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Vita Začesta

Anal Sphincter Muscle Activity Changes in Women after Delivery

Summary of the 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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Abbreviations used in the Thesis

AAI	amplitude asymmetry index
AI	anal incontinence
ANOVA	one way analysis of variance
ARV	averaged rectified value
CMC	coefficient of multiple correlations
CS	caesarean section
EAS	external anal sphincter
EMG	electromyography
FI	faecal incontinence
GA	global amplitude
IAS	internal anal sphincter
ICC	intraclass correlation coefficient
iEMG	intramuscular electromyography
IZ(s)	innervation zone(s)
MLE	mediolateral episiotomy
MRI	magnetic resonance imaging
MVC	maximal voluntary contraction
NMJ	neuromuscular junctions
OAB	overactive bladder
OASI(s)	obstetrical anal sphincter injury(-ies)
ODS	obstructed defecation syndrome
POP	pelvic organ prolapse
PFDs	pelvic floor disorders
PFM	pelvic floor muscles
PNTML	pudendal nerve terminal motor latency
sEMG	surface electromyography
SUI	stress urinary incontinence
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. PFDs 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.

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. 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.

Although electromyography (EMG) is a well-established electrophysiological test, research on multichannel surface EMG (sEMG) applied to obstetrics are still at a pioneer stage. Recent advances in pelvic floor EMG have made functional analysis of the external sphincter (EAS) possible with a minimally invasive rectal probe. 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.

The present thesis presents a series of follow-up studies on the application of multichannel sEMG on the EAS muscle. The specific objective is to investigate and evaluate strategies for preventing or reducing the possible iatrogenic damage during delivery with episiotomy. This study proposes the introduction of multichannel surface EMG with anal probes in current obstetrics to make vaginal childbirth safer.

Aim of the Thesis

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

Objectives of the Thesis

The objectives of the thesis were to:

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

Hypotheses of the Thesis

After vaginal delivery, the EMG amplitude and the number of innervation zones (IZ) from the external anal sphincter decrease. 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 IZ distribution and EAS asymmetry could help choose the correct side of episiotomy, thus avoiding iatrogenic damage.

Novelty of the Thesis

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. The figure below shows possible damage to IZs 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.

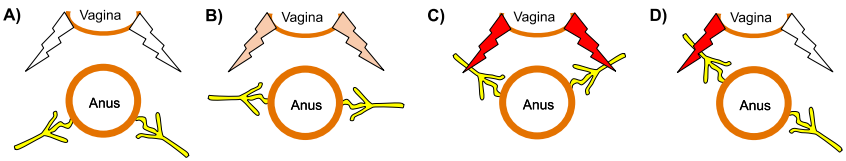

Figure 1 **Schematic representation of possible sphincter damage due to episiotomy***

* 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 – 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).

1 Literature review

1.1 Episiotomy

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

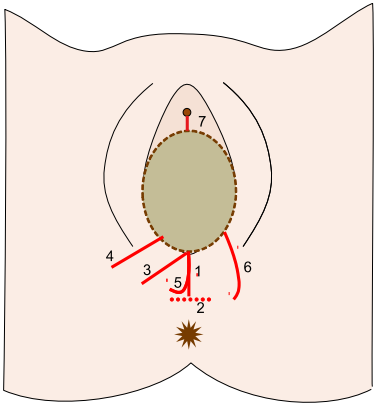

Figure 1.1 **Types of episiotomy***

* 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. 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; Lai et al., 2009).

Randomised controlled trials were carried out to prove the uselessness of systematic episiotomy, and a new approach – selective episiotomy instead of routine – was introduced. 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). The decision to perform episiotomy depends on the clinician's opinion and is based on the clinical scenario at the delivery time. 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 (VD) is necessary. Neither operative VD nor shoulder dystocia alone is considered an absolute indication for the episiotomy.

