Vaginal prolapse surgery

An epidemiological perspective

Studies of native tissue repair versus implants, surgeons’ practical experiences and five year follow-up in the Swedish National Quality Register for Gynecological Surgery

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“The best thing for being sad is to learn something. That’s the only thing that never fails. You may grow old and trembling in your anatomies, you may lie awake at night listening to the disorder of your veins, you may miss your only love, you may see the world about you devastated by evil lunatics, or know your honour trampled in the sewers of baser minds. There is only one thing for it then — to learn. Learn why the world wags and what wags it. That is the only thing which the mind can never exhaust, never alienate, never be tortured by, never fear or distrust, and never dream of regretting.”

Merlin

T.H. White, The Once and Future King
# TABLE OF CONTENTS

Abstract .......................................................................................................... iii  
Svensk sammanfattning ................................................................................ vi  
Dansk resumé ............................................................................................... ix  
Deutsche Zusammenfassung ......................................................................... xii  
Original papers ............................................................................................. xv

## Introduction and background ................................................................. 1
  Synthesis ........................................................................................................ 1
  Historical overview ...................................................................................... 1
  Definitions and prevalence .......................................................................... 3
  Pathophysiology and risk factors .................................................................. 3
    Anatomy ..................................................................................................... 3
    Age ............................................................................................................ 5
    Childbirth/parity ....................................................................................... 5
    Obesity ..................................................................................................... 5
    Other risk factors ..................................................................................... 5
  Symptoms of pelvic organ prolapse ............................................................... 6
    Local symptoms ......................................................................................... 6
    Urinary symptoms ...................................................................................... 6
    Sexual symptoms ..................................................................................... 6
    Other symptoms ....................................................................................... 6
  Pelvic organ prolapse, and taboo ................................................................. 7

## Diagnostic considerations .......................................................................... 7
  The Pelvic Organ Prolapse Quantification system ......................................... 7
  Size of the prolapse protrusion in relation to the hymen (centimeter hymen) .... 8
  Patient-reported symptoms ......................................................................... 8

## Treatment of pelvic organ prolapse ........................................................... 9
  Non-surgical treatment ................................................................................. 9
    Adjunct therapy ........................................................................................ 9
    Pelvic floor muscle training .................................................................... 9
    Menopausal hormone therapy .................................................................... 9
    Pessaries .................................................................................................. 10
  Surgical treatment ...................................................................................... 10
    Native tissue repair (colporrhaphy) .......................................................... 10
    Mesh-augmented repair ......................................................................... 11
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prognosis and results of surgical treatments</td>
<td>12</td>
</tr>
<tr>
<td>Long-term follow-up</td>
<td>12</td>
</tr>
<tr>
<td>Comparison of treatments, and introduction of surgical mesh</td>
<td>12</td>
</tr>
<tr>
<td>Impact of surgeon experience on operative results</td>
<td>16</td>
</tr>
<tr>
<td>Epidemiology of national register studies</td>
<td>16</td>
</tr>
<tr>
<td>The Swedish health care system – and the link to national patient registers</td>
<td>17</td>
</tr>
<tr>
<td>Population-based health care registers and quality registers in Sweden</td>
<td>18</td>
</tr>
<tr>
<td>Terminology used in national quality registers</td>
<td>19</td>
</tr>
<tr>
<td>The Swedish National Quality Register for Gynaecological Surgery</td>
<td>20</td>
</tr>
<tr>
<td>Scientific rationale</td>
<td>22</td>
</tr>
<tr>
<td>Aims</td>
<td>23</td>
</tr>
<tr>
<td>Methods</td>
<td>24</td>
</tr>
<tr>
<td>Papers I &amp; II</td>
<td>24</td>
</tr>
<tr>
<td>Paper III</td>
<td>27</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>29</td>
</tr>
<tr>
<td>Paper IV</td>
<td>29</td>
</tr>
<tr>
<td>Register data – risk of retreatment within 5 years</td>
<td>29</td>
</tr>
<tr>
<td>Validation and design of the 5-year questionnaire</td>
<td>30</td>
</tr>
<tr>
<td>Ethical considerations</td>
<td>35</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>35</td>
</tr>
<tr>
<td>Papers I &amp; II</td>
<td>35</td>
</tr>
<tr>
<td>Paper III</td>
<td>35</td>
</tr>
<tr>
<td>Paper IV</td>
<td>36</td>
</tr>
<tr>
<td>Results</td>
<td>37</td>
</tr>
<tr>
<td>Paper I 37</td>
<td></td>
</tr>
<tr>
<td>Paper II 39</td>
<td></td>
</tr>
<tr>
<td>Paper III</td>
<td>43</td>
</tr>
<tr>
<td>Single-surgeon cohort</td>
<td>43</td>
</tr>
<tr>
<td>Surgeon &amp; assistant cohort</td>
<td>45</td>
</tr>
<tr>
<td>Paper IV</td>
<td>46</td>
</tr>
<tr>
<td>Five-year follow-up by questionnaire: validation</td>
<td>52</td>
</tr>
<tr>
<td>General discussion</td>
<td>55</td>
</tr>
<tr>
<td>Papers I &amp; II</td>
<td>59</td>
</tr>
<tr>
<td>Paper III</td>
<td>60</td>
</tr>
<tr>
<td>Paper IV</td>
<td>61</td>
</tr>
<tr>
<td>Conclusion</td>
<td>63</td>
</tr>
<tr>
<td>Further research</td>
<td>63</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>64</td>
</tr>
<tr>
<td>References</td>
<td>65</td>
</tr>
</tbody>
</table>

Appendix

Paper I-IV
ABSTRACT

Background

Pelvic organ prolapse (POP) is a common condition that impacts on quality of life for many women. The mean age of Swedish women operated for POP is 60 years, and with a life expectancy of approximately 84 years this means that the average patient will live 24 years subsequent to the operation. Therefore, sustainable long-term results of POP surgery are essential.

In an effort to improve long-term outcomes of vaginal prolapse surgery, mesh materials have been developed for this purpose. In Sweden, synthetic mesh is used in 7.4% of all primary operations without any coherent consensus about their use. Prolapse surgery is regarded as a routine procedure performed at almost every hospital in Sweden, but a large proportion of the surgeons are inexperienced. In actuality, 73% of them perform the procedure once a month or less frequently. Simultaneously, surgery for POP has been reported to have a high failure rate internationally. For most surgeons, the operation is a low-frequency procedure, and outcomes have been reported as unsatisfactory.

The specific aims of these thesis were to examine:

- Mesh-augmented repairs impact on operative results compared to native tissue repair.
- Surgical experience in performing a specific operation and utilize this knowledge in analysing how it may (or may not) affect operative results.
- Long-term (5 year) national follow up of POP operations, regarding both the objective epidemiological data and the patient-reported outcomes.

Methods

The studies in this thesis are based on data from the Swedish National Quality Register for Gynaecological Surgery (GynOp), which covers approximately 90% of all gynaecological operations in Sweden. The comparative follow-up of POP surgery using non-absorbable polypropylene mesh versus colporrhaphy using native tissue was analysed in two different cohorts, of women with a primary cystocele and women with a relapse after surgery for a rectocele. Both surgeon-reported results and patient-reported outcomes (PROMs) were analysed 1 year post-surgery.

Information about surgeons’ experience in performing POP operations was extracted from GynOp over 9 years. Inclusion criteria were otherwise healthy patients who underwent anterior or posterior native tissue repair, or both. The operations were divided into four groups according to the operative experience of the surgeon (measured as average number of operations per active year). Both PROM results and surgeon-reported outcomes after 1 year were investigated.
For the long-term follow-up 5 years after any operation for a vaginal prolapse, a new questionnaire to capture PROM data was designed, validated and nationally distributed. Information about re-operations was extracted directly from GynOp.

Results

Mesh-augmented repair of a primary cystocele had a significantly better outcome in terms of absence of symptoms, compared with native tissue repair, OR 1.53 (95% CI 1.10-2.13), but also had more complications directly related to the procedure (OR 1.51, RD=6.6%). For recurrent rectocele, mesh was superior to native tissue repair, OR 2.06 (95% CI 1.03-4.35); the number of postoperative complications was equal in the two groups.

Among the 1,092 surgeons who were active POP surgeons during the study, 803 (73%) participated in POP operations once a month or less frequently in their active years. No differences in patient or surgeon-reported outcomes were seen between the “experience groups”.

Kaplan-Meier curves for re-operation after a primary POP operation showed an overall retreatment rate of 11.2% after 5 years. The response rate for the patient questionnaire was 74.9%. Overall, 70% of the patients reported no symptoms, and around 72% and 82% were satisfied with the operative results and felt that their symptoms had improved, respectively.

Discussion

Mesh use was, after 1 year of follow-up, generally characterized by a high cure rate and varying degrees of complications, such as postoperative pain. However, for recurrent rectocele, we found no immediate drawbacks of the method compared with native tissue repair, with the same high cure rate as seen in other compartments.

Surgeon experience had no impact on the native tissue operation, and any inconsistency of outcome is more likely inherent in the method than attributable to a surgeon’s lack of experience.

The 5-year results indicate that native tissue repair produces much better results, judging from overall Swedish results, than previously thought. This is backed up both by objective data indicating a minimal number of re-operations within 5 years for the most common cases (i.e. primary rectocele and cystocele) and by the outcomes reported by the patients themselves.
Conclusions

- Mesh-augmented repair is more effective than native tissue repair for recurrent rectocele, and without increased risk of complications. Drawbacks of mesh repair vary for other compartments, and for primary operations.

- Surgeons’ operative experience in routine POP operations using native tissue has no impact on outcome after 1 year.

- Long-term results of POP repair with native tissue are excellent, with a low risk of re-operation and a persistent absence of subjective symptoms.

**Keywords:** pelvic organ prolapse, Kaplan-Meier curves, long-term follow-up, quality register, questionnaire, patient reported outcome, cystocele, rectocele, colporrhaphy, non-absorbable mesh, surgical experience
SVENSK SAMMANFATTNING

Bakgrund

Prolaps av bäckenbottens organ, vaginalprolaps (POP) är en vanlig åkomma och påverkar livskvaliteten negativt för många kvinnor.

Genomsnittsalder för kvinnor som blir opererade för POP är 60 år och med en medellivslängd på cirka 84 år, betyder detta att den genomsnittliga patienten skall leva 24 år med operationsresultatet. Hållbara resultat av kirugi över lång tid är därför helt essentiell.

I ett försök att förbättra långtidsresultaten av vaginalprolapsoperationer, blev nätmaterial (mesh) introducerat. I Sverige blir 7,4 % av alla primäroperationer (första operationen) gjorda med syntetiskt nätmaterial, utan någon samlad konsensus av hur och när näten skall användas.

I Sverige anses POP-kirurgi vara rutinoperationer, som utförs på nästan alla sjukhus med en stor andel av operatörer med liten eller ingen rutin av operationen. Sammantaget blir 73 % av operationerna som utförs, gjorda av operatörer som i genomsnitt opererar POP en gång i månaden eller mindre. De flesta kirurger opererar alltså med låg frekvens och resultaten anses vara otillfredsställande. I ett globalt perspektiv, har rapporterats att operation för vaginalprolaps ofta misslyckas.

Målen med avhandlingen var att undersöka:
- Inflytande på det operativa resultatet när nät används jämfört med operationer utan nät.
- Hur operatörens erfarenhet påverkar operationsresultat.
- En nationell långtidsuppföljning (5 år) av prolapsoperationer, avseende både objektiva epidemiologiska data och patientrapporterade utfall.

Metod

Studierna i denna avhandling är alla baserade på data från Nationella kvalitetsregistret inom gynekologisk kirurgi (GynOp) som täcker drygt 90 % av alla gynekologiska operationer utförda i Sverige. De komparativa analyserna av uppföljning av prolapsskirurgi efter antingen operation med icke-resorberbar polypropylenmesh (nät) eller operation utan nät, blev analyserade i två olika kohorter: Kvinnor med primär cystocele (framfall urinblåsan) och kvinnor med återfall av rektosle (framfall ändtarmen).

Både läkarrapporterade resultat och patientrapporterade utfall (PROM) blev analyserade efter 1 år.
Information avseende kirurgens operativa erfarenhet av prolapsoperationer extraherades från GynOp databasen under en tidsperiod på 9 år. Avseende patienter var inklusionskriterier att de skulle vara i övrigt friska och genomgått antingen främre eller bakre plastik, eller en kombination av enbart de två. Operationerna blev uppdelade i 4 grupper, efter operatörernas praktiska erfarenhet (genomsnittligt antal operationer per aktivt år som operatör). Både PROM och läkarrapporterade resultat efter 1 år blev analyserade.


**Resultat**

Nätoperationer vid primär cystocele hade signifikant bättre resultat ett år efter operation avseende patientrapporterad frånvaro av prolapsymptom än operation utan nät OR 1,53 (95% CI 1,10-2,13) men det rapporterades också fler komplikationer relaterade till operationen när nät användes (OR 1,51, RD=6,6%).

För recidiverande rectocele var nätoperation överlägsen operationer utan nät OR 2,06 (95% CI 1,03-4,35) Mängden av postoperativa komplikationer var här densamma i båda operationsgrupperna.

Av de 1092 operatörer som var registrerade som aktiva POP operatörer i studien, var 803 (73 %) aktiva i POP operationer enbart 1 gång per månad eller mindre de år de var aktiva. Det var ingen mätbar skillnad mellan ”erfarenhetsgrupper” avseende patientrapporterade eller läkarrapporterade parametrar.

Kaplan Meier kurvor (hållbarhetskurvor) för reoperationer efter en primär POP operation utan nät, visade en återbehandlingsfrekvens på 11,2 % efter 5 år. Svarsfrekvensen på enkäten var 74,9 %.

Av de som ej behandlats igen med operation hade 70 % av patienterna inga symptom, och respektive 72 % var nöjda med operationsresultaten och 82 % kände att deras symptom hade minskat.

**Diskussion**

Användning av nät, med 1 års uppföljning, jämför med utan nät, karakteriserades av en högre botandegrad, men med fler komplikationer, bland annat postoperativ smärta.

Detta undantaget recidiverande rectocele där inga skillnader i komplikationer jämfört med operationer utan nät hittades och med samma höga botandegrad som övriga nätoperationer.
Operatörens erfarenhet hade inget inflytande på operationens resultat, och en eventuellt låg botandegrad tycks vara mer sannolikt beroende på metoden, än på operatörens brist på erfarenhet.

5 års resultaten indikerar att operationer utan nät har mycket bättre resultat än hittills känt, baserat på de övergripande svenska resultaten. Detta stöds av både objektiva epidemiologiska data, som indikerar en minimal mängd reoperationer inom 5 år för de vanligaste fallen (såsom primära cysto- och rectocele), och av patientens egna svar på enkäten.

**Konklusioner**

- Nätoperationer är mer effektiva i att bota recidiverande retocele, och har inga mätbara nackdelar avseende komplikationer.
- Operatörens manuella erfarenhet med operationer utan nät hade inget inflytande på 1 års resultaten.
- Långtidsresultaten efter operation utan nät är bra, med låg risk för reoperation och bestående frånvaro av prolapssymptom efter 5 år.
DANSK RESUMÉ

Baggrund

Prolaps af bækkenbundens organer (POP) er en almindelig lidelse, der stærkt påvirker livskvaliteten for mange kvinder.

Den gennemsnitlige svenske kvinde opereret for POP er 60 år ved operationen, og med en forventet gennemsnitlig levealder på 84 år betyder dette, at patienten sandsynligvis vil leve omkring 24 år med operationsresultaterne. Netop derfor er pålidelige, holdbare langtidsresultater af operationen essentielle.

I et forsøg på at forbedre især langtidsresultater af POP kirurgi, er net (mesh) materialer blevet introduseret. I Sverige bliver 7,4 % af alle primære operationer opereret med kirurgisk mesh uden nogen øjensynlig konsensus eller ensartethed hvad angår deres optimale brug.

I Sverige bliver POP kirurgi ligeledes anset som rutineoperationer udført på stort set ethvert hospital med en stor proportion af uerfarne operatører. I realiteten opererer 73 % af samtlige operatører, der har noget at gøre med POP operationer, mindre end 1 POP-operation om måneden i gennemsnit. POP er i litteraturen desuden rapporteret at være behæftet med en høj rate af mislykkede operationer.

Det vil sige, at for de fleste kirurger bliver denne procedure udført med meget lav frekvens, og samtidigt er resultaterne øjensynligt utilfredsstillende.

Målene med denne doktorafhandling var at undersøge:
- Operationsresultater med mesh sammenlignet med operation uden mesh.
- Lægens manuelle erfaring med native POP operationer, og hvordan (eller hvordan ikke) den har indflydelse på resultaterne.
- Langtidsresultaterne (5 år) på national basis for POP operationer, både i forhold til de objektive epidemiologiske data og de patientrapporterede udfald.

Metoder

Både de lægerapporterede og de patientrapporterede resultater (PROM) blev analyseret 1 år efter operationen.

Information angående lægens erfaring med POP blev taget direkte fra GynOp databasen, og er opsamlet over en periode på 9 år. Inklusionskriterier for patienter var at de skulle være ellers raske, og været opereret med enten kolporrafia anterior eller kolporrafia posterior (eller begge). Operationer blev opdelt i 4 grupper, alt efter den mængde manuel erfaring lægerne havde (målt som gennemsnitligt antal operationer per aktivt år). Både PROM og lægerrapporterede parametre blev undersøgt efter 1 år.
For at undersøge langtidsresultater 5 år efter operationen, blev et helt nyt spørgeskema designet, valideret, og distribueret nationalt. Information angående reoperationsfrekvens blev taget direkte fra GynOp databasen.

**Resultater**

Ved primære cystoceler, havde operation med kirurgisk mesh bedre resultater end den native operation hvad angår patienternes prolapssymptomer 1 år efter operationen OR 1.53 (95% CI 1.10-2.13), men var også behæftet med væsentligt flere operationskomplikationer (OR 1.51, RD=6.6%).

For recidiverende rectocele, var mesh også overlegen den native operation OR 2.06 (95% CI 1.03-4.35), men ikke behæftet med flere komplikationer i kølvandet af operationen.

Iblandt de 1092 kirurger der var aktive som Pop operatører under studiet, opererede 803 (73 %) mindre end 1 gang om måneden i snit i deres aktive år. Ingen forskel i patient- eller lægerapporterede parametre blev set mellem de forskellige erfaringsgrupper.

Den overordnede reoperationsfrekvens vist ved Kaplan Meier kurver efter primære POP operationer var 11,2% efter 5 år.

Svarsfrekvensen på spørgeskemaet var 74,9 %. Overordnet efter 5 år, svarede omkring 70 % af alle patienter at de ikke havde prolapssymptomer, samt 72 % angav at være tilfredse med operationsresultatet. Desuden angav 82 % at deres prolapssymptomer var væsentligt forbedrede i forhold til inden operationen.

**Diskussion**

Resultater af mesh med 1 års follow up sammenlignet med nativoperation, er generelt karakteriseret ved en høj grad af symptomfravær, men varierende grader af ulemper såsom en øget mængde postoperativ smerte. Dog, unikt for recidiverende rektocele ses også denne samme høje grad af symptomfrihed, uden nogen umiddelbare ulemper i forhold til den native operation.

Operatørens erfaring har ikke nogen indflydelse på den native operation, og utilfredsstillende resultater er mere sandsynligt iboende metoden end at dette skal henføres til operatørens mangel på erfaring.

Resultaterne efter 5 år indikerer, at kolporrafi producerer meget bedre resultater på nationalplan end først antaget. Dette bakkes op af både de rent objektive data der indikerer et minimalt antal re-operationer i løbet af 5 år i de mest almindelige tilfælde (primære, raske, cystocele og rektocele patienter) og af patienternes egne svar ved 5 års followup.
Konklusioner

- Mesh-operationer er at foretrække ved recidiverende rektocèle, men har en varierende komplikationsprofil ved primære operationer, og operationer i andre compartment.

- Operatørens manuelle erfaring med nativ-operationer har ingen indflydelse på det overordnede resultat af operationen efter 1 år.

- Langtidsresultater efter nativ-operationer er ganske udmærkede, med en lav risiko for re-operation og et vedholdende fravær af patientrapporterede symptomer.
DEUTSCHE ZUSAMMENFASSUNG

Hintergrund

Prolaps der weiblichen Beckenorgane (POP) ist eine häufige Erkrankung, die sich auf die Lebensqualität vieler Frauen auswirkt.


In dem Bestreben, die langfristigen Ergebnisse nach einer Operation für Vaginalprolaps zu verbessern, wurden Netzmaterialien zum Einsatz gebracht. In Schweden wird synthetisches Netz bei 7,4 % aller Primäroperationen verwendet, ohne dass ein kohärenter Konsens über deren Verwendung besteht.

In Schweden wird die POP-Operation als Routineoperation angesehen, die in fast allen Krankenhäusern durchgeführt wird. Ein großer Teil der Chirurgen ist unerfahren, 73 % führen den Eingriff einmal im Monat oder weniger durch. Gleichzeitig weisen POP-Operationen in globaler Sicht eine hohe Ausfallrate auf.

Das Ziel dieser Arbeit ist es zu untersuchen:

- Einfluss von netzverstärkten Operationen auf die operativen Ergebnisse im Vergleich zu Plastiken mit nativem Gewebe.
- Hat chirurgische Erfahrung mit POP-Operationen Bedeutung für die operativen Ergebnisse von Nativoperationen (und in welchem Ausmaß)?
- Langfristige (5-jährige) nationale Verlaufskontrolle von native POP-Operationen, sowohl in Bezug auf objektive epidemiologische Daten als auch auf die von Patienten gemeldeten Ergebnisse.

Methoden

Alle verwendeten Daten wurden aus der Datenbank des Nationalen Qualitätsregisters für gynäkologische Chirurgie (GynOp) extrahiert.

In Bezug auf die Erfahrungen der Chirurgen mit POP-Operationen wurden über neun Jahre kontinuierlich und prospektiv gesammelte GynOp Daten verwendet.

Sowohl die vom Chirurgen als auch die vom Patienten berichteten Ergebnisse (PROM) wurden nach einem Jahr analysiert.

Einschlusskriterien waren ansonsten gesunde Patienten, bei denen eine Reparatur des anterioren oder posterioren Kompartment (oder beides) mit nativem Gewebe durchgeführt wurde.
Die Operationen wurden je nach manueller Erfahrung des Chirurgen in vier Gruppen eingeteilt (durchschnittliche Anzahl Operationen pro aktives Jahr).


**Ergebnisse**

Die netzverstärkte Operationen einer primären Zystozele zeigten ein signifikant besseres Ergebnis in Bezug auf das Fehlen von Prolaps Symptomen im Vergleich zur Operation mit nativen Gewebe, OR 1,53 (95% CI 1,10-2,13), aber auch eine erhöhte Anzahl Komplikationen, die in direktem Zusammenhang mit der Operation standen (OR 1,51; RD = 6,6 %). Bei rezidivierenden Rektozelen war das Netz der Operation mit nativem Gewebe klar überlegen OR 2.06 (95% CI 1.03-4.35). Die Anzahl der postoperativen Komplikationen war in beiden Gruppen gleich.

Unter den 1 092 Chirurgen, die während der Studie operativ aktiv waren, nahmen 803 Chirurgen (73 %) in ihren aktiven Jahren einmal im Monat oder weniger an einer POP-Operation teil. Es wurden keine Unterschiede in den von Patienten oder Chirurgen berichteten Ergebnissen zwischen den „Erfahrungsgruppen“ festgestellt.

Nach fünf Jahren zeigte eine Kaplan-Meier-Kurve eine chirurgische Reoperationsrate von 11,2 %. Die Rücklaufquote des Patientenfragebogens betrug 74,9 %. Insgesamt gaben 70 % der Patienten keine Symptome an. 72 % und 82 % waren mit den operativen Ergebnissen zufrieden und fühlten, dass sich ihre Symptome besserten.

**Diskussion**

Die Netzanwendung ist nach einjähriger Nachsorge im Allgemeinen durch eine hohe Heilungsrate und unterschiedlich schwere Komplikationen sowie postoperative Schmerzen gekennzeichnet.

Bei rezidivierenden Rektozelen wurden jedoch keine unmittelbaren Nachteile der Netzanwendung im Vergleich zur nativen Gewebereparatur festgestellt. Gleichzeitig sieht man signifikant verbesserte Heilungsraten wie in anderen Kompartments.


**Schlussfolgerungen**

- Bei rezidivierenden Rektozelen ist eine netzverstärkte Operation signifikant haltbarer als eine Operation mit nativem Gewebe, mit vergleichbaren Komplikationsprofil. Die Vor- und Nachteile sind für die anderen Fällen variierend.

- Die operative Erfahrung eines Chirurgen (Anzahl POP Operationen mit nativem Gewebe) hat keinen Einfluss auf das 1-Jahres Ergebnis von Operationen mit nativem Gewebe.

- Die Langzeitergebnisse nach POP Operationen mit nativem Gewebe sind ausgezeichnet, mit einem geringen Risiko für eine Reoperation und einem anhaltenden Fehlen subjektiver Prolaps Symptomen.
ORIGINAL PAPERS


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INTRODUCTION AND BACKGROUND

Synthesis

Pelvic organ prolapse (POP) is a common condition in middle-aged and older women. When conservative treatments fail, surgical intervention is the treatment of choice. Finding the best possible method with minimal complications and maximum improvement for a specific surgical problem is desired. This includes an understanding of the individual surgeon’s experience, and how it impacts the operation, and an evaluation of whether the improvement in the prolapse is sustainable over time.

Historical overview

Pelvic organ prolapse is a medical problem that has apparently been recognized for thousands of years. In fact, the oldest existing medical literature refers to uterine prolapse. One of the Kahun papyrus manuscripts from around 1835 BC describes a woman “whose posterior, belly, and branching of her thighs are painful, say thou as to it, it is the falling of the womb”. The recommended treatment at about that time, recorded some 200 years later by a physician named Ebers, was to “correct a displaced womb: with oil of earth (petroleum), with fedder (manure) and honey; rub the body of the patient”.

