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**SCHOOL OF MEDICINE**

**3-DIMENSIONAL ULTRASOUND IN THE EVALUATION OF  
FEMALE PELVIC ORGAN PROLAPSE OF THE POSTERIOR  
COMPARTMENT.**

**Thesis submitted by**

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In 25 February 2014

For the degree of Doctor of Philosophy  
in the School of Medicine at  
James Cook University

## DECLARATION

I declare that this thesis is my own work and has not been submitted in any other form for any other degree or diploma at any University or other institution of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text and a list of references is given.

C. L. Barry  
25 February 2014

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## ABSTRACT

Studies in the USA suggest that approximately 1 in 9 women will require an operation for pelvic organ prolapse (POP) by the age of 80, and of significant concern is that up to 30% of these women will require re-operation. This implies that either our assessment or our treatment of POP is unsatisfactory. Comparison of therapeutic interventions in the research setting has been difficult due to a lack of standardisation of assessment. Most clinical methods to quantify POP have not been rigorously tested. In an attempt to standardise the assessment of pelvic organ descent a pelvic organ prolapse quantification system (POPQ) has been developed, which has been validated for reliability and reproducibility. However, only 40% of clinicians who have a special interest in urogynaecology actually utilise this system in routine clinical practice. In addition it has been difficult to quantify defects of the lateral vaginal support mechanisms.

The place of two-dimensional ultrasound for the investigation and management of women with gynaecological problems is now well established. Both transabdominal and transvaginal scanning permit the identification of the uterus and adnexae with excellent resolution to more accurately direct appropriate management. However transabdominal ultrasonography provides poor imaging of the lower pelvic structures, due to the depth of the tissues from the transducer. Transvaginal ultrasound permits excellent visualisation of the bladder, urethra and the posterior compartment but distorts the pelvis thereby precluding accurate assessment of POP. Transperineal ultrasonography avoids these problems. Ultrasonography may therefore improve assessment for both clinical and research purposes by adding a further objective measuring system to vaginal examination. The addition of three-dimensional ultrasonography provides the opportunity for visualisation of the axial plane of the pelvis (the third dimension), the ability to store volumes of data (data as opposed to images are stored) and therefore allow offline, independent audit by remote observers.

The objective of this thesis was to study the use of 3-dimensional ultrasonography in the investigation of disorders of the posterior compartment of the vagina. The initial experiment was designed to obtain normal values for the incidence and measurement of rectocele prolapse and other posterior compartment defects of the rectovaginal septum, descent of the perineum of the pelvis, and measurements of the levator hiatus. After initial training in the technique and confirmation of the

protocol, a test-retest series together with intraclass correlation test was undertaken in 12 women who were undergoing objective measurements for suburethral sling position, as part of a large, randomised sub-urethral sling outcome study and in whom it was clinically noted that they had at least a grade 2 (Baden-Walker grading system) rectocele prolapse. This first experiment confirmed the reliability of measurements with intraclass correlation (ICC) of between 0.68 and 0.79 between observation measurements and test-retest series of between 0.72 and 0.84. Mean depth of defects was 1.45cm, width 0.95cm with a mean perineal excursion of 0.46cm. Mean levator area dimensions increased from 15.6cm<sup>2</sup> to 28.4cm<sup>2</sup>. The technique was therefore felt to be reliable enough for the following experiments.

Ninety-seven nulliparous women then underwent the same standardised technique and methodology of ultrasound evaluation. Eighty-nine datasets were available for analysis. Results demonstrated a wide variation of dimensions for levator hiatal diameters and area at rest and on straining. Rectocele protrusions were seen in 11 women (12%), 10 women had protrusions less than 1cm in depth. Median depth was 0.69cm (SD 0.3), width 0.45cm (SD 0.3). There was no correlation with bowel symptoms ( $p=0.12$  ANOVA). Levator area ranged from a mean 17.76cm<sup>2</sup> at rest to 20.9cm<sup>2</sup> on strain. Again the technique seemed reliable and confirmed in a nulliparous population the presence of congenital or acquired rectocele defects.

Having obtained normal values in this control population and confirmed the methodology, the same methods were applied to 82 women who had undergone a standardised surgical repair of a rectocele with mesh overlay, to assess the technique as an objective audit tool. Comparisons were made with clinical evaluation and symptomatology using two-sample t-test and Pearson correlation. Seventy-one datasets were available. Average duration following surgery was 0.7 years. Clinical evaluation revealed recurrence in 4 women (5.6%), while on ultrasound (US), 16 women (23%) had recurrence. Most of the defects seen on US were small and less than 1 cm. Mean depth of rectocele was 0.92cm (SD 0.2), width 1.56cm (SD 0.35). There was no correlation with bowel symptoms ( $p=0.477$  two-sample t-test), but a moderate negative correlation with descent of the rectal ampulla and levator hiatal area on strain ( $r= -0.428$ ,  $p=0.002$ ). In addition there was an association between a larger levator hiatal area and who on ultrasound had evidence of a recurrence of a defect ( $p=0.031$ ) as well as recurrence clinically but less so ( $p=0.067$ ). This would suggest identification of defects was more common with ultrasound but correlation with post-operative symptomatology was poor. This

may relate to the depth of the rectocele recurrence which were mostly less than 1cm, and therefore below the threshold for symptoms. There was however a trend noted between failure of surgery and increased levator hiatal dimensions on straining.

In view of the reproducibility and reliability of the techniques a further experiment was undertaken to compare US against Magnetic Resonance Imaging (MRI). Eleven women with rectocele prolapse underwent 3D US evaluation and rapid sequence MRI scans using T2 image acquisition at rest and on straining. Intra-class correlation using dot-plots were analysed for all the measurements. Women underwent examination using the POPQ scoring system. Pre-op  $A_p$  was 0.2cm (SD 1.2),  $B_p$  was -0.3cm (SD 1.4), and overall clinical grading was 2. US was significantly better at diagnosing enterocele prolapse versus clinical ( $p=0.3$ ) but less so MRI ( $p=0.11$ ). There was no correlation between symptoms and rectocele parameters on either MRI nor US. Correlation between US and MRI for all levator dimensions and rectocele measurements was poor precluding formal analysis. ICC was also poor at 0.485 for levator area at rest and 0.16 for levator area on strain. This study found poor correlation between the two techniques, however small numbers were involved in a group of women with multiple compartmental prolapse.

To test 3D US prospectively, 33 women with a diagnosis of rectocele awaiting surgery were recruited and prospective data gathered on ultrasound parameters, POPQ and symptoms. Twenty-nine datasets were available for analysis. Mean age was 59 years and average ordinal staging was 2 with point  $B_p$  was 0. All women had fascial repair and composite mesh graft. Enterocele prolapse was again diagnosed more commonly on US than clinically (3 vs. 1). All symptoms improved with surgery. However again there was poor correlation between clinical measurements, ultrasound quantification and symptomatology in relation to successful treatment. Although there was a trend towards more accurate diagnosis of enterocele with ultrasound as defined by surgical staging this did not reach statistical significance.

Why is there such a poor correlation between symptoms and both clinical and ultrasound findings. This may relate to the complex interaction between rectal function, neurological damage and prolapse of the vagina. It is proposed that larger studies be conducted to further identify the place of ultrasonography and assessment of POP in women and in particular the pre-operative factors that may influence outcome.

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### PRESENTATIONS OF RESEARCH TO LEARNED SOCIETIES

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Finding the Flaws in the Floor. Keynote speaker RANZCOG ASM Hobart 2005  
The use of 3D US for imaging abnormalities of the female pelvis.

3D ultrasonography- imaging to guide the pelvic surgeon- results from a prospective study of 3D US versus clinical assessment for outcome related to rectocele repair. Annual CFA (Continence Foundation of Australia) meeting 2005.



## ACKNOWLEDGEMENTS

I would like to thank Professor Roger Soames and Professor Yik-Hong Ho for their kind support, work and guidance throughout this study.

Dr Hans Peter Dietz for his patience, inspiration and continuing support and advice on ultrasonography techniques and guidance for experimental studies.

I would like to thank Prof Ajay Rane for his inspiration and access to clinical subjects.

I would like to thank James Cook University for providing logistical support in the form of use of the ultrasound equipment for the project.

For their individual contributions during this period of clinical research I would also like to thank:

Professor Richard Hays for his encouragement and enthusiasm as well as his practical advice for organising the thesis

Assoc. Professor Reinhold Muller for guiding me through the interpretation of statistical data

Ms Sarah Hitchins for providing clerical support in contacting and co-ordinating women to participate in the studies.

Dr Sandeep Bhuta for helping me with the interpretation and measurement of MRI data.

All the nursing and midwifery support for their help in providing information to women seeking to participate in the study.

My wife Alison for her patience and support

My children Patrick and Nicholas

## ABBREVIATIONS

|       |   |
|-------|---|
| DCP   | Defaecating cystoproctography   |
| FDP   | Fluoroscopic defaecating proctography                                 |
| ICS   | International Continence Society                                      |
| MR    | Magnetic resonance  |
| MRI   | Magnetic resonance imaging  |
| OAB   | Overactive Bladder  |
| POP   | Pelvic organ prolapse   |
| POPQ  | Pelvic organ prolapse quantification- a system for measuring prolapse |
| QoL   | Quality of life   |
| UI    | urinary incontinence  |
| US    | ultrasonography   |
| 3D    | 3 dimensional   |
| 4D    | 4 dimensional   |
| ICC   | Intraclass correlation coefficient                                    |
| ANOVA | Analysis of Variance  |
| SP    | symphysis pubis   |
| 2D    | 2 dimensional   |
| CT    | Computerised Tomography   |
| SD    | standard deviation  |
| AP    | anteroposterior   |
| TD    | transverse diameter   |
|       |   |

## OVERVIEW

### Aim.

Does three-dimensional ultrasonography of the pelvis provide useful information in the evaluation of pelvic floor prolapse in women?

To help answer this question the following questions will be addressed:

1. Can 3-dimensional ultrasound accurately measure the variables listed while performing dynamic imaging of the pelvis compared to magnetic resonance imaging, the gold standard?
  - a. size of prolapse of the posterior compartment, including depth and width
  - b. location of defect
  - c. mobility of prolapse
  - d. levator hiatal dimensions
2. If 3-dimensional ultrasound is reproducible as clinical assessment measurement techniques, then does it correlate better with clinical symptoms than current clinical methods of evaluation?

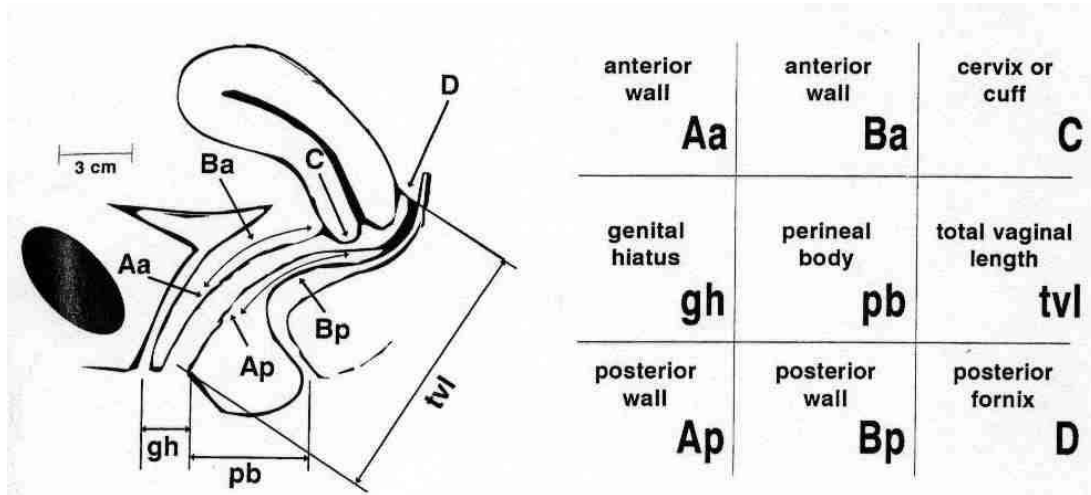
**Background.** This thesis has been undertaken by frustration at the lack of scientific evidence for the correct management of pelvic organ prolapse, especially in relation to the appropriate surgical techniques for repair of the posterior compartment of the vagina.



**Figure 0.1** Why women need to have optimal assessment and treatment based on validated assessment and treatment. Personal files.

Studies in the United States of America have suggested that 1 in 9 women will require an operation for pelvic organ prolapse (POP) by the age of 80, and of significant concern is that up to 30% of these women will require re-operation (Olsen, et al. 1997). This would suggest that either the assessment is less than satisfactory, or treatment is unsatisfactory. Success rates of between 70 and 100% have been reported in the literature for repair of rectocele (Arnold, et al. 1990, Kahn and Stanton 1997, Kenton, et al. 1997, Lopez, et al. 2001, Mellgren, et al. 1995). There is a significant discrepancy between studies, which relates to different clinical assessments and outcome parameters. When individual symptoms are sub-analysed then the disparity increases.

Comparison of treatments in the research setting has been difficult due to a lack of standardisation of assessment methods. Initial attempts to quantify POP using clinical assessment utilized the Baden-Walker classification system (Baden and Walker 1992), which allowed the degree of POP to be described and documented as a grading scale of I-IV but which was never validated for its reproducibility. In an attempt to standardise the assessment of pelvic organ descent a pelvic organ prolapse quantification system (POPQ) (Fig 0.2) (Bump, et al. 1996) has been developed, which has been validated for both intra- and inter-observer reliability (Hall, et al. 1996), and adopted by the International Continence Society (ICS) (Weber, et al. 2001). However, in a recent study it was suggested that only 40% of clinicians who have an interest in urogynaecology actually utilise this system on a routine basis, as it is considered by some to be clumsy to use (Auwad 2004). In addition this system does not address potential defects of the lateral vaginal support mechanisms, which may or may not be important in the pathogenesis of pelvic organ prolapse (Miklos and Kohli 2000, Shull and Baden 1989).



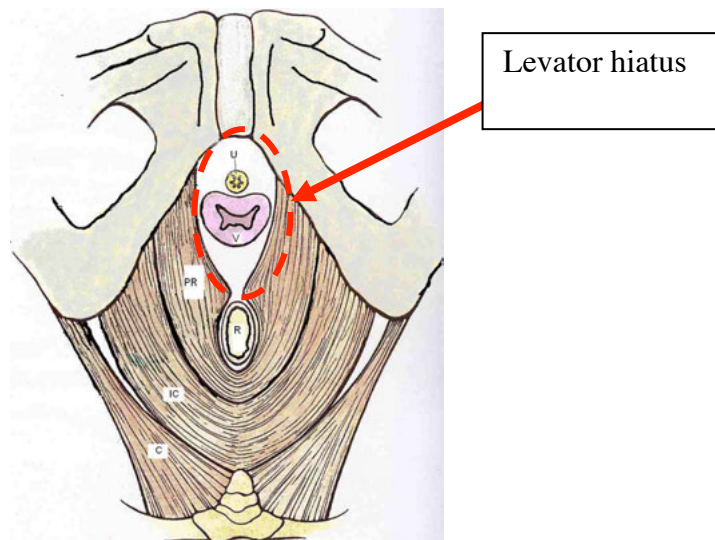
**Figure 0.2** POPQ (ICS) measurement scheme for POP. Reproduced with permission (Hall, et al. 1996).

Three-dimensional ultrasonography may permit the study of anatomical changes of the female pelvis and thereby provide an investigative method, which may correlate better with both clinical symptoms and objective outcome, as compared to currently available methods.

The place of two-dimensional ultrasound in the investigation and management of women with gynaecological problems is now well established. Both transabdominal and transvaginal scanning permit identification of the uterus and adnexae with excellent resolution to direct appropriate management. However transabdominal ultrasonography provides poor imaging of the lower pelvic structures, particularly the support structures of the vagina and levator muscle group, due to the depth of the tissues from the transducer. Transvaginal ultrasound permits excellent visualisation of the bladder, urethra and the posterior compartment but distorts the pelvis thereby precluding accurate assessment of POP (Quinn, et al. 1988). In an attempt to overcome this investigators have utilised transintroital (Tunn and Petri 2003), transperineal and translabial ultrasonography (Khullar and Cardozo 1998, Koelbl, et

al. 1988). Information can be obtained with no discomfort to the patient as part of a routine pelvic examination. It is therefore possible to improve the understanding of POP using transperineal ultrasound for both clinical and research purposes by providing an alternative objective measuring system to the ICS POPQ system. The addition of three-dimensional ultrasonography provides the opportunity for visualisation of the axial plane of the pelvis, improved data storage and therefore independent audit.

Three-dimensional ultrasonography has lagged behind imaging modalities such as computed tomography and magnetic resonance imaging. Substantial improvements in three-dimensional ultrasound have developed in the last 13 years, as a result of improved mechanised sector transducers and computer software. For the first time this allows a relatively simple and easy to use technique for the dynamic evaluation of the female lower pelvis, with reasonable resolution in the axial plane. Deeper structures of the pelvis can be assessed, such as the muscles of the levator hiatus and its fascial attachment, that are not visible on routine clinical examination. A diagrammatic representation of the area of the female pelvis of interest is shown in Figure 0.3.

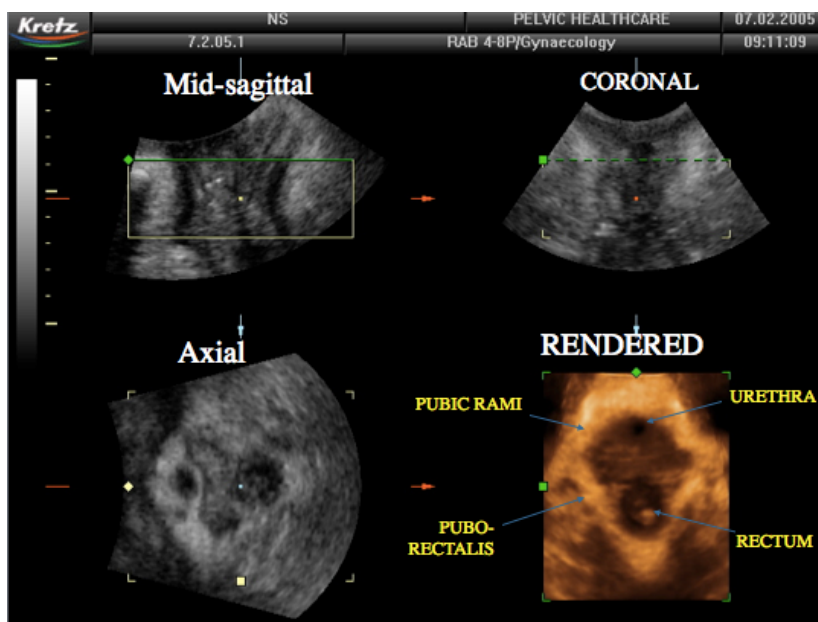


**Figure 0.3** Diagrammatic drawing of transverse plane of female pelvis demonstrating the levator hiatus from an inferior view. The red circle indicates the area of interest visualised on imaging. IC (Iliococcygeus); PR (Puborectalis); C (Coccygeus); U (Urethra); V (Vagina); R (Rectum.) Adapted with permission from Dalley and Moore: Clinical Orientated Anatomy. 4th Ed. p156.

The posterior compartment of the female pelvis is subject to structural changes resulting from a number of factors, including childbirth, ageing, collagen abnormalities, co-morbidities such as obesity and smoking-related diseases as well as hormonal changes. The relative contribution of each factor is not known. In addition it is not clear why some women are affected by these factors and some are not. Do structural changes in the support mechanisms of the posterior female pelvic compartment lead to functional bowel or vaginal symptoms? This is also not clear. Are surgical treatments correctly dealing with both anatomical and functional changes? None of these questions have been adequately addressed in the literature.

Anatomical changes are the final consequences of these other influences. If specific changes to support structures can be identified this may provide clues as to the

relative contributions of each of these factors. The anatomical structures encompassing and supporting the vagina may now be assessable, allowing morphometric and biomechanical changes of the levator hiatus to be studied using 3-dimensional ultrasonography. Postpartum assessment as well as the effect of biomechanics, fascial tissue differences, lifestyle factors, and surgical techniques as factors influencing surgical outcome. Figure 0.4 gives an example of the image acquisition in all 3 planes using 3-dimensional volume acquisition in ultrasonography. A better understanding of the use of this imaging modality will lead on to further research in this poorly understood area and thus attempt to resolve some of the dilemmas in terms of standardising clinical assessment, so that reliable and scientific comparisons of treatment options become available. I also wish to test whether this technology compares with measurements obtained and symptoms of pelvic organ prolapse/ dysfunction obtained through other imaging modalities.



**Figure 0.4** Bitmap image of a volume of data stored using 3-dimensional ultrasonography of the female pelvis at rest. The bottom right image is the rendered image, i.e. a computer derived 3D impression. (Personal files)



## **Clinical Significance and Outcomes**

These are the clinical outcome measures that may result in publication of the studies listed above and become incorporated into mainstream clinical practice to improve outcomes for women.

Outcome A A method of independent, objective audit of surgeon's results for the purposes of clinical governance.

Outcome B Independent audit of scientific data on surgical outcomes to strengthen research conclusions.

Outcome C Improvements in pre-operative assessment to lower surgical morbidity.

Outcome D Identify women at greater risk of pelvic floor dysfunction prior to going through vaginal childbirth, to offer preventative strategies.

## **Support**

The main financial cost of the thesis involved the cost of the ultrasound equipment. This was obtained with the help of a research grant. Other costs include stationary and consumables have been resourced separately through the Pelvic Health Care fund. Administrative assistance is available through the generous support of the School of Medicine, by way of funding for 3 years for a research assistant. Ethics committee approval was obtained through the Townsville Hospital and Queensland Health for all the studies.

These studies were based on initial studies using data collected during ultrasound assessment of women who had undergone insertion of the sub-urethral sling for urinary incontinence to identify its biomechanics. Based on this work it was noted that visualisation of the posterior compartment appeared to correlate subjectively with the outcome of posterior vaginal prolapse surgery. It was therefore thought that it may have a role in the assessment of structural changes of the female pelvis.

## **Personal Development**

By undertaking this thesis I wish to understand the methodology of research techniques as well as answer the question that has been posed.

## **HYPOTHESIS.**

This study aims to test the following hypotheses.

1. Three dimensional US is a reliable and reproducible technique to identify and quantify the severity of rectoceles as well as measure levator hiatus dimensions for the posterior compartment.

2. Three-dimensional US can be used for the identification of posterior compartment defects and quantification of levator hiatus dimensions in a control population of primiparous women.

3. Three-dimensional US can be used as an independent measurement tool in the assessment of posterior compartment prolapse.

4. Three-dimensional US correlates as well as magnetic resonance imaging for dynamic imaging of the pelvic floor.

5. Three-dimensional US is better at predicting findings at surgery than clinical examination alone in women with pelvic organ prolapse.

## **CHAPTER 1**

### **LITERATURE REVIEW**

#### **1.1 INTRODUCTION**

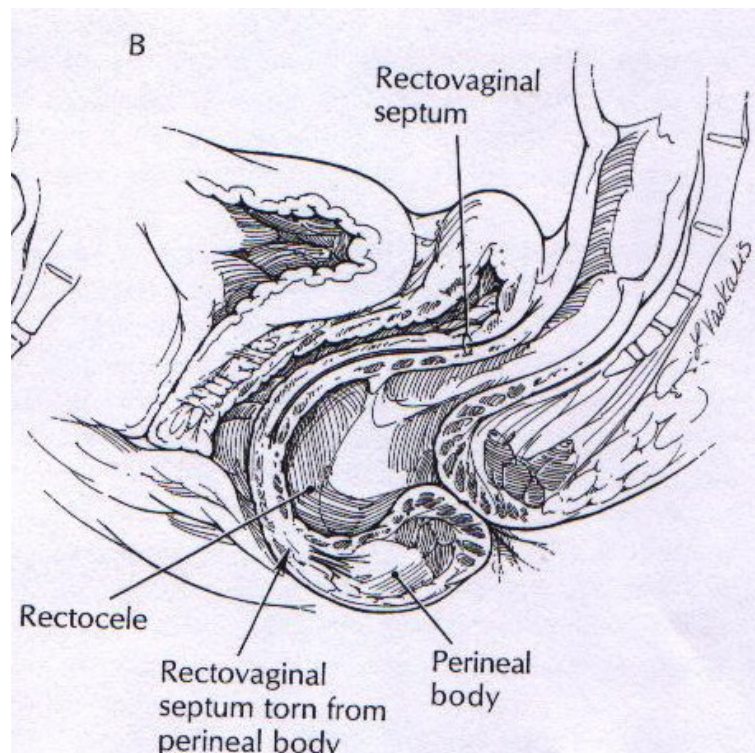
This review was undertaken to provide a thorough understanding of the literature pertaining to the anatomy and imaging of the posterior compartment of the female pelvic floor, which is an integral part of this thesis. In addition I have identified publications relevant to imaging of this area of the female pelvis, to provide comprehensive information of all aspects of assessment of pelvic organ prolapse, and confirm that the work that I propose is original.

In order to do this I identified all the English-speaking textbooks relevant to the subject material. A search was then undertaken using electronic Medline facilities through the Pub Med NCHI web portal, from 1966–2013, for all articles pertaining to the following search terms using the MESH database of keywords. These included; pelvic organ prolapse, rectocele, surgery, imaging, ultrasound, 3 dimensional ultrasound, pregnancy, MRI, magnetic resonance imaging, evacuatory proctography, defaecating proctography, dynamic cystoproctography, clinical examination, incontinence (urinary and faecal), pelvic organ prolapse quantification (POPQ), and female. In total 1789 references have been filed into Endnote, the electronic database reference manager. Further hand searches were made of review articles to identify missing references and all journals, which may contain relevant articles but which were not referenced on the Medline database.

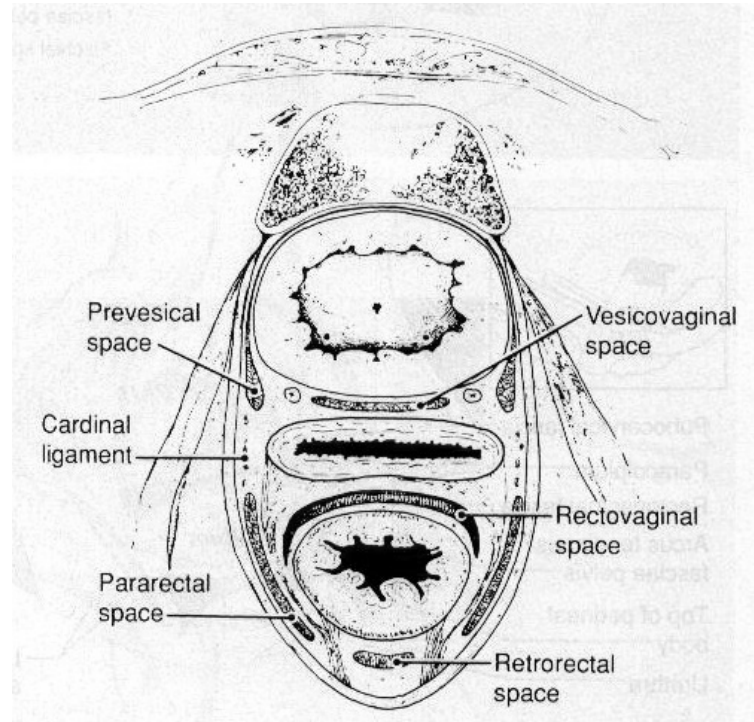
#### **1.2 Review of anatomy of the posterior compartment of the female pelvis**

The posterior compartment of the female pelvis is bounded anteriorly by the vaginal wall, caudally by the perineal body, cranially by the vaginal vault and lower extremity of the pouch of Douglas, with the muscular pelvic floor providing the deep ventral boundary of the compartment. Within it is contained the rectum and caudally the anus. Laterally the posterior compartment is formed by the pararectal space, which contains loose areolar tissue, and in turn is bounded laterally by the continuation of the levator ani, which covers the lateral aspects of the pelvic floor. The anatomy is

illustrated in Figures 1.1 and 1.2. The lateral boundaries consist of the iliopectineal line of the ischium of the bony pelvis, which extends down to the ischial tuberosities laterally, and progress anteriorly to form the pubic rami of the pubic bone. Posteriorly the compartment is enclosed by the sacrum and coccyx.



**Figure 1.1.** Mid-sagittal view of the posterior compartment. Reproduced with permission Chapter 11, p260 (Nichols and Randall 1996).



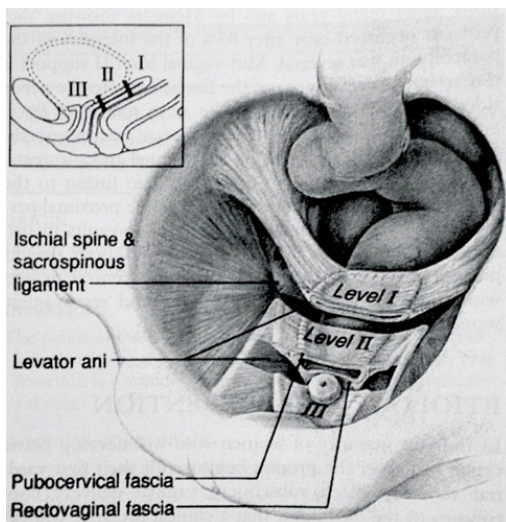
**Figure 1.2.** Axial view at the level of the upper-vagina. Reproduced with permission and adapted chapter 1, p 31(Nichols and Randall 1996).

The rectovaginal septum is a distinct fibromuscular elastic tissue septum, which is fused to the under surface of the muscularis of the posterior vaginal wall. It therefore demarcates the anterior aspect of the posterior vaginal compartment. It has also been described as the anterior layer of Denonvilliers fascia (Tobin and Benjamin 1945): there is sufficient cadaveric evidence clearly identifying the existence of this particular fascia (Milley and Nichols 1969). It appears to form by peritoneal fusion and extends from the peritoneal pouch created by the Pouch of Douglas to the proximal edge of the perineal body. It provides a clear demarcation point, as it is the upper part for fixation of the perineal body, which therefore provides the start of the inferior margin of the posterior compartment. It is therefore crucial not only for stability of this portion of the vagina but is also likely to be the area of weakness through which a hernia defect, such as a rectocele, can occur.

Histologically the septum consists of a fibromuscular elastic layer of dense collagen with abundant smooth muscle and coarse elastic fibres (Milley and Nichols 1969). Embryologically this area becomes fused as the cloacal area of the embryo forms. Its strength not only prevents herniation into the vagina but may also be important for normal defaecation. Defects may arise in the septum as a result of congenital or

acquired defects. Laterally the rectovaginal septum coalesces with the parietal endopelvic fascia.

The vagina itself is a distensible, hollow structure, approximately 10 cm in length and changes shape from its distal to the proximal ends. This change in cross-section shape is related to the different support structures of the vagina, and is considered to be at three different levels (DeLancey 1992), (Figure 1.3). The anterior wall of the vagina is slightly shorter being approximately 7.5cm, compared to the posterior wall, which is approximately 9cm; its width increases as it ascends. The upper part of the vagina attaches and becomes confluent with the cervix uteri approximately one third of the distance from the external to the internal os of the cervix. Its lower margin comes from the remnants of the hymen, which demarcates it from the vulva where it continues as the vestibule of the vulva.



**Fig 1.3.** Three levels of support of the vagina with divisions of attachments at level I, II and III, Anatomic aspects of vaginal eversion after hysterectomy. *American Journal of Obstetrics and Gynecology* 166: 1718. Reproduced with permission (DeLancey 1992)

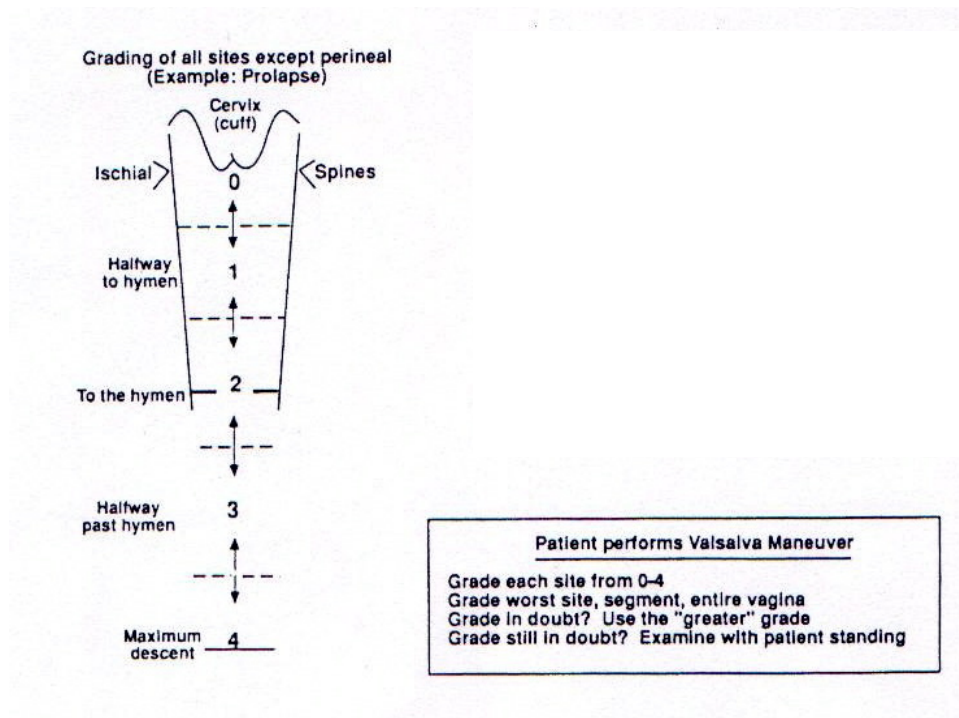
The vestibule separates the vaginal orifice from the labia minora, which are two folds of cutaneous epithelium that are devoid of fat. The vagina extends posterosuperiorly but is deflected where it is attached to levator ani creating an angle of approximately 120-130°. The shape of the vagina in the transverse plane can be described as an H-shape or W-shape due to the convex indentation both anteriorly, posteriorly and laterally. This is caused by the nature of the support structures and the impression of the visceral organs, i.e. bladder, urethra, rectum and anal canal. In addition, fat deposits laterally may lead to further bulging of the lateral walls into the cavity of the vagina. Anterolaterally and posterolaterally these form ridges or sulci which at the upper half of the vagina carry on to form small recesses known as the anterior and

posterior fornices of the vagina. The upper part of the vagina is more capacious as the distal third is narrowed by the levator ani, which tends to compress the vagina against the urethra and pubic bone.

The lower third of the vagina is fused anteriorly with the urethra, posteriorly with the perineal body and laterally to the levator ani. In the middle third it attaches to the bladder neck and bladder base anteriorly, with the rectum posteriorly and is continuous laterally with levator ani (DeLancey 1990). The upper third of the anterior vagina is adjacent to the bladder and ureters, posteriorly is the pouch of Douglas, and laterally the cardinal ligaments of the vagina.

### **1.3 Clinical assessment of pelvic organ prolapse (POP)**

There have always been concerns about how to standardise the assessment of pelvic organ prolapse (POP) to quantify defects of the female pelvic floor and therefore adequately compare results for treatment for these defects. The advantage of such a system would be to communicate easily and effectively between clinicians to adequately describe anatomic position of the pelvic organs, thereby not only allowing comparison of the success of treatment but also give some insight into the aetiology of pelvic organ prolapse. Attempts have been made to use scoring systems to quantify pelvic organ prolapse. Traditional teaching suggests the use of the terms mild, moderate and severe to assess the degree of prolapse. Although simple to use such a system has never been tested for intra-observer or inter-observer variation and reproducibility. The Baden-Walker Half Way classification of vaginal defects (Baden and Walker 1992), at least offers an attempt to define numerically the position and thereby the extent of POP, and can be applied to all three compartments of the female pelvis (anterior, central and posterior). It uses a mid-sagittal grading system of I, II, III and IV. This is assessed at 6 points, two on the anterior vaginal wall, two at the cervix or pericervical cuff of the vagina (in the absence of the uterus) and two on the posterior wall. It is defined as follows: On maximal straining the leading edge of the prolapsed wall or organ is measured from the hymenal ring. Using a measuring system whereby a negative sign indicates distance within the vagina and a positive sign a distance outside the vagina, with the hymen being 0 centimetres, Grade 1 is descent to -1 from the hymenal ring, Grade II to the hymenal ring, Grade III is  $>+1$  to the hymenal ring, and Grade 4 complete eversion. A positive sign indicates a more distal prolapse. This is illustrated in Figure 1.4.



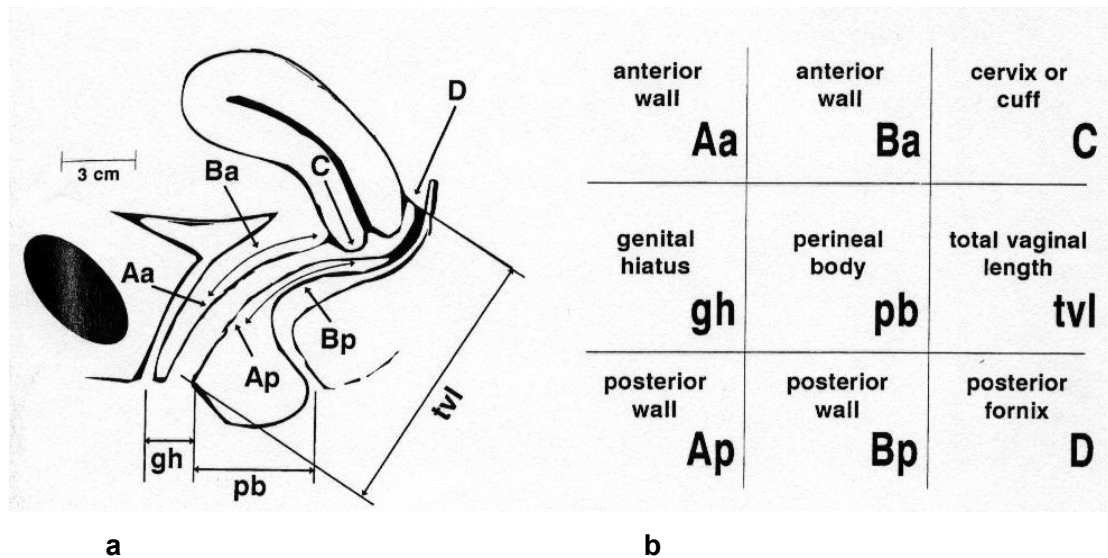
**Figure 1.4.** Baden-Walker grading system for pelvic organ prolapse. Reproduced with permission from Te Lind's Operative Gynaecology 9<sup>th</sup> Ed Chapter 35; 940, Chapter editor, Zimmerman (Rock and Jones 2003).