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). 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 at al., 2020). Euro-Peristat reports show that episiotomy rates remain high in Europe, e.g., 42.3 % and 62.4 % (all deliveries and primiparous respectively) in Belgium (2017), 20.1 % and 34.9 % in France (2016), 35.1 % in Croatia (2017), 22.21 % in Lithuania (data from 2018), 25.7 % in Luxembourg (2016).

The episiotomy rate in Latvia is stable at around 13–16 %. 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). Fig. 1.2 shows the episiotomy and OASI trends in Latvia in the last decade (data from the Health statistics database).

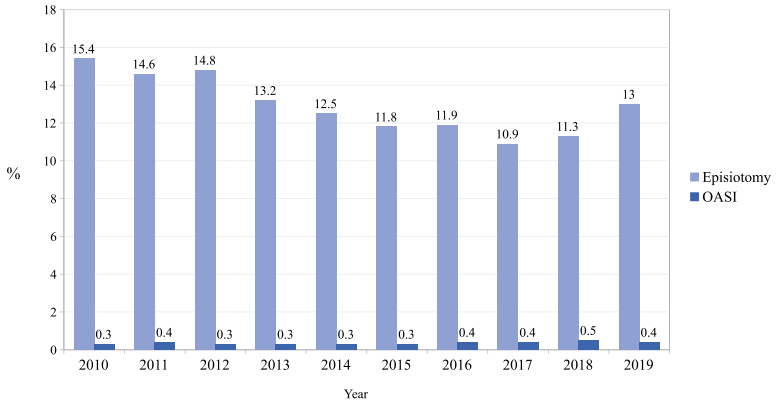

Figure 1.2 **Episiotomy and OASI rates in Latvia from 2010 to 2019**

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

Pelvic floor disorders include stress urinary incontinence, urgency urinary incontinence, overactive bladder, faecal or anal incontinence (FI, AI) and pelvic organ prolapse (Hallock & Handa, 2016). The author, later in the text, will focus on issues related to FI and AI 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).

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). The injury to the pudendal nerve can cause its demyelination and subsequent EAS and puborectalis denervation, following muscle re-innervation (Fynes & O'Herlihy, 2001; Sultan et al., 2009).

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). FI is associated with higher health care costs, both direct and indirect. 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). In the United States (USA), the annual costs of PFD were 298 million USD in 2005–2006 (Sung et al., 2010).

PFDs are very common and often coexist (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). In the USA, the prevalence of at least one PFD was 23.7 %, and 9.0 % of women had faecal incontinence (Nygaard, 2008). In the UK, 5.7 % of women reported faecal incontinence (Perry, 2002); in Sweden, this number was 10.9 % (Walter et al., 2002). 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); additionally, the rate of PFDs increases with increasing parity (Patel et al., 2006). The effect of parity decreases in postmenopausal women when age as a risk factor becomes more critical (Nygaard, 2006). Figure 1.3 shows the prevalence of FI and AI (MacLennan et al., 2000).

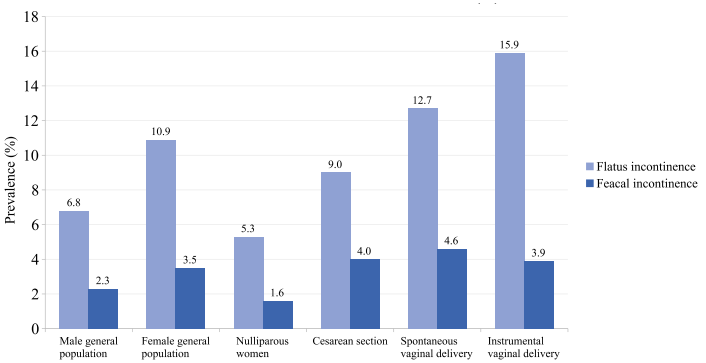

Figure 1.3 **Prevalence of faecal and flatus incontinence**

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) or injury to the pudendal nerve. OASI, in literature also described as severe perineal tears, includes both third and fourth-degree perineal lacerations. A long term follow-up showed that 29.2 % of women suffer from affected 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.

