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Surgery for Pelvic Floor Dysfunction: Risks and Effects on Sexual Function

A Population Based and Clinical Study

Thesis for the degree of Philosophiae Doctor

Trondheim, April 2015

Norwegian University of Science and Technology
Faculty of Medicine
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Norsk sammendrag – Kirurgi for bekkenbunndysfunksjon: Risikofaktorer og effekt på seksualfunksjon

Dysfunksjon i bekkenbunnen hos kvinner inkluderer tilstandene underlivsfremfall og urininkontinens av typen stressinkontinens. Disse tilstandene kan opereres, og hovedformålet med slike operasjoner er å forbedre kvinnenes livskvalitet, inkludert seksualfunksjonen. Det finnes få studier som undersøker forekomst av bekkenbunnskirurgi. Risikofaktorer for både bekkenbunnsdysfunksjon og kirurgisk behandling av tilstanden antas å være økende alder og antall vaginale barnefødslerparitet. Vi vet mindre om ikke-obstetriske risikofaktorer. Nyere forskning tyder på at kirurgisk behandling av bekkenbunnsdysfunksjon kan forbedre seksualfunksjonen hos de opererte kvinnene, men vi vet stort sett ikke hvilke faktorer som kan predikere forbedring. Svært få forskere har undersøkt seksualfunksjonen hos mannlige partnere av de kvinnene som er operert for bekkenbunnsdysfunksjon.

Formålet med denne avhandlingen var å undersøke forekomsten av kirurgisk behandling av bekkenbunnsdysfunksjon i et nordisk land og å finne ut om det fantes risikofaktorer som ikke hadde med vaginale barnefødsler å gjøre. I tillegg ville jeg undersøke hvilke faktorer var involvert i forandret seksualfunksjonen blant kvinnelige pasienter som ble operert for bekkenbunnsdysfunksjon, samt å utforske om deres mannlige partneres seksualfunksjon forandret seg etter slik kirurgi.

Grunnlaget for beregninger av forekomst og risiko faktorer er hovedsakelig basert på informasjon fra den tredje Helseundersøkelsen i Nord-Trøndelag (HUNT 3). Dette er en tverrsnittsundersøkelse basert på selvrapportering via spørreskjema og på kliniske undersøkelser. Omtrent halvparten av hele kvinnelig befolkning over 30 år i dette fylket hadde svart på spørsmål om operativ behandling av bekkenbunnsdysfunksjon.
I tillegg spurte vi kvinner som ble operert ved St. Olavs Hospital i Trondheim for bekkenbunnsdysfunksjon og deres partnere om seksualfunksjonen. Dette var en oppfølgingsstudie, der informasjon fra selvrapporterte spørreskjema fra både kvinnene og deres partnere ble samlet in før og ett år etter bekkenbunnskirurg. I tillegg gjennomførte vi både før og etter kirurgi en standardisert klinisk undersøkelse av kvinnenes bekkenbunn og informasjonen fra pasienten sin pasient journal ble samlet inn.

Blant kvinner over 80 år rapporterte henholdsvis 17 og 7 % at de hadde fått utført operasjon for underlivsfremfall og urininkontinens.
Fra HUNT-3 fant vi at kronisk forstoppelse, overvekt og kronisk obstruktiv lungesykdom økte sjansen både for operasjon for underlivsfremfall og for urininkontinens, i tillegg til økende alder og antall fødte barn. Astma og røyking var kun risiko faktorer for operasjon for urininkontinens.
Blant de opererte pasientene fra St. Olavs Hospital fant vi at seksualfunksjonen i gjennomsnitt hadde forbedret seg ett år etter kirurgi. God generell helse eller urinlekkasje under samleie før operasjonen predikerte forbedring, mens psykologisk stress eller et håp om å forbedre tarmtømmingen predikerte forverring av

seksualfunksjonen. For menn var seksuell drift, ereksjon og tilfredshet med seksuallivet uforandret, mens ejakulasjonen hadde blitt litt bedre. Denne forbedringen syntes å ha sammenheng med det, at etter operasjon færre menn opplevde at kvinnene hadde samleiesmerter.

Konklusjonen i avhandlingen blir at livstidsrisiko for å bli operert for bekkenbunnsdysfunksjon er relativt høy også i Norge. Faktorer som øker belastningen på bekkenbunnen var assosiert med høyere forekomst av slik kirurgi. Blant kvinnelige pasienter som ble operert ble seksualfunksjonen bedre hvis de hadde generelt god helse, ingen mentale helseplager eller urinlekkasje under samleie før operasjonen. For mannlige partnere var seksualfunksjonen stort sett uforandret eller litt bedre.

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Torsdag, 16.april 2015

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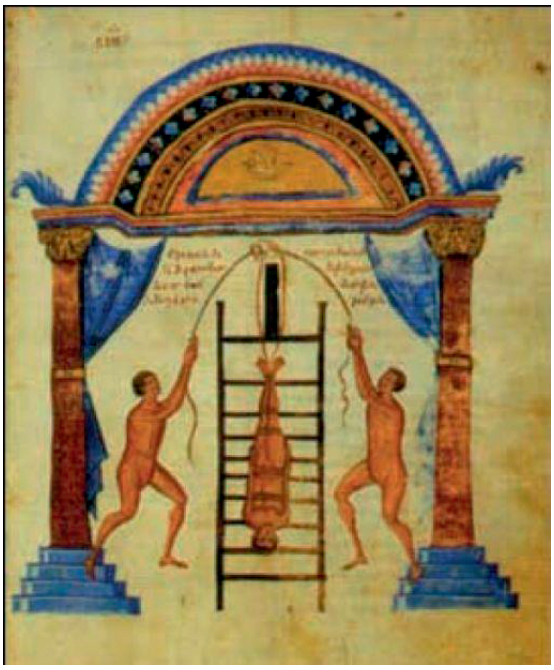
Motto

"I had to laugh so hard, that the tears were running down my legs!"

Anonymous women, suffering from stress urinary incontinence



Treatment for pelvic organ prolapse at the time of Hippocrates.

"Research is formalized curiosity. It is poking and prying with a purpose."

Zora Neale Hurston 1891-1960

Acknowledgements

This thesis was financed by the Liaison Committee between the Central Norwegian Regional Health Authority (RHA) and the Norwegian University of Science and Technology (NTNU). I would like to thank the Norwegian tax payers for giving me the fantastic opportunity and privilege to spend just over three years to really explore a fascinating topic, develop my skills as a researcher and receive an education in sexual medicine.

I want to thank the women and their partners from the clinical trial, who spent their time filling out questionnaires. I am grateful to the HUNT research center for giving me access to the data set and for always willing to help when another variable was urgently needed.

My deepest gratitude goes to my principal supervisor Berit Schei! She managed to shape my sometimes quite unfocused curiosity and enthusiasm about all sorts of things with her critical and constructive guidance. Your instinct of what is interesting, combined with a merciless "Kill your darlings" approach, was impressive and really appreciated. The once in a lifetime opportunity you gave me, spending six months in Melbourne, Australia, to work together with Lorraine Dennerstein, has also taught me a lot.

I also would like to thank my co-supervisors, Siv Mørkved and Øyvind Salvesen. Øyvind, thanks to your patience I really enjoy statistics! Siv, thank you for always giving me positive feedback, particularly at difficult times.

Of course, I must thank my colleagues and friends at the gynecological department, in particular Merete Myklebost, my boss. You always supported me, giving me time when it was necessary, as well as expert advice on urogynecological matters. A thank you

goes also to Runa Heimstadt, our head of department, for giving me time off from our busy unit. All my colleagues contributed willingly by collecting data; a special thanks goes to Ingrid Volløyhaug for additional urogynecological and musical advice. Olaug Storrø, our own sexologist, is the one I have to thank for professional advice when designing the questionnaires, before I seriously began to study sexual medicine. You opened the door to this really fascinating topic! Professor Moen, thanks for creative tips.

A sincere thank you goes to Anita Stølan and Maya Rendal for sending out forms and reminding women, always friendly and welcoming. Another big thank you is for the theater nurses for relentlessly reminding my colleagues to fill in POP-Q forms, and to Anita Vanvikan in urogynecologic outpatients as well, to follow up patients with me and to the nurses of the general gynecologic ward who create a professional and warm atmosphere, facilitating participation! Thanks as well to Lene and Elisabeth to help me with printing, stapling and numbering of questionnaires.

I need to mention my room- mates and colleagues form the 5th floor, including the ethical committee, I shared the past three years with. What inspiring discussions we had, both in the office and during lunch - thanks for adding additional flavor (literally!) and enjoyment to this period! Thank you Cecilie, my colleague and friend, for sharing the pain and gain: you are always there when needed and to contributed much to improving both the layout of my presentations and proper Norwegian sentences!

I will have to be eternally grateful to Herman, the best husband in the world, my fantastic sons Cecil, Guus, and Aslak and my sweet daughters Rosanna and Årolilja who had to sacrifice some quality time for my sake! I know, I was not always as appreciative as I should have been and I will try to improve. But I do have the idea that you guys also seem to have the curiosity gene in you- and it wasn't too bad "down under", was it?

List of papers

This thesis is based on the following papers, centered on results from two studies:

Study one: Helse Undersøkelsen Nord Trøndelag

I. Lonnée-Hoffmann RAM, Salvesen Ø, Mørkved S, Schei B. Self- reported pelvic organ prolapse surgery- prevalence and non-obstetric risk factors- a HUNT study

Int Urogynecol J 2014:e-pub ahead of print.

DOI: 10.1007/s00192-014-2509-4

Supplementary results. Lonnée-Hoffmann RAM. Self-reported stress urinary incontinence surgery- prevalence and non-obstetric risk factors- a HUNT study

Study two: BEkkenbunn and SEksualitet

II. Lonnée-Hoffmann RAM, Salvesen Ø, Mørkved S, Schei B. What predicts improved sexual function after pelvic floor surgery? A follow up study

Acta Obstet Gynecol Scand 2013;92(11): 1304-1312.

DOI 10.1111/aogs.12237

III. Lonnée-Hoffmann RAM, Salvesen Ø, Mørkved S, Schei B. Male sexual function and pelvic floor surgery of their female partner - a one year follow up study

Post Reprod Health 2014; 20(2):55-61.

DOI 10.1177/1754045314524950

Abbreviations

BMI	Body mass index
BESE	Pelvic floor and sexuality study (**BE**kkenbunn og **SE**ksualitet)
BI	Body image
BSFI	Brief sexual function index (men)
ED	Erectile dysfunction
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
HUNT	Nord Trøndelag Health Study (**H**else**U**ndersøkelse i **N**ord **T**røndelag)
OR	Odds ratio
PISQ-12	Pelvic organ prolapse and incontinence questionnaire, short form (women)
PFD	Pelvic floor dysfunction
POP	Pelvic organ prolapse
Q1	Questionnaire 1 (HUNT)
Q2	Questionnaire 2 (HUNT)
UI	Urinary incontinence
SD	Standard deviation
SUI	Stress urinary incontinence
TVT	Tension free Vaginal Tape® (Gynecare, Somerville, NJ, USA)
TVT-O	Tension free Vaginal Tape –Obturator® (Gynecare, Somerville, NJ, USA)

Summary

Surgery for pelvic floor dysfunction (PFD) is a common treatment for pelvic organ prolapse (POP) and stress urinary incontinence (SUI). It is mainly performed to improve quality of life, which includes sexual function. Prevalence may differ depending on the setting and is addressed in a small number of studies only. Increasing age and parity are considered risk factors for PFD and PFD requiring surgery. Less is known about non-obstetric risk factors. More recent research suggests that pelvic floor surgery improves female sexual function. Yet, prognostic factors for improvement are largely unknown. For partner sexual function after surgery for POP or SUI, there is a general lack of studies.

The aims of this thesis were to estimate prevalence for POP and SUI surgery in a Nordic population and to examine non-obstetric risk factors, to analyze which factors were predictive for improved sexual function among women after POP or SUI surgery and to examine if sexual function of their male partners changed.

Prevalence rates and risk factor estimates for POP and SUI surgery were based on mostly cross- sectional information from the Nord Trøndelag Health survey 3
(HUNT 3). Information was collected from questionnaires and clinical examinations. Of the total female population above age 30 in the county, 20 285 women (50 %) were included in the study population for POP surgery and 17809 (44.2 %) in the study population for SUI surgery.

Questions on sexuality were addressed in an observational follow up study at the St Olavs hospital, Trondheim, Norway, separately for women and their partners. Self-administered questionnaires containing a collection of validated instruments and exploratory questions were administered both before POP or SUI surgery and one year

after. For women, standardized measurements of the pelvic floor were performed at both times. Changes in female (n= 65) and male (n=36) sexual function were examined.

Results: Of women above the age of 80, 16.5 % had reported POP surgery and 6.9 % reported SUI surgery. Apart from increasing age and parity, chronic constipation, above normal body mass index and chronic obstructive pulmonary disease (COPD) were risk factors both for POP and SUI surgery. Asthma as well as smoking was associated with higher odds for SUI surgery only.

In the patient population, one year after surgery for POP or SUI, sexual function had improved among women. Good health prior to surgery or coital incontinence predicted improvement, while psychological distress or the goal of improving defecation was inversely related to improvement. Further factors differed for women after POP or SUI surgery.

Among men, scores for sexual drive, erection and overall satisfaction were unchanged and the ejaculation score had improved mildly. The reduction in the proportion of men reporting their partners to suffer from dyspareunia was correlated to this improvement.

Conclusion: Lifetime risk for surgery for PFD is high in Norway and we found evidence that factors causing chronic strain on the pelvic floor are risk factors. For the large majority of women and men, sexual function improved or remained unchanged. For women, this change was related to general and mental health and coital incontinence, while for men it was related to partner-dependent factors.

1. BACKGROUND

1.1 *Perspective*

In my last year of training as a gynecologist, during preoperative counseling for a hysterectomy, a patient asked me, how sex with her partner was going to be after surgery. I had not come across this question and was at a loss.

A literature search in 1998 revealed only a single qualitative study about the partner's view (Lalos *et al.* 1996). The result was a small and retrospective study, which gave me a probable answer to that inspiring question (Lonnee-Hoffmann *et al.* 2006). Having been sensitized to sexual concerns in a gynecological setting, I had the clinical impression that some women were hoping to improve sexuality in their relationship by undergoing pelvic floor surgery. A literature search in 2007 did not identify a single publication on male sexuality in this context. This was the background to initiate a prospective observational study at the institution where I was working. While data collection progressed slowly, I had the opportunity to acquire more research skills and became interested in working with larger and population-based datasets - the obvious choice in Trondheim being the HUNT survey. Unfortunately, in the HUNT survey so far, not a single question covered sexual function. In the literature, conflicting evidence from the few studies examining non-obstetric risk factors for pelvic floor surgery was found. Most of these risk factors could be examined in the HUNT data set.

The following section provides definitions for main terms and conditions discussed in this thesis and presents background from available literature. The aspects around the condition of PFD are reviewed briefly, while risk factors and sexual function in relation to POP -and SUI surgery are examined thoroughly.

1.2 *Female pelvic floor and female pelvic floor dysfunction*

1.2.1 Concepts

The pelvic floor is a compound structure closing the bony pelvic outlet. The most cranial layer is the peritoneum covering the pelvic viscera, the main elements of the middle part are the pelvic floor muscles and fibrous elements, while the most distal part is the skin of the vulva and peritoneum (Wei *et al.* 2004) (figure 1).

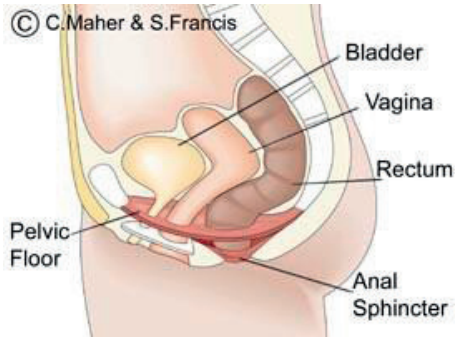


Figure 1. The pelvic floor in relation to the surrounding organs.
With permission from C.Maher.

To allow clinicians and researchers precise communication about closely related disorders of the pelvic floor, the International Continence Society has published guidelines with updates on the terminology of female pelvic floor dysfunction (PFD) since 1973 and later has published them together with the International Urogynecolgical Association (Bump 1996, Haylen 2010). The terminology used in this thesis conforms to the definitions recommended by these authorities. The diagnosis of PFD should only be made in the presence of both symptoms and signs and, if applicable, results of diagnostic investigations. Symptoms of female PFD can be divided into five groups: lower urinary tract-, prolapse-, bowel- sexual- and pain symptoms. The two main signs for PFD elicited at clinical examination are urinary incontinence and pelvic organ prolapse (Haylen *et al.* 2010). The most common (> 10% prevalence among women presenting with symptoms of PFD) diagnosis of PFD are SUI, detrusor overactivity, bladder

oversensitivity, voiding dysfunction, POP and recurrent urinary tract infections (Haylen *et al.* 2010). Of those conditions, only urinary incontinence (UI) with a predominant stress component (SUI or mixed incontinence) and POP are suitable for surgical treatment.

Further in this thesis, PFD will be discussed as one entity or separately as POP and SUI depending of the available information or if results apply to both or only the one condition.

It has been suggested, that (stress) urinary incontinence and POP share similar risk profiles and commonly coexist (Bump *et al.* 1998). In a Norwegian cohort, 38% of women presenting with urinary incontinence had "significant" prolapse (Seim *et al.* 1996). Therefore both conditions are considered in this thesis.

The etiology for PFD conditions is thought to be multifactorial. A combination of predisposing causes (mainly genetic), neurologic and tissue damage to the pelvic floor, both direct (second stage in labor, surgery) and indirect- (repetitive straining, increased weight) as well as changes in tissue structure (ageing, hormones, smoking) may be involved (Smith *et al.* 1989; Schaffer *et al.* 2005; Twiss *et al.* 2008).

Already in 1998, Richard Bump et al. developed a model for the development of PFD in women, based on expert opinion and limited epidemiologic and clinical evidence (figure 2). He suggested that promoting factors may be the most amendable of the risk factors, yet with little data to support at the time (Bump *et al.* 1998).

In the current thesis, five of these promoting factors will be examined-constipation, occupation, obesity, lung disease and smoking. All of these are modifiable. To account for confounding, also age and childbirth are included as confounders in the evaluation.

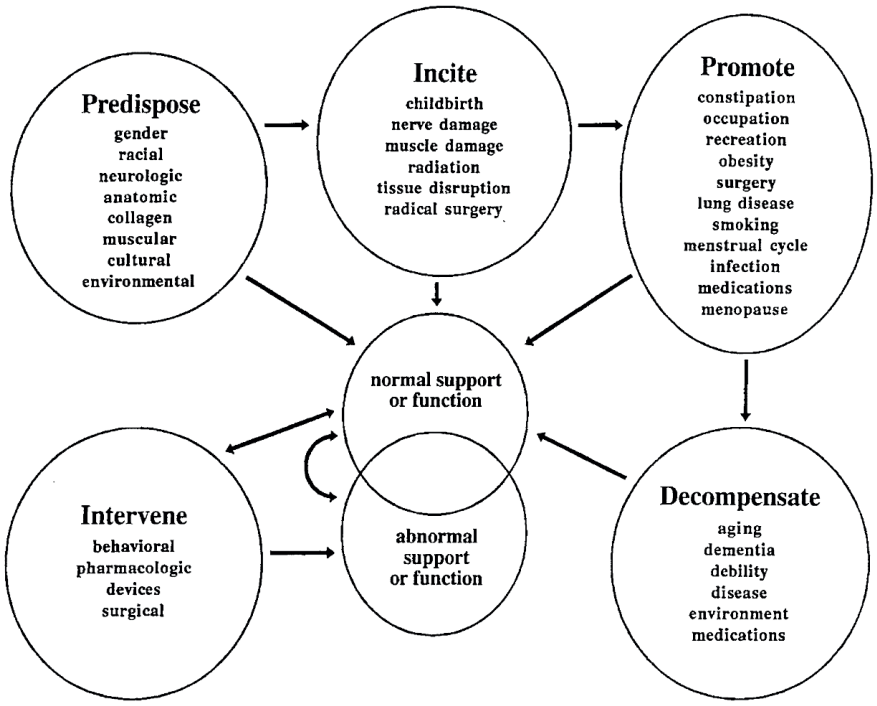


Figure 2. Model for risk factors for the development of pelvic floor dysfunction in women. With permission from Elsevier, Bump R. et al. 1998. Obsterics and Gynecology Clinics of North America.

1.2.2 Definition and prevalence

1.2.2.1 Pelvic organ prolapse:

POP is defined as the descent of the anterior or posterior vaginal wall, the uterus (cervix) or the vault of the vagina. To be clinically relevant, the presence of such a *sign* should be associated with relevant POP symptoms (Bump *et al.* 1996; Haylen *et al.* 2010). Symptoms commonly occur, when the prolapse is at or beyond the level of the hymen (Haylen *et al.* 2010).

Typical POP *symptoms* are vaginal bulging, pelvic pressure or increased feeling of heaviness and may include low backache (Haylen *et al.* 2010). However, these symptoms are unspecific and therefore a validated measure was developed, the Pelvic

Organ Prolapse Quantification System (POPQ), to describe and stage the descent. (Bump *et al.* 1996; Mouritsen 2005) (figure 3). Researchers are required to apply this system measuring the distance from the hymenal ring to 5-6 distinct points as well as the length of the defined genital hiatus under specified conditions (Weber *et al.* 2001; Hunskaar 2005).

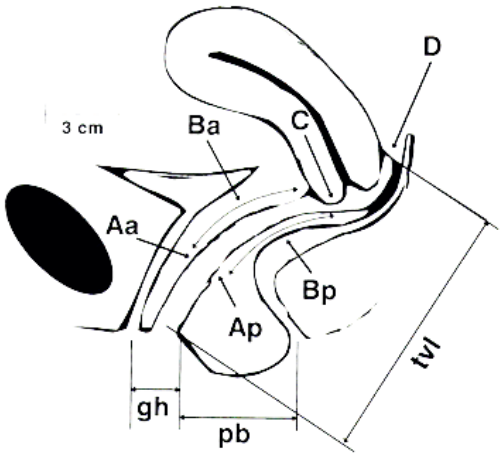


Figure 3. Pelvic Organ Prolapse Quantification System (POPQ).
Reprinted from (Bump *et al.* 1996). With permission from Elsevier.

Four stages of prolapse are defined, which can be located in the anterior, posterior or apical compartment (Bump *et al.* 1996; Haylen *et al.* 2010; Gomelsky *et al.* 2011) (figure 4). The point of reference for prolapse description is the hymen.

Stage 0: No prolapse is demonstrated.

Stage 1: Most distal part of prolapse is more than 1 cm above the level of the hymen.

Stage 2: Most distal part of prolapse is ≤ 1 cm proximal or distal to the plane of the hymen.

Stage 3: Most distal part of prolapse is ≥ 1 cm below the plane of the hymen.

Stage 4: Complete eversion of the total length of the lower genital tract

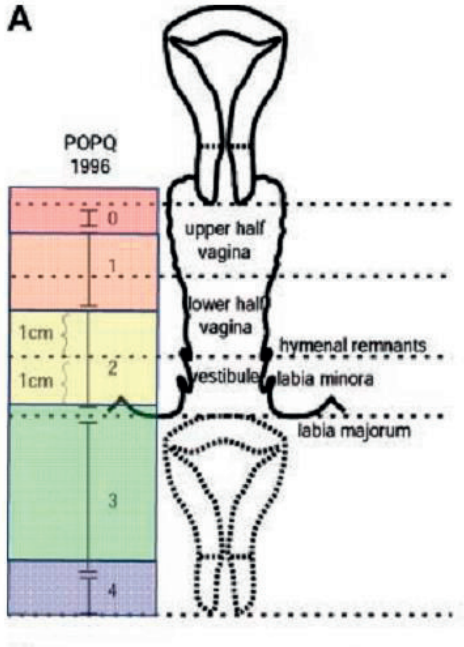


Figure 4. Pelvic organ prolapse staging 0,1,2,3 and 4.
Reprinted from (Haylen *et al*. 2010). With permission from John Wiley and sons.

The prevalence of Stage 1 prolapse has been described as high as 94 % in a clinical population (Hunskaar 2005). In the general population, prevalence of any stage was estimated to be approximately 50% (Samuelsson *et al.* 1999). The prevalence of prolapse symptoms is much lower; in two Swedish population-based cohorts the range was between 8.3% and 16% (Uustal Fornell *et al.* 2004; Tegerstedt *et al.* 2005).

1.2.2.2 Stress urinary incontinence

The *symptom* of SUI is the complaint of involuntary loss of urine on physical effort or sudden increase of intra-abdominal pressure like coughing (Haylen *et al.* 2010). This is in contrast to the symptom of urgency incontinence, when the loss of urine is associated with urgency (Haylen *et al.* 2010). The *sign* of SUI is the observation of involuntary leakage of urine from the urethra, synchronous with coughing or physical effort (Haylen

et al. 2010). The term for the definite diagnosis is urodynamic stress incontinence. This phrase should only be applied, when involuntary urine leakage is observed while performing a filling cystometry (urodynamic test), during increased intra-abdominal pressure and in the absence of a detrusor contraction. When observing an involuntary detrusor contraction during urodynamic testing, the diagnosis detrusor overactivity should be made (Haylen *et al.* 2010). Mixed urinary incontinence refers to a combination of incontinence symptoms or urodynamic conditions in an individual.

In this thesis the term UI will be used, when not specifically referring to SUI.

Prevalence rates from population-based samples are mostly based on symptoms of self-reported UI. Overall, one quarter of all women reported having any involuntary loss of urine in the second Health Survey in Nord Trøndelag (HUNT 2) (Hannestad *et al.* 2000). Approximately half of all incontinent women suffer from SUI, a smaller proportion from mixed UI and the smallest group from urge incontinence (Milsom *et al.* 2009). The prevalence of UI increases with age, but after the age of 60, mixed urinary incontinence is more common than SUI (Ebbesen *et al.* 2013). About half of the women report slight incontinence only, severity increases with age (Hannestad *et al.* 2000).

