Variation in Surgical Technique (VaST):
How and why do surgical techniques to perform
native tissue pelvic organ prolapse repairs vary
between UK based surgeons and does this affect
the outcome of surgery?

A thesis submitted to the University of Manchester for the degree of
MPhil Medicine in the Faculty of Biology Medicine and Health

2016

Dr Emily Sara Fairclough

School of Medical Sciences
Contents

List of tables .......................................................................................................................... 5
List of figures .......................................................................................................................... 6
Abbreviations ......................................................................................................................... 7
Definitions ............................................................................................................................. 9
Overall abstract .................................................................................................................... 10
Lay abstract .......................................................................................................................... 11
Declaration ............................................................................................................................ 12
Copyright statement ............................................................................................................ 13
Acknowledgements ............................................................................................................. 14
Preface .................................................................................................................................. 15
Context of research ............................................................................................................. 18

Chapter 1: Introduction ........................................................................................................ 20
1.1 Background information ............................................................................................... 21
1.2 Definition of prolapse ................................................................................................. 21
1.3 Epidemiology of prolapse ......................................................................................... 22
1.4 The anatomy of the vaginal wall ............................................................................... 23
1.5 Surgical success of pelvic organ prolapse repairs ....................................................... 24
  1.5.1 Surgical outcome measures for pelvic organ prolapse repairs ......................... 25
  1.5.2 A comparison of native tissue and graft/mesh repairs ........................................ 27
1.6 Surgical techniques for pelvic organ prolapse repairs .............................................. 32
  1.6.1 The history of native tissue repair ..................................................................... 32
  1.6.2 Choice of pelvic organ prolapse operation type .............................................. 33
  1.6.3 Variation of surgical techniques to repair pelvic organ prolapse ..................... 35
1.7 Why is there surgical technique variation? ................................................................. 38
1.8 What are the controversies and what is the importance of this research? ............... 39
1.9 Aims and objectives .................................................................................................... 40

Chapter 2: Methodology ..................................................................................................... 42
2.1 Introduction .................................................................................................................. 43
2.2 Quantitative research methods – questionnaire based survey .................................. 43
2.3 Qualitative research methods – variation in surgical technique ............................... 44
  2.3.1 The choice moments ......................................................................................... 46
2.3.1.1 Inhabiting a position ........................................ 46
2.3.1.2 Framing the study ........................................ 49
2.3.1.3 Using a research approach ................................ 51
2.3.1.4 Collecting data ........................................... 51
2.3.1.5 Working with data ....................................... 53
2.3.2 Other considerations ......................................... 55
  2.3.2.1 Quality of data ........................................... 55
  2.3.2.2 Ethical considerations .................................. 55
  2.3.2.3 Obstacles related to site approvals ...................... 56
2.4 Quantitative research methods – variation in surgical technique ........................................... 58
  2.4.1 Data request procedure .................................. 58
  2.4.2 Study criteria ............................................. 58
  2.4.3 Outcome measures ....................................... 59
  2.4.4 Covariates .................................................. 60
  2.4.5 End points .................................................. 61
  2.4.6 Themes ..................................................... 61
  2.4.7 Analysis objectives ...................................... 61
  2.4.8 Handling of missing values and other data conventions ........................................... 61
  2.4.9 Statistical missing values and other data conventions ........................................... 62
2.5 Reporting ................................................................ 63

Chapter 3: (Paper 1) A UK questionnaire survey of current techniques used to perform pelvic organ prolapse repair ........................................... 64

Abstract ........................................................................ 66
Introduction .................................................................... 68
Methodology ................................................................... 69
Results ........................................................................... 70
Discussion ....................................................................... 75

Chapter 4: (Paper 2) Variation in surgical technique (VaST): A qualitative study of the surgical technique used in the UK for native tissue anterior pelvic organ prolapse repair ........................................... 79

Abstract ........................................................................ 81
Introduction ..................................................................... 83
| Methodology | 85 |
| Results | 88 |
| Discussion | 103 |

**Chapter 5: (Paper 3) Variation in surgical technique (VaST): Reasoning behind practice: An observational study of surgery**

| Abstract | 109 |
| Introduction | 110 |
| Study Methods | 119 |
| Study Findings | 121 |
| Discussion | 133 |

**Chapter 6: (Paper 4) The influence of surgical technique on the outcome of native tissue pelvic organ prolapse repair**

| Abstract | 139 |
| Introduction | 141 |
| Methodology | 142 |
| Results | 146 |
| Discussion | 151 |

**Chapter 7: Overall discussion**

| 7.1 Overall discussion | 158 |
| 7.2 Strengths | 163 |
| 7.3 Limitations | 164 |
| 7.4 Future research | 170 |

**References**

**Appendix**

| Study protocol | 189 |
| Questionnaire (PROSPECT) | 226 |

**Final word count:** 53, 282
**List of Tables**

**Table 1.1:** National survey of pelvic organ prolapse procedures (native tissue) ........ 34

**Table 1.2:** National survey of pelvic organ prolapse procedures (graft/mesh) ........ 35

**Table 3.1:** The depth of dissection for native tissue pelvic organ prolapse repair ...... 70

**Table 3.2:** The method of fascial dissection for native tissue pelvic organ prolapse repairs .................................................................................................................................................. 71

**Table 3.3:** The methods of fascial repair for native tissue pelvic organ prolapse repairs .................................................................................................................................................. 71

**Table 3.4:** The suture material and method of closure of the fascia and skin for native tissue and graft/mesh pelvic organ prolapse repairs .................................................................................................................. 72

**Table 3.5:** The surgeons previous mesh kit experience ........................................... 73

**Table 4.1:** Topic guide for semi structured interviews with surgeons ................. 86

**Table 4.2:** Demographics of surgeons and details of concomitant surgery ............. 89

**Table 4.3:** Views on infiltration placement .................................................................................................................. 91

**Table 4.4:** Summary of themes of surgery and the variations seen in each step ...... 93

**Table 6.1:** The themes and frequency of repairs in this theme ................................. 143

**Table 6.2:** POP SS questions, responses and scoring ............................................. 144

**Table 6.3:** Demographics of women and procedures ............................................. 146

**Table 6.4:** Subjective and Objective outcomes ..................................................... 147
List of Figures

Figure 1.1: Stages of pelvic organ prolapse...............................................................22

Figure 1.2: Histology of the vaginal wall .................................................................24

Figure 4.1: Photographic illustrations of fascial dissection......................................92

Figure 4.2: Fascial suture placement ........................................................................97

Figure 4.3: Methods of suturing for fascial repair ...............................................99

Figure 5.1: Hierarchy of evidence ..........................................................................113

Figure 6.1: Photographic illustrations of fascial dissection....................................148
### List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMS</td>
<td>American medical system</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>Coef.</td>
<td>Coefficient</td>
</tr>
<tr>
<td>EBM</td>
<td>Evidence based medicine</td>
</tr>
<tr>
<td>EBP</td>
<td>Evidence based practice</td>
</tr>
<tr>
<td>EUGA</td>
<td>European Urogynaecology Association</td>
</tr>
<tr>
<td>ICS</td>
<td>International Continence Society</td>
</tr>
<tr>
<td>ICC</td>
<td>Intra class correlation</td>
</tr>
<tr>
<td>IQR</td>
<td>Inter quartile range</td>
</tr>
<tr>
<td>IUGA</td>
<td>International Urogynecological Association</td>
</tr>
<tr>
<td>PDS</td>
<td>Polydioxanone suture</td>
</tr>
<tr>
<td>PGA/Vicryl</td>
<td>Polyglycolic acid suture</td>
</tr>
<tr>
<td>POP</td>
<td>Pelvic organ prolapse</td>
</tr>
<tr>
<td>POP Q</td>
<td>Pelvic organ prolapse quantification system</td>
</tr>
<tr>
<td>POP SS</td>
<td>Pelvic organ prolapse symptoms score</td>
</tr>
<tr>
<td>PR</td>
<td>Per rectal/ rectal examination</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
<tr>
<td>---------</td>
<td>------------</td>
</tr>
<tr>
<td>PROSPECT</td>
<td>PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>VaST</td>
<td>Variation in Surgical Technique</td>
</tr>
</tbody>
</table>
List of Definitions

Pelvic organ prolapse

“The decent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vaginal (vaginal vault). The presence of any such sign should be correlated with symptoms. More commonly this correlation would occur at the level of the hymen or beyond (entrance of the vagina).” [1]

Colporraphy

Suture of the vagina or the operation of denuding and suturing the vaginal wall to narrow the vagina

Anterior/Posterior Repair

Same as “Colporraphy”, the repair is on the front/back walls of the vagina

Native tissue

Women’s own tissue, a group or layer of similarly specialised cells that together perform a special function.

Graft/Mesh

A biological or synthetic implant used to augment native tissue pelvic organ prolapse repair
**Overall Abstract**

University of Manchester    Dr Emily Sara Fairclough    M Phil Medicine

28 December 2016

**Variation in Surgical Technique (VaST): How and why do the surgical techniques to perform native tissue pelvic organ prolapse repairs vary amongst UK based surgeons?**

**Introduction**

Surgical techniques used to perform native tissue pelvic organ prolapse (POP) repair vary between surgeons in the UK and other countries. There is a lack of evidence exploring whether this variation in practice influences the outcomes of surgery.

**Objective**

To evaluate how and why a cohort of UK surgeons use particular surgical techniques when performing native tissue POP surgery and whether this influences the outcome of surgery.

**Method**

A mixed methods study. A questionnaire survey was conducted to detail current surgical techniques for native tissue and graft/mesh POP repairs performed by a cohort of UK surgeons recruiting to a large multicentre prolapse trial (PROSPECT). This informed qualitative research (video observations of surgery, audio taped interviews with surgeons and fieldwork) to categorise how surgeons operate and why surgeons use certain surgical techniques when performing native tissue POP surgery. The influence of different aspects of the surgical technique on patient outcomes following native tissue anterior repair in women recruited to the PROSPECT trial were then investigated using the themes from the qualitative part of the study.

**Results**

Surgical techniques used to perform POP surgery vary between surgeons who recruited to the PROSPECT and VaST studies. The techniques used varied between surgeons in each step of the procedure and themes were derived from these steps rather than the procedure in its entirety. Categorisation of themes was challenging due to the subjective elements of surgery and the lack of standard terminology to describe techniques. Four themes were identified to explain why variation in surgical practice exists; The surgical journey; Rationalising practice; Contextual factors; And, Concepts of success. Although surgeons expressed a willingness to incorporate evidence based medicine into practice there was a reported lack of evidence on which to base practice. Certain aspects of technique (depth of dissection, method of repair, fascia suture material and skin suture method) were observed to influence the subjective and anatomical outcomes of surgery.

**Conclusion**

Native tissue anterior repair surgery has been categorised and the reasons for practice variation identified. Aspects of surgical technique were found to influence the outcomes of POP surgery. Standardisation of surgical terminology is required. These results should raise awareness of the influence of surgical technique on outcomes and should inform future RCT in this area to identify if a change in practice is required.
Lay abstract

Prolapse is a common condition in women and the symptom that women commonly describe is “the feeling of a lump or bulge at the entrance of or coming out of the vagina”. There are 3 compartments or walls of the vagina including the front (anterior), back (posterior) and top (vault or cervix). Prolapse can occur in any of these compartments.

One of the treatments for prolapse is surgery. There are concerns about the success rate of the surgical repair of prolapse especially the front wall. There have been some studies that show the surgical techniques used to repair prolapse of the front and back walls vary between different surgeons but the findings have been limited by the quality of data and lack of clear definitions.

This study looks in more detail at how the surgical techniques to repair the front and back walls of the vagina vary as well as the reasons behind these variations in surgical technique. It is not clear currently whether this surgical technique variation affects the outcome of surgery and the results of this study will be used to assist in answering this question.
Declaration

No portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification of this or any other university or institute of learning.
Copyright statement

The author of this thesis (including any appendices and/or schedules to this thesis) owns certain copyright or related rights in it (the “Copyright”) and s/he has given The University of Manchester certain rights to use such Copyright, including for administrative purposes.

Copies of this thesis, either in full or in extracts and whether in hard or electronic copy, may be made only in accordance with the Copyright, Designs and Patents Act 1988 (as amended) and regulations issued under it or, where appropriate, in accordance with licensing agreements which the University has from time to time. This page must form part of any such copies made.

The ownership of certain Copyright, patents, designs, trade marks and other intellectual property (the “Intellectual Property”) and any reproductions of copyright works in the thesis, for example graphs and tables (“Reproductions”), which may be described in this thesis, may not be owned by the author and may be owned by third parties. Such Intellectual Property and Reproductions cannot and must not be made available for use without the prior written permission of the owner(s) of the relevant Intellectual Property and/or Reproductions.

Further information on the conditions under which disclosure, publication and commercialisation of this thesis, the Copyright and any Intellectual Property and/or Reproductions described in it may take place is available in the University IP Policy (see http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=487), in any relevant Thesis restriction declarations deposited in the University Library, The University Library’s regulations (see http://www.manchester.ac.uk/library/aboutus/regulations) and in The University’s policy on Presentation of Theses.
Acknowledgements

With grateful thanks to everyone for their participation in, help with and their guidance and support throughout this research journey. These people have been instrumental in the completion of this M Phil research degree.

VaST study participants, both surgeons and women

VaST R&D teams including Central Manchester Foundation Trust, Sarah Leo and Jo Ann Leonard

PROSPECT Study participants, Centre Staff and Gynaecologists

PROSPECT Trial manager, Suzanne Breeman and Chief Investigator, Charis Glazener

PROSPECT Statisticians – John Norrie and Andrew Elders

First Class Transcription Services, Harry Heyes & University IT /Kelly Dean

Lucy Dwyer – Research Nurse/Manager, Central Manchester Foundation Trust

Joy Stewart, PGR Administrator & Dorothy Prato, Examinations Officer

Caroline Sanders, Senior Lecturer in Medical Sociology, University of Manchester

Ian Crocker, PGR Tutor and Professor Colin Sibley, PGR Advisor

My Supervisors, Fiona Reid, Jenny Myers, Julia Segar and Anthony Smith

Warrell Unit Colleagues, Central Manchester Foundation Trust

My Family, Gillian and Stuart Fairclough & Owen and Chloe Bromley
Preface

I graduated in 2005 from Newcastle Upon Tyne University, MBBS. I have been a Specialty Trainee doctor in Obstetrics and Gynaecology since 2007. This M Phil degree was completed part time over 2 years at the University of Manchester. The research time was extended by 6 months to account for delays in ethical approvals at the individual sites. It was undertaken along side a part time surgical fellowship in Urogynaecology at Central Manchester Foundation Trust Hospital. I am now a Sub Specialty Trainee doctor in Urogynaecology and this research degree will fulfill the research component required in this training programme.

Following submission of this degree I will be working full time as a doctor. As a busy clinician, my supervisory team and I felt the best way to publish the work generated by this degree was by submitting this work in an alternate style thesis. The format of this thesis allows the papers to be written and included in the thesis. This approach will ensure submission for publication is not delayed.

Publications and Presentations

Paper 1

Results from this paper were presented as oral presentation at the United Kingdom Continence Society Meeting (UKCS), Bradford 2013 and as an oral podium presentation at the International Urogynaecology Association meeting (IUGA), Dublin 2013.

**Paper 2**
It is planned that this paper will be submitted for publication to the British Journal of Obstetrics and Gynaecology (BJOG) in 2017.

Results from this paper have been presented as an oral presentation at UKCS, Aberdeen 2015 and as an oral poster at the IUGA conference, NICE 2015.


**Paper 3**
The plan is to submit this paper to the Sociology of Health and Illness Journal in 2017-2018.

**Paper 4**
It is planned that this paper will be submitted for publication to the British Journal of Obstetrics and Gynaecology (BJOG) in 2017 as a linked paper to Paper 2 see above.

Results from this paper have been presented at the UKCS, Newcastle 2017 and will be submitted as an abstract to the European Urogynaecological Association (EUGA) meeting 2017.

**The supervisory team**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr F Reid</td>
<td>Chief Investigator, co supervisor</td>
</tr>
<tr>
<td>Dr J Myers</td>
<td>Main supervisor</td>
</tr>
<tr>
<td>Dr J Segar</td>
<td>Co Supervisor</td>
</tr>
<tr>
<td>Professor A Smith</td>
<td>Consultant Urogynaecologist</td>
</tr>
<tr>
<td>Mr I Crocker</td>
<td>Postgraduate tutor</td>
</tr>
<tr>
<td>Professor C Sibley</td>
<td>Postgraduate advisor</td>
</tr>
</tbody>
</table>
C Glazener, Chief Investigator PROSPECT study and S Breeman, Trial Manager PROSPECT study had input into the manuscript editing of paper 1. S Breeman was involved in the coordination of PROSPECT outcome data release and collection of questionnaires. J Norrie and A Elders have provided input with the statistical analysis in paper 4 and provided the requested PROSPECT data. Due to absence of J Segar during my writing period, C Sanders has had input into the manuscript editing of paper 3.
Context of research

Introduction
The introduction defines prolapse and describes the histology of the vaginal wall. It describes the types of operations to repair anterior wall prolapse and the outcomes of these procedures as found in the literature. It also discusses the management of prolapse with grafts/mesh and how this compares to native tissue repairs. Lastly it looks at how surgical techniques vary and how the PROSPECT trial has highlighted that variation in surgical techniques still exists and is a key area for future research.

Methods
This is a mixed methods study. The use of a questionnaire-based study was used to assess surgical techniques of surgeons recruiting to the PROSPECT trial. PROSPECT was a pragmatic RCT and the rationale behind the questionnaire based study was to document the techniques in practice. In view of the limitations associated with questionnaires, qualitative research methodology was used to evaluate how and why surgeons use a variety of techniques to repair native tissue pelvic organ prolapse. Clinicians have concerns about the success of native tissue repairs and the complications related to graft/mesh repairs. The rationale of the VaST study was to improve our understanding of how and why surgical techniques vary and develop themes of surgical technique to allow an assessment of the influence of surgical technique on the outcome of surgery.

Results
Paper 1
A questionnaire based study exploring how surgeons recruiting to PROSPECT were performing native tissue anterior and posterior pelvic organ prolapse repairs and repairs using grafts/mesh. An assessment of the use of packs and how POP – Q measurements were taken were also made.
Paper 2
Qualitative methods including video taped observations of surgery, audiotaped interviews with surgeons and field notes were used to assess how surgeons were performing native tissue anterior pelvic organ prolapse repairs.

Paper 3
The same data from paper 2 was used to explore why surgeons were performing a variety of different surgical techniques when repairing pelvic organ prolapse.

Paper 4
A mixed methods paper using the themes of surgical technique identified in paper 2 to evaluate if the variation in surgical technique observed in qualitative study influences the outcome of native tissue anterior pelvic organ prolapse repairs. The outcome data used was from the multicentre surgical RCT, PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials).

Overall discussion
This highlights the key findings, strengths and limitations from the individual papers in this thesis.

Future work
The amount of data was too great to include in this MPhil and so the posterior repair data is not presented. VaST study data will be used to inform future RCT assessing the influences of surgical techniques on native tissue surgery for pelvic organ prolapse. Focus groups could aid standardisation of the terminology of surgical techniques and related vocabulary used by surgeons. If one surgical technique is identified as better than others the work surrounding the theory of practice could aid the implementation of practice change.
CHAPTER 1: INTRODUCTION
Chapter 1
Introduction

1.1 Background information

The only problem left unresolved in plastic gynaecology is the permanent cure of cystocele [2].

Surgeons continue to feel discontented with the success of pelvic organ prolapse (POP) repairs, in particular with anterior POP repairs [3]. To date research associated with the native tissue POP surgery has focused on outcome measures used to assess its success and with the identification of alternative techniques including various grafts/meshes with the aim of improving outcomes [3, 4]. An area, which is under researched and is the subject of this thesis, is the variation of native tissue surgical techniques used to repair POP and whether this has an influence on the outcome of POP surgery.

The background information below includes; a definition of POP, an assessment of the prevalence of POP and a review the histology of the vagina wall. The latter will be important for the understanding of the surgical techniques discussed later.

1.2 Definition of pelvic organ prolapse

The International Continence Society (ICS) and the International Urogynecological Association (IUGA) define pelvic organ prolapse as,

The descent of one or more of the anterior (front) vaginal wall, posterior (back) vaginal wall, the uterus (cervix) or the apex of the vagina (vault/top). The presence of any such sign should be correlated with symptoms. More commonly this correlation would occur at the level of the hymen (entrance of the vagina) or beyond [1].
There are a number of ways of measuring the severity of the prolapse. Commonly this is assessed through examination and the use of the ICS standardised system, Pelvic Organ Prolapse Quantification (POP Q) [1]. This system makes measurements at 9 different points in the vagina. These measurements are made in centimeters and the reference point is the hymen (with points above the hymen being negative and those below positive). Prolapse is staged depending on its severity (Figure 1.1) [1].

![Image of POP Q staging](image)

**Figure 1.1: Stages of pelvic organ prolapse** [1]

As well as anatomical/objective measures of the affect of prolapse (assessed through examination) there are symptomatic/subjective (presence of a vaginal bulge/lump), functional (effect on bowel, bladder and sexual function) and quality of life measures. These factors are commonly assessed using questionnaires e.g. Electronic Patient Assessment Questionnaire (ePAQ) [5].

### 1.3 Epidemiology of pelvic organ prolapse

POP is a common condition. It is frequently quoted that 50% of women who have had children develop prolapse and 20% of these women experience symptoms and seek assessment of this [6]. The anterior compartment (front wall of vagina) is the most common site for POP to develop, followed by the posterior compartment (back wall of vagina) and then the apex (top of vagina) [7, 8]. The anterior compartment has the highest recurrence rate [3].
A review of the literature [9] shows the overall prevalence of POP is variable depending on the outcome measure used (3 – 50 %). When symptoms of prolapse are used the prevalence is between 3- 6 % [9]. In comparison, the prevalence is between 41 – 50 % when examination findings are used [9]. This discrepancy will be discussed in more detail below. As a result of the aging population it is projected that the prevalence of POP will increase [10].

There are several options available to patients for management of POP. Surgery is one option. The lifetime risk of a woman having surgery for urine incontinence and prolapse is often cited as 11% by 80 years old and for prolapse alone 6.3% [11]. The hospital episodes data for England, between 2011 – 2012, showed there were 26,108 transvaginal operations performed for management of POP [12]. These operations included anterior and posterior colporraphy (repairs) (n = 24,753), paravaginal repairs (n = 60), graft/mesh repairs (n = 1,145) and other none specified repairs (n = 150) [12].

1.4 The anatomy of the vaginal wall

When performing a POP repair an incision is made in the anterior or posterior vaginal wall. The vaginal wall is made up of several layers. Underneath the vaginal epithelium (skin) there is a tissue layer that surgeons commonly refer to as “fascia”. In women who have POP this tissue is damaged or deficient and the surgeons aim is to repair this tissue. In 1866, the first histological study of the vaginal tissue demonstrated that a “loose cellular tissue” (fascia) lay between the vaginal epithelium and the underlying organs [13].

It has been suggested by others that there is contention surrounding the existence of “fascia” [14, 15]. Ricci et al [14] defined fascia as, “a sheet of compact connective tissue of variable thickness, completely devoid of muscle substance and possessing tensile strength for supportive and reconstructive purposes.” In their review of 22 cadaveric specimens, they concluded that there was, “no microscopic evidence whatsoever to substantiate belief in the existence of a so-called, fascia”. They
suggested that surgeons who were able to isolate “fascia” had split the vaginal wall into two layers.

Subsequently, Weber et al [13] performed gross and histological examinations of full thickness sections of the vagina from cadaveric specimens. In this study it was identified that the vagina was made up of 3 layers including mucosa, muscularis and adventicia (Figure 1.2). The mucosa consisted of 2 parts, a non-kertinising squamous epithelium overlying a loose connective tissue layer, the lamia propria. The muscularis layer was made up of smooth muscle, collagen and elastin. Lastly the adventicia was a discrete connective tissue layer made of collagen and elastin.

![Histology of the Vaginal Wall](image)

**Figure 1.2: Histology of the Vaginal Wall [13]**

### 1.5 Surgical success of pelvic organ prolapse repairs

The premise of this study is based on the notion that it is unknown whether variation in surgical techniques between surgeons influences the outcome of surgery. As highlighted earlier, the focus of the majority of research relating POP surgery has been on the outcome measures used to assess the success of POP surgery and in the comparison between grafts/mesh and native tissue POP repairs. The main points surrounding these discussions will be outlined below.
1.5.1 Surgical outcome measures for pelvic organ prolapse repairs

It is commonly quoted that native tissue repairs have a relatively high recurrence rate with up to 1/3 women requiring further surgery [11]. The outcome measure from which this study and other early studies were based was the cure of stress urine incontinence [11, 16, 17]. When using this outcome measure the success of surgery was found to range from 12.5% to 80% [18].

Over time the outcome measures used to assess the success of POP surgery have changed. In 2001 the National Institutes of Health (NIH) produced a document to standardise pelvic floor terminology for researchers [19] and they suggested the use of anatomical outcome measures (examination findings) as being the preferred way to assess surgical success. It was defined that the “optimal” outcome was when the prolapse was at stage 0 (3cm above the hymen) and “satisfactory” when the prolapse was stage 1 (2cm above the hymen).

Studies report a wide range of success when anatomical measures are used. Stanford et al [18] reported success of between 30 – 97%. In a RCT comparing three methods of repairing anterior POP repair (anterior colporraphy, paravaginal repair and mesh repair) [20] a cure of between 30 – 46% was identified. In another review paper which included 11 RCT’s [21], that all used anatomical outcomes, the success of surgery was found to be between 27-75% for native tissue repairs and 38 – 93% for graft/mesh repairs.

More recently it was suggested that symptomatic outcome measures provided a better assessment of the success of POP surgery [22]. The POSST study data [23] showed that the NIH anatomical definition of success was too strict when the aim for POP repair was the resolution of patient’s symptoms. In the CARE study subjective outcome measures were associated with an improved success of surgery and overall improvement in patient’s quality of life [22]. Reanalysis of Weber’s paper [24] using subjective outcome measures rather than objective measures also showed POP surgery was more successful.
The POSST study [23] was a multicentre observational study of 1004 women aged 18 – 83 years who attended gynaecology outpatients for annual review. Patients completed a quality of life questionnaire and were examined using the POP Q scoring system. They identified that in 75% of cases where anatomical category “optimum” (stage 0) and in 40% where “satisfactory” outcome (stage 1) was not achieved these women were asymptomatic. In addition, in 35% of women with stage 2 POP, only 1 out 7 responses were positive for bother related to prolapse. Hence a significant proportion of women with stage 1 – 2 prolapse were either asymptomatic or minimally symptomatic and a third of women with a significant prolapse were not bothered by it.

The CARE trial [22] included women with stage 2 – 4 prolapse having an abdominal sacrocolpopexy (prolapse operation that attaches the top of the vagina to the sacrum using a graft/mesh) with or without a Burch colposuspension (a urine incontinence operation). The outcome of surgery was assessed using 18 different outcome measures. The results showed the outcomes varied greatly depending on the outcome measures used, 19.2% - 97.2%. The lowest success rates were found when anatomical outcomes measures were used that required “all support to be proximal to the hymen”, 19.2% - 57.2%. A greater level of success was identified when symptomatic measures where used, including “absence of the prolapse beyond the hymen” (94%), “absence of the bulge” (92%) and “absence of repeat treatment” (97.2%).

Research has shown that the symptom that correlates best with advanced prolapse is the symptomatic outcome measure, “presence of a vaginal bulge” [25, 26]. The National Institute of Child Health and Human Development of pelvic floor disorders network redefined surgical success of POP surgery using the symptomatic outcome measure, “no objective prolapse beyond the hymen” [22].
1.5.2 A comparison of native tissue and graft/mesh repairs

The perception that the failure rate of native tissue repairs was unacceptably high [11] led to the development and usage of grafts/mesh in POP surgery [21] without prior assessment of their safety and efficacy in adequately powered studies. Complications that are unique to grafts/mesh (e.g. exposure or extrusion through the skin or pelvic organs) are a concern and have led to debate surrounding their continued usage [21, 27, 28].

Authorities highlighted their concerns about the use of grafts/mesh in preference to native tissue repairs [27, 28] and the Scottish Government recently banned the use of grafts/mesh in gynaecological surgery. There has been no guidance surrounding the situations where a graft/mesh should be used in preference to native tissue repair. The new cochrane review assessing surgery for the anterior POP [3] states that current evidence does not support the use of grafts/mesh in the anterior compartment because of the increased morbidity. The review highlights that many of the grafts/meshes in the reviewed studies have been voluntarily removed from the market and the newer lighter weighed meshes have not been assessed. They advise caution in using products where the safety and efficacy is unknown [3].

There are several types of graft/mesh available to augment POP repair. Grafts/mesh can be categorised into 4 groups including non-absorbable synthetic (e.g. polypropylene), absorbable synthetic (e.g. polyglactin), biological (e.g. acellular collagen derived from bovine or porcine sources) or a combination of these three categories [27]. These grafts/mesh can be inserted as over lay (between the skin and the fascia that overlies the bladder or rectum) or an inlay (between the fascia and bladder or rectum) and attached by stitches to the pelvic sidewall or inserted using trocar guided kits.

1.5.2.1 Efficacy of pelvic organ prolapse surgery (native tissue v graft/mesh)

At the start of this study (2013) the cochrane review entitled “Surgical management of POP in women” was published [29]. Subsequently this year (2016) two new reviews
have been released assessing, “Surgery for women with anterior compartment prolapse” [3] and “Transvaginal mesh or grafts compared native tissue repair for vaginal prolapse” [4]. All reviews discuss how surgeons have used different techniques (i.e. the use of grafts/mesh) to minimise the recurrence rates after traditional native tissue repairs. Using these documents a comparison of the efficacy of native tissue and graft/mesh-augmented repairs will be summarised, with the focus being on anterior compartment prolapse, as this is the subject of this thesis.

In 2013 [29], it was found that the anatomical failure rate of anterior native tissue repairs was significantly greater compared to biological grafts (specifically porcine graft e.g. pelvicol). In these studies, no difference in the “awareness of graft” was found irrespective of the type of graft/mesh used [30–35]. The recent cochrane review (2016) [3] showed that when comparing native tissue and biological grafts there was few or little differences when the outcome measures, “awareness of the prolapse”, “repeat surgery” and postoperative (1 – 2 years) “stress urine incontinence” (SUI) or “dyspareunia” were used. However, there was a greater risk of “recurrence in the anterior compartment” when a native tissue repair (27 – 42%) was performed compared to biological graft (26%).

When reviewing studies comparing absorbable synthetic graft/mesh (polyglactin) and native tissue use in 2013 [29] the former was shown to have a significantly lower recurrence rate [20, 36]. Similarly in 8 out of 10 trials considering non-absorbable synthetic graft (polypropylene) [34, 37–46] the recurrence rate was lower, when an anatomical outcome measure was used, compared to native tissue anterior POP repair. The superiority of grafts/mesh was seen irrespective of the insertion approach (inlay or transobturator armed self-styled or commercial kits) [29].

Following this, in the 2016 review, which included 16 studies, the “awareness of POP”, “repeat surgery” and “recurrent anterior compartment prolapse” were more likely when native tissue repair were performed compared to polypropylene mesh [3]. In comparison, the “repeat surgery for prolapse, SUI and mesh exposure” was less likely in native tissue repairs (4 – 8%) compared to mesh repair (10%). There were few or no differences in the postoperative de novo “SUI” and “dyspareunia” rates between the two groups. When comparing native tissue and absorbable synthetic
mesh (3 studies), it is unclear whether results show any difference when assessing, “awareness of prolapse”, “repeat surgery for prolapse” and postoperative “SUI” rates. It is probably more likely to have recurrent “anterior compartment prolapse” after native tissue repair (29 – 55%) compared to absorbable synthetic mesh (27%) [3].

Lee et al [21] reviewed the success of surgery in 12 RCT comparing native tissue repair and graft/mesh for the treatment of anterior wall prolapse using the symptomatic outcome measure “absence of bulge”. The rates of success ranged from 62 – 100% for native tissue repair and 75 – 96% for synthetic graft/mesh. Only 2 of the studies showed a significant difference between the two treatments [39, 41]. In the first study [41] found a significantly better outcome with graft when using the symptomatic outcome measure POPDI – 6. However with 2 other outcome measures (PFDI – 20, PFIQ – 7) there was no difference in outcome. Altman et al [39] found that graft/mesh was significantly better when using the outcome measure “absence of vaginal bulge” however again when using 2 other symptomatic outcome measures (UDI/ PISQ 12) no difference was found between the 2 procedures. The author discusses how there is little evidence to show that mesh/grafts are better than native tissue repairs when symptomatic outcome measures are used.

1.5.2.2 Complications related to grafts/mesh

In the UK complications related to transvaginal grafts/mesh are reported to the Medicine and Healthcare Products Regulatory Agency (MRHA). At the beginning of 2012 they held a workshop to discuss the issue of graft/mesh complications and they produced a document to outline the responsibility of clinicians, the MRHA and manufacturers. They also suggested the information that should be given to patients about the risk of graft/mesh complications. NICE also produced guidance on this topic and suggested that grafts/mesh should be used with special arrangements for clinical governance, consent, audit and research [28]. The joint IUGA/ICS paper outlines a system of defining complications relating to grafts/mesh used in gynaecological operations [47].

In the 2013 cochrane review of surgery for POP [29] the graft/mesh erosion rate was quoted as 11.4% and the rate of surgical intervention to treat complications was 6.8%.
The risk of subsequent surgery for recurrence, USI, graft/mesh exposure and pain was significantly less in women having native tissue repair (5%) compared to those where non-absorbable trans-vaginal grafts/mesh was used (10%).

In a systematic review of Medline publications from 1950 – 2010 [48] which assessed the complications of transvaginal grafts/mesh, the overall graft/mesh erosion rate was found to be 10.3% (0-29.7%). They found the rate of erosion to be similar for both synthetic (10.3%) and biological (10.1%) grafts/mesh. In comparison, in another review performed by the FDA, synthetic mesh was found to be the cause of erosion in more than half of cases [27]. Murphy [49] suggested that the variation in graft/mesh erosion rates seen in a systematic review by Abed et al may be related to the surgical techniques used and the surgeon’s experience in grafts/mesh insertion [49].

The FDA published a document to inform and raise awareness of the complications caused by transvaginal grafts/mesh [27]. They stated that these serious adverse events have increased between 2008 and 2010. The most frequently reported complications were vaginal erosion, pain (including that with intercourse), infection, urine problems, bleeding and organ perforation. Other risks identified included recurrent prolapse, neuromuscular problems, vaginal shrinkage/shortening, necessity for additional surgical treatment and 3 deaths (2 secondary to bowel perforations and 1 due to hemorrhage). In a different paper we are reminded that the only complication that is unique to grafts/mesh is erosion through the vaginal skin or into pelvic organs [49].

The systematic review by Abed [48] highlighted complications of grafts/mesh that are not unique to these products including tissue granulation and dyspareunia. Granulation occurred in 7.8% of cases (0 – 19%). More wound granulation was found with biological grafts (9.1%) as opposed to synthetic grafts (6.8%). Seventy studies reported dyspareunia as a complication with an overall rate of 9.1%. In these studies similar rates of dyspareunia were found when using synthetic (8.9%) or biological (9.6%) grafts/mesh.

During the cochrane review of the surgical management of POP in women [29] the frequency of complications were assessed. There were no differences in the blood loss [33, 35], voiding dysfunction [35] or dyspareunia (pain with intercourse) [30, 35]
between native tissue and biological graft repairs. Women having polypropylene graft kits were more likely to develop apical or posterior wall prolapse. Different questionnaires were used to assess the quality of life of patients who had synthetic mesh and anterior native tissue repairs. There were no differences in the QOL or sexual function found. However, in patients having a transobturator graft/mesh significantly more blood loss and a longer surgical duration was seen. There were no significant differences in the de novo dyspareunia rates whereas a greater risk of de novo SUI was seen following synthetic mesh.

The FDA produced a statement explaining there was uncertainty regarding graft/mesh superiority to native tissue repair and highlighting the use of grafts/mesh may pose greater risks to patients [27]. They suggested that patients should be informed that grafts/mesh are permanent and may result in the need for additional surgery, which in some circumstances may not rectify the problem. In response, the Association of Pelvic Surgeons [49] stated that although they agreed with several points raised by the FDA they believed their review of the literature was not always accurate and in some instances biased. They concluded that the use of grafts/mesh can be beneficial in certain patient groups where the risk of native tissue repair failing is thought to be high. In these circumstances they explained the benefits might outweigh the risks of complications.

The large UK based multicentre RCT, PROSPECT [50], aim was to give further information about the safety and efficacy of native tissue and graft/mesh repairs in women having both primary and secondary repairs. The objective was to inform clinicians whether there are situations when grafts/mesh should be used in practice. This awaits publication in the Lancet.
1.6 Surgical techniques for pelvic organ prolapse repairs

Native tissue anterior POP repair techniques are the main focus of this study. In this section, the history of these techniques will be discussed and then the literature surrounding surgical variation will be summarised.

1.6.1 The history of native tissue repair

Management of prolapse is documented as early as the 15th century [51]. Surgical management became more prevalent in the 19th century with the development of anaesthesia, asepsis, suture material and antibiotics [51]. Sims described the management of vaginal prolapse in 1866 [52]. He noted that when a procedentia (a complete prolapse of uterus) was replaced with two fingers were on the front wall of the vagina that the pelvic organs remained supported. His account highlights the experimental nature of surgery at that time and how surgical technique development has been on a case-by-case basis.

Hence the idea of wholly removing the redundant portion of the anterior wall of the vagina occurred to me...” He described removing, “a very large portion of the anterior wall” and stated, “the chasm it left was fearful.” He went on to say, “my surprise was equaled by my own delight when I simply removed the hypertrophied (enlarged) tissue and the bladder remained intact. [52]

Sims concern with this procedure was the degree of blood loss. He described performing a V shaped removal of vaginal skin and suturing together the, “raw areas” in an attempt to repair prolapse and at the same time reduce blood loss [52].

In 1913 Kelly described midline plication of fascia (stitches to reinforce tissue between skin and bladder) [53]. This surgery was initially described for the treatment of SUI but is now the procedure of choice for repairing midline defects in the fasica [54, 55]. This procedure is known as colporraphy. An alternative and less commonly performed surgical technique, is a paravaginal repair [55] (repair of outer vaginal defects) and this was first described by White in 1909 [2].
Posterior repair by plication of the levator ani muscle and inferior aspect of the vagina (bringing together pelvic floor muscles and the bottom of vagina) was described by Simon of Hendberg in 1867 [51]. In the 1960s this technique was performed less frequently because it caused pain with intercourse and did not manage enterocele (prolapse higher up the back wall of the vagina) [56]. Following on from this, surgeons began repairing the posterior compartment by plicating the fascia in the midline similar to the anterior repair, by either a trans vaginal or trans anal route [51].

The current version of Bonney’s Gynaecological Surgery textbook [57] describes the surgical techniques to perform an anterior and posterior native tissue repair. The text details the following steps: Infiltration of adrenaline and local anesthetic into the sub epithelial space (space below the skin), midline incision on the vaginal wall, separation of the vaginal skin from the fascia (tissue layer) and either bladder or rectum, interrupted sutures into the fascia to reduce the prolapse, excision of redundant tissue and closure of the skin. An indwelling catheter is left in situ and in some instances a vaginal pack.

Despite prolapse being a common condition that has been surgically managed since the 19th century there has been no standardisation in the surgical techniques or surgical procedures used by surgeons. Literature shows that the choice of operation and the surgical techniques used vary among surgeons and individual surgeons also vary their own surgical technique [13, 54, 55, 58–61].

### 1.6.2 Choice of pelvic organ prolapse operation

A UK national survey assessing the types of POP procedures in everyday practice was performed in 2005 and 2010 [54, 55]. The studies objectives were to assess any variation of surgical management and to make a comparison between surgeons practicing in different hospital settings. A postal questionnaire was sent out to UK Obstetricians and Gynaecologists using the addresses obtained from the Gynaecare database. A similar survey was conducted in Australia and New Zealand and comparisons have been made to UK practice [62].
Most UK based surgeons perform a native tissue anterior repairs (77% [55] and 71% [54]) compared to a graft/mesh repairs (10% [55] and 11% [54]) (Table 1.1). When performing a secondary repair, a native tissue repair was more frequently performed in 2005 (45%) [55] whereas in 2010 a graft/mesh repair was the preferred choice (56%) [54]. The preferred graft/mesh type changed from biological in 2005 [55] to synthetic in 2010 [54] (Table 1.2). The methods used to repair prolapse were found to be similar in both compartments (Table 1.1). A few surgeons performed paravaginal repair (anterior wall) and site-specific repair (posterior wall) (Table 1.1).

<table>
<thead>
<tr>
<th></th>
<th>% UK 2005</th>
<th>% UK 2010</th>
<th>% ANZ 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anterior</td>
<td>Posterior</td>
<td>Anterior</td>
</tr>
<tr>
<td>Primary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colporraphy</td>
<td>77</td>
<td>75</td>
<td>66</td>
</tr>
<tr>
<td>Graft</td>
<td>10</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Paravaginal</td>
<td>6</td>
<td>NA</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Site specific</td>
<td>NA</td>
<td>11</td>
<td>NA</td>
</tr>
<tr>
<td>Skin bridge</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Secondary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colporraphy</td>
<td>45</td>
<td>38</td>
<td>21</td>
</tr>
<tr>
<td>Graft</td>
<td>34</td>
<td>49</td>
<td>56</td>
</tr>
<tr>
<td>Paravaginal</td>
<td>15</td>
<td>NA</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>Site specific</td>
<td>NA</td>
<td>6</td>
<td>NA</td>
</tr>
</tbody>
</table>

Table 1.1: National survey of pelvic organ prolapse procedures (native tissue) [54, 55, 62]
Table 1.2: National survey of pelvic organ prolapse procedures (graft/mesh) [54, 55, 62]

<table>
<thead>
<tr>
<th></th>
<th>% UK 2005</th>
<th>% UK 2010</th>
<th>% ANZ 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anterior</td>
<td>Posterior</td>
<td>Anterior</td>
</tr>
<tr>
<td>Primary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synthetic</td>
<td>24</td>
<td>40</td>
<td>52</td>
</tr>
<tr>
<td>Biological</td>
<td>76</td>
<td>60</td>
<td>48</td>
</tr>
<tr>
<td>Secondary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synthetic</td>
<td>28</td>
<td>44</td>
<td>55</td>
</tr>
<tr>
<td>Biological</td>
<td>72</td>
<td>56</td>
<td>45</td>
</tr>
</tbody>
</table>

There were some differences identified when comparing the management of general gynaecologists, gynaecologists with special interest and tertiary centre consultants [54, 55]. General gynaecologists were found to be more likely to perform primary anterior native tissue repair (91%) compared to tertiary specialists (66%). Whereas tertiary consultants are more likely to perform graft/mesh repairs as compared to generalists. When a secondary repair of the posterior wall was required more than half of general gynaecologists would refer to the designated specialists [54, 55]. About 1/5 of surgeons would change the procedure if the patient was not sexually active and almost half of surgeons would not perform surgery if the patient’s family was incomplete [54, 55].

1.6.3 Variation of surgical techniques to repair pelvic organ prolapse

Questionnaire based studies have been used to described the surgical techniques to perform native tissue POP repair used by surgeons in clinical practice [59, 61]. Questionnaires were distributed to fellows and members of the Royal College of Obstetricians and Gynaecologists [61] and to the Dutch Urogynecology Society [59]. The response rates were 48% and 65% respectively. These studies have shown that surgical technique is variable in all aspects of an anterior native tissue POP repair and
that variation in surgical technique is not unique to a particular country. Both studies investigated the surgical techniques used before, during and after the operation.

Preoperatively the system used to examine the prolapse severity (POP Q) was assessed. In the UK it was found that only a small proportion of surgeons used the POP Q system (15%) [61]. In comparison in Denmark 77% of surgeons used this system, although only 52% used it routinely [59].

At the start of the operation infiltration was used by 76% of Dutch surgeons [59]. There was variation in the type of infiltration that they used. Saline and adrenaline was used by 24% of surgeons and 41% used saline alone. The most commonly used infiltrate used by UK based surgeons [61] was marcaine or lignocaine diluted in saline. In both studies the majority of surgeons then used a midline incision. In the UK a greater variety of other incisions were described being used in practice including racquet, diamond, inverted Y, elliptical and triangle [61]. The most common method of dissection for both studies was a combination of sharp and blunt dissection, though some surgeons use one technique alone. The Dutch study [59] commented on the level of dissection, with 43% of surgeons dissecting the skin from the fascia (tissue layer under the skin) as thin as possible. When considering the repair of the fascia, 50% of UK surgeons performed buttress sutures (stitches to bring together tissue) [61]. Surgeons varied the number of layers of buttressing sutures inserted, including one layer (53.6%), two layers (37.3%) or three layers (9.1%) [61]. The suture material used to repair the fascial defect was either Vicryl or PDS in both studies [59, 61]. In the UK [61] it was found that there was variation in those that reported trimming vaginal skin, with 45% always trimming, 51% dependent on the amount of tissue and 4% never. Post operatively the majority of surgeons used a pack and inserted a catheter [59, 61].

Surgical techniques to perform POP repairs augmented with graft/mesh have also been assessed with questionnaire based studies [58, 61]. A variety of different grafts/mesh were being used in clinical practice. In the UK, prolene was the most frequently used synthetic graft and pelvicol the most frequently used biological graft [61]. In a separate paper, the use of mesh kits by a cohort of Dutch surgeons was assessed [58]. The most commonly used graft kit was prolift (55%). This paper also
discussed the use antibiotics when inserting grafts/mesh, the preoperative variation in vaginal oestrogen use (45.7% all of the time, 26.6% most of the time and 26.6% only when vagina atrophy) and incidence of surgeons changing their gloves prior to the graft/mesh insertion (52.6%) [58].

A medline review of the literature carried out between 1966 – 1995, identified that in peer review journals and textbooks there were different surgical techniques described to repair anterior vaginal wall [13]. The review splits the techniques into two categories, colporraphy (repair of tissue defect in the midline) and paravaginal repair (repair of outer tissue defects).

Several variations of the colporraphy are described in Weber’s review [13]. The first technique described was an excision of part of the anterior vaginal wall using either an oval or rectangular incision and then sutures were used to close the incision [52, 63, 64]. The next description included dissection of the vaginal wall off the underlying fascia followed by its plication (bringing together the tissue between the vaginal skin and bladder using stitches) [63, 65]. Another variation included creation of flaps of fascia which were overlapped to create tissue support [66, 67]. Lastly, grafts/mesh were used to reinforce repairs and were described as being placed over the repaired fascia [68] as an additional layer [66, 69] or by needle suspension [70]. The authors of this review concluded that there is need for further research, a RCT, to compare the different categories of technique identified. Very few studies have assessed the efficacy of different surgical techniques used in POP repair.

One RCT of surgical techniques compared the efficacy of native tissue colporraphy, ultra lateral colporraphy and native tissue colporraphy plus polyglactin graft (absorbable synthetic graft) [20]. The primary outcome measure used was anatomical and categorised as “optimal” (stage 0) and “satisfactory” (stage 1). Cure was achieved when either of these outcomes were reached at 6 months, 1 year and 2 years follow up. Patients also completed a questionnaire about their urinary and sexual function. Out of 114 women randomised, 109 had the operation and 76% of these attended for follow up. The percentage of women achieving cure at follow up was 30% having native tissue colporraphy, 42% standard colporraphy plus mesh and 46%
with ultra-lateral colporraphy. There was no significant difference in outcome found between these three techniques in this study ($p = 0.578$).

Another paper identified compared 3 different surgical techniques to insert graft/mesh as part of anterior POP repairs [71]. The grafts/mesh inserted used were a 2-armed graft inserted into the retropubic space (behind the pubic bone) (RP), a 2 - 4 arm obturator graft (TO) and a graft fixed to arcus tendineus fascia (pelvic side wall) (FG). The study showed that the RP graft/mesh had a significantly worse outcome. They used an anatomical outcome measure and a quality of life questionnaire for this assessment.

1.7 Why is there surgical technique variation?

It is interesting to consider why a surgeon performs a particular surgical technique and what factors influence the variation in techniques between surgeons. Lomas et al [72] investigated what influenced practice of Obstetricians and concluded that, “the practices of physicians are influenced by many things besides research evidence.” The technique to repair POP appears to have developed over time [51] and some have associated this variation in surgical practice with a lack of evidence to guide on what is best practice [59].

Pope [73] explored the sources of surgical variation in USI surgery which is another commonly performed Urogynaecological operation. In another paper this author goes on to explore in detail the link between surgical variation and a resistance to evidence based medicine (EBM) [74]. In the introduction to paper 3 these issues will be discussed in more detail and EBM is defined and discussed. In addition, sources are used to explain why it is more difficult to perform RCT during surgical trials. This along with other factors will be used to explain why there is surgical technique variation in clinical practice today.
1.8 What are the controversies and what is the importance of the research area?

POP surgery and indeed all urogynaecology surgeries are performed to improve women’s quality of life by reducing the bother of symptoms. When considering whether to operate it is important to balance the benefits related to the reduction in bother from symptoms with the risks of complications that may be related directly to the operation or indirectly from bladder, bowel or sexual dysfunction.

Native tissue POP repair is the traditional approach used for the repair of prolapse and remains the procedure of choice for primary repairs [54, 55]. The concern that this repair method was associated with an unacceptably high failure rate [11] and led to the development of an alternative approaches, including graft/mesh repairs. However from the literature review above it is understood that these techniques are associated with other risks including graft/mesh erosion, de novo USI, bladder injury and a greater rate of repeat surgery for POP, SUI and mesh exposure.

Since the publication of early papers like Olsen’s [11] the outcomes measures used to define the success of surgery have been reassessed. Contemporary measures of success are related to the patient’s symptoms and show the best measure of assessing cure is “the absence of a vaginal bulge”. When reassessing native tissue repairs with symptomatic outcome measures the success is improved which makes us more cautious when graft/mesh usage is considered.

It is unknown whether surgical technique influences the outcome of surgery. There is no recognised “best surgical technique” to perform a native tissue POP repair. The literature demonstrates that surgical techniques to perform native tissue and graft/mesh repairs vary between surgeons practicing in the UK and other countries [58–61]. There is limited evidence as the whether this variation affects the outcome of surgery. To date studies assessing POP repair technique variation has been through questionnaires. There are limitations to this approach including inability to understand the finer details of surgical technique, missing answers, multiple answers and uncertainty regarding the terminology of surgeons to describe their surgical technique.
With these issues in mind this may be a good time to reassess the traditional native tissue repair and consider whether there is a “best technique” that could improve outcomes for patients. This study will focus on native tissue repairs. By using qualitative interviews and observations of surgery (including video) we will be able to more fully understand the variation in the steps used to perform a native tissue repair. We will be able to eliminate multiple answers and missing answers and understand when surgeons vary their technique and why. We will also be able to identify if the terminology that the surgeons used to describe their technique is uniform. In addition it also gives us the opportunity to understand why surgeons choose to perform a particular technique.

The PROSPECT study is a large RCT with outcome measures for more than 2000 women. By interviewing the surgeons that were involved in recruiting women to this study and defining their surgical techniques into categories this gave us a unique future opportunity of assessing the influence of surgical technique on the outcome of surgery in a large group of women.

1.9 Aims and Objectives

The aim of this study is to use qualitative methods to prospectively investigate how and why the surgical technique of an anterior and posterior native tissue repair varies between UK based surgeons. Because of the large quantity of data collected only the anterior data is presented in paper 2. Using the qualitative outcomes and PROSPECT outcome data an assessment of the influence of surgical technique on subjective, objective and functional outcomes for patients was made.
Aims

Aim 1 is presented in paper 1, 2 – 4 in paper 2, 5 in paper 3 and 6 in paper 4.

1. To present the native tissue and graft/mesh surgical techniques used to perform pelvic organ prolapse repair, documented in a questionnaire by a cohort of surgeons recruiting to a large randomised controlled trial (PROSPECT).
2. To identify how the surgical technique of a native tissue POP repair varies between surgeons.
3. To make an assessment of the terminology used by surgeons to describe their surgical techniques.
4. To develop themes of surgical technique
5. To identify why the surgical technique of a native tissue POP repair varies between surgeons
6. To assess if themes of surgical technique influence the outcome of surgery.

Objectives

1. To analysis the questionnaire surveys completed by surgeons recruiting to a large randomised controlled trial of prolapse surgery (PROSPECT) and to present the surgical techniques used by this group of surgeons for both native tissue and mesh repairs (paper 1).
2. To carry out video taped observations, audio taped interviews and take contemporaneous field notes to identify how surgical technique varies between surgeons (paper 2).
3. To organise surgical techniques and surgeons reasons for performing these techniques in to qualitative research themes (papers 2 and 3).
4. To carry out video taped observations, audio taped interviews and tape contemporaneous field notes to understand why surgical technique varies between surgeons (paper 3).
5. To perform a subgroup analysis of PROSPECT outcome data to assess how surgical technique theme influences the outcome of surgery (paper 4).
CHAPTER 2: METHODOLOGY
Chapter 2
Methodology

2.1 Introduction

The study used mixed methods and was comprised of three components. Firstly the analysis of a questionnaire based survey completed by a cohort of surgeons recruiting to a large multicentre randomised controlled trial of prolapse surgery, (PROlapse Surgery: Pragmatic Evaluation and randomized Controlled Trials, PROSPECT) [50]. This informed the following two aspects of the study. The second part used qualitative research methods and assessed the surgical techniques used to perform native tissue anterior and posterior pelvic organ prolapse (POP) repairs by a group of UK based consultant surgeons. In addition, an assessment of the reasons behind these choices was made. The last part of the study used the themes of anterior POP repair surgical technique, developed in the qualitative study, to make an assessment of the influence of surgical technique on the outcome of surgery. The outcome data from the larger trial (PROSPECT) were used for this assessment.

This chapter discusses the methodology and theory used in this study. A detailed methods section is also included in the individual papers.

2.2 Quantitative research methods - questionnaire based survey

The PROSPECT study was a large UK based multicentre RCT that compared the efficacy, safety and cost effectiveness of native tissue and graft/mesh POP repairs. There were several components to this trial and both primary and secondary surgeries were included. Women were randomised to have a native tissue repair or a repair with a specified graft. The primary outcome measure was the patient reported Pelvic Organ Prolapse Symptom Score (POP SS) and an assessment of the effect on quality of life, measured at baseline, 6, 12 and 24 months post surgery. The results are awaiting publication in the Lancet Journal.
The PROSPECT study was pragmatic, allowing the use of surgical techniques performed in clinical practice by the recruiting surgeons. A questionnaire-based survey (Appendix 2) was developed with the aim of documenting the intraoperative surgical techniques used for both native tissue anterior and posterior POP repairs and graft/mesh POP repairs. The questionnaire also included questions about the use of packs and the methods used to perform POP Q examination. Surgeons were asked to document and use the techniques that they used most often.

How the questionnaire was developed and distributed, the number and details of questions included and the ethical approvals are detailed in the methods section of paper 1. In addition, a copy of the questionnaire is included in the Appendix.

2.3 Qualitative research methods - Variation in Surgical Technique

The premise for this study was based on the results of the questionnaire based study (above) that showed variation in surgical techniques used to perform a native tissue and graft/mesh POP repairs. These findings corroborate previous questionnaire based studies (see introduction). The limitations of the questionnaire-based studies (see paper 1 discussion) meant a series of unanswered questions remained and indicate that further research is necessary to develop an understanding of how and why surgical techniques vary between surgeons performing these POP repairs.

The Variation in Surgical Technique (VaST) study used qualitative research methods to identify how and why UK based surgeons vary their surgical techniques when performing a native tissue POP repair. The data was collected over a 12 months period, from August 2013 - August 2014. The surgeons who were recruited to this study included 30 consultant surgeons working in the UK (England and Scotland) who as part of their routine clinical practice perform POP surgery.

There are a number of different definitions to describe what qualitative research is.

1. Qualitative research is an umbrella cross and interdisciplinary term unifying very diverse methods with often contrasting assumptions, which defies simple definitions [75].
2. Qualitative research is a form of social inquiry that focuses on the way people interpret and make sense of their experiences and the work in which they live. A number of different approaches to understand the social reality of individuals, groups and cultures. Researchers use qualitative approaches to explore the behaviour, perspectives and experiences of the people they study. The basis of qualitative research lies in the interpretive approach to social reality [76].

3. Qualitative research, also called naturalistic inquiry, developed within the social and human sciences and refers to theories on interpretation (hermeneutics) and human experience (phenomenology). They include various strategies for systematic collection, organisation and interpretation of textual material obtained while talking with people or through observation. The aim of such research is to investigate the meaning of social phenomena as experience by people themselves [77].

From the array of different definitions, we can appreciate the diversity of this research type and the methods chosen are a reflection of the research question being asked. Holloway [76] stated that, “researchers use qualitative research to explore the behaviour, perspectives and experiences of the people they study”. The aim of this study was to make sense of the behaviour or more specifically, the surgical techniques of surgeons and their experiences when performing POP surgery. The questionnaire based study gave an initial insight into this under researched area. The qualitative methods were chosen to allow a greater exploration of this subject matter.

To ensure that the data collected and the study outcomes were reliable, the choices of methods to answer this research question were important. Savin - Baden and Major [78] describe these choices of research design as “choice moments”. These authors describe five important choices in research methodology and these have been used to guide the qualitative methods and approach to this study.
2.3.1. The choice moments

1. Inhabiting a position
2. Framing the study
3. Using a research approach
4. Collecting data
5. Working with data

During this part of the methodology chapter, the choice of qualitative research methods will be explained using the “choice moments” as described to by Savin-Baden and Howell Major [78].

2.3.1.1 Inhabiting a position

The first choice moment described is that of inhabiting a position in the research and having an understanding of who we are as the researcher, which these authors highlight is the first important steps to ensuring good quality research. This will be discussed under the 3 headings; Philosophical stance; Positionality statement; and Reflexivity.

Philosophical stance

Savin - Bayden and Howell Mayer [78] stated;

*The views and ultimately the research is guided by philosophical stance and that by outlining the stance of the researcher this informs us of their assumptions with which they conduct their research.*

This openness is thought to make the research more reliable and robust. A philosophical stance suggests the researchers’ view of reality, which in turn informs their perspectives and approach to methods. It also allows the researcher to be clear about the reasons they have chosen a particular research design [79].

The analysis of the questionnaire-based study (above) produced a series of unanswered questions. The detail of how surgeons performed surgery, the
terminology surgeons used to describe techniques and why surgeons performed surgery in a specific way were unknown. A qualitative research study was considered an ideal way of exploring these unknowns as this methodology provided an opportunity to observe surgery in real time and subsequently have discussions with the surgeons about the surgery observed.

As a researcher new to the theories of qualitative research, a pragmatic stance appeared the most intuitive to adopt as it allowed the research to be based on the questions needing answered rather than a theoretical orthodoxy. When a pragmatic stance is used, “the research problem is central and applies the approaches to understanding the problem” [80]. Pragmatists are known to use a range of methods to answer research questions. Being a doctor with a scientific background, this practical approach seemed more familiar and appeared to offer the best approach to this study. Within the healthcare setting this approach is increasingly being used [78].

**Positionality statement**

Prior to this research I was a specialty trainee doctor in obstetrics and gynaecology. I had spent time observing and then latterly performing pelvic floor surgery. I have worked in 3 different parts of the UK and every year changed the hospital centre and the consultant surgeons I worked with. From this experience I gained an awareness that surgical practices vary. The analysis of the PROSPECT questionnaire based study (above) provided confirmation of this clinical experience.

Prior to undertaking this research, I took time to consider what I thought this research might uncover. In view of my previous experiences I thought it likely variations in practice between surgeons would be found. The ultimate aim was to use the results of this research to categorise surgical technique variation into themes so that a subgroup analysis of the PROSPECT outcome data could be performed and an assessment of the influence of technique on the outcome surgery could be made. I went into the study relatively open minded with respect as to whether or not the variations identified would influence outcome of surgery. This mind set hopefully reduced bias in the discussions had with surgeons.
I am female doctor in senior training post working at a tertiary hospital centre. I am scientifically minded and as a result fairly practical and analytical of subject matter. My outlook on life is generally very open minded and I believe I have the ability to listen to others view points and have insight not to sway others views to reflect my own. My aim was to approach this subject matter as the researcher and be an impartial observer of the surgeons in the study.

**Reflexivity and the insider v outsider perspective**

I was the sole investigator, performing all site visits and data collection. As a doctor training in Urogynaecology I had an insider perspective to this research. At the start of the research I reflected on my position and opinions with regards to this topic and how this would affect how I carried out the research process (positionality statement, above).

The benefits to being an insider in this research were firstly the access this allowed to the study group. The supervisors of this study have a role in and have recruited to the large RCT, PROSPECT. The trial manager gained consent form the surgeons to share their contact details for this study. Other non-PROSPECT surgeon contacts were gained from the investigators in this study and from my trainee placements.

Secondly I had prior knowledge and clinical experience in the subject topic of prolapse surgery. This meant that I was able to have in depth conversations about the techniques performed by the surgeons and I was familiar with terms and phrases they used. Lastly I was accepted into the theatre environment with ease and felt comfortable in this setting, as this is part of my routine clinical job. As a result there were no difficulties negotiating access into theatres or in recruiting surgeons.

In comparison with to those with an outsider perspective, my prior clinical knowledge and experience will have influenced the approach to this project and it is likely to be different to that of a social scientist with qualitative research experience. The key focus was to answer how surgeons performed surgery to allow subsequent analysis of the influence of surgical technique on outcome. In view of this, I may have missed
some of the wider context of the theatre and environment. This may also be a result of my familiarity with this working environment. In addition, it is likely that I will have had some preconceived ideas of what I may discover.

I attempted to step back from my role as a doctor and place myself in the role of a researcher. I was reflective in my approach and conscious of not allowing my insider position bias the research. At the start of the process I reflected on this, considered my personal stance and produced a positionality statement (above).

2.3.1.2 Framing the study

The decision regarding the subject matter and participants was derived from the unanswered questions following the PROSPECT questionnaire-based study of surgical techniques (above). The subject of investigation was the variation of surgical techniques to perform native tissue POP repair between surgeons. The participants included both PROSPECT and non-PROSPECT surgeons and the data collected included interview transcripts, video observations and field notes.

A purposive sampling approach was taken. Details of sampling, the research setting, methods of recruitment of the participants (surgeons and patients) and of consent are all outlined in the methods sections of papers 2 and 3.

Participant Selection

A purposive sampling strategy was used to select participants. This included surgeons who had recruited to the PROSPECT trial and non-PROSPECT surgeons. The predominant participant population was PROSPECT surgeons. Those surgeons who had recruited a large number of patients to the trial were targeted. This was to allow the future subgroup analysis of the influence of surgical technique using PROSPECT outcome data. The sample of non-PROSPECT surgeons was included to ensure a representative sample and recruitment concluded with saturation of themes. Consideration was also taken to ensure a range of gender, training and experience of surgeons.
In total 30 surgeons were recruited, 22 were PROSPECT surgeons and 8 non-PROSPECT surgeons. There were 2 pilot interviews and the other 28 surgeons were involved in the main study. Ten surgeons were female and 20 male and the numbers of years of consultant experience ranged from 3 to 31 years. The surgeons had different training experience including, 14 surgeons gynaecologists with a special interest in urogynaecology, 14 sub specialists, 1 general gynaecologist and 1 urologist.

**Participant Relationship**

Recruitment took place within a relatively small pool of specialists practicing urogynaecology within in the UK. The investigators professional networks helped to recruit individuals to this study.

**Research Setting**

The research was undertaken in the surgeon’s own hospital environment. The surgical observation was performed in the operating theatre during a routine theatre list. The subsequent interview was also in the hospital setting. It was requested that the interview was in a quiet and private place to allow audio recording and confidentiality of data. The range of venues included offices/rooms within the theatre environment, the consultant's offices or a seminar room.

**Approach to patients involved in surgical observations**

After approvals to allow hospital site access were gained, the surgeon was requested to identify a theatre session where an anterior repair (mandatory) plus a posterior repair (if possible but not mandatory) was scheduled. First contact with the patients came from the host site. Patient participant information and return slip was posted to the identified patients. The patients returned the slip to the investigator team to inform them if they were willing to participate.
Consent

Participant information sheets (Appendix 1) containing study details were distributed to the surgeons and patients ahead of the research visit. Written consent (Appendix 1) was taken from participants on the day of the site visit. The patients consented to have their surgery observed and filmed and the surgeons consented to be observed and filmed performing surgery and have an audio taped interview.

2.3.1.3 Using a research approach

The research approach chosen for this study was also pragmatic. A pragmatic approach allowed the methods to be chosen based on those that best answered the research question. This method is seen more frequently among professionals such as healthcare professionals, where this research is based [81]. The benefit to this approach is that it can be completed within a shorter time frame to allow a more immediate improvement in practice.

The timeframe for data collection was one year. This approach to methods was therefore more suitable compared to in depth ethnography or phenomenology. As a quality measure, a triangulation of methods were used including audio taped interviews, video taped observations and field notes. Data collection continued until saturation had been met (i.e. no further themes were being uncovered). At this point 3 further surgeons were recruited and this confirmed saturation.

2.3.1.4 Collecting data

Audio taped interviews

Semi structure interview guide

A semi structured interview guide was developed in collaboration with the supervisory team using existing knowledge of surgery and following background theoretical reading (Appendix 1). A semi-structured guide was chosen to give more flexibility allowing surgeons to raise ideas or elaborate on points. It acted as a
prompt, ensuring all topics were discussed with each surgeon being interviewed. The nature of this process meant that some surgeons explored some topic areas more detail than others. The topic guide was transcribed and taken to all interviews. As time progressed some additional questions were added.

Pilot interviews

Two formal pilot interviews were completed prior to data collection commencing. The purpose of these interviews was to assess the performance of the semi structured topic guide and to give experience in the interview process. Some minor changes to the topic guide were made following the pilot interviews. The surgeons who participated in the pilot interviews were a female specialist urogynaecologist working in a tertiary setting and a male general gynaecologist with a special interest in urogynaecology working in a district general hospital.

Interviews with surgeons

An audio taped interview was performed following the observation of the surgery. There were 3 instances where the interview was performed before surgical observation. The surgeons were given an estimation of interview time of 30 – 60 minutes. The actual interview length ranged from 21.10 - 60.19 minutes. All surgeons were interviewed on one occasion.

Additional data was gained from informal conversations following the interview, between theatre cases and during the observation of the surgery. The surgeons chose the interview location. It was requested that the interview would be performed in a quiet and private location to allow the interview to be audio-taped and ensure anonymity. The locations included rooms within the theatre suite, the consultant's office and seminar rooms out side theatre. At the surgeons request a doctor in training observed one interview. All interviews were audio-recorded using an olympus hand held recorder and a windows media audio (WMA) data file was created.
**Video-taped surgical observation**

The 28 surgeons participating in the main study had their surgery observed and one investigator performed these observations. A cannon video camera with a HD memory card was used. The camera was placed on a tripod and access was gained via the left side of the operating surgeon.

An anterior repair was observed for every participating surgeon and this procedure was performed either alone or in combination with another procedure. Where possible a posterior repair was also observed. Between one and two surgeries were observed for each surgeon and this was completed during a single theatre session.

**Field notes**

Field notes were taken during the interviews and from informal discussions. Following the research visit further notes were written, which included ideas and thoughts from the site visit including emerging themes and suggestions from surgeons.

**2.3.1.5 Working with data**

**Transcription of data**

The interviews were all transcribed into a word document by the transcription services, first class secretaries (as recommended by the University of Manchester). The files were anonymised and were uploaded onto the companies secure server. The data was displayed under the titles, Interviewer and Respondent, and the option of intelligent verbatim was chosen to ensure that documentation was accurate.

From the subsequent observations of the videos, written accounts were made and a pictorial representation drawn to summarise techniques used. A second investigator observed all videos and a comparison of interpretations was made to ensure accuracy and quality of the data analysis. A third investigator observed a subset of videos in order to validate the interpretation of the other 2 investigators.
Computer software

NVIVO computer based software was used to aid the analysis of the data. All the interview transcriptions and field notes were uploaded onto a project within this programme.

Thematic analysis

The analysis has been an iterative process. Analysis began and took place along side fieldwork allowing development of ideas and concepts as they were being raised. This sequential approach [82] allowed emerging themes to be discussed with the surgeons in subsequent interviews.

A thematic analysis as described by Braun and Clarke [83] was undertaken. Following data collection, there was a period of data immersion, which included reading and re-reading transcripts and watching videos. The 6 steps of analysis were followed [83]. These 6 steps included; Familiarising self with the data; generating initial codes; searching for themes; reviewing themes; defining and reviewing themes; and production of a report. Two investigators were involved in steps 1 – 3 and a further investigator also involved in steps 4 – 6.

The descriptions reflect the whole data set. This approach was taken in view of this being a under researched area, to give broad account and understanding of the topic area. In addition we approached the data in an intuitive way [84] meaning the themes were closely linked to the data rather than being guided by theory. This approach was more in keeping with the question that was being asked and the pragmatic approach taken. The results of the posterior repair technique are not included in this thesis due to amount of data being too great to include in this thesis.

During data analysis there was close supervision of the process by an investigator proficient in qualitative methodology. This investigator was directly involved with
each step of the process, including the analysis of a subset of the interviews and in the reviewing and defining of study themes.

2.3.2 Other considerations – qualitative research

2.3.2.1 Quality of data

A number of steps were taken to ensure the quality of the research data. The guidelines, consolidated criteria for reporting qualitative research (COREQ) [85] and critical appraisal skills programme (CASP) [86] were utilised. During the analysis, the 15-point checklist of criteria for good thematic analysis was followed [83]. In addition the following recognised strategies [78] including pilot interviews, reflexivity, triangulation, inter-rater reliability and respondent validation were used.

The use of pilot interviews and reflexivity have been discussed. The use of triangulation ensured breadth of data was collected. This was established by the use multiple methods of data collection [87] and multiple researchers being involved in undertaking of the study. The later improved the validity of the data. Lastly the sequence of surgical observation followed by an interview with the surgeon allowed immediate respondent validation. In addition a sub set of the transcripts were emailed to the surgeons to ensure the accuracy of the accounts. Additional questions were qualified during this email exchange.

2.3.2.2 Ethical considerations

Approval for the study

Ethical approval was gained through proportionate review from the Sunderland Ethics Committee (REC number: 13/NE/0158). After agreement from the surgeon to participate in the study, every sites research and development department was approached for local approvals. This aspect of the process was relatively time consuming, as there was no standardisation of the documents required from each trust. Both trust approval and a letter of access from each site were required to allow completion of each site visit.
Confidentiality and Anonymity

Each surgeon and patient recruited was given a letter and number (e.g. Surgeon A and their patients A1 and A2) to anonymise the data. A list of the recruited surgeons details was kept with in the site file to allow future sub group analysis (linked data file). This file was kept in research office in a locked room and filing cabinet. The investigators named in the protocol had access to the participating surgeons personal information during the study. Patient identifiable information was anonymised at source. The videos included images of the operations however there were no images of the women's face or other aspects of their bodies that could make them identifiable.

Data Protection

All data was stored securely to ensure confidentiality of the participants. Both the audiotape and media files were transferred on an encrypted memory stick (FIPS encrypted memory stick). A back up of this data was kept on an encrypted data stick in a locked research room. At the lead site data was kept on a secured shared P drive. All consent forms and trust approvals were kept in a locked filing cabernet within the research office.

2.3.2.3 Obstacles related to site approvals

A 6-month extension to this study was required due to the sometimes lengthy process of the individual trust approvals processes. The obstacles met in the approvals processes and study coordination are listed below.

- The investigator had limited experience in the management of a multicentre study and the navigation the R&D approval processes in different Trusts. Support was gained from the local R&D department and Gynaecology research nurse manager.

- The coordination of all aspects of the study was performed by one investigator. The application to adoption this as a portfolio study linked to the PROSPECT trial was
declined as the trial steering committee (TSC) thought this might negatively bias the PROSPECT. Portfolio studies are provided with additional administrative support.

- There is not a central site coordinating and processing approval documents in England. In comparison in Scotland there is a central coordinating site and once the application process was completed additional sites in Scotland could be added without additional documentation.

- As the surgeons were the participants they could not be the principal investigator (PI) at that site. The majority of centres allowed the investigator to take on this role. However in some centres the PI needed to be employed in that trust. In this situation an alternative member staff member was approached.

- The documentation required varied between centres. In some cases further documentation was requested at a later time point. Documents required in addition to the standard forms included: Contract agreements; Costing Tool; Confirmation of funds form; Caldecott Approval documents; Feasibility Form; Participant information and consents requiring local details.

- The time to achieve a first response and then to process the documentation was variable and in some cases prolonged with the maximum time period to achieve approvals being 3.5 months.

- In some sites the personnel completing the trust approvals and letter of access were different and required coordination from the investigator.

- Two centres R&D departments required a site visit prior to commencement of the study with ID to support the application.
2.4 Quantitative research methods – Variation in Surgical Technique

2.4.1 Data request procedure

The study protocol was sent to Aberdeen at the start of the VaST study. The PROSPECT team gave their agreement for the undertaking of the study. However, the agreement for the release of outcome data for subgroup analysis was stipulated to be after study completion. The chief investigator completed a letter outlining this agreement. The initial plan was to perform this subgroup analysis after submission of this thesis. However an extension resulting from maternity absence has allowed its inclusion.

A request was sent to Aberdeen, the lead site of PROSPECT, to gain access to the outcome data to allow the subgroup analysis. A data request proposal and a statistical analysis plan were completed. The investigator designated to perform the VaST statistical analysis had additional discussions about the analysis with the PROSPECT study statistician. Agreement from the trial steering committee was required before the data was released.

2.4.2 Study criteria

The patient outcome data from the PROSPECT study of the 22 surgeons who had simultaneously recruited to PROSPECT study and the VaST study was requested. The inclusion and exclusion criteria for the patient data requested were a follows:

**Inclusion criteria**

All patients having an anterior native tissue repair (primary repairs, secondary repairs and RCT and cohort patients).

**Exclusion criteria**

All patients having a native tissue posterior repair and graft/mesh repairs.
Of the 22 surgeons, 2 of the surgeons were excluded from analysis, no data one was received for one patient and the other had performed one procedure. For the theme depth of dissection, 2 surgeons’ data (n=85) were excluded, as data could not be categorised as deep or superficial (table 1). From the theme fascial suture placement cases where sutures were placed in the skin rather than fascia were excluded (n= 37). When separate fascial defect repair was performed these cases (n= 50) were removed from the categories fascial suture placement, method of fascial repair and number of layers as these varied depending on the defects identified.

**Time frame**

The baseline, 12 month and 24 months data for these patients was requested.

**2.4.3 Outcome measures**

**Primary**

*Subjective outcome measure - POP – SS score*

The POP SS score is based on a validated questionnaire that includes 28 questions relating to all compartments of the pelvic floor. The clinically important change in this score has been found to be 2. An assessment of the change in score from the baseline measurement was made.

**Secondary**

*Anatomical outcome measure – POP Q, Ba measurement*

Patients were examined preoperatively and postoperatively at 12 months using the POP Q examination system (see introduction for explanation of POP Q). The postoperative data was divided into cure (measurements -3cm, -2cm and -1cm above the hymen) and failure (0cm/at the hymen or more).
Other

An assessment of the affect of the themes of surgical technique and use of pack/catheter on the postoperative complications was made.

The complications reviewed included;
- Wound infection
- Hematoma
- Urine tract infection
- Urine retention

2.4.4 Covariates

Information about the following confounding variables, for each patient, was also requested;

Age at time of operation
BMI
Parity
Concomitant surgery (including vault procedure, posterior repair and incontinence procedure)
Primary or secondary procedure

2.4.5 End points

The primary endpoint of this study is a change in POP SS score of more than 2. Symptomatic outcome measures have been shown to better reflect the cure of the patient and measurements were performed at 12 and 24 months postoperatively.

The secondary end point used the Ba measurement and was defined as the most dependent part of the prolapse being above the level of the hymen (0) including Ba measurements of -1cm, -2cm and -3 at 12 months. Consideration of using Ba as the
primary endpoint was made however the measurement was only performed in the RCT cohort of patients at 12 month.
An assessment of the affect on the quality of life was made using the question, “Overall how much does your prolapse affect your everyday life?”. The response was a scale of 0 – 10 (0 not at all and 10 a great deal). The change in quality of life score was calculated from baseline at 12 and 24 months.

2.4.6 Themes

Themes of surgical technique for native tissue anterior repair were created (see Paper 1 and Appendix). An assessment of the influence of each surgical technique theme on outcome measures was made.

2.4.7 Analysis objectives

The objective of this analysis was to see if any surgical technique theme influenced the outcome of native tissue anterior POP surgery. Previously there have been a limited number of studies assessing the impact of surgical techniques on outcome. This is an under researched area. The majority of surgeons in the VaST study had recruited patients to PROSPECT. The decision for the inclusion of these surgeons into the VaST study was made with the knowledge that this analysis using PROSPECT outcome data would be performed. Consent was gained from the chief investigator and trial manager of PROSPECT from the outset.

2.4.8 Handling of missing values and other data conventions

No missing data values were anticipated as the primary outcomes of the PROSPECT study were requested and the data collected for the VAST study was complete for all participating surgeons. Statistical analyses only included participant outcomes where complete data was available.
2.4.9 Statistical Methodology

Statistical Procedures

The investigator performing the statistical analysis was blinded to the identity of the surgeons in each theme. The surgeons were grouped for each theme using a code. All continuous data was checked for normality and transformed prior to analysis. The POP SS score was assessed on a linear scale of change of 1 point. Ba measurement was dichotomised into cure (-3cm to -1cm) above the hymen) and failure (0cm to 6cm beyond the hymen).

Descriptive statistics were used to describe the population demographics and a summary of the primary and secondary outcomes. A series of regression models were fitted to the dependent outcome variable (POP SS and Ba) incorporating the differences in surgical techniques and covariates (age, BMI, parity, primary or secondary surgery and concomitant vault or posterior wall repairs). If the covariates were borderline or significant (p =/< 0.1) or the interclass correlation (ICC) was >10% in mixed level regression accounting for surgeon, these factors were then included in the analysis models. Assessment of model fit was assessed using standard post estimation metrics and models compared using likelihood ratio testing.

Where an association was identified between surgical technique and outcome the contribution of other components of surgical technique were tested using interaction terms. Consideration to over fitting was given and variables collapsed/omitted where analyses were limited by small numbers. A POP SS change of -2 or more was considered clinically significant. A p = 0.01 or less was deemed as a significant finding to account for multiple testing.

Measures to adjust for multiplicity, confounders and heterogeneity
Confounders were incorporated within the regression analyses.

Sensitivity Analysis
No sensitivity analyses was performed.
2.5 Reporting

It was decided to write this report using the alternate thesis format. This thesis was completed to fulfill the research component of the investigators sub-specialty training in Urogynaecology. Following thesis submission the investigator will be in full time clinical work. As a busy clinician, the supervisory team and investigator felt this would be the best way to publish this work. The papers written as part of this thesis will be submitted for publication either before or after submission.

The structure of the thesis was guided by the university guideline, “presentation of thesis policy” and the sections include are;

- Introduction

- Methodology

- Results – written in alternative format in the form of papers (1 – 4)
  - Paper 1: A survey of the surgical techniques used to repair pelvic organ prolapse in the UK
  - Paper 2: Variation in surgical technique (VaST), The use of qualitative research methods to evaluate how surgical technique varies amongst UK based surgeons when performing a standard anterior POP repair.
  - Paper 3: Variation in surgical technique (VaST), Reasoning behind practice: An observational study of surgery
  - Paper 4: Variation in surgical technique (VaST), The influence of surgical technique on the outcome of native tissue anterior repair

- Overall Discussion

- Future Work
CHAPTER 3: PAPER 1

A UK questionnaire survey of current techniques used to perform pelvic organ prolapse repair
Chapter 3
Paper 1

A UK questionnaire survey of current techniques used to perform pelvic organ prolapse repair

Emily Fairclough¹,², Jenny Myers¹,², Anthony Ross Broadhurst Smith¹,², Suzanne Breeman³ and Fiona Reid¹,²

1. Saint Mary's Hospital, Central Manchester University Hospital NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, M13 9WL.
2. Maternal & Fetal Health Research Centre, Manchester Academic Health Science Centre, University of Manchester, Manchester, M13 9WL.
3. Health Services Research Unit, University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD.

Corresponding author:
Fiona Reid
St Mary's Hospital, Central Manchester University Hospital NHS Foundation Trust, Oxford Road, Manchester. M13 9WL
Tel: 0161 2766910  Fax: 0161 2766085  Email: Fiona.Reid@cmft.nhs.uk

Authors contribution to manuscript:
Emily Fairclough: Management of data analysis, Manuscript writing
Jenny Myers: Manuscript editing
Anthony Smith: Development of questionnaire, Manuscript editing
Suzanne Breeman: Development of questionnaire, Manuscript editing
Fiona Reid: Development of questionnaire, Manuscript editing

FINANCIAL DISCLAIMER/ CONFLICTS OF INTEREST: None
Abstract

Introduction

Evidence based medicine should result in more standardisation of practice. This study aims to evaluate whether there remains variation in surgical techniques in native tissue and graft/mesh repairs of pelvic organ prolapse (POP) in UK practice.

Methods

A questionnaire survey was conducted to detail current surgical techniques for native tissue and graft/mesh POP repairs performed by a cohort of UK surgeons recruiting to a large multicentre prolapse trial (PROSPECT).

Results

The questionnaire return rate was 90% (n=56/62). Substantial variations in surgical techniques were seen in every step of the procedures. Native tissue repair: The majority of surgeons used infiltration, 95% (n=53/56) but the volume used varied (10–80 ml). All but one surgeon performed a midline incision; this surgeon performed an elliptical incision. The depth of tissue dissection varied; being both above and below the vaginal muscularis (fascia). Fascial repair methods included midline, closure of separate fascial defects, paravaginal repair and rectal/levator plication. Graft/mesh repairs: Many different products and manufacturers were used. There was variation in the method of attachment of graft/mesh inserts and their placement in relation to the fascia. For both native tissue and graft/mesh repairs, method of fascial dissection, suturing methods and suture material varied. The majority of surgeons inserted a pack, 91% (n=50/55), soaked in varying substances prior to use.
Conclusion

There is considerable variation between UK based surgeons in the surgical techniques used to perform both native tissue and graft/mesh augmented POP repairs. Further research is required to determine whether these differences influence outcome.

Key Words

Graft, Mesh, Native Tissue, Pelvic Organ Prolapse, Surgical Technique

Brief Summary

A prospective questionnaire study demonstrating how techniques to repair pelvic organ prolapse continue to vary amongst UK based surgeons recruiting to a large surgical trial.
Introduction

It is frequently quoted that recurrence of pelvic organ prolapse (POP) or incontinence occurs in up to third of women after surgical repair [11]. In view of discontent with native tissue POP repairs surgeons began to augment repairs with biological grafts or synthetic meshes [88]. In 2010, a national study showed the majority of UK surgeons continued to perform primary native tissue POP repairs (71%) [54]. However just over half of the surgeons were performing a graft/mesh repair for secondary POP repairs (56%) [54]. Today the use of grafts/mesh is more controversial as there are concerns about the long term safety of grafts/mesh [29].

Over the last 10 years questionnaire based studies have shown surgical techniques used to perform native tissue POP repairs and the types of graft/mesh for augmented POP repairs vary between surgeons [60, 89–91]. However, the intraoperative techniques used for the insertion of graft/mesh and whether variations in techniques have any impact on the outcome of the surgery are currently unknown.

The aim of this questionnaire survey was to prospectively describe the current surgical techniques to perform both native tissue and graft/mesh POP repairs used by a cohort of UK surgeons recruiting women to a large multicentre prolapse trial (PROSPECT) [50].
**Methodology**

This study received ethical approval from the North of Scotland Ethics Committee (NOSRES), (REC/09/SO802/56).

A questionnaire was developed to assess the surgical techniques used by surgeons recruiting to a large, pragmatic, multicentre, randomised controlled trial (RCT) assessing prolapse management (PROSPECT) [50]. The pragmatic nature of the trial gave the opportunity to assess current practices of a cohort of UK surgeons. The questions included were developed in a small focus group of surgeons; then surgeons from one hospital site checked the face validity. The 52 questions addressed 5 domains; native tissue techniques for anterior POP repair, native tissue techniques for posterior POP repair, techniques used to perform graft/mesh POP repairs, details on insertion of packs and the methods used to perform POP-Q (Appendix 1). The study did not consider techniques for vault/apical surgery for prolapse.

The questionnaires were distributed by email to the lead research nurse at each site. The research nurse ensured that each surgeon recruiting to the PROSPECT study completed the questionnaire. Reminders were distributed via email to the lead research nurse.

The responses were manually transferred from paper questionnaire into a spreadsheet. Each question was presented in a column and the data was coded. Data was analysed in a series of one-way tables. Some sections of the questionnaire were not relevant to every respondent, so responses were presented as the proportion of surgeons responding to each question.
Results

There were 35 centres and 62 surgeons involved in the recruitment of participants to PROSPECT. Of these recruiting surgeons, 90% \((n=56/62)\) completed and returned the questionnaire. The results presented relate to the intraoperative surgical techniques.

Native tissue anterior and posterior POP repairs

Infiltration: 53 surgeons \((95\%, n=53/56)\) used infiltration for native tissue anterior and posterior POP repairs. However, there was variation in the volume of fluid infiltrated, ranging from 10 – 80 mls; most surgeons used between 10 - 20 mls \((67\%, n=35/52)\).

Incision: All but one surgeon performed a midline incision to open the anterior and posterior vaginal walls; this surgeon performed an elliptical incision as routine practice.

Dissection: The depth of dissection in the anterior and posterior vaginal walls is summarised in table 3.1 and the method used to perform this dissection is shown in table 3.2.

<table>
<thead>
<tr>
<th>Depth of dissection</th>
<th>Anterior POP Repair ((n = 56))</th>
<th>Posterior POP Repair ((n = 56))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissect fascia of the vaginal epithelium</td>
<td>37 %</td>
<td>34 %</td>
</tr>
<tr>
<td>Leave fascia on the vaginal epithelium</td>
<td>18 %</td>
<td>21 %</td>
</tr>
<tr>
<td>Both techniques used</td>
<td>45 %</td>
<td>45 %</td>
</tr>
</tbody>
</table>

Table 3.1: The depth of dissection used for native tissue pelvic organ prolapse repairs
**Method of fascial dissection**

<table>
<thead>
<tr>
<th>Method of fascial dissection</th>
<th>Fascia dissected of the vaginal epithelium ( (n = 46) )</th>
<th>Fascia left on the vaginal epithelium ( (n = 35) )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blunt dissection</td>
<td>4%</td>
<td>14%</td>
</tr>
<tr>
<td>Sharp dissection</td>
<td>63%</td>
<td>43%</td>
</tr>
<tr>
<td>Both method dissection</td>
<td>33%</td>
<td>43%</td>
</tr>
</tbody>
</table>

**Table 3.2:** The method of fascial dissection used for native tissue pelvic organ prolapse repairs

Fascial repair: The most common technique used to repair the fascia for both anterior and posterior POP repairs was midline plication (table 3.3). Other techniques included closure of separate fascial defects, paravaginal repair and rectal plication (table 3.3). Three surgeons (5%, \( n=3/56 \)) documented that they performed levator plication as part of their routine native tissue posterior POP repair. When performing a posterior POP repair, 46 surgeons (84%, \( n=46/55 \)) stated they routinely performed a rectal examination during dissection or at the end of the procedure to ensure sutures did not penetrate the rectal wall.

<table>
<thead>
<tr>
<th>Vaginal compartment</th>
<th>Midline Plication ( (n = 46/47) )</th>
<th>Closure of separate defects ( (n = 23/39) )</th>
<th>Paravaginal repair ( (n = 11/44) )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>97 %</td>
<td>59 %</td>
<td>25 %</td>
</tr>
<tr>
<td>Midline Plication</td>
<td>( (n = 39/43) )</td>
<td>Closure of separate defects ( (n = 32/43) )</td>
<td>Rectal Plication ( (n = 17/43) )</td>
</tr>
<tr>
<td>Posterior</td>
<td>91 %</td>
<td>74 %</td>
<td>40 %</td>
</tr>
</tbody>
</table>

**Table 3.3:** The methods of fascial repair used for native tissue pelvic organ prolapse repairs
Suturing: The type of suture material used and method of closure of both the skin and fascia is seen in table 3.4. All surgeons closed the fascia and the skin separately. There were almost an equal proportion of surgeons used polydioxanone (PDS) (53%, n=30/56) and polyglactin 910 (Vicryl) sutures (43%, n=24/56) to close the fascia whereas most surgeons used Vicryl to close the skin (94%, n=53/56). The majority of surgeons used interrupted sutures on the fascia (66%, n=37/56) and the most frequently used skin closure method was continuous locking sutures (61%, n=34/56).

<table>
<thead>
<tr>
<th>Suture material</th>
<th>Native Tissue</th>
<th>Graft/Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fascia (n = 56)</td>
<td>Skin (n = 56)</td>
<td>Fascia (n = 34)</td>
</tr>
<tr>
<td>PDS</td>
<td>53% 2%</td>
<td>38% 2%</td>
</tr>
<tr>
<td>Vicryl</td>
<td>43% 94%</td>
<td>62% 94%</td>
</tr>
<tr>
<td>Both PDS and Vicryl</td>
<td>4% na</td>
<td>na na</td>
</tr>
<tr>
<td>Monocryl</td>
<td>na 2%</td>
<td>na 2%</td>
</tr>
<tr>
<td>Polysorb</td>
<td>na 2%</td>
<td>na 2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method of closure</th>
<th>Native Tissue</th>
<th>Graft/Mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fascia (n = 56)</td>
<td>Skin (n = 56)</td>
<td>Fascia (n = 40)</td>
</tr>
<tr>
<td>Continuous locking</td>
<td>7% 61%</td>
<td>8% 45%</td>
</tr>
<tr>
<td>Continuous non locking</td>
<td>25% 29%</td>
<td>30% 35%</td>
</tr>
<tr>
<td>Interrupted</td>
<td>66% 10%</td>
<td>60% 20%</td>
</tr>
<tr>
<td>Purse string</td>
<td>2% na</td>
<td>2% na</td>
</tr>
</tbody>
</table>

Table 3.4: The suture material and method of closure of fascia and skin for native tissue and graft/mesh pelvic organ prolapse repairs
Graft/Mesh POP repairs

Of the 56 surgeons who returned the questionnaire, 3 surgeons did not perform any graft/mesh procedures in this trial. There were a variety of different grafts/mesh materials used. All synthetic inserts where type 1 polypropylene from Boston Scientific, Coloplast and Ethicon. There were several types of mesh inserted from Ethicon including Gynaemesh, Prosimia and Ultrapro. Seven surgeons did not state the manufacturer of the polypropylene mesh insert. There were 3 manufacturers of biological inserts used from Bard, Boston Scientific, and Cook. The mesh kits used were from American Medical Systems (AMS), Bard, Boston Scientific, Cory Bros and Ethicon. Surgeon’s prior experience of mesh kits usage varied (table 3.5).

<table>
<thead>
<tr>
<th>Number of mesh kits</th>
<th>Surgeons’ previous mesh kit experience (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10</td>
<td>34 %</td>
</tr>
<tr>
<td>10 - 20</td>
<td>18 %</td>
</tr>
<tr>
<td>20 - 49</td>
<td>30 %</td>
</tr>
<tr>
<td>&gt;50</td>
<td>18 %</td>
</tr>
</tbody>
</table>

Table 3.5: The surgeons’ previous mesh kit experience

The graft/mesh inserts were soaked in a substance prior to use by 15 surgeons (30%, n=15/49). These substances included; Normal Saline (n=11/49), Cefotaxime (n=1/49), Savalon (cetrime and chlorhexidine gluconate) (n=1/49), Gentamycin (n=1/49) and Iodine (n=1/49). The inserts were of a variable size but the actual measurements were not accurately recorded. Some surgeons described varying the size of the insert depending on the findings during surgery.

The placement of the graft/mesh insert was reported as being inserted below the fascial layer (inlay) by 38 surgeons (79%, n=38/48), above the fascial layer (overlay) by 6 surgeons (13%, n=6/48) and 4 surgeons (8%, n=4/48) performed both
techniques. Of those surgeons who only inserted graft/mesh as an overlay, both biological grafts and synthetic mesh materials were used (2 used synthetic mesh only, 2 biological grafts only and 2 both biological and synthetic grafts/mesh).

The graft/mesh inserts were attached either to the pelvic side wall (12%, \(n=5/43\)), white line/sacrospinous ligament (86%, \(n=37/43\)) or fascia (2%, \(n=1/43\)). In addition, 40 surgeons (89%, \(n=40/45\)) attached the graft insert to the cervix anteriorly. A branded suture device (Capio) was used by 22 of recruiting surgeons to aid graft/mesh attachment and the remaining surgeons used another method. As with native tissue repairs, closure of the fascia and skin was performed with a variety of suture types and methods of suturing (Table 3.4); 7 surgeons closed in 1 layer only.

**Use of Packs**

A pack was used following surgery by the majority of surgeons (91%, \(n=50/55\)) and it was most commonly soaked in proflavine (acridine-3, 6-diamine), an antiseptic lubricant (82%, \(n=41/50\)). Other substances used to lubricate the pack included; oestrogen cream (\(n=3\)), betadine (povidone-iodine) (\(n=2\)), dalacin (clindamycin) (\(n=2\)), hibitane (chlorhexidine) (\(n=4\)), normal saline (\(n=1\)) and savlon (cetrimide and chlorhexidine gluconate) (\(n=1\)).
Discussion

Summary of findings

This is the first questionnaire study to report that a significant proportion of surgeons are dissecting beneath the vaginal muscularis (often called fascia by surgeons) in native tissue repairs. It is likely that this “deeper dissection technique” described in this questionnaire survey has developed from techniques used for the insertion of mesh. Typically mesh is placed below the vaginal muscularis (fascia) directly against the rectum or bladder; as described by Muffly & Barber in 2010 [92]. The traditional plane of dissection is more superficial; the vaginal epithelium is split from the underlying muscularis to enable its plication [90, 93, 94]. Most surgeons in this study continue to use this technique and a past study of Dutch Urogynecologic Society members showed that almost half of the surgeons attempted to, “dissect the vaginal mucosa as thin as possible from the bladder” (43%). The remaining Dutch surgeons (47%) considered thickness less important and dissected in the “most optimal surgical plane” [90]. There was no clear definition of this plane nor was the impact of the differing techniques studied.

The volume of infiltration used in this study varied greatly from 10 - 80 mls. The larger volumes of infiltration, may again relate to techniques used for mesh insertion. Larger volumes of infiltration are thought to facilitate a full thickness dissection of the vaginal muscularis from the bladder or rectum and allow placement of the graft/mesh below it [92]. In older descriptions of native tissue POP repair no infiltration was used [93, 95]. Infiltration type was not recorded in this study however in other studies it has been and the most commonly used infiltrate varied between local anaesthetic [89] and normal saline [90, 96]. Surgeon’s rationale for using local infiltration has been assessed [96] but the reason behind the choice of infiltrate was not evaluated.
In this study, the most commonly performed incision into the vaginal wall was midline, only one surgeon used a different approach, an elliptical incision. In an earlier UK questionnaire study, a much larger range of incisions were reported including midline, racquet, diamond, inverted T, elliptical and triangular [89]. The reason for the change in practice is unclear.

The majority of surgeons in this and other studies report repair of the fascia in the midline. This approach was first described by Kelly in 1913 [95] for the management of urinary stress incontinence. Other vaginal fascial repair techniques described include closure of separate fascial defects, paravaginal repair, rectal and levator plication. As in other studies, fewer surgeons performed these methods [60, 89, 90]. The reason why midline plication remains the most widely performed method may relate to the success of this method or the ease of repair however there is very limited literature assessing how technique of native tissue repair affects the outcome of surgery [88]. Despite this questionnaire recommending that levator plication should not be performed, 3 surgeons in this study documented doing this in practice. This technique is associated with an increase in dyspareunia and a decrease in sexual function postoperatively [97].

In this study, almost equal proportions of surgeons used Vicryl and PDS for fascial plication whereas the predominant suture for skin closure was Vicryl. This was different from the techniques described by the Dutch surgeons [90], where Vicryl was the most commonly used suture for fascial plication. Determining why surgeons chose a particular suture material was beyond the scope of the questionnaire. There is very little evidence about the optimal suture material to use. One small RCT of 66 patients [98] found no difference in prolapse symptoms scores but a significantly lower prolapse - related quality of life and urine incontinence scores when Vicryl was used compared to PDS. A single centre RCT of pack usage suggested there was no significant difference in patient’s pain experience postoperatively with or with out packing [99]. Future large scale multicentre RCT studies would help assess different aspects of technique to provide more evidence on which to base practice.
In this study the most commonly used suture method for fascial plication was interrupted sutures (66%). However in the Dutch study, there were an equal number of surgeons using interrupted (32%), continuous locking (32%) and continuous sutures (35%) for plication of the fascia [90]. There is no literature demonstrating the best suture method for fascial closure and this may be the reason for the variation seen. There is a recently published feasibility trial that gives some insight into the method of suturing to close the vaginal skin [100]. The pain scores were higher in women 24 hours post closure when interrupted sutures were used compared to a continuous single suture however qualitative research showed women rated this postoperative pain as insignificant.

Unlike other questionnaire studies [89, 91], this study details the intraoperative techniques used by surgeons for the insertion of graft/mesh. There is a lack of evidence to confirm whether the technique for graft/mesh insertion affects surgical outcome. There is literature that outlines what expert opinion deems acceptable technique [92]. The key practice points described include; catheterisation to drain bladder; antibiotic usage; avoidance of T incision when performing concomitant hysterectomy/colporraphy; adequate use of infiltration (20 – 80 ml) to expose the vesicovaginal/rectovaginal space; placement of the graft/mesh below the vaginal muscularis; attachment of the graft/mesh loosely to allow for its contraction; not trimming the vaginal skin; and closure with a non locking continuous absorbable suture. Given the concern about the integrity of prolapse repairs it is remarkable that we have so little evidence to define the appropriate management of the key practice points.

The majority of surgeons in this study placed the graft/mesh below the "fascia" in line with expert opinion. The identification of this space is made possible by a "loss of resistance" technique where the infiltration is placed in an avascular space between the vaginal muscularis and the bladder/rectum [92]. This creates a fluid bubble that can be identified following dissection through the vaginal wall. A proportion of surgeons in this study (13%) placed graft/mesh above the vaginal muscularis and this
included both synthetic and biological grafts/mesh. It might be expected that this variation in technique could affect the vaginal skin exposure rate but there is no literature assessing this.

**Study Limitations**

This surgical technique questionnaire was not fully validated. There were incomplete responses and documentation of multiple methods, which made it difficult to fully evaluate the most commonly used techniques. In addition, multiple responses could suggest surgeons vary their own technique but from these results we cannot distinguish what determines the approach taken in individual cases. The layout of the questionnaire may have been a contributing factor to the incomplete responses. It was beyond the scope of this questionnaire to determine why surgeons chose one technique over another. In addition we are unable to determine if all surgeons used the same terminology to describe techniques being practiced. In view of the variation in surgical techniques between surgeons that has been identified in this study the pragmatic design of PROSPECT provides the best way of ensuring results are clinically relevant to UK clinicians at this time.

**Further research**

In view of the limitations of questionnaire studies, further qualitative research (Variation in Surgical Technique, VaST) is being undertaken within the PROSPECT trial [50] to create categories of surgical technique to enable a secondary analysis of their influence on outcome.

**Conclusion**

In summary, surgical techniques to repair both native tissue and graft/mesh POP repairs varied between UK surgeons. Further research is required to assess whether variation in surgical technique influences the outcome of surgery.
CHAPTER 4: PAPER 2

Variation in Surgical Technique (VaST): A qualitative study of the surgical technique used in the UK for native tissue anterior pelvic organ prolapse repair.
Chapter 4

Paper 2

Variation in Surgical Technique (VaST):
A qualitative study of the surgical technique used in the UK for native tissue anterior pelvic organ prolapse repair.

Title page

Authors: E Fairclough 1,2, J Segar 3, J Myers 1, ARB Smith 1 and FM Reid 1,2
1. St Mary’s Hospital, Central Manchester Foundation Trust, Oxford Road, Manchester. M13 9WL
2. Maternal & Fetal Health Research Centre, Manchester Academic Health Centre, University of Manchester. M13 9WL
3. University of Manchester, Institute of Population Health, Oxford Road, Manchester, M13 9PL

Financial disclaimer/ conflict of interest: None

Participation in manuscript

E Fairclough: Development of protocol, data collection, data analysis, manuscript writing
J Myers: Development of protocol, manuscript editing
J Segar: Manuscript editing
ARB Smith: Concept, development of protocol, manuscript editing
FM Reid: Concept, development of protocol, data analysis, manuscript editing

Corresponding author

FM Reid
St Mary’s Hospital, Central Manchester Foundation Trust, Oxford Road, Manchester. M13 9WL
Tel: 0161 276 6910 Fax: 0161 276 6085
Email: Fiona.Reid@cmft.nhs.uk

Key Words: Pelvic Organ Prolapse, Native Tissue Repair, Surgical Technique, Qualitative Research
Abstract

Objective

To categorise surgical techniques used to perform a native tissue anterior repair to allow the future assessment of the influence of surgical technique on the outcome of surgery.

Design

Prospective qualitative study

Setting

Multicentre study in 21 tertiary and secondary care hospital in the UK

Population

UK based consultant surgeons

Method

A purposive sampling strategy was used to recruit 30 surgeons. Data was collected through audio-recorded interviews, video recorded observations of surgical operations and field notes. Thematic analysis was performed using computer based software (NVIVO) and themes of surgical technique were developed.

Results

Variation in surgical technique was seen in all steps of the anterior repair, including infiltration, dissection, method of facial repair, type and method of suture & suture placement. Most surgeons used the term “fascia” to describe the tissue they were repairing. However when surgeons were asked to explain the term, the concept of
fascia in histological terms was not uniform amongst surgeons. The placement of the infiltration by some surgeons was claimed to be within a specific plane; in a superficial plane which was described as under the epithelium or in a deep plane under the fascia. This is in contrast to others who stated it was difficult to know exactly where the fluid was placed; “I let it find the plane itself”. The incision into the anterior vaginal wall was commonly midline and in 1 case elliptical; made with a scalpel, diathermy pen or tunneling technique using scissors. The depth of the dissection varied. A superficial dissection was described, attempting to leave the fascia on the bladder. Others performed a deep dissection in which the fascia was left on the vaginal epithelium. Video footage identified that the depth of dissection varied and was not always consistent with the surgeon’s description. Similarly, there was variation in the technique and terminology used to describe the repair of the fascia. Plication was commonly midline; some above & others below fascia. Some performed separate fascial defect repair. Fascial suture method including interrupted (box, running and mattress) and continuous sutures (box, running, purse string) and placement of these sutures varied from close to the midline, to lateral and ultra lateral in the white line or over the obturator foramen.

**Conclusion**

Compared to previous questionnaire studies the use of qualitative methods has given a greater insight into the variation of surgical techniques used to perform a native tissue anterior repair for pelvic organ prolapse. Surgeons’ terminology to describe their practices varied and these descriptions were not consistent between surgeons. There is a need to formally standardise terminology and to perform trials to compare different techniques of native tissue repair.
Introduction

Studies have suggested that mesh/grafts could offer a better anatomical cure [6], however the risk of mesh extrusion is reported as up to 10% [6] and the long term safety of mesh/grafts for this indication are unknown. A large UK based surgical randomised controlled trial (RCT) (PROSPECT, PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials) [50] was conducted to compare native tissue repairs to those augmented with mesh/graft. This study was pragmatic, with participants using the surgical techniques from their clinical practice. A questionnaire [101] was completed at commencement of this study to document techniques, for both native tissue and mesh/graft repairs. This questionnaire demonstrated significant variation in the surgical technique used to perform an anterior repair for POP.

Over the last 10 years other questionnaire based studies have shown that, both native tissue and graft/mesh surgical techniques used to repair POP vary amongst surgeons in the UK [61], USA [60] and in Holland [58, 59]. However, none of the previous questionnaires were able to evaluate if the variation described had an impact on the outcome of surgery.

Questionnaire based studies are able to generate a large amount of data from a geographically spread population in a cost effective way [102]. However, the closed questions used in such studies have meant that many details about surgical technique are unknown. The questionnaire completed by PROSPECT surgeons [101] had several flaws. There were questions that were not answered and some questions had multiple responses. Multiple responses could suggest that surgeons vary their own surgical techniques from case to case. In addition, there is uncertainty that all surgeons use the same terminology so responses could vary on this basis. Lastly the questionnaire was unable to answer why techniques vary between surgeons and whether variation affects outcome.

In view of the limitations associated with the questionnaire study of surgical technique, a qualitative study was proposed to gain greater insight into surgical technique variation and to understand why in the age of evidence based medicine such
an extensive variation of practice continues to exist exists. The objective of this part of the VaST study was to categorise surgical techniques used to perform a native tissue anterior repair to allow the future assessment of the influence of surgical technique on the outcome of surgery.
Methodology

This multi-centered U.K. based prospective observational study used qualitative methodology to evaluate the surgical techniques used for native tissue anterior POP repairs. A purposive sample was drawn from a cohort of surgeons who had recruited to a large surgical prolapse study, PROSPECT [50]. This sample was chosen to allow a future subgroup analysis of the influence of surgical technique on outcome. An additional sample of non-PROSPECT surgeons was included to ensure a representative sample and recruitment concluded following saturation of themes.

Data collection was performed at the individual surgeons’ hospital sites and the surgery observed during routine theatre schedules. The same investigator performed all interviews and observations. Firstly a video recorded observation of a native tissue anterior repair/s was undertaken. This was followed by a face-to-face semi-structured audio-recorded interview with the participating surgeon. This allowed immediate participant validation of the investigator findings and exploration of observations as well as discussions around the preset semi structured interview schedule (Table 4.1). This included predominantly open questions as well as a list of steps in the operative procedure to ensure all were discussed. Additional field notes were taken.
<table>
<thead>
<tr>
<th>VaST - Topic guide for semi structured interview with surgeon</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tell me about your training and whom you have worked with?</td>
</tr>
<tr>
<td>2. How many repairs do you perform each year?</td>
</tr>
<tr>
<td>3. Tell me about the surgical technique that you use to perform a native tissue anterior repair?</td>
</tr>
<tr>
<td>- Pre-operative care</td>
</tr>
<tr>
<td>Antibiotics</td>
</tr>
<tr>
<td>Examination/ POP Q</td>
</tr>
<tr>
<td>- Intraoperative</td>
</tr>
<tr>
<td>Incision (Site, depth, length, starting point)</td>
</tr>
<tr>
<td>Hydro dissection (Amount, type)</td>
</tr>
<tr>
<td>Dissection of skin from fascia/leave fascia on skin</td>
</tr>
<tr>
<td>Is your dissection blunt or sharp or both?</td>
</tr>
<tr>
<td>Plication of fascia/repair other facial defect/paravaginal repair/rectal plication</td>
</tr>
<tr>
<td>Excision of skin</td>
</tr>
<tr>
<td>Closure (Material- type and grade, method of suture)</td>
</tr>
<tr>
<td>- Post op care (pack, catheter, length of stay, follow up)</td>
</tr>
<tr>
<td>4. What factors have led you to use the surgical technique that you have described?</td>
</tr>
<tr>
<td>Surgeon factors (skills/training/experience)</td>
</tr>
<tr>
<td>Patient factors (Age/sexual activity)</td>
</tr>
<tr>
<td>Other (trends/location in UK/gender/evidence based medicine)</td>
</tr>
<tr>
<td>5. Does your technique ever vary over time or between patients and what influences this variation?</td>
</tr>
<tr>
<td>6. Do you consider whether there is a central or lateral defect when repairing the prolapse?</td>
</tr>
<tr>
<td>7. Do you know any other surgical techniques apart from your own and what are these?</td>
</tr>
<tr>
<td>8. Is any aspect of your surgical technique based on evidence-based medicine?</td>
</tr>
<tr>
<td>9. What aspects of your surgical technique do you think my influence the outcome of surgery?</td>
</tr>
</tbody>
</table>

Table 4.1: Topic guide for semi-structured interview with surgeon
All interviews were professionally transcribed in a verbatim manner and a subset sent to the surgeons to ensure accuracy. Thematic analysis (Braun and Clarke 2008) [83] using all data was performed and the 6 phases of analysis were followed. Stages 1 – 3 (familiarisation with data, generating initial codes and searching for themes) involved 2 of the investigators. A further investigator was also involved in stages 4 – 6 (reviewing themes, defining and naming themes and producing a report) and in independently reviewing a subset of videos. The computer software (NVIVO) was used in the analysis of data to code and develop themes.

The aims of the study were firstly, to assess in detail the current practices used to perform a native tissue anterior repair and to develop themes of surgical technique to allow a future subgroup analysis of the influence on outcome. Secondly, to establish an understanding of the terminology used to describe these techniques.

Ethical approval was gained from the Sunderland Ethics Committee (REC number: 13/NE/0158).
Results

Thirty surgeons were recruited to the VaST study; 2 surgeons were interviewed and 28 surgeons interviewed and filmed. These UK based consultant surgeons worked in one of 21 hospitals across England and Scotland. Table 4.2 summarises the background demographics of the surgeons and details of the procedures (isolated anterior repairs or concomitant procedures). The mean duration of the interviews was 38.33 minutes (range 21.10 - 60.19) and the surgical observations, 54.6 minutes (range 12.57 – 123.14).

The details of surgical techniques in this cohort of surgeons will be described using the following steps in the procedure including; Infiltration; Incision; Dissection; Fascial repair (method, number of layers, suture placement, method and material); Skin Trimming; And Skin Closure (method and material).
<table>
<thead>
<tr>
<th>Type of surgeon</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROSPECT</td>
<td>22</td>
</tr>
<tr>
<td>Non - PROSPECT</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender of surgeon</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>20</td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of consultant appointment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>General Gynaecologist</td>
<td>1</td>
</tr>
<tr>
<td>Gynaecologist with special interest</td>
<td>14</td>
</tr>
<tr>
<td>Accredited subspecialist in Urogynaecology</td>
<td>14</td>
</tr>
<tr>
<td>Urologist</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years since consultant appointment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean 12 years (Range 3 – 31)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedures Observed</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior Repair Alone</td>
<td>12</td>
</tr>
<tr>
<td>Anterior Repair + Sacrospinous Fixation</td>
<td>4</td>
</tr>
<tr>
<td>Anterior repair, Posterior repair + Sacrospinous Fixation</td>
<td>4</td>
</tr>
<tr>
<td>Anterior and Posterior Repair</td>
<td>5</td>
</tr>
<tr>
<td>Anterior repair, posterior repair and vaginal hysterectomy</td>
<td>6</td>
</tr>
<tr>
<td>Anterior repair, posterior repair and Manchester repair</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 4.2: Demographics of surgeons and details of concomitant surgery</th>
</tr>
</thead>
</table>

**How do surgeons perform native tissue anterior repairs?**

**Infiltration Type**

At the start of the procedure most surgeons used infiltration in the anterior wall (n = 25/28). A variety of different solutions and quantities of infiltration were used; these included saline, adrenaline and local anaesthetic. The combinations of infiltration used included: local anaesthetic alone; local anaesthetic and saline; local anaesthetic
and adrenaline; local anaesthetic, adrenaline and saline; and adrenaline and saline. None used saline alone. The types of local anaesthetic used included Marcaine, Bupivicaine, Xilocaine, Chirocaine and Lidocaine. The volume of infiltration varied from 3mls - 80 mls (Median 20 mls).

Surgeons were asked where they placed the infiltration. The placement of the infiltration by some surgeons was claimed to be within a specific plane and described as being placed superficially or deep, others were less certain (Table 4.3).

**Infiltration placement**

**Superficial infiltration**

**Surgeon I:** *It’s just underneath the vaginal skin. Obviously it is very difficult when you’re infiltrating to judge whether you are underneath the fascia or not but I try to be superficial so that I get a layer between the fascia and the skin. Not always that’s possible, especially if they had previous surgery.*

**Deep infiltration**

**Surgeon L:** *That’s an interesting one and we have been arguing about for years as to exactly where you are but I think that I am sub-fascial. So you have got skin, superficial fascia and deep fascia and I think that you are below that deep fascia.*

**Uncertain of site of infiltration**

**Surgeon AB:** *It “finds the plane itself”.*

**Surgeon Q:** *I’m infiltrating it so that... the skin goes white. What layer that is, I have no idea, but essentially what I’m trying to do, without any good evidence, is to make it go whiter. That is apparently the area that seems to work for me.*

Some surgeons used the presence or absence of blanching of the skin to inform them whether the infiltration was in the correct place. Some surgeons took the presence of blanching to signify a superficial placement of infiltration.
Surgeon E: *Oh, just under the skin, enough to do the bulge but it should not be blanching.*

Surgeon R: *I inject local and adrenaline in the operation site underneath the fascial layer so I don’t want to see skin blanching.*

In some cases the verbal description of the placement of infiltration appeared to match that which was observed during the operation. However it was the investigators view on observing the films that just over a third of surgeons placed the fluid in multiple planes rather than in one distinctive plane (Table 4.3).

<table>
<thead>
<tr>
<th>Placement of infiltration</th>
<th>Surgeons View</th>
<th>Investigators view</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Superficial</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Deep</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Mixed</td>
<td>0</td>
<td>11</td>
</tr>
</tbody>
</table>

**Table 4.3:** Views on infiltration placement

**Incision**

One surgeon used an elliptical incision of the anterior wall (Surgeon Z); all other surgeons used a midline incision. On occasions one surgeon who routinely does a midline incision performs a diamond or triangle incision (Surgeon N). The incision were made most commonly with a scalpel, occasionally scissors and one surgeon used a diathermy pen. Some surgeons changed their technique if a concomitant vaginal hysterectomy was performed using scissors rather than a scalpel. When scissors were used to make an incision, they were placed superficially under the vaginal epithelium and with an opening movement a plane was created between the vaginal epithelium and underlying muscularis and a vertical cut then made in the vaginal epithelium.
Surgeon M: Then tunnel under the anterior wall, superficial to the fascia if you can establish that plane.

The surgeons were asked where they started and ended their incisions on the anterior vaginal wall. When considering the caudal aspect of the vaginal incision all surgeons ensured that they avoided the area overlying the urethra. The terminology to describe this caudal landmark varied including: “bladder neck”; “2cm”, “3cm”, or “4 cm below the urethra”; “just below the urethra”; “urethro-vaginal sulcus”; “where rugosity is lost”; “at the extent of the bulge”; and “experience dictates”. When considering the cephalad extent of the incision most surgeons stated, the cervix or the vault. Other surgeons stated, 1cm from the cervix/vault, as far as they could reach or to the extent of the prolapse. One surgeon failed to articulate any anatomical landmark and stated, “It is related to experience” (Surgeon J).

Dissection

The depth of the incision through the anterior vaginal wall varied (Table 4.4). Some performed a superficial dissection aiming to leave the fascia on the bladder others a deep dissection aiming to leave the fascia on the vaginal epithelium. In Figure 4.1 there are photographic illustrations of the different depths of dissection. One surgeon (Surgeon F) described that he dissected the vaginal muscularis from both the vaginal epithelium and the bladder creating fascial flaps (Figure 4.1c).

Figure 4.1: Photographic Illustrations of Fascial Dissection a) Superficial dissection (left), b) deep dissection (middle) and c) fascial flap (right)
<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Dissection Depth</th>
<th>Fascial Repair Method</th>
<th>Fascial suture Placement</th>
<th>Number Fascial Layers</th>
<th>Fascial Suturing Method</th>
<th>Fascial Suture Material</th>
<th>Skin Trimming Method</th>
<th>Skin Suture Material</th>
<th>Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>Deep</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>P2</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>A</td>
<td>Superficial</td>
<td>Ultra lateral</td>
<td>Ultra lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>B</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>C</td>
<td>Deep</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>D</td>
<td>Deep</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>E</td>
<td>Superficial</td>
<td>Midline</td>
<td>Medial</td>
<td>2</td>
<td>Continuous</td>
<td>PDS + PGA</td>
<td>No</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>F</td>
<td>Neither, see repair method</td>
<td>Fascial Flaps</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>G</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>3</td>
<td>Continuous</td>
<td>PDS + PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>Surgeon</td>
<td>Dissection Depth</td>
<td>Fascial Repair Method</td>
<td>Fascial suture Placement</td>
<td>Number Fascial Layers</td>
<td>Fascial Suturing Method</td>
<td>Fascial Suture Material</td>
<td>Skin Trimming</td>
<td>Skin Suture Method</td>
<td>Skin Suture Material</td>
</tr>
<tr>
<td>---------</td>
<td>------------------</td>
<td>-----------------------</td>
<td>--------------------------</td>
<td>----------------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td>---------------</td>
<td>-------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>H</td>
<td>Deep</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CNL</td>
<td>Monocryl</td>
</tr>
<tr>
<td>I</td>
<td>Superficial</td>
<td>Skin</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>No</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>J</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Continuous</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>K</td>
<td>Superficial</td>
<td>Skin</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>L</td>
<td>Mid plane</td>
<td>Midline</td>
<td>Lateral</td>
<td>2</td>
<td>Continuous</td>
<td>PDS + PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>M</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>N</td>
<td>Mid plane</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>O</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Continuous</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>P</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>Q</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>2</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>R</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CNL</td>
<td>PGA</td>
</tr>
<tr>
<td>S</td>
<td>Superficial</td>
<td>Separate Fascial defect</td>
<td>Varies with defect</td>
<td>Varies with defect</td>
<td>Varies with defect</td>
<td>PDS</td>
<td>Yes</td>
<td>Bunny</td>
<td>PGA</td>
</tr>
<tr>
<td>Surgeon</td>
<td>Dissection Depth</td>
<td>Fascial Repair Method</td>
<td>Fascial Suture Placement</td>
<td>Number Fascial Layers</td>
<td>Fascial Suturing Method</td>
<td>Fascial Suture Material</td>
<td>Skin Trimming</td>
<td>Skin Suture Method</td>
<td>Skin Suture Material</td>
</tr>
<tr>
<td>---------</td>
<td>------------------</td>
<td>-----------------------</td>
<td>--------------------------</td>
<td>----------------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td>---------------</td>
<td>-------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>T</td>
<td>Superficial</td>
<td>Midline</td>
<td>Medial</td>
<td>2</td>
<td>Continuous</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>U</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>V</td>
<td>Superficial</td>
<td>Separate fascial defect</td>
<td>Varies with defect</td>
<td>Varies with defect</td>
<td>Varies with defect</td>
<td>PGA</td>
<td>No</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>W</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>X</td>
<td>Deep</td>
<td>Midline</td>
<td>Lateral</td>
<td>2</td>
<td>Continuous</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>Y</td>
<td>Superficial</td>
<td>Ultra laterl</td>
<td>Ultra laterl</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>Z</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>3</td>
<td>Continuous</td>
<td>PDS</td>
<td>Yes</td>
<td>Interrupted</td>
<td>PGA</td>
</tr>
<tr>
<td>AA</td>
<td>Deep</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PGA</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
<tr>
<td>AB</td>
<td>Superficial</td>
<td>Midline</td>
<td>Lateral</td>
<td>1</td>
<td>Interrupted</td>
<td>PDS</td>
<td>Yes</td>
<td>CL</td>
<td>PGA</td>
</tr>
</tbody>
</table>

Table 4.4: Summary of themes of surgery and variations seen in each step of anterior repair procedure
Several surgeons described dissecting to the plane, “that seems right” but don’t specify what this plane is. When analysing the videos it is evident that the depth of dissection that is described to be deep or superficial by one surgeon may be different to that described by another surgeons. Surgeons describe the patients’ tissue quality to be a factor in determining the depth of their dissection. Some surgeons may be aiming to perform deep dissection but the quality of the patient tissue may mean the dissection becomes more superficial.

The extent of lateral dissection was discussed with the surgeons. There were some clear bony landmarks described – “to the pubic arch” (P1), “underneath the pubic rami” (P2, Surgeons E, F, O, S, AB) and ‘behind the symphysis pubis”. Others described the extent of their lateral dissection using muscular landmarks; “to the white line” / “arcus tendoneous fascia pelvis (ATFP)” (Surgeon A), “to the obturator internus (Surgeon J, Y) and “the pelvic side wall” (Surgeon AA). A proportion do not look for any landmarks and surgeons discussed the extent of dissection as either something that was difficult to articulate or that was related to intuition at the time of surgery.

Surgeon M:  *No I don’t look for any specific landmarks actually. I go as far as I think I need to go that perhaps sounds rather vague and unacceptably vague but that’s what I do.*

**Fascial repair methods**

The most common method of fascial repair was a “midline plication” (Table 4.4). Observation and video analysis showed in practice there were two approaches to this depending on the depth of dissection. If a superficial dissection was performed then the sutures were placed in the fascia that was left on the bladder. If a deep dissection was performed then the plication sutures were placed in the fascia that had been left attached to the skin. The former was the most commonly observed of the two approaches.

When performing a midline plication between 1 and 3 layers of sutures were placed in the fascia (Table 4.4). There were also variations in the observed placement of the
plication sutures in relation to the midline seen most easily in the superficial plane (Figure 4.1a). The placement of fascial sutures ranged from midline (around 1 cm either side), to lateral placement up to the pubic arch and finally ultra lateral (Figure 4.2).

![Diagram showing midline, lateral, and ultra lateral placement of fascial sutures.]

**Figure 4.2:** Placement of fascial sutures

Two surgeons reported ultra lateral placement of sutures, firstly placement in the white line on one side and to lateral fascia on the other side and secondly placement into the obturator internus bilaterally. The observation saw placement beyond the pubic arch and in one case 2 needle holders were used to allow this ultra lateral placement of sutures. Other methods of fascial repair observed included separate fascial defect repair (n = 2), placement of sutures in the skin when the fascia was left on the bladder (n=2), placement of sutures in the bladder wall when fascia was left in the skin (n=2) and bringing together 2 flaps of fascia which had been dissected from the skin and bladder (Table 4.4).
When sutures were placed in the fascia that had been left attached to the bladder there were a variety of suture methods used to perform the plication (Figure 4.3). The suture method was either interrupted or continuous. Interrupted sutures included box, mattress sutures or running plication stitch (Figure 4.3). Continuous sutures included purse string sutures that were placed at the lateral parameter of the bulge (Figure 4.3) or a running suture that either came down the length of the bulge in the midline or laterally taking bites of the fascia either vertically or horizontally or both. The suture material used for facial plication included polyglycolic acid suture (PGA), polydioxanone suture (PDS) or a combination of both in cases where 2 or more fascial layers of repair were performed (Table 4.4).

**Skin Trimming**

Skin excision was performed, to some extent, by the majority (90%) of the surgeons in the study (Table 4.4). Those surgeons who do not routinely trim the vaginal skin discussed certain situations when they excise vaginal skin, illustrated by the following quotes,

Surgeon I:  *Not usually, unless not sexually active.*

Surgeon V:  *Not usually, unless it is hanging out of the vagina as it will retract.*

And one surgeon stated that sometimes,

Surgeon Z:  *Rather than trim the skin off we cross it over rather like a double breasted blazer.*

Most surgeons who trimmed the vaginal skin stated they were careful only to remove a small amount. Others stated that the amount of skin trimmed was dependent on the amount of redundant skin or the size of the bulge/prolapse. Lastly one surgeon stated;

Surgeon AA:  *Enough so skin lay without being under any tension*
Figure 4.3: Methods of suturing for fascial repair
Skin Closure

The skin was closed predominantly with PGA suture but of varying calibers (0, 1, 2.0) or equivalents (Polysorb 2.0 and Safil 1) (Table 4.4). One surgeon closed the skin with poliglecaprone 25 (Monocryl). The main method of closure was continuous locking (CL) (n=23/28) (Table 4.4) and the other methods of closure included continuous non locking (CNL) (n=2/28), Interrupted (n=1/28), Mattress sutures (n=1/28) and one surgeon described a specific suture which they called “the bunny suture” (n=1/28). It was described as repetitions of 3 continuous non locking sutures in the vaginal epithelium followed by a separate interrupted suture through the fascia and then back to the vaginal epithelium.

Surgeon S: It was described as the rabbit coming out of the hole and round the tree and going back into its hole again... One of my colleagues always called it the bunny stitch.

Variation of surgeon’s own techniques

Surgeons were asked if they varied their technique over time or between cases. A proportion of surgeons learnt a particular technique and continued to use this technique as taught.

Surgeon A: I think it might have marginally varied over time, but marginally if at all, but this is what I’ve been taught and the one I did today is what I’ve been taught as a trainee and I’ve continued using that for a long time.

Surgeon F: I’ve used the same technique probably pretty much since I started as a consultant, even before that time.

Other surgeons vary their techniques and some reasons given for this included patient factors (age and if sexually active or not), when performing concomitant procedures or if performing a repeat procedure for recurrent prolapse.
Surgeon T:  
Yes, the technique has changed with time. The changes have been related predominantly to the increasing need to take care of sexual dysfunction.

The reasons why surgeons operate in a given way will be discussed in a separate paper.

**Terminology**

**What is Fascia?**

Most surgeons used the term “fascia” to describe the tissue they were repairing. The concept of fascia was not uniform amongst surgeons. If surgeons used the term fascia they were asked to explain the term. Some described fascia as being part of the vaginal skin, others a separate entity and some had uncertainty about what the tissue was or what planes they were operating in.

Surgeon X:  
It’s part of the skin; there are 2 layers of the fascia.

Surgeon L:  
Well it’s a layer and you can separate it off the skin. I think that you need to say it is a separate layer from the skin it is not part of the skin.

Surgeon J:  
I can get into a plane quite comfortably and very easily where I think I’m leaving most of the “fascia” on the bladder, but would I describe it as a bladder tissue or a vaginal tissue, I don’t know. Can I sit on the fence on that one?

**Discrepancy video and interviews**

In this study most surgeons stated they performed either a “superficial” or “deep” dissection of the vagina wall. When analysing video clips, the superficial and deep planes that surgeons described were clearly seen and differentiated from each other (Figure 4.1). In the superficial plane (Figure 4.1 a) the surgeons stated their aim was
to dissect the “fascia” off the skin and leave it on the bladder and the surgeons dissecting deep were aiming to dissect beneath the vaginal muscularis (Figure 4.1b).

Surgeon L and Surgeons F reported performing a “deep dissection”. The investigators categorised Surgeon L dissection as mid plane, the dissection did not reach the infiltration above the bladder and some of the vaginal muscularis remained on the bladder. The investigators categorised Surgeon F technique as dissection of fascial flaps, both deep dissection removing the vaginal muscularis from the bladder and from the vaginal epithelium was seen.
Discussion

Main Findings

This study illustrates that despite the era of evidence based medicine variation between surgeons in the surgical techniques used when performing anterior repairs for POP continues to exist in clinical practice today. Qualitative methods (video observation and interviews) have allowed categorisation of the entire procedure. The degree of variation seen was greater than had previously been described in the literature. This is the first study of variation in surgical technique for which outcome data is available for each technique in the POP repair procedure.

When performing anterior repair surgeons did not appear to follow a single method as described in the literature [2, 20, 53] but instead the techniques used were mixture of multiple methods (Table 4.4). The categorisation of surgery and development of overarching themes of technique was therefore not possible. The themes developed reflect this and represent the variations seen in the steps of the procedure rather than reflecting the procedure as a whole (Table 4.4). The themes of surgery include, Depth of dissection; Method of fascial repair; Placement of fascial suture; Number of fascial layers; Fascial Suture Material; Fascial suture Method; Skin Trimming; Skin Suture Material; Skin Suture Method; And Packing.

In a number of cases, there was a difference between the investigators view of the techniques observed in real time and on video and the techniques described by the surgeons during interview. The lack of agreed terminology to describe these surgical technique and the anatomical landmarks is likely to be a contributing factor. In this group of UK surgeons the term fascia was commonly used but on further questioning it was poorly defined. In addition there are aspects of technique that surgeons had more difficulty in describing because they are more subjective aspect of the procedure e.g. the extent of lateral dissection. Previous questionnaires studies will not have been able to capture these tacit issues.
Strengths and Limitations

A key strength of this paper is that the qualitative methods allowed a greater understanding of the variation of surgical technique used in an anterior repair procedure. A good sample size was gained (30), at participant 27 saturation was reached and a further 3 surgeons were recruited to ensure this was the case. The demographic spread of the surgeons was probably representative of practice in the UK (table 4.2). Video observations have given a perspective that is not possible to be gained from questionnaire or interviews alone. It is likely that this has been helpful in mitigating the difficulties of surgical description and understanding the subjective aspects of technique. The sequence of observation of the surgery followed by interview of the surgeon allowed immediate validation of findings with the surgeons and generated areas for discussion. Videoing surgery has proved feasible and may be beneficial in a number of settings for example training and in illustrating different techniques.

It has not been possible to create overarching themes of surgery that define the procedure as a whole. This was due to the multiple combinations of the variable steps seen in each surgeon’s method of repair (Table 4.4). In order to observe surgeons operating in their own surroundings the investigator needed to travel across the whole of the UK. This meant that it was only possible to attend each site on one occasion and hence surgery was only observed at one time point. This limited the ability to observe variation of technique within the individual surgeon’s practice however this was discussed in the subsequent interviews with the surgeons. This form of triangulation of methods should have reduced the impact of this limitation.

Interpretation

This study has developed themes of surgical technique for native tissue anterior repair. The categorisation of this procedure was not straightforward due to variations existing in all steps of the procedure, inability of surgeons to articulate aspects of their surgical technique and lack of agreement on terminology.
Within the literature there are descriptions of different techniques, which are categorised under the umbrella term of “anterior repair” [2, 20, 53–55, 59–61, 103, 104]. As with previous questionnaire studies this study identified that most surgeons dissect in a superficial plane and this was frequently combined with a midline fascial repair. This technique was first described by Kelly in 1913 for the treatment of stress urine incontinence [53].

In the methodology section of randomised control trials it is often reported that a midline incision was performed, followed by superficial dissection and midline plication. We know from our study that in clinical practice each of these steps may have considerable variation. Surgeons will probably continue to evolve their technique making small adjustments that ultimately lead to one surgeon’s midline fascial repair not equating to another’s. This highlights the importance of studying surgery in pragmatic trials across many centers to ensure the external validity of the results.

The difficulty in the categorisation of surgical technique can be firstly explained by there being both objective and subjective aspects of technique, with variation being seen in both. Video analysis allows us to view aspects of subjective technique not possible from questionnaires or interviews alone. It is more difficult to categorise subjective techniques compared to objective ones. The difficulty of teaching subjective aspect of surgery did not appear to account for the variation in practice recorded in our study because there was an equal amount of variation in both the objective and subjective steps of the procedure.

The terminology used by most surgeons when describing the tissue they repair during an anterior repair was “fascia”. This term was also used to describe the placement of infiltration, depth of dissection and placement of the sutures. Few surgeons could articulate what fascia was. There is contention within the literature as to the existence of “fascia” [14]. A group of investigators have performed gross and histological examinations of full thickness cadaveric vaginal tissue. They identified 3 layers to this tissue including, mucosa (non keratinised squamous epithelium overlying loose connective tissue), muscularis (smooth muscle, collagen and elastin) and adventitia [13] A limitation to this study was that histological examinations were not performed.
on this excised vaginal tissue. This would have given us more evidence as to the layers of the vagina in which surgeons were operating. However, the use of video records enabled the investigators to review the operations and confirm the steps in a standard manner.

When describing surgery, the use of histological terms could improve the descriptions and understanding of the techniques that surgeons use. From the analysed data, it is our interpretation that when performing a “deep dissection” the plane that surgeons are developing is below the adventitia and above the bladder. This group of surgeons used infiltration to identify this plane. In the video footage this plane appears less vascular and required minimal force with mainly blunt dissection to develop. This “deep dissection” technique has been described in the literature previously and it is the level at which mesh/grafts are placed [105]. Surgeons involved in the insertion of mesh/grafts as part of the PROSPECT trial, were the only surgeons performing this level of dissection for native tissue repairs and it is likely that this technique has been extrapolated from the dissection used for insertion of graft/mesh.

The themes of surgical technique generated from this study will be used to assess the influence of surgical technique on the outcome of surgery (Paper 4). As well as having an understanding how the operation varies we also need to consider why surgical technique varies and this will be the subject of further research (Paper 3).

**Conclusion**

This study detailed, from video evidence and in depth interviews, how surgeons performed anterior repairs. The use of qualitative methods used enabled greater detail of the degree of variation to be captured and compared to previous questionnaire based studies. However, the extensive number of variations and subjective nature of some aspects of the surgery made categorisation challenging. Terminology to describe surgery needs to be standardised and using histological terms for the anatomy of the vagina may improve clarity about techniques used.
CHAPTER 5: PAPER 3

Variation in Surgical Technique (VaST): Reasoning behind practice:
An observational study of surgery
Chapter 5
Paper 3

Variation in Surgical Technique (VaST)
Reasoning behind practice: An observational study of surgery

Title page:
Dr E Fairclough 1, 2, Dr F Reid 1, 2, Dr J Myers 1, 2, Professor ARB Smith 1, 2 and Dr J Segar 3
1. St Mary's Hospital, Central Manchester Foundation Trust, Oxford Road, Manchester, M13 9WL
2. Maternal & Fetal Health Research Centre, Manchester Academic Health Centre, University of Manchester. M13 9WL
3. University of Manchester, Institute of Population Health, Oxford Road, Manchester, M139PL.

Financial disclaimer/ conflict of interest: None

Participation in manuscript:
E Fairclough: Development of protocol, Data collection/ analysis, manuscript writing
F Reid: Development of protocol, Data analysis, Manuscript editing
J Myers: Manuscript editing
ARB Smith: Manuscript editing
J Segar: Data analysis, manuscript writing and editing

Corresponding author:
Dr E Fairclough: St Mary's Hospital, CMFT, Oxford Road, Manchester. M13 9WL
Tel: 0161 2766910 Fax: 0161 276 6085 Email: Emily.Fairclough@cmft.nhs.uk

Key Words: Practice, Surgical Technique, Contingencies, Evidence based medicine, Qualitative research

Brief Summary: An observational study exploring the factors that influence surgeons' practices.
Abstract

Social theory has been used to explain human action in relation to health and wellbeing. Modern theorists have explained the importance of placing health outcomes into a social context and considering the practicalities of everyday life. In particular, the need to consider practice as a performance with a trajectory and the materialities associated with practice. Previous work has identified that contingencies (surgeon, patient and external) and chance factors were influential in causing surgical practice variation.

This paper explores surgeons' perceptions of why surgical practice varies in a well-established urogynaecological procedure. This observational study was based in the operating theatre and used the findings from video recorded observations, audio recorded interviews and fieldnotes to develop themes that explore this issue. The themes identified include; the surgical journey; rationalising practice; contextual factors; and concepts of success. Despite surgeon's apparent willingness to incorporate evidence into practice the wide range of factors identified that influence practice including the materialities (non-human factors) within healthcare, could present challenges in the standardisation of surgery.

The theories of practice offer insight into why surgical practice is variable and lower quality evidence exists, and could offer ways of targeting change if certain surgical techniques are found to be more effective.
Introduction

Over time social theory has been used to explain human action in relation to health and wellbeing. The ideas of traditional theorists focused on the behaviours and choices of individuals. Since, using the concepts of Giddens [106] and Bourdieu [107], theorists have moved beyond this, placing health outcomes into a social context and giving consideration to the practicalities of everyday life [108–112]. Maller et al [113] suggest that the likelihood of improvement of health through social change to be greater when the focus is on practices, rather than the individuals who practice [113].

Despite this theoretical change in focus of studying social practice as an entity the definitions of “practice” vary. A commonly cited definition of practice is;

*The routinised behaviour that involves interconnected elements of bodily and mental activities, objects or materials and shared competences, knowledge and skills* [109].

A more recent definition of practice includes;

*How and why to do things (cultural conventions, expectations and socially shared meanings), materials (objects, tools and infrastructures), and competences both tacit and explicit (knowledge and embodied skills)* [110].

What these definitions show is the complexity of practices and the multiple factors that influence such processes. Maller et al [113] discuss two important issues when considering the theories relating to practices. Firstly, the differentiation of practice as an entity and practice as a performance and secondly the need to consider the materiality i.e. the non human factors involved in practice. They suggest consideration of these issues when considering practice change.

The need to distinguish between practice entity and performance is important when researchers are considering practice change. In contrast to entity, through repeated
performance practice, practice can either persist and evolve or fade away and disappear [113]. Theorists have explained that practices have a course that develops through minor modifications of past performances and a changing combination of elements [109] and this is illustrated by following quote;

_The concept of practice inherently combines a capacity to account for both reproduction and innovation. At any given point in time a practice has a set of established understandings, procedures and objectives…. However, performances in the same practice are not always the same_ [109].

In addition concept that practices often coexist and influence each other should be considered [113].

Secondly, Maller et al [113] suggest the need to target all elements of practice to evoke a practice change including materials, meanings and competencies. There have been a number of studies that have looked at the importance of considering these non human factors or materialities of practice [114]. Theorists explain that through consideration of the materialities that exist this changes the focus of humans being central to practice [110].

**Evidence based medicine / practice**

Evidence based medicine (EBM) has sought to reduce clinical practice variations. However the procedure of prolapse repair, like other well established surgeries was developed before the concept of EBM began. In this next section EBM and evidence based practice (EBP) will be defined, what constitutes good evidence will be outlined and the reasons why surgery is more difficult to incorporate into high quality trials will be examined. Qualitative research has previously been used effectively to identify sources of surgical practice variations. We will review how the contingencies of practice led to practice variation in stress urinary incontinence surgery [73]. This work was used as a reference during this assessment of the practice variation prolapse surgery in this study.
Definitions

Evidence based medicine (EBM) is a concept that is important in medical practice today and is defined as;

…the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients [115].

Evidence based practice (EBP) means;

…Integrating individual clinical expertise with the best available clinical evidence from systematic research [115].

Archie Cochrane identified a gap between the research evidence produced and its implementation in clinical practice. At that time, clinicians based their clinical decisions on small trials and personal experience and as a result management and outcomes were variable. A study comparing operations in the UK and USA identifies that, “the indications for surgery are sufficiently imprecise to allow for a 100% variation in rate of operations”.

Cochrane wanted treatment decisions to be based on a systematic review of clinical evidence. The development of the RCT was key for implementing this ambition [115]. Two physicians Guyatt and Sackett were instrumental in the adoption of the concept of EBM in the early 1990s [116].

Today patient care has benefited from the implementation of EBM into practice. Practice is now predominantly lead by protocols and guidelines, EBM is part of formal education and systematic reviews are available to summarise evidence and provide clinicians easy access to the best available evidence [3, 6]. Although there have been advances to ensure practice is evidence based our field of study highlights
that healthcare practices are still based on small studies and anecdotal evidence. The surgical management of prolapse is based on low and medium level evidence [3, 6]. Reducing practice variation was central to the mission of EBM. Practice variation is a continuing issue within surgical specialties. Variation is seen both in the choice of operation being performed and the surgical techniques that are used. As a result of this variation this presents challenges for the incorporation of surgical procedures into randomised controlled trials (RCT). This is especially difficult when surgical practices are already established and “standard practice”. Firstly we will outline what is thought to constitute good evidence and then discuss some of the challenges surrounding the assessment of surgery within RCT.

**What constitutes good evidence?**

Hierarchies of evidence were developed to aid clinicians appraisal of the available literature and to guide judgments with regards to the best evidence on which to base practice. The pictorial illustration of this is in the form of a pyramid (Figure 1) [117]. The systematic review of a group of RCT with or without meta-analysis and RCT are placed at the top of this hierarchy and considered to be gold standard evidence. Whereas the poorest available evidence is placed at the bottom of the pyramid and this includes small case reports/series and expert opinion.

**Figure 5.1:** Hierarchy of evidence [117]
A RCT or a collection of RCT is widely considered as the best way of showing that a treatment causes the outcome affect. RCTs ensure internal validity by methods to minimise bias (randomisation, concealment allocation, blinding, intention to treat and complete follow up) and reduce random error (sample size calculation). There have been comparisons made between RCTs and large well performed observational trials. Two papers published in the New England Journal of Medicine [118, 119] compared observational trials with RCT and meta-analysis of RCT with meta-analysis of cohort and cases studies and found the outcomes to be similar. This was counter argued by [120] who stated that the RCT is still the gold standard but they emphasise the importance of considering the methodology of such trials. He highlighted the importance of considering the quality of RCT methodology rather than assuming it and explained that RCT are less powerful when they are small or have poor follow up. There are situations and areas of medicine that do not lend them self as well to the RCT methodological approach. Surgery is an area of medicine where there are challenges associated with the incorporation into RCT and these issues will now be explored.

The difficulties of performing surgical RCT studies

Surgeons have been criticised for not adopting evidence based medicine in the same manner as physicians. To date most surgical research has been retrospective case series and included small patient numbers [121]. In comparison to internal medicine, general surgical treatments are half as likely to be based on RCT [122] and a systematic review of treatment questions for surgical trials performed by Solomon et al [123]showed that only 40% of treatment questions could be answered by RCT. Surgical procedures are often performed in clinical practice without rigorous assessment and unlike medicines there was previously no requirement by the FDA to assess procedures before being used in the public domain [124].

There are issues associated with surgery that make these procedures more difficult to incorporate into RCT. Mc Culloch et al [125] discuss the problems faced when performing surgical RCT and offers possible solutions. These problems could help to explain why the “standard” prolapse repair has not been standardised and offer an
explanation for why the majority of surgery is based on smaller, poorer quality studies. This paper divides these issues into 2 categories including historical and technical and the following two paragraphs will highlight these points.

Historically operations like the POP repair developed before the introduction of EBM and RCTs. Once established, it becomes difficult and often unethical to compare a surgical treatment against placebo. Mc Cullough [125] suggests the need to review the literature to identify old techniques where new trials maybe beneficial. A further issue is that of surgeon and patient equipoise where either a surgeon perceives one procedure is better than another or the patient identifies a particular treatment as best for them. Lastly there is limited funding for surgical trials which could explain why in the past studies have been low level evidence.

There are several technical problems unique to surgery that poses problems in RCT including the learning curve of the operation, variable surgical definitions, development versus research and blinding [125]. During the learning curve poorer outcomes and complications are more likely. This needs to be recognised and evaluation using appropriate statistical techniques is suggested. Mc Cullough [125] states that variations in operations are common and so precise definitions are important. In addition they highlight that surgery typically progresses through small modifications. The investigators suggest clinical audit and continuous performance evaluation to help assess surgical practices.

In surgical trials non-standardised surgical techniques pose an issue when trying to perform RCT. In circumstances like this it may be appropriate to adopt a pragmatic approach to RCT. In contrast to explanatory trials (traditional approach to RCT) where the benefit of a treatment is assessed under controlled conditions with a homogeneous population, the treatment is standardised and a comparison is made with placebo, pragmatic trials make an assessment of the procedure in a clinical setting with a heterogeneous population and the procedure is not standardised. The benefit of this approach is a greater external validity i.e. the results are more generalisable to clinical practice. However to allow for this greater variation in practice and population, the sample size needs to be greater and the follow up longer.
From the above we see that there are issues to be considered when performing RCT that include surgical procedures. The RCT may not be the most appropriate method when evaluating certain aspects of surgical technique. Questions that seek to probe how surgery is performed, what techniques are used and why particular surgical techniques are employed may require alternative methodological approaches. Qualitative research can be used to explore these issues of how, what and why and as such may be instrumental in understanding the variation in surgical practice that exists.

**Social enquiry into surgical technique variation**

Pope [73] gives an insightful account of the sources of practice variation that exist in urine stress incontinence procedures. This work has been used as a reference during this study's assessment of the surgical technique variations in prolapse surgery. This study included 34 surgeons both Gynaecologists and urologists, from England (n 29) and the USA (n 5). Qualitative methods including interviews, observations and informal conversations were used and data analysed with a partial sequential approach. The typology developed categorised the sources of variation seen in surgical practice into conditional and chance factors. The conditional factors were divided into 3 categories including case, surgeon and external factors. Pope refers to these conditional and chance factors as contingencies in surgical work. The presence of contingencies was assessed in the decision to operate, the choice of operation and during the operation itself.

Pope informs us that contingency was most visible during the operative event, which is of particular relevance to this studies assessment of surgical technique. In this study surgical technique varied to deal with the case contingency introduced by each patient. The example given was that the length of the incision varied depending on the tissue scarring and surgical preferences. Other patient factors included previous surgery, co morbidities, anatomy and tissue quality. Surgeon factors were found to be more complex but less discussed by surgeons. They included surgeons' preferences, past experiences and sensory responses. An example of this included a female surgeon being precluded from performing a textbook operation by the size of her
hands and this resulted in the modification of her technique. Lastly external factors identified included presence of surgical assistance (nurses, junior surgeons and anaesthetists) and the availability of equipment.

Following on from this Pope [74] uses the results of the above study to illustrate that surgeons use the variable nature of surgery to justify their inability to use evidence in practice. These findings draw on the notion that surgery is seen as an art or craft rather than a science. As a result of contingencies in everyday practice surgeons explained that the techniques observed would differ from those read in textbooks and journals. The fact that surgeons were faced with contingencies in practice meant that surgeons had to draw on practical skills developed through trial and error experience rather than what could be learnt through evidence based studies. These issues were used by some of the surgeons to defend the lack of EBM in their practice and instead “keep to what they knew” which meant practice based predominantly on personal experience.

**Study Context**

This research examines surgeons' perspectives of why there is variation in the practice of a commonly performed Gynaecological operation that repairs pelvic organ prolapse. The International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for pelvic floor dysfunction define pelvic organ prolapse as;

*The descent of one or more of the anterior (front) vaginal wall, posterior (back) vaginal wall, the uterus (cervix) or the apex of the vagina (top of vagina when patients already had a hysterectomy).* [126]

Questionnaire based studies [59–61] have documented the practice variation that exists between surgeons performing prolapse surgery. There is currently limited evidence to guide clinicians as to the “best surgical technique” or to inform whether
the variations that exist in practice influence the outcome of surgery. The process of surgery is complex and a decision was made to use qualitative research to help understand this process better.

This paper sets out to understand the perspectives of surgeons as to why there is variation in their practices despite EBM being a widely accepted concept and to establish if this variation is a circumstance of continued resistance to incorporate EBM or if there are other important factors that govern practice.
Study Methods

This research sought to understand the process of prolapse surgery and this paper explores the perspectives of surgeons and why they use particular surgical techniques in their clinical practice. A pragmatic approach to stance and methods was followed. Pragmatic qualitative research is defined as;

*An approach that draws upon the most sensible and practical methods available in order to answer a given research question... Research using this approach seeks to discover and understand a phenomenon, a process or perspectives of the people involved”* [127].

A pragmatic approach is more commonly described in professional settings, where it is used to inform practices such as healthcare [128]. A purposive sample was drawn from a cohort of surgeons who had recruited to a large surgical prolapse study, PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials)[50]. This aspect of enquiry was part of a larger mixed methods study and the sample was chosen to allow a future subgroup analysis of the influence of surgical technique on outcome. An additional sample of non-PROSPECT surgeons was included to ensure a representative sample and recruitment concluded following saturation of themes. The sample included both sexes and a range of training backgrounds and experience.

Prior to study commencement two formal pilot interviews were undertaken. The investigators produced a semi structure topic guide based on the findings from these preliminary interviews and their prior medical knowledge. The guide included predominantly open questions exploring why surgeons used particular techniques in their practice and what if any evidence informed the process.

The fieldwork was carried out by the first author who is a trainee surgeon specialising in the field of Urogynaecology. Data collection was performed at the individual surgeons’ hospital sites and the surgery observed during routine theatre schedules. The same investigator performed all interviews and observations. Firstly a video recorded observation of surgery was undertaken and was followed by a face-to-face
semi-structured audio-recorded interview with the participating surgeon. This allowed immediate participant validation of the investigator findings and exploration of observations as well as discussions around the preset semi-structured interview schedule. Additional field notes were taken. One site visit was made to each surgeon. Written consent was gained from both the surgeons and patients. Ethical approval was gained through proportionate review from the Sunderland Ethics Committee (REC number: 13/NE/0158).

All interviews were professionally transcribed in a verbatim manner and a subset sent to the surgeons to ensure accuracy. Thematic analysis (Braun and Clarke 2008) [83] using all data was performed and the 6 phases of analysis followed. Stages 1 – 3 (familiarisation with data, generating initial codes and searching for themes) involved 2 of the investigators. A further investigator was also involved in stages 4 – 6 (reviewing themes, defining and naming themes and producing a report). The computer software (NVIVO) was used in the analysis of data to code and develop themes.

From this work four themes were identified and these are used to explain the surgical practices of these surgeons. In addition, an understanding was gained of the evidence surgeons base their practice on and if there was any resistance to incorporating evidence into their practice. Some of these ideas raised add to those that have been outlined in previous literature. It is clear that there is limited evidence on which to base surgery and there are a considerable number of factors that influence surgical practice. Some of the findings contrast aspects of previous work where surgeons were found to resist evidence [74]. The findings will be discussed under the headings of the themes identified and include; “The surgical journey”; “Rationalising practice”; “Contingencies in practice including Contextual factors” and “Concepts of success”.

120
Study Findings

The Surgical Journey

The theme surgical journey describes reasons for the adoption of certain surgical techniques that are related to the career of a surgeon from their early surgical training to retirement and includes initial training and continuing education including both formal courses or conferences and the informal sharing of ideas between colleagues. The hands-on surgical training of surgeons was described as an important influencing factor in their surgical practice. Surgeons were asked at the beginning of the interview to discuss their training. All respondents worked with several different surgeons during their training spending between 6 months and several years with a trainer. A key reason given for the adoption of practices was early learning from mentors during medical training. The surgeons described specific people, eminent in the field of Urogynaecology with whom they worked and learnt their surgical techniques.

Surgeon A:  *That technique was learnt in (place name) with (surgeon’s name).*

For some one mentors practices were prominent in their adoption of surgical technique.

Surgeon I:  *No. My technique is purely picked up... If you go and see my mentor, (Consultants name), it’s exactly the same.*

Others learnt from a number of different surgeons. These descriptions inform us that some surgeons choose specific aspects technique from several mentors and their resulting technique was an amalgamation of what they perceived to be the “best”.

Surgeon C:  *It's just gradual modification of going through various consultants and coming up with your own way of doing it.*
Surgeon R:  *I thought I’d take what I felt was the best bits of some people and discard what I personally thought were the less good bits, but obviously that’s just a personal choice and wasn’t based on any objective evidence.*

The continued practice of surgeons after their training varied with some continuing to use their mentor’s practices;

Surgeon A  *The one I did today is what I’ve been taught as a trainee and I’ve continued using that for a long time.*

And others reported varying their technique over time based on a range of different factors (discussed below).

Firstly reasons given for keeping practice the same after securing a consultant position are discussed. A number of surgeons explained that their continuation of technique was because they became more solitary in their practices.

Surgeon K:  *It’s a long time since I’ve watched anybody else doing an operation.*

This later solitary working is highlighted by a number of surgeons expressing their uncertainty as to how colleagues at other hospitals operated.

Surgeon A:  *I mean, just out of interest, obviously since you’ve been around, what do you think other people are doing?*

Surgeon H:  *Can you spill the beans; does any one do anything similar to me?*

Other factors expressed were “historical reasons” i.e. what has always been done,

Surgeon Z and keeping to “what is known and works best” for them Surgeon K.

Surgeon K:  *Maybe it’s the slightly old-fashioned person in me coming out but I feel that what I’m doing works for me and for my patients.*
Factors stated as reasons for changing their technique over time included experience, dissatisfaction with the operation and trial and error.

Surgeon O: *We train in a particular way, and only the effect, either good or bad, that has on patients will have a significant effect. So we might have some experiences where we tried something that did work or didn’t work well… and then you don’t do that any more, so only the personal experience shapes what you do.*

Trends were also cited as an influencing factor and the continuation and discontinuation of these was dependent on their perceived success in practice.

Surgeon AA: *In the... mid ’90s I did go to the States... (Surgeon name) embraced the fascia defect theory… but I didn’t find I could reproduce the results that they were producing... there was some literature around where people were finding they couldn’t get great results too. So I became less convinced that that was the answer.*

Interestingly this trend described by surgeons AA was taught to their trainee surgeon F and this surgeon continues to use this technique learnt from their mentor. Surgeon F finds this technique to be successful in their patients.

A recent trend in practice is the use of grafts/mesh in prolapse surgery with the aim to reduce recurrence. Some surgeons describe continuation of the techniques used for mesh/graft insertion as part of their routine surgical technique. Simplicity and reduction in bleeding were given reasons.

Surgeon AA: *I think the real influence was the introduction of Prolift (mesh) type devices where you’re putting a mesh in at a deeper level… It seemed simpler and I didn’t see why you should get an inferior result.*

Continuing education in the form of conferences and workshops was identified as a factor in change of surgical practice. However Surgeons A explained that the most
influential courses were practical where a similar hands on approach of teaching, like that experienced in early training, allowed certain techniques to be learnt.

Surgeon A: …if I go to conferences and workshops… people do various things, but that’s not done massive changes to my technique, it’s not close observation and it’s not something that they teach or tell you what to do… there was a big workshop that influenced the way I did it… that’s where I learnt the technique of repositioning the rectal vagina fascia back to the cervical ring.

Some surgeons informed me that they learnt certain surgical techniques from trainees who were still exposed to various techniques of other consultants. Other surgeons spent time with their peers operating in their own hospitals (“buddy list”) or by visiting other hospitals in this country or abroad. Surgeon U changed the type and placement of infiltration after spending time operating with another surgeon.

Surgeon U: … I think I changed when (surgeons name) came down, to the one and 200,000 (saline and adrenaline), really distending things. And I like that because I think it does make dissection actually slightly easier.

The key idea behind EBM (as discussed above) is to reduce variation in practice. Interestingly a number of surgeons express that modification in practice was a positive thing and there were instances where this was required.

Surgeon B: I think it's good to be able to modify your technique if you need to. In fact one surgeon expressed a concern for future trainees, in view of training becoming more fixed in one area, they were concerned they would have less exposure to different techniques.

Surgeon R: I was getting trained under consultants that had come from all round Britain so there were a variety of different techniques to be seen, but now the trainees come here and virtually all the consultants were trained here.
Rationalising Practice

Surgeons were asked why they performed certain aspects of surgical technique and their responses gave justification for this. A small part of this included research evidence. Predominantly practice was described as being based on reasoned thinking and anecdotal evidence. Surgeons’ clearly sought and expressed reasoning behind the techniques they practiced and so the next theme was entitled rationalising practice.

From these findings and review of the literature, it is evident that evidence on which to base surgical practice is limited. Surgeons were asked about what evidence they base their practice on and a recurring response was:

Surgeon G:  No, not evidence I’ve read actually. I don't think there's enough evidence out there...

Some surgeons did make reference to specific small trials on which they based some of their practice; Infiltration type [96]; Suture type [129]; Pack usage [99]; Posterior repair skin closure technique [130]; Suture technique [100]. In addition some more general evidence was quoted;

Surgeon Y:  That was actually influenced by the article in TOG…. Yes. That was a really good article. That has changed my practice. I think I’m a bit better since I read that article.

Surgeon R:  Well, there’s evidence that taking catheters out at midnight results in better voiding function.

In contrast to the surgeons studied during Popes work where there was resistance to EBM, surgeons within this study group appeared receptive to incorporating EBM.

Surgeon I:  I’m a very open-minded surgeon so I would love to know what’s best to offer my patients, because I still am not happy. I’m not satisfied most of the time.
Surgeon P: If there were evidence on which was the best suture to use, I would change.

Surgeon Z: I think that if it was technique difference that I could understand and there was robust data that I could understand then I might change.

Surgeon H went on to explain;

Surgeon H: In the absence of data people try and be as logical as they can. Indeed, surgeons gave explanations to be that rationalised the practices that they adopted;

Surgeon R: I just know that (suture type) loses 50 per cent of its tensile strength in three weeks or so, and there’s no way that the (tissue) healing has occurred… by that stage so it’s purely those principles. I’ve not got any objective evidence.

Surgeon AA: I use a locking suture because I think it’s probably a bit more haemostatic (helps stop bleeding)… And also perhaps because with just a running suture, it’s more likely to bunch up… the concern then is that you shorten the vagina.
**Contextual factors**

Previous work [73] has described how contingencies in practice (surgeon, case and external) affected surgeons’ choices during surgery. This links with theoretical ideology of placing health outcomes into a social context and considering the practicalities of everyday life. In terms of the external factors identified, this study has identified a greater range of influences with these factors not only being in the operating theatre but including the wider context of surgery. These factors included; the influence of management, funding, protocol, enhanced recovery and the type of organisation in which the surgeon is working.

**Surgeon factors**

There were aspects of technique that could be attributed to a surgeon's personality including; Striving for simplicity of approach; Wanting to be in control; And the importance of aesthetics.

Surgeon AA:  *It seemed simpler… I didn’t see why you should get an inferior result.*”

Surgeon J:  *But I mean, that’s normally to satisfy my need to be in control rather than anything for the patient.”*

Surgeon S:  *And I do that because I once saw someone do it and it just looked nice and I thought I’ll do it like that.*”

Further evidence surgeons wanting results to be aesthetically pleasing are seen in video footage where surgeon Q marks the excess skin with diathermy (an instrument that produces heat to seal bleeding vessels) to ensure that skin is taken of evenly.
**Patient factors**

Influential patient factors identified included age of patient, BMI, co-morbidities and desire for sexual function. These factors influenced both the technique and preoperative counseling.

Surgeon I:  *If the patient has a fairly big prolapse and she’s 72 and she’s not sexually active, I’ll do a tight repair.*

Some surgeons stated that they would not perform surgery if patients BMI was too high, they were smokers or the patient had co-morbidities that would affect the safety of surgery.

Surgeon R:  *Here we don’t operate on people for quality of life conditions with a BMI over 35.*

In addition, there are aspects of the patient’s anatomy that leads surgeons to change their practice. Surgeon M discussed how the lateral dissection for different patients this also highlights the idea of surgery being a craft rather than a science.

Surgeon M:  *I don’t look for any specific landmarks actually. I go as far as I think I need to go that perhaps sounds rather vague and unacceptably vague but that’s what I do.*

Surgeon V discusses and illustrates on video that the defect in the tissue are variable depending on the patient and explained that the technique used was dependent on the defect found.

**Contextual factors**

Factors that affect surgery with in the operating theatre that were discussed include availability of equipment and particular surgical assistants. Financial budgets in some
circumstances have led the use of different brands of sutures from cheaper sources and protocols are described to guide the choice of antibiotics.

There are a variety of different reasons for needing to reduce the length of stay for patients in hospitals. A number of these factors including enhanced recovery programs, lack of beds and management's choice to change of operating location, have lead to surgeons needing to change their practice.

Surgeon A:  
*So I used to use a pack for every single patient and then we started bringing this enhanced recovery in (day case surgery), I thought then, if I put it in (a pack), it delays them going home.*

Surgeon S explains how a management decision that led to operating in a day case unit resulted in the not using catheters post operatively and to allow patients to go home the same day. Anecdotal evidence from one patient’s positive experience of this change was used to justify this practice.

Surgeon S:  
*Just before the overnight stay had stopped a lady had declined to have a catheter with her anterior repair, so we said let’s give it a try, and another lady said, I’ll try too. Neither of them had any difficulties; they went home pretty quickly and we thought, well let’s not bother anymore.*

The frustration of management cancelling lists led to one surgeon to use local rather than general anaesthetic.

Surgeon AA:  
*One afternoon I had three posterior repairs... and they said, your list’s cancelled. I said, well I’m going to do it anyway, and we did them under local in theatre...*

Another change in practice influenced by management choices was the discontinuation of routine follow up in some centres. This has lead to the surgeons either not following patient’s up or telephone/nurse led follow up. In contrast other trust allow follow up between 6 weeks and 6 months.
Concept of success

Surgeons were asked if they thought that this operation (pelvic organ prolapse repair) was a good operation or not. Surgeons described performing certain technique or avoided other techniques based on their concept of how this affected the outcome.

There were mixed responses regarding surgeon’s perceptions of the success of this procedure. Some felt dissatisfied;

Surgeon F:  *It’s not a procedure that makes sense.*

Surgeon AA:  *I think anterior repair still is a problem... I mean a lot of women do find the feeling a lump does go afterwards. I think the anatomical results are less good in my experience and I think particularly that’s the case for the anterior wall. That’s how I’d sum it up.*

Others thought it was a good operation;

Surgeon I:  *It is a jolly good primary procedure.*

Surgeon U:  *Yes. And I’ll tell you for why, because I think the systematic results are not bad and the re-operation rates are low for a recurrent anterior compartment prolapse.*

Surgeons were asked if there were any aspects of surgical technique that they felt would either improve or worsen the success of surgery. There is very little literature on the outcomes of specific surgical techniques to guide practice. Surgeons discussed small studies attempting to answer these questions and described these having influenced their practice. In addition some surgeons explained that they used follow up patients and used output from a national audit database to guide practice and legitimize their continuation techniques.
Surgeon J:  I wanted to know what my results were like. My rather naïve initial hypothesis was would my results change as I’d been a consultant for longer, i.e. do you become a better surgeon? I’ve got it on a poster on my wall where I consult, and therefore I’ve got that as a reference point for patients and for me.

Predominantly surgeon’s views of success were based on experience and anecdotal evidence. Aspects of surgical technique that surgeons stated may affect the success of surgery included; use of infiltration, suture type, performing another procedure at the same time, degree of dissection and trimming skin.

Surgeon K:  I think it’s choosing the right operation for the right patient and not leaving that posterior wall. If it’s saggy and baggy and with a deficient perineum, they’ll be back.

At times surgeon’s perceptions of what would make a successful operation were contradictory and this is highlighted by the example of suture choice.

Surgeon C:  I think choice of suture, I think a long lasting suture, PDS, makes better sense although I am not aware that there is any evidence that its any better.

Surgeon V:  I think the use of vicryl, ironically, having gone back to it… We actually did a small study… and we found that it (PDS) was worse. So that’s why I went back to using vicryl.

Surgeon M:  I’d say it’s more likely to be that than using PDS as opposed to vicryl, I can’t see that that makes such a critical difference really.

Surgeon AA highlights this point by stating;

Surgeon AA:  Some people attach great importance to some things that other people consider trivial.
Other surgeons suggested that it was not the surgical technique that influenced the outcome but surgeons using the technique they knew or wider contextual factors.

Surgeon J:  *My hunch is it’s more to do with what works for the surgeon so it’s not necessarily one technique is hugely superior to another, it’s what works for that surgeon.*

Surgeon Q:  *I think that that’s probably too simplistic a question... because there are certainly other factors involved; Surgical factors, patient factors and then occupation, recreation, lifestyle can cause disease or play a part. So I don’t think you can nail it down to the operation.*

There appeared to be uncertainty amongst the surgeons about what was the “best technique” and the language used by surgeons demonstrated this.

Surgeon H:  *So many unknowns aren’t there... It could be all a load of hocus-pocus for all I know.*

The surgeons discussed what their “beliefs” were and expressed needing “courage” or “faith” with regards to this operation.

Surgeon H:  *But I have not quite had the courage to do it yet.*

Surgeon S:  *It’s why I say the finger and eye of faith.*

This language gives supports the notion that the choice of techniques is not evidence based.
Discussion

Surgical practices to repair prolapse have been shown to vary between surgeons in this and other studies. Surgeons expressed their concerns about the outcomes of this surgery and its recurrence rate. We decided to use social theory and qualitative research to explore this subject matter to help understand the surgical context and why this is the case.

This data highlights the variable nature of surgery and the multiple factors influencing current surgical techniques with research evidence being only a small part of this. These findings corroborate work by Griffiths (1998) [131] who stated that;

\[\text{\ldots the practices of physicians are influenced by many things besides research evidence.}\]

Through analysis of the fieldwork from this study four themes were identified that explained why surgical practice in this study group was variable and these themes include; The surgical journey; Rationalising practice; Contextual facts; and Concepts of success.

Apprenticeship style training is identified as a key influence in all of the surgeons’ practices. The hands on training was described as more influential than later teaching in conferences or courses. Some surgeons described their techniques remaining the same as when taught in training and explanations for keeping practice largely the same included historical, satisfaction with their own technique and isolated working. However some surgeons’ practices were shaped by their experiences, trial and error, anecdotal evidence, their personality and trends. An influential trend in a proportion of PROSPECT surgeons was the use of mesh/grafts and the extrapolation of these techniques in traditional surgery.

Like Pope [73] who found contingencies in practice (case, surgeon and external) as being sources of variation in USI surgery this was also the case in prolapse surgery.
Compared to the work by Pope [74] the external factors in this study encompassed the wider context of surgery with factors outside the operating theatre including the influence of management, funding, protocol, enhanced recovery and the type of organisation in which the surgeon was working.

Pope [74] described surgeons as being resistant to evidence based practice. A good example of this is highlighted in the following quote from this study.

\textit{One has to accept that no two surgeons do the same procedure exactly the same. We're not automatons and we're not robots… In reality an anterior repair is as individual as the individual that tackles it.}

This raises the concept that surgery is more of a craft than a science that could be incorporated into trial. Pope [74] suggested that surgeons offered these defenses by a way of protecting their profession and maintaining an air of superiority. The interviews and observations of this study demonstrate that current surgical practice to repair prolapse is largely not evidence based. In contrast to the surgeons in Popes study, the surgeons in this study openly voiced a willingness to incorporate evidence into their practice. However the prominent view was that there was a lack of evidence on which to base practice. Surgeons highlighted that only small studies on this subject matter existed.

There is literature exploring the difficulties of incorporating surgery into RCT studies [125]. The subjective nature of surgery described and the huge number of sources for variation provides some understanding of the difficulties in categorising technique and incorporating it into a RCT.

In response to a lack of evidence, this data shows that surgeons seek logic to justify their practices. Surgeons’ language to describe their practices highlights the uncertainties that exist and a sense of trying to offer reason for the techniques they use was seen. Surgeons’ beliefs on what techniques are best also differ and this creates another source for variation. The following quote summarises this point well,
Some people attach great importance to some things that other people consider trivial (Surgeon AA).

RCT is felt to be the gold standard for assessment of medical treatments. However this study has shown the benefit of the complimentary usage of qualitative methods, which has given a greater insight into this study area. Video analysis and interviews used in this study identified additional factors that are important to the understanding of why surgeons use specific techniques. The pragmatic approach taken allowed the process of surgery to be observed in real time and then subsequently in the interviews the perspectives of surgeons were explored. These findings will now inform healthcare practices.

The complexity and abundance of the data could have afforded more time for evaluation and the pragmatic research approach to methods used may be thought by some to be inferior to other more theory grounded approaches. The large sample has given insight into the practices of a wider population of surgeons. However spending more time with an individual surgeon could have seen a greater detail and understanding of one surgeon’s techniques. The lead researcher was a surgical trainee and so had a insider position and this was beneficial as it allowed easier access to the sites, surgeons being familiar with trainees observing their surgery and a prior medical knowledge to aid questioning during interview. Acknowledgement of the researchers position was made prior to the study and an attempt to view the subject from an outsider perspective made. Despite this, insight into things that would be routine to the researcher may have been overlooked.

The increased understanding of the causes of variation provides an area of practice that could be targeted if surgical technique was found to influence the outcome of surgery. The apprentice style training was stated as key factor in the practices of surgeons. This type of training has been shown to be important to help surgeons deal with contingencies in practice [132]. There appears to be a need for a greater openness in practices being performed and a willingness to share surgical experience especially after training has been completed.
We have found that video imaging has given a huge insight into the practices of surgeons and the use of media footage could be used to review our own techniques as well as sharing an understanding of techniques among colleagues. This would be useful early in training but also later in a consultants career where some have voiced that they become more isolated and practice tends to continue as previously taught despite changes in practices elsewhere. Small group teaching and hands on training were stated by surgeons to be more useful than large lectures when learning about surgical technique. Buddy lists were also stated by some as helpful. Consideration could be given to joint operating between surgeons from different centres to reduce the lone working later in surgeon’s careers.

This research was undertaken due to the observed variation in surgical techniques and practitioners lack of awareness as to whether this variation affects the outcome of surgery. Surgeons have stated in the literature that there is a need to standardise surgery [133]. However the nature of surgery and given the array of factors identified as sources practice variation, it raises the question of how possible this would be. From the previous paper in this series looking at how surgeons perform a native tissue anterior repair there does appear to be some objective aspects of technique that could afford further research. Whether surgical technique influences outcome will be the next important factor to consider.

**Conclusion**

Surgical techniques used in the surgical practice of repairing prolapse are predominantly based on low level evidence including small case series and expert opinion. Surgical procedures like this have been developed prior to the concept of EBM. Surgeons expressed their willingness to incorporate evidence into practice. However, this study shows there are a wide variety of factors influencing surgeons’ practice other than EBM that will make standardisation challenging. Qualitative research and social theories of practice have aided an increased understanding of this subject matter.
CHAPTER 6: PAPER 4

Variation in Surgical Technique (VaST): The influence of surgical technique on the outcome of native tissue anterior repair
Chapter 6

Paper 4

Variation in Surgical Technique (VaST)

The influence of surgical technique on the outcome of native tissue anterior repair

Authors: E Fairclough 1,2, J Myers1, J Segar 3, S Breeman4, ARB Smith1 and FM Reid 1,2

1. St Mary’s Hospital, Central Manchester Foundation Trust, Oxford Road, Manchester. M13 9WL
2. Maternal & Fetal Health Research Centre, Manchester Academic Health Centre, University of Manchester. M13 9WL
3. University of Manchester, Institute of Population Health, Oxford Road, Manchester, M13 9PL
4. Health Services Research Unit, University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD.

Financial disclaimer/conflict of interest None

Participation in manuscript

E Fairclough: Development of protocol, data collection, data analysis, manuscript writing.
J Segar: Manuscript editing.
J Myers: Development of protocol, data analysis, manuscript editing
ARB Smith: Concept, development of protocol, manuscript editing.
FM Reid: Concept, development of protocol manuscript editing.

Corresponding author

FM Reid
St Mary’s Hospital, Central Manchester Foundation Trust, Oxford Road, Manchester. M13 9WL
Tel: 0161 276 6910 Fax: 0161 276 6085 Email: Fiona.Reid@cmft.nhs.uk

Key Words
Pelvic Organ Prolapse, Native Tissue Repair, Surgical Technique, Linear regression, Surgical Outcome.
Abstract

Objective

To evaluate if variation in surgical technique observed in qualitative study of surgeons participating in the PROSPECT trial, affects the outcome of native tissue anterior pelvic organ prolapse repairs.

Design

Prospective mixed methods study

Setting

Multicentre study in 20 tertiary and secondary care hospitals

Population

A subgroup of consultant surgeons who recruited to both a large RCT of prolapse surgery and participated in the qualitative study, VaST. All patient participants who were recruited by these surgeons and underwent a native tissue anterior repair were included.

Method

A qualitative study used video taped observations of surgery and audio taped interviews with surgeons to evaluate the surgical techniques used to perform a native tissue anterior repair by a cohort of 30 consultant surgeons. Thematic analysis was performed using computer-based software, data was coded and themes of surgical technique identified.

From this study, 22 of the surgeons had also recruited to a large multicentre surgical randomised controlled trial, (PROSPECT). Surgeons in this study used the surgical
technique that they used most often in clinical practice. The influence of different aspects of the surgical technique (themes) on patient outcomes following native tissue anterior repair in women recruited to the PROSPECT trial was investigated.

**Results**

The subgroup of 20 surgeons who also recruited to PROSPECT performed 809 native tissue anterior repairs both alone and in combination with concomitant procedures. The study group had a median age of 51 years (IQR 53 - 68), BMI 27.05 (IQR 24 - 31) and parity 2 (IQR 2-3). The median change in POP SS score at 12 and 24 months was -8 (IQR -12 – -4); a clinically significant change in score is considered to be -2. At 12 months the number of patients who had an anatomical cure (Ba -3cm - (-1cm) above the hymen) was 192/276 (70%).

The themes that significantly influenced the symptomatic outcome measure POP SS at 12 and 24 months were the use of fascial flap repair compared to midline plication (p=0.011, Coef. -2.50, [95% CI -4.42 – 0.57] & p=0.001, Coef. -3.34, 95% [CI -5.33 - -1.34]) and continuous locking compared to continuous closure of the skin (p=0.01 Coef. -1.94 [95% CI -3.42 – (-0.45)] & p=0.015 Coef. -1.91 [95% CI -3.43 – -0.37]). In addition at 24 months a deep dissection method was shown to be significantly less effective than superficial dissection (p=0.012, Coef 1.47, 95% CI 0.32 – 2.60). The analysis of the anatomical measure (Ba at 12 months) identified separate fascial defect repair to be less effective than midline plication (p=0.06, OR 6.06 [CI 1.82 – 3.52]) and polydioxanone (PDS) to be weakly associated with more women having a cure, compared to polyglycolic acid (PGA) (p=0.04, OR 0.35 [95% CI 0.12-0.99]).

**Conclusion**

This exploratory study has identified certain aspects of technique that could influence the outcome of surgery. This study should be used to inform future RCT of surgical technique rather than cause a change in clinical practice.
Introduction

In 1909 White stated, “The only problem in plastic gynaecology left unresolved is the permanent cure of cystocele.” [2]. Despite this being over a hundred years ago, the recurrence of cystocele and its optimum management remain key concerns for surgeons today.

Failure rates for native tissue anterior repair are reported to vary from 37 to 97% [39, 134]. The literature shows that the outcome measure used objective versus subjective [23, 135, 136] and whether the assessment was made in a single compartment or not [137], influence the rate of recurrence. Several studies have reported risk factors associated with the development of prolapse and to its recurrence following surgery [138–140]. To date there has been a limited evaluation of the affect of surgical technique on the outcome of anterior repair [20, 96, 99, 100, 129].

Questionnaire studies have shown that surgical techniques used in native tissue prolapse surgery vary between different surgeons in this and other countries [59–61]. However, whether this variation in technique affects the outcome of surgery is under researched. There have been very few RCTs comparing these different techniques. Webber et al [20] found no difference in outcomes between two native tissue techniques, midline and ultra lateral plication of the fascia. Several questionnaires have shown that the surgical techniques used to repair POP vary between surgeons.

In a previous qualitative study [141], surgical technique for repair of anterior vaginal wall prolapse has been shown to vary between surgeons. These techniques could not be categorised as single operations as previously described in the literature. Instead each step of the procedure was categorised. The aim of this paper is to assess whether surgical technique theme affects the subjective and anatomical outcomes of native tissue surgery for anterior compartment prolapse.
Methodology

Ethical approval was gained from the Sunderland Ethics Committee (REC number: 13/NE/0158).

A qualitative study (VaST, Variation in Surgical Technique) [141] used video taped observations of surgery and audio taped interviews with surgeons to evaluate the surgical techniques used to perform native tissue anterior repairs by a cohort of 30 consultant surgeons. The study group was a purposive sample drawn from a cohort of surgeons who had recruited to a large surgical prolapse study, PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials) [50] and a sample of non-PROSPECT surgeons, to ensure a representative sample. Recruitment concluded following saturation of themes. Thematic analysis was performed [83] and table 6.1 outlines the themes of surgical technique identified.

During the PROSPECT study, surgeons were requested to use the surgical technique they used most often in clinical practice. This enabled a subgroup analysis using PROSPECT outcome data, assessing the influence of themes of surgical technique generated in the qualitative study on outcomes. The inclusion criteria were women having a native tissue anterior repair performed by this subgroup of surgeons (n = 22). Two surgeon’s data were excluded as <1 procedure were performed. In the theme “depth of dissection” 2 surgeon’s data (n=85) were excluded, as it could not be categorised as deep or superficial. From the theme “fascial suture placement” cases when sutures were placed in the skin rather than fascia these women’s data was excluded (n=37). When a separate fascial defect repair was performed as an additional procedure, these cases (n=50) were also removed from the themed analyses including “fascial suture placement”, “method and number of layers” as these varied depending on the defects identified.
<table>
<thead>
<tr>
<th>Category</th>
<th>Theme</th>
<th>Number of women</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth of fascial dissection</td>
<td>Superficial</td>
<td>482/724</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td>Deep</td>
<td>242/724</td>
<td>33</td>
</tr>
<tr>
<td>Method of fascial repair</td>
<td>Midline</td>
<td>611/809</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>Ultra lateral</td>
<td>61/809</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Separate fascial defect</td>
<td>50/809</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Skin i.e. no fascial repair</td>
<td>37/809</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Facial Flap Repair</td>
<td>50/809</td>
<td>6</td>
</tr>
<tr>
<td>Fascial suture placement</td>
<td>Midline Central</td>
<td>157/722</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Midline lateral</td>
<td>504/722</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>Ultra lateral</td>
<td>61/722</td>
<td>8</td>
</tr>
<tr>
<td>Number of fascial layers</td>
<td>1</td>
<td>588/759</td>
<td>77</td>
</tr>
<tr>
<td></td>
<td>≥2</td>
<td>171/759</td>
<td>23</td>
</tr>
<tr>
<td>Fascial suture material</td>
<td>PGA</td>
<td>411/809</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>PDS</td>
<td>347/809</td>
<td>43</td>
</tr>
<tr>
<td></td>
<td>PGA + PDS</td>
<td>51/809</td>
<td>6</td>
</tr>
<tr>
<td>Fascial suture method</td>
<td>Continuous</td>
<td>293/759</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>Continuous locking</td>
<td>78/759</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Interrupted</td>
<td>388/759</td>
<td>51</td>
</tr>
<tr>
<td>Skin Trimming</td>
<td>Yes</td>
<td>139/809</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>670/809</td>
<td>83</td>
</tr>
<tr>
<td>Skin Suture material</td>
<td>PGA</td>
<td>751/809</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>Monocryl</td>
<td>58/809</td>
<td>7</td>
</tr>
<tr>
<td>Skin Suture Method</td>
<td>Continuous</td>
<td>84/809</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Continuous locking</td>
<td>725/809</td>
<td>90</td>
</tr>
</tbody>
</table>

Table 6.1: Themes of surgical technique and the frequency/percentage of native tissue repairs in each theme.
Data was released from PROSPECT [50] following approval from the trial steering committee and agreement of a statistical analysis plan. The investigator performing the statistical analysis was blinded to the identity of the surgeons in each theme. The primary outcome measure used was the pelvic organ prolapse symptom score (POP SS) [142] which is a validated symptomatic global outcome measure. The details of the questions, responses and scoring for POPSS are seen in table 6.2. Both 12 and 24 month data was analysed and the distribution of scores was normalised by the removal of outliers with a score > 10 (n=3).

<table>
<thead>
<tr>
<th>POP SS Questions</th>
<th>POP SS responses</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1 A feeling of something coming down from or in your vagina?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>A2 An uncomfortable feeling or pain in your vagina, which is worse when standing?</td>
<td>Occasionally</td>
<td>1</td>
</tr>
<tr>
<td>A3 A heaviness or dragging feeling in your lower abdomen/tummy?</td>
<td>Sometimes</td>
<td>2</td>
</tr>
<tr>
<td>A4 A heaviness or dragging feeling in your lower back?</td>
<td>Most of the time</td>
<td>3</td>
</tr>
<tr>
<td>A5 A need to strain (push) to empty your bladder?</td>
<td>All of the time</td>
<td>4</td>
</tr>
<tr>
<td>A6 A feeling that your bladder has not emptied completely?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A7 A feeling that your bowel has not emptied completely?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 6.2: POP SS questions, responses and scoring. A score range of 0 – 28 with a clinically significant change in score being 2 [142].
The secondary anatomical outcome measure using was the POP Q measurement Ba, which is the most dependent part of the anterior wall. Only 12 month data was available for analysis. The post operative Ba measurement was dichotomised into cure (-3cm – (-1cm) above the hymen) and failure (0cm – 6cm beyond the hymen). In addition a quality of life measure was assessed. Women were asked, "Overall how much do your prolapse symptoms affect your everyday life?" The response was a scale from 0 – 10 (0 not at all to 10 a great deal). Change in quality of life score was calculated from the 12 and 24 months questionnaire data.

**Statistical analysis**

The data was checked for normality and transformed where necessary prior to analysis. For each outcome measure the influence of all covariates was assessed using linear or logistic regression models as appropriate. The covariates included were, age, parity, BMI, primary or secondary repair, inclusion in the RCT or cohort study, concomitant surgery (posterior repair and vault/incontinence procedure)).

Covariates with borderline or significant association with the dependent variable were included in the subsequent themed analysis for that outcome. The association between each of the themes and the primary and secondary outcomes was then investigated with adjustment for significant covariates. The influence of individual surgeon was assessed using mixed level regression; an intraclass coefficient of >10% was considered a significant effect of individual surgeon. A POP SS change of -2 or more was considered clinically significant. Significance was set at p≤0.01 to account for multiple testing.
Results

The 20 VaST surgeons who recruited women into the PROSPECT study, performed in total 809 native tissue anterior repairs. These procedures were performed alone and in combination with concomitant procedures including posterior repairs, vault and continence (n = 623). The demographics of these women are seen in table 6.3.

<table>
<thead>
<tr>
<th>Patient Demographics</th>
<th>Median</th>
<th>Range (p25 - p75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covariant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>51</td>
<td>53 - 68</td>
</tr>
<tr>
<td>BMI</td>
<td>27</td>
<td>24 - 31</td>
</tr>
<tr>
<td>Parity</td>
<td>2</td>
<td>2-3</td>
</tr>
</tbody>
</table>

Table 6.3: Demographics of women

Primary outcome

Overall at 12 and 24 months, the median change in POP SS score was -8 (IQ Range -12 – -4). A clinically significant change in score is demonstrated by a reduction of score by 2. This data demonstrates that a large proportion of the women were subjectively better following surgery.

At 12 months the confounding variables that were shown to have an influence on the primary outcome were concomitant posterior repair (p=0.146, Coef. – 0.79, [95% CI -1.85 - 0.27]) and incontinence procedure (p=0.085, Coef. 1.67, [95% CI -0.23 -3.50]). The impact of individual surgeon was negligible, ICC 0.02 [95% CI 0.006 - 0.09] and was therefore not included in the subsequent analysis.

At 12 months women who had fascial flap repair (n = 43) had a significantly better outcome compared to midline plication (n=477) (p=0.01, Coef. -2.49 [95% CI -4.42 - 0.57]) and when continuous locking method (n=579) of skin closure was performed these women had a significantly better outcome compared to continuous non locking skin closure (n=77) (p=0.01 Coef. -1.94 [95% CI -3.43 - -0.45]) (table 6.4).
<table>
<thead>
<tr>
<th>Category (comparative theme)</th>
<th>Theme</th>
<th>p value</th>
<th>CI (95%)</th>
<th>Coef.</th>
<th>p value</th>
<th>CI (95%)</th>
<th>Coef.</th>
<th>p value</th>
<th>CI (95%)</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth of Fascial Dissection (Superficial)</td>
<td>Deep</td>
<td>0.66</td>
<td>-1.36 - 0.86</td>
<td>-0.24</td>
<td>0.01</td>
<td>0.32 - 2.6</td>
<td>1.47</td>
<td>0.44</td>
<td>0.44</td>
<td></td>
</tr>
<tr>
<td>Fascial Repair Method (Midline)</td>
<td>Ultra lateral</td>
<td>0.55</td>
<td>0.55</td>
<td>-0.52</td>
<td>0.055</td>
<td>-3.48 - 0.03</td>
<td>-1.72</td>
<td>0.69</td>
<td>0.30</td>
<td>1.37</td>
</tr>
<tr>
<td>Separate fascial defect</td>
<td></td>
<td>0.70</td>
<td>0.70</td>
<td>0.36</td>
<td>0.068</td>
<td>-3.588 - 0.12</td>
<td>-1.73</td>
<td>0.006</td>
<td>1.82 - 35.2</td>
<td>6.06</td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td>0.25</td>
<td>0.25</td>
<td>1.36</td>
<td>0.170</td>
<td>-3.995 - 0.70</td>
<td>-1.64</td>
<td>Numbers too low</td>
<td>1.82</td>
<td>Number too low</td>
</tr>
<tr>
<td>Fascial Flap</td>
<td></td>
<td>0.01</td>
<td>-4.4 to -0.57</td>
<td>-2.5</td>
<td>0.001</td>
<td>-5.33 to 1.34</td>
<td>-3.34</td>
<td>0.95</td>
<td>0.18</td>
<td>1.02</td>
</tr>
<tr>
<td>Fascial suture placement (Midline central)</td>
<td>Midline lateral</td>
<td>0.96</td>
<td>1.3</td>
<td>-0.31</td>
<td>0.146</td>
<td>2.4</td>
<td>1.05</td>
<td>0.779</td>
<td>0.21</td>
<td>3.26</td>
</tr>
<tr>
<td></td>
<td>Ultra lateral</td>
<td>0.71</td>
<td>1.0</td>
<td>-0.38</td>
<td>0.685</td>
<td>1.7</td>
<td>-0.44</td>
<td>0.882</td>
<td>0.15</td>
<td>8.82</td>
</tr>
<tr>
<td>Number of fascial layers (1)</td>
<td>2+</td>
<td>0.37</td>
<td>1.7</td>
<td>0.54</td>
<td>0.822</td>
<td>1.3</td>
<td>0.14</td>
<td>0.253</td>
<td>0.16</td>
<td>1.6</td>
</tr>
<tr>
<td>Fascial suture material (PGA)</td>
<td>PDS</td>
<td>0.26</td>
<td>1.5</td>
<td>0.57</td>
<td>0.201</td>
<td>1.7</td>
<td>0.68</td>
<td>0.047</td>
<td>0.124</td>
<td>0.987</td>
</tr>
<tr>
<td></td>
<td>PDS + PGA</td>
<td>0.15</td>
<td>3.4</td>
<td>1.45</td>
<td>0.091</td>
<td>-0.297 - 4.0</td>
<td>1.86</td>
<td>0.141</td>
<td>0.12</td>
<td>0.98</td>
</tr>
<tr>
<td>Fascial suture method (Continuous non locking)</td>
<td>Continuous Locking</td>
<td>0.86</td>
<td>1.9</td>
<td>0.16</td>
<td>0.351</td>
<td>0.96</td>
<td>-0.87</td>
<td>0.400</td>
<td>0.34</td>
<td>14.1</td>
</tr>
<tr>
<td></td>
<td>Interrupted</td>
<td>0.08</td>
<td>-1.964 - 9.1</td>
<td>-0.93</td>
<td>0.106</td>
<td>0.19</td>
<td>-0.91</td>
<td>0.272</td>
<td>0.61</td>
<td>5.74</td>
</tr>
<tr>
<td>Skin Trimming (No)</td>
<td>Yes</td>
<td>0.87</td>
<td>1.4</td>
<td>0.11</td>
<td>0.056</td>
<td>-0.035 - 2.6</td>
<td>1.31</td>
<td>0.525</td>
<td>0.13</td>
<td>2.84</td>
</tr>
<tr>
<td>Skin Suture material (PGA)</td>
<td>Monocryl</td>
<td>0.14</td>
<td>3.1</td>
<td>1.35</td>
<td>0.053</td>
<td>-0.0204 - 3.7</td>
<td>1.86</td>
<td>0.716</td>
<td>0.14</td>
<td>1.24</td>
</tr>
<tr>
<td>Skin suture method (Continuous non locking)</td>
<td>Continuous Locking</td>
<td>0.01</td>
<td>-3.42 to -0.45</td>
<td>-1.94</td>
<td>0.015</td>
<td>-3.43 - 0.37</td>
<td>-1.91</td>
<td>0.767</td>
<td>0.13</td>
<td>4.43</td>
</tr>
<tr>
<td>Pack (No)</td>
<td>Yes</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.997</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 6.4:** Subjective and Objective outcomes * Bold outcomes = significant findings
The use of the fascial flap repair method was also associated with a clinically significant change in score (median change in score, -2); this did not change significantly following adjustment for surgeon (p=0.019; -2.66 [-4.89 -0.44], ICC 0.006 [0.0001-0.24]. The remaining themes were not found to have a significant an effect on subjective outcome at 12 months (table 6.4).

Figure 6.1 a) illustrates dissection of the vaginal muscularis from the vaginal epithelium and the underlying bladder creating “fascial flaps”. Sutures were placed in the vaginal muscularis and the fascia was brought together in the midline. For a full explanation of the different techniques performed in the qualitative study, see the earlier paper in this series [141].

![Figure 6.1: a) Dissection of fascial flaps b) Superficial dissection c) Deep dissection
Photographic illustrations of the methods of fascial dissection](image)

At 24 months, following removal of outlying scores (n=2), again the confounding factors were identified as concomitant posterior repair (p=0.088, Coef. - 0.98, 95% CI -2.09 - 0.14]) and incontinence procedure (p=0.07, Coef. 1.86, [95% CI -0.15 – 3.8). There was no effect of individual surgeon of subjective outcome, ICC 0.03 [95% CI 0.01 – 0.11].

At 24 months, fascial flap repair method (n=37) was found to have a better symptomatic outcomes compared to midline plication of the fascia (n=404) (p=0.001; Coef. -3.33 [95% CI-5.33- -1.34]) and continuous locking method of skin closure had
better outcome compared to continuous non-locking method (p=0.015; Coef. -1.90 [-3.44 - -0.38]). The later did not reach clinical or statistical significance following adjustment for surgeon (p = 0.05). When the technique of deep dissection, (below the vaginal muscularis) (figure 6.1 c) was compared to superficial dissection (between the vaginal epithelium and vaginal muscularis (figure 6.1b)), the outcomes were worse when deep dissection was performed (p=0.012; Coef. 1.47 [95% CI 0.32 – 2.60]). This affect was not changed following adjustment for surgeon. The effect did not quite reach clinical significance. All other themes did not have a significant affect on the symptomatic outcome at 24 months.

**Secondary outcome**

The most dependent part of the anterior compartment prolapse (Ba) was measured postoperatively at 12 months in women recruited into the RCT (n=276) and compared to the postoperative measurements. The number of patients having an anatomical failure (Ba measurement below the level of the hymen) was n = 83 (30%). The covariant variable found to significantly affect anatomical outcomes was concomitant posterior repair (p=0.038; OR 0.54 [95% CI 0.30 – 0.96]) and the ICC (effect of surgeon) was 16% [95% CI 0.050 – 0.42]. Both factors were included in the subsequent analysis.

Women who had a separate fascial defect repair had a significantly worse objective outcome compared to those who had midline plication (p=0.006; OR 6.06 [95% CI 1.82 – 35.26]). When polydioxanone suture (PDS) (n=93/156) was used to repair the vaginal muscularis this was associated with proportionally more women being cured compared to when polyglycolic acid (PGA) (n75/92) suture was used (p=0.04; OR0.35 [95% CI 0.12 – 0.99]) but significance was not reached (table 6.4). The remaining themes did not significantly influence objective outcome at 12 months.

**Quality of life measure**

Change in quality of life score was calculated at 12 and 24 months. Outliers (who had not completed both questionnaires) were removed and the effect of covariates and
surgical themes was assessed using regression analysis as above. None of age, parity, BMI, type of concomitant procedure or surgeon influenced the change in quality of life score and none of the surgical technique themes were associated with a change in score (data not shown).

**Complications**

The complications that were recorded were hematoma, wound infection, urine retention and urine infection. The numbers were small so it is not possible to comment on their effect on the outcome. The number of participants sustaining heamatoma and wound infection was considered as these could have directly affected by the surgical technique used.

There were 6% (n=49/809) of women who had a wound infection documented postoperatively. The covariates that identified as being weakly associated with this complication were BMI and being part of the cohort group (compared to the RCT). The number of women who had a wound infection in the RCT and cohort were 28/312 and 21/448, respectively. There was no effect of the surgeon (ICC <1%) on the rate of infection. No aspect of technique was seen to influence the wound infection rate.

Eight patients (1%) had a hematoma postoperatively. All eight women had had a primary procedure, the use of continuous locking skin suture method and PGA as the skin suture material. Considering these 8 patients, 4 (50%) had had a pack inserted following the operation and 4 (50%) did not.
Discussion

The main finding of this study was that there are themes of surgical technique that could influence the subjective outcomes (POP SS score) at 12 and 24 months and the objective outcomes (Ba measurement) at 12 months. It should be noted that this is an exploratory study and as such is not intended to lead to a change in practice but to highlight the need for further collaborative research of surgical technique and its role in the recurrence of cystocele.

The aspects of surgical technique that have been found to have an influence on the subjective outcome include, the depth of dissection, method of fascial repair and method of skin closure. At 12 and 24 months a better subjective outcome was seen when fascial flap compared to midline plication and continuous locking compared to continuous non locking method of skin closure were performed. At 24 months those who had a deep dissection performed had a worse subjective outcome compared to superficial dissection. The method of fascial repair was also found to affect the objective outcomes, with women who had a separate fascial defect repair having a worse outcome compared to midline plication at 12 months.

Strengths

It is known that surgical technique for performing native tissue POP repair varies between surgeons in the UK and other countries [59–61, 141]. However the affect this has on the outcome of surgery is under researched [20]. This study attempts to raise the issue of that surgical technique could influence the outcomes of this procedure. The majority of previous studies have made comparisons between the outcomes of native tissue POP repairs and those augmented with grafts/mesh [29, 103]. In the methodology of these papers, authors have reported that a “standard approach” [3, 29, 88, 134, 143] to native repair was taken, however a ‘standard’ method of performing this procedure does not exist and as such there is the potential for significant bias in the RCTs that have evaluated this procedure.
The themes used in this study were developed from qualitative work that explored in detail the surgical techniques used to repair native tissue anterior POP repairs by a cohort of surgeons [141]. Steps were taken to ensure that the quality of the current study was of a high standard [82, 83, 85, 86]. A representative group of surgeons was sampled, including a variety of different surgeons (gender, geographical location, experience, training), triangulation of methods (video recorded observations, audio recorded interviews and field notes) were used, there was immediate validation of the observed data through subsequent interviews with surgeons, recruitment completed just beyond saturation point and there was involvement of multiple investigators for the review and categorisation of data.

The purposive sampling strategy that was adopted in the preceding qualitative study [141] ensured that the majority of surgeons recruited, had also recruited a large number of participants to the multicentre surgical prolapse study, PROSPECT [50]. This enabled the outcome data from the PROEPSECT study to be paired with the themed analysis of surgical technique. A large number of native tissue anterior repair procedures were available to this study (n = 809) for this assessment.

Limitations

The first limitation of this study is that the surgical technique assigned to the surgeon was based on the observation of one or two procedures and subsequent interviews during a single site visit. However the surgeons were all participating in the PROSPECT study, a pragmatic RCT in which surgeons were requested to use the techniques they used most often throughout the study process and these techniques were documented in a questionnaire [101]. Although surgeons were asked to use the technique they performed most often, surgeons in this study have stated they need to vary their technique on occasions and this could have introduced systematic bias.

The outcome data used in this study, included women recruited to both the RCT and cohort aspects of the PROSPECT study. The data set available for analysis of the affect of surgical technique on the anatomical outcome measure (Ba measurement) was much smaller (n= 276) than the complete data set. A postoperative POP Q examination was only performed in the RCT part of the study at baseline and 12
months follow up. The POP SS and QOL measures were derived from a
questionnaire output at baseline, 6, 12 and 24 months time points (n=809).

It was not possible to categorise surgical technique, as a procedure in its entirety as
there was variation seen in each step of the procedure and different combinations of
these variations existed between the surgeons [141]. During the analysis, while an
assessment of the influence of one aspect of surgical technique on the outcome of
surgery was made, it was not possible to control for all the variations seen in other
steps of the procedure specifically. A broad assessment of the effect of the other steps
included in the procedure was investigated by assessing the influence of surgeon
within the regression models; for the most part the contribution of different surgeon
on the outcome measures was negligible, although the sample was not sufficiently
powered to detect a subtle effect. Whilst it was not possible to perform a formal
sample size for this exploratory study, the assessment of some of the surgical themes
will inevitably be underpowered (thereby potentially missing a significant effect on
outcome), the majority of themes were performed in at least 10% of the cases
investigated, although in some instances by only a small number of surgeons.

Interpretation

The recurrence rate of cystocele in this study, defined as the leading edge of the
anterior wall at or beyond the level of the hymen at 12 months, was 30 % (n =
84/276). This finding compares to the widely reported data presented by Olsen [11].
It should be remembered however that an anatomical recurrence doesn’t always
equate with the return of symptoms or warrant further surgery [22]. A UK
retrospective case review of 207 cases found a low reoperation rate (3.4%) for
recurrent cystocele [144]. In our study, the median change in the symptomatic score
measure was -8 (IQR -12 - -4); meaning more than 50% of women had a clinically
significant improvement in their symptoms (change in score equaling 2 or more). The
subjective failure rates of POP surgery are poorly reported [144] but are known to be
less than the objective failures [22, 23].

A recent systematic review [140] has made an assessment of the risk factors for
primary prolapse and for the recurrence of prolapse following surgery. Of the 5, 093
articles reviewed 15 met the selection criteria. Only factors that were significantly (p< 0.05) associated with POP in multivariate analysis of at least 2 studies were considered as risk factors. Parity, BMI, age and vaginal delivery were considered as risk factors for primary prolapse and pre operative stage for POP recurrence. In this study, the factors associated with having a significant affect on the symptomatic outcome of surgery were concomitant surgery (posterior repair and incontinence surgery). In the recently mentioned systematic review, the affect of concomitant surgery was only assessed in one trial that found that sacrospinous fixation was a significant factor associated with POP recurrence [140]. The apical support of the vagina at the same time as cystocele repair is known to be important factor in the prevention of recurrence [145].

In a sub analysis of the UK TVT RCT Hilton [146] identified that in the procedures compared there was a wide variation in the cure rates between the centres (TVT 0 – 90% and colposuspension 0 – 92%). Surgeon experience was identified as being a causal factor with larger recruiters achieving better success. Moen et al [147] suggest that surgeon performance is also a key contributor in the wide variation in success of native tissue POP repairs and they recommend the reporting of surgeon factors in all future RCT. The effect of surgeon was not seen to influence the subjective and quality of life outcomes in this study but an affect on the anatomical outcomes was seen and as such surgeon was included in this regression model. In a recent systematic review [140], surgeon experience was not found to be a significant risk factor in the recurrence of cystocele. Our data suggest that surgical technique is a causal factor in the recurrence of cystocele and this is independent of the influence of surgeon.

A small number of studies have compared the success of certain aspects of the anterior repair procedure. Firstly, in a RCT comparison of 3 methods of fascial repair technique (standard colporraphy, ultralateral colporraphy or standard colporraphy + polyglactin 910 mesh) similar anatomical cure rates [20] and symptom resolution [135] was seen for all techniques. In our study, 5 different methods of fascial repair were identified (midline plication, ultra lateral plication, separate fascial defect repair, fascial flaps repair and no fascial repair i.e. skin opposition) and compared. Our study identified the fascial flaps repair was significantly better and separate fascial defect
repair significantly worse when compared with midline plication. Midline plication was the method most performed by the surgeons in our study group and is the most reported in the literature [3, 54, 55].

There have been no reported affects of the depth of dissection on the outcome of surgery. A “deep dissection technique”, where the incision goes beneath the vaginal muscularis, is likely to be extrapolated from techniques used to inserted grafts/mesh [105]. Our study suggests that the depth of dissection could influence the outcome of surgery. In addition, PDS appears to provide a slightly better outcome compared to PGA for fascial repair. This finding differs from those presented in one small RCT of 66 patients [129], where no difference in prolapse symptoms scores were found but a significantly lower prolapse - related quality of life and urine incontinence score was identified, when Vicryl (PGA) was used compared to PDS for fascial repair. In a recently published feasibility trial some insight into the method of vaginal skin suture method is gained [100]. The pain scores were higher in women 24 hours post closure when interrupted sutures were used compared to a continuous single suture however qualitative research showed women rated this postoperative pain as insignificant. Our study shows better outcomes when skin closure is with continuous locking compared to continuous non- locked method.

The “standard anterior repair” has progressed through small modifications and was developed prior to the concept of evidence-based medicine. The current lack of evidence to inform clinicians of the “best techniques” is likely to be a contributing factor in the continued variation in practice seen. A number of difficulties of incorporating surgery into RCT have been identified and give some reason for the low quality trials that exist. As this study has identified that some aspects of surgical technique influence the success of prolapse surgery, collaborative RCTs of surgical techniques are warranted. If future studies identify specific techniques as being superior to others, consideration as to why practices vary (the subject of a separate paper), will be important for the implementation of practice change.
Conclusion

This exploratory study has identified certain aspects of technique that could influence the outcome of surgery. This study should be used to inform future RCT of surgical technique rather than cause a change in clinical practice.
CHAPTER 7: OVERALL DISCUSSION
Chapter 7

7.1 Overall Discussion

“The only problem left in plastic gynaecology is that of recurrent cystocele.” [2]

Within the field of Urogynaecology there remains discontent among surgeons with the outcomes related to the routinely performed operation of native tissue POP repair particularly in the anterior compartment [3]. Despite this native tissue repairs remain the most widely performed procedures for this complaint [54, 55]. Graft/mesh has been used in POP repairs in an attempt to reduce the recurrence of cystocele [144].

The PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomized Controlled Trials) study [50] was designed to compare the efficacy and safety of native tissue and graft/mesh repairs. This study awaits publication in the Lancet. There are currently concerns relating to graft/mesh use in vaginal surgery [27–29] and the long term effects are unknown.

The literature review, presented in the introduction to this thesis, demonstrates how the assessment of success of POP surgery is affected by the outcome measures chosen [22, 23] and a number of studies have made a comparison between the success of native tissue and graft/mesh repairs [3, 6]. The recent Cochrane review of the surgical management of the anterior compartment advises that current evidence does not support the use of graft/mesh in preference to native tissue POP repairs due the increased morbidity associated with these products [3]. Previous questionnaire based studies have shown that surgical techniques used to perform POP repair vary between surgeons [58–61]. It is not known whether surgical technique variations affect the outcome of POP surgery. If surgical technique variations are identified as causal factors then this under researched area could offer a focus for practice change and a reduction in cystocele recurrence.
Papers 1–3 are a series of studies evaluating how and why surgical techniques vary between a UK cohort of surgeons performing native tissue anterior POP repairs. The results of these studies were used to inform an assessment of influence of surgical technique on the outcome of POP surgery, see in paper 4. We focused on native tissue repairs, as these remain the most widely performed [54, 55] procedures in the surgical management of POP. Qualitative research provided the ideal research approach to answer these questions. This methodology allowed the investigator to observe the surgeons in real time and then immediate validation of the findings through a subsequent interview was possible. Prior to this study, only questionnaire based studies have investigated how surgical techniques vary between surgeons [58–61].

Firstly, the surgical techniques of UK based surgeons recruiting a multicentre surgical prolapse study (PROSPECT) were assessed in a questionnaire based study (Paper 1) [101]. A decade on from the last UK assessment of this kind [61], this initial work identified that surgical variation continues to be an ongoing phenomena. This questionnaire prospectively documented the surgical techniques being used to perform both a native tissue anterior and posterior POP and graft/mesh augmented repairs and technique variations between surgeons were seen in both procedures. There has been no previous UK based questionnaire study assessing the surgical techniques used to insert grafts/mesh [58]. Tawfeek et al [61] reported the types of graft/mesh being inserted by surgeons but not the surgical techniques being used.

This questionnaire study highlighted important aspects of surgical technique variation not discussed in previous studies. Firstly when considering native tissue repair, this study showed that surgeons choose to dissect at different depths in the vaginal wall, either superficial/above or deep/below the vaginal muscularis [101]. In almost half of the respondents, they documented performing both techniques. It was beyond the scope of the questionnaire to understand why this was the case. Secondly the insertion of the grafts/mesh inlay was reported as either above or below the vaginal muscularis. Most surgeons placed the graft/mesh below this tissue layer inline with guidance in literature [105]. However a proportion of surgeons placed the graft/mesh
above the vaginal muscularis. It might be expected that this could affect the vaginal skin exposure rate but there is no literature assessing this.

The limitations of the questionnaire based study methodology (discussed below) reinforced the necessity for further evaluation of surgical technique variations using an alternative approach. The findings of this study were used to inform and were the premise for the subsequent mixed methods study, Variation of Surgical Technique (VaST). Qualitative research methodology presented the ideal approach to gain additional detail and a greater understanding of this subject area. The first part of the VaST study, presented in papers 2 and 3, prospectively assessed how and why surgical technique varies when performing native tissue POP repairs.

Through qualitative research (paper 2) it can be appreciated that there are a greater number of variations in surgical technique that exist in clinical practice than have been reported in previous questionnaire based studies [58–61]. Categorisation of surgical techniques for POP repair was more challenging than had been anticipated. It was not possible to categorise surgical technique using overarching themes and instead themes were based on the steps of the procedure. Variation was seen in each step of the procedure and few surgeons performed the same combination of steps. When reviewing the literature it should be appreciated that when it has been reported that a “standard anterior repair” has been performed [103], it is likely that aspects of the technique performed have been variable and pragmatic trials may offer better external validity at this time [50].

Two additional factors contributing to the challenge of surgical technique categorisation were the lack of standardised terminology and the subjective nature of surgery. The sequence of observation of surgery and subsequent interviews with surgeons allowed confirmation that terminology varied. These differences were seen in both the terms used for techniques and anatomy and in the definitions used. A consensus for surgical terminology needs to be agreed before further RCT in this area is undertaken. This has been helpful in the improved communication of other aspects of pelvic floor dysfunction and the related outcomes and complications [126, 148, 149] (see further work). The use of the histological terms relating to the vagina wall
may aid the explanation of techniques relating infiltration, level of dissection and repair of the tissues rather than the use of the generic term “fascia”.

Qualitative research in particular the video observation of surgery has allowed a greater appreciation of the surgical techniques used by surgeons. It has been possible to observe the subjective aspects of surgery that have not previously been reported in questionnaire based studies [58–61]. A parallel can be drawn with the work on surgical knowledge where Nonaka and Takechib [150] described the concepts of explicit and tacit knowledge. Like explicit (objective) knowledge, there are explicit techniques that are easily shared, documented and used. Where as tacit (subjective) knowledge there are techniques that are more individual, context specific and so difficult to communicate to others. Surgeons in this study had difficulty in communicating aspects of technique or explained that that technique was based on experience. These aspects of technique support the notion that surgical practice is a craft rather than a science and is one factor that explains the variation in practice seen.

The surgeons’ perspectives of why surgical techniques to repair POP varied were explored in paper 3, in addition to concepts relating to the evidence based medicine and the theories of practice. The evidence available in this research area is mainly low level [3] and it is clear from the interviews that practice is based on more than research evidence. Mc Cullough's [125] work was reviewed and this gives some explanations for the difficulties of incorporating surgery in to trials. Unlike the surgeons in the work presented by Pope [74], the surgeons in this study state their willingness to incorporate evidence into practice but highlight the lack of data to inform their practices. As a result of this lack of evidence surgeons were seen to give reasoned justifications for their practices.

The four themes identified to explain the surgical variations seen were; the surgical journey, rationalising practice, contextual factors and concepts of success. An important factor mentioned by all was the initial training with a mentor. The hands on nature of teaching are highlighted as being an important factor in influencing practice. As with the work by Pope [73] factors including surgeons, patient, external
and chance were seen to influence the practices of surgeons. In terms of the external factors identified, this study has identified a greater range of influences with these factors not only being in the operating theatre but also including the wider context of surgery. These factors included; the influence of management, funding, protocol, enhanced recovery and the type of organisation in which the surgeon is working.

This is the first study where there have been patient outcomes available to assess every aspect of technique. Other studies have looked as certain aspects of technique [20, 96, 99, 100, 129]. The themes of surgical technique generated in paper 2 were used to make an assessment of the influence of surgical technique on the outcome of surgery. Aspects of technique were identified as having an influence on the outcome of native tissue anterior POP repairs. This study is an exploratory study and in view of the limitations linked to the methodology used (see limitations below) this information should be used to inform future RCT studies.

The acronym **VaST** turns out to be very appropriate for the findings in this study both in the multiple combinations of variations of technique seen in each step of the operation, the subjective and objective aspects of technique, the terminology of surgeons and in the reasons that have led to this variation in practice. Qualitative research has been instrumental to the increased understanding of this subject area and this highlights its importance along with quantitative studies to provide an improved understanding in under researched areas. The number of potential variable factors along with the social context that surgery is practiced in gives an explanation for why surgery continues to vary. The issue of needing to standardise surgery has been raised in the literature [133] and this thesis illustrates the complexity of this task. There appear to be some aspects of technique that could influence the outcome of surgery (paper 4) and further research is needed to confirm this (see further work). The social theory of practice (paper 3) could be drawn on to help implement future practice change if specific techniques were found superior to others.
7.2 Strengths of the VaST study

The strengths of this study are outlined in the discussion sections of papers 1 – 4. Below are the key strengths of this work.

- Multiple steps were taken to ensure the quality of the data collected (see methodology)

- A greater understanding of this under researched area has been developed.

- The first questionnaire based study to identify that a proportion of surgeons are dissecting beneath the vaginal muscularis (fascia) in native tissue pelvic organ prolapse repairs. It is likely that this technique has been extrapolated from the dissection used to perform graft/mesh repairs.

- Qualitative research methods have allowed a greater understanding of the extent of surgical technique variations, the terminology used by surgeons to describe their techniques and the subjective aspects of surgery.

- The entire procedure of anterior pelvic organ prolapse repair has been categorised and this is the first study to have outcome data available for each aspect of technique in this procedure

- This study highlights the issue that surgical technique variation could influence the outcomes of surgery. It is an exploratory study and highlights the need for future collaborative research of surgical technique and its role in the recurrence of cystocele.

- This study gives a surgeons perspective of why surgical technique varies and this builds on previous work within a similar area of medicine.
7.3 Limitations of the VaST study

The limitations of the study are presented below; these include methodological limitations and other general limitations of the study. Again in each paper there is an account of the limitations relating to that paper in the discussion section.

Study Methods

Choice of research approach

There were a number of limitations identified with the questionnaire based study including incomplete responses and documentation of multiple methods, which made it difficult to fully evaluate the most commonly used techniques. It was beyond the scope of the questionnaire to determine why surgeons chose one technique over another. In addition I was unable to determine if all surgeons used the same terminology to describe techniques being practiced. These limitations reinforced the necessity for further evaluation of surgical technique variation using an alternative approach.

At the start of the VaST study consideration was given to the best methodological approach and a pragmatic method was chosen. This type of qualitative research approach may be less well known or considered by social science academics. The reasons for this choice are discussed in the methodological section. Several steps were taken to ensure the quality of the data including pilot interviews, reflexivity, triangulation, inter rater reliability and respondent validation.

Issues regarding this research approach that maybe considered limitations include it being less theoretically or philosophically rigorous, there being no commonly accepted approach to methods and being viewed as an “easy” or fast way to carry out qualitative research [78]. Thorne et al. (1997:170) suggest this approach to be the “cruelest form of inquiry”. As well as a description of the surgeons’ practices there has been consideration of the underlying philosophical stance and a comparison with similar work and theory [73, 74, 125]. Although this approach has allowed the
question to be answered within the time frame available. It has ensured that a systematic approach has been followed and that the details of this are communicated clearly within the methodology.

There are several reasons related to the methodology of paper 4 that explain why this should be seen as an exploratory study and not generate practice changes. The first limitation of this study is that the surgical technique assigned to the surgeon was based on the observation of one or two procedures and subsequent interviews during a single site visit. The PROSPECT study was a pragmatic RCT and surgeons were requested to use the techniques they used most often throughout the study process and these techniques were documented in a questionnaire [101]. Variation in practice at the time of the PROSPECT study procedures compared to the assessment in this study (VaST), could have introduced systematic bias.

The outcome data used in this study, included women recruited to both the RCT and cohort aspects of the PROSPECT study. The data set available for analysis of the affect of surgical technique on the anatomical outcome measure (Ba measurement) was much smaller (n= 276) than the complete data set. A postoperative POP Q examination was only performed in the RCT part of the study at baseline and 12 months follow up. The POP SS and QOL measures were derived from a questionnaire output at baseline, 6, 12 and 24 months time points (n=809).

It was not possible to categorise surgical technique, as a procedure in its entirety as there was variation seen in each step of the procedure and different combinations of these variations existed between the surgeons [141]. During data analysis, while an assessment of the influence of one aspect of surgical technique on the outcome of surgery was made, it was not possible to control for the variations seen in other steps of the procedure. It should be remembered that outcome data used in this study was not powered for assessment of the effect of surgical technique on outcome. However the majority of themes analysed were performed by more than 10% of the dataset, although some by very few surgeons.
Number of surgeons recruited and operations observed

The approach was taken to recruit the maximum number of surgeons possible over the time period available. This was to ensure that enough surgical technique had been observed by surgeons who had previously recruited a large number of women to PROSPECT study to allow the possibility of future sub group analysis from this studies outcome data. The sites were geographically distant and there was only one investigator attending all sites. In view of this each site was only visited on one occasion. This limited the understanding of how surgeons vary their techniques over time and between cases as this could only be discussed through the interview and not captured through video observation at subsequent visits.

Effect of observation

The video observation of the surgical procedures may have influenced the surgical techniques used by a surgeon. Surgeon R stated that he decided to perform a Manchester repair concomitantly because I, the researcher, was based in Manchester. It is unknown whether this choice would have been different in the absence of the study. However it should be remembered that consultant surgeons in the majority of cases have their surgery observed by surgical trainees. As the research fellow was a surgical trainee it would be anticipated the effect of the observation/filming would be minimised.

Concomitant procedures

In 20 of the 32 anterior repairs a concomitant procedure was performed. In some cases the surgeon changed their surgical techniques because a concomitant procedure was performed. The opportunity to observe an isolated anterior repair was limited by surgeons’ availability, time frame and surgeons' frequency of performing a sole anterior repair.
**Sequence of observation and interview**

The sequence of firstly observing the surgery and then subsequently interviewing the surgeons allowed findings to be confirmed and discussed at the interview and this approach aided the understanding of surgeons’ terminology. In two cases, due to the surgeon’s schedule, the interview was performed before the observation of the surgery and this may have limited the findings in these cases. However informal conversations allowed discussion of any uncertainty at the time of the surgery which was recorded on the video and documented in field notes.

**Study Process**

**Not adopted as a portfolio study**

The research portfolio did not adopt this study as it was felt that this might negatively impact the larger study PROSPECT. The coordination of this multicentre study was performed solely by the investigator. A process for local ethical approvals was required at each site as there is no coordinating body. An extension of 6 months was required to allow for this process (methodology).

**Non participation**

Several surgeons did not respond to an initial request to participate or to a follow up request. Two surgeons actively declined participation. The total number of participants for this type of study appeared to be in line with similar work of this kind [73, 151].

**Study Content**

**Tissue samples histology not assessed**

A discrepancy in surgeons’ terminology to describe fascia was identified following the data analysis. The surgeons and investigators view of what constituted “deep
dissection” was found to vary. Histological assessment of the excess skin that was excised and discarded potentially could have shown the exact level of dissection in which surgeons are dissecting and aided the development of terminology to describe it.

**Study Analysis**

**Time for data emersion**

A large amount of data was generated by this study. The time constraint of 2 years part time (MPhil) meant that the immersion in the data had to be limited to a few months. A longer time for data immersion may have generated more themes in the work that was analysed and given time to analyse and present the posterior surgical technique data set.

**Practical issues**

**Patient participant agreement**

The surgeons identified suitable patients from their operating lists and information about the study was sent out to the patient by the hospital team. In some cases due to the time frame between the patient being listed and the operating day this was inadequate time for the research fellow to receive the formal letter of agreement to participate. This was difficult as in some cases the hospital sites were remote from the central site and the research fellow had to take a chance that the patient would participate. There was a good take up on this study and only 2 patients declined this study (1 patient was too nervous and 1 for religious reasons).

**Encryptment of files**

The first video file was encrypted and in this form it could not be analysed using NVIVO or be edited. The remaining video data was stored in line with the University of Manchester guidance.


Breech to protocol

In one site, information about the study was sent out to the patients before the local approvals were finalised. This issue was recorded and the research fellow did not attend the hospital until the appropriate approvals was gained.
7.4 Future research

Analysis and presentation of posterior surgical techniques data

Due to time constraints the posterior POP technique data has not been analysed and presented in this thesis. The decision to analyse the anterior repair surgical techniques only was as a result of the greater recurrence risk compared to the other compartments [7, 8] and more anterior repair procedures were observed which gave a greater amount of data to draw conclusions from.

In the future this additional data could be analysed and presented. Questionnaire studies have shown that surgical techniques also vary between surgeons performing posterior repairs, however there is less literature detailing these variations. As with anterior compartment, analysis of the posterior repair data would give a more detailed understanding of how surgeons repair posterior compartment prolapse, document the variations that currently exist in clinical practice and will establish the terminology surgeons use to describe this procedure. Using themes developed from future analysis, an assessment of the influence of posterior repair techniques on outcomes could also be made.

Standardisation of terminology used for pelvic floor surgery

There have been a number of terminology reports written by the joint ICS/IUGA working groups that have standardised terminology for female pelvic dysfunction, surgical outcomes and complications relating to POP repairs [126, 148, 149]. This standardised terminology has allowed improved communication between clinicians.

The VaST study has found that the terminology used to describe surgical techniques and the anatomy relating to a native tissue POP repair varies. Before further research in this area is possible it would be important to standardise terminology to allow a mutual understanding of this topic area. Focus groups with surgeons would be an ideal forum to discuss surgical terminology and the VaST video clips could be used to guide discussions and develop a common language for different aspects of technique.
Future involvement of the ICS/IUGA working group would be important for the
development of a common language used to describe surgical techniques.
Standardised terminology would allow better documentation of techniques in the
literature, make comparisons of techniques easier in clinical trials and would be
essential for future RCT comparing the effects of surgical techniques on the outcomes
of surgery.

Assessment of the influence of surgical technique on the outcome of pelvic floor
surgery

This work is an exploratory study, which has identified aspects of surgical technique
that could influence surgical outcomes in native tissue POP surgery. Further research
investigating the affect of surgical technique on the outcomes of surgery and its role
in the recurrence of cystocele needs to be performed.

This assessment of the influence of technique on the outcomes was made using
retrospectively derived themes. Although surgeons were asked to use the techniques
that they use most often throughout PROPSECT study it is likely that some variation
in a surgeons own technique existed and this is a source of bias. A prospective RCT
of surgical technique would mitigate this bias. To recruit a sufficient number of
women a collaborative multicentre study would be required.

The themes that have been shown to have a potential influence on outcome should be
those that are assessed further in a RCT. These aspects of technique include, the
depth of dissection, the method of fascial repair and the type of suture/method of
suturing. It would be necessary to ensure that all surgeons that are participating fully
understand the differences in technique and that standardisation of techniques and
terminology (see above) is ensured before an assessment of their affect on outcome is
made. If differences in outcome are identified the work in paper 3 and the theories
behind practice could help implement change.
Application in the wider context of surgery

This work illustrates how qualitative research can give a more detailed understanding of under researched areas of healthcare. There is a definite place for this methodological approach and it should be seen as complementary to RCTs. Although observational studies are considered to be a lower level in the hierarchy of evidence, this methodological approach answers the how and why questions that exist in practice which cannot be answered through RCT. A lot of healthcare practices are not evidence based as they have developed over time before this concept existed. As a result procedures are not standardised and outcomes could be variable.

The questionnaire-based study raised additional questions about how and why surgeons practice in a given way. Qualitative methodology identified the reality of practice was far more complex and variable compared to what had been shown in questionnaire studies. This methodological approach has allowed an assessment between what people say they do and what they actually do in clinical practice. It has also been important in establishing the full range of techniques being performed in everyday practice and will now inform future quantitative studies assessing the influence of techniques on the outcome of surgery.

There will be other areas of surgery that could also draw on these methods to gain a greater understanding of surgical practices. Firstly in assessing whether there are other well established surgical procedures where surgical techniques vary between surgeons. Pope [74, 151] has already performed similar work with surgeons performing stress urine incontinence procedures. This work highlighted that contingencies in practice lead to surgical variation and that boundaries existed in incorporating evidence based medicine into practice.

Observational studies would also be a useful methodology to use for education in and the teaching of surgical practices. In the field of ear nose and throat surgery (ENT) qualitative methodology has been used to show how brief episodes of instruction enable complex procedures to be understood and followed [132]. The VaST study has highlighted that surgeons learn mainly from one on one interactions and that
Surgeons can become isolated later in training, resulting in the continuation of certain practices and uncertainty about the techniques used. Observing procedures back after completion of surgery would offer both the opportunity for learning from what has been done and also a way of sharing practices with others in different centres. Many procedures are now filmed including laparoscopy, cystoscopy and hysteroscopy and this will facilitate the future use of qualitative methods in the teaching of surgical practices.

Lastly observational studies have been shown to inform us of patient’s perspectives of surgical choices [131]. Patient’s choice is important in Urogynaecology as the successes of procedures are based on subjective outcomes and the effect of conditions on the patient’s quality of life. In addition there are several options of procedure that patients can choose for the same condition. Further qualitative research in this area will be important to ensure that patients make the correct choices of procedures for them considering factors like age, desire for future fertility and acceptability of the risks related to different procedures.
REFERENCES
References


52. JM S (1866) Clinical notes on uterine surgery. Robert Hardwicke

doi: 10.1136/pgmj.18.202.154


75. Gabrielian V (1999) Qualitative research methods: An overview. Marcel Dekker


183


APPENDIX
Appendix 1: Study Protocol (Methodology)

Study Protocol

VaST

(Variation in Surgical Technique)

How does the surgical technique of a non-graft pelvic organ prolapse repair vary and does the variation affect surgical outcome?

Researchers: 1. Dr Emily Fairclough, 2. Dr Jenny Myers, 3. Prof Anthony Smith, 4. Prof Charis Glazener 5. Dr Fiona Reid
St Mary’s Hospital, Manchester 1,2,3,5
Health Service Research Unit, University of Aberdeen 4

Cover page
Variation in Surgical Technique: How does the surgical technique of a non-graft pelvic organ prolapse repair vary and does the variation affect surgical outcome?

Study identifiers: protocol V2, REC number 13/NE/0158

Sponsor details: Central Manchester University Hospitals NHS Foundation Trust

Chief Investigator: Fiona Reid

Collaborators/authors: Emily Fairclough, Jenny Myers, Anthony Smith, Charis Glazener

Lead Site: Warrell unit, St Mary’s Hospital, Manchester, M13 9WL
<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Fiona Reid</td>
<td></td>
</tr>
<tr>
<td>Dr Emily Fairclough</td>
<td></td>
</tr>
<tr>
<td>Dr Jenny Myers</td>
<td></td>
</tr>
<tr>
<td>Dr Anthony Smith</td>
<td></td>
</tr>
<tr>
<td>Prof Charis Glazener</td>
<td></td>
</tr>
</tbody>
</table>
# Table of contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol summary</td>
<td>6</td>
</tr>
<tr>
<td>Background and Rationale</td>
<td>7 - 8</td>
</tr>
<tr>
<td>Aims, Objectives and Hypothesis</td>
<td>9</td>
</tr>
<tr>
<td>Study Design</td>
<td>10</td>
</tr>
<tr>
<td>Consent</td>
<td>11</td>
</tr>
<tr>
<td>Participant Selection and withdrawal</td>
<td>11 - 12</td>
</tr>
<tr>
<td>Participant recruitment</td>
<td>12 - 13</td>
</tr>
<tr>
<td>Method of data collection</td>
<td>13 - 14</td>
</tr>
<tr>
<td>Data analysis</td>
<td>14</td>
</tr>
</tbody>
</table>

Study procedures by visit                                               14 - 15

Statistical analysis                                                    15
End of Study                                                            15
Ethical and other approvals                                             15
Dissemination and Publication                                           15 - 16
Finance and Insurance                                                  16
Glossary/abbreviations                                                 16
References                                                             17

Appendix: Associated documents                                          18

- Topic guide to semi structured interview                             18
- Flow chart of study                                                  19
- Letter of invitation to the participant – surgeons                   20
- Letter of invitation to the participant – patient                    21 - 22
- Participants information sheet - patient                             23 - 27
- Participants information sheet - surgeons                            26 - 28
- Participant consent form - patient                                   29
- Participant consent form - surgeons                                  30
Protocol Summary

How does the surgical technique of a non graft anterior and posterior pelvic organ prolapse repair vary between surgeons and does variation in surgical technique affect the subjective and anatomical outcome of pelvic organ prolapse surgery?

Considered for entry: Surgeons who have recruited women into the PROSPECT Populations:

1. Surgeons recruiting non graft anterior repairs
2. Surgeons recruiting non graft posterior repairs

Study Entry: All surgeons recruiting women with pelvic organ prolapse for a non-graft repair

Outcome assessment:

Qualitative data
Assessment of surgical technique through several methods
1. Semi structured interview (audio taped)
2. Observation of surgery (video taped)
3. Field notes
4. Standardisation of surgical procedures PROSPECT
   Surgical technique will be grouped based on themes identified

Quantitative data
Correlation between surgical technique theme and PROSPECT outcome data:
1. Subjective outcome (POP SS and QOL effect 12 month)
2. Objective outcome (POP Q assessment – at the hymen or above)
3. Functional outcome (urine, bowel, sexual function)

Coordination of study: Warrell unit, St Mary’s Hospital, Manchester M13 9WL
Tel: 0161 276 6910
Ethics Sunderland REC

Funding: Warrell Unit charitable funds, St Mary’s Hospital, Manchester

Start date: April 2013
Completion date: April 2016

August 2014 (Qualitative/Part1) April 2016 (Quantitative/Part 2)
**Background and rationale**

Pelvic organ prolapse (POP) is a common condition. The ICS definition of POP is, “a downward descent of pelvic organ(s) which results in the protrusion of the vagina and/or cervix” \(^1\). It is frequently quoted that up to fifty percent of parous women have a POP and twenty percent experience symptoms \(^2\). It is estimated that the incidence of this condition will double over the next thirty years as a result of the aging population \(^3\).

One option available for the management of POP is surgery. In the UK around twenty eight thousand women per year have a surgical procedure to manage their POP and the majority of these operations involve the anterior and posterior compartments \(^4\). The lifetime risk of a woman having to have any pelvic organ surgery is often cited as eleven percent by eighty years old \(^5\).

There is currently debate relating to several issues pertaining to POP repair. The areas of uncertainty include the use of mesh (graft), the type of operation and surgical technique to give the optimum outcome and which outcome measures best demonstrate the success of surgery.

The traditional approach to repair of the anterior and posterior compartments is the use of the patient’s own tissues. The technique of an anterior vaginal wall repair was first described by Kelly in 1913 and the posterior vaginal wall repair by Simon of Heidelberg in 1867 \(^6\). Unfortunately literature shows that the recurrence rate of non-graft repairs is relatively high with up to a third of women requiring further surgery \(^5\). The use and development of mesh has ensued in response to the perceived unacceptably high recurrence rate of non-graft repairs. There has been an attempt to identify the risk factors that lead to the recurrence of POP \(^7\). Currently there is a paucity of data to show the optimum way to repair a POP in order to achieve a lasting cure for patients. A number of studies have attempted to compare the outcomes of mesh and non-graft repairs. This comparison has been made difficult by studies having different outcome measures and including a combination of surgeries and relatively small numbers of patients \(^8\).
The PROSPECT study is a large UK based multicentre randomised control trial that is comparing the use of mesh with non-graft repair. It seeks to address which prolapse operation is the safest and most effective for women with POP. There are two arms to the trial and these include women having either a primary or a secondary repair. Women are being randomised to have a non-graft repair or a repair with a specified mesh. The primary outcome is patient reported prolapse symptoms (Pelvic Organ Prolapse Symptom Score (POP SS) and effect on quality of life which is measured at 12 months post surgery 9).

The concern with regard to mesh is that studies to date report a greater number of complications than non-graft repairs. In a review by Stamford et al 8 they quote the rate of complications for non-graft to be 8 % and mesh 0 – 19%. Mesh repairs have all the same complications as non-graft however there are additional complications unique to mesh. These additional complications include mesh erosion/exposure and nerve, vascular and visceral injury. The US Food and Drug Administration have issued warnings with regard to mesh use 8 and NICE suggest that mesh should be used with special arrangements for clinical governance, consent, audit and research 10. In view of the current uncertainties regarding mesh it appears that this is an opportune time to reassess non-graft repairs. A national survey of prolapse in the UK shows that non graft repairs are the primary surgical choice of operation when repairing prolapse. Anterior and posterior vaginal wall repairs are being performed in seventy one and sixty percent of cases respectively 11. Despite this and it being the most well established surgery 6 there has been no standardisation of surgical technique for repairing pelvic organ prolapse.

PROSPECT is a pragmatic study and as such reflects current practice. Each surgeon completed a standardisation of surgical practice form prior to recruiting women into this study. These forms give details about the surgical techniques that are being performed by the surgeons and they suggest that the surgical technique of a non-graft anterior and posterior POP repair varies among surgeons in the UK. Literature from Denmark 12 and the USA 13 has also identified through questionnaire-based surveys that there is variation of surgical technique. The relevance of this variation in technique is as yet unknown.
The aim of this study is to use qualitative methods to prospectively investigate how the surgical technique of an anterior and posterior non-graft repair varies between surgeons in the UK. If differences in surgical technique are identified the outcome data from PROSPECT will be used to discover if differences in surgical technique affect the subjective and anatomical outcomes for patients. This information will inform surgeons regarding the surgical techniques that are currently being practiced with in the UK. This may help define an optimal technique and demonstrate whether technique employed has an influence on outcome.
Aims, objectives and hypothesis

Aims

1. To identify how the surgical technique of a non-graft pelvic organ prolapse repair varies between surgeons?

2. To determine if a particular surgical technique of a non graft pelvic organ prolapse repair affects the subjective, anatomical and functional outcomes of surgery?

Objectives

1. To carry out qualitative interviews with surgeons who have randomised women into PROSPECT in order to identify how surgical technique varies between surgeons. In order to ensure the data is robust a triangulation of methods will be used and these additional methods include a videotape of surgery, field notes and a completed standardisation of surgical procedures form.

2. To organise surgical techniques into categories and then assess if themes of variation in surgical technique affect subjective (Pelvic organ prolapse symptom score and effect on QOL), anatomical (POP Q – at or above the level of the hymen) and functional (urine, bowel and sexual function) outcomes at 12 months.

Hypothesis

The variation in surgical technique of a non-graft pelvic organ prolapse repair that exists does not affect the subjective, anatomical or functional outcomes of surgery at 12 months.
Study Design

This is a mixed methods prospective study. Firstly a qualitative research study will be performed to identify how surgical technique of an anterior and posterior pelvic organ prolapse repair varies between surgeons in the UK. The methods that will be used in order to perform this part of the study will include an audio taped interview with the surgeons, a filmed record of their surgery and field notes. A standardisation of surgical procedures form has already been completed as a part of PROSPECT. The information collected will be analysed in order to identify any categories in variation in surgical technique of a non-graft POP repair and themes of surgical technique will be developed.

The second part of the study will be a quantitative research study. The outcome data from PROSPECT non-graft repairs will be used to assess the affect of variation in technique on surgical outcome. PROSPECT is a large multicentre randomised control study comparing outcomes of non graft and mesh repairs in women having either primary or secondary surgery. For each category of surgical technique the outcome data from patients having non graft repair will be assessed. The primary outcome is subjective (POP SS and QOL effect) and the secondary outcomes are anatomical (POP Q at or above the hymen) and functional (urine, bowel and sexual function).

Endpoints

a) Qualitative study

3 A complete description of surgical technique though interview with surgeons

- A video recording of non-graft anterior and posterior prolapse repair surgery
4 Written information (field notes and standardisation of surgical procedures form PROSPECT)

b) Quantitative study

Primary outcome

5 Subjective outcome: Symptoms of prolapse

- Pelvic organ prolapse symptom scale (POP SS)
- QOL outcome – overall effect of POP symptoms on everyday life

6 Secondary outcome: Anatomical outcome

- POP Q at or above hymen at 12 months

Functional outcomes

- Urine, Bowel and Sexual function

Consent

The researchers will contact the surgeons recruiting women to PROSEPCT to invite them to be involved in this study. The surgeons will be sent a letter of invitation and written information about the study. On the day the study centre is visited written consent will be taken from the surgeon to formalise their agreement to be interviewed about their surgical technique of a non-graft POP repair and have their surgical technique video taped (see appendix).

The patient invitation letter, information sheet and consent forms will be sent to the participating surgeons. The surgeons will be asked to approach patients to see if they will be involved in this study. A reply slip and self address envelope will be included so that the patient can inform the lead research site of their agreement to participate in
this study. Their written consent will be taken on the day of the surgery by the surgeons or research fellow to allow their surgery to be observed and filmed (see appendix). It should be highlighted that this study is purely observational and no aspect of their care will be affected.

**Participant selection**

**Inclusion**

**Qualitative study**

- Interview: Any surgeon who has randomised women into PROSPECT study to have a non-graft repair
- Observation: Any patient having a non-graft repair by a surgeon who has been involved in randomising women to PROSPECT study to have a non-graft repair.

**Quantitative study**

- Patients who have complete outcome data and have been randomised or included in the cohort to have had a non-graft repair in the PROSPECT

**Exclusion**

**Qualitative study**

- Interview: Any surgeon who has not randomised women to have a non-graft repair in the PROSPECT study.
- Observation: Patient having a non-graft repair but the surgeon has not been involved with in recruiting women into the PROSPECT study or mesh repairs performed by a surgeon who is recruiting patients to PROSPECT.
Quantitative study

- Patients with incomplete outcome data
- Patients that have been randomised to have a mesh repair in the PROSPECT study

Participant withdrawal

A centre, individual surgeon and patient are free to withdraw from their participation in this study at any time. The patient should be made aware that withdrawal from this study does not affect their treatment now or in future and their consent can be withdrawn without giving any reason for this.

Participant numbers

Qualitative study

- Surgeons will be recruited into this trial for interview until the interview does not develop any new themes and saturation is met. There are 34 centres and 65 surgeons that have recruited women into PROSPECT.

- For each surgeon recruited into the study 2 women will be approached for observation of their surgery, one having an anterior non-graft repair and the other having a posterior non-graft repair.

Quantitative study

- N = 1624 women are projected to be randomised (1° n=1450 and 2° n=174) into the PROSPECT trial.
Where and how participants be recruited

A list of surgeons involved in recruiting women into the PROSPECT trial will be accessed from the PROSPECT research manager at Aberdeen. In addition to this the number of patients each surgeon has randomised into PROSPECT to have a non graft repair will be sought.

The chief investigator of this study will contact the surgeons and invite them to be involved in this study. An invitation letter and an information sheet will be sent to each surgeon. The surgeons who have randomised the greatest numbers into PROSPECT will be contacted first to ensure numbers they are recruiting will reach significance to allow analysis of surgical technique themes with outcome data from PROSPECT. If saturation of themes is not met surgeons recruiting smaller numbers in the study will be contacted to be involved in the study in order to be included in the first part of the study.

A patient invitation letter, reply slip and information sheet will also be sent to the surgeons. The surgeons will be asked to recruit two women to have their surgery observed, a non-graft anterior and posterior repair at a time that is convenient for that surgeon. On the day of the site visit written consent will be sought by the research fellow from the surgeons. Written consent will be also taken from the patients by either the surgeon or the research fellow.

Methods of data collection

Several methods will be used in order to perform the qualitative aspect of the study. All information and imaging will be anonymised.

Interviews

Surgeons will be involved in a semi-structured interview about their surgical technique in performing a non-graft repair. The interview will be one session and last between 30- 60 minutes. It will take place in the surgeons hospital centre in a quiet setting. An interview topic guide will be developed, trialed and modified in a series
of pilot interviews. Each interview will be recorded with audiotape, field notes taken
to guide interview and then following the interview these will be transcribed. A
preliminary topic guide is included in the appendix. Additional information that will
be collected at the time of the interview includes;

- Does an individual surgeon's technique vary and why?
- Training of surgeon – subspecialist or special interest
- Experience of surgeon – number of years of clinical practice
- HES data - no of repairs/ year

Pilot interviews

The research fellow has got skills in interview through clinical practice and
consultation with patients. In order to ensure good interview technique to derive
optimum data analysis a series of interviews with consultant colleagues and junior
doctors at St Mary’s Hospital will be carried out. Open questions will be trialed and
developed to ensure prior to the study commencing the researcher has developed
adequate skills in research interviewing.

Videos

The surgery will be videoed with two video recorders a hand held and fixed video
recorder. The videos will contain no images by which you can identify the patient.
Patient care will not be affected in any way by this study. The study is purely
observational and will not affect the choice of surgery or technique performed.

Questionnaire

A standardisation of surgical technique questionnaire has already been completed as a
part of the PROSPECT study. Following the interview any missing data from this
questionnaire will be completed.
Validation of methods of data collection for qualitative study

Audio and videotapes will be assessed by the research fellow and the chief investigator to ensure that the methods are appropriate and the same conclusions about the content are drawn. If there is dispute about the methods or content the opinion of Dr A Smith will be sought.

Data Analysis

Data analysis will be ongoing as interviews/videos take place. Surgical technique will be coded and as interviews progress emergent themes will be recorded. Interviews will continue until no new themes are recorded (saturation). The audio and videotapes will be analysed by the research fellow and the chief investigator. They will assess what surgical technique is being carried out and if this matches the standardisation of surgical procedures form completed by the surgeon as part of PROSPECT.

In order that the information collected is robust the following steps will be taken;

- Piloting of interview technique and interview topics
- Triangulation of methods
- Analysis by more than one researcher and when disputes in content arise the opinion of another researcher will be sought.

Themes in surgical technique variation will be developed and documented. For each theme of surgical technique identified the outcome data from PROSPECT will be analysed to discover if the differences in surgical technique affect the outcome of surgery (pelvic organ prolapse symptom scale (POP-SS) and a QOL measure of overall effect of prolapse symptoms on everyday life) at 6 and 12 months after surgery.
Study procedures by visit

1. Surgeons approached for recruitment (Chief investigator)

2. Centre visited (Research fellow)

The aim will be to complete the data collection during a single visit to the sites. A second visit may be necessary to observe both non-graft prolapse repairs.

- Informed consent taken from surgeon (approx. 15 minutes)

- Interview with surgeon (30 – 60 minutes)

- Informed consent from patient to participate (approx. 15 minutes)

- Observation of surgery
  - Anterior repair (approx. 45 minutes)
  - Posterior repair (approx. 45 minutes)

- Flow chart of study (see appendix)

Statistical analysis

Statistical analysis for the second part of the study will depend on the outcomes of the initial qualitative research and the final outcomes of the PROSPECT trial. A conservative estimate for the sample size, given that there were 2000 surgeries included within the PROSPECT trial, would give a sample of 100 operations per outcome group (based on up to six surgical techniques), this allows for 20%
incomplete data. A post hoc analysis will be conducted to identify possible confounders including surgeon and centre. Binary outcomes will be analysed using Chi squared and multiple logistic regression applied to determine the influence of cofounders. Continuous and categorical demographic variables will be analysed using appropriate tests between groups (ANOVA, Krskall Wallis).

End of the study

The study will be carried out between April 2013 – April 2016. The qualitative data will be analysed and a report completed by August 2014. Quantitative data will be analysed and reported on after PROSPECT has completed.

Ethical and other approvals

Ethics approval will be sought from the Sunderland Research Ethics Committee. This study will seek ethical approval for completion of this study separate to that gained for PROSPECT. An approval letter from the chief investigator of PROSPECT will be sought to use the non graft 6 and 12 outcome data. The study will also seek local R&D approval and approval from University of Manchester.

Dissemination and publications

The results of this study will be written as part of an MPhil research qualification at the Manchester University. In addition the aim would be to publish 2 papers;

- The variation of surgical technique of a non graft pelvic organ prolapse repair in the UK
- The affect of variation in surgical technique on the subjective and anatomical outcome of non graft pelvic organ prolapse repair in the UK
Finance and insurance

The study will gain funding from charitable funds from the Warrell Unit, St Mary’s Manchester. The study will use NHS indemnity.

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>POP</td>
<td>Pelvic organ prolapse</td>
</tr>
<tr>
<td>POP Q</td>
<td>Pelvic organ prolapse quantification</td>
</tr>
<tr>
<td>POP SS</td>
<td>Pelvic organ prolapse symptoms score</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>PROSPECT</td>
<td>Prolapse surgery: Pragmatic evaluation and randomised controlled trials</td>
</tr>
<tr>
<td>NT</td>
<td>Native tissue</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
</tbody>
</table>
References


9 Hagen S The pelvic organ prolapse symptoms score system. BJOG 2009 116 (1) 25 - 31

10 www.nice.org.uk/N1604overview (surgical repair of vaginal wall prolapse using mesh

11 Jha S et al The UK national prolapse survey: 5 years on. Int Urogynecol J. 2010, 22: 517 -528


13 Shippey S Contempory approaches to cystocele repair: a survey of AUGS members J Repro Med 53 (11): 832-836
VaST - Topic guide for semi-structured interview with surgeon

Introduction with surgeons: Qualification, career path, number of repairs per year

Tell me about your technique in performing an anterior/posterior non graft repair?

- Pre operative care
  - Antibiotics
  - POP Q

- Intraoperative
  - Incision (Site, depth, length, starting point)
  - Hydro dissection (Amount, type)
  - Dissection of skin from fascia/leave fascia on skin
  - Plication of fascia/repair other facial defect/paravaginal repair
  - Excision of skin
  - Closure (Material- type and grade, method of suture)

- Post op care (pack, catheter, length of stay, follow up)

  Why do you perform this technique of surgery?
  - Surgeon factors (skills/training/experience)
  - Patient factors (Age/sexual activity)
  - Other (trends/location in UK/gender/evidence based medicine)

Does your technique ever vary and what would influence this variation?

Questions on terminology – usage of images/videos
VaST - Flow chart of study

Information from PROSPECT study sought
Names of Surgeons involved in recruiting non graft repairs
Completed standardisation of surgical technique forms
↓
Surgeons approached for involvement into VaST study
↓
Surgeons contact patients to recruit 2 patients to have surgery observed
↓
Visit of centre (Research Fellow)
Informed consent from surgeon and patients (approx. 15 minutes)
Interview performed with surgeon (approx. 30 - 60 minutes)
Observation of surgery
Non-graft anterior repair (approx. 45 minutes)
Non-graft posterior repair (approx. 45 minutes)
↓
A second visit to a centre maybe required to observe both surgeries.
↓
Data Analysis
Written literature (field notes and standardisation surgical procedures)
Audio tape/Video tape
On-going analysis during data collection (until saturation of themes)
↓
Categories/themes of surgical technique developed
↓
Outcomes of PROSPECT (non graft) analysed against outcomes from VaST
Letter of Invitation - surgeons

Date: 
Surgeons Name/Address

Dear

I would like to invite you to take part in a research project looking at the variation in surgical technique (VaST) of a non graft pelvic organ prolapse repair. You have been involved in recruiting women to the PROSPECT study. An analysis of the completed surgical standardisation of procedures form in PROSPECT suggests that there is variation in surgical techniques and this supports current literature. It is not known whether this variation in surgical technique affects the outcome of surgery and so this warrants further research.

We propose a mixed method study. Your involvement would be in the initial qualitative research study. We aim to interview and observe surgery performed by surgeons who have been involved in recruiting to PROSPECT. From these interviews we will categorise and develop themes of variation in surgical technique. The second
part of the study will be an anonymised subgroup analysis of PROSPECT outcome data for native tissue. We will assess how identified surgical themes affect the outcome of surgery. All data will be anonymised and look at surgical technique not individual surgeons’ outcomes.

We would be very grateful for your involvement in this study. If you are happy to take part please contact us by email or post and we will contact you with more information.

Yours sincerely

Dr A Smith, Dr E Fairclough, and Dr F Reid
Dear Patient name,

You have been listed for a prolapse repair in our unit. We are taking part in a study looking at the surgical technique of prolapse repair. We are writing to you to see if you would like to be involved in this study. This study will involve a researcher (who is also a gynaecologist) observing your surgery. This will not affect your care or choice of surgery. The study will hopefully help us understand the best technique to repair prolapse when using patient’s own tissues.

If you would like to be involved in this study please contact Dr Emily Fairclough at St Mary’s Hospital Manchester by returning this self addressed reply slip or by sending her an email (Emily.fairclough@cmft.nhs.uk).

You will then be contacted with more information about the study. If you do not wish to take part in the study this will not affect your normal care.

Yours Sincerely,
VARIATION IN SURGICAL TECHNIQUE OF PROLAPSE REPAIR

I agree to be contacted about the above study.

By telephone;
Tel: ________________________________

By post: Address

___________________________________________________________

___________________________________________________________

Or by Email: ________________________________

Patient’s name: ________________________________

Patient’s signature: ________________________________

Hospital patient having operation: ________________________________

PLEASE RETURN THIS INFORMATION IN THE SELF ADDRESSED ENVELOPE PROVIDED.

MANY THANKS FOR YOUR CONSIDERATION OF THIS STUDY.
Participant information sheet- surgeon

Investigators: Dr Emily Fairclough, Dr Fiona Reid and Dr Anthony Smith

Variation in the surgical technique
This research aims to identify how surgical technique of a non graft anterior and posterior pelvic organ prolapse (POP) repair varies and whether that variation affects the outcome of surgery.

You are being invited to take part in this research study. I would be grateful if you could take time to read this information sheet which outlines the study. If you wish any further clarification regarding this please contact us using the contact details outlined at the end of this leaflet.

Why have I been chosen and what is the purpose of the study?
As you are aware there is currently debate relating to several issues pertaining to POP repair. The areas of uncertainty include the use of mesh, the type of operation and which surgical technique gives the optimum outcome.

The literature indicates that the surgical technique of a non graft repair varies and there is no standardisation in technique. It is also possible that there is a variation in
the terminology used to describe prolapse surgery. The first aim of this study is to use qualitative methods to prospectively investigate how surgical technique of an anterior and posterior non-graft POP repair varies between surgeons in the UK and to standardise our terminology.

We are inviting you to take part in this study because you have recruited women into the PROSPECT study. Analysis of the surgical procedures questionnaire that you and other surgeons completed suggests there is variation in surgical techniques and terminology of a non-graft repair. We aim to categorise surgical technique and then use outcome data from PROSPECT to discover if differences in technique affect the subjective and anatomical outcomes of non-graft POP repair.

**Do I have to take part?**
No you do not have to take part in the study. Participation is completely voluntary.

**If I agree to take part, can I withdraw from the study at any time?**
YES. You can decide to withdraw from the study at any stage.

**What will happen if I take part?**
If you agree to take part we would ask to interview you about your surgical technique of a non-graft POP repair. We will audiotape this so that it can be analysed at a later time by a number of researchers. In addition we would like to observe and video your surgery for a non-graft anterior and posterior repair.

Prior to visiting your hospital we would kindly ask you to recruit two women, a patient having an anterior repair and a posterior repair. We would send you a patient information leaflet and a letter of invitation for the patients.

All information collected will be anonymised. This research is about identifying themes in variation in technique not about analysing success of an individual surgeon’s technique.
**What are the disadvantages and risks of taking part?**

Participation in the research study will require you to volunteer 30 – 60 minutes of your time being interviewed and recruit two patients who are willing to have their surgery filmed.

**What are the possible benefits of taking part?**

The majority of pelvic floor repairs in the UK use native tissue. The benefit in taking part in this study is to inform us and to better understand how and why practice in repairing a pelvic organ prolapse using non graft varies within the UK. If variation is identified (which is suggested through the PROSPECT surgical procedures questionnaire) we aim to identify if there is technique that may provide better outcomes for our patients. This may alter how we practice or inform us that our technique doesn’t affect the outcome of our surgery for patients.

**Will my taking part in the study be kept confidential?**

Any information that is collected about you will be anonymised. When the results are analysed your name will be removed so that you cannot be recognised.

**What will happen to the results of the research study?**

The results will be hopefully be presented at clinical and scientific meetings and be published in journals. Direct quotations may be used in publications and in presentations. You will not be identified in any of our results, however if you wish you can be identified/cited as a collaborator in this study please inform us of this.

**Who is organizing the research?**

The research is being organised by the Warrell unit, St Mary’s Hospital, Manchester.

**Who has reviewed the study?**

The study has been reviewed by the Sunderland Research Ethics Committee, who have given a favorable opinion.
Will I get the results of the research?
If you are interested in finding out the results of the study, please contact Dr Emily Fairclough (contact details at bottom of sheet) and we can contact you with information at the end of the study.

What if there is a problem?
If you have a concern or comments about any aspect of this study then please to speak to the researchers who will do their best to answer your questions.

Contact for further information
Thank you for reading this information sheet and for taking the time to consider our study. If you have any questions or concerns please contact:

Dr Emily Fairclough MRCOG

Clinical research fellow
The Warrell unit, St. Mary's Hospital, Manchester, M13 9WL.
Tel: +44 (0)161 701 6963 Fax: +44 (0)161 276 6143
Email: Emily.Fairclough@cmft.nhs.uk

OR

Dr A Smith MD FRCOG or Dr F Reid MD MCROG

Consultant Urogynaecologists
The Warrell unit, St. Mary's Hospital, Manchester, M13 9WL.
Tel: +44 (0)161 701 6963 Fax: +44 (0)161 276 6143
Email: arbs@dsl.pipex.com and Fiona.Reid@cmft.nhs.uk
Variation of Surgical Technique

Participant information sheet – patients

Investigators: Dr Emily Fairclough, Dr Anthony Smith and Dr Fiona Reid

Variation in the surgical technique:
This research aims to identify how surgical technique in prolapse operations varies and whether that variation in technique affects the surgical outcome.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why have I been chosen and what is the purpose of the study?
We are inviting you to take part in this study because you are having either an anterior or posterior repair; or both.
Pelvic floor prolapse is a very common condition and 28,000 women in England and Wales have a surgical procedure to correct this per year. Unfortunately up to 1 in 3 women may have a recurrence of their prolapse that may need further surgery. We are attempting to find out if there is a best technique to repair prolapse. This study will observe how prolapse repairs are performed. The aim is to look what techniques are being used to repair prolapse across the UK and how technique varies between different surgeons.

Your surgeon is involved in recruiting women into a large randomised controlled trial called PROSPECT. As part of this study the outcome of surgery is being studied. If we identify that there is variation in surgical technique of a prolapse repair we will use the outcomes from the larger trial PROSPECT to see if variation in surgical technique affects the outcome of surgery. If there is no difference this will inform us that all surgeons are providing the best surgery possible. However if the variation in technique affects the outcome it could give us the opportunity to change our practice so all surgeons are providing the best operation possible.

**Do I have to take part?**

No you do not have to take part in the study. Participation is completely voluntary. Whatever your decision the standard of care you receive will be the same. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Taking part in this study will not influence your treatment in anyway.

**If I agree to take part, can I withdraw from the study at any time?**

YES. You can decide to withdraw from the study at any stage without affecting your treatment now or in future and without giving any reason.

**What will happen if I take part?**

You will be asked to complete a consent form prior to your surgery to show you agree to take part in this study. Your surgery will be observed by the researcher and videoed. You will not be identifiable in any way from this video. This study is only observational and aims to document the surgical technique used by your surgeon.
The study will not alter any part of your surgery or care that you have discussed with your surgeon.

**What are the disadvantages and risks of taking part?**
Participation in the research study will extend your preoperative review by approximately 15 minutes, to allow us to complete your consent form.

**What are the possible benefits of taking part?**
There is no direct benefit for you. However, our research will help doctors understand how surgical techniques in the UK vary and if that affects the outcome of surgery for patients. The information collected during this research study could allow us to understand what technique provides the best outcome so that doctors can be sure they are offering the best operation to their patients in the future.

**Will my taking part in the study be kept confidential?**
Any information that is collected about you will be anonymised. This means that when the results are looked at your name will be removed so that you cannot be recognised.

**What will happen to the results of the research study?**
The results will be presented at clinical and scientific meetings and will be published in journals read by doctors who care for women with prolapse. You will not be identified in any of our results.

**Who is organizing the research?**
The research is being organised by the Warrell Unit, St Mary’s Hospital, Manchester.

**Who has reviewed the study?**
The study has been reviewed by the Sunderland Research Ethics Committee, who has given a favorable opinion.
Will I get the results of the research?
The results will be used for research purposes only and will NOT affect your treatment in any way. If you are interested in finding out the scientific results of the study, please contact Dr Emily Fairclough (contact details at bottom of sheet) and we can contact you with information at the end of the study.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact PALS.

Patients Advice and Liaison Service (PALS)
PALS are also able to provide independent advice on any queries or complaints you may have. Please contact 0161 276 8686 or pals@cmft.nhs.uk for the office at the Central Manchester University Hospitals NHS Foundation Trust.

Contact for further information
Thank you for reading this information sheet and for taking the time to consider our study. If you have any questions or concerns please contact:

Dr Emily Fairclough MRCOG
Clinical Research Fellow
The Warrell unit, St. Mary's Hospital, Manchester, M13 9WL.
Tel: +44 (0)161 701 6963Fax: +44 (0)161 276 6143
Email: Emily.fairclough@cmft.nhs.uk

OR

Dr A Smith MD FRCOG or Dr F Reid MD MCROG
Consultant Urogynaecologists
The Warrell unit, St. Mary's Hospital, Manchester, M13 9WL.
Tel: +44 (0)161 701 6963 Fax: +44 (0)161 276 6143
Email: arbs@dsl.pipex.com and Fiona.Reid@cmft.nhs.uk
VaST (Variation of Surgical Technique)

Participant consent form - surgeons

Dr Emily Fairclough, Dr Anthony Smith and Dr Fiona Reid

We would like to invite you to take part in a study: How does the surgical technique of a non-graft pelvic organ prolapse repair vary and does this affect surgical outcome?

1. I confirm that I have read and understand the information sheet dated …/…/…, for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

3. I agree to be interviewed (including audio tape) about surgical technique and for my surgical technique to be observed and filmed with a video recorder.

4. I understand that videos/audiotapes will be analysed to look for themes in variation in surgical technique between different surgeons in the UK.

5. I understand that the outcome data from PROSPECT will be used to identify if a particular technique of non-graft repair improves outcome.

6. I understand all data will be anonymised and confidentiality kept.

7. I understand that the information collected could be presented at clinical or scientific meetings or published in journals.

8. I agree to take part in the study.

<table>
<thead>
<tr>
<th>Name of Participant</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Person taking Consent</td>
<td>Date</td>
<td>Signature</td>
</tr>
</tbody>
</table>

Copies: 1 for participant    1 for researcher
Participant consent form – patients

Dr Emily Fairclough, Dr Anthony Smith and Dr Fiona Reid
We would like to invite you to take part in a study: How does the surgical technique of a prolapse repair vary and does this affect success of surgery?

1. I confirm that I have read and understand the information sheet dated …/…/… and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that my surgery will be video recorded. This is an observational study only and it will not affect my surgery or care in any way.

4. I understand that videos will be analysed by the researcher to look at how surgery is performed. The information or video clips may be used in presentations at clinical or scientific meetings or in medical journals. I understand that I will not be identifiable in anyway from these clips.

5. I understand all data is completely anonymised and all personal information kept confidential.

6. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
7. I agree to take part in the study

Name of Patient          Date          Signature
Name of Person taking Consent Date          Signature
Copies: 1 for patient  1 for researcher  1 to be filed in hospital notes
Appendix 2: Questionnaire based study (Paper 1)

**Standardisation of Surgical Procedures in PROSPECT**

Please complete last column to indicate your own practice when performing prolapse surgery (circle or amend). If you vary your technique, please tell us about the one you use most often.

Name……………………………………………………………………………………………………………………………..
Centre……………………………………………………………………………………………………………………………..

1. Native tissue anterior repair

<table>
<thead>
<tr>
<th>Date:</th>
<th>Procedures</th>
<th>Local practice (variations)</th>
</tr>
</thead>
</table>
| ……/……/20….. | Midline skin incision through fascial layer and dissection of bladder off cervix / vault | Midline incision Other (details)………………
|             |                                                                             | ………
|             |                                                                             | ………………………
|             |                                                                             | ………………………
<table>
<thead>
<tr>
<th>Date:</th>
<th>Procedures</th>
<th>Local practice (variations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>……/……/20…..</td>
<td></td>
<td>Please circle or amend</td>
</tr>
</tbody>
</table>

| +/- Hydrodissection with 1 in 200,000 adrenaline | Yes | No |
| Volume: ...............ml | |

<table>
<thead>
<tr>
<th>Anterior Repair Type 1</th>
<th>Dissect fascia off vaginal epithelium</th>
<th>Blunt dissection?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Sharp dissection?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anterior Repair Type 2</th>
<th>Leave fascia on vaginal skin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dissection laterally (but not all the way to the ‘white line’ and sutures placed into fascia in this area)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2. Native tissue Posterior repair

<table>
<thead>
<tr>
<th>Date:</th>
<th>Procedures</th>
<th>Local practice (variations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>……/……/20…</td>
<td></td>
<td>Please circle or amend</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Midline skin incision through fascial layer</td>
<td>Midline incision</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(details)……………………..</td>
</tr>
<tr>
<td></td>
<td></td>
<td>…………………………......</td>
</tr>
<tr>
<td></td>
<td>+/- Hydrodissection with 1 in 200,000 adrenaline</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Volume: ……………….ml</td>
</tr>
<tr>
<td>Posterior</td>
<td>Dissect fascia off vaginal epithelium</td>
<td>Blunt dissection?</td>
</tr>
<tr>
<td>Repair Type 1</td>
<td></td>
<td>Sharp dissection?</td>
</tr>
<tr>
<td>Posterior Repair Type 2</td>
<td>Leave fascia on vaginal skin</td>
<td>Blunt dissection?</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td></td>
<td>Dissection laterally (but not all the way to the sacrospinous ligament) and sutures placed into fascia in this area</td>
<td>Sharp dissection?</td>
</tr>
<tr>
<td>Rectal plication</td>
<td>Optional</td>
<td>Yes No</td>
</tr>
<tr>
<td>Closure</td>
<td>Fascia and skin closed separately (2-layer closure)</td>
<td>FASCIA</td>
</tr>
<tr>
<td></td>
<td>Plicate fascia over rectum in midline if midline defect? Yes No</td>
<td>PDS or Vicryl?</td>
</tr>
<tr>
<td></td>
<td>Separate closure of other fascial defects? Yes No</td>
<td>Fascial sutures:</td>
</tr>
<tr>
<td></td>
<td>Skin closed</td>
<td>• continuous locking</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• continuous non-locking</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• interrupted?</td>
</tr>
</tbody>
</table>

SKIN
PDS or Vicryl?
Skin sutures:
• Continuous
<table>
<thead>
<tr>
<th>Levator plication in midline</th>
<th>NOT to be done as causes dyspareunia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal examination</td>
<td>PR examination during dissection or after operation to ensure sutures do not penetrate rectal wall</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>
3. **Graft / graft inlay**

<table>
<thead>
<tr>
<th>Date:</th>
<th>Procedures</th>
<th>Local practice (variations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>....../....../20.....</td>
<td></td>
<td>Please circle or amend</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonabsorbable graft</td>
<td>Type:</td>
<td>........................................</td>
</tr>
<tr>
<td>Biological graft</td>
<td>Type:</td>
<td>........................................</td>
</tr>
<tr>
<td>Graft Kit</td>
<td>Type:</td>
<td>........................................</td>
</tr>
<tr>
<td></td>
<td>How many kit procedures have you performed?</td>
<td>&lt;10; 10-20; 20-49; &gt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral dissection of pubocervical fascia from vaginal wall</td>
<td>Separate bladder / rectum from fascia using blunt / sharp dissection +/- Hydrodissection with 1 in 200,000 adrenaline Dissect fascia off vaginal epithelium</td>
<td>Blunt dissection?  Sharp dissection?  Hydrodissection with 1 in 200,000 adrenaline?</td>
</tr>
<tr>
<td>Optional</td>
<td>Dissect out to pelvic side wall (white line or sacrospinous ligament)</td>
<td>Lateral dissection to white line or sacrospinous ligament?</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------------------------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Graft / graft inlay</th>
<th>Cut material to size and lay below fascia (inlay, recommended): OR above fascial layer: Size of graft/graft:</th>
<th>Below fascial layer (INLAY), OR above fascial layer (OVERLAY) Size of graft patch: ………… cm²</th>
<th>Rifampicin? OR Other fluid? .........................</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Optional] soak graft in Rifampicin? OR Other fluid?</td>
<td>ATTACHING THE Graft Fix at least 2 PDS/Vicryl sutures or 2 non-absorbable sutures to pelvic side wall / coccygeus muscle on</td>
<td>PDS to attach graft? Vicryl to attach graft?</td>
<td></td>
</tr>
<tr>
<td>Each side</td>
<td>Non-absorbable suture?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>Attach to white line (ant)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attach to white line or sacrospinous ligament</td>
<td>Attach to sacrospinous ligament (post)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+/- Capio suturing device</td>
<td>Capio suturing device?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. **Graft / graft inlay (continued)**

<table>
<thead>
<tr>
<th>Closure</th>
<th>Two layer closure (PDS or Vicryl):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Fascial sutures inserted back from skin edge over graft/graft (INLAY)</td>
</tr>
<tr>
<td></td>
<td>2. Skin closed as second layer (OVERLAY)</td>
</tr>
</tbody>
</table>

| FASCIA | |
|--------| |
| PDS or Vicryl? |
| Fascial sutures: |
| • continuous locking |
| • continuous non-locking |
| • interrupted? |

| SKIN | |
|------| |
| PDS or Vicryl? |
| Skin sutures: |
| • continuous locking |
| • Continuous non-locking |
| • interrupted? |
4. Vaginal packs and lubricants

<table>
<thead>
<tr>
<th>Date:</th>
<th>Procedures</th>
<th>Local practice (variations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>……/……/20…..</td>
<td></td>
<td>Please circle or amend</td>
</tr>
<tr>
<td>Vaginal pack used for up to 24 hours</td>
<td>Yes No</td>
<td></td>
</tr>
<tr>
<td>(If yes) Lubricated?</td>
<td></td>
<td>Oestrogen Proflavine Betadine Dalacin Hibitane Obstetric cream Saline Savlon Aquagel Dry pack</td>
</tr>
</tbody>
</table>
5. POP-Q native tissue

<table>
<thead>
<tr>
<th>Position</th>
<th>Recommended</th>
<th>Local practice (variations)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lithotomy / in leg rests</td>
<td>Lithotomy / in leg rests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>On back on flat bed or table</td>
</tr>
<tr>
<td></td>
<td></td>
<td>On side</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Standing up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In theatre / under anaesthetic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sims speculum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plastic speculum (halved)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
</tr>
<tr>
<td>Conditions</td>
<td>Bladder status not specified but recorded</td>
<td>Full bladder</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Empty bladder</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not specified but</td>
</tr>
<tr>
<td></td>
<td></td>
<td>recorded</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bladder status not</td>
</tr>
<tr>
<td></td>
<td></td>
<td>assessed</td>
</tr>
<tr>
<td>Bowel loading recorded</td>
<td></td>
<td>Bowel loading recorded</td>
</tr>
<tr>
<td>Full extent of prolapse seen?</td>
<td></td>
<td>Bowel loading not</td>
</tr>
<tr>
<td></td>
<td></td>
<td>recorded</td>
</tr>
<tr>
<td>During Valsalva / pushing down</td>
<td></td>
<td>Full extent recorded</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Full extent not</td>
</tr>
<tr>
<td></td>
<td></td>
<td>recorded</td>
</tr>
<tr>
<td>Ruler / measuring stick</td>
<td></td>
<td>At rest</td>
</tr>
<tr>
<td></td>
<td></td>
<td>During Valsalva /</td>
</tr>
<tr>
<td></td>
<td></td>
<td>pushing down</td>
</tr>
<tr>
<td></td>
<td></td>
<td>During cough</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ruler / measuring stick</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Finger measure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estimate by eye</td>
</tr>
</tbody>
</table>