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 (Dahl & Kjølhede, 2006; Samarasekera et al., 2009). Overall, studies looking at the incidence of OASIS report an incidence of 4 % to 6.6 % of all VD, with higher rates in assisted deliveries (6 %) than in spontaneous VD (5.7 %) (Harvey et al., 2015). 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 %. (Guzmán Rojas et al., 2013).

The available imaging modalities of anal sphincter include endoanal ultrasound (EAUS), transvaginal ultrasound (TVUS), transperineal / translabial ultrasound (TPUS), with or without three-dimensional (3D) imaging, and MRI. **EAUS** is still considered the modality of choice and is also used widely by gastroenterologists and colorectal surgeons (Eisenberg et al., 2019, Sbeit et al., 2021). **TPUS** is at least as good as EAUS in sphincter evaluation (Eisenberg et al., 2019). Both transvaginal and transabdominal probes can be used in TPUS, placing them in the area of the fourchette. Advantages of the TPUS 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 TPUS 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).

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. Multichannel EMG is the summation of electrical contributions from individual motor units detected with multiple electrodes. EMG signals can be detected with electrodes inserted inside the muscle (intramuscular electromyography – iEMG) or with surface electrodes (surface electromyography – sEMG).

A **motor unit (MU)** is composed of anterior horn cell, axon, axonal branches, motor end-plates, and muscle fibres innervated by this cell. The ensemble of the neuromuscular junctions between the axonal branches and the muscle fibres is **innervation zone (IZ)** of that motor unit (Figure 1.4).

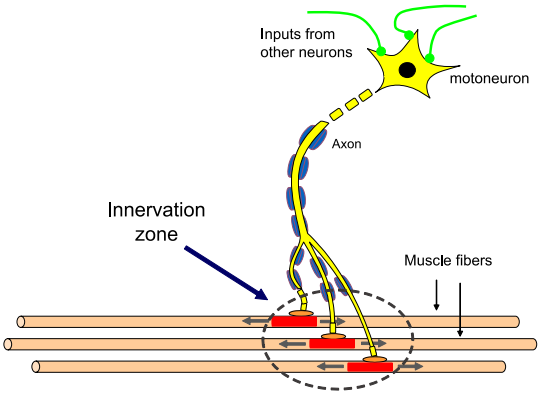

Figure 1.4 **Motor unit and its innervation zone**

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 of muscle contractions' strength, electrical activity is considered a representation of the level of strength developed by the muscles (Bocardi et al., 2018). EMG can detect signals only from striated muscles that are close to the skin or mucosa surface, thus, the muscles that are suitable for EMG detection are only EAS, levator ani and puborectalis muscles.

Different **types of probes** have been developed to assess the EMG activity of the pelvic floor. Superficial (adhesive around perineal zone), concentric needle electrodes, needle-guided wire electrodes, circular vaginal or anal probes have been investigated. Recent advances in pelvic floor electromyography and the achievements of the researcher group guided by prof. Merletti allowed the functional analysis of EAS with a minimally invasive anal probe (Merletti et al., 2004).

Different automatic offline algorithms can obtain a reliable and repeatable estimation of IZ distribution of EAS from high-density sEMG (Cescon et al., 2011; Marateb et al., 2016; Mesin et al., 2009; Ullah et al., 2014).

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 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.

Riga Maternity Hospital was the reference centre for measurement sessions in Latvia. Two 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 for the third phase of the study. The flow chart of the subjects in different phases of the study is represented in Figure 2.1.