1.2.3 Risk factors for pelvic floor dysfunction

1.2.3.1 General considerations

A growing body of evidence elucidates that POP and SUI both share and have unique risk factors (Rortveit *et al.* 2010), table 1. Comparison between studies evaluating risk factor for PFD as one of their main outcomes is however difficult, because study populations and conditions vary. Samples are either population-based or derived from a clinical cohort. In population-based samples, both SUI (UI) and POP were self-reported and were therefore by definition assessing symptoms and not the diagnosis. Self-

reported POP has a high sensitivity for the condition in populations with a high prevalence of POP, like in clinical cohorts. In populations with a low prevalence, as in population-based studies, sensitivity has been shown to be as low as 35% and as high as 67% (Tegerstedt *et al.* 2005; Barber *et al.* 2006). This may result in misclassification bias when applying outcomes based on self- reported symptoms to the diagnosis of POP or SUI. Further, examining risk factors for a condition defined by self-reported symptoms (like population-based surveys on PFD) is problematic when considering the high incidence of surgical treatment. When treatment is followed by a decrease of symptoms (like bulge or SUI), treatment itself may become a confounder when examining an association between risk factors and the condition.

Clinical samples, on the other hand, are drawn from selected populations, limiting their generalizability.

In studies, the definition of UI, SUI or POP varied with regard to the definition, making comparisons difficult. Additionally, milder degrees may lack clinical relevance.

Only some studies have specified the type of UI, although risk factors differ considerably between stress-, urgency-, or mixed urinary incontinence (Hunskaar *et al.* 2003; Minassian *et al.* 2008). Important selection bias may be present in studies not specifically reporting risk factors for SUI. Studies not specifically examining SUI are listed under the category "UI" in table 1. Finally, some studies examine women with both SUI (UI) and POP, while others assess only one of the conditions (table 1).

1.2.3.2 Specific risk factors

Age and parity, particularly vaginal childbirth, are considered risk factors for both POP and SUI (Hunskaar 2008; Lamont 2012; Gyhagen *et al.* 2013). Studies examining potentially modifiable, non-obstetric risk factors presented in paper I are listed in table 1.

Based on these studies, constipation was a consistent risk factor for both SUI and POP. Being overweight or obese and chronic pulmonary disease were a consistent risk factor for UI/SUI but for POP there was no or conflicting evidence. Occupation involving lifting was a risk factor for POP and an inconsistent risk factor for SUI. Only one of the studies supported cigarette smoking as a risk factor for UI.

Other suggested risk factors for PFD include genetic factors, menopause, prior gynecologic surgery, cognitive and functional impairment and vitamin D deficiency (Hunskaar 2005; Badalian *et al.* 2010).

Table1. Non-obstetric risk factors in population-based studies for (symptoms of) urinary incontinence (UI), stress urinary incontinence (SUI) and pelvic organ prolapse (POP)

Condition	Studies examining risk factors and association found or not found									
	Cigarette smoking		Overweight/ Obesity		Occupation (heavy lifting)		Chronic pulmonary disease		Chronic constipation/ Straining	
	Positive	**No**	**Positive**	**No**	**Positive**	**No**	**Positive**	**No**	**Positive**	**No**
POP		*15*	*2,5,8*	*9,11, 12,15,*	*8,14*			*15*	*8,9*	
UI	*4*	*15, 20*	*1,3,4,9, 13,26*		*7*		*6,15, 19*		*1,10, 11,19*	
SUI		*20*	*9,18*		*7*	*18*	*7*		*18*	

1.(Chiarelli *et al*. 1999)
2. (Gyhagen *et al*. 2013)
3.(Lamont 2012)
4.(Hannestad *et al*. 2003)
5.(Hendrix *et al*. 2002)
6. (Maggi *et al*. 2001)
7. (Manonai *et al*. 2006)
8. (Miedel *et al*. 2009)
9. (Mishra *et al*. 2008)
10. (Rortveit *et al*. 2010)
11.(Rortveit *et al*. 2007)
12.(Samuelsson *et al*. 1999)
13. (Sherburn *et al*. 2001)
14. (Slieker-ten Hove *et al*. 2009)
15. (Uustal Fornell *et al*. 2004)
16. (Washington *et al*. 2010)
17.(Waetjen *et al*. 2007)
18. (Zhu *et al*. 2008)
19. (Zhu *et al*. 2009)
20. (Tahtinen *et al*. 2011)

1.3 *Surgery for pelvic floor dysfunction*

The two most common signs of pelvic floor dysfunction are urinary incontinence and pelvic organ prolapse (Haylen *et al.* 2010). Surgery is a common treatment for SUI and POP. Women undergoing surgery for PFD represent a subgroup of women with POP and/ or SUI.

The decision or indication for surgery depends not only on the severity of POP or SUI, but also on patient – and physician preferences, access to medical care (in non-Nordic countries), and possibly socioeconomic status and cultural norms (Shah *et al.* 2008). In addition, indications and procedures for both POP and SUI have changed during the past decades.

Lifetime risk of undergoing surgery for either POP or SUI has been estimated at 11% in a managed care population in the United States during the 90s (Olsen *et al.* 1997). This estimate has been cited more than 2200 times by 2014 (Google Scholar). Similar figures were reported from a general population in Great Britain (Abdel-Fattah *et al.* 2011). Mainly due to an ageing population, it has been predicted, that by 2050, the absolute numbers of women undergoing SUI and POP surgery will increase by close to 50% in the United States (Wu *et al.* 2011). This will have a considerable impact on health economy for countries with similar developments.

1.3.1 Surgery for pelvic organ prolapse

As first line treatment for POP, lifestyle modifications have been recommended, although no evidence is currently available to support the effectiveness of this approach (Thiagamoorthy *et al.* 2014). Randomized controlled trials have shown, that pelvic floor muscle training is effective for the treatment of POP, although the effect on sexual

function in this context has not been well established (Bo 2012). Women treated with vaginal pessaries have reported similar improvements of sexual function, compared to surgery (Abdool *et al.* 2011). No randomized trials have been identified, comparing surgery with pessaries, we can therefore not exclude that demographics of women choosing the one or other treatment are different (Thiagamoorthy *et al.* 2014). Complications from vaginal pessaries, coexisting SUI, prolapse stage and distress caused by the symptoms of PFD were predictive for the choice of the surgical alternative (Chan *et al.* 2012). The definite treatment of POP remains surgery (Thiagamoorthy *et al.* 2014).

Recent population-based estimates for lifetime risk for at least one POP surgery for an 80 year old woman vary from 9.5 % in the United Kingdom to 19 % in Australia and Denmark (Smith *et al.* 2010; Abdel-Fattah *et al.* 2011; Lowenstein *et al.* 2014).

A reason for differing estimates is changing trends over time, differing between age groups. In Denmark, a marked change for the rate of POP surgery has been described (Lowenstein *et al.* 2014). The annual rate per 10 000 women in the 1970s was approximately 3 procedures, in the late 1990s 1.5 procedures and in 2009 the rate increased again to 2. Decreasing trends until the year 2002 were also reported from the United States (Boyles *et al.* 2003; Babalola *et al.* 2008). A trend for older and fewer younger women to undergo POP surgery was noted in all three studies.

Surgery for POP includes a wide range of procedures, differing between countries and changing over time. The vaginal route for POP surgery is the most common. The type depends on the compartment affected, previous vaginal operations, sexual activity and coexisting UI (Thiagamoorthy *et al.* 2014). POP surgery has been categorized into anterior, posterior and apical repairs (Crafoord *et al.* 2006; Gomelsky *et al.* 2011). In the

Nordic countries, the NOMESCO classification of surgical procedures (NCSP) is used to code procedures. In table 2, the different procedures are presented according to the compartments they are expected to repair

In Scandinavia in the 80s, combined anterior and apical (Manchester Fothergill operation) or combined anterior and posterior surgical procedures were performed in approximately 90 % of primary POP procedures (Tegerstedt *et al.* 2004). Following reports of urinary and sexual problems during the 90ties, the tendency to perform complete and "prophylactic" repairs changed to selected ("site specific") repairs (Crafoord *et al.* 2006; Lowenstein *et al.* 2014). During the past decade the discussion in urogynecologic forums has been dominated by pros- and cons for synthetic meshes (Gomelsky *et al.* 2011). The mesh problem will only be discussed marginally within this thesis.

Table 2. Types of operations for prolapse of the vagina, uterus or vault, as listed in the NOMESCO Classification of surgical procedures, version 1.16.

<table>
<tr><th colspan="3">Affected compartment and type of procedure</th></tr>
<tr><th>Anterior</th><th>Apical</th><th>Posterior</th></tr>
<tr><td>Anterior colporrhaphy</td><td></td><td>Posterior colporrhaphy</td></tr>
<tr><td></td><td></td><td>Coplpoperineoplasty</td></tr>
<tr><td></td><td>Vaginal or laparoscopic repair of enterocele</td><td></td></tr>
<tr><td></td><td>Colpopexy after previous hysterectomy, abdominal, vaginal or laparoscopic</td><td></td></tr>
<tr><td></td><td colspan="2">Vaginal hysterectomy and colpoperineoplasty</td></tr>
<tr><td colspan="3">Partial or total colpocleisis</td></tr>
<tr><td colspan="3">Other (laparoscopic) operations for uterus or vaginal vault prolapse</td></tr>
</table>

1.3.2 Surgery for stress urinary incontinence

Pelvic floor training has been shown to improve sexual function among women with SUI in a randomized controlled trial (Bø *et al.* 2000). Surgery for bothersome SUI is

indicated if conservative measure fails, but also as primary treatment (Leach *et al.* 1997). Very sparse information about lifetime risk for SUI surgery is available. A British study estimated a 3.6 % risk for an octogenarian to undergo SUI surgery (Abdel-Fattah *et al.* 2011). A substantial increase is reported since the mid-1990s both in the United States and Australia (Lee *et al.* 2010; Jonsson Funk *et al.* 2012). The annual rate per 10 000 commercially insured women in the United states for both in – and outpatient SUI surgery was 21 in year 2000, while in 2009, it was 27 (Jonsson Funk *et al.* 2012). In the United States, about half of the procedures are performed in outpatient settings (Elliott *et al.* 2013). More than 200 operations for SUI have been proposed, with the Burch colposuspension most commonly performed until the turn of the millennium, when the first mid – urethral sling was approved by the U.S. Food and Drug Administration (Leach *et al.* 1997; Jonsson Funk *et al.* 2012). The TVT is the blind, retro pubic application of a mid-urethral sling via a small incision, while the TVT-O passes through the obturator foramen. The TVT-O may be slightly less effective but it causes fewer complications (Leach *et al.* 1997). Midurethral slings currently account for about 85 % of all SUI procedures, followed by the injection of bulking agents (Lee *et al.* 2010).

1.3.3 Risk factors for surgery for pelvic floor dysfunction

Age is a definite risk factor not only for PFD but also for surgery for PFD. For POP surgery after the year 2000, the highest incidence rates are reported in the age group 60-80 years while two decades earlier the peak incidence was between 50-70 (Smith *et al.* 2010; Lowenstein *et al.* 2014). For SUI surgery, the trend is in the opposite direction. More recently, peak incidence is among women aged 40-50, while previously this peak was a decade later (Jonsson Funk *et al.* 2012).

Parity, vaginal (forceps) delivery and age at delivery have repeatedly been demonstrated

as a risk factors for surgery for PFD as well, although there is conflicting evidence about whether younger or older age at first birth increases this risk (Erata *et al.* 2002; Moalli *et al.* 2003; Ghetti *et al.* 2007; Abdel-Fattah *et al.* 2011; Leijonhufvud *et al.* 2012). Interestingly, one register study investigating obstetric risk factors for SUI surgery, found a protective effect of both cesarean section and instrumental delivery compared to vaginal delivery (Persson *et al.* 2000).

Of the genetic factors, being white has been reported to be a risk factor for surgery for PFD, compared to being black or from "other" race (Shah *et al.* 2007).

1.3.3.1 Non-obstetric, potentially modifiable risk factors for pelvic floor dysfunctions requiring surgery

Seven studies investigating non-obstetric, modifiable risk factors for surgery for PFD have been identified (table 3). Most of these studies included both POP and SUI surgery and about half analyzed risk factors for both types of surgery together. Data collection was cross sectional or retrospective in all studies. Evidence regarding the risk factors examined in paper I (overweight, cigarette smoking, chronic pulmonary disease, constipation) was overall less consistent for PFD requiring surgery, than for the condition of PFD. Conflicting evidence was reported for increasing BMI, for type of occupation, smoking, chronic pulmonary disease and constipation. These differences may be explained by differing populations (population-based, clinical settings, managed care populations) and different strengths for detecting risk factors (number of cases from *n = 80 to n = 28 619).*

Table 3. Studies reporting non-obstetric, **potentially modifiable risk factors** for pelvic floor dysfunctions requiring surgery.

Study	Country Year	Study population	Method	Risk factor OR (95%CI) POP surgery	SUI surgery
(Jorgensen *et al.* 1994)	Denmark 1988	Cases nurses age 40-70 n = 28 619 Cohort all Danish women age 20-69 n = 1 652 533	Population-based cohort, Register study.	**Occupation involving heavy lifting** OR 1.6 (1.3-1.9)	
(Olsen *et al.* 1997)	USA 1995	Cases POP /SUI surgery n = 384 Cohort managed care n = 149 554	Cohort study, medical records.		**Obesitiy** 38% SUI vs 23% POP, p=0.01 **Chronic lung disease** 30% SUI vs 18% POP, p= 0.02
(Erata *et al.* 2002)	Turkey 1995-1999	Cases POP/SUI surgery: n = 180 Controls age/ BMI matched : n = 290	Case control study, medical recor ds.	**Smoking** 33% cases vs 23% controls, p=0.01	
(Moalli *et al.* 2003)	USA 1999-2000	Cases POP/SUI/anal sphincter surgery n = 80 Controls no prolapse, > para 1 n = 176	Case control study, medical records.	**BMI**, mean: 29 (cases) vs 26 (controls), p= 0.01 **Previous gynecologic surgery**: 34% (cases) vs 16% (controls), p= 0.003	
(Ghetti *et al.* 2007)	USA 1995	Cases, POP/SUI surgery: n = 245 Controls, managed care, age matched n = 287	Case control study, medical records.	**Chronic pulmonary disease**: OR 2.4 (1.4-4.2) BMI or smoking: ns	
(Blandon *et al.* 2009)	USA 1965-2002	Cases, hysterectomized,,POP surgery n = 144 Controls, hysterectomized n = 144 matched (age, pelvic floor disorder)	Case control study, register based.	**Chronic pulmonary disease:** OR 22 (1.5-328) Chronic constipation: ns	
(de Boer *et al.* 2011)	Nether-lands	Cases n = 119 self - reported POP/SUI surgery Cohort all women in Brielle, age 45-985, n = 1 397 response rate 47%	Population-based cohort, self-reported questionnaires	**BMI:** OR crude 1.8 (1.2-2.6), OR multivariate 1.6 (1.0-2.5) **Previous hernia surgery:** OR multivariate 2.2 (1.1-4.3). **Constipation symptoms:** more common (p = 0.02). Smoking, pulmonary disease, heavy work: ns	

1.4 *Sexual function and dysfunction*

1.4.1 Concepts

Sexuality includes a wide and overlapping range of behavioral, psychological and functional aspects. In this thesis the term "sexual function" is used when referring to overall or specific outcomes of sexual function instruments, sexual behavior, sexual response, sexual difficulties or sexual dysfunctions. No accepted definition of the term "sexual function" was identified in the literature of the past 15 years.

Sexual function is complex and involves many factors like intact physical sexual response, body image, partner sexual function, emotional and relationship issues (Pauls 2010). Sexual function has been divided into the dimensions of libido and arousal, orgasm or ejaculation and satisfaction (Berman 2005). Yet the term is used in the literature to describe different dimensions related to sexuality:

- Behavior, for example frequency of intercourse.
- Response, physiological (i.e. erection,); response, or emotional (i.e. satisfaction).
- Outcomes of sexual function instruments.

In this thesis, the term "sexual function" refers to these aspects and when possible, specific terms are applied.

Partner-related sexual activity is reciprocal. A problem in one of the partners may trigger a problem in the other. Therefore it is necessary to assess sexual difficulties or dysfunctions in both partners (Althof *et al.* 2010).

1.4.1.1 Sexual behavior

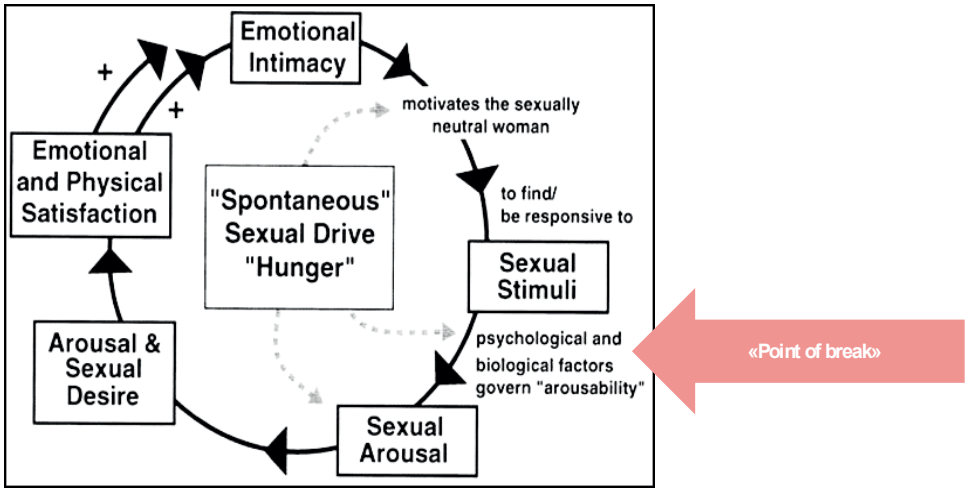
About two thirds of women are sexually active in the fifth and sixth decade and one half at the start of the seventh decade (Lindau *et al.* 2010; Lonnee-Hoffmann *et al.* 2014).

Men, in general, are more likely to be sexually active and these gender differences increases with age (Lindau *et al.* 2010). More frequent sexual activity is associated with higher marital quality (Galinsky *et al.* 2014).

1.4.1.2 Sexual response

"Sexual response" describes the sequence of physical and emotional changes occurring when a person is aroused by any type of sexual activity (Gruenwald 2012). The classic linear model developed by Masters and Johnson half a century ago, describes four phases and was designed for both genders (Masters *et al.* 1966). The model starts with an excitement phase, followed by a plateau, resulting in an orgasmic/ejaculation phase and finally leads to resolution. For the male, a refractory period follows. In 1974 Helen Kaplan added a desire phase to the model (Kaplan 1974). Male sexual response and sexual dysfunction continues to be evaluated according to these models. Regarding the female sexual response, both models model have been criticized for their linearity and focus on physiologic aspects (Tripodi *et al.* 2012). The female sexual response is characterized by high inter- and intra- personal variability (Tripodi *et al.* 2012). A number of differing models have been proposed, Basson's circular model is a commonly cited pattern for female sexual response, figure 5 (Basson 2001; Gruenwald 2012). According to this model, the "point of break" in the sexual response cycle interferes with arousability to sexual stimuli and is triggered by psychological and biological factors. PFD or aging, represent biologic factors and depression and body image concerns represent examples for psychological factors which are examined in this thesis (Tripodi *et al.* 2012). Surgical Treatment for PFD represents also a potential point of break (for example when it causes dyspareunia), but is considered more likely a "repair" of this point of break.

Figure 5. Basson's cirular model for female sexual response



From: Female Sexual Response: The Role of Drugs in the Management of Sexual Dysfunction.Basson, Rosemary; MB, BS Obstetrics & Gynecology. 350-353, August 2001. With permission from Wolters and Kluwer, copyright.

1.4.1.3 Sexual difficulties and sexual dysfunctions

Disturbance in sexual response may result in decreased sexual function, more specifically sexual difficulty or sexual dysfunction. Close to half of the female and one third of the male population in the United States qualified for at least one form of female sexual dysfunctions, when not measuring associated distress (Laumann *et al.* 1999). Yet only about half of these women experienced their condition as distressing (Lewis *et al.* 2004; Roos *et al.* 2014). This resulted in a lively discussion in the sexual medicine forum during the past 15 years (Moynihan 2003; Basson *et al.* 2004). As a consequence, in the two most recent *Diagnostic and Statistic Manuals for Mental Disease* (DSM IV and V), a personal distress element is required, to diagnose a specific sexual dysfunction (AmericanPsychiatricAssociation. 2000; AmericanPsychiatricAssociation 2013). In the most recent DSM the main categories for female sexual dysfunctions have been reduced from four to three: combined sexual interest and arousal disorder, orgasmic disorder, and

genito-pelvic pain/penetration disorder. Male sexual dysfunctions have been reduced to three: erection-, desire-, premature and delayed ejaculation disorder.

The definitions of specific sexual dysfunctions (F52) from the most recent International Classification of Diseases (ICD-10) lack the distress element. In sexual medicine forums, the *DSM* classifications and definitions are preferred, at least when the etiology is thought to be predominantly non-organic (ESSM 2012). In particular for sexual pain disorders with an apparent organic cause, an ICD -10 diagnosis (N94.1) may still be the most appropriate.

In this thesis, the only sexual dysfunction assessed, is erectile dysfunction.

1.4.2 Pelvic floor dysfunction - impact on sexuality

To assess changes of sexual function after surgery it is necessary to understand how PFD may lead to a point of break in the sexual response cycle. Sexual arousal of the women and her partner can be affected by PFD due to anatomic (bulge, laxity, vaginal dimensions), functional (urine leakage, lubrication) or psychological (embarrassment, distress) mechanisms (Giraldi *et al.* 2013). This interference can lead to sexual difficulties or dysfunctions.

Women seeking surgery for POP demonstrated a higher prevalence of depressive symptoms, as well as lower body image and quality of life compared to women without POP (Jelovsek *et al.* 2006; Ghetti *et al.* 2010).

Qualitative studies confirmed the clinical impression, that improvement of sexual function was one of the three most important goals with planned surgical treatment among patients with POP or SUI (Srikrishna *et al.* 2009; Sung *et al.* 2014). This may indicate that women attribute deterioration of their (or their partners) sexual experience to the PFD.

1.4.3 Measuring sexual function among women with pelvic floor dysfunction and their partners

Male sexual response is most commonly measured in terms of the ability to achieve erection and ejaculation, while measuring sexual response for women is more difficult (Moynihan 2003). Sexual function among women with a specific condition has been examined with three different types of sexual function instruments. Ad hoc instruments have not undergone testing for validity (measuring what it is supposed to) and reliability (consistent measuring) and may not measure the study question or may not be able to detect change (Sears *et al.* 2012). Generic instruments are applicable to women in general, while condition-specific instruments are validated for women with a specific condition. The latter is recommended for use when comparing sexual function within groups (for example women with PFD), to be able to detect more subtle differences (Pons 2009). The Prolapse and Incontinence Sexual Function Questionnaire (PISQ) has until recently been the only validated, condition-specific sexual function instrument for women with PFD, - both the original version including 31 questions and the short form with 12 questions (PISQ-12) (Rogers *et al.* 2003; Espuña Pons 2009). A number of major criticisms have been raised against PISQ. Firstly, it does not assess sexual activity: therefore, patients refraining from sexual activity due to their conditions were excluded (Espuña Pons 2009). Secondly, distress associated with sexual difficulties is not evaluated; therefore, firm conclusions as to associations with sexual dysfunctions cannot be drawn (Fenner 2008; Thakar *et al.* 2008). Thirdly, partner related aspects have been shown to be of limited reliability (Thakar *et al.* 2008). Recently a revised version of the PISQ questionnaire has been published, where the first two shortcomings have been eliminated (Rogers *et al.* 2013).

No condition-specific questionnaires for partners of women with PFD were identified.

1.4.3.1 Studies on the woman

Conflicting evidence has been published on the overall effect of PFD on sexual function. When generic questionnaires were applied, commonly, no differences between women with or without pelvic floor dysfunction were found (Weber *et al.* 1995; Espuña Pons 2009; Fashokun *et al.* 2013). Studies using a condition-specific questionnaire reported reduced sexual function among women with pelvic floor dysfunction (Rogers *et al.* 2001; Handa *et al.* 2004). More symptom distress from PFD has been associated with more sexual difficulties in all three female sexual dysfunction categories (Handa *et al.* 2008).

A literature review including studies from 1980 to 2007 concluded that bladder dysfunction contributed to sexual dysfunction among premenopausal women (Mehta *et al.* 2008). The types of UI may have differing effects on sexual function. Measured with PISQ12, SUI had more negative impact than detrusor overactivity, but mixed UI had the greatest impact (Coksuer *et al.* 2011). Among women with SUI, sexual dysfunction was associated with lower quality of life; the authors did not examine other types of UI (Tennstedt *et al.* 2007). How may UI affect sexual function? About half of the women with UI stated that their sexual life was somewhat spoilt by their condition, and they were worried about coital incontinence (urinary leakage during intercourse); two thirds of UI women were concerned about odor and unattractiveness (Nilsson *et al.* 2011). The prevalence of coital incontinence has been reported to be between 10-30 % among women with UI (Serati *et al.* 2009). It has been suggested that UI during penetration is more likely to be associated with SUI, while UI during orgasm is more due to detrusor overactivity (Serati *et al.* 2009). Increasing parity has been identified as the only predictive factor for lower sexual function among women with SUI, while anatomic

measures were not associated (Yang *et al.* 2008).

Among women with POP, about one third stated that the condition interfered with sexual activity (Barber *et al.* 2002). Little evidence is available that shows that the anatomical configuration causes sexual difficulties. Two studies reported impaired sexual function associated with worsening POP; however, both had applied an ad hoc sexual function instrument, and the age of the women had not been considered as a confounder (Ellerkmann *et al.* 2001; Digesu *et al.* 2005). No evidence for correlation with sexual functions was found for POP stage or the thickened vaginal wall described among women with POP in two studies applying validated questionnaires (da Silva Lara *et al.* 2009; Thibault *et al.* 2012). Diminished body image is the only consistently found mechanism showing how POP may be affecting sexual function (Jelovsek *et al.* 2006; Lowenstein *et al.* 2009; Lowder *et al.* 2011; Zielinski *et al.* 2012). The key role of body image in sexual function among women with POP has also been confirmed in a recent qualitative study, particularly affecting her "motivation" to engage in sexual activity (Roos *et al.* 2014).

1.4.3.2 Studies on male partners

For elderly men, the "lost penis syndrome" has been described, due to decreased mechanical stimulation by the introitus or the vaginal wall and resulting in delayed ejaculation (Cruz *et al.* 2012).

Only two studies were identified which investigated male sexual function in the specific context of PFD. Bekker *et al*. used a validated generic questionnaire and described diminished overall sexual function and lower satisfaction among male partners of women with UI compared to women with other urogynecologic complaints, adjusting for age of the woman; age of the male partner had not been available (Bekker *et al.*

2010). Nilsson *et al*. described that 23% of male partners reported coital incontinence by the women, and about 36% of these considered this as a problem (Nilsson *et al.* 2011).