There are however several limitations to this assessment system. Firstly, it has never been validated; i.e. intra and inter observer variation of measurements: secondly it does not describe the axial or coronal plane but simply refers to mid-sagittal plane. It provides no assessment of vaginal length, paravaginal sulci, nor does it describe the ordinal point of the vagina that is lowest and does not include a description of the variability in vaginal wall elasticity. There is no attempt to precisely define the area of the defect.

In an attempt to improve pelvic organ prolapse quantification to aid research, the International Continence Society and American Urogynecological Society, as well as the Society of Gynaecological Surgeons, devised a method quantifying female pelvic organ prolapse and pelvic dysfunction. It is intended to be an objective site-specific system for describing, quantifying and staging pelvic support and position of the vagina. These measurements have been validated in a number of multicentre, international studies, and to date provides the only validated, clinical quantification of prolapse (Abrams, et al. 2002, Bump, et al. 1996). Figure 1.5 illustrates the points on



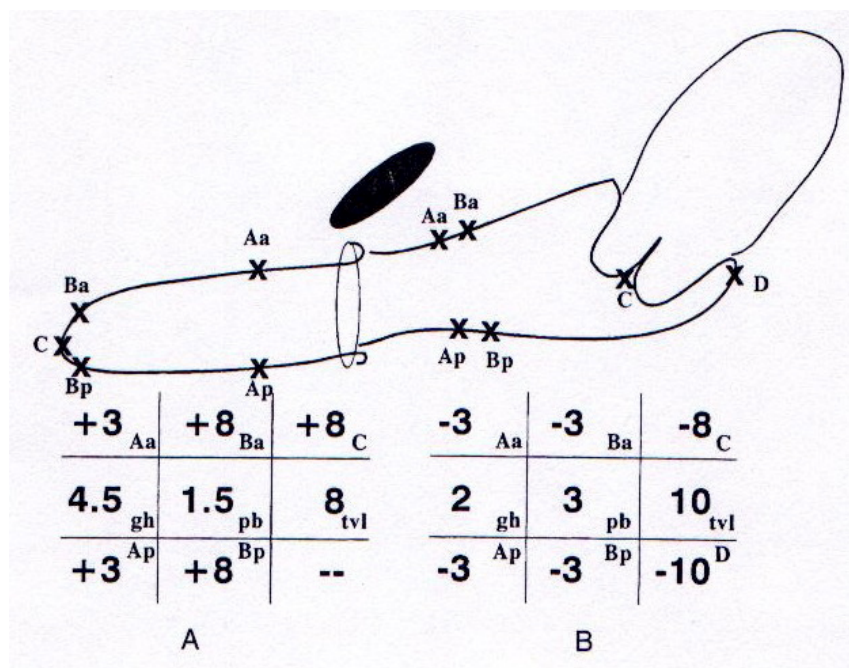
the vagina, which are used as co-ordinates for the measurement system of the POPQ.



**Figure 1.5.** ICS POPQ. a) Identifies points of reference on the vagina. b) how these results are tabulated.  $A_a$  indicates a point 3cm cranial to the hymen on the anterior vaginal wall, corresponding to the urethra-vesical junction;  $B_a$  is the point on the anterior vaginal wall which is the most caudal on straining; C is the anterior fornix of the vagina or most anterior portion of the cervix; gh is the genital hiatus; pb perineal body length; tvL total vaginal length;  $A_p$  point on posterior wall normally 3cm cranial to hymen;  $B_p$  is the point on the posterior vaginal wall which is the most caudal on straining; D only present with cervix present is posterior fornix. Reproduced with permission American Journal Obstetrics Gynecology 1996; 174:10 (Bump et al 1996).

The basis of the system is that reference points in the vagina are utilised to identify specific sites, to indicate descent in the mid-sagittal plane, with the level of the hymen used as the reference point and nominated as station zero. In addition the genital hiatal dimensions, perineal body length (anteroposterior in anatomical position) and perineal movement are also added. Measurements of total vaginal length, anterior and posterior wall descent, if they are both present are undertaken at rest and on maximal straining. An example of these measurements is shown in severe prolapse of the vaginal vault Figure 1.6. As compared to the Baden-Walker system where proportions are used to measure descent, there is a continuum of measurements taken in centimetres. Several papers have provided evidence validating the technique (Bland, et al. 1999, Hall, et al. 1996, Kobak, et al. 1996). Both inter-observer and intra-observer validation demonstrate high levels of concordance using Spearman's

rank correlation and tau B coefficient of correlation. In the study by Hall et al correlations of inter-observer reliability for each of the nine measurements were highly significant (rs 0.5- 0.89, p = 0.0008). Staging and sub-staging were also highly reproducible (tau b 0.702 and 0.652). In the same study of intra-observer reliability, 25 subjects were used and correlations for each of the nine measurements were equally strong (rs 0.69- 0.93). These examinations were all undertaken with the patient supine. Measurements in upright examinations were also highly reproducible (tau b 0.712 and 0.712). Therefore it would seem to be a reliable method of assessment for mid-sagittal, ordinal quantification of vaginal position relative to its normal intra-corporeal location.



**Figure 1.6.** An example of POPQ assessment of severe prolapse. This schematic drawing represents a mid-sagittal map with co-ordinates defined by crosses and described in numerical terms to define the severity of the prolapse. Adapted from Bump RC et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Reprinted with permission (Am J Obstet Gynecol 1996; 175:10)

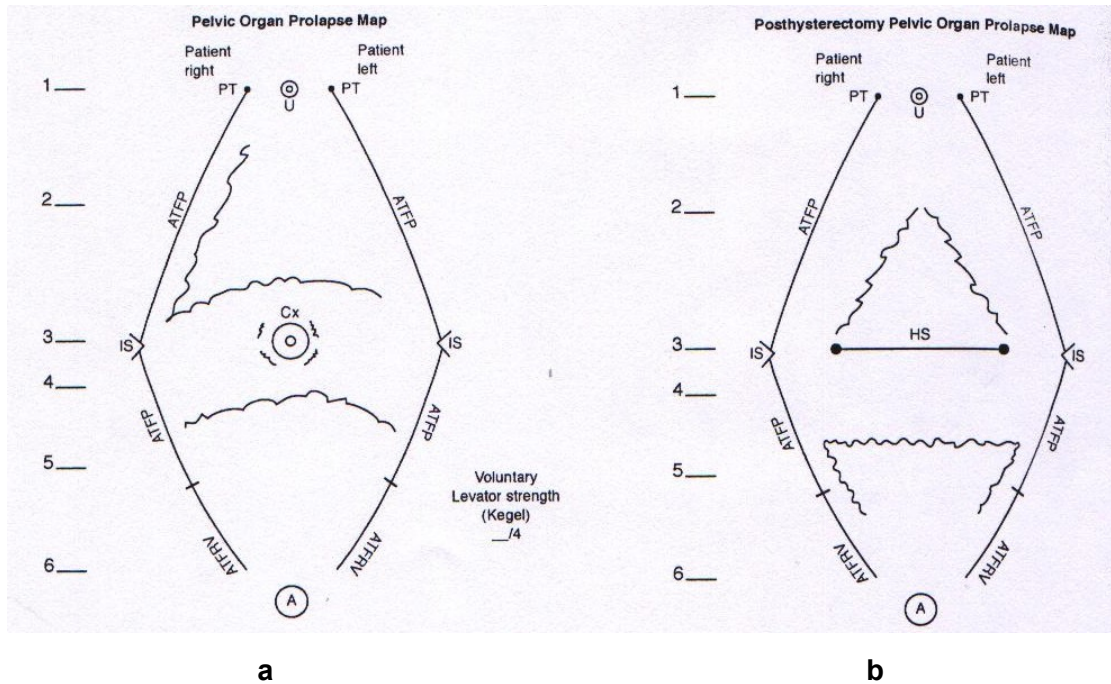
The assessment examination is simple to perform once taught but has still been seen by many gynaecologists as being time consuming within a busy clinical practice. An audit of gynaecological members of The International UroGynaecological Association

(IUGA), a body with a self-declared interest in pelvic organ prolapse, found that less than 40% of members used the system in routine clinical practice (Auwad 2004).

Furthermore, the International Continence Society (ICS) document on standardisation of terminology incorporates the addition of qualitative information concerning the degree of prolapse with supplementary physical examination and investigations (Abrams, et al. 2002). This may include endoscopic findings, photography, imaging procedures such as ultrasound, radiography, CT scans and MRI imaging. It also permits reassessment and re-evaluation of surgical procedures with descriptions of defects together with pre-operative assessment of pelvic floor integrity, muscle bulk, muscle function and integrity of the vaginal tissues.

It is clearly important to describe functional symptoms, as well as including urinary, bowel and sexual function, and address associated effects on quality of life (QoL) parameters for patients. The qualitative information is optional and therefore variable in recording, despite evidence that QoL measures are an important determinant of success for women undergoing treatment (Radley and Brown 2005). Although this system provides an attempt to quantify the extent of the problem it still allows the potential for errors to be made. In addition it demands commitment on the part of the clinician to document adequately the findings. It does not address paravaginal or axial plane defects and there is no standardisation in terms of pressure on the pelvic floor during straining. It is for this reason that imaging techniques allowing precise measurements could offer potential for greater accuracy in the assessment of pelvic organ prolapse.

An extension to the above system is to clinically identify the location of specific defects, not only in the sagittal plane but also in the axial and coronal planes, and attempt to translate this into a two-dimensional line drawing. This can be semi-quantitative by adding measurement parameters: this is illustrated in Figure 1.7. There is however no evidence to show that the system shown in Figure 1.7 is reproducible between and within observers, however it may add information as to the presence of lateral defects of the vagina.



**Figure 1.7.** A schematic diagram of the paravaginal sulci with anatomical reference points. IS, ischial spine; ATFP, arcus tendineous fascia pelvis; Cx, cervix; HS, hysterectomy sulci; A, anus; U, urethra; PT, pubic tubercle. Areas with jagged lines represent defects detected. a) diagram with cervix b) diagram without cervix. Adapted from Te Lind's Operative Gynaecology 9<sup>th</sup> Ed. Chapter 35; 944, Chapter editor, Zimmerman (Rock and Jones 2003) Reproduced with permission.

## 1.4 IMAGING MODALITIES FOR PELVIC ORGAN PROLAPSE OF THE POSTERIOR COMPARTMENT

### 1.4.1 Computed Tomography (CT)

CT has been used in a limited number of studies in relation to POP. One small study using fast image acquisition in lithotomy demonstrated prolapse correctly in 5 of 7 women when compared to surgical findings, although the author commented that adequate Valsalva was difficult to achieve (Pannu 2003). This is not adequate evidence to recommend CT imaging to identify POP, especially in view of the concerns over radiation to the pelvis. A recent abstract demonstrated the image acquisition and 3-dimensional modelling capabilities of helical CT imaging, to identify grafts inserted for POP and urinary incontinence (Palma 2006, Palma, et al. 2010). Subtraction modelling using 3-dimensional software was undertaken to identify placement and final resting location of a barium-impregnated prosthetic used for the surgical treatment of incontinence and prolapse. No attempt however was made to

quantify or identify the type of POP or surgical grafts on straining. In addition there was no mention of the radiation emitted by this technique, which may raise concerns with the use of Barium impregnated implants within a human subject. No comment was made as to the dose of radiation released or the safe excretion of the Barium (Palma 2006, Palma, et al. 2010). At present there is no literature relating to the use of CT imaging specifically for the posterior compartment.

#### **1.4.2 Magnetic Resonance Imaging (MRI)**

##### **1.4.2a Comparison with anatomy**

MRI permits the use of non-radiation image acquisition with superior definition of soft tissues of the pelvis compared to computed tomography. To correlate these images with tissue and organ positioning within the pelvis, direct comparison with anatomical dissection has been undertaken. These studies (Hussain, et al. 1996, Strohbehn, et al. 1996a) have been undertaken utilising cadaveric dissection particularly of the anterior compartment of the pelvis and to a lesser extent of the posterior compartment. Initial studies identified the separate components of the endoanal complex in 8 patients undergoing abdominoperineal resection of colon for rectal tumours and 10 controls using cadavers (Hussain, et al. 1996). In particular the different layers of the wall of the anal canal, incorporating the internal sphincter, longitudinal muscles, external sphincter and puborectalis muscle were correctly identified. Levator ani and ligamentous attachments were also identified and correlated with imaging location. Further studies were undertaken using two female cadaveric prosections: one of the prosections was imaged to permit axial and the other coronal slices to be examined in detail with anatomic correlation (Strohbehn, et al. 1996a). Cross-sectional anatomical tissue dissection permitted levator ani to be identified and insertion points correlated with MRI: there was excellent correlation. Similar histological comparison for microscopic anatomy of the urethra and anterior compartment complex has also been undertaken, again with good correlation (Strohbehn, et al. 1996b). It would seem that MRI accurately reflects the anatomy present. Examination of the posterior compartment specifically and correlation with cadaveric specimens has, however not been undertaken.

##### **1.4.2b Comparisons with surgical findings**

Studies correlating MRI findings specifically with surgical findings are limited (Cortes, et al. 2004, Kester, et al. 2003). Two studies have provided evidence regarding the accuracy of MRI. The first involved 31 women imaged with severe multi or single

compartment prolapse pre-operatively. There was a significant correlation between surgical and MRI diagnosis of POP (Kester, et al. 2003). Another study specifically targeting level I or vault prolapse, suggested that MRI may identify other compartmental prolapses missed at surgery (Cortes, et al. 2004). The evidence suggests that there may be greater accuracy with MRI, which implies that it could be a useful imaging tool in the surgical setting for the pre-operative assessment of gross POP.

#### **1.4.2c Fascial and muscle morphology of the pelvis**

Central vaginal bulging can be identified clinically with loss of rugae over the herniation, specific areas of weakness and can be identified by rectal examination to find a defect. Evidence of the integrity of paravaginal support structures is inferred by collapse of the posterior lateral sulci. Specific endovaginal fascial defects are difficult to identify (Adekanmi, et al. 2002). Identification of defects in the rectovaginal fascia can be identified, in addition to rectal prolapse and intussusception, as long as rectal contrast is administered and the patient defaecates during the study (Wang, et al. 2005). Imaging the anal sphincter allows the precise delineation of the anatomy if an endorectal coil is used (Hussain, et al. 1995, Stoker, et al. 2001, Stoker, et al. 2002). The use of endovaginal and endoanal coils in magnetic resonance undoubtedly improves imaging of the anatomy, but distorts the vagina so that prolapse is difficult to visualise.

With the good correlation between MR imaging and anatomical landmarks in cadavers and continued development of software, three-dimensional reconstruction of static, and possibly dynamic, in vivo anatomy is possible. These techniques will allow morphological aspects, volume measurements, hiatal and defect measurements to be analysed in different planes (Fielding, et al. 2000, Frohlich, et al. 1997). Changes following surgery can also be demonstrated (Healy, et al. 1997b). The morphological and morphometric aspects of levator ani have been studied using these techniques to identify patterns associated with POP in asymptomatic women and women who have had vaginal obstetric deliveries. One study examined 30 women including 10 case matched subjects with no symptoms, urinary incontinence (UI) or POP. Determination of levator hiatal height, bladder neck to pubococcygeal line, levator plate angle, and perineal descent at rest and maximum Valsalva was undertaken. In addition, manual segmentation and surface modelling was applied to generate 3-dimensional models of the separate organs. The models were then measured to determine levator muscle volume, shape and hiatus width, distance between symphysis and levator sling

muscle, posterior urethrovesical angle, bladder neck descent, and levator plate angle. Both the two and three dimensional data demonstrated differences between control and symptomatic patients although 3 dimensional data was stratified rather than segmented between the groups, i.e. there was significant cross-over of variables between the two groups (Hoyte, et al. 2001b). Similar results were shown with levator colour mapping to measure thickness, although there was some overlap of the data between groups (Hoyte, et al. 2004). Post delivery disruption of levator ani support particularly for pubococcygeus has been significantly correlated with vaginal delivery, parity and urinary stress incontinence (Dannecker, et al. 2004, DeLancey, et al. 2003, Tunn, et al. 1999). It has been suggested that some of these changes are early changes following pregnancy which appear to resolve as muscle and fat is replaced by scar tissue (Tunn, et al. 1999).

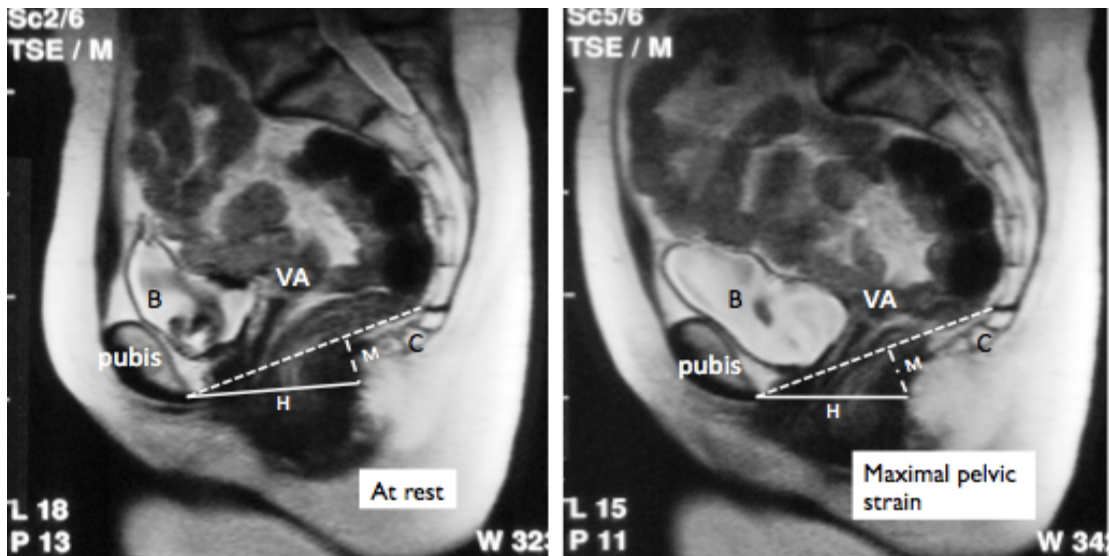
Despite the excellent definition offered by this imaging modality, its use for imaging pelvic organ prolapse has been limited by its high cost and the static nature of the image acquisition. However, it is now possible to achieve image acquisition times of only two seconds with single shot, fast spin echo sequences using a T2-weighted technique (Unterweger, et al. 2001). Thus dynamic imaging of the pelvis under strain, to obtain a sagittal and axial image at rest, on straining and even during defaecation with the use of contrast can be obtained. It is also now possible to obtain standing MR images with a vertical configuration of magnets, or sitting using an open configuration of magnets (Hilfiker, et al. 1998). However these are extremely expensive and therefore limited to a small number of research units. One potential problem with obtaining such images is that the anatomy may be altered as well as adjusting for the configuration of magnets. There is, however no evidence either way as no comparisons have been undertaken between the supine and other positions. Nevertheless the newer configurations allows abnormalities associated with defaecation, such as anismus and rectal intussusception to be further evaluated (Lamb, et al. 2000). It has been suggested that abnormalities thought to be difficult to interpret compared to defaecating proctography, such as surrounding muscle spasm and anatomy, not seen easily in simple fluoroscopy may be identified more readily (Barber, et al. 2000, Hilfiker, et al. 1998). The goal is to mimic the strain that is placed on the female pelvic organs during normal activity to reproduce anatomical and symptomatic changes. These measures outlined above attempt to address this important issue. There also appears to be some merit in performing image acquisition in the seated position compared to supine, where levator ani morphology on straining appears different (Bo, et al. 2001, Sentovich, et al. 1995).

Although dynamic imaging can be undertaken, difficulties arise in achieving a reliable and consistent Valsalva especially in the supine position, where controlling for Valsalva straining is difficult without direct access to the subject or pressure measurements in the vagina. Variance in inter-measurement analysis has been observed in repeated scans taken from the same patient: care is therefore required to minimise these variations (Morren, et al. 2005): one factor is consistent straining. Recent attempts to control for this have utilised MRI suitable transducers but in regular practice this may not be possible (Borghesi, et al. 2006).

#### **1.4.2d Comparison with clinical assessment**

Studies utilising MRI, have been undertaken with a limited number of subjects comparing the measurement of displacement of pelvic organs between rest and strain in symptomatic (26) and asymptomatic (16) women. Using a line drawn from the posteroinferior midline of the symphysis pubis to the tip of the most distal coccygeal bone, POP was quantified in all three pelvic compartments using measurements of organ descent below this line, to define the normal and abnormal range. A line drawn along the attachment of the pubococcygeus from the posteroinferior aspect of the pubic rami to the junction of the sacrococcygeal junction permits a co-ordinate from which to measure organ descent (Goh, et al. 2000, Yang, et al. 1991). Other researchers have similarly used this measurement system to validate its use (Goh, et al. 2000). An example of this measurement is shown in Figure 1.8 using the pubococcygeal line. Modification of this technique using rectal and vaginal contrast has provided better evaluation of images to likewise adopt similar guidelines for the measurement of POP (Lienemann, et al. 1997).





Reference Lines

SCIP line and midpubic axis

H line = AP diameter hiatus approx 5cm

M line = levator hiatus descent approx 2cm

Normal Study

**Figure 1.8.** Measurements showing reference points utilizing the pubococcygeal line on MRI for estimation of POP. This is a normal study. Reproduced with permission Dr Voyvodic

There have also been attempts to use the levator hiatus, as in the HMO classification by drawing an H (levator hiatal) line from the pubis to the posterior anal canal, which measures the width of the levator hiatus and an M line (muscular pelvic floor relaxation) to measure the descent of the levator plate relative to the pubococcygeal line (Comiter, et al. 1999). The O represents organ descent relative to the H line. The transverse diameter can then be measured using this technique. Further classification suggests that the pubic bone may be used as a reference point as it correlates with the hymenal ring (Cortes, et al. 2004). In this study of 20 patients with prolapse a strong correlation was observed with clinical staging in 75% of patients (Cortes, et al. 2004): however it was not tested against the only validated scoring system, the POPQ. Nevertheless, using the pubococcygeal line seems to improve the clinical correlates of MRI over Yang's original suggested guidelines (Yang, et al. 1994). All of these studies have been conducted on small numbers of women: it is therefore difficult to promote them as reliable sources of quantification of pelvic organ prolapse. A study into morphological features and their correlation with prolapse investigated 61 women subdivided into Stage I, II, III and IV (Baden-Walker grading system section 1.8) and also included nine asymptomatic volunteers (Singh, et al. 2002). Three-dimensional models were constructed and identified the levator symphysis gap, the

width and length of the levator hiatus as well as assessment of iliococcygeus, identifying its maximum width, direction of fibres and levator plate angle. This detailed study used short image acquisition times, and was undertaken in the supine position. The subjects did not undergo defaecation with the MRI imaging. Assessment was therefore undertaken as for the POPQ. Interestingly alterations in levator ani morphology were not related to grade of prolapse, however levator symphysis gap and levator hiatus did increase with the stage of prolapse. Singh et al (2002) posed the question, “does levator morphological changes and gap dimensions predict the success of surgery?”; however from their data it remains unanswered. Although their results are interesting there was no validation of Valsalva between clinical and MRI assessment, the patients were in a supine position with legs not in lithotomy. Without vaginal pressure transducers it would be difficult to determine if there was a consistent Valsalva between studies. In addition there is no way of knowing whether levator ani was activated involuntarily during MRI without defaecation, as this can occur as a reflex during Valsalva, being readily recognized on real-time ultrasound imaging (Dietz 2004b). This study does provide interesting information regarding the potential for comparison between the two methods for preoperative assessment of the pelvis, not only for clinical evaluation but also as a predictor of surgical outcome. No studies appear to have been undertaken that predict outcome of surgery in relation to MRI findings.

Comparisons between the POPQ and MRI have demonstrated a reasonable correlation with a  $\lambda$  of 0.61, however only 20 women were studied (Singh, et al. 2001). MRI provided additional information particularly the demonstration of enteroceles. More recent comparisons using the POPQ suggest that the reference line on MRI may have to change depending on the compartment that is most affected by POP. This was studied in forty-one asymptomatic women and compared retrospectively with women who underwent cine-MRI investigation for pelvic symptoms. On MRI, the distance between the bladder-neck, the distal edge of the cervix/posterior fornix, and the most ventrocaudal point of the ventral rectal wall, from the pubococcygeal line (PCL), the horizontal tangent of the inferior rim of the pubic bone, and a line drawn through the long axis of the pubic bone was measured. The measurements were correlated with the respective clinical findings using descriptive analysis: for the posterior compartment the hymenal line showed the best correlation (Lienemann, et al. 2004). Correlation with simple subjective clinical examination was also found to be good, with positive predictive values greater than 75% for all

compartments including the posterior (Gousse, et al. 2000). Diagnosis of intra-pelvic pathology was also better with MRI.

Comparison of MRI and fluoroscopy would be expected to have a reasonable correlation, although MR appears to be better at predicting uterine prolapse and enterocele when correlated with findings under anaesthesia (Lienemann, et al. 1997, Lienemann, et al. 2000) (Kelvin, et al. 2000). One important finding in this study was that to improve MR imaging detail defaecation during the image acquisition was necessary. This of course is embarrassing for the patient and not tolerated by some for benign symptoms. There do not appear to be any comments in the above studies of patient's perceptions of this investigation. In another study of 10 women there appeared to be no advantage of MRI over evacuatory proctography, except that patients much preferred the non-invasive nature of external magnet field scanning. This was partly due to the need for barium paste insertion in the fluoroscopy group. However, it was estimated that the costs were 10 times greater in the MRI group (Matsuoka, et al. 2000).

The difficulties of comparing MRI albeit using dynamic imaging and clinical examination using the POPQ, is that not only are the reference points different, as previously mentioned, but also the position of the hymenal ring is variable, being closely related to the attachments at level III of vaginal support. Translating these findings into clinical symptoms is more difficult as in one study (Swift 2000) 50% of patients with Grade II prolapse on POPQ were asymptomatic. The problem with all the studies using imaging is that there are relatively few normal patients for comparative purposes. It appears to be clear, however that radiological imaging diagnoses a higher incidence of pelvic organ prolapse, particularly posterior compartment prolapse, compared to physical examination: however, this may not translate into symptoms. The issue is, in the presence of specific physical examination findings, which findings correlate with patient symptoms and is anything to be gained by imaging?

For the purposes of research and audit the relationship between findings and symptoms is critical. Imaging may provide additional information outside the lower pelvic floor, such as the presence of ovarian cysts, masses and uterine anomalies, which themselves may be a cause of pelvic organ symptoms. It would also seem logical that anatomic correction is most likely to lead to improvement of functional disorders. Therefore if the anatomical changes, which are deep to the vaginal mucosa

can be identified more accurately this would logically translate into better anatomical correction and more appropriate management.

#### **1.4.2e Summary of MRI**

MRI provides detailed in vivo anatomical information of the static structural anatomy of the female pelvis, and may add information prior to surgery in gross POP. Small studies comparing MRI to clinical evaluation have been undertaken, including the use of the POPQ, with reasonable correlation, however the number of patients investigated has been small. There is poor evidence as to the usability of MRI in dynamic assessment other than during defaecation. No studies comparing the evaluation between MRI and US appear to have been undertaken. As far as the posterior compartment is concerned, MRI can identify anterior rectoceles but does so better with concomitant defaecation, similarly with enterocele identification. Endoanal anatomy is best viewed with an endoanal coil on MRI and therefore limits the examination in relation to dynamic anatomy. Upper vault prolapse can be viewed better than simple clinical evaluation and anatomical defects of levator ani are visible, although clinically there is no evidence to suggest it alters surgical outcome.

#### **1.4.3 Fluoroscopic Dynamic Cystoproctography (FDP)**

Fluoroscopic imaging techniques have been available for some time and provide different information to that of clinical vaginal examination. With respect to the posterior compartment the use of contrast techniques helps identify both anterior and posterior rectoceles. It also helps with the identification of rectal prolapse and intussusception, and in conjunction with peritoneography can help identify an enterocele by direct visualisation. An example of an anterior rectocele is shown in Figure 1.9. It also permits the identification of discoordinate puborectalis contraction of the levator sling (anismus). Detractions of this technique include concerns over the use of radiation, the fact that the investigation is invasive and women find it embarrassing to defaecate in front of an X-ray machine. Definitions of pelvic organ prolapse on fluoroscopic defaecating proctography (FDP) seem limited. Attempts to use the pubococcygeal line to define prolapse uses the following criteria: anything three centimetre below this line is a minor grade, between 3 and 6 centimetres a medium grade, and greater than six centimetres a severe grade. Studies suggest there is a wide margin for interpretation between observers (Kelvin, et al. 2000). There is also a paucity of data on normal asymptomatic women.



rectum and vaginal mucosa when compressed by the examining finger or instrument. Another advantage of FDP is that measurements may be made in relation to fixed landmarks such as the pubococcygeal line. Certainly identification of prolapse in all three compartments may be improved with imaging and therefore hopefully lead to lower re-operation rates (Maglante, et al. 1999). In view of the use of radiation, discomfort and loss of dignity, an alternative non-invasive imaging technique to identify defects of the posterior compartment would be useful. Comparative studies have been undertaken between ultrasound (US) and FDP and also MRI. These studies would suggest that evacuatory proctography with contrast and concomitant defaecation are comparable to ultrasound, identifying defects of the posterior compartment equally as well for measurement of the anorectal angle (Beer-Gabel, et al. 2002). FDP provide similar results to MRI for measurement of anorectal configuration but less information on subtle anatomical changes with poorer patient satisfaction (Deval, et al. 2003, Healy, et al. 1997, Matsuoka, et al. 2000, Pannu 2002, Stoker, et al. 2002). The majority of these studies investigated women with constipation rather than prolapse as their predominant symptom.

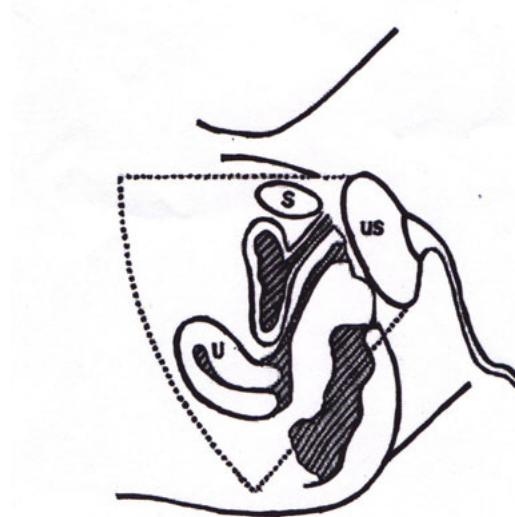
The addition of peritoneal contrast through peritoneal injection appears to improve the diagnosis of posterior compartment defects (Bremmer, et al. 1995, Halligan and Bartram 1995). Without peritoneography only 50% of defects were visualized. Enterocèles are more easily visualized which may not be apparent on simple defaecography (Bremmer, et al. 1998). Peritoneography may therefore deserve further merit and consideration.

A number of studies have compared FDP to the POPQ with between 30 and 88 women in each study. Vaginal topography correlated poorly with fluoroscopic techniques, but the latter correlated better with symptoms in one study. The ability of either technique appears to be poor in predicting the severity of symptoms (Altman, et al. 2004, Altman, et al. 2005a, Kenton, et al. 1997)

#### **1.4.4 Ultrasound (US)**

Ultrasonography utilises ultrasonic, frequency modulated beams of sound waves to create reflective images of tissue. The place of two-dimensional ultrasound for the investigation and management of women with gynaecological problems is now well established. Both transabdominal and transvaginal scanning permit identification of the uterus and adnexae with excellent resolution to direct appropriate management. Devised for the assessment of fetuses in-utero it has found application in the investigation of the female pelvic floor in 2-dimensional B mode and more specifically for the assessment of lower urinary tract dysfunction (Schaer, et al. 1995a, Schaer, et al. 1995b). Advances in ultrasound technology incorporating better definition and resolution with noise cancellation have been made possible by computer hardware and software improvements, permitting the imaging technique to be used in areas where there is poor fluid-tissue contrast, such as in the lower pelvis, i.e. that area caudal to the pelvic floor consisting of the levator ani muscle group. This improvement in technology has permitted more accurate imaging of the posterior compartment, an area with poor contrast, using transabdominal, transvaginal, endoanal, introital and transperineal/ translabial ultrasound. However, transabdominal ultrasonography provides poor imaging of the lower pelvic structures, particularly the support structures of the vagina and levator muscle group, due to the depth of the tissues from the transducer. Endoanal ultrasound permits the identification of defects of the internal and external anal sphincter, as well as information on puborectalis with its morphological features and defects created by trauma, particularly those associated with childbirth. However with the discomfort involved and relatively poor spatial orientation for identifying pelvic organ prolapse, particularly perineal hypermobility this has had a limited use in pelvic organ prolapse assessment. Transvaginal ultrasound permits excellent visualisation of the bladder, urethra and the posterior compartment but distorts the pelvis thereby precluding accurate assessment of POP (Quinn, et al. 1988). In an attempt to overcome this investigators have utilised introital (Tunn and Petri 2003), transperineal and translabial ultrasonography (Khullar and Cardozo 1998, Koelbl, et al. 1988). Information can be obtained as part of a routine pelvic examination with no discomfort to the patient. It may therefore be possible to improve the understanding of POP using transperineal ultrasound for both clinical and research purposes by adding a further objective measuring system to the POPQ system. The addition of three-dimensional ultrasonography may provide the opportunity for visualisation in the axial plane of the pelvis, improved data storage and

therefore independent audit. This discussion concentrates on transperineal/translabial ultrasound and how it relates to assessment of the posterior compartment of the pelvis. Figure 1.10 represents the position of the transperineal transducer relative to the perineum and patient during such an examination.

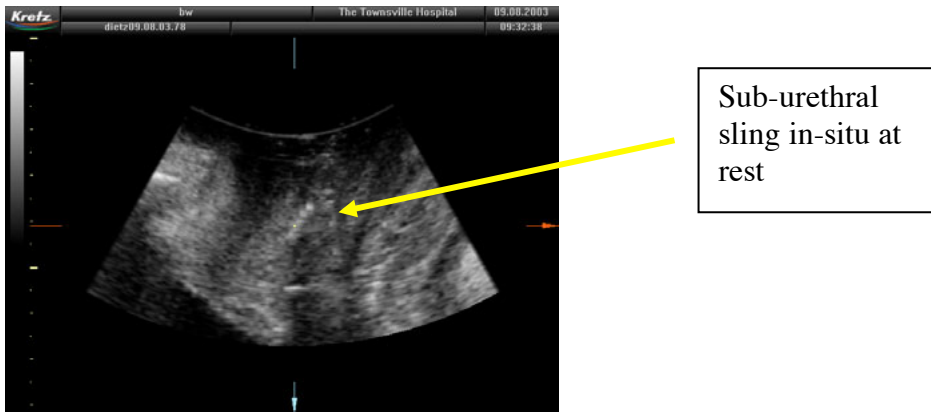


**Figure 1.10** Diagram of US transducer placement for translabial scanning. S, symphysis pubis; US, ultrasound transducer; U, uterus; B bladder; R, rectum. Reproduced with permission (Dietz 2004a).

Several studies have used transperineal ultrasound for the identification of anterior vaginal compartment anatomy, biodynamics and prolapse (Dietz and Clarke 2001a). Imaging of the anterior compartment allows visualisation of the bladder, urethra, and surrounding support structures. This can aid in the diagnosis of vaginal, bladder and urethral pathology such as Gartner duct cysts, bladder stones, congenital abnormalities, haematoma, diverticula and tumours. Transperineal ultrasonography can add clinical information on bladder neck opening (Tunn and Petri 2003, Voigt, et al. 1994), mobility (Huang and Yang 2003, King and Freeman 1998, Reed, et al. 2002) and incontinence. It appears to provide as much information as videocystourethrography (Dietz and Wilson 1998). In women with symptoms of urinary incontinence, particularly with overactive bladder (OAB) symptoms, a measurement of bladder wall thickness, which has been shown to correlate with evidence of OAB (Khullar, et al. 1996), can be added. The biomechanics of pelvic tissues can be quantified by measuring bladder neck descent and urethral rotation. This body of evidence suggests that ultrasound offers a reproducible assessment



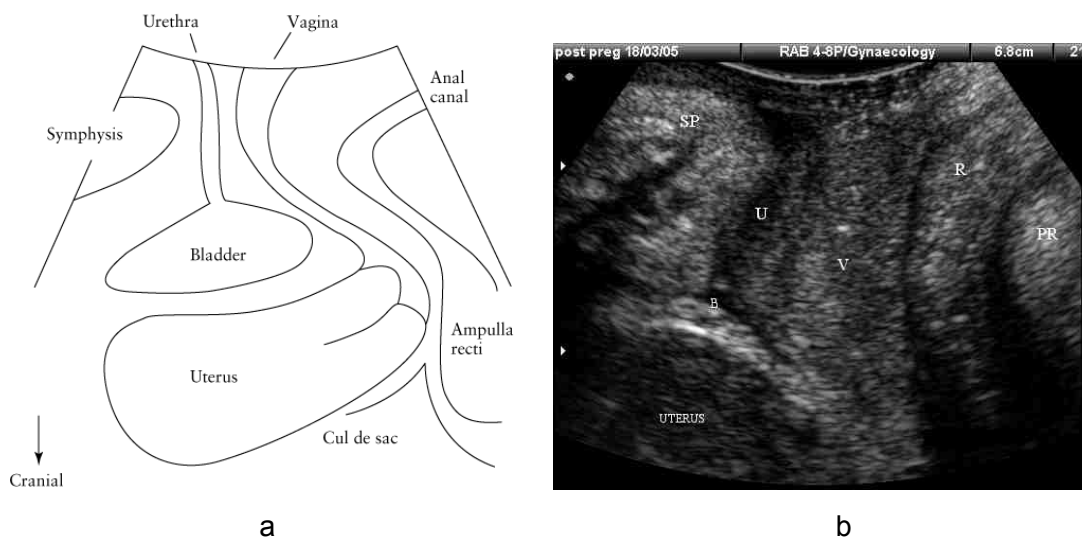
technique for the anterior female pelvis. In addition, it provides information not only on the presence of cystoceles but also the location of prostheses (Dietz, et al. 2003)(Figure 1.12).