Over 1000 years later, during the era of Hippocrates (460-377 BC), research into vaginal prolapse led to the widely accepted hypothesis that the uterus and pelvic organs were, and acted, as independent organisms. Hippocrates’ own treatments included “fumigation”, in which pleasant-smelling fumes were released at the woman’s head, while vile odors (of manure and the like) were released at the prolapse site, to stimulate the uterus (or other organs) to decide to retreat towards the more pleasant smelling odors at the woman’s head. These treatments were not always effective, so Polybus (a student and successor of Hippocrates) revolutionized the treatment of POP by placing “a vinegar-soaked sponge or halved pomegranate” in the woman’s vagina, thus tightening the tissues. If this failed, Polybus recommended hanging the woman upside down, and bouncing her repeatedly, until, hopefully, the prolapse was reduced and the patient was cured.
Illustration 1. The hanging technique - Illustration of the “hanging technique”, an ancient Greek method for treating a prolapsed uterus that has extended through and beyond the vaginal introitus.

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The first modern scientific study of POP was published in 1926 by W.E. Fothergill. Pelvic organ prolapse had been classified as a surgical problem since 1912, having previously been treated with conventional therapy or with various pessaries. The recommended surgical treatment was developed in Manchester, and was thus dubbed the “Manchester operation”. This approach is remarkably similar to modern native tissue repair, and can briefly be described as the excision of vaginal-wall tissue at the prolapse site and subsequent suturing of the remaining tissue, tightening the vaginal wall at the site of the prolapse. Since its introduction, the Manchester operation has been the most common and widespread, principal surgical approach to POP.
Definitions and prevalence

Pelvic organ prolapse is a pelvic floor disorder that causes symptoms in the lower genito-urinary and gastro-intestinal tracts. “Prolapse” (from the Latin *prolapsus*, “a slipping forth”) refers to a “descent” or “drooping” of any of the pelvic floor organs, including the bladder, uterus, vagina, small intestine, or rectum, into or outside the vaginal canal. Depending on the organ, the afflicted segment (compartment) of the vagina can be the anterior, posterior, or apex of the vagina, as well as the vaginal vault in the case of a previous hysterectomy. Depending on the prolapsing organ and the corresponding compartment of the vagina, POP is characterized into different subtypes. Cystocele (bladder prolapse), located in the anterior vaginal compartment, and rectocele (rectum prolapse), located in the posterior vaginal compartment, are the most common subtypes, representing 30.3% and 17.7% of all prolapse cases, respectively, according to the Swedish National Quality Register for Gynaecological Surgery (GynOp). Other subtypes are small intestine, uterine, and vaginal vault prolapses, or combinations of these. In addition to relevant textbooks, the American College of Obstetricians and Gynecologists have produced illustrative videos that show the anatomical layout.

Pelvic organ prolapse is a common condition in women, and the lifetime prevalence for women is estimated to be 11-19%, based on American, Swedish and Australian observational studies. Correspondingly, with the high prevalence, this condition demands considerable hospital resources; in Sweden alone, around 6,000 POP operations are performed each year. On a global scale, because the incidence of POP increases with age, changing world demographics will result in even more affected women, as the world’s elderly population is expected to almost double from 2012 to 2050. Each year, POP leads to a large amount of sick leave, and it also leads to early retirement and social isolation among women.

Pathophysiolo:gy and risk factors

Anatomy

Anatomical support for the pelvic and adjacent viscera is mainly provided by the levator ani muscle complex (comprising the pubococcygeus, puborectalis, and iliococcygeus muscles) and connective tissue attachments of the endopelvic fascia.
The levator ani muscle complex is normally tonically contracted at rest, acting to close the genital hiatus and provide a stable platform for the pelvic viscera. An impairment or weakening of these components can lead to loss of structural support and, ultimately, to prolapse of the pelvic organs.\textsuperscript{18}

Pelvic organ prolapse is first and foremost a failure of the connective tissue to support the genital organs.\textsuperscript{19} Many recent studies have concerned the modulation of collagen synthesis as an underlying factor in POP.\textsuperscript{20} It has become clear that collagen is the key modulator with regard to the structural integrity of the tissue, making weakening and thinning of collagen the main reason for failing structural support in the pelvic floor.\textsuperscript{21-26} There are several pathophysiological mechanisms that can contribute to structural instability and that are associated with POP.\textsuperscript{27}
Age
Increase in women’s age leads to a weakening of the endopelvic ligaments and fascia. This is believed to be due partly to continuous mechanical strain over the years, but it is also closely associated with decreasing levels of oestrogen. Menopause is therefore frequently cited as a risk factor for POP. It is still unclear whether it is the decreasing oestrogen levels themselves or the loss of oestrogen receptors in the connective tissues that play the main role in tissue degradation. It is worth noting, however, that studies of hormonal status and prolapse have failed to establish a direct link between oestrogen status and POP.

Childbirth/parity
A decline in normal levator ani muscle complex tone by denervation or direct muscle trauma can result in the levator plane assuming a bowl-like shape, which is associated with POP. Both direct muscle trauma and neuropathic injury are associated with childbirth. First-time vaginal birth seems to be strongly associated with development of POP later in life. There is a correlation between additional vaginal births and further increase in POP. However, the literature is still unclear as to the strength of the association.

Obesity
Elevated body mass index (BMI) is a lifestyle-related factor increasing the risk for developing POP. The increased overall risk of pelvic floor disorders associated with elevated BMI has been recognized for many years, although a direct link between obesity and the development of POP and other pelvic floor disorders has not been established. A recently published review concluded that “the most probable mechanism of POP development among obese women is the increase in intra-abdominal pressure that causes weakening of the pelvic floor muscles and fasciae”.

Other risk factors
Chronic constipation, chronic obstructive pulmonary disease and conditions affecting connective tissues in general, such as Ehler-Danlos disease or Marfan’s syndrome, affect the stability of the pelvic floor. Patients with these ailments have been shown to have a greater prevalence of POP and urinary incontinence.
Symptoms of pelvic organ prolapse

Local symptoms
The most common symptom of POP is a patient-reported feeling of a vaginal bulging. This symptom is diagnostically specific to POP, and is used not only as a diagnostic criterion, but as the decisive criterion for POP surgery in Sweden. Other pelvic symptoms can also occur, such as local pain and a feeling of attrition from friction and abrasion.

Urinary symptoms
Following a prolapse, various urinary symptoms are common. Urinary incontinence, presenting either as the worsening of previous symptoms or as de novo incontinence, is observed in 19-83% of POP patients. Pelvic organ prolapse is also coupled with both stress incontinence and urgency, in which the patient experiences an involuntary loss of urine. Pelvic organ prolapse is further strongly associated with voiding difficulties and residual urine.

Sexual symptoms
In general, studies suggest that women with POP have the same amount of sexual activity as do women of the same age without POP. Women who have POP, however, are more prone to cite pelvic floor symptoms as a reason for decreased sexual activity than are women without POP. However, the most common reasons for POP patients to become sexually inactive, despite an ongoing relationship, are reported to be ageing, menopause, and/or lack of sexual desire. Dyspareunia has also been suggested to be a negative consequence of POP. However, dyspareunia has a complex, multifactorial aetiology, and is a common symptom in older women due to low oestrogen levels and resulting vaginal dryness.

Other symptoms
Bowel symptoms are common in cases of posterior-wall POP. Problems with starting or completing defecation, as well as straining, incontinence and urgency are frequent symptoms reported by patients with rectocele. How severe these symptoms are for the individual patient is difficult to assess, as there is only a weak association between the severity of prolapse and the degree of bowel dysfunction.
**Pelvic organ prolapse, and taboo**

Many women with POP “suffer in silence”, without knowing anything about the disease or the help that is available.\textsuperscript{77,78} This is largely due to a lack of readily available information, not only in the media, but also in the public domain and provided by caregivers. Education would allow patients to confirm symptomatic prolapse by themselves; lack of education leads to the unnecessary suffering of many patients, who could have sought help earlier.\textsuperscript{79} The daily colorized press provides minimal information about prolapse, and the subject is rarely discussed, in contrast to urinary incontinence, which is discussed openly and frequently.\textsuperscript{77,13} Pelvic organ prolapse has, sadly, been branded a taboo subject; and this has been affecting women’s health-seeking behaviour and made POP a hidden disease.\textsuperscript{77}

**Diagnostic considerations**

The three most common methods to diagnose and/or quantify POP are through a gynaecological speculum examination, the Pelvic Organ Prolapse Quantification (POP-Q) system or measurement of the protrusion, in centimetres, of the prolapse in relation to the hymen, and patient-reported outcome measures.

**The Pelvic Organ Prolapse Quantification system**

The objective anatomical verification of POP has been standardized since 1996 in the POP-Q system. This is an objective site-specific system for describing, quantifying and staging POP. In short, it allows the description of a total of nine defined points in the vaginal wall in relation to the hymen. Staging is subsequently done, ranging from stage 0 (no prolapse) to stage 4 (complete vaginal eversion of the prolapse). The reproducibility and great detail of the POP-Q system has made it the most used system in scientifically documenting POP.\textsuperscript{80,81}
Illustration 3. Pelvic Organ Prolapse Quantification (POP-Q) scoring explained.

Illustration of the POP-Q points. A score of 0 is given when there is no prolapse in the anterior or posterior points, and points Aa, Ba, Ap and Bp are all at -3 cm and either C or D is between total vaginal length (TVL) and TVL-2 cm. A total score of 4 (maximum) represents a complete prolapse, where the most distal part protrudes to at least TVL-2 cm.

Image kindly approved for use by authors Tsaitgaist and Huckfinne.

**Size of the prolapse protrusion in relation to the hymen (centimeter hymen)**

In routine clinical examination and quantification of pelvic prolapse, a simpler approach is often used. The most protruding part of the prolapse is described with regard to its origin (i.e. anterior, posterior, or cervical, or the vaginal apex) and how far, in cm, it protrudes in relation to the hymen. This is the preferred method of quantifying POP among Swedish gynaecologists and is the measurement used when reporting to GynOp.

**Patient-reported symptoms**

The patient’s symptoms play a minor role in the quantification of a manifest prolapse. The only specific symptom associated with POP is the patient’s own awareness of vaginal bulge, which is regarded as a valid way of establishing the presence of prolapse. However, in terms of quantification, POP is exactly quantified as part of a gynaecological examination, primarily by the gynaecologist, typically utilizing the POP-Q system or measurement of the protrusion from the hymen.
The patient plays a vital role in diagnosing POP, however. In every publication in this thesis, the patient-reported cure rate (absence of a vaginal bulge) has been the main criterion for the success or failure of an operation, partly because of the high validity of patient-reported symptoms, and also because the indication for surgery is not primarily an anatomical defect in itself, but the symptoms associated with or directly deriving from the prolapse, as reported by the patient. In practical terms, the physician’s evaluation is secondary to the patient’s evaluation.  

**Treatment of pelvic organ prolapse**

Modern POP treatment can be managed non-surgically as in the past, or by POP surgery. The non-surgical approach will be briefly discussed below. It encompasses adjunct therapy, pelvic floor muscle training, hormone therapy, and pessaries.

**Non-surgical treatment**

**Adjunct therapy**

Adjunct therapy seeks to ameliorate the symptoms of the prolapse rather than treat the prolapse itself, and the approach is completely unrelated to the severity of the prolapse. For example, dietary and fluid intake schedules can be formulated to help alleviate urinary and bowel symptoms. These alterations in lifestyle, diet and exercise are always balanced against the severity of symptoms, and if this therapy is ineffective, surgery is typically recommended.

**Pelvic floor muscle training**

A training regimen to strengthen the pelvic floor muscles has been found to be beneficial for patients suffering from urinary and faecal incontinence, and may be beneficial for POP. Physiotherapy, in combination with adjunct therapy or pessaries, is a large field, and the general consensus is that it might be underused as a form of non-surgical therapy and prophylaxis.

**Menopausal hormone therapy**

Polymorphisms in oestrogen receptors, as well as decreased levels of estrogen or expression of oestrogen receptors, have been known to play a role in the structural integrity of the pelvic floor. Hormone therapy seems to play only a minor role in postmenopausal women with pelvic floor dysfunction already present. In premenopausal women, the overall prophylactic effect is still unknown, but is a highly discussed topic. In postmenopausal women, local oestrogen therapy is mandatory to avoid decubitus ulcers of the vaginal mucosa when a pessary is used (see below).
**Pessaries**

The pessary was introduced in the era of Hippocrates, and pessaries have been widely used as a POP intervention ever since. Pessaries are the only available non-surgical intervention directly targeting POP. Around 20 types of pessaries now exist, all made of silicone or plastic. They are inserted into the vagina to provide structural support and relieve pressure on the affected organs. Pessaries are typically used for patients who are waiting for surgery, or have declined surgery, or who are poor surgical candidates because of comorbidities or other complicating circumstances. Overall, few published works address the indications, management and effectiveness of pessary treatment.

**Surgical treatment**

The main goal of surgery is to relieve symptoms and reduce risks of complications from the prolapse. Depending on the circumstances, the goal is, further, to restore the normal vaginal anatomy, and restore or maintain sexual function. In some cases, it is, however, more realistic to focus primarily on symptom relief, and accept a more restructured approach to the vaginal anatomy, for example colpocleisis. There are currently three possible routes for conducting this operation: vaginal, abdominal, and laparoscopic. To discuss at length which is the most favourable approach to which type of genital prolapse is beyond the scope of this thesis. In general, the vaginal approach is the most common, as it is straightforward, has fewer complications from the incisions than does laparotomy, costs less than abdominal surgery, and is associated with less pain and a shorter hospital stay.

**Native tissue repair (colporrhaphy)**

Native tissue repair utilizes the patient’s own tissue, without augmentation from an implantable device, and is the modern version of the original Manchester operation. The vaginal epithelium is separated from the underlying connective tissue, and a midline plication of the vaginal muscularis is done by means of a series of sutures. Excess epithelium is then removed, followed by closure. There are variations and subtypes of this principal operation. However, the principles of this surgery have not changed drastically since the introduction of the Manchester operation, and the overall approach is the same: removing stretched or redundant vaginal tissue and tightening the vaginal wall at the incision site by suturing the remaining tissue together, thus restoring anatomical support in the area.
Mesh-augmented repair

The mesh approach in prolapse repair is not to use the degraded connective tissue, but instead to use a surgical mesh graft to reinforce the anatomical structures. Surgical mesh is a medical device similar to a net, that is utilized to provide additional anatomical support to weakened or damaged tissue. Utilized in numerous surgical specialties in the last decade, mesh materials range from small “patches” that expedite the healing process after a lumbar puncture, to larger mesh sheets used in orthopaedic surgery. Perhaps the best-known use of surgical mesh is in inguinal hernia repair, for which mesh procedures were proposed in 1958 and became standard treatment in the 1980s. In abdominal surgery, mesh materials are used to reinforce the abdominal wall and lower the risk of recurring herniation of the abdominal wall. The success and widespread use of surgical mesh in abdominal surgery is in part what prompted gynaecological surgeons to implement similar materials and procedures. The general idea is that the mesh material, in addition to the surrounding tissue, will act as a structural support and promote the successful fixation of anatomical structure(s). In principle, there are only two main subtypes of surgical mesh: the biological type and a non-resorbable (synthetic) type, as well as hybrids of both non-resorbable and biological materials.

Biological mesh is often made of animal-derived materials, typically from bovine (cow) or porcine (pig) sources, but can also come from other biological sources, such as human dermis. These types of mesh are absorbable, which means that, over time, they will be infiltrated by soft tissue at the repair site, and integrated into the body.

Unfortunately, this remodelling process also appears to lead to a rapid reduction in the mechanical strength of the mesh, so for long-term stability, the patient must rely on new tissue growth to provide structural strength to the repair site. The practical question of new tissue growth being adequate has been contested more or less as long as biological meshes have existed. Biological mesh use has decreased in recent years, and is steadily being phased out in clinical treatment of POP.

Non-resorbable mesh is typically made from synthetic materials such as polypropylene or other nanofibrous compounds. Unlike the biological mesh types, these materials do not degrade over time, and are meant to permanently support the anatomical structures at the repair site. They are therefore considered to be permanent surgical implants, and should be able to provide persistent, unyielding structural support at the anatomical site.
Numerous types of new compounds, such as polyvinylidene fluoride, which could potentially be coupled with stem cell coating, are being studied for possible applications of surgical mesh implants. These are being developed primarily for implantation in immunologically highly active areas, and will not be further elaborated in this thesis. In gynaecology, synthetic mesh procedures have been used since 1996, especially for repair of vaginal prolapse.

**Prognosis and results of surgical treatments**

**Long-term follow-up**

The specific 1-3-year prognosis for surgical treatment of POP varies between studies. No article solely addressing the long-term prognosis for native tissue repair was found, as this is typically not the topic of interest, but is the by-product of a comparative analysis. In general, trials incorporating long-term analysis use small datasets comprising a few hundred cases, are conducted on highly heterogeneous groups of patients, without considering concomitant procedures, and vary by up to 13 years between patients regarding when patients are followed up.

To summarize the information on length of follow-up, the longest consistent follow-up, allowing prognostic conclusions regarding the specific treatments, has been at around three years. The best available evidence suggests that the anterior vaginal wall recurrence of prolapse within three years is around 40% for colporrhaphy and 10-15% for mesh-augmented patients. However, recent randomized controlled trials (RCTs) and cohort studies have hinted that results of native tissue repair are likely better than previously reported.

**Comparison of treatments, and introduction of surgical mesh**

The studies cited below have compared the outcomes of the native tissue repair procedure and procedures using various types of mesh and include their authors’ interpretations and conclusions. The studies’ design, material size, follow-up time, outcome measures and results are summarized in Table 1.
Table 1. Follow-up studies included in the thesis.

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Study design</th>
<th>Material and size</th>
<th>Follow-up time</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Comments by authors</th>
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<tbody>
<tr>
<td>Milani et al. (2018)</td>
<td>Retrospective cohort study</td>
<td>111 patients with symptomatic vaginal vault prolapse (post-hysterectomy) operated with native tissue repair</td>
<td>1-3 years</td>
<td>POP-Q stage verification, Patient-reported bulging symptoms, Patient satisfaction via PGI-I score</td>
<td>7.2% postoperative complications, 2.7% re-intervention, POP-Q-scored recurrence in 25.2%, subjective recurrence in 5.4%</td>
<td>Native tissue procedures are safe and effective in correcting post-hysterectomy vaginal vault prolapse and represent a valid alternative to prosthetic procedures for vaginal vault prolapse treatment.</td>
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<tr>
<td>Milani et al. (2018)</td>
<td>Randomized controlled trial</td>
<td>194 women with recurrent POP, randomized to native tissue repair or mesh</td>
<td>7 years</td>
<td>PROM and surgeon-reported outcomes</td>
<td>Repeat surgery was 25% for mesh, 16% for native tissue. Mesh exposure rate was 42%. Composite success was around 51% after 7 years, for both groups (combined PROM and surgeon-reported outcomes). Mesh did not reduce long-term repeat surgery rates due to de novo POP in non-mesh-treated vaginal compartments.</td>
<td>Mesh is not recommended for primary anterior repair. Mesh may have a role in recurrent posterior prolapse.</td>
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<tr>
<td>Devaseelan &amp; Fogarty (2009)</td>
<td>Review cohort study</td>
<td>19 cohort studies (1,740 women in all)</td>
<td>5-36 months</td>
<td>PROM</td>
<td>Type I monofilament polypropylene mesh seems to be the synthetic mesh of choice at present. With the literature available, no recommendation can be made on the efficacy and safety of synthetic mesh in the repair of anterior vaginal wall prolapse. 18 Data on patient satisfaction, quality of life and impact on bowel, bladder and sexual function are limited.</td>
<td>Mesh is not recommended for primary anterior repair. Mesh may have a role in recurrent posterior prolapse.</td>
</tr>
<tr>
<td>Weintraub et al. (2015)</td>
<td>Retrospective cohort study</td>
<td>79 women, operated with surgical mesh. Both recurrent and primary prolapse All types of prolapse</td>
<td>79-104 months</td>
<td>Multivariate logistic regression: adverse outcomes and follow-up time Oral interviews, patient-reported symptoms</td>
<td>Age, parity, previous hysterectomy, baseline and post-surgical POP-Q points not associated with symptoms or repeat operation, 13.9% recurrence of symptoms, 11 patients (9.1%) had repeat surgery.</td>
<td>Difficulties in drawing conclusions due to variance in follow-up and material size.</td>
</tr>
<tr>
<td>Derman et al. (2008)</td>
<td>Prospective cohort study</td>
<td>374 women &gt;20 years old who underwent surgery for POP-UI</td>
<td>10 years</td>
<td>Kaplan-Meyer curves for re-operation rates</td>
<td>17% re-operation rates within 10 years.</td>
<td>The unacceptably high recurrence rate is probably underestimated.</td>
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<tr>
<td>Thys et al. (2011)</td>
<td>Prospective cohort study</td>
<td>192 patients with vaginal apex prolapse 96 patients underwent Manchester-Fothergill (MF) operation and 96 had vaginal hysterectomy (VH) as repair</td>
<td>17-112 months</td>
<td>PROM, surgeon-reported data on the operation</td>
<td>MF procedure survived on average 9 months shorter with regard to re-operation. No difference regarding quality of life (tested by questionnaire). Blood loss and operation time significantly less for the Manchester operation. Incomplete bladder emptying more prevalent in the MF group.</td>
<td>The MF operation is not an obsolete procedure.</td>
</tr>
<tr>
<td>Funk et al. (2013)</td>
<td>Cross-sectional cohort study</td>
<td>27,809 women operated with native tissue repair or mesh</td>
<td>5-year cumulative risk</td>
<td>Kaplan-Meyer curves Outcomes: repeat surgery of any kind or repeat surgery for recurrence of prolapse</td>
<td>Any repeat surgery was 15.2% for native tissue repair and 9.8% for vaginal mesh. The 5-year risk for prolapse repeat surgery was similar, with 10.4% and 9.3% risk, respectively.</td>
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<tr>
<td>Aigmueller et al. (2008)</td>
<td>Prospective follow-up</td>
<td>99 women who had undergone a sacrospinous fixation for vaginal wall prolapse</td>
<td>Between 2 and 15 years postoperatively</td>
<td>Examination with POP-Q and patient-reported &quot;symptoms of descent&quot;</td>
<td>POP-Q: 29% developed de novo cystocele. 16% developed vaginal vault prolapse. PROM: 76% had urinary symptoms. 16% had prolapse symptoms.</td>
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<tr>
<td>Nieminen et al. (2010)</td>
<td>Randomized controlled trial</td>
<td>200 patients with anterior vaginal wall prolapse, operated with or without mesh Preoperatively, and at 2, 12, 24 and 36 months by both examination and questionnaire</td>
<td>Primary outcome: anatomic re-examination for recurrence Secondary outcomes: symptomatic resolution, re-operation and mesh exposure</td>
<td>Mesh reduced anatomic recurrences, with 41% recurrence in the colporrhaphy group and 13% in the mesh group. There was no difference in symptomatic recurrence. Mesh erosion rate was 19%.</td>
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PGI-I = Patient Global Impression of Improvement; POP = pelvic organ prolapse; POP-Q = Pelvic Organ Prolapse Quantification system; POP-UI = pelvic organ prolapse-urinary incontinence; PROM = patient-reported outcome; VH = vaginal hysterectomy.
Milani et al.\textsuperscript{124} conducted a retrospective cohort study of 111 hysterectomized patients with symptomatic vaginal vault prolapse, operated with native tissue repair. The cohort were followed up for 1-3 years after the operation. The authors report a rate of 7.2\% of postoperative complications, and of 2.7\% of (surgical) re-intervention after 1-3 years. An interesting finding was that the POP-Q-measured recurrence was significantly higher than the subjective feeling of having a prolapse recurrence reported by the patients themselves, with 25.2\% POP-Q-reported, and 5.4\% patient-reported outcome (PROM) recurrence, respectively.

Milani et al. also conducted a RCT\textsuperscript{125} in which they followed up 194 women after 7 years. The patients all had recurrence of a previously surgically treated POP, and were randomized to native tissue, or mesh repair. Altogether 25\% of the mesh patients, and 16\% of the native tissue patients were re-operated within 7 years. Mesh exposure rates were 42\%. Composite success of both operations was around 51\%. The authors commented that the main reason why mesh was not associated with reduced long-term, repeat surgery was that, in the mesh group, there was de novo POP in non-mesh-treated vaginal compartments, which was not seen as frequently in the native tissue repair group.

Devaseelan & Fogarty\textsuperscript{109} performed a review of 19 cohort studies including 1,740 women in all, regarding surgical mesh. All studies used some form of PROM, and had a range in follow-up of 5-36 months. Overall results were, that with the available literature, no recommendation can be made on the efficacy and safety of synthetic mesh in the repair of anterior vaginal wall prolapse. Data on patient satisfaction, quality of life and impact on bowel, bladder and sexual function are overall limited.

The authors concluded that the best available evidence suggests that mesh is not recommended for primary, anterior repair, but may have a role in posterior prolapse.

Weintraub et al.\textsuperscript{116} conducted a single-centre, long-term follow-up of 79 patients operated using surgical mesh. The material included both recurrent and primary prolapse, as well as any type of prolapse. Follow-up time varied between 79 and 104 months. Patients were followed up by oral interviews. Multivariate logistic regression on the relationship between adverse outcomes and follow-up time was performed. The authors reported a 13.9\% recurrence of symptoms for POP, and a 9.1\% risk of repeat surgery. Age, parity, previous hysterectomy and POP-Q scoring (before and after operation) were not associated with symptoms or repeat operation with mesh. The authors noted that they had difficulty in drawing conclusions because of variance in follow-up and a relatively small material.

Denman et al.\textsuperscript{117} conducted a prospective cohort study of 374 women. The inclusion criteria were >20 years of age, and having had surgery for POP. Patients were not stratified with regard to the operative method, which in almost all cases was POP-UI (POP surgery combined with a urinary incontinence operation). The re-operation rate within 10 years, calculated using Kaplan-Meyer curves, was
17%. The authors concluded that the results were probably flawed because of the mix of different surgical methods at baseline, and that the “A reoperation rate of 17% is unacceptably high and likely represents an underestimate of the true rate. Most of the factors that influence reoperation have not yet been identified”.

Thys et al.\textsuperscript{118} followed up a heterogeneous group of 196 patients with uterine descent, in a study comparing the outcome of the Manchester operation with that of a transvaginal hysterectomy. The aim was to determine the difference between the treatments, and not map the results of either one. Follow-up ranged from 17 to 112 months for the Manchester operation and from 41 to 110 months for hysterectomy. Both patient- and surgeon-reported data (with regard to re-operation) were used. Twenty per cent of patients were lost to follow-up. On average, the results of the Manchester operation lasted 9 months shorter, with regard to re-operation, than those of hysterectomy, and no difference regarding quality of life (elicited by questionnaire) was found. Bladder emptying difficulties were more prevalent in the Manchester group. The authors concluded that the Manchester operation is not to be regarded as obsolete.

Funk et al.\textsuperscript{123} identified health care claims of 27,809 women who underwent a colporrhaphy with or without surgical mesh between 2005 and 2010. Using Kaplan-Meyer curves, the authors sought to estimate the cumulative risk of repeat surgery or revision/removal of the mesh. Patients were followed up after approximately 5 years and the results were that patients operated with mesh were re-operated more often than those without mesh. The women included were identified through “health care claims”; the only inclusion criteria were (1) being ≥18 years of age; and (2) having undergone an anterior colporrhaphy, either with or without mesh. The study controlled for hysterectomies or vaginal slings as treatment, but controlled for no other possible concomitant procedures. The authors made no recommendations for specific patient groups, based on the results.

Aigmueller et al.’s study\textsuperscript{120} followed up 99 women who had undergone a sacrospinous fixation for vaginal wall prolapse. Patients were followed up between 2 and 15 years postoperatively, using a POP-Q examination and patient-reported symptoms of “uterine descent”. Altogether, 29% developed de novo cystocele, 16% had developed de novo vaginal vault prolapse, 76% had urinary symptoms and 16% had prolapse symptoms.

Nieminen et al.\textsuperscript{126} randomized 200 patients with anterior vaginal wall prolapse to mesh or non-mesh repair with a follow-up time of three years. The study was well designed, carefully executed, and of overall very high clinical and scientific value. The authors’ conclusion, after three years, was that mesh reinforcement significantly reduced anatomic recurrences of anterior vaginal prolapse, but that there was no difference in relapse of symptoms. Mesh erosion rate was 19% within 3 years.
The overall conclusions regarding surgical POP treatment reached in the scientific community are that: (1) mesh procedures have a better short-term (up to one year) cure rate, but are not without complications; and (2) the long-term outcomes of mesh repair versus colporrhaphy are still unclear, but mesh is expected to be associated with long-term morbidity, which makes colporrhaphy a more desirable alternative. This is further summarized in previous Cochrane reviews performed by Maher et al.\textsuperscript{127,128}

Almost all studies above aimed to establish whether the patients had a recurrence of POP and a re-operation of POP. Only one study\textsuperscript{120} distinguished whether the recurrence was located in the previously operated compartment or was a new POP in another compartment with a new primary operation in that compartment.

**Impact of surgeon experience on operative results**

Research regarding the importance of the individual surgeon’s operation volume is generally restricted to extensive abdominal and thoracic surgery. The consensus is that surgical experience is a critical factor in cases of major surgery.\textsuperscript{129-131} In obstetrics, a positive correlation between the surgeon’s annual operation volume and decreased morbidity in Caesarean section delivery was recently shown.\textsuperscript{132}

In gynaecology, an association between operative volume and improved surgical outcome has been demonstrated regarding various types of hysterectomies.\textsuperscript{133-136} This association was confirmed in a recent meta-analysis of hysterectomies, gynaecological cancer surgery, surgical mesh complications and incontinence procedures.\textsuperscript{137} In 2006, an assessment of a large number of urogynaecological procedures concluded that hospital and surgeon volumes might influence morbidity and mortality, but conclusive results were not presented.\textsuperscript{138}

**Epidemiology of national register studies**

**Epidemiology** is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.\textsuperscript{139-141}

**Epidemiological evidence** can show that a certain risk factor is associated with (correlated to) a higher incidence of disease in the population exposed to that risk factor. Also, epidemiology measures the efficiency of a treatment using different measurements.

The cohorts in epidemiological studies are generally large\textsuperscript{139-141} and the data used are often health register data.
Epidemiological studies, overall:

(A) can be retrospective where both the data are collected and the study questions are formulated after the event.\textsuperscript{142,143}

(B) can use prospectively collected data, with the study rationale defined after the data has been collected.\textsuperscript{144-146}

(C) can be prospective, where the study rationale is defined before data collection begins.\textsuperscript{147-149}

Type A design has an inherently lower level of evidence, because the data collection is retrospective, and hence there may be recall bias. Type B studies are generally based on existing registers, where data have already been collected and validated. The establishment and development of registers is a slow, initially expensive and time-consuming process, but yields studies of this type, which are reliable as the data are prospectively collected and further have the advantage of being cost-effective. Type C studies are similar to Type B in level of evidence, and produce thorough, reliable results.

Not all epidemiological studies are based on register data, but using existing register data saves extensive work on data collection, and is therefore less expensive and time-consuming.

The Swedish health care system – and the link to national patient registers

The Swedish health care system is organized at the county level. Swedish counties are fairly independent political units responsible for all health services within their boundaries.\textsuperscript{150} Public hospitals are owned by the counties and financed by county taxes. There are few private clinics, and these mostly specialize in elective surgery. These clinics are contracted to the county councils and are reimbursed by them for operations they perform on Swedish patients, as all Swedes are covered by the national health system. In an effort to make the hospital system more efficient, some counties have supported specialization at specific hospitals, with the consequence that differences in practice patterns, for example the use of mesh at a particular hospital, may in some cases have organizational rather than medical rationales.\textsuperscript{151} All surgical treatments are covered by the tax-financed health care system and the financial remuneration of surgeons is not dependent on the type of surgical procedure chosen. Therefore, money is not a confounder in the decision as to whether or not to undertake a certain type of operation.
Population-based health care registers and quality registers in Sweden

All Swedes have a personal identity number,¹⁵² which makes it possible to track patients and achieve a high follow-up rate.

There are two types of national population-based registers in Sweden, covered by their own legislation, namely health care registers, and national quality registers.

Health care registers are run by the Swedish National Board of Health and Welfare. This is a government agency and the Swedish parliament and government decide the alignment of its work.

There are six health care registers for which reporting is obligatory, both for patients and caregivers. Patient identification is by social security number. Health care registers are an integral part of Sweden’s hospital system. These registers are secured with the highest possible level of secrecy. Data are anonymized and are available for research. The registers have a total of 22 statistical databases that are public, and open for analyses on the Swedish Board of Health and Welfare homepage (https://www.socialstyrelsen.se) (Table 2).

These databases do not provide access to bibliographic information and are therefore difficult to refer to. The data are accessible on the registers’ website; in cases where an URL has been changed, navigation via the Swedish Board of Health and Welfare homepage is recommended.

Table 2. Health registers and statistical databases of special interest for this thesis.

<table>
<thead>
<tr>
<th>Health registers</th>
<th>Statistical databases</th>
</tr>
</thead>
<tbody>
<tr>
<td>The National Patient Register</td>
<td>Cause of death</td>
</tr>
<tr>
<td></td>
<td>Inpatient clinic operations</td>
</tr>
<tr>
<td>The Swedish Cancer Register</td>
<td>Outpatient clinic operations</td>
</tr>
<tr>
<td>The Swedish Medical Birth Register</td>
<td></td>
</tr>
<tr>
<td>The Swedish Pharmaceutical Register</td>
<td></td>
</tr>
<tr>
<td>The Swedish Communes Register for efforts in health care</td>
<td></td>
</tr>
<tr>
<td>The Swedish Dental Health register</td>
<td></td>
</tr>
</tbody>
</table>

*Information available in English.

National quality registers are initiated and administered by health care professionals with different medical specialties. These registers are voluntary, and some hospitals/clinics choose not to report to them. Regarding the patients, the legislation states that patients have an “opt out” option, which means that they are to be informed that they have the option to deny participation. Unless they actively decline participation, the patients can be included. All Swedish counties recommend (and many demand) that their health care providers/clinics participate in these registers.
The first national quality register was the Hip Prosthesis Register, which started as a scientific project in 1967. At present (2019), there are a total of 110 national quality registers in Sweden, all almost exclusively financed by the state, to the total amount of 200 million SEK annually. The state and the Swedish Association of Local Authorities and Regions (SKL) have appointed an organization to control and give grants to the quality registers. The national quality registers therefore have become an integral part of the Swedish hospital system, and a great number of reports are generated using their databases every year. National information about the national quality registers can be found on the website http://kvalitetsregister.se/ with weblinks to all of the registers.

**Terminology used in national quality registers**

In the following, we define the terminology commonly used in, and in connection with, registers.

“Coverage” – the proportion of medical departments (typically, whole hospitals) that report a specific medical intervention to a register, relative to the total number of departments that perform the same intervention. “Coverage” is often confused with “completeness” and “response rate”. Coverage, however, includes only the number of departments reporting to a register; it conveys no information about individual patients.

“Completeness” – the proportion of individual patients who are recorded in the registers, and therefore how many of the total number of treated patients are surveyed.

“Response rate” – the proportion of patients who have completed a questionnaire provided by the register. “High coverage” and “high completeness” do not necessarily mean a high patient response rate. The response rate is a direct marker of the patients’ willingness to be included in the register, how effective the register is in soliciting patient answers, and how well functioning the questionnaire is.

“Incomplete data” and “missing values” – Patients and medical professionals completing a questionnaire or medical form do not always respond to every single item, for whichever reason. This means that there will be missing values and incomplete data for single parameters, which can sometimes make interpretation difficult. It is important to examine the response rate for each item individually, as it can vary widely between items. It should be noted that sometimes data will be falsely denoted as “missing”, and that the response rates will correspondingly be falsely low. This happens if an item requires a certain response in a previous item in order to be relevant to the individual. For example, item A may be “Have you had any postoperative complications?” and question B, “Have you been admitted to hospital because of postoperative problems?” In this case, a “no” response to question A makes question B inapplicable, and a non-response to question B should therefore not be considered a missing value.
“Validation” – The validity of a register cannot be greater than the quality of the individual constituent questionnaires. External validity measures how data have been collected, i.e. it measures the coverage, completeness, and response rate. Internal validity measures whether the patient/health professional has understood the question as intended. Misunderstandings and ambiguous questionnaires yield unreliable results. Questionnaire validation should be patient-centred, and entails testing and retesting the questionnaire by means of in-depth interviews of a large group of relevant patients. The high validity of the register results is maintained by means of retrospective quality control of the recorded responses, as well as suitable questionnaire development and revision.

“Non-response analysis” – Every register has a certain percentage of incomplete data. This varies between registers, and also internally between constituent questionnaires or items. Non-response analysis is centered on the characteristics of the patients who declined to participate, or who passively declined by not completing the questionnaire. Non-response analyses are obligatory for a register. The introduction of bias can be overlooked if these non-responding patients are assumed to be equivalent to those who completed the questionnaire.

**The Swedish National Quality Register for Gynaecological Surgery**

All research in this thesis has been conducted within the framework of GynOp, which is an integral part of the Swedish health care system. This register includes all gynaecological operations performed in Sweden. Since 2006, GynOp has registered prolapse operations on a national scale, including a one-year follow-up of all patients. Today, the register contains complete information on more than 55,000 POP procedures, and the database is increasing by approximately 6,000 new POP operations a year. The data collection process includes both surgeon- and patient-derived data up to one year after the operation.

All patients are included in the register when a urogynaecological operation is decided on. Written informed consent is not needed, according to Swedish law, but the patients are informed that they can decline to be registered in the database.

When the operation is decided, patients complete a pre-operative health declaration form and a validated questionnaire about prolapse symptoms. Two months after the operation, they fill in a postoperative questionnaire about their wellbeing and treatment-related complications. This questionnaire has previously been validated and provides complete post-treatment information. One year after the operation, the patients complete a final questionnaire about any complications that occurred later than two months post-surgery, as well as the results of the operation, and their health status one year postoperatively. The one-year health questionnaire mirrors the pre-operative health declaration,
enabling comparison of patients’ health status before and one year after the operation.

The surgeon completes a form about pre-operative, objective findings, an operation form describing the operation in detail, and a postoperative form at discharge. All three patient questionnaires are reviewed by the operating gynaecologist, who adds his or her evaluation of the patients’ responses and can take action if deemed necessary. The questionnaires and the surgeon’s evaluation are recorded in the register. The reports of operation results are based on the 1-year follow-up. Patients are considered cured if they never or hardly ever had a feeling of genital protrusion postoperatively.

GynOp coverage

Since 2016, all gynaecological departments in Sweden that perform surgery have been participating in the GynOp Register.\textsuperscript{159}

GynOp completeness

Comparison with the Swedish National Patient Register (where all Swedish surgical procedures are registered by law) shows that GynOp’s coverage of Swedish prolapse operations since 2009 has consistently been >95%.\textsuperscript{159}

Response rate

Two-month postoperative follow-up questionnaires for all registered operations in 2016-2018 were answered in 82.6%, 89.4% and 84.1% of cases, respectively, according to SKL data.\textsuperscript{160}

For 2018, when analyzing prolapse operations, the pre-operative health declaration form had a 90% response rate; two month postoperative forms had a 90% response rate; and one-year postoperative questionnaires were answered in 82% of cases.

Incomplete data and missing values

Overall, patients responded to almost all questions with the same high frequency. The least answered questions (intercourse-related questions) had a response rate of around 45%, while the majority of questions were answered in >70% of cases.\textsuperscript{144,161}

Validation

The preoperative health questionnaire has been validated and is well accepted by patients.\textsuperscript{162} The questions about prolapse symptoms has been validated previously.\textsuperscript{46,158} The urological questions are taken from the Norwegian Register of Incontinence Surgery.\textsuperscript{163} All major complications were reported both by the surgeon and by the patient responding to the postoperative questionnaire.\textsuperscript{13}
Patients’ pre-operative health declaration form, postoperative form and one year follow-up questionnaires are scrutinised by surgeons, and used as a tool in patient care. Thus, systematic misunderstandings of patients are screened in this process as well. Over 90% of postoperative questionnaires are evaluated and the evaluation is noted in the register.\textsuperscript{164}

Non-response analysis

The non-response analysis is done within the individual studies conducted using GynOp data. Typically, the patients’ pre-operative health care forms are used as a means to check for homogeneous patient groups.\textsuperscript{144,161,165-167}

Scientific rationale

The scientific rationale for this thesis and its constituent studies is the need for long-term follow-up results after surgery for POP, strict compartment-specific analysis of different surgical methods, and a critical analysis of the impact of surgical experience on operative results.

The existing literature lacks evidence regarding long-term follow-up of compartment- and method-specific POP repair. The literature consists of research that either is of relatively high statistical power, but is based on heterogeneous cases, or is based on homogeneous cases, but is lacking in size and statistical power. Large-scale studies with sufficient power are needed, that examine highly specialized groups without case mix from comorbidities or concomitant surgery. A quality register such as GynOp, with national coverage, provides a large enough database for such a study.

Additionally, we failed to find any previous study focusing on the surgeon’s impact on the operative results of POP repair, rather than on the method used. An investigation of the surgeon’s own impact on the operative results would be possible with information from GynOp where the number of operations per year and surgeon are registered continuously. More knowledge about the importance of the surgeon’s operative experience could help improve the results of surgical POP repair and the practical management of this surgery at a national level.
AIMS

The specific aims of these thesis were to examine:

- Mesh-augmented repairs impact on operative results compared to native tissue repair.

- Surgical experience in performing a specific operation and utilize this knowledge in analysing how it may (or may not) affect operative results.

- Long-term (5 year) national follow up of POP operations, regarding both the objective epidemiological data and the patient-reported outcomes.
METHODS

The four studies comprising this thesis all utilized data extracted from GynOp. The prolapse portion of GynOp contains, to date, information about approximately 55,000 POP procedures in Sweden (see “Background” for more information about the register). Both patient and surgeon-derived data are registered up to 1 year postoperatively. For Study IV (Paper IV), a new questionnaire collecting PROM data 5 years after the original operation was developed.

Data were collected prospectively for these large observational cohort studies. For Study I (Paper I), 6,603 eligible patients who had undergone an operation for a primary, anterior vaginal wall prolapse (cystocele) between January 2006 and September 2013 were identified in GynOp. For Study II (Paper II), 626 eligible patients who had undergone an operation for a relapse of a posterior vaginal wall prolapse (recurrent rectocele) between January 2006 and September 2017 were identified. For Study III (Paper III), 1,092 surgeons who together had performed 14,676 primary POP repairs (for cystocele or rectocele) between January 2006 and January 2016 were identified. For Study IV, data from 32,086 patients who had undergone an operation for a primary prolapse were used for the survival analyses measuring frequency of re-operation. In total 4,380 patient were identified in GynOp and deemed eligible for the long-term follow-up study 5 years after their primary operation.

Papers I & II

In Papers I and II, the outcome of two different surgical procedures, i.e. native tissue repair and repair using non-absorbable polypropylene mesh, was compared in two different populations (patients with a primary cystocele and patients with a rectocele recurrence).

A total of 6,603 consecutively included patients were operated for primary, anterior vaginal wall prolapse between 1 January 2006 and 1 September 2013 in Sweden. The patients were operated using anterior colporrhaphy (n=6,247) or with implantation of a non-absorbable mesh (n=356) (Table 3).
### Table 3. Descriptives of participants with anterior vaginal wall prolapse repaired using classical anterior colporrhaphy or implant. Sweden, 2006-2013.

<table>
<thead>
<tr>
<th></th>
<th>Implant (N = 356)</th>
<th>No implant (N = 6247)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age, years (SD)</strong></td>
<td>65.5 (9.5)</td>
<td>64.9 (10.4)</td>
<td>0.302</td>
</tr>
</tbody>
</table>

**Patient questionnaires**

<table>
<thead>
<tr>
<th>BMI (SD)</th>
<th>Mean</th>
<th>n (%)</th>
<th>Mean</th>
<th>n (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>26.1 (3.5)</td>
<td>36 (10.1)</td>
<td>26.1 (3.6)</td>
<td>595 (9.5)</td>
<td>0.890</td>
</tr>
<tr>
<td>BMI ≥ 30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.721</td>
</tr>
<tr>
<td>Missing</td>
<td>35 (9.8)</td>
<td>665 (11.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.726</td>
</tr>
<tr>
<td>0-2</td>
<td>183 (51.4)</td>
<td>3226 (51.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3+</td>
<td>144 (40.4)</td>
<td>2441 (39.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>29 (8.1)</td>
<td>580 (9.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.326</td>
</tr>
<tr>
<td>Yes</td>
<td>33 (9.3)</td>
<td>579 (9.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>302 (84.8)</td>
<td>5162 (82.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>21 (5.9)</td>
<td>506 (8.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative estrogen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.054</td>
</tr>
<tr>
<td>Yes</td>
<td>161 (45.2)</td>
<td>2481 (39.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>162 (45.5)</td>
<td>2982 (47.7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>33 (9.3)</td>
<td>784 (12.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Surgeon completed forms**

<table>
<thead>
<tr>
<th>Leading edge of the anterior vaginal wall in relation to the hymen (cm) median (range)</th>
<th>Implant</th>
<th>No implant</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>+2 (-3;8)</td>
<td>109</td>
<td>2027</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Degree of prolapse&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (-3 cm)</td>
<td>5 (1.4)</td>
<td>123 (2.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1 (&gt; -3; &lt; -1)</td>
<td>5 (1.4)</td>
<td>240 (3.8)</td>
<td></td>
</tr>
<tr>
<td>2 (≥ -1; ≤ 1)</td>
<td>97 (27.2)</td>
<td>2455 (39.3)</td>
<td></td>
</tr>
<tr>
<td>3/4 (&gt;1)</td>
<td>140 (39.3)</td>
<td>1402 (22.4)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>109 (30.6)</td>
<td>2027 (32.4)</td>
<td></td>
</tr>
</tbody>
</table>

**Number of primary anterior vaginal wall prolapse operations in unit**

|                                | Implant (N = 356) | No implant (N = 6247) | P-value |
|                                | 166 (46.6)        | 3701 (59.2)           | <0.001  |
|                                | 190 (53.4)        | 2546 (40.8)           |         |

*a = Degree of prolapse (+/- cm from hymen)*

All patients operated on for recurrent, posterior vaginal wall prolapse in Sweden between 1 January 2006 and 30 October 2016 were included. A total of 433 women underwent posterior colporrhaphy, and 193 were operated on using non-absorbable mesh (Table 4).
Table 4. Characteristics of participants with recurrent posterior vaginal wall prolapse receiving classic posterior colporrhaphy or mesh implants, Sweden, 2006–2016.

<table>
<thead>
<tr>
<th></th>
<th>Implant (N = 193)</th>
<th>No implant (N = 433)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years (SD)</td>
<td>63.8 (10.4)</td>
<td>58.6 (12.5)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### Patient questionnaires

<table>
<thead>
<tr>
<th></th>
<th>Implant (N = 193)</th>
<th>No implant (N = 433)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (SD)</td>
<td>26.7 (3.7)</td>
<td>26.6 (4)</td>
<td>0.735</td>
</tr>
<tr>
<td>Parity n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-2</td>
<td>84 (52.8%)</td>
<td>171 (52.3%)</td>
<td>0.989</td>
</tr>
<tr>
<td>3+</td>
<td>75 (47.2%)</td>
<td>156 (47.7%)</td>
<td>0.989</td>
</tr>
<tr>
<td>Missing</td>
<td>34 (17.6%)</td>
<td>106 (24.5%)</td>
<td>0.072</td>
</tr>
<tr>
<td>Smoking n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8 (5.1%)</td>
<td>25 (9%)</td>
<td>0.198</td>
</tr>
<tr>
<td>No</td>
<td>149 (94.9%)</td>
<td>253 (91%)</td>
<td>0.198</td>
</tr>
<tr>
<td>Missing</td>
<td>36 (18.7%)</td>
<td>155 (35.8%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pre-operative oestrogen n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>29 (16%)</td>
<td>42 (9.7%)</td>
<td>0.071</td>
</tr>
<tr>
<td>No</td>
<td>164 (94%)</td>
<td>301 (90.3%)</td>
<td>0.071</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

### Surgeon-completed forms

<table>
<thead>
<tr>
<th>Degree of prolapse</th>
<th>Implant (N = 193)</th>
<th>No implant (N = 433)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (-3 cm)</td>
<td>6 (4.5%)</td>
<td>4 (1.7 %)</td>
<td>0.201</td>
</tr>
<tr>
<td>1 (&gt;3 cm to &lt;1 cm)</td>
<td>10 (7.6%)</td>
<td>18 (7.6 %)</td>
<td>1</td>
</tr>
<tr>
<td>2 (≥1 cm to ≤1 cm)</td>
<td>80 (50.0%)</td>
<td>183 (77.5 %)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3/4 (&gt;1 cm)</td>
<td>36 (27.3%)</td>
<td>31 (13.1 %)</td>
<td>0.001</td>
</tr>
<tr>
<td>Missing</td>
<td>61 (31.6%)</td>
<td>187 (45.5%)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

\(\text{a} = \text{Degree of prolapse (± cm from hymen).}\)

The methodology used on the respective materials was identical in the two studies. In both studies, only healthy patients (American Society of Anesthesiologists (ASA) physical status class I or II) were included. Patients were excluded if they had a prolapse in any other vaginal compartment, had undergone a concurrent operation of any kind (including incontinence procedures), or had been operated on using a biological mesh.

Both patient-reported and surgeon-reported information about outcomes was collected from the database. Patient background data and pre-operative symptoms were derived from the pre-operative health declaration form. Patient-reported pain and complications were derived from the patient questionnaire 2 months after the operation. Patient satisfaction, functional parameters, and feeling of protrusion were extracted from the 1-year questionnaire.
Organ damage was reported by the surgeon either during the operation, or at patient discharge or in connection with the surgical 2-month evaluation. All medical complications, including re-operations, were registered by the surgeon, at the very latest in connection with the surgeon’s 1-year evaluation.

The reported 1-year results are a combination of the 2-month and the 1-year questionnaire. We combined this information, controlling for double reporting. This sequential reporting made it possible to distinguish between short-term (within 2 months) and long-term (2 months to 1 year) complications.

**Paper III**

A group of 14,676 patients who had undergone primary anterior, primary posterior, or combined anterior-posterior vaginal wall repair during 9 consecutive years were identified in GynOp (Figure 1).

Patients were excluded if they had a recurrent prolapse, had undergone prolapse surgery in any other compartment, or had any concurrent operations (including incontinence surgery) or if the procedure included the use of mesh. Furthermore, they were excluded if they had an ASA classification of III or more. This resulted in a uniform group of 14,676 healthy patients. They were divided into two cohorts: operated either by a single surgeon (n=8,913) or by a surgeon–assistant team (n=5,763), as shown in Figure 1.
We analysed the results of all surgeons who performed the operation at least once as the main surgeon during the observation period (n=1,092). An “active year” for a surgeon was defined as a calendar year in which she or he was registered at least once as the main surgeon. We defined “surgical volume” as the total number of POP operations in all active years, during which the surgeon acted either as the main surgeon or as the assistant surgeon. “Surgical experience” was subsequently
calculated by dividing surgical volume by the number of active years, and shows the surgeon’s average number of operations per active year. For the performance analysis, surgeons were divided into four groups according to their surgical experience, from between one and six (bottom group) to >24 operations (top group) per active year, and then compared.

Both patient-reported and surgeon-reported outcomes were analysed from the database. Patient-reported pain and complications were derived from the patient questionnaire 2 months after the operation. Patient satisfaction, functional parameters, and feeling of protrusion were extracted from the 1-year questionnaire. Organ damage was reported by the surgeon either during the operation, or at patient discharge or in connection with the surgical 2-month evaluation. All medical complications, including re-operations, were registered by the surgeon, at the very latest in connection with the surgeon’s 1-year evaluation.

Outcome measures

The only symptom specific to POP is the patient’s awareness of a vaginal bulge or protrusion. This is regarded as a valid way of measuring the presence of prolapse. The cure rate, our main outcome measurement, was, therefore, defined in terms of absence or presence of a patient-reported feeling of a genital protrusion 1 year after surgery. In addition, we examined resource parameters (operation time and length of hospital stay), patient-reported parameters (number of days using painkillers at home; patient-reported complications within 2 months requiring medical attention; rehospitalization; and patient-reported satisfaction 1 year after surgery) and surgeon-reported parameters (a composite of all surgeon-reported complications up to 2 months postoperatively; perioperative bleeding; organ damage; and rehospitalization within 1 year).

Paper IV

Register data – risk of retreatment within 5 years

The risk of retreatment was calculated directly from the prolapse section of the GynOp register. A total of 42,446 patients were recorded in the register as having undergone surgery with no previous POP operation. Utilizing the pre-operative health declaration done by both the physician and the patient, we cross-tabulated the questionnaire responses. Cross-tabulation of a patient’s and surgeon’s responses (n=4,629) where a previous operation is already registered for that patient is performed to allow data matching between the patient’s and surgeon’s responses and the register data. The finding that either the patient or the surgeon reports that a previous operation did take place provides confirmation of the register data. In this study, data were correct in 97% of cases, and almost none (0.5%) of the operations did not have data on previous operations.
To create the study database including only the primary patients who underwent native tissue repair, the cross-tabulation results were used to exclude patients for whom a previous operation was reported. Out of the original 41,828 patients, 8,294 (19.8%) were excluded. Additionally, all patients who were operated using surgical mesh were excluded, except in the vaginal apex cohort (n=1448; 3.4%) to avoid case-mix bias.

Finally, except for the vaginal apex cohort, the group consisted solely of primary patients who underwent native tissue repair. This specific group of 32,086 women became our study group, and their register data were used for the survival curve analyses.

**Validation and design of the 5-year questionnaire**

The 5-year questionnaire consisted of both previously validated questions, used routinely for follow-up in GynOp (pre-operative forms and 1-year follow-up), and a set of new questions. All PROMs, as well as the patient-reported feeling of genital bulge or protrusion, came from the previous questionnaire. New questions regarded mainly mesh-specific questions, as well as including a series of questions designed to assess patient-reported re-operation results, and the patient’s own recollection of the type of operation they had undergone.

The 5-year questionnaire validation was done in two rounds, including 40 patients in total (Figure 2). We selected 20 patients at random from GynOp who had been operated 5 years previously. Ten of these patients had been operated using surgical mesh, and 10 using standard colporrhaphy. The patients were contacted by letter, and asked if they would agree to a telephone interview with a researcher from GynOp regarding a new questionnaire. Also, they were asked to give constructive feedback to help improve the questionnaire and make it more user-friendly. Approximately a week after the patients received the letter, they were contacted by telephone, and interviewed regarding comprehensibility of the questions, as well as whether the questions were too indiscreet or in any way offensive, and time and ease of questionnaire completion. The in-depth interviews were done to face-validate the questionnaire, and all questions were scrutinized individually by the patient and interviewer. The interview was around 40 minutes long. This procedure was repeated for a total of two validation rounds.
Figure 2. Flowchart, validation process of the 5 year questionnaire with in-depth telephone interviews (n=24).
The 5-year internet-based questionnaire was released to eligible patients after the validation process was complete.

To find all patients eligible to answer the questionnaire 5 years postoperatively, we first identified all patients at the start of the inclusion period, who had been operated between 5 and maximally 5.9 years previously. After having identified this initial inclusion group, we continuously followed up patients who had been operated 5 years previously, using the existing data in GynOp. During the inclusion period, a total of 9,565 patients were initially identified in the database (Figure 3). Exclusion was done based on a number of local, technical and absolute criteria, such as death, emigration, dementia, malignancy, language barriers, concomitant surgery (such as incontinence procedures) and patients being unreachable. Also, patients re-operated for POP at any point during the follow-up period of 5 years were excluded.

The final patient group eligible for follow-up consisted of 4,380 patients (Figure 3).
Methods | 33

Figure 3. Flowchart showing the selection of participants, and final material for 5-year follow up (n=3283).
The questionnaires were sent out electronically by e-mail, and subsequently as a mailed letter with a reminder, after 2 weeks, of the electronic questionnaire. Finally, if patients had not responded, a complete paper questionnaire was sent to them 4 weeks after the original e-mail. Patients logged in with their social security number, and a unique code that they received from GynOp.

To ensure that the patient-reported results of this study reflected the original native tissue operation and yielded directly clinically applicable results we selected the following groups for the PROM analysis:

- Patients operated with native tissue repair solely for cystocele (n=928).
- Patients operated with native tissue repair solely for rectocele (n=410).
- Patients solely operated for both rectocele and cystocele as a combination (n=444).

The term “solely” is used to mean that no prolapse other than the above stated occurred in any of the patient groups.
ETHICAL CONSIDERATIONS

The Swedish National Register for Gynaecological Surgery is approved by the Regional Ethical Review Board in Umeå, Sweden (Dnr 04-107). All women are informed that their participation is voluntary and that they can decline to be registered. In addition, the studies in this thesis, including the use of data from the GynOp register, were approved by the Regional Ethical Review Board in Umeå (Dnr 08-076 M). Some patients might find specific questions in the follow-up questionnaires, in particular intimate questions about sexuality or incontinence, intrusive. This was taken into consideration when the 5-year follow-up questionnaire was validated through in-depth interviews.

Statistical methods

Papers I & II

We used the chi-square test to analyse categorical data, and the t-test and Mann–Whitney U-test to analyse continuous data. Multiple logistic regression models were constructed to examine the association between type of operation and each of the outcomes. Risks are presented as unadjusted and adjusted odds ratios (ORs) with 95% confidence intervals (CIs), and as unadjusted risk differences (RDs). As potential confounders, we included age (continuous), pre-operative use of oestrogen (yes/no), degree of prolapse (protrusion, in cm, from the hymen) and number of primary anterior vaginal wall prolapse operations, in units/year (≥200/<200). For missing data regarding specific outcomes and covariates, we performed relevant sensitivity analyses.

Paper III

We analysed the material in two steps, using logistic regression and group analysis. The initial analysis applied logistic regression to examine the relationship between surgical experience and surgeon-reported re-operations or patient-reported cure rate. In the subsequent group analysis, data were handled in two ways. When the dependent variable was interval (or quasi-interval)-scaled, a univariate analysis of variance was performed. In those instances where the dependent variable was nominally scaled, a chi-square test for independence was carried out.
**Paper IV**

Survival functions for the time to re-operation was analysed using Kaplan-Meier curves. Observations were censored if no re-operation had occurred at the time of extraction of the data from the register. Statistical analysis was conducted using R v3.5.3 (2019; R Core Team, Vienna, Austria) and SPSS for Windows, version 24.0 (IBM Corp, Armonk, NY, USA).

Student’s t-test was used to compare pre-operative symptoms and PROM results after 5 years. Further, t-test was used for comparison of pre-operative POP symptoms with postoperative answers. These analyses were done using SPSS version 24.0 (SPSS Inc., Chicago, IL, USA).
RESULTS

Paper I

Baseline characteristics of the cohort are presented in Table 3. No significant differences between the patients operated with mesh and those operated with native tissue were found regarding BMI, parity, smoking or use of oestrogen. The patients who underwent a mesh repair had a significantly more advanced prolapse than those who were operated with native tissue.

Mesh patients were satisfied with their operation 12% more often than native tissue patients (OR=2.45), and reported a higher rate of improvement (OR=2.99, RD=9.4%), despite having more complications (OR=1.51, RD=6.6%) (severe enough for the patients to seek medical attention) and indications of more postoperative pain within the first 2 months (Table 5).

Eighty per cent of all reported complications surfaced within 2 months, but only 20% were recorded for between 2 months and 1 year postoperatively. There was no significant difference between mesh and colporrhaphy in the number of complications detected after 2 months. Mesh patients self-administered painkillers for 1.8 days more compared with the colporrhaphy group (p<0.001) and more often reported persisting pain in the loins at 2 months (OR 3.58, RD=5.3%) (Table 5). There seemed to be no difference in functional consequences of the operation between groups when comparing sexuality including the degree of dyspareunia. Most patients improved substantially with regard to urinary incontinence and urge problems, but did so equally in the two groups.
Table 5. Patient reported outcomes: anterior vaginal wall prolapse repaired using classical anterior colporrhaphy or implant. Sweden, 2006-2013.

<table>
<thead>
<tr>
<th>Patient satisfaction</th>
<th>missing</th>
<th>N</th>
<th>n</th>
<th>RD</th>
<th>ORu(^a) (95% CI)</th>
<th>ORA(^b) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction one year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>2177</td>
<td>4070</td>
<td>3186</td>
<td>0.120</td>
<td>2.57 (1.66-3.98)</td>
<td>2.45 (1.58-3.80)</td>
</tr>
<tr>
<td>Implant</td>
<td>120</td>
<td>236</td>
<td>213</td>
<td>0.120</td>
<td>2.57 (1.66-3.98)</td>
<td>2.45 (1.58-3.80)</td>
</tr>
<tr>
<td>Improvement one year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>2802</td>
<td>3445</td>
<td>2947</td>
<td>0.094</td>
<td>3.15 (1.70-5.82)</td>
<td>2.99 (1.62-5.54)</td>
</tr>
<tr>
<td>Implant</td>
<td>140</td>
<td>216</td>
<td>205</td>
<td>0.094</td>
<td>3.15 (1.70-5.82)</td>
<td>2.99 (1.62-5.54)</td>
</tr>
</tbody>
</table>

Patient-reported complications

<table>
<thead>
<tr>
<th>Patient reported complications within two months, with medical attention</th>
<th>missing</th>
<th>N</th>
<th>n</th>
<th>RD</th>
<th>ORu(^a) (95% CI)</th>
<th>ORA(^b) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No implant</td>
<td>885</td>
<td>5362</td>
<td>909</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>37</td>
<td>319</td>
<td>75</td>
<td>0.066</td>
<td>1.51 (1.15-1.97)</td>
<td>1.51 (1.15-1.97)</td>
</tr>
<tr>
<td>Patient reported complications after two month and within one year receiving medical attention (only patients not previously reported)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>2914</td>
<td>3333</td>
<td>229</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>165</td>
<td>191</td>
<td>17</td>
<td>0.020</td>
<td>1.32 (0.79-2.22)</td>
<td>1.40 (0.83-2.36)</td>
</tr>
</tbody>
</table>

Complications needing hospitalization by patient up to two months after surgery

<table>
<thead>
<tr>
<th>Urinary infection post-operatively</th>
<th>missing</th>
<th>N</th>
<th>n</th>
<th>RD</th>
<th>ORu(^a) (95% CI)</th>
<th>ORA(^b) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No implant</td>
<td>3555</td>
<td>892</td>
<td>124</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>288</td>
<td>68</td>
<td>8</td>
<td>-0.021</td>
<td>0.83 (0.39-1.77)</td>
<td>0.74 (0.34-1.60)</td>
</tr>
<tr>
<td>Urinary retention (more than 1 day post operatively up to two months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>414</td>
<td>5833</td>
<td>314</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>15</td>
<td>341</td>
<td>27</td>
<td>0.025</td>
<td>1.52 (1.01-2.26)</td>
<td>1.45 (0.96-2.19)</td>
</tr>
</tbody>
</table>

Patient-reported pain

<table>
<thead>
<tr>
<th>Number of days using pain killers at home after surgery</th>
<th>N</th>
<th>Mean (SD)</th>
<th>Median</th>
<th>Min - max</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No implant</td>
<td>2955</td>
<td>3292 (5.8)</td>
<td>3</td>
<td>0 - 100</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Implant</td>
<td>147</td>
<td>209 (6.2)</td>
<td>5</td>
<td>0 - 60</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Pain in the loin (within two months)

| No implant                                            | 0   | 6247 (140) | 1      |         |         |
| Implant                                               | 0   | 356 (27)   | 0.053  | 3.58 (2.34-5.49) | 3.58 (2.32-5.52) |

Patient reported feeling of genital protrusion (never or hardly ever) one year after surgery

<table>
<thead>
<tr>
<th>Patient-reported pain</th>
<th>NNT</th>
<th>ORu(^a) (95% CI)</th>
<th>ORA(^b) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No implant</td>
<td>4005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>2931</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patient-reported cure rate

<table>
<thead>
<tr>
<th>Patient-reported cure rate</th>
<th>missing</th>
<th>N</th>
<th>n</th>
<th>RD</th>
<th>ORu(^a) (95% CI)</th>
<th>ORA(^b) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant</td>
<td>13.5</td>
<td>242</td>
<td>195</td>
<td>0.074</td>
<td>1.52 (1.10-2.11)</td>
<td>1.53 (1.10-2.13)</td>
</tr>
</tbody>
</table>

There was a difference in surgeon-reported complications (OR=2.27, RD=13.3%) and risk of re-operation (OR=6.87, RD=3.6%) within 1 year, in favour of colporrhaphy. Implant surgery dramatically increased the risk of bladder injury, with an OR of 7.19 (RD=2.4%) (Table 6). A few other incidents of organ damage were reported, which all seemed to be independent of operation type. No fistulas occurred in any of the 6,603 operations. There was a difference regarding the time it took for patients to return to normal activities of daily living (ADLs). Perioperative blood loss, operation time and time in hospital all had better results with colporrhaphy (p<0.001).

The patient-reported cure rate was higher in the mesh group, with an OR of 1.53 (95% CI 1.10-2.13, RD=7.4%), corresponding to a number needed to treat (NNT) of 13.5 (Table 5).

<table>
<thead>
<tr>
<th>Resource parameters</th>
<th>missing</th>
<th>N</th>
<th>Mean (SD)</th>
<th>Median</th>
<th>Min - max</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time (minutes)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>1241</td>
<td>5006</td>
<td>36.8 (15.1)</td>
<td>34</td>
<td>11 - 180</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Implant</td>
<td>34</td>
<td>322</td>
<td>51.5 (22.3)</td>
<td>48</td>
<td>22 - 315</td>
<td></td>
</tr>
<tr>
<td>Time in hospital (days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>232</td>
<td>6015</td>
<td>0.5 (0.8)</td>
<td>0</td>
<td>0 - 10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Implant</td>
<td>11</td>
<td>345</td>
<td>1.2 (1.2)</td>
<td>1</td>
<td>0 - 9</td>
<td></td>
</tr>
<tr>
<td>Medical complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor reported complication within one year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>6247</td>
<td>871</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>356</td>
<td>97</td>
<td>0.133</td>
<td>2.31 (1.81-2.95)</td>
<td>2.27 (1.77-2.91)</td>
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<tr>
<td>Reoperation within one year</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>6247</td>
<td>38</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>356</td>
<td>15</td>
<td>0.036</td>
<td>7.19 (3.92-13.20)</td>
<td>6.87 (3.68-12.80)</td>
</tr>
<tr>
<td>Haemorrhage during operation (ml)</td>
<td></td>
<td></td>
<td>Mean (SD)</td>
<td>Median</td>
<td>Min - max</td>
<td>p-value</td>
</tr>
<tr>
<td>No implant</td>
<td>1207</td>
<td>5040</td>
<td>26.8 (28.5)</td>
<td>20</td>
<td>0 - 550</td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>29</td>
<td>327</td>
<td>73.3 (92.4)</td>
<td>50</td>
<td>0 - 1100</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Organ damage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder lesion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>6247</td>
<td>25</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>356</td>
<td>10</td>
<td>0.024</td>
<td>7.19 (3.43-15.10)</td>
<td>6.71 (3.14-14.33)</td>
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<tr>
<td>Urethral lesion</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>6247</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>356</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intestinal lesion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>6247</td>
<td>3</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>356</td>
<td>1</td>
<td>0.002</td>
<td>5.86 (0.61-56.51)</td>
<td>6.14 (0.62-60.94)</td>
</tr>
<tr>
<td>Vaginal lesion</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>6247</td>
<td>5</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>356</td>
<td>1</td>
<td>0.002</td>
<td>3.52 (0.41-30.18)</td>
<td>3.45 (0.39-30.68)</td>
</tr>
<tr>
<td>Fistulas</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>6247</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>356</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a = Unadjusted
b = Adjusted for age, preoperative estrogen, degree of prolapse and number of primary operations in unit

Paper II

Baseline characteristics of the cohort are presented in Table 4. No significant differences between the patients operated with mesh compared with native tissue were found regarding BMI, parity, smoking or use of oestrogen. The patients who underwent a mesh repair had a more advanced prolapse than those who had native tissue repair.

In patients re-operated for recurrent posterior vaginal wall prolapse, the 1-year cure rate was higher for the mesh group compared with the colporrhaphy group, with an OR of 2.06 (95% CI 1.03-4.35, RD=10.3%), corresponding to an NNT of 9.7 (Table 7). Mesh patients were generally more satisfied (OR=2.38, RD=13.9%) and reported a higher degree of improvement (OR=2.13, RD=16.1%) overall, 1 year after the operation (Table 7). There was no statistical difference in patient-
reported complications, re-admissions due to complications, urinary infection, urinary retention, or postoperative pelvic pain between the two groups (Table 7). The rate of self-administered painkillers reported by the patients was not significantly different between the two groups (Table 7).

**Table 7.** Patient-reported outcomes: recurrent posterior wall prolapse repaired using classic posterior colporrhaphy or a mesh implant, Sweden, 2006–2016.

<table>
<thead>
<tr>
<th>Missing</th>
<th>N</th>
<th>n</th>
<th>RD</th>
<th>ORu&lt;sup&gt;a&lt;/sup&gt; (95% CI)</th>
<th>ORA&lt;sup&gt;b&lt;/sup&gt; (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Satisfaction at one year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No implant</td>
<td>155</td>
<td>433</td>
<td>278</td>
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</tr>
<tr>
<td>Implant</td>
<td>66</td>
<td>193</td>
<td>127</td>
<td>13.9% 1.96 (1.22-3.21) 2.38 (1.2-4.97)</td>
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</tr>
<tr>
<td><strong>Improvement at one year</strong></td>
<td></td>
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<tr>
<td>No implant</td>
<td>202</td>
<td>433</td>
<td>231</td>
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<tr>
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<td>65</td>
<td>193</td>
<td>128</td>
<td>16.1% 2.41 (1.43-4.19) 2.13 (1.02-3.82)</td>
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<tr>
<td><strong>Patient-reported complications</strong></td>
<td></td>
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<tr>
<td>Patient-reported complications within two months, with medical attention sought</td>
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<tr>
<td>No implant</td>
<td>101</td>
<td>433</td>
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<td>Implant</td>
<td>27</td>
<td>193</td>
<td>166</td>
<td>1.2% 1.07 (0.68-1.68) 1.23 (0.58-1.99)</td>
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<td>Patient-reported complications, after two months and within one year, receiving medical attention (only patients not previously reported)</td>
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<td>433</td>
<td>286</td>
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<tr>
<td>Implant</td>
<td>66</td>
<td>193</td>
<td>127</td>
<td>-0.5% 0.97 (0.56-1.67) 0.81 (0.38-1.68)</td>
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<tr>
<td>Complications needing hospitalization of patient up to two months after surgery</td>
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<tr>
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<td>43</td>
<td>111</td>
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<tr>
<td>Implant</td>
<td>21</td>
<td>61</td>
<td>40</td>
<td>5.81% 1.8 (0.63-5.22) 2.15 (0.67-7.87)</td>
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<tr>
<td>Urinary infection post-operatively</td>
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<tr>
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<td>4</td>
<td>433</td>
<td>429</td>
<td>1</td>
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<tr>
<td>Implant</td>
<td>6</td>
<td>193</td>
<td>187</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Urinary retention (more than 1 day post-operatively up to two months)</td>
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<td>17</td>
<td>193</td>
<td>176</td>
<td>1.46% 1.79 (0.57-5.47) 0.99 (0.19-4.31)</td>
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<td><strong>Patient-reported pain</strong></td>
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<tr>
<td>Number of days using painkillers at home after surgery</td>
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<tr>
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<td>197</td>
<td>433</td>
<td>236</td>
<td>6.8 (7.55) 5.0 [2, 10]</td>
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<td>56</td>
<td>193</td>
<td>137</td>
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<td>Pain in the loin (within two months)</td>
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<td>433</td>
<td>329</td>
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<td>Implant</td>
<td>31</td>
<td>193</td>
<td>162</td>
<td>1.26% 1.71 (0.49-5.78) 3.36 (0.77-17.39)</td>
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<td>Patient-reported absence of genital protrusion one year after surgery (patient-reported cure rate)</td>
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<td>158</td>
<td>433</td>
<td>275</td>
<td>10.3% 1.80 (1.07-3.12) 2.06 (1.03-4.35)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> = unadjusted.

<sup>b</sup> = adjusted for age, preoperative oestrogen, and degree of prolapse.

N = number of patients, eligible to answer a specific question.

N = number of eligible patients, who answered the question.

N/A = not applicable, OR = odds ratio, RD = risk difference, SD = standard deviation.

Fewer surgeon-reported minor medical complications within 12 months were reported with colporrhaphy (OR = 2.74, RD=11.71%) (Table 8). Operation time and time in hospital were shorter (around 2.5 minutes and 1/3 day, respectively) for patients in the posterior colporrhaphy group. Re-operation rates within 1 year and perioperative bleeding were comparable for the two groups (Table 8). No other organ damage, and no recto-vaginal fistulas occurred in any of the 626 operations.
**Table 8.** Surgeon-reported parameters: recurrent posterior wall prolapse repaired using classic posterior colporrhaphy or a mesh implant, Sweden, 2006–2016.

<table>
<thead>
<tr>
<th>Resource parameters</th>
<th>Missing</th>
<th>n</th>
<th>N</th>
<th>Mean (SD)</th>
<th>Median [25%, 75%]</th>
<th>p-value</th>
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<td><strong>Operation time (minutes)</strong></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>No implant</td>
<td>51</td>
<td>382</td>
<td>433</td>
<td>44.34</td>
<td>22.4</td>
<td>0.006</td>
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<td>155</td>
<td>193</td>
<td>46.88</td>
<td>16.6</td>
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<tr>
<td><strong>Time in hospital (days)</strong></td>
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<td>No implant</td>
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<td>427</td>
<td>433</td>
<td>0.71</td>
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<td>&lt;0.001</td>
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<td>185</td>
<td>193</td>
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<td>0.9</td>
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**Medical complications**

<table>
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<tr>
<th>Resource parameters</th>
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<th>N</th>
<th>n</th>
<th>RD</th>
<th>OR&lt;sup&gt;a&lt;/sup&gt; (95% CI)</th>
<th>OR&lt;sup&gt;b&lt;/sup&gt; (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon-reported complications (minor) within one years</td>
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<tr>
<td>No implant</td>
<td>0</td>
<td>433</td>
<td>433</td>
<td></td>
<td>11.71%</td>
<td>2.18 (1.42–3.35)</td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>193</td>
<td>193</td>
<td></td>
<td>2.27 (0.53–9.69)</td>
<td>4.99 (0.88-39.4)</td>
</tr>
<tr>
<td>Reoperation within one years</td>
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<td></td>
</tr>
<tr>
<td>No implant</td>
<td>0</td>
<td>433</td>
<td>433</td>
<td></td>
<td>1.15</td>
<td>2.27 (0.53–9.69)</td>
</tr>
<tr>
<td>Implant</td>
<td>0</td>
<td>193</td>
<td>193</td>
<td></td>
<td>2.27 (0.53–9.69)</td>
<td>4.99 (0.88-39.4)</td>
</tr>
<tr>
<td>Haemorrhage during operation (ml)</td>
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<tr>
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<td>0</td>
<td>433</td>
<td>34</td>
<td>37.1</td>
<td>25</td>
<td>1.15</td>
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<td>193</td>
<td>38</td>
<td>28.3</td>
<td>25</td>
<td>1.15</td>
</tr>
<tr>
<td>Organ damage</td>
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<td>RD</td>
<td>OR&lt;sup&gt;a&lt;/sup&gt; (95% CI)</td>
<td>OR&lt;sup&gt;b&lt;/sup&gt; (95% CI)</td>
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<td>Bladder lesion</td>
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<tr>
<td>Intestinal lesion</td>
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<td>Vaginal lesion</td>
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<tr>
<td>Fistula</td>
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<td></td>
<td></td>
<td>N/A</td>
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</table>

<sup>a</sup> = Unadjusted.  
<sup>b</sup> = Adjusted for age, preoperative oestrogen and degree of prolapse.  
CI = confidence interval; OR = odds ratio; RD = risk difference; SD = standard deviation.

The type of operation did not seem to have an impact on functional urogynaecological parameters. Patient-reported urinary incontinence 1 year after the operation was comparable in the two groups (Table 9). *De novo* defaecation problems, as well as patient-reported worsening of symptoms, were similar in both groups (Table 7). Changes in sexuality (continued, stopped, or started having penetrating sex after the operation), degree of dyspareunia and the time to return to normal daily life were the same in both groups (Table 9).

<table>
<thead>
<tr>
<th>Functional parameters</th>
<th>Missing</th>
<th>N</th>
<th>n</th>
<th>RD</th>
<th>ORa (95% CI)</th>
<th>ORb (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Started having sexual intercourse (patients who did not engage in intercourse before the operation)</td>
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</tr>
<tr>
<td>No implant</td>
<td>208</td>
<td>433</td>
<td>225</td>
<td>-1.8%</td>
<td>0.75 (0.26-1.87)</td>
<td>1.47 (0.4-4.96)</td>
</tr>
<tr>
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<td>89</td>
<td>193</td>
<td>104</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stopped having sexual intercourse (patients who reported engaging in intercourse before surgery)</td>
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</tr>
<tr>
<td>No implant</td>
<td>208</td>
<td>433</td>
<td>225</td>
<td>5.2%</td>
<td>2.10 (0.88-4.96)</td>
<td>1.10 (0.33-3.43)</td>
</tr>
<tr>
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<td>89</td>
<td>193</td>
<td>104</td>
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<tr>
<td>Dyspareunia, improved or symptom-free</td>
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<tr>
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<td>348</td>
<td>433</td>
<td>85</td>
<td>4.71%</td>
<td>1.38 (0.48-3.76)</td>
<td>1.35 (0.16-8.52)</td>
</tr>
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<td>158</td>
<td>193</td>
<td>35</td>
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<td>Dyspareunia, worsened</td>
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<td></td>
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<td></td>
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<tr>
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<td>433</td>
<td>85</td>
<td>-1.51%</td>
<td>0.87 (0.23-2.76)</td>
<td>2.04 (0.36-9.93)</td>
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<td>35</td>
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<tr>
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<td>433</td>
<td>85</td>
<td>4.71%</td>
<td>1.38 (0.48-3.76)</td>
<td>1.35 (0.16-8.52)</td>
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<td>193</td>
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<td>Urinary incontinence, improved</td>
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<td></td>
</tr>
<tr>
<td>No implant</td>
<td>205</td>
<td>433</td>
<td>228</td>
<td>-1.8%</td>
<td>0.91 (0.53-1.53)</td>
<td>0.80 (0.40-1.57)</td>
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<td>Urinary incontinence, worsened</td>
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<td>-3.16%</td>
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<td>0.98 (0.31-2.77)</td>
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<td>Urinary incontinence, de novo</td>
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<tr>
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<td>433</td>
<td>228</td>
<td>5.9%</td>
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<td>1.76 (0.73-4.23)</td>
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<td>0.88 (0.45-1.68)</td>
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<td>433</td>
<td>221</td>
<td>-5.39%</td>
<td>0.57 (0.25-1.2)</td>
<td>0.67 (0.2-2.8)</td>
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<tr>
<td>Urge problems, de novo</td>
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<tr>
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<td>232</td>
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<td>Defecation problems, de novo</td>
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<tr>
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<td>232</td>
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<td>1.8 (0.79-4.03)</td>
<td>1.98 (0.61-6.68)</td>
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<tr>
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<td>[1, 7]</td>
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<td>144</td>
<td>4.9</td>
<td>3</td>
<td>[1, 7]</td>
<td>0.966</td>
</tr>
</tbody>
</table>

a = unadjusted.
b = adjusted for age, preoperative oestrogen, and degree of prolapse.
N = number of patients, eligible to answer a specific question.
N = number of eligible patients, who answered the question.
CI = confidence interval, N/A = not applicable, OR = odds ratio, RD = risk difference, SD = standard deviation.
**Paper III**

Data from the GynOp database show that, out of 1,092 surgeons who were active POP surgeons during 2006-2014, altogether 803 (73%) participated in POP operations once a month or less often in their active years.