1.5 *Surgery for pelvic floor dysfunction - impact on sexuality*

Surgery for PFD may affect sexual function of the couple by means of different pathways. A positive effect on both partners would be expected by relief of symptoms and/or improved body image, with a positive effect on motivation/desire for the woman. An adverse effect on both partners could be caused by changes in local sensibility and congestive capacities. Changes in anatomical dimensions or tissue elasticity could theoretically result in both improved arousability and orgasmic function for both partners. Alternatively, anatomic changes could lead to dyspareunia and cause reduced sexual function for both partners.

1.5.1 POP surgery and sexual function of the woman

Two recent overviews and one systematic review with a specific focus on POP and sexual function, concluded with overall improved sexual function after surgical repair (Wehbe *et al.* 2010; Rogers 2013; Jha *et al.* 2014). Repair of the posterior compartment (also without levatorplasty) and mesh insertion appear to have less favorable outcomes in terms of postoperative sexual function (Wehbe *et al.* 2010; Rogers 2013). Dua *et al*. found that women after posterior repair did not demonstrate significant improvement in dyspareunia (Dua *et al.* 2012). Mesh exposure is a known complication with mesh, and young age and sexual activity were identified as risk factors for mesh exposure by another study (Kaufman *et al.* 2011). The authors of the systematic review concluded, that mesh in the anterior compartment was not associated with worsening sexual function, but that information was insufficient to draw evidence based conclusions about

posterior mesh (Jha *et al.* 2014).

Studying the pathways of how POP surgery may influence sexual function, a prospective study demonstrated decreased vaginal vasocongestion and sensibility after erotic stimuli in specified vaginal areas after POP surgery (Lakeman *et al.* 2013). Yet, sexual function measured with a generic questionnaire had not changed. Improved body image after POP surgery was demonstrated and this improvement was associated to improved sexual function (Lowder *et al.* 2010; Lowenstein *et al.* 2010).This association supports an instrumental role of body image for sexual function among women with POP, also confirmed in a recent qualitative study (Roos *et al.* 2014).

1.5.2 POP surgery and sexual function of the male partner

Apart from case reports about partner dyspareunia in the context of synthetic mesh use, three studies were identified which reported partner sexual function after POP surgery during the project period. The results varied. A prospective, observational study reported improved interest, sexual drive and satisfaction among partners (n=64) after different types of POP surgery, applying a validated instrument (Kuhn *et al.* 2009). A randomized controlled trial compared repair of the anterior compartment with or without synthetic mesh and found no change among partners (n= 59), also applying a validated instrument (Vollebregt *et al.* 2012).

A recent qualitative study described direct improvements of the man's physical sensations during sexual intercourse due to changes in vaginal tightness and cure of the pelvic floor disorder, and indirect improvements because of positive changes in sexual behavior of the woman (Roos *et al.* 2014).

1.5.3 SUI surgery and sexual function of the woman

The authors of a recent systematic review reported, that improved sexual function was

three times as likely as deterioration, while about half of the women were likely to experience no change in sexual function (Jha *et al.* 2012). Postoperative coital incontinence was significantly reduced (OR 0.13, 95% CI 0.09-1.17).

The two currently most commonly used procedures, the TVT and TVT-O, could theoretically affect sexual function differently. TVT has been found to disturb clitoral blood flow and innervation, compared to TVT-O (Caruso *et al.* 2007). The authors of the systematic review found similar odds for improved sexual function for both types (Jha *et al.* 2012).

Coital incontinence was shown to be a prognostic factor for improved postoperative sexual function (Bekker *et al.* 2009). In a recent Danish study, only women with lower sexual function at baseline improved postoperatively (Glavind *et al.* 2014).

1.5.4 SUI surgery and sexual function the male partner

Authors from a Swedish, qualitative study from nearly 20 years ago interviewed women and their partners before and after SUI surgery (Berglund *et al.* 1996). Postoperatively, no change in frequency of sexual intercourse was reported, but half of the men and one third of the women reported an increase in desire. A very recent Italian study reported an improvement in sexual function among about 80% of men after TVT or TVT-O surgery of the woman (Schettino *et al.* 2014). A Swiss study examined only partners of woman with mesh erosion (Mohr *et al.* 2011). They created the term “hispareunia,” referring to pain experienced by the male during intercourse. They reported associated decrease of sexual interest and described successful treatment.

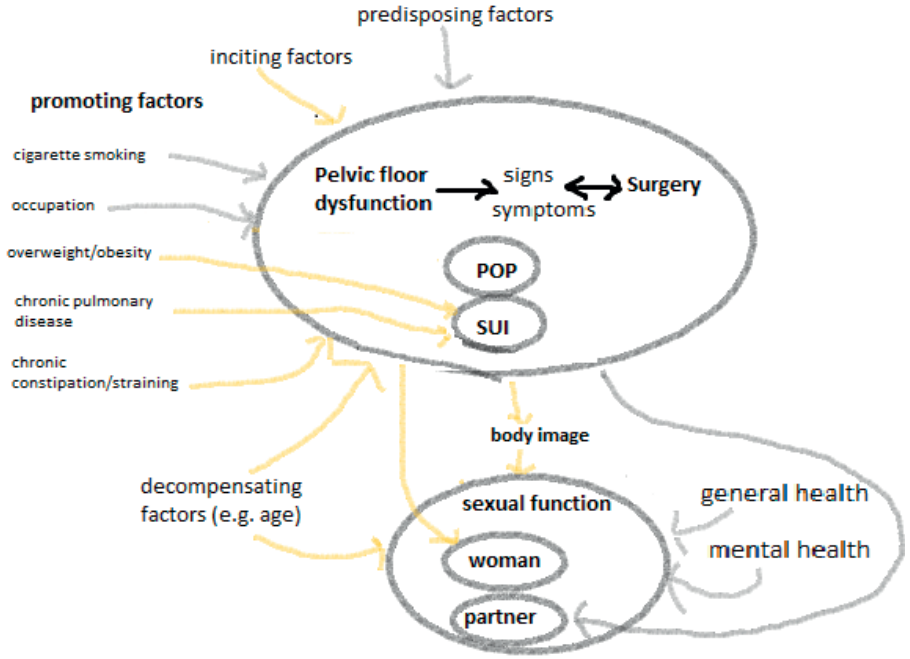
1.6 *Why study risk factors and sexual function in the context of surgery for pelvic floor disease?*

Many women will have experienced surgery for PFD during the course of their lives, making this type of surgery an important topic both from the society's and the individual's perspective. Society may require prevalence and incidence estimates in order to plan distribution of resources in the health service. From a socioeconomic view, it would be attractive to reduce numbers; one way to achieve this in the long term is to identify modifiable risk factors (Drutz *et al.* 2006). Increasing age and parity are established risk factors, but age is not modifiable and to modify quantity or mode of parity has major consequences. The individual may be interested in avoiding factors which increase her risk for surgery as well. There is a lack of evidence based knowledge about non-obstetric, modifiable risk factors for anterior pelvic floor surgery which will be addressed in this thesis.

The assessment of treatment outcomes from surgery for PFD has changed during the past decade, with a focus away from anatomic to more functional and patient oriented outcomes (Segal *et al.* 2012). One of the most important goals with surgery for PFD is to improve sexual function for many women (Srikrishna *et al.* 2009; Sung *et al.* 2014). Pelvic floor surgery does improve sexual function of women, according to current consensus. An understanding of the mechanisms involved in this improvement could form the basis for an individualized preoperative prognosis for treatment outcomes. Current knowledge as to those mechanisms is limited and will be addressed in this thesis.

See figure 6 for a suggested model for associations between PFD, surgery for PFD, risk factors and sexual function.

Figure 6. Model for current knowledge about associations between (surgery for-) pelvic floor dysfunction, risk factors and sexual function.



Associations: established or likely with little or controversial evidence

1.6.1 Limitations of current knowledge attempted to address in this thesis

- Relative lack of studies specifying type of UI when studying risk factors.
- POP with no or mild symptoms may not be clinically relevant- surgically treated POP may be clinically more relevant.
- Problems with sensitivity for self- reported PFD in population-based studies- self reported surgery for PFD may be more sensitive.
- Conflicting evidence for most of the suggested promoting factors for PFD.
- Conflicting evidence for all of the suggested promoting factors for PFD requiring surgery.

- A paucity of information on factors prognostic for changed sexual function after surgery for PFD.
- A lack of studies reporting sexual function of partners after surgery for PFD.

2 AIMS

2.1 *General objective*

The overall aim was to examine prevalence of pelvic floor dysfunction requiring surgery, investigate modifiable risk factors for this type of surgery and to study the impact on sexual function of the woman and her partner after surgery.

2.2 *Specific objectives*

- To estimate the prevalence of women having undergone POP and SUI surgery in a Nordic population.
- To examine non-obstetric risk factors for POP and SUI surgery.
- To assess change of sexual function of women after surgery for pelvic floor dysfunction.
- To assess change of sexual function of male partners after surgery for pelvic floor dysfunction.
- To explore differences and similarities among women and their partners treated by SUI compared to POP surgery.

3 METHODS

3.1 *Design*

3.1.1 Study one: Paper I and Supplementary results

Outcomes from a population-based study are reported. Results are based on material from the Nord Trøndelag Health Study 3 (HUNT 3). The HUNT 3 study has been conducted between 2006-2008, and is the currently latest of three large health surveys, inviting the whole population of Nord Trøndelag in approximately 10 year intervals. Data collection was with one exception cross sectional. Answers referred to prior events for the main outcome and some of the investigated risk factors. Based on this consideration, the design may be characterized best as cross sectional with participant recall. For one of the variables (constipation) data from the Nord Trøndelag Health Study 2 (HUNT 2) was used; for this variable, the design was prospective. Descriptive and analytic statistical methods were applied.

3.1.2 Study two: Paper II and III

This is a clinical, observational and prospective study. The "BESE-study" (BEkkenbunn og SEksualitet = pelvic floor and sexuality) was designed and supervised by the PhD candidate. A cohort of women and their partners undergoing POP or SUI surgery was assessed preoperatively and followed up one year after surgery. Outcomes were based on self-reported outcomes applying a selection of validated, generic and ad hoc instruments, clinical observations and information from patient journals. The study was conducted at the St. Olavs Hospital, Trondheim University Hospital, Norway between April 2008 and January 2011. Descriptive and analytical statistical methods were applied.

3.2 *Study population and data collection*

3.2.1 Study one

3.2.2 The Nord Trøndelag Health Study and HUNT 3

The Norwegian county of Nord Trøndelag is located in the central part of the country with a relatively stable population of 128 694 inhabitants in 2006 and an average life expectancy of 83 years among women (Krokstad *et al.* 2013) (figure7).Three percent of the population are non-Caucasians.

Figure 7. The Kingdom of Norway and the county of Nord- Trøndelag (darker blue).

The county is considered representative of Norway in most aspects, although it lacks larger cities and has a slightly lower educational level and income than Norway on average (Krogstad S *et al.* 2011).

HUNT is Norway's largest health survey and has been conducted in Nord Trøndelag three times: 1984-1986 (HUNT 1), 1995-1997 (HUNT 2) and 2006-2008 (HUNT 3) (Krogstad S *et al.* 2011). This thesis, HUNT 3 data was used, and for one variable (constipation) HUNT 2 data.

3.2.2.1 Study population and data collection

All residents of the county who were 20 years and above, were invited and sent Questionnaire 1 (Q1) by mail. Participants delivered the completed Q1 at the temporarily located health examination sites. There, among other measurements, BMI

was recorded, participants were interviewed among other topics about their parity and questionnaire 2 (Q2) was handed out. Only women age 30 and above were included in the current study, because POP and SUI surgery is very rarely performed below the age of 30 (Olsen *et al.* 1997; Abdel-Fattah *et al.* 2011). In addition the proportion of non-responders for HUNT 3 was particularly high (> 60 %) among women below the age of 30 (Krogstad S *et al.* 2011). Further, only women responding to Q2 were included, because the question defining the main outcomes (POP – or SUI surgery) was contained in this questionnaire, see figure 8.

Of the women reporting to have undergone POP surgery, 7 % (n=81) indicated that it had been performed before the age of 30 years. These were excluded from analysis for age- specific and cumulative incidence, because a reference group below age 30 would have been required in the study population.

3.2.3 Study two

Consecutive women scheduled for SUI or POP surgery at the St Olavs Hospital in Trondheim received an information leaflet and a postal questionnaire for themselves and their partners (appendix I, II, III). Exclusion criteria were age over 80 and inability to communicate in Norwegian. Standardized measurements of the vagina and the perineum were performed preoperatively. A number of variables were collected from patient records. SUI and POP surgery were performed according to local routines. Follow-up assessments were conducted one year after surgery. One year after surgery, together with an information leaflet, the women and their partners received a second set of self-administered questionnaires, and an appointment for an examination including standardized measurements of the vaginal and the perineum. For recruitment, attrition and exclusion from the final study population see flowchart (figure 9).

Figure 8. Flow chart for Study one: Study population pelvic organ prolapse (POP) and stress urinary incontinence (SUI) surgery. Nord Trøndelag Health Study, 2006-2008, Norway.
Q1: questionnaire 1. Q2: questionnaire 2.

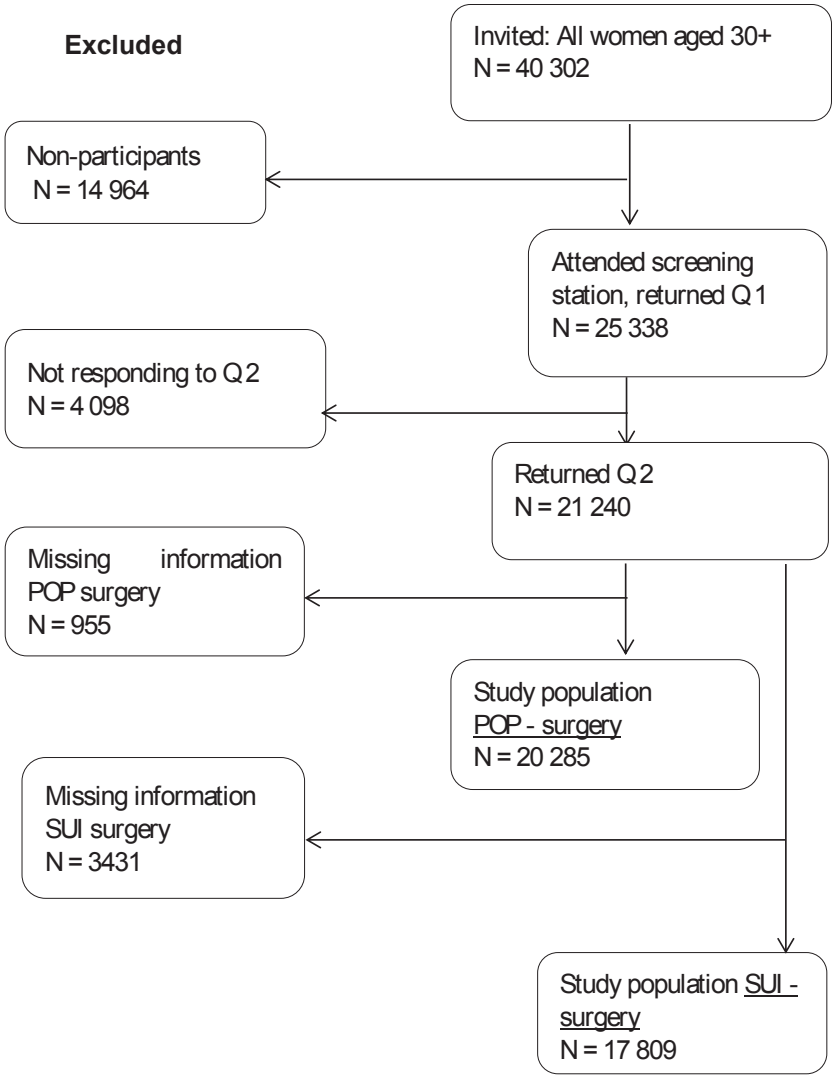
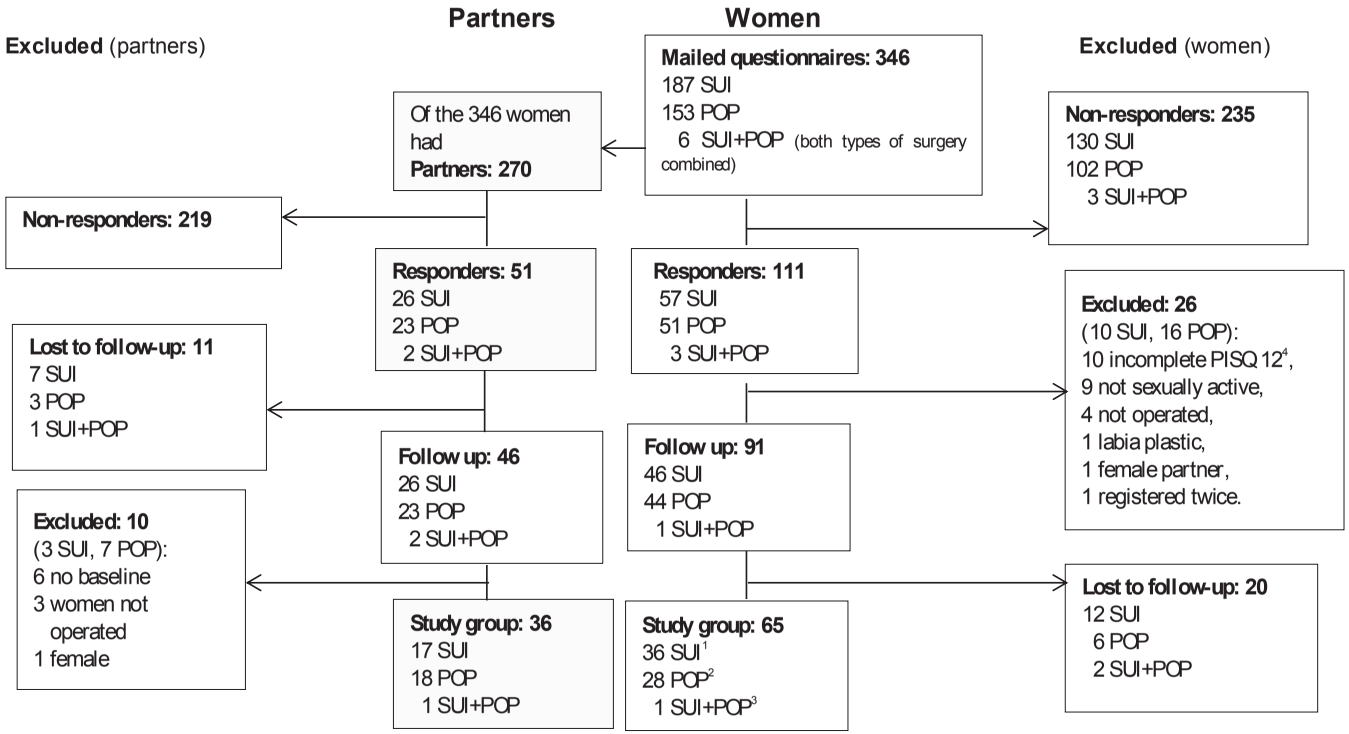


Figure 9. Flow chart Study two: Sexual function of women and their partners before and after pelvic organ prolapse (POP) or stress urine incontinence (SUI) surgery. St Clavs Hospital 2008-2011, Trondheim, Norway.



[1] **SUI surgery**: 35 tension-free vaginal tape (TVT), 1 tension-free vaginal tape, obturator (TVT-O)
[2] **POP surgery:** 18 anterior colporrhaphy, 10 colpoperineoplasty, 7 posterior colporrhaphy, 6 cervix amputation, 3 anterior synthetic mesh. 16 patients with 2-3 procedures
[3] **SUI and POP surgery:** TVT and perineoplasty
[4] Pelvic Organ Prolapse and Urinary Incontinence Sexual Function Questionnaire- short form

3.3 *Variables and instruments*

3.3.1 Study one

3.3.1.1 Main outcome measure

The estimates for POP surgery were based on the answer to the question: "Have you ever had a repair operation for uterine or vaginal prolapse?" Response alternatives were "Yes," "No," and "I don't know." Women answering "I don't know" (n=114) or with missing information (n=841) were excluded (n=955) from the study population. An additional question about age when the operation had been performed was answered by 92% of the women reporting POP surgery.

The estimates for SUI surgery had been based on the answer to the question: "Have you ever been treated for UI?" Response alternatives were "No, I have never had UI" (n=12311), "No, I had UI, but it became better on its own" (n=1647) and "Yes" (n=1761). Women answering "Yes" were given four options, more than one answer was possible: "Operation for UI" (n=839), "Pelvic floor exercise for UI" (n=984), "Medication for UI" (n=547), and "Other treatment for UI" (n=404). Women indicating the first alternative were defined as having undergone SUI surgery. Women answering "No" to treatment for UI (n= 13 958), or "Yes," but not "Operation for UI" (n=1016) were defined as not having undergone SUI surgery.

3.3.1.2 Covariates

A risk factor can be defined as an exposure associated with an increased probability of an outcome. It may be a risk marker and not necessarily a causal factor. A modifiable risk factor is an exposure that can be modified by intervention, thereby reducing the probability of occurrence of the outcome. (Porta 2008).

In this thesis, risk markers will be examined as proxies for modifiable risk factors in

addition to presumed modifiable risk factors.

Information on *occupation* was collected, asking participants to indicate how physically heavy their paid or unpaid occupation was. Preformulated alternatives were "Mostly sitting," "Much walking," "Much walking and lifting," or "Heavy, physical labor." Occupation at the time of data collection was used as a proxy for occupation before POP surgery. *Asthma* and *chronic obstructive pulmonary disease* (COPD) were assessed by the questions: "Have you ever had or do you have asthma?" and "Have you ever had or do you have chronic bronchitis, emphysema or COPD?" In addition, women were asked to indicate their age at the onset of the disorder. *Constipation* was assessed as part of a list of symptoms following the question: "To what degree have you had the following during the past 12 months?" Response alternatives were "Never," "A little," and "Much." For this variable, answers from the HUNT 2 survey were utilized. The reported age at POP surgery had been after data collection for HUNT II for approximately 75 % of women in the study population. *Body mass index* (BMI) was computed from measurements at the HUNT 3 examination station (kg/m^2) and was used as a proxy for BMI at the time of surgery. Women were grouped following the WHO classifications: normal BMI (below 25 kg/m^2), overweight (25-29.9kg/m^2), obesity class 1 (30-34.9 $kg(m^2)$ and obesity class 2-3 (over 35 kg/m^2) (WHO 2000). Information about *cigarette smoking* was collected by the question: "Do you smoke?" Answers categories were "No, I quit smoking" referred to as "Former smoking," "Yes, daily cigarettes/cigarillos," referred to as "Current smoking" and "No, never" or "Yes occasionally cigarettes/cigarillos," referred to as "NO or occasional smoking." The latter two were merged into one group because they both defined women with a low degree of exposure. Information about age at time of survey, parity and education was collected because these constituted known or suspected confounders. Information about e*ducation* was

obtained from the National Education Database.

3.3.2 Study two

The postal questionnaires for women and their partners consisted of a collection of validated instruments and exploratory questions (appendix II, III). Sets for women and partners differed due to different measures for sexual function and different exploratory questions. The wording for questionnaires at baseline compared to follow had been was adjusted accordingly. See Appendix II

3.3.2.1 Main outcome measure for paper II

The *main outcome* was for this paper was sexual function, measured with the Prolapse and Incontinence Sexual Function Questionnaire, short form (PISQ-12). This is a validated short instrument to measure sexual function in women with pelvic organ prolapse and urinary incontinence.

PISQ-12 was translated into Norwegian by a certified translator, using the double translation technique. Women were asked to indicate their response on a five graded scale in which 0 corresponded to worst function or experience and 4 to best. Women with more than two answers missing were excluded (n=10). Item scores of patients with 1-2 questions missing (n=5) were replaced by the patient´s mean score (Rogers *et al.* 2003). We used PISQ-12 summary scores at baseline and follow up, the difference between both (changes of PISQ-12), and scores of the single factors at baseline (when examining factors predictive for change).

PISQ-12 was the recommended instrument for examining sexual function in this group of patients at the time of study design (Rogers *et al.* 2003; Espuña Pons 2009). It has been shown to be sensitive for change, therefore suitable for evaluating treatment results (Teleman *et al.* 2011). The PISQ-12 has shortcomings; important for the current study is the lack of assessment of the effect of PFD on sexual activity, because PISQ-12

is only applicable to sexually active women (Espuña Pons 2009). Therefore, recently a revised version was validated (Rogers *et al.* 2013). To compensate, we had added the question: "How often do you and your partner have intercourse or are sexually active?" Five alternatives were given: daily, 1-3 times per week, 1-3 times per month, less than once a month, never. If the question was answered with "never," patients were classified as sexually inactive.

3.3.3 Main outcome measures for paper III

Male sexual function was measured with the Brief Sexual Function Index (BSFI). The original instrument contains 11 questions, covering three functional subscales (sexual drive, erection, and ejaculation), problem assessment and overall satisfaction. (O'Leary *et al.* 1995). Each question has a possible range from 0-4 (higher values = better). O'Leary recommended evaluation of individual questions or summary scores of the subscales, not a single score. This instrument has been validated in Norwegian (Mykletun *et al.* 2005). The three functional items and overall satisfaction were selected as outcome variables. Missing answers to a BSFI item, led to exclusion of the particular item, as recommended by the original instrument (O'Leary *et al.* 1995). In total, 6.4% of the BSFI items were excluded.

ED was confirmed if the question "Are you able to get and keep an erection good enough for sexual intercourse?" was answered "sometimes" or " never," according to the criteria of the U.S. National Institutes of Health and the American Urologic Association (Panel 1993). ED was classified as a sexual dysfunction when it caused marked distress, according to the Diagnostic and Statistical Manual of mental disorders DSM –IV-TR of the American Psychiatric Association (AmericanPsychiatricAssociation. 2000).

