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PELVIC FLOOR DYSFUNCTION AFTER CHILDBIRTH - SYMPTOMS, DIAGNOSIS, TREATMENT

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Pelvic Floor Dysfunction After Childbirth -

symptoms, diagnosis, treatment

THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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The thesis will be defended in public at Erna Möller Lecture Hall, Blickagången 16, Karolinska Institutet, Campus Flemingsberg on **Friday December 2nd, 2022, at 9 am.**

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To my family

I was taught that the way of progress was neither swift nor easy

\- Marie Curie

ABSTRACT

Vaginal delivery is a trauma to the levator ani muscles, the perineal muscles, and the anal sphincter complex (1-3). A levator ani deficiency cannot be surgically remedied and increases the risk of pelvic floor dysfunction later in life (4-6). Contrarily, an injury to the perineal body can be sutured directly following vaginal birth, however, perineal trauma may in the aftermath result in a deficient perineum. There is a lack of knowledge regarding the natural history of recovery after vaginal childbirth, which symptoms are reported, and how high the prevalence of persistent symptoms is. Thus, there is a need for improved tools to identify and diagnose women displaying symptoms of deficiencies in either level of the pelvic floor and develop refined treatment options, with the ultimate goal of improved quality of life. Therefore, the overall aim of this thesis was to explore the symptoms, diagnostics, and possible surgical treatment associated with a deficient perineum and concomitant levator ani muscle defects.

Study I was a prospective cohort study investigating symptoms in non-instrumentally delivered primiparas with no more than a second-degree perineal tear, one year after delivery. In total, 410 women completed an inventory of questions encompassing fecal incontinence, bowel emptying difficulties, and sexual dysfunction. The results showed that symptoms from the posterior compartment were common irrespective of the extent of the perineal tear. In conclusion, these symptoms must be considered and addressed in all women after vaginal delivery.

Study II was an observational study to evaluate how consistently different raters can assess levator ani defects using the Levator Ani Deficiency (LAD) score system in a subsample of primiparas from study I. In addition, rates of LAD in this low-risk subsample were estimated. By using two different endovaginal probes, three-dimensional ultrasound volumes of 141 women were assessed on two occasions. Correlations of scores and categories within and between raters and probes were calculated using Kendall's tau-b coefficient. Overall, intra- and interrater, and -probe correlations were very high with correlations for intrarater comparisons of >0.79 and interrater comparisons of >0.78. However, the rate of LAD in this low-risk subsample was, as expected, low, 13-15% had scores correlating to a moderate or severe injury. In conclusion, the LAD scoring system can be reproduced consistently.

Study III was a mixed methods study to construct and initially validate an inventory to estimate symptoms of a deficient perineum. The preliminary inventory was tested on 170 patients diagnosed with a deficient perineum and results were compared to 54 primiparous women one year after elective caesarian section and 338 nulliparous women. Results showed that the final 11-item inventory, the 'Karolinska Symptoms After Perineal Tear Inventory' (KAPTAIN) could discern patients with symptoms such as an acquired sensation of wide vagina, vaginal flatulence, and bowel emptying difficulties, from the two control groups with high sensitivity (100%) and specificity (87–91%) when using a cut-off of 8 points out of a maximum score of 33 points. To conclude, the KAPTAIN inventory can detect symptomatic women with high

accuracy and might be used to identify women in need of further support and investigation after vaginal birth.

Study IV was a follow-up study one year after standardized perineal reconstructive surgery of 131 patients with long-term symptoms of a deficient perineum. Patients with symptoms e.g., an acquired sensation of wide vagina, and a confirmed perineal body defect, completed the KAPTAIN inventory preoperatively and at one-year follow-up. All patients were examined with 3D ultrasound to evaluate concomitant LAD. The hypothesis that the primary outcome "sensation of wide vagina" would not improve as much in patients with LAD as in patients with an intact levator ani muscle was rejected. There was an overall significant score reduction after surgery for the whole group. In conclusion, a standardized perineal reconstruction can alleviate symptoms of a deficient perineum independent of LAD.

SAMMANFATTNING

Bäckenbottendysfunktion är ett samlingsbegrepp som beskriver olika besvär och åkommor som är kopplade till bäckenbottens muskler och stödjevävnader. Historiskt sett har besvären delats in i tre huvudgrupper: urinläckage, avföringsläckage och framfall av slidans väggar eller av livmodern. Det finns dock en mängd mindre uppmärksammade symptom som påverkar många kvinnors livskvalitet. Den översta nivån av bäckenbottens stöd utgörs av levator ani muskulaturen och den nedersta nivån utgörs av mellangården. Skador på mellangården kan åtgärdas kirurgiskt men levatormuskulaturen är tyvärr svår att komma åt. Det saknas kunskap om vilka symptom kvinnor har efter en vaginal förlossning och hur vanliga långvariga symptom är. Det behövs också bättre diagnostik och behandlingsalternativ för de kvinnorna som har uttalade besvär efter en vaginal förlossning. Avhandlingens övergripande syfte var att utforska de symptom kvinnor har efter förlossning, hur diagnostiken kan förbättras och om en rekonstruktion av mellangården kan vara av värde även för kvinnor med skador på levatormuskulaturen.

Studie I var en prospektiv kohortstudie som undersökte bäckenbottenbesvär hos förstföderskor ett år efter förlossning. Alla deltagare var icke-instrumentellt förlösta och fick första eller andra gradens bristningar i samband med förlossningen. Totalt 140 kvinnor besvarade en enkät som innehöll frågor om avföringsläckage, tarmtömningsbesvär och samlivsbesvär. Hypotesen var att kvinnor med ingen eller en första gradens förlossningsbristning skulle beskriva mindre besvär än de som blivit diagnosticerade med en andra gradens bristning, men resultaten visade inga statistiskt signifikanta skillnader mellan grupperna. Sammanfattningsvis tyder studiens utfall på att besvär som avföringsläckage, tarmtömningsbesvär och samlivsbesvär förekommer och måste fångas upp hos alla kvinnor efter vaginal förlossning oberoende av förlossningsbristning.

Studie II var en observationsstudie där tillförlitligheten av ett poängsättningssystem (LAD score) för bedömning av skador på levator ani muskulaturen testades med tredimensionellt ultraljud. Två olika granskares upprepade skattningar av tredimensionella ultraljudsbilder med två olika prober jämfördes. Sammanlagt jämfördes 141 undersökningar utförda på kvinnor från kohorten i studie I. Skador på muskulaturen poängsattes och kategoriserades enligt LAD score (milda/moderata/svåra). Samstämmigheten för undersökningar av samma och mellan de två granskarna beräknades med Kendall's tau-b korrelationskoefficient. Sammantaget var samstämmigheten hög både enskilt (korrelationer >0.79), mellan granskare (korrelationer >0.78) och mellan ultraljudsproberna. Som förväntat var andelen levatorskador låg bland de undersökta kvinnorna. Summerat kan LAD score systemet återskapas med hög samstämmighet, men skulle behöva anpassas om det planeras användas i en lågrisk population.

Studie III var en studie med målet att skapa och primärt validera ett instrument för att skatta symtom som uppkommer på grund av en felläkt mellangård. Instrumentet skapades med hjälp av resultat från en tidigare kvalitativ studie samt genom att se över olika befintliga instrument. Föreslagna frågor granskades sedan av experter inom urogynekologi, samt av kvinnor med symtom. Frågor togs bort, ändrades och lades till och ett preliminärt instrument om 41 frågor

skapades. Instrumentet testades på 170 patienter med defektläkt mellangård. Principal komponent analys användes för att reducera antalet frågor. Studien resulterade i ett formulär bestående av elva frågor, 'Karolinska Symptoms After Perineal Tear Inventory', KAPTAIN. Instrumentet validerades mot 54 förstföderskor minst ett år efter planerat kejsarsnitt, samt 338 kvinnor som aldrig varit gravida. Resultaten visade att vid 8 poäng på KAPTAIN av max 33 poäng var 100% av patienterna medräknade och endast 9–13% av kvinnorna i de andra två grupperna. Följaktligen dras slutsatsen att KAPTAIN kan upptäcka kvinnor med besvär med hög precision och skulle kunna användas för att hitta kvinnor i behov av utökad undersökning efter vaginalförlossning.

Studie IV var en uppföljningsstudie av 131 patienter ett år efter melllangårdsrekonstruktion. Patienter som remitterats till Karolinska universitetssjukhusets bäckenbottencentrum på grund av vidhetskänsla, och med en bekräftad mellangårdsdefekt, genomgick en gynekologisk undersökning med bland annat tredimensionellt ultraljud för bedömning av levator ani muskulaturen samt besvarade KAPTAIN (studie III) vid inklusion i studien. KAPTAIN besvarades sedan igen ca ett år efter operationen. Hypotesen att kvinnor med levatorskador skulle gagnas mindre av kirurgisk rekonstruktion än kvinnor med intakt levator ani muskulatur förkastades. Symtomreduktion kunde ses för symtomet vidhetskänsla samt generellt för alla frågor i KAPTAIN. Således kan slutsatsen dras att standardiserad mellangårdsrekonstruktion kan lindra besvär av en felläkt mellangård oberoende av samtidig levatorskada.

LIST OF SCIENTIFIC PAPERS

The following papers will be referred to by their roman numerals.

I. **Rotstein E**, Åhlund S, Lindgren H, Lindén Hirschberg A, Rådestad I, Tegerstedt G
Posterior compartment symptoms in primiparous women one year after non-assisted vaginal deliveries – a Swedish cohort study
International Urogynecology Journal 2021 Jul;32(7):1825–1832.

II. **Rotstein E**, Ullemar V, Starck M, Tegerstedt G
Intra- and interrater reliability in levator ani deficiency scoring with 360° three-dimensional endovaginal ultrasonography in primiparous women
Manuscript

III. **Rotstein E**, von Rosen P, Karlström S, Elings Knutsson J, Rose N, Forslin E, Palmgren PJ, Tegerstedt G, Engberg H
Development and initial validation of the 'Karolinska Symptoms After Perineal Tear Inventory'
BMC Pregnancy Childbirth. 2022 Aug 13;22(1):638.

IV. **Rotstein E**, Ullemar V, Engberg H, Lindén Hirschberg A, Ajne G, Tegerstedt G
One-year follow-up after perineal reconstruction in women with deficient perineum after vaginal delivery
Manuscript

LIST OF RELATED PAPERS

Åhlund S, **Rothstein E,** Rådestad I, Zwedberg S, Lindgren H.
Urinary incontinence after uncomplicated spontaneous vaginal birth in primiparous women during the first year after birth.
International Urogynecology Journal 2020 Jul;31(7):1409-1416.

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LIST OF ABBREVIATIONS

AI	Anal incontinence
CS	Caesarean section
EVUS	Endovaginal ultrasonography
FI	Fecal incontinence
KAPTAIN	The Karolinska Perineal Tear Inventory
LAD	Levator ani deficiency
LAM	Levator ani muscle
MRI	Magnetic resonance imaging
OASI	Obstetric anal sphincter injury
PCA	Principal component analysis
PFD	Pelvic floor disorder
POP	Pelvic organ prolapse
UI	Urinary incontinence
3D	Three-dimensional

1 INTRODUCTION

Childbirth is the most natural thing in the world - what could possibly go wrong? In Western society, it might be that the dilemma of the dual focus in obstetrics usually results in the focus lying heavily on the wellbeing of the fetus, less on potential long-term consequences for the woman. All immense advances of humankind have also resulted in a disproportionally large brain and scull, regrettably the rest of the female pelvic is still lagging as far as adaptational changes are concerned. This leaves us with a unproportionally large fetal head making its way through an already compromised area: the levator ani hiatus and the vaginal opening. Even though the fetal head does adapt its shape somewhat during the descent into and through the birth canal, the fibromuscular tissues are stretched and compressed far beyond reasonable physiology (1, 3).

In Sweden, about one in 20 women giving birth is diagnosed with a severe perineal injury involving the anal sphincter muscles (OASI) with short and long-term consequences that may include pain, difficulties controlling bladder or bowel, and different forms of sexual dysfunction. (7). The corresponding number for a deficient perineum resulting from a tear not involving the anal sphincter complex can only be speculated on, considering that roughly 70-85% of all vaginal deliveries result in non-OASI tears (8). However, there is a multitude of pelvic floor symptoms that greatly impair the quality of life, but are difficult to address freely, which is why they are frequently neglected by patient and health care provider alike (9-11).

In the context of women empowerment and social media bridging geographical and social gaps to facilitate conversations and lift old taboos, a new group of patients is emerging, eager to shine a light on poorly explored symptoms and demanding active participation in their own treatment.

The awareness of pelvic floor symptoms after pregnancy and delivery increases at an exponential rate as women become more conscious and demand enhanced diagnostics and treatment options. This has been further explored by the Swedish Agency for Health Technology Assessment of Social Services (SBU) in its report on how this group of patients are received and treated by health care workers (9). Amongst others, it states the lack of diagnostic tools supplying consistent patient information, and validated instruments to aid health care workers and patients to address, verbalize, and form treatment strategies for postpartum pelvic floor dysfunction.

Therefore, this thesis highlights the diagnostics, symptoms, and treatment of a deficient perineum, an elusive topic connected with many social and cultural taboos. Thus, I hope it may contribute to helping affected women.

2 THESIS AT A GLANCE

Study	Research question(s)	Method(s)	Results	Conclusions
I	Do women with a second-degree perineal tear experience more posterior compartment symptoms in comparison with women with none-or-first-degree perineal tears?	Prospective cohort study of 410 primiparas one year after vaginal delivery. Symptoms questionnaire analyzed by descriptive and univariate statistics.	1 in 5 women report bowel emptying difficulties regardless of perineal tear. No statistically significant differences between the groups were found regarding reported posterior compartment symptoms.	Symptoms after vaginal birth are not dependent on grade of perineal tear. Therefore, information regarding symptoms after vaginal birth, regardless of perineal tear, could help women when to seek care.
II	Is the LAD score a feasible and reproduceable assessment? How consistently can different raters assess the LAD score in 3D ultrasound volumes measured by different probes?	Observational cross-sectional study. Using 3D endovaginal ultrasound, 141 primiparas were examined with two different probes. The LAM was scored by two raters at two separate times. Kendall's tau-b was used for comparisons.	The overall intra- and interrater reliability was high for both probes with Kendall's tau correlation coefficients >0.7 across all comparisons.	The LAD score is a feasible and reproducible system in assessing the levator ani muscle integrity. The LAD score should be correlated to clinical findings and symptoms and not be used as a screening assessment in a low-risk population.
III	How can a clinical screening inventory be developed and validated to measure symptoms in women with a deficient perineum?	Mixed methods study; Construction of items: literature review, expert panel, and Think Aloud interviews. PCA for item reduction. Scores were compared between patients with deficient perineum and two control groups. ROC curves for optimal score cut-off.	An 11-item inventory that could distinguish symptomatic patients with a deficient perineum from control groups with 100% sensitivity and 87-91% specificity at a cut-off of 8 points out of 33 possible.	The inventory can distinguish symptomatic women with deficient perineum. It may be a valuable screening tool for detection of symptoms of a deficient perineum and an inventory for follow-up after perineal reconstructive surgery.
IV	Can standardized perineal reconstructive surgery alleviate symptoms in patients with a deficient perineum irrespective of concomitant LAD?	Observational follow-up study; 131 patients with a deficient perineum, LAD score and symptom inventory (study III) at baseline and follow-up. Score difference for individual items and in total is calculated.	A statistically significant score reduction for the symptom of an acquired sensation of wide vagina, irrespective of concomitant LAD.	Standardized perineal reconstructive surgery reduces symptoms of a deficient perineum both in patients with and without a concomitant LAD.

