in obstetrics.

General considerations

Although one could conclude that episiotomy should be avoided to preserve external anal sphincter innervation, the author of the Thesis would avoid this generalisation. Clinicians have to consider other risk factors related to Caesarean section and the benefits of episiotomy during vaginal delivery and the risk of OASI. In the present study, all the episiotomies were performed because of suspected foetal compromise or threat of severe perineal tears, and no routine episiotomy was performed. In this case, we cannot predict the degree of spontaneous lacerations that would have occurred if episiotomy had not been performed. Subjects included in the study mainly had first or second-degree spontaneous lacerations. These lacerations do not significantly affect the innervation of the EAS muscle. The small number of OASI in the study population is worth noting; it is in line with the country's general statistics. Still, occult laceration or misdiagnosed sphincter injury requires consideration.

Implications for future research

The results of the Thesis showed that spontaneous vaginal delivery reduces global EAS muscle amplitude six weeks after delivery, compared with CS, but the amplitude recovers one year after delivery. An interval of about four to eight weeks is usually necessary for anatomical and functional recovery after delivery, but complete nerve regeneration might last longer. Since pelvic floor dysfunction could appear much later in life than one year after delivery, further primary studies on sphincter EMG with longitudinal designs and long-term follow-up periods, comparing anal sphincter muscle function after childbirth, would be valuable. Another objective for future research would be to see the differences between different types of VD and analyse the subgroup of operative vaginal deliveries (the small number of operative deliveries in the present study did not allow this analysis).

Future research should look into the possible reinnervation of the EAS and see if anal incontinence occurs more commonly in patients who have had severe loss of this muscle's innervation. Analysing EMG changes when the side of episiotomy is decided based on EMG acquired during pregnancy would also be an interesting study.

Conclusions

The present study shows that multichannel sEMG in obstetrics is a novel and reliable non-invasive method to acquire quantitative electrophysiological measurements of the anorectum.

The findings of the study confirm that the global EMG amplitude and IZs distribution have sizeable inter-individual variability. A higher number of IZs is observed laterally compared to the ventral and dorsal positions.

- The study shows that **episiotomy reduces the number of IZs and EMG amplitude** of the EAS in the quadrant, where it is performed. Significant reduction of IZs is observed in the right ventral quadrant after delivery with right side MLE, and no significant changes are visible in IZs distribution after CS or after vaginal delivery with spontaneous lacerations or intact perineum.
- The study's findings demonstrate that the **asymmetry of EAS innervation exists** in equal proportions between the left and the right asymmetry. The asymmetry index changes after delivery with episiotomy.
- EMG signal amplitude ARV slightly decreases after delivery in all subjects, **significantly decreasing 6–8 weeks after VD compared to CS**. This difference is **not visible one year after** delivery.
- The **incontinence scores slightly but not significantly increase** 6–8 weeks after the delivery in 20 % of caesarean and 30 % of vaginal deliveries, with low clinical significance. 10 % of women have an increase in incontinence score one year after delivery (maximal score 2 for any delivery type).
- EMG signals detected during pregnancy could be used **to decide the optimal side of episiotomy**, reducing the damage of episiotomy to the sphincter innervation.

This study does not provide recommendations for the best method of delivery. It has to be decided by the gynaecologists considering many clinical factors. Although, in an era when women are increasingly requesting elective CS to preserve the pelvic floor, this study provides new data to reassure women and health care providers, offering a new tool towards **making vaginal childbirth safer** and focusing on preventative strategies.

Study clinical implications and future aspects

The present work showed how multichannel surface EMG could be applied in obstetrics and help clinicians improve their daily practice, even for such a routine and common intervention as an episiotomy. If the midwives or the doctors knew the distribution of IZs before delivery, they could choose the more appropriate side of the incision. Reducing the consequences of episiotomy by minimising damage to the EAS innervation would substantially influence the cost of the health care system and the quality of life of women. In countries where episiotomy is a common practice, this would be of utmost importance.

Multichannel sEMG can have an increasing relevance not only in obstetrics but also in colorectal surgery, particularly pre and post-surgical evaluation and rehabilitation. Multichannel sEMG can have a vital role to diagnose the aetiology of FI. A simple, computer-aided, electromyography-based algorithm is developed (Nowakowski et al., 2014) and could be introduced wider in proctological practice for this purpose. In urogynaecology, anal sphincter EMG becomes an indispensable parameter for diagnosis and a treatment option for patients with pelvic floor dysfunction and further replace urethral sphincter EMG (Qu et al., 2011), or can be used to assess the PFM training efficacy.

Both clinical research laboratories and practitioners could gain from introducing sEMG in everyday work. In recent decades, sEMG has shifted from neurophysiological research to neurorehabilitation, preventive medicine, ergonomics, and assessment of interventions (Merletti&Muceli, 2019). Multichannel sEMG provides information on the functional level associated with prevention, monitoring, assessment, and treatment planning.

There are wide opportunities for sEMG in gynaecology, proctology, basic and clinical neurophysiology, neurological and orthopaedic rehabilitation, sports, ageing and space medicine, occupational therapy, kinesiology, orthodontics, physiotherapy. sEMG can be applied in these areas with different aims: to evaluate muscle coordination and activation intervals, muscle force, spasticity, muscle overactivity, primitive synergies, postural control, muscle fatigue, pain, cramps, muscle activity and innervation zones localisation (Campanini et al, 2020).

Recent advances have turned the sEMG into an easy to learn and simple to use technique. Researchers have made enormous efforts to provide open-access tutorials and clinical guidelines online (Merletti&Muceli, 2019). The novel amplifiers are pocket-sized, can be easily carried to different locations, have internal batteries, and signal transition occurs in Wi-Fi mode. It is also easy to use: all the necessary elements (hardware, software) are provided by different manufacturers for an affordable price and are compatible with all computers, smartphones or tablets. Also, new anorectal high-density EMG probes have been developed (Merletti et al., 2004, Paskaranandavadivel et al., 2020). Multichannel sEMG is minimally invasive, painless, does not involve radiation or produce electrical impulses and is very safe.

Despite that, the widespread application of sEMG is still limited by different kinds of barriers, such as cultural (e.g. the inappropriate comparison with the needle EMG), technical (clinically relevant information is not visible directly without the software), educational (lack of physiological and technological literacy – only a few European schools offer courses in sEMG and even fewer PhD programs), economic, such as health insurance issues (Campanini et al., 2020).

The author of the present Thesis would like to encourage colleagues, gynaecologists and other specialists to adopt this advanced and innovative technology and enrich their clinical practice.

Practical recommendations

- Introduce multichannel sEMG as a tool of evaluation of innervation pattern during antenatal visits. Information about the distribution of IZs before delivery allows the practitioners to choose the more appropriate side of the episiotomy if needed. Trained staff and equipment would be necessary.
- Provide educational programs on sEMG application for gynaecologists, proctologists, physiotherapists.
- Encourage future PhD students to plan studies on the multichannel anal sEMG in collaboration with rehabilitation specialists and international teams.

Publications and presentations to congresses

Web of Sciences, Scopus, ERIH PLUS databases:

Peer-reviewed papers:

1. Začesta, V., Rācene, L., Cescon, C., Plaudis, H., Rezeberga, D. Sphincter muscle activity before and after delivery. Does it depend on the type of birth? *The Journal of Obstetrics and Gynaecology Research*. 2021 Feb; 47(2):705-712. DOI: 10.1111/jog.14587. Epub Dec 2020. PMID: 33263219.
2. Začesta, V., Rezeberga, D., Plaudis, H., Drusany-Staric, K., Cescon, C. Could the correct side of mediolateral episiotomy be determined according to anal sphincter EMG? *Int Urogynecol J.* 2018 Oct; 29(10):1501-1507. DOI: 10.1007/s00192-018-3560-3. PubMed PMID: 29480430.
3. Drusany-Staric, K., Zacesta, V., Cescon, C., Vitagliano, A., Bukovec, P. Multichannel electromyography for the assessment of pelvic floor muscle function. *Climacteric.* 2018 Dec; 21(6):617-618. DOI: 10.1080/13697137.2018.1514007. Epub 2018 Oct 2. PubMed PMID: 30277095.
4. Drusany-Staric, K., Lukanovic, A., Petrocnik, P., Zacesta, V., Cescon, C., Lucovnik, M. Impact of mediolateral episiotomy on incidence of obstetrical anal sphincter injury diagnosed by endoanal ultrasound. *Midwifery.* 2017 Aug; 51:40-43. DOI: 10.1016/j.midw.2017.05.008. Epub 2017 May 18. PubMed PMID: 28544989.
5. Merletti, R., Riva, D., Cescon, C., Zacesta, V. The correct episiotomy: Does it exist? *International Urogynecology Journal* 2015 Nov. DOI 10.1007/s00192-015-2879-2.
6. Cescon, C., Raimondi, E. E., Začesta, V., Drusany-Starič, K., Martsidis, K., Merletti, R. Characterization of the motor units of the external anal sphincter in pregnant women with multichannel surface EMG. *International Urogynecology Journal*: Volume 25, Issue 8 (2014), 1097–1103. DOI: 10.1007/s00192-014-2356-3.
7. Cescon, C., Riva, D., Začesta, V., Drusany-Starič, K., Martsidis, K., Protsepko, O., Baessler, K., Merletti, R. Effect of vaginal delivery on the external anal sphincter muscle innervation pattern evaluated by multichannel surface EMG: results of the multicentre study TASI-2. *International Urogynecology Journal* J. 2014 Nov; 25(11):1491-9. DOI: 10.1007/s00192-014-2375-0.

Other publications and conference proceedings:

1. Zacesta, V., Rezeberga, D., Plaudis, H., Braga, A., Caccia, G., Cescon, C. Should mediolateral episiotomy side be decided according to anal sphincter EMG? *Neurourology and Urodynamics*. 2017; 36:S6–S87: 24-26, DOI: 10.1002/nau.23302
2. Zacesta, V., Rezeberga, D., Plaudis, H., Cescon, C. Combined effect of episiotomy and sphincter innervation asymmetry on pelvic floor activity post-partum. *European Journal of Obstetrics and Gynecology and Reproductive Biology*, 2016 Nov, Volume 206: e120–e121. DOI: 10.1016/j.ejogrb.2016.07.311
3. Riva, D., Raimondi, E. E., Cescon, C., Merletti, R., Zacesta, V. Multichannel EMG evaluation of anal sphincter pre and post vaginal delivery: results of an international study. *International Journal of Gynecology & Obstetrics*, 2012 Oct, 119:S463-S464. DOI: 10.1016/S0020-7292(12), 61005-4
4. Drusany-Staric, K., Cescon, C., Lukanovic, A., Zacesta, V., Zelenova, O., Riva, D., Raimondi, E. E., Martsidis, K., Protsepko, O., Baessler, K., Barbero, M., Merletti, R. Changes of external anal sphincter innervation pattern after episiotomy evaluated with multichannel EMG. (Results of the multicenter study TASI-2). Annual meeting of International Continence Society, Beijing, China, October 15–19, 2012, *Neurourology and Urodynamics*, 31(6), 709–1102. DOI: 10.1002/nau.22287

5. Baessler, K., Cescon, C., Drusany, K., Raimondi, E., Riva, D., Martsidis, K., Paoletti, A., Rezeberger, D., Zacesta, V., Merletti, R. Distribution of innervation zones of the external anal sphincter and changes after vaginal delivery: preliminary results of a multicenter study – TASI-2 (Technologies for Anal Sphincter Analysis and Incontinence). *Neurourology and Urodynamics*. 2010 Aug; Volume 29, issue 6, 1014–1016. DOI: 10.1002/nau.20973
6. Riva, D., Cescon, C., Baessler, K., Drusany, K., Raimondi, E. E., Marongiu, D., Martsidis, K., Zacesta, V., Merletti, R. Evaluation of delivery trauma on the external anal sphincter (EAS) by means of surface electromyography. Proceedings of the first Congress AIUG-SICCR. Alghero, Italy, October 7–9, 2010. *Urogynaecologia International Journal* 2010; 24:1. 113–114. DOI: 10.4081/uij.2010.1.1

Presentations to congresses:

Oral presentations to international congresses:

1. Racene, L., Zacesta, V., Snippe, K., Rezeberga, D., Cescon, C. EMG as a tool to detect anal sphincter recovery after severe perineal tear. *2nd International Congress on the Multidisciplinary Management of pelvic Floor Diseases*, December 14–15, 2017, Pisa, Italy.
2. Začesta, V., Cescon, C., Zelenova, O., Drusany-Starič, K., Raimondi, E. E., Martsidis, K., Protsepko, O., Baessler, K., Merletti, R. Evaluation of child delivery trauma on anal sphincter muscle by means of surface electromyography (Results of the multicenter study TASI-2), *XXIV European Congress of Perinatal Medicine*, June 3–7, 2014, Florence, Italy.

Oral presentations to national congresses:

1. Začesta, V., Rācene, L., Plaudis, H., Rezeberga, D. External anal sphincter muscle recovery detected with surface EMG after perineal tear: a case study, *RSU research week 2019*, 02.04.2019, Riga.
2. Začesta, V., Baranovska, D., Elksne, K., Jermakova, I., Plaudis, H., Rezeberga, D., Vidnere, I., Zeļenova, O. Anālā sfinktera izmaiņu analīze sievietēm pēc dzemdībām. *Latvijas ginekologu un dzemdību speciālistu 7. kongresss*, Rīga, Latvija, 2014. g.
3. Začesta, V., Zeļenova, O., Rezeberga, D. Anālā sfinktera inervācijas pārmaiņas pēc dzemdībām. *Latvijas ginekologu un dzemdību speciālistu 6. kongresss*, Rīga, Latvija, 2011. g.
4. Začesta, V., Rezeberga, D., Plaudis, H., Snippe, K. Surface multichannel EMG investigation of external anal sphincter innervation pre and post vaginal delivery. *Rīga Stradiņš University Collection of Scientific papers 2013*, S1: 47.