3.3.3.1 Covariates

For both women and their partners, we collected information about education and current medication. For mental and general health, validated questions were used (Strand *et al.* 2003; Bowling 2005). Age was self-reported among partners, while for women, information about age, menopausal status, parity, and prior surgery was collected from patient files. BMI (m^2 /kg) for women was calculated from self-reported height and weight. Women's body image was measured with four questions selected from the Hopewood Body image scale (Hopwood *et al.* 2001). This scale had been shown to have good discriminant validity and internal consistency for women with POP (Jelovsek *et al.* 2006). These four of the original 10 questions were used because these had previously been translated into Norwegian (Sprangers *et al.* 1996). For anatomic measures of women's POP, POPQ was applied (Bump *et al.* 1996). For patients scheduled for SUI, the amount of urine leakage during a routine stress-test was recorded; an urge component was documented either by urodynamic investigation or described clinically in the file. In the exploratory part, questions were developed together with a clinical sexologist and based on clinical experience to describe problems related to pelvic floor surgery. For women, this consisted of seven questions exploring different goals with the pelvic floor surgery (appendix II). Response alternatives (not, a bit, quite, very important) were dichotomized and only the last alternative was defined as important. We added a question for women covering overall satisfaction with sex, with four graded response alternatives. For men, the exploratory part consisted of 11 questions on subjective experiences related to female pelvic floor surgery (appendix III, 4). Response alternatives were yes/no, and for each item, the degree of distress was quantified (not at all, a little, quite a bit, very much). For descriptive purposes, the last two answers were summarized into "marked bother."

At follow up, questionnaires were similar. Women were asked if those specific goals had

been realized. A question about sexual performance enhancing medication was added for the partners: this had mistakenly been omitted in the baseline questionnaire.

3.4 *Statistical analysis*

3.4.1 Study one

To describe women reporting POP surgery (SUI surgery) and women not reporting this type of surgery, absolute numbers and percentages were used. To compare differences between groups (for example women returning Q2 vs not), two-sample t-tests were used for continuous outcomes, Mann-Whitney U test for ordinal outcomes and Chi square test for dichotomous outcomes. Cumulative incidence and age-specific incidences were calculated for POP surgery only, using the Kaplan Meyer formula. Person time was defined as age at time of survey: "failure" was defined when POP surgery was reported. Time of failure was age at surgery.

The associations between POP/SUI surgery and the risk factors cigarette smoking, BMI, occupation, asthma, COPD, and constipation were estimated as odds ratios (OR) applying multivariable logistic regression for each risk factor separately. Based on a priori assumptions, age at survey and parity were considered important confounders. We found that both age and parity demonstrated a highly significant, positive linear association with log-odds of POP surgery, as well as a negative quadratic association (indicating a less steep increase in OR with increasing age). Applying the Likelihood ratio test, we compared the models for POP surgery with age to the model also including age squared. The model including age squared fitted the data significantly better (POP: $p<0.001$; SUI: $p< 0.001$). Similar testing was performed for parity, while adjusting for age. The model including parity as a squared variable also fitted significantly better (POP: $p=0.0002$, SUI: $p<0.001$). Age and/or parity were therefore included both as linear and squared variables, when adjusting for age and/or parity. Additional potential

confounders were selected a priori and were included in three models, identical for each risk factor. In model one, we adjusted for age (at survey), in model two, we additionally adjusted for socio-demographic factors (education and number of children born), and in model three, we added the lifestyle factors BMI and smoking. As a last step, to avoid mixing the effects of potential confounders and mediators, for each of the examined risk factors we considered different constellations of covariates (Tilling *et al.* 2013). For this purpose, we used directed acyclical graphs (DAG) as a tool to consider causal relations between the included variables (Sung 2012). For example, when assessing cigarette smoking as a risk factor we added in an additional model type of occupation as a potential confounder to the confounders used in model three. As another example, when assessing type of occupation as a risk factor, we removed cigarette smoking in an additional model from model three, because we considered smoking rather to be a mediator, than a confounding factor for pelvic floor surgery.

The proportion of missing information for the covariates was small, except for "occupation." Assuming, that the risk factors could be potentiated by increasing parity, we constructed interaction terms between risk factors (categorical variables) and parity (continuous variable). Under the assumption that these covariates were missing completely at random, the regression tests were performed as complete case analysis (Rothmann 2008). All tests were two sided. The level of significance was defined as $p \leq 0.01$, to limit type 1 error due to multiple testing; CI was set at 99%.

3.4.2 Study two

Normality of the variables was examined graphically and with the Kolmogorov Smirnov test. At baseline, continuous and normally distributed variables were compared with independent student-t test. Dichotomous variables were compared with Fisher's exact test; not normally distributed variables, or variables with more than two categories, were

compared with Mann-Whitney U-test. To compare BSFI items at baseline with population-based estimates, one-sample t – test was used, as advised by the authors of the estimate (Mykletun *et al.* 2005). Differences at baseline between POP and SUI surgery were tested with logistic regression, while adjusting for age.

To analyze changes for the samples at follow up, paired t-test or Wilcoxon signed rank test was used, as appropriate. In paper II, factors associated with changes in sexual function were analyzed one at a time with univariable linear regression and multivariable linear regression, adjusting for age only. Sample size was insufficient to adjust for more covariates when stratifying into POP and SUI surgery. In paper III, Spearman rank correlation was used to examine associations.

All tests were two sided; the level of statistical significance was set at 5 % and CI was 95 %.

3.5 *Ethics*

Study one is based on HUNT data; participants had signed written, informed consent before attendance. For study two, female patients and their partners received written information about the study (appendix I). When presenting for surgery, all women were reminded of the study one time. None of the attending health workers were aware if a patient participated in the study. Signed consent was obtained from the female participants, while men consented by choosing to return the questionnaires without personal identification and could not be contacted directly. Both studies were approved by the regional committee for research ethics (2011/2521/REK midt, 4.2007.1812). Study two was also approved by the Norwegian Social Science Data Services (NSD).

We considered that women or their partners might become conscious of sexual problems and offered counseling by a clinical sexologist, if required.

4 RESULTS

4.1 *Paper I: Self reported pelvicp organ prolpase surgery - prevalence and non-obstetric risk factors, a HUNT study*

We estimated prevalence and incidence rates for POP surgery in a representative Nordic cohort. In the county of Nord Trøndelag, POP surgery was reported by 1123 (5.3 %) of all women, by 0.7 % below age 40, by 3.1% between 40-59 years, and by 10.8 % above age 60. Cumulative incidence by age 85 was 14.6 %. Mean age at surgery was 51.6 years (SD14.7). For the type of occupation, a high proportion of missing answers was noted (32 %); women not answering this question were on average 18 years older than women answering.

We examined epidemiologic evidence for non-obstetric risk factors for this type of surgery. Age and parity were considered confounders between the examined risk factors and POP surgery. As expected, both increasing age and increasing parity were strongly associated with higher odds for POP surgery. If OR for reporting POP surgery were adjusted only for age or in addition for sociodemographic and lifestyle factors, outcomes were very similar. After adjustment, we found significantly higher odds for reporting POP surgery for women with marked constipation (reported one decade prior) compared to no constipation (OR 1.83, CI 1.30-2.56), with BMI categories above normal, compared to normal weight (OR 1.58-1.64, CI 1.10-2.25), and for women reporting COPD compared to reporting no COPD (OR 1.51, CI 1.06-2.16). Women reporting occupation involving lifting compared to sitting had borderline higher odds (OR 1.40, CI 0.98-2.01), as well as women reporting asthma compared to reporting no asthma (OR 1.25, CI 0.98-1.59). Cigarette smoking was no longer significantly associated. Increasing parity did not have a significant effect on any of the examined risk factors.

In summary, we found constipation, BMI above normal, and COPD to be risk factors for POP surgery.

4.2 *Supplementary analysis Self reported stress urinary incontinence surgery – prevalence and non - obstetric risk factors, a HUNT study*

Among women above the age of 30 receiving the questionnaire containing the question about SUI surgery, 4.7 % (n=839) reported to have undergone SUI surgery, while 16.9 % (n=3431) did not answer this question. Characteristics of women reporting SUI or no SUI surgery or with a missing answers are presented in table 4. A high proportion of women not answering the question about type of occupation was noted (33 %). On average, women with missing answer to this question were 19 years older than women answering. The prevalence of SUI-surgery was 0.9 % for women aged 30-39 years, at age 40-49, it was 2.6 %, at age 50-59, it increased to 5.2 % and above age 60 it remained at approximately 7 %. No information about age at SUI surgery had been collected.

For 17309 women, information about both POP and SUI surgery was available. Both POP and SUI surgery was reported by 224 women (1.3 %). Either POP or SUI surgery was reported by 1480 (8.6 %) of all women, and by 20.1 % among women aged 80 and above in this subgroup.

The odds for SUI surgery increased significantly with age ($p<0.001$), this effect diminished with advancing age ($p<0.000$). Compared with a 40 year old woman, the OR at age 50 was 2.4, at age 60, it was 4.2, and at age 70, it was 5.3.

After adjusting for age, increasing parity was associated with significantly higher odds for SUI surgery ($p< 0.001$). This effect tapered significantly with increasing parity ($p<0.000$), but this decreasing effect was less pronounced than with POP surgery. Compared with a nullipara, the OR for a para one was 1.58, for a para two it was 2.28, for a para three 3.04, for a para four 3.72 and a para five 4.19. Assuming that increasing parity could potentiate the effect of the other risk factors on SUI surgery, we constructed interaction terms between parity (continuous variable) and each examined risk factor. No significant interactions were observed, indicating that the odds for SUI surgery given a

specific risk factor did not significantly change, depending on the parity of the woman. Education was no longer significantly associated with SUI surgery in the age adjusted model. The following risk factors for SUI surgery were examined with multivariable logistic regression, adjusting for sociodemographic and lifestyle factors (table 5).

Cigarette smoking

Both former and current cigarette smoking were strongly associated in most models with 30-50 % higher odds for SUI surgery, compared to no/occasional smoking.

Body mass index

Elevated BMI was associated in all models with higher odds for SUI surgery. Compared with women with a BMI below 25, the odds were 70 % higher for women with a BMI of 25- 30, and increased to more than threefold higher odds for women with BMI above 35.

Occupations with different grades of physical strain

None of the types of occupation were significantly associated with SUI surgery in any of the models.

Chronic lung disease

Women reporting asthma or COPD had an approximately two fold higher odds for SUI surgery, compared to women not reporting these diseases. These associations were attenuated in the models adjusted for socio-demographic and lifestyle factors, but remained highly significant. In addition, when adjusting mutually for asthma or COPD, the OR for COPD fell below significance to 1.51 (99% CI 0.99-2.30) and for asthma to 1.61 (99%CI 1.22-2.12), still remaining significant.

Constipation

Compared to no constipation, marked constipation was in all models significantly and consistently associated with twofold elevated odds for SUI surgery.

Table 4. Sociodemographic characteristics and potential risk factors for stress urinary incontinence (SUI) surgery among women reporting or not reporting SUI surgery and women with missing responses. Nord Trøndelag Health Study 2006-2008, Norway.

Percentages are column percentages and do not add up to 100% due to missing responses.
[1]Chronic obstructive pulmonary disease

Characteristic	No SUI surgery N=16 970		SUI surgery N=839		Missing response N=3431	
	n	%	n	%	n	%
Age distribution (years) n=21240						
30-39	2747	16.2	25	3.0	331	9.6
40-49	3713	21.9	100	11.9	679	19.8
50-59	4079	24.0	224	26.7	780	22.7
60-69	3592	21.2	270	32.2	714	20.8
70-79	2041	12.0	161	19.2	583	17.0
80+	798	4.7	59	7.0	344	10.0
Education (years) n= 21240						
≤10	3746	22.1	223	26.6	787	22.9
>10 ≤14	8024	47.3	393	46.8	1409	41.1
>14	4694	27.7	170	20.3	773	22.5
Parity n= 19106						
0	232	1.4	2	0.2	18	0.5
1	7713	45.4	283	33.7	1283	37.4
2	6778	39.9	431	51.4	1344	39.2
>3	775	4.6	64	7.6	183	5.3
Occupation n=13728						
Sedentary	3561	21.0	138	16.4	564	16.4
Walking	4415	26.0	161	19.2	655	20.0
walking and lifting	3280	19.3	116	13.8	553	16.1
heavy, physical	228	1.3	9	1.1	48	1.4
Body mass index (kg/m^2) n= 20215						
≤ 24.9	6353	37.4	166	19.8	855	24.9
25 - 29.9	6415	37.8	330	39.3	1194	34.8
30 - 34.9	2709	16.0	195	23.2	641	18.7
≥ 35	1003	5.9	91	10.8	263	7.7
Cigarette smoking n=19697						
never, occasional	8104	47.8	318	37.9	1382	40.3
Former	4983	29.4	288	34.3	958	27.9
Current	2989	17.6	149	17.8	526	15.3
Asthma n=20282						
Yes	1842	10.8	158	18.8	397	11.6
No	14678	86.5	628	74.8	2579	75.2
COPD[1] n= 20281						
Yes	497	2.9	61	7.3	144	4.2
No	16023	94.4	724	86.3	2832	82.5
Constipation reported 1995 -1997 n=15289						
no	8889	52.4	386	46.0	1517	44.2
Mild	2899	17.1	151	18.00	592	17.2
Marked	649	3.8	61	7.3	145	4.2

Table 5. Risk factors for Stress Urinary Incontinence surgery. Multivariable models, for each risk factor separately, presenting odds ratios (OR) and 99%confidence intervals (CI). Women aged 30+; Nord Trøndelag Health Study, 2006-2008, Norway.

	Model 1[1]		Model 2[2]		Model 3[3]	
Risk factors	OR	99% CI	OR	99%CI	OR	99%CI
Cigarette smoking						
no or occasional	1		1		1	
former	**1.34**	**1.07 - 1.66**[b]	**1.34**	**1.07 - 1.67**[b]	**1.34**	**1.07 – 1.67**[b]
current	1.30	0.99 – 1.69	**0.34**	**1.02 - 1.75**[a]	**1.55**	**1.18 – 2.05**[b]
Body mass index (m/kg2)						
<25	1		1	1	1	
25-29.9	**1.70**	**1.32 – 2.19**[b]	**1.71**	**1.32 - 2.21**[b]	**1.74**	**1.33 – 2.26**[b]
30-34.9	**2.29**	**1.73 – 3.04**[b]	**2.25**	**1.69 – 3.00**[b]	**2.38**	**1.77 – 3.20**[b]
≥35	**3.12**	**2.20 – 4.43**[b]	**3.16**	**2.20 – 4.52**[b]	**3.41**	**2.36 – 4.91**[b]
Occupation						
sitting	1		1		1	
walking	0.89	0.66-1.21	0.83	0.61– 1.14	0.84	0.62 – 1.16
walking / lifting	0.96	0.69-1.34	0.88	0.63 – 1.24	0.84	0.59 – 1.19
heavy physical	0.86	0.67 -2.13	0.74	0.28 – 1.94	0.65	0.23 - 1.8
Asthma						
No	1		1		1	
Yes	**2.03**	**1.59-2.58**[b]	**1.99**	**1.56-2.55**[b]	**1.77**	**1.37 – 2.29**[b]
COPD[4]						
No	1		1		1	
Yes	**2.20**	**1.52 – 3.18**[b]	**2.19**	**1.50 – 3.20**[b]	**1.94**	**1.31 – 2.87**[b]
Constipation 1995-1997						
no	1		1		1	
mild	1.21	0.94 – 1.56	1.21	0.93 – 1.57	1.24	0.95 – 1.61
marked	**2.00**	**1.38 – 2.90**[b]	**2.03**	**1.39 – 2.96**[b]	**2.02**	**1.36 – 2.99**[b]

Significant associations (0.01≥p) are printed bold.
[a] 0.01 ≥ p > 0.001
[b] 0.001 ≥ p

[1] Each risk factor adjusted for age and age[2]
[2] Each risk factor adjusted for age, age[2] education, parity and parity[2]
[3] Each risk factor adjusted for age, age[2], education, parity, parity [2], BMI and cigarette smoking
[4] Chronic obstructive pulmonary disease (COPD)

4.3 *Paper II: What predicts improved sexual function after pelvic floor surgery – a one year follow-up study*

The aim of this study was to assess changes in sexual function after surgery for PFD in a clinical setting and to explore differences between POP and SUI surgery. The study population consisted of 65 women (POP n=28, SUI n=36). For one third of the women undergoing SUI surgery and for more than half of the women undergoing POP surgery, the goal to improve sexuality was very important. Sexual function improved significantly in the total group one year after surgery (P=0.000). Overall satisfaction with sex was unchanged. After stratification into SUI and POP surgery, improvement only remained significant after SUI surgery (p=0.001). Improvement for the total group was predicted by preoperative reporting of good health or coital incontinence, while psychological distress or the goal of improved defecation predicted deterioration. For women undergoing SUI surgery, increasing age, parity, or the goal of improving sexuality or body image predicted improvement. For women undergoing POP surgery, menopausal status or anterior colporrhaphy predicted improvement, while posterior colporrhaphy predicted deterioration. Of the body image scores, for SUI surgery, the mean score for "physically attractive" had improved significantly, while for POP surgery, the mean score for "less feminine" had improved. Improvement of sexual function was not associated with the improvement of body image. Of the selected anatomic measures, only vaginal length had changed significantly after surgery; this was not significant if analyzed separately for POP and SUI surgery. This shortening was not associated with change in sexual function. Baseline sexual function scores of the partners (n=36) was not predictive for change in female sexual function. In summary, improved sexuality was observed after pelvic floor surgery. Predictive factors for change differed for women undergoing SUI and POP surgery.

4.4 *Paper III: Sexual function of the male partner after pelvic floor surgery - a one year follow up study*

The primary aim of this study was to examine, whether surgery for female PFD changed sexual function of their male partner. A secondary aim was to describe subjective sexual experiences of the partner related to POP and SUI surgery, for the purpose of finding potential intermediate factors for change in male sexual function.

The study population consisted of 36 partners (POP n=19, SUI n=16). At baseline, sexual function measured with the BSFI was not significantly different from population-based controls. Coital incontinence of their partner was reported by 14 % of the men (POP n=2, SUI n=3), while vaginal wind was reported by 34 % (POP n=8, SUI n=4). Marked distress ("bother") was reported by 23 % (POP n=6, SUI n=2); the main causes were feeling a bulge, dry vagina and the partner avoiding intercourse.

One year after surgery for PFD of the woman, scores for sexual drive, erection, and overall satisfaction from the BSFI were unchanged; only the ejaculation score had mildly improved from a range of 4 (median 4) to a range of 3.5 (median 4) (p=0.014). The proportion of men with erectile dysfunction was unchanged. A reduction in the proportion of men reporting their partners with dyspareunia was significantly correlated with improvement in the ejaculation score (Spearman's rho 0.42, p=0.019). Improved ejaculation was not associated with reduced vaginal dimensions or reduced coital incontinence. Postoperatively, none of the men noted coital incontinence, and significantly fewer reported vaginal wind. The proportion of men reporting marked distress ("bother") by one of the subjective problems was not decreased after surgery (POP n=8, SUI n= 2); the main causes were wide or dry vagina, female partner avoiding sex or experiencing pain, and worry about interfering with the surgical result.

In summary: Sexual function of male partners was unchanged or mildly improved after pelvic floor surgery.

5 DISCUSSION

5.1 *Summary of main findings*

The overall aim was to examine prevalence and associated non-obstetric risk factors of PFD requiring surgery among women in a Nordic population and to investigate changes in sexual function as a result of such surgery in a clinical cohort.

We found that PFD requiring surgery was common in Nord Trøndelag - more than one quarter of women above the age of 80 had reported either POP or SUI surgery. Apart from age and parity, we found increased BMI, constipation and COPD to be risk factors for both POP and SUI surgery. Work involving lifting was a risk factor for POP surgery only and smoking or asthma were only risk factors for SUI surgery. Surgery for PFD improved female sexual function in general. Improvement was predicted by good preoperative health or coital incontinence; further predicting factors differed between POP and SUI surgery. Sexual function of male partners was postoperatively unchanged or mildly improved. This improvement was not associated with surgery related changes in anatomy, but to subjective experiences of the partners.

In the following chapters, the accuracy, originality, and importance of these findings will be discussed.

5.2 *Accuracy of main findings*

The term “accuracy” describes if the results of a study are true, or the absence of error (Porta 2008). Truth, according to Karl Popper, cannot be proven, only falsified (Popper 1957). Therefore, the main attempt will be to identify (potential) errors, and secondarily on reporting supporting results. Errors in epidemiology are traditionally divided into random and systematic errors (Rothmann 2012). Random error is a thread to the precision of a result and systematic error is a thread to the validity.

5.2.1 Precision

Precision means a relative absence of random error (Porta 2008). Random error is assumed to be due to chance, not related to other variables; it decreases with increasing sample size. The p-value indicates the probability that the observed difference is due to chance, figure 10. A measure of imprecision is the standard error of a measurement. The calculation of CI is based on standard errors. A CI of 95 % represents approximately two standard errors and reflects a 95 % probability that the "true population value" will fall within the given range, given the absence of bias and use of correct test.

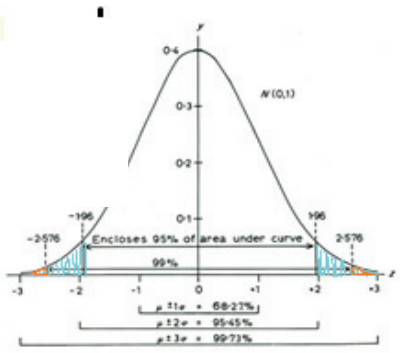


Figure10. Graphical display of 95% and 99% Confidence interval.

Proportion of significant outcomes as a chance finding, given p-value 0.05
Proportion of significant outcomes as a chance finding, given p-value 0.01

Random error can give rise to type 1 error (detecting a difference, when there is none) and type 2 error (not detecting a difference, when there is one).

The HUNT study was based on a large sample size corresponding to half the eligible population of Nord Trøndelag. This resulted in minor random error, reflected in (mostly) narrow confidence intervals for both prevalence measurements as well as estimates for associations between risk factors for POP or SUI surgery. The level of significance was chosen at 0.01 to reduce type 1 error, figure 10.

For the BESE study the small sample size, in particular of the partner sample (n=36), was the major weakness. The a priori sample size calculation for the BESE study had been performed for the partner sample. However, the calculation was based on a cross sectional design and was not appropriate for the analysis of change over time. A post hoc

power analysis supported that the actually obtained partner sample had 80% power to detect a change of 0.5 points for the subscales of sexual drive, erection, ejaculation and overall satisfaction (range 0-4). This effect size was considered clinically relevant. We therefore assume the main outcomes from the BESE study to be sufficiently precise. However, when stratifying into POP and SUI surgery, small sample size may have caused type 2 error. An example from paper II is that improved SF (mean change 1.6, SD 4.4) among women after POP surgery (n=28) lacks statistical significance (p=0.063). With a larger sample size, this change may have been significant. An example from paper III is that preoperatively, 14% of men (n=5) reported that they experienced their partner with coital incontinence, while none of the men reported this postoperatively. Yet this absolute decrease in prevalence lacked statistical significance because of the very small numbers (p=0.063).

The chance of type 1 error increases with multiple testing. For example, when the chosen level of significance is 0.05 and four different tests are performed, there can be an up to 20 % risk of a result which is statistically significant due to chance. We cannot exclude this error in particular for borderline significant results from paper II and III, for example the improved ejaculation score with p = 0. 017.

In summary, precision is one of the main strengths in the HUNT study. In the BESE study, precision appears adequate to assess change in sexual function when both types of surgery for PFD are evaluated together. When sub-group analyzes was performed for SUI and POP surgery separately, power was probably insufficient to demonstrate significant change or predictive factors for this change of sexual function. This change may however have been small and lacking clinical significance.

5.2.2 Validity

Errors remaining, if sample size would be infinitely large, are called systematic errors, or

bias, resulting in reduced validity (Rothmann 2011). Internal validity is the degree to which a study is free from such bias and depends on methods used to select subjects and to collect information, as well as the application of appropriate statistics (Porta 2008). Commonly, this bias is divided into three types: selection and information bias, and confounding (Rothmann 2011). Each type of bias is presented in general terms followed by examples from the HUNT and BESE study. External validity is described in section 5.2.2.3.

5.2.2.1 Selection bias

"Associations between exposure and outcome differ from participant to non-participant" (Rothmann 2012).

Depending on whether and how detailed information about the not represented population is available, it is possible to control selection bias, either by statistical weighing techniques or by specifying generalizability.

The study population in the HUNT study consisted of approximately 50 % of the invited. The large proportion of women not represented in the study population implicates a substantial risk of selection bias in terms of having undergone POP/SUI surgery. This could potentially influence both prevalence and risk factor estimates in any. Therefore, we attempted to obtain detailed information related to their risk for POP/SUI surgery from the women not included. These women can be categorized into three groups: non participants (37 % of eligible population), non-responders to Q2 (10 % of eligible population), and women responding to Q2, but with missing information on the main outcome (2 % paper I, 9 % supplementary results, of eligible population). A non-participation study from the HUNT research center accounted for the most important characteristics for 59 % of the female non- participants and concluded that there was "no reason to be concerned about introduction of bias in association and causal

studies" (Langhammer *et al.* 2012). This supports the finding of another study that associations are affected to a small degree and prevalence estimates to a larger degree by non-participant bias (Van Loon *et al.* 2003).

We aimed to approximate in which direction prevalence estimates for POP/SUI surgery may deviate for women not included in the study population. For this purpose, we compared the prevalence of risk factors for POP/SUI surgery among women not included in the study to their respective reference group. Further, we deducted the direction of a prevalence estimate for POP/SUI surgery among those three groups of women, not included in the study population. On average, among non-participants, compared to participants was a higher proportion of either older or younger women and women with a higher or lower BMI, a higher prevalence of chronic diseases and were more often cigarette smokers ($p< 0.001$) (Langhammer *et al.* 2012). This indicates that the prevalence of POP/SUI surgery may be rather higher among non-participants, compared to the study population. Because cigarette smoking was only a risk factor for SUI surgery, in particular the prevalence of SUI surgery may be higher among non-participants. Non-responders to Q2, compared to responders to Q2 on the other hand, were on average younger, had a lower BMI, but more often reported an occupation involving lifting ($p<0.001$). This suggests that the prevalence of POP/SUI surgery among non-responders to Q2 may be rather lower compared to the study population. Lastly, women with missing information on the main outcome were on average older, had a higher BMI, higher parity, reported more often COPD and constipation ($p<0.001$), compared to the study population. This again indicates that the prevalence for POP/SUI surgery may be higher among women with missing information, compared to the study population.

Effects on prevalence and risk estimates for POP/SUI surgery due to selection bias are

deducted and the precise effect size is not known. Therefore prevalence measured in the study population, represents a relative coarse estimation of prevalence in the population. It may appear that overall risks for POP/SUI surgery are in opposite directions when comparing the different groups of women not included in the study and possibly cancel each other in terms of effect on prevalence rates.

Because the HUNT study covers a broad range of health issues, participation is not expected to be related directly to pelvic floor surgery. Long term reconvalescence is required only in exceptional cases after POP or SUI surgery; even women after recent surgery are expected to have been able to participate.