3 BACKGROUND

Historically, cadaver dissection was the only way to gain knowledge of anatomic structures, and there was no way to study the functional anatomy of the pelvic floor and its dysfunction in vivo. Great advances were made by the research group of James Ashton-Miller and John DeLancey – a biomechanical engineer and an anatomist, who joined forces to explore the pelvic floor via MRI and subsequent biomechanical models. Albeit their early focus being primarily the etiology of pelvic organ prolapse, it nevertheless paved the way of understanding the importance of the levator ani muscle (LAM) complex on the functional anatomy of pelvic floor and the repercussions of vaginal delivery on its anatomy as a whole (1, 3, 12-15).

3.1 THE FUNCTIONAL ANATOMY OF THE PELVIC FLOOR

There is no consistency in the definition of the pelvic floor in literature. In this thesis, we have chosen to define the pelvic floor as all the soft tissues enclosed by the bony pelvis, barring the viscera, namely the supportive connective tissues and the pelvic floor muscles (1). The bony pelvis is made up of the two paired bones of the ilium and ischium of the pubic bone, and the sacrum with the coccyx attached to it. They are joined together anteriorly by the pubic symphysis, and posteriorly by the paired sacroiliac joints, and are commonly referred to as the pubic ring (16-19). The stability of the bony structures is further supported by several ligaments, such as the sacroiliac, sacrotuberous and sacrospinous ligaments to name the major ones. Furthermore, the endopelvine fascia is a strong yet elastic sheath that attaches the vaginal walls and uterine cervix to the ligaments and bony structures of the pelvic. This collagenous tissue contains elastin, smooth muscle fibers, as well as nerves and lymph vessels, and thickens into the arcus tendineus fascia pelvic and levator ani respectively, as well as the uterosacral and cardinal ligaments (20). Moving on to the pelvic floor muscles, they comprise a funnel-like structure leading from the apical layers at the level of the pelvic inlet to the most caudal part of the body at the vaginal introitus and the perineum. The deepest layers consist of the LAM complex, a hammock-like group of muscles spanning from one arcus tendineus to the other laterally, and from pubic bone to sacrum and coccyx in anterior-posterior view (21). Caudally, it is connected to the more superficial layers of the pelvic floor – the profound and superficial transverse perineal muscles, the bulbocavernosus muscle and the external anal sphincter (20-22). The uniqueness of the pelvic floor muscles lies in their multifunctionality.

3.1.1 The levator ani muscles

Contrary to most skeletal muscles, the LAM maintain a constant tone, thus keeping the levator hiatus closed and supporting the urogenital organs at rest. During voiding and defecation, it relaxes and opens the hiatus, which in turn reduces the compression of the urethra, vagina, and rectum against the pubic bone. The LAM is frequently referred to as the pelvic diaphragm, and constitute the largest functional unit of the pelvic floor (20). There are differences in nomenclature of the LAM complex as well, however, here it will be referred as a unit of three muscle sections. Firstly, the most posterio-lateral section, which attaches to the arcus tendineus levator ani and inserts into the anococcygeal ligament and coccyx: the iliococcygeal muscle, which expands posteriorly along the pelvic sidewalls. Second, the most medial portion of the LAM complex, the pubococcygeal muscle (12), inserts onto the medial pubic bone and spans along the lateral vaginal walls (pars pubovaginale), and into the perineal body (pars puboperineale) and into the interspincteric groove (pars puboanale) (15, 16, 23-26). Finally, the puborectalis muscle, attaches to both sides of the pubic symphysis, thus forming a sling around the rectum (17, 19, 21). The levator hiatus is the central opening of the pelvic diaphragm. It envelopes the urethra and bladder neck, the vagina, and the rectum, forms the anorectal angle, and is the largest hernial orifice of the female body (27).

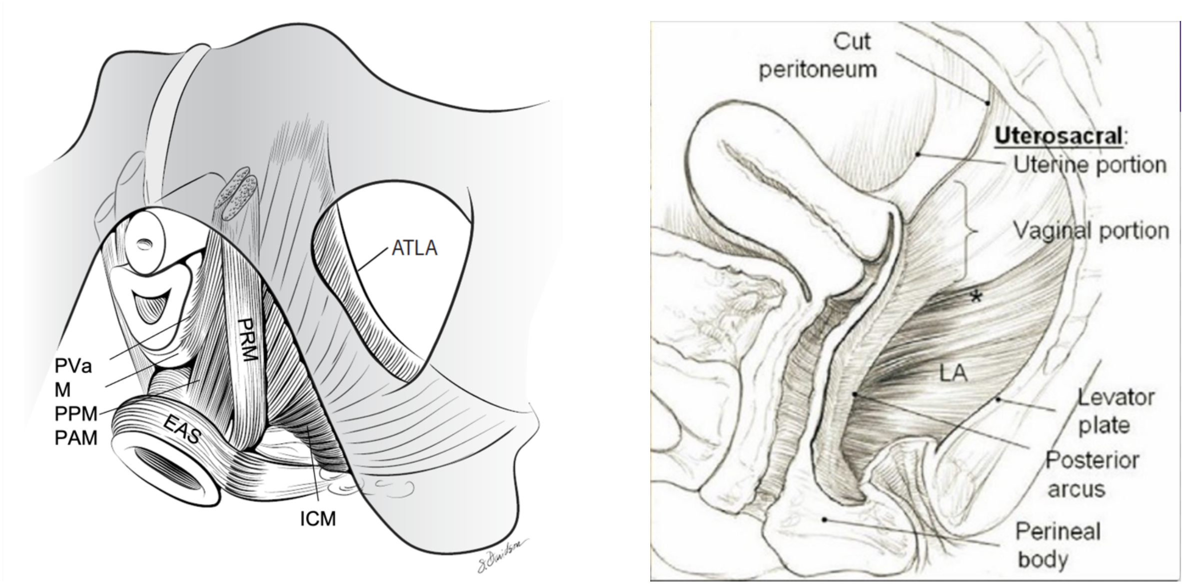

Figure 1. Levator ani muscle (LAM) from below after the vulvar structures and perineal membrane have been removed. Arcus tendineus levator ani (ATLA); external anal sphincter (EAS); puboanal muscle (PAM); pubovaginal muscle (PVa), puboperineal muscle (PPM); iliococcygeal muscle (ICM); puborectal muscle (PRM). Reprinted with the permission of John DeLancey.

3.1.2 The perineal body

The perineal body is situated at the midline of the perineum and connects fascial structures and muscles in a the central hub (28). Although in plain sight as the distal-most part of the pelvic floor it is an intricate system of fibromuscular structures. It is situated in the perineal midline between the anus and posterior fourchette of the vulva. As mentioned previously, it is an integral part of the pelvic floor support. It constitutes the attachment point of the bulbocavernosus muscle anterolaterally, the deep and superficial transverse perineal muscles proximally and laterally respectively, and the external anal sphincter posteriolaterally (29). In addition, the perineal fascia, also called the perineal membrane, envelopes the deep transverse perineal muscles and attaches to perineal body anteriorly, and the rectovaginal septum connects to it proximally. Furthermore, the puboperinealis and puboanalis muscle portions adhere to the perineal body laterally and proximally (30).

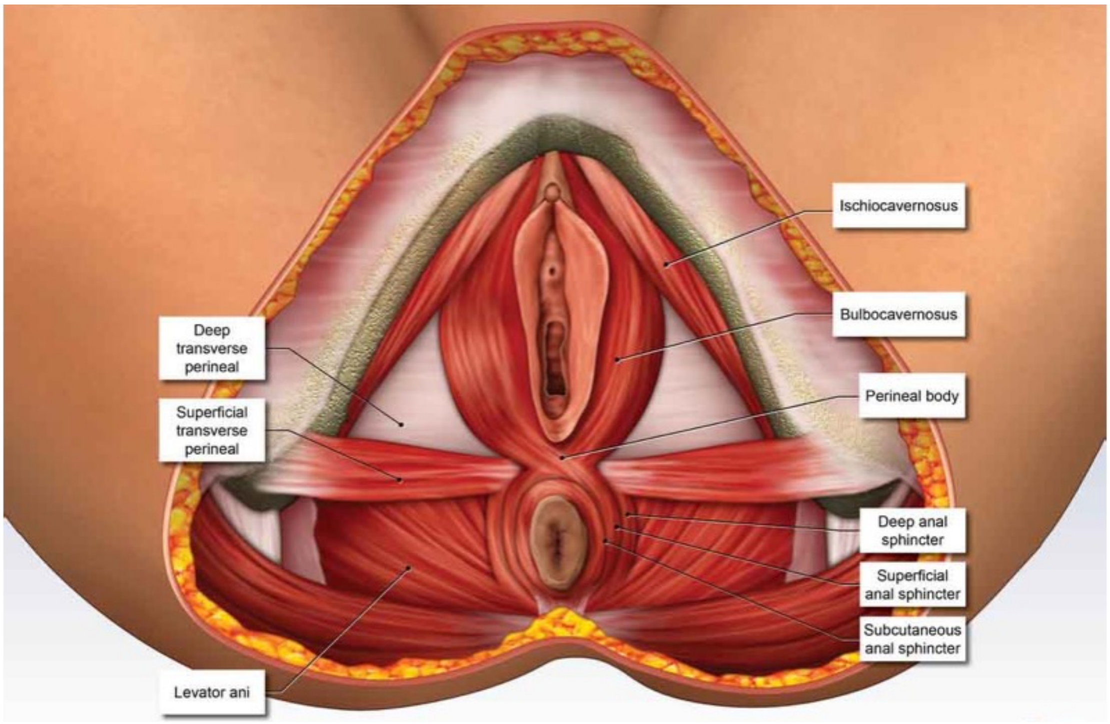

Figure 2. The muscles attaching to the perineal body. Reprinted with the permission of Trial Exhibits.

Rodenbaugh at al. suggest imagining the perineal body as multiple cords strung up together into a knot; if one cord breaks, the balance of the knot shifts thus causing an imbalance which impairs its function (31).

3.2 THE PELVIC FLOOR, PREGNANCY AND VAGINAL BIRTH

Changes of impaired pelvic organ support may occur during pregnancy and are accentuated after vaginal delivery (32, 33). Despite the recent shift in focus toward pelvic floor dysfunction postpartum, the physiological mechanisms preceding such disorders remain mostly uncertain. An assessment of its pathology is therefore essential in the understanding of pelvic floor dysfunction (34).

3.2.1 Classification of obstetric tears

Obstetric perineal trauma varies greatly from very small lacerations of the skin or mucosa of the vulva and vagina to extensive tears involving the fibrous structures and muscles of the perineal body and anal sphincter complex. As far as the diagnostics of OASI are concerned, the different dimensions referring to the extent of the torn structures have been addressed as a subdivision of anal sphincter tears is in use. However, this established classification by the

Royal College of Obstetricians and Gynaecologists (RCOG) which is widely adapted, does not differentiate between minor or more expansive injuries to the perineum not involving the sphincter complex; they are all referred to as a second-degree perineal tear (Table 1). Attempting to sharpen this diagnostic tool, the Swedish Society of Obstetrics and Gynecology has recently put forth a subclassification for second-degree perineal tears (Table 2).

Table 1. Classification of perineal trauma, RCOG (35).

Degree of perineal tear	Definition
First degree	Rupture of the perineal skin and vaginal epithelium
Second degree	Rupture of the perineal muscles but not involving the anal sphincter muscles
Third degree	Injury to the perineal muscles and the anal sphincter complex; subdivided into three categories: 3a: less than 50% external sphincter muscle thickness ruptured 3b: more than 50% external sphincter muscle thickness ruptured 3c: both external and internal anal sphincter muscles ruptured
Fourth degree	Rupture of the external and internal anal sphincter muscles and anorectal mucosa

Table 2. Subclassification of second-degree perineal tears, Swedish Society of Obstetrics and Gynecology 2020 (36).

ICD-10 code	Definition
O70.1A	Second degree perineal tear involving <50% of the perineal body. May include a vaginal tear with a depth <2 cm.
O70.1B	Second degree perineal tear involving >50% of the perineal body. May include a vaginal tear with a depth <2 cm.
O70.1C	Second degree perineal tear involving the entire perineal body and a vaginal tear of ≥2 cm depth but ≤4 cm length
O70.1D	Second degree perineal tear involving the entire perineal body and a vaginal tear of ≥2 cm depth and ≥4 cm length

3.2.2 Levator ani muscle defects

The main purpose of the LAM is to support the pelvic organs and keeping the hiatal opening at minimal dimensions, thus maintaining continence (13). Controversially, it also calls for extraordinary elasticity during vaginal delivery, when it must distend considerably to facilitate and allow the fetus to pass through the birth canal (27, 37, 38). LAM resting tone and contractility are both vital to assert continence and prevent POP. LAM defects, particularly avulsion injuries, are associated with an enlargement of the genital hiatus of 20–30% which leads to decreased resting tone and impaired contractility (4, 34, 39-41). It appears that levator trauma is most likely to occur at the first vaginal delivery (1, 3, 34, 42-44). Trauma to the LAM is often occult and not diagnosed at the time of vaginal delivery (41, 45), although perineal and vaginal tears may be useful clinical indicators of levator avulsion (2, 3, 34, 45-47). An avulsion injury, when the muscle is torn from its insertion to the pubic ramus, constitutes a major risk factor for pelvic organ prolapse , yet it is still debated whether it is also a risk factor for anal incontinence (AI) and urinary incontinence (UI)

In addition to avulsion, the straining efforts of vaginal delivery stretch and compress the nerves of the pelvic floor, potentially leading to ischemia, edema and damaged nerve function (48). It has been shown that nerve damage during delivery can result in atrophy of the LAM, which changes its morphology and function (49). There are hypotheses that nerve damage and muscle trauma occurs in most women after vaginal delivery, though in many cases, wound healing, physiological reinnervation, and muscle rehabilitation compensate these effects (14, 50). However, in some women (5–20%), irreversible impairment of pelvic floor function is the result of injured nerves and LAM avulsion (14, 51-54).

3.2.3 The deficient perineum

The deficient perineum is an anatomical defect essentially attributable to the trauma of vaginal delivery. There are known adverse outcomes associated with perineal tears and surgical perineal repair, such as short-term pain, voiding or defecation difficulties, discomfort from the suture material and disruption of reverting to normal daily function postpartum. In the long-term perspective, dyspareunia, persistent perineal pain, urinary, and fecal incontinence (flatus and/or formed stool) have been described (43, 55-60). The long-term effects of OASI are quite well studied, and the knowledge of e. g., persistent fecal incontinence is established (55, 61-65). In addition, a shortened or reduced perineal body has been shown to be associated with pelvic organ prolapse, in particular, of the posterior vaginal wall (66).

A study published by Gommesen et al. in 2019 examined women with first- to fourth degree perineal tears one year after birth. Severe obesity and episiotomy were found to increase the risk of perineal wound complications such as infection or dehiscence (67). The same group has also found that sexual dysfunction one year after childbirth such as dyspareunia was commonly seen especially in women diagnosed with second-to-fourth degree lacerations (68). This is in line with a previous study that has shown that women who do not experience perineal trauma with their deliveries report minor symptoms, and the greater the trauma, the higher the frequency or severity of postpartum dyspareunia, indicating that it is important to strive to minimize the extent of perineal damage (58, 69). Reported symptoms of a deficient perineum include bowel-emptying difficulties, incontinence of loose stool and flatus, as well as vaginal flatulence, dyspareunia, a sensation of bearing down, and the sensation of a gaping or wide vaginal opening (41, 70-73). However, there is a lack of studies reporting outcomes after treatment of a deficient perineum with management often delayed and with a variety of surgical alternatives.