In the single-surgeon cohort, patient characteristics were statistically comparable for all parameters except for minor differences in age, degree of prolapse, and pre-operative oestrogen use. There was a maximum of 8 mm difference in prolapse size, and the larger degrees of prolapse were in the group operated by the most experienced surgeons. The largest difference in mean age between groups was 2.4 years. The patient group operated by the most experienced surgeons used oestrogen supplements up to 8.1% less frequently than the least experienced group, and 6.1% less often than both other groups. The surgeon–assistant cohorts were comparable on all parameters.

The logistic regression analysis showed no association between surgical experience and surgeon-reported complications for both cohorts (p=0.463 and p=0.128 for single-surgeon and surgeon-assistant cohorts, respectively). Likewise, no association was found between surgical experience and patient-reported cure rate 1 year after the operation (p=0.195 and p=0.128 for the single-surgeon and surgeon-assistant cohorts, respectively). Hence, regarding the main outcome, no effect of surgeon’s operative experience was found.

**Single-surgeon cohort**

Subsequent group analysis showed an impact of surgical experience on resource parameters. Both the duration of the procedure and the length of the hospital stay were substantially reduced with increased surgical experience (Table 10). Further, surgeon-reported parameters showed that perioperative blood loss was reduced with increased surgical experience. There was no difference in surgeon-reported number of complications across the four surgical experience groups or in re-operation rates (Table 10). No specific complication was more prevalent in any of the groups, regardless of surgical experience. There were very few instances of organ damage, and those that did occur were evenly distributed among the experience groups (Table 10). However, patient-reported duration, in days, of using painkillers at home was associated with surgical experience and was lower with increasing experience of the surgeon (Table 11). All other patient-reported parameters, including patient satisfaction, rehospitalization, and patient-reported complications, were not affected by the surgeon’s frequency of performing the procedure (Table 11). Patient-reported cure rate after 1 year was not associated with surgical experience (Table 11).
## Table 10. Surgeon-reported outcomes of single-surgeon operations.

<table>
<thead>
<tr>
<th>Surgical experience (number of operations per active year)</th>
<th>≤6</th>
<th>&gt;6 and &lt;12</th>
<th>≥12 and &lt;24</th>
<th>≥24</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative bleeding (ml)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>32.97</td>
<td>30.26</td>
<td>29.33</td>
<td>31.08</td>
<td>0.004</td>
</tr>
<tr>
<td>SD</td>
<td>37.26</td>
<td>32.53</td>
<td>34.08</td>
<td>29.42</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>2092</td>
<td>2887</td>
<td>2172</td>
<td>580</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2517</td>
<td>3232</td>
<td>2488</td>
<td>676</td>
<td></td>
</tr>
<tr>
<td>Reoperation due to complications within one year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>0.8%</td>
<td>0.7%</td>
<td>0.7%</td>
<td>0.7%</td>
<td>0.926</td>
</tr>
<tr>
<td>95% CI</td>
<td>(0.5-1.3)</td>
<td>(0.4-1.0)</td>
<td>(0.4-1.1)</td>
<td>(0.2-1.7)</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2214</td>
<td>2748</td>
<td>2243</td>
<td>615</td>
<td></td>
</tr>
<tr>
<td>Surgeon-reported complication (of any kind) within one year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>16.0%</td>
<td>15.5%</td>
<td>14.3%</td>
<td>13.5%</td>
<td>0.219</td>
</tr>
<tr>
<td>95% CI</td>
<td>402</td>
<td>502</td>
<td>357</td>
<td>91</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2214</td>
<td>2748</td>
<td>2243</td>
<td>615</td>
<td></td>
</tr>
<tr>
<td>Organ damage (perforation: bladder, urethra, or intestine)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.0%</td>
<td>0.752</td>
</tr>
<tr>
<td>95% CI</td>
<td>(0.01-0.3)</td>
<td>(0.01-0.22)</td>
<td>(0.025-0.35)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2517</td>
<td>3232</td>
<td>2488</td>
<td>676</td>
<td></td>
</tr>
<tr>
<td>Operation time (min)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>42.31</td>
<td>41.33</td>
<td>37.18</td>
<td>29.01</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>18.231</td>
<td>17.970</td>
<td>16.945</td>
<td>13.426</td>
<td>0.000</td>
</tr>
<tr>
<td>n</td>
<td>2078</td>
<td>2908</td>
<td>2159</td>
<td>576</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2517</td>
<td>3232</td>
<td>2488</td>
<td>676</td>
<td></td>
</tr>
<tr>
<td>Time in hospital (days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0.64</td>
<td>0.47</td>
<td>0.43</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>.840</td>
<td>.848</td>
<td>.699</td>
<td>.474</td>
<td>0.000</td>
</tr>
<tr>
<td>n</td>
<td>2381</td>
<td>3159</td>
<td>2437</td>
<td>663</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2517</td>
<td>3232</td>
<td>2488</td>
<td>676</td>
<td></td>
</tr>
</tbody>
</table>

95% CI = 95% confidence interval; n = number of patients with available information; N = total number of participants in each group; SD = standard deviation.

## Table 11. Patient-reported outcomes of single-surgeon operations.

<table>
<thead>
<tr>
<th>Surgical experience (Number of operations per active year)</th>
<th>≤6</th>
<th>&gt;6 and &lt;12</th>
<th>≥12 and &lt;24</th>
<th>≥24</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of days using painkillers at home after the surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>4.65</td>
<td>4.55</td>
<td>4.61</td>
<td>3.52</td>
<td>0.004</td>
</tr>
<tr>
<td>SD</td>
<td>7.13</td>
<td>6.13</td>
<td>5.95</td>
<td>6.06</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>1639</td>
<td>2301</td>
<td>1761</td>
<td>490</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2517</td>
<td>3232</td>
<td>2488</td>
<td>676</td>
<td></td>
</tr>
<tr>
<td>Patient-reported complications within two months with medical attention sought</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>20.0%</td>
<td>18.1%</td>
<td>18.4%</td>
<td>15.9%</td>
<td>0.104</td>
</tr>
<tr>
<td>95% CI</td>
<td>(18.3-21.8)</td>
<td>(16.7-19.6)</td>
<td>(16.8-20.1)</td>
<td>(13.1-19.1)</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>2099</td>
<td>2788</td>
<td>2175</td>
<td>603</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2517</td>
<td>3232</td>
<td>2488</td>
<td>676</td>
<td></td>
</tr>
<tr>
<td>Complications needing hospitalization up to two months after surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>4.2%</td>
<td>3.7%</td>
<td>2.9%</td>
<td>3.1%</td>
<td>0.142</td>
</tr>
<tr>
<td>95% CI</td>
<td>(3.4-5.2)</td>
<td>(2.9-4.5)</td>
<td>(2.2-3.7)</td>
<td>(1.8-4.9)</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>1915</td>
<td>2561</td>
<td>2025</td>
<td>553</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2517</td>
<td>3232</td>
<td>2488</td>
<td>676</td>
<td></td>
</tr>
<tr>
<td>Satisfaction, one year after the surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>77.1%</td>
<td>74.8%</td>
<td>77%</td>
<td>73.3%</td>
<td>0.139</td>
</tr>
<tr>
<td>95% CI</td>
<td>(75.0-79.1)</td>
<td>(72.9-76.6)</td>
<td>(75.0-79.0)</td>
<td>(69.4-77.8)</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>1740</td>
<td>2167</td>
<td>1760</td>
<td>471</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2214</td>
<td>2748</td>
<td>2243</td>
<td>615</td>
<td></td>
</tr>
<tr>
<td>Patient-reported feeling of genital protrusion, one year after surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>74.0%</td>
<td>72.8%</td>
<td>73.2%</td>
<td>71.8%</td>
<td>0.765</td>
</tr>
<tr>
<td>95% CI</td>
<td>(71.8-76.7)</td>
<td>(70.8-74.7)</td>
<td>(70.9-75.2)</td>
<td>(67.6-75.8)</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>1743</td>
<td>2124</td>
<td>1721</td>
<td>479</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2214</td>
<td>2748</td>
<td>2243</td>
<td>615</td>
<td></td>
</tr>
</tbody>
</table>

Satisfaction and failure rate results are taken from the one year questionnaire, covering operations from January 1st, 2006, to December 31st, 2015. 95% CI = 95% confidence interval; n = number of patients with available information; N = total number of participants in each group; SD = standard deviation.
Surgeon & assistant cohort

The assistant’s experience did not influence perioperative blood loss, surgeon-reported complications or re-operation rates (Table 12). Neither presence of patient-reported complications, nor patient satisfaction or cure rate, was affected by the assistant’s experience (Table 12).

Table 12. Surgeon-reported and Patient-reported outcomes of operations performed by surgeon-assistant teams.

<table>
<thead>
<tr>
<th>Surgeon-reported outcomes</th>
<th>Surgical experience of main surgeon: ≤12 operations/year</th>
<th>Assistant performing ≤6 POP operations/year as main surgeon</th>
<th>Assistant performing ≥24 POP operations/year as main surgeon</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative bleeding (ml)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>30.32</td>
<td>35.23</td>
<td></td>
<td>0.494</td>
</tr>
<tr>
<td>SD</td>
<td>33.45</td>
<td>14.92</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>576</td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperation within one year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>1.4%</td>
<td>0.0%</td>
<td></td>
<td>0.544</td>
</tr>
<tr>
<td>95% CI</td>
<td>(0.65-2.68)</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgeon-reported complication (of any kind) within one year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>15.1%</td>
<td>11.5%</td>
<td></td>
<td>0.619</td>
</tr>
<tr>
<td>95% CI</td>
<td>(12.4-18.1)</td>
<td>(2.4-30.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organs damage (Perforation: Bladder, urethra, or intestine)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>0%</td>
<td>0%</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>95% CI</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>643</td>
<td>26</td>
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<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient-reported outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of days using painkillers at home after surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mean</td>
<td>4.75</td>
<td>6.44</td>
<td></td>
<td>0.344</td>
</tr>
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<td>SD</td>
<td>0.310416667</td>
<td>0.471527778</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>455</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient-reported complications within two months, with medical attention sought</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>21.6%</td>
<td>31.8%</td>
<td></td>
<td>0.250</td>
</tr>
<tr>
<td>95% CI</td>
<td>(13.9-54.9)</td>
<td>(13.9-54.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>565</td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complications needing hospitalization up to two months after surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>2.7%</td>
<td>5.0%</td>
<td></td>
<td>0.586</td>
</tr>
<tr>
<td>95% CI</td>
<td>(1.5-4.5)</td>
<td>(0.1-24.9)</td>
<td></td>
<td></td>
</tr>
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<td>n</td>
<td>512</td>
<td>20</td>
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<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient-reported satisfaction, one year after the surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>72.1%</td>
<td>60.0%</td>
<td></td>
<td>0.241</td>
</tr>
<tr>
<td>95% CI</td>
<td>(63.1-80.9)</td>
<td>(61.1-82.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>462</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient-reported feeling of genital protrusion, one year after surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, %</td>
<td>70.7%</td>
<td>56.5%</td>
<td></td>
<td>0.146</td>
</tr>
<tr>
<td>95% CI</td>
<td>(68.3-74.9)</td>
<td>(23.2-65.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>458</td>
<td>23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>643</td>
<td>26</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Satisfaction and failure rate results are taken from the 1-year questionnaire, covering operations from January 1st, 2006, to December 31st, 2015. 95% CI = 95% confidence interval; n = number of patients with available information; N = total number of participants in each group; POP = pelvic organ prolapse; SD = standard deviation.

All outcomes are for otherwise healthy patients operated by an inexperienced main surgeon (performing no more than twelve colporrhaphy operations per active year) and an assistant surgeon. Results are stratified by the assistant surgeon’s experience as main surgeon.
Paper IV

The baseline characteristics of patients (n=32,086) used in the Kaplan-Meier analysis are shown in Table 13. Rectocele patients were on average 3-5 years younger than the women in the other groups. The vaginal apex operations took significantly longer (around 35 minutes more). The rectocele group included 3-4% more patients with chronic cough and asthma, and a higher number of patients currently employed (around 20%). Parity, active smoking, regular physical work, BMI, and ASA scores were comparable between groups. When observing all types of POP pooled together (n=32,086), there was a total survival probability of cure from the primary operation of 88.8%, (95% CI [88.4-89.2]) (Figure 4).

Table 13. Baseline characteristics of the study cohort (n=32 086) at the time of the original, primary operation for pelvic organ prolapse.

<table>
<thead>
<tr>
<th></th>
<th>Cystocele</th>
<th>Rectocele</th>
<th>Vaginal apex</th>
<th>Remaining typesa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=13 809)</td>
<td>(n=5846)</td>
<td>(n=4533)</td>
<td>(n=7898)</td>
</tr>
<tr>
<td>Age (mean yrs, 95% CI)</td>
<td>64.8 (64.8-64.9)</td>
<td>57.1 (56.8-57.5)</td>
<td>63.5 (63.2-63.8)</td>
<td>4533 0</td>
</tr>
<tr>
<td>ASA score (mean, 95% CI)</td>
<td>1.53 (1.52-1.54)</td>
<td>1.48 (1.47-1.49)</td>
<td>1.59 (1.57-1.61)</td>
<td>5770 1.3</td>
</tr>
<tr>
<td>Parity (mean no, 95% CI)</td>
<td>2.45 (2.43-2.46)</td>
<td>2.52 (2.49-2.55)</td>
<td>2.52 (2.49-2.55)</td>
<td>5026 13.3</td>
</tr>
<tr>
<td>BMI (95% CI)</td>
<td>26.0 (25.9-26.1)</td>
<td>26.5 (26.4-26.6)</td>
<td>25.8 (25.7-25.9)</td>
<td>5008 14.3</td>
</tr>
<tr>
<td>Active smokers (%, 95% CI)</td>
<td>9.2 (8.70-9.70)</td>
<td>9.4 (8.6-10.2)</td>
<td>9.4 (8.5-10.3)</td>
<td>5181 11.4</td>
</tr>
<tr>
<td>Chronic coughing or asthma (%), 95% CI)</td>
<td>15.7 (15.1-16.3)</td>
<td>20.3 (19.2-21.4)</td>
<td>15.7 (14.6-16.8)</td>
<td>5159 11.8</td>
</tr>
<tr>
<td>Currently employed (%, 95% CI)</td>
<td>42.0 (41.4-42.9)</td>
<td>56.0 (54.6-57.4)</td>
<td>44.0 (42.4-45.6)</td>
<td>4838 17.2</td>
</tr>
<tr>
<td>Pensioners (%, 95% CI)</td>
<td>43.0 (42.1-43.9)</td>
<td>24.0 (22.8-25.2)</td>
<td>44.0 (42.4-45.6)</td>
<td>4838 17.2</td>
</tr>
<tr>
<td>Heavy physical labour (%, 95% CI)</td>
<td>18.0 (17.3-18.7)</td>
<td>21.0 (19.9-22.1)</td>
<td>21.0 (19.8-22.2)</td>
<td>5262 10.0</td>
</tr>
<tr>
<td>Operation time (no. of min, 95% CI)</td>
<td>45 (45-46)</td>
<td>47 (46-48)</td>
<td>5300 9.3</td>
<td>81 (80-82)</td>
</tr>
</tbody>
</table>
Figure 4. Shows a survival curve, of all primary POP operations in the GynOp register, representing the overall reoperation rate for all types of prolapse operations, with or without mesh.

For primary operations done only in the anterior compartment (n=13,089), which is by far the largest group, the 5-year survival probability of a primary operation was 88%, (95% CI [87.7-88.9]). Stratifying for the site of re-operation showed that the most common re-operation was performed in the same (anterior) compartment, as seen in 7.9%, (95% CI [7.4-8.4]) of patients. Re-operation involving a de novo prolapse occurred in 4.1% (95% CI [3.7-4.5]) of cases (Figure 5).
Figure 5. Survival curves for primary patients, operated with native tissue repair, solely for cystocele. The curves have been split up, to represent the risk of either a relapse in the same compartment, or a de-novo prolapse in a different vaginal compartment.
For primary operations done only in the posterior compartment (n=5,846), the 5-year survival probability was 88.5% (95% CI [87.8-89.9]) (Figure 6). Rather than anterior repair, the most common site for re-operation was another compartment (de novo prolapse), which occurred in 8.0% (95% CI [7.2-8.9]) of patients. Re-operation involving the posterior compartment occurred in only 3.5% (95% CI [2.9-4.1]) of cases.

**Figure 6.** Survival curves for primary patients, operated with native tissue repair, solely for rectocele. The curves have been split up, to represent the risk of either a relapse in the same compartment, or a de-novo prolapse in a different vaginal compartment.
A combination of anterior and posterior repair, with or without concurrent cervix surgery (n=5,502), is considered the “classical Manchester operation”. The 5-year survival probability for this procedure was 91%, (95% CI [90-91.9]) (Figure 7).

Figure 7. Survival curve of patients operated with a Combination of posterior and anterior native tissue repair, with or without cervical amputation.
Primary vaginal apex operations (n=4,533) can be performed in several different ways, using the open, laparoscopic or vaginal approach, with and without mesh, and various fixations to anatomical structures. All vaginal apex operations are pooled into one group. The overall 5-year survival for vaginal apex re-operations was 87.1% (95% CI [86.0-88.2]) (Figure 8).

![Figure 8. Survival curves for primary patients, operated for vaginal apex prolapse. Patients were operated using various techniques, including surgical implants, representing the overall survival of patients operated within the surgical praxis used in Sweden.]

The remaining primary vaginal POP operations, with or without concurrent surgery, represent a minority of all the operations performed (n=2,396) and exclude the previous groups of sole anterior, sole posterior, combined posterior/anterior, and vaginal apex operations. None of these were operated using surgical mesh or other implants. This group were operated for: anterior compartment cystocele (n=288; 12%) or posterior compartment (rectocele) (n=1,103; 46%), combined with either incontinence or enterocele surgery; colpocleisis (n=216; 9%); or total hysterectomy (n=522; 22%), in 41 cases combined with enterocele. A total of 267 cases (11%) were not possible to classify. For this more heterogeneous group, the 5-year survival rate for re-operation was 89% (95% CI [88.1-90.7]) (Figure 9).
Figure 9. Remaining after all previous groups have been excluded, were anterior or posterior repair, combined with incontinence or enterocele surgery, colpokleisis, hysterectomies (on indication of prolapse) and a small group of unclassified patients. This curve therefore represents all remaining types of POP operations, including combinations.

Five-year follow-up by questionnaire: validation

After the primary validation round, major revisions were made regarding new, mesh-specific questions. All in all, five questions were changed. In the second round only minor changes were made, and therefore additional validation was not deemed necessary (Figure 2). During both validation rounds, none of the previously used questions, transferred directly from the 1-year questionnaire, was criticized by any patient during the systematic validation and therefore the questions were left unchanged throughout the entire validation process. A drop-out analysis was performed and showed that excluded patients were similar on all parameters to the patients included in the study, the only exception being the lack of an e-mail address, and the finding that the mean age of excluded patients was slightly higher (2 years). The overall response rate was 74.9%, yielding a final cohort of 3,283 patients who completed the 5-year questionnaire (Figure 3). There was an equally compliant response rate, regardless of whether follow-up was done using electronic questionnaires or by letter (as was done with mesh patients who did not have an electronic address). The physical letters were
answered in 76.4% of cases, and electronic follow-up had a participation rate of 74.4%.

Five years after the operation, primary cystocele patients (n=928) reported a cure rate of 68.2%. Patients were satisfied or very satisfied with the 5-year results in 75.5% of cases. Similarly, there was a high rate of improvement of symptoms compared with the situation prior to the operation (83.1%). Patient-reported urinary symptoms, defaecation problems, sexual activity, and occurrence of vaginal chafing are presented in the first column of Table 14.

The cure rate reported by primary rectocele patients (n=410) 5 years after the operation was 70.2%. The patients in this group were satisfied or very satisfied with the result of the operation in 70.2% of cases. The improvement of symptoms (compared with pre-operatively) was 78.3%. Patient-reported urinary symptoms, defaecation problems, sexual activity, and occurrence of vaginal chafing are presented in the second column of Table 14.

Women operated with native tissue repair for a combination of anterior and posterior prolapse (n=444) reported a cure rate of 74.4%, 5 years after the operation. They were satisfied or very satisfied with the 5-year result in 73.2% of cases. The reported rate of improvement of symptoms (compared with pre-operatively) was 82.2%. Patient-reported urinary symptoms, defaecation problems, sexual activity and occurrence of vaginal chafing are presented in the third column of Table 14.

For the three groups above, urinary and/or defaecation problems varied, both in intensity and in the proportion of patients who experienced them (Table 14). Overall, 95.2% of the patients had reported a feeling of vaginal bulging or protrusion as a significant symptom in the pre-operative health questionnaire. A highly significant reduction of this core symptom was established for the whole cohort of women with POP in this study (p<0.001) (Table 14).

Compared with symptom frequency reported in the pre-operative health questionnaire, the 5-year follow-up revealed that all urinary symptoms were significantly reduced after a cystocele operation (p<0.001); defaecation problems were significantly reduced after a rectocele operation (p<0.001); and sexual activity was reduced 5 years postoperatively regardless of operation type.

A total of 4.8% of patients stated in the pre-operative health questionnaire that they had no genital bulging.

The paired t-test was highly significant with regard to a decrease in vaginal bulging pre-operatively, versus 5 years after the operation (p<0.001), corresponding to the results of the PROM data in Table 14.
<table>
<thead>
<tr>
<th>PROM</th>
<th>Cystocele (n=928)</th>
<th>n</th>
<th>Missing n (%)</th>
<th>Rectocele (n=410)</th>
<th>n</th>
<th>Missing n (%)</th>
<th>Combination (n=444)</th>
<th>n</th>
<th>Missing n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure rate (%), 95% CI</td>
<td>68.2 (65.2-71.2)</td>
<td>917</td>
<td>11 (1.2)</td>
<td>70.2 (65.7-74.7)</td>
<td>404</td>
<td>6 (1.5)</td>
<td>74.4 (70.3-78.5)</td>
<td>441</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>Overall satisfied with the operation (%), 95% CI</td>
<td>75.5 (72.7-78.3)</td>
<td>924</td>
<td>4 (0.4)</td>
<td>70.2 (65.8-74.6)</td>
<td>408</td>
<td>2 (0.5)</td>
<td>73.2 (69.1-77.4)</td>
<td>437</td>
<td>7 (1.6)</td>
</tr>
<tr>
<td>Symptoms improved (%), 95% CI</td>
<td>63.1 (80.7-85.5)</td>
<td>924</td>
<td>4 (0.4)</td>
<td>78.3 (74.3-82.3)</td>
<td>409</td>
<td>1 (0.2)</td>
<td>82.2 (78.6-85.8)</td>
<td>438</td>
<td>6 (1.4)</td>
</tr>
<tr>
<td>Vaginal chafing (%), 95% CI</td>
<td>12.8 (10.6-14.9)</td>
<td>919</td>
<td>9 (1.0)</td>
<td>18.7 (14.9-22.5)</td>
<td>406</td>
<td>4 (1.0)</td>
<td>13.1 (10.0-16.3)</td>
<td>440</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>Voiding difficulties (%), 95% CI</td>
<td>28.7 (25.8-31.6)</td>
<td>918</td>
<td>10 (1.1)</td>
<td>33.6 (29.0-38.2)</td>
<td>406</td>
<td>4 (1.0)</td>
<td>60.4 (55.8-64.9)</td>
<td>438</td>
<td>6 (1.4)</td>
</tr>
<tr>
<td>Urinary incontinence (%), 95% CI</td>
<td>32.1 (29.1-35.1)</td>
<td>919</td>
<td>9 (1.0)</td>
<td>44.4 (39.6-49.2)</td>
<td>407</td>
<td>3 (0.7)</td>
<td>34.7 (30.3-39.2)</td>
<td>440</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>Urgency (%), 95% CI</td>
<td>48.5 (45.3-51.7)</td>
<td>917</td>
<td>11 (1.2)</td>
<td>55.1 (50.3-59.9)</td>
<td>407</td>
<td>3 (0.7)</td>
<td>52.4 (47.7-57.0)</td>
<td>441</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>Defecation problems (%), 95% CI</td>
<td>29.8 (26.8-32.8)</td>
<td>915</td>
<td>13 (1.4)</td>
<td>50.7 (45.8-55.6)</td>
<td>406</td>
<td>4 (1.0)</td>
<td>39.2 (34.6-43.8)</td>
<td>440</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>Sexually active (%), 95% CI</td>
<td>43.4 (40.2-46.6)</td>
<td>915</td>
<td>13 (1.4)</td>
<td>56.3 (51.5-61.1)</td>
<td>407</td>
<td>3 (0.7)</td>
<td>52.0 (47.3-56.7)</td>
<td>440</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>Dyspareunia (%), 95% CI</td>
<td>10.7 (7.7-13.7)</td>
<td>401</td>
<td>2 (0.5)</td>
<td>21.3 (16.0-26.6)</td>
<td>231</td>
<td>0</td>
<td>18.1 (13.1-23.1)</td>
<td>229</td>
<td>10 (0.9)</td>
</tr>
</tbody>
</table>
GENERAL DISCUSSION

The majority of scientific publications concerning surgery for POP report unsatisfactory results, i.e. high re-operation rates for traditional native tissue POP repair. This thesis seeks to explore whether surgical techniques have an impact on the operative results for different prolapse types and whether the surgeon’s manual experience has an impact on the surgical results, and, further, to clarify the long-term results of the most common POP operations.