For most covariates, the proportion of missing answers was low, except for the covariate "type of employment." One third of women in the study group did not answer this question. These women were on average 18 year older. Selection bias is likely to compromise validity of results concerning this covariate in in an unknown direction.

In the BESE study, the proportion of women in the study group was 19 % of all eligible persons, and of male partners 13 %. For the BESE study, selection bias can be subdivided into response and attrition bias. The response rate was 32 % for women and 15 % for partners. This is in the lower range of response rates reported between 34 % and 85 % in surveys about sexual function in Nordic countries (Mykletun *et al.* 2005; Eplov *et al.* 2007; Christensen *et al.* 2011). The range of response rates for studies based on clinical samples range between 14 % - 83 % (Bekker *et al.* 2010; Dua *et al.* 2012). For men, participation rates for similar studies are commonly lower than for women (Christensen *et al.* 2011; Vollebregt *et al.* 2012). An earlier Norwegian study indicated, that non-responders in sexual surveys are randomly distributed (Stigum *et al.* 1997).

In the BESE study, the only information collected for non- participants, was age of the women and type of scheduled surgery, resulting in very limited direct comparisons

between responders and non- responders. Non-responders were 5 years older, compared to participants (95% CI 1.7-7.2), while there was no significant difference for the type of surgery. Two indirect parameters were identified, indicating important differences between responders and non-responders: baseline sexual function and level of education. Baseline sexual function scores for women in the BESE study (mean 34, SD 6) were equal to normative scores from an North American population without PFD (mean 34, SD 3) (Lowder *et al.* 2010). This was unexpected because it is in contrast to results from studies using condition-specific questionnaires (see chapter PFD and sexual function). This finding may indicate selection bias towards women with better sexual function among the responders, given that Norwegian women have a similar sexual function compared to North American women. For men, we found a relatively low prevalence of erectile difficulties (15 %) and ED (5 %) compared with Danish population-based figures (>50 % for erectile difficulties and about 10 % ED in men aged 50-60 years) (Christensen *et al.* 2011). This may indicate selection bias towards men with better sexual function as well.

Men with university education were overrepresented and men with only compulsory education were underrepresented among responders, compared with a population-based sample of Norwegian men (Mykletun *et al.* 2005). Low educational level has been associated with erectile dysfunction in a number of studies (Nicolosi *et al.* 2003; Lyngdorf *et al.* 2004). When comparing baseline sexual function scores of partners in the current sample with the scores of a population-based sample only adjusted for age, scores were not statistically different; the tendency of the scores was towards better sexual function among men in the study sample (table 6).

When sexual function scores from the study sample were however adjusted for education, they indicated lower sexual function, compared to the age adjusted scores

from the population based sample (table 6, blue). A weighing technique had been applied for both adjustments and comparing two weighted scores, no p-value could be calculated (Mykletun *et al.* 2005) .

Table 6. Comparing sexual function scores of partners after pelvic floor surgery with population-based controls (Mykletun *et al.* 2005), measured with the brief sexual function index (BSFI). BSFI scores of population based sample are adjusted for age of clinical sample. BSFI scores of partners are adjusted for education of population based sample.

BSFI items	Partners N=47 Mean(SD)	Population-based sample N=1092 Mean(SD)	p- value	*Partners N=47 Mean*
Sexual drive	2.35(0.97)	2.25(0.84)	0.48	***2.16***
Erection	3.12(1.05)	2.97(1.13)	0.35	***2.63***
Ejaculation	3.59(0.83)	3.40(0.95)	0.13	***3.15***
Overall satisfaction	2.72(1.08)	2.60(1.05)	0.44	***2.57***

Attrition of female responders in the BESE study was 41 %. Of those, 18 % were due to dropouts and 23 % due to protocol violations (e.g. missing information, not sexually active), see figure 9. Proportionally more women in the study population had partners or were interested in improving sexual function, compared to women lost to attrition; there were no other significant differences for important covariates. This probably indicated that women specifically interested in improved sexual function were overrepresented in the study population. For men, the attrition rate was 29 %; of those 24 % were drop outs and only 5 % protocol violations. We found no significant differences for age, education, ED or the four sexual function scores between men lost to attrition compared to the study population.

In summary, for the HUNT study, selection bias appears reasonably well described. It probably does not affect the validity of the risk estimates to a major degree. Prevalence rates may be more affected by selection bias, in particular for SUI surgery. When assessing generalizability, measured prevalence rates have to be considered as approximations. The “true prevalence” of POP surgery in the population may be fairly

similar to the measured rates. For SUI surgery, the measured prevalence may underestimate the true prevalence of SUI surgery in the population to some degree. For the BESE study, the potential for selection bias is larger. Results may be predominantly valid for both women and their partners with relative good prior sexual function, as well as for women specifically interested in improving sexual function with surgery for PFD.

5.2.2.2 Information bias

" Information collected about or from study subjects is erroneous" (Rothmann 2012).

Recall, misclassification and measurement bias are types of information bias. They can be differential or non-differential, related to other study variables or not. Differential bias may lead to both over or underestimations, while non-differential bias mostly leads to a dilution of estimates (Rothmann 2012). Important limitations for the HUNT study are recall and misclassification bias, because the main outcome and most covariates were self-reported, as well as measurement bias when examining risk factors with a cross sectional design. As for recall, validity for self-reported hysterectomy has been shown to be 96 % (95% CI 91-99%), when comparing to medical records (Green *et al.* 1997). Therefore, the large majority of women who had undergone POP surgery can be expected to recall this correctly and recall is expected to be non-differential, because the question was one of many in a large survey. Recall for age at surgery may be vague, particularly if the surgery was performed many years ago. This bias is expected to be non- differential with an unknown direction, possibly leading to imprecise estimates for age-specific incidence rates for POP surgery.

In terms of misclassification of the main outcome, a mixing up with other types of surgery is possible. This potentially reduces the validity of prevalence and association estimates. SUI surgery can have been mixed up with POP surgery, but questions about both types of surgery were included, reducing this risk. Women who underwent

cosmetic genital surgery may have reported POP surgery, but this type of surgery was very uncommon in Nord Trøndelag, reducing these possibilities substantially. An unknown number of women may have reported POP or SUI surgery when they had undergone a (secondary) repair for obstetric injury. This proportion may have been higher among women reporting POP surgery below the age of 30 (n=81). This consideration was one of the factors for why incidence rates were only calculated for women above age 30. When analyzing risk factors for POP surgery, we performed a tentative analysis excluding women below age 30, yet this did not change OR's or CI's to an appreciable degree.

As all examined risk factors apart from BMI were self-reported, misclassification should be considered. In the study population, mean-age of onset for asthma seemed atypically late at 29 years and the prevalence high at 13 %. We therefore compared prevalence rates of asthma and COPD with other population-based prevalence rates. A Norwegian study reported the prevalence of diagnosed asthma at about 9 % and of asthma like symptoms at 13-19 % (Brogger *et al.* 2003). For COPD, prevalence rate was similar (Buist *et al.* 2007). These observations suggest, that a number of women with asthma like symptoms, and thus potentially minimal strain on the pelvic floor, were most likely included, possibly causing a dilution of the estimate for association between asthma and POP surgery. We expect misclassification, if present, to be non- differential for all risk factors.

The cross sectional design was a potential source of measurement bias, when examining risk factors for pelvic floor surgery. To be clinically meaningful, risk factors should be modifiable. This necessitates a temporal sequence with the risk factor preceding the outcome. If the risk factor is measured *after* surgery for PFD has occurred, it could be a result of the surgery. The collected information about the risk factor (= the proxy) may

not represent what was supposed to be investigated and introduce measurement bias. Apart from constipation, the investigated risk factors were measured *after* pelvic floor surgery had occurred and were proxies for the condition prior to the time of surgery. We suggest that an appropriate temporal sequence is likely for most of the examined risk factors.

Cigarette smoking: The large majority of women (and men) start smoking during their teens or tweens (Giovino *et al.* 1995). Therefore, the proportion of women only starting to smoke after pelvic floor surgery is assumed to be very small.

Body mass index: In the U.S. population, it has been demonstrated that the greatest increase in the prevalence of women being overweight is during the early thirties, and that the average weight change during a ten year period is about 2 kg (Williamson 1993). Therefore, we assumed that the large majority of overweight or obese women at the time of the survey were in the same BMI category at the time of surgery. For some women, surgery for PFD may have caused inactivity due to anxiety of recurrence, resulting in increased BMI.

Occupation: We observed occupation at the time of survey and used this as a proxy for occupation at the time preceding surgery. This may have introduced differential information bias when assessing the type of occupation as a risk factor for causing POP/SUI surgery. Women with symptomatic POP/SUI or after surgery for these conditions may have chosen a lighter type of work because of worsening or recurrence of symptoms. In other words, specifically those women reporting POP/SUI surgery may actually report less strenuous current work. We can therefore not draw any conclusions about type of employment as a cause of POP/SUI surgery.

Chronic lung disease: Mean age of onset for both COPD and asthma were before mean age of surgery for POP in this population and reported mean age for SUI surgery in the

U.S. (Waetjen *et al.* 2003). This time sequence allows direct risk factor deductions on a group level, assuming recall for age was valid.

For the BESE study, validated questionnaires were a main strength of the study and are expected to measure a well-defined outcome. In addition, for anatomic measurements of the genitalia, the standardized POPQ system was applied, to optimize validity. Yet, potential for information bias is present, due to the following reasons. The two main instruments to measure sexual function (PISQ-12, BSFI) were validated psychometric measures in their original language (English), but the translation had not been linguistically and culturally validated, as advised by other researchers in the field of PFD (Omotosho *et al.* 2009). A forward and back translation had been performed by a professional translator; cultural differences with regards to sexuality are not expected to be major between USA and Norway. We therefore assume information bias due to lack of cultural validation of the instruments to be small.

A major shortcoming of PISQ-12 was that it did not measure distress. Consequently, PISQ-12 is not valid to diagnose female sexual dysfunctions (Mehta *et al.* 2008). At the time of study design PISQ-12 was the only validated, condition-specific questionnaire, in the meantime a revised version has been published (Rogers *et al.* 2013).

Despite using POPQ as a standardized, objective measure for the degree of prolapse and the genital hiatus, we detected little change in the measurements one year after surgery. Only vaginal length had shortened. This was only significant when women after POP and SUI surgery were analyzed together. The possibility of measurement bias has to be considered. Preoperative measurements had been performed by different health professionals on the operation table. Written and graphic instructions about how to perform these measurements were printed on the data collection sheet for each patient, but no quality control had been performed. Postoperative examinations had been

performed mostly by the main author or two urogynecological nurses on a gynecological chair in the outpatients department. It is possible that a systematic difference in POPQ measurements between baseline and follow up can have occurred, causing information bias. Because no indication as to the direction of this bias is available, associations between anatomic measurements and sexual function may either be under- or over-estimated. Alternatively, and probably less likely, surgery had been performed very conservatively, or progression of POP after one year had occurred.

Another threat to the validity of the anatomic measurements was the large proportion of missing measurements for vaginal length. We therefore compared sexual function scores for women with or without available vaginal length. No significant difference was detected, indicating that if bias was present, it was non-differential.

The instrument applied to measure BI among women with PFD was a potential source of information bias for two reasons. Firstly, the scale we planned to use was the modified Hopewood Body Image Scale; the original version had been designed for women with breast cancer and had been modified to study the BI of women with POP (Hopwood *et al.* 2001; Jelovsek *et al.* 2006). The modified version, using eight of ten questions, had not been formally validated and may have had insufficient psychometric validity to measure BI among women with PDF; recently, two condition-specific genital body image instruments were validated (Zielinski *et al.* 2012; Lowder *et al.* 2014). In addition and due to a technical error, only seven questions were printed in the baseline questionnaire, rendering it inappropriate to calculate an overall score. It was decided to analyze four of these questions, because those had been previously translated into Norwegian (Sprangers *et al.* 1996). These four questions may have not had the psychometric properties to assess body image among the participants.

For the BSFI, four considerations emerged, which potentially reduced the instruments

validity to measure sexual function in the context of this study. Firstly, the BSFI is a generic instrument and may not have been sensitive enough, to detect more subtle changes in male sexual function specifically related to PFD of the woman. Currently, no male sexual function instrument exists which is condition-specific for female PFD. Secondly, the BSFI has not been tested for responsiveness, which may weaken its ability to detect changes in sexual function over time. Thirdly, we observed a ceiling effect for the ejaculation score; 82 % of all responders reported a score of 3.5 or more at baseline (range 0-4). This could have caused an underestimation of improved ejaculation after surgery. Fourthly, due to a technical failure, we did not collect information about problem assessment for the ejaculation domain. This weakened our ability to assess sexual dysfunctions.

The questions about subjective sexual experience of partners with women with PFD were not validated and represent a potential for information bias, because they were not proven to measure what they were meant to. To minimize this risk, these questions had been designed together with a clinical sexologist.

In summary, for the prevalence estimates in the HUNT study, information bias is expected to have minor impact, despite the self-reported nature of the outcome. Age specific incidence rates should be viewed as approximate measures. Of the risk factors for PFD requiring surgery, the estimate of association for asthma may be too low because of misclassification bias. The effect of heavy occupation or occupation involving lifting may have been underestimated due to use of an invalid proxy.

For the BESE study, the lack of association between POPQ measurements and sexual function of both women and their partners should be viewed with caution due to possible systematic measurement bias. Likewise, lack of association between BI with sexual function may be secondary to information bias caused by an insufficiently valid

instrument. The changes in male sexual function, particularly ejaculation, may be underestimated due to measurement bias.

5.2.2.3 Confounding

"Mixing of effects" occurs when the effect of the exposure is mixed with the effect of another variable. A confounder must be causally (or as a proxy for a cause) associated with the exposure and it must be associated with the outcome, but not be an effect of the outcome (Rothmann 2012).

The main reason to identify and control for confounding, is to proceed from reporting associations to accumulate evidence for causal inferences. Associations are not directed, (i.e. the outcome could have caused the exposure), while causation is directed; sample associations are directly observable, causations are not (Rothmann 2008). This aspect was of particular importance for the HUNT study, in order to add clinical meaning to detected risk factors for POP surgery.

The identification of confounders has been the source of intense discussions within the past decade among epidemiologists, resulting in different schools of thinking. To detect confounders, mathematical methods like "change in estimates" are favored by one group, as opposed to a priori determination of confounders, based on expert knowledge by another (McNamee 2003; Janszky *et al.* 2010). Supporters of the latter point out that it is important to differentiate colliders (result of both exposure and outcome) and mediators (lying in the causal pathway between exposure and outcome) from confounders. It has been suggested that inclusion of these in statistical regression models can result in weaker associations and erroneous results, due to the creation of new bias (Janszky *et al.* 2010; Tilling *et al.* 2013). Causal diagrams, like directed acyclical graphs (DAG) can be helpful in differentiating between these three types of covariates (Rothmann 2008).

Confounding can be controlled by various means (Rothmann 2012). In the HUNT and BESE studies, stratification, weighing, and statistical regression techniques were used. Stratifying implies examination of the data by categories of the confounding variable. For example, in the BESE study, we considered the type of surgery as confounder when examining change of subjective experience of partners and therefore stratified for POP and SUI surgery. Stratification is impractical if many confounders are considered, as in the HUNT study. Another descriptive, statistical technique to account for confounding is weighting, applied in the BESE study: To compare baseline sexual function among partners of women with PFD with a given, population-based sample, age was considered an important confounder. Sexual function scores of the population-based sample had been available, already stratified into age groups. These scores were multiplied with proportions of partners in the same age groups, resulting in sexual function scores for the population as if it had the age distribution of the study sample. The third possibility for handling confounding is to use regression models, with analytical statistics as a tool. To apply regression techniques correctly, a number of assumptions have to be fulfilled. This has been a limiting factor for the BESE study. For example, the assumption of normal distribution was not met by the main outcome for partners. For women, the number of observation was only sufficient to adjust for one confounder (age) when examining change in sexual function. For the HUNT study, sample size and number of collected variables offered good opportunities to control for confounding with regression models. One challenge was that five different risk factors with potentially different patterns for confounding had to be accounted for. Another challenge was to classify covariates as confounders, colliders or mediators. To deal with both problems, we presented three different multivariable logistic regression models. In addition, with the help of causal diagrams, we considered separate models for each risk factor, removing or adding

confounders thought to be important. As an example, the causal diagram for type of occupation as a risk factor for POP surgery is presented, figure 11.

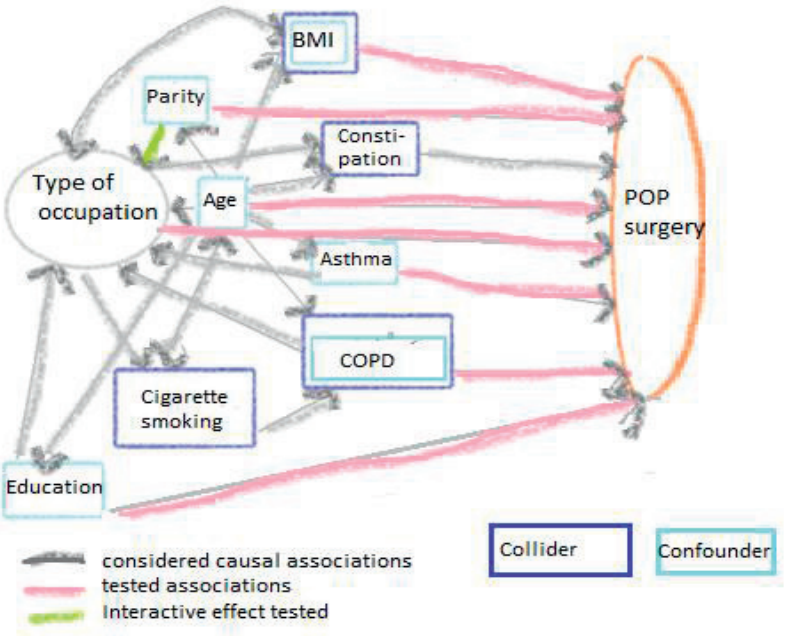


Figure 11.

Causal diagram for relationship type of occupation as risk factor for pelvic organ prolapse (POP) surgery:

Based on the model which included socio-demographic and lifestyle factors, cigarette smoking or BMI were considered as colliders and removed from the model, while the pulmonary diseases were added as potential confounders. However, effect size and significance level of the ORs remained similar.

Physical activity was a potentially unmeasured confounder for the HUNT study. A low level of physical activity was associated with increased BMI and could also be associated with fewer symptoms from POP. This could explain the lack of increasing risk for POP surgery among women in the highest BMI groups.

In the BESE study, regression modelling could only be applied to control for confounding by age of the woman in paper II. Parity could be a potential confounder, because it is a risk factor for both the exposure (pelvic floor surgery) and was found to be predictive for the outcome, change in sexual function. One study supporting parity as

an individual risk factor for sexual function had demonstrated worse sexual function among identical twins, in the parous twin (Botros *et al.* 2006). However, PISQ-12 had been used as a measure and this condition-specific instrument is probably not suitable to compare sexual function among women with or without PFD. Further we found little evidence for parity to be independently associated with sexual function and suggest that it may be a mediator for SUI or POP symptoms. BMI has been demonstrated to be a risk factor for pelvic floor surgery, but was not associated with change in sexual function. BMI is therefore less likely to be a confounder. Coital incontinence is considered to be a mediator in the exposure-outcome relation.

Numbers of participants were not large enough to examine, if the variables predictive for change in sexual function were independent of each other.

In the BESE study, we failed to ask about sexual performance enhancing medication at baseline. It is possible that partners of women with PFD were using such medication prior to surgery. Yet, none of the men reported use at follow up and it is highly unlikely that discontinuation this medication could have resulted in improved ejaculation. We cannot account for unmeasured confounders, for instance, vaginal elasticity.

In summary, for both the HUNT and BESE studies, a serious effort was made to control for confounding and strengthens the validity of the results.

5.2.2.4 External validity

" The degree to which results of a study may… be generalized to …groups that did not participate in the study" (Porta 2008). For conclusions about external validity, in-depth knowledge about the subject may be more relevant than for internal validity, where methodological knowledge may be more important.

Considering results from the HUNT study, generalizability for prevalence rates and risk factor estimates may differ. For prevalence rates, available health services and current

attitudes among health care providers as well as patients may have additional importance. For the risk factors, the relative importance of other factors for the development of PDF, such as predisposing and inciting factors (figure 2), could be expected to modify the effect of identified risk factors. These aspects may differ considerably between cultures, political and social situations, and different genetic backgrounds.

In the chapter on selection bias, generalizability of prevalence and risk estimates from the study population to the population of Nord Trøndelag has been discussed.

The population of Nord Trøndelag lives mainly in rural areas and compared to the Norwegian population, health status has been described to be representative (Langhammer *et al.* 2012). We therefore assume that prevalence rates of POP/SUI surgery in Nord Trøndelag are probably generalizable to most of Norway. In bigger cities prevalence rates may be different. Further, it may be reasonable to expect similar prevalence rates for POP/SUI surgery in other Scandinavian countries with a similar social welfare, cultural background, and risk profile for PFD's. Prevalence rates cannot be generalized outside the Nordic countries due to those limitations.

As to the identified risk factors, we assume that increased BMI, constipation, and chronic pulmonary disease are likely risk factors for POP/SUI surgery in high income societies with predominantly Caucasian inhabitants. The prevalence and distribution of cigarette smoking and occupation involving lifting may differs considerably between Nordic and other high income countries. Therefore, the rationale for generalization outside the Nordic countries is limited for those risk factors.

Results from the BESE study are only applicable to sexually active women and their partners and may be relevant mainly to women and their partners interested in improving their sexual function. Furthermore, these results are expected to be applicable only in

similar cultural settings, because sexuality, including sexual function, depends strongly on cultural norms (Schmitt 2005). Mean age of women in the BESE study was 52 (SD 11) years, but it is possible that results may be applicable to older women maintaining their sexual activity as well. For these women sexual function has been shown to be maintained well into the seventies (Lonnee-Hoffmann *et al.* 2014).

5.3 *Interpretation of main findings in light of other studies*

After having reflected on the accuracy of results, in the spirit of Karl Poppers' hypothesis testing, these results may be true, until they are not refuted by other studies. Another approach to support causal inference are to assess the causal criteria of Hill (Hill 1965). Of the originally nine criteria, strength, consistency, specificity, temporality, biologic gradient and plausibility will be discussed, in the light of evidence of other studies and if applicable. The other criteria are omitted, because they seem redundant (coherence), not applicable (experimental evidence), or the application appears only limited by creativity (analogy).

5.3.1 Prevalence of POP and SUI surgery in a Nordic cohort

- The measured prevalence of self-reported POP surgery among octogenarians (15 %) falls in between the lowest (United States, Great Britain) and the highest (Australia, the Netherlands, Denmark) prior published life time risks (Olsen *et al.* 1997; Smith *et al.* 2010; Abdel-Fattah *et al.* 2011; de Boer *et al.* 2011; Lowenstein *et al.* 2014). Prevalence of SUI surgery at age 80 was 7 %. This is twice as high as the only other lifetime estimate identified (Abdel-Fattah *et al.* 2011). Different health care systems and populations compared to the HUNT study and changes in rates over time with both increasing and decreasing trends complicate comparisons between studies. The estimate for lifetime risk among current 80 year old women for POP surgery is consistent with other reports.

There are insufficient published studies to compare the estimate of SUI surgery. Selection and information bias is likely to be present in the current study; the overall effect is evaluated to be minor for the prevalence of POP surgery, but may have led to some underestimation of the prevalence of SUI surgery. Details have been discussed in previous sections.

5.3.2 Non-obstetric risk factors for POP and SUI surgery

- We found that women reporting *marked constipation* have an approximately 80% higher odds for POP surgery and two fold higher odds for SUI surgery during the subsequent decade compared with women not reporting constipation (table 5; paper I). Consistent with our results, more current constipation symptoms among women reporting POP or SUI surgery have been demonstrated in a small cohort study (de Boer *et al.* 2011). Another case control study did not confirm these associations when investigating risk factors for POP surgery (Blandon *et al.* 2009). The reason for this discrepancy might be that all women had undergone prior hysterectomy. At least 11 studies were identified, consistently reporting constipation as a risk factor for the condition of POP or SUI (table 1). We propose, based on the available evidence that marked constipation is probably causally associated with SUI and POP surgery. This evaluation is strengthened by a temporal sequence, biological plausibility and consistency with other studies describing constipation as a risk factor. However, genetic predisposition could be an unmeasured confounding factor, causing both constipation and PFD.
- We found *overweight and obesity* to be consistently associated with POP and SUI surgery; the effect size for SUI surgery was larger and exhibited in addition a gradient (table 5; paper I). Two studies have previously shown that higher BMI

was associated with POP/SUI surgery (Moalli *et al.* 2003; de Boer *et al.* 2011). Effect size measured by ORs for POP/SUI surgery for women being overweight compared to normal weight table were in addition similar in de Boer's and the current study (table 3, 5, paper I). One study from the US failed to support this association (Ghetti *et al.* 2007). An explanation for the differing results might be that both cases and controls were chosen from a selected cohort (managed care). Already Olsen et al. had reported higher risk for SUI compared to POP surgery among overweight/obese women (table 2). Although a time sequence has not been observed directly, associations were found to consistent, strong, plausible and exhibiting a gradient. Considering the available evidence, inclusive the large numbers of studies supporting overweight to be a risk factor for UI/SUI (table 1), it appears likely that increased BMI is one of the causes for POP surgery and that it is a particularly important cause for SUI surgery.

- We found that POP surgery was significantly associated with COPD, while SUI surgery was significantly associated with both *COPD and asthma* (table 5; paper I). There has been conflicting evidence for chronic pulmonary disease as a risk factor for POP/SUI surgery, table 2 (Olsen *et al.* 1997; Ghetti *et al.* 2007; Blandon *et al.* 2009; de Boer *et al.* 2011). Chronic pulmonary disease was a consistent risk factor for SUI/UI but not for POP, table 1. The results of the current study may contribute to explaining these conflicting reports. None of the studies had specified the type of chronic pulmonary disease and we suggest that asthma may have been an unmeasured confounder in studies not finding a significant association between chronic pulmonary disease and POP surgery. The different effects of these two types of pulmonary disease on the pelvic floor could be caused by, on average, more repetitive strain with COPD. Based on the

available evidence, chronic pulmonary disease appears to be involved in the causal pathway more for SUI than for POP surgery. COPD and asthma appear to exhibit differing effect size for POP compared to SUI surgery.