3.2.4 Pregnancy and mode of delivery

It has been shown that pregnancy, especially the first pregnancy, may uncover inherent frailty of the pelvic supportive structures and is a predictive measure for future symptoms of pelvic floor dysfunction. Studies on the connective tissue structure in women with or without stress urinary incontinence have shown that there are defects in the connective tissue in women with stress urinary incontinence (74-76). Usually, incontinence in pregnancy is transient and could be interpreted as the result of predisposing hereditary factors, hormonal fluctuation, and the increased pressure on the bladder-neck that a progressing pregnancy constitutes (33, 74-81). This may also serve as a valid explanation as to why cesarean delivery, elective or after onset of labor, is not totally protective against future pelvic floor dysfunction. Aiming to identify women susceptible to PFD later in life, Siafarikas et al., using 3D pelvic floor ultrasound, found that a large levator ani hiatus antenatally was protective against levator avulsion (82). In addition, such techniques offer the opportunity for antenatal counseling and might add valuable information for preventive treatment strategies in the future (83-85).

Several research articles state the association of vaginal delivery with the development of PFD, but there is no agreement on whether cesarean section is protective (34, 86-88). Elenskaia et al. showed that a woman's first vaginal delivery is when she is most likely to sustain pelvic floor damage. The effect of obstetric factors is to some extent transitory and pelvic floor muscle function recovers greatly in the year after delivery. Correspondingly, van Deft et al. have shown that up to 35% of primiparas who have delivered vaginally may present with a hematoma at the insertion site of the LAM within the first four days postpartum, but when reexamined at three months postpartum only 12% were diagnosed with manifest LAM avulsions. However, for some women, symptoms persist or may develop to PFD later in life (51, 77).

Moreover, studies employing 3D ultrasound illustrated the significant distension that the pelvic floor muscles undergo at the crowning-phase of vaginal delivery (76). The degree of muscular distension may lead to either a lesion or avulsion, especially of the puborectalis muscle, the latter being important to the physiopathology of pelvic organ prolapse (29,30). The extent of damage can range from an increase in levator hiatus due to overdistension to an avulsion of the muscles, as well as perineal tears resulting in disruption of the perineal body and anal sphincter complex (89). LAM injury has been shown to be strongly associated with future pelvic floor morbidity such as POP, whereas a deficient perineum leads to multiple less described symptoms with, to a large extent, unknown long-term consequences (56, 90, 91).

The relationship between parity, childbirth, and PFD has been shown in cross-sectional observational and large, population-based epidemiological studies (76, 92, 93). Blomquist et al. showed a substantial difference in the incidence of PFD based on a woman's obstetrical characteristics, where the cumulative incidence of each PFD (UI divided into stress urinary incontinence or overactive bladder syndrome, AI, or POP) was significantly associated with delivery mode. Compared to spontaneous vaginal delivery, the risk of all kinds of urinary incontinence and pelvic organ prolapse was significantly lower after cesarean delivery (38).

There are multiple obstetric variables to consider when reviewing the short- and long-term effects on pelvic floor function, such as mode of delivery i.e. assisted vaginal delivery, especially forceps assisted delivery, prolonged duration of second stage of labor, episiotomy, perineal laceration, particularly OASI, increased birth weight, and head circumference, increased maternal age, and use of oxytocin (6, 32, 49, 55, 89, 94-98). Assisted vaginal delivery is associated with a significantly higher risk of PFD and the risk was especially high for pelvic organ prolapse (42).

One previous study has stated episiotomy as a risk factor for LAM injury, but in most studies, including a large study stratifying for other obstetric factors, no association between episiotomy and levator trauma was found (3, 32, 42, 58, 99-101). A tentative explanation could be that episiotomy is more often used in operative vaginal delivery, which is thought to be a risk factor for levator trauma. There is also some evidence supporting the fact that there is a slight protective effect of higher BMI on LAM injury, as seen in the results of a study by Caudwell-Hall et al. (102).

3.3 RELEVANT DIAGNOSTICS OF PELVIC FLOOR DISORDERS

3.3.1 Clinical assessment of pelvic floor disorders

A pelvic examination to assess the pelvic floor should consist of both visual and palpatory inspection to ascertain structural as well as functional characteristics of the area.

Pelvic Organ Prolapse Quantification (POP-Q)

POP-Q is a standardized measurement system using nine defined points around the vagina (two anterior, two posterior, and two apical) to describe the anatomical characteristics of the pelvic floor (103). They are all defined in relation to the hymenal plane; a point above the hymen is expressed as a negative number, and if positioned distally to the hymen, a positive number is assigned. The nine anatomic points are as follows: 1) point Aa, 3 cm proximal to the external urethral meatus in the anterior vaginal wall; 2) point Ba, the most distal point of the anterior vaginal wall; 3) point C, the most distal point of the cervix or vaginal cuff; 4) point D, the posterior fornix; 5) point Ap, located in the midline of the posterior vaginal wall 3 cm proximal to the hymen; 6) point Bp, the most distal position of the posterior vaginal wall. Furthermore, there are measurements of the genital hiatus (Gh), measured from the middle of the external urethral meatus to the posterior fourchette; the perineal body (Pb), measured from the posterior margin of the genital hiatus to the middle of the anal opening; and total vaginal length (Tvl), the greatest depth of the vagina.

All measurements are assessed with the patient with flexed hips and in semi-supine lithotomy position. A standard vaginal speculum, a vaginal depressor, and a disposable q-tip marked at 3 cm intervals from 0 to 12 cm are commonly used. The first measurements obtained are the genital hiatus and the perineal body, followed by the anterior and posterior points A and B using the vaginal speculum to retract the opposing vaginal wall, and using the q-tip to measure. The speculum is then retracted and points C and D and Tvl are measured with reference to the hymenal ring. All nine parameters apart from total vaginal length are measured while the patient is bearing down or performing a Valsalva maneuver.

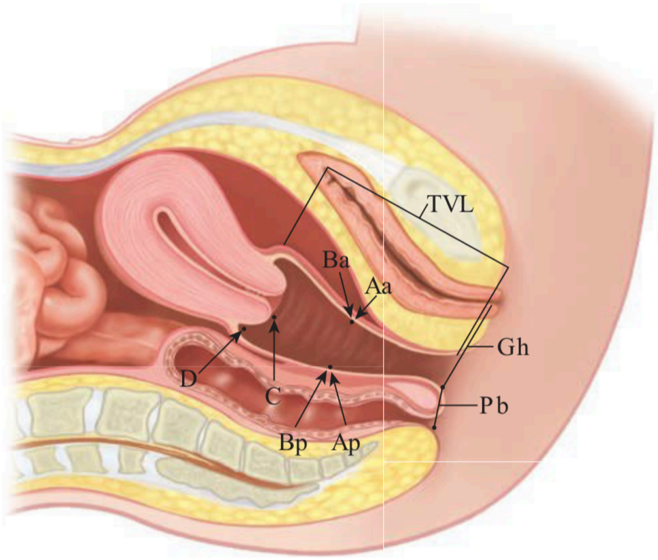

Figure 3. Anatomic landmarks used during Pelvic Organ Prolapse Quantification (POP-Q). Reprinted with the permission of McGraw-Hill publications.

Modified Oxford Scale (MOS)

Pelvic floor muscle function may be assessed subjectively by digital palpation while inserting one or two lubricated gloved fingers approximately 4 cm into vagina (104, 105). The patient is then instructed to squeeze their pelvic floor muscles without activating other muscle groups such as abdominal, gluteal or adductor muscles. Muscle strength is graded using a six-point scale by which 0 signifies no contraction; 1: a minor muscle flicker; 2: a weak muscle contraction; 3: a moderate muscle contraction, 4: a good, and 5: a strong muscle contraction against resistance by the examining finger. The same scale can be used to assess the integrity and function of the perineal body and anal sphincter muscles by bidigital palpation, placing a lubricated gloved index finger in the anal canal and juxtaposing the thumb of the same hand, or the counter-lateral index finger in the posterior fourchette of the vagina before asking the patient to squeeze.

The efficacy of perineal muscle function, measured with a perineometer, has not been shown to be relatable to the degree of perineal trauma, but rather to the extent of regular physical exercise (106-108).

3.3.2 Pelvic floor imaging

A transverse view of the pelvic floor muscles was for a long time restricted to the axial plane of MRIs, but restrictions due to costs and availability pushed for a more accessible modality for everyday clinical use in addition to research (109-114). With the development of pelvic floor 3D and 4D ultrasound techniques, this knowledge has been greatly expanded, as it also allows for dynamic (2D/4D) assessment of the pelvic floor muscles. Pelvic floor ultrasonography has indeed revolutionized both the clinical approach to diagnosing and assessing pelvic floor dysfunction and has also contributed greatly to the research methodology in investigating the pathophysiology of such disorders. PFD often consist of a cluster of symptoms, hence a multi-compartmental approach such as ultrasound imaging is well suited for diagnostics (113, 115-117). Its application has proven valuable in the understanding of the pathology of the mid- and posterior vaginal compartments, where the dysfunction of the LAM and injuries to the perineal body can be investigated in a non-invasive and low-cost manner. As our research group primarily utilizes 3D endovaginal (EVUS) pelvic floor ultrasound for assessment, the focus of this thesis will be on this imaging modality (115, 117-120).

The pelvic floor is a complex three-dimensional structure with a range of fibromuscular components that each represent specific functional and anatomical areas. The validity of 3D EVUS for the visualization of LAM anatomy has been established and correlated through comparison with cadaveric dissection and has shown high interobserver reliability (117, 121). There is a described and evaluated standardized protocol to acquiring EVUS images, that in nulligravidae has shown very good interobserver reliability (118, 122-125). In addition, a sample of parous women were analyzed according to the same standardized protocol for the reliability of LAM biometry and injuries, with similar results (122, 126).

The 3D EVUS automatically acquires and constructs high-resolution data volumes consisting of parallel transaxial or radial 2D images, which ensures that the true dimensions of the images are represented rather than computerized renditions of such (117, 127). As previously mentioned, studies show the occurrence of LAM injury on 13-36% of women undergoing vaginal delivery (34). This range might depend on the imaging modality and the assessment mode, and that definitions of LAM injury vary, but also on the timing of diagnosis in relation to the time of delivery (37, 89, 128, 129). Morgan et al. have devised a scoring system for LAM defects, however this system analyses MRI-rendered images (129), which are quite different from 3D endovaginal images. In order to supply a better functional description of the injuries, the terminology of endovaginal ultrasonography is based on the LAM subgroups, namely the puborectalis, pubococcygeus and puboperinealis/pubo-analis muscles (119).

Although the clinical visual and digital examination of the perineal body is sufficient in assessing its integrity, perineal or endoanal 3D EVUS can also be used to rate it (130). There are few published studies on the subject, and none were found that correlate symptoms to ultrasound findings. Khullar et al. recently published a cross-sectional study of prolapse patients and nulliparous women to assess whether it is possible to measure the length of the perineal body using 2D ultrasound as an objective modality to measure perineal deficiency (131). They conclude that it could be a valuable addition to the POP-Q point Pb, as it estimate the height but not the length of the perineal body .

It is important to stress, that even though pelvic floor ultrasonography has become an invaluable and central tool in the day-to-day clinical diagnostics of levator trauma, it is still just a structural measurement. Thus, it is essential to remember that the pelvic exam supplies valuable additional information by digitally palpating the pelvic floor muscles and scoring the strength of contractility by using instruments such as the Modified Oxford Score (107, 120, 132).

3.4 MANAGEMENT OF THE DEFICIENT PERINEUM

Perineal tears can, and should, be diagnosed and repaired immediately after delivery by clinical inspection and palpation (35, 133-135). Contrary to LAM trauma, perineal injuries are in clear view after vaginal delivery. The examination after delivery should include a digital rectal examination to evaluate the perineal body integrity as well as the anal sphincter complex (136). From here, the midwife or obstetrician can decide the route of repair that is required.

However, as late as in 2011, a Cochrane review stated that there was limited evidence from RCTs to support the benefit of surgical over non-surgical repair of first- or second-degree perineal tears (137). Thus, the decision to suture or not was suggested to be left to the clinician's judgement and women's preference as there was lacking knowledge of long-term outcomes and a possibility of better overall feeling if the tear was left unsutured (137).

In a study by Gommesen et al. 18% of women suffered wound dehiscence after a second-degree perineal tear and 13% of women suffered wound dehiscence after OASI (67). Risk factors for wound dehiscence have been proposed in a Danish study to be severe obesity (BMI >35 kg/m^2) and episiotomy, and the authors suggested that those at risk might benefit from prophylactic antibiotics (67) . In addition, Jallad et al. identified smoking, nulliparity, third- or fourth-degree tears, repair performed by a midwife, and the usage of chromic sutures as independent risk factors (138).

Nevertheless, there is a shortage of evidence on how to treat wound dehiscence. Regarding management of dehisced perineal tears, a Cochrane review from 2013 evaluating the therapeutic efficacy of secondary suturing compared to expectancy, claimed insufficient evidence to either support or refute secondary reconstruction (139). Moreover, Feigenberg et al. amongst others, suggest the use of adhesive glue as far superior to stitches as far as cosmetic and functional results of first-degree tears are concerned, as it also brought a shorter procedure, less need for local anesthesia, and less pain (140, 141). Furthermore, Ganapathy et al. reported good results of secondary repair in patients complaining of superficial dyspareunia, vulvo-vaginal pain, and a gaping wound, where women with dyspareunia had a later onset of complaints that the other issues studied (142). As early as 1994, Arona et al. published a case series of 23 women with dehisced OASI who were treated surgically in an outpatient setting after 4-10 days, refuting the traditional 3-4 month long wait for secondary reconstruction (143). Further, a retrospective analysis of 126 women with non-OASI were assessed by photo documentation to have anatomically acceptable results from early secondary repair, although it may be argued how such conclusions may be drawn without complete clinical exam (100).

The procedure of perineorrhaphy or perineoplasty is commonly performed concomitant to posterior colporrhaphy (144). There is no described standardized surgical protocol as far as indication or surgical procedure is concerned, which is cumbersome in counselling patients preoperatively. It does, however, seem to reduce many complaints of pelvic floor dysfunction, as shown in a RCT by Bergman et al. (145). Of the few studies found, the predominant outcome measures are cosmetic results, the sensation of wide vagina (71), and some also address sexual dysfunction such as dyspareunia (146). It is stressed though, that even though dyspareunia may improve with surgical treatment if the indications are correct (147), the above mentioned problem of a standardized protocol for surgical indication as well as procedure is still lacking.

3.5 RATIONALE FOR THIS THESIS

It is in a sense mind-blowing in this modern day and age, that there are still so many uncertainties as to the pathophysiology and symptomatology of the obstetric levator ani trauma and the deficient perineum. How can it be that many of these symptoms are still considered too taboo and difficult to address, making patient's and doctor's delay a reality for many women after vaginal childbirth and paving way to internet forums and support groups forming in lieu of health care providers providing, well, health care?

The bulk of literature and research on PFD in general focuses on anatomical findings. Screening methods and diagnostic tools, as well as surgical outcomes and comparators mostly address anatomic landmarks and reduction of clearly measurable findings. The cardinal symptoms of the historical triad of PFD - UI, AI, and POP - are still by far the most evaluated ones, whereas symptoms such as wide vagina, vaginal flatulence, chafing, bearing down, and instability are all bundled up into the realm of cosmetic surgery, somehow making them less valid. Hence, there is a lack of scientific papers that address a comprehensive summary of the symptomatology of the deficient perineum. As an illustration, a PubMed search of the term 'acquired sensation of wide vagina' produces only six results, with four of the papers published by the same (sole) author and one of the others being a published reply to that sole author (148-153).