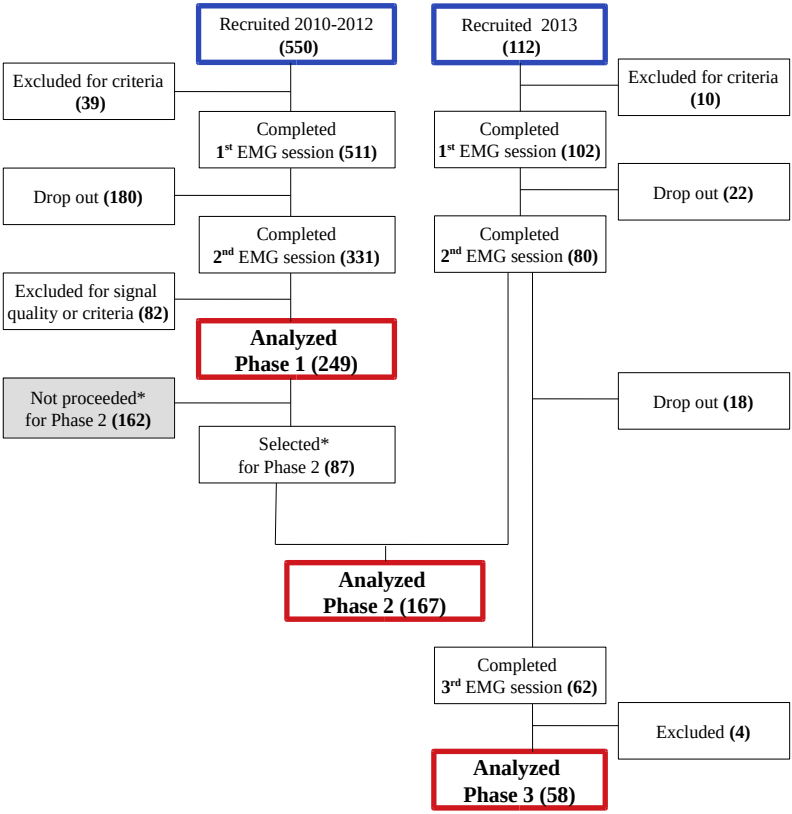

Figure 2.1 **Flow chart of the three study phases***
* Only the signals from Riga and Ljubljana were used for the analysis in phase 2.

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** 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 EAS EMG amplitude distribution and detect amplitude asymmetry index (AAI) in pregnant women. First, we divided the women into two groups: **1)** "Episiotomy" – women who underwent MLE, **2)** "Other" – other types of delivery – women who underwent CS or had spontaneous lacerations or intact perineum 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 and AAI left, **1B** – Episiotomy right and AAI right, **2A** – Other and AAI left, **2B** – Other and 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 and to compare the EMG amplitude in women who had vaginal delivery (VD) to those who had caesarean section (CS). The women were divided into two groups according to the type of delivery: **caesarean section and vaginal delivery**.

2.2 Inclusion and exclusion criteria

Subjects meeting the following criteria were included: expected first VD, normally progressing pregnancy from the 28th till the 36th week of gestation, signed informed consent form. We excluded subjects with the following conditions: FI 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, multiple pregnancies. Additionally, women with breech delivery, instrumental VD, 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.

2.3 Data collection and clinical questionnaires

Demographic data and clinical information regarding delivery (age, body mass index, 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.

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, subjects' past medical history and evaluation for the obstructed defecation syndrome (ODS). During the second measurement session, 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. 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 (Renzi et al., 2013). The total score is in the range of 0 (best) to 24. For FI 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 score of 0–20 (0 = perfect continence, 20 = complete incontinence) (Damon et al., 2006; Jorge & Wexner, 1993).

2.4 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 electrodes. 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 2kHz (Figure 2.2).

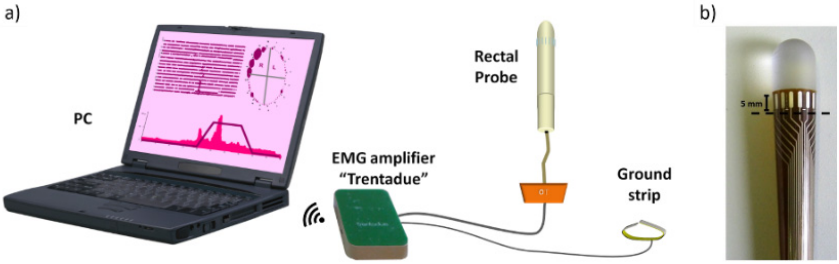

Figure 2.2 **Experimental set-up***

* a) laptop and wireless multichannel EMG amplifier, b) rectal probe.