Poster presentations at international congresses:

1. Zacesta, V., Rezeberga, D., Plaudis, H., Drusany-Staric, K., Cescon, C. Evaluation of external anal sphincter innervation asymmetry in obstetrics, *XXI Congress of the International Society of Electrophysiology and Kinesiology*, Chicago, July 5–8, 2016.
2. Začesta, V., Zelenova, O., Berza, N., Miskova, A., Rezeberga, D. Changes of external anal sphincter innervation after childbirth, using surface electromyography , *31st Edition Fetus as a patient*, Saint Petersburg, June 11–13, 2015.
3. Začesta, V., Bērza, N., Elksne, K., Drusany-Starič, K., Plaudis, H., Snipe, K., Rezeberga, D. Assymetry of external anal sphincter innervation detected by surface electromyography, *2nd European Congress on Intrapartum Care*, Porto, May 21– 24, 2015.
4. Zacesta, V., Berza, N., Baranovska, D., Jermakova, I., Rezeberga, D. Asymmetry of pelvic floor innervation detected by surface electromyography. *11th Congress of the European Society of Gynecology*, Prague, Czech Republic, October 21–24, 2015.

5. Drusany-Staric, K., Zacesta, V., Lukanovic, A., Merletti, R. Changes of external anal sphincter innervation pattern after delivery. *Annual meeting of Mediterranean Incontinence and Pelvic Floor Society*, Nimes, France, November 26–29, 2014.
6. Drusany-Staric, K., Cescon, C., Zacesta, V., Lukanovic, A. Right mediolateral episiotomy and anal sphincter injury in primiparous women during delivery. *Annual meeting of International Continence Society*, Rio de Janeiro, October 20–24, 2014.
7. Drusany-Staric, K., Zacesta, V., Lukanovic, A., Merletti, R. Effect of the side of episiotomy on external anal sphincter innervation. *7th Leading Lights in Urogynaecology congress* , Athens, Greece, October 2–4, 2014.
8. Začesta, V., Plaudis, H., Drusany-Starič, K., Zelenova, O., Stūrmane, A., Baranovska, D., Jermakova, I., Vidnere, I., Rezeberga, D. Surface multichannel electromyography investigation of external anal sphincter innervation before and after childbirth. Proposal of a clinical protocol, *23rd European Congress of Obstetrics and Gynaecology*, Glasgow, Scotland, May 7–10, 2014.
9. Riva, D., Raimondi, E. E., Botter, A., Lukanovic, A., Drusany-Staric, K., Cescon, C., Zacesta, V., Merletti, R. EMG analysis of anal sphincter innervations after episiotomy. *Mediterranean Incontinence and Pelvic Floor Society Inaugural Meeting*, Noto, Italy, November 29–30, 2013. Best oral presentation award
10. Drusany-Staric, K., Cescon, C., Zacesta, V., Lukanovic, A. The role of endoanal ultrasound in diagnosing of anal sphincter tears. *Mediterranean Incontinence and Pelvic Floor Society Inaugural Meeting*, Noto, Italy, November 29–30, 2013.
11. Cescon, C., Baessler, K., Drusany, K., Raimondi, E., Riva, D., Marongiu, D., Martsidis, K., Rezeberga, D., Zacesta, V., Merletti, R. Evaluation of child delivery trauma on the external anal sphincter muscle by means of surface electromyography (preliminary results of a multicenter study). "*7th International Pelvic Floor Dysfunction Society World Congress and FIGO task force meeting*", Palermo, Italy, May 10–12, 2010.

Poster presentations at national congresses:

1. Začesta, V., Bērza, N., Plaudis, H., Rezeberga, D. Ārējā anālā sfinktera inervācijas asimetrija sievietēm pirms un pēc dzemdībām. *RSU Zinātniskā konference* 26.–27.03.2015.
2. Zacesta, V., Zelenova, O., Rezeberga, D. Evaluation of episiotomy related trauma on anal sphincter muscle by means of surface electromyography (Results of the multicenter study TASI). *7^{th} Latvian Congress of Obstetricians and Gynecologists*, Riga, Latvia, 16.–18.10.2014.
3. Zacesta, V., Plaudis, H., Snippe, K., Rezeberga, D. Ārējā sfinktera inervācijas un anatomijas izmaiņu analīze sievietēm pēc dzemdībām. *RSU Zinātniskā konference*, 10.–11.04.2014
4. Zeļenova, O., Začesta, V., Rezeberga, D. Anālā sfinktera pēcdzemdību bojājumu novērtēšana ar elektromiogrāfijas (EMG) metodi. *Latvijas ginekologu un dzemdību speciālistu 6. kongress*, Riga, Latvia, 13.–15.10.2011.

References

1. Abdool, Z., Sultan, A. H., & Thakar, R. 2012. Ultrasound imaging of the anal sphincter complex: A review. *The British Journal of Radiology*, 85(1015), 865–875. https://doi.org/10.1259/bjr/27314678

2. Abramov, Y., Sand, P. K., Botros, S. M., Gandhi, S., Miller, J.-J. R., Nickolov, A., & Goldberg, R. P. 2005. Risk Factors for Female Anal Incontinence: New Insight Through the Evanston-Northwestern Twin Sisters Study: *Obstetrics & Gynecology*, *106*(4), 726–732. https://doi.org/10.1097/01.AOG.0000161367.65261.16

3. Abramowitz, L., Sobhani, I., Ganansia, R., Vuagnat, A., Louis Benifla, J., Darai, E., Madelenat, P., & Mignon, M. 2000. Are sphincter defects the cause of anal incontinence after vaginal delivery?: Results of a prospective study. *Diseases of the Colon & Rectum*, *43*(5), 590–596. https://doi.org/10.1007/BF02235567

4. Afshari, P., Dabagh, F., Iravani, M., & Abedi, P. 2016. Comparison of pelvic floor muscle strength in nulliparous women and those with normal vaginal delivery and caesarean section. *International Urogynecology Journal*, *46*, Article 46. https://doi.org/10.1007/s00192-016-3239-6

5. Alhadi, M., Geary, M., Byrne, P., & McKenna, P. 2001. Shoulder dystocia: Risk factors and maternal and perinatal outcome. *Journal of Obstetrics and Gynaecology*, *21*(4), 352–354.

6. Allen, R. E., Hosker, G. L., Smith, A. R. B., & Warrell, D. W. 1990. Pelvic floor damage and childbirth: A neurophysiological study. *BJOG: An International Journal of Obstetrics and Gynaecology*, *97*(9), 770–779. https://doi.org/10.1111/j.1471-0528.1990.tb02570.x

7. Altomare, D. F., Spazzafumo, L., Rinaldi, M., Dodi, G., Ghiselli, R., & Piloni, V. 2007. Set-up and statistical validation of a new scoring system for obstructed defaecation syndrome. *Colorectal Disease*, *0*(0), 070621084454021-??? https://doi.org/10.1111/j.1463-1318.2007.01262.x

8. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Obstetrics. 2016. Practice Bulletin No 165: Prevention and Management of Obstetric Lacerations at Vaginal Delivery. *Obstetrics and gynecology*, *128*(1), e1–e15. https://doi.org/10.1097/AOG.0000000000001523

9. Ampt, A. J., Patterson, J. A., Roberts, C. L., & Ford, J. B. 2015. Obstetric anal sphincter injury rates among primiparous women with different modes of vaginal delivery. *International Journal of Gynecology & Obstetrics*, *131*(3), 260–264. https://doi.org/10.1016/j.ijgo.2015.06.025

10. Andrews, V, Sultan, A., Thakar, R., & Jones, P. 2006. Risk factors for obstetric anal sphincter injury: A prospective study. *Birth*, *33*(2), 117–122. https://doi.org/10.1111/j.0730-7659.2006.00088.x

11. Andrews, Vasanth, Sultan, A. H., Thakar, R., & Jones, P. W. 2006. Occult anal sphincter injuries–Myth or reality? *BJOG: An International Journal of Obstetrics and Gynaecology*, *113*(2), 195–200. https://doi.org/10.1111/j.1471-0528.2006.00799.x

12. Baghestan, E., Irgens, L. M., Børdahl, P. E., & Rasmussen, S. 2010. Trends in Risk Factors for Obstetric Anal Sphincter Injuries in Norway: *Obstetrics & Gynecology*, *116*(1), 25–34. https://doi.org/10.1097/AOG.0b013e3181e2f50b

13. Barrett, J. F. R., Hannah, M. E., Hutton, E. K., Willan, A. R., Allen, A. C., Armson, B. A., Gafni, A., Joseph, K. S., Mason, D., Ohlsson, A., Ross, S., Sanchez, J. J., & Asztalos, E. V. 2013. A Randomized Trial of Planned caesarean or Vaginal Delivery for Twin Pregnancy. *New England Journal of Medicine*, *369*(14), 1295–1305. https://doi.org/10.1056/NEJMoa1214939

14. Bellussi, F., Montaguti, E., Youssef, A., Salsi, G., Ghi, T., & Pilu, G. 2019. Dynamic 2-dimensional transperineal ultrasound evaluation in labor room as a screening tool for anal sphincter injuries and anal incontinence in primiparous women. *American Journal of Obstetrics & Gynecology MFM*, 1(3), 100037. https://doi.org/10.1016/j.ajogmf.2019.100037

15. Best, C., Drutz, H. P., & Alarab, M. 2012. Obstetric Anal Sphincter Injuries: A Survey of Clinical Practice Among Canadian Obstetricians. *Journal of Obstetrics and Gynaecology Canada*, *34*(8), 747–754. https://doi.org/10.1016/S1701-2163(16)35338-5

16. Bharucha, A. E., Dunivan, G., Goode, P. S., Lukacz, E. S., Markland, A. D., Matthews, C. A., Mott, L., Rogers, R. G., Zinsmeister, A. R., Whitehead, W. E., Rao, S. S. C., & Hamilton, F. A. 2015. Epidemiology, Pathophysiology, and Classification of faecal Incontinence: State of the Science Summary for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Workshop. *The American Journal of GASTROENTEROLOGY*, *110*, 10.

17. Bihler, J., Tunn, R., Reisenauer, C., Kolenic, G. E., Pauluschke-Froehlich, J., Wagner, P., Abele, H., Rall, K. K., Naumann, G., Wallwiener, S., Wallwiener, M., Sohn, C., Brucker, S. Y., & Huebner, M. 2019. The preferred mode of delivery of medical professionals and non-medical professional mothers-to-be and the impact of additional information on their decision: An online questionnaire cohort study. *Archives of Gynecology and Obstetrics*, *299*(2), 371–384. https://doi.org/10.1007/s00404-018-4970-7

18. Blomquist, J. L., Muñoz, A., Carroll, M., & Handa, V. L. 2018. Association of Delivery Mode With Pelvic Floor Disorders After Childbirth. *JAMA*, *320*(23), 2438–2447. https://doi.org/10.1001/jama.2018.18315

19. Blondel, B., Alexander, S., Bjarnadóttir, R. I., Gissler, M., Langhoff-Roos, J., Novak-Antolič, Ž., Prunet, C., Zhang, W.-H., Hindori-Mohangoo, A. D., Zeitlin, J., & Euro-Peristat Scientific Committee. 2016. Variations in rates of severe perineal tears and episiotomies in 20 European countries: A study based on routine national data in Euro-Peristat Project. *Acta obstetricia et gynecologica Scandinavica*, *95*(7), 746–754. https://doi.org/10.1111/aogs.12894

20. Bo, K., Frawley, H. C., Haylen, B. T., Abramov, Y., Almeida, F. G., Berghmans, B., Bortolini, M., Dumoulin, C., Gomes, M., McClurg, D., Meijlink, J., Shelly, E., Trabuco, E., Walker, C., & Wells, A. 2017. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. *International Urogynecology Journal*, *28*(2), 191–213. https://doi.org/10.1007/s00192-016-3123-4

21. Bø, K., & Sherburn, M. 2005. Evaluation of female pelvic-floor muscle function and strength. *Physical Therapy*, *85*(3), 269–282.

22. Bocardi, D. A. S., Pereira-Baldon, V. S., Ferreira, C. H. J., Avila, M. A., Beleza, A. C. S., & Driusso, P. 2018. Pelvic floor muscle function and EMG in nulliparous women of different ages: A cross-sectional study. *Climacteric*, *21*(5), 462–466. https://doi.org/10.1080/13697137.2018.1453493

23. Botelho, S., Riccetto, C., Herrmann, V., Pereira, L. C., Amorim, C., & Palma, P. 2010. Impact of delivery mode on electromyographic activity of pelvic floor: Comparative prospective study. *Neurourology and Urodynamics*, *29*(7), 1258–1261. https://doi.org/10.1002/nau.20864

24. Botlero, R., Bell, R. J., Urquhart, D. M., & Davis, S. R. 2011. Prevalence of faecal incontinence and its relationship with urinary incontinence in women living in the community: *Menopause*, *18*(6), 685–689. https://doi.org/10.1097/gme.0b013e3181fee03b

25. Brown, J. 1999. Prevalence of urinary incontinence and associated risk factors in postmenopausal women. *Obstetrics & Gynecology*, *94*(1), 66–70. https://doi.org/10.1016/S0029-7844(99)00263-X

26. Campanini, I., Disselhorst-Klug, C., Rymer, W. Z., & Merletti, R. 2020. Surface EMG in Clinical Assessment and Neurorehabilitation: Barriers Limiting Its Use. *Frontiers in Neurology*, *11*, 934. https://doi.org/10.3389/fneur.2020.00934

27. Carroli, G., & Mignini, L. 2012. Episiotomy for vaginal birth (Review). *Cochrane Database of Systematic Reviews, Issue 1*, CD000081. DOI: 10.1002/14651858.CD000081.pub2. https://doi.org/10.1002/14651858.CD000081.pub2

28. Cescon, C. 2006. Automatic Location Of Muscle Innervation Zones From Multi-Channel Surface EMG Signals. *IEEE International Workshop on Medical Measurement and Applications, 2006. MeMea 2006.*, 87–90. https://doi.org/10.1109/MEMEA.2006.1644467

29. Cescon, C., Mesin, L., Nowakowski, M., & Merletti, R. 2011. Geometry assessment of anal sphincter muscle based on monopolar multichannel surface EMG signals. *Journal of Electromyography and Kinesiology*, *21*(2), 394–401. https://doi.org/10.1016/j.jelekin.2010.11.003