Similarly, the main aspect considered when evaluating sexual dysfunction and PFD is dyspareunia, negating many other aspects of female sexuality. Altogether, this closes many doors for women seeking advice and treatment suggestions without displaying symptoms of either incontinence or prolapse. The social media hashtag #alltserfintut ("everything looks fine") tells of a multitude of women whose concerns and bothers are refuted by obstetricians, gynecologists, and other health care providers for not displaying adequate or enough anatomical findings.

As these symptoms are given more attention in the clinical setting, a new group of patients is forming, that is well-read and eager to play an active role in the development of their own treatment (154). This poses new challenges on health care providers and has been addressed by the Swedish Agency for Health Technology Assessment of Social Services (SBU) that explored these issues in a multidisciplinary report including the patient perspective (5). The report concludes that there is knowledge gap regarding reliable diagnostic tools helping patients to verbalize their symptoms as well as aiding health care providers in supplying consistent and objective information.

Therefore, the aim of this thesis was to explore women’s symptoms one year or more after vaginal delivery, adding diagnostic instruments to evaluate and compare potential deficiencies of the levator ani and the perineal body, and evaluating a possible surgical treatment of symptoms of the deficient perineum, with the potential goal to deepen the understanding of how long-term symptoms, diagnostics and management can improve caretaking and quality of life in women after vaginal birth.

4 AIMS

The overarching aim of this thesis was to investigate the symptomatology of women with a deficient perineum after vaginal delivery. It was also to examine the possibility of improving the diagnostics of this patient group, and potentially better the treatment of their ailments.

Pre-specified hypotheses:

1. Women with second-degree perineal tears have more posterior compartment symptoms one year after low-risk vaginal birth, than those with none or first-degree tears.
2. The Levator Ani Deficiency scoring system (LAD score) is a feasible and reproducible assessment and independent raters can rate LAD score with high intra- and interrater reliability.
3. Women with a deficient perineum have specific symptoms that distinguish them from women who have an intact perineum.
4. Perineal reconstructive surgery reduces symptoms in women with deficient perineum.
5. Women without levator ani deficiency will improve more after perineal reconstructive surgery than those with a deficiency.

The specific objectives addressing the overarching aim were:

- To compare the posterior compartment symptomatology of women with second-degree perineal tears to women with none or first-degree tears, one year after vaginal birth (Study I).
- To evaluate the repeatability of a previously published scoring system for assessment of levator ani deficiency in three-dimensional endovaginal ultrasound (Study II).
- To construct and initially validate an inventory to distinguish women with symptoms of a deficient perineum (Study III).
- To evaluate whether standardized perineal reconstruction can alleviate symptoms of a deficient perineum, defined as score reduction of the KAPTAIN inventory, in women with and without concomitant levator ani deficiency (Study IV).

5 METHODS

Table 3. Schematic overview of methods in Studies I-IV

Study	Hypothesis	Study design	Study sample	Data	Analysis
I	Women with second-degree tears experience more symptoms from the posterior compartment than women with none or first-degree perineal tears after low-risk deliveries.	Prospective cohort study	407 primiparous women with non-OASI tears after non-instrumentally assisted vaginal deliveries.	Symptoms questionnaire.	Descriptive and univariate statistics.
II	The LAD score is a feasible and reproducible assessment and independent raters can rate LAD score with high intra- and interrater reliability.	Cross-sectional study	141 primiparous women with non-OASI tears after non-instrumentally assisted vaginal deliveries.	Two assessments by two different raters of LAD-score in 3D ultrasound volumes from two different probes.	Kendall's tau-b for calculation and comparisons.
III	Women with a deficient perineum have specific symptoms that separate them from women with an intact perineum.	Mixed methods study	170 women with deficient perineum. 54 primiparas after elective caesarean section and 388 nulliparas.	Preliminary inventory of 41 questions.	PCA to reduce the number of items. Mann Whitney U for comparisons of scores. ROC curves for cut-off scores.
IV	Perineal reconstructive surgery can reduce symptoms in women with deficient perineum. Those without a concomitant LAD will improve more compared to those with LAD.	Observational follow-up study	131 patients diagnosed with a deficient perineum and eligible for perineal reconstructive surgery.	LAD score and symptom inventory (study III) scores at baseline and follow-up.	Score difference (mean and median) for individual items and in total is calculated

5.1 STUDY I

This study was designed as a prospective cohort study to test the hypothesis that women with extensive second-degree tears experience more symptoms of a deficient perineum than women with none or first-degree perineal tears after low-risk deliveries.

Study population and sample

The study population is a follow-up cohort from the Midwives' Management during the second stage of labor (MIMA) study, which was a cohort study with an intervention, that included participants from two delivery wards in Stockholm between 2013 and 2015 (155). The underlying MIMA study included 597 primiparous Swedish-speaking women, with spontaneous onset of labor or induction of labor at the gestational age of ≥ 37 full weeks of pregnancy. Of these, 466 completed the follow-up questionnaire one year after birth. Due to novel pregnancies, 56 women were excluded, and three participants were excluded due to incomplete data. Thus, the study population for Study I constituted 410 women.

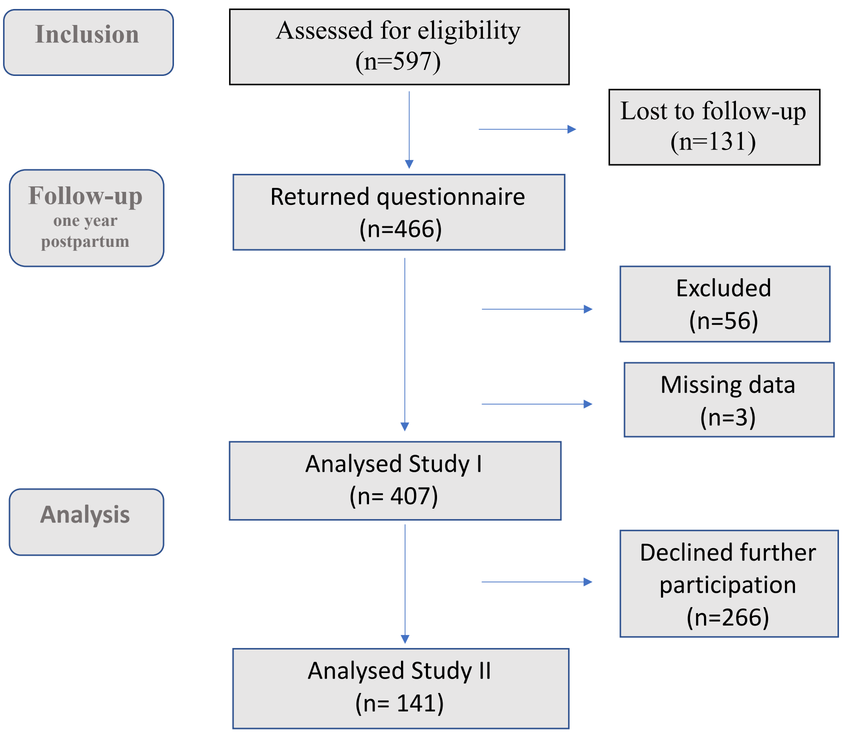

Figure 4. Flow chart for inclusion, follow-up, and analysis in Study I and II.

Data collection

Delivery information was retrieved from obstetric charts after signed consent as part of the study questionnaire described further below. Data on perineal injuries was retrieved from the original study protocol.

A questionnaire had previously been developed by researchers and co-authors from the MIMA-study (156). It covered known and suggested symptoms of pelvic floor dysfunction with questions from previously validated questionnaires. Figure 5 describes the different parts of the questionnaire. The first six questions covered background characteristics such as height and weight, marital status, educational level, and smoking habits. The next seven questions were about the pregnancy and postnatal period, then followed nine questions on the birthing experience on general health selected from a previously validated questionnaire, the Childbirth Experience Questionnaire (CEQ) (157). Furthermore, there were five questions on the postpartum visit (commonly 6-12 weeks postnatally) and five questions chosen from the Pelvic Organ Prolapse / Urinary Incontinence Sexual Questionnaire (PISQ-12). Nine questions were taken from the Pelvic Floor Distress Inventory (PFDI-20), an inventory which includes the Urinary Distress Inventory 6 (UDI-6), that have both been validated in Swedish (158). The study questionnaire also included four questions addressing AI and bowel-emptying difficulties and seven questions on the impact on daily life and on psychological wellbeing sampled from other validated PFD inventories (158, 159). The entire study questionnaire was eleven pages long and included 52 questions.

Replies targeted symptoms experienced in the preceding three months and was sent by postal carrier 12 months after delivery to all women included in the MIMA study. All participants received one reminder to respond or else were excluded.

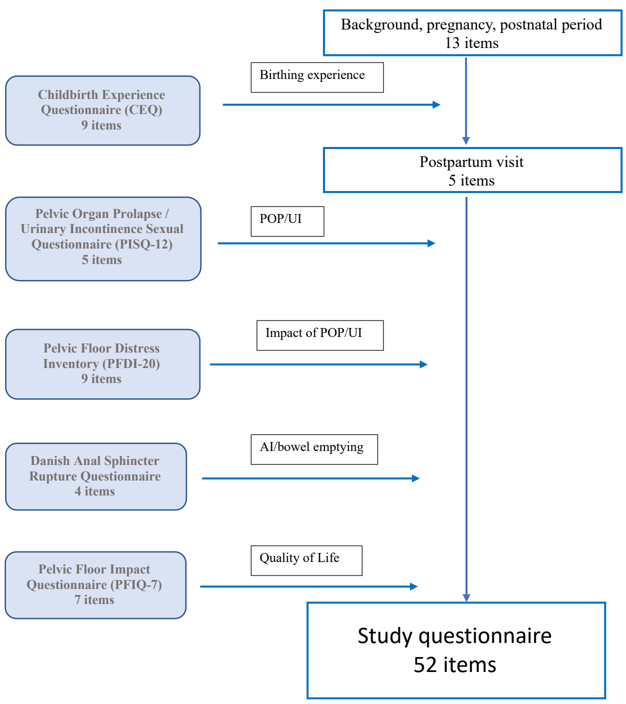

Figure 5. Flow-chart of the inventories supplying items to the study questionnaire.

Data analysis

Study I was a continuation of the MIMA-study; an interventional study in which participants were randomized into either a combination of several measures applied during delivery or to standard care. However, study I was considered a follow-up of the entire original MIMA study, the participants were evaluated as one cohort, regardless of which group they were allotted in the original study. By including both control and intervention groups from MIMA in this study, we regarded the total study population as receiving standard care based on the general practice of delivery by midwives in Sweden. As such, we chose to not further differentiate the groups.

Perineal tears were defined into standard categories none-to-first degree, second degree, and third-to-fourth degree. In addition, in the original study protocol, they were measured in three dimensions, marked in a schematical illustration, and described in their own words by the delivering midwives. This was an attempt to refine the diagnostics due to the issues surrounding the rough definition of a second-degree tear which have been addressed in the Background section. Consequently, category none-to-first degree included no tear at all, a labial tear only, tears of the perineal skin and/or tears involving the vaginal mucosa no deeper than 0.5 cm. If the tear extended to the vagina (i.e., above the hymenal plane) and exceeded 0.5 cm in length or depth, it was categorized as a second-degree tear, as were all episiotomies.

All second-degree tears were analyzed and compared to those with minor tears i.e., none-to-first degree tears. We assumed that the tears categorized as minor did not involve the fibromuscular structures of the perineal body, keeping this functional unit intact, and were therefore considered the reference group. All second-degree tears however were assumed to involve the perineal body and were defined as the exposure group.

Descriptive analysis (n, percentage, mean) were used to present background characteristics of the participants. Continuous variables such as age, BMI and fetal birth weight were categorized, and head circumference (</> 35 cm) and birth positions (upright/supine) were dichotomized. Continuous variables were presented as means and standard deviations (SD) or medians (range or inter-quartile range, IQR) dependent on distribution. Categorical variables were presented as numbers, percentages, and p-values lower than 0.05 were considered statistically significant. The Pearson Chi-square or Fisher's exact test, and the Student's t-test were used to compare the continuous and categorical variables respectively for the obstetric characteristics and posterior compartment symptoms of women with second-degree perineal tears and those with none or minor tears. In addition, a non-response analysis was carried out to compare variables between the included women (n=407) and the women who did not respond to the questionnaire (n=131). The statistical analyses were performed using SPSS version 24 (IBM, Armonk, NY, USA).

5.2 STUDY II

This study was designed as a cross-sectional study with the primary aim to evaluate how consistently different raters with different probes can assess the LAD score system in 3D endovaginal ultrasound volumes. In addition, we wanted to estimate the rate of LAD using the levator ani deficiency scoring system (LAD score) in a sample of low risk primiparas.

Study population and sample

As in study I, the study population was originally derived from the MIMA-study (155). As part of follow-up, the 597 participants from the MIMA-study received a questionnaire one year after birth, which included an invitation to the Karolinska Pelvic Floor Center for a pelvic exam including three-dimensional ultrasound. A total of 141 women responded to the offer, thus forming the study sample.

Data collection

All 141 participants underwent 360° 3D EVUS performed with two different probes by the same urogynecologist (hereafter called Rater 1). The examination was done in an office setting, with the patient in semi-supine position with flexed and abducted hips. No specific preparation of bladder or bowel was required. Attempting to minimize unnecessary pressure on the anatomic structures, the endovaginal probe was inserted into the vagina in a neutral position. All images were rendered during rest and stored digitally for analysis. A BK Medical Flexfocus 500 (Peabody, MA, USA) machine was used for all examinations.

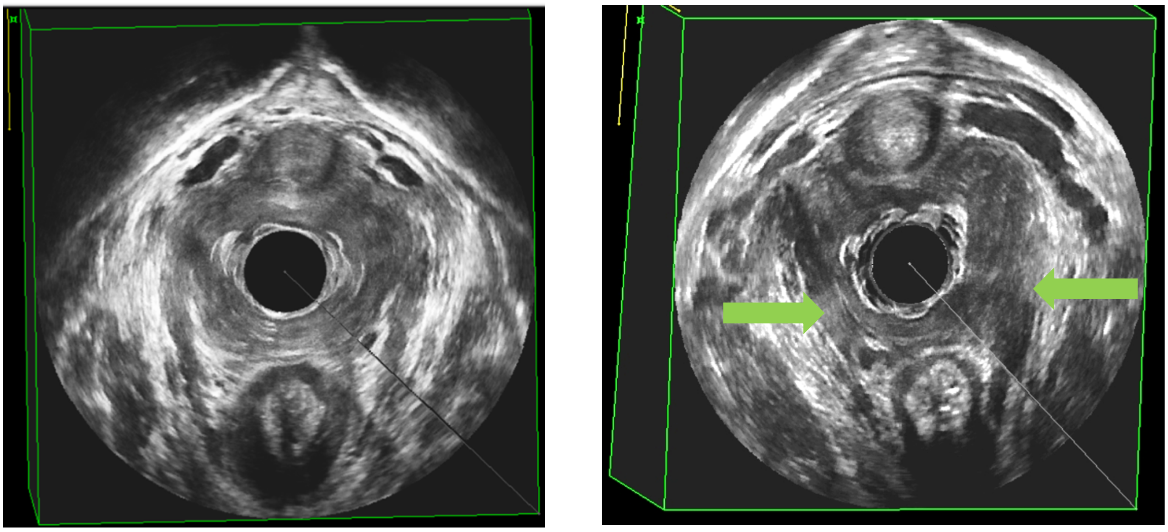

Figure 6. The levator ani muscles as seen on 3D EVUS. Axial view of intact muscles (left) and partial avulsion indicated by marker, LAD score 8 points (right).