**Figure 1.11.** Identification of sub-urethral sling in vaginal wall on mid-sagittal ultrasound Dr Barry personal study (not published).

With respect to pelvic organ descent and prolapse a number of studies have been conducted (Beer-Gabel, et al. 2002, Creighton, et al. 1992, Healy, et al. 1997b, Tunn, et al. 2003)). In these studies only 6 women were investigated using this technique prior to undergoing anti-incontinence procedures. ANOVA analysis confirmed the reproducibility of repeated measurements of pelvic organ descent and bladder neck mobility. In Beer-Gabel's study dynamic transperineal ultrasound of the pelvic floor, particularly looking at the rectum and external anal sphincter, identified the different compartments of the female lower pelvis and demonstrated similar findings when the same patients had either endoanal ultrasound or evacuatory proctography. The study was undertaken in 10 patients on their left lateral side, which may have interfered with the Valsalva and contraction of the pelvic muscles. No comparison has been made with patients on the left lateral side versus the supine position. Some women however found it too uncomfortable as contrast medium was used in both the rectal and vaginal cavity, and refused to continue. This suggests that unless it was used in preference to evacuatory proctography it is unlikely that the use of rectal contrast would have a place in the routine assessment of women with POP as excellent images can be obtained without contrast and without discomfort. In a large study to date (Dietz, et al. 2001) involving 145 women, there was good correlation between ultrasound assessment and POPQ assessment in the mid-sagittal plane. This

suggests that imaging definition with transperineal ultrasound is sufficiently accurate to identify herniation of pelvic structures and allow measurement of the defects. With a correlation coefficient of 0.72 for central and anterior defects and 0.53 for recto-enteroceles both methods seemed satisfactory for assessment. However no attempt was made to correlate clinical findings in the outpatient setting, ultrasound findings and the defects seen at the time of surgery, to add greater validity to the type and degree of defects present. Examples of images and diagrammatic drawings are shown in Figure 1.12.



**Figure 1.12 a;** Diagrammatic appearance of a normal ultrasound view of the pelvis. Taken from "Ultrasound imaging of the pelvic floor. Part I: two-dimensional aspects." *Ultrasound in Obstetrics & Gynaecology* 23(1): 80-92, (Dietz 2004a); **b;** transperineal 2D image of the female pelvis orientated as for the real time image (Barry personal image files).

Maximal descent was measured at maximal Valsalva straining in the study one study (Dietz, et al. 2001), but there have been concerns that this may not give consistent reproducible results, as some patients seem unable to perform this manoeuvre to maximal strain. Therefore a consistent rise in intra-abdominal pressure may not be assured between subjects potentially jeopardising reproducibility. Attempts to standardize the Valsalva manoeuvre have involved the use of spirometry (King and Freeman 1998), intra-vaginal pressure transducers (Wijma, et al. 2003) and oral pressure measuring devices using a sphygmomanometer (King and Nevill 2004). The latter study measured intra-abdominal pressure changes in 80 women undergoing urodynamic investigation and compared maximum Valsalva to a standard rise using a

modified sphygmomanometer. Rises in intra-abdominal pressure were more reproducible and consistent using a sphygmomanometer. Despite this some authors prefer to use maximum Valsalva. Excellent test-retest parameters for measurement of bladder neck mobility using this technique would confirm the validity of this method (Dietz, et al. 2003). However, great care must be taken to avoid reflex contraction of levator ani irrespective of whether standardisation for Valsalva pressures is attempted. Following completion of the studies associated with this thesis a study with good retest parameters and variance within pressure coefficients and Valsalva using a valve controlled valsalvometer has been published (Greenland, et al. 2007).

Another consideration in obtaining measurements is whether prolapse is better diagnosed and quantified standing or supine. Another study specifically looking at the anterior compartment suggests that there is no difference in the final resting place of the bladder or urethra on maximal Valsalva (Dietz and Clarke 2001b). Further analysis may be warranted for examination of the posterior compartment.

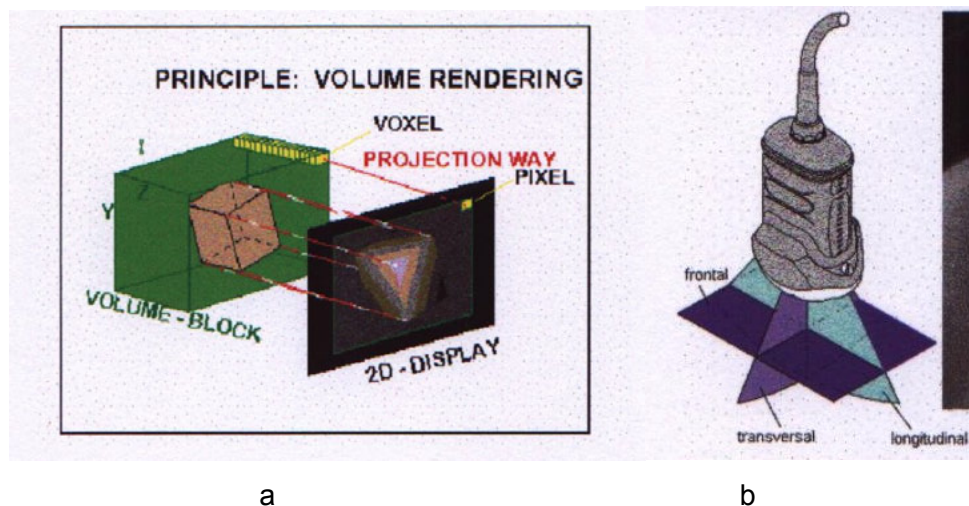
Could examination be enhanced by the use of contrast? It has been reported that patient tolerance to contrast in the bladder, rectum and vagina was not well tolerated (Beer-Gabel, et al. 2004), nevertheless a direct comparison of the use or non-use of contrast are required to resolve this issue.

It is possible to identify rectoceles, cystoceles and enteroceles without contrast media (Tunn and Petri 2003), and in two dimensions with ultrasound: this also correlates well with international standardised scoring systems (Dietz, et al. 2001). It is also possible to measure bladder neck descent, urethral descent, perineal hypermobility and changes in anorectal angle on Valsalva which are an indirect measure of the biomechanical property of the vaginal fascia, muscular layers as well as the support ligaments and lateral wall muscles (Dietz, et al. 2002, King and Freeman 1998, Mouritsen and Bach 1994). Can more information be obtained about the paravaginal support that a number of authors consider so critical to the integrity of the vaginal lumen (Chou and DeLancey 2001, DeLancey 1999, Richardson, et al. 1976, Richardson, et al. 1981, Shull and Baden 1989). In addition, is it the underlying muscle complex that is the important aetiological factor causing prolapse or resulting in surgical failures (Delancey and Hurd 1998, Tunn, et al. 1999)? A number of studies have used abdominal scanning to help identify anterior paravaginal defects but the reliability of this method has been questioned due to image quality and positioning (Martan, et al. 2002, Nguyen, et al. 2000, Ostrzenski, et al. 1997). Consequently more

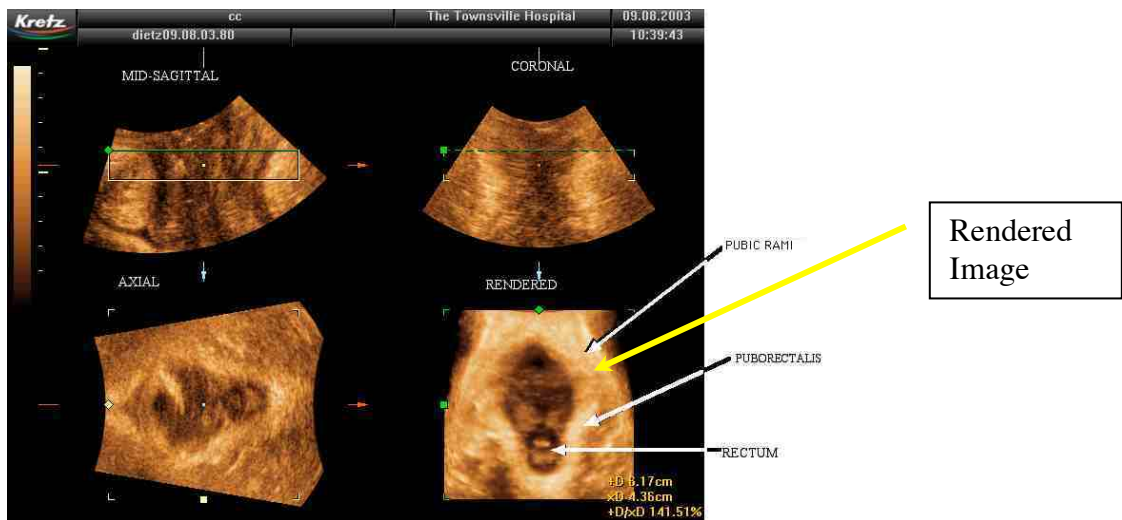
information is needed regarding dynamic visualisation of pelvic organ function in three dimensions.

#### 1.4.5 3-dimensional ultrasonography

Development in 3-dimensional data acquisition has been progressing since the 1970s and 1980s (Gritzky and Brandl 1998). Three-dimensional scanners were originally used to acquire images using freehand or motorised withdrawal techniques, and were predominantly intracavitary. Image acquisition can now be achieved by rapid oscillation of a group of elements within the transducer head. By moving within sectional planes this information can then be charted using computer software and because each pixel is orientated in 3-dimensions volumes can be recorded. These areas are no longer called pixels but voxels to define them as pockets of information allowing them to be orientated with 3 dimensions. Images can be displayed in all three planes with the rendered image in the fourth viewing box. This rendered image represents a semi-transparent representation of all the voxels in an area defined by the computer software. This also allows the ability to manipulate the image in all three dimensions thereby permitting independent analysis at a later stage or to review it for further studies. Figure 1.13 is a diagrammatic reconstruction of the image produced by computer analysis of the voxel data.



**Figures 1.13 (a)** Diagrammatic view of Voxels being used to create a 2 dimensional screen image. (b) 3D probe with scanning sectors. Kindly reproduced with permission from GE.



**Figure 1.14** 3D ultrasound volume of pelvic floor, using translabial ultrasound volume in three-dimensions in coloured Sepia mode. Mid-sagittal plane at top left, coronal plane on top right, axial plane bottom left. The bottom right image shows a rendered volume visualising the puborectalis muscle. (Barry archived volumes with permission 2004)



**Figure 1.15** Images of the levator hiatus in axial view with anatomical drawing for comparison. (a) Axial plane imaging at rest (left) and on Valsalva (right). Unlabelled arrows indicate insertion point of puborectalis (Dietz with permission). (b) Diagram of levator hiatus as seen from caudally. (U, urethra, V, vagina, R, rectum, PR, puborectalis, IC, ischiococcygeus, C, coccygeus) (d) Measurement of anteroposterior and transverse diameters and area of levator hiatus on Valsalva (Reproduced with permission from: Dalley, Moore. Clinical Oriented Anatomy 4th Edition 2005, p356. Lippincott, Williams & Wilkins: Philadelphia.)

Four-dimensional imaging allows the real time acquisition of volumes, which again can be viewed either in all three orthogonal planes or as the rendered volume. This allows correct alignment of the transducer and the imaging of defects as it permits identification of the tissues below the surface of the vaginal mucosa. More importantly identification of submucosal and muscle defects can be viewed in real time, providing an exciting capability for dynamic imaging of the pelvis.

### 1.5 Summary

The advent of three- and four-dimensional ultrasound has now provided an imaging modality which has the same advantage of MR imaging, i.e. images in three planes, particularly the axial plane. This allows not only midline measurements but also assessment of the paravaginal anatomy. An example of this is shown in Figure 1.16, where the right side of the paravaginal sulcus is seen to “come away” on Valsalva. There have been no studies to date using three-dimensional ultrasound and the objective identification of pelvic organ prolapse pre- and post surgery and in particular comparison with the POPQ scoring system. Furthermore there have been no comparative studies of ultrasound versus MR imaging and only limited studies of its use in normal populations. There have been no studies published on the use of 3D ultrasonography for the assessment of the posterior compartment of the lower female pelvis with three-dimensional ultrasound.



**Figure 1.16.** A right-sided paravaginal defect on three-dimensional ultrasound as shown by the arrows.

## **1.6 Preliminary Conclusion**

Ultrasound has the advantage of being relatively cheap, simple to learn and safe. MRI although having excellent definition of tissue is expensive, cumbersome and difficult to adjust for dynamic movement of the pelvis, especially on Valsalva. Proctography utilises X-rays and can be cumbersome. Patients may find it uncomfortable to sit in front of the screen and evacuate. For these reasons ultrasound may have advantages over these other imaging modalities.

The evidence to date is limited in the use of both two-dimensional and three-dimensional ultrasound as a quantitative, reliable measure of pelvic organ prolapse. There have been no studies comparing MR imaging and ultrasound nor have there been any studies looking at pre- and postoperative assessment of the posterior compartment of the vagina using ultrasound and comparing these findings with clinical evaluation. There have now been limited studies since this thesis was started investigating the normal and pregnant populations to define the normal parameters for levator dimensions and abnormalities of the posterior compartment. Defects in the recto-vaginal septum are seen in nulliparous women occurring in approximately 10% of women (Dietz and Clarke 2005). Levator hiatal dimensions have been shown to vary by a factor of 6 on straining with levator area demonstrating the best test-retest reliability (Shek, et al. 2004).

Gynaecologists have long desired to have an objective method of quantifying prolapse and ultrasound offers an exciting potential method. A validated method of quantifying anatomical defects in the female pelvis would enable researchers to have an independent system that permits reliable comparison using a series of standardised imaging measurements as well as detailed qualitative description in all three axes thus reducing one confounding factor when comparing different therapies.



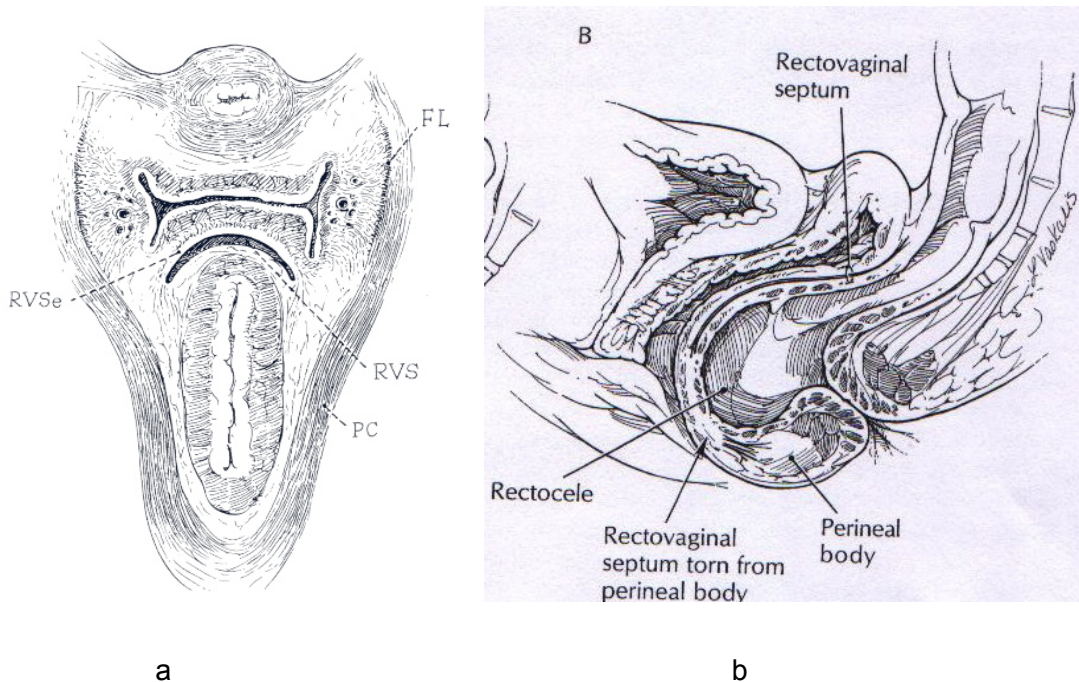
## CHAPTER 2

### REVIEW OF NORMAL AND ABNORMAL ANATOMY OF THE POSTERIOR COMPARTMENT OF THE FEMALE PELVIS

In the following chapter the normal and abnormal anatomy of the posterior compartment will be described with particular emphasis on the structural supports of the female pelvic organs and pelvic floor. Theoretical aspects for the development of pelvic organ prolapse will be discussed.

#### Normal anatomy of the posterior compartment of the female lower pelvis

##### 2.1 Boundaries of the posterior compartment



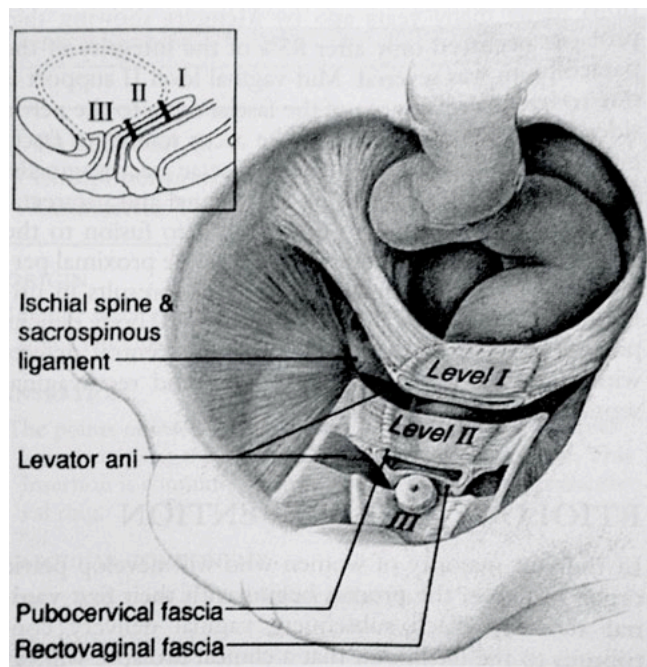
**Figure 2.1 a**, Cross-sectional view in axial plane of midvagina showing loop of pubococcygeus (PC), rectovaginal septum (RVS), fascia of levator (FL), chapter 1, p23; **b**; sagittal view of posterior compartment, chapter 11, p260. Reproduced with permission from (Nichols and Randall 1996).

For the purposes of this description the orientation of the anatomical axes will be in the normal anatomical position; i.e. as if woman was standing in the vertical position. The posterior compartment of the vagina is bounded anteriorly by the vaginal wall and distally by the perineal body, proximally by the vaginal vault and lower extremity of the



pouch of Douglas, with the muscular pelvic floor providing the deep ventral boundary of the compartment. Within it is contained the rectum and caudally the anus. Laterally the posterior compartment is formed by the pararectal space, which contains loose areolar tissue and in turn is bounded laterally by the continuation of the levator ani, which covers the lateral aspects of the pelvic floor. The boundaries of the posterior compartment are illustrated in Figure 2.1a and Figure 2.1b. The peripheral boundaries consist of the iliopectineal line of the ischium of the bony pelvis laterally, which extends down to the ischial tuberosities laterally but caudally, and progress anteriorly to form the pubic rami of the pubic bone. Posteriorly it is enclosed by the sacrum and coccyx.

The vagina itself is a distensible, hollow viscus, which is approximately 8cm in length and changes shape from its distal end to the proximal end. This change in shape in the axial plane is related to the different support structures of the vagina, which can be divided into three different levels (DeLancey 1992)(Figure 2.2). The anterior wall of the vagina is slightly shorter in length at approximately 7.5cm, compared to the posterior wall, which is approximately 9cm; its width increases as it ascends. The upper part of the vagina attaches and becomes confluent with the cervix uteri approximately one third of the distance from the external to the internal os of the cervix. Its lower margin comes from the remnants of the hymen, which demarcates it from the vulva where it continues as the vestibule of the vulva. The vestibule separates the vaginal orifice from the labia minora, which are two folds of cutaneous epithelium that are devoid of fat. The vagina extends posterosuperiorly but deflects at the region where it is attached to the levator ani muscles causing it to form an angle of approximately 120-130 degrees. The shape of the vagina in cross-section can be described as an H shape or W shape due to the convex indentation both anteriorly, posteriorly and laterally. This is caused by the nature of the support structures and the impression of the visceral organs; i.e. bladder, urethra, rectum and anal canal. In addition fat deposits laterally may lead to further bulging of the lateral walls. Anterolaterally and posterolaterally these form ridges or sulci which at the upper half of the vagina carry on to form small recesses known as the anterior and posterior fornices of the vagina. The upper part of the vagina is more capacious as the distal third is narrowed by the levator ani, which tends to compress the vagina against the urethra and pubic bone.



**Figure 2.2.** Three levels of support of the vagina with divisions of attachments at level I, II and III. Anatomic aspects of vaginal eversion after hysterectomy. *American Journal of Obstetrics and Gynecology* 166: 1718. Reproduced with permission from (DeLancey 1992)

The lower third of the vagina is fused anteriorly with the urethra, posteriorly with the perineal body and laterally to the levator ani. In the middle third it attaches to the bladder neck and base anteriorly, with the rectum posteriorly and continues along with the levator muscles laterally. The upper third of the anterior vagina is adjacent to the bladder and ureters, posteriorly is the pouch of Douglas, and laterally the cardinal ligaments of the vagina.

### **Description of the organs and structural support of the posterior compartment**

#### **2.2 Vagina**

The vagina itself is composed of a number of different layers, which lie in apposition to each other in the normal relaxed state. The most luminal layer consists of stratified squamous epithelium with rugal folds, which permit distension for parturition. Immediately below the epithelium is a very thin layer of elastic fibres and deep to this layer is the fibromuscular layer. The smooth muscle fibres lie in a longitudinal direction towards the medial aspects of the vagina and as they move laterally towards

the periphery, they progress in a circular direction (Smout 1969). Moving through the vaginal tissue layers there is a fibrous capsule, which surrounds the muscular coat, which contains many elastic fibres and large venous plexuses. This interesting arrangement therefore allows a significant amount of intermixing of the different types of tissue, such that it condenses laterally to form bundles of connective tissue and smooth muscle enclosing vaginal blood vessels connecting to the more substantial lateral muscular groups. It therefore allows the vagina to distend as necessary. Below the vagina and anteriorly to the rectum there are spaces, which permit a certain amount of movement to help with this distension. Dorsal or deep to the vagina is found the rectovaginal septum. This provides the roof of the recto-vaginal space anteriorly.

### **2.3 Rectovaginal septum**

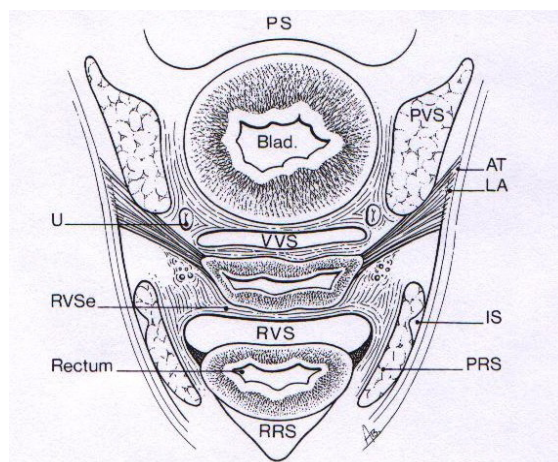
The rectovaginal septum is a distinct fibromuscular elastic tissue which is fused to the under surface of the muscularis of the posterior vaginal wall. It therefore nicely demarcates the anterior aspect of the posterior vaginal compartment. It has also been described as the anterior layer of Denonvilliers fascia and has been identified using cadaveric dissection and comparison with comparative anatomy (Milley and Nichols 1969). It appears to have been created by peritoneal fusion and extends from the peritoneal pouch created by the cul-de-sac of Douglas to the proximal edge of the perineal body. It provides a nice demarcation point, as it is the upper part for fixation of the perineal body, which therefore provides the start of the inferior margin of the posterior compartment. It is therefore crucial not only for stability of this portion of the vagina but is likely to be the area of weakness through which the hernial defect known as a rectocele occurs.

Histologically the septum consists of a fibromuscular elastic layer of dense collagen with abundant smooth muscle and coarse elastic fibres. Embryologically this area becomes fused as the cloacal area of the embryo forms. Its strength not only prevents herniation into the vagina but also may be important for normal defaecation. Defects in the septum may be as a result of congenital or acquired defects. Laterally the rectovaginal septum coalesces with the parietal endopelvic fascia.

### **2.4 The rectovaginal space**

The rectovaginal space commences just above the perineal body, which is approximately 3cm internal to the vaginal introitus. Its upper margin extends well into

the cul-de-sac of the pouch of Douglas and laterally around the sides of the rectum to the attachment of the rectovaginal septum where it extends to the endopelvic fascia. It contains loose areolar tissue and therefore provides a useful cleavage plane during surgery. Laterally at the upper part of the vagina the rectovaginal space is completed by the extension of the cardinal-uterosacral ligament complex, which passes downwards behind the vagina and connects to the lateral walls of the rectum and continues to the sacrum. These are otherwise known as the rectal pillars. This permits the rectovaginal space to be separated from the lateral pararectal spaces. It is these latter areas that are helpful when accessing the upper part of the rectosigmoid junction, as gynaecologists can utilise the strong support ligaments known as the sacrospinous ligaments for fixation of the vagina. This space is important in terms of allowing free movement of the different organs of the vagina and rectum. The roof formed by the cul-de-sac of Douglas is created by the peritoneum of this area and the space ends where the levator ani muscles attach to the cranial part of the perineal body (Figure 2.3).



**Figure 2.3.** Cross-section in axial plane of lower female pelvis at mid-vagina. This illustrates the surrounding compartments of the pelvis. Prevesical space (PS), paravesical spaces (PVS), pararectal spaces (PRS), rectovaginal septum (RVSe), ischial spine (IS), retrorectal space (RRS), rectovaginal space (RVS), arcus tendineus (AT), levator ani (LA). Chapter 1, p31. Reproduced with permission (Nichols and Randall 1996).

## 2.5 The rectum and anal canal

The rectum is continuous with the sigmoid colon and is the major component of the posterior compartment of the vagina. It commences at the level of the second sacral vertebra, descends along the sacrococcygeal concavity with an anteroposterior curve.

This is described as the sacral flexure of the rectum. This follows the sacrum downwards and finally moves forwards to join the anal canal passing through the pelvic diaphragm. The levator ani complex forms this diaphragm, and in particular the puborectalis as it loops around below the ampulla of the rectum and anal canal, vagina and urethra attaching to the symphysis pubis anteriorly. An important area is the anorectal junction, which is 2-3cm in front of and slightly below the tip of the coccyx. The puborectalis then passes down and backwards from the lower end of the rectum, otherwise known as the perineal flexure of the rectum. The rectum deviates in three different directions the upper being convex to the right, the middle deviates to the left and the lower aspect of the rectum again goes to the right. Both the beginning and the end of the rectum remain in the medium plane.

The rectum is approximately 12cm long and 4cm in diameter. The lower part of the rectum dilates to form the rectal ampulla. The rectum differs from the sigmoid colon in having no circular muscles, appendices, epiploicae or mesentery. Taenia blends in at about 5cm above the rectosigmoid junction, which then go on to form two wide muscular bands, which descend anteriorly, and posteriorly in the rectal wall. The distance between the pouch of Douglas and the anus is approximately 5.5cm. There are permanent semilunar transverse folds, which become more obvious when the rectum is distended. There are two major types of muscle fibres in the rectum. A circular muscular layer and the other contain longitudinal muscle fibres as well as circular muscle fibres. There are usually three folds and the upper one normally commences at the beginning of the rectum. The middle fold is the largest and the most constant and lies immediately above the ampulla projecting just below the level of the anterior peritoneal reflection. The lowest fold is about 2.5cm below the middle fold and is inconsistent (Jit 1961). This area is important in terms of providing landmarks for imaging, ultrasound and defaecography. It has been suggested that the folds demarcate an area of the rectum providing two different functional parts related to their embryological development (Patterson 1912). The upper part contains faeces and is free to distend while the lower more confined area acts as a temporary holding bay prior to defaecation. It has previously been noted that when distended this area results in the sensation to defaecate (Denny-Brown and Robertson 1935). Posterior to the rectum is the retrorectal space. This lies in the midline between the sacrum and the serosal tissue of the rectum and is bounded by the posterior portion of the rectal pillars. It communicates with the pararectal spaces above the uterosacral ligament.

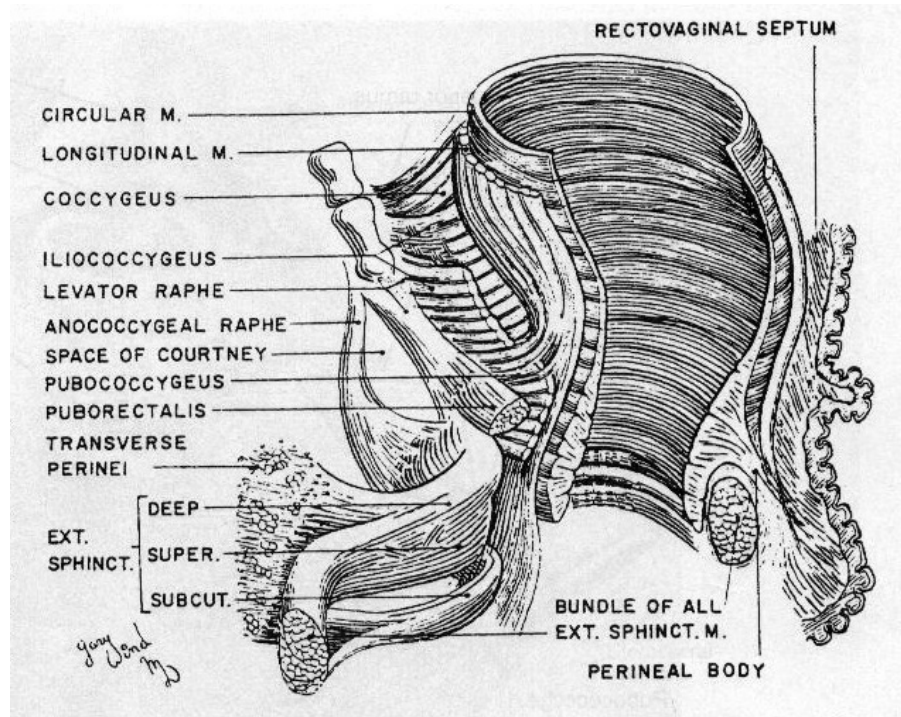
## **2.6 Posterior boundary of posterior compartment**

Posteriorly to the retrorectal space are the lower three sacral vertebrae, coccyx, median sacral vessels, ganglion impar and a branch of the superior rectal vessels. Bounding the area on the left and right is the piriformis muscle, the anterior rami of the lower three sacral and coccygeal nerves, sympathetic trunk, lower lateral sacral vessels, the coccygeal and levator ani. The rectum attaches to the sacrum along the lines of the anterior sacral foramina by fibrous connective tissue which encloses the sacral nerves and the pelvic splanchnic nerves from the anterior rami of the second foramina sacral nerves, which join the pelvic plexuses on the rectal wall; laterally are the superior rectal vessels, lymphatic vessels, lymph nodes and loose pararectal fat.

## **2.7 The anal canal**

The anal canal begins where the rectal ampulla suddenly narrows and passes backwards and downwards towards the anus. It is approximately 4cm long and like the vagina the anterior wall is slightly shorter than the posterior wall. Posteriorly the anal canal consists of fibromuscular tissue, which connects it to the tip of the coccyx as the anococcygeal ligament. Anteriorly it is separated by the perineal body from the lower vagina with the ischiorectal fossa lying laterally to it. It is enclosed in a complex arrangement of muscles, which form both internal and external sphincters (Oh 1972) (Figure 2.4). Tissues similar to that of the rectum line the upper part of the anal canal. These consist of simple glandular cells some of which are secretory and some absorptive. In the lower half of the anal canal this changes to a non-keratinised stratified, squamous epithelium of the perianal epidermis (Walls 1958). In this part of the canal are 6-10 vertical folds, the anal columns, that can be difficult to define. Each one is a terminal branch of the superior rectal artery and vein and are largest in the left lateral, right posterior and right anterior quadrants of the wall of the canal. These result in the primary internal haemorrhoids. They also provide a landmark for imaging of this area. At the end of these columns are small, crescentic mucous folds otherwise known as the anal valves, above which are the anal sinuses. It may provide an embryological junction between the endodermal cloacal and ectodermal or proctodeal parts of the canal. The anal canal extends about 15mm below the anal valves. This epithelium is non-keratinised, stratified squamous and intermediate in thickness throughout the mucosa and the epidermis in its lower part. This area of the transition zone overlies the internal venous plexus and is shiny and bluish. It provides another landmark where there is underlying dense connective tissue to anchor the

area to the surrounding anal muscle. This area is called the white line, which in a living person is usually bluish pink. The final 8mm or so below the white line is lined by true dull white skin, which may be brown in colour. The zone can be difficult to find sometimes.



**Figure 2.4.** Illustration of the internal and external sphincter complex of the anorectal canal. Sphincter is cut in mid-sagittal plane. Reproduced with permission. Oh et al. Anatomy of the external sphincter. British Journal of Surgery 1972;59:717-772.

## 2.8 Anorectal sphincter complex

### 2.8a Internal sphincter

The internal sphincter is a thickened 5-8mm wall of circular smooth muscle, which represents the thickening of the rectal muscularis externa. It encloses the upper three quarters of the anal canal, extending from the anorectal junction down to the white line, which marks its lower border. The internal sphincter lies just inside the external anal sphincter and is separated from it by a visible inter-sphincteric groove. It extends within it by just a few millimetres at the caudal extent.

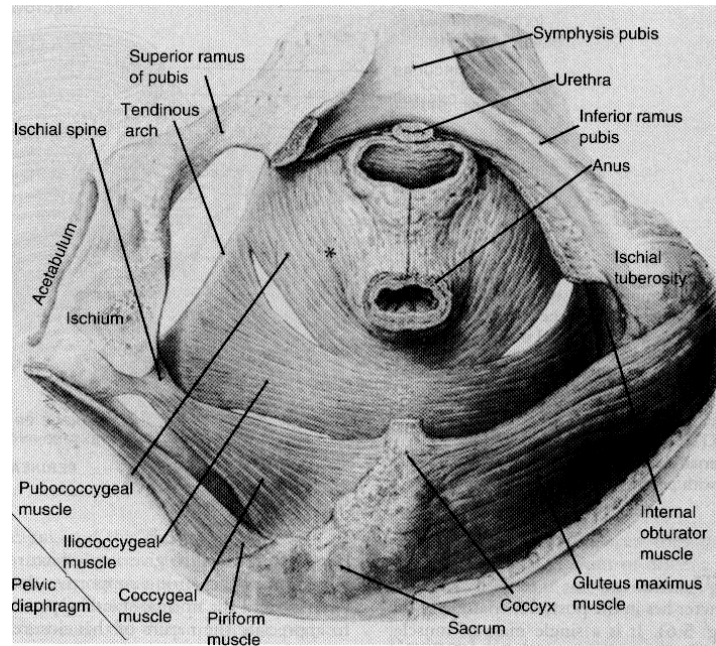
### **2.8b External Sphincter**

The external sphincter can be subdivided into a deep, superficial and subcutaneous portion. The superficial portion is adherently attached to the perianal skin and therefore forms a ring around the anal canal forming folds in this skin. It attaches to the coccyx posteriorly and also attaches inferior to the perineal body anteriorly. A deeper muscle group passes around the rectum and is almost indistinguishable from the puborectalis muscle, which loops around the surface of the anorectum and inserts anteriorly into the lower part of the pubic bone. Fibres that pass into the perineal body also become partially attached to the transverse perineal muscles, which help form the caudal aspect of the posterior compartment of the vagina. Both sets of sphincters are liable to damage during childbirth and are important mechanisms for maintaining continence of faeces.

### **2.9 Levator ani and pelvic sidewall**

The levator ani consists of a number of different groups of muscles that effectively form the floor or shelf of the pelvis in the standing position (Anson 1950)(Figure 2.5). In cadaveric dissection the muscles appear to have a distorted funnel shape, which is greater in capacity posteriorly as opposed to anteriorly. It provides the floor of the pelvis between the bones and muscles of the pelvic wall and is made up of four groups of muscles called the pubococcygeal, iliococcygeal, puborectalis and coccygeal muscles. The puborectalis-pubococcygeal muscles form the bulk of the levator ani sphincter, which encircles the rectum, vagina and urethra. It thereby acts as a closure mechanism for the vaginal outlet. The fibres do not directly insert into the urethra but simply pass around it and offers support by attaching to the inferior and inner aspect of the pubic bones. The muscle group therefore forms a sling, which pulls the rectum forward at the anorectal junction, creating a 90° angle. This can be seen clearly on defaecating proctography. The fibres of the pubococcygeal pass posteriorly ventral to the iliococcygeal muscle and the fibres intermingle and insert between the internal-external anal sphincter muscles at the point of the intersphincteric groove, thereby forming a sling behind the rectum. Some fibres pass through the cranially aspect of the iliococcygeal muscle to reach the sacrum and the coccyx.



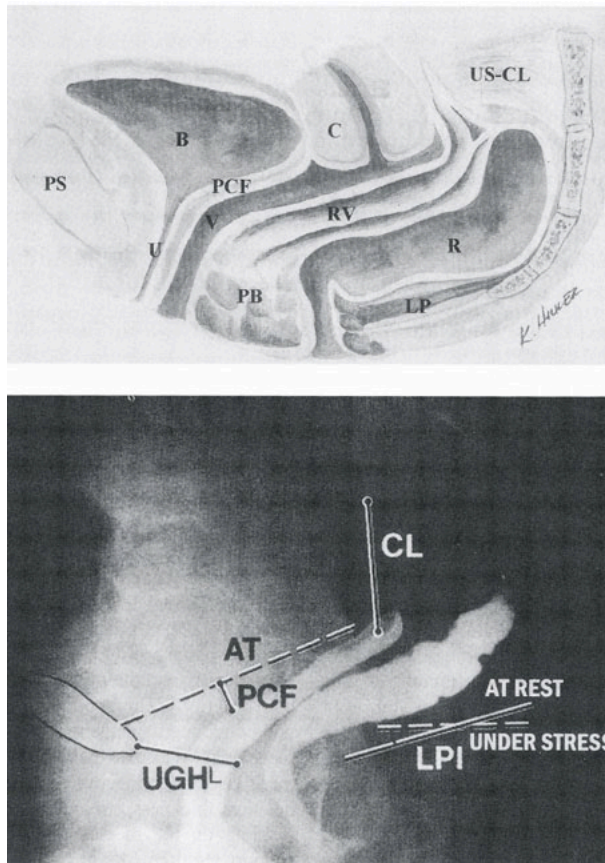


**Figure 2.5.** An inferior view of the levator ani complex with attachments. Reproduced with permission from Anson et al. *An atlas of human anatomy*. Chapter 3, page 46 Philadelphia: WB Saunders, 1950.