- We could not corroborate *type of occupation* as a risk factor for PFD requiring surgery. Occupation involving lifting has been demonstrated as a risk factor for POP surgery in a nationwide study from Denmark, and for POP or SUI in five studies; only one study did not support these associations (table 1, 2) (Jorgensen *et al.* 1994). Most of the studies reporting a positive association, had adjusted for important confounders and reported from comparable populations (Woodman *et al.* 2006; Miedel *et al.* 2009; Slieker-ten Hove *et al.* 2009). As discussed in section 5.2.2., it is possible, that differential information bias resulted in obscuring of an existing association and weakened the validity of this particular covariate. In the light of these considerations, the absence of a significant association between occupation involving lifting and POP/SUI surgery in our study should be regarded with caution.
- We found *cigarette smoking* to be a risk factor for SUI - but not for POP surgery (table 5, paper I). Prior evidence for smoking to be a risk factor for POP/SUI surgery was conflicting, but all identified studies had evaluated POP and SUI surgery together (Erata *et al.* 2002; Ghetti *et al.* 2007; de Boer *et al.* 2011). Another Norwegian study described smoking as a risk factor for UI (Hannestad *et al.* 2003). However, results of this study had been based on the same population, the HUNT 2 survey. Further studies, most importantly a large, well designed Finish population-based study, did not support smoking as a risk factor for UI/SUI (Tahtinen *et al.* 2011). We cannot explain this discrepancy and a causal relationship should not be deducted without further evidence.

5.3.3 Factors predictive for change in sexual function among women after POP/SUI surgery

Overall improved sexual function had been observed, as expected after POP/SUI surgery.

- *Coital incontinence* as a prognostic factor for improved sexual function had been described previously, see section 1.6. It seems reasonable to assume a causal relationship between postoperative decreased coital incontinence and improved postoperative SF, based on temporal sequence, plausibility, consistency and specificity of results. This could also explain to some extent, why SUI surgery improved sexual function more than POP surgery.
- The finding, that female sexual function improved more after *anterior colporrhaphy* than after other POP surgery has been described by other studies (Komesu *et al.* 2007; Dua *et al.* 2012). In contrast to Dua *et al*., this improvement was not related to reported dyspareunia. In our study, women after POP surgery reported less coital incontinence symptoms as well. Although we were not able to test associations because of small numbers, it would be plausible to assume, that coital incontinence improves more after surgery in the anterior vaginal compartment and that coital incontinence is the mediator for improved sexual function after anterior colporrhaphy.
- Improving *BI* as a goal was a further prognostic factor for improved SF - but only for women undergoing SUI surgery. Improved BI has been suggested to be causally involved in the improvement of SF among women after POP surgery, see section 1.6.1. No studies have been identified examining BI in the context of SUI surgery. Our failure to demonstrate similar associations among women after POP surgery may be due to information bias or type two error, as described previously. This finding supports BI as a mediator between sexual function and

surgery for PFD.

- Preoperative *psychological distress* as a prognostic factor for postoperative reduced sexual function is in line with findings from a study reporting deteriorated sexual function after hysterectomy among depressed women (Rhodes *et al.* 1999). Depression has previously been shown to be associated with sexual activity as well as sexual dysfunction, and is likely to be involved in the causal pathway (Hayes *et al.* 2008; Lonnee-Hoffmann *et al.* 2014).
- No studies were identified examining *age, parity, or menopausal status* as predictive factors for improved sexual function after surgery for PFD. One other study identified parity as the only factor predictive of deteriorated sexual function among women with UI (Yang *et al.* 2008).

5.3.4 Sexual function of male partners in the context of pelvic floor surgery

- Our finding that 20 % of partners of women scheduled for SUI surgery reported *coital incontinence* is very similar to the 23 % reported previously in a cross-sectional study (Nilsson *et al.* 2011).
- In line with our findings, Nilsson *et al*. concluded that *coital incontinence was not considered a problem* for most of the partners
- We reported mildly *improved ejaculation after POP/SUI surgery* in our study. Four studies for comparison have been identified. One recently published study reported improved male sexual function after SUI surgery of the woman, supporting our findings (Schettino *et al.* 2014). Two studies reported sexual function of partners after POP surgery, with somewhat differing results (Kuhn *et al.* 2009; Vollebregt *et al.* 2012). Kuhn *et al*. described significant improvement for sexual interest and sexual drive, as well as overall satisfaction. A number of differences may explain the different findings in Kuhn *et al.'s* study. Kuhn *et al*.

had applied the same sexual function instrument, but compared change for the 11 single questions, while we had analyzed change in composite domain scores. The study of Kuhn *et al.* was larger (n=64) and the domain score for sexual drive also showed in our study a tendency for improvement; this may have been significant with larger numbers. Further differences could explain different patterns of improved SF. Men in Kuhn *et al*. study were on average 10 - 20 years older, their partner's had only undergone POP surgery, and the follow up period was shorter (three months). Vollebregt *et al*. reported no change after POP surgery, although there was a non-significant tendency for improved erection in mesh group. Vollebregt *et al*. had examined change in sexual function as a secondary outcome, when comparing synthetic mesh with anterior colporrhaphy in a randomized controlled trial. Sample size in each group had been small (n=22 and n=29) and another sexual function instrument had been used. These differences possibly explain different findings. One small qualitative study (n=8) concluded with improved sexual function of the men due to changes in vaginal tightness and improved sexual behavior of the women (Roos *et al.* 2014). This is in line with our findings and particularly interesting, because the improvement in ejaculation in our sample was associated with *men reporting that their partner experienced less dyspareunia*. However, the proportion of women reporting dyspareunia in our study had not decreased; in light of other findings, it is possible that men interpreted better sexual function among women as reduced dyspareunia.

5.4 *Conclusions and implications*

Approximately one in five Norwegian women will experience surgery for PFD during her lifetime. Because of the large numbers affected, this has a substantial economic impact on the society. Identifying modifiable risk factors could contribute to reduce this proportion in the long term. We found evidence for most of the proposed promoting factors for PFD also to be risk factors for surgery for PFD. BMI above normal, chronic constipation, and COPD increased the risk between 1.6 and 3 fold for POP or SUI surgery. Asthma and smoking were risk factors only for SUI surgery.

For the individual woman, subjective symptoms are important when evaluating the outcome of surgery for PFD. For a large proportion of women, we demonstrated that improving SF was a very important goal. Our results can be used, to counsel women interested in improving their sexual function, prior to surgery for PFD. A woman suffering from coital incontinence and healthy women is more likely to experience improved sexual function, while a woman with depression is more likely to experience deterioration. When SUI surgery is indicated, the older woman, or the woman having born more than two children, may be more likely to experience postoperative improved sexual function. When POP surgery is indicated, the postmenopausal woman or a woman requiring anterior colporrhaphy is more likely to improve her sexual function, while the woman requiring posterior colporrhaphy is more likely to experience deterioration. It might be helpful, to inquire about coital incontinence among all sexually active women with PFD and inform them, that their partners are probably not bothered by their coital incontinence. Women may be interested in the information, that sexual function of their male partner is likely to remain unchanged, or mildly improved.

Results of paper II could be used in the construction of a condition specific sexual function instrument for partners of women with PFD.

5.5 *Implications for future research*

1. Is occupation involving lifting a risk factor for POP/SUI requiring surgery?
2. Does weight loss reduce the risk of pelvic floor surgery? Some evidence supporting this hypothesis has been published (Daucher *et al.* 2010).
3. Could appropriate use of pelvic floor muscles among patients with COPD or chronic constipation reduce the risk of pelvic floor surgery?

A longitudinal design is required for causal inferences for these research questions. For questions 1 and 2, information from HUNT 1 or 2 could be used, while question 3 a prospective intervention study would be appropriate.

4. Does good or normal sexual function prevent PFD?

To investigate this, a large population-based survey like the HUNT Study should include screening tools for sexual function. The outcome, surgery for PFD, would be measured after some decades.

5. Why do women seeking surgery for posterior vaginal compartment – or defecatory problems improve sexual function to a lesser degree or even experience deterioration?

A qualitative approach could be most informative.

6. Does the laxity of the vagina change after surgery for PFD? And if yes, is this associated with improved sexual function of the partner?

For this purpose a new instrument would need to be constructed, to measure vaginal elasticity.

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7 APPENDICES

Appendix I: Preoperative information leaflet for patient and partner and consent.

Appendix II: Questionnaire BESE women – preoperative

Appendix III: Questionnaire BESE men – preoperative

Paper I

Is not included due to copyright

Paper II

AOGS
ACTA Obstetricia et Gynecologica Scandinavica

AOGS MAIN RESEARCH ARTICLE

What predicts improvement of sexual function after pelvic floor surgery? A follow-up study

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Key words
Coital incontinence, female sexual function, pelvic floor disorders, pelvic organ prolapse surgery, stress urinary incontinence surgery, urogynecology

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Abstract

Objective. To analyze factors predictive for changes in sexual function after pelvic floor surgery and explore differences between stress urinary incontinence (SUI) and pelvic organ prolapse (POP) surgery. *Design.* Prospective observational study. *Setting.* St Olav Hospital, Trondheim University Hospital, Norway. *Sample.* Of 346 mailed questionnaires for women scheduled for SUI and POP surgery, 65 questionnaires were available for analysis together with examination findings before and 1 year after surgery. *Methods.* Postal questionnaires including Prolapse and Incontinence Sexual Function Questionnaire (PISQ 12), Hopkins Symptom Checklist 5 for psychological distress, questions from the validated Body Image Questionnaire, a general health question, questions addressing goals for improvement after surgery, clinical findings based on the Pelvic Organ Prolapse Quantification System and Brief Sexual Function Index for partners. Uni- and multivariate linear regressions adjusting for age were performed. *Main outcome measures.* Change in PISQ 12 score at follow-up. *Results.* Sexual function significantly improved in the total group ($p = 0.000$). After stratification into SUI and POP surgery, improvement only remained significant after SUI surgery ($p = 0.001$). Improvement for the total group was predicted by good health or coital incontinence, whereas psychological distress or the goal of improved defecation predicted deterioration. For women undergoing SUI surgery, increasing age, parity or the goal of improving sexuality or body image predicted improvement, while for women undergoing POP surgery, menopausal status or anterior colporrhaphy predicted improvement. *Conclusion.* Significantly improved sexuality was observed after pelvic floor surgery. Predictive factors for change differed for women undergoing SUI surgery and and those undergoing POP surgery.

Abbreviations: PISQ 12, Prolapse and Incontinence Sexual Function Questionnaire, short form; POP, pelvic organ prolapse; POPQ, Pelvic Organ Prolapse Quantification system; SUI, stress urinary incontinence.

Key Message

Sexual function improved after pelvic floor surgery among sexually active women. Increasing age, coital incontinence, desire to improve sexuality or body image predicted improved sexual function after stress urinary incontinence surgery. Menopause and good health predicted improvement after pelvic organ prolapse surgery.

Introduction

About two-thirds of women between the ages of 55 and 64 and about one-third between the ages of 65 and 75 are sexually active, and a substantial number may be undergoing pelvic floor surgery (1). Lifetime risk for undergoing stress urinary incontinence (SUI) and pelvic organ prolapse (POP) surgery has been estimated to be

12% in a recent study from the UK, mainly affecting women above the age of 40 (2). Within the past decade, research has been conducted examining the potential effect of pelvic floor surgery on sexuality. Improved sexual function has been described for about 70% of patients when using a condition-specific questionnaire, whereas studies not applying condition-specific questionnaires repeatedly show no improvement (3,4).

Recent studies have focused on factors that may explain decreased sexual function in women with pelvic floor disorders. For example, worries about coital incontinence, rather than actual coital incontinence, as well as depression, dyspareunia or decreased body image have been identified as potential factors, but not anatomical measures (5–8).

Few studies assess factors associated to changes in sexual function after pelvic floor surgery. One study identified coital incontinence before surgery as a predictor for improvement in sexual function after SUI surgery (9). Other studies described associations between observations made after pelvic floor surgery and sexual function, reporting associations between both improved body image and sexual function, as well as associations between persistent coital incontinence or increasing age and reduced sexual function (10–12). Female sexual function is complex and should be assessed by applying a biopsychosocial approach, in terms of measuring its various aspects (13).

The aim of this study was to assess social, biological, and psychological factors predictive for changes in sexual function of women after pelvic floor surgery and to explore differences and similarities between groups of women treated by SUI or POP surgery.

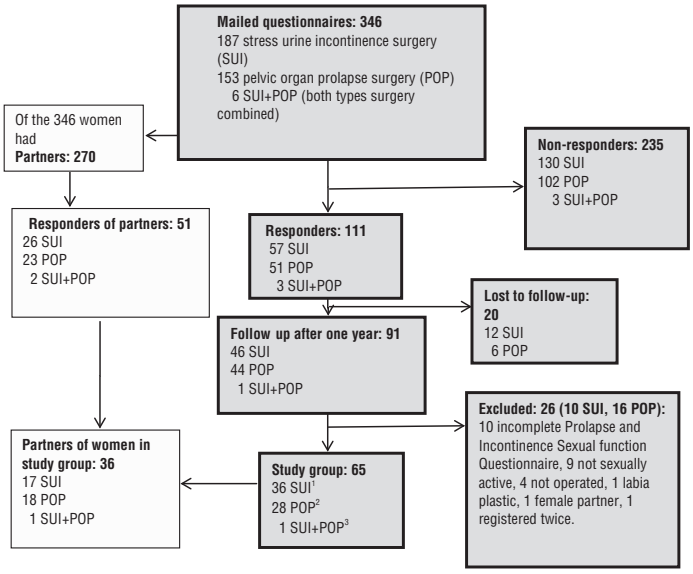
Material and methods

An observational follow-up study was conducted at St Olavs Hospital, Trondheim University Hospital, Norway, between April 2008 and January 2011. Consecutive women scheduled for SUI or POP surgery received a questionnaire for themselves and their partners. Exclusion criteria were age over 80 and inability to communicate in Norwegian. Measurements of the vagina and the perineum were performed preoperatively for all women applying the Pelvic Organ Prolapse Quantification System (POPQ). SUI and POP surgery were performed according to local routines. Follow-up assessments were conducted 1 year after surgery (mean 13 months, SD 2.3) using a second set of questionnaires for the women and for their partners, and by POPQ measurements. Patients were excluded from analysis due to sexual inactivity if they answered "never" to the question "How often do you and your partner have intercourse or are sexually active?" For other exclusion criteria, see Figure 1.

The main outcome was measured with the Prolapse and Incontinence Sexual Function Questionnaire, short form (PISQ 12), which is a validated short questionnaire on sexual function in women with POP and urinary incontinence. PISQ 12 is currently the recommended instrument for examining sexual function in this group of patients (14,15). The questionnaire was translated into Norwegian by a certified translator, using a double translation technique. Women were asked to indicate their response on a graded scale of 1–4, in which 0 corresponded to worst function or experience, and 4 to best. Women with more than two answers missing were excluded ($n = 10$). Item scores of patients with one or two questions missing ($n = 5$) were replaced by the patient's mean score (14). We used PISQ 12 summary scores at baseline and follow-up to assess overall change, as well as the difference between scores (changes of PISQ 12). Scores of the single factors at baseline were used to examine factors predictive for change. The two items covering coital incontinence and dyspareunia were dichotomized because of their particular clinical relevance for descriptive purposes only: "Always," "Usually," and "Sometimes" were coded as "Yes," and "Seldom" and "Never" were coded as "No."

Information on education, having a partner, weight and height, and medication were self-reported, but age, menopausal status, parity, and prior surgery were extracted from the medical records of the patient.

General Health was assessed by the question "How is your health now?" and responders were asked to indicate whether it was "Poor," "Not so good," "Good" or "Very good" (16). For analysis, responses were dichotomized into "Not good" for the first two answers and "Good" for the last two. Mental Health was assessed by a short version of the Hopkins Symptoms Checklist (SCL-5) (17). The score ranged from 0 to 15, and was used as a continuous variable. For both instruments, existing Norwegian translations were used (17,18). Body image was measured by four single questions already translated into Norwegian from a modified version of the Hopewood Body Image scale (19,20). The modified version was previously shown to have good discriminant validity and internal consistency for women with POP (20,21). Answers were graded from 0 to 3 (not at all, a little, quite a bit, very much), with increasing scores indicating worse body image. Seven questions about goals for improvement with the scheduled pelvic floor surgery were constructed for the baseline questionnaire, based on clinical experience. The response alternatives ("Not important," "A bit important," "Quite important" and "Very important") were dichotomized into Not important for the first three and Important for the last. One question about frequency of intercourse was included.



[1]**SUI surgery** : 35 tension-free vaginal tape (TVT), 1 tension-free vaginal tape, obturator (TVT-O)
[2]**POP surgery :** 18 anterior colporrhaphy, 10 colpoperineoplasty, 7 posterior colporrhaphy, 6 cervix amputation, 3 anterior synthetic mesh. 16 patients with 2-3 procedures
[3]**SUI +POP surgery:** TVT & perineoplasty

Figure 1. Flow chart inclusion of patients (and their partners). [1]SUI surgery: 35 tension-free vaginal tape (TVT), one tension-free vaginal tape, obturator (TVT-O). [2]POP surgery: 18 anterior colporrhaphy, 10 colpoperineoplasty, seven posterior colporrhaphy, six cervix amputation, three anterior synthetic mesh. Sixteen patients had two or three procedures. [3]SUI + POP surgery: TVT and perineoplasty.

The POPQ was applied for anatomic measures (22). Vaginal length (distance from top of posterior fornix to hymenal ring, reduced to normal position) and genital hiatus (distance from middle of external urethral meatus to inferior hymenal ring) were measured in centimeters and used as a continuous variable. Prolapse of the anterior-, middle-, and posterior compartment was graded from 0 (none) – 4 (procedentia) and was used as a categorical variable. For 23% of the women, there was one of the nine POPQ measurements at one time point missing; an experienced uro-gynecologist estimated the grade of prolapse if appropriate descriptions were available for the particular compartment and the particular time point. This resulted in one patient with missing grade of prolapse, and 19 patients with missing vaginal length; 15 of these also had a missing genital hiatus measurements at one time point. Patients scheduled for SUI performed a routine stress-test; uro-flow and post void residual urine volume was measured. Information about an urge component was collected from the medical record, either documented by urodynamic investigation or described clinically.

Male sexual function was measured with the Brief Sexual Function Index, validated in Norwegian (23).The mean scores with a possible range from 0 to 4 (higher values = better) of three functional items (drive, erection, ejaculation) and overall satisfaction were selected as outcome variables. For the included women, 37 complete questionnaires of partners (51% in SUI group, 64% in POP group) were available. Missing data for the covariates were below 8%, with the exception of vaginal length (30%) and genital hiatus (23%).

Informed, signed consent was obtained from the female participants and the Regional Committee for Medical and Health Research Ethics approved of the study.

Data analysis

Statistical analysis was performed with SPSS version 19.0 (SPSS Inc., Chicago, IL, USA). All tests were two-sided, with a 5% significance level. Confidence intervals (CI) were set at 95%. Approximate normality for continuous baseline data, changes in PISQ 12, as well as residuals in linear regression, were confirmed with the Kolmogorov–Smirnov test.

For comparison between SUI and POP surgery at baseline, continuous, normally distributed variables were com-

pared with an independent *t*-test and dichotomous variables were compared with Fisher's exact test. Not normally distributed variables or variables with more than two categories were compared with the Mann–Whitney *U*-test. Differences between SUI and POP surgery at baseline, while adjusting for age, were tested with logistics regression. Changes for PISQ 12, vaginal length, and genital hiatus were calculated with a paired *t*-test. Change for dependent, non-normal distributed variables (items of body image scale) was tested with the Wilcoxon rank sum exact test. Factors associated with changes in sexual function after surgery (changed PISQ 12) were analyzed one at a time with univariate linear regression and with multivariable regression using age as the only covariate. Logistic regression was used for associations with dichotomous outcome.

Results

Response rate at baseline was 32% and follow-up rate after 1 year was 82% (Figure 1). Mean age of responders was significantly lower than that of non-responders ($p = 0.002$) Compared with the 46 women lost to follow-up or who were excluded, proportionally more women in the study group had a partner (95% vs. 54%, $p = 0.000$) or were interested in improving sexual activity (46% vs. 20%, $p = 0.011$). No other significant differences were found.

Comparing women scheduled for SUI surgery to women scheduled for POP surgery, a number of significant differences were observed (Table 1). Only differences in menopausal status fell below significance after adjusting for age with logistic regression. Women in both groups reported frequency of intercourse on average one to three times per week; this did not change postoperatively.

Sexual function measured by mean PISQ 12 score significantly improved ($p = 0.000$; CI 1.3–3.7) in the total group between baseline 34.4 (SD 5.6) and follow-up 36.9 (SD 5.9). When stratified into women undergoing SUI surgery and women undergoing POP surgery, improvement was significant for women in the SUI group ($p = 0.001$) with a mean change of 3.2 (SD 5.1) points, whereas for women in the POP group the improvement was borderline significant ($p = 0.063$) with 1.6 (SD 4.4) points. For the proportions of women with improved, unchanged or decreased PISQ 12 scores see Figure 2.

Of the 12 items in the PISQ 12 instrument, scores for five had significantly improved after pelvic floor surgery. After stratification into SUI and POP surgery, intensity of orgasm score had fallen below significance; we present the data for the four items remaining significant (Table 2). We dichotomized answers for the coital incontinence item as well as for the dyspareunia item for descriptive purposes. Preoperative coital incontinence was reported in 40% ($n = 15$) of SUI and 21% ($n = 6$) of POP patients and postoperatively in 5% ($n = 2$) of SUI and 7% ($n = 2$) of POP patients. Dyspareunia was reported by 25% ($n = 16$) of women both before and after surgery. Of those, three patients described de novo dyspareunia after SUI (tension-free vaginal tape) and three after POP surgery (two anterior, one posterior colporaphy).

With change in PISQ 12 score after surgery as the outcome, we tested all baseline characteristics for significant associations, adjusting for age. For the total group, undergoing pelvic floor surgery and good health predicted improvement, whereas mental distress or having the goal of improving defecation predicted deterioration. We also tested whether single items from the PISQ 12 questionnaire at baseline could predict change in the total PISQ 12 score after adjusting for age. Coital incontinence and fear of incontinence predicted improvement for the total group. After stratification into SUI and POP surgery, the association with mental distress fell below significance and we observed different factors associated with improvement or deterioration for each group (Table 2 for PISQ 12, Table 3 for baseline factors). Assessing only women who had undergone SUI surgery, we found no association between the amount of preoperative leakage during stress test and improved sexual function. Assessing only women who had undergone POP surgery, anterior colporaphy predicted improved sexual function (β 4.1, SE 1.7), whereas posterior colporaphy predicted reduced sexual function (β −4.9, SE 1.8); this remained significant after adjustment for age.

We analyzed baseline sexual function scores of the 36 available male partners to see whether these could predict change in female sexual function after surgery, but we found no significant associations with the total group or after stratification into SUI and POP surgery. We examined whether body perception or examination findings had changed after surgery and whether those changes might be correlated to the observed change in sexual function. Of the four questions concerning body image, three items had improved significantly for the total group after pelvic floor surgery (data not shown). After stratification, the mean score for "Less physically attractive" had improved after SUI surgery ($p = 0.003$) and the mean score for "Feeling less feminine" after POP surgery ($p = 0.047$). The improvement for mean score "Dissatisfied with body" fell below significance when examining improvement after SUI and POP surgery separately. Improvement of sexual function was not associated with the improved scores for these body image questions. Of the selected anatomic measures (Table 1), only vaginal length had shortened significantly after surgery, but only in the total group ($p = 0.032$, CI 0.03–0.7); if analyzed

Table 1. Baseline characteristics of women scheduled for SUI surgery compared with POP surgery.

	SUI[a], *n* = 37		POP, *n* = 28		
	n	%	*n*	%	*p*-Value
Sociodemographic background					
Age, years; mean (SD)	50 (11)		55 (11)		0.035[d]
Menopausal	10	27	18	67	0.000[e]
Parity; mean (range)	2.5 (1–4)		2.6 (2–5)		0.70[f]
Parity greater than two	17	46	14	50	0.80
Living at home	36	97	28	100	1.0[e]
Partner	37	100	25	89	0.075[e]
Educational level					0.89[f]
Low (compulsory)	4	11	2	7	
Middle (college)	14	38	13	46	
High (university)	19	51	13	46	
Health					
BMI; mean (SD)	26 (4)		27 (4)		0.35[d]
Good/excellent general health, self-reported,	33	92	18	64	0.011[e]
Medication					
Antihypertensive ± statins	5	14	6	21	0.51[e]
Estrogen (systemic or local)	3	8	12	43	0.002[e]
Antidepressives ± sleeping	2	5	3	11	0.64[e]
Anti-diabetics	1	3	0		1.0[e]
Prior POP/SUI surgery	1	3	8	29	0.004[e]
Mental health, mean (SD)[b]	1.39 (0.51)		1.61 (0.87)		0.33[f]
Body perception[c]					
Feeling less					
Physically attractive, mean (SD)	1.1 (0.9)		1.1 (1.1)		0.89[f]
Feminine, mean (SD)	0. 6 (0.8)		1.1 (1.2)		0.07[f]
Problem to see oneself naked, mean (SD)	0.3 (0.8)		0.6 (0.9)		0.24[f]
Dissatisfied with body, mean (SD)	0.9 (0.9)		1.0 (0.8)		0.53[f]
Examination					
Vaginal length, mean, cm (SD), *n* = 46	9.3 (1.3)		8.7 (1.4)		0.14[d]
Genital hiatus, mean, cm (SD), *n* = 50	2.9 (0.9)		3.9 (1.0)		0.001[d]
Prolapse stage, mean (range):					
Anterior compartment	0.4 (0–2)		1.7 (1–4)		0.000[f]
Middle compartment	0.9 (0–2)		1.1 (0–4)		0.21[f]
Posterior compartment	0.5 (0–3)		1.0 (0–3)		0.019[f]
Stress test mL, mean (SD)	42 (0–160)		–		–
Goal to improve					
Physical activity	27	73	17	61	0.57[e]
Urinary function	24	65	10	36	0.034[e]
Social activity	19	51	10	36	0.43[e]
Body image	11	30	10	36	0.58[e]
Sexuality	13	35	15	54	0.20[e]
Heaviness	2	5	14	50	0.00[e]
Defecation	2	5	9	32	0.015[e]

SUI, stress urinary incontinence; POP, pelvic organ prolapse.

[a]One patient included with both SUI surgery and perineoplasty. Four patients with urge component.

[b]Hopkins Symptom Checklist 5, possible range 0–15, >2: mental distress.

[c]Possible range 0–3. Lower values indicate better body image.

[d]Independent *t*-test.

[e]Fisher's exact test.