The 3D EVUS was performed with two separate high-definition automated probes. Probe 1 (BK 2052) is a 6-16 MHz probe with an internal automated motorized system that allows an acquisition of transaxially aligned two-dimensional (2D) images resulting in a cube of 300 transaxial images of 0.2 millimeters each. Probe 2 (BK 8838) has a built-in 360° automatic linear array and was set up at an acquisition of 1440 2D images of 0.25° each. Both transducers allow 3D acquisition of 2D images without any movement of the probe during the exam. A set-up of 9 MHz was used for both probes.

The EVUS volume was defined as interpretable if it included the pubic symphysis and levator ani plate in an anterior-posterior array, and all the LAM subdivisions were visible. In case of non-interpretable images, the volume was not scored and thus resulted in a missing value. All ultrasound volumes were assessed offline by two raters with differing experience to explore whether the scoring system would be equally reliable regardless of which probe was used or the level of experience of a potential rater.

The scoring system was based on previously published work by Rostaminia et al. (121). The three LAM subsections were evaluated in an axial plane where the full length of each muscle subsection could be visualized, and were scored (0 = no defect, 1 = minimal defect with <50% muscle loss, 2 = major defect with >50% muscle loss, 3 = total absence of the muscle) on each side, resulting in a maximum score of 9 points per side in case of a full avulsion of all muscle subsections. In total, a cumulative LAD score that ranged between 0 and 18 was possible. Furthermore, the score was categorized into three groups: mild (0-6 points), moderate (7-12 points) and severe (13-18 points).

3D EVUS volumes were analyzed independently by two raters with different levels of experience (4 vs 15 years). The raters were blinded to patient history, clinical data, and the other rater's assessments. To enable intrarater comparisons each rater scored the same volume on two separate occasions (assessments 1 and 2). The elapsed time stipulated between the two assessments was at least four weeks, and the ultrasound volumes for both probes were randomly ordered at both evaluations.

Data analysis

Continuous variables were presented as means and standard deviations (SD) or medians and inter-quartile range (IQR) depending on distribution. Categorical variables were presented as numbers and percentages. P-values lower than 0.05 were considered statistically significant. As LAD score has a non-normal distribution, the mean absolute deviation (MAD) was presented together with the mean and median values. Mean absolute deviation (MAD) refers to the average distance of each value from the mean in a dataset. Similar to standard deviation (SD) it is a description of the variation or spread of values within a dataset. MAD is considered to be more resilient to outliers in a data set and is favored by many as statistically more robust. Kendall's tau-b correlation coefficient, a non-parametric rank-based correlation was applied to compare correlations between raters, assessments, and probes. SPSS version 26 (IBM, Armonk, NY, USA) was used to perform the statistical analyses.

Kendall's tau-b vs Spearman's rho

Several statistical measures of correlation exist, and as far as non-parametric rank correlations are concerned, there are two mainly accepted measures: Kendall's tau-b and Spearman's (rho) rank correlation coefficient (160).

The Spearman's rank correlation coefficient calculations are based on ranking the deviations of the studied variable. The Kendall tau-b correlation coefficient on the other hand investigates the number of concordances and discordances in paired observations such as those of the raters, probes or assessments of our study. One of the main advantages of using Kendall's tau-b are that it better handles two concordant values (tied matches) which is the case in our material. It is also less sensitive to small sample sizes, and interpretation in terms of the probabilities of observing the agreeable (concordant) and non-agreeable (discordant) pairs is very direct (161, 162).

5.3 STUDY III

This study was designed as a mixed methods study with the aim to create an accessible and valid inventory to estimate symptoms in women with deficient perineum. We also aspired to rule out vaginal delivery as well as pregnancy as a contributing factor to the development of symptoms by comparing the responses from the patient group to those of primiparas who had not delivered vaginally and to nulliparous women.

Study population and sample

Patients referred to the Karolinska Pelvic Floor Centre, a tertiary center at the Karolinska University Hospital and diagnosed with a deficient perineum defined as a visible perineal scar and anatomical defect with a perineal body < 2 cm (POP-Q point Pb < 2). Additional inclusion criteria were no ongoing pregnancy and at least one year after delivery, of fertile age, and the ability to understand written Swedish to complete the inventory. In total, 170 patients were eligible for the study.

For control groups women who had given birth by elective caesarean section at the Obstetrics departments of the Karolinska University Hospital and the Hospital of Västmanland, Västerås, were asked to participate in the study. These participants were included if delivered by elective caesarean section (CS) due to e. g. breech position or non-medical indication. In all, 54 women completed the inventory. Furthermore, nulliparous women were asked to participate as part of another on-going study at Karolinska Pelvic Floor Centre and 338 women completed the inventory.

Data management

The methodology in this study can be subdivided into two main components: the construction of the inventory and its initial validation.

Construction of the inventory

First, a literature review to identify existing validated inventories evaluating symptoms of deficient perineum more than one year postpartum was conducted, however, none were found. In addition, related inventories evaluating PFD were assessed for possible symptoms. Using the findings from a previous qualitative study by Karlström et al. (163) and the existing PFD inventories, an item pool was constructed encompassing seven symptom domains: *a feeling of wide vagina*, *vaginal flatulence*, *bowel symptoms*, *bearing down sensation*, *pain*, *sexual dysfunction*, and *quality of life*. When the item pool had been constructed an advisory panel was invited to review the items and a response format suggested for each item. Such a panel consists of a number of experts (164) and previous research states that there should be at least five persons in the panel to control chance agreement. The members of the advisory panel were urogynecologists with each over 10 years' experience in PFD and were asked to grade the items according to relevance as stated by Lawshe et al. (165): *1 = not relevant, 2 = has some relevance*, *3 = somewhat relevant but needs revision,* and *4 = highly relevant*. Thereafter, a content validity ratio (CVR) was calculated for each question (166).

After the advisory panel the inventory was changed accordingly and cognitive interviews using the "Think Aloud" method were carried out to partly ensure the instrument's face validity. Face validity determines whether the instrument appears to measure what it's supposed to measure, as well as if it seems relevant and appropriate on the surface (167, 168). This was done in separate interviews with three Swedish-speaking women of fertile age, with completed non-medical university degrees, who described subjective symptoms after second-degree perineal tears. Each woman were asked to 'think aloud' for each item with the aim of letting the interviewer know if she understood the item, if she understood the item in the way the researcher intended, and how she calibrated the item and its response options (169). The interviews were audio-recorded and transcribed verbatim, whereafter the items were yet again altered according to the suggestions from the respondents. All described steps together resulted in a preliminary inventory of 41 items with 40 questions with a 4 point Likert scale response and 2 questions with binary response (yes/no).

Initial validation of the inventory

Kaiser-Meyer-Olkin (KMO) and Bartlett's test of sphericity confirmed that the properties of the dataset made it appropriate for PCA for reduction of items. Principal component analysis (PCA) was used to reduce the number of items. 38 items were included in PCA, 4 were excluded due to missing more than 50% data or due to binary response option. PCA is a method to condense datasets to increase interpretability while minimizing information loss. This is done by creating new uncorrelated variables that maintain as much statistical information as possible. These new variables are called the principal components and are defined for each individual data set which makes this method adaptable to various kind of data types. The method of PCA can be divided into five steps:

1. Standardizing items' scores into comparable scales to make each one contribute equally to the analysis.
2. Exploring potential relationships between the variables of the data set, as highly correlated variables may contain redundant information. To identify such correlations, a covariance matrix is computed.

3. Computing the eigenvectors and eigenvalues of the covariance matrix to identify the principal components, which are the new variables constructed as linear combinations of the initial variables.
4. Choosing which principal components to keep and discard by ordering eigenvectors in descending order.
5. Reorienting the data from the original axes to the ones represented by the principal components.

After PCA a clinical round table was held to discuss the reduction of items in a pragmatic and clinically valid manner. Items with the highest loadings in 10 different components were retained. If an item did get a high loading but for some reason was regarded as adding great clinical value, that item was also retained. PCA correlation were done carried out on the retained items and if two items with high correlations were identified, they were once again discussed at a round table and one item was retained and the other one discarded according to clinical relevance.

Pearson's correlation coefficient was used for correlation of items, and Mann-Whitney-U-tests were applied to compare patients to control groups to ascertain construct validity. Finally, receiver operating characteristic (ROC) curves were applied to assure the ability of the inventory to detect patients, and to decide on the best cut-off points to distinguish patients from control groups. The statistical analyses were performed using SPSS version 26 (IBM, Armonk, NY, USA) and R version 4.0.4 (R Development Core Team, 2021).

5.4 STUDY IV

This study was designed as an observational follow-up study. The hypothesis was that women with symptoms of a deficient perineum after vaginal birth would report less symptoms after perineal reconstructive surgery. In addition, women with a concomitant LAD would report less improvement than those without a LAD.

Study population and sample

The study population for Study IV were 131 patients eligible for perineal reconstructive surgery. The inclusion criteria also included a visible perineal scar and anatomical defect (Pelvic Organ Prolapse- Quantification, POP-Q, point Perineal body < 2 cm), the ability to understand and complete questionnaires in Swedish, age at least 18 years, and deemed eligible for perineal reconstructive surgery.

Data collection

An acquired sensation of wide vagina was chosen as primary outcome, as previous research has proved it to be the predominant symptom of a deficient perineum (41, 70, 71). Participants were invited to the study if they met the inclusion criteria and were deemed eligible for perineal reconstructive surgery. All participants provided full oral and written informed consent. During the preoperative visit, patient-specific clinical history was collected, 3D endovaginal ultrasound was performed to examine the LAM integrity, a POP-Q assessment was performed, and they were asked to complete the KAPTAIN inventory from Study III. Perineal reconstructive surgery was performed according to a standardized operative procedure; the surgeon was blinded to KAPTAIN data and LAD score. All patients were treated according to routine care. The surgical technique involved identification and repair of the rectovaginal septum and puboperinealis muscles, as well as the deep and superficial transverse perineal muscles and the bulbocavernosus muscles where applicable. Patients were invited back for follow-up one year postoperatively and pelvic exam, 3D EVUS and KAPTAIN was repeated.

In addition, after the follow-up visit patient records were assessed for information on patients' age, body mass index (BMI), parity including number of vaginal deliveries and time since last vaginal delivery, menopausal status, and smoking, as well as information on patients seeking emergency care in the Stockholm region within thirty days of surgery with surgery-related complaints such as anxiety, pain, fever, or abnormal discharge from the wound or prescribed treatment with antibiotics.

Data analysis

Continuous data such as age, body mass index and parity were not normally distributed and thus presented as median and range or inter-quartile range (IQR). A dichotomous variable was created for comparisons of no LAD (LAD-category mild) or LAD (LAD-categories moderate and severe). Pre- and postoperative KAPTAIN scores for each item of the inventory was calculated, as well as total score difference.

The median was calculated as the results were not normally distributed, however, the mean was also calculated as additional information for reader to further illustrate the differences in the data. As the assessment scale only consisted of four points, the median can be considered a quite crude measurement, and the mean thus contrasts smaller changes.

Comparisons between pre-and post-operative scores were calculated using the Wilcoxon signed rank test for dependent samples was used for comparison within the LAD/no-LAD-groups, and Wilcoxon rank sum test between groups. The Bonferroni method was used to correct for multiple testing. A p-value <0.05 was considered statistically significant. The statistical analyses were performed using SPSS version 28 (IBM, Armonk, NY, USA).

5.5 ETHICAL CONSIDERATIONS

As far as general ethical research conduct is concerned, there were multiple conversations about how to deal with adverse results or results that don’t support our hypotheses. A negative result could still contribute to advancing the knowledge of the field, and there is never any excuse for fabricating data.

All data was handled according to GDPR regulations and Swedish law. Data were anonymized according to Good Clinical Practice in data management. Results from all studies in this thesis are presented at a group level whereby no individual study participant can be identified.

When planning and designing our studies, great care was taken to protect our study population according to the Helsinki declaration. Each participant was approached orally and/or in writing and was also informed that they were free to decline further participation without negative impact to potential future care. We supplied oral and written information and attained written informed consent from every participant on each study. All research data was coded, and the code key kept locked up separately to ensure and protect the participants' privacy. The authorship and order of contributing authors for each study was discussed and decided prior to manuscript writing and the ICMJE authorship criteria were revised on numerous occasions to make certain they were adhered to. COI-documents were supplied for the submitted manuscripts. Manuscript submittal was only considered to well-known, peer reviewed scientific journals, and not when approached for publication or offered publication fees. There have been no grants or cooperation with ultrasound manufacturers or other industrial partners.

We considered the benefit for the individual participant to greatly outweigh the risk of participation. All participants for studies I and II were examined by the same examiner (Study I involves only treatment of data), the same goes for the follow-up visits of Study IV. Admittedly, a pelvic exam, especially including endovaginal ultrasound exams may be an unpleasant or exposing experience, however the participants were all given detailed written information on all parts of the participation before signing the consent. One could possibly consider the psychological impact of learning of muscular defects that puts one at risk for future pelvic floor dysfunction. We are, however, convinced that each woman has the right to know about possible injuries despite no current surgical treatment is available, and even though they may indeed never impact their lives. Every woman displaying muscular defects and symptoms was offered follow-up through our pelvic floor center. Finally, all participants were examined in the same manner, using the same protocol, and most of them by the same examiner who was blinded to background data.

Details of Ethical Approval

All four studies in this thesis were reviewed and approved by Stockholm Regional Ethics Board. Study I: 2013/859-31/2; Study II: 2013/859-31/2; Study III: 2013/445-31, 2021-02860; Study IV: 2017/1418-31/2.

6 FINDINGS

Table 4. Schematic overview of main findings in studies I-IV

Study	Specific objectives	Research question	Approach	Findings
I	To compare the presence of posterior compartment symptoms one year after vaginal birth in women with second-degree perineal tears to women with none or first-degree tears.	Do women with a second-degree perineal tear experience more posterior compartment symptoms in comparison with women with none or first-degree perineal tears?	Prospective cohort	Approximately every fifth woman with a second-degree perineal tear report bowel emptying difficulties and 7% report incontinence of loose stool one year after their first vaginal delivery. No statistically significant differences could be found when comparing symptoms in women with different non-OASI tears.
II	To evaluate the reproducibility of the LAD-score system for assessment of levator ani deficiency with three-dimensional endovaginal ultrasound.	Is the LAD-score a feasible and reproduceable assessment? How consistently can different raters assess the LAD score in 3D ultrasound volumes measured by different probes?	Cross-sectional study	The proportions of examinations divided in the three LAD categories were comparable between raters and probes in both assessments. Intrarater comparisons showed high LAD-score correlations between probes and assessments (Kendall's tau-b > 0.78). Correlations between LAD categories ranged between 0.80 and 1.00 and the assessment of Probe 1 by Rater 1 for LAD category showed perfect correlation (Kendall's tau 1.00, p <0.01). The interrater correlation of LAD score between the two raters was also high (Kendall's tau >0.78, p <0.01). The presence of LAD in the studied populations was low (13.1-15.1 %).
III	To construct and initially validate an inventory to distinguish women with symptoms of a deficient perineum.	How can a clinical screening inventory be developed and validated to measure symptoms in women with a deficient perineum?	Mixed method	The construction of the inventory resulted in a 41-item preliminary inventory. The PCA and the clinical round table discussions resulted in 11 items. with 1-2 items per symptom domain, with a total score range of 0-33. Mann-Whitney U-tests showed significantly higher scores in the patient group compared to the two control groups. The optimal cut-off value was estimated to 8 points to discriminate patients from controls.
IV	To evaluate whether a standardized perineal reconstruction can alleviate symptoms of a deficient perineum, defined as score reduction of the KAPTAIN inventory, in women with or without concomitant LAD.	Can standardized perineal reconstructive surgery alleviate symptoms of an acquired sensation of wide vagina in patients with a deficient perineum with or without a concomitant LAD?	Follow-up study	Significant score reduction of the primary outcome 'Do you feel that your vagina is too wide/loose?'. No significant difference in score reduction between patients with or without LAD. All KAPTAIN items showed significant score reduction for the whole group but when stratified by LAD nine out of eleven were significantly reduced.