Our results in Paper II suggest that the most advantageous utilization of mesh implants is for recurring posterior compartment prolapse, where mesh produces better results than native tissue repair, without any indication of a higher prevalence of postoperative complications. In other situations concerning the anterior and posterior compartment the situation is more complex, with both advantages (most prominently a higher 1-year cure rate for mesh) and drawbacks (such as increased postoperative pain after mesh use). For native tissue repair, the experience of the operating surgeon plays only a minor role, and has no impact on the results of the most common POP operations.

The re-operation rates of native tissue operations within 5 years are low overall, with a 11.2% re-operation rate of POP in the same or another compartment. The GynOp data open up to the unique possibility to stratify results, to a degree where it is possible to determine the aetiology of the recurring prolapse in those cases where patients have a re-operation. We noticed, for example, that when operated in the anterior compartment, patients had a tendency to have a relapse in the same (anterior) compartment almost twice as frequently as having a de novo prolapse in a different compartment. Interestingly, when looking at the posterior compartment, the relationship was inverse, and posterior repair patients most commonly had a relapse in a different compartment, which was more than twice as frequent as same (posterior)-compartment relapse. Both groups had an overall surgical retreatment rate that was completely comparable to the overall retreatment rate.

When analysing PROM data from patients who had been operated 5 years previously and had not been re-operated since, we found that results were highly positive. The patient-reported cure rate was 74.4% overall. In addition, 73.2% of patients in this category were satisfied with the operative results, and 82.2% reported that the operation had significantly improved their symptoms, compared with how they had felt before the operation. For those not cured, the symptoms might come from another, unoperated, compartment. Therefore, from a national perspective, the traditional prolapse operation appears to offer patients a treatment option of high, long-term quality.
The use of implants is an often discussed topic in gynaecology. There is no clear consensus on the subject, and there are both numerous studies showing advantages and studies reporting possible drawbacks of using meshes.

Concerns with mesh (among other things because of erosion) were raised in 2012 by the Food and Drug Administration (FDA) in the USA, cautioning against mesh use because of lack of sufficient evidence to prove that the benefits of implants outweigh the risks. At the time, this was solely a warning against a possible problem with mesh use, without any specific guidelines or conclusive data. In 2016 the FDA reclassified surgical meshes into a Class III (high-risk) intervention, where the products required even more rigorous premarket testing and safety assurances before they could be legally used. Continued discrepancy in reports on safety of mesh use has led to a new standpoint by the FDA in April 2019, ordering all manufacturers of surgical mesh intended for vaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing their products until further notice. This was based on the conclusion that the manufacturers (Boston Scientific and Coloplast) did not demonstrate reasonable assurance of safety and effectiveness for vaginal mesh in cystocele. The results in this thesis concur with this decision, as no distinct advantage in cystocele could be found in mesh use within 1 year without considerable drawbacks, warranting consideration whether this material should be used in anterior repair at all. The use of vaginal meshes for other types of prolapse are at present being scrutinized by the FDA. The vaginal mesh discussion is a global topic, and the results presented in Papers I and II in this thesis, as well as in two previous publications using GynOp data, are intended to be used in the clinical decision of where and when to use mesh. Vaginal meshes as a concept, despite the new FDA restrictions and complete withdrawal in New Zealand, are in all probability going to continue to be a part of health care providers’ arsenal globally.

Meshes used in the anterior compartment, as well as in primary rectocele patients, should be used with caution. However, this thesis advocates for considering vaginal mesh in recurrent prolapses, especially if the recurrence is in the posterior compartment (Paper II). Further extensive research on mesh-specific problems will be done utilizing the new 5-year cohort, where a comparison between mesh use and native tissue repair will be the research focus.

This thesis and recent studies included herein have found that the urgent demand for an alternative to the native tissue operation, due to expected high recurrence rates and failure to correct the prolapse, is not as pressing as previously predicted. The native tissue operation is an operation of high quality, offering long-term relief to patients, and seems to be a very viable treatment option for primary prolapse patients (Paper IV).

As discussed, the only subjective symptom specific to prolapse is the awareness of a vaginal bulge or protrusion, which is regarded as a valid way of measuring presence of a prolapse. Other, more specific urogynaecological symptoms
have been shown to have a weak link with direct measures such as the POP-Q tool, compared with the symptom of “bulging”.\textsuperscript{46} Patient-reported cure rates can be argued to be unreliable, as they are not objectively verified by a physician.\textsuperscript{177} The indication for POP surgery is not an anatomical defect, but the presence of subjective symptoms, and POP is a condition that “… requires no treatment when asymptomatic”.\textsuperscript{115} Globally, BMJ best-practice bulletins are used as the best available information for clinicians when approaching a practical medical or surgical problem. The most recent BMJ best-practice recommendations for prolapse are based on patient symptoms, and treatment algorithms are solely based on symptoms. The recommendation is that “observation or watchful waiting is appropriate” for “asymptomatic patients or women who have few minor symptoms [and who] report little or no bother as a result of the disorder”.\textsuperscript{176} Verification of POP-Q stage will not alter the patient’s symptoms and does not contribute to whether an operation is successful or not.

Utilizing GynOp data, four separate works were published concerning the use of mesh compared with colporrhaphy on a full national material; two of these works are not included in this thesis.\textsuperscript{144, 2} The author of this thesis participated in all four studies. After examining and publishing the 1-year outcomes including both patient and surgeon-reported parameters for primary cystocele (Paper I) and recurring cystocele,\textsuperscript{167} and primary rectocele\textsuperscript{144} and recurring rectocele (Paper II), the overall conclusion in this thesis is that:

- Surgical mesh has a higher patient-reported cure rate, in all four operations.
- For primary and recurring cystocele, as well as primary rectocele, the higher cure rate must be weighed against varying levels of complications and postoperative pain.
- For recurrent rectocele, surgical mesh has a considerably higher cure rate, and has equal drawbacks as the native tissue operation.

According to these findings, the use of mesh can be considered a viable option, especially if a previous native tissue operation has failed to correct the patient’s symptoms. There are potential complications that must be weighed in the individual patient, which the publications’ site-specific data attempt to support. In sole recurrence of rectocele, mesh should be considered as a viable option, as gynaecological mesh has a higher cure rate for this group, and the same number of postoperative complications as the native tissue operation.

Strengths and weaknesses of this thesis are strongly linked to GynOp. External validity (coverage, completeness and response rate) is documented to be very high. Documentation about internal validity of GynOp has, however, been less consistent throughout the years.

The 1-year and pre-operative questionnaires were developed and validated by the Department of Applied Educational Science (formerly the Department of Educational Measurements). In the 5-year questionnaire, questions about
symptoms and results were re-used from the pre-operative health declaration and 1-year follow-up questionnaires. None of the 22 main questions and five sub-questions was criticized by patients during the two rounds of validation, and therefore the questions were left unchanged. This strengthens the internal validity not only of the 5-year questionnaires, but also of the already implemented questionnaires. A sub-question in the patients’ pre-operative health declaration regarding previous operations was analysed by cross-tabulation, where previous operations were already known. This also showed a very high concordance between patient answers and factual occurrence of a previous operation.

One of the main strengths of GynOp studies is that they reflect the effectiveness of a surgical intervention in a routine health care setting, in a large material representative of both the Swedish population of women with POP, and national surgical practice. Large register-based studies have increasingly won ground over recent years, because of the feasibility of studies such as the ones included in this thesis. Randomized trials, large enough to reach statistical power, and comparing different POP operations in different compartments, are not realistic from both a time and a resource perspective. Regarding the impact of surgical experience, an ethical problem will also present itself, as we assumed at the start of the study that more experienced surgeons would have superior results. Randomization to a theoretically inferior treatment option would be problematic from an ethical standpoint.

A weakness of a study design utilizing a large register for data is that analyses have to be done on already collected data. This means that additional questions cannot be added, except by telephone or letter, which would undermine the point of having a register in the first place, as well as introducing possible recall bias.

The included studies are all cohort studies based on the GynOp register, and not clinical trials, and by definition only associations can be concluded between interventions and outcome. However, it is highly valuable to be able to ascertain the effectiveness of these interventions, especially from a socio-economic and developmental point of view, as this can provide valuable insight into how the intervention functions in a “real-life” setting, and we are not restricted to a clinical trial setting.

As there is no randomization, the risk of overlooking confounding factors is ever present. However, as we have included all confounding factors currently known to be of major interest with regard to POP and operative results, and a thorough analysis of both participants and drop-outs of every study has been done in the individual articles, the possibility of critical confounding is kept to a minimum.

To develop and maintain a quality register is a precarious and expensive process, both in terms of labour intensity and in strictly monetary terms. Also, registers such as GynOp can only be run in a limited number of countries. They require a reliable social security number system. They also require the population’s trust and acceptance of this kind of register, as well as trust among health care
employees, including nurses and doctors, and a publicly financed and general health care system for the whole population, which supports the registers both politically and financially. However, such registers, once established, are invaluable in the daily development of medical practice within a country. They have been described as veritable gold mines in terms of promoting reliable, major scientific activity within their field of interest.\textsuperscript{180}

Another clear advantage is that the registers are run by health care professionals, mainly doctors, who all take a personal and professional interest in register work. In contrast to a register simply dictated by the government, this probably has a positive effect on the trust in the registers, as well as on further development of quality registers. The number, quality and coverage of the different Swedish national quality registers are rare elsewhere in the world.

**Papers I & II**

Results in both Paper I and Paper II are presented as ORs as well as RDs. This was done deliberately, as ORs and RDs complement each other in interpretation of results. Odds ratios are inherently hard to interpret, but have distinct advantages with regard to adjustments for covariates, being suitable for all types of analysis (compared with relative risks), as well as having no variance in labelling events and non-events.\textsuperscript{181} Risk difference shows the absolute difference between two interventions, and is very easy to interpret: an RD of 5% means an excess risk of 5% for one intervention compared with another.\textsuperscript{182} Together, the two measures complement each other in giving both a relative and an absolute measurement of the impact on results of the mesh intervention compared with colporrhaphy.

The Tables presented in the papers show differences between the two operative methods, as per the objectives of the studies. There is no representation of the results in the individual groups, only a difference or ratio between them. Even though this was not the goal of the papers, presenting absolute numbers would have been informative, and would have given a clearer picture of patients’ status 1 year after the operation.

We found a statistically significant difference regarding operation time, blood loss during the operation, and return to ADLs, in favour of colporrhaphy. When yielding statistically significant results from large numbers of data, the absolute clinical value of the following results must be considered: a few mL of blood, around 10-12 minutes of operating time, and a few hours’ difference in return to ADLs. Although statistically significant, these values can be argued to have no practical, clinical consequence, and more likely to be a byproduct of the large datasets.

A weakness of the studies is the lack of randomization, and therefore they may have confounding factors, as well as selection and information bias. We are aware that our study design only allows for interpreting associations between
interventions and results, and does not detect causality. Further research in the form of a randomized trial could confirm a causality for the subgroups in Papers I and II, but concerning re-operations of rectocele would require a randomization of every single eligible Swedish patient for at least 5 years to have enough analytical power (estimated from the 1.2% incidence of recurring rectocele).

Mesh types are not all alike and the studies do not distinguish between brands of non-resorbable polypropylene mesh. However, the difference between brands is subtle, and there is no difference in the general method of application of vaginal mesh.

Complication registration within the database is not implant-specific. It covers all types of expected surgical complications. It is therefore not possible to distinguish between complications characteristic of implants (e.g. bleeding due to erosions) and general surgical complications (e.g. bleeding from the suture line). Surgeon-reported complications are graded with regard to severity, into major and minor complications. The criterion for this to be interpreted as a surgical complication in the analysis was that the patient sought medical attention for the specific problem. The degree of severity, beyond this, is unknown.

Clear strengths of both studies are the large sample sizes, and the “real-life” setting provided through the continuous monitoring of the Swedish health care system by the quality registers, showing the effectiveness rather than the efficacy of an intervention. Whether it is more valuable to measure efficacy or effectiveness is dependent on the research question. When a pragmatic research question is raised, where the goal is to assess whether an intervention works under real-life conditions in terms that matter to the patients, the effectiveness of the intervention is of greater interest than efficacy, which shows the results of an intervention under optimal conditions.183

Paper III

Surgical results are highly dependent on being able to identify the optimal treatment for a specific patient with a distinct surgical problem. The surgery itself, however optimal the setting, still encompasses aspects of personal and manual skills that rely mainly on the surgeon.

As surgical operative experience seems to be a critically important factor in cases of major surgery,129-131,137 Caesarean delivery132 and hysterectomies,133-136 we raised the question whether this is the case in simpler, less extensive surgery as well. In the case of POP, we discovered that surgeon’s experience played only a very minor role with regard to resource parameters, such as how long the operation took, and had no impact whatsoever on the operative results 1 year postoperatively. Inexperienced surgeons evidently do not impair operative results in POP surgery. This may be due to the simple nature of the operation, and to the setting of the Swedish hospital system, which provides clinical supervision. In a hospital setting, these results indicate that less experienced
surgeons can and should be allowed to perform simple operations, and should expect good results.

One of the issues we had when compiling the yearly operative volume of surgeons was due to a mismatch between surgeons’ names and their respective identification numbers in the system. If surgeons had operated in several different hospitals, and there were errors or alternative inputs of their name (e.g. Mats Löfgren, M. Löfgren, Mats L., etc), the system would erroneously give them as separate surgeons. This required a complete manual control of the entire database, and rigorous testing, before we were able to be as certain as possible that there were no mistakes. However, this remained a potential weakness since errors could have occurred if there were spelling differences or, even harder, when the surgeon had changed their name (following marriage, divorce, etc). An operation is performed by a whole team, and not only by the surgeon. Skills and experience of other team members can also influence the results, of which we have no data available.

**Paper IV**

The long-term re-operation rates in both the same compartment and new compartments (de novo prolapse) are surprisingly low, as shown by the Kaplan-Meier curve where 5-year survival exceeded 88%. This is much higher than expected – and it is higher compared with many previous studies reporting 1-year re-operation rates exceeding 30%, prevalent long-term morbidity and “unacceptably high recurrence rates”\(^{117}\). Some, however, such as Funk et al.,\(^ {123}\) have found results more similar to ours. Moreover, our PROM data show that patients who had not had a re-operation since their original operation 5 years previously, reported that they were cured (i.e. did not feel a vaginal bulge) in excess of 70% of cases, and reported an even higher rate of patient satisfaction and symptom reduction. Therefore, native tissue repair, when looking at national data, yields overall highly satisfactory long-term results, which is in direct contrast to the general opinion on the effectiveness of native tissue repair.\(^ {173,185-187}\)

Many studies have been skeptical about the long-term stability of native tissue repair, and one of the main purposes of this thesis was to paint a clearer picture regarding both the number of re-operations, and what to expect as patient undergoing native tissue repair, in terms of success of the original operation and need for a re-operation. The results in some previous studies are to some extent unfair when discussing re-operations, in that they consider a re-operation to be directly linked to the primary operation, and do not stratify operations by compartment. In many studies the patient is reported to have had a relapse of POP and its symptoms, and therefore to have to be re-operated, with the conclusion drawn that the previous operation has “failed”. However, in the present thesis, with the most common POP operations (solely anterior and rectocele operations), the 5-year re-operation rate was only 7.9% and 3.5%, respectively. The rest were not re-operations but new POP symptoms from
another, unoperated compartment. The new operations would therefore be in another compartment. At least in part, the large proportion of failure to correct a prolapse could therefore be argued to not be directly linked to the previous operation, but to represent de novo prolapse in a different compartment.

The results have by far surpassed expectations, as in our material the 5-year survival for POP operations exceeded 88% overall, and the qualified majority of patients (between 75% and 80%) stated that they were satisfied with the operative result, and that they were significantly improved compared with pre-operatively.
CONCLUSION

Mesh use is, at 1-year follow-up, generally characterized by a high cure rate and varying degrees of complications, such as postoperative pain. However, for recurrent rectocele, we have found no immediate drawbacks of the method compared with native tissue repair, and mesh resulted in the same high cure rate as seen in other compartments.

Surgeon experience in our study has had no impact on the native tissue operation, and any inconsistency of outcome is more likely inherent in the method than being attributable to the surgeon’s lack of experience.

The 5-year results indicate that native tissue repair produces much better results, judging from overall Swedish results, than previously thought. This is backed up both by objective data indicating a minimal number of re-operations within 5 years for the most common cases (i.e. primary rectocele and cystocele) and by the outcomes reported by the patients themselves.

In summary:

- Mesh-augmented repair is more effective than native tissue repair for recurrent rectocele, and without increased risk of complications. Drawbacks of mesh repair vary for other compartments, and for primary operations.

- Surgeons’ operative experience in routine POP operations using native tissue has no impact on outcome after 1 year.

- Long-term results of POP repair with native tissue are excellent, with a low risk of re-operation and a persistent absence of subjective symptoms.

Further research

Future studies of 5-year results will include the stratification of PROM results for vaginal apex prolapse, as well as a thorough, stratified analysis and comparison of vaginal mesh procedures. Comparative studies of mesh versus native tissue repair recurrence rates within 5 years will also be done utilizing the new material. The GynOp register is an extensive, detailed tool not only for the development of prolapse surgery, but for gynaecological surgery in general, and continuous utilization of GynOp resources is vital for the further development of gynaecological surgery. Sweden has a rich resource of robust, large registers, which places Swedish research as a forerunner in epidemiological research internationally. Sweden’s large national registers enable development of new methods of utilizing large databases in terms of conducting randomized trials, providing continuous quality control, and facilitating scientific cooperation within and across national borders.
ACKNOWLEDGEMENTS

As this is in all probability the only part of the thesis people will read from end-to-end, I shall endeavor to keep it entertaining.

Thus, I would like to start by thanking everyone who expressed their extreme scepticism towards the feasibility, possibility, legality and mental sanity of writing a doctorate dissertation during my time as a medical student in Århus.

As I can express myself freely in the acknowledgements:

“How d’ya like them apples?”

But I digress... for these cases were comparatively few looking back at the enormous amount of support given to me as things slowly progressed.

Mats Löfgren, who became my dear friend throughout the years. You believed in me, from beginning to end. You taught me more than you know, and without you, this book would not exist. Mats not only took it upon himself to teach me scientific method, but in an admirable attempt to keep me out of trouble also worked tirelessly to teach me scientific etiquette and the “rules of conduct within academia”. As is quite evident from above, the latter did not stick as well as the former.

Umeå University, for giving me the opportunity of a lifetime.

Marie Bixo, for making sure that the real world around us didn’t collapse while Mats and I were consumed by our shared fascination of numbers. We would probably not even have noticed if the university was on fire, unless Marie pointed it out. Professor, you were a confident voice of reason from beginning to end, and still had a wonderful air of laughter around you. I am privileged to have had you in my corner.

Emil K. Nüssler, who showed me how beautiful it is to learn how the world wags, and what wags it. Thank you for your patience, your love and support for your reckless son. The world can be a wonderful place, not only when people like you inhabit it, but because of it. The single most beautiful thing this thesis has gifted me, was my many hours spent with you.

Also, my mother Anette for putting up with my father and I during this time. Not an easy task, mom. I love you.

Furthermore, it is absolutely obligatory to thank all the thousands of healthcare professionals, and tens-of-thousands of patients, who have made this thesis (and many others) possible. You have selflessly given. We are all indebted to you.

... And lastly, my most heartfelt thanks goes to Marie Löfgren, who took a stranger into her home, many years ago and made him feel like family.
REFERENCES


13. Pakbaz M. Vaginal prolapse—clinical outcomes and patients’ perspectives: a study using quantitative and qualitative methods, Umeå University; 2011.


46. Teleman P, Laurikainen E, Kinne I, Pogosean R, Jakobsson U, Rudnicki M. Relationship between the Pelvic Organ Prolapse Quantification system (POP-Q), the Pelvic Floor Impact Questionnaire (PFIQ-7), and the Pelvic Floor Distress Inventory (PFDI-20) before and after anterior vaginal wall prolapse surgery. *International Urogynecology Journal*. 2015;26(2):195-200.


Forms and questionnaires

The Swedish National Quality Register of Gynecological Surgery utilizes three routine questionnaires: The Preoperative health declaration, and follow up questionnaires after both two months and after one year. The questionnaires are dynamic, and questions are modified depending on the individual operation and patients age. For example: A 65 year old woman is not asked about her menstruation cycle or use of contraceptives. In our examples, the appended questionnaires are the ones generated for a woman of 65 years. They were used in the Swedish form, and validated in Swedish, and therefore appended in the original language. (Appendix 2-4).

Apart from paper questionnaires, the material is also available in electronic form. Examples are appended illustrating the electronic version (appendix 5). All questionnaires are available in translated form at https://www2.gynop.se/home/

The 5–year follow-up study had a specific questionnaire, which is also appended. In the electronic version it functions exactly as the earlier questionnaires.

The surgeons’ forms are only available in dynamic electronic version. Examples are also shown in this Appendix.
Enkät inför operation

Din enkät finns på www.gynop.se, klicka ”Logga in”. Ditt lösenord är 48mpnn.

Hej Testsson!

**Det här är ett informationsbrev till dig som planeras genomgå en framfallsoperation**

Vi behöver information från dig. Uppgifterna från frågeformuläret används som en del i det medicinska underlaget inför din operation.

Vi önskar svar så snart som möjligt, gärna via Internet. Dina svar går till den klinik där du ska opereras.

**Tiden efter operationen**

Tre dagar efter operationen uppger hälften av alla patienter att de kan utföra normala vardagliga aktiviteter och klara sig själva utan mer hjälp än före operationen.


**Oväntade besvär och komplikationer**

Efter operationen kan oväntade besvär/komplikationer inträffa. Vanligast är lättbehandlad blås-/urinvägsinfektion (5 av 100), för mera allvarlig infektion finns en mycket liten risk.

Om du skulle få feber över 38 grader, ökande smärtor, riklig blödning eller illaluktande flytningar under den närmaste tiden efter operationen **SKA** du kontakta sjukhuset.

**Uppföljning efter operationen**

Vi vore mycket tacksamma om du även **efter** operationen kan besvara frågeformulär om hur du mår.

För ytterligare information se [www.gynop.se](http://www.gynop.se).

Vänliga hälsningar och tack på förhand

Sixten Sand  
Leg läkare  
Övningsklinik  
Övningssjukhus
Registrering i GynOp


Data samlas in av vårdpersonalen och från patienterna. Dessutom kommer viss data från patientjournaler och folkbokföringen.


Mer information finns på www.gynop.se

Du bidrar till bättre vård

Stöd i lagen
Alla som behandlar personuppgifter måste ha stöd i lagen för detta. Hanteringen av personuppgifter i kvalitetsregister regleras av dataskyddsförordningen, GDPR, och kapitel sju i patientdatalagen, PDL.

Det är tillåtet att registrera data i kvalitetsregister eftersom uppgifterna är av allmänt intresse för samhället och viktiga inom sjukvården. Den personal som hanterar personuppgifter i kvalitetsregister omfattas av en lagstadgad tystnadsplikt.

Så används uppgifter om dig
Uppgifterna om dig i kvalitetsregister får bara användas för att utveckla och säkra vårdens kvalitet, framställa statistik samt för forskning inom hälso- och sjukvården. Uppgifterna får även, efter sekretessprövning, lämnas ut till någon som ska använda dem för något av dessa tre ändamål. Om uppgifter får lämnas ut kan det ske elektroniskt.

Sekretess
Uppgifterna om dig i kvalitetsregister skyddas av hälso- och sjukvårdssekretessen i offentlighets- och sekretesslagen. Det innebär som huvudregel att uppgifter om dig bara får lämnas ut från kvalitetsregister om det står klart att varken du eller någon närstående till dig lider men om uppgifterna lämnas ut.

Säkerhet

Åtkomst
Behörig personal på den vårdenhet som har matat in uppgifterna i kvalitetsregistret har åtkomst till just
dessa uppgifter. Ingen annan vårdgivare kommer åt uppgifterna. Behörig personal som arbetar på kvalitetsregistret har åtkomst till alla uppgifter i registret.

**Lagringstid och gallring**
Uppgifter om dig tas bort när de inte längre behövs för att utveckla och säkra vårdens kvalitet.

**Dina rättigheter**
- Du har rätt att säga nej till att uppgifter om dig registreras i kvalitetsregistret.
- Du har rätt att när som helst få uppgifter om dig själv raderade ur kvalitetsregistret.
- Du har rätt att få veta om uppgifter om dig finns i kvalitetsregistret och i så fall få en kopia av dem kostnadsfritt, ett så kallat registerutdrag. Du har rätt att få uppgifterna i elektronisk form.
- Du har rätt att få felaktiga uppgifter om dig rättade. Du har rätt att få ofullständiga uppgifter kompletterade.
- Du har rätt att få information om vilka vårdenheter som haft åtkomst till uppgifter om dig och när, så kallat loggutdrag.
- Du har rätt till skadestånd om uppgifterna om dig hanteras i strid med dataskyddsförordningen eller patientdatalagen.
- Du har rätt att inge klagomål till Integritetsskyddsmyndigheten som är tillsynsmyndighet på detta område.

Mer utförlig information om patientdatalagen och dataskyddsförordningen finner du på [http://www.datainspektionen.se](http://www.datainspektionen.se)

**Kontaktuppgifter**
När uppgifter om dig finns med i ett kvalitetsregister har du vissa rättigheter. Läs mer om dem nedan. Vill du komma i kontakt med GynOp angående dina rättigheter, använd dessa kontaktuppgifter:

GynOp-kansliet, Kvinnokliniken, Norrlands universitetssjukhus, 901 85 UMEÅ
Tfn 090-785 04 64, E-post gynopregistret@regionvasterbotten.se

Du kan också vända dig till ett dataskyddsombud med frågor som rör uppgifter om dig i kvalitetsregister. Datskyddsombuden övervakar att lagar som rör behandling av personuppgifter följs.

Dataskyddsombudet hos Övningsklinik nås via:
Övningssjukhusets Personuppgiftsombud Övningssjukhus 00 111 Övningsstad Tel 000 010101

Dataskyddsombudet hos Regionstyrelsen i Region Västerbotten nås via e-post: dataskyddsombud@regionvasterbotten.se
Enkät inför operation
Dr Sixten Sand

1234567890
Testsson Test

Besvara gärna din enkät via www.gynop.se
Klicka ”Logga in”.
Ditt lösenord är 48mpnn

Personnummer: ...... ...... ...... - ............
Namn............................................................
Adress...........................................................
Postnummer...........Ort..................................
Telefon ................................................
E-post......................................................

Telefonnummer saknas
E-post: Saknas

Om uppgifter saknas ovan eller är felaktiga, fyll i här

Det finns luckor i frågenummringen eftersom vissa frågor inte är aktuella för dig.

1. Datum när enkäten besvaras: ..............-........-........

2  Vet du vilken operation som planeras för dig  □ Ja  □ Nej
   Om ja, vilken? ........................................................................................................................
   ....................................................................................................................................................


   Skriv siffrorna i rutorna. T.ex. 1 3 2

   □ Smärtor
   □ Blödningar
   □ Tryck- och tyngdbesvär (t ex tyngdkänsla, tryck mot blåsa, tryck mot tarm)
   □ Framfall (något putar ut ur slidan)
   □ Urinläckage/urininkontinens
   □ Andra besvär/orsaker, vilka? ...................................................................................................

   ....................................................................................................................................................

4. Har du smärtor i underlivet/nedre delen av buken?

☐ Nej

☐ Ja. Ange graden av smärta

- Smärta i buken
  - Nej, ingen smärta
  - Ja, lite smärta
  - Ja, måttlig smärta
  - Ja, stark smärta
  - Ja, olidlig smärta

- Underlivssmärta, beskriv:
  - Nej, ingen smärta
  - Ja, lite smärta
  - Ja, måttlig smärta
  - Ja, stark smärta
  - Ja, olidlig smärta

5a. Har du haft underlivsblödningar under det senaste året?  ☐ Nej  ☐ Ja

5c. Har du blödningar som kommer när de inte borde komma?  ☐ Ja  ☐ Nej

6. Om ja på fråga 5a, för hur länge sedan hade du din senaste underlivsblödning?

☐ Mindre än 6 veckor  ☐ 6 veckor – 6 månader  ☐ 7 månader – 1 år  ☐ Mer än 1 år

7. Har eller har du haft övergångsbesvär/klimakteriebesvär (blodvallning, svettning, hjärtklappning)?

☐ Nej
☐ Vet ej
☐ Ja

8. Använder du hormonpreparat med östrogen?

☐ Nej
☐ Ja mot övergångsbesvär/klimakteriebesvär.
☐ Ja mot underlivsproblem
☐ Ja mot problem med urin/urinvägar
☐ Ja, av annan anledning .................................................................

9a. Har du en känsla av att något buktar ut ur slidan?

☐ Aldrig  ☐ Nästan aldrig  ☐ 1–3 ggr per månad  ☐ 1–3 ggr per vecka  ☐ Dagligen

9b. Har du skavningsbesvär i underlivet?

☐ Aldrig  ☐ Nästan aldrig  ☐ 1–3 ggr per månad  ☐ 1–3 ggr per vecka  ☐ Dagligen
9c Använder du ring/inlägg mot framfall?
- Nej, har aldrig haft ring
- Nej, inte nu, men har tidigare haft ring
- Ja, har ring nu
- Vet ej

10a Har du svårt att tömma urinblåsan?
- Aldrig
- Nästan aldrig
- 1–3 gånger per månad
- 1–3 gånger per vecka
- Daglig

10b Har du besvär av urinträngningar (en hastigt påkommande, stark känsla av att behöva kissa)?
- Aldrig
- Nästan aldrig
- 1–3 gånger per månad
- 1–3 gånger per vecka
- Daglig

10c Behöver du gå upp på natten och kissa?
- Aldrig
- Nästan aldrig
- Oftast en gång
- Oftast två gånger
- Mer än två gånger

10d Har du urinläckage eller ofrivillig urinavgång?
- Aldrig
- Nästan aldrig
- 1–3 gånger per månad
- 1–3 gånger per vecka
- Daglig

Om du har svarat Aldrig – Nästan aldrig på ovanstående fråga 10d, gå till fråga 12

Kryssa i ett av alternativen i var och en av frågorna 11a – 11j

11a Läcker du urin när du stiger upp ur sängen?
- Ja
- Nej

11b Hur ofta läcker du urin i samband med fysisk aktivitet, när du skrattar, hostar eller nyser?
- Aldrig
- 1–4 gånger per månad
- 1–6 gånger per vecka
- 1 gång per dag
- Mer än 1 gång per dag

11d. Hur ofta upplever du en hastigt påkommande, stark känsla av att behöva kissa och läcker urin innan du når fram till toaletten?
- Aldrig
- 1–4 gånger per månad
- 1–6 gånger per vecka
- 1 gång per dag
- Mer än 1 gång per dag

11g. Undviker du aktiviteter (t ex fysisk träning eller att gå ut) för att du är rädd för att läcka?
- Aldrig
- Sällan
- Ibland
- Ofta
- Alltid
11h. Undviker du platser och situationer där du vet att toalett inte finns tillgänglig?

☐ Aldrig  ☐ Sällan  ☐ Ibland  ☐ Ofta  ☐ Alltid

11i. Påverkar ditt urinläckage din semester?

☐ Ja  ☐ Nej

Påverkar ditt urinläckage ditt familjeliv?

☐ Ja  ☐ Nej

Påverkar ditt urinläckage ditt sexliv?

☐ Ja  ☐ Nej

Påverkar ditt urinläckage ditt sociala liv (gå ut, träffa vänner etc)?

☐ Ja  ☐ Nej

Påverkar ditt urinläckage ditt nattsömn?

☐ Ja  ☐ Nej

Påverkar ditt urinläckage ditt arbetsliv?

☐ Ja  ☐ Nej

12a. Händer det att du har svårt att tömma tarmen?

☐ Aldrig  ☐ Nästan aldrig  ☐ 1–3 ggr per månad  ☐ 1–3 ggr per vecka  ☐ Dagligen

12b. Händer det att du behöver hålla emot bakre slidväggen för att tömma tarmen?

☐ Aldrig  ☐ Nästan aldrig  ☐ 1–3 ggr per månad  ☐ 1–3 ggr per vecka  ☐ Dagligen

13a. Har du svårt att hålla avföring eller gaser?

☐ Nej

☐ Ja

Om du har svarat nej på ovanstående fråga, hoppa till fråga 15a

13b. Händer det att du släpper dig även när det är olämpligt?

☐ Aldrig

☐ Nästan aldrig

☐ Ja, 1-3 gånger i månaden

☐ Ja, 1-3 gånger i veckan

☐ Ja, dagligen

13c. Har du läckage av lösv föring?

☐ Aldrig

☐ Nästan aldrig

☐ Ja, 1-3 gånger i månaden

☐ Ja, 1-3 gånger i veckan

☐ Ja, dagligen
13d. Har du läckage av fast avföring?
  □ Aldrig
  □ Nästan aldrig
  □ Ja, 1-3 gånger i månaden
  □ Ja, 1-3 gånger i veckan
  □ Ja, dagligen

13e. Använder du skydd pga avföringsläckage?
  □ Aldrig
  □ Nästan aldrig
  □ Ja, 1-3 gånger i månaden
  □ Ja, 1-3 gånger i veckan
  □ Ja, dagligen

13f. Påverkar dina läckageproblem din livsstil?
  □ Aldrig
  □ Nästan aldrig
  □ Ja, 1-3 gånger i månaden
  □ Ja, 1-3 gånger i veckan
  □ Ja, dagligen

15a. Har du haft samlag de senaste 3 månaderna?
  □ Ja  □ Nej  □ Ej aktuellt  □ Avstår från att svara

15b. Om ja på fråga 15a ovan, känner du smärta i underlivet vid samlag?
  □ Nej, ingen smärta
  □ Ja, lite smärta
  □ Ja, måttlig smärta
  □ Ja, stark smärta
  □ Ja, olidlig smärta
15d. Om ja på fråga 15a, upplever du
slidöppningen alltför liten/trång? □ Ja □ Nej
slidöppningen alltför stor/öppen? □ Ja □ Nej
smärta i slidöppningen? □ Ja □ Nej
andra besvär från slidöppningen? □ Ja □ Nej

Om ja, vilken typ av besvär? .................................................................

.................................................................

FÖR ATT KUNNA BEDÖMA DIN SITUATION OCH PLANERA DEN GYNEKOLOGISKA
BEHANDLINGEN PÅ BÄSTA SÄTT BEHÖVER VI EN DEL BAKGRUNDSINFORMATION.

16a Hur många gånger har du blivit gravid ..........b. Antal förlossningar ............
c. Därav antal kejsarsnitt .............

18. Har läkare informerat dig om att du har eller har haft någon/några av dessa sjukdomar/besvär?
□ Nej □ Ja

<table>
<thead>
<tr>
<th>Om Ja, vilken eller vilka</th>
<th>Markera även Nej för de du inte haft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Äggledareinflammation?</td>
<td>□ Nej □ Ja</td>
</tr>
<tr>
<td>Endometrios (&quot;chokladcystor&quot;)?</td>
<td>□ Nej □ Ja</td>
</tr>
<tr>
<td>Cystor i äggstockarna?</td>
<td>□ Nej □ Ja</td>
</tr>
<tr>
<td>Cellförändringar på livmodertappen?</td>
<td>□ Nej □ Ja</td>
</tr>
<tr>
<td>Myom/muskelknutor?</td>
<td>□ Nej □ Ja</td>
</tr>
<tr>
<td>Annat?</td>
<td>□ Nej □ Ja</td>
</tr>
</tbody>
</table>
19a. Har du genomgått någon av nedanstående operationer?

- Nej  □ Ja

<table>
<thead>
<tr>
<th>Operation</th>
<th>Nej</th>
<th>Ja</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skrapning för blödningar, missfall eller abort?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Förändring på livmodertappen?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kejsarsnitt?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilisering?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utomkvedshavandeskap?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cystor, förändringar i äggstock/äggledare?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myom, muskelknutor?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Livmodern avlägsnats?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urininkontinens?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Framfall?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annan underlivs-/gynekologisk operation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blindtarmsoperation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annan bukoperation?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Markera även Nej för de du inte genomgått

19b. Har du genomgått någon/några **andra operationer** (ej underliv/buk)?

- Nej
- Ja. Ange vilken operation

FÖR ANESTESI/BEDÖVNING OCH ANNAN VÅRDPLANERING BEHÖVER VI ÄVEN SVAR PÅ FRÅGOR SOM INTE HANDLAR OM GYNEKOLOGI.

20. Yrkesarbetar du? □ Nej  □ Ja, jag arbetar som

- Mitt arbete är:
  - □ Fysiskt krävande
  - □ Ej fysiskt krävande

21. Är du sjukskriven?

- □ Ja, pga. orsaken till att jag skall opereras
- □ Ja, jag är sjukskriven av annan orsak
- □ Nej, jag är inte sjukskriven

22a. Hur lång är du? ....... cm

b. Hur mycket väger du? ....... kg
23. Röker du?

☐ Ja, 1-5 cigaretter per dag
☐ Ja 6-20 cigaretter per dag
☐ Ja mer än 20 cigaretter per dag
☐ Nej, har aldrig rökt
☐ Nej, slutade år ............

24. Brukar du drabbas av åksjuka och/eller sjösjuka? ☐ Nej ☐ Ja

25a. Har du haft någon allvarlig allergisk reaktion mot läkemedel (medicin) som medfört akut läkarbesök?

☐ Nej  ☐ Vet ej  ☐ Ja

Om ja, beskriv vad du reagerat på samt hur du reagerat:

..................................................................................................................................
..................................................................................................................................

25b. Har du någon lindrig allergi mot läkemedel?

☐ Nej  ☐ Ja

Om ja, beskriv vad du reagerar på samt hur du reagerar:

..................................................................................................................................
..................................................................................................................................

25c. Har du haft någon allvarlig allergisk reaktion mot något födoämne, pollen, parfym etc som medfört akut läkarbesök?

☐ Nej  ☐ Ja

Om ja, beskriv vad du reagerat på samt hur du reagerat:

..................................................................................................................................
..................................................................................................................................

25d Har du någon lindrig allergi mot något födoämne, pollen, parfym etc?

☐ Nej  ☐ Ja

Om ja beskriv vad du reagerar på samt hur du reagerar:

..................................................................................................................................
..................................................................................................................................

26. Har du eller någon annan i din släkt någon ärfilig sjukdom (t. ex. porfyri, amyloidos, ärfliga muskelsjukdomar eller malign hypertermi)? ☐ Nej  ☐ Ja  ☐ Vet ej
27. Har du några av följande problem? □ Nej □ Ja
   Om ja, vilket eller vilka?
   Lätt för att blöda näsblod □ Nej □ Ja
   Blöder längre än 10 minuter från små sår □ Nej □ Ja
   Stora blåmärken □ Nej □ Ja

28. Har läkare konstaterat att du haft någon blodpropp? □ Nej □ Ja
   Om ja, var satt proppen?

29. a. Måste du stanna och vila när du går uppför två trappor? □ Nej □ Ja
   b. Måste du stanna och vila när du går uppför en halv trappa? □ Nej □ Ja

30. Har läkare konstaterat att du har eller har haft någon hjärtsjukdom?
□ Nej □ Ja
   Om ja, vilken eller vilka?
   Hjärtsvikt □ Nej □ Ja
   Hjärtinfarkt □ Nej □ Ja
   Kärllkramp från hjärtat □ Nej □ Ja
   Hjärtmuskelinflammation □ Nej □ Ja
   Fel på någon hjärtklaff □ Nej □ Ja
   Rytvmrubbnin, förmaksflimmer □ Nej □ Ja
   Någon annan hjärtsjukdom □ Nej □ Ja

31a. Har läkare konstaterat att du har någon lungsjukdom? □ Nej □ Ja
   Om ja, vilken eller vilka?:
   KOL (kronisk obstruktiv lungsjukdom) □ Nej □ Ja
   Astma? □ Nej □ Ja
   Någon annan lungsjukdom? □ Nej □ Ja

31b. Har du besvär från luftvägarna eller lungorna? □ Nej □ Ja
   Om ja, vad av följande:
   Ihållande hosta senaste halvåret? □ Nej □ Ja
   Att det piper/väser ibland när jag andas? □ Nej □ Ja
   Andra luftvägsbesvärf? □ Nej □ Ja

32. Har du besvär från mage eller tarm? □ Nej □ Ja
   Om ja, vilket/vilka besvär:
   Diarréer? □ Nej □ Ja
   Kräkningar/halsbränna? □ Nej □ Ja
   Svåra smärtor? □ Nej □ Ja
   Förstoppling? □ Nej □ Ja
   Andra besvär? □ Nej □ Ja
33a. Har läkare konstaterat någon av nedanstående sjukdomar?

<table>
<thead>
<tr>
<th>sjukdom</th>
<th>Nej</th>
<th>Ja</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hjärnblödning?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Högt blodtryck?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Stroke/slaganfall?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Njurproblem?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Struma?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Diabetes?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Lever-/gallsjukdom?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Gulsot?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

33b. Har läkare konstaterat någon av nedanstående sjukdomar?

<table>
<thead>
<tr>
<th>sjukdom</th>
<th>Nej</th>
<th>Ja</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blodsjukdom?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ledsjukdom?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Reumatism?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Muskelsjukdom?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Neurologiska sjukdomar</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>(t.ex. epilepsi, MS)?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Psykiska problem?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Annat?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

34a. Har du, vid något tillfälle under det senaste halvåret varit inlagd på sjukhus? ☐ Nej ☐ Ja

Om ja, ange antal gånger du har varit inlagd:.................................

Om ja, vilket/vilka sjukhus och för vad?
..................................................................................................................................

34b. Har du under de senaste 6 mån:

<table>
<thead>
<tr>
<th>sjukdom</th>
<th>Nej</th>
<th>Ja</th>
</tr>
</thead>
<tbody>
<tr>
<td>sökt läkare eller tandläkare utomlands?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>behandlats för multiresistenta bakterier?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
35. Använder du någon medicin regelbundet (även värktabletter, spray, ögondroppar, insulinsprutor, p-pillar, hälsokostpreparat)? □ Nej □ Ja

**Om du svarat Ja, skriv medicinens namn, styrka och hur ofta du tar den.**

<table>
<thead>
<tr>
<th>Medicinens namn</th>
<th>Medicinens styrka</th>
<th>Hur ofta tar du den?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

36. Har du under de senaste tre månaderna använt kortisontabletter? □ Nej □ Ja

37. Har du sövts eller fått bedövning tidigare? □ Nej □ Ja

Om ja, uppstod det några problem? □ Nej □ Ja

Om ja, beskriv ........................................................................................................................................................................
........................................................................................................................................................................
........................................................................................................................................................................

38. Har du någon sjukdom som smittar via blodet (t ex HIV eller hepatit)? □ Nej □ Ja


40. Har du något av nedanstående?

   Urinkateter eller andra slangar in i kroppen? □ Nej □ Ja
   Bensår? □ Nej □ Ja
   Eksem? □ Nej □ Ja

41. Har du svårt att gapa stort, t ex hos tandläkare? □ Nej □ Ja

42. Har någon släkting haft problem när de sövts eller fått bedövning? □ Nej □ Vet ej □ Ja

43. Godkänner du att vi får ta del av väsentliga journalhandlingar inför operationen? □ Ja □ Nej
44. För att kunna ta hand om dig på bästa sätt är det bra att veta om du har värk eller smärta i någon annan kroppsdel än den som ska opereras. Det är också viktigt att veta om du har andra behov som kan påverka vården.

Har du några av nedanstående problem/behov? □ Nej □ Ja

**Om ja, jag har**
- □ Nej □ Ja värk och/eller smärta
- □ Nej □ Ja nedsatt hörsel
- □ Nej □ Ja nedsatt syn
- □ Nej □ Ja rörelsehindrad
- □ Nej □ Ja behov av tolk

45 Har du haft problem med att förstå någon eller några frågor i enkäten? □ Nej □ Ja

Om ja, skriv numret på frågan och beskriv problemet:
........................................................................................................................................................
........................................................................................................................................................
........................................................................................................................................................
........................................................................................................................................................
........................................................................................................................................................

46 Finns det något ytterligare som du anser är viktigt att berätta om?
........................................................................................................................................................
........................................................................................................................................................
........................................................................................................................................................
........................................................................................................................................................

................................................................................................

Namn (den som fyllt i frågeformuläret)
Enkät 8 veckor efter operation

Din enkät finns på www.gynop.se, klicka ”Logga in”. Ditt lösenord är 73xyyh.

Hej Testsson

Vi vill höra hur det har gått för dig efter operationen.

Vi önskar svar så snart som möjligt, gärna via Internet. Dina svar går till den klinik där du har opererats.


Vi vill på detta sätt erbjuda dig en uppföljning efter operationen. Detta kan leda till att vi kontaktar dig om det framkommer besvär relaterade till operationen. Om du har kvarvarande och/eller nya besvär och vi inte kontaktar dig bör du vända dig till din ordinarie läkare t.ex. vid din vårdecentral.

För ytterligare information se www.gynop.se.

Vänliga hälsningar och tack på förhand

Margareta Nilsson
Läkare
Övningsklinik
Övningssjukhus
Din värdering av operationen
(ca 8 veckor)
Dr Margareta Nilsson

Besvara gärna din enkät via www.gynop.se
Klicka ”Logga in”. Ditt lösenord är 73xyyh

1. Datum när enkäten fylls i: ...............................................................

2. Vad anser du om längden på din sjukhusvistelse?
   - Lagom
   - För lång
   - För kort

3. Har du behövt ta smärtstillande mediciner p. g. a. operationen, efter du lämnat sjukhuset?
   - Nej
   - Ja. Hur många dagar? ................................

4. Har du haft underlivsblödningar p.g.a. operationen?
   - Nej
   - Ja. Hur många dagar? …………………
      Hur stora var blödningarna?
      - Inga/obetydliga
      - Små
      - Måttliga
      - Rikliga
      - Mycket rikliga

5a. Har du svårt att tömma urinblåsan?
   - Aldrig
   - Nästan aldrig
   - 1–3 ggr per månad
   - 1–3 ggr per vecka
   - Dagligen

5b. Har du besvär av urinträngningar?
   - Aldrig
   - Nästan aldrig
   - 1–3 ggr per månad
   - 1–3 ggr per vecka
   - Dagligen

Telefonnummer saknas
E-post: Saknas

⇒ Saknas uppgifter ovan eller är de felaktiga i så fall fyll i här

Det finns luckor i frågenummeringen eftersom vissa frågor inte är aktuella för dig.
5c Behöver du gå upp på natten och kissa?

☐ Aldrig  ☐ Nästan aldrig  ☐ Oftast en gång  ☐ Oftast två ggr  ☐ Mer än två ggr

5d Har du urinläckage eller ofrivillig urinavgång?

☐ Aldrig  ☐ Nästan aldrig  ☐ 1–3 ggr per månad  ☐ 1–3 ggr per vecka  ☐ Dagligen

6a. Har du varit sjukskriven på grund av operationen?

☐ Nej, jag har inte varit sjukskriven  
☐ Jag var sjukskriven av annan anledning i samband med operationen, varför det ej går att svara på frågan  
☐ Ja, jag är fortfarande sjukskriven  
☐ Ja, jag har varit sjukskriven

6b. Om du varit sjukskriven, vilket datum återgick du till arbete i samma omfattning som före operationen?

........... - ......... - .......... 
år  mån  dag

6c. Om du varit sjukskriven, vad tycker du om sjukskrivningsperiodens totala längd?

☐ För lång  
☐ Lagom  
☐ För kort  
☐ Jag var sjukskriven av annan anledning i samband med operationen, varför det ej går att svara på frågan.


8. Vad anser du om operationsresultatet så här långt? Mitt tillstånd är:

☐ Mycket förbättrat  
☐ Förbättrat  
☐ Oförändrat  
☐ Försämrat  
☐ Mycket försämrat

Efter en operation finns en del besvär som är normala, övergående och förväntade eftersom man har genomgått en operation. För ett fåtal blir besvären efter operationen mer långdragna.

9. Har du under perioden sedan du kom hem efter operationen fram till nu haft besvär/komplikationer till följd av operationen?

☐ Nej, hoppa till fråga 16a  
☐ Ja, lindriga  
☐ Ja, svåra/allvarliga  
☐ Ja, både lindriga och svåra/allvarliga
11a. Har du behövt uppsöka sjukvården under tiden efter operationen p.g.a. dessa besvär/komplikationer?

☐ Nej  ☐ Ja.

<table>
<thead>
<tr>
<th>Om ja. Vilken sjukvårdsinrättning besökte du?</th>
<th>Namn på klinik och sjukhus/ vårdcentral som du besökte</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Kvinnokliniken där du opererades</td>
<td>..................................................................................</td>
</tr>
<tr>
<td>☐ Vårdecentral</td>
<td>..................................................................................</td>
</tr>
<tr>
<td>☐ Annan vårdinrättning</td>
<td>..................................................................................</td>
</tr>
</tbody>
</table>

11b. Om ja, när besökte sjukvårdsinrättning första gången efter hemkomsten?

☐ Inom 1 vecka  ☐ 1 till 2 veckor  ☐ 2 till 4 veckor  ☐ Senare än 4 veckor

**Behandling av komplikationer och besvär**

11c. Om ja på fråga 11a: Blev du inlagd på sjukhus pga komplikationen?

☐ Nej, lämnade sjukhuset samma dag.
☐ Ja, stannade kvar en natt.
☐ Ja, stannade kvar två nätter eller fler.

11d. Om ja på fråga 11a: Ingick operation i behandlingen av komplikationen?  ☐ Nej  ☐ Ja.

11e. Om ja på fråga 11a: Behandlades dina besvär/komplikationer?

Välj ett eller flera svarsalternativ

☐ Nej
☐ Ja, kontrollerades med ytterligare återbesök och/eller utredning
☐ Ja, smärtstillande
☐ Ja, med såromläggning
☐ Ja, annan behandling. Beskriv: .................................................................................................
.................................................................................................................................

11f. Om ja på fråga 11a: Medförde komplikationen förlängd sjukskrivning?

☐ Nej
☐ Ja, antal veckor.......................
Beskriv dina besvär/komplikationer genom att välja ett eller flera av följande alternativ.

12a. Kryssa för de organ/kroppsdelar som drabbades:

- □ Operationssår
- □ Blodkärl
- □ Livmoder
- □ Nerv/Känsel
- □ Urinblåsa
- □ Annat/annan (Beskriv vid fråga 13f)

12b. Medförde komplikationen något av följande problem:

- □ Bristning av operationsärret som krävt ny operation (sårruptur)
- □ Falsk gång till slidan tarmen eller urinblåsan (fistel)
- □ Inget av ovanstående problem.

Olika typer av komplikationer.

13a. Blödning:

- □ Riklig / långdragen blödning från underlivet
- □ Blödning i bukvägg / buksåret
- □ Blödning inne i bukhålan

- □ Blodbrist
- □ Annan blödning (Beskriv vid fråga 13f)
- □ Ingen blödning

13b. Infektion:

- □ Feber mer än 38 o i mer än 2 dagar
- □ Urinvägsinfektion
- □ Infektion i underlivet, illaluktande flytningar
- □ Infektion i operationssåret
- □ Livmoderinfektion

Om du kryssat i någon infektion, behandlades infektionen med antibiotika/penicillin?

- □ Ja
- □ Nej

13c. Smärta:

- □ Smärta i buken, magen
- □ Smärta i underlivet
- □ Smärta i/vid blygdbenet

- □ Smärta i/vid ljumsken, ljumskarna
- □ Smärta annan plats (Beskriv vid fråga 13f)
- □ Ingen smärta
13d. Vattenkastningsbesvär:

☐ Svårigheter att tömma urinblåsan som krävt behandling
  ☐ Resturinkontroll (mätning av kvarvarande urin i urinblåsan efter att ha kisat) vid antal tillfällen (ungefärligt) ..............
  ☐ Tappning av urinblåsan vid antal tillfällen (ungefärligt) ........
  ☐ Självkateterisering i antal dagar (ungefärligt) ............
  ☐ Kateterbehandling i antal dagar (ungefärligt ) ............
  ☐ Annan behandling i antal dagar ......., ange vilken ..........
  ☐ Smärtor när du kisar fortfarande kvar mer än 1 månad efter operationen
  ☐ Svårt att hålla urinen (urininkontinens)
  ☐ Annat (Beskriv vid fråga 13f)
  ☐ Inga vattenkastningsbesvär

13e. Allmän medicinsk komplikation:

☐ Onormal trötthet, orkeslöshet
  ☐ Svår förstoppning
  ☐ Tarmvred (ileus / subileus)
  ☐ Blodpropp (trombos, emboli) med regelbundna kontroller pga blodförtunnande mediciner
  ☐ Annan komplikation (Beskriv vid fråga 13f)
  ☐ Inget av ovanstående

13f. Beskriv de besvär/komplikationer du kryssat i ovan:...........................................................................................................
........................................................................................................................................................................
........................................................................................................................................................................
........................................................................................................................................................................
........................................................................................................................................................................

14. Har du fortfarande besvär med något av det du angett i frågorna 9-13?

☐ Nej
☐ Ja

Om ja, beskriv:..............................................................................................................................................................
........................................................................................................................................................................

15. Om du svarat ja på någon av frågorna 9-14 godkänner du att vi får ta del av journalhandlingar om detta?

☐ Nej
☐ Ja
Frågor om att kunna hålla avföring:

16a. Har du svårt att hålla avföring eller gaser?
   □ Nej
   □ Ja

Om du har svarat nej på ovanstående fråga, **hoppa till fråga 17**

16b. Händer det att du släpper dig även när det är olämpligt?
   □ Aldrig
   □ Nästan aldrig
   □ Ja, 1-3 gånger i månaden
   □ Ja, 1-3 gånger i veckan
   □ Ja, dagligen

16c. Har du läckage av lös avföring?
   □ Aldrig
   □ Nästan aldrig
   □ Ja, 1-3 gånger i månaden
   □ Ja, 1-3 gånger i veckan
   □ Ja, dagligen

16d. Har du läckage av fast avföring?
   □ Aldrig
   □ Nästan aldrig
   □ Ja, 1-3 gånger i månaden
   □ Ja, 1-3 gånger i veckan
   □ Ja, dagligen

16e. Använder du skydd pga avföringsläckage?
   □ Aldrig
   □ Nästan aldrig
   □ Ja, 1-3 gånger i månaden
   □ Ja, 1-3 gånger i veckan
   □ Ja, dagligen

16f. Påverkar dina läckageproblem din livsstil?
   □ Aldrig
   □ Nästan aldrig
   □ Ja, 1-3 gånger i månaden
   □ Ja, 1-3 gånger i veckan
   □ Ja, dagligen
17. Har du några ytterligare problem som hänger samman med operationen?
   □ Nej
   □ Ja

....................................................................................................................................................................
....................................................................................................................................................................
....................................................................................................................................................................

18a. Är du kallad eller kommer du att kallas för återbesök/kontroll pga. operationen?
   □ Ja
   □ Nej
   □ Vet ej

18b. Om Nej eller Vet ej, behöver du kontakt med kvinnokliniken med anledning av operationen?
   □ Nej, jag hör av mig om det blir några problem.
   □ Ja, jag önskar bli kontaktad angående………………………………………………

19. Har du haft problem med att förstå någon eller några frågor i enkäten? □ Nej □ Ja
    Om ja, skriv numret på frågan och beskriv problemet:
....................................................................................................................................................................
....................................................................................................................................................................

....................................................................................................................................................................

Namn (den som fyllt i formuläret)
Enkät 1 år efter operation

Din enkät finns på www.gynop.se, klicka ”Logga in”. Ditt lösenord är 75dccb.

Hej Testsson

Det är nu cirka ett år sedan du opererades. Vi vill höra hur det har gått för dig och hur resultatet har blivit efter operationen.

Vi önskar svar så snart som möjligt, gärna via Internet. Dina svar går till den klinik där du har opererats.

Vi hoppas utifrån dina svar kunna utvärdera hur operationen fungerat för dig och förhoppningsvis förfinna operationsmetoden till nytta för framtida patienter. Även om du besökt kliniken sedan du opererades önskar vi att du besvarar frågeformuläret så väl du kan utifrån vad som hänt efter operationen. Dessa enkäter ingår i den kvalitetskontroll av sjukvården vi utför och som är förordad i hälso- och sjukvårdslagen.

Vi vill på detta sätt erbjudas dig en uppföljning efter operationen. Detta kan leda till att vi kontaktar dig om det framkommer besvär relaterade till operationen. Om du har kvarvarande och/eller nya besvär och vi inte kontaktar dig bör du vända dig till din ordinarie läkare t.ex. vid din vårdcentral.

För ytterligare information se www.gynop.se.

Vänliga hälsningar och tack på förhand

Margareta Nilsson
Läkare
Övningsklinik
Övningssjukhus
Din värdering efter operationen (ca 1 år)

Dr Margareta Nilsson

Besvara gärna din enkät via www.gynop.se
Klicka ”Logga in”.
Ditt lösenord är 75dccb

1234567890
Testsson Test

Personnummer: ...... ...... ...... - .............
Namn...............................................................
Adress..............................................................
Postnummer.............Ort...................................
Telefon ...................................
E-post...................................................….........

Telefonnummer saknas
E-post: Saknas

 Lidig
Saknas uppgifter ovan eller är de felaktiga i så fall fyll i här

Det finns luckor i frågenummeringen eftersom vissa frågor inte är aktuella för dig.

1. Datum när enkäten ifylls: .................................................................

2. Har du smärtor i underlivet/nedre delen av buken?
   ☐ Nej
   ☐ Ja.
   • Smärta i buken ☐ Nej, ingen smärta
         ☐ Ja, lite smärta
         ☐ Ja, måttlig smärta
         ☐ Ja, stark smärta
         ☐ Ja, olidlig smärta
   • Underlivssmärta, beskriv:

         ...........................................................
         ...........................................................

   ☐ Nej, ingen smärta
   ☐ Ja, lite smärta
   ☐ Ja, måttlig smärta
   ☐ Ja, stark smärta
   ☐ Ja, olidlig smärta

3a. Har du haft underlivsblödningar under det senaste året? ☐ Nej ☐ Ja

3c. Har du blödningar som kommer när de inte borde komma? ☐ Ja ☐ Nej

3e. Hur skulle du beskriva dessa blödningar?
   ☐ Har inga/upphört
   ☐ Små
   ☐ Måttliga
   ☐ Rikliga
   ☐ Mycket rikliga
   ☐ Varierar mycket från gång till gång
4. Har du övergångsbesvär/klimakteriebesvär (blodvallning, svettning, hjärtklappning)?
   □ Nej
   □ Ja
   □ Vet ej

5. Använder du hormonpreparat med östrogen?
   □ Nej
   □ Ja, mot övergångsbesvär/klimakteriebesvär
   □ Ja, mot underlivsproblem
   □ Ja, mot problem med urin/urinvägar
   □ Ja, av annan anledning .................................................................

6a. Har du en känsla av att något buktar ut ur slidan?
   □ Aldrig  □ Nästan aldrig  □ 1–3 ggr per månad  □ 1–3 ggr per vecka □ Dagligen

6b. Har du skavningsbesvär i underlivet?
   □ Aldrig  □ Nästan aldrig  □ 1–3 ggr per månad  □ 1–3 ggr per vecka □ Dagligen

6c. Använder du ring/inlägg mot framfall efter operationen? Kryssa i ett alternativ:
   □ Aldrig haft ring efter operationen
   □ Har haft ring efter operationen men inte nu
   □ Har ring nu
   □ Vet ej

7a. Har du svårt att tömma urinblåsan?
   □ Aldrig  □ Nästan aldrig  □ 1–3 ggr per månad  □ 1–3 ggr per vecka □ Dagligen

7b. Har du besvär av urinträngningar (en hastigt påkommande, stark känsla av att behöva kissa)?
   □ Aldrig  □ Nästan aldrig  □ 1–3 ggr per månad  □ 1–3 ggr per vecka □ Dagligen

7c. Behöver du gå upp på natten och kissa?
   □ Aldrig  □ Nästan aldrig  □ Oftast en gång  □ Oftast två ggr □ Mer än två ggr

7d. Har du urinläckage eller ofrivillig urinavgång?
   □ Aldrig  □ Nästan aldrig  □ 1–3 ggr per månad  □ 1–3 ggr per vecka □ Dagligen
Om du har svarat Aldrig – Nästan aldrig på ovanstående fråga 7d, **hoppa till fråga 9a**

Kryssa i **ett av alternativen** i var och en av frågorna 8a – 8i

8a Läcker du urin när du stiger upp ur sängen?  □ Ja □ Nej

8b Hur ofta läcker du urin i samband med fysisk aktivitet, när du skrattar, hostar eller nyser?
□ Aldrig
□ 1–4 gånger per månad
□ 1–6 gånger per vecka
□ 1 gång per dag
□ Mer än 1 gång per dag

8d. Hur ofta upplever du en hastigt påkommande, stark känsla av att behöva kissa och läcker urin innan du når fram till toaletten?
□ Aldrig
□ 1–4 gånger per månad
□ 1–6 gånger per vecka
□ 1 gång per dag
□ Mer än 1 gång per dag

8h. Undviker du aktiviteter (t ex fritidssysselsättning, fysisk träning eller att gå ut) för att du är rädd för att läcka?
□ Aldrig □ Sällan □ Ibland □ Ofta □ Alltid

8i. Undviker du platser och situationer där du vet att toalett inte finns tillgänglig?
□ Aldrig □ Sällan □ Ibland □ Ofta □ Alltid

Kryssa i ja eller nej på **alla frågorna** under punkt 8j.

8j. Påverkar ditt urinläckage
   din semester? □ Ja □ Nej
   ditt familjeliv? □ Ja □ Nej
   ditt sexliv? □ Ja □ Nej
   ditt sociala liv (gå ut, träffa vänner etc)? □ Ja □ Nej
   din nattsömn? □ Ja □ Nej
   ditt arbetsliv? □ Ja □ Nej

9a Händer det att du har svårt att tömma tarmen?
□ Aldrig □ Nästan aldrig □ 1–3 ggr per månad □ 1–3 ggr per vecka □ Dagligen

9b Händer det att du behöver hålla emot bakre slidväggen för att tömma tarmen?
□ Aldrig □ Nästan aldrig □ 1–3 ggr per månad □ 1–3 ggr per vecka □ Dagligen
Frågor om att kunna hålla avföring:

10a. Har du svårt att hålla avföring eller gaser?
- Nej
- Ja

Om du har svarat nej på ovanstående fråga, hoppa till fråga 12a

10b. Händer det att du släpper dig även när det är olämpligt?
- Aldrig
- Nästan aldrig
- Ja, 1-3 gånger i månaden
- Ja, 1-3 gånger i veckan
- Ja, dagligen

10c. Har du läckage av lös avföring?
- Aldrig
- Nästan aldrig
- Ja, 1-3 gånger i månaden
- Ja, 1-3 gånger i veckan
- Ja, dagligen

10d. Har du läckage av fast avföring?
- Aldrig
- Nästan aldrig
- Ja, 1-3 gånger i månaden
- Ja, 1-3 gånger i veckan
- Ja, dagligen

10e. Använder du skydd pga. avföringsläckage?
- Aldrig
- Nästan aldrig
- Ja, 1-3 gånger i månaden
- Ja, 1-3 gånger i veckan
- Ja, dagligen

10f. Påverkar dina läckageproblem din livsstil?
- Aldrig
- Nästan aldrig
- Ja, 1-3 gånger i månaden
- Ja, 1-3 gånger i veckan
- Ja, dagligen
12a. Har du haft samlag de senaste 3 månaderna? □ Ja □ Nej □ Ej aktuellt □ Avstår från att svara

12b. Om ja på fråga 12a, känner du smärta i underlivet vid samlag?
□ Nej, ingen smärta
□ Ja, lite smärta
□ Ja, måttlig smärta
□ Ja, stark smärta
□ Ja, olidlig smärta

12d. Om ja på fråga 12a, upplever du
slidöppningen alltför liten/trång? □ Ja □ Nej
slidöppningen alltför stor/öppen? □ Ja □ Nej
smärta i slidöppningen? □ Ja □ Nej
andra besvär från slidöppningen? □ Ja □ Nej

Om ja, vilken typ av besvär? …………………………………………………………………………………………………

13. Vad anser du om operationsresultatet så här långt? Mitt tillstånd är:
□ Mycket förbättrat
□ Förbättrat
□ Oförändrat
□ Försvämt
□ Mycket försvämt

14. Har du under perioden två månader efter operationen fram till nu haft besvär/komplikationer till följd av operationen?
□ Nej, hoppa till fråga 20
□ Ja, lindrig
□ Ja, svår/allvarlig

15. Är dessa besvär/komplikationer så allvarliga att de är anmälda? (t.ex. till patientförsäkring)
□ Nej
□ Ja
16a. Har du perioden två månader efter operationen fram till nu behövt uppsöka sjukvården pga. dessa besvär/komplikationer?

☐ Nej
☐ Ja.

<table>
<thead>
<tr>
<th>Om ja, vilken sjukvårdsinrättning besökte du?</th>
<th>Namn på klinik och sjukhus/vårdcentral som du besökte</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Kvinnokliniken där du opererades</td>
<td>...........................................................................</td>
</tr>
<tr>
<td>☐ Vårdcentral</td>
<td>...........................................................................</td>
</tr>
<tr>
<td>☐ Annan vårdinrättning</td>
<td>...........................................................................</td>
</tr>
</tbody>
</table>

16b. Om ja på fråga 16a: Blev du inlagd på sjukhus pga. komplikationen?

☐ Ja, stannade kvar två nätter eller fler.
☐ Ja, stannade kvar en natt.
☐ Nej, lämnade sjukhuset samma dag.

16c. Om ja på fråga 16a: Ingick operation i behandlingen av komplikationen? ☐ Nej ☐ Ja

16d. Om ja på fråga 16a: Föranledde dina besvär/komplikationer någon annan åtgärd?

☐ Nej
☐ Ja, kontrollerades med ytterligare återbesök och/eller utredning
☐ Ja, smärtstillande
☐ Ja, annan behandling. Beskriv: ................................................................................................................
...........................................................................................................................................................

16e. Om ja på fråga 16a: Medförde komplikationen förlängd sjukskrivning?

☐ Nej
☐ Ja, antal veckor ........
Beskriv dina besvär/komplikationer genom att välja ett eller flera av följande alternativ.

17a. Vilket/vilka organ drabbades?
- □ Bukärr, operationsärr
- □ Nerv/Känsl
- □ Livmoder
- □ Urinblåsan
- □ Urinledaren från njuren till urinblåsan (uretären)
- □ Urinrör
- □ Slida
- □ Tarm
- □ Annat/annan (Beskriv vid fråga 17c)

17b Olika typer av besvär / komplikationer.
- □ Smärtor vid vattenkastning längre tid än 2 månader efter operation
- □ Urinstämma, (urinretention) som krävt sjukvårdsbesök, urintappning
- □ Urinläckage / urininkontinens
- □ Bråck i operationsärret (ärrbråck)
- □ Framfall (prolaps)
- □ Tarmvred (ileus / subileus)
- □ Falsk gång till slidan, tarmen eller urinblåsan (fistel)
- □ Smärtor i ljumskar
- □ Smärta vid blygdbenet
- □ Smärta i bukväggen
- □ Annat (Beskriv vid fråga 17c)

17c. Beskriv de besvär/komplikationer du kryssat i ovan: .................................................................................................................................
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........................................................................................................................................................................................................
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........................................................................................................................................................................................................
........................................................................................................................................................................................................

18. Har du fortfarande besvär som beror på operationen?
- □ Nej
- □ Ja Om Ja, beskriv: .................................................................................................................................................................................................
19. Om du svarat ja på fråga 14-18, godkänner du att vi får ta del av journalhandlingar om detta?
   □ Nej
   □ Ja

20. Vad tycker du om resultatet efter operationen?
   □ Mycket nöjd
   □ Nöjd
   □ Varken nöjd eller missnöjd
   □ Missnöjd
   □ Mycket missnöjd

24. Har du haft problem med att förstå någon eller några frågor i enkäten? □ Nej □ Ja
   Om Ja, skriv numret på frågan/ frågorna och beskriv problemet:
   ....................................................................................................................................................................
   ....................................................................................................................................................................
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Namn (den som fyllt i formuläret)
Påminnelse

Bästa
Du opererades vid XXXXXXXXX kvinnoklinik för framfall [datum].
Vi önskar din hjälp för att öka vår kunskap om långtidsresultat efter den operationen.

Din kvinnoklinik är vidtalad och har godkänt att vi kontaktar dig.

Din enkät finns även på www.gynop.se, klicka "Logga In". Ditt lösenord är «PatientID».

Självfallet är deltagandet frivilligt

Har du frågor angående denna enkät eller studie kontakta:

Emil Nüssler, Forskare
Nationella kvalitetsregistret inom gynekologisk kirurgi
Norrlands universitetssjukhus
901 85 Umeå
Emil.Nussler.jr@umu.se

Nota bene: All questions marked with grey in this appendix are questions implemented directly from the preoperative and one year questionnaires. They were left unchanged throughout the validation process, as described in the manuscript.
Din värdering efter operationen  
(ca 5 år)

<table>
<thead>
<tr>
<th>Personnummer: ...... ...... ...... - ..................</th>
</tr>
</thead>
<tbody>
<tr>
<td>Namn:.......................................................................</td>
</tr>
<tr>
<td>Adress:.....................................................................</td>
</tr>
<tr>
<td>Postnummer...........Ort......................................</td>
</tr>
<tr>
<td>Tel. bost ....................... Tel. arb......................</td>
</tr>
<tr>
<td>Övrig telefon .................................</td>
</tr>
<tr>
<td>E-post...............................................................</td>
</tr>
</tbody>
</table>

Detta är en uppföljning av den framfallsoperation du genomgick för 5 år sedan. Vi undrar hur du har det idag.

1. Datum när enkäten ifylls:.................................................................

2. Har du en känsla av att något buktar ut ur slidan?  
   - Aldrig  
   - Nästan aldrig  
   - 1–3 ggr per månad  
   - 1–3 ggr per vecka  
   - Dagligen

3. Har du skavningsbesvär i underlivet?  
   - Aldrig  
   - Nästan aldrig  
   - 1–3 ggr per månad  
   - 1–3 ggr per vecka  
   - Dagligen

4. Har du svårt att tömma urinblåsan?  
   - Aldrig  
   - Nästan aldrig  
   - 1–3 ggr per månad  
   - 1–3 ggr per vecka  
   - Dagligen

5. Har du besvär av urininträngningar (en hastigt påkommande, stark känsla av att behöva kissa)?  
   - Aldrig  
   - Nästan aldrig  
   - 1–3 ggr per månad  
   - 1–3 ggr per vecka  
   - Dagligen

6. Behöver du gå upp på natten och kissa?  
   - Aldrig  
   - Enstaka nätter  
   - Oftast en gång  
   - Oftast två ggr  
   - Mer än två ggr

7. Har du urinläckage eller ofrivillig urinavgång?  
   - Aldrig  
   - Nästan aldrig  
   - 1–3 ggr per månad  
   - 1–3 ggr per vecka  
   - Dagligen

8. Händer det att du har svårt att tömma tarmen?  
   - Aldrig  
   - Nästan aldrig  
   - 1–3 ggr per månad  
   - 1–3 ggr per vecka  
   - Dagligen

9. Händer det att du behöver hålla emot bakre slidväggen för att tömma tarmen?  
   - Aldrig  
   - Nästan aldrig  
   - 1–3 ggr per månad  
   - 1–3 ggr per vecka  
   - Dagligen

10. Har du läckage av fast avföring?  
    - Aldrig  
    - Nästan aldrig  
    - 1–3 ggr per månad  
    - 1–3 ggr per vecka  
    - Dagligen
11a. Har din läkare konstaterat ett nytt framfall (prolaps) efter operationen för fem år sedan?
   □ Nej
   □ Ja
   □ Vet inte
   □ Ingen läkarundersökning utförd

11b. Om ja, har du blivit opererad för det nya framfallet?
   □Ja  □ Nej

11c. Tror du själv att du har ett nytt framfall nu?
   □ Ja  □ Nej

12a. Lades det in ett nät vid operationen för fem år sedan?
   □Ja  □Nej  □Vet ej

12b. Om ja på fråga 12 a, har du haft några problem som du tror beror på nätet?
   □ Nej
   □Ja, framfallet kom tillbaka
   □Ja, blödning eller flytningar
   □Ja, en känsla av att slidan har blivit för trång
   □Ja, smärtor/värk
   □Ja, smärtor/obehag hos min partner vid samlag
   □Annat……………………………

12c. Om ja på fråga 12 a, har du och/eller din läkare konstaterat att:
   □ Nätet tränger igenom slidväggen
   □ Nätet tränger in i urinblåsan
   □ Nätet tränger in i ändtarmen
   □ Det har uppstått inflammation/infektion omkring nätet
   □Annat……………………………
   □Vet ej

13a. Har du blivit opererad igen på grund av nätet?
   □Ja  □Nej

13b. Om ja på fråga 13 a,
   □ Delar av nätet har opererats bort
   □Hela nätet har opererats bort
   □Annan operation pga nätet ……………………………

14a. Har du haft samlag de senaste 3 månaderna?
   □Ja  □Nej

14b. Om ja på fråga 14 a: Känner du smärta i underlivet vid samlag?
   □Nej, ingen smärta
   □Ja, lite smärta
   □Ja, måttlig smärta
   □Ja, stark smärta
   □Ja, olidlig smärta
14c. Om ja på fråga 14 a: Upplever du slidöppningen alltför liten/trång? □ Ja □ Nej
slidöppningen alltför stor/öppen? □ Ja □ Nej
smärta i slidöppningen? □ Ja □ Nej
andra besvär från slidöppningen? □ Ja □ Nej

Om ja, vilken typ av besvär? .................................................................
.................................................................................................

14d. Om ja på fråga 14 a: Har din partner påtalat återkommande besvär vid samlag som ni relaterar till
framfallsoperationen?
□ Ja □ Nej

Om ja, beskriv besvären: ........................................................................
.................................................................................................

Det finns några andra allmänna faktorer som kan påverka resultatet som vi även önskar svar på

15a. Har du haft menstruationer/underlivsblödningar under det senaste året?
□ Ja □ Nej

15b. Kommer dina menstruationsblödningar med jämna intervall? □ Ja □ Nej

15c. Har du blödningar som kommer när de inte borde komma? □ Ja □ Nej

15d. Åter du hormonpreparat som ger förväntade blödningar? □ Ja □ Nej

16. Använder du hormonpreparat med östrogen?
□ Nej
□ Ja, mot övergångsbesvär/klimakteriebesvär
□ Ja, mot underlivsproblem
□ Ja, mot problem med urin/urinvägar
□ Ja, som preventivmedel
□ Ja, av annan anledning .................................................................


18. Röker du?
□ Ja, ungefär.......(antal) cigaretter per dag
□ Nej, slutade år .............
□ Nej, har aldrig rökt
19. Har du sedan framfallsoperationen [datum] medicinerat regelbundet (dagligen eller varje vecka) med kortison (tabletter eller sprutor, dock inte kräm/salva) t ex Prednisolon, Prednison, Betapred, Betametason, Dexametason, Kortisonacetat?

- Nej, aldrig
- Ja men mindre än 1 år
- Ja, ungefär ............år
- Ja, i princip hela tiden

Till sist önskar vi ställa några övergripande frågor om framfallsoperationen

20. Vad anser du om resultatet av framfallsoperationen som utfördes för 5 år sedan? Mitt tillstånd är:

- Mycket förbättrat
- Förbättrat
- Oförändrat
- Försämrat
- Mycket försämrat

21. Vad tycker du om resultatet av framfallsoperationen som utfördes för 5 år sedan?

- Mycket nöjd
- Nöjd
- Varken nöjd eller missnöjd
- Missnöjd
- Mycket missnöjd

22. Du som angivit komplikationer eller operationer på någon av frågorna, godkänner du att vi får ta del av journalhandlingar om detta

- Nej  □ Ja

23. Finns det något ytterligare som hänger samman med framfallsoperationen som du vill berätta om

....................................................................................................................................................................
....................................................................................................................................................................
....................................................................................................................................................................

24. Har du haft problem med att förstå någon eller några frågor i enkäten?

- Nej  □ Ja

Om ja, skriv numret på frågan och beskriv problemet:

....................................................................................................................................................................
....................................................................................................................................................................
....................................................................................................................................................................

Namn (den som fyllt i formuläret)
Appendix 6

In the electronic version of the questionnaires, drop-down list are used when suitable. If a chosen alternative renders more questions, they are subsequently shown. For every page the responder is notified if there are incomplete questions. After activating “save = spara” unanswered questions get a red border to attract attention. At submission, another reminder is presented about missing answers.

Example of a drop-down list:
Example of questions made available when marking “ja=yes”
Surgeon’s preoperative form.

The preoperative forms are only available in electronic form. All mandatory questions are marked orange and the color disappears when a question is answered. The number of unfinished questions is also presented. When saving the form, if there are unfinished questions, the surgeon is notified. The notification remains as long as there are unfinished questions. If an answered question renders more questions they are made visible and are marked orange if mandatory.

Examples of the preoperative form for POP:
If “earlier POP = Tidigare Prolapsop” is answered “Yes= ja” as well as “Prolaps – POP” new obligatory alternatives are shown:
Surgeon’s operative form.

First a minor form is presented, as seen in example 1.

Question answers opens more questions, depending on which alternatives were chosen. After choosing the specific operation, the final choices are shown.

Example 1
After the first choice for “prolapse surgery” is made, the surgery form for POP is opened.
And after expansion, a specific compartment is chosen.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolapsurgi</td>
<td>Teknik</td>
<td>Implantat</td>
</tr>
<tr>
<td></td>
<td>Material</td>
<td>Resorberbar</td>
</tr>
<tr>
<td>Cervicampulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penisaugoppplugging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peniapplugning</td>
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<td>Enterociteplastic</td>
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<tr>
<td>Plastikkur</td>
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<tr>
<td>(meda eller övervägande)</td>
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</tr>
<tr>
<td>Resorberbar</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[Diagram showing surgical options and choices]