30. Cescon, C., Raimondi, E. E., Začesta, V., Drusany-Starič, K., Martsidis, K., & Merletti, R. 2014. Characterization of the motor units of the external anal sphincter in pregnant women with multichannel surface EMG. *International urogynecology journal*, *25*(8), 1097–1103. https://doi.org/10.1007/s00192-014-2356-3

31. Chen, X., Gong, Y., Wu, D., Li, X., Li, H., Tong, X., & Cheng, W. 2014. Pre- and postoperative evaluation of pelvic floor muscle function in POP patients using surface electromyography and digital palpation: Evaluation of Pelvic Floor Muscle Function in POP Patients With Surface EMG. *Neurourology and Urodynamics*, *33*(4), 403–407. https://doi.org/10.1002/nau.22430

32. Christensen, A. F., Nyhuus, B., Nielsen, M. B., & Christensen, H. 2005. Three-dimensional anal endosonography may improve diagnostic confidence of detecting damage to the anal sphincter complex. *The British Journal of Radiology*, *78*(928), 308–311. https://doi.org/10.1259/bjr/72038963

33. Christianson, L. M., Bovbjerg, V. E., McDavitt, E. C., & Hullfish, K. L. 2003. Risk factors for perineal injury during delivery. *American Journal of Obstetrics and Gynecology*, *189*(1), 255–260. https://doi.org/10.1067/mob.2003.547

34. Clesse, C., Lighezzolo-Alnot, J., De Lavergne, S., Hamlin, S., & Scheffler, M. 2018. Statistical trends of episiotomy around the world: Comparative systematic review of changing practices. *Health Care for Women International*, *39*(6), 644–662. https://doi.org/10.1080/07399332.2018.1445253

35. Clesse, C., Lighezzolo-Alnot, J., De Lavergne, S., Hamlin, S., & Scheffler, M. 2019. Socio-historical evolution of the episiotomy practice: A literature review. *Women & Health*, 1–15. https://doi.org/10.1080/03630242.2018.1553814

36. Coats, P. M., Chan, K. K., Wilkins, M., & Beard, R. J. 1980. A comparison between midline and mediolateral episiotomies. *BJOG: An International Journal of Obstetrics and Gynaecology*, *87*(5), 408–412. https://doi.org/10.1111/j.1471-0528.1980.tb04569.x

37. Cohen, J. 2013. *Statistical Power Analysis for the Behavioral Sciences*. Elsevier Science. https://search.ebscohost.com/login.aspx?direct = true&scope = site&db = nlebk&db = nlabk&AN = 923159

38. Combs, C. A., Murphy, E. L., & Laros, R. K. 1991. Factors associated with postpartum hemorrhage with vaginal birth. *Obstetrics and Gynecology*, *77*(1), 69–76.

39. Cornelia, L., Stephan, B., Michel, B., Antoine, W., & Felix, K. 2002. Trans-perineal versus endo-anal ultrasound in the detection of anal sphincter tears. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *103*(1), 79–82. https://doi.org/10.1016/S0301-2115(02)00021-0

40. Cunningham, G., Leveno, K., Bloom, S., Dashe, J., Hoffman, B., Casey, B., & Catherine, S. 2018. *Williams Obstetrics 25th Edition*. McGraw-Hill Education.

41. Dahl, C., & Kjølhede, P. 2006. Obstetric anal sphincter rupture in older primiparous women: A case–control study. *Acta Obstetricia et Gynecologica Scandinavica*, *85*(10), 1252–1258. https://doi.org/10.1080/00016340600839890

42. Damon, H., Guye, O., Seigneurin, A., Long, F., Sonko, A., Faucheron, J.-L., Grandjean, J.-P., Mellier, G., Valancogne, G., Fayard, M.-O., Henry, L., Guyot, P., Barth, X., & Mion, F. 2006. Prevalence of anal incontinence in adults and impact on quality-of-life. *Gastroentérologie Clinique et Biologique*, *30*(1), 37–43. https://doi.org/10.1016/S0399-8320(06)73076-7

43. Deering, S. H., Carlson, N., Stitely, M., Allaire, A. D., & Satin, A. J. 2004. Perineal body length and lacerations at delivery. *The Journal of Reproductive Medicine*, *49*(4), 306–310.

44. Deutekom, M., Dobben, A. C., Dijkgraaf, M. G. W., Terra, M. P., Stoker, J., & Bossuyt, P. M. M. 2005. Costs of outpatients with faecal incontinence. *Scandinavian journal of gastroenterology*, *40*(5), 552–558. https://doi.org/10.1080/00365520510012172

45. Dobben, A. C., Felt-Bersma, R. J. F., ten Kate, F. J. W., & Stoker, J. 2008. Cross-sectional imaging of the anal sphincter in faecal incontinence. *AJR. American journal of roentgenology*, *190*(3), 671–682. https://doi.org/10.2214/AJR.07.2920

46. Driusso, P., Beleza, A. C. S., Mira, D. M., de Oliveira Sato, T., de Carvalho Cavalli, R., Ferreira, C. H. J., & de Fátima Carreira Moreira, R. 2020. Are there differences in short-term pelvic floor muscle function after caesarean section or vaginal delivery in primiparous women? A systematic review with meta-analysis. *International Urogynecology Journal*, *31*(8), 1497–1506. https://doi.org/10.1007/s00192-020-04231-6

47. Dudding, T. C., Vaizey, C. J., & Kamm, M. A. 2008. Obstetric Anal Sphincter Injury. *Annals of Surgery*, *247*(2), 224–237. https://doi.org/10.1097/SLA.0b013e318142cdf4

48. Dunivan, G. C., Heymen, S., Palsson, O. S., von Korff, M., Turner, M. J., Melville, J. L., & Whitehead, W. E. 2010. faecal incontinence in primary care: Prevalence, diagnosis, and health care utilization. *American Journal of Obstetrics and Gynecology*, *202*(5), 493.e1-493.e6. https://doi.org/10.1016/j.ajog.2010.01.018

49. Eisenberg, V. H., Valsky, D. V., & Yagel, S. 2019. Transperineal ultrasound assessment of the anal sphincter after obstetric anal sphincter injury (OASI). *Ultrasound in Obstetrics & Gynecology*, 53(2), 158–165. https://doi.org/10.1002/uog.19058

50. Ekéus, C., Nilsson, E., & Gottvall, K. 2008. Increasing incidence of anal sphincter tears among primiparas in Sweden: A population-based register study. *Acta Obstetricia et Gynecologica Scandinavica*, *87*(5), 564–573. https://doi.org/10.1080/00016340802030629

51. Elenskaia, K., Thakar, R., Sultan, A. H., Scheer, I., & Beggs, A. 2011. The effect of pregnancy and childbirth on pelvic floor muscle function. *International Urogynecology Journal*, *22*(11), 1421–1427. https://doi.org/10.1007/s00192-011-1501-5

52. Enck, P., Hinninghofen H, Merletti R, & Azpiroz, F. 2005. The external anal sphincter and the role of surface electromyography. *Neurogastroenterology and Motility*, *17*(s1), 60–67. https://doi.org/10.1111/j.1365-2982.2005.00660.x

53. Enck, P. 2004. Foreword. *Digestion*, *69*(2), 84–86. https://doi.org/10.1159/000077873

54. Enck, P., Hinninghofen, H., Wietek, B., & Becker, H. D. 2004. Functional asymmetry of pelvic floor innervation and its role in the pathogenesis of faecal incontinence. *Digestion*, *69*(2), 102–111. https://doi.org/10.1159/000077876

55. Enck P, Franz H, Davico, E., Mastrangelo, F., Mesin, L., & Merletti, R. 2009. Repeatability of innervation zone identification in the external anal sphincter muscle. *Neurourology and Urodynamics*, n/a-n/a. https://doi.org/10.1002/nau.20749

56. Enck P & Vodušek D.B.. 2006. Electromyography of pelvic floor muscles. *Journal of Electromyography and Kinesiology*, *16*(6), 568–577. https://doi.org/10.1016/j.jelekin.2006.08.007

57. Eogan, M., Daly, L., O’Connell, P., & O’Herlihy, C. 2006. Does the angle of episiotomy affect the incidence of anal sphincter injury?*. *BJOG: An International Journal of Obstetrics and Gynaecology*, *113*(2), 190–194. https://doi.org/10.1111/j.1471-0528.2005.00835.x

58. Evers, E. C., Blomquist, J. L., McDermott, K. C., & Handa, V. L. 2012. Obstetrical anal sphincter laceration and anal incontinence 5-10 years after childbirth. *American Journal of Obstetrics and Gynecology*, *207*(5), 425.e1-425.e6. https://doi.org/10.1016/j.ajog.2012.06.055

59. Faltin, D. L., Boulvain, M., & Irion, O. 2000. *Diagnosis of Anal Sphincter Tears by Postpartum Endosonography to Predict faecal Incontinence* (N. 5). *95*(5), 643–647. https://doi.org/10.1016/s0029-7844(99)00631-6

60. Farina, D., Cescon, C., & Merletti, R. 2002. Influence of anatomical, physical, and detection-system parameters on surface EMG. *Biological Cybernetics*, *86*(6), 445–456. https://doi.org/10.1007/s00422-002-0309-2

61. Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. 2007. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, *39*(2), 175–191. https://doi.org/10.3758/BF03193146

62. Fenner, D. E., Genberg, B., Brahma, P., Marek, L., & DeLancey, J. O. L. 2003. faecal and urinary incontinence after vaginal delivery with anal sphincter disruption in an obstetrics unit in the United States. *American Journal of Obstetrics and Gynecology*, *189*(6), 1543–1549. https://doi.org/10.1016/j.ajog.2003.09.030

63. Fernando, R. J., Sultan, A. H., Radley, S., Jones, P. W., & Johanson, R. B. 2002. Management of obstetric anal sphincter injury: A systematic review &national practice survey. *BMC Health Services Research*, *2*, 1–10. https://doi.org/10.1186/1472-6963-2-1

64. Fitzgerald, M. P., Weber, A. M., Howden, N., Cundiff, G. W., & Brown, M. B. 2007. Risk factors for anal sphincter tear during vaginal delivery. *Obstetrics and gynecology*, *109*(1), 29–34. https://doi.org/10.1097/01.AOG.0000242616.56617.ff

65. Fitzpatrick, M. & C. O'Herlihy. 2001. The effects of labour and delivery on the pelvic floor. *Best Practice & Research Clinical Obstetrics & Gynaecology*, *15*(1), 63–79. https://doi.org/10.1053/beog.2000.0149

66. Fitzpatrick, Myra, Behan, M., O'Connell, P. R., & O'Herlihy, C. 2003. Randomised clinical trial to assess anal sphincter function following forceps or vacuum assisted vaginal delivery. *BJOG: An International Journal of Obstetrics and Gynaecology*, *110*(4), 424–429.

67. Flury, N., Koenig, I., & Radlinger, L. 2017. Crosstalk considerations in studies evaluating pelvic floor muscles using surface electromyography in women: A scoping review. *Archives of Gynecology and Obstetrics*, *295*(4), 799–809. https://doi.org/10.1007/s00404-017-4300-5

68. Fodstad, K., Staff, A. C., & Laine, K. 2014. Effect of different episiotomy techniques on perineal pain and sexual activity 3 months after delivery. *International Urogynecology Journal*, *25*(12), 1629–1637. https://doi.org/10.1007/s00192-014-2401-2

69. Fodstad, K., Staff, A. C., & Laine, K. 2016. Sexual activity and dyspareunia the first year postpartum in relation to degree of perineal trauma. *International Urogynecology Journal*, *27*(10), 1513–1523. https://doi.org/10.1007/s00192-016-3015-7

70. Frankman, E. A., Wang, L., Bunker, C. H., & Lowder, J. L. 2009. Episiotomy in the United States: Has anything changed? *American journal of obstetrics and gynecology*, *200*(5), 573.e1-7. https://doi.org/10.1016/j.ajog.2008.11.022

71. Friedman, A. M., Ananth, C. V., Prendergast, E., D'Alton, M. E., & Wright, J. D. 2015. Variation in and Factors Associated with Use of Episiotomy. *JAMA*, *313*(2), 197. https://doi.org/10.1001/jama.2014.14774

72. Frudinger, A., Bartram, C. I., & Kamm, M. A. 1997. Transvaginal versus anal endosonography for detecting damage to the anal sphincter. *American Journal of Roentgenology*, *168*(6), 1435–1438. https://doi.org/10.2214/ajr.168.6.9168703

73. Fynes, M., & O'Herlihy, C. 2001. The influence of mode of delivery on anal sphincter injury and faecal continence. *The Obstetrician & Gynaecologist*, *3*(3), 120–125. https://doi.org/10.1576/toag.2001.3.3.120

74. Gerdin, E., Sverrisdottir, G., Badi, A., Carlsson, B., & Graf, W. 2007. The role of maternal age and episiotomy in the risk of anal sphincter tears during childbirth. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, *47*(4), 286–290. https://doi.org/10.1111/j.1479-828X.2007.00739.x

75. Glazer, H. I., Romanzi, L., & Polaneczky, M. 1999. Pelvic floor muscle surface electromyography. Reliability and clinical predictive validity. *The Journal of Reproductive Medicine*, *44*(9), 779–782.

76. Gold, D. M., Halligan, S., Kmiot, W. A., & Bartram, C. I. 1999. Intraobserver and interobserver agreement in anal endosonography. *The British Journal of Surgery*, *86*(3), 371–375. https://doi.org/10.1046/j.1365-2168.1999.01032.x

77. Gordon, T., & Stein, R.B. 1982. Time course and extent of recovery in reinnervated motor units of cat triceps surae muscles. *Journal of Physiology* 323, 307–323. doi:10.1113/jphysiol.1982.sp014074.

78. Graham, I. D. 1998. Processes of change in obstetrics: A cross-national case-study of episiotomy. *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine*, *2*(4), 403–433. https://doi.org/10.1177/136345939800200407

79. Graham, I. D., Carroli, G., Davies, C., & Medves, J. M. 2005. Episiotomy Rates Around the World: An Update. *Birth*, *32*(3), 219–223. https://doi.org/10.1111/j.0730-7659.2005.00373.x

80. Grape, H. H., Dedering, Å., & Jonasson, A. F. 2009. Retest reliability of surface electromyography on the pelvic floor muscles. *Neurourology and Urodynamics*, *28*(5), 395–399. https://doi.org/10.1002/nau.20648

81. Guise, J.-M., Morris, C., Osterweil, P., Li, H., Rosenberg, D., & Greenlick, M. 2007. Incidence of faecal incontinence after childbirth. *Obstetrics and gynecology*, *109*(2 Pt 1), 281–288. https://doi.org/10.1097/01.AOG.0000254164.67182.78

82. Guzmán Rojas, R. A., Shek, K. L., Langer, S. M., & Dietz, H. P. 2013. Prevalence of anal sphincter injury in primiparous women. *Ultrasound in Obstetrics and Gynecology*, *42*(4), 461–466. https://doi.org/10.1002/uog.12481

83. Hallock, J. L., & Handa, V. L. 2016. The Epidemiology of Pelvic Floor Disorders and Childbirth. An Update. *Obstetrics and Gynecology Clinics of North America*, *43*(1), 1–13. https://doi.org/10.1016/j.ogc.2015.10.008

84. Hamdy, S., Enck, P., Aziz, Q., Uengoergil, S., Hobson, A., & Thompson, D. G. 1999. Laterality effects of human pudendal nerve stimulation on corticoanal pathways: Evidence for functional asymmetry. *Gut*, *45*(1), 58–63. https://doi.org/10.1136/gut.45.1.58

85. Handa, V. L., Blomquist, J. L., Knoepp, L. R., Hoskey, K. A., McDermott, K. C., & Muñoz, A. 2011. Pelvic floor disorders 5-10 years after vaginal or caesarean childbirth. *Obstetrics and Gynecology*, *118*(4), 777–784. https://doi.org/10.1097/AOG.0b013e3182267f2f

86. Handa, V. L., Blomquist, J. L., McDermott, K. C., Friedman, S., & Muñoz, A. 2012. Pelvic Floor Disorders After Vaginal Birth. *Obstetrics & Gynecology*, *119*(2, Part 1), 233–239. https://doi.org/10.1097/AOG.0b013e318240df4f

87. Handa, V. L., Danielsen, B. H., & Gilbert, W. M. 2001. *Obstetric Anal Sphincter Lacerations* (N. 2). *98*(2), 6.

88. Hartmann, K., Viswanathan, M., Palmieri, R., Gartlehner, G., Thorp, J., & Lohr, K. N. 2005. Outcomes of Routine Episiotomy: A Systematic Review. *JAMA*, *293*(17), 2141. https://doi.org/10.1001/jama.293.17.2141

89. Harvey, M.-A., Pierce, M., Alter, J.-E. W., Chou, Q., Diamond, P., Epp, A., Geoffrion, R., Harvey, M.-A., Larochelle, A., Maslow, K., Neustaedter, G., Pascali, D., Pierce, M., Schulz, J., Wilkie, D., Sultan, A., Thakar, R., & Society of Obstetricians and Gynaecologists of Canada. 2015. Obstetrical Anal Sphincter Injuries (OASIS): Prevention, Recognition, and Repair. *Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC*, *37*(12), 1131–1148.

90. Haylen, B. T., de Ridder, D., Freeman, R. M., Swift, S. E., Berghmans, B., Lee, J., Monga, A., Petri, E., Rizk, D. E., Sand, P. K., & Schaer, G. N. 2010. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *International Urogynecology Journal*, *21*(1), 5–26. https://doi.org/10.1007/s00192-009-0976-9

91. He, S., Jiang, H., Qian, X., & Garner, P. 2020. Women's experience of episiotomy: A qualitative study from China. *BMJ Open*, 10(7), e033354. https://doi.org/10.1136/bmjopen-2019-033354

92. Heitmann, P. T., Rabbitt, P., Schloithe, A., Patton, V., Skuza, P. P., Wattchow, D. A., & Dinning, P. G. 2019. Relationships between the results of anorectal investigations and symptom severity in patients with faecal incontinence. *International Journal of Colorectal Disease*, *34*(8), 1445–1454. https://doi.org/10.1007/s00384-019-03331-0

93. Hojberg, K.-E., Salvig, J. D., Winslow, N. A., Bek, K. M., Laurberg, S., & Secher, N. J. 2000. Flatus and faecal incontinence: Prevalence and risk factors at 16 weeks of gestation. *BJOG: An International Journal of Obstetrics and Gynaecology*, *107*(9), 1097–1103. https://doi.org/10.1111/j.1471-0528.2000.tb11107.x

94. Holobar, A., Enck, P., Hinninghofen, H., & Merletti, R. 2008. Decomposition of Surface Emg from External Anal Sphincter. *XVII Congress of the International Society of Electrophysiology and Kinesiology, Niagara Falls, Ontario*, 1–2.

95. Howden, N. L. S., Weber, A. M., & Meyn, L. A. 2004. Episiotomy Use Among Residents and Faculty Compared With Private Practitioners: *Obstetrics & Gynecology*, *103*(1), 114–118. https://doi.org/10.1097/01.AOG.0000103997.83468.70

96. Hutton, E.K., Hannah, M.E., Ross, S., Joseph, K.S., Ohlsson, A., Asztalos, E.V., Willan, A.R., Allen, A.C., Armson, B.A., Gafni, A., Mangoff, K., Sanchez, J.J., & Barrett, J.F. for the Twin Birth Study Collaborative Group. 2015. Maternal outcomes at 3 months after planned caesarean section versus planned vaginal birth for twin pregnancies in the Twin Birth Study: a randomised controlled trial. *British Journal of Obstetrics and Gynaecology*; 122, 1653–1662.

97. Jandér, C., & Lyrenäs, S. 2001. Third and fourth degree perineal tears. Predictor factors in a referral hospital. *Acta Obstetricia Et Gynecologica Scandinavica*, *80*(3), 229–234.

98. Jangö, H., Langhoff-Roos, J., Rosthøj, S., & Sakse, A. 2020. Wexner score and quality of life in women with obstetric anal sphincter injury. *International Urogynecology Journal*, *31*(6), 1115–1121. https://doi.org/10.1007/s00192-019-04134-1

99. Jenabi, E., Khazaei, S., Bashirian, S., Aghababaei, S., & Matinnia, N. 2019. Reasons for elective caesarean section on maternal request: A systematic review. *The Journal of Maternal-foetal & Neonatal Medicine*, *7058*, 1–6. https://doi.org/10.1080/14767058.2019.1587407

100. Jha, S., & Sultan, A. H. 2015. Obstetric anal sphincter injury: The changing landscape. *BJOG: An International Journal of Obstetrics & Gynaecology*, *122*(7), 931–931. https://doi.org/10.1111/1471-0528.13019

101. Jiang, H., Qian, X., Carroli, G., & Garner, P. 2017. *Selective versus routine use of episiotomy for vaginal birth (Review)* (N. 2). *2*, Article 2. https://doi.org/10.1002/14651858.CD000081.pub3.www.cochranelibrary.com

102. Johanson, J. F., & Lafferty, J. 1996. Epidemiology of faecal incontinence: The silent affliction. *The American Journal of Gastroenterology*, *91*(1), 33–36.

103. Johanson, R., Kettle, C., Sultan, A., Fernando, R., & Radley, S. 2003. Methods of repair for obstetric anal sphincter injury. *The Cochrane Database of Systematic Reviews*, *12*, Article 12. https://doi.org/10.1002/14651858.cd002866

104. Jorge, M. J. N., & Wexner, S. D. 1993. Etiology and management of faecal incontinence. *Diseases of the Colon & Rectum*, *36*(1), 77–97. https://doi.org/10.1007/BF02050307

105. J.W. de Leeuw, Struijk, P. C., Vierhout, M. E., & Wallenburg, H. C. S. 2001. Risk factors for third degree perineal ruptures during delivery. *BJOG: An International Journal of Obstetrics and Gynaecology*, *108*(4), 383–387. https://doi.org/10.1111/j.1471-0528.2001.00090.x

106. Kalis, V, Laine, K., de Leeuw, J., Ismail, K., & Tincello, D. 2012. Classification of episiotomy: Towards a standardisation of terminology: International classification of episiotomy. *BJOG: An International Journal of Obstetrics & Gynaecology*, *119*(5), 522–526. https://doi.org/10.1111/j.1471-0528.2011.03268.x

107. Kalis, Vladimir, Karbanova, J., Horak, M., Lobovsky, L., Kralickova, M., & Rokyta, Z. 2008. The incision angle of mediolateral episiotomy before delivery and after repair. *International Journal of Gynecology & Obstetrics*, *103*(1), 5–8. https://doi.org/10.1016/j.ijgo.2008.05.026

108. Kamm, M. A. 1998. Fortnightly review: Faecal incontinence. *BMJ*, *316*(7130), 528–532. https://doi.org/10.1136/bmj.316.7130.528

109. Kapoor, D. S., Thakar, R., & Sultan, A. H. 2015. Obstetric anal sphincter injuries: Review of anatomical factors and modifiable second stage interventions. *International Urogynecology Journal*, *26*(12), 1725–1734. https://doi.org/10.1007/s00192-015-2747-0

110. Kirss, J., Huhtinen, H., Niskanen, E., Ruohonen, J., Kallio-Packalen, M., Victorzon, S., Victorzon, M., & Pinta, T. 2019. Comparison of 3D endoanal ultrasound and external phased array magnetic resonance imaging in the diagnosis of obstetric anal sphincter injuries. *European Radiology*, *29*(10), 5717–5722. https://doi.org/10.1007/s00330-019-06125-8

111. Klein, M. 1988. Episiotomy and the second stage of labour. *Canadian Family Physician Medecin De Famille Canadien*, *34*, 2019–2025.

112. Klein, M. C., Gauthier, R. J., Robbins, J. M., Kaczorowski, J., Jorgensen, S. H., Franco, E. D., Johnson, B., Waghorn, K., Gelfand, M. M., Guralnick, M. S., Luskey, G. W., & Joshi, A. K. 1994. Relationship of episiotomy to perineal trauma and morbidity, sexual dysfunction, and pelvic floor relaxation. *American Journal of Obstetrics and Gynecology*, *171*(3), 591–598. https://doi.org/10.1016/0002-9378(94)90070-1

113. Koenig, I., Luginbuehl, H., & Radlinger, L. 2017. Reliability of pelvic floor muscle electromyography tested on healthy women and women with pelvic floor muscle dysfunction. *Annals of Physical and Rehabilitation Medicine*, *60*(6), 382–386. https://doi.org/10.1016/j.rehab.2017.04.002

114. Krhut, J., Zachoval, R., Rosier, P. F. W. M., Shelly, B., & Zvara, P. 2018. ICS Educational Module: Electromyography in the assessment and therapy of lower urinary tract dysfunction in adults. *Neurourology and Urodynamics*, *37*(1), 27–32. https://doi.org/10.1002/nau.23278

115. Lai, C. Y., Cheung, H. W., Hsi Lao, T. T., Lau, T. K., & Leung, T. Y. 2009. Is the policy of restrictive episiotomy generalisable? A prospective observational study. *The Journal of Maternal-foetal & Neonatal Medicine*, *22*(12), 1116–1121. https://doi.org/10.3109/14767050902994820

116. Laine, K., Gissler, M., & Pirhonen, J. 2009. Changing incidence of anal sphincter tears in four Nordic countries through the last decades. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *146*(1), 71–75. https://doi.org/10.1016/j.ejogrb.2009.04.033

117. Lalwani, N., Khatri, G., EL Sayed, R. F., Ram, R., Jambhekar, K., Chernyak, V., Kamath, A., Lewis, S., Flusberg, M., Scholz, F., Arif-Tiwari, H., Palmer, S. L., Lockhart, M. E., & Fielding, J. R. 2019. MR defecography technique: Recommendations of the society of abdominal radiology's disease-focused panel on pelvic floor imaging. *Abdominal Radiology*. https://doi.org/10.1007/s00261-019-02160-7

118. Lam, K. W., Wong, H. S., & Pun, T. C. 2006. The practice of episiotomy in public hospitals in Hong Kong. *Hong Kong Medical Journal = Xianggang Yi Xue Za Zhi*, *12*(2), 94–98.

119. Larsson, C., Hedberg, C. L., Lundgren, E., Söderström, L., Tunón, K., & Nordin, P. 2019. Anal incontinence after caesarean and vaginal delivery in Sweden: A national population-based study. *The Lancet*, *393*(10177), 1233–1239. https://doi.org/10.1016/S0140-6736(18)32002-6

120. Lawrence, J. M., Lukacz, E. S., Nager, C. W., Hsu, J.-W. Y., & Luber, K. M. 2008. Prevalence and Co-Occurrence of Pelvic Floor Disorders in Community-Dwelling Women: *Obstetrics & Gynecology*, *111*(3), 678–685. https://doi.org/10.1097/AOG.0b013e3181660c1b

121. Laycock, J., & Jerwood, D. 2001. Pelvic Floor Muscle Assessment: The PERFECT Scheme. *Physiotherapy*, *87*(12), 631–642. https://doi.org/10.1016/S0031-9406(05)61108-X

122. Lee, Y. Y., Erdogan, A., & Rao, S. S. C. 2013. High resolution and high definition anorectal manometry and pressure topography: Diagnostic advance or a new kid on the block? *Current Gastroenterology Reports*, *15*(12), 360. https://doi.org/10.1007/s11894-013-0360-2

123. Li, H., R. Wu, F. Qi, A. Xiao, Z. Ma, Y. Hu, W. Zhang, W. Li & Z. Wang. 2015. Postpartum pelvic floor function performance after two different modes of delivery. *Genetics and molecular research.* 14(2), 2994-3001.

124. Loganathan, A., Schloithe, A. C., Hakendorf, P., Liyanage, C. M., Costa, M., & Wattchow, D. 2013. Prolonged pudendal nerve terminal motor latency is associated with decreased resting and squeeze pressures in the intact anal sphincter. *Colorectal Disease*, *15*(11), 1410–1415. https://doi.org/10.1111/codi.12368

125. Lukacz, E. S., Lawrence, J. M., Contreras, R., Nager, C. W., & Luber, K. M. 2006. Parity, mode of delivery, and pelvic floor disorders. *Obstetrics and gynecology*, *107*(6), 1253–1260. https://doi.org/10.1097/01.AOG.0000218096.54169.34

126. Lund, N. S. 2016. Episiotomy in vacuum-assisted delivery affects the risk of obstetric anal sphincter injury: A systematic review and meta-analysis. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *27*, 193–199. https://doi.org/10.1016/j.ejogrb.2016.10.013

127. MacLennan, A. H., Taylor, A. W., Wilson, D. H., & Wilson, D. 2000. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. *BJOG: An International Journal of Obstetrics and Gynaecology*, *107*(12), 1460–1470. https://doi.org/10.1111/j.1471-0528.2000.tb11669.x

128. Madoff, R. D., Parker, S. C., Varma, M. G., & Lowry, A. C. 2004. Faecal incontinence in adults. *The Lancet*, *364*(9434), 621–632. https://doi.org/10.1016/S0140-6736(04)16856-6

129. Marateb, H. R., Farahi, M., Rojas, M., Mañanas, M. A., & Farina, D. 2016. Detection of Multiple Innervation Zones from Multi-Channel Surface EMG Recordings with Low Signal-to-Noise Ratio Using Graph-Cut Segmentation. *PLOS ONE*, *11*(12), e0167954. https://doi.org/10.1371/journal.pone.0167954

130. Marshall, K., Walsh, D. M., & Baxter, G. D. 2002. The effect of a first vaginal delivery on the integrity of the pelvic ‘oor musculature. *Clinical Rehabilitation*, *16*(7), 795–799. https://doi.org/10.1191/0269215502cr556oa

131. Martinho, N., Botelho, S., Nagib, A., Jales, R. M., Turel, F., Caagbay, D., & Riccetto, C. 2020. Four-dimensional translabial ultrasound concordance with digital palpation and surface electromyography during dynamic pelvic floor muscles assessment: A cross-sectional study. *Neurourology and Urodynamics*, *39*(1), 403–411. https://doi.org/10.1002/nau.24220

132. May, J. L. 1994. Modified median episiotomy minimizes the risk of third-degree tears. *Obstetrics and Gynecology*, *83*(1), 156–157.

133. McPherson, K. C., Beggs, A. D., Sultan, A. H., & Thakar, R. 2014. Can the risk of obstetric anal sphincter injuries (OASIs) be predicted using a risk-scoring system? *BMC Research Notes*, *7*(1), 471. https://doi.org/10.1186/1756-0500-7-471

134. Medved, V., & Cifrek, M. 2011. Kinesiological Electromyography. In *Biomechanics in Applications*. InTech. https://doi.org/10.5772/21282

135. Meister, M. R. L., Cahill, A. G., Conner, S. N., Woolfolk, C. L., & Lowder, J. L. 2016. Predicting obstetric anal sphincter injuries in a modern obstetric population. *American Journal of Obstetrics and Gynecology*, *215*(3), 310.e1-310.e7. https://doi.org/10.1016/j.ajog.2016.02.041

136. Mellgren, A., Jensen, L. L., Zetterström, J. P., Wong, D. W., Hofmeister, J. H., & Lowry, A. C. 1999. Long-term cost of faecal incontinence secondary to obstetric injuries: *Diseases of the Colon & Rectum*, *42*(7), 857–865. https://doi.org/10.1007/BF02237089

137. Meriwether, K. V., Lockhart, M. E., Meyer, I., & Richter, H. E. 2019. Anal Sphincter Anatomy Prepregnancy to Postdelivery Among the Same Primiparous Women on Dynamic Magnetic Resonance Imaging: *Female Pelvic Medicine & Reconstructive Surgery*, *25*(1), 8–14. https://doi.org/10.1097/SPV.0000000000000504

138. Merletti, R., Bottin, A., Cescon, C., Farina, D., Gazzoni, M., Martina, S., Mesin, L., Pozzo, M., Rainoldi, A., & Enck, P. 2004. Multichannel surface EMG for the non-invasive assessment of the anal sphincter muscle. *Digestion*, *69*(2), 112–122. https://doi.org/10.1159/000077877

139. Merletti, R., & Muceli, S. 2019. Tutorial. Surface EMG detection in space and time: Best practices. *Journal of Electromyography and Kinesiology*. 49, 102363. 10.1016/j.jelekin.2019.102363.

140. Merletti, Roberto. 2016. Pelvic Floor EMG: Principles, Techniques, and Applications. In *Childbirth-Related Pelvic Floor Dysfunction* (p. 83–99). Springer International Publishing. https://doi.org/10.1007/978-3-319-18197-4_7

141. Mesin, L., Gazzoni, M., & Merletti, R. 2009. Automatic localisation of innervation zones: A simulation study of the external anal sphincter. *Journal of Electromyography and Kinesiology*, *19*(6), e413–e421. https://doi.org/10.1016/j.jelekin.2009.02.002

142. Miner, P. B. 2004. Economic and personal impact of faecal and urinary incontinence. *Gastroenterology*, *126*, S8–S13. https://doi.org/10.1053/j.gastro.2003.10.056

143. Muhleman, M. A., Aly, I., Walters, A., Topale, N., Tubbs, R. S., & Loukas, M. 2017. To cut or not to cut, that is the question: A review of the anatomy, the technique, risks, and benefits of an episiotomy: To Cut or Not to Cut, That is the Question. *Clinical Anatomy*, *30*(3), 362–372. https://doi.org/10.1002/ca.22836

144. Muraca, G. M., Liu, S., Sabr, Y., Lisonkova, S., Skoll, A., Brant, R., Cundiff, G. W., Stephansson, O., Razaz, N., & Joseph, K. S. 2019. Episiotomy use among vaginal deliveries and the association with anal sphincter injury: A population-based retrospective cohort study. *Canadian Medical Association Journal*, *191*(42), E1149–E1158. https://doi.org/10.1503/cmaj.190366

145. Murphy, D. J., Macleod, M., Bahl, R., & Strachan, B. 2011. A cohort study of maternal and neonatal morbidity in relation to use of sequential instruments at operative vaginal delivery. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *156*(1), 41–45. https://doi.org/10.1016/j.ejogrb.2011.01.004

146. Murphy, D., Macleod, M., Bahl, R., Goyder, K., Howarth, L., & Strachan, B. 2008. A randomised controlled trial of routine versus restrictive use of episiotomy at operative vaginal delivery: A multicentre pilot study. *BJOG: An International Journal of Obstetrics & Gynaecology*, *115*(13), 1695–1703. https://doi.org/10.1111/j.1471-0528.2008.01960.x

147. Naidu, M., Sultan, A. H., & Thakar, R. 2017. Reducing obstetric anal sphincter injuries using perineal support: Our preliminary experience. *International Urogynecology Journal*, *28*(3), 381–389. https://doi.org/10.1007/s00192-016-3176-4

148. Nama, V., & Wilcock, F. 2011. Caesarean section on maternal request: Is justification necessary? *The Obstetrician & Gynaecologist*, *13*(4), 263–269. https://doi.org/10.1576/toag.13.4.263.27693

149. Navarro Brazález, B., Torres Lacomba, M., de la Villa, P., Sánchez Sánchez, B., Prieto Gómez, V., Asúnsolo del Barco, Á., & McLean, L. 2018. The evaluation of pelvic floor muscle strength in women with pelvic floor dysfunction: A reliability and correlation study. *Neurourology and Urodynamics*, *37*(1), 269–277. https://doi.org/10.1002/nau.23287

150. Necesalova, P., Karbanova, J., Rusavy, Z., Pastor, Z., Jansova, M., & Kalis, V. 2016. Mediolateral versus lateral episiotomy and their effect on postpartum coital activity and dyspareunia rate 3 and 6 months postpartum. *Sexual & Reproductive Healthcare*, *8*, 25–30. https://doi.org/10.1016/j.srhc.2016.01.004

151. Nelson, L., Furner, S., Westercamp, M., & Farquhar, C. 2010. caesarean delivery for the prevention of anal incontinence. *Cochrane Database of Systematic Reviews*, *2*, Article 2. https://doi.org/10.1002/14651858.CD006756.pub2.

152. Nelson, R. L. 2004. Epidemiology of faecal incontinence. *Gastroenterology*, *126*, S3–S7. https://doi.org/10.1053/j.gastro.2003.10.010

153. Newman, D. K., & Laycock, J. 2008. Clinical Evaluation of the Pelvic Floor Muscles. In K. Baessler, K. L. Burgio, P. A. Norton, B. Schüssler, K. H. Moore, & S. L. Stanton (A c. Di), *Pelvic Floor Re-education* (pagg. 91–104). Springer London. https://doi.org/10.1007/978-1-84628-505-9_9

154. Nowakowski, M., Tomaszewski, K. A., Herman, R. M., Sałówka, J., Romaniszyn, M., Rubinkiewicz, M., & Walocha, J. A. 2014. Developing a new electromyography-based algorithm to diagnose the etiology of faecal incontinence. *International Journal of Colorectal Disease*, *29*(6), 747–754. https://doi.org/10.1007/s00384-014-1859-1

155. Nowakowski, M., Tomaszewski, K. A., Machura, \Lukasz, Trybek, P., & Herman, R. M. 2017. Sensitivity and specificity of multichannel surface electromyography in diagnosing faecal incontinence. *Folia medica Cracoviensia*, *57*(1), 29–38.

156. Nygaard, I. 2006. Urinary Incontinence: Is caesarean Delivery Protective? *Seminars in Perinatology*, *30*(5), 267–271. https://doi.org/10.1053/j.semperi.2006.07.007

157. Nygaard, I. 2008. Prevalence of Symptomatic Pelvic Floor Disorders in US Women. *JAMA*, *300*(11), 1311. https://doi.org/10.1001/jama.300.11.1311

158. Oberwalder, M., Connor, J., & Wexner, S. D. 2003. Meta-analysis to determine the incidence of obstetric anal sphincter damage. *British Journal of Surgery*, *90*(11), 1333–1337. https://doi.org/10.1002/bjs.4369

159. Palm, A., Israelsson, L., Bolin, M., & Danielsson, I. 2013. Symptoms after obstetric sphincter injuries have little effect on quality of life: Symptoms after obstetric sphincter injuries. *Acta Obstetricia et Gynecologica Scandinavica*, *92*(1), 109–115. https://doi.org/10.1111/j.1600-0412.2012.01532.x

160. Pandit, B., Palshetkar, N., Kale, D., Palshetkar, R., Tambe, P., & Pai, R. 2018. Chapter-11 Management of Third and Fourth-degree Perineal Tears. *Smart Obstetrics & Gynecology Handbook*, *29*, 101–110. https://doi.org/10.5005/jp/books/13082_12

161. Papaconstantinou, H. T. 2005. Evaluation of Anal Incontinence: Minimal Approach, Maximal Effectiveness. *Clinics in Colon and Rectal Surgery*, *18*(01), 9–16. https://doi.org/10.1055/s-2005-864076

162. Paskaranandavadivel, N., Varghese, C., Lara, J., Ramachandran, S., Cheng, L., Holobar, A., Gharibans, A., Bissett, I., Collinson, R., Stinear, C., & O'Grady, G. 2020. A Novel High-Density Electromyography Probe for Evaluating Anorectal Neurophysiology: Design, Human Feasibility Study, and Validation with Trans-Sacral Magnetic Stimulation. *Annals of Biomedical Engineering*. https://doi.org/10.1007/s10439-020-02581-2

163. Patel, D. A., Xu, X., Thomason, A. D., Ransom, S. B., Ivy, J. S., & DeLancey, J. O. L. 2006. Childbirth and pelvic floor dysfunction: An epidemiologic approach to the assessment of prevention opportunities at delivery. *American Journal of Obstetrics and Gynecology*, *195*(1), 23–28. https://doi.org/10.1016/j.ajog.2006.01.042

164. Peng, Y., He, J., Khavari, R., Boone, T. B., & Zhang, Y. 2016. Functional mapping of the pelvic floor and sphincter muscles from high-density surface EMG recordings. *International Urogynecology Journal*, *27*(11), 1689–1696. https://doi.org/10.1007/s00192-016-3026-4

165. Pergialiotis, V., Vlachos, D., Protopapas, A., Pappa, K., & Vlachos, G. 2014. Risk factors for severe perineal lacerations during childbirth. *International Journal of Gynecology & Obstetrics*, *125*(1), 6–14. https://doi.org/10.1016/j.ijgo.2013.09.034

166. Perone, N. 2007. Risk factors for primary and subsequent anal sphincter lacerations: A comparison of cohorts by parity and prior mode of delivery. *American Journal of Obstetrics and Gynecology*, *197*(6), 688–689. https://doi.org/10.1016/j.ajog.2007.09.019

167. Perry, S. 2002. Prevalence of faecal incontinence in adults aged 40 years or more living in the community. *Gut*, *50*(4), 480–484. https://doi.org/10.1136/gut.50.4.480

168. Pretlove, S., Thompson, P., Toozs-Hobson, P., Radley, S., & Khan, K. 2008. Does the mode of delivery predispose women to anal incontinence in the first year postpartum? A comparative systematic review. *BJOG: An International Journal of Obstetrics & Gynaecology*, *115*(4), 421–434. https://doi.org/10.1111/j.1471-0528.2007.01553.x

169. Qu, C., Xu, D., Wang, C., Chen, J., Yin, L., & Cui, X. 2011. Anal Sphincter Electromyogram for Dysfunction of Lower Urinary Tract and Pelvic Floor. In *Advances in Applied Electromyography*. InTech. https://doi.org/10.5772/21853

170. Quoc Huy, N. V., Phuc An, L. S., Phuong, L. S., & Tam, L. M. 2019. Pelvic Floor and Sexual Dysfunction After Vaginal Birth with Episiotomy in Vietnamese Women. *Sexual Medicine*, 7(4), 514–521. https://doi.org/10.1016/j.esxm.2019.09.002

171. Räisänen, S., Vehviläinen-Julkunen, K., Gissler, M., & Heinonen, S. 2012. Hospital-based lateral episiotomy and obstetric anal sphincter injury rates: A retrospective population-based register study. *American Journal of Obstetrics and Gynecology*, *206*(4), 347.e1-347.e6. https://doi.org/10.1016/j.ajog.2012.02.019

172. Ramm, O., Woo, V. G., Hung, Y. Y., Chen, H. C., & Ritterman Weintraub, M. L. 2018. Risk factors for the development of obstetric anal sphincter injuries in modern obstetric practice. *Obstetrics and Gynecology*, *131*(2), 290–296. https://doi.org/10.1097/AOG.0000000000002444

173. Rashid, A., & Khuroo, S. 2014. Obstructed Defecation Syndrome: A Treatise on Its Functional Variant. *Internal Medicine: Open Access*, *s1*(01). https://doi.org/10.4172/2165-8048.S1-005

174. Renzi, A., Brillantino, A., Di Sarno, G., & D'Aniello, F. 2013. Five-item score for obstructed defecation syndrome: Study of validation. *Surgical Innovation*, *20*(2), 119–125. https://doi.org/10.1177/1553350612446354

175. Resende, A. P. M., Petricelli, C. D., Bernardes, B. T., Alexandre, S. M., Nakamura, M. U., & Zanetti, M. R. D. 2012. Electromyographic evaluation of pelvic floor muscles in pregnant and nonpregnant women. *Int Urogynecol J*, 5.

176. Revicky, V., Nirmal, D., Mukhopadhyay, S., Morris, E. P., & Nieto, J. J. 2010. Could a mediolateral episiotomy prevent obstetric anal sphincter injury? *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *150*(2), 142–146. https://doi.org/10.1016/j.ejogrb.2010.03.002

177. Richter, H. E., Brumfield, C. G., Cliver, S. P., Burgio, K. L., Neely, C. L., & Varner, R. E. 2002. Risk factors associated with anal sphincter tear: A comparison of primiparous patients, vaginal births after caesarean deliveries, and patients with previous vaginal delivery. *American Journal of Obstetrics and Gynecology*, *187*(5), 1194–1198. https://doi.org/10.1067/mob.2002.126977

178. Richter, H. E., Fielding, J. R., Bradley, C. S., Handa, V. L., Fine, P., FitzGerald, M. P., Visco, A., Wald, A., Hakim, C., Wei, J. T., & Weber, A. M. 2006. Endoanal Ultrasound Findings and faecal Incontinence Symptoms in Women With and Without Recognized Anal Sphincter Tears: *Obstetrics & Gynecology*, *108*(6), 1394–1401. https://doi.org/10.1097/01.AOG.0000246799.53458.bc

179. Rortveit, G., Subak, L. L., Thom, D. H., Creasman, J. M., Vittinghoff, E., Van Den Eeden, S. K., & Brown, J. S. 2010. Urinary Incontinence, faecal Incontinence and Pelvic Organ Prolapse in a Population-Based, Racially Diverse Cohort: Prevalence and Risk Factors. *Female Pelvic Medicine & Reconstructive Surgery*, *16*(5), 278–283. https://doi.org/10.1097/SPV.0b013e3181ed3e31

180. Ros, C., Martínez-Franco, E., Wozniak, M. M., Cassado, J., Santoro, G. A., Elías, N., López, M., Palacio, M., Wieczorek, A. P., & Espuña-Pons, M. 2017. Postpartum two- and three-dimensional ultrasound evaluation of anal sphincter complex in women with obstetric anal sphincter injury. *Ultrasound in Obstetrics & Gynecology*, *49*(4), 508–514. https://doi.org/10.1002/uog.15924

181. Rygh, A. B., Skjeldestad, F. E., Korner, H., & Eggebo, T. M. 2014. Assessing the association of oxytocin augmentation with obstetric anal sphincter injury in nulliparous women: A population-based, case-control study. *BMJ Open*, *4*(7), e004592–e004592. https://doi.org/10.1136/bmjopen-2013-004592

182. Rygh, Astrid Betten, & Krner, H. 2010. The overlap technique versus end-to-end approximation technique for primary repair of obstetric anal sphincter rupture: A randomized controlled study. *Acta Obstetricia et Gynecologica Scandinavica*, *89*(10), 1256–1262. https://doi.org/10.3109/00016349.2010.512073

183. Sagi-Dain, L., Bahous, R., Caspin, O., Kreinin-Bleicher, I., Gonen, R., & Sagi, S. 2018. No episiotomy versus selective lateral/mediolateral episiotomy (EPITRIAL): An interim analysis. *International Urogynecology Journal*, *29*(3), 415–423. https://doi.org/10.1007/s00192-017-3480-7

184. Sagi-Dain, L., & Sagi, S. 2015. The correct episiotomy: Does it exist? A cross-sectional survey of four public Israeli hospitals and review of the literature. *International Urogynecology Journal and Pelvic Floor Dysfunction*, *26*(8), 1213–1219. https://doi.org/10.1007/s00192-015-2680-2

185. Samarasekera, D. N., Bekhit, M. T., Preston, J. P., & Speakman, C. T. M. 2009. Risk factors for anal sphincter disruption during child birth. *Langenbeck's Archives of Surgery*, *394*(3), 535–538. https://doi.org/10.1007/s00423-008-0441-0

186. Sangkomkamhang, U., Kongwattanakul, K., Kietpeerakool, C., Thinkhamrop, J., Wannasiri, P., Khunpradit, S., Thepsuthamarat, K., Jampathong, N., & Lumbiganon, P. 2020. Restrictive versus routine episiotomy among Southeast Asian term pregnancies: A multicentre randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*, 127(3), 397–403. https://doi.org/10.1111/1471-0528.15982

187. Sbeit, W., Khoury, T., & Mari, A. 2021. Diagnostic approach to faecal incontinence: What test and when to perform? *World Journal of Gastroenterology*, 27(15), 1553–1562. https://doi.org/10.3748/wjg.v27.i15.1553

188. Scharschmidt, R., Derlien, S., Siebert, T., Herbsleb, M., & Stutzig, N. 2020. Intraday and interday reliability of pelvic floor muscles electromyography in continent woman. *Neurourology and Urodynamics*, *39*(1), 271–278. https://doi.org/10.1002/nau.24187

189. Schoon, P. G. 2001. A Guest Editorial: Episiotomy: Yea or Nay. *Obstetrical and Gynecological Survey*, *56*(11), 667-9. https://doi.org/10.1097/00006254-200111000-00001

190. Serati, M., Salvatore, S., & Rizk, D. 2019. Episiotomy in modern clinical practice: Friend or foe? *International Urogynecology Journal*, 10–12. https://doi.org/10.1007/s00192-019-03912-1

191. Shmueli, A., Gabbay Benziv, R., Hiersch, L., Ashwal, E., Aviram, R., Yogev, Y., & Aviram, A. 2017. Episiotomy–risk factors and outcomes*. *Journal of Maternal-foetal and Neonatal Medicine*, *30*(3), 251–256. https://doi.org/10.3109/14767058.2016.1169527

192. Snooks, S. J., Swash, M., Henry, M. M., & Setchell, M. 1986. Risk factors in childbirth causing damage to the pelvic floor innervation. *International Journal of Colorectal Disease*, *1*(1), 20–24. https://doi.org/10.1007/BF01648831

193. Snooks, S. J., Swash, M., Mathers, S. E., & Henry, M. M. 1990. Effect of vaginal delivery on the pelvic floor: A 5-year follow-up. *British Journal of Surgery*, *77*(12), 1358–1360. https://doi.org/10.1002/bjs.1800771213

194. Snooks, S. J., Swash, M., Setchell, M., & Henry, M. M. 1984. Injury to innervation of pelvic floor sphincter musculature in childbirth. *The Lancet*, *324*(8402), 546–550. https://doi.org/10.1016/S0140-6736(84)90766-9

195. Starck, M., Bohe, M., & Valentin, L. 2003. Results of endosonographic imaging of the anal sphincter 2-7 days after primary repair of third- or fourth-degree obstetric sphincter tears: Endosonographic imaging after anal sphincter tear repair. *Ultrasound in Obstetrics and Gynecology*, *22*(6), 609–615. https://doi.org/10.1002/uog.920

196. Stedenfeldt, M., Pirhonen, J., Blix, E., Wilsgaard, T., Vonen, B., & Øian, P. 2012. Episiotomy characteristics and risks for obstetric anal sphincter injuries: A case-control study. *BJOG: An International Journal of Obstetrics and Gynaecology*, *119*(6), 724–730. https://doi.org/10.1111/j.1471-0528.2012.03293.x

197. Steiner, N., Weintraub, A. Y., Wiznitzer, A., Sergienko, R., & Sheiner, E. 2012. Episiotomy: The final cut? *Archives of Gynecology and Obstetrics*, *286*(6), 1369–1373. https://doi.org/10.1007/s00404-012-2460-x

198. Stones, R. W., Paterson, C. M., & StG Saunders, N. J. 1993. Risk factors for major obstetric haemorrhage. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *48*(1), 15–18. https://doi.org/10.1016/0028-2243(93)90047-G

199. Sultan, A., Fenner, D. E., & Thakar, R. 2009. *Perineal and Anal Sphincter Trauma*.

200. Sultan, A. H. 2003. The role of anal endosonography in obstetrics: Opinion. *Ultrasound in Obstetrics and Gynecology*, *22*(6), 559–560. https://doi.org/10.1002/uog.947

201. Sultan, A. H., Kamm, M. A., Hudson, C. N., & Bartram, C. I. 1994. Third degree obstetric anal sphincter tears: Risk factors and outcome of primary repair. *BMJ*, *308*(6933), 887–891. https://doi.org/10.1136/bmj.308.6933.887

202. Sung, V. W., Washington, B., & Raker, C. A. 2010. Costs of ambulatory care related to female pelvic floor disorders in the United States. *American Journal of Obstetrics and Gynecology*, *202*(5), 483.e1-483.e4. https://doi.org/10.1016/j.ajog.2010.01.015

203. Thacker, S. B., & Banta, H. D. 1983. Benefits and risks of episiotomy: An interpretative review of the English language literature, 1860-1980. *Obstetrical & Gynecological Survey*, *38*(6), 322–338.

204. Tincello, D. G., Williams, A., Fowler, G. E., Adams, E. J., Richmond, D. H., & Alfirevic, Z. 2003. Differences in episiotomy technique between midwives and doctors. *BJOG: An International Journal of Obstetrics and Gynaecology*, *110*(12), 1041–1044. https://doi.org/10.1111/j.1471-0528.2003.03030.x

205. Ullah, K., Cescon, C., Afsharipour, B., & Merletti, R. 2014. Automatic detection of motor unit innervation zones of the external anal sphincter by multichannel surface EMG. *Journal of Electromyography and Kinesiology*, *24*(6), 860–867. https://doi.org/10.1016/j.jelekin.2014.05.003

206. van Bavel, J., Hukkelhoven, C. W. P. M., de Vries, C., Papatsonis, D. N. M., de Vogel, J., Roovers, J.-P. W. R., Mol, B. W., & de Leeuw, J. W. 2018. The effectiveness of mediolateral episiotomy in preventing obstetric anal sphincter injuries during operative vaginal delivery: A ten-year analysis of a national registry. *International Urogynecology Journal*, *29*(3), 407–413. https://doi.org/10.1007/s00192-017-3422-4

207. Varma, A., Gardiner, A., Lindow, S. W., & Duthie, G. S. 1999. Obstetric anal sphincter injury. *Dis Colon Rectum*, *42*(12), 1537-1543.

208. Verghese, T. S., Champaneria, R., Kapoor, D. S., & Latthe, P. M. 2016. Obstetric anal sphincter injuries after episiotomy: Systematic review and meta-analysis. *International Urogynecology Journal*, *27*(10), 1459–1467. https://doi.org/10.1007/s00192-016-2956-1

209. Vodušek, D. B. 2004. Anatomy and neurocontrol of the pelvic floor. *Digestion*, *69*(2), 87–92. https://doi.org/10.1159/000077874

210. Voorham-van der Zalm, P. J., Voorham, J. C., van den Bos, T. W. L., Ouwerkerk, T. J., Putter, H., Wasser, M. N. J. M., Webb, A., DeRuiter, M. C., & Pelger, R. C. M. 2013. Reliability and differentiation of pelvic floor muscle electromyography measurements in healthy volunteers using a new device: The multiple array probe leiden (MAPLe): Reliability of the Multiple Array Probe. *Neurourology and Urodynamics*, *32*(4), 341–348. https://doi.org/10.1002/nau.22311

211. Wald, A. 1994. Colonic and anorectal motility testing in clinical practice. *The American Journal of Gastroenterology*, *89*(12), 2109–2115.

212. Wallner, C., Maas, C. P., Dabhoiwala, N. F., Lamers, W. H., & DeRuiter, M. C. 2006. Innervation of the Pelvic Floor Muscles: A Reappraisal for the Levator Ani Nerve. *Obstetrics & Gynecology*, *108*(3, Part 1), 529–534. https://doi.org/10.1097/01.AOG.0000228510.08019.77

213. Walter, S., Hallbook, O., Gotthard, R., Bergmark, M., & Sjodahl, R. 2002. A Population-based Study on Bowel Habits in a Swedish Community: Prevalence of Faecal Incontinence and Constipation. *Scand J Gastroenterol*, 7.

214. WHO recommendations: Intrapartum care for a positive childbirth experience. 2018. Geneva: World Health Organization. Licence: CC BY-NC-SA 3.0 IGO.

215. Wietek, B. M., Hinninghofen, H., Jehle, E. C., Enck, P., & Franz, H. B. 2007. Asymmetric sphincter innervation is associated with faecal incontinence after anal sphincter trauma during childbirth. *Neurourology and Urodynamics*, *26*(1), 134–139. https://doi.org/10.1002/nau.20307

216. Wilson, A. N., & Homer, C. S. E. 2020. *Third- and fourth-degree tears: A review of the current evidence for prevention and management*. 1–8. https://doi.org/10.1111/ajo.13127

217. Woodman, P. J., & Graney, D. O. 2002. Anatomy and physiology of the female perineal body with relevance to obstetrical injury and repair. *Clinical Anatomy*, *15*(5), 321–334. https://doi.org/10.1002/ca.10034

218. Wu, J. M., Kawasaki, A., Hundley, A. F., Dieter, A. A., Myers, E. R., & Sung, V. W. 2011. Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050. *American Journal of Obstetrics and Gynecology*, *205*(3), 230.e1-230.e5. https://doi.org/10.1016/j.ajog.2011.03.046

219. Wu, J. M., Matthews, C. A., Vaughan, C. P., & Markland, A. D. 2015. Urinary, faecal, and Dual Incontinence in Older U.S. Adults. *Journal of the American Geriatrics Society*, *63*(5), 947–953. https://doi.org/10.1111/jgs.13385

220. Yang, J., & Bai, H. 2021. Knowledge, attitude and experience of episiotomy practice among obstetricians and midwives: A cross-sectional study from China. *BMJ Open*, 11(4), e043596. https://doi.org/10.1136/bmjopen-2020-043596

221. Young, C. J., Zahid, A., Koh, C. E., & Young, J. M. 2017. Hypothesized summative anal physiology score correlates but poorly predicts incontinence severity. *World Journal of Gastroenterology*, *23*(31), 5732–5738. https://doi.org/10.3748/wjg.v23.i31.5732

222. Zetterström, J., López, A., Anzén, B., Norman, M., Holmström, B., & Mellgren, A. 1999. Anal sphincter tears at vaginal delivery: Risk factors and clinical outcome of primary repair. *Obstetrics and Gynecology*, *94*(1), 21–28.

223. Zifan, A., Ledgerwood-Lee, M., & Mittal, R. K. 2016. A Predictive Model to Identify Patients With faecal Incontinence Based on High-Definition Anorectal Manometry. *Clinical Gastroenterology and Hepatology: The Official Clinical Practice Journal of the American Gastroenterological Association*, *14*(12), 1788-1796.e2. https://doi.org/10.1016/j.cgh.2016.07.021

Online resources:

224. Australian Institute of Health and Welfare. National Core Maternity Indicators. Available at: https://www.aihw.gov.au/reports/mothers-babies/ncmi-data-visualisations/contents/labour-and-birth-indicators/episiotomy. Accessed 23.07.2021

225. Croatian health statistics yearbook 2017. Avaialable at: https://www.hzjz.hr/wp-content/uploads/2019/03/Ljetopis_2017.pdf. Accessed 23.07.2021

226. European Perinatal Health Report released by the Euro-Peristat project. Available at: https://www.europeristat.com/images/EPHR2015_web_hyperlinked_Euro-Peristat.pdf. Accessed 23.07.2021.

227. French National Perinatal Survey 2016. Avaialble at: https://www.europeristat.com/images/doc/NPHR/French_National_Perinatal_Survey_2016.pdf. Accessed 23.07.2021

228. Health statistics database of Latvia. Available at: https://statistika.spkc.gov.lv/pxweb/lv/Health/Health__Mates_berna_veseliba/?tablelist = true. Accessed 06.02.2021

229. Lithuanian Medical data of Births 2018. Avaiable at: https://hi.lt/uploads/pdf/leidiniai/Statistikos/Gimimu/gimimai_2018.pdf. Accessed 23.07.2021

230. Malta National Obstetric Information System Annual Report 2019. Available at: https://deputy primeminister.gov.mt/en/dhir/Documents/rpt_NOIS_19_Annual_finalz.pdf. Accessed 23.07.2021

231. Non-invasive Electromyography, online resources. Available at https://www.roberto merletti.it/en/emg/material/teaching/. Accessed 15.01.2021

232. Nordic perinatal statistics 2018. Available at: https://www.julkari.fi/bitstream/handle/10024/139767/Perinatal_statistic_2018.pdf?sequence = 1&isAllowed = y. Accessed 23.07.2021

233. Perinatale Activiteiten In Vlaanderen 2017. Available at: https://www.europeristat.com/images/doc/NPHR/SPE_Evaluatierapport-2017_DEFINITIEF.pdf. Accessed 23.07.2021

234. Surveillance de la Santé Périnatale au Luxembourg. Rapport sur les naissances 2014-2015-2016 et leur évolution depuis 2001. Avaialble at: https://sante.public.lu/fr/publications/s/surveillance-sante-perinatale-lux-2014-2015-2016/surveillance-sante-perinatale-lux-2014-2015-2016.pdf. Accessed 23.07.2021

235. World Health Organization. International Classification of Diseases (ICD). Geneva (CG): WHO; 2015. Available at: http://www.who.int/classifications/icd/en. Accessed 15.01.2021

236. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. Available at https://doi.org/10.1001/jama.2013.281053. Accessed 23.02.2020

Acknowledgements

I sincerely thank the scientific supervisors of this Doctoral Thesis: Prof. Dace Rezeberga and Prof. Haralds Plaudis for their help, insistence and persistence, informative scientific discussions and practical advice, engaging stories and their genuine interest in my work.

I am very grateful to my alma mater – The Riga Stradiņš University – for memorable years of study, a source of valuable knowledge and a most appreciated sharing of experiences. I am equally grateful for having had the opportunity to have met such open and supportive people.

I am immensely grateful to Corrado Cescon, PhD Ing. for his continuous support, scientific advice and investment in the development of this Doctoral Thesis, also for his patience in introducing me to the world of EMG and for his valuable help in statistics and graphics.

My special thanks go to Prof. Roberto Merletti for initiating the project and for his inspiration, for enthusing the project with his passion and, in doing so, completely changing my life.

I thank Andrea Bottin and the team of OT-Bioelettronica for the technical support.

My sincere gratitude goes to Dr. Oļesja Zeļenova, Dr. Karlīna Elksne, Dr. Natālija Bērza and Dr. Laura Rācene for their selfless hard work in EMG signal acquisition, for being ready to acquire new knowledge and for dedicating their time to EMG. Additionally, I express particular gratitude to Dr. Laura Rācene for her scientific ideas and exceptional support throughout my doctoral study years.

I thank Dr. Kristina Drusany-Starič for her enthusiasm and help in signal acquisition. I also thank all TASI-2 partners for their work.

I offer my appreciation and thanks to my colleagues Dr. Daiga Baranovska and Dr. Irina Jermakova and all the cordial staff in “Quartus” for their moral and practical support during the recruitment of subjects.

I am grateful to all the pregnant women who, unconditionally and willingly, participated in the study and dedicated their time to my research.

Many thanks to my colleagues, Dr. Ināra Miltiņa and Dr. Linda Grīnberga, and all the gynaecologists and midwives of The Riga Maternity Hospital for supporting the research work.

I give my heartfelt thanks to Prof. Gunta Lazdāne for saying the right words at the right critical moments.

I sincerely thank my first teacher in gynaecology, Dr. Aija Brežinska, for accompanying me on my initial steps in this specialism and revealing obstetrics' beauty.

I am thankful for the stimulating and pertinent mottos of my student organisation, the sorority “Imeria”: “For fatherland and science.” and “One for all and all for one.” I have greatly appreciated the moral support and the intelligent, expeditious help of members of “Imeria”.

In this regard, I particularly single out my sorority friends, Assoc. Prof. Anita Straujuma and Asst. Prof. Sigita Kazūne, whose lively discussions about science and the offers of opportunities of spending time in academic retreats supported and cheered me up on this long journey to my degree.

I owe a huge thank-you to my family for their unconditional love and support during all these years. To my mother and father, I offer my deep and sincere gratitude for laying the foundations of my studies and career. I am grateful also to my children for their patience and understanding.

Finally, I will be eternally grateful to my husband for his never-ending support, encouragement and belief in me. If this Thesis were a novel, it would be dedicated to him.

Appendices

Appendix No 1

Letter from corresponding author

POLITECNICO DI TORINO
Dipartimento di Elettronica e Telecomunicazioni

To Whom it may concern

Torino, Italy, March 1, 2021

As Coordinator of the Multicenter Project "Technology for Anal Sphincter analysis and Incontinence" (TASI-2) I wish to certify that Dr Vita Zacesta (Riga Maternity House, Latvia) has been a partner of the project and contributed to the preparation of the project, collection of data and interpretation of results, together with other partners in other countries.

The results of this project have been published in the following two articles of which I was the corresponding author:

1. Cescon C, Raimondi EE, Zacesta V, Drusany-Staric K, Martsidis K, Merletti R. Characterization of the motor units of the external anal sphincter in pregnant women with multichannel surface EMG. Int Urogynecol J. 2014 Aug;25(8):1097-103.
2. Cescon C, Riva D, Zacesta V, Drusany-Staric K, Martsidis K, Protsepko O, Baessler K, Merletti R. Effect of vaginal delivery on the external anal sphincter muscle innervation pattern evaluated by multichannel surface EMG: results of the multicentre study TASI-2. Int Urogynecol J. 2014 Nov;25(11):1491-9.

and in a number of presentations to international congresses. The contribution of Dr. Zacesta was substantial for both articles.

I hereby authorize dr. Vita Zacesta to include the data collected within the TASI -2 project in her PhD thesis.

Sincerely yours,

RMerletti

Roberto Merletti, PhD
Former Full Prof of Rehabilitation Engineering
Politecnico di Torino, Italy
roberto.merletti@formerfaculty.polito.it

Dipartimento di Elettronica e Telecomunicazioni
Politecnico di Torino Corso Duca degli Abruzzi, 24 – 10129 Torino – Italia
roberto.merletti@formerfaculty.polito.it

Appendix No 2

Authorisation from co-author

Ljubljana, Slovenia, March 10th , 2021

Kristina Drusany Starič
Ljubljana University Medical Center
Medical faculty, University of Ljubljana
Slovenia

To Riga Stradins University

As a partner of the Multicenter Project "Technology for Anal Sphincter analysis and Incontinence" (TASI-2) I authorize dr. Vita Začesta to include in her PhD thesis the data I acquired in Ljubljana Univeristy Medical Center within TASI-2 project and the mutual projects after TASI-2.

Sincerely,

Prof. Kristina Drusany Starič, MD, PhD

Appendix No 3

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Wolters Kluwer

2 March 2021

Vita Začesta
Riga Stradins University
Dzirciema iela 16
Riga, Latvia
Phone: +371 29249574
Email: vita.zacesta@gmail.com

Dear Dr. Začesta,

Figure(s): Nerves of the female perineum [74742]

Topic: Barber MD. Surgical female urogenital anatomy.

UpToDate, Inc. received your reprint request and we are pleased to give you permission to the non-exclusive rights to reproduce and publish this material from its database in your upcoming Doctoral Thesis, "Anal sphincter muscle activity changes in women after delivery" (Začesta, 2021).

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Phone: 781.392.2952 | Fax: 781-370-4793| Email: chris.conley@wolterskluwer.com

Appendix No 4

Written information sheet for consent – in Latvian

Informēta piekrišana dalībai zinātniskā darbā

INFORMĀCIJA PAR TESTU MUSKUĻU NOVĒRTĒŠANAI

Ārsta vārds: Vita Začesta Veidlapa Nr: 001

Pacienta vārds un uzvārds: ……………..………….…… Datums: …………………

VISPĀRĒJS APRAKSTS

Šī pētījuma mērķis ir izvērtēt ārējā anālā sfinktera muskulatūras elektrofizioloģiskās īpašības, analizējot muskuļu radīto elektrisko aktivitāti tā kontrakcijas laikā.

Kad muskulis saraujas, ir iespējams noteikt elektrisku signālu (elektromiogrāfijas vai mioelektrisku signālu). Šis pētījums iegūst anatomisku informāciju pēc elektromiogrāfiskiem signāliem, kurus uztver ar taisnajā zarnā ievietotu rektālu zondi (detektoru). Pētījumu veic ar ļoti minimālu iejaukšanos, un netiek lietotas adatas vai ķīmiskas vielas. Pētījumā iegūtā informācija kalpos diagnostisku izmeklējumu metožu novērtēšanai.

Es, ………………………….…………………………(vārds, uzvārds, personas kods) brīvprātīgi piekrītu piedalīties pētījumā saskaņā ar tā protokolu, un Dr. Začesta izsmeļoši un saprotami informēja mani par iespēju iesaistīties zinātniskā projektā, veicot elektromiogrāfijas testu.

Šis izmeklējums nav invazīvs (neiejaucas organismā), un tā veikšanā neizmanto adatas vai elektrisku stimulāciju, signālus tikai reģistrē, nevis rada, tādējādi izmeklējums nav sāpīgs un to panes labi. Šo izmeklēšanas metodi vairākus gadus lieto zarnu izmeklēšanā proktoloģijā, ieliekot cilindrisku zondi taisnajā zarnā, lai novērtētu ārējā anālā sfinktera inervācijas zonu.

Zondes diametrs ir 14 mm, un tā ir savienota ar datoru, kas reģistrē ārējā sfinktera muskuļa elektrisko aktivitāti miera stāvoklī. Tiks reģistrētas arī sfinktera 2 kontrakcijas (katra 10 sekundes ilga), lūdzot Jums maksimāli sasprindzināt muskuli. Starp katru no trim sfinktera kontrakcijām būs vienu minūti ilgs atelpas brīdis, kura laikā zondi neizņem.

Pētījums ir daļa no izpētes protokola, kas paredz elektromiogrāfijas signālu reģistrēšanu trīs atsevišķās reizēs: pirmo reizi grūtniecības otrajā trimestrī (apmēram 30.

muskuļa amplitūdu, spektra raksturojumu un anatomiskās īpašības pirms un pēc dzemdībām.

Piekrītot sadarboties šajā pētījumā, man nebūs nekāds personisks ieguvums. Pētījuma rezultātus izsniegs katram pacientam pēc pētījuma beigām.

Atteikšanās no piedalīšanās pētījumā:

Es zinu, ka varu atteikties piedalīties šajā izmeklējumā un varu pārtraukt mērījumu veikšanu jebkurā laikā, un tāpēc man nebūs nekādas sekas.

Jautājumi:

Esmu saņēmusi izsmeļošas atbildes uz saviem jautājumiem, un ja man radīsies papildu jautājumi, man ir ļauts sazināties ar izpētes grupas pārstāvjiem pa šo telefonu: 29249574

INFORMĒTĀS PIEKRIŠANAS PAZIŅOJUMS

ES PAZIŅOJU, KA ESMU IZLASĪJUSI UZ IZPRATUSI IEPRIEKŠ MINĒTOS PUNKTUS UN BRĪVPRĀTĪGI IZLEMJU PIEDALĪTIES ŠAJĀ PĒTĪJUMĀ.