6.1 STUDY I

The response rate of the questionnaire was 68.7% (n=410). Mean age at delivery was 29.6 years (SD 4.5) and the mean BMI was 23.0 (SD 3.4), roughly 21% had minor perineal tears, and 75% presented with a second-degree perineal tear. The groups did not differ significantly in regard to socio-demographic or obstetric characteristics. The non-response analysis revealed that the non-responders were significantly younger and smoked to a higher extent ($p<0.05$). Correspondingly, the non-response analysis did not reveal any differences regarding obstetric outcomes.

In the group with second-degree tears, 18.9% reported bowel emptying difficulties, 7.2% and 2.9% incontinence of loose and formed stool respectively, and 38.4% reported flatus incontinence. The rate of fecal urgency in this group was 19.9%. The corresponding numbers for women with none-to first-degree tears were 20.0% for bowel emptying difficulties, 1,2% incontinence of formed stool, and 3.5% for loose stool, and 32.9% for flatus incontinence. There were 21.2% with fecal urgency in this group with minor tears. There were no statistically significant differences between the respondents with minor tears compared to those with second-degree tears concerning any outcome measures.

6.2 STUDY II

In all, 141 participants were examined; mean age was 30.58 years (SD 3.91), mean BMI was 22.83 kg/m^2 (SD 3.36), and mean time from delivery to examination was 18.82 months (SD 2.80). No more background data was available. Depending on rater, probe, and assessment, 75.9-80.1% were rated as LAD-category mild, 6.4-9.2% as LAD-category moderate, and 4.3-6.4% as LAD-category severe.

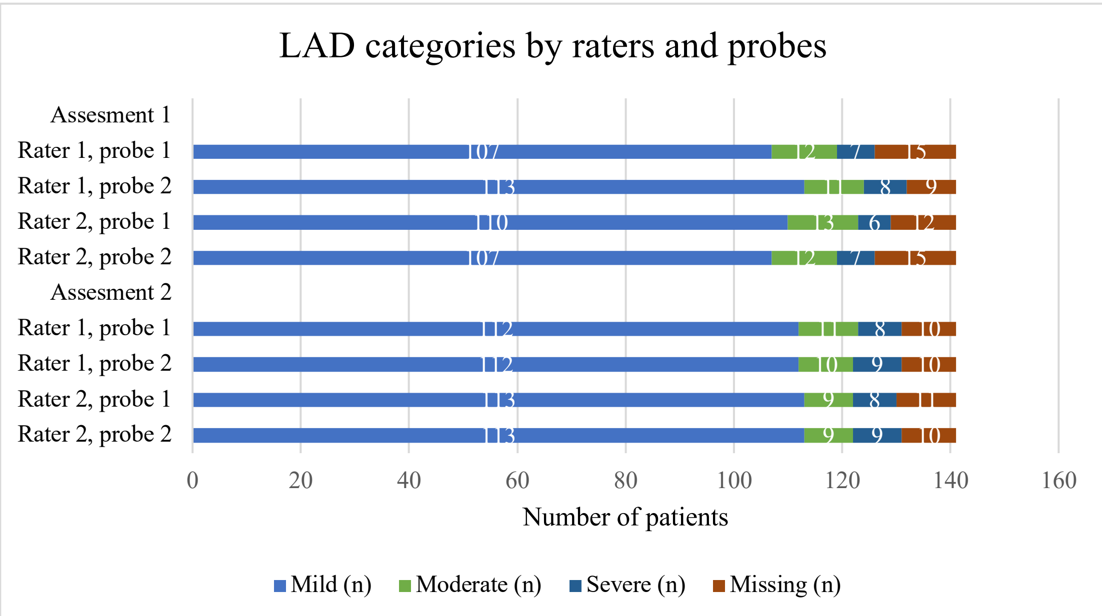

Figure 7. Number of patients allocated to each LAD category divided by raters (1 and 2) and probes (1 and 2) and presented according to the first and second assessment.

Overall, the proportions of examinations divided in the three LAD categories were similar between raters and probes in both assessments as shown in Figure 7.

Altogether, LAD score correlations were high between raters and assessments, with Kendall's tau-b >0.78 for all intrarater comparisons. Correlations between LAD categories ranged between 0.80 and 1.00 (Table 5a) and with a perfect correlation (Kendall's tau 1.00, p <0.01) in the assessment of Probe 1 by Rater 1 for the LAD category. Finally, a high interrater correlation of LAD score between the two raters (Kendall's tau >0.78, p <0.01) was seen (Table 5b).

Table 5a. Kendall's tau-b correlations for intrarater comparisons of LAD score and LAD category by rater and between assessments

	Rater 1		**Rater 2**	
	Probe 1 *Assessment 1 vs 2*	Probe 2 *Assessment 1 vs 2*	Probe 1 *Assessment 1 vs 2*	Probe 2 *Assessment 1 vs 2*
n (% of total study population)	126 (89.4)	131 (92.9)	122 (86.5)	127 (90.1)
LAD score	0.997*	0.944*	0.860*	0.787*
LAD category	1.000*	0.996*	0.801*	0.863*

*Indicates p<0.01

Table 5b. Kendall's tau-b correlations for interrater comparisons of LAD score and LAD category by rater and between probes

	Rater 1		**Rater 2**	
	Assessment 1 *Probe 1 vs 2*	Assessment 2 *Probe 1 vs 2*	Assessment 1 *Probe 1 vs 2*	Assessment 2 *Probe 1 vs 2*
n (% of total study population)	125 (88.7)	124 (87.9)	124 (87.9)	126 (89.4)
LAD score	0.800*	0.816*	0.832*	0.964*
LAD category	0.801*	0.863*	0.831*	0.848*

*Indicates p<0.01

Participants were identified within all three possible LAD categories and as expected a majority scored 0 points (no LAD) but according to the LAD-categories categorized as a mild LAD (0-6 points). An example of the score distribution for rater 1, probe 2 is presented in Figure 8. The mean score for all participants ranged from 1.55-1.89 points between the two raters and the two probes (Table 6).

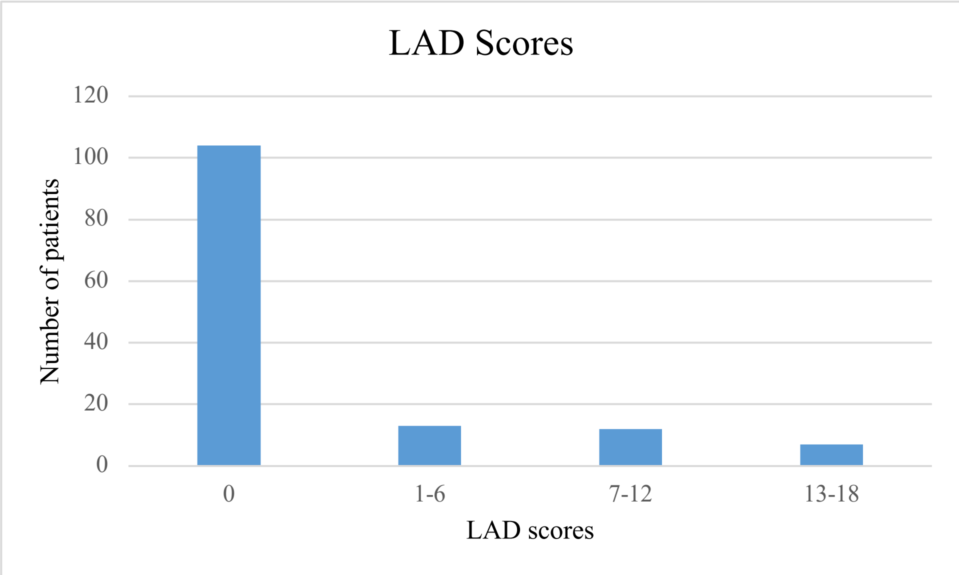

Figure 8. The distribution of LAD scores for all participants by rater 1, probe 2.

	Rater 1 Assessment 1		**Rater 2 Assessment 1**		**Rater 1 Assessment 2**		**Rater 2 Assessment 2**	
	Probe 1	Probe 2	Probe 1	Probe 2	Probe 1	Probe 2	Probe 1	Probe 2
Mean	1.89	1.82	1.67	1.77	1.88	1.78	1.55	1.66
Median	0	0	0	0	0	0	0	0
MAD[1]	2.97	2.87	2.77	2.87	2.94	2.86	2.54	2.76
Range	0-17	0-16	0-16	0-16	0-17	0-16	0-17	0-17

[1] MAD = median absolute deviation

Table 6. Mean LAD score for all participants for rater 1 and 2 and probe 1 and 2.

6.3 STUDY III

Mean patient age was 37.4 years (SD 6.6) with mean BMI 23.8 kg/m^2 (SD 4.8), and mean parity was 2.2 (SD 0.8). The Nullipara group (n=338) was significantly younger (p<0.05) than the Patient group with a mean age of 31.4 years (SD 7.5) with higher mean BMI 24.9 (SD 6.1), which was not statistically significant (p =0.06). Women with elective CS were also significantly younger than the Patient group (p<0.05) with a mean age of 34.9 years (SD 4.4), however no information on BMI was obtained.

Based on the PCA, a ten-component solution was chosen, explaining a cumulative variance of 70%. The PCA and the clinical round table discussions resulted in 11 items retained (1-2 items per component) according to the criteria of PCA and one item was deemed clinically relevant from the preliminary 41-item-inventory. Two of the components of the PCA had high correlations, and after another round table discussion, one item was retained. Thus, the final version of the '**KA**rolinska Symptoms After **P**erineal **T**e**A**r **IN**ventory' (KAPTAIN) consisted of 11 items with 1-2 items per symptom domain, with a total score range of 0-33 (Figure 9).

Number	Question	Reply
1	Do you feel that your *vagina* is too lax/loose?	__ Strongly disagree __ Disagree __ Agree __ Strongly agree
2	Do you have a feeling of looseness deep inside the vagina?	__ Strongly disagree __ Disagree __ Agree __ Strongly agree
3	Are you bothered by air entering the vagina?	__ Always __ Often __ Sometimes __ Never
4	Are you bothered by sounds caused by air escaping from the vagina (vaginal flatulence)?	__ Always __ Often __ Sometimes __ Never
5	Are you bothered by a feeling of heaviness in the genital area?	__ Always __ Often __ Sometimes __ Never
6	Are you bothered by faecal incontinence (leakage of loose faeces)?	__ Always __ Often __ Sometimes __ Never
7	During defecation, do you need to help by putting your fingers inside the vagina and applying pressure or around the anus?	__ Always __ Often __ Sometimes __ Never
8	Do you have to sit or stand in a particular position to be able to defecate?	__ Always __ Often __ Sometimes __ Never
9	Are you bothered by pain in the genital area when you have sex?	__ Always __ Often __ Sometimes __ Never
10	Are you experiencing discomfort in the genital area that limits your sexual activity?	__ Strongly disagree __ Disagree __ Agree __ Strongly agree
11	Are you experiencing discomfort in the genital area that affects your quality of life?	__ Strongly disagree __ Disagree __ Agree __ Strongly agree

Figure 9. The Karolinska Symptoms After Perineal Tear Inventory.

When comparing the results between the different groups, Mann-Whitney U-tests showed that the Patient group scored a median of 19 points (IQR 16-22) of maximum 33 score on the final 11-item inventory, and that this was significantly (p <0.001) higher compared to the two other groups. The women giving birth by elective CS scored a median of 2 (IQR 0-3) and the Nullipara group scored a median of 4 point (IQR 2-7). The 95% confidence interval for score differences, based on 2,000 bootstrap samples, between the Patient group and the elective Cesarean group was 16-18 and, compared to nulliparous women, 14-16.

The optimal cut-off value was estimated by ROC curves and with 8 points or more the inventory could discriminate patients from the women who had undergone elective CS with a sensitivity of 100% and a specificity of 91%. When applying the same cut-off value to distinguish patients from nulliparous women ROC curves yielded a sensitivity of 100% and of 87%.

6.4 STUDY IV

In total, 131 participants were included in the study and underwent reconstructive surgery. Median age was 36.1 years (IQR 7.9), and median follow-up time was 13.2 months (IQR 3.9). Close to all (97.7%) ultrasound volumes were deemed interpretable, and 128 participants (97.7%) were scored according to LAD score. Of these, 54 (41.2%) had a LAD score > 6, indicating a LAD. Of 131 participants, 119 completed follow-up (90,8%). The pre-and postoperative groups did not differ significantly with respect to age, BMI, parity, or mean follow-up time.

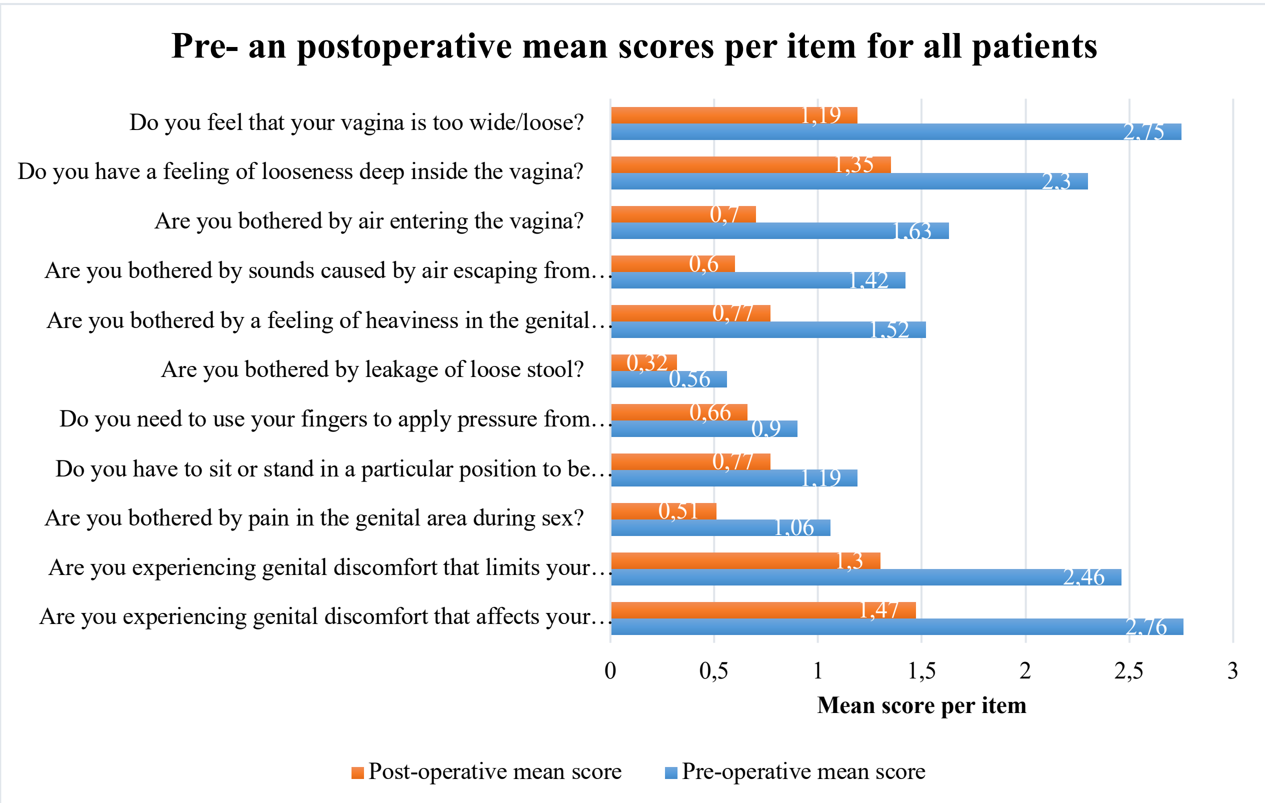

Figure 10. Mean score per KAPTAIN item for all patients pre- and post operatively.

The primary outcome was an acquired feeling of wide vagina and secondary outcomes symptoms encompassed remaining KAPTAIN items. The median and mean score difference between baseline and follow-up and stratified by LAD were calculated. There was a significant score reduction of the primary outcome 'Do you feel that your vagina is too wide/loose?' of -1.56 (SD 0.96) from a mean score of 2.75 (SD 0.59) at baseline indicating symptom relief. There was no significant difference in score reduction between patients with or without LAD. All KAPTAIN items showed significant score reduction for the whole group (Figure 10) however when stratified by LAD nine out of eleven were significantly reduced; the items "Are you bothered by leakage of loose stool?" and "Are you bothered by pain in the genital area during sex?" showed no significant score reduction.

The mean total score reduction of the inventory was 9.1 (SD 5.3) points, $p<0.001$. There was no significant difference in mean score difference comparing the group with no LAD (mean score difference -9.1, SD 4.5) to the group with LAD (mean score difference -9.1, SD 6.2), $p>0.001$ (Figure 11).

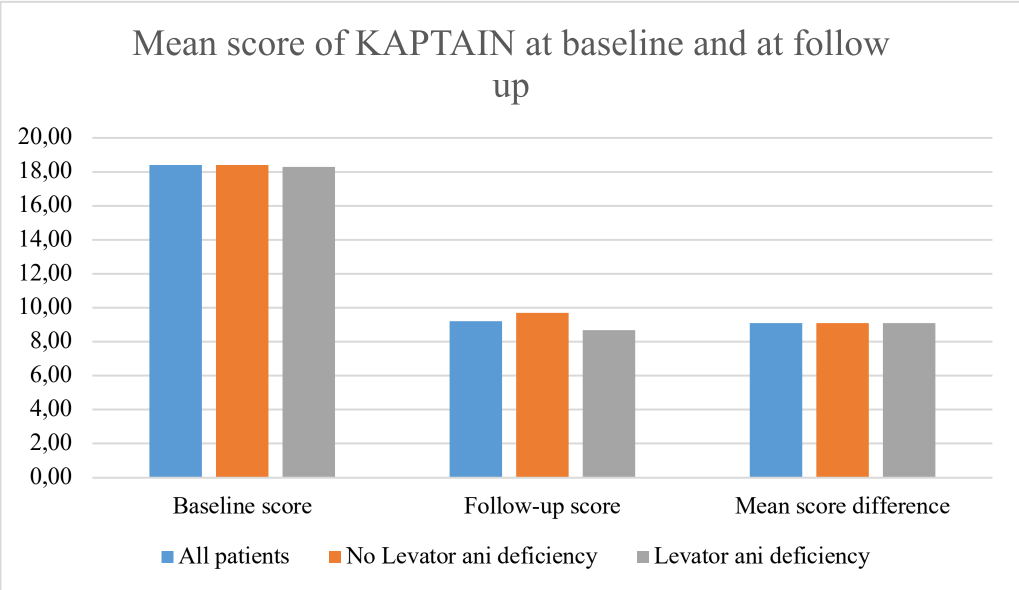

Figure 11. Total mean score out of 33 and mean score reduction of KAPTAIN at baseline and follow-up stratified by levator ani deficiency or not.

A total of 30 patients sought emergency care within one month after surgery with postoperative complaints, and of these, 17 received prescription antibiotics. No severe e.g., anorectal injury or anovaginal fistulae, adverse events were reported.

7 DISCUSSION

7.1 MAIN FINDINGS AND INTERPRETATION

7.1.1 Study I

The main findings of this study were that one year after their first vaginal delivery 20% of women with a second-degree perineal tear reported defecatory difficulties and 7 % surprisingly reported incontinence of loose stool. Another unanticipated result was that the proportions of symptoms were comparable in the control group of women with none-to-first degree perineal injuries.

As in previous research, most women attain a perineal tear of some extent after their first vaginal delivery, and as shown by de Leeuw et al. most of those tears do not involve the anal sphincters (44, 170). It has previously been suggested that almost two thirds of all primiparous women complain of symptoms of one or more PFDs postpartum, and it is also well-known that AI in all forms is a factor that significantly reduces reported quality of life (43, 171).

Our results were comparable those of Handa et al. who found an incidence of AI in 12% of women after perineal tears in general, and 19% in women after OASI when followed long-term up to 5-10 years after first delivery (38, 42). Forceps deliveries and perineal lacerations, but not episiotomies, were associated with PFD 5–10 years after a first delivery. In 2014, Rikard-Bell et al. published a study of primiparous women, which reported some differences between the defined perineal outcome (intact perineum, episiotomy, or spontaneous tear) and symptoms of urinary dysfunction, yet it did not show statistically significant differences between the perineal outcomes and other PFD, such as bowel dysfunction, POP, or sexual dysfunction (172).

Furthermore, a publication in 2017 examined pelvic floor outcomes at 6 months postpartum, stratified by degree of perineal laceration (173). This prospective study described that the proportion of women reporting at least one incident of anal incontinence was higher among those with perineal trauma (57%) (compared to intact/minor laceration, 45%), but that rates of fecal incontinence did not differ between groups (7% for intact/minor laceration vs 10% for 2+ degree laceration). The rates of anal and fecal incontinence they report are somewhat higher than those reported here, however their interpretation is quite different. Their conclusion is that "women having second-degree laceration are not an increased risk for pelvic floor dysfunction other than increased pain, and slightly lower sexual function scores at 6 months postpartum" (173). Our findings add even more evidence that women diagnosed with no obstetric perineal tears also suffer from pelvic floor dysfunction.

Unfortunately, the original MIMA study did not supply any data of functional bowel symptoms preceding delivery (i.e., before or during pregnancy) which would have been an interesting aspect to explore further, especially since such diagnoses may influence the interpretation of the outcomes. In a previous study by Larsson et al., high maternal age and increased birth weight was associated with an increased risk of any anal incontinence (AI) in vaginal deliveries

(OR of 1.40, 95% CI 1.40-1.57 for a 1-kg-increase in birth weight), adjusted for age and parity (174).

A second-degree perineal tear can range from a minor injury to the superficial parts of the bulbocavernosus or superficial transverse perineal muscles to a total rupture of the perineal body (excluding the external anal sphincter) (35). Anatomically, the anterior and lateral support to the anal canal is mainly formed by the rectovaginal fascia and the pubococcygeal muscle, which may both be affected by a second-degree perineal tear (15, 23, 175). This support and its innervation are crucial not only to the functionality of defecation, but indeed for the entire pelvic floor (23, 41, 61, 175-178). In this study, an extended classification to describe second-degree perineal tears more accurately has been suggested (36). It has been evaluated by different health professionals and has recently been introduced to the International Classification of Disease codes (ICD-11) by the Swedish Society of Obstetrics and Gynecology (179). A conclusion that can be drawn from the results of this study is that more attention should be paid to the complaints of women with non-OASI; a deficient perineum may follow second-degree perineal tears as well, as shown in other studies (58, 173, 180).

The development of PFD after vaginal childbirth, including FI, is clearly not only the result of perineal injury at delivery but is also a product of obstetric management of labor during both the first and second stages. Collaboration between midwives and obstetricians/gynecologists is of the essence for achieving the best possible maternal and fetal outcome (181-183). Factors such as advanced maternal age, fetal birth weight, duration of labor, as well as changes to tissue elasticity due to increased levels of Estrogen and Progesterone throughout pregnancy in preparation for delivery all play significant roles (14, 32, 38, 58, 64, 87, 90, 184-187). Instrumentally assisted vaginal deliveries are well-known risk factor for the development of PFD, whereas the protective of detrimental effects during management of labor including augmentation of labor, epidural administration, as well as methods of perineal protection are still being discussed (155, 180, 188-190).

Strengths and limitations

The strengths of this study are the addition to the relatively scarce literature available specifically on bowel dysfunction following even minor perineal trauma from vaginal deliveries defined as uncomplicated. Second, we used items from four internationally validated and clinically relevant questionnaires as tools to evaluate patient symptomatology, and the list of outcomes captures posterior compartment symptoms (158, 159, 191). Finally, the time frame chosen to evaluate patients' symptoms (questionnaire completion at 12 months, reflecting on the prior 3 months) is appropriate, given that most women will experience some degree of temporary postpartum pelvic floor dysfunction and sampling participants too early would inevitably lead to more false positive responses that are less likely to be clinically relevant as they may resolve with time (43, 50, 95, 97, 192, 193).

A substantial challenge in interpreting the results of this study arise with the diagnosis and definition of second-degree perineal tears, as the new subcategorization was used, Some lacerations may thus be assigned a second-degree ear diagnosis because the depth exceeds 0.5 cm but are otherwise uncomplicated, whereas other second-degree lacerations could involve bilateral high and deep side wall lacerations (and along with this, presumed levator ani avulsions) (45, 47, 194). Our initial ambition was to subgroup these larger second-degree perineal tears to explore whether such complex tears (that do not involve the anal sphincter or rectal mucosa) may in fact place women at a higher risk of postpartum pelvic floor dysfunction compared to those with an intact perineum. However, this group was considered too small for analysis (n=35).

In addition, determining whether known risk factors of FI apply to all types of incontinence as we had subdivided them (formed stool, loose stool, flatus, with intercourse or physical activity) was an appealing aspect. Unfortunately, the sample size in our study did not allow for a multivariate logistic regression of birth weight as a risk factor for all specific features of FI, as the total numbers of individuals experiencing some of these features were low (i.e., n=10 with FI with formed stool, n=25 FI with loose stool and n=5 FI with vaginal intercourse). In addition, there was no significant difference in mean birth weight between the groups with none-to-first degree or second-degree injuries respectively. Thus, while increasing birth weight is a known risk factor for AI, the assumption was made that the effect would be similar in both exposure (second-degree) and reference (none-to-first degree) groups. Furthermore, no conclusions on the effect of e.g., of wound dehiscence on the results could be made as data on postpartum wound healing was not obtained.

This study is designed as a cohort study, an observational study design where participants are grouped based on exposure and then compared to unexposed. In this cohort, primiparas with low-risk births are compared on the exposure defined second-degree to controls of none-to-first degree perineal tears (195). One of the major critiques of this study design is the inability to account for imbalances in patient characteristics due to its lack of randomization (195-197).

Though the response frequency was high (68.7%), it can be argued that there are some issues with selection bias in the original study as 71.2% of the women reported a college or university level education. Furthermore, the mean BMI of 23 kg/m^2 is not representative of women giving birth, nor was there information available on ethnicity. The ability to generalize the results of a study is referred to as external validity and is based on the assumption that the study population is a random sample representing all primiparous women giving birth without instrumental assistance (198). Agreeing with this assumption, the results may indeed be generalizable.

Selection bias occurs by either non-participation at recruitment or loss to follow-up (195). In this study, non-responders did not differ significantly as far as demographic or obstetric data is concerned, However, symptomatic women may be more willing to participate in studies compared with asymptomatic women, or on the contrary, women who had a negative or traumatic experience of their delivery would be hesitant to accept the study invitation as to prevent negative feeling. In either case the issue of external validity could be raised here as well (199).

Another limitation is the lack of a validated questionnaire. The term validity refers to whether the questionnaire measures what it is supposed to measure or not. The questionnaire in this study underwent a test of face validity but did not undergo a whole validation procedure to make sure that it would accurately measure what it was aimed to do (200, 201). In addition, by just using five out of ten items in a validated questionnaire (e.g. five questions chosen PISQ-12) and thereby modifying the questionnaire, the precision of the measurement is no longer intact (202). Thus, it is not an individual item or question that is validated but the whole questionnaire. Hence, there is a limitation that we cannot say that the questionnaire used in this study measures what it says it measures even though some questions are from previously validated inventories.

In line with this, inaccurately recorded or measured information in studies result in information bias. In this study data on current weight, height, and PFD symptoms were reported by participants via the questionnaire and thus susceptible to the participants' capacity as well as amenability to supply true information. However, misunderstanding questions or supplying wrong data may led to misinterpretation of the outcomes and the internal validity could be questioned (198). This occurs to some extent in all studies, however, if the measurement errors are random, the bias is generally towards the null (195).

7.1.2 Study II

This study reports the results of intra- and interrater reliability among two different raters in assessing the integrity and severity of levator ani deficiencies according to the LAD score using 3D EVUS with two different probes. The results show very high levels of agreement between raters and probes indicating that LAD score is a reproducible method when assessing levator ani deficiencies. Secondarily, the presence of LAD in a low-risk population consisting of primiparas with maximum a second-degree tear was, as expected, low. Only 6-9% fulfilled the criteria for moderate LAD and 4-6% for severe LAD. This is in line with previous research by Dietz et al. amongst others who have explored the prevalence of levator ani defects after childbirth (37, 46, 49). Van Delft et al. have studied LAM avulsion postpartum and found a prevalence of approximately 21% avulsions in a study population of 191 women who were examined at 36 weeks of pregnancy and returned three months postpartum. Similar results were shown by a Norwegian group examining primiparous women during pregnancy and postpartum (82). However, it has also been shown that many partial levator avulsions diagnosed in the early postpartum period seem to heal with a regress in symptoms during the first year after childbirth, which is why it is advisable to practice expectancy in diagnosing avulsions by ultrasound until one year has passed from the time of delivery (129, 203).

However, these findings draw the attention to the limitation of the LAD score in a low-risk population given that the score has only three categories with mild LAD also involving women with 0 points. This is a weakness of the score and if used in a population with unknown status of PFD this must be acknowledged, and a fourth category of no LAD might improve its usability in heterogenous samples. In a clinical setting the LAD score can only be used in women with clinical findings of LAD to further strengthen the diagnosis.

The results regarding high intra- and interrater reliability are promising with pelvic floor ultrasound emerging as a primary diagnostic tool in a clinical setting. Previous research has shown that 3D EVUS is comparable to MRI in its ability to identify both normal and abnormal LAM anatomy (77, 113).

Perineal pelvic floor ultrasound has previously been found to have good correlation with the assessment of the LAM by palpation (123). Parallel to endoanal ultrasonography being the gold standard of diagnostics of the anorectum by colorectal specialists, the same is suggested for assessment of the LAM (113, 204). Dietz et al. described a classification system for perineal 3D ultrasound, rating muscle defects as complete, partial, or no avulsion (205). This is a classification that has also shown good interrater reliability (206).

However, there is no gold standard for diagnosis and classification of levator ani defects across all imaging modalities. Vergeldt et al. suggest that rather than comparing the rating systems of different modalities the focus should lie on correlation to clinical outcome which certainly makes sense for the individual patient (207). A parallel could be drawn to the adjustments of the POP-Q system used in many clinical settings where clinical findings are described using the hymenal plane as a reference point as in the original POP-Q when assessing the anterior, apical and posterior compartments, however refraining from protocolling all nine measurement points.

A challenge that arises with developing and advancing imaging techniques more accessible in an office setting, is how to interpret and compare the different descriptions of LAM defects in different modalities such as MRI and different ultrasound methods. DeLancey et al. have advocated a terminology where defects are divided into major, minor, or no defects using MRI (3, 4). This classification system has been proven to be reliable between different raters, however MRI is a costly and non-freely accessible modality for clinical setting (208).

Confusion may arise though, as the terminology of defining defects in the two systems differs. While the MRI technique measures the amount of missing muscle bulk, the perineal ultrasound used by Dietz et al. utilizes a technique of tomographic slices, counting the number of cross-sections displaying defects. (2, 3). Both systems however agree that distinguishing major defects is of the highest clinical relevance, as such avulsions are associated both with the development in general of POP as well as the degree of severity of POP (4, 205).

Strengths and limitations

Strengths of this study are the large sample size, the validated technique of LAD scoring and two experienced raters that can reproduce previous findings of high reliability of the LAD scoring system. Raters were also blinded to potential patient symptoms and obstetric history apart from the information that the sample were primiparous women one year after vaginal delivery. This would thus warrant an assessment that is not influenced by expected findings due to pervious knowledge of maternal or obstetric risk factors of LAD (3, 6, 32, 38, 46, 49, 90, 209). In addition to this, there was a refinement to the evaluation as the ultrasound volumes rendered with two different probes were separated.

The advantages of the cross-sectional design of the study is that since it is a snapshot in time, the data collection does not require much time and is usually cost-effective (210). We could thus confirm previous findings on the low prevalence of LAD after low-risk deliveries (58, 76). However, having very few participants with LAD according to the LAD score might impact the results with artificially high agreement.

Nevertheless, there are several limitations that must be kept in mind when interpreting our results. We used a low-risk sample, and we have no background data such as POP-Q or clinical examination to validate our findings (211, 212). Furthermore, the participants were originally recruited from the MIMA-study, thus making this a small subset. Hence, no conclusions can be drawn on the rate of LAD in the MIMA-cohort. By choosing a sample of women after instrumental delivery and thus a higher risk of trauma in combination with more background data we might have been able to show that the LAD categories can distinguish between PFD or no PFD (120, 213, 214).

Moreover, by using two probes the high attrition rate can be interpreted as a potential source of selection bias. Even though the probes were inserted in a neutral position to minimize pressure of anatomic structures this is a disadvantage compared to for example MRI and other less invasive approaches such as perineal ultrasound. However, all studies using image interpretation are subject to inherent limitations of image analysis.

In addition, the purpose of this study was to test the system in a clinical research setting other than that of the research group of Shobeiri et al. in which it was originally constructed and has been used for several publications (113, 118, 119, 121, 122, 213-217).

We considered this cross-sectional design to be a first step in a validation process of the scoring system. With the rationale being that testing the assessment in a low-risk sample first would give us an indication on its feasibility before using it in a clinically more appropriate and indeed useful setting of symptomatic patients, e.g., with different levels of POP.

7.1.3 Study III

An 11-item inventory, the Karolinska Symptoms after Perineal Tear Inventory (KAPTAIN), was constructed and initially validated as well as found to be psychometrically stable.

The study showed that women with a deficient perineum scored significantly higher on the inventory compared to women after elective CS and women who have never given birth with a high sensitivity and high specificity.

Given the scarcity of previous studies evaluating symptoms of deficient perineum, the KAPTAIN is a promising new inventory and a valuable addition to the clinical assessment of symptoms after vaginal birth. In a Swedish setting, women who have given birth irrespective of obstetric tear are offered a registry-based follow-up through the National Medical Birth Registry. The aim of the registry is to identify women in need of further clinical evaluation postpartum. However, today, as validated screening inventories are lacking, and women with symptoms of deficient perineum are not identified today. This is in line with a review identifying nine validated instrument assessing PFD but none for PFD postpartum (218) and reports that validated diagnostic instruments are sought after by clinicians and patient representatives alike and of paramount importance to further the knowledge and improve treatment (9, 11).

It has been shown that there is a link between non-OASI tears and PFD thus it is important to identify these women in order to provide further clinical assessment. Huber et al. recently published a study showing a link between second-degree tear and pelvic floor symptoms (180). Other published work includes longitudinal studies that show that women diagnosed with a second-degree tear have a doubled risk for stress incontinence compared to women who have given birth by CS (219). In addition, Gommesen et al. have shown that every second woman presenting with anal incontinence one year after vaginal delivery had not been diagnosed with an OASI, and that impairment of sexual health is common among primiparous women after vaginal delivery, albeit increasingly with greater vaginal tear, but still significant in non-OASI tear (68, 220). Moreover, Gyhagen et al. state that women who had been diagnosed with second-degree perineal tears or OASI experienced perineal pain and dyspareunia and had an increased risk of concomitant PFD in registry-based studies 20 years after vaginal delivery (187, 219, 221). The prevalence of coexistent PFD was doubled in women after vaginal delivery compared to women who had given birth with CS (187, 222, 223).

Extensive literature review revealed sparse information on specific inventories addressing the symptomatology of a deficient perineum after vaginal childbirth in the time extending past the postpartum and primary healing period. The review revealed the General Health Questionnaire (GHQ-28) which assesses the maternal health in postpartum period, but does not addresses perineal health specifically (224). Shoorab et al. published the WRPPIQ questionnaire in 2020 which measures women's experience of perineal recovery in the postpartum period, however this inventory investigates general health recovery in the postpartum period rather than specifically targeting symptoms of a deficient perineum in a mid-range time frame of more than one year after birth (225).

Strengths and limitations

The strengths this study includes the different steps taken to establish content validity as well as psychometric evaluation (164, 169, 200, 226). Correspondingly, to use expert panels as well as clinical round tables made sure that the clinical relevance was secured both for items as well as cut-off scores (164, 167, 168).

Limitations include the fact that KAPTAIN is only validated in Swedish. Another limitation is the lack of control group with second-degree tears but not diagnosed with a deficient perineum. Therefore, we can’t say that the results are unique for women with a deficient perineum but might mirror the symptoms of women regardless of perineal trauma. However, we can say that it does not mirror symptoms related to only pregnancy.

Generalizability of data is limited as patients were included only within a tertiary setting. Similarly, only gynecologists were used as experts for the advisory panel as well as the round table discussions. By including other perspectives from health care professionals or patient representatives in the selection of items we might have increased face validity.

In addition, data on BMI were missing for the women in the Elective CS group as they were only controlled for inclusion criteria at study start. However, BMI does not seem be a confounder affecting the scoring as the group scores significantly lower than the patients. Confounding can distort the association between exposure and outcome (227). This occurs when a variable is associated with the exposure and influences the outcome. Consequently, a confounder must be associated with both the exposure of interest in the study as well as with the outcome, but it should not be in the causal pathway between exposure and outcome.

7.1.4 Study IV

This is the first and largest study estimating symptom reduction one year after perineal reconstructive surgery. In addition, the use of a validated inventory and stratifying the results by concomitant LAD is a novel approach.

Main findings include a significant reduction in score in total as well in individual items assessed in the KAPTAIN inventory regardless of the presence of levator ani deficiency. Concordant to our results, previous research have shown that perineal reconstruction reduces the acquired sensation of a wide vagina (70, 228). Surprisingly, our study showed significant score reduction in total as well as in most individual items of the KAPTAIN inventory, irrespective of LAD. This is an important finding as previous research has indicated that there is an association between LAD and PFD overall and that surgical results are negatively impacted by a concomitant LAD (4, 5, 216, 229, 230).

In line with previous studies, surgery aimed at optimizing the pelvic floor support to reduce symptoms (146, 231), and the surgical technique used in the present study aimed to restore the entire perineal body and structures such as the rectovaginal fascia and the insertion of the puboperinealis muscle. This might also be a contributing factor in the fact that there was a statistically significant score reduction regarding incontinence of loose stool in patients in the "no LAD"-group. It was a rare symptom with low preoperative scores, nevertheless a score reduction was noted and might be due to the connection between the LAM and the perineal body to increase pelvic floor support being restored by the surgery thus improving the functional anatomy of the pelvic floor (1, 232-234). However, there was no significant score reduction in patients with LAD, highlighting the importance of the integrity of LAM in anal incontinence (110, 217). In addition, this result should be interpreted with precaution, as there are many other factors to consider as far as the functionality of the bowel is concerned, making it unlikely that a sole surgical intervention remedy them all.

Another unexpected result was that even though there was a very small score reduction sexual dysfunction seem to be improved; however, it could be argued that the preoperative score was low to begin with, making the score difference neglectable. However, in light of dyspareunia being one of the strongest arguments against perineal reconstruction, this result is encouraging (144, 176, 235, 236).

Consistent with other studies on this topic, the surgical intervention showed improved quality of life at follow-up, indicating satisfied patients (71, 147, 237). The absence of major adverse events reported is an encouraging counterpart to previously voiced concerns of postpartum dyspareunia or far worse sequelae such as organ damage or fistulae (147, 176, 235, 238-240). It can be argued that there is a placebo effect of receiving treatment, and a surgical intervention that might influence replies and enhance the positive effect of the intervention as has been suggested in similar studies (241). This will certainly have to be explored further. Nevertheless, several studies point towards strong association between the size of the genital hiatus and the development of pelvic organ prolapse, as well as stating a defect of the perineal body as marker of an enlarged genital hiatus, making the need greater for evaluated surgical methods to repair a deficient perineum (73, 242, 243).

Strengths and limitations

The strengths of this study are that women were included based of both symptoms and anatomical findings and to our knowledge, this is the largest number of patients included and followed after perineal reconstructive surgery. In addition, our study is one of the studies with the longest follow-up time to date (70, 244). Moreover, the surgeries were performed in a standardized way by experienced urogynecologists safeguarding that the technique used was reproduceable and all patients received standardized care including choice of sutures and local anesthesia.

Recruitment was dependent on the treating physician, hence, if any, non-participation was associated rather to neglect to invite a potential participant due to time limitations rather than inclusion criteria not being filled. Selection may therefore be considered non-differential and would not bias the outcomes (195).

In addition, due to the pandemic, a longer time from inclusion to surgical intervention, and correspondingly to follow-up was expected. However, the study had an all-over high follow-up rate of 90% for the inventory, and over 80% for the clinical examinations with a median follow-up time of 13.2 months. This would rather mirror the hesitance to return to hospital setting during a pandemic than be counted as loss to follow-up, and thus, the risk of selection bias due to differential attrition is considered low.

We aimed at exploring outcomes of perineal reconstructive surgery in patients with an acquired sensation of wide vagina and a deficient perineum. Using a validated inventory, standardized surgical intervention and structured follow-up ensured conformity to the best of our knowledge. However, misinterpretation of questions, inaccurate medical chart data or the inherent social expediency to complete the inventory in what the responder deemed to be a beneficial or benevolent way may lead to false conclusions and an over- or underestimations of outcome effects.

8 POINTS OF PERSPECTIVE

The results of the studies in this thesis will add a substantial piece to the presently far from completed puzzle that is pelvic floor disorders after childbirth. However, scraping the surface of the complex symptomatology seem to raise more questions than it answers. Our results highlight the importance of dedicating resources toward further exploring women's symptoms and experiences after childbirth, irrespective of perineal tear. We need to address the fact that PFD is multifactorial and may arise equally from the far larger cohort of women diagnosed with non-OASI, and span far past the classical triad of POP, UI and AI.

While the findings presented here have shed light on levator ani defect diagnostics, and have added an instrument to detect women with symptoms of a deficient perineum, here are some further queries to consider:

- Levator ani deficiency increases the lifetime risk factor of developing PFD. To date there is no established surgical method to reapir an avulsion injury. Thus there is a great need to focus of prevention, addressing modifiable obstetric factors and exploring the pathophysiologic pathway of LAD utilizing biomechanical models
- Symptoms of LAD and of a deficient perineum have great impact on women's everyday life. Yet there is a scarcity of research on the natural history of perineal trauma in the aftermath of the first year postpartum. It would certainly be interesting to explore the prevalence of persistens symptoms after perineal trauma and linking them to the inital injury and present clinical findings
- The KAPTAIN inventory has shown high precision in detecting patient with symptoms of a deficient perineum in the initial validation. It now needs to be further validated by performing tests and re-test, as well as performing a validation in larger cohort of women one year postpartum.
- There is also a knowledge gap about the prevalence of long-term symptoms after perineal tears other than OASI
- The anatomical hypothesis in Study IV was that reconstructive surgery would reinforce the support to the pelvic floor that is lost in the deficient perineum. As an enlarged genital hiatus is a risk factor for POP, it would be interesting to follow the patient cohort over a prolonged time period in regard to development of POP in the participants diagnosed with or without LAD.

9 CONCLUSIONS

The aim of this thesis was to investigate the symptomatology of women after non-OASI perineal tears, to explore and add possible diagnostic tools and to examine whether perineal reconstructive surgery could alleviate symptoms specific of a deficient perineum.

Women with minor or moderate perineal tears may experience pelvic floor symptoms that have previously only been associated with anal sphincter injuries. This knowledge is important to supply the proper support and improve care for these women.

Levator ani muscle integrity plays a vital role in pelvic floor health, and diagnostic techniques such as imaging methods are developing and being refined. It is important to have a standardized nomenclature when making diagnoses and counselling patients. The levator ani deficiency score is a scoring system with high intra- and interrater concordance regardless of specific probe, thus aiding in supplying accurate and consistent information to potential patients. However, ultrasound can never replace the clinical examination in assessing the dynamic and functional anatomy of the pelvic floor, albeit a useful complement.

Symptoms of an acquired sensation of a wide vagina, vaginal flatulence and bowel emptying difficulties are improved after standardized perineal reconstructive surgery. This symptom reduction is seen regardless of whether the patients have concomitant levator ani deficiencies.

Our findings emphasize the importance of focusing on women's symptoms and listening to their concerns, regardless of the severity of the initial obstetric injury. PFD is not only limited to women with severe perineal trauma, and this awareness will improve health care and enhance quality of life for all women after vaginal childbirth.

There is further need for studies focusing on symptomatology linked to anatomical findings - rather than anatomic changes being the primary outcomes, exploring symptoms and striving to ameliorate them will truly improve women’s quality of life.

10 PERSONAL REFLECTIONS

Looking back on six highly rewarding and quite bumpy years, I am grateful for the lessons learned and the collaborative network that has evolved around me. It has been a time period filled with new insights, old realizations, highs and lows, a lot of new knowledge, and pride. Ultimately this educational journey has led to this thesis, and I would like to allow myself some personal reflections.

The studies in this thesis were planned and performed to reach the overarching aims. They were also chosen to educate me and to mentor me towards becoming an independent researcher. Out of the four studies in this thesis, different research methods are applied in three, and while I certainly would not claim expertise in any of them, I have experienced and discussed the advantages and challenges of them repeatedly. My most important lesson has been to know when to ask for help!

Theoretically, it all began with discussions in a clinical setting which led to the first thought babies on **Study IV**. In actuality, it began with a chance meeting that resulted in a somewhat hasty acceptance to jump aboard an already ongoing research study. Initially this resulted in many evenings of waiting for participants of **Study II** to show up. Sometimes they did, teaching me the inherent gratitude and awe of first-time mothers taking the time out of their days and nights to venture to a suburban hospital to help improve understanding and knowledge that would benefit future women rather than themselves. In case they didn't show up, there was instead time for literature review and database searches - also an indispensable part of learning!

Listening to these women's experiences also further fueled my interest in this group. Rather than being supported by health care practitioners, they found comfort, support and information from social media groups and conversations on playgrounds or at book circles, sharing their fear and frustration of not being heard and seen when seeking help.

It has been an equally motivating and humbling experience to realize how little we know and how much remains to be explored concerning the effect that vaginal delivery has on the pelvic floor and indeed on women's quality of life. The gap between anatomical knowledge and functional anatomy is considerable and linking it to symptomatology has been demanding - not least in the efforts of getting a manuscript accepted for publication. I have now truly learnt the importance of clearly state my rationale!

To conclude, these years as a clinician and doctoral student have taught me that research is grueling and elating, stimulating and frustrating, that there are many answers to each question, and that none of them is perfect. While the findings from this thesis may raise new questions, I hope it will in also contribute to filling the knowledge gap in order to better help out patients.

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