After EMG signal acquisition, a visual inspection was performed, and signal quality was checked. Artefacts and distorted signals were discarded (when present). 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.

2.5 Assessment of outcomes

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. 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. Figure 2.3 shows an example of single differential EMG signals detected on a representative subject with an AAI of 45 %.

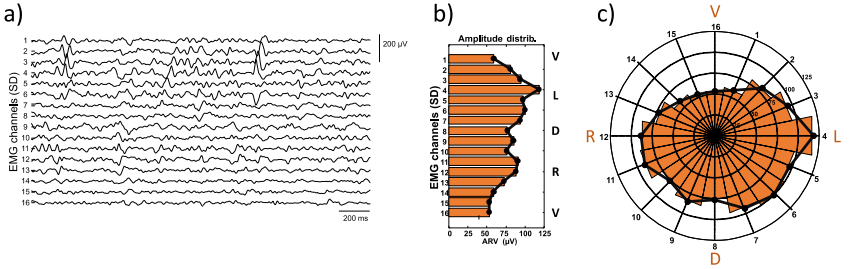

Figure 2.3 **Amplitude distribution***

* a) example of single differential EMG signals, b) amplitude distribution of the 16 channels. c) Distribution of amplitude as in panel b, represented in circular coordinates.

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. Figure 2.4 shows the distribution of IZs identified on one patient during MVC.

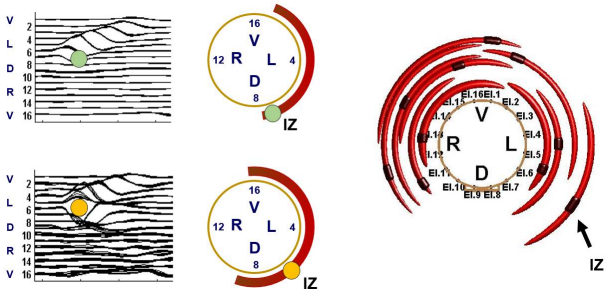

Figure 2.4 **Identification of the innervation zones** *

2.6 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 % CI. The model is a generalisation of standard linear models which allows random effects and non-normally distributed count responses, in our case, the IZ number, which is modelled as having Poisson distribution. For the second phase of the study, where the primary outcome was the EMG signal 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). For the third phase of the study, a statistical power analysis was performed using the "G*Power V" software (Faul et al., 2007; Cohen, 2013). 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.

2.7 Ethical issues

The study was conducted following the Declaration of Helsinki “Ethical principles in human medical research” and according to national legislation. All the participants signed informed consent form before measurements. The local Ethics Committee approved the study.

3 Results

3.1 Results of phase 1: evaluation of IZ distribution changes

For the first measurement session 511 women were recruited and participated in the multicentre study. For the second measurement session 331 women participated, the dropout rate being 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 N = 60 respectively), and in cases of VD, they were divided into intact perineum (N = 32), spontaneous perineal tears / lacerations (N = 75) and mediolateral right episiotomy (N = 82).

No statistically significant difference was observed for the subjects' BMI and infants' weight parameters between the four groups of subjects.

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, just upon the 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 VD with MLE pre and postpartum in Figure 3.1: significant reduction of IZs was observed on the right side after delivery, and the ARV at right side electrodes was reduced after MLE.

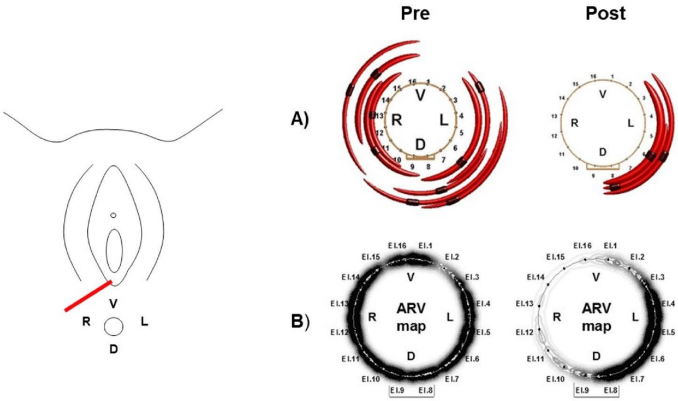

Figure 3.1 **Changes of IZs and ARV after MLE***

* V, L, R, D – corresponding quadrants. A) representation of MUs and IZs. Each red arch 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.

Table 3.1 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 3.1.

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 3.2 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).

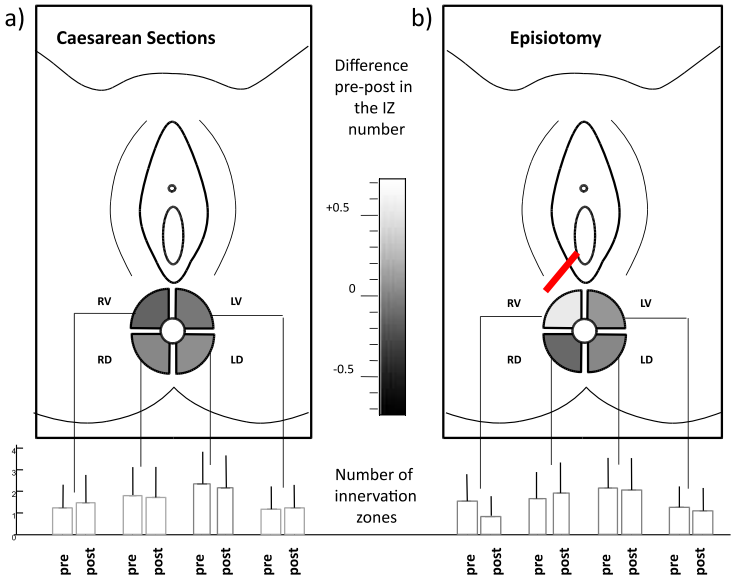

Figure 3.2 **Graphical representation of the estimates of the difference (pre to post-delivery) in the number of IZs***

* 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 analysis results 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 CS or VD with spontaneous lacerations.

3.2 Results of phase 2: amplitude asymmetry index

In total, 245 subjects concluded the first measurement session. 167 subjects were included for the analysis in the second session.

No significant differences were found between groups regarding clinical data, time of measurement, questionnaire results, and delivery type. None of the women had sphincter damage before pregnancy or wound complications or third or fourth-degree lacerations after delivery. The pregnancy duration 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 3.3).

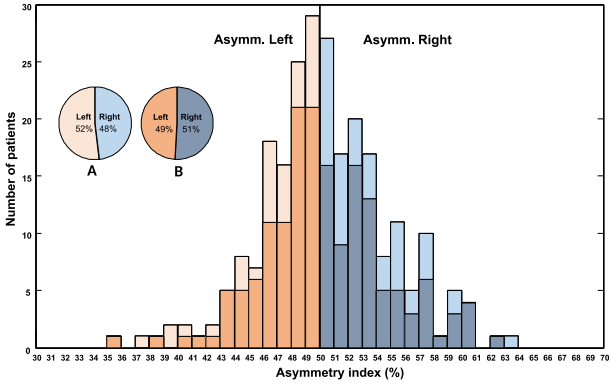

Figure 3.3 **Amplitude asymmetry index distribution before delivery***

* 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. No significant EMG amplitude changes were observed between the CS, spontaneous lacerations, or VD 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 (Fig. 3.4).

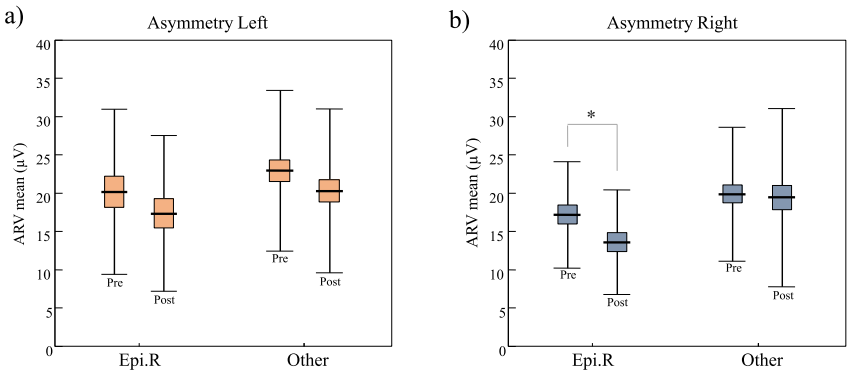

Figure 3.4 **Amplitude change after delivery: episiotomy versus other types of delivery***

* 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

112 women gave informed consent to participate in the study. 62 women completed all three sessions. Breech deliveries and instrumental VD were excluded at the second session according to exclusion criteria. Two groups were compared in this study: VD versus CS. 58 women (10 CS and 48 VD) were considered in the following analysis. The total dropout and exclusion percentage after three measurement sessions was 43 %. No significant difference was observed in demographic and clinical data between the two groups of women (CS and VD). 29 % of the women in the VD 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 MLEs were performed, and the average length and angle were 33 ± 0.9 mm and 42 ± 8 degrees, respectively.

Amplitude was evaluated in rest and MVC status in each subject at every measurement session for every channel. The ARV was calculated and compared between the VD and CS groups and the types of delivery. 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 3.5).

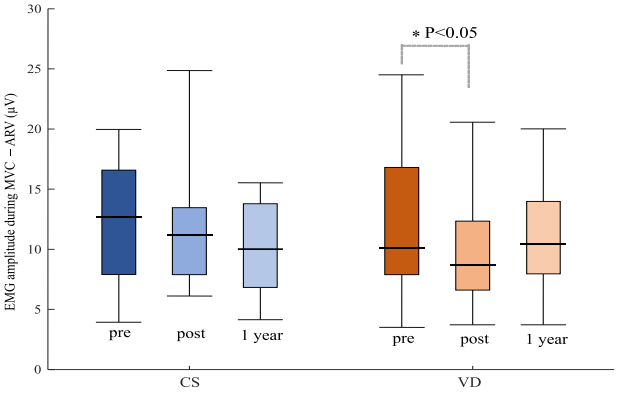

Figure 3.5 **Change of amplitude (ARV) in VD and CS groups over time**

Regarding clinical outcomes, the **incontinence score** was evaluated. The incontinence score slightly increased (but not significantly) after the delivery for both groups, Fisher test P = 0.67. About 30 % in CS and 20 % of women in the VD group showed a score equal to one or greater six weeks after delivery, compared to zero 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. No association was observed between the increase of incontinence score and the decrease of EMG signal amplitude (see Figure 3.6).

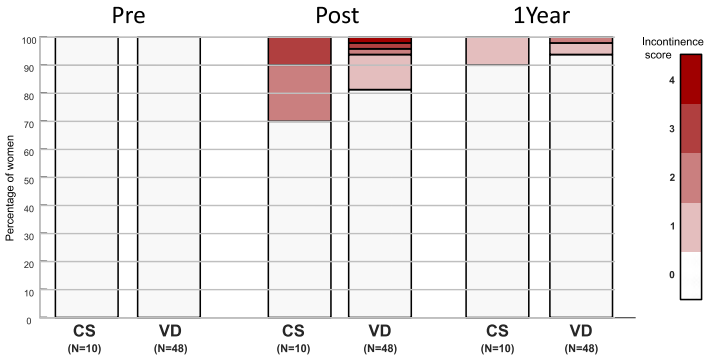

Figure 3.6 **Incontinence score changes between CS and VD**

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
- 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 % – had 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

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). Wietek et al. 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 (Wietek et al., 2007). 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. The decrease of amplitude observed after delivery was reported previously in a study where perineometry assessments of PFMF were performed at 20 and 36 weeks gestation and 14 weeks and 12 months after VD (Elenskaia et al., 2011). 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.

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 VD with episiotomy, normal VD without episiotomy or caesarean section) (Afshari et al., 2016). In the above study, women who had a VD with episiotomy had lower pelvic muscle strength than the nulliparous women, women with normal VD 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 VD or elective CS six months after delivery, and the results of the present thesis are in line with these findings.

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).

Other studies that used EMG for PFM assessment after delivery were based on vaginal probes. Li et al. performed pelvic muscle electrophysiological examination 8–12 weeks after delivery with a muscle potential probe inserted into the vagina (Li et al, 2015). Contrary to the thesis results, they did not find a significant difference in early postpartum PFM strength between the CS (66 cases) and VD (83 cases) groups and they did not compare the status before and after delivery. 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.

Regarding clinical outcomes, in our study, the FI 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 FI (Heitmann et al., 2019; Young et al., 2017) since the heterogeneity of anorectal dysfunction exists and many other contributing factors 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 AI. *Kaiser Permanente Continence Associated Risk Epidemiology Study* found AI in 16 % of the CS 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. The results of both studies cannot be compared directly since, in the Kaiser study, more than half of the women were postmenopausal. Larsson performed another population-based study, showing that women after VD were more likely to have AI than women who underwent only CS (Larsson et al., 2019). 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. A meta-analysis using a comparable time frame to the thesis – first 12 months postpartum – showed that women having any type of VD compared with a CS had an increased risk of developing symptoms of solid, liquid or flatus anal incontinence (OR 1.32) (Pretlove et al., 2008). Similar to the conclusions of the thesis, the meta-analysis

concluded that we do not have sufficient evidence to advocate CS for the reduction of incontinence symptoms in women without antenatal symptoms of AI. Also, Nelson (Nelson et al., 2010) concluded that no benefit could be demonstrated for CS over VD in the preservation of AI.

The main limitation of the thesis study is that MLE was always performed on the right side. Since there were no episiotomies on the left side, it is assumed that the behaviour could be considered the same in a "mirrored" situation. Another limitation of the study is the number of dropouts postpartum. Still, the percentage of dropouts is low compared to other similar design studies, e.g. the study assessing PFM force with perineometry reported just 39 % of initially recruited women included in the final analysis (Elenskaia et al, 2011).

The strength of our research is the prospective longitudinal design, which provides data of the same measurements with one antenatal and two postnatal assessments. The present study is the first study on anal sphincter sEMG in pregnant women with three measurement sessions and one-year follow-up. 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.

Although one could conclude that episiotomy should be avoided to preserve EAS innervation, the author of the thesis would avoid this generalisation. Clinicians have to consider other risk factors related to CS and the benefits of episiotomy during VD 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.

Conclusions

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

- The findings of the study confirm that the global EMG amplitude and IZs distribution have considerable 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, while no significant changes are visible in IZs distribution after CS or after VD 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. Episiotomy changes the asymmetry index.
- 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 of 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, since 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.

In conclusion, the author offers some **practical recommendations**:

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

Clinical implications and future aspects of the study

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.

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 evaluation 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.

There are large 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 over activity, 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 and 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.

Publications

Publications in 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.
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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.
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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.

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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.

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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). *Latvijas ginekologu un dzemdību speciālistu 7. kongresss*, Rīga, Latvija, 2014. g.

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