[f]Mann–Whitney *U*-test Missing data <8% except vaginal length and genital hiatus.

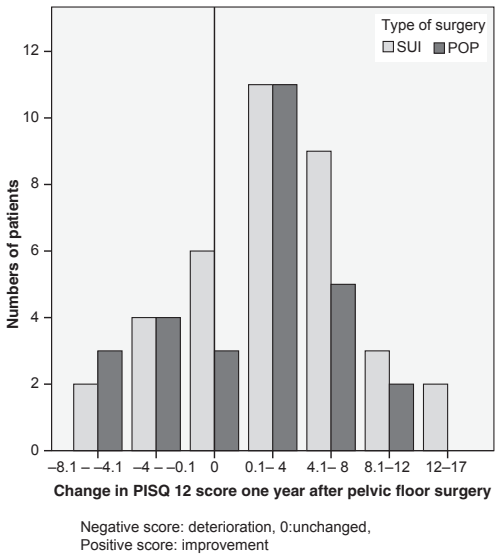


Figure 2. Change in Prolapse and Incontinence Sexual Questionnaire (PISQ) scoring 1 year after pelvic floor surgery, presented separately by type of surgery: stress urinary incontinence (SUI), $n = 35$, and pelvic organ prolapse (POP) $n = 28$.

separately for SUI and POP surgery, the change had fallen below significance. The shortening of vaginal length in the total group was not associated to change in sexual function. Finally, we examined the association between age of the women and sexual function scores both pre- and postoperatively because of the surprising finding that increasing age predicted improved sexual function after SUI surgery. As expected, we found increasing age to be associated to lower sexual function both at baseline ($p = 0.000$, CI −0.37 to −1.3) as well as at follow-up ($p = 0.018$, CI −0.31 to −0.03) in the total group as well as after stratification into SUI and POP surgery.

Discussion

This study showed significant improvement of sexual function after pelvic floor surgery. This improvement was statistically significant for women after SUI surgery but not after POP surgery. Improvement of sexual function was observed in about two-thirds of the patients, after both SUI and POP surgery. Coital incontinence as well as good health predicted improvement, whereas mental distress predicted reduced sexual function for the total group. We found that after SUI surgery, increasing age predicted improvement, whereas after POP surgery, post-

Table 2. Sexual function measured with Prolapse and Incontinence Sexual Function Questionnaire (PISQ 12) at baseline, change 1 year after pelvic floor surgery and associations between baseline factors and change. Stress urine incontinence surgery (SUI $n = 37$) and pelvic organ prolapse surgery (POP $n = 28$) are reported separately.

PISQ 12 item score range 0–4 (most problems, most reduced function = 0, no problems, best function = 4)	Baseline PISQ 12 single item mean score (SD)		Postoperative change PISQ 12 single item mean change (SD)		Association baseline to change of total mean score PISQ 12 (2.5) β (SE)	
	SUI	POP	SUI	POP	SUI	POP
How frequent desire?	2.7 (0.7)	2.7 (1.0)	0.1 (0.7)	0.1 (0.9)	−0.1 (1.2)	0.1 (1.0)
Orgasm during intercourse?	2.0 (1.2)	2.1 (1.2)	0.5 (1.2)[a]	−0.1 (0.5)	−0.5 (0.7)	−0.8 (0.8)
Sexually aroused by partner?	3.0 (0.9)	2.8 (1.1)	0.2 (1.0)	0.0 (1.1)	−0.3 (0.9)	−0.4 (0.9)
Satisfied with variation sex life?	2.7 (0.8)	2.4 (1.0)	0.2 (0.9)	0.2 (1.0)	−0.3 (1.0)	−0.4 (0.8)
Pain during intercourse?	3.2 (0.8)	2.8 (1.1)	0.1 (0.6)	−0.1 (1.0)	−1.0 (1.0)	0.3 (0.8)
Coital incontinence?	2.6 (1.2)	3.3 (0.9)	1.1 (1.3)[a]	0.4 (0.7)[a]	−2.2 (0.5)[b]	−0.3 (1.0)
Fear of incontinence limiting sexual activity?	2.8 (1.2)	3.2 (1.1)	0.8 (1.2)[a]	0.5 (1.0)[a]	−1.4 (0.6)[c]	−0.3 (0.8)
Avoiding sex because of bulging in vagina?	3.9 (0.5)	2.6 (1.3)	0.0 (0.9)	0.6 (1.3)[a]	−2.9 (1.5)	−0.1 (0.7)
Negative emotions during sex?	3.6 (0.8)	3.7 (0.7)	0.0 (0.9)	−0.3 (1.1)	−1.8 (1.0)	1.4 (1.3)
Partner with erection problems?	3.2 (0.9)	3.4 (0.9)	−0.1 (0.9)	0.2 (0.8)	−1.8 (0.7)[d]	0.8 (1.2)
Partner with premature ejaculation?	3.3 (0.9)	3.4 (0.9)	0.1 (0.7)	−0.3 (0.8)	0.8 (1.1)	−0.9 (0.9)
Strength of orgasm past 6 months, compared with previous orgasms	1.8 (0.5)	1.4 (0.8)	0.2 (0.7)	0.3 (1.0)	−2.4 (1.6)	0.1 (1.1)

Interpretation β (regression coefficient) – difference in mean change PISQ12 score per unit increase.
Example: β = −2.2 for coital incontinence: One unit less problematic coital incontinence at baseline results in 2.2 units decrease in the PISQ 12 mean change score (2.5–2.2 = 0.3 mean change).
[a]Significant postoperative change, $p < 0.05$ (paired Student's *t*-test).
[b]$p = 0.000$ (CI −3.3 to −1.1).
[c]$p = 0.031$(CI −2.7 to −0.1) (multivariate linear regression, adjusted for age).
[d]$p = 0.022$(CI −3.3 to −0.3).

Table 3. Biopsychosocial factors predictive for change in sexual function after pelvic floor surgery. Measured with Prolapse and Incontinence Sexual Function Questionnaire (PISQ 12). PISQ 12 mean change 2.5 (4.9). Linear regression, univariate and multivariate adjusted for age.

	SUI surgery, $n = 37$		POP surgery, $n = 28$	
	β[a] crude (SE)	β[a] adjusted for age (SE)	β[a] crude (SE)	β[a] adjusted for age (SE)
Sociodemographic background				
Age, years, mean (SD)	0.2[c] (0.09)	–	0.01 (0.08)	–
Menopausal	2.7 (1.9)	0.1 (2.4)	2.3 (1.9)	6.5[c] (3.0)
Parity greater than two	1.3 (1.7)	3.5[c] (1.7)	0.9 (1.7)	0.9 (1.7)
Health				
Good general health	−0.8 (3.1)	1.2 (3.1)	3.6[c] (1.8)	3.8[c] (1.7)
Taking antidepressive or sleeping medication	2.6 (3.7)	1.2 (3.6)	−6.0[c] (2.5)	−7.8[d] (2.7)
Mental health[a]	−2.1 (1.5)	−2.3 (1.5)	−1.5 (1.0)	−1.8 (1.1)
Body image perception[b]				
Feeling less feminine because of problem, mean (SD)	0.6 (1.0)	−0.1 (1.0)	−1.4[c] (0.7)	−1.4[c] (0.7)
Goal to improve				
Sexuality	3.8[c] (1.5)	3.8[c] (1.5)	0.5 (1.8)	0.8 (2.1)
Body image	3.4[c] (1.5)	3.2[c] (1.5)	−0.8 (1.8)	−0.8 (1.8)
Defecation	−3.6 (2.9)	−3.1 (2.8)	−4.0[c] (1.7)	−4.0[c] (1.7)

Interpretation of β (regression coefficient): Difference in mean change PISQ 12 score per unit increase of factor.
[a]Possible range 0–15, increasing values: more mental distress.
[b]Possible range: 0–3; increasing values: worse body image perception.
[c]p-value $0.05 \geq p \leq 0.001$.
[d]p-value $< 0.001 > p \geq 0.0001$.

menopausal status was associated with improvement. To our knowledge, this has not been previously shown and is particularly interesting because of the known association between age and decreasing sexual function, which was confirmed in our study. In agreement with our results, improved sexual function for about two-thirds of patients has been reported by others (3,24,25). Coital incontinence has also been shown by Bekker et al. (5,9) to be a prognostic factor for improvement of sexuality after SUI surgery, whereas worrying about coital incontinence has been shown to be detrimental for sexual function. It seems reasonable to assume a causal relationship between reduced coital incontinence postoperatively and improved postoperative sexual function, which could also explain to some extent why SUI surgery improved sexual function more than POP surgery did. However, we were not able to demonstrate statistically an association between reduced coital incontinence and improved sexual function because change in coital incontinence was part of the main outcome (change in sexual function).

Our finding that women improved more after anterior colporrhaphy, before and after adjusting for age, is in line with the result of another recent study which specifically assessed different types of POP surgery in relation to sexual function (26).

Lowenstein et al. (10) found improved body image to be related to improved sexual function for women after POP surgery, whereas we failed to confirm an association between the improved body image scores and improved sexual function. We used single questions in contrast to Lowenstein et al., who used a summary score, and his sample size was larger, possibly explaining different results. However, we did observe more improved sexual function among women who had improving their body image as a very important goal with surgery for SUI. The questions exploring goals were not validated and thus must be viewed with caution.

To our knowledge, improved sexual function after SUI surgery associated with multiparity has not been demonstrated previously. One possible explanation for this finding may be that multiparous women had a greater potential to regain their previous sexual function after correction of their problem. Alternatively, this finding may be spurious due to multiple testing, and should be confirmed by others. Our observation that women with increasing psychological distress had reduced sexual function postoperatively is in line with findings of Rhodes et al. (27), who also found deterioration of sexual function after hysterectomy in patients suffering from depression. This finding could be important for clinicians both for preoperative assessment and counseling; however, considering the small sample size of this study, the scant research identified on this topic and the prevalence of depressive symptoms, further research examining the

effect of depression on sexual function after gynecologic surgery is indicated.

The strengths of our study are the prospective design, age adjustments and application of a biopsychosocial model assessing multiple factors potentially playing a role for female sexuality. However, multiple testing should be kept in mind when assessing the statistical significance of our findings, in terms of interpreting the borderline significant results with caution.

The main limitation of our study was the low recruitment rate, resulting in a selection bias towards younger and sexually active women and a relatively small sample size. As a consequence, our results cannot be generalized to older or sexually inactive women. For example, our finding that improving sexuality with the scheduled pelvic floor surgery was an important goal for a large proportion of women may be reflecting the fact that more women with this motivation chose to participate in this study. The low recruitment rate may cause other selection biases resulting from unknown characteristics of the non-participants. Our study would have benefitted from larger numbers, particularly when stratifying into SUI and POP surgery: for example, the improvement after POP surgery is likely to have been significant as well. Due to the small numbers, the associations between type of prolapse surgery, medication, and sexual function should be viewed with caution; small numbers were also the reason why we were not able to construct a multivariate linear regression model with multiple covariates. Measures for vaginal length and genital hiatus may not be representative, because up to 30% of those particular measures were missing at one of two time points. However, we did not find significant differences in change of postoperative sexual function compared to women with available measurements. In addition, our findings with regard to anatomy are in line with findings from Weber et al. (28) in 2000, who also found surprisingly small anatomical changes after POP surgery and no association with sexual function. An important aspect to consider in this context is a lack of available measures of vaginal elasticity, which may play a role in changes in sexual function after pelvic floor surgery. Lastly, the heterogeneity of our sample may be viewed as a limiting factor, with nearly one-third of the POP patients having undergone prior POP or SUI surgery. This factor was not associated with change in sexual function either for the whole group or after stratification, but we cannot exclude interaction with other factors. At the same time, the sample is likely to be representative for an uro-gynecologic clinic in Scandinavia.

In summary, we found that sexual function improved after pelvic floor surgery in our sample of sexually active women. Improvement was predicted by good health, preoperative coital incontinence and fear of incontinence. After stratification into SUI and POP surgery, overall improvement was only significant after SUI surgery; predictive factors for improved or reduced sexual function differed for both groups and also included preoperative goals; however, anatomy did not seem to play a significant role.

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Paper III

Male sexual function and pelvic floor surgery of their female partner: A one-year follow-up study

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Male sexual function and pelvic floor surgery of their female partner: A one-year follow-up study

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Abstract

Objective: The aim of this study was to examine if sexual function of male partners changed after surgery for pelvic floor disorders and to explore associated factors.

Study design: This was an observational follow-up study at the Gynecological Department at the St Olavs University Hospital, Trondheim. The sample consisted of 35 male partners of women scheduled for pelvic organ prolapse or stress urinary incontinence surgery. Self-administered questionnaires, containing validated instruments as well as exploratory questions, were sent to women and their partners before and one year after pelvic floor surgery. Vaginal dimensions were measured in all women according to the Pelvic Organ Prolapse Quantification System, both before and after the surgery.

Main outcome measures: The Brief Sexual Function Instrument and the presence of erectile dysfunction.

Results: One year after pelvic floor surgery, scores for sexual drive, erection and overall satisfaction from the Brief Sexual Function Instrument were unchanged; the ejaculation score (range 0–4) had mildly improved from a range of 4 (median 4) to a range of 3.5 (median 4), ($p = 0.014$). The proportion of men with erectile dysfunction was unchanged, while the proportion of men reporting vaginal wind had significantly decreased ($p = 0.016$). None of the baseline factors, subjective experiences or vaginal dimensions at baseline or follow-up were associated with the improved ejaculation score; only a reduction in the proportion of men reporting their partners with dyspareunia (ns) was significantly correlated (Spearman's rho 0.42, $p = 0.019$).

Conclusion: Sexual function of male partners was unchanged or mildly improved after pelvic floor surgery.

Keywords

Coital incontinence, male sexuality, pelvic floor dysfunction, pelvic organ prolapse surgery, stress urinary incontinence surgery

Introduction

Pelvic organ prolapse (POP) and stress urinary incontinence (SUI) surgery are the two most common types of surgery for female pelvic floor dysfunction (PFD), with an overall lifetime risk of 12%.[1] The majority of women undergoing this procedure are over 40 years of age, and since populations in industrialized countries are ageing, the absolute numbers are likely to increase.[1] A recent survey from the United States showed that majority of both women and men between 57 and 87 years of age are still sexually active, although sexual dysfunction does increase.[2]

Many studies within the past decade have investigated sexual function among women after POP and SUI surgery separately or have included both types, because both conditions commonly coincide.[3,4] Level B evidence suggests that female sexual function can

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be negatively affected by POP and SUI and can be improved with surgery.[5] Currently, research is focusing on how POP or SUI may affect female sexuality: for example, coital incontinence has been identified as an important factor for female sexual function.[6] Anatomical considerations of the vagina have resulted in conflicting evidence; Schimpf et al.[7] (2010) showed that vaginal anatomy had no effect on female sexual function, while Ellerkmann et al.[8] (2001) found increasing severity of POP to be associated with female sexual dysfunction.

Considerably more elderly men than women show interest in sexual activity. This proportion has increased during the past 10 years, parallel to the introduction of PDF-5 inhibitors.[2] To our knowledge, only two studies investigated sexual function of men after POP surgery, the first study reported improved and the second unchanged sexual function.[9,10] No study was identified assessing male partners after SUI surgery, while two studies described reduced sexual function of partners of women suffering from SUI.[11,12]

The primary aim of this study was to examine if surgery for female PFD changes sexual function of their male partner. Secondary aim was to assess subjective sexual experiences of the partner, specifically related to SUI and POP surgery and to find potential intermediate factors for change in male sexual function. We hypothesized that sexual function of partners improves after surgery for PFD in women.

Methods

This paper reports results for male partners as part of an observational study on sexual function after pelvic floor surgery, conducted in Trondheim, Norway at the St Olavs University Hospital. Between April 2008 and January 2011, male partners of women scheduled for POP or SUI surgery were included. Consecutive women and their partners were sent a questionnaire with a combination of validated instruments as well as exploratory questions. Women above 80 years and not able to communicate in Norwegian were excluded. Vaginal dimensions were measured preoperatively for all women according to the Pelvic Organ Prolapse Quantification System (POP-Q).[13,14] Follow-up was one year after surgery and completed in January 2012. The follow-up consisted of a second questionnaire for both the patient and her partner and an examination of the women including POP-Q measurements.

Female participants gave informed, signed consent; men consented by choosing to return the questionnaires without personal identification and could not be contacted directly. Male sexual function was assessed by the Brief Sexual Function Instrument (BSFI), validated in Norwegian, as well as a standardized question to diagnose self-reported erectile dysfunction (ED), translated into Norwegian according to standard double translation technique.[15,16] The three functional items of the BSFI (sexual drive, erection, ejaculation) and overall satisfaction were covered by eight questions, with five graded answers per question. Mean summary scores were calculated for the items, with a possible range from 0 to 4, with increasing values corresponding to better function or more satisfaction. ED was confirmed if the question, 'Are you able to get and keep an erection good enough for sexual intercourse'? was answered 'sometimes' or ' never', according to the criteria of the U.S. National Institutes of Health and the American Urologic Association.[16] ED was classified as a sexual dysfunction when it caused marked distress, according to the Diagnostic and Statistical Manual of Mental Disorders DSM-IV-TR of the American Psychiatric Association.[17] Previously published, age-stratified scores of a random sample of 1185 Norwegian men assessed with BSFI were used to compare preoperative sexual function of partners with a population-based estimate.[15] To adjust for age, the population estimates were weighted for age proportions in our sample, as suggested by the authors of the normative dataset.[15] To assess subjective sexual experience related to pelvic floor surgery, the men were asked to indicate whether they had experienced specific symptoms/sensations and if this had caused distress. For this purpose, 11 study-specific questions based on clinical experience were constructed, each with alternatives yes/no and quantified distress (not at all, a little, quite a bit, very much), (see Table 2). For descriptive purposes, the last two alternatives were summarized into 'distress'.

For *vaginal dimensions*, genital hiatus and vaginal length measurements were used in cm and the degree of POP was graded 0–4 in the anterior-, middle- and posterior compartment, according to the standardized measurement procedure of the POP-Q.[14,18] Definitions for SUI and POP conform to the standards jointly recommended by the International Continence Society and the International Urogynecological Association, except where specifically noted.[13]

Partner's age was recorded in decades. *Type* of performed *surgery* (incontinence, type of prolapse surgery) was recorded. *Educational level* was categorized into compulsory, college - and university level. Taking *medication* to treat hypertension, hypercholesterolaemia, depression or diabetes mellitus was recorded. Using medication to improve sexuality was only recorded in the follow-up questionnaire. *General health* was assessed with the question, validated in Norwegian, 'How is your health now'? The answer possibilities, 'Poor', 'Not so good', 'Good', 'Very good' were dichotomized for the first two into 'not good' and last two

into 'good'.[19] *Mental health* was assessed by the Hopkins Symptom Check List-5, validated in a general Norwegian population.[20]

Statistical analysis was performed with SPSS version 19.0 (SPSS Inc., Chicago, IL, USA). All tests were two-sided, with a 5% statistical significance. Confidence intervals (CI) were 95%. Missing answers for BSFI questions led to the exclusion of that particular item, as recommended by the author of the original instrument.[21] In total, 6.4% of BSFI items were excluded. Continuous, normal distributed data were compared with independent Student *t*-test. For comparison of binomial data, Fisher's exact test was used. BSFI scores were not normally distributed; therefore, non-parametric tests (Mann–Whitney U, Wilcoxon signed rank, Spearman rank correlation) were used, except when baseline scores were compared to the population-based estimate. These were compared with one-sample *t*-tests, as advised by authors of the population-based estimates.[15] To analyse changes in the sample at follow-up, a paired test was used (Wilcoxon signed rank).

Table 1. Characteristics of male partners of women scheduled for pelvic floor surgery.

Characteristics	Partners before pelvic floor surgery ($N = 36$), *n* (%)
Age group, median	50–59 years
Below 50 years	13 (36)
50–69 years	20 (55)
70–79 years	3 (8)
Level of education	
Low (compulsory)	1 (3)
Middle	15 (45)
High	20 (55)
General health	
Not good	3 (8)
Good/excellent	33 (92)
Mental health, mean (SD)	1.16 (0.31)
Medication to treat	
High blood pressure	9 (25)
Anxiety/depression	0
Diabetes mellitus	1 (3)
Impotence	0[a]
Type of surgery	20 (55)
Stress urinary incontinence[b]	16 (44)
Pelvic organ prolapse	19 (55)
Both	1 (3)

[a]Number of partners using medication to enhance sexual performance at follow-up; not asked at baseline.
[b]Tension-free vaginal tape. POP surgery included anterior repair for cystocele ($n = 16$), three of those with Prolift vaginal mesh, posterior repair for rectocele ($n = 8$), colpoperineoplasty ($n = 7$), cervix amputation ($n = 6$), vaginal hysterectomy ($n = 1$), sacrospinous vaginal fixation ($n = 1$); 10 patients underwent two or three of these prolapse operations.

Results

Of 346 mailed questionnaires, 111 (32%) women responded, 78% had a male partner. In total, 51 partners (15% of all mailed questionnaires, 58% of partners) returned completed questionnaires at baseline. For non-responding women, no significant difference was found for type of surgery ($p = 0.80$), but they were significantly older with a mean age of 59 years, versus 54 years of responders ($p = 0.002$; CI 1.7–7.2). After one year (mean 13, range 10–22 months), 46 men returned follow-up questionnaires, follow-up rate of those with baseline was 76%. Ten partners were excluded from follow-up: for six, no baseline was available, one partner was female and three of the women had not undergone surgery. This left 36 male partners for analysis of change after surgery, with 0–8% of the answers missing. All men were living at home. For baseline characteristics, see Table 1.

Preoperative BSFI scores of partners were not statistically different compared to population-based estimates, adjusted for age ($0.12 \leq p \leq 0.51$). There was no difference for the BSFI scores for partners of women scheduled for SUI compared to POP surgery ($0.29 \leq p \leq 0.89$). At baseline, the proportion of men with ED was 15% ($n = 7$), the proportion with ED causing distress was 4% ($n = 2$). All partners with ED were 50 years or older.

One year after pelvic floor surgery, no significant change in the presence of ED ($p = 1.00$) and three of the four BSFI scores ($0.25 \leq p \leq 0.64$) was observed (Figure 1). For the ejaculation score, a small and significant improvement from a range of 4 (median 4, mean 3.54, SD 0.9) to a range of 3.5 (median 4, mean 3.71, SD 0.7) was reported ($p = 0.014$ for non-parametric test; 95% CI for paired *t*-test 0.02–0.31, $p = 0.025$) (Figure 1).

See Table 2 for subjective sexual experiences before and after pelvic floor surgery, reporting separately for partners of women with SUI and POP surgery. The number of partners reporting distress by at least one of the questions in Table 2 did not decrease after surgery: 17% ($n = 8$) before surgery, compared to 24% ($n = 10$) after surgery (data not shown). None of the men reporting coital incontinence indicated that this caused distress.

We found no significant rank correlation between the improved ejaculation score, age ($p = 0.47$) and level of education ($p = 0.23$) of the men; their general ($p = 0.38$) or mental health ($p = 0.63$) or use of

medication at baseline ($0.36 \leq p \leq 0.89$) or at follow-up ($p = 0.46$, 0.97, $0.61 \leq p \leq 0.98$). Type of surgery ($p = 0.85$), use of vaginal estrogen ($p = 0.75$) or vaginal dimensions at baseline ($0.14 \leq p \leq 0.92$) or at follow-up ($0.21 \leq p \leq 1.00$) were not correlated to the improved ejaculation score. Of the subjective experiences, only the postoperative decrease in proportion of men answering 'Yes' to the question 'Does your partner experience pain during intercourse' was significantly associated with the improved ejaculation score (Spearman's rho -0.42; $p = 0.019$).

Discussion

This follow-up study showed no change for sexual drive, erection or overall satisfaction for male partners of women after pelvic floor surgery, while the ejaculation score had minimally but statistically significantly improved in about one-fifth of partners. This improvement was not predicted by any baseline factors or associated with vaginal dimensions. At follow-up, none of the men experienced their partner with coital incontinence, compared to 14% preoperative and the proportion of men reporting vaginal wind was significantly reduced. However, only the reduced proportion of men reporting their partner with dyspareunia was significantly associated with the improved ejaculation score. Our finding of unchanged or modestly improved sexual function falls in between the results of Kuhn et al. and Vollebregt et al. The former also applied the BSFI and described significantly imroved sexual interest, drive and overall satisfaction.[9] The latter applied another sexual function instrument and reported no change after POP surgery.[10] Diverging results between the three studies could be explained by the application of different sexual function instruments for two studies. Kuhn et al. applied the same instrument as in our study, but the average age for men was 10–20 years older and follow-up was half compared to our study. These differences could explain different patterns of improved sexual function. In addition, our study included partners also after SUI

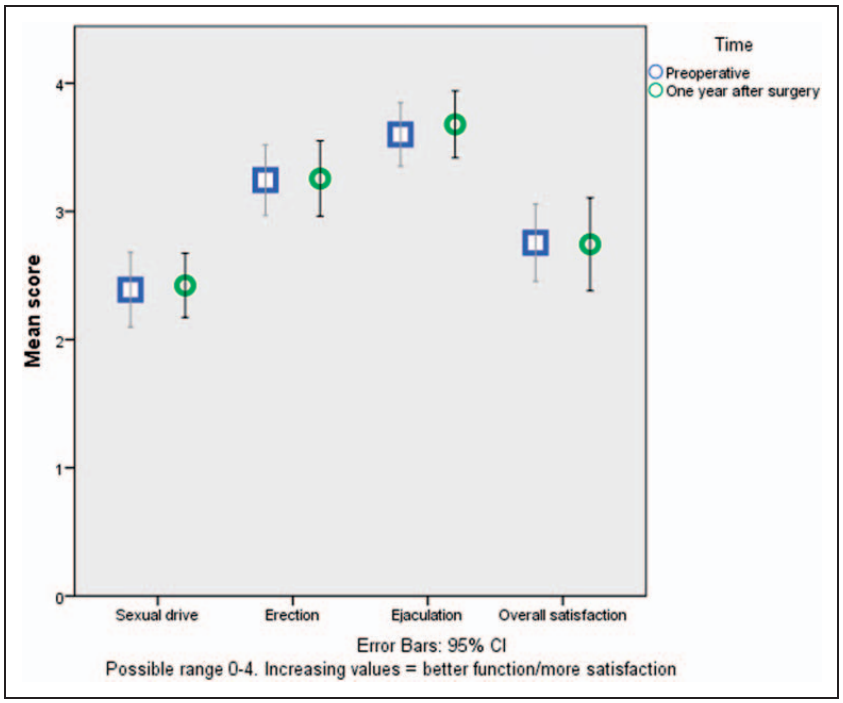

Figure 1. Sexual function of partners ($n = 36$) before and one year after pelvic floor surgery of the woman, measured with Brief Sexual Function Index.

surgery and although we did not find significant differences in BSFI items after SUI compared to POP surgery, this heterogeneity may have resulted in a dilution of effects.