The iliococcygeal muscle originates from the obturator internus at a point which is a fibrous coalescence called the arcus tendineus levator ani (ATLA). It therefore provides a very broad base which then pass behind the rectum and inserts into the midline at the anococcygeal raphe and coccyx. The coccygeal muscles themselves, which are separate, pass from the anterolateral aspect of the coccyx and join with the sacrospinous ligament to insert in the midline. The interaction of these four groups of muscles form the pelvic floor that provides support for the abdominal and pelvic contents as well as permitting the dynamic rotation of the fetus during parturition as it descends through the pelvis. A central portion of the muscle complex, which effectively forms the midline raphe, is called the levator plate. It is on this plate that the vagina, rectum and uterus rest on in the standing position as it lies horizontally. Tension is maintained between the coccyx and sacrum posteriorly, the ischial spine and ischium laterally and the pubococcygeal, and puborectalis muscle as it attaches anteriorly to the pubic ramus. These skeletal muscle groups are in a state of constant contractility thereby allowing dynamic support of the pelvis and protection of the surrounding support structures such as the endopelvic fascia and uterosacral ligament.

In summary passing from anterior to posterior the puborectalis and pubococcygeal muscles pass approximately 1.5cm on either side of the midline attaching to the

support fascia of the urethra, vagina, perineal body and rectum, the support tissue being connective tissue. There is some debate as to the different contributions of the different structures of the lower pelvis, such that the pubococcygeus appears to provide greater support in the formation of a sling-like structure for the urethra, otherwise known as the pubourethral ligament as well as providing posterior support to the rectum. While the puborectalis provides posterior support to the rectum. It has been suggested that the puborectalis is in fact a distinct development of the most medial portion of the pubococcygeus (Bacon and Ross 1954). There are some however who believe that the two muscles are quite distinct and simply intermingle anteriorly while being far more distinct posteriorly. In truth it is probably that there is such variation in individuals that it is difficult to isolate which is correct. Variation can be seen where there is decussation of the puborectalis into different slips running from the belly of the muscle to the lateral margin of the perineal body. Anterior to this muscle, bundles run from the medial portion of the pubococcygeus to the posterior lateral surface of the vaginal wall and inwards towards the perineal body. Anterior to the posterior wall of the rectum the muscle complex permits formation of a hiatus by connecting with connective tissue, which surrounds the three openings of the rectum, vagina and urethra. Posteriorly however they fuse in the midline to close the hiatus. The relationship to the levator plate was confirmed in one study (Berglas 1966). They performed radiograms with the presence of contrast material in women who in the erect position demonstrated the position while resting and straining which elegantly showed the effectiveness of the angles of the vagina in closure during increased abdominal pressure. Similar studies have been undertaken in cadavers to allow comparison with anatomical dissection (DeLancey 1994b)(Figure 2.6).



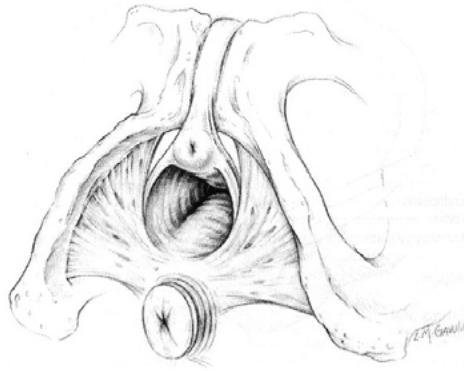
**Figure 2.6.** Comparative illustration of anatomy with old radiograph demonstrating closure of the urogenital hiatus in the upright position. Levator plate inclination (LPI), urogenital hiatus (UGH), cardinal ligament (CL), arcus tendineus (AT), pubocervical fascia (PCF). Reproduced with permission from Delancey 1994 Vaginographic examination of pelvic floor, *International Urogynaecology Journal* 5:21.

The iliococcygeus is thinner than the pubococcygeus and measures between 0.5 and 1cm in thickness. This muscle curves inwards in a convex manner, which is probably the result of fat within the ischiorectal fossa putting pressure on the belly of the muscle. The coccygeus muscle attaches to the lower sacrum and coccyx from the ischial spine and becomes intertwined with sinewy fibres from the anterior aspect of the sacrospinous ligament, the sacrospinous ligament acting as the tendon of the coccygeus muscle.

The detailed description of the levator muscle complex, is an important part of this study in attempting to determine the changes to this structure, which may be important for protecting the women from developing pelvic organ prolapse.

## 2.10 The Perineal Body

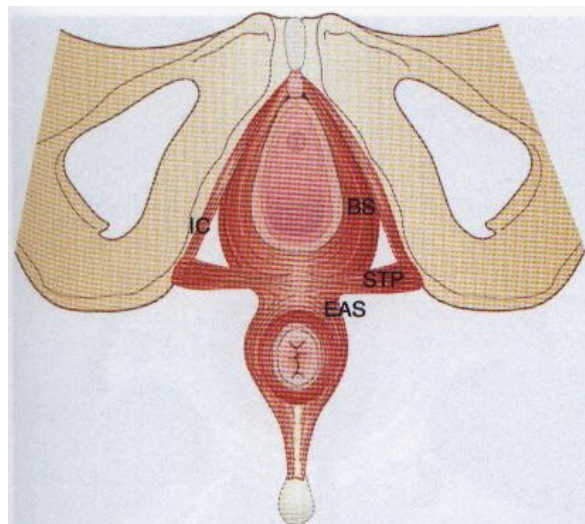
The perineal body represents what may be described as Level III support. It permits the insertion of the perineal membrane which itself is attached laterally at the ischiopubic rami in the midline it extends cranially for approximately 3cm above the hymenal ring. The largest volume of fibres are present at the distal part of the perineal body and progressively get thinner cranially. The perineal body is also the attachment for the supportive mechanism at Level II of the vagina. It is therefore an important point of inferior support for the posterior compartment of the vagina. The lateral margin of the perineal body is the end fibres of the bulbocavernosus muscle. Along the posterior margin are striated muscle fibres termed the superficial transverse muscles of the perineum, which run along the posterior aspect of the perineal membrane. Figure 2.7 is a diagrammatic illustration of the basic anatomy of the perineal body (DeLancey 1999). Of importance is the direct connection of the levator ani muscles to the upper surface of the perineal membrane thereby stabilising the compartment. The perineal body lies aligned between the ischial tuberosities at the level between the rectum and the vagina. It appears to be a fibromuscular elastic structure. Detailed dissection would suggest that the perineal body is divided into two distinct parts and has morphological features in different individuals (Joachimovits 1969). There is a distal fibrous portion and then a cranial portion as previously described. The latter seems to contain more smooth and striated muscle fibres. Embryologically this structure forms from two vertical folds of the lateral wall of the cloaca, which essentially grow as ventral and dorsal portions of the perineal body. They fuse in the midline to form a crescent-shaped fold of mesenchyme which is covered with epithelium and permanently separates the rectum from the urogenital sinus. Because the distal portion of the perineal body arises from mesenchyme it is really only by fate that it is combined with the larger dorsal part. The superficial portion of the perineal body is attached to the ischial tuberosities by way of the superficial perineal muscles. Superficially the external aspect of the perineal body is attached to Colles fascia.



**Figure 2.7.** Perineal membrane and its attachments to the pubic ramus. *American Journal of Obstetrics and Gynecology* 180: 821. Reproduced with permission from (DeLancey 1999).

### 2.11 Superficial perineal muscles

Within the urogenital diaphragm (perineal membrane) lie the deep transverse perineal muscles, which arise from the inferior rami of the ischium. Few of these fibres cross the midline. The superficial transverse perinei arise from the pubic rami and attach to the perineal body as previously stated. However the deep portion blends with the external anal sphincter but does not appear to be of significance.

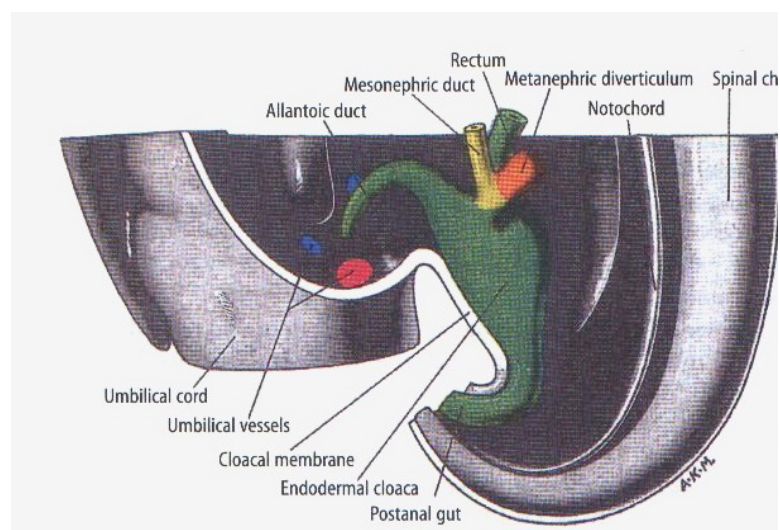


**Figure 2.8.** Superficial muscles and their attachments of the perineum. Ischiocavernosus (IC), bulbospongiosus (BS), superficial transverse perinei (STP), External anal sphincter (EAS). With permission Bartram, DeLancey 2003; *Imaging Pelvic Floor Disorders* 2003; 1:9.

## 2.12 Embryology

The embryology of the posterior compartment arises from the development of the allantoic hindgut. After proliferation and migration of the urorectal septum the cloacal region is divided into a dorsal portion which is the rectum and a ventral portion which can be subdivided into the vesico-urethral canal, a narrow channel of the pelvic portion, and a deep phallic section closed externally by the urogenital membrane. The latter two parts constitute the urogenital sinus.

Mesenchymal proliferation occurs around the rim of the ectodermal aspect of the anal membrane and therefore the rectum lies at the bottom of the depression as the proctoderm. With the disappearance of this membrane there is then communication between the anus and rectum. Therefore the lower part of the anal canal is formed from the proctodeal ectoderm mesenchyme but the upper part is lined by endoderm (Figure 2.9). As previously mentioned the line of union otherwise known as the white line corresponds to the anal valve in the adult. A plate formed by sinus proliferation enlarges cranially to form a cylindrical structure as central cells desquamate, thereby establishing a vagina. It is not clear whether both mesonephric and paramesonephric ducts are involved in this formation (Linkevich 1969). Cranially the vaginal plate grows up towards the cervix and then enlarges to form the vaginal fornices. The urogenital sinus starts to shorten to form the vestibule, which then opens, through a cleft between the genital folds.



**Figure 2.9.** Embryological development of the cloacal region at 5 weeks of age. Reproduced from Bannister et al 1995, p207 with permission.

## **Support and function of the posterior compartment of the vagina**

### **2.12 Support Structures**

The structural support of this area is an important aspect in understanding the defective problems of the posterior compartment. Extensive work by DeLancey has reinforced the idea that the vagina is in fact supported at three different levels. This consists of upper vaginal support (Level I) by the uterosacral and cardinal ligament complex. Level II, which encompasses the bulk of the vagina held together by coalescence of connective tissue known as the endopelvic fascia. Level III support, which is the most caudal aspect of the vagina attaches to the urogenital diaphragm. This consists of the perineal membrane, perineal body and the pubococcygeus/puborectalis of the levator ani complex. With regards to the posterior compartment the muscularis layers of the vagina to a minor extent anteriorly maintain support, but the majority of the strength is from the endopelvic fascia, which crosses the midline of the vagina and attaches to the levator ani laterally to coalesce and insert at the arcus tendineus levator ani. The posterior aspect of the compartment is supported by the lower sacral vertebrae and coccyx and the levator plate which curves inferiorly from the coccygeal tip to the posterior aspect of the rectum. This support is then continued around the rectum in the form of the puborectalis and pubococcygeus to once again insert into the perineal body. Further around inferiorly, this in turn is caudally attached to the perineal membrane with fibres of the somewhat weak transverse perinei and bulbocavernosus muscles. Muscle and fascial attachment move cranially from the perineal body to the underside of the vagina and attach laterally to the anterior aspect of the levator ani as it moves to the midline to ensheath the rectum and the vagina. The roof of the posterior compartment, although it is enclosed by peritoneum, is also supported to a certain extent by the lateral and posterior extension of the cardinal ligaments, which consist of endopelvic fascia, and continuation of the uterosacral complex as it inserts into the cervix and upper vagina. This moves laterally around the posterior compartment and the rectum to insert into the levator ani. Support of the rectum is maintained by connective tissue (endopelvic fascia and perineal membrane) and striated muscle (levator ani muscle); therefore appears that the muscle of the levator ani add additional support to relieve the pressure on the connective tissue, which acts like a diaphragm, during times of extra strain and it could therefore be hypothesised that weakness or deficiency or



congenital increase of levator hiatus dimensions would predispose to posterior compartment herniation. The perineal membrane has connective tissue fibres that traverse the anterior triangle between the ischiopubic rami, but moving up in to the mid-vagina these fascial sheets move in a parallel fashion in the parasagittal plane, which then go on to connect to the inner surface of the pelvic diaphragm. In a normal non-straining situation the resting tone of the levator ani permits closure of the vagina such that the anterior and posterior vaginal walls are in apposition and pressure is taken off the Level II support. The perineal membrane maintains level III and therefore no matter how strong the muscle is it is unlikely that this will help prevent herniation or prolapse of the rectum. Evidence for this comes from surgical and anatomical studies (Nichols and Randall 1996, Richardson 1995, Richardson 1993). These studies have suggested that putting pressure when the paravaginal supports are compromised at the Level II region results in descent through Level III support. What is not clear are the biomechanical properties in different individuals as to why they may be susceptible to weaknesses at the different levels of support. It seems increasingly clear that the endopelvic fascial fibres, which are thought to be most prominent in the midline of the vagina where they allegedly cross the midline, in fact run in a longitudinal direction and then towards the midline. Further studies are required to address the issue of where the endopelvic fascia has its highest potential for disruption. In more recent work it has been suggested that the deep transverse perinei muscles do not exist in terms of support other than providing a few stray muscle fibres.

#### **2.14 Pathological variations in the anatomy of the posterior compartment**

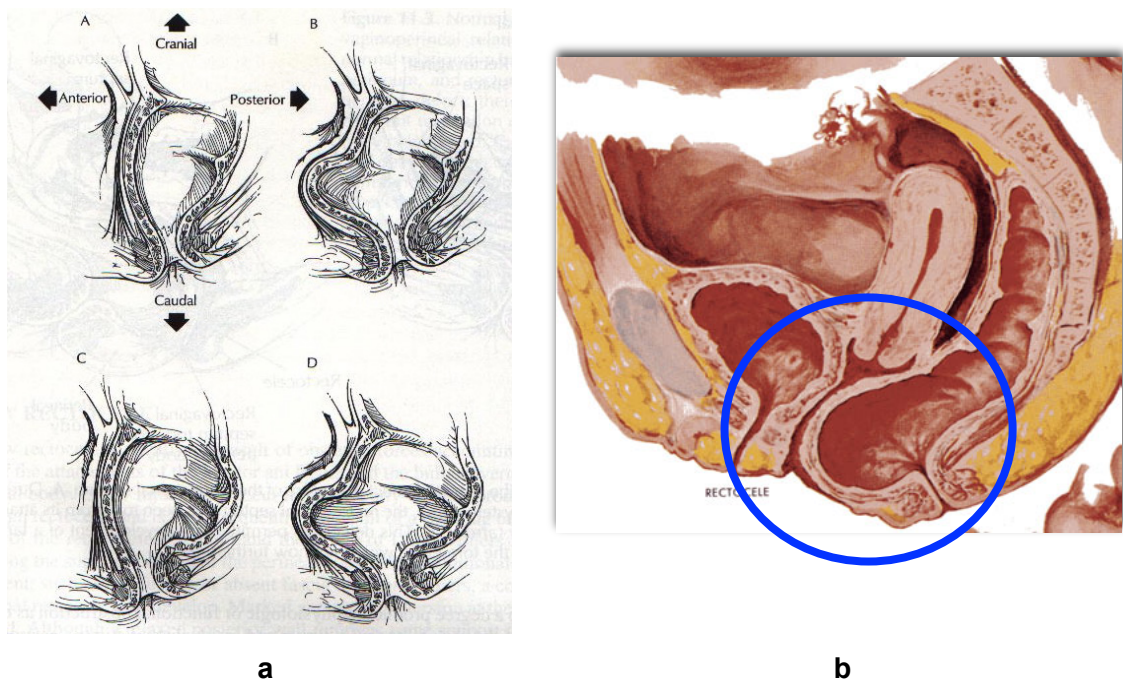
In the last 10-20 years a better understanding has arisen of the complexity of symptomatology and therefore treatment of the specific pathologies that occur in this area (Kenton, et al. 1999b). Prolapse of the posterior compartment, some examples of which are shown in Figure 2.10, can be due to:

1. A true rectocele.
  - a. Predominantly anterior protruding herniation into vaginal cavity

In addition to this a rectocele, which is defined as an abnormal protrusion of the rectum outside its normal borders, can be classified as follows:

- b. Interior rectocele
- c. Posterior rectocele
- d. Lateral rectocele





**Figure 2.10 a.** Sagittal views of both anterior and posterior rectocele. A. Normal rectum; the vagina is to the left. B. Anterior rectocele displacing the vagina. C. The rare posterior rectocele. D. Combined anterior and posterior rectoceles. Adapted from Nicholls D.H. (1996) *Vaginal Surgery* (4<sup>th</sup> Ed) Williams & Wilkins p 259. (Nichols and Randall 1996). **b.** midsagittal view of female pelvis demonstrating an anterior rectocele protruding into the vagina. With permission Netter Collection Medical Illustration 2<sup>nd</sup> Ed, p145.

2. Disruption of the perineal membrane otherwise known as perineal prolapse.
3. False rectoceles

These can be attributed to the following:

- a. Perineal hypermobility, which may be related to normal distension of the perineum or hypermobility of the rectum and ampulla.
- b. A propulsion false rectocele, created by the descent of the vaginal apex or enterocele superiorly above the posterior compartment either leading to incorrect diagnosis of the herniation of the posterior compartment or providing traction pulling down on the posterior vaginal wall resulting in folding of the rectovaginal junction.
- c. Rectal prolapse through the anus

Anterior rectoceles account for 90% of rectoceles (Matsuoka, et al. 2001) the weakest site is almost certainly the midline area of the rectovaginal septum where it is

suspected that over-distension during childbirth, results in weakness or separation of this supportive connective tissue layer. The lateral margins of the posterior compartment appear to have the strongest attachment and contains the greatest number of fibres (DeLancey 1999), which results in permanent distortion of the rugal folds overlying the site of the rectovaginal septum. Disruption of the rectovaginal septum (fascia of Denonvilliers) allows disruption at a number of different sites (Tobin and Benjamin 1945). This may be a simple midline separation, or a lateral detachment, transverse superior detachment or detachment from the perineal body (Richardson 1993). Although clinically this may therefore represent similar findings with careful inspection subtle differences may be obvious. Within the underlying rectum there is enormous capacity for distension, which therefore permits herniation through any defect created. This is related to a presence of collagen in the submucosal layer which provides a honeycombed pattern allowing blood and lymph vessels to enter and leave the muscularis mucosa and mucosa (Lord, et al. 1977). This muscularis mucosa is not present in the anal canal.

Detachment may also occur in the lateral attachment of the vagina but this is common due to the strength of these ligaments and the supporting structures, which attach to the cardinal ligament complex and the arcus tendineus levator ani laterally. This detachment probably results from chronic or acute intra-abdominal pressure rise, or from parturition. The appearance of this can be manifested as a collapsing vagina, which typically makes assessment of the upper vagina or cervix during a speculum examination difficult due to the folding of the vaginal walls. Complete disruption may lead to impaired scarring and fibrosis, which allows a certain degree of support but at a different level, further down the vagina with gradual worsening of the prolapse symptoms as the woman advances in age.

To recap, a rectocele is therefore by definition a herniation of the rectum and posterior vaginal wall into the lumen of the vagina and may displace the posterior vaginal wall at one or several levels and can be classified as a low, mid or high rectocele anteriorly.

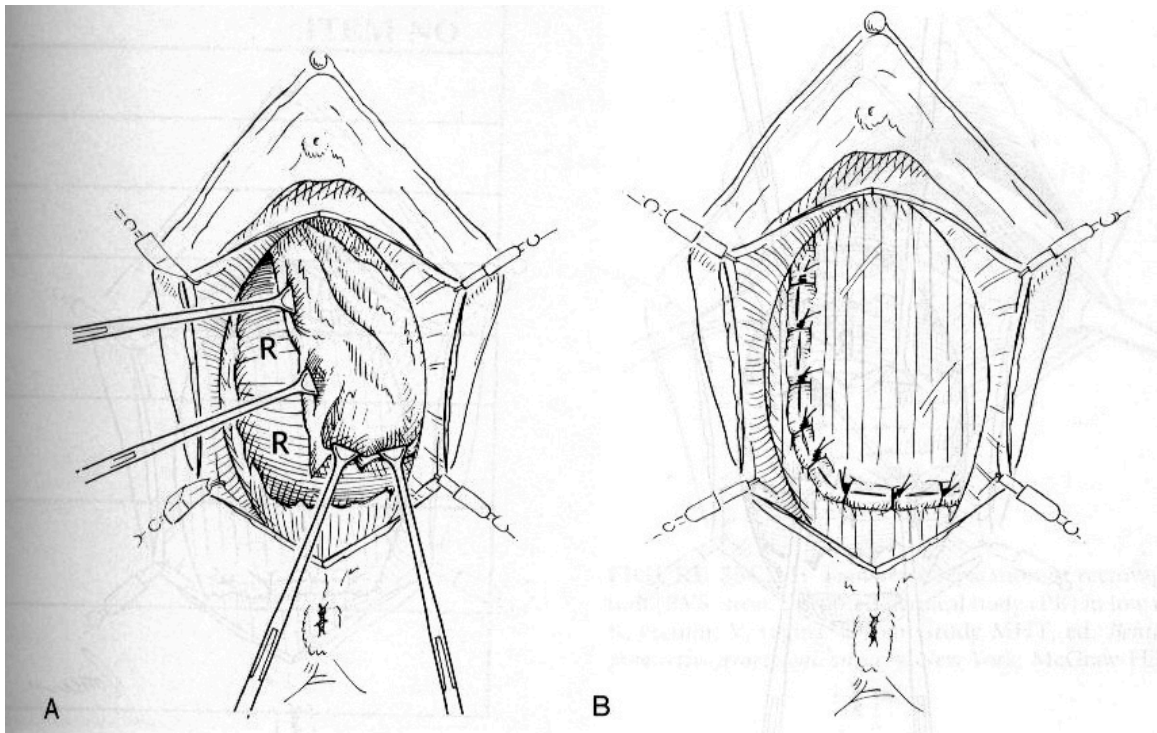
A lower rectocele is probably related to obstetric injury and poor reconstitution of the anatomy following episiotomy or tears. By not reattaching the perineal body to the appropriate rectovaginal septum it permits detachment with weakened scarring and of the gap between the rectocele as previously described.

A high rectocele probably represents chronic strain on the anterolateral attachments of the cardinal ligaments, which help support the roof of the posterior compartment by attaching to the vagina and cervix. Thus a descending uterus or upper vaginal vault prolapse secondary to disruption of the Level I support, may lead to a propulsion high rectocele. Clinically this can become obvious if the rectum is depressed while examining a posterior wall in the supine position. An area of importance is the posterior wall of the cul-de-sac or pouch of Douglas; it is this fascia, which provides support cranially that may be critical to the development of a high rectocele.

In addition to the rectoceles described above there may also be an impression of a widened genital hiatus which can be related to the disruption of the perineal membrane with consequent bulging or genital acquired widening of the levator hiatus. Alteration of the vaginal axis may result in upper or anterior compartment disruption contributing to the severity of associated rectocele prolapse.

### **2.15 The rectovaginal septum**

This tissue is important for the posterior compartment pelvic integrity. It starts at the top of the pouch of Douglas and is thin. Most of the fibres run on the lateral margins down to the perineal body. It is a trapezoidal layer that fuses with the iliococcygeal fascial coverings. It consists of dense collagen fibres with some smooth muscle mostly in the midline. Elastin is distributed throughout the entire structure, which contributes to its strength. It is more dense here than anywhere in the entire pelvis and has a unique cellular composition. This tissue was thought to attenuate as a result of the aging process, but anatomical studies have identified the presence of defects as opposed to simple tissue degeneration (Richardson 1993) (Figure 2.4).



**Figure 2.11** Diagrammatic representation of specific defects and their location of the rectovaginal septum. Te Lind's Operative Gynaecology 9<sup>th</sup> Ed. Chapter 35; 971, Chapter editor, T. Grody (Rock and Jones 2003) (Reproduced with permission)

## 2.16 Symptomatology of posterior compartment defects

Symptoms can be differentiated into:

Rectal

Vaginal

Associated bladder

### 2.16.1 Rectal

Rectal symptomatology can include straining to pass motion, constipation, digitation, discomfort, urgency, incontinence and symptoms of rectal prolapse. Herniation of the rectum through the rectovaginal septum leading to a rectocele essentially causes out pouching either anteriorly or posteriorly. This may have a number of effects with regard to defecation. Firstly it may cause entrapment of stool leading to incomplete evacuation of the rectum during defecation. Disruption of the rectovaginal septum probably allows over-distension of the anterior wall of the rectum thereby not directing stool into the ampulla and anus thereby permitting evacuation. Therefore the woman will tend to strain excessively in order to try and empty and will have the symptom of constipation. Constipation itself can be related to a number of aetiological causes of

which rectocele may be just one. A careful history is required to exclude causes such as prolonged gut transit time, inadequate diet or fluid intake in addition to neurological impairment of rectal and anal function. This is as opposed to constipation where despite perceived fullness of the rectum the woman is unable to empty her bowels and may have to digitate the perineum or vagina to complete defaecation. In the long term this may lead to hardness of stool exacerbating symptoms. It is for this reason digitation may be a very useful symptom to help differentiate the functional effects of a rectocele.

Posterior compartment defects may also cause discomfort, which symptomatically appears to come from the rectum in view of stool entrapment, pain from a hardened motion due to poor rectal function, which in turn may lead to anal fissures or haemorrhoids. In addition outpouching posteriorly although very rare may cause significant discomfort due to pressure effects in the ischiorectal fossa, impinging on the levator ani. There is no clear association of urgency of defaecation with structural defects of the posterior compartment. The rectum may prolapse out of the anus thereby causing the sensation of a lump and discomfort, especially if there is entrapment or obstruction of this hernial defect. Interestingly this phenomenon is more common in nulliparous women who are thin and elderly (Kupfer and Goligher 1970).

There may be an enterocele sac containing small bowel within the rectal prolapse and there is thickening of the rectal wall. There may be single or multiple layered thickness of the rectum. This can be confused with mucosal prolapse. The key to the diagnosis is the arrangements of the folds. With regards to incontinence other than simple overflow incontinence as a result of constipation, which may be related to rectovaginal septal defects and perineal herniation, incontinence of flatus, solid and fluid faeces is either related to disruption of the external and internal anal sphincter complex, or neuromuscular denervation of this area. Continence is therefore maintained by a constant tone both of the internal and external anal sphincter and defecation is permitted with relaxation of the external anal sphincter. Innervation of the external sphincter is via the pudendal nerve but continence is also probably maintained by the levator hiatus and levator angle produced by puborectalis. Maintenance of continence is via feedback from the intrinsic striated muscular content of levator ani, which arises from the S3 and S4 nerve roots.

### **2.16.2 Vaginal Symptomatology**

Vaginal symptoms may include the sensation of a lump, which is the most common presenting symptoms for the gynaecologist or a dragging sensation (Brubaker 1996).

The latter symptom can be difficult to distinguish from other aetiological causes such as back pain, nerve root involvement, chronic constipation or musculoskeletal problems. The lump may only appear at the vaginal introitus during periods of straining or lifting or in the vertical position. More recently the symptom of vaginal flatus has been recognised which may have a number of causes. It may be that there is some air entrapment as a result of weak prolapse causing intermittent obstruction of the vagina. A widened genital hiatus in association with a widened levator hiatus may be the cause of this rather unusual symptom. Sexual function may also be impaired either with regards to discomfort because of the sensation of a lump or shortening of the vagina precluding satisfactory intercourse or entrapment of the stool leading to pressure effects. There may also be loss of satisfaction due to the association of the widened hiatus and discomfort because of perineal movement or stretching during intercourse.

### **2.16.3 Associated bladder**

It has been suggested that there are associated bladder symptoms and that women with posterior compartment defect may have an increased risk of urinary incontinence (Mouritsen 2005). This may be as a result of disruption of the perineal membrane, which continues anteriorly to provide support for the urethral sphincter mechanism. In addition to disruption of the levator ani impaired closure of the urethra as part of this mechanism. The presence of prolapse may also lead to urgency and frequency of urine and possibly incomplete emptying due to semi-obstructive effect of the prolapse.

In view of this association it is important to investigate these women thoroughly for urinary symptoms as part of the assessment of women with posterior compartment defects. It is also important to perform a thorough clinical examination of the vagina and rectum, urodynamic investigations, which include filling cystometry, Uroflowmetry and pressure, flow cystometrogram. In addition it is prudent to consider anorectal studies such as pressure measurements and neurophysiological studies of the pudendal nerve. In addition to assessment of the external/internal sphincter complex if there are symptoms such as incontinence or constipation, imaging may also have a place, which will be discussed later.

## **2.14 Aetiological factors**

Childbirth

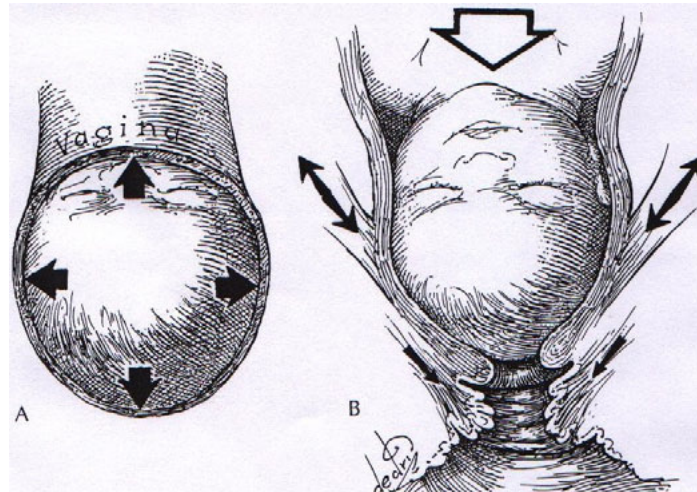
Chronic raised intra-abdominal pressure

Collagen impairment

Menopause

### **2.14a Childbirth**

Childbirth has been thought to have a major potential cause of injury to the posterior compartment. Studies by Delee and Gainey (Delee 1928, Gainey 1955) as to the precise nature of defects following childbirth, where there was just the one clinician attending a cohort of women described the injuries following childbirth. Of interest they also noted that certain injuries may be reduced by the judicious use of forceps to help control delivery and that routine episiotomy did not protect against certain types of injury. There has been considerable work looking at the short-term effects of injury related to different obstetric factors. There is evidence that episiotomy repair is associated with both anterior and posterior compartment defects in addition to forceps or outlet-assisted operative delivery, and length of second stage. Rapid delivery may be just as bad in terms of long term outcome for the posterior compartment as prolonged second stage. A problem is direct correlation with certain injuries and long-term problems as it may be many years before a woman presents with symptoms related to structural or functional defects of the pelvic floor. Therefore most studies either relate to short-term symptomatology or function or rely on long-term retrospective recall studies (MacLennan, et al. 2000, Snooks, et al. 1984, Swash, et al. 1987).



**Figure 2.12.** The stress areas on the uterosacral/ cardinal ligament complex  
As shown by the arrows with descent of the fetal head into the pelvis. With permission from Nichols 1989 chapter 2:47.

The manner in which injury may occur as a result of childbirth can be postulated as follows. Injury may be related to over distension of the vaginal walls either as a result of a large foetus or compound presentation which thereby overstretches the vaginal walls essentially overcoming the elastic breaking point beyond which it is difficult for the tissue to regain tone. Therefore it may present as a vagina that collapses medially rather than along the craniocaudal axis. Other mechanisms may include detachment of the Level 1 uterosacral/cardinal ligament complex as a result of prolonged traction or compression leading to ischemic necrosis (Figure 2.12). This may also be a factor in the lower aspect of the vagina where folding of the vagina leads to pressure on a potential source of weakness; i.e. the transverse superior connection between the rectovaginal septum and the pouch of Douglas cul-de-sac. This effectively causes detachment of the fascia, which leads to an upper transverse defect. A similar mechanism may be related to the lower rectovaginal septum where it attaches to the perineal body. This may be more likely to be related to rapid expansion of the perineum causing disruption to the perineum either as a result of the size of the foetus, rapidity of labour or trauma related to a second or third degree tear or episiotomy. It is in this situation that a forceps delivery or Ventouse delivery may initiate continuing trauma by causing an increase in the width that the vagina is forced to distend to.

In addition to these factors there may also be unilateral defects whereby rotation of the fetal head or compound presentations cause specific disruption of the support



mechanism either in the rectovaginal septum or in the lateral support of the vaginal wall which may be torn at the point of the insertion of the endopelvic fascia. Again it can be postulated that this may either be due to physical disruption or pressure effects as related to prolonged first, late first or second stage or sudden expansion. This results in ischemia of the muscularis layer thereby creating weak scar tissue post-partum. It is also interesting to postulate that in a nulliparous woman who has the fetal presenting part slowly distending the vagina as the presenting part engages, may be at less risk due to the gradual relaxation and accommodation of the foetus such that there is a gradual distension. The different levels of injury may relate to the forces applied at different parts of the labour. For example if progress is held up by unusually strong uterosacral cardinal ligaments this may therefore put pressure prior to full dilatation of the cervix. Sudden rapid delivery of the baby causes disruption of the rectovaginal septum, which is accentuated at the vaginal outlet for the perineal body and perineal diaphragm.

#### **2.14b Chronic raised intra-abdominal pressure**

There is an association between conditions that cause raised intra-abdominal pressure either on a continuous or intermittent basis (Hendrix, et al. 2002). These include obesity, chronic cough, abdominal distension and malignancy. Certainly improvement in the woman's peri-operative co-morbidity factors such as obesity and chest complaints may improve the outcome of surgery. It is postulated that the raised intra-abdominal pressure places strain on either previously weakened or structurally damaged supports such that over time there is continuing stretching of the previous scar tissue to the point where any resulting elastin in the connective tissue or endopelvic fascia is stretched or broken beyond capacity.

#### **2.14c Collagen**

Collagen is an important component to the structural integrity of the fascial layers particularly the endopelvic fascia and rectovaginal septum. Undoubtedly there must be congenital factors that predispose some women to genital organ prolapse. There have been associations with hypermobility at the elbow joint, suggesting an underlying connective tissue abnormality and more recently ultrasound studies have demonstrated that hypermobility of the bladder has a high association in twins with a concordance rate of  $r=0.48$  (Hansell, et al. 2004, Norton, et al. 1995). There are different ratios of collagen/elastin to collagen Type I and Type III. The latter seen in new tissue is replaced by collagen Type I which forms stronger longer-lasting structural support. This may replace elements of elastin in areas where there has

been significant denudation or tissue damage. The type of collagen present may be a congenital factor and may have bearing on those women with genital prolapse however the precise changes are still under study (Jackson, et al. 1996, Wong, et al. 2003).

#### **2.14d Menopause**

A decline in skin collagen and thickness after menopause related to the reduction in oestrogen levels (Brincat, et al. 1983). Comparing those women who were having hormone replacement and those who were not there is a clear correlation in vaginal skin thickness. Undoubtedly the menopause has a significant effect on thinning of the vaginal mucosa but also the muscularis layer replacement of elastin with flexible matrix in the connective tissue. However there have been no studies that have confirmed that replacement of oestrogen causes regression of the changes seen with those women with genital prolapse.

#### **2.15 Treatment options**

Treatment options include conservative or surgical therapy. Conservative measures have been seemingly poor in terms of symptomatic treatment of women who present particularly with a lump or difficulty with digitation in having to pass motion. The reason being that traditional support devices such as ring, Hodge or shelf pessaries are primarily aimed at supporting the uterus of the anterior compartment. They depend on the horizontal position of the levator plate to maintain and restore this position, using the symphysis pubis as one part supporting framework in order to prevent descent of the anterior wall or anterior compartment. Posteriorly however if there is a defect particularly in the perineum then one axis of the support structure cannot be reinforced. This allows movement of the prolapse underneath any supporting device. Treatment with hormone replacement therapy, physiotherapy to strengthen the levator muscle, electro stimulation therapy or other exercises appear to fail to improve what is essentially structural damage to the posterior compartment supporting mechanism.

There have been a number of surgical treatments and sadly over many years it was thought that the different structural components or functional components of the posterior compartments could be repaired on the premise of one or two operations. Essentially these revolved around the notion that a rectocele could be closed just using the muscularis layer with often vaginal mucosa being excised to “close the hole”. The other option was to obliterate the genital hiatus performing a levatorplasty,

which involves closure of the genital hiatus and surrounding levator ani thereby causing an obstructive mechanism to the levator floor. However newer techniques have evolved as the understanding of the underlying pathological problems have improved due to the identification of specific defects in the rectovaginal septum. We are now in a rapid phase of discovery and tailoring surgical operations for specific defects. This may include repair of defect specific injuries to the rectovaginal septum using absorbable sutures or providing a neofascia with fully absorbable or composite mesh overlay techniques. Perineal defects can be repaired using fascial reattachment to the rectovaginal septum or a constitution of the perineal membrane with apposition of disrupted muscle fibres underlying this. A high rectocele can be repaired with a simultaneous structural reconstitution of the vault axis with vault suspension operation or neostructural support using permanent mesh implants. Efficacy of these different surgical approaches has often not been tested, as there has been disagreement as to what is the most appropriate approach and also to appropriately classify the abnormalities prior to surgery.

It is in this context that a suitable means of assessment is required to test new therapies against old ones.

## CHAPTER 3

### METHODOLOGY

#### 3.1 Aim

The aim of the following studies was to determine whether 3-dimensional ultrasound of the female lower pelvis is a useful investigation in the assessment of women complaining of genital organ prolapse, with particular reference to the posterior compartment of the pelvis.

#### 3.2 Experiments for the study

In order to address whether 3 dimensional ultrasound imaging is a clinically relevant investigative modality there are four parts to the study. These are as follows:

1 A prospective study using 3-dimensional (3D) ultrasonography to study and measure the posterior rectovaginal septum with any attendant defects, to test the reproducibility of these measurement methods.

2 In addition to measure and define the range of measurements for levator hiatus dimensions, in women in their first pregnancy, after 34 weeks gestation, so as to define the incidence in a normal population of women of congenital rectoceles. Measurements will be undertaken at rest, on contraction of the pubovisceral muscle i.e. the pubococcygeus and puborectalis complex. These measurements will then be correlated with responses to pelvic floor symptom questionnaires, to identify correlation with abnormal pelvic floor symptomatology. It will provide a set of data for normal nulliparous women for the local population.

3 An audit of surgical repair of rectocele using a single surgical technique and single operator, using parameters of vaginal wall prolapse (previously defined on ultrasound), and comparing the findings with clinical assessment of vaginal wall prolapse by an experienced gynaecologist. Data will be prospectively collected on pelvic floor function, clinical degree of prolapse utilizing the Baden-Walker (Baden and Walker 1992) measurement scoring of POP, as well as data on concomitant surgery and pre-operative demographics at the time of ultrasound examination. On ultrasound measurements of rectovaginal septal defect size, perineal hypermobility in the mid-sagittal plane, and identification of associated enterocele prolapse will be recorded. Validation of the measurement techniques will be tested with an

independent investigator who will review the data volumes separately. The coefficient of variation will be analysed using ANOVA and the two-sample t-test to test the variation between dimensions. In addition Pearson's correlation will be used to compare levator hiatus dimensions and recurrence of rectocele fascial defects.

4 To compare the current imaging modality of choice, MRI and 3D ultrasonography, for identification of the structural landmarks in the posterior female pelvic compartment, including measurements of the levator hiatus and rectovaginal septum. Comparison of measurements will involve analysis of Pearson's coefficient for reliability, and intra-class correlation. In addition a cost evaluation of the two modalities will be made and compared.

5 A prospective investigation comparing ultrasonography with a validated clinical measurement system, the POPQ, pre-operatively and post-operatively at approximately 6 months. Patients will be studied to measure the variance of the two measuring systems for recurrence of rectocele and other posterior compartment prolapse as well as levator ani dimensions in the axial plane. In this way data obtained will provide prospective, objective imaging data for the success of surgery for the posterior compartment. Analysis will be comparative within the same subject, comparing outcome using clinical evaluation versus objective ultrasound measurement and subjective symptoms. Paired t-test analysis, with intra-class correlation of the two methods.

These studies are expected to provide sufficient data to evaluate the use of ultrasonography for objective assessment of the posterior vaginal compartment. However at the end of each study reviews will be undertaken to modify the methodology as required.

### **3.3 Technique of obtaining volume data sets using transperineal ultrasonography**

For ultrasound assessment women will be placed in the supine position, having emptied their bladder. A GE Kretz Voluson 730 ultrasound machine, using a Kretz 7-4 MHz volume transducer is placed on the perineum in the mid-sagittal plane. The transducer is covered with a powder-free glove prior to the examination. The probe is pressed firmly but without causing discomfort such that the introitus is covered and no air bubbles are present to interfere with image quality. A diagrammatic representation

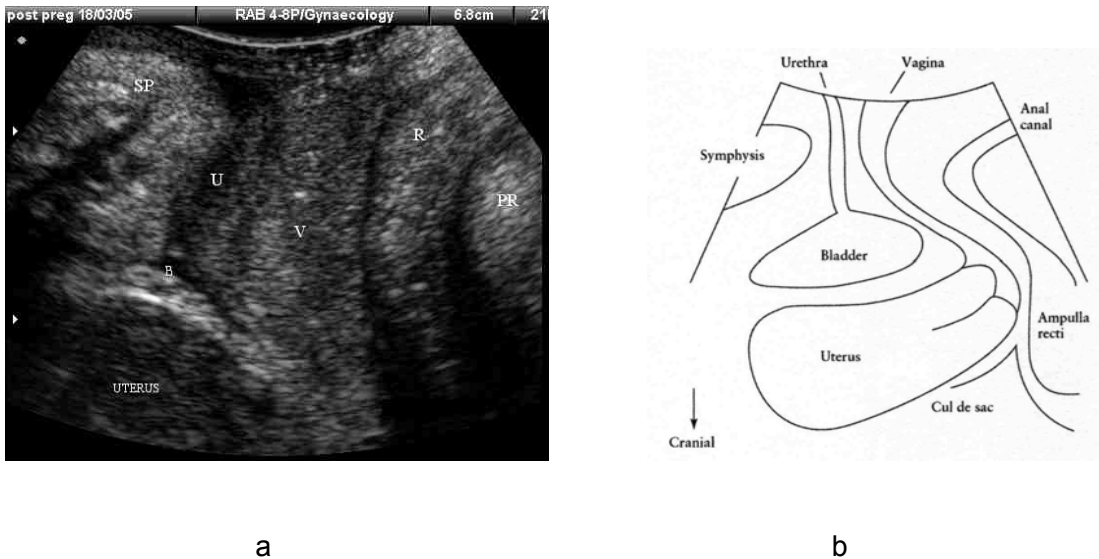
of the position of the probe is shown in Figure 3.1. Pressure must be released on the transducer head when identifying prolapse as this may reduce the accuracy of measurement. The transducer settings are set for maximal acquisition angle both anteroposterior and laterally which usually equates to 70° and 70- 85° respectively. The image should contain the lower part of the symphysis pubis, urethra, bladder upper vault or uterus, rectum, Pouch of Douglas and anorectal junction. That part of the levator ani that is the puborectalis and pubococcygeus should also be visible, as may the external anal sphincter. For a complete examination an abdominal and transvaginal scan will be performed to exclude other gynaecological causes that may relate to presenting symptomatology of a prolapse.



**Figure 3.1.** Diagrammatic representation of position of subject and transducer head for acquisition of volume data set. With permission from Prof Dietz.

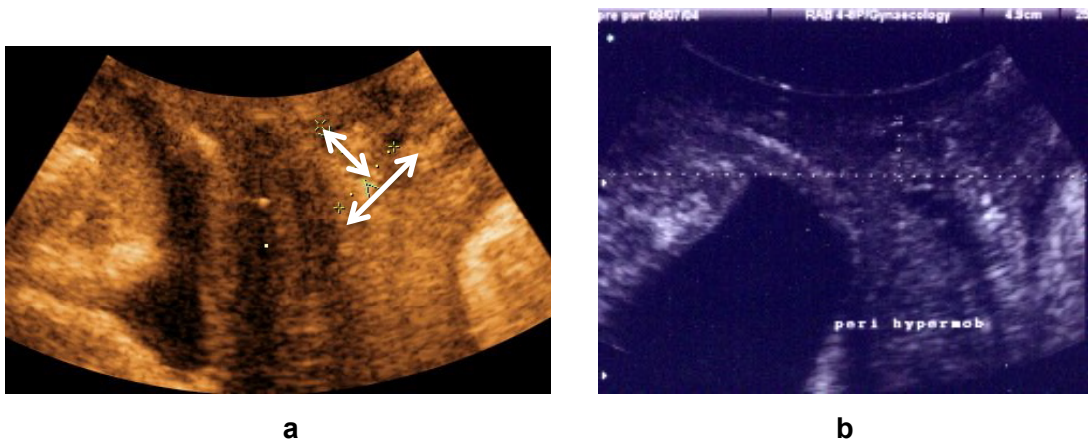
Using ultrasonic jelly at the interface, volume data is acquired at rest and on maximum Valsalva strain, having undertaken the manoeuvre at least 3 times as practice, under close supervision. Maximum Valsalva straining is achieved with coaching and after training the subject, if necessary with the help of real-time ultrasonographic cine loop to show the direction of the strain. However, great care must be taken to avoid reflex contraction of the Levator ani and this is true regardless of whether standardisation for Valsalva pressures is attempted. Careful observation of

real-time ultrasonography (US) can identify this potential confounder and artefact easily. A mid-sagittal image is obtained as shown in Figure 3.2.

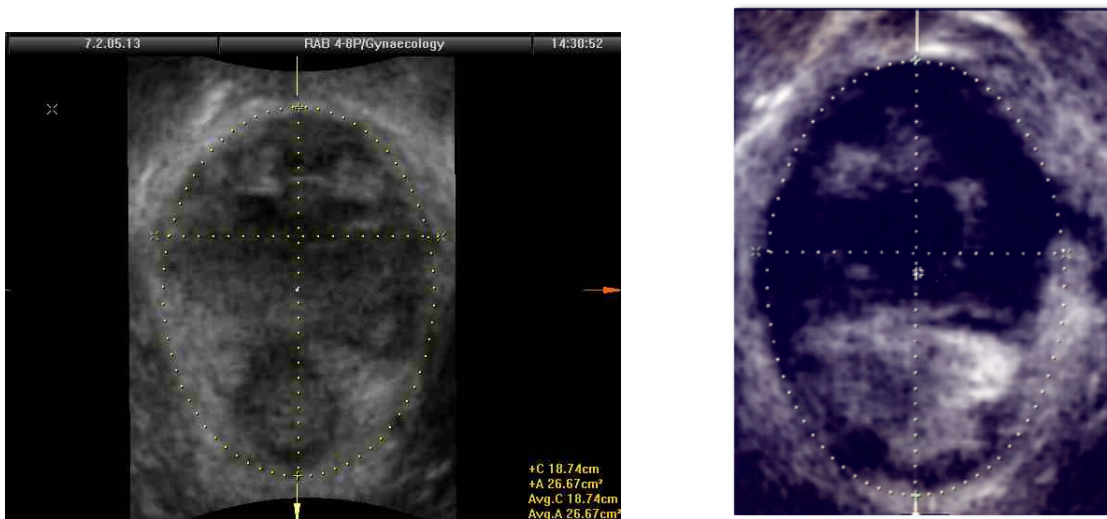


**Figure 3.2.** a; image in the mid-sagittal plane with the pelvic organs labelled, SP symphysis pubis, V, vagina, R, rectum, U, urethra, B, bladder, PR, puborectalis. b; diagrammatic illustration highlighting the structures visualised of image a, during transperineal US. Reproduced with permission from Prof Dietz.

Defects in the rectovaginal septum will be noted subjectively in addition to other posterior compartment defects and measured in the oblique cranio-caudal diameter as well as vertically to obtain the depth of the defect (Figure 3.3). In addition the degree of perineal mobility will be assessed by measuring caudal displacement of the rectal ampulla, relative to the inferior margin of the symphysis pubis. The diameters and area of the levator hiatus at rest and on Valsalva will be measured as shown below in Figure 3.4, such that the plane chosen is symmetrical, containing the shortest distance between symphysis pubis anteriorly and levator muscle posteriorly.



**Figure 3.3.** a; two-dimensional mid-sagittal view of defect seen of rectovaginal septum on Valsalva, with measurements of depth and anteroposterior diameters as shown. (From personal image files), b; measurement of perineal mobility by measuring the ampulla relative to the symphysis pubis.



**Figure 3.4.** (a) Levator dimension at the line of narrowest introital antero-posterior dimension at rest. (b) Same dimensions on Valsalva. (Taken from personal image files)

Validation of the technique for inter-observer correlation will be undertaken by independent review in a blinded fashion by someone who has extensive experience in 3-dimensional ultrasound analysis. Inter-observer correlation will be tested to measure the reliability of the test to determine if it can therefore be reliably used for further studies. Volumes will be stored with back up off-site on external hard drives and reviewed at a later date. The primary observer was trained on 40 subjects prior to commencing the study as party of another study to confirm sufficient training by an experienced clinician who had undertaken over 700 such similar examinations.



### **3.4 The use of standardised measurement tools for clinical assessment of POP.**

For clinical assessment the POPQ (Bump, et al. 1996) will be used (Appendix 1).

### **3.5 The use of questionnaires for evaluation of clinical symptoms**

In addition the following information will be collected:

Symptoms of urinary, bowel and POP are collected using the questionnaire listed in Appendix 2.

Further methodological details will be given in each of the studies.

## CHAPTER 4

### EXPERIMENT 1

**A prospective observational study to test the reproducibility and reliability of rectocele prolapse and levator measurements of the posterior compartment of the female pelvis.**

**4.1 Hypothesis:** 3-dimensional ultrasound is a reliable and reproducible technique to identify and quantify the severity of rectoceles as well as measure levator hiatal dimensions for the posterior compartment.

#### **4.2 Introduction**

Previous work has looked at the use of transperineal US for bladder neck function and structure. These have been proven to be reliable and reproducible (Atherton and Stanton 2000, Reddy, et al. 2001). Rectocele formation is one aspect of posterior compartment dysfunction that is a common finding in women who present with POP, accounting for approximately 18% of women in the Womens Health Initiative and 25% of diagnosed prolapse (Hendrix, et al. 2002). It is associated with symptoms of constipation, incomplete bowel emptying, stool trapping and pelvic pressure sensation (Janssen and van Dijke 1994, Siproudhis, et al. 1992). Other types of prolapse may co-exist such as enterocele formation, perineal ballooning or hypermobility as well as perineal deficiency related to muscle loss following vaginal delivery. In addition supporting structures of the vagina such as the deep levator muscle complex anatomically provide not only a conduit but potentially a secondary support mechanism posteriorly at the mid to lower posterior vagina (DeLancey 1999). Clinical examination may reveal some information but does not identify the specific areas of disruption deep to the vaginal mucosa. Surgery has to disrupt tissue planes making identification of defects difficult and does not allow comment on muscle integrity, which are usually paralysed anyway. Defaecating proctography does allow useful information on defects and anal relaxation but involves radiation (Agachan, et al. 1996). Although tolerated it involves insertion of contrast into the rectum, which can be considered by some subjects to be unpleasant. This experiment was designed to test the intra-observer and inter-observer reproducibility and therefore reliability of these investigative measurements.

### **4.3 Methods**

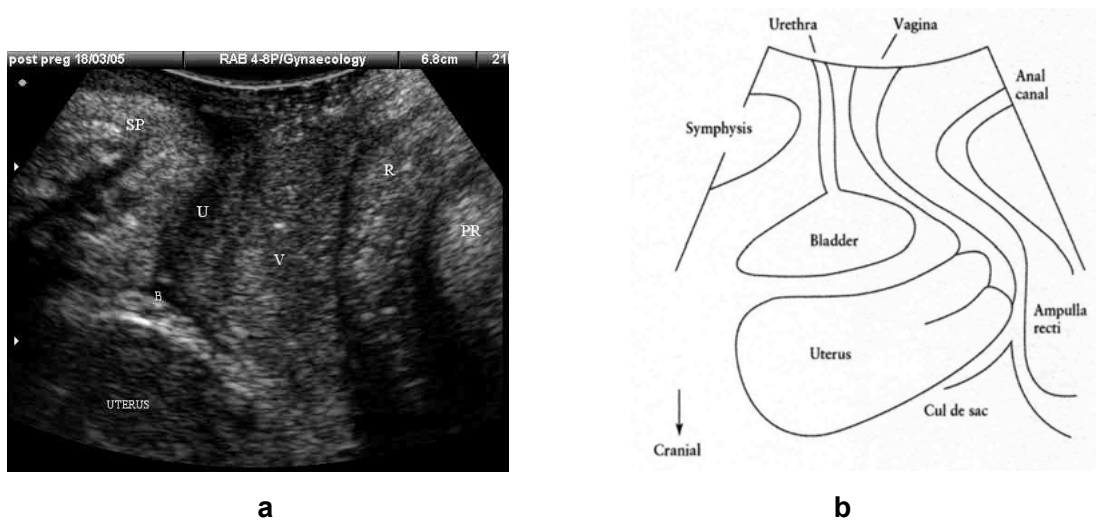
This was an observational study. Observer 1 (Dr Christopher Barry) was trained how to perform the assessment and measurements for rectocele identification, perineal mobility and levator dimensions on 20 patients by observer 2 (Prof Hans Dietz) who was experienced in these measurements with over 700 previous scans. This allowed sufficient training to establish the technique. Twelve women with incidental rectocele prolapse as part of a separate study on post incontinence treatment were identified to use for a test-retest series (Dietz, et al. 2005). Information was collected on the presence or absence of rectovaginal defects, size of defect, mobility of the rectal ampulla, and levator hiatal dimensions (diameters and area). A urinary, bowel and prolapse questionnaire was taken by direct interview. The first observer undertook the measurements listed above. Observer 2 was out of the room with the subject left in the same position without recourse to previous measurements straight after assessment. The second observer then undertook the same measurements and the two were compared. The first observer then rechecked the measurements two weeks later using the offline tool for volume manipulation with volume data storage feature. This did not allow access to the previous measurements.

### **4.4 Technique of Obtaining Volume Data Sets using transperineal ultrasonography**

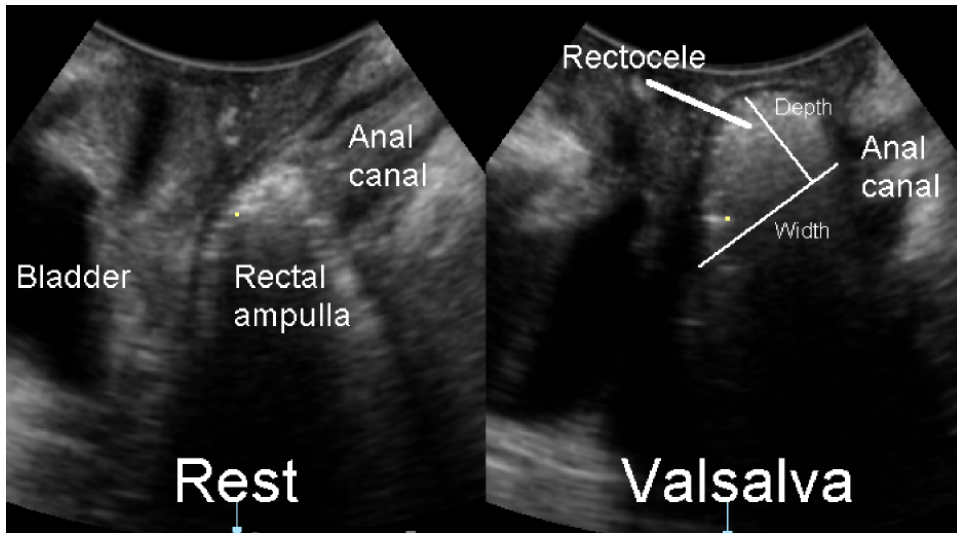
A GE Kretz Voluson 730 ultrasound machine, using a Kretz 7-4 MHz volume transducer was placed on the perineum in the mid-sagittal plane. Prior to the study the patient was asked to empty her bladder and preferably her bowels as this was thought to reduce the maximum dimensions on maximal Valsalva strain. The patient was placed in the lithotomy position, with the knees bent at 90 degree angle and feet approximately 30cm apart to minimise the discomfort. She was covered with a sheet to also minimise embarrassment. The transducer was covered with a powder-free glove prior to the examination. The probe was pressed firmly but without causing discomfort such that the introitus was covered and no air bubbles were present to interfere with image quality. Pressure must be released on the transducer head when identifying prolapse as this may reduce the accuracy of measurement. The transducer settings were set for maximal acquisition angle both antero-posterior and laterally which usually equates to 70° and 70- 85° respectively. The image contains the lower part of the symphysis pubis, urethra, bladder upper vault or uterus, rectum, Pouch of Douglas and anorectal junction (Figure 4.1). That part of the levator ani that is the puborectalis and pubococcygeus should also be visible, as may the external

anal sphincter. The patient is asked to Valsalva three times in order to train the subject how to produce sufficient strain and then the maximum value is used for the final measurement.

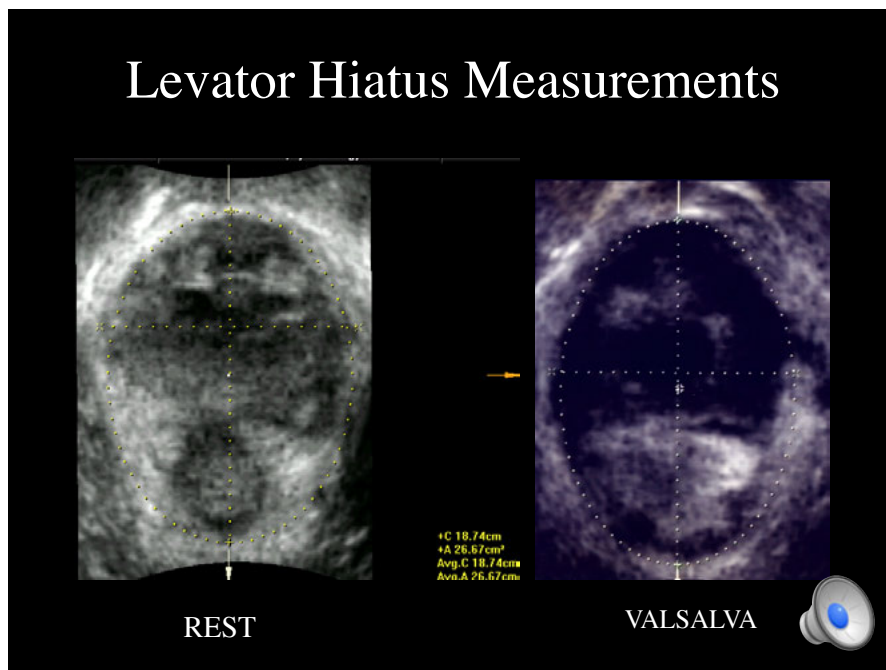
- Posterior rectovaginal defects were measured in the oblique cranio-caudal diameter as well as vertically to obtain the depth of the defect (Figure 4.2).
- The diameters and area of the levator hiatus at rest and on Valsalva were measured as shown in Figure 4.3, such that the plane chosen was symmetrical, containing the shortest distance between symphysis pubis anteriorly and levator muscle posteriorly.
- Subjective observations of defects in the rectovaginal septum (Figure 4.4).
- Perineal mobility was assessed by measuring caudal displacement of the rectal ampulla, relative to the inferior margin of the symphysis pubis (Figure 4.5).



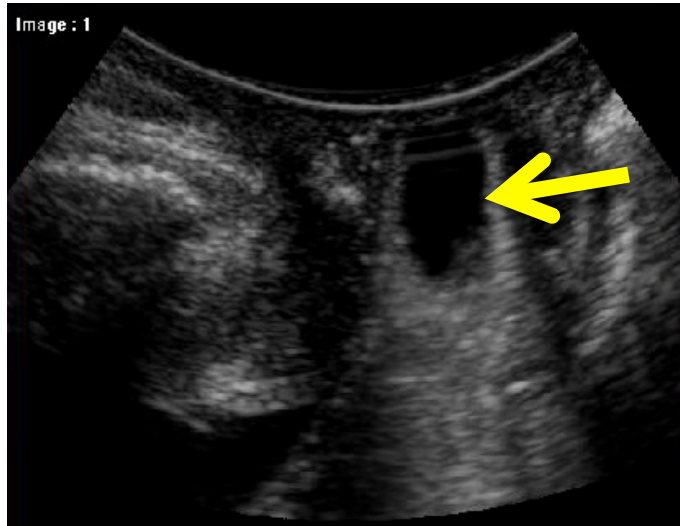
**Figure 4.1 a;** This image demonstrates a typical picture in a normal woman at rest in the correct mid-sagittal plane. The rectum (R), symphysis pubis (SP) and bladder neck (BN) can all be seen in the image. Also seen are the urethra shadow (U), puborectalis (PR) and uterus. **b;** represents a diagrammatic representation of the captured image (with permission from Prof Dietz 2001).



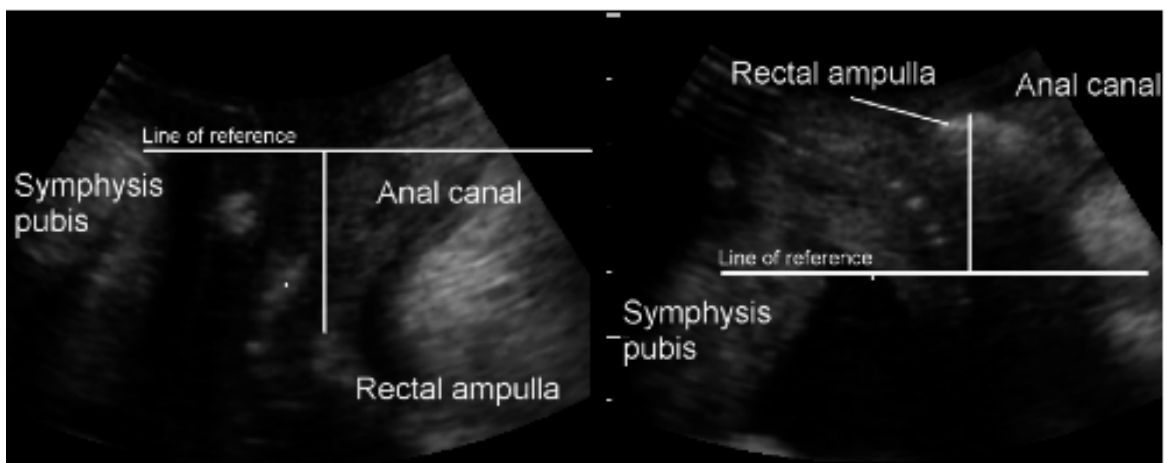
**Figure 4.2.** Images on 2-dimensional, mid-sagittal plane, of rectum at rest and on Valsalva strain demonstrating the measurements taken of a rectocele herniation. Reproduced with permission from Prof Dietz.



**Figure 4.3.** The levator hiatus of minimal dimensions at rest and on Valsalva strain showing antero-posterior, transverse and circumferential measurements.



**Figure 4.4.** An ultrasound image in mid-sagittal plane of enterocele prolapse as identified by the arrow. Bowel gas can give an echolucent area but is not always present.



**Figure 4.5.** This image demonstrates the measurement of rectal ampullary movement with the image on the left being at rest and Valsalva strain on the right. A line is drawn horizontally from the inferior margin of the symphysis pubis and a second vertical line is drawn to the sonodense area in the rectum corresponding to the ampulla. Excursion is measured between the two depending on the caudal displacement. Reproduced with permission from Prof Dietz.

ICC (Intraclass correlation) was used for means of measures between observers  
 Test-retest correlation for intra-observer measurements. Cohens Kappa was used for non-exchangeable categorical data. SPSS Chicago II version 11.0, Licensed to JCU.

All data was stored on secure electronic databases with secure back up and hard data in a locked storage facility.

#### 4.4 Results

Twelve women were identified as having a rectocele. Mean age was 54.2 years (range 36-73 years); BMI was 29.3 (range 24.4- 37.7). Parity 3 (range 1-5). Four had had posterior vaginal repair operations at the time of their incontinence surgery. On clinical examination all women had a rectocele diagnosed > Gr 2 (7 = Gr2, 4= Gr 3) (Baden-Walker scale). One woman had no rectocele but an enterocele on US (p=0.32 Fishers exact test). One woman had no rectocele on US and no obvious defect on US. Median depth of such defects was 1.45 cm (SD 0.6) and width was 0.95cm (SD 0.4). The median was used due to the presence of outlying results. Perineal mobility from rest position was 0.46cm (SD 1.23) with a maximum point in relation to symphysis pubis of + 0.6mm. Cohens kappa for rectocele presence or not was 0.71. Levator ani dimensions at rest and on Valsalva are shown in Table 4.1.

| <b>The intraclass correlations between measurements of</b> |
|--|
| rectocele depth =0.79                                      |
| rectocele width =0.69                                      |
| perineal descent =0.64                                     |

| <b>A test-retest series yielded a correlation of</b> |       |
|--|-------|
| rectocele depth                                      | =0.82 |
| rectocele width                                      | =0.84 |
| perineal descent                                     | =0.72 |

| Levator dimensions | Minimum             | SD  | ICC rest | Test-retest At rest | Maximum             | SD  | ICC Valsalva | Test-retest Valsalva |
|--------------------|---------------------|-----|----------|---------------------|---------------------|-----|--------------|----------------------|
| Antero-posterior   | 6.2cm               | 1.2 | 0.73     | 0.89                | 8.9cm               | 1.4 | 0.71         | 0.81                 |
| Transverse         | 3.8cm               | 0.8 | 0.78     | 0.91                | 4.9cm               | 1.0 | 0.69         | 0.82                 |
| Area               | 15.6cm <sup>2</sup> | 2.8 | 0.65     | 0.76                | 28.4cm <sup>2</sup> | 4.3 | 0.64         | 0.79                 |

**Table 4.2** Levator dimensions with minimum and maximum dimensions and standard deviations. ICC and test-retest series shown for dimensions at rest and maximum Valsalva.

#### 4.5 Discussion

Rectocele prolapse are considered to be a herniation of areas of the rectovaginal septum (RVS), that cause the rectum or at least part of the anterior wall of the rectum to protrude outside of its normal position and into the vagina (Nichols and Genadry 1993). Rectocele prolapse can be diagnosed with the use of US as has been previously demonstrated (Creighton, et al. 1992). The precise location of defects in the RVS do not seem possible clinically and even during surgery, but on US the weakness seems to be mostly at the midvagina near the ampulla where a projection or break in the continuity of the rectal serosa can be seen. It would seem sensible that repairs of rectocele incorporate resolution of the primary pathology, which cannot be determined clinically. Worse would be applying techniques that do not treat correctly the underlying condition because of mis-diagnosis and may indeed account for relatively high failure rate of rectocele repair in the past (Arnold, et al. 1990, Kahn and Stanton 1997).

This study demonstrates good reproducibility both within the observer and between observers for measurement for rectocele dimensions, perineal mobility and levator hiatal dimensions. In addition US detected one enterocele where it was thought to be a rectocele. Also interesting is that US disagreed with one subject's clinical finding by suggesting no rectocele but appeared to be due to mobility of the rectal ampulla. It is concerning that there may be discrepancy in diagnosis clinically when compared to ultrasound: surgical correlation would help confirm which modality would be more accurate for the diagnosis of enteroceles and sigmoidoceles. Previous surgery may confuse the issue, as an "apparent rectocele" may in fact be mucosal heaping or overlap due to previous surgical technique for closure of the mucosa. Therefore it is possible that US is more accurate in diagnosing the underlying defect in the posterior compartment.

It seems to be important to train patients to Valsalva strain properly to see the maximum protrusion otherwise this could be a confounding factor for reliability of US measurements. Consistency in technique is therefore important being careful to allow movement of the transducer, as well as complete emptying of the bladder and bowel prior to imaging. Perineal mobility may possibly mimic a pseudo rectocele and may relate to distensibility of the pelvic floor or perineal attachment. Noticing that rectoceles were observed in women with previous surgery is a concern in terms of recurrence. Maybe this again may affect the choice of instrument to measure outcomes.



Levator dimension measurements are also reproducible and show wide variation even at rest between different subjects. This may have a bearing on outcome following surgery due to the supportive nature of the underlying muscle. For this reason 3D US provides an advantage over 2D US imaging by allowing visualisation of the axial plane and a potential tool for measurement of levator dimensions pre and post surgery. Previous studies required expensive MRI assessment, which in turn may not have allowed adequate Valsalva strain when undertaking imaging.

#### **4.6 Conclusion**

The presence of rectoceles can be identified using this technique together with their quantification. In addition levator hiatal dimensions can easily be measured using transperineal 3D ultrasonography. The technique is well tolerated and non-invasive and may provide a useful mechanism to audit pelvic surgical outcome. 3D US with volume acquisition allows independent audit and measurement at a later stage. This data allows further study to ascertain the use of this technique in the clinical environment. US may identify an alternative pathology by distinguishing between different forms of posterior compartment pathology.

**The null hypothesis is accepted in that 3-dimensional ultrasound is a reliable and reproducible technique to identify and quantify the severity of rectoceles as well as measure levator hiatal dimensions for the posterior compartment.**

## CHAPTER 5

### EXPERIMENT 2

**A prospective observational longitudinal study of the incidence of rectocele prolapse and measurement of levator hiatal muscular dimensions in nulliparous women.**

**5.1 Hypothesis:** 3-dimensional ultrasound can be used to identify and quantify the severity of rectoceles as well as measure levator hiatal dimensions accurately to provide an objective set of normal data for the posterior compartment dimensions in nulliparous women.

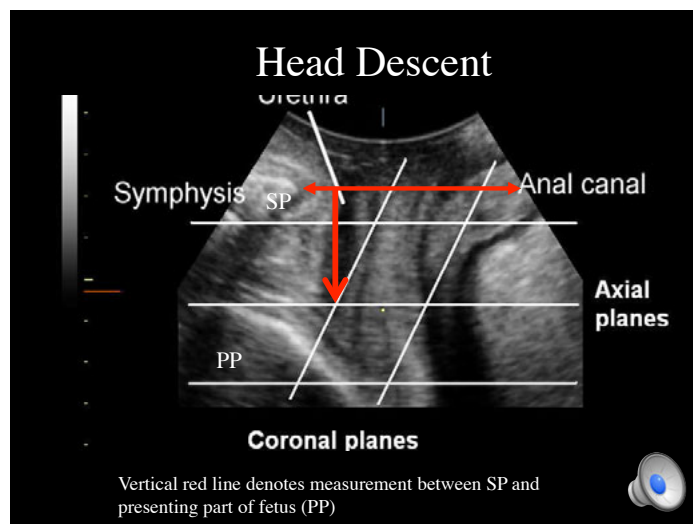
#### 5.2 Introduction

This study was designed to provide data on the incidence and nature of defects of the rectovaginal septum in the posterior vaginal compartment and normal values of the levator hiatus, using nulliparous women as a control population because they are a motivated population routinely undergoing ultrasound examination anyway. There have been a number of studies investigating the changes in anorectal physiology and structural anatomy of pregnant women, specifically studying the internal and external anal sphincter muscle complex, to identify birth related trauma and subsequent bowel dysfunction (Campbell, et al. 1996, Deen, et al. 1993, Rieger, et al. 1998). This has involved the use of endoanal ultrasound scanning, pudendal nerve latency measurements together with anorectal pressure measurements. These techniques are invasive, uncomfortable and the information obtained appears to correlate poorly with anorectal dysfunction and structural changes of the posterior compartment (Fitzpatrick and O'Herlihy 2001, Rieger and Wattchow 1999). B-mode transperineal ultrasonography has been used to identify lower pelvic floor anatomy and function associated with urinary incontinence (Wijma, et al. 1991). It is non-invasive and well tolerated. In addition, with the advent of three and four-dimensional ultrasound it is possible to record volumes of data to quantify structures and reconstruct images of pelvic structural anatomy (Stuhldreier, et al. 1997). Three dimensional ultrasound can potentially provide useful information, which is less invasive in women in a population that has not been subject to childbirth, which may be a factor in the development of rectocele and other posterior compartment abnormalities (Aldridge and Watson 1935).

### 5.3 Methods

This was an observational study. Women were recruited through written information and posters made available in public and private antenatal clinics over 6 months. All women gave written consent after both verbal information and written information sheets had been provided. Women were excluded if they had had any previous pregnancy continuing beyond 12 weeks, hypertension, placenta praevia, or known fetal problems such as growth restriction. All women were nulliparous and underwent a transperineal ultrasound examination, as per the method previously described (section 4.3) between 34 and 42 weeks. Information was collected on the presence or absence of rectovaginal defects, size of defect, mobility of the rectal ampulla, and levator hiatus dimensions (diameters and area). A urinary, bowel and prolapse questionnaire was taken by direct interview (appendix 2). Ethics committee approval was given by the attending hospitals (protocol 52/04, appendix 3).

Measurements were undertaken by the principal investigator using data collected and stored in volumes on electronic storage media. Presenting part descent was measured as shown in Figure 5.1, with a more caudal position of the presenting part representing a more positive figure. Convention was used that cranial to a horizontal line drawn from the inferior margin of the symphysis pubis was negative and caudal to the symphysis pubis (SP) was positive.



**Figure 5.1.** Vertical red line denotes measurement between SP and presenting part (PP) of fetus. This was taken as head descent into the pelvis. Image kindly reproduced with permission from Prof Dietz.

Analysis was undertaken using SPSS (Chicago, IL version 11 for Mac licensed to JCU) with data stored electronically and in paper versions in a locked format and locked storage. Students t-test, and ANOVA was used for correlation coefficient and Pearson's correlation for variables with  $\chi^2$  for symptom analysis.

#### 5.4 Results

Eighty-nine women with complete datasets were studied. Three sets of twin pregnancy were included. Mean age was 27.2 yrs (range 21-38 years); pre-pregnancy BMI was 25.3 (range 21.4- 34.7). Average gestational age was 36.3 weeks (34.1-41.2) weeks. On ultrasound 11 women (12%) had defects of the posterior rectovaginal septum, all of these had a defect less than 2 cm in depth and 10 (10%) had defects less than 1 cm. Median depth of such defects was 0.69 cm (SD 0.3) and width was 0.45cm (SD 0.3). The degree of head descent of the presenting part, levator dimensions and perineal excursion relative to the symphysis pubis are shown in Table 5.1.

|               | Lev diam cm | AP diam cm | Lev Tr diam cm | Levator Area cm <sup>2</sup> | Head descent cm | Perineal Mobility cm | Lev AP diam cm | Lev T diam cm | Levator Area cm <sup>2</sup> |
|---------------|-------------|------------|----------------|------------------------------|-----------------|----------------------|----------------|---------------|------------------------------|
| Minimum Value | 3.75        |            | 3.25           | 8.72                         | 5.80            | -3.58                | 4.65           | 3.27          | 9.89                         |
| Maximum Value | 7.30        |            | 5.68           | 30.31                        | -2.80           | 1.52                 | 9.01           | 6.45          | 44.83                        |
|               |             |            |                |                              |                 |                      |                |               |                              |
| SD            | 0.79        |            | 0.46           | 3.96                         | 1.26            | 1.15                 | 0.94           | 0.62          | 6.12                         |
| Median        | 5.60        |            | 4.31           | 17.79                        | 2.35            | -1.20                | 5.89           | 4.50          | 19.85                        |
| Average       | 5.64        |            | 4.31           | 17.76                        | 1.85            | -1.01                | 6.10           | 4.53          | 20.96                        |

**Table 5.1.** The range of results, standard deviation and mean are shown. The shaded area represents measurements on Valsalva straining. Head descent is taken as the distance from the symphysis pubis (SP) and is positive if cranial to line drawn horizontally from the SP. Perineal mobility (PM) are absolute values also taken from a line drawn from the SP with a negative value being cranial to the SP and positive value distal or caudal to the SP.

There was no correlation between levator area, AP and transverse diameters at rest or on Valsalva or perineal mobility with age, gestation, BMI or bowel symptoms ( $p=0.12$ , ANOVA). However there were only 3 women that complained of significant bowel symptoms all described as constipation with digitation but occasional straining

at stool. All were on iron supplements. There was no correlation between this symptom and of a defect as seen on ultrasound ( $p=0.89$ , t-test). There was no correlation between urinary or prolapse symptoms and any of the levator dimensions. There was no correlation between head descent and levator dimensions ( $r=0.12$ ,  $p=0.09$ ) nor perineal mobility ( $r= 0.23$ ,  $p=0.16$ , Pearsons correlation).

## 5.5 Discussion

Pregnancy is an ideal time to study the pelvic floor of women due to the increase in intracellular fluid resulting in better contrast and resolution of tissue planes. In addition it provides a control group of subjects to avoid bias as a result of childbirth. Pregnancy affects tissues within the pelvis as it does elsewhere in the female body mediated by hormonal changes, which can alter the supportive matrix through collagen and elastin biochemical properties (Kristiansson, et al. 1999, Wahl, et al. 1977). However the effects of pregnancy on the tissue may act as a confounder as a result of increased elasticity of collagen. However, there is no clear evidence as to the effects of pregnancy on pelvic tissue and whether this might alter ultrasound measurement of pelvic biometry. Urinary incontinence is seen to increase during pregnancy along with symptoms of constipation and pelvic discomfort (Chaliha and Stanton 2002, Derbyshire, et al. 2006) and so care needs to be used when extrapolating data obtained in pregnancy to the non-pregnant state.

Vaginal childbirth apart from causing perineal disruption, is thought to cause disruption of the rectovaginal septum, and therefore may lead to subsequent rectocele and enterocele formation later in life (Karram and Porter 2001), which in turn may be associated with bowel symptoms (MacLennan, et al. 2000). However a direct link has not been conclusively proven. Retrospective studies are subject to bias including the confounders of age, parity, lifestyle and it may be that factors other than childbirth trauma are equally or more relevant. In addition the affects of neurapraxia and neuropathies may affect the development of POP, although the significance of neurological damage is not clear until some years after childbirth (Beevors, et al. 1991, Dolan, et al. 2003).

The presence of rectoceles before childbirth would suggest that women may have a congenital weakness, i.e. hypermobility of the connective tissue affecting the composition or mechanical properties of collagen and elastin within supportive

mesenchymal tissue. Work has previously looked at this aspect and found alterations in the ratios of different collagen types associated with POP (Jackson, et al. 1996). However comparative studies between women with incontinence and those without found no difference in the quantity of collagen and the degree of incontinence (Fitzgerald, et al. 2000). Further studies have suggested that altered collagen may be stiffer and more likely to lead to disruption during trauma (Wong, et al. 2003). Overall however the specific alterations to supportive tissue matrix and their contribution to childbirth related or long term POP is not clear. Genetic studies of twins suggest a high concordance with the physical parameters suggestive of hypermobility, when the biomechanics of pelvic organ mobility has been examined on ultrasound (Hansell, et al. 2004). This would suggest that genetic predisposition relates to the causation of rectoceles.

More recent evidence from ultrasound studies identified an incidence of 12% for rectoceles in 178 nulliparous women. Rectoceles were defined as a defect of greater than 1cm depth projecting into the vagina from the rectomucosal border anteriorly (Dietz and Clarke 2005).

If congenital rectoceles really do exist are they symptomatic? This could help unravel the extent of the effects of childbirth. Does the size of the levator hiatus confer a greater or lesser tendency to pelvic floor damage and does it contribute to symptoms? Ligament or muscle detachment, which then leads to failure of certain aspects of the support mechanism of the female pelvis, may also be important factors.

These results provide the basis for validation of these measurements and a control series for the presence and size of congenital abnormalities in a nulliparous population as well as levator dimensions. It seems clear that there is a wide variation in levator dimensions at rest and on Valsalva. It is reasonable to suppose that on Valsalva there are a number of factors including muscle strength, muscle elasticity, fascial elasticity and size of the subject that may all have an influence. In this study 6% of women have a congenital defect of the recto-vaginal septum although without surgical or anatomical dissection this cannot be proven. The mean levator dimensions at rest varied less than on Valsalva.

Criticism of the technique used can be made, as this was not standardised using physical recording Valsalvometers or intravaginal transducers. One study has shown

better correlation using a sphygmometer attachment rather than maximal induced Valsalva to reproduce pressure measurements (King and Nevill 2004). Co-efficient of variation was reduced in one further study when applied to pregnancy values of urethral mobility (Wijma, et al. 2003). However previously validated techniques comparing ultrasound diagnosis of POP with clinical POPQ estimate showed significant reproducibility so it therefore seems reasonable to use maximal Valsalva straining for this experiment (Dietz, et al. 2004).

With these results it is now possible to test the use of this measurement technique on women who have undergone surgery. This will form part of the next phase of the study to determine whether 3D ultrasonography can provide valid information for post-operative assessment of recurrent prolapse of the posterior compartment. In particular the application of levator dimensions may add information as to the reason why some surgery appears to fail to provide adequate anatomical correction. Therefore normal has been defined and its use for abnormal needs clarification.

## **5.6 Conclusion**

The presence of rectoceles can be identified using this technique together with their quantification. In addition levator hiatal dimensions can be measured easily using transperineal 3D ultrasonography. The technique is well tolerated and non-invasive and may provide a useful mechanism to audit pelvic surgical outcome.

This data can now be used in the clinical setting, where problems arise with pathological defects in the posterior compartment. With a set of normal values and the understanding of the baseline incidence in women before their first pregnancy the incidence in a symptomatic population can be investigated.

**The second hypothesis is therefore accepted that 3-dimensional ultrasound can be used to identify and quantify the severity of rectoceles as well as measure levator hiatal dimensions accurately to provide an objective set of normal data for the posterior compartment dimensions in nulliparous women.**

## CHAPTER 6

### EXPERIMENT 3

**An independent audit of outcome using 3D ultrasound following surgery using composite polypropylene and polyglactin mesh for the treatment of ventral herniation of the posterior vaginal compartment.**

**6.1 Hypothesis:** Three-dimensional ultrasound can be used as an independent measurement tool in the assessment and audit of posterior compartment prolapse surgery.

The aim of this study was to use 3-dimensional ultrasound to compare in an independent and blinded manner the occurrence of sagittal pelvic organ prolapse of the posterior compartment and compare with the evaluation of the attending clinician. A secondary aim of the study was to investigate whether levator dimensions post-operatively correlate with poor outcome. Each woman was scanned independent of the outcome of surgery and have been selected as they have all had the same procedure for surgical repair, undertaken the same way by or supervised by the same surgeon, therefore eliminating some of the confounding bias that is a problem with auditing any surgical technique. Data was collected on these subjects as part of an ongoing, long term study into mesh repair of rectoceles. Information on the recurrence can be therefore be correlated with symptoms. This study follows on from the baseline data obtained from the first part of the study confirming its validity and reliability of measurement in women with posterior compartment prolapse.

### 6.2 introduction

The management of rectoceles in women has been complicated by the lack of correlation with symptoms, poor assessment tools and a myriad of variations in surgical correction without standardised methods of follow-up (Brubaker 1996). Surgical correction has traditionally employed vaginal surgery usually by plicating rectovaginal fascia, often with part of the levator complex (Nichols and Randall 1996). Success rates of up to 85% have been quoted in prospective studies (Arnold, et al. 1990, Kahn and Stanton 1997, Mellgren, et al. 1995), but there have been concerns



about the incidence of dyspareunia and pain following this procedure, which have ranged from 6-27%, with the figure higher in the larger studies. As a result of anatomical studies, suggesting that rectocele formation might be due to specific, identifiable defects in the fascia, correction has employed closure of these rectovaginal fascial defects (Richardson 1995, Richardson 1993). The success of this surgical approach has been studied in a small number of prospective, longitudinal studies, with surgical correction in 77-82% of cases and improvement in the occurrence of dyspareunia (Cundiff, et al. 1998, Glavind and Madsen 2000, Kenton, et al. 1999a, Porter, et al. 1999). An alternative method for fascial reinforcement employs artificial, inert mesh to reinforce the fascial remnants, which are often attenuated in older women and follows the rationale that the protrusion of a rectocele can be likened to a hernia. Large studies on abdominal hernia repair advocate artificial permanent mesh for correction, as the recurrence is lower than traditional surgical methods alone (Collaboration 2000). The operations used Vicryl-Prolene mesh (Gynecare<sup>®</sup>, Vipro II), using the four-point attachment overlay technique, to attempt to improve the success of surgical rectocele. A short to medium term study has recently been published with recurrence rates of 16% and new dyspareunia rates of 3.4% (Lim, et al. 2005). This suggests that this technique may offer reduced dyspareunia rates with equivalent recurrence to other techniques. As part of this ongoing evaluation, this study was undertaken to compare 3-dimensional ultrasound with clinical assessment, as an independent objective assessment tool.

Transperineal ultrasound has been used to assess surgical placement of the sub-urethral sling, bladder and urethral hypermobility and bladder wall measurements as a research tool for urinary incontinence (Dietz and Wilson 1998, Kohorn, et al. 1986, Tunn and Petri 2003). In addition 2-dimensional transperineal ultrasound has previously been shown to correlate closely with the POPQ scoring system, for assessment of pelvic organ prolapse (Dietz, et al. 2001). Three-dimensional ultrasound, although available for some years, has been hampered by slow development of software, and the necessity of operator controlled sector scanning. Recent improvements in processor speed, software and automated image acquisition have considerably improved the quality and reliability of imaging assessments. Volume ultrasound now permits imaging of pelvic structures in any user defined plane, orthogonal or oblique, allowing qualitative and quantitative assessment of structures such as the posterior vaginal wall. Combined with the ability to review images at a later stage, in any plane, it provides a potentially useful tool for the assessment of female pelvic prolapse.

### **6.3 Study design, materials and methods**

This was a retrospective, single blinded study of the outcome of rectocele repair in 82 women. Consecutive women were recruited from two hospitals (The Townsville Hospital and Mater Hospital), having been operated on with a standard technique using composite Vicryl-Prolene mesh (Gynecare, Vipro II) cut to lay over the posterior wall defect, which was then secured at 4 points without tension using absorbable sutures. The vagina was then closed using a single 2/0 Vicryl absorbable suture. All operations were undertaken by or under the supervision of one senior experienced surgeon Prof Ajay Rane. Prospective demographic data, which was not available to the investigators at the time of the study or volume analysis, was subsequently analysed. This included age, parity, menopausal status, previous surgery in addition to concomitant surgery, and peri-operative and post-operative complications. Using the Baden-Walker scoring system pre and post-operative comparisons were made with the ultrasound findings. All subjects were studied having been granted ethics approval (protocol number 52/03 appendix 3) from the Townsville Hospital.

Associations was analysed using ANOVA and differences between dimensions the two-sample t-test. In addition Pearson's correlation was used to compare levator hiatal dimensions and recurrence of rectocele fascial defects. SPSS 11.0, licensed to James Cook University) Chicago, IL was used for statistical analysis.

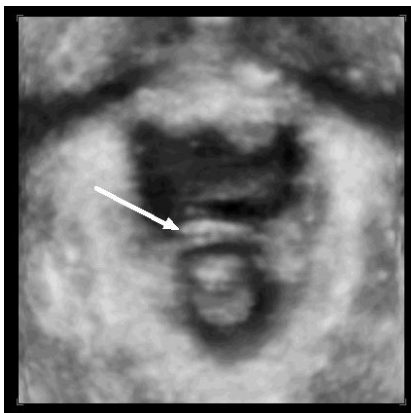
### **6.4 Results**

Seventy-one women with complete datasets were studied. Clinical evaluation was undertaken post-operatively at the same session when 3D US was undertaken. Eleven women had insufficient pre-operative or ultrasound data to be included in the study. There was no difference in the demographics between those women excluded and those included in the study. Mean age was 58.6 years (SD 12.4), mean parity of 3. Thirteen women (19%) had had previous vaginal wall prolapse repairs. Fifty women (71%) had other concomitant prolapse repairs, hysterectomy or urethrotomy undertaken at the time of surgery. Of those 50 women, 26 (37%) had anterior wall repairs, 4 (6%) had hysterectomies, 2(4%) had a vault suspension and 24 (48%) had a suburethral sling. Some women had more than one surgical procedure undertaken at the same time. The average length of time following surgery at follow-up was 0.7 years (SD 0.29).

Clinical evaluation revealed a recurrence of the rectocele in 4 women (5.6%). Three were classified as Grade I and one had a Grade II recurrence. On ultrasound 16 women (23%) had persistent defects of the posterior rectovaginal septum. Of these one (1.5%) had a defect greater than 2 cm in depth and 6 (8.5%) had defects greater than 1 cm. Mean depth of such defects was 0.92 cm (SD 0.2) and width was 1.56cm (SD 0.35 cm). Mean areas of the levator hiatus were 17.87 (SD 3.72 cm) at rest and 23.76 cm (SD 4.43) on Valsalva. The rectal ampulla reached -0.13 cm (SD 1.32) above the symphysis pubis on average.

There was no correlation between levator area, AP and transverse diameters at rest or on Valsalva or perineal mobility with age, parity, follow-up time, or the symptom of incomplete bowel emptying. Nor was there any correlation between this symptom and persistence of a defect as seen on ultrasound ( $p=0.477$ , two-sample T-test). There was however a moderate negative correlation between descent of the rectal ampulla and levator hiatal area on Valsalva ( $r= -0.428$ ,  $p=0.002$ ) as well as the hiatal AP diameter on Valsalva ( $r= -0.39$ ,  $p=0.006$ ). In addition there was an association towards a larger levator hiatus in those who clinically ( $p= 0.067$ ) and on ultrasound ( $p=0.031$ ) had evidence of a recurrence. Depth ( $r= 0.306$ ,  $p= 0.01$ ) and width ( $r= 0.343$ ,  $p= 0.003$ ) of a recurrent defect of the rectovaginal septum were also associated with hiatal area on Valsalva.

Subjectively it was noted that 2 women with clinical and ultrasound recurrence had mesh that appeared to be detached from one side or the other. However this was not statistically significant ( $p=0.23$ ).



a

b

**FIGURE 6.1:** a; Axial view of the levator hiatus after successful mesh repair (left, arrow points to mesh anterior to anorectal junction) and b; midsagittal view of recurrent rectocele (arrow, right). Personal file images and reproduced with permission from Prof Dietz.

## 6.4 DISCUSSION

This study is the first using three-dimensional ultrasound to audit the results of pelvic floor surgery and compare this with clinical evaluation. It demonstrates a persistence of defects of the rectovaginal septum in over 20% of women after rectocele repair using a mesh implant. However, most of these defects were very small, and persistence of a defect did not correlate with symptoms of incomplete bowel emptying. Many patients also showed a significant degree of perineal hypermobility, and this correlated with increasing dimensions of the levator hiatus on Valsalva. There was also an association towards clinical and ultrasound diagnosed recurrence of rectovaginal septal defects with increased levator dimensions. Failure to close the levator hiatus may therefore account for those failures of surgery, which can be postulated to reduce support for the fascia thereby negating the protective effect of the levator muscle complex. Even if the defect in the rectovaginal septum is reduced or closed, underlying perineal hypermobility due to genetic or mechanical disruption may still not be addressed and lead to apparent failures, or else marked levator widening on Valsalva may expose the repaired area to increased strain, resulting in a higher likelihood of recurrence.

Criteria for when and how to surgically repair rectoceles are lacking, due in some part to non-standardised methods of pre and post-operative evaluation. Attempts to standardise the clinical assessment have either not been validated (Baden and Walker 1992) or address the defects only in the sagittal plane POPQ (Bump, et al. 1996). To make matters worse even clinicians with an interest in urogynaecology have been slow to adopt the POPQ scoring system (Auwad 2004).

Three-dimensional pelvic floor ultrasound is quick and may offer an independent and objective assessment of pelvic floor surgery for the correction of posterior vaginal wall prolapse. Studies in this area validating ultrasonography for the posterior female pelvic compartment have been limited to the two-dimensional plane (Beer-Gabel, et

al. 2002, Creighton, et al. 1992, Dietz, et al. 2001, Dietz, et al. 2004, Petri, et al. 1999) but have demonstrated not only that defects can be identified but also there is good correlation with the POPQ assessment. The ability to assess lateral and central support using three-dimensional ultrasound permits more detailed offline evaluation of the underlying muscle and fascial support (Shek, et al. 2004).

In this study there was a wide variation in ultrasound findings postoperatively, with the mesh sometimes being clearly seen either providing coverage of the defect or having moved laterally. Persistent defects of the rectovaginal septum at an average follow-up time of 7 months are common but mostly small and not associated with persistence of symptoms. At other times the mesh was not visible at all, and in such cases it could be speculated that the mesh provides no lasting support (Figure 6.1).

There were significant correlations between levator area on Valsalva and perineal hypermobility as defined on ultrasound, between clinical rectocele recurrence and hiatal area on Valsalva, and also between a recurrence of fascial defects and levator hiatal area.

The dimensions of the levator hiatus on Valsalva (i.e., the presence of 'levator ballooning') may be important for the correction of posterior compartment prolapse. Two main explanations may be offered. Clinical recurrence maybe more likely in women with levator ballooning- either because of a failure to address a wide hiatus before surgery, resulting in persistent perineal hypermobility postoperatively, or a widened hiatus may expose any repair to more strain, resulting in a higher likelihood of recurrence of fascial defects.

It is postulated that pre-operative assessment of levator dimensions might assist the surgeon in a number of ways. If there is a defect of the rectovaginal septum, then such a defect should be closed. If there is marked enlargement of the hiatus on Valsalva and perineal hypermobility, then the most effective way to reduce posterior compartment prolapse may be a levatorplasty (Zacharin and Hamilton 1980), although this concept is currently rather unpopular in view of the stated risk of dyspareunia (Gershenson, et al. 2001). In general, one suspects that the dimensions

of the levator hiatus may be important not just for recurrence of rectocele, but for prolapse recurrence in general.

Limitations of this study are that it is mostly retrospective and that there were no pre-operative ultrasound volume data sets to compare with postoperative results. In addition symptom questionnaires were non-standardised prior to surgery and the Baden-Walker system of classification was utilised, which may not be the optimal method for assessment of pelvic organ prolapse. Prospective studies were therefore performed in the final experiment using the POPQ classification with ultrasound assessment before and after surgery, together with validated questionnaires assessing pelvic symptoms and quality of life, to further elucidate the place of 3D US in assessment. The results of these studies should help to further define the place of 3D-ultrasound in the assessment and for the objective follow-up of women with pelvic organ prolapse. Longer follow up would be useful to investigate if early recurrence leads to more pronounced and symptomatic recurrences of posterior compartment defects later.

## **6.5 Conclusion**

Neither clinical assessment nor 3D ultrasonography correlate well with pelvic floor symptoms related to the posterior compartment. Recurrences of rectocele fascial defects are identified more accurately by ultrasonography but whether they are clinically significant is not clear from this study. Although not definitely proven levator hiatal dimensions may influence the outcome after surgery as a result of the trend towards more failures on clinical studies and ultrasonography. Comparison with other imaging techniques are required. To that end a comparison with MRI might help identify the place of 3D US in pelvic floor imaging.

**Null hypothesis is accepted that three-dimensional ultrasound can be used as an independent measurement tool in the assessment and audit of posterior compartment prolapse surgery.**

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## CHAPTER 7

### EXPERIMENT 4

#### **A comparative study of magnetic resonance imaging versus 3-dimensional ultrasound for the assessment of levator hiatus and pelvic floor prolapse of the posterior compartment.**

##### **7.1 Hypothesis:**

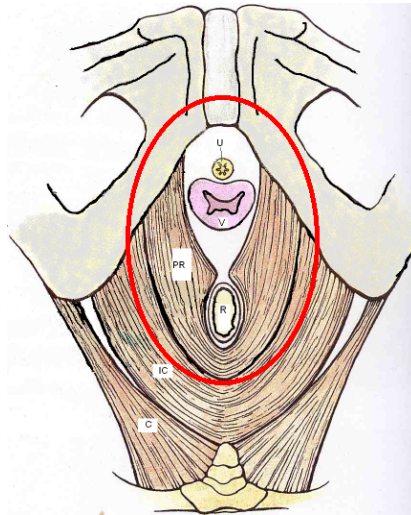
Three-dimensional ultrasound correlates as well as magnetic resonance imaging for the dynamic imaging of the pelvic floor in terms of identification of prolapse in the posterior compartment, measurement of rectocele prolapse and measurement of levator dimensions.

The results from the previous three studies demonstrate that 3D ultrasound assessment of rectovaginal defects and levator hiatal dimensions is possible and reproducible so it is appropriate therefore to compare this modality with the accepted imaging modality of choice, i.e. MRI (Magnetic Resonance Imaging). Previous studies using MRI have shown good correlation with symptoms in women who were nulliparous, compared to women with urinary incontinence and who were parous. However the ability of MRI to detect changes to levator must be questioned due to the very nature of image acquisition, which is fixed by pre-determined co-ordinates. This study will provide the first comparative data on this subject.

##### **7.2 Introduction**

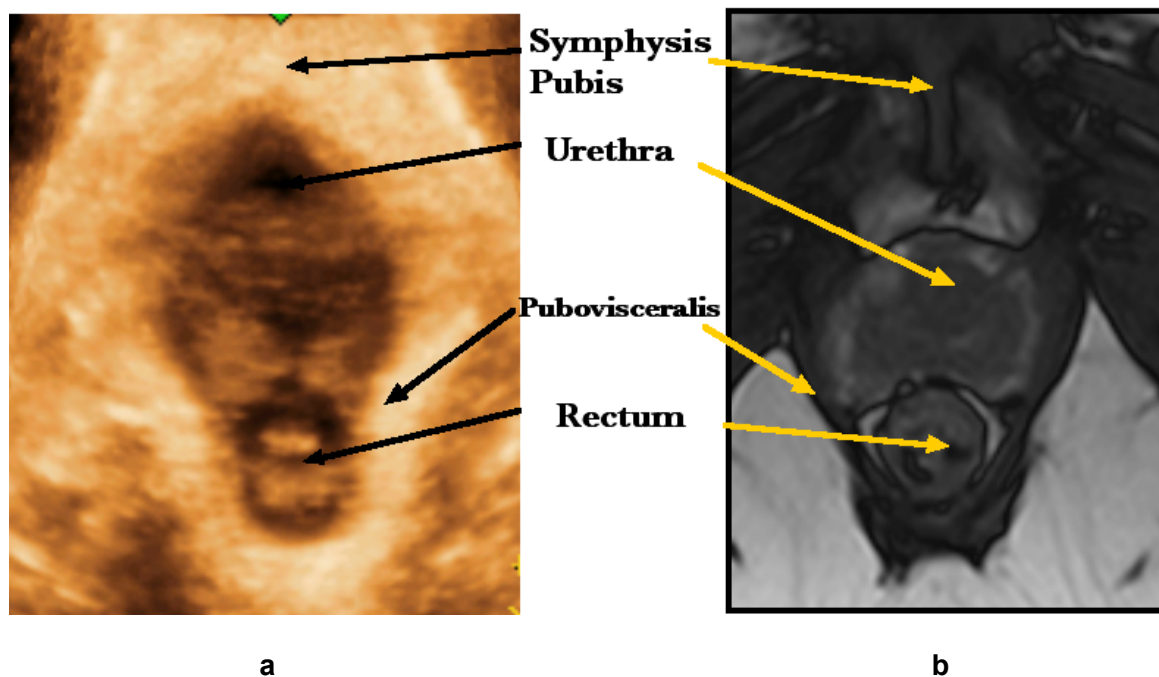
The true prevalence of rectoceles in the female population is not known. Clinical assessment can be objectively measured using the POPQ ICS (Bump, et al. 1996). However this does not address paravaginal structural changes, cannot assess deeper support structures. MRI has been used to identify both normal and abnormal female pelvic anatomy, permitting resolution and tissue definition not previously possible, with faster acquisition times adding to the understanding of dynamic pelvic anatomy (Strohbehn, et al. 1996a). These systems are however expensive and limited to tertiary centres. 3D ultrasound (US) has seen major advances in development, such that dynamic axial plane imaging has become feasible. This study aims to compare the two imaging modalities in the assessment of the levator hiatus.

Three-dimensional ultrasound has been developing slowly since its inception in the 1980s. However improvements in software and automated acquisition devices have enabled its use for pelvic imaging with accurate tissue definition. Two-dimensional transperineal ultrasound can be used for pelvic organ assessment and correlates well with the POPQ ICS for all three compartments (Dietz, et al. 2001). Three-dimensional ultrasound permits visualization of the axial plane and therefore potentially combines the advantage of dynamic, low cost ultrasound imaging as well as addressing the deeper levator muscle group. This pilot study was undertaken to compare the assessment of the levator hiatus. The area of interest is shown diagrammatically in Figure 7.1, with annotation of comparative 3D USS and MRI images Figure 7.2.



**Figure 7.1.** Diagrammatic drawing of levator hiatus. The red circle indicates the area of interest visualised on imaging. IC (Iliococcygeus); PR (Puborectalis); C (Coccygeus); U (Urethra); V (Vagina); R (Rectum.) Reproduced with permission from: Dalley, Moore. Clinical Oriented Anatomy 4th Edition 2005, p356, Lippincott, Williams & Wilkins: Philadelphia.



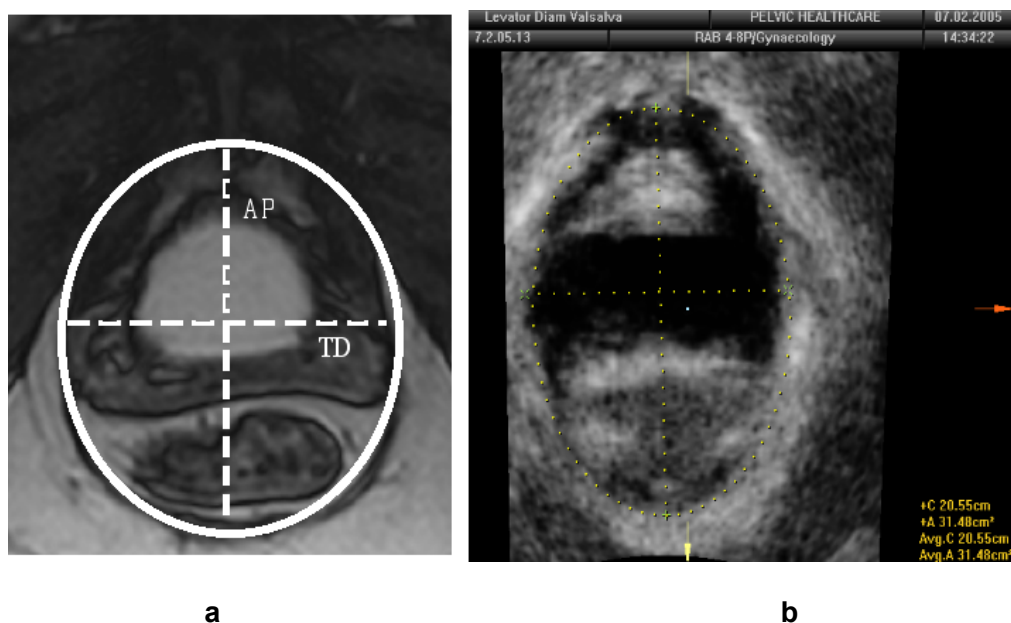


**Figure 7.2.** Comparison of anatomical landmarks on a; US (left) and b; MRI (right) axial images of the levator hiatus. Personal image files from study.

### 7.3 Materials and Methods

Eleven women undergoing surgery for anterior rectocele repair were recruited and consented. Exclusion criteria included any contraindication to MRI scanning, and inclusion criteria were having a rectocele greater than grade 2 on the Baden-Walker scale. They were assessed using transperineal three-dimensional ultrasound (3D US) and magnetic resonance imaging (MRI). For the US assessment women were placed in the supine position, having emptied their bladder. A GE Voluson 730 US, using a Kretz 7-4 MHz volume probe was placed on the perineum in the midsagittal plane. Using ultrasonic jelly at the interface, volume data were acquired at rest and on maximum Valsalva, having undertaken the manoeuvre at least 3 times as practice, under close supervision. Volumes were stored and reviewed at a later date. Defects in the rectovaginal septum were noted and measured in the cranio-caudal diameter as well as vertically to obtain the depth of the defect. In addition, the degree of perineal mobility was assessed by measuring caudal displacement of the rectal ampulla, relative to the symphysis pubis. The diameters and area of the levator hiatus at rest and on Valsalva were measured as shown in Figure 7.3, such that the plane chosen was symmetrical, containing the shortest distance between the symphysis pubis anteriorly and levator muscle posteriorly.

Similar measurements were undertaken in the equivalent axial slice on MRI scan. Fast acquisition T2 weighted scans using a Siemens Symphony Magnetron 1.5T MRI system, were taken at rest and after Valsalva after using an asymptomatic nulliparous volunteer to test the settings. The settings for MRI acquisition were pre-Valsalva T2 truefisp sagittal images for 2mins 46 secs, and 1 min 50 secs in the axial plane. During Valsalva T2 truefisp sagittal images lasting 14 secs and 8 seconds in the axial plane. Ten slices were taken at 4 mm for 0.4 mm gaps, -1AV. K = 46°. Examples of images from both modalities showing the measurements undertaken are given in Figure 7.3.



**Figure 7.3. a;** Dimensions of levator hiatus on Valsalva for MRI on left (a) and **b;** 3D USS on right (b). AP (antero-posterior), TD (transverse diameter), A (area). Images from personal files.

Information was collected on age, parity and previous surgery. Independent clinical pelvic examination was performed by the clinical fellow of the unit who was blinded to the imaging results, to assess POPQ measurements and identification of co-existent prolapse. Patients gave informed consent and ethics committee approval was given (TTH 57/03 appendix 3).

Statistical analysis was carried out using Pearsons correlation coefficient for inter-observer variability, Fishers exact test for categorical variables and ANOVA for

associations. Intraclass correlation and dot plots for correlation between imaging measurements. SPSS Chicago II version 11.0 was used and data was stored electronically and as hard copy and stored securely.

### 7.3 Results

Eleven women had complete datasets. The mean age was 58 years, parity 3, with 46% (5) having had a hysterectomy, 55% (6) vaginal Oestradiol replacement, BMI 30 (mean), 18% (2) previous cystocele repair. On direct interview 82% (9) of the 11 women had a sensation of a lump, 55% (6) had constipation, 36% (4) had stool trapping. Clinical grading on POPQ was 2 (median). Pre-op- A<sub>p</sub> = 0.2 cm (SD 1.2), B<sub>p</sub>= -0.3 (SD 1.4), GH 4.8cm (SD 1.3), C - 4.6cm (SD 2.2) (prolapse grading and measurements as per POPQ scoring system, (Bump, et al. 1996)). All had rectoceles at surgery, 8 (Grade 2), 3 (grade 3), with one woman diagnosed with an enterocele. Forty-six percent (5) having coexistent cystoceles, 18% (2) level 1 prolapse, and 82% (9) having enteroceles.

Table 7.1 summarizes the findings for measurements and quantitative diagnosis of posterior compartment defects. US was significantly better for diagnosis of enterocele at surgery vs clinical (p= 0.03), although no significant difference between MRI and US (p= 0.11) nor MRI and clinical (p=0.25). There was no correlation between grade of rectocele size and symptoms.

| Exam     | Rectocele present | Rectocele Mean depth cm (SD) | Rectocele Mean width cm (SD) | Enterocele present | Lump sensation p | Strain to defaecate p | Digitation to defaecate p |
|----------|-------------------|------------------------------|------------------------------|--------------------|------------------|-----------------------|---------------------------|
| Clinical | 11                | N/A                          | N/A                          | 1                  | 0.09             | 0.46                  | 0.79                      |
| US       | 11                | 1.78 (0.56)                  | 2.56 (0.71)                  | 9                  | 0.14             | 0.23                  | 0.11                      |
| MRI      | 9                 | 1.92 (0.76)                  | 2.19 (0.69)                  | 3                  | 0.24             | 0.34                  | 0.56                      |

**Table 7.1.** Summarizes the findings of both qualitative and quantitative findings from all examination modalities. Statistical significance is taken as p <0.05 with p values for the correlation of symptoms and either the presence or not of rectocele or measurements of rectocele on US and MRI imaging using ANOVA.

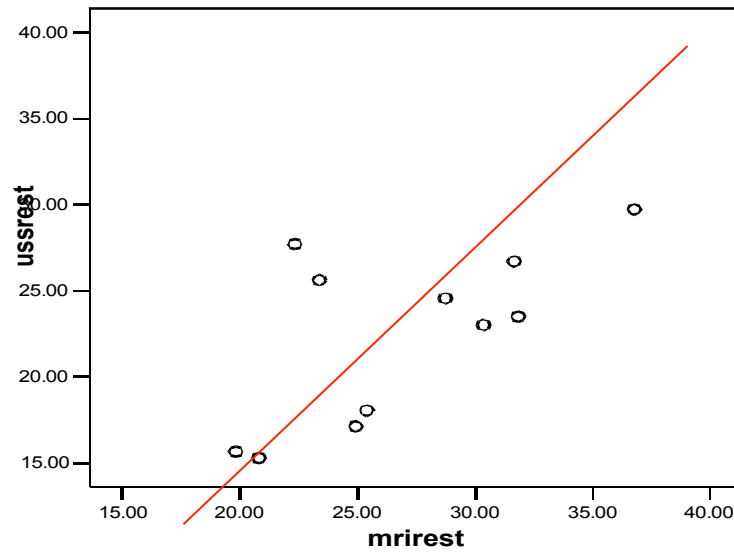
Descriptive statistical analysis is tabulated in Table 7.2 and 7.3. Pearson's correlation coefficient were as follows. Levator area at rest (USS vs. MRI) = 0.648 (P=0.071), levator area on Valsalva (US vs. MRI)= 0.220 (P = 0.515). Correlation between levator hiatal measurements on 3D US and MRI was poor for all parameters between observers, precluding formal analysis for agreement. Intraclass correlation (ICC) was also poor being 0.485 for the levator area at rest and 0.13 on Valsalva. Dot plot analysis for ICC is shown in Figure 7.4.

| Variable              | Minimum | Maximum | Q1    | Q3    |
|-----------------------|---------|---------|-------|-------|
| Lev Area USS rest     | 15.28   | 29.72   | 17.12 | 26.70 |
| Lev Area USS Valsalva | 21.08   | 50.24   | 23.19 | 37.77 |
| Lev Area MRI rest     | 19.83   | 36.77   | 22.34 | 31.66 |
| Lev Area MRI Valsalva | 23.04   | 60.20   | 35.79 | 54.97 |

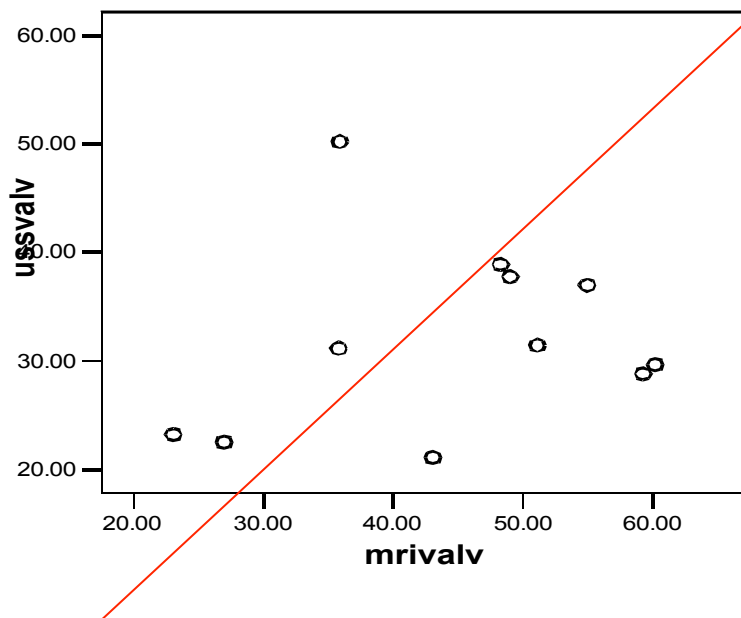
**Table 7.2.** Range of area (cm<sup>2</sup>) US and MRI measurements of levator hiatus. Quartiles are shown on the right for 25<sup>th</sup> (Q1) and 75<sup>th</sup> (Q3).

| Variable              | N  | Mean  | Median | TriMed | StDev | SE Mean |
|-----------------------|----|-------|--------|--------|-------|---------|
| Lev Area USS rest     | 11 | 22.45 | 23.49  | 22.43  | 5.10  | 1.54    |
| Lev Area USS Valsalva | 11 | 31.97 | 31.15  | 31.16  | 8.62  | 2.60    |
| Lev Area MRI rest     | 11 | 26.91 | 25.39  | 26.61  | 5.35  | 1.61    |
| Lev Area MRI Valsalva | 11 | 44.32 | 48.27  | 44.92  | 12.54 | 3.78    |

**Table 7.3.** Descriptive statistics for minimum and maximum area on US and MRI. Also shown are trimedians, SE means and StDev to identify the potential effect of outliers on the results.



**Figure 7.4a.** Dotplots for intraclass correlation between MRI and 3D US for area of levator hiatus at rest. Levator area ICC = 0.485 (x axis MRI measurements, y axis US measurements).



**Figure 7.4b.** Dotplots for intraclass correlation between MRI and 3D USS for area of levator hiatus on Valsalva. Levator area ICC = 0.13 (x axis MRI measurements, y axis US measurements).

#### **7.4 Discussion**

MRI imaging has been the gold standard for clinical anatomical definition in the female pelvis. In particular MRI imaging has been used to identify changes to the levator muscles following childbirth (Tunn, et al. 1999, Tunn, et al. 2003, Tunn and Petri 2003) and in those women complaining of POP and urinary incontinence (Hoyte, et al. 2001b, Pannu 2002). Comparative studies with cadaveric dissection (Hussain, et al. 1996, Strohbehn, et al. 1996b) and surgical findings would suggest that correlation with MRI is good (Kester, et al. 2003). In addition, morphometric measurements and qualitative assessment of the levator group of muscles can be studied (Hoyte, et al. 2001a). However dynamic imaging requires fast image acquisition times to identify defects on Valsalva. Imaging in the upright or sitting position can aid identification of pelvic structures but adds to the cost (Bo, et al. 2001). Three-dimensional ultrasound has seen significant advances in the last 5 years in resolution and image acquisition. The infero-levator anatomy is ideally suited to this modality due to the close proximity of tissues and pelvic organs. This has been demonstrated for assessing biomechanical properties of vaginal tissues (Dietz, et al. 2002), the function of prosthetic implants (Wang, et al. 2002) as well as the identification of lower urogenital tract abnormalities (Tunn and Petri 2003) Ultrasound imaging of the axial plane permits examination of the levator muscles and more precisely the pubococcygeus and puborectalis muscles.

Why is this important? Debate continues as to what provides support for the female pelvis. It has been suggested that there are three levels of support of the vagina utilizing different structures, including condensations of endopelvic fascia. However this may provide only a secondary support mechanism with primary support being provided by the levator muscle group and more specifically the pubococcygeus, as evidenced by disruption on MRI imaging following childbirth (DeLancey, et al. 2003). Attempts to quantify muscle disruption with morphometric analysis and 3-dimensional modelling using MRI have suggested, but not proven an association with stress urinary incontinence (USI) and POP (Hoyte, et al. 2001a, Hoyte, et al. 2001b). Variations in levator hiatal size may provide indirect evidence for disruption of muscles, decreased muscle density or altered biomechanical properties of this support structure (Delancey and Hurd 1998, Tunn, et al. 1999).

If this is the case, then imaging can help study the causal effect of changes, particularly with strain exerted on the pelvic organs and their support structures. This is a dynamic process and needs a dynamic means of evaluation. MRI is unable to adapt its acquisition angle to compensate for alteration in the levator plate. Three-dimensional ultrasound offers a dynamic imaging modality. This study demonstrates poor intra-class correlations between the two modalities. These differences in image modalities may be explained by the degree of prolapse and limited study numbers. 3D ultrasound may offer an alternative method of imaging assessment but further studies using controls are required.

Comparing imaging modalities often assumes a gold standard and has multiple potential confounding factors. Adequate Valsalva strain would be a significant potential confounder with the ability to adequately coach subjects difficult without measurements of intra-abdominal pressures. This may explain why dotplot ICC were somewhat better at rest than on strain. With this cohort of subjects there was a high incidence of true enteroceles, which was higher than would normally be expected. However they were relatively older, had a high prevalence of previous surgery and multiple compartment pelvic organ prolapse which might explain this. The degree of hydration as well can alter the outline of tissue borders, which may also be an issue in the older population. Enterocele prolapse was better diagnosed with US but did not improve diagnosis as well as at surgery. However it was better than clinical examination: of note enterocele diagnosis clinically has not been tested versus surgical diagnosis but is more difficult due to difficulties examining the upper part of the posterior compartment of the vagina.

## **7.5 Conclusion**

This is the first study to compare 3-dimensional ultrasound and MRI with specific reference to levator hiatal assessment. Despite poor correlation between the two modalities in this pilot study, further studies are needed to provide adequate data before final conclusions can be drawn. If 3-dimensional ultrasound is comparable to MRI then this may provide a more cost effective and more dynamic method of assessment not only in women with POP, but also following childbirth and in women without evidence of pelvic floor dysfunction. Despite the results from this small study it is possible larger numbers would demonstrate an advantage over MRI. The earlier

studies show that the technique is reproducible. Enteroceles are better diagnosed on US than either MRI or clinically.

To assess 3D ultrasound in the clinical setting the next part of the study will concentrate on acquiring prospective data of untreated POP and comparing formal clinical assessment with symptomatology and surgical findings. If the final hypothesis is proven then further work would be warranted to compare imaging modalities in larger studies.

**The null hypothesis is accepted that three-dimensional ultrasound correlates as well as magnetic resonance imaging for the dynamic imaging of the pelvic floor.**

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## CHAPTER 8

### EXPERIMENT 5

**A prospective, observational study comparing ultrasound assessment against clinical evaluation of prolapse of the posterior compartment using the POPQ system of prolapse classification, both pre- and post-operatively.**

#### **8.1 Hypotheses:**

a; Three-dimensional ultrasound correlates better than clinical assessment with symptoms associated with posterior compartment prolapse.

b; Levator hiatal measurements can provide a means of predicting outcome of surgery in women with pelvic organ prolapse of the posterior compartment.

The first two studies demonstrated that 3D ultrasonography can provide a reproducible method for the measurement and assessment of the posterior vaginal compartment and levator hiatal opening. The fourth study suggested correlation with MRI is poor. There is evidence that defects of continuity of fascial and muscle supports visualised on MRI of the insertion of pubococcygeus, correlates with urinary incontinence and OAB symptoms, but this study refers to the anterior compartment (DeLancey, et al. 2003). This study (experiment 5) has been designed to prospectively compare ultrasonography assessment using the methodology derived from previous studies, versus formal objective clinical assessment to identify which best correlates with posterior compartment prolapse associated symptomatology. Women were chosen who had been clinically diagnosed as having a rectocele on Baden-Walker with a grade of greater than 2, and who had decided to have surgery to correct this prolapse.

## 8.2 Introduction

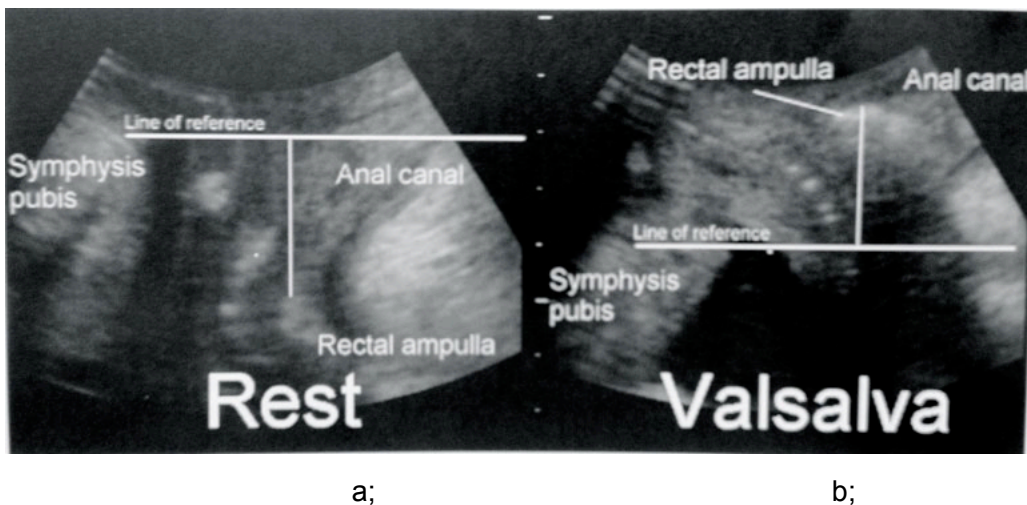
This part of the study aimed to utilise the methodology previously validated for 3D ultrasonography measurements, to prospectively study clinical symptomatology pre and post surgery. POP, particularly of the posterior compartment, has a poor correlation between clinical symptoms and the severity of clinically diagnosed prolapse (Altman, et al. 2005a). Previous studies have mostly been retrospective and utilised non-validated measures thus making comparisons difficult (Arnold, et al. 1990, Kahn and Stanton 1998). Although prospective studies have been undertaken these have involved different surgical techniques (Abramov, et al. 2005, Altman, et al. 2005b, Altman, et al. 2006, de Tayrac, et al. 2006, Regadas, et al. 2005, Sardeli, et al. 2005). The need for standardised outcomes was highlighted some years ago and yet there appears to be no consensus as to a gold standard (Brubaker 1996). This study will utilize a standardised measuring system for POP (POPQ) and in addition surgical assessment will be included to corroborate clinical assessment. This is important as staging at the time of surgery has found to change the degree of POP staging by upto 30% (Vineyard, et al. 2002). This may not be due to errors in the pre-operative clinical staging of the POPQ, but confounding factors i.e. pelvic floor relaxation under anaesthesia. If one or the other method provides a more reliable correlation with symptoms then this may translate into a pre-operative assessment which is not only better at comparing outcomes but also at predicting outcomes.

## 8.3 Methodology

This was a prospective observational study. Women were recruited from urogynaecology clinics, who had a clinical diagnosis of a rectocele greater than grade 2 (Baden-Walker) and had opted for surgical treatment. Women were not excluded on the basis of associated concomitant POP. All women gave informed consent. The women were then asked to respond to an interviewer-directed structured symptom specific questionnaires (Appendix 2), were examined clinically to measure the POPQ ordinates (Appendix 1), and then underwent 3D transperineal ultrasonography, as described in the methodology chapter (section 4.3). The following parameters were measured on ultrasound.

- a. Rectocele- present or not in the mid-sagittal plane as defined by a break in the continuity of the rectal wall outside its normal position on its anterior wall.

- b. If present- then the depth and width were measured on maximal Valsalva strain
- c. Perineal hypermobility, using the ampulla of the rectum as the reference point, compared to a line drawn from the symphysis pubis horizontally, on maximal Valsalva (Figure 8.1).
- d. Levator hiatal width at rest and on Valsalva
- e. Levator hiatal anteroposterior length at rest and on Valsalva
- f. Levator hiatal area at rest and on Valsalva



**Figure 8.1** Image **a** represents the perineum and rectal ampulla at rest, while image **b** is on maximal Valsalva. The line of reference moves caudally (vertically up) denoting the direction of movement and can be measured. With permission from Prof Dietz.

Demographic data was also collected. A further assessment was undertaken during surgery defining the type of prolapse. Following surgery a review was carried out at 6 months again with clinical assessment using the POPQ classification, symptom questionnaire, and 3D ultrasonography undertaken by Dr Christopher Barry. To reduce confounding bias, clinical assessment was performed independently to the ultrasonography pre-operatively and post-operatively by an examiner experienced in POPQ assessment. Ethics committee approval was given by Townsville Hospital (52/03).

Statistical analysis was performed using SPSS version 11 for Macintosh (SPSS, Chicago, IL, licensed to JCU). ANOVA correlation for association, paired sampling for paired samples and Pearsons coefficient were used for analysis. Likelihood Ratios

were initially calculated to look for trends with linear association. Fishers exact t-test both one and two tail were applied.

#### **8.4 Results**

Of the 33 women in the study, there were 29 complete datasets. Mean age was 59, parity 3. Nine women (26%) had had previous prolapse surgery, 18 (62%) had had a hysterectomy. Four had urinary incontinence, four had faecal incontinence. Twenty five women (80%) had a sensation of lump, 20 (69%) had a dragging sensation, 21 (72%) had constipation, 10 (35%) women needed to digitate to defaecate, 4 of the 7 women who were still actively having intercourse had poor sensation during coitus. Eight (28%) women had concomitant anterior compartment defects, five women (17%) had level 1 defects; i.e. upper vaginal or uterine prolapse.

Twenty-one (72%) of the women required an enterocele repair at the time of surgery and two (7%) had a hysterectomy. The average ordinal grading of posterior compartment prolapse was 2, point B<sub>p</sub> was 0 (refer Appendix 1). The women had a fascial repair using sutures and mesh overlay with composite polyglactin and polypropylene graft. At surgery all women had a rectocele present. Pre-operatively enteroceles were present on US in 3 women where the clinical diagnosis was one of rectocele in isolation. Surgery was performed to correct these clinically identified enteroceles at the same time as rectocele surgery but could have helped confirm the diagnosis prior to surgery, allowing better surgical planning. No other ultrasound findings changed surgical procedures for these women.

Post-operatively the average grade of rectocele was 1, with point B<sub>p</sub> of -1. This was a significant change from pre-operative assessment ( $p < 0.01$ ) as were the ultrasound findings (rectocele present or not,  $p < 0.001$ ). Symptomatology improved significantly. There were significant changes in the incidence of symptoms of a lump ( $p < 0.001$ ), requirement to digitate ( $p < 0.04$ ), dragging sensation ( $p < 0.01$ ), constipation ( $p < 0.04$ ) and pelvic pain/dragging ( $p < 0.01$ ), Table 8.1.

| Symptom              | Pre-op n(%) | Post-op n (%) | p value |
|----------------------|-------------|---------------|---------|
| Lump                 | 23 (79)     | 2 (7)         | 0.001   |
| Digitate             | 10 (35)     | 1 (4)         | 0.037   |
| Strain               | 16 (55)     | 6 (21)        | 0.048   |
| Faecal incontinence  | 4 (14)      | 4 (14)        | 0.78    |
| Pelvic pain/dragging | 20 (70)     | 5 (17)        | 0.012   |
| Constipation         | 21 (72)     | 10 (35)       | 0.033   |

**Table 8.1.** Comparison of symptom frequency pre-operatively versus post-operatively using paired t-test, level of significance  $p < 0.05$ .

There was a poor correlation between clinical assessment and all symptoms using overall grade and specific measures of point  $A_p$  and  $B_p$  (Table 8.2). There were no linear trends with any symptom of the posterior compartment and grade of prolapse. The same was true comparing ultrasound measurements of rectocele depth and width although there was a trend when ultrasound measurements were compared to a lump sensation and digitation to defaecate. When analysing the data for ultrasound measurements comparisons were made for those with and without the symptom utilising the means of measurement using t-test with two-tailed level of significance due to the normal distribution. The same was true post-operatively as well for both assessment modalities (Table 8.3).

In addition there were no significant correlations between US and clinical grading  $p=0.75$ ,  $0.76$  (both one-way analysis of variance) and  $p=0.86$  (t-test) for  $A_p$ ,  $B_p$  and grade respectively. No trend was evident. Neither did levator hiatal area, or other dimensions correlate with clinical grading. There were no significant correlations between levator dimensions either at rest or on straining and symptomatology (Table 8.2 and 8.3).

|                       | Point A <sub>p</sub><br>value (p) | Point B <sub>p</sub><br>value (p) | US depth<br>value (p) | US width<br>value (p) | Levator hiatal<br>area value (p) |
|-----------------------|-----------------------------------|-----------------------------------|-----------------------|-----------------------|----------------------------------|
| Lump                  | 2.79 (0.34)                       | 3.09 (0.68)                       | 1.03(0.07)            | 1.71(0.09)            | 5.3 (0.17)                       |
| Digitate to defaecate | 4.81 (0.25)                       | 2.81(0.44)                        | 1.67(0.09)            | 1.89(0.11)            | 0.32 (0.92)                      |
| Strain to defaecate   | 4.63 (0.56)                       | 6.08 (0.46)                       | 3.40(0.12)            | 5.91(0.27)            | 3.33 (0.55)                      |
| Faecal incontinence   | 1.24 (0.76)                       | 3.06 (0.94)                       | 2.67(0.78)            | 6.53(0.65)            | 2.14 (0.64)                      |
| Pelvic pain           | 5.63 (0.43)                       | 6.80 (0.22)                       | 7.13(0.34)            | 4.21(0.43)            | 3.41 (0.42)                      |
| Constipation          | 7.04 (0.52)                       | 2.71 (0.70)                       | 5.67(0.23)            | 2.76(0.30)            | 1.09 (0.76)                      |

**Table 8.2.** Comparison point A<sub>p</sub>, B<sub>p</sub>, US depth of rectal protrusion and levator hiatal area and posterior compartment symptoms pre-operatively, (Pearson correlation & linear by linear association, level of significance p<0.05).

|                       | Point A <sub>p</sub><br>value (p) | Point B <sub>p</sub><br>value (p) | US depth<br>value (p) | US width<br>value (p) | Levator<br>hiatal area<br>value (p) |
|-----------------------|-----------------------------------|-----------------------------------|-----------------------|-----------------------|-------------------------------------|
| Lump                  | 4.61 (0.09)                       | 1.65(0.35)                        | 5.62(0.14)            | 3.84(0.08)            | 7.53(0.26)                          |
| Digitate to defaecate | 2.31(0.16)                        | 3.78(0.87)                        | 5.74(0.45)            | 3.41(0.11)            | 0.24(0.67)                          |
| Strain to defaecate   | 1.68(0.29)                        | 3.88(0.55)                        | 2.05(0.31)            | 7.09(0.46)            | 2.40(0.87)                          |
| Faecal incontinence   | 4.98(0.78)                        | 1.37(0.67)                        | 8.51(0.87)            | 4.36(0.44)            | 1.93(0.76)                          |
| Pelvic pain           | 7.89(0.65)                        | 2.61(0.67)                        | 7.56(0.67)            | 1.91(0.21)            | 3.26(0.65)                          |
| Constipation          | 6.30(0.97)                        | 4.90(0.39)                        | 3.97(0.55)            | 3.97(0.28)            | 8.52(0.46)                          |

**Table 8.3.** Comparison of point A<sub>p</sub>, B<sub>p</sub>, US depth of rectal protrusion and levator hiatal area and posterior compartment symptoms post-operatively. (Pearson correlation & linear by linear association, level of significance p<0.05).

|                       | US perineal excursion<br>Pre-op<br>value (p) | US perineal excursion<br>Post-op<br>value (p) |
|-----------------------|--|---|
| Lump                  | 5.02(0.67)                                   | 2.39(0.34)                                    |
| Digitate to defaecate | 4.36(0.19)                                   | 1.67(0.18)                                    |
| Strain to defaecate   | 1.56(0.48)                                   | 9.64(0.76)                                    |
| Faecal incontinence   | 2.00(0.63)                                   | 5.43(0.13)                                    |
| Pelvic pain           | 8.91(0.23)                                   | 1.09(0.49)                                    |
| Constipation          | 3.33(0.43)                                   | 2.29(0.51)                                    |

**Table 8.4.** Comparison of perineal mobility and posterior compartment symptoms post-operatively, level of significance  $p > 0.05$ .

The range of depth of the rectocele on Valsalva strain pre-operatively was 0.47-2.30 cm (mean 1.84cm, SD 0.35cm) and width 0.97-3.23 cm (mean 2.34cm, SD 0.49cm). Post-operatively the recurrences ranged in dimensions from 0.46-1.65 cm in depth (mean 0.96cm, SD 0.18cm) to 1.34-2.71 cm (mean 1.91cm, SD 0.24cm) in width. Perineal excursion reflected as a change in position of the ampulla towards the symphysis pubis was 1.6cm (SD 1.9cm) pre-operatively and 0.3cm (SD 1.1cm) post-operatively. This was not statistically significant  $p = 0.75$ . There was no correlation with symptoms (Table 8.5).

On clinical POPQ measurement there was one recurrence > grade 1 which would be considered a failure and 2 women on US who had a rectocele depth > 1cm. The woman with the clinical recurrence had a rectocele on US less than 1 cm. There appeared to be no correlation between recurrence and levator area as seen in experiment 2 ( $p = 0.98$ ).

Levator dimensions pre-operatively and post-operatively were not significantly different as a result of surgery. The dimensions are shown in Table 8.4. Neither were any significant differences between those with recurrence (N=3, combining ultrasound and POPQ assessment) and those without recurrence in all three measurements  $p = 0.12$  (AP),  $p = 0.24$  (D),  $p = 0.09$  (Area), using paired t-test observed. However when preoperative levator hiatal dimension were compared between those with no recurrence and those with a recurrence there was a trend to higher recurrence with larger levator hiatal area dimensions pre-operatively ( $p = 0.07$ ).

|  | Pre-op<br>N<br>(standard deviation) | Post-op<br>N<br>(standard deviation) | p value |
|--|-------------------------------------|--------------------------------------|---------|
| Levator antero-posterior (AP) cm           | 5.87<br>(SD 0.80)                   | 5.85<br>(SD 0.76)                    | 0.13    |
| Levator diameter cm (D) cm                 | 4.98<br>(SD 0.57)                   | 4.53<br>(SD 0.51)                    | 0.25    |
| Levator hiatal area- cm <sup>2</sup>       | 21.19<br>(SD 4.53)                  | 21.13<br>(SD 3.68)                   | 0.12    |
| <b>Levator antero-posterior (AP) cm</b>    | 6.41<br>(SD 0.94)                   | 6.02<br>(SD 0.86)                    | 0.28    |
| <b>Levator diameter cm (D) cm</b>          | 5.95<br>(SD 0.75)                   | 5.69<br>(SD 0.81)                    | 0.43    |
| <b>Levator hiatal area- cm<sup>2</sup></b> | 28.07<br>(SD 8.39)                  | 26.9<br>(SD 7.12)                    | 0.18    |

**Table 8.5.** Levator hiatal dimensions pre and post-operatively, means and standard deviation. Clear boxes represent women with no recurrence post-operatively. Shaded boxes are the subjects with recurrence (N=3) seen clinically and on ultrasound. Value of p<0.05 taken as significant.

## 8.5 Discussion

Gynaecologists require better and highly reproducible assessment methods to identify specific abnormalities of pelvic organ support so as to correctly tailor surgical treatment and identify who will gain the most benefit from surgical intervention. Symptomatology can be multi-factorial and have multiple aetiologies. As previously stated symptoms have correlated poorly with clinically diagnosed prolapse. This maybe as a result of chronic functional alterations, as well as structural anatomical changes. An additional benefit is to have a potentially independent, reliable method, which is reproducible and quantitative to compare surgical outcomes. This study represents the first attempt to correlate symptoms, clinical findings, surgical findings and ultrasonography.

Clinical symptoms particularly of a lump, constipation, and difficulty evacuating bowels appeared to correlate no better with US than the POPQ assessment. This seems at odds with the concept of a rectocele being a pocketing created due to weak



rectal serosa and rectovaginal septum, which conceptually would allow a direct correlation with size and therefore measurement of the defect (Karram and Porter 2001). Straining to defaecate and digitation to evacuate stool is consistent with this theory. Symptoms would be worse with a greater defect. However chronic constipation with transit time delay, poor pelvic muscle co-ordination for pseudo obstructed rectal emptying or even reverse rectal peristalsis, may all play a part in symptomatology (Prokesch, et al. 1999). Precise location of the defect along the posterior wall may change the sensations patients complain of. The questionnaire itself did not allow for degrees of symptoms. New validated questionnaires for pelvic dysfunction permit a scale or degree of symptom impairment, which more accurately reflects the degree of dysfunction patients feel with each symptom (Baessler, et al. 2009, Broekhuis, et al. 2009, Digesu, et al. 2005, Price, et al. 2006). The use of a consistent reproducible method of pelvic straining may provide more reliability between subjects and within subjects, especially in the older age group where they often find it difficult to “bear down” despite coaching. The examination of women in the standing position may be more reliable although awkward for the examiner. There is some evidence that this may be the case (Barber, et al. 2000). Therefore the maximal extent of the prolapse may not be revealed. Perineal hypermobility is a concept that may or may not be a secondary phenomena where the pelvic floor descends to a greater extent. Again there was no correlation between the level of descent of the rectal ampulla and symptoms. The rectal ampulla is a convenient marker of the pelvic floor as it is easily identified but can be affected by rectal loading (Dietz and Wilson 1999). It is therefore important to ask patients to empty their bowels prior to any assessment.

There was a trend towards surgical findings being more accurately predicted by US than POPQ and clinical assessment. This did not reach statistical significance. This may be as a result of the small sample size and the multiple compartmental prolapse the subjects had, thus introducing confounding bias at assessment. However, it may also demonstrate an advantage of ultrasound, which permits the identification of other underlying defects as well as changes to the surrounding visceral structures to exclude other causes of these symptoms e.g. sepsis and fistula.

Levator dimensions did not correlate statistically with prolapse recurrence or symptoms. This maybe because of the specific compartment in this study and the dynamics of different prolapse areas in the pelvis may be influenced more by the muscle support at the opening of the vagina. Conversely, the procedure did not

appear to significantly change the hiatal dimensions of the pelvis, which may be important not only for success and a reduction of recurrence but also complications such as dyspareunia following surgery. The levator findings are interesting again with a trend towards POP recurrence on US, but this was not statistically significant. This may mean addressing the muscle support structures at the time of surgery could influence outcome and has implications for the choice of surgery in different women. Simply covering over the defect maybe insufficient in some women. Does a larger hiatus matter? Do women get more pelvic dysfunction symptoms if they have a larger hiatus? This has not been fully addressed in this study but may warrant further investigation.

Shortcomings of this study are the multiple compartmental nature of POP in this group of women, which may have confounded the association of symptoms. However although the study focused on the posterior compartment of the female pelvis in reality it is unusual for women to present with just one compartmental failure. There is no clear evidence as to when women should be followed up and most researchers would recommend at least two years, to assess the success of surgery. It may be that further failures may have occurred and a more significant correlation with one of the many parameters that were measured on US such as levator dimensions could have an influence on the results. No sub-analysis has been undertaken to determine at what level of defect do symptoms appear due to the small number of subjects. This would be very useful, as cut off points as to when prolapse becomes symptomatic for the posterior compartment may vary from symptom to symptom. As part of this assessment comparison with evacuatory proctography may have been useful. With the trend towards some correlation between US measurements of depth and width of rectocele in those women complaining of a sensation of a lump and digitation to defaecate, a greater sample size may therefore have detected a greater predictive effect of US with a larger study.

The numbers of subjects with so few recurrences meant it was difficult to test the influence of levator hiatal dimensions on outcome. This is a potential use of 3D US for morphometric measurements of axial structures such as the levator muscle complex. The use of two different surgical techniques was also a potential confounder and if repeated attempts to standardize surgery should be undertaken.

## **8.6 Conclusion**

In conclusion this study suggests that 3D ultrasonography does not appear to correlate better with symptoms, surgical findings and subsequent outcome than the POPQ clinical staging system. This pilot study needs to be translated into a larger study with a more specific cohort of women with certain compartmental prolapse before the place of ultrasound imaging and clinical examination can be ascertained with regards to women's symptoms of prolapse and their subsequent resolution.

**The null hypothesis is accepted that three dimensional ultrasound correlates better than clinical assessment with symptoms associated with posterior compartment prolapse and that levator hiatal measurements can provide a means of predicting outcome of surgery in women with pelvic organ prolapse of the posterior compartment.**

## CHAPTER 9

### DISCUSSION

Management of posterior compartment prolapse constitutes a significant proportion of the workload associated with the treatment of pelvic organ prolapse in women. In Australia, Medicare statistics recorded that 21,500 operations for posterior and anterior and posterior compartment repair were undertaken in 2005 (ACHW stats, Medicare item numbers 35571, 35573). The precise pathogenesis of posterior compartment abnormalities and rectocele is not clear (Zbar, et al. 2003). In addition the natural progression of rectoceles is unclear (Handa, et al. 2004). Although rectoceles are common the direct association with specific pelvic symptoms has been poor. The treatment of rectoceles has been hampered by poor studies, because they have utilised different surgical techniques as well as variable outcomes, which have not always been validated (Brubaker 1996).

Posterior compartment prolapse does not just involve rectocele prolapse but incorporates other pathology to be considered in the assessment, diagnosis and subsequent outcome of surgery. These include enterocele prolapse, hypermobility of pelvic tissue, and defects of the rectal support mechanisms, underlying muscle function as well as other prolapse of the pelvis, which may mimic or confuse the clinical picture. This integral interconnection of support for the pelvis means rectocele abnormalities may not be in isolation (Petros and Woodman 2008).

This study specifically looked at those anatomical areas that were felt to lend themselves to investigation with ultrasound. There is a need for uniformity of assessment for definition, diagnosis, progression and outcomes of treatment. Clinical evaluation may be insufficient for this purpose as only the external features of the defects can be visualised with no information on the deep structures, which are likely to be involved in the aetiology of the prolapse. The addition of objective scoring systems improves objectivity but tells the investigator little about the specific abnormality deep to the mucosa. In addition there is no information about the axial plane other than a descriptive one.

## 9.1 Evidence from the studies undertaken

In Experiment 1 the measurements for defects of the posterior compartment, specifically anterior rectocele prolapse and levator hiatal dimensions were tested to confirm the validity of the technique and more importantly the reliability and reproducibility of measurements between and within observers. Correlation was good for all measurements and meant the technique for obtaining measurements was valid using the technique of US placement, Valsalva strain technique and also re-analysis of data offline with computer analysis of volumetric data.

In Experiment 2 the technique for evaluation of the posterior compartment was used on control subjects to study the prevalence in a normal population who had not given birth, thereby eliminating one of the potential aetiological factors for rectocele and posterior compartment defects, i.e. vaginal childbirth. Childbirth, specifically parturition and to a certain extent labour is thought to alter the integrity of support for muscle, fascia and ligaments of the pelvis (Karasick and Spettell 1997, Kuhn and Hollyock 1982). Expansion of the vagina may need to be six-fold to allow the passage of the fetal head and computer models based on stress points within the pelvis would suggest that stretching of the posterior compartment has to account for most of this expansion with potential for disruption of vaginal and rectovaginal septal fascia (Lien, et al. 2004). This experiment provided the basic datasets for the incidence of rectovaginal septal defects, perineal mobility and levator dimensions at rest and straining. It confirmed the validity of the measuring technique as a feasible method for obtaining measurements, which could then be analysed offline.

This study investigated the levator hiatal outlet during pregnancy, which would be difficult with MRI, as MRI has had limited application due to unknown risks to the fetus (De Wilde, et al. 2005, Kanal 1994). US on the other hand has been extensively studied and appears to have no significant risks (Torloni, et al. 2009). Therefore this imaging modality allows the assessment both subjectively and objectively of the changes that occur with childbirth which in turn may predispose women to POP and incontinence later in life (MacLennan, et al. 2000). This experiment was unable to give information about women who maybe at higher risk predelivery as postdelivery data were not available but may allow comparative studies with women being their own controls before and after a vaginal delivery. The study may have introduced other confounders, which could have affected the range of results. The effect of the fetus on pelvic organ mobility or levator dimensions between 34 and 39 weeks may

be important, especially in relation to the station of the fetal presenting part within the pelvis ("station" refers to the Obstetric term for descent within the pelvis relative to the level of the ischial spines). Fluid retention occurring in pregnancy although permitting greater definition of tissues may alter the biomechanical function of the tissues. There may also have been bias of the women who attended for the study, as they may have been more motivated and therefore "fitter" women, although there is no evidence to suggest this alters the incidence of rectovaginal defects there is some evidence in nulliparous elite athletes that levator dimensions expand more on Valsalva strain than a control group (21.53 vs. 14.91 cm<sup>2</sup>, P = 0.013) (Kruger, et al. 2007). Women who have not had children find it harder to strain, as they have not experienced the bearing down sensation of vaginal childbirth. The first part of the study therefore provided a set of normal values in a nulliparous pregnant population and confirmed the use of the technique for the third part of the study.

Experiment 3 used this assessment technique in the clinical setting to audit the results of surgery for posterior compartment rectocele defects. During this study it was found that defects in the rectovaginal septum can be clearly seen as per experiment 1 and that ultrasonography was more sensitive than clinical assessment in their detection. The correlation with prolapse symptoms of the posterior compartment was not statistically significant with clinical or ultrasound evidence of women with recurrence. However, it was interesting that there was a trend to more surgical failures as defined by both clinical assessment and ultrasonography when the levator hiatal area was greater. This may be an important factor for pre-operative assessment and requires further study. The numbers within the study precluded sufficient power for a conclusive outcome. This assessment method will identify failures of surgery more accurately but whether this translates into clinically significant use remains to be seen.

This study provides useful information for the use of ultrasound in the evaluation of outcome for surgical treatment of prolapse. This audit was undertaken using one standard technique by one surgeon thereby reducing some potential causes of variation in results and errors. However this was not an homogenous group of patients as they had other surgery at the same time because they had variable degrees of different types of POP. The biggest concern of this study is that although it was a prospective study for US, it used retrospective surgical data with an average follow-up of only 7 months. It could be postulated that levator dimensions or more

particularly levator ballooning on straining was present before surgery and therefore this morphological difference is just a co-association, with failure of surgical management or indeed an aetiological agent. Only a prospective study can help answer this hypothesis. By undertaking a prospective study prior to treatment the individual symptoms and specific defects in the posterior compartment could be compared more accurately to identify whether specific abnormalities correlate with specific symptoms, and of course predict successful outcome when these areas are addressed. Life-table analysis of the outcome of any prolapse surgery demonstrates a deterioration with time and so 7 months maybe too short to evaluate recurrence (Cruikshank and Muniz 2003). It leads to the intriguing question as to whether the greater sensitivity of ultrasound may highlight early failures that have not yet become symptomatic.

In view of the results of experiment 3 the use of ultrasonography was compared to MRI (Magnetic Resonance Imaging) in experiment 4 for the assessment both of recto-vaginal septal defects and levator hiatal dimensions, as this mode of imaging has previously been found useful for assessment of female pelvic anatomy (Strohbehn, et al. 1996a, Tunn, et al. 1998) . Women with different stages of prolapse were found to have greater hiatal dimensions at rest and Valsalva on fast image acquisition (Singh, et al. 2003). Inter-observer correlation has also been shown to be good for these measurements (Tunn, et al. 1998).

Experiment 4 demonstrated poor intra-class correlation between the two modalities. In this experiment it was concluded that it was not possible to recommend one modality over another. However the study could be criticised in a number of ways. Most significantly only a small number of women were studied making it less likely to have the power to detect significant differences but also more susceptible to outlying results. In addition they were women with complex pelvic organ prolapse, which may have affected the accuracy of measurements with either one or the other imaging modality. The cost implications and relationship to clinical outcome was not compared. In addition test-retest parameters for adequate Valsalva manoeuvre have not been undertaken in this study and reliable reproducible straining may not have been achieved given the limitations of access to the patient during image acquisition during MRI. It would have been useful to have non-metallic, intravaginal pressure monitoring during MRI imaging to confirm adequate Valsalva strain.

The cost and dynamic capabilities of 3D ultrasonography warrants further investigation with larger numbers, as the technology continues to improve with faster frame rates and greater resolution of the tissues. It is a potentially cost effective research tool when compared to MRI.

Experiment 5 was the final experiment to subject the assessment method for further scrutiny prospectively, studying women who had been diagnosed with posterior compartment prolapse. Ultrasonography revealed defects not noted clinically in a number of subjects, which was statistically significant. In this aspect alone ultrasonography appears to demonstrate some advantage over standardised clinical assessment. Correlation with symptoms was no different between formal clinical evaluation and 3D ultrasonography, but ultrasonography improved prediction of surgical diagnosis and altered surgical management, which in turn may improve pre operative counselling for patients given to patients, as well as planning for surgery. The continuing poor correlation with symptoms again probably represents either the complex interaction between abnormalities of pelvic function and disrupted anatomy. It may however also mean that this testing is too inaccurate to elucidate the correct association of defects with symptomatology, i.e. trying to find multiple logistic comparisons are too many for too few patients.

The aim of this last experiment was to determine if three-dimensional ultrasound correlates better with symptoms than standardised clinical assessment of posterior compartment prolapse. But also whether levator hiatal measurements can provide a means of reliability of predicting outcome of surgery in women with pelvic organ prolapse. Although correlation with symptoms was poor levator hiatal measurements demonstrated trends, which may suggest larger numbers of subjects, may indeed demonstrate a significant difference.

The whole posterior compartment is dependent on the integrity of the supports attaching the rectovaginal septum, laterally, inferiorly and superiorly. Any break or stretch may cause a weakness and subsequent discontinuity leading to a hernial type prolapse or increased mobility of the rectum depending on the injury or weakness. Hence different patterns of POP may emerge on US appearance and with different symptomatology. Thus there is a feeling of pressure with perineal hypermobility but no lump and conversely stool trapping if pocketing occurs with rectal serosa and muscularis herniation through a rectovaginal septal defect. Underpinning this support



is the levator complex of muscles which when deficient, torn or have impaired function leads to failure of the secondary support mechanism. It is postulated this may also confuse the issue of aetiology of recurrent failures of surgery. This study is not able to directly answer these questions but intimates that this maybe be a factor in recurrence.

## **9.2 Are the hypotheses proven?**

The aim of the study was to answer the following question:

*Does three-dimensional ultrasonography of the pelvis provide useful information in the evaluation of pelvic floor prolapse in women?*

In order to answer this question the following hypotheses were put forward:

1. Three dimensional US is a reliable and reproducible technique to identify and quantify the severity of rectoceles as well as measure levator hiatal dimensions for the posterior compartment.

2. Three-dimensional US can be used for the identification of posterior compartment defects and quantification of levator hiatal dimensions in a control population of primiparous women.

3. Three-dimensional US can be used as an independent measurement tool in the assessment of posterior compartment prolapse.

4. Three-dimensional US correlates as well as magnetic resonance imaging for the dynamic imaging of the pelvic floor.

5. Three-dimensional US is better at predicting findings at surgery than clinical examination alone in women with pelvic organ prolapse.

In answer to these hypotheses from the evidence of the first two experiments 3D-ultrasonography can identify defects in the posterior compartment and specifically rectocele and enterocele formation better than simple clinical examination. The measurement system is reliable and reproducible. Measurement of the levator hiatal dimensions is also reliable and reproducible. Both retrospective and prospective

evidence suggested that levator dimensions may affect outcome. The first two hypotheses are therefore proven. The third experiment confirmed its use for subjective and objective measurements of women post surgery and identified defects not seen clinically. This is therefore proven. The fourth experiment would suggest there is poor correlation with MRI and it is difficult to determine whether one offers an advantage for clinical use over another. The fourth hypothesis has not been proven, although ultrasonography was better at predicting enterocele prolapse at surgery than clinical and MRI.

Experiment 5 did not demonstrate better correlation with symptoms than clinical assessment just greater sensitivity in identifying defects. Again levator hiatal dimensions appeared to be associated with recurrence so US did not otherwise seem to offer an advantage with respect to the question asked.

In answer to the original question 3D-ultrasonography does have a role in the evaluation of posterior compartment defects, as it appears to be more sensitive at measuring and identifying abnormalities. However its place in the clinical management of patients has not been made clear by these studies and so further larger prospective studies looking for specific indicators of clinical symptomatology need to evaluate this further.

### **9.3 Evidence from new studies**

Since this study started there have been a number of articles published on this subject. A large study looked at 198 women undergoing investigation for urogynaecological disorders through a urodynamic clinic (Dietz and Steensma 2005). One hundred and twelve of these women had a rectocele diagnosed clinically. Of these, 56% had a rectovaginal septal defect noted on ultrasonography similar to the criteria used in these experiments reported here. In contrast to this study's results it showed a strong correlation with clinical grading ( $p < 0.001$ ) but also that in 34% of supposed rectoceles had no defect detected on ultrasound. There was a low incidence of enterocele (3%) prolapse in their population. Test-retest and intra-class correlation were excellent. This suggests there is a complex interaction of pathology for prolapse diagnosis and it remains possible that strict criteria for the diagnosis of enterocele prolapse is required to exclude high rectoceles or prolapsing sigmoid colon.

The incidence of rectoceles may be congenital in some cases as suggested by twin studies with an increased incidence noted with identical twins (Dietz and Clarke 2005). In this study one hundred and seventy eight women underwent ultrasound assessment transperineal and of these 52 women had adequate datasets after imaging and returned for follow up. As well as studying concordance between twins, it was noted that 12% of these nulliparous women had a defect greater than 10mm or pocketing with stool in it; there was an association with constipation and BMI in that group. It may therefore be postulated an inherent weakness may exist and that body size or poor habits maybe an additional factor rather than an effect.

The effect of childbirth has also been studied with an increase in the incidence of rectoceles following childbirth from 3% to 15% but not necessarily leading to symptoms as 50% of women diagnosed on ultrasound did not have symptoms (Dietz and Steensma 2006a). In addition movement of the rectal ampulla increased by 22mm which was statistically different from pre-childbirth displacement on Valsalva. Confirmation of the technique and reproducibility for measuring all aspects of the posterior compartment have demonstrated high Kappa correlation ( $\kappa = 0.78$ ) for levator hiatal dimensions (Dietz, et al. 2005). In this study of 52 nulligravida, non-pregnant women (18-24 years), puborectalis biometry was studied together with levator hiatal dimensions. Average diameters of the puborectalis muscle was; 0.4-1.11cm with a mean of 0.73cm. At rest the levator hiatal area ranged from 6.34 to 18.06cm<sup>2</sup> (mean 11.25), and 6.67-35.01cm<sup>2</sup> (mean 14.05). This was less than seen for our pregnant population study, but in a further study on pregnant nulliparous women at rest was 14.13 cm<sup>2</sup> (range 8.33- 24.37); on Valsalva strain the mean was 20.17cm<sup>2</sup> (range 9.74-42.39) which compares more closely with this study's results. Pregnancy itself may not have been an ideal setting in which to identify normal values presumably as a result of pressure and physiological changes that occur during pregnancy. Also for rectocele and enterocele measurement with perineal descent (Dietz and Steensma 2005). More importantly the identification of specific bowel symptoms and ultrasound findings in the posterior compartment of symptomatic women would suggest that there is a correlation between these findings and symptomatology (Dietz and Korda 2005). In the last study 505 women were studied with 64% having a rectocele diagnosed clinically. When specific questions were asked about incomplete bowel emptying ( $p=0.001$ ) and digitation to defaecate ( $p=0.001$ ) there was a strong correlation with US findings of a true rectocele, which in turn correlated well with clinical assessment ( $p=0.001$ ). There was a poor correlation with the term chronic constipation ( $p=0.04$ ). It would seem specific clinical findings

correlate with specific symptoms thereby making it important as to the specific questionnaires used.

The cut off points for size of defect when symptoms become noticeable to patients was not studied in these experiments. What would be considered a cut off point for rectocele size or depth, which are likely to be symptomatic? In the study by Blain receiver-operator characteristics (ROC) were determined for women undergoing investigation for urogynaecological symptoms of which 48 of 735 women had a “symptomatic” rectocele prolapse i.e. a lump sensation. A cut off point of 15mm below the symphysis pubis strongly associated with prolapse symptoms (ROC area under the curve 0.821) (Blain and Dietz 2008). This was a different measurement to those that were used in the studies where defect depth and width from the normal contour of the rectum were measured and may explain the poorer association with symptoms noted. In addition work undertaken to try and limit the confounder of associated prolapse when identifying symptoms and correlation with prolapse would suggest that cystocele and rectocele have a strong association independently with sensation of prolapse or a lump. This may have affected our results by those women who complained of a lump not related to posterior compartment prolapse, thereby reducing the correlation between US and clinical findings. In contrast other studies have suggested that US did not appear to offer an advantage over POPQ and ordinal staging in comparison to symptoms with similar ROC for both assessment techniques (Kluivers, et al. 2008). In this study of 265 women the ROC ranged from 0.715 to 0.783 and both POPQ and ordinal staging performed better than US assessment ( $p=0.048$  and  $0.015$  respectively).

Also confounding any association are transit time constipation and stool texture. When 242 women were studied prospectively they were asked to record their stool consistency using the Bristol stool chart. Of those women 40% had a rectocele on US. Of the symptoms straining at stool, chronic constipation, vaginal digitation and incomplete bowel emptying, only vaginal digitation was significantly associated with a true rectocele (Dietz 2009). In the case of other bowel related symptoms there was a greater correlation with stool form. However stool quality is not a confounder of true rectoceles when tested using regression analysis. Thus bowel habits and stool consistency maybe important if not allowed for in studies.

Further work assessing the use of transperineal 3D US suggested a role in the diagnosis and evaluation of obstructed defaecation when compared with transanal US as compared to defaecating proctography (Brusciano, et al. 2007). This would be less invasive for the patient undergoing investigation. A similar study investigating 43 women evaluating anorectal angle and rectocele demonstrated excellent concordance between US and defaecating coloproctogram with an intraclass correlation coefficient of 0.67 for anorectal angle, as well as rectal intussusception (0.91 Cohen's kappa index) (Grasso, et al. 2007). However although 100% of rectoceles were identified on introital US when greater than 4cm in depth on coloproctography there was only a moderate agreement with US in general (0.41,  $P < 0.01$ ). Indeed rectal intussusception, which we did not identify in the patients in this study, may well cause bowel emptying symptoms and those of vaginal prolapse symptoms, complicating the associations that were identified in the studies (Rodrigo, et al. 2011).

MRI imaging permits morphological analysis of levator muscle structure but it has been noted on 3D US imaging that not only can levator hiatal area be determined but also defects within the more superficial parts of the muscle complex i.e. the puborectalis and pubococcygeus. These defects have been seen in upto 15% of women in a population with urinary symptoms and can be uni or bilateral at the attachment to the pubic rami (Dietz and Steensma 2006b). There was a strong association with anterior and central pelvic compartment prolapse ( $p < 0.001$ ). These defects have been studied using tomographic slices to assess the size and extent of muscle damage. Updated technological advances in US image acquisition allows definition to 2mm tomographic resolution of acquired volumes. Of 262 women presenting with urinary symptoms 50 were found to have defects of which 17 were right sided, 12 left sided and 21 bilateral (Dietz 2007). The area affected ranged from the whole of the muscle to occupying only 14%. There was a greater association with prolapse than incontinence in this study group. If levator avulsion reduces the ability to contract the pubovisceralis muscle there is likely to be less support of the secondary mechanisms of pelvic organ support such as the endopelvic fascia. This has been suggested in a study using the Oxford scale of pelvic muscle strength to compare against avulsion defects in women. The grading reduced from 2.81 to 2.07 ( $p < 0.001$ ) when avulsions were present (Dietz and Shek 2008). However it is not just avulsions per se but possibly the elasticity of the levator puborectalis and pubococcygeus muscle that causes greater hiatal dimensions and therefore POP to develop. A blinded study of 538 women analysing datasets and levator dimensions, demonstrated receiver-operator curves (ROC) for hiatal area at rest of 0.65 and 0.71

on Valsalva. This suggested a levator hiatal area of  $> 25\text{cm}^2$  strongly correlates with prolapse symptoms (Dietz, et al. 2008b). If an avulsion is present the relative risk (RR) is 1.9 for all prolapse and for rectocele 1.4. Therefore, there seems to be a lesser effect on the posterior compartment. This may also translate into levator hiatal dimensions or distensibility, which would be consistent with the less pronounced association with symptomatology in this study. A study investigating 414 women with urogynaecological symptoms identified those with uni or bilateral levator avulsion (30% of parous women) with levator hiatal dimensions. The RR of abnormal distensibility was 3.5 (95% CI, 1.7-6.5) (Abdool, et al. 2009).

The levator hiatal dimensional measurements are similar to published series since this experiment was undertaken and where the technique has been validated for inter-rater variability (Dietz, et al. 2005, Yang, et al. 2006). Retrospective evidence has suggested an increased risk of prolapse recurrence when levator avulsions are present (Model, et al. 2010). This was a heterogeneous mix of 737 women with previous surgery for incontinence and prolapse. The relative risk for those women having an avulsion injury having further prolapse was between 2.3 and 3.3. This may account for the increased trend towards recurrence in this study, experiment 5, as we had not identified levator avulsion injuries and so had identified these defects as a risk factor.

Other studies compared women with prolapse against a normal population and there appeared to be no difference in pubococcygeal thickness at rest but there was a difference with resting levator hiatal area between groups (normal  $13.5\text{cm}^2$ , prolapse  $17.8\text{cm}^2$ )( $p= 0.002$ ) and greater degree of prolapse correlated with increasing levator hiatal area ( $p<0.001$ ). This study was undertaken with a relatively small group of women 43 in the study and 24 in the control group using 2D US. Although there was good intraclass correlation 2D US is not sufficiently dynamic in the axial plane and involves movement of the probe to get adequate dimensions (Athanasίου, et al. 2007). Although a study comparing 2 and 3 dimensional US in 17 women found good intraclass correlation for all measures of levator hiatal dimensions (Braekken, et al. 2008). The biometry of the levator may not only change with POP but also race and body mass index (BMI) as shown in a Chinese study who compared their normal population with that of Caucasian women (Yang, et al. 2006). In addition elite athletes demonstrate greater puborectalis muscle bulk but also greater dimensions of the levator hiatus on Valsalva, which may be as a result of high impact pressure on the

pelvic muscles thereby potentially predisposing them to later prolapse when compared to normal nulliparous women (Kruger, et al. 2007).

Differences in levator hiatus dimensions were seen pre-pregnancy but this may be aggravated by pregnancy during vaginal birth, as the hiatus has to expand to allow passage of the fetus. Those women with a smaller hiatus may well have to expand more increasing the risk of avulsion which in turn may increase levator distension and therefore prolapse later in life. For some women only a 25% increase may be necessary whereas for others this increase may be up to 245% (Svabik, et al. 2009).

Interestingly further studies comparing MRI with 3D US on 27 asymptomatic nulliparous women using similar criteria to experiment 4 found interobserver repeatability was fair to excellent for all parameters (ICC 0.59-0.78) but for Valsalva measurements MRI yielded higher area measurements making comparison between the two methods poor (Kruger, et al. 2008). This was attributed to differences in resolution causing differing minimal dimension estimates. This could well explain the discrepancies in our study. In addition attempts to confirm the true levator transverse minimal dimension may not be accurate. When US and MRI are compared for apparent transverse diameter in the axial plane they have close correlation but when compared in the coronal plane on MRI, due to the dynamic nature of the levator complex and 3D spatial anatomy, they do not correlate well (Kruger, et al. 2010). This may complicate measurements when comparing MRI and US, with the changing axis compared to the axis of the pelvis.

In contrast studies looking at static anatomy biometry of the puborectalis muscle in 18 nulliparous volunteers demonstrated good ICC for measurements of levator dimensions, area, muscle width and levator (puborectalis insertion point)-urethral gap (Majida, et al. 2010). However only one person undertook the analysis and these were only undertaken at rest in healthy volunteers so may not necessarily extrapolate to a clinical population where tissue hydration, Valsalva strain and contraction limits its applicability.

A more recent study looked at comparing MRI reconstructed volume data with 3D US volume data for the identification of levator trauma (Zhuang, et al. 2011). There was good correlation between the two modalities despite not performing levator contraction or strain in the MRI group. However reconstructing MRI 3 dimensional models to correctly identify avulsion injuries and morphology was found to be time

consuming and expensive with the conclusion that 3D US provides a more practicable way to screen for injuries that may predispose to POP.

A different study aimed to use 3D US to determine anal canal length anatomically but also functionally to identify the importance of the puborectalis muscle in anal canal closure. Comparison was made with dynamic MRI, 3D US and anal manometry on 15 nulliparous asymptomatic volunteers (Raizada, et al. 2011). The anal canal was seen to move cranially on MRI and 3D US on contraction and pressure profiles indicate an important function of the puborectalis more proximally on the anal canal for closure as compared to the external anal sphincter complex which affects the distal end of the anal canal. This demonstrates a further use for 3D US in the posterior compartment when combined with physiological studies.

#### **9.4 Future Research**

The place of 3D ultrasonography for the assessment of pelvic organ prolapse needs further research. The direction of this research predominantly needs to be large studies involving women with both single compartment disease and multi-compartment POP, with blinded comparison against the POPQ classification, validated symptom questionnaires and independent detailed surgical staging. This should then be combined with MRI assessment. It is important that a standardised means of vaginal pressure transducer is used for comparisons. Further work would then look at post-surgical assessments with all the above methods to identify reasons for surgical failure, i.e. predictors of surgical outcome.

An extension of this could look at the impact of reducing levator opening on surgical outcome and finally a randomised trial comparing 3D ultrasonography versus clinical assessment to see if outcomes are improved for women presenting with POP. Further use in pregnant women may also identify a cohort of women at greater risk post vaginal delivery.

It may also allow a non-invasive marker for tissue biomechanics before and after surgery to further understand variation in these factors amongst women.

Of interest a multicentre study in the Netherland has just been registered to look at the accuracy and clinical usefulness of MRI as compared to 3D US. It is hoped to



recruit 140 patients and indicates the considered importance of imaging in the assessment of pelvic floor dysfunction.

## CHAPTER 10

### CONCLUSION

In conclusion this study has shown that 3-dimensional ultrasonography provides a tool for the storage and analysis of objective measurement of the female pelvis both in real-time and offline. Three-dimensional ultrasound can be used for the identification and quantification of both levator hiatal dimensions and posterior compartment defects in women. It can be used as an independent measurement tool in the assessment of posterior compartment prolapse, as volumes of data can be analysed independently of the operator so long as the initial data acquisition is adequate. Three-dimensional ultrasound correlates poorly with magnetic resonance imaging for the dynamic imaging of the pelvic floor. However this may have been due to the population studied. Three-dimensional ultrasound correlates better with symptoms than clinical assessment of posterior compartment prolapse, but neither appear to significantly correlate with symptomatology well and identify women who do better from surgical treatment.

Levator hiatal measurements may provide a means of predicting outcome of surgery in women with pelvic organ prolapse of the posterior compartment and thereby identify a sub-group of women who require a different form of treatment.

In answer to the question “Does three-dimensional ultrasonography of the pelvis provide useful information in the evaluation of pelvic floor prolapse in women? “, it seems it does have a role in the assessment of women with prolapse, at least in the posterior compartment. It is certainly as good as clinical assessment and is better able to detect more subtle abnormalities. It is not clear whether this translates into a more accurate correlation with symptoms. The use of 3-dimensional technology for assessment of levator function indirectly by assessing levator hiatal expansion does appear promising and requires further study to see if this may alter treatment success. The dynamic assessment of the female pelvis using 3-dimensional ultrasonography does seem useful but larger studies are required to identify its place in women with POP. With the development of more sophisticated technology the defined role may still change further.

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## APPENDIX

### Appendix 1

#### DESCRIPTION OF POPQ MEASUREMENT

##### Technique of Examination

It is critical that the examiner sees and describes the maximum protrusion noted by the individual during her daily activities. Criteria for the end point of the examination and the full development of the prolapse should be specified in any report. Suggested criteria for demonstration of maximum prolapse should include one or all of the following (1) Any protrusion of the vaginal wall has become tight during straining by the patient. (2) Traction on the prolapse causes no further descent. (3) The subject confirms that the size of the prolapse and the extent of the protrusion seen by the examiner are as extensive as the most severe protrusion that she has had. The means of this confirmation should be specified. For example, the subject may use a small handheld mirror to visualize the protrusion. (4) A standing, straining examination confirms that the full extent of the prolapse was observed in other positions used.

Other variables of technique that should be specified during the quantitative description and ordinal staging of pelvic organ prolapse include the following: (a) the position of the subject; (b) the type of examination table or chair used; (c) the type of vaginal specula, retractors, or tractors used; (d) diagrams of any customized devices used; (e) the type (e.g., Valsalva maneuver, cough) and, if measured, intensity (e.g., vesical or rectal pressure) of straining used to develop the prolapse maximally; (f) fullness of bladder and, if the bladder was empty, whether this was by spontaneous voiding or by catheterization; (g) content of rectum; and (h) the method by which any quantitative measurements were made.

## **Quantitative description of pelvic organ position**

This descriptive system is a tandem profile in that it contains a series of component measurements grouped together in combination, but listed separately in tandem, without being fused into a distinctive new expression or “grade.” It allows for the precise description of an individual woman's pelvic support without assigning a “severity value.” Second, it allows accurate site-specific observations of the stability or progression of prolapse over time by the same or different observers. Finally, it allows similar judgments regarding the outcome of surgical repair of prolapse. For example, noting that a surgical procedure moved the leading edge of a prolapse from 0.5 cm beyond the hymeneal ring to 0.5 cm above the hymeneal ring denotes more meager improvement than stating that the prolapse was reduced from grade 3 to grade 1, as would be the case using some current grading systems.

### **Definition of anatomic landmarks**

Prolapse should be evaluated by a standard system relative to clearly defined anatomic points of reference. These are of two types: a fixed reference point and defined points that are located with respect to this reference.

#### **Fixed point of reference**

Prolapse should be evaluated relative to a fixed anatomic landmark that can be consistently and precisely identified. The hymen will be the fixed point of reference used throughout this system of quantitative prolapse description. Visually, the hymen provides a precisely identifiable landmark for reference.

Although it is recognized that the plane of the hymen is somewhat variable depending on the degree of levator ani dysfunction, it remains the best landmark available. “Hymen” is preferable to the ill-defined and imprecise term “introitus.” The anatomic position of the six defined points for measurement should be centimeters above or proximal to the hymen (negative number) or centimeters below or distal to the hymen (positive number) with the plane of the hymen being defined as zero. For example, a cervix that protruded 3 cm distal to the hymen would be +3 cm.

### **Defined points**

Six points (two on the anterior vaginal wall, two in the superior vagina, and two on the posterior vaginal wall) are located with reference to the plane of the hymen.

The first points are on the anterior vaginal wall. Because the only structure directly visible to the examiner is the surface of the vagina, anterior prolapse should be discussed in terms of a segment of the vaginal wall rather than the organs that lie behind it. Thus the term “anterior vaginal wall prolapse” is preferable to “cystocele” or “anterior enterocele” unless the organs involved are identified by ancillary tests. There are two anterior sites.

- Point Aa: A point located in the midline of the anterior vaginal wall 3 cm proximal to the external urethral meatus, corresponding to the approximate location of the “urethrovesical crease,” a visible landmark of variable prominence that is obliterated in many patients. By definition, the range of position of point Aa

relative to the hymen is -3 to +3 cm.

- Point Ba: a point that represents the most distal (i.e., most dependent) position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to point Aa. By definition, point Ba is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in women with total posthysterectomy vaginal eversion.

Two points are on the superior vagina. These points represent the most proximal locations of the normally positioned lower reproductive tract.

- Point C: A point that represents either the most distal (i.e., most dependent) edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar) after total hysterectomy.
- Point D: A point that represents the location of the posterior fornix (or pouch of Douglas) in a woman who still has a cervix. It represents the level of uterosacral ligament attachment to the proximal posterior cervix. It is included as a point of measurement to differentiate suspensory failure of the uterosacral-cardinal ligament complex from cervical elongation. When the location of point C is significantly more positive than the location of point D, it is indicative of cervical elongation, which may be symmetric or eccentric. Point D is omitted in the absence of the cervix.

Two points are on the posterior vaginal wall. Analogous to anterior prolapse, posterior prolapse should be discussed in terms of segments of the vaginal wall

rather than the organs that lie behind it. Thus the term “posterior vaginal wall prolapse” is preferable to “rectocele” or “enterocele” unless the organs involved are identified by ancillary tests. If small bowel appears to be present in the rectovaginal space, the examiner should comment on this fact and clearly describe the basis for this clinical impression (e.g., by observation of peristaltic activity in the distended posterior vagina, by palpation of loops of small bowel between an examining finger in the rectum and one in the vagina, etc.). In such cases a “pulsion” addendum to the point Bp position may be noted (e.g., Bp = +5 [pulsion]; see below for further discussion).

- Point Bp: A point that represents the most distal (i.e., most dependent) position of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to point Ap. By definition, point Bp is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in a woman with total posthysterectomy vaginal eversion.
- Point Ap: A point located in the midline of the posterior vaginal wall 3 cm proximal to the hymen. By definition, the range of position of point Ap relative to the hymen is -3 to +3 cm.

### **Other landmarks and measurements**

The genital hiatus is measured from the middle of the external urethral meatus to the posterior midline hymen. If the location of the hymen is distorted by a loose band of skin without underlying muscle or connective tissue, the firm palpable

tissue of the perineal body should be substituted as the posterior margin for this measurement. The perineal body is measured from the posterior margin of the genital hiatus to the midanal opening. Measurements of the genital hiatus and perineal body are expressed in centimeters. The total vaginal length is the greatest depth of the vagina in centimeters when point C or D is reduced to its full normal position. (Note: Eccentric elongation of a prolapsed anterior or posterior vaginal wall should not be included in the measurement of total vaginal length.) The points and measurements are presented in Figure 1.

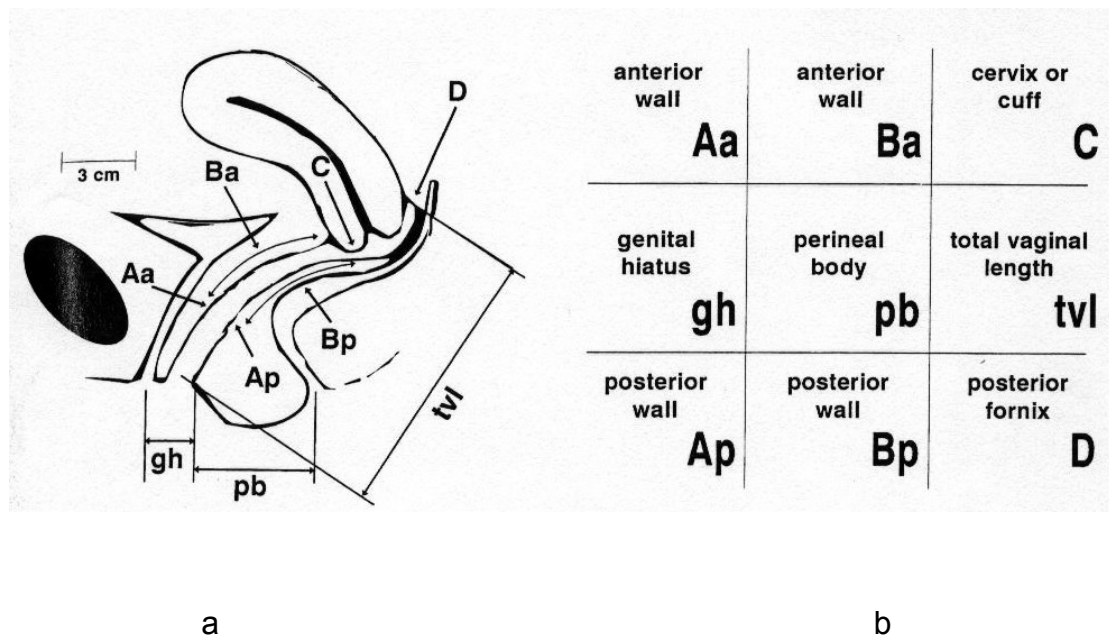


Figure 1a. Six sites (points *Aa*, *Ba*, *C*, *D*, *Bp*, and *Ap*), genital hiatus (*gh*), perineal body (*pb*), and total vaginal length (*tvl*) used for pelvic organ support quantitation; b, Three-by-three grid for recording quantitative description of pelvic organ support.

### Making and recording measurements



The position of points Aa, Ba, Ap, Bp, C, and (if applicable) with reference to the hymen should be measured and recorded. Positions are expressed as centimeters above or proximal to the hymen (negative number) or centimeters below or distal to the hymen (positive number) with the plane of the hymen being defined as zero. Although an examiner may be able to make measurements to the nearest 0.5 cm, it is doubtful that further precision is possible. All reports should clearly specify how measurements were derived. Measurements may be recorded as a simple line of numbers (e.g., -3, -3, -7, -9, -3, -3, 9, 2, 2 for points Aa, Ba, C, D, Bp, Ap, total vaginal length, genital hiatus, and perineal body, respectively). Note that the last three numbers have no + or - sign attached to them because they denote lengths, not positions relative to the hymen. A line diagram of the configuration can be drawn, as noted in Figure 2 and Figure 3. Figure 2 is a grid and line diagram contrasting measurements indicating normal support to those of posthysterectomy vaginal eversion. Figure 3 is a grid and line diagram representing predominant anterior and posterior vaginal wall prolapse with partial vault descent.

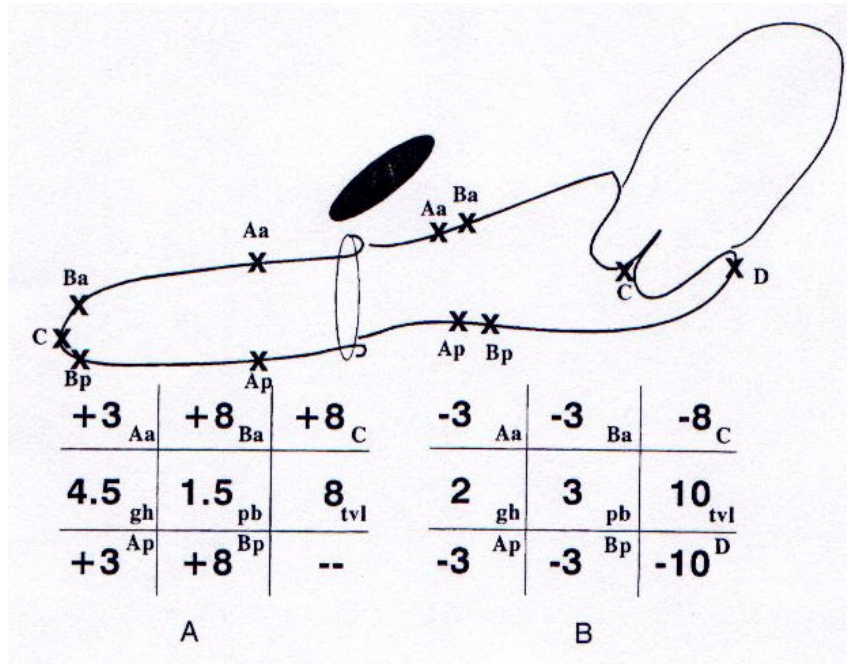


Figure 2. Grid and line diagram of complete eversion of vagina. Most distal point of anterior wall (point *Ba*), vaginal cuff scar (point *C*), and most distal point of the posterior wall (point *Bp*) are all at same position (+8) and points *Aa* and *Ap* are maximally distal (both at +3). Because total vaginal length equals maximum protrusion, this is stage IV prolapse. Normal support. Points *Aa* and *Ba* and points *Ap* and *Bp* are all -3 because there is no anterior or posterior wall descent. Lowest point of the cervix is 8 cm above hymen (-8) and posterior fornix is 2 cm above this (-10). Vaginal length is 10 cm and genital hiatus and perineal body measure 2 and 3 cm, respectively. This represents stage 0 support.

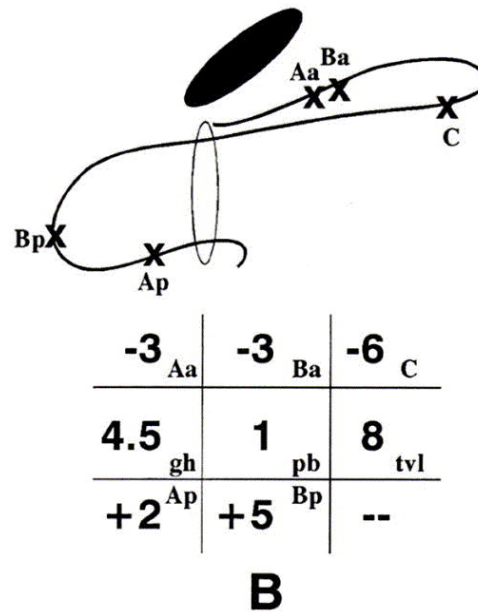


Figure 3. Predominant posterior support defect. Leading point of prolapse is upper posterior vaginal wall, point *Bp* (+5). Point *Ap* is 2 cm distal to hymen (+2) and vaginal cuff scar is 6 cm above hymen (-6). Cuff has undergone only 2 cm of descent because it would be at -8 (total vaginal length) if it were perfectly supported. This represents stage III *Bp* prolapse.

### Ordinal stages of pelvic organ prolapse

The tandem profile for quantifying prolapse provides a precise description of anatomy for individual patients. Stages are assigned according to the most severe portion of the prolapse when the full extent of the protrusion has been demonstrated. For a stage to be assigned to an individual subject, it is essential that her quantitative description be completed first. The 2 cm buffer related to the total vaginal length in stages 0 and IV is an effort to compensate for vaginal distensibility and the inherent imprecision of the measurement of total vaginal length. The 2 cm buffer around the hymen in stage II is an effort to avoid confining a stage to a single plane and to acknowledge practical limits of

precision in this assessment. Stages can be subgrouped according to which portion of the lower reproductive tract is the most distal part of the prolapse by use of the following letter qualifiers: a = anterior vaginal wall, p = posterior vaginal wall, C = vaginal cuff, Cx = cervix, and Aa, Ap, Ba, Bp, and D = the points of measurement already defined. The five stages of pelvic organ support (0 through IV) are as follows:

- Stage 0: No prolapse is demonstrated. Points Aa, Ap, Ba, and Bp are all at -3 cm and either point C or D is between -TVL (total vaginal length) cm and -(TVL-2) cm (i.e., the quantitation value for point C or D is  $\leq$ -(TVL-2) cm). Figure 1 represents stage 0.
- Stage I: The criteria for stage 0 are not met, but the most distal portion of the prolapse is >1 cm above the level of the hymen (i.e., its quantitation value is <-1 cm).
- Stage II: The most distal portion of the prolapse is  $\leq$ 1 cm proximal to or distal to the plane of the hymen (i.e., its quantitation value is  $\geq$ -1 cm but  $\leq$ +1 cm).
- Stage III: The most distal portion of the prolapse is >1 cm below the plane of the hymen but protrudes no further than 2 cm less than the total vaginal length in centimeters (i.e., its quantitation value is >+1 cm but <+[TVL-2] cm).
- Stage IV: Essentially, complete eversion of the total length of the lower genital tract is demonstrated. The distal portion of the prolapse protrudes to at least (TVL-2) cm (i.e., its quantitation value is  $\geq$ +[TVL-2] cm). In most instances, the

leading edge of stage IV prolapse will be the cervix or vaginal cuff scar

Adapted from The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Richard C. Bump MD, Anders Mattiasson MD, Kari Bø PhD, Linda P. Brubaker MD, John O.L. DeLancey MD, Peter Klarskov MD, PhD, Bob L. Shull MD and Anthony R.B. Smith MD in American Journal of Obstetrics & Gynaecology, 175(1); 1996; 10-17.

## Appendix 2

### Urinary and Bowel Symptom Questionnaire

Name

DOB

Date

**History:** Parity                      Height                      Weight

stress incontinence                      Urge incontinence

Previous pelvic surgery

**Symptoms:** stress incontinence                      monthly                      weekly                      daily

Urge incontinence                      monthly                      weekly                      daily

Frequency                      8-12                      13-17                      more

Nocturia                      2                      3-4                      more

Voiding:                      hesitancy                      poor stream                      stop-start

strain                      incomplete emptying

number of urinary tract infections in last year .....

Prolapse:                      lump,                      drag,                      pain,

dyspareunia                      bleed                      discharge

Bowel:                      constipation                      frequent straining

incomplete emptying                      digitation to evacuate

incontinence                      pain on defaecation

Used with permission Assoc Prof. HP Dietz.

## Appendix 3. Consent and information Sheets Experiment 1



**Queensland  
Government**  
Queensland Health

Townsville Health Service District  
Institutional Ethics Committee

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### PATIENT CONSENT FORM

**PROTOCOL NAME:** A prospective, observational pilot study assessing the effect of vaginal childbirth on the mobility of the posterior vaginal compartment, anal sphincter complex and de novo postpartum vaginal wall prolapse, using 3-dimensional ultrasound.

**INVESTIGATORS:** *Dr Christopher Barry, MBBS, FRANZCOG, MRCOG*

The nature and purpose of the research project has been explained to me. I understand it, and agree to take part

1. I have been given an Information Sheet which explains the purpose of the study, the possible benefits, and the possible risks.
2. I understand that I may not directly benefit from taking part in the trial.
3. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
4. I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.
5. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

**NAME OF SUBJECT:** \_\_\_\_\_

**SIGNED:** \_\_\_\_\_

**DATED:** \_\_\_\_\_

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved

**SIGNATURE OF INVESTIGATORS:** \_\_\_\_\_

**PATIENT INFORMATION SHEET**

**PROTOCOL NAME:** A prospective, observational pilot study assessing the effect of vaginal childbirth on the mobility of the posterior vaginal compartment, anal sphincter complex and de novo postpartum vaginal wall prolapse, using 3-dimensional ultrasound.

**INVESTIGATORS:** *Dr Christopher Barry, MBBS, FRANZCOG, MRCOG*

If you choose to participate in the study you will be invited to have an ultrasound scan at about 36 weeks of your pregnancy, to assess the position of the ligaments that support the vagina and back of the vagina, as well as the muscle group that surround the anus, which is important for bowel function. This area, we believe may change after childbirth, but as yet these changes have not been studied using this three dimensional ultrasound technology. We wish to analyse these changes as it maybe a helpful predictor of those women at higher risk of pelvic floor prolapse and dysfunction later in life. This is performed with a scan transducer, which is gently placed between the legs and rests on the perineum (the area between the vagina and anus). It is the same device as used for scanning your baby but you will not need to have a full bladder. There have been no adverse problems reported using ultrasound in this way on pregnant women. We will then ask you to bear down, which is the same as closing your nostrils and mouth, and blowing hard. Certain measurements will then be undertaken of the movement of the pelvic floor using the ultrasound scanner.

A summary record of your delivery will then be kept in the notes, with a unique identifier, which cannot identify you directly, until the research nurse removes it for later analysis of the ultrasound results.

A repeat ultrasound scan will then be performed at six months in the same way as before you have you're baby, to see if any changes have occurred.

Should any problems become apparent as a result of your scan then you will be referred back to your original specialist to discuss treatment. It is your choice as to the nature of treatment that you have and also participation in the study. You may withdraw at any time. **It is important that you understand that we will not be looking abnormalities of your baby or problems with it. Any concerns should be addressed with the doctor looking after you.**

**INVESTIGATOR CONTACT NAME:** *Dr Christopher Barry*

**INVESTIGATOR CONTACT TELEPHONE NO.** *07 4796 1468*

**ETHICS COMMITTEE SECRETARY; Dr Andrew Johnson** **Contact No: 07 4796 1003****DATED:**

---



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**PATIENT CONSENT FORM**

**PROTOCOL NAME:** An observational study of the anterior, central and posterior vaginal compartments of the female pelvis, before and after corrective surgery for prolapse of these compartments using 3-dimensional transperineal ultrasound.

**INVESTIGATORS:** *Dr Christopher Barry, MBBS, FRANZCOG, MRCOG*

The nature and purpose of the research project has been explained to me. I understand it, and agree to take part

6. I have been given an Information Sheet which explains the purpose of the study, the possible benefits, and the possible risks.
7. I understand that I may not directly benefit from taking part in the trial.
8. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
9. I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.
10. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

**NAME OF SUBJECT:** \_\_\_\_\_

**SIGNED:** \_\_\_\_\_

**DATED:** \_\_\_\_\_

---

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved

**SIGNATURE OF INVESTIGATORS:**

---

*Investigators are responsible for including an appropriate statement regarding payments to subjects on the Information Sheet*

---

**PATIENT INFORMATION SHEET**

**PROTOCOL NAME:** An observational study of the anterior, central and posterior vaginal compartments of the female pelvis, before and after corrective surgery for prolapse of these compartments using 3-dimensional transperineal ultrasound.

**INVESTIGATORS:** *Dr Christopher Barry, MBBS, FRANZCOG, MRCOG*

Your doctor has decided that your condition known as a prolapse would benefit from surgery. As part of the James Cook University, we are interested in understanding the changes in the structures within the lower pelvis, which have caused the prolapse. In order to do this we would like to perform an ultrasound scan of your pelvis, which can be done using high frequency sound waves. This is performed with a scan transducer, which is gently placed between the legs and rests on the perineum (the area between the vagina and anus). It is the same device as used for scanning a baby but you will not need to have a full bladder. There is no known risks related to performing ultrasound. In addition, a very thin pressure device is placed into the vagina to help with the measurement of the pressure in the vagina, which will be part of the assessment of the strength with which you are able to bear down. We will then ask you to bear down, which is the same as closing your nostrils and mouth, and blowing hard. Certain measurements will then be undertaken of the movement of the pelvic floor using the ultrasound scanner.

By doing the scan, we will build up a three-dimensional picture of the anatomy of the lower part of your pelvis. The scan would then be repeated after you have your surgery at 3 months to see how your surgery has changed the position of the vagina within the pelvis. The procedure should not be uncomfortable. After the scans have been performed, details of your surgery will be reviewed to compare the findings from your ultrasound examinations.

Should any problems become apparent as a result of your scan then you will be referred back to your original specialist to discuss treatment. It is your choice as to the nature of treatment that you have and also participation in the study. You may withdraw at any time.

---

**INVESTIGATOR CONTACT NAME:** *Dr Christopher Barry*

**INVESTIGATOR CONTACT TELEPHONE NO.** *07 4796 1468*

**ETHICS COMMITTEE SECRETARY; Dr Andrew Johnson Contact No: 07 4796 1003**

**DATED:**

**SIGNATURE OF CONTACT INVESTIGATOR:**

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