Es zinu, ka šis ir eksperimentāls pētījums, esmu izlasījusi iepriekš minētos punktus un ar pētījumu saistītās veidlapas. Es paziņoju, ka man ir pieņemama šī procedūra, kas man saprotamā veidā detalizēti un izsmeļoši ir paskaidrota.

Datums: ....

Pacienta paraksts: ....

Ārsta paraksts: ....

Questionnaires in Latvian

1.veidlapa: Pirms dzemdībām

Subjekta kods...Datums......................

Vecums......................Vieta:...

Svars...................... Svars pirms grūtniecības.....................Augums ....

PM .... Gestācijas laiks .... Dzemdību termiņš.........

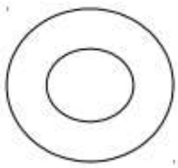
Nākamā mērījuma laiks...............................

Anamnēze (problēmas)

....

....

Anālā sfinktera bojājumi US jā nē



Komentāri

....

ODS Longo skala

	Jautājums	**Punkti**			
1	Medikamenti defekācijas akta veikšanai (klizma, svecītes)	0	1	2	3
2	Defekācijas grūtības	0	1	2	3
3	Palīdzība ar pirkstu	0	1	2	3
4	Atkārtotas defekācijas nepieciešamība	0	1	2	3
5	Nepilnīgas iztukšošanās sajūta	0	1	2	3
6	Spiešanās	0	1	2	3
7	Defekācijai nepieciešamais laiks	0	1	2	3
8	Ietekme uz dzīvesveidu	0	1	2	3
	Kopā				

1.-6. jaut.: 0 = nekad, 1 = mazāk nekā 1x nedēļā, 2 = 1–6 x ned., 3 = katru dienu;

7.jautājums: 0 = < 5 min, 1 = 6–10 min, 2 = 11–20 min, 3 = >20 min;

8.jautājums: 0 = neietekmē, 1 = ietekmē nedaudz, 2 = mēreni ietekmē, 3 = nopietni ietekmē.

2. veidlapa: Informācija par dzemdībām

Subjekta kods ....

Dzemdību vieta:...……………...

Datums......................... Gestācijas laiks ....nedēļas .... dienas

Dzemdētājas svars dzemdībās ....

Grūtniecības komplikācijas

- diabēts
- preeklampsija
- citas.....................................

....

Dzemdību ilgums

1.periods .... stundas, minūtes

2. periods .... stundas, minūtes

Dzemdības (atzīmēt lodziņā, ja atbilst)

- vaginālas
- ķeizargrieziens ....periodā
- epidurālā analgēzija
- Starpenes plīsuma pakāpe 1 2 3 4
- Oksitocīna izmantošana II periodā
- Spiediens uz fundus uteri (Kristellera paņēmies) izstumšanas periodā
- Vakuumeskstrakcija vai stangas

Priekšgulošā daļa galviņa augļa iegurņa priekšguļa

Epiziotomija **labajā pusē** **kreisajā**

Epiziotomijas leņķis

- 0° (perineotomija)
- 20-40°
- 40-60°

Epiziotomijas griezienа garums

- 2 cm
- 3 cm
- 4cm
- >4 cm

Jaundzimušā svars ....g Novērtējums pēc Apgares skalas ……..

3. veidlapa: 6-8 nedēļas pēc dzemdībām

Subjekta kods.. Svars.............................

Vieta:.. Datums...

ODS Longo skala

	Jautājums	Punkti			
1	Medikamenti defekācijas akta veikšanai (klizma, svecītes)	0	1	2	3
2	Defekācijas grūtības	0	1	2	3
3	Palīdzība ar pirkstu	0	1	2	3
4	Atkārtotas defekācijas nepieciešamība	0	1	2	3
5	Nepilnīgas iztukšošanās sajūta	0	1	2	3
6	Spiešanās	0	1	2	3
7	Defekācijai nepieciešamais laiks	0	1	2	3
8	Ietekme uz dzīvesveidu	0	1	2	3
	Kopā				

1.-6. jaut.: 0 = nekad, 1 = mazāk nekā 1x nedēļā, 2 = 1–6 x ned., 3 = katru dienu;
7.jautājums: 0 = < 5 min, 1 = 6–10 min, 2 = 11–20 min, 3 = >20 min;
8.jautājums: 0 = neietekmē, 1 = ietekmē nedaudz, 2 = mēreni ietekmē, 3 = nopietni ietekmē.

Inkontinences skala:

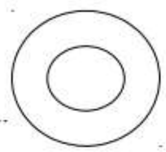
Inkontinences veids	**Nekad**	**< 1x mēnesī**	**>1x ned. <1x mēn.**	**< 1x d. >1x ned.**	**Katru dienu**
Cietas fēces	0	1	2	3	4
Šķidras	0	1	2	3	4
Gāzes	0	1	2	3	4
Pakešu lietošana	0	1	2	3	4
Dzīves veida izmaiņas	0	1	2	3	4
Kopā punkti					

Brūces infekcija dzīšanas laikā jā nē

Iekšējais sfinkters (anamnēzes un apskates dati)

vesels

traumēts (aprakstīt bojājumu) ....



Ārējais sfinkters (anamnēzes un apskates dati)

vesels

traumēts (aprakstīt bojājumu) ....

Ārējā anālā sfinktera bojājumi US jā nē

Komentāri ....

4. veidlapa: gadu pēc dzemdībām

Subjekta kods.. Svars.............................

Vieta:... Datums...

ODS Longo skala

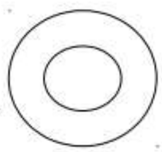
	Jautājums	**Punkti**			
1	Medikamenti defekācijas akta veikšanai (klizma, svecītes)	0	1	2	3
2	Defekācijas grūtības	0	1	2	3
3	Palīdzība ar pirkstu	0	1	2	3
4	Atkārtotas defekācijas nepieciešamība	0	1	2	3
5	Nepilnīgas iztukšošanās sajūta	0	1	2	3
6	Spiešanās	0	1	2	3
7	Defekācijai nepieciešamais laiks	0	1	2	3
8	Ietekme uz dzīvesveidu	0	1	2	3
	Kopā				

1.-6. jaut.: 0 = nekad, 1 = mazāk nekā 1x nedēļā, 2 = 1–6 x ned., 3 = katru dienu;
7.jautājums: 0 = < 5 min, 1 = 6–10 min, 2 = 11–20 min, 3 = >20 min;
8.jautājums: 0 = neietekmē, 1 = ietekmē nedaudz, 2 = mēreni ietekmē, 3 = nopietni ietekmē.

Inkontinences skala:

Inkontinences veids	**Nekad**	**< 1x mēnesī**	**>1x ned. <1x mēn.**	**< 1x d. >1x ned.**	**Katru dienu**
Cietas fēces	0	1	2	3	4
Šķidras	0	1	2	3	4
Gāzes	0	1	2	3	4
Pakešu lietošana	0	1	2	3	4
Dzīves veida izmaiņas	0	1	2	3	4
Kopā punkti					

Iekšējais sfinkters (anamnēzes un apskates dati)



vesels

traumēts (aprakstīt bojājumu) ....

Ārējais sfinkters (anamnēzes un apskates dati)

vesels

traumēts (aprakstīt bojājumu) ....

Ārējā anālā sfinktera bojājumi US jā nē

Komentāri ....

EU Declaration of Conformity

otbioelettronica.it
e.mail: mail@otbioelettronica.it - mail@pec.otbioelettronica.it
Sede legale: Via Vincenzo Lancia 62 Sc. A, 10141 Torino, Italy
Sede operativa: C.so Unione Sovietica 312, 10135 Torino, Italy
Tel./Fax: +39 011 6198 498
C.F./P.IVA: 09550700018
R.E.A.: 1061971

UE DECLARATION OF CONFORMITY

This is a declaration made in compliance with the general safety and performance requirements set out in Annex I of MDR 2017/745 and ISO 14971: 2019 "Medical devices - Application of risk management to medical devices".

This declaration of conformity is issued under the sole responsibility of the manufacturer:

OT Bioelettronica S.R.L

Object of the declaration, cl. I rule 1 Annex VIII:

MULTICHANNEL BIOELECTRICAL SIGNAL AMPLIFIER SESSANTAQUATTRO

Basic UDI: 805697785PORTABLEEMG002SF

Ref. : OT0106

And its accessories

ISO-AUXSE	Ref.: OT0107
SyncSE	Ref.: OT0108
CUSB01SE	Ref.: OT0096
AD8x1SE	Ref.: OT0087
ADx2SE	Ref.: OT0088
AD1x16SE	Ref.: OT0089
AD4x4SE	Ref.: OT0111
ADx4SE	Ref.: OT0127
AD4x8SE	Ref.: OT0126
ADx8SE	Ref.: OT0128
AD2x32SE	Ref.: OT0090
AD1x64SE	Ref.: OT0091
Forza-J	Ref.: OT0179

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The object of the declaration above fulfills the general safety and performance requirements of Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The object above is in compliance with Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011, on the restriction of certain hazardous substances in electrical and electronic equipment, and Directive 2015/863 of 31 March 2015 laying down modification of Annex II of Directive 2011/65/EC.

As certified by passing the Electromagnetic Compatibility (EMC) tests EN 60601-1 Standard, Electrostatic Discharge (ESD) EN 60601-1-2 Standard and Electromagnetic and Radio Compatibility ETSI EN 301489-1 v.2.2.0 Standard:Part 1 of 09/07/2019, under Annex II of Regulation (EU) 2017/745 and is put on the market in compliance with Regulation (EU) 2017/745.

Turin, 10/12/2020

Andrea Bottin (CEO)

Ethical Committee's approvals

Veidlapa Nr. E-9 (2)

RSU ĒTIKAS KOMITEJAS LĒMUMS

Rīga, Dzirciema iela 16, LV-1007
Tel. 67409101

	Komitejas sastāvs	Kvalifikācija	Nodarbošanās
1.	Asoc. prof. Olafs Brūvers	Dr.theo.	teologs
2.	Profesore Vija Sīle	Dr.phil.	filozofs
3.	Docente Santa Purviņa	Dr.med.	farmakologs
4.	Asoc. prof. Voldemārs Arnis	Dr.biol.	rehabilitologs
5.	Profesore Regīna Kleina	Dr.med.	patalogs
6.	Asoc. prof. Guntars Pupelis	Dr.med.	ķirurgs
7.	Asoc. prof. Viesturs Liguts	Dr.med.	toksikologs

Pieteikuma iesniedzējs: **Dr. Vita Začesta**
Medicīnas fakultāte

Pētījuma nosaukums: „Anālā sfinktera inervācija izmaiņu analīze sievietēm pēc dzemdībām"

Iesniegšanas datums: 04.09.2013.

Pētījuma protokols: Izskatot augstāk minētā pētījuma pieteikuma materiālus protokolu) ir redzams, ka pētījuma mērķis tiek sasniegts veicot ar dalībniecēm (bez kāda apdraudējuma veselībai) elektromiogrāfijas signālu reģistrēšanas testus (nav invazīvs) , iegūto datu apstrādi un analīzi, kā arī izsakot priekšlikumus. Personu (pacientu, dalībnieku) datu aizsardzība, brīvprātīga informēta piekrišana piedalīties pētījumā un konfidencialitāte tiek nodrošināta. Līdz ar to pieteikums atbilst pētījuma ētikas prasībām.

Izskaidrošanas formulārs: ir

Piekrišana piedalīties pētījumā: ir

Komitejas lēmums: **piekrist** pētījumam

Komitejas priekšsēdētājs Olafs Brūvers   Tituls: Dr. miss., asoc. prof.

Paraksts ____________________

ĒTIKAS KOMITEJA

Ētikas komitejas sēdes datums: 12.09.2013.

Veidlapa Nr E-9 (2)

RSU ĒTIKAS KOMITEJAS LĒMUMS

Rīga, Dzirciema iela 16, LV-1007
Tel.67409137

Komitejas sastāvs	Kvalifikācija	Nodarbošanās
1. Asoc. prof. Olafs Brūvers	Dr.miss.	teologs
2. Docente Santa Purviņa	Dr.med.	farmakologs
3. Asoc. prof. Voldemārs Arnis	Dr.biol.	rehabilitologs
4. Profesore Regīna Kleina	Dr.med.	patanatoms

Pieteikuma iesniedzējs: Dace Rezeberga (projekta koordinatore Latvijā)
Dzemdniecības un ginekoloģijas katedra

Pētījuma nosaukums: TASI-2 (Technologies for Anal Sphincter analysis and Incontinence)

Iesniegšanas datums: 20.09.2010.

Pētījuma protokols:
(X) Pētījuma veids: Šī kolektīvā pētījuma (ar ārzemju kolēģiem) mērķis ir izvērtēt anālā sfinktera muskulatūras elektrofizioloģiskās īpašības, analizējot muskuļu radīto elektrisko aktivitāti tā kontrakcijas laikā. Izmeklējums nab invazīvs (neiejaucas organismā) un tā veikšanai neizmanto adatas vai elektrisku stimulāciju, signālus tikai reģistrē, tādejādi izmeklējums nav sāpīgs un to panes labi. Pacientu piedalīšanās ir brīvprātīga, saskaņota ar katra cilvēka informētu piekrišanu (informed consent), personas datu aizsardzība, konfidencialitāte un brīvprātība (autonomija) pilnībā ievērota.
(X) Pētījuma populācija:
(X) Informācija par pētījumu:
(X) Piekrišana dalībai pētījumā:

Citi dokumenti:

1. Rīgas pašvaldības SIA „Rīgas Dzemdību nams" vadības piekrišana

Lēmums: piekrist biomedicīniskajam pētījumam

Komitejas priekšsēdētājs Olafs Brūvers Tituls: Dr.miss., asoc.prof.

Paraksts ____________

Ētikas komitejas sēdes datums: 23.09.2010.

RĪGAS STRADIŅA UNIVERSITĀTE ĒTIKAS KOMITEJA

Appendix No 8

Pictures of study setting