Our finding of 20% of partners of women scheduled for SUI surgery reporting coital incontinence is very similar to the 23% reported by Nilsson et al.[12] in their cross-sectional study of partners of women with urinary incontinence.

To our knowledge, this is the first study investigating sexual function of partners after SUI surgery or exploring male sexual experiences specifically related to potential problems before or after pelvic floor surgery. Strengths of our study are its prospective design and the use of validated subjective and objective instruments.[14,15] Apart from possibly stimulating further research into this underinvestigated subject, the results of this study can aid clinicians during counselling of women considering pelvic floor surgery. If appropriate, women could be reassured that sexual function of their partners is likely to remain unchanged or may improve mildly after pelvic floor surgery. In addition, women may benefit from the information that male sexual function seems rather unaffected by coital incontinence, vaginal wind or change in vaginal dimensions after surgery. Our finding that partners before both SUI surgery (one in 10) and POP surgery (one in 20) reported coital incontinence while none was reported postoperatively is interesting and has to our knowledge not been demonstrated before.

The main limitation of this study is the low recruitment rate for women, resulting in relatively small numbers as well as possible selection bias for male partners. Low recruitment rates are common for this type of study; Bekker et al.[11] had a 24% recruitment rate for women and 14% for men. The recruited women in our study were on average five years younger than non-responders, which may have resulted in a selection bias in favour of younger men. To reduce this confounding factor, we only used age-adjusted population-based estimates to compare with sexual function of partners in our sample at baseline. The rather low proportion of ED in our sample (15%) compared to other population-based studies (increasing from 12% to 54% from age 45 to 70) may suggest that proportionally more men with sexual dysfunction chose not to participate, resulting in a selection bias towards men with better sexual function.[23] On the other hand, mean age-adjusted sexual function scores of partners did not differ significantly from population-based estimates.[15] In summary, our results may not be representative for older men or men with sexual dysfunction.

The resulting sample size of 36 men had according to our post hoc sample size calculation a power of 80% to detect a 0.5 unit change in the BSFI items, applying a

Table 2. Change of subjective experiences of partners of women before and one year after undergoing pelvic floor surgery, presented separately for SUI and POP surgery.

	Baseline, $N=35$[a]				Follow-up, $N=35$[a]				Change, $N=35$[a]
	SUI		POP		SUI		POP		
Partner experience during intercourse	$n=16$	%[b]	$n=19$	%[b]	$n=16$	%[b]	$n=19$	%[b]	p
Coital urine incontinence reported by male partner	3	20	2	10	0		0		0.063
Anal incontinence	0		0		0		0		1.00
Bulge, something coming down	2	12	5	26	1	6	4	22	0.62
Vaginal wind	4	27	8	47	2	12	3	17	0.016
Dry vagina	1	7	4	24	2	13	4	24	1.00
Too wide vagina	5	33	3	24	0		7	39	0.55
Too tight vagina	0		1	6	0		0		0.50
Dyspareunia in woman reported by the partner	0	1	8	44	0		3[c]	18	0.25
'Hispareunia'[d]	0		1	6	0		0		0.50
Avoiding intercourse because of at least one of these problems	0		6	32	0		2	11	0.25
Worried about interfering with surgical result	–		–		0		2	11	–

SUI: stress urinary incontinence; POP: pelvic organ prolapse.
[a]One partner of the total sample excluded, the woman underwent combined SUI and POP surgery.
[b]Percentage of responses.
[c]No de novo dyspareunia.
[d]Men experiencing painful intercourse.[22]

double-sided test at a 0.05 significance level. Mean change detected for the ejaculation item was 0.17 units, which is considerably less than 0.5 units and may indeed be questioned for its clinical significance. We are therefore confident that our sample size was sufficient to detect a clinically relevant change in the BSFI items. We failed to detect confounding or effect modification for the improved ejaculation score, by applying rank correlation for all relevant factors both at baseline and follow-up, yet with a larger sample size weaker associations may have become significant. Type two error is, however, almost certainly the reason that the reduction in proportion of men reporting post-operative coital incontinence was only borderline significant ($p = 0.063$) (Table 2).

Further limitations are that our exploratory questions were not validated, that we failed to ask about sexual performance-improving medication at baseline. However, no use was reported at follow-up, and it seems unreasonable to assume that potential cessation of sexual performance-enhancing medication could account for improved ejaculation; moreover, erectile function was unchanged after the one-year follow-up. Another limitation of our study might be that the measures applied for vaginal dimensions (POP-Q score) were not assessing elasticity or vaginal girt. These could be important aspects of vaginal dimensions associated with the improved ejaculation score.

In summary, sexual function of male partners after pelvic floor surgery remained unchanged or improved modestly. The only identified factor associated to the improvement was a reduced proportion of men post-operatively reporting their partner to have pain during intercourse.

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Ethics

Medical Research Ethics Committee for Middle Norway approved of the study.

Conflict of interest

All of the authors explicitly declare that there are no conflicts of interest in connection with this study.

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How To Cite

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Appendix I

Forespørsel til **KVINNER** om å delta i en vitenskaplig studie ved St Olavs hospital

BEkkenlidelser og SEksualitet - en livskvalitetstudie

Trondheim, .. /.. / ....

Dette er et forespørsel om å delta i en spørreundersøkelsen for å øke kunnskapen om underlivslidelser. Du har blitt henvist til gynekologisk avdeling ved St Olavs Hospital for behandling av plager enten knyttet til fremfall av skjedeveggen (vaginalprolaps) eller plager knyttet til urinlekkasje (inkontinens). Vi vet mye om hva som hjelper rent medisinske sett, men mindre om livskvalitet og seksualitet spesielt i sammenheng med kirurgi for disse plager.

Det er frivillig å delta. Hvis du blir med, kan du trekke deg ut når som helst, så lenge navnelister oppbevares.
Hva innebærer en deltagelse for deg:

- **Vi ber om at du fyller ut vedlagte spørreskjema.** Det tar omtrent 30 minutter. Skjemaet sendes tilbake i separat**, vedlagte konvolutt i løpet av 2 uker med samtykke erklæring.**
- Dersom du har en **partner** og ønsker at også han deltar, ber vi deg **å gi "forespørsel til partner" og "spørreskjema til partner" til ham.**
- Vi ber deg og eventuelt partneren din **å fylle ut et nytt skjema etter ett år,** for å undersøke effekten av behandlingen. Du får tilbud om en kontrollundersøkelse etter ett år. Dette er kun for deltager, da vi vanligvis ikke har kontroller etter operasjoner.

Skjemaet er merket med et studienummer som er unikt for deg. Svarene du gir blir ikke lest, men bare kodet inn i en datafil. Dette gjør at ingen vet at det er du som har svart, heller ikke de legene du møter. Behandlende leger vet ikke om du deltar i studien eller ikke, med mindre du forteller det selv. Løpenummeret på skjema gjør at prosjektleder kan finne fram til navnet ditt når du skal blir tilsendt nytt skjema. Det skal legges til noen medisinske opplysninger fra din pasientjournal som innbefatter tidligere sykdommer, antall barn og opplysninger rundt ditt aktuelle problem. Navnelisten oppbevares forskriftsmessig og slettes når datainnsamling avsluttes, vinter 2011/12. Alt datamaterialet vil bli anonymt etter dette.

All informasjon blir behandlet konfidensielt. Alle som ha kontakt med data er underlagt taushetsplikt i henhold til forvaltningslovens § 13 og helsepersonellovens § 21.
Studien er tilrådet av Den Regionale Komité for Medisinsk og Helsefaglig Forskningsetikk, Midt-Norge, og er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste AS.

Har du spørsmål, kan du gjerne kontakte meg eller min medarbeider. Skulle du eller din partner i sammenhang med undersøkelsen oppdage at dere ønsker hjelp med seksuallivet, kan vi formidle kontakt med en utdannet sexolog.

Med vennlig hilsen

Risa Lonnée-Hoffmann
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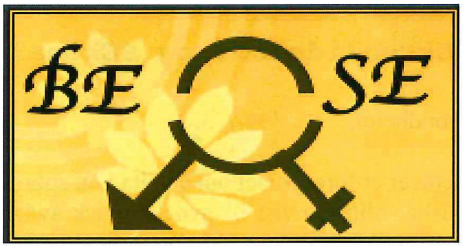
Merete Myklebost,
Seksjonsoverlege generell gynekologi

Berit Schei
Professor dr. med
Institutt for samfunnsmedin, NTNU

Til Kvinne



Samtykke erklæring til deltagelse i prosjektet:

BEkkenlidelser og Seksualitet - en livskvalitetstudie

☐ Jeg har lest informasjonsskrivet og har hatt anledning til å stille spørsmål.
Jeg samtykker i å delta i prosjektet.

....

Sted Dato Underskrift

Løpenummer: ……..

Forespørsel til **PARTNER** om å delta i en vitenskapelig studie ved St Olavs Hospital

BEkkenlidelser og SEksualitet- en livskvalitetsstudie

Trondheim, .. / .. / ....

Dette er et forespørsel om å delta i et spørreundersøkelsen for å øke kunnskapen om underlivslidelser hos kvinner.
Du får dette brevet fordi din partner har blitt henvist til gynekologisk avdeling ved St Olav Hospital til behandling av plager enten knyttet til fremfall av skjede veggen (vaginalprolaps) eller plager knyttet til urinlekkasje (inkontinens).
Vi vet mye om hva som hjelper rent medisinske sett, men mindre om livskvalitet og seksualitet spesielt i sammenheng med kirurgi for disse plager. Vi trenger derfor økt kunnskap om dette.

Det er frivillig å delta. Hvis du blir med, kan du trekke deg ut når som helst, så lenge navnelister til deltagende kvinner oppbevares.
Hva innebærer en deltagelse for deg:

- Du gir samtykke ved å fylle ut vedlagte "spørreskjema for partnere" som tar omtrent 20 minutter. Vi ber deg om å sende den tilbake i det vedlagte separate konvolutt i løpet av 2 uker.
- Du vil få et lignende spørreskjema etter omtrent ett år. Samtidig får din partner også ett nytt skjema.

Ditt skjema er merket med et studienummer som er unikt for deg. Studienummeret på skjema gjør at prosjektleder, etter elektronisk behandling av skjemaene kan sammenholde dine svar med din partners. Men ditt navn skrives ikke på noen liste. Navnelisten til deltagende kvinner slettes når datainnsamling avsluttes, vinter 2011/12. All informasjon blir behandlet konfidensielt. Alle som ha kontakt med data er underlagt taushetsplikt i henhold til forvaltningslovens § 13 og helsepersonellovens § 21. Studien er tilrådet av Regionale Komité for Medisinsk og Helsefaglig Forskningsetikk, Midt-Norge og er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste AS.

Har du spørsmål, kan du gjerne kontakte meg eller min medarbeider.
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Berit Schei
Professor dr. med
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Appendix II

Spørreskjema 1 **Kvinner**
Seksualitet og Bekkenbunnsproblemer

1.1 **Hvor bor du?**

☐ Hjemme ☐ Sykehjem ☐ Trygdebolig

1.2. **Hvilken utdanning er den høyeste du har fullført?**

☐ Grunnskole, ungdomsskole 7-10 år ☐ Videregående skole ☐ Høgskole/universitet

1.3. **Hva slags arbeidssituasjon har du nå?**

☐ Lønnet arbeid ☐ Selvstendig næringsdrivende ☐ Heltid husarbeid

☐ Utdanning ☐ Arbeidsledig, permittert ☐ Pensjonist, trygdet

1.4. **Har du en partner?** ☐ Ja ☐ Nei

2. **Skriv anslagsvis høyde og vekten i centimeter og kilo**

Høyde ☐☐☐ cm **Vekt** ☐☐☐ kg

3. **Tar du noen av følgende medisiner regelmessig?**

☐ Medisin for høy blodtrykk ☐ Medisin mot depresjon

☐ Medisin mot sukkersyke ☐ Sovemedisin

☐ Blod fett- eller kolesterol senkende ☐ Ingen

☐ Hormonbehandling (preparater med østrogen)

4. **Kryss av en eller flere som passer best med det du ønske å forbedre med behandlingen av dine bekkenbunnsproblemer :**

	Ikke viktig	Litt viktig	Ganske viktig	Svært viktig
4.1. Forbedre vannlatings funksjon	☐	☐	☐	☐
4.2. Forbedre situasjon med avføring	☐	☐	☐	☐
4.3. Forbedre tyngdefølelse	☐	☐	☐	☐
4.4. Forbedre fysiske aktiviteter	☐	☐	☐	☐
4.5. Forbedre sosiale aktiviteter	☐	☐	☐	☐
4.6. Forbedre seksuelle aktiviteter	☐	☐	☐	☐
4.7. Forbedre selv bilde	☐	☐	☐	☐

5. Fikk du noen av disse behandlingene for ditt bekkenbunnsproblem?

☐ Vaginal ring ☐ Fysioterapi ☐ Elektrostimulring

☐ Vaginal hormon behandling ☐ Nei, ingen

6. Under finner du en liste over noen plager og problemer som man av og til har. Har du opplevd noe av dette i løpet av de siste 14 dagene?

	Ikke plaget	Litt plaget	Ganske mye plaget	Veldig mye plaget
6.1. Stadig redd eller engstelig	☐	☐	☐	☐
6.2. Nervøsitet, indre uro	☐	☐	☐	☐
6.3. Følelse av håpløshet med tanke på framtida	☐	☐	☐	☐
6.4. Nedtrykt, tungsindig	☐	☐	☐	☐
6.5 Mye bekymret eller urolig	☐	☐	☐	☐

7. Nå blir du spurt om hvordan din utseende kjennes og om forandringer som har kommet i sammenheng med dine bekkenbunnsproblemer. Les hver setning nøye og kryss av for det svar som passer best til den måten du følte deg i siste uke.

	Ikke i det hele tatt	Litt	Ganske mye	Svært mye
7.1. Har du følt deg kroppsbevisst?	☐	☐	☐	☐
7.2. Har du følt deg mindre fysisk attraktivt pga dine bekkenbunnsproblemer?	☐	☐	☐	☐
7.3. Har du vært misfornøyd med utseende ditt i påkledt tilstand?	☐	☐	☐	☐
7.4. Har du følt deg mindre kvinnelig pga av dine bekkenbunnsproblemer?	☐	☐	☐	☐
7.5. Har du problemer med å se deg selv naken?	☐	☐	☐	☐
7.6. Unngår du folk fordi du er misfornøyd med utseende ditt?	☐	☐	☐	☐
7.7. Har du vært misfornøyd med kroppen din?	☐	☐	☐	☐

8. Nå kommer det en liste med spørsmål om deg og din partners seksualliv. Kryss av det feltet som best besvarer spørsmålet for deg. Når du svarer, tenk på seksuallivet ditt gjennom de siste 6 måneder.

8.1. **Hvor ofte har du og partneren din samleie eller seksuell aktivitet?**

☐ Hver dag ☐ 1-3 ganger per uk ☐ 1-3 ganger pr måned

☐ Mindre enn en gang pr måned ☐ Aldri

8.2. **Hvor ofte skulle du gjerne ha samleie eller seksuell aktivitet?**

☐ Hver dag ☐ 1-3 ganger per uk ☐ 1-3 ganger pr måned

☐ Mindre enn en gang pr måned ☐ Aldri

8.3. **Har partneren din problem med ereksjonen som påvirker din seksuelle aktivitet?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.4. **Har partneren din problem med fortidlig utløsning som påvirker din seksuelle aktivitet?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.5. **Får du orgasme når du onanerer?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.6. **Får du orgasme ved samleie med din partner?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.7. **Har du orgasme når partneren onanerer deg?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.8. **Kjenner du noen av det følgende når du har sex med din partner: pusten og pulsen din blir raskere; skjeden blir fuktig; du har gode følelser i dine bryster og underlivet?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.9. **Kjenner du deg seksuelt opphisset når du har sex med din partner?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.10. **Hvor ofte kjenner du seksuell lyst? Denne følelsen kan omfatte ønske om å ha sex, planer om å ha sex, å være frustrert pga for lite sex og så videre.**

☐ Daglig ☐ Ukentlig ☐ Månedlig ☐ Mindre enn en gang pr måned ☐ Aldri

8.11. **Kjenner du smerter under samleie?**

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.12. **Kjenner du at skjeden din er så "tørr" at du ikke kan ha samleie?**

☐ Svært tørr ☐ Ganske tørr ☐ Nokså tørr ☐ Litt tørr ☐ Ikke tørr i det hele tatt

8.13. Er skjedeåpningen din så trang at du ikke kan ha samleie?

☐ Svært trang ☐ Ganske trang ☐ Nokså trang ☐ Litt trang ☐ Ikke trang i det hele tatt

8.14. Klager partneren din på at skjeden din er for trang?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.15. Unngår du seksuell aktivitet fordi skjeden kjennes for lang eller for kort?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.16. Unngår du samleie fordi noe kommer frem i skjedeåpningen (enten blære, endetarm eller skjede)?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.17. Har du anal eller oral sex fordi penis i skjeden er ubehaglig på grunn av ett eller annet?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.18. Har du urin lekkasje ved seksuell aktivitet?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.19. Har du lekkasje av avføring ved seksuell aktivitet?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.20. Begrenser angsten for lekkasje av urin eller avføring din seksuell aktivitet ?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.21. Begrenser forlegenhet grunnet lekkasjen din seksuell aktivitet?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.22. Generelt sett, hvor tilfreds er du med seksuallivet med din partner?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.23. Generelt sett, hvor tilfreds mener du partneren din er med deres seksuallivet?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.24. Hvor tilfreds er du med variasjonen i deres seksualliv?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.25. Når du har sex med din partner, har du negative følelsesmessige reaksjoner sånn som angst, avsky, skam eller skyld?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.26. Hvor ofte kjenner du tilfredshet etter seksuell aktivitet?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.27. Hvor ofte klarer du å oppleve orgasme?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.28. Sammenlignet med de orgasmer du vanligvis har hatt, hvor intens er orgasmene i de siste 6 måneder?

☐ Mye mindre intens ☐ Mindre intens ☐ Samme intensistet ☐ Mer intens ☐ Mye mer intens

8.29. Fullfør denne setningen: I mitt forhold, er det jeg som tar initiativ til samleie...

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.30. Unngår du samleie på grunn av forlegenhet?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.31. Tror du at partneren din unngår samleie med deg på grunn av lekkasjen din eller noe som kommer ut (-enten blære, endetarm eller skjede)?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

8.32. Plages du ved seksuell aktivitet med luft i skjeden?

☐ Alltid ☐ Vanligvis ☐ Noen ganger ☐ Sjelden ☐ Aldri

9. Under finner du en liste over noen plager og problemer som man av og til har. Har du opplevd noe av dette i løpet av de siste 14 dagene?

	Ikke plaget	Litt plaget	Ganske mye plaget	Veldig mye plaget
9.1. Stadig redd eller engstelig	☐	☐	☐	☐
9.2. Nervøsitet, indre uro	☐	☐	☐	☐
9.3. Følelse av håpløshet med tanke på framtida	☐	☐	☐	☐
9.4. Nedtrykt, tungsindig	☐	☐	☐	☐
9.5 Mye bekymret eller urolig	☐	☐	☐	☐

10. Hvordan er helsen din nå?

☐ Dårlig ☐ Ikke helt god ☐ God ☐ Svært god

TAKK FOR DIN TID!

Skriv gjerne noen kommentarer

Spørreskjema 1 **Partner**
Seksualitet og Bekkenbunnsproblemer

1.1. **Hvor bor du?**

☐ Hjemme ☐ Sykehjem ☐ Trygdebolig

1.2. **Hvilken utdanning er den høyeste du har fullført?**

☐ Grunnskole, ungdomsskole 7-10 år ☐ Videregående skole ☐ Høgskole/universitet

1.3. **Hva slags arbeidssituasjon har du nå?**

☐ Lønnet arbeid ☐ Selvstendig næringsdrivende ☐ Heltid husarbeid
☐ Utdanning ☐ Arbeidsledig, permittert ☐ Pensjonist, trygdet

2. **Kryss av for aldersgruppen du hører til:**

☐ under 40 år ☐ 40-49 år ☐ 50-59 år ☐ 60-69 år ☐ 70-79 år ☐ over 80 år

3. **Tar du noen av følgende medisiner regelmessig?**

☐ Medisin for høy blodtrykk ☐ Medisin mot depresjon
☐ Medisin mot sukkersyke ☐ Sovemedisin
☐ Blod fett- eller kolesterol senkende ☐ Ingen
☐ Hormonbehandling (preparater med østrogen)

4. **Hvordan er helsen din nå?**

☐ Dårlig ☐ Ikke helt god ☐ God ☐ Svært god

5. *Under finner du en liste over noen plager og problemer som man av og til har. Har du opplevd noe av dette i løpet av de siste 14 dagene?*

	Ikke plaget	Litt plaget	Ganske mye plaget	Veldig mye plaget
5.1. Stadig redd eller engstelig	☐	☐	☐	☐
5.2. Nervøsitet, indre uro	☐	☐	☐	☐
5.3. Følelse av håpløshet med tanke på framtida	☐	☐	☐	☐
5.4. Nedtrykt, tungsindig	☐	☐	☐	☐
5.5. Mye bekymret eller urolig	☐	☐	☐	☐

6. Du blir nå spurt om noe du kan oppleve under seksuell aktivitet med partneren din. Hvis svar er vanligvis "ja" kryss også av om hvor mye du plages med det. Hvis svaret er "nei" trenger du ikke å krysse av "Hvor mye plager det deg..."

6.1. **Har din partner urin lekkasje under seksuell aktivitet?** ☐ Nei ☐ Ja

6.1.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.2 **Har din partner lekkasje av avføring under seksuell aktivitet?** ☐ Nei ☐ Ja

6.2.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.3. **Kjenner du under samleie noe som kommer ned i eller utenfor skjeden?** ☐ Nei ☐ Ja

6.3.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.4. **Kommer det luft fra skjeden under samleie?** ☐ Nei ☐ Ja

6.4.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.5. **Kjennes skjeden for tørr under samleie?** ☐ Nei ☐ Ja

6.5.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.6. **Kjennes skjeden for vid under samleie?** ☐ Nei ☐ Ja

6.6.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.7. **Kjennes skjede for trang eller under samleie?** ☐ Nei ☐ Ja

6.7.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.8. **Har partneren din vanligvis smerter under samleie?** ☐ Nei ☐ Ja

6.8.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.9. **Har du vanligvis smerter under samleie?** ☐ Nei ☐ Ja

6.9.1. Hvor mye sjeneres du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

6.10. **Unngår du seksuell aktivitet med partneren din på grunn av noen av de nevnte årsaker?** ☐ Nei ☐ Ja

6 10.1. Hvor mye plages du av det? ☐ Ikke i det hele tatt ☐ Litt ☐ Ganske mye ☐ Svært mye

7. La oss definere seksualdrift som en følelse som kan omfatte ønsker om seksuell aktivitet (onani eller samleie), tanken på å ha sex eller frustrasjon som følge av mangel på sex. Kryss av for det svaret som passer.

Seksualdrift

7.1. **Hvor mange dager har du følt seksualdrift de siste 30 dagene?**

☐ Ingen dager ☐ Bare noen få dager ☐ Noen dager ☐ De fleste dagene ☐ Nesten hver dag

7.2. **Hvordan vurderer du nivået på seksualdriften din de siste 30 dagene?**

☐ Ingen drift ☐ Lav drift ☐ Middels drift ☐ Ganske sterk drift ☐ Sterk drift

Reisning

7.3. **Hvis du blitt seksuelt stimulert på noen måte de siste 30 dagene; hvor ofte har du fått delvis eller full reisning?**

☐ Aldri ☐ Noen få ganger ☐ Ganske ofte ☐ Vanligvis ☐ Alltid

7.4. **Hvis du har hatt reisning de siste 30 dager: hvor ofte var penis stiv nok til at du kunne ha samleie?**

☐ Aldri ☐ Noen få ganger ☐ Ganske ofte ☐ Vanligvis ☐ Alltid

7.5. **Hvor store problemer har du hatt med reisning de siste 30 dagene?**

☐ Har ikke fått reisning ☐ Store vansker ☐ Noen vansker ☐ Få vansker ☐ Ingen vansker

7.6. Sviktende reisning defineres som " manglende evne til å få og/eller beholde en reisning av tilstrekkelig stivhet til å gjennomføre et samleie". Hvilken av de følgende kategoriene beskriver din situasjon?

☐ **Fullstendig reisningssvikt:** Aldri stand til å få og beholde reisningen godt nok til å gjennomføre et samleie.

☐ **Moderat reisningssvikt:** Av og til i stand til å få og beholde reisningen godt nok til å gjennomføre samleie.

☐ **Minimal reisningssvikt:** Vanligvis i stand til å få og beholde reisningen godt nok til å gjennomføre et samleie.

☐ **Ingen reisningssvikt:** Alltid i stand til å få og beholde reisningen godt nok til å gjennomføre et samleie.

Sæduttømming

7.7. Hvor store vansker har du hatt med å få sæduttømming når du er blitt seksuelt stimulert de siste 30 dagene?

☐ Har ikke hatt seksuell stimulering de siste 30 dagene ☐ Store vansker

☐ Noen vansker ☐ Få vansker ☐ Ingen vansker

7.8. I hvilken grad har du over de siste 30 dagene sett på mengden sæd ved uttømming som et problem for deg?

☐ Stort problem ☐ Middels problem ☐ Lite problem ☐ Ganske lite problem ☐ Ikke noe problem

Problemvurdering

7.9. I hvilken grad har du over de siste 30 dagene sett på manglende seksualdrift som et problem?

☐ Stort problem ☐ Middels problem ☐ Lite problem ☐ Ganske lite problem ☐ Ikke noe problem

7.10. I hvilken grad har du over de siste 30 dagene vurdert din evne til å få og beholde reisningen som et problem?

☐ Stort problem ☐ Middels problem ☐ Lite problem ☐ Ganske lite problem ☐ Ikke noe problem

7.11. Hvor tilfreds har du samlet sett vært med ditt seksualliv de siste 30 dagene?

☐ Veldig utilfreds ☐ For det meste utilfreds ☐ Omtrent like tilfreds som utilfreds

☐ For det meste tilfreds ☐ Svært tilfreds

TAKK FOR DIN TID!

Skriv gjerne noen